





| Approval Signature:    | Date: |
|------------------------|-------|
| Approved By:<br>Title: |       |
| Approval Signature:    | Date: |
| Approved By:<br>Title: |       |

#### **VERSION HISTORY**

| Author      | Revision | Date        | Change History           |
|-------------|----------|-------------|--------------------------|
| Steve Clark | 1.0      | 23-Dec-2022 | <b>Document Creation</b> |
|             |          |             |                          |



# **Table of Contents**

| 1 | Defi | nitions/ Acronyms8                                     |  |  |  |  |  |  |  |  |  |  |
|---|------|--------------------------------------------------------|--|--|--|--|--|--|--|--|--|--|
| 2 | Wha  | t's New in CTMS v1.3?                                  |  |  |  |  |  |  |  |  |  |  |
|   | 2.1  | Settings9                                              |  |  |  |  |  |  |  |  |  |  |
|   | 2.1. | Company Name and Logo9                                 |  |  |  |  |  |  |  |  |  |  |
|   | 2.1. | Final Statuses9                                        |  |  |  |  |  |  |  |  |  |  |
|   | 2.1. | Custom Fields for Milestones10                         |  |  |  |  |  |  |  |  |  |  |
|   | 2.1. | Site Visit Custom Fields related to Visit Types10      |  |  |  |  |  |  |  |  |  |  |
|   | 2.1. | New Lookup options                                     |  |  |  |  |  |  |  |  |  |  |
|   | 2.2  | Milestones11                                           |  |  |  |  |  |  |  |  |  |  |
|   | 2.2. | Milestone Groups11                                     |  |  |  |  |  |  |  |  |  |  |
|   | 2.2. | Auto Apply11                                           |  |  |  |  |  |  |  |  |  |  |
|   | 2.3  | Activities12                                           |  |  |  |  |  |  |  |  |  |  |
|   | 2.3. | Activity ID Number                                     |  |  |  |  |  |  |  |  |  |  |
|   | 2.4  | Study Management12                                     |  |  |  |  |  |  |  |  |  |  |
|   | 2.4. | Study Team vs Access Permissions12                     |  |  |  |  |  |  |  |  |  |  |
|   | 2.4. | Managing Study Access Permissions12                    |  |  |  |  |  |  |  |  |  |  |
|   | 2.4. | Managing the Study Team13                              |  |  |  |  |  |  |  |  |  |  |
|   | 2.4. | Study Milestones Dashlet13                             |  |  |  |  |  |  |  |  |  |  |
|   | 2.5  | Site Management14                                      |  |  |  |  |  |  |  |  |  |  |
|   | 2.5. | Managing Site Contacts14                               |  |  |  |  |  |  |  |  |  |  |
|   | 2.5. | Closing a Site                                         |  |  |  |  |  |  |  |  |  |  |
| 3 | Org  | nizations15                                            |  |  |  |  |  |  |  |  |  |  |
|   | 3.1  | Pre-Requisites                                         |  |  |  |  |  |  |  |  |  |  |
|   | 3.2  | Creating an Organization16                             |  |  |  |  |  |  |  |  |  |  |
|   | 3.3  | Editing an Organization18                              |  |  |  |  |  |  |  |  |  |  |
|   | 3.4  | Associating an Address to an Organization20            |  |  |  |  |  |  |  |  |  |  |
|   | 3.5  | Associating an Organization to a Parent Organization21 |  |  |  |  |  |  |  |  |  |  |
|   | 3.6  | Associating a Contact to an Organization22             |  |  |  |  |  |  |  |  |  |  |
|   | 3.7  | Reviewing Studies Associated to an Organization23      |  |  |  |  |  |  |  |  |  |  |



| 4 | Spo  | nsors                                                     | 25 |
|---|------|-----------------------------------------------------------|----|
|   | 4.1  | Pre-Requisites                                            | 25 |
|   | 4.2  | Defining a Sponsor                                        | 25 |
|   | 4.3  | Defining Sponsor Settings                                 | 26 |
|   | 4.4  | Associating a Product to a Sponsor                        | 27 |
|   | 4.5  | Creating a Program for a Sponsor                          | 28 |
|   | 4.6  | Creating a Study for a Sponsor                            | 29 |
|   | 4.7  | Reviewing Sites for a Sponsor                             | 30 |
| 5 | Con  | tacts                                                     | 31 |
|   | 5.1  | Pre-requisites                                            | 31 |
|   | 5.2  | Levels of Contact Creation in the Application             | 31 |
|   | 5.3  | Creating a Contact                                        | 32 |
|   | 5.4  | Editing a Contact at Domain, Site and Organization Levels | 33 |
|   | 5.5  | Editing a Contact                                         | 33 |
| 6 | Stuc | dies                                                      | 35 |
|   | 6.1  | Pre-Requisites                                            | 35 |
|   | 6.2  | Creating a Study                                          | 35 |
|   | 6.3  | Blinded Studies                                           | 36 |
|   | 6.3. | 1 Adding Unblinded Personnel to a Blinded Study           | 36 |
|   | 6.4  | Editing a Study                                           | 36 |
|   | 6.5  | Entering Study Settings                                   | 38 |
|   | 6.6  | Defining Study specific Regions                           | 41 |
|   | 6.7  | Editing Study Regions                                     | 42 |
|   | 6.8  | Defining and Editing Countries Within a Study             | 43 |
|   | 6.9  | Associating Organizations to a Study                      | 45 |
|   | 6.10 | Defining Study Partners                                   | 45 |
|   | 6.11 | Associating Contacts to a Study                           | 47 |
|   | 6.12 | Creating Sites within a Study                             | 48 |
|   | 6.13 | Reviewing Subjects Within a Study                         | 49 |
|   | 6.14 | Study Sites Pre-Requisites                                | 50 |
|   | 6.15 | Editing a Site in a Study                                 | 51 |



Page 5 of 130

|   | 6.16 | Tracking Informed Consents (ICFs) for a Site |  |
|---|------|----------------------------------------------|--|
|   | 6.17 | Tracking Site Addresses                      |  |
|   | 6.18 | Associating an Organization to a site55      |  |
|   | 6.19 | Change of Principal Investigator (PI)56      |  |
|   | 6.20 | Creating Site Visits                         |  |
|   | 6.21 | Updating a Site visit                        |  |
|   | 6.22 | Tracking Subjects                            |  |
|   | 6.23 | Editing a Subject60                          |  |
|   | 6.24 | Tracking Subjects Visits                     |  |
|   | 6.25 | Editing a Subject Visit                      |  |
|   | 6.26 | Reviewing and Tracking Country Details63     |  |
|   | 6.27 | Tracking Country Informed Consents (ICFs)64  |  |
|   | 6.28 | Creating Site within a Country               |  |
|   | 6.29 | Associating an Organization with a Country   |  |
|   | 6.30 | Associating Contacts with a Country67        |  |
| 7 | Site | Visit Documentation                          |  |
|   | 7.1  | Pre-Requisite                                |  |
|   | 7.2  | Navigation to Site Visit                     |  |
|   | 7.3  | Site Visit Attendees                         |  |
|   | 7.4  | Site Visit Locations                         |  |
|   | 7.5  | Site Visit Activities                        |  |
|   | 7.6  | Site Visit Subjects                          |  |
|   | 7.7  | Site Visit Enrollment Summary75              |  |
|   | 7.8  | Site Visit Confirmation Letter Creation      |  |
|   | 7.9  | Site Visit Draft Report Generation           |  |
|   | 7.10 | Site Visit Final Report Generation80         |  |
|   | 7.11 | Site Visit Follow-up Letter Creation         |  |
| 8 | Proc | luct80                                       |  |
|   | 8.1  | Creating a Product                           |  |
|   | 8.2  | Reviewing and Editing a Product82            |  |
|   | 8.3  | Associating an Organization to a Product     |  |



| 8.4    | Associating a Contact to a Product                     | 84 |
|--------|--------------------------------------------------------|----|
| 9 Pro  | gram                                                   | 85 |
| 9.1    | Pre-Requisites                                         | 85 |
| 9.2    | Create a Program                                       | 85 |
| 9.3    | Reviewing and Editing a Program                        | 87 |
| 9.4    | Associating an Organization to a Program               |    |
| 9.5    | Associating a Contact to a Program                     |    |
| 9.6    | Associating a Product to a Program                     | 91 |
| 10 A   | ctivities                                              | 91 |
| 10.1   | Associating Domain library Activity Records to a Study | 91 |
| 10.2   | Creating Domain library Activity Records               | 93 |
| 10.3   | Editing Domain Library Activity Records                | 94 |
| 10.4   | Deleting Domain Activity Records                       | 95 |
| 10.5   | Inactivating Domain Activity Records                   | 96 |
| 10.6   | Creating Domain Library Activity Plans                 | 97 |
| 10.7   | Editing Draft Activity plans                           |    |
| 10.8   | Publishing Activity Plans                              |    |
| 10.9   | Retiring Activity Plans                                |    |
| 10.10  | Copying Activity Plans                                 |    |
| 10.11  | Associating Activity Plan Templates to a Study         |    |
| 10.12  | Scheduling Activity Plans                              |    |
| 10.13  | Tracking Activities Outside of Activity plans          |    |
| 10.14  | Tracking Actions Taken Toward Activity Completion      |    |
| 11 Mil | estones                                                |    |
| 11.1   | Pre-Requisites                                         |    |
| 11.2   | Creating Domain Library Milestone Template             |    |
| 11.3   | Creating a Study Milestone from a Template             |    |
| 11.4   | Editing Domain Milestone Templates                     |    |
| 11.5   | Deleting Domain Milestone Templates                    |    |
| 11.6   | Publishing Milestone Templates                         |    |
| 11.7   | Retiring Milestone Templates                           |    |



Page 7 of 130

| 11.8   | Copying Milestone Templates                     |
|--------|-------------------------------------------------|
| 11.9   | Associating Milestone Templates to a Sponsor116 |
| 11.10  | Defining Sponsor-Specific Milestone Templates   |
| 11.11  | Defining Study Milestone Templates (New)120     |
| 11.12  | Tracking Milestones                             |
| 12 Das | hlets                                           |
| 12.1   | The Portfolio Dashlet                           |
| 12.2   | The Top Countries Dashlet                       |
| 12.3   | The Studies Dashlet                             |
| 12.4   | The CRA Visit Report Performance Dashlet        |
| 12.5   | Reviewing Studies via their Dashboard128        |
| 12.6   | Reviewing Countries via their Dashboard130      |
| 12.7   | Reviewing Site Dashboard                        |
| 12.8   | Site Visit Report Review Status Dashlet         |
| 13 Use | r and Team Management                           |
| 13.1   | Creating Users                                  |
| 13.2   | Editing a User                                  |
| 13.3   | Editing a User's Permissions                    |
| 13.4   | Study Team Management                           |
| 13.5   | Deactivating a User Account                     |
| 13.6   | Resending a User's Invite                       |
| 13.7   | Removing Users from a Team list                 |

# 1 Definitions/ Acronyms

| Term/<br>Acronym | Explanation                         | Definition                                                                                                                                                                        |
|------------------|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| стмѕ             | Clinical Trial<br>Management System | An application used as a centralized location to manage clinical trial data.                                                                                                      |
| CSM              | Clinical Study<br>Manager           | A key clinical study team member that assists in the conduct of clinical trial activities in accordance with all applicable regulations governing the conduct of clinical trials. |
| CRA              | Clinical Regulatory<br>Associate    | A CRA is a clinical study team member that monitors the progress of investigators in a clinical study.                                                                            |
| ICF              | Informed Consent<br>Form            | An ICF is used to ensure everyone involved in clinical research is a willing participant, with full knowledge of the potential risks and benefits to the extent that is possible. |

# 2 What's New in CTMS v1.3?

#### 2.1 Settings

Trial Interactive's CTMS v1.3 introduces several updates to the Settings are of the system. Access to these functions is limited to users with Company Administrator level access.

#### 2.1.1 Company Name and Logo

Users can now change the name a logo associated with their CTMS environment in order to keep up with the changes that happen over the course of a company's lifetime. To do this, users will need to navigate to the Settings area and select the General menu.

To change the Company Logo:

- 1. While in Settings, hover over the logo at the top-left of the screen and select one of the available options: Edit or Delete
  - a. Deleting the existing file will remove it from the company environment.
  - b. Selecting 'Edit' will allow the user to select a file from their computer for upload. Once the file is selected, it will appear in the logo area at the top-left of the screen.

To change the company's name:

- 1. Navigate to the Settings are and to the General menu.
- 2. Click the 'Edit' button in the menu ribbon at the top of the menu.
  - a. The menu will become editable.
- 3. Type a new name for the organization into the "Client Name" field.
- 4. Press 'Save' in the menu ribbon at the top of the menu.

#### 2.1.2 Final Statuses

Managing statuses has not changed much in CTMS v1.3 but users now have the ability to indicate which of the available statuses is considered a Final or 'End' status. Once an entity has reached the end status, unless specifically set up otherwise or adjusted, the status cannot be set back to a non-final status. Sites will be discussed in their own section but there are additional updates to this process where closing a site is concerned.

Entities in the system which are in a final state prior to the rollout of this feature will not be locked. In order to lock them, the user should revert the entity to a non-final status and the back to the final status in order to lock the data.

To set an 'End' status:

- 1. Navigate to the Settings area and go to the Statuses menu.
- 2. Select the particular area of interest (Programs, Sites, etc.)



- a. Note: This is not available for all areas.
- 3. Select the status which should be indicated as an 'End' or 'Final' status using the checkbox.
- 4. Press the 'Edit' button in the menu above the list.
- 5. Check the box in the 'Is End' column (or uncheck the box to indicate a status as non-final)
- 6. Press the 'Save' button in the menu above the list.

#### 2.1.3 Custom Fields for Milestones

With CTMS v1.3, users can now add custom fields for Milestones.

To create a custom field:

- 1. Navigate to the Settings area and select the Fields menu.
- 2. Select the sub-type (Activities, Contacts, etc.)
- 3. Press the 'Add Field' button in the menu above the list of fields.
  - a. The 'Add Custom Field' window will open.
- 4. Select the type of field
  - a. Please note that the steps below may vary slightly depending upon the type of field chosen.
- 5. Press 'Next'
- 6. Give the new field a name and, if desired, a description.
- 7. If the new field should be mandatory, check the box next to 'Required'
- 8. Press 'Next' and select any other necessary information such as validation options as required.
- 9. Press 'Create'

#### 2.1.4 Site Visit Custom Fields related to Visit Types

CTMS v1.3 allows users to set custom fields for Site Visits as well. It is critical to bear in mind that creating a field will not automatically make it available across all visit types. It is likely that any one field will not be applicable to all visit types across the board so, in order to allow for a customized list based on the visit type, once a custom site visit field has been created, the user must navigate to the Site Visit Types in Settings and manually choose to add the new field to the associated visit type before it will be applied.

To apply a custom field to a site visit type:

- 1. Create the custom field using the steps outlined previously.
- 2. Navigate to the Settings area and go to the Site Visit Types menu.
- 3. Select the site visit type to be edited and press the 'Edit' button in the menu above the list of visit types.
  - a. The 'Edit Site Visit Type' window will open
- 4. Use the 'Include Additional Fields' toggle switch to enable the inclusion of new fields.
- 5. Press the 'Add' button
  - a. A dropdown will appear in the grid below the 'Add' button.
- 6. Using the dropdown menu, select the appropriate field
- 7. Press 'Save'

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2022 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

#### 2.1.5 New Lookup options

T R I A L INTERACTIVE

For those who spend time in the Settings area of the CTMS, you'll know that the term 'Lookups' refers to the options found in various dropdown menus throughout the system. For the release of CTMS v1.3, we have created several additional standard values available in these menus. Because we do not want to impact existing data collections efforts, these new values are added to the system in an 'inactive' state and will need to be manually activated in order for users to see them.

To activate a lookup value:

- 1. Navigate to the Settings area and choose the Lookups menu.
- 2. Select the sub-menu to be edited (Activity Plans, Addresses, Contacts, etc.)
- 3. Above the list of values is a dropdown menu indicating which field's values are shown. Use the dropdown menu to select the correct field.
- 4. Select a value using the checkbox and press 'Edit' in the menu above the list of values.
- 5. Check the box in the 'Active' column
- 6. Press 'Save'

#### 2.2 Milestones

The application of Milestones to studies in CTMS v1.3 has undergone some minor changes in order to help our users better apply milestones quickly and efficiently to a study.

As a note, with CTMS v1.3 Milestones that are retired at the Global level are retired in all levels of the data hierarchy. If you want to continue to track a milestone after retiring it at the Global level, it is imperative that you make a copy of the milestone at the Sponsor level or lower before retiring the milestone at the Global level.

#### 2.2.1 Milestone Groups

Creating milestones in the CTMS has not changed but now we're offering users the ability to create and apply groups of milestone templates as needed. Only published milestone templates may be added to a group. Milestone groups may be set up at the Global or Study level by users with sufficient access to either level of data.

| Milesto     | Milestone Templates TRACKING STARTED |        |  |  |          |  |  |  |  |
|-------------|--------------------------------------|--------|--|--|----------|--|--|--|--|
| Milestone T | Milestone Templates Groups A         |        |  |  |          |  |  |  |  |
| 🕒 Add 🐱     | Create Group                         | 🖋 Edit |  |  | Q Search |  |  |  |  |

#### 2.2.2 Auto Apply

It can be difficult, at times, to remember to apply a newly added or created milestone to a study. To that end, we have added the 'Auto Apply Templates' toggle switch at the top-right corner of the Milestone Templates screen at the study level. This way, our Study Manager level users will be able to indicate whether or not milestones should be applied manually, as needed, or automatically once they are published and added to a study.



It should be noted that this would not apply the template to sites created after this switch is activated. For future sites, we recommend using the scheduler for activity plans.

#### 2.3 Activities

#### 2.3.1 Activity ID Number

All activities in the CTMS will now be given a unique ID number. This number will be applied retroactively so there's no need to recreate your activities.

| 3 Act | 3 Activities     |        |            |           |                |                   |              |                 |                    |             |  |  |
|-------|------------------|--------|------------|-----------|----------------|-------------------|--------------|-----------------|--------------------|-------------|--|--|
|       | Activity Name    | Status | Туре       | Subtype   | Owner          | Responsible Party | Planned Date | Associated Plan | Description        | ID          |  |  |
|       | 🛱 Health Wells S | OPEN   | Site Visit | Deviation | CSM 001        |                   |              |                 | First Deviation    | A-STD-15-10 |  |  |
|       | 🖄 Study Submis   | OPEN   | Submission | Initial   | 🛔 Hope Weisser |                   |              | Study Start-Up  | Initial submission | A-STD-15-5  |  |  |
|       | 🛱 Study Approval | OPEN   | Approval   | Initial   | Hope Weisser   |                   |              | Study Start-Up  | Initial study appr | A-STD-15-6  |  |  |

#### 2.4 Study Management

TI v1.3 makes some significant changes to study management, especially where user access permissions and managing the study team are concerned.

#### 2.4.1 Study Team vs Access Permissions

Up until now, adding someone to the study team meant awarding them some level of access to the study (ex. Study Viewer, Study Manager, etc.). With the rollout of CTMS v1.3, we are separating the study team from access permissions for the study. When the new version rolls out, your list of Study Team members will be blank. This does not mean that we have wiped all of your hard work from the system and blocked your CRAs from accessing their sties.

| Теа                                                     | Team                                                 |              |                       |          |                 |  |  |  |  |  |  |  |
|---------------------------------------------------------|------------------------------------------------------|--------------|-----------------------|----------|-----------------|--|--|--|--|--|--|--|
| • Access Permissions                                    |                                                      |              |                       |          |                 |  |  |  |  |  |  |  |
| <b>O</b> A                                              | ♦ Add 🖉 Edit 🗢 Remove 🕹 Export Q. Search 🔍 🕇 Filters |              |                       |          |                 |  |  |  |  |  |  |  |
| Role All V Start Date All V End Date All V Current Team |                                                      |              |                       |          |                 |  |  |  |  |  |  |  |
|                                                         | Name                                                 | Role         | Start Date            | End Date | Email           |  |  |  |  |  |  |  |
|                                                         | 🛔 Admin 003                                          | Data Manager | 14 Dec 2022, 12:00 AM |          | Admin003@ti.com |  |  |  |  |  |  |  |

#### 2.4.2 Managing Study Access Permissions

You will see a new 'Access Permissions' button at the top-right of the Study Team area. Your previous entries for the site team have all been moved to this new area. Clicking on that button will take you to the Site Settings area and the Access Permissions menu. Managing your user's access rights to different areas of the study will function the same as it used to in this new location.

| *                  | 👗 Study<br>Health Well Meds - HW9 | -     | Study Settings     | Access Permissions  | 5                 |                     |                              |               |  | Search   | Q | sc 🗸             |
|--------------------|-----------------------------------|-------|--------------------|---------------------|-------------------|---------------------|------------------------------|---------------|--|----------|---|------------------|
| Health Well Meds - |                                   | Ac    | Access Permissions |                     |                   |                     |                              |               |  |          |   |                  |
| Ā                  | HW9<br>STUDY                      | 0 /   | dd 🛛 🔛 Edit P      | ermissions C Active |                   | 🛔 Set as Owner      |                              |               |  | Q Search |   | <b>Y</b> Filters |
|                    | PLANNED                           | Теа   | m Members Only     | All with Access     | Status All ~ Acce | ss Permission All ~ |                              |               |  |          |   | c                |
| Sponsor<br>Product | Health Well Meds<br>Cort-9        | 2 Use | ers                |                     |                   |                     |                              |               |  |          |   | UTEN             |
|                    |                                   |       | Name               |                     | † Status          |                     | Access Permission            | Email         |  | End Date |   |                  |
| •                  | General                           |       | 🛔 CRA 002          |                     | ACTIVE            |                     | Study Viewer                 | CRA002@ti.com |  |          |   |                  |
| N                  | Regions                           |       | 🛔 CSM 001          |                     | ACTIVE            |                     | Clinical Study Manager (CSM) | CSM001@ti.com |  |          |   |                  |
| •                  | Milestone Templates               |       |                    |                     |                   |                     |                              |               |  |          |   |                  |
| <b>A</b> .         | Access Permissions                |       |                    |                     |                   |                     |                              |               |  |          |   |                  |

#### 2.4.3 Managing the Study Team

T R I A L INTERACTIVE

So, that leaves the question of what the Study Team area is for now that we've changed it. Essentially, this area of the study details is just for recording the part or multiple parts that people play in the actual study itself. For example, will the selected person be a biostatistician, a data manager, or a technical writer? You will be able to have multiple lines for a single individual to reflect the reality that many people fulfill multiple roles on the study team. Each entry will have a start and end date as well so that you can better track the evolution of the study team.

It should be noted that, while you can edit the team member's entry, you will not be able to change the 'Role' field. If someone begins to fulfil a new role on the team, the preferred process would be to provide an end date (if applicable) to the prior role and then to create a new entry for their new role.

| Теа        | Team                                                                                                                    |              |                       |          |                    |  |  |  |  |  |  |
|------------|-------------------------------------------------------------------------------------------------------------------------|--------------|-----------------------|----------|--------------------|--|--|--|--|--|--|
|            |                                                                                                                         |              |                       |          | Access Permissions |  |  |  |  |  |  |
| <b>O</b> A | Add                                                                                                                     |              |                       |          |                    |  |  |  |  |  |  |
|            | Role All ~     Start Date All ~     End Date All ~     Current Team      Provide All All All All All All All All All Al |              |                       |          |                    |  |  |  |  |  |  |
|            | Name                                                                                                                    | Role         | Start Date            | End Date | Email              |  |  |  |  |  |  |
|            | 🛔 Admin 003                                                                                                             | Data Manager | 14 Dec 2022, 12:00 AM |          | Admin003@ti.com    |  |  |  |  |  |  |

#### 2.4.4 Study Milestones Dashlet

With CTMS v1.3, we are adding a new dashlet to the study dashboard. This new dashlet will track milestones as defined in the study settings.





#### 2.5 Site Management

#### 2.5.1 Managing Site Contacts

TI CTMS v1.3 also includes some updates to the way that site contacts work. The functionality here will be similar to the improvements described above in the section about managing the study team. Each contact can have multiple entries as needed to indicate the various roles that they may play at the site. Importantly, for the purposes of entering the same person more than once, there is now a 'Copy' option in the menu above the list of site contacts. The system will verify that you intend to create another record for the same person, especially if you are doing so in order to change some detail of their information (for example, someone's last name might have changed).

#### 2.5.2 Closing a Site

With the ability to indicate final statuses naturally comes the action of closing a site. Because, as we mentioned earlier, an entity which hits a final status cannot be brought back to an earlier status, we need to take care that the site is ready to be closed before the status can be successfully applied.

Once a site's status has been set to it's penultimate status, whether that be 'Closeout' or 'Ready to Close' or something similar, the ability to close a site will become active. At the bottom of the Site Details area is now a 'Close Site' block with a red button labeled 'Close Site.'





Once that button is pressed, a Site Health Card window is displayed indicating the completion status of the site-related Milestones, Site Visits, Subjects, Activities, and Activity Plans. This gives the user a chance to locate and deal with any unresolved items before they become locked.

| Si | te Health Card                    |                              |                                     | τ×          |
|----|-----------------------------------|------------------------------|-------------------------------------|-------------|
|    | All Site data must be recond      | ciled to close the Site. Thi | s Site contains data that should be | reconciled. |
|    | Entity                            | Open                         | Reconciled                          |             |
|    | O reconciled                      |                              |                                     |             |
|    | C Site Visit<br>0 reconciled      |                              |                                     |             |
|    | C Subject<br>0 reconciled         |                              |                                     |             |
|    | Activity<br>1 of 1 not reconciled | 1<br>Open                    |                                     |             |
|    | C Activity Plan<br>0 reconciled   |                              |                                     |             |
|    |                                   |                              |                                     |             |
|    |                                   |                              |                                     |             |
|    | A                                 | re you sure you would lil    | ke to close your Site?              |             |
|    |                                   | Cancel                       |                                     |             |
|    |                                   |                              |                                     |             |

Once all of the items are resolved, and nothing is left undone, the 'Yes, Close' button is activated and the site can be closed.

# 3 Organizations

#### 3.1 Pre-Requisites

Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to users' accounts so that they can perform these steps.

#### 3.2 Creating an Organization

T R I A L INTERACTIVE

- 1. Click on the **organization** link in the Navigation Menu in the panel at the left side of the screen.
  - a. This opens the "Organization" window, and all the organizations at the domain level are displayed.

|   | *        | Organizations                         |       |                               |                  |                             |                        |                   | Search Q AA -             |
|---|----------|---------------------------------------|-------|-------------------------------|------------------|-----------------------------|------------------------|-------------------|---------------------------|
|   | «        | E                                     | Org   | anizations                    |                  |                             |                        |                   |                           |
|   |          |                                       | O Ac  | dd 🥒 Edit 💿 Activate          | Q Search Tilters |                             |                        |                   |                           |
|   |          |                                       | 122 0 | organizations                 |                  | 0                           |                        |                   |                           |
|   |          | TrialInteractive                      |       | Name                          | Status           | Parent Organization         | Туре                   | Subtype           | Primary Contact           |
|   |          |                                       |       | j&j                           | Attive           |                             | Hospital               |                   |                           |
|   | 8        | Dashboard                             |       | ARI                           | Active           |                             | Partner                |                   |                           |
|   |          | Sponsors                              |       | China Holding Corp            | Active           |                             | Partner                |                   |                           |
|   |          | Programs                              |       | Central Lab of China          | Active           |                             | Lab                    |                   |                           |
|   | <u>ک</u> | Products<br>Studies                   |       | Jiahui International Hospital | Active           |                             | Hospital               |                   |                           |
|   |          | Organizations                         |       | Astroville Corporation        | Approved         |                             | Pharmaceutical Company |                   |                           |
|   | 쑙        | Contacts                              |       | Dermeron                      | Active           |                             | Sponsor                |                   |                           |
|   |          | User Management<br>Activities Library |       | Vickie and Jack Farber Insti  | Active           | Thomas Jefferson Universi   | Investigative Site     | Local             |                           |
|   |          | Activity Plan Templates               |       | Thomas Jefferson Universi     | Active           | Thomas Jefferson University | Hospital               | Local             |                           |
|   | 9        | Milestone Templates                   |       | Thomas Jefferson University   | Active           |                             | University             | Local             |                           |
|   |          |                                       |       | Scotts Labels                 | Active           |                             | Partner                |                   |                           |
|   |          |                                       |       | Scott Works                   | Active           |                             | Sponsor                |                   | 🛔 Jordan Martin           |
|   |          |                                       |       | Sydney Neurology              | Active           |                             | Clinic                 | Central and local |                           |
|   |          |                                       |       |                               |                  |                             |                        |                   |                           |
| ٠ |          |                                       |       |                               |                  |                             |                        |                   |                           |
| T |          |                                       |       |                               |                  |                             |                        |                   | Previous     1 of 10 Next |

- 2. Click the **Add** button at the top-left of the screen.
  - a. This opens the "Create Organization" window.
- Here we need to enter the mandatory metadata to create an organization i.e., Name, Number, Type and Status as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Create** button displaying the fields which need to be filled to create an organization successfully.

# TI CTMS USER GUIDE v1.2

|   | *        | Organizations                                  |                                      |     |                   | Search Q                | <b>AA</b> -     |
|---|----------|------------------------------------------------|--------------------------------------|-----|-------------------|-------------------------|-----------------|
|   | «        | $\sim$                                         | Organization Create Organization     |     |                   |                         |                 |
|   |          | To                                             | General Information                  |     | Press             | F11 to exit full screen | <b>F</b> ilters |
|   |          |                                                | 122 Organizations                    |     |                   |                         | G               |
|   |          | TrialInteractive                               | Name                                 |     | Subtype           | Primary Contact         | O OPEN          |
|   |          |                                                | J&J                                  |     |                   |                         |                 |
|   | 63       | Dashboard                                      | ARI Parent Organization              |     |                   |                         |                 |
|   |          | Sponsors                                       | China Holding C                      |     |                   |                         |                 |
|   | 2        | Programs                                       | Central Lab of C Type* Subtype       |     |                   |                         |                 |
|   | <u> </u> | Products                                       | jiahui Internation                   |     |                   |                         |                 |
|   |          | Studies<br>Organizations                       | Astroville Corpor                    | iny |                   |                         |                 |
|   |          | Contacts                                       | Dermeron                             | -   |                   |                         |                 |
|   | ===      | User Management                                | Primary Contact                      |     | Local             |                         |                 |
|   |          | Activities Library                             |                                      |     |                   |                         |                 |
|   | •        | Activity Plan Templates<br>Milestone Templates | Thomas jefferso Phone Numbers        |     | Local             |                         | - 1             |
|   |          | winestone remplates                            | Thomas jefferso 🗢 Add                |     | Local             |                         |                 |
|   |          |                                                | Scotts Labels Notes                  |     |                   |                         |                 |
|   |          |                                                | Scott Works                          |     |                   | 🛔 Jordan Martin         |                 |
| ≡ |          |                                                | Sydney Neurolo                       |     | Central and local |                         |                 |
| ÷ |          |                                                | Cancel Select and Add Another Create |     |                   |                         |                 |
| ¥ |          |                                                |                                      |     |                   |                         |                 |
| C |          |                                                |                                      |     |                   | Previous     1 of 10 No | ext 🕨           |

5. **(Optional)** Click on the **Add** symbol below **Phone Number** to add a contact number to that organization.

**Note**: When creating an organization record with at least one phone number, you will need to designate one phone number as the primary number.

6. **(Optional)** Click **Include Address**, select a type for the address, and enter the address information.

**Note**: The Search functionality can be utilized to search for addresses.

- 7. Finally, before clicking **Create**, verify all the fields are entered correctly in the Create Organization window.
- 8. Click **Create** or **Select and Add Another** depending on whether you intend to create another organization right away.

# TI CTMS USER GUIDE v1.2

|   | *         | Organizations                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                      |                   | Search Q AA -            |
|---|-----------|----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-------------------|--------------------------|
|   | «         |                                                                      | Cre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | eate Organization                    |                   | •                        |
|   |           | $\mathcal{E}$                                                        | Add     Phon     Add     Phon     Add     Add | e Numbers<br><sup>bad</sup>          |                   | Q Search T Filters       |
|   |           | TrialInteractive                                                     | Name J&j Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                      | Subtype           | Primary Contact          |
|   | <b>B</b>  | Dashboard<br>Sponsors                                                | ARI 🖹 🗄                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                      |                   | _                        |
|   |           | Programs Products                                                    | Central                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | e Address                            |                   |                          |
|   |           | Studies<br>Organizations                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ess Information                      |                   |                          |
|   | **<br>*** | Contacts<br>User Management<br>Activities Library                    | Dermer Addres                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | ss type*                             | Local             |                          |
|   |           | Activities Library<br>Activity Plan Templates<br>Milestone Templates | Thoma: Search                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | n<br>inter address and press Return  | Local             |                          |
|   | V         | witestone remplates                                                  | Thoma: Primar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | ry Address*                          | Local             |                          |
|   |           |                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ss Line 2                            |                   | 🛎 Jordan Martin          |
| • |           |                                                                      | Day & C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | ce lina à                            | Central and local |                          |
| č |           |                                                                      | Montre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Cancel Select and Add Another Create | Local             |                          |
| 6 |           |                                                                      | _                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                      |                   | Previous     1 of 7 Next |

#### 3.3 Editing an Organization

- Click on the **Organizations** link in the Navigation Menu in the panel at the left side of the screen.
   a. This opens the "Organization" window.
- 2. Click on the checkbox next to the organization name.
  - a. A quick-view panel will display on the right side of the screen.
- 3. Now, click on the **Edit** button (pencil icon).
- 4. Make any necessary changes.
- 5. Click on the **Save** button to apply the changes.

# TI CTMS USER GUIDE v1.2

|   | *             | Organizations               |             |                              |              |                   |                    |                   |                 | Search                         |                        |  |
|---|---------------|-----------------------------|-------------|------------------------------|--------------|-------------------|--------------------|-------------------|-----------------|--------------------------------|------------------------|--|
|   | «             | $\sim$                      | Organiz     | ations                       |              |                   |                    |                   |                 |                                |                        |  |
|   |               | Fa                          | 🔂 Add       | 🖉 Edit 🛛 🗢 Acti              | vate 🗊 Delet | e                 |                    |                   |                 | Q Search                       | <b>T</b> Filt          |  |
|   |               | $\mathcal{O}$               | 122 Organiz | 122 Organizations 1 Selected |              |                   |                    |                   |                 |                                | Astroville Corporation |  |
|   |               | TrialInteractive            | Name        |                              |              | Parent Organizati | Туре               | Subtype           | Primary Contact | AC Approved<br>08 Sep 2021     | _                      |  |
|   |               |                             | j&j         | _                            | ctive        |                   | Hospital           |                   |                 |                                |                        |  |
|   | 89<br>10<br>2 | Dashboard                   | ARI         | _                            | ctive        |                   | Partner            |                   |                 | Organization Information       | 1                      |  |
|   |               | Sponsors<br>Programs        |             |                              | ctive        |                   | Partner<br>Lab     |                   | _               | Number<br>1247982021           | Status Approved        |  |
|   | <u>₽</u><br>▲ | Products<br>Studies         | Jiahui      | Internatio                   | ctive        |                   | Hospital           |                   |                 | Name<br>Astroville Corporation |                        |  |
|   |               | Organizations               | Astrov      | ville Corpo                  | pproved      |                   | Pharmaceutical     |                   |                 |                                |                        |  |
|   | **            | Contacts<br>User Management | Derm        | eron 🛛 🗛                     | ctive        |                   | Sponsor            |                   |                 | Parent Organization            |                        |  |
|   |               | Activities Library          | Vickie      | and Jack 🛛 🗛                 | ctive        | Thomas Jeffers    | Investigative Site | Local             |                 | Туре                           | Subtype                |  |
|   |               | Activity Plan Templates     | Thom        | as Jeffers 🗛                 | ctive        | Thomas Jeffers    | Hospital           | Local             |                 | Pharmaceutical Compa           |                        |  |
|   | 8             | Milestone Templates         | Thom        | as Jeffers 🛛 🗛               | ctive        |                   | University         | Local             |                 | Description                    |                        |  |
|   |               |                             | Scotts      | s Labels                     | ctive        |                   | Partner            |                   |                 |                                |                        |  |
| _ |               |                             | Scott       | Works                        | ctive        |                   | Sponsor            |                   | 🛓 Jordan Martin |                                |                        |  |
|   |               |                             | 5ydne       | y Neurolo                    | ctive        |                   | Clinic             | Central and local |                 | Notes                          |                        |  |
| • |               |                             | Day &       | Day Ship                     | ctive        |                   | Partner            |                   |                 |                                |                        |  |
|   |               |                             | Montr       | real Neur                    | ctive        | McGill Universit  | Investigative Site | Local             | Þ               |                                |                        |  |
| 5 |               |                             |             |                              |              |                   |                    | Previous          | 1 of 7 Next 🕨   |                                |                        |  |

6. **(Optional)** Clicking on the organization name will open the "Organization Details" page. Editing an organization may also be done on the organization details page.

|        | Organization     Central Lab of China      Or                                    | ganization Details                                                                       | Search Q AA -                                       |
|--------|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------------------|
|        | «                                                                                | Central Lab of China FEDIT V Expand All                                                  | Assue<br>Press F11 to exit full screen Ptdt History |
|        | Central Lab of China                                                             | Organization Information                                                                 | 8                                                   |
|        | Organization Details     Studies     Stes     Related Organizations     Contacts | Name       Central Lab of China       Parent Organization       Type     Subtype   Notes |                                                     |
|        |                                                                                  | Lab                                                                                      | \$                                                  |
|        |                                                                                  | Contact Information                                                                      | Ø                                                   |
| ≣      |                                                                                  | Additional Information                                                                   | æ                                                   |
| *<br>T |                                                                                  |                                                                                          |                                                     |

#### 3.4 Associating an Address to an Organization

- Click on the **Organizations** link in the Navigation Menu in the panel at the left side of the screen.
   a. This opens the "Organization" window.
- 2. Locate the organization to which you want to associate an address and click on the organization's name.
  - a. This opens "Organization Details" window.
- 3. Click the **Edit** button in the Organization window.
- 4. Click on the [+] sign next to **Contact Information** to expand that section.
- 5. Click on the **Add** button in the **Addresses** section.
  - a. This opens the "Add Address" window.
- Here we need to enter the mandatory metadata to create an address i.e., Address Type,
   Primary Address, Country, and Postal Code which have an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.

**Note**: The Search functionality can be utilized to search for addresses.

7. If any of the required fields are missing, an error will appear when we click on the **Add Address** button displaying the fields which need to be filled to create an address successfully.

|   | <ul> <li>⑦ Organization</li> <li>ARI ▼</li> </ul> | zation Details                                                                 | Search Q 🗛 🗸   |
|---|---------------------------------------------------|--------------------------------------------------------------------------------|----------------|
|   | «                                                 | ARI                                                                            | Active         |
|   |                                                   | <pre>// Edit → Expand All</pre> Add Address □ ×                                | ී Edit History |
|   | ARI                                               | Organization Info                                                              | æ              |
|   | i Organization Details                            | Contact Informati                                                              | •              |
|   | Studies     Sites                                 | Q. Enter address and press Return       Primary Contact       Primary Address* |                |
|   | Related Organizations                             | Address Line 2                                                                 |                |
|   |                                                   | Address Line 3                                                                 |                |
|   |                                                   | Addresses                                                                      |                |
|   |                                                   | O Add                                                                          |                |
|   |                                                   | Phone Numbers Cancel Add and Create Another Add Address                        |                |
| ۰ |                                                   |                                                                                |                |
| C |                                                   | Additional Information                                                         | ß              |

8. (Optional) Click Add and Create Another if you intend to create another address right away.



#### 3.5 Associating an Organization to a Parent Organization

- 1. Click on the **Organizations** link in the Navigation Menu in the panel at the left side of the screen.
  - a. This opens the "Organization" window.
- 2. Click on the Name for any non-sponsor organization record from the list displayed.
  - a. This opens the "Organization Details" window.

|        | Organization     Farmacia merulana dei dottori ş                                                                                                      | ue                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Search Q AA -            |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|        | «                                                                                                                                                     | Farmacia merulana dei dottori guerra & del pio snc<br>Z Edit – V Expand All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Active<br>3 Edit History |
|        | Farmacia merulana<br>dei dottori guerra &                                                                                                             | Organization Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | •                        |
|        | i       Organization Details         iii:       Studies         iii:       Stres         iii:       Related Organizations         iii:       Contacts | 01     3275262021     Active       01     Name       Farmacia merulana dei dottori guerra & del pio snc       Parent Organization       Image: Construction       Im |                          |
|        |                                                                                                                                                       | Contact Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                          |
| •<br>E |                                                                                                                                                       | Additional Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 8                        |

- 3. Click the **Edit** button in the "Organization Detail" window, within the **Parent Organization** field select a parent organization.
- 4. Click the **Save** button.
- 5. The association can be verified by navigating to the Related Organizations area for the selected parent organization. (See the screenshot below)

# TI CTMS USER GUIDE v1.2

|   | Organization     Farmacia Internazionale | Related Organizations                              |          |                         |          | Search Q | <b>AA</b> • |
|---|------------------------------------------|----------------------------------------------------|----------|-------------------------|----------|----------|-------------|
|   | «                                        | Related Organizations                              |          |                         |          |          |             |
|   |                                          | 🕒 Add 🥒 Edit 🛛 S3 Remove                           | Q Search | <b>T</b> Filters        |          |          |             |
|   | Farmacia                                 | 2 Organizations                                    |          |                         |          |          | G           |
|   | Internazionale                           | Name                                               | Status   | Parent Organization     | Туре     | Subtype  | Primar P    |
|   |                                          | Farmacrimi                                         | Active   | Farmacia Internazionale | Pharmacy |          |             |
|   | i Organization Details                   | Farmacia merulana dei dottori guerra & del pio snc | Active   | Farmacia Internazionale | Pharmacy |          |             |
|   | <u>⊥</u> Studies                         |                                                    |          |                         |          |          |             |
|   | Sites                                    |                                                    |          |                         | 2        |          |             |
|   | Related Organizations                    |                                                    |          |                         |          |          |             |
|   | Contacts                                 |                                                    |          |                         |          |          |             |
|   |                                          |                                                    |          |                         |          |          |             |
|   |                                          |                                                    |          |                         |          |          |             |
|   |                                          |                                                    |          |                         |          |          |             |
|   |                                          |                                                    |          |                         |          |          |             |
|   |                                          |                                                    |          |                         |          |          |             |
|   |                                          |                                                    |          |                         |          |          |             |
| ≣ |                                          |                                                    |          |                         |          |          |             |
|   |                                          |                                                    |          |                         |          |          |             |
| ٠ |                                          |                                                    |          |                         |          |          |             |
| T |                                          |                                                    |          |                         |          |          |             |
| 6 |                                          |                                                    |          |                         |          |          |             |

### 3.6 Associating a Contact to an Organization

- 1. Click on the **Organizations** link in the Navigation Menu at the left side of the screen.
  - a. This opens the "Organization" window.
- 2. Click on the Name of any organization record in the list.
  - a. This opens the "Organization Details" window.
- Click on the **Contacts** link in the Navigation Menu in the panel at the left side of the screen.
   a. This opens the "Create Contact in Organization" window.
- 4. Click **Add** and enter the required contact details.
- 5. Click Create.

# TI CTMS USER GUIDE v1.2

|        | 👘 Organization<br>Jiahui International Hospital 💌                                   | Contacts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                  |                        | Search Q. AA -     |
|--------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|------------------------|--------------------|
|        | <ul> <li>Jiahui International<br/>Hospital</li> </ul>                               | Contacts  Add Contacts Contacts Name Contacts Name Contacts Contac | Create Contact in Organization   X  Q Search for Contacts  General Information  Profix  First Name*  Middle Name | Email<br>Lee@email.com | Q, Search<br>Phone |
|        | Organization Details     Studies     Studies     Related Organizations     Contacts |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Last Name® Suffix<br>job Title Contact Type*<br>Email Address<br>Phone Numbers<br>• Add<br>Include Address •     |                        |                    |
| ≡<br>≎ |                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Cancel Create and Add Another Create                                                                             |                        |                    |
| T      |                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                  |                        |                    |

#### 3.7 Reviewing Studies Associated to an Organization

- Click on the **Organization** link in the Navigation Menu at the left side of the screen.
   a. This opens the "Organization" window.
- 2. Click on the organization's name in the list.
  - a. This opens the "Organization Details" window.
- 3. Click on the **Studies** link in the Navigation Menu at the left side of the screen.
  - a. This opens the "Studies" window.
- 4. The list of studies is displayed.

# TI CTMS USER GUIDE v1.2

|       | ☆ Study<br>KingDerm1 •                                                                                                                                                                                                          | Organizations              |                  |        |                     |                  |       | [               | Search              | Q (AA) -         |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------|--------|---------------------|------------------|-------|-----------------|---------------------|------------------|
|       | « T                                                                                                                                                                                                                             | Organization               | 5                |        |                     | de la            |       |                 |                     |                  |
|       |                                                                                                                                                                                                                                 | 🕒 Add 🥒 Edit               | S Remove         |        |                     | 15               |       |                 | Q Search            | <b>T</b> Filters |
|       | KingDerm1                                                                                                                                                                                                                       | 1 Organizations            | Status           |        | Parent Organization | Tura             |       | Subtract        | Drimony Cont        | o oper           |
|       |                                                                                                                                                                                                                                 | Name<br>King Trucking and  |                  |        | King Research       | Type<br>Supplier |       | Subtype         | Primary Cont        | ž                |
| ■ • ℃ | <ul> <li>Study Details</li> <li>Dashboard</li> <li>Milestones</li> <li>Countries</li> <li>Sites</li> <li>Subjects</li> <li>Organizations</li> <li>Contacts</li> <li>Team</li> <li>Activities</li> <li>Activity Plans</li> </ul> |                            |                  |        |                     |                  |       |                 |                     |                  |
|       | Organization     King Trucking and Distrib     «                                                                                                                                                                                | ution - Studies<br>Studies |                  |        |                     |                  |       |                 | Search<br>Q. Search | Q AA ▼           |
|       |                                                                                                                                                                                                                                 | 1 Studios                  |                  |        |                     |                  |       |                 | Q Search            | , mers           |
|       | King Trucking and<br>Distribution                                                                                                                                                                                               | Name                       | Protocol Number  | Status |                     | Program          | Phase | Therapeutic Are |                     | # Planned Subje  |
| ≡ * 6 | Organization Details     Stos     Related Organizations     Contacts                                                                                                                                                            | KingDerm1                  | koo1-11193252021 | faund  | King Research       | *                | 840   |                 | 100                 | 1000             |

# 4 Sponsors

T R I A L INTERACTIVE

#### 4.1 Pre-Requisites

Users creating or managing **Sponsors** in an organization should have **CSM** user access. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to users' accounts so that they can perform these steps.

### 4.2 Defining a Sponsor

- 1. Click on **Sponsors** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Sponsors" window, and Sponsors list is displayed.

|   | *                                      | Sponsors                              |                               |            |                     |         |         | Search Q A               | •     |
|---|----------------------------------------|---------------------------------------|-------------------------------|------------|---------------------|---------|---------|--------------------------|-------|
|   | *                                      | $\sim$                                | Sponsors                      |            |                     |         |         |                          |       |
|   |                                        | Y                                     | 🕥 Add 🥒 Edit 🛛 Activate       | Delete     |                     |         |         | Q Search T Fi            | lters |
|   |                                        | $\mathcal{O}$                         | 33 Organizations              |            |                     |         |         |                          | 0     |
|   |                                        | TrialInteractive                      | Name                          | Status     | Parent Organization | Туре    | Subtype | Primary Contact          | OPEN  |
|   |                                        |                                       | Dermeron                      | Active     |                     | Sponsor |         |                          |       |
|   | B                                      | Dashboard                             | Scott Works                   | Active     |                     | Sponsor |         | 🛔 Jordan Martin          |       |
|   |                                        | Sponsors                              | Myzer Rx                      | Active     |                     | Sponsor |         |                          |       |
|   |                                        | Programs                              | Waxo Smyth Clean Products     | Active     |                     | Sponsor |         |                          |       |
|   | 11111111111111111111111111111111111111 | Products<br>Studies                   | Wayer Pharmaceuticals         | Active     |                     | Sponsor |         |                          |       |
|   |                                        | Organizations                         | Acme Pharmaceuticals          | Active     |                     | Sponsor |         |                          |       |
|   | 쓥                                      | Contacts                              | Sangra Drugs                  | Active     |                     | Sponsor |         |                          |       |
|   | <br>12                                 | User Management<br>Activities Library | RK Meds                       | Approved   | Work Anywhere       | Sponsor |         |                          |       |
|   |                                        | Activity Plan Templates               | Wiser Meds                    | Approved   |                     | Sponsor |         |                          |       |
|   | 9                                      | Milestone Templates                   | Takeda Pharmaceutical Co. Ltd | Approved   |                     | Sponsor |         |                          |       |
|   |                                        |                                       | Mari Tech                     | Activo     |                     | Sponsor |         |                          |       |
|   |                                        |                                       | B-Ready Medicine              | Active     |                     | Sponsor |         |                          |       |
|   |                                        |                                       | A+ Drugs                      | Active     |                     | Sponsor |         |                          |       |
|   |                                        |                                       | Acme Drugs                    | Active     |                     | Sponsor |         |                          |       |
|   |                                        |                                       | Best Meds                     | Inactive   |                     | Sponsor |         |                          |       |
|   |                                        |                                       | Working 4U                    | In Review  |                     | Sponsor |         |                          |       |
|   |                                        |                                       | Winning World Medicine        | De not use |                     | Sponsor |         |                          |       |
|   |                                        |                                       | King Research                 | Approved   |                     | Sponsor |         |                          |       |
|   |                                        |                                       | ACI Pharmaceuticals           | Active     | ACI Limited         | Sponsor |         |                          |       |
|   |                                        |                                       | ACI Limited                   | Active     |                     | Sponsor |         |                          |       |
| ٠ |                                        |                                       |                               |            |                     |         |         |                          |       |
| Ŧ |                                        |                                       |                               |            |                     |         |         |                          |       |
| 6 |                                        |                                       |                               |            |                     |         |         | Previous     1 of 2 Next | •     |

- 2. Click the **Add** button in the top-left of the screen.
  - a. This opens the "Create Sponsor" window.
- Here we need to enter the mandatory metadata to create a sponsor i.e., Name, Number, Type, Status, as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a sponsor successfully.
- 5. **(Optional)** Click on the **Add** button in the **Phone Number** area to add a contact number to that sponsor.



**Note**: When creating a contact record with at least one phone number, you will need to designate one phone number as the primary number.

6. **(Optional)** Click **Include Address**, select a type for the address, and enter the address information.

Note: The Search functionality can be utilized to search for addresses.

- 7. Finally, before clicking **Create**, verify all the fields are entered correctly in the create sponsor window.
- 8. Click **Create** or **Select and Add Another** depending on whether you intend to create another sponsor right away.
  - a. After clicking **Create**, the "Create Sponsor" window will close, and the sponsor record will be displayed in the list.

|   | *        |                                               |                                                             |                 | - 🗛 -            |
|---|----------|-----------------------------------------------|-------------------------------------------------------------|-----------------|------------------|
|   | •        |                                               |                                                             |                 |                  |
|   |          |                                               | O Ade                                                       |                 | <b>T</b> Filters |
|   |          | $\mathcal{O}$                                 | 33 Organizations Create Sponsor • ×                         |                 | 6                |
|   |          | TrialInteractive                              |                                                             | Primary Contact | OPEN             |
|   |          |                                               | Dermeron General Information                                |                 |                  |
|   | R        | Dashboard                                     | Sopt Works                                                  | 🛔 Jordan Martin |                  |
|   |          |                                               | Myrer Rx                                                    |                 |                  |
|   | 1        | Programs                                      | Wexx Smyth Clean Products                                   |                 |                  |
|   | <u> </u> | Products<br>Studies                           | Weyer Pharmaceuticals Parent Organization                   |                 |                  |
|   |          | Organizations                                 | Acree Pharmaceusicals                                       |                 |                  |
|   | -        | Contacts                                      | Sangra Drugs Type* Subtype                                  |                 |                  |
|   |          | User Management                               | RK Meds Sponsor                                             |                 |                  |
|   |          | Activities Library<br>Activity Plan Templates | Wiser Meds                                                  |                 |                  |
|   | 0        | Milestone Templates                           | Takede Pharmaceutical Co. Ltd Primary Contact               |                 |                  |
|   |          |                                               | Man Tech                                                    |                 |                  |
|   |          |                                               | B-Beady Medicine Phone Numbers                              |                 |                  |
|   |          |                                               | A+Drugs O Add                                               |                 |                  |
|   |          |                                               | Acme Drugs Acme Drugs Notes                                 |                 |                  |
|   |          |                                               | Best Meds E 2 2 B I U 5                                     |                 |                  |
|   |          |                                               | Working 4U                                                  |                 |                  |
|   |          |                                               | Winning World Medicine Cancel Select and Add Another Create |                 |                  |
|   |          |                                               | King Research                                               |                 |                  |
| = |          |                                               | ACI Pharmaceuticals Aci Limited Sponsor                     |                 |                  |
| • |          |                                               | ACI Limited Acre Sponsor                                    |                 |                  |
| ~ |          |                                               |                                                             |                 |                  |
| C |          |                                               |                                                             |                 | Next 🕨           |

#### 4.3 Defining Sponsor Settings

- 1. Click on **Sponsors** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Sponsors" window, and the Sponsors list is displayed.
- 2. Navigate to the sponsor's name you want to edit and click on it.
  - a. This opens "Sponsor Details" window.



- 3. Click on the **Settings** button in the top-right of the screen.
  - a. This opens Sponsor settings window Milestone Templates screen.
- 4. Click on the milestone you want to edit.
- a. This opens Edit Milestone Template window.
- 5. Make any necessary changes required in the Edit Milestone Template window.
- 6. Click **Save** for the changes to apply.

|    |      | Sponsor<br>+ Drugs 👻 Sponso | or Settings Milestone Tem | plates                                |        |                |              | Search Q 🗛 🗸                    |
|----|------|-----------------------------|---------------------------|---------------------------------------|--------|----------------|--------------|---------------------------------|
|    | ĸ    |                             | Milestone Ten             |                                       |        |                |              |                                 |
|    |      |                             | 🕒 Add 🗠 🥒 Edit            | 📋 Delete 🛛 Set to Retired 🔶 Publish 🖻 | Сору   |                |              | Q Search Tilters                |
|    |      | A+ Drugs                    | Edit Milesto              | ne Template                           |        |                | Step 1 🔹 🗖 🗙 | Sort By Unknown ~               |
|    |      |                             | General Informatio        | n General Information                 |        |                |              | 🛱 Site                          |
|    | 0 14 | lestone Templates           |                           | Level*<br>Study                       | ~      |                |              | Updated 08 Sep 2021 admin admin |
|    |      | natorie rempilitea          |                           | Template Name*                        |        | Classification |              | 🛱 Ste                           |
|    |      |                             |                           | Last Subject Last Visit               |        | Enrollment ×   |              | _                               |
|    |      |                             |                           | Description                           |        |                |              | Updated 08 Sep 2021 admin admin |
|    |      |                             |                           |                                       |        |                |              | 🗒 Site                          |
|    |      |                             |                           |                                       |        |                |              | Updated 08 Sep 2021 admin admin |
|    |      |                             |                           |                                       |        |                |              | ∐ Study                         |
|    |      |                             |                           |                                       |        |                |              | Updated 08 Sep 2021 admin admin |
|    |      |                             |                           |                                       |        |                |              |                                 |
|    |      |                             |                           |                                       |        |                |              | <u>∆</u> Study                  |
|    |      |                             |                           |                                       |        |                |              | Updated 08 Sep 2021 admin admin |
|    |      |                             |                           |                                       |        |                |              | <u>∆</u> Study                  |
|    |      |                             |                           |                                       |        |                |              | Updated 08 Sep 2021 admin admin |
|    |      |                             |                           |                                       | Cancel | Save           |              |                                 |
| =  |      |                             | Manual                    |                                       |        |                |              | 👗 Study                         |
| .= |      |                             | mandal                    |                                       |        |                |              | Updated 08 Sep 2021 admin admin |
| ۰  |      |                             | Draft                     | Regulatory                            |        |                |              | 👗 Study                         |
| T  |      |                             | Manual                    | • 1st Ethics Approval (Site)          |        |                |              | Updated 08 Sep 2021 admin admin |
| 0  |      |                             |                           |                                       |        |                |              |                                 |

#### 4.4 Associating a Product to a Sponsor

- 1. Click on Sponsors in the Navigation menu at the left side of the screen.
  - a. This opens the "Sponsors" window, and the list of sponsors is displayed.
- 2. Click on the name of the sponsor to which you want to associate a product.
  - a. This opens the "Sponsors Details" window.
- 3. Click on the **Products** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Product" window.
- 4. Click on the **Add** button at the top-left of the screen.
  - a. This opens "Create Product" window.
- 5. Here we need to enter the mandatory metadata to create a product i.e., **Product Name, Type, Status, Status Date, Sponsor** as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.



- 6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a product successfully.
- 7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to associate another product to this sponsor immediately.

|   | *   | Sponsor<br>A+ Drugs • Products |              |          |                                              |          |               |                | Search Q | <b>AA</b> ~      |
|---|-----|--------------------------------|--------------|----------|----------------------------------------------|----------|---------------|----------------|----------|------------------|
|   | •   |                                |              |          |                                              |          |               |                |          |                  |
|   |     |                                | 🖸 Add 🥒 Edit |          |                                              |          |               |                |          | <b>T</b> Filters |
|   |     | A+ Drugs                       | 1 Products   |          |                                              |          |               |                |          |                  |
|   |     |                                | Product      | Programs |                                              | pe       | Modifier      | Owner          | Sponsor  |                  |
|   |     |                                | Diagnova     | 诸 Diagno | Create Product                               | <b>×</b> | System system | 👗 Steven Clark | A+ Drugs |                  |
|   |     | Sponsor Details<br>Programs    |              |          | Product Name* Type*                          |          |               |                |          |                  |
|   |     | Products                       |              |          |                                              | ~        |               |                |          |                  |
|   |     | Studies<br>Sites               |              |          | Status* Status Date* Planned 0 ~ 20 Sep 2021 | <b></b>  |               |                |          |                  |
|   |     | Organizations                  |              |          | Sponsor*                                     |          |               |                |          |                  |
|   | 202 | Contacts                       |              |          | A+ Drugs                                     |          |               |                |          |                  |
|   |     |                                |              |          | Indications 0 Indications Select             |          |               |                |          |                  |
|   |     |                                |              |          |                                              |          |               |                |          |                  |
|   |     |                                |              |          |                                              |          |               |                |          |                  |
|   |     |                                |              |          | Description                                  |          |               |                |          |                  |
|   |     |                                |              |          |                                              |          |               |                |          |                  |
|   |     |                                |              |          |                                              |          |               |                |          |                  |
|   |     |                                |              |          | Cancel Create and Add Another                | Create   |               |                |          |                  |
|   |     |                                |              |          |                                              |          | J             |                |          |                  |
|   |     |                                |              |          |                                              |          |               |                |          |                  |
| = |     |                                |              |          |                                              |          |               |                |          |                  |
|   |     |                                |              |          |                                              |          |               |                |          |                  |
|   |     |                                |              |          |                                              |          |               |                |          |                  |
| C |     |                                |              |          |                                              |          |               |                |          |                  |

### 4.5 Creating a Program for a Sponsor

- Click on **Sponsors** link in the Navigation menu in the panel at the left side of the screen.
   a. This opens the "Sponsors" window, and the list of Sponsors is displayed.
- 2. Click the name of the sponsor to be associated with the new program.
  - a. This opens "Sponsor Details" window.
- 3. Click on the **Programs** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Program" window.
- 4. Click on the **Add** button in the top-left of the screen.
  - a. This opens the "Create Program" window.
- Here we need to enter the mandatory metadata to create a program i.e., Program Name, Number, Status, Status Date, Sponsor, Products as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 6. If any of the required fields are missing, an error will appear when we click on the Create button, displaying the fields which need to be filled to create a program successfully.



7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another program right away.

|   | *                                      | Sponsor<br>A+ Drugs 👻 Programs                                        |                             |                                                                        |          |          | Search Q | •                |
|---|----------------------------------------|-----------------------------------------------------------------------|-----------------------------|------------------------------------------------------------------------|----------|----------|----------|------------------|
|   | •                                      |                                                                       |                             |                                                                        |          |          |          |                  |
|   |                                        |                                                                       | 🖉 Add 🥒 Edit                |                                                                        |          |          |          | <b>T</b> Filters |
|   |                                        | A+ Drugs                                                              | 2 Programs                  |                                                                        |          |          |          |                  |
|   |                                        |                                                                       | Program Name<br>Diagnova321 | Create Program                                                         | • ×      | Sponsor  | Product  |                  |
|   | ÷                                      | Sponsor Details                                                       | A+.008                      | Program Name* Number*                                                  | _        | A+ Drugs | â2       |                  |
|   | 山田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田 | Programs<br>Products<br>Studies<br>Sites<br>Organizations<br>Contacts |                             | Satura Status Date* Vitaming V (20 Sep 2021 Status* A+ Drugs Products* | <u>.</u> |          |          |                  |
|   |                                        |                                                                       |                             | Description                                                            |          |          |          |                  |
|   |                                        |                                                                       |                             | Cancel Crease and Add Anosher Cruse                                    |          |          |          |                  |
| = |                                        |                                                                       |                             |                                                                        |          |          |          |                  |
| ۰ |                                        |                                                                       |                             |                                                                        |          |          |          |                  |
| T |                                        |                                                                       |                             |                                                                        |          |          |          |                  |

#### 4.6 Creating a Study for a Sponsor

- 1. Click on **Sponsors** in the Navigation menu at the left side of the screen.
  - a. This opens the "Sponsors" window, and the Sponsors list is displayed.
- 2. Click on the name of the sponsor for the new study.
  - a. This opens "Sponsor Details" window.
- 3. Click on **Studies** in the Navigation menu at the left side of the screen.
  - a. This opens the "Study" window, and the Studies list is displayed.
- 4. Click on the **Add** button in the top-left of the screen.
  - a. This opens the "Create Study" window.
- Here we need to enter the mandatory metadata to create a study i.e., Protocol Number, Study Name, Protocol Title, Status, Status Date, Primary Product, Phase, Design as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a Study successfully.

Note: Sponsor field is already populated with the name of the sponsor you are working with.



|   | * | A+ Drugs - Studies        |            |               |                 |                         |                  |         |   |                     |              | Search    | Q,             | <b>AA</b> -      |
|---|---|---------------------------|------------|---------------|-----------------|-------------------------|------------------|---------|---|---------------------|--------------|-----------|----------------|------------------|
|   | • |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
|   |   |                           | <b>O</b> A | dd 🥒 Edit     |                 |                         |                  |         |   |                     |              |           |                | <b>T</b> Filters |
|   |   | A+ Drugs                  | 5 Stu      | dies          |                 |                         |                  |         |   |                     |              |           |                |                  |
|   |   | AT DIGES                  |            | Name          | Protocol Number | Create Study            |                  | • ×     | e | Therapeutic Area(s) | # Planned Tr | ial Sites | # Planned Subj | cts              |
|   |   |                           |            | Diagnova      | 00123           | Sponsor*                |                  |         |   |                     | 1            |           | 5              |                  |
|   | i | Sponsor Details           |            | Test1         | 001             | Sponsor*                |                  |         |   |                     | 5            |           | 50             |                  |
|   |   | Programs                  |            | Downton Now   | B215302         | Protocol Number*        | Study Name       |         |   | Unknown             | 0            |           | 0              |                  |
|   |   | Products<br>Studies       |            | AMed42021     | 8066142021      |                         |                  | 0       |   |                     | 0            |           | 0              |                  |
|   | Ê | Sites                     |            | Tremors Study | 1052618-2021    | Protocol Title*         |                  |         |   |                     | 0            |           | 0              |                  |
|   |   | Organizations<br>Contacts |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 | Types 0 Types<br>Select |                  |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 | Owner<br>admin admin    |                  |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 | Status*                 | Status Date*     |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 | Planned 🛛 🕹 🗸           | 20 Sep 2021      | <b></b> |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 | Program                 | Primary Product* | ~       |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 | Cance                   | Create           |         |   |                     |              |           |                |                  |
|   |   |                           |            |               |                 |                         |                  | -       |   |                     |              |           |                |                  |
| = |   |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
| ٠ |   |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
| T |   |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |
| 6 |   |                           |            |               |                 |                         |                  |         |   |                     |              |           |                |                  |

#### 4.7 Reviewing Sites for a Sponsor

- 1. Navigate to the Home and click on the **Sponsors** link in the Navigation menu at the left side of the screen.
- 2. Click on the name of the sponsor.
  - a. This opens the "Sponsor Details" window
- 3. Click on the Sites in the Navigation menu at the left side of the screen.
  - a. This opens the "Sites" window



|   | # A          | Sponsor<br>Drugs - Sites |                         |        |                                         |                 |            | Search Q -          |
|---|--------------|--------------------------|-------------------------|--------|-----------------------------------------|-----------------|------------|---------------------|
|   | *            |                          | Sites                   |        |                                         |                 |            |                     |
|   |              |                          | All Sites Active Closed |        |                                         |                 |            |                     |
|   |              | A+ Drugs                 | J Edu                   |        |                                         |                 |            | Q Search TRitters   |
|   |              |                          | 9 Sites                 |        |                                         |                 |            | 0                   |
|   | 1.1          |                          | Name                    | Status | Organization                            | Investigator    | Region     | Completed Milestone |
|   |              | onsor Details<br>ograms  | 📄 🗇 201 - Alam          | New    | Vickie and Jack Farber Institute for Ne | 🛔 Sheista Alem  | M Americas | HR PSSV             |
|   |              | aducts                   | 101 - Pollard           | New    | Sydney Neurology                        | A John Pollard  | Dceania    |                     |
|   | 🚊 Stu        | idies                    | 🗇 001 - Vieira          | New    | Montreal Neurological Institute-Hospi   | Lucy Vieira     | M Americas |                     |
|   | <b>1</b> Sec |                          | 🗇 Jones - 002           | New    | A+ Drugs                                | 🛔 Barbara jones |            |                     |
|   |              | ganizations<br>ntacts    | 🗇 🗇 Jones - 001         | New    | A+ Distributors                         | 🛔 Barbara jones |            |                     |
|   |              |                          | ==( ()                  | Active | A+ Drugs                                | Alison Foster   |            |                     |
|   |              |                          | ABC Matry               | Active | A+ Distributors                         | Ab DE           |            |                     |
|   |              |                          | Cusick622               | New    | Metro Hospital North                    | Vincent Cusick  |            |                     |
|   |              |                          | Paul96                  | New    | General Medicine Clinic of Tuisa        | 🛎 Linda Paul    |            |                     |
|   |              |                          |                         |        |                                         |                 |            |                     |
|   |              |                          |                         |        |                                         |                 |            |                     |
|   |              |                          |                         |        |                                         |                 |            |                     |
|   |              |                          |                         |        |                                         |                 |            |                     |
|   |              |                          |                         |        |                                         |                 |            |                     |
|   |              |                          |                         |        |                                         |                 |            |                     |
|   |              |                          |                         |        |                                         |                 |            |                     |
|   |              |                          |                         |        |                                         |                 |            |                     |
| ٠ |              |                          |                         |        |                                         |                 |            |                     |
| T |              |                          |                         |        |                                         |                 |            |                     |
| 0 |              |                          |                         |        |                                         |                 |            |                     |

### 5 Contacts

#### 5.1 Pre-requisites

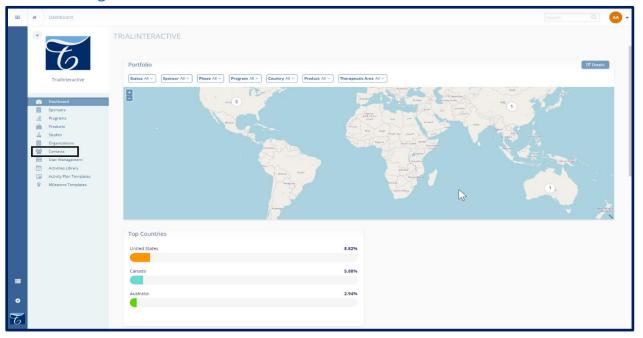
Each organization will need to decide who should create Contacts. It may be a specific group of people in the organization who are assigned to handle this to reduce the chances of creating duplicate records. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to user's accounts to that they can perform this step.

#### 5.2 Levels of Contact Creation in the Application

There are multiple levels of creating and managing a contact, one is at the Domain Level, if a contact is created at Domain level it can be accessed and used anywhere in the system. The other way of creating and managing a contact is at their respective sub level (Site, Organization, Product, etc.). Contacts may be used at the level at which they are created as well as any lower levels of the data hierarchy.



#### 5.3 Creating a Contact



- 1. Navigate to the appropriate level in the data hierarchy (i.e., Domain, Study, Site).
- 2. Click on the **Contact** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Contact" screen.
- 3. Click on the **Add** button at the top-left of the screen.
  - a. The "Create Contact" window is opened.
- Here we need to enter the mandatory metadata to create a contact i.e. First Name, Last Name, Email Address and Status which have an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button and it displays the fields which need to be filled to create a contact successfully.
- 6. **(Optional)** Click on the **Add** symbol below **Phone Number** to add a contact number to that person.

**Note**: When creating a contact record with at least one phone number, you will need to designate one phone number as the primary number.

7. **(Optional)** Click **Include Address**, select a type for the address, and enter the address information.

Note: The Search functionality can be utilized to search for addresses.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2022 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

# TI CTMS USER GUIDE v1.2

|   | Gontacts                                        |                                                                  |                                                                              |                                              | Search Q. 🗛 🗸                      |
|---|-------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------|------------------------------------|
|   |                                                 | Contacts                                                         | Create Contact                                                               |                                              | Q. Search                          |
|   | 6                                               | 110 Contacts                                                     | General Information Prefix First Name* Middle Name                           | Email                                        | Phone                              |
|   | TrialInteractive                                | a Joe Leo                                                        | Zhang                                                                        | Jae@email.con                                |                                    |
|   | Dashboard                                       | 👗 Eun He Lea                                                     | Last Name* Suffix<br>Ziyi                                                    | M@email.con<br>zz@email.con                  |                                    |
|   | Sponsors Programs                               | 👗 Zhang Ziyi                                                     | Job Title                                                                    | ZZ@email.com                                 | +86 3713944547                     |
|   | Products                                        | <ul> <li>Br. Shaista Alam</li> <li>Kelly Hibbit</li> </ul>       | Email Address* Status*                                                       | shaista@jeff.edu<br>kellyh@email.con         | +1 215 555 5555                    |
|   | Organizations     Contacts                      | 🔹 🛔 Jordan Martin                                                | This field is required                                                       | Jordan@email.con                             |                                    |
|   | User Management                                 | <ul> <li>Prof John Pollard</li> <li>&amp; Fred Malcom</li> </ul> | Phone Numbers                                                                | j-pollard@neuro.com<br>Fred.Malcom@email.con |                                    |
|   | Activity Plan Templates     Milestone Templates | 👗 Dr. Lucy Vieira                                                | • Add Primary                                                                | lucy@vleira.com                              |                                    |
|   |                                                 | Ligo Tognazzi                                                    | Phone number is invalid for the selected country                             | donna@email.con<br>Ugo@email.con             |                                    |
|   |                                                 | 🗌 🛔 James Martin                                                 | Complete all fields and delete unnecessary phone #(s) Jan                    | James@email.con                              |                                    |
|   |                                                 | Robert Glockner Rod Lockner                                      | Include Address                                                              | RGW@email.con<br>RG@email.con                |                                    |
|   |                                                 | 👗 Mary Hunter                                                    | Address Type* Please review these fields: Email Address                      | MLG@email.con                                |                                    |
|   |                                                 | Anita Rodriguez                                                  | This field is required Phone Numbers Phone Number 1 Address Type             | Anita@email.con<br>YV@email.con              | +1 212 339 1802<br>+1 212 339 0005 |
|   |                                                 | Linda Jackson                                                    | Search Primary Address Q. Enter address and press Return Country Postal Code | Linda@email.con                              | +1 212 335 0200 x12                |
| - |                                                 | Chris Smith                                                      | Cancel Create and Add Another Create                                         | Orm@email.con<br>chris@smith.edu             | +1 301 456 7890                    |
| ۰ |                                                 | Chris Malcom Smith                                               | Site Coordinator                                                             | abc@ge.go                                    |                                    |
| C |                                                 | ·····                                                            |                                                                              |                                              | Previous 1 of 5 Next               |

- 8. Finally, before clicking **Create**, verify that all the fields are entered correctly in the Create Contact window.
- 9. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another contact right away.

### 5.4 Editing a Contact at Domain, Site and Organization Levels

• The user must have been assigned the necessary permissions by the Company Administrator.

#### 5.5 Editing a Contact

- 1. Click on the check box before the contact's name.
  - a. A quick view panel will display on the right side of the screen
- 2. Click on the **Edit** button (pencil icon) and make any necessary changes to the contact information.
- 3. Click on the **Save** button at the bottom of the quick view panel.

# TI CTMS USER GUIDE v1.2

|   | *        | Contacts                    |                         |          |                        |                       |                            | Search Q 🗛 🗸                   |
|---|----------|-----------------------------|-------------------------|----------|------------------------|-----------------------|----------------------------|--------------------------------|
|   | *        |                             | Contacts                |          |                        |                       |                            |                                |
|   |          | F                           | 🗘 Add 🥒 Edit 👔 Delete   | Q Search |                        |                       |                            |                                |
|   |          | $\left( \right)$            | 110 Contacts 1 Selected |          |                        |                       |                            | Zhang Zini                     |
|   |          |                             | Name                    | Status   | Job Title              | Email                 | Phone                      | Zhang Ziyi                     |
|   |          | TrialInteractive            | 📄 🛔 Joe Leo             | ACTIVE   |                        | Jae@email.con         |                            | 09 Sep 2021                    |
|   |          |                             | 👗 Eun He Lea            | ACTIVE   |                        | M@email.con           |                            | 🗃 Email 🥾 Dial                 |
|   | 2        | Dashboard                   | 💄 Zhang Ziyi            | ACTIVE   |                        | zz@email.con          |                            | General Information            |
|   |          | Sponsors                    | 🖌 🤮 Zhang Ziyi          | ACTIVE   | Principal Investigator | ZZ@email.com          | +86 3713944547             | Prefix. First Name*            |
|   | <u>ک</u> | Programs<br>Products        | 📄 💄 Dr. Shaista Alam    | ACTIVE   | Principal Investigator | shaista@jeff.edu      | +1 215 555 5555            | Zhang                          |
|   | Ā        | Studies                     | 👗 Kelly Hibbit          | ACTIVE   | Account Executive      | kellyh@email.con      |                            | Middle Name                    |
|   |          | Organizations               | 📄 🔺 Jordan Martin       | ACTIVE   |                        | Jordan@email.con      |                            |                                |
|   |          | Contacts<br>User Management | 🛔 Prof John Pollard     | ACTIVE   | Principal Investigator | j-pollard@neuro.com   | N                          | Last Name* Suffix              |
|   | ø        | Activities Library          | Fred Malcom             | ACTIVE   |                        | Fred.Malcom@email.con | 12                         | Ziyi                           |
|   |          | Activity Plan Templates     | 💄 Dr. Lucy Vieira       | ACTIVE   | Principal Investigator | lucy@vieira.com       |                            | Status<br>Active • •           |
|   | 0        | Milestone Templates         | 📄 💄 Donna Baker         | ACTIVE   |                        | donna@email.con       |                            | Job Title                      |
|   |          |                             | 💄 Ugo Tognazzi          | ACTIVE   | CEO                    | Ugo@email.con         |                            | Principal Investigator         |
|   |          |                             | 📄 💧 James Martin        | ACTIVE   |                        | James@email.con       |                            | Preferred Languages 0 Language |
|   |          |                             | 🛔 Robert Glockner       | ACTIVE   |                        | RGW@email.con         |                            |                                |
|   |          |                             | Rod Lockner             | ACTIVE   |                        | RG@email.con          |                            | Preferred Communication Method |
|   |          |                             | 🚨 Mary Hunter           | ACTIVE   |                        | MLG@email.con         |                            |                                |
|   |          |                             | 🔒 Anita Rodriguez       | ACTIVE   |                        | Anita@email.con       | +1 212 339 1802            | Time Zone Best Contact Time    |
|   |          |                             | 🛔 Yvonne Martinez       | ACTIVE   |                        | YV@email.con          | +1 212 339 0005            |                                |
|   |          |                             | 📄 🛔 Linda Jackson       | ACTIVE   |                        | Linda@email.con       | +1 212 335 0200 ×12        | Contact Information            |
|   |          |                             | 👗 Orm Wensin            | ACTIVE   |                        | Orm@email.con         |                            |                                |
| • |          |                             | Chris Smith             | ACTIVE   |                        | chris@smith.edu       | +1 301 456 7890            |                                |
| * |          |                             | 🛔 Chris Malcom Smith    | ACTIVE   | Site Coordinator       | abc@ge.go             |                            | Cancel Save Save & Next        |
| T |          |                             | · ····                  | _        | · · · ·                |                       | Previous     1 of 5 Next I |                                |

- 4. Make sure to check the all the fields and click on the **Save** Button for the changes to apply.
- 5. **(Optional)** Clicking on the Contact's name will open the Contact Details page. Editing a contact may also be done on the Contact Details page.

|   | * | 🚨 Contact<br>Zhang Ziyi 💌 |                                   | Search Q AA -                  |
|---|---|---------------------------|-----------------------------------|--------------------------------|
|   | « |                           | Zhang Ziyi Principal Investigator | ZZ@email.com<br>+8603713944547 |
|   |   | ZZ                        | ✓ Edt: * Expand All               | D Edit History                 |
|   |   |                           | General Information               | ۲                              |
|   |   | Contact Details           |                                   | æ                              |
|   |   | Organizations<br>Sites    | Experience Information            | Ξ                              |
|   |   |                           | Additional Information            | æ                              |
|   |   |                           |                                   |                                |
|   |   |                           |                                   |                                |
|   |   |                           | Ν                                 |                                |
|   |   |                           |                                   |                                |
|   |   |                           |                                   |                                |
|   |   |                           |                                   |                                |
|   |   |                           |                                   |                                |
| • |   |                           |                                   |                                |
| T |   |                           |                                   |                                |
|   |   |                           |                                   |                                |

# 6 Studies

#### 6.1 Pre-Requisites

Users creating or managing Studies in an organization should have CSM user access. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to user's accounts so that they can perform these steps.

#### 6.2 Creating a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the Add button at the top-left of the screen.
  - a. The "Create Study" window will open.

|          | *        | Studies                                        |                                                               |                    |                      |               |
|----------|----------|------------------------------------------------|---------------------------------------------------------------|--------------------|----------------------|---------------|
|          | *        | E                                              | Studies<br>Create Study<br>35 Studies<br>Name                 |                    | ) to exit full scree | _             |
|          |          | TrialInteractive                               | Protocol Number* Study Name                                   | Pain and Anesthesi |                      | 400           |
|          | 63       | Dashboard                                      | Derm 001 Protocol Title*                                      |                    | 0                    | 0             |
|          |          | Sponsors                                       | MI Patch Peds                                                 |                    | 0                    | 0             |
|          |          | Programs                                       | ACIMed001                                                     |                    | 0                    | 0             |
|          | <u>п</u> | Products<br>Studies                            | Role test 2 Types 0 Types                                     |                    | 0                    | 0             |
|          |          | Organizations                                  | May Study Tes-                                                |                    | 0                    | 0             |
|          | 205      | Contacts                                       | Scotts 92021                                                  | Endocrine          | 58                   | 220           |
|          |          | User Management                                |                                                               |                    | 0                    | 0             |
|          |          | Activities Library                             | Owner admin admin                                             |                    | 0                    | 0             |
|          | •        | Activity Plan Templates<br>Milestone Templates |                                                               |                    |                      | -             |
|          |          |                                                | Planned 🚯 🗸 17 Sep 2021                                       |                    | 1                    | 5             |
|          |          |                                                | Program Primary Product*                                      |                    | 5                    | 50            |
|          |          |                                                | Downton Now                                                   | Unknown            | 0                    | 0             |
|          |          |                                                | AR- Gastro080                                                 | Dermatology        | 58                   | 250           |
| 8        |          |                                                | Cancel Create                                                 | Anti-Infective     | 0                    | 0             |
| <u> </u> |          |                                                | China test China TEST-001 Pairred ACI Pharmace Mays Limbs III |                    | 50                   | 520           |
| C        |          |                                                |                                                               |                    |                      | 1 of 2 Next 🕨 |

- Here, we need to enter the mandatory metadata to create a study i.e., Sponsor, Protocol Number, Protocol Title, Status, Status Date, Primary Product, Phase, Design and Blinded as indicated by asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 4. This is also where you will indicate whether or not this is a blinded trial. You can do this directly from the Study Details page after the study has been created but this is your first chance to indicate that this study will have a blinded component.



- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a study successfully.
- 6. Finally, before clicking **Create**, verify all the fields are entered correctly in the Create Study window.
  - a. The Create Study window closes, and the study record is displayed in the list.

#### 6.3 Blinded Studies

Studies that have been indicated as blinded will have the ability to display appropriate information only to specifically indicated personnel.

#### 6.3.1 Adding Unblinded Personnel to a Blinded Study

Unblinded personnel can only be added to a study by an unblinded study manager. In order to safeguard this information, the only way to add an unblinded study manager to a study is to contact the Trial Interactive Service Desk. Service Desk personnel will verify the intent and authenticity of the request prior to proceeding. The unblinded study manager is able to add unblinded members to the study team using the steps outlined in the related section of the User Guide.

#### 6.4 Editing a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Studies" window, and the study list is displayed.
- 2. Click on the check box next to the name of the study and click on the **Edit** button at the top-left of the screen.
  - a. The "Study Details" window is displayed.

### TI CTMS USER GUIDE v1.2

|   | *             | Studies                               |       |                               |                 |                       |              |          |               | 2                  | iearch               |                 |
|---|---------------|---------------------------------------|-------|-------------------------------|-----------------|-----------------------|--------------|----------|---------------|--------------------|----------------------|-----------------|
|   | «             | $\sim$                                | Stu   | dies                          |                 |                       |              |          |               |                    |                      |                 |
|   |               | 6                                     | 35 St | dd 🥒 Edit<br>udies 1 Selected |                 |                       |              |          |               | Press F1           | 1 to exit full scree | rn Filters      |
|   |               | TrialInteractive                      |       | Name                          | Protocol Number | Status                | Sponsor      | Program  | Phase         | Therapeutic Are    | # Planned Trial      | # Planned Subje |
|   |               |                                       |       | INTEGRITY_IV                  | INT-IV-001      | Planned               | Dermeron     | Integ_IV |               | Pain and Anesthesi | 25                   | 400             |
|   | 8             | Dashboard                             |       | Derm-001                      | Der992021       | Protocol Synopsis Ava | Dermeron     |          | 11-111        |                    | 0                    | 0               |
|   |               | Sponsors                              |       | MI Patch Peds                 | MI001-136       | Planned               | Medical Immu |          | 1-11          |                    | 0                    | 0               |
|   | <u>M</u>      | Programs                              |       | ACIMed001                     | ACI982021       | Planned               | ACI Pharmace |          | 1-II          |                    | 0                    | 0               |
|   | <u>ش</u><br>ح | Products<br>Studies                   |       | Role test 2                   | 817922021       | Planned               | May & May Ph |          | Г <del></del> |                    | 0                    | 0               |
|   |               | Organizations                         |       | May Study Tes                 | 813922021       | Planned               | May & May Ph |          | 1             |                    | 0                    | 0               |
|   | 44            | Contacts                              |       | Scotts 92021                  | 1229912021      | Planned               | Scott Works  |          | ш             | Endocrine          | 58                   | 220             |
|   |               | User Management<br>Activities Library |       | Anuj                          | 2238312021      | Submitted to Reg Aut  | Medical Immu |          | Ш             |                    | 0                    | 0               |
|   |               | Activity Plan Templates               |       | W4U-Study                     | 2148272020-W4U  | Planned               | Working 4U   |          | 1             |                    | 0                    | 0               |
|   | 9             | Milestone Templates                   |       | Diagnova                      | 00123           | Planned               | A+ Drugs     |          | 1             |                    | 1                    | 5               |
|   |               |                                       |       | Test1                         | 001             | Submitted to Reg Aut  | A+ Drugs     |          | 0             |                    | 5                    | 50              |
|   |               |                                       |       | Downton Now                   | B215302         | Enrolling             | A+ Drugs     | abc      | н             | Unknown            | 0                    | 0               |
| ≣ |               |                                       |       |                               |                 |                       |              |          |               |                    |                      |                 |
|   |               |                                       |       |                               |                 |                       |              |          |               |                    |                      |                 |
| ٠ |               |                                       |       |                               |                 |                       |              |          |               |                    |                      |                 |
| C |               |                                       |       |                               |                 |                       |              |          |               |                    | Previous             | 1 of 3 Next 🕨   |

- 3. Make any necessary changes to the Study information.
- 4. Click the **Save** button for the changes to apply.

|   | ★ Study<br>INTEGRITY_IV_001 ▼                          | Study Details                            | Search Q AA -           |
|---|--------------------------------------------------------|------------------------------------------|-------------------------|
|   |                                                        | INTEGRITY_IV_001<br>∰ Dermeron& Integ IV | Planed                  |
|   |                                                        | Save Collapse All                        | D Edit History          |
|   | INTEGRITY_IV_001                                       | Sponsor                                  | Integucaine PRIMARY     |
|   |                                                        | Virtual Study 💽 🚯                        | integrating instant     |
|   |                                                        |                                          |                         |
|   | i Study Details                                        | Protocol Information                     | -                       |
|   | Milestones                                             |                                          | -                       |
|   | Countries                                              | Protocol Title*                          | Phase*                  |
|   | 🛱 Sites                                                | Protocol title                           |                         |
|   | 1 Subjects                                             |                                          | Types 1 Types           |
|   | Organizations                                          |                                          | New indication ×        |
|   | Contacts                                               | Protocol Summary                         |                         |
|   | n Team                                                 |                                          |                         |
|   | <ul> <li>Activities</li> <li>Activity Plans</li> </ul> |                                          | Mechanisms 0 Mechanisms |
|   | Activity Plans                                         |                                          | Select                  |
|   |                                                        |                                          |                         |
|   |                                                        | Therapeutic Areas 1 Therapeutic Areas    |                         |
|   |                                                        | Pain and Anesthesia × ×                  | Objectives 0 Objectives |
|   |                                                        |                                          | Select                  |
| ٠ |                                                        |                                          |                         |
|   |                                                        | Indications 0 Indications Select         | Designs 1 Designs*      |
| E |                                                        |                                          | Open-Label ×            |
|   |                                                        |                                          |                         |

### 6.5 Entering Study Settings

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the name of the study in the list.
  - a. The dashboard for the study is displayed.
- 3. Click on the Study Details in the Navigation menu at the left side of the screen.
  - a. The "Study Details" window is displayed.

|   | #               | ≪ ***     ✓                                     | Dashboard                                                                                | Search | Q        | AA -    |
|---|-----------------|-------------------------------------------------|------------------------------------------------------------------------------------------|--------|----------|---------|
|   | «               |                                                 | KingDerm1<br>E King Research                                                             |        | (        | Planned |
|   |                 | KingDerm1                                       | Study Enrollment       Status All ~       (Year All ~       (Country All ~)   Site All ~ | £      | Export ~ |         |
|   | i<br>20<br>⊗    | Study Details<br>Dashboard<br>Milestones        |                                                                                          |        |          |         |
|   |                 | Countries<br>Sites<br>Subjects<br>Organizations | 4                                                                                        |        |          |         |
|   | ***<br>↑<br>(♡) | Contacts<br>Team<br>Activities                  | NO DATA FOUND                                                                            |        |          |         |
|   |                 | Activity Plans                                  |                                                                                          |        |          |         |
| • |                 |                                                 |                                                                                          |        |          |         |
| E |                 |                                                 |                                                                                          |        |          |         |



- 4. Click **Settings** in the top-right corner of the **study details** window.
  - a. This opens Study Settings General window.

|   | ★ Study<br>KingDerm1 ▼ | Study Details         |                  |                                        | Search                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                |
|---|------------------------|-----------------------|------------------|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|   | » Д                    | KingDerm1             |                  |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Planned        |
|   |                        | 🖋 Edit 🛛 😤 Expand All |                  |                                        | de la constanción de la constancición de la constanción de la constanción de la cons | D Edit History |
|   | KingDerm1              |                       |                  |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Settings       |
|   |                        | General Informatio    | n                |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ⊞              |
|   | i Study Details        |                       |                  |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
|   | 🚯 Dashboard            | Protocol Informati    | on               |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | æ              |
|   | Milestones             |                       |                  |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
|   | Countries              | Project Manageme      | nt               |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | æ              |
|   | L Subjects             |                       |                  |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
|   | Organizations          | Subject and Recrui    | tment            |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | •              |
|   | Contacts               | # Planned Trial Sites |                  | # Planned Subjects Entered Trial       | Enrolled 😧                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                |
|   | Activities             | 100                   |                  | 1,000                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
|   | Activity Plans         | First Site Enrolled   | Last Site Closed | # Planned Subjects Entered Treatment   | Completed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                |
|   |                        |                       |                  | 0                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
|   |                        |                       |                  | # Planned Subjects Completed Treatment | Screened                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                |
|   |                        |                       |                  | 0                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
|   |                        |                       |                  |                                        | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                |
| ٠ |                        |                       |                  |                                        | Screen Failed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                |
|   |                        |                       |                  |                                        | Jersen nantes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                |
| C |                        |                       |                  |                                        | UAT - Actual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                |

5. Click Edit from the study settings window at the top-left of the screen.

|   | ★ < •••<br>KingDerm1 ▼ Still   | udy Settings General                  | Search Q A -   |
|---|--------------------------------|---------------------------------------|----------------|
|   |                                | KingDerm1<br>■ King Research          | Planned        |
|   |                                |                                       | ී Edit History |
|   | KingDerm1                      | General Settings                      | •              |
|   | 🔅 General                      |                                       |                |
|   | Regions<br>Milestone Templates | Monitoring Information                | -              |
|   |                                | SVR Submission Days SVR Approval Days |                |
|   |                                | Site Visit Frequency                  |                |
|   |                                | 0 Types                               |                |
|   |                                | Visit Type Frequency                  |                |
|   |                                | No records available                  |                |
| ≡ |                                |                                       |                |
| ٠ |                                | Reviewers                             | •              |
| T |                                | 0 Reviewers                           |                |

- 6. Make any necessary changes in the Study Settings General window.
- 7. Click on **Save** at the top-left of the window.

T R I A L INTERACTIVE

|   | ★ study<br>KingDerm1 ▼         | Study Settings General                | Search Q AA •  |
|---|--------------------------------|---------------------------------------|----------------|
|   | × д                            | KingDerm1<br>I King Research          | Planned        |
|   |                                | Save Cancel A Collapse All            | ື Edit History |
|   | KingDerm1                      | General Settings                      | •              |
|   | 🔅 General                      |                                       |                |
|   | Regions<br>Milestone Templates | Monitoring                            | -              |
|   |                                | SVR Submission Days SVR Approval Days |                |
|   |                                | Site Visit Frequency                  |                |
|   |                                | 🗘 Add 🥒 Edit 🏢 Delete                 | Q Search       |
|   |                                | 0 Types                               |                |
|   |                                | Visit Type Frequency                  |                |
|   |                                | No records available                  |                |
|   |                                |                                       |                |
| ٠ |                                |                                       |                |
| C |                                | Reviewers                             | -              |



**Note**: Turning off Subject Tracking will prevent the creation of subject records. Actual subject enrollment statistics are still rolled-up from the site level.

#### 6.6 Defining Study specific Regions

- Click on the **Studies** in the Navigation Menu at the left side of the screen.
   a. This opens the "Studies" window.
- 2. Click on the name of the study for which you want to define regions.
  - a. This opens the dashboard for the study.
- 3. Click on the **Study Details** in the Navigation menu at the left side of the screen.
- 4. Click on the **Settings** button in the top-right corner of the screen.
  - a. This opens the **Study Settings** window.
- Click on **Regions** in the Navigation menu at the left side of the screen.
   a. The "Regions Window" is displayed.
- 6. Click on the **Add** button at the top-left of the screen.
  - a. This opens the "Create Region" Window.
- 7. Here we need to enter the mandatory metadata to create a Region i.e., **Region Name, Countries** as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 8. Click **Create** or **Create and Add Another** depending on whether you intend to create another Region right away.

|   | ★ study<br>INTEGRITY_IV_001 ▼         | Study Settings Regions               | Search Q 🗛 🗸              |
|---|---------------------------------------|--------------------------------------|---------------------------|
|   | «д                                    | Regions                              |                           |
|   |                                       | Add     Delete     Zedt              | Q Search <b>Y</b> Filters |
|   | INTEGRITY_IV_001                      | Region Create Region                 | Cities                    |
|   | 🔅 General                             | Region Name*                         |                           |
|   | Regions           Milestone Templates | Countries*                           |                           |
|   |                                       | State/Province                       |                           |
|   |                                       | Cities                               |                           |
|   |                                       |                                      |                           |
|   |                                       | Cancel Create and Add Another Create |                           |
| ≣ |                                       |                                      |                           |
| ٠ |                                       |                                      |                           |
| C |                                       |                                      |                           |

**Note**: To enter the State/Province and Cities values you must select only a **single country** for your region definition.

#### 6.7 Editing Study Regions

T R I A L INTERACTIVE

- 1. Navigate to the Regions area for the study you wish to edit.
  - a. The necessary steps are found <u>here</u>.
- 2. Click on the region name from the list you want to Edit.
  - a. This opens "Region Details" window.
- 3. Click on the **Edit** button in the-top-left corner.

|   | ▲ study<br>INTEGRITY_IV_001 ▼ | Study Settings                  |                           |   |
|---|-------------------------------|---------------------------------|---------------------------|---|
|   | «                             | A+                              |                           |   |
|   |                               | ▶ Edit                          |                           |   |
|   | A+                            | Region Information              |                           | ۰ |
|   |                               | Region Name*<br>A+              | Study<br>INTEGRITY_IV_001 | 0 |
|   | Region Details                | Country 1 Country*              | City <b>0 City</b>        |   |
|   |                               |                                 |                           |   |
|   |                               | State/Province 0 State/Province |                           |   |
|   |                               | *                               |                           |   |
|   |                               |                                 |                           |   |
|   |                               |                                 |                           |   |
|   |                               |                                 |                           |   |
|   |                               |                                 |                           |   |
| * |                               |                                 |                           |   |
| C |                               |                                 |                           |   |

- 4. Make any necessary changes in the **Region Details** window.
- 5. Click on **Save** button in the top-left for the changes to apply.

|        | ☆ study<br>INTEGRITY_W_001 ▼ | Study Settings                           |                           | Search Q AA - |
|--------|------------------------------|------------------------------------------|---------------------------|---------------|
|        | «                            | A+<br>Save Save ∧ Collapse All           |                           |               |
|        | A+                           | Region Information                       | Study<br>INTEGRITY_IV_001 | •<br>•        |
|        | Region Details               | Country 1 Country <sup>4</sup> <ul></ul> | City 0 City               |               |
|        |                              |                                          |                           |               |
| ≣      |                              |                                          |                           |               |
| *<br>6 |                              |                                          |                           |               |

#### 6.8 Defining and Editing Countries Within a Study.

- 1. Click on **Studies** in the Navigation Menu at the left side of the screen.
  - a. This opens the "Studies" window.
- Click on the name of the study in which you want to define countries.
   a. This opens the dashboard for the study.
- 3. Click on **Countries** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Countries" window, and countries list is displayed.
- 4. Click **Add** in the top-left of the screen.
  - a. This opens Create Study-Country window.
- Here we need to enter the mandatory metadata to create a Region i.e., Country, Owner, Status, Status Date as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- Click the Create button, the country is created, and the "Create Study-Country" window is closed.

|        |                                                                          | Countries                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Search Q A -      |
|--------|--------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
|        | ×٦                                                                       | Countries                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                   |
|        | INTEGRITY_IV_001                                                         | Create Study-Country     X       Country     X       Study Name     Regions       Regions     INTEGRITY_IV_001                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Q, Search Tilters |
|        | <ol> <li>Study Details</li> <li>Dashboard</li> <li>Milestones</li> </ol> | Country Code Coun |                   |
|        |                                                                          | Brazil     admin admin      Status*     Status Dato*     UAT Country     T7 Sep 2021      Regions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                   |
|        | Activity Plans                                                           | Cancel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Ŀ                 |
| *<br>C |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                   |

- 7. To edit the country, click on the check box before the name of the country you want to edit.
- 8. Click **Edit** in the top-left of the screen.
  - a. A quick view panel will display on the right side of the screen.
- 9. Make any necessary changes in the quick view panel.
- 10. Click Save.

T R I A L INTERACTIVE

|   | *  | Study                     | , ) c | ountries               |              |             |       |         |       | Search Q A                            | 14     |
|---|----|---------------------------|-------|------------------------|--------------|-------------|-------|---------|-------|---------------------------------------|--------|
|   | *  |                           | Со    | untries                |              |             |       |         |       |                                       |        |
|   |    |                           | •     | Add 🥒 Edit             | 🗊 Delete     |             |       |         |       | Q Search                              | Filter |
|   | IN | TEGRITY_IV_001            | 4 Co  | 4 Countries 1 Selected |              |             |       |         |       | Germany                               |        |
|   |    |                           |       | Country                | Country Code | Status      | Owner | Regions | Notes | Active                                |        |
|   |    |                           |       | Germany                | DE           | Active      |       |         |       |                                       |        |
|   | i  | Study Details             |       | O United States        | US           | UAT Country |       |         |       | General Information                   |        |
|   |    | Dashboard                 |       | 🛛 Canada               | CA           | UAT Country |       |         |       |                                       |        |
|   | 9  | Milestones                |       | @ Brazil               | BR           | UAT Country |       |         |       | Country Country Code Germany DE       |        |
| P |    | Countries                 |       |                        |              |             |       |         |       | Study                                 |        |
|   |    | Sites                     |       |                        |              |             |       |         |       | INTEGRITY_IV_001                      |        |
|   |    | Subjects<br>Organizations |       |                        |              |             |       |         |       | Notes                                 |        |
|   |    | Contacts                  |       |                        |              |             |       |         |       | NOCES                                 | -      |
|   |    | Team                      |       |                        |              |             |       |         |       |                                       |        |
|   |    | Activities                |       |                        |              |             |       |         |       |                                       |        |
|   |    | Activity Plans            |       |                        |              |             |       |         |       |                                       |        |
|   |    |                           |       |                        |              |             |       |         |       | Country Management                    | E      |
|   |    |                           |       |                        |              |             |       |         |       |                                       |        |
|   |    |                           |       |                        |              |             |       |         |       | Status Status Date Active 15 Sep 2021 |        |
|   |    |                           |       |                        |              |             |       |         |       |                                       | _      |
|   |    |                           |       |                        |              |             |       |         |       | Li Change Status                      |        |
|   |    |                           |       |                        |              |             |       |         |       | Cancel Save & Next                    |        |
|   |    |                           |       |                        |              |             |       |         |       | < Previous Nex                        | xt 3   |

#### 6.9 Associating Organizations to a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Studies" window.
- Locate the study to which you want to associate an organization and click on it.
   a. This opens the dashboard for that study.
- 3. Click on the **Organization** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Organization" window, organizations associated to the study are displayed.
- 4. Click on the **Add** button at the top-left of the screen.
  - a. This opens the "Add Organization" window.

|   | #   | ≤ *** ▲ Study<br>KingDerm1 ▼ | Organizations    | Add Organization                     |         | Search Q AA -    |
|---|-----|------------------------------|------------------|--------------------------------------|---------|------------------|
|   | «   |                              | Organization     | Q Search for the Organizations       |         |                  |
|   |     |                              | 🕒 Add 🥒 Edit     | General Information                  |         | Q Search Tilters |
|   |     | KingDerm1                    | 1 Organizations  | Name*                                |         | G                |
|   |     | in goot in t                 | Name             | Number*                              | Subtype | Primary Contact  |
|   |     |                              | King Trucking an |                                      |         |                  |
|   | i   | Study Details                |                  | Parent Organization                  |         |                  |
|   | -   | Dashboard                    |                  | ×                                    |         |                  |
|   | 0   | Milestones                   |                  | Type* Subtype                        |         |                  |
|   | Ø   | Countries                    |                  | × ×                                  |         |                  |
|   | ů   | Sites                        |                  | Status*                              |         |                  |
|   | Ŀ   | Subjects                     |                  | Active 🗸                             | 1       |                  |
|   |     | Organizations                |                  | Primary Contact                      |         |                  |
|   | -   | Contacts                     |                  | <b>A</b>                             |         |                  |
| ≣ | T T | Team<br>Activities           |                  | Phone Numbers                        |         |                  |
|   |     | Activity Plans               |                  |                                      |         |                  |
| ٠ |     |                              |                  | O Add                                |         |                  |
| C |     |                              |                  | Cancel Select and Add Another Create |         |                  |

- 5. If you need to create a new organization, follow these steps showing how to create an <u>Organization</u>.
- 6. If the organization has already been created, use the search area to locate and select the organization.
- 7. Click **Add** or **Add and Add Another** depending upon whether you need to associate another organization to this study.

#### 6.10 Defining Study Partners

- Click on the **Studies** link in the Navigation menu at the left side of the screen.
   a. This opens the "Studies" window and study list is displayed.
- Click on the name of the study to which you want to add partner information.
  - a. The dashboard for the study is displayed.
- 3. Click on the Study Details in the Navigation menu at the left side of the screen.



- a. The "Study Details" window is displayed.
- 4. Click on the [+] sign next to the **Partner Information** to expand that section.
- 5. Click on the **Edit** button in the top-left of the screen.

|   | ★ Comparison of the second | Study Details                | Search Q AA   |
|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|---------------|
|   | « Д                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | KingDerm1<br>≣ King Research | Planned       |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ✔ Edit ¥ Expand All          | ී Edit Histor |
|   | KingDerm1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | General Information          | 0             |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Protocol Information         | Đ             |
|   | i Study Details Dashboard Milestones                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Project Management           | ⊕             |
|   | Milestones     Countries     Sites                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Subject and Recruitment      | •             |
|   | <ul> <li>Subjects</li> <li>Organizations</li> <li>Contacts</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Informed Consent             | œ             |
|   | <ul> <li>Team</li> <li>Activities</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Partner Information          |               |
|   | Activity Plans                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Monitoring Partner           |               |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Data Management Partner      |               |
| ٠ |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Lab Handling Partner         |               |
| T |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Additional Information       | œ             |

- 6. Make the necessary changes in the partner information section.
- 7. Click the **Save** button in the top-left of the screen.

|   | ★ study<br>KingDerm1 ▼                                                  | Study Details              | Search Q 🗛 🗸   |
|---|-------------------------------------------------------------------------|----------------------------|----------------|
|   | × X                                                                     | KingDerm1                  | Planned        |
|   |                                                                         | Save D Cancel V Expand All | D Edit History |
|   | KingDerm1                                                               | General Information        | Ξ              |
|   |                                                                         | Protocol Information       | ⊞              |
|   | i Study Details                                                         |                            |                |
|   | Dashboard                                                               | Project Management         | œ              |
|   | Milestones     Countries     Sites                                      | Subject and Recruitment    | 8              |
|   | <ul> <li>§ Subjects</li> <li>Organizations</li> <li>Contacts</li> </ul> | Informed Consent           | œ              |
|   | 🛉 Team                                                                  | Partner Information        | =              |
|   | Activity Plans                                                          | Monitoring Partner         |                |
|   |                                                                         | Data Management Partner    |                |
| • |                                                                         | Lab Handling Partner       |                |
| C |                                                                         | Additional Information     |                |

#### 6.11 Associating Contacts to a Study

- Click on the **Studies** link in the Navigation menu at the left side of the screen.
   a. This opens the "Studies" window and study list is displayed.
- 2. Click on the name of the study to which you want to associate contacts.
  - a. The dashboard for the study is displayed.
- 3. Click on the **Contacts** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Contacts" window and all the contacts for the study are listed.
- 4. Click on the **Add** button at the top-left of the screen.
  - a. This opens the Create Contact in Study window.
- Here we need to enter the mandatory metadata to create a Contact i.e., Organization, First Name, Last Name, Contact Role, Email Address, Status as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 6. **(Optional)** Click on the **Add** symbol below **Phone Number** to add a contact number to that person.

**Note**: When creating a contact record with at least one phone number, you will need to designate one phone number as the primary number.

7. **(Optional)** Click **Include Address,** select a type for the address, and enter the address information.

**Note**: The Search functionality can be utilized to search for addresses.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2022 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



- 8. Finally, before clicking **Create**, verify all the fields are entered correctly in the **Create Contact in Study** window.
- 9. (Optional) Click Create or Create and Add Another depending on whether you intend to create another Contact right away.

Note: Contacts can only be created for organizations associated to the study.

10. When editing one of the contact records from the list, only data that is part of the contextual to study can be updated.

|   | #            | ≤ ***                                            | Contacts           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |       |            | <u> </u> |
|---|--------------|--------------------------------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------------|----------|
|   | «            |                                                  | Contacts           | Create Contact in Study                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       |            | Q Search |
|   |              | KingDerm1                                        | 0 Contacts<br>Name | General Information Organization*  Prefix First Name* Middle Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Phone | Start Date | C OPEN   |
|   | i<br>∰<br>♀  | Study Details<br>Dashboard<br>Milestones         |                    | Last Name* Suffix                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |       | Þ          |          |
|   |              | Countries<br>Sites<br>Subjects<br>Organizations  |                    | Job Title Contact Role* Contac |       |            |          |
|   | **<br>*<br>* | Contacts<br>Team<br>Activities<br>Activity Plans |                    | Active       Start Date       Iday month year                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |       |            |          |
|   |              |                                                  |                    | Phone Numbers<br>O Add                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |       |            |          |
| ٠ |              |                                                  |                    | Cancel Create and Add Another Create                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |       |            |          |
| C |              |                                                  |                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |       |            |          |

#### 6.12 Creating Sites within a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the name of the study to which you want to add Sites.
  - a. The dashboard for the study is displayed.
- 3. Click on the **Sites** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Sites" window, and all the sites are listed for the study.
- 4. Click on the **Add** button at the top-left of the screen.
  - a. This opens the Create Site window.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2022 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



- Here we need to enter the mandatory metadata to create a site i.e., Site Number, Principal Investigator, Site Organization, Site Location, Owner, Status and Status Date as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
  - a. If the site is a satellite site, this is also where you would identify the parent site. Please note that the parent site will need to already be created and associated with the study before identifying a site as a satellite site.

**Note**: The **Site Number** field is limited to 5 characters. Satellite sites can either have a unique site number or they can use the same number as the parent site.

|   | ★ Study<br>KingDerm1 ▼                                                                                                                             | Sites                                                                                             | Search Q 🗛 -        |
|---|----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|---------------------|
|   | » д                                                                                                                                                | Sites Create Site                                                                                 |                     |
|   | KingDerm1                                                                                                                                          | All Sites Active General Information<br>C Add ✓ Edit Study*<br>2 Sites This is a satellite site ① | Q Search Tilters    |
|   | <ul> <li>Study Details</li> <li>Dashboard</li> <li>Milestones</li> <li>Countries</li> <li>Stes</li> <li>Subjects</li> <li>Organizations</li> </ul> | Name Region Region                                                                                | Completed Milestone |
|   | <ul> <li>Contacts</li> <li>Team</li> <li>Activities</li> <li>Activity Plans</li> </ul>                                                             | Site Location* Owner* admin admin Status* Status Date* New 18 Sep 2021                            | ь                   |
| • |                                                                                                                                                    | Cancel Create and Add Another Create                                                              |                     |

- 6. Finally, before clicking **Create**, verify all the fields are entered correctly in the **Create Site** window.
- 7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another Site right away.

#### 6.13 Reviewing Subjects Within a Study



**Note**: Subjects is only available if the study is tracking subjects within CTMS. This list will be populated with the current list of subjects for the study.

- 1. Click on the Studies link in the Navigation menu at the left side of the screen.
  - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the name of the study whose subjects you wish to review.
  - a. The dashboard for the study is displayed.
- 3. Click on the **Subjects** link in the Navigation menu at the left side of the screen.
  - a. This displays all the subjects for the study.

|        | ñ       | ≪ •••• Ä Study<br>KingDerm1 ▼                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Subjects   |        |                      |                  | Search   | a 🗛 -            |
|--------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------|----------------------|------------------|----------|------------------|
|        | » Д     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Subjects   |        |                      |                  |          |                  |
|        |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 🥒 Edit     |        | l≽                   |                  | Q Search | <b>Y</b> Filters |
|        |         | KingDerm1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 0 Subjects |        |                      |                  |          | O OPEN           |
|        |         | in good in the second sec | Subject ID | Status | Screening Number     | Subject Initials | Site     | DPEN             |
|        |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |            |        | No records available |                  |          |                  |
|        | i       | Study Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |            |        |                      |                  |          |                  |
|        | €®<br>♀ | Dashboard<br>Milestones                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |            |        |                      |                  |          |                  |
|        | Ö       | Countries                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |            |        |                      |                  |          |                  |
|        | Ê       | Sites                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |            |        |                      |                  |          |                  |
|        | Ŀ       | Subjects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |            |        |                      |                  |          |                  |
|        |         | Organizations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |            |        |                      |                  |          |                  |
|        | 쓭       | Contacts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |            |        |                      |                  |          |                  |
|        |         | Team                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |            |        |                      |                  |          |                  |
|        | Ċ       | Activities                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |            |        |                      |                  |          |                  |
|        |         | Activity Plans                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |            |        |                      |                  |          |                  |
|        |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |            |        |                      |                  |          |                  |
|        |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |            |        |                      |                  |          |                  |
|        |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |            |        |                      |                  |          |                  |
| ٠      |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |            |        |                      |                  |          |                  |
| $\sim$ |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |            |        |                      |                  |          |                  |
| C      |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |            |        |                      |                  |          |                  |

#### 6.14 Study Sites Pre-Requisites

The user who is responsible for creating or managing sites in any study should have **CRA** user access. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to users' accounts so that they can perform these steps.



Page 51 of 130



### 6.15 Editing a Site in a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
- 2. Navigate to the study you want to access.
- Click on Sites in the Navigation menu at the left side of the screen.
   a. This opens the "Study Site" window and study site list is displayed.
- 4. Click on the name of the site you want to edit.
  - a. This opens the dashboard window for the site.
- 5. Click on **Site Details** in the Navigation menu at the left side of the screen.
  - a. This opens the "Site Details" window for the site.
- 6. Click on the **Edit** button at the top-left of the screen.

|   | *        | ≪ ***<br>Derm-001 ▼                      | 🗒 Site<br>Baker - 740 👻 Site                          | Details                |        |                                | Search Q AA -      |
|---|----------|------------------------------------------|-------------------------------------------------------|------------------------|--------|--------------------------------|--------------------|
|   | «        |                                          | Baker - 740<br>Bake OBGYN& Dor<br>Z Edit ¥ Expand All | nna Baker              |        |                                | New D Edit History |
|   |          | Baker - 740<br>Donna Baker<br>Bake OBGYN | Site Infor                                            | mation                 |        |                                | •                  |
|   |          |                                          | Study                                                 |                        | 3      | Site Location                  |                    |
|   | i        | Site Details                             | Derm-001                                              |                        | 0      | 3645 Las Vegas Boulevard South |                    |
|   | 6        | Dashboard                                | Site Number                                           | Principal Investigator |        | Regions                        |                    |
|   | 0        | Milestones                               | 740                                                   | Donna Baker            | Change |                                |                    |
|   |          | Site Visits                              | Site Name                                             |                        |        |                                |                    |
|   |          | Subjects                                 | Baker - 740                                           |                        |        |                                |                    |
|   | <b>.</b> |                                          | baker - 740                                           |                        |        |                                |                    |
|   |          | Organizations                            | Site Organization                                     |                        |        | Notes                          |                    |
|   |          | Contacts                                 | Bake OBGYN                                            | V                      |        |                                |                    |
|   |          | Team                                     |                                                       |                        |        |                                |                    |
|   | Ċ        | Activities                               |                                                       |                        |        |                                |                    |
|   | •        | Activity Plans                           |                                                       |                        |        |                                |                    |
| ٠ |          |                                          |                                                       |                        |        |                                |                    |
|   |          |                                          |                                                       |                        |        |                                |                    |
| C |          |                                          | Site Mana                                             | agement                |        |                                | æ                  |

- 7. Make the required changes in the site details window.
- 8. Click on the **Save** button at the top-left of the screen for the changes to apply.

|        | #                             | < •••                                                | Baker - 740 ▼                                                   |                         |                  |                                                             | Search C |                       |
|--------|-------------------------------|------------------------------------------------------|-----------------------------------------------------------------|-------------------------|------------------|-------------------------------------------------------------|----------|-----------------------|
|        | «                             |                                                      | Baker - 740<br>Bake OBGYN& Donna Bake<br>Save D Cancel V Expans |                         |                  |                                                             |          | New<br>D Edit History |
|        |                               | Baker - 740<br>Donna Baker<br>Bake OBGYN             | Site Informatio                                                 |                         | Þ                |                                                             |          |                       |
|        | i<br>∰                        | Site Details<br>Dashboard<br>Milestones              | Study Derm-001 This is Satellite Site Site Number*              | Principal Investigator* | 0                | Site Location 3645 Las Vegas Boulevard South Regions Select |          |                       |
|        |                               | Site Visits<br>Subjects<br>Organizations<br>Contacts | 740<br>Site Name*<br>Baker - 740                                | Donna Baker             | Change<br>Change | Notes                                                       |          |                       |
|        | <ul><li>♠</li><li>∅</li></ul> | Team<br>Activities<br>Activity Plans                 | Site Organization                                               |                         |                  |                                                             |          |                       |
| *<br>C |                               |                                                      | Site Managem                                                    | ent                     |                  |                                                             |          | ⊞                     |

#### 6.16 Tracking Informed Consents (ICFs) for a Site

- 1. Navigate to the Site Details area for the related site.
  - a. The necessary steps are found here.

T R I A L INTERACTIVE

2. Click on the [+] sign next to the Informed Consent to expand that section.

Page 53 of 130

|   | ★ Contract A Study<br>Derm-001 ▼                               | 🛱 Site<br>Baker - 740 👻 Site Details | Search Q AA -  |
|---|----------------------------------------------------------------|--------------------------------------|----------------|
|   |                                                                | Baker - 740<br>Bake Donna Baker      | New            |
|   |                                                                | ✔ Edit ¥ Expand All                  | D Edit History |
|   | Baker - 740<br>Donna Baker<br>Bake OBGYN                       | Site Information                     | 8              |
|   | i Site Details                                                 | Site Management                      | æ              |
|   | Dashboard     Milestones     Site Visits                       | Informed Consent                     | Ξ              |
|   | <ul> <li>Subjects</li> <li>Organizations</li> </ul>            | Site Addresses                       | Œ              |
|   | <ul> <li>Contacts</li> <li>Team</li> <li>Activities</li> </ul> | Subject and Recruitment              | Œ              |
|   | Activity Plans                                                 |                                      |                |
|   |                                                                |                                      |                |
| ≣ |                                                                |                                      |                |
| ٠ |                                                                |                                      |                |
| T |                                                                |                                      |                |

- 3. Click on the **Edit** button in the top-left of the screen.
- 4. Click on the **Add** button in the informed Consent section.

|   |                                                       | ster Site Details                                            | Search   | Q (AA) -          |
|---|-------------------------------------------------------|--------------------------------------------------------------|----------|-------------------|
|   |                                                       | Baker - 740<br>Bake 0801NA Donna Baker<br>Felit v Expand All |          | New Dedit History |
|   | Baker - 740<br>Donna Baker<br>Bake OBGYN              | Site Information                                             |          |                   |
|   | i Site Details                                        | Site Management                                              |          | ۲                 |
|   | Dashboard     Milestones     Site Visits     Subjects | Informed Consent                                             | Q Search | -                 |
|   | Organizations     Contacts                            | 0 Informed Consents                                          |          |                   |
|   | 🛊 Team                                                | Name Effective Date No records available                     |          |                   |
|   |                                                       |                                                              |          |                   |
| ٠ |                                                       | Site Addresses                                               |          | œ                 |
| C |                                                       | Subject and Recruitment                                      |          |                   |

5. Enter site specific Name and Effective Date.

|   | ñ | < ••• ▲ Study<br>Derm-001 ▼                                                                                             | Baker - 740 ▼                            | Search Q |                |
|---|---|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------|----------|----------------|
|   | « |                                                                                                                         | Baker - 740<br>E Bake OBGYN& Donna Baker |          | New            |
|   |   |                                                                                                                         |                                          |          | ී Edit History |
|   |   | Baker - 740<br>Donna Baker<br>Bake OBGYN                                                                                | Site Information                         |          | •              |
|   |   | Site Details                                                                                                            | Site Management                          |          | œ              |
|   |   | Deshboard<br>Milestones<br>Site Visits<br>Subjects<br>Organizations<br>Contacts<br>Team<br>Activities<br>Activity Plans | Informed Consent                         | Q Search | 8              |
| ≣ |   |                                                                                                                         |                                          |          |                |
| ٠ |   |                                                                                                                         | Site Addresses                           |          | •              |
| T |   |                                                                                                                         |                                          |          |                |
| 6 |   |                                                                                                                         | Subject and Recruitment                  |          | œ              |

6. Click Create.

T R I A L INTERACTIVE

Click on the Save button in the informed consent section to save the record.
 a. This creates site level ICF for the site.

#### 6.17 Tracking Site Addresses

- Navigate to the Site Details area for the related site

   The necessary steps are found here.
- 2. Click [+] next to the site addresses to expand that section.
- 3. Site location within the site addresses section is displayed as primary address.
- 4. Site Location is listed as a primary address for the site.
- 5. Click on the Add button under Site Addresses section.
  - a. This opens the Add Address window.
- 6. Here we need to enter the mandatory metadata to create an Address i.e., Address Type, Organization, Address as indicated by an asterisk (\*) symbol next to the field title.
- 7. Click on the **Save** button.

Note: Only addresses associated to the selected site organization are available for selection.

Page 55 of 130

|   | *           |                                          | Baler-740 + Site Details                                                                                                                                                                                                                                                  | Search Q A -   |
|---|-------------|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|   | K           |                                          | Baker - 740<br>Bake OBGYN& Donna Baker                                                                                                                                                                                                                                    |                |
|   |             |                                          | ✓ Edit V Expand All                                                                                                                                                                                                                                                       | D Edit History |
|   |             | Baker - 740<br>Donna Baker<br>Bake OBGYN | Site Information                                                                                                                                                                                                                                                          | ۳              |
|   | _           |                                          | Site Management                                                                                                                                                                                                                                                           |                |
|   |             | Site Details                             |                                                                                                                                                                                                                                                                           |                |
|   | 0           | Dashboard<br>Milestones<br>Site Visits   | Informed Consent Add Address                                                                                                                                                                                                                                              |                |
|   | *<br>•<br>• |                                          | Site Addresses     Address Type*          • Address Type*         • Address Type*           • Address Type*         • Address Type*           • Primary         • Organization*           • Site Losseine         • Address*           • Site Losseine         • Address* | C Search       |
|   |             |                                          | United States                                                                                                                                                                                                                                                             |                |
|   |             |                                          | Subject and Recruitment                                                                                                                                                                                                                                                   | ۳              |
|   |             |                                          |                                                                                                                                                                                                                                                                           |                |
|   |             |                                          |                                                                                                                                                                                                                                                                           |                |
| ٠ |             |                                          |                                                                                                                                                                                                                                                                           |                |
| T |             |                                          |                                                                                                                                                                                                                                                                           |                |

#### 6.18 Associating an Organization to a site

- 1. Navigate to the Site to which you wish to associate an organization.
- 2. Click on the **Organization** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Organization" window.
- 3. Click on **Add** button at the top-left of the screen.
  - a. This opens "Add organization" window.

|        |       | A Study<br>Derm-001 ↔                                                          | Organizations                                                      |                     |         | Search                       | 3 🔷 -     |
|--------|-------|--------------------------------------------------------------------------------|--------------------------------------------------------------------|---------------------|---------|------------------------------|-----------|
|        | •     | Derm-001                                                                       | Organizations<br>C Ada 2 For S Bereve<br>O Organizations<br>Name 5 | Add Organization    | Sultype | Q. Search<br>Primary Contact | T Filters |
|        | 🔮 Con | hboard<br>estones<br>untries<br>is<br>ojects<br>privations<br>tracts<br>tracts |                                                                    | General Information |         |                              |           |
| •<br>6 |       |                                                                                |                                                                    |                     |         |                              |           |

- 4. Here we need to fill the required metadata to create an organization with an address.
- 5. Click on the **Create** button.

#### 6.19 Change of Principal Investigator (PI)

- 1. Navigate to the Site Details area for the related site.
  - a. The necessary steps are found <u>here</u>.
- 2. Click on the [+] sign next to the Site Information to expand that section.
- 3. Click on the **Change** button in the site information section.



|   | *       |                                          | in Site<br>Bøker - 740 ▼               |                                       |        |                                                 | Search C | 2 🗛 -          |
|---|---------|------------------------------------------|----------------------------------------|---------------------------------------|--------|-------------------------------------------------|----------|----------------|
|   | *       |                                          | Baker - 740<br>Bake OBGYN& Donna Baker |                                       |        |                                                 |          | New            |
|   |         |                                          |                                        |                                       |        |                                                 |          | S Edit History |
|   |         | Baker - 740<br>Donna Baker<br>Bake OBGYN | Site Information                       |                                       |        |                                                 |          | •              |
|   |         |                                          | Study<br>Derm-001                      |                                       | 0      | Site Location<br>3645 Las Vegas Boulevard South |          |                |
|   |         | Site Details                             |                                        |                                       | 0      |                                                 |          |                |
|   | ee<br>Q | Dashboard<br>Milestones                  | Site Number<br>740                     | Principal Investigator<br>Donna Baker | Change | Regions                                         |          |                |
|   |         | Site Visits                              | Site Name                              |                                       |        |                                                 |          |                |
|   | 1       | Subjects                                 | Baker - 740                            |                                       |        |                                                 |          |                |
|   | 8<br>66 | Organizations<br>Contacts                | Site Organization                      |                                       |        | Notes                                           |          |                |
|   | -       | Team                                     | Bake OBGYN                             |                                       |        |                                                 |          |                |
|   |         | Activities                               |                                        |                                       |        |                                                 |          |                |
|   |         | Activity Plans                           |                                        |                                       |        |                                                 |          |                |
|   |         |                                          |                                        |                                       |        |                                                 |          |                |
|   |         |                                          | Site Management                        |                                       |        |                                                 |          |                |
|   |         |                                          | Informed Consent                       |                                       |        |                                                 |          | ۲              |
|   |         |                                          | Site Addresses                         |                                       |        |                                                 |          |                |
|   |         |                                          | Subject and Recruitn                   | nent                                  |        |                                                 |          | æ              |
|   |         |                                          |                                        |                                       |        |                                                 |          |                |
|   |         |                                          |                                        |                                       |        |                                                 |          |                |
| ۰ |         |                                          |                                        |                                       |        |                                                 |          |                |
| T |         |                                          |                                        |                                       |        |                                                 |          |                |
| 6 |         |                                          |                                        |                                       |        |                                                 |          |                |

- 4. Confirmation window is popped up, select **Yes** in the confirmation window.
  - a. This opens "Change Principal Investigator" window.

**Note**: Use the search box to find the contact.

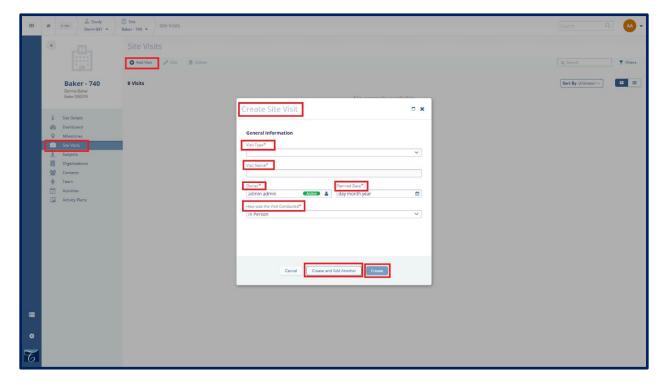
5. Click on the **Save** button.

|   | #   | ≪ ****                                   | Site Baker - 740 - Site Details        |                              |                            |               | Search Q 🗛 🗸   |
|---|-----|------------------------------------------|----------------------------------------|------------------------------|----------------------------|---------------|----------------|
|   | ×   |                                          | Baker - 740<br>Bake OBGYN& Donna Baker |                              |                            |               | Rev            |
|   |     |                                          |                                        |                              |                            |               | D Edit History |
|   |     | Baker - 740<br>Donna Baker<br>Bake OBGYN | Site Information                       | Change Principal Investig    |                            |               | -              |
|   |     |                                          | Study                                  |                              |                            |               |                |
|   | i   | Site Details                             | Derm-001                               | General Information          |                            | alevard South |                |
|   | Ð   | Dashboard                                | Site Number Principal                  | Prefix First Name*           | Middle Name                |               |                |
|   | 0   | Milestones                               | 740 Donna                              | E                            |                            |               |                |
|   |     | Site Visits                              | Site Name                              | Last Name*                   | Suffix                     |               |                |
|   | ż   | Subjects                                 | Baker - 740                            |                              |                            |               |                |
|   |     | Organizations                            | Site Organization                      | Job Title                    | Contact Role*              |               |                |
|   | 205 | Contacts                                 | Bake OBGYN                             | juo nue                      | Principal Investigator     |               |                |
|   | *   | Team                                     |                                        | Email Address*               | Status*                    |               |                |
|   |     | Activities                               |                                        | Email Address                | Active                     |               |                |
|   |     | Activity Plans                           |                                        |                              |                            | -             |                |
|   |     |                                          |                                        | Start Date<br>day month year | End Date<br>day month year |               |                |
|   |     |                                          |                                        | uay nontriyear 📖             | uaymontriyear              |               |                |
|   |     |                                          | Site Management                        |                              |                            |               | ۲              |
|   |     |                                          |                                        | Phone Numbers                |                            |               |                |
|   |     |                                          | Informed Consent                       | O Add                        |                            |               |                |
|   |     |                                          |                                        |                              |                            |               |                |
|   |     |                                          | Site Addresses                         |                              |                            |               | œ              |
|   |     |                                          | Subject and Recruitment                | Cancel                       | Save                       |               | œ              |
| = |     |                                          |                                        |                              |                            |               |                |
|   |     |                                          |                                        |                              |                            |               |                |
| • |     |                                          |                                        |                              |                            |               |                |
|   |     |                                          |                                        |                              |                            |               |                |
| T |     |                                          |                                        |                              |                            |               |                |
| 6 |     |                                          |                                        |                              |                            |               |                |
|   |     |                                          |                                        |                              |                            |               |                |



#### 6.20 Creating Site Visits

- 1. Navigate to the site for which you wish to create a site visit.
- Click on Site Visits in the Navigation menu at the left side of the screen.
   a. This opens "Site Visits" window.
- Click on the Add Visits button at the top-left of the screen.
   a. This opens "Create Site Visit" window.
- Here we need to enter the mandatory metadata to create a Site Visit i.e., Visit Type, Visit Name, Owner, Planned Date, how was the visit Conducted as indicated by an asterisk (\*) symbol next to the field title.
- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a Site Visit successfully.
- 6. Finally, before clicking **Create**, verify all the fields are entered correctly in the create Site Visit window.
  - a. Create Site Visit window closes, and site visit record is created and displayed in the list.
- 7. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another Site Visit right away.





#### 6.21 Updating a Site visit

- 1. Navigate to the site whose visit you need to update.
- Click on the Site Visits in the Navigation menu at the left side of the screen.
   a. This opens "Site Visits" window.
- Navigate to the Site Visit record you want to update and click on the name.
   a. This opens "Visit General Information" window.
- 4. Make the required changes in this window for the site visit.
- 5. Click on the **Save** button which is at the bottom of the screen.

|        |                                                           | Site     Site | Search Q 🗛 🗸                |
|--------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
|        |                                                           | Last Visit<br>« Collegee All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | (Pleaved)<br>S Edit History |
|        | Last Visit                                                | Visit Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | -                           |
|        |                                                           | Visit Type*         Voit Satus*           Close out         V           Planned         0 v           Durston                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                             |
|        | Visit General Information<br>Visit Attendees<br>Locations | Valt Name*<br>Last Visit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                             |
|        | Visit Checklist<br>0%<br>Activities                       | Orner*     Vise Planned Data*       (admin admin     ▲)       Was Suro Data     Was End Data                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                             |
|        | Subjects<br>Enrollment Summary                            | (day month year diay month year diay month year diay month year diay was the Vast Conducted* Visit Checklist Template                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                             |
|        | Visit Report O Confirmation Letter O Follow-Up Letter     | in Person v v                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                             |
|        |                                                           | Visit Report                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | •                           |
|        |                                                           | Report Satus Revewer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                             |
|        |                                                           | Generator Draft Report                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                             |
| °<br>T |                                                           | C Previous Step © Add Activity "O Discard Charges Sove and Next.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Next Step >                 |

#### 6.22 Tracking Subjects

- 1. Navigate to the site whose subjects you wish to track.
- 2. Click on **Subjects** in the Navigation menu at the left side of the screen.
  - a. This opens the "Subjects" window.
- 3. Click on the **Add** button at the top-left of the screen.
  - a. This opens Create Subject window.
- Here we need to enter the mandatory metadata to create a Subject i.e., Subject ID, Status, Status Date as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.



- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a subject successfully.
- 6. Finally, before clicking **Create**, verify all the fields are entered correctly in the create subject window.
  - a. Create Subject window closes, subject record is created and displayed in the list.
- 7. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another subject right away.

**Note**: Subjects will not be displayed for navigation when Subject Tracking is turned off within Study > Settings for the study.

|   | *             |                                       | Site Subjects                     |                                                            |                  |                  | ۹ 🗛  | •     |
|---|---------------|---------------------------------------|-----------------------------------|------------------------------------------------------------|------------------|------------------|------|-------|
|   | K             |                                       | Subjects<br>O Add 2 Edit 1 Delete |                                                            |                  |                  | T Fi | lters |
|   |               | Bash-961                              | 0 Subjects                        |                                                            |                  |                  |      | 0     |
|   |               | Betty Bash<br>Daily Clinic - Atlanta  | Subject ID                        | Status                                                     | Screening Number | Subject Initials |      | PEN   |
|   |               | Site Details<br>Dashboard             | l                                 | Create Subject                                             | - <b>x</b>       |                  |      |       |
|   | <b>♀</b><br>≘ | Milestones<br>Site Visits<br>Subjects |                                   | Study*<br>KingDerm1                                        | 0                |                  |      |       |
|   |               | Organizations<br>Contacts             |                                   | Site*<br>Bash-961                                          |                  |                  |      |       |
|   | •             | Team<br>Activities                    |                                   | Subject ID*                                                |                  |                  |      |       |
|   |               | Activity Plans                        |                                   | Status <sup>#</sup> Status D<br>Surceired <b>0</b> V (daym | onth year        |                  |      |       |
|   |               |                                       |                                   | Date of Birth Subject day month year                       | Initials         |                  |      |       |
|   |               |                                       |                                   | Cancel Create and Add Anoth                                | ner Create       |                  |      |       |
|   |               |                                       |                                   |                                                            |                  |                  |      |       |
| • |               |                                       |                                   |                                                            |                  |                  |      |       |
|   |               |                                       |                                   |                                                            |                  |                  |      |       |
| T |               |                                       |                                   |                                                            |                  |                  |      |       |

#### 6.23 Editing a Subject

- 1. Navigate to the site whose subject requires editing.
- 2. Click on the **Subjects** in the Navigation menu at the left side of the screen.
  - a. This opens the "Subjects" window.
- 3. Click on the checkbox before the Subject name.
  - a. A quick view panel will display on the right side of the screen.
- 4. Now, click on the **Edit** button (pencil icon) in the top-right of the screen.
  - a. This opens the "Subject Details" window.
- 5. Make any necessary changes to the subject information.
- 6. Click on the **Save** button at the top-left of the screen.



|               | ☆ Study<br>KingDerm1 • | Site     Subject       Bash-961 •     123456 • |                  |                                            | Search Q 🗛 🔻   |
|---------------|------------------------|------------------------------------------------|------------------|--------------------------------------------|----------------|
|               | •                      | 123456<br>@ Bash-961                           |                  |                                            | Screened       |
|               |                        | Save Save A Collapse All                       |                  |                                            | D Edit History |
|               | 123456<br>Bash-961     | Subject Information                            |                  |                                            | •              |
|               |                        | Subject ID*                                    | Subject Initials | Screening Number                           |                |
|               | i Subject Details      | 123456                                         |                  |                                            |                |
|               | Subject Visits         | Date of Birth                                  | Site             | Informed Consent Name Signature Date       |                |
|               |                        | day month year 🛍                               | Bash-961         |                                            | Add            |
|               |                        | Enrollment ID                                  | Randomization ID | 2 <sup>th</sup> Informed Consent - History |                |
|               |                        |                                                |                  |                                            |                |
|               |                        |                                                |                  |                                            |                |
|               |                        | Subject History                                |                  |                                            | •              |
|               |                        | Current Status                                 |                  | Screening Failure Reason (0)               |                |
|               |                        | 🖸 Add 🖀 Delete 🗸 Set as Garrent.               |                  |                                            |                |
|               |                        | Name                                           | Date             |                                            |                |
|               |                        | CURRENT STATUS                                 | 12 Sep 2021      | Early Termination Reason (0)               |                |
|               |                        |                                                |                  | carry termination reason (o)               |                |
|               |                        |                                                |                  |                                            |                |
|               |                        |                                                |                  |                                            |                |
|               |                        |                                                |                  |                                            |                |
|               |                        | Summary Information                            |                  |                                            | -              |
|               |                        | Notes                                          |                  | Subject Outcome                            |                |
|               |                        | ■ = = B I U S                                  |                  |                                            |                |
|               |                        |                                                |                  |                                            |                |
| ۰             |                        |                                                |                  |                                            |                |
| $\overline{}$ |                        |                                                |                  |                                            |                |
| T             |                        |                                                |                  |                                            |                |

#### 6.24 Tracking Subjects Visits

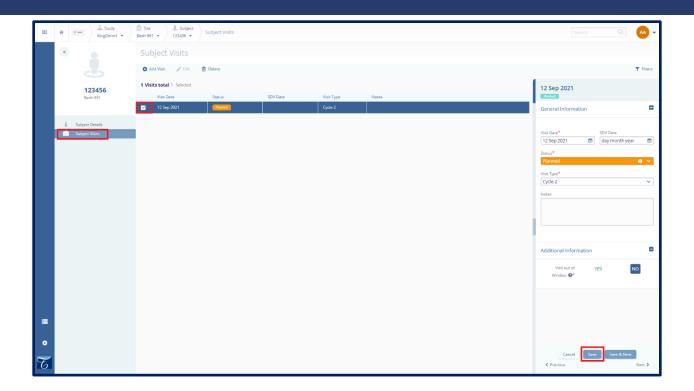
- 1. Navigate to the site in question.
- 2. Click on the **Subjects** in the Navigation menu at the left side of the screen.
  - a. This opens the "Subjects" window.
- 3. Navigate to the subject name you want to access and click on it.
- 4. Click on the **Subjects Visits** in the Navigation menu at the left side of the screen.
  - a. This opens "Subject Visits" window.
- 5. Click on the Add Visit button in the top-left of the screen.
  - a. This opens Create Subject Visit window.
- Here we need to enter the mandatory metadata to create a subject visit i.e., Visit Status, Visit Type, Visit Date as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 7. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a subject successfully.
- 8. Finally, before clicking **Create**, verify all the fields are entered correctly in the create subject visit window.
  - a. Create Subject Visit window closes, subject visit record is created and displayed in the list.
- 9. (Optional) Click Create or Create and Add Another depending on whether you intend to create another subject visit right away.

|       |                                    | Site Subject Subject Visits   |                               | Search 🧠 🤷 👻 |
|-------|------------------------------------|-------------------------------|-------------------------------|--------------|
|       |                                    | Subject Visits                |                               |              |
|       | ° i                                | Add Visit / Edit  Delete      |                               | ▼ Fitters    |
|       |                                    | 1 Visits total                |                               | 6            |
|       | 123456<br>Bash-961                 | Visit Date Status SDV Date    | Visit Type Notes              | OPEN         |
|       |                                    | 12 Sep 2021                   | Cycle 2                       |              |
|       | Subject Details     Subject Visits | Create Subject                | Visit 🗖 🗙                     |              |
|       |                                    | Subject                       |                               |              |
|       |                                    | 123456                        |                               |              |
|       |                                    | Visits Status*                | Visit Type*                   |              |
|       |                                    | Visit Date*                   | SDV Date                      |              |
|       |                                    | day month year<br>Notes       | 🖆 day month year 🖀            |              |
|       |                                    |                               |                               |              |
|       |                                    | Visit out of Window O*<br>YES | NO                            |              |
|       |                                    |                               |                               |              |
|       |                                    | Cancel                        | Create and Add Another Create |              |
|       |                                    |                               |                               |              |
|       |                                    |                               |                               |              |
| 1.000 |                                    |                               |                               |              |
|       |                                    |                               |                               |              |
| ٠     |                                    |                               |                               |              |
| T     |                                    |                               |                               |              |

#### 6.25 Editing a Subject Visit

T R I A L INTERACTIVE

- 1. Navigate to the site whose visit needs to be edited.
- 2. Click on the **Subjects** in the Navigation menu at the left side of the screen.
  - a. This opens the "Subjects" window.
- 3. Navigate to the subject name you want to access and click on it.
- 4. Click on the Subjects Visits in the Navigation menu at the left side of the screen.a. This opens "Subject Visits" window.
- 5. Navigate to the Subject visit record you want to edit and Click on the checkbox before the Subject visit name.
  - a. A quick view panel will display on the right side of the screen.
- 6. Now, click on the **Edit** button (pencil icon) in the top-right of the screen.
- 7. Make any necessary changes to the subject visit information.
- 8. Click on the Save button in the right bottom of the screen.



#### 6.26 Reviewing and Tracking Country Details

- 1. Navigate to the country whose details you wish to edit.
  - a. This can be done via the navigation menu at the left side of the screen.
- 2. Navigate to the country in the list you want to edit and click on it.
  - a. This opens the dashboard for the country.
- 3. Click on the **Country Details** in the Navigation Menu at the left side of the screen.
  - a. This opens the "Country Details" window.
- 4. Navigate to the section you want to review in the screen and click on the [+] sign next to the name to expand it.
- 5. Click on the **Edit** button on the top-left of the screen to make any changes and before returning, click on the **Save** button for the changes to apply.

### TI CTMS USER GUIDE v1.2

Page 64 of 130

|   | Study<br>KingDerm1 ▼                        | Study Country United States      Country Details | Search Q 🗛 🗸   |
|---|---------------------------------------------|--------------------------------------------------|----------------|
|   | ° A                                         | United States                                    | D Edit History |
|   | United States                               | Country Information                              | Θ              |
|   |                                             | Country Management                               | ۲              |
|   | i Country Details                           | Subject and Recruitment                          | Θ              |
|   | <ul> <li>Sites</li> <li>Subjects</li> </ul> | Informed Consent                                 |                |
|   | Organizations     Contacts     Team         |                                                  |                |
|   | Activities                                  |                                                  |                |
|   |                                             |                                                  |                |
|   |                                             |                                                  |                |
|   |                                             |                                                  |                |
|   |                                             |                                                  |                |
|   |                                             |                                                  |                |
|   |                                             |                                                  |                |
| * |                                             |                                                  |                |
| T |                                             |                                                  |                |

#### 6.27 Tracking Country Informed Consents (ICFs)

- 1. Click on **Countries** in the Navigation menu at the left side of the screen.
- 2. Navigate to the country in the list you want to edit and click on it.
  - a. This opens the dashboard for the country.
- 3. Click on the **Country Details** in the Navigation Menu at the left side of the screen.
  - a. This opens the "Country Details" window.
- 4. Click on the [+] sign next to the informed Consent to expand the section.
- 5. Click on the **Add** button in the informed consent section.
- 6. Click on the dropdown in the Name field.
  - a. Study level ICF is displayed and a country specific ICF can be created.

Page 65 of 130

|   | Study<br>KingDerm1 ▼                | Study Country United States      Country Details | Search Q 🗛 🗸   |
|---|-------------------------------------|--------------------------------------------------|----------------|
|   | • 👗                                 | United States                                    | D Edit History |
|   | United States                       | Country Information                              | 8              |
|   |                                     | Country Management                               | Ξ              |
|   | i Country Details                   | Subject and Recruitment                          | Θ              |
|   | Sites                               | Informed Consent                                 | •              |
|   | Organizations     Contacts     Team |                                                  |                |
|   | Activities Activity Plans           |                                                  |                |
|   |                                     |                                                  |                |
|   |                                     |                                                  |                |
|   |                                     |                                                  |                |
|   |                                     |                                                  |                |
|   |                                     |                                                  |                |
| ٠ |                                     |                                                  |                |
| T |                                     |                                                  |                |

- 7. Select the study ICF from the list and click on the save button in the informed consent section.
- 8. You can add country level ICF by adding name and effective date in the informed consent section and click on the save button.

|   | *            | KingDerm1 •                                | Geostry Country Details     Country Details                                                                                                                      | Search Q 🗛 🗸 |
|---|--------------|--------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
|   | ×            |                                            | United States                                                                                                                                                    |              |
|   |              |                                            | ✓ Edit:                                                                                                                                                          | Edit History |
|   |              | United States                              | Country Information                                                                                                                                              | ۲            |
|   |              |                                            | Country Management                                                                                                                                               | ۲            |
|   |              | Country Details<br>Dashboard<br>Milestones | Subject and Recruitment                                                                                                                                          | Ð            |
|   | 1<br>1       | Subjects                                   | Informed Consent                                                                                                                                                 | -            |
|   | 명<br>상상<br>· | Organizations<br>Contacts<br>Team          | • Sive D Cancel                                                                                                                                                  | Q Search     |
|   |              | Activities                                 | 0 Informed Consents                                                                                                                                              |              |
|   |              | Activity Plans                             | Name Effective Date       V     daymonth year                                                                                                                    | <b>m</b>     |
|   |              |                                            | Start typing to create a Country-specific informed Consent     Q       Swedy     available       Initial Protocol ICF Template     Initial Protocol ICF Template | _            |
|   |              |                                            |                                                                                                                                                                  |              |
|   |              |                                            |                                                                                                                                                                  |              |
|   |              |                                            |                                                                                                                                                                  |              |
| • |              |                                            |                                                                                                                                                                  |              |
| T |              |                                            |                                                                                                                                                                  |              |
|   | -            |                                            |                                                                                                                                                                  |              |



#### 6.28 Creating Site within a Country

- 1. Click on **Countries** in the Navigation menu at the left side of the screen.
- 2. Navigate to the country in the list you want to edit and click on it.
  - a. This opens the dashboard for the country.
- 3. Click on the **Sites** link in the Navigation menu at the left side of the screen.
- 4. Click on the **Add** button in the top-left of the screen.
  - a. This opens the "Create Site" window.
- 5. Fill in the required information and click **Create**.
  - a. More detailed instructions regarding this step can be found here.

|   |                                                                            | Study Country United States      Sites |                                                                                    |            |        | Search Q 🗛 🗸        |
|---|----------------------------------------------------------------------------|----------------------------------------|------------------------------------------------------------------------------------|------------|--------|---------------------|
|   | • д                                                                        |                                        |                                                                                    |            |        |                     |
|   |                                                                            | All Sites Active Closed                |                                                                                    |            |        |                     |
|   | United States                                                              | Add Add                                | Create Site in United States                                                       | • ×        |        | Q Search T Filters  |
|   | <ul> <li>Country Details</li> <li>Deshboard</li> <li>Milestones</li> </ul> | Name Stat                              | General Information<br>Study <sup>4</sup><br>KingDerm1                             | θ          | Region | Completed Milestone |
|   | Sites     Subjects     Organizations     Contacts                          |                                        | This is a satellite site   Ster Number*  Principal Investigator*  Site Name        |            |        |                     |
|   | <ul> <li>Team</li> <li>Accivity Plans</li> </ul>                           |                                        | Six Organization*                                                                  | •          |        |                     |
|   |                                                                            |                                        | Owner*<br>admin admin                                                              |            |        |                     |
|   |                                                                            |                                        | Senus" Senus Date"<br>Netw O V 20 Sep 2021<br>Carcel Create and Add Another Create | <b>#</b> ) |        |                     |
| = |                                                                            |                                        |                                                                                    | _          |        |                     |
| ۰ |                                                                            |                                        |                                                                                    |            |        |                     |
| C |                                                                            |                                        |                                                                                    |            |        |                     |

#### 6.29 Associating an Organization with a Country

- 1. Select **Countries** from the menu at the left side of the screen.
- 2. Click on the name of the country to which you wish to associate an organization.
- 3. Click on the Organization link in the Navigation menu at the left side of the screen.
- 4. This open the organization window, and organization list is displayed.
- 5. Click on the Add button in the top-left of the screen.
  - a. This opens Add Organization window.
- 6. Search for an Organization or create a new one if necessary.
  - a. More detailed instructions for this step may be found <u>here</u>.

|   | ∰ < === Å Study<br>KingDerm1 ▼                                    | Study Country United States   Organizations                                                           |                                  |         | Search Q A        | •      |
|---|-------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|----------------------------------|---------|-------------------|--------|
|   |                                                                   | Organizations                                                                                         |                                  |         | Q Search T Filter | 3      |
|   | United States                                                     | Organizations     Add Organizati     Name     Sam     G. Search for the Organ     General Information | izations                         | Subtype | Primery Contact   | O OPEN |
|   | Deshboard     Milestones     Sites     Subjects     Organizations | Name*                                                                                                 |                                  |         |                   |        |
|   | Contacts  Contacts  Activities  Activity Plans                    | Parrett Organization                                                                                  | Subspe                           |         |                   |        |
|   |                                                                   | Active<br>Primary Contact                                                                             | <u>ب</u>                         |         |                   |        |
|   |                                                                   | © Add<br>Nones                                                                                        | t Select and Add Another Creates |         |                   |        |
| • |                                                                   |                                                                                                       |                                  |         |                   |        |
| C |                                                                   |                                                                                                       |                                  |         |                   |        |

#### 6.30 Associating Contacts with a Country

T R I A L INTERACTIVE

- 1. Navigate to the country to which you wish to associate a contact.
- 2. Click on the name of the country to which you wish to associate a contact.
- 3. Click on the Contacts link in the Navigation menu at the left side of the screen.
  - a. This opens the "Contacts" window, and contacts list is displayed.
- 4. Click on the **Add** button in the top-left of the screen.
  - a. This opens the "Create Contact in Country" window.

Note: Search field can be used to locate and select existing CTMS contacts.

- Here we need to enter the mandatory metadata to create a contact i.e., Organization, First Name, Last Name, Contact Role, Email Address, Status, Start Date as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a contact successfully.
- 7. Finally, before clicking **Create**, verify all the fields are entered correctly in the create contact window.
- 8. Create contact in country window closes, contact record is created and displayed in the list.
- 9. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another contact right away.

### TI CTMS USER GUIDE v1.2

|        |                                                                                                                                                                 | Ø Study Country<br>Uniced States             •             Constants               Constants                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Search Q 🗛 •          |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
|        | United States                                                                                                                                                   | Contacts Contacts Contacts Create Contact in Country Rame Status Create Contacts O                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Q, Search<br>End Date |
| -      | Country Densis     Dashbaard     Cathorne     Siss     Solytes     Cognitations     Team     Cognitations     Team     Activities     Activities     Activities | General Information  Capacitation*  Prefix Prefix Prefix Prefix Prefix Prefix Suffix S |                       |
| *<br>6 |                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                       |

### 7 Site Visit Documentation

Site visits and can be set up so that they trigger specific site-related events directly in an associated eTMF room. This can include generating placeholders for required documentation associated with the site. For more information about configuring your CTMS to work with Trial Interactive's eTMF solution, please reach out to your Trial Interactive representative.

#### 7.1 Pre-Requisite

The user who is responsible for creating and managing **Site Visit Documentation** in an **Organization** must have **Clinical Regulatory Associate** user access.

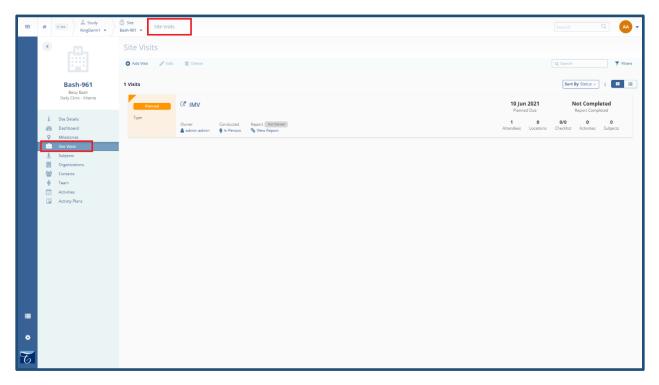
Unblinded users will have the right to create unblinded site visits and related documentation which will only be visible to other unblinded personnel.

#### 7.2 Navigation to Site Visit

- 1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Studies" window.



- Navigate to the Study you want to review site visits for and click on the name field.
   a. This opens the dashboard for the study.
- Click on the Sites link in the Navigation menu at the left side of the screen.
   a. This opens the "Sites" window.
- 4. Navigate to the site you want to review site visit for and click on the Name filed value.
  - a. This opens the dashboard for site.
- 5. Click on the **Site Visits** in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Site Visits" window.



- 6. Navigate to the Visits you want to review and click on it.
  - a. This opens the Visit General Information window.
- 7. Review the site visit information and make any necessary changes if required and click on the **Save** button in the bottom of the screen, for the changes to apply.

| Study<br>KingDerm1 ▼               | Site         matching         Site Visit           Bash-961 ⋅         IMV ⋅         Visit General Information | Search Q        |
|------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------|
|                                    | IMV                                                                                                           |                 |
|                                    |                                                                                                               | D Edu           |
| IMV                                | Visit Information                                                                                             | -               |
|                                    | Visit Type* Viet Status* Viet Status* Viet Status* Viet Status* Viet Status*                                  | Duration        |
| Visit General Information          | Visit Name*                                                                                                   | General Comment |
| Visit Attendees                    | IMV                                                                                                           |                 |
| Locations<br>Visit Checklist       | Owner* Visit Planned Date*                                                                                    |                 |
|                                    |                                                                                                               |                 |
| Activities                         | Visit Start Date Visit End Date day month year                                                                |                 |
| Subjects                           |                                                                                                               |                 |
| Enrollment Summary<br>Visit Report | How Was The Visit Conducted* Visit Checklist Template                                                         |                 |
| O Confirmation Letter              |                                                                                                               |                 |
| O Follow-Up Letter                 | Visit Report                                                                                                  |                 |
|                                    | Report Status                                                                                                 | Resileaver      |
|                                    | Not Started                                                                                                   | ×               |
|                                    | Status Date                                                                                                   |                 |
|                                    | 6/22/2021                                                                                                     |                 |
|                                    |                                                                                                               |                 |
|                                    | Generate Draft Report                                                                                         |                 |
|                                    |                                                                                                               |                 |
|                                    |                                                                                                               |                 |
|                                    |                                                                                                               |                 |
|                                    |                                                                                                               |                 |

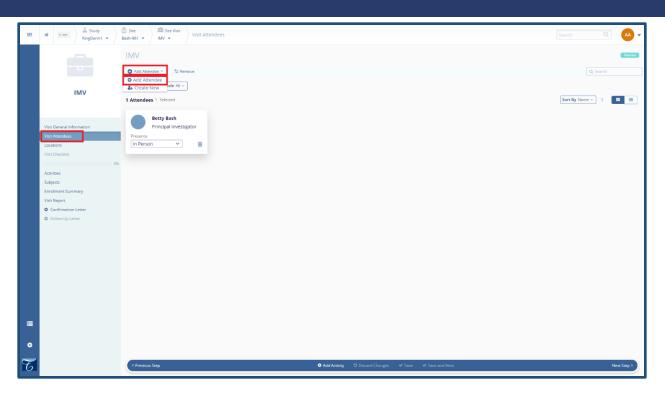
#### 7.3 Site Visit Attendees

T R I A L INTERACTIVE

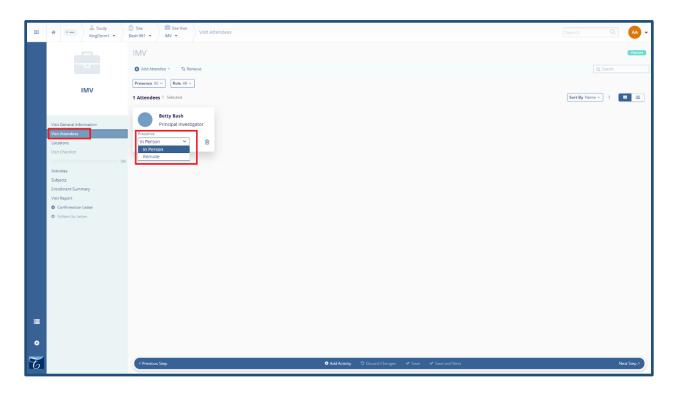
- 1. Navigate to the Site Visit area for the related site.
  - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Visit Attendees link in the Navigation menu at the left side of the screen.
  - a. This opens the "Visit Attendees" window.
- 3. Click on the Add Attendee button in the top-left of the screen.
- 4. Click on the **Add Attendee** from the dropdown of "Add Attendee" button.
  - a. This opens the "Add Attendees" window.
- 5. Select an existing site contact and click on **Add** button in the bottom of the Add Attendees window.
  - a. Attendee is added to the visit report and the "Add Attendees" window is closed.

**Note**: Clicking **Create New** will create a new/additional site contact.

T R I A L INTERACTIVE



6. We can also the review the **presence** of the Attendee and make any changes if required.





#### 7.4 Site Visit Locations

- 1. Navigate to the Site Visit area for the related site.
  - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Locations link in the Navigation menu at the left side of the screen.
  - a. This opens the "Locations" window.

**Note**: If the visit was stated as being conducted remotely, a location will not be required to generate a final visit report.

- 3. Click on the **Add Location** button in the top-left of the screen.
- 4. Click on the **Add Location** from the dropdown of the "Add Location" button.
  - a. This opens the "Add Locations" window.

Note: Clicking Create New will create a new/additional site address.

- Select an existing location and click on the Add button in the bottom of the "Add Locations" window.
  - a. Location is added to the visit report and the "Add Locations" window is closed.

|   | # <                          | Ä Study<br>KingDerm1 ▼ | ₿ Site<br>Bash-961 ▼ | Site Visit             | Locations |          |                        |                                                        |              |                          |                          |      | Search | Q,       | <b>AA</b> ~ |
|---|------------------------------|------------------------|----------------------|------------------------|-----------|----------|------------------------|--------------------------------------------------------|--------------|--------------------------|--------------------------|------|--------|----------|-------------|
|   |                              |                        | IMV                  |                        |           |          |                        |                                                        |              |                          |                          |      |        |          | Parved      |
|   |                              | Add Location ~         |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   |                              |                        | 0 Locations          |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   | IMV No records available     |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   |                              |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   | Visit General In             |                        | A                    | dd Locations           |           |          |                        |                                                        |              |                          |                          | ×    |        |          |             |
|   | Visit Attendees<br>Locations |                        |                      | Selected Locations     | 1         |          |                        |                                                        |              |                          |                          | - 11 |        |          |             |
|   | Visit Checklist              |                        | Pre                  | evious Locations       | 0         | Q Searc  |                        |                                                        |              |                          |                          |      |        |          |             |
|   | Activities                   |                        |                      | Site Locations         | 1         | 1 Locati | Organization Name      |                                                        | Address Type | Address                  |                          |      |        |          |             |
|   | Subjects<br>Enrollment Sur   |                        |                      |                        |           |          | Daily Clinic - Atlanta |                                                        | Institution  | 🚽 1455 Parkway Cafe, Lis | ncoln Parkway East, Atle |      |        |          |             |
|   | Visit Report                 | innary                 |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   | O Confirmatio                |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   | O Follow-Up L                |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   |                              |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   |                              |                        |                      |                        |           |          |                        |                                                        |              |                          |                          | - 64 |        |          |             |
|   |                              |                        |                      | Cancel Add 1 Locations |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   |                              |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   |                              |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   |                              |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
| = |                              |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
| ۰ |                              |                        |                      |                        |           |          |                        |                                                        |              |                          |                          |      |        |          |             |
|   |                              |                        |                      |                        |           |          |                        | _                                                      |              |                          | 1                        |      |        |          |             |
| C | C Previous Step              |                        |                      |                        |           |          | O Ad                   | Add Activity Discard Changes V Save And Next Next Stee |              |                          |                          |      |        | t Step > |             |

#### 7.5 Site Visit Activities

1. Navigate to the Site Visit area for the related site.



## TI CTMS USER GUIDE v1.2

- a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Activities link in the Navigation menu at the left side of the screen.
  - a. This opens the "Activities" window.
- 3. Click on the Add button in the top-left of the screen
- 4. Click on the **Add Activities** from the dropdown of the Add button.
  - a. This opens the "Add Activities" window.
- 5. Select an existing site activity from the list of All Site Activities.
- 6. Click on the Add button in the Add Activities window.

**Note**: Clicking **Create New** will create a new activity for the site.

|   | *                               | Ä Study<br>KingDerm1 ▼ | Bash-961 • | Site Visit      | Activities |                          |                         |                                 |                        |             | Search C               |             |
|---|---------------------------------|------------------------|------------|-----------------|------------|--------------------------|-------------------------|---------------------------------|------------------------|-------------|------------------------|-------------|
|   |                                 |                        | IMV        |                 |            |                          |                         |                                 |                        |             |                        | Flamed      |
|   |                                 |                        | Acti       | vities          |            |                          |                         |                                 |                        |             |                        |             |
|   |                                 | IMV                    | O Add      | 🖌 🥒 Edit 🛛 🏥    |            |                          |                         |                                 |                        |             |                        | T Filters   |
|   |                                 |                        | 0 Activit  |                 |            |                          |                         |                                 |                        |             |                        | G<br>P      |
|   | Visit General<br>Visit Attendee |                        |            | Activity Name   | Status     | Туре                     | Subtype                 | Description                     | Owner                  | Responsible | Planned Date Completed | ŝ           |
|   | Locations<br>Visit Checklist    |                        | ×          | Selected Items  | 0          | Q, Search                |                         |                                 |                        |             |                        |             |
|   | -                               |                        | 0%         | evious Visit    | 0          | Type/Subtype 0 filters ~ | Status All ~ By Owner A | II V By Responsible Party All V | By Planned Date All ~  |             |                        |             |
|   | Activities<br>Subjects          |                        | A          | Site Activities | 0          | 0 Activities             | Janus All - Usy owner A | by responsible Party All        | by Plainted Date All - |             |                        |             |
|   | Enrollment Si<br>Visit Report   | immary                 |            |                 |            | Activity Name            | Status Type             | Subtype Description             | Owner Responsibi       | le Planned  |                        |             |
|   | Confirmat                       | ion Letter             |            |                 |            |                          |                         | No records available            |                        |             |                        |             |
|   | O Follow-Up                     | Letter                 |            |                 |            |                          |                         |                                 |                        |             |                        |             |
|   |                                 |                        |            |                 |            |                          |                         |                                 |                        |             |                        |             |
|   |                                 |                        |            |                 |            |                          | Cancel                  | Id 0 Activities                 |                        |             |                        |             |
|   |                                 |                        |            |                 | _          |                          | _                       |                                 |                        |             |                        |             |
|   |                                 |                        |            |                 |            |                          |                         |                                 |                        |             |                        |             |
|   |                                 |                        |            |                 |            |                          |                         |                                 |                        |             |                        |             |
| = |                                 |                        |            |                 |            |                          |                         |                                 |                        |             |                        |             |
|   |                                 |                        |            |                 |            |                          |                         |                                 |                        |             |                        |             |
| T |                                 |                        | < Previ    | ous Step        |            |                          | O Add Ac                | tivity 🏾 Discard Changes 🗸 🗸    | Save 🗸 Save and Next   |             |                        | Next Step > |

**Note**: When a previous visit has occurred a user can select **Previous Visit** to select Activities that were associated with the previous visit report.

#### 7.6 Site Visit Subjects

- 1. Navigate to the Site Visit area for the related site.
  - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Subjects link in the Navigation menu at the left side of the screen.
  - a. This opens the "Subjects" window.
- 3. Click on the Add button in the top-left of the screen.
- 4. Click on the Add Subject from the dropdown of the Add button



- a. This opens the "Add Subjects" window.
- 5. Select an existing site subject from the list of **All Site Subjects**.
- 6. Click on the **Add** button in the **Add Subjects** window.

Note: Clicking Create New will create a new subject for the site.

|   |                                    | Site Site Visit<br>Bash-961 ▼ MV ▼ | Subjects        |                  |                               |                        |                         | Search Q                                 | <b>AA) -</b> |
|---|------------------------------------|------------------------------------|-----------------|------------------|-------------------------------|------------------------|-------------------------|------------------------------------------|--------------|
|   |                                    | IMV                                |                 |                  |                               |                        |                         |                                          | Renned       |
|   |                                    | 🔘 Add 🗠 🥒 Edit 🛛 🛇                 | Remove 🗇 Verify |                  |                               | Q, Search              | Filters                 |                                          |              |
|   | IMV                                | 1 Subjects 1 Selected              |                 |                  |                               |                        |                         | <b>a</b> 10012021                        | 1            |
|   |                                    | Subject ID                         | Status          | Screening Number | Subject Initials              | Verified ICFs          | verified Subject Visits | Screened<br>01 Oct 2021                  |              |
|   |                                    | 10012021                           | Screened        |                  |                               | 0                      | 0                       | Subject Info Verification Subject Visits | ts           |
|   | Visit General Information          | Add Subjects                       |                 |                  |                               |                        | <b>× ×</b>              | C Informed Consent - History             |              |
|   | Visit Attendees                    | Selected Subjects                  | 0               |                  |                               |                        |                         | Subject History                          |              |
|   | Visit Checklist                    | Previous Site Visit Su             |                 |                  |                               | Q Search               | T Filters               | Current Status                           |              |
|   | 0%<br>Activities                   | All Site Subjects                  | T Subjects      |                  |                               |                        |                         | Name Date                                |              |
|   | Subjects                           | All site subjects                  | 1 Subjects ID   |                  | Screening Number              | Subject Initials       | Notes                   | CURRENT STATUS 01 Oct 2021               |              |
|   | Enrollment Summary<br>Visit Report |                                    |                 |                  |                               |                        |                         | Screening Failure Reason (0)             | _            |
|   | Confirmation Letter                |                                    |                 |                  |                               |                        |                         |                                          |              |
|   | O Follow-Up Letter                 |                                    |                 |                  |                               |                        |                         |                                          | _            |
|   |                                    |                                    |                 |                  |                               |                        |                         | Early Termination Reason (0)             | _            |
|   |                                    |                                    |                 |                  |                               |                        |                         |                                          |              |
|   |                                    |                                    |                 |                  |                               |                        |                         |                                          |              |
|   |                                    |                                    |                 | Cancel           | Add 0 Subjects                |                        |                         | Summary Information                      |              |
|   |                                    |                                    |                 |                  |                               |                        |                         | Summary mormation                        | _            |
|   |                                    |                                    |                 |                  |                               |                        |                         | Notes                                    | _            |
|   |                                    |                                    |                 |                  |                               |                        |                         |                                          |              |
| = |                                    |                                    |                 |                  |                               |                        |                         |                                          |              |
| ۵ |                                    |                                    |                 |                  |                               |                        |                         | Subject Outcome                          | — I          |
|   |                                    |                                    |                 | _                |                               |                        | -                       | subject Outcome                          |              |
| T |                                    | < Previous Step                    |                 | • Ad             | d Activity "O Discard Changes | ✓ Save ✓ Save and Next |                         | Next S                                   | Step >       |

**Note**: When a previous visit has occurred a user can select **Previous Visit** to select subjects that were associated with the previous visit report.

- 7. Add Subjects window is closed, and the subject is displayed in the list.
- 8. To Verify navigate to the subject and click on the check box before subject ID field value.
- 9. Click on the Verify button in the top-left of the screen.
  - a. This opens "Subject Verification" window.
- 10. Select a subject visit to verify during the site visit.
- 11. Click on the Go to ICFs button in the bottom on the subject verification window.
- 12. Select an ICF to verify and click on the **Save** button.

# TI CTMS USER GUIDE v1.2

|    |                                          | i Site<br>Bash-961 ▼ IMV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | site Visit<br>• Subjects |                |                |                          |                  |                        | Search Q                               |                  |
|----|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------|----------------|--------------------------|------------------|------------------------|----------------------------------------|------------------|
|    |                                          | IMV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                          |                |                |                          |                  |                        |                                        | Fired            |
|    |                                          | O Add 🗸 🖉 Ed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | dit 🖇 Remove 🗮 Venfy     |                |                |                          |                  |                        |                                        | <b>T</b> Filters |
|    | IMV                                      | Subject 10012                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 2021 Verification        |                |                |                          |                  | Step 1 🔹 o 🗖 🗙         | 1012021                                | 1                |
|    |                                          | Subject Visits                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Select Visits to A       | dd to Report   |                |                          |                  |                        | Oct 2021<br>It Info Verification Subje | ect Visits       |
|    | Visit General Information                | ICES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                          |                |                |                          |                  |                        | formed Consent - History               |                  |
|    | Visit Attendees                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Selected Visit Dates     |                |                |                          |                  |                        | ct History                             | •                |
|    | Locations<br>Visit Checklist             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        |                                        |                  |
|    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Visit Date               | 1 Visit Status | SDV Date       | Visit Type               | Visit Notes      | Subject Visit Comments | nt Status<br>ne Date                   |                  |
|    | Activities<br>Subjects                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                | Norma          |                          |                  |                        | ened<br>ENT STATUS 01 Oct 20           |                  |
|    | Enrollment Summary                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                | No recor       |                          |                  |                        | ing Failure Reason (0)                 |                  |
|    | Visit Report                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        | ing a minimized and the                |                  |
|    | Confirmation Letter     Follow-Up Letter |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        |                                        |                  |
|    | • Pollow-up Letter                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        | simination Reason (0)                  |                  |
|    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        | ermination Keason (U)                  |                  |
|    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        |                                        |                  |
|    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        |                                        |                  |
|    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        | nary Information                       |                  |
|    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        |                                        |                  |
|    |                                          | Previous Subject                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                          | Cancel         | Go to ICF Save | Save and Next Subject    |                  | Next Subject >         |                                        |                  |
|    |                                          | and the second sec |                          |                |                |                          |                  | and any at P           |                                        |                  |
|    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        |                                        |                  |
| •  |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  |                        |                                        |                  |
|    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                |                |                          |                  | Subje                  | ect Outcome                            |                  |
| To |                                          | Previous Step                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                          |                | Add Activity   | Discard Changes 🛛 🛩 Save | ✓ Save and Next. |                        |                                        | Next Step >      |

### 7.7 Site Visit Enrollment Summary

T R I A L INTERACTIVE

- 1. Navigate to the Site Visit area for the related site.
  - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the **Enrollment Summary** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Enrollment Summary" window.
- 3. Click on the Add button in the top-left of the screen.

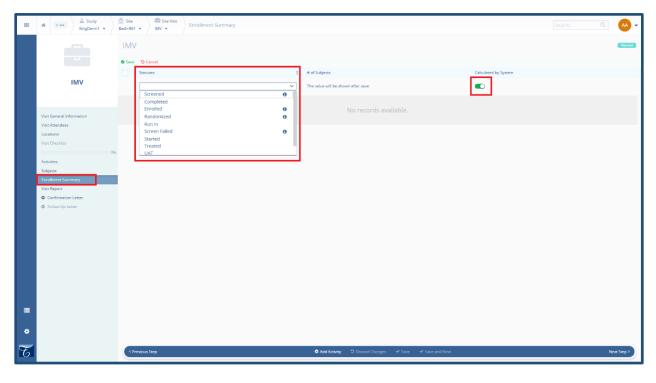
## TI CTMS USER GUIDE v1.2

|   |                                                             | © Site     Bosh-961 ▼     IMV ▼     Enrollment Summary |                 |                                             |                      | Search Q | <b>AA</b> - |
|---|-------------------------------------------------------------|--------------------------------------------------------|-----------------|---------------------------------------------|----------------------|----------|-------------|
|   |                                                             | IMV                                                    |                 |                                             |                      |          | Plenned     |
|   |                                                             | O Add                                                  | 1 # of Subjects |                                             | Calculated by System |          |             |
|   | IMV                                                         |                                                        |                 | No records available.                       |                      |          |             |
|   | Visit General Information<br>Visit Attendees                |                                                        |                 |                                             |                      |          |             |
|   | Locations<br>Visit Checklist                                |                                                        |                 |                                             |                      |          |             |
|   | 0<br>Activities<br>Subjects                                 | **                                                     |                 |                                             |                      |          |             |
|   | Enrollment Summary<br>Visit Report<br>O Confirmation Letter |                                                        |                 |                                             |                      |          |             |
|   | O Follow-Up Letter                                          |                                                        |                 |                                             |                      |          |             |
|   |                                                             |                                                        |                 |                                             |                      |          |             |
|   |                                                             |                                                        |                 |                                             |                      |          |             |
|   |                                                             |                                                        |                 |                                             |                      |          |             |
| = |                                                             |                                                        |                 |                                             |                      |          |             |
| ٠ |                                                             |                                                        |                 |                                             |                      |          |             |
| T |                                                             | < Previous Step                                        | Add Activit     | ty ⊃ Discard Changes 🗸 Save 🖌 Save and Next |                      | N        | Next Step > |

4. Select the subject Statuses from the dropdown.

T R I A L INTERACTIVE

5. Indicate if the system should calculate the enrollment statistic or should it be manually entered by the visit report author.





- 6. Click on the **Save** button in the top-left of the screen.
  - **Note**: By turning off **Calculated by System**, the system will allow the user to manually enter the site's enrollment statistics for the site at the time of the site visit.

#### 7.8 Site Visit Confirmation Letter Creation

- 1. Navigate to the Site Visit area for the related site.
  - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the **Confirmation Letter** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Generate Confirmation Letter" window.

Note: Confirmation letter content will be based on the visit preparation data selected.

- 3. Review the sections within the confirmation letter that are relevant
- 4. Click on the **Next** button in the bottom of the **Generate Confirmation Letter** window.
  - **Note**: A user can turn off any section that is not relevant to a visit related confirmation letter. Regardless of user selection/incorporation a letter will only display content that there is a location within the template to display that data.

|   |                                                                              | Sae         ==         Sae Vait           Bash-961 *         IMV *         Confirmation Letter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Search | Q,  | <b>AA</b> ~ |
|---|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|-----|-------------|
|   |                                                                              | IMV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |        |     | Planned     |
|   | IMV                                                                          | Generate Confirmation Letter     Step 1 • • • • • • • □ ¥       Select Sections     Select sections to be included in confirmation letter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |        |     |             |
|   | Visit General Information<br>Visit Attendees<br>Locations<br>Visit Checklist | Select Activities     Activities       Select Attendees     Attendees       Select Locations     Locations       Select Subjects     Subjects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |        |     |             |
|   | 0%<br>Activities<br>Subjects<br>Enrollment Summery<br>Visit Report           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |        |     |             |
|   | Confirmation Letter     Follow-Up Letter                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |        |     |             |
|   |                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |        |     |             |
|   |                                                                              | Greet                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |        |     |             |
| • |                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |        |     |             |
| T |                                                                              | O Add Activity D Discard Charges      Save      Sav |        | Nex | ct Step >   |

- 5. Click on the **Create** button in the bottom of the **Generate Confirmation Letter** window, once all the selections are made for the letter.
- 6. This generates the site visit confirmation letter as per our selections.



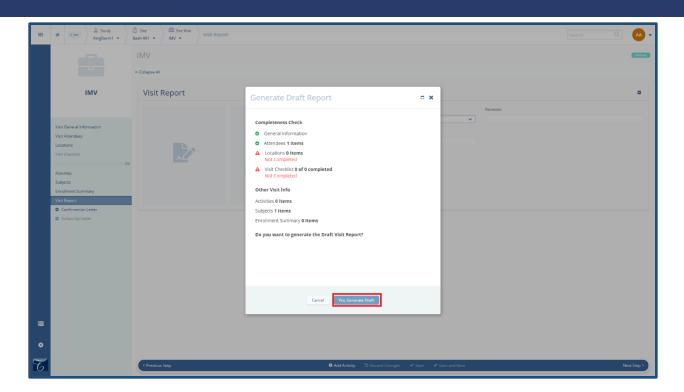
### 7.9 Site Visit Draft Report Generation

- 1. Navigate to the Site Visit area for the related site.
  - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Visit Report link in the Navigation menu at the left side of the screen.
  - a. This opens the "Visit Report" window.
- 3. You can update the **Report Status** to **In Progress** and click on the **Save** button.

|   |                                                                                                                                                   | Site ash-961 ▼ IMV ▼ Visit Report |                                                                                                                      | Search Q AA 🗸 |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------------------------------------------------------------------------------------------------------|---------------|
|   |                                                                                                                                                   | IMV                               |                                                                                                                      | Florest       |
|   |                                                                                                                                                   | A Collapse All                    |                                                                                                                      |               |
|   | IMV                                                                                                                                               | Visit Report                      |                                                                                                                      | •             |
|   | Visit General Information<br>Visit Atlandess<br>Locations<br>Visit Charlotte<br>Visit Charlotte<br>Subjects<br>Experiment Summary<br>Visit Report | Generate Draft Report             | Report Statut         Review           Not Started            In Progress            Statut UM#            6/22/2021 | ee<br>        |
| - | Conformation Letter     O Fallow-Up Letter                                                                                                        |                                   |                                                                                                                      |               |
| ٠ |                                                                                                                                                   |                                   |                                                                                                                      |               |
| T |                                                                                                                                                   | < Previous Step                   | ● Add Activity ⊃ Discard Changes ✓ Save ✓ Save and Next                                                              | Next Step >   |

- 4. Click on the Generate Draft Report button in the screen.
  - a. This opens the "Generate Draft Report" window.
- 5. Click on the Yes, Generate Draft button in the bottom of the window.

## TI CTMS USER GUIDE v1.2



6. It shows as Generating Draft Report please wait when we click on Yes, Generate Draft button.

|   |                                              | Image: State     Image: State State       Bash-961 +     Image: State | •          |
|---|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
|   |                                              | IMV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Flanned    |
|   |                                              | A Collapse All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |            |
|   | IMV                                          | Visit Report                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | •          |
|   |                                              | Report Sonus Reviewer Not Started                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |            |
|   | Visit General Information<br>Visit Attendees | Not Started  Sanus Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |            |
|   | Locations<br>Visit Checklist                 | 6/22/021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |            |
|   | Activities 0%                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
|   | Subjects<br>Enrollment Summary               | Please wait                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |            |
|   | Visit Report Confirmation Letter             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
|   | O Follow-Up Letter                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
|   |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
|   |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
|   |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
|   |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
|   |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
|   |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
| ۰ |                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
| T |                                              | O Mid Active     O Discard Changes     ✓ Save      ✓ Save      ✓ Save and Nost     N                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | ext Step > |

7. Draft visit report is generated, and origami is opened displaying the draft report.



## 7.10 Site Visit Final Report Generation

- 1. Navigate to the Site visit area for the related site.
  - a. More detailed instructions on this step can be found <u>here</u>.
- Click on the Visit Report link in the Navigation menu at the left side of the screen.
   a. This opens the "Visit Report" window.
- 3. Click **Generate Report** in the visit report window.
  - a. This open the "Generate Visit Report" window
- 4. Click on the Yes, Generate button in the Generate Visit Report.

**Note**: A final visit report can be routed through the submission/review/approval process within origami.

## 7.11 Site Visit Follow-up Letter Creation

- 1. Navigate to the Site Visit area for the related site.
  - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Follow-up Letter link in the Navigation menu at the left side of the screen.
  - a. This opens the Follow-up Report window.

Note: Follow-up letter content will be based on the final visit report data selected.

- 3. Review the sections within the confirmation letter that are relevant.
- 4. **Generate Follow-up Letter** window displays the selected sections and the selected content from the final report
- 5. Click on the **Next** button on the screen.
  - Note: A user can turn off any section that is not relevant to a visit related follow-up letter. Regardless of user selection/incorporation a letter will only display content that there is a location within the template to display that data.
- 6. Click on the Create button of the window.
- 7. Follow-up letter is generated, and origami is opened displaying the letter

# 8 Product

## 8.1 Creating a Product

- 1. Click on the **Product** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Products" window, and the products list is displayed.

| # Products                             |                       |               |         |             |                 |                | Search Q AA                |
|----------------------------------------|-----------------------|---------------|---------|-------------|-----------------|----------------|----------------------------|
| •                                      | Products              |               |         |             |                 |                |                            |
| Ŧ                                      | 🕒 Add 🥒 Edit 👔 Delete |               |         |             |                 |                | Q Search                   |
| (2)                                    | 33 Products           |               |         |             |                 |                |                            |
| TrialInteractive                       | Product               | Programs      | Status  | Туре        | Modifier        | Owner          | Sponsor                    |
| Triainteractive                        | WWMedocort            |               | Planned | Medicinal   | 🛔 admin admin   | 🛔 admin admin  | Winning World Medicine     |
| Dashboard                              | Wisenanol             |               | Planned | Palliative  | 🛔 admin admin   | 🛔 admin admin  | Wiser Meds                 |
| Sponsors                               | TestUAT004            |               | Planned | Combination | 🛔 admin admin   | 🚢 admin admin  | A+ Drugs                   |
| Programs                               | 🚔 TestUAT             |               | Planned | Vaccine     | 🛔 admin admin   | 👗 admin admin  | Dermeron                   |
| Products                               | Gastrotube            |               |         |             | 🛔 admin admin   | 🛔 admin admin  | Gastroclean Inc            |
| Organizations                          | MedicalImmune Patch   | 🔏 MI Patch    | Planned | Custom      | 👗 system system | 👗 admin admin  | Medical Immune             |
| Contacts                               | 📄 🚔 Integucaine       | Ճ Integ_IV    | Active  | Palliative  | 👗 system system | 👗 admin admin  | Dermeron                   |
| User Management     Activities Library | Scotts Wash           |               | Planned | Combination | 👗 system system | 👗 admin admin  | Scott Works                |
| Activity Plan Templates                | MMGyn                 | <u>a</u> 2    | Active  | Diagnostic  | 🛔 system system | 👗 admin admin  | May & May Pharmaceutica    |
| Milestone Templates                    | WorkIMP4              | 🔏 WorkP1      | Planned | Diagnostic  | 👗 system system | 👗 admin admin  | Working 4U                 |
|                                        | Diagnova              | 👌 Diagnova321 | Planned | Medicinal   | 👗 system system | 👗 Steven Clark | A+ Drugs                   |
|                                        | MMGenerics            | <u></u> 2     | Planned | Custom      | 👗 system system | 👗 admin admin  | 📕 May & May Pharmaceutica  |
|                                        | 🗎 ммов                | <u>at</u> 2   | Planned | Custom      | 👗 system system | 🚨 admin admin  | May & May Pharmaceutica    |
|                                        | AMMEar                | <u>di 2</u>   | Active  | Device      | 🛔 system system | 🚨 admin admin  | May & May Pharmaceutica    |
|                                        | MMEye                 | <u>ه ۲</u>    | Planned | Diagnostic  | 🛔 system system | 🚨 admin admin  | May & May Pharmaceutica    |
|                                        | MMDental              | <u>di 2</u>   | Planned | Custom      | 🛔 system system | 🚨 admin admin  | May & May Pharmaceutica    |
|                                        | MMOrtho               | <u>a</u> 2    | Active  | Device      | 🚨 system system | 🚨 admin admin  | May & May Pharmaceutica    |
|                                        | MMCardio              | <u>di 2</u>   | Planned | Device      | 🛔 system system | 🚨 admin admin  | May & May Pharmaceutica    |
|                                        | MMAllergy             | <b>di</b> 3   | Planned | Custom      | 🛔 system system | 🚨 admin admin  | May & May Pharmaceutical   |
|                                        | MMVax                 | <u>di 2</u>   | Planned | Vaccine     | 🛔 system system | 🚨 admin admin  | May & May Pharmaceutical   |
|                                        | MMPeds                | <u>at</u> 2   | Planned | Custom      | 🚔 system system | 🚨 admin admin  | 🛃 May & May Pharmaceutical |

- 2. Click on the **Add** button in the top-left of the screen.
  - a. This opens the "Create Product" Window.
- Here we need to enter the mandatory metadata to create a product i.e., Product Name, Type, Status, Status Date, Sponsor as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a product successfully.
- 5. **(Optional)** Click Create or **Create and Add Another** depending on whether you intend to create another product right away.

| Products                    |                       |                   |                   |                    |                   |                | Search Q               |
|-----------------------------|-----------------------|-------------------|-------------------|--------------------|-------------------|----------------|------------------------|
|                             |                       |                   |                   |                    |                   |                |                        |
|                             | 🖸 Add 🥒 Edit 🔹 Delete |                   |                   |                    |                   |                | Q, Search              |
| ()                          | 33 Products           |                   |                   |                    |                   |                |                        |
|                             | Product               | Programs          | Status            | Туре               | Modifier          | Owner          | Sponsor                |
| TrialInteractive            | WWMedocort            |                   | Plenned           | Medicinal          | 🐣 admin admin     | 🛔 admin admin  | Winning World Medicine |
| Dashboard                   | Wisenanol             | Crea              | te Product        |                    | 🗆 🗙 🍰 admin admin | 🛔 admin admin  | Wiser Meds             |
| Sponsors                    | TestUAT004            |                   |                   |                    | admin admin       | 🛔 admin admin  | A+ Drugs               |
| Programs                    | TestUAT               | Product           | Name*             | Type*              | 🗸 🔒 admin admin   | 👗 admin admin  | Dermeron               |
| Products                    | Gastrotube            | Status*           |                   | Status Date*       | 🚨 admin admin     | 🚨 admin admin  | Gastroclean Inc        |
|                             | Medicallmmune Patch   | MI Pate Planne    | d 🛛 🔿 🗸           | 23 Sep 2021        | 🟥 🏝 system system | 👗 admin admin  | Medical Immune         |
| Contacts<br>User Management | Integucaine           | A Integ_I Sponsor |                   |                    | System system     | 🚨 admin admin  | Dermeron               |
| Activities Library          | Scotts Wash           |                   | s 0 Indications   |                    | System system     | 🛔 admin admin  | Scott Works            |
| Activity Plan Templates     | MMGyn                 | 32 Select         |                   |                    | a system system   | 🛔 admin admin  | May & May Pharmaceut   |
| Milestone Templates         | WorkIMP4              | 🖄 WorkP           |                   |                    | 🚨 system system   | 🚨 admin admin  | Working 4U             |
|                             | Diagnova              | 者 Diagno          |                   |                    | a system system   | 🛔 Steven Clark | A+ Drugs               |
|                             | MMGenerics            | 2 Descripti       | on                |                    | 🚔 system system   | 🛔 admin admin  | May & May Pharmaceut   |
|                             | 🗌 🚔 ммов              | <u>#</u> 2        |                   |                    | 🚔 system system   | 🛔 admin admin  | May & May Pharmaceut   |
|                             | MMEar                 | <u>2</u>          | Cancel Create and | Add Another Create | 🚔 system system   | 🛔 admin admin  | May & May Pharmaceut   |
|                             | MMEye                 | <u>at 2</u>       |                   |                    | 🚨 system system   | 🚨 admin admin  | May & May Pharmaceut   |
|                             | MMDental              | 2                 | Planned           | Custom             | 🚔 system system   | 🚨 ədmin ədmin  | May & May Pharmaceut   |
|                             | MMOrtho               | <u>a</u> 2        | Active            | Device             | 💄 system system   | 👗 admin admin  | May & May Pharmaceut   |
|                             | MMCardio              | <u>at 2</u>       | Planned           | Device             | 🚨 system system   | 🚨 admin admin  | May & May Pharmaceuti  |
|                             | MMAllergy             | <b>ali</b> 3      | Planned           | Custom             | 🚨 system system   | 🚨 ədmin ədmin  | May & May Pharmaceut   |
|                             | MMVax                 | <u>a</u> 2        | Planned           | Vaccine            | 🚨 system system   | 🚨 admin admin  | May & May Pharmaceuti  |
|                             | MMPeds                | <u>a</u> 2        | Planned           | Custom             | 🚨 system system   | 🛔 ədmin ədmin  | May & May Pharmaceuti  |

## 8.2 Reviewing and Editing a Product

- 1. Click on the **Product** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Products" window, and the products list is displayed.
- 2. Click on the name of the product you want to edit.
  - a. This opens the "Product Details" window.
- 3. Click on the **Edit** button in the top-left of the screen.



# TI CTMS USER GUIDE v1.2

|   | Product     MedicalImn | t<br>mune Patch 👻 | Product Details                     |                           |                  |                           | search Q 🗛 🗸 |
|---|------------------------|-------------------|-------------------------------------|---------------------------|------------------|---------------------------|--------------|
|   |                        |                   | ✓ Edit A Collapse All               |                           |                  |                           | Edit History |
|   |                        |                   | Product Informatio                  | n                         |                  |                           | •            |
|   | MedicalImm             | une Patch         | Product Name<br>Medicalimmune Patch |                           |                  | Regulatory Identifiers    |              |
|   | 1 Product Det          | ais               | Sponsor<br>Medical Immune           |                           |                  |                           |              |
|   | 🗟 Programs             |                   | Owner<br>admin admin                | Type                      |                  | Indications 0 Indications |              |
|   | Sites                  | ns                | Status<br>Planned                   | Status Date 0 07 Sep 2021 | Change Status    |                           |              |
|   | 曫 Contacts             |                   | Status Notes                        |                           |                  | Description               |              |
|   |                        |                   |                                     |                           |                  |                           |              |
|   |                        |                   |                                     |                           | ී Status History | Notes                     |              |
|   |                        |                   | IND                                 |                           |                  |                           |              |
|   |                        |                   | Drug Safety Code                    |                           |                  |                           |              |
|   |                        |                   |                                     |                           |                  |                           |              |
|   |                        |                   |                                     |                           |                  |                           |              |
|   |                        |                   |                                     |                           |                  |                           |              |
| • |                        |                   |                                     |                           |                  |                           |              |
| T |                        |                   |                                     |                           |                  |                           |              |

- 4. Make the necessary changes in the product details window.
- 5. Click on the **Save** button in the top-left of the screen.

|        | *                                                                               | Product<br>MedicalImmune Patch 👻       | Product Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Search Q AA -  |
|--------|---------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|        | ×                                                                               |                                        | O Save D Centreel A Collegee All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 3 Ediz History |
|        | Med                                                                             | icallmmune Patch                       | Product Information Product Name* Regulatory Identifiers Regulatory | •              |
|        |                                                                                 | Product Details<br>Programs<br>Studies | Image: Control of the second                       |                |
|        | ()<br>()<br>()<br>()<br>()<br>()<br>()<br>()<br>()<br>()<br>()<br>()<br>()<br>( | Sites<br>Organizations<br>Contacts     | Status Status Date Planned 0 075ep 2021 Change Status Status Notes Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                |
|        |                                                                                 |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |
|        |                                                                                 |                                        | Notes<br>Sisterus History                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                |
|        |                                                                                 |                                        | Drug Sefety Code                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                |
|        |                                                                                 |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |
|        |                                                                                 |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |
| ہ<br>ح |                                                                                 |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |
| 6      |                                                                                 |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |



#### 8.3 Associating an Organization to a Product

- 1. Click on the **Product** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Products" window, and the products list is displayed.
- 2. Click on the name of the Product you want to associate to an organization.
  - a. This opens the "Product Details" window.
- 3. Click on the **Organization** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Organization" window.
- 4. Click **Add** and either search for an existing organization or create a new one.
- 5. Press **Create** when done.
  - a. More detailed instructions on this step can be found <u>here</u>.

| -      | # Pro<br>Medica                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | duct<br>Immune Patch 👻 | Organizations                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |           | Search Q. 🗛 🗸             |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------------------|
|        | •                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                        | Organizations                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |           | Q Search <b>T</b> Filters |
|        | MedicalIm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | imune Patch            | O Organizations     Name Sta | Add Organization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | X Subtype | Primary Contact           |
| -      | i Product<br>Propun<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States<br>States | tions                  |                              | Cancel Informations      General Information      Name*      Immediate      Parent Organization      Type*     Subsyse      Subsyse      Type*     Subsyse      Subsyse      Type*     Subsyse      Subsyse      Subsyse      Subsyse      Subsyse      Type*     Subsyse |           |                           |
| *<br>T |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                        |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |           |                           |

#### 8.4 Associating a Contact to a Product

- 1. Click on the **Product** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Products" window, and the products list is displayed.
- 2. Click on the name of the product to which you wish to associate a contact.
  - a. This opens the "Product Details" window.
- 3. Click Add and either search for an existing Contact or create a new one.
- 4. Press Create when done.
  - a. More detailed instructions on this step can be found <u>here</u>.

## TI CTMS USER GUIDE v1.2

| ш | # Product<br>Medicalimmune Patch * | Contacts               |                        |                      |       |            | [starth: Q] |
|---|------------------------------------|------------------------|------------------------|----------------------|-------|------------|-------------|
|   | °                                  | Contacts               |                        |                      |       |            | Q.Search    |
|   | MedicalImmune Patch                | 0 Contacts Name Status | Create Product Contact |                      | Phone | Start Date | End Date    |
|   |                                    |                        | Q Search for Contacts  | 0                    |       |            |             |
|   | i Product Deteils                  |                        | Organization*          | ~                    |       |            |             |
|   | Sites                              |                        | Prefix First Name*     | Middle Name          |       |            |             |
|   | Contects                           |                        | Last Name*             | Suffix               |       |            |             |
|   |                                    |                        | Job Tide               | Contact Role*        |       |            |             |
|   |                                    |                        | Email Address*         | Status* Active       |       |            |             |
|   |                                    |                        |                        | day month year 📫     |       |            |             |
|   |                                    |                        | Phone Numbers<br>• Add |                      |       |            |             |
|   |                                    |                        | Cancel Create an       | d Add Another Create |       |            |             |
| = |                                    |                        |                        |                      |       |            |             |
| * |                                    |                        |                        |                      |       |            |             |
| C |                                    |                        |                        |                      |       |            |             |

## 9 Program

#### 9.1 Pre-Requisites

Each Organization will need to decide who should handle Program creation and managing. It may be a specific group of people in the organization who are assigned to handle this to reduce the chances of creating duplicate program records. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to user's accounts to that they can perform this step.

### 9.2 Create a Program

- 1. Click on the **Programs** link in the Navigation Menu at the left side of the screen.
  - a. This opens the "Programs" window, and the programs list is displayed.

| - | Programs            |                            |          |               |                             | Search Q. AA        |
|---|---------------------|----------------------------|----------|---------------|-----------------------------|---------------------|
|   | •                   | Programs                   |          |               |                             |                     |
|   | Ŧ                   | 🗘 Add 🥒 Edit 📋 Delete      |          |               |                             | Q Search T Filter   |
|   | $\mathcal{O}$       | 20 Programs                |          |               |                             |                     |
|   | TrialInteractive    | Program Name               | Status   | Number        | Sponsor                     | Product             |
|   | mainteractive       | TestUATP                   | Reving   | 111           | Dermeron                    | Astrogum            |
|   | Dashboard           | Integ_IV                   | Ranning  | 20211609_1013 | Dermeron                    | integucaine         |
|   | Sponsors            | MI Patch                   | Planning | 133982021     | Medical Immune              | Medicalimmune Patch |
|   | Programs            | MM-One                     | Planning | 928912021     | May & May Pharmaceuticals   | MMAilergy           |
|   | Products            | MM-Some                    | Ranning  | 925912021     | May & May Pharmaceuticals   | 13                  |
|   | Crganizations       | MM-ALL                     | Active   | 920912021     | May & May Pharmaceuticals   | ( <b>1</b> 4)       |
|   | Contacts            | WorkP1                     | Ranning  | 2108272021    | Working 4U                  | WorkIMP4            |
|   | User Management     | Diagnova321                | Planning | 321           | A+ Drugs                    | 2                   |
|   | Activities Library  | abc                        | Ranning  | 111           | ACI Pharmaceuticals         | Astrogum            |
|   | Milestone Templates | MMOnc                      | Planning | 872021359     | May & May Pharmaceuticals   | MMOnc MMOnc         |
|   |                     | Galashegos524              | Planning | #1245524      | Galashegos Pharmaceuticals  | 🚔 Dragon Steel      |
|   |                     | Mays Limbs                 | Planning | 429-6160      | May & May Pharmaceuticals   |                     |
|   |                     | () A+-008                  | Closed   | 008-01        | A+ Drugs                    | ( <b>2</b> )        |
|   |                     | RKTrans                    | Planning | 3006142021    | RK Meds                     | A TransPure         |
|   |                     | C King Peds                | Planning | 9425122021    | King Research               | Kings Cream         |
|   |                     | May & May Vaccines Program | Active   | 8555112021    | May & May Pharmaceuticals   | <b>a</b> 3          |
|   |                     | May&May Market Device Test | Planning | 10184262021   | 関 May & May Pharmaceuticais | 2                   |
|   |                     | King Derma                 | Planning | 11183252021   | King Research               | 🚔 Kings Cream       |
|   |                     | AstroRA-32021              | Reving   | 132021        | Astrovile                   | 2                   |
|   |                     | Wellness Program           | Planning | 123-1         | Morvarty                    |                     |
|   |                     |                            |          |               |                             |                     |

- 2. Click on the **Add** button in the top-left of the screen.
  - a. This opens the Create Program window.
- Here we need to enter the mandatory metadata to create a program i.e., Program Name, Number, Status, Status Date, Sponsor, Products as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a program successfully.
- 5. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another program right away.

Note: Program records can be created in multiple locations within the system:

- 1. Programs
- 2. Sponsors  $\rightarrow$  Programs
- 3. Product  $\rightarrow$  Programs

## TI CTMS USER GUIDE v1.2

| *                                      | Programs                              |                            |                |                            |                               | Search Q A          |
|----------------------------------------|---------------------------------------|----------------------------|----------------|----------------------------|-------------------------------|---------------------|
|                                        |                                       |                            |                |                            |                               |                     |
|                                        | $\mathbf{F}$                          | 🔘 Add 🛛 🥒 Edit 🍵 Delete    |                |                            |                               | Q Search T Filters  |
|                                        |                                       | 20 Programs                |                |                            |                               |                     |
|                                        |                                       | Program Name               |                |                            | Sponsor                       | Product             |
|                                        | TrialInteractive                      | TestUATP                   | Create Program |                            | Dermeron                      | Astrogum            |
|                                        |                                       | Integ_IV                   | Program Name*  | Number*                    | Dermeron                      | Lincegucaine        |
|                                        | ) Dashboard<br>Sponsors               | MI Patch                   | Program Name"  | Number-                    | Medical Immune                | AddicalImmune Patch |
|                                        | Programs                              | MM-One                     | Status*        | Status Date*               | May & May Pharmaceuticals     | MMAllergy           |
|                                        | Products                              | MM-Some                    | Planning       | ✓ 23 Sep 2021 ×            | 🕻 🌐 May & May Pharmaceuticals | <b>1</b> 3          |
| 「日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日 | Studies<br>Organizations              | MM-ALL                     | Sponsor*       |                            | May & May Pharmaceuticals     | 14                  |
| 10                                     | Contacts                              | WorkP1                     | Products*      |                            | Working 4U                    | WorkIMP4            |
|                                        | User Management<br>Activities Library | Diagnova321                | PIGALS         |                            | A+ Drugs                      | 2                   |
|                                        | Activity Plan Templates               | abc                        |                |                            | ACI Pharmaceuticals           | Astrogum            |
| 0                                      | Milestone Templates                   | MMOnc                      |                |                            | May & May Pharmaceuticals     | MMOnc               |
|                                        |                                       | Galashegos524              | Description    |                            | Galashegos Pharmaceuticals    | Dragon Steel        |
|                                        |                                       | Mays Limbs                 |                |                            | May & May Pharmaceuticals     | <b>2</b>            |
|                                        |                                       | A+-008                     |                |                            | A+ Drugs                      | <b>2</b>            |
|                                        |                                       | RKTrans                    |                |                            | RK Meds                       | TransPure           |
|                                        |                                       | King Peds                  |                |                            | King Research                 | Kings Cream         |
|                                        |                                       | May & May Vaccines Program | Cancel         | ate and Add Another Create | May & May Pharmaceuticals     | <b>à</b> 3          |
|                                        |                                       | May&May Market Device Test |                |                            | May & May Pharmaceuticals     | <b>2</b>            |
|                                        |                                       | King Derma                 | Planning       | 11183252021                | King Research                 | Kings Cream         |
|                                        |                                       | AstroRA-32021              | Planning       | 132021                     | Astrovile                     | <b>2</b>            |
|                                        |                                       | Wellness Program           | Ranning        | 123-1                      | Morvarty                      |                     |

### 9.3 Reviewing and Editing a Program

- 1. Click on the **Programs** link in the Navigation Menu at the left side of the screen.
  - a. This opens the "Programs" window, and the programs list is displayed.
- 2. Navigate to the program you want to review or edit and click on the name.
  - a. This opens the "Program Details" window.
- 3. Click on the **Edit** button in the top-left of the screen.



# TI CTMS USER GUIDE v1.2

|   | *            | Program<br>Diagnova321 • Progra | m Details                      |                            |                                  |              |                              | Se                             | arch Q 🗛 🗸     |
|---|--------------|---------------------------------|--------------------------------|----------------------------|----------------------------------|--------------|------------------------------|--------------------------------|----------------|
|   | ĸ            |                                 | ✓ Edit                         |                            |                                  |              |                              |                                | D Edit History |
|   |              |                                 | Program Informa                | ation                      |                                  |              |                              |                                | -              |
|   |              | Diagnova321                     | Number<br>321                  |                            | Program Name<br>Diagnova321      |              | Notes                        |                                |                |
|   |              | Program Details                 | Sponsor<br>A+ Drugs            |                            |                                  |              |                              |                                |                |
|   | ₩<br>▲<br>@  | Products<br>Studies<br>Sites    | Description                    |                            |                                  |              |                              |                                |                |
|   | 년<br>상품<br>· | Organizations<br>Contacts       |                                |                            |                                  |              |                              |                                |                |
|   | 1            | Team                            | Project Managen                | nent                       |                                  |              |                              |                                | •              |
|   |              |                                 | Status<br>Planning             | Status Date<br>25 Aug 2021 | Change Status                    | itatus Notes |                              |                                | Status History |
|   |              |                                 | Planning Informa               | ation                      |                                  |              |                              |                                |                |
|   |              |                                 | Number of Planned Studies<br>O |                            | Number of Planned Countries<br>0 |              | Number of Planned Sites<br>0 | Number of Planned Subject<br>0 | s              |
|   |              |                                 | Additional Inform              | nation                     |                                  |              |                              |                                | •              |
|   |              |                                 |                                |                            | Number of Program                | m related    |                              |                                |                |
| * |              |                                 |                                |                            | Ye                               | rs No test   |                              |                                |                |
| C |              |                                 |                                |                            |                                  |              |                              |                                |                |

- 4. Make any necessary changes in the sections you want.
- 5. Click on the **Save** button on the top-left of the screen, for the changes to apply.

| === | *       | 🖹 Program<br>Diagnova321 👻 Pro | gram Details               |                             |                         | Search Q AA -              |
|-----|---------|--------------------------------|----------------------------|-----------------------------|-------------------------|----------------------------|
|     | *       |                                | Save Cancel A Collapse All |                             |                         | Edit History               |
|     |         |                                | Program Information        |                             |                         | •                          |
|     |         | Diagnova321                    | Number*                    | Program Name*               | Notes                   |                            |
|     |         |                                | 321                        | Diagnova321                 |                         |                            |
|     |         |                                | Sponsor*                   |                             |                         |                            |
|     | i       | Program Details                | A+ Drugs                   | Active                      | ✓                       |                            |
|     | Ê       | Products                       | Description                |                             |                         |                            |
|     | Ā       | Studies                        |                            |                             |                         |                            |
|     | â       | Sites                          |                            |                             |                         |                            |
|     | []<br>상 | Organizations                  |                            |                             |                         |                            |
|     | -       | Contacts                       |                            |                             |                         |                            |
|     |         | 100111                         | Droject Management         |                             |                         | -                          |
|     |         |                                | Project Management         |                             |                         | -                          |
|     |         |                                | Status Status Date         | Status Notes                |                         |                            |
|     |         |                                | Planning 25 Aug 2021       | Change Status               |                         |                            |
|     |         |                                |                            |                             |                         | 🕲 Status History           |
|     |         |                                | Planning Information       |                             |                         |                            |
|     |         |                                | Number of Planned Studies  | Number of Planned Countries | Number of Planned Sites | Number of Planned Subjects |
|     |         |                                | 0                          | 0                           | 0                       | 0                          |
|     |         |                                |                            |                             |                         |                            |
|     |         |                                | Additional Information     |                             |                         |                            |
|     |         |                                |                            | Number of Program related   | ÷                       |                            |
|     |         |                                |                            | products 🕑                  | v .                     |                            |
| ٠   |         |                                |                            | Yes No test                 | YES NO                  |                            |
|     |         |                                |                            |                             |                         |                            |
| T   |         |                                |                            |                             |                         |                            |
|     |         |                                |                            |                             |                         |                            |



#### 9.4 Associating an Organization to a Program

- 1. Click on the **Programs** link in the Navigation Menu at the left side of the screen.
  - a. This opens the "Programs" window, and the programs list is displayed.
- Click on the name of the program to which you wish to associate an organization.
   a. This opens the "Program Details" window.
- 3. Click on the **Organization** link in the Navigation menu at the left side of the screen.
- a. This opens the "Organization" window, and the organization list is displayed.
- 4. Click **Add** and either search for an existing organization or create a new one.
- 5. Press **Create** when done.
  - a. More detailed instructions on this step can be found here.

|     | *        | Program<br>Diagnova321 • Organiz | ations                 |                                                                                                                                                                                                                                                                                                                   | Search Q. 🗛 🗸              |
|-----|----------|----------------------------------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
|     | ×        |                                  | Organizations          |                                                                                                                                                                                                                                                                                                                   | Q, Search <b>T</b> Filters |
|     |          | Diagnova321                      | 1 Organizations        | Add Organization                                                                                                                                                                                                                                                                                                  |                            |
| = • | <br><br> | Program Details                  | Name Stat<br>A H Drugs | Q. Search for the Organizations         General Information         Number*         Remet Organization         Type*         Solutype         Status*         Attive         Phenery Contact:         O Add         Notes         Cancel       Create and Add Another         Cancel       Create and Add Another | Primary Contrac:           |
| C   |          |                                  |                        |                                                                                                                                                                                                                                                                                                                   |                            |

#### 9.5 Associating a Contact to a Program

- 1. Click on the **Programs** link in the Navigation Menu at the left side of the screen.
  - a. This opens the "Programs" window, and the programs list is displayed.
- 2. Click on the name of the program to which you wish to associate a contact.
  - a. This opens the "Program Details" window.
- 3. Click on the **Contacts** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Contacts" window, and the contacts list is displayed.
- 4. Click on the Add button in the top-left of the screen.
  - a. This opens Create Contact in program window.

## TI CTMS USER GUIDE v1.2

|        | * | 🚔 Program<br>Diagnova321 👻 Contac | 15                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Search Q. 📣 🗸                   |
|--------|---|-----------------------------------|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
|        | × | Diagnova321                       | Contacts<br>Contacts<br>Nome Status | Create Contact in Program        A search for Contacts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Q Search<br>Start Date End Date |
|        |   |                                   |                                     | General Information Cripercannet Prefix Terres Name*  Prefix Terres Name*  Made Name  Suffix  Suffix Suffix Suffix Suffix Suffix Suffix Suffix Suffix |                                 |
|        |   |                                   |                                     | Phone Numbers<br>• Ads<br>Cancel Crease and Add Acother Crease                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                 |
| *<br>T |   |                                   |                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                 |

- 5. Here we need to enter the mandatory metadata to create a Contact i.e., Organization, First Name, Last Name, Contact Role, Email Address, Status, Include Address as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a contact successfully.
- 7. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another contact right away.

**Note**: The search bar at the top of the "Create Contact in program" window can be used to search for an existing CTMS contact record for associate to the program.

**Note**: The system will restrict the level of data that can be updated to only information relevant to the association of the contact to the program. All other data will need to be updated at the Home > Contacts level.



#### 9.6 Associating a Product to a Program

- 1. Click on the **Programs** link in the Navigation Menu at the left side of the screen.
  - a. This opens the "Programs window", and the programs list is displayed.
- 2. Click on the name of the program you want to associate to a product.
  - a. This opens the Program Details window.
- 3. Click on the **Products** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Products" window, and the products list is displayed.
- 4. Click the **Add** button in the top-left of the screen.
  - a. This opens Add Product window.
- 5. Select a product from the available products list.

|   | *                | <ul> <li>Program</li> <li>Diagnova321 •</li> </ul>                     | S                       |               |         |           |                 | (              | Search Q  | <b>AA</b> •      |
|---|------------------|------------------------------------------------------------------------|-------------------------|---------------|---------|-----------|-----------------|----------------|-----------|------------------|
|   | «                |                                                                        |                         |               |         |           |                 |                |           |                  |
|   |                  |                                                                        | 🔵 Add 🥒 Edit 🛛 🖏 Remove |               |         |           |                 |                |           | <b>T</b> Filters |
|   |                  | Diagnova321                                                            | 2 Products              |               |         |           |                 |                |           |                  |
|   |                  | Diagnova321                                                            | Product                 | Programs      | Status  | Туре      | Modifier        | Owner          | Sponsor   |                  |
|   |                  |                                                                        | Diagnova                | 🖄 Diagnova321 | Plenned | Medicinal | 🚔 system system | 👗 Steven Clark | A+ Drugs  |                  |
|   | ▲<br>●<br>■<br>替 | Program Deals<br>Product<br>State<br>Organizations<br>Contacts<br>Team | Azconelia               | Add Product   |         | - X       | 1               | A admin admin  | Attrovile |                  |
|   |                  |                                                                        |                         |               |         |           |                 |                |           |                  |
| ٠ |                  |                                                                        |                         |               |         |           |                 |                |           |                  |
| T |                  |                                                                        |                         |               |         |           |                 |                |           |                  |

## **10** Activities

#### 10.1 Associating Domain library Activity Records to a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Studies" window.
- 2. Click on the name of the study.
  - a. This opens dashboard for the study.



- Click on the Activity Plans link in the Navigation menu at the left side of the screen.
   a. This opens the "Activity Plans" window.
- 4. Click on **Templates** in the top-left center of the screen.a. This opens the "Templates" window.
- 5. Click on the **Add** button in the top-left of the screen.
  - a. Now click on Associate from the dropdown menu.

|   | *                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Activity Plans             | s Templates                                                          | Search (          | 2 🗛 -            |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------------|-------------------|------------------|
|   | ×                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                            | Activity Plans                                                       |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            | Plans In Use Scheduled Plans Templates                               |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            | Add - Add - Add - Copy & Apply CO Activate @ Set to Retired 👚 Delete | Q Search          | <b>Y</b> Filters |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            | Associate     O Create mplates                                       | Sort By Unknown ~ |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Study Details<br>Dashboard | No records available                                                 |                   |                  |
|   | 9<br>0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Milestones<br>Countries    |                                                                      |                   |                  |
|   | in the second se | Sites<br>Subjects          |                                                                      |                   |                  |
|   | 8<br>8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Organizations<br>Contacts  |                                                                      |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Team                       |                                                                      |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Activity Plans             |                                                                      |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |
|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |
| • |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |
| T |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |
| 6 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                                                                      |                   |                  |

6. This opens the Associate Activity Plan Templates to study "Study name is displayed".

# TI CTMS USER GUIDE v1.2

|   | *        |                                                       | Activity P    |                                                                                          |                                  |                                                                  |                     |                 |                   |
|---|----------|-------------------------------------------------------|---------------|------------------------------------------------------------------------------------------|----------------------------------|------------------------------------------------------------------|---------------------|-----------------|-------------------|
|   |          |                                                       |               |                                                                                          |                                  |                                                                  |                     |                 |                   |
|   |          | Diagnova                                              | O Add ~       | the activity plan templates yo                                                           |                                  | s to Study "Diagnova"<br>e for the study                         |                     | - ×             | Q Search          |
|   | @30<br>♀ | Study Details<br>Dashboard<br>Milestones<br>Countries | 0 Available 1 | i plan templates<br>ry Study Start-Up x<br>All ~ Classification All ~                    |                                  |                                                                  |                     |                 | Sort By Unknown v |
|   | 1        | Sites<br>Subjects<br>Organizations<br>Contacts        |               | Vity Plan Templates 1 Select<br>Plan Name<br>Study Start-Up                              | Classification<br>Start-up       | Description                                                      | Level               | Activities<br>2 |                   |
|   | Ċ        | Team<br>Activities<br>Activity Plans                  |               | Country Study Start-Up<br>1 Related Flan Site Start-up Plan SSU for Peds 2 Related Plans | Start-up<br>Start-up<br>Start-up | Country EC start-up<br>Initial Site EC start-up<br>SSU Pediatric | Country             | 2<br>2<br>2     |                   |
|   |          |                                                       |               | SSU for Peds Country<br>1 Related Plan SSU for Peds Site                                 |                                  |                                                                  | 🚱 Country<br>🖹 Site | 1               |                   |
|   |          |                                                       |               |                                                                                          |                                  |                                                                  |                     |                 |                   |
| ■ |          |                                                       |               |                                                                                          |                                  | Cancel                                                           |                     |                 |                   |
| * |          |                                                       |               |                                                                                          |                                  |                                                                  |                     |                 |                   |

- 7. Click on the **check box** before the plan name you want to associate to a study.
- 8. Click on the Associate button in the bottom of the Associate Activity Plan Template.

### 10.2 Creating Domain library Activity Records

T R I A L INTERACTIVE

- 1. Click on the Activities Library link in the Navigation menu at the left side of the screen.
  - a. This opens the "Activities Library" window.
- 2. Click on the **Add** button in the top-left of the screen.
  - a. This opens the Create Activity window.
- Here we need to enter the mandatory metadata to create an Activity i.e., Activity, Type, Sub Type, Description as indicated by an asterisk (\*) symbol next to the field title.
- 4. Initially Sub Type is greyed out, once you select a value for the Type from the dropdown menu the related values for the sub type will appear in the dropdown menu.
- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create an activity successfully.
- 6. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another activity right away.

## TI CTMS USER GUIDE v1.2

| *        | Activities Library                                                |                                   |                   |               |                          |     |                                          |             | Search Q        |
|----------|-------------------------------------------------------------------|-----------------------------------|-------------------|---------------|--------------------------|-----|------------------------------------------|-------------|-----------------|
|          |                                                                   | Activities Library                |                   |               |                          |     |                                          |             |                 |
|          | $\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{F}}}}}}$ | 🔿 Add 🥒 Edit 🏥 Delete 🛛 Set /     |                   |               |                          |     |                                          |             | Q Search T Fi   |
|          | ()                                                                | 35 Activities                     |                   |               |                          |     |                                          |             |                 |
|          |                                                                   | Activity Name                     | Status Ty         | ype           | Subtype                  |     | Description                              | Modified    | Modifier        |
|          | TrialInteractive                                                  | CTMS 1.1 UAT DRY RUN 010_Activity |                   | dknowlegement | IRB/EC                   |     | CTMS 1.1 UAT DRY RUN 010_TEST Acti       | 21 Sep 2021 | admin admin     |
|          |                                                                   | CTMS 1.1 UAT DRY RUN 010 - ACTI   |                   |               |                          |     | ST                                       | 21 Sep 2021 | admin admin     |
|          | Dashboard<br>Sponsors                                             | CTMS 1.1 UAT DRY RUN 010 - ACTI   | Create A          | Activity      |                          | • × | #2                                       | 21 Sep 2021 | 🛔 admin admin   |
|          | Programs                                                          | Number 2                          |                   |               |                          |     | cond Activity Approval                   | 17 Sep 2021 | 🛔 admin admin   |
| <u> </u> | Products                                                          | Number 1                          | Activity*         |               |                          |     | tivity Acknowledgment                    | 17 Sep 2021 | 🛔 admin admin   |
| <u>A</u> | Studies                                                           | UAT Authoring Activity            |                   |               |                          |     | thoring                                  | 10 Sep 2021 | 🚨 admin admin   |
| 目後       | Organizations<br>Contacts                                         | Anuj                              | Type*<br>Approval |               | Subtype*                 | ~   | r Anuj to see how the library works.     | 10 Sep 2021 | 🛔 system system |
|          | User Management                                                   | Refrig Log                        | Description*      | -             |                          |     | 51                                       | 10 Sep 2021 | 🛔 system system |
|          | Activities Library                                                | Monitoring Schedule definition    | C                 |               |                          |     | finition of visit schedule expected fo   | 10 Sep 2021 | 🚨 admin admin   |
|          | Activity Plan Templates<br>Milestone Templates                    | Zeta Team Agenda                  |                   |               |                          |     | ta TMF Plan meetings agenda              | 10 Sep 2021 | 👗 system system |
|          |                                                                   | Clinical Monitoring Plan Workshop |                   |               |                          |     | orkshop to define the Program moni       | 10 Sep 2021 | 🛔 system system |
|          |                                                                   | Tremor Start-up Survey            |                   |               |                          |     | tial evaluation of start-up process fo   | 10 Sep 2021 | 👗 system system |
|          |                                                                   | IRB/EC Submission of Site Closure |                   |               |                          |     | e is required to notify the sites gove   | 10 Sep 2021 | 🛔 system system |
|          |                                                                   | Feasibility Questionnaire         |                   |               |                          |     | sal Study feasibility questionnaire      | 10 Sep 2021 | 👗 system system |
|          |                                                                   | Receipt Log                       |                   | Cancel        | e and Add Another Create |     | g to be checked off and signed by st     | 10 Sep 2021 | 👗 system system |
|          |                                                                   | Cover Letter                      | ACTIVE CO         | ommunication  | Letter                   |     | Letter included in shipment detailing s  | 10 Sep 2021 | 🛔 system system |
|          |                                                                   | Patient Brochure                  | ACTIVE            | locument      | Protocol                 |     | Initial protocol patient brochure for wa | 10 Sep 2021 | 🛔 system system |
|          |                                                                   | Marketing Introduction letter     | ACTIVE            | ommunication  | Email                    |     | Letter to sites introducing the marketi  | 10 Sep 2021 | a system system |
|          |                                                                   | Interest Questionaire             | ACTIVE            | ommunication  | Fax                      |     | Initial study interest                   | 10 Sep 2021 | 🛔 system system |
|          |                                                                   | Destruction supplies communicati  | ACTIVE            | ommunication  | Letter                   |     | Letter set to site with destruction mate | 10 Sep 2021 | 🛔 system system |
|          |                                                                   | Empty ISF Binders                 | ACTINE            | locument      | Protocol                 |     | Empty binders for the housing of ISF d   | 10 Sep 2021 | 🛔 system system |
|          |                                                                   | Submission                        | ACTIVE            | locument      | Protocol                 |     | Submission document of study annual      | 10 Sep 2021 | 🚨 system system |

### 10.3 Editing Domain Library Activity Records

- Click on the Activities Library link in the Navigation menu at the left side of the screen.
   a. This opens the "Activities Library" window.
- 2. Navigate to the activity name you want to edit and click the check box before the activity name or click directly on the activity name.
- 3. Click on the **Edit** button in the top-left of the screen.
  - a. This opens the quick view panel on the right side of the screen.
- 4. Make necessary changes in the quick view panel.
- 5. Click on the **Save** button in the bottom right of the screen.

**Note**: Updates to an activity record will not be reflected within activity plans already actively applied or tracking. Updated activity records will be used for any new application or tracking of an activity plan containing the updated record.

# TI CTMS USER GUIDE v1.2

| Activities Lib                    | ary           |                      |                  |                 |                              |             |                 | Search Q AA                           |
|-----------------------------------|---------------|----------------------|------------------|-----------------|------------------------------|-------------|-----------------|---------------------------------------|
| (e)                               | Activities    | Library              |                  |                 |                              |             |                 |                                       |
| F                                 | O Add         | f Edit 🎁 Delete 💠 S  | et Inactive      |                 |                              |             |                 | Q Search T Fit                        |
| $\bigcirc$                        | 35 Activities | Selected             |                  |                 |                              |             |                 | 🗇 Number 2                            |
| Trialinterad                      | Activity      | Name Status          | Type             | Subtype         | Description                  | Modified    | Modifier        |                                       |
|                                   |               | VIS 1.1 UAT DRY R    | M Acknowlegement | IRE/EC          | CTMS 1.1 UAT DRY RUN 0       | 21 Sep 2021 | 🛔 admin admin   | General Information                   |
| Dashboard                         |               | VIS 1.1 UAT DRV R    | M Acknowlegement | IRB/EC          | TEST                         | 21 Sep 2021 | 📥 admin admin   | Activity*                             |
| Deshboard     Sponsors            | () 😁 🗇 (1)    | VIS 1.1 UAT DRY R    | Approval         | Annual Renewal  | test2                        | 21 Sep 2021 | 🛔 edmin admin   | Number 2                              |
| Programs                          | 🗹 🖨 Nut       | mber 2               | Mi Approval      | Initial         | Second Activity Approval     | 17 Sep 2021 | 🔒 admin admin   | Type* Subtype*                        |
| Products                          | 📄 😂 Nu        | mber 1 🛛 🚺 🚺         | Acknowlegement   | IR8/EC          | Activity Advnowledgment      | 17 Sep 2021 | 🛔 ədmin ədmin   | Approval V Initial                    |
| ∆ Studies                         | to UA         | T Authoring Activity | ME Communication | Letter          | Authoring                    | 10 Sep 2021 | 🍰 admin admin   | Description* Second Activity Approval |
| Organizations                     | 🗌 💆 Anu       | a) (AC               | M Document       | ICF Template    | For Anuj to see how the li   | 10 Sep 2021 | 🋔 system system | second rearry reproto                 |
| User Managem                      | nt 😁 Ref      | rig Log              | Document         | Protocol        | Test                         | 10 Sep 2021 | 🛔 system system |                                       |
| Activities Librar                 | Mo 💬 Mo       | nitoring Schedule    | Meeting          | Monitoring Plan | Definition of visit schedul  | 10 Sep 2021 | 🛔 admin admin   | Associated Plans                      |
| Activity Plan Te<br>Milestone Tem | pells Zet     | a Team Agenda        | Meeting          | TMF Plan        | Zeta TMF Plan meetings a     | 10 Sep 2021 | 🛔 system system |                                       |
| · ······                          |               | sical Monitoring Pl  | Meeting          | Monitoring Plan | Workshop to define the P     | 10 Sep 2021 | 👗 system system |                                       |
|                                   | Tre           | mor Størt-up Surv    | M Document       | Protocol        | Initial evaluation of start  | 10 Sep 2021 | 🍐 system system |                                       |
|                                   | E RB          | /EC Submission o AC  | M Document       | Protocol        | Site is required to notify t | 10 Sep 2021 | 🛔 system system | 1                                     |
|                                   | Fea           | sibility Questionn   | TTE Document     | Protocol        | Initial Study feasibility qu | 10 Sep 2021 | 🛔 system system |                                       |
|                                   | C 🛱 Rec       | eipt Log AC          | NE Document      | Protocol        | Log to be checked off an     | 10 Sep 2021 | 🛔 system system | 1                                     |
|                                   | 😁 Cov         | ver Letter           | M Communication  | Letter          | Letter included in shipme    | 10 Sep 2021 | 🛔 system system |                                       |
|                                   | Pat           | ient Brochure        | NE Document      | Protocol        | Initial protocol patient br  | 10 Sep 2021 | a system system | 1                                     |
|                                   | 💭 Ma          | rketing Introducti   | NE Communication | Email           | Letter to sites introducing  | 10 Sep 2021 | 👗 system system |                                       |
|                                   |               | erest Questionaire   | Mi Communication | Fax             | Initial study interest       | 10 Sep 2021 | 🛔 system system |                                       |
|                                   |               | struction supplies   | Communication    | Letter          | Letter set to site with des  | 10 Sep 2021 | 🛔 system system |                                       |
|                                   |               | pty ISF Binders      | WI Document      | Protocol        | Empty binders for the ho     | 10 Sep 2021 | 👗 system system |                                       |
|                                   | (🗇 Sub        |                      | M Document       | Protocol        | Submission document of       | 10 Sep 2021 | a system system | Cancel Save Save & Next               |

## 10.4 Deleting Domain Activity Records

- Click on the Activities Library link in the Navigation menu at the left side of the screen.
   a. This opens the "Activities Library" window.
- 2. Navigate to the activity name you want to delete and click the check box before the activity name or click directly on the activity name.
- 3. Click on the **Delete** button in the top-left of the screen.
- 4. This deletes the Activity record.

**Note**: The system will restrict the ability to delete an activity record that is being used within the system, the user should inactive such records and not delete them.

# TI CTMS USER GUIDE v1.2

| Activities Library                              |                          |                   |                 |                              |             |                 |                                         | AA   |
|-------------------------------------------------|--------------------------|-------------------|-----------------|------------------------------|-------------|-----------------|-----------------------------------------|------|
|                                                 | Activities Library       |                   |                 |                              |             |                 |                                         |      |
| Ŧ                                               | 🔿 Add 🥒 Edit 📋 Delete    | e 🗢 Set Inactive  |                 |                              |             |                 | Q Search                                | T Re |
| $\bigcirc$                                      | 35 Activities 1 Selected |                   |                 |                              |             |                 | 🖄 Number 2                              |      |
| TrialInteractive                                | Activity Name            | Status Type       | Subtype         | Description                  | Modified    | Modifier        |                                         |      |
| manneracuve                                     | CTMS 1.1 UAT DRY R_      | ACTMI Acknowlege  | ment IRE/EC     | CTMS 1.1 UAT DRY RUN 0       | 21 Sep 2021 | 💄 admin admin   | General Information                     |      |
| 0.000                                           | CTMS 1.1 UAT DRV R       | Actme Acknowlege  | ment IRB/EC     | TEST                         | 21 Sep 2021 | 👗 admin admin   | Activity                                |      |
| Dashboard     Sponsors                          | CTMS 1.1 UAT DRY R       | MACTIVE Approval  | Annual Renewal  | test2                        | 21 Sep 2021 | 🚨 ədmin ədmin   | Number 2                                |      |
| Programs                                        | 🗹 🛱 Number 2             | ACTIVE Approval   | Initial         | Second Activity Approval     | 17 Sep 2021 | 🐣 admin admin   | Type Subtype                            |      |
| Products                                        | Number 1                 | ACTIVE Acknowlege | ment IRB/EC     | Activity Acknowledgment      | 17 Sep 2021 | 🛔 admin admin   | Approval Initial                        |      |
| ▲ Studies                                       | UAT Authoring Activity   | ACTIVE Communica  | tion Letter     | Authoring                    | 10 Sep 2021 | 🔒 admin admin   | Description<br>Second Activity Approval |      |
| Organizations     Contacts                      | Anuj                     | ACTIVE Document   | ICF Template    | For Anuj to see how the IL   | 10 Sep 2021 | 🛔 system system | accond Activity Approval                |      |
| User Management                                 | Refrig Log               | Document          | Protocol        | Test                         | 10 Sep 2021 | 🋔 system system |                                         |      |
| Activities Library                              | Monitoring Schedule      | ACTIVE Meeting    | Monitoring Plan | Definition of visit schedul  | 10 Sep 2021 | 🛔 admin admin   | Associated Plans                        |      |
| Activity Plan Templates     Milestone Templates | Zeta Team Agenda         | RACTWE Meeting    | TMF Plan        | Zeta TMF Plan meetings a     | 10 Sep 2021 | 🛔 system system |                                         |      |
| <ul> <li>winescone remplates</li> </ul>         | Clinical Monitoring Pl   | ACTIVE Meeting    | Monitoring Plan | Workshop to define the P     | 10 Sep 2021 | 🏯 system system |                                         |      |
|                                                 | Tremor Start-up Surv     | ACTIVE Document   | Protocol        | Initial evaluation of start  | 10 Sep 2021 | a system system |                                         |      |
|                                                 | IRB/EC Submission o      | ACTM Document     | Protocol        | Site is required to notify t | 10 Sep 2021 | a system system | 1                                       |      |
|                                                 | Feasibility Questionn    | Active Document   | Protocol        | Initial Study feasibility qu | 10 Sep 2021 | a system system |                                         |      |
|                                                 | Receipt Log              | ACTIVE Document   | Protocol        | Log to be checked off an     | 10 Sep 2021 | System system   | 1                                       |      |
|                                                 | Cover Letter             | ACTML Communica   |                 | Letter included in shipme    | 10 Sep 2021 | a system system |                                         |      |
|                                                 | Patient Brochure         | ACTIVE Document   | Protocol        | Initial protocol patient br  | 10 Sep 2021 | a system system | 1                                       |      |
|                                                 | Marketing Introducti     | ACTIVE Communica  |                 | Letter to sites introducing  | 10 Sep 2021 | System system   |                                         |      |
|                                                 | Interest Questionaire    | ACINE Communica   |                 | Initial study interest       | 10 Sep 2021 | System system   | 1                                       |      |
|                                                 | Destruction supplies     | Communica         |                 | Letter set to site with des  | 10 Sep 2021 | System system   |                                         |      |
|                                                 | Empty ISF Binders        | ACTIME Document   | Protocol        | Empty binders for the ho     | 10 Sep 2021 | system system   | 1                                       |      |
|                                                 | Submission               | ACIMI Document    | Protocol        | Submission document of       | 10 Sep 2021 | a system system |                                         |      |

### **10.5 Inactivating Domain Activity Records**

- 1. Click on the **Activities Library** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Activities Library" window.
- 2. Navigate to the activity name you want to set as Inactive and click the check box before the activity name or click directly on the activity name.
- 3. Click on the **Set Inactive** button in the top-left of the screen.
- 4. This Inactivates the Activity record.

# TI CTMS USER GUIDE v1.2

| Activities Library                              |                            |                       |                 |                              |             |                 | Search Q                                |
|-------------------------------------------------|----------------------------|-----------------------|-----------------|------------------------------|-------------|-----------------|-----------------------------------------|
| •                                               | Activities Library         |                       |                 |                              |             |                 |                                         |
| Ŧ                                               | 🗿 Add 🥒 Edit 🏦 Delete 🚺    | Set Inactive          |                 |                              |             |                 | Q Search Y F                            |
| $\bigcirc$                                      | 35 Activities 1 Selected   |                       |                 |                              |             |                 | 🖄 Number 2                              |
| TrialInteractive                                | Activity Name Statu        | is Type               | Subtype         | Description                  | Modified    | Modifier        | Provide and a second second             |
| mainteractive                                   | CTMS 1.1 UAT DRY R_        | Acknowlegement        | IRE/EC          | CTMS 1.1 UAT DRY RUN 0       | 21 Sep 2021 | 🛔 admin admin   | General Information                     |
|                                                 | CTMS 1.1 UAT DRYR          | Active Acknowlegement | IRB/EC          | TEST                         | 21 Sep 2021 | admin admin     | Activity                                |
| Dashboard     Sponsors                          | 📋 😁 CTMS 1.1 UAT DRY R 🧰   | Active Approval       | Annual Renewal  | test2                        | 21 Sep 2021 | 🚨 edmin admin   | Number 2                                |
| Programs                                        | 🗹 🛱 Number 2               | ACTIVE Approval       | Initial         | Second Activity Approval     | 24 Sep 2021 | 🔒 admin admin   | Type Subtype                            |
| Products                                        | 📄 🗑 Number 1               | ACTIVE Acknowlegement | IRB/EC          | Activity Advnowledgment      | 17 Sep 2021 | 🛔 ədmin ədmin   | Approval Initial                        |
| ▲ Studies                                       | 😂 UAT Authoring Activity 🚺 | ACTIVE Communication  | Letter          | Authoring                    | 10 Sep 2021 | 🛔 admin admin   | Description<br>Second Activity Approval |
| Organizations<br>Contacts                       | 🗌 🗑 Anuj 🗰                 | ACTIVE Document       | ICF Template    | For Anuj to see how the IL   | 10 Sep 2021 | 🛔 system system | account recently repriored              |
| User Management                                 | 😁 Refrig Log               | NCTIVE Document       | Protocol        | Test                         | 10 Sep 2021 | 🛔 system system |                                         |
| Activities Library                              | Monitoring Schedule        | ACTIVE Meeting        | Monitoring Plan | Definition of visit schedul  | 10 Sep 2021 | 🛔 admin admin   | Associated Plans                        |
| Activity Plan Templates     Milestone Templates | 💆 Zeta Team Agenda 🛛 💼     | Meeting               | TMF Plan        | Zeta TMF Plan meetings a     | 10 Sep 2021 | 🛔 system system |                                         |
| <ul> <li>winestone remplates</li> </ul>         |                            | ACTIVE Meeting        | Monitoring Plan | Workshop to define the P     | 10 Sep 2021 | 🏯 system system |                                         |
|                                                 | 🛱 Tremor Start-up Surv     | ACTIVE Document       | Protocol        | Initial evaluation of start  | 10 Sep 2021 | 🋔 system system |                                         |
|                                                 | Feasibility Questionnaire  | ACTIVI Document       | Protocol        | Site is required to notify t | 10 Sep 2021 | 🛔 system system | 1                                       |
|                                                 | 📄 😁 Feasibility Questionn  | ACTIVE Document:      | Protocol        | Initial Study feasibility qu | 10 Sep 2021 | 🏝 system system |                                         |
|                                                 |                            | ACTIVE Document       | Protocol        | Log to be checked off an     | 10 Sep 2021 | 🛔 system system | 1                                       |
|                                                 |                            | ACTIVE Communication  | Letter          | Letter included in shipme    | 10 Sep 2021 | 🛔 system system |                                         |
|                                                 |                            | ACTIVE Document       | Protacol        | Initial protocol patient br- | 10 Sep 2021 | 🛔 system system | 1                                       |
|                                                 | Marketing Introducti       | Communication         | Email           | Letter to sites introducing  | 10 Sep 2021 | 👗 system system |                                         |
|                                                 |                            | ACTIVE Communication  | Fax             | Initial study interest       | 10 Sep 2021 | 🛔 system system |                                         |
|                                                 |                            | Active Communication  | Letter          | Letter set to site with des  | 10 Sep 2021 | a system system |                                         |
|                                                 |                            | ACTIVE Document       | Protocol        | Empty binders for the ho     | 10 Sep 2021 | a system system |                                         |
|                                                 |                            | ACTM Document         | Protocol        | Submission document of       | 10 Sep 2021 | 🛔 system system |                                         |

## 10.6 Creating Domain Library Activity Plans

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Activity Plans Templates" window.
- 2. Click on the **Create Template** in the top-left of the screen.
  - a. This opens the Create Activity Plan Template window.
- Here we need to enter the mandatory metadata to create an activity plan template i.e., Activity Plan Name, Level as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Next Add Activities** button, displaying the fields which need to be filled to create an activity plan template successfully.



|   | # | Activity Plan Templates                      |                           | Search Q       | •       |
|---|---|----------------------------------------------|---------------------------|----------------|---------|
|   |   | Create Activity Plan Ter                     | nplate                    | Step 1 🔹 🔉 🗖 🗙 |         |
|   |   | General Information<br>Associated Activities | Second Information        |                | T fries |
|   |   |                                              | Cancel New Add Activities |                |         |
| * |   |                                              | Cancel Non Add Activities |                |         |
| C |   |                                              |                           |                |         |

- 5. This opens the Associated Activities window.
- Click on the Create button in the associated activities window.
   a. This opens Create Activity window.
- Here we need to enter the mandatory metadata to create an activity for the template i.e., Activity, Type, Sub Type, Description as indicated by an asterisk (\*) symbol next to the field title.
- 8. Initially Sub Type is greyed out, once you select a value for the Type from the dropdown menu the related values for the sub type will appear in the dropdown menu.
- 9. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create an activity successfully.
- 10. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another activity right away.

**Note**: The activity records created in this location will be records within the Activities Library, available for future selection.



|   | *                 | Activity Plan Templates                   |                                                                            |                                                            |     |          |          | Search Q     | <b>AA</b> • |
|---|-------------------|-------------------------------------------|----------------------------------------------------------------------------|------------------------------------------------------------|-----|----------|----------|--------------|-------------|
|   | 4                 | Create Activity Plan Te                   |                                                                            |                                                            |     |          |          | Step 2 💿 🖷 🗙 |             |
|   |                   | General Information Associated Activities | Associated Activities Q. Search Library / Quick Select C. Creece S. Remove | G. Search Library / Quick Select     G Crease     G Remove |     |          |          |              | ▼ Fitters   |
|   | 8                 |                                           | 0 Activities Activity Name                                                 | Create Activity                                            | • × | Modified | Modifier |              |             |
|   | 「「「」「」「」「」「」」「」」」 |                                           |                                                                            | Acturity*                                                  |     |          |          |              |             |
|   |                   |                                           |                                                                            |                                                            |     |          |          |              |             |
| * |                   |                                           |                                                                            | Cancel Previous Save Activities                            |     |          |          |              |             |
| C |                   |                                           |                                                                            |                                                            |     |          |          |              |             |

- 11. Click on the **Save Activities** button in the create activity plan template window.
  - a. The create activity plan template closes and a template is created.

**Note**: Activity plans default to Draft status to allow for review and updates before making the plan available for selection by the user community throughout the system.

#### 10.7 Editing Draft Activity plans

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Activity Plans Templates" window.
- 2. Navigate to the plan you want to edit.
- 3. Click on the **Edit** button in the top-left of the screen.
  - a. This opens the Edit Activity Plan Template window.
- 4. Make any necessary changes in the Edit Activity Plan Template window.
- 5. Click on **Save Activities** in the bottom of the edit activity plan template window.

## TI CTMS USER GUIDE v1.2

|   | *                                        | Activity Plan Templates               |                                          |                        |                          |                               |           |            |                | (             | Search Q AA -    |
|---|------------------------------------------|---------------------------------------|------------------------------------------|------------------------|--------------------------|-------------------------------|-----------|------------|----------------|---------------|------------------|
|   | «                                        | $\sim$                                | Activity Plan Tem                        |                        | Publish Ø Set to Retired | 🝵 Delete                      |           |            |                |               | Q Search Titters |
|   |                                          | $T_{\Omega}$                          |                                          |                        |                          |                               |           |            |                |               |                  |
|   |                                          |                                       | 15 Activity Plan Templates               | s 1 Selected<br>Status | Classification           | Description                   | Level     | Activities | Parent Plan    | Modified Date | Modifier         |
|   |                                          | TrialInteractive                      | Demo                                     | Draft                  |                          |                               | A Study   | 1          |                | 24 Sep 2021   | 🐣 admin admin    |
|   |                                          |                                       | CTMS 1.1 UAT DRY RUN 0                   | Recired 0              | Amendment                | CTMS 1.1 UAT DRY RUN 010_TEST | A Study   | 2          |                | 21 Sep 2021   | 🚨 admin admin    |
|   | en e | Dashboard<br>Sponsors                 | Starter                                  | Draft                  |                          |                               | A Study   | 2          |                | 17 Sep 2021   | 着 admin admin    |
|   |                                          | Programs                              | Test Plan 2                              | Draft                  |                          |                               | Q Country | 2          |                | 10 Sep 2021   | 🚨 admin admin    |
|   | A                                        | Products<br>Studies                   | UAT plan                                 | Recired                | Archival                 |                               | A Study   |            |                | 10 Sep 2021   | 🛔 admin admin    |
|   |                                          | Organizations                         | SSU for Peds Site                        | Published              |                          |                               | 🛱 Site    | 1          | SSU for Peds C | 10 Sep 2021   | 💄 system system  |
|   | 쑵                                        | Contacts                              | SSU for Peds Country<br>1 Related Plan   | Published              |                          |                               | Country   | 1          | SSU for Peds   | 10 Sep 2021   | 💄 system system  |
|   | <br>121                                  | User Management<br>Activities Library | SSU for Peds<br>2 Related Plans          | Published              | Start-up                 | SSU Pediatric                 | A Study   | 2          |                | 10 Sep 2021   | 🛔 system system  |
|   |                                          | Activity Plan Templates               | Test Plan                                | Draft                  |                          |                               | Q Country | 1          |                | 10 Sep 2021   | 🚨 system system  |
|   | 0                                        | Milestone Templates                   | 🛄 Status test plan                       | Recired                |                          |                               | A Study   |            |                | 10 Sep 2021   | 🛔 system system  |
|   |                                          |                                       | Site Close-out                           | Retired                | Close-out                |                               | 🛱 Site    |            |                | 10 Sep 2021   | 🛔 system system  |
|   |                                          |                                       |                                          | Retired                |                          |                               |           |            |                |               |                  |
|   |                                          |                                       | Site Start-up Plan                       | Published              | Start-up                 | Initial Site EC start-up      | 🛱 Site    | 2          | Country Study  | 10 Sep 2021   | 🛔 system system  |
|   |                                          |                                       | Country Study Start-Up<br>1 Related Plan | Published              | Start-up                 | Country EC start-up           | Q Country | 2          |                | 10 Sep 2021   | 💄 system system  |
|   |                                          |                                       | Study Start-Up                           | Published              | Start-up                 |                               | A Study   | 2          |                | 10 Sep 2021   | 💄 system system  |
|   |                                          |                                       |                                          |                        |                          |                               |           |            |                |               |                  |
|   |                                          |                                       |                                          |                        |                          |                               |           |            |                |               |                  |
|   |                                          |                                       |                                          |                        |                          |                               |           |            |                |               |                  |
|   |                                          |                                       |                                          |                        |                          |                               |           |            |                |               |                  |
| ٠ |                                          |                                       |                                          |                        |                          |                               |           |            |                |               |                  |
| T |                                          |                                       |                                          |                        |                          |                               |           |            |                |               |                  |
| 0 |                                          |                                       |                                          |                        |                          |                               |           |            |                |               |                  |

#### **10.8 Publishing Activity Plans**

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Activity Plan Templates" window.
- 2. Navigate to the plan name which is in **Draft** status you want to publish it and click on it.
- 3. Click on the **Publish** button in the top-left of the screen.
- 4. Activity plan is displayed with a status of published and can no longer be updated.

## TI CTMS USER GUIDE v1.2

|   | Activity Plan Templates                         |                                                                  |               |                              |                                                 |                |            |                | [             | Search Q                    |           |
|---|-------------------------------------------------|------------------------------------------------------------------|---------------|------------------------------|-------------------------------------------------|----------------|------------|----------------|---------------|-----------------------------|-----------|
|   | ° Z                                             | Activity Plan Ten O Create Template                              | idit 🗈 Copy 🤇 | Publish     Ø Set to Retired | 會 Delete                                        |                |            |                |               | Q Search                    | ▼ Filters |
|   | TrialInteractive                                | 14 Activity Plan Template<br>Plan Name<br>CTMS 1.1 UAT DRY RUN O | Status        | Classification<br>Amendment  | Description<br>CTMS 1.1 UAT DRY RUN 010_TEST    | Level          | Activities | Parent Plan    | Modified Date | Modifier<br>🏝 admin admin   |           |
|   | 避 Deshboerd                                     | Starter                                                          | Dut           | _                            |                                                 | <u>▲</u> Study | 2          |                | 17 Sep 2021   | 🚢 admin admin               |           |
|   | Sponsors     Programs     Products              | UAT plan                                                         | Dat.          | Archivel                     |                                                 | Country        | 2          |                | 10 Sep 2021   | 🛓 admin admin               |           |
|   | Studies                                         | SSU for Peds Site<br>SSU for Peds Country<br>1 Related Plan      | Published     |                              |                                                 | Site           | 1          | SSU for Peds C | 10 Sep 2021   | System system               |           |
|   | Contacts User Management Activities Library     | SSU for Peds<br>2 Related Plans                                  | Published     | Start-up                     | SSU Pediatric                                   | 👗 Study        | 2          |                | 10 Sep 2021   | 🛔 system system             |           |
|   | Activity Plan Templates     Milestone Templates | Status test plan                                                 | Resired       |                              |                                                 | 👗 Study        |            |                |               | System system System system |           |
|   |                                                 | Investigator Meeting                                             | Retired       | • 2                          | Study Start-up Investigator meeting activities  | A Study        |            |                |               | 🛔 system system             |           |
|   |                                                 | Site Start-up Plan Country Study Start-Up Related Plan           | Published     | Start-up<br>Start-up         | Initial Site EC start-up<br>Country EC start-up | Country        | 2          | Country Study  | 10 Sep 2021   | system system system system |           |
|   |                                                 | Study Start-Up                                                   | Published     | Start-up                     |                                                 | A Study        | 2          |                | 10 Sep 2021   | 💄 system system             |           |
|   |                                                 |                                                                  |               |                              |                                                 |                |            |                |               |                             |           |
| = |                                                 |                                                                  |               |                              |                                                 |                |            |                |               |                             |           |
| ٠ |                                                 |                                                                  |               |                              |                                                 |                |            |                |               |                             |           |
| C |                                                 |                                                                  |               |                              |                                                 |                |            |                |               |                             |           |

### **10.9 Retiring Activity Plans**

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the **Activity Plan Templates** window.
- 2. Navigate to the plan name which is in **Published** status you want to retire and click on it.
- 3. Click on the Set to Retired button in the top-left of the screen.
  - a. Confirmation window for activity plan retirement is displayed.
- 4. Enter a reason for retiring the activity plan.
- 5. Click on the **Set to Retired** button in the window.



## TI CTMS USER GUIDE v1.2

|   | _            |                                                |                                          |           |                              |                                          |       |            |                |               |                 |             |
|---|--------------|------------------------------------------------|------------------------------------------|-----------|------------------------------|------------------------------------------|-------|------------|----------------|---------------|-----------------|-------------|
|   | *            | Activity Plan Templates                        |                                          |           |                              |                                          |       |            |                |               |                 | <b>AA</b> - |
|   | ( «          |                                                | Activity Plan Ter                        |           |                              |                                          |       |            |                |               |                 |             |
|   |              | $\sim$                                         | Create Template                          |           | Publish     Ø Set to Retired | 育 Delete                                 |       |            |                |               |                 | ▼ Filters   |
|   |              | 10                                             | 14 Activity Plan Template                |           |                              |                                          |       |            |                |               |                 |             |
|   |              |                                                | Plan Name                                | Status    | Classification               | Description                              | Level | Activities | Parent Plan    | Modified Date | Modifier        |             |
|   |              | TrialInteractive                               | CTMS 1.1 UAT DRY RUN 0                   | Redred 🕜  | Set to Retired               |                                          | - ×   |            |                |               | 🚨 admin admin   |             |
|   |              | Dashboard                                      | Starter                                  | Draft     | Set to Kethed                |                                          |       | 2          |                | 17 Sep 2021   | 🚨 admin admin   |             |
|   | 围            |                                                | Test Plan 2                              | Draft     | Do you want to set the foll  | owing Activity Plan Template to Retired? |       | 2          |                | 10 Sep 2021   | 🚨 admin admin   |             |
|   |              |                                                | UAT plan                                 | Refred    |                              |                                          |       | 2          |                | 10 Sep 2021   | 🚔 admin admin   |             |
|   | <u>≜</u><br> |                                                | SSU for Peds Site                        | Published | Template Name                | SSU for Peds Site                        |       | 1          | SSU for Peds C | 10 Sep 2021   | 🛔 system system |             |
|   |              |                                                | SSU for Peds Country<br>1 Related Plan   | Published | Classification               |                                          |       |            | SSU for Peds   | 10 Sep 2021   | 🛔 system system |             |
|   |              | Contacts<br>User Management                    | SSU for Peds<br>2 Related Plans          | Published | Associated Activities        | 1                                        |       | 2          |                | 10 Sep 2021   | 🛔 system system |             |
|   |              | Activities Library                             | Test Plan                                | Draft     | Description                  |                                          |       | 1          |                | 10 Sep 2021   | System system   |             |
|   |              | Activity Plan Templates<br>Milestone Templates | 🔝 Status test plan                       | Retired   | Parent Plan Name             | SSU for Peds Country                     |       |            |                |               | 🚨 system system |             |
|   | v            | witescorie remplaces                           | Site Close-out                           | Refred    | Reason                       |                                          |       |            |                |               | 👗 system system |             |
|   |              |                                                | Investigator Meeting                     | Retired   |                              |                                          |       |            |                |               | 🚨 system system |             |
|   |              |                                                | Site Start-up Plan                       | Published |                              |                                          |       | 2          | Country Study  | 10 Sep 2021   | a system system |             |
|   |              |                                                | Country Study Start-Up<br>1 Related Plan | Published |                              |                                          |       | 2          |                | 10 Sep 2021   | 🛔 system system |             |
|   |              |                                                | Study Start-Up                           | Published |                              |                                          |       | 2          |                | 10 Sep 2021   | 🛔 system system |             |
|   |              |                                                |                                          |           |                              | Cancel Set to Retired                    |       |            |                |               |                 |             |
|   |              |                                                |                                          |           |                              |                                          |       |            |                |               |                 |             |
|   |              |                                                |                                          |           |                              |                                          |       |            |                |               |                 |             |
| = |              |                                                |                                          |           |                              |                                          |       |            |                |               |                 |             |
| • |              |                                                |                                          |           |                              |                                          |       |            |                |               |                 |             |
|   |              |                                                |                                          |           |                              |                                          |       |            |                |               |                 |             |
| E |              |                                                |                                          |           |                              |                                          |       |            |                |               |                 |             |
| 0 |              |                                                |                                          |           |                              |                                          |       |            |                |               |                 |             |

### 10.10 Copying Activity Plans

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Activity Plan Templates" window.
- 2. Navigate to the plan you want to copy and click on it.
- 3. Click on the **Copy** button in the top-left of the screen.
  - a. This opens the **Copy Activity Plan Template** window.
- 4. Update the necessary fields and click on Next Add Activities.
  - a. This displays all the associated activities.
- 5. Click Browse All Activities in the Copy Activity Plan Template window.
- 6. Select an existing library activity for association to the activity plan.
- 7. Click Save Activities in the Copy Activity Plan Template window.

Note: Draft and Retired activities are not available for selection for any entity.



|                | #     | Activity Plan Templates                     |                                 |          |                            |                               |             | Search Q                  |                  |
|----------------|-------|---------------------------------------------|---------------------------------|----------|----------------------------|-------------------------------|-------------|---------------------------|------------------|
|                | *     | Copy Activity Plan Tem                      | nplate                          |          |                            |                               |             | Step 2 💿 🖷 🕱              |                  |
|                |       | General Information Associated Activities 2 | Associated Activities           |          |                            |                               |             |                           | <b>T</b> Filters |
|                |       |                                             | Q Search Library / Quick Select |          |                            |                               |             | Browse Activities Library |                  |
|                | a     |                                             | 2 Activities                    |          |                            |                               |             |                           |                  |
|                |       |                                             | Activity Name                   | Туре     | Subtype                    | Description                   | Modified    | Modifier                  |                  |
|                | N Bu. |                                             | EC Submission                   | Document | Protocol                   | Initial EC Submission         | 10 Sep 2021 | 🛔 System System           |                  |
|                | 2     |                                             | IRB Submission                  | Document | Protocol                   | Close-out notification to EC. | 10 Sep 2021 | 🛔 System System           |                  |
|                |       |                                             |                                 |          |                            |                               |             |                           |                  |
| ٠              |       |                                             |                                 |          | Cancel Previous Save Activ | ties                          |             |                           |                  |
| $\overline{F}$ |       |                                             |                                 |          |                            |                               |             |                           |                  |
| E              |       |                                             |                                 |          |                            |                               |             |                           |                  |

## 10.11 Associating Activity Plan Templates to a Study

- Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
   a. This open the "Studies" window and the studies list is displayed.
- 2. Navigate to the study you want to associate to an activity plan template and click on it.
  - a. This opens the dashboard for the study.
- 3. Click on the Activity Plans link in Navigation menu at the left side of the screen.
  - a. This opens the "Activity Plan" window's **Plans in Use** section.
- 4. Click on **Templates** in the top-left of the screen.
  - a. This opens the "Templates" window and templates list is displayed.
- 5. Click on the **Add** button in the top-left of the screen.
- 6. Now click on the **Associate** from the dropdown menu.
- 7. This opens the Associate Activity Plan Templates to study window.
- 8. Click on the check box before the plan name you want to associate to a study.
- 9. Click on the Associate button in the bottom of the Associate Activity Plan Template window.

**Note**: Activity plans default to Draft status to allow for review and updates before making the plan available for selection by the user community throughout the system.



|   | *      | ∆ Study<br>Diagnova ▼ Activity Plar | ns Templates                                                                                  | Search Q A        |
|---|--------|-------------------------------------|-----------------------------------------------------------------------------------------------|-------------------|
|   | ۲      | X                                   | Activity Plans                                                                                |                   |
|   |        | Diagnova                            | Plans In Use Scheduled Plans Templates                                                        |                   |
|   |        |                                     | Associate     Associate     Associate     Associate     Associate     Associate     Associate | Q, Search Tilters |
|   |        | Study Details<br>Dashboard          | No records available                                                                          |                   |
|   | 0      | Milestones<br>Countries             |                                                                                               |                   |
|   | Ĩ.     | Sites<br>Subjects<br>Organizations  |                                                                                               |                   |
|   | 상<br>+ | Contacts<br>Team                    |                                                                                               |                   |
|   |        | Activities<br>Activity Plans        |                                                                                               |                   |
|   |        |                                     |                                                                                               |                   |
|   |        |                                     |                                                                                               |                   |
|   |        |                                     |                                                                                               |                   |
|   |        |                                     |                                                                                               |                   |
| = |        |                                     |                                                                                               |                   |
| * |        |                                     |                                                                                               |                   |
| C |        |                                     |                                                                                               |                   |

#### **10.12 Scheduling Activity Plans**

- Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
   a. This open the studies window and studies list is displayed.
- 2. Click on the name of the study to which you want to associate an activity plan template.
  - a. This opens the **dashboard** for the study.
- 3. Click on the Activity Plans link in Navigation menu at the left side of the screen.
  - a. This opens the Activity Plan window's Plans in Use section.
- 4. Click on the **scheduled Plans** button in the activity plans screen.
  - a. This opens the Scheduled Plan window.
- 5. Click on the **Add** button in the top-left of the screen.
  - a. This opens the "Scheduled Activity Plan for Study: "Study Name" Sites" window.
- 6. Navigate to the activity Plan you want to schedule, click on it.

## TI CTMS USER GUIDE v1.2

|        | *           | ∑ Study<br>Diagnova ▼ Activity Plan                                           | ns Schedul                                                   | ed Plans                                         |                                                                    |                                                         |                                       | Search Q 🗛 -                                         |
|--------|-------------|-------------------------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------|--------------------------------------------------------------------|---------------------------------------------------------|---------------------------------------|------------------------------------------------------|
|        | •           |                                                                               | Activity                                                     |                                                  |                                                                    |                                                         |                                       |                                                      |
|        |             | Diagnova                                                                      |                                                              | Schedule Activity Pla                            | n for Study: "Diagno                                               | ova" Sites                                              | Step 1 • • • 🗆 🗶                      |                                                      |
|        |             | -                                                                             | <ul> <li>Add</li> <li>1 Scheduled</li> </ul>                 | Select Template<br>Plan Details<br>Schedule Plan | Please select Template from the list Level All - Classification Al | t that you want to schedule for Study: "Diagnova" Sites |                                       | Q, Search Y Filters                                  |
|        | i<br>∰<br>♀ | Milestones<br>Countries<br>Sites                                              | Counce<br>Counce<br>Scheduled O<br>24 Sep 2021<br>admin admi | Schedule Han                                     | 3 Available Templates 1 Sele                                       | ceed                                                    | ✓ Schedule plan                       | ✓ 0 Countries Applied Country 1<br>Country Acousties |
|        |             | Subjects<br>Organizations<br>Contacts<br>Team<br>Activities<br>Activity Plans |                                                              |                                                  | Country<br>Active<br>Not Applied                                   | SSU for Peds Country                                    | Activities  Schedule plan  Activities |                                                      |
|        |             |                                                                               |                                                              |                                                  | Site<br>Active<br>Not Applied                                      | SSU for Peds Site                                       | ✓ Schedule plan<br>1<br>ActiVities    |                                                      |
|        |             |                                                                               |                                                              |                                                  |                                                                    | _                                                       |                                       |                                                      |
| =      |             |                                                                               |                                                              |                                                  |                                                                    | Cancel                                                  |                                       |                                                      |
| *<br>6 |             |                                                                               |                                                              |                                                  |                                                                    |                                                         |                                       |                                                      |

- Now click on the Next button in the bottom on the window.
   a. This opens the "Schedule Plan" tab on the window.
- 8. Select at least one level of status by clicking on the dropdown.
  - a. Select one value from the dropdown.
- 9. Click on **Schedule** button on the bottom of the window.

## TI CTMS USER GUIDE v1.2

| ш | #            | ∑ Study<br>Diagnova ▼ Activity Pla   | ans Schedul                                | ed Plans              |                                                                                   | Search Q. 🗛 🗸         |
|---|--------------|--------------------------------------|--------------------------------------------|-----------------------|-----------------------------------------------------------------------------------|-----------------------|
|   | *            |                                      | Activity                                   |                       |                                                                                   |                       |
|   |              | Diagnova                             | Plans In U                                 | Schedule Activity Pla | n for Study: "Diagnova" Countries Step 3 • • • • • • • • • • •                    | Q Search TRiters      |
|   | i            | Study Details                        | 1 Scheduled                                |                       | Please select at least one level status<br>Country Status                         | Sert By Unknown v     |
|   | 89<br>9<br>0 | Dashboard<br>Milestones<br>Countries | Coun<br>Coun<br>Scheduled O<br>24 Sep 2021 |                       | Study Status The Activity Plan will be applied to the Study: "Diagnova" Countries | ✓ 0 Countries Applied |
|   | •••          | Sites<br>Subjects<br>Organizations   |                                            |                       | when the selected statuses are reached for each level selected                    | Consect Accides       |
|   | · 출<br>      | Contacts<br>Team<br>Activities       |                                            |                       |                                                                                   |                       |
|   |              | Activity Plans                       |                                            |                       |                                                                                   |                       |
|   |              |                                      |                                            |                       |                                                                                   |                       |
|   |              |                                      |                                            |                       |                                                                                   |                       |
| = |              |                                      |                                            |                       | Cancel Previous Schedule                                                          |                       |
| * |              |                                      |                                            |                       |                                                                                   |                       |
| C |              |                                      |                                            |                       |                                                                                   |                       |

- 10. If you want to cancel the scheduled plans which was scheduled.
- 11. Navigate to scheduled plans window and click on the scheduled activity plan you want to cancel.
- 12. Click on the **Cancel Schedule** button in the top-left of the screen.

|   | *      | La Study<br>Diagnova ▼ Activity Plans    | Scheduled Plans                                     | Search            | • 🗠                   |
|---|--------|------------------------------------------|-----------------------------------------------------|-------------------|-----------------------|
|   | «      |                                          | Activity Plans                                      |                   |                       |
|   |        |                                          | Plans In Use Scheduled Plans Templates              |                   |                       |
|   |        | Diagnova                                 | O Add ∥ Edit. 🚫 Cancel Schedule                     | Q Search          | <b>T</b> Filters      |
|   |        |                                          | 1 Scheduled Plans 1 Selected                        | Sort By Unknown ~ |                       |
|   |        | Study Details<br>Dashboard<br>Milestones | Country SSU for Peds Country                        | ✔ 0 Co            | untries Applied       |
|   | 0      | Countries                                | Schwisied On<br>24 Sep 2022, US00 PM<br>admin admin | Q 😭               | untry 1<br>Activities |
|   | i<br>i | Sites<br>Subjects                        |                                                     |                   |                       |
|   |        | Organizations                            |                                                     |                   |                       |
|   | 삼      | Contacts<br>Team                         |                                                     |                   |                       |
|   | , e    | Activities                               |                                                     |                   |                       |
|   |        | Activity Plans                           |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |
| ٠ |        |                                          |                                                     |                   |                       |
| T |        |                                          |                                                     |                   |                       |
|   |        |                                          |                                                     |                   |                       |

### 10.13 Tracking Activities Outside of Activity plans

- 1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
  - a. This open the "Studies" window and studies list is displayed.
- 2. Click on the name of the study for which you need to check the activities.
  - a. This opens the dashboard for the study.
- 3. Click on the **Activities** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Activities" screen.
- 4. Click on the **Add** button in the top-left of the screen.
  - a. This opens the Create Activity window.
- 5. Here we need to fill the mandatory metadata to create an activity i.e., **Activity Name, Type, Sub Type, Description** as indicated by an asterisk (\*) symbol next to the field title.
- 6. Initially Sub Type is greyed out, once you select a value for the Type from the dropdown menu the related values for the sub type will appear in the dropdown menu.
- 7. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create an activity successfully.
- 8. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another activity right away.

|   | *      | Activities                   |                                                |               |                         |                            |       |              |                 | Search                        | ۹ 💊                             |
|---|--------|------------------------------|------------------------------------------------|---------------|-------------------------|----------------------------|-------|--------------|-----------------|-------------------------------|---------------------------------|
|   | ×      |                              | Activities                                     |               |                         |                            |       |              |                 |                               |                                 |
|   |        |                              | All Open Unplanned I                           | ast Due Close | d                       |                            |       |              |                 |                               |                                 |
|   |        | Diagnova                     | 🖸 Add 🧪 Edit 🏦 Delete                          |               |                         |                            |       |              |                 | Q, Sear                       | ch <b>Y</b> Filters             |
|   |        |                              | 1 Activities 1 Selected                        |               |                         |                            |       | Planned Date | Associated Plan | Site Meeting                  | 1                               |
|   |        | Study Details<br>Dashboard   | Activity Name Status     Site Meeting     Open | Type<br>Crea  | Subtype<br>ate Activity | Description                | Owner |              | Associated Plan | General Information           | •                               |
|   | 0      | Milestones<br>Countries      |                                                | Activ         | ity Name*               |                            |       |              |                 | Activity Name<br>Site Meeting |                                 |
|   | i<br>i | Sites<br>Subjects            |                                                | Туре          |                         | Subtype                    |       |              |                 | Туре                          | Subtype<br>Investigator Meeting |
|   |        | Organizations                |                                                |               |                         | <ul> <li>Survpe</li> </ul> |       | ~            |                 | Description                   | investigator meeting            |
|   | +      | Contacts<br>Team             |                                                | Desc          | ription*                |                            |       | _            |                 | Site investigator meetin      | ng                              |
|   |        | Activities<br>Activity Plans |                                                |               |                         |                            |       |              |                 |                               |                                 |
|   |        |                              |                                                |               |                         |                            |       |              |                 | Associated Plan               |                                 |
|   |        |                              |                                                |               |                         |                            |       |              |                 | Applied Date                  | Applied By                      |
|   |        |                              |                                                |               | Cancel                  | eate and Add Another       | eate  |              |                 |                               |                                 |
|   |        |                              |                                                |               |                         |                            | _     | _            |                 | Activity Management           | •                               |
|   |        |                              |                                                |               |                         |                            |       |              |                 | Status Status Open 🚯 30 A     |                                 |
|   |        |                              |                                                |               |                         |                            |       |              |                 | Status Notes                  |                                 |
|   |        |                              |                                                |               |                         |                            |       |              |                 |                               |                                 |
| ۰ |        |                              |                                                |               |                         |                            |       |              |                 |                               |                                 |
| C |        |                              |                                                |               |                         |                            |       |              |                 | Owner*                        | C Status History                |

- 9. To edit any activity, select the activity name and click on the **Edit** button in the top-left of the screen.
- 10. This opens the quick-view window on the right side of the screen, make necessary changes in the activity.
- 11. Click on the **Save** button in the bottom right of the screen.



|   | *       | La Study<br>Diagnova ▼ Activities |                             |            |                      |                    |               |              |                 | Search Q 🗛 🗸                                      |
|---|---------|-----------------------------------|-----------------------------|------------|----------------------|--------------------|---------------|--------------|-----------------|---------------------------------------------------|
|   | *       |                                   | Activities                  |            |                      |                    |               |              |                 |                                                   |
|   |         |                                   | All Open Unplanned Past Due | Closed     |                      |                    |               |              |                 | Q Search T Filters                                |
|   |         | Diagnova                          | 1 Activities 1 Selected     |            |                      |                    |               |              |                 | Site Meeting                                      |
|   |         |                                   | Activity Name Status        | Type Su    | ubtype D             | escription         | Owner         | Planned Date | Associated Plan |                                                   |
|   | i<br>B  | Study Details<br>Dashboard        | ☑ 🛱 Site Meeting Com        | Meeting In | vestigator Meeting S | ite investigator m | 🐣 Admin Admin |              |                 | General Information                               |
|   | 9<br>03 | Milestones                        |                             |            |                      |                    |               |              |                 | Activity Name*                                    |
|   | ¢       | Countries<br>Sites                |                             |            |                      |                    |               |              |                 | Site Meeting Type* Subtype*                       |
|   | ま       | Subjects<br>Organizations         |                             |            |                      |                    |               |              |                 | Meeting V Investigator Meetin V                   |
|   | 쇖       | Contacts                          |                             |            |                      |                    |               |              |                 | Description*                                      |
|   | +       | Team<br>Activities                |                             |            |                      |                    |               |              |                 | Site investigator meeting                         |
|   |         | Activity Plans                    |                             |            |                      |                    |               |              |                 |                                                   |
|   |         |                                   |                             |            |                      |                    |               |              |                 | Associated Plan*                                  |
|   |         |                                   |                             |            |                      |                    |               |              |                 | Applied Date Applied By                           |
|   |         |                                   |                             |            |                      |                    |               |              |                 |                                                   |
|   |         |                                   |                             |            |                      |                    |               |              |                 | Activity Management                               |
|   |         |                                   |                             |            |                      |                    |               |              |                 | Status Status Date Open 30 Aug 2021 Change Status |
|   |         |                                   |                             |            |                      |                    |               |              |                 | Status Notes                                      |
|   |         |                                   |                             |            |                      |                    |               |              |                 |                                                   |
| ٠ |         |                                   |                             |            |                      |                    |               |              |                 |                                                   |
| T |         |                                   |                             |            |                      |                    |               |              |                 | Cancel Save Save & Next >                         |

### 10.14 Tracking Actions Taken Toward Activity Completion

Some activities associated with studies or sites, especially records of deviations associated with site visits, may require correction or additional steps associated with their eventual completion. Users may enter these actions in the right-side menu. See the screenshot below:

| Ac                | Activities |                            |            |                    |                |       |      |              |                               |          |                                                                   |
|-------------------|------------|----------------------------|------------|--------------------|----------------|-------|------|--------------|-------------------------------|----------|-------------------------------------------------------------------|
| <u>All</u><br>• A | Open       | Unplanned<br>Edit 📋 Delete | Past Du    |                    | osed           |       |      |              |                               |          | Q Search Y Filters                                                |
| 4 Act             | Activi     | ielected<br>Status         | Туре       | Subty              | Descr          | Owner | Resp | Planned Date | Assoc                         | Unbli    | Study Investigator Meeting                                        |
|                   | ₩          | OPEN<br>OPEN               | Sub<br>App | Initial<br>Initial | Initi<br>Initi | ▲ A   |      |              | 🗳 S                           | No<br>No | Actions Taken                                                     |
|                   | ₩          | IN PROGRESS                | Mee<br>Doc | Inve<br>Prot       | Inve<br>Initi  | ≗ A   |      |              | <ul><li>S</li><li>S</li></ul> | No<br>No | Add Action                                                        |
|                   |            |                            |            |                    |                |       |      |              |                               |          | Invitations sent  26 May 2022  Meeting scheduled for 12 June 2022 |

# 11 Milestones

T R I A L INTERACTIVE

#### **11.1 Pre-Requisites**

Any users who are responsible for creating and managing **Milestones** must have been granted appropriate access rights by the Company Administrator.

#### 11.2 Creating Domain Library Milestone Template

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Milestone Templates" window.
- 3. Click the **Create** button in the top-left of the screen.
  - a. This opens the "Create Milestone Template" window.
- Here we need to enter the mandatory metadata to create a milestone template i.e., Level, Template Name as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information as necessary.
- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button displaying the fields which need to be filled to create a milestone template successfully.

|        | *           | Milestone Templates                                                  |                                                | Search Q 🗛 🗸                               |
|--------|-------------|----------------------------------------------------------------------|------------------------------------------------|--------------------------------------------|
|        | ×           |                                                                      | Milestone Templates                            | Q Search Thters                            |
|        |             | $\bigcirc$                                                           | Create Milestone Template                      | Sort By Unknown -                          |
|        | 676         | TrialInteractive                                                     | General Information General Information        | 🛱 Site                                     |
|        |             |                                                                      | Template Rame* Casofication Select Description | 🖶 Site                                     |
|        | ▲<br>問<br>ਿ |                                                                      |                                                | Country Updated 23 Sep 2021 admin admin    |
|        |             | Activities Library<br>Activity Plan Templates<br>Milestone Templates |                                                | Lipdated 23 Sep 2021 admin admin           |
|        |             |                                                                      |                                                | Lipdated 10 Sep 2021 admin admin           |
|        |             |                                                                      |                                                | Diplated 01 Sep 2021 admin admin           |
|        |             |                                                                      | Cancal                                         | <u></u> Study                              |
| -      |             |                                                                      | Manual                                         | Updated 31 Aug 2021 admin admin            |
| *<br>6 |             |                                                                      | Amendment<br>P test                            | 👗 Study<br>Updated 10 Sep 2021 admin admin |

6. The **Create Milestone Template** window will close, and milestone template will be displayed.

### 11.3 Creating a Study Milestone from a Template

- 1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Studies" window, and study list is displayed.
- 2. Click on the name of the study for which you want to create a milestone.
  - a. This opens the study.

T R I A L INTERACTIVE

- 3. Click on the **Study Details** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Study Details" window.
- 4. Click on the **Settings** button in the top-right of the screen.

|   |                 | tudy Details                          | Search Q 🗛 🗸            |
|---|-----------------|---------------------------------------|-------------------------|
|   | ×<br>ح          | Diagnova<br>II A+ Drugs               | Parent                  |
|   |                 | ✔ Edit                                | D Edit History          |
|   | Diagnova        |                                       | • Settings              |
|   |                 | General Information                   | •                       |
|   | 1 Study Details | Protocol Number Name                  | Program                 |
|   | 🚯 Dashboard     | 00123 Diagnova                        |                         |
|   | Ø Milestones    | Sponsor                               | Products 1 Product      |
|   | Countries       | A+ Drugs                              | Diagnova PRIMARY        |
|   | Sites Subjects  | Virtual Study 🕕 🚯                     |                         |
|   | Organizations   |                                       |                         |
|   | Contacts        |                                       |                         |
|   | 🛉 Team          | Protocol Information                  | •                       |
|   | Activity Plans  | Protocol Title                        | Phase                   |
|   |                 | Diagnova 321                          | I                       |
|   |                 |                                       | Types 0 Types           |
|   |                 |                                       |                         |
|   |                 | Protocol Summary                      |                         |
|   |                 |                                       |                         |
|   |                 |                                       | Mechanisms 0 Mechanisms |
|   |                 |                                       |                         |
|   |                 |                                       |                         |
|   |                 | Therapeutic Areas 0 Therapeutic Areas | Objectives 0 Objectives |
|   |                 |                                       | Ubjectives U Ubjectives |
|   |                 |                                       |                         |
| ٠ |                 | Indications 0 Indications             |                         |
|   |                 |                                       | Designs 1 Designs       |
| T |                 |                                       | Case-Control            |
| 0 |                 |                                       |                         |

- Click on the Milestone Templates link in the Navigation menu at the left side of the screen.
   a. This opens the "Milestone Template" window.
- Click on the Add button in the top-left of the screen.
- 7. Click on Add from Sponsor in the drop-down menu.
  - a. This opens the "Add Milestone Template from Sponsor" window. A list of all the available milestone templates is displayed, select one if you have the milestone template you are looking for.



|   | ☆ Study<br>Diagnova ▼                                   | Study Settings Milestone Templates                                         | Search Q 🗛 🗸      |
|---|---------------------------------------------------------|----------------------------------------------------------------------------|-------------------|
|   | • •                                                     | Milestone Templates                                                        |                   |
|   |                                                         | 🔕 Add 🗸 🖉 Start Tracking 🖉 Edit 👔 Delete 🐵 Set to Resired 🔶 Publish 🗠 Copy | Q Search Tilters  |
|   | Diagnova                                                | Ab Add From Sponsor     Create New                                         | Sort By Unknown > |
|   | -                                                       | No records available                                                       |                   |
|   | 🔅 General                                               |                                                                            |                   |
|   | Regions           Regions           Milestone Templates |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
|   |                                                         |                                                                            |                   |
| • |                                                         |                                                                            |                   |
| T |                                                         |                                                                            |                   |
| 0 |                                                         |                                                                            |                   |

#### 8. Click on the Add button in the Add Milestone Template from Sponsor window.

|   | # | Care Study<br>Diagnova - Study Study St | ettings | Milestone Templates               |        |                                          |        |                | Search   | Q   | <b>AA</b> ) ~    |
|---|---|-----------------------------------------|---------|-----------------------------------|--------|------------------------------------------|--------|----------------|----------|-----|------------------|
|   | * | Add Milestone Templ                     | ate Fr  | om Sponsor                        |        |                                          |        |                |          | • × |                  |
|   | L | ₩ Selected Milestones 0                 |         |                                   |        |                                          |        |                | Q Search |     | <b>Y</b> Filters |
|   |   | Sponsor Milestones                      | Level A | II ~ Classification All ~         |        |                                          |        |                |          |     |                  |
|   |   |                                         | 5 Miles | tones Templates                   |        |                                          |        |                |          |     |                  |
|   |   |                                         | _       | Milestone                         | Level  | Description                              | Туре   | Classification |          |     |                  |
|   | 4 |                                         |         | First Subject Enrolled            | Study  | This milestone will be achieved when the |        |                |          |     |                  |
|   | 1 |                                         |         | Initial Ethics Approval (IRB/IEC) | Site   |                                          | Manual | Regulatory     |          |     |                  |
|   | - |                                         |         | PSSV                              | Site   |                                          | Manual |                |          | - 1 |                  |
|   |   |                                         |         | SIV                               | Site   |                                          | Manual |                |          |     |                  |
|   |   |                                         |         | 0.07                              | 200    |                                          | manuar |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
| • |   |                                         |         |                                   | Cancel | Add                                      |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
| E |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |
|   |   |                                         |         |                                   |        |                                          |        |                |          |     |                  |



#### **11.4 Editing Domain Milestone Templates**

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Milestone Templates" window.
- 3. Click on the milestone template you want to edit.
- 4. Click on the Edit button in the top-left of the screen.a. This opens the "Edit Milestone Template" window.
- 5. Make any necessary changes.
- 6. Click the **Save** button.
- 7. The Milestone Template is **Updated** and displayed in the list

Note: You can edit only milestone templates with Draft status.

|   | *      | Milestone Templates                                              |                     |                                                                      |                        |              | Search Q. 🗛 🗸                    |
|---|--------|------------------------------------------------------------------|---------------------|----------------------------------------------------------------------|------------------------|--------------|----------------------------------|
|   | *      | $\sim$                                                           | Milestone Templa    | attes<br>Delete @ Set to Restrict                                    |                        |              | Q Search Titlers                 |
|   |        | $\bigcirc$                                                       | Edit Milestone      |                                                                      |                        | Step 1 🔹 🗖 🗙 | Sort By Unknown 🗸 🇮 📰            |
|   |        | TrialInteractive                                                 | General Information | General Information                                                  |                        |              | 🛱 Site                           |
|   | 20<br> | Dashboard<br>Sponsors                                            |                     | Level*                                                               |                        |              | Updated 23 Sep 2021 admin admin  |
|   | 2      | Programs Products                                                |                     | Template Name <sup>4</sup> (Third - Copy (Milestone UAT) Description | Ossification<br>Select |              | 🛱 Site                           |
|   |        | Studies<br>Organizations<br>Contacts                             |                     |                                                                      |                        | ]            | Country                          |
|   | Ċ      | User Management<br>Activities Library<br>Activity Plan Templates |                     |                                                                      |                        |              | Updated 23 Sep 2021 admin admin  |
|   | 9      | Milestone Templates                                              |                     |                                                                      |                        |              | Updated 23 Sep 2021 admin admin  |
|   |        |                                                                  |                     |                                                                      |                        |              | Lipdated 10 Sep 2021 admin admin |
|   |        |                                                                  |                     |                                                                      |                        |              | t .                              |
|   |        |                                                                  |                     | _                                                                    |                        |              | Updated 01 Sep 2021 admin admin  |
|   |        |                                                                  | Manual              | Cancel                                                               | Save                   |              | <u></u> ∆ Study                  |
| - |        |                                                                  | _                   |                                                                      |                        |              | Updated 31 Aug 2021 admin admin  |
| ٠ |        |                                                                  |                     | nendment<br>test                                                     |                        |              | 👗 Study                          |
| C |        |                                                                  | Menuel              |                                                                      |                        |              | Updated 10 Sep 2021 admin admin  |

#### **11.5 Deleting Domain Milestone Templates**

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Milestone Templates" window.
- 3. Click on the milestone template which needs to be deleted.
  - a. Please note that the template needs to be in Draft status to be deleted.



- 4. Click on the **Delete** button in the top-left of the screen.
  - a. This opens the "Confirmation" window.
- 5. Click on the **Delete** button in the confirmation page.
- 6. The Milestone Template will be **Deleted** from the list.

|        | *   | Milestone Templates                                                |                     |                                    |                                                |                           | Search Q                                      |
|--------|-----|--------------------------------------------------------------------|---------------------|------------------------------------|------------------------------------------------|---------------------------|-----------------------------------------------|
|        | ۲   | E                                                                  | Milestone Ter       | Delete @ Set to Retired            | ◆ Publish () Copy                              |                           | Q Search Y Filters                            |
|        | 63  | TrialInteractive                                                   | Manual              | <b>የ</b> Third - Copy (Mileston    | ne UAT)                                        |                           | 🛱 Site<br>Updated 23 Sep 2021 admin admin     |
|        |     | Programs<br>Products                                               | Published           | ♀ Third                            |                                                |                           | <br>🛱 Site<br>Updated 23 Sep 2021 admin admin |
|        | === | Organizations<br>Contacts<br>User Management<br>Activities Library | Rational Manual     | 9 Second                           | Confirmation<br>Do you want to delete the sele | ected Milestone Template? | Country Updaced 23 Sep 2021 admin admin       |
|        |     | Activity Plan Templates<br>Milestone Templates                     | Published<br>Manual | 9 First                            | Cancel                                         | Delete                    | ↓ Study<br>Updated 23 Sep 2021 admin admin    |
|        |     |                                                                    | Dive                | Amendment<br>9 test - Copy         |                                                |                           | Updated 10 Sep 2021 admin admin               |
|        |     |                                                                    | Published<br>Menuel | Regulatory  Initial Ethics Approva | al (IRB/IEC)                                   |                           | Dupdated 01 Sep 2021 admin admin              |
| -      |     |                                                                    | Robinhed            | Close-out<br>9 Anuj Milestone      |                                                |                           | A Study                                       |
| *<br>G |     |                                                                    | Refered             | Amendment<br>9 test                |                                                |                           | A Study                                       |

#### **11.6 Publishing Milestone Templates**

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Milestone Templates" window.
- 3. Select the **Draft** template you want to publish.
- 4. Click on the **Publish** button in the top-left of the screen.
  - a. This opens the "Please Review Milestone Template" window.
- 5. Click on the **Publish Milestone Template** button in the **Please Review Milestone Template** window.
- 6. Milestone Template is **Published** and displayed in published status on the list.

Note: Milestone Templates are not available for selection by the user community until Published.

# TI CTMS USER GUIDE v1.2

|        |                                             | Milestone Templates                                                |                                                                     |                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Search Q. 😣 🗸                                                                           |
|--------|---------------------------------------------|--------------------------------------------------------------------|---------------------------------------------------------------------|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
|        | ×                                           | Trialinteractive                                                   | Milestone Temp<br>Crese PEdit<br>15 Milestones 1 Selected<br>Manual |                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Q Search ▼ Filters<br>Sert By Unknown ~ ■ ■<br>© Ste<br>Updated 23 Sep 2021 admin admin |
|        | 10 M                                        | Dashboard<br>Sponsors<br>Programs<br>Products<br>Studies           | Published<br>Manual                                                 | 9 Third                              | Please Review Milestone Template  Very State Sta | 武 Soc<br>Updated 23 Sep 2021 admin admin                                                |
|        | ·<br>·<br>································· | Organizations<br>Contacts<br>User Management<br>Activities Library | Published                                                           | ♥ Second                             | available for selection and use.<br>Level: SITE<br>Template Name: Third - Capy (Mitestone UAT)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Q Country<br>Updated 23 Sep 2021 admin admin                                            |
|        |                                             | Activity Plan Templates<br>Milestone Templates                     | Published<br>Manual                                                 | ♥ First                              | Description<br>Classification<br>Type Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ▲ Study<br>Updated 23 Sep 2021 admin admin                                              |
|        |                                             |                                                                    | Manual                                                              | Amendment<br>• test - Copy           | Cancel Publich Milestone Templace                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Lypdared 10 Sep 2021 admin admin                                                        |
|        |                                             |                                                                    | Manual                                                              | Regulatory     Initial Ethics App    | roval (IRB/IEC)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 🖄 Sce<br>Updated 01 Sep 2021 admin admin                                                |
| •      |                                             |                                                                    | Manual                                                              | Close-out<br><b>9</b> Anuj Milestone |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Lpdeted 31 Aug 2021 admin admin                                                         |
| *<br>6 |                                             |                                                                    |                                                                     | Amendment<br>9 test                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Lipoteted 10 Sep 2021 admin admin                                                       |

#### **11.7 Retiring Milestone Templates**

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Milestone Templates" window.
- 3. Navigate to the milestone template you want to retire and click on it.
- 4. Click on the **Set to Retired** button in the top-left of the screen.
  - a. This opens the "Set to Retired" window.
- 5. Click on the **Set to Retired** button in the "Set to Retired" window.
- 6. Milestone Template is Retired and displayed in the list

Note: Only Published templates can be Retired.

# TI CTMS USER GUIDE v1.2

|        | Hilestone Templates                                          |                                                                                                                                                                    | Search Q 🗛 🗸                                                                              |
|--------|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
|        | <ul> <li>Trailnteractive</li> </ul>                          | Milestone Templates C Create C C Create C C Create C C Create C C C C C C C C C C C C C C C C C C C | C, Search T Filters<br>Sear By Urishown V E E<br>C Sea<br>Updated 23 Sep 2021 admin admin |
|        | Deshboard     Sponsors     Programs     Products     Studies | P Third         Do you want to set the following Milestone Template to Revine3?           Manual         Level         SITE                                        | Updated 23 Sep 2021 admin admin                                                           |
|        |                                                              | Result         Second         Description           Manual         Classification         Type           First         First         Type                          | Q Country<br>Updated 23 Sep 2021 admin admin                                              |
|        | V Milestone Templates                                        | Manual Prist Resch<br>Resch<br>Wanual 9 test - Copy                                                                                                                | Updated 23 Sep 2021 admin admin                                                           |
|        |                                                              | Marual Regulatory Cancel Set to Resred                                                                                                                             | Updated 10 Sep 2021 admin admin<br>Sto<br>Updated 01 Sep 2021 admin admin                 |
| =      |                                                              | Close-out<br>Merual P Anuj Milestone                                                                                                                               | ▲ Study<br>Updated <b>31 Aug 2021 admin admin</b>                                         |
| *<br>E |                                                              | Marrush Researchment 9 test                                                                                                                                        | Lipdated 10 Sep 2021 admin admin                                                          |

#### **11.8 Copying Milestone Templates**

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
  - a. This opens the "Milestone Templates" window.
- 3. Navigate to the milestone template you want to copy and click on it.
- 4. Click on the **Copy** button in the top-left of the screen.
  - a. This opens the "Copy Milestone Template" window.
- 5. Click on the Copy button in the Copy Milestone Template window.
- 6. Milestone Template is Copied, and the copy is displayed in the list

# TI CTMS USER GUIDE v1.2

|   | *                                        | Milestone Templates                                                                                                                                                                                                  |                            |                                                                                                |                               |              | Search Q AA -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------------------------------------------------------------------------------------|-------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | ×                                        | TrialInteractive                                                                                                                                                                                                     | Copy Milestone Te          | te 🖉 Set to Retired 🔷 Publish 🚺 Copy                                                           |                               | Step 1 • 🗖 🗙 | Q Search Y Fitters<br>Sort By Unknown v II III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|   | 12 11 11 11 11 11 11 11 11 11 11 11 11 1 | Deshboard<br>Sponson<br>Programs<br>Studies<br>Studies<br>Organizations<br>Contacts<br>User Management<br>Activities Liberry<br>Activities Liberry<br>Activities Liberry<br>Activities Liberry<br>Activities Liberry | General Information        | General Information Level* Site Template Name* Third - Copy (Milestone UAT) - Copy Description | Countries Catefloation Select |              | Control de la control de l |
| • |                                          |                                                                                                                                                                                                                      | Manual<br>Manual<br>Manual |                                                                                                | Cay                           | _            | Updated 01 Sep 2021 admin admin<br>Study<br>Updated 31 Aug 2021 admin admin<br>Study<br>Updated 10 Sep 2021 admin admin                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

#### 11.9 Associating Milestone Templates to a Sponsor

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Sponsors** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Sponsors" window and list of sponsors is displayed.
- 3. Click on the sponsor to which you wish to associate a template.
  - a. This opens the "Sponsor Details" window.
- 4. Click on the **Settings** button in the top-right of the screen.
  - a. This opens the "Sponsors Setting Milestone Template" screen.



|   |               | Sponsor<br>Dermeron - Sponsor                 | r Details                               | Search Q AA -          |
|---|---------------|-----------------------------------------------|-----------------------------------------|------------------------|
|   | ĸ             |                                               | Dermeron                                | دینه<br>D Edic History |
|   |               | Dermeron                                      |                                         | • Settings             |
|   |               | Sponsor Details<br>Programs                   | Organization Information                | •                      |
|   | <u>≙</u><br>≧ | Products<br>Studies<br>Sites<br>Organizations | Name<br>Dermeron<br>Parent Organization |                        |
|   |               | Contacts                                      | Type Subtype Notes<br>Sportsor          |                        |
|   |               |                                               |                                         |                        |
|   |               |                                               | Contact Information                     | -                      |
|   |               |                                               | Primary Contact                         |                        |
|   |               |                                               | View All Contacts                       |                        |
| * |               |                                               | Addresses                               |                        |
| C |               |                                               | No records available                    |                        |

- 5. Click on the **Add** button on the top-left of the screen.
- 6. Click on **Add from Domain** in the dropdown menu.

| ш |   | Sponsor<br>Dermeron • Sponso | r Settings Milestone Te       | mplates                                                                                        | Search Q. A                                                | • |
|---|---|------------------------------|-------------------------------|------------------------------------------------------------------------------------------------|------------------------------------------------------------|---|
|   | ٠ |                              | Milestone Ter                 |                                                                                                |                                                            |   |
|   |   |                              | Add      Add      Create New  | 📋 Delete 🛛 Set to Retired 🔷 Publish 🕅 Copy                                                     | Q loanth T Filter<br>Sert By Unknown V = III               |   |
|   |   | Dermeron                     | Published                     | Start-up                                                                                       | ∑ Study                                                    | 2 |
|   | Ŷ | Milestone Templates          | Manual                        | Final Protocol                                                                                 | Updated 16 Sep 2021 admin admin                            |   |
|   |   |                              | Published                     | Regulatory  V Initial Ethics Approval (IRB/IEC)                                                | हैं। Size                                                  |   |
|   |   |                              | Manual                        |                                                                                                | Updated 01 Sep 2021 admin admin                            |   |
|   |   |                              | Published<br>Domain<br>Manual | First Subject Enrolled<br>This milestone will be achieved when the first subject for the study | ⊥ Stady<br>Updated <b>91 Sep 2021 ad</b> min <b>ad</b> min |   |
|   |   |                              |                               |                                                                                                |                                                            |   |
|   |   |                              |                               |                                                                                                |                                                            |   |
|   |   |                              |                               |                                                                                                |                                                            |   |
|   |   |                              |                               |                                                                                                |                                                            |   |
|   |   |                              |                               |                                                                                                |                                                            |   |
|   |   |                              |                               |                                                                                                |                                                            |   |
| ٠ |   |                              |                               |                                                                                                |                                                            |   |
| T |   |                              |                               |                                                                                                |                                                            |   |

# TI CTMS USER GUIDE v1.2

| 🔍 Add Milestone Tem      | plate From Domain                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |                                          |                                      | - ×          |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------------------------------------|--------------------------------------|--------------|
| `≡ Selected Milestones 0 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |                                          |                                      | T            |
| Domain Milestones        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |                                          |                                      | Q search     |
| Domain Milescones        | Level All ~ Classification All ~                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         |                                          |                                      | -            |
|                          | 6 Milestones Templates                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |                                          |                                      | <u>∆</u> Stu |
|                          | Milestone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Level   | Description                              | Type Classificat                     | ion          |
|                          | First Subject Enrolled                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Study   | This milestone will be achieved when the | Manual                               | in adm       |
|                          | Anuj Milestone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Study   |                                          | Manual Close-out<br>Manual Regulator |              |
|                          | First                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Study   |                                          | Manual Regulator                     | ,            |
|                          | Second                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Country |                                          | Manual                               | in adm       |
|                          | Third                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Site    |                                          | Manual                               | 👗 Stu        |
|                          | in the second seco | 5100    |                                          | reign rulen                          |              |
|                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |                                          |                                      |              |
|                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |                                          |                                      |              |

- 7. This opens the Add Milestone Template from Domain window.
- 8. Select one of the milestone templates from the list and click on the Add button.
- 9. The Milestone Template is added to the list.

#### 11.10 Defining Sponsor-Specific Milestone Templates

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Sponsors** link in the Navigation menu in the panel at the left side of the screen.
- a. This opens the "Sponsors" window, and the sponsors list is displayed.
- 3. Click on the sponsor that you want to associate with a milestone template.
  - a. This opens the "Sponsor Details" window.
- 4. Click on the **Settings** button in the top-right of the screen.
  - a. This opens the "Sponsors Setting Milestone Template" screen.
- 5. Click on the **Add** button on the top-left of the screen.
- 6. Click on the Create New button from the dropdown.

|   | Sponsor     Dermeron • | or Settings Milestone Templates                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Search Q. 🗛 🗸                   |
|---|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
|   | «                      | Milestone Templates                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                 |
|   |                        | O 445 - J Edit   Copy  A 404 From Domain  Copy  Copy Copy | Q Search Y Filters              |
|   | Dermeron               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
|   | Milestone Templates    | Manual Startup                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                 |
|   |                        | Extended     Regulatory     Doman     P Initial Ethics Approval (IRB/IEC)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 🗊 Site                          |
|   |                        | Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Updated 01 Sep 2021 admin admin |
|   |                        | P First Subject Enrolled     This milestone will be achieved when the first subject for the study                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                 |
|   |                        | Marual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Updated 01 Sep 2021 admin admin |
|   |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
|   |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
|   |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
|   |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
|   |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
|   |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
| * |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |
| T |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |

- 7. This opens the Create Milestone Template window.
- 8. Here we need to fill the mandatory metadata to create milestone template i.e., **Level, Template Name** as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information as necessary.
- 9. If any of the required fields are missing, an error will appear when we click on the **Create** button displaying the fields which need to be filled to create a milestone template successfully.
- 10. Click on the **Create** button in the **Create Milestone Template** window.



|   | Sponsor     Dermeron      Sponsor S | Settings V Milestone Templates                            |              | Search Q 🗛 🗸                    |
|---|-------------------------------------|-----------------------------------------------------------|--------------|---------------------------------|
|   | •                                   | Milestone Templates                                       |              |                                 |
|   |                                     | 🗘 Add 🗸 🥒 Edit 🍵 Delete 🖉 Set to Retired 🔷 Publish 🗈 Copy |              | Q Search Tilters                |
|   | Dermeron                            | 2 Create Milestone Template                               | Step 1 🔹 🗖 🗙 | Sort By Unknown ~               |
|   |                                     | General Information General Information                   |              | <u>∆</u> Study                  |
|   | Milestone Templates                 | Level*                                                    |              | Updated 16 Sep 2021 admin admin |
|   |                                     | Template Name* Gassification                              | _            | 🛱 Site                          |
|   |                                     | Description                                               |              | Updated 01 Sep 2021 admin admin |
|   |                                     |                                                           |              |                                 |
|   |                                     |                                                           |              | 👗 Study                         |
|   |                                     |                                                           |              | Updated 01 Sep 2021 admin admin |
|   |                                     |                                                           |              |                                 |
|   |                                     |                                                           |              |                                 |
|   |                                     |                                                           |              |                                 |
|   |                                     |                                                           |              |                                 |
|   |                                     |                                                           |              |                                 |
|   |                                     |                                                           |              |                                 |
|   |                                     | Cancel                                                    |              |                                 |
|   |                                     |                                                           |              |                                 |
| * |                                     |                                                           |              |                                 |
| T |                                     |                                                           |              |                                 |

#### 11.11 Defining Study Milestone Templates (New)

- Click on the **Study** link in the Navigation menu in the panel at the left side of the screen.
   a. This opens the "Studies" screen.
- 2. Click on the name of the study for which you want to define a new template.
  - a. This opens the study dashboard.
- 3. Click on the **Study Details** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Study Details" window.
- 4. Click on the **Settings** button in the top-right of the screen.
  - a. This opens the "Study Settings General" window.



|   | ★ C +++ → A Study<br>Diagnova → A Study           | Study Details                         | Search Q A •                   |
|---|---------------------------------------------------|---------------------------------------|--------------------------------|
|   |                                                   | Diagnova<br>∎ Ar Drugs                | (2003)                         |
|   |                                                   | Edit V Expand All                     | D Edit History                 |
|   | Diagnova                                          |                                       | • Settings                     |
|   |                                                   | General Information                   | •                              |
|   | study Details                                     | Protocol Number Name                  | Program                        |
|   | <ul> <li>Dashboard</li> <li>Milestones</li> </ul> | 00123 Diagnova                        | Products 1 Product             |
|   | Q Countries                                       | Sponsor  A + Drugs                    | Diagnova PRIMARY               |
|   | Sites Subjects                                    | Virtual Study 💽 🖲                     |                                |
|   | Organizations                                     |                                       |                                |
|   | Contacts                                          | Protocol Information                  | 8                              |
|   | Activities                                        |                                       | •                              |
|   | Activity Plans                                    | Protocol Title<br>Diagnova 321        | Phase                          |
|   |                                                   |                                       | Types 0 Types                  |
|   |                                                   |                                       |                                |
|   |                                                   | Protocol Summary                      |                                |
|   |                                                   |                                       | Mechanisms 0 Mechanisms        |
|   |                                                   |                                       |                                |
|   |                                                   | Therapeutic Areas 0 Therapeutic Areas |                                |
|   |                                                   |                                       | Objectives 0 Objectives        |
|   |                                                   |                                       |                                |
| ٠ |                                                   | Indications 0 Indications             |                                |
| ~ |                                                   |                                       | Designs 1 Designs Case-Control |
| T |                                                   |                                       |                                |

- 5. Click on the **Milestone Template** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Milestone Template" window.
- 6. Click on the **Add** button in the top-left of the screen.
- 7. Click on Add from Sponsor from the dropdown.

|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               | •••                                                           |
|---------|--------------------|----------------------------------------------------|-------------------|--------------------------------------|-------------------------------------------------|--------------------------------------------------------|----------------------------------------------------------------------------|---------------------------------------------|--------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
|         |                    |                                                    | ne Templat        |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    | Add Fron                                           | n Sponsor         | 🖉 Edit 🛛 🏌                           | Delete                                          | Ø Set to Retired                                       | Publish                                                                    | 🖺 Сору                                      |                                      |                                                                              |                                                                | Q Search                                                                |                                                               | Y Filters                                                     |
| Dia     | gnova              | • Create Ne                                        | w                 |                                      |                                                 |                                                        |                                                                            |                                             | No records available                 |                                                                              |                                                                | Sort By Unknown ~                                                       |                                                               |                                                               |
| Garant  |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
| Regions |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
|         |                    |                                                    |                   |                                      |                                                 |                                                        |                                                                            |                                             |                                      |                                                                              |                                                                |                                                                         |                                                               |                                                               |
| U       | General<br>Regions | Lagnova<br>General<br>Repose<br>Motorare Terrepose | General<br>Regors | Ar Add From Sponsor     O Create New | Add From Sponsor      Create New  General Regon | Add From Sponsor      Diagnova      General      Regon | de Add From Sponsor      Diagnova      Greate New      General      Regone | Add From Sponsor  Create New  General Regon | Diagnova O Create New General Regons | Add From Sponsor<br>Diagnova<br>Create New<br>No records available<br>Regone | Add From Sponsor      Create New  No records available  Regene | Add From Sponsor      O Create New  No records available  Cerema Regore | Ar Add From Sponsor     O Create New     No records available | Ad Add From Sponsor     O Create New     No records available |



**Note**: Clicking Add from Sponsor will allow for the selection of a milestone template that is already associated to your study sponsor.

- 8. Select an available Milestone Template from the list.
- 9. Click on the Add button in the bottom of the Add Milestone Template from Sponsor window.
- 10. The selected sponsor Milestone Templates are displayed in the list

|   | * | ≪ ••• A Study<br>Diagnova → Study Setti | ings    | Milestone Templates               |       |                                          |        |                | Search   | • 🗠       |
|---|---|-----------------------------------------|---------|-----------------------------------|-------|------------------------------------------|--------|----------------|----------|-----------|
|   |   | Add Milestone Templat                   | e Fr    | om Sponsor                        |       |                                          |        |                |          | ×         |
|   |   | ₩ Selected Milestones 0                 |         |                                   |       |                                          |        |                | Q Search | ▼ Filters |
|   |   | Sponsor Milestones                      | Level A | Classification All V              |       |                                          |        |                |          |           |
|   |   | 5                                       | Miles   | tones Templates                   |       |                                          |        |                |          |           |
|   |   |                                         | _       | Milestone                         | Level | Description                              | Туре   | Classification |          |           |
|   | < |                                         |         | First Subject Enrolled            | Study | This milestone will be achieved when the | Manual |                |          |           |
|   | I |                                         |         | Initial Ethics Approval (IRB/IEC) | Site  |                                          | Manual | Regulatory     |          |           |
|   | 9 |                                         |         | PSSV                              | Site  |                                          | Manual |                |          |           |
|   |   |                                         |         | SIV                               | Site  |                                          | Manual |                |          |           |
|   |   | L                                       |         | COV                               | Site  |                                          | Manual |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
| _ |   |                                         |         |                                   |       |                                          |        |                |          |           |
| = |   |                                         |         |                                   |       |                                          |        |                |          |           |
| ٠ |   |                                         |         |                                   | Cano  | bbA Is                                   |        |                |          |           |
|   |   |                                         |         |                                   |       |                                          |        |                |          |           |
| C |   |                                         |         |                                   |       |                                          |        |                |          |           |

- 11. To create a new Milestone Template, follow these steps.
- 12. Click on the **Add** button in the top-left of the screen.
- 13. Click on the **Create New** button form the dropdown list.

Note: Clicking Create New will allow for the creation of a new study specific milestone template.



|   |                       | Study Settings Milestone Templates                                                                                  | Search Q AA -         |
|---|-----------------------|---------------------------------------------------------------------------------------------------------------------|-----------------------|
|   | <ul> <li>π</li> </ul> | Milestone Templates                                                                                                 |                       |
|   |                       | Add Y     @ Seart Tracking      P Edit     @ Delete     @ Set to Retired     Plublish     Copy     Add From Sponsor | Q, Search Tilters     |
|   | Diagnova              | Create New                                                                                                          | Sort By Unknown 🗸 📰 📰 |
|   |                       | No records available                                                                                                |                       |
|   | General<br>Regions    |                                                                                                                     |                       |
|   | Milestone Templates   |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
| • |                       |                                                                                                                     |                       |
|   |                       |                                                                                                                     |                       |
| T |                       |                                                                                                                     |                       |

- 14. Here we need to fill the mandatory metadata to create a milestone template i.e., **Level**, **Template Name** as indicated by an asterisk (\*) symbol next to the field title. Enter any additional information as necessary.
- 15. If any of the required fields are missing, an error will appear when we click on the **Create** button displaying the fields which need to be filled to create a milestone template successfully.

|   |                                                                 | Study Settings Milestone Templates                                        |              | Search Q 🐼         | - |
|---|-----------------------------------------------------------------|---------------------------------------------------------------------------|--------------|--------------------|---|
|   | <ul> <li>π</li> </ul>                                           | Milestone Templates                                                       |              |                    |   |
|   |                                                                 | 🗘 Add 🛩 😟 Start Tredting 🥒 Edit 🏦 Delete 🐵 Set to Refred 🔶 Publish 🖺 Copy | _            | Q Search T Filters |   |
|   | Diagnova                                                        | Create Milestone Template                                                 | Step 1 🔹 🗖 🗙 | Sort By Unknown ~  | ) |
|   |                                                                 | General Information General Information                                   |              |                    |   |
|   | General                                                         | ×                                                                         |              |                    |   |
|   | <ul> <li>Image: Regions</li> <li>Milestone Templates</li> </ul> | Template Name* Classification Select                                      |              |                    |   |
|   |                                                                 | Detrofption                                                               |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |
|   |                                                                 | Cancel                                                                    |              |                    |   |
| = |                                                                 |                                                                           |              |                    |   |
| ۰ |                                                                 |                                                                           |              |                    |   |
| T |                                                                 |                                                                           |              |                    |   |
|   |                                                                 |                                                                           |              |                    |   |





### 11.12 Tracking Milestones

- 1. Navigate to the Milestones you want to track.
- 2. Click on **Start Tracking** in the top-left of the screen.
  - a. This opens the "Start Tracking" window.
- 3. Click on the Yes, start tracking button in the Start Tracking window.

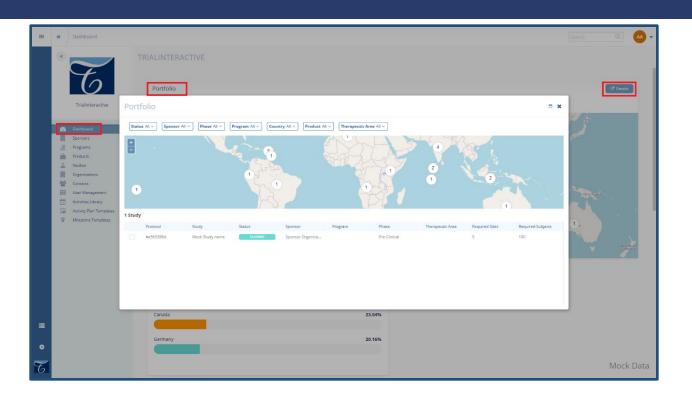
**Note:** The milestone will not be displayed for tracking at any level until Start Tracking is clicked for the desired milestone.

| ш | * | ≤ ···· Diagnova ▼   | Study Settings Milest | ane Templates                                                                               | Search Q.                       |
|---|---|---------------------|-----------------------|---------------------------------------------------------------------------------------------|---------------------------------|
|   | ۲ |                     | Milestone Te          |                                                                                             |                                 |
|   |   |                     | 🔘 Add 🗠 🛛 🛛 Start     | Trading 📝 Lide 📋 Delete. 🐵 Set to Recred 🕹 Publish. 🛅 Copy                                  | Q Search Tilters                |
|   |   | Diagnova            | 1 Milestones          |                                                                                             | Sort By Unknown -               |
|   |   |                     | Published             | First Subject Enrolled This milestone will be achieved when the first subject for the study | 👗 Study                         |
|   |   | General<br>Regions  | Manual                |                                                                                             | Updated 01 Sep 2021 admin admin |
|   |   | Milestone Templates |                       |                                                                                             |                                 |
|   |   |                     |                       | Start Tracking                                                                              |                                 |
|   |   |                     |                       | Do you want to start tracking milestones for the study?                                     |                                 |
|   |   |                     |                       | bo you main to saint adexing timestories to tan, studyt                                     |                                 |
|   |   |                     |                       | Cancel Yes, start tracking                                                                  |                                 |
|   |   |                     |                       |                                                                                             |                                 |
|   |   |                     |                       |                                                                                             |                                 |
|   |   |                     |                       |                                                                                             |                                 |
|   |   |                     |                       |                                                                                             |                                 |
|   |   |                     |                       |                                                                                             |                                 |
|   |   |                     |                       |                                                                                             |                                 |
| ۰ |   |                     |                       |                                                                                             |                                 |
| T |   |                     |                       |                                                                                             |                                 |

# 12 Dashlets

# 12.1 The Portfolio Dashlet

- 1. Log into the CTMS.
- 2. Click on the **Dashboard** link in the Navigation menu in the panel at the left side of the screen.
- 3. The **Portfolio** dashlet is displayed on the screen.
- 4. Click on the **Details** button in the top-right of the screen to expand the portfolio window.
- 5. We can use the dropdowns available in the portfolio to restrict our select list to view.



### 12.2 The Top Countries Dashlet

- 1. Click on the **Dashboard** link in the Navigation menu in the panel at the left side of the screen.
- 2. This displays 3 **Top Countries** on the screen.
- 3. This list shows the countries with most activities in the system.



|   | # | Dashboard                                     |                                                                           |                                                                                                |          |                    |          |                        |                        | Search             | Q 🗛 🗸           |
|---|---|-----------------------------------------------|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|----------|--------------------|----------|------------------------|------------------------|--------------------|-----------------|
|   |   | Dashodard                                     |                                                                           |                                                                                                |          |                    |          |                        |                        |                    |                 |
|   | × | $\sim$                                        | TRIALINTERACTIVE                                                          |                                                                                                |          |                    |          |                        |                        |                    |                 |
|   |   | $\mathcal{C}$                                 |                                                                           | 10<br>Argenter                                                                                 |          |                    |          |                        |                        |                    | New Xeland C.   |
|   |   | TrialInteractive                              | Top Countries                                                             |                                                                                                |          |                    |          |                        |                        |                    |                 |
|   |   | Dashboard<br>Sponsors                         | USA                                                                       |                                                                                                | 39.92%   |                    |          |                        |                        |                    |                 |
|   | 2 | Programs<br>Products<br>Studies               | Canada                                                                    |                                                                                                | 23.04%   |                    |          |                        |                        |                    |                 |
|   | 병 | Organizations<br>Contacts                     | Germany                                                                   |                                                                                                | 20.16%   |                    |          |                        |                        |                    |                 |
|   |   | Activities Library<br>Activity Plan Templates |                                                                           |                                                                                                |          |                    |          |                        |                        |                    |                 |
|   | 8 | Milestone Templates                           | Studies                                                                   |                                                                                                |          |                    |          |                        |                        |                    | C Details       |
|   |   |                                               | Group by Status ~<br>Status All ~ Sponsor All ~ Phase All ~ Program All ~ |                                                                                                |          |                    |          |                        |                        |                    |                 |
|   |   |                                               |                                                                           | <ul> <li>— 10 Closeout</li> <li>— 10 Postponed</li> </ul>                                      | Protocol | Study Name         | Status   | Sponsor                | Program                | # of Planned Sites | # Planned Subje |
|   |   |                                               |                                                                           | <ul> <li>10 Postponed</li> <li>12 Cancelled</li> <li>13 Protocol Synopsis Available</li> </ul> | #111     | Study 1            | PLANNED  | Sponsor 1              | Program 1              | 1                  | 1               |
|   |   |                                               |                                                                           | 14 Cust<br>15 Archived                                                                         | #222     | Study 2            | ARCHIVED | Sponsor 2              | Program 2              | 2                  | 2               |
|   |   |                                               | 220 Planned                                                               | 18 C-Test<br>25 On Hold<br>29 Wel-Def                                                          | #333     | Study 3            | PLANNED  | Sponsor 3              | Program 3              | 3                  | 3               |
|   |   |                                               | Total Studies                                                             | - 29 WEHDEI                                                                                    | #444     | Study 4            | ARCHIVED | Sponsor 4              | Program 4              | 4                  | 5               |
|   |   |                                               |                                                                           | — 65 Enrolling                                                                                 | #555     | Study 5<br>Study 6 | ARCHIVED | Sponsor 5<br>Sponsor 6 | Program 5<br>Program 6 | 6                  | 6               |
| ٠ |   |                                               |                                                                           | - 104 New-Test                                                                                 | #000     | Study 0            | PLANNED  | Sponsor 7              | Program 7              | 7                  | 7               |
| C |   |                                               |                                                                           | - 104 NEW-1651                                                                                 |          |                    |          |                        |                        |                    | Mock Data       |

#### 12.3 The Studies Dashlet

- 1. Click on the Dashboard link in the Navigation menu at the left side of the screen.
- 2. Scroll down to Studies in the dashboard screen.
- 3. This displays the **Studies** information in grid and in pie chart form.
- 4. We can use the Group by dropdown to select a value for grouping.
- 5. Click on the **Details** button to expand the Studies window.



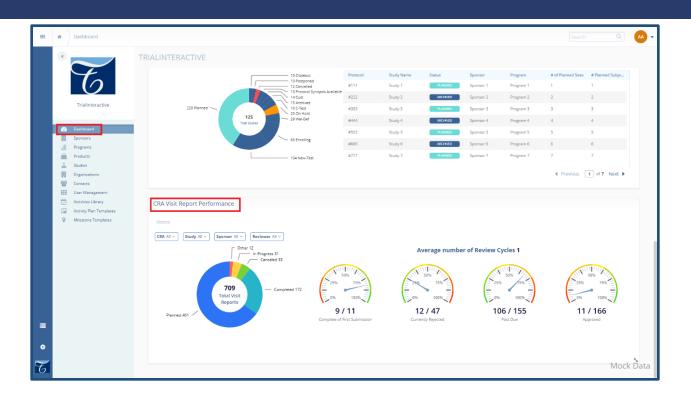
|   | *     | Dashboard                                                |           |                   |                          |                                           |          |            |              |               |           |                    | ۹ (             |
|---|-------|----------------------------------------------------------|-----------|-------------------|--------------------------|-------------------------------------------|----------|------------|--------------|---------------|-----------|--------------------|-----------------|
|   | ĸ     | TrialInteractive                                         | Germany   | RACTIVE           |                          |                                           | 20.16%   |            |              |               |           |                    |                 |
| ١ |       | Deshboard<br>Sponsors<br>Programs<br>Products<br>Studies | Status Al | Status<br>Sponsor | hase All ~ Program All ~ | ]                                         |          |            |              |               |           |                    | C Details       |
|   |       | Organizations                                            |           | Phase<br>Program  |                          | 10 Closeout                               | Protocol | Study Name | Status       | Sponsor       | Program   | # of Planned Sites | # Planned Subje |
|   | 쓥     | Contacts                                                 |           |                   |                          | 10 Postponed<br>12 Cancelled              | #111     | Study 1    | PLANNED      | Sponsor 1     | Program 1 | 1                  | 1               |
|   | <br>₿ | User Management<br>Activities Library                    |           |                   |                          | 13 Protocol Synopsis Available<br>14 Cust | #222     | Study 2    | ARCHIVED     | Sponsor 2     | Program 2 | 2                  | 2               |
|   |       | Activity Plan Templates                                  |           | 220 Planned 🔨     |                          | 15 Archived<br>18 C-Test                  | #333     | Study 3    | PLANNED      | Sponsor 3     | Program 3 | 3                  | 3               |
|   | 0     | Milestone Templates                                      |           |                   | 125<br>Total Studies     | 25 On Hold<br>29 Wel-Def                  | #444     | Study 4    | ARCHIVED     | Sponsor 4     | Program 4 | 4                  | 4               |
|   |       |                                                          |           |                   |                          |                                           | #555     | Study 5    | PLANNED      | Sponsor 5     | Program 5 | 5                  | 5               |
|   |       |                                                          |           |                   |                          | └── 65 Enrolling                          | #655     | Study 6    | ARCHIVED     | Sponsor 6     | Program 6 | 6                  | 6               |
|   |       |                                                          |           |                   |                          | - 104 New-Test                            | #777     | Study 7    | PLANNED      | Sponsor 7     | Program 7 | 7                  | 7               |
|   |       |                                                          |           |                   |                          |                                           |          |            |              |               |           | Previous           | 1 of 7 Next     |
|   |       |                                                          | CRA Visit | Report Performa   | nce                      |                                           |          |            |              |               |           |                    |                 |
|   |       |                                                          | Home      |                   |                          |                                           |          |            |              |               |           |                    |                 |
|   |       |                                                          | CRA All ~ | Study All v Spo   | Cother 12                | )                                         |          | A          | verage numbe | r of Review ( | Cycles 1  |                    |                 |
|   |       |                                                          |           |                   | Canceled 33              |                                           | 11000    | _          | NI DO        |               | 5005      | _                  | Mock Da         |

#### 12.4 The CRA Visit Report Performance Dashlet

- 1. Click on the Dashboard link in the Navigation menu at the left side of the screen.
- 2. Scroll down to CRA Visit Report Performance on the dashboard.
- 3. This displays the data in grid and pie chart format.
- 4. We can use the dropdowns available to filter the search criteria to view.

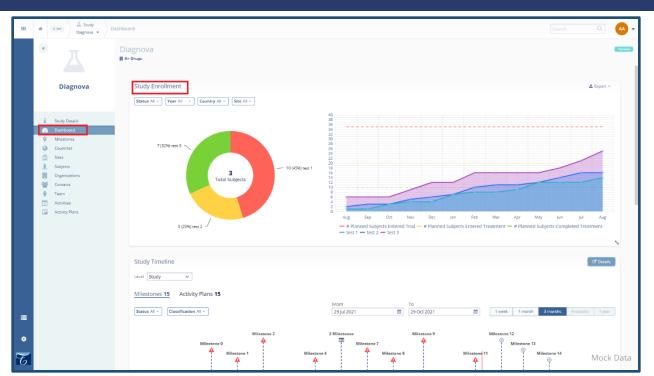


## TI CTMS USER GUIDE v1.2

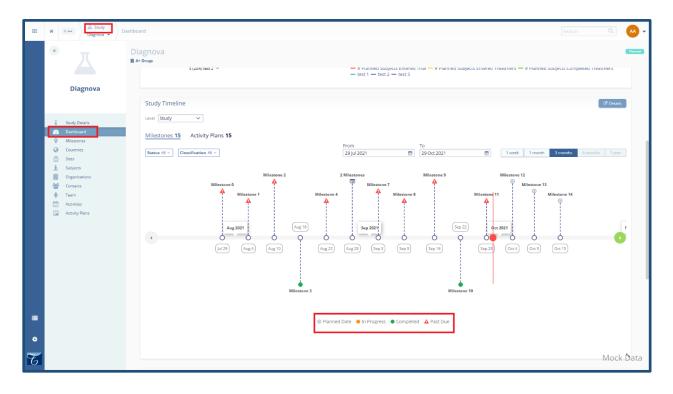


#### 12.5 Reviewing Studies via their Dashboard

- Click on the **Studies** link in the Navigation menu at the left side of the screen.
   a. This opens the "Studies" window.
- 2. Navigate to the study you want to review.
- 3. Study Enrollment, Study Timeline, and Activities dashlets are displayed.
- 4. Navigate to **Study Enrollment** in the dashboard.
  - a. This reflects planned and actual numbers.



- 5. Navigate to the **Study Timeline** in the dashboard.
  - a. This shows a red dot and a line indicating today on the timeline.
- 6. It shows the status of each milestone in the study.





Page 130 of 130

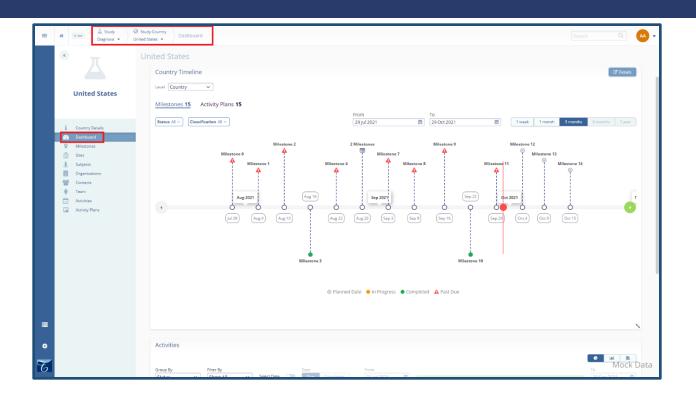
- 7. Navigate to **Activities** on the dashboard.
- 8. This shows data for **Study General Activities**, **Site Total Activities**, **Country Total Activities** in pie chart, that can be changed to a bar graph if preferred.

|   | * | «                                        | Ä Study<br>Diagnova ▼       | Dashboard                                                                                                                                          | Search Q AA -  |
|---|---|------------------------------------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
|   | ĸ |                                          |                             | Diagnova<br>R A prop                                                                                                                               | Power          |
|   |   | Dia                                      | gnova                       | Milestone 3 Milestone 10                                                                                                                           |                |
|   |   | Countrie<br>Sites<br>Subjects<br>Organiz | ard<br>tes<br>tis<br>ations | Planned Date     In Progress     Completed     A Past Due                                                                                          |                |
|   |   |                                          |                             | Group By     Fitter By     Date     From       Status     Show All     Image: Completed     01 jul 2021       Type/Subtype 0 filters     Owner All | To 29 Sep 2021 |
| = |   |                                          |                             | In Progress                                                                                                                                        |                |
| T |   |                                          |                             |                                                                                                                                                    | Mock Data      |

#### 12.6 Reviewing Countries via their Dashboard

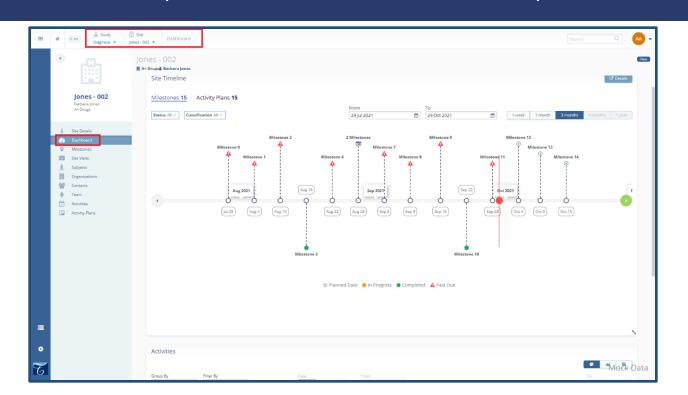
- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Studies" window.
- 2. Click on the name of the study you want to review.
  - a. This opens the dashboard for the study.
- 3. Click on the **Counties** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Countries" screen.
- 4. Click on the name of the country you want to review.a. This opens the dashboard for the country.
- 5. This displays the **Country Timeline** and **Activities** in the dashboard.

Page 131 of 130



#### 12.7 Reviewing Site Dashboard

- Click on the **Studies** link in the Navigation menu at the left side of the screen.
   a. This opens the "Studies" window.
- 2. Click on the name of the study you want to review.
  - a. This opens the dashboard for the study.
- 3. Click on the **Sites** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Sites" screen.
- 4. Click on the name of the site you want to review.
  - a. This opens the dashboard for the site.
- 5. This displays the **Site Timeline** and **Activities** in the dashboard.



#### 12.8 Site Visit Report Review Status Dashlet

The Site Visit Report Review Status dashlet is intended to allow users who are indicated as site visit report reviewers to see the status of any reports generated for their studies. Users can filter their view to identify overdue documents along with a number of other available filters.

Users can navigate directly to the Site Visit in question by clicking on the name of the visit as shown in the grid or they can navigate directly to the report to be reviewed by clicking on the "View Report" link in the grid.



|                                  | eport Review   |               |                                   |                                   |                 |             |            |                    | 🏦 Export |
|----------------------------------|----------------|---------------|-----------------------------------|-----------------------------------|-----------------|-------------|------------|--------------------|----------|
|                                  |                | No Reviev     | ver <b>1</b><br>Report Status All | <ul> <li>✓ Owner All ✓</li> </ul> | Reviewer All ~  | Study All ~ | Site All ~ | Visit End Date All |          |
| <b>Site Visits</b><br>Visit Name | Visit End Date | Report Status | Report Statu                      | Visit Report                      | Report Due      | Owner       | Reviewer   | Study Name         | Site Nam |
| IMV #1                           | 27 May 2022    | SUBMITTED     | 06 Jun 2022                       | <b>%</b> View Report              | <b>0</b> 27 May | CRA 003     |            | DT-001-US          | Sunshine |
|                                  |                |               |                                   |                                   |                 |             |            |                    |          |
|                                  |                |               |                                   |                                   |                 |             |            |                    |          |

# 13 User and Team Management

#### 13.1 Creating Users

- 1. Click on the **User Management** link in the Navigation menu at the left side of the screen.
  - a. This opens the "User Management" screen.
- 2. Click on the Invite button in the top-left of the screen.
  - a. This opens the Invite User window.
- 3. Here we need to enter the required mandatory metadata to create a user i.e., **Email**, **First Name**, **Last Name**, **Global Role** as indicated by an asterisk (\*) symbol next to the field title.
- 4. If any of the required fields are missing, an error will appear when we click on the **Invite** button, displaying the fields which need to be filled to invite a user successfully.
- 5. **(Optional)** Click **Invite** or **Invite and Add Another** or **Invite and go to User Profile** depending on whether you intend to create another user right away.

# TI CTMS USER GUIDE v1.2

|   | H User Management                               |                                |                                           |                                       | Search Q. 🙌 🔻                  |
|---|-------------------------------------------------|--------------------------------|-------------------------------------------|---------------------------------------|--------------------------------|
|   |                                                 | User Management                |                                           |                                       |                                |
|   | $\mathcal{A}$                                   | 🕒 Invite 🥒 Edit 🗘 Deactivate 🖽 |                                           |                                       | Q Search Titers                |
|   |                                                 | 22 Users                       |                                           |                                       | Q                              |
|   | TrialInteractive                                | Name                           | Status                                    | Global Role                           | Email                          |
|   | mainteractive                                   | test ti                        | INVITED                                   |                                       | yogitest@ti.com                |
|   |                                                 | Linda Munn                     | INVITED                                   |                                       | Linda@ti.com                   |
|   | <ul> <li>Dashboard</li> <li>Sponsors</li> </ul> | a yog test                     | Invite Lines                              | <b>-</b> ×                            | yogtest123@ti.com              |
|   | Programs                                        | CRA DEMO                       | Invite User                               | · · · · · · · · · · · · · · · · · · · | crademo@tl.com                 |
|   | Products                                        | A UAT First UAT Last           |                                           |                                       | dofourt@gmail.com              |
|   | Studies                                         | Elain Cusack                   | Fill in information below to create a use | r                                     | elain@email.con                |
|   | Contacts                                        | George Smyth                   | Email*                                    |                                       | smytmichael@gmail.com          |
|   | User Management                                 | Abhijit Kamble                 | First Name*                               | lame*                                 | akamble@transperfect.com       |
|   | Activities Library  Activity Plan Templates     | 📄 🤷 Sufiya Sultana             |                                           |                                       | ssultana@transperfect.com      |
|   | Milestone Templates                             | 💄 Lakshmi Kadiyala             | Global Role*                              |                                       | lkadiyala@transperfect.com     |
|   |                                                 | Ar. Kennon Atkeson             | None                                      | ~                                     | katkeson@transperfect.com      |
|   |                                                 | 🔒 Mr. Owen Omoijuanfo          |                                           |                                       | comoijuanfo@transperfect.com   |
|   |                                                 | Ars. Susan Geers-Meiners       |                                           |                                       | sgeersmeiners@transperfect.com |
|   |                                                 | Ars. Sandesh Visoriya          | Cancel Invite and Add another Invite      | e and go to User Profile              | svisoriya@transperfect.com     |
|   |                                                 | Nancy Drew                     |                                           |                                       | abdul.anwer@gmail.com          |
|   |                                                 | A Hope Weisser                 | ACINE                                     |                                       | howeisser@transperfect.com     |
|   |                                                 | Abdul Anwer                    | ACTIVE                                    |                                       | aanwer@transperfect.com        |
|   |                                                 | 🔒 John Doe                     | ACTIVE, INUCTIVE, INVITED                 |                                       | userT@mail.com                 |
| = |                                                 | 💄 John Doe                     | ACTIVE, INUCTIVE, INVITED                 |                                       | test@mail.com                  |
|   |                                                 |                                |                                           |                                       |                                |
|   |                                                 |                                |                                           |                                       |                                |
| ~ |                                                 |                                |                                           |                                       |                                |
| C |                                                 |                                |                                           |                                       | Previous     1 of 2 Next       |

#### 13.2 Editing a User

- 1. Click on the User Management link in the Navigation menu at the left side of the screen.
  - a. This opens the User Management screen.
- Navigate to the name of the user you want to edit and click the check box before the username.
   a. This opens the quick view on the right side of the screen.
- 3. Click the **Edit** button on the top-left of the screen or click on the **Pencil Icon** in the quick view panel to make changes in the user account.
- 4. Make any necessary changes to the user account.

# TI CTMS USER GUIDE v1.2

| 1 4 | User Management             |                              |                                      |             |                                |                              | ۹ 🗛               |
|-----|-----------------------------|------------------------------|--------------------------------------|-------------|--------------------------------|------------------------------|-------------------|
| 6   |                             | User Management              |                                      |             |                                |                              |                   |
|     | F                           | 🔹 Invite 📝 Edit 🗇 Descrivate | 🖽 Edit Permissions 🛛 🖂 Resend Invite |             |                                | Q, See                       | rch 🕇 🕇           |
|     | ()                          | 21 Users 1 Selected          |                                      |             |                                | test ti                      | Г                 |
|     |                             | Name                         | Status                               | Global Role | Email                          | TT boded                     | -                 |
|     | TrialInteractive            | 🖌 🛓 test ti                  |                                      |             | yogitest@ti.com                | 24 Sep 2021                  |                   |
|     |                             | 🛔 Linda Munn                 | INVITED .                            |             | Linde@ti.com                   | E Emai                       |                   |
| 6   | B Dashboard                 | 🗌 📥 yog test                 | ACTIVE                               |             | yogtest123@ti.com              | General Information          |                   |
|     | III Sponsors                | 👗 CRA DEMO                   | ACTIVE                               |             | crademo@ti.com                 | Prefix First Name            | Middle Name       |
|     |                             | UAT First UAT Last           | ACTIVE                               |             | dofourl@gmail.com              | test                         |                   |
|     | A Studies                   | 🛔 Elain Cusack               | ewitted                              |             | elain@email.con                | Last Name                    | Suffix            |
|     | Organizations               | George Smyth                 | TRATED                               |             | smytmichael@gmail.com          | ti                           |                   |
| l C | Contects<br>User Management | 👗 Abhijit Kamble             | ACTIVE                               |             | akamble@transperfect.com       | Global Role<br>None          |                   |
|     | Activities Library          | 🔄 👗 Sufiya Sultana           | ACTIVE                               |             | ssultana@transperfect.com      |                              |                   |
|     | Activity Plan Templates     | 🔒 Lakshmi Kadiyala           | ACTIVE                               |             | lkadlyala@transperfect.com     | Status<br>Invited            | Type<br>Regular   |
|     | Milestone Templates         | Mr. Kennon Ackeson           | ACTIVE                               |             | katkeson@transperfect.com      | User Since                   | Created By        |
|     |                             | 🛔 Mr. Owen Omoijuanfo        | ACTIVE                               |             | oomoijuanfo@transperfect.com   | 24 Sep 2021                  | admin admin       |
|     |                             | Mrs. Susan Geers-Meiners     | ACTIVE                               |             | sgeersmeiners@transperfect.com | Preferred Languages 0 Langua | age               |
|     |                             | 👗 Mrs. Sandesh Visoriya      | ACTIVE                               |             | svisoriya@transperfect.com     |                              |                   |
|     |                             | Nancy Drew                   | ewmo:                                |             | abdul.anwer@gmail.com          | Preferred Communication Met  | thod              |
|     |                             | A Hope Weisser               | ACTIVE                               |             | howeisser@transperfect.com     |                              |                   |
|     |                             | Abdul Anwer                  | ACTIVE                               |             | aanwer@transperfect.com        | Time Zone                    | Best Contact Time |
|     |                             | 💄 John Doe                   | ACTIVE, INACTIVE, INVITED            |             | userT@mail.com                 |                              |                   |
|     |                             | 🔄 🛔 John Dae                 | ACTIVE INACTIVE INVITED              |             | test@mail.com                  | Contact Information          |                   |
|     |                             | 🛔 John Test                  | ACTIVE, INACTIVE, INVITED            |             | user@mail.com                  | 220 000 00                   |                   |
| i   |                             | 🔲 🛔 admin admin              | ACTNE                                |             | ctms.admin@transperfect.com    | Phone Numbers<br>No recor    | ds available      |
|     |                             |                              |                                      |             |                                | Email                        |                   |
|     |                             |                              |                                      |             |                                | Primary                      |                   |

5. Click on the **Save** button in the bottom right of the screen, for the changes to apply to the user account.

#### 13.3 Editing a User's Permissions

- Click on the User Management link in the Navigation menu at the left side of the screen.
   a. This opens the "User Management" screen.
- 2. Navigate to the user whose permissions should be edited and **click the check box**.
- 3. Click on the Edit Permissions button in the top-left of the screen.
  - a. This opens the "Edit Permissions" window.

**Note**: Study membership role is inherited throughout the study team lists and can be updated on the individual entity level to increase the user's access.

# TI CTMS USER GUIDE v1.2

| 📾 User Management           |                              |                                    |             |                                |                         | earch Q           |
|-----------------------------|------------------------------|------------------------------------|-------------|--------------------------------|-------------------------|-------------------|
| •                           | User Management              |                                    |             |                                |                         |                   |
| F                           | 🗿 Invite 🥒 Edit 🛛 Descrivate | 🖾 Edit Permissions 🛛 Resend Invite |             |                                |                         | Q Search          |
| $\left( \right)$            | 21 Users 1 Selected          |                                    |             |                                | test ti                 |                   |
|                             | Name                         | Status                             | Global Role | Email                          | (π)                     | 3                 |
| TrialInteractive            | 🗹 💄 test ti                  |                                    |             | yogitest@ti.com                | 24 Sep 21               |                   |
|                             | 🛔 Linda Munn                 | (INVITED )                         |             | Linda@ti.com                   |                         | al                |
| Dashboard                   | 🗌 👗 yog test                 | ACTIVE                             |             | yogtest123@ti.com              | General Informatio      | n                 |
| Sponsors Programs           | CRA DEMO                     | ACTINE                             |             | crademo@ti.com                 | Prefix First Name       | e Middle Name     |
| Products                    | 🔄 🚨 UAT First UAT Last       | ACTIVE                             |             | dofourl@gmail.com              | test                    |                   |
| ▲ Studies                   | 🛔 Elain Cusack               | ewitted                            |             | elain@email.con                | Last Name               | Suffix            |
| Organizations               | George Smyth                 | INVITED                            |             | smytmichael@gmail.com          | ti                      |                   |
| Contacts<br>User Management | 📥 Abhijit Kamble             | ACTIVE                             |             | akamble@transperfect.com       | Global Role             |                   |
| Activities Library          | 🔄 🔺 Sufiya Sultana           | ACTIVE                             |             | ssultana@transperfect.com      | None                    |                   |
| Activity Plan Templates     | 💄 Lakshmi Kadiyala           | ACTIVE                             |             | lkadiyala@transperfect.com     | Status<br>Invited       | Type<br>Regular   |
| Milestone Templates         | 🗌 🔺 Mr. Kennon Atkeson       | ACTIVE                             |             | katkeson@transperfect.com      | User Since              | Created By        |
|                             | 🛔 Mr. Owen Omoijuanfo        | ACTIVE                             |             | oomoijuanfo@transperfect.com   | 24 Sep 2021             | admin admin       |
|                             | 🔄 🦀 Mrs. Susan Geers-Meiners | ACTIVE                             |             | sgeersmeiners@transperfect.com | Preferred Languages 0 L | Language          |
|                             | 💄 Mrs. Sandesh Visoriya      | ACTIVE                             |             | svisoriya@transperfect.com     |                         |                   |
|                             | 🔷 💄 Nancy Drew               | Catavia                            |             | abdul.anwer@gmail.com          | Preferred Communication | on Method         |
|                             | A Hope Weisser               | ACTIVE                             |             | howeisser@transperfect.com     |                         |                   |
|                             | Abdul Anwer                  | ACTIVE                             |             | aanwer@transperfect.com        | Time Zone               | Best Contact Time |
|                             | 💄 John Dae                   | ACTIVE, INACTIVE, INVITED          |             | userT@mail.com                 |                         |                   |
|                             | 🔄 👗 John Dae                 | ACTIVE INACTIVE INVITED            |             | test@mail.com                  | Contact Information     | n                 |
|                             | 📃 🛔 John Test                | ACTIVE, INACTIVE, INVITED          |             | user@mail.com                  |                         |                   |
|                             | 🔄 👗 admin admin              | ACTIVE                             |             | ctms.admin@transperfect.com    | Phone Numbers           | records available |
|                             |                              |                                    |             |                                | Email                   |                   |
|                             |                              |                                    |             |                                | Primary                 |                   |

- 4. Navigate through the list of organizations below or use the search box to find the sponsor.
- 5. Expand the selected organization and select the appropriate product or study.
- 6. Assign the user a specific role associated with that product or study.
- 7. Click on the Save button the bottom of the edit permission window.

|                          | User Management Edit Permissions                                                                     | <b>- x</b>                                                        |                                                           |
|--------------------------|------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-----------------------------------------------------------|
| TrialInteractive         | © Invice                                                                                             |                                                                   | Q Search <b>Y</b> Fil                                     |
|                          | Global Role Global Role Internal User (Manager)                                                      |                                                                   | yogitest@tl.com                                           |
| Deshboard     Sponsors   | A Lovels Permissions                                                                                 |                                                                   | Linda@ti.com<br>yogtest123@ti.com                         |
| Programs                 | GRA DEMO     Show All     Show Assigned Permissions                                                  |                                                                   | crademo@sl.com                                            |
| Studies                  | LAT First UAT Last     None     Apply to Selected     Introduction     Introduction     Introduction | Q Search                                                          | dofourl@gmail.com<br>elain@email.con                      |
| Contacts User Management | Levels                                                                                               | Role                                                              | smytmichael@gmail.com                                     |
| Activities Library       | Abhiji: Kamble     Abhiji: Kamble     Afree Annors Study     Asury Sultana                           | None                                                              | akamble@transperfect.com<br>ssultana@transperfect.com     |
| Milestone Templates      | Lakshmi Kadiyala     AMed42021     ATest                                                             | None V                                                            | lkadiyela@transperfect.com                                |
|                          | A Mr. Kennon Askeson     Askeson     A Mr. Owen Omoljuanfo     Diagnoxe                              | None Y                                                            | katkeson@transperfect.com<br>oomoljuanfo@transperfect.com |
|                          | Mrs. Susan Geers-Meine<br>Global Permissions                                                         | Clinical Study<br>Manager test<br>Clinical Study<br>Manager (CSM) | sgeersmeiners@transperfect.com                            |
|                          | A Mrs. Sandesh Visoriya     Permissions     Description                                              | CRA Manager<br>Clinical Research                                  | svisoriya@transperfect.com<br>abdul.anwer@gmail.com       |
|                          | Invite/Manage Users This is permission for Inviting/Managing Users                                   | Contract CRA                                                      | howeisser@transperfect.com                                |
|                          | Abdul Anwer      Abdul Anwer      Abdul Anwer                                                        | Country Manager<br>(CM)<br>Çlinical Tri <u>al</u>                 | aanwer@transperfect.com<br>userT@mail.com                 |
|                          | 🛔 John Doe                                                                                           |                                                                   | test@mail.com                                             |
|                          | A dmin admin                                                                                         |                                                                   | user@mail.com<br>ctms.admin@transperfect.com              |



Version 1.0

**Note**: Turning on **Invite/Manage** Users under Global Permissions will allow for the user to create and invite users to the system.

#### 13.4 Study Team Management

- 1. Navigate to the study name and click on it.
- 2. Click on the **Team** link in the Navigation menu at the left side of the screen.
  - a. This opens the "Team" window.
- 3. Select the username from the list displayed that has the status of **PENDING.**
- 4. Click on the Activate button in the top-left of the screen to activate the user.

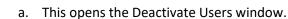
|             | ★ C ···· A Study<br>Diagnova ▼                                                                                                                                                                | Team                                                                       |                                           |                                   |                          | Search Q AA -                   |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|-------------------------------------------|-----------------------------------|--------------------------|---------------------------------|
|             | C Jiagnova                                                                                                                                                                                    | Team<br>♦ Ad  ☐ Edd Permissions ● Accord 1 Users 1 Selected Name  ▲ text 5 | Remove & Set as Owner Status Finitization | Role<br>Circui Souly Manager text | Email<br>yogitest(hikkom | C, Search Y Filters<br>End Date |
|             | <ul> <li>Study Details</li> <li>Dashboard</li> <li>Milestones</li> <li>Countries</li> <li>Stats</li> <li>Subjects</li> <li>Organizations</li> <li>Contacts</li> <li>Activety Plans</li> </ul> |                                                                            |                                           |                                   |                          |                                 |
| =<br>*<br>6 |                                                                                                                                                                                               |                                                                            |                                           |                                   |                          |                                 |

Please note that only study team members listed as Unblinded team members will be able to see unblinded study data where applicable. An Unblinded Clinical Study Manager may assign study team members to Unblinded roles but a Blinded Clinical Study Manager cannot.

#### 13.5 Deactivating a User Account

- 1. Click on the User Management link in the Navigation menu at the left side of the screen.
  - a. This opens the User Management screen.
- 2. Navigate to the user you want to deactivate, click the check box before the username.
- a. This opens the quick view on the right side of the screen.
- 3. Click on the **Deactivate** button in the top-left of the screen.





4. Click on the **Deactivate** button in the **Deactivate user's** window.

Note: The reverse of this action can be done to activate a user.

| * | User Management                                |                                                                                   |                           |             |                           |                |                                |                           | A   |
|---|------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------|-------------|---------------------------|----------------|--------------------------------|---------------------------|-----|
|   |                                                | User Management                                                                   |                           |             |                           |                |                                |                           |     |
|   | $\mathcal{E}$                                  | © Invite   ✓ Edit   ① Deactivate  III Edit Permissions  Eli Resend limite         |                           |             |                           |                |                                | Q Search                  | T B |
|   |                                                | 21 Users 1 Selected                                                               |                           |             |                           |                | yog                            | test                      |     |
|   |                                                | Name                                                                              | Status                    | Global Role | Email                     |                | YT 🚾                           | ch <del>uir</del>         |     |
|   | TrialInteractive                               | 📋 👗 test ti                                                                       | INVITED .                 |             | yogitest@ti.com           |                | 22.5et                         |                           |     |
|   |                                                | 🗌 👗 Linda Munn                                                                    | INATED                    |             | Unda@ti.com               |                |                                | mail                      |     |
|   | b Dashboard                                    | 🖾 🛔 yog test                                                                      |                           |             |                           |                | General Informat               | ion                       |     |
|   |                                                | CRA DEMO                                                                          | _                         | 4           | mo@ti.com                 |                | Prefox First Na                | me Middle Name            |     |
|   |                                                | UAT First UAT Last                                                                | Deactivate Users          |             | n@gmail.com               |                | yog                            |                           |     |
| Z |                                                | Boan Cusack     Do you want to dearthwate the following user(s)?     George Smyth | Demail.con                |             | Last Name                 | Su             | uffix                          |                           |     |
| 茵 |                                                |                                                                                   |                           |             | nichael@gmail.com         |                | test                           |                           |     |
|   | Contacts User Management  C Activities Library | Abhijit Kamble                                                                    | User(s) yog test          |             | ble@transperfect.com      |                | Global Role                    |                           |     |
|   |                                                | 🔄 👗 Sufiya Sultana                                                                |                           |             | ina@transperfect.com      |                | None                           |                           |     |
|   | Activity Plan Templates                        | 👗 Lakshmi Kadiyala                                                                |                           |             | ala@transperfect.com      |                | Active                         | Type<br>Regular           |     |
| 9 | Milestone Templates                            | Mr. Kennon Atkeson                                                                |                           |             | son@transp                | perfect.com    | User Since                     |                           |     |
|   |                                                | 👗 Mr. Owen Omoijuanfo                                                             |                           |             | ijuanfo@tre               | ansperfect.com | 22 Sep 2021                    | Created By<br>admin admin |     |
|   |                                                | Mrs. Susan Geers-Meiners                                                          | Cano                      | Deactivate  | smeiners@transperfect.com |                | Preferred Languages 0 Language |                           |     |
|   |                                                | 👗 Mrs. Sandesh Visoriya                                                           | Cano                      | Descrivate  | lyaßtransp                | erfect.com     |                                |                           |     |
|   |                                                | A Nancy Drew                                                                      | INVITED                   |             | abdul.anwer@gm            | nail.com       | Preferred Communic             | ation Method              |     |
|   |                                                | A Hope Weisser                                                                    | ACTIVE                    |             | howeisser@trans           | sperfect.com   |                                |                           |     |
|   |                                                | Abdul Anwer                                                                       | ACTIVE                    |             | aanwer@transpe            | rfect.com      | Time Zone                      | Best Contact Time         |     |
|   |                                                | 👗 John Dae                                                                        | ACTIVE, INACTIVE, INVITED |             | userT@mail.com            |                |                                |                           |     |
|   |                                                | Lichn Doe                                                                         | ACTIVE INACTIVE INVITED   |             | test@mail.com             |                | Contact Informat               | ion                       |     |
|   |                                                | A John Test                                                                       | ACTIVE INACTIVE INVITED   |             | user@mail.com             |                |                                |                           |     |
|   |                                                | admin admin                                                                       | ACTIVE                    |             | ctms.admin@trar           | nsperfect.com  | Phone Numbers                  |                           |     |
|   |                                                |                                                                                   |                           |             |                           |                |                                | io records available      |     |
|   |                                                |                                                                                   |                           |             |                           |                | Email                          |                           |     |
|   |                                                |                                                                                   |                           |             |                           |                | Primary<br>yogtest123@ti.co    | m                         |     |

#### 13.6 Resending a User's Invite

- 1. Click on the **User Management** link in the Navigation menu at the left side of the screen.
  - a. This opens the **User Management** screen.
- 2. Navigate to the user whose invitation you want to resend and click the check box.
  - a. This opens the quick view on the right side of the screen.
- 3. Click on the **Resend Invite** button in the top-left of the screen.
  - a. This opens the Resend Invite window.
- 4. Click on the **Resend** button in the **Resend Invite** window.

Note: You can only resend an invite to a user with an Invited status.

# TI CTMS USER GUIDE v1.2

| 🖷 User Management        |                                |                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                         |                                | Search          | <u> </u>                                |  |  |
|--------------------------|--------------------------------|-----------------------------------------------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------|-----------------|-----------------------------------------|--|--|
|                          | User Management                |                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                         |                                |                 |                                         |  |  |
| <i>F</i>                 | O Invite 🖌 Edit (D) Descrivate | 🔕 Invite 🥒 Edit 💷 Deschuster 🛄 Edit Permissions 🔯 Resend Invite |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                         |                                |                 | Q Search                                |  |  |
|                          | 21 Users 1 Selected            |                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                         | 10                             | test ti         |                                         |  |  |
|                          | Name                           | Status Global Role                                              |                 | Email                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                         | п                              | bisted          | r i i i i i i i i i i i i i i i i i i i |  |  |
| Trialinteractive         | 🖾 🚔 test ti                    | (INVITED)                                                       |                 | yogitest                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | @tl.com                 |                                | 24 Sep 2021     |                                         |  |  |
|                          | 🛓 Linda Munn                   | (INVITED)                                                       |                 | Linda@t                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 1.com                   |                                | 🛤 Email         |                                         |  |  |
| Deshboard                | yog test                       | ACTIVE                                                          |                 | yogtest1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 123@ti.com              | General                        | nformation      |                                         |  |  |
| Sponsors                 | CRA DEMO                       | _                                                               |                 | and the second se | ogti.com                | Prefix                         | First Name      | Middle Name                             |  |  |
| Programs                 | 🚨 UAT First UAT Last           | Resend Invite                                                   |                 | <b>×</b> -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 8gmail.com              |                                | test            |                                         |  |  |
| Studies                  | Bain Cusack                    | Do you want to resend an invite to the following user(s)?       |                 | Pernail.con                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | mail.con                | Last Name                      |                 | Suffix                                  |  |  |
| Organizations            | Ceorge Smyth                   | User(s) test ti                                                 | nowing user(s): | nichselb@mail.com<br>sle@transperiect.com<br>ma@transperiect.com                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | chael@gmail.com         | ti                             |                 |                                         |  |  |
| Contacts User Menagement | 👗 Abhijit Kamble               | User(s) test ti                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Global Role             |                                |                 |                                         |  |  |
| Activities Library       | 🔄 👗 Sufiya Sultana             |                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | @transperfect.com       | None                           |                 |                                         |  |  |
| Activity Plan Templates  | 👗 Lakshmi Kadiyala             | Cancel                                                          |                 | ala                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | a@transperfect.com      | Status                         |                 | Type<br>Regular                         |  |  |
| Milestone Templates      | 🗌 👗 Mr. Kennon Atkeson         |                                                                 |                 | 50                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | n@transperfect.com      | User Since                     |                 | Created By                              |  |  |
|                          | 👗 Mr. Owen Omoijuanfo          |                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | anfo@transperfect.com   | 24 Sep 2                       | 021             | admin admin                             |  |  |
|                          | Mrs. Susan Geers-Meiners       |                                                                 |                 | sa                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | einers@transperfect.com | Preferred Languages 0 Language |                 | lage                                    |  |  |
|                          | 👗 Mrs. Sandesh Visoriya        |                                                                 |                 | - Ny a                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | a@transperfect.com      |                                |                 |                                         |  |  |
|                          | A Nancy Drew                   | awrite a                                                        |                 | abduLar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | nwen@gmail.com          | Preferred C                    | ommunication Me | thod                                    |  |  |
|                          | Hope Weisser                   | ACTIVE                                                          |                 | howeiss                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | er@transperfect.com     |                                |                 |                                         |  |  |
|                          | 📥 Abdul Anwer                  | ACTIVE                                                          |                 | aanwer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Stransperfect.com       | Time Zone                      |                 | Best Contact Time                       |  |  |
|                          | 📓 John Dae                     | ACTIVE, INACTIVE, INVITED                                       |                 | userT@r                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | mail.com                |                                |                 |                                         |  |  |
|                          | 🔄 🛔 John Doe                   | ACTIVE, INACTIVE, INVITED                                       |                 | test@mi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | ail.com                 | Contact I                      | nformation      |                                         |  |  |
|                          | 🛔 John Test                    | ACTIVE INACTIVE INVITED                                         |                 | user@m                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | ailcom                  |                                |                 |                                         |  |  |
|                          | admin admin                    | ACTIVE                                                          |                 | ctms.ad                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | min⊈sransperfect.com    | Phone N                        |                 | rds available                           |  |  |
|                          |                                |                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                         | Email                          |                 |                                         |  |  |
|                          |                                |                                                                 |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                         | Primary                        |                 | <b>X</b>                                |  |  |

### 13.7 Removing Users from a Team list

- 1. Navigate to Studies screen and click on the name of the study whose team you wish to edit.
- 2. Click on the Team link in the Navigation menu at the left side of the screen.
- 3. Navigate the user you want to remove from a team list and select them.
- 4. Click the **Remove** button in the top-left of the screen.
  - a. This opens the **Delete user from a Team** window.
- 5. Click on the **Remove** button in the bottom of the **Delete user from a Team** window.



# TI CTMS USER GUIDE v1.2

