TRIAL INTERACTIVE

Trial Interactive CTMS v2.0 USER GUIDE v1.0

TRANSPERFECT LIFE SCIENCES

APPROVAL

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VERSION HISTORY

Author	Revision #	Date	Comment
Samuel Pawar Salil Joshi	1.0	26-Jul-2024	Initial version finalized.

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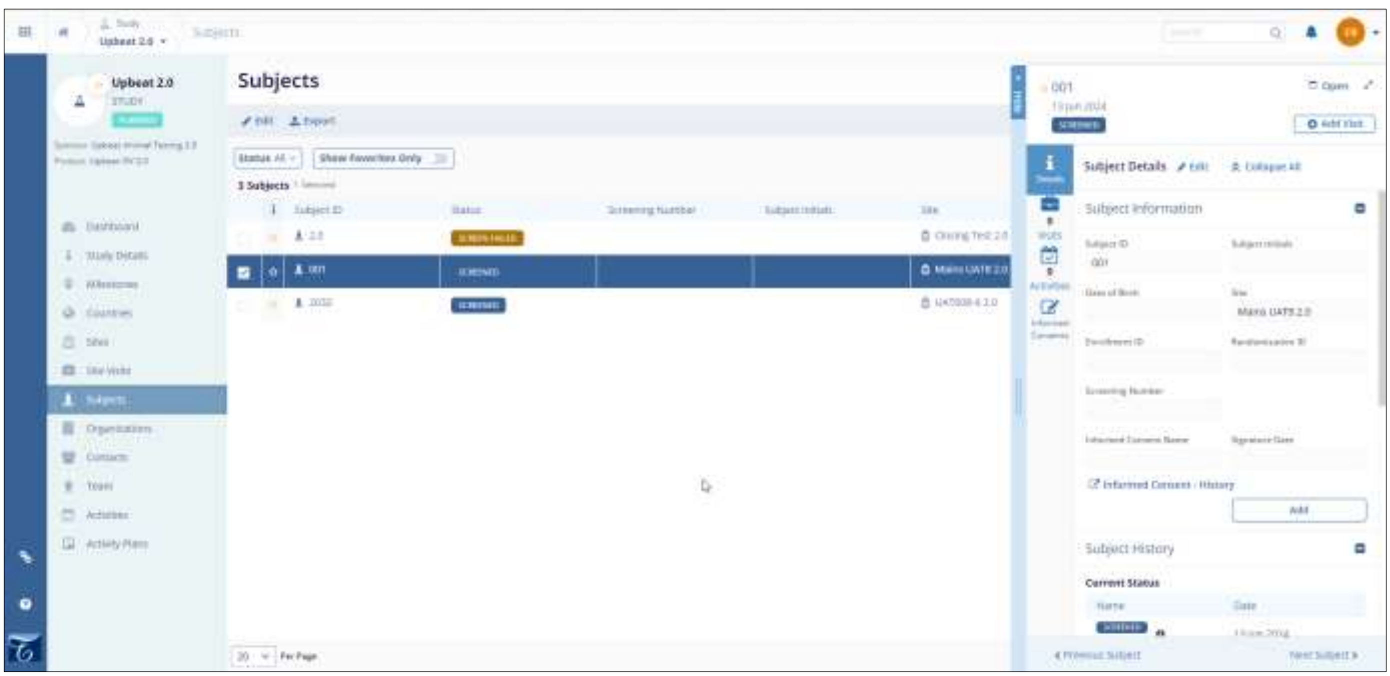
What's New in CTMS v2.0?

Enhanced Subject Tracking

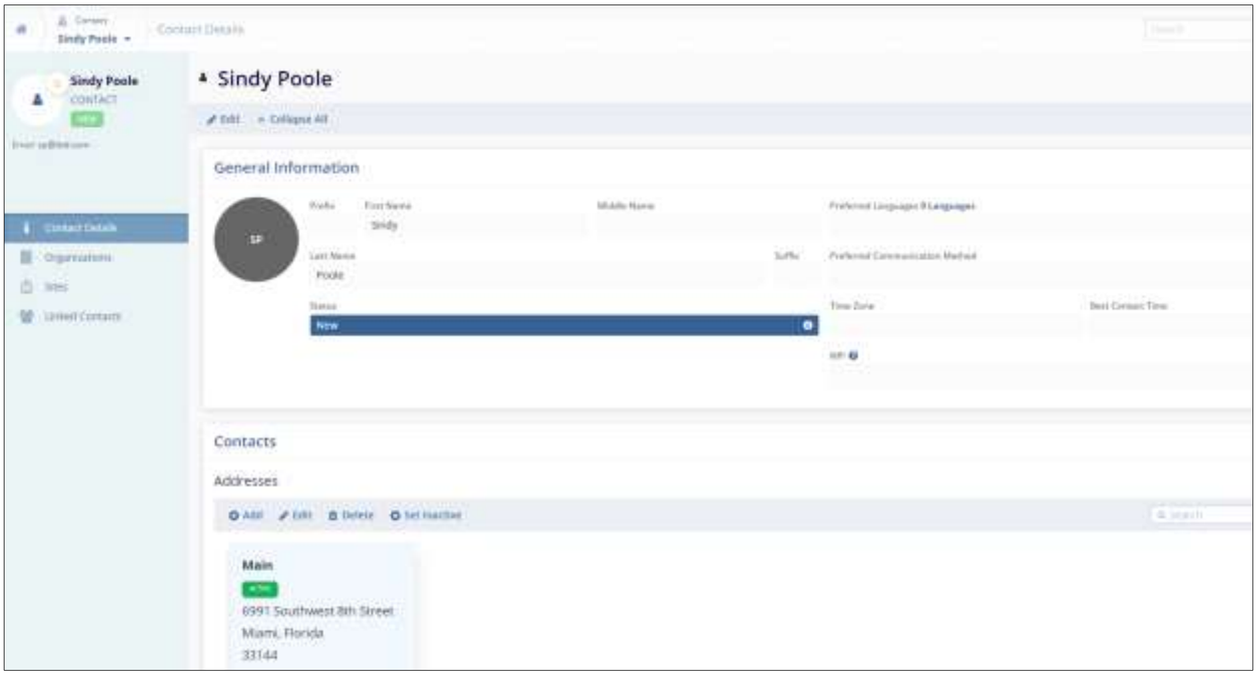
With the release of CTMS 2.0, we are enhancing the subject-tracking functionality to allow for more study-specific tracking capabilities. The aim is to maintain the core subject-tracking features while introducing expanded options for users who require more comprehensive tracking. Key improvements include:

- Study-Specific Subject Visit Schedules (SVS): Users can now define and apply SVS on a study-by-study basis.
- SVS Modification and Reuse: Users can copy existing SVS for modification and reuse, streamlining the setup process.
- Association of Visit Types and Statuses: Users can link specific visit types and statuses to a treatment visit schedule for each study.
- Activity Association and Viewing: Activities can be directly assigned to a subject and easily viewed within the subject's record, reducing the need for excessive navigation.
- Reassignment of Site Subjects: Subjects can be reassigned to different SVSs within the same site, allowing for changes in treatment arms.
- Cross-Site Subject Transfer: The system enables the transfer of subjects between sites within a study, minimising subject loss and improving enrollment retention.



New Financial Reference Data Tracking

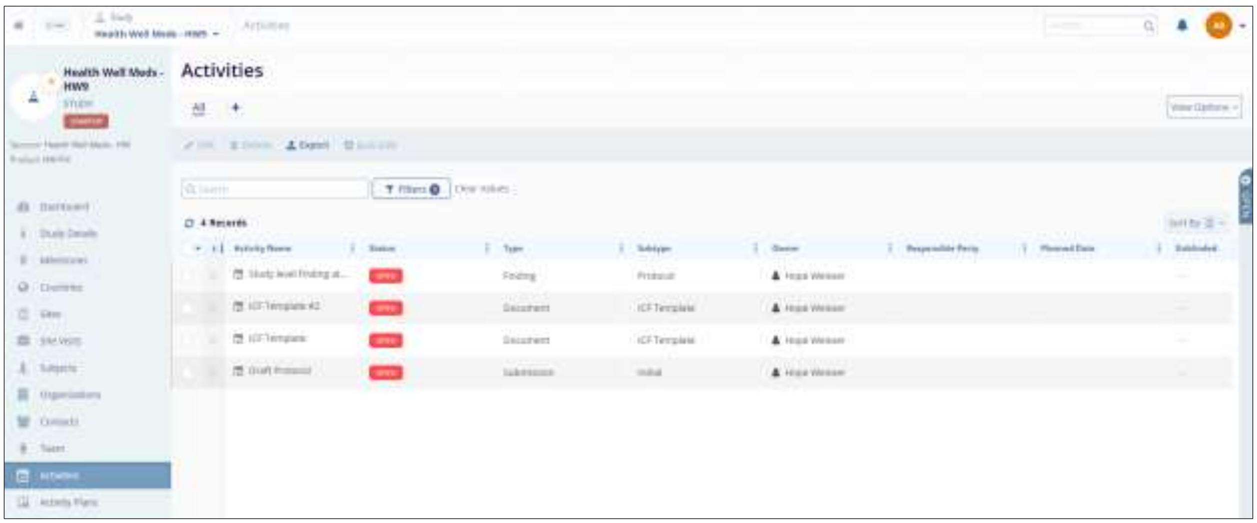
The goal of CTMS 2.0 is to enable the capture of essential financial reference data required for regulatory financial reporting. Regulatory bodies mandate the tracking of key financial information in clinical trials. CTMS 2.0 will allow users to capture and include valuable study-related financial details in their reports. This capability will enable customers to generate more comprehensive reports for regulatory compliance.



New Field Type – URL

The goal of CTMS 2.0 is to provide the ability to associate URLs with any entity type, such as linking documents directly to activity records. This feature allows users with the necessary access to view documents stored in eTMF, collaborative workspaces, other document repositories, or related locations tracked within CTMS.

By providing direct links to documents, study team members can easily access the final results of any actions tracked within TI CTMS. Activity records, which are captured at the Study, Country, and Site levels, can now include document reference links. This enhancement benefits not only CRAs but also study and country managers.



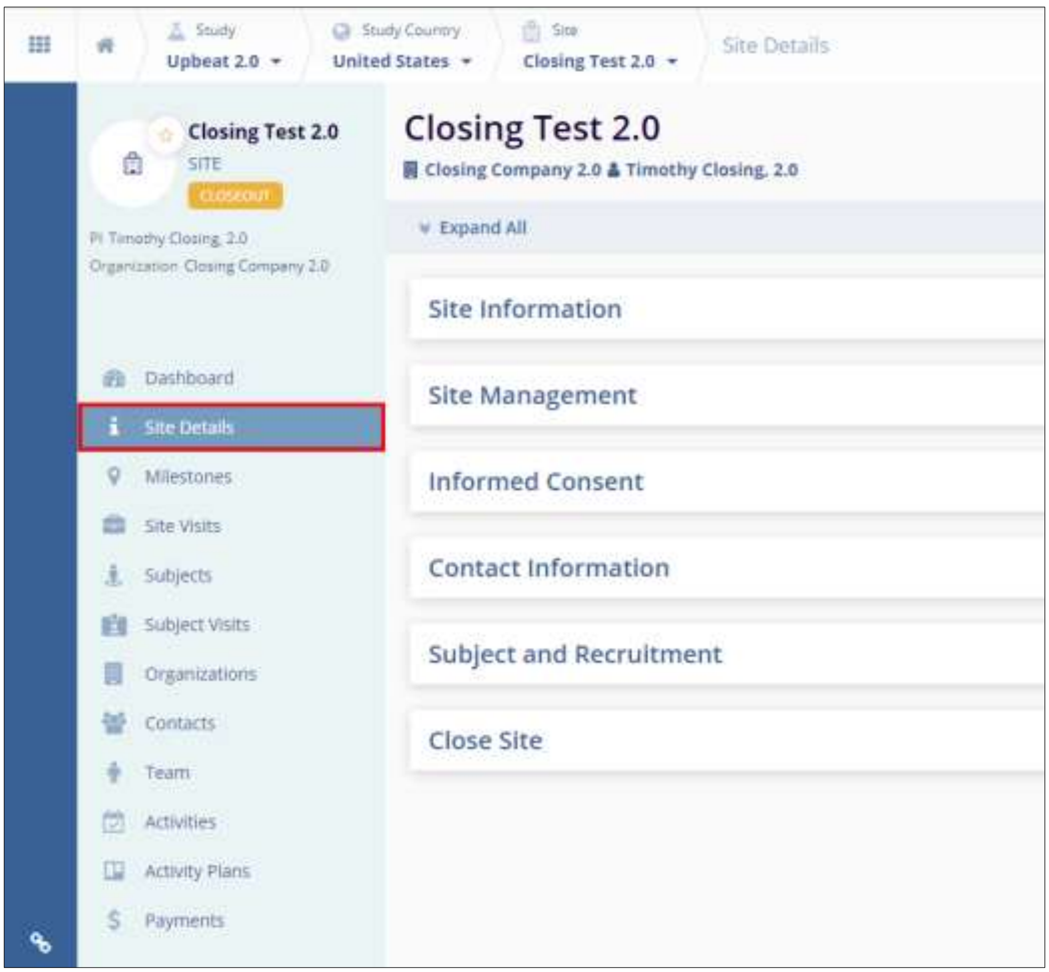
Enhanced Site Detail Tracking

With the enhancement to site details tracking, users will now have the ability to capture additional general contact information for a site.

This improvement includes the ability to capture overall site-related details such as:

- Email address
- Phone number
- Fax number

These details will not be associated with any specific contact but will be linked to the site record as a whole. This can be particularly useful when site contact lists become outdated or when there is a need to contact the general site rather than an individual.



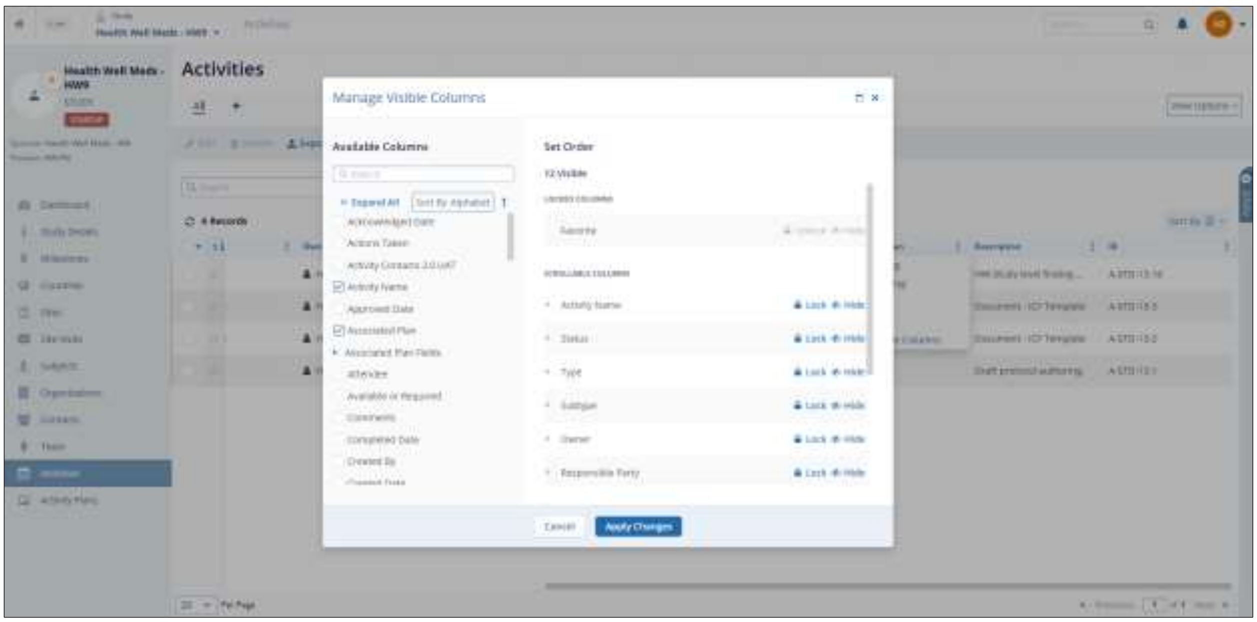
Expanded Custom Save View and Filters

With the 2.0 release, UI functionality will be further enhanced to provide a seamless and personalized user experience. This update improves users' ability to specify the data displayed to them within the UI when working with records.

Users will be able to filter selected data, ensuring that relevant information is always displayed when completing tasks associated with key business processes.

This expanded view functionality will be available in various parts of the system, with the 2.0 release specifically extending it to:

- Global Contacts

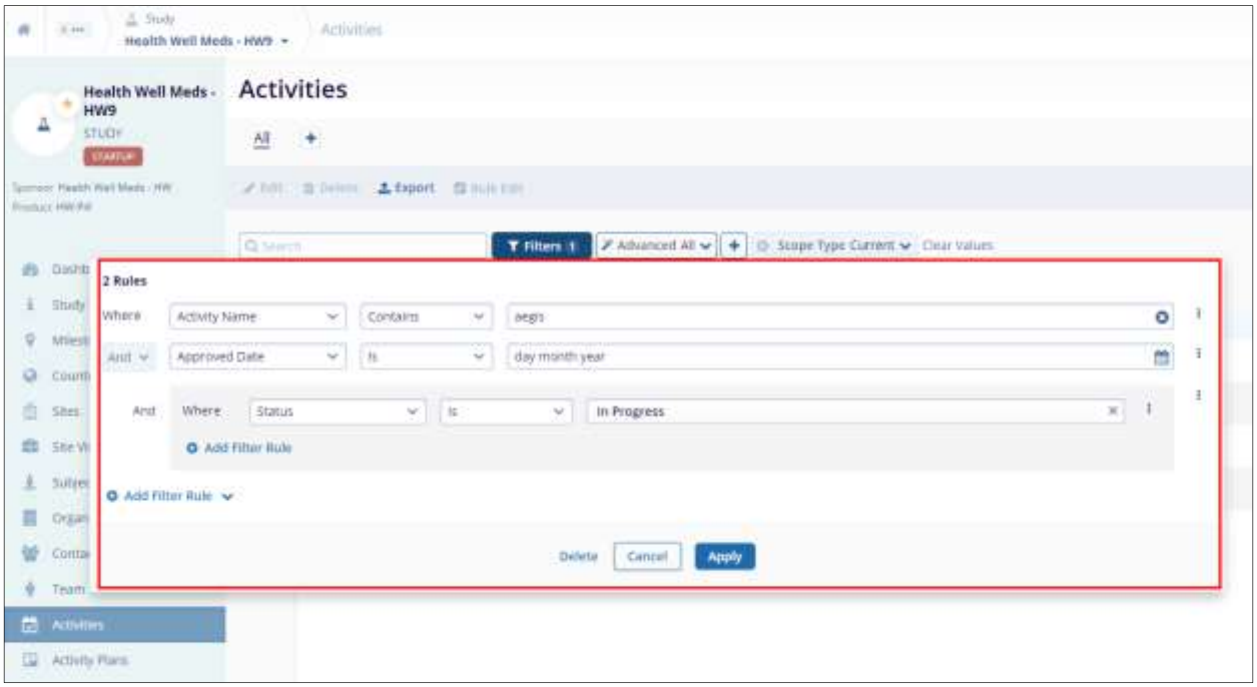


New Advanced Filtering Functionality

With the 2.0 release, CTMS will introduce advanced filtering capabilities, allowing users to define criteria for their filtering results.

This feature addresses the need to compile lists based on multiple variables. For example, users can filter to show all contacts where the status is "Active" and the due date is "yesterday," or where the status is "In Progress" and the due date is "yesterday."

This advanced filtering functionality will be continually expanded throughout the application in future releases of CTMS.

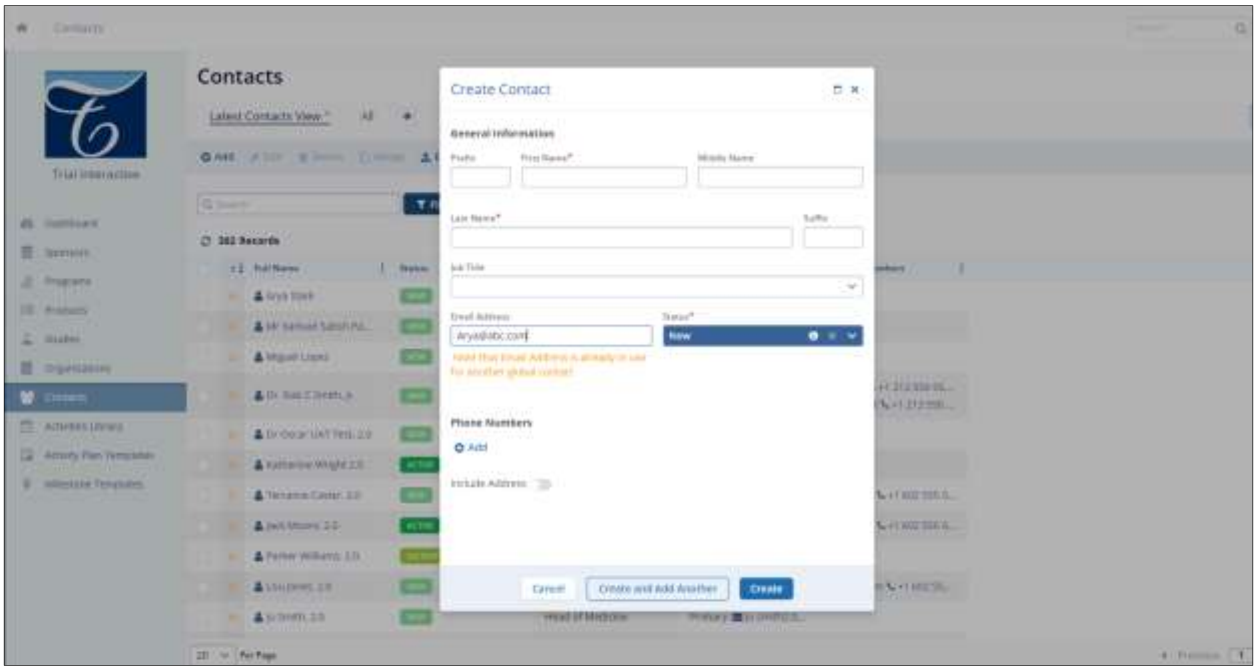


New Deduplication Functionality

TI CTMS currently provides the ability to identify when creating a record that is a potential duplicate, for example when creating a contact record. Even with in-application notifications to the user a user still can create a duplicate record.

With this improvement, the goal is to provide the ability to analyse the data already captured within the CTMS and reconcile records that are considered duplicates based on your organisation's criteria.

Utilizing such functionality will help to ensure the data utilized is always the most up-to-date and accurate data.



Dashboard

The Dashboard screen offers a visual summary of the countries with the most active studies, as well as a world map showing study activity by country. Users can also view a pie chart and table of studies, with customizable visualization options. Additionally, the CRA Visit Report performance allows users to view and analyze CRA visit report data with the ability to apply different filters for visualization.

Accessing Dashboard

To access the Dashboard screen and its associated dashlets follow the steps below

1. From the left-hand navigation links, select the Dashboard link.
2. On this screen, the user can view the following dashlets
    a. Top Countries
    b. Portfolio
    c. Studies
    d. CRA Visit Report

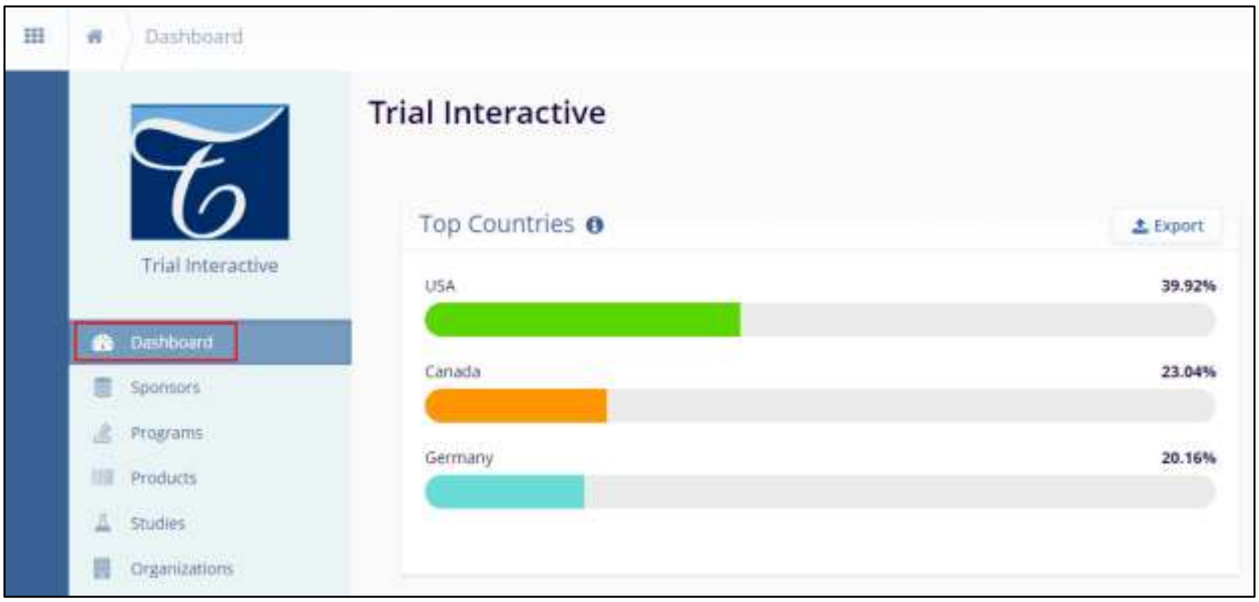


Figure: Accessing Dashboard

This section below describes the dashlets available on the dashboard screen.

Dashlets

Top Countries Dashlet

The Top Countries dashlet displays a horizontal stacked bar chart with the top three countries with the most activities in the system.

A user can perform the following actions on this dashlet.

1. Hover over each bar to reveal the total number of studies associated with that country compared to the overall studies.
2. Click on the Export button to export the chart in different file formats.

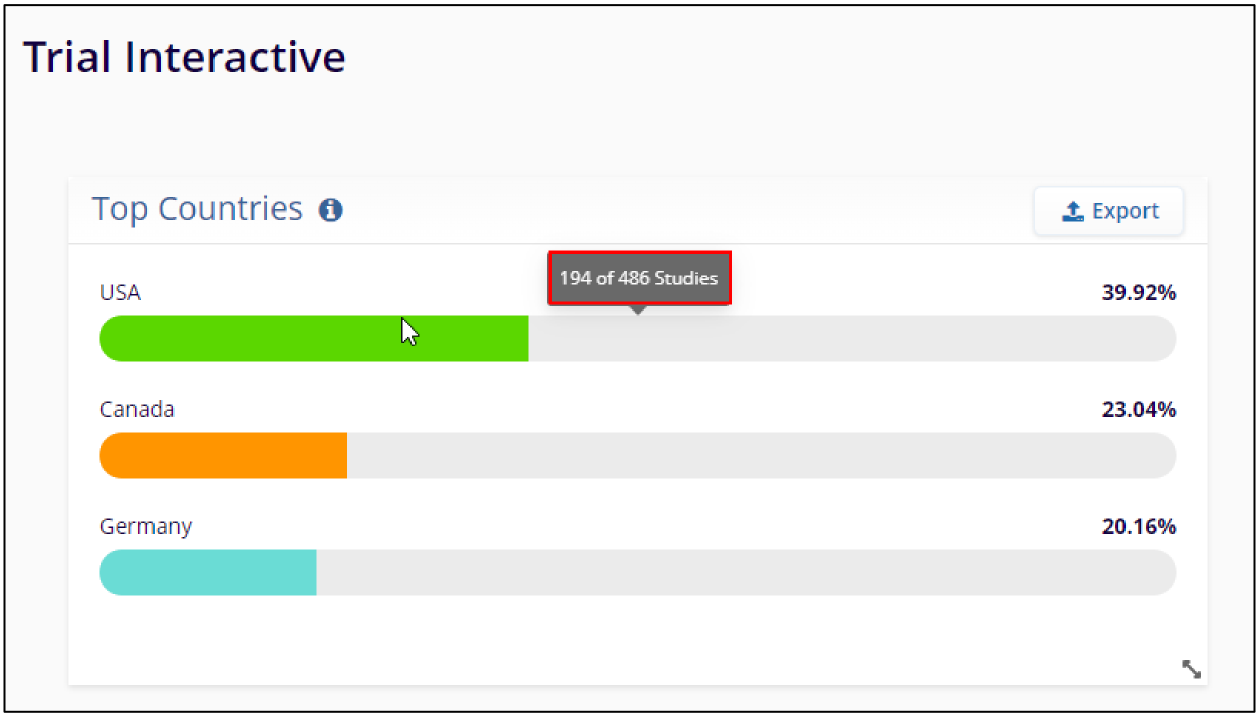


Figure: Top Countries

3. Click either on the PDF Document or PNG Image radio button from the Export Chart Options screen.
4. Click on Export once the required option is selected.

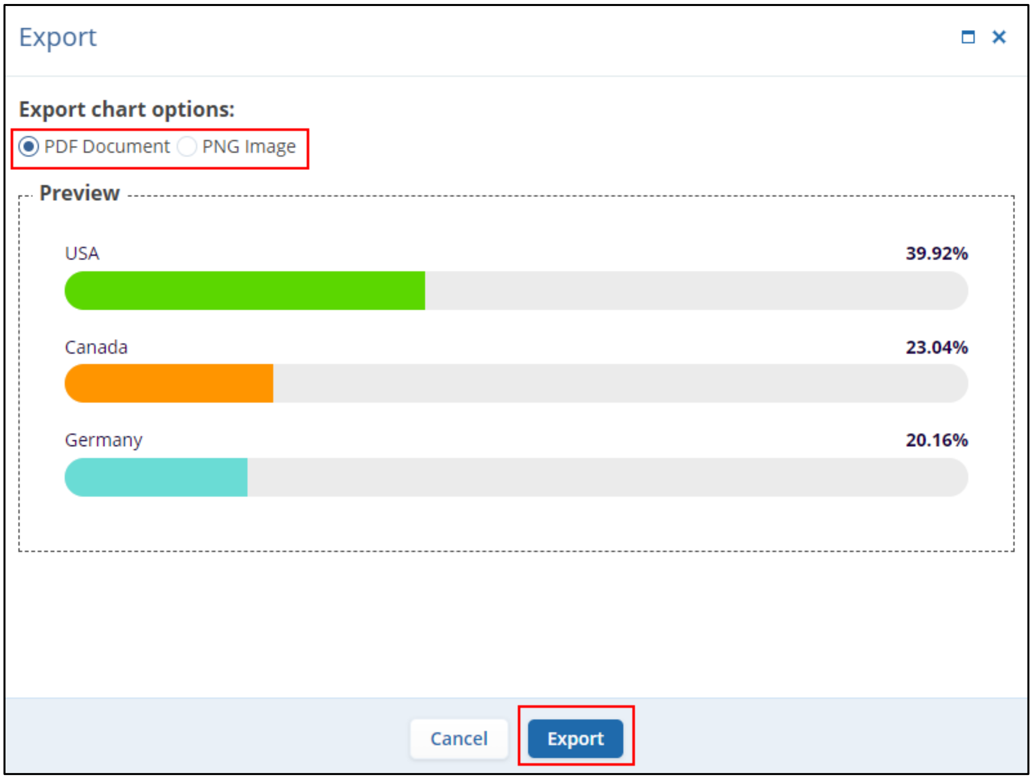


Figure: Export Chart Options

Portfolio Dashlet

The Portfolio Dashlet displays a world map, showing the number of studies associated with a particular country.

A user can perform the following actions on this dashlet.

1. Click on the below-mentioned filters dropdown to customize the world map according to the filters applied:
   a. Status
   b. Sponsor
   c. Phase
   d. Program
   e. Country
   f. Product
   g. Therapeutic Area

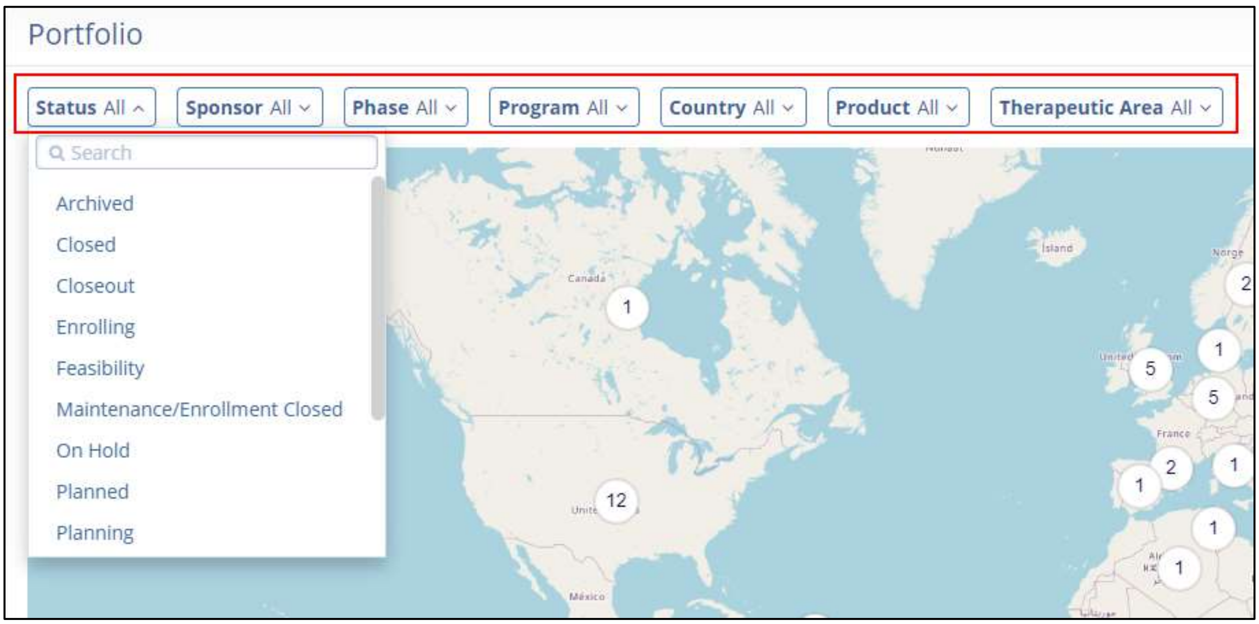


Figure: Portfolio dashlet filters

2. Click on Details to expand the Portfolio screen and view the world map along with the study data in a tabular format.

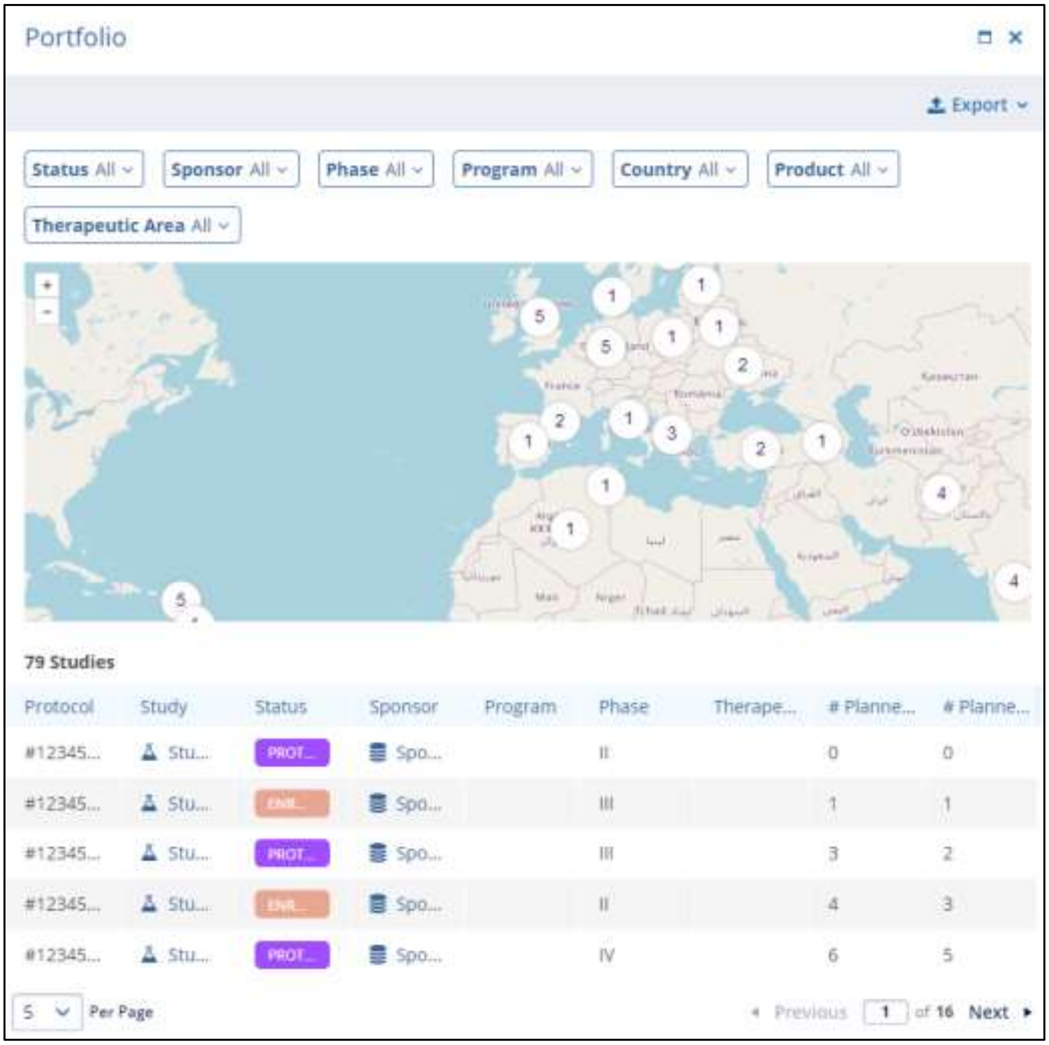


Figure: Expanded Portfolio screen

On this screen, perform the following.

a. Apply filters by selecting the available options from the filters dropdown.
b. Click on Export to retrieve an export of the portfolio screen in the Grid or Chart format.
   i. Export Grid: The Export Grid option allows exporting the data in CSV or XLSX file format. Refer to the [Exporting Contacts] section to understand the export process in detail.

   ii. Export Chart: The Export Chart option allows exporting the data in PDF Document or PNG Images. Refer to the [Top Countries Dashlet] section to understand the process.

Note:

- The columns and details in the Portfolio export files are different but the export process is similar as to Exporting Contacts.
- The process for exporting Portfolio charts is similar across all dashlets.

3. Hover over the numbers on the world map with the mouse to reveal the country names and their associated studies.

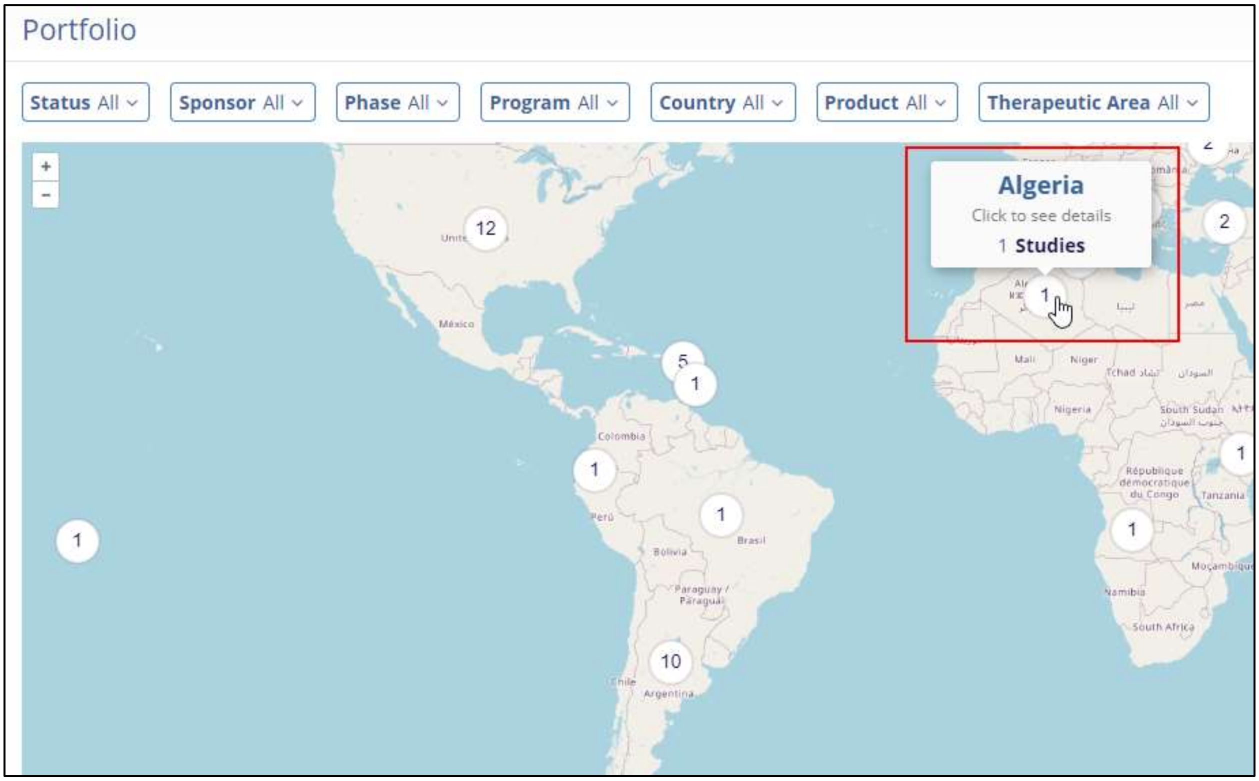


Figure: Country name and number of studies

4. Additionally, click on the number to get additional details associated with that particular study.
5. In the Study table, click on the Up and Down arrows to sort the data in ascending and descending orders respectively.

   Note: Follow the similar filtering, exporting, and sorting process listed above.

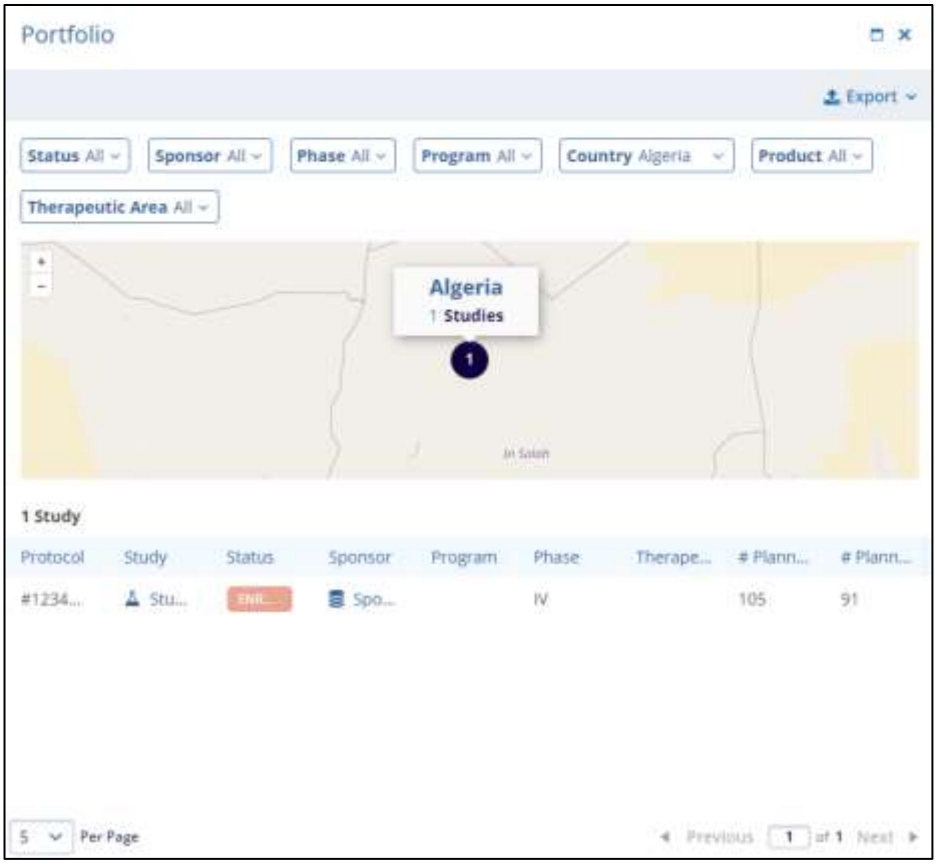


Figure: Study details by individual country

Studies Dashlet

The Study dashlet shows a customizable pie chart with the associated filters along with Study details in a tabular format.

A user can perform the following actions on this dashlet.

1. Click on the Pie or Bar Chart icons to choose between different types of charts for data visualization.

Figure: Select the data visualization type

2. Click on Group by and select the required grouping criteria from the available options. The pie chart details will be populated as per the selected grouping criteria. Select the number of Items in the chart to select the number of items to display in the chart.

   In the image below, the pie chart shows the total number of studies bifurcated by the Status.

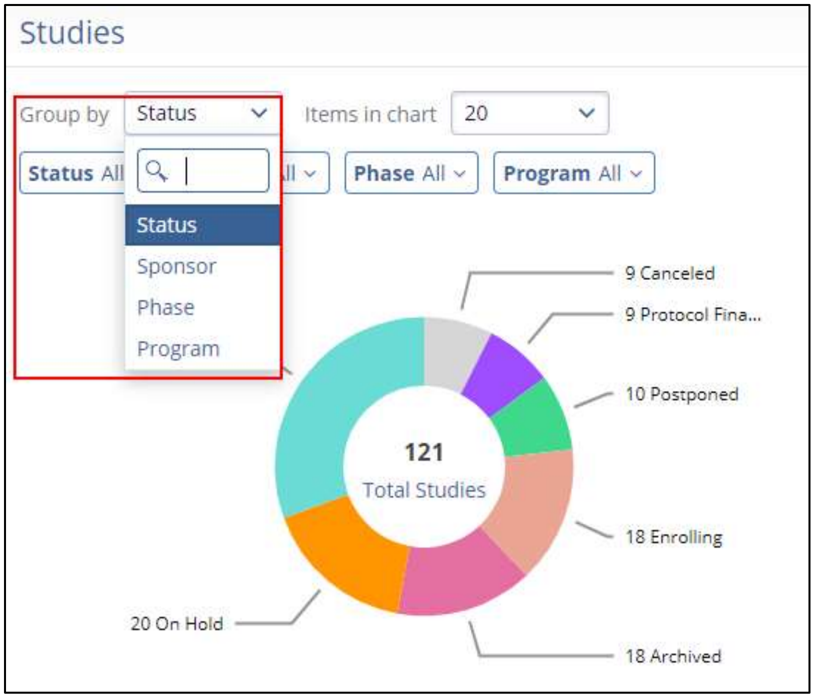


Figure: Grouping pie chart

3. Select and Apply the filters to customize the pie chart.
    a. Status
    b. Sponsor
    c. Phase
    d. Program

4. In the table, click on the Up and Down arrows to sort the data in ascending or descending order respectively.

Figure: Sort data in ascending and descending order

5. Additionally, click on the arrow pinned to the study name to open the Study details page.
6. Click on the Details button to open the modal view of the Studies and perform the similar functions as listed above.
7. Additionally click on Export on the Regular and Modal view to retrieve an export of the Studies data.
    a. Refer to the Exporting Contacts section to understand the Export Grid process.
    b. Refer to the Top Countries Dashlet section to understand the Export Chart process.

Note:

- The columns and details in the Study export files are different but the export process is similar to Exporting Contacts.
- The process for exporting Portfolio charts is similar across all dashlets.

CRA Visit Report Performance Dashlet

The CRA Visit Report Performance Dashlet shows a pie chart displaying the total number of visit reports bifurcated by their status. Additionally, a dial chart displays

A user can perform the following on this dashlet.

1. Click on the CRA, Study, Sponsor, and Reviewer filters to customize the dial chart.

Figure: CRA Visit Report Performace filters

2. The dial charts show the site visit reports categorized by their statuses. Hovering over the dial chart reveals a brief description of the chart statistics.

In the above image, the Complete on First Submission dial chart shows that 9 out of 11 are approved site visit reports that were never rejected.

3. Click on an individual chart to open the chart-related details in a tabular format as well.

Figure: Tabular view for CRA visit reports

4. Click on the Export button to retrieve an export of the current or custom pages. Refer to the Exporting Contacts section to understand the export process.

Note:

- The details in the file exported differ but the process is similar to Exporting Contacts.

Study Dashboards

To access the Study Dashboards, follow the steps below.

1. From the left-hand navigation links, select the Studies.
2. On the Studies screen, click on the Study Name to review.
3. The screen will display the following dashboards

The Study Dashboard contains the following dashlets

Study Milestone

The Study Milestones dashlet tracks milestones as defined in the study settings. Please note that no data will be displayed until the relevant fields in the milestone management area have values entered.

Figure: Study Milestones dashlet

Study Enrolment

The Study Enrolment dashlet displays a pie chart showing the total subjects bifurcated by the filters applied. The trend chart displays the month-wise distribution of subjects with their statuses.

Note: If the year and month are not selected, the system displays the data of the current year. Refer to the screenshot below.

Figure: Study Enrollment dashlet

Study Timeline

The Study Timeline dashlet can be customized at a Study, Country, and Site level. Refer to the sequence in the screenshot below to understand the characteristics of the dashlet.

1. The red dot and line indicate today's date on the timeline.
2. The bottom section of the screen displays the milestone status.

Status	Indicator
Planned	Gray radio box
In Progress	Yellow square
Completed	Green Circle
Past Due	Red Warning sign

3. The date range filters allow specifying a range of dates (From and To) and choosing a predefined viewing period (e.g., 1 week, 1 month, 3 months, 6 months, 1 year) for displaying data within that timeframe.

4. The Status and Classification filters allow to customize the chart per the filters applied.

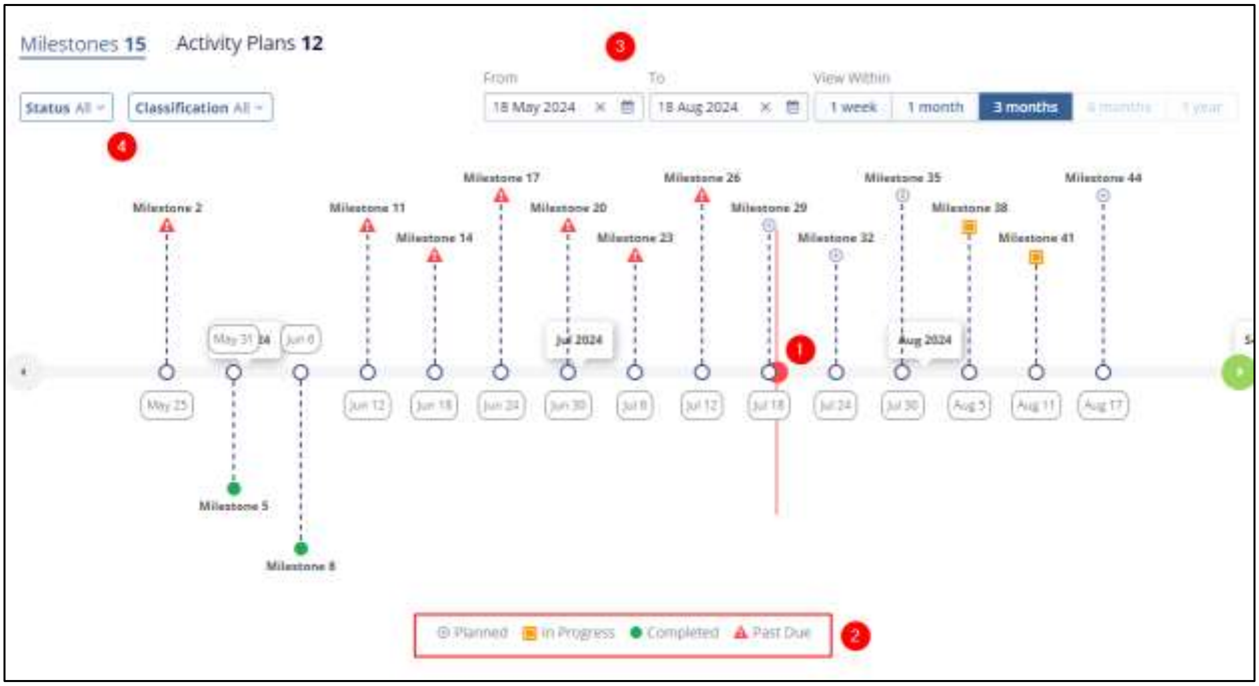


Figure: Study Timeline dashlet

Activities

The Activities dashlet shows customizable Study General Activities, Country Total Activities, and Site Total Activities. Refer to the sequence in the screenshot below to understand the characteristics of the Activities dashlet.

1. Apply the Group By and Filter By criteria by selecting from the available dropdown options and the charts will be populated with data accordingly. Additionally, apply the Status, Type/Subtype, and Owner filters to customize the charts.
2. Apply the date range filters by specifying a range of dates (From and To) and choosing a predefined viewing period for displaying data within that timeframe. Turn on the Select Data toggle to add the date range.
3. Click on the Pie Chart, Bar Chart, or Histogram icons to choose between different types of charts for data visualization.

Figure: Activities dashlet

4. Click on an individual chart and it displays the Activity details in a tabular format.

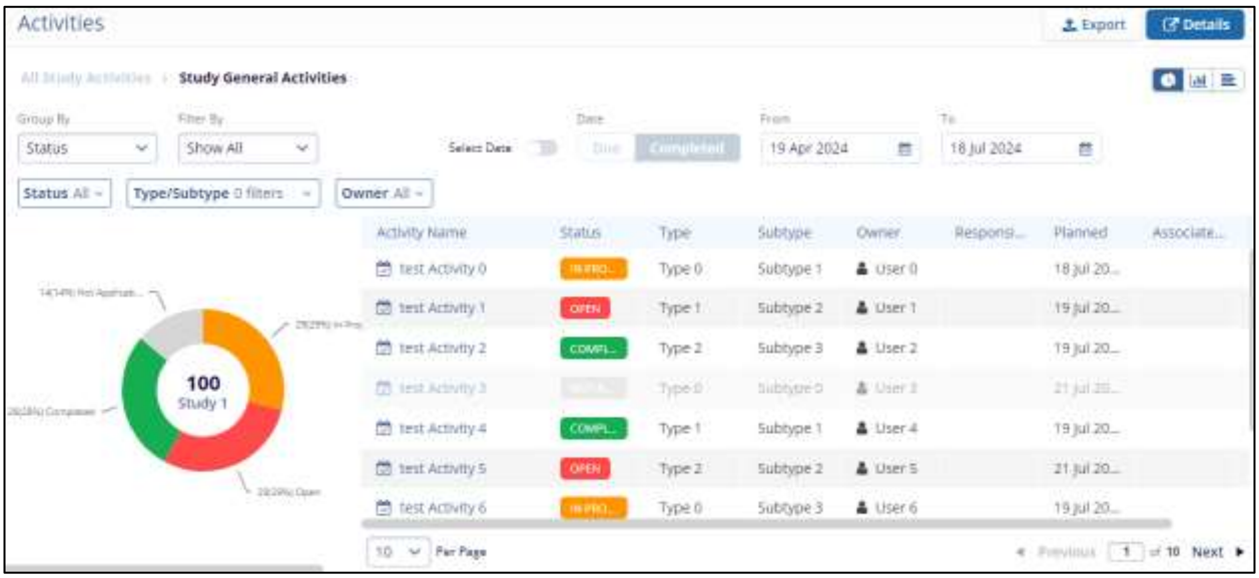


Figure: Study General Activities view

Note:

- The Export functionality is similar across all the dashboards. Refer to any one of the previous sections where Export functionality is detailed.
- The functionality to switch to modal view (by selecting Details) is standard across all dashboards.

Countries Dashboard

To access the Countries Dashboard, follow the steps below.

1. From the left-hand navigation links, select the Studies.
2. On the Studies screen, click on the Study Name to review.
3. Navigate again to the left-hand navigation links and select Countries.
4. Click on a Country name to view the related dashboard.

Country Timeline

The Country Timeline dashlet can be customized at a Country, and Site level.

Refer to the Study Timeline dashlet which has similar functionalities to the Country Timeline dashlet.

Activities

The Activities dashlet shows customizable visualization of Study General Activities, Country Total Activities, and Site Total Activities.

Refer to the Activities dashlet which has similar functionalities to the Activities dashlet for countries.

Site Dashboard

To access the Countries Dashboard, follow the steps below.

1. From the left-hand navigation links, select the Studies.
2. On the Studies screen, click on the Study Name to review.
3. Navigate again to the left-hand navigation links and select Sites.
4. Click on a Site name to view the related dashboard.

Site Timeline

Refer to the Study Timeline dashlet having similar functionalities to the Site Timeline dashlet.

Activities

The Activities dashlet shows customizable visualization of Sites.

Refer to the Activities dashlet having similar functionalities to the Activities dashlet for sites.

Sponsors

Pre-Requisites

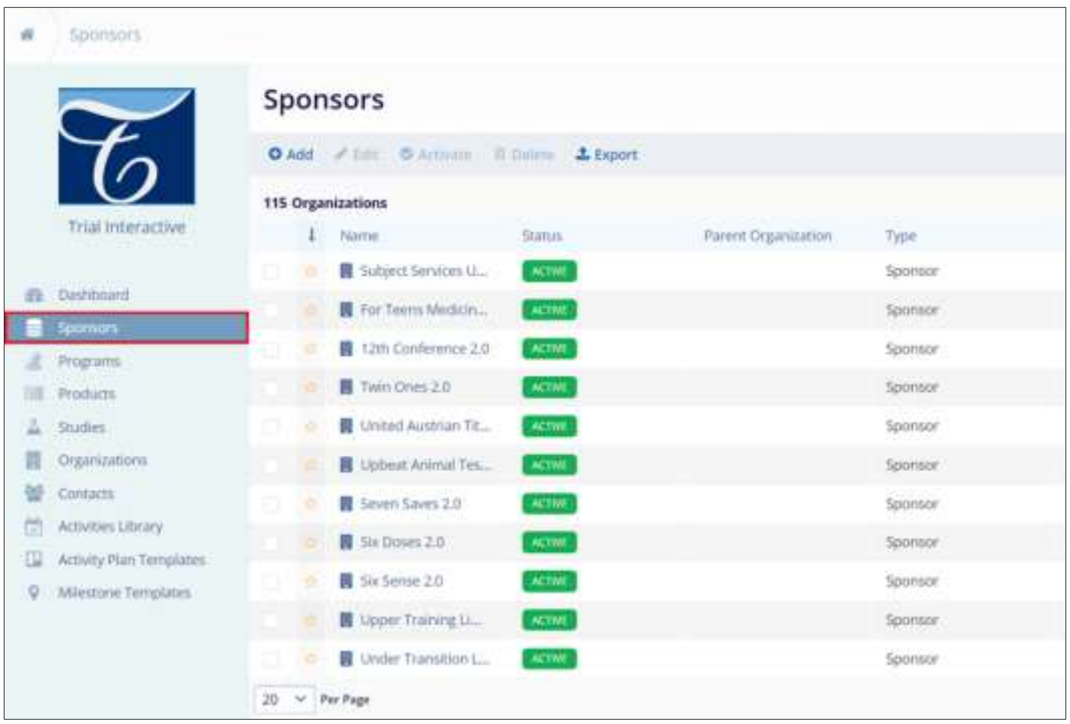
To perform any of the following actions, users must have an account with system access permissions that allow them to Create, Edit, Activate, Deactivate, Delete, and Export sponsors:

How to Create a Sponsor:

Navigate to the Sponsor list

To navigate to the “Sponsor” list and view all Global-level sponsors, follow these steps:

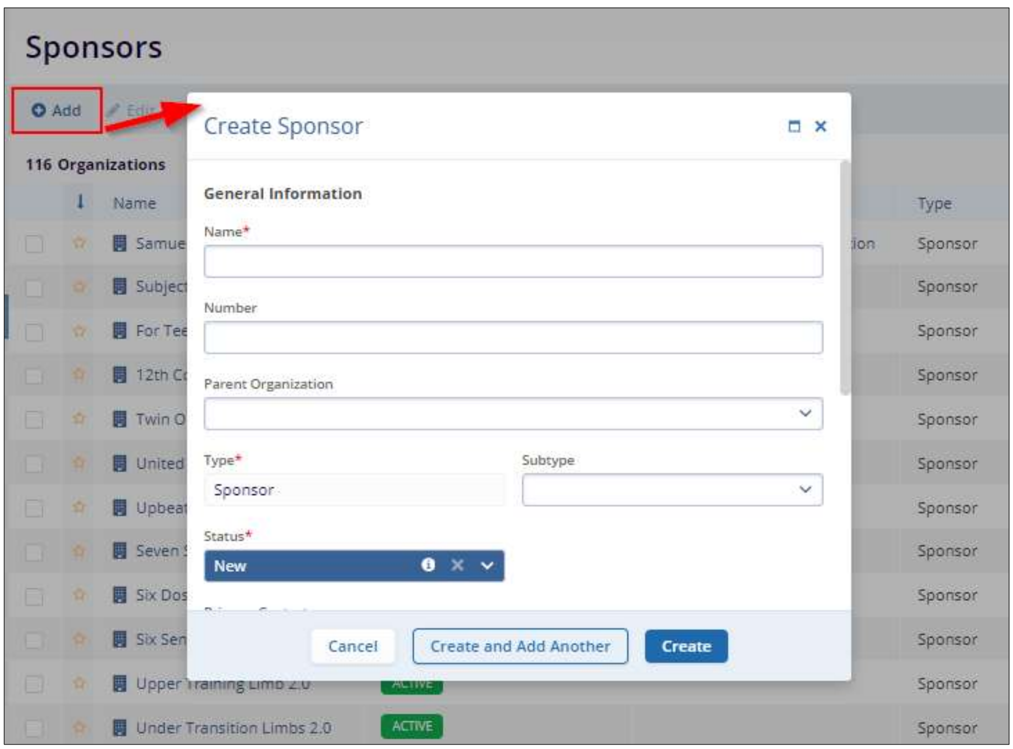
1. Click on the "Sponsor" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Sponsor" page where all Sponsors at the global level are displayed as shown in the below image.



Steps to Add a New Sponsor

1. To add a new organization, click the "+Add" button from the menu bar above the grid.

2. This action will open the “**Create Sponsor**” Screen.

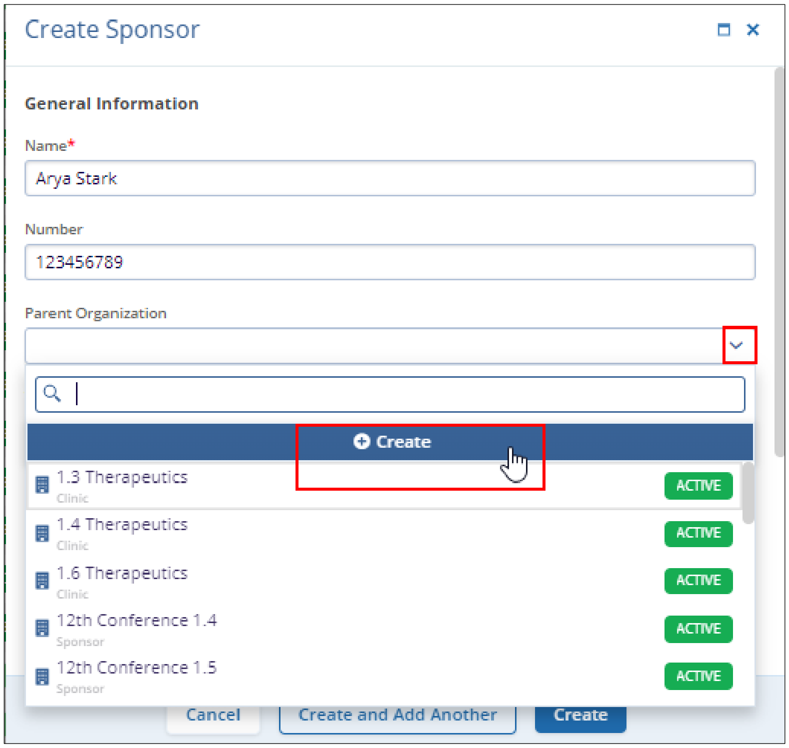


Note: To create a sponsor, you must enter the mandatory fields Name, Type, and Status which are marked with an asterisk (*) next to the field title. Other fields are optional.

<u>Step by Step All fields are explained below:</u>

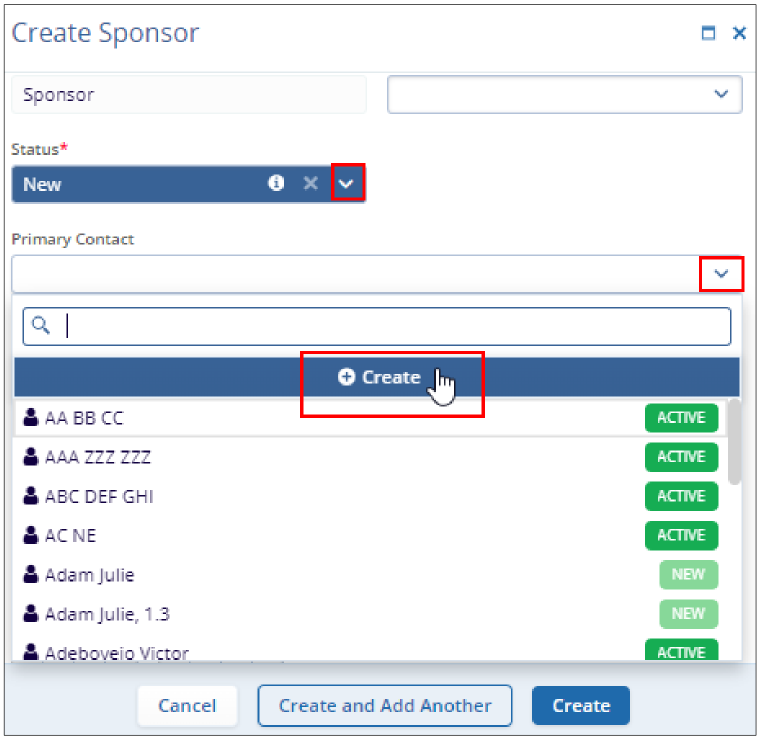
1. Name: Enter the sponsor name in the "Name" field.
2. Number: Enter the unique number for a sponsor.

3. Parent Organization field: To add an organization to the sponsor, click on the drop-down arrow and select the appropriate organization from the list. To create a New organization, click on the “+Create” button. Refer to the screenshot below.

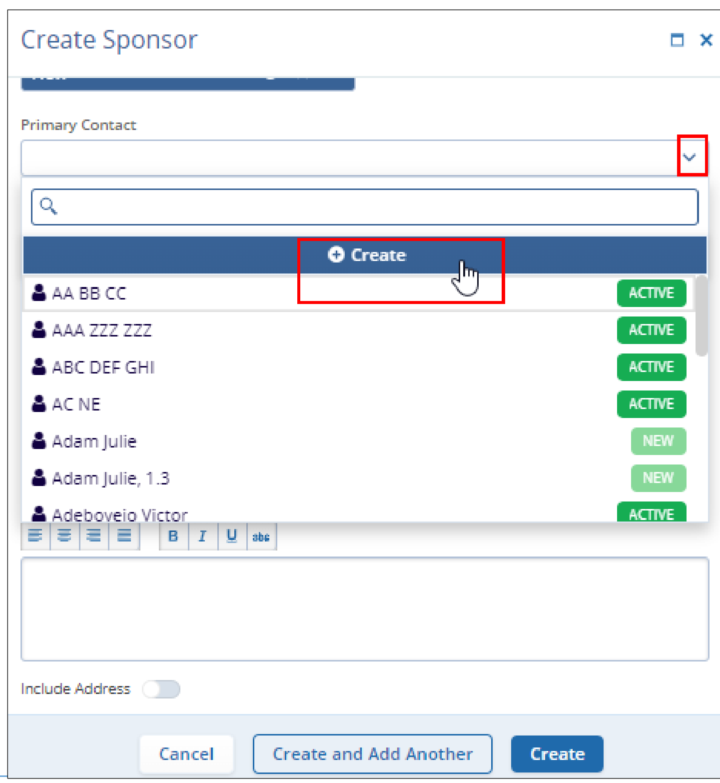


Note: To learn How to Create an Organization. Click here.

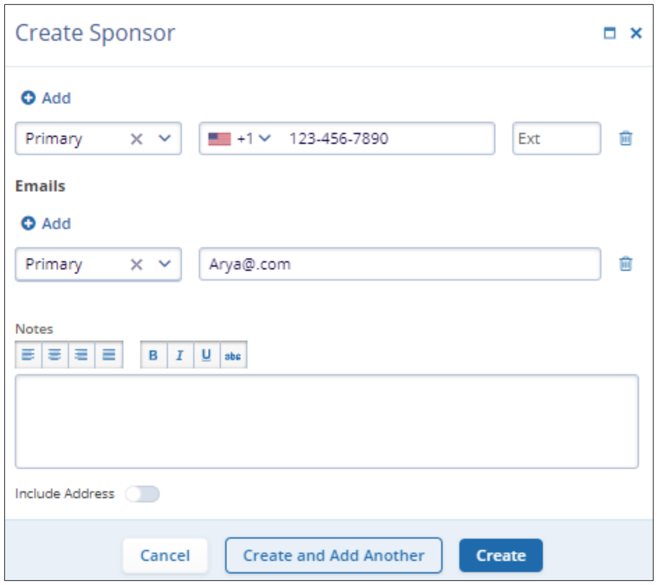
4. Type: As we are creating the sponsor this field is pre-selected as "Sponsor" and it's not editable.
5. Subtype: Select the appropriate subtype from the drop-down menu.
6. Status: By default, the user will be able to “New” Status. To add the status to the sponsor click on the drop-down arrow and select the status as per your requirement.



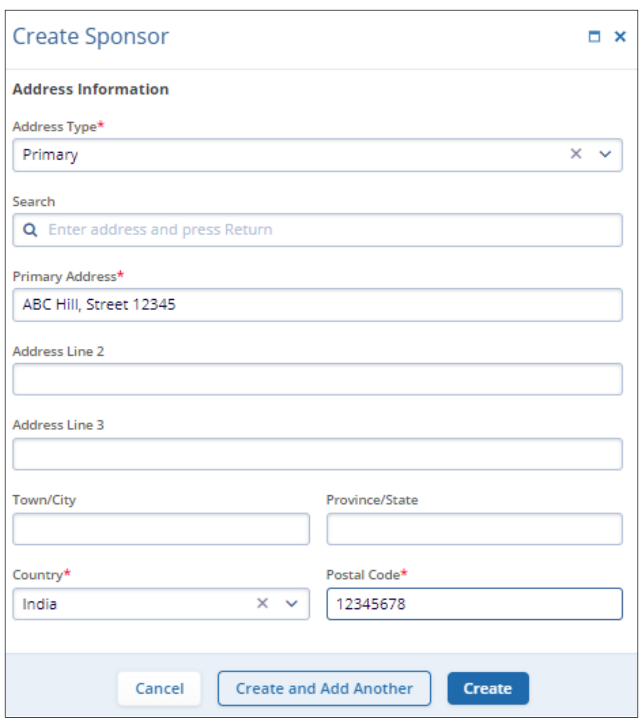
7. Primary Contact: To add a contact to the sponsors, click on the drop-down arrow and select the appropriate Contact from the list. To create a New contact click on the "+Create" button. Users can access this link to understand How to Create a Contact.



8. Phone Numbers: Click on "+Add" to input phone numbers. Enter the phone number in the provided field.
9. Emails Address: Click on "+Add" to enter email addresses. Enter the email address in the provided field.
10. Notes Message Box: Enter any additional notes regarding the Sponsor in the "Notes" field.



11. Include Address: Toggle the switch if you want to include an address. All address-related fields will appear. Please refer to the screenshot below.

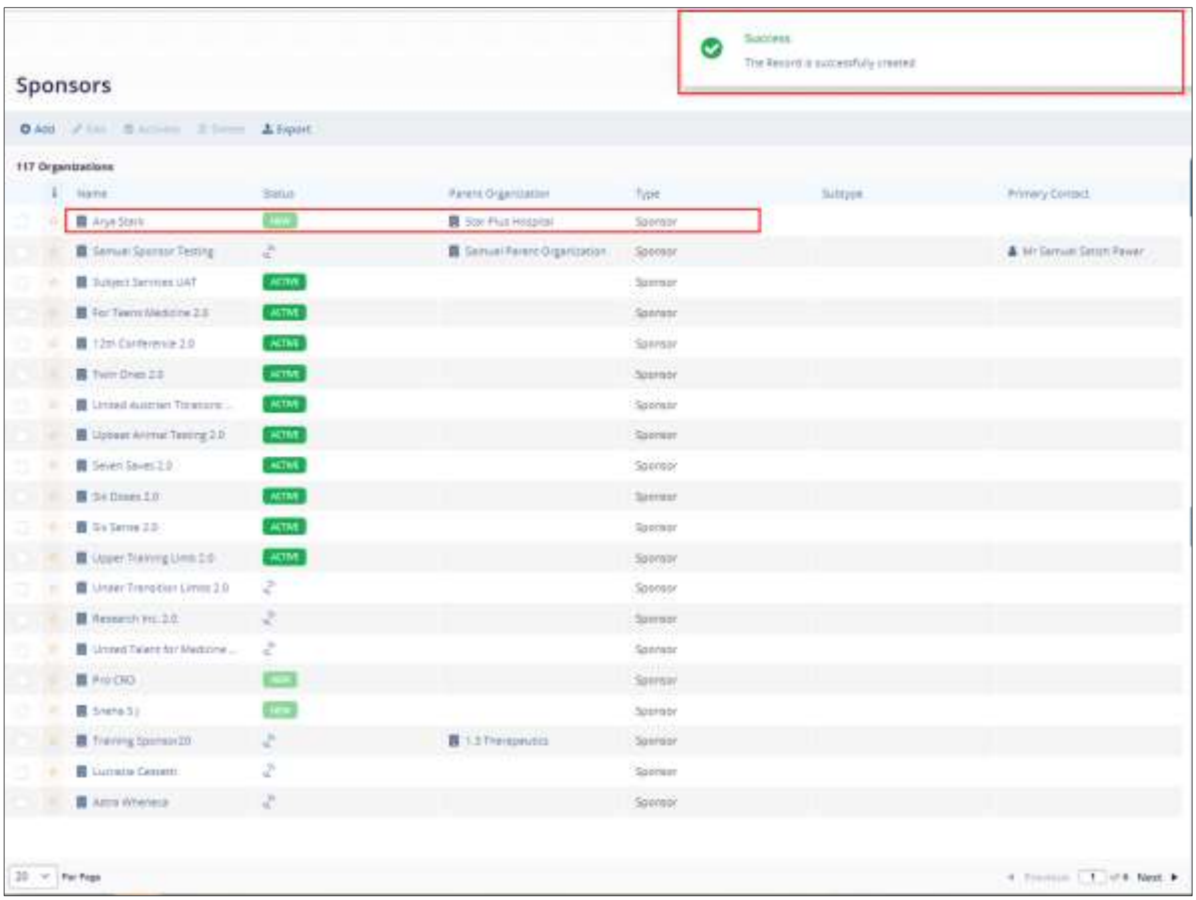


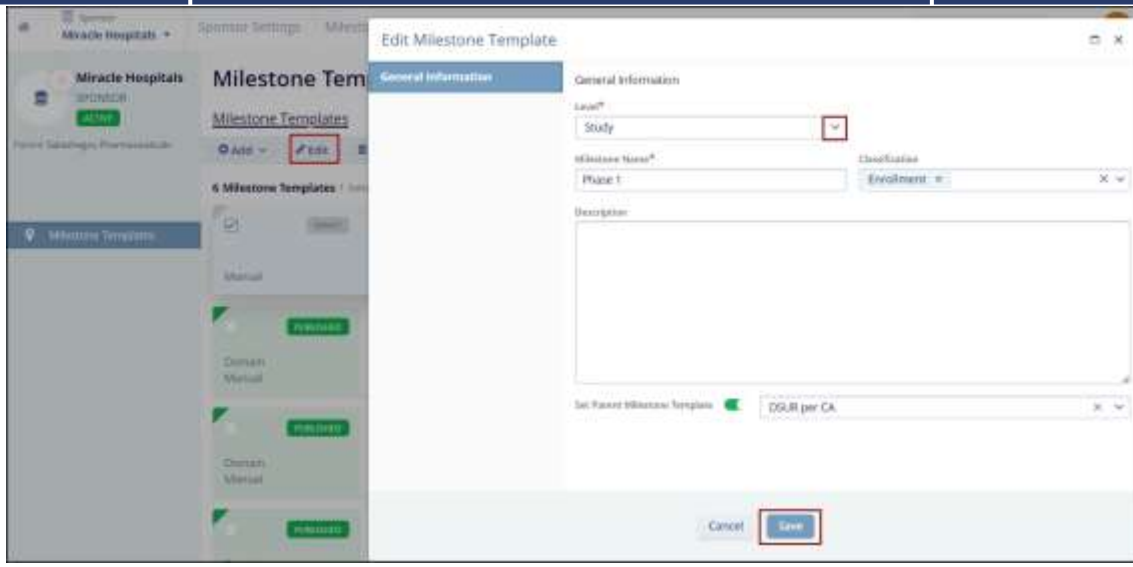
Note: To include an address, you must enter the mandatory fields Address Type, Primary Address, and Country and Postal code which are marked with an asterisk (*) next to the field title. Other fields are optional.

12. Search Address: Click on the search icon to search for the address and enter your address it will show you an auto-populated list.
13. After filling in all required fields, you have three options at the bottom of the form.

    - Create: Saves the new organization and closes the screen.
    - Create and Add Another: Saves the new organization and opens a new screen to add another organization.
    - Cancel: Discards the information and closes the screen.

14. When the user clicks on the “Create” button. This action will create a sponsor and it will display a successfully created pop-up. The created sponsor can also be seen in the grid. Refer to the screenshot below.





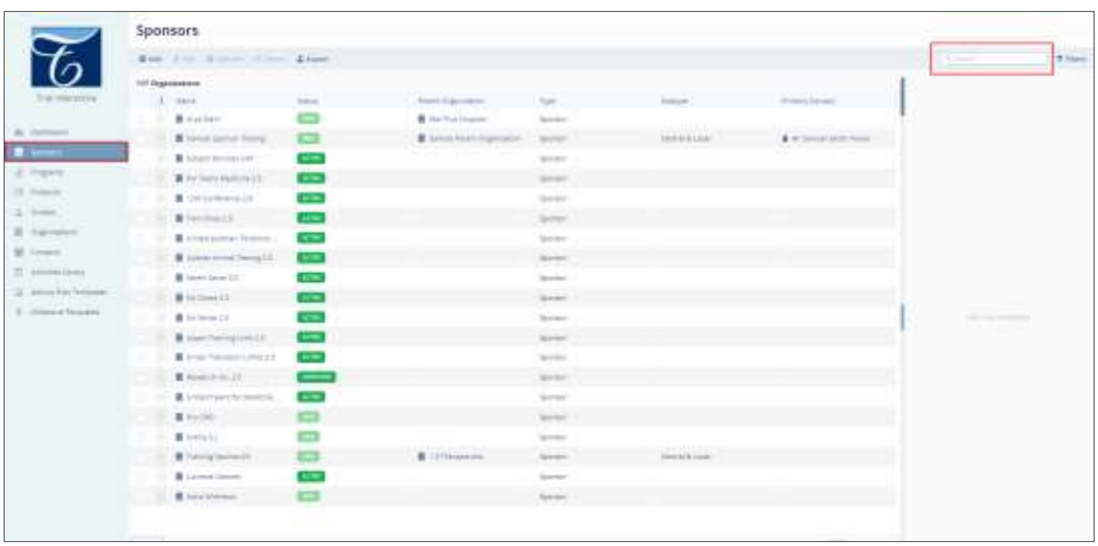
Note: Editing a sponsor follows the same process as editing an organization. Refer to the "How to Edit an Organization" section, To Edit a Sponsor. [Click here]

How to Search for a Sponsor

To learn how to navigate to the Sponsor list. [Click here]

Steps to search for a sponsor

- From the sponsor main menu in the top right corner, click on the "Magnifying Glass" icon or the "Search" textbox. Refer to the screenshot below.

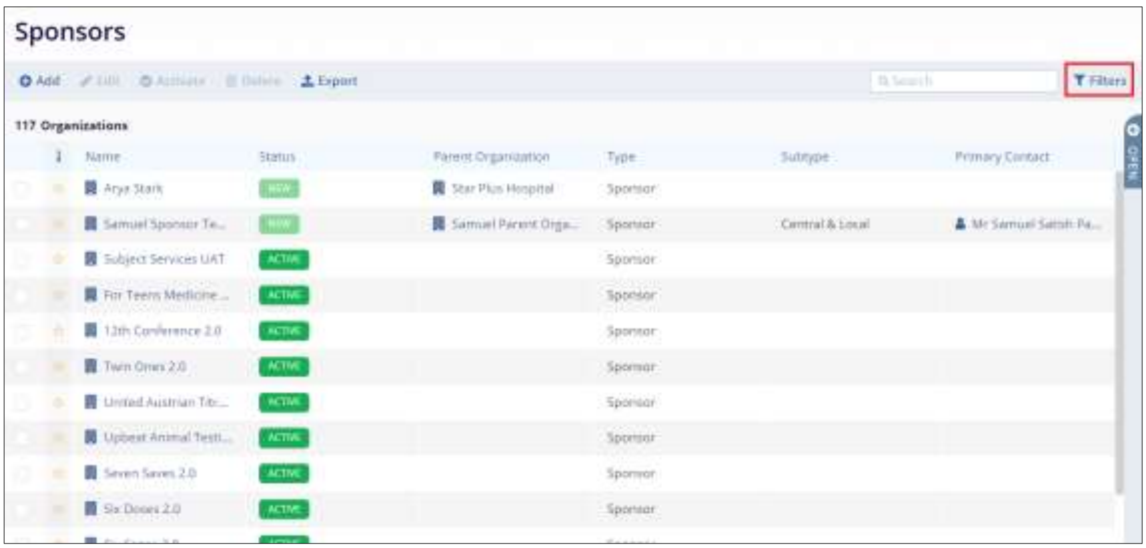


- To search for the sponsor, Enter the Sponsor's name or a related keyword into the search bar.
- The user does not need to press the enter button. It will automatically show all related results. Refer to the below screenshot.

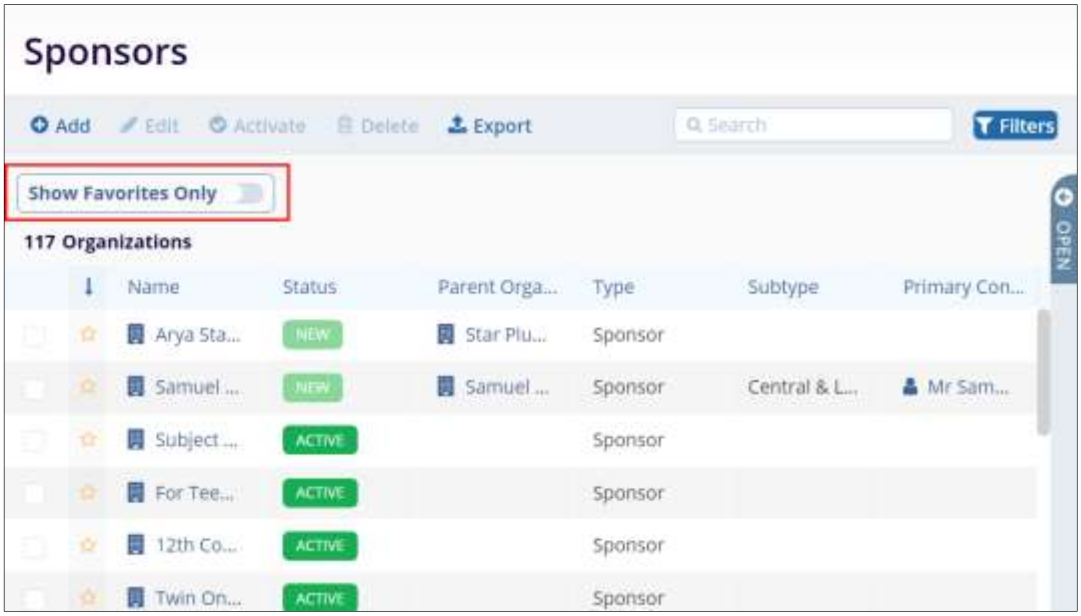
Steps to Apply Filter

To learn how to navigate to the Sponsor list. Click here

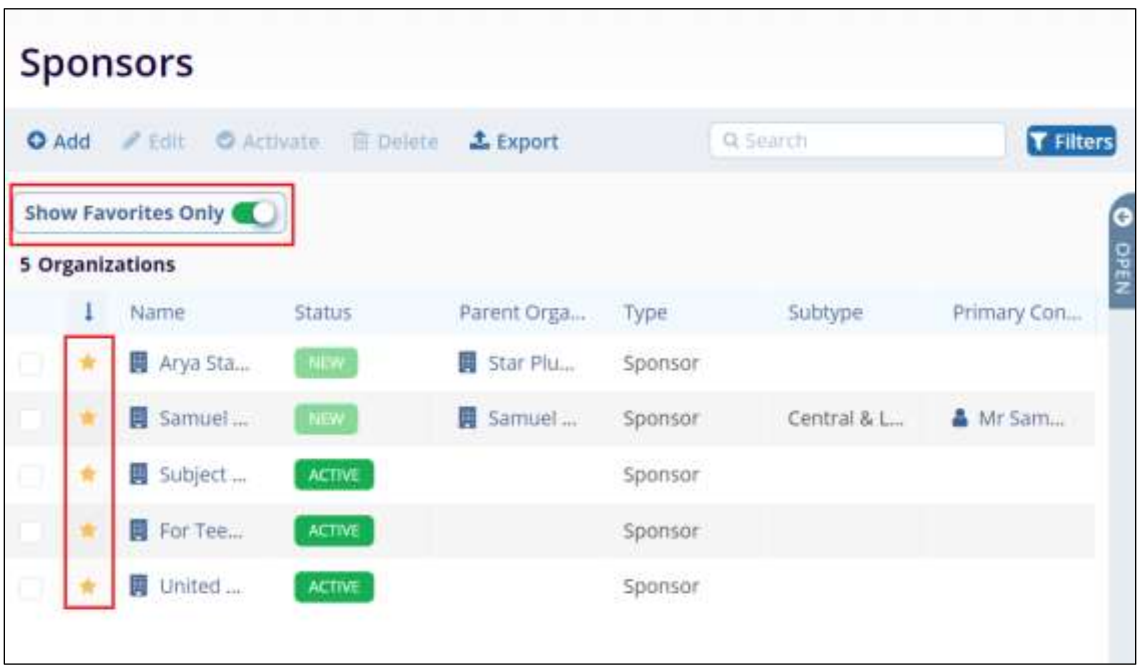
1. From the sponsor main menu in the top right corner, click on the "Filter" button to apply filters. Refer to the screenshot below.



2. After clicking the filter button the "Show Favorite Only" Switch button will appear below the main menu. Refer to the screenshot below.



3. To view all your favorite sponsors, click the switch button. All favorite sponsors will then appear in the grid. Refer to the screenshot below.



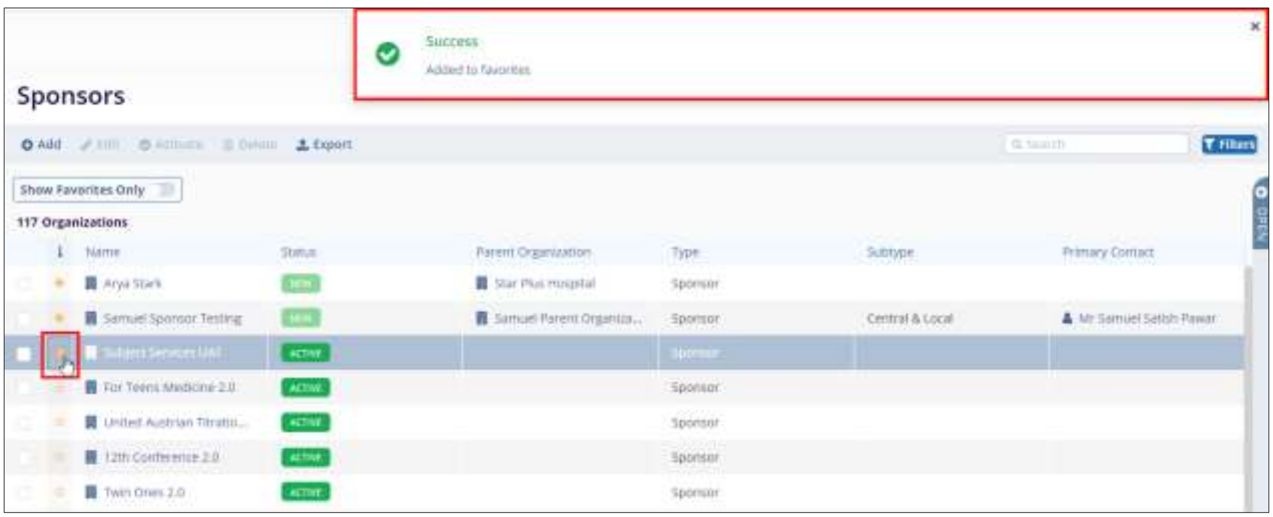
How to Add and Remove Favorites

To learn how to navigate to the Sponsor list. [Click here](#)

Steps to add Favorites to the sponsors.

1. Click the "Star" symbol next to the sponsor's name to add a favorite to the sponsor. Refer to the screenshot below.

2. After clicking the Star symbol, you have successfully marked your sponsor as a favorite and the user will receive a notification as successful. Refer to the screenshot.



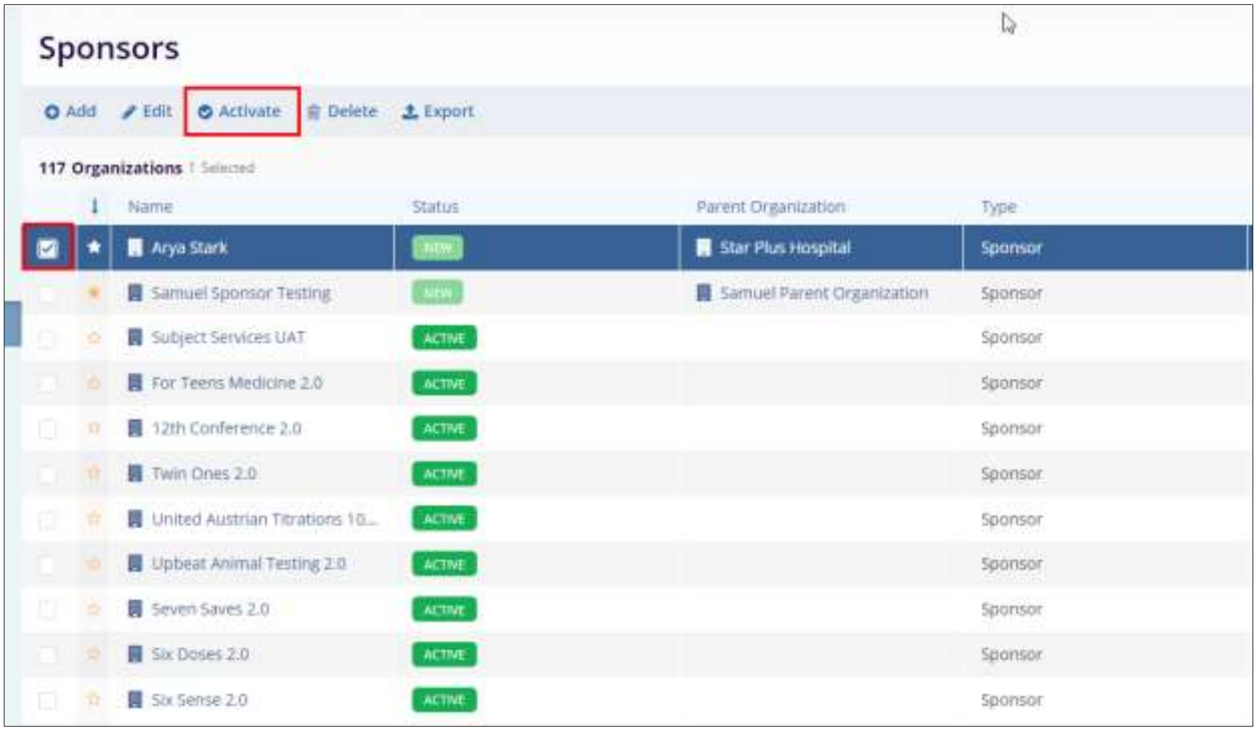
3. To mark the sponsor as unfavorite, click that solid Star. You have successfully marked your sponsor as unfavorite and the user will receive a notification as successful. Refer to the screenshot.

How to Activate A Sponsor

To learn how to navigate to the Sponsor list. Click here

Steps to Activate a Sponsor

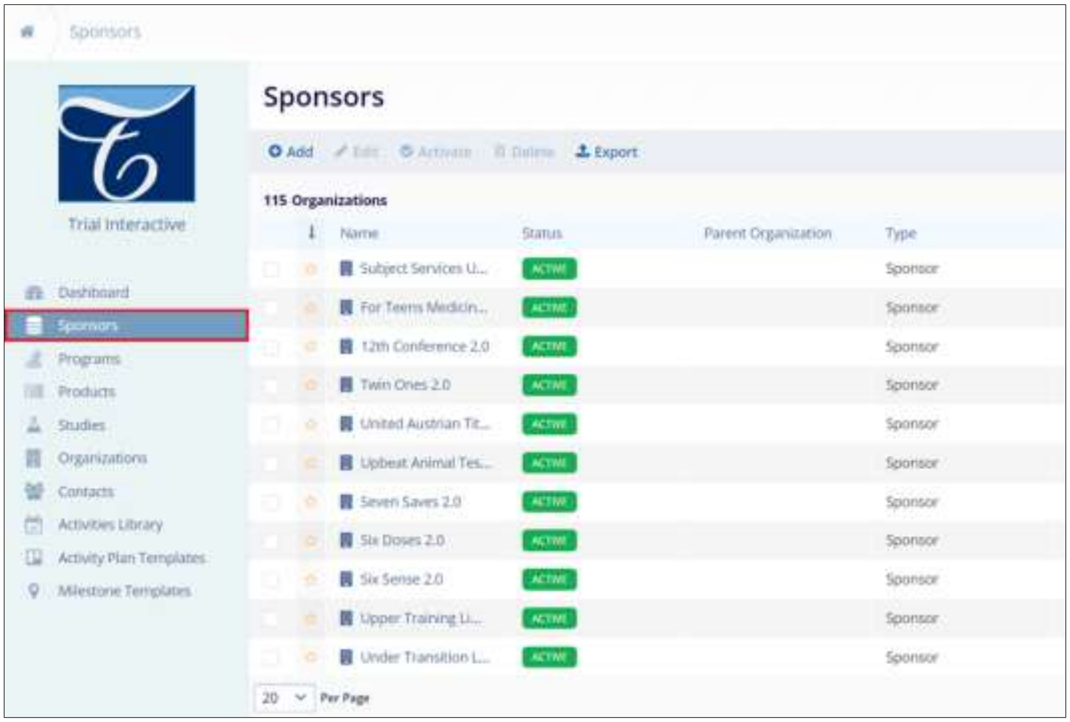
1. Select the sponsor, that the user needs to Activate the sponsor and click on the



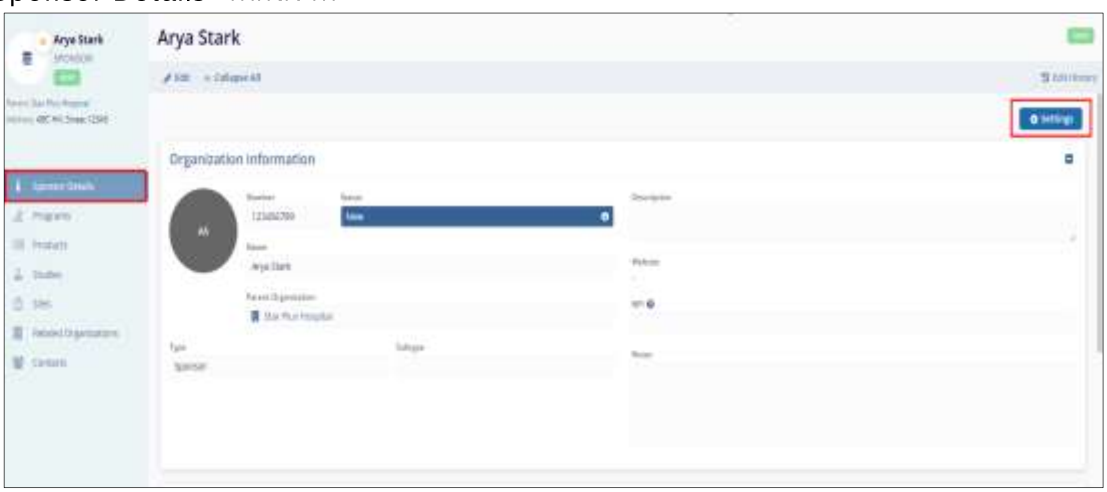
Defining Sponsor Settings

To navigate to the "Sponsor" list and view all global sponsors, follow these steps:

1. Click on the "Sponsor" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Sponsor" grid view where all Sponsors at the global level are displayed.

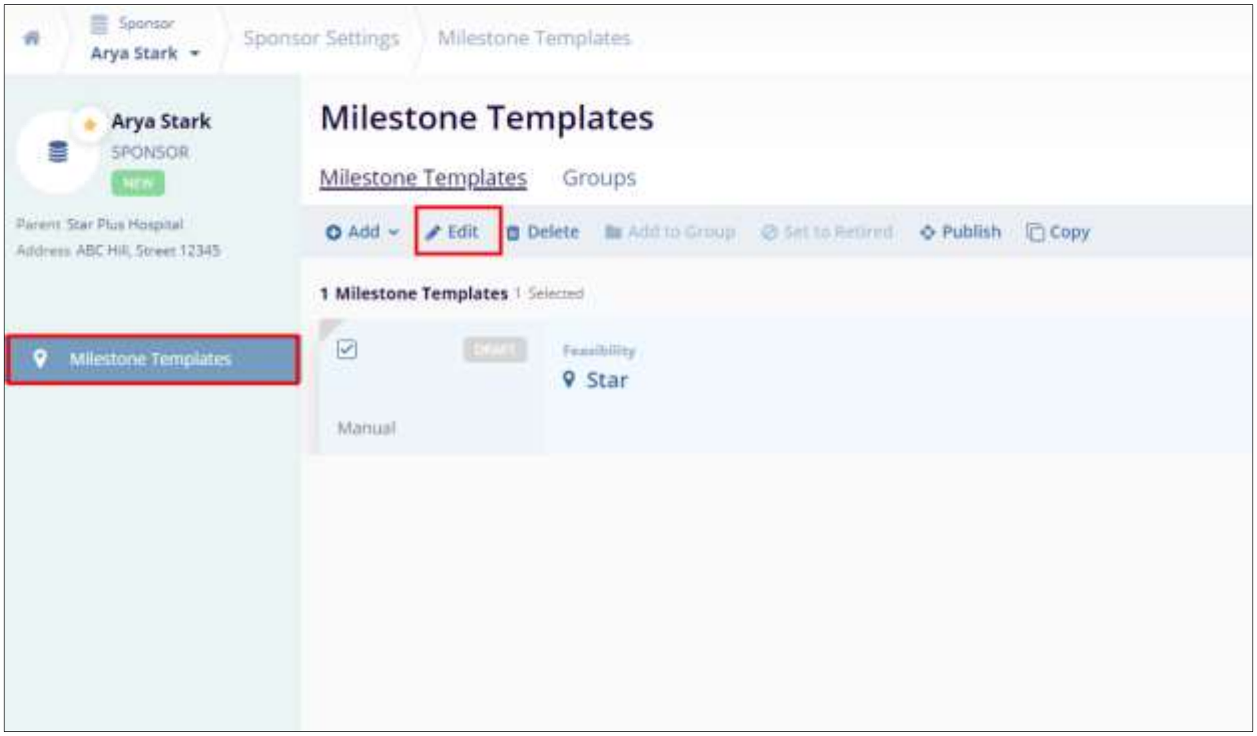


3. Navigate to the sponsor's name you want to edit and click on it. This opens the "Sponsor Details" window.



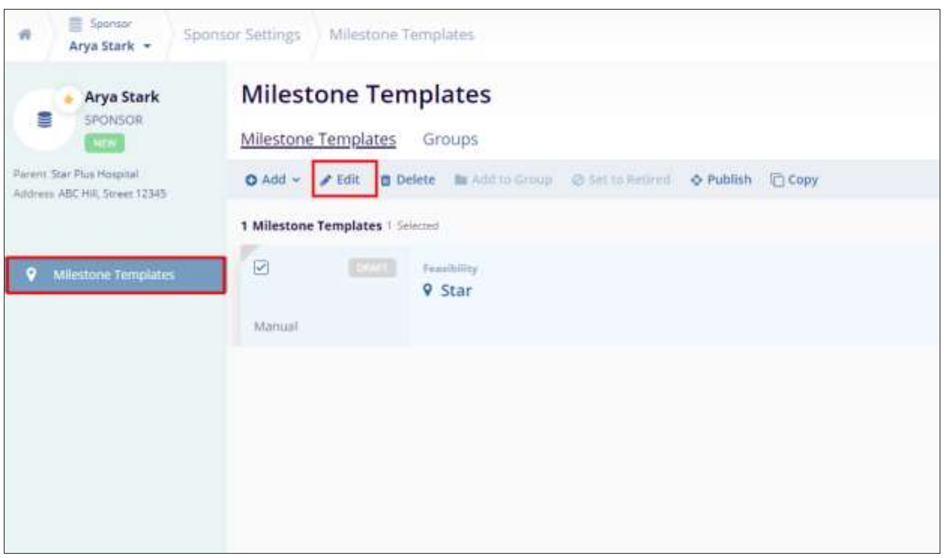
4. Click on the "Setting" button in the top-right of the screen. This will redirect you to the "**Sponsor Settings"-> Milestone Template's"** screen.

5. Click on the Edit button for the milestone you want to edit.



Note: The Milestone Templates that display a 'Draft' status can be edited.

6. This opens the Edit Milestone Template window.



7. As per the requirement, the user can make necessary changes in the milestone templates.
8. Click Save for the changes to apply.

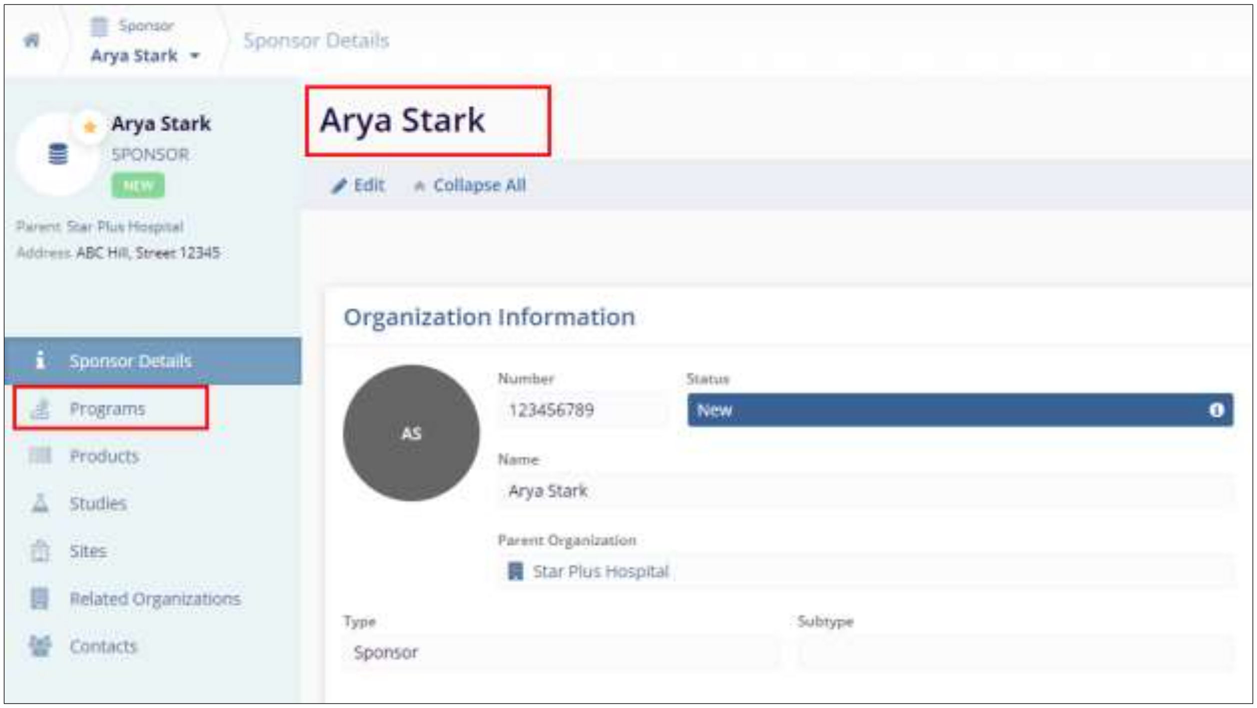
Note: To learn more about Milestone Templates functionality. For Example: How to Add, Delete, Publish, Copy and so on. Refer to the Milestone Template section. Click Here.

Creating a Product for a Sponsor

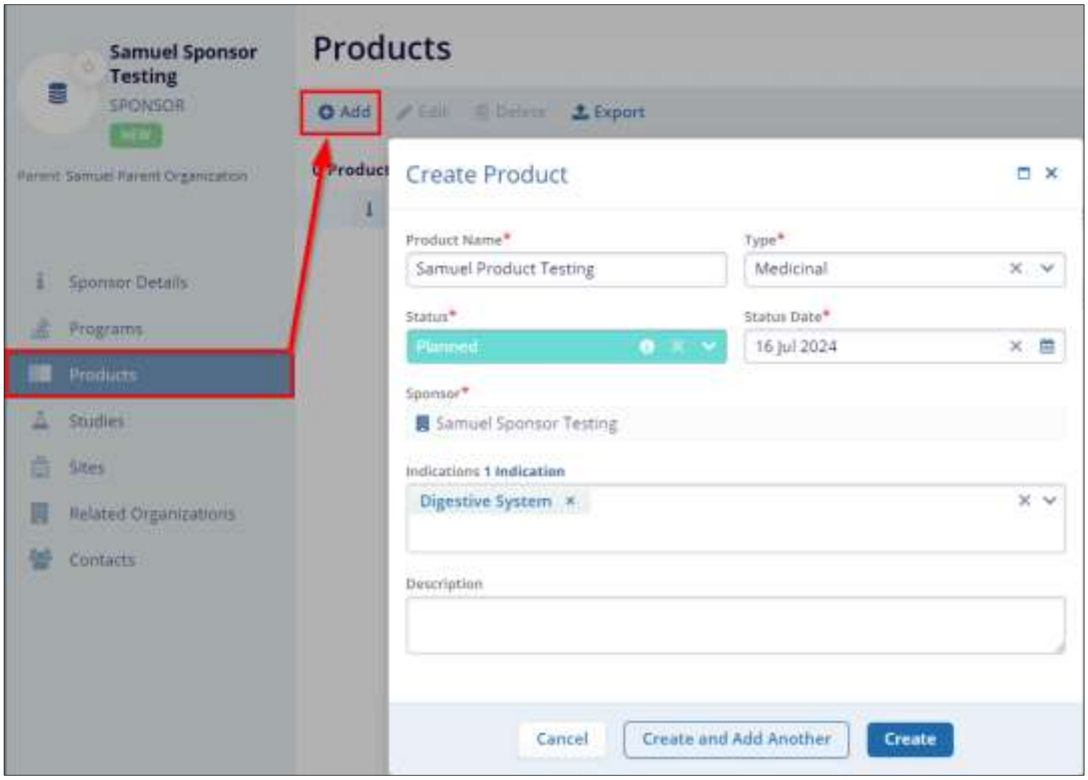
To learn how to navigate to the Sponsor list. Click here

Steps to create a product for a Sponsor

1. Click on the "Sponsor name", It will redirect you to the Sponsor Details screen.



2. To create a product for a sponsor user should click on "Products" from the navigation link to the left side of your screen. It will redirect you to the "Products" screen.



Step-by-step instructions to fill in product details.

1. Fill in the Product Name

   - Field: Product Name
   - Description: Enter the name of the product you want to create. This is a mandatory field.
   - Example: Samuel Product Testing

2. Select the Product Type

   - Field: Type
   - Description: Choose the type of product from the dropdown menu. This is a mandatory field.
   - Example: Medicinal

3. Set the Product Status

   - Field: Status
   - Description: Select the current status of the product from the dropdown menu. This is a mandatory field.
   - Example: Planned

4. Specify the Status Date
    - Field: Status Date
    - Description: Enter or select the date corresponding to the product status. This is a mandatory field.
    - Example: 16 Jul 2024
5. Assign a Sponsor
    - Field: Sponsor
    - Description: The Sponsor field is predefined and cannot be edited. This is a mandatory field.
    - Example: Samuel Sponsor Testing
6. Indications
    - Field: Indications
    - Description: Select any relevant indications for the product. This is optional.
    - Example: Choose from the dropdown menu if applicable.
7. Provide a Description
    - Field: Description
    - Description: Enter a brief description of the product. This is optional.
    - Example: [Leave blank or provide a detailed description as needed]
8. Save the Product
    - Buttons:
        - Cancel: Click this button if you want to discard the information and cancel creating the product.
        - Create and Add Another: Click this button if you want to save the current product and immediately start creating another product.
        - Create: Click this button to save the product and complete the creation process.

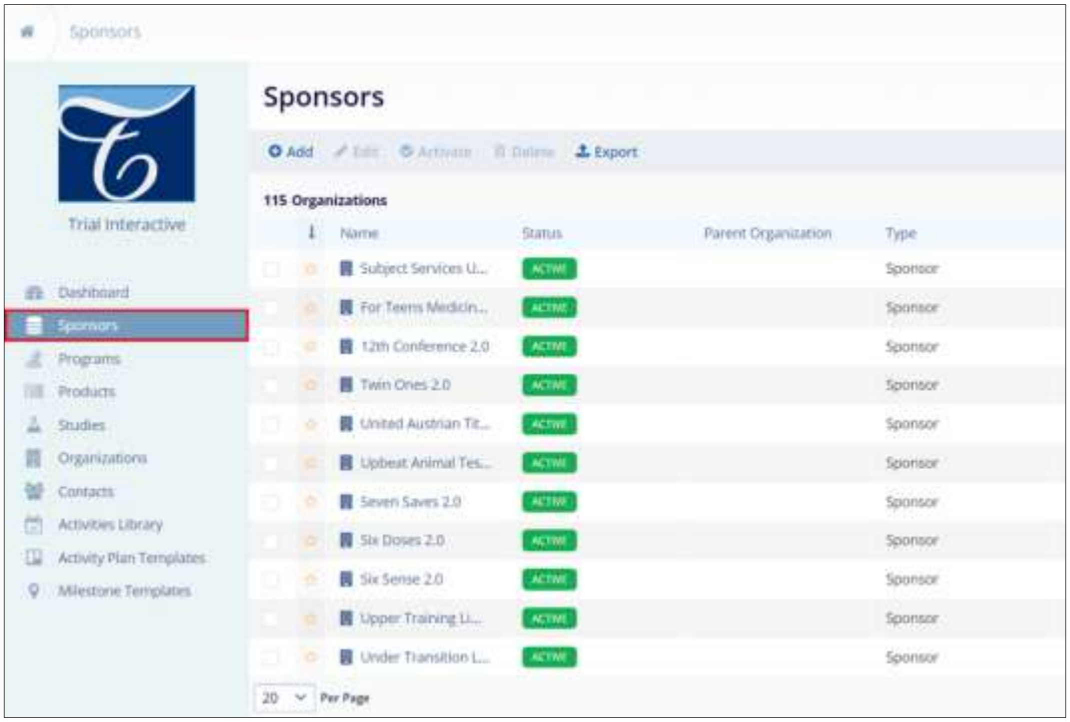
    Notes:

    - Make sure all mandatory fields (marked with a red asterisk *) are filled out before attempting to save the product.
    - Use the calendar widget to easily select the status date.
    - The "Sponsor" field is predefined and cannot be edited.
    - Review all entered information for accuracy before clicking the "Create" button
9. Now user will be able to see this product is successfully associated with the sponsor.

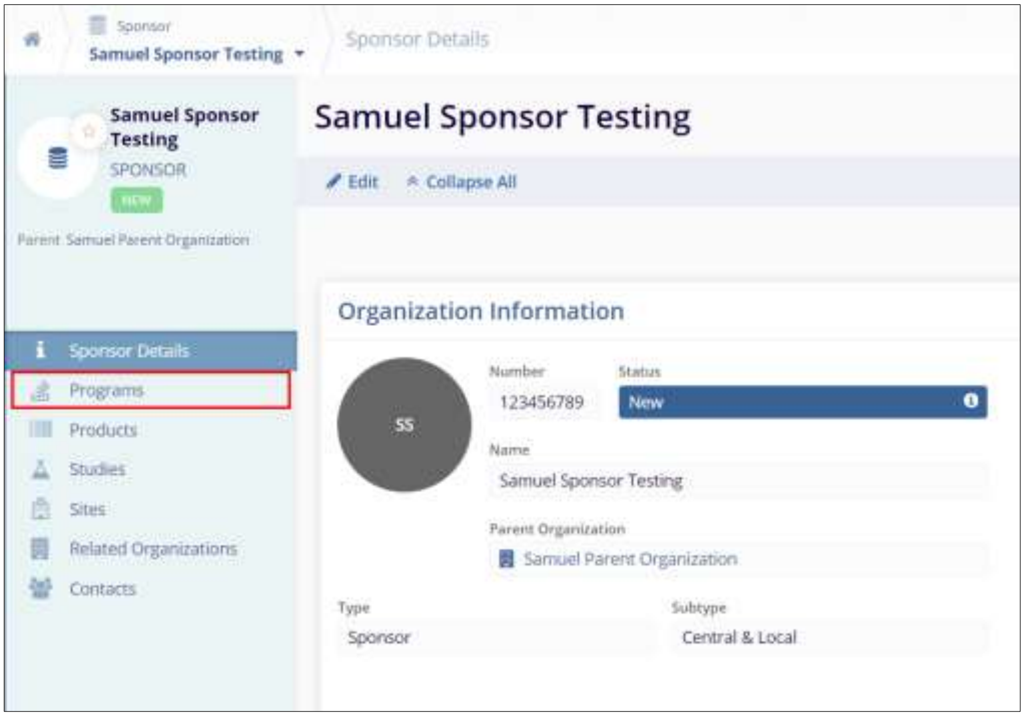
Creating a Program for a Sponsor

To navigate to the “Sponsor” list and view all global sponsors, follow these steps:

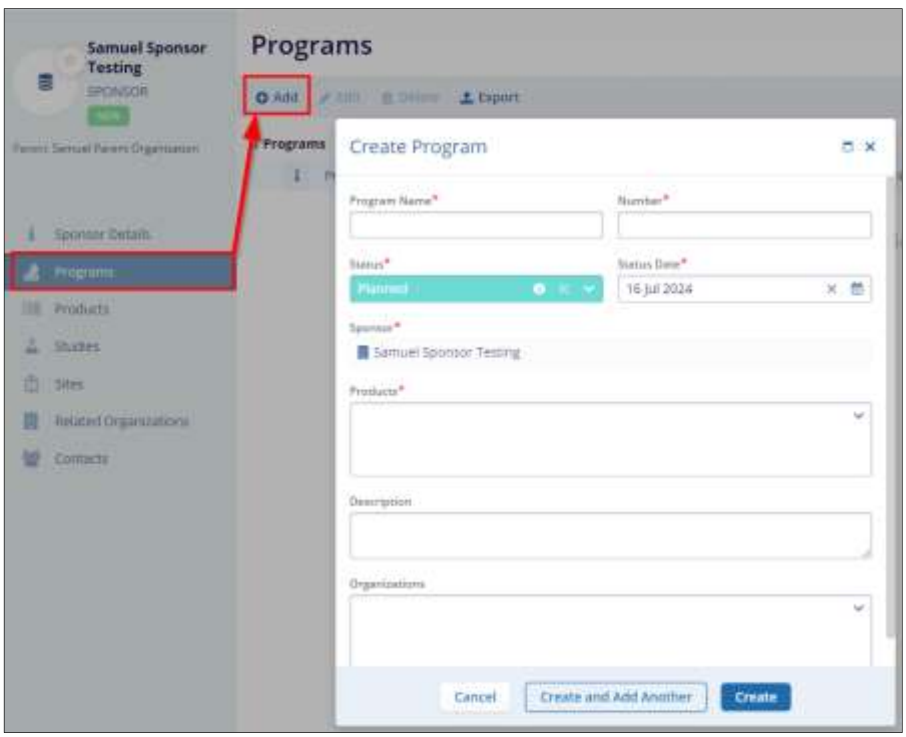
1. Click on the "Sponsor" tab located in the navigation panel on the left side of the screen.
2. This action will redirect you to the "Sponsor" page where all Sponsors at the global level will be displayed.



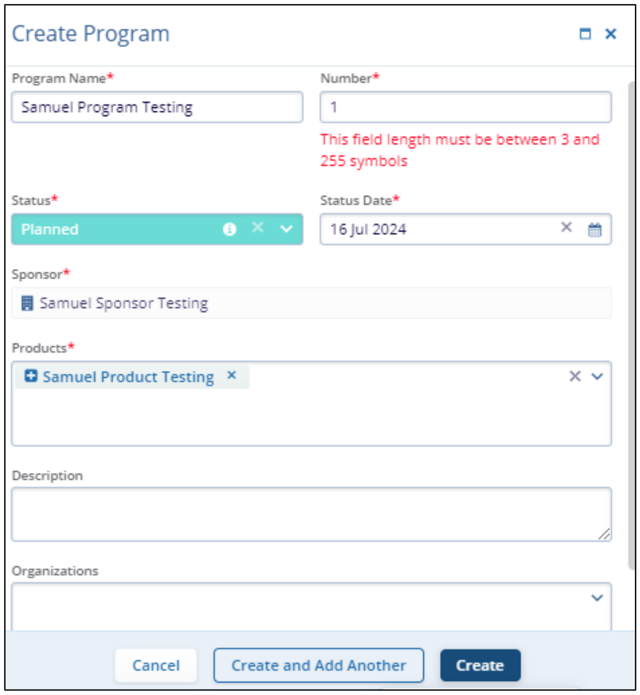
3. Click on the name of the sponsor to which you want to associate program. It will redirect you to the “Sponsor Details” page and click on the “Program” link in the Navigation menu on the left side of the screen.



4. You will be able to see the "**Program Details**" Page. To create the program click on the **"+Add"** button at the top of the grid.



Step-by-step instructions to fill in program details.



1. Fill in the Program Name

   - Field: Program Name
   - Description: Enter the name of the program you want to create. This is a mandatory field.
   - Example: Samuel Program

2. Enter the Program Number

   - Field: Number
   - Description: Enter a unique number for the program. This is a mandatory field and must be between 3 and 255 characters.
   - Example: In the screenshot 1 number is not acceptable.
   - Note: Ensure the number complies with the character length requirement.

3. Set the Program Status

   - Field: Status
   - Description: Select the current status of the program from the dropdown menu. This is a mandatory field.
   - Example: Planned

4. Specify the Status Date

   - Field: Status Date
   - Description: Enter or select the date corresponding to the program status. This is a mandatory field.

- Example: 16 Jul 2024

5. Assign a Sponsor

- Field: Sponsor
- Description: The Sponsor field is predefined and cannot be edited. This is a mandatory field.
- Example: Samuel Sponsor Testing

6. Add Products

- Field: Products
- Description: Select the products associated with the program. This is a mandatory field.
- Example: Samuel Product

7. Provide a Description

- Field: Description
- Description: Enter a brief description of the program. This is optional.
- Example: [Leave blank or provide a detailed description as needed]

8. List Organizations

- Field: Organizations
- Description: Enter any relevant organizations associated with the program. This is optional.
- Example: [Leave blank or list organizations as needed]

9. Save the Program

- Cancel: Click this button if you want to discard the information and cancel creating the program.
- Create and Add Another: Click this button if you want to save the current program and immediately start creating another program.
- Create: Click this button to save the program and complete the creation process.

Notes:

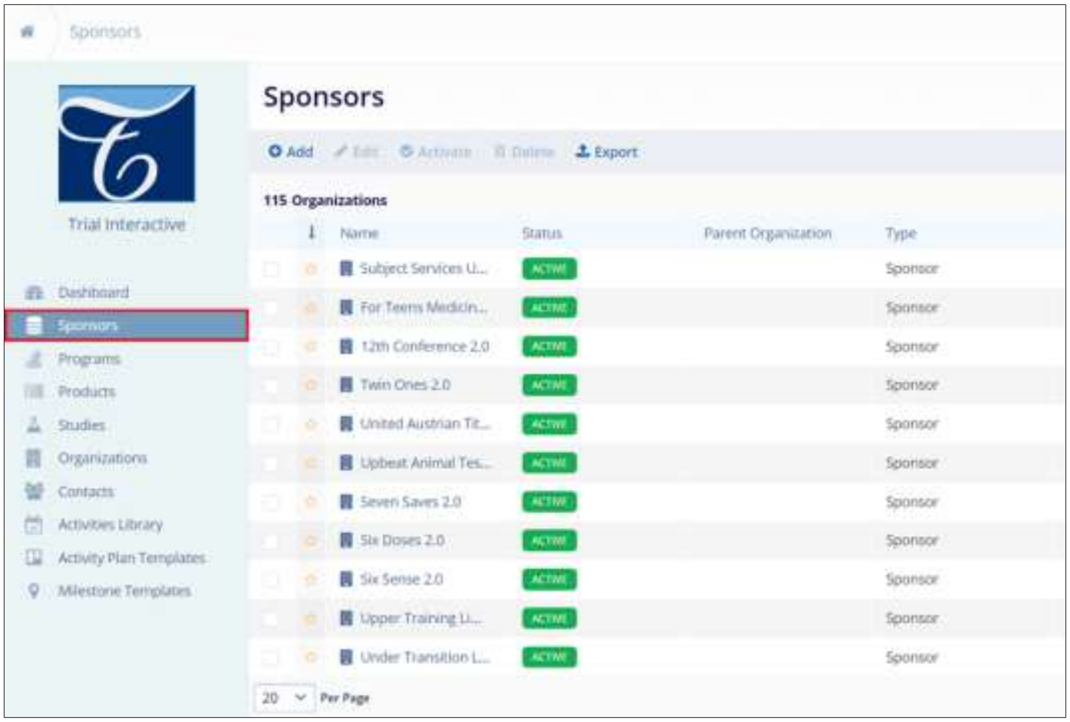
- Make sure all mandatory fields (marked with a red asterisk *) are filled out before attempting to save the program.
- Use the calendar widget to easily select the status date.
- Review all entered information for accuracy before clicking the "Create" button.
- If the program number is too short or too long, adjust it to meet the 3 to 255 character requirement.

5. Now user will be able to see this program iis successfully associated with the sponsor.

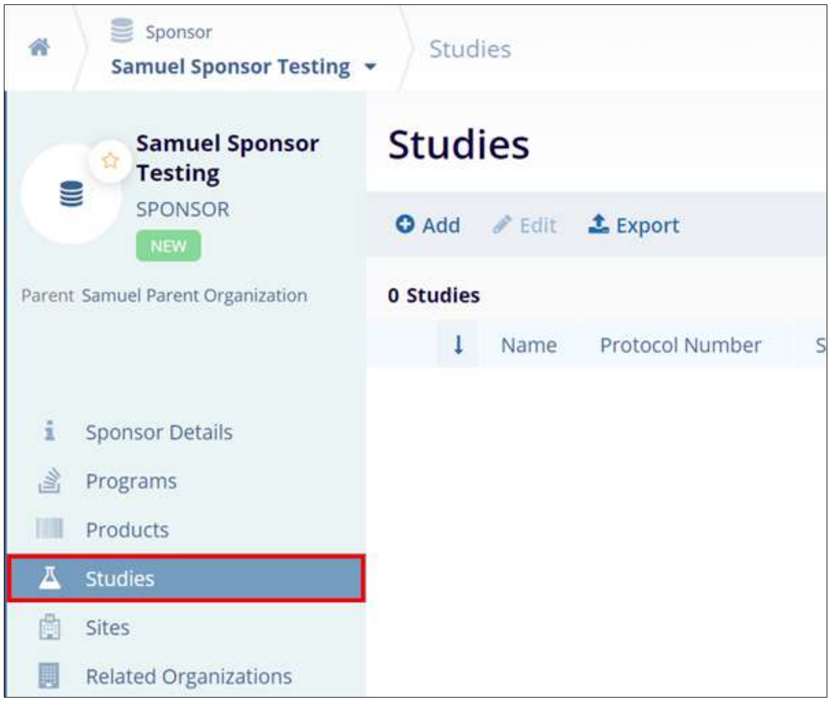
Creating a Study for a Sponsor

To navigate to the “Sponsor” list and view all global sponsors, follow these steps:

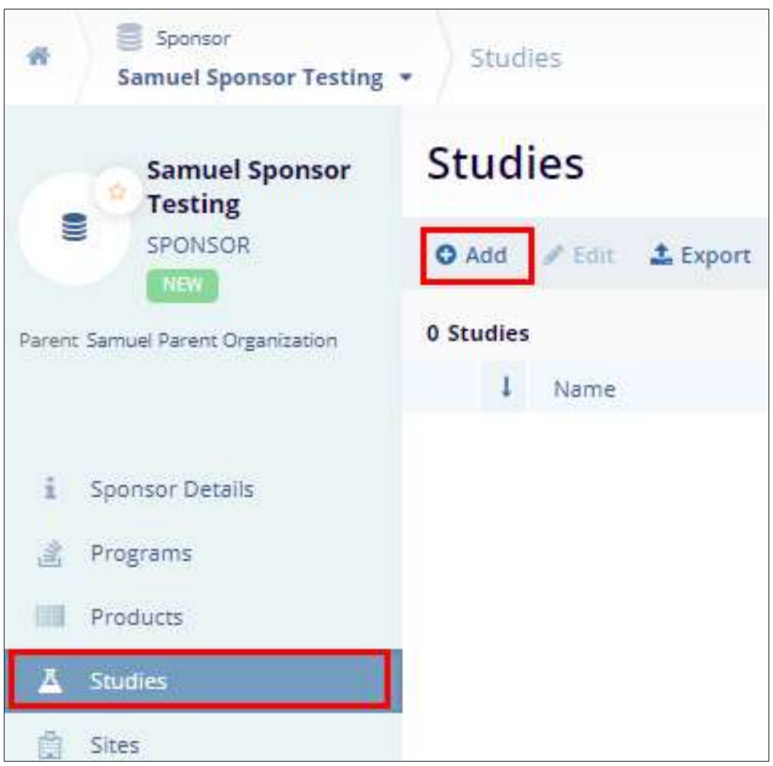
1. Click on the "Sponsor" tab located in the navigation panel on the left side of the screen.
2. This action will redirect you to the "Sponsor" page where all Sponsors at the global level will be displayed.



3. Click on the name of the sponsor to which you want to associate study. It will redirect you to the “Sponsor Details” page and click on the “Studies” link in the Navigation menu on the left side of the screen.



4. You will be able to see the "Studies" page. To create the Study click on the **"+Add"** button at the top of the grid.

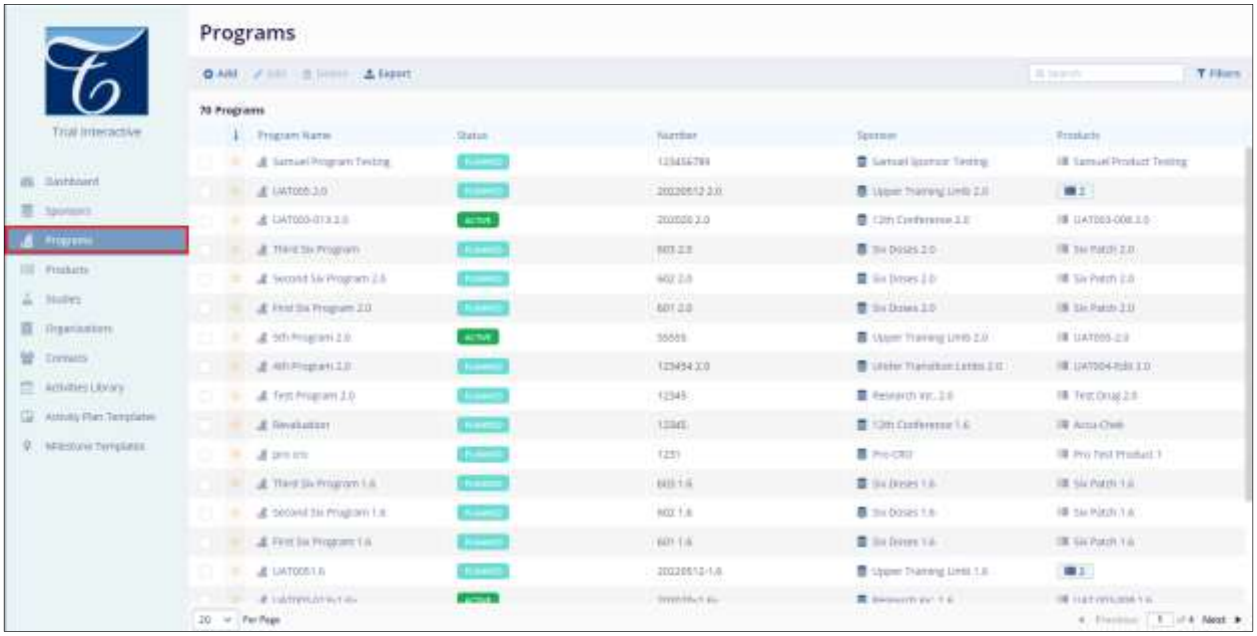


Program

Creating a Program

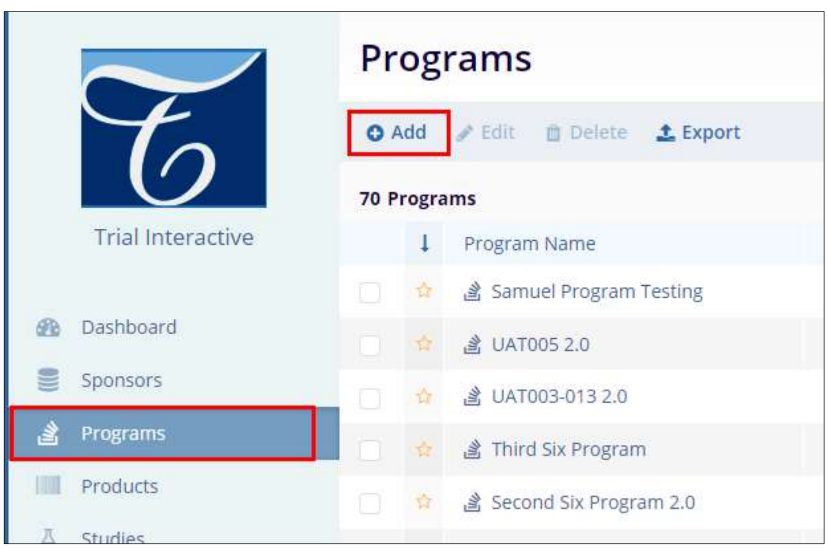
To navigate to the Program screen and view all the Program entries, follow the steps below.

1. From the left-hand navigation pane, select Program which will open the Program screen with a list of existing Programs.

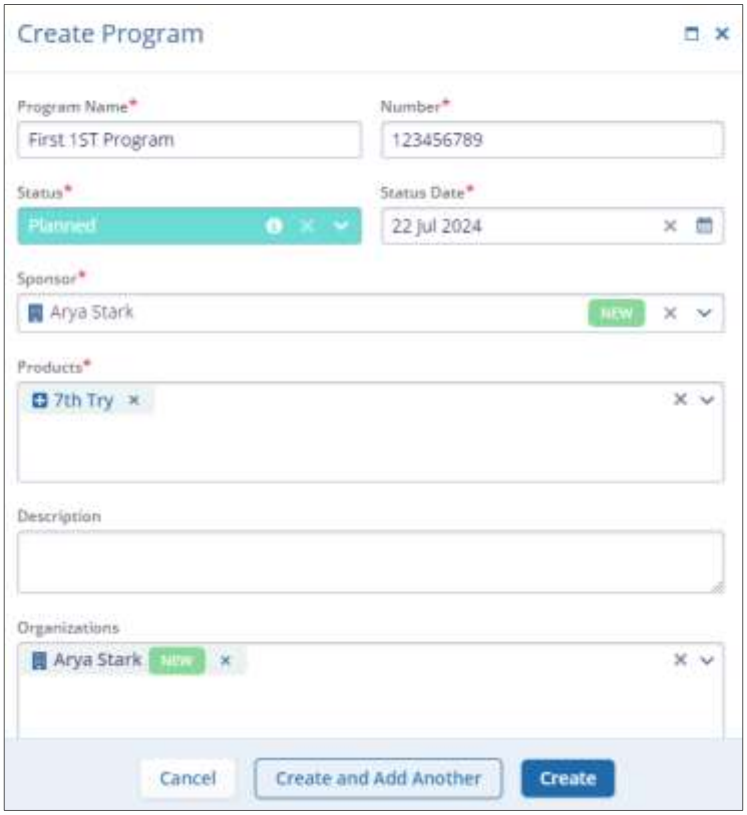


Steps to add a new Program

1. Click on +Add from the top menu bar.



2. On the Create Program window, fill in all the mandatory metadata.



Note: To create a Program, you must enter the mandatory fields Program Name, Number Status, Status Date, Sponsor, Products and Status which are marked with an asterisk (*) next to the field title. Other fields are optional.

Metadata field(s)	Description
Program Name	Enter a suitable name for the Program.
Number	Enter the unique number for the Program.
Status*	Select a suitable status from the available dropdown options. • Planned: The program is planned. • Active: The program is currently being actively used. • Approved: The program has been approved. • Archived: Program data has been archived • Cancelled: The Program has been cancelled. • Closed: The Program has reached the end and no additional data will be tracked. • Inactive: The inactive program. • Pending Approval: The Program is pending an approval.

	• Postponed: The program is postponed until a future date. • Rejected: Rejected program. Note: • The Status field will be displayed in a different color depending upon the status selected. • A tooltip showing the status description is visible after hovering over the icon.
Status Date	Enter the status date.
Sponsor	Select the sponsor's name from the available dropdown options.
Products	Select the product from the available dropdown options.
Description	Enter a suitable description for the Program.
Organization	Select the related organization.

3. Once all the mandatory metadata fields are entered and reviewed, click on Create

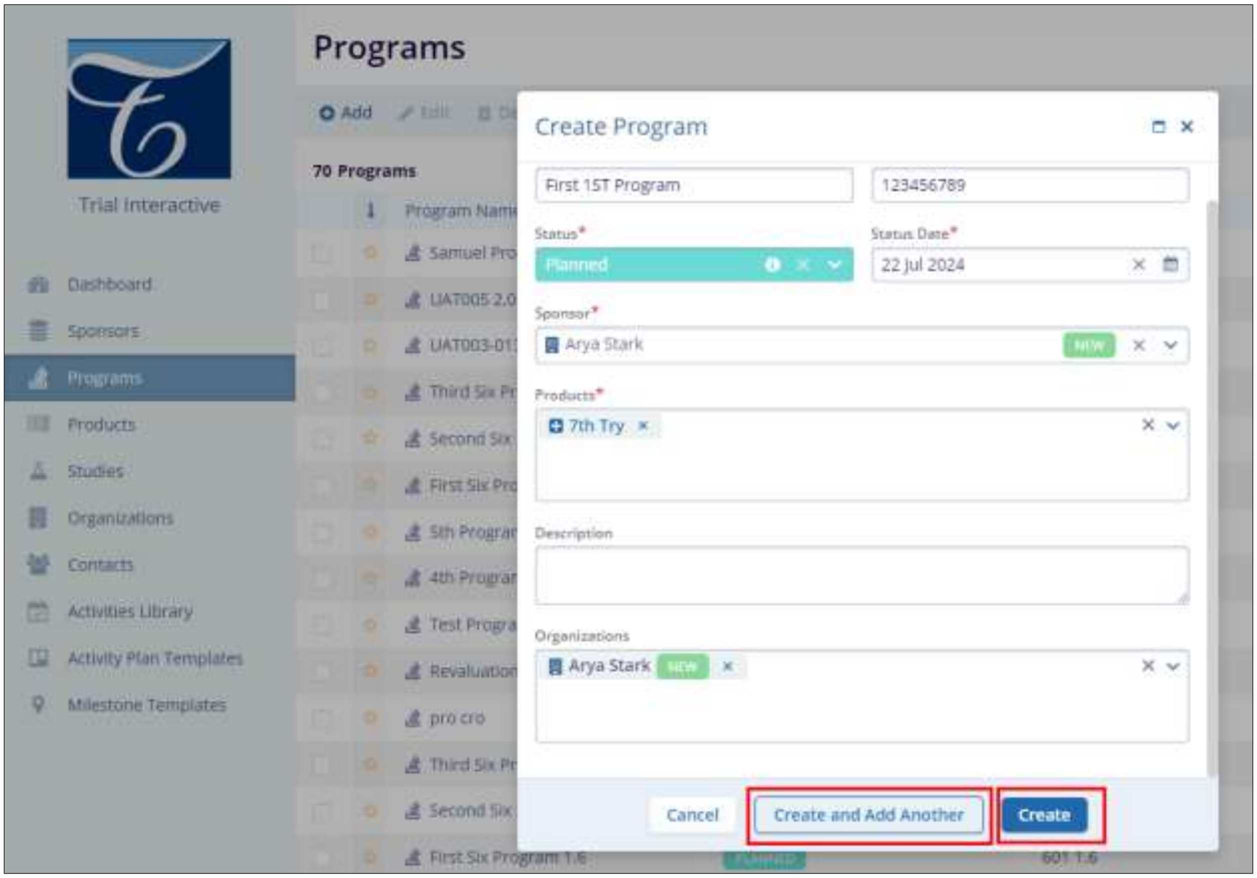


Figure: Create Program

4. The newly created Program will appear on the Program home screen.

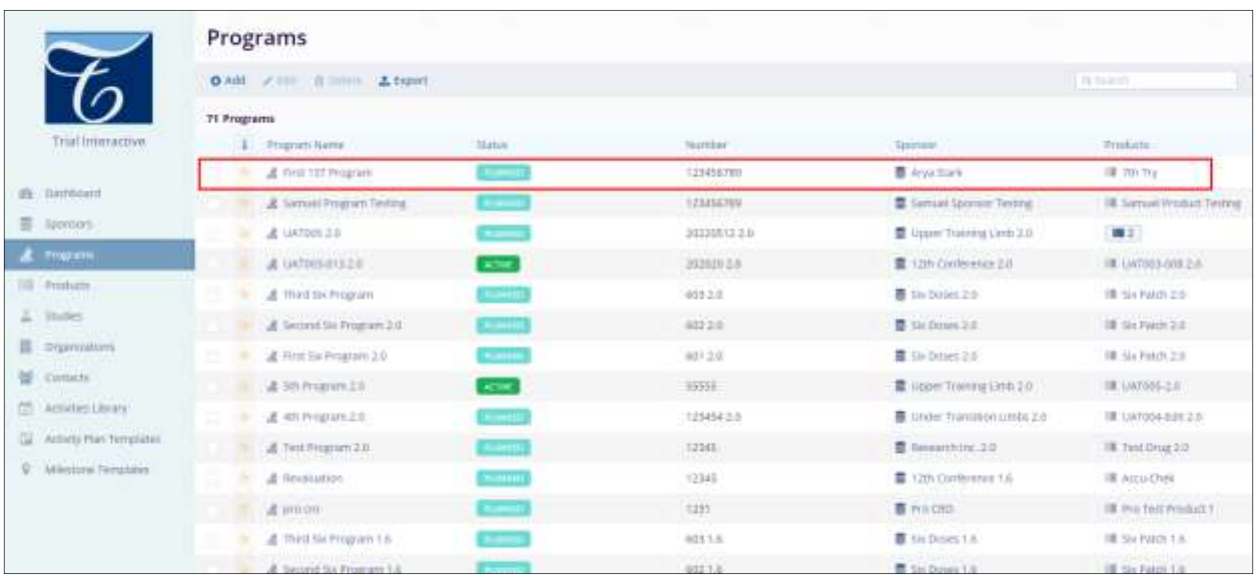


Figure: Newly created Program on the Program home screen

Important Behaviour of Create Program

- An error will appear if the user clicks on Create and any one of the mandatory metadata fields is blank.
- If the user selects Create and Add Another, the system will save the initially created Program and enable creating a new Program right away.
- If the user selects Cancel, the system will discard all the changes made to the Create Program window.

Editing and Reviewing a Program

To review and edit Program details, follow the steps below.

1. From the left-hand navigation pane, click on the Program which will open the Program screen with a list of existing Programs.
2. There are two methods to edit the Program details.

Method 1

1. Click on the “Program Name” to edit button from the main menu.

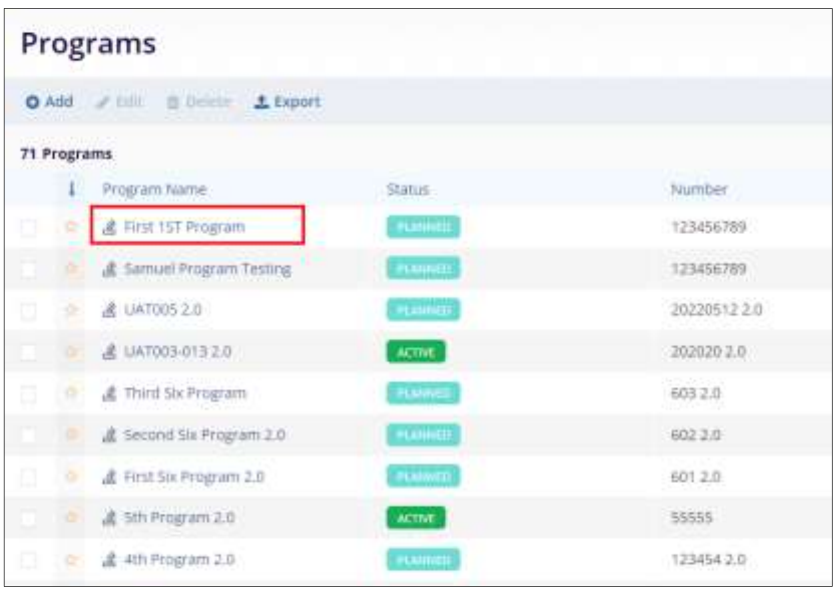


Figure: Select a Program to edit

2. It will redirect you to the Program Details screen, To click on the Edit (pencil) icon.

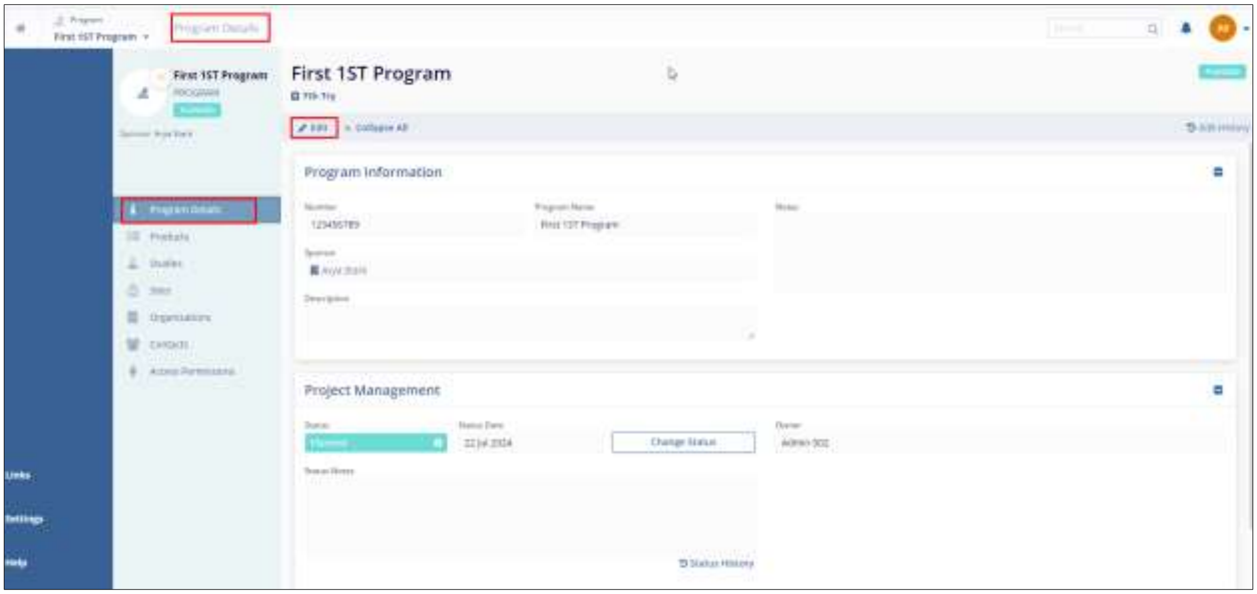


Figure: Program Details screen

3. Make the required edits in the Program Information section.
   a. Change Status:
      i. Click on Change Status.
      ii. On the Change Status screen, update the Status*, and Status Date* and enter notes if required.
      iii. Once the required changes are made, click on "Change" and the respective status-related field will be updated with the latest status, date, and notes if any.

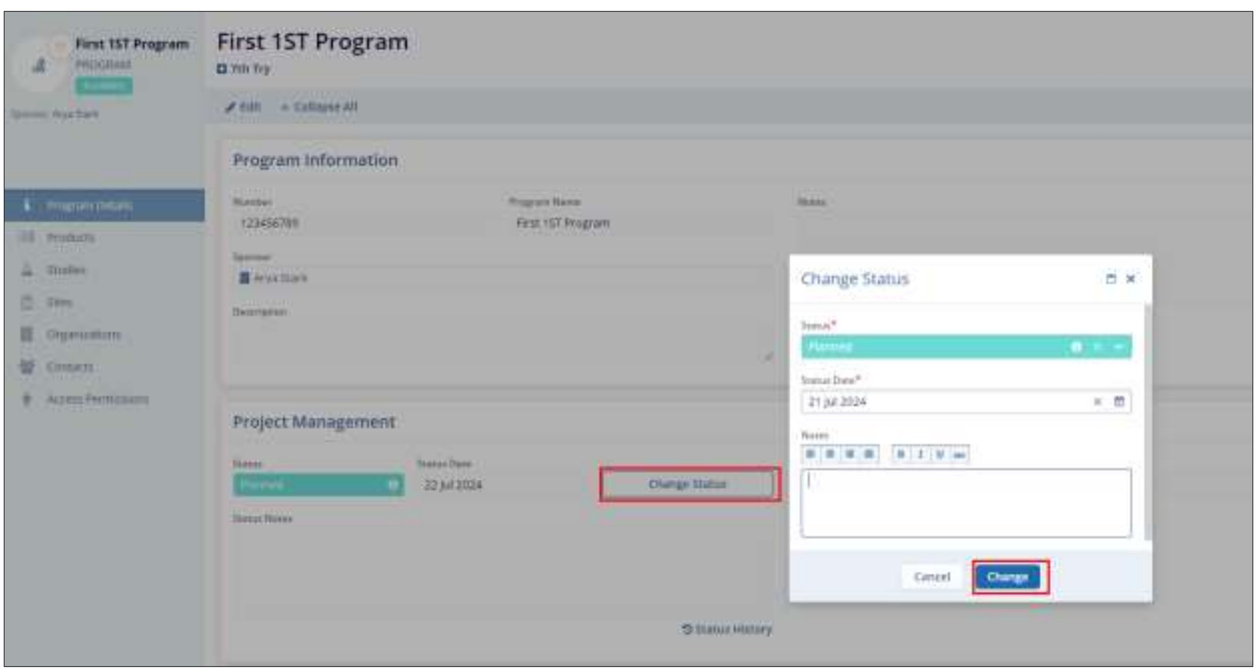


Figure: Change Status

b. Status History:

i. Click on the Status History icon.

ii. On the Status History box, the user can view the status change trail.

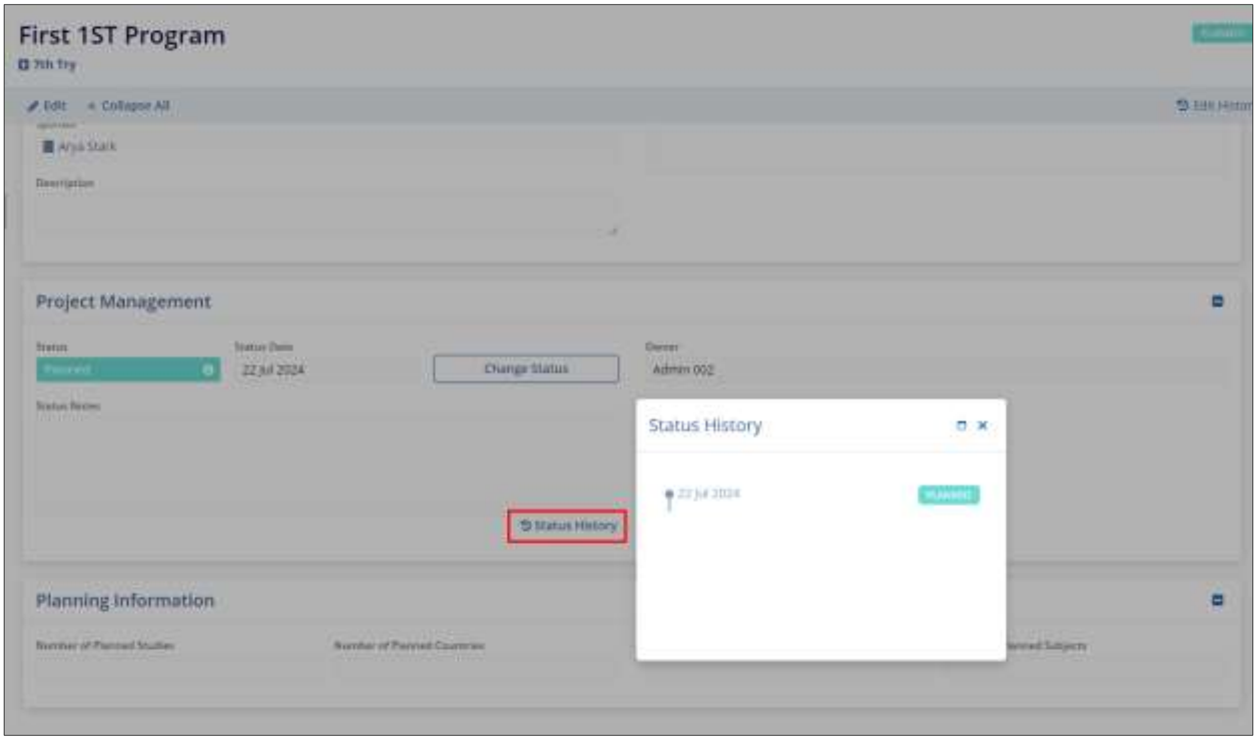
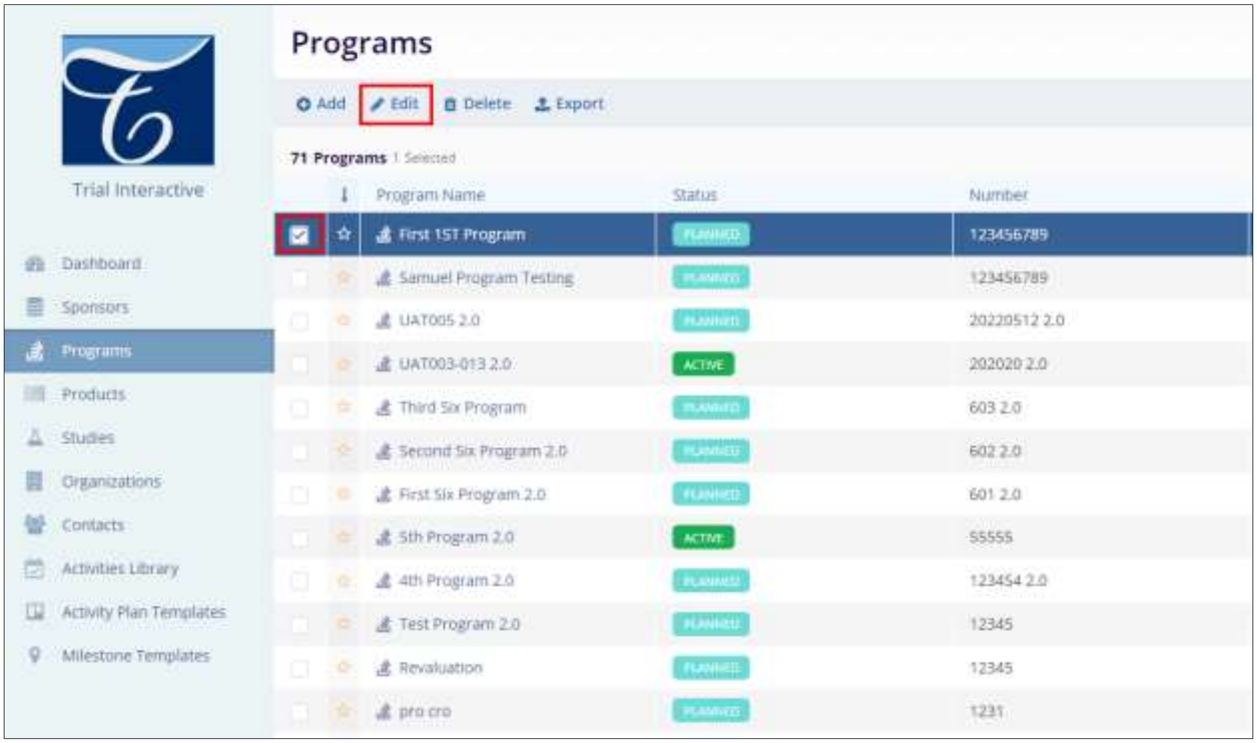


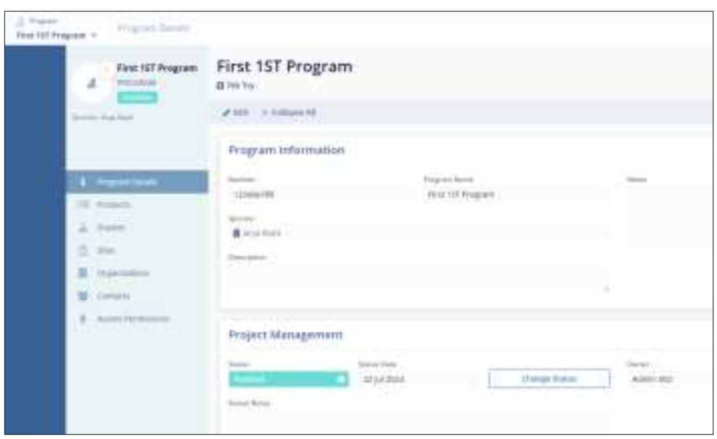
Figure: Status History

4. Once all the details are edited/updated, click on 'Save'.



Method 2

1. Click on the checkbox for the particular Program.
2. Click on the Edit (pencil) icon to edit, it will redirect you to the "Program details" screen.



3. Follow the steps detailed in Method 1 to edit and save all the Program-related details.

Deleting a Program

To delete a Program, follow the steps below.

1. Select a Program (s) by clicking on that Program checkbox.
2. Click on the Delete icon in the top menu bar and the confirmation popup will be displayed prompting to confirm the deletion.
3. Click on Delete to confirm the Program deletion.

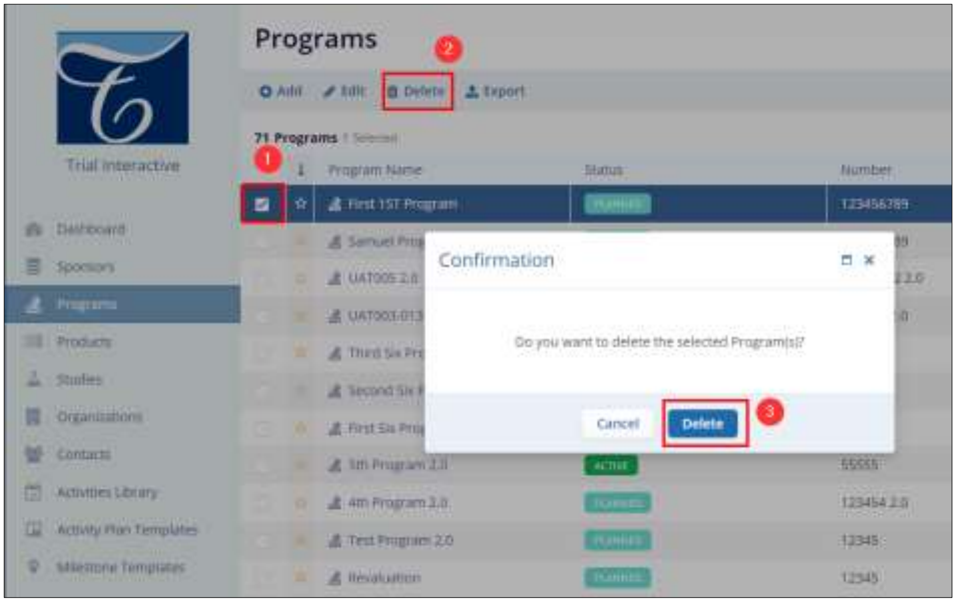


Figure: Delete Program

Exporting Program

To export Program details from CTMS, refer to the standard export steps detailed in the 'Exporting Contacts' section.

Customzing Program screen

Filters

To apply filters to the Program screen, follow the steps below.

1. To apply filters to the Program screen, click on 'Filters' situated on the right-hand side of the Program screen.
2. Click on the 'All Filter' dropdown to select and apply the required filter from the available dropdown options.

Note: By default, the Status filter is applied to the Program screen, and the dropdown options display all the statuses the user can select.

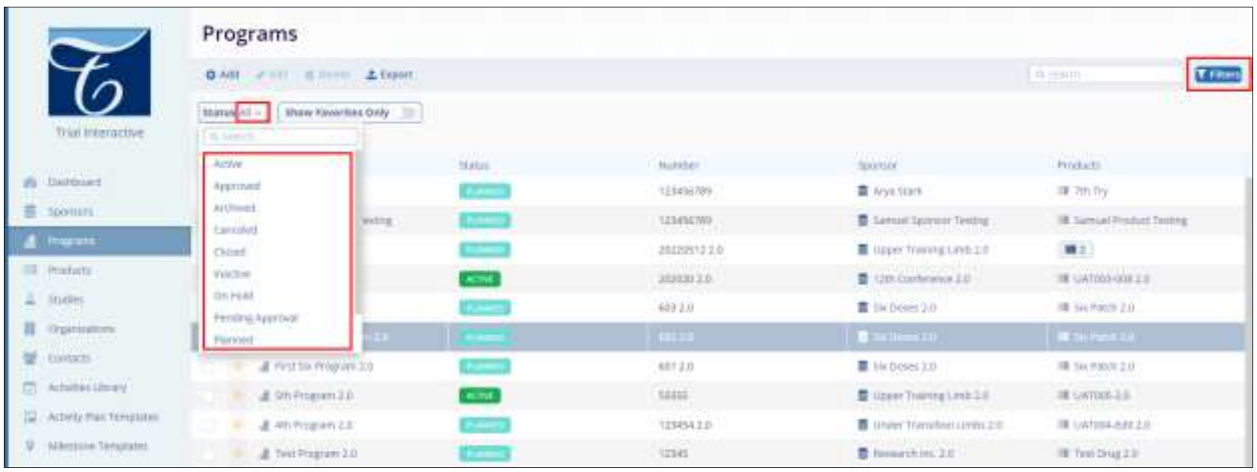


Figure: Apply Status filter

3. Switch the 'Show Favorites Only' toggle button to display records marked as favorites. Refer to the '[Marking a Program as Favorite'](#) section.

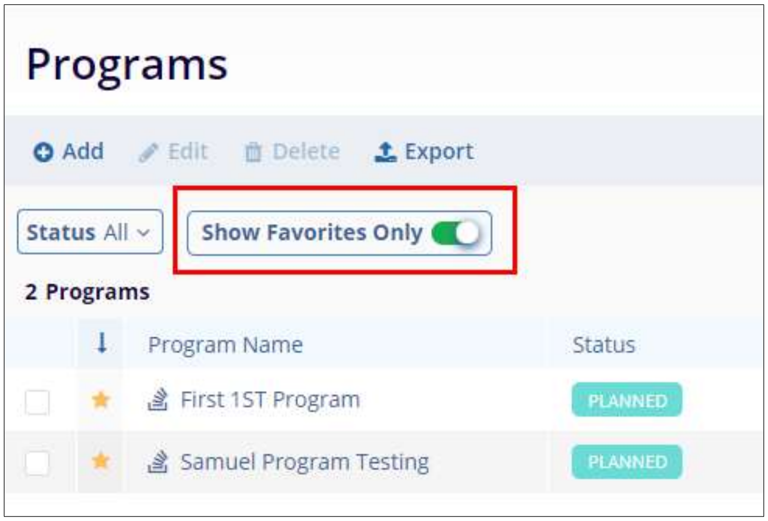


Figure: Show Favorites Only toggle

4. Click on each header's ‘Up’ and ‘Down’ arrows to sort the columns in ascending and descending order, respectively.

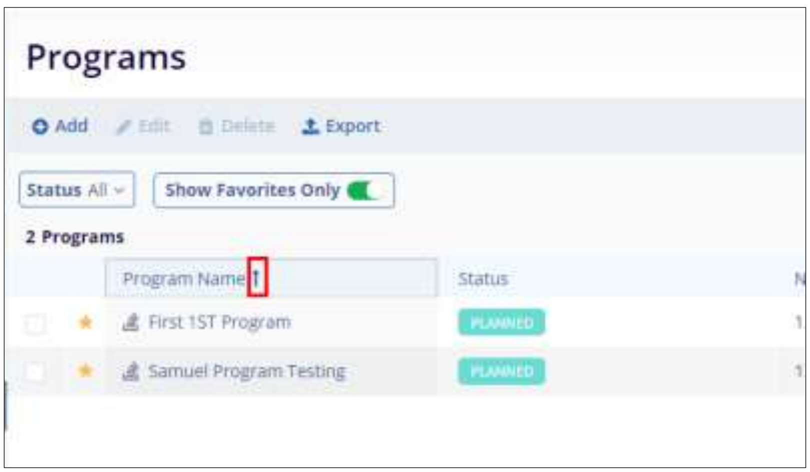


Figure: Sort column in ascending and descending order

Marking a Program as Favorite

To mark a Program as a favorite, follow the steps below.

1. To mark a Program as a favorite, simply click on the star icon next to the Program.

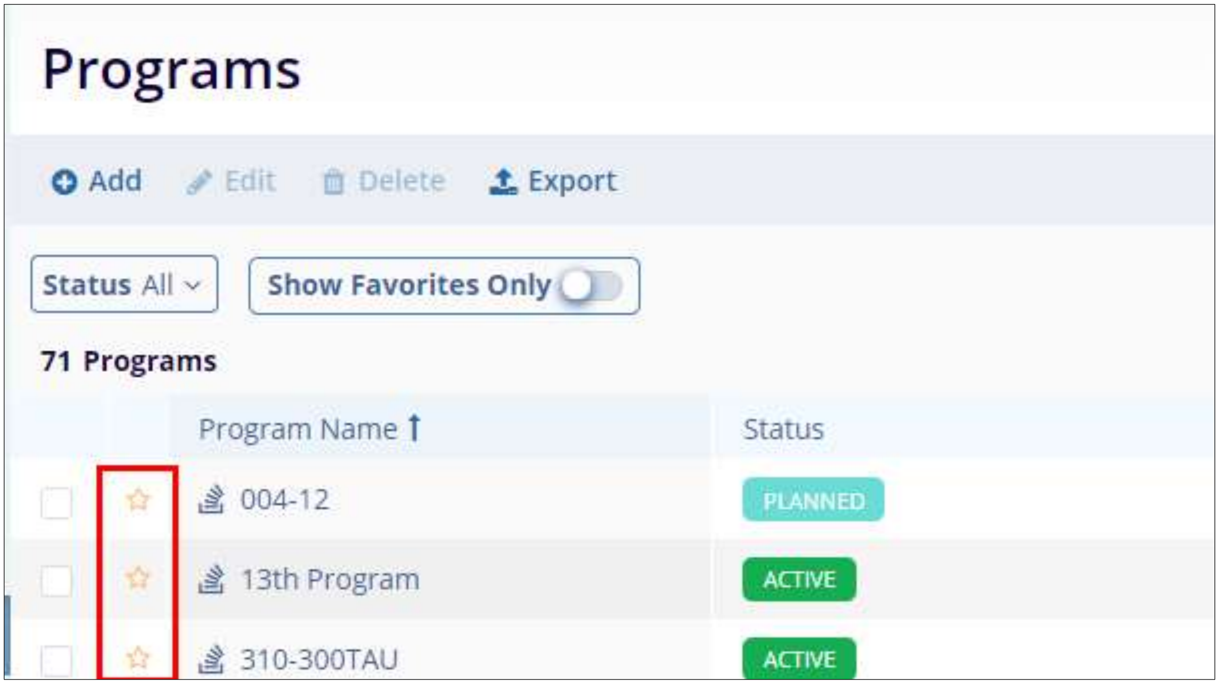


Figure: Mark as Favorite

2. Click on the same icon again to remove that Program from the favorites list.

Product

Creating a Product

To navigate to the Products screen and view all the product entries, follow the steps below.

2. From the left-hand navigation links, select Product which will open the Products screen with a list of existing products.

Steps to add a new product

5. Click on +Add from the top menu bar.
6. On the Create Product window, fill in all the mandatory metadata.

Metadata field(s)	Description
Product Name*	Enter a suitable name for the product.
Type*	Select the product type from the available dropdown options. • Combination • Custom • Device • Medicinal
Status*	Select a suitable status from the available dropdown options. • Planned: Product is planned • Active: Product is currently being actively used • Approved: Product has been approved • Archived: Product data has been archived • Cancelled: The product has been canceled • Closed: The product has reached the end and no additional data will be tracked • In Use: Product is currently in use • Inactive: Product is not currently in use • Pending Approval: The product is pending an approval • Postponed: Product is postponed until a future date • Terminated: Product has been terminated Note: • The Status field will be displayed in a different color depending upon the status selected. • A tooltip showing the status description is visible after hovering over the icon.
Status Date*	Enter the status date

Sponsor*	Select the sponsor's name from the available dropdown options.
Indications	Select one or more indications from the available dropdown options. NOTE: The Indications differ from client to client and are configured by Super Admin users.
Description	Enter a suitable description for the product.

7. Once all the mandatory metadata fields are entered and reviewed, click on Create

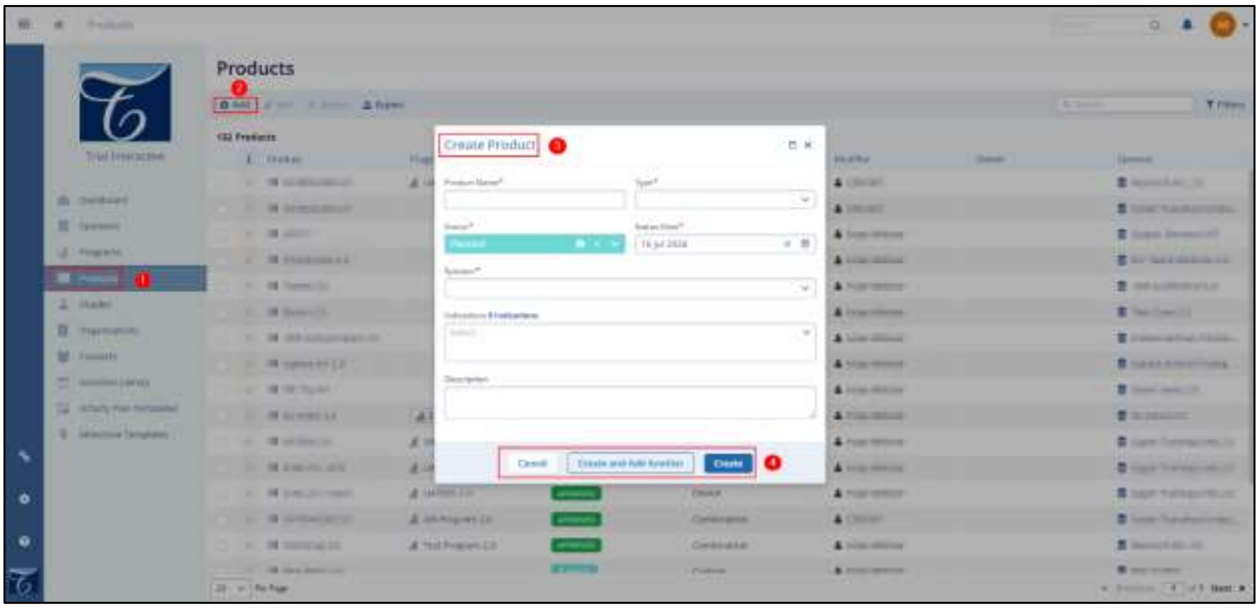


Figure: Create Product

8. The newly created product will appear on the Products home screen.

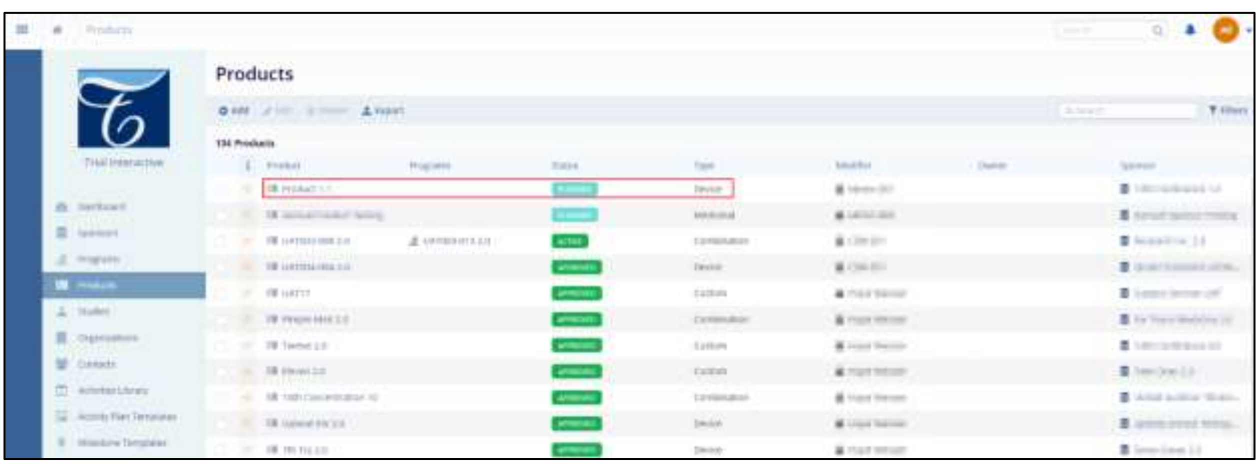


Figure: Newly created product on the Products home screen

Important Behaviour of Create Product

- An error will appear if the user clicks on Create and any one of the mandatory metadata fields is blank.
- If the user selects Create and Add Another, the system will save the initially created product and enable creating a new product right away.
- If the user selects Cancel, the system will discard all the changes made to the Create Product window.

Editing and Reviewing a product

To review and edit product details, follow the steps below.

3. From the left-hand navigation links, click on the Products which will open the Products screen with a list of existing products.
4. There are two methods to edit the product details.

Method 1

5. Click on the Product name to edit which will then open the Product Details screen.

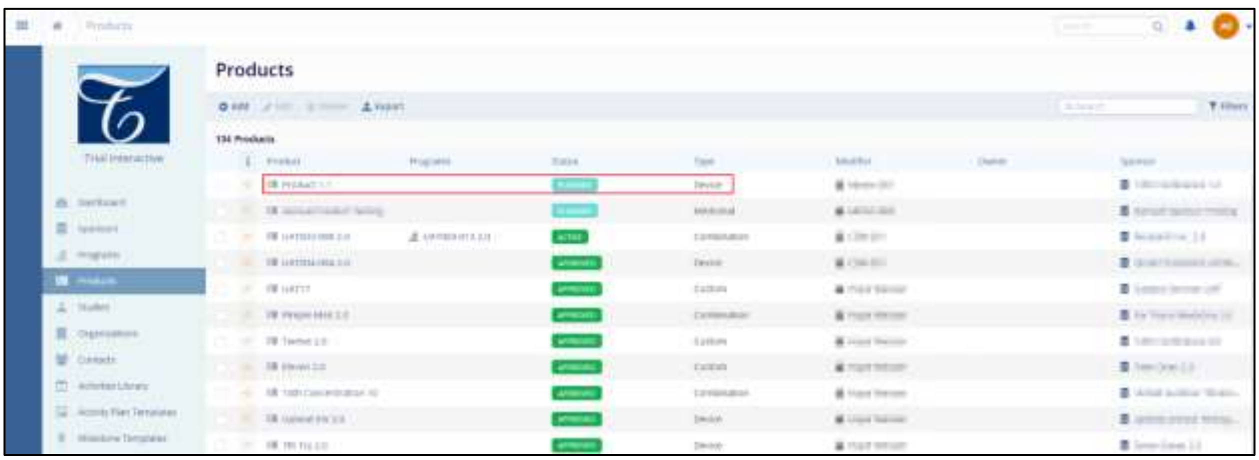


Figure: Select a product to edit

6. On the Product Details screen, click on the Edit (pencil) icon.

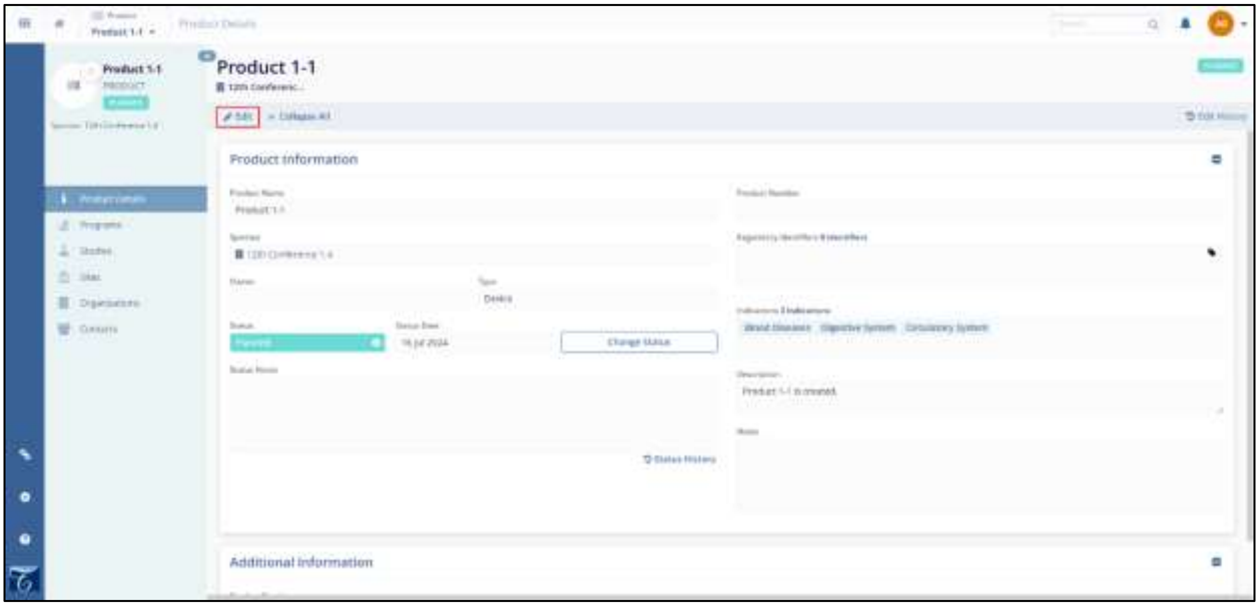


Figure: Product Details screen

7. Make the required edits in the Product Information section along with the following.
   a. Change Status:
      i. Click on Change Status.
      ii. On the Change Status screen, update the Status*, and Status Date* and enter notes if required.
      iii. Once the required changes are made, click on Change and the respective status-related field will be updated with the latest status, date, and notes if any.

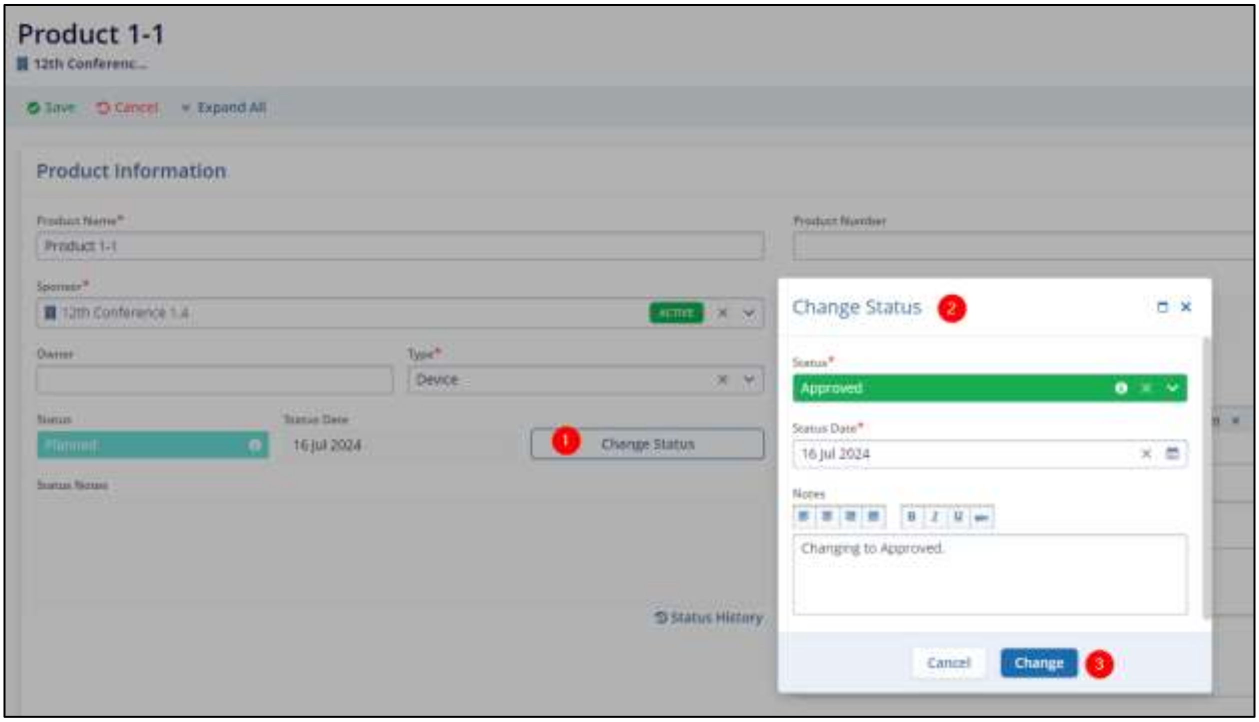


Figure: Change Status

b. Status History:
   i. Click on the Status History icon.
   ii. On the Status History box, the user can view the status change trail.

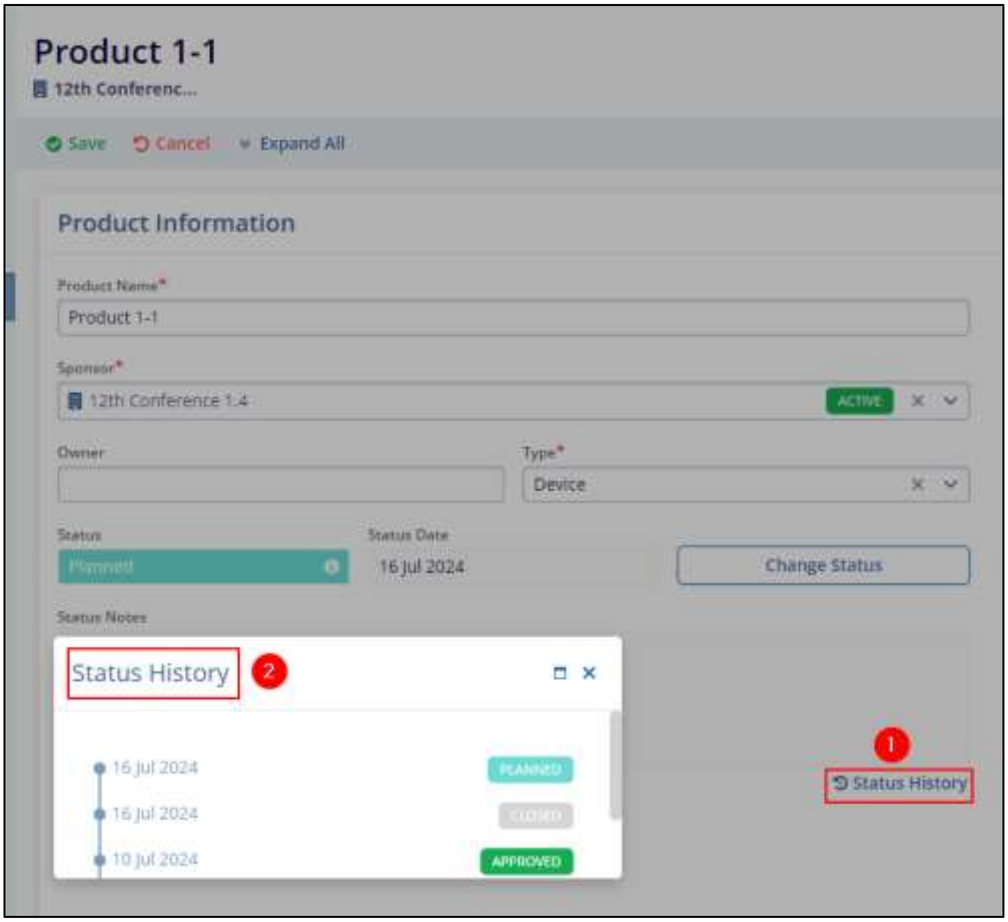


Figure: Status History

c. Regulatory Identifiers
   i. Click on the Regulatory Identifier edit (pencil) icon
   ii. Click on +Add to add a new Regulatory identifier

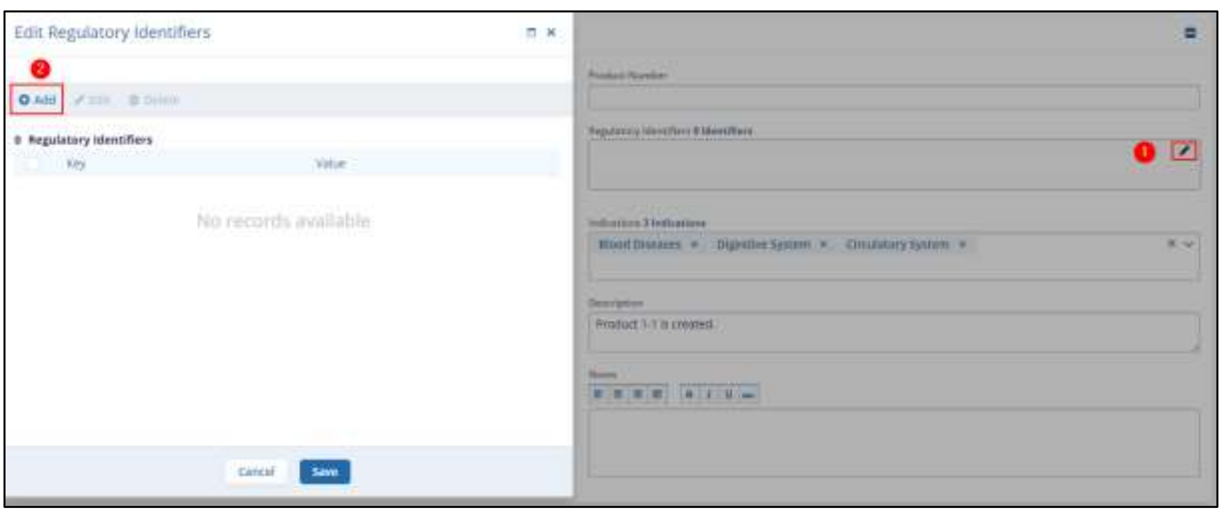


Figure: Add Regulatory identifiers

iii. In the Key field, select the required value from the available dropdown options.
iv. Enter the suitable value in the Value field.
v. Once the required details are added, click on Save

Figure: Add a value to the Key and Value fields

vi. Click on the checkbox for the newly added Regulatory Identifier and click on Save.

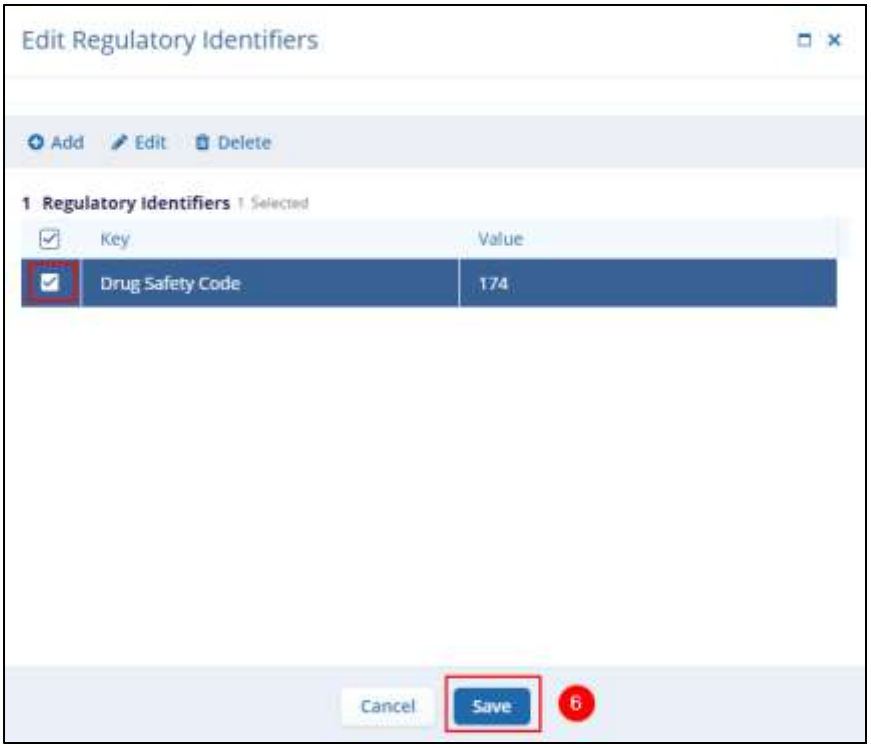


Figure: Save the new Regulatory Identifier

8. Once all the details are edited/updated, click on Save

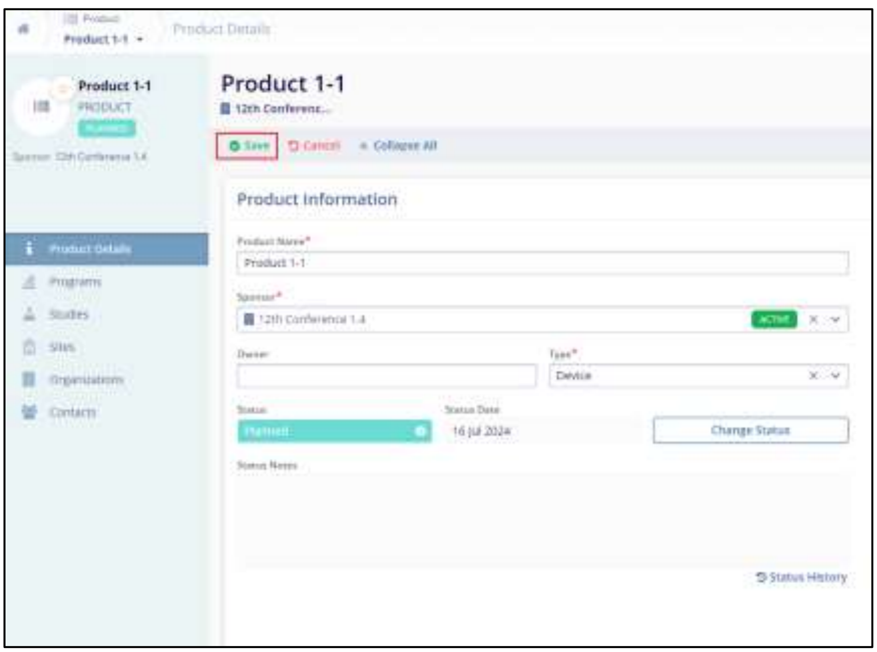


Figure: Save the edited/updated product details

Method 2

4. Click the checkbox for the particular product
5. Click on the Edit (pencil) icon to edit the product details
6. Follow the steps detailed in Method 1 to edit and save all the product-related details.

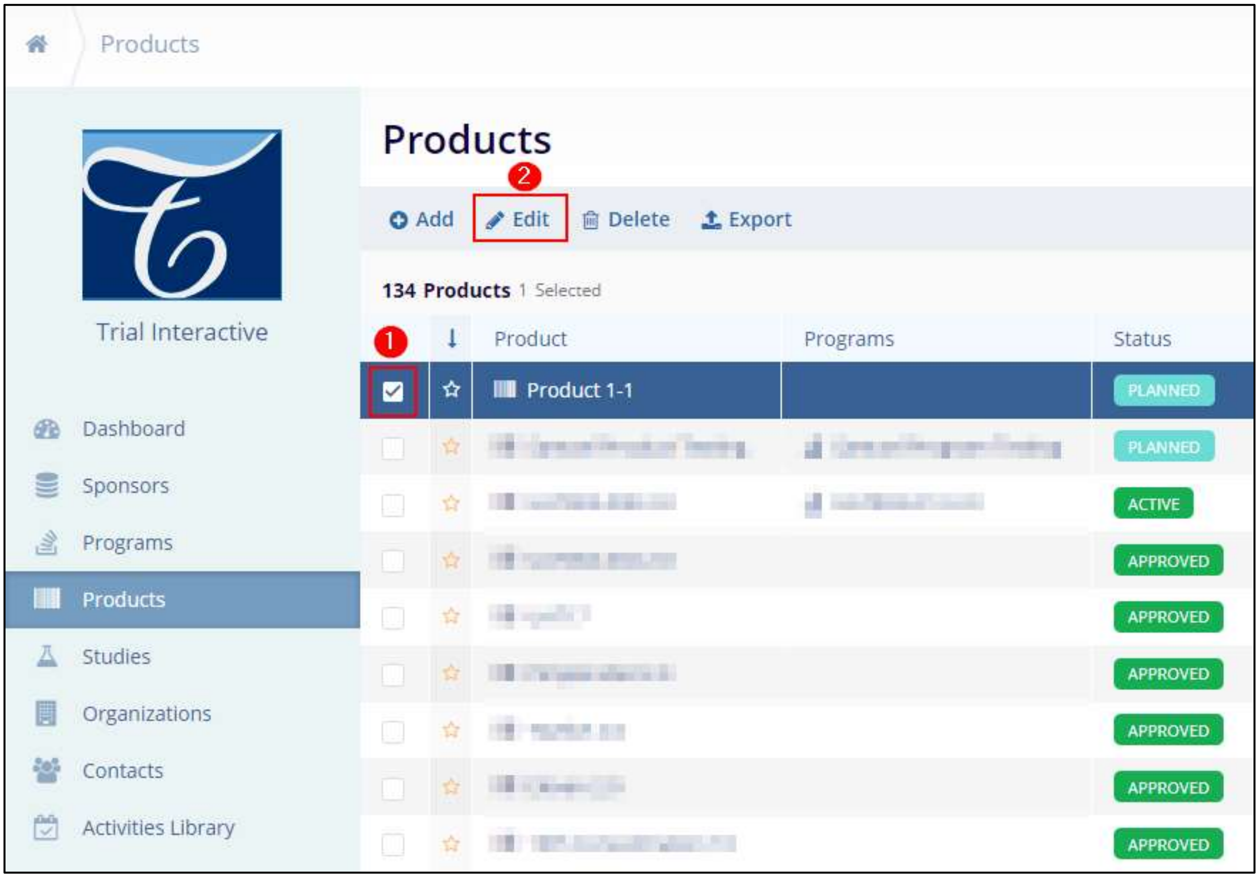


Figure: Edit Product details

Deleting a Product

To delete a product, follow the steps below.

4. Select a product (s) by clicking on that product checkbox.
5. Click on the Delete icon in the top menu bar and the confirmation popup will be displayed prompting to confirm the deletion.
6. Click on Delete to confirm the product deletion.

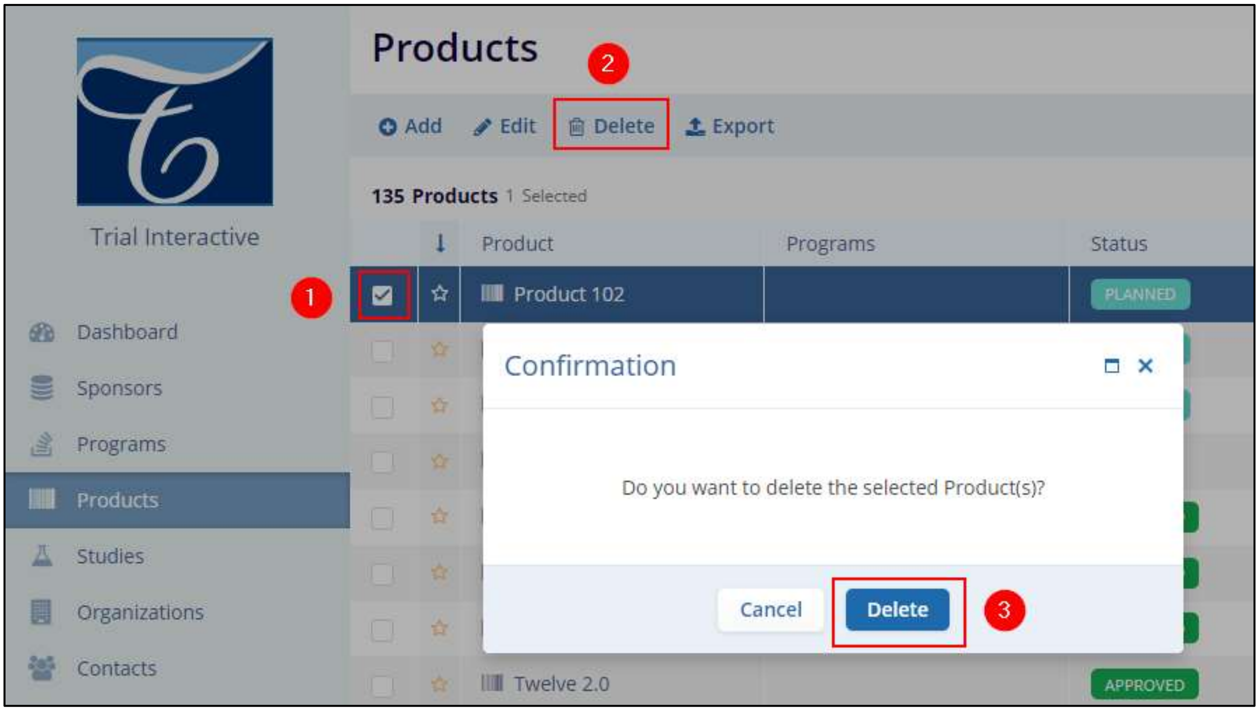


Figure: Delete product

Exporting Products

To export product details from CTMS, refer to the standard export steps detailed in the Exporting Contacts section.

Customzing Products screen

Filters

To apply filters to the product screen, follow the steps below.

5. To apply filters to the Products screen, click on Filters situated on the right-hand side of the Products screen.
6. Click on the All Filter dropdown to select and apply the required filter from the available dropdown options.

   Note: By default, the Status filter is applied to the Products screen, and the dropdown options display all the statuses the user can select.

Figure: Apply Status filter

7. Switch the Show Favorites Only toggle button to display records marked as favorites. Refer to the Marking a product as Favorite section.

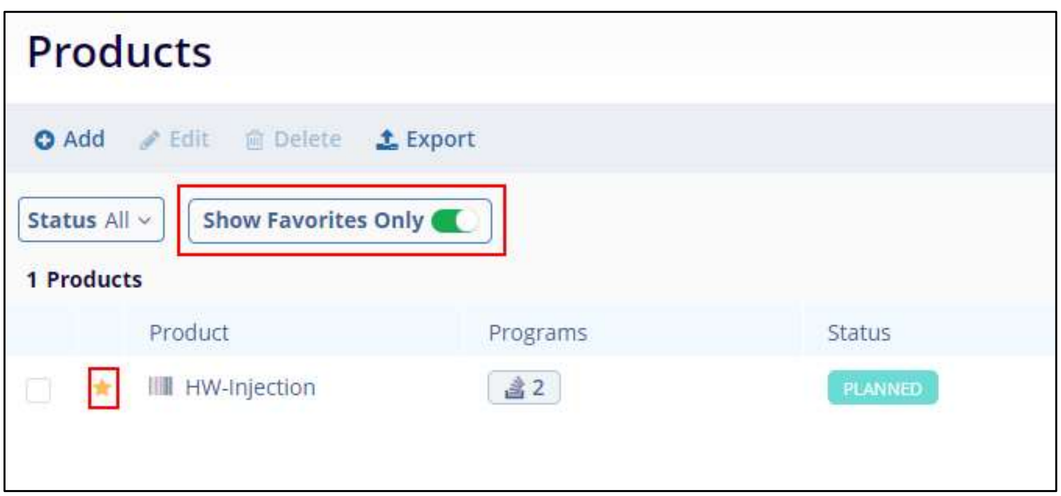


Figure: Show Favorites Only toggle

8. Click on each header's Up and Down arrows to sort the columns in ascending and descending order, respectively.

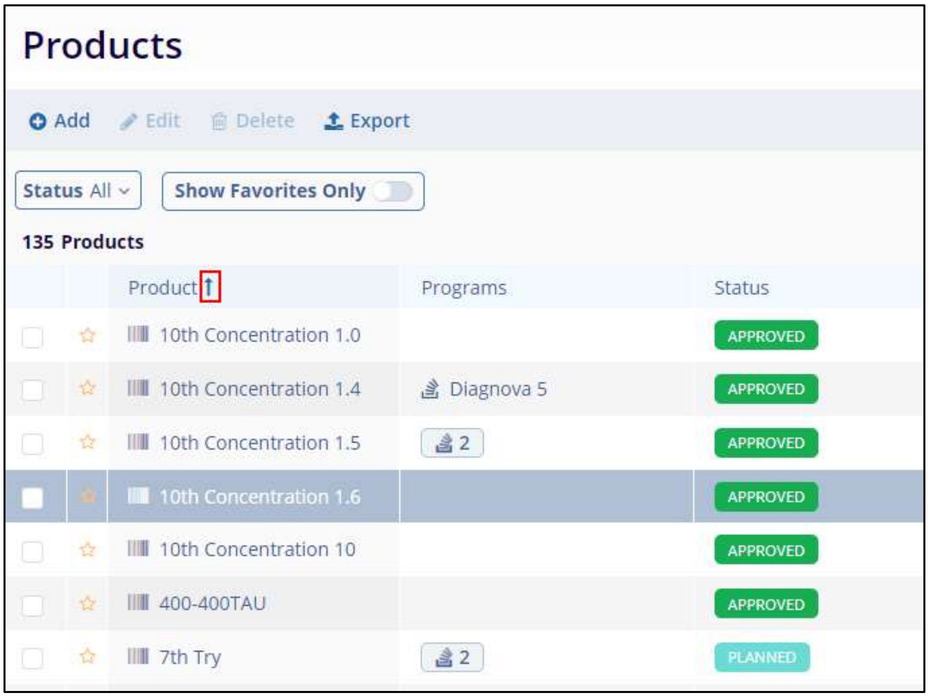


Figure: Sort column in ascending and descending order

Marking a product as Favorite

To mark a product as a favorite, follow the steps below.

3. To mark a product as a favorite, simply click on the star icon next to the product.

Figure: Mark as Favorite

Click on the same icon again to remove that product from the favorites list.

Site Visit Documentation

Site visits 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 CTMS to work with Trial Interactive's eTMF solution, please reach out to the Trial Interactive representative.

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.

Site Visit Navigation

To navigate to the site visit, follow the steps below

1. From the left-hand navigation links, click on Studies.
2. Click on the study's name to select that particular study.

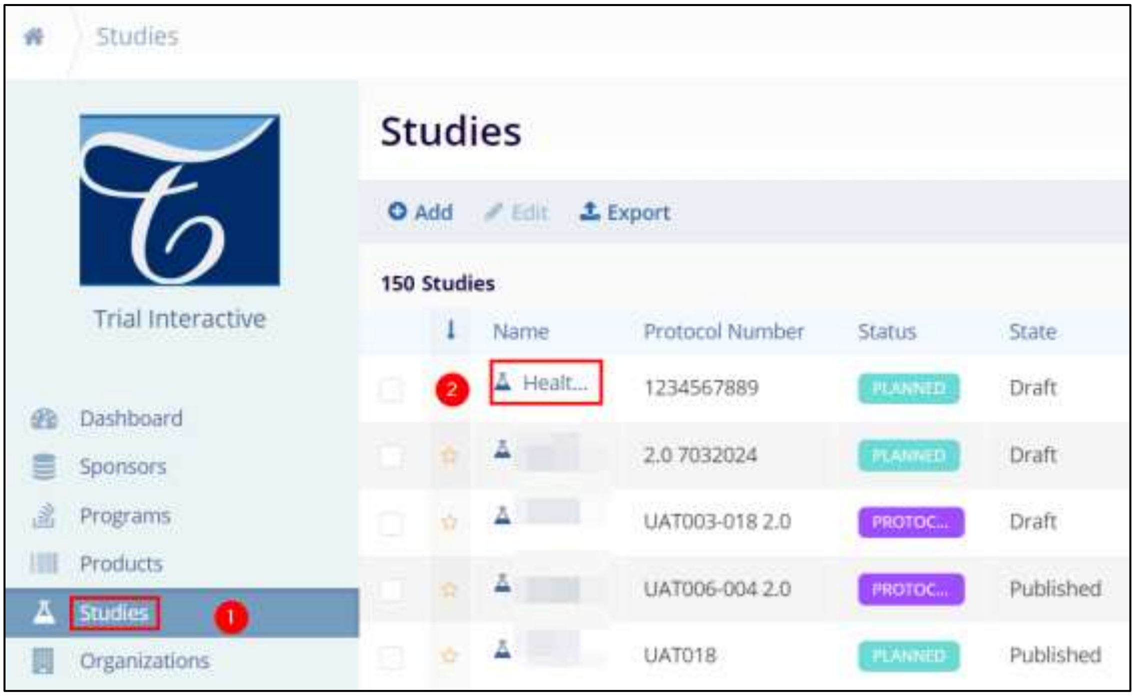


Figure: Select a Study and a study name

3. On the Study Dashboard, navigate to the left-hand navigation links and click on Sites.

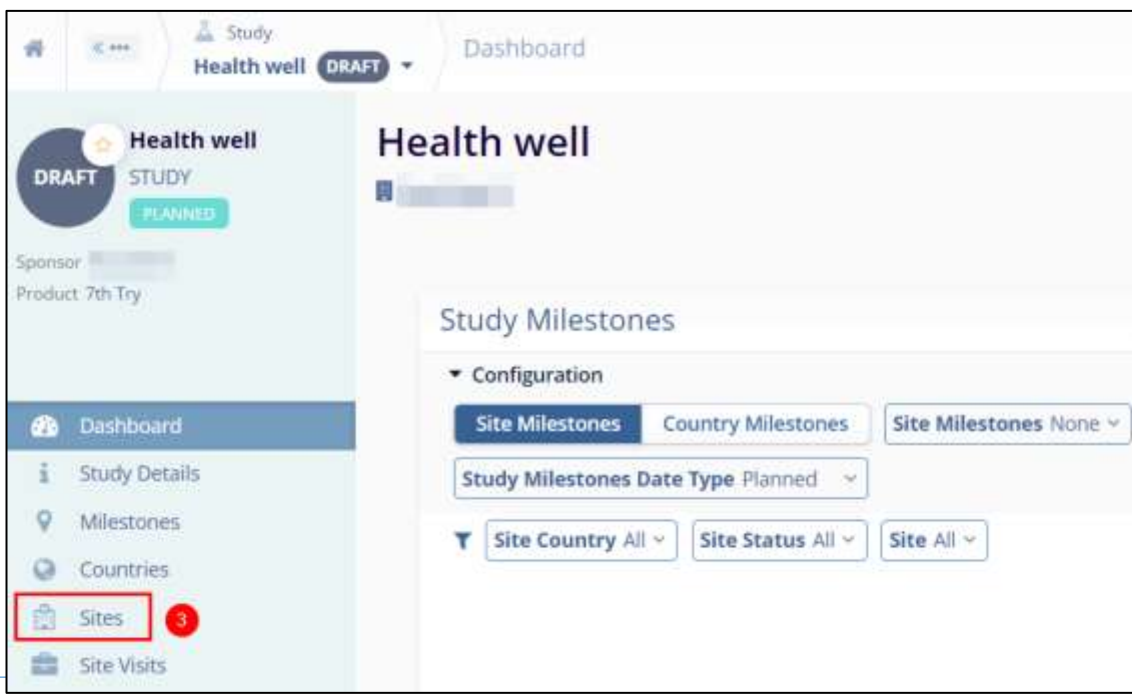


Figure: Select Sites from the Study Dashboard

4. On the Sites screen, navigate to the site records section and select a site by clicking on the site name.

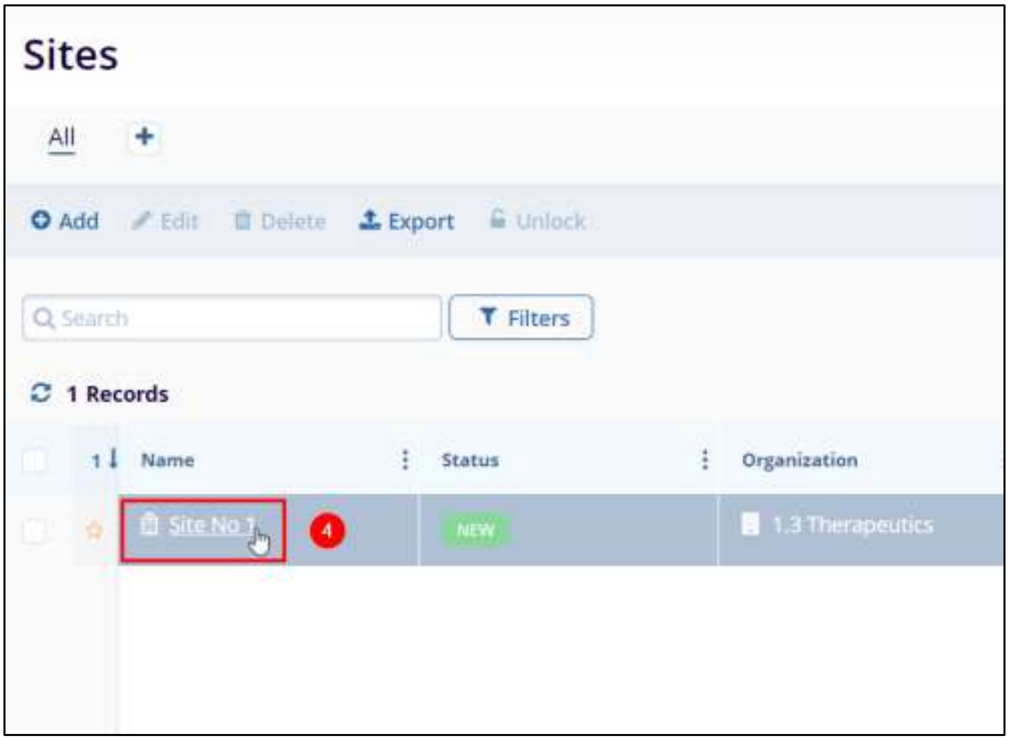


Figure: Select site

5. On the selected site window, navigate to the left-hand navigation links and select Site Visits.

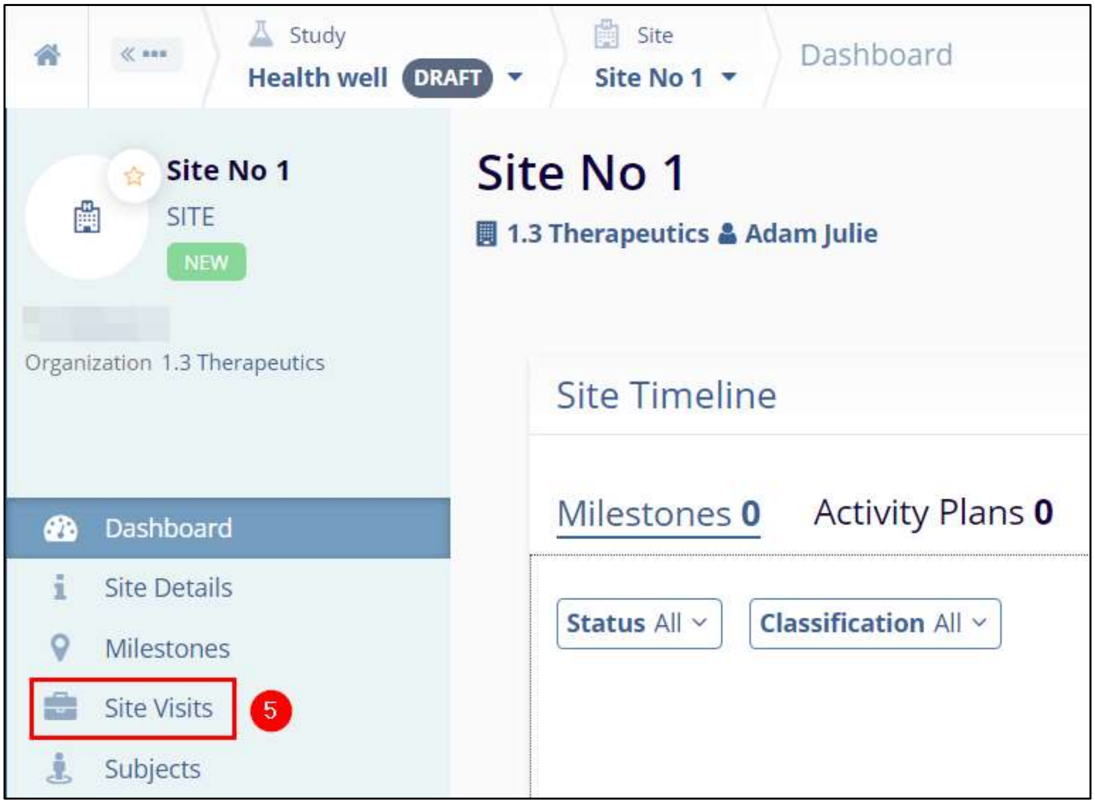


Figure: Select Site Visits

6. On the Site Visits screen, select the visit to review by clicking on the visit name.

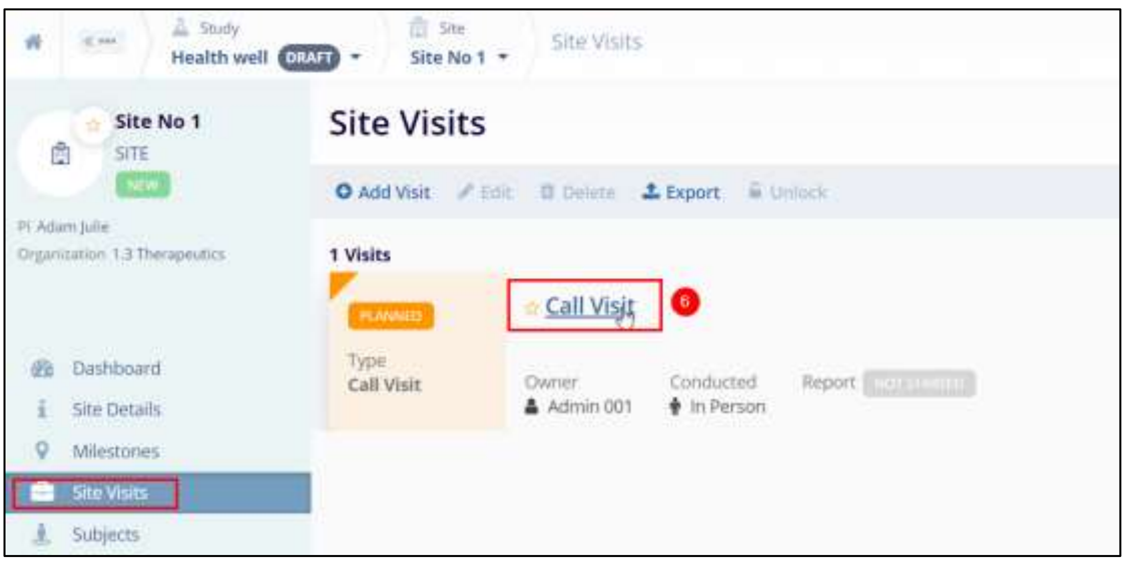


Figure: Select a visit

7. On the Site Visit General Information window, review the visit details, make the required changes if any, and click on the following buttons.

a. Add Activity: Refer to the [Creating Domain Library Activity Records] section to add an activity.
b. Discard Changes: Click on Discard Changes to remove any changes made.
c. Save: Click on the Save button to save the changes made
d. Click on the Save and Next button to save the changes on the current activity and move on to the other activity.
e. Next Step: Clicking on Next Step will display a confirmation popup and clicking on Yes will display further details regarding the site visit.

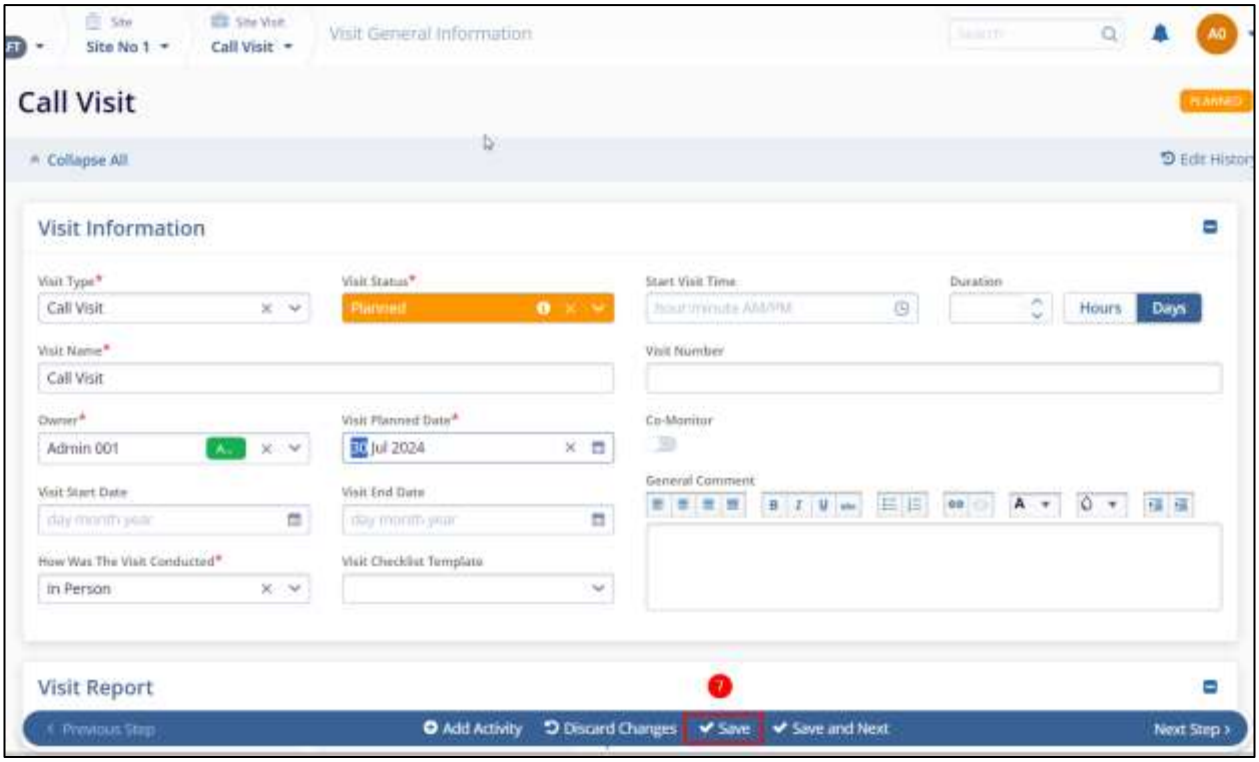


Figure: Updating site visit information

Site Visit Attendees

To view the site visit attendee details, follow the steps below.

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Visit Attendees link.
2. Click on the +Add Attendees dropdown and select + Add Attendees button.

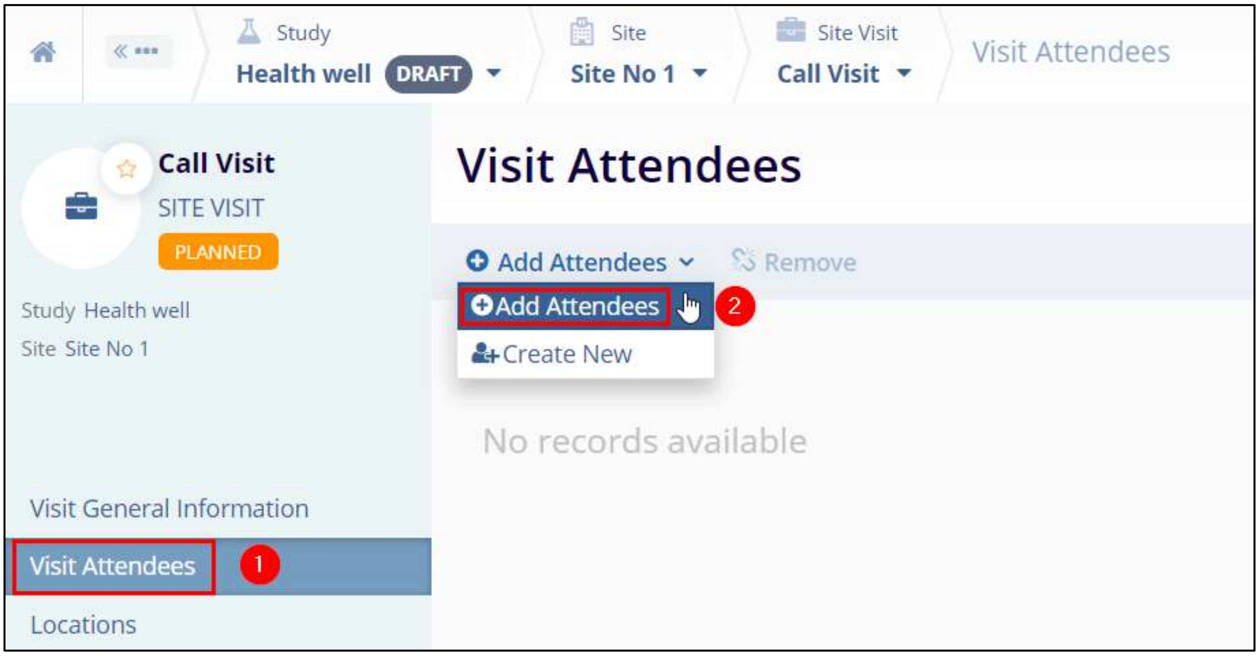


Figure: Add Attendees

3. On the Add Attendees screen click on the All Site Contacts option.
4. Select attendees by clicking on the checkbox.
5. Once the attendees are selected, click on the Add Attendees button.

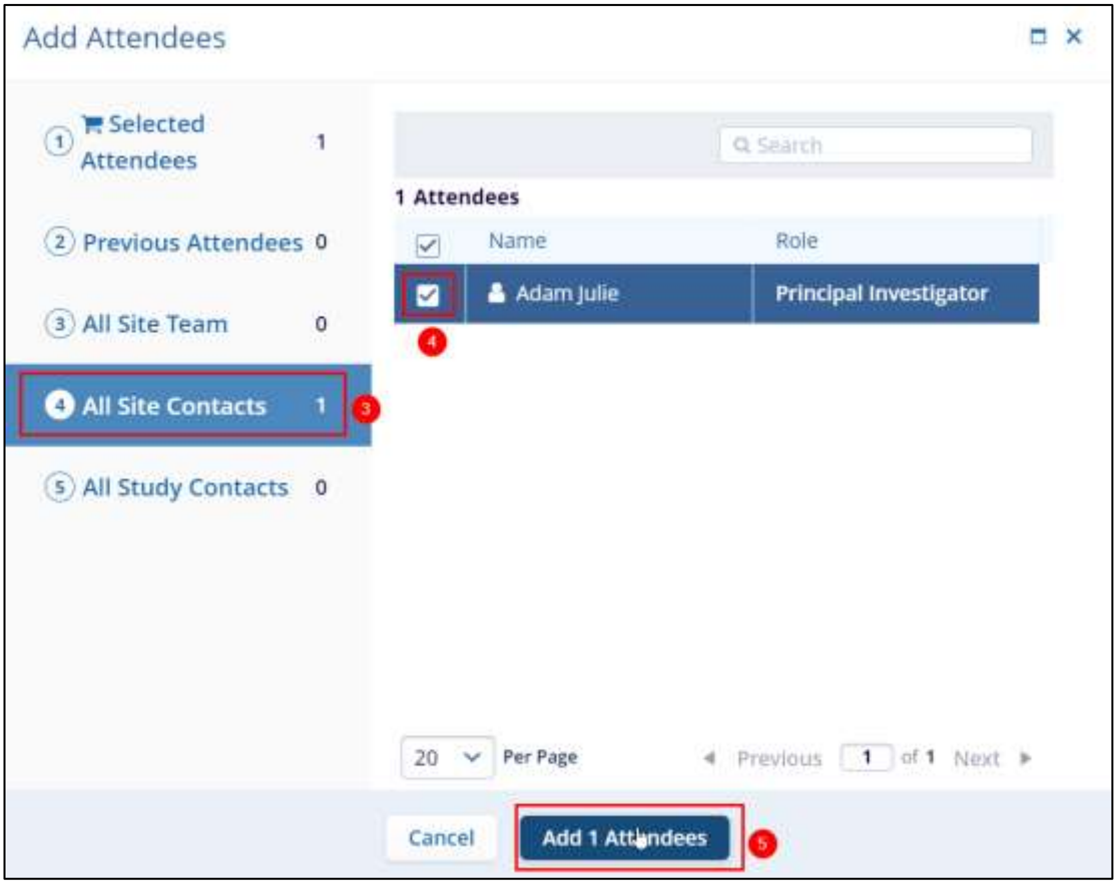


Figure: Add attendees from All Site Contacts

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

Site Visit Locations

To access Site Visit Locations, follow the steps below.

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Locations link.
2. Click on +Add Locations dropdown and select +Add Locations option.

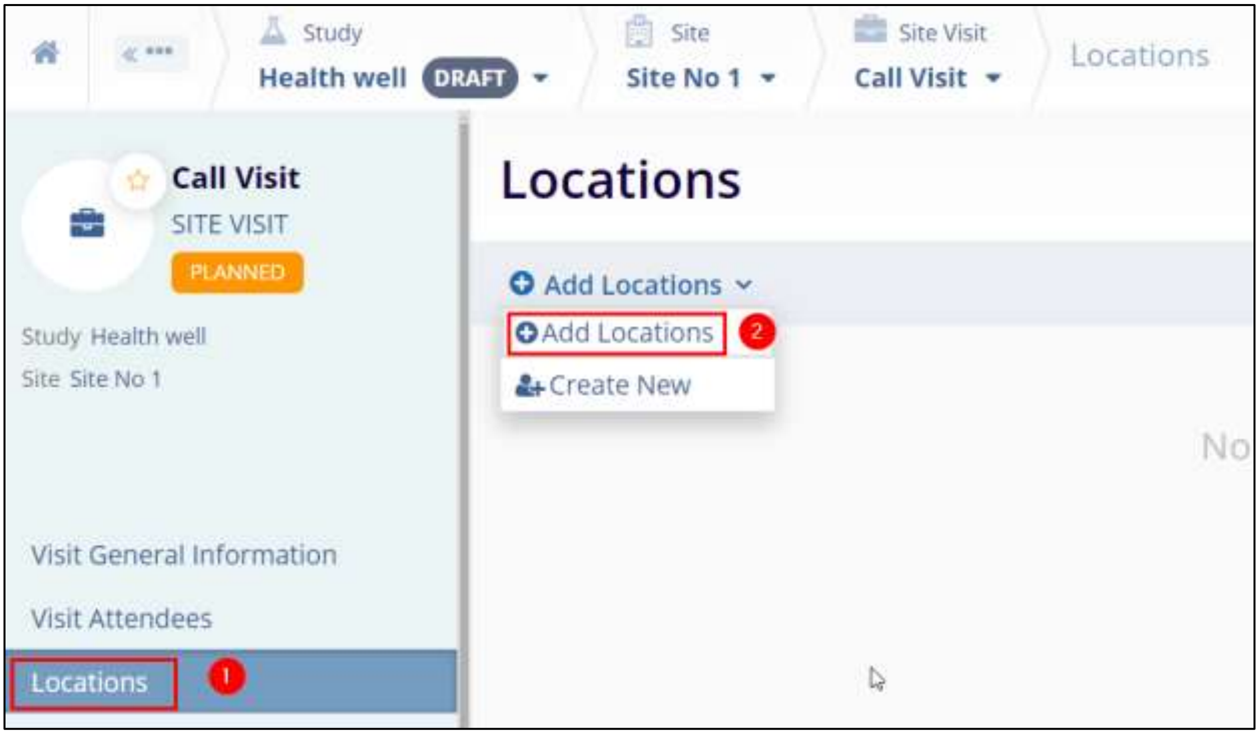


Figure: Add Locations

3. On the Add Locations screen click on the All Site Locations option.
4. Select the organization name by clicking on the checkbox.
5. Once the locations are selected, click on the Add Locations button.

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

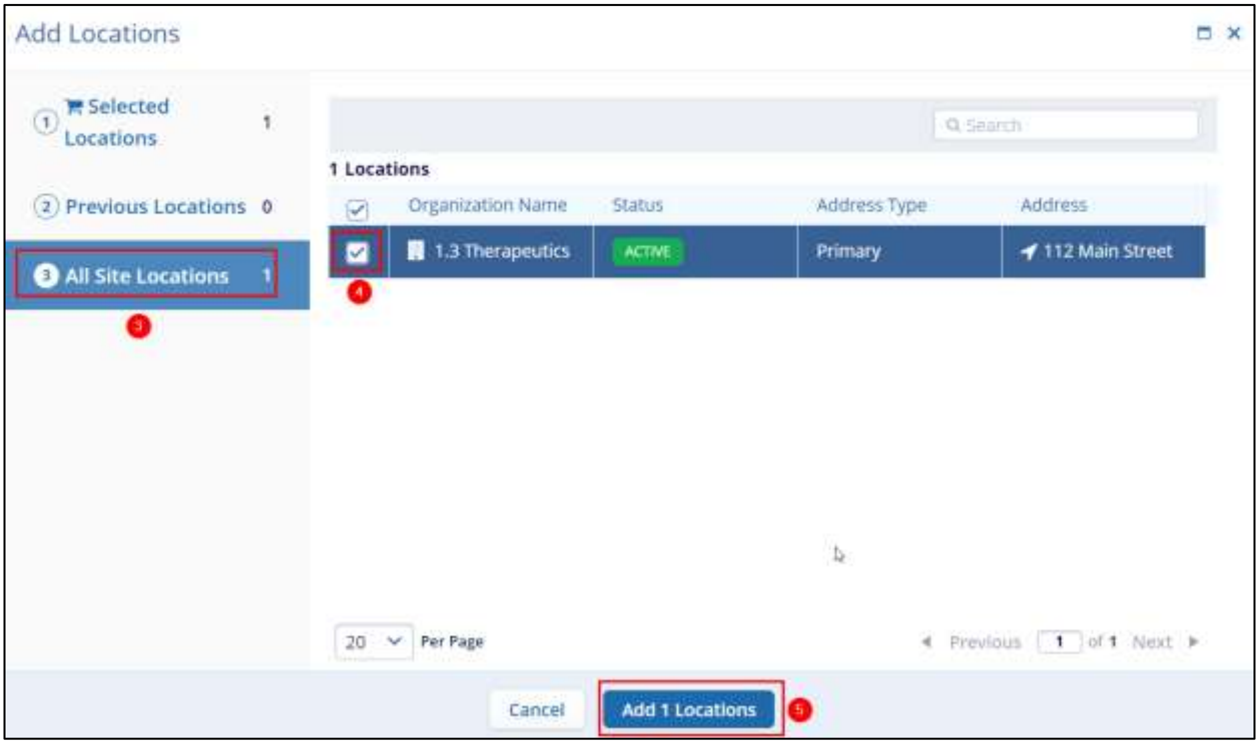


Figure: Add location from All Site Locations

Site Visit Checklist

To access the Site Visit Checklist, follow the steps below.

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Visit Checklist link.
2. On the Viist Checklist screen, expand the respective sections by clicking on the + icon
3. Selecting appropriate answers to the questions in their respective sections.
4. Once all the questions are answered, click on the Save button.

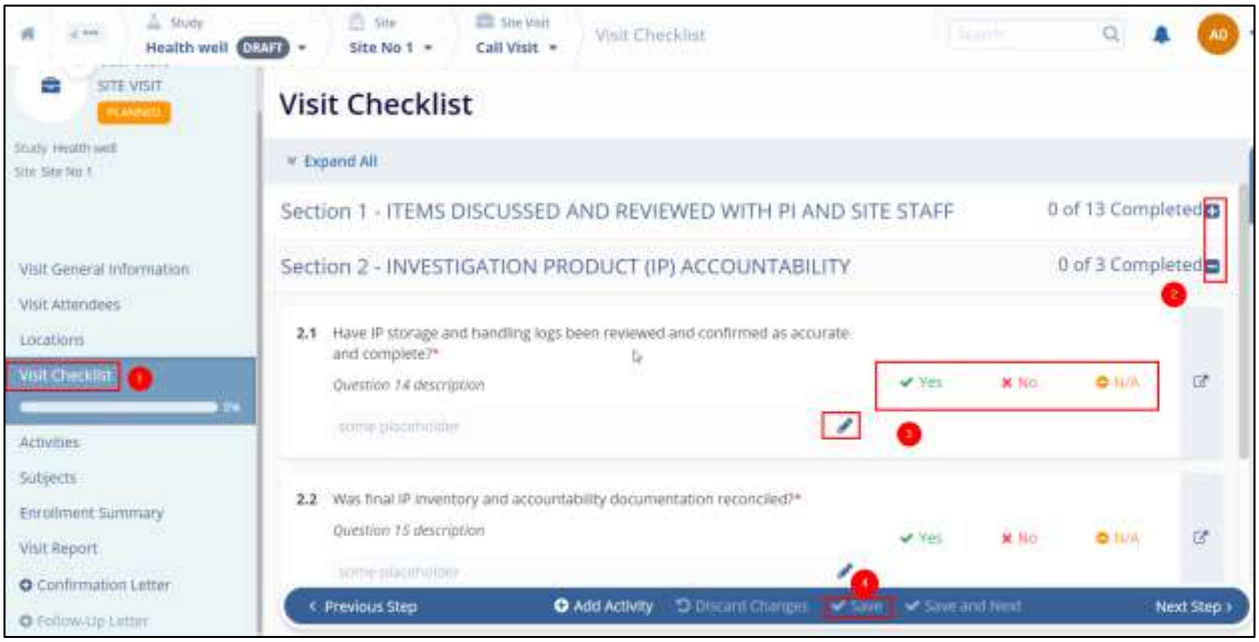


Figure: Visit Checklist

Note

- The Visit Checklist option becomes accessible when a template is specified in the Visit General Information.
- The answer is selected and saved only after a comment is mentioned in the empty field.
- It is mandatory to answer all questions.

Site Visit Activities

To access Site Visit Activities, follow the steps below.

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Activities link.
2. Click on +Add Activities dropdown and select +Add Activities.

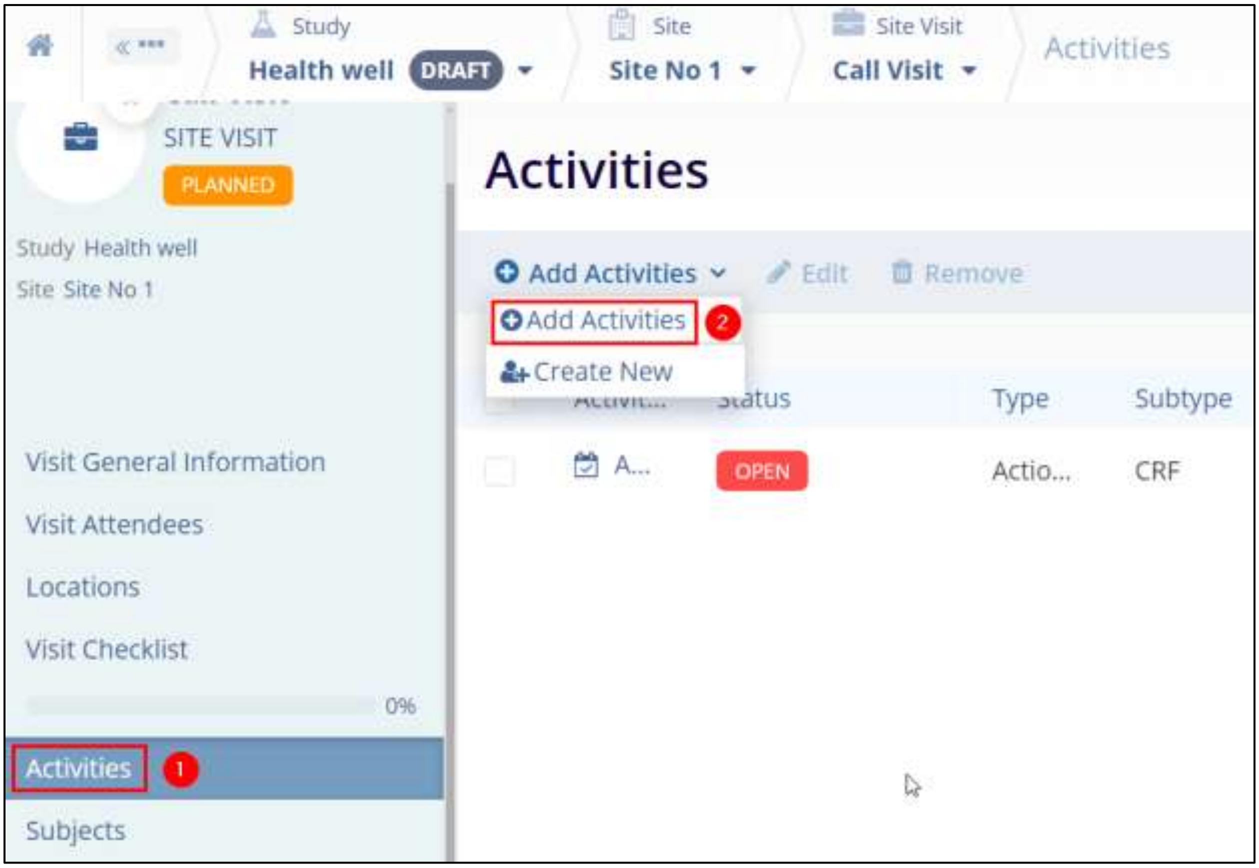


Figure: Add Activities

3. On the Add Activities screen click on the All Site Activities option.
4. Select the activity name by clicking on the checkbox.
5. Once the activities are selected, click on the Add Activities button.

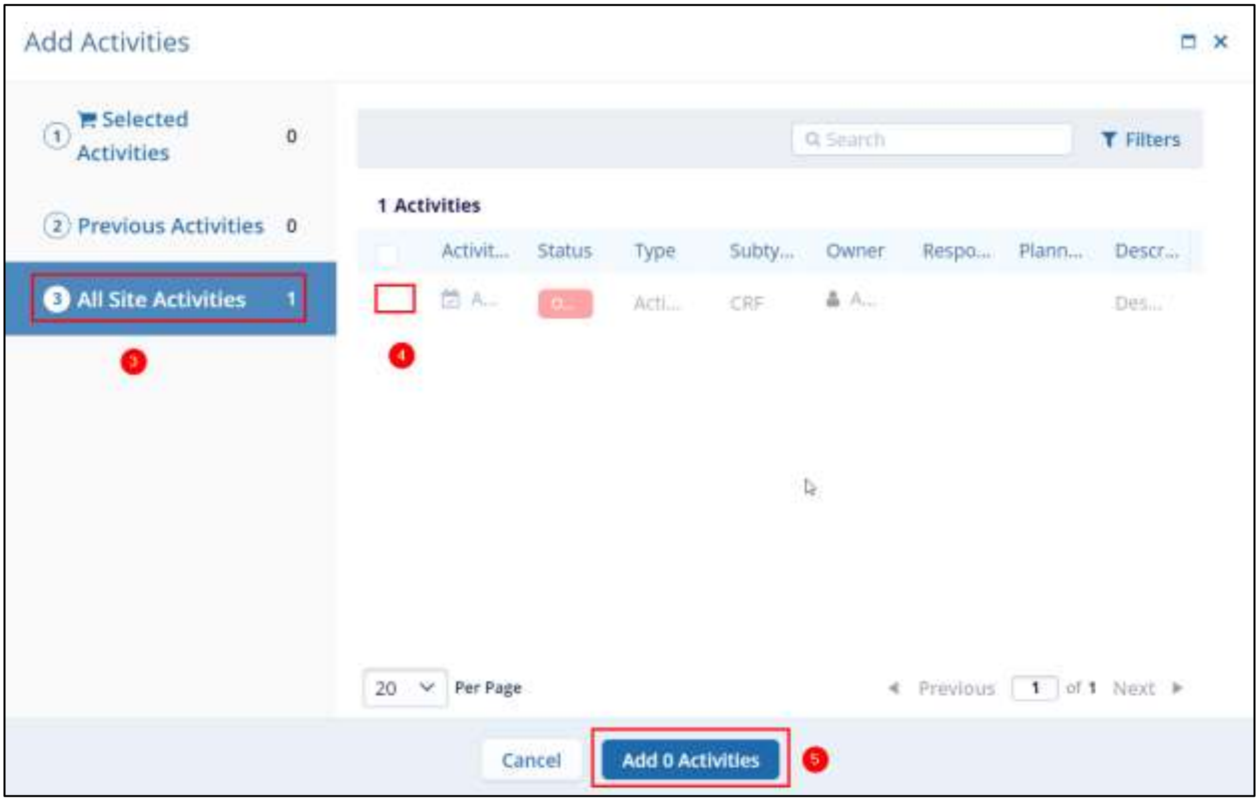


Figure: Add activities from All Site Activities

Site Visit Subjects

To access Site Visit Subjects, follow the steps below

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Subjects link.
2. Click on +Add Subjects dropdown and select +Add Subjects.

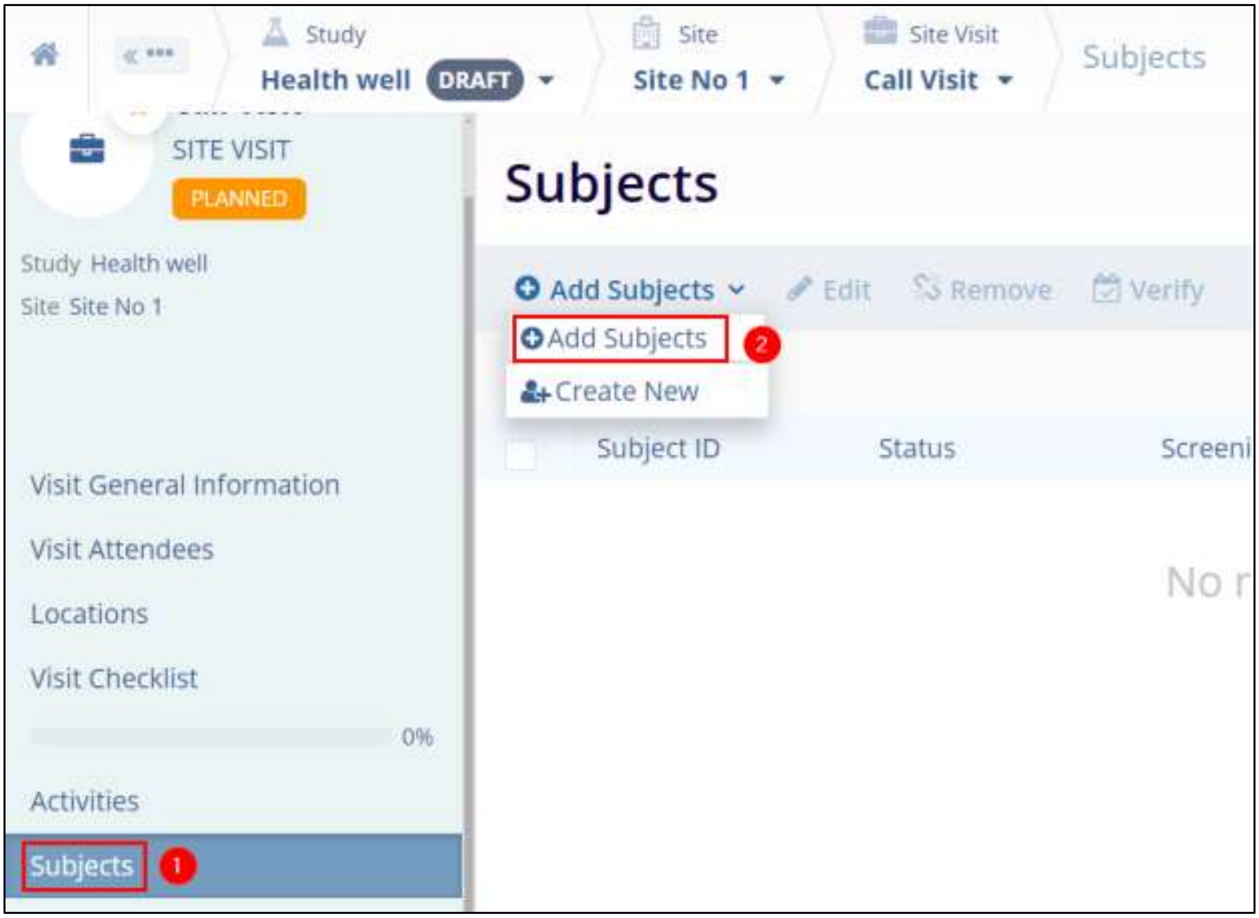


Figure: Add Subjects

3. On the Add Subjects screen click on the All Site Subjects option.
4. Select the subject name by clicking on the checkbox.
5. Once the activities are selected, click on the Add Subjects button.

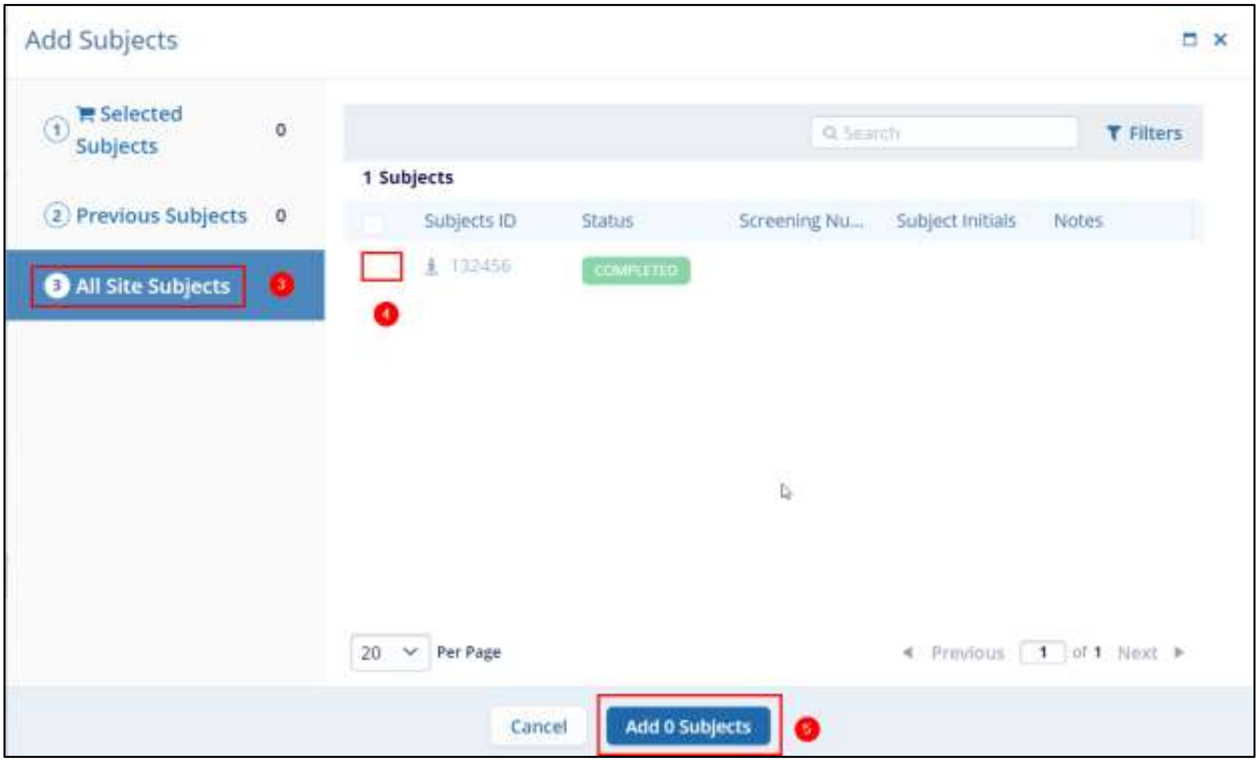


Figure: Adding subjects from All Site Subjects

6. To verify a subject navigate to the subject screen and click on Verify.
7. On the Subject Visit window, select a subject to verify and click on Go to ICF
8. Select an ICF to verify and click on Save.

Site Visit Enrollment Summary

To access the Site Visit Enrollment Summary, follow the steps below.

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Enrollment Summary link.
2. On the Enrollment Summary screen, click on +Add

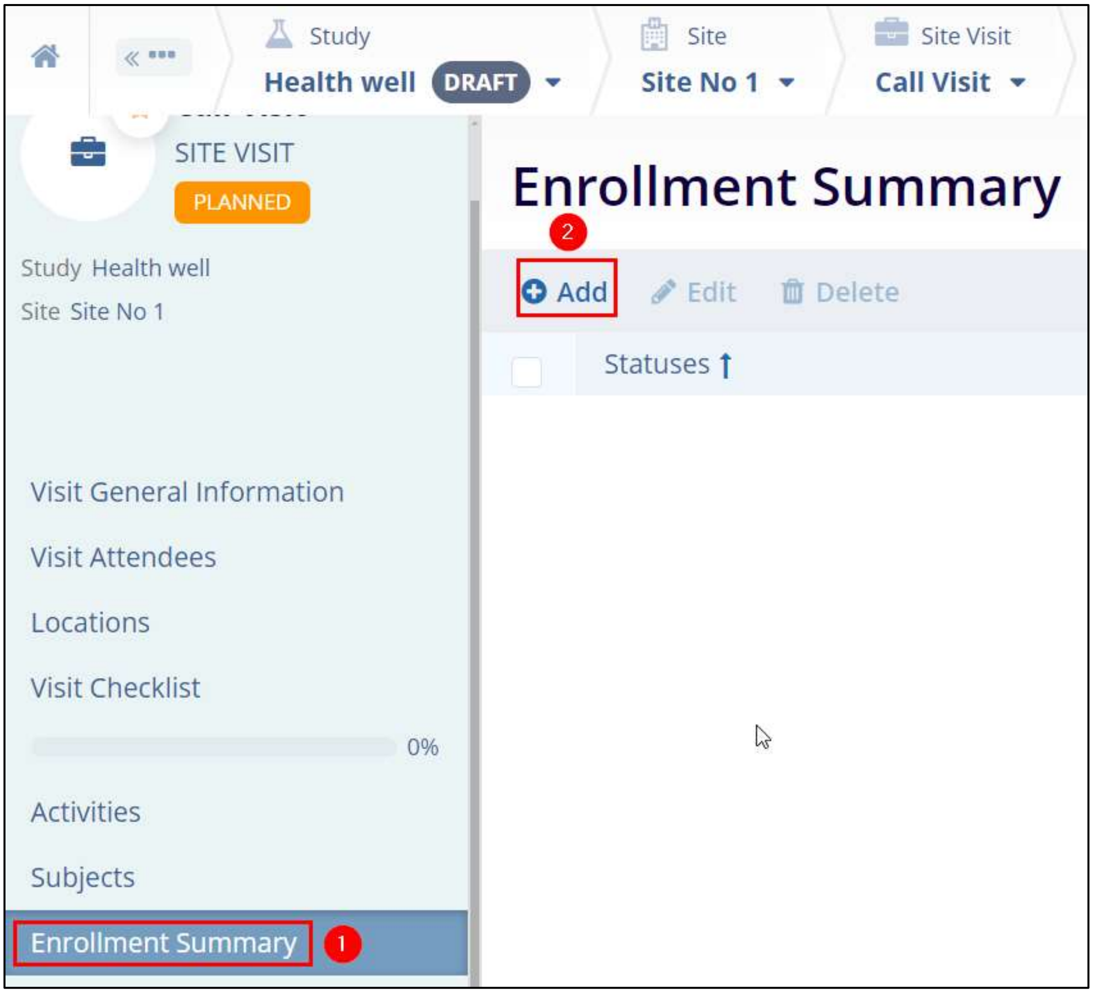


Figure: Add Enrollment Summary

3. Select the required option from the Statuses dropdown, and click on Save.

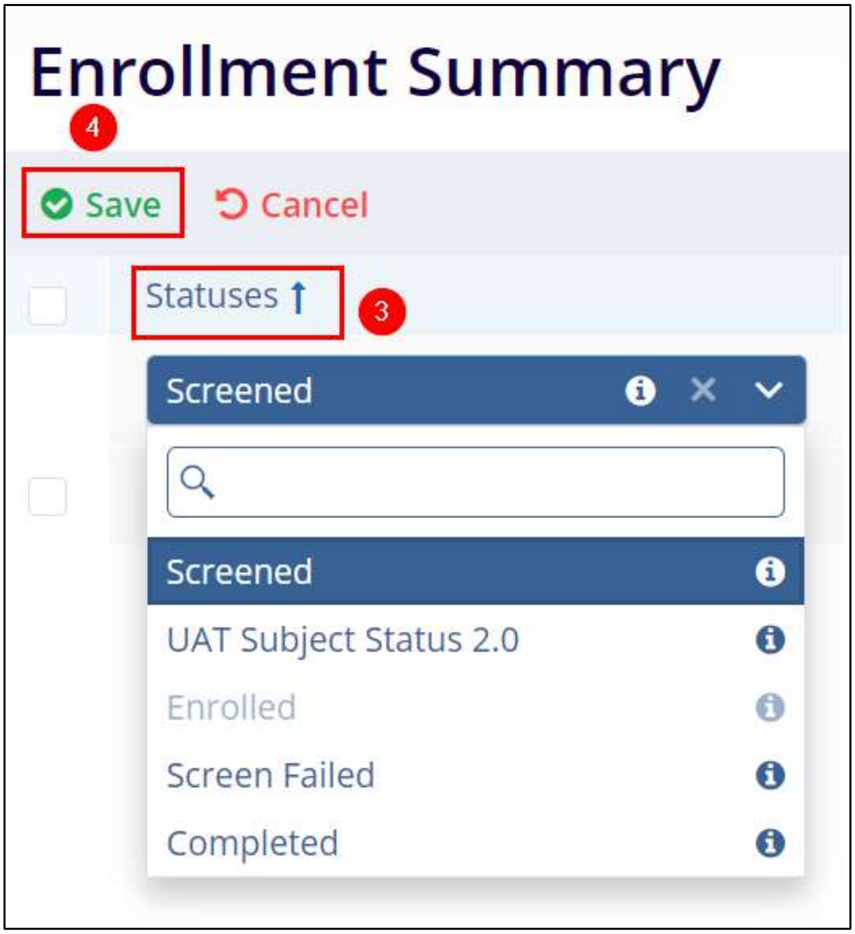


Figure: Select Summary Status

Note

- The statuses that are added once are greyed out from the dropdown menu and cannot be added again.
- To Edit or Delete a record select the respective icons from the top menu bar.

Site Visit Confirmation Letter Creation

To create a Site Visit Confirmation Letter, follow the steps below

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the +Confirmation Letter link.
2. On the Confirmation Letter screen, click on Generate Letter.

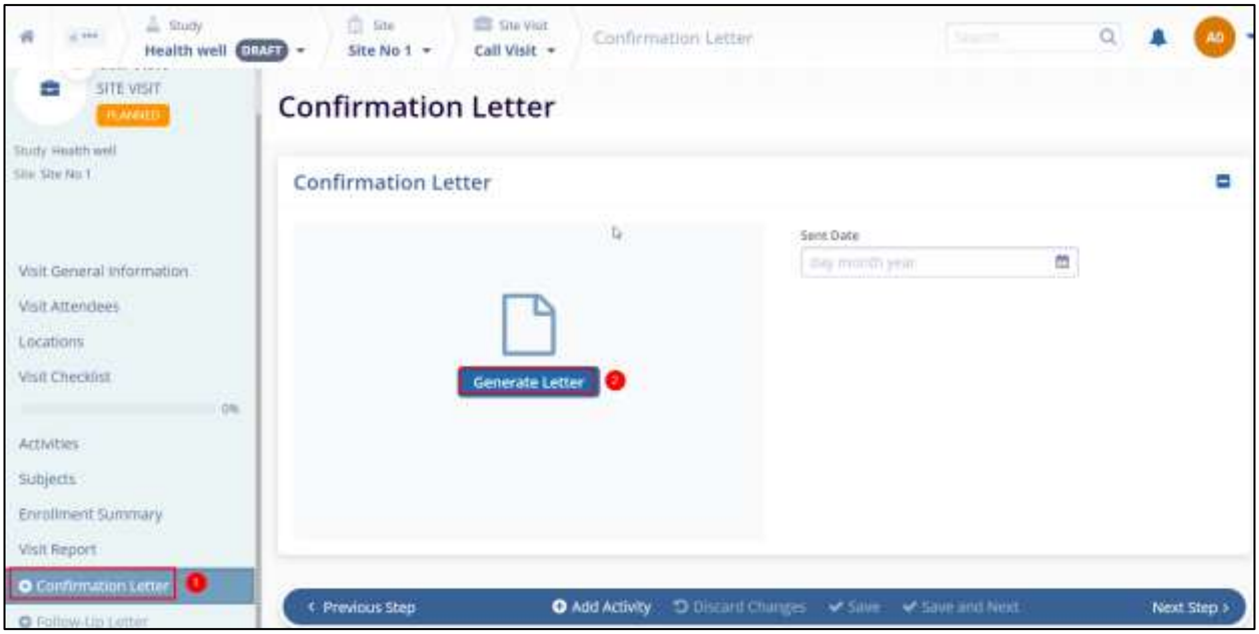


Figure: Generate Confirmation Letter

3. On the Generate Confirmation Letter screen, perform the following on the following screens and click on the Next button until the last step.
    a. Select Sections: Switch On or Off the Activities, Attendees, Locations, and Subjects toggle to access the particular sections.
    b. Select Activities: Select the required activities by clicking on the checkbox.
    c. Select Attendees: Select the required attendees by clicking on the checkbox.
    d. Select Locations: Select the required locations by clicking on the checkbox.
    e. Select Subjects: Select the required subjects by clicking on the checkbox.

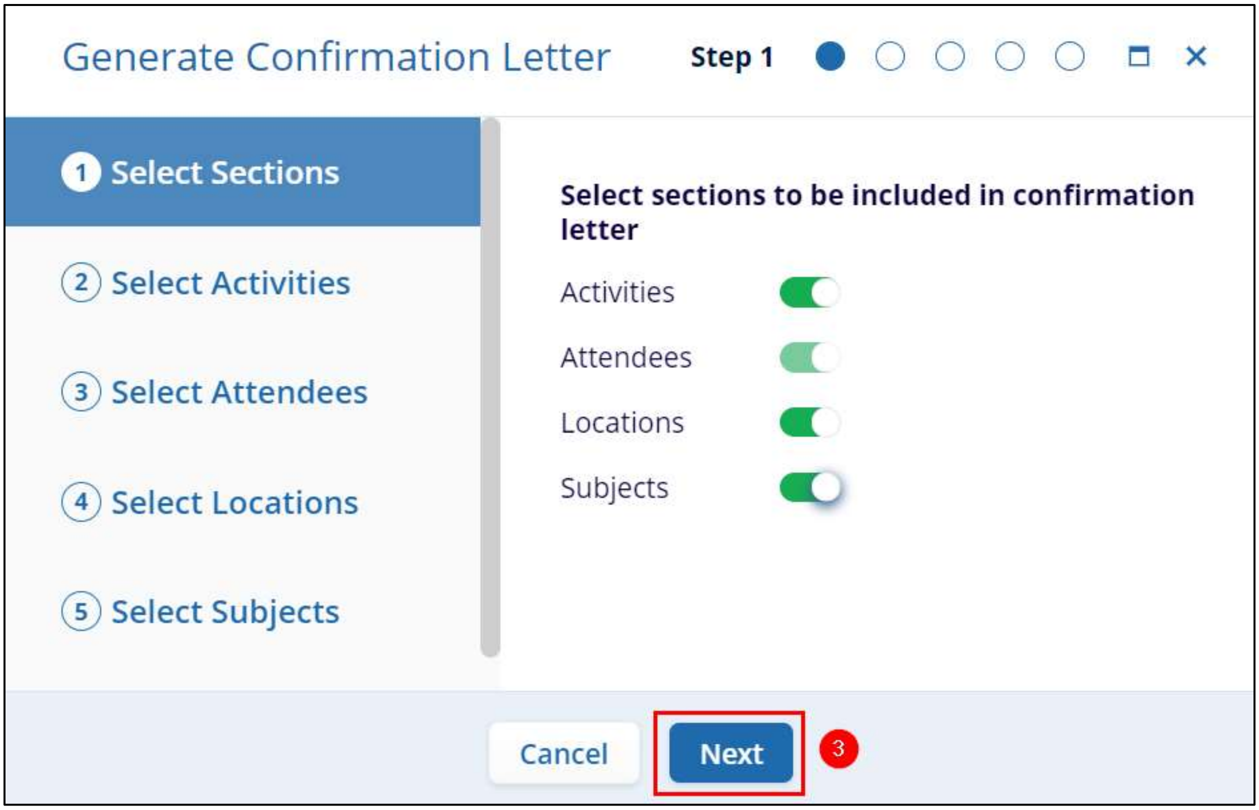


Figure: Generate Confirmation letter steps

Signing the Document and Workflow Approval

To sign a document and initiate the approval workflow, follow the steps below.

1. Click the View Letter button the in Confirmation Letter link.

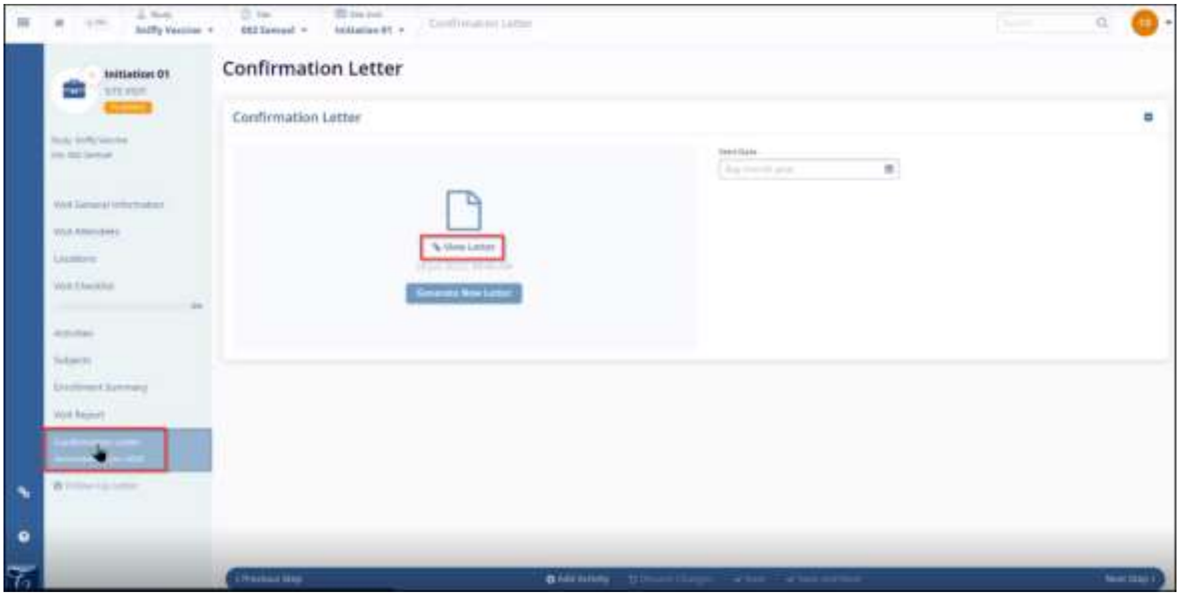


Figure: View Letter

2. On the Trial Interactive Collaborative Room in a new tab of the browser, click the Edit Document button displayed in the top left corner.
3. Make the required changes in the document and click Save at the bottom right of the window.

   Note: The page is refreshed and all the values that are entered in the Visit Report Checklist are displayed in the document.

4. Click the Start Approval Workflow button displayed in the top left corner.

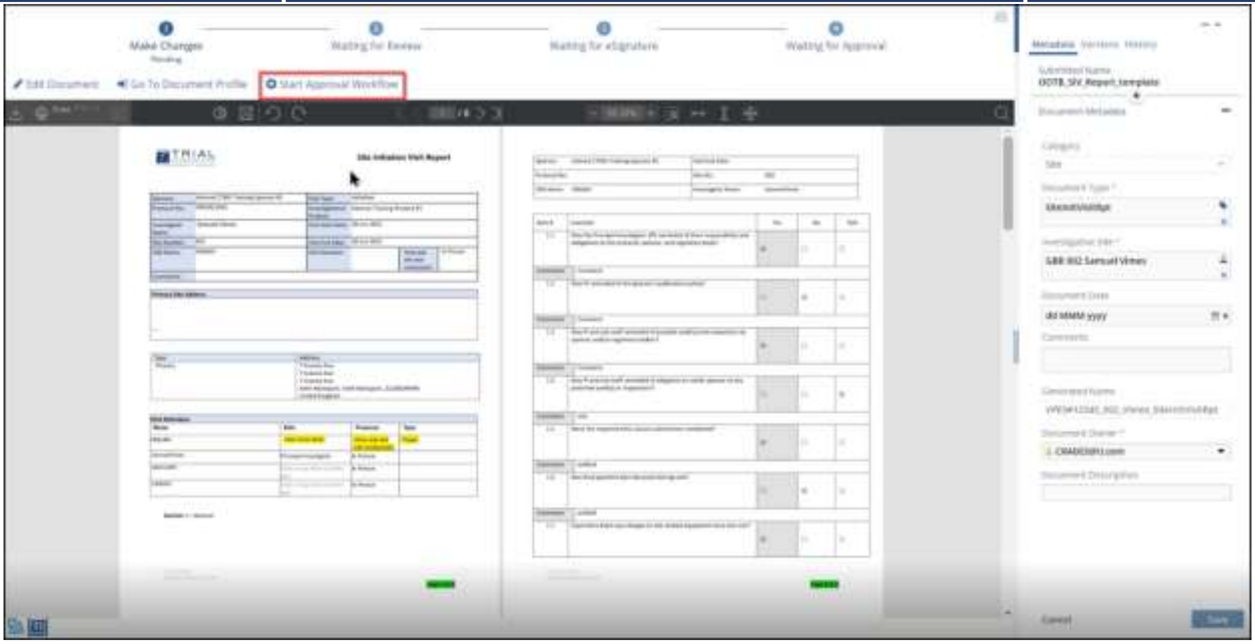


Figure: Start Approval Workflow

5. A notification is displayed in the top right corner – Add document(s) to Monitoring Visit Workflow.
   Note: The Make Changes stepper displayed in the top right corner shows a green tick mark with Complete status. Refer to the screenshot below.

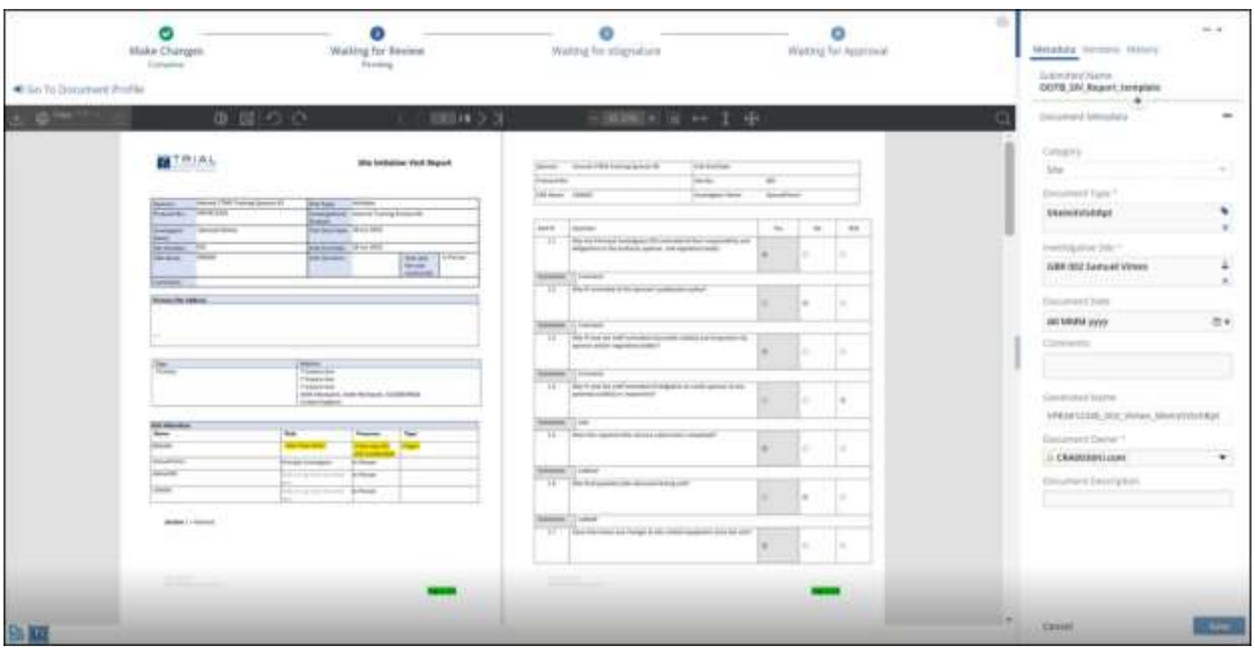


Figure: Add document(s) to monitoring

6. The Document is now sent to the reviewer. The Reviewer signs/approves the review.
   Note: The Waiting for Review stepper displayed at the top shows a green tick mark

with a Complete status with the email ID of the reviewer and the date of process. Refer to the screenshot below.

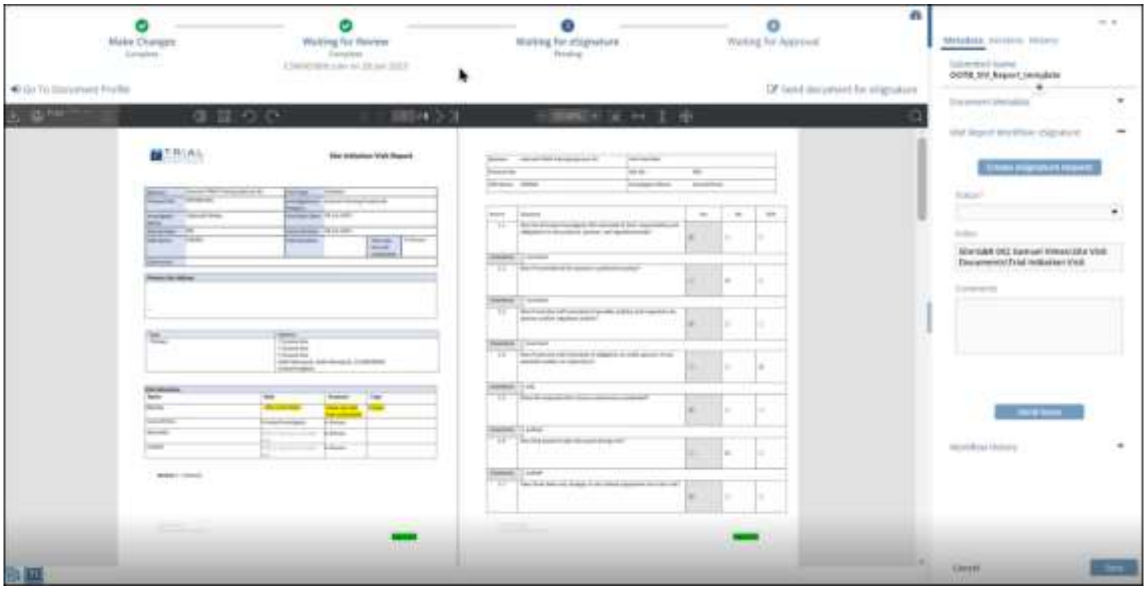


Figure: Waiting for Review

7. The Status is changed to Submitted in the Site Visits tab. Refer to the screenshot below.

Figure: Status changed to Submitted

8. Click the Send document for eSignature button displayed in the top right corner.

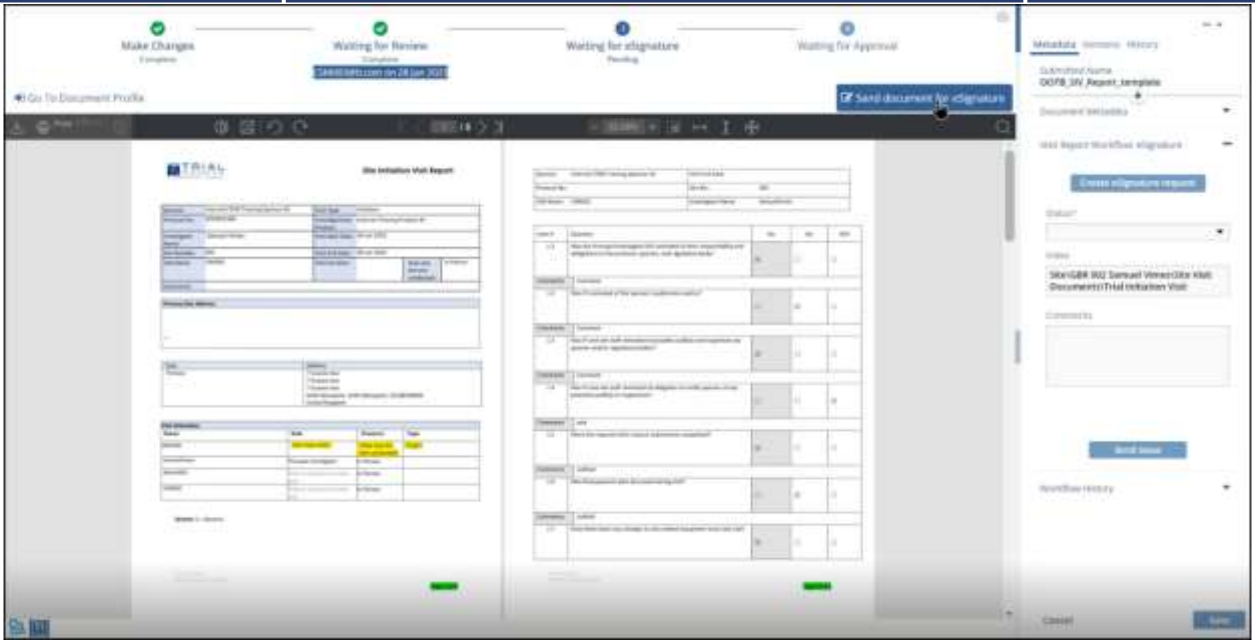


Figure: Send document for eSignature

9. On the eSignature screen, select a radio button for eSignature Type – Parallel or Serial.
10. Select the checkbox(s) displayed in front of the email IDs and click OK at the bottom of the screen.

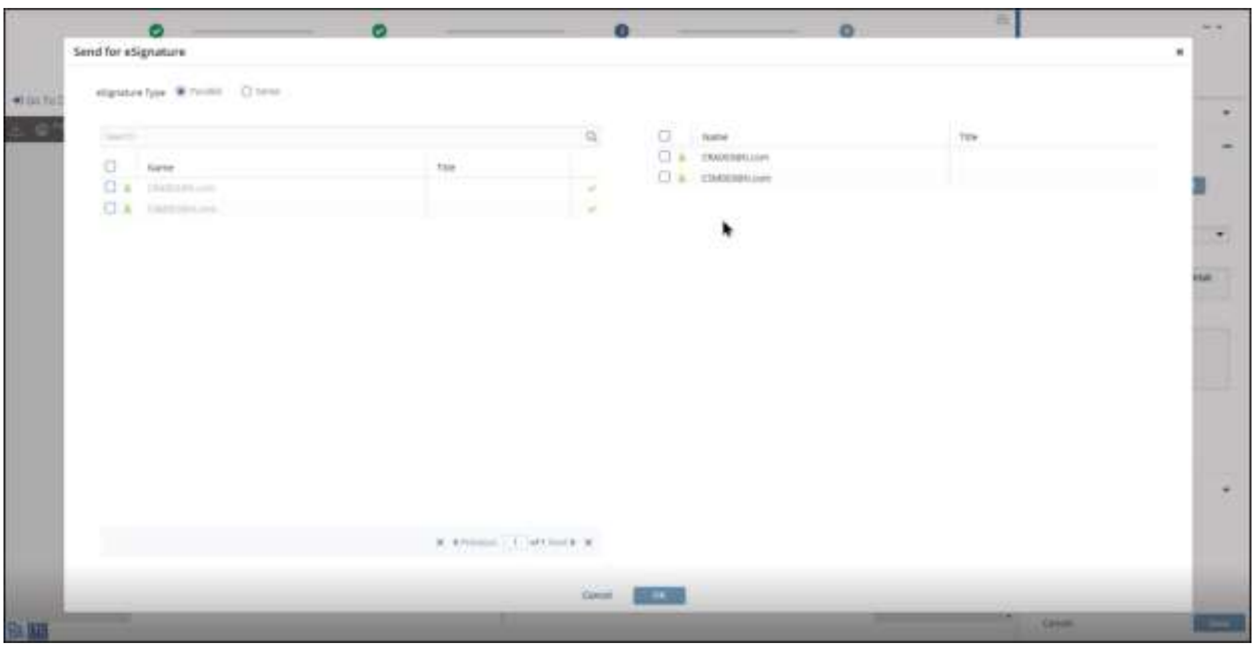


Figure: Send for eSignature screen

11. The Waiting for eSignature stepper displays In Progress with the number of signers. It also displays the 'Sign Document' and 'Decline Signature' buttons in the top right corner.
12. Click the Sign Document button.

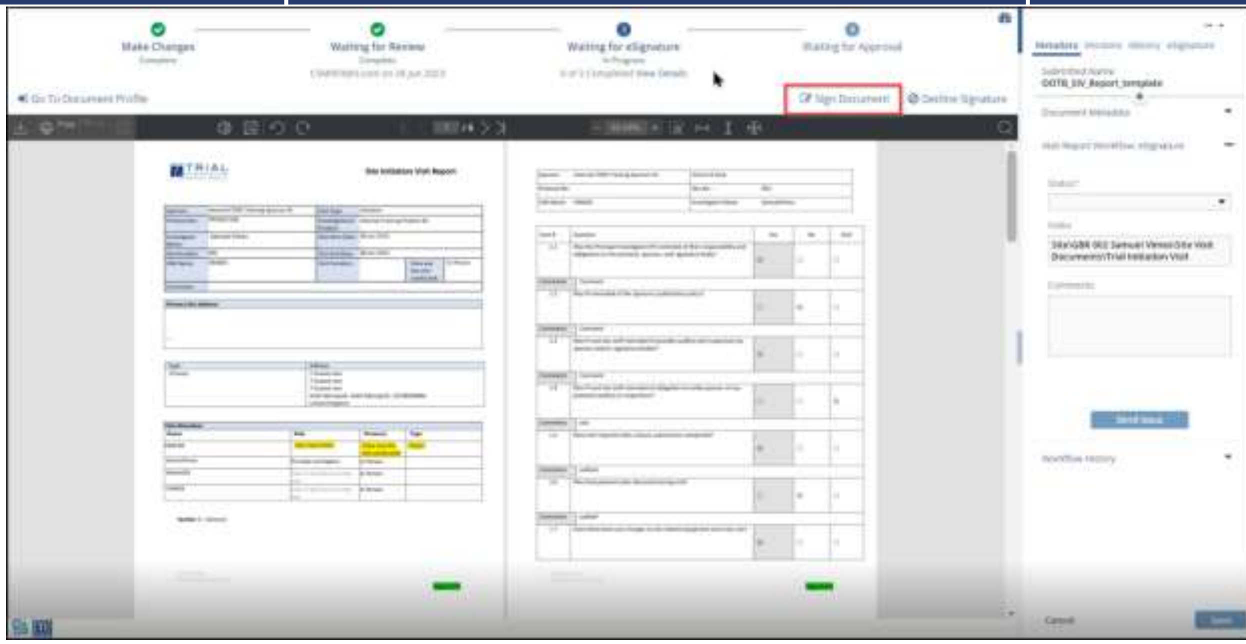


Figure: Sign Document option

13. On the Sign Document screen, select a reason from the down arrow menu as indicated by an asterisk (*).

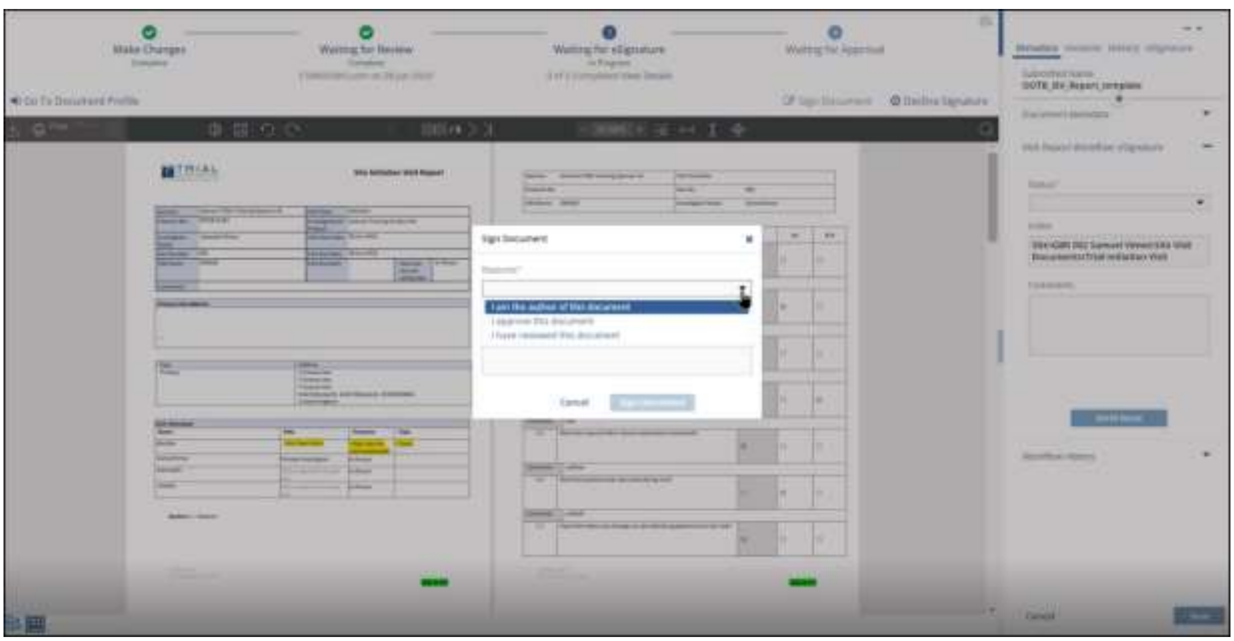


Figure: Sign Document screen

14. Enter the comments if required and click the Sign Document button.

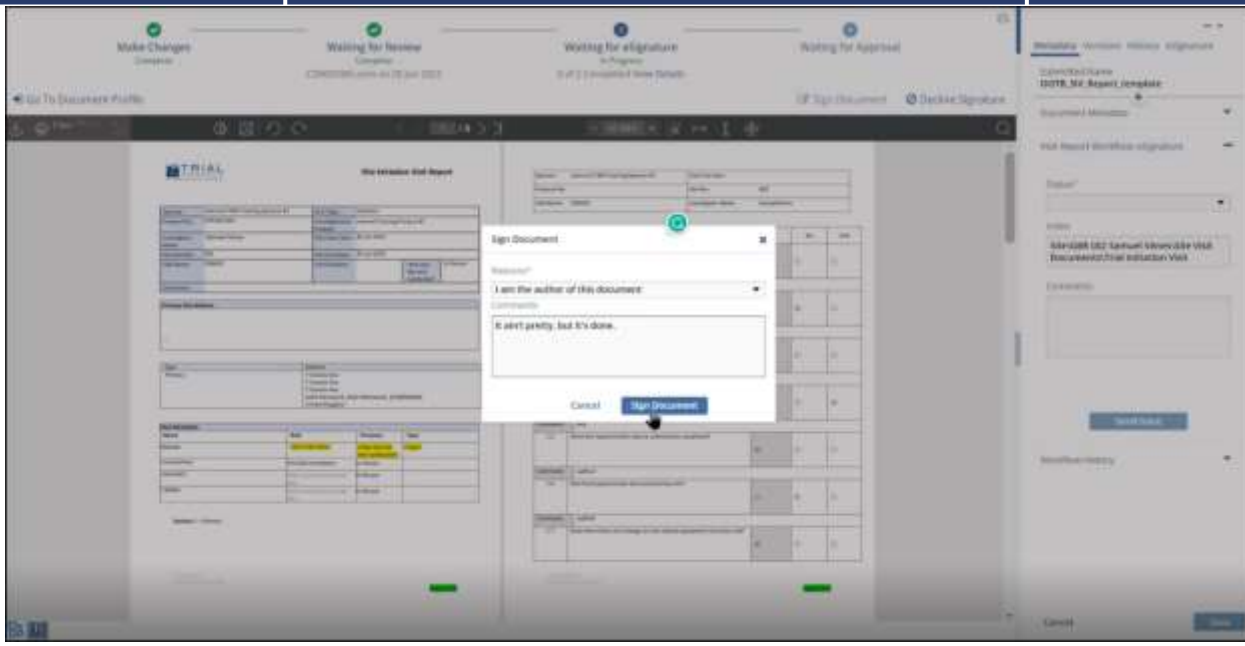


Figure: Entering comments

15. On the Please Provide Your Credentials screen, enter the Username and Password in the fields as indicated with an asterisk(*) and click OK.

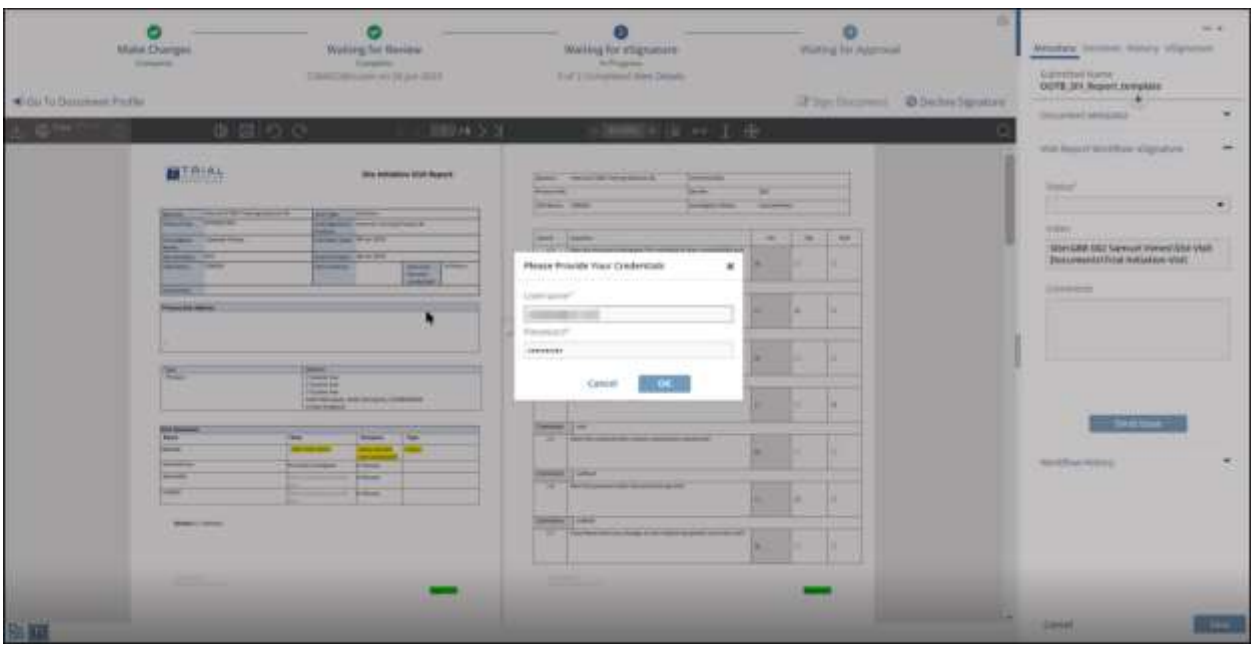


Figure: Please Provide Your Credentials screen

16. The document is signed and approved. The Waiting for Approval stepper displays a green tick mark with the email ID of the signed user and the date of signature below. Refer to the screenshot below.

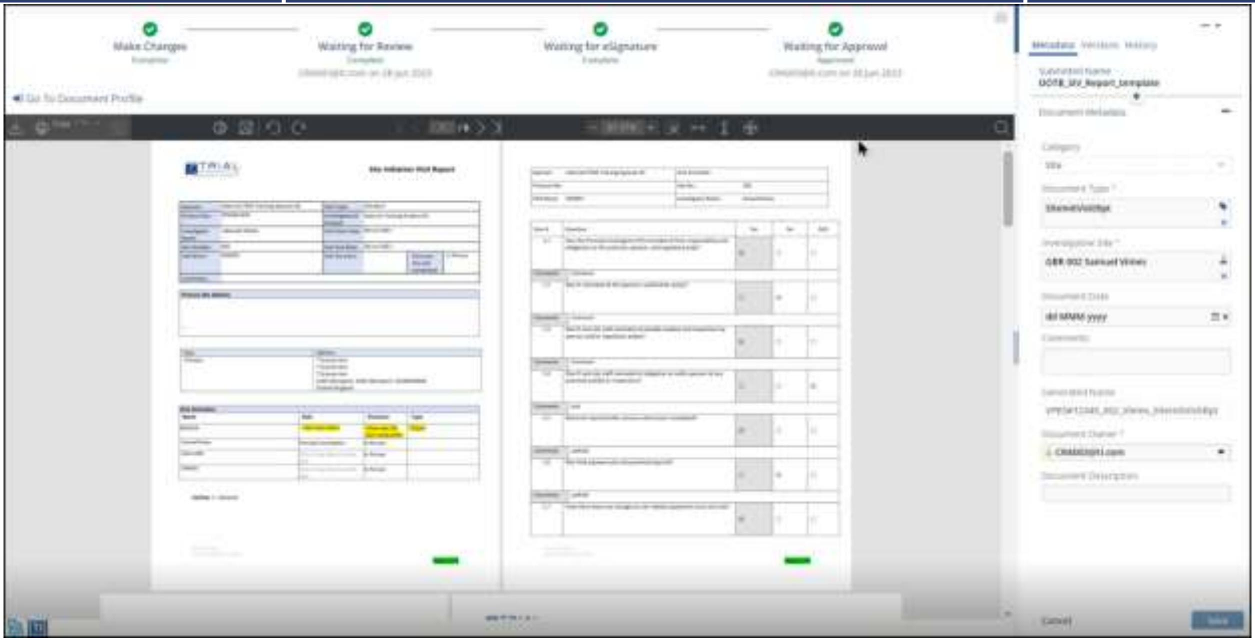


Figure: Approved and Signed Document

Site Visit Draft Report Generation

To generate a Site Vist Draft Report, follow the steps below.

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Visit Report link.
2. Update the Report Status as In Progress and click on the Save button.
3. Click on Create Visit Report.

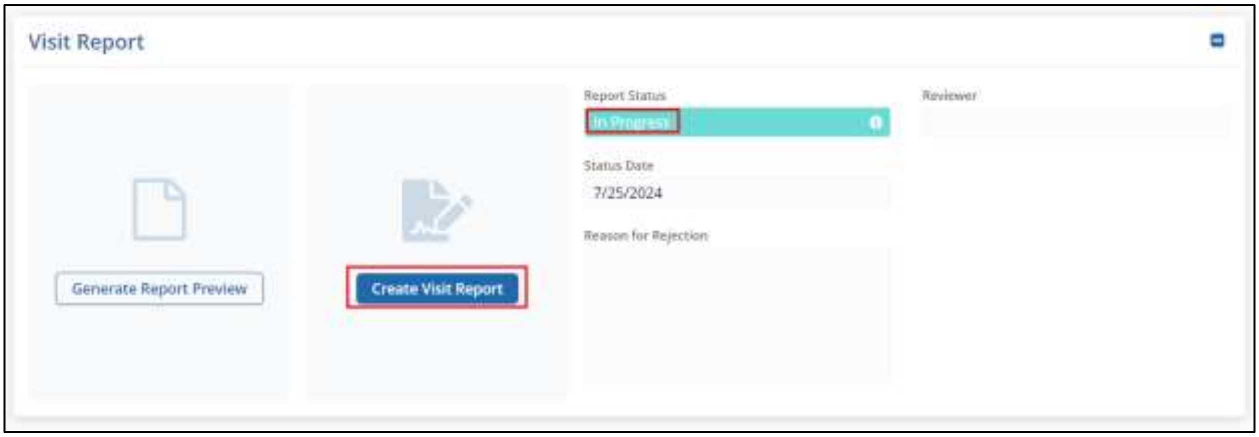


Figure: Create Visit Report

4. On the Create Visit Report screen, click on Generate Report.

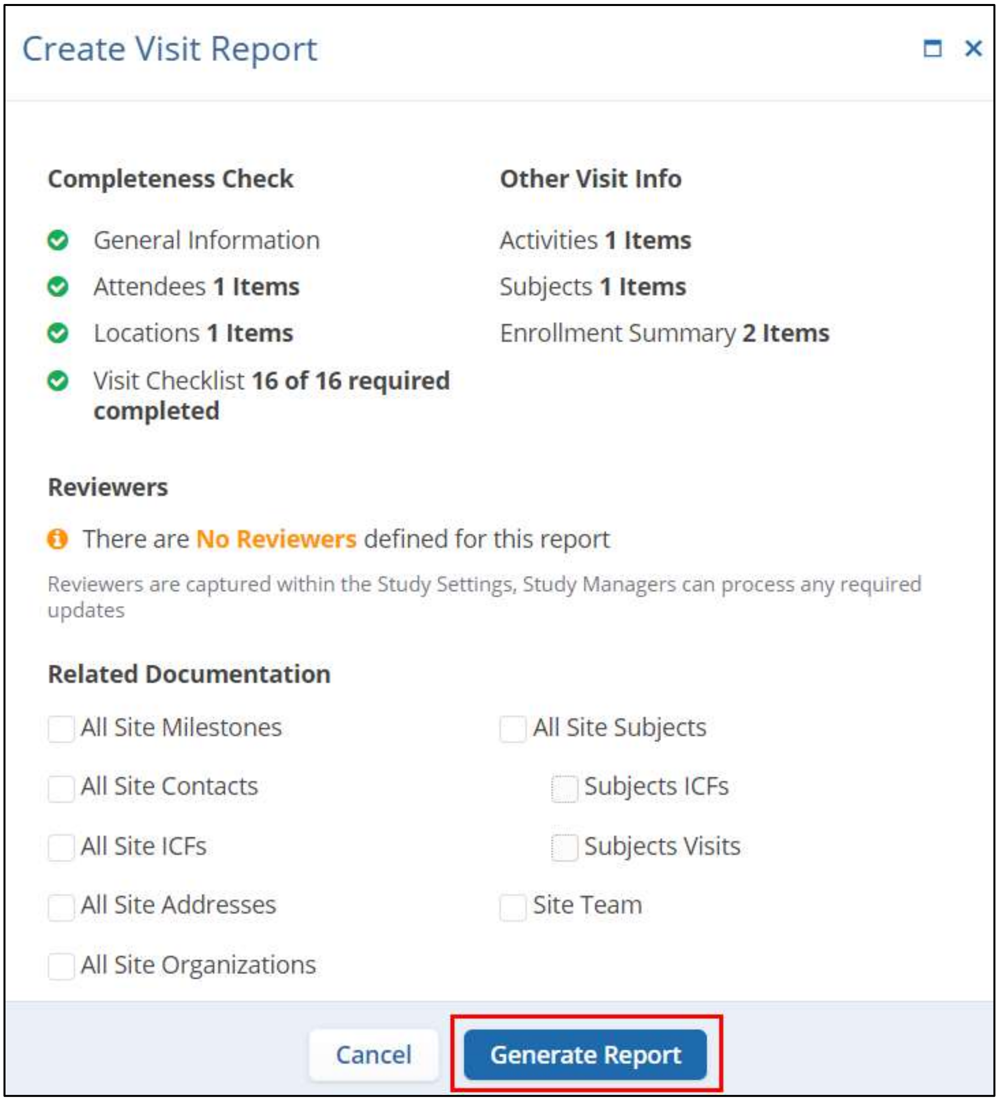


Figure: Generate Report

Note: The Generate Report button is disabled if the 'Visit Checklist' is not completed. The Generate Draft Report window displays the fields in red color that are not filled. Refer to the screenshot below.

5. On the Generate Report screen, click on Yes, Generate Draft.

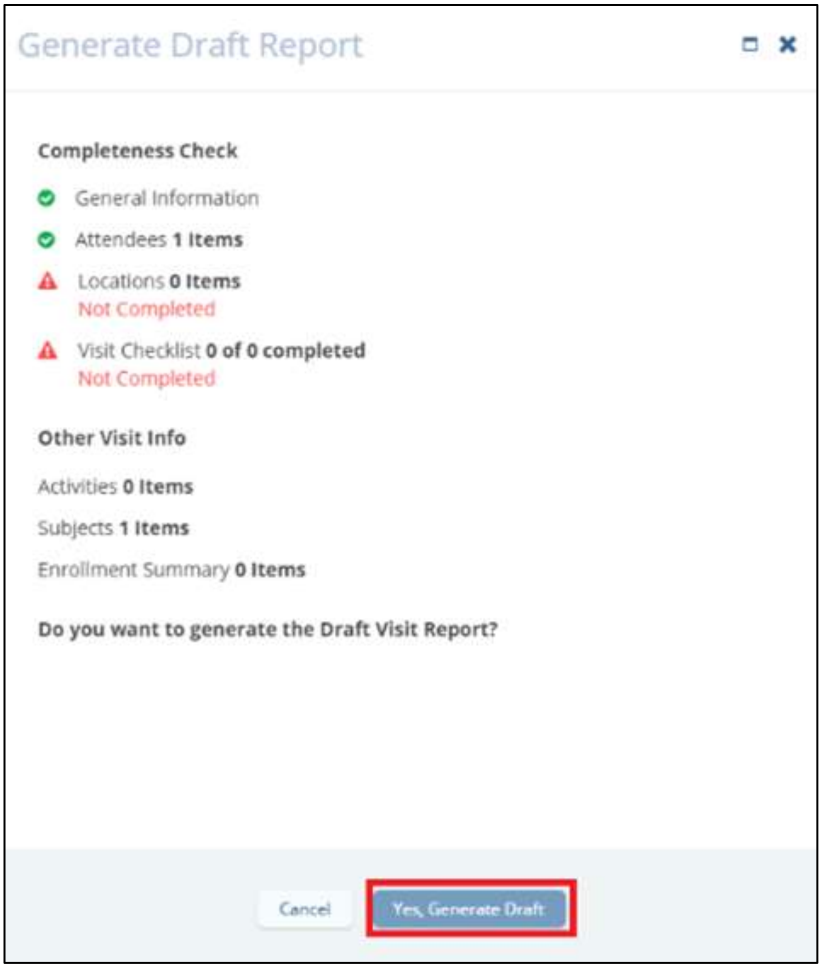


Figure: Yes Generate Draft option

6. The screen shows as Generating Draft Report please wait until the user clicks on the Yes, Generate Draft button.

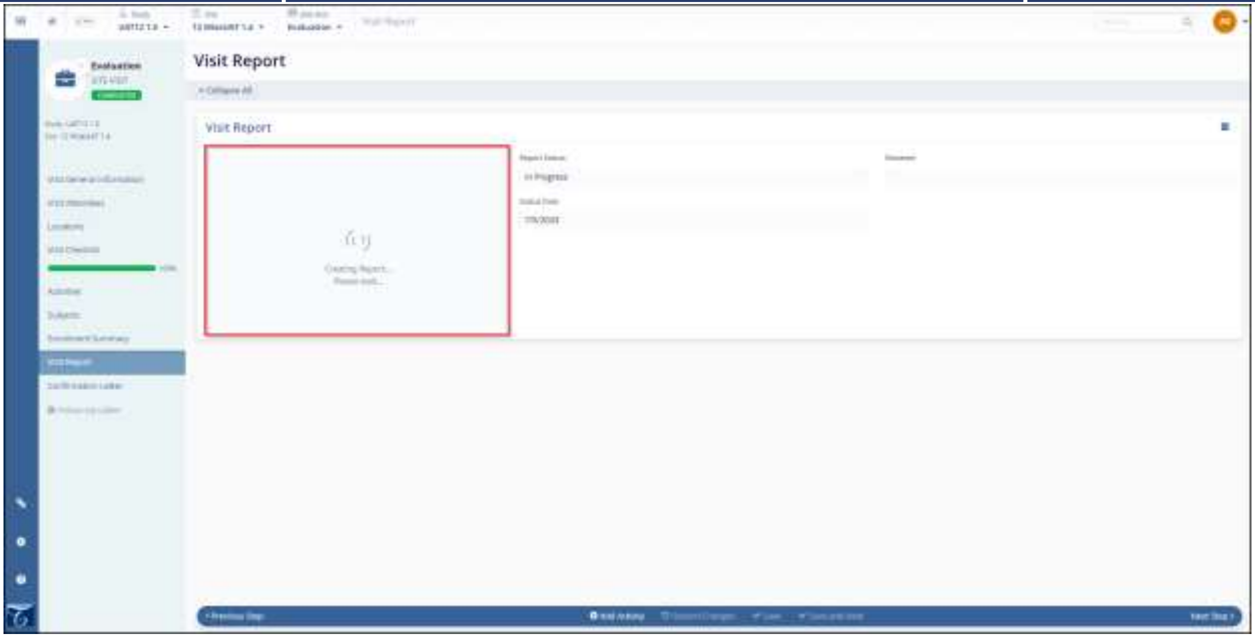


Figure: Generate Report notification

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

Site Visit Final Report Generation

To generate the Site Visit Final Report, follow the steps below

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Visit Report link.
2. On the Visit Report window, click on Generate Report.
3. On the General Visit Report window, click on Yes, Generate Report.

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

Site Visit Follow-up Letter Creation

To create a Site Visit Follow-up letter, follow the steps below.

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the +Follow-Up Letter link.
2. On the Follow-up Report screen, review the sections within the confirmation letter that are relevant.
3. The Generate Follow-up Letter window displays the selected sections and the selected content from the final report.
4. Click on the Next button on the screen.
5. Click on the Create button in the window.
6. A Follow-up letter is generated, and origami is opened displaying the letter.

Access Permissions

The Access Permissions feature helps the user add, edit, activate, and remove access permissions for other users.

Follow the steps below to view the access permissions and make the required changes.

1. From the left-hand navigation screens, click on Studies.
2. Select a Study by clicking on the study name to manage its access permissions.

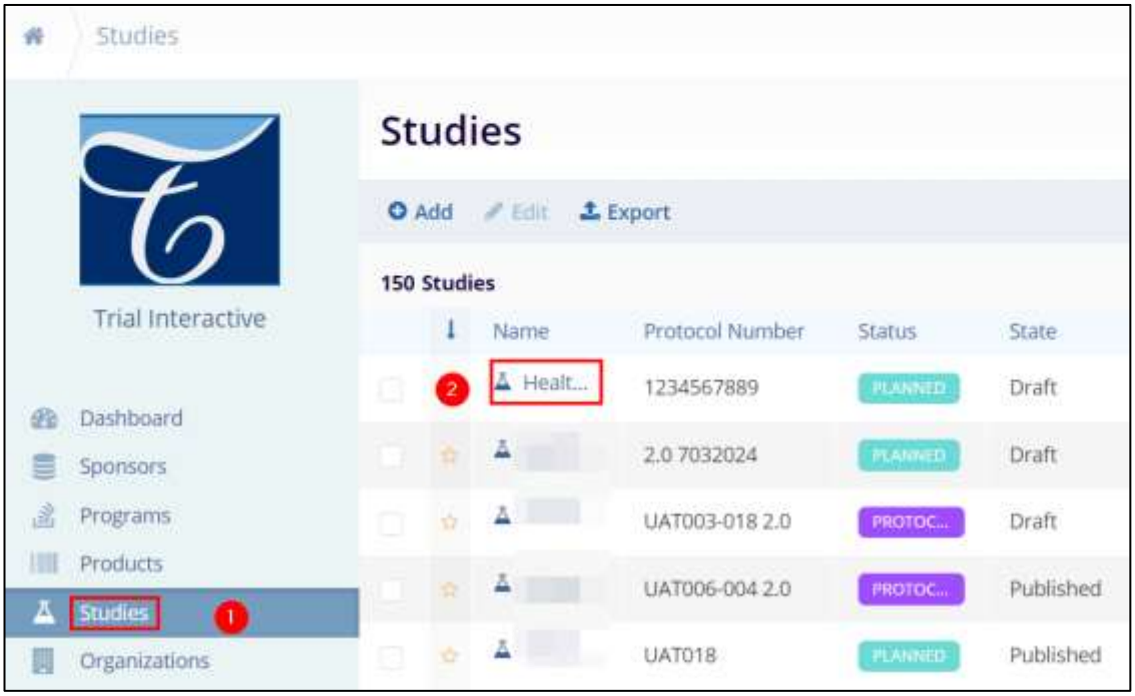


Figure: Select a Study and a study name

3. On the Study Dashboard, navigate to the left-hand navigation links and select Team.
4. Click the Access Permissions button displayed in the top left corner of the screen.

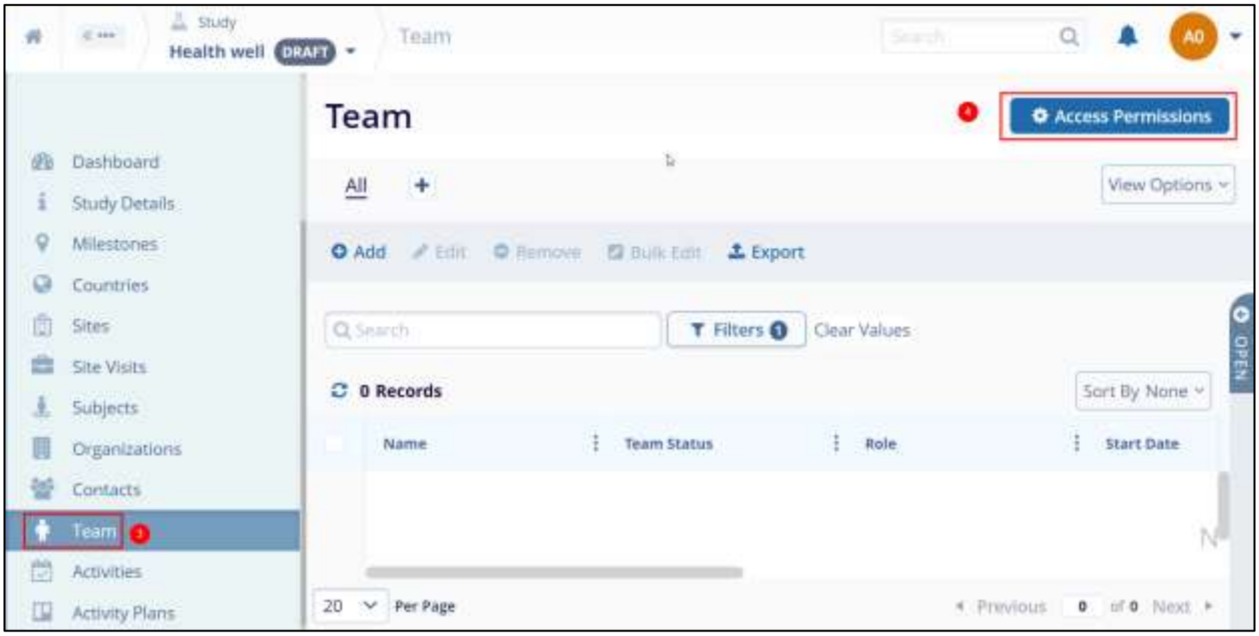


Figure Access Permissions

5. Select the name of the user by clicking on the checkbox and the following top menu bar options become accessible.
    a. Add:
        i. Click on the +Add button to open the Add User Study Access Permission, specify the mandatory details, and click on Save.

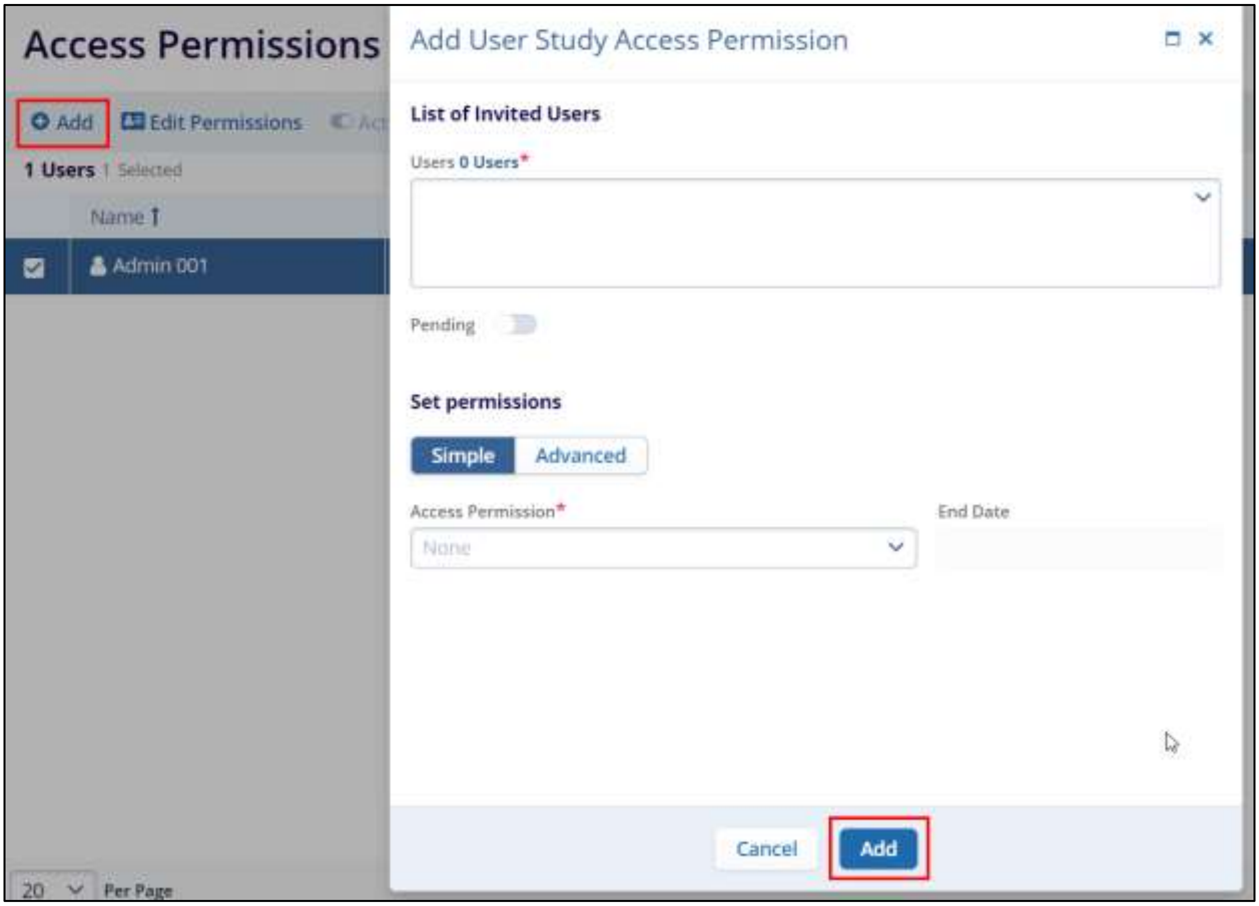


Figure: Add User

b. Edit:
   i. Click on the user name checkbox and click on Edit Permissions
   ii. On the Edit Study Permissions, the Simple Permissions screen is displayed by default.
   iii. Specify the Access Permission, and End Date and click on Save.

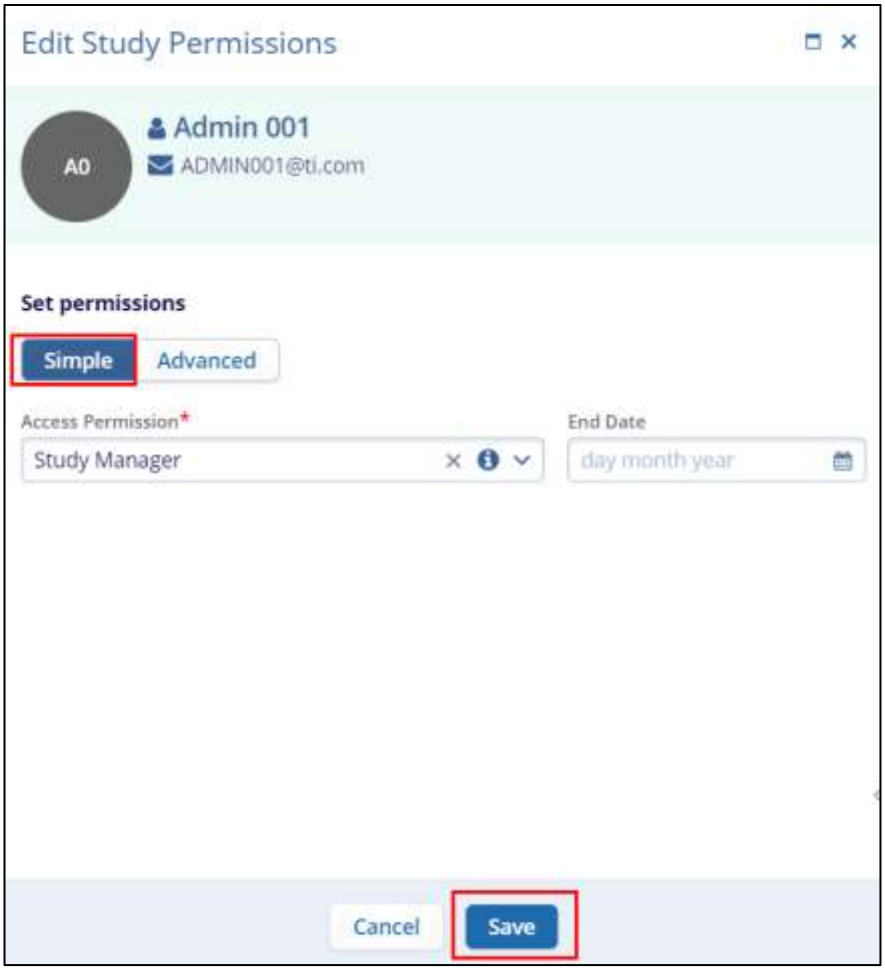


Figure: Edit Study Permissions-Simple

iv. Click on the Advanced option and select either Show All or Show Assigned Permissions by clicking on the radio button.
v. Select Role from the dropdown menu and click on the checkbox. Click on the Apply to the selected button.
vi. Select End Date by accessing the calendar icon.

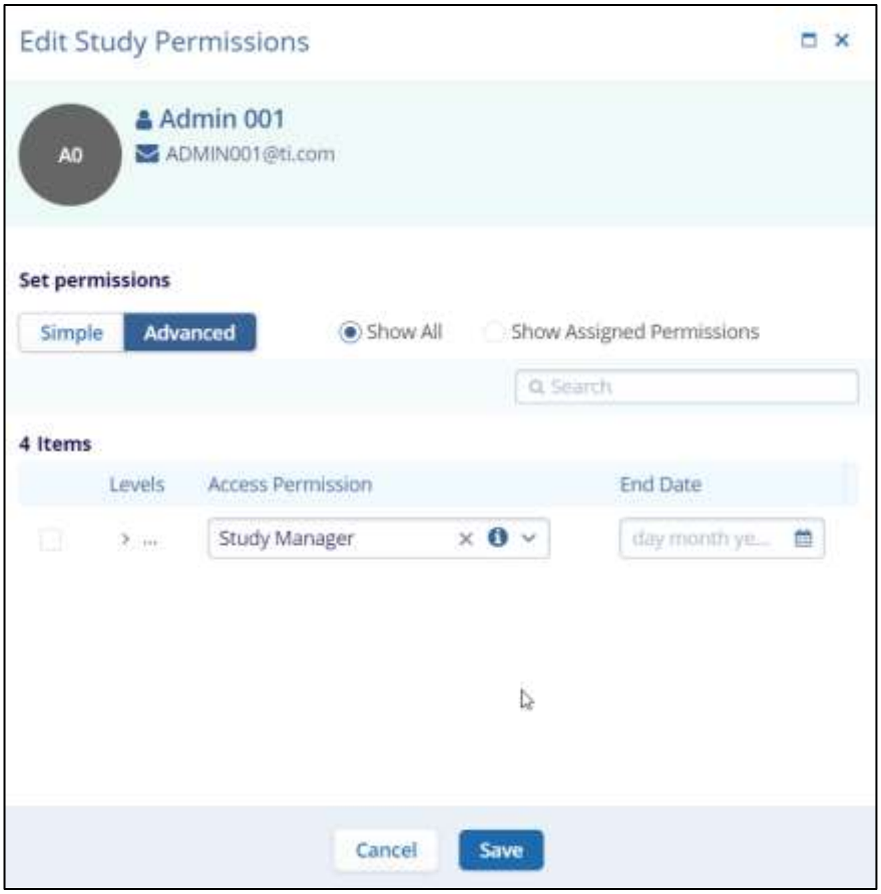


Figure: Edit Study Permissions-Advanced

c. Activate:
   i. Select a user with Pending status by clicking on the checkbox.
   ii. Click the Activity toggle button.
   iii. Click on Activate on the confirmation popup.

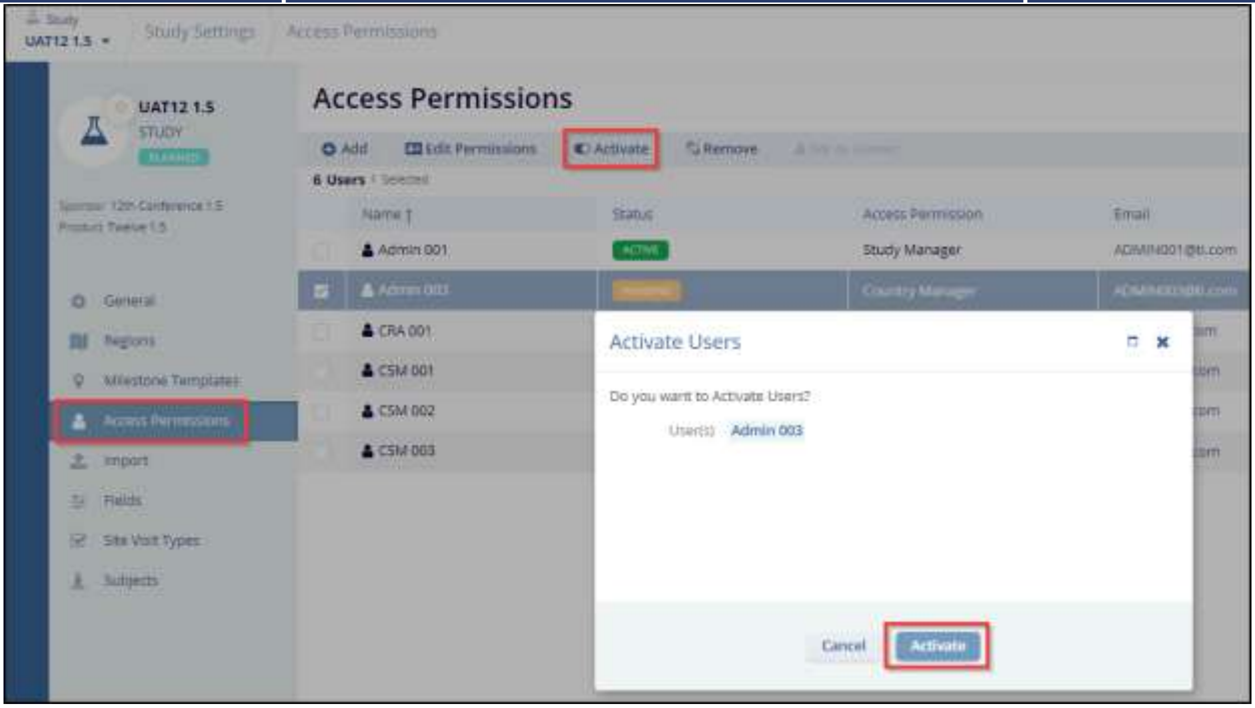


Figure: Activate users

d. Remove
   i. Select a user by clicking on the checkbox.
   ii. Click on the Remove icon from the top menu bar
   iii. Click on the Remove button on the confirmation popup.

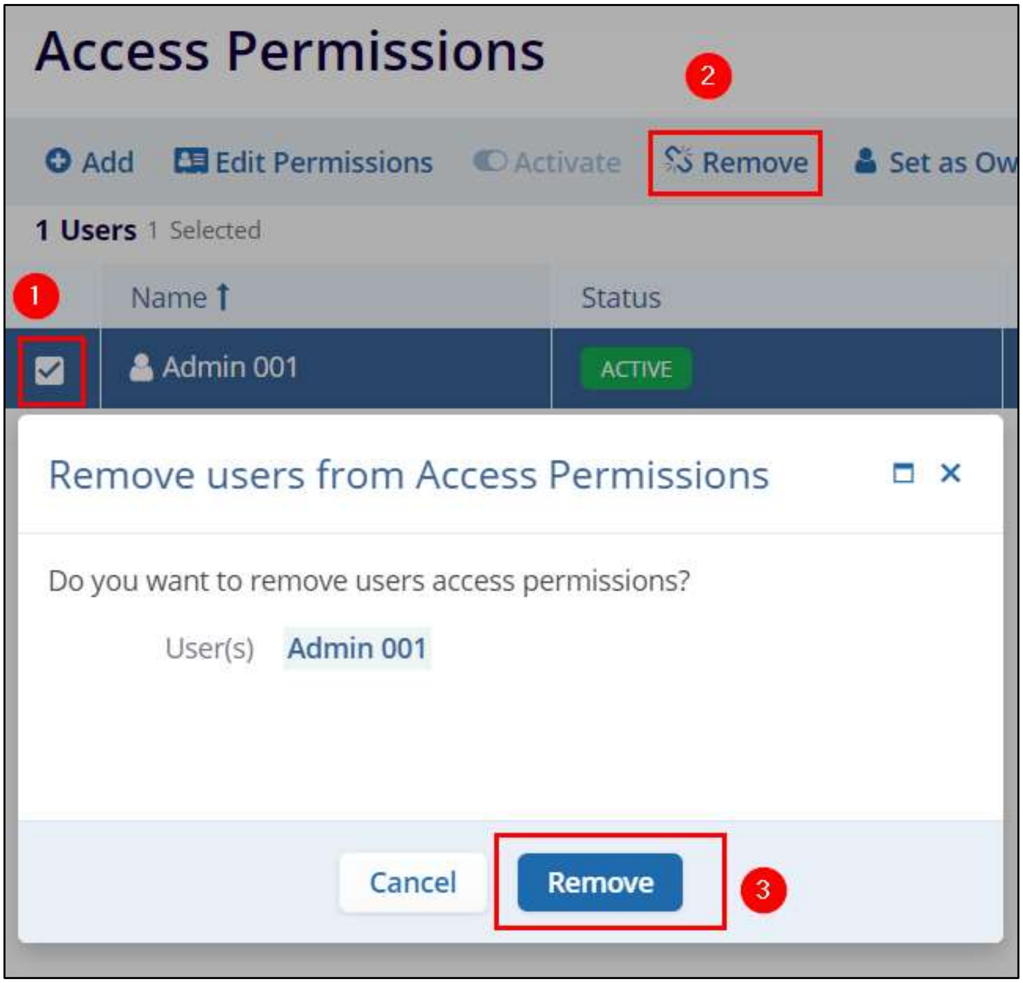


Figure: Remove the user

e. Set as Owner
   i. Select a user by clicking on the checkbox.
   ii. Click on the Set as Owner from the top menu bar
   iii. Click on the Change button on the confirmation popup.

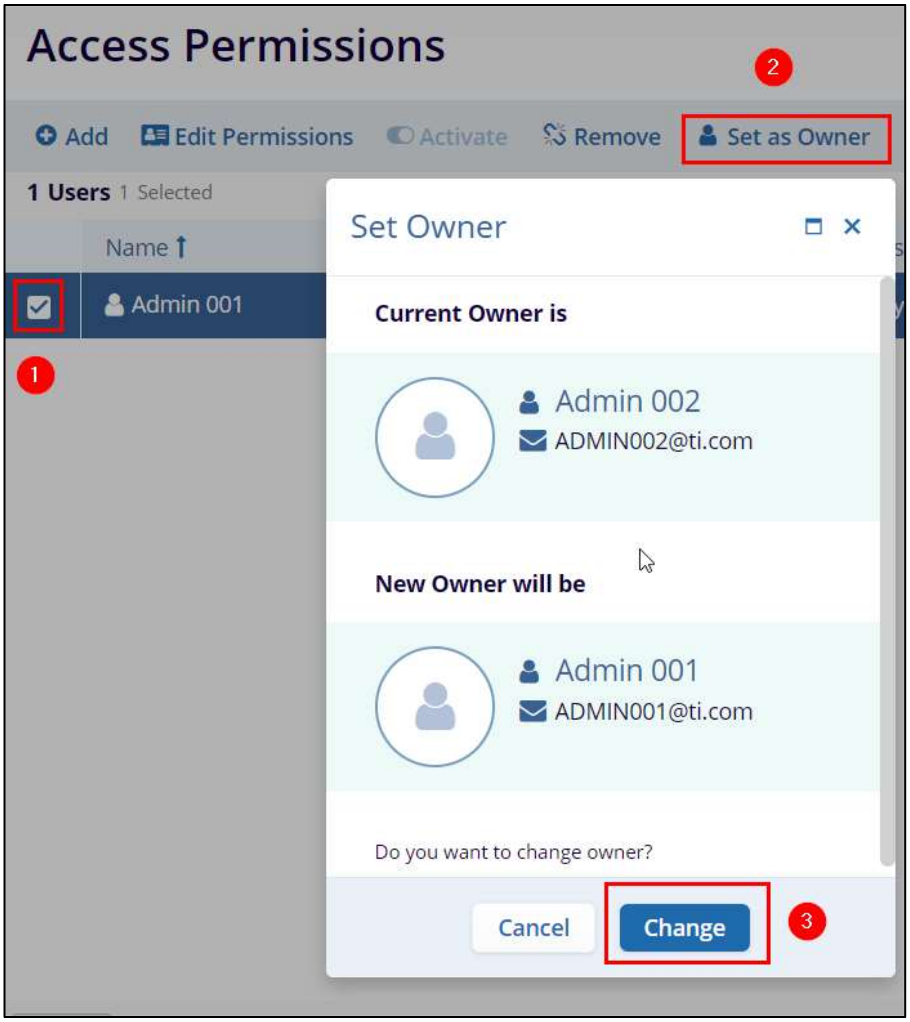


Figure: Set as Owner

f. History
   i. Select a user by clicking on the checkbox.
   ii. Click on the History from the top menu bar
   iii. On the History screen, click on Export to retrieve the historical details of the user.

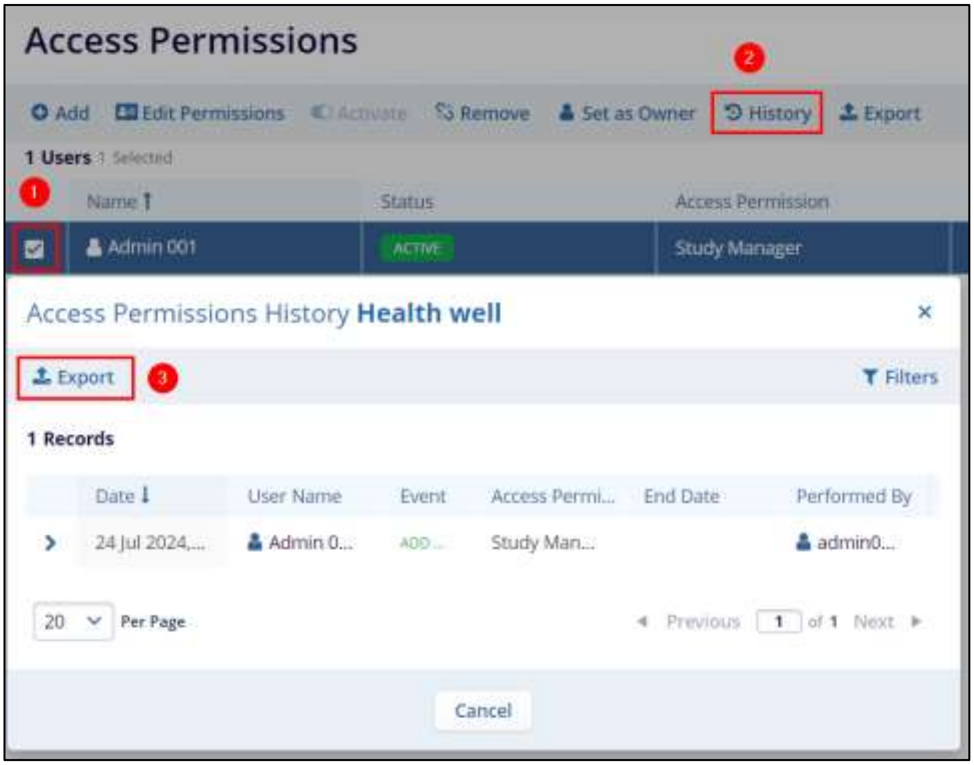


Figure: History

g. Export

i. Click on Export to retrieve an export of Access Permission details. Refer to [Exporting Contacts] section for detailed process.

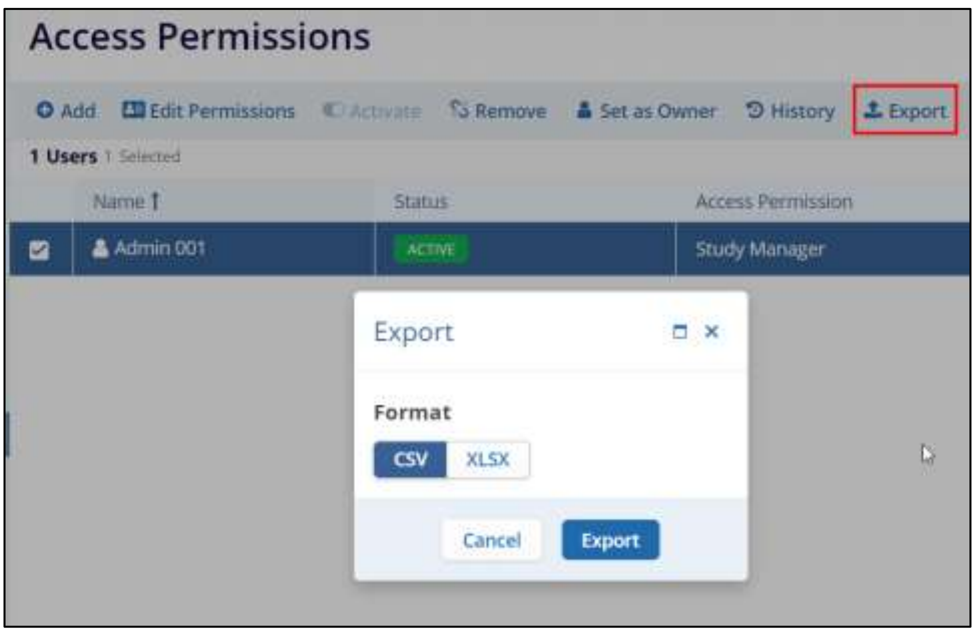


Figure: Export user details

Manage Visible Columns

To manage visible columns, follow the steps below.

1. From the left-hand navigation screens, click on Studies.
2. Select a Study by clicking on the study name to manage its access permissions.

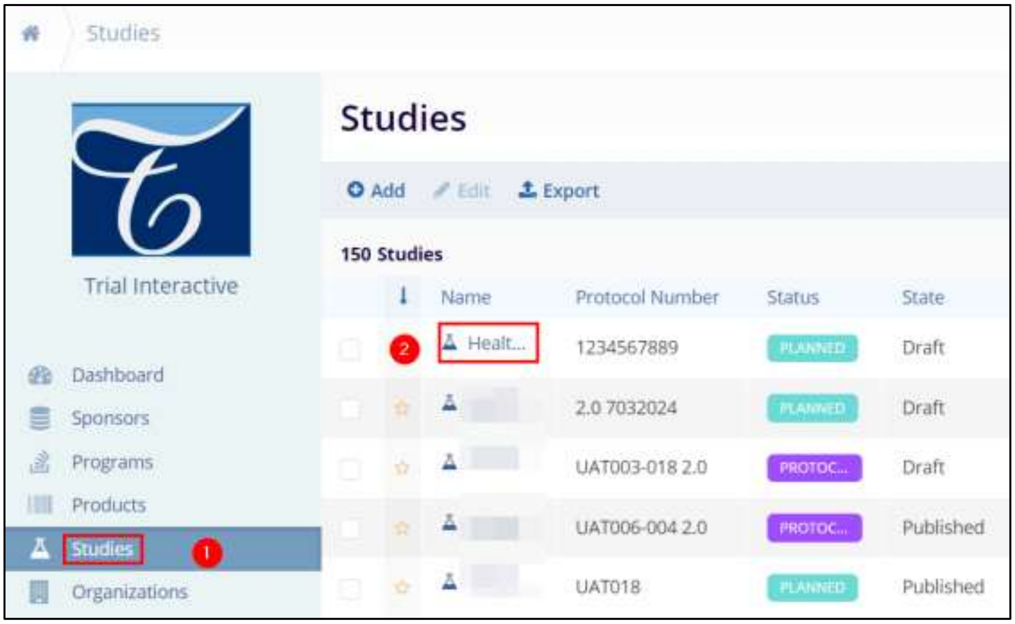


Figure: Select Study and Study name

3. On the Study Dashboard, navigate to the left-hand navigation links and click on Sites.

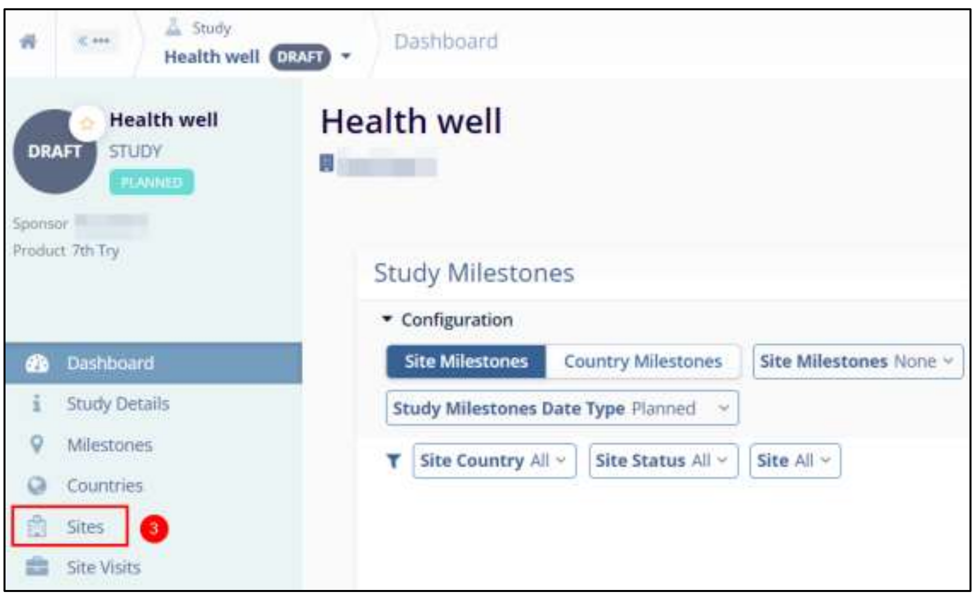


Figure: Select Sites

4. On the Site screen, navigate to the left-hand navigation links and select Activities.

5. Click on the Ellipsis (three-dot menu) displayed next to the Activity Name column.

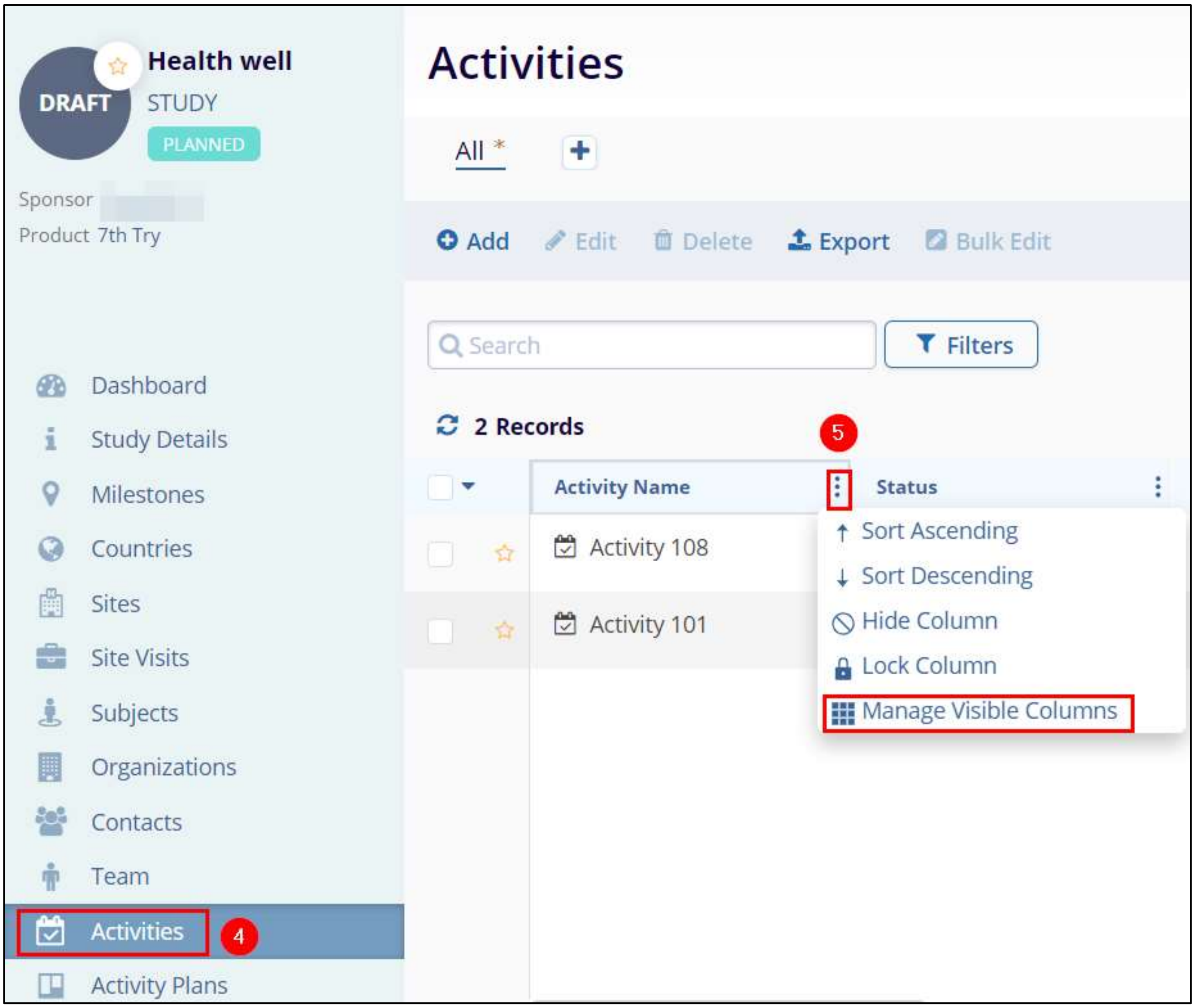


Figure: Manage Visible Columns

Refer to the [Manage Visible Columns](#) section for detailed information.

Create Contact Copy

To create a contact copy, follow the steps below.

1. From the left-hand navigation links, click on Studies.
2. Click on the study's name to select that particular study.

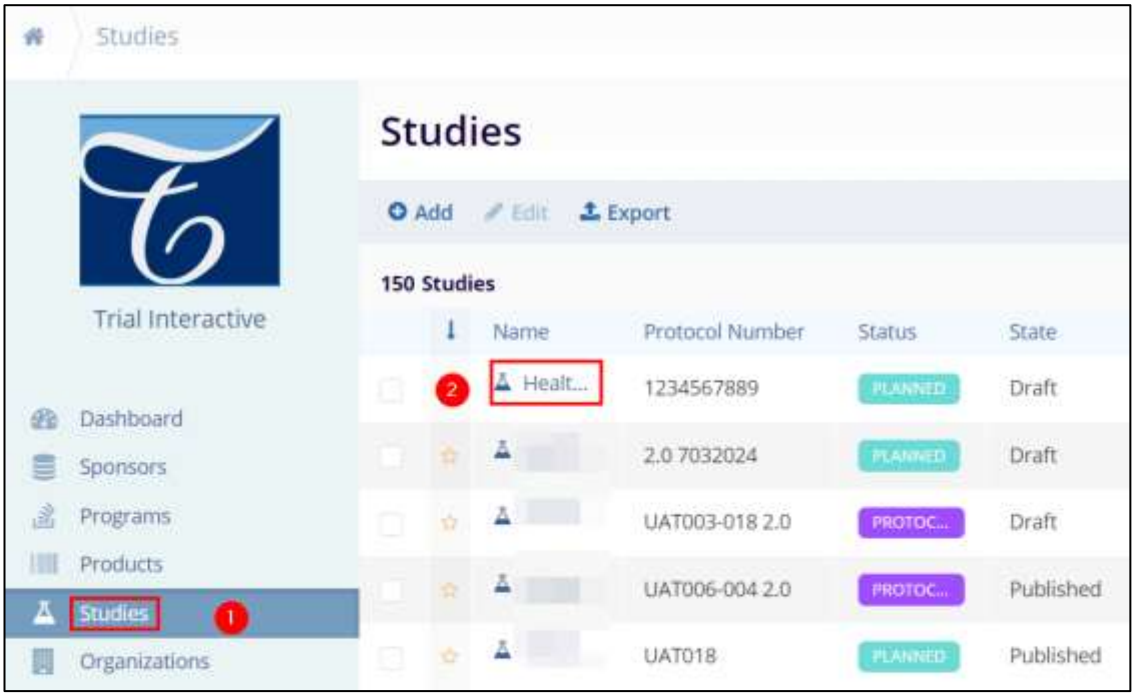


Figure: Select a Study and a study name

3. On the Study Dashboard, navigate to the left-hand navigation links and click on Sites.

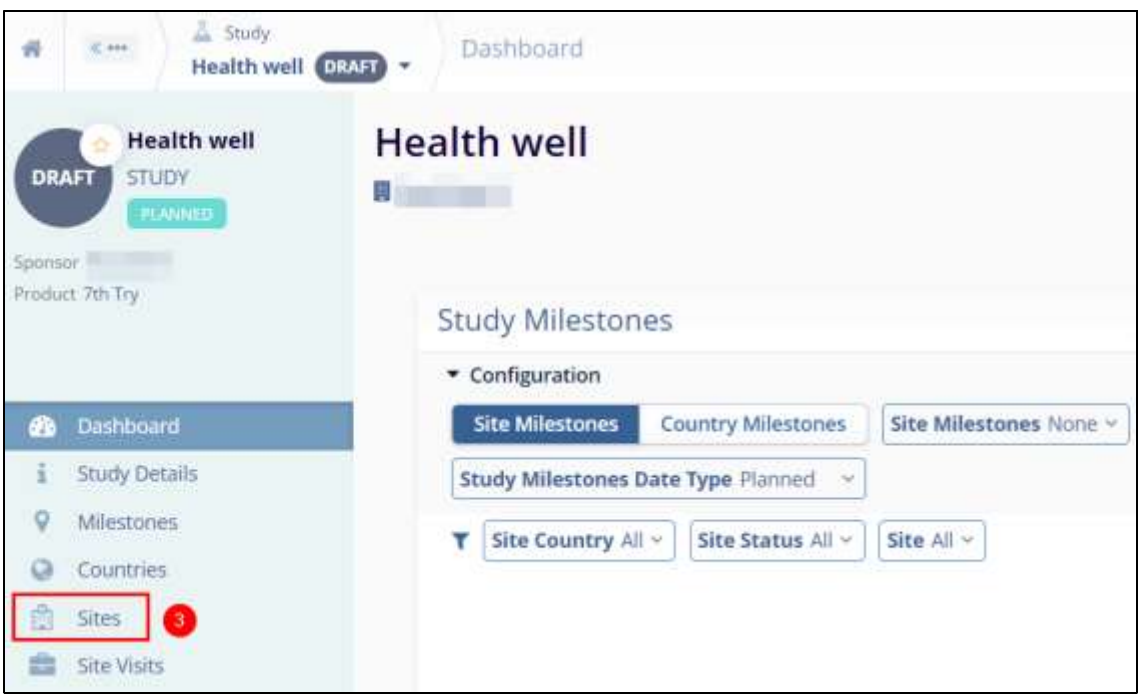


Figure: Select Sites from the Study Dashboard

4. On the Sites screen, navigate to the site records section and select a site by clicking on the site name.

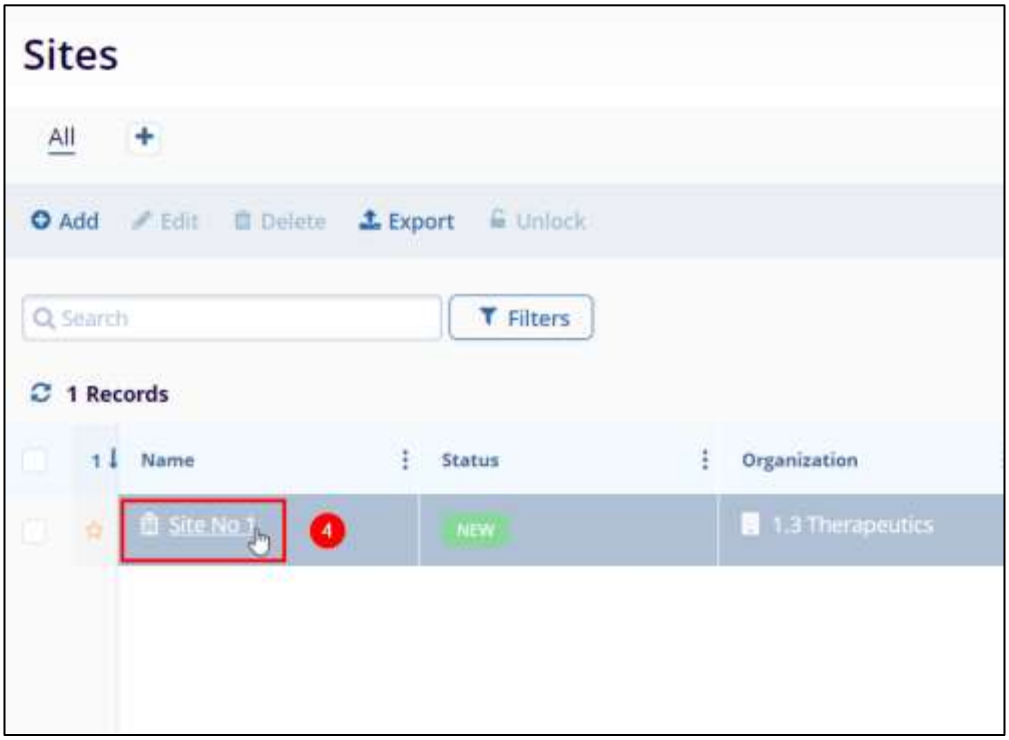


Figure: Select site

5. Click on Contacts from the left-hand navigation links.
6. Click on the checkbox of the contact to copy.
7. Click on the Copy button from the top menu bar.
8. Click on Create once the required details are verified and edited.

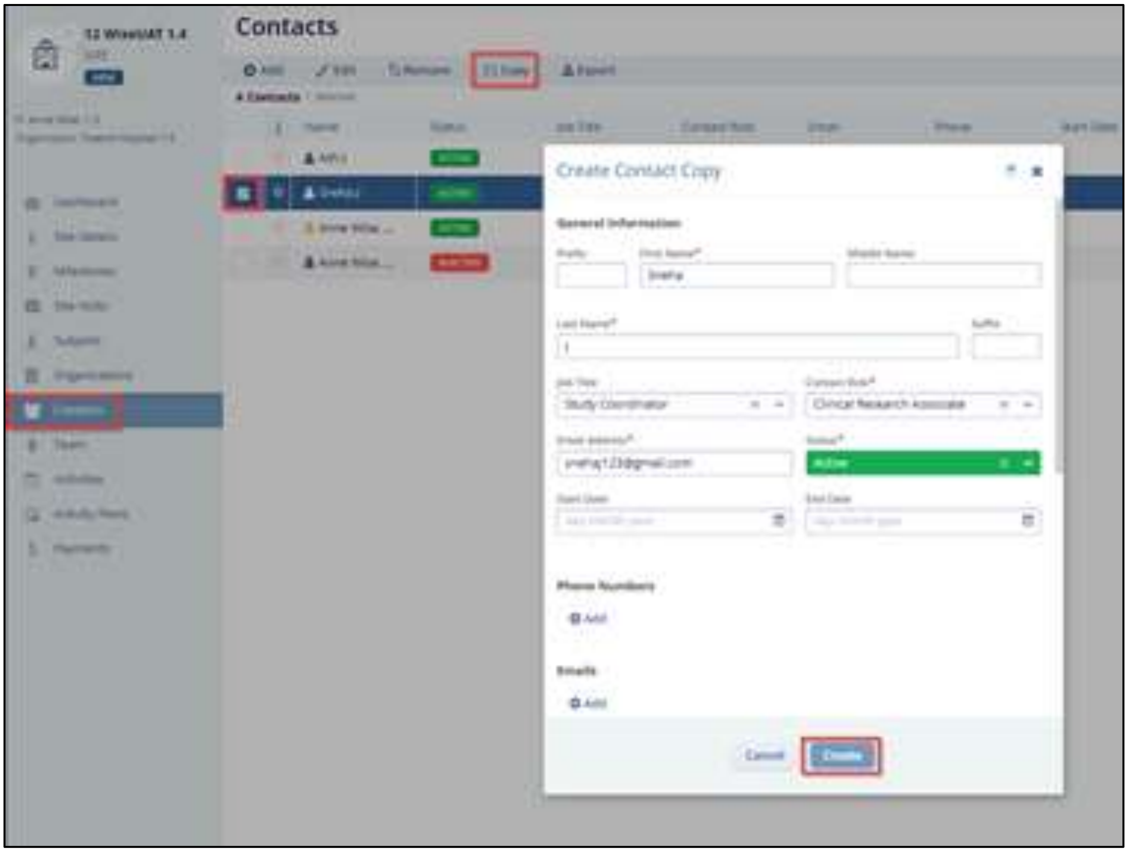


Figure: Create Contact Copy

User-Defined Site Visit Checklists

Company Administrator users can create, edit, and retire site visit checklists rather than needing to channel all requests through the Trial Interactive Service Desk.

Creating a Site Visit Checklist

To create a Site Visit Checklist, follow the steps below

1. Navigate to the side menu bar and select Settings > Site Visit Checklist Templates.

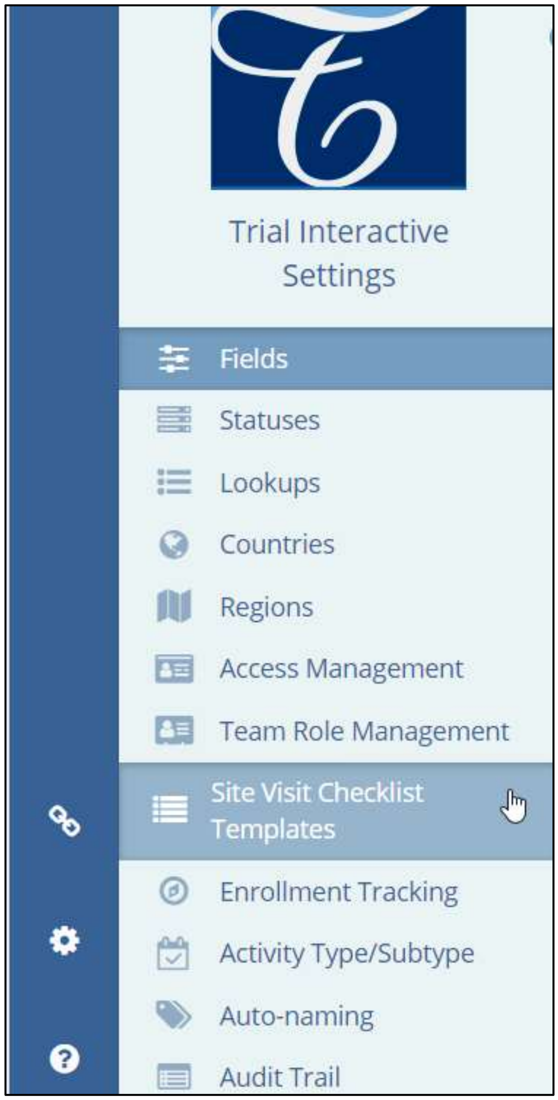


Figure: Site Visit Checklist Templates

2. Press the +Create Template button at the top of the grid area.
   If users are creating a new template as a copy of an existing template, first, select the existing template and then press the Copy button.

Figure: Create Template

3. The ‘Create Site Visit Checklist Template’ window is displayed

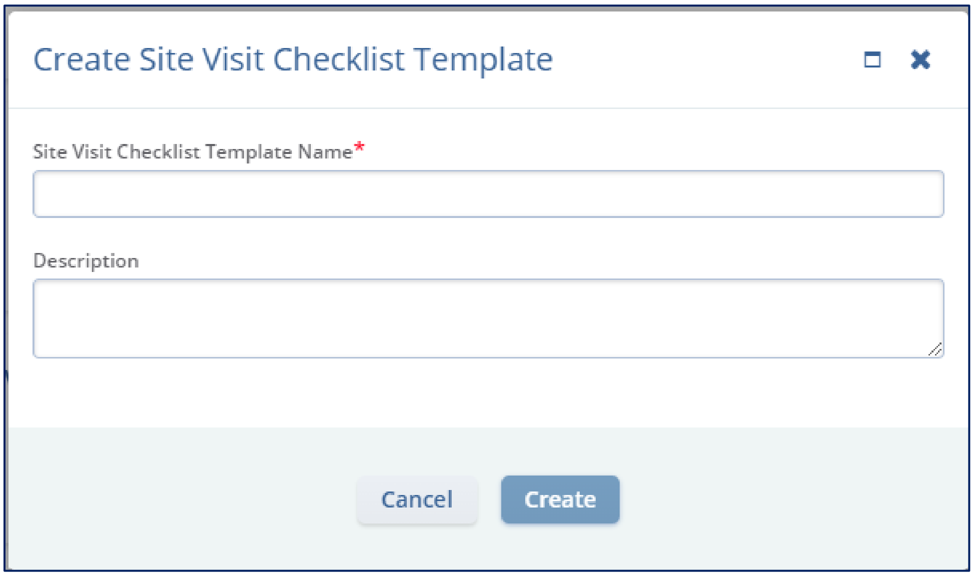


Figure: Create Site Visit Checklist template

4. Give the site visit checklist template a name and, if desired, a description.

Note: We recommend providing a description whenever possible, especially when you may have multiple similar checklist templates. The description can assist you in applying the correct checklist when needed.

5. Press Create and the window will close and the checklist template will appear in the list.

Note: The checklist will be in Draft status initially because we still need to add questions to the checklist before publishing it for use.

6. Select the new checklist from the list.
7. Click Edit from the menu bar at the top of the grid.

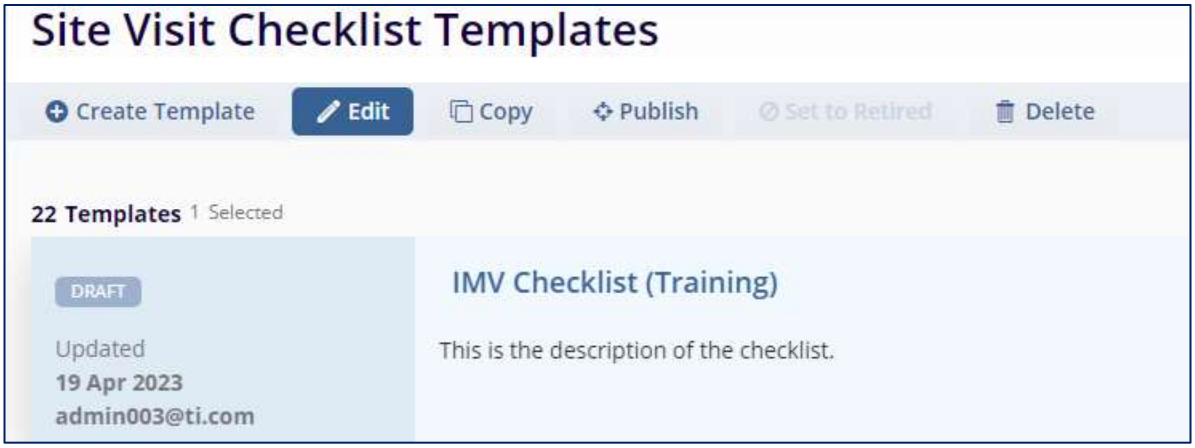


Figure: Edit Template

8. The checklist profile will load.

   Note: This can also be done by clicking on the name of the checklist in the grid.

Figure: Checklist Profile

9. Using the toggle switch, indicate if the sections and questions in the checklist should be ordered and, if so, whether the ordering should be alphabetical or numerical.
10. Press +Add Section and a new section box will appear.

Figure:New Section

11. Give the section a title and, if desired, a description.
12. Press the +Add Question button in the new section.

Figure: Add Question

13. Type in the question and select the type of question from the dropdown menu.

Note: The selection that you make in ‘Type of Question’ will determine what other elements need to be selected/completed.

14. When the question is ready, press the Save button in the menu bar at the top of the screen.
15. Continue adding sections and questions until the checklist is complete.
16. Press Save.

Publishing a Site Visit Checklist

To Publish a Site Visit Checklist Template, follow the steps below

1. Navigate to the Settings area and select the Site Visit Checklist Templates option from the navigation links at the left side of the screen.

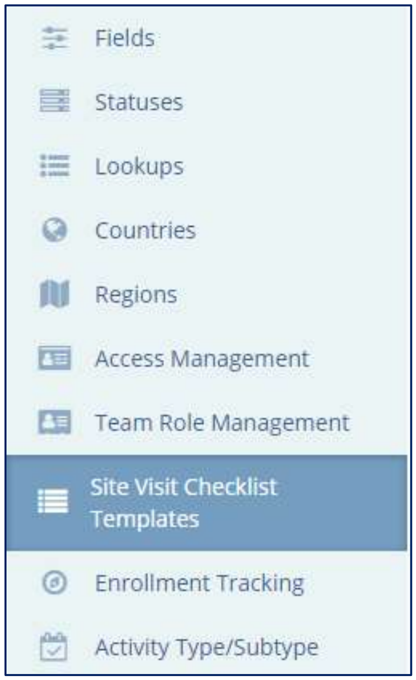


Figure: Site Visit Checklist Templates

2. Select the checklist from the list displayed.
3. Press the Publish button in the menu bar at the top of the screen.

   Note: This will differ somewhat depending on whether the user selects the checklist in the list by clicking on the name of the checklist or by clicking elsewhere. Regardless, the user will need to click on the Publish button and follow the remaining steps.

4. The 'Publish Site Visit Checklist Template' window will open.

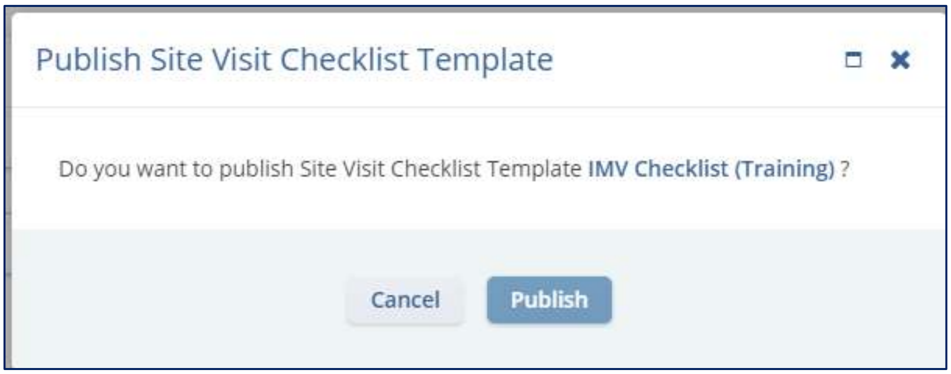


Figure: Publish Site Visit Template

5. Click Publish and the checklist will be displayed in a Published status in the list.

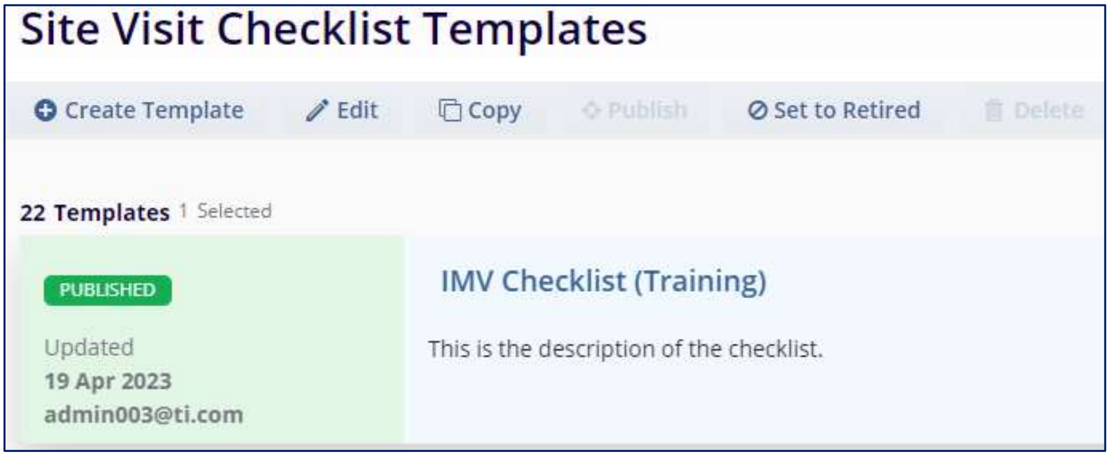


Figure: Published Template

Retiring a Site Visit Checklist

Note: Once a Site Visit Checklist has been retired, it cannot be re-published. You would need to copy the checklist and publish the new copy if you needed to use the checklist again.

To Retire a Site Visit Checklist Template:

1. Navigate to the Settings area and select the Site Visit Checklist Templates option from the navigation links at the left side of the screen.

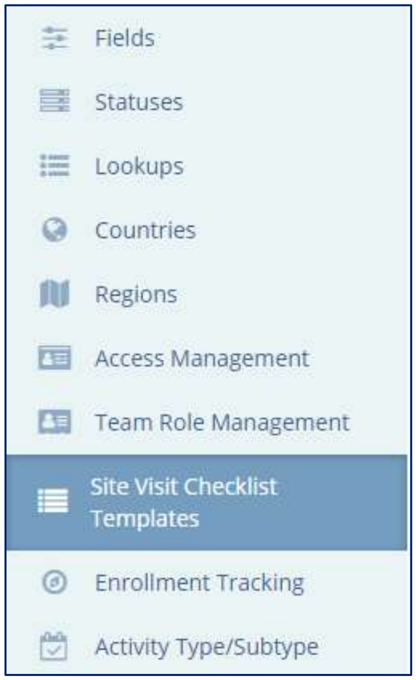


Figure: Site Visit Checklist Templates

2. Select the checklist from the list displayed.
3. Press the Set to Retired button in the menu bar at the top of the screen.

   Note: This will differ somewhat depending on whether you select the checklist in the list by clicking on the name of the checklist or by clicking elsewhere. Regardless, you'll need to click on the Set to Retired button and follow the remaining steps.

4. The 'Set Retired Site Visit Checklist Template' window will open.

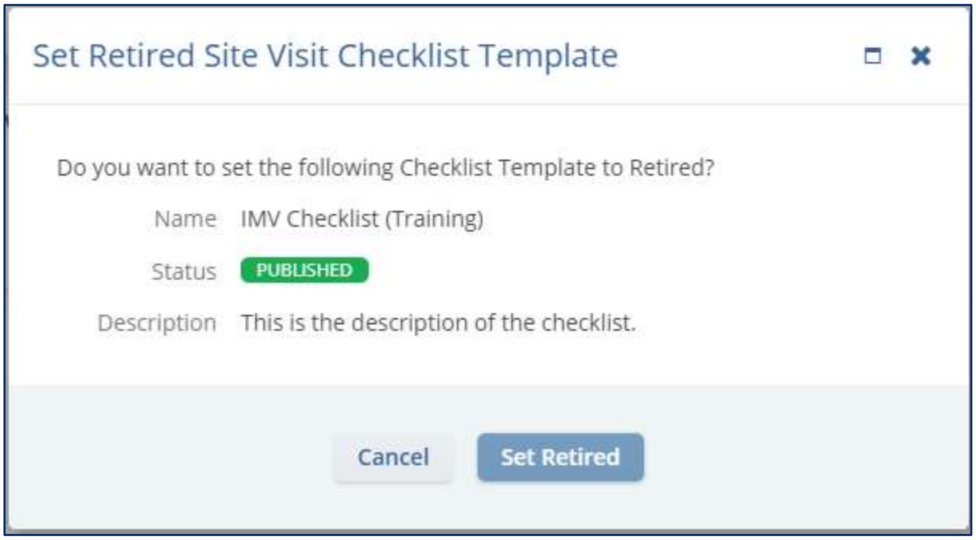


Figure: Set template as Retired

5. Click Set Retired and the checklist will be displayed in a Retired status in the list.

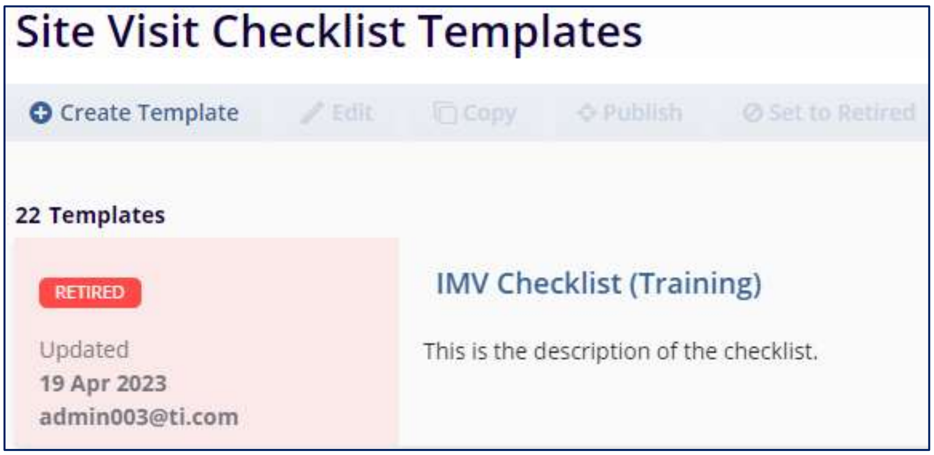


Figure: Retired Template

Deleting a Site Visit Checklist

Deleting a site visit checklist can only be done once the checklist has been retired. Please perform those steps before continuing.

To Retire a Site Visit Checklist Template, follow the steps below

1. Navigate to the Settings area and select the Site Visit Checklist Templates option from the navigation links at the left side of the screen.

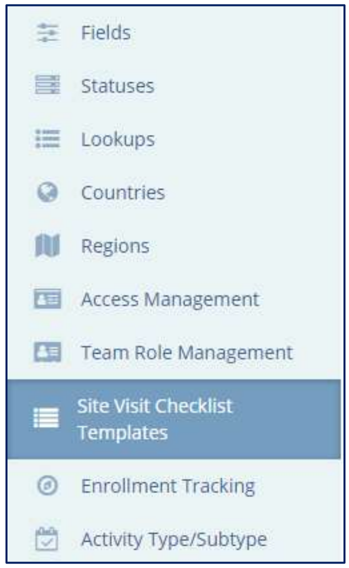
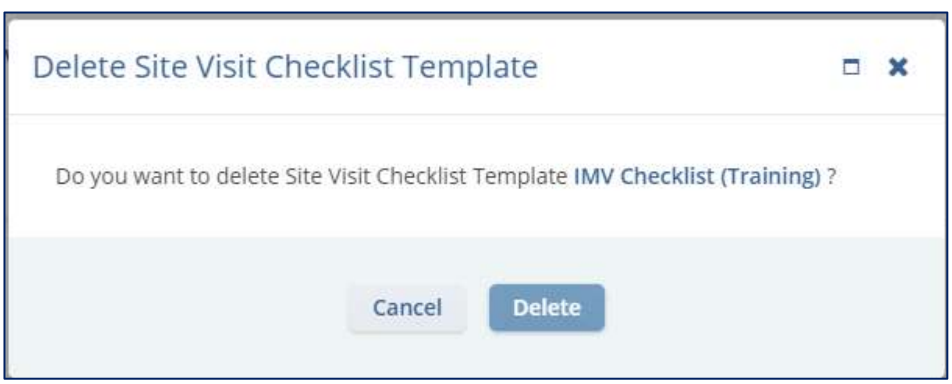


Figure: Site Visit Checklist Templates

2. Select the checklist from the list displayed.
3. Press the Delete button in the menu bar at the top of the screen.

   Note: This will differ somewhat depending on whether you select the checklist in the list by clicking on the name of the checklist or by clicking elsewhere. Regardless, you'll need to click on the Delete button and follow the remaining steps.

4. The 'Delete Site Visit Checklist Template' window will open.



5. Click Delete and the checklist will be removed from the list.

Auto-Saving Answers for Site Visit Checklists

When a user is filling out a site visit checklist, their answers will automatically save when they move on to another question. The screen will refresh between questions and the visit checklist progress bar will be updated to display the user's current progress toward completion.

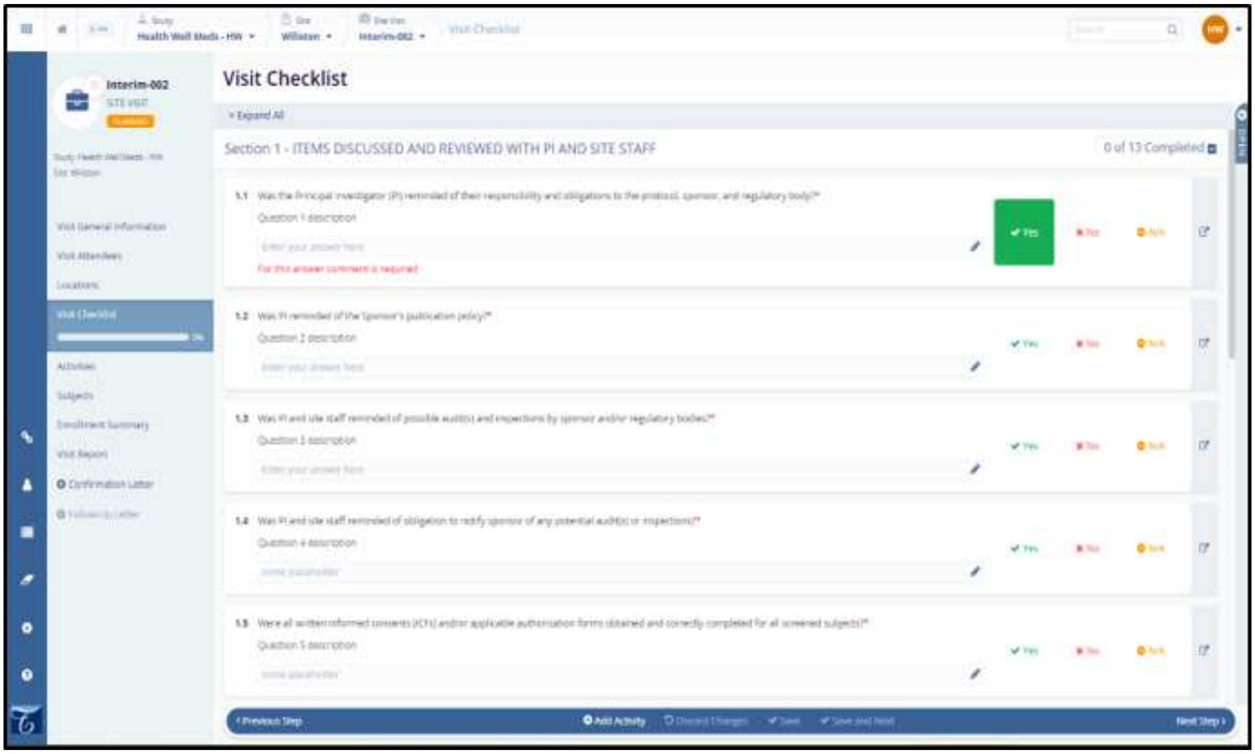


Figure: Auto Saving Answers

Unblinded Visit Type Naming Requirements

Users can indicate that a visit type is unblinded without the necessity of having '**unblinded'** appear in the name of the visit type.

CTMS ensures all unblinded content is restricted to unblinded team members –

- Site Visits,
- Site Visit Reports,
- Visit Report Content (responses),
- Subject related comments, and
- Unblinded activities/actions.

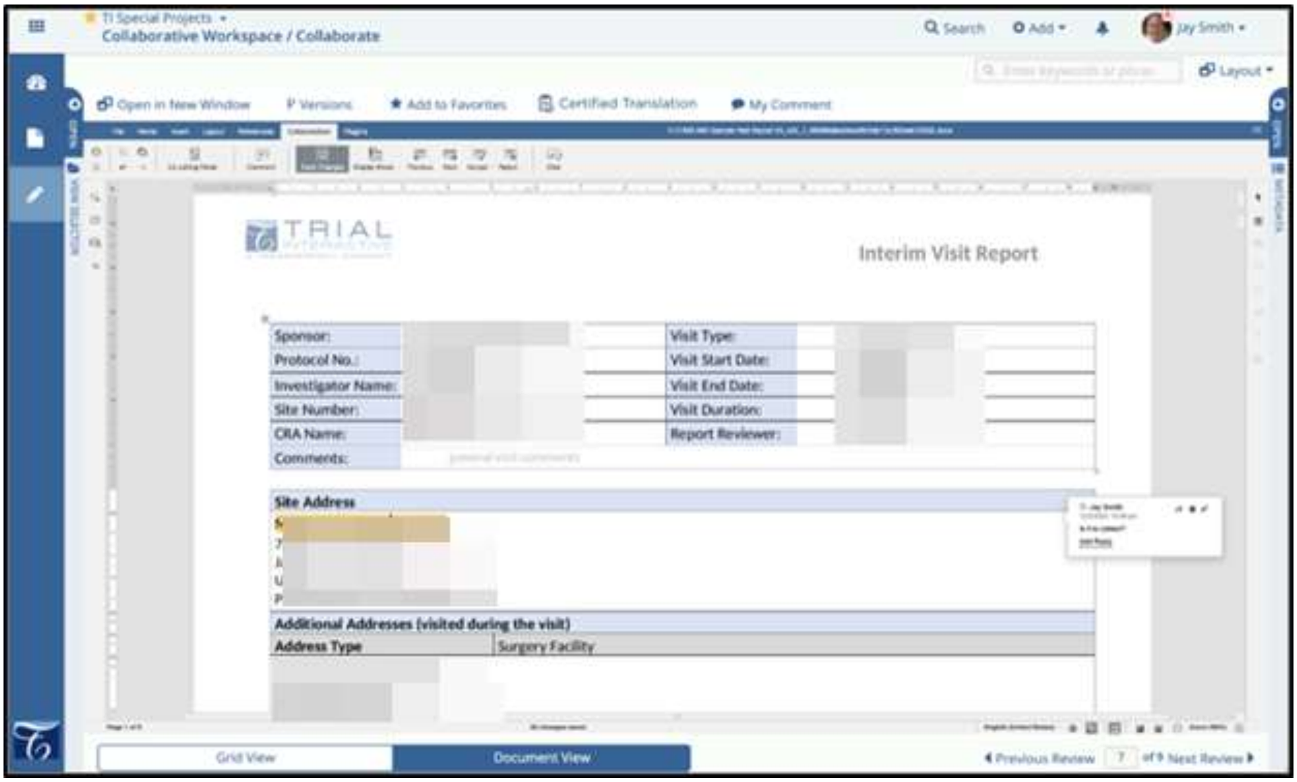


Figure: Unblinded Visit Type Naming Requirements

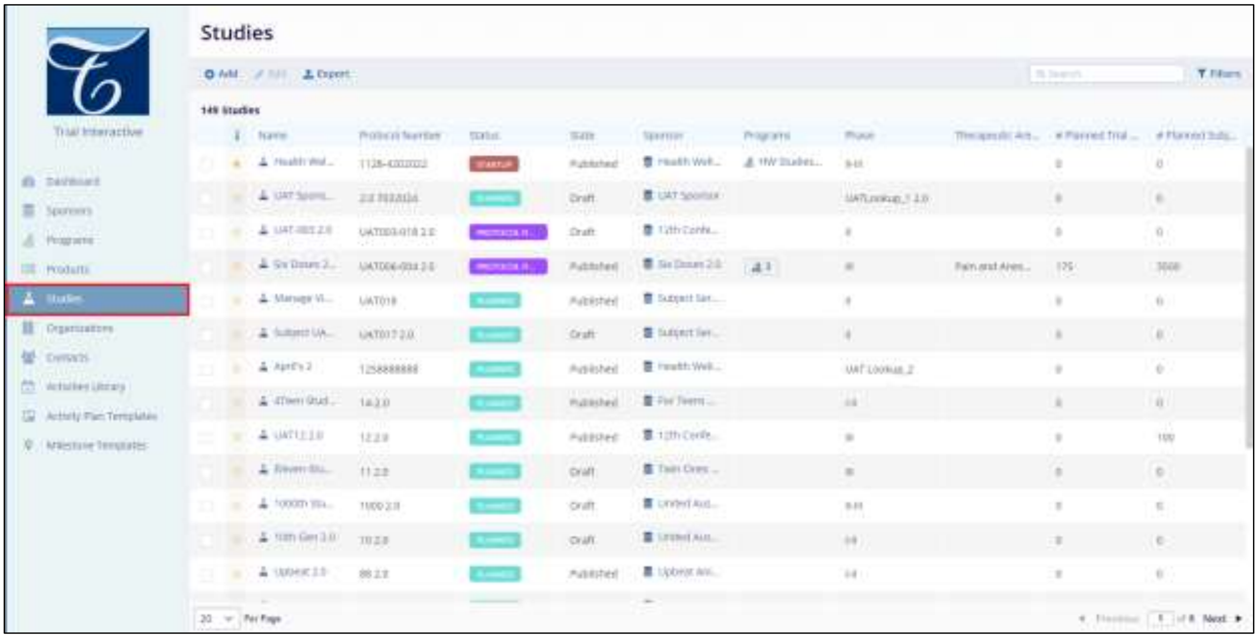
Studies

Pre-Requisites

Users creating or managing studies in an organization should have CSM user access. Company administrators must assign CREATE, UPDATE, EDIT, and DELETE permissions to these users' accounts, enabling them to perform these tasks effectively.

Navigate to Studies.

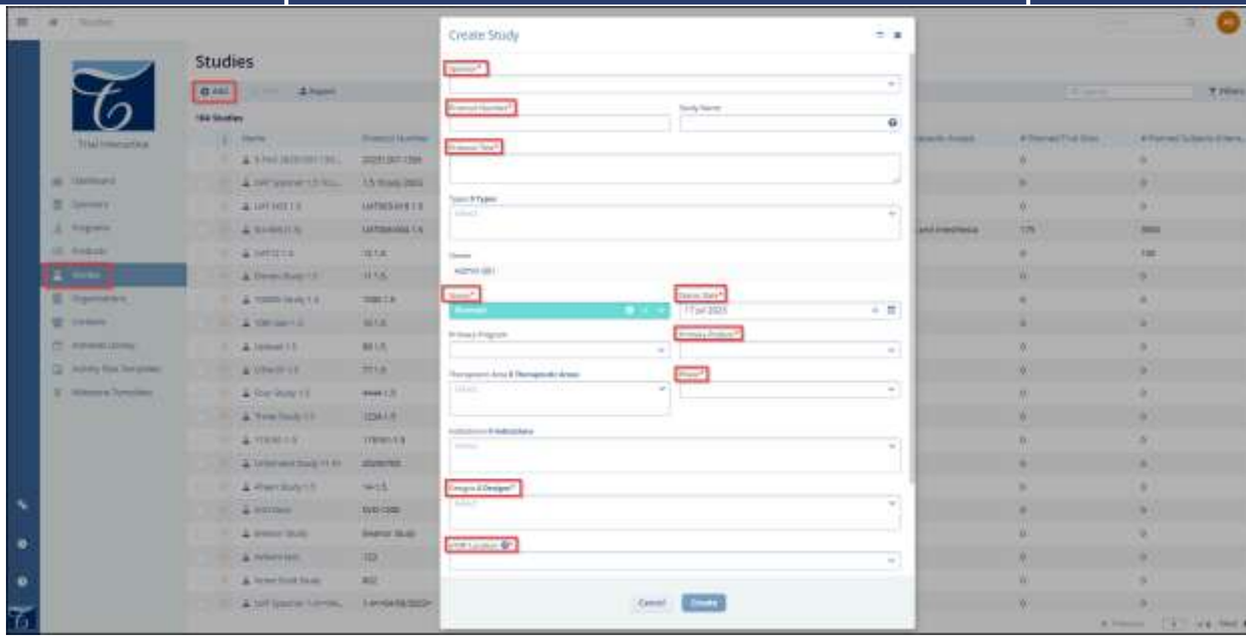
1. To navigate a studies screen, click on the Studies link in the Navigation menu at the left side of the screen. It will redirect you to the Studies screen.



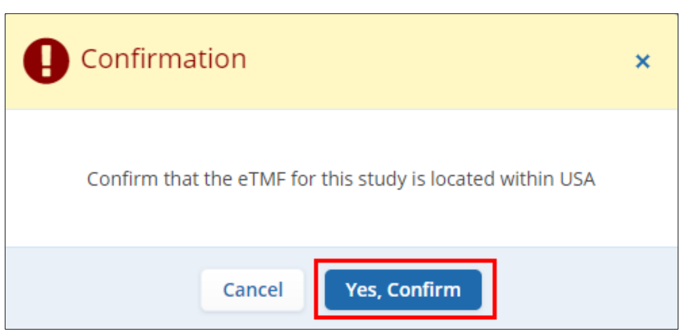
Steps to Add Studies

1. To add a study, click on the '**Add**' button from the top main menu.

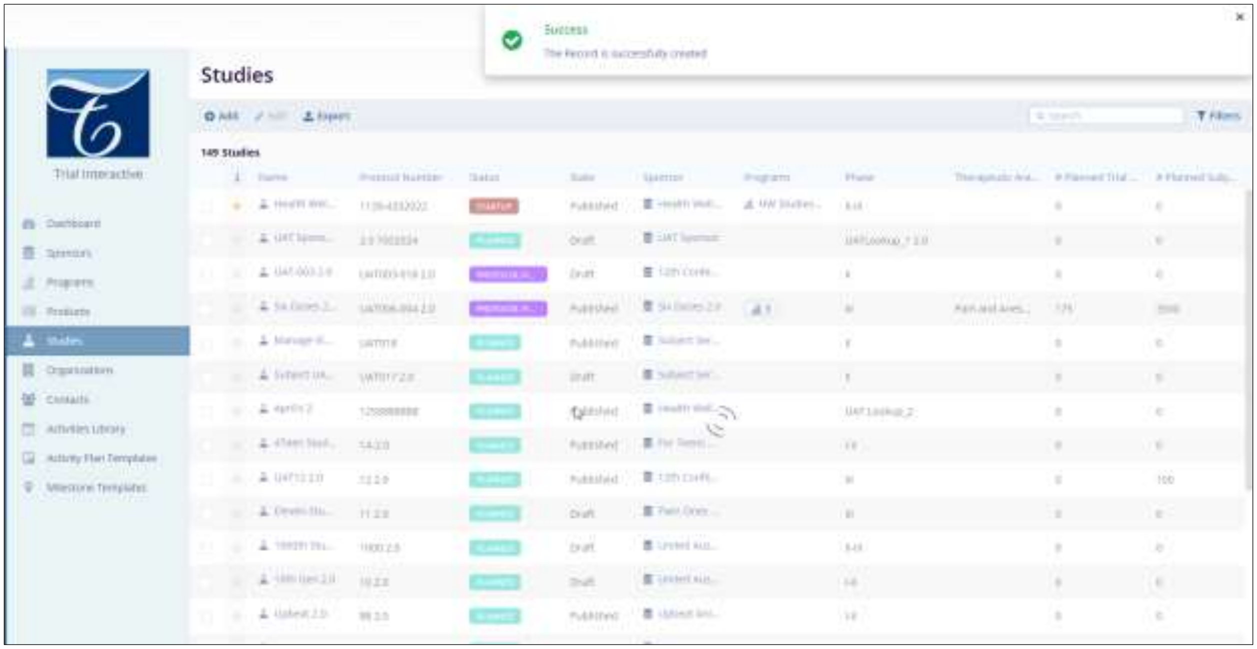
2. It opens the 'Create Study' window.



3. Enter the mandatory metadata to create a study (Sponsor, Protocol Number, Protocol Title, Status, Status Date, Primary Product, Phase, Design, and eTMF Location). These fields are marked with an asterisk (*) next to the field title. You may also enter any additional information as necessary.
4. Indicate whether this is a blinded trial on the Study Details page. Although you can update this information after the study has been created, this is your first opportunity to specify that the study will include a blinded component.
5. If any required fields are missing, an error message will appear when the user clicks the ‘Create’ button, listing the fields that need to be filled to create the study successfully.
6. Click the ‘Toggle’ buttons for Virtual Study, Subject Tracking, and Is this a blinded trial. These fields are optional.
7. To create a study, click the ‘Create’ button. If you wish to cancel the study creation, click the ‘Cancel’ button.
8. After clicking the Create button the user will receive a confirmation message regarding the ETMF location. Users need to confirm the location and click on the “Yes, Confirm” button to proceed further. Please refer to the screenshot below.



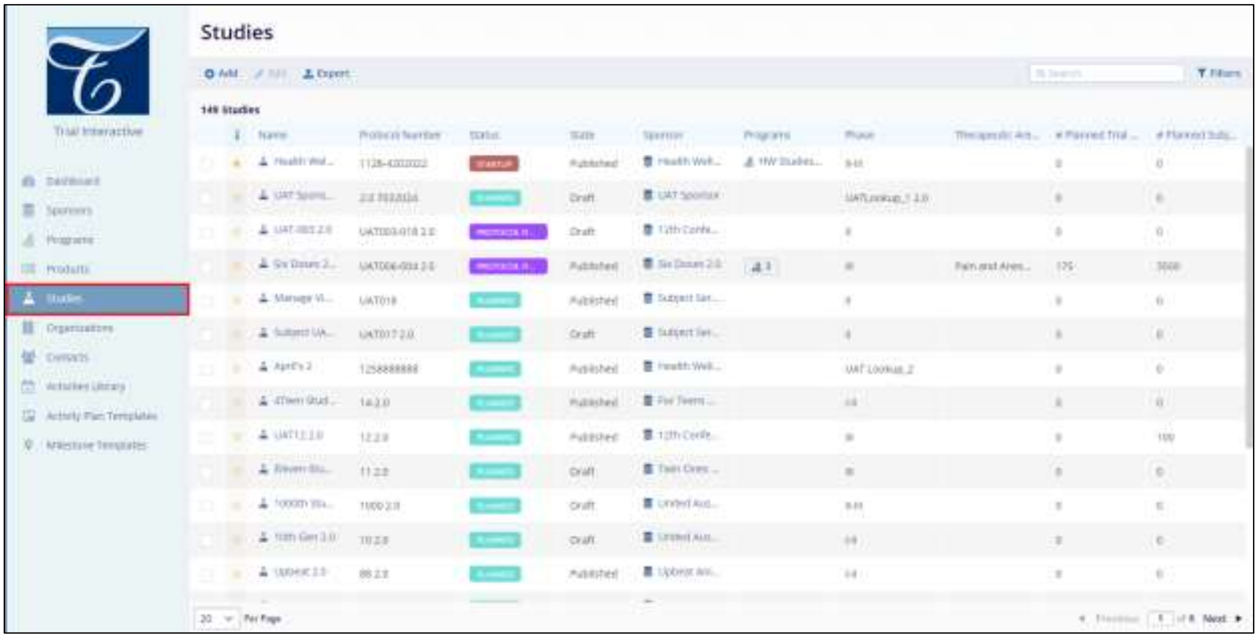
9. Once the user confirms by clicking the Yes, Confirm button, a success message will pop up on the top left side of the screen, and the newly created study will be available in the grid view.



How to Edit a Study

Navigate to Studies.

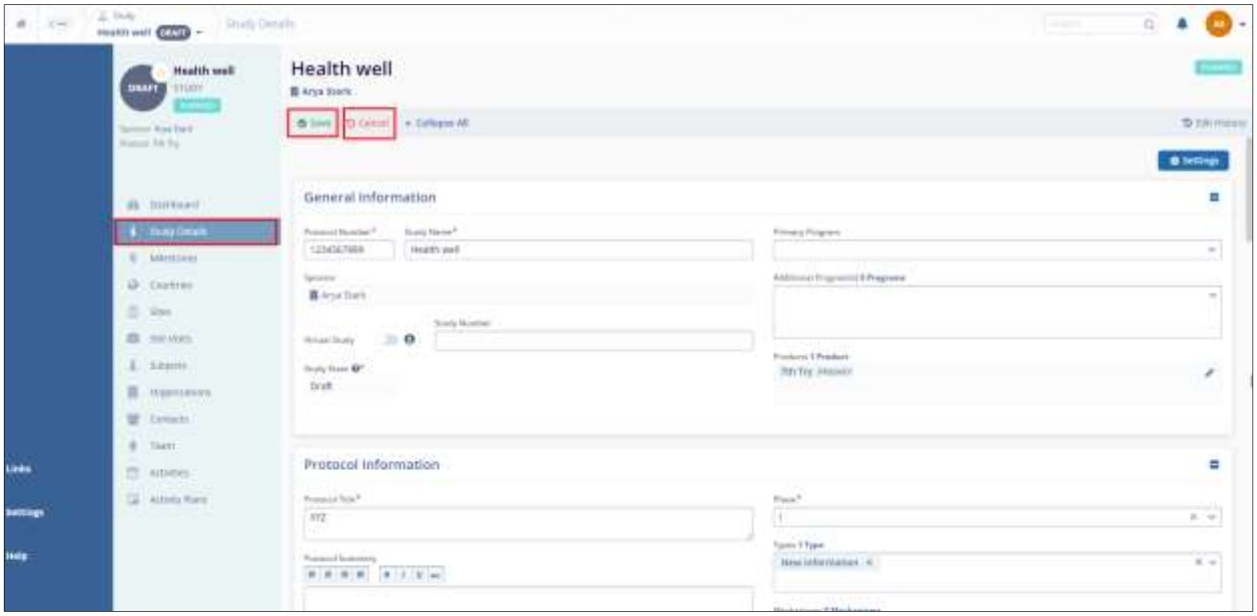
1. To navigate a studies screen, click on the '**Studies'** link in the Navigation menu at the left side of the screen. It will redirect you to the Studies screen.



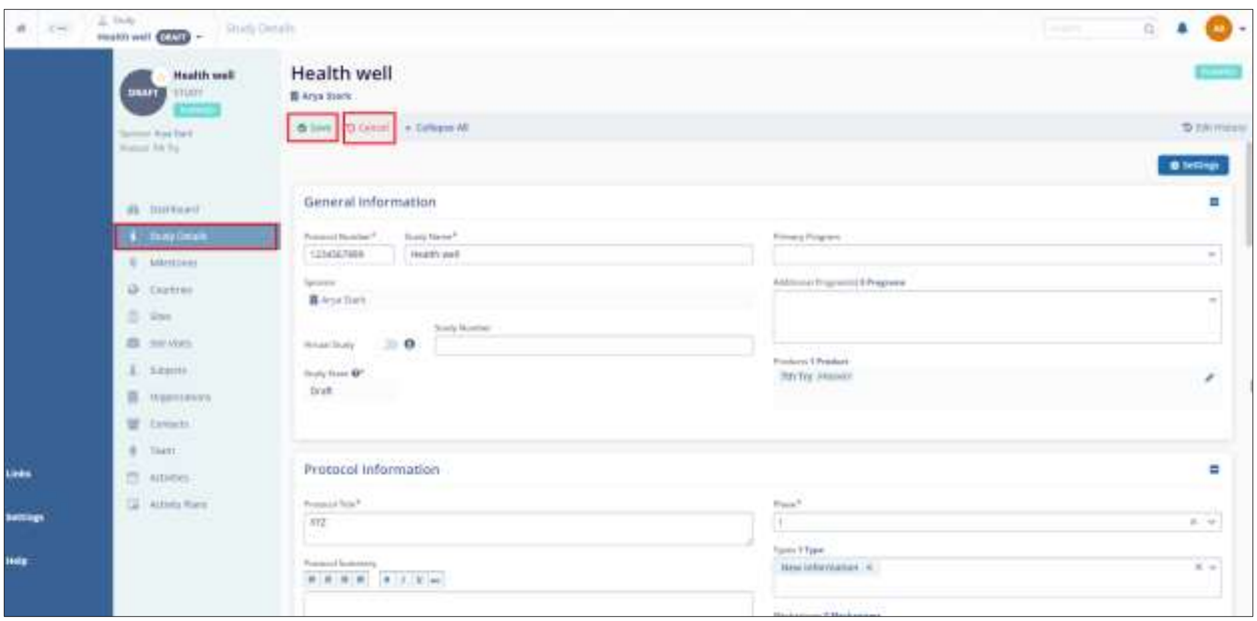
Steps to Edit Study

1. Click on the check box next to the name of the study and click on the '**Edit'** button from the top main menu. Refer to the screenshot below.

   a. The 'Study Details' window is displayed.



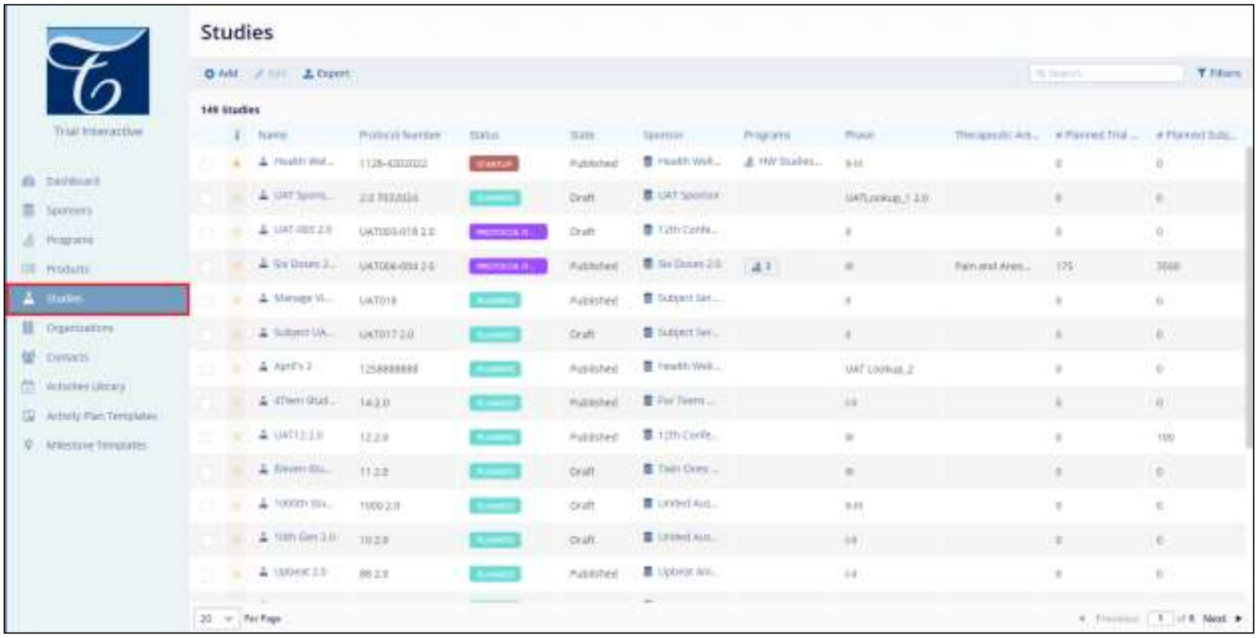
1. Make any necessary changes to the Study information.
2. Click the ‘Save’ button for the changes to apply or to discard the changes click on the ‘**Cancel**’ button.



Study Settings

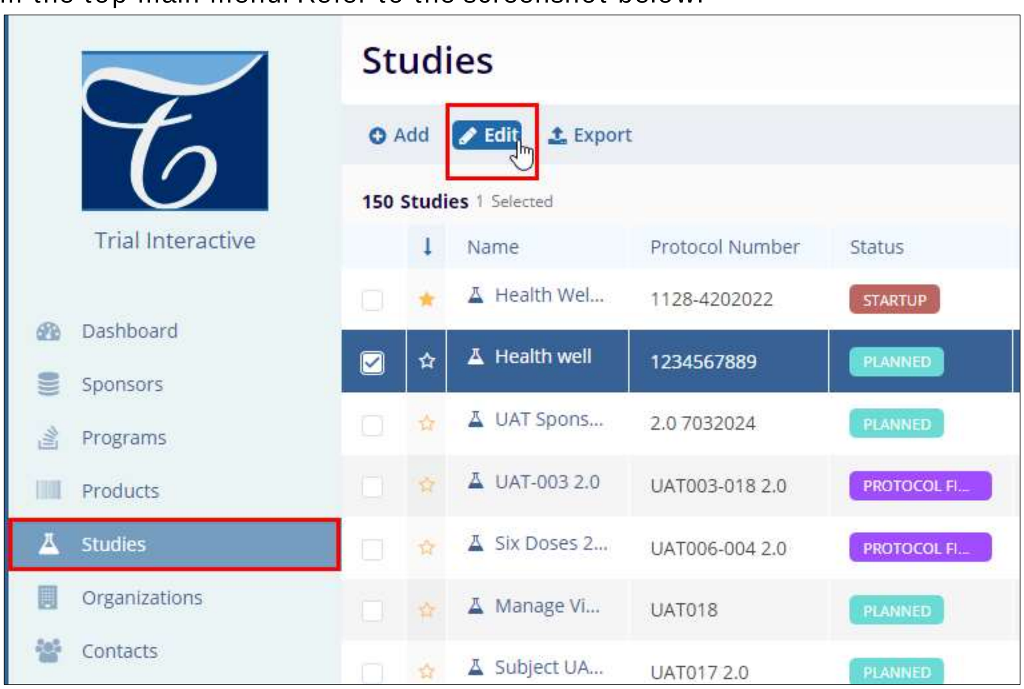
Navigate to Studies.

1. To navigate a studies screen, click on the '**Studies'** link in the Navigation menu at the left side of the screen. It will redirect you to the Studies screen.

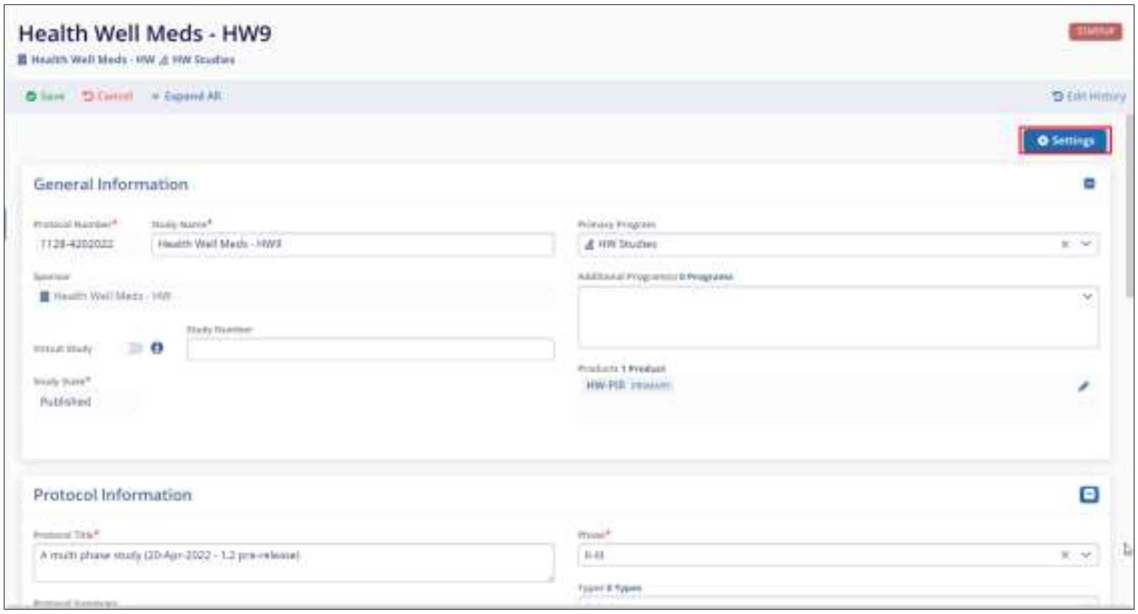


Steps to Manage Study Settings

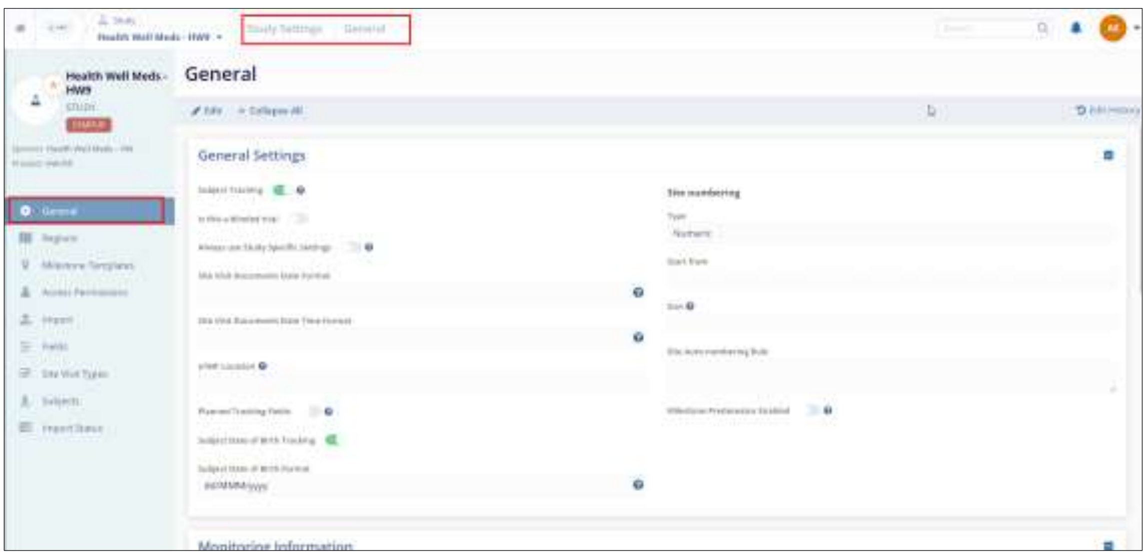
1. Click on the check box next to the name of the study and click on the '**Edit'** button from the top main menu. Refer to the screenshot below.



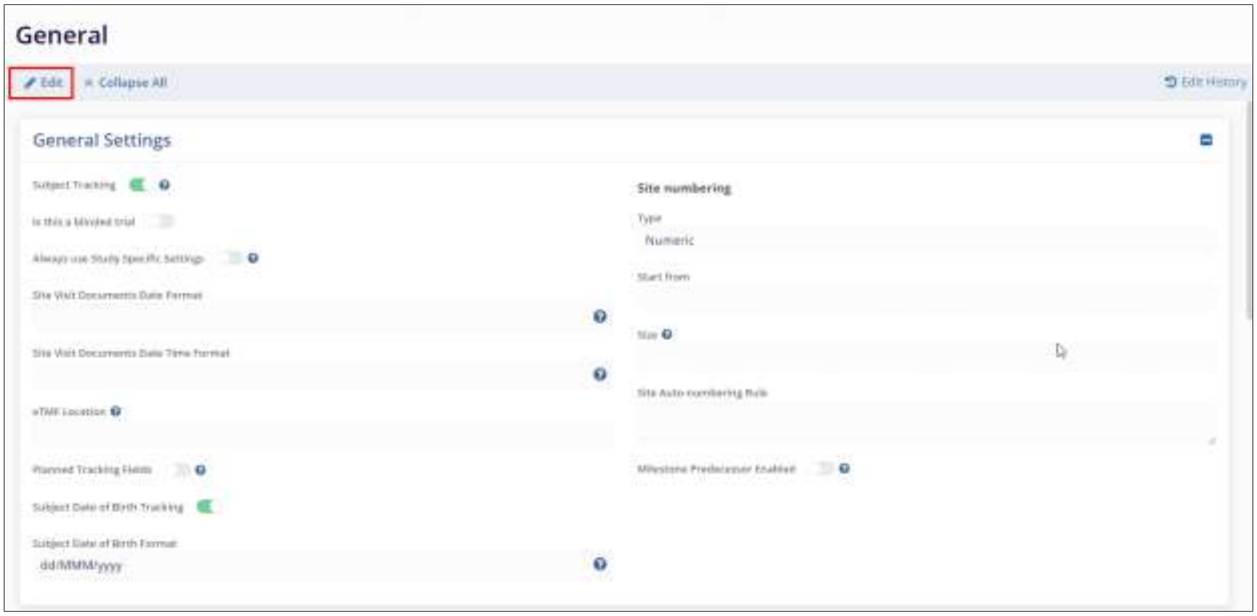
2. The '**Study Details'** window is displayed.



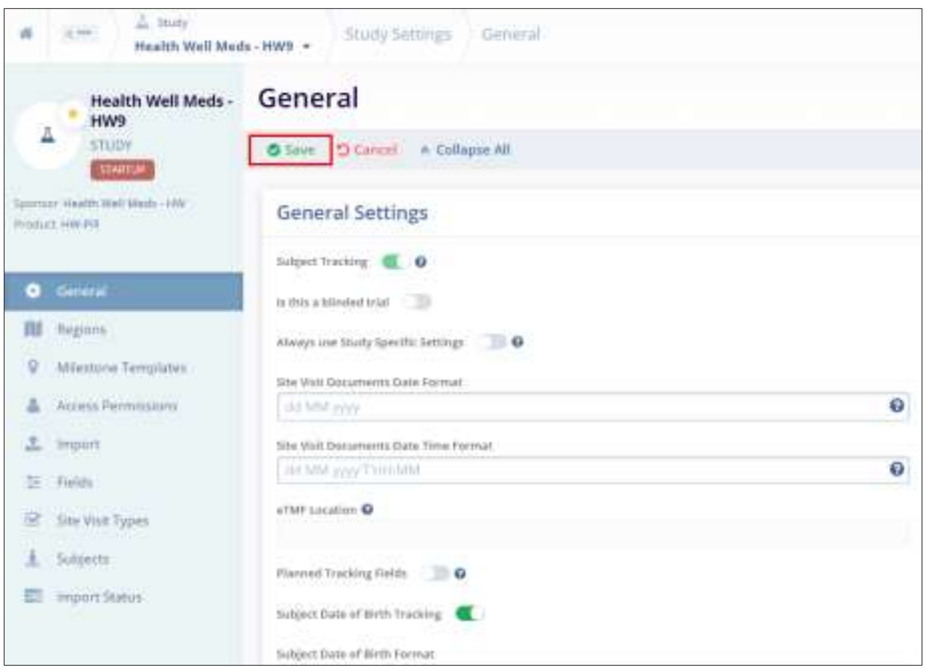
3. It will redirect you to the study general settings. Refer to the below screenshot.



4. To edit the general study setting, the user needs to click "Edit" in the study settings window at the top-left of the screen.



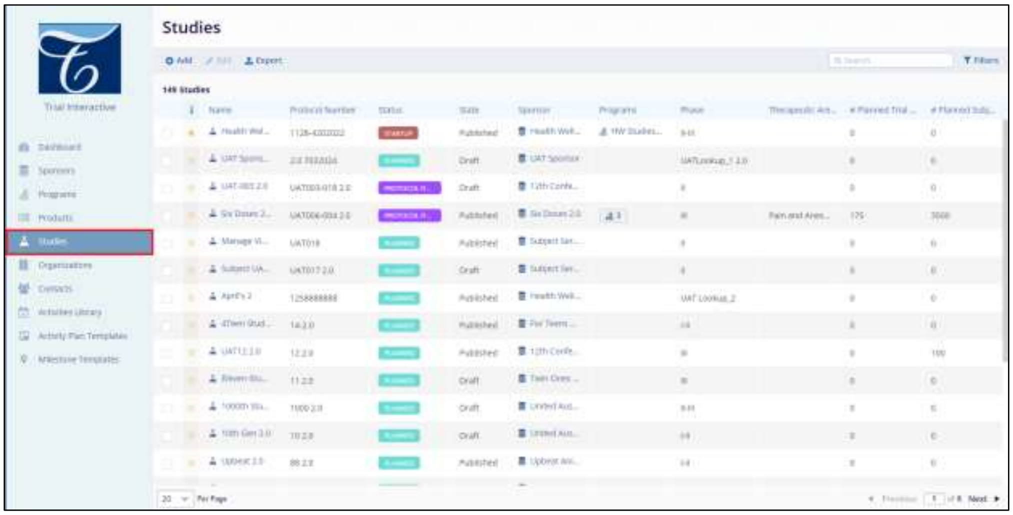
5. Make any necessary changes in the "Study Settings General" window.



5. Click "Save" at the top-left of the window.

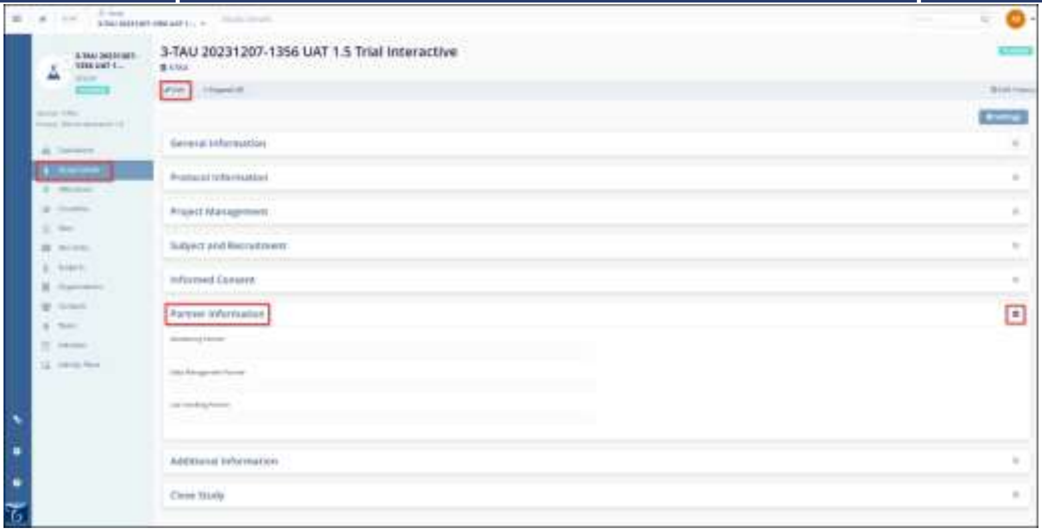
Defining Study Partners

1. Click on the Studies link in the Navigation menu at the left side of the screen. This opens the "**Studies**" window and the study list is displayed.

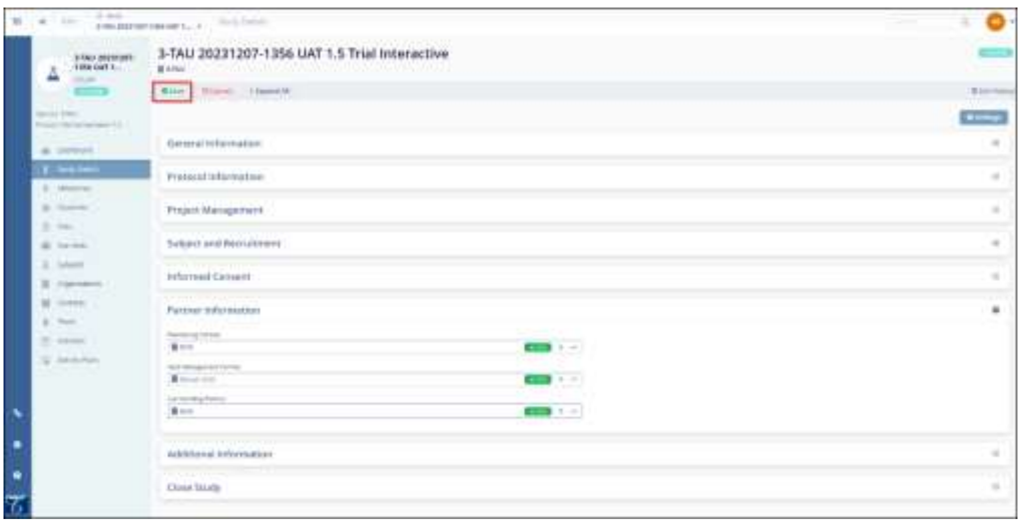


2. Click on the name of the study to which you want to add partner information. The dashboard for the study is displayed.

3. Click on the Study Details in the Navigation menu at the left side of the screen. The "**Study Details**" window is displayed.
4. Click on the [+] sign next to the '**Partner Information**' to expand that section. Click on the Edit button in the top-left of the screen. Refer to the below screenshot.



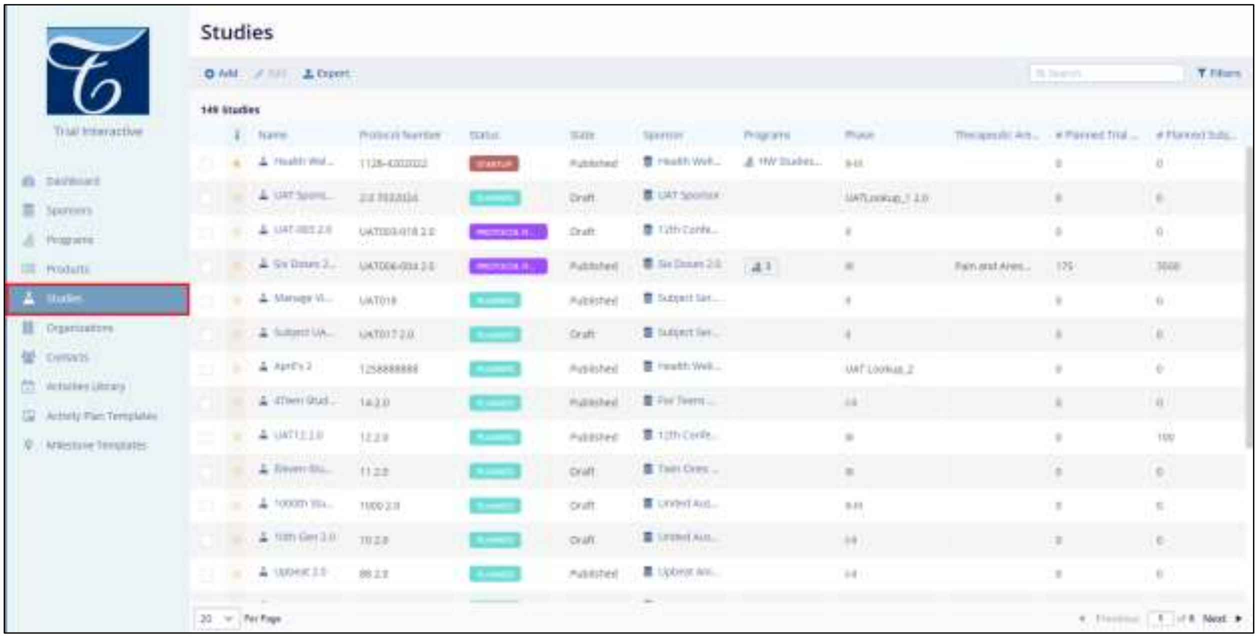
5 Make the necessary changes in the partner information section.
6 Click the Save button in the top-left of the screen.



Study Dashboard

Navigate to the Studies Dashboard

1. To navigate a Studies Dashboard, click on the '**Studies'** link in the Navigation menu at the left side of the screen. It will redirect you to the studies screen.

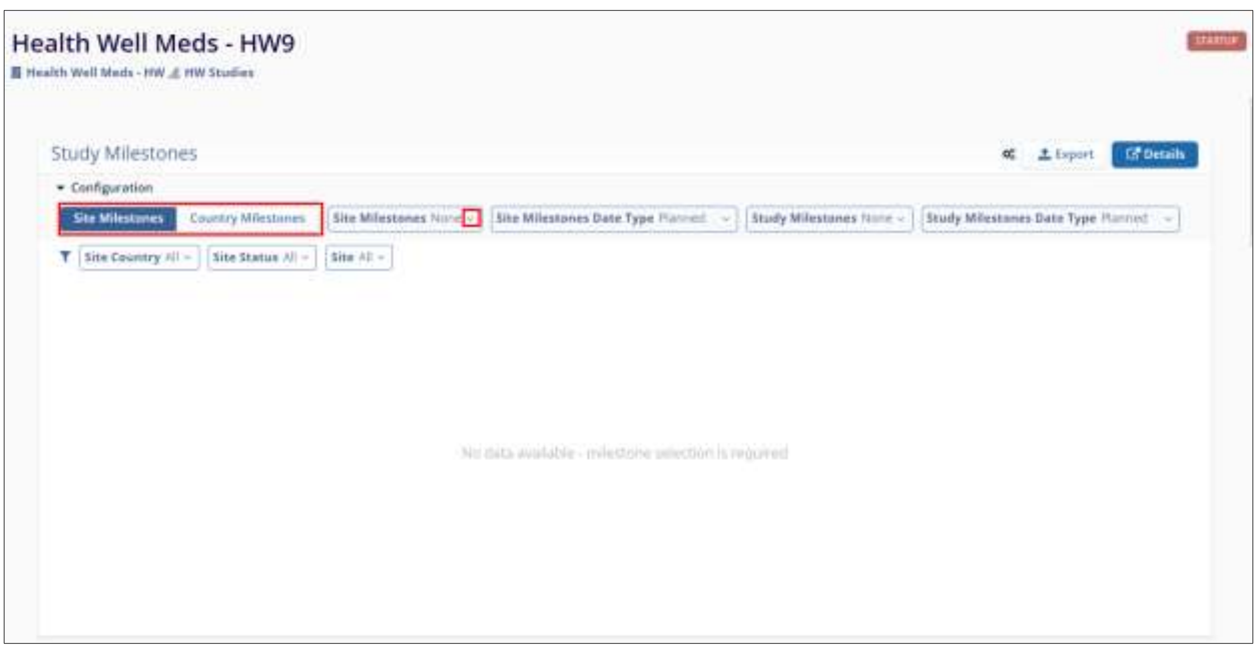


6. Click on the check box next to the name of the study and click on the '**Edit'** button from the top main menu or Directly click on the Study name. Refer to the screenshot below.

7. It will redirect the user to the Study Details screen. From the navigation pane, Click on the Dashboard. It will redirect you to the **Study's Dashboard**.

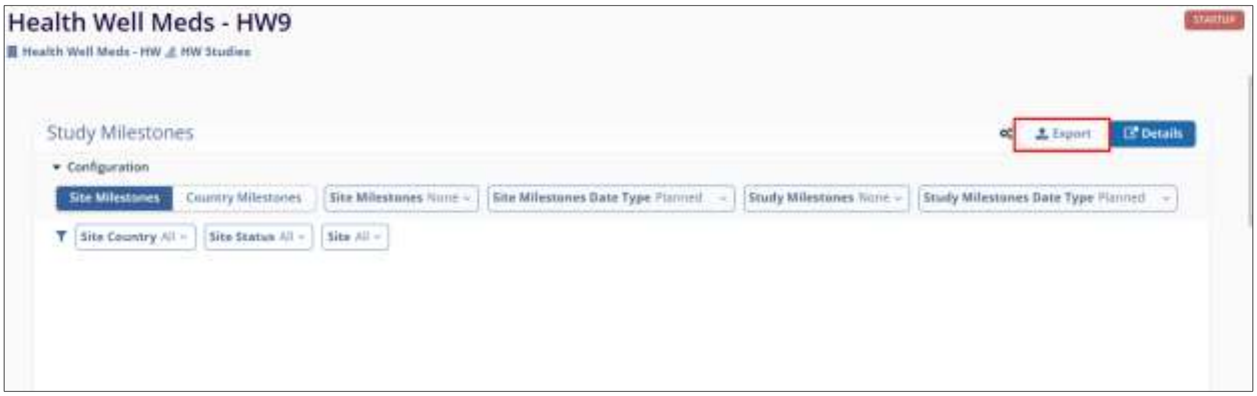
Note: When a user clicks on the Study Name directly. The user will be redirected to the Study's Dashboard screen. Refer to the below screen.

8. In the study dashboard we have Study Milestone, Study Enrollment, Study Enrollment, and Study Activities.
9. In the study milestone window, we have Site Milestones and Country Milestones. Users can click on the specific milestone as per the requirement. Refer to the below screenshots.

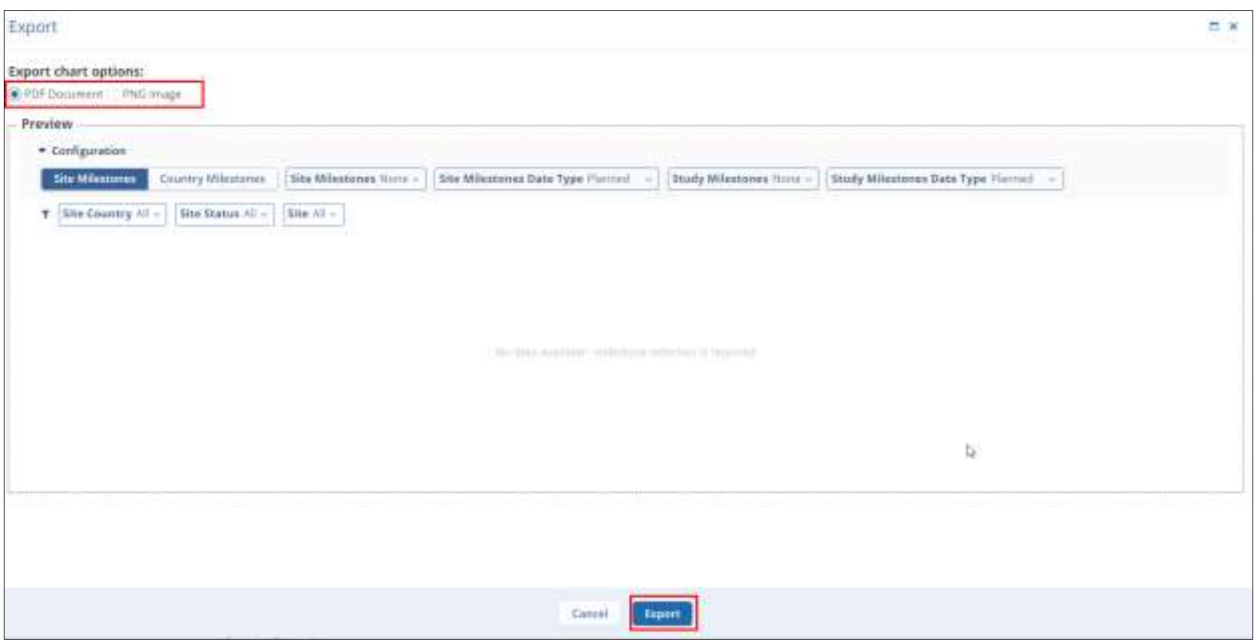


10. To apply filters, click on the drop-down arrow from the available fields and select the appropriate option as per the requirement.
11. To set up a default view, the user can click on the Gear icon from the top left corner. Users can customize the view as per the requirement. Refer to the below screenshot.

To export the milestone view, click the "Export" button located at the top left side of the window.



9. You will be redirected to the Export screen. User will have two options: export as a PDF document or as a PNG image. Select the desired option by clicking the corresponding radio button, then click the "Export" button to complete the process.

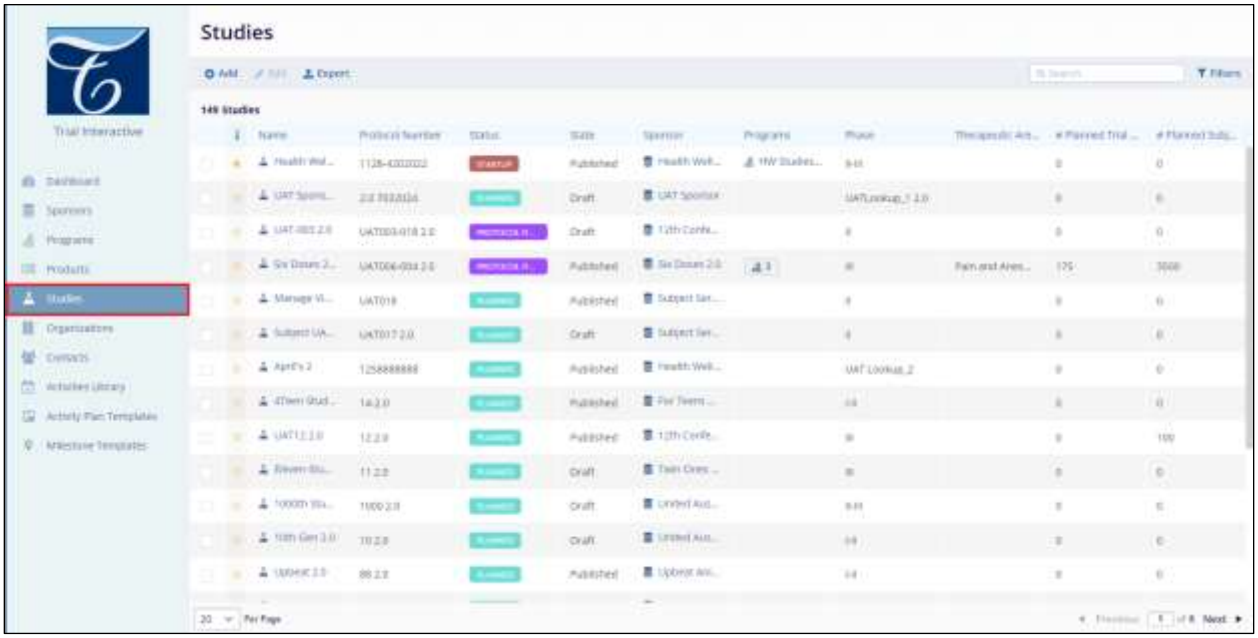


Note. For Study Enrollment, the Study Enrollment and Study Activities sections users can perform the same activities to view, export, apply filters, and so on.

Study Milestones

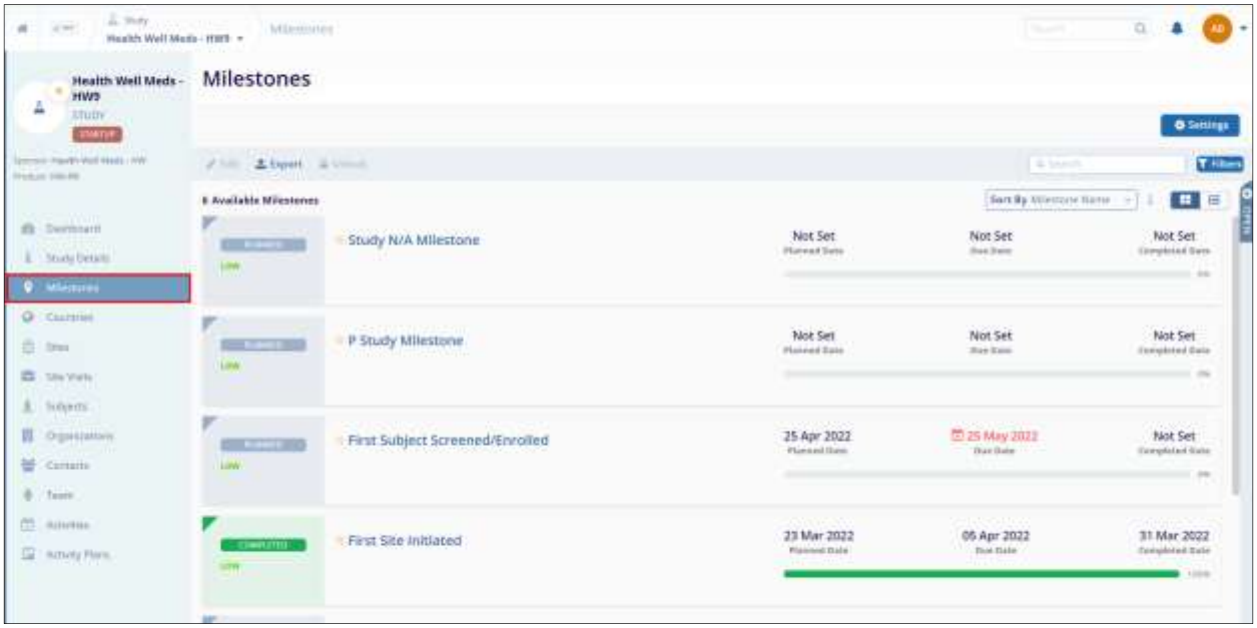
Navigate to Study's milestone

1. To navigate a Studies Milestone, click on the '**Studies'** link in the Navigation menu at the left side of the screen. It will redirect you to the studies screen.

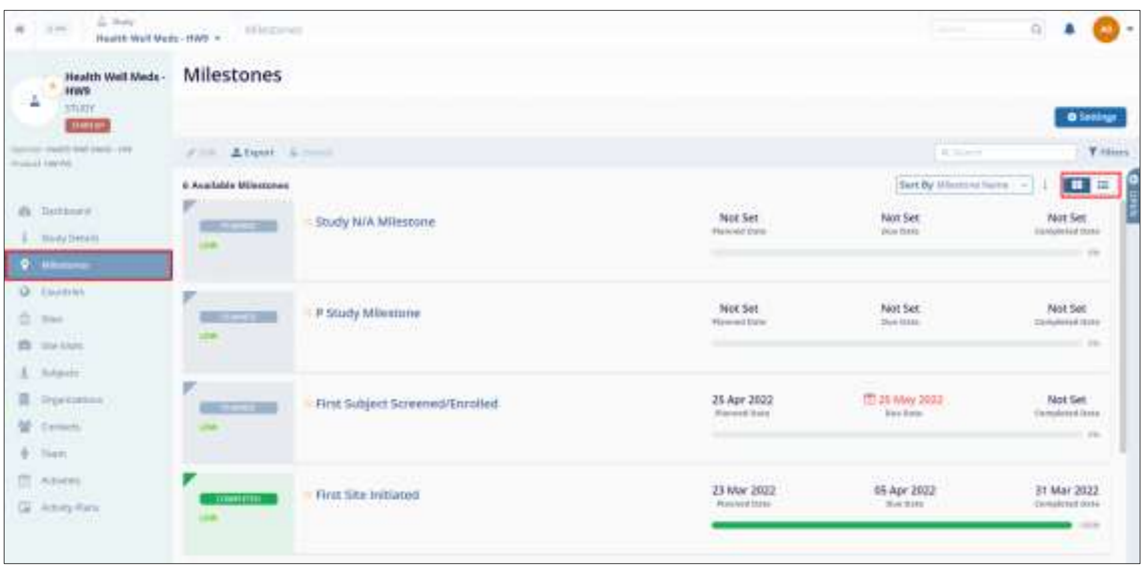


2. Click on the check box next to the name of the study and click on the '**Edit'** button from the top main menu. Refer to the screenshot below.

3. It will redirect the user to the Study Details screen. From the navigation pane, Click on the Milestone. It will redirect the user to the **Study's** Milestone.



4. Users have two options to view Milestone Card view and List view. Select the appropriate view at your convenience.



5. To apply a filter, click on the Filter button from the top left side of the screen. Refer to the below screenshot.

6. It will display all fields with the drop-down, click on the the drop-down arrow and select the appropriate option as per the requirement.

7. As per the applied filter it user will able to see the results in the grid.

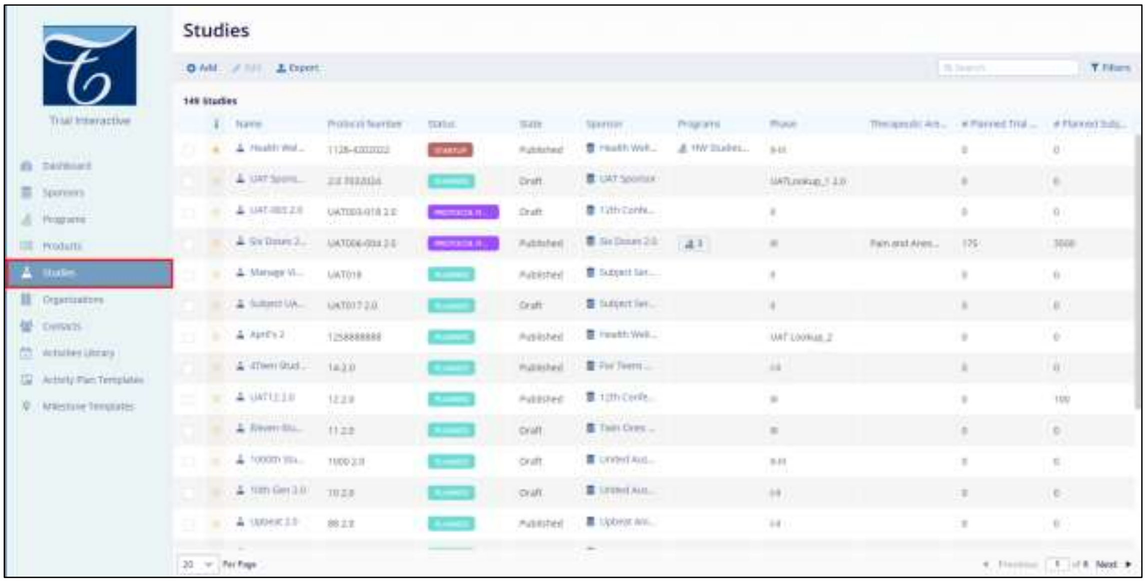
Note: Marking favorite and Exporting will be the same as Contact. To learn [How to mark favorite] and [export]. Click the hyperlinks.

8. To learn how to edit the Milestone, [click here].

Study Countries

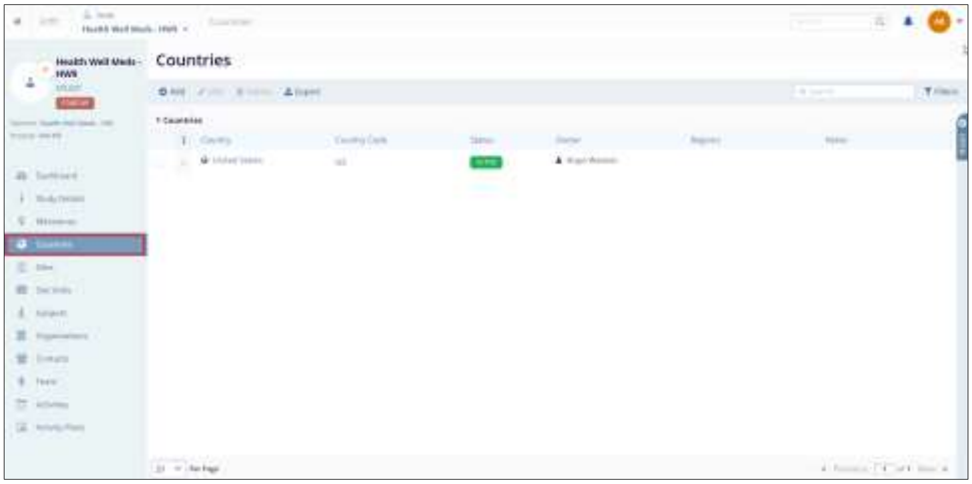
Defining and Editing Countries within a Study

1. Click on "Studies" in the navigation menu on the left side of the screen. This opens the "Studies" window.

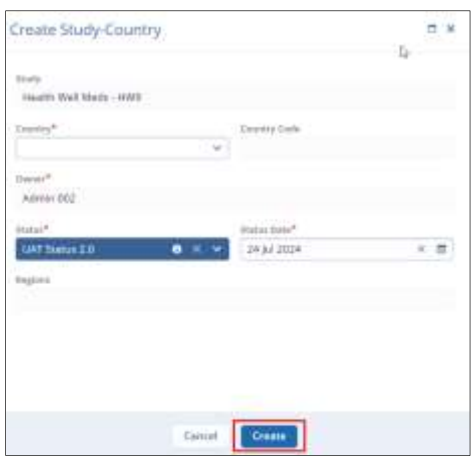


2. Click on the name of the study in which you want to define countries. This opens the study's dashboard.

3. Click on the "Countries" link in the navigation menu on the left side of the screen. This opens the "Countries" window, and the countries list is displayed.

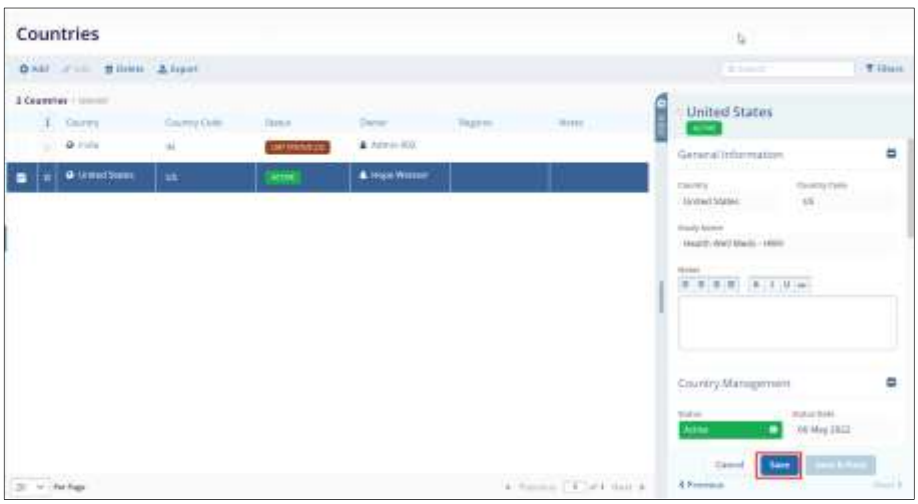


4. Click "Add" at the top-left of the screen. This opens the "Create Study-Country" window.



5. Enter the mandatory metadata required to create a region, such as Country, Owner, Status, and Status Date. These fields are indicated by an asterisk (*) next to their titles. Enter any additional information, as necessary.
6. Click the "Create" button. The country is created, and the "Create Study-Country" window is closed.
7. To edit a country, click the checkbox next to the name of the country you want to edit and Click "Edit" at the top-left of the screen.

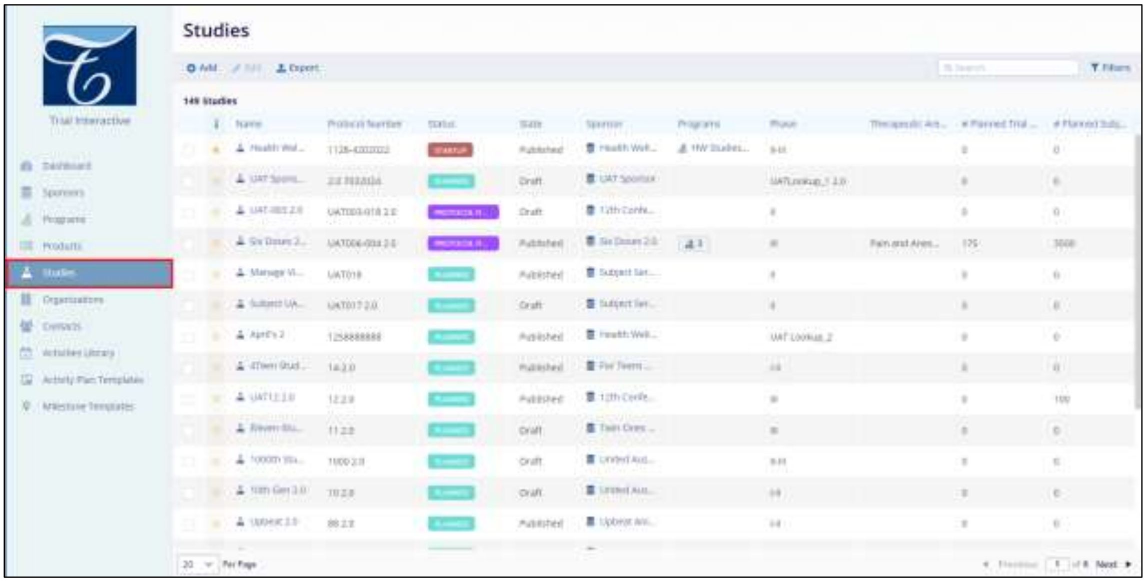
8. A quick view panel is displayed on the right side of the screen. Make any necessary changes in the quick view panel.



9. Click "Save" at the bottom of the quick view panel.

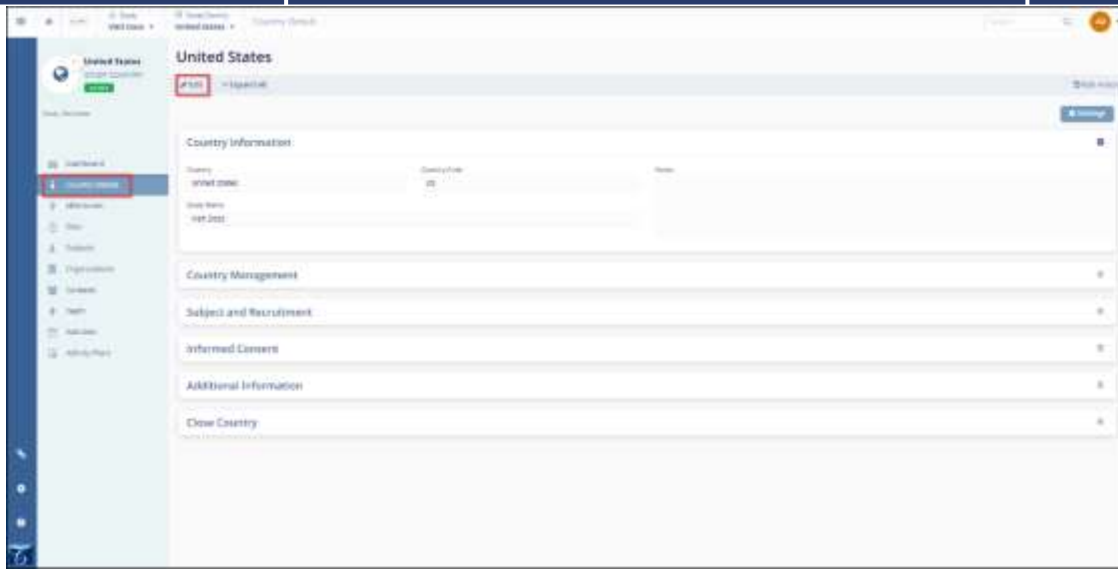
Reviewing and Tracking Country Details

1. Click on "Studies" in the navigation menu on the left side of the screen. This opens the "Studies" window.

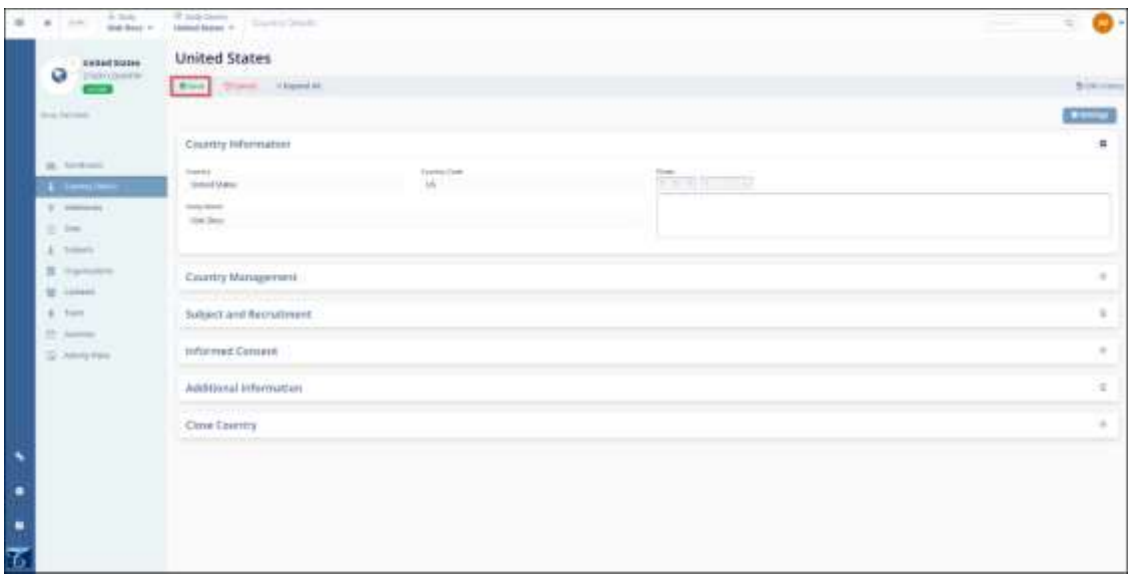


2. Click on the name of the study in which you want to define countries. This opens the study's dashboard.

3. Click on the "Countries" link in the navigation menu on the left side of the screen. This opens the "Countries" window, and the countries list is displayed.
4. Navigate to the section you want to review on the screen and click on the [+] sign next to the name to expand it.

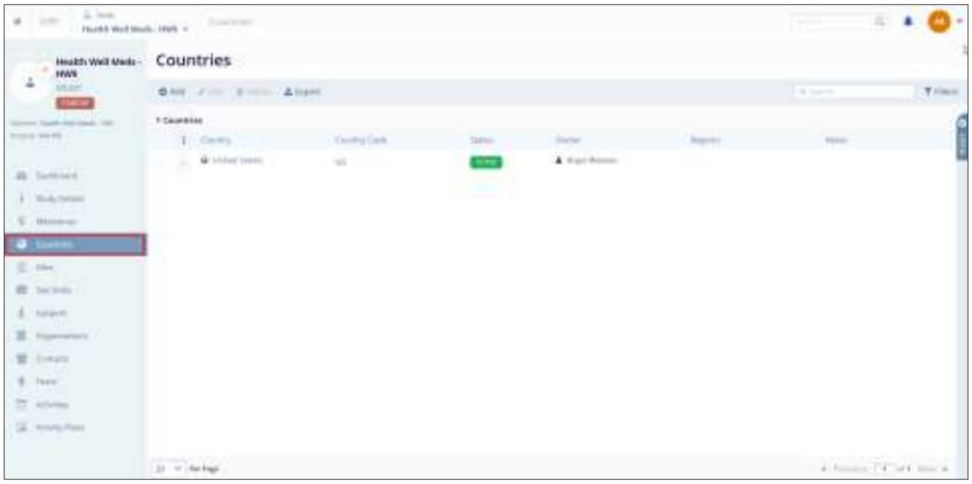


5. Click on the Edit button on the top-left of the screen to make any changes and before returning, click on the Save button for the changes to apply.

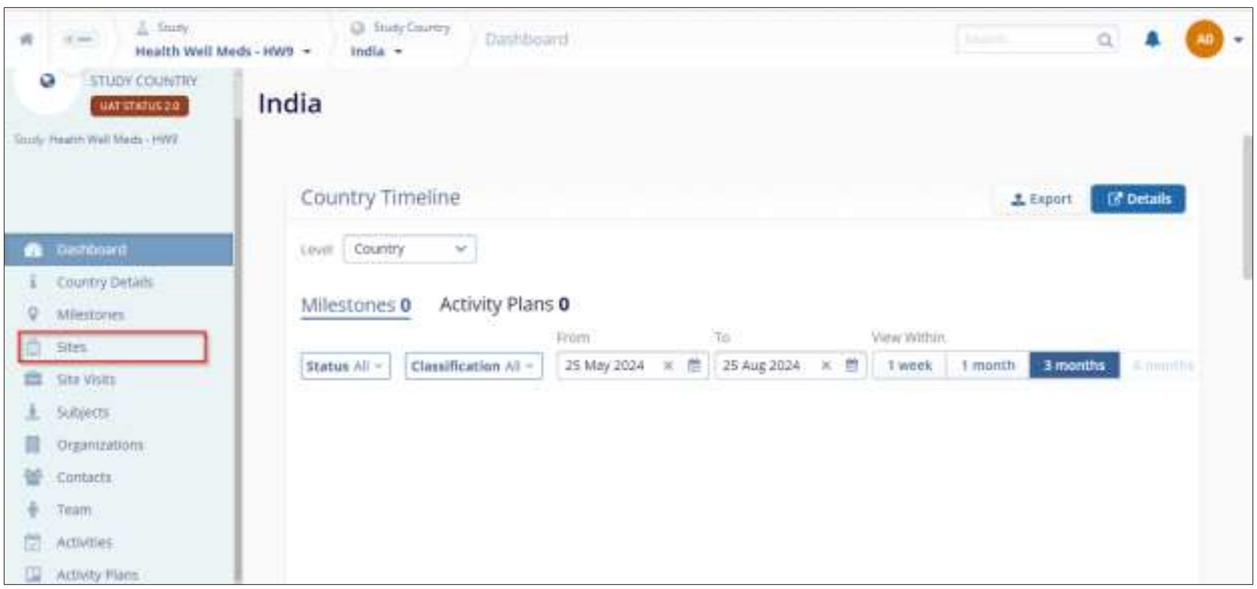


Creating a Site within a Country

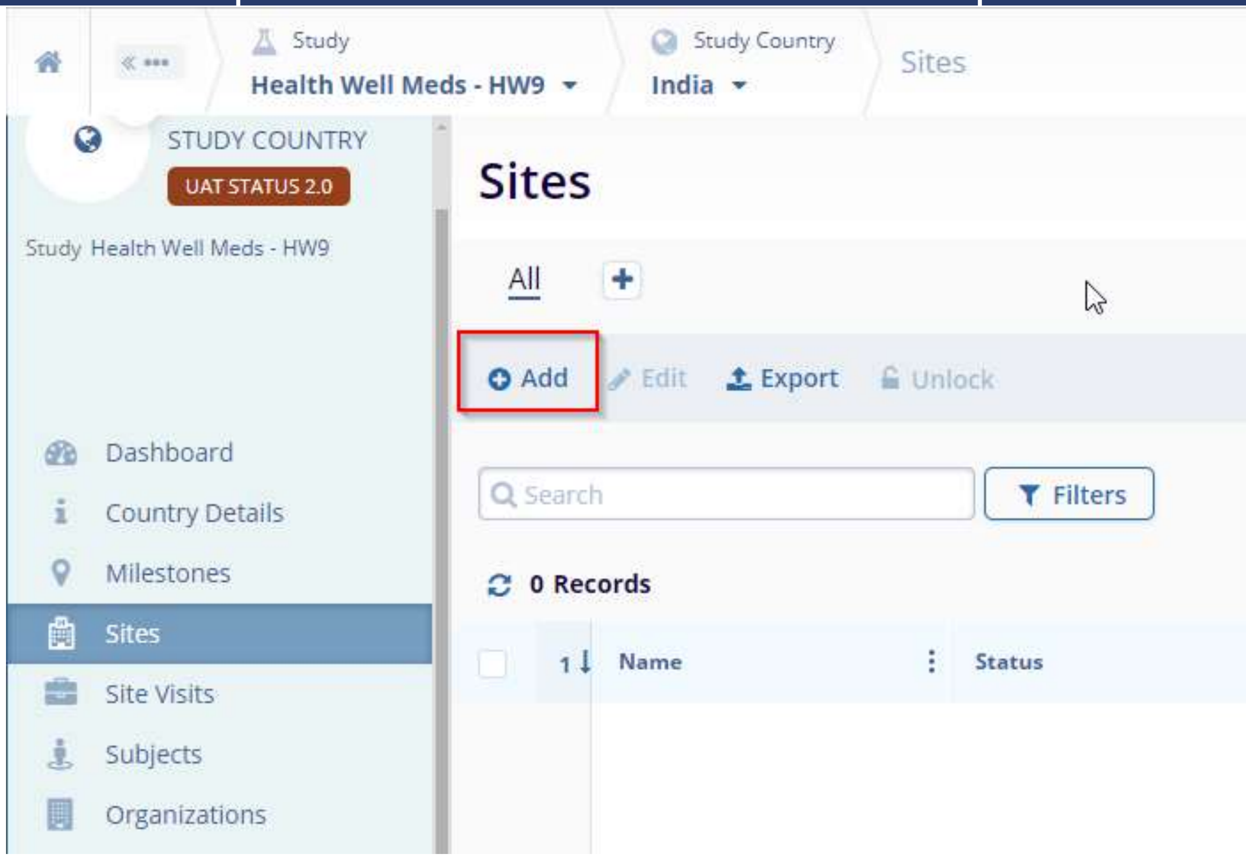
1. Click on Countries in the Navigation menu at the left side of the screen.



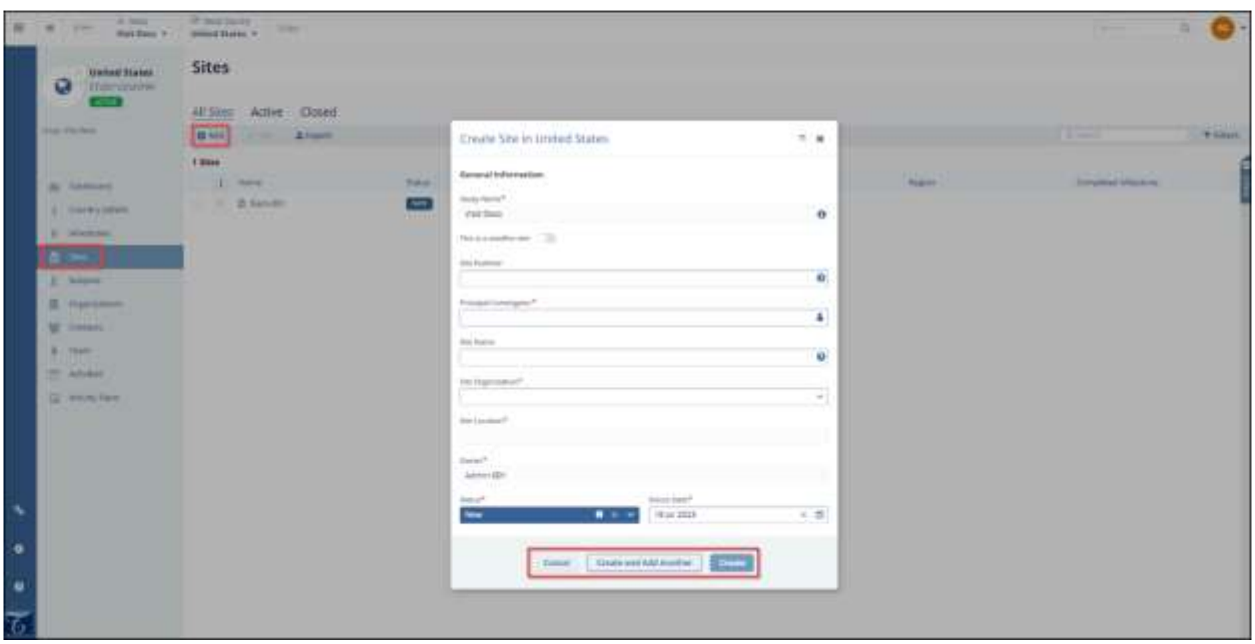
2. Navigate to the country in the list you want to edit and click on it. This opens the dashboard for the country.
3. Click on the Sites link in the Navigation menu at the left side of the screen.



4. Click on the Add button in the top-left of the screen. It will open the “Create Site” window.

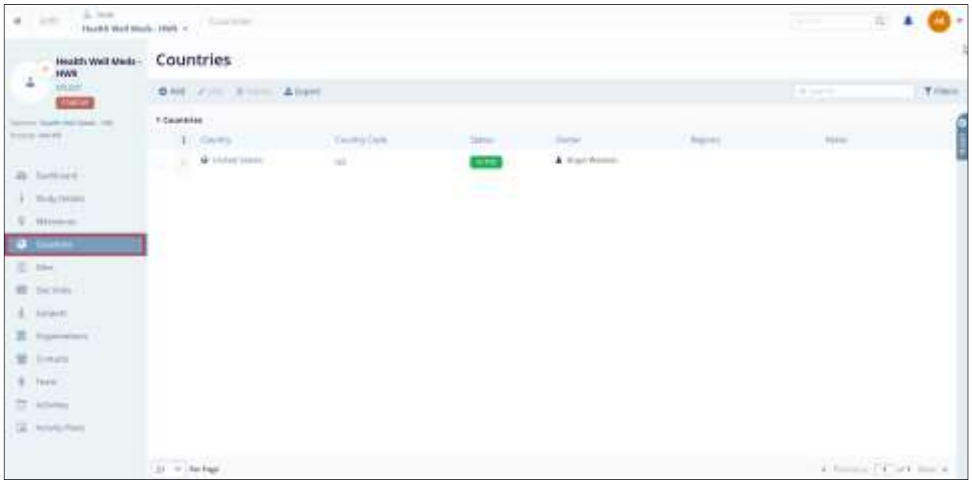


5. Fill in the required information and click Create.
    a. More detailed instructions regarding this step can be found here.

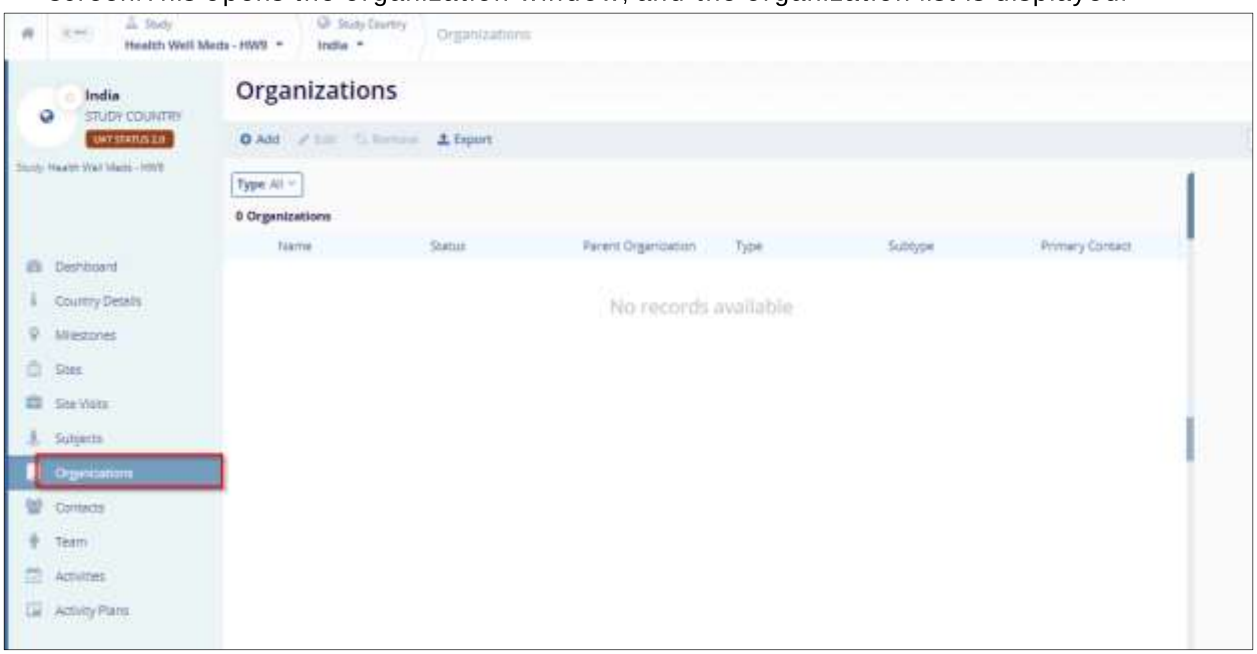


Associating an Organization with a Country

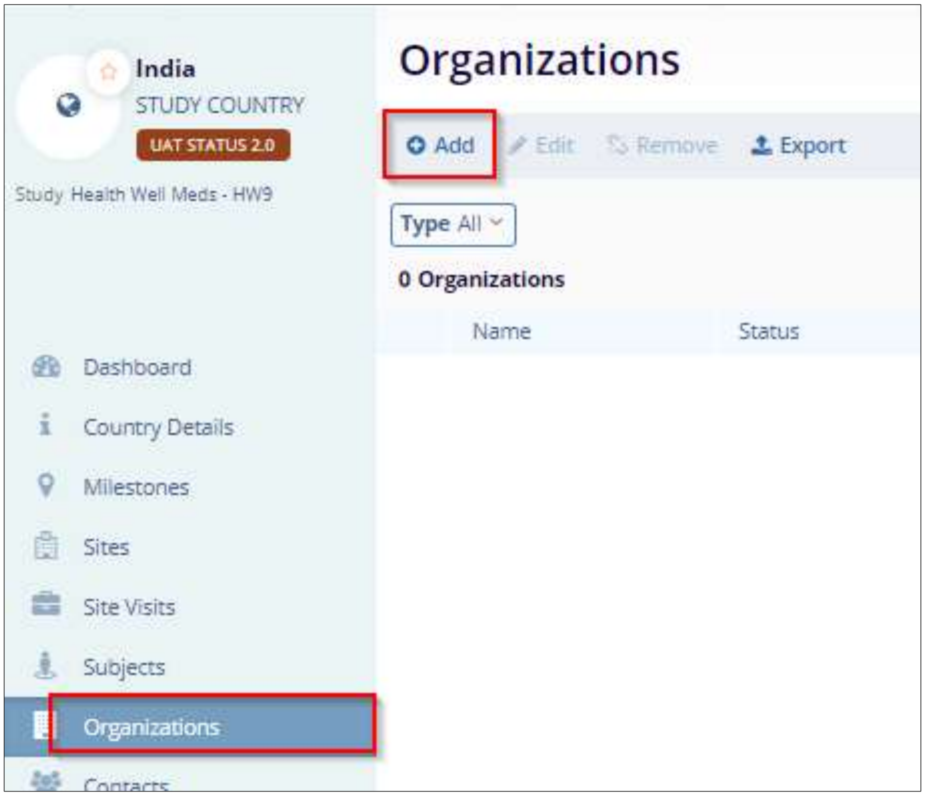
1. Select Countries from the menu on the left side of the screen and Click on the name of the country to which you wish to associate an organization.



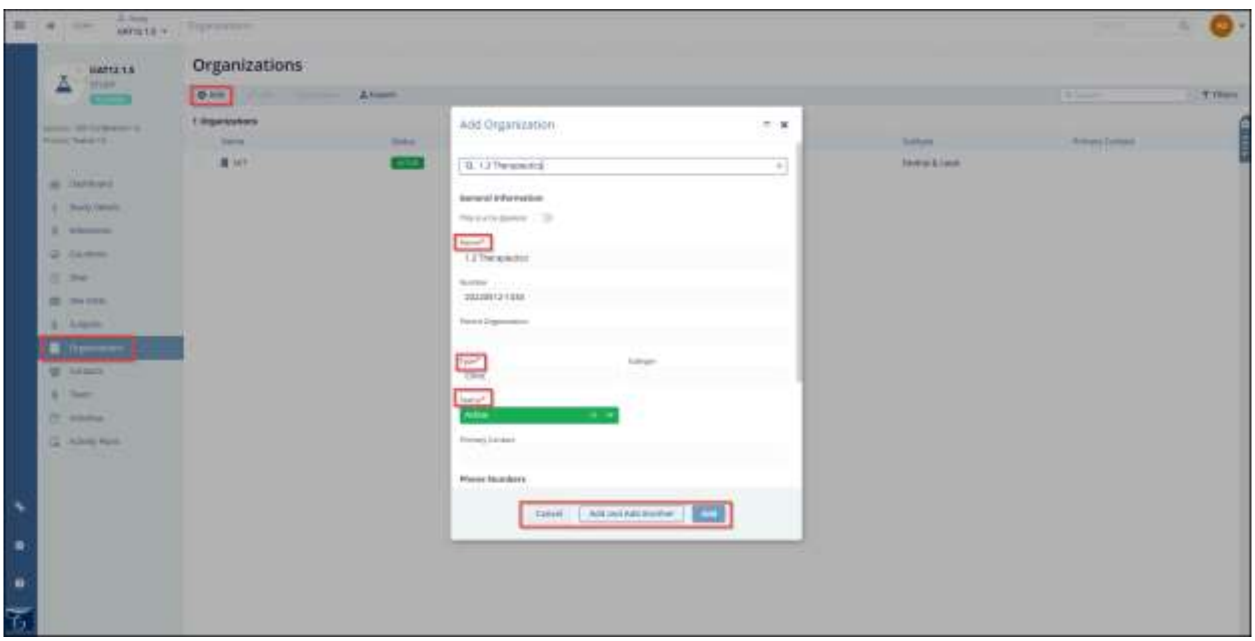
2. Click on the Organizations link in the Navigation menu at the left side of the screen.This opens the organization window, and the organization list is displayed.



3. Click on the Add button in the top-left of the screen. This opens the Add Organization window.

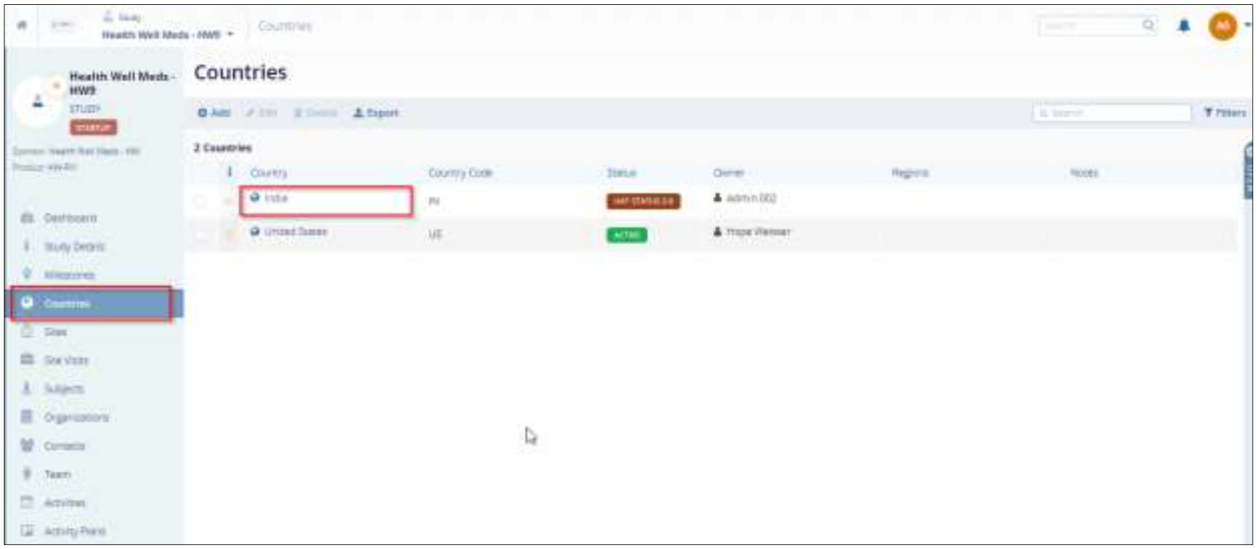


4. Search for an Organization or create a new one if necessary.
   a. More detailed instructions for this step may be found [here].

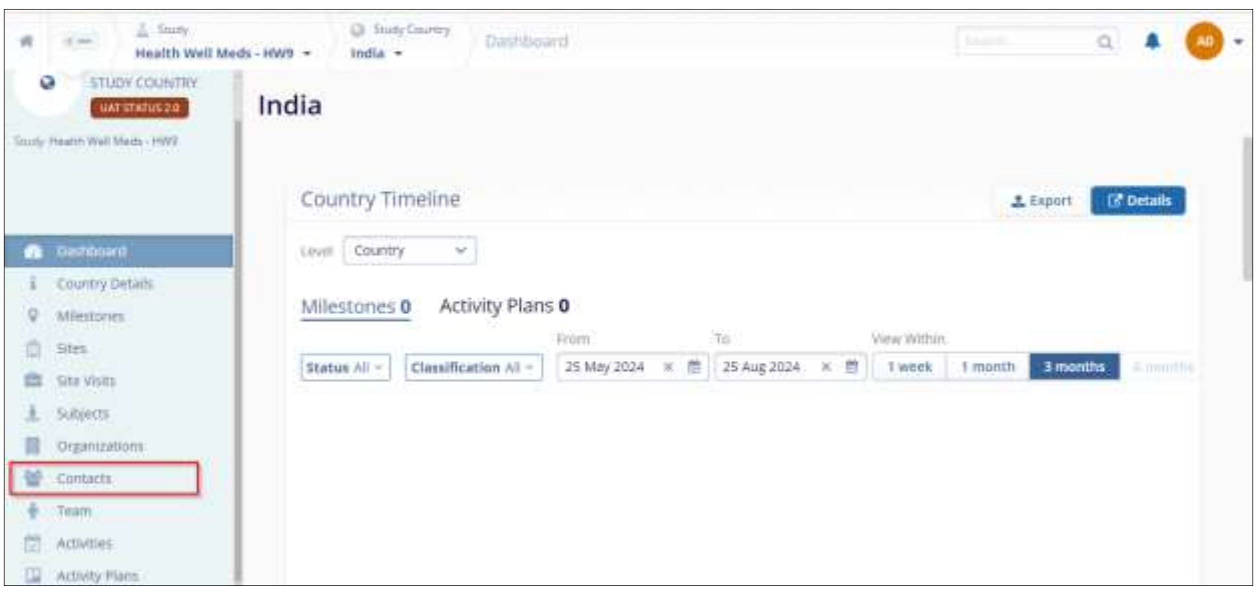


Associating Contacts with a Country

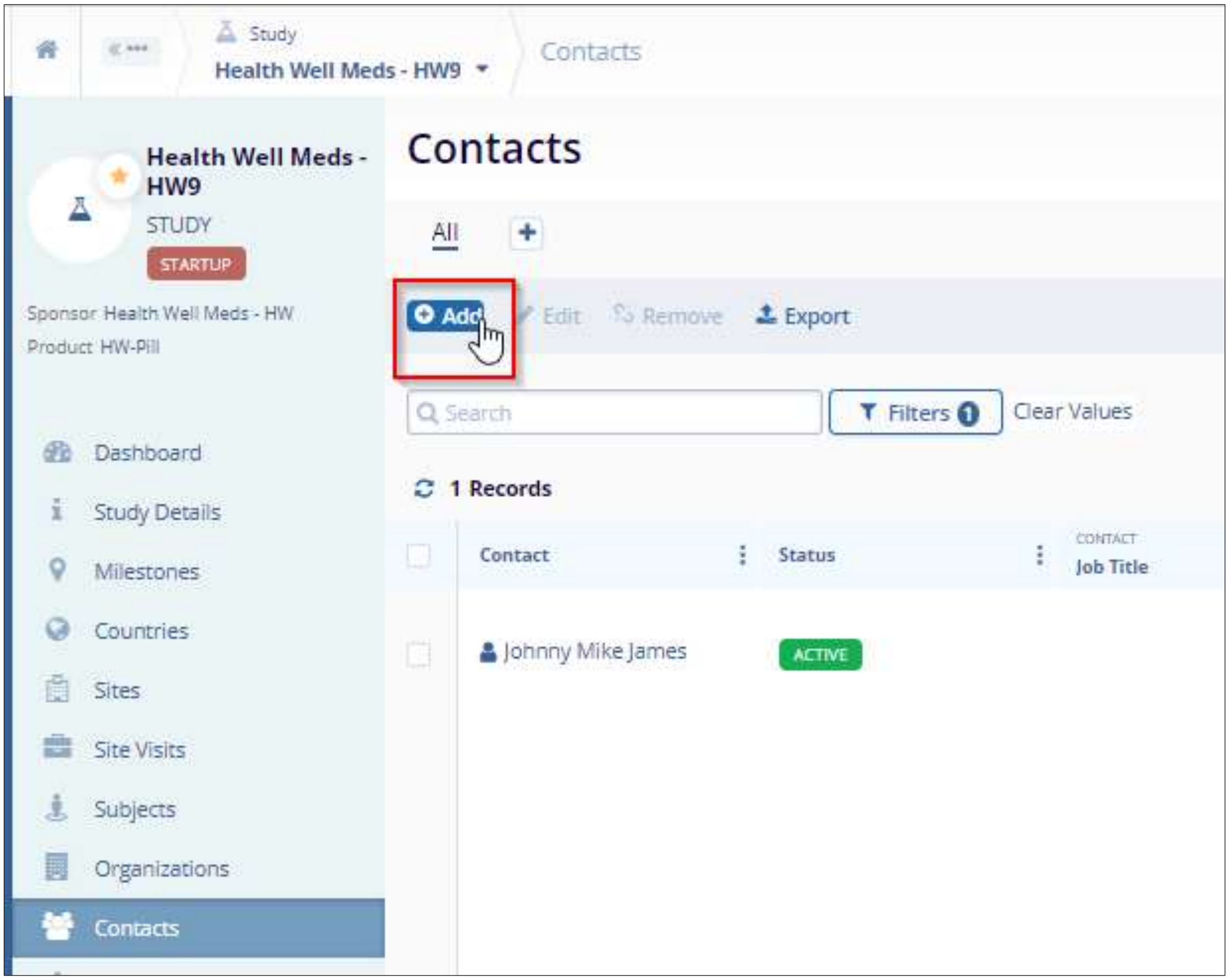
1. Navigate to the country to which you wish to associate a contact.
2. Click on the name of the country to which you wish to associate a contact.



3. Click on the Contacts link in the Navigation menu at the left side of the screen. This opens the “Contacts” window, and the contacts list is displayed.

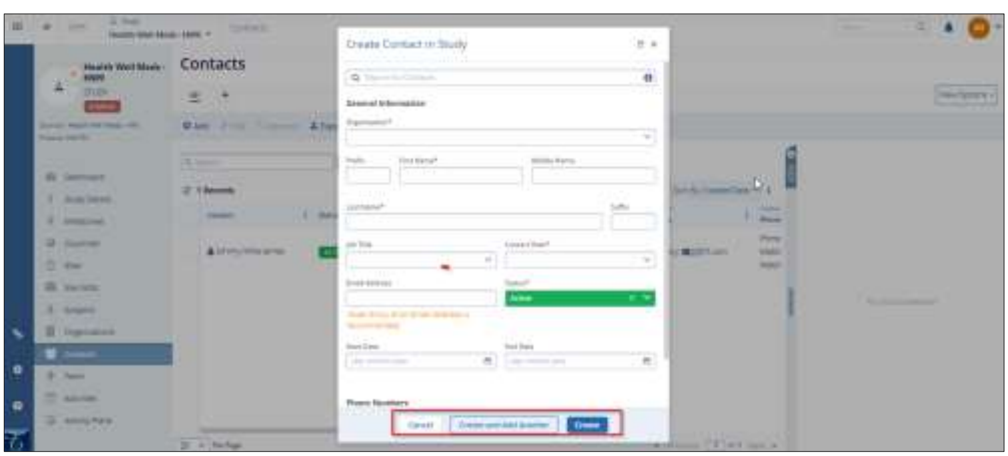


4. Click on the Add button in the top-left of the screen. This opens the “Create Contact in Country" window.

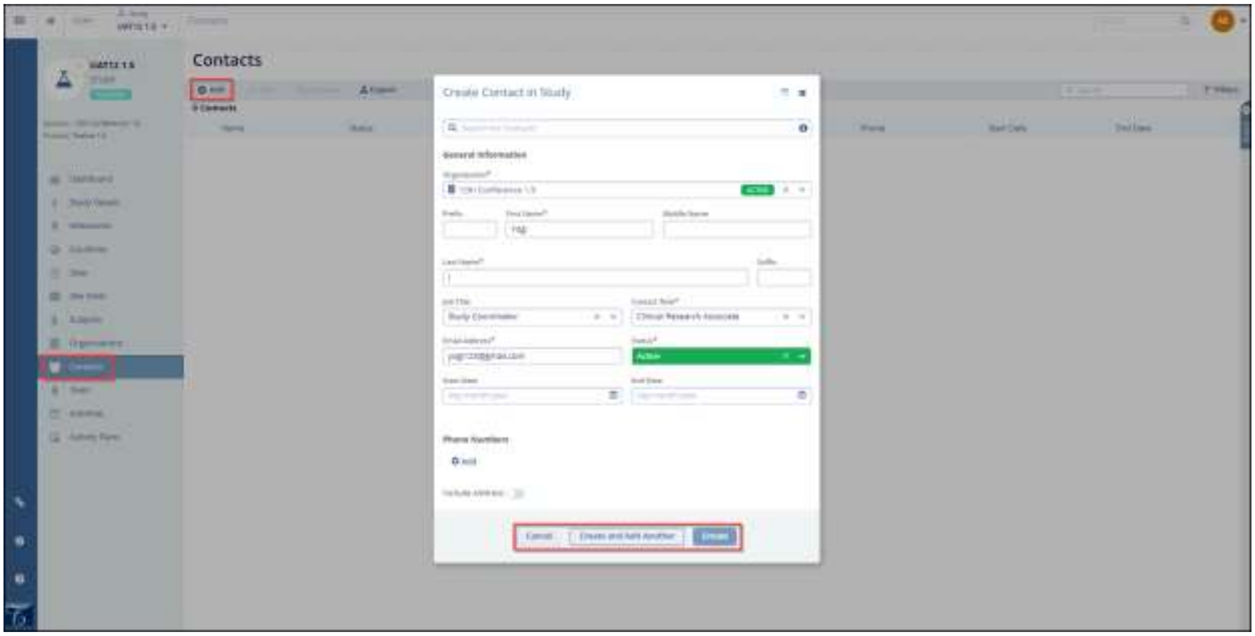


Note: The search field can be used to locate and select existing CTMS contacts.

5. Here we need to enter the mandatory metadata to create a contact i.e., Organization, First Name, Last Name, Contact Role, Email Address, and Status, 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 that 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.



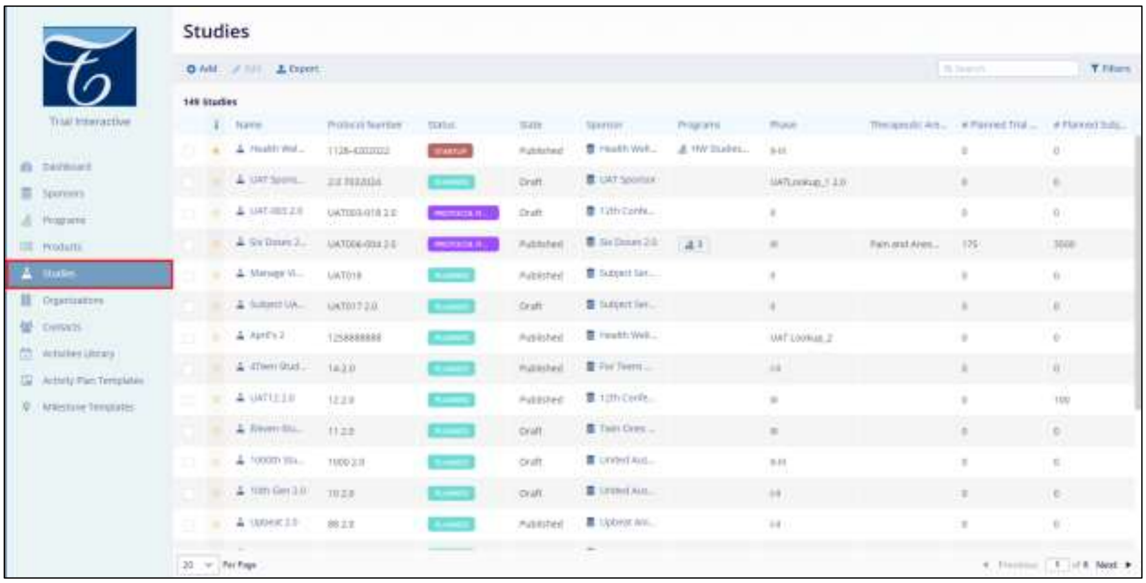
Study Sites

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.

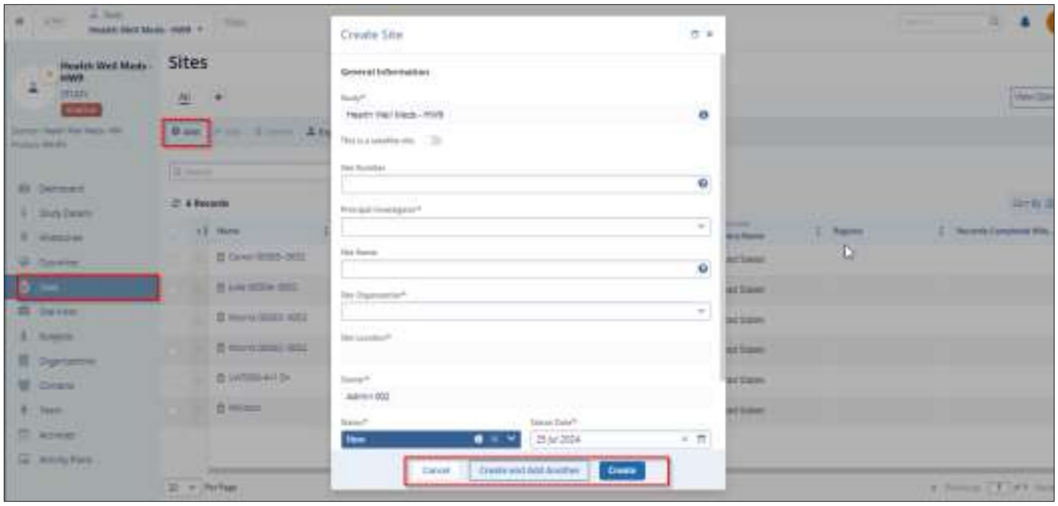
Associating Sites within Study

1. Click on the Studies link in the Navigation menu at the left side of the screen. This opens the "Studies" window and the study list is displayed.



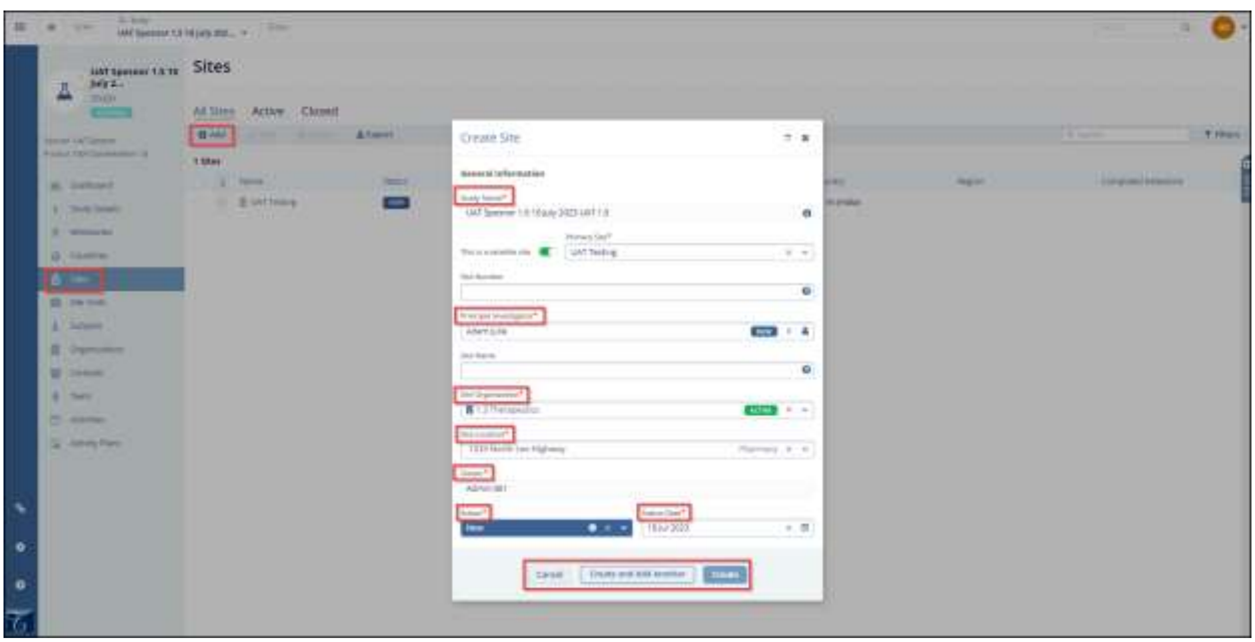
2. Click on the study name to which you want to add Sites. The dashboard for the study is displayed.
3. Click on the Sites link in the Navigation menu at the left side of the screen. This opens the "Sites" window, and all the sites are listed for the study.

4. Click on the Add button at the top-left of the screen. This opens the Create Site window.



5. 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.
    b. Select the Primary Site from the dropdown menu displayed next to the toggle button as indicated by an asterisk (*).

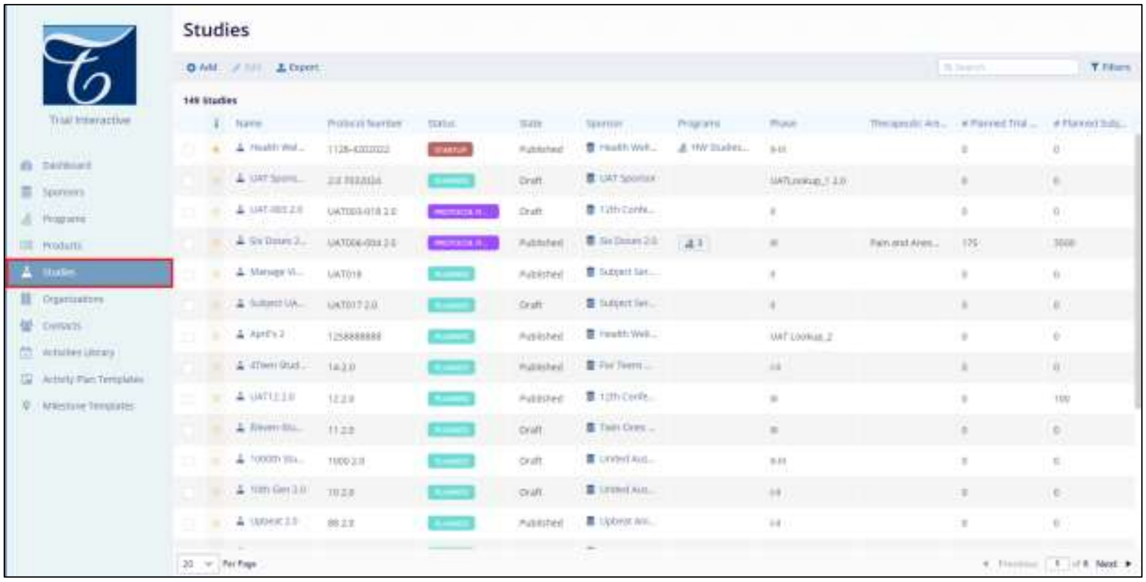
Note: The Site Number field is limited to 5 characters. Satellite sites can either have a unique site number or they can use the same number as the parent site.



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

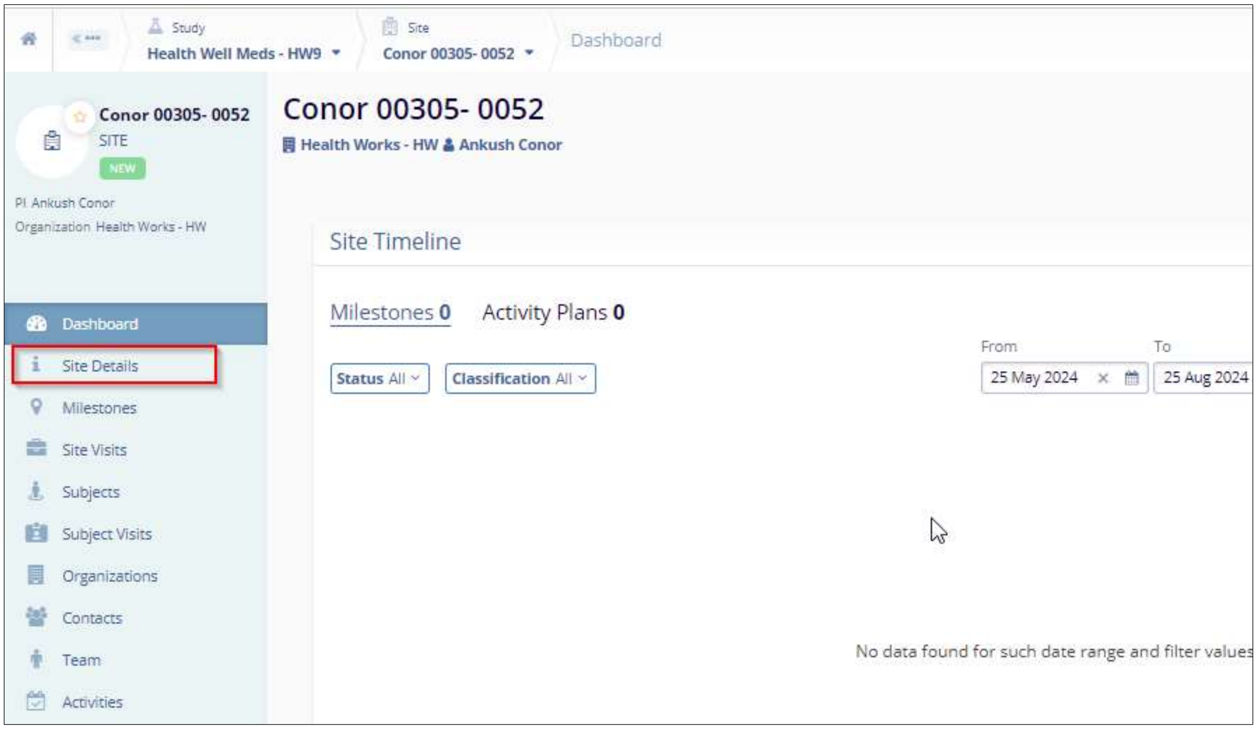
Editing a Site in a Study

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.

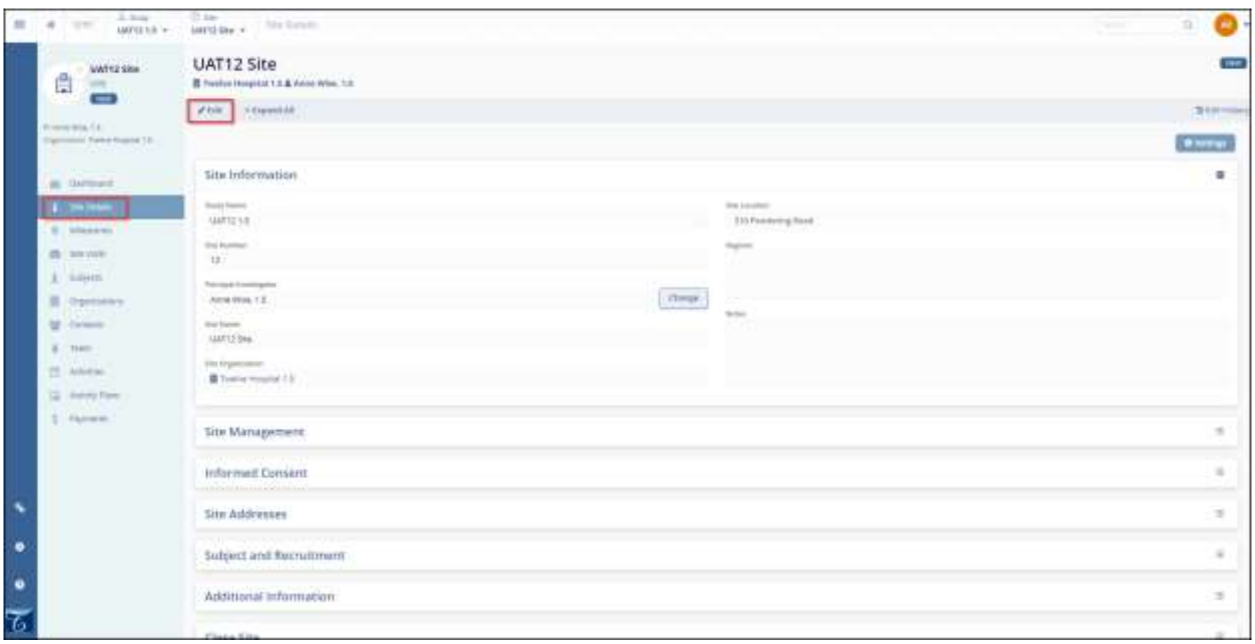


3. Click on Sites in the Navigation menu at the left side of the screen. This opens the "Study Site" window and the study site list is displayed.

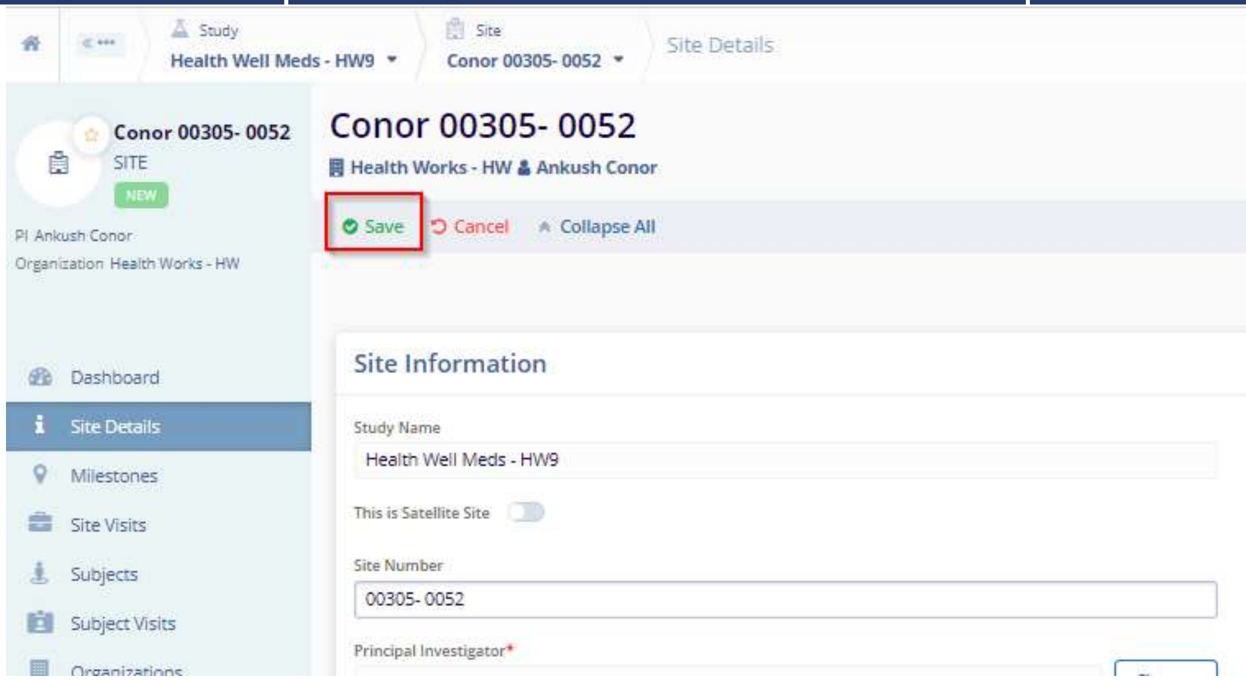
4. Click on the name of the site you want to edit. This opens the dashboard window for the site.
5. Click on Site Details in the Navigation menu at the left side of the screen. This opens the "**Site Details"** window for the site.



6. Click on the Edit button at the top-left of the screen.

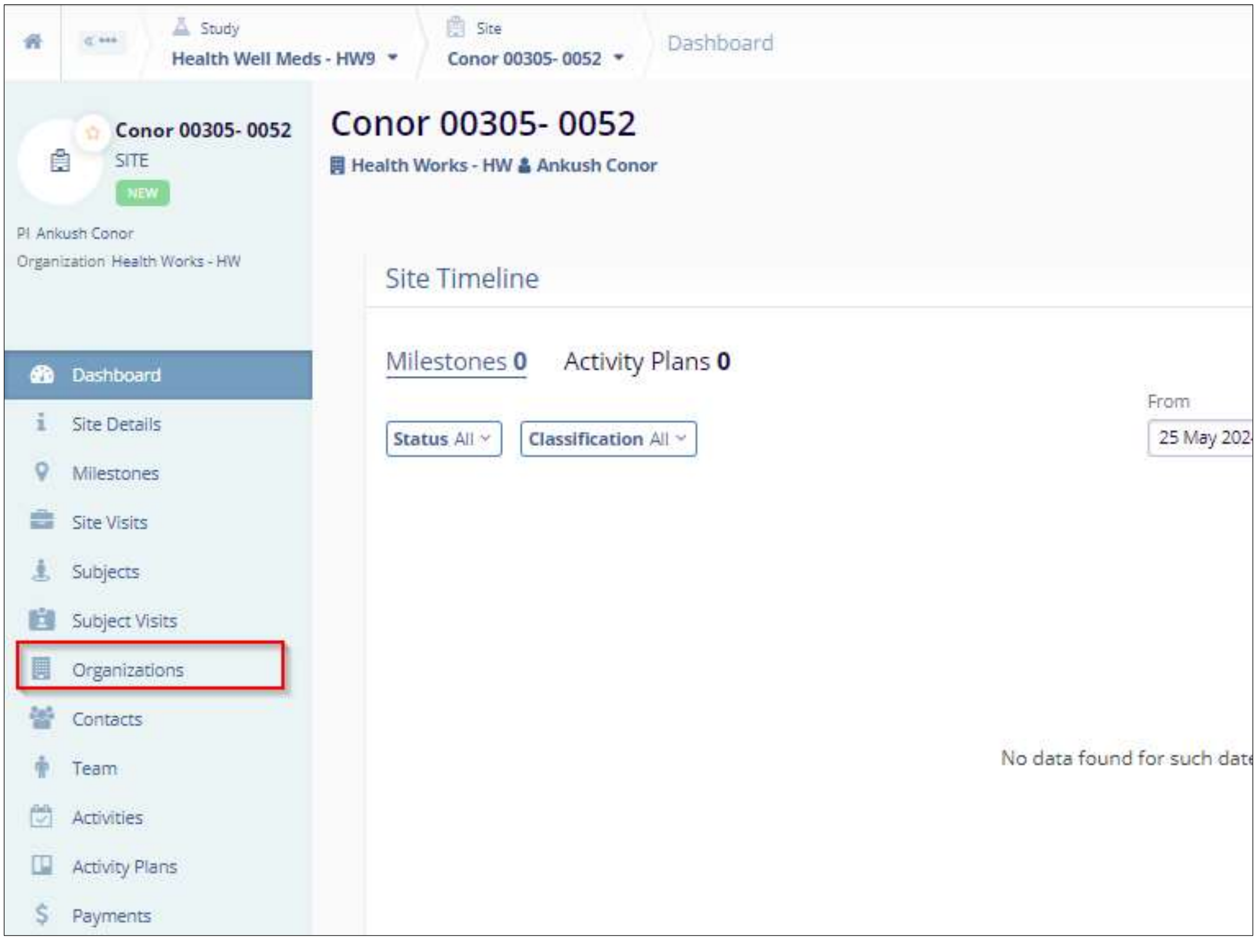


7. Make the required changes in the site details window.
8. Click on the Save button at the top-left of the screen for the changes to apply.

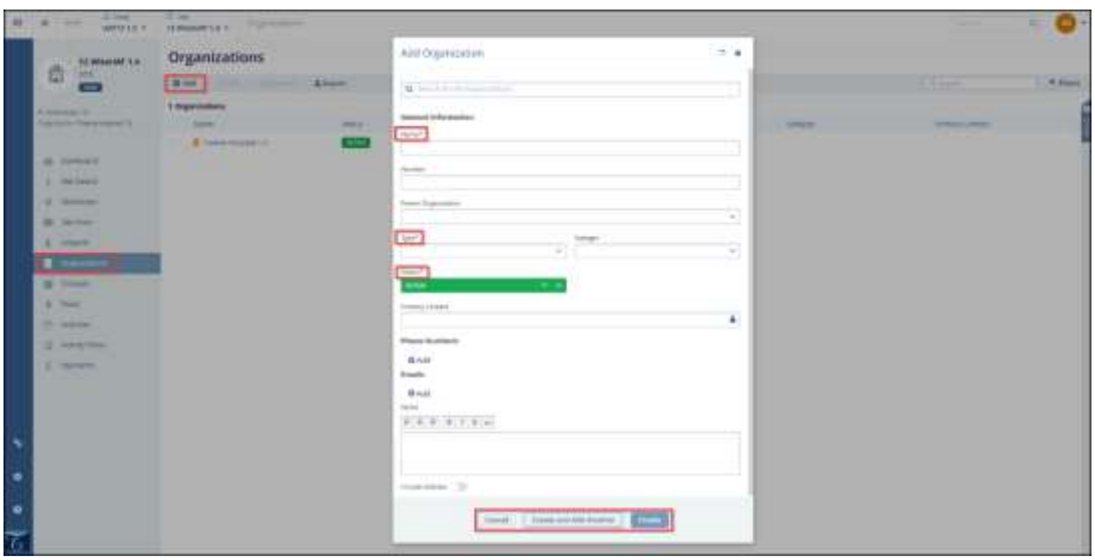


Associating an Organization with a site

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. This opens the “Organization” window.



3. Click on the Add button at the top-left of the screen. This opens the "Add organization" window.



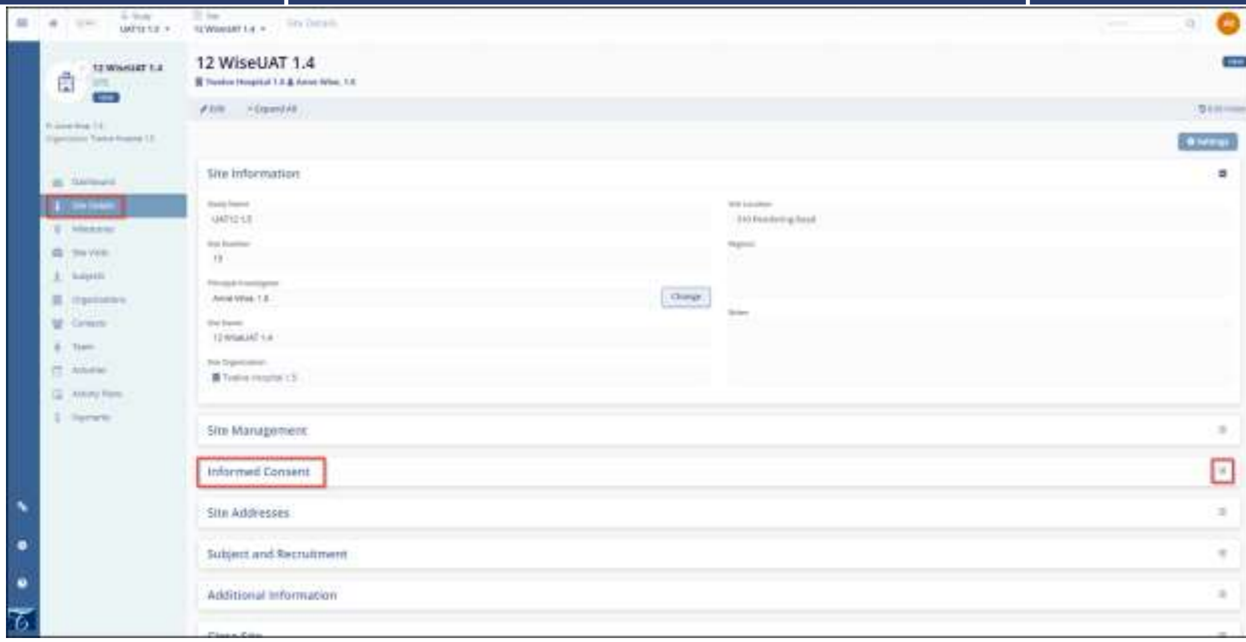
4. Here we need to fill the required metadata to create an organization with an address.
5. Click on the Create button.

Managing Site Contacts

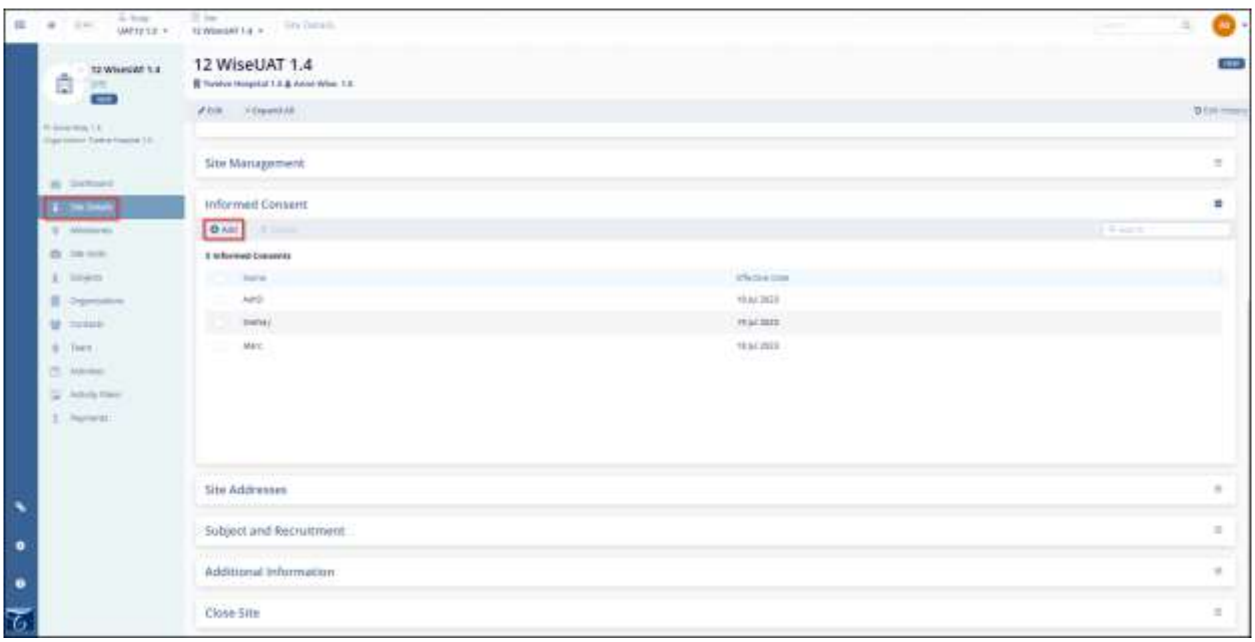
The functionality here is similar to the improvements described above in the section about managing the study team. Each contact can have multiple entries as needed to indicate the various roles that they may play at the site. Importantly, to enter the same person more than once, there is now a 'Copy' 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 to change some detail of their information (for example, someone's last name might have changed).

Tracking Informed Consents (ICFs) for a Site

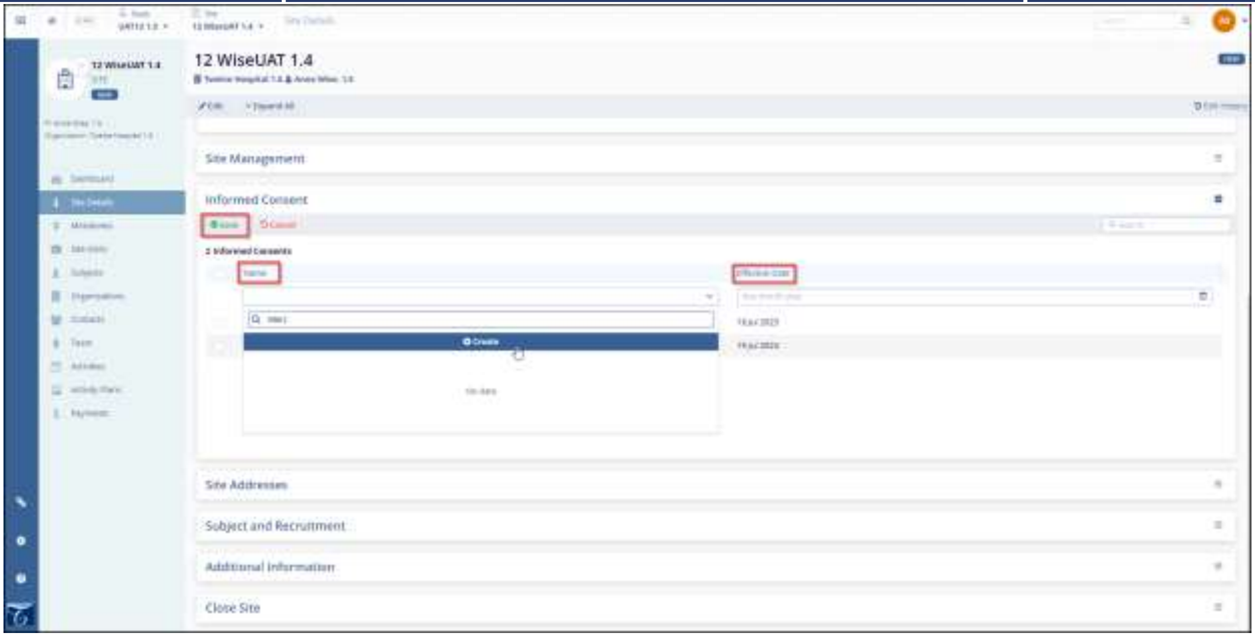
1. Navigate to the Site Details area for the related site. The necessary steps are found here.
2. Click on the [+] sign next to the Informed Consent to expand that section.



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



5. Enter site-specific Name and Effective Date.

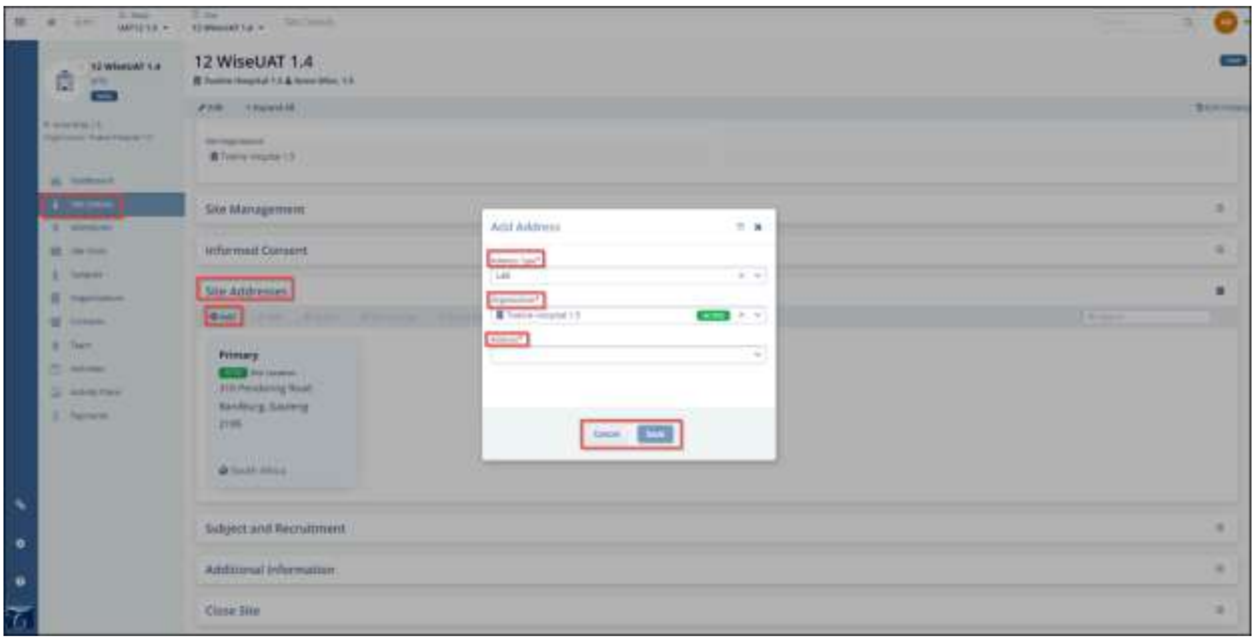


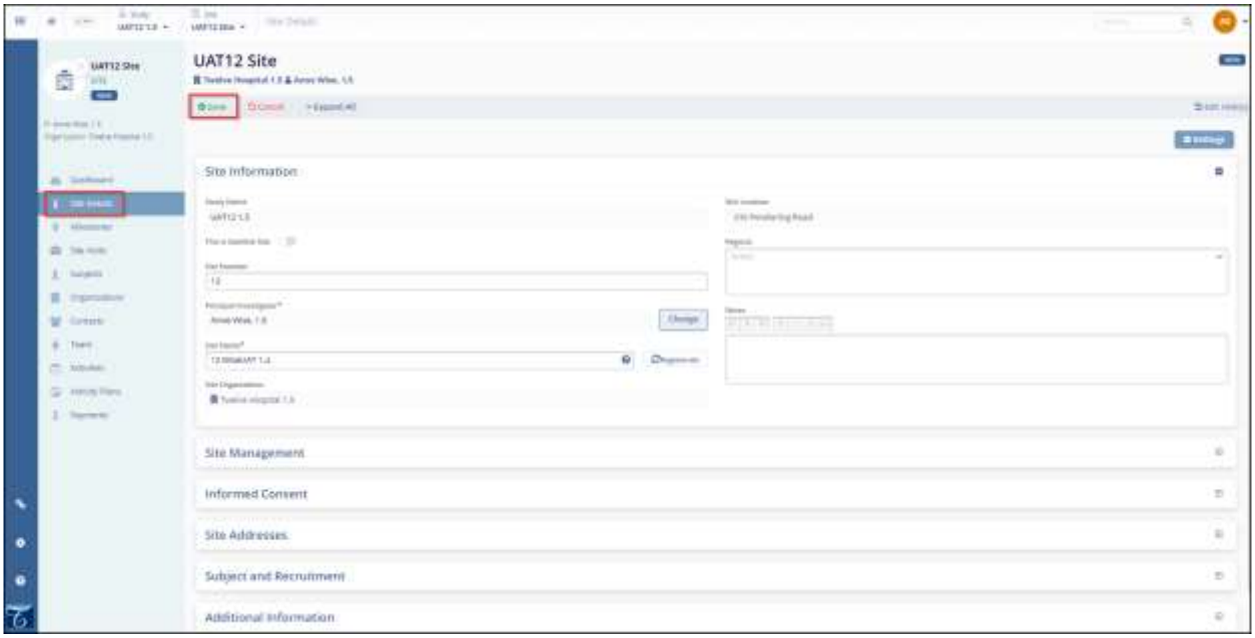
6. Click Create.
7. Click on the Save button in the informed consent section to save the record. This creates site-level ICF for the site.

Tracking Site Addresses

1. 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 the Site Addresses section. This opens the Add Address window.
6. Here we need to enter the mandatory metadata to create an Address i.e., Address Type, Organization, and Address as indicated by an asterisk (*) symbol next to the field title.
7. Click on the Save button.

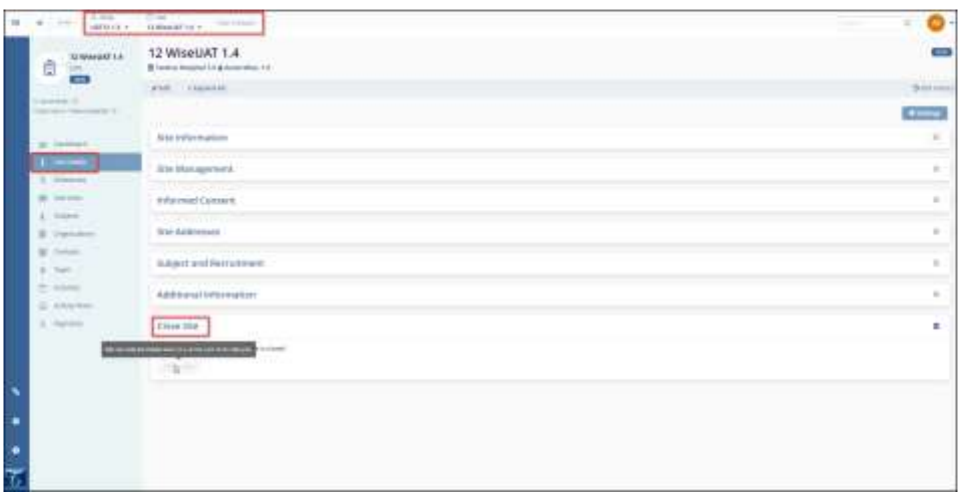
Note: Only addresses associated with the selected site organization are available for selection.

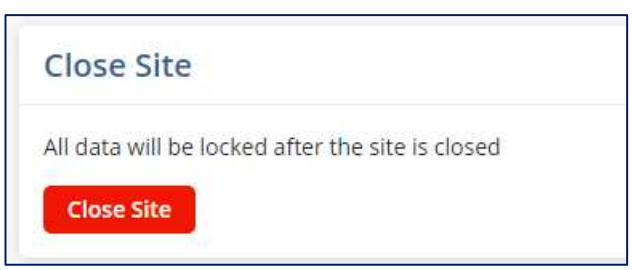




Closing a Site

1. To learn how to navigate site details screen, [click here.]()
2. Navigate to the Site details screen and Click on the Close Site option to close the Site.



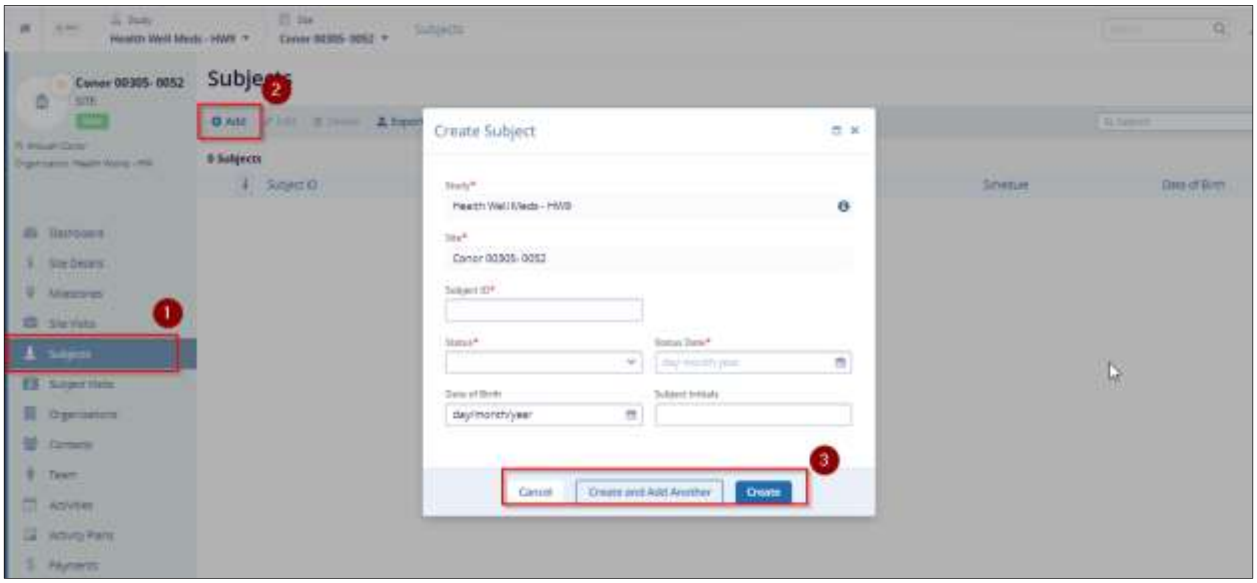


Note :Once that button is pressed, a Site Health Card window is displayed indicating the completion status of the site-related Milestones, Site Visits, Subjects, Activities, and Activity Plans. This gives the user a chance to locate and deal with any unresolved items before they become locked.

Study Subjects

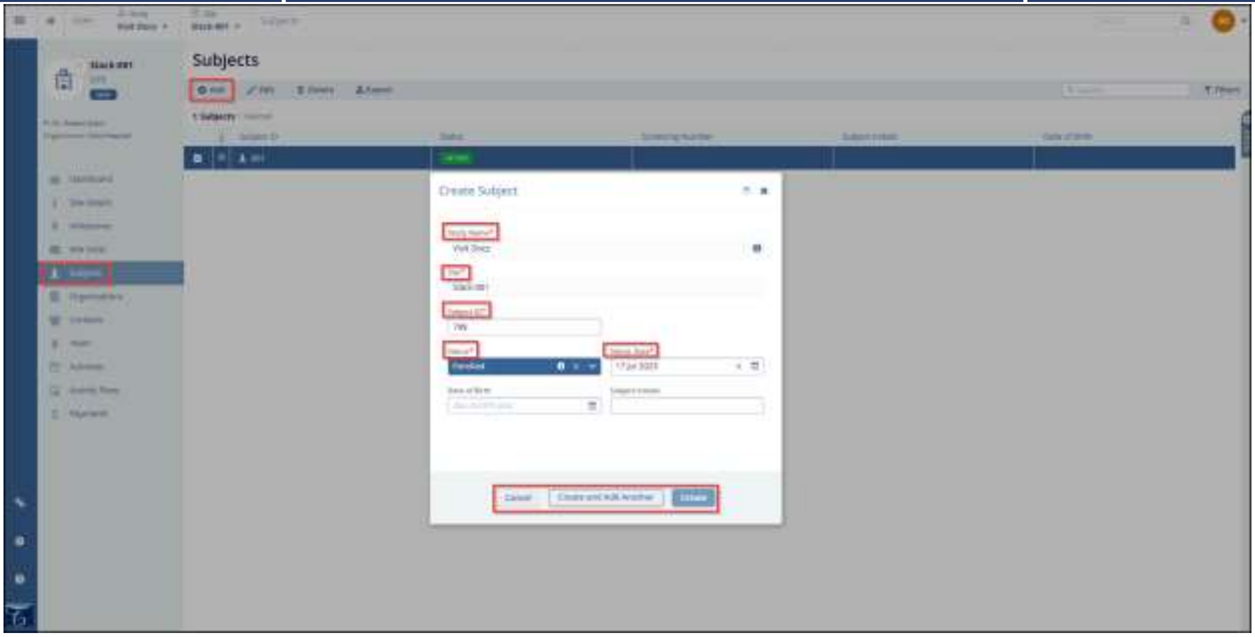
Tracking Subjects

1. Navigate to the site to track the subjects.
2. Click on Subjects in the Navigation menu at the left side of the screen. This opens the “Subjects” window.



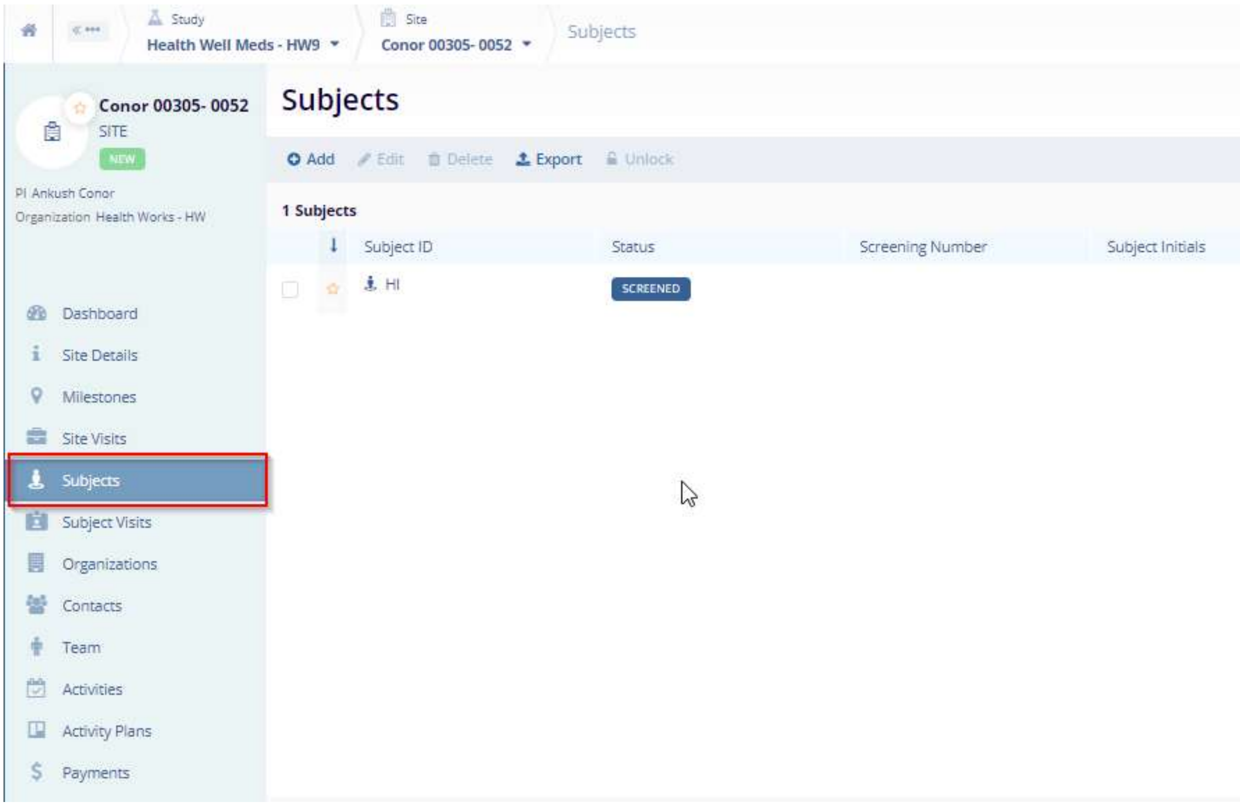
3. Click on the Add button at the top-left of the screen and This opens the Create Subject window.
4. Here we need to enter the mandatory metadata to create a Subject i.e., Study Name, Site, Subject ID, Status, Status Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional 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, and the 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.

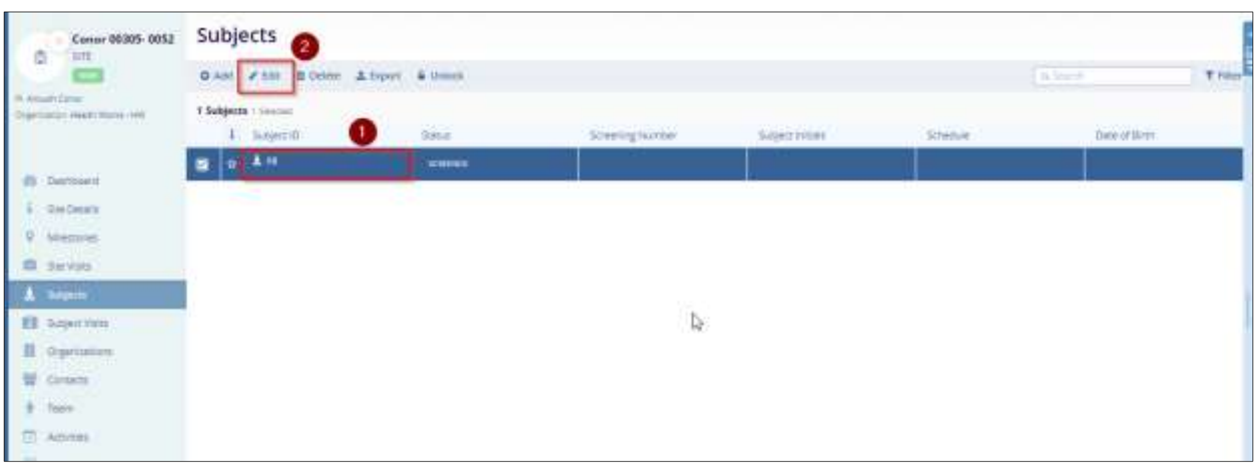

Subjects
Create Subject

Editing a Subject

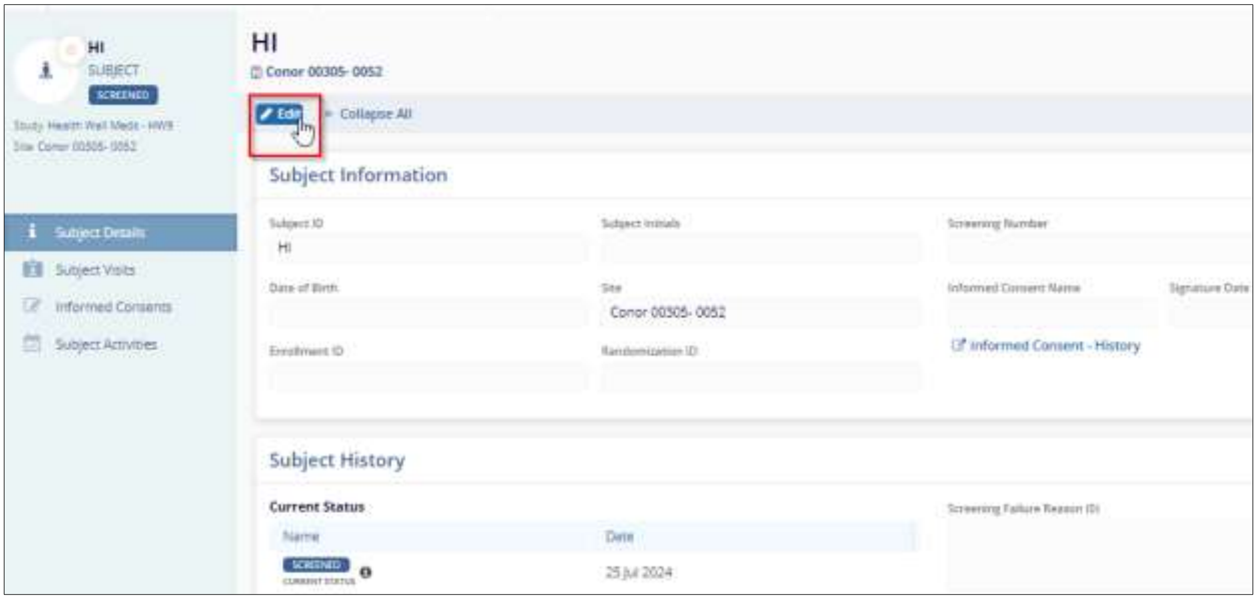
1. Click on the Subjects in the Navigation menu at the left side of the screen. This opens the “Subjects” window.



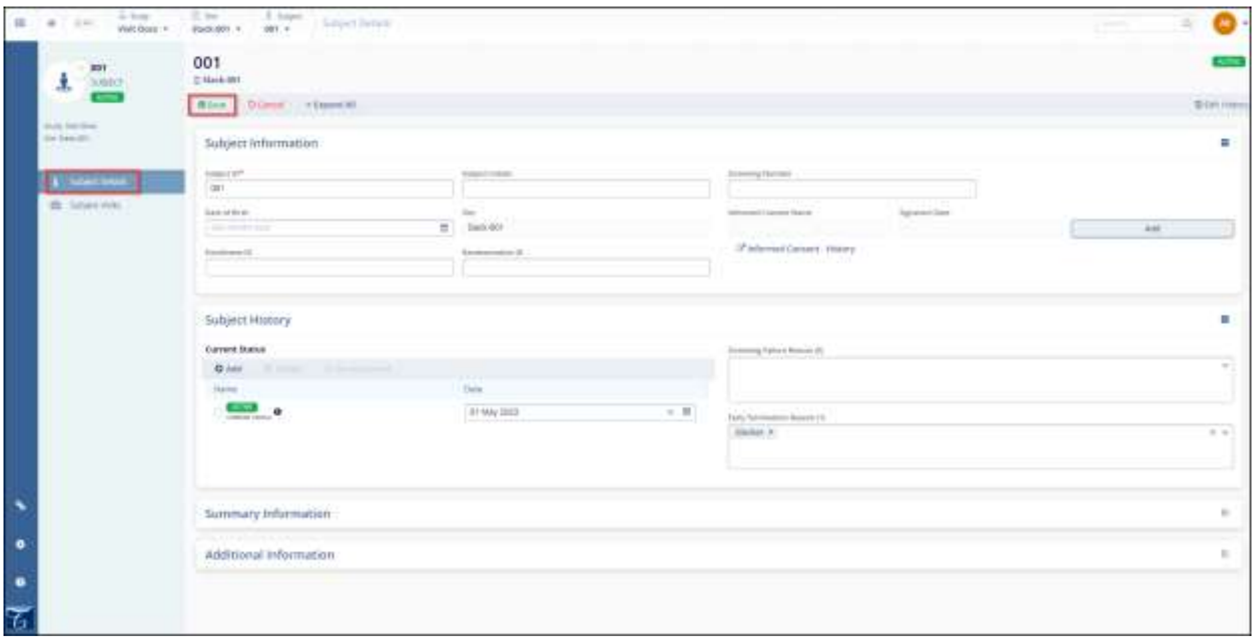
2. Click on the checkbox before the Subject name or the edit button. A quick view panel will display on the right side of the screen.



3. Now, click on the Edit button (pencil icon) in the top-right of the screen. This opens the “Subject Details” window.



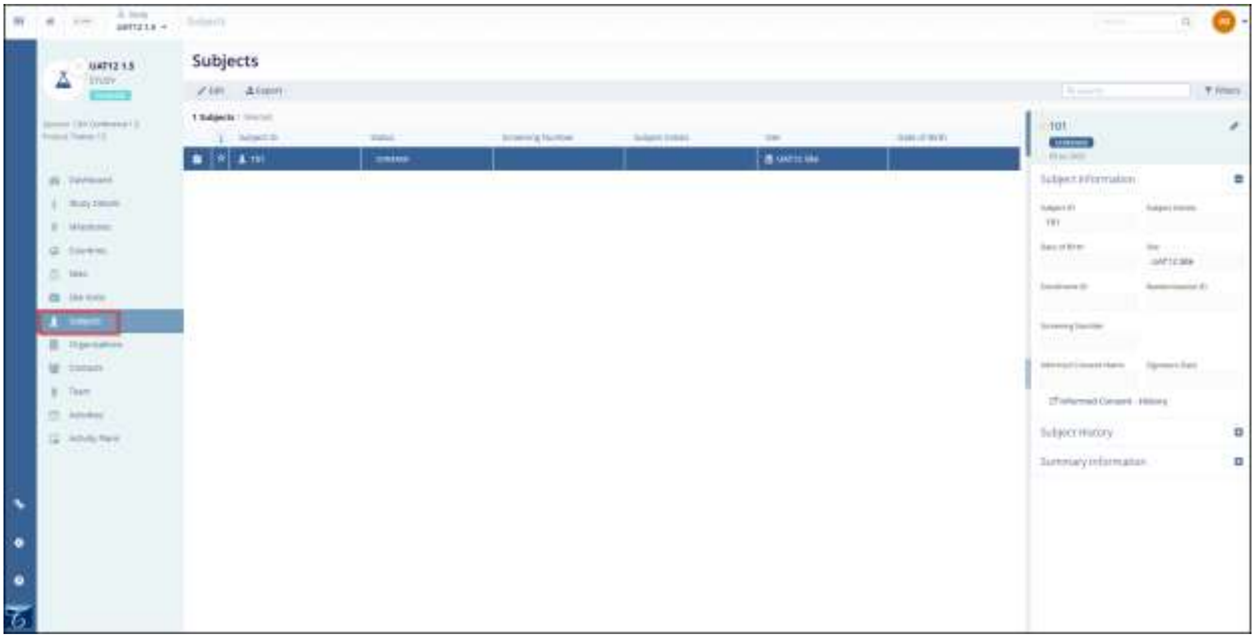
4. Make any necessary changes to the subject information.
5. Click on the Save button at the top-left of the screen.



Reviewing Subjects Within a Study

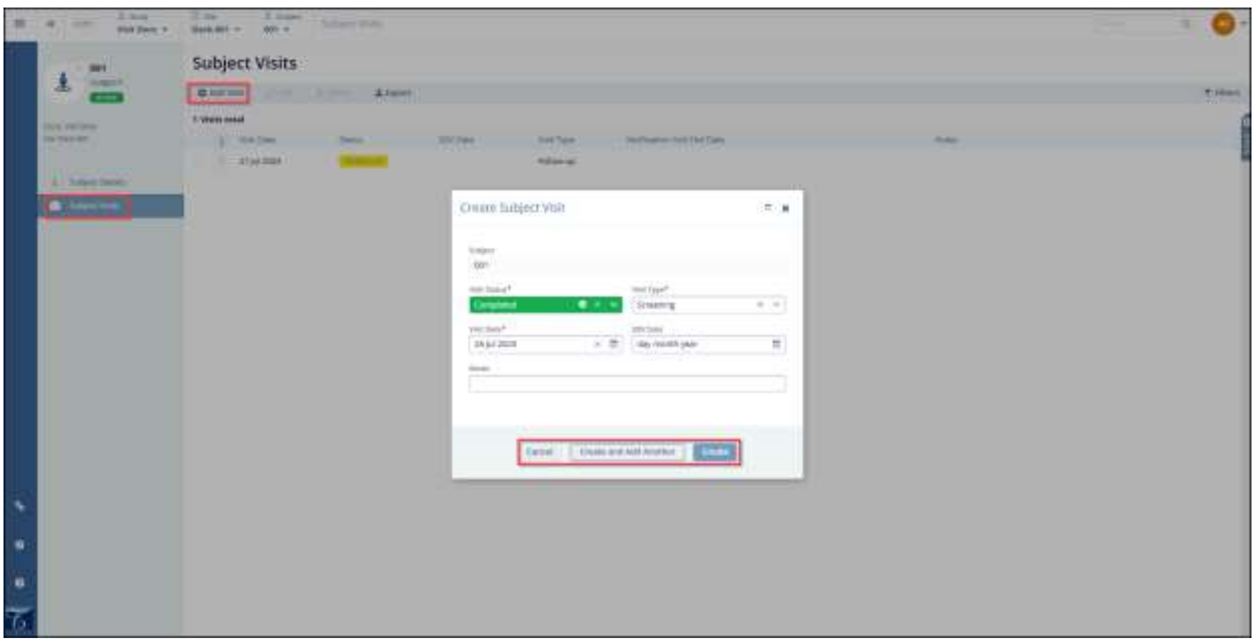
Note: Subjects is only available if the study is tracking subjects within CTMS. This list will be populated with the current list of subjects for the study.

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



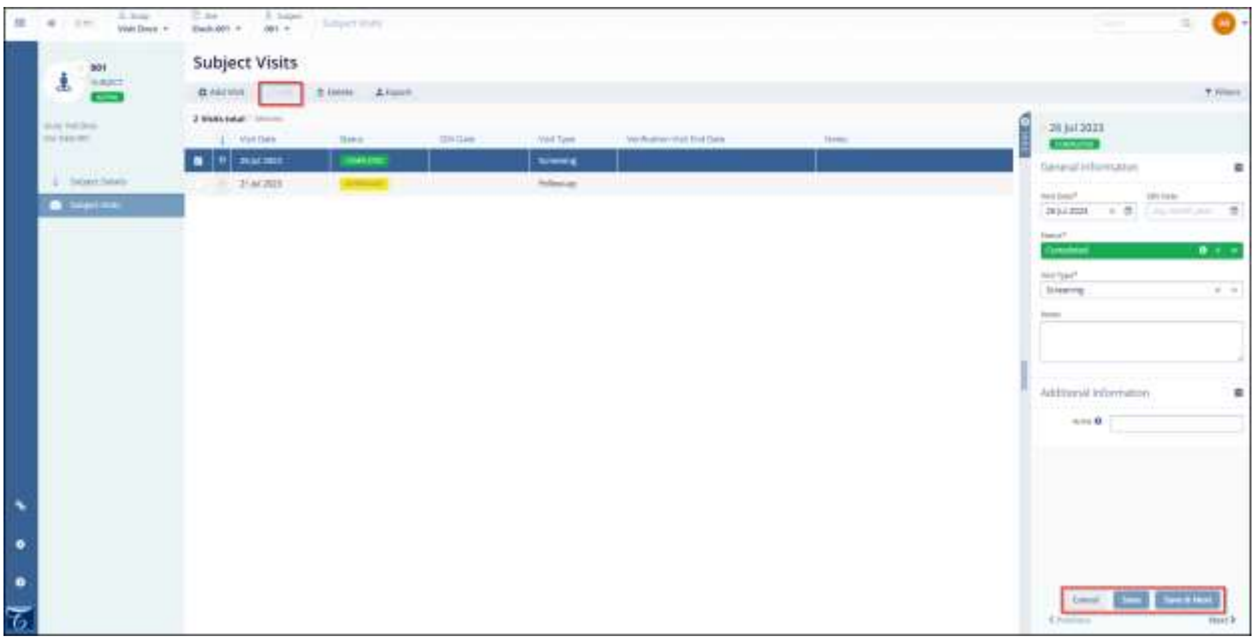
Tracking Subjects Visits

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 the "Subject Visits" window.
5. Click on the Add Visit button in the top-left of the screen.
   a. This opens the Create Subject Visit window.
6. 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 that 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.



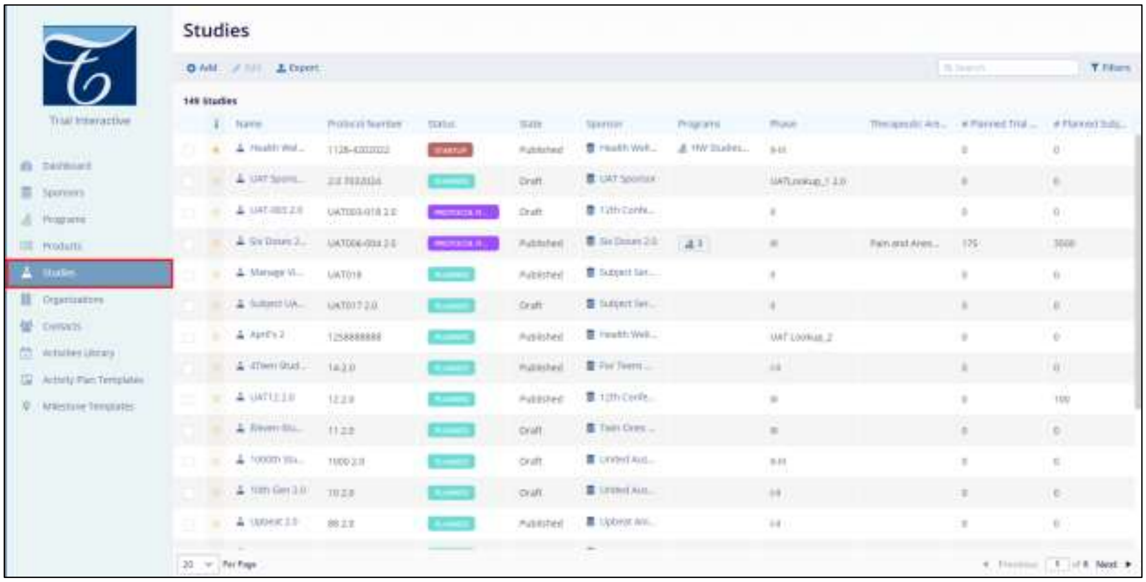
Editing a Subject Visit

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 the “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. A quick view panel is open on the right side. Make any necessary changes to the subject visit information.
8. Click on the Save button at the right bottom of the screen.



Study Organization

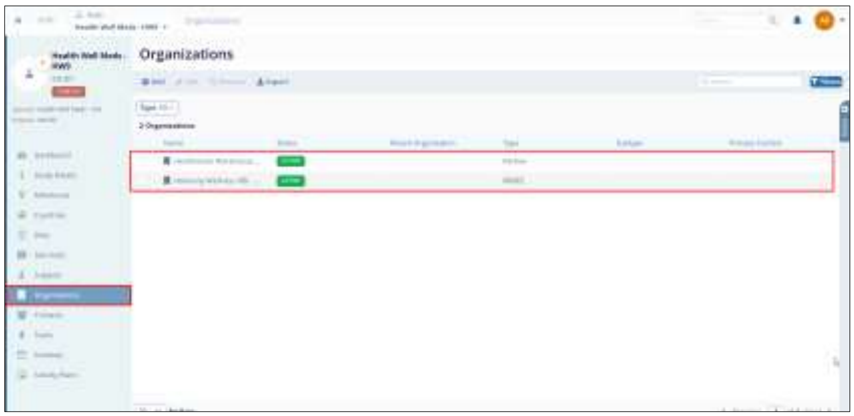
1. Click on the "Studies" link in the navigation menu on the left side of the screen. This opens the "Studies" window.



2. Locate the study to which you want to associate an organization and click on it. This opens the dashboard for that study.

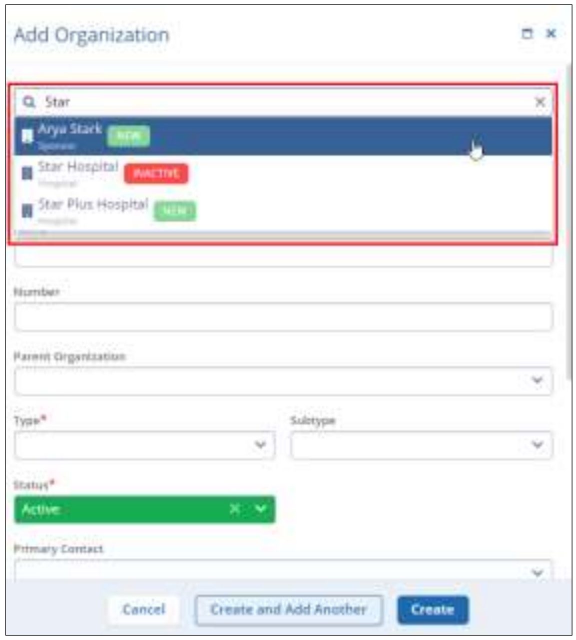
3. Click on the "s" link in the navigation menu on the left side of the screen.

4. This opens the "Organization" window, displaying organizations associated with the study.



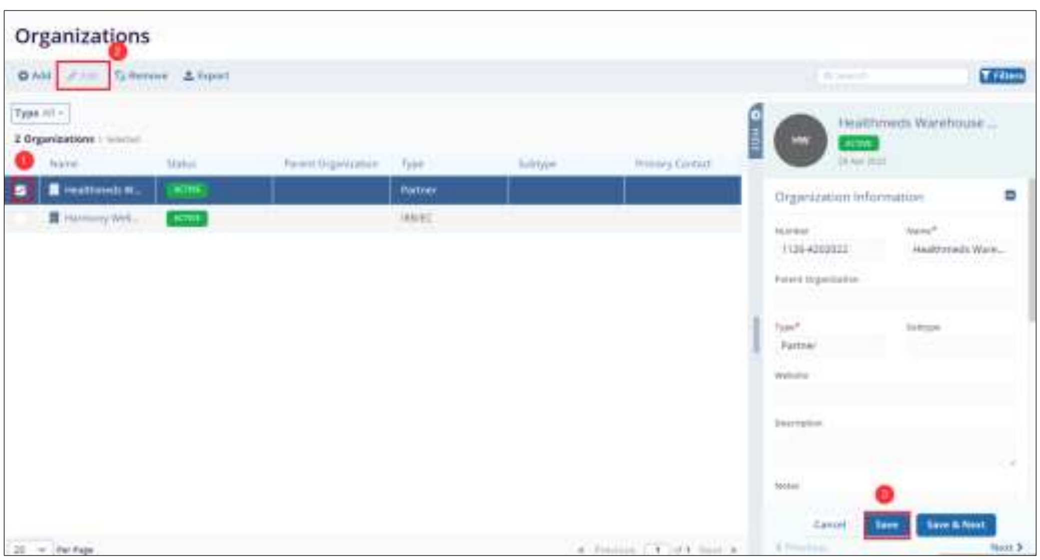
5. Click the "Add" button at the top-left of the screen.

6. It will open the Create organization window. To learn How to create organization click here.
7. If the organization has already been created, use the search area to locate and select the organization.

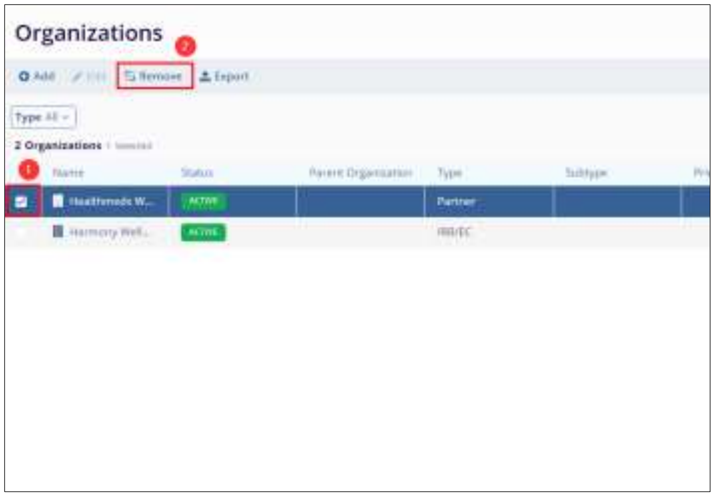


8\. Click "Create" or "Create and Add Another" depending on whether the user needs to associate another organization with this study.

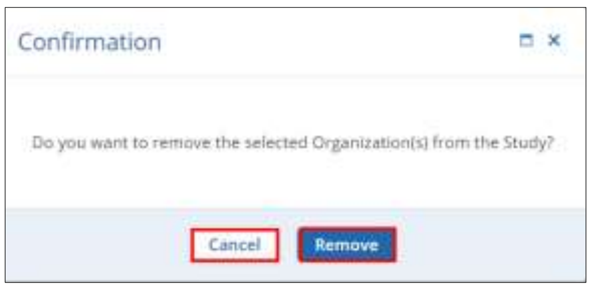
6\. To edit an organization, select the organization and click the “Edit” button from the top menu. A quick view panel is displayed on the right side of the screen. Make any necessary changes in the quick view panel. Click "Save" at the bottom of the quick view panel. Refer to the screenshot below.



9\. To remove the organization that is associated with the study, Select the organization. Click the ‘Remove’ button from the top main menu.



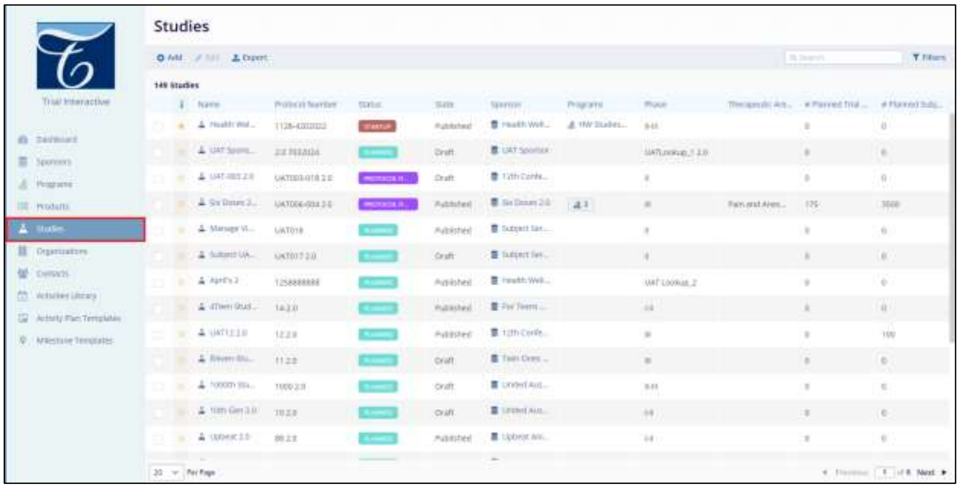
10. The user will receive the confirmation pop-up, To proceed further click on the '**Remove'** button or click on 'Cancel' to discard it.



11. To learn how to export the organization, click here.

Study Contacts

1. Click on the "Studies" link in the navigation menu on the left side of the screen. This opens the "Studies" window and displays the study list.

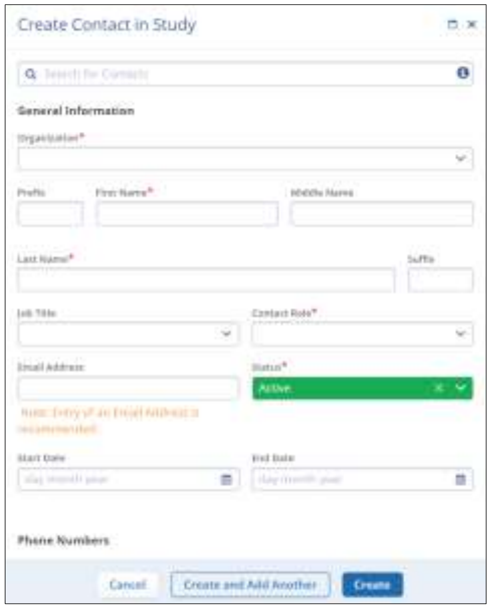


2. Click on the name of the study to which you want to associate contacts. The dashboard for the study will be displayed.

3. Click on the "Contacts" link in the navigation menu on the left side of the screen. This opens the "Contacts" window, displaying all contacts for the study.

4. Click the "Add" button at the top-left of the screen.

5. The "Create Contact in the Study" window will display.



6. Enter the mandatory metadata to create a contact, Organization, First Name, Last Name, Contact Role, Email Address, and Status, as indicated by an asterisk (*) next to the field title. Enter any additional information as necessary.

Note: When creating a contact record with at least one phone number, designate one number as the primary number.

7. To learn how to create a contact, [click here.]

Note: The search functionality can be used to search for addresses.

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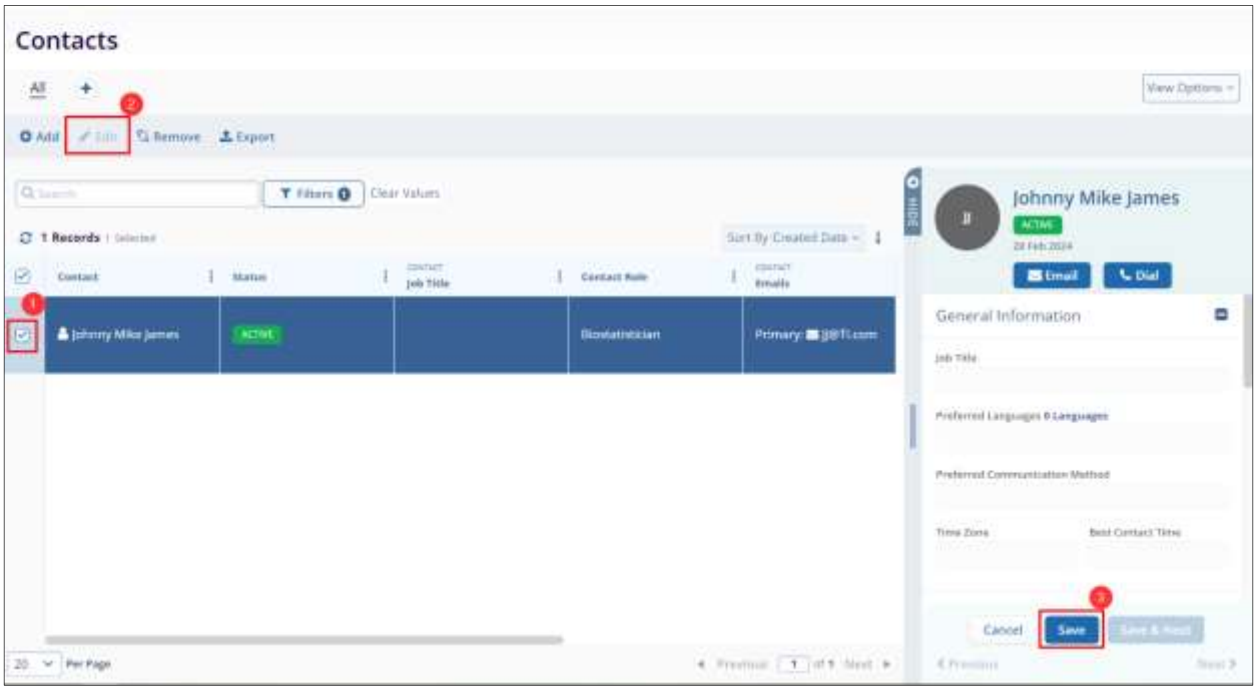
8. Before clicking "Create," verify that all fields are entered correctly in the "Create Contact in the Study" window.
9. Click "Create" or "Create and Add Another" depending on whether you intend to create another contact immediately.

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

10. When editing a contact record from the list, only data that is contextual to the study can be updated.
11. To edit a contact, select the contact and click the “Edit” button from the top menu. A quick view panel is displayed on the right side of the screen. Make any necessary changes in the quick view panel. Click "Save" at the bottom of the quick view panel. Refer to the screenshot below.



12. To remove the Contact that is associated with the study, Select the Contact. Click the ‘Remove’ button from the top main menu.

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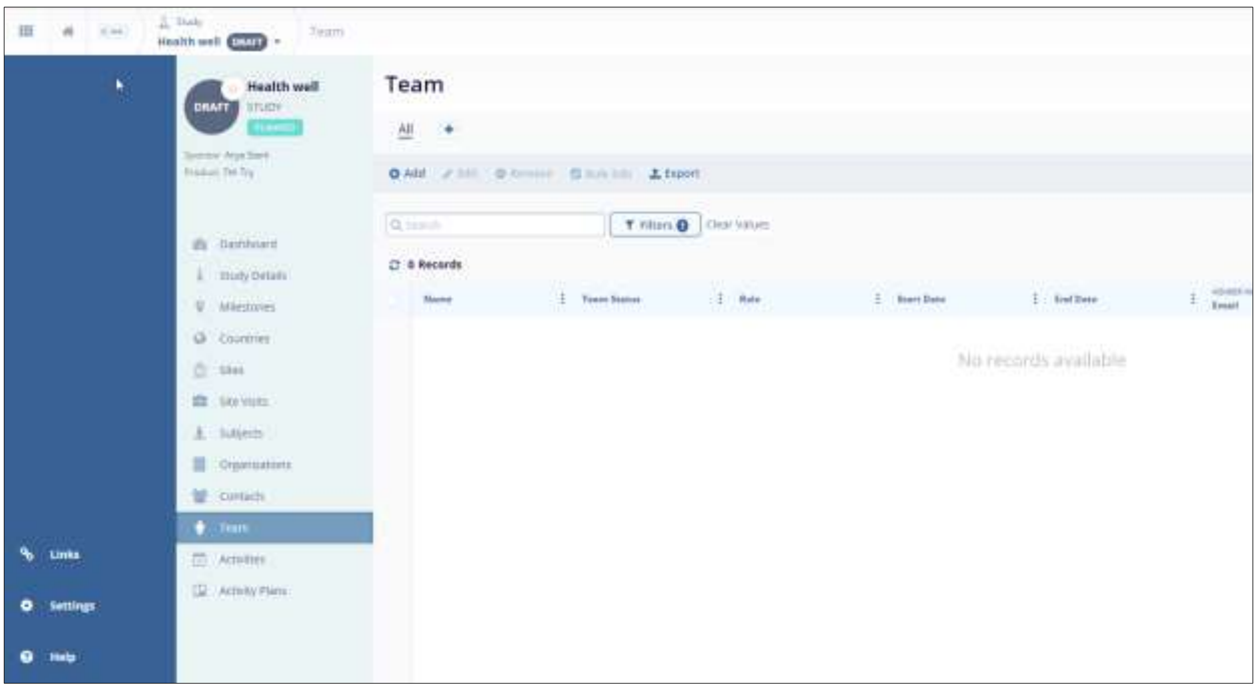
13. The user will receive the confirmation pop-up, To proceed further click on the ‘**Remove’** button or click on ‘Cancel’ to discard it.

14. To learn how to export the organization, click here.

Study Team vs Access Permissions

TI CTMS separates the study team from access permissions for the study. Managing the study team is done from the Team area at the study level by using the navigation links at the left side of the screen.

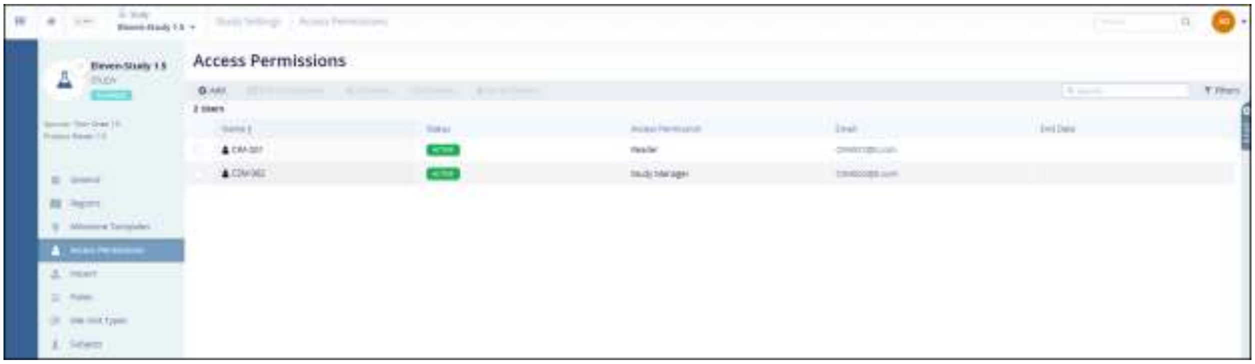


Some important points to note about managing study team members are:

- When someone is added to the study team, they are not awarded access to view study information in the CTMS. This area is specifically designed to track members of the team and which role(s) they are fulfilling for this specific study.
- Once an entry has been made, the role will not be editable. If you have made an error, you will need to delete the entry and create a new one. For correct entries, if a team member moves on to a new role within the study, the study manager should enter an end date for the old role and create a new entry for the new role. This is to aid in providing tracking for each study team member and the roles that they may play throughout a study.

Managing Study Access Permissions

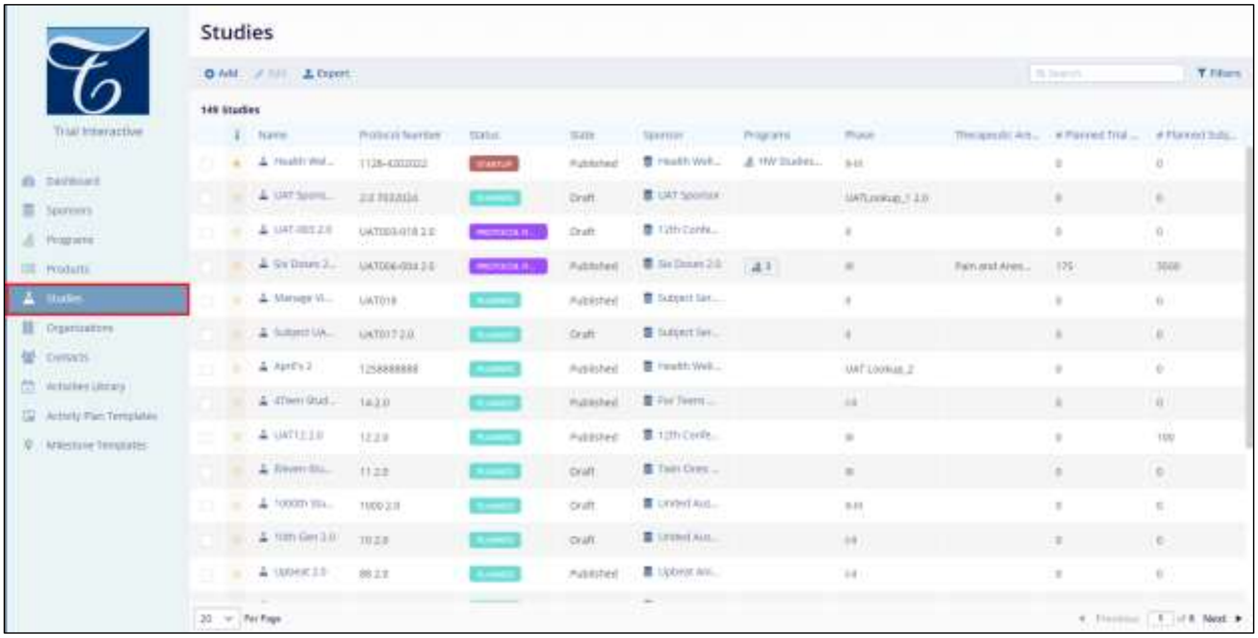
Users will see an 'Access Permissions' button at the top-right of the Study Team area. Clicking on that button will take you to the Site or Study Settings area as appropriate and the Access Permissions menu. Users can also navigate directly thereby accessing the settings area directly.



Entering Study Settings

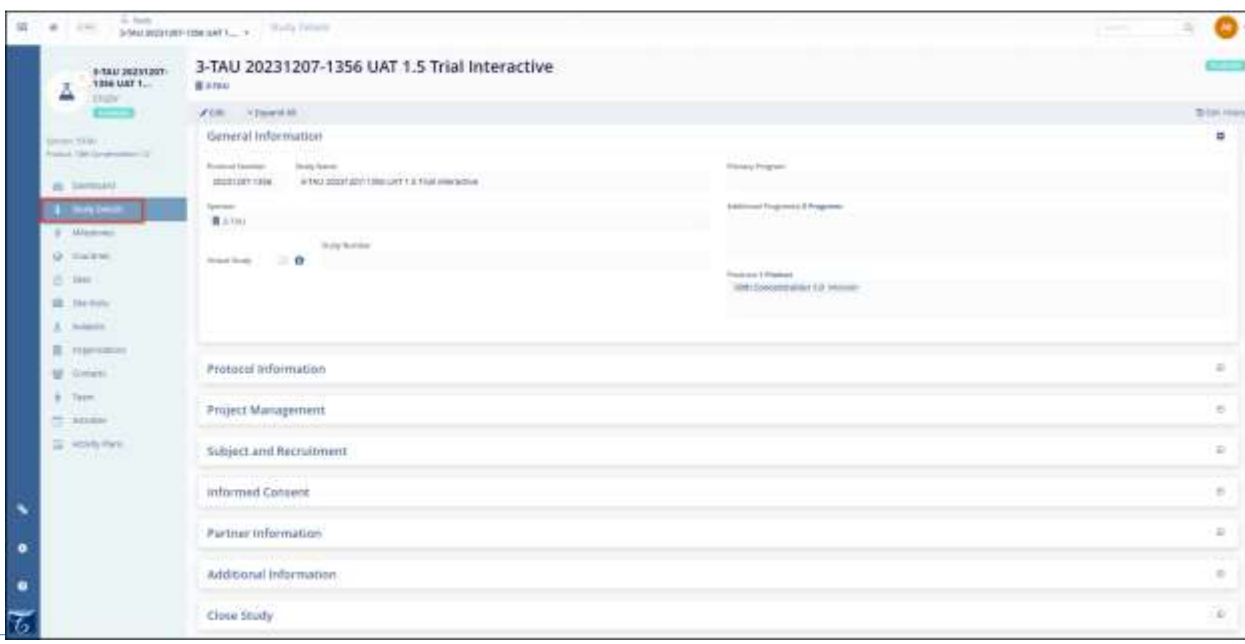
Navigate to Studies.

2. To navigate a studies screen, click on the '**Studies'** link in the Navigation menu at the left side of the screen. It will redirect you to the Studies screen.

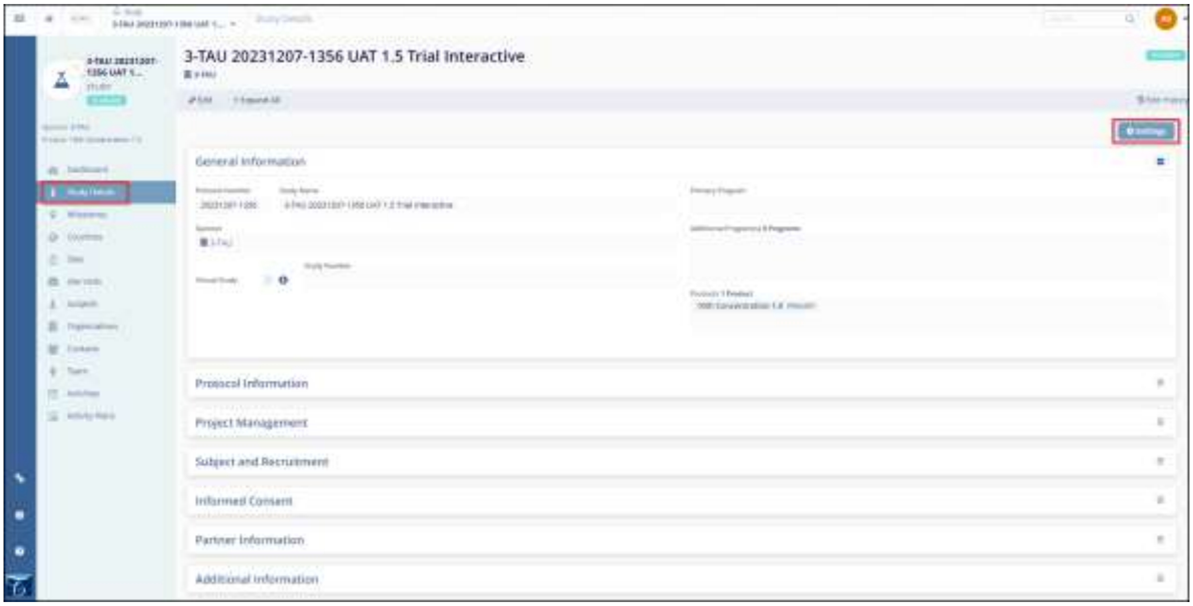


Steps to Manage Study Settings

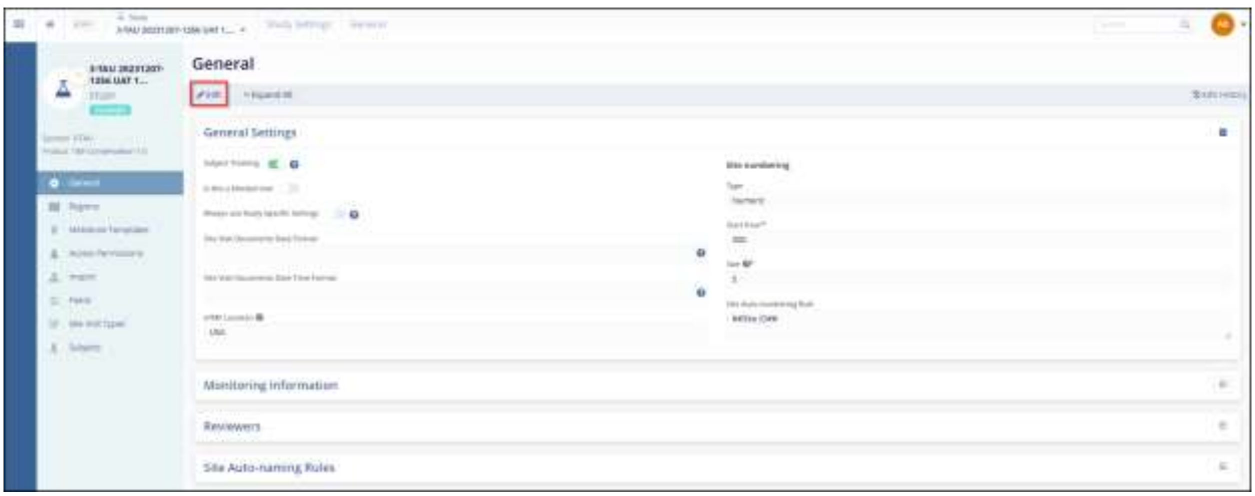
1. Click on the name of the study in the list.
    a. The dashboard for the study is displayed.
2. Click on the Study Details in the Navigation menu at the left side of the screen.
    a. The "Study Details" window is displayed.



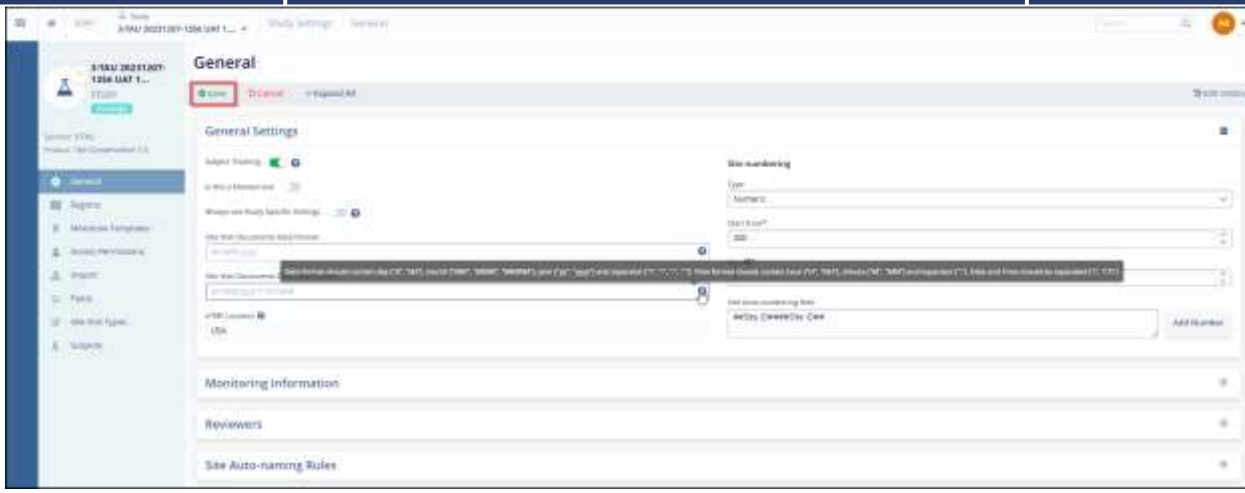
3. Click Settings in the top-right corner of the study details window. This opens the Study Settings General window.



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



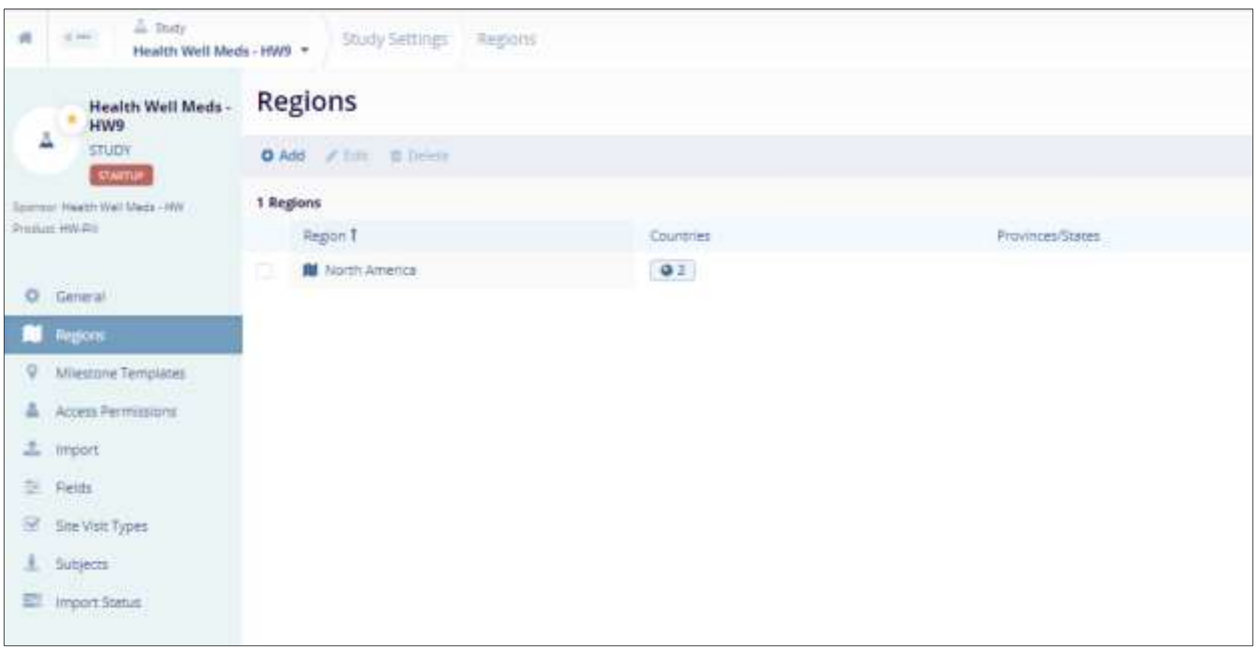
5. Make any necessary changes in the Study Settings General window.
6. Click on Save at the top-left of the window.



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

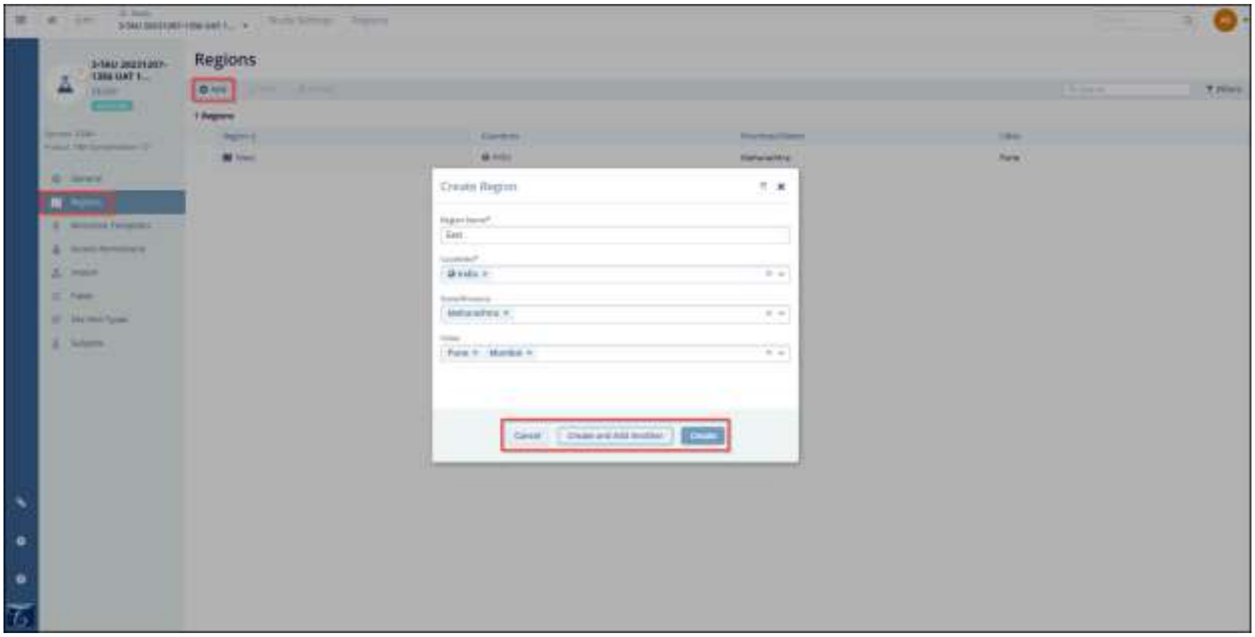
Defining Study-Specific Regions

1. To learn to understand how to navigate to the study setting click here.
2. Click on Regions in the Navigation menu at the left side of the screen. The “Regions Window” is displayed.



3. Click on the Add button at the top-left of the screen. This opens the “Create Region” Window.
4. 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.

5. Click Create or Create and Add Another depending on whether you intend to create another Region right away.

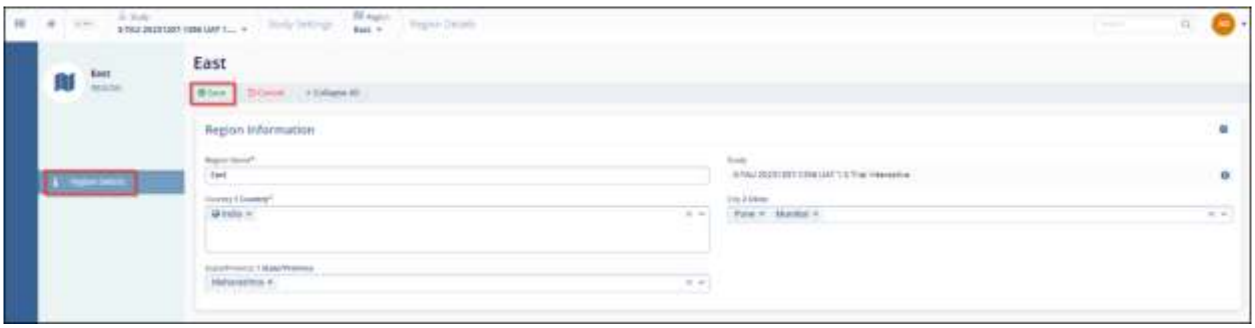


Note: To enter the State/Province and Cities values you must select only a single country for your region definition.

Editing Study Regions

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

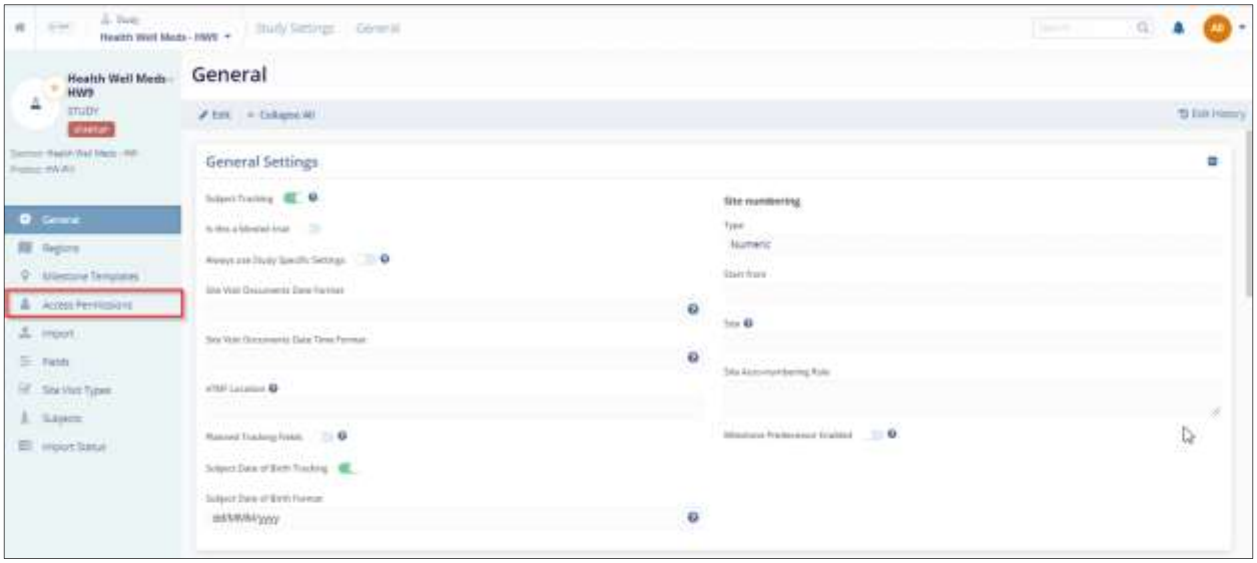
4. Make any necessary changes in the Region Details window.
5. Click on the Save button in the top-left for the changes to apply.



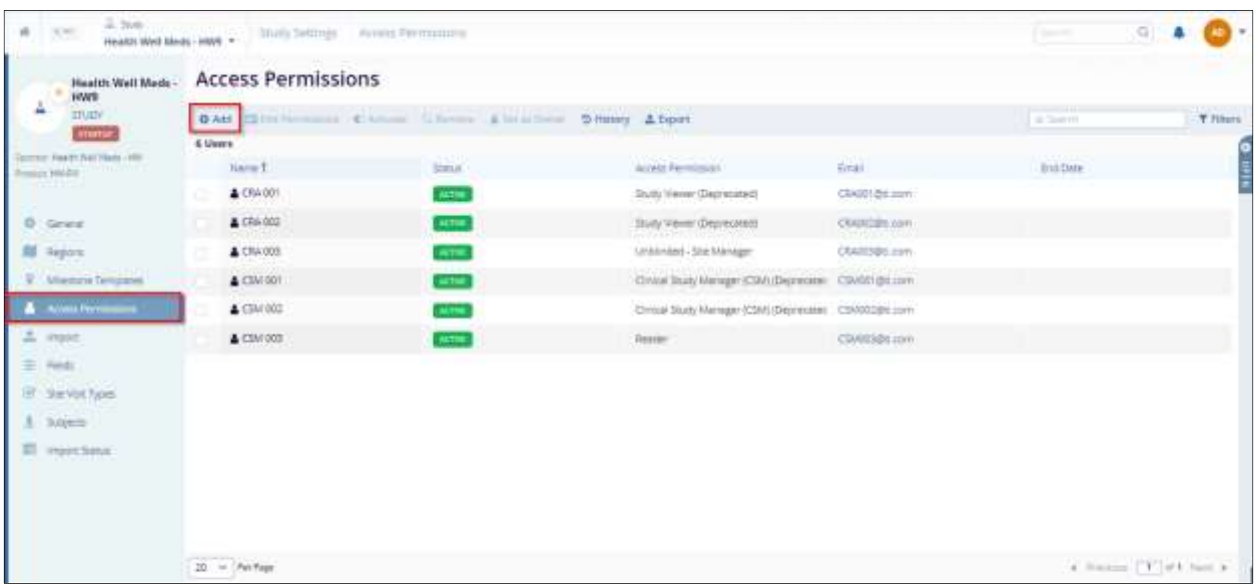
Access Permission in Study Settings

To learn to understand how to navigate to the study setting [click here.]

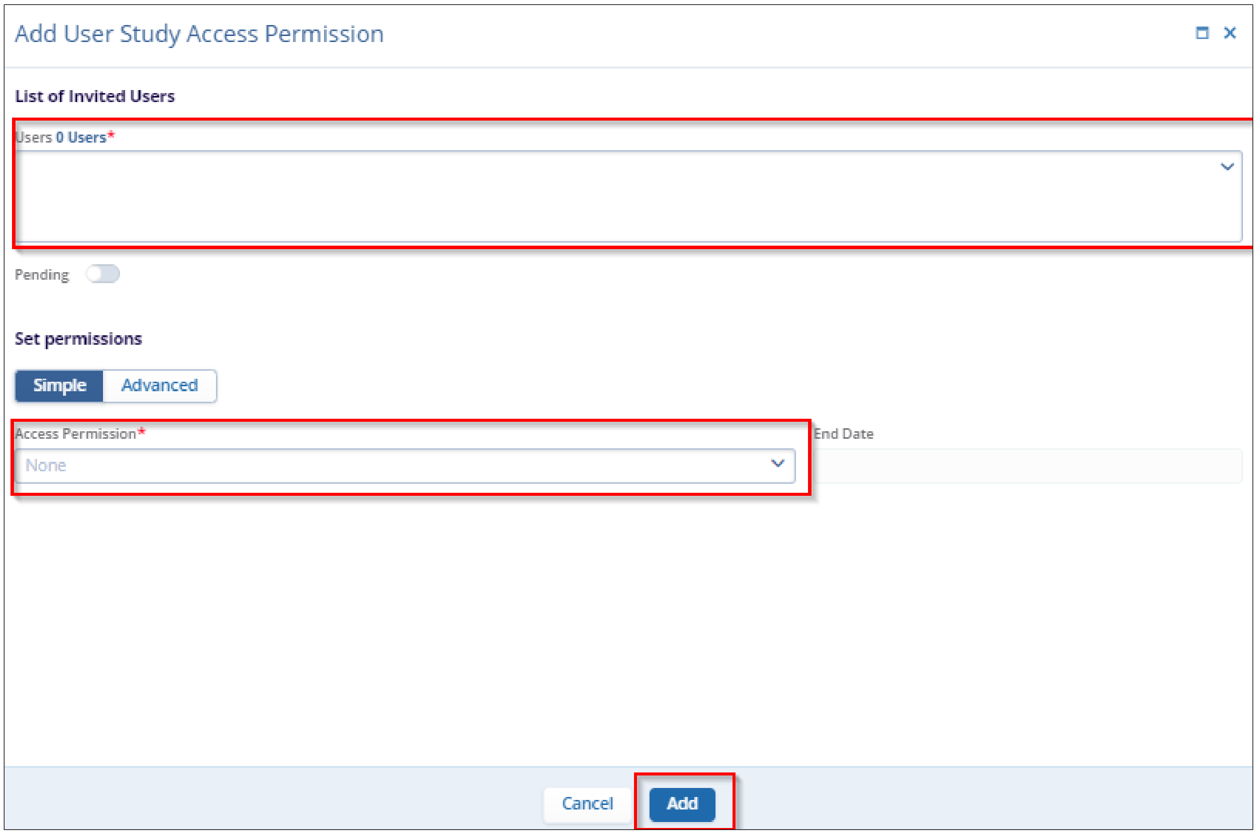
1. Once the user is on the Study Setting screen, Click on the Access Permission tab from the navigation pane.



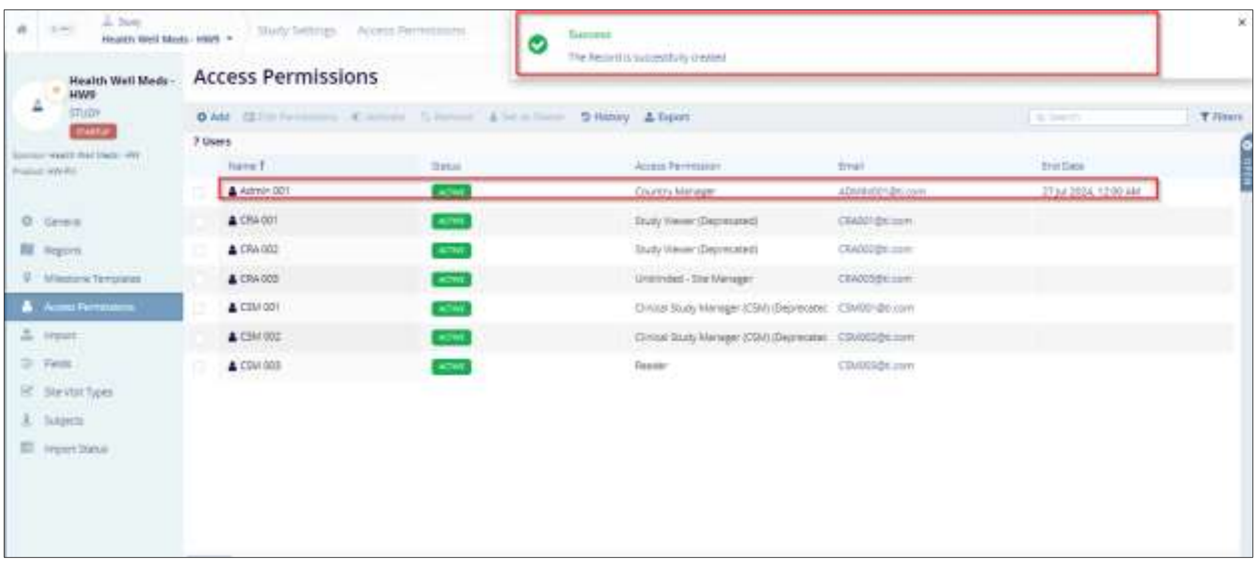
2. It will open the access permission screen. To add the user click on the Add button. Refer to the screenshot below.



3. It will open the Add User Study Access Permission window. User and Access Permission field are mandatory fields. Other will are optional. Enter other information as per your requirement.



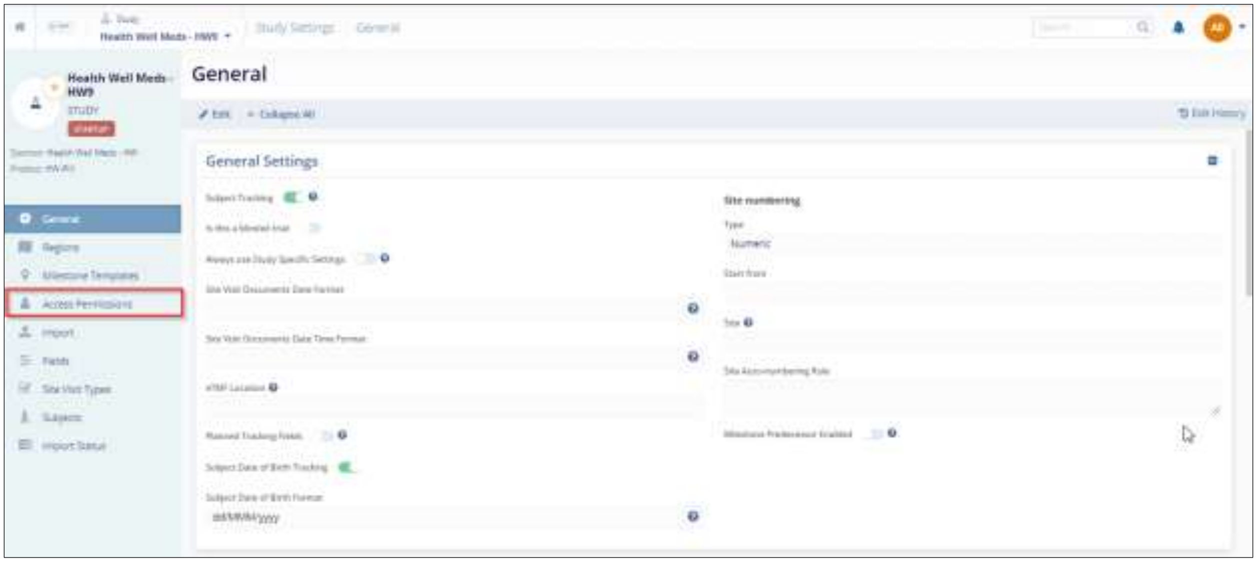
4. Click on the '**Add'** Button to add the user. After click on the add button user will receive a successfully pop-up and the user will be available in the grid. Refer to the below screenshot.



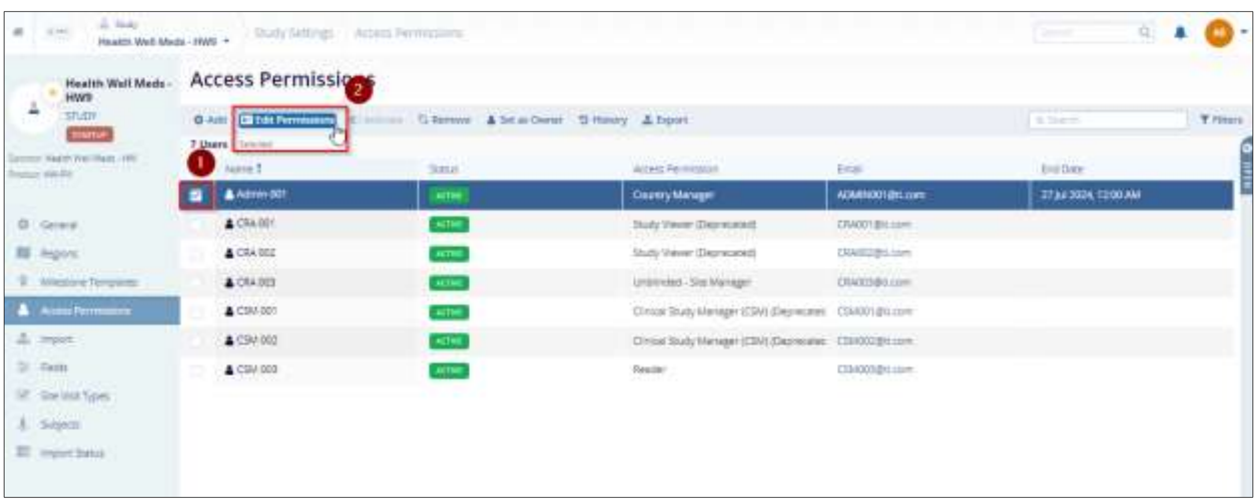
Steps to Edit a User Permission

To learn to understand how to navigate to the study setting [click here.]

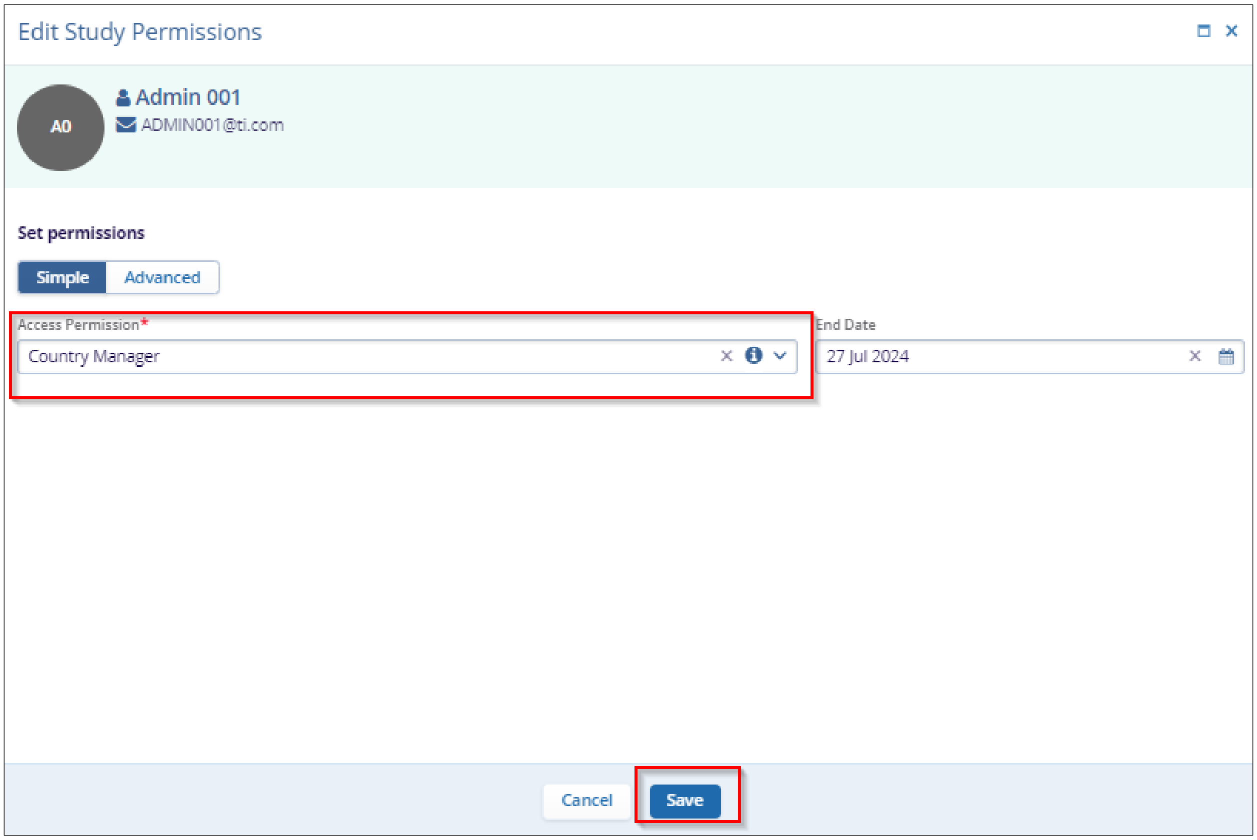
1. Once the user is on the Study Setting screen, Click on the Access Permission tab from the navigation pane.



2. It will open the access permission screen. To Edit Permission, Select the user from the grid and click on the Edit button. Refer to the screenshot below.



3. Here, the user can set permission and change the access permission and end date. The access permission is the mandatory field. The user should make the changes are per the requirement.

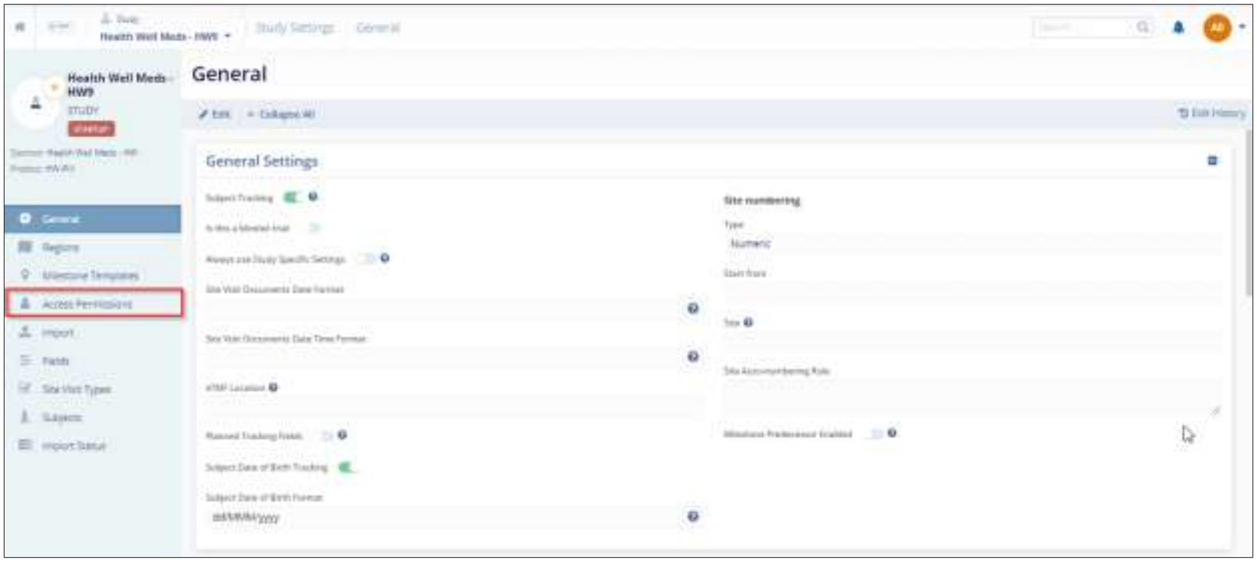


4. Click on the Save button to edit the user permission or click on the Cancel below to discard the changes.

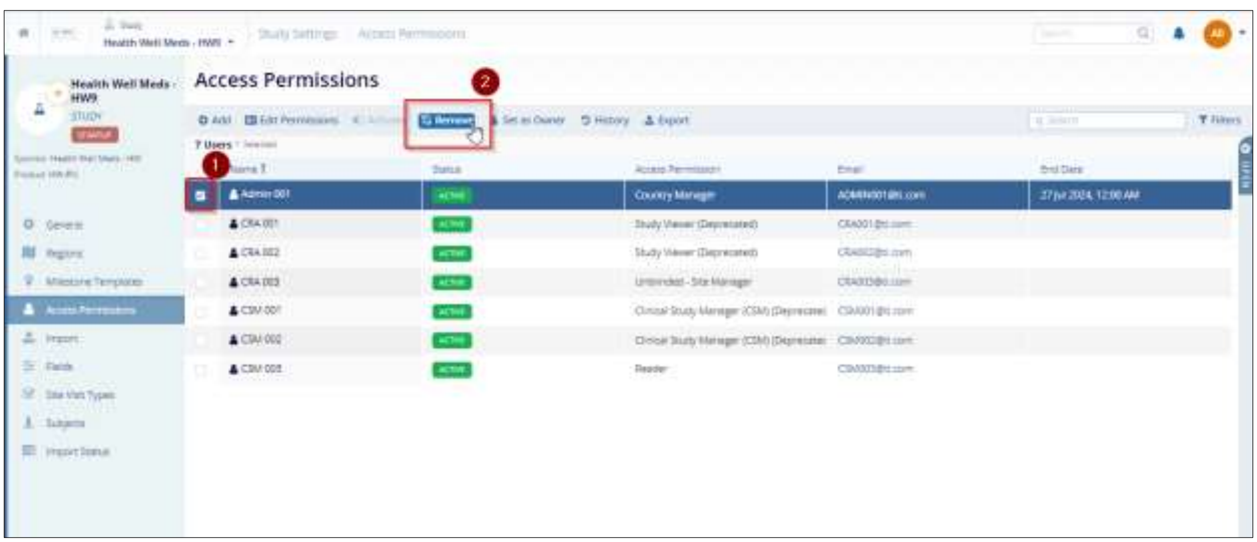
Remove user permission

To learn to understand how to navigate to the study setting [click here.]

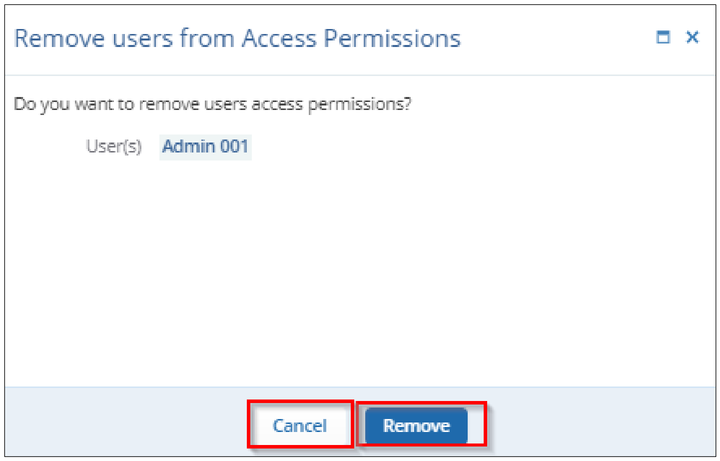
1. Once the user is on the Study Setting screen, Click on the Access Permission tab from the navigation pane.



2. It will open the access permission screen. To Remove Permission, Select the user from the grid and click on the Removed button. Refer to the screenshot below.



3. The user will receive a pop-up message for confirmation of removal. Click on the Remove button to proceed further or Click on the Cancel button to discard the changes.

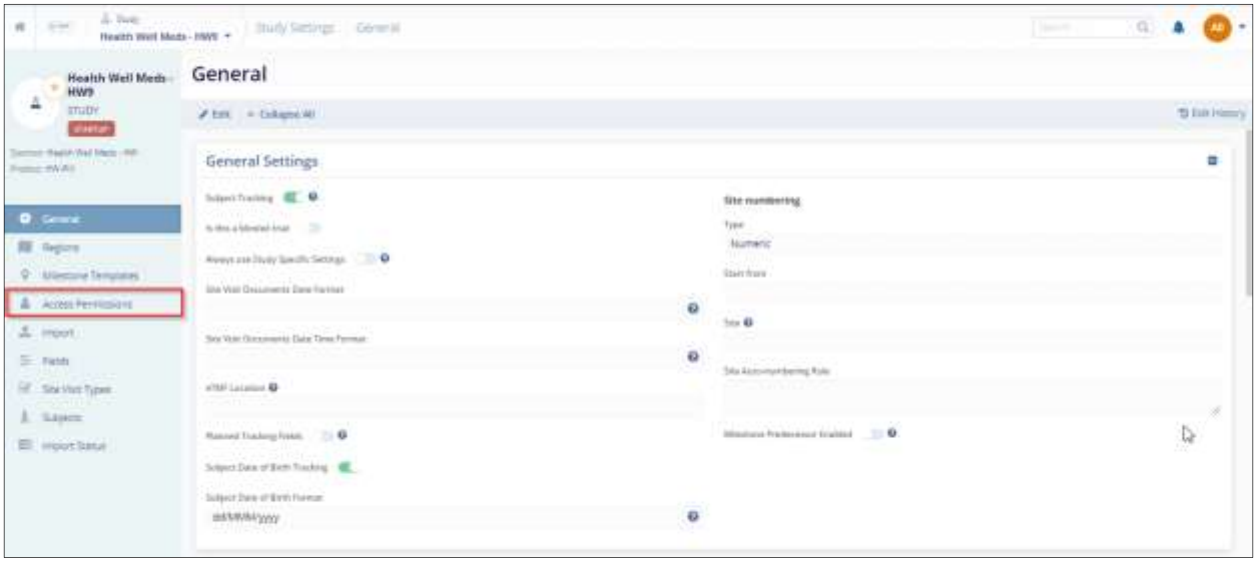


4. After clicking the Remove button, the user will receive a successful removal pop-up and will disappear from the grid.

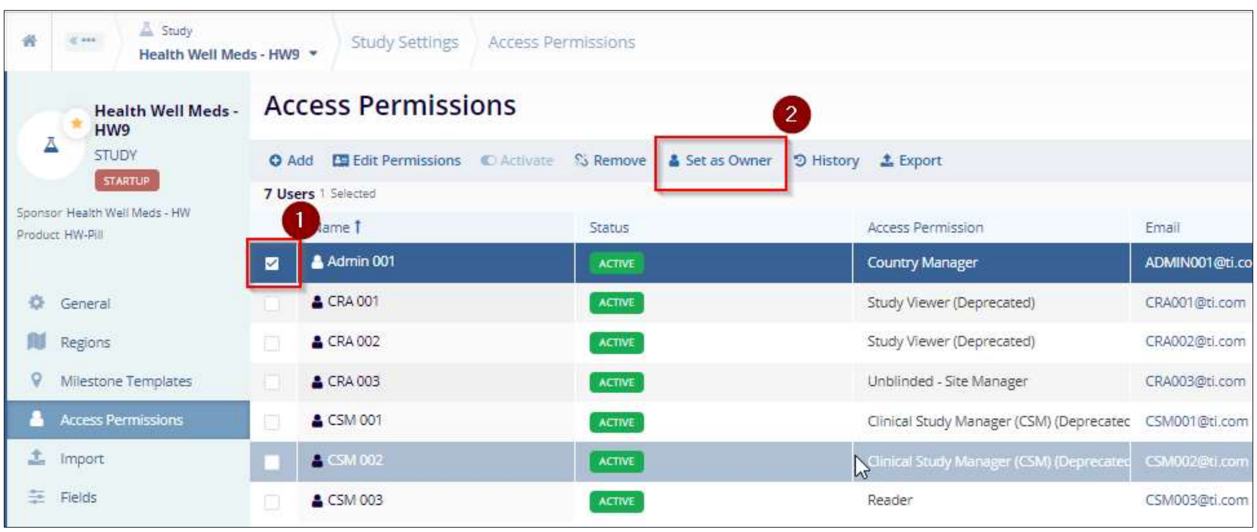
Set as Owner in Access Permission

To learn to understand how to navigate to the study setting click here.

1. Once the user is on the Study Setting screen, Click on the Access Permission tab from the navigation pane.



2. It will open the access permission screen. To set a user as an owner, Select the user from the grid and click on the Set as Owner button. Refer to the screenshot below.



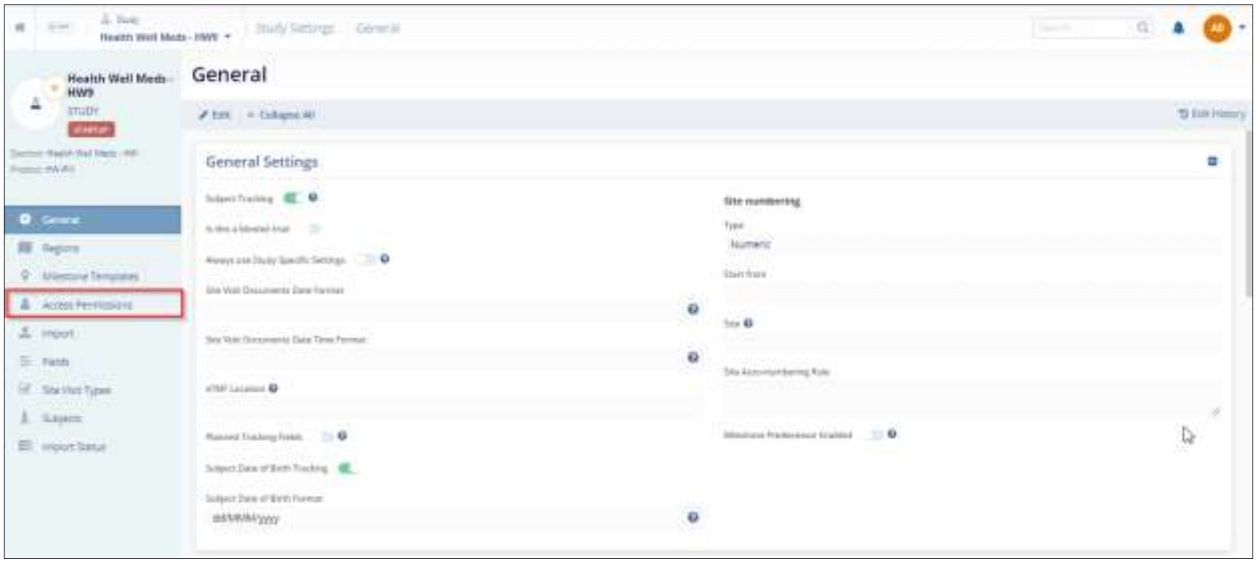
3. The user will receive a pop-up with who the current owner is and who will be the new owner. To add the new owner click on the Confirm button.

4. After clicking on the Confirm button. The user will receive a successful pop-up and the owner will be changed.

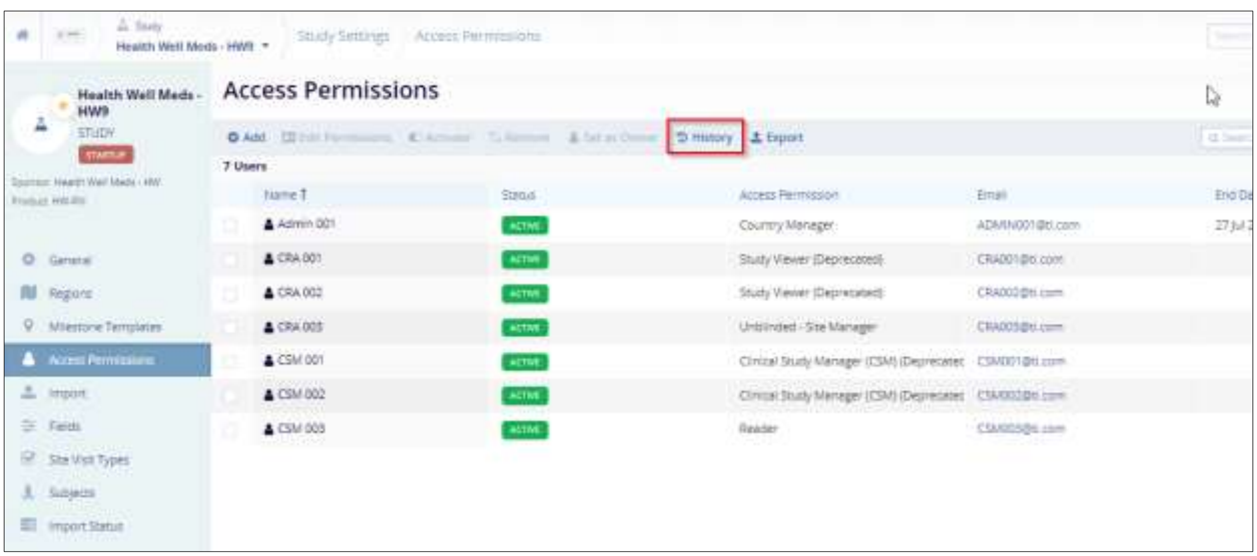
History of Access Permission

To learn to understand how to navigate to the study setting <u>click here.</u>

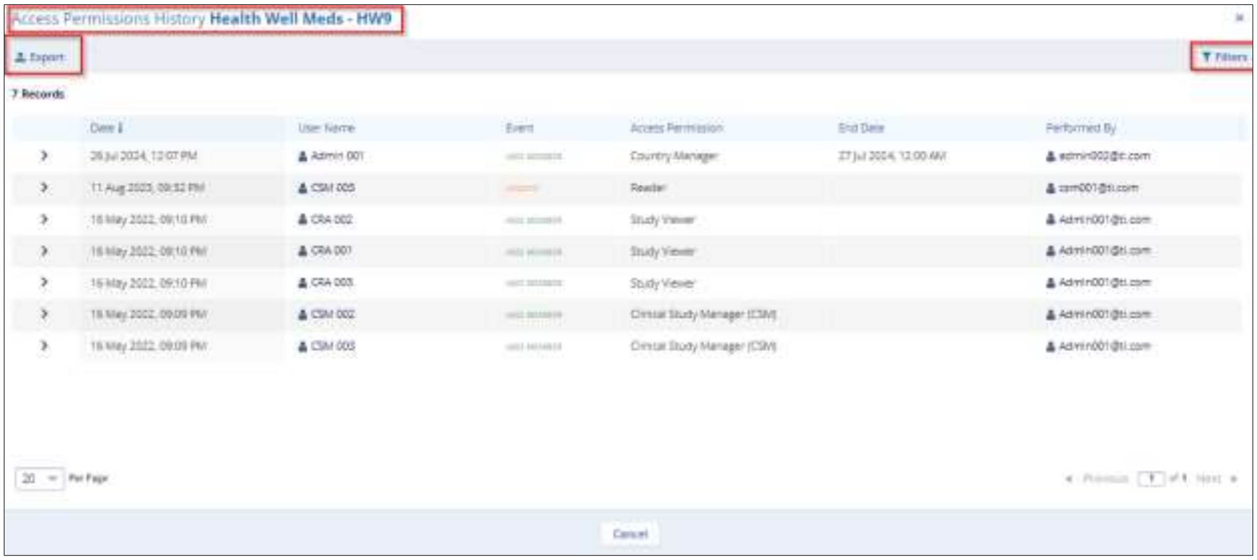
1. Once the user is on the Study Setting screen, Click on the Access Permission tab from the navigation pane.



2. It will open the access permission screen. User need to click on the History button to check the history and their status. Refer to the screenshot below.



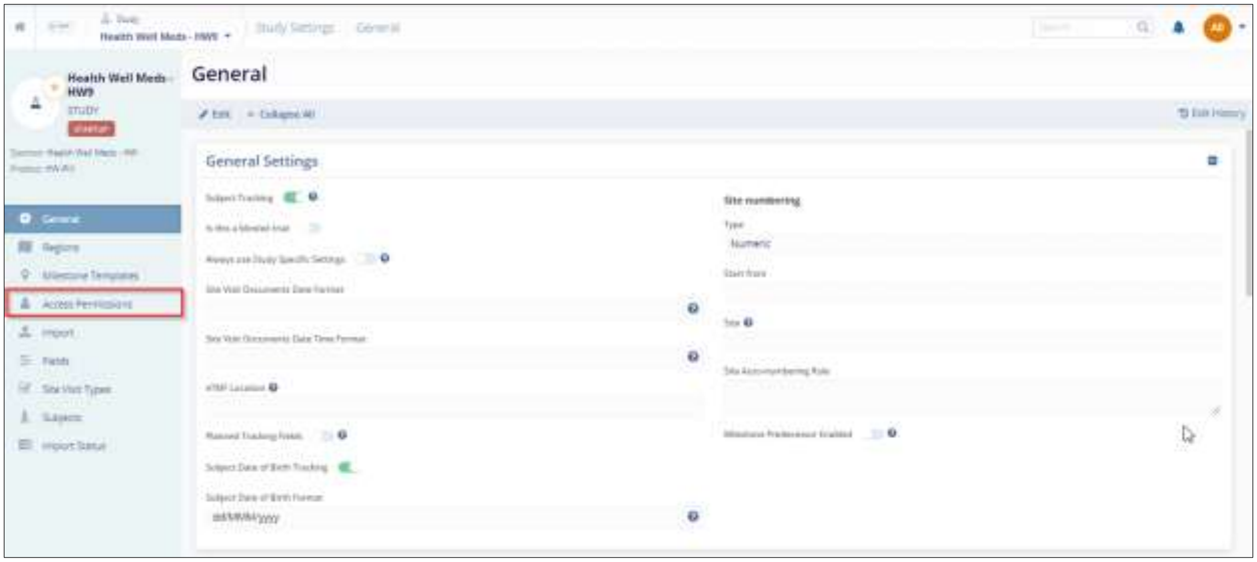
3. After clicking on the History button. The access permission history page will appear for this dedicated study. Users can use filter functionality and can export the history as well. Refer to the screenshot below for a better understanding.


Access Permissions History Health Well Meds - HW9
Export
Filters
7 Records
Date
User Name
Event
Access Permission
End Date
Performed By
26 Jul 2024, 12:07 PM
Admin 001
Country Manager
27 Jul 2024, 12:00 AM
11 Aug 2023, 09:52 PM
CSM 005
Reader
16 May 2022, 09:10 PM
CRA 002
Study Viewer
CRA 001
CRA 003
16 May 2022, 09:09 PM
CSM 002
Clinical Study Manager (CSM)
CSM 003
Per Page
Cancel

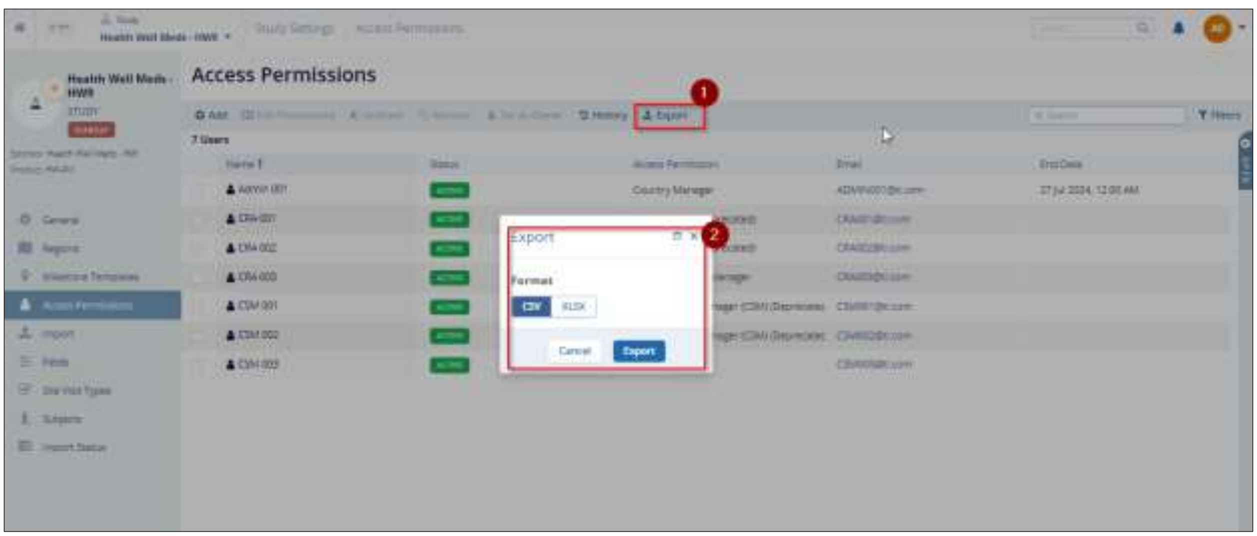
Access Permission Export

To learn to understand how to navigate to the study setting click here.

1. Once the user is on the Study Setting screen, Click on the Access Permission tab from the navigation pane.

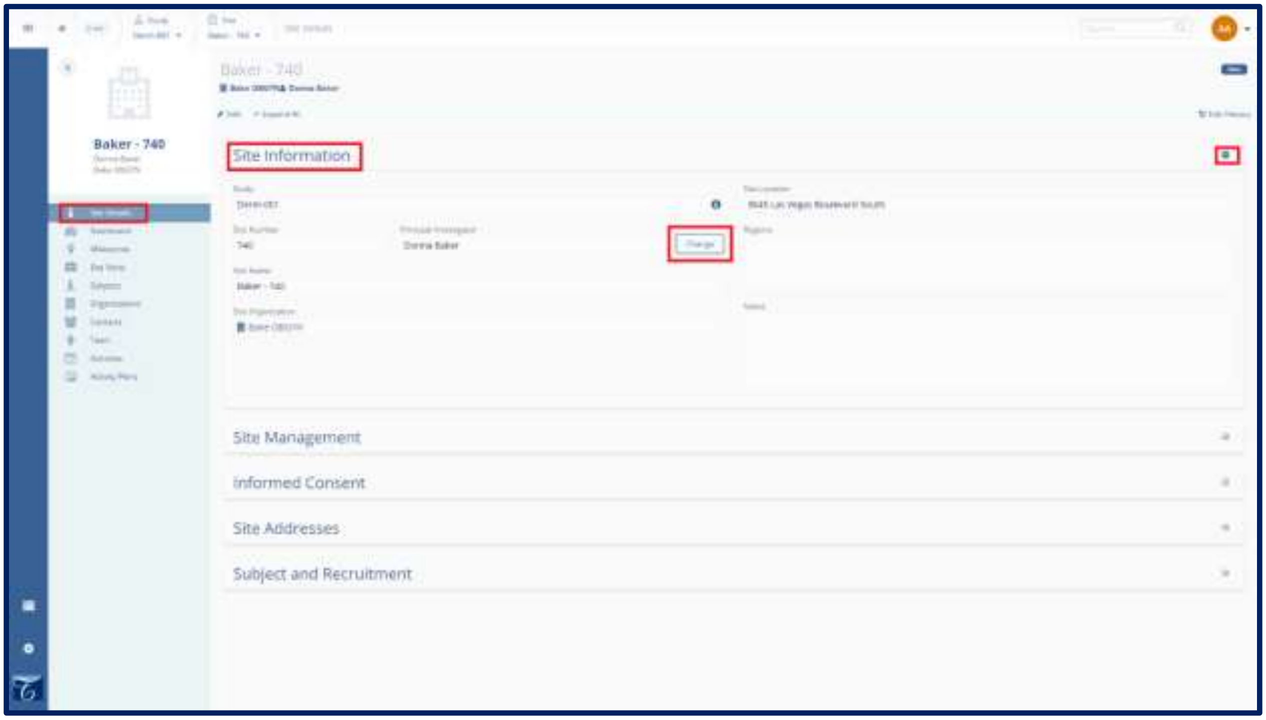


2. It will open the access permission screen. Users can export the data. Click on the export button. Refer to the screenshot below.



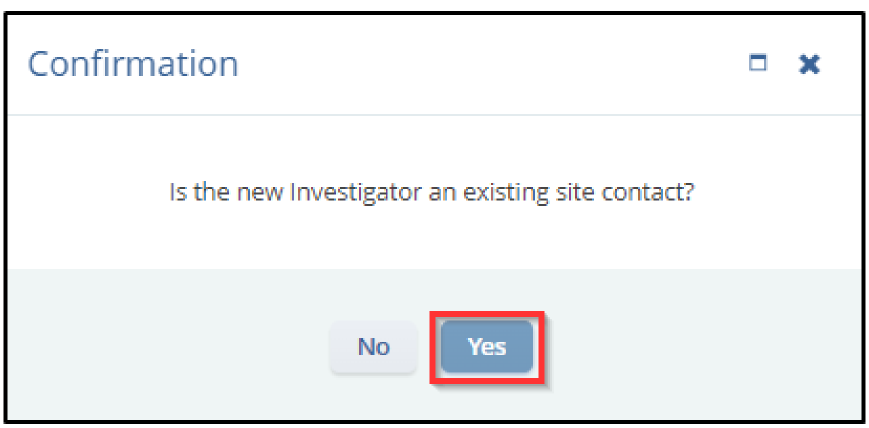
Change of Principal Investigator (PI)

3. Navigate to the Site Details area for the related site.
   a. The necessary steps are found here.
4. Click on the [+] sign next to the Site Information to expand that section.
5. Click on the Change button in the site information section.

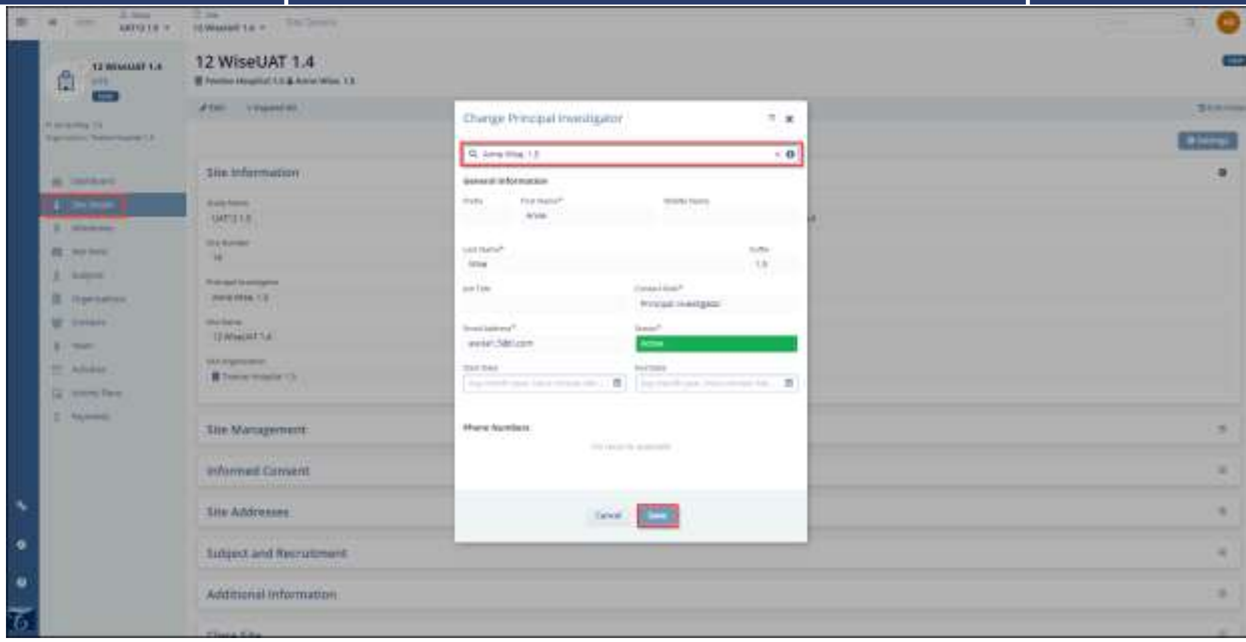


6. A confirmation window is popped up, select Yes in the confirmation window.
   a. This opens the "Change Principal Investigator" window.

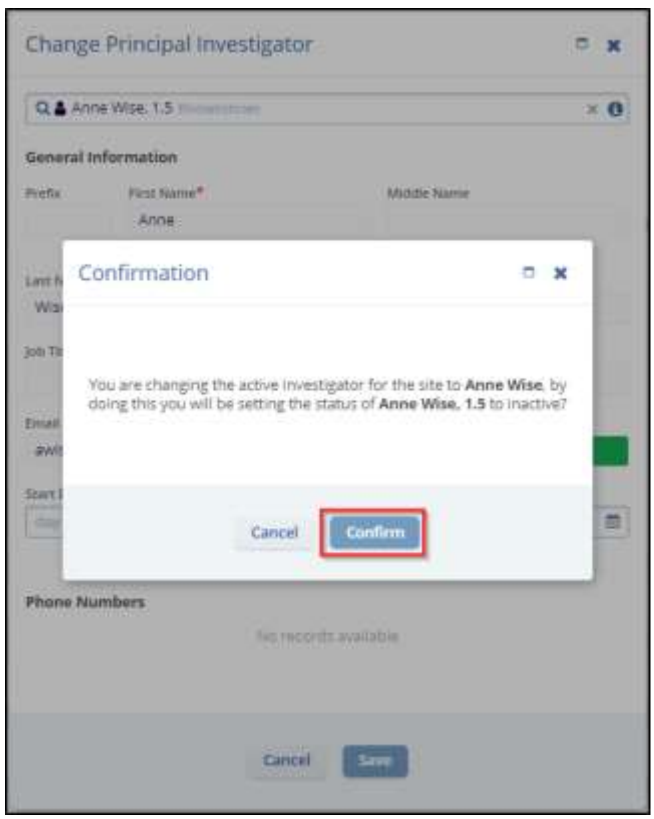
Note: Use the search box to find the contact.



7. Click on the Save button.

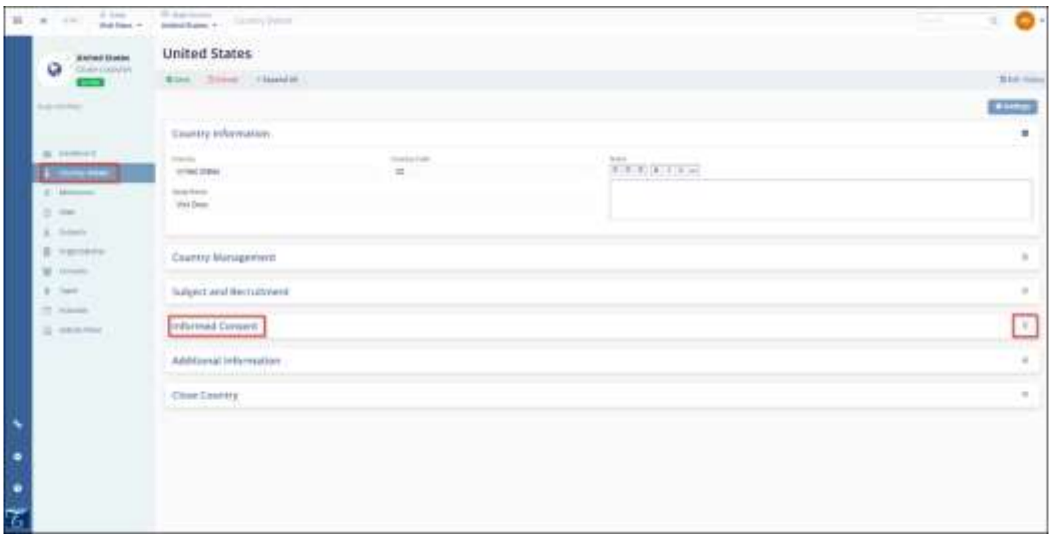


8. Click Confirm in the Confirmation popup window to save the changes.



Tracking Country Informed Consents (ICFs)

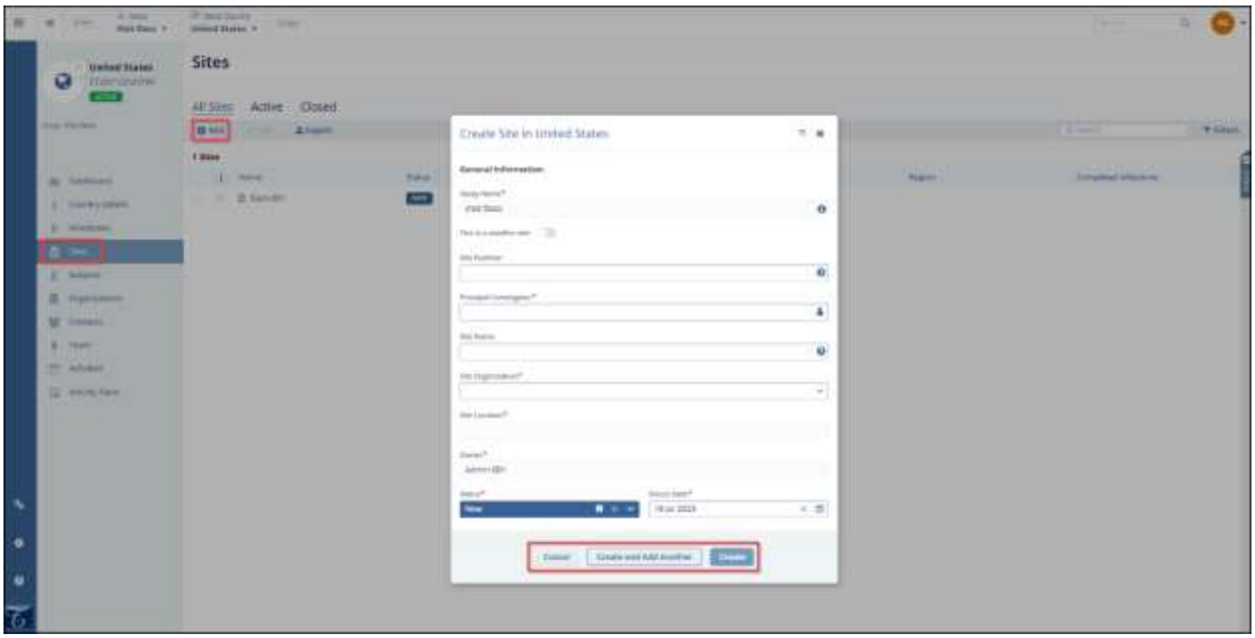
1. Click on Countries in the Navigation menu at the left side of the screen.
2. Navigate to the country in the list you want to edit and click on it.
   a. This opens the dashboard for the country.
3. Click on the Country Details in the Navigation Menu at the left side of the screen.
   a. This opens 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.



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 the name and effective date in the informed consent section and clicking on the save button.

Creating a Site within a Country

6. Click on Countries in the Navigation menu at the left side of the screen.
7. Navigate to the country in the list you want to edit and click on it.
   a. This opens the dashboard for the country.
8. Click on the Sites link in the Navigation menu at the left side of the screen.
9. Click on the Add button in the top-left of the screen.
   a. This opens the “Create Site” window.
10. Fill in the required information and click Create.
    a. More detailed instructions regarding this step can be found here.

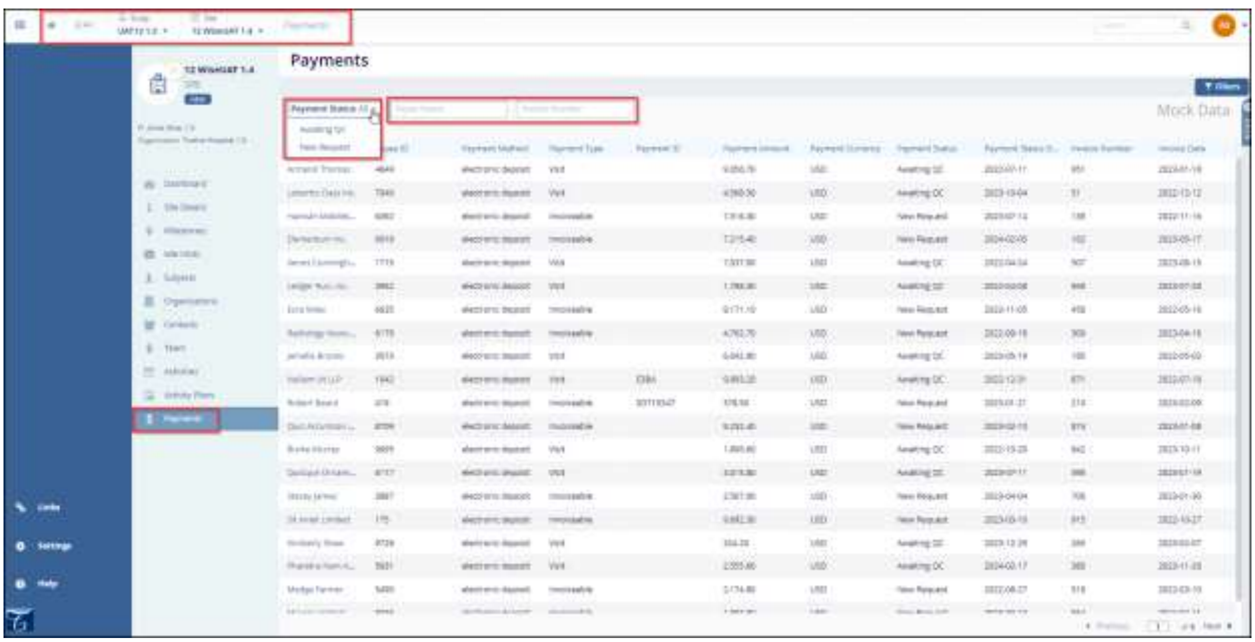


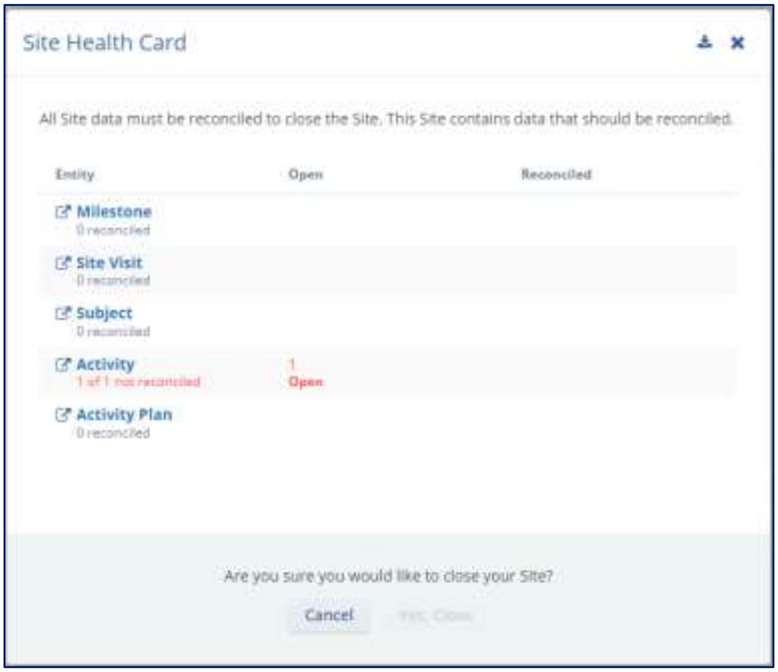
Integrated Payments View

TI CTMS has the ability for a user to review high-level payment details when an integration has been established between TI CTMS and an external payments system. The integration is view-only in the CTMS and any modifications still need to be made within the originating payment system.

Having access to high-level summary payment details allows users to provide timely responses to customers and sites regarding payments without additional navigation to payment-related systems. Users requiring additional payment-related details and reports can utilize the payment system link within TI CTMS to quickly navigate to the payment system and perform all payment-related tasks. Follow the steps below to view the payments related information.

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.
3. 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 view the payments.
   a. This opens the dashboard window for the site.
5. Click the Payments link displayed in the left side of the screen.
   a. This opens the Payments window in the center of the screen.
6. The user can apply filters to view the required payments for 'Awaiting QC' and 'New Request'.
7. The user can also search for a payment 'Payee Name' and 'Invoice Number'. Refer to the screenshot below.

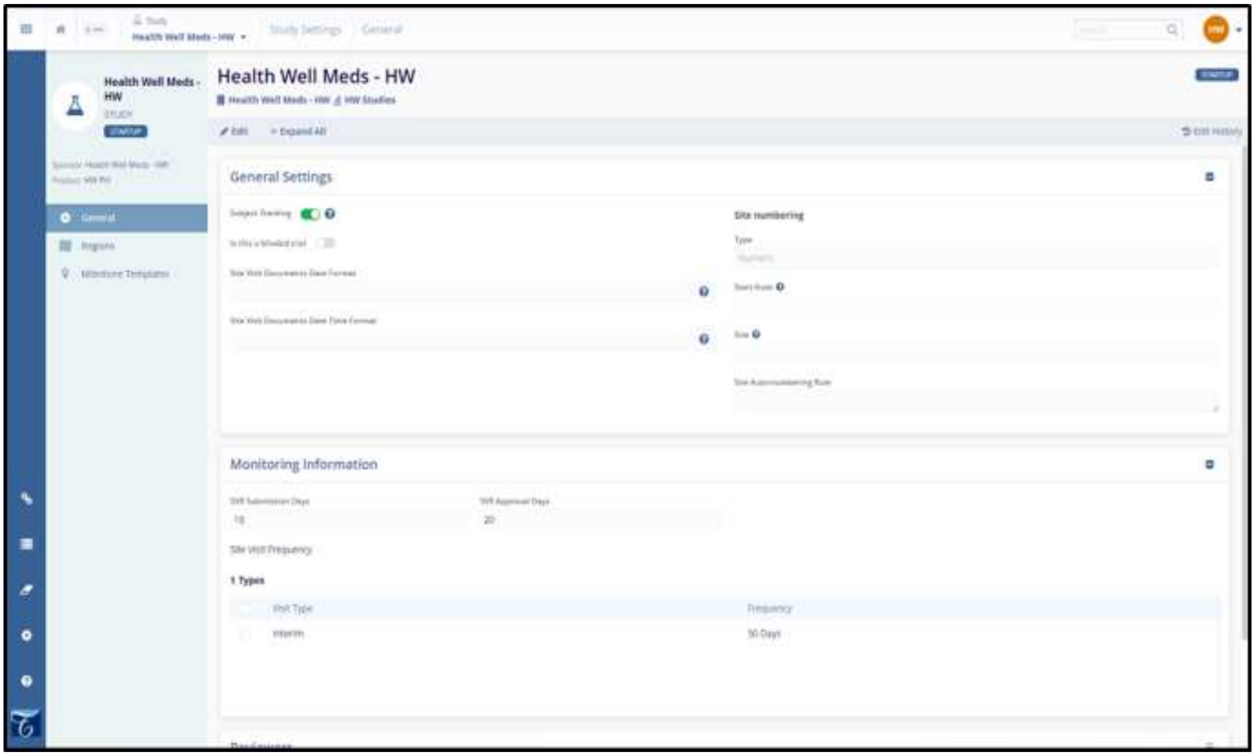




Once all of the items are resolved, and nothing is left undone, the 'Yes, Close' button is activated and the site can be closed.

Study Specific Settings

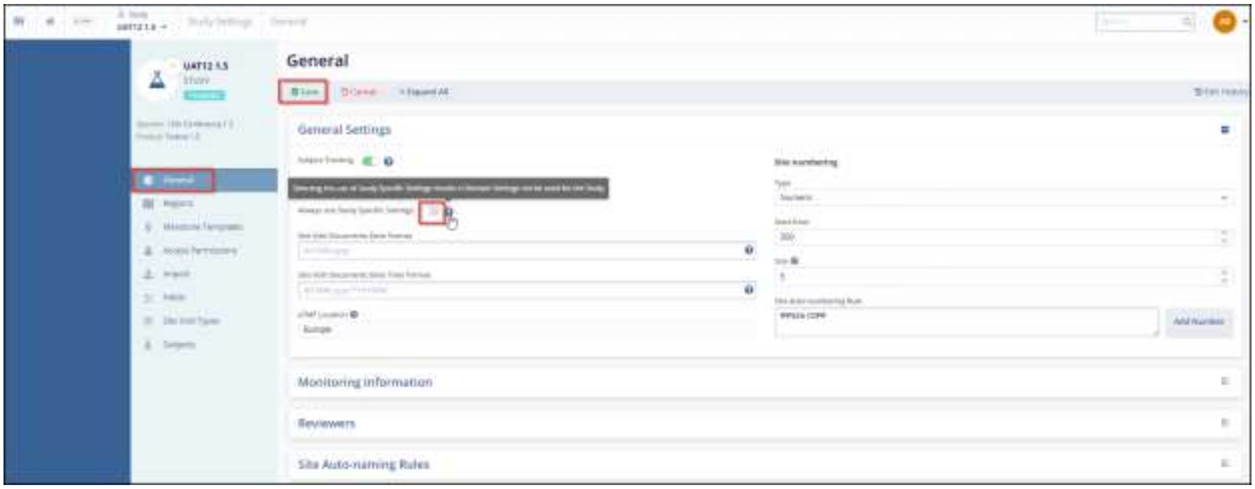
CTMS v1.5 makes clear to the user when the system/domain level settings are being utilized or study-defined settings are in use. This improvement ensures the study managers are always aware of what data is available to users within their study and the impact on the available data within the study if changing study-specific settings are interacted with. Enhancing the overall user experience and reducing user confusion.



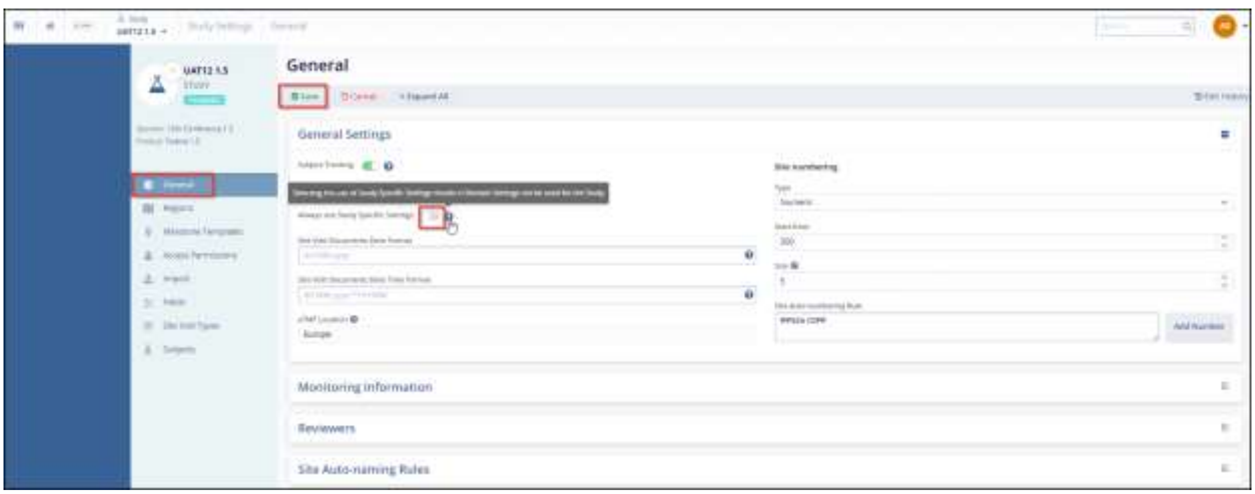
Follow the steps below to navigate to the General Settings of the Studies.

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 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 Settings button displayed in the top right corner.
   a. This opens the ‘Study Settings – General’ window.
5. Expand the General settings window by clicking the + icon on the right side of the screen.

6. Click the Edit button displayed on the top left corner.



7. Click the Always use Study Specific Settings toggle button.
8. Hover the mouse over the ? icon to view the tooltip.



9. Selecting this toggle button helps the user to not add any custom fields.

Fields

Follow the steps below to apply study-specific settings for – Milestones, Sites, Studies, Countries, Subjects, Subject Visits, and Team Members.

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 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 Settings button displayed in the top right corner.
    a. This opens the 'Study Settings – General' window.

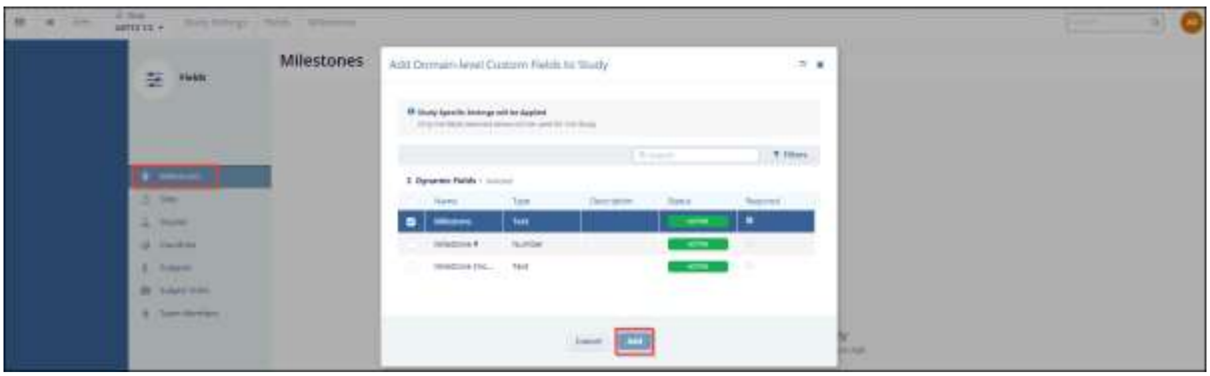
5. The left side navigation menu displays new added fields – Fields, Site Visit Types and Subjects.

6. Click the Fields link.
    a. This opens the 'Study Settings – Fields' window.
7. Click on the Milestones link from the center of the window.
    a. This opens the Study Settings – Fields – Milestones window.

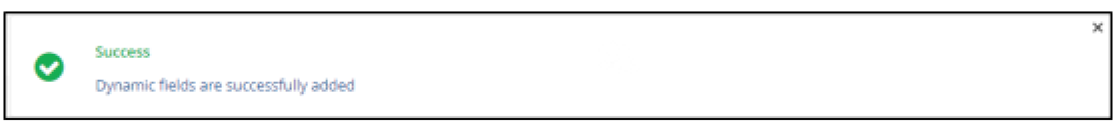
8. Click the Add button displayed in the center of the page to apply domain settings to the study.

   a. This opens the Add Domain-level Custom Fields to Study window.

9. Select the checkbox(s) before the Name field and click Add button.



10. A notification of Success is displayed in the top right corner of the screen.



11. The dynamic added field is displayed with the status in the center of the screen and 'Study Specific Settings are Applied' is displayed in the top right corner of the screen.

12. Select the checkbox of the added dynamic field.
13. This enables the Remove button. Click the Remove button to delete the dynamic field.

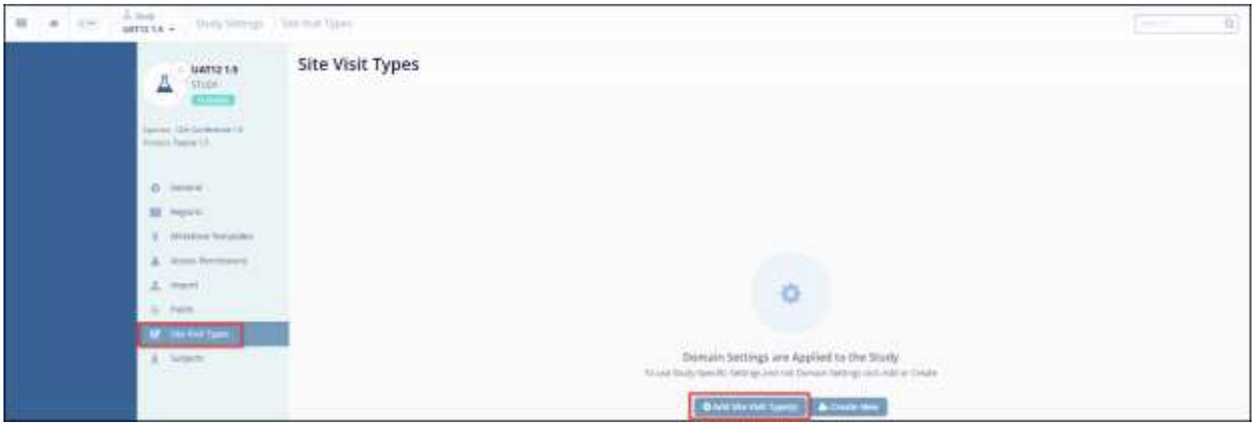
Note: Likewise, the user can apply Domain Settings applied to Study for Sites, Studies, Countries, Subjects, Subject Visits, and Team members. Follow the above steps to add dynamic fields.

Site Visit Types

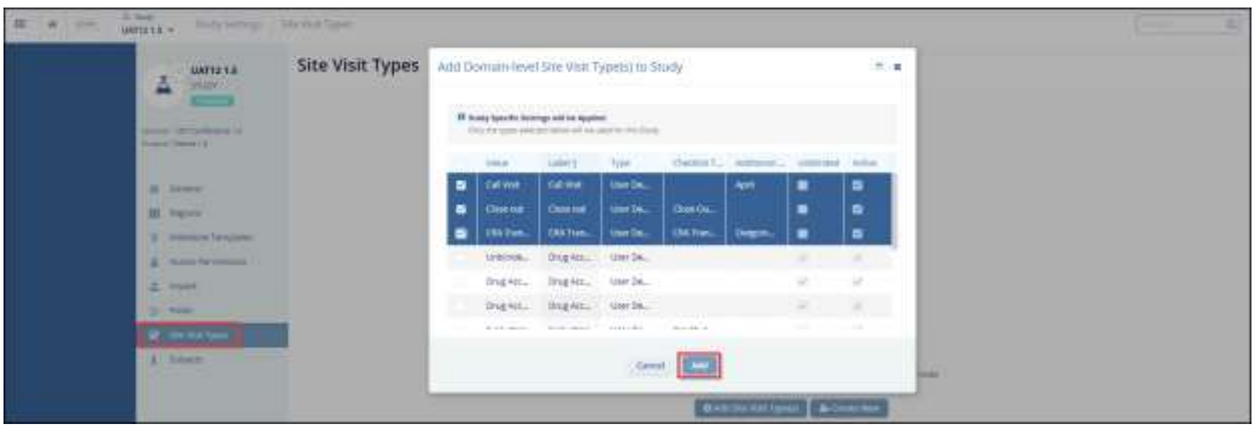
With this, the user can apply the Domain Settings to study by - adding a site visit type and creating a new site visit type. Follow the steps below to apply domain settings to the study.

1. Click on the Studies link in the Navigation menu at the left side of the screen.
   a. This opens the "Studies" window and the study list is displayed.
2. 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 Settings button displayed in the top right corner.
   a. This opens the 'Study Settings – General' window.

5. Click the Site Visit Types option in the navigation menu at the left side of the screen.
   a. This opens the ‘Study Settings – Site Visit Types’ window.
6. Click the Add Site Visit Type(s) button.
   a. This opens the ‘Add Domain-level Site Visit Type(s) to Study window.

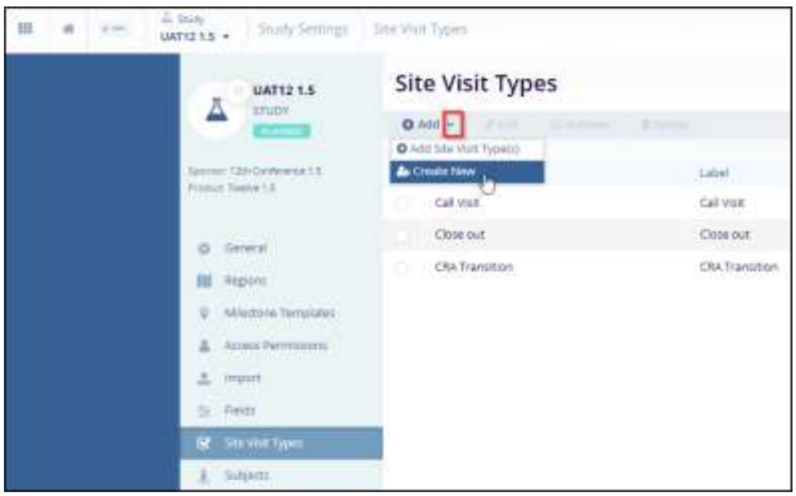


7. Select a checkbox(s) before the value column and click Add button.



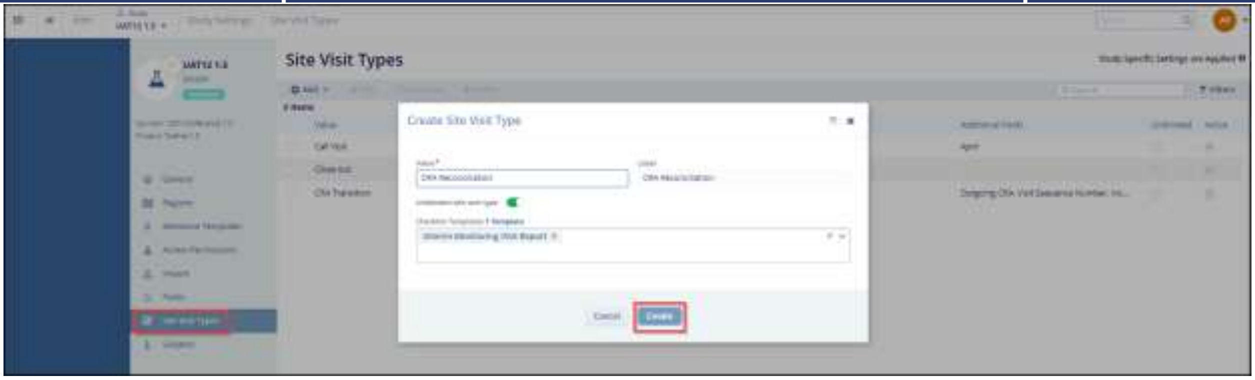
8. A notification of Success is displayed in the top right corner of the screen.
9. The dynamic added field is displayed in the center of the screen and ‘Study Specific Settings are Applied’ is displayed in the top right corner of the screen.

10. Notice that the 'Create New button' is disappeared and is now displayed below the '+ Add' dropdown menu.
11. Click the Create New option from the +Add Dropdown menu.



a. This opens the 'Create Site Visit Type' window.

12. Enter a name in the Value field as indicated by an asterisk (*).
13. Notice that the Label field displays the same name mentioned in the value field.
14. (Optional) Select the toggle button of Unblinded Site Visit Type.
15. (Optional) Select the Checklist Template from the dropdown menu. The user can select 1 or all templates from the dropdown menu.
16. Click Create.



17. The newly added site visit type is displayed in the grid.
18. The user has the ability to Add, Edit, Activate and Delete the Site Visit Types.
19. Click on the checkbox of the site to enable the – Edit, Deactivate (toggle button) and Delete the site visit type.

20. Perform the required action.

Subjects

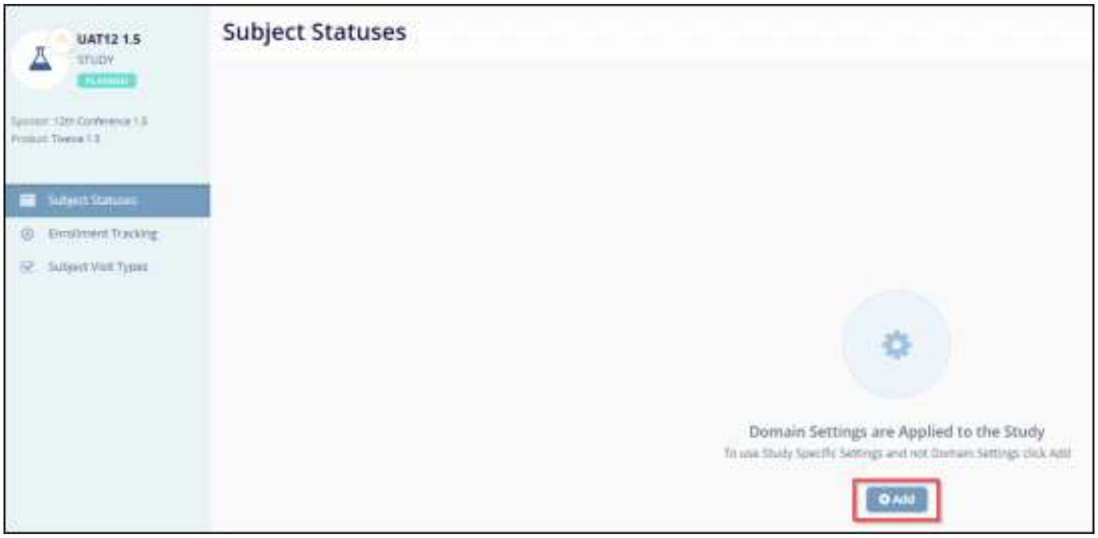
User can apply the Domain Settings to study by - adding Subject Statuses, Enrollment Tracking and Subject Visit Types. Follow the steps below to apply domain settings to the study.

1. Click on the Studies link in the Navigation menu at the left side of the screen.
   a. This opens the "Studies" window and the study list is displayed.
2. 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 Settings button displayed in the top right corner.
   a. This opens the 'Study Settings – General' window.

5. Click the Subjects option in the navigation menu at the left side of the screen.

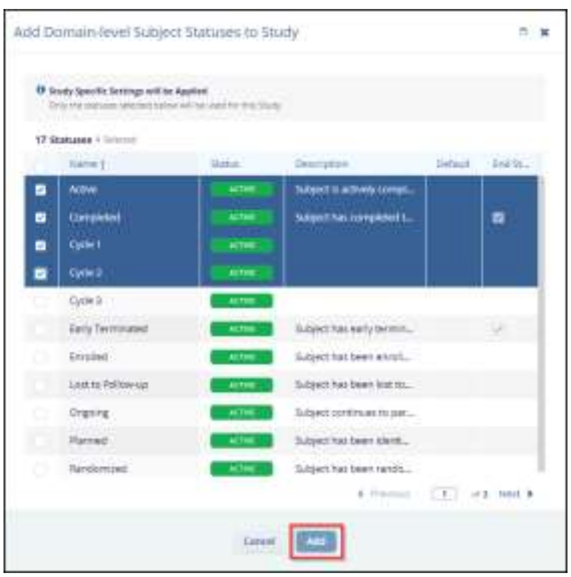
a. This opens the 'Subjects – Subject Statuses' window.

6. Click the Add button displayed in the center of the screen.



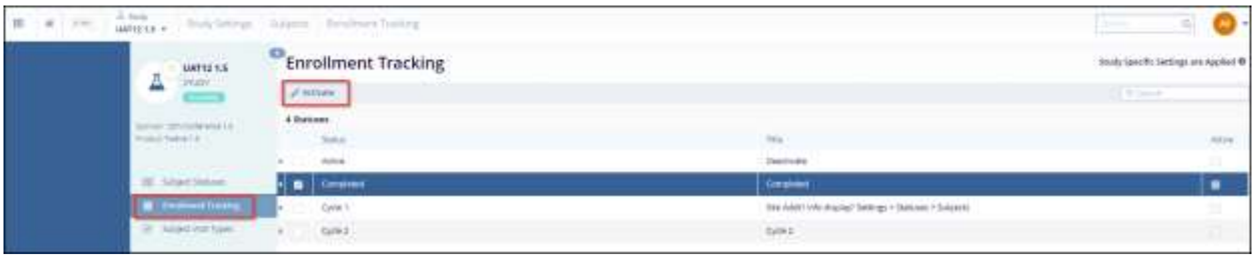
a. This opens the Add Domain-level Subject Statuses to Study window.

7. Select a checkbox(s) before the value column and click Add button.



8. A notification of Success is displayed in the top right corner of the screen.
9. The dynamic added field is displayed in the center of the screen and 'Study Specific Settings are Applied' is displayed in the top right corner of the screen.

10. Click on the Enrollement Tracking link in the left navigation menu.
    a. This opens the 'Subjects – Enrollement Tracking' window.
11. Notice that the newly added subject statuses are displayed in the grid.
12. Here, the user can only select a status by clicking the checkbox and either 'Activate' or 'Deactivate' a status.



13. Click the Subject Visit Types option in the left navigation menu.
14. Follow [these steps](#) to add the Domain-level Subject Visit Type(s) to Study.

Organizations

Pre-requisites

Users must have an account with system access permissions that enable them to perform the following actions:

- Create an Organization
- Edit an Organization
- Activate an Organization
- Deactivate an Organization
- Delete an Organization
- Export an Organization
- Import an Organization
- Associate an address to an Organization
- Associate an Organization with a Parent Organization
- Associate a Contact to an Organization

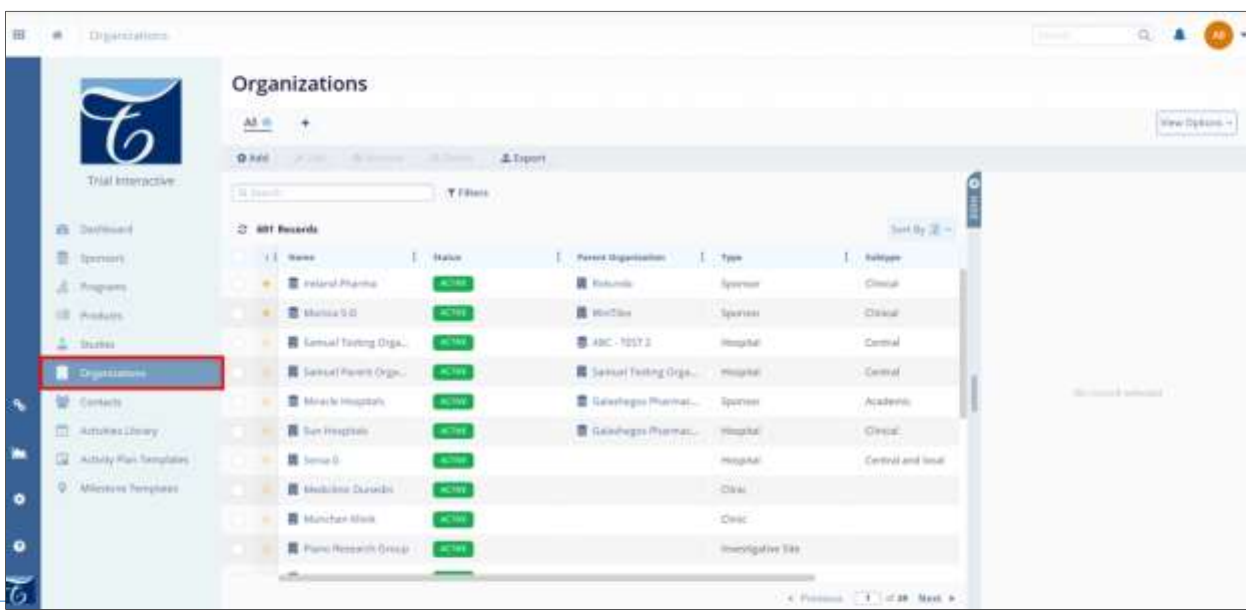
Users with system access permissions can perform the following actions:

- Review Studies associated with an Organization
- Review Sites associated with an Organization
- Customize Data Export

Creating an Organization

To navigate to the organization list and view all global organizations, follow these steps:

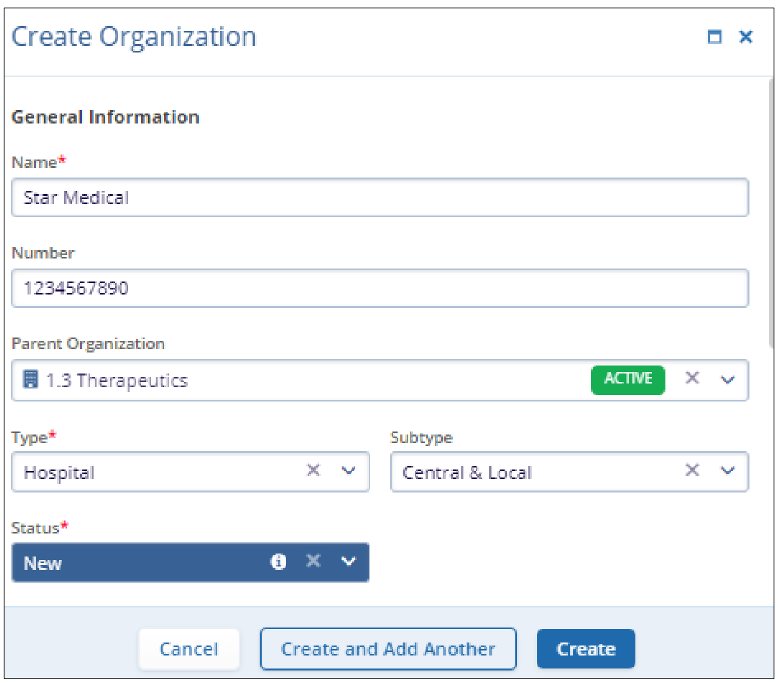
1. Click on the "Organizations" located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" list where all organizations at the Global level are displayed.



Steps to Add a New Organization

3. To add a new organization, click the "+Add" button from the menu bar above the grid.

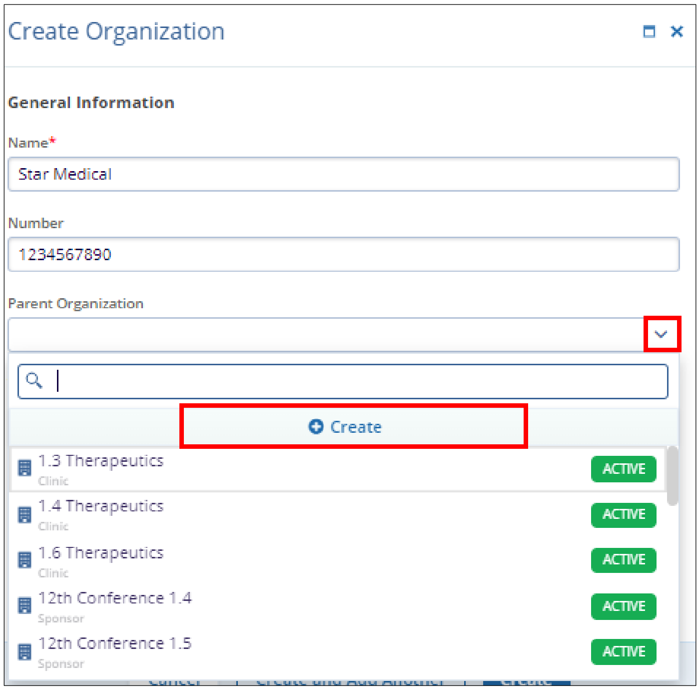
- This action will open the "Create Organization" screen.



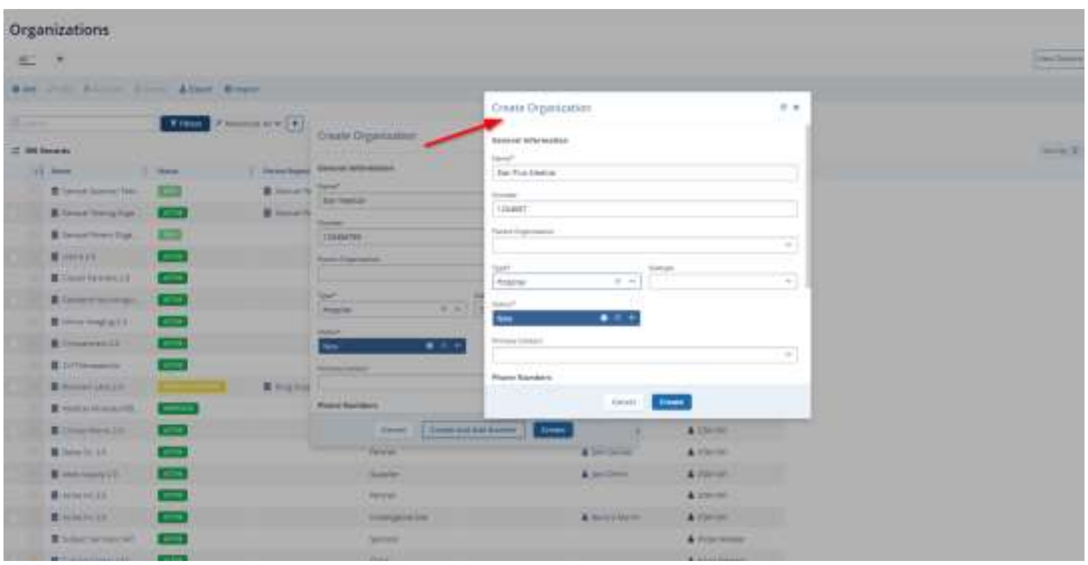
Note: To create an organization, you must enter the mandatory fields Name, Type, and Status which are marked with an asterisk (*) next to the field title. Other fields are optional.

<u>Step by Step All fields are explained below:</u>

15. Name: Enter the name of the organization in the "Name" field.
16. Number: Enter the unique number for an Organization.
17. Parent Organization: To add a parent organization to this child organization, click on the drop-down arrow and select the appropriate parent organization from the list. To create a New parent organization, click on the “+Create” button. Refer to the screenshot below.

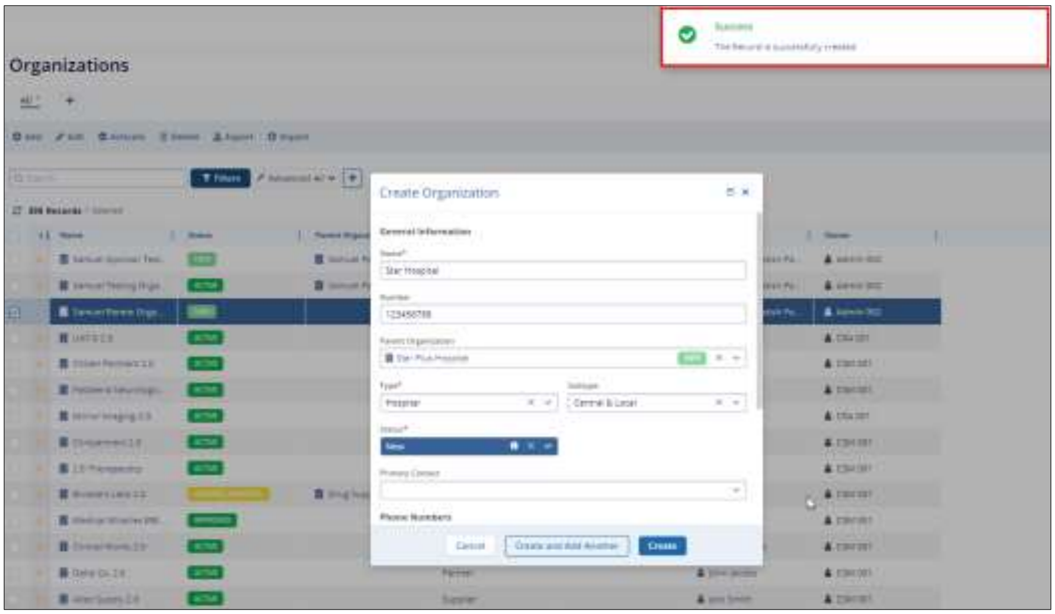


18. When the user click on the “Create” button, the screen opens on the same child organization. To prevent confusion, move the form to one side of your screen and fill in the information accordingly.

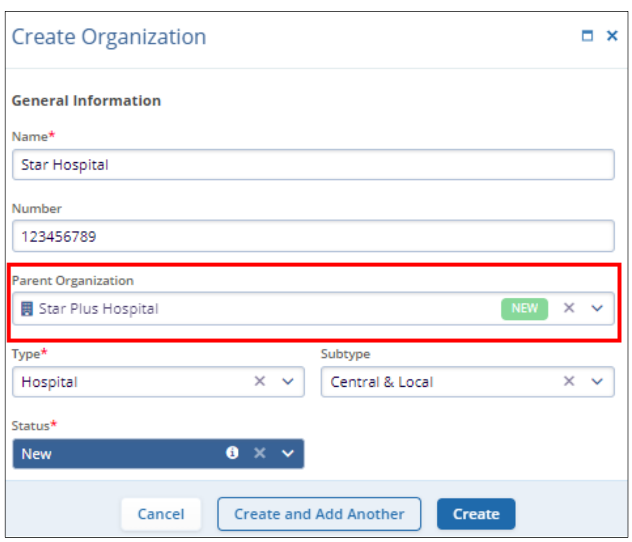


Note: To create a Parent Organization, you must enter the mandatory fields Name, Type, and Status which are marked with an asterisk (*) next to the field title. Other fields are optional.

19. Click on the "Create" button to create a Parent Organization. It will display a pop-up that the record is successfully created.



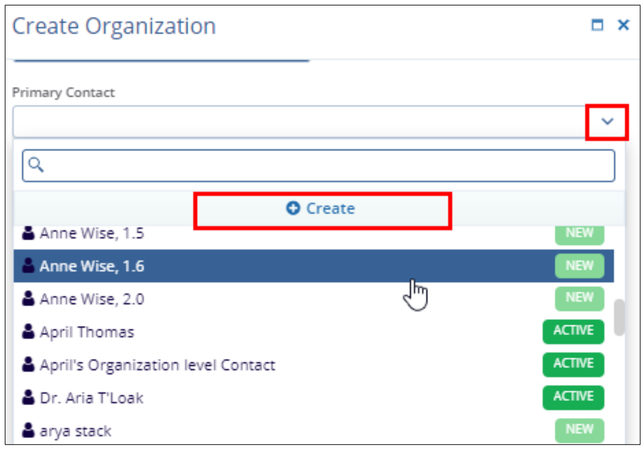
20. The parent organization will now be automatically populated in the parent field of the child organization. Please refer to the screenshot below.

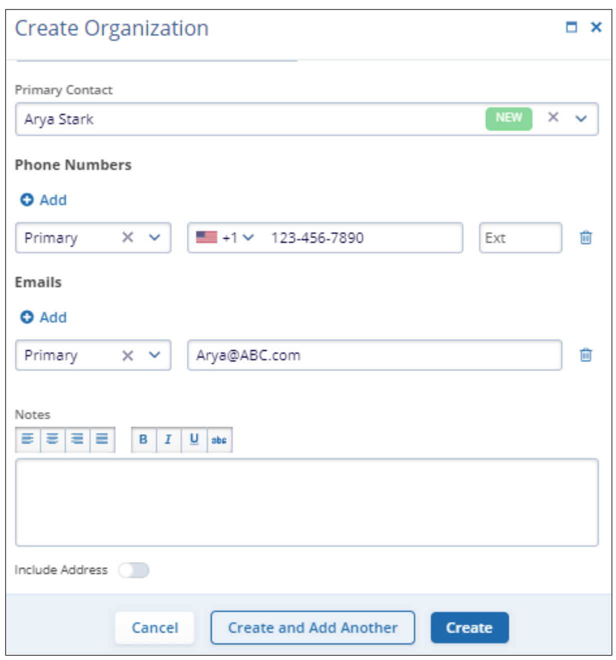


21. Type: Select the type of organization from the dropdown menu.

22. Subtype: Select the subtype that best describes the Organization.
23. Status: Choose the status as your requirement.

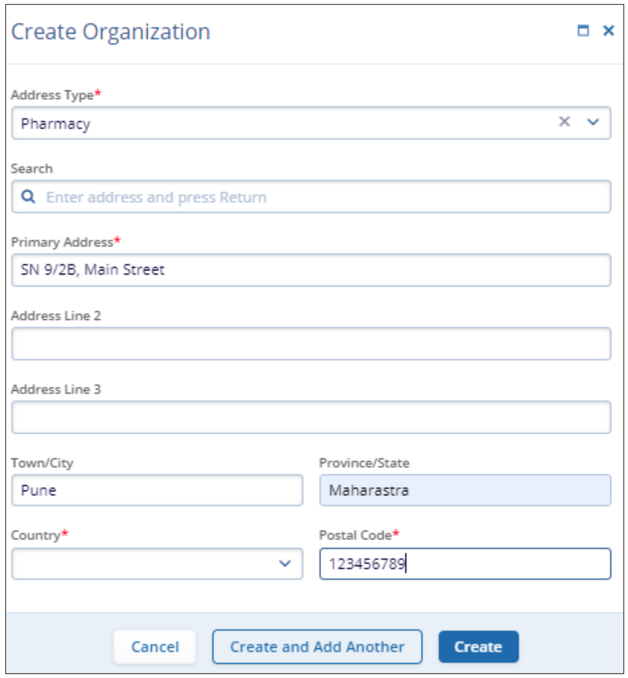
24. Primary Contact: To add a contact to the organization, click on the drop-down arrow and select the appropriate Contact from the list. To create a New contact click on the "+Create" button. Users can access this link to understand How to Create a Contact.





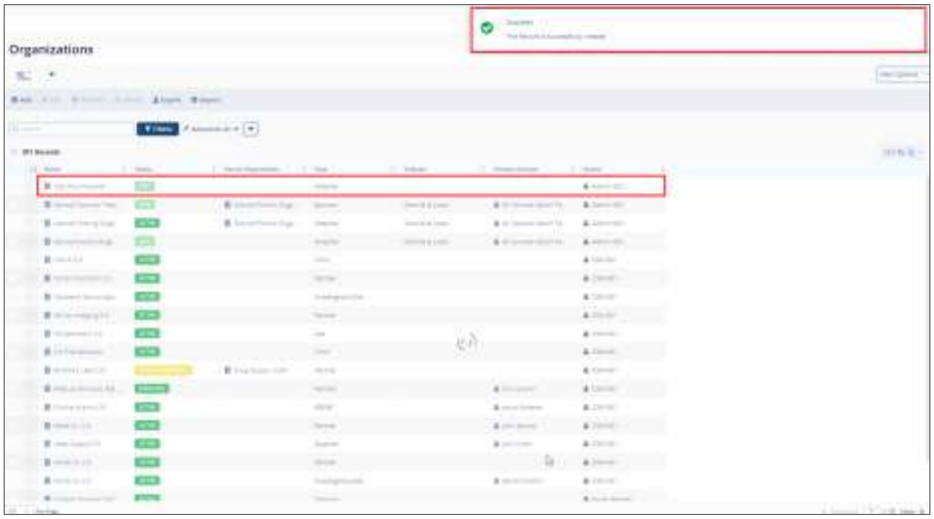
- Phone Numbers: Click on "+Add" to input phone numbers. Enter the phone number in the provided field.
- Emails Address: Click on "+Add" to enter email addresses. Enter the email address in the provided field.

- Notes Message Box: Enter any additional notes regarding the organization in the "Notes" field.
- Include Address: Toggle the switch if you want to include an address. All address related fields appear. Please refer to the screenshot below.



Note: To include an address, you must enter the mandatory fields Address Type, Primary Address, and Country and postal code which are marked with an asterisk (*) next to the field title. Other fields are optional.

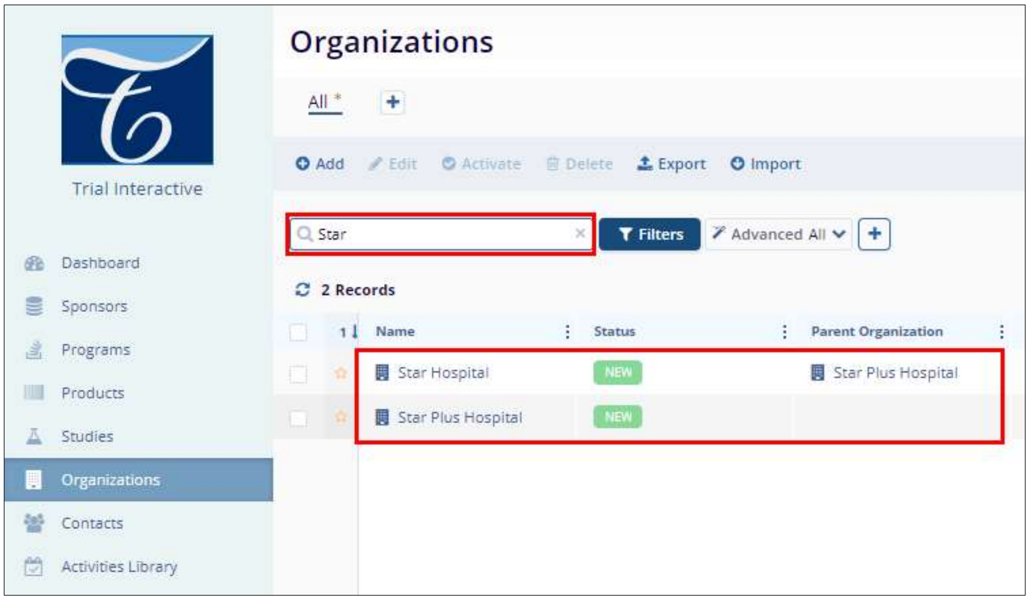
- Search Address: Click on the search icon to search for the address and enter your address it will show you an auto-populated list.
- After filling in all required fields, you have three options at the bottom of the form.
    - Create: Saves the new organization and closes the screen.
    - Create and Add Another: Saves the new organization and opens a new screen to add another organization.
    - Cancel: Discards the information and closes the screen.
- When the user clicks on the "Create" or "Create and Add Another" button. This action will create an organization and it will display a pop-up


Organizations

How to Search for an Organization

Steps to Search for an Organization

- From the navigation links on the left, select "Organizations" to display the Organizations list.
- At the top of the page, click on the "Magnifying Glass" icon or the "Search" textbox.
- Enter the organization's name or a related keyword into the search bar.
- Press "Enter" or click on the search icon to begin your search.



Customizing Organization Screen

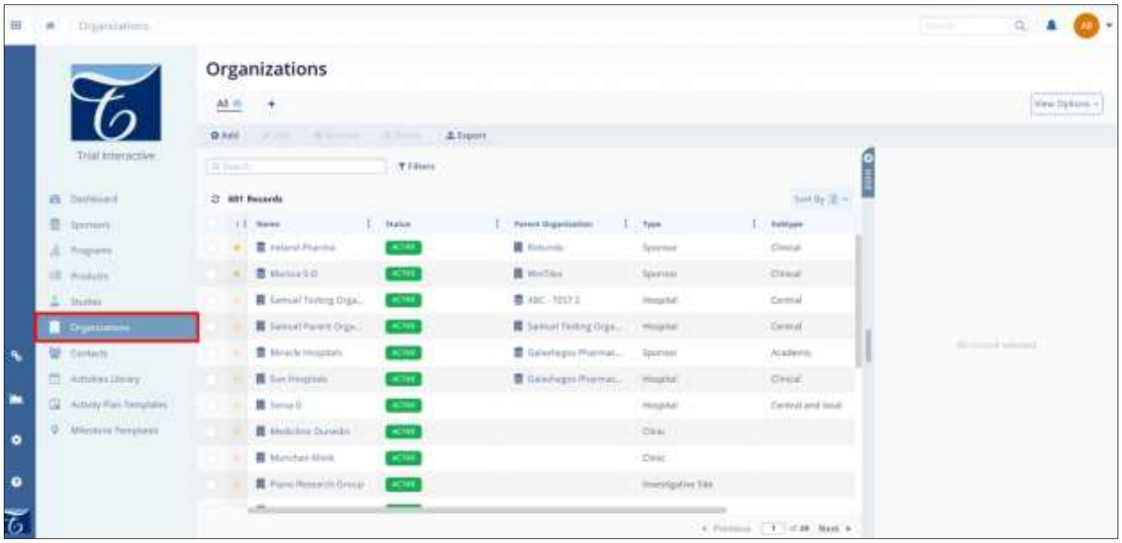
The procedure to perform the mentioned actions is standard across Organizations and Contacts.

- Filters: To learn how to apply standard and advanced filters, click here.
- Favourite: To learn how to mark an organization as Favourite, click here.
- Customize Columns: To learn how to Hide, Lock, Manage Visible Columns and Sort Columns, click here.

Editing an Organization

To navigate to the organization list and view all global organizations, follow these steps:

1. Click on the "Organizations" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.

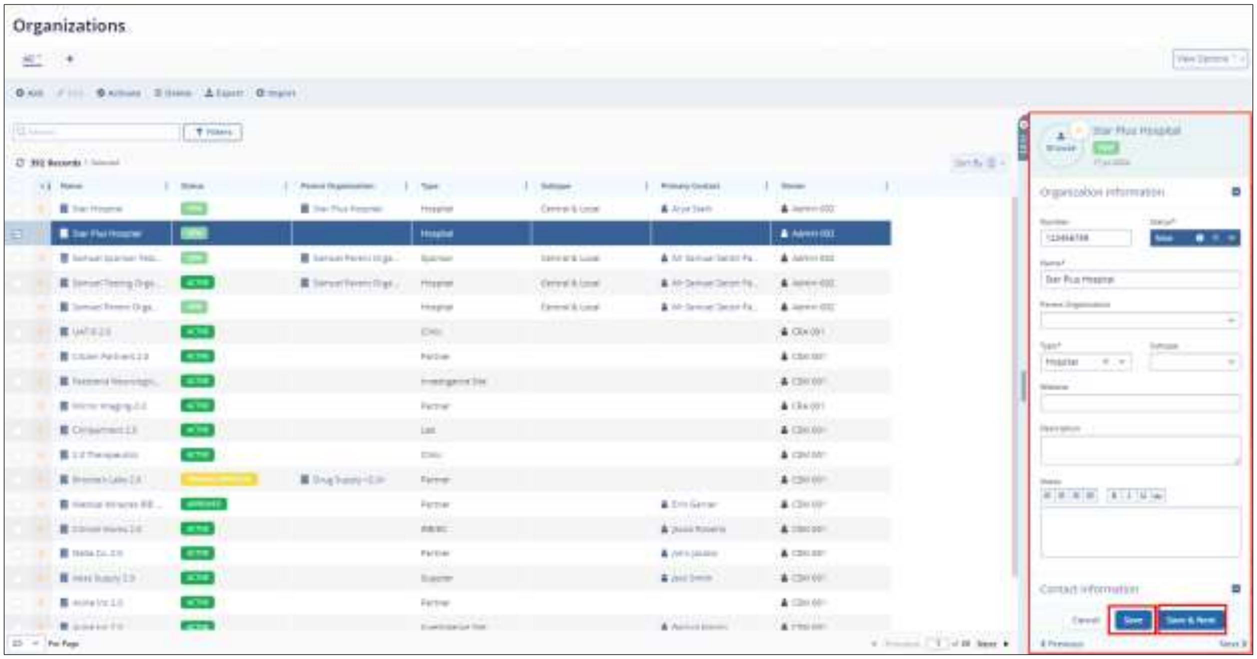


Steps to Edit an Organization:

There are two ways to Edit an Organization explained below.

1. The first method to edit a specific organization is to click the checkbox next to the organization name. Then, click the "Edit" button (pencil icon). Refer to the screenshot below.

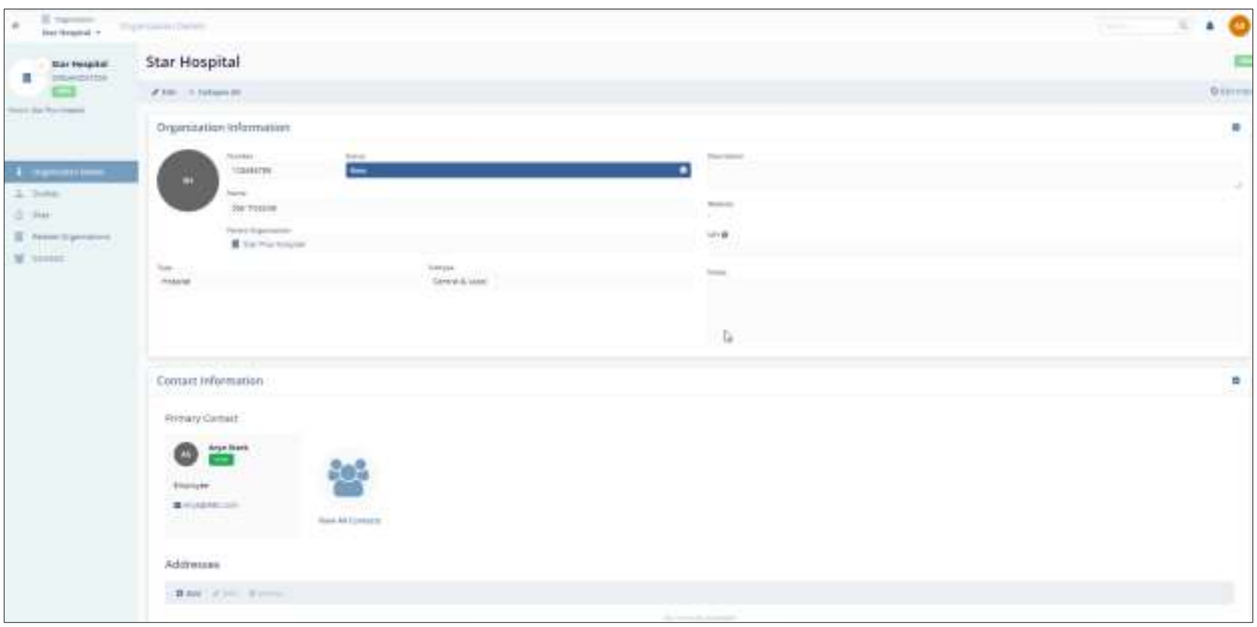
2. The Quick View panel will display in the editable stage on the right side of the screen.



3. Once the updates are made, click the "Save" button. Refer to the screenshot below.

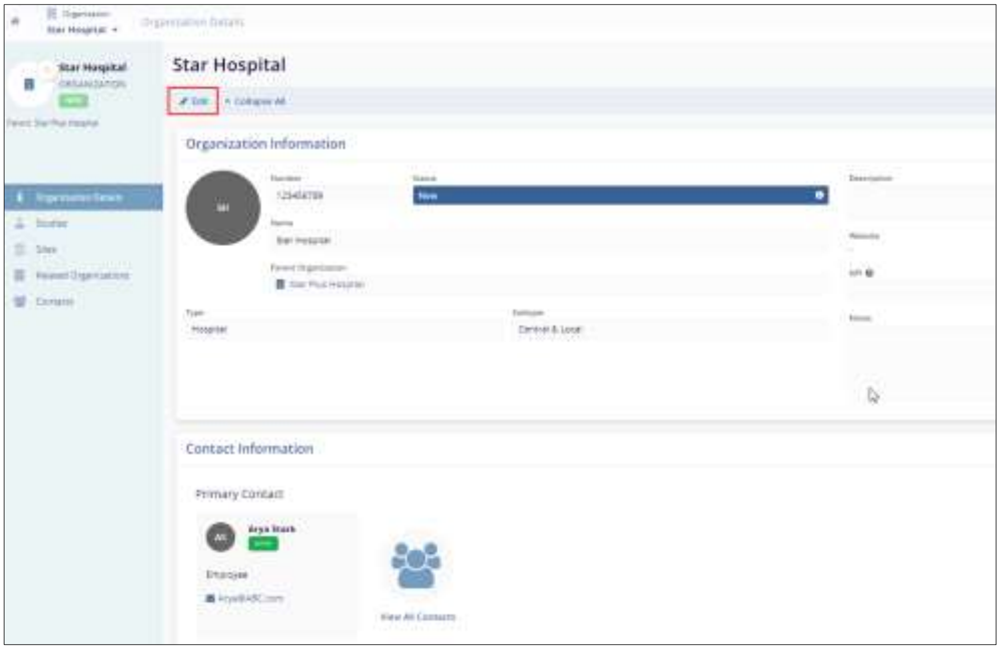
<u>Second method to edit an Organization</u>

1. To edit an organization to click the organization name directly. This will open the "Organization Details" page.

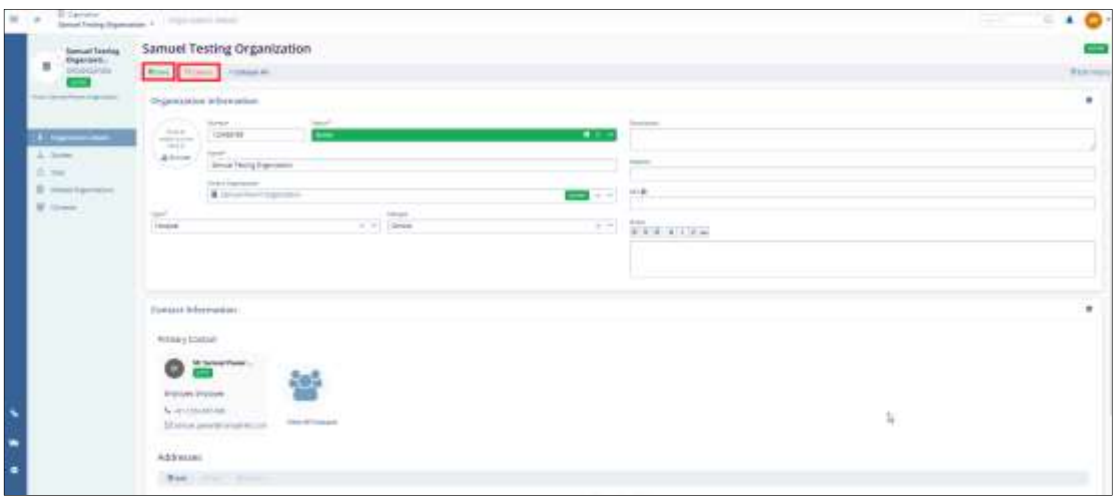


2. <u>Note:</u> The "Organization Details" page contains additional fields that are not available within the quick-view panel (For Example: NPI, Website, etc.)

3. To edit the organization, click the "Edit" button located on the Organization Details page. Select the fields you need to edit and make the necessary changes.



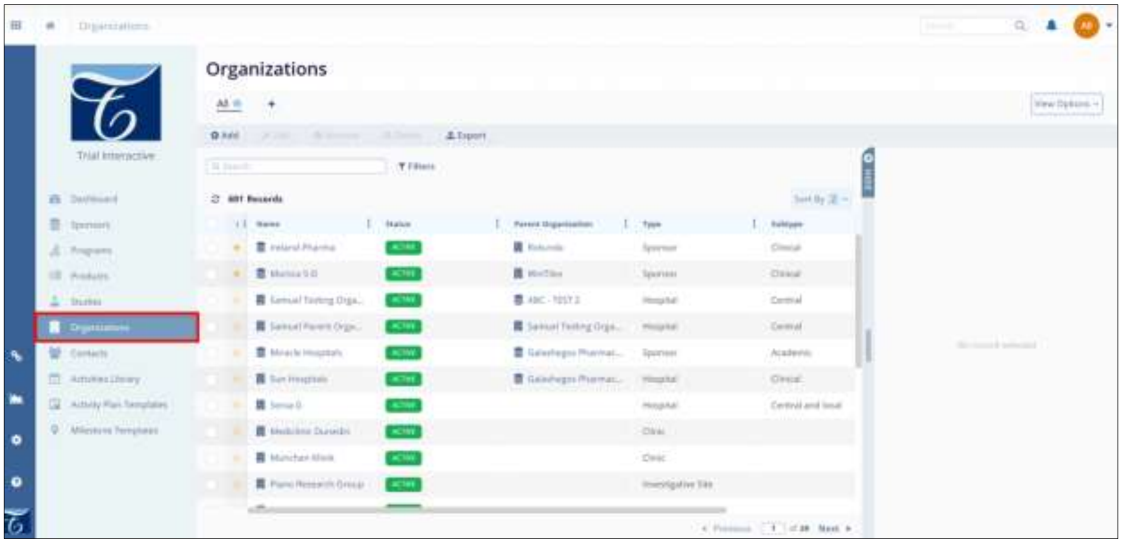
4. Once the changes are made, click the "Save" button to save the updates, or click the "Cancel" button to discard them.



How to Activiate Organziations

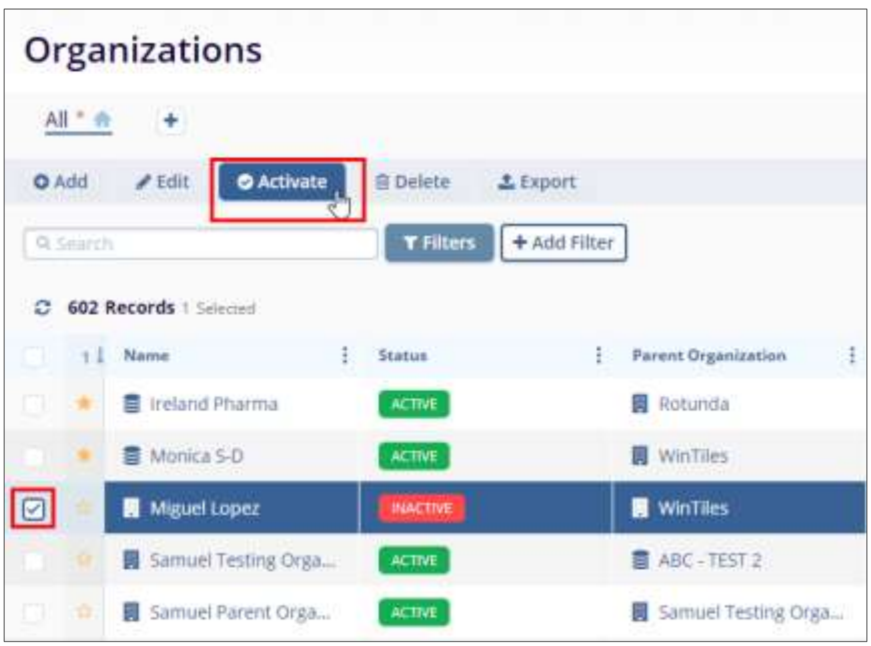
To navigate to the organization list and view all global organizations, follow these steps:

1. Click on the "Organizations" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.

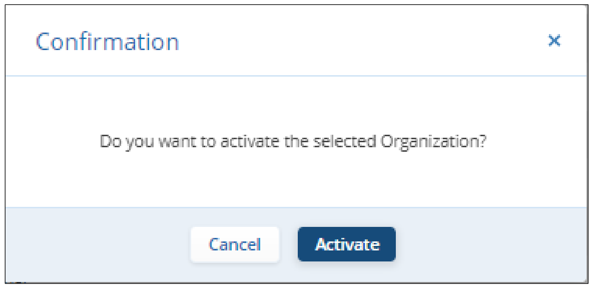


Steps to Activate Organization:

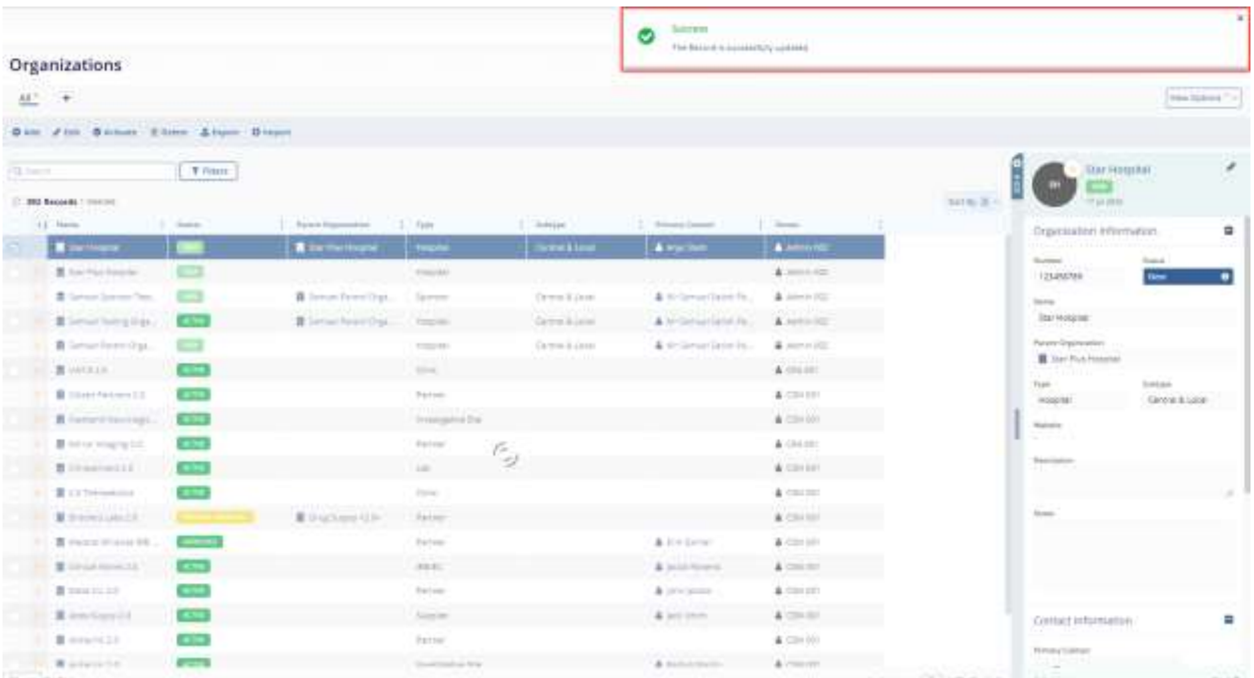
1. Select the organization by clicking the checkbox next to its name. Then, click the "Activate" button at the top of the grid to initiate the activation process.



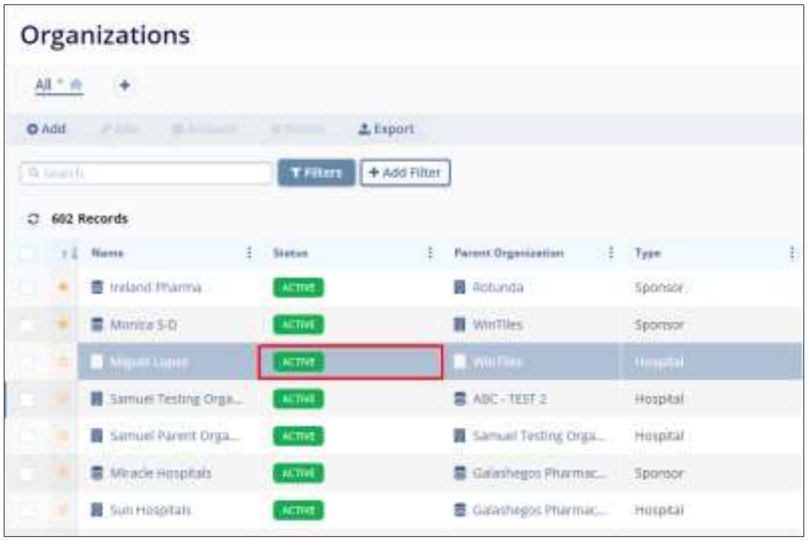
1. A confirmation pop-up window will appear. Click the "Activate" button to proceed with activation or "Cancel" to discontinue.



2. Upon successful activation, you will receive a success notification at the top right corner of the screen.



3. The status of the organization will now be updated to "Active" and displayed in the status field of the grid.



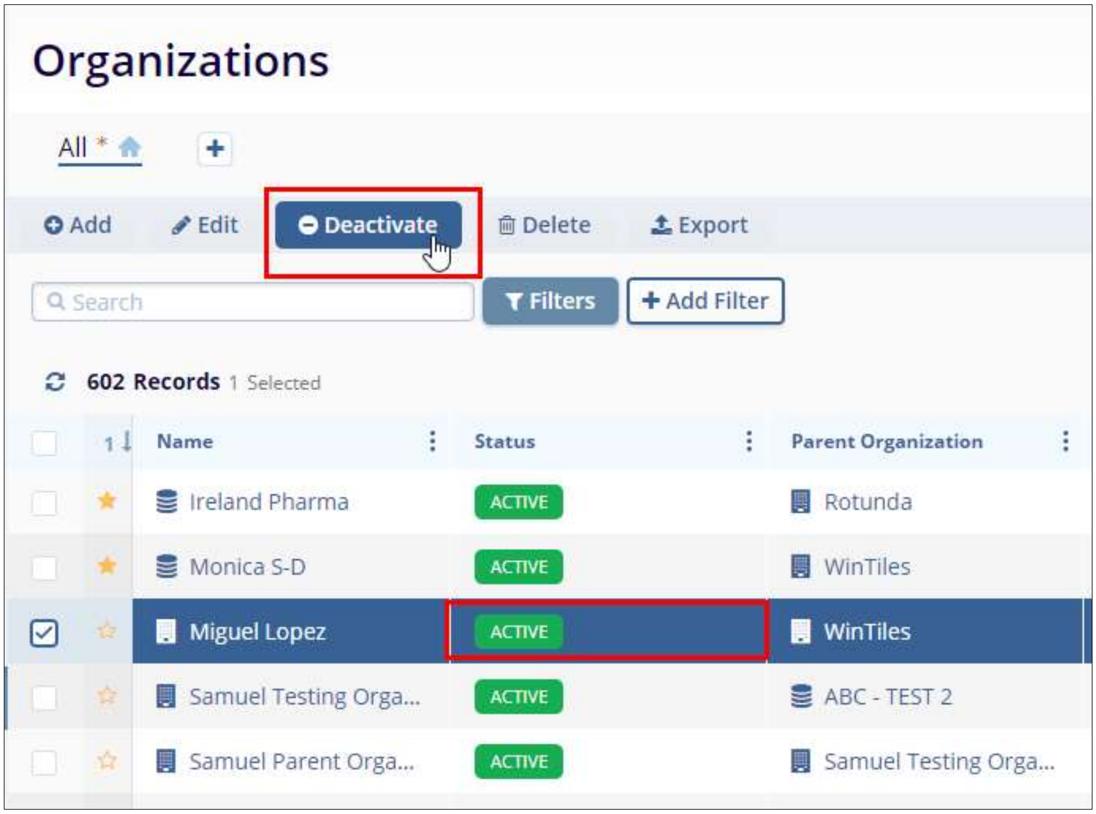
How to Deactivate Organisations

To navigate to the organization list and view all global organizations, follow these steps:

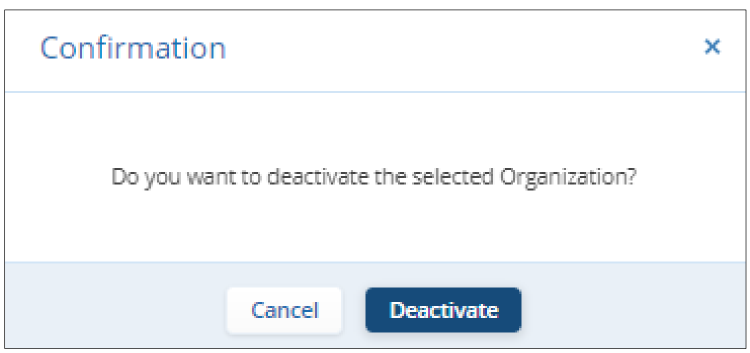
1. Click on the "Organizations" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.

Steps to Deactivate Organization:

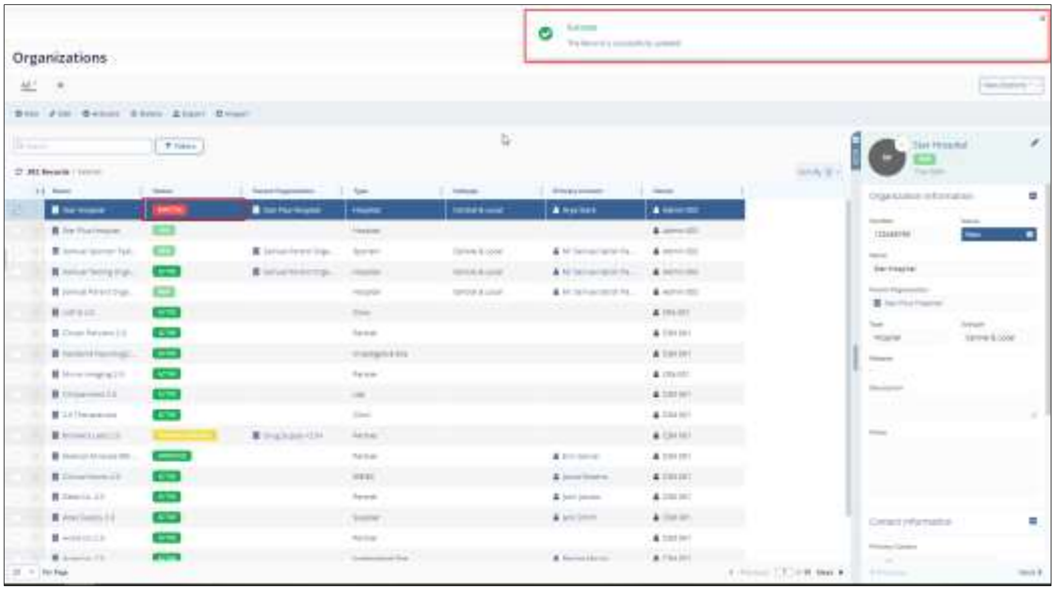
1. Select the organization by clicking the checkbox next to its name. Then, click the "Deactivate" button at the top of the grid to initiate the activation process.



2. A confirmation pop-up window will appear. Click the "Deactivate" button to proceed with activation or "Cancel" to discontinue.



3. Upon successful Deactivation, you will receive a success notification at the top right corner of the screen.

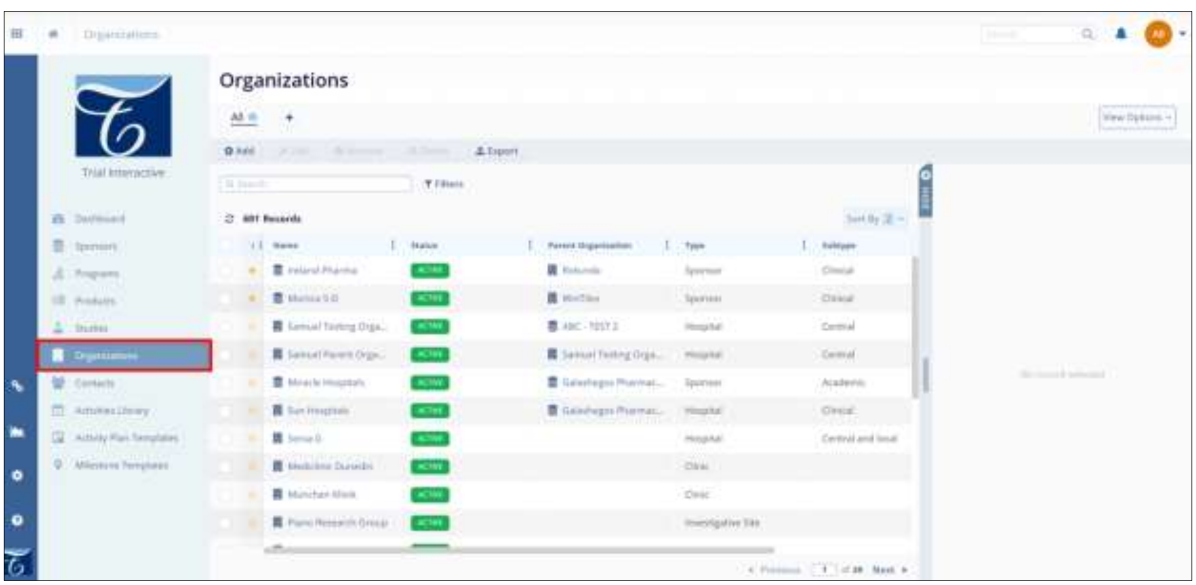


4. The status of the organization will now be updated to "Inactive" and displayed in the status field of the grid.

Associating an Address to an Organization

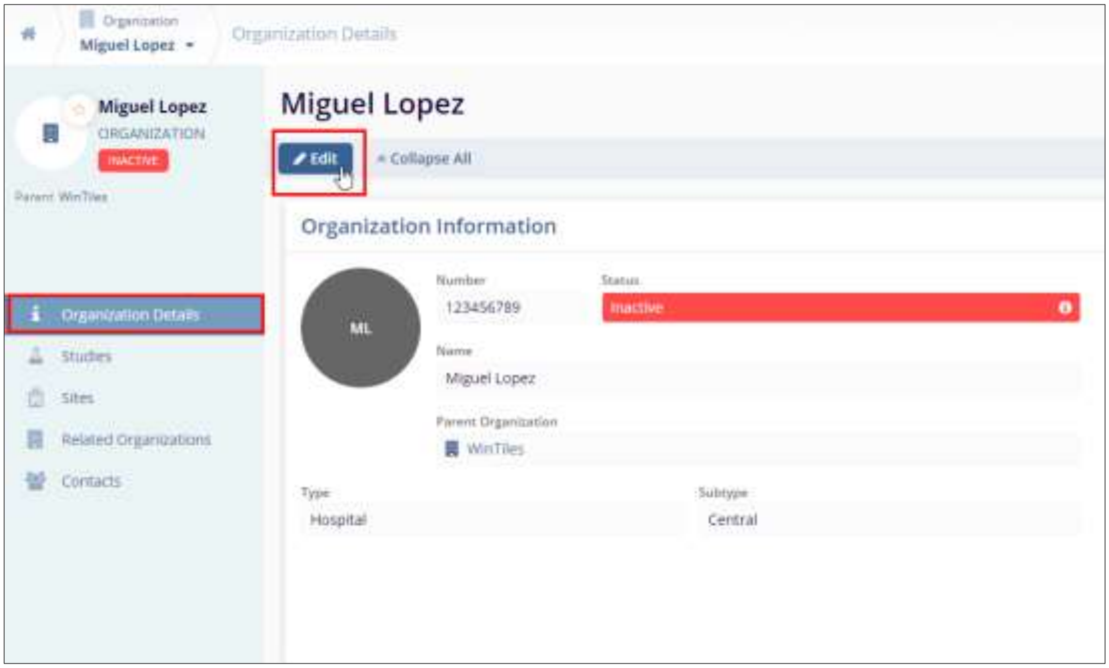
To navigate to the organization list and view all global organizations, follow these steps:

1. Click on the "Organizations" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.



Steps to Associate an address to an Organization.

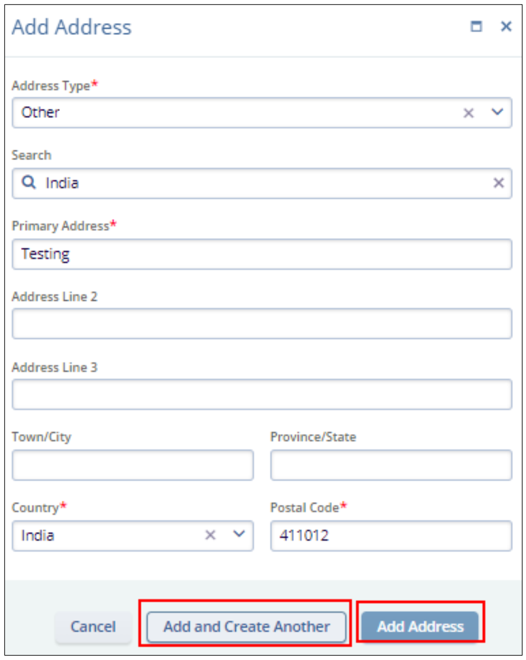
1. Locate the organization to which you want to associate an address and click on the organization's name. It will open an Organization detail page.
2. Click the "Edit" button on the Organization detail page. Refer to the screenshot below.



3. Click on the "+Add" button in the Addresses section.

4. Here we need to enter the mandatory metadata to create an address. The mandatory metadata Address Type, Primary Address, Country, and Postal Code

which has an asterisk (*) symbol next to the field title. Enter any additional information, as per your requirement.

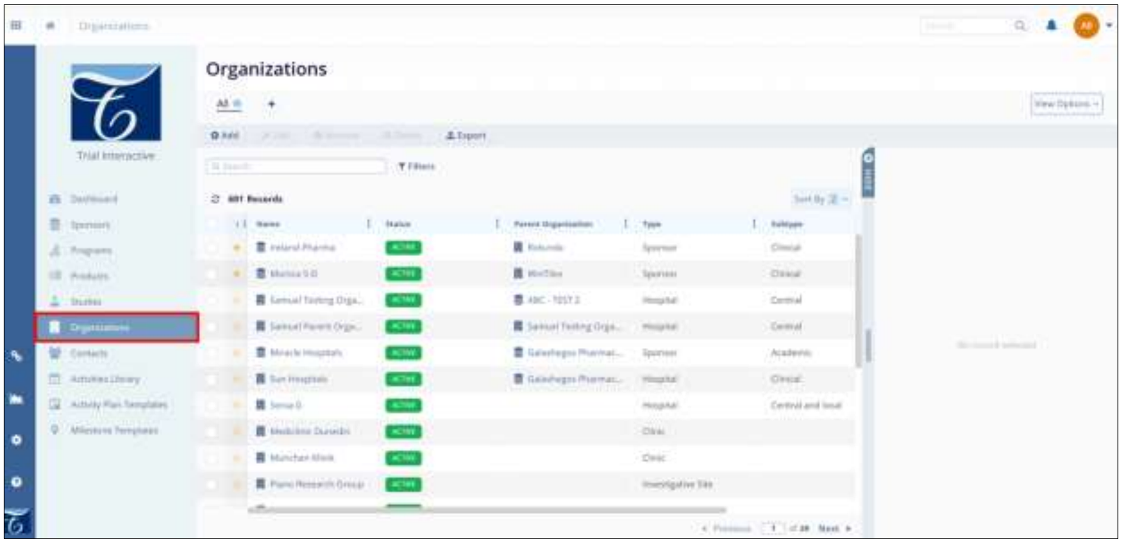


5. Here, you have two options to add addresses:
   - Add and Create Another: This option allows you to add the current address and immediately start creating another one.
   - Add Address: This option allows you to create only the address you are currently working on.

Associating an Organization to a Parent Organization

To navigate to the organization list and view all global organizations, follow these steps:

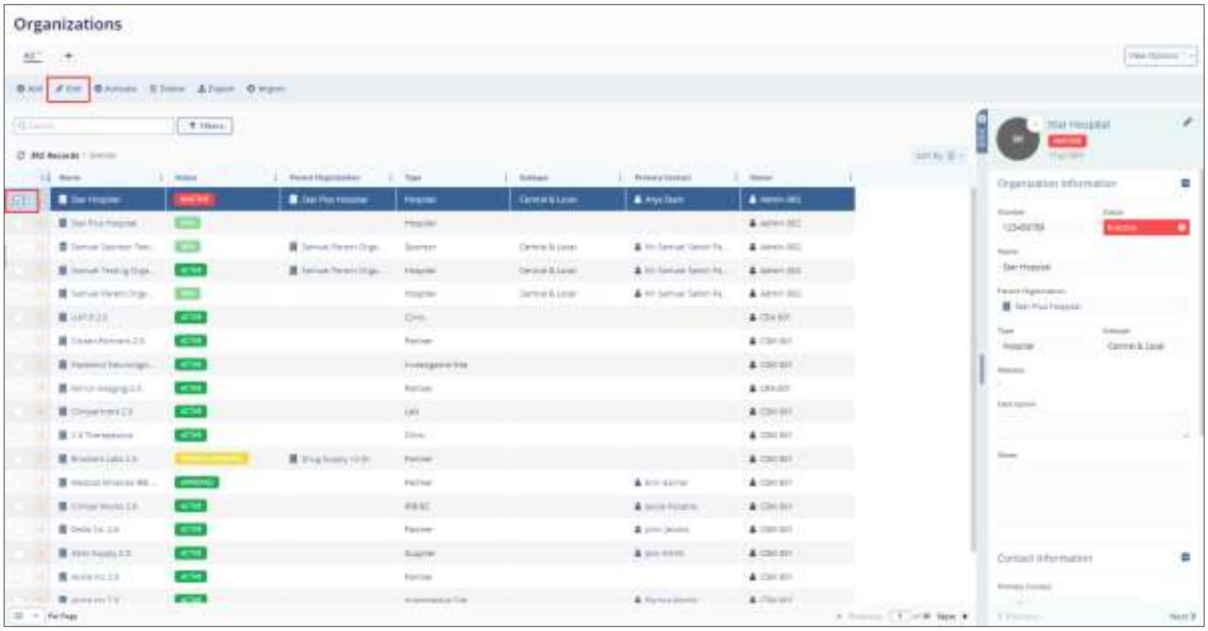
1. Click on the "Organizations" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.



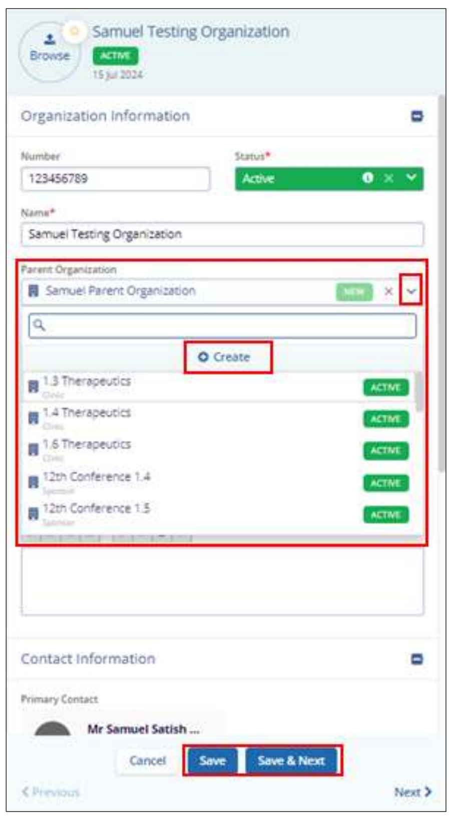
Steps to associate an organization with a parent organization, follow the steps below:

There are two ways to associate an Organization with a Parent organization

1. The first method, locate the organization you want to associate with a parent organization and click the checkbox beside the organization name and click the Edit button from the main menu from the grid. This is opem “Quick View” Panel in editable mode.



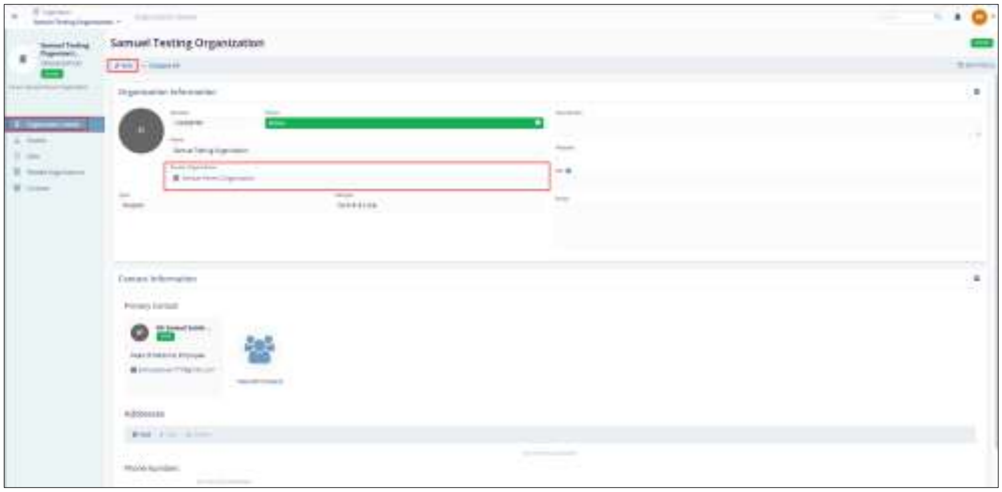
2. Click the drop-down arrow displayed in the parent organization field, and select the appropriate parent organization.
3. If you need to create a new parent organization, please refer to this link to learn " How to create a Parent Organization".



4. After creating the parent organization, In metadata, click the "Save" button to save the changes, or click "Save and Next" to continue editing.

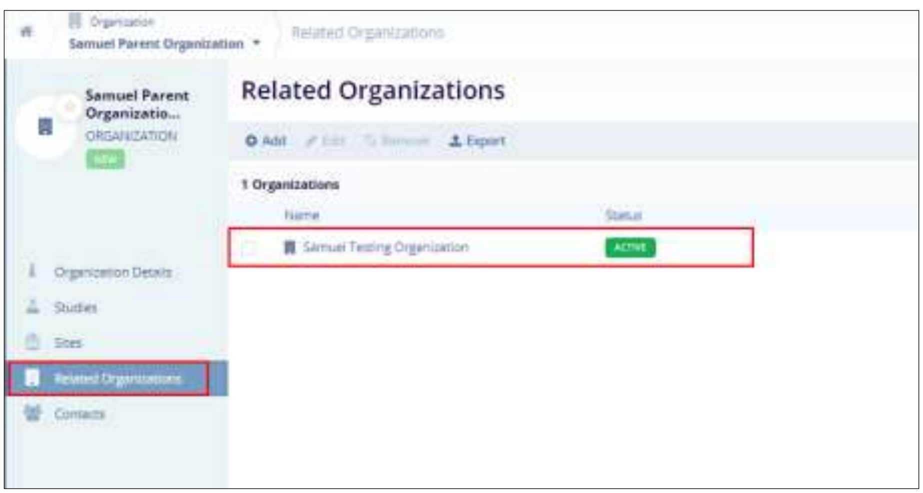
The second method of associating a parent organization.

1. Locate the organization to which you want to associate a parent organization and click on the organization's name. It will open an Organization detail page.



Note: The "Organization Details" view contains additional fields that are not available within the quick-view panel (For Example: NPI, Website, etc.)

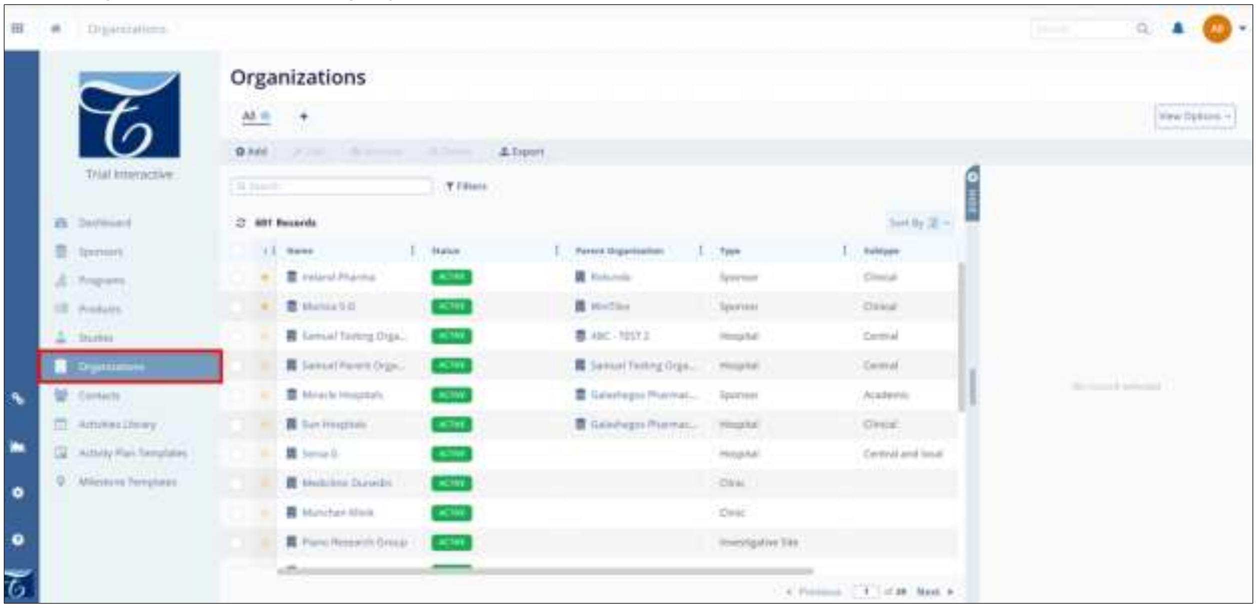
2. Please refer to the "[Creating an Organization"](#) section to understand how to create a parent organization.
3. From the Parent Organization details page, users can view associated child organizations under the "Related" tab. Refer to the screenshot below.



Reviewing Studies Associated with an Organization

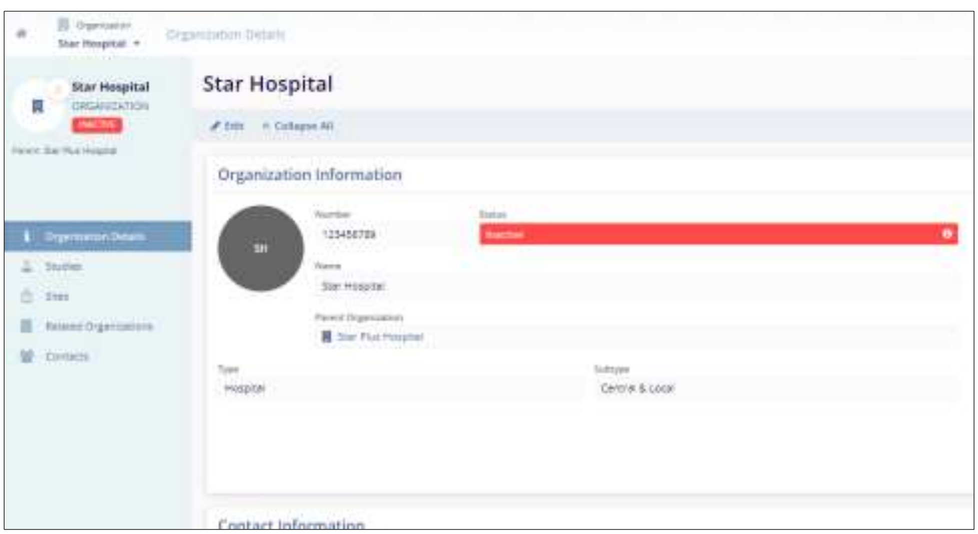
To navigate to the organization list and view all global organizations, follow these steps:

1. Click on the "Organizations" tab located in the navigation link panel on the left side of the screen.
2. This action will redirect you to the "Organizations" list where all organizations at the global level are displayed.



To review the studies associated with an organization follow the below steps.

1. Click on the organization's name in the list. This opens the "Organization Details" window.



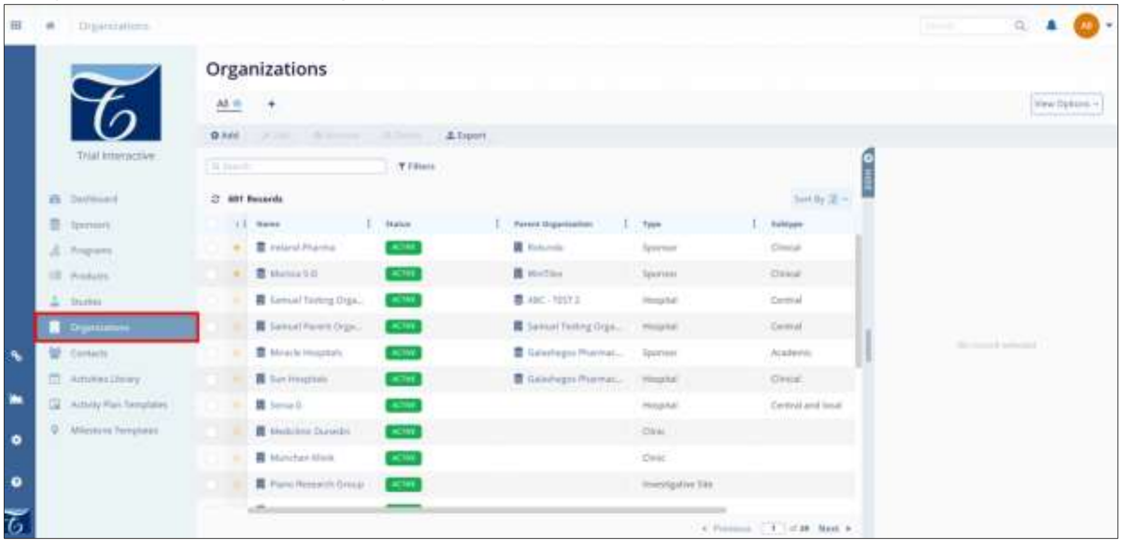
2. Click on the "Studies" from the Navigation link on the left side of the screen. This opens the "Studies" window.

Note: To review sites associated with an organization, follow the same process. However, instead of clicking on the 'Studies' tab from the navigation link on the left side of the screen, click on the 'Site' tab to view all associated sites.

Customized Data Export

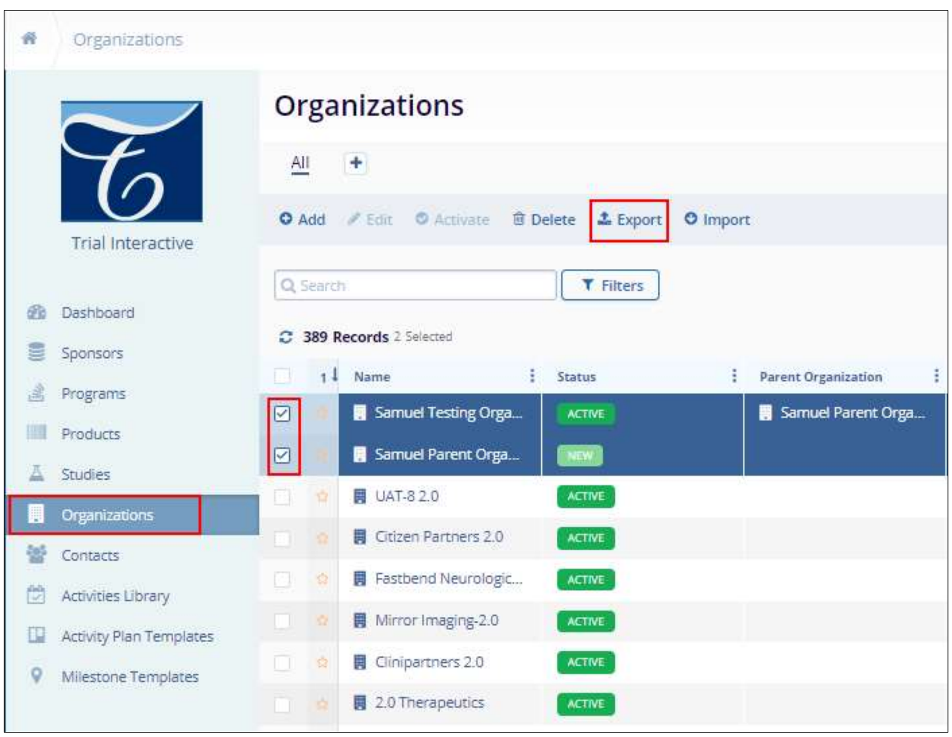
To navigate to the organization list and view all global organizations, follow these steps:

1. Click on the "Organizations" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.



To Customized Data Export, Follow the below steps:

1. Locate the organization you want customize and export click the checkbox beside the organization name and click on the Export button at the top of the grid.

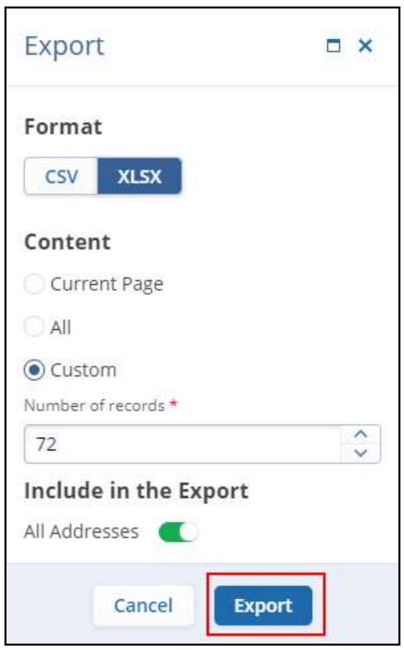


2. On the Export dialog box, select the file format to export the contacts data. Users can export Organization in either CSV or XLSX file formats.
   For the CSV or XLSX file formats, select either of the following:

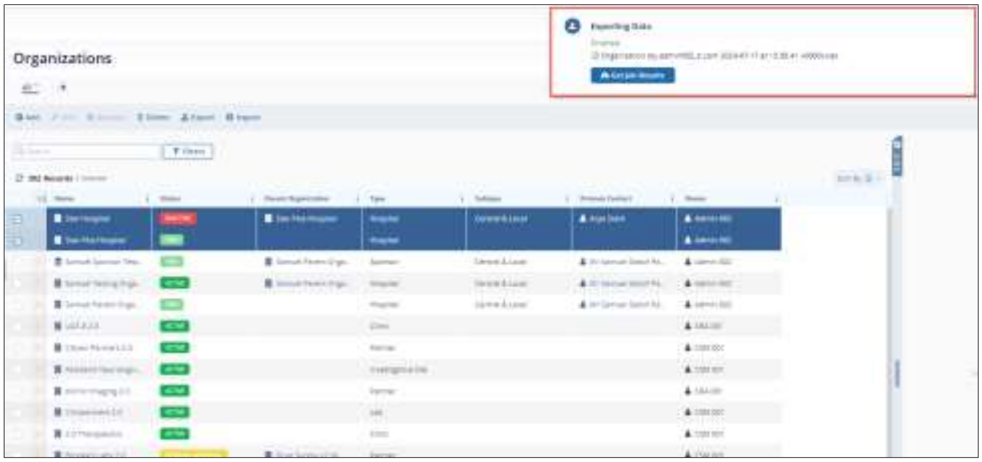
   - Current Page: This option will export data on the existing page of the organization screen.
   - All: This option will consider all the contact data.
   - Custom: Here, specify the number of records to be exported by either clicking on the up and down arrows or entering the number of records since it is a free text field.
   - Include in Report: Click on the All Addresses toggle button to include addresses in the exported file.

     Note: The Include in Report option is available only if the XLSX file format is selected.

3. Once the desired file format and the content is selected, click on Export.



4. Once the export is finished, the system will display a notification message on the top right corner of the screen stating the data export is completed. Here, click on the Get Job Results option to download the export file on the local system.



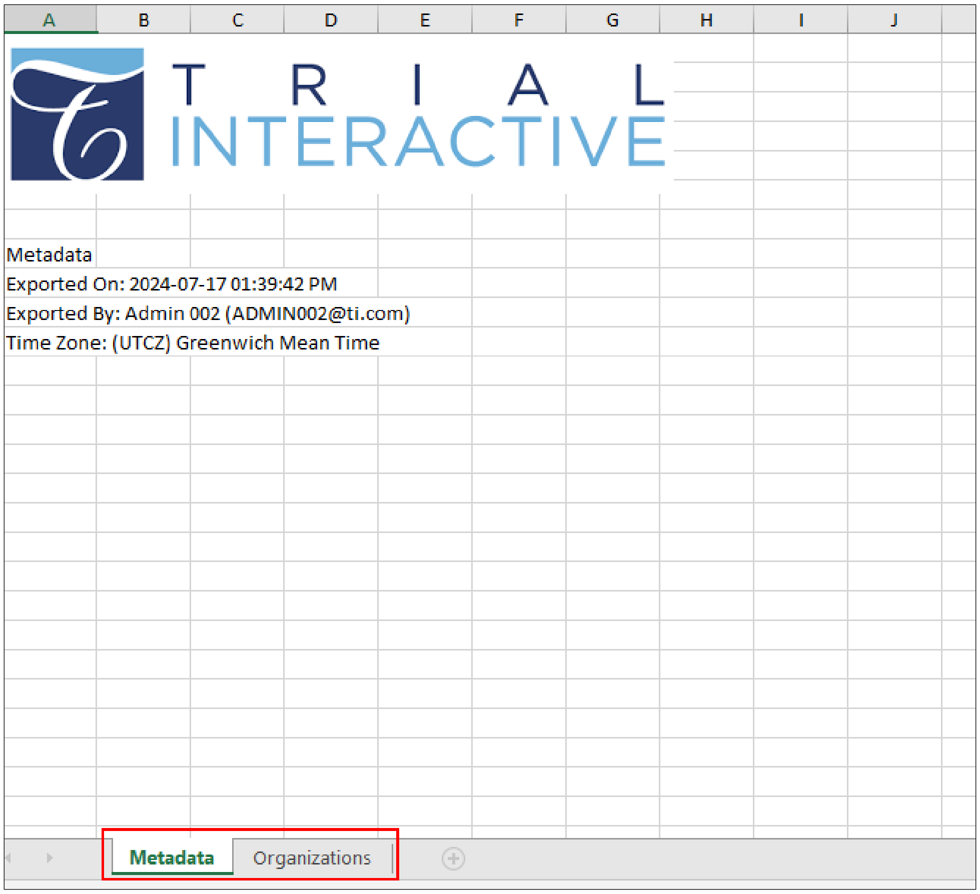
5. The files will be downloaded the local systems and will display the file formats.
   - The CSV file will display, just one tab with the contact details.

Favorite	Name	Status	Parent Or	Type	Subtype	Primary C	Owner
No	Star Hospi	Inactive	Star Plus H	Hospital	Central &	Arya Stark	Admin 002
No	Star Plus H	New		Hospital			Admin 002
No	Samuel Sp	New	Samuel Pa	Sponsor	Central &	Mr Samue	Admin 002
No	Samuel Te	Active	Samuel Pa	Hospital	Central &	Mr Samue	Admin 002
No	Samuel Pa	New		Hospital	Central &	Mr Samue	Admin 002
No	UAT-8 2.0	Active		Clinic			CRA 001
No	Citizen Pa	Active		Partner			CSM 001
No	Fastbend	Active		Investigative Site			CSM 001
No	Mirror Ima	Active		Partner			CRA 001
No	Clinipartn	Active		Lab			CSM 001
No	2.0 Therap	Active		Clinic			CSM 001
No	Brooke's L	Pending A	Drug Supp	Partner			CSM 001
No	Medical M	Approved		Partner		Erin Garne	CSM 001
No	Clinical W	Active		IRB/EC		Jacob Rob	CSM 001
No	Delta Co.	Active		Partner		John Jacol	CSM 001
No	Atlas Supp	Active		Supplier		Jack Smit	CSM 001
No	Acme Inc	Active		Partner			CSM 001
No	Acme Inc	Active		Investigative Site		Barbra Ma	CSM 001
No	Subject Se	Active		Sponsor			Hope Weisser
No	Subject Ce	Active		Clinic			Hope Weisser

Organization (by admin002_ti.co

The XLSX file will display the following two tabs:

- Metadata: This tab has details like the time of export, name, and email of the person who initiated the export, and time zone.



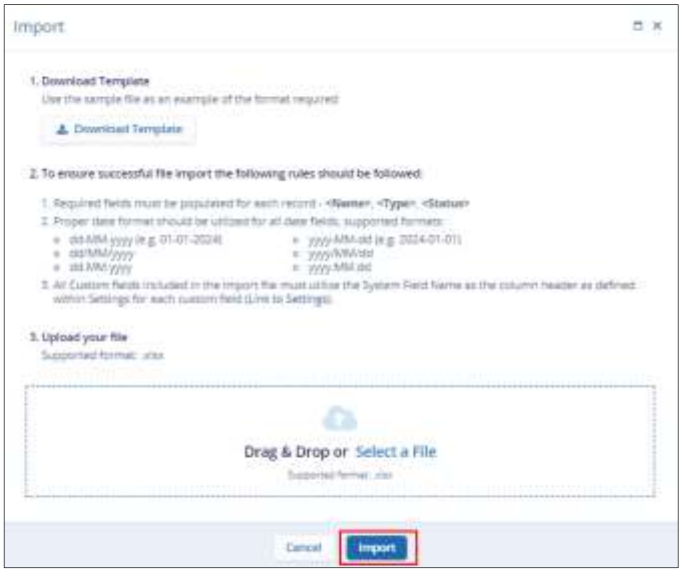
- Organization: This tab has the organization details.

Import Data

To navigate to the organization list and view all global organizations, follow these steps:

1. Click on the "Organizations" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.
3. To import the data, Click on the import button.

4. It will open the import window, Click on the **"Download Template"** button, this is the sample file as an example. Refer to the below screenshot below.



5. Read the instructions carefully, Click on the "Select a file" link and choose the file or you can drag and drop the file.

6. Click the "Import" button.

Contacts

Pre-requisites

Users with Company Administrator and Study Manager roles have the right to the right to Create, Assign, Edit, Update, and Delete contacts. The contact creation process can be carried out from Contacts and Organizations but the process remains the same for both.

Levels of Contact Creation in the Application

There are multiple levels of creating and managing a contact.

- Global level: If a contact is created at the Domain level it can be accessed and used anywhere in the system.

- Sub-level: The other way of creating and managing a contact is at their respective sub-level i.e., Site, Organization, Product, etc. Contacts may be used at the level at which they are created and any lower levels of the data hierarchy.

Creating a Contact

To navigate to the contacts list and view all the contacts, follow these steps:

1. From the left-hand navigation links, select Contacts.
2. It directs the user to the Contacts screen where contacts are displayed at a global level.

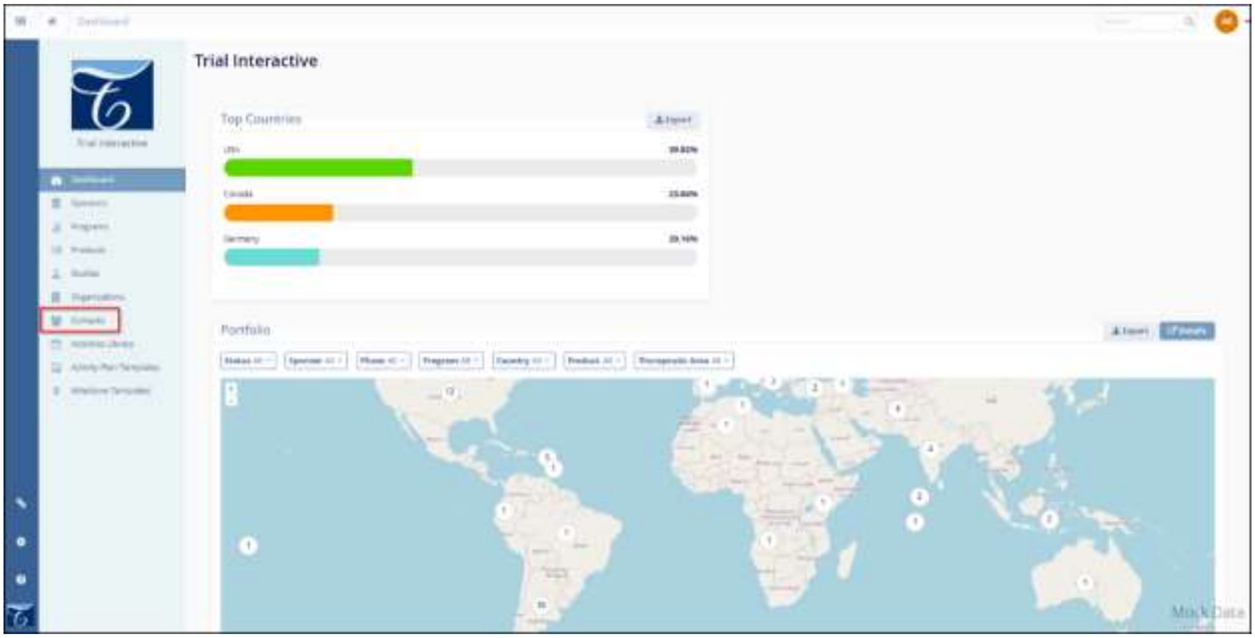


Figure: Select Contacts

Steps to create a contact

1. Click on the +Add button on the top menu bar from the Contacts screen.

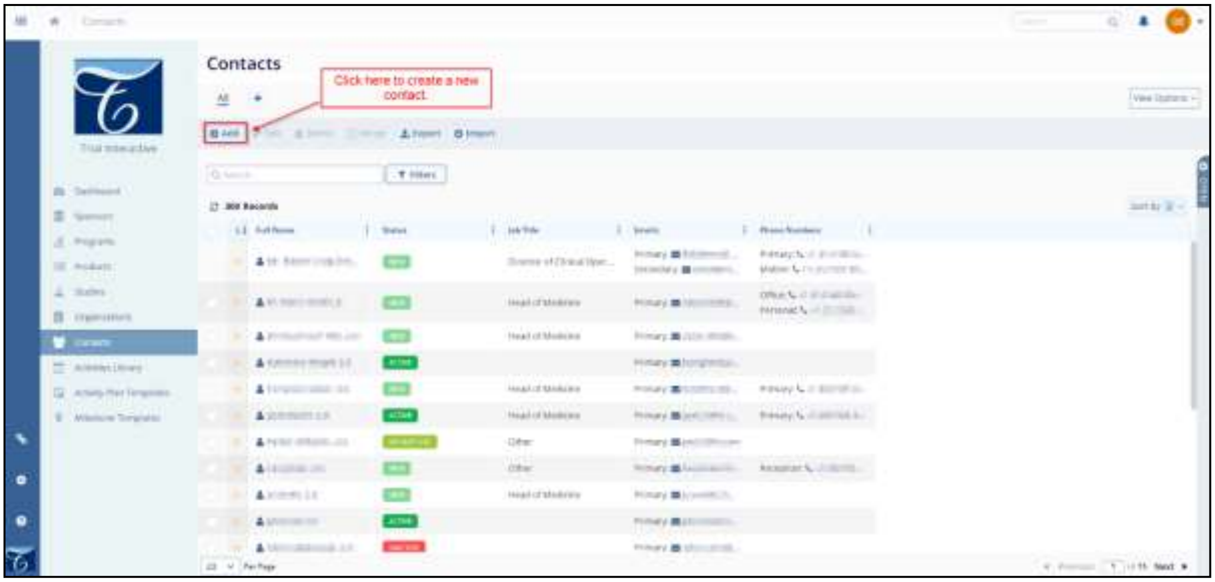


Figure: Create a new contact

2. On the Create Contact window, fill up the following mandatory information into the respective fields to create a contact. Certain fields are optional but are recommended to be filled.

   Note: Fields highlighted with a red asterisk (*) mark require a mandatory update.

   a. Prefix: Enter the prefix (e.g., Mr., Mrs., Dr.) if applicable.
   b. First Name*: Enter the first name of the contact. E.g., Miguel
   c. Middle Name: Enter the middle name if applicable.
   d. Last Name *: Enter the last name of the contact. E,g., Lopez
   e. Suffix: Enter the suffix (e.g., Jr., Sr., III) if applicable.
   f. Job Title: Enter the job title of the contact if applicable.
   g. Email Address: Enter the email address of the contact. Entry of an email address is recommended for better communication.
   h. Status*: Select the status of the contact from the dropdown menu. A tooltip showing the status meaning is visible for each status.
      i. New
      ii. Active
      iii. Approved
      iv. Do not use
      v. Inactive
      vi. No longer needed
      vii. Pending Approval

   i. Phone Numbers: Click on the +Add button to include phone numbers for the contact.
   j. Include Address: Toggle the switch to include the address for the contact. Enter the address details if the switch is turned on.

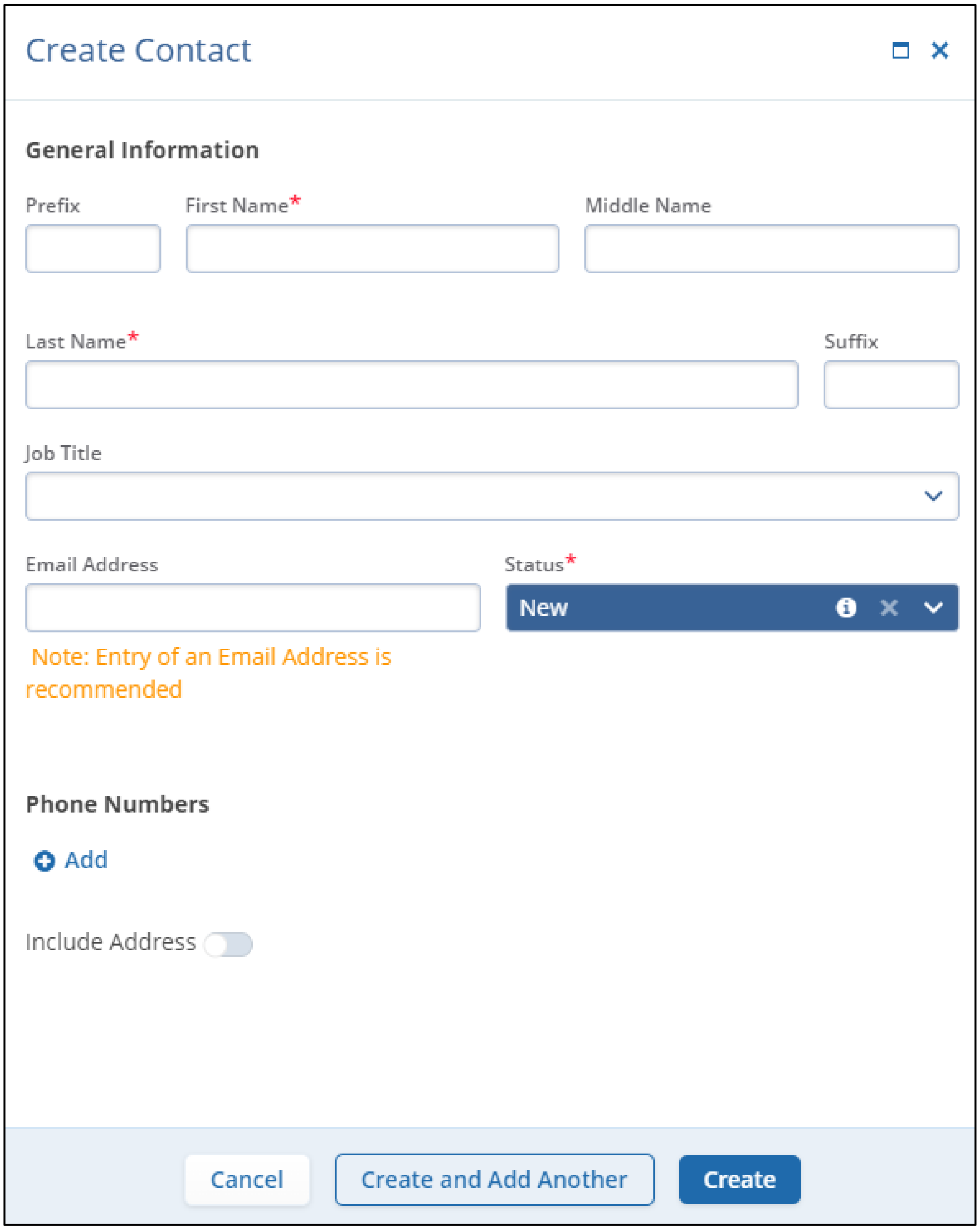


Figure: Add contact details

3. Once all the required details are entered and verified, the user can perform the following actions.
   - Clicking on the Create button saves the contact details.
   - Clicking on the Create and Add Another button saves the contact but enables the user to add another contact there itself since the Create Contact screen will remain intact.
   - Clicking on the Cancel button will cease the contact creation process.
4. Once the contact is successfully created, it will appear on the Contacts screen.

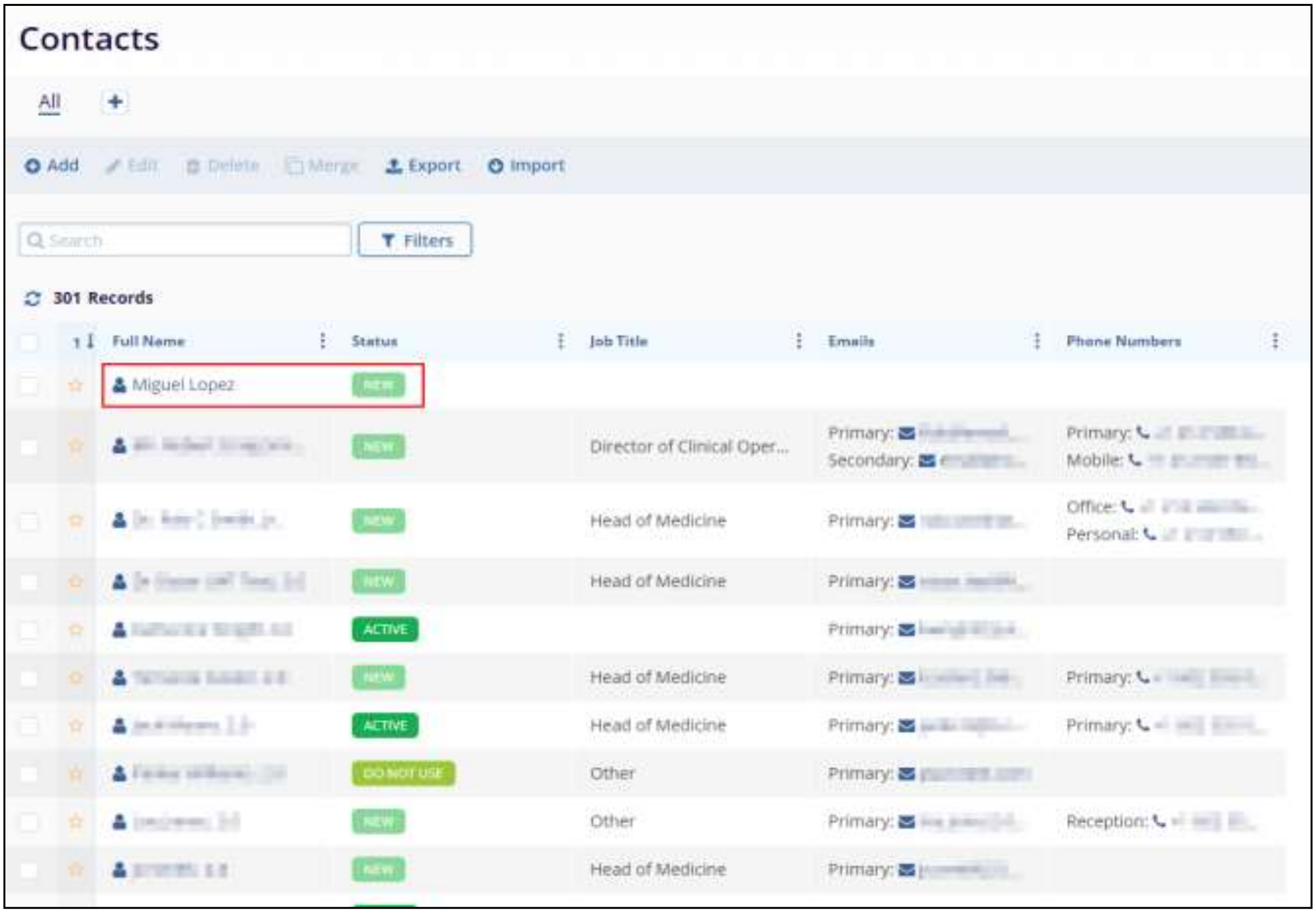


Figure: New Contact

Editing a Contact

To edit a Contact, follow the steps below.

1. Click on the checkbox before the contact name.
2. Click on the Edit (pencil) icon and it opens a quick view panel on the right side of the screen.
3. Make the required changes to the contact information in the panel.
4. Once all the changes are made and verified, click on the Save button.

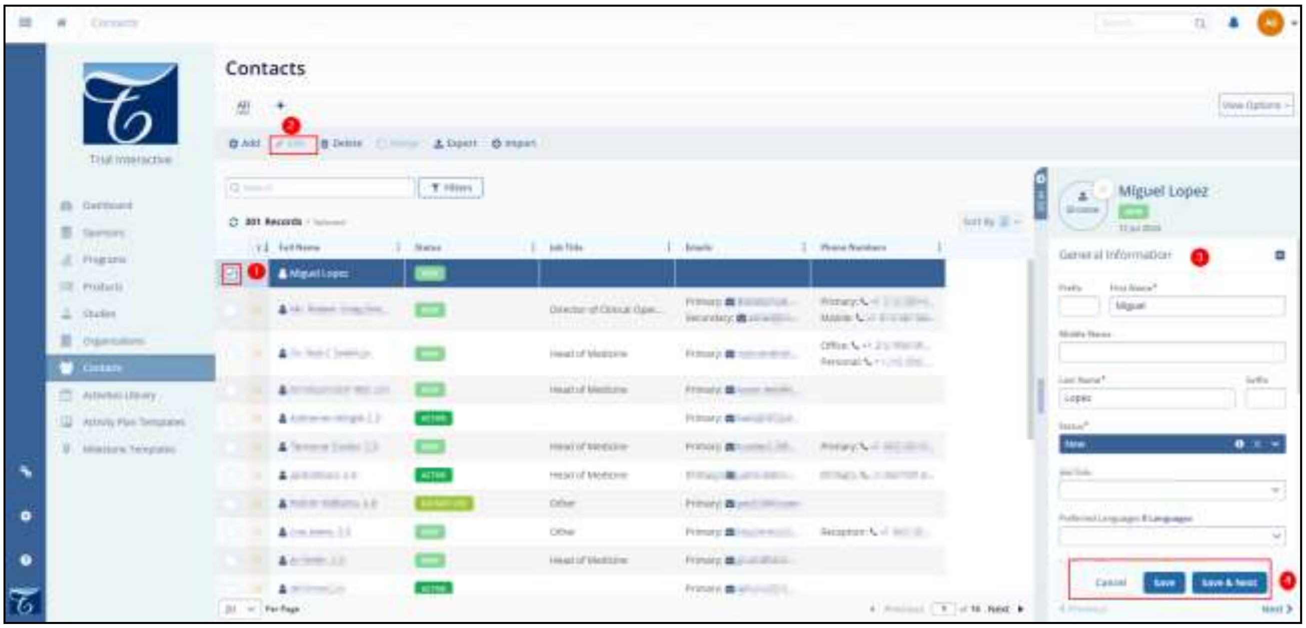


Figure: Editing a Contact

Note:

- Clicking on the Save & Next button saves the contact's edited details and the quick view panel displays details of the contact next in the list.
- Clicking on the Cancel button, will discard all the edits and updates.

Additionally, the contact details can also be edited by clicking on the contact name which will open the Contact Details page.

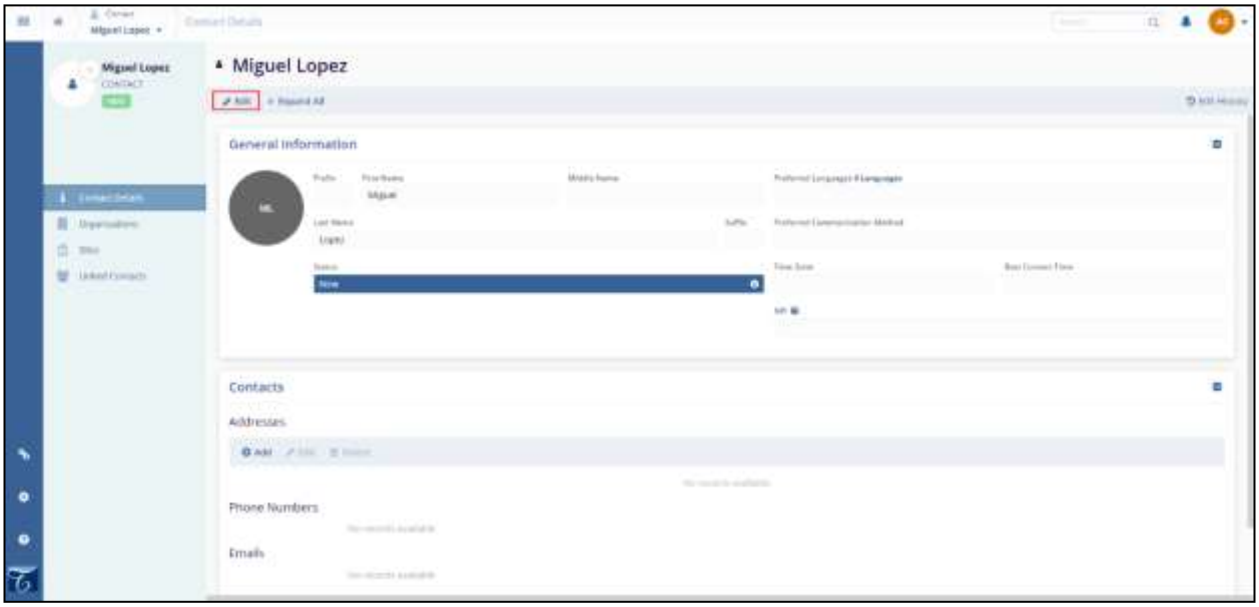
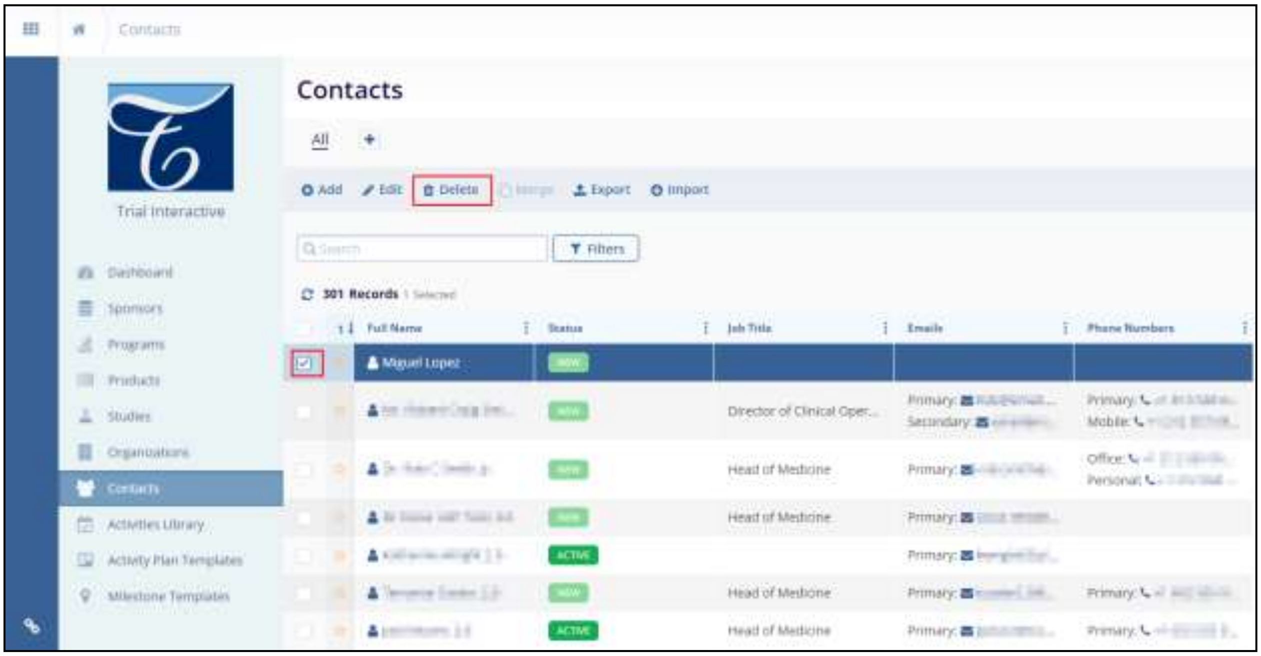


Figure: Edit contact on the Contact Details page

Deleting a Contact

To delete a contact from the existing contact list, follow the steps below.

1. Click on the checkbox beside the contact name, to select a contact to delete.
2. Click on the Delete icon in the top menu bar.



3. Once the user clicks Delete, a dialog box prompts the user to confirm the contact deletion. Click on Delete to remove the contact from the list.

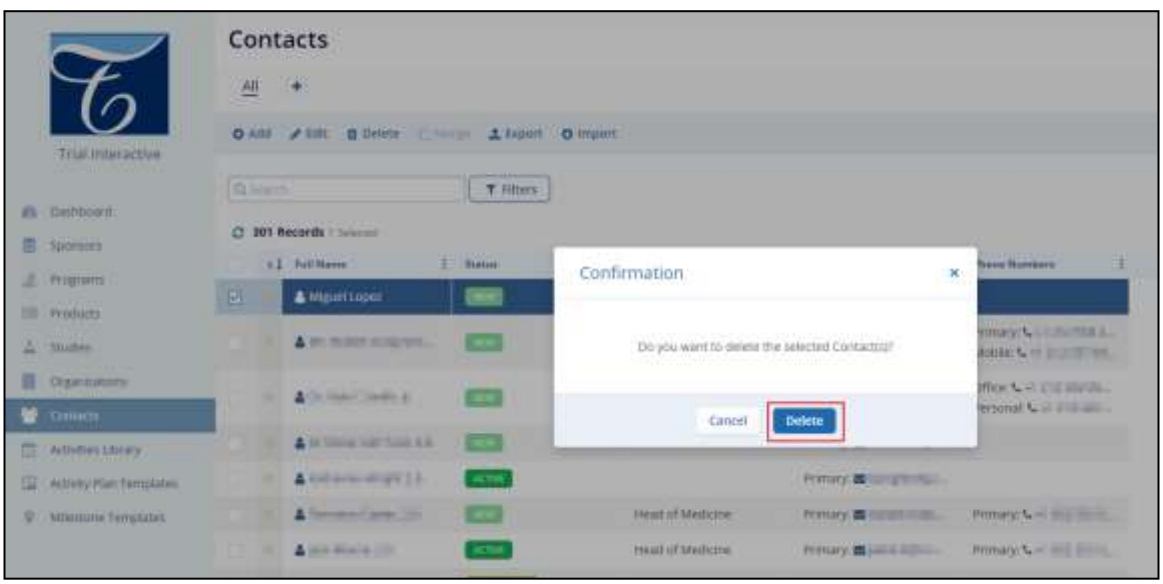


Figure: Contact deletion confirmation message

Merging Contacts

To merge contacts, follow the steps below.

1. Select two or more contacts by clicking on the checkboxes for each contact.
2. Click on Merge from the top menu bar.

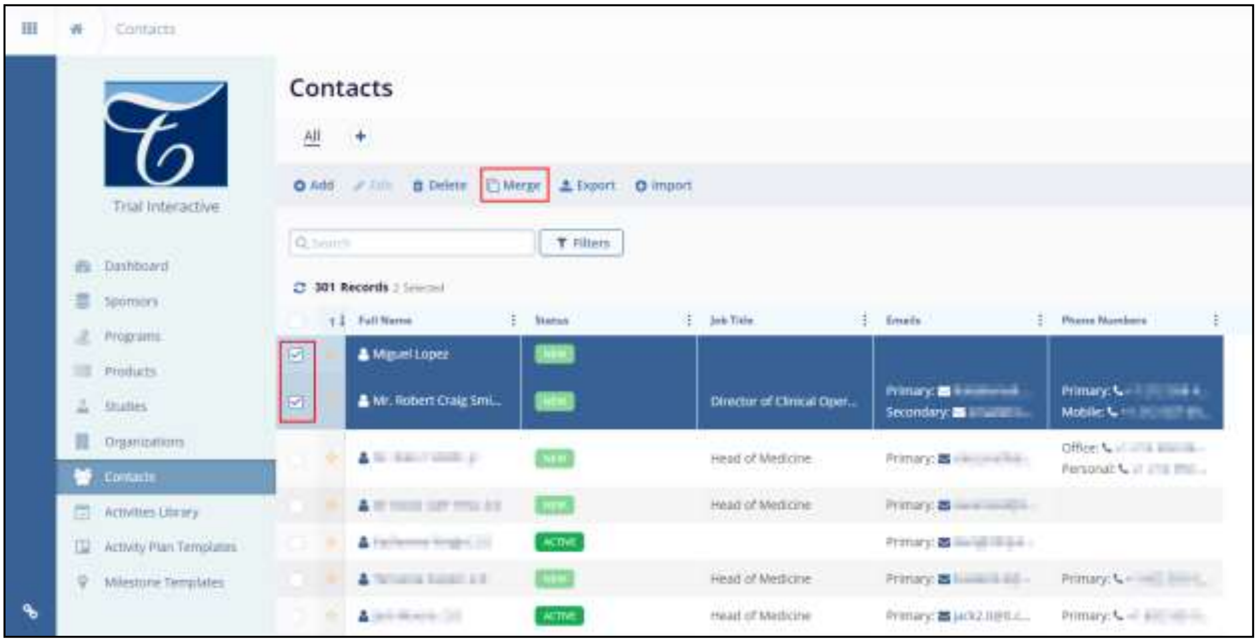


Figure: Merge Contacts

3. The Merge screen will display the main contact resulting from the merge and the selected contacts. By default, the main contact information is populated using information from the Contact 1 column.

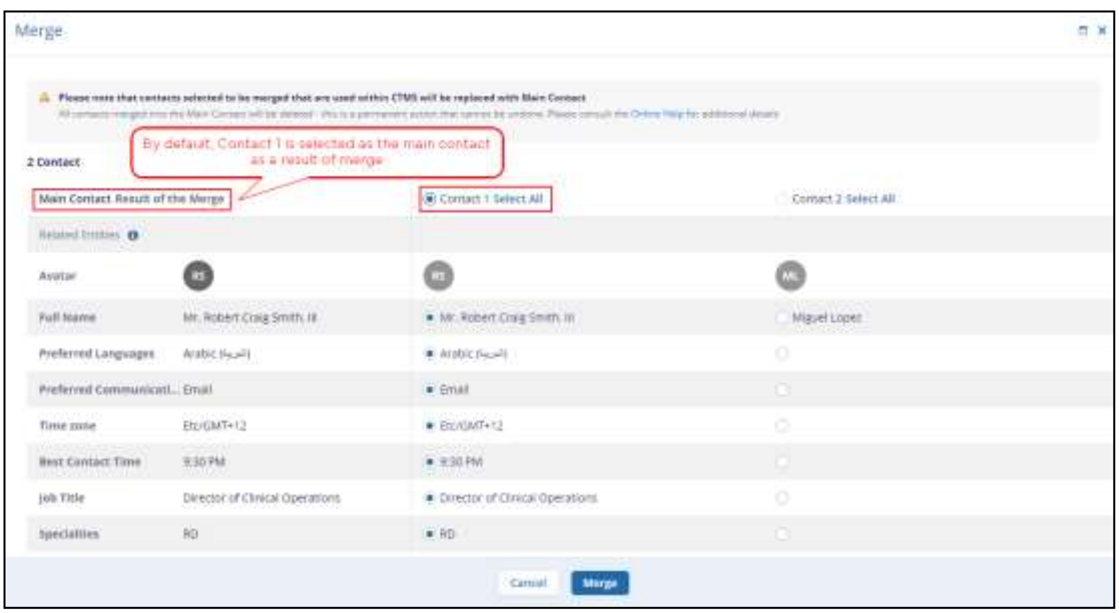


Figure: Contact 1 as the main contact

4. To merge specific details from Contact 2, click on the individual radio button for each entry.

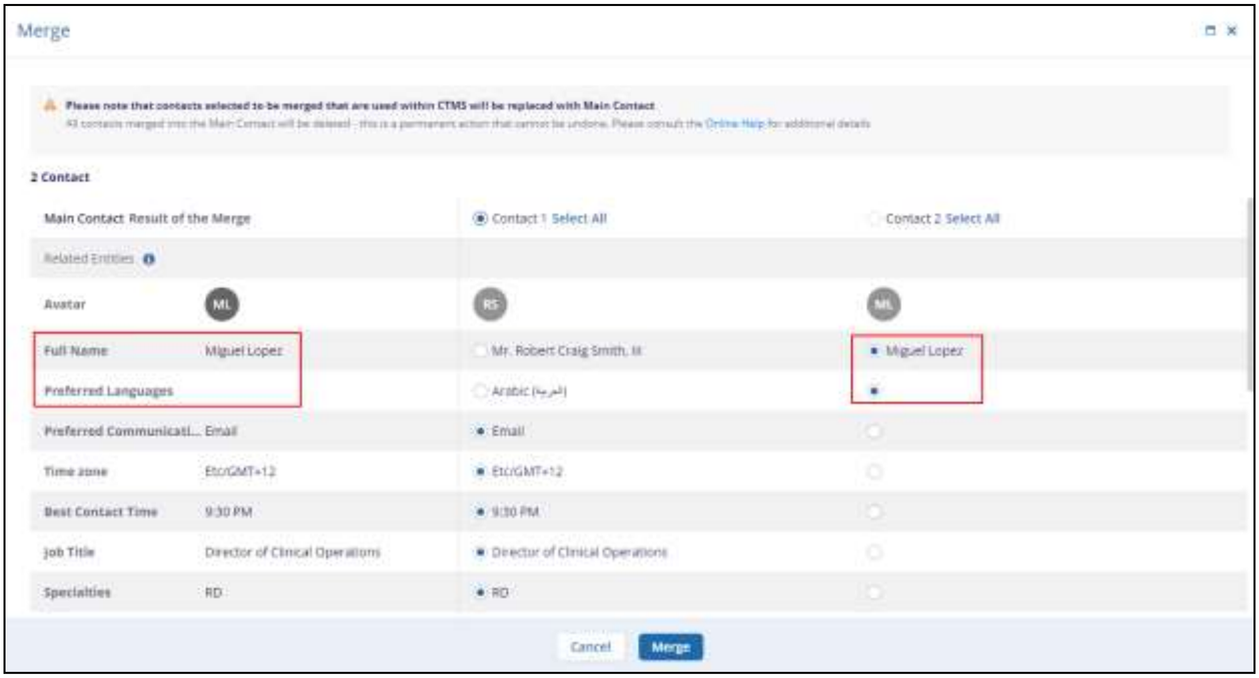


Figure: Merge individual entries from Contact 2

5. To merge all the details from Contact 2, click on Select All. Once all the entries required to be merged selected and reviewed, click on the Merge button.

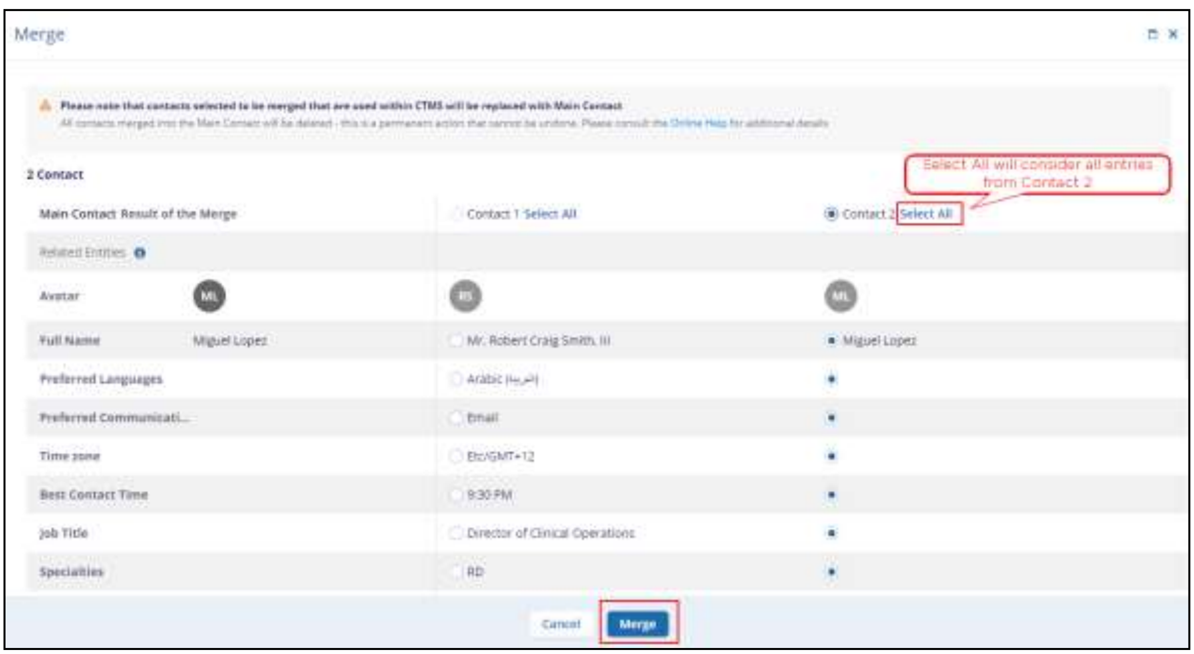


Figure: Merge all entries from contact 2

6. Once the user selects Merge, the Merge Contacts confirmation popup displays certain actions that cannot be undone and prompts the user to read those before confirmation. (Refer to the image below to read all actions that cannot be undone)
7. Click on Merge once all the details about actions that cannot be undone are read and confirmed.

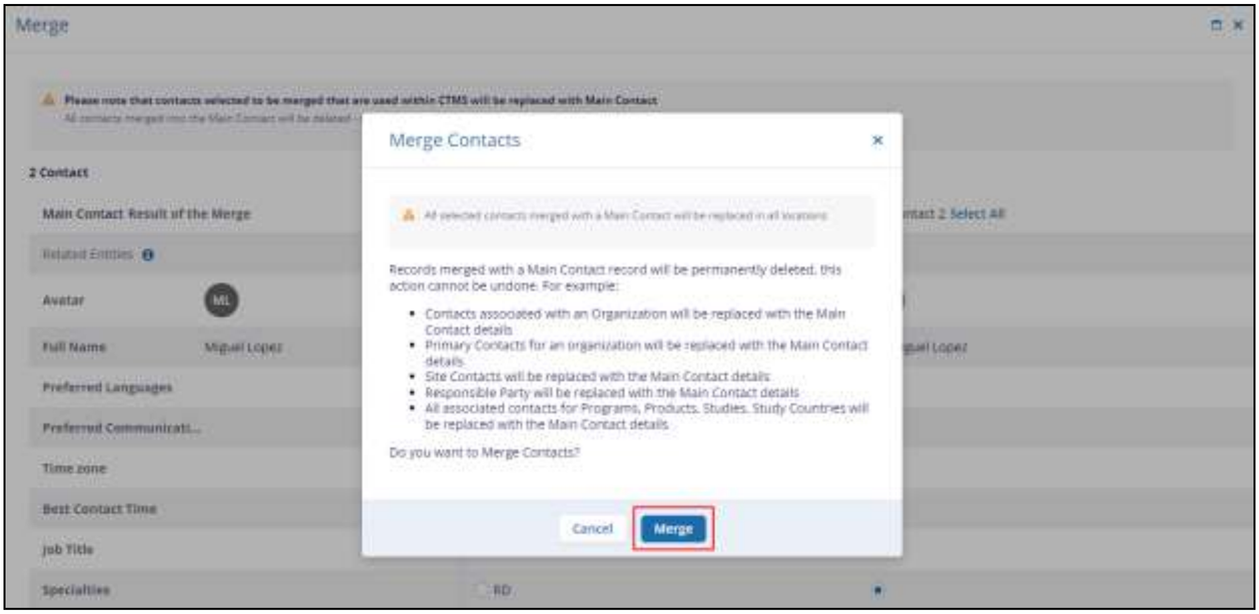


Figure: Merge Contacts confirmation popup

Exporting Contacts

To export contacts, follow the steps below.

6. On the Contacts screen, click on Export from the top menu bar.

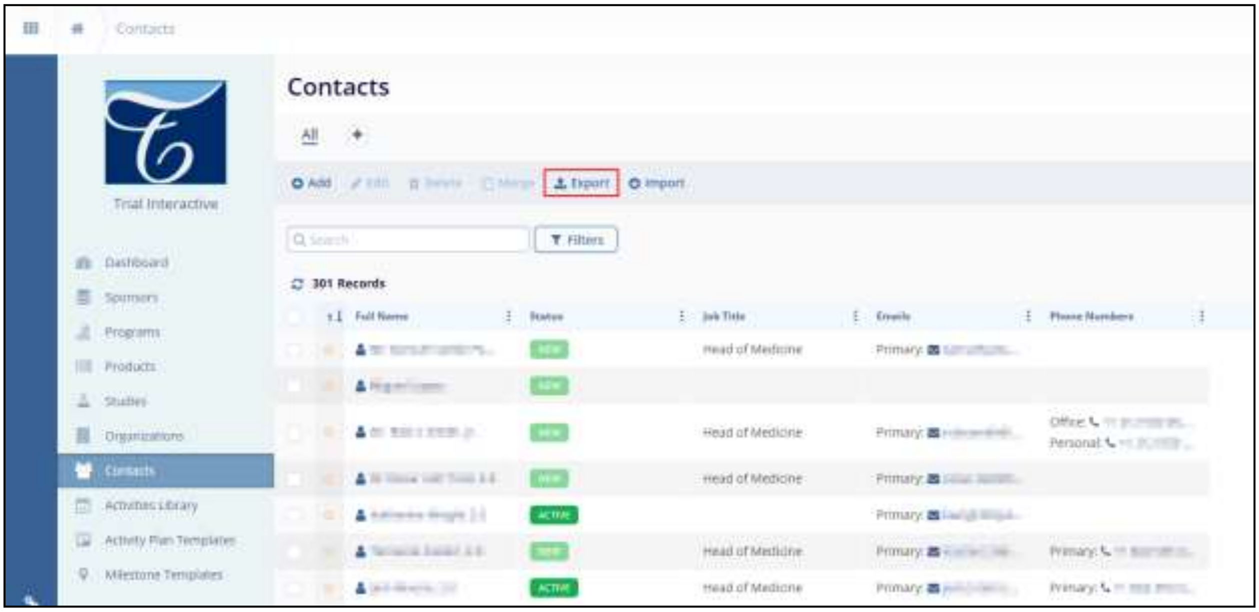


Figure: Select Export

7. On the Export dialog box, select the file format to export the contacts data. Users can export contacts in either CSV or XLSX file formats.

8. For the CSV or XLSX file formats, select either of the following:

    - Current Page: This option will export data on the existing page of the Contacts screen.
    - All: This option will consider all the contact data.
    - Custom: Here, specify the number of records to be exported by either clicking on the up and down arrows or entering the number of records since it is a free text field.
    - Include in Report: Click on the All Addresses toggle button to include addresses in the exported file.

      Note: The Include in Report option is available only if the XLSX file format is selected.

9. Once the desired file format and the content is selected, click on Export.

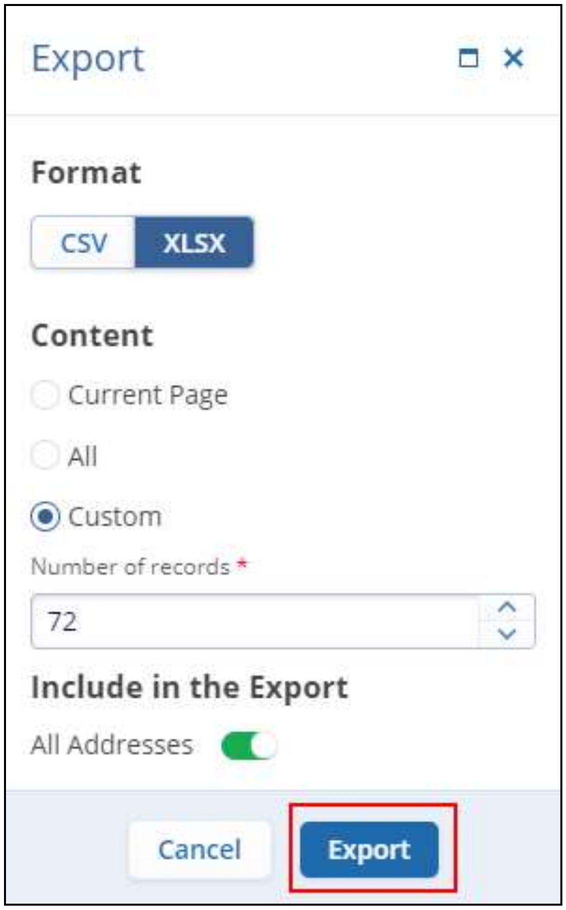


Figure: Export contacts file formats

10. Once the export is finished, the system will display a notification message on the top right corner of the screen stating the data export is completed. Here, click on the Get Job Results option to download the export file on the local system.

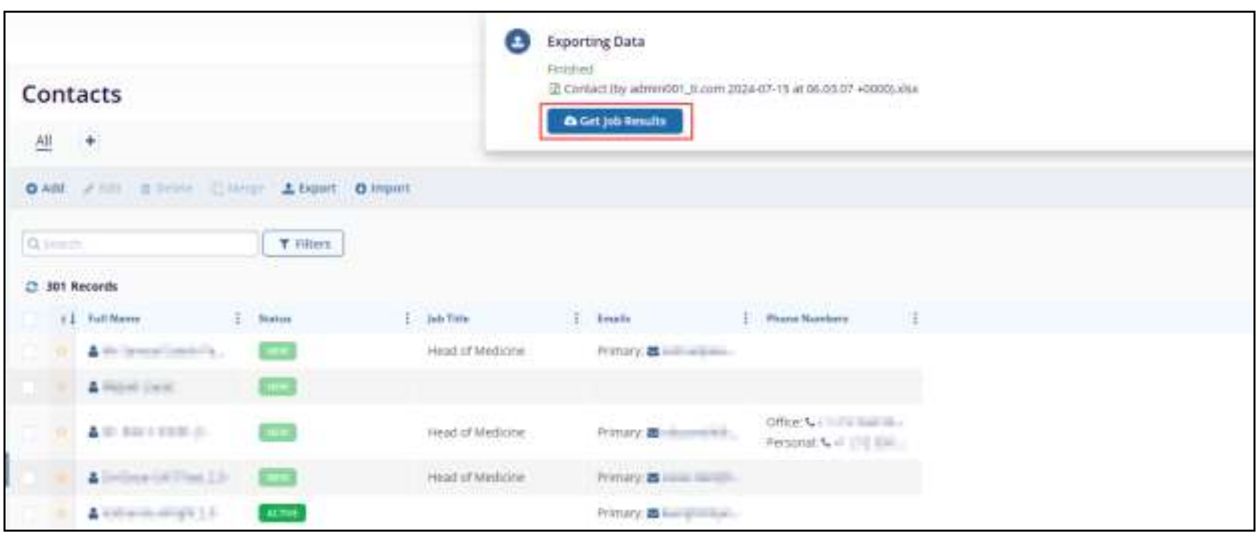


Figure: Get Job Results

11. The files will be downloaded the local systems and will display the file formats.

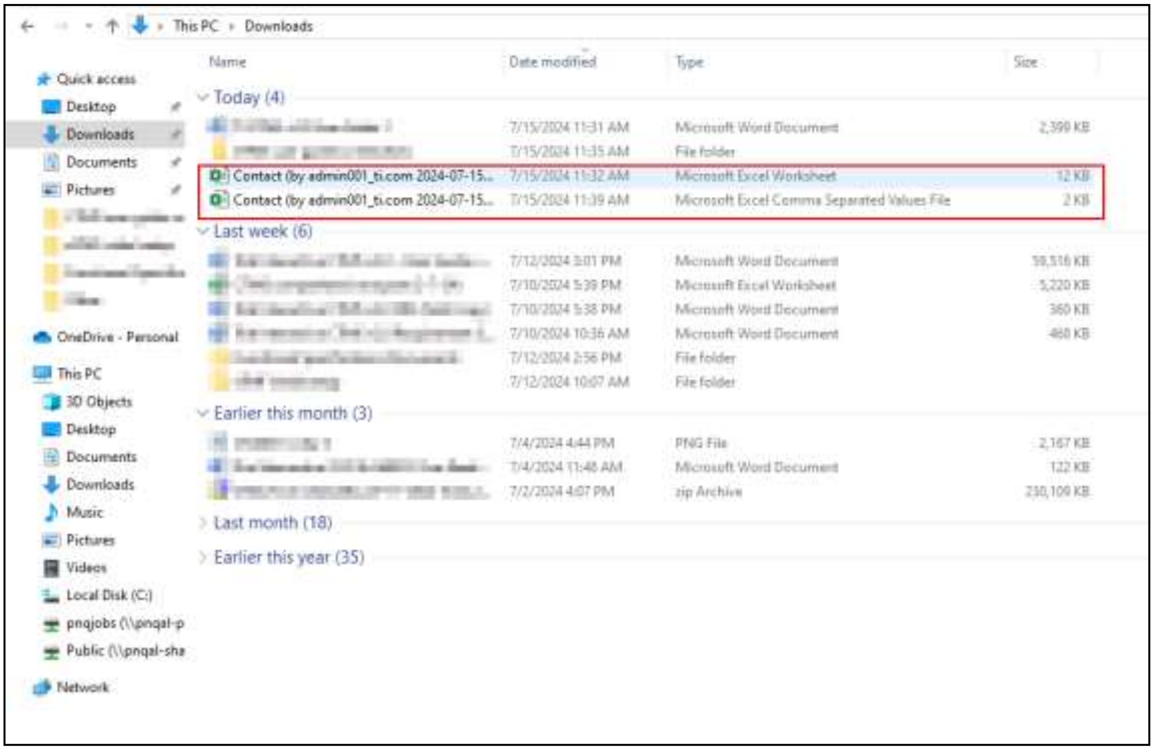


Figure: Exported files in CSV and XLSX file format

The CSV file will display, just one tab with the contact details.

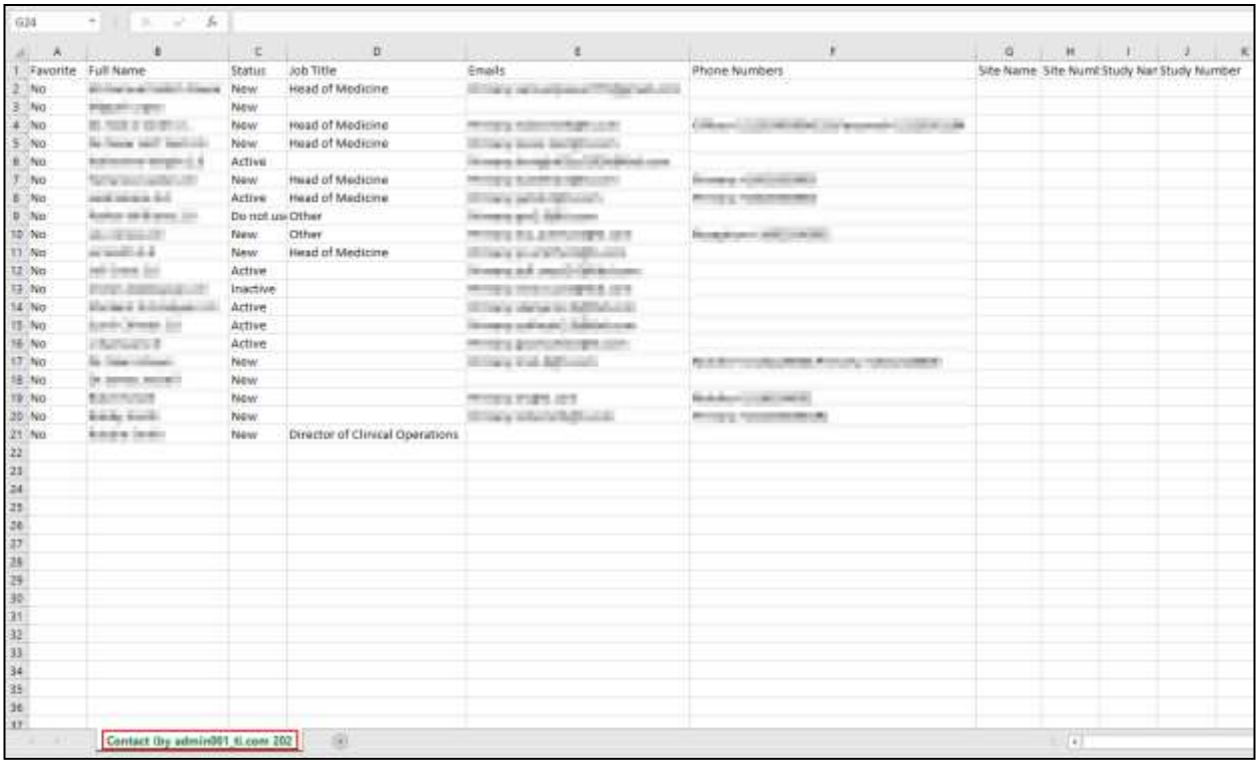


Figure: CSV file export

The XLSX file will display the following two tabs:

- Metadata: This tab has details like the time of export, name, and email of the person who initiated the export, and time zone.

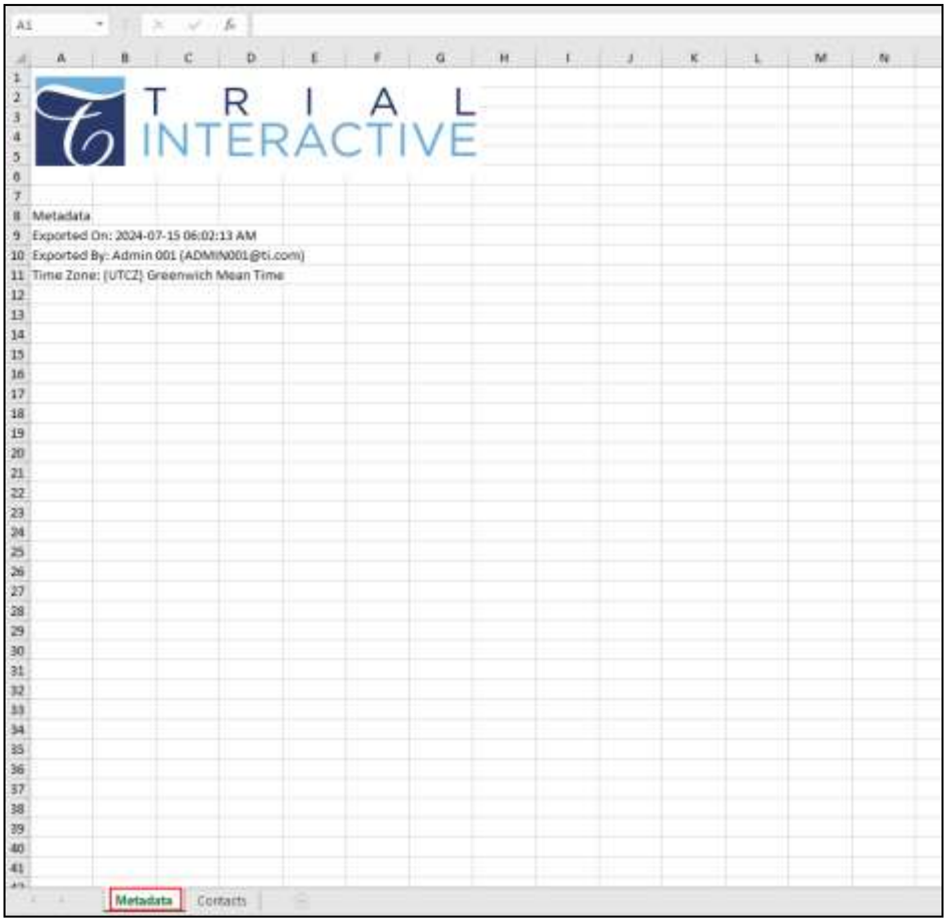
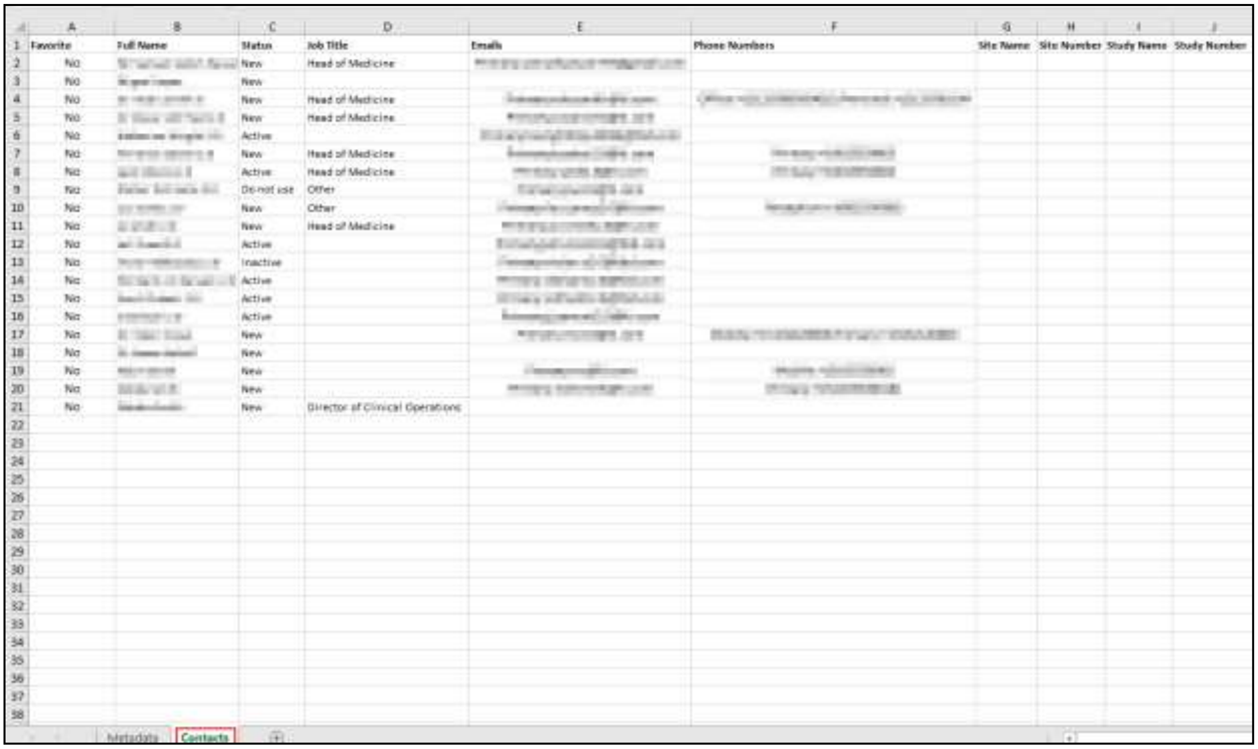


Figure: XLSX file-Metadata tab

- Contacts: This tab has the contact details.



	Favorite	Full Name	Status	Job Title	Emails	Phone Numbers	Site Name	Site Number	Study Name	Study Number
2	No	[illegible]	New	Head of Medicine	[illegible]					
3	No	[illegible]	New							
4	No	[illegible]	New	Head of Medicine	[illegible]	[illegible]				
5	No	[illegible]	New	Head of Medicine	[illegible]					
6	No	[illegible]	Active		[illegible]					
7	No	[illegible]	New	Head of Medicine	[illegible]	[illegible]				
8	No	[illegible]	Active	Head of Medicine	[illegible]	[illegible]				
9	No	[illegible]	Do not use	Other	[illegible]					
10	No	[illegible]	New	Other	[illegible]	[illegible]				
11	No	[illegible]	New	Head of Medicine	[illegible]					
12	No	[illegible]	Active		[illegible]					
13	No	[illegible]	Inactive		[illegible]					
14	No	[illegible]	Active		[illegible]					
15	No	[illegible]	Active		[illegible]					
16	No	[illegible]	Active		[illegible]					
17	No	[illegible]	New		[illegible]	[illegible]				
18	No	[illegible]	New							
19	No	[illegible]	New		[illegible]	[illegible]				
20	No	[illegible]	New		[illegible]	[illegible]				
21	No	[illegible]	New	Director of Clinical Operations						

Metadata | Contacts

Figure: XLSX file-Contacts tab

Importing Contacts

To import contacts in CTMS, follow the steps below.

1. On the Contacts screen, click on Import from the top menu bar.

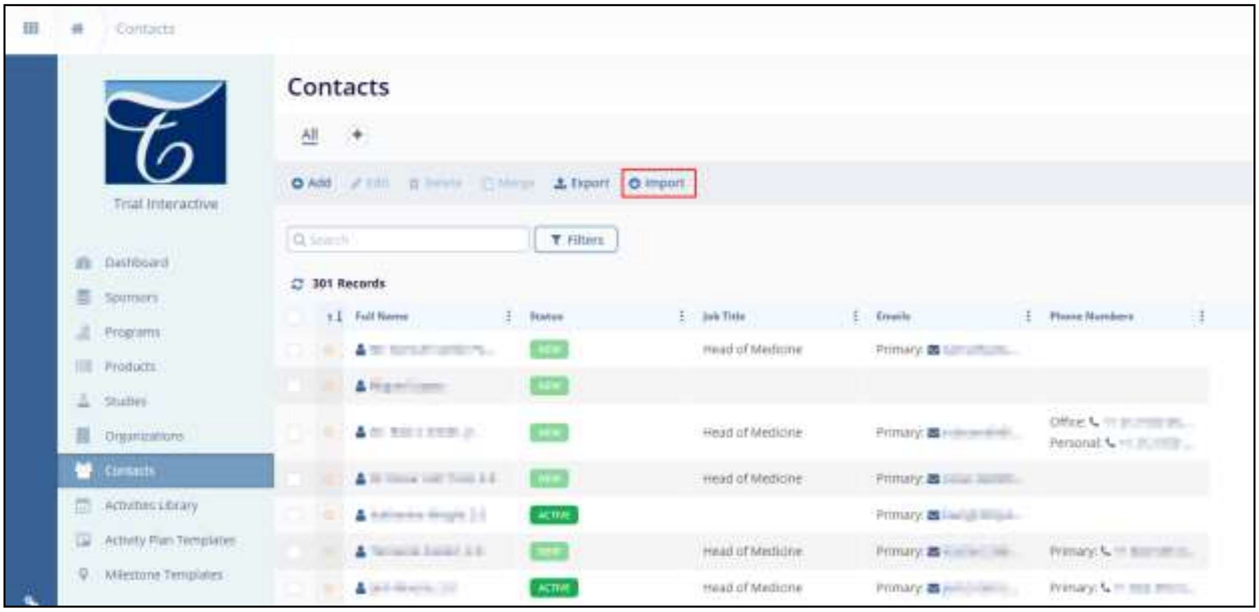


Figure: Select Import

2. On the Import screen, perform the following to import contact data. Refer to the numbers on the screenshot and follow the steps accordingly.

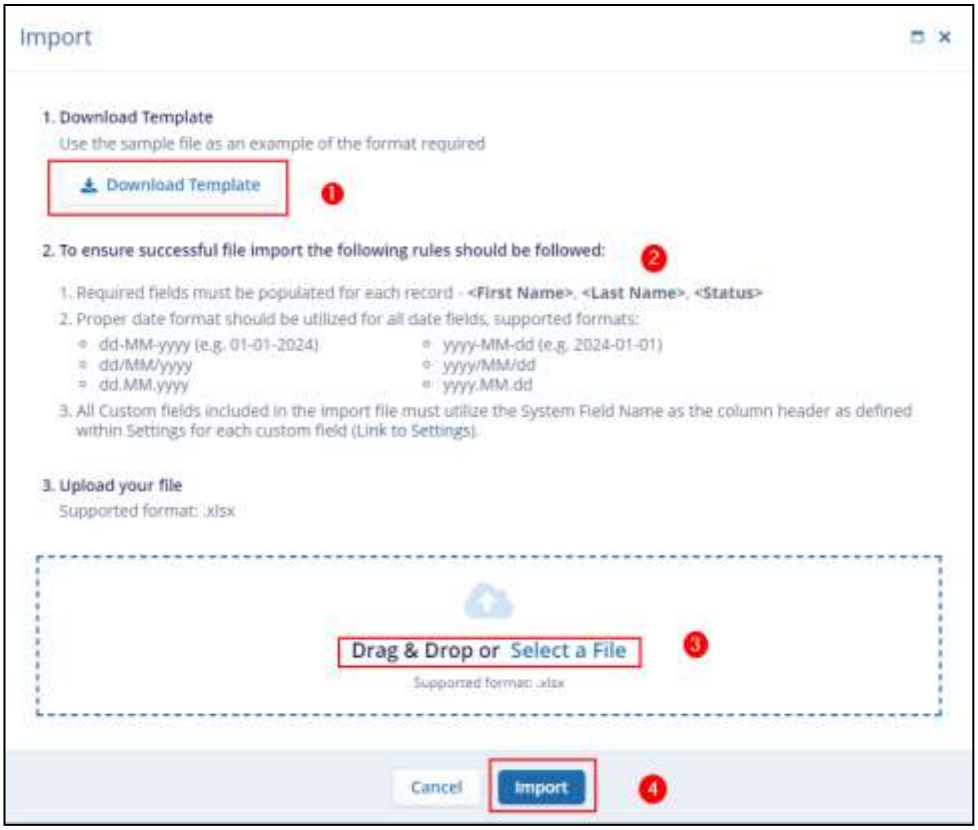


Figure: Import contacts process

1. Click on the Download Template button to get a specimen of the required format.
2. Enter the required details into each column by adhering to the naming convention, date, and custom field-related rules. Refer to the steps detailed in the Contacts import template.

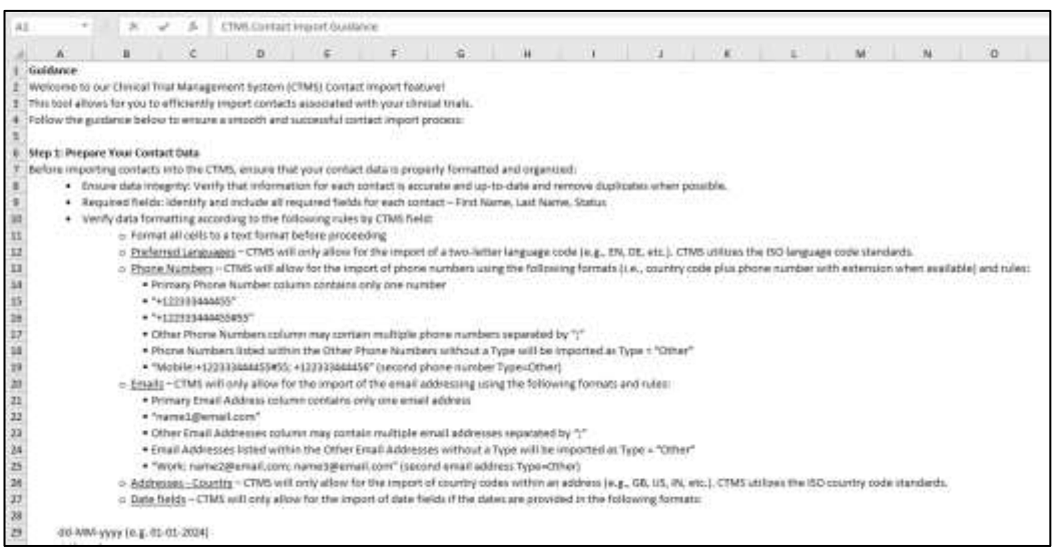


Figure: Contacts import template-Import Guidance

Prefix	First Name	Middle Name	Last Name	Suffix	Status	Preferred Languages	Preferred Communication Methoc	NPI

Figure: Contacts import template-Contacts

3. Upload the file in .xlsx file format either by selecting the file or using the Drag & Drop functionality.
4. Click on Import once the file is successfully uploaded.

Contacts Views

Creating a Contact View

To create a Contact View, follow the steps below.

1. Click on the All hamburger icon and select Save as New View.

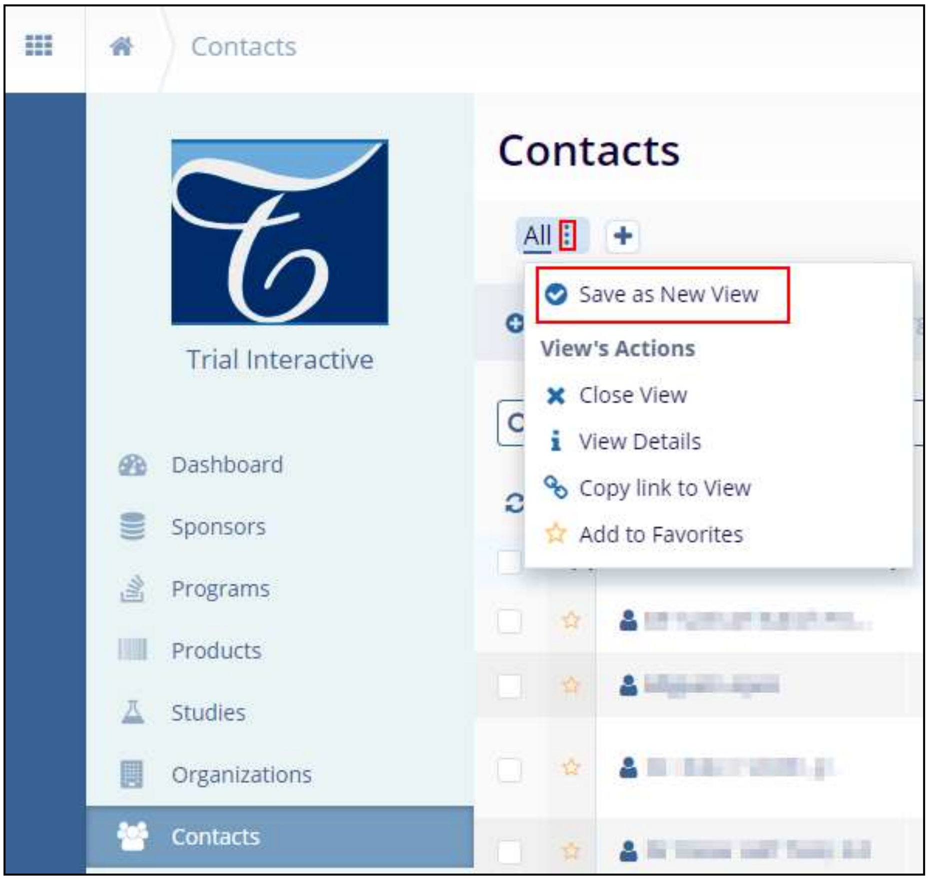


Figure: Save as New View

2. On the Save as New View screen, specify View Name, Description, and Sharing Options-Private or Public. For Public, it is possible to set it as a default view by enabling the Set as Default toggle button.

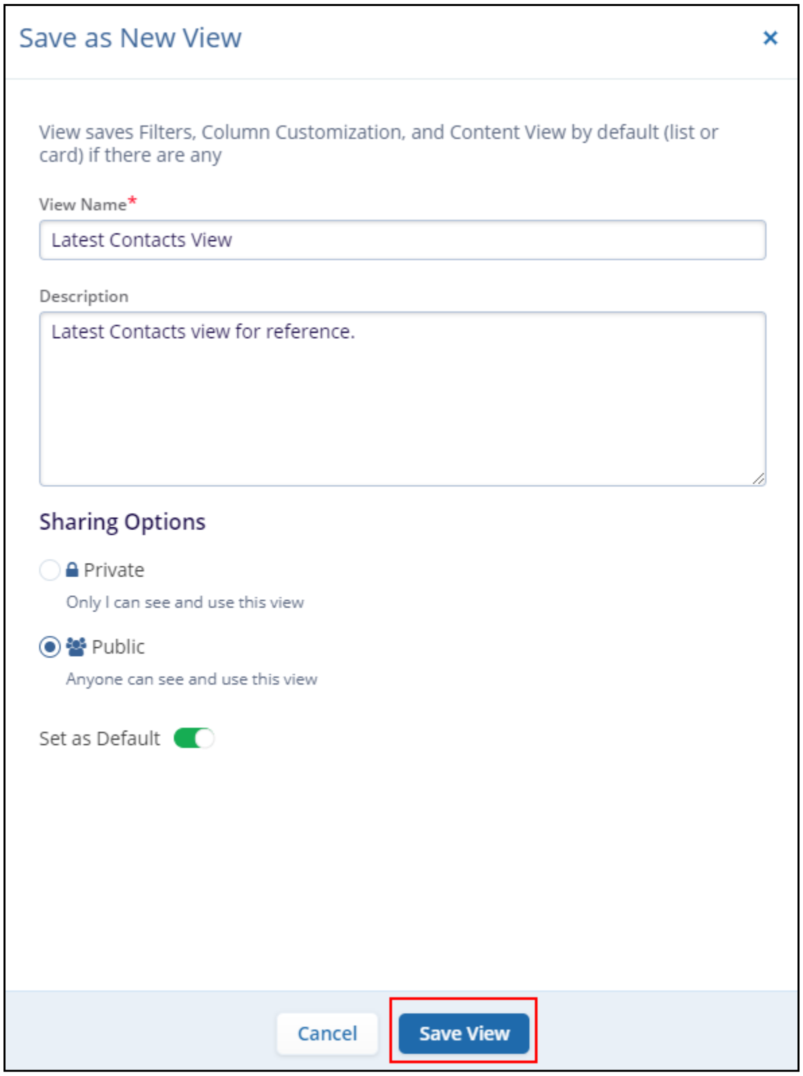


Figure: Save as New View Configuration

3. Once all the details are entered and configured click on Save View and it will appear on the Contacts home screen.

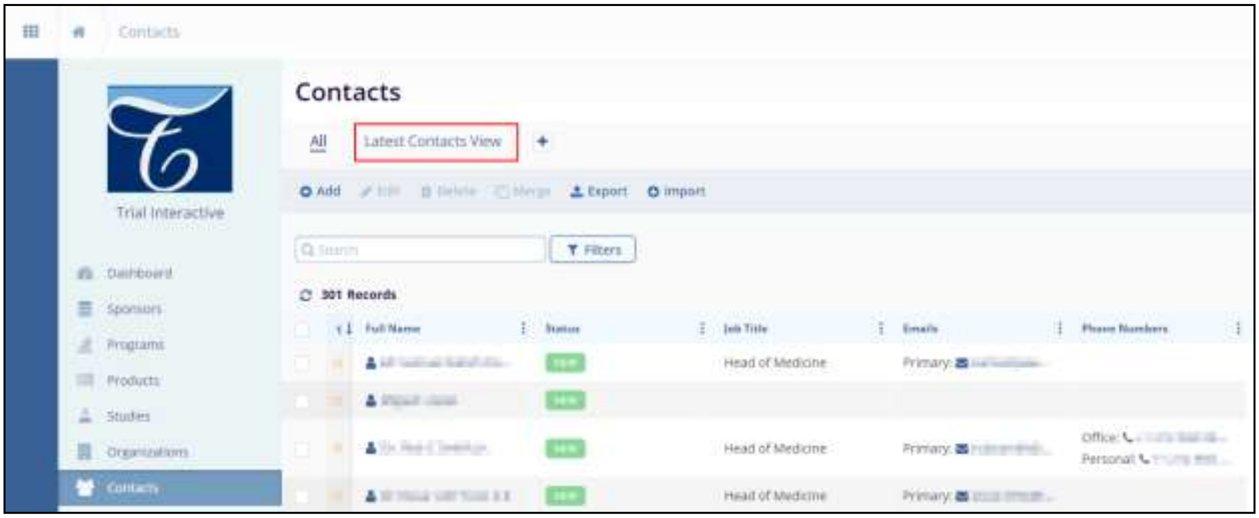


Figure: New contacts view on the home screen

Accessing View's Actions

The View's Actions allow performing the following actions with the newly created contacts view as well as the default view.

1. To access **View's Actions**, click on the hamburger icon for either the newly created or the default view.

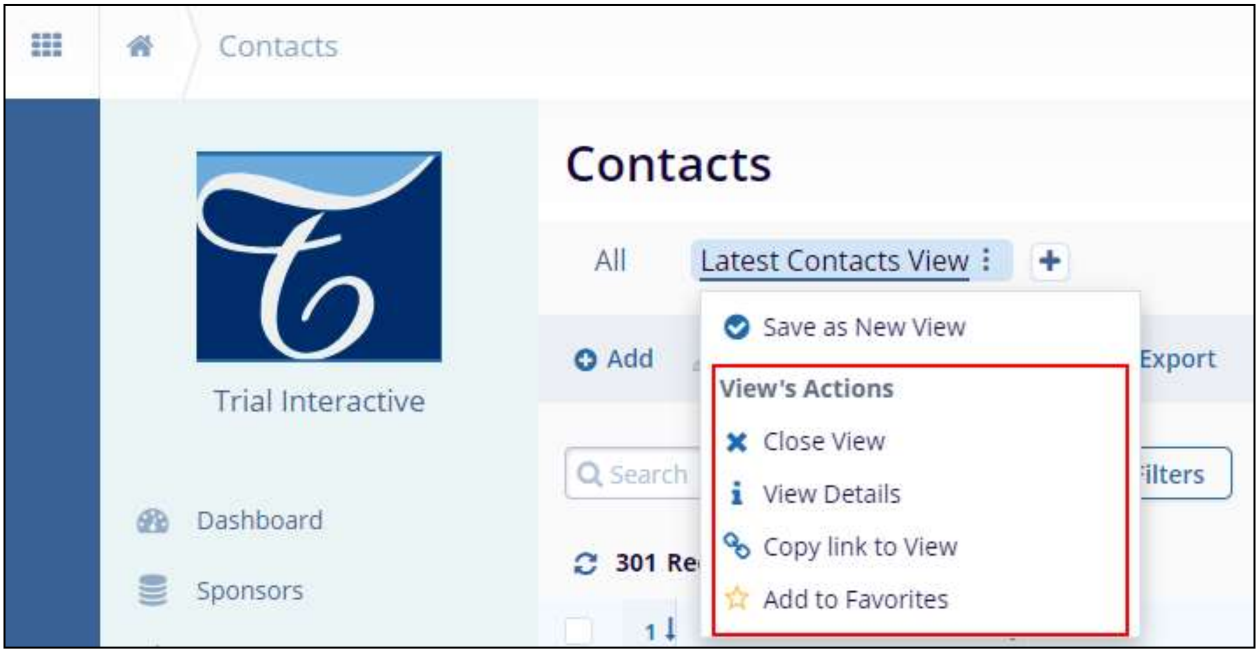


Figure: Accessing View's Actions

The following **Views's Actions** are available

- Close View: Selecting this option will permanently delete the view
- View Details: Selecting View Details will open a panel with all the view details. Clicking on the edit (pencil) icon will allow editing of the view details.
- Copy link to view: This option will copy the link of this view and enable opening the same view in another tab of the browser.
- Add to Favorites: Clicking on the star icon will add the current view to favorites.

Adding a View

To add a view, click on the + icon and select the view to apply from either the Favorites tab or the All views tab.

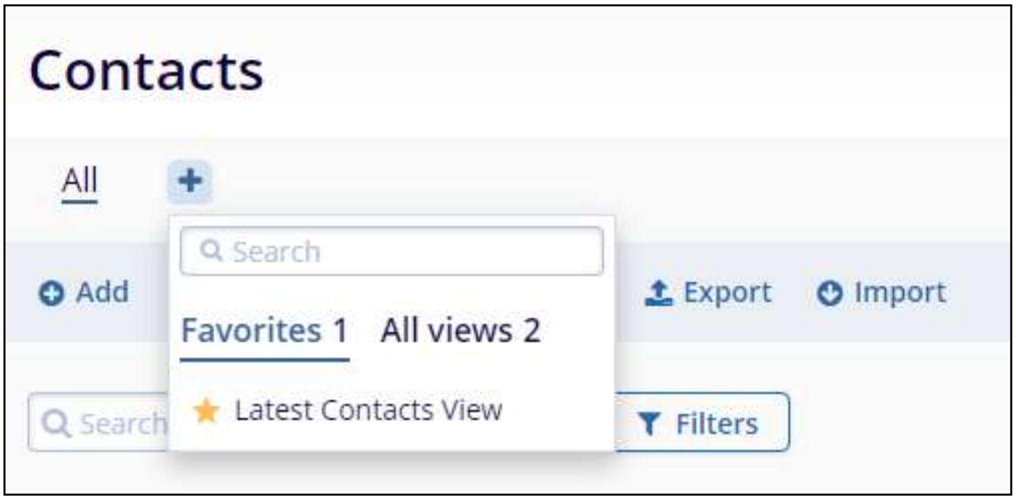


Figure: Adding a new

Note: Creating a contact view and accessing View Actions can also done from Contacts > View Options.

All View's Actions

To access All View's Actions, from the left-hand navigation pane, select Contacts > View Options dropdown.

Figure: All View's Actions

Under the All View's Actions, the following options are available.

1. Manage Views: The Manage View's screen displays views bifurcated by All Views, Favorites, Created By Me, and Default. On this screen, perform the following actions.

    a. Access all the **View's Actions** by selecting an individual view.
    b. Filter the records by applying the Created By, Share Options, and Add to Page filters.
    c. Click on +Add to add the view on the Contacts home page.
    d. Sort the data in Ascending and Descending order by applying different sorting criteria.

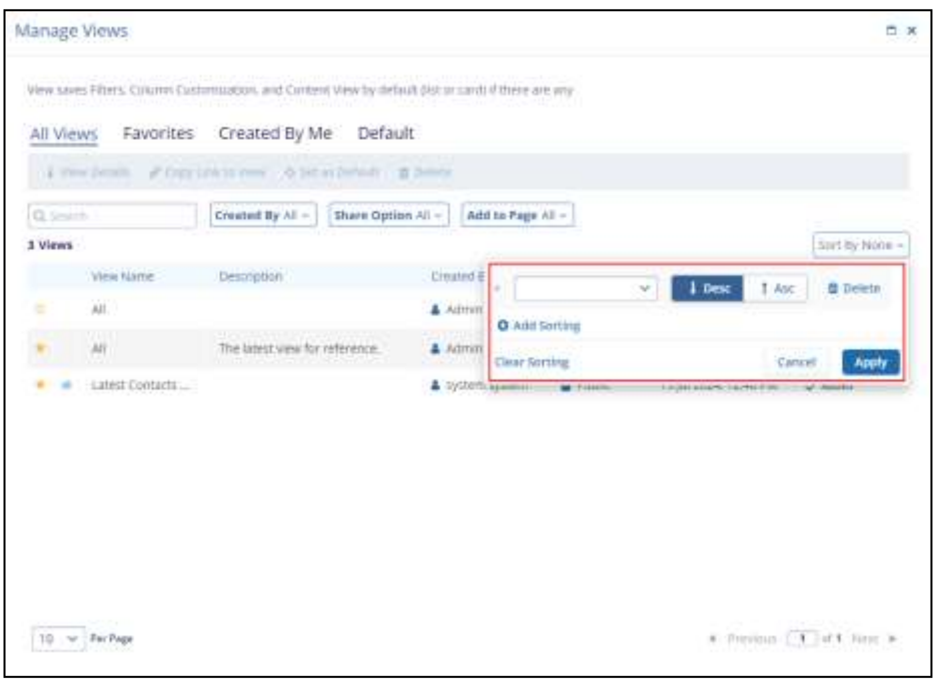


Figure: Sort views

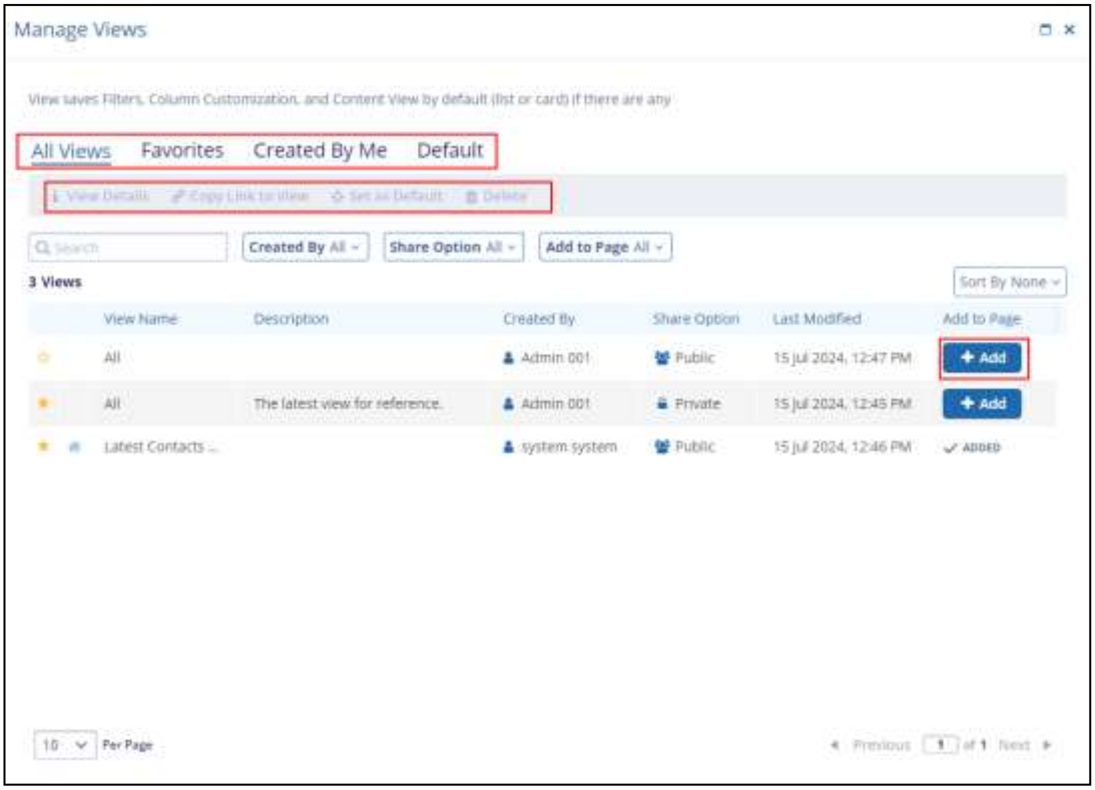


Figure: Manage Views

2. Reset to Default Views Config: Selecting this option will reset all views to the system default views. Once this option is selected, click on Reset to default on the confirmation popup

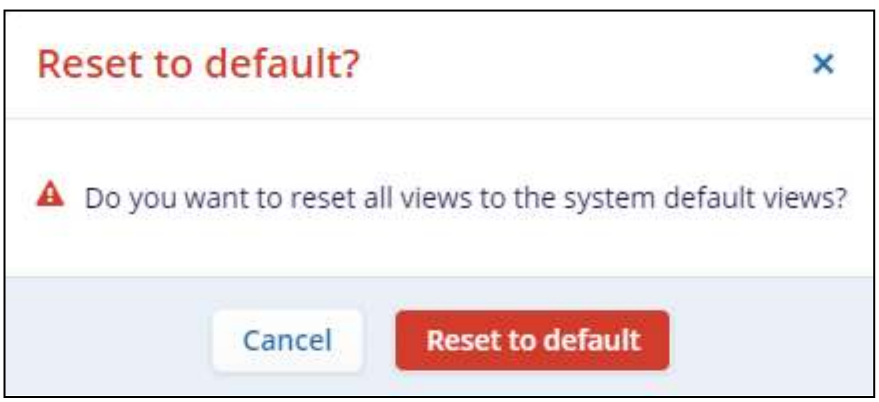


Figure: Reset to Default Views Config

Customizing Contacts screen

Filters

To apply filters to the Contacts view, click on the Filters button to add the Standard and Advanced filters.

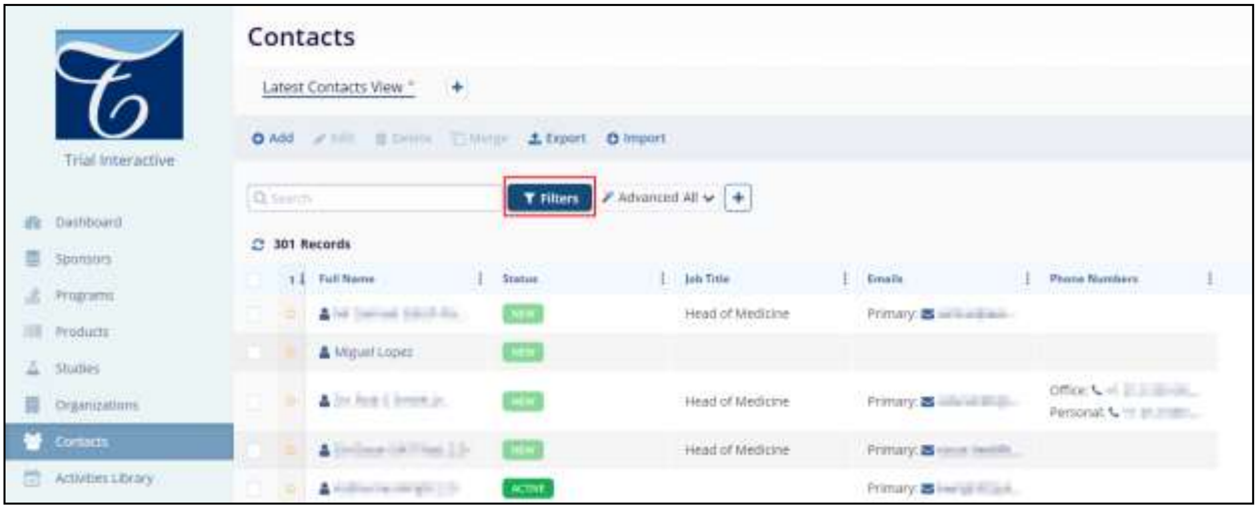


Figure: Add Filters

Standard Filters

To add the Standard filters, click on +, select the required criteria, and click on Apply.

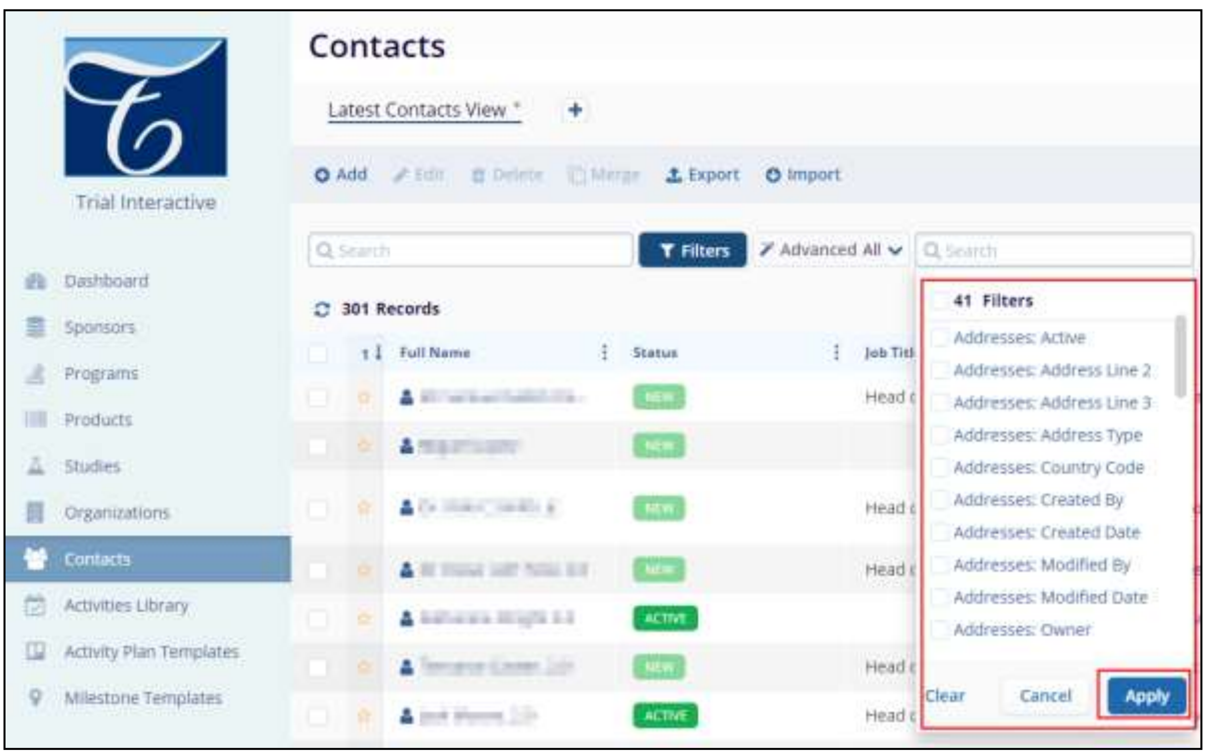


Figure: Apply standard filters

Advanced Filters

To add advanced filters, click on Advanced All dropdown > + Add Filter Rule > Add Filter Rule or Add Filter Group.

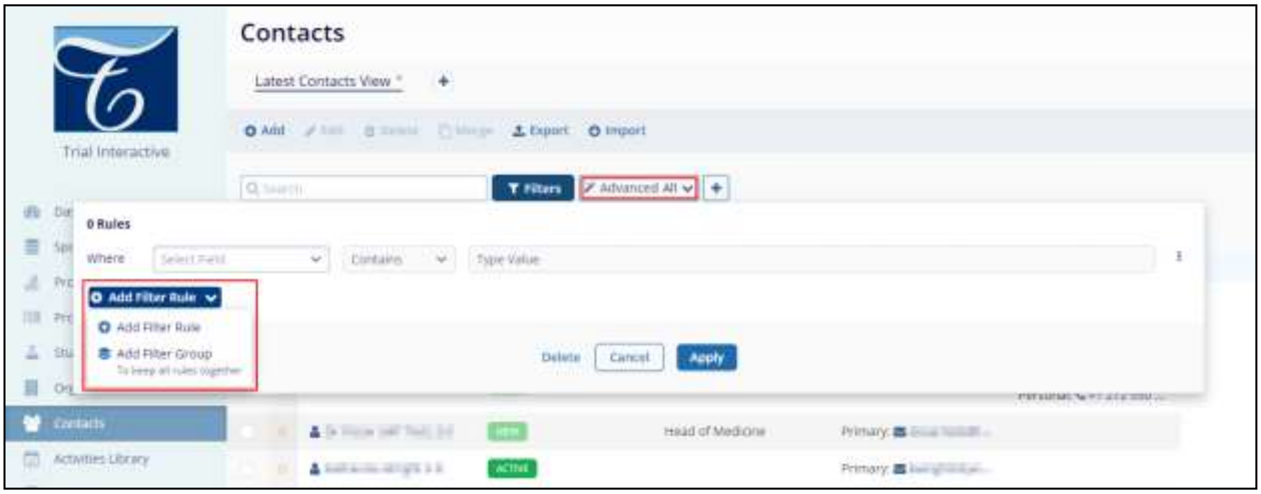


Figure: Apply Advanced Filters

The Advanced filters allow to filtering of the data by applying certain logical operators.

- For the +Add Filter Rule, select the required option from the Select Field dropdown.
- Select any one of the logical operators.

Important

- For the Addresses Active field, the following logical operators can be applied.

Logical operator	Description
Is	The address is either active or inactive. Select either Yes or No.
Is blank	The address is blank irrespective of whether it is active or inactive
Is not blank	The address is not blank irrespective of whether it is active or inactive.

- For other fields, the following logical operators can be applied.

Logical Operator	Description
Is	The content in the selected field matches to one entered in the text field beside the operator field.
Is not	The content in the selected field does not match the one entered in the text field.

Contains	The content in the selected field contains the following words mentioned in the text field.
Does not contain	The content in the selected field does not contain the words mentioned in the text field.
Starts with	The content in the selected field starts with the words mentioned in the text field.
Ends with	The content in the selected field ends with the words mentioned in the text field.
Is blank	The selected field is blank and does not contain any details.
Is not blank	The selected field is not blank and has some details entered.

In the example below, the applied filter will display all the records where:

Addresses: Address Line 2 is 134, Red Lion Street, London

- Selected Field: Addresses: Address Line
- Operator: Is
- Text: 134, Red Lion Street, London

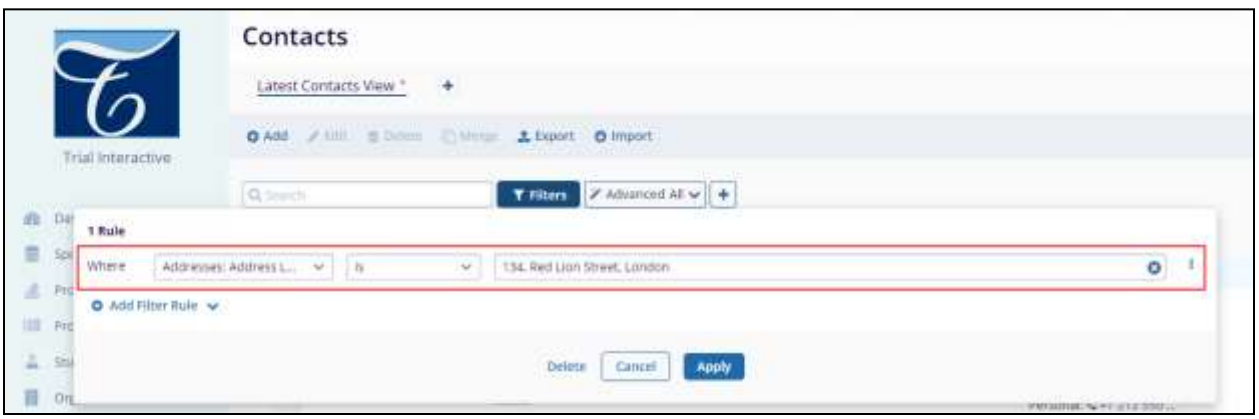


Figure: Configure Advanced filters

Furthermore, it is possible to add the And/Or conditions to the filters.

Referring to the above example, an additional filter with a different address line is added.

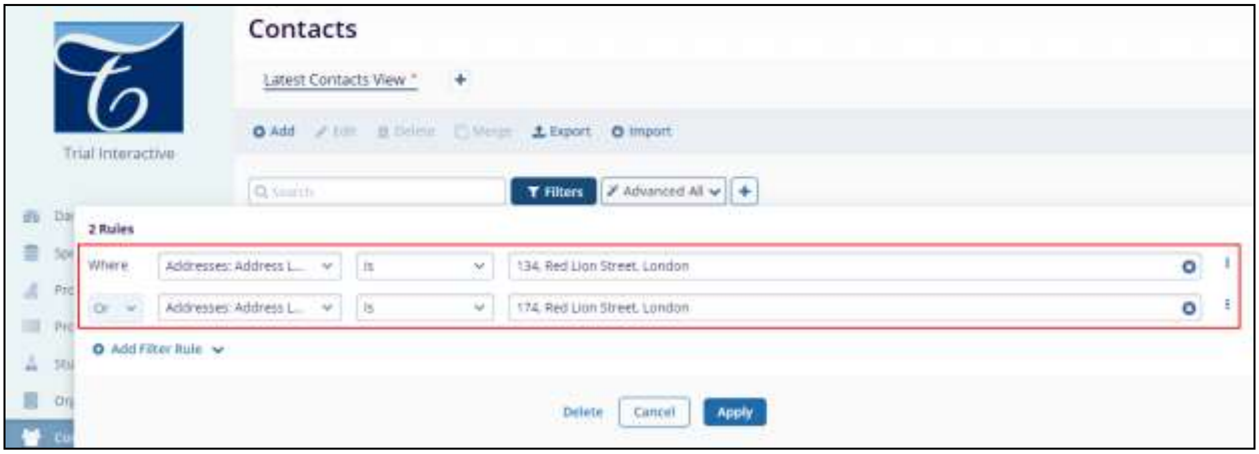


Figure: Advanced filters with And/Or conditions

Now, if And condition is applied, the system will display records that have both address lines i.e., 134, Red Lion Street, London, and 174, Red Lion Street, London

When the Or condition is applied, 134, Red Lion Street, London will be displayed by the system, as the initially configured filter takes precedence over the others.

Note: The same conditions apply to the Add Filter Group.

Once all the criteria and conditions are configured, click on Apply.

Customize Columns

Hide Column

To hide a column, follow the steps below.

1. Click on the ellipsis (vertical three dots) icon present beside each header field and select Hide Column.

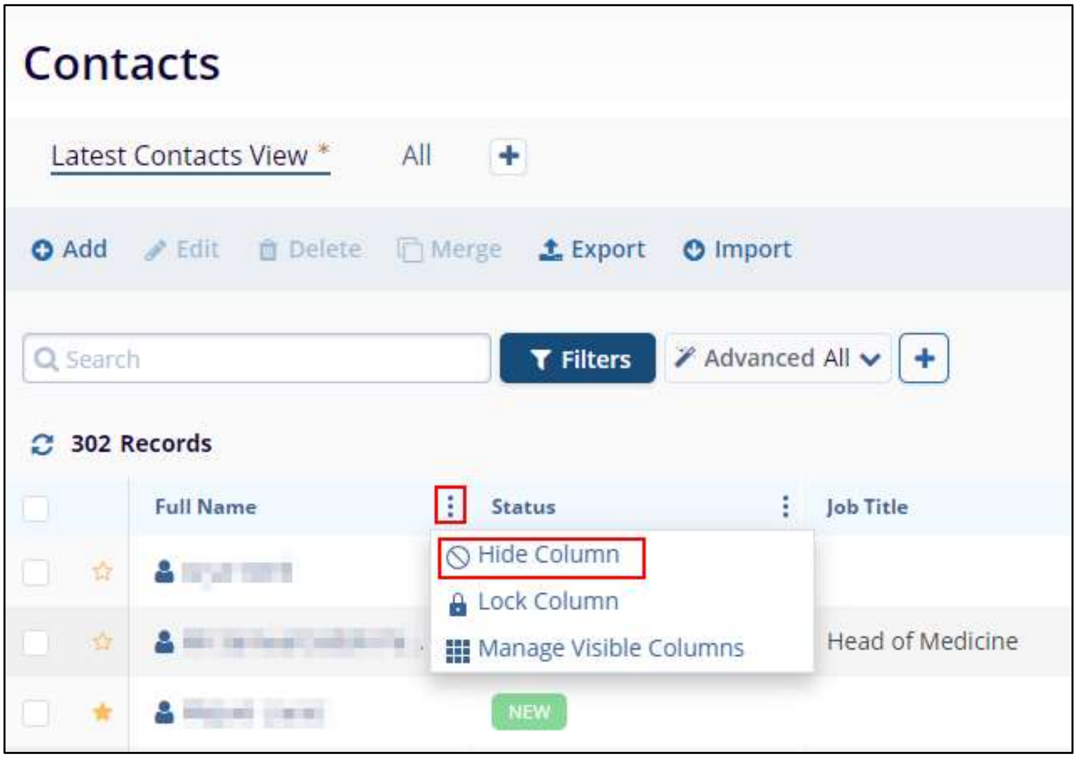


Figure: Hide Column

2. The particular column will not be visible on UI until and unless it is enabled by accessing the Manage Visible Columns option of any other column.

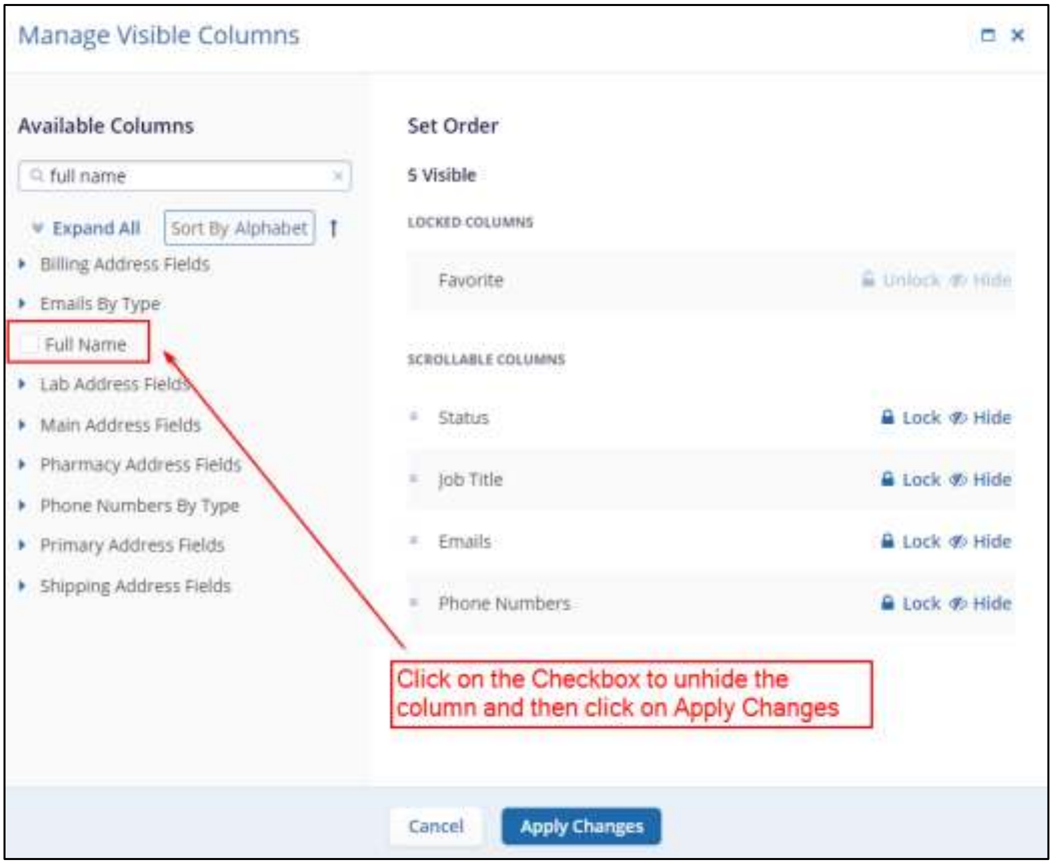


Figure: Unhide column

Lock Column

To lock a column, follow the steps below.

1. Click on the ellipsis (vertical three dots) icon present beside each header field and select Lock Column.

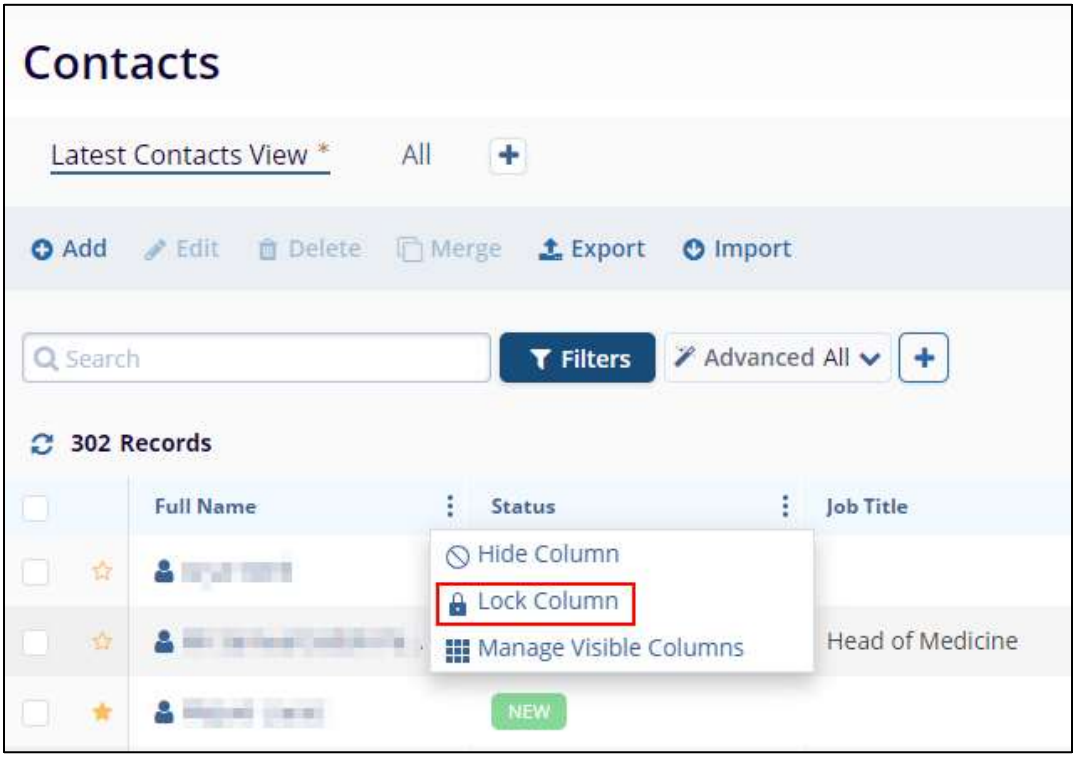


Figure: Lock Column

2. Once the Lock Column option is selected, that particular column will be pinned beside the favorites column.
3. To unlock a column, click on the ellipsis icon and select Unlock Column.

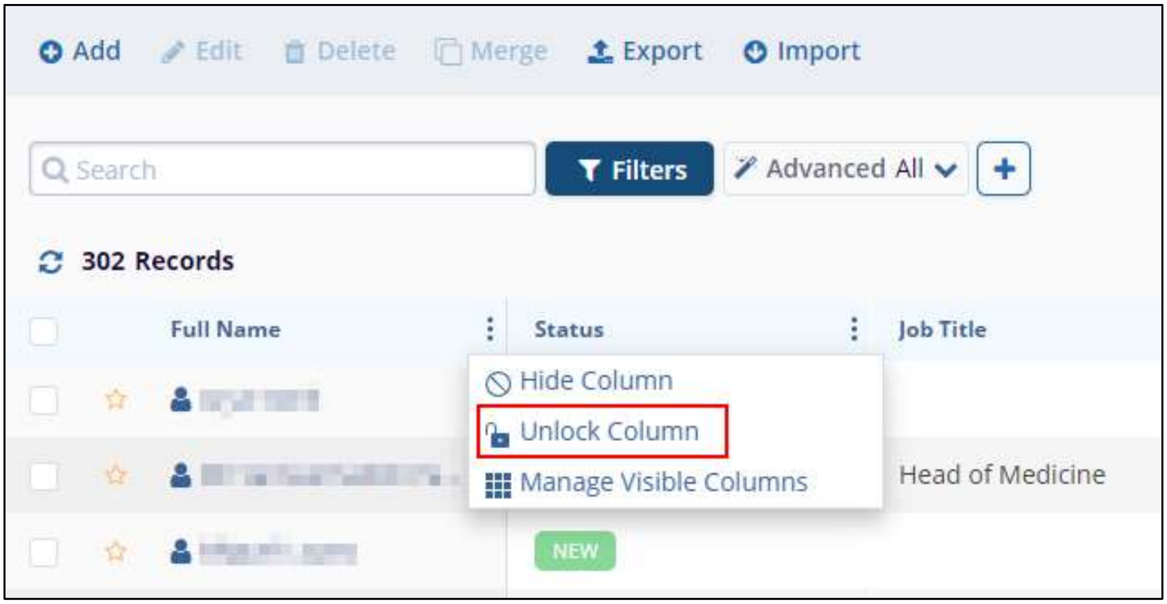


Figure: Unlock Column

4. It is also possible to unlock a column by accessing the Manage Visible Columns screen and selecting the unlock option.

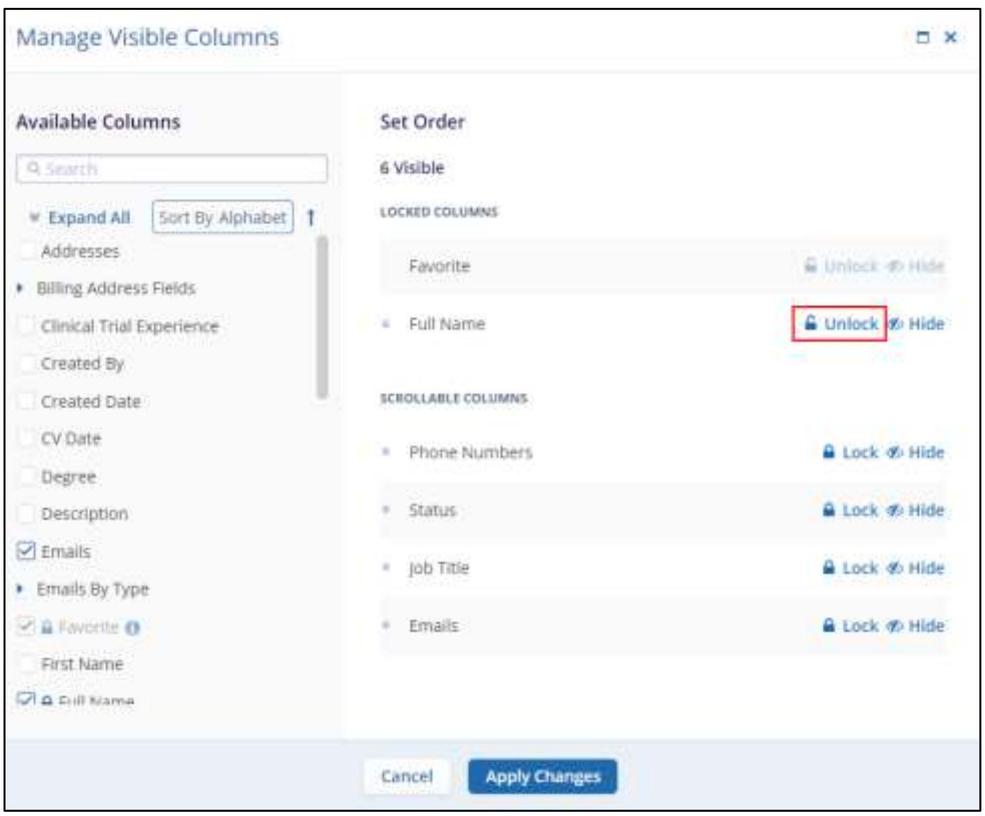


Figure: Unlock column through Manage Visible Columns

Manage Visible Columns

To access the Manage Visible Columns functionalities, follow the steps below

1. Click on the ellipsis (vertical three dots) icon present beside each header field and select Manage Visible Columns.

   Note: This option is visible only for those columns visible on the main Contacts screen.

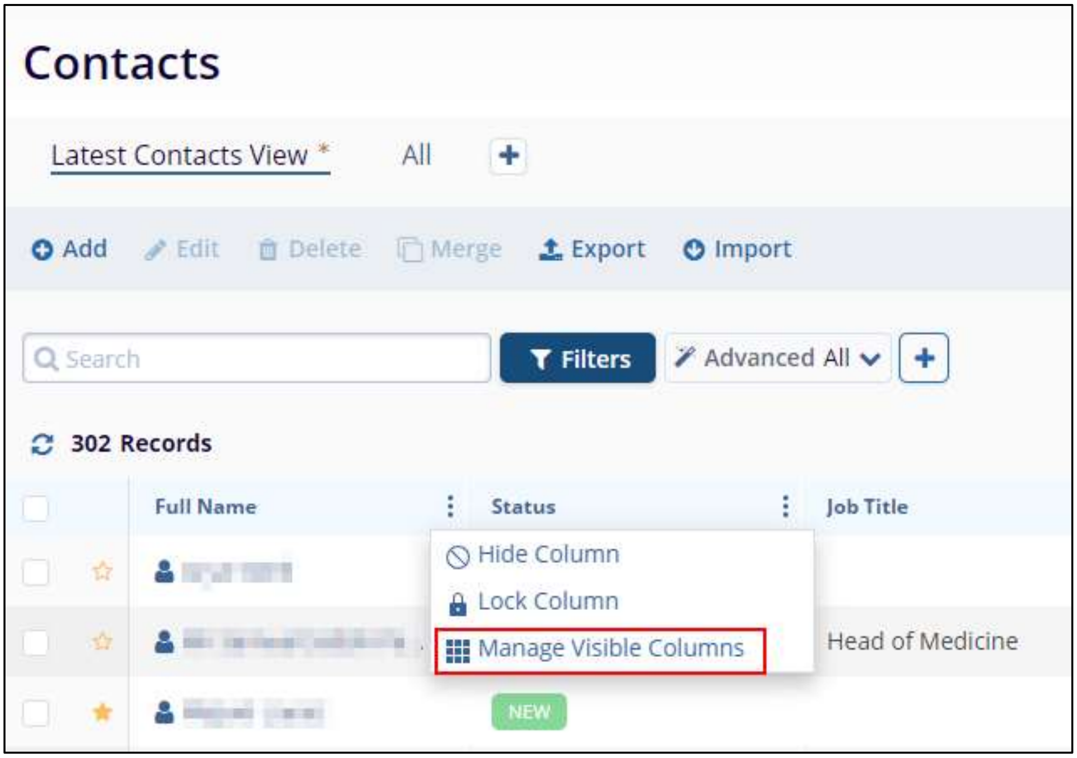


Figure: Manage Visible Columns

2. On the Manage Visible Columns screen, users can perform the following actions.
   a. Sort the available columns in ascending or descending order by clicking on the Sort By Alphabet arrow.
   b. Enter the search term in the Search box to retrieve the desired column name.
   c. Click on Unlock or Hide in the Locked Columns section so that the corresponding actions will be reflected on the main Contacts screen.
   d. Drag and place the columns in the desired sequence.

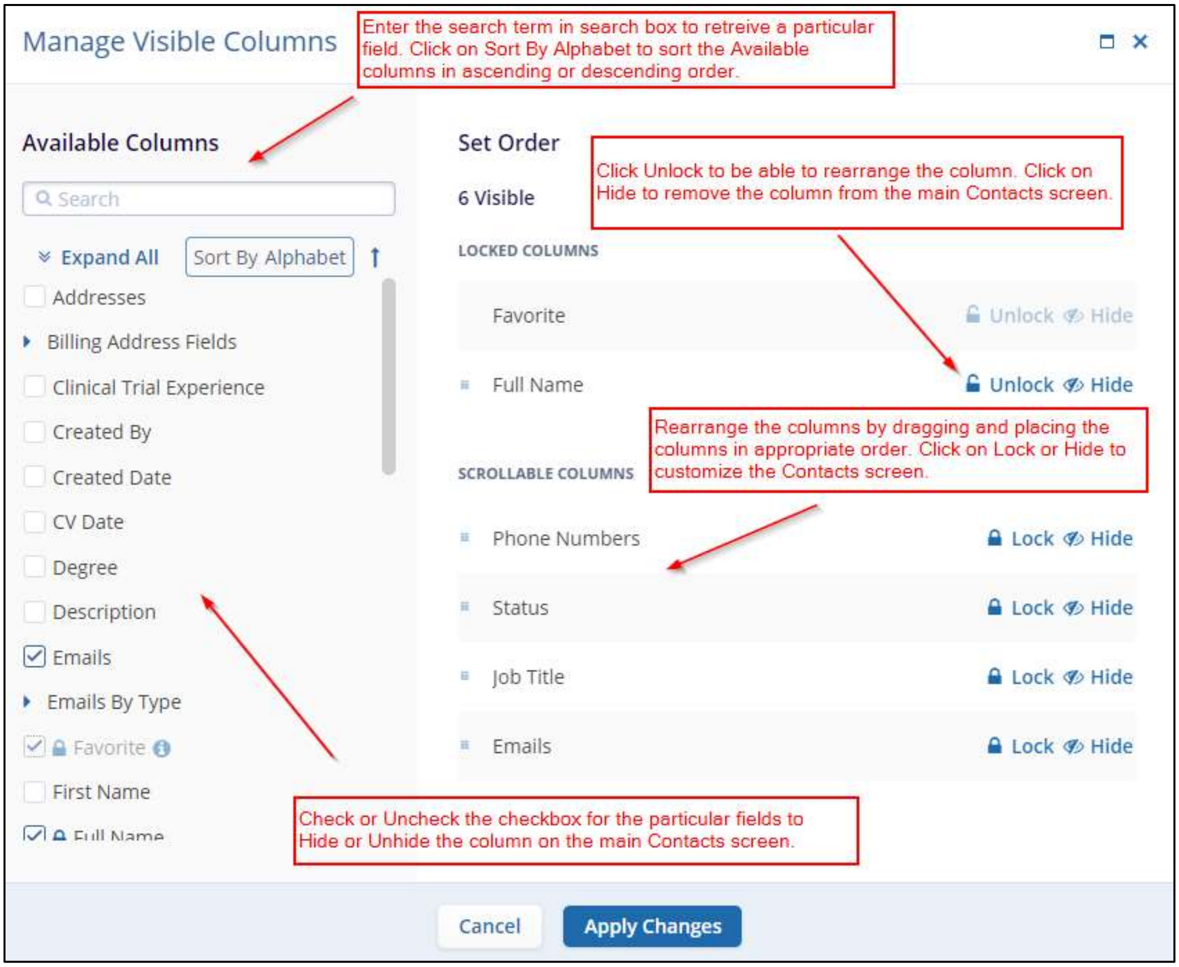


Figure: Manage Visible Columns options

3. Click on the Apply Changes button and the main Contacts screen will reflect all the customizations made on this screen.

Sorting Columns

To sort columns on the main Contacts screen, follow the steps below.

1. Click on the Sort By button situated on the right side of the screen.
2. Click on the +Add Sorting button to add multiple sorting criteria.
3. Select a sorting criteria from the available dropdown options.
4. Select either Descending or Ascending.
5. Click on Apply and the columns will display records based on the sorting criteria applied.

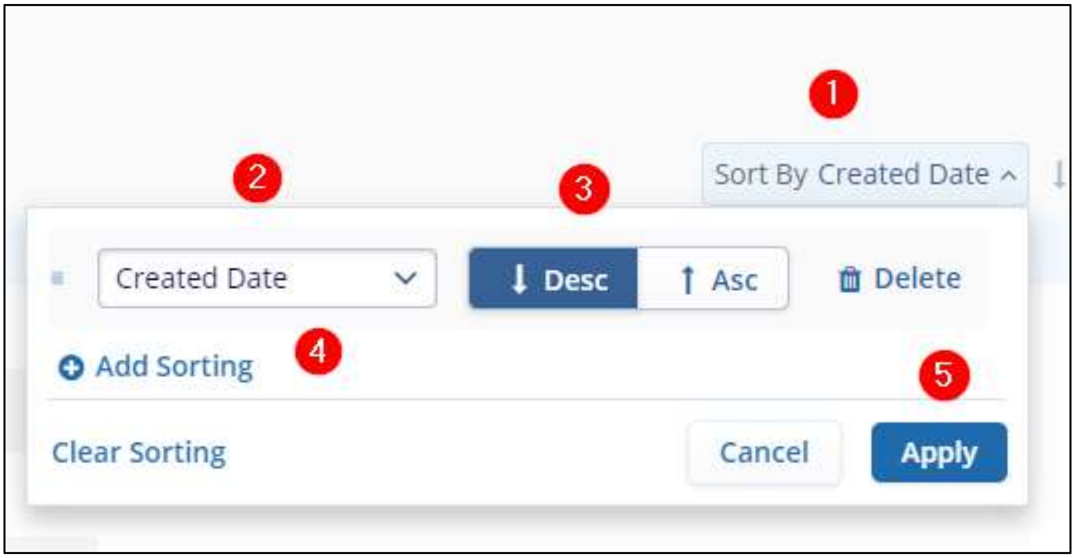


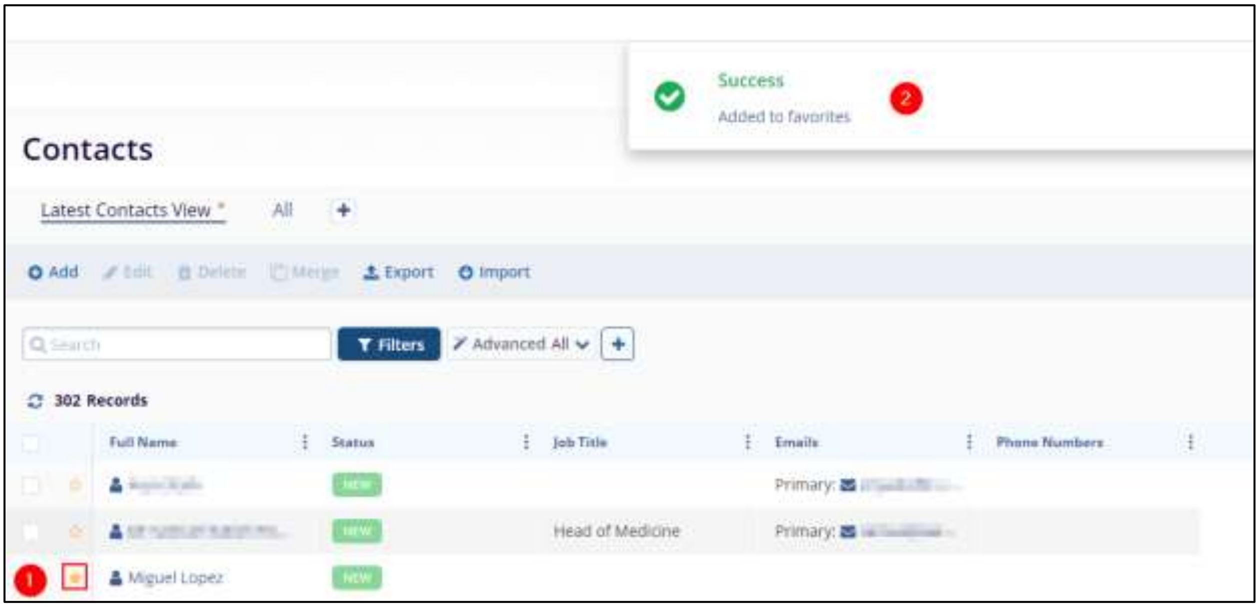
Figure: Apply sorting criteria

6. Additionally, click on Clear Sorting to remove all the sorting criteria and the Delete icon to remove individual sorting criteria.

Mark a contact as a favorite

To mark a contact as a favorite, follow the steps below.

1. Click on the mark as favorite (star) icon for a particular contact name.
2. The system displays a success notification once a contact is successfully added as a favorite.



Activities Library

Accessing Activities

To access the Activities Library, follow the steps below.

1. From the left-hand navigation links, select Activities Library.

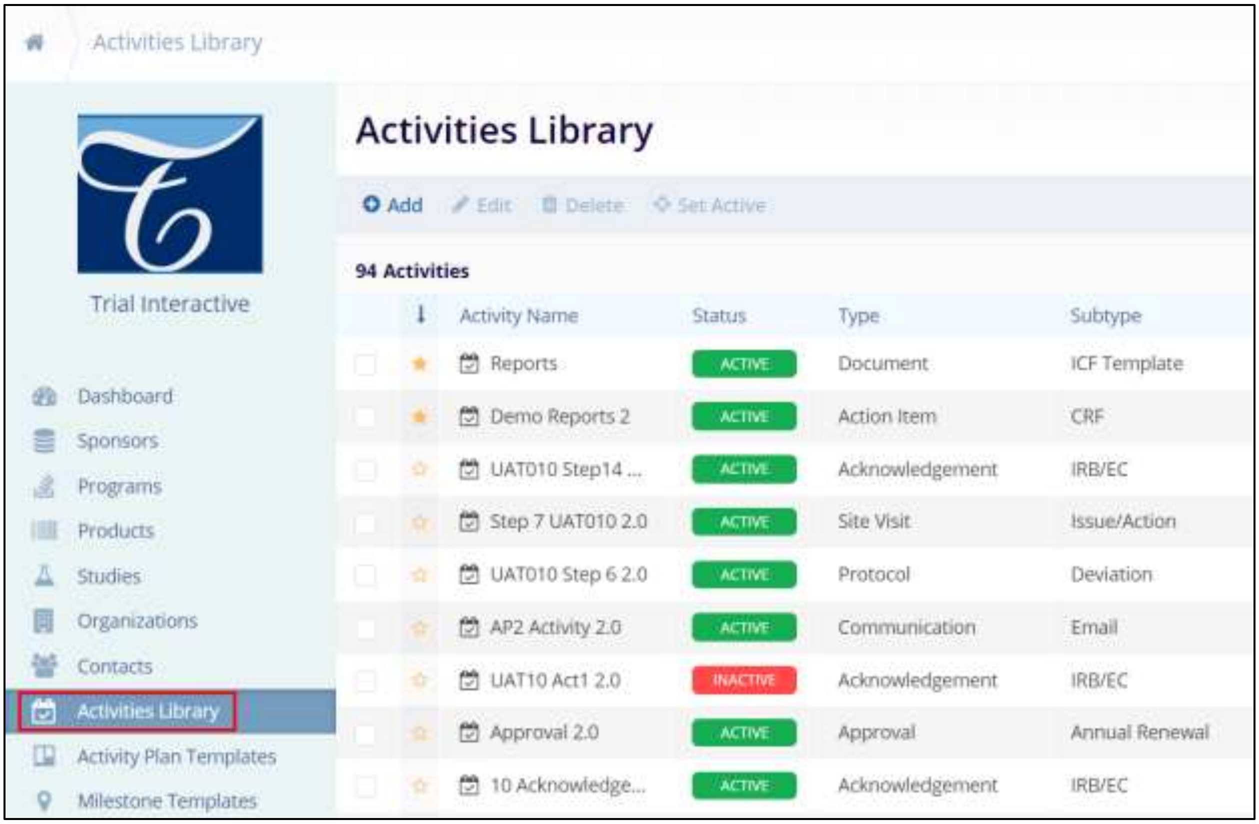


Figure: Accessing Activities Library

Creating Domain Library Activity Records

To create Domain Library Activity Records, follow the steps below.

1. On the Activities Library screen, click on the Add button in the top-left of the screen.
2. On the Create Activity screen, we need to enter the mandatory metadata to create an Activity.
   Note: Fields highlighted with a red asterisk (*) mark require a mandatory update.
   a. Activity
   b. Type
   c. Sub Type
   d. Description
3. Click on the Create button once all the mandatory details are filled.

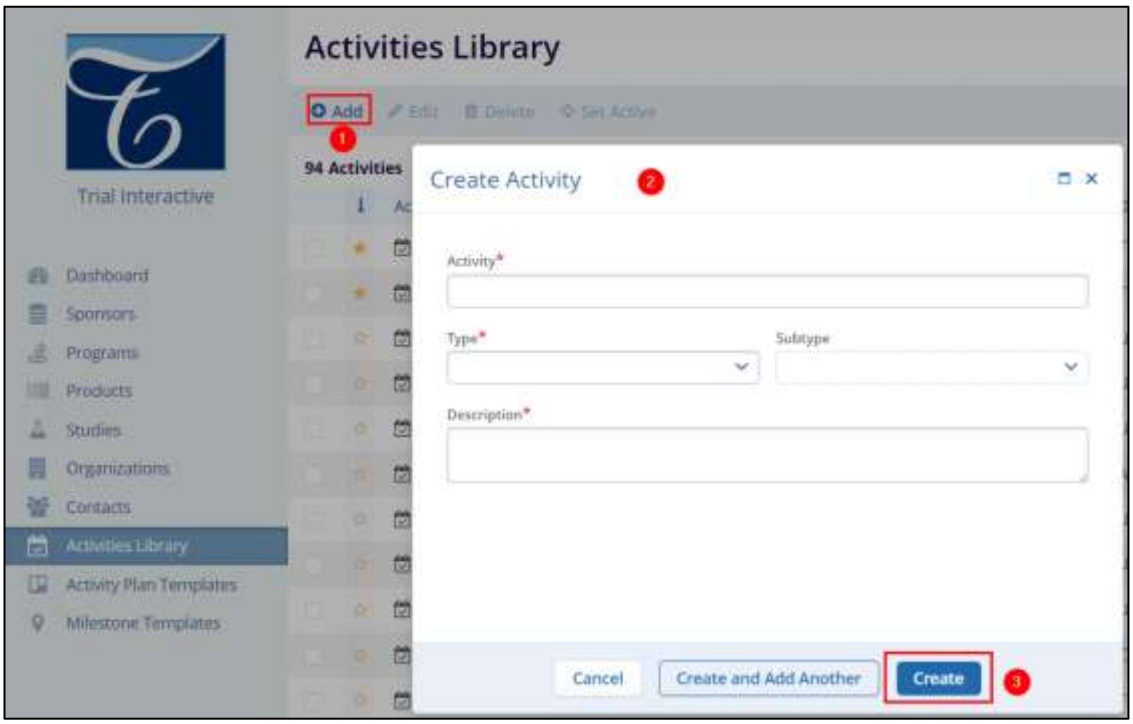


Figure: Creating Domain Library Activity Records

Note:

- Initially, the Sub Type field is greyed out. Once the user selects a value for the Type from the dropdown menu the related values for the sub-type appear in the dropdown menu.
- Click Create or Create and Add Another button and users can add another activity on the same screen without accessing the +Add button.

Editing Domain Library Activity Records

To edit Domain Library Activity Records, follow the steps below.

1. Navigate to the activity name to edit and click the check box of the activity name.
2. Click on the Edit button on the top menu bar which opens the quick view panel.
3. On the quick view panel make the required changes
4. Click on the Save button once all the details are edited.

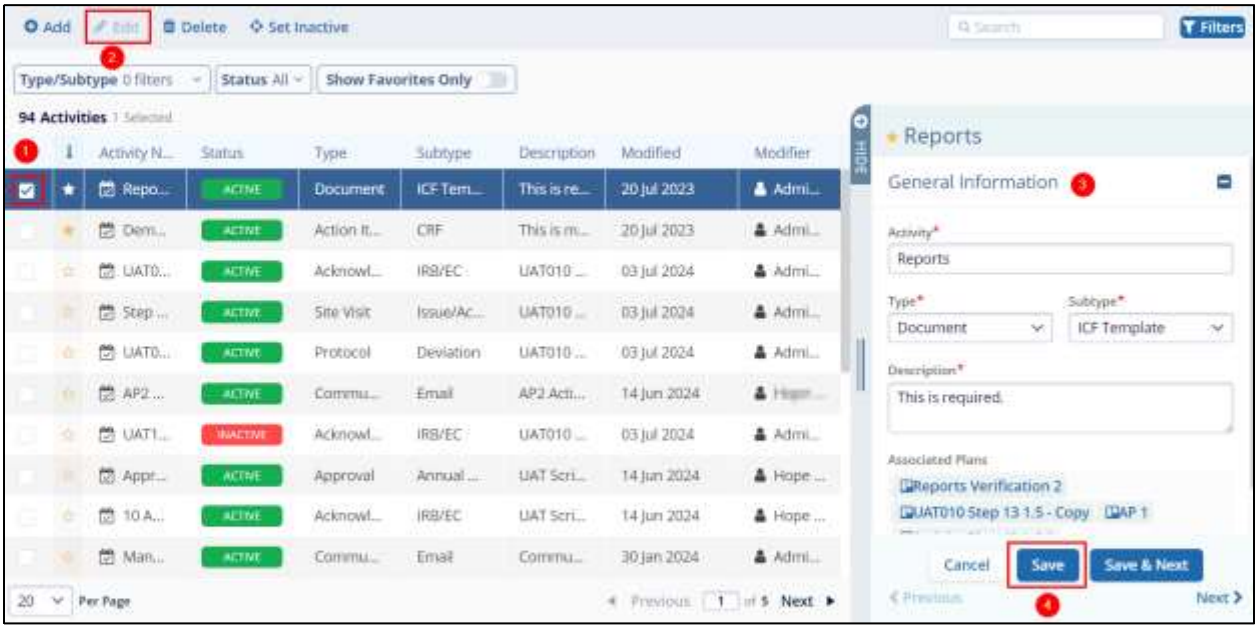


Figure: Editing Domain Library Activity Records

Deleting Domain Activity Records

To delete Domain Library Activity Records, follow the steps below.

1. Navigate to the activity name to edit and click the check box of the activity name.
2. Click on the Delete button on the top menu bar which opens the quick view panel.
3. Click on the Delete button on the confirmation popup.

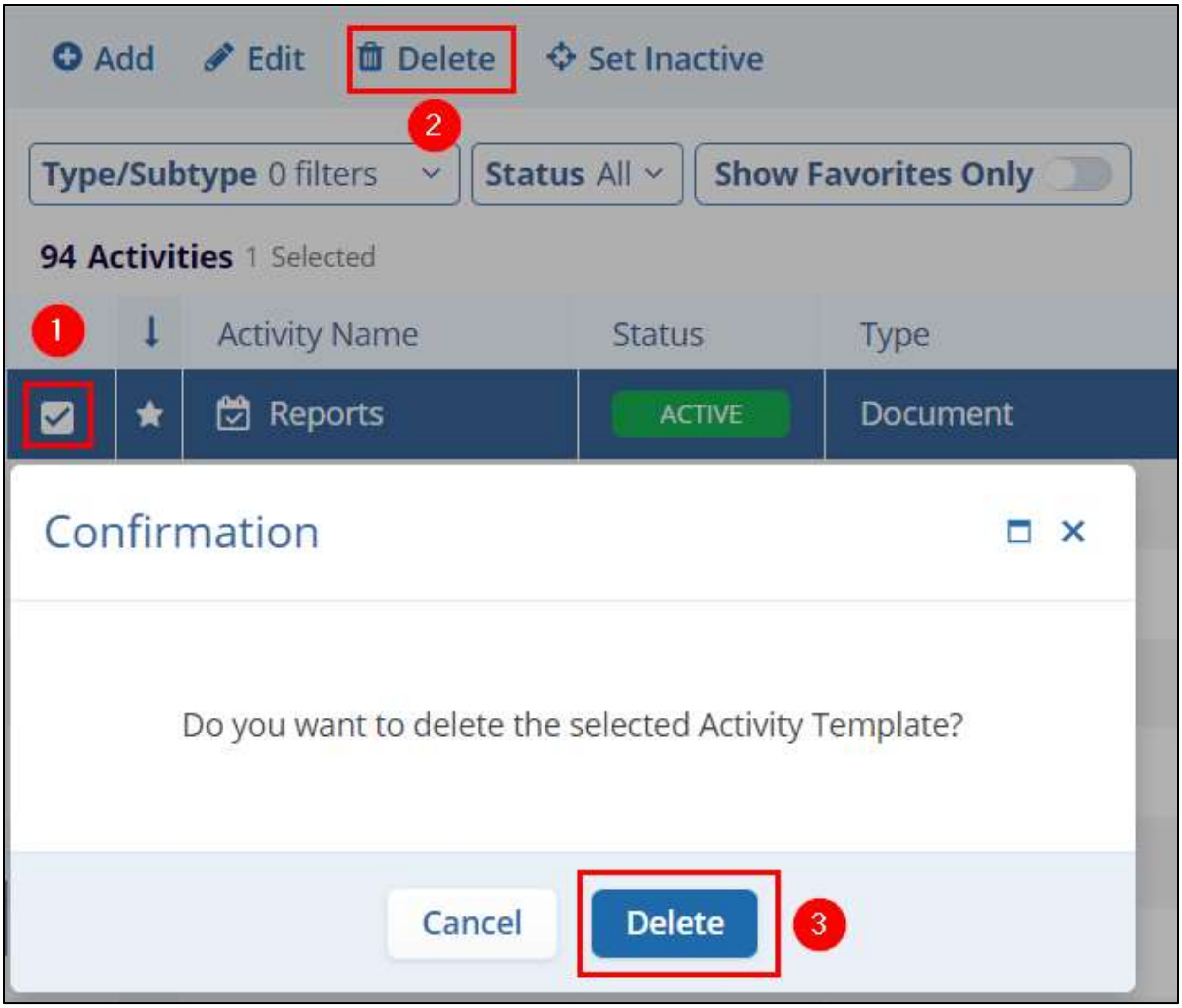


Figure: Deleting Domain Activity Records

Setting Domain Activity Records to Inactive

To set an active activity record to inactive, follow the steps below.

1. Navigate to the activity name to edit and click the checkbox of the activity name with an Active status.
2. Click on the Set Inactive button from the top menu bar.
3. Click on Set Inactive on the confirmation popup.

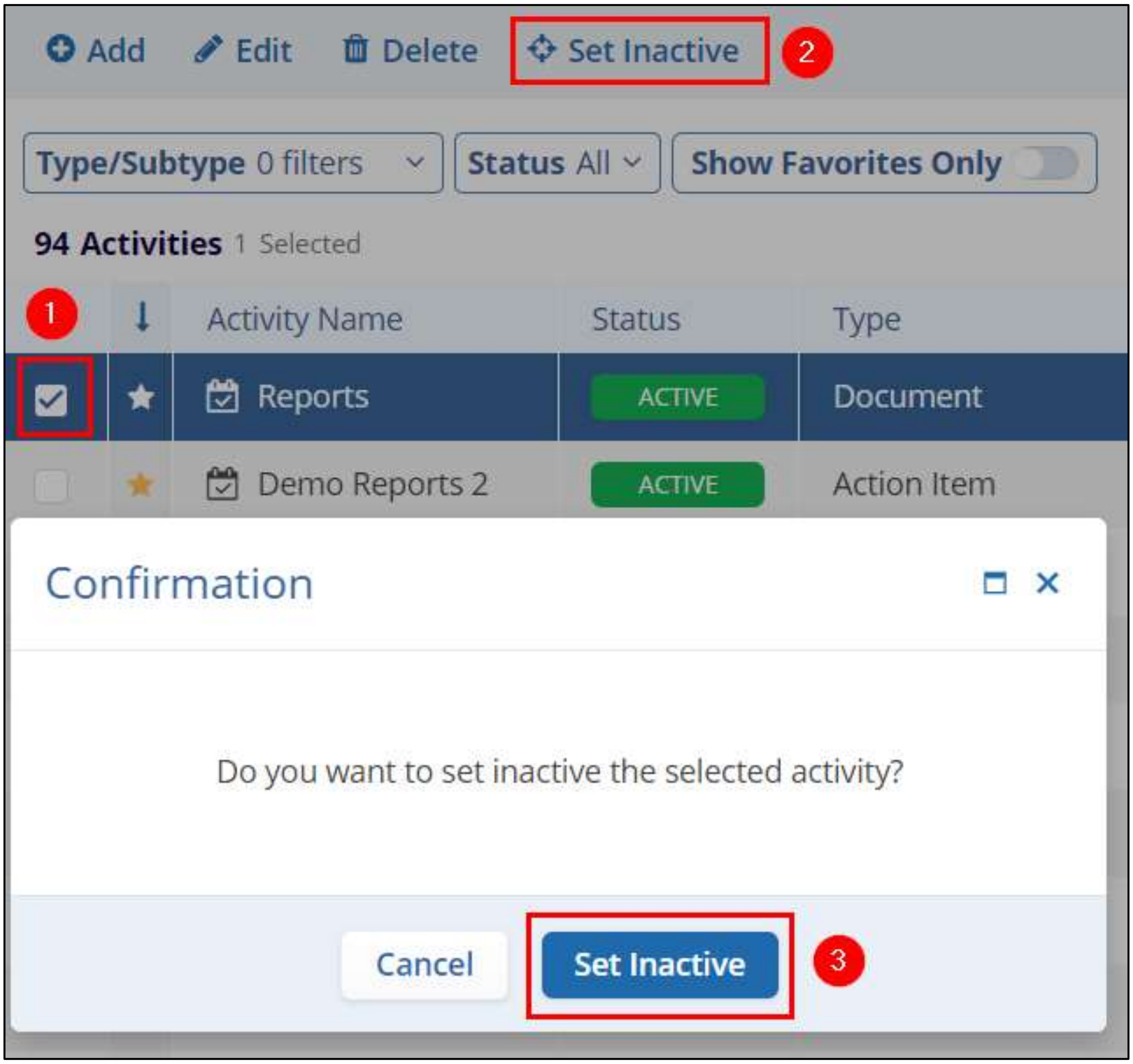


Figure: Change activity record status to Inactive

Customizing Activities Library screen

Filters and Sorting

To apply filters and sort columns, follow follow the steps below

1. Click on Filters, beside the search box and apply the following filters.
    a. Type/SubType: Select the type or subtype from the dropdown options
    b. Status: Select either Active or Inactive
    c. Show Favorites Only: Switch the toggle to display records marked as favorites.
2. To sort the data in ascending and descending order, click on the arrow in the favorites column header.

Marking an activity as a favorite

To mark an activity as a favorite follow the standard steps detailed in Mark a contact as a favorite section.

Activity Plan Templates

Accessing Activity Plan Templates

To access Activity Plan Templates, follow the steps below.

1. From the left-hand navigation links, select Activity Plan Templates.

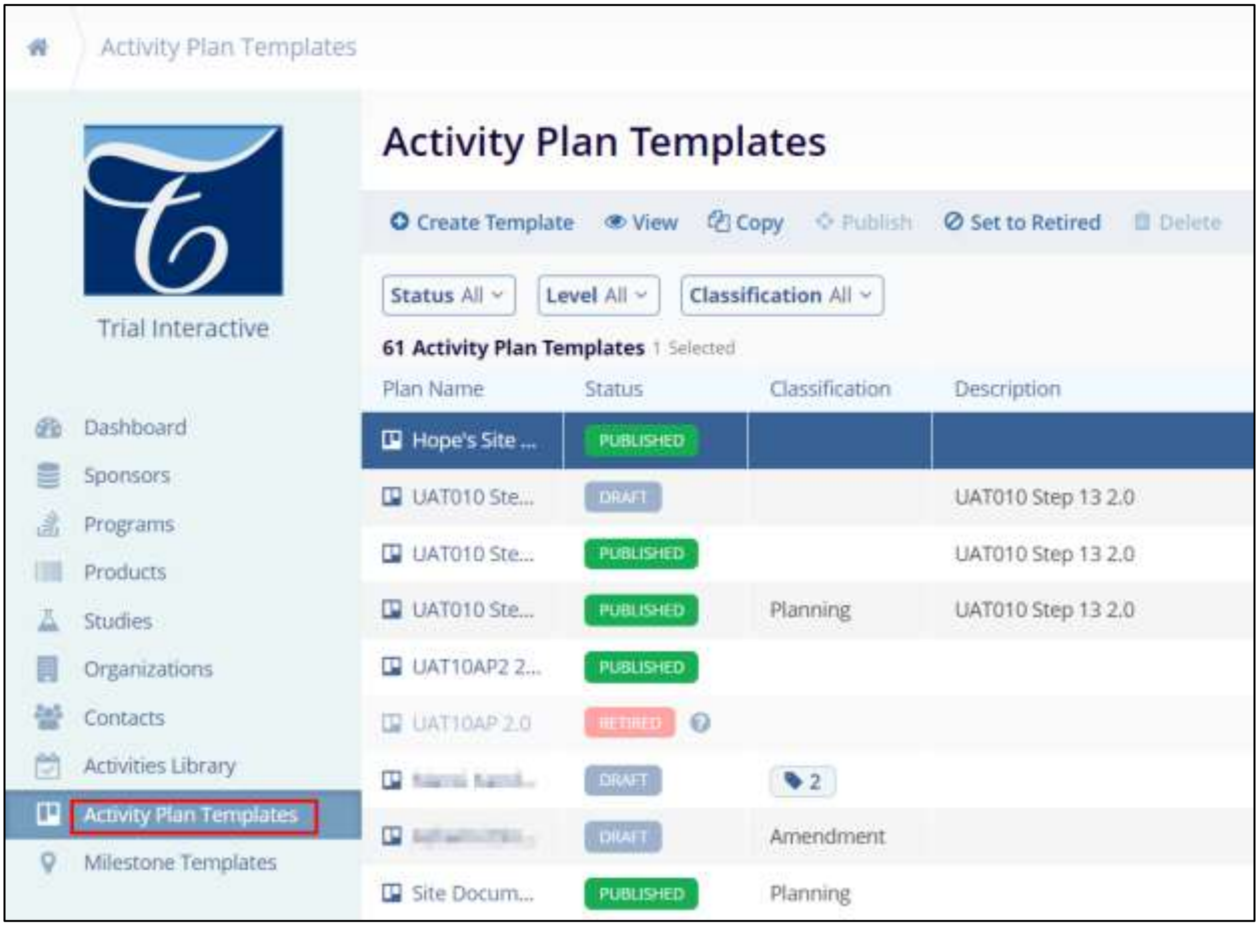


Figure: Accessing Activity Plan Templates

Creating Domain Library Activity Template

To create a Domain Library Activity Template, follow the steps below.

1. On the Activity Plan Templates screen, click on +Create Template.

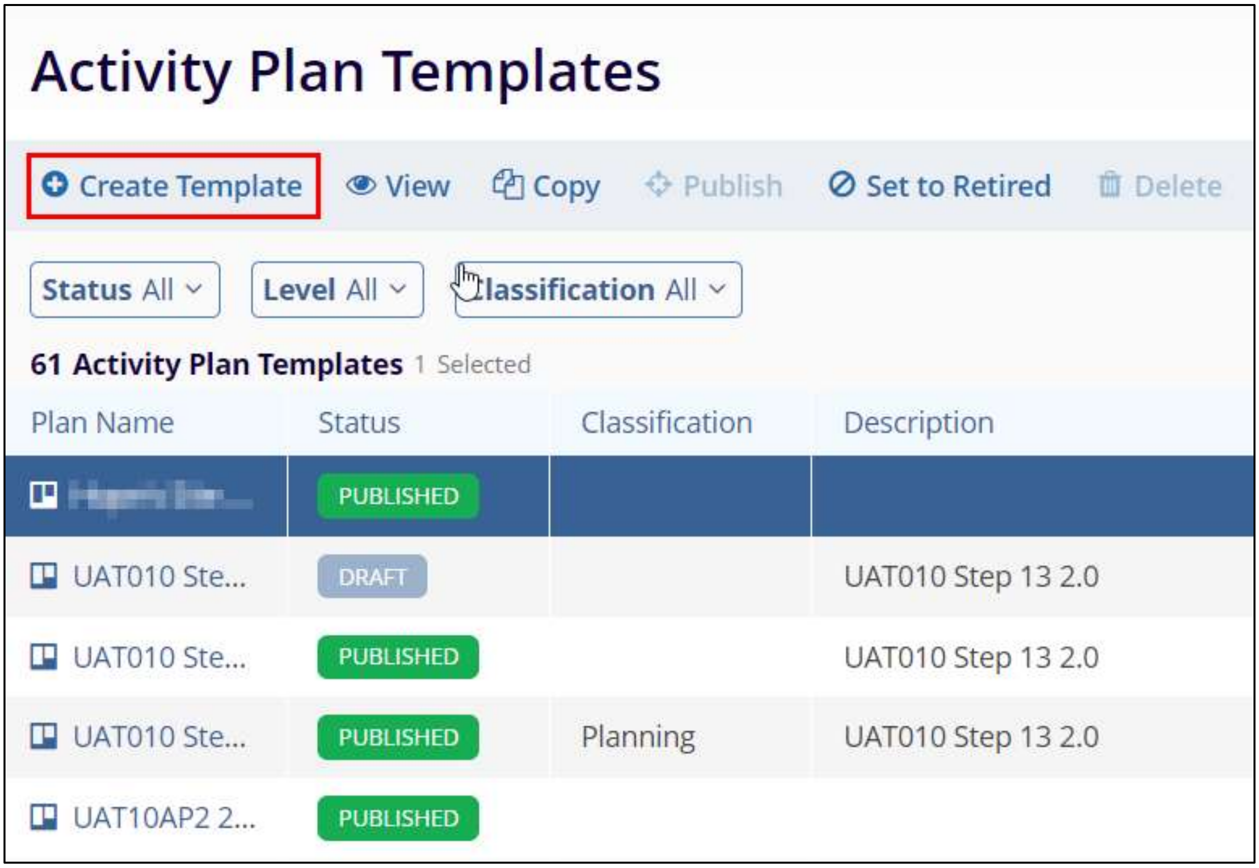


Figure: Create Domain Library Activity Template

2. On the General Information screen, fill in the following details
   a. Activity Plan Name*: Enter a name for the Activity Plan
   b. Level*: Select whether the template is to be created at the Study, Country, or Site level.
   c. Classification: Select the classification criterion from the available dropdown options.
   d. Description: Enter a suitable description for the Activity plan
   e. Status: By default, the template will be in Draft status.
   f. Select Parent Plan: Switch the toggle and select a Parent Plan* from the available dropdown options.

   Note: Fields highlighted with a red asterisk (*) mark require a mandatory update.

3. Click on Create, and Next Add Activities button once all the details are added.

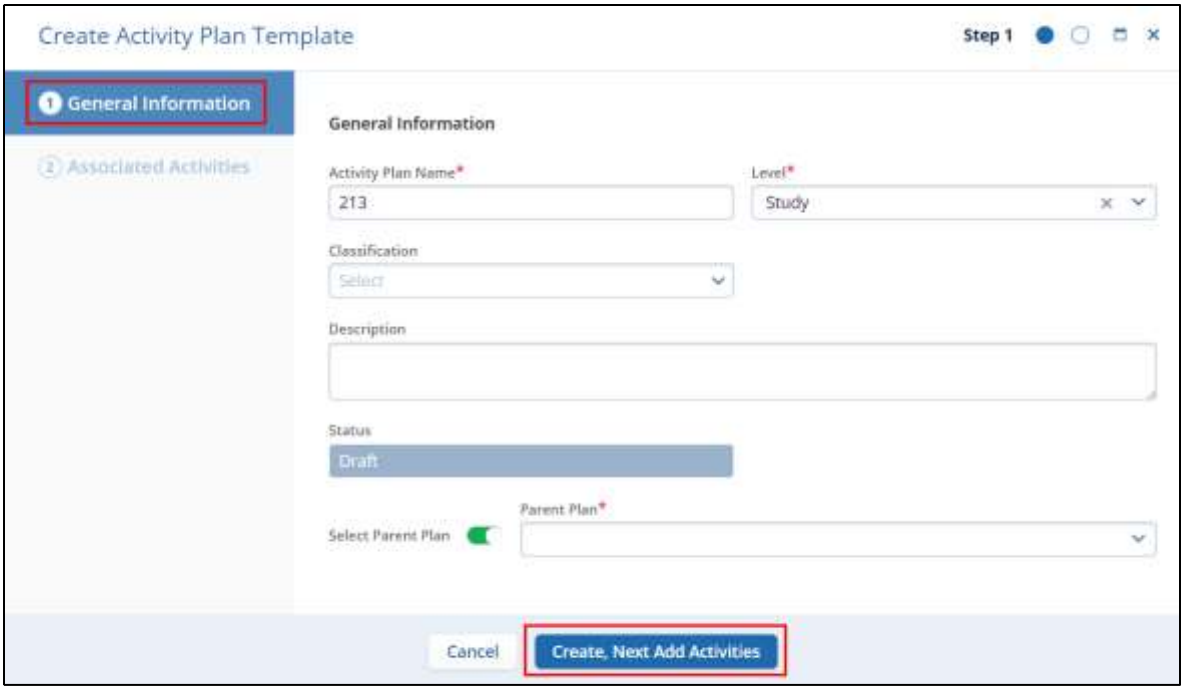


Figure: Domain Library Activity Template-General Information

4. On the Associated Activities screen, perform the following to complete creating the Domain Library Activity Template.

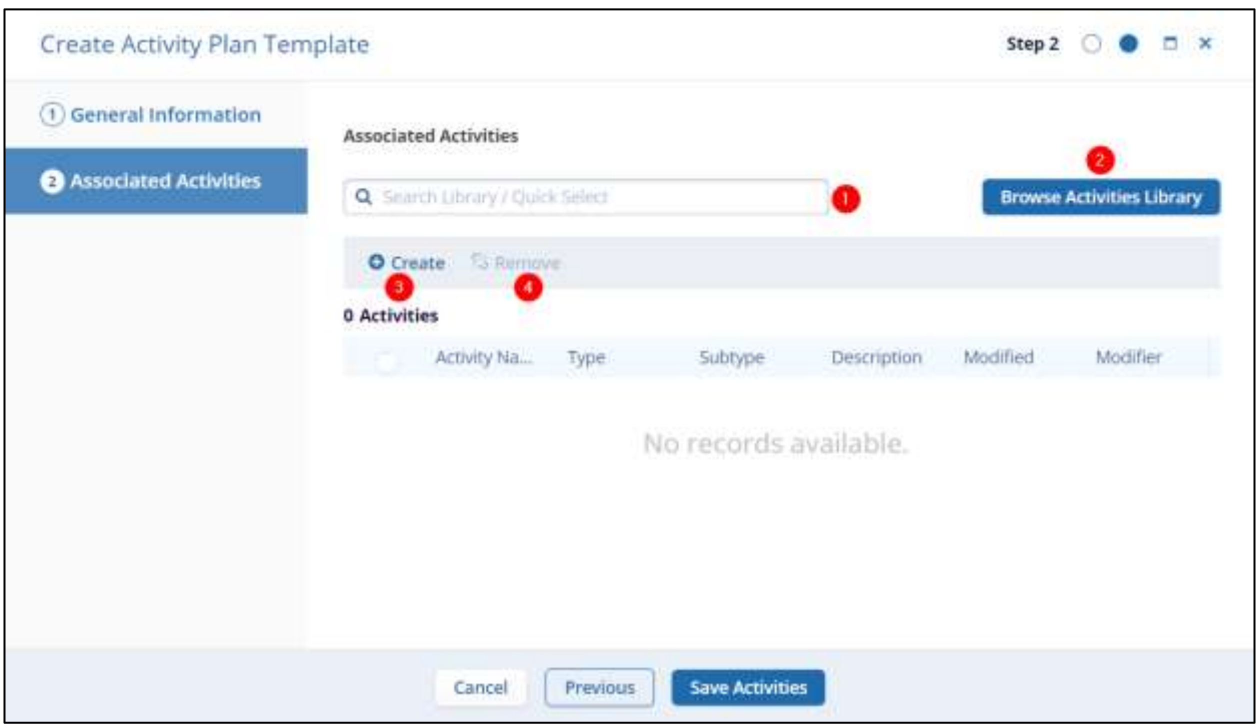


Figure: Domain Library Activity Template-Associated Activities

a. Search Library/Quick Select: Click on the search box and enter the library to add it to the template. Once the library is selected it gets added to the template.

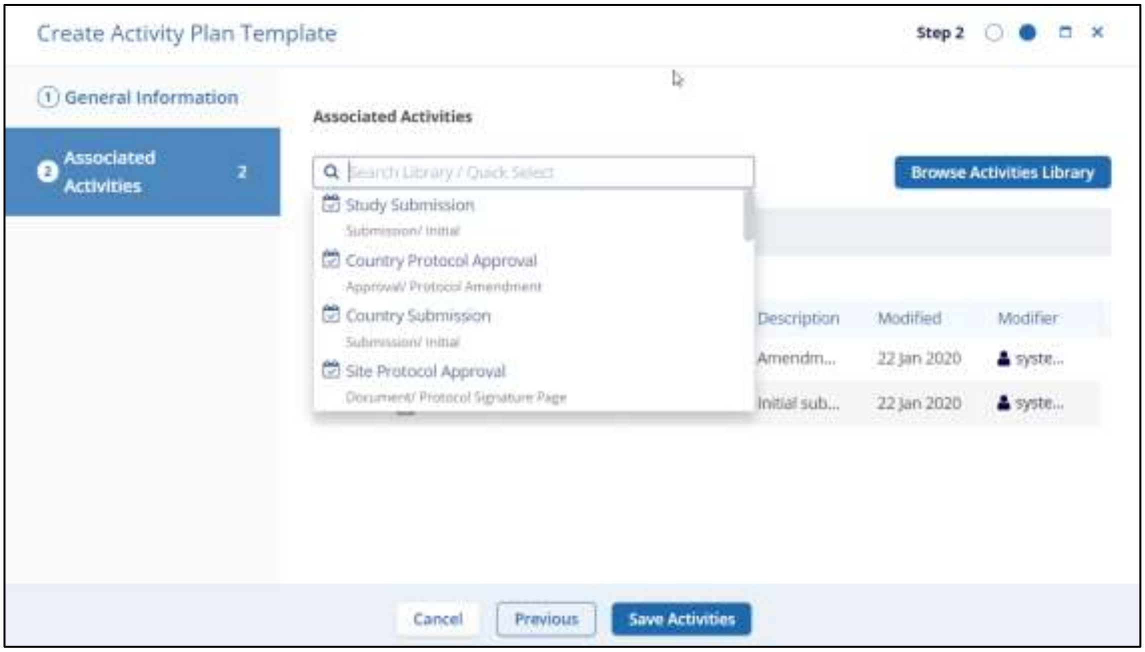


Figure: Search Library and Quick Select

b. Browse Activities Library: Click on the Browse Activities Library button to get a list of all library types. Click on the required library's checkbox to select and click on the Add Activities button.

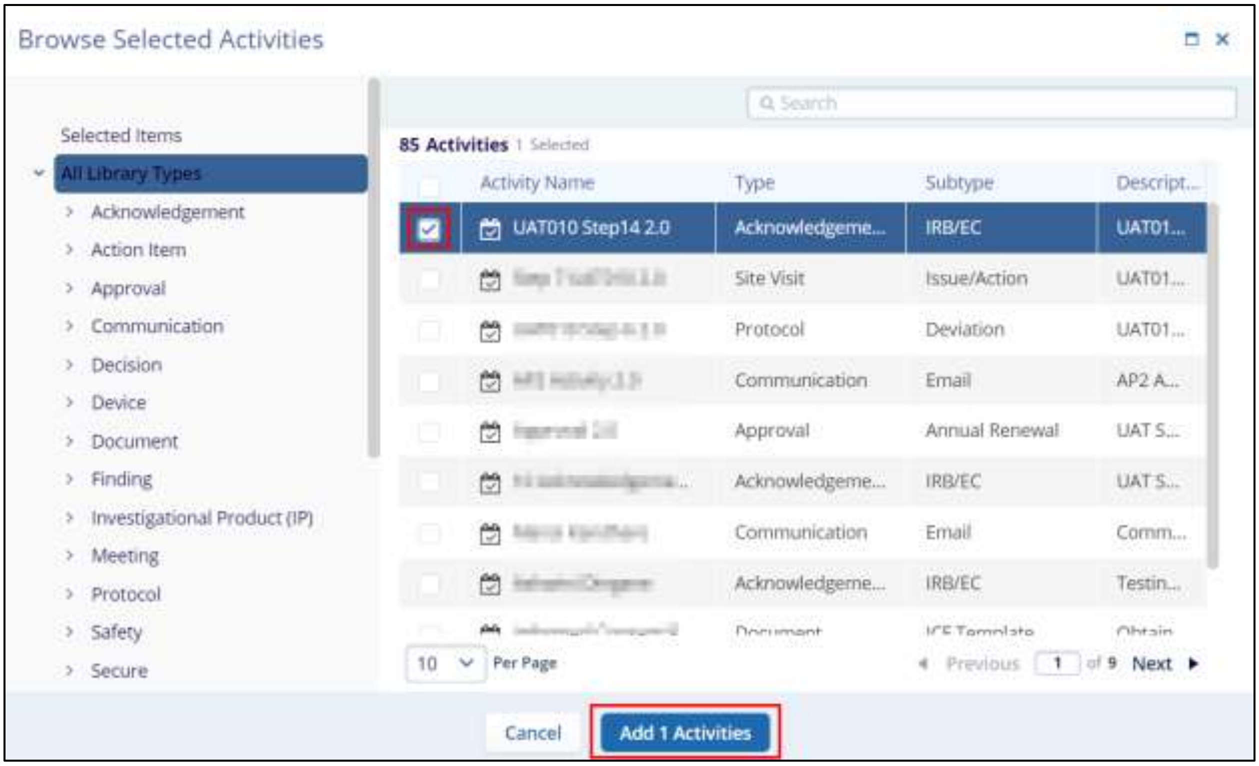


Figure: Browse Activities Library

c. Create Activity: Click on +Create to create a new activity and enter the mandatory details into their respective fields.

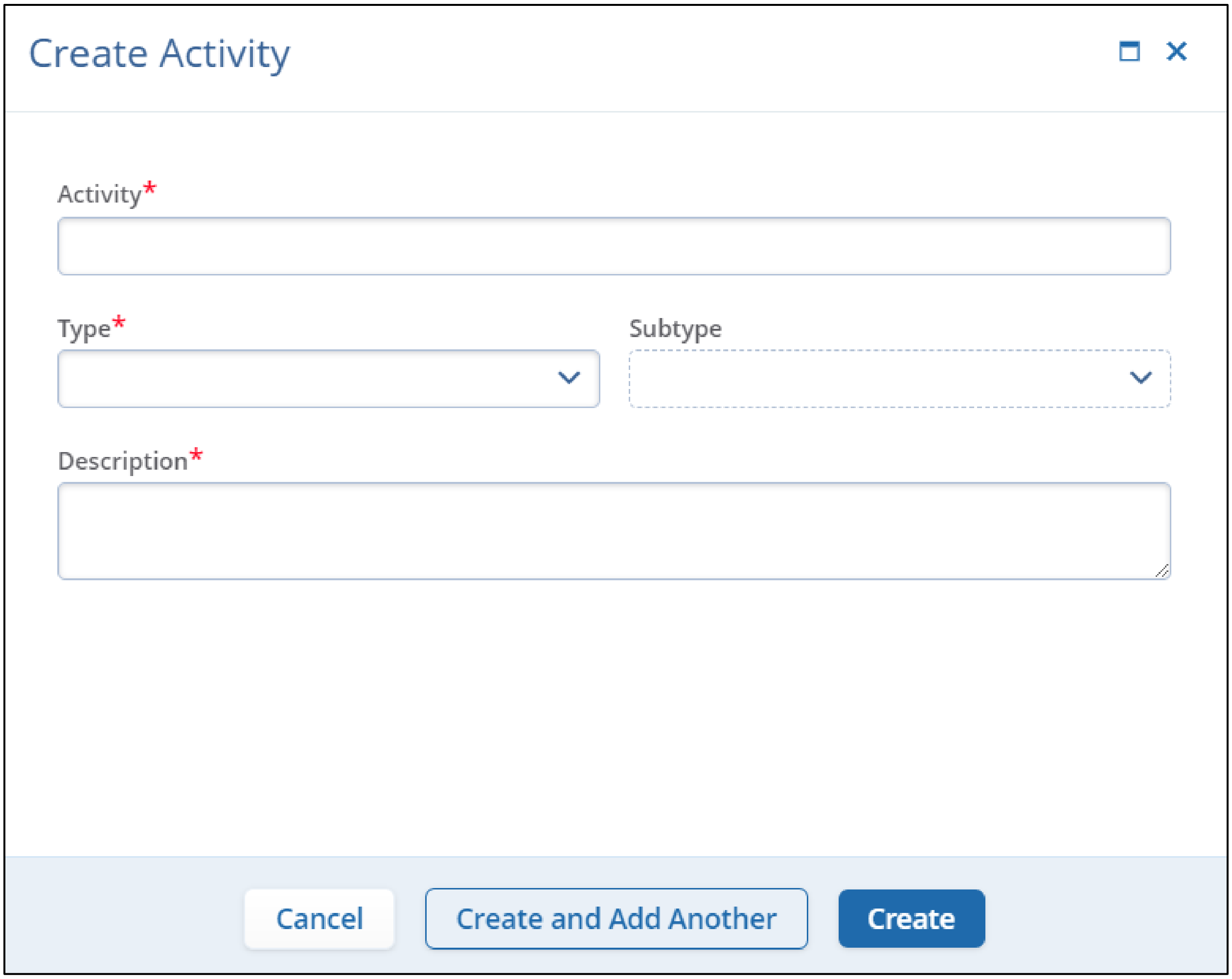


Figure: Create New Activity

d. Remove Activity: Click on the checkbox of activity to select and click the Remove Activity button to discard it from the template.

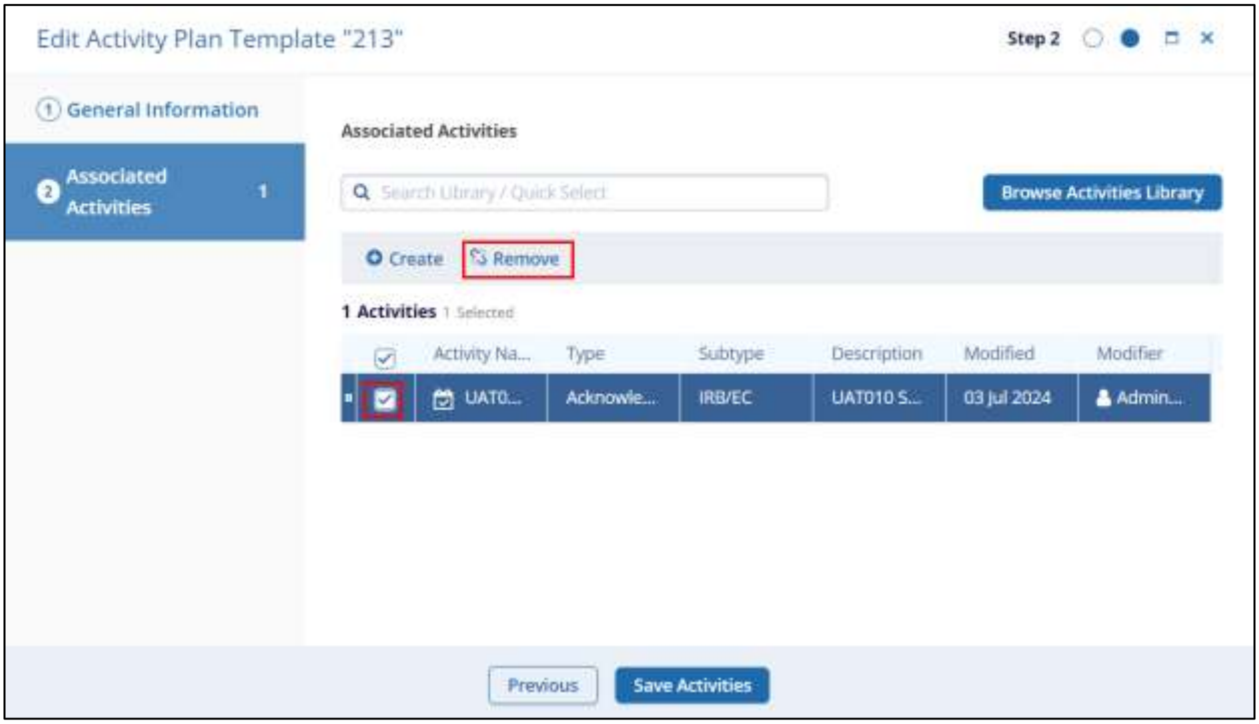


Figure: Remove Activities

5. Once all the details are entered click on Save Activities.

View Published Template Details

To view the published template details, follow the steps below.

1. Select an activity plan template in the Published state and the View icon becomes visible in the top menu bar
2. Click on the View icon.
3. View the General Information and Associated Activities details on the View Activity Plan Template screen.

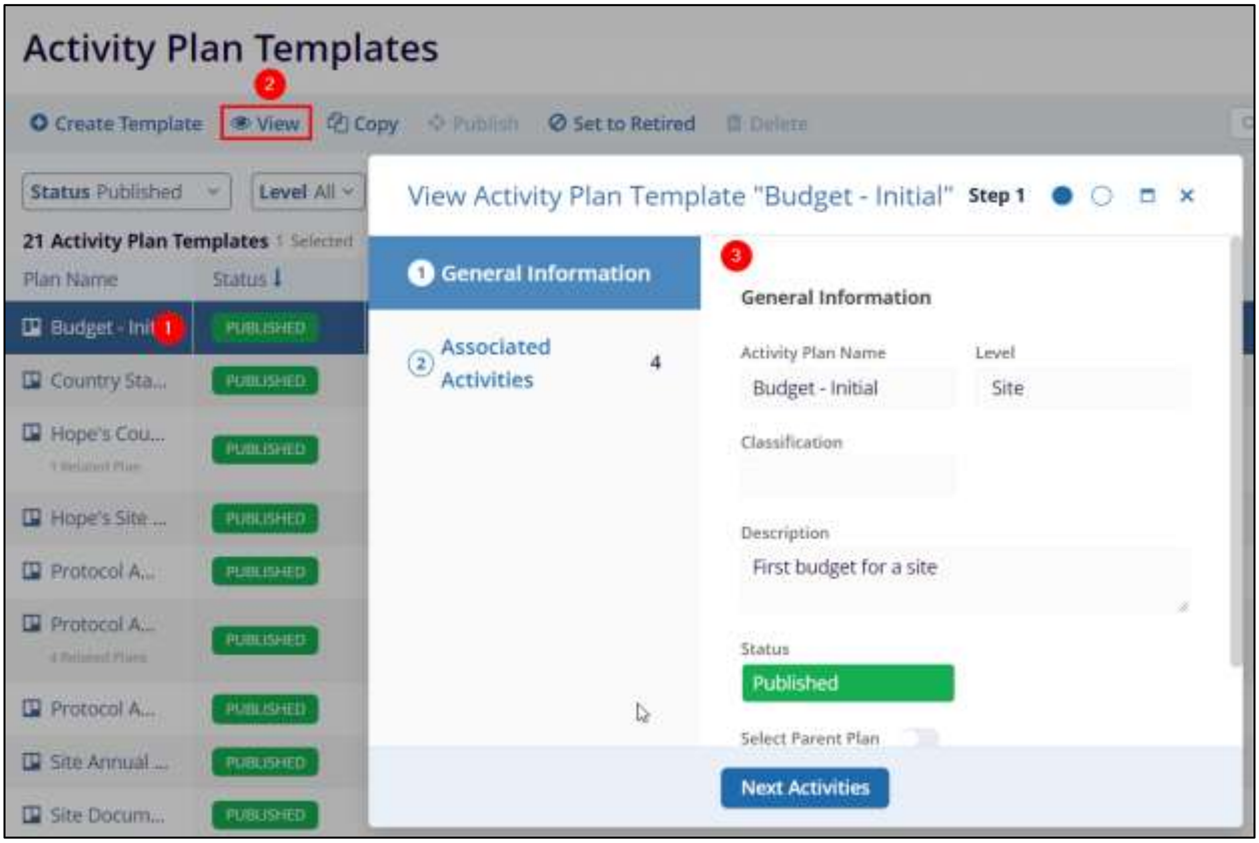


Figure: View Activities Plan Template

Editing Activity Plan Templates

To edit an Activity Plan Template, follow the steps below.

Method 1

1. Select a plan by clicking on the plan tile.
2. Click on the Edit icon from the top menu bar.
3. On the Edit Activity Plan Template Window, access the General Information and Associated Activities screen to make edits and save the changes.

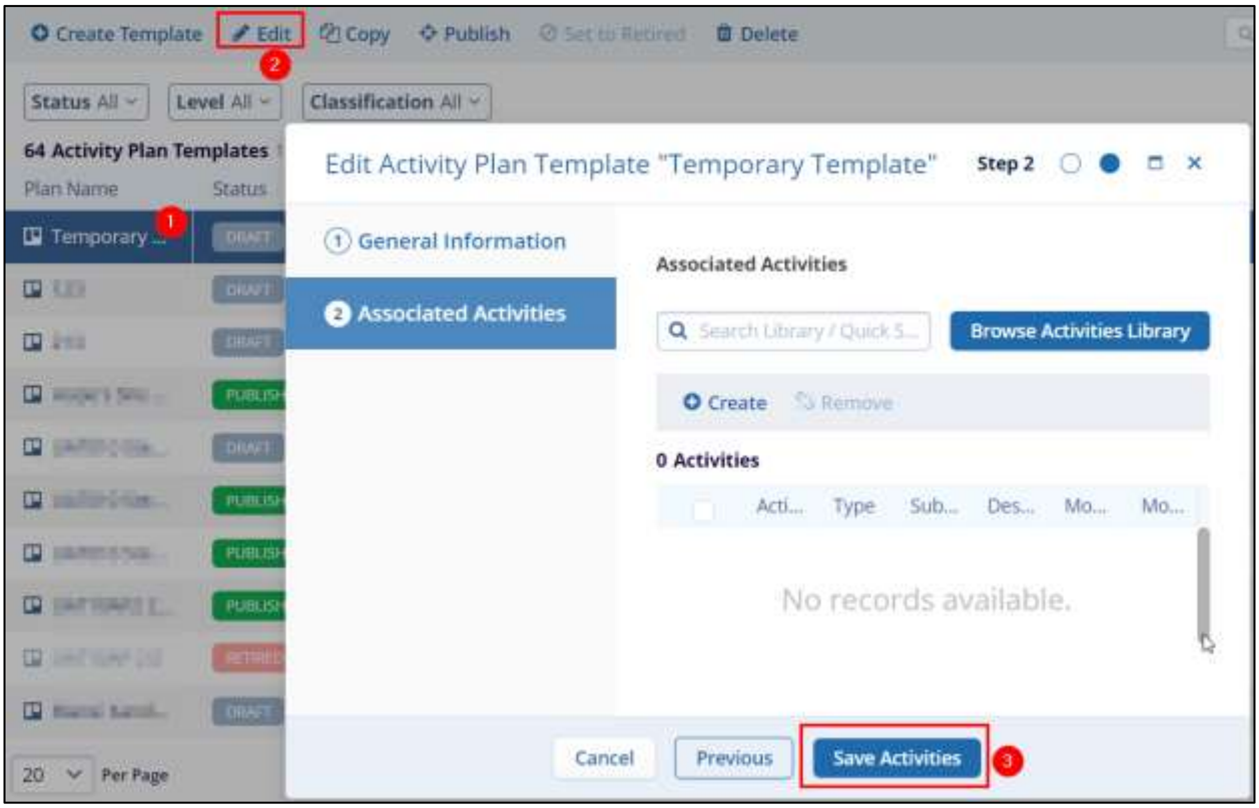


Figure: Edit Activity Plan Template-Method 1

Note: Do not click on the plan name since it directly opens the Edit Activity Plan Template screen which is another method to edit an activity plan.

Method 2

1. Select an activity plan by specifically clicking on the plan name.

Figure: Select plan name

2. Click on the Edit (Pencil) icon on the View Activity Plan Template.

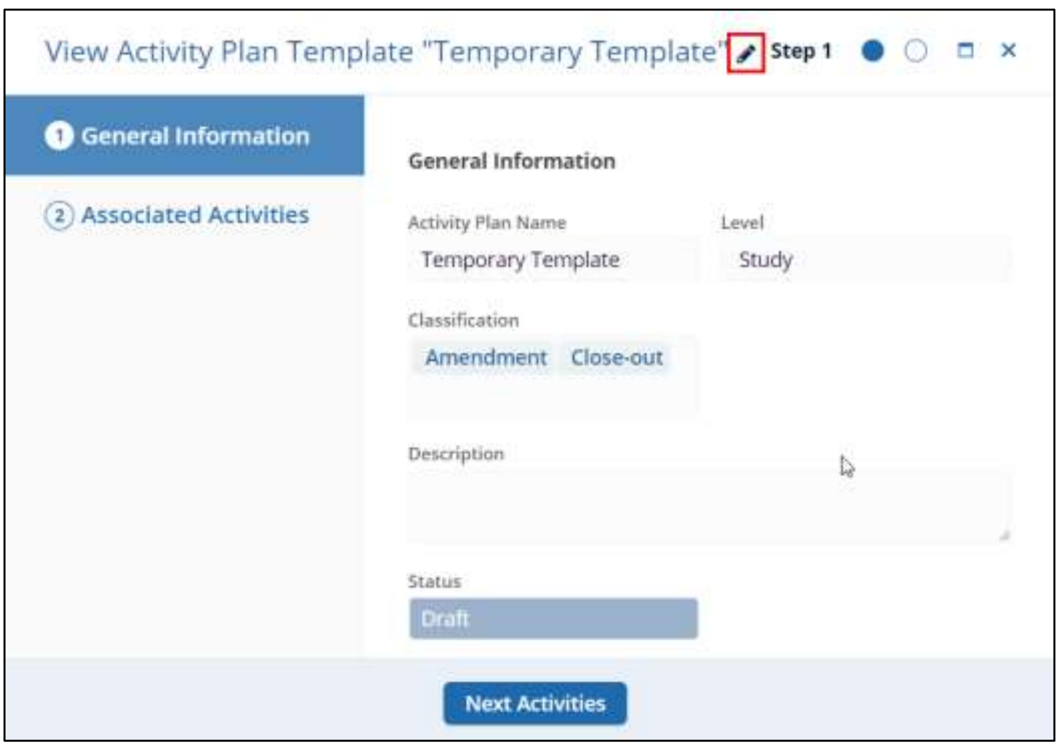


Figure: Select the Edit icon

3. On the Edit Activity Plan Template Window, access the General Information and Associated Activities screen to make edits and save the changes.

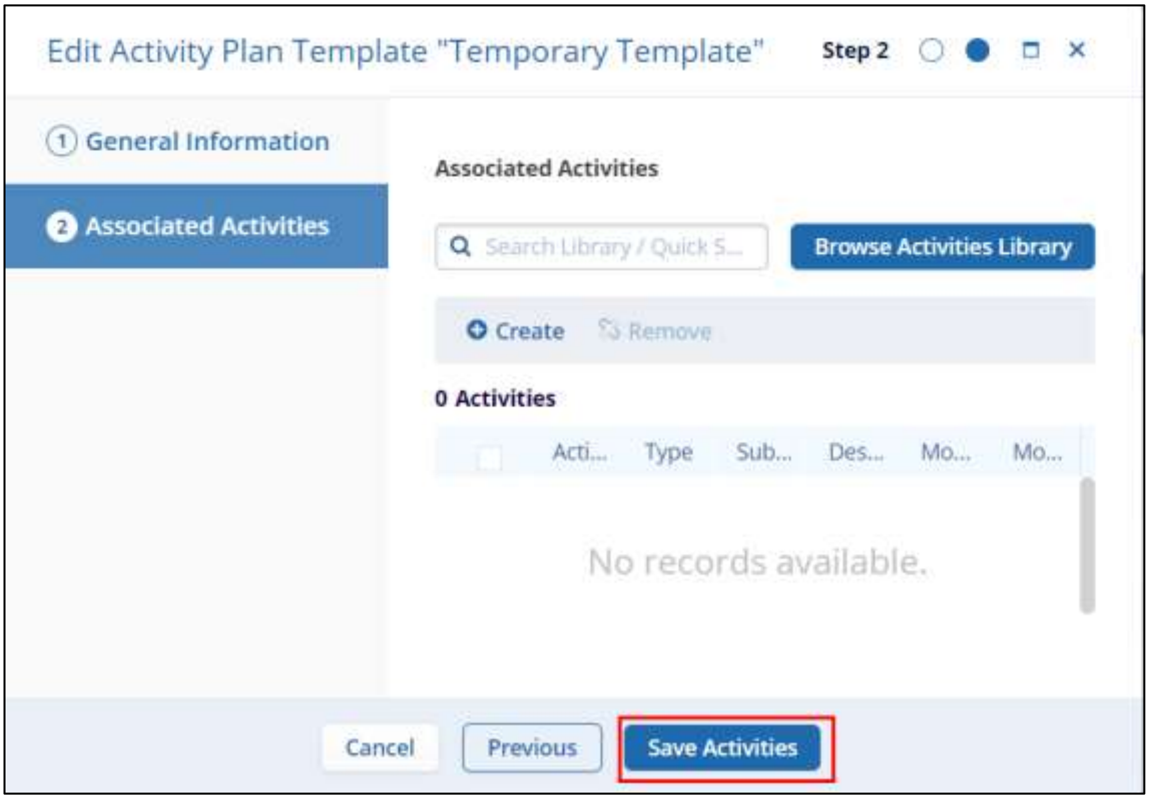


Figure: Edit Activity Plan Template-Method 2

Publishing Activity Plan Templates

To publish an activity plan, follow the steps below.

1. Select an activity plan in the Draft state.
2. Click on the Publish icon from the top menu bar.
3. Click on Publish Plan Template on the Activity Plan Template Review screen.

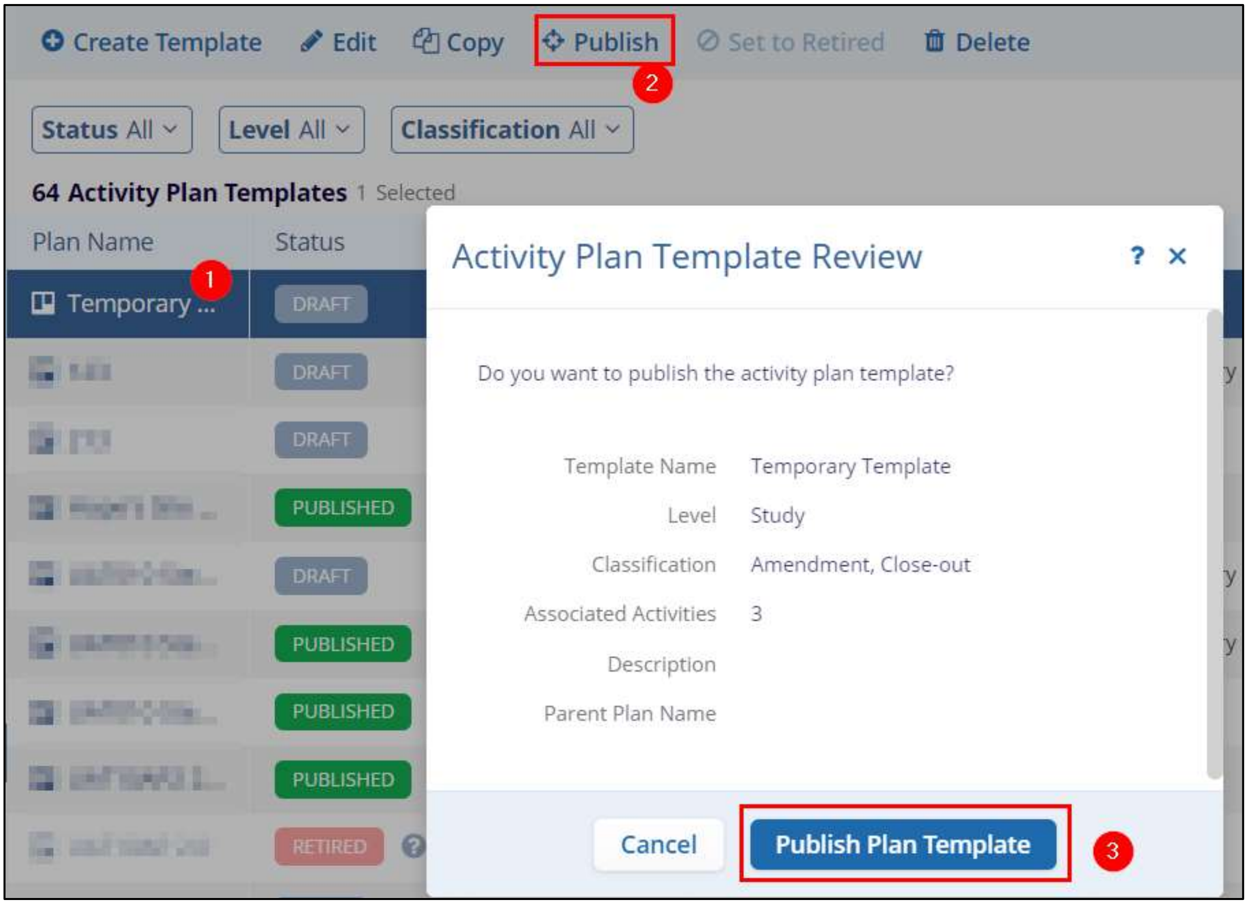


Figure: Publishing Activity Plan Template

Note

- Activity plans with Draft status can only be published
- If no activities are associated with the Activity Plan Template, the Information notification popup displays the related message and prompts the user to add activities to the plan.

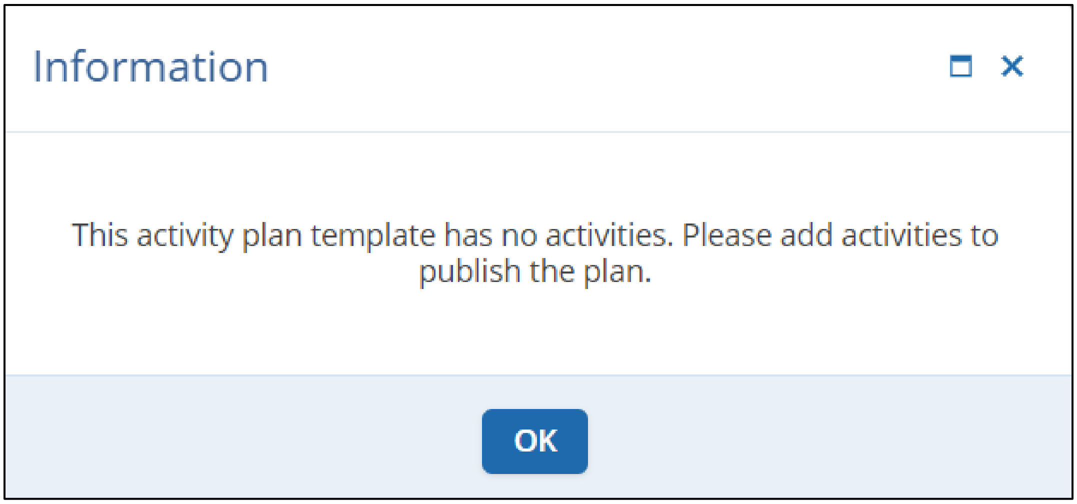


Figure: Information popup prompting to add templates

Retire Activity Plan Templates

To retire an active Active Activity Plan Template, follow the steps below.

1. Select any Activity Plan Template in the Published state.
2. Click on the Set to Retired icon from the top menu bar.
3. Click on the Set to Retired button on the Set to Retire confirmation screen.

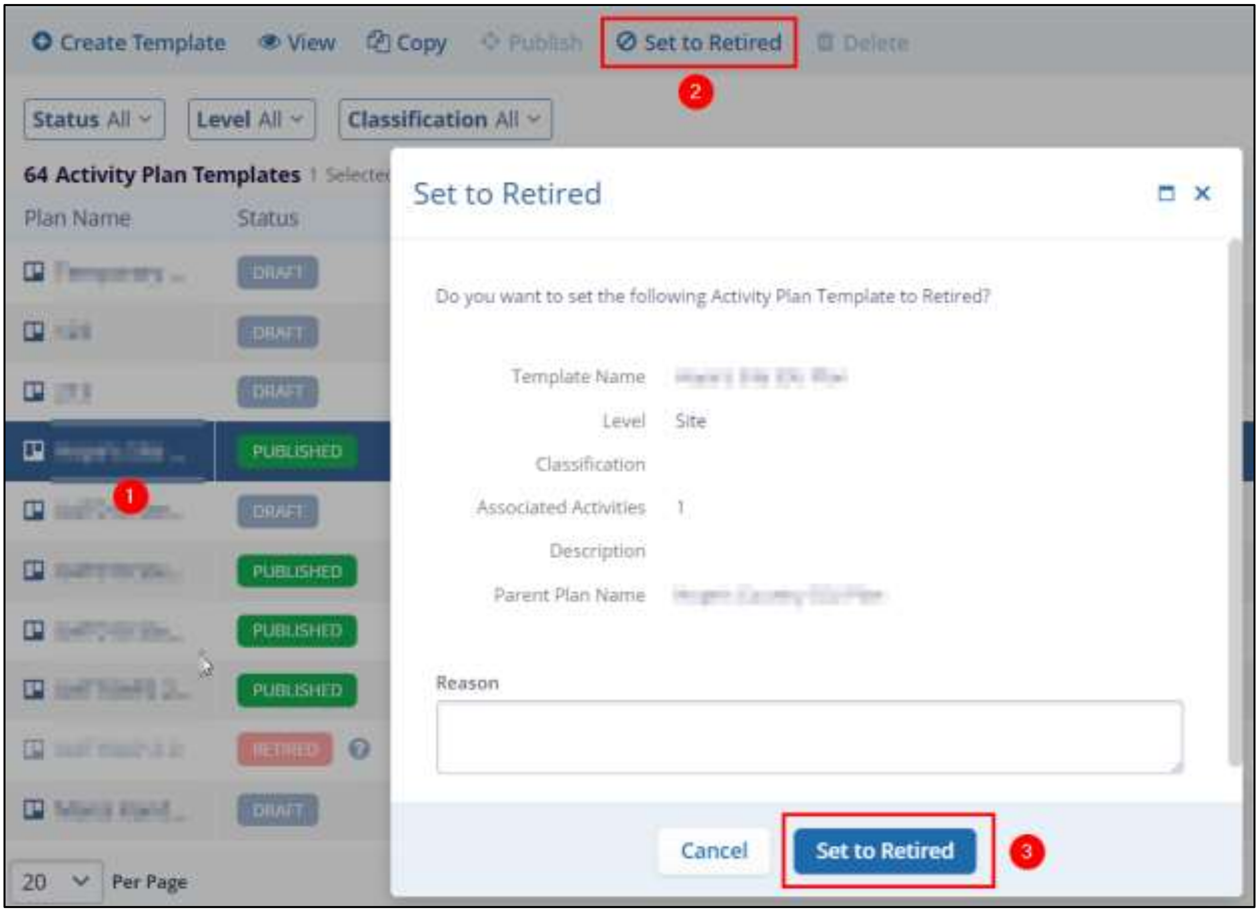


Figure: Retire Activity Plan Template

Note:

- Only Activity Plan Templates with Published status can be retired.

Copying Activity Plan Templates

To copy an Activity Plan Template, follow the steps below.

1. Select a plan by clicking on the tile.
2. Click on the Copy icon from the top menu bar.
3. On the Copy Activity Plan Template, modify or verify the General Information and Associated Activities details and click on Save Activities.

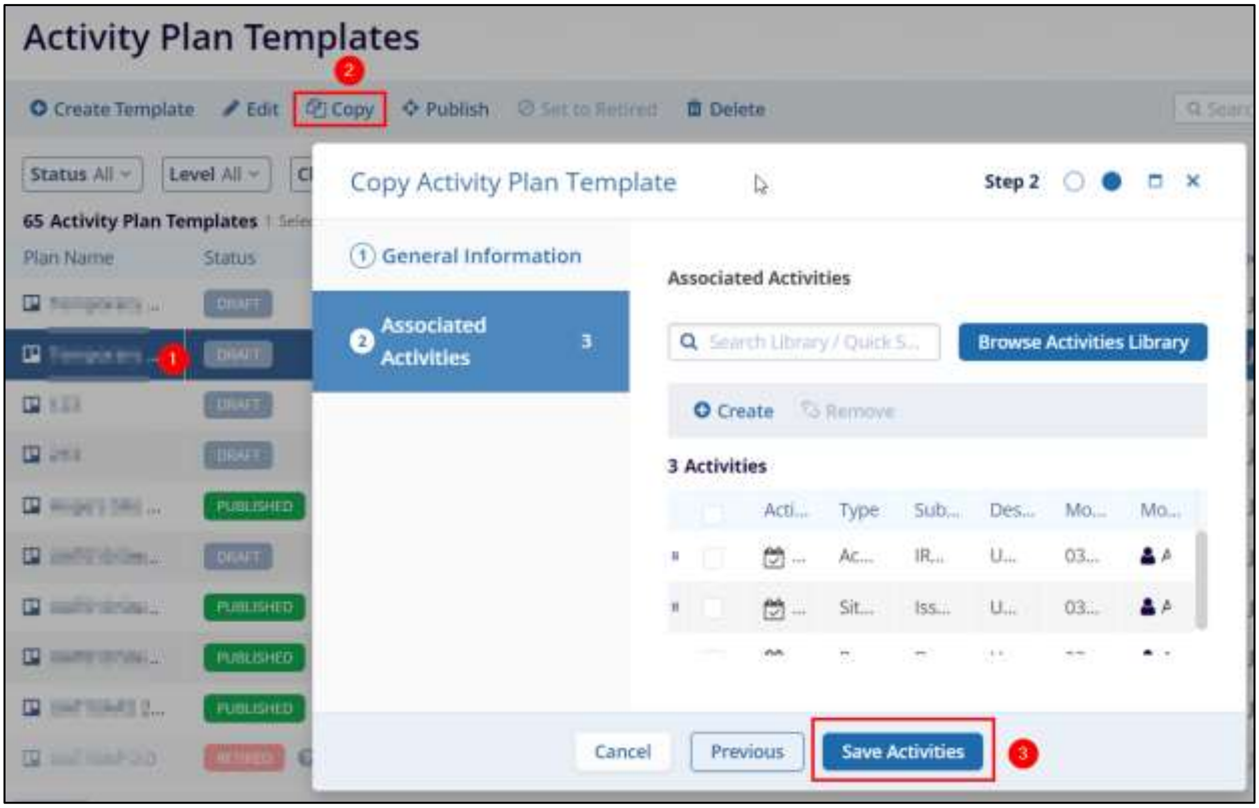


Figure: Copy Activity Plan Templates

Associating Activity Plan Templates to a Study

To associate an Activity Plan Template to a Study, follow the steps below.

1. From the left-hand navigation links, click on Studies.
2. Select a study by clicking on the study's name.

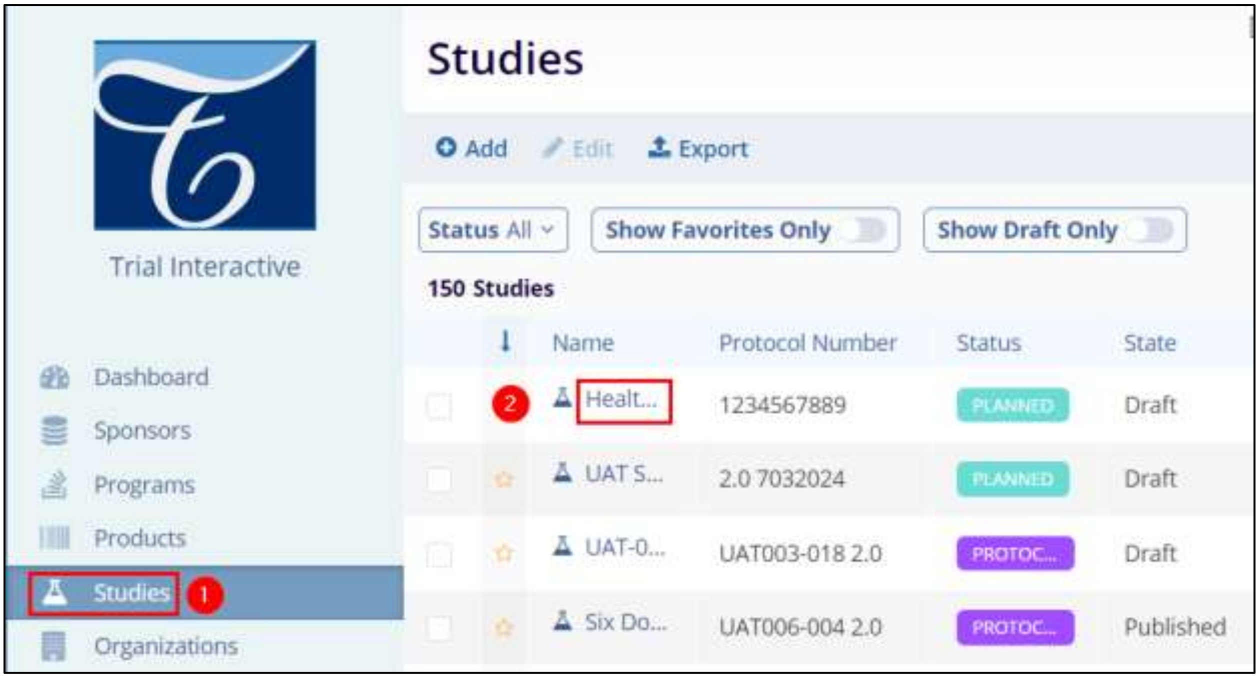


Figure: Selecting a Study

3. On that Study's screen, navigate to the left-hand navigation links and select Activity Plans.

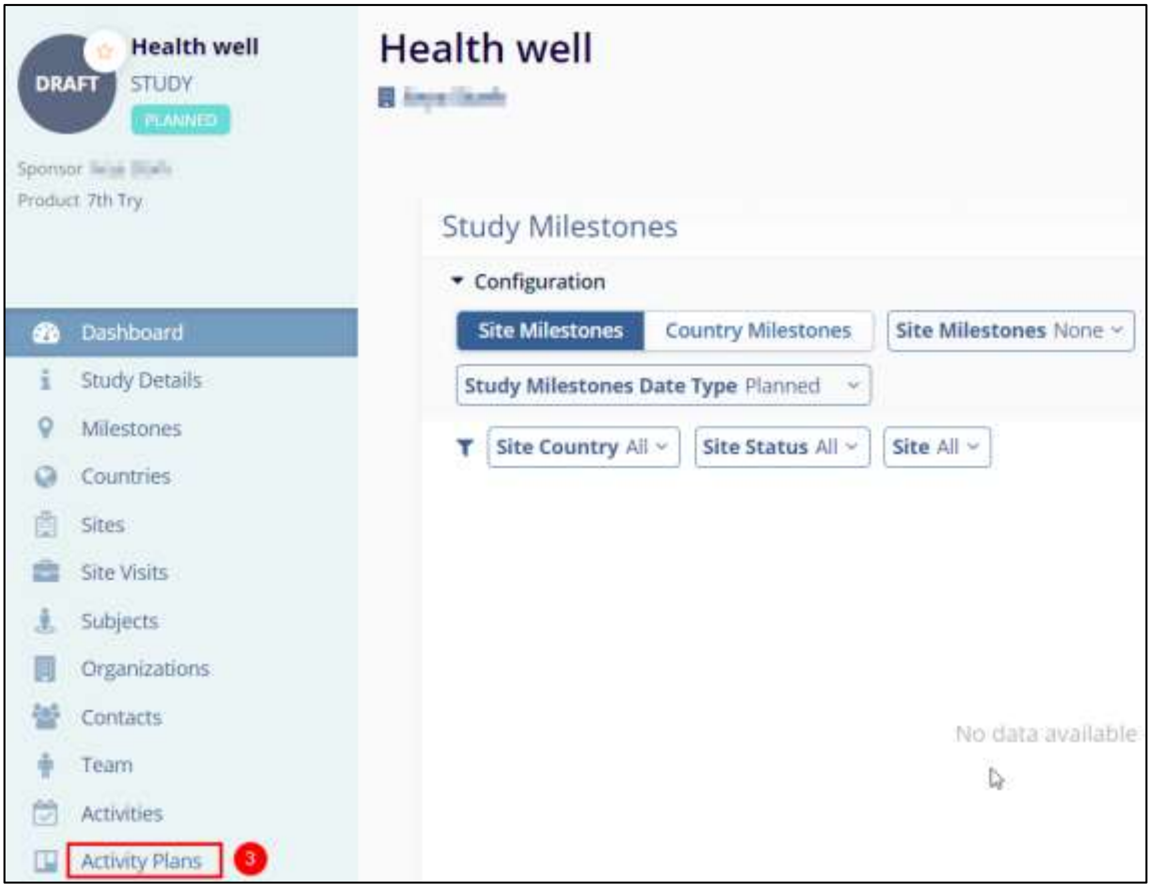


Figure: Select Activity Plans

4. On the Activity Plans Template screen, click on the Templates tab.
5. Click on +Add > +Associate buttons.

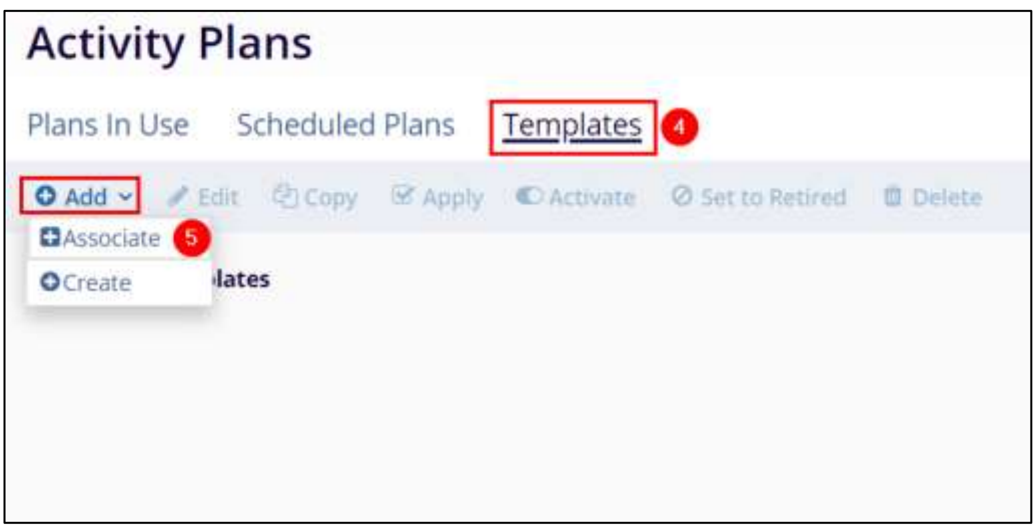


Figure: Select the Templates tab and access the Add and Associate buttons

Note: To Create a new activity plan for the study click on +Add > +Create and follow the steps detailed in Creating Domain Library Activity Template section.

6. On the Associate Activity Plan Template to Study, select activity plans by clicking on their respective checkbox.
7. Click on Associate once the required activity plans are selected.

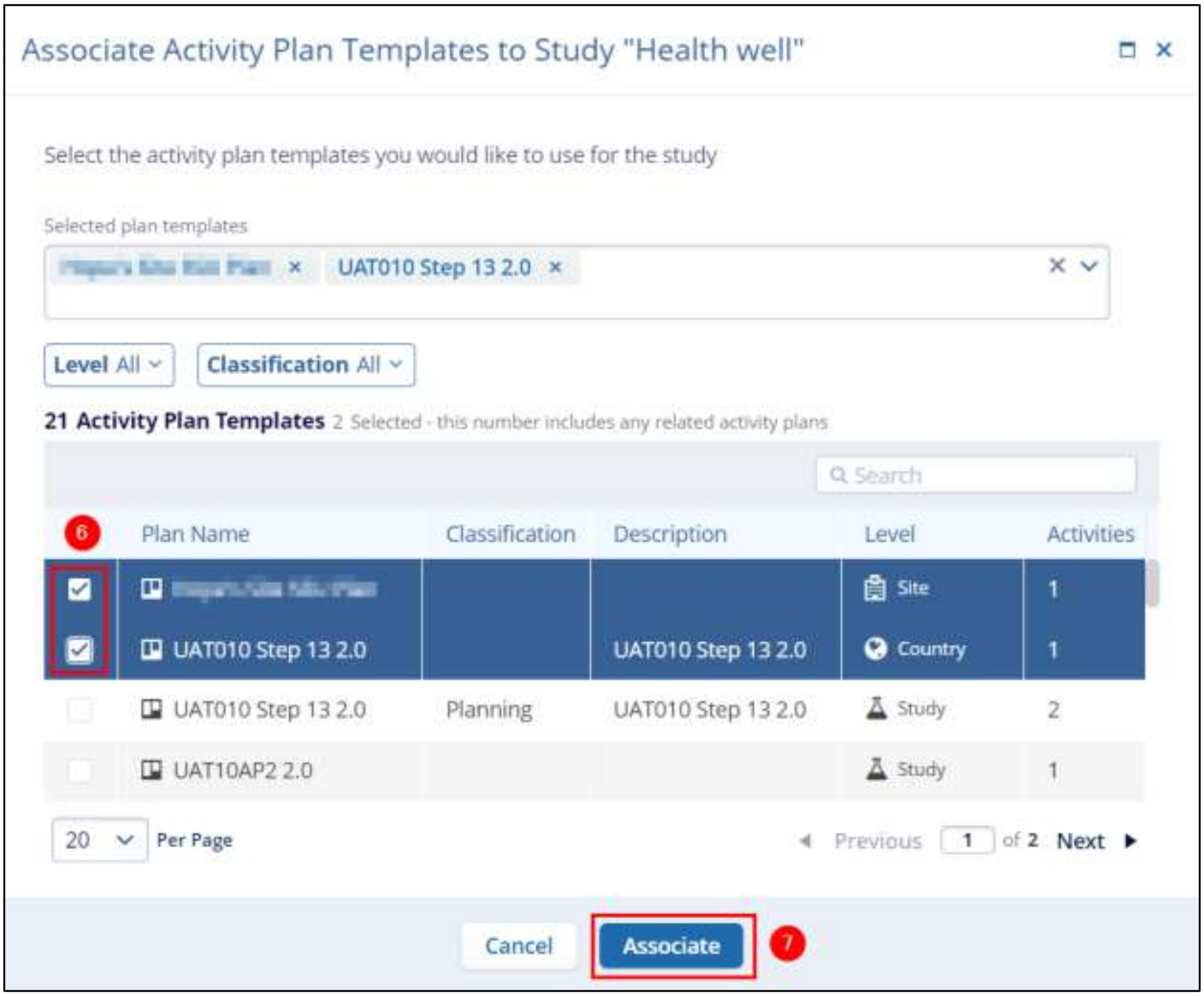


Figure: Associate Activity Plan Template to Study Screen

Scheduling Activity Plans

To schedule Activity plans, follow the steps below.

1. From the left-hand navigation links, click on Studies.
2. Select a study by clicking on the study's name.

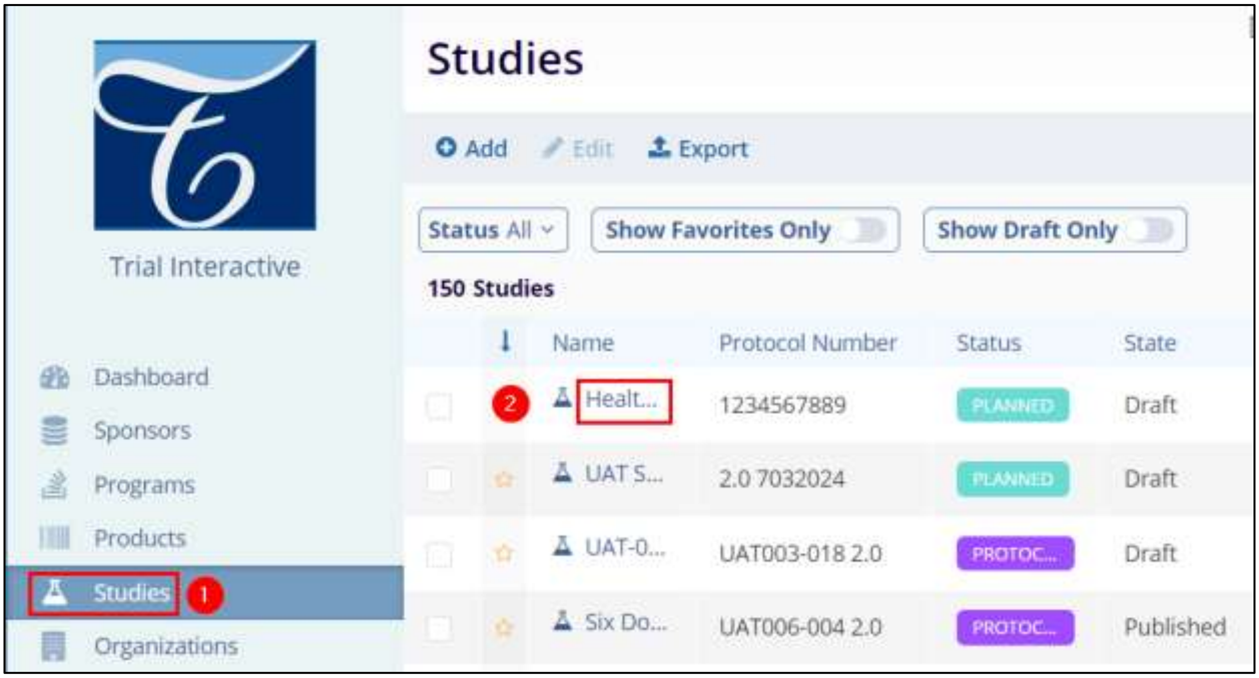


Figure: Selecting a Study

3. On that Study's screen, navigate to the left-hand navigation links and select Activity Plans.

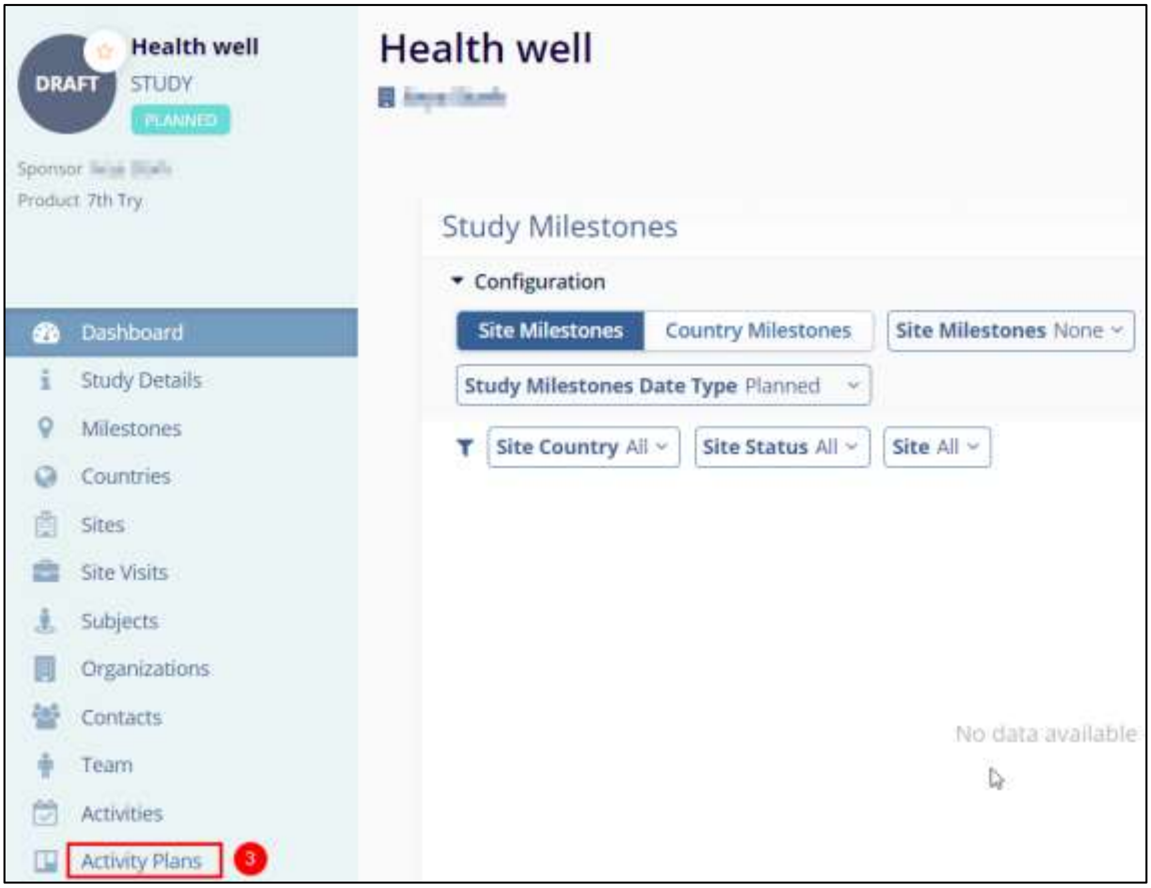


Figure: Select Activity Plans

4. On the Scheduled Activity Plan screen, select the Scheduled Plans tab > +Add

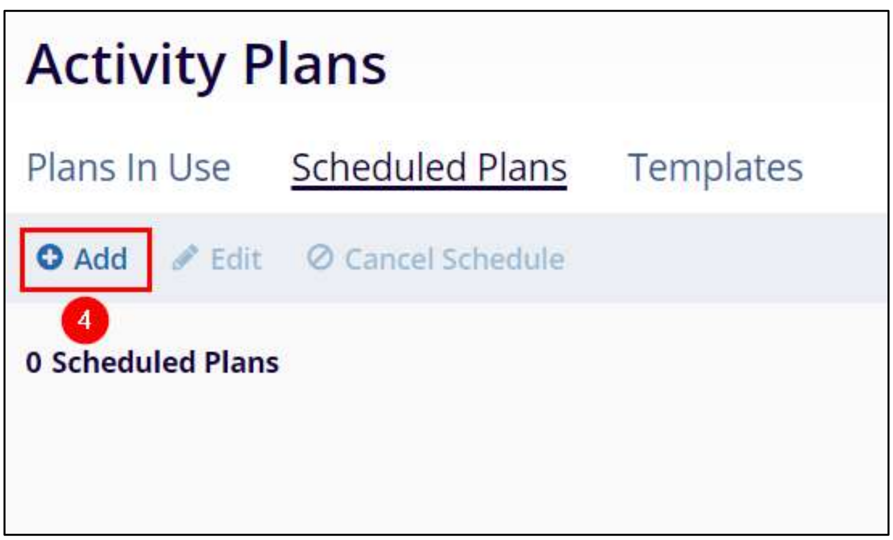


Figure: Scheduled Plans tab

5. On the Schedule Activity Plans for Study screen, perform the following.

a. Select Templates: Click on Schedule plan or the templates tile to select the template and click on the Next button.

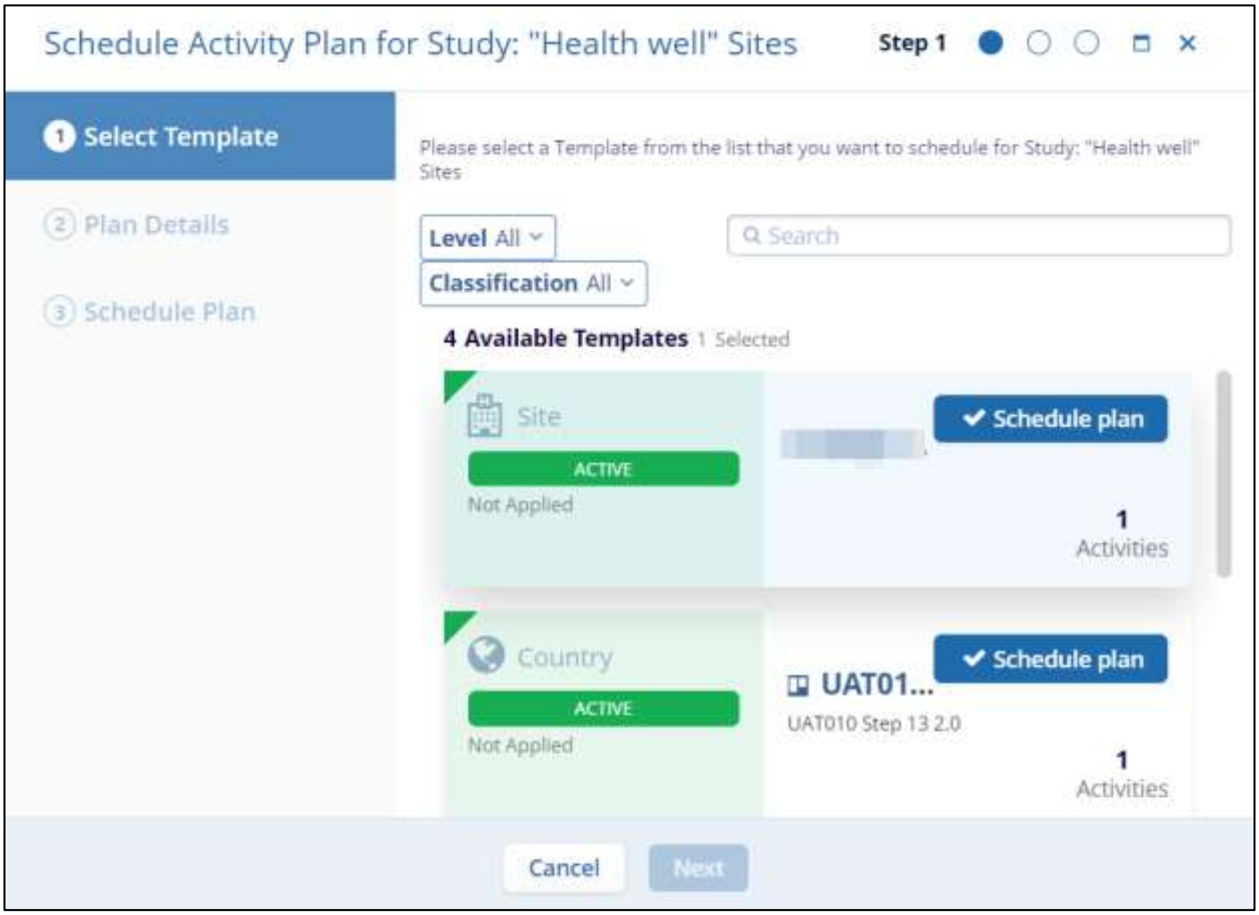


Figure: Schedule Activity Plan for Study-Select Template

b. Plan Details: On the Plan Details screen, add a suitable plan description and click on the Next button.

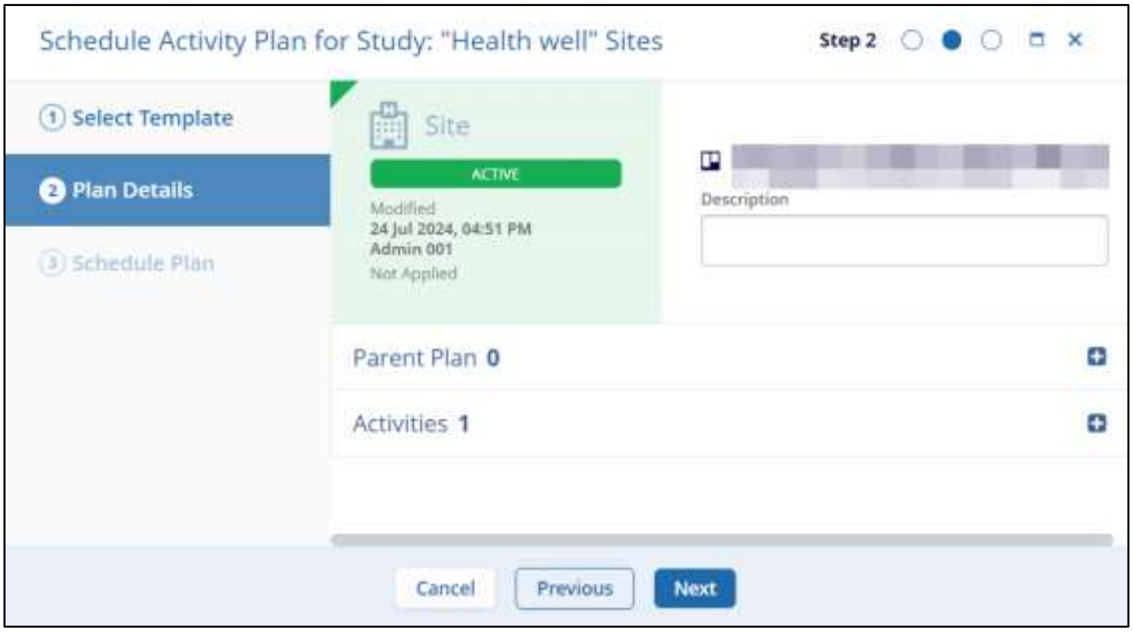


Figure: Schedule Activity Plan for Study-Plan Template

c. Schedule Plan: On the Schedule Plan screen enter the Stie, Country, and Study Status from their dropdown options and select Schedule.

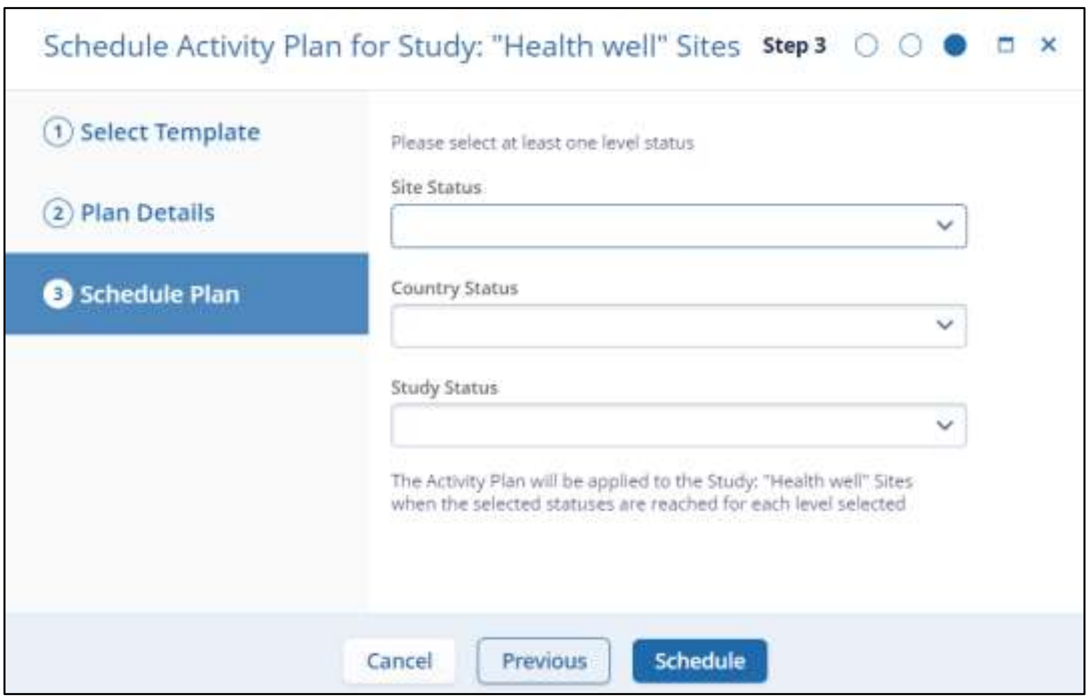


Figure: Schedule Activity Plan for Study-Schedule Plan

Tracking Activities Outside of Activity Plans

To track activities outside of Activity Plans, follow the steps below.

1. From the left-hand navigation links, click on Studies.
2. Select a study by clicking on the study's name.

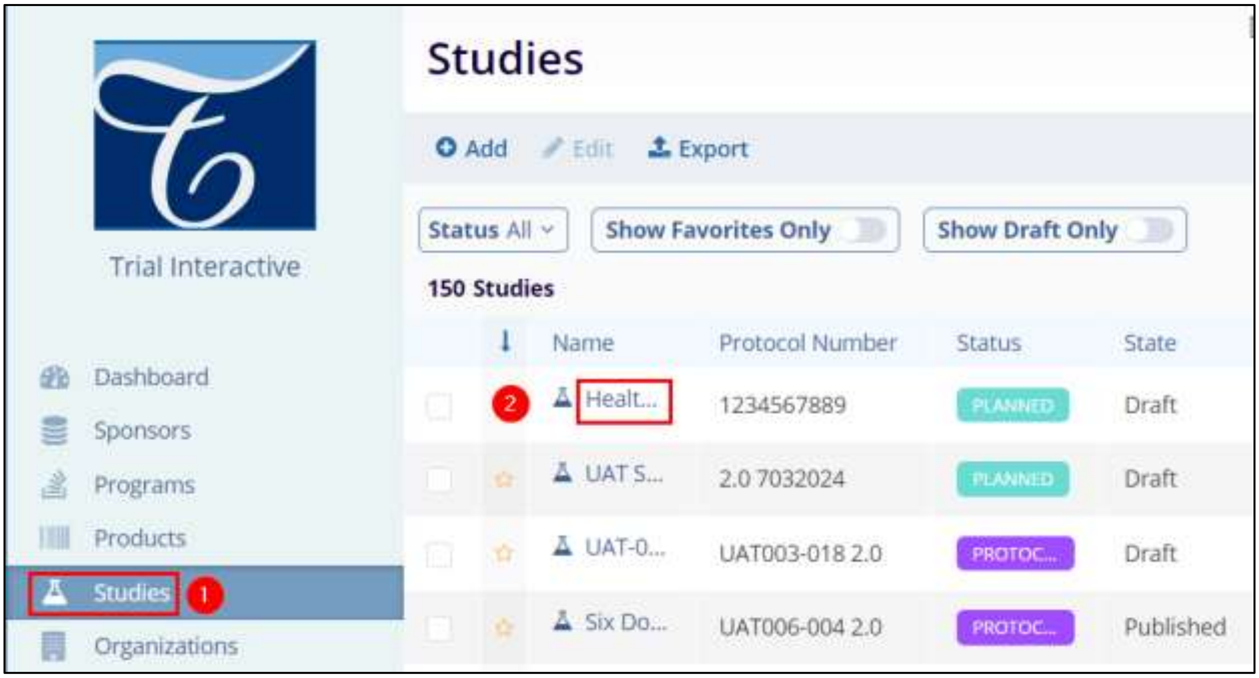


Figure: Selecting a Study

3. Click on Activities from the left-hand navigation links
4. Click on the +Add button on the Activities screen.

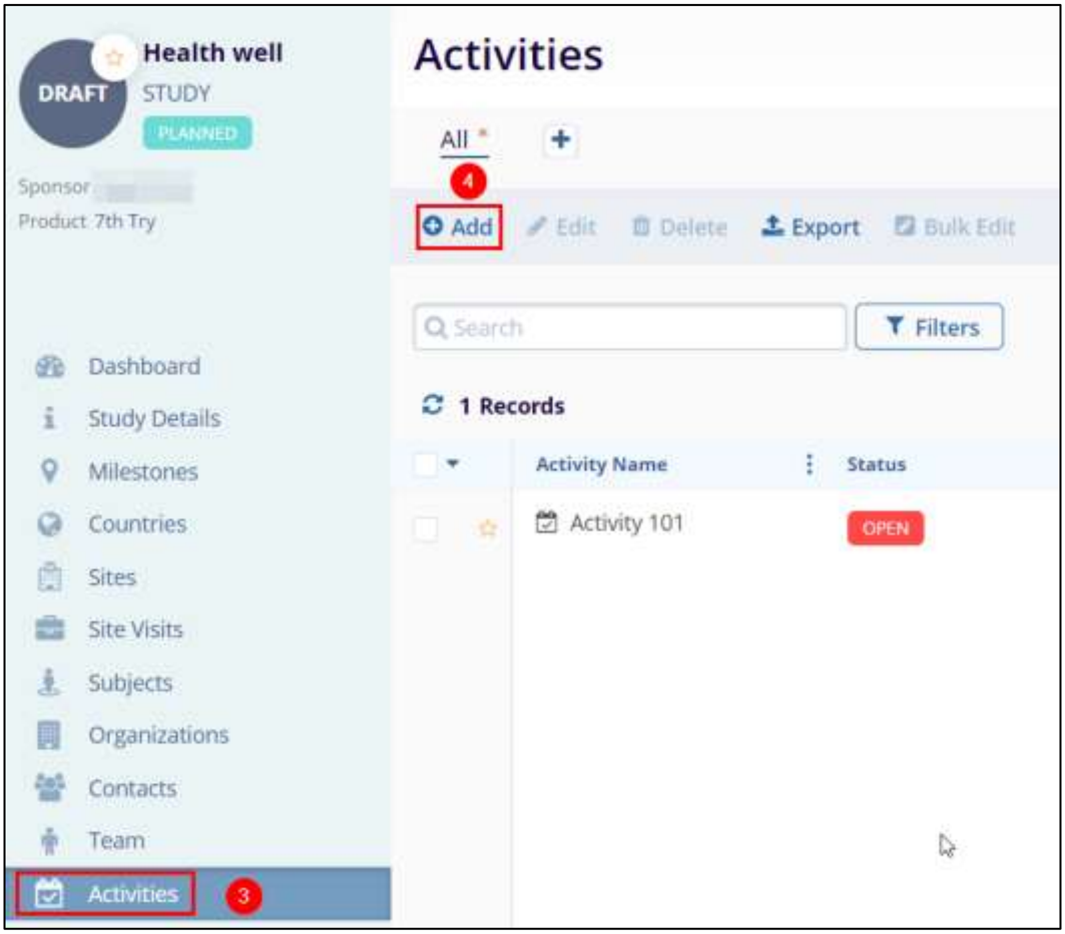


Figure: Select Add Activities

5. On the Create Activity Window, fill in all the mandatory details.
6. Click on Create or Create and Add Another.

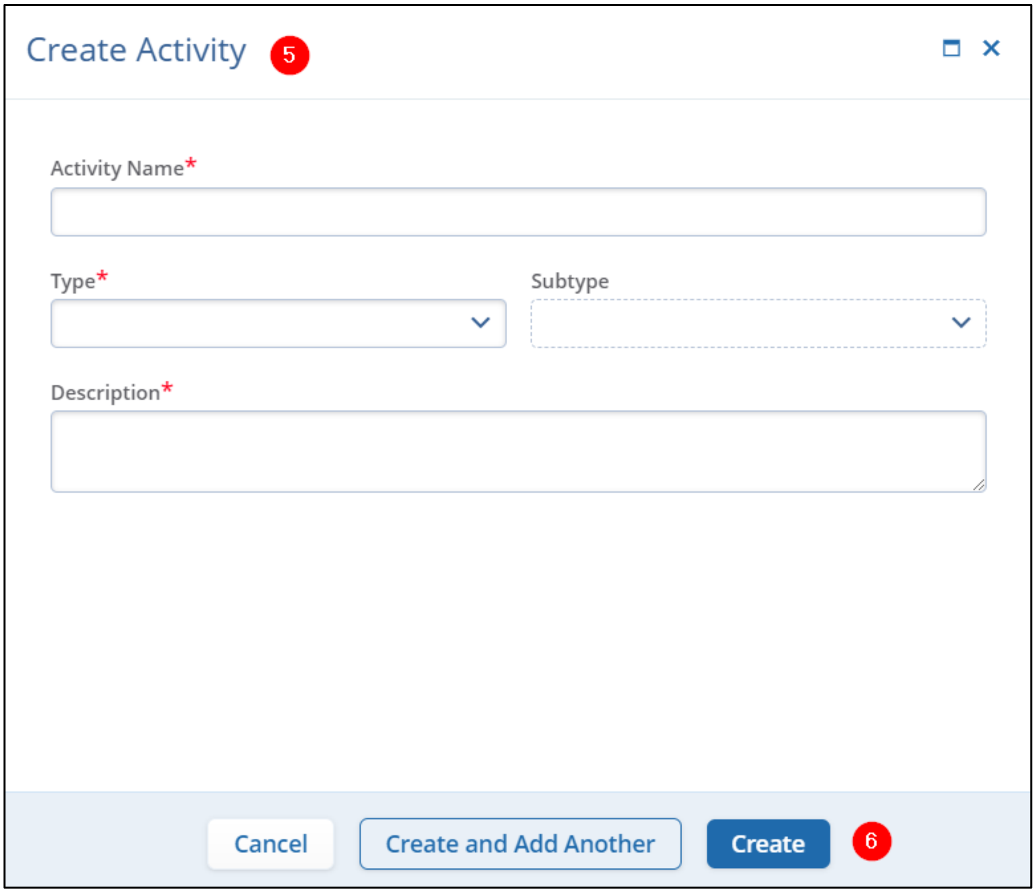


Figure: Tracking Activities

To edit any activity, follow the steps below

1. Select the activity name and
2. Click on the Edit button on the top menu bar and make the required changes on the quick view panel.
3. Click on the Save button.

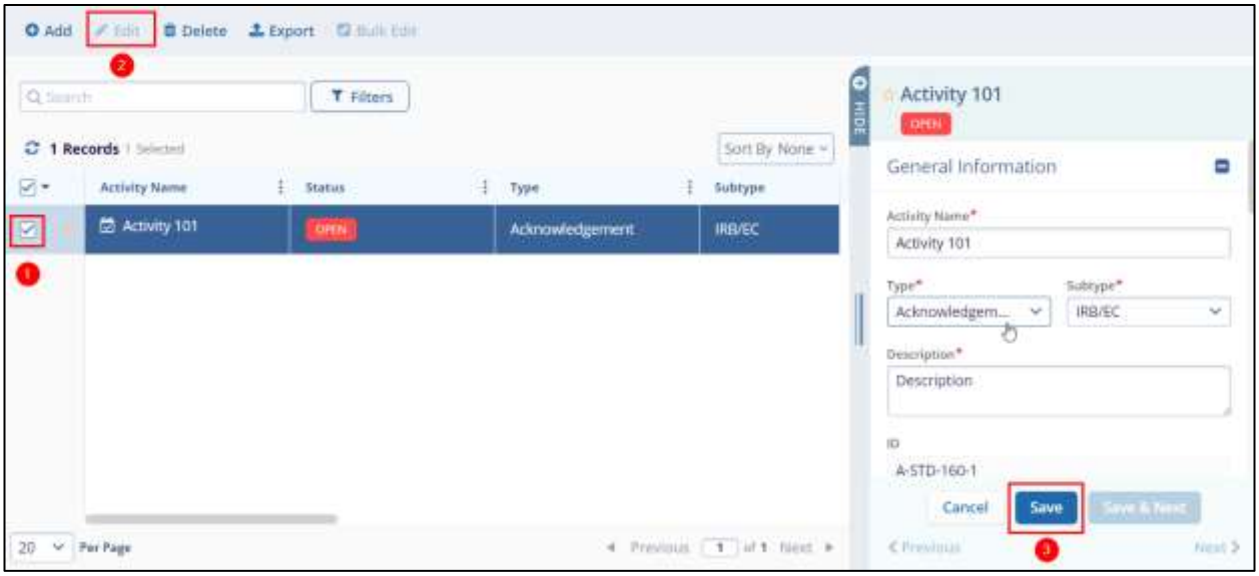


Figure: Editing Activities outside of the Activity Plan

Tracking Actions Towards 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.

To track activity completion actions follow the steps below.

1. From the left-hand navigation links select Studies > Study Name > Activities. Refer to the process detailed in the above section.
2. Select the Activity by clicking on the checkbox.
3. On the quick view panel, navigate to the Actions Taken section and click on +Add Action.

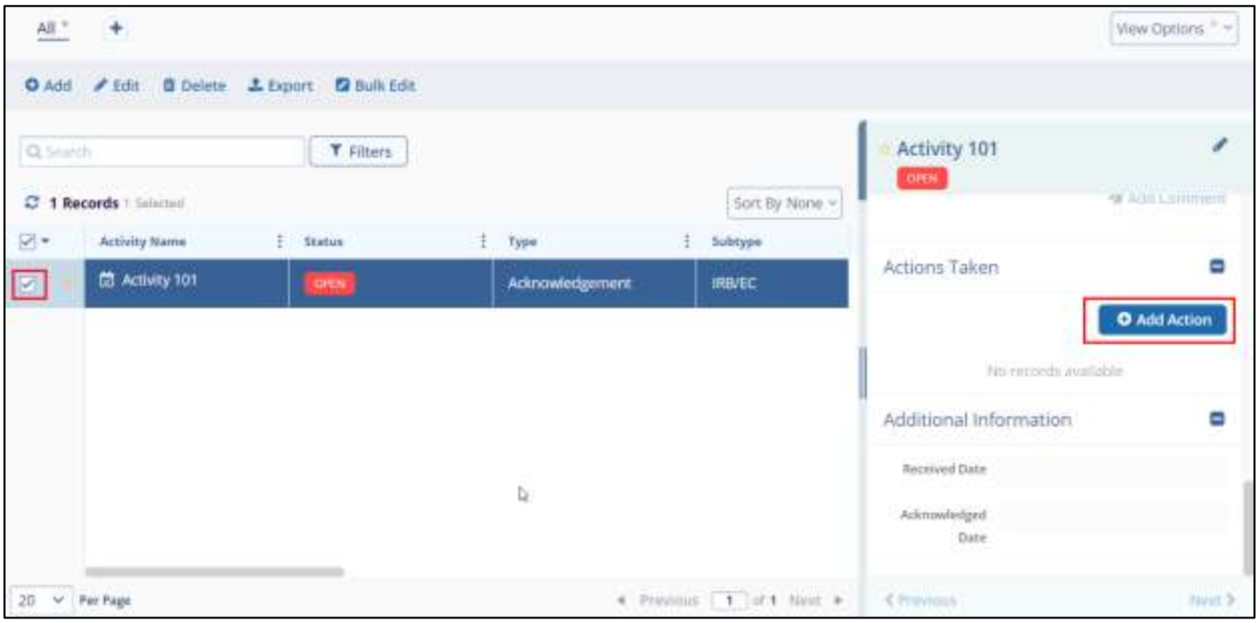


Figure: Actions Taken on quick view panel

4. On the Add Action screen, specify the Action Date and Description.
5. Click on the Add button once the necessary details are added.

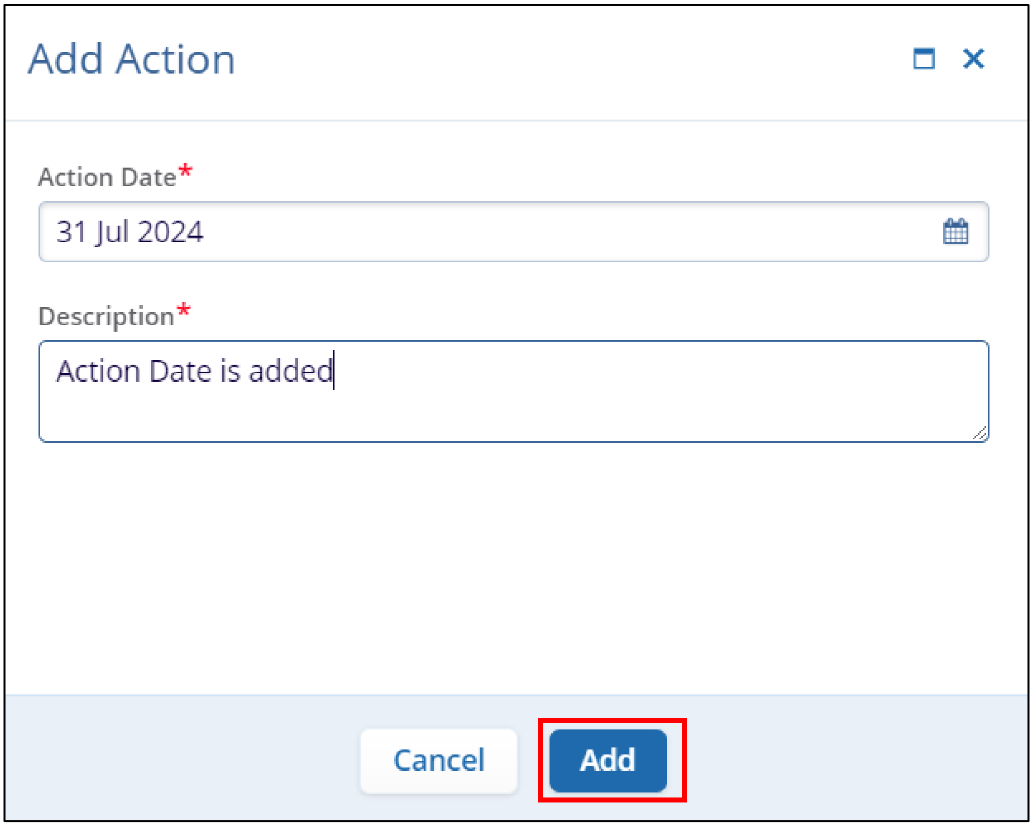


Figure: Add Action screen

Customizing Activity Plan Templates screen

Filters

Click on the Filters icon and apply the Status, Level, and Classification filters by selecting the available dropdown options.

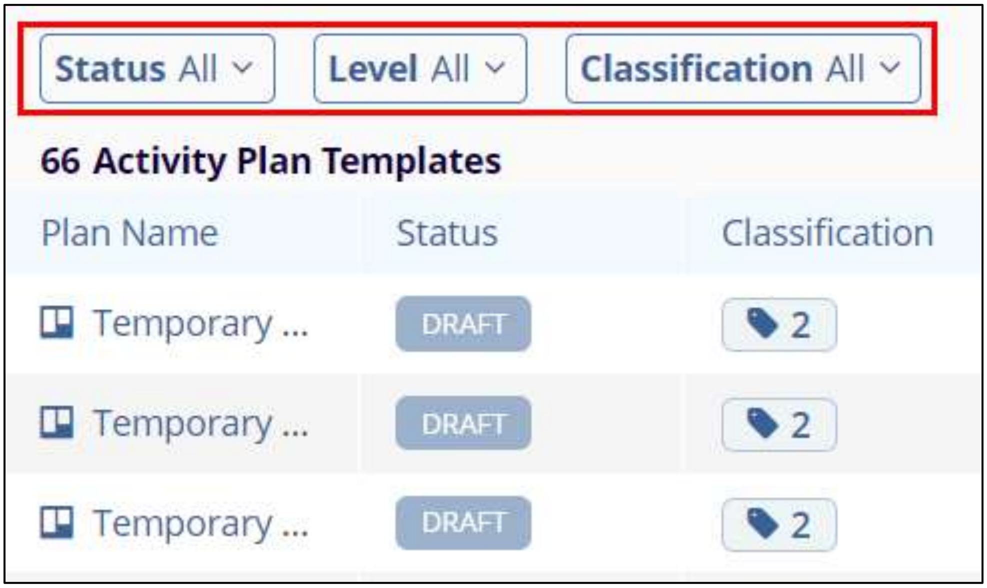


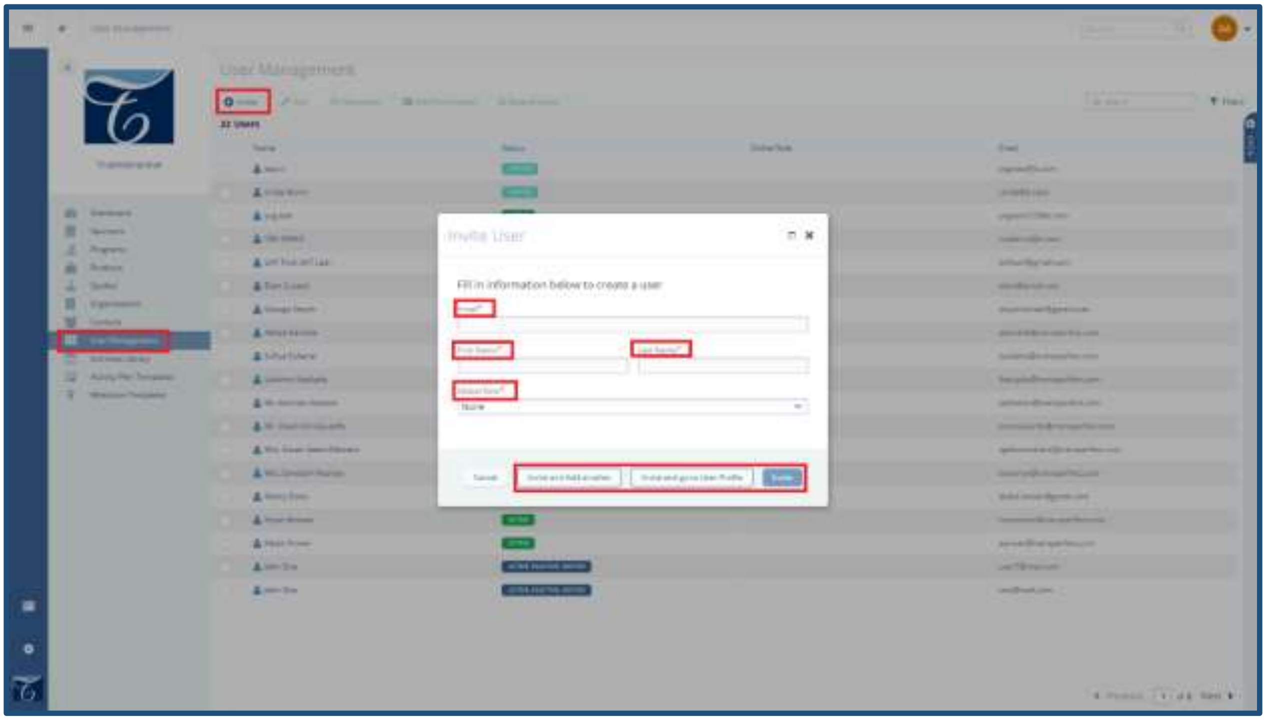
Figure: Activity Plan Templates screen filters

Team Management

This section describes about creation and management of users and teams in the application.

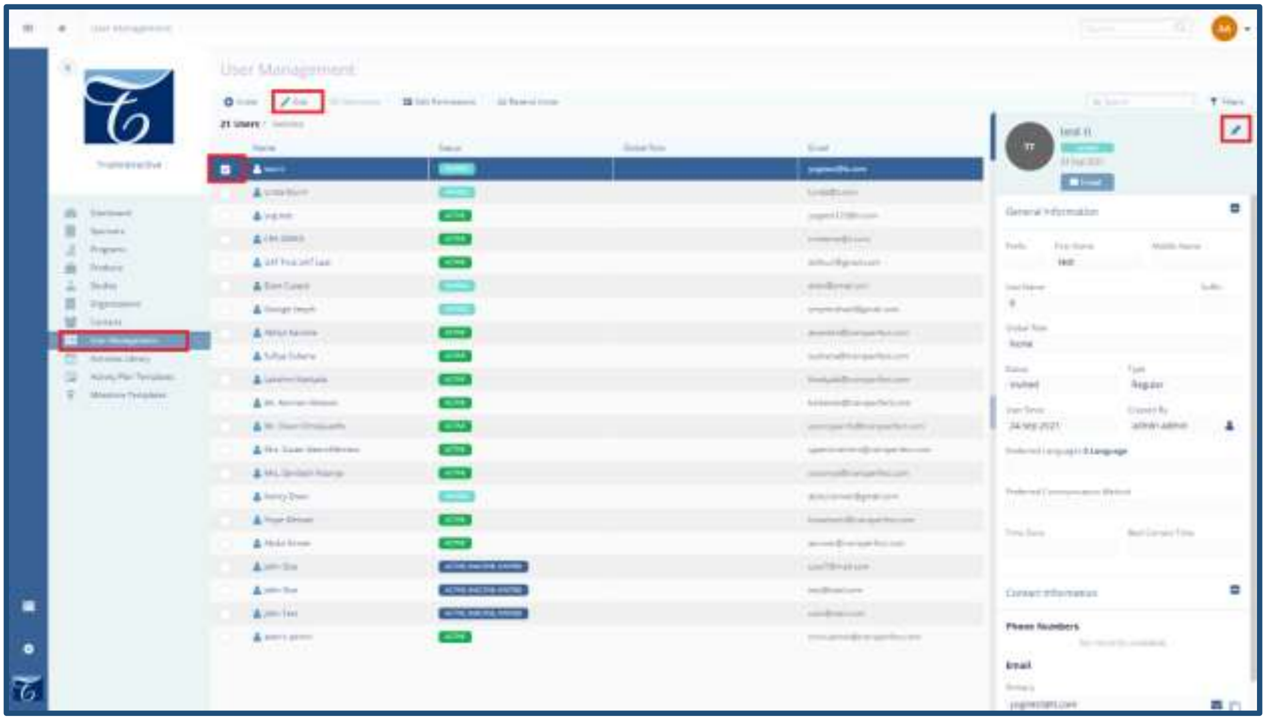
Creating Users

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.



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.
2. 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.

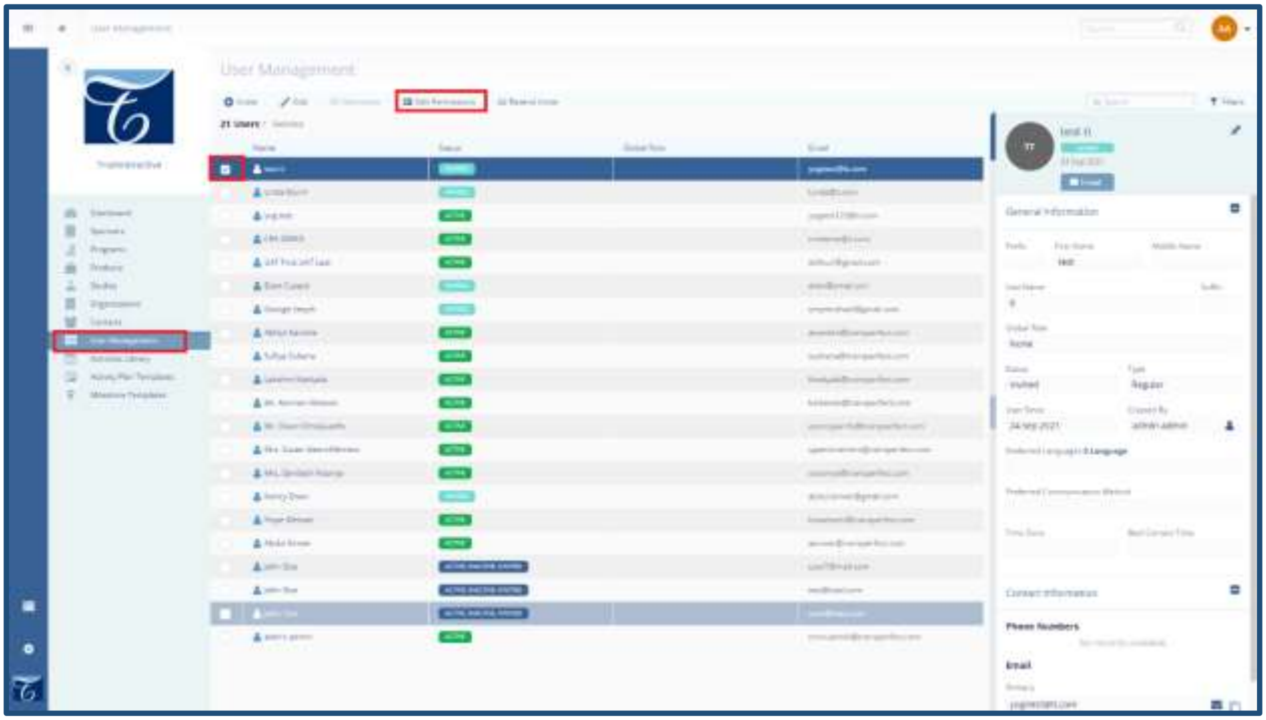


5. Click on the Save button in the bottom right of the screen, for the changes to apply to the user account.

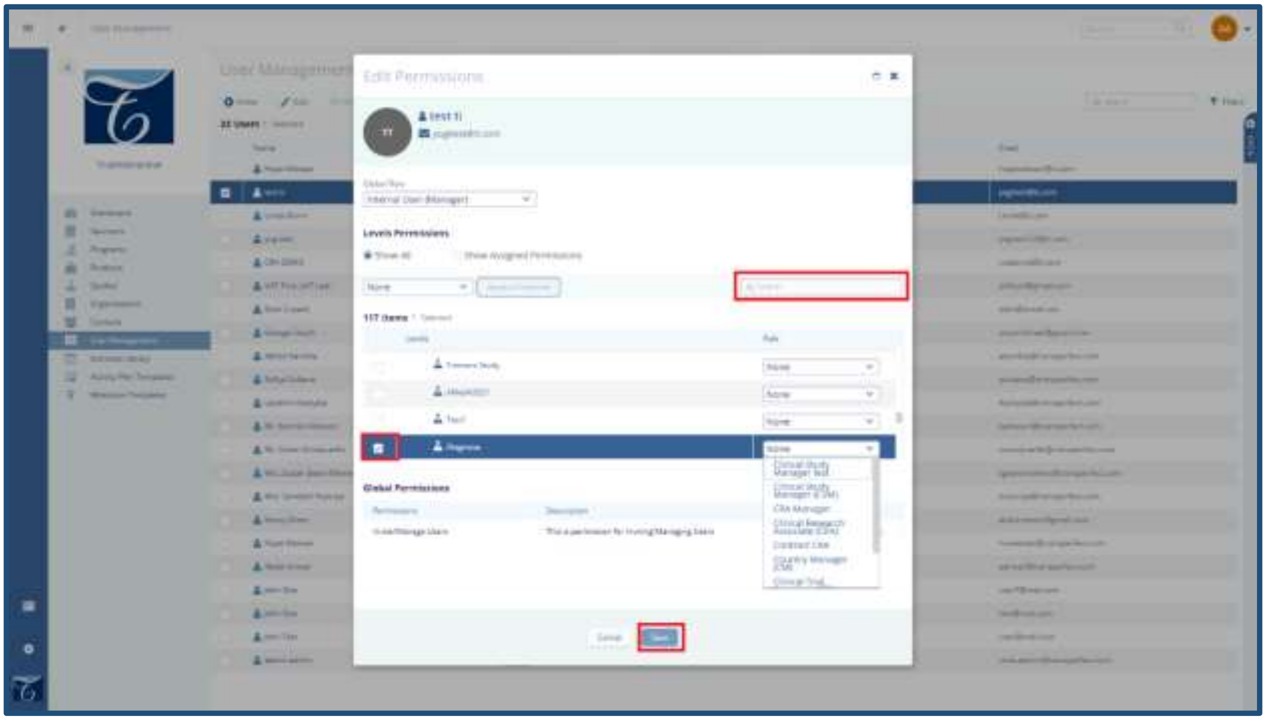
Editing a User's Permissions

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 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.



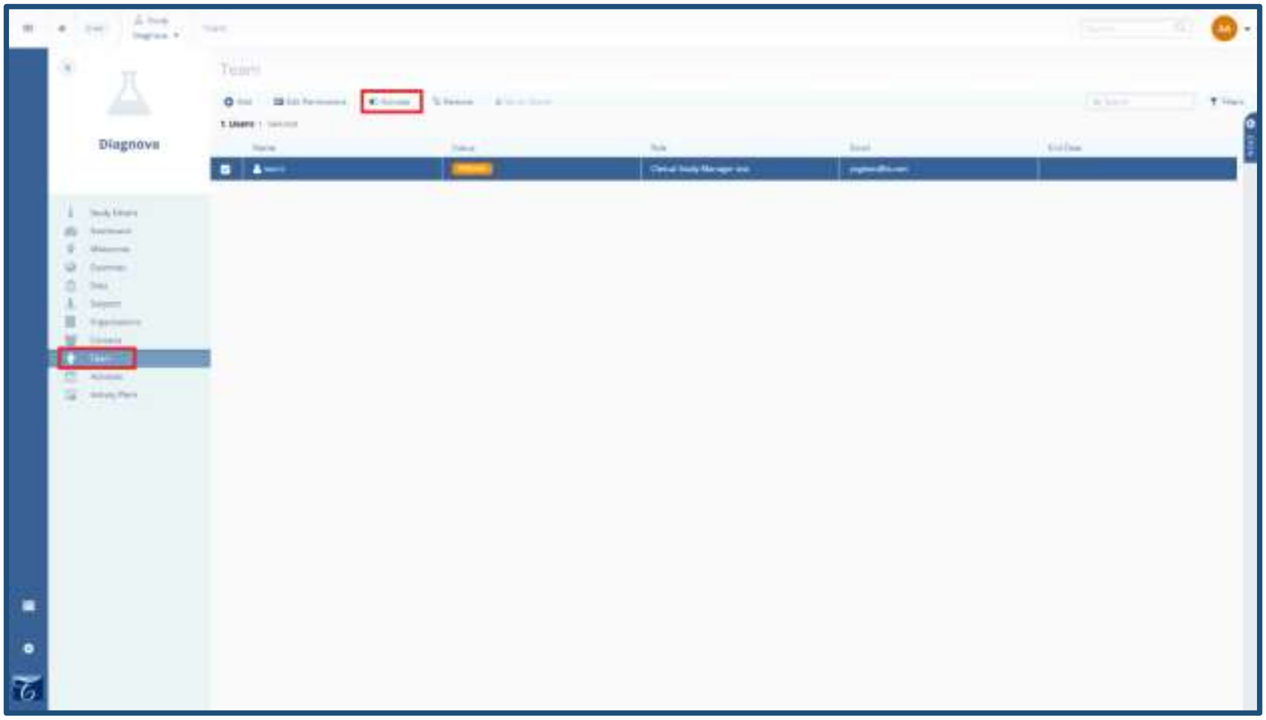
4. Navigate through the list of organizations below or use the search box to find the sponsor.
5. Expand the selected organization and select the appropriate product or study.
6. Assign the user a specific role associated with that product or study.
7. Click on the Save button the bottom of the edit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



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

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.

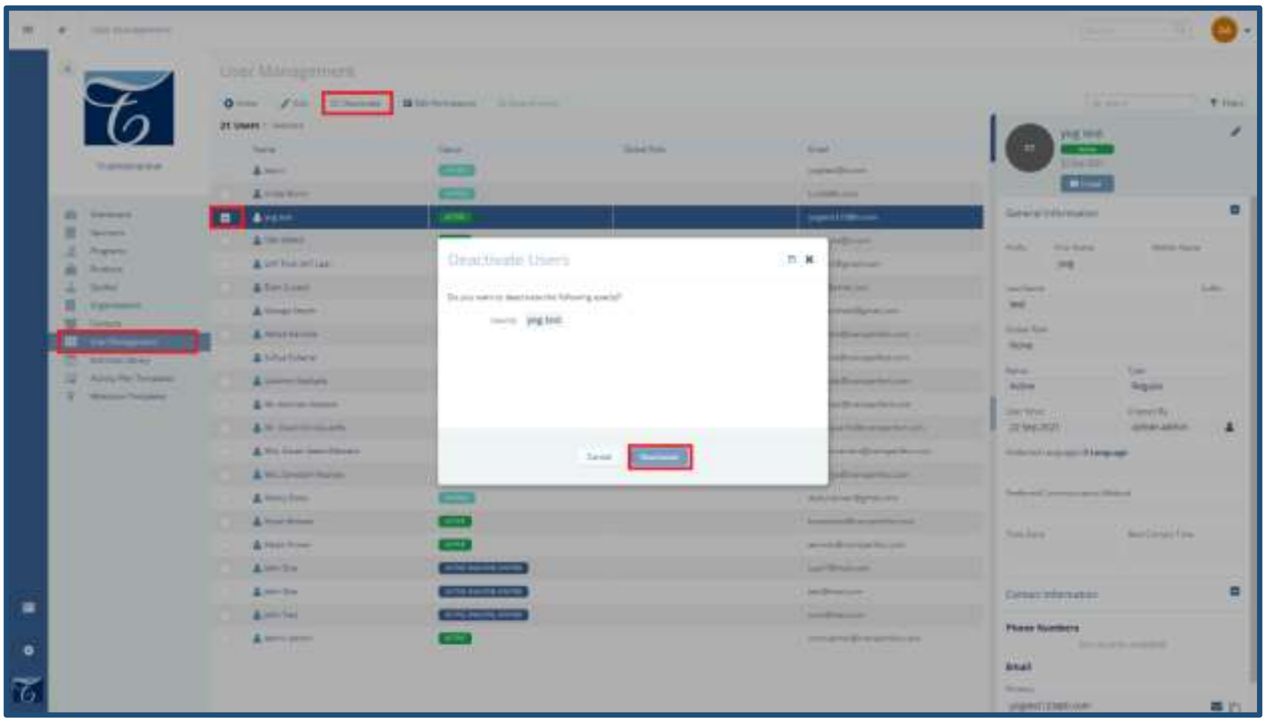


Please note that only study team members listed as Unblinded team members will be able to see unblinded study data where applicable. An Unblinded Clinical Study Manager may assign study team members to Unblinded roles but a Blinded Clinical Study Manager cannot.

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.
   a. This opens the Deactivate Users window.
4. Click on the Deactivate button in the **Deactivate user's** window.

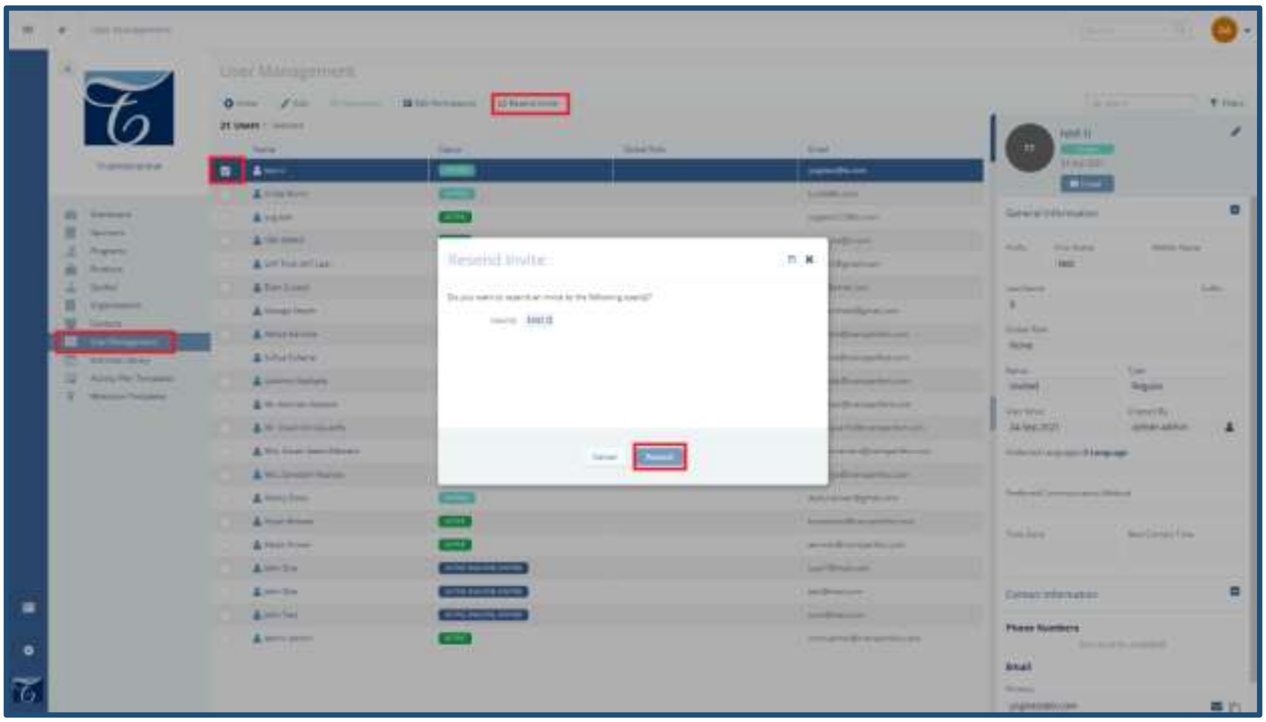
Note: The reverse of this action can be done to activate a user.



Resending a User's Invite

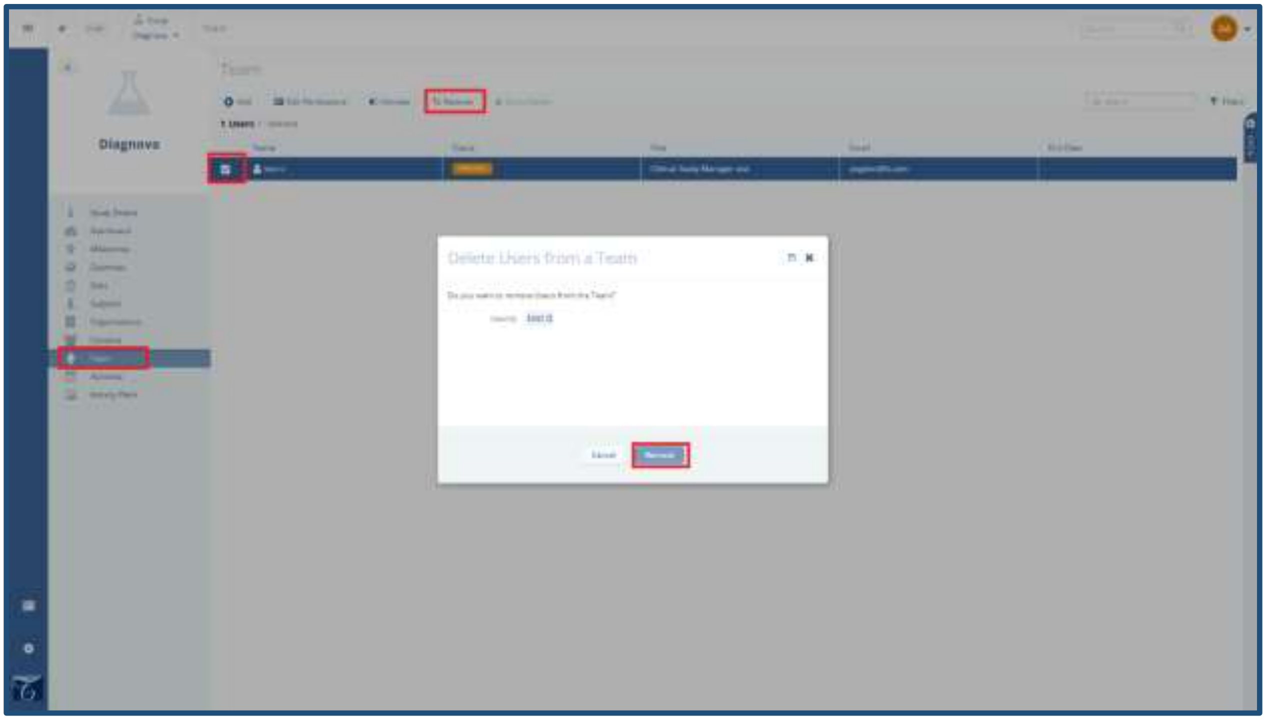
1. Click on the User Management link in the Navigation menu at the left side of the screen.
   a. This opens the User Management screen.
2. Navigate to the user whose invitation you want to resend and click the check box.
   a. This opens the quick view on the right side of the screen.
3. Click on the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



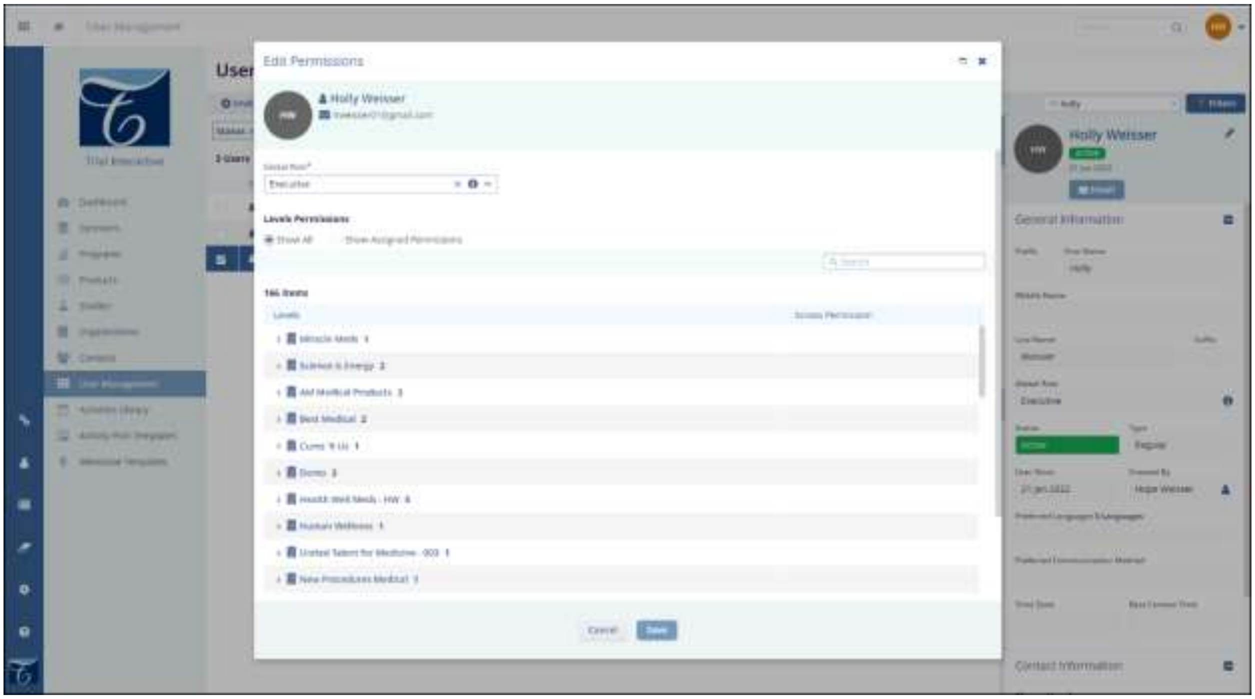
Removing Users from a Team list

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.



Access Management

Access Management is more improved, more intuitive user access matrix, clearly stating how the user will be expected to interact with CTMS data for studies, countries, and sites. With regard to Study access, the previous user access terminology is still present but will have the word 'Deprecated' after it to indicate that we have moved on to other terminology such as, in the case of a CRA, 'Site Editor', for example.



Milestones

This section describes about Milestones module in the application.

Important

- The Milestones to studies application in CTMS have undergone some minor changes to help our users better apply milestones quickly and efficiently to a study.
- CTMS Milestones that are retired at the Global level are retired in all levels of the data hierarchy. If users want to continue to track a milestone after retiring it at the Global level, it is imperative to make a copy of the milestone at the Sponsor level or lower before retiring the milestone at the Global level.

Pre-Requisites

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

Creating Domain Library Milestone Template

To create a Domain Library Milestone Template, follow the steps below. Refer to the sequence in the screenshot.

1. From the left-hand navigation links, click on the Milestone Templates which opens the Milestone Templates window.
2. Click the +Create button at the top-left of the screen.
3. On the Create Milestone template, enter the following metadata details.
   Note: Fields highlighted with a red asterisk mark (*) require a mandatory update.
   a. Level*: Specify whether the milestone is to be created at a Study, Site, or Country level by selecting the option from the dropdown.
   b. Milestone Name*: Enter a name for the milestone template.
   c. Classification: Select the classification criteria from the available dropdown options.
   d. Description: Enter a suitable description for the template
   e. Set Parent Milestone Template: Turn on the Set Parent Milestone Template toggle to add a parent template for the current template. Select a template from the available dropdown options.
   f. Countries: The Countries field is only visible if the template is created at the Site or Country level. Select the countries from the available dropdown options.
4. Click on Create once all the necessary details are entered in the respective fields.

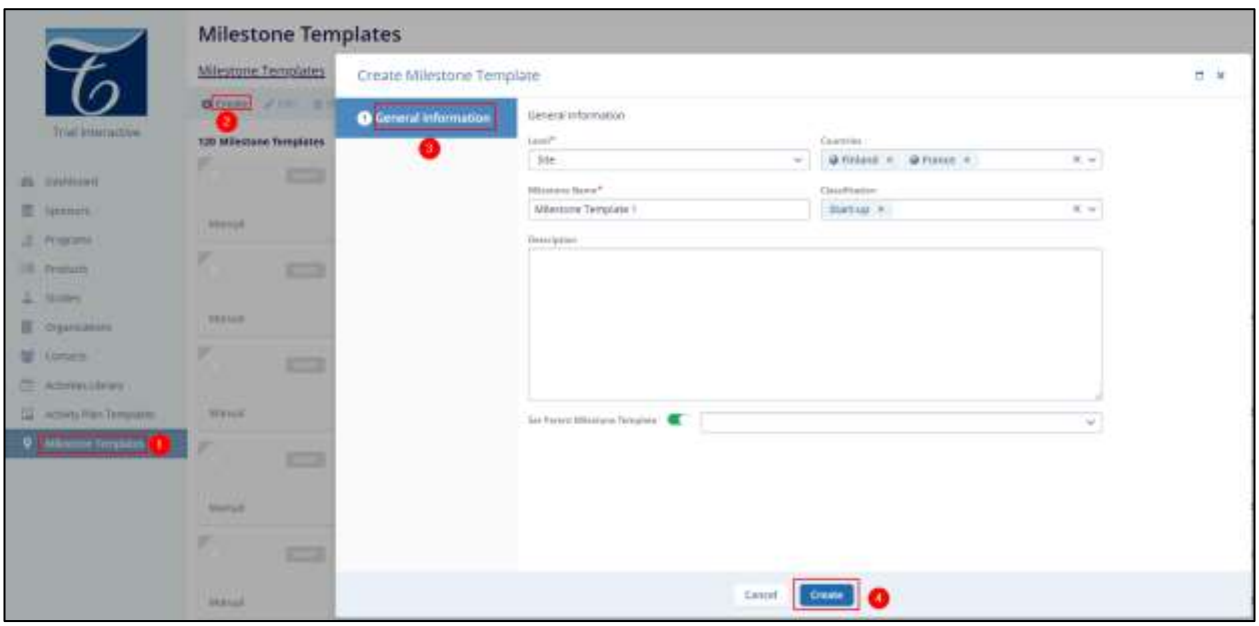


Figure: Creating Domain Library Milestone Template

5. The newly created template is visible on the Milestone Templates screen.

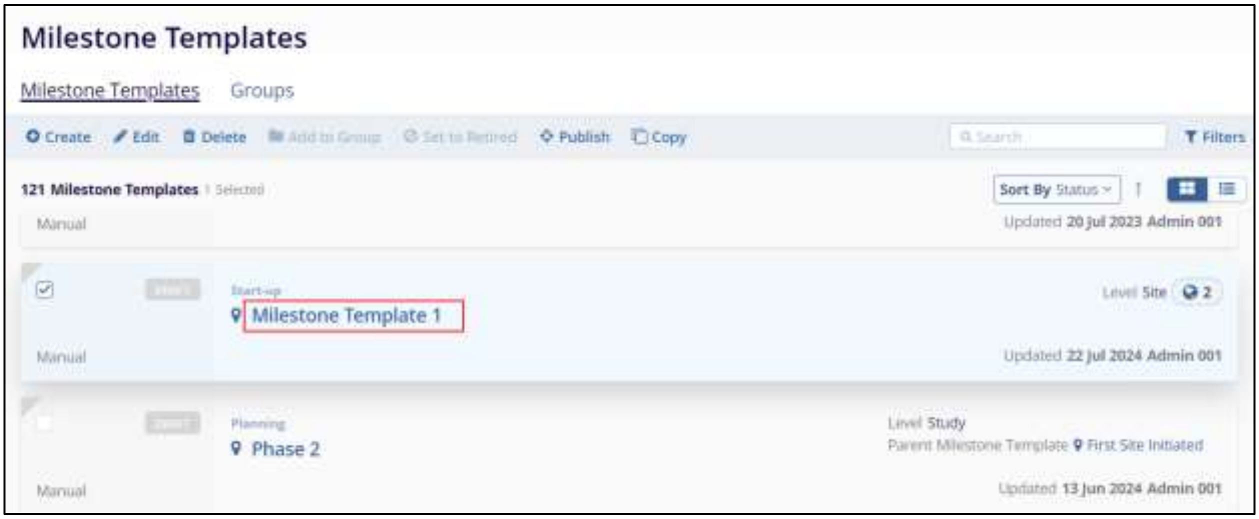


Figure: Newly created milestone template

Note: If any of the mandatory fields are missing and the user clicks on the Create button an error will appear prompting the user to review the necessary fields.

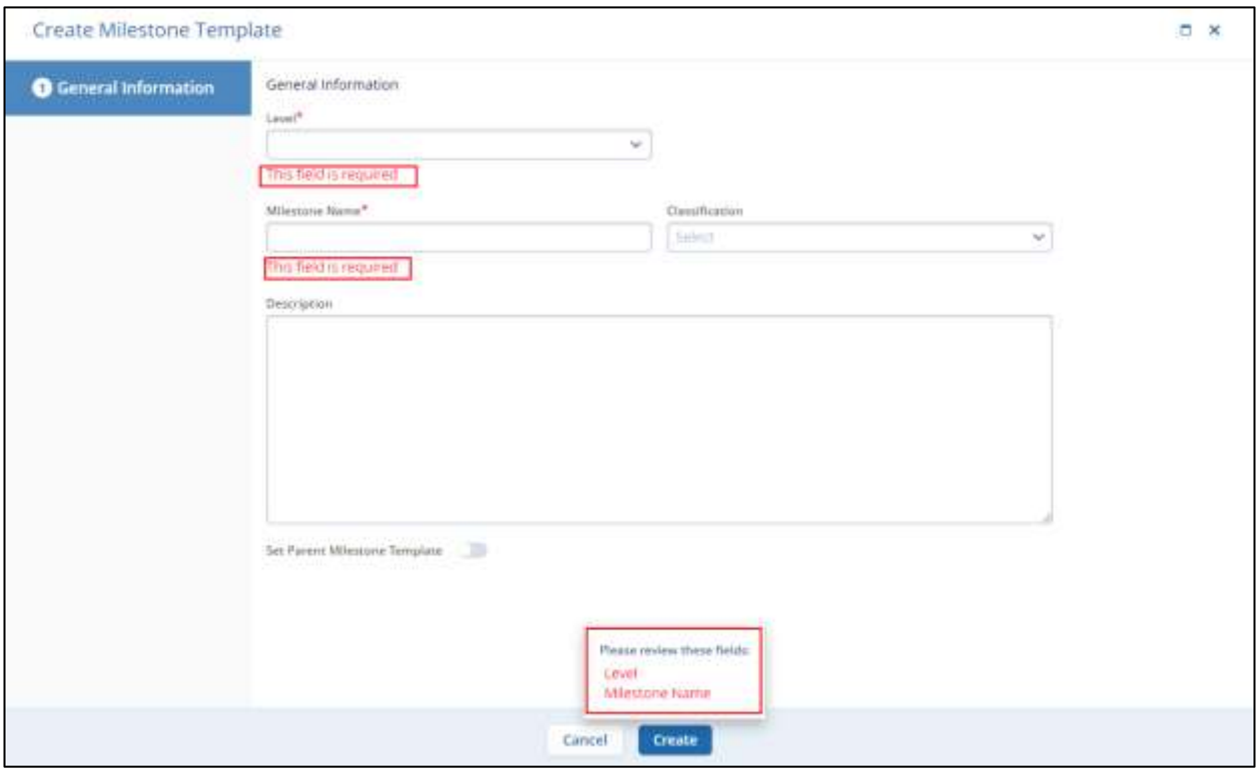


Figure: Mandatory fields error

Creating a Study Milestone from a Template

To create a Study Milestone from a Template, follow the steps below.

1. From the left-hand navigation links click on the Studies.
2. On the Studies window, click on the name of the study to create a milestone.

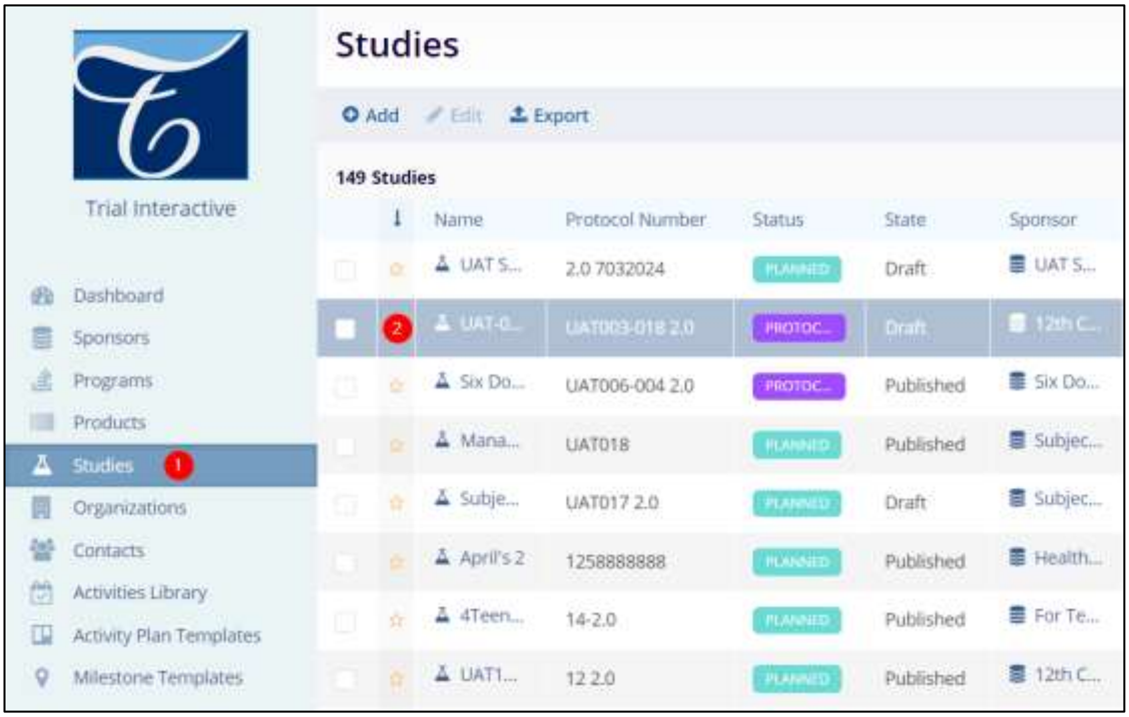


Figure: Selecting a study

3. On the selected studies window, navigate to the left-hand navigation links and click on the Study Details.

Figure: Select Study Details

4. On the Study Details screen, click on the Settings button in the top-right of the screen.

Figure: Select Settings on the Study Details screen

5. Click on the Milestone Templates link in the Navigation menu at the left side of the screen.

6. Click on the +Add button on the on the top-left of the screen.

7. Click on Add From Sponsor.

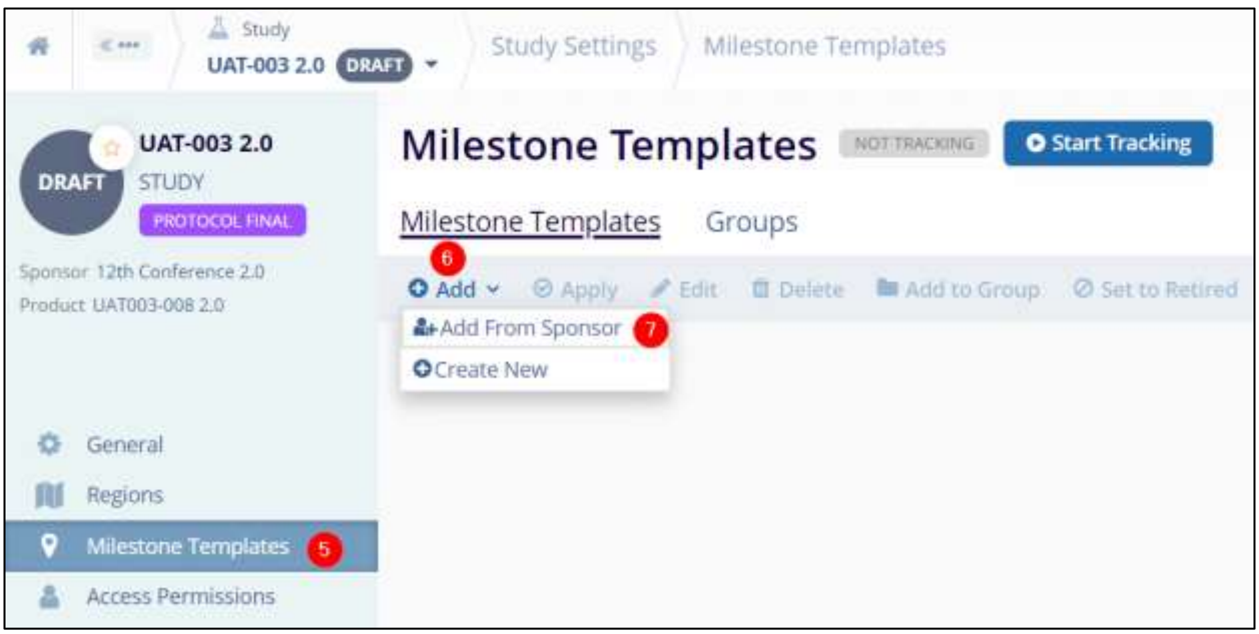


Figure: Select Add From Sponsor

8. On the Add Milestone Template From Sponsor screen, select the milestone template.

9. Click on the Add button.

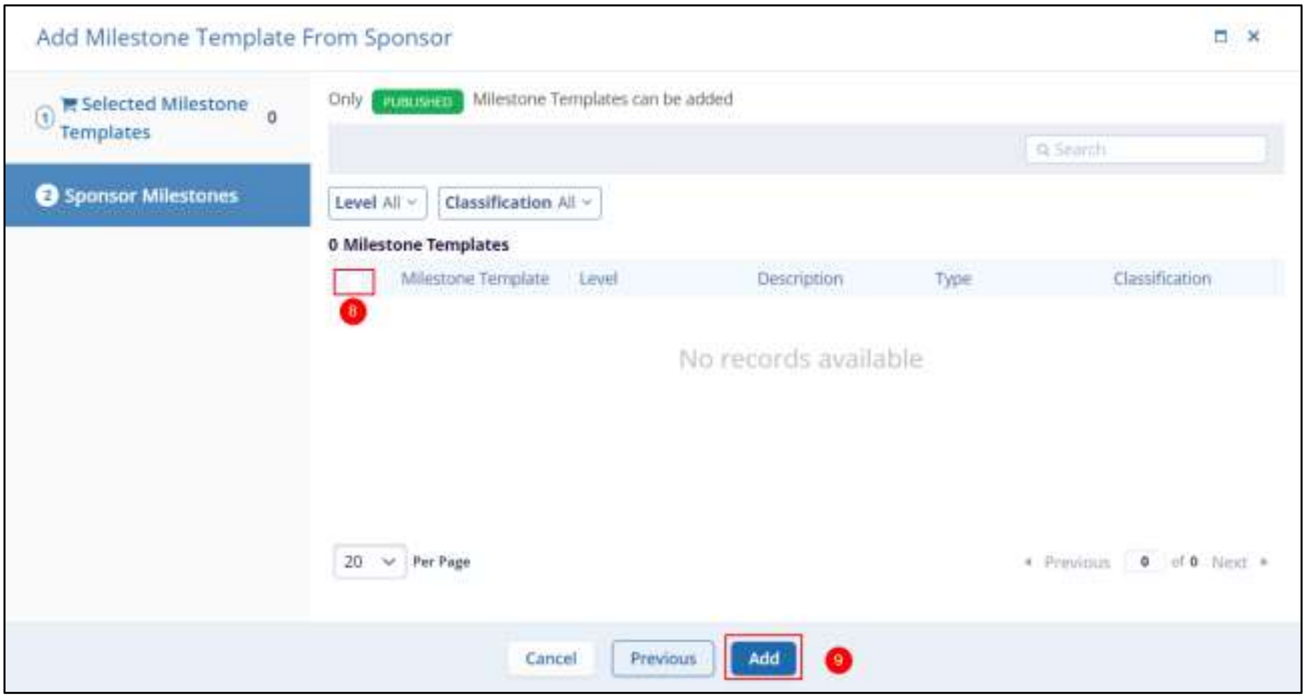


Figure: Add Milestone Template From Sponsor

Additionally, to create a new template, follow the steps below.

1. Click on the Add button in the top-left of the screen and select the Create New option from the dropdown list.

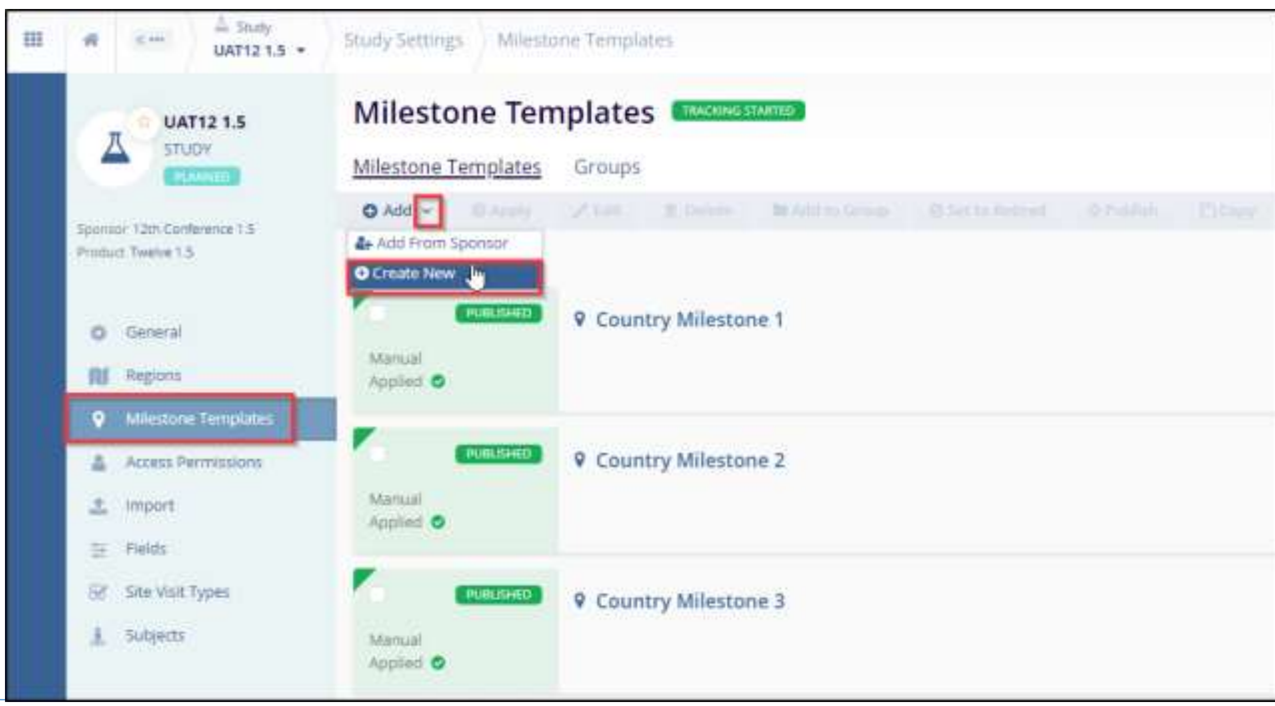


Figure: Create a New Template

2. Fill in 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.

3. Click on Create once all the details are entered.

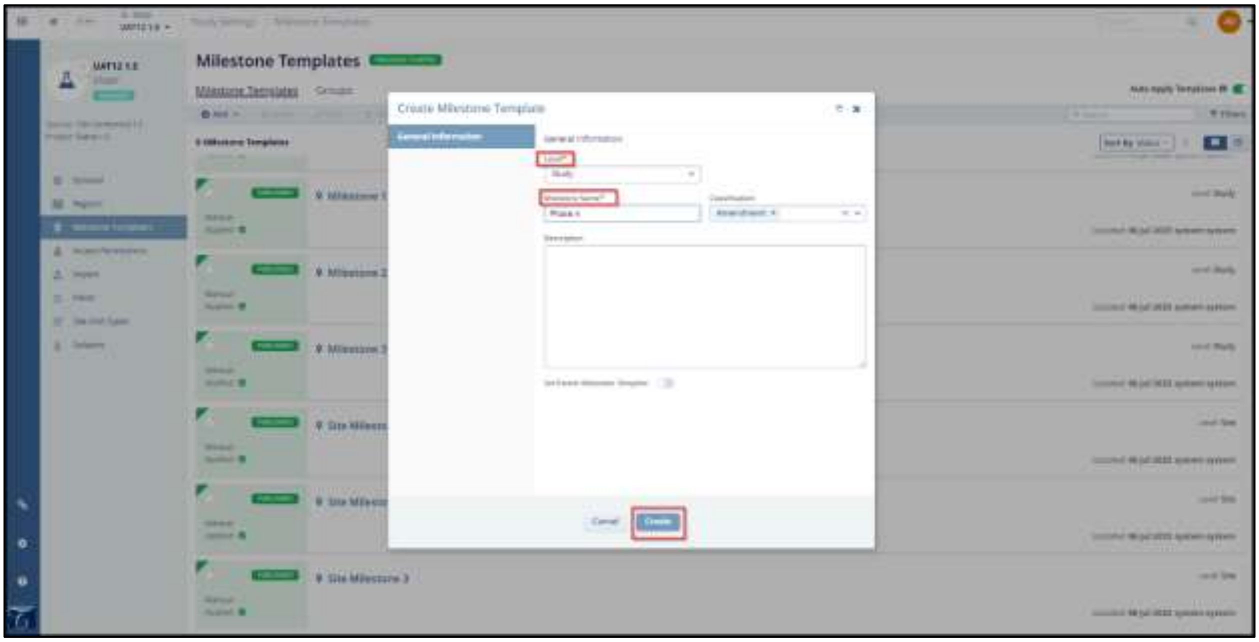


Figure: Save the new template

Note: If any of the required fields are missing, an error will appear when we click on the Create button displaying the fields that need to be filled to create a milestone template successfully.

Editing Domain Milestone Templates

To edit Domain Milestone Templates, follow the steps below.

1. From the left-hand navigation links, select Milestone Templates.
2. On the Milestone Templates screen, click on the milestone template to edit.
3. Click on the Edit button in the top-left of the screen. This opens the Edit Milestone Template screen.

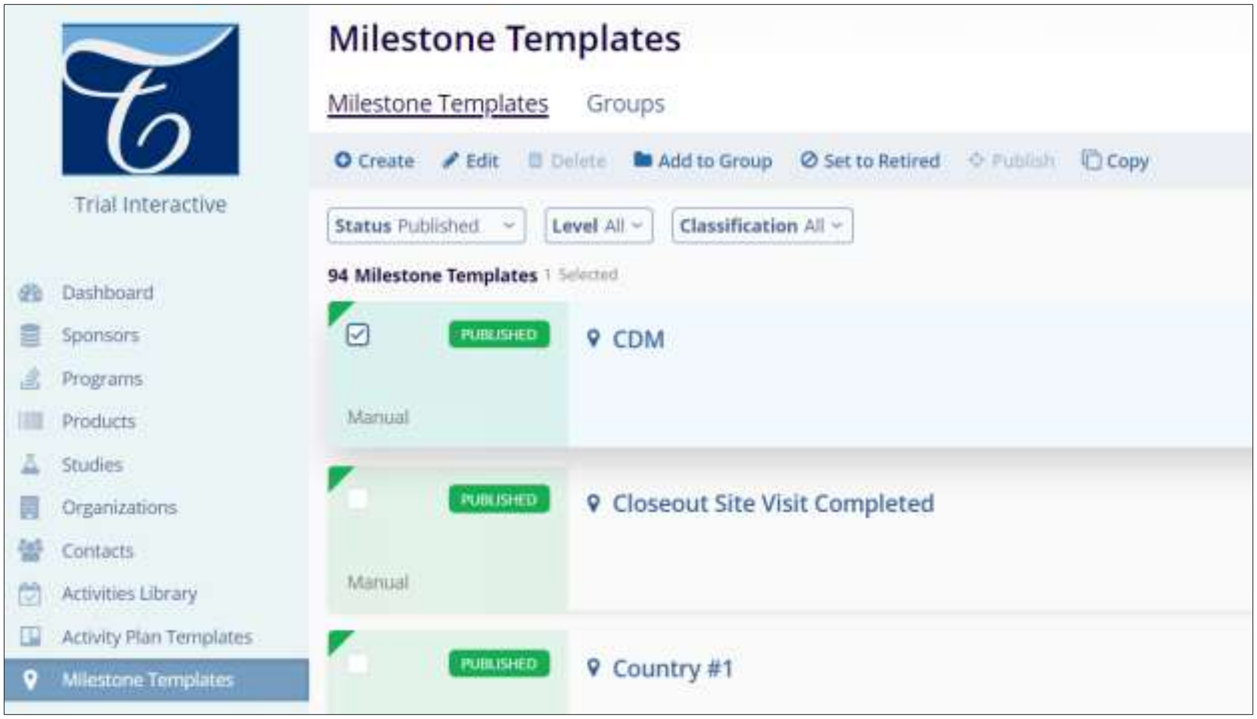


Figure: Select a template to edit

4. On the Edit Milestone Template, Make any necessary changes and click on the Save button.

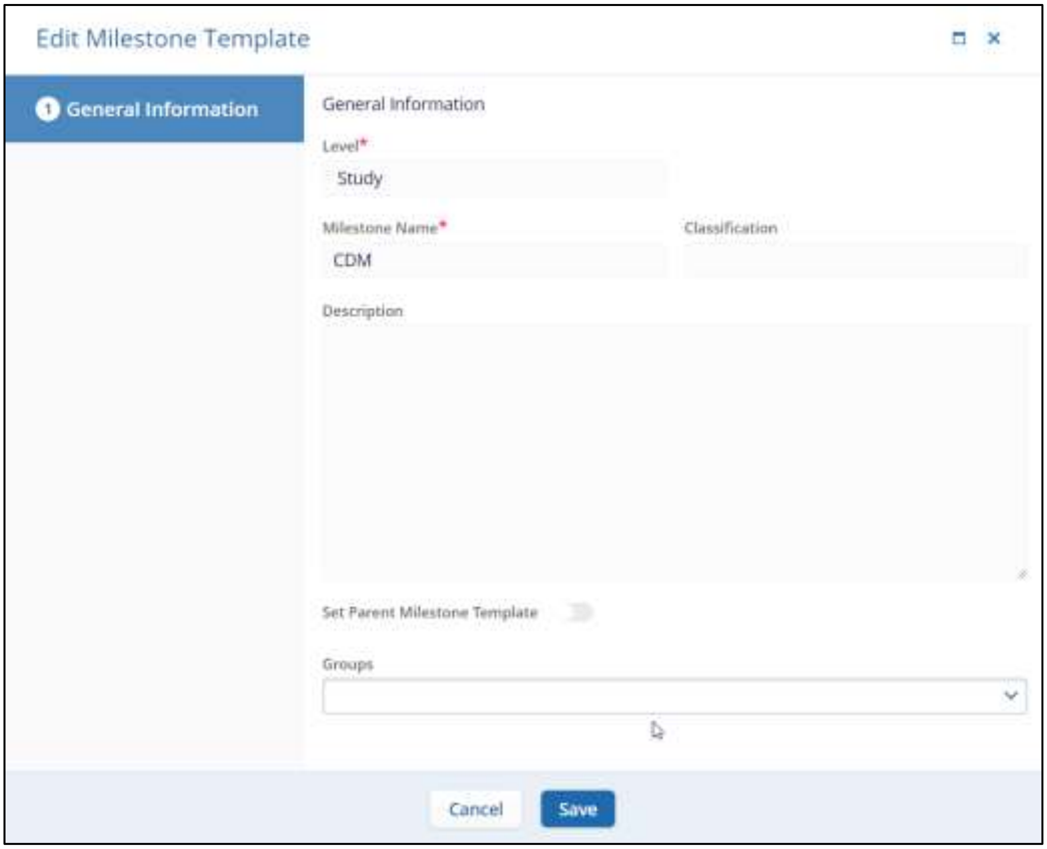


Figure: Edit Milestone Template

Note: Users can only edit templates with Draft or Published status.

Deleting Domain Milestone Templates

To delete Domain Milestone Templates, follow the steps below.

1. On the Milestone Templates screen, click on the milestone template that needs to be deleted.
2. Click on the Delete button in the top-left of the screen which opens the Confirmation window.
3. Click on the Delete button on the confirmation page.

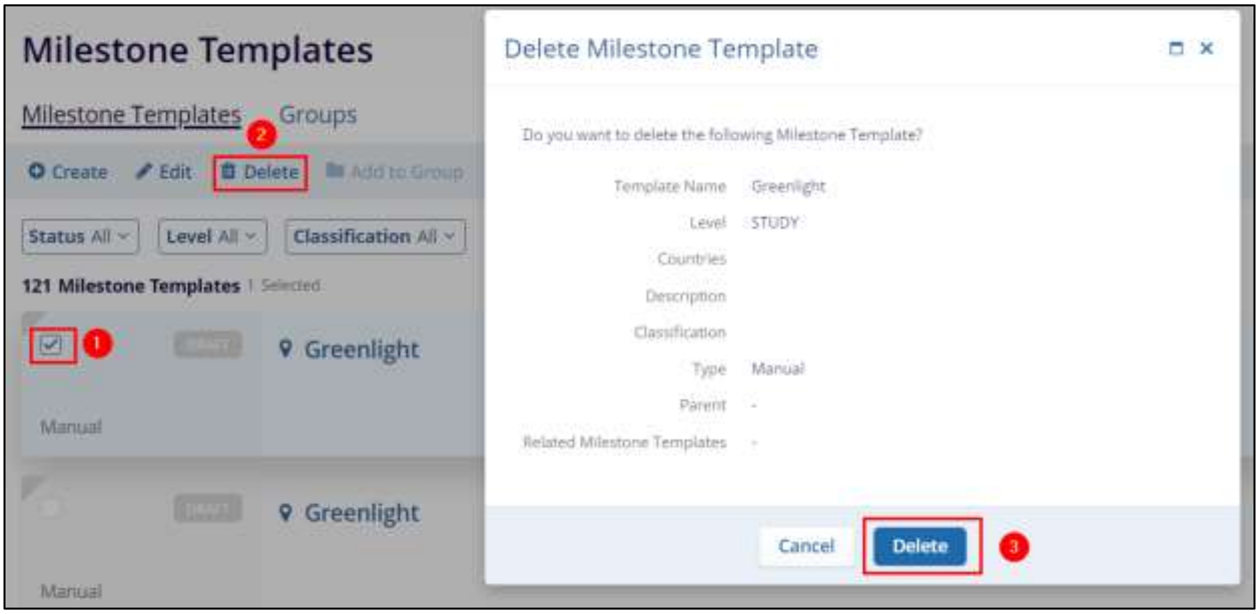


Figure: Deleting Milestone Template

Note: The template needs to be in 'Draft' status to be deleted.

Publishing Milestone Templates

To publish Milestone Templates, follow the steps below.

1. On the Milestone Templates select a template with a Draft status
2. Click on the Publish button in the top-left of the screen.
3. Click on the Publish Milestone Template button in the Please Review Milestone Template window.

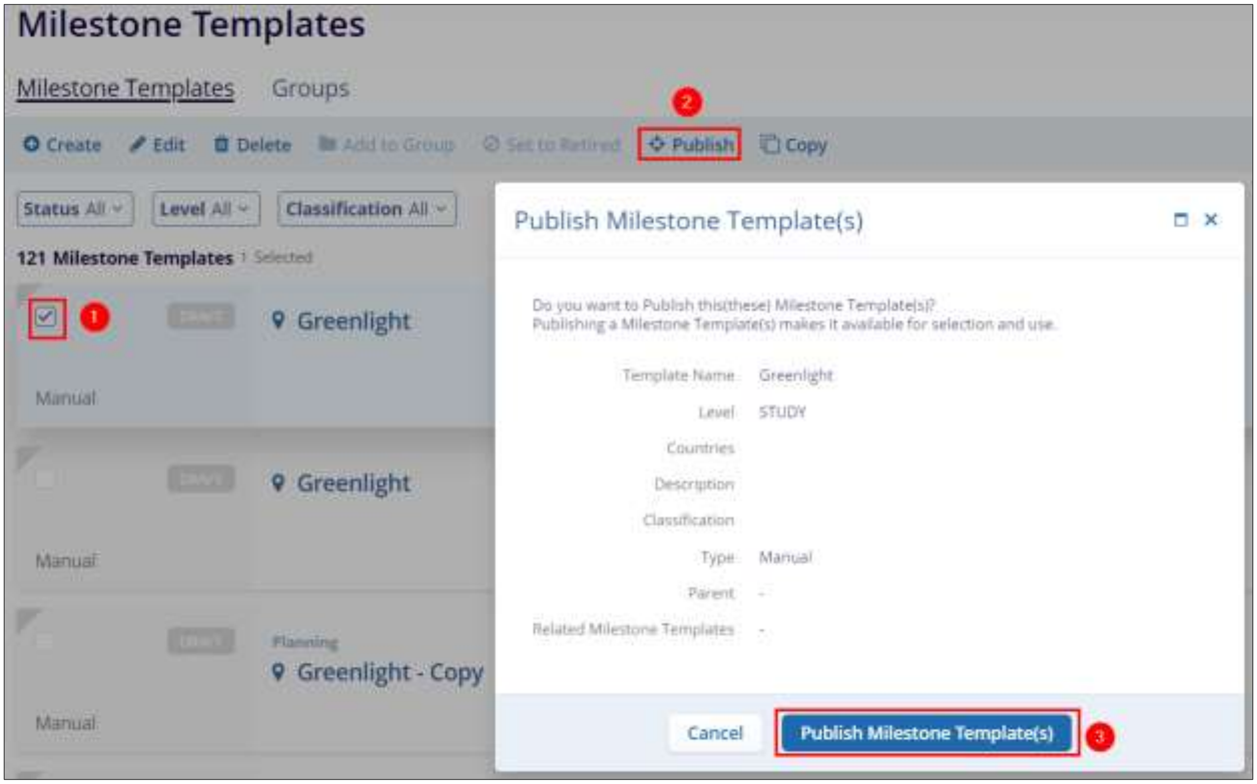


Figure: Publishing Milestone templates

Note: Milestone Templates with Draft status can be published.

Retiring Milestone Templates

Milestones at the Global level are retired in all data hierarchy levels. Suppose users want to continue to track a milestone after retiring it at the Global level. In that case, users must make a copy of the milestone at the Sponsor level or lower before retiring the milestone at the Global level.

To retire a Milestone Template, follow the steps below.

1. On the Milestone Templates screen, select a milestone template in the Published state.
2. Click on the Set to Retired button from the top menu bar.
3. On the Set to Reitred screen mention a reason to retire a template (optional), and click on the Set to Retired button.

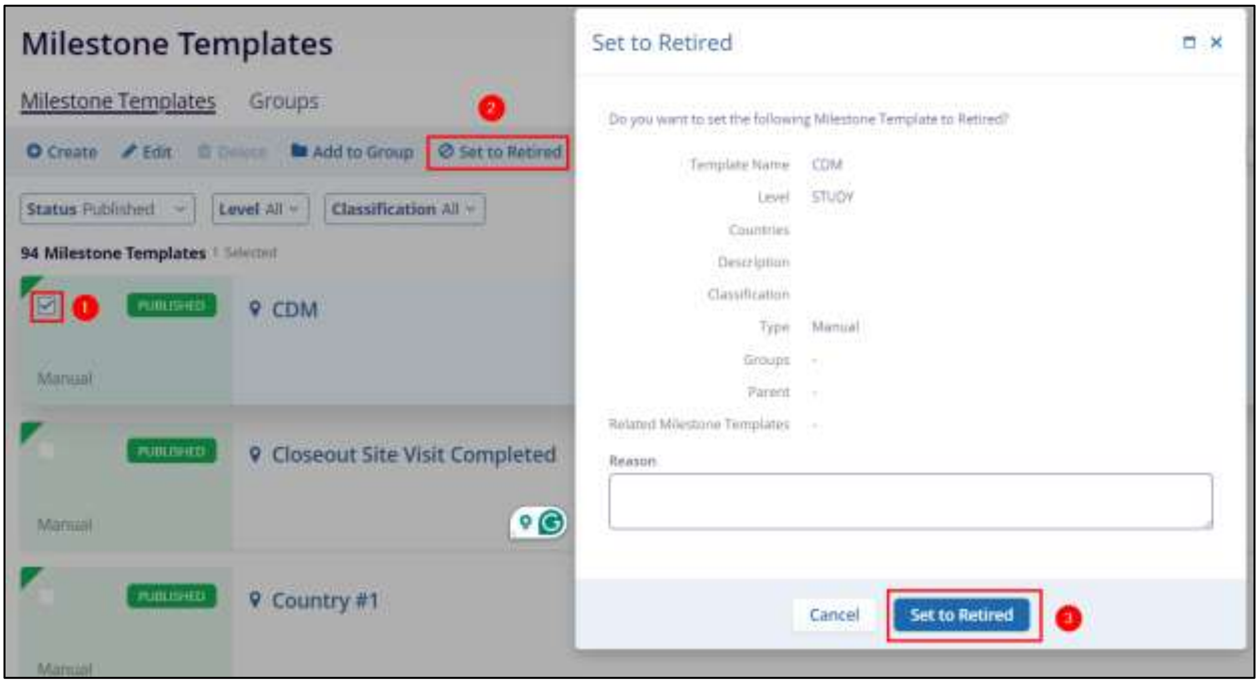


Figure: Retiring Milestone Template

Copying Milestone Templates

To copy Milestone Templates, follow the steps below.

1. Select a template to copy by clicking on the checkbox of the particular template.
2. Click on the Copy button from the top menu bar.
3. On the Copy Milestone Template screen, click on the Create button.

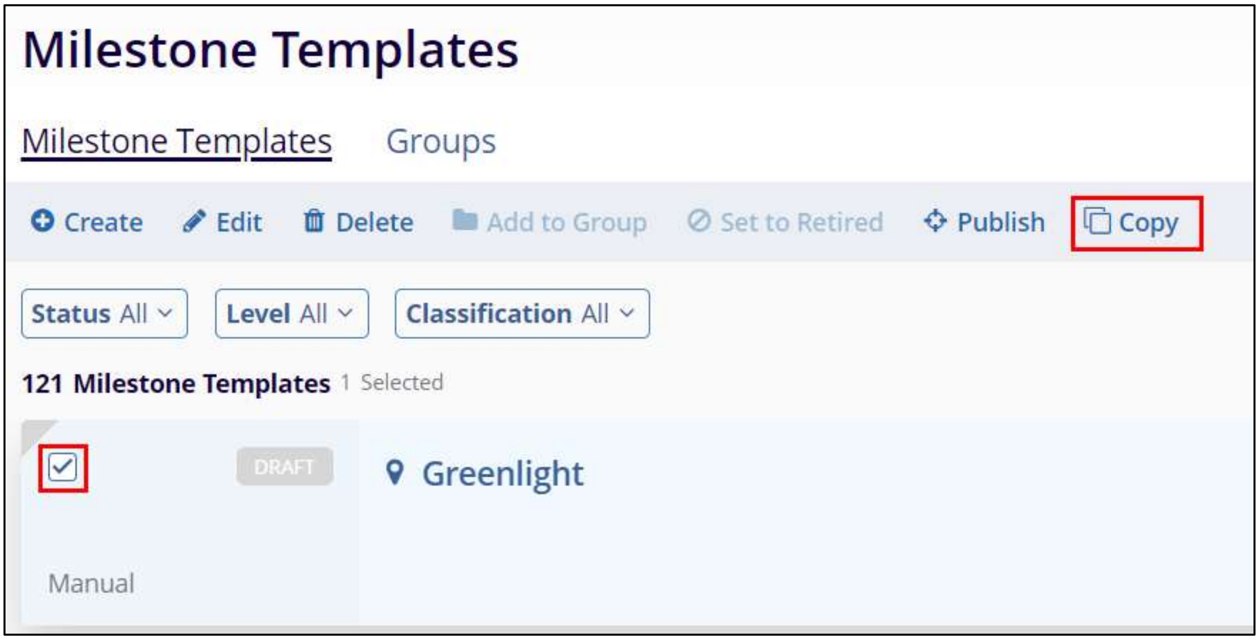


Figure: Copying a milestone template

Note: The milestone templates displaying both Draft and Published status can be copied, only one at a time

Associating Milestone Templates to a Sponsor

To associate a Milestone Template with a Sponsor, follow the steps below.

1. From the left-hand navigation links, select Sponsors
2. On the Sponsors screen, select a sponsor by clicking on the name.

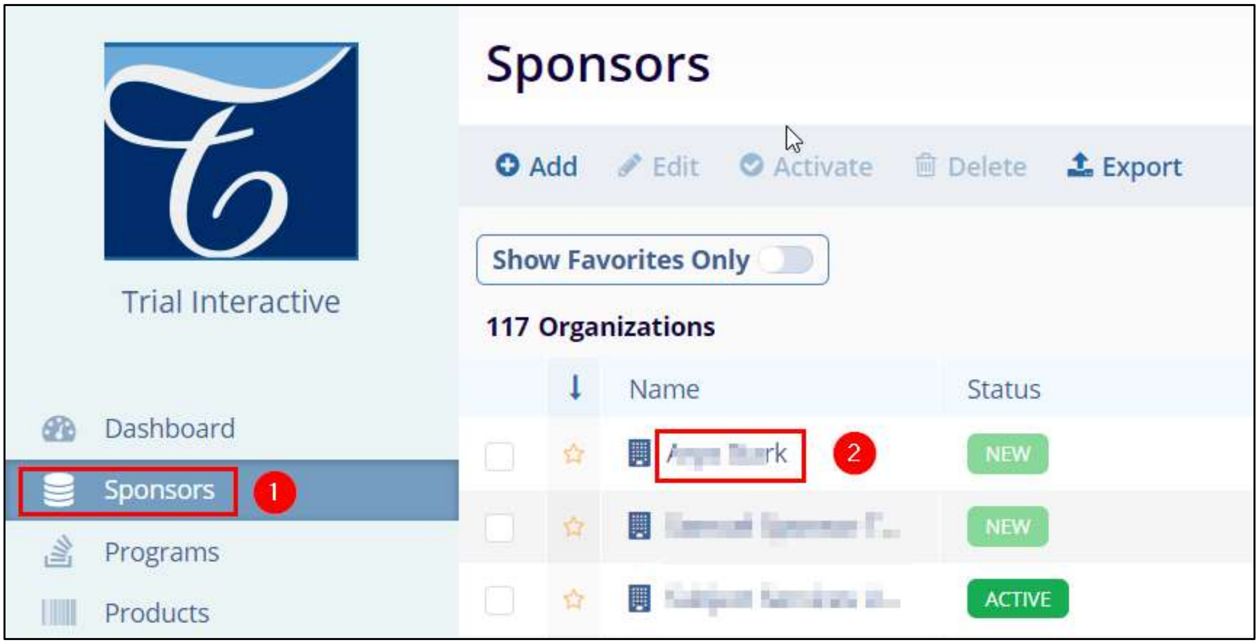


Figure: Select Sponsors

3. On the Sponsor Details screen, click on the Settings button on the top-right of the screen.

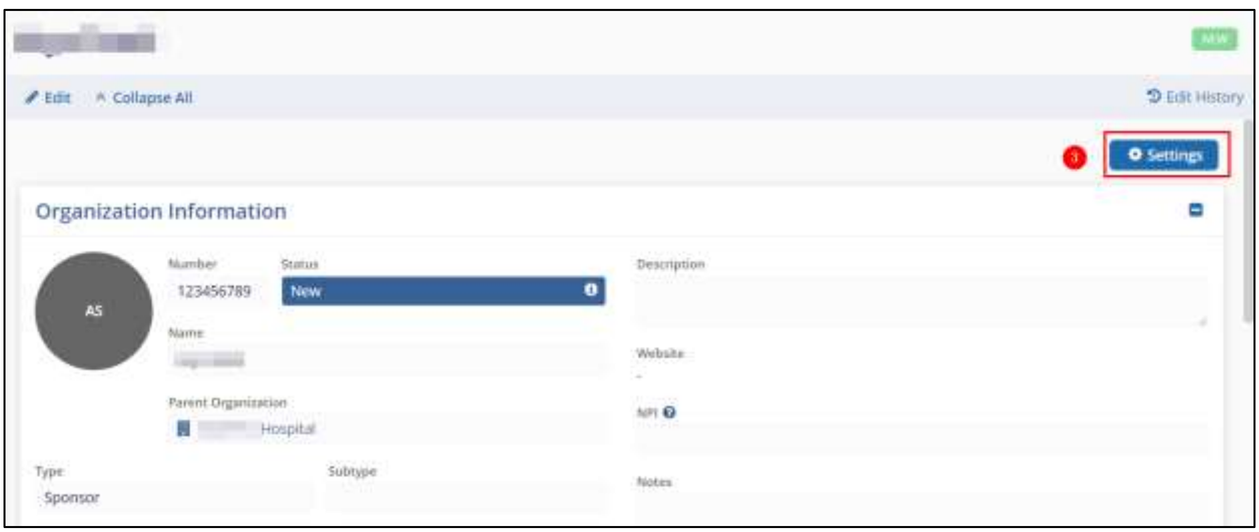


Figure: Access Setting on the Sponsor Details screen

4. On the Sponsors Milestone Templates, click on the +Add > +Add From Domain buttons.

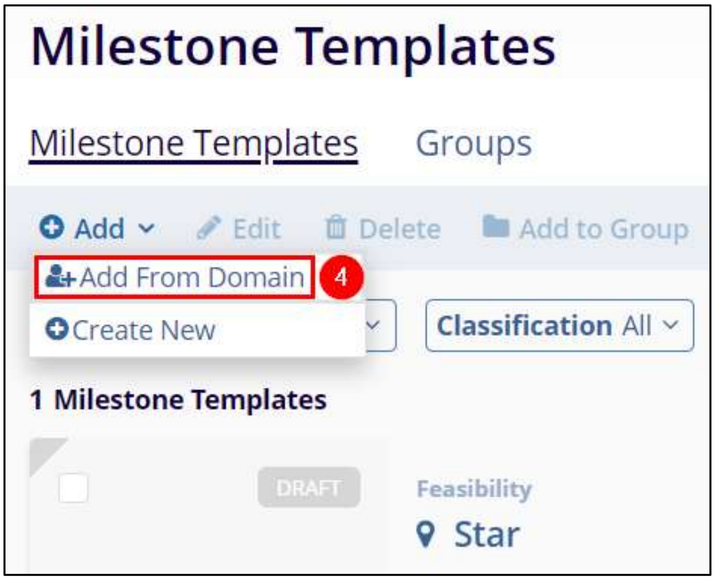


Figure: Add Template From Domain

5. On the Add Milestone Template from the Domain window, select one of the milestone templates by clicking on the milestone templates checkbox.

6. Click on the Add button once all the required templates are selected.

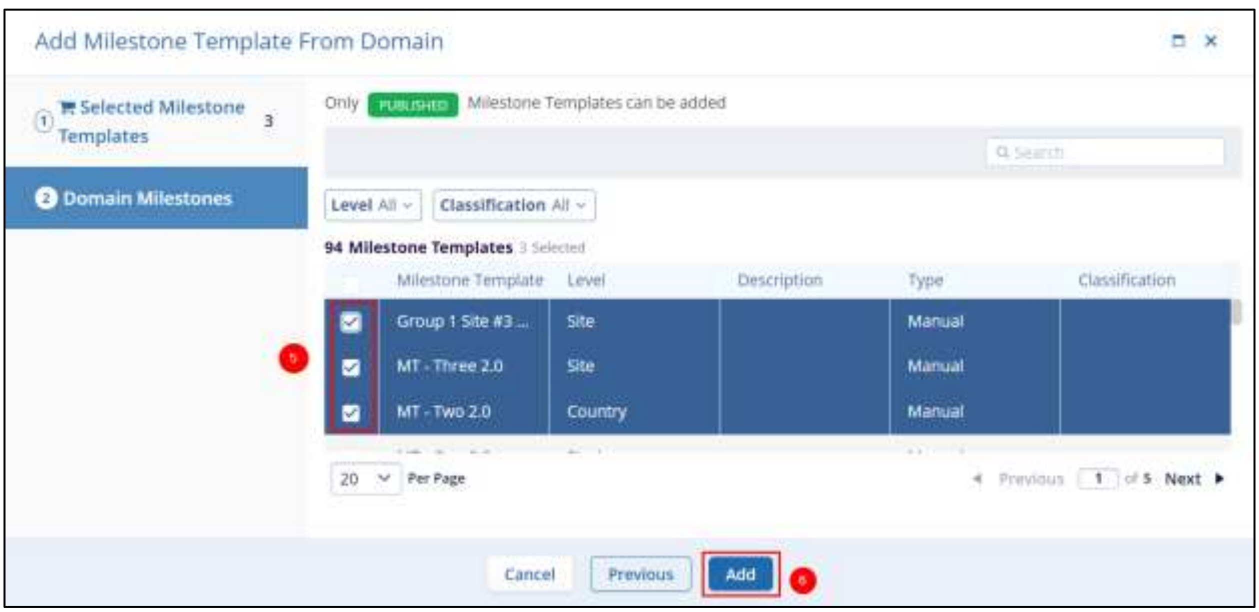


Figure: Add Milestone From Domain screen

Defining Sponsor-Specific Milestone Templates

To define sponsor-specific Milestone Templates, follow the steps below.

To associate a Milestone Template with a Sponsor, follow the steps below.

1. From the left-hand navigation links, select Sponsors
2. On the Sponsors screen, select a sponsor by clicking on the name.

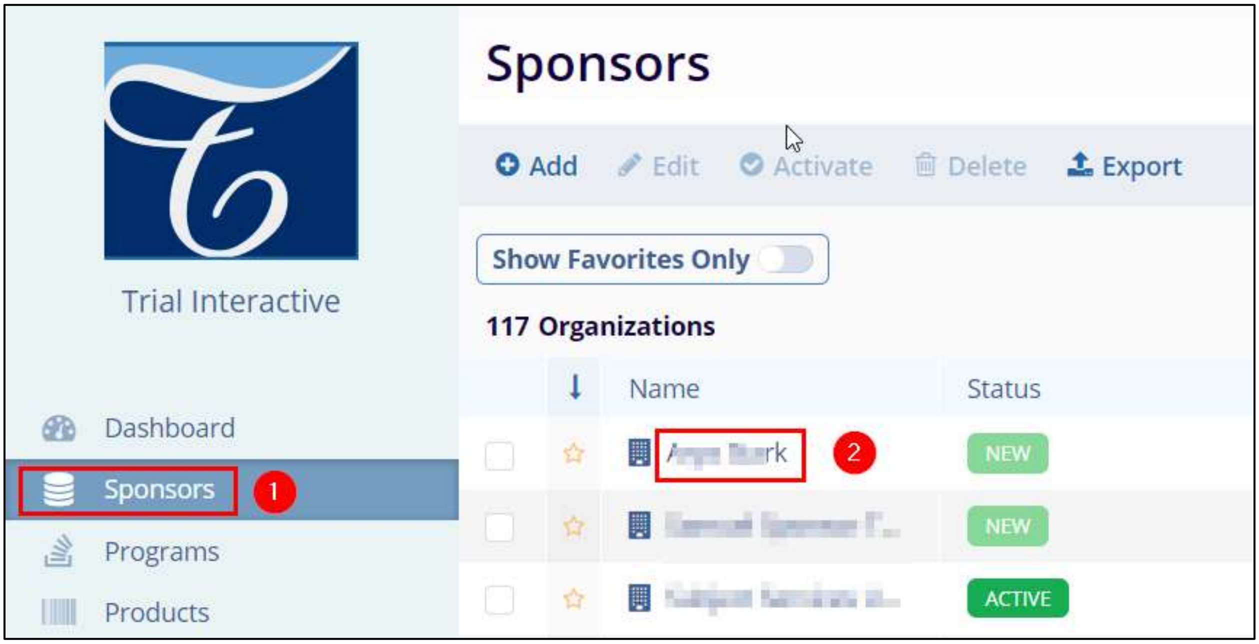


Figure: Select Sponsors

3. On the Sponsor Details screen, click on the Settings button on the top-right of the screen.

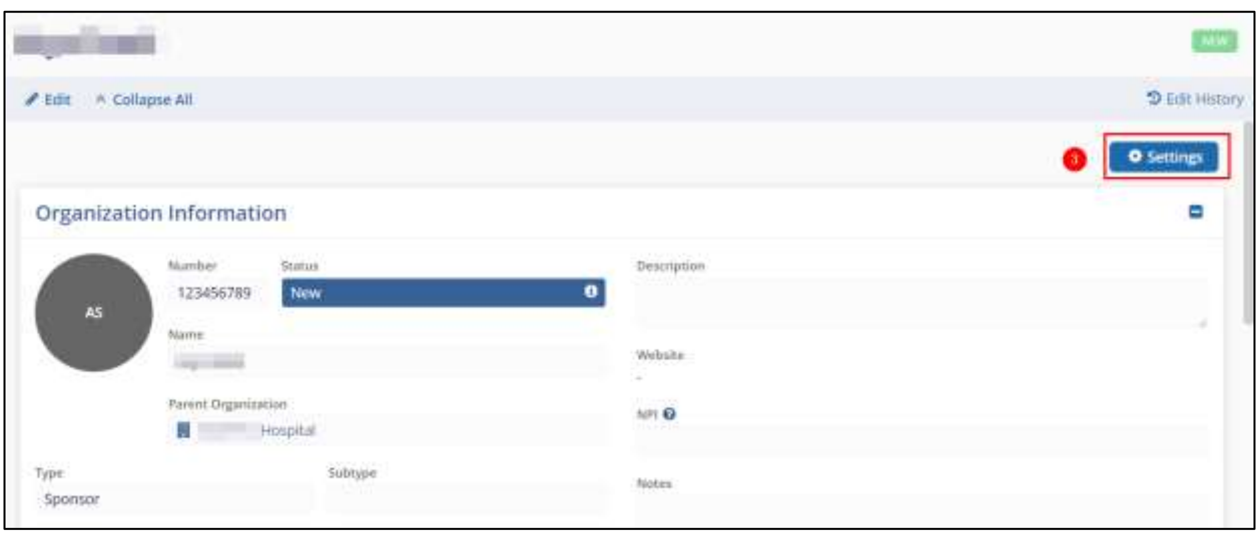


Figure: Access Setting on the Sponsor Details screen

4. On the Sponsors Milestone Templates, click on the +Add > +Create New buttons.

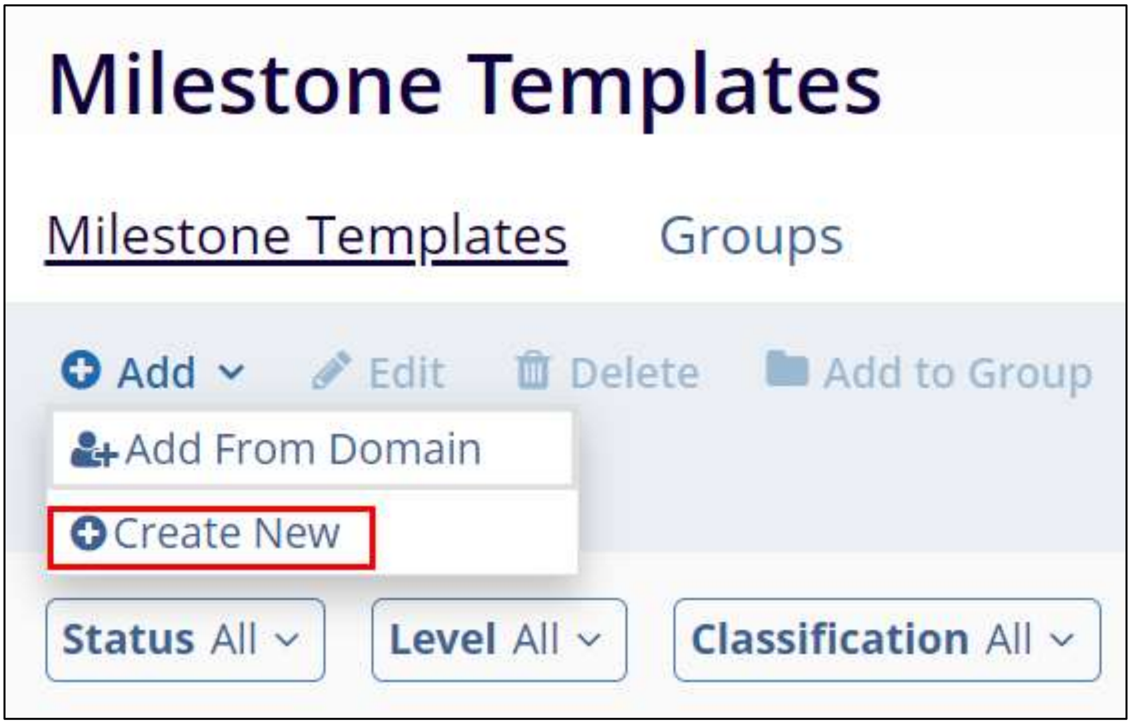


Figure: Create new milestone template for the sponsor

5. On the Create Milestone Template from the Domain window, add all the mandatory details.

6. Click on the Add button once all the mandatory details are entered.

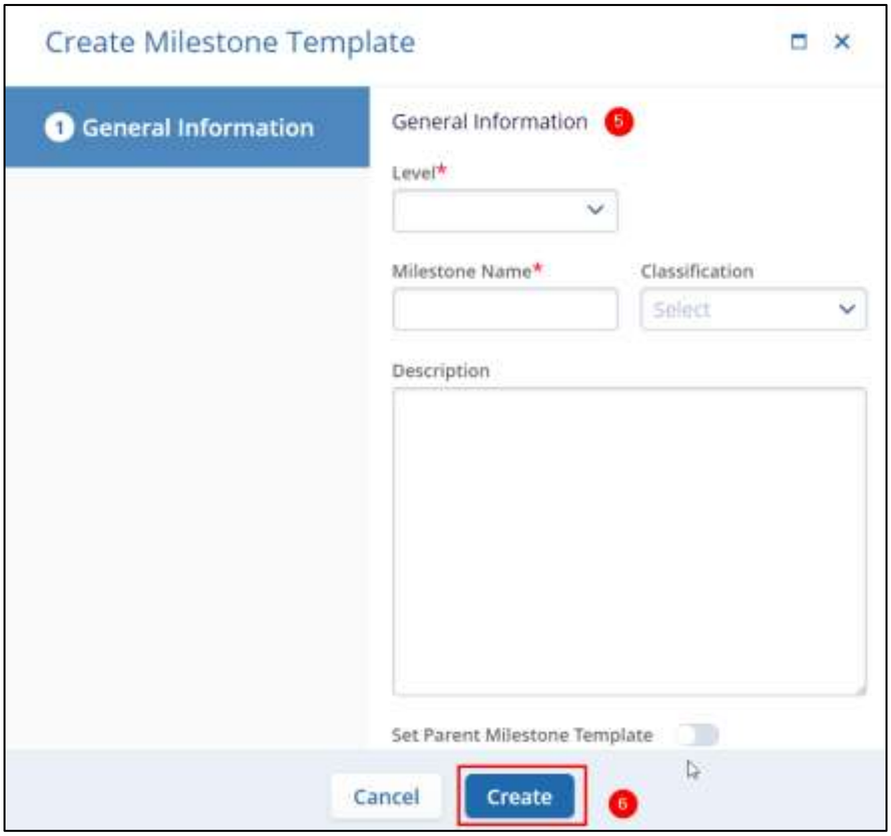


Figure: Creating new milestone template for sponsor

Tracking Milestones

To track milestones, follow the steps below.

1. From the left-hand navigation links click on the Studies.
2. On the Studies window, click on the name of the study.
3. On the selected studies window, navigate to the left-hand navigation links and click on the Study Details.
4. On the Study Details screen, click on the Settings button in the top-right of the screen.
5. Click on Start Tracking in the top-left of the screen. This opens the Start Tracking confirmation window.
6. Click on the Yes, start tracking button which will result in all milestones to be applied and start tracking, not just the selected milestone.

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

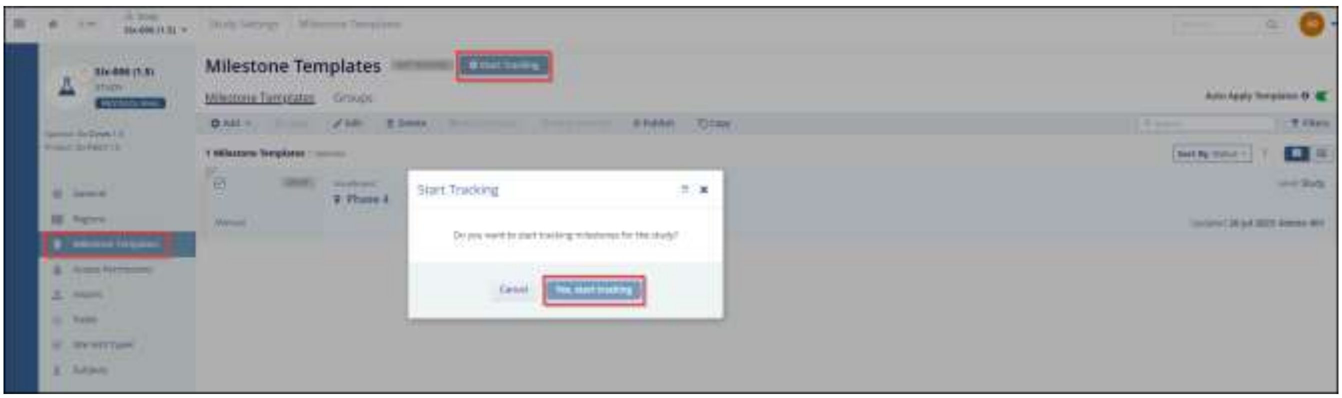


Figure: Tracking Milestones

Auto Apply

It can be difficult, at times, to remember to apply a newly added or created milestone to a study. The Auto Apply Templates toggle switch at the top-right corner of the Milestone Templates screen at the study level. This way, Study Managers can indicate whether or not milestones should be applied manually, as needed, or automatically once they are published and added to a study.

Figure: Auto Apply Templates

Note: This would not apply the template to sites created after this switch is activated. For future sites, it is recommended to use the scheduler for activity plans.

Milestone Groups

Users can 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.

Creating Milestone Groups

To create Milestone Groups, follow the steps below. Refer to the screenshot and steps for the sequence.

1. From the left-hand navigation links, select Milestone Templates.
2. Click on Groups on the Milestone Templates screen.

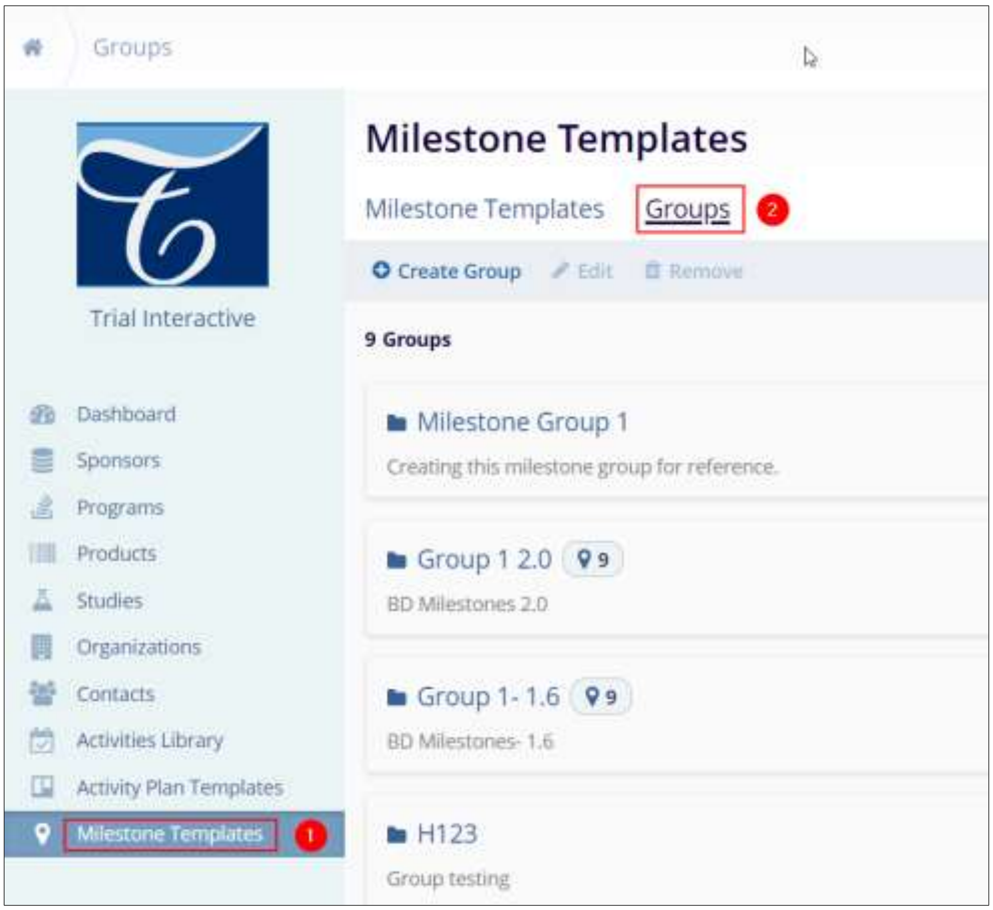


Figure: Milestone Groups

3. Click on +Create Group.
4. On the Create a Group screen, fill in the following details.
   a. Title*: Enter a suitable title for the group
   b. Description*: Enter the necessary description for the group.
5. Click on Create once all the necessary details are entered.

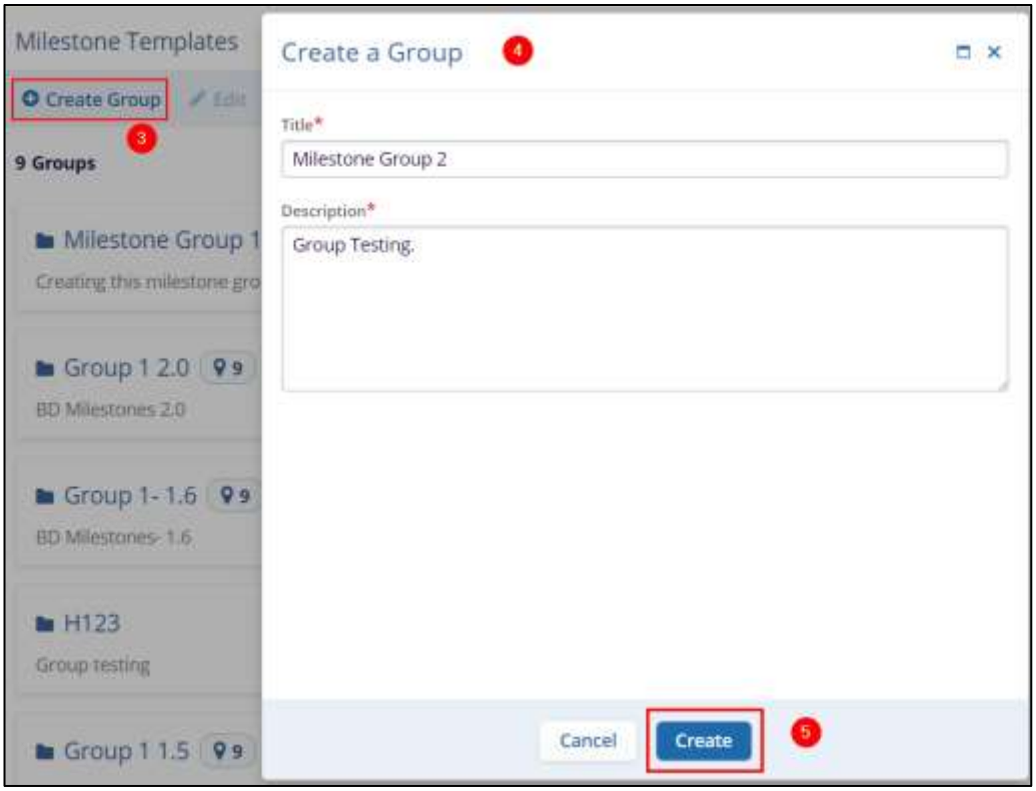


Figure: Create a Group

6. Once the record is successfully created, users will get a success message and the newly created group will appear on the Groups screen.

Figure: Success notification for the newly created group.

Adding Template to a Milestone Group

To add templates to a Milestone Group, follow the steps below

1. Click on the Milestone Group name (Milestone Group 2)

Figure: Adding Template to a Milestone Group

2. On that Milestone Groups screen, templates that are added to that group are visible. To add more templates, click on +Add.

Figure: Group Details

3. Click on the respective templates checkboxes to select the templates and then click on Add.

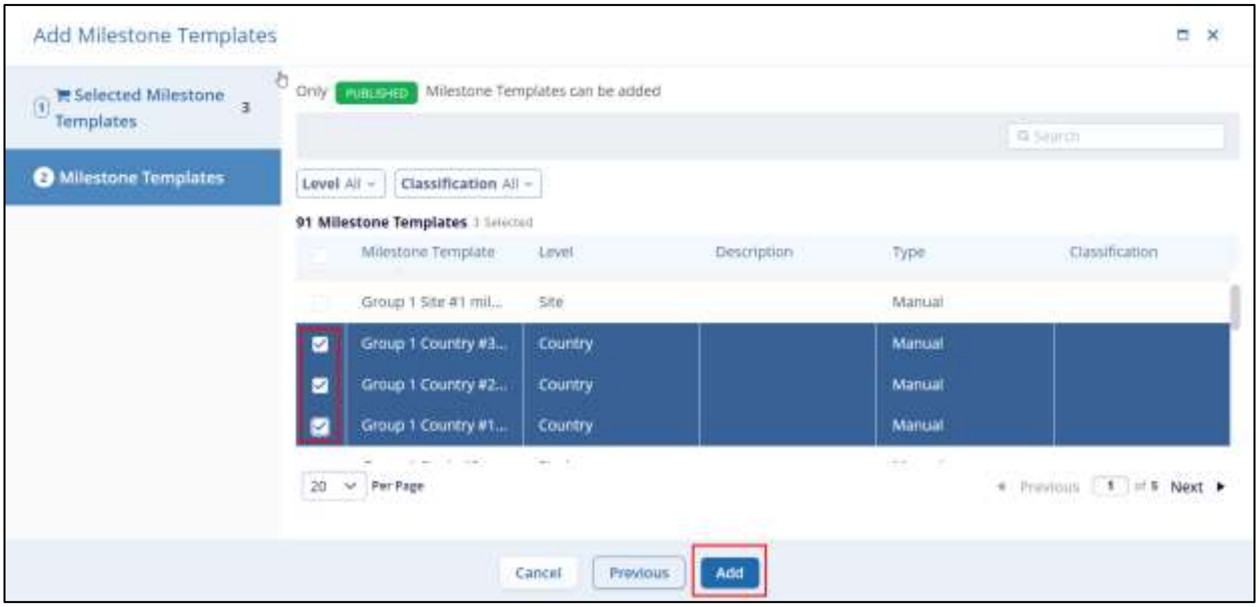


Figure: Select and Add milestone templates to groups

4. The screen displays a success notification once templates are added to the groups. The Group Details screen displays the total number of templates associated with that group.

Figure: Milestone template success notification

Removing Templates from Milestone Groups

To remove templates from a Milestone Group, follow the steps below. Refer to the screenshot for the sequence.

1. Select a template by clicking on that particular template checkbox.
2. Click on the Remove button from the top menu bar
3. On the Remove From Group confirmation popup, click on the Remove button.

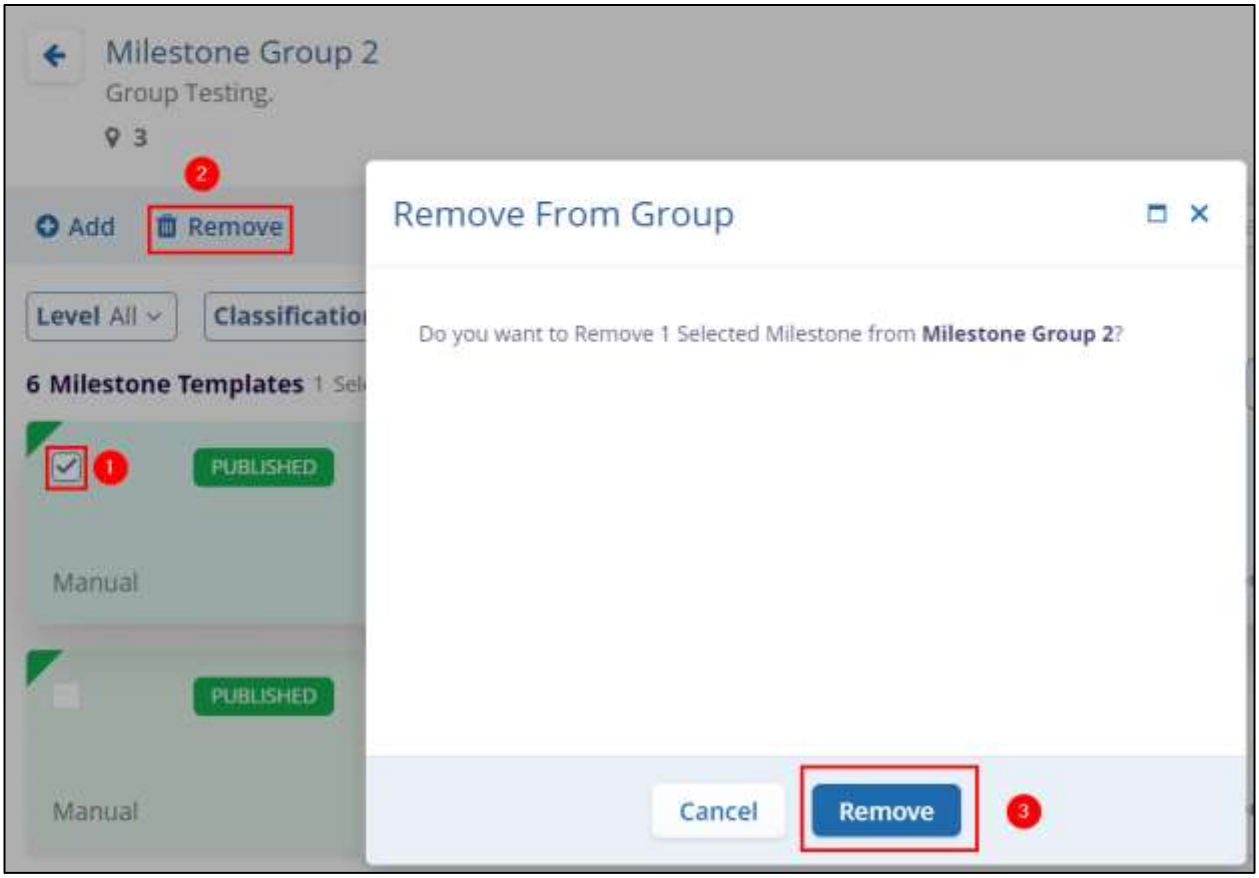


Figure: Removing templates from group

Customizing Milestone Groups screen

Users can apply filters and sorting criteria, as well as customize the screen view of the selected milestone group.

Filters

To apply filters, follow the steps below

1. Click on Filters situated beside the search box.
2. By, default the screen displays milestones created at a Country, Site, and Study level. Click on the Level dropdown and select the appropriate option.
3. Click on the Classification dropdown and select the required option.

Figure: Filters

Sorting

To sort the screen, follow the steps below

1. Click on the Sort By dropdown and select the appropriate sorting criteria. By default, the Status sorting criteria are applied.
2. Click on the arrow to sort the screen in ascending or descending order.

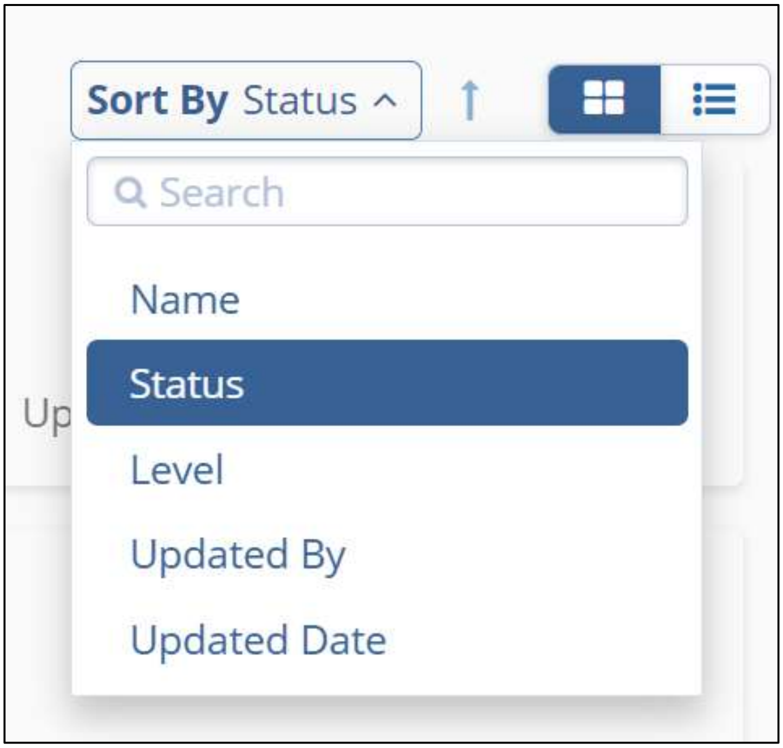


Figure: Sorting criteria

View

To customize the screen view, follow the steps below

1. Navigate to the screen customization icons situated beside Sort By dropdown.
2. Select either Grid View or List View.

Note: By default, Grid View is selected.

Figure: Grid View or List View

Editing Group

To edit the group, follow any one of the two methods listed below

Method 1

1. From the left-hand navigation links, select Milestone Templates > Groups
2. Select a group by clicking on the group tile.
3. Click on the Edit icon from the top menu bar.

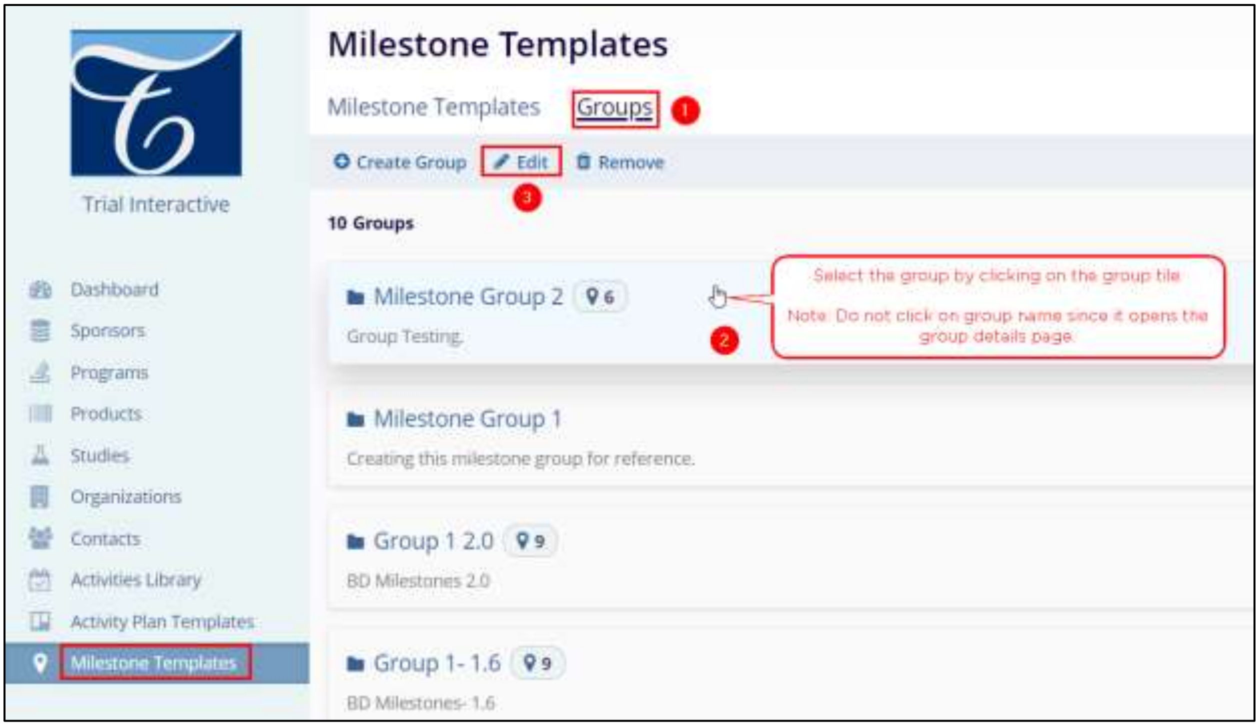


Figure: Editing Group

4. On the Edit Group Details page, make the required changes to the Title* or Description*.
5. Click on the Edit button, which will become accessible when edits are made, once the required details are updated.

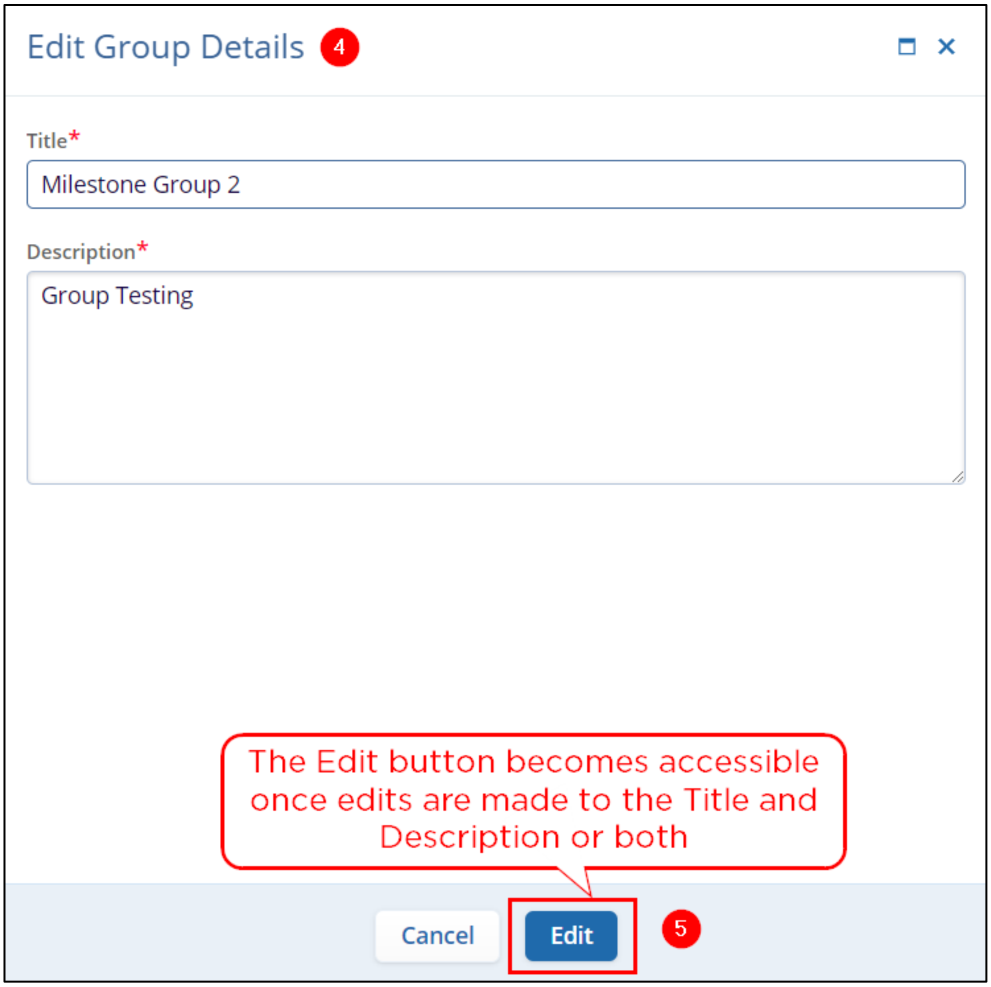


Figure: Edit Group Details screen

Method 2

1. From the left-hand navigation links, select Milestone Templates > Groups
2. Click on the name of a group that needs to be edited which will then open that particular group's screen.

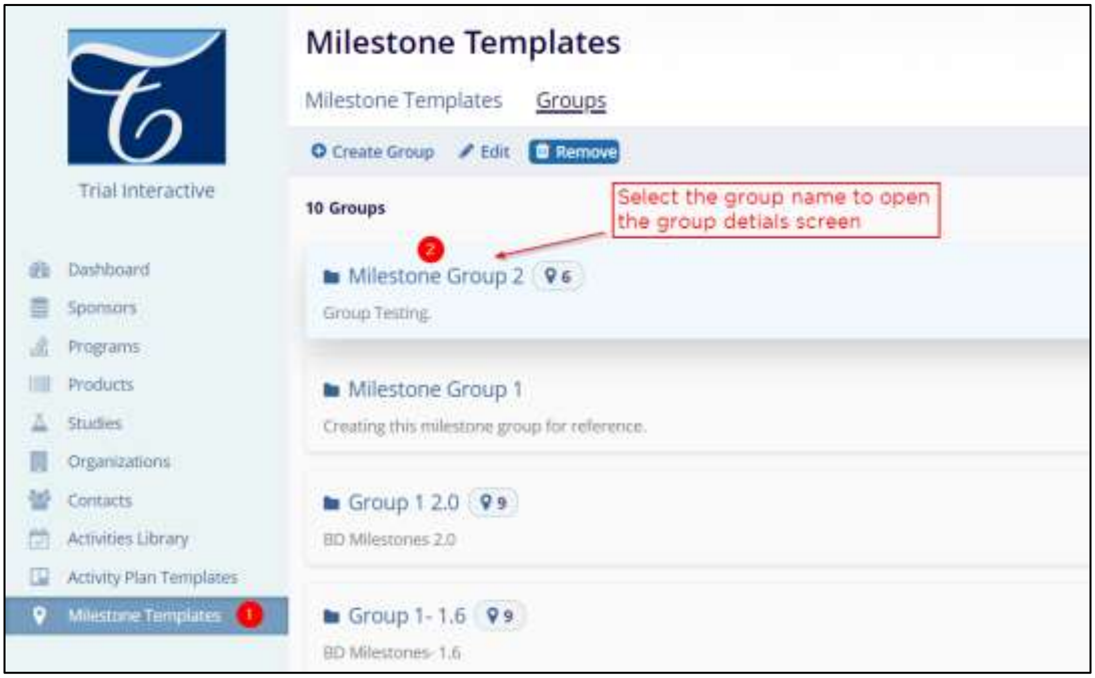


Figure: Select the group name

3. Click on Edit Details,
4. Make the required changes on the Edit Group Details screen, and select Edit.

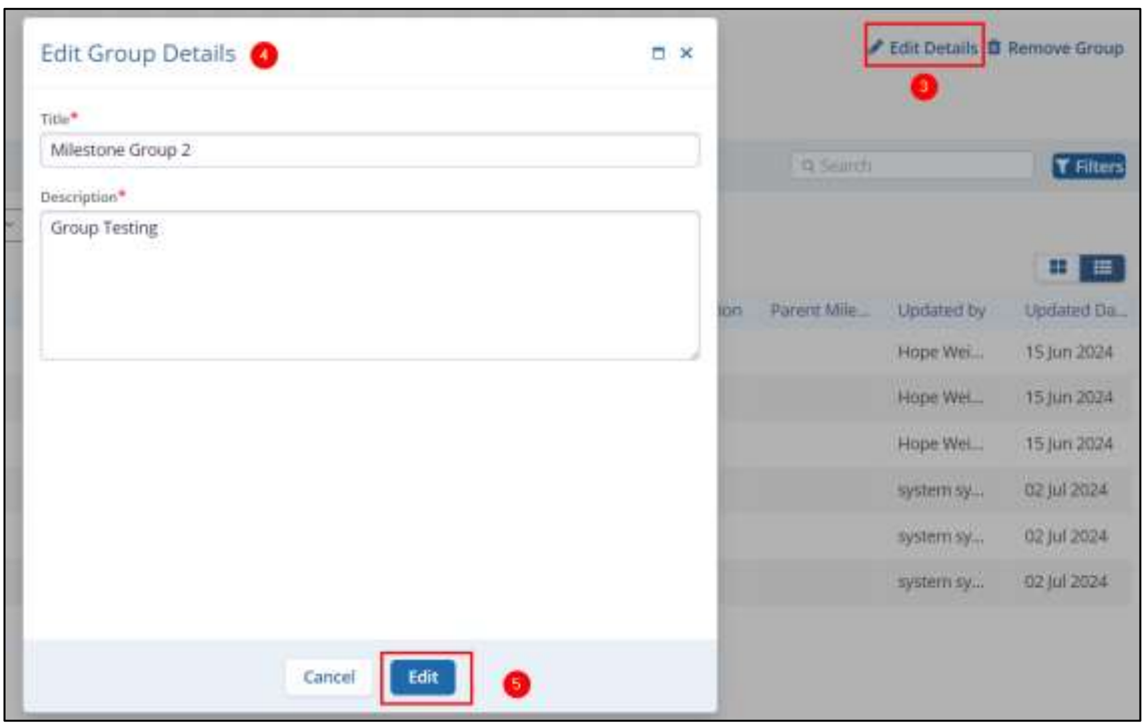


Figure: Edit Group Details-method 2

Removing Group

Method 1

1. From the left-hand navigation links, select Milestone Templates > Groups.
2. Select a group by clicking on the group tile.
3. Click on the Remove icon from the top menu bar.

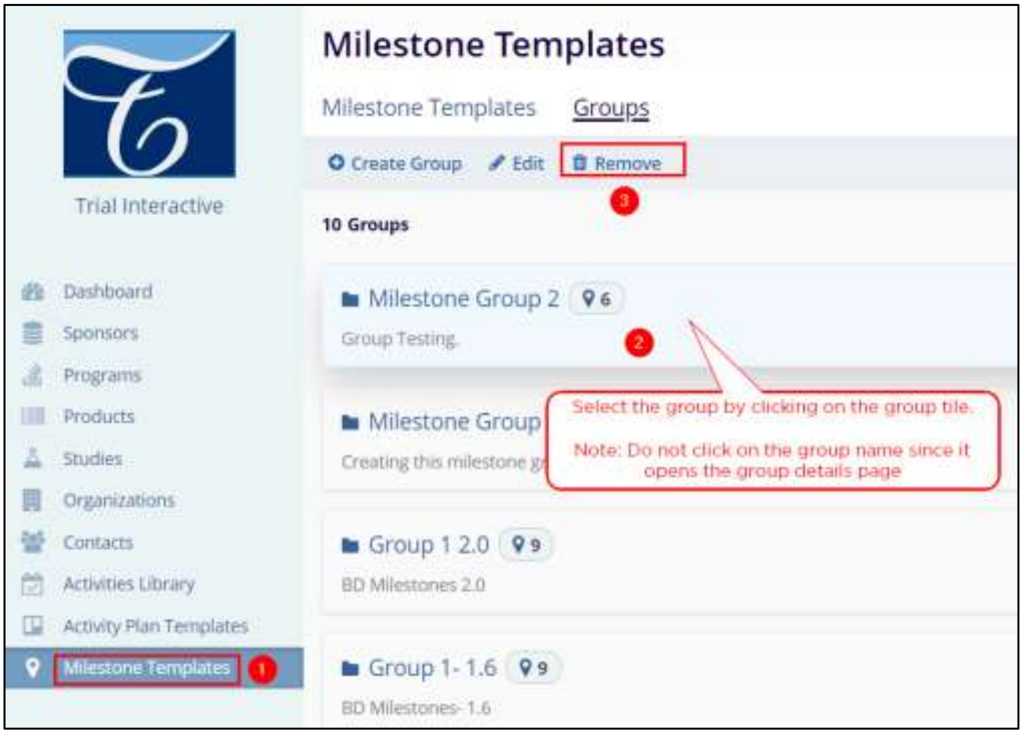
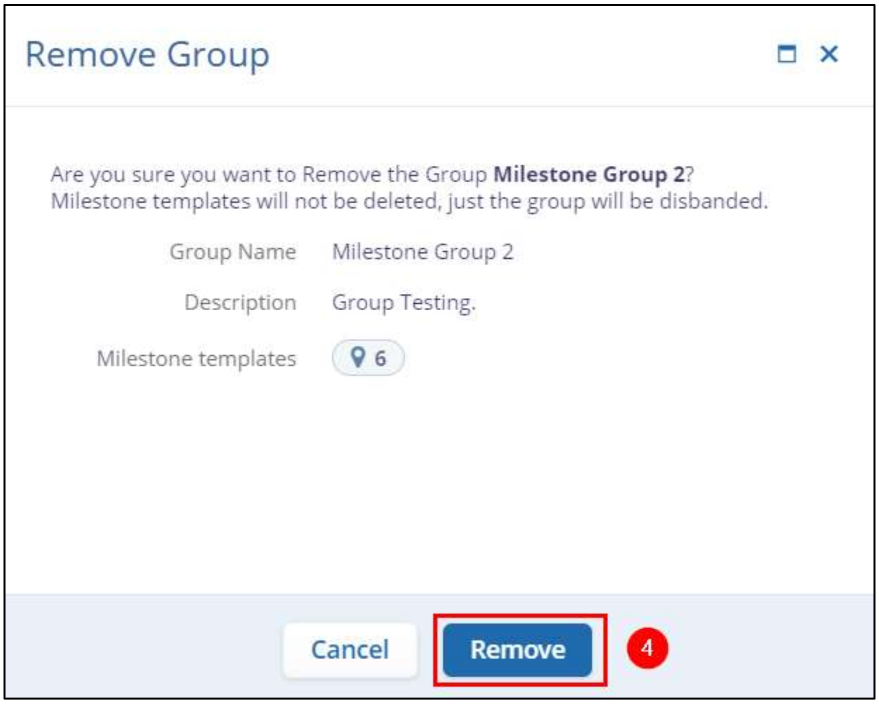


Figure: Removing Group-method 1

4. Click on the Remove button on the Remove Group screen.



Method 2

1. From the left-hand navigation links, select Milestone Templates > Groups
2. Click on the name of a group that needs to be edited which will then open that particular group's screen.

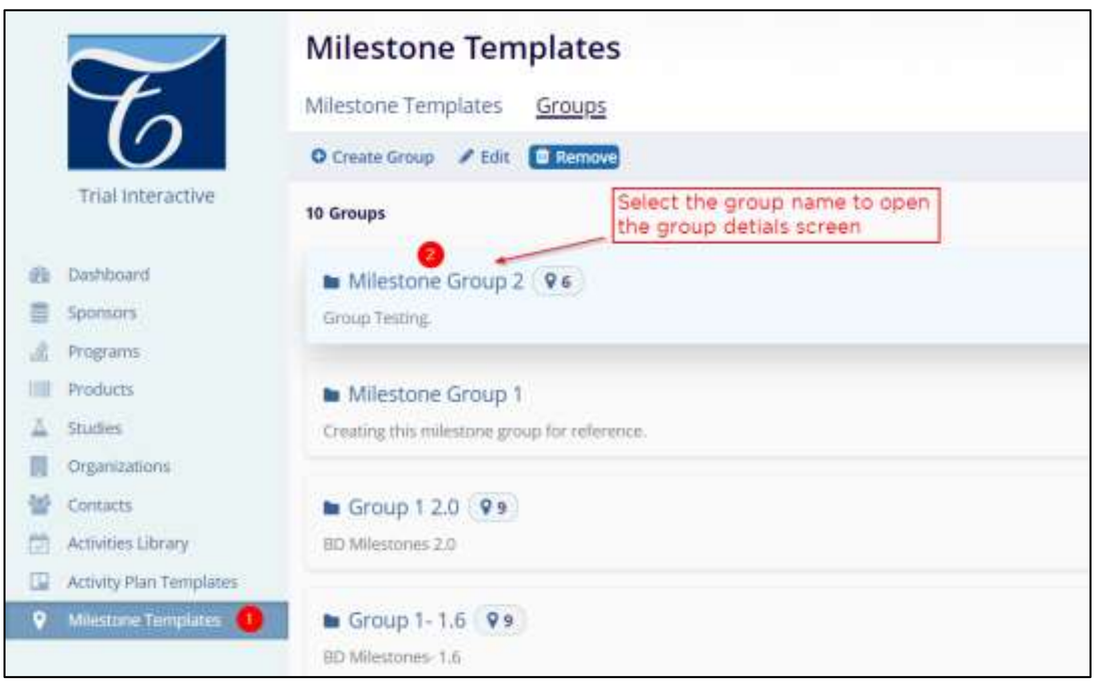


Figure: Select the group name

3. Click on the Remove Group button.

4. Click on the Remove button on the Remove Group screen.

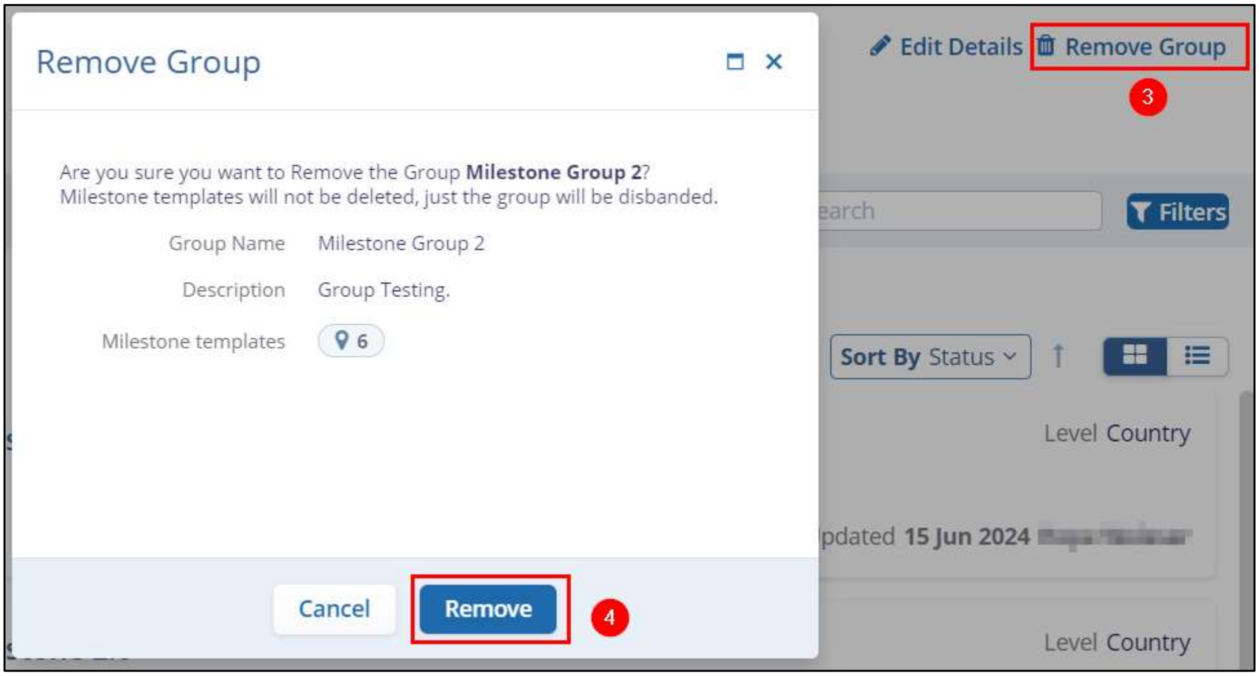


Figure: Remove Group-method 2

Accessing Platform Links

To access all the Platform Links, follow the steps below.

1. Click on the waffle icon to expand the side menu bar and select Links.
2. Select the required link
3. Click on the required platform links from the available options and it will open the specific platforms page.

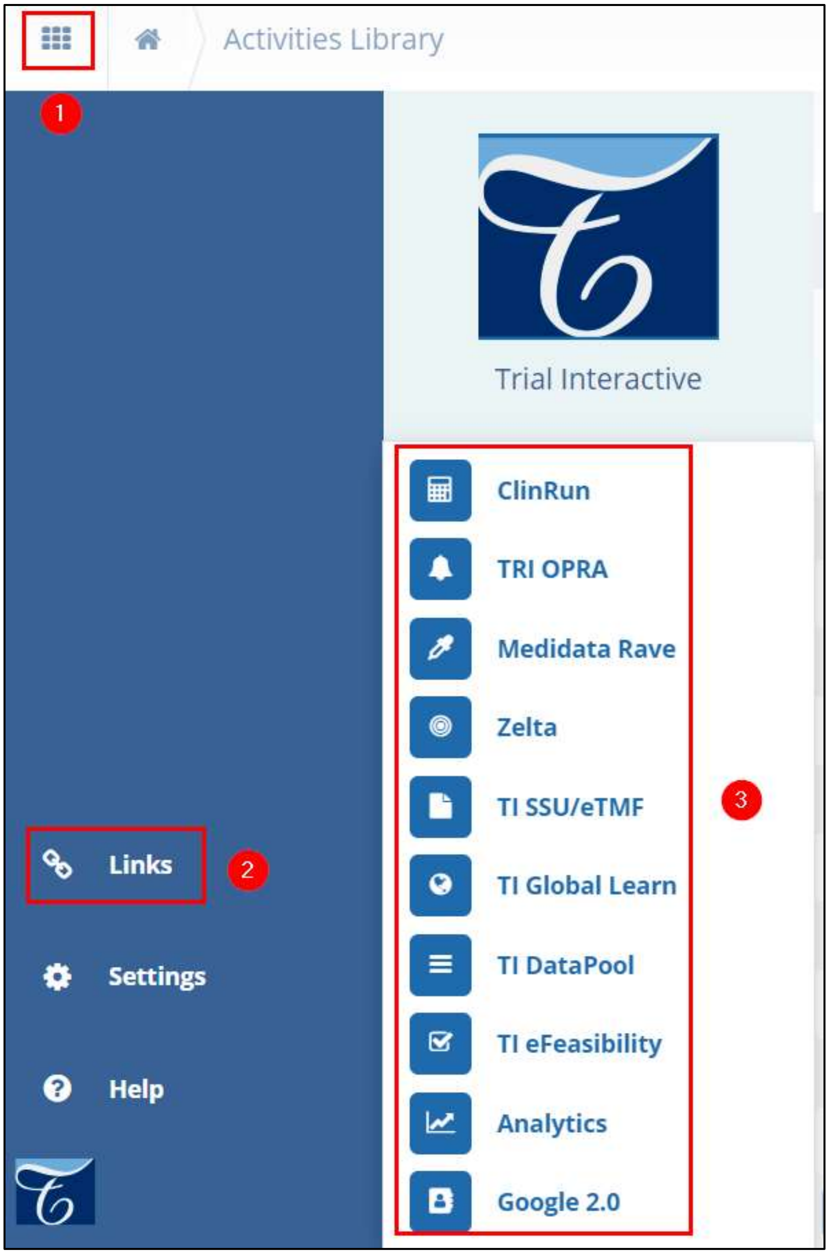


Figure: Accessing Platform links

Settings

Users with Company Administrator access to the CTMS will be able to make changes to settings which impact all users.

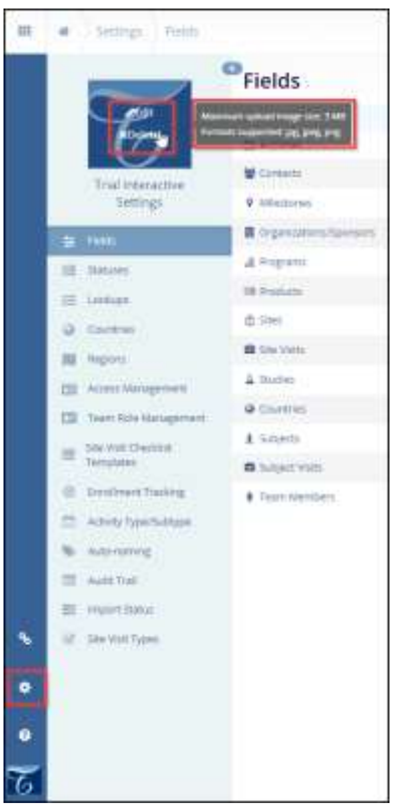
Company Name and Logo

Users can change the name and 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.

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.
    Note: The maximum size of the image and the formats supported are displayed after hovering the image. Refer to the screenshot below.



To change the company's name:

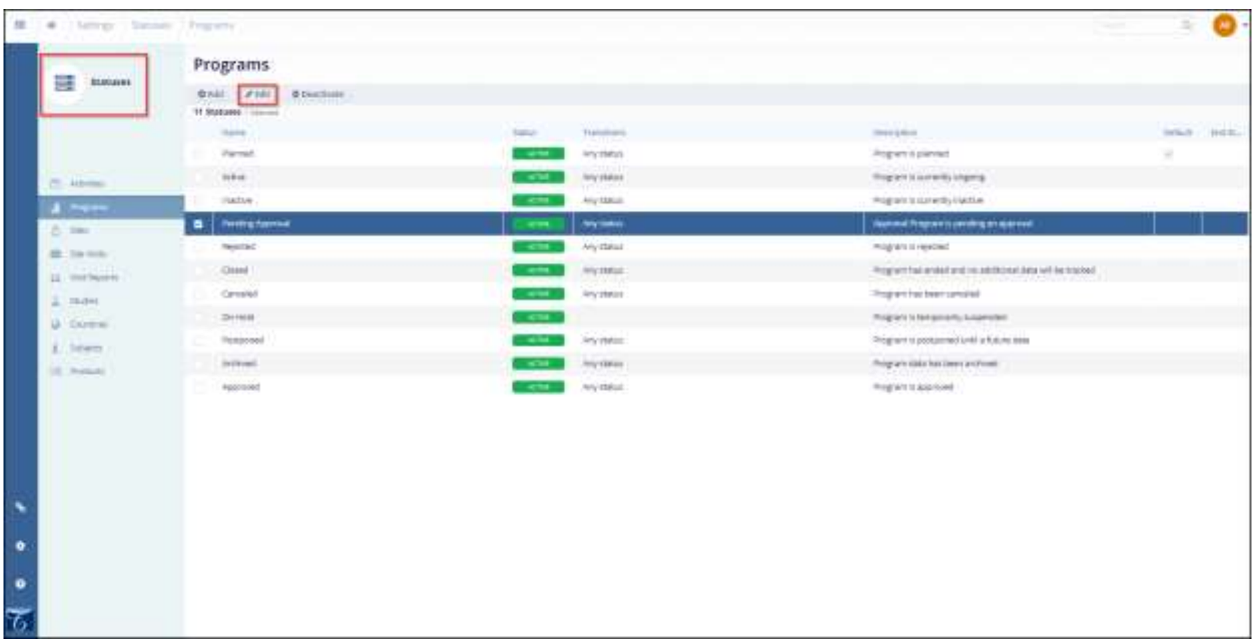
1. Navigate to the Settings are and to the General menu.
2. Click the 'Edit' button in the menu ribbon at the top of the menu.
    a. The menu will become editable.
3. Type a new name for the organization into the "Client Name" field.
4. Press 'Save' in the menu ribbon at the top of the menu.

Final Statuses

Users have the ability to indicate which of the available statuses is considered a Final or 'End' status.

To set an 'End' status:

1. Navigate to the Settings area and click 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.



Custom Fields for Milestones

To create a custom field:

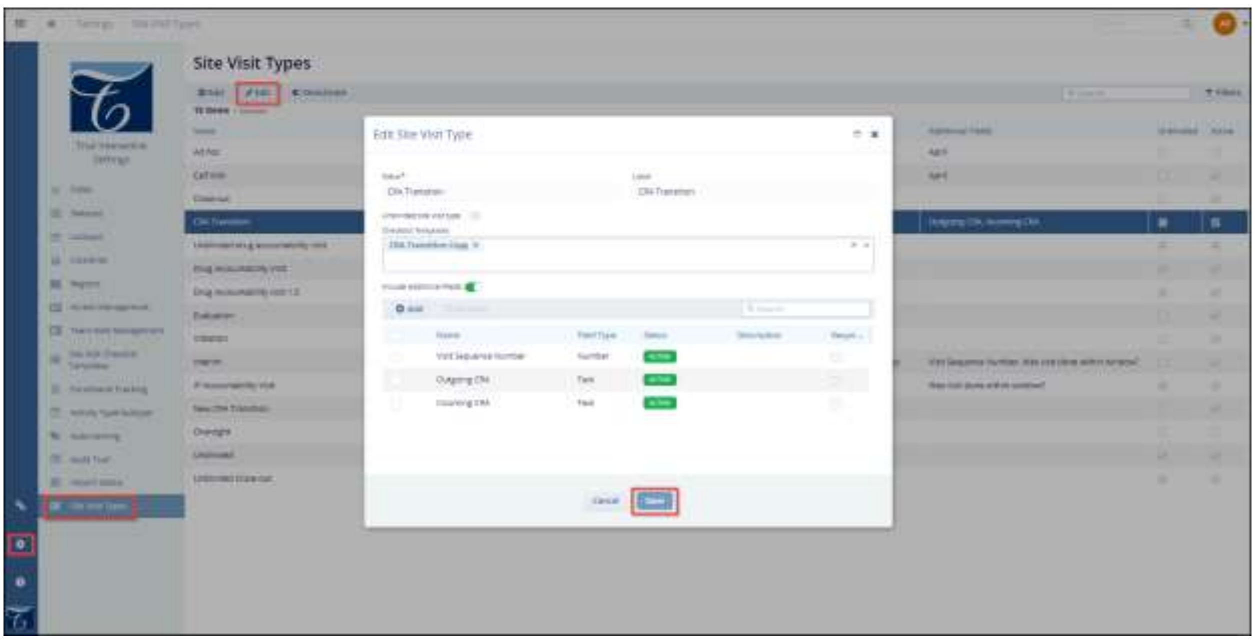
1. Navigate to the Settings area and select the Fields menu.
2. Select the sub-type (Activities, Contacts, etc.)
3. Press the 'Add Field' button in the menu above the list of fields.
   a. The 'Add Custom Field' window will open.
4. Select the type of field
   a. Please note that the steps below may 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'

Site Visit Custom Fields related to Visit Types

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'.

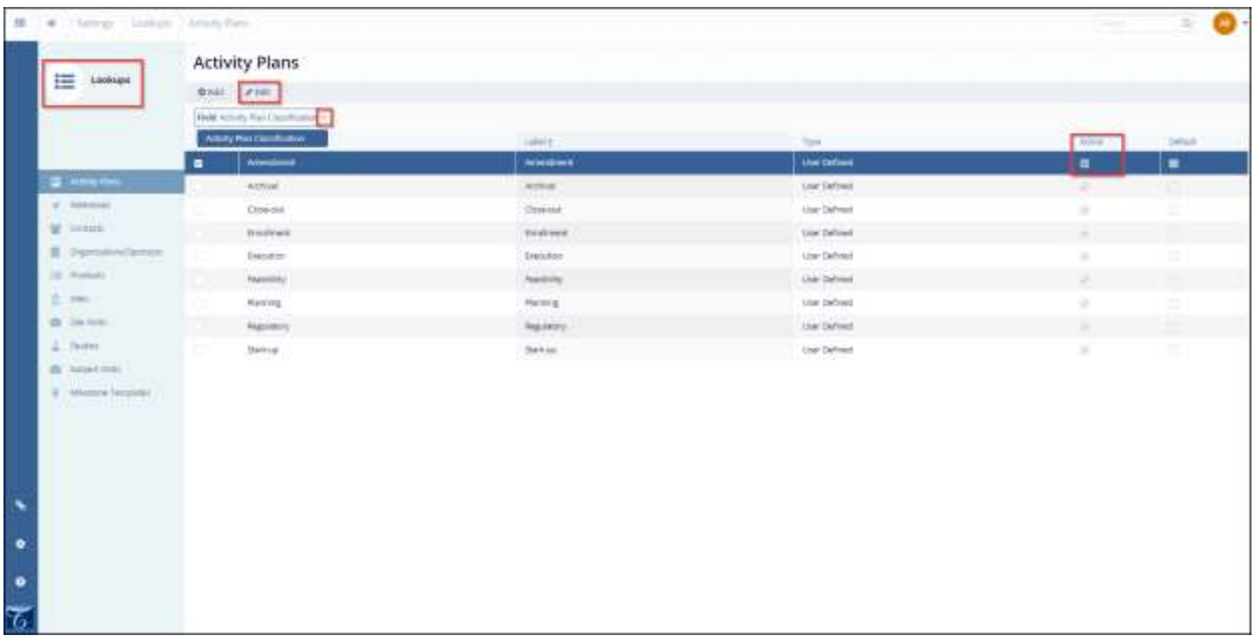


Lookups Field

The term 'Lookups' refers to the options found in various dropdown menus throughout the system. If your group is upgrading to a new version of CTMS which includes additional standard values, in order to avoid impacting current study data, these values will be added in an 'inactive' status and will need to be manually updated if desired.

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'



Favorites

CTMS has the ability for a user to denote a record as a favorite. Users now have the ability to define a record as a personal favorite within the CTMS or via myTI, and have the indication displayed within both applications.

The ability to designate a record as a favorite provides users with the ability to quickly locate items within lists without having to create specific “filtered” views. Favorites can be used when sorting lists to reduce the number of relevant records displayed.

The user can select the following fields as favorites:

- Sponsors
- Programs
- Products
- Studies
- Organizations
- Contacts and
- Activities Library

Click the star icon to turn it yellow. The selected field is added to favorites with a notification displayed in the top right corner. Refer to the screenshots below.