TRIAL INTERACTIVE

TI CTMS USER GUIDE v1.2

TRANSPERFECT LIFE SCIENCES

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VERSION HISTORY

Author	Revision	Date	Change History
Steve Clark	1.0	01-Jun-2022	Document Creation

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1 Definitions/ Acronyms

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

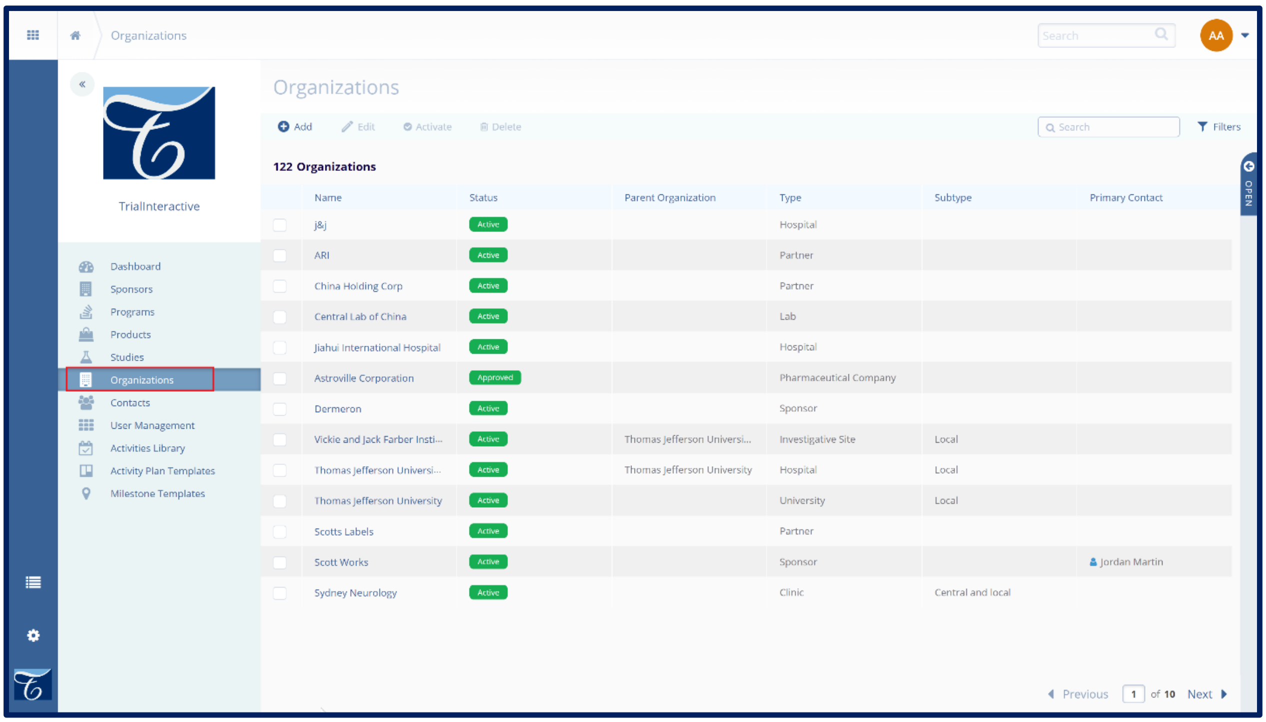
2 Organizations

2.1 Pre-Requisites

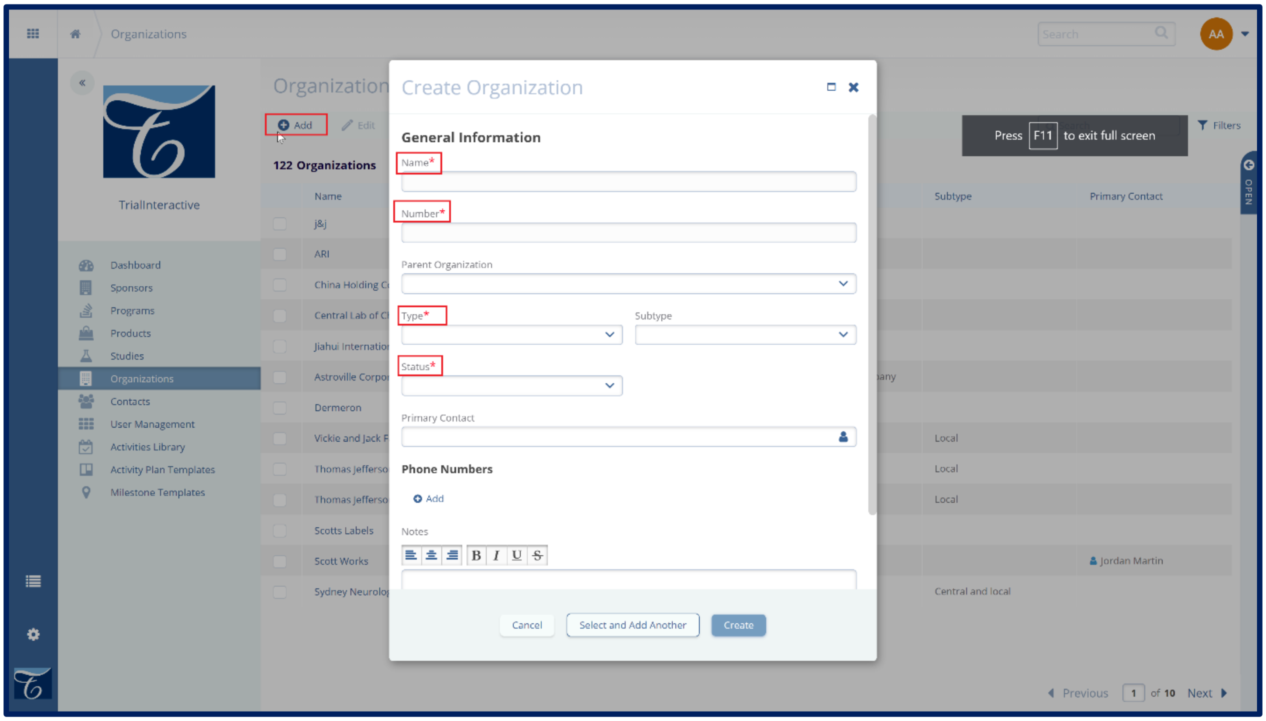
Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to users' accounts so that they can perform these steps.

2.2 Creating an Organization

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



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



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

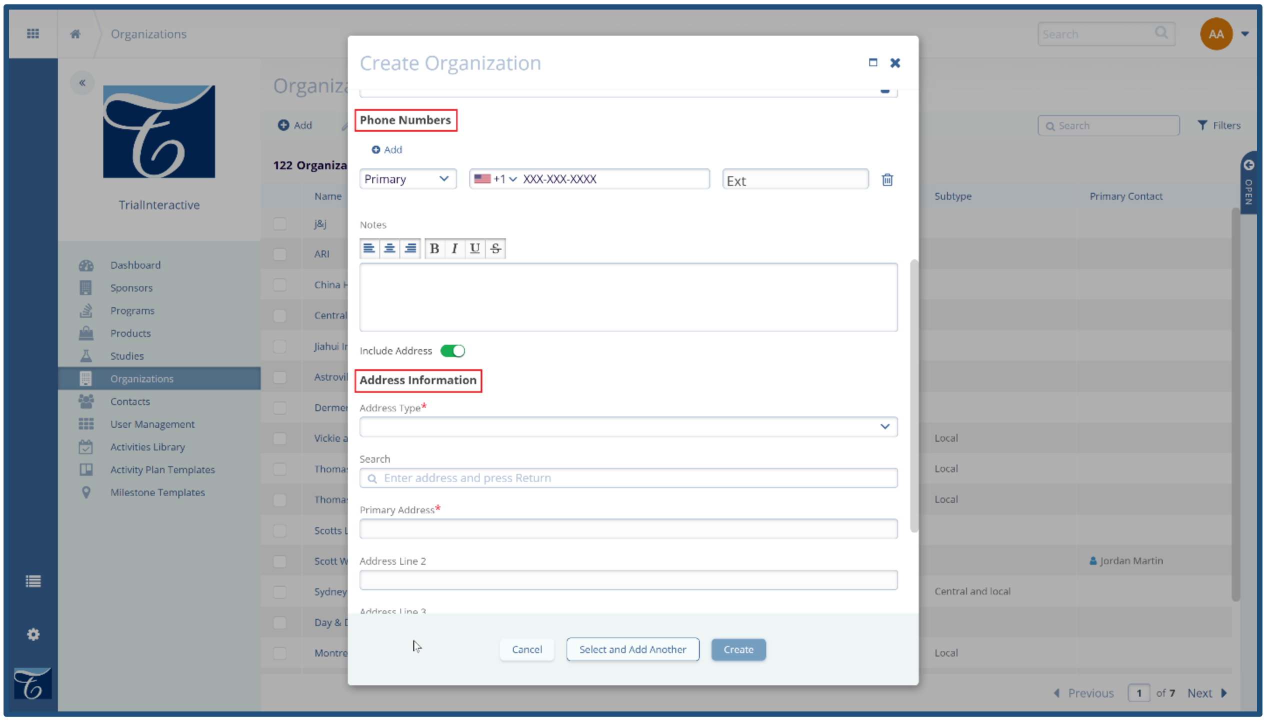
   Note: When creating an organization record with at least one phone number, you will need to designate one phone number as the primary number.

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

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

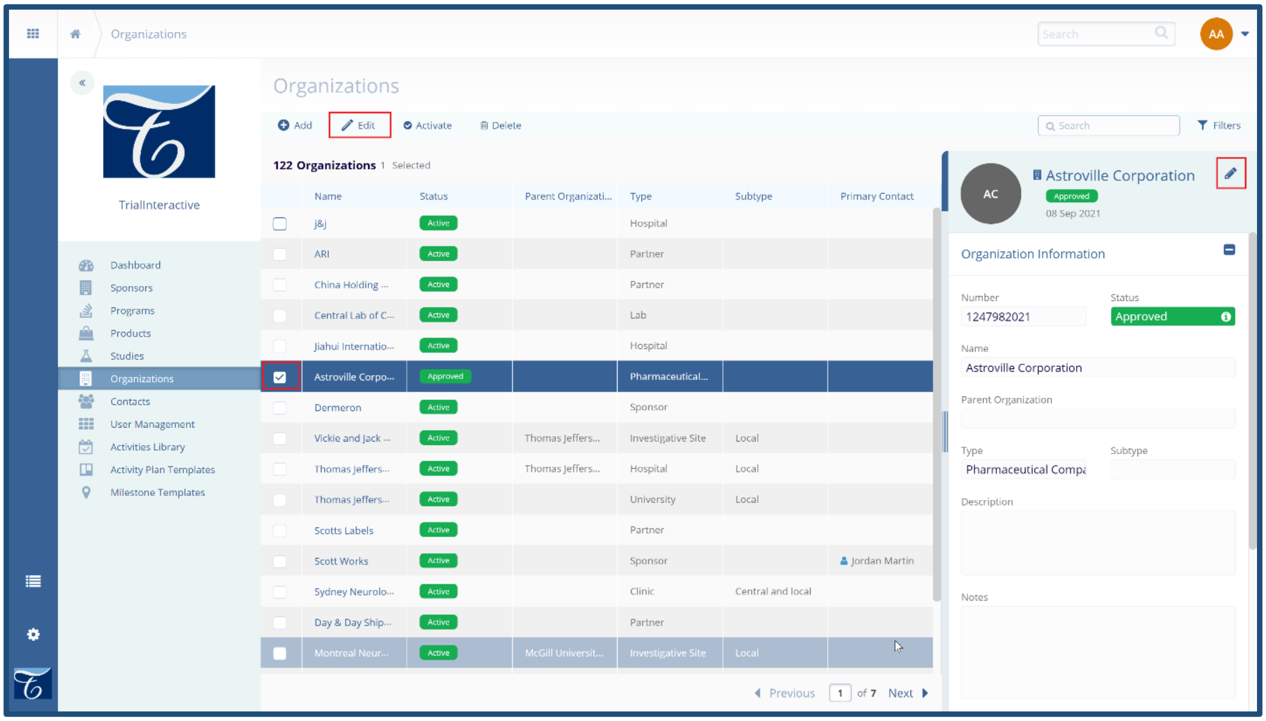
7. Finally, before clicking **Create,** verify all the fields are entered correctly in the Create Organization window.

8. Click **Create** or **Select and Add Another** depending on whether you intend to create another organization right away.

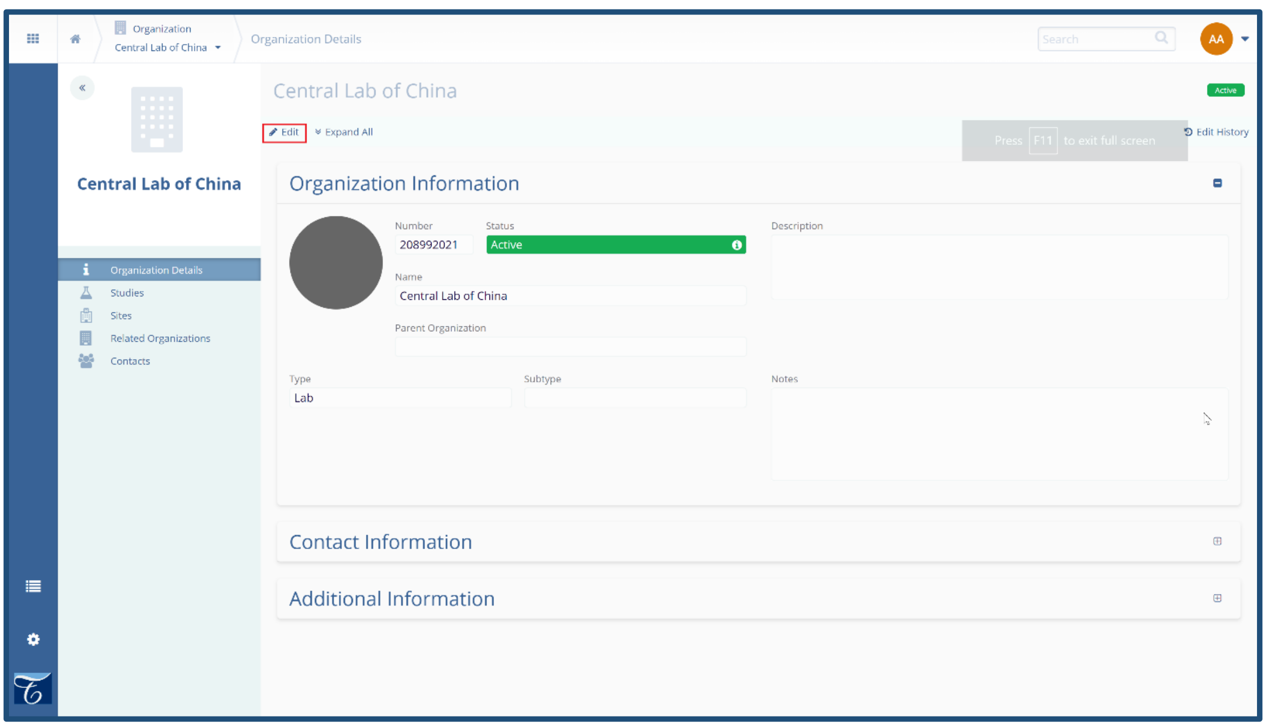


2.3 Editing an Organization

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



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

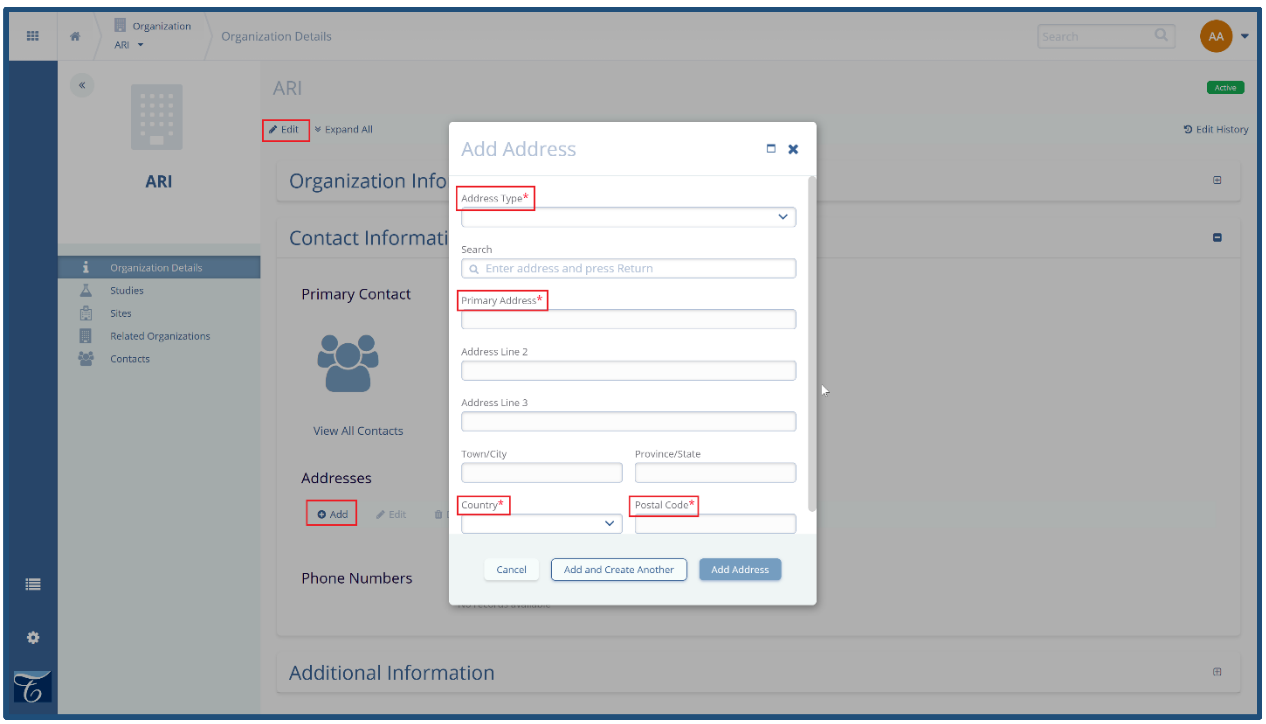


2.4 Associating an Address to an Organization

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

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

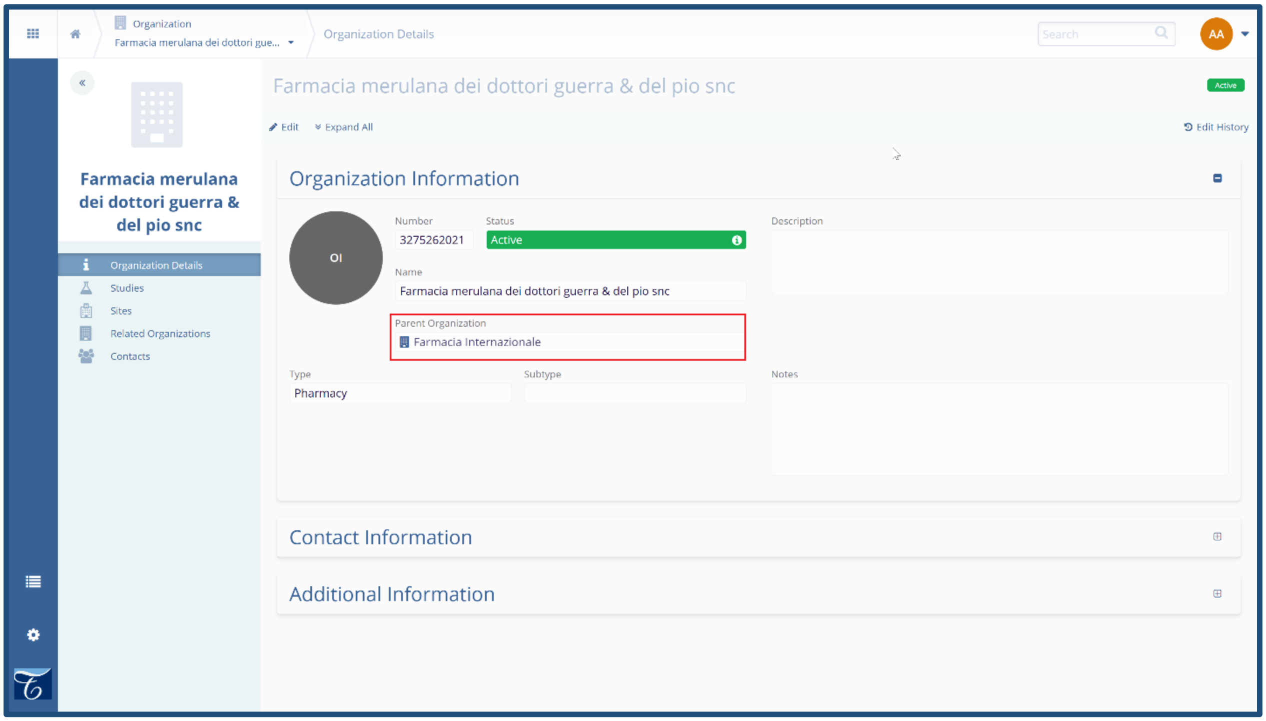
7. If any of the required fields are missing, an error will appear when we click on the **Add Address** button displaying the fields which need to be filled to create an address successfully.



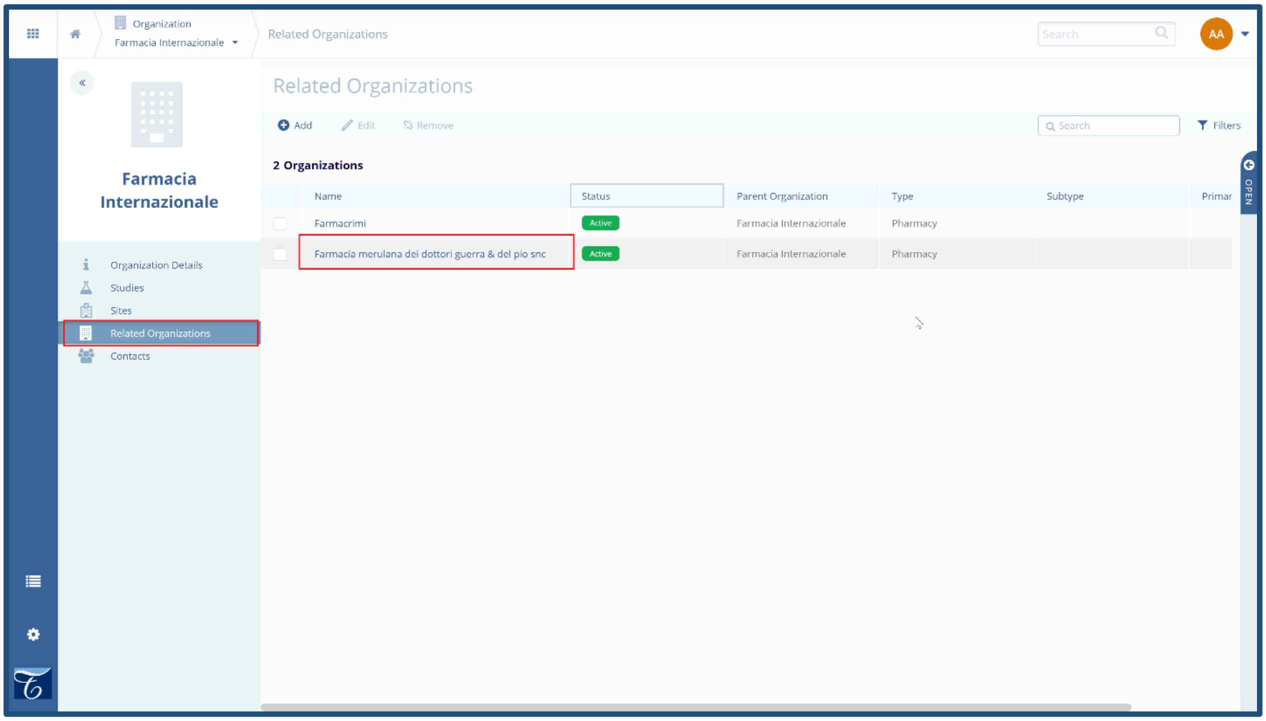
8. (Optional) Click **Add and Create Another** if you intend to create another address right away.

2.5 Associating an Organization to a Parent Organization

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

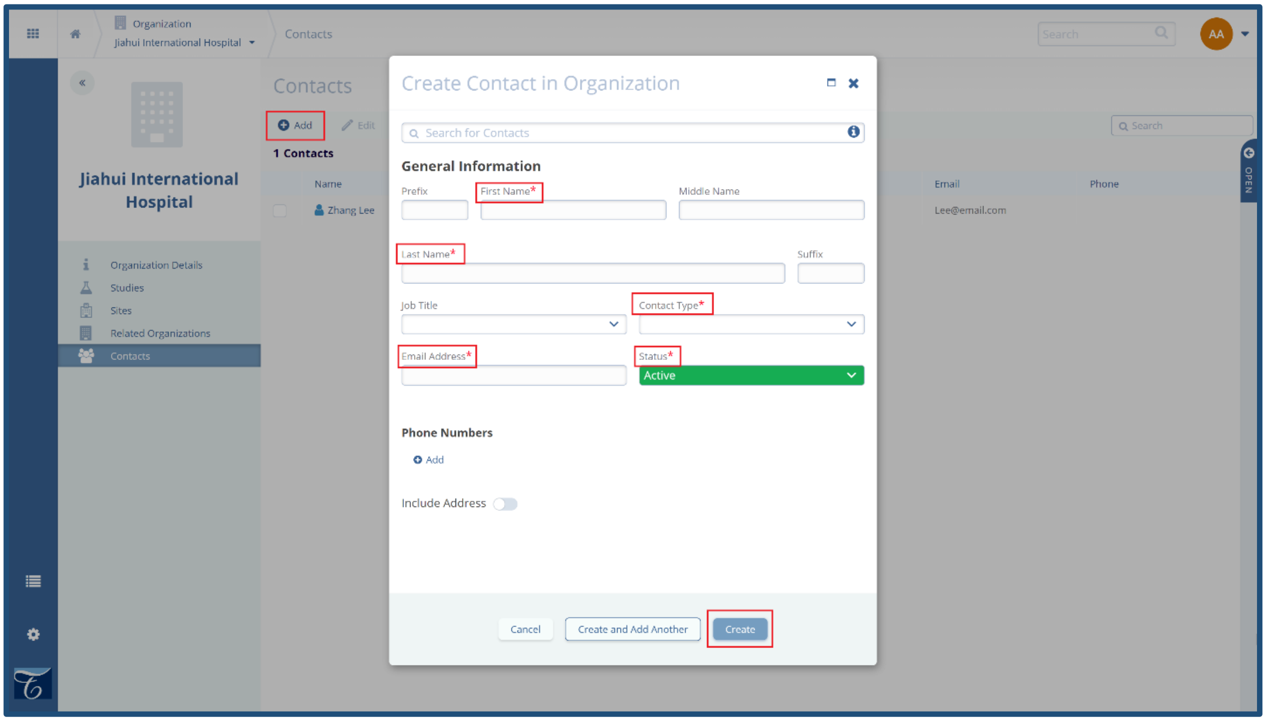


3. Click the **Edit** button in the “Organization Detail” window**,** within the **Parent Organization** field select a parent organization.
4. Click the **Save** button.
5. The association can be verified by navigating to the Related Organizations area for the selected parent organization. (See the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



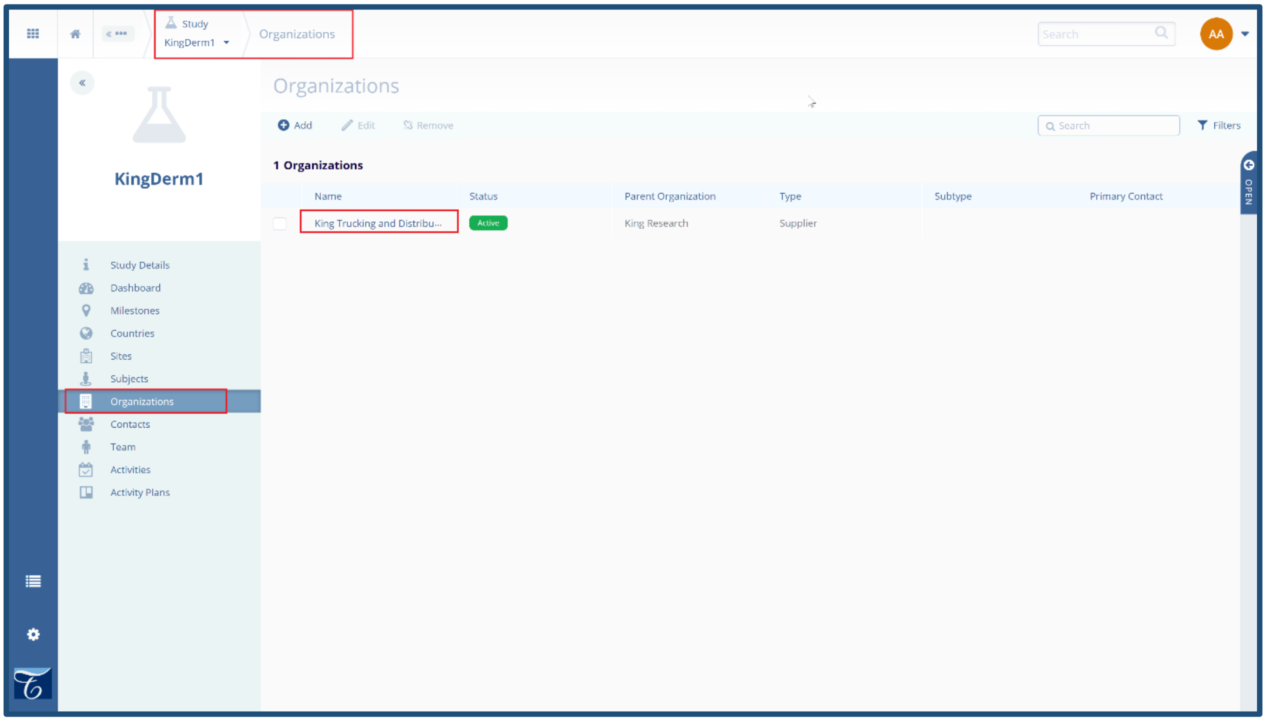
2.6 Associating a Contact to an Organization

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



2.7 Reviewing Studies Associated to an Organization

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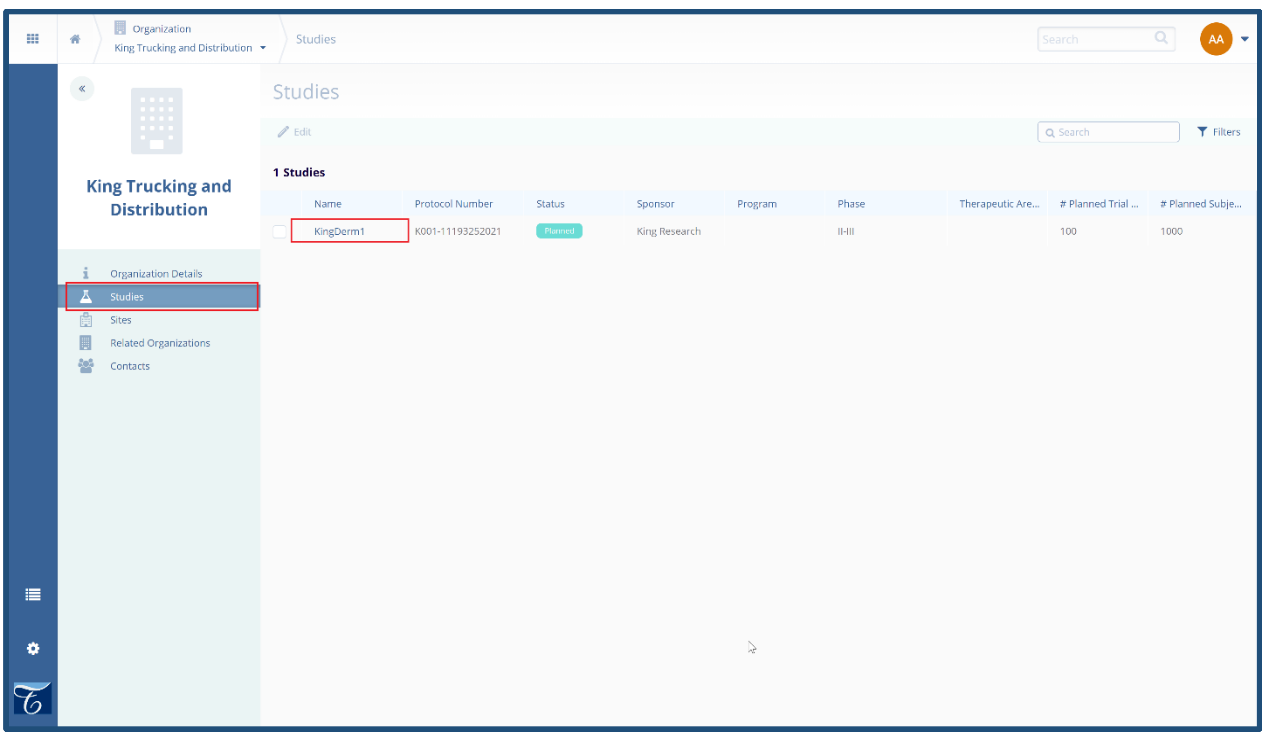
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Organization Details
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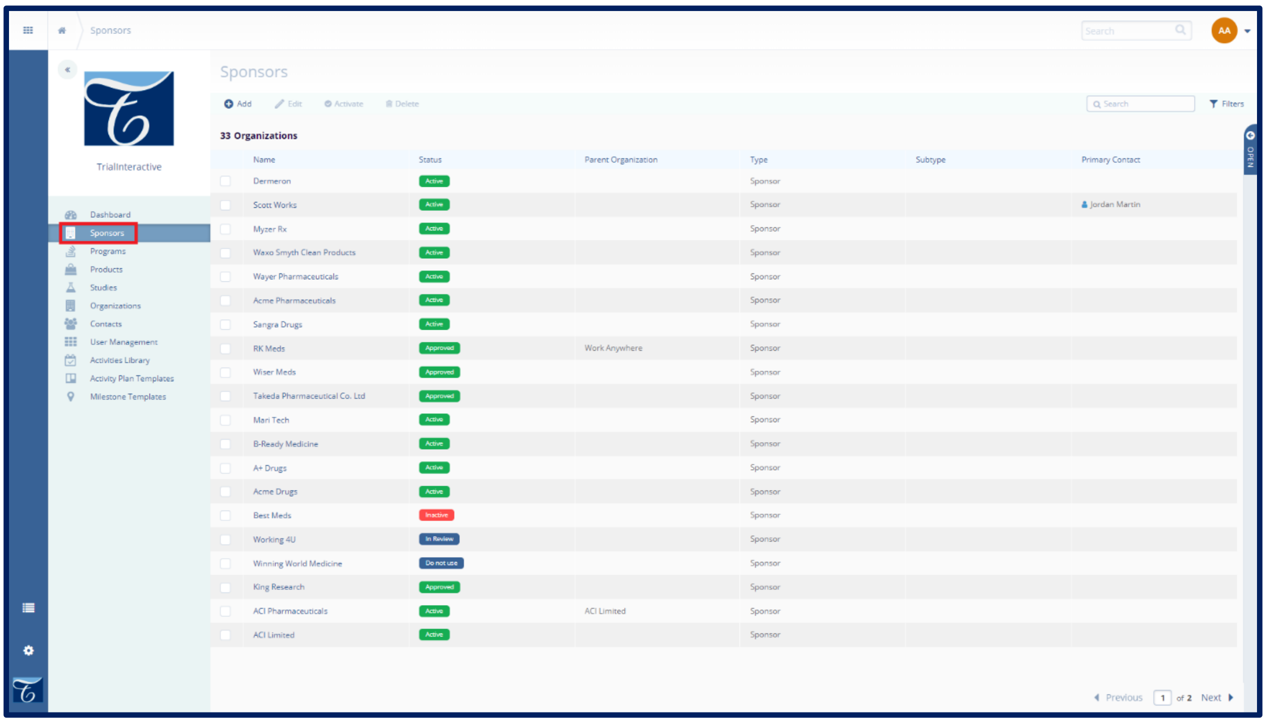
3 Sponsors

3.1 Pre-Requisites

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

3.2 Defining a Sponsor

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



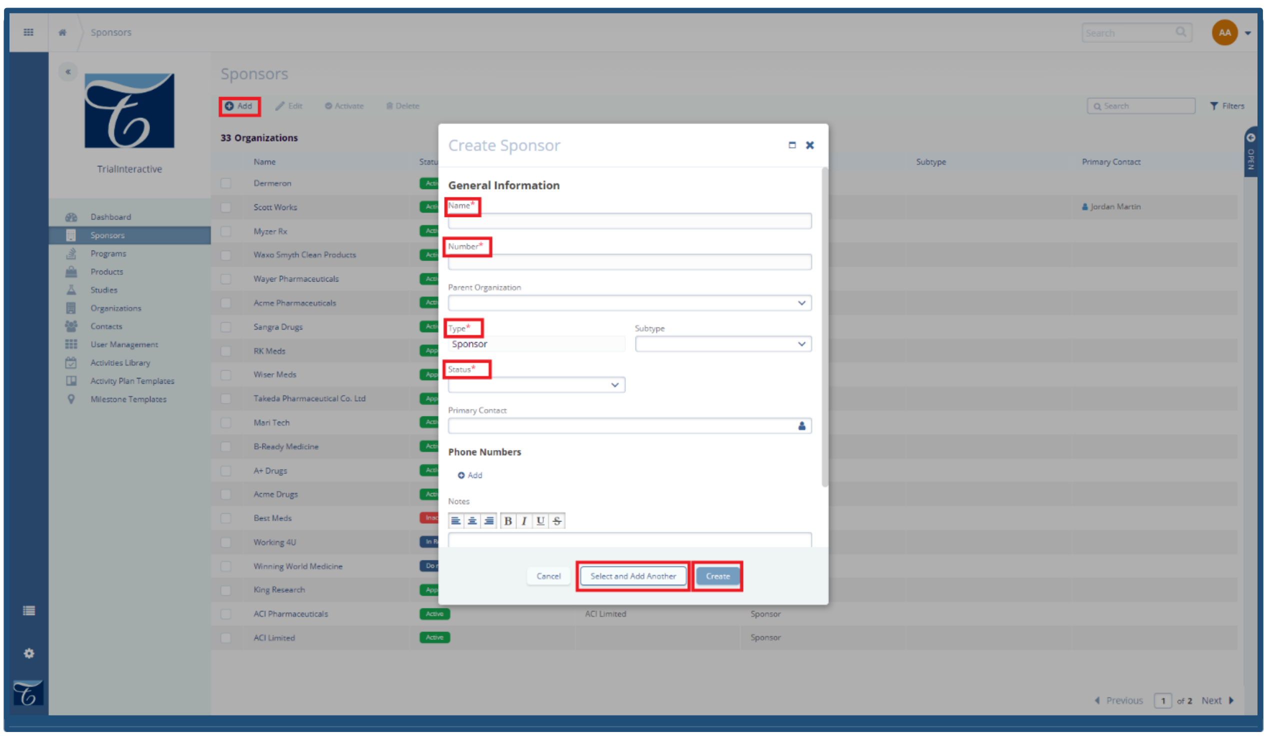
2. Click the **Add** button in the top-left of the screen.
   a. This opens the "Create Sponsor" window.
3. Here we need to enter the mandatory metadata to create a sponsor i.e., **Name, Number, Type, Status,** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information,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

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

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

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

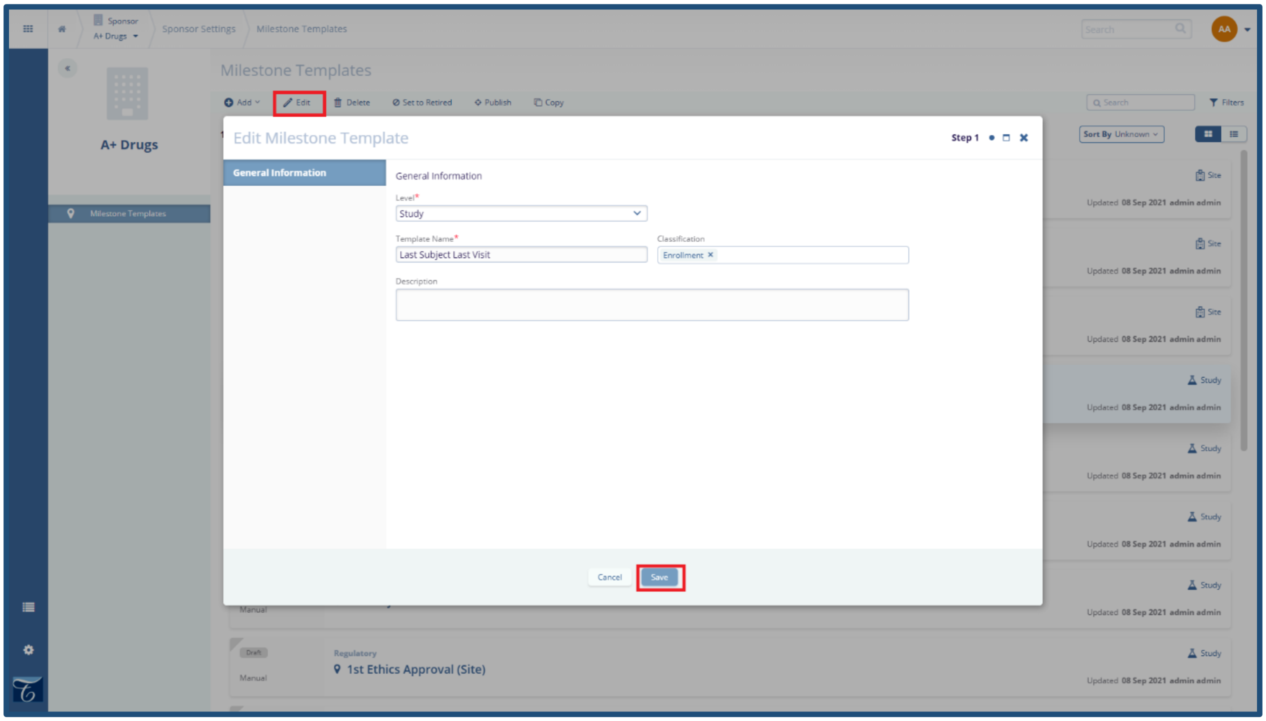
7. Finally, before clicking **Create**, verify all the fields are entered correctly in the create sponsor window.
8. Click **Create** or **Select and Add Another** depending on whether you intend to create another sponsor right away.
   a. After clicking **Create,** the "Create Sponsor" window will close,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



3.3 Defining Sponsor Settings

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

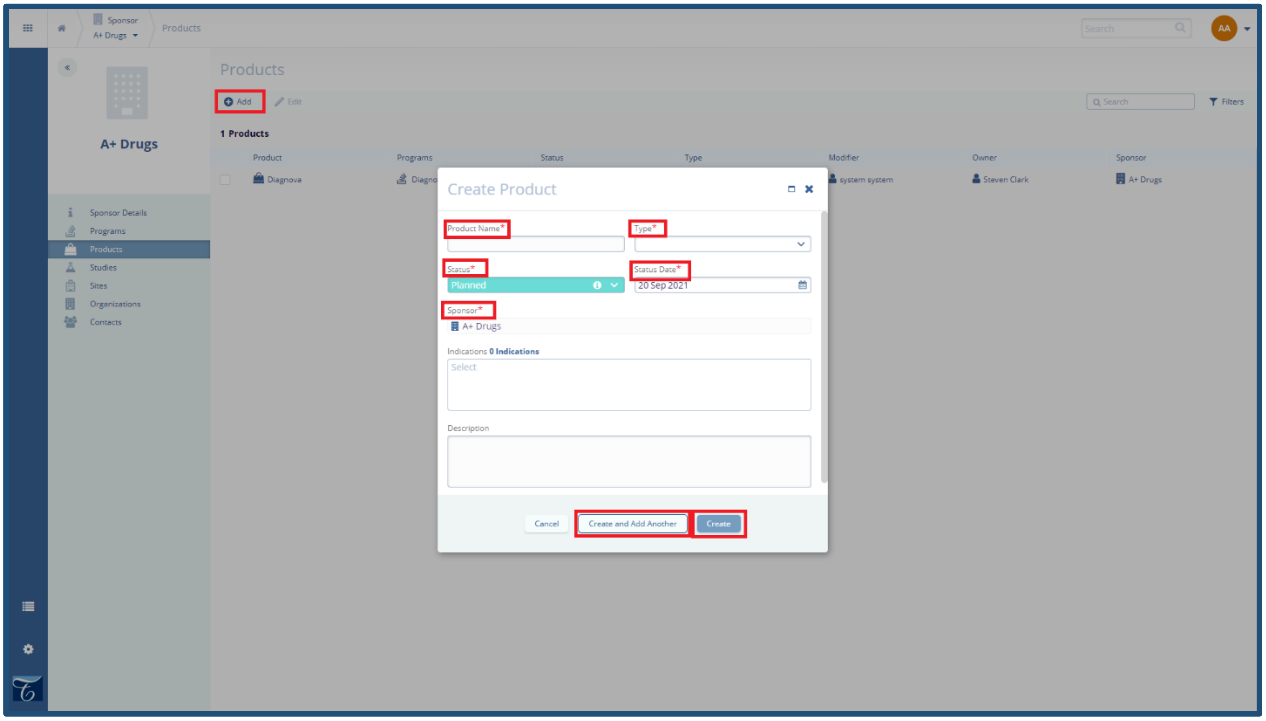
   a. This opens Sponsor settings window Milestone Templates screen.
4. Click on the milestone you want to edit.
   a. This opens **Edit Milestone Template** window.
5. Make any necessary changes required in the Edit Milestone Template window.
6. Click **Save** for the changes to apply.



3.4 Associating a Product to a Sponsor

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

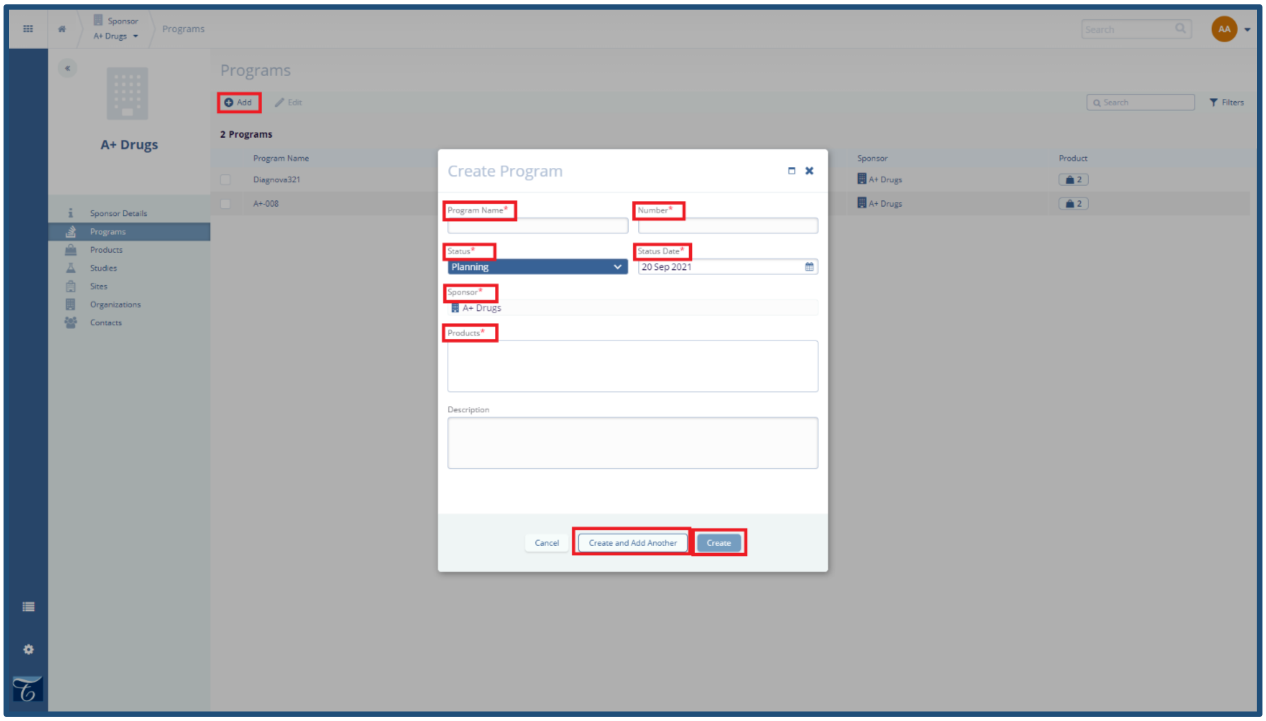
6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a product successfully.
7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to associate another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



3.5 Creating a Program for a Sponsor

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

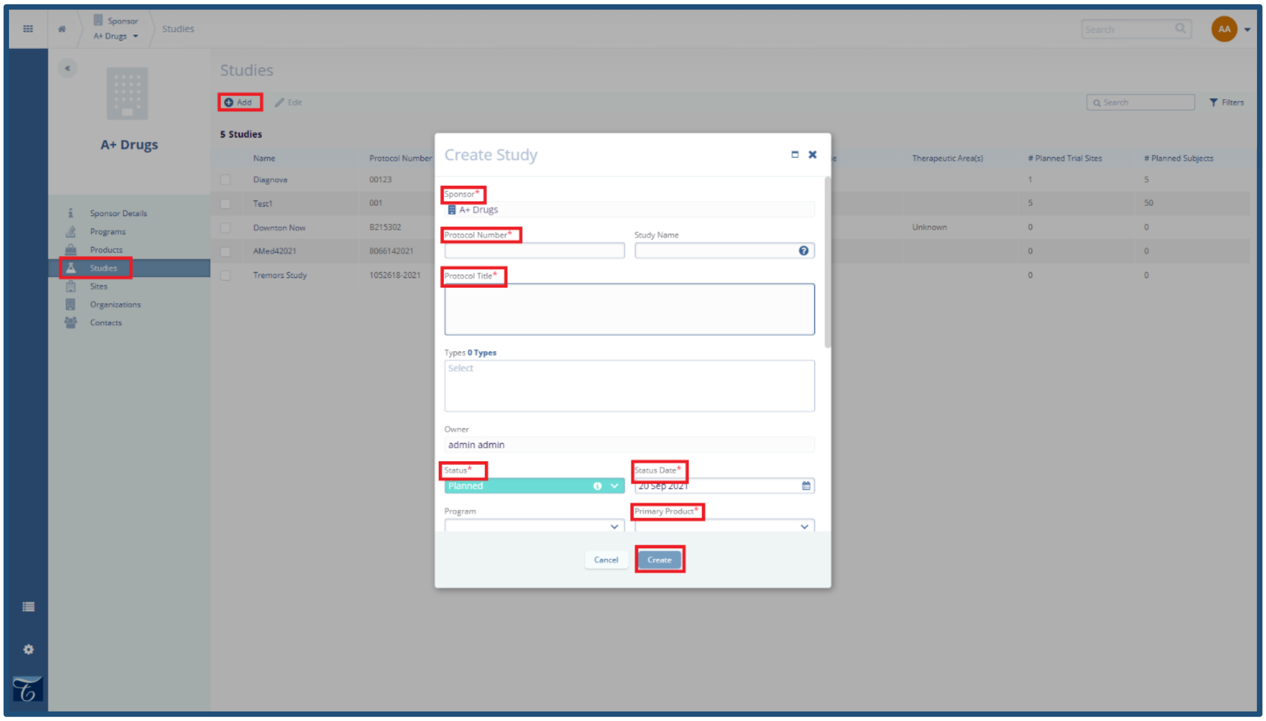
7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another program right away.



3.6 Creating a Study for a Sponsor

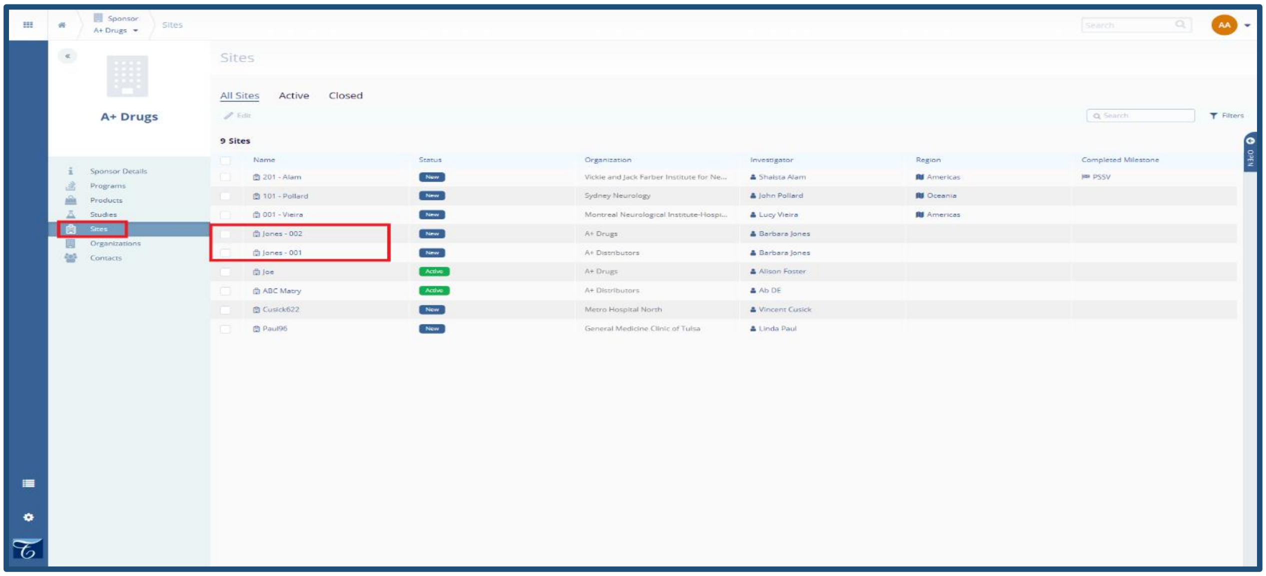
1. Click on **Sponsors** in the Navigation menu at the left side of the screen.
   a. This opens the "Sponsors" window, and the Sponsors list is displayed.
2. Click on the name of the sponsor for the new study.
   a. This opens "Sponsor Details" window.
3. Click on **Studies** in the Navigation menu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

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



3.7 Reviewing Sites for a Sponsor

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



4 Contacts

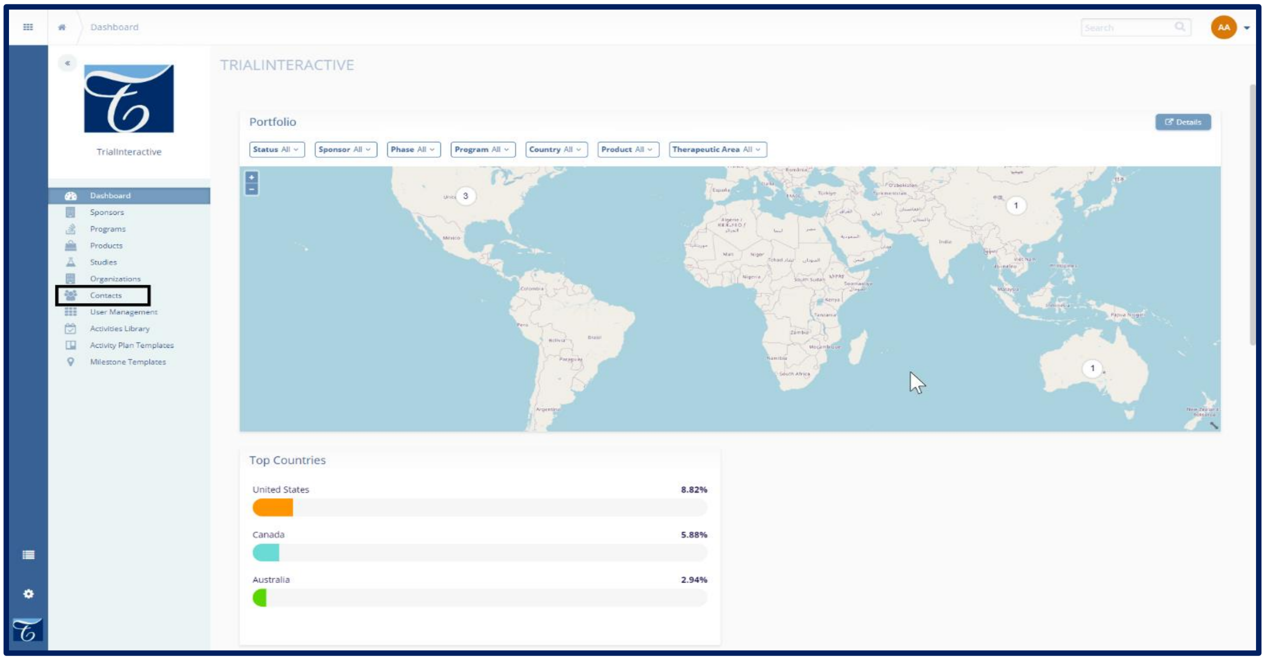
4.1 Pre-requisites

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

4.2 Levels of Contact Creation in the Application

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

4.3 Creating a Contact

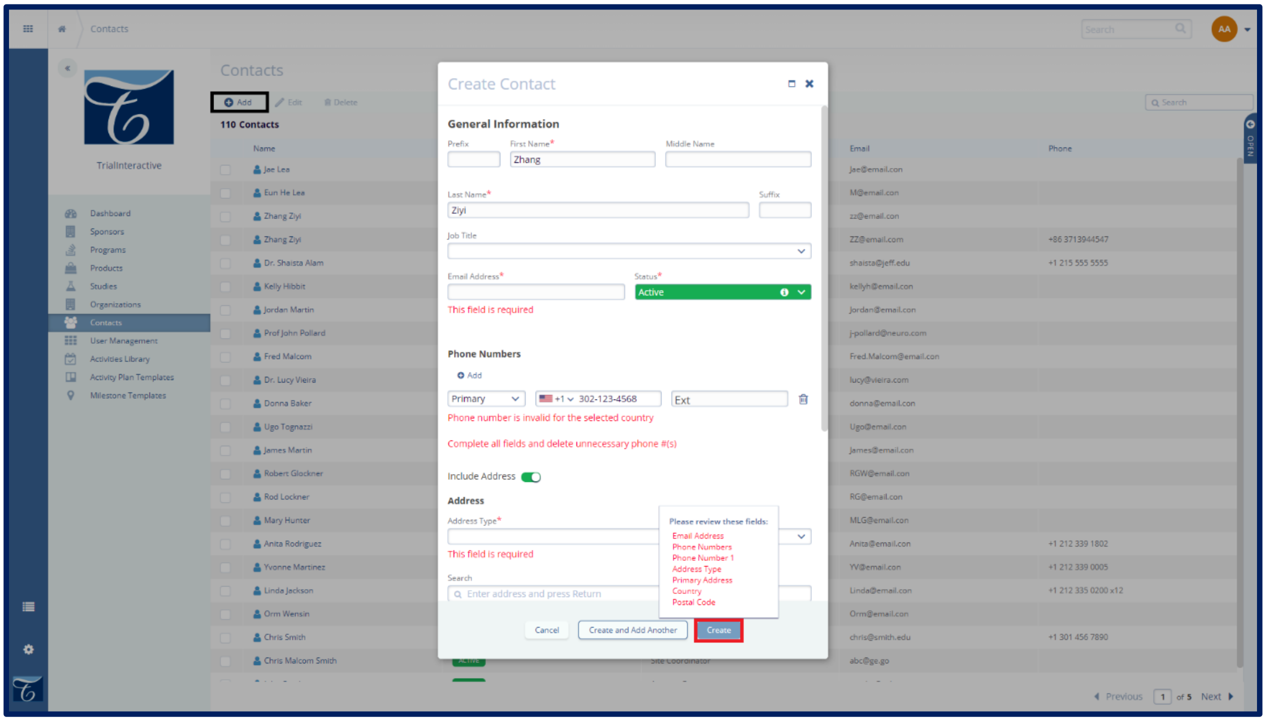


1. Navigate to the appropriate level in the data hierarchy (i.e., Domain, Study, Site).
2. Click on the **Contact** link in the Navigation menu at the left side of the screen.
    a. This opens the "Contact" screen.
3. Click on the **Add** button at the top-left of the screen.
    a. The "Create Contact"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

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

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

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



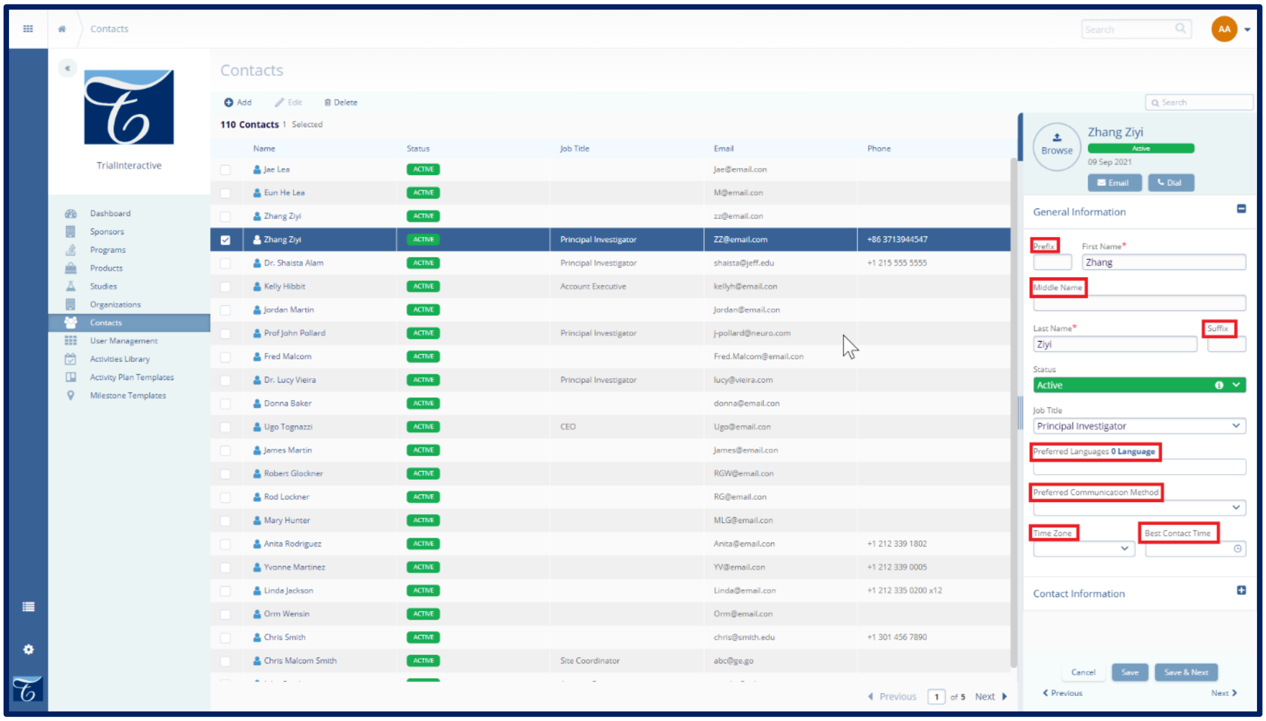
8. Finally, before clicking **Create,** verify that all the fields are entered correctly in the Create Contact window.
9. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another contact right away.

4.4 Editing a Contact at Domain, Site and Organization Levels

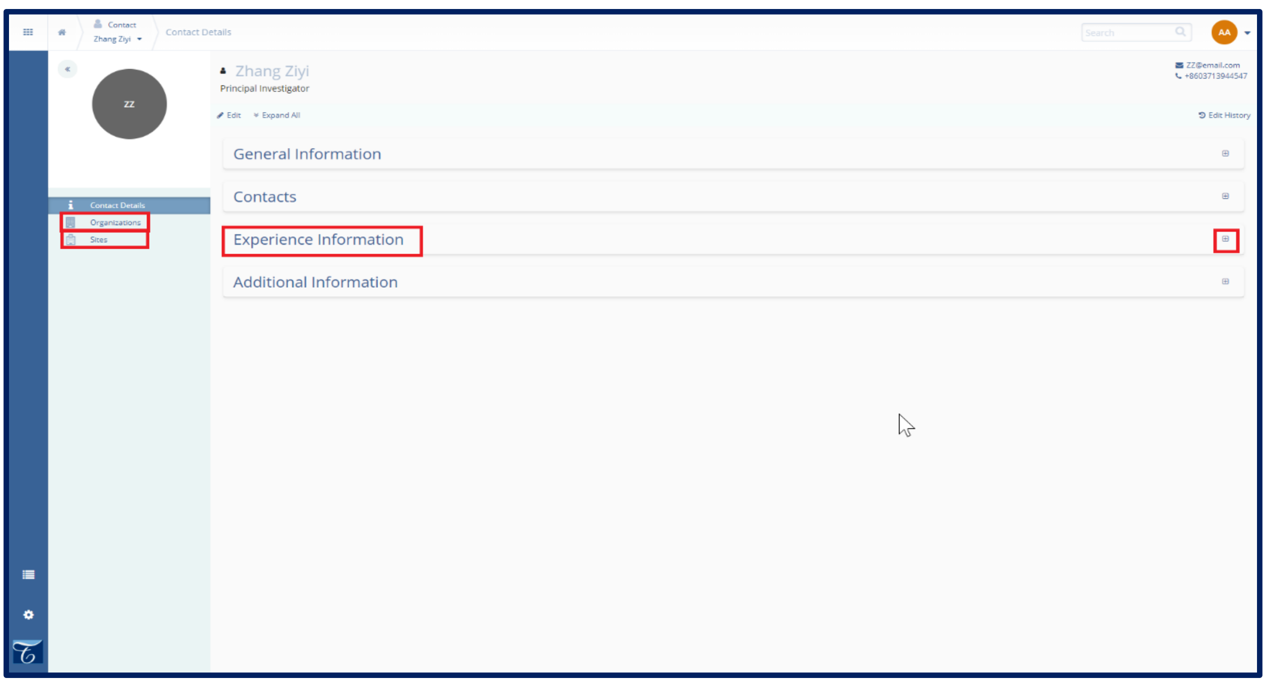
- The user must have been assigned the necessary permissions by the Company Administrator.

4.5 Editing a Contact

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



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



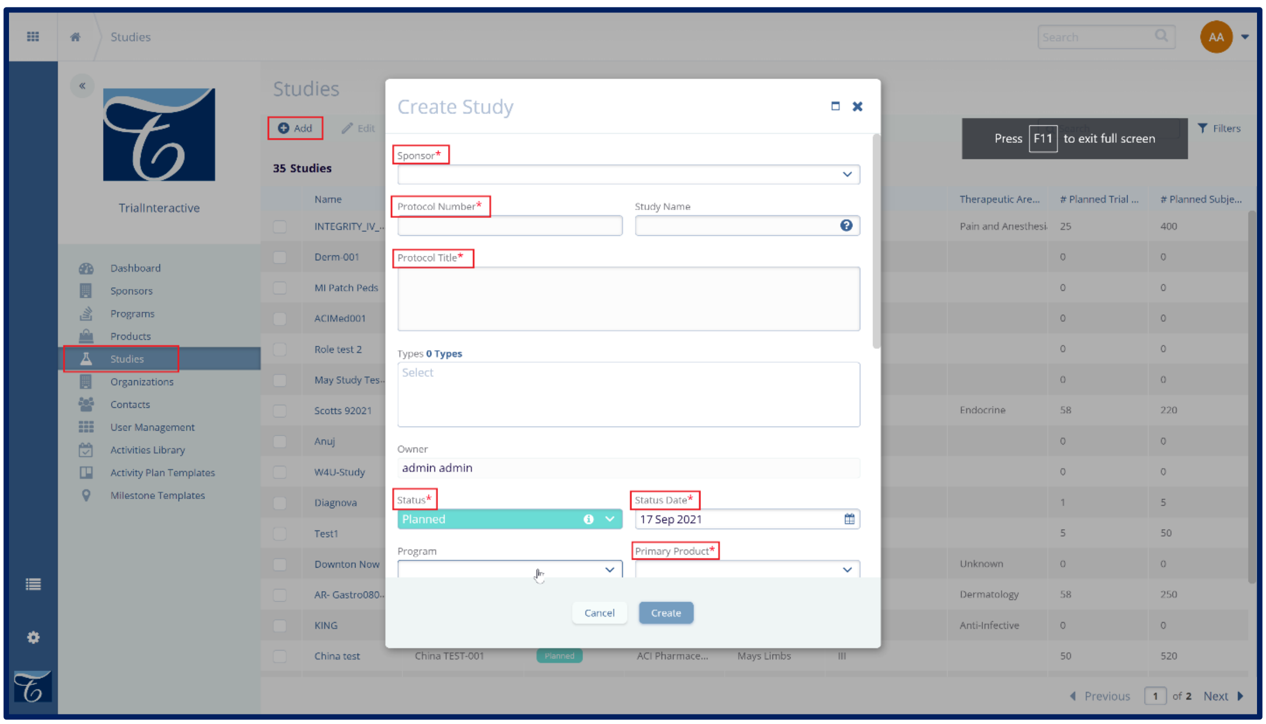
5 Studies

5.1 Pre-Requisites

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

5.2 Creating a Study

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



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

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

5.3 Blinded Studies

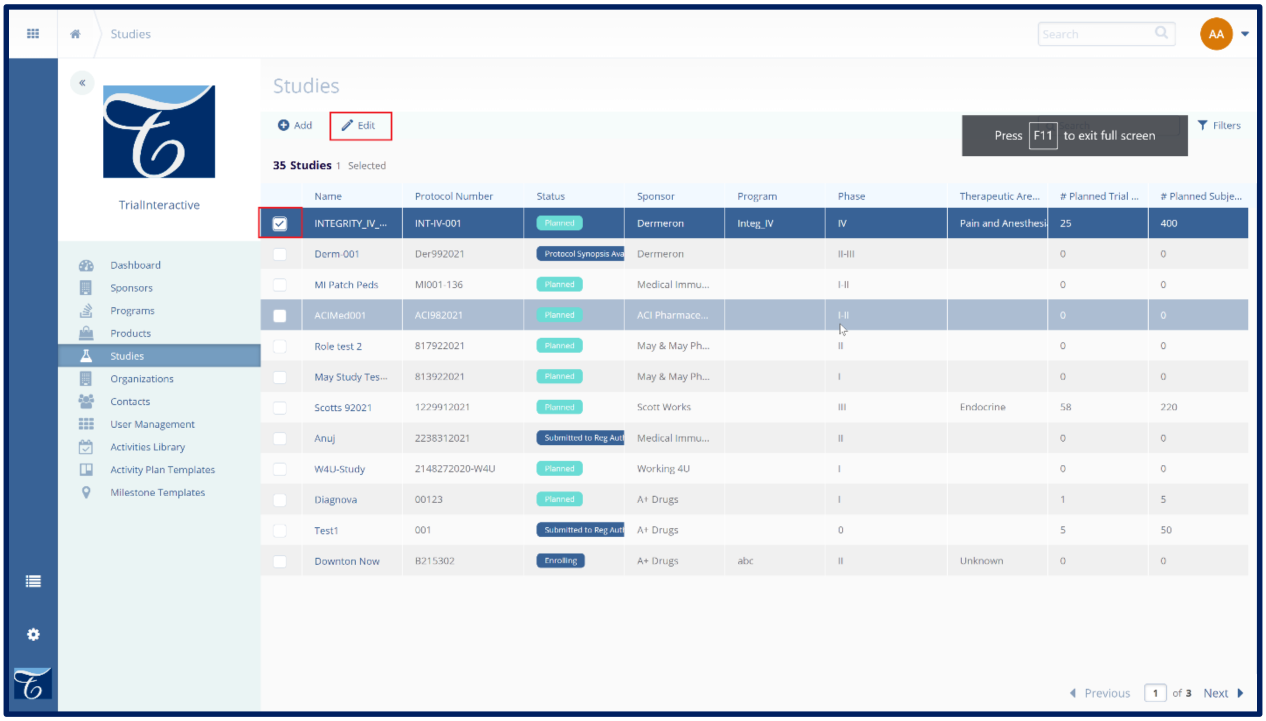
Studies that have been indicated as blinded will have the ability to display appropriate information only to specifically indicated personnel.

5.3.1 Adding Unblinded Personnel to a Blinded Study

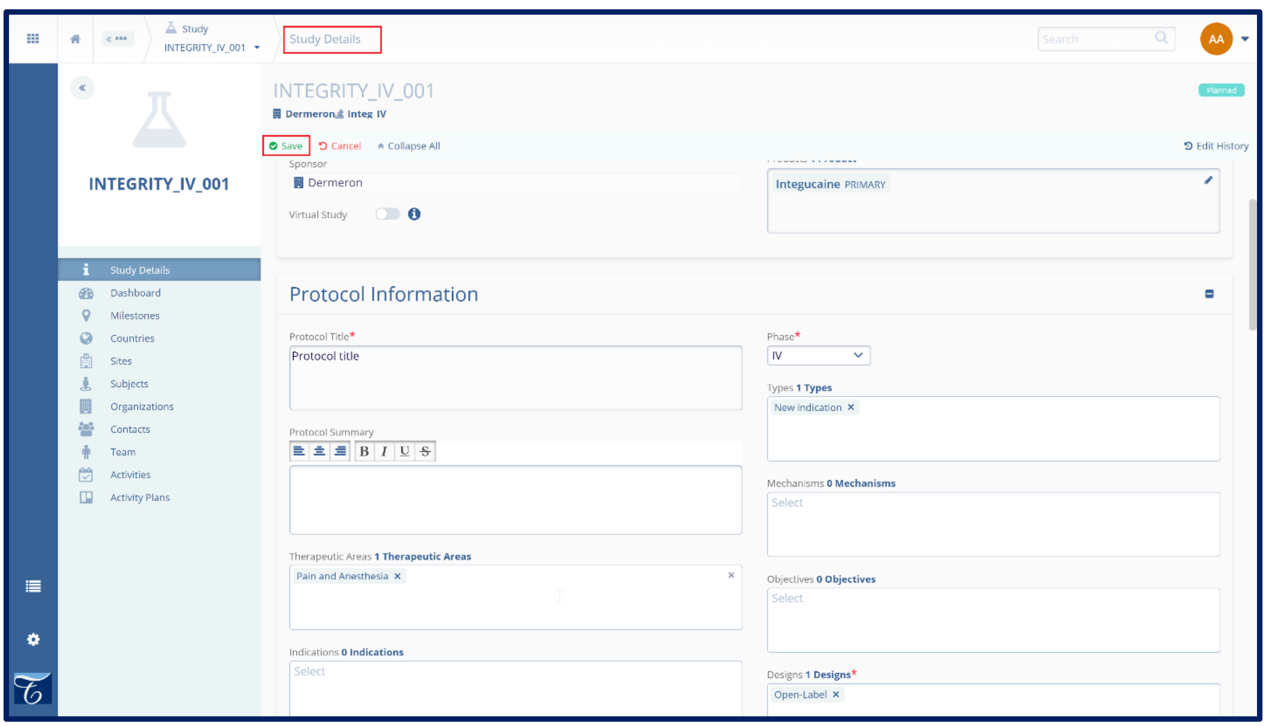
Unblinded personnel can only be added to a study by an unblinded study manager. In order to safeguard this information, the only way to add an unblinded study manager to a study is to contact the Trial Interactive Service Desk. Service Desk personnel will verify the intent and authenticity of the request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

5.4 Editing a Study

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

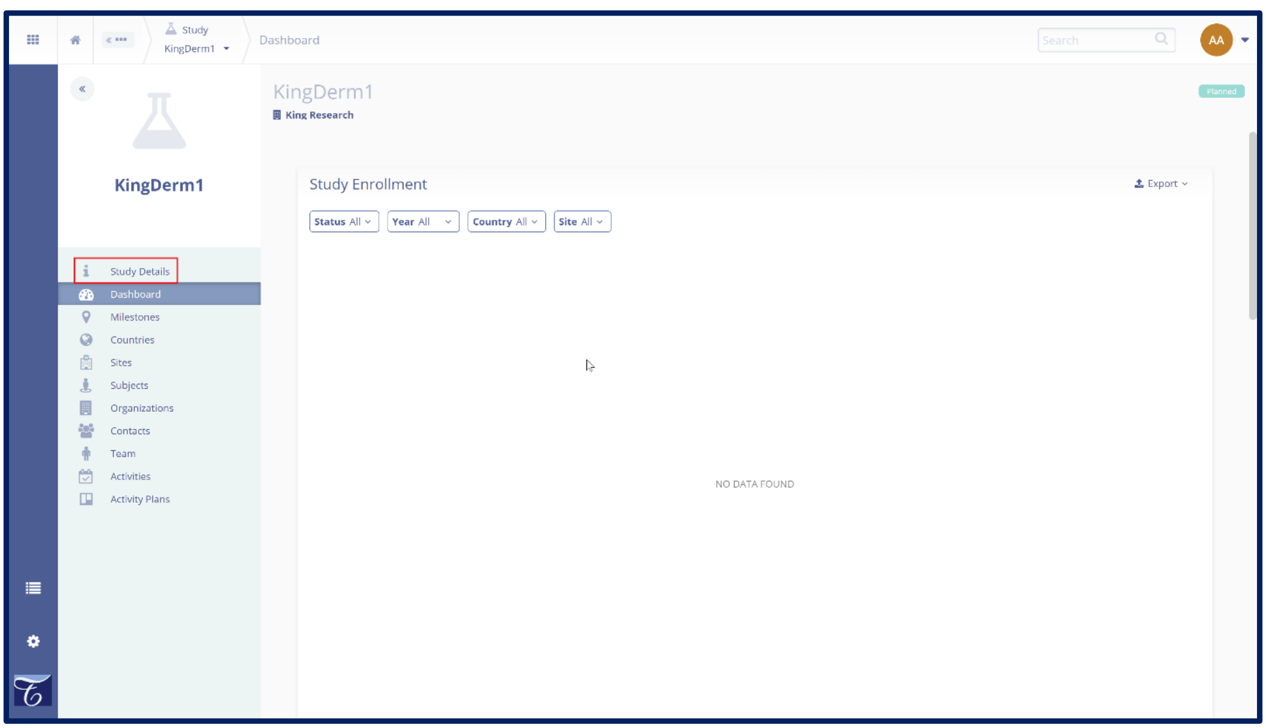


3. Make any necessary changes to the Study information.
4. Click the **Save** button for the changes to apply.

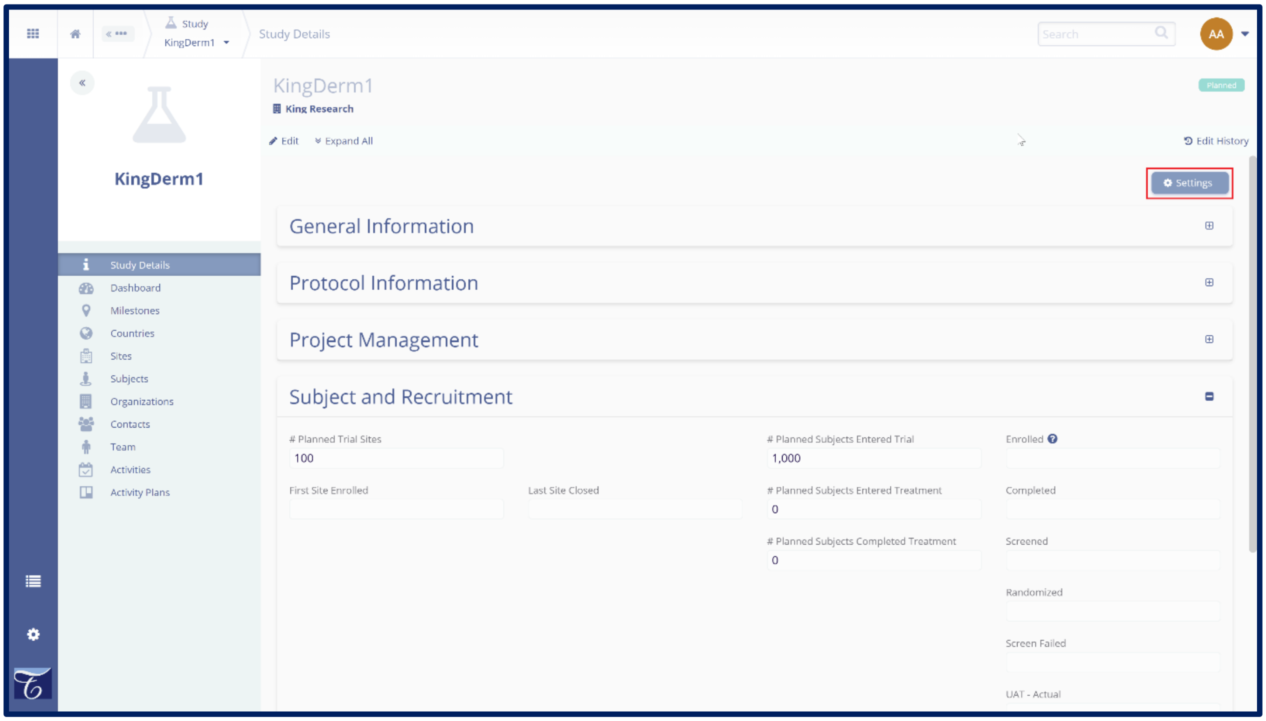


5.5 Entering Study Settings

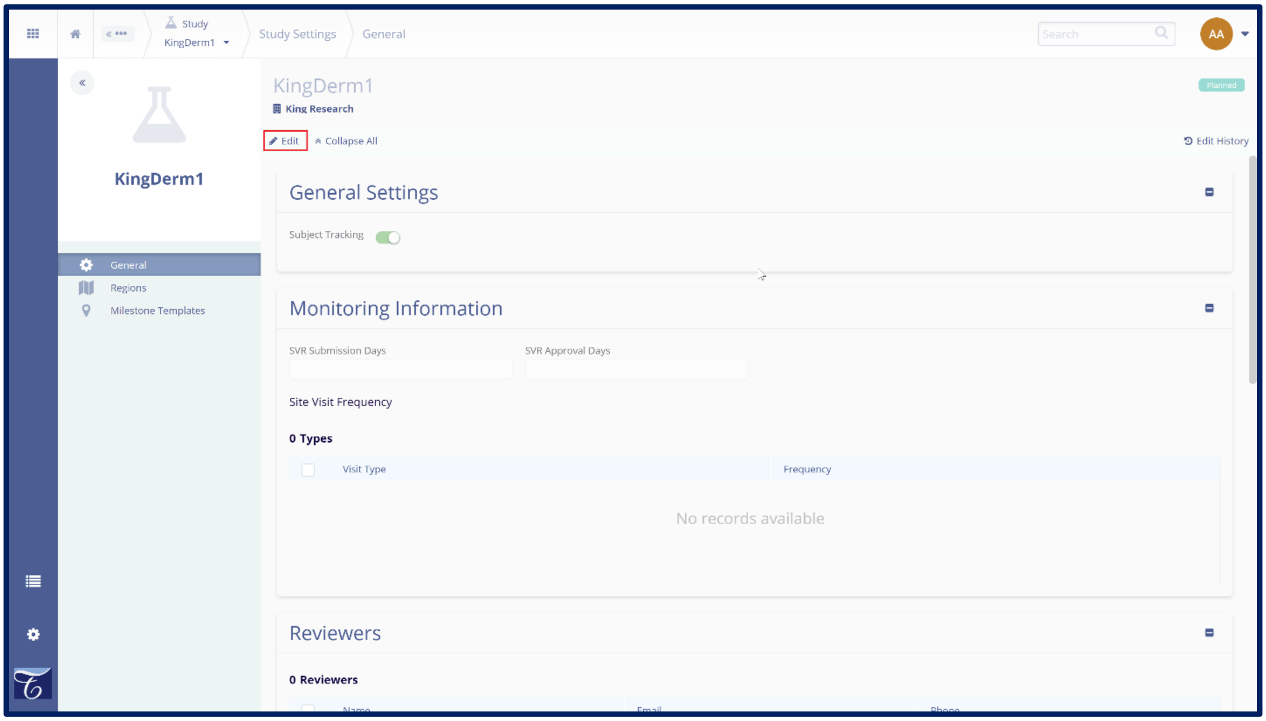
1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
   a. This opens the “Studies” window and study list is displayed.
2. Click on the name of the study in the list.
   a. The dashboard for the study is displayed.
3. Click on the **Study Details** in the Navigation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



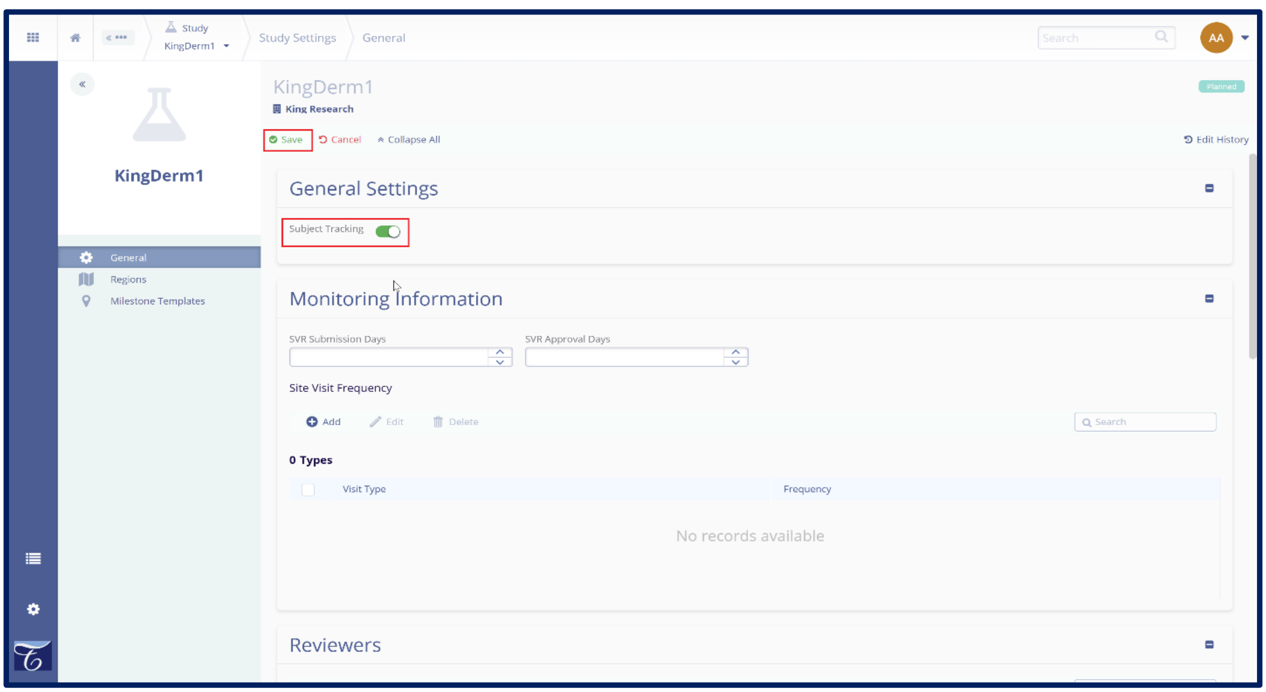
4. Click **Settings** in the top-right corner of the **study details** window.
   a. This opens **Study Settings General** window.



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



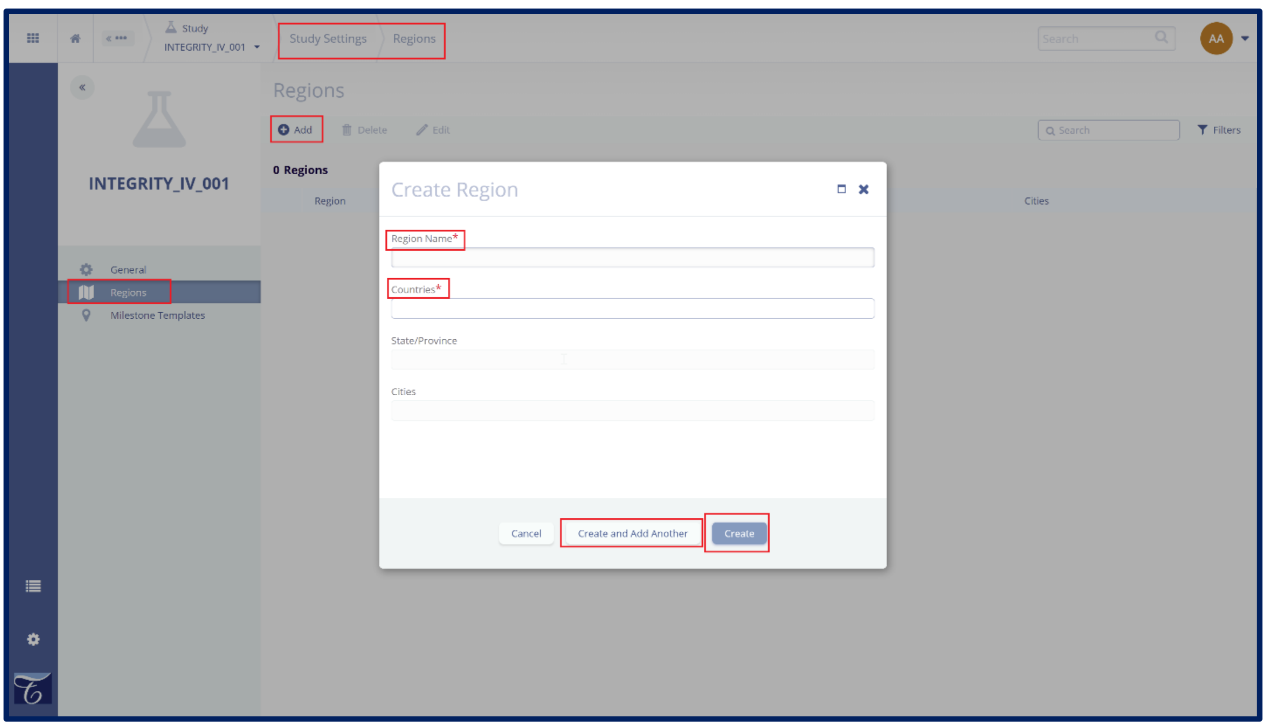
6. Make any necessary changes in the **Study Settings General** window.
7. Click on **Save** at the top-left of the window.



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

5.6 Defining Study specific Regions

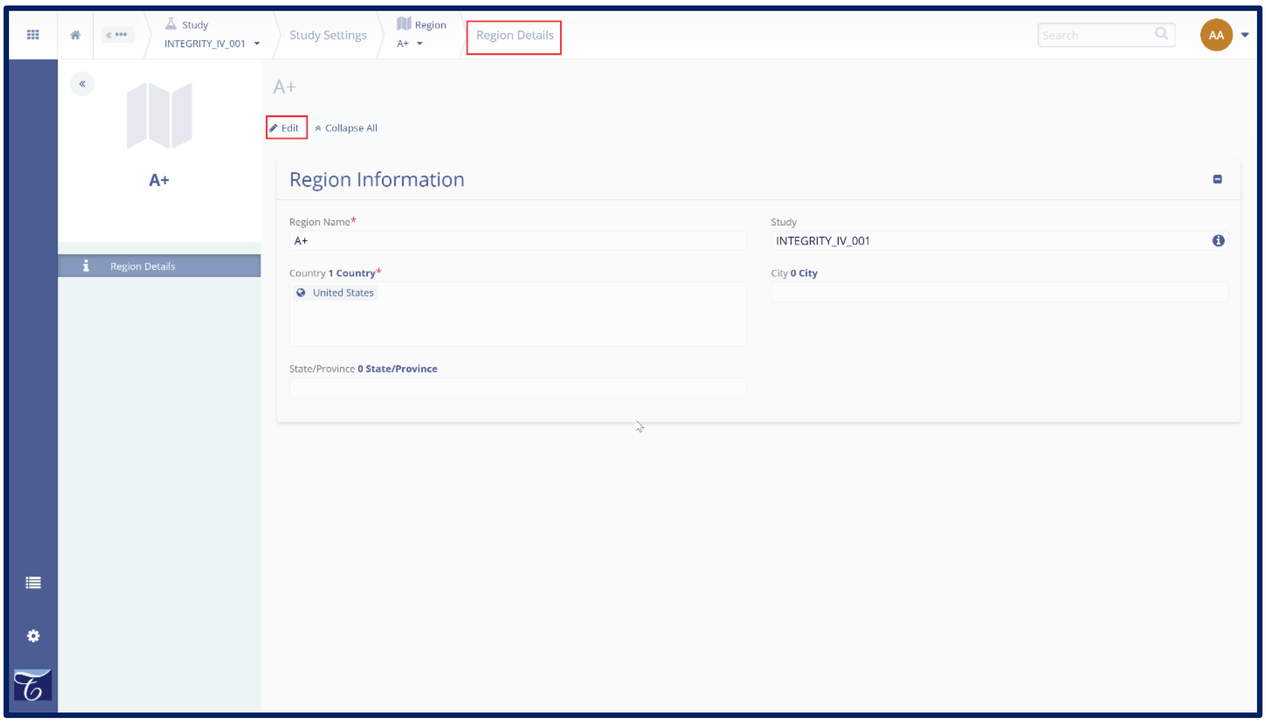
1. Click on the **Studies** in the Navigation Menu at the left side of the screen.
   a. This opens the "Studies" window.
2. Click on the name of the study for which you want to define regions.
   a. This opens the dashboard for the study.
3. Click on the **Study Details** in the Navigation menu at the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



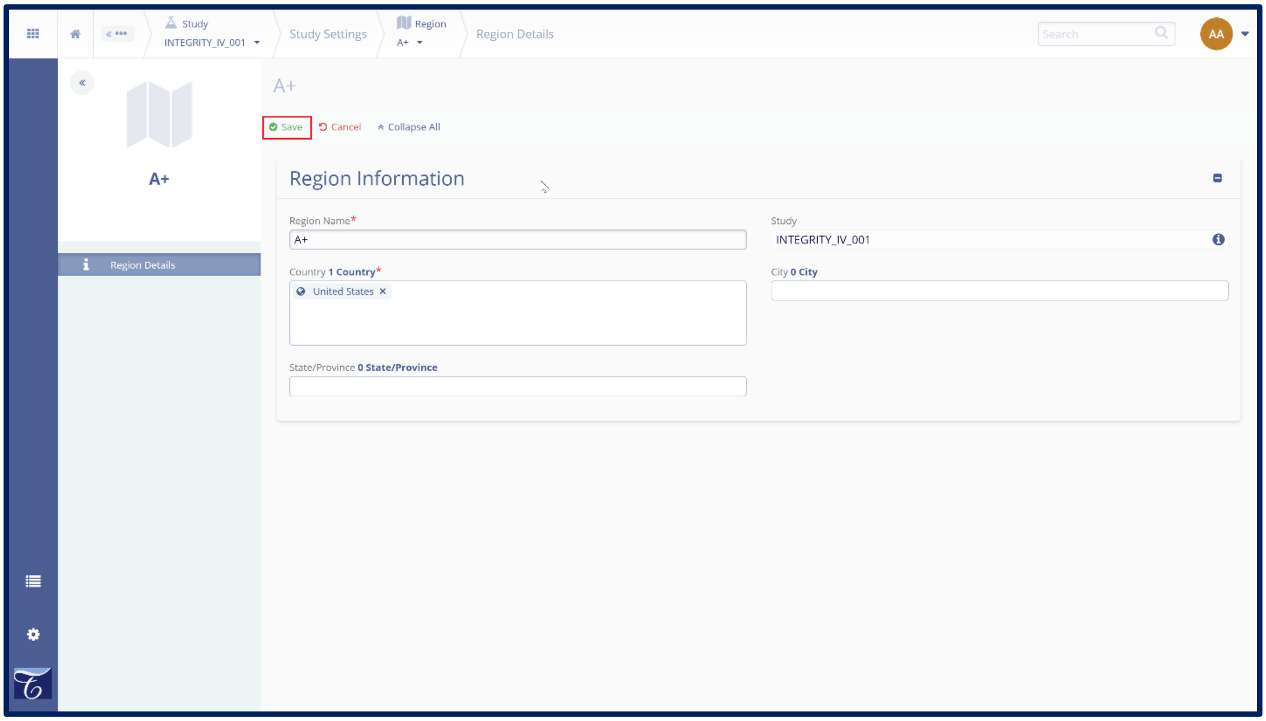
Note: To enter the State/Province and Cities values you must select only a **single country** for your region definition.

5.7 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 "Region Details" window.
3. Click on the **Edit** button in the-top-left corner.

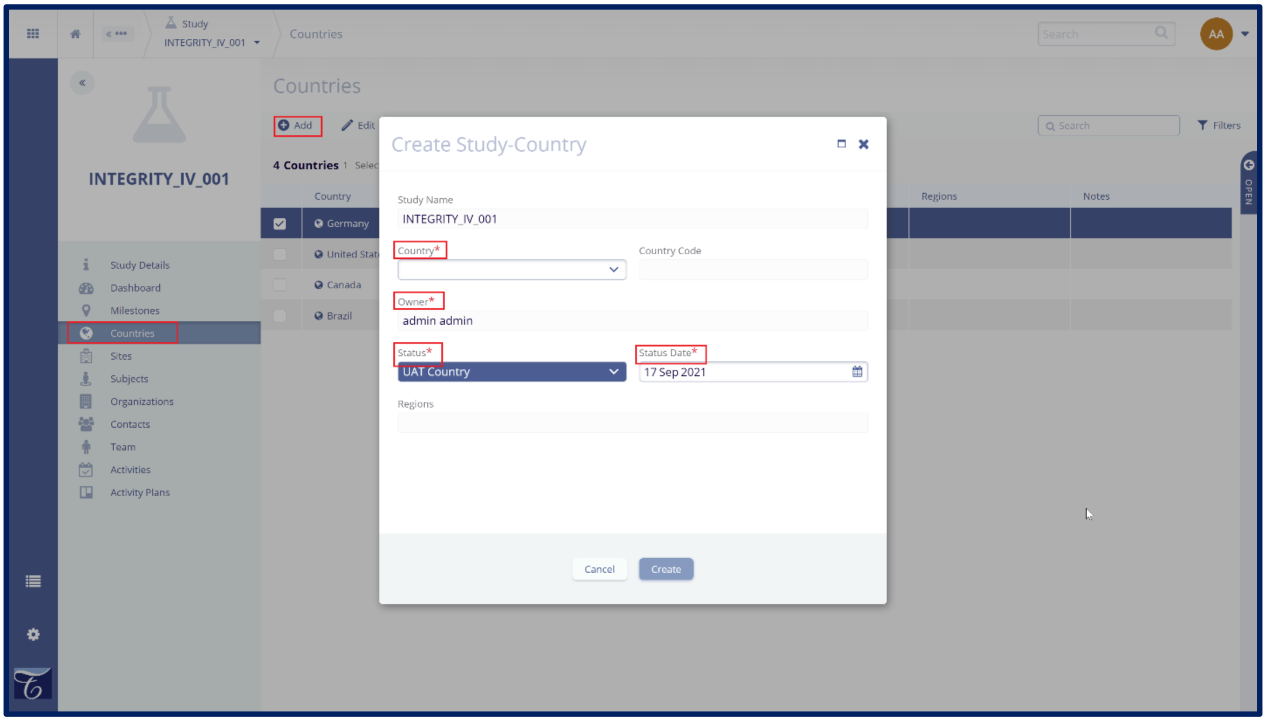


4. Make any necessary changes in the **Region Details** window.
5. Click on **Save** button in the top-left for the changes to apply.

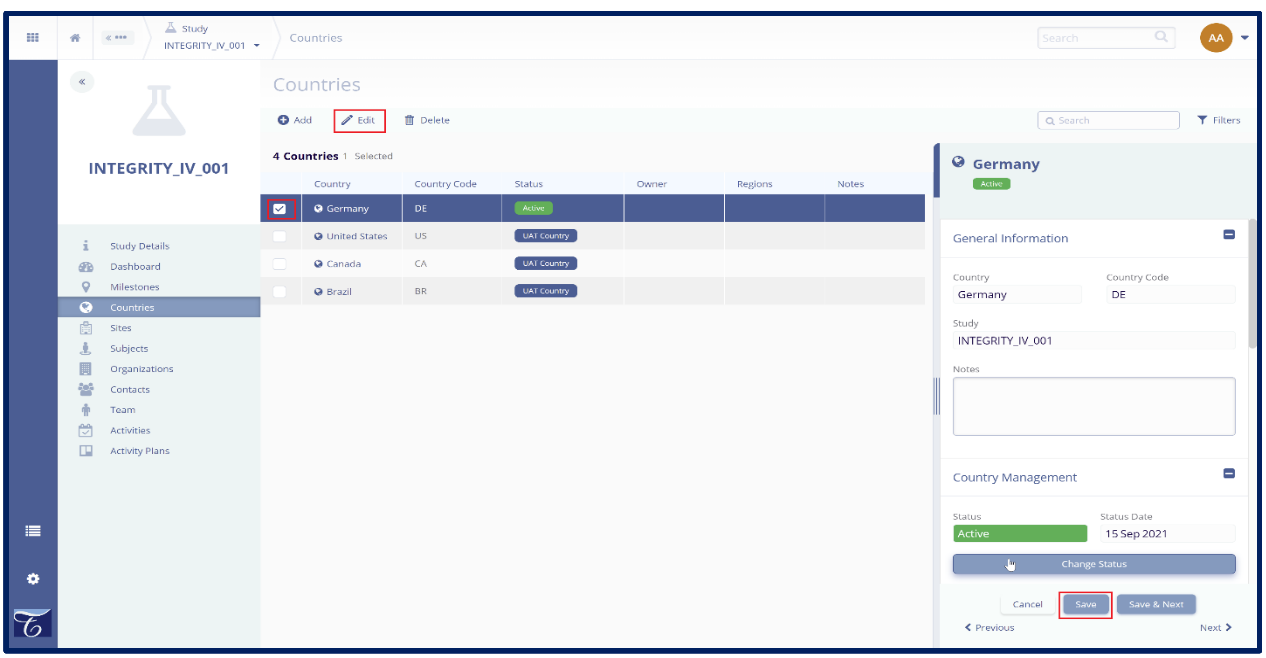


5.8 Defining and Editing Countries Within a Study.

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

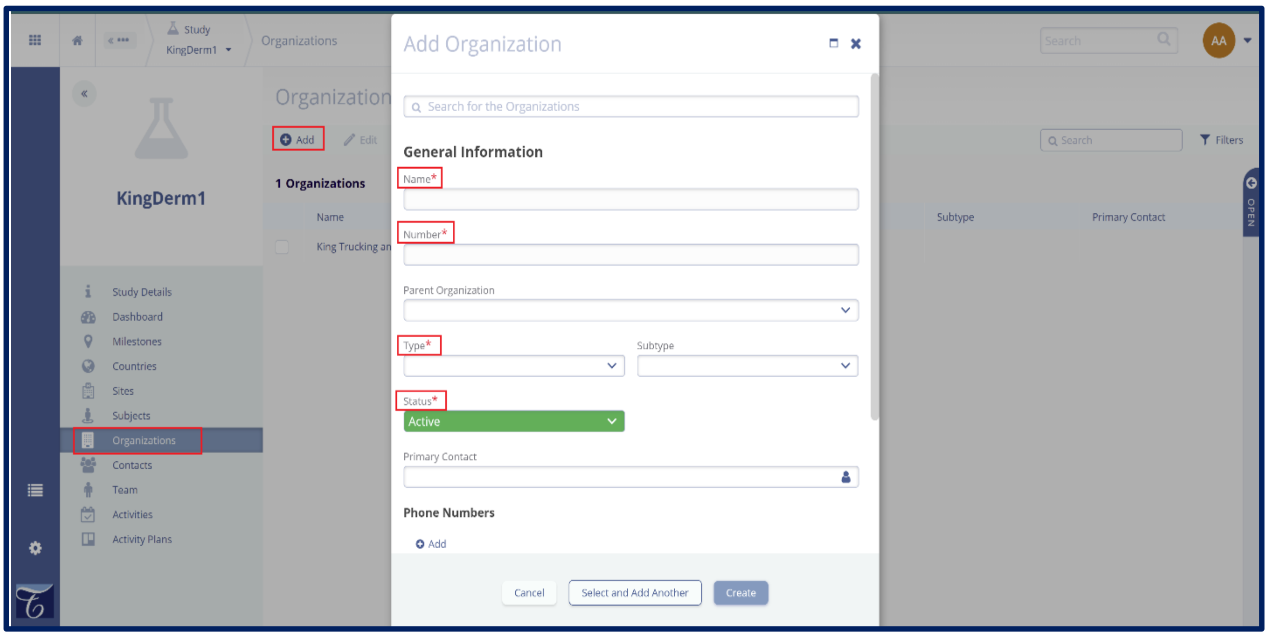


7. To edit the country, click on the check box before the name of the country you want to edit.
8. Click **Edit** in the top-left of the screen.
   a. A quick view panel will display on the right side of the screen.
9. Make any necessary changes in the quick view panel.
10. Click **Save**.



5.9 Associating Organizations to a Study

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



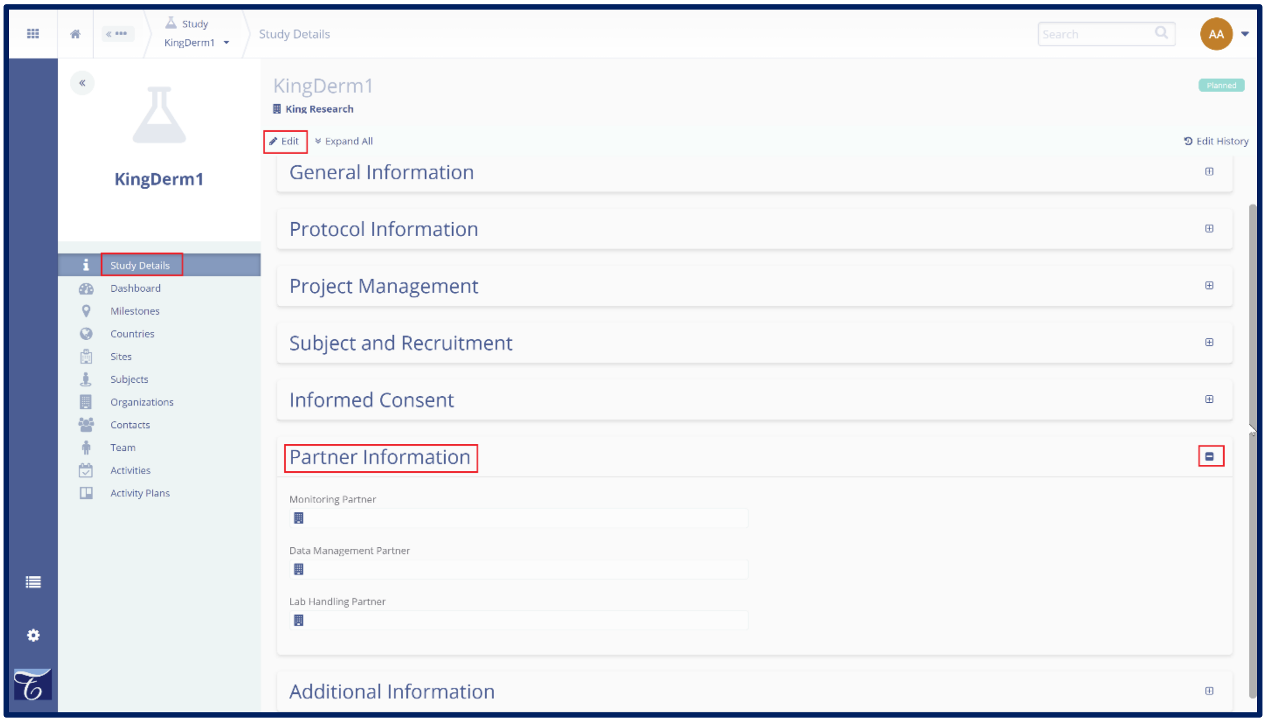
5. If you need to create a new organization, follow these steps showing how to create an Organization.
6. If the organization has already been created, use the search area to locate and select the organization.
7. Click **Add** or **Add and Add Another** depending upon whether you need to associate another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

5.10 Defining Study Partners

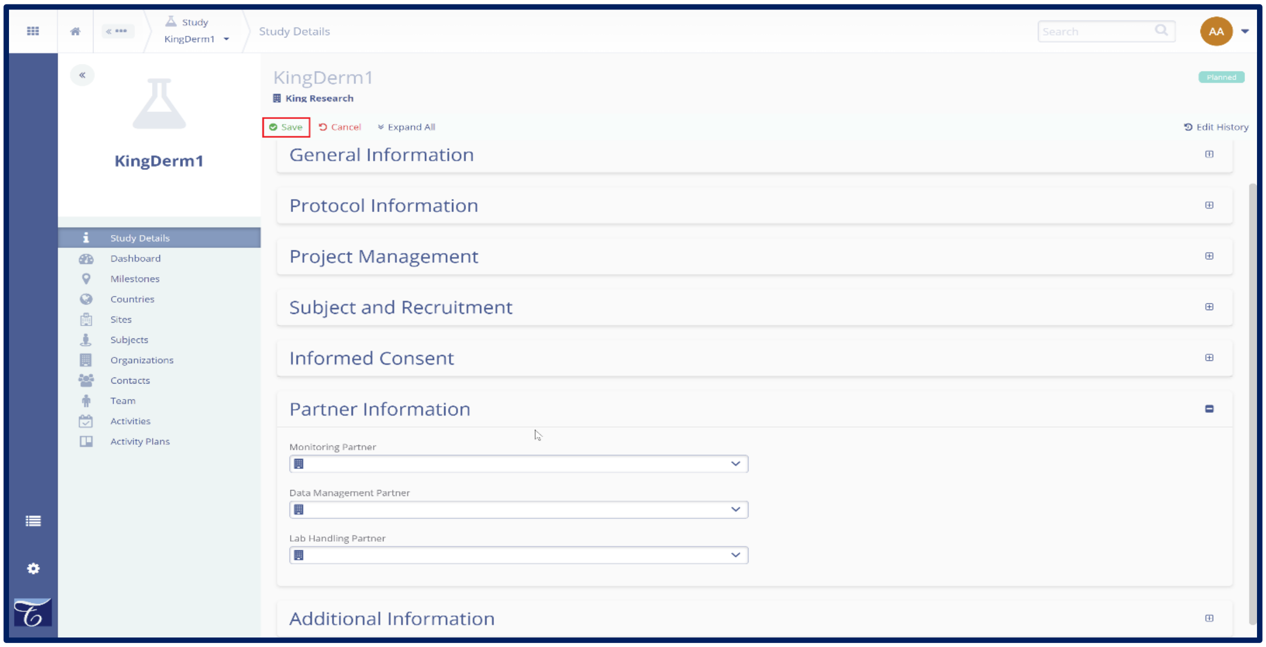
1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
   a. This opens the “Studies” window and study list is displayed.
2. Click on the name of the study to which you want to add partner information.
   a. The dashboard for the study is displayed.
3. Click on the **Study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

   a. The "Study Details" window is displayed.

4. Click on the **[+]** sign next to the **Partner Information** to expand that section.
5. Click on the **Edit** button in the top-left of the screen.



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



5.11 Associating Contacts to a Study

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

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

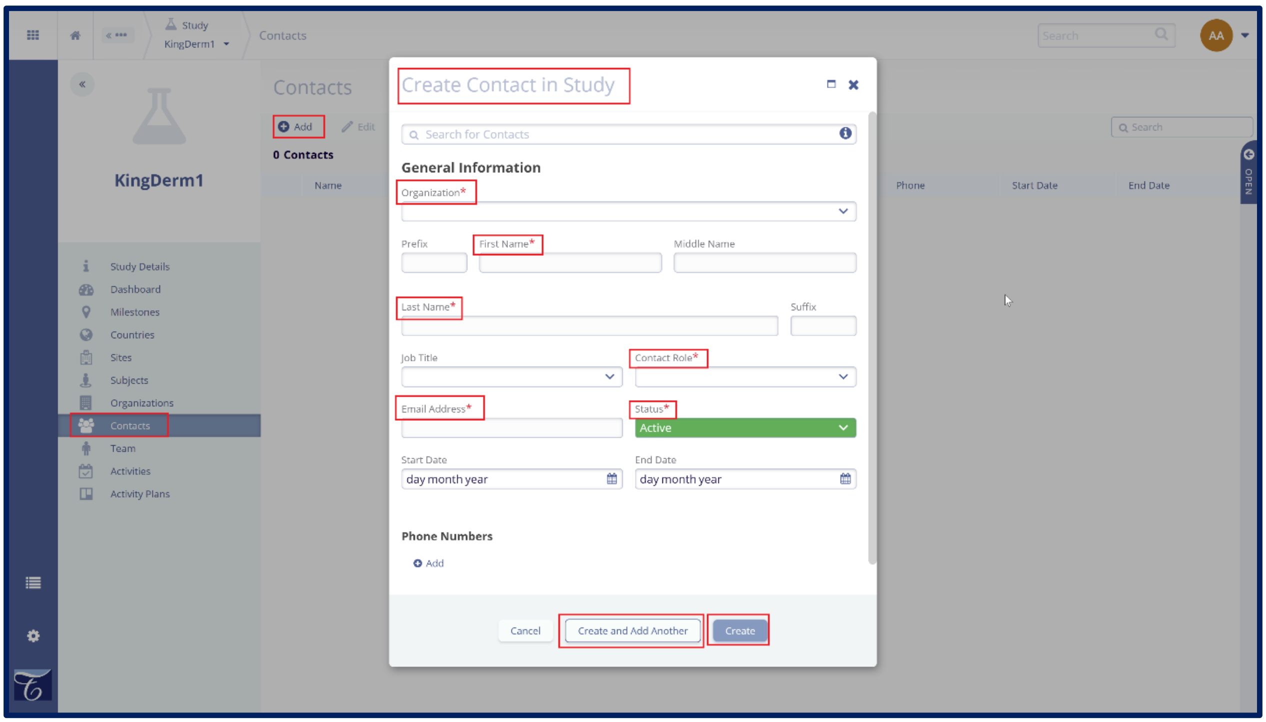
7. **(Optional)** Click **Include Address,** select a type for the address, and enter the address information.

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

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

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

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

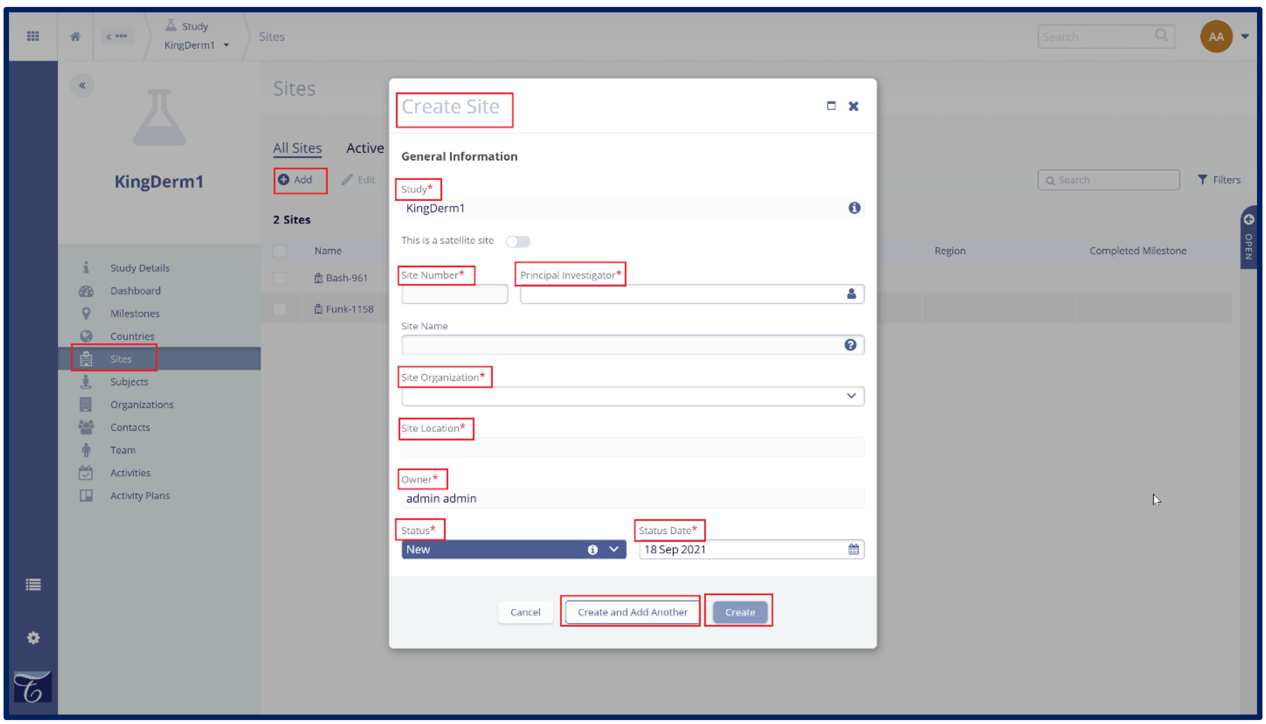


5.12 Creating Sites within a Study

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

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.

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.

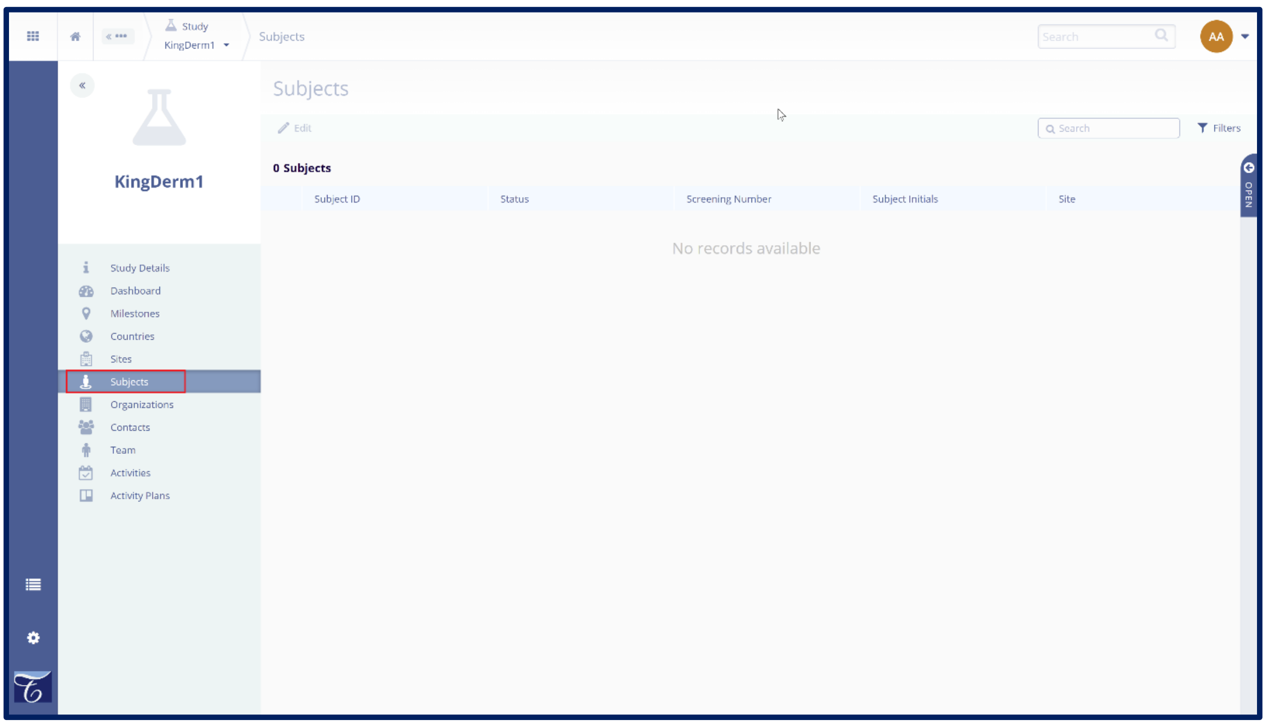


6. Finally, before clicking **Create,** verify all the fields are entered correctly in the **Create Site** window.
7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another Site right away.

5.13 Reviewing Subjects Within a Study

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

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



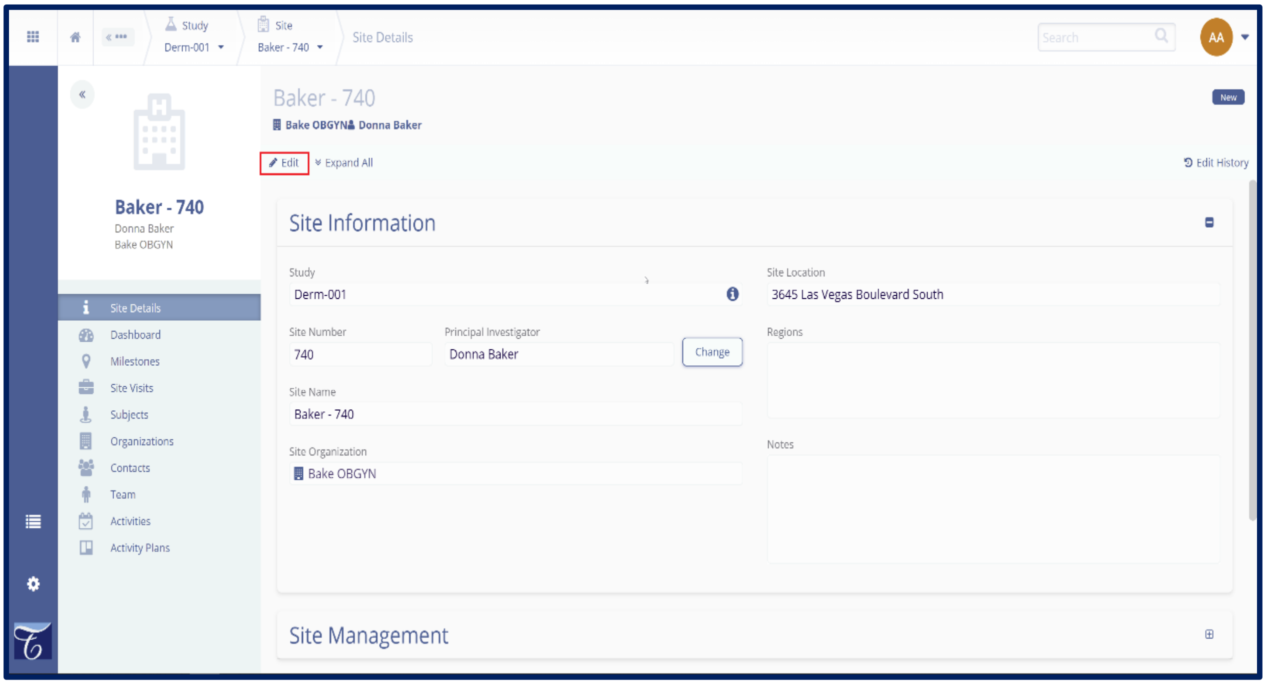
5.14 Study Sites Pre-Requisites

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

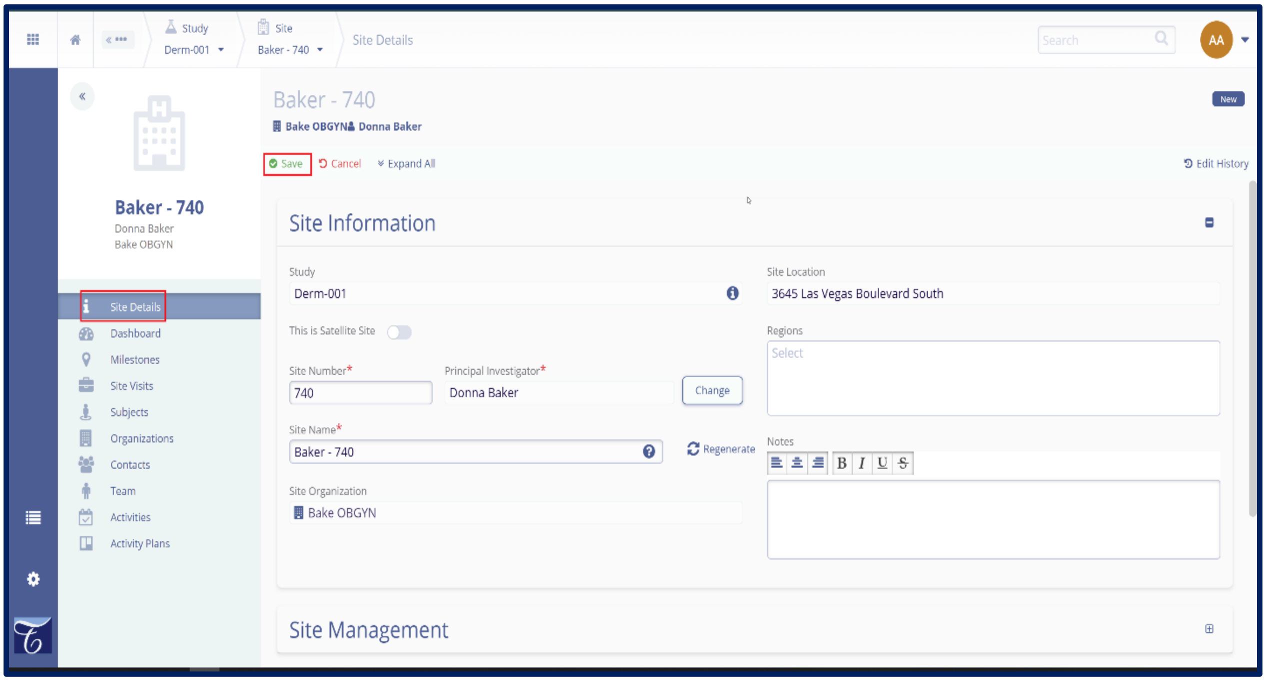
5.15 Editing a Site in a Study

1. Click on the **Studies** link in the Navigation menu at the left side of the screen.

2. Navigate to the study you want to access.
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 edit.
    a. This opens the dashboard window for the site.
5. Click on **Site Details** in the Navigation menu at the left side of the screen.
    a. This opens the "Site Details" window for the site.
6. Click on the **Edit** button at the top-left of the screen.

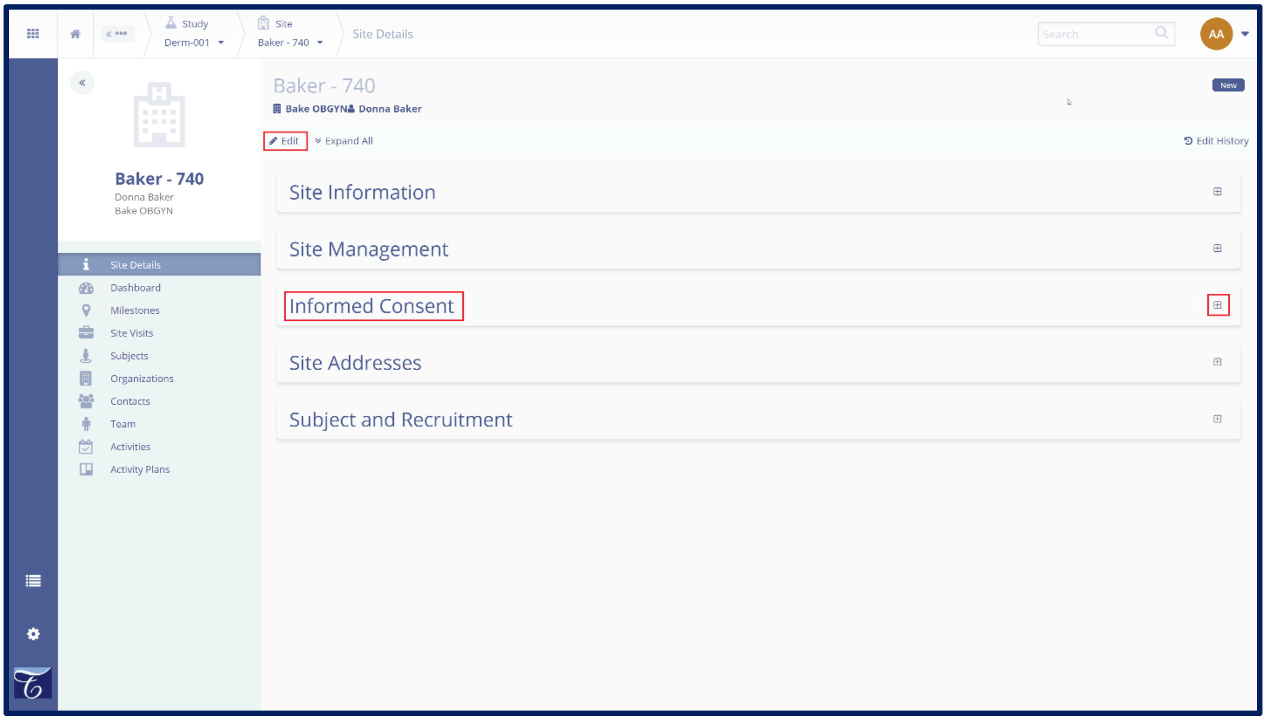


7. Make the required changes in the site details window.
8. Click on the **Save** button at the top-left of the screen for the changes to apply.

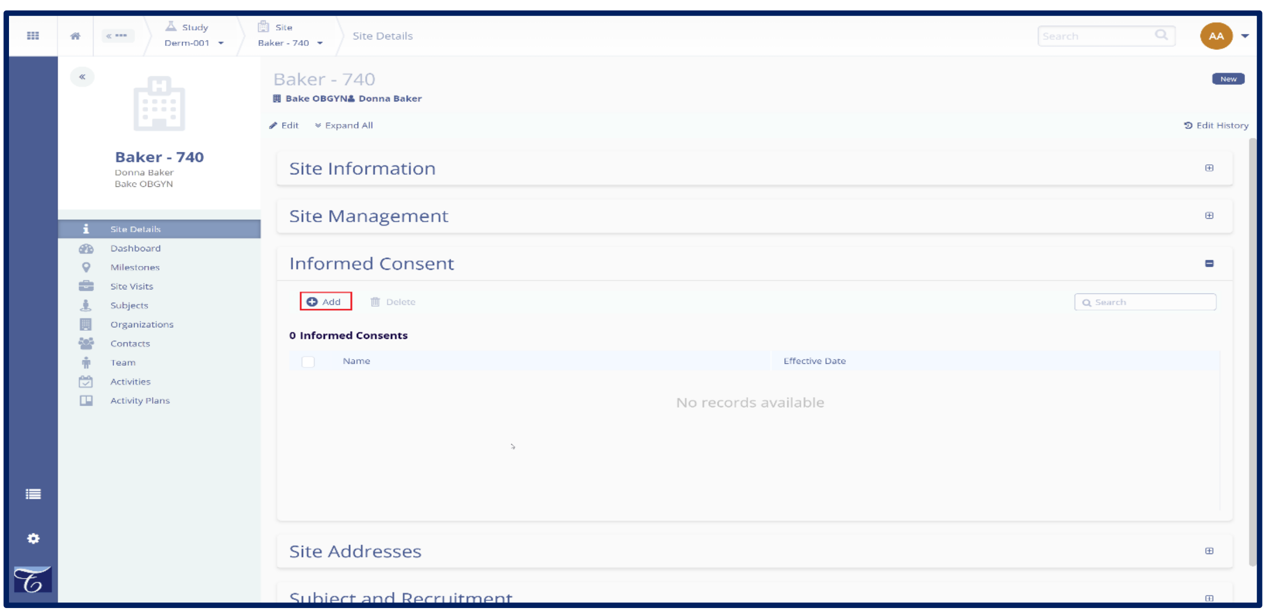


5.16 Tracking Informed Consents (ICFs) for a Site

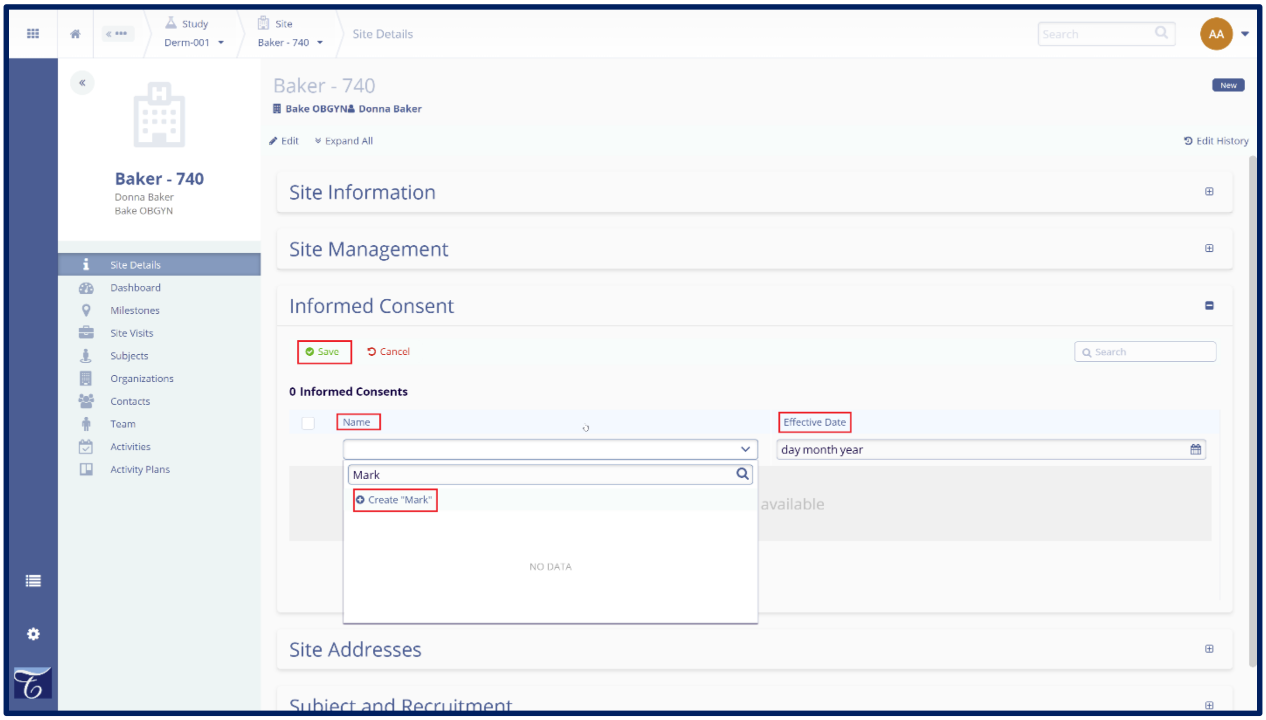
1. Navigate to the Site Details area for the related site.
   a. The necessary steps are found here.
2. Click on the [+] sign next to the Informed Consent to expand that section.



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.**

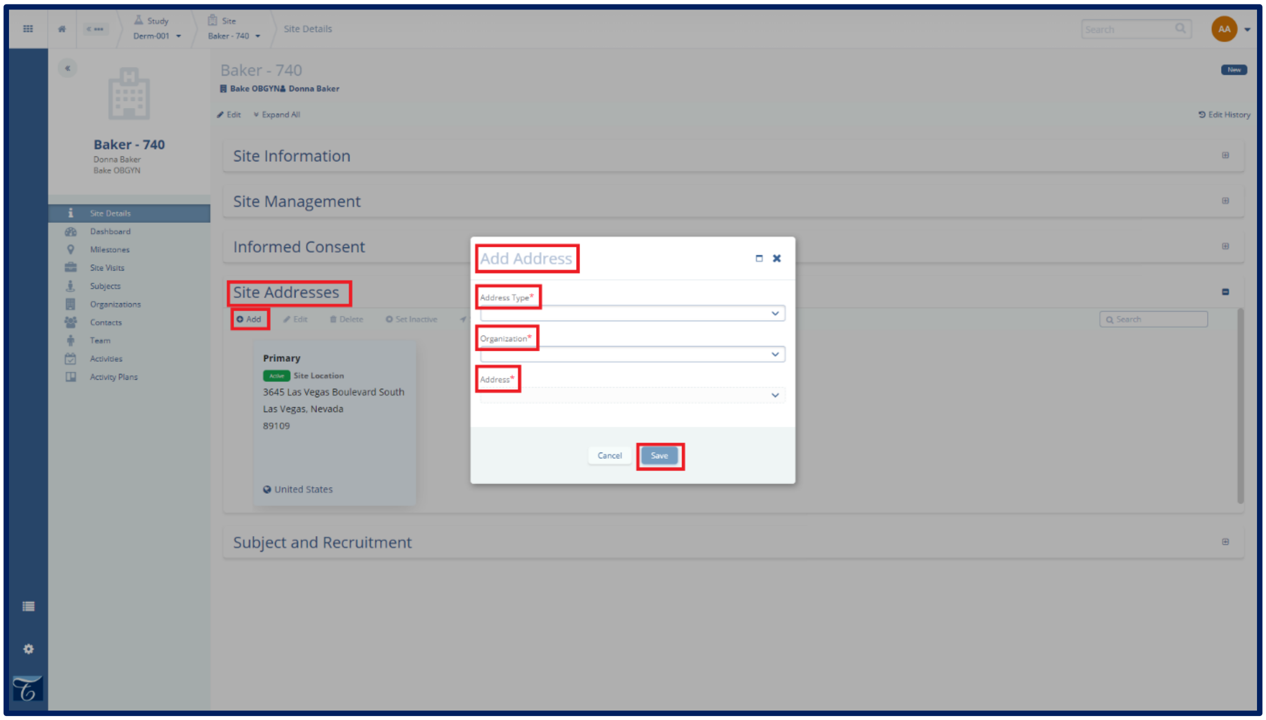


6. Click **Create**.
7. Click on the **Save** button in the informed consent section to save the record.
   a. This creates site level ICF for the site.

5.17 Tracking Site Addresses

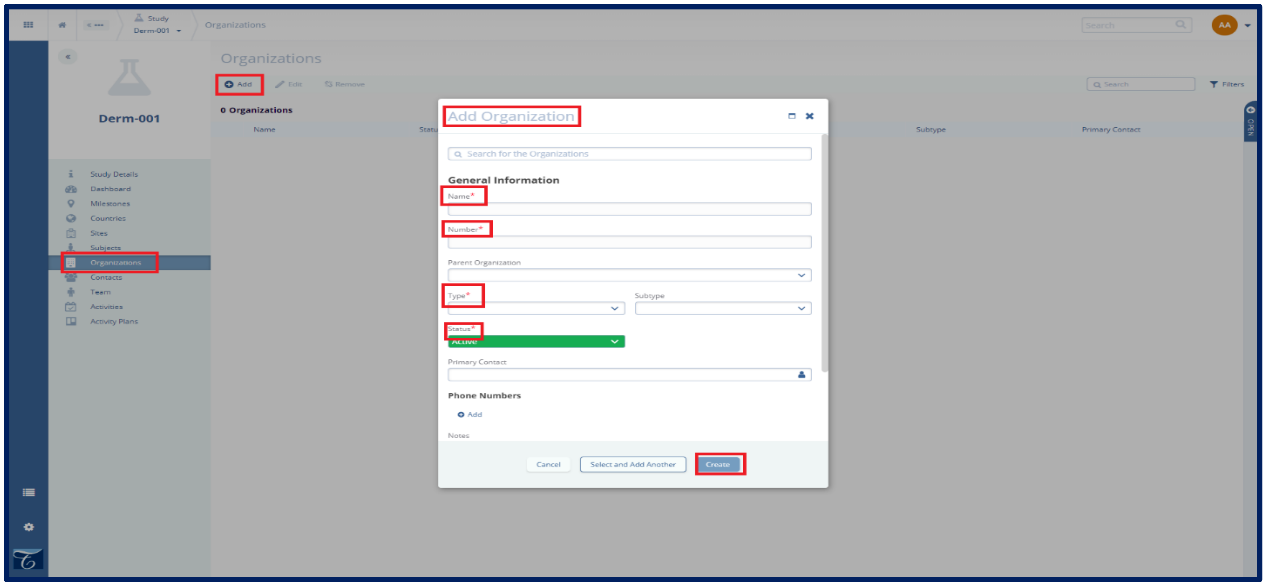
1. Navigate to the Site Details area for the related site
   a. The necessary steps are found here.
2. Click [+] next to the site addresses to expand that section.
3. **Site location** within the **site addresses** section is displayed as **primary** address.
4. **Site Location** is listed as a **primary**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

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



5.18 Associating an Organization to a site

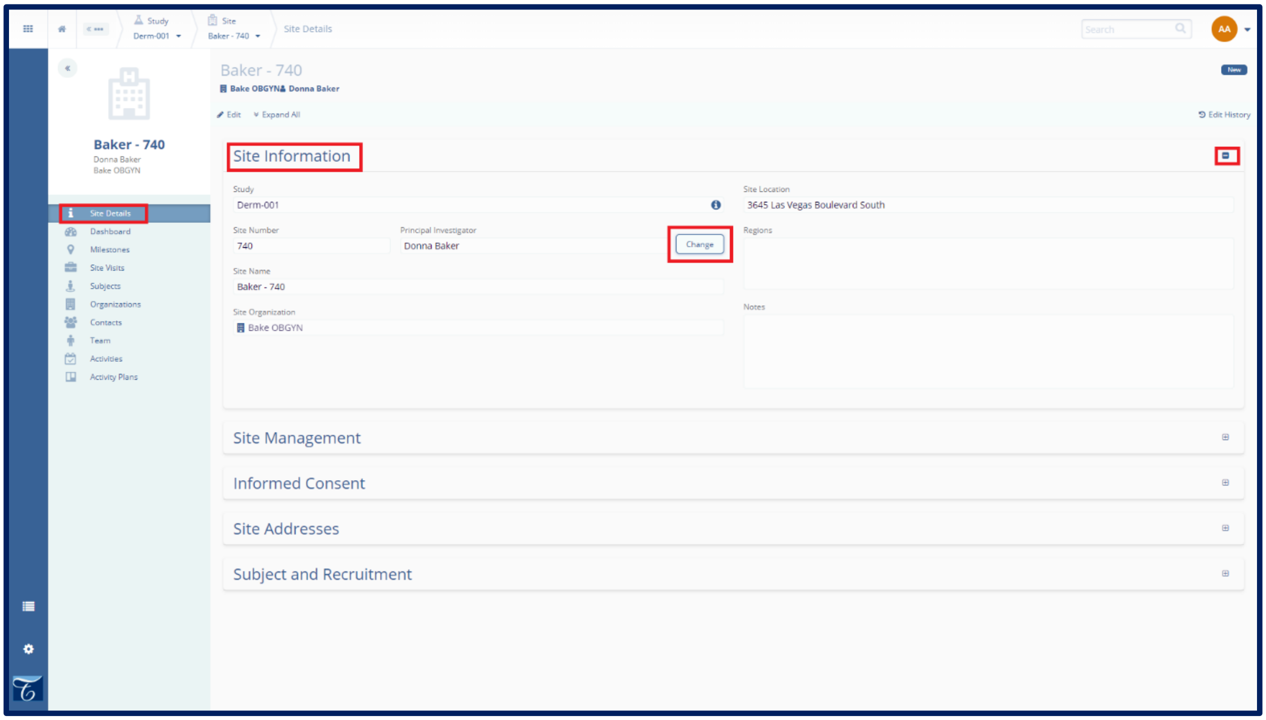
1. Navigate to the Site to which you wish to associate an organization.
2. Click on the **Organization** link in the Navigation menu at the left side of the screen.
    a. This opens the “Organization” window.
3. Click on **Add** button at the top-left of the screen.
    a. This opens “Add organization”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



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

5.19 Change of Principal Investigator (PI)

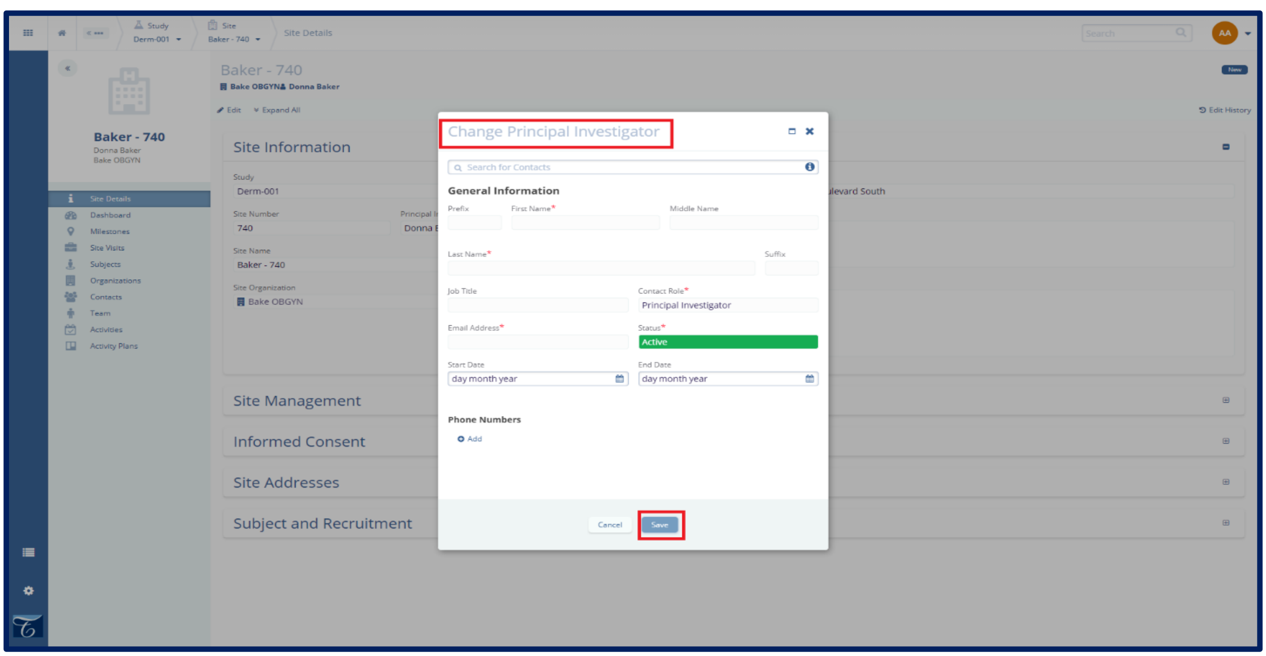
1. Navigate to the Site Details area for the related site.
   a. The necessary steps are found here.
2. Click on the [+] sign next to the **Site Information** to expand that section.
3. Click on the **Change** button in the site information section.



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

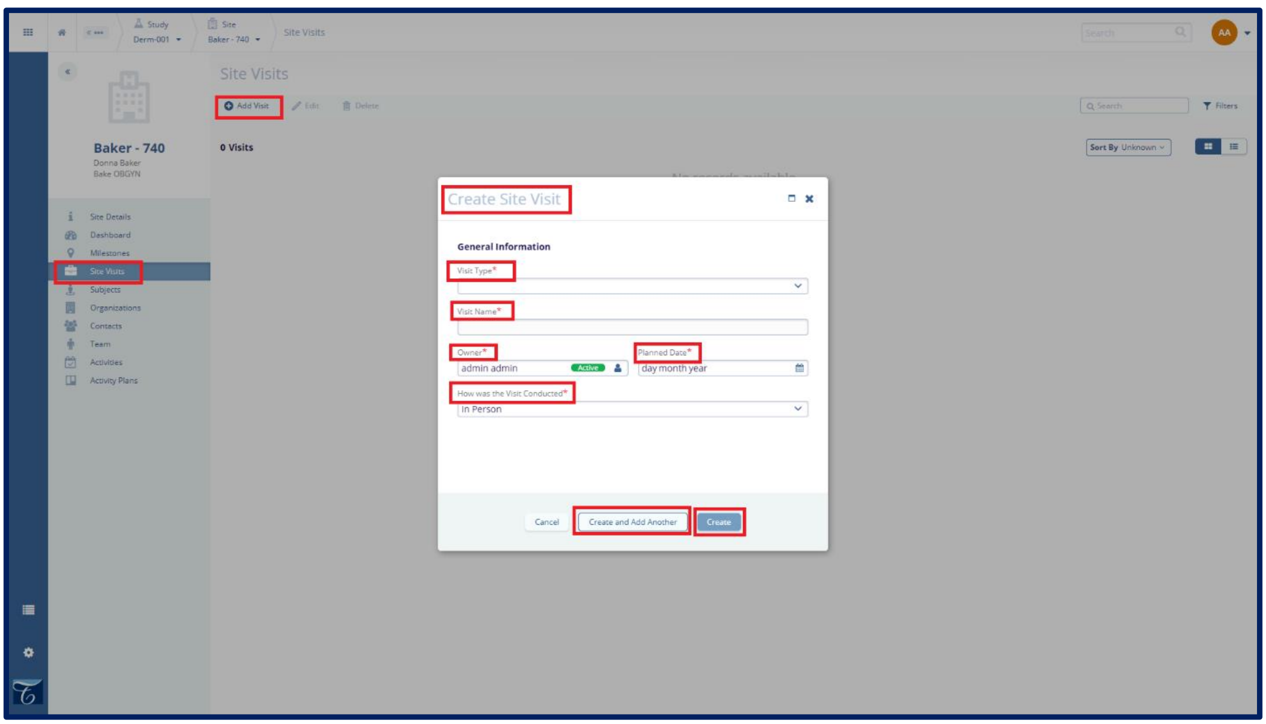
   Note: Use the search box to find the contact.

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



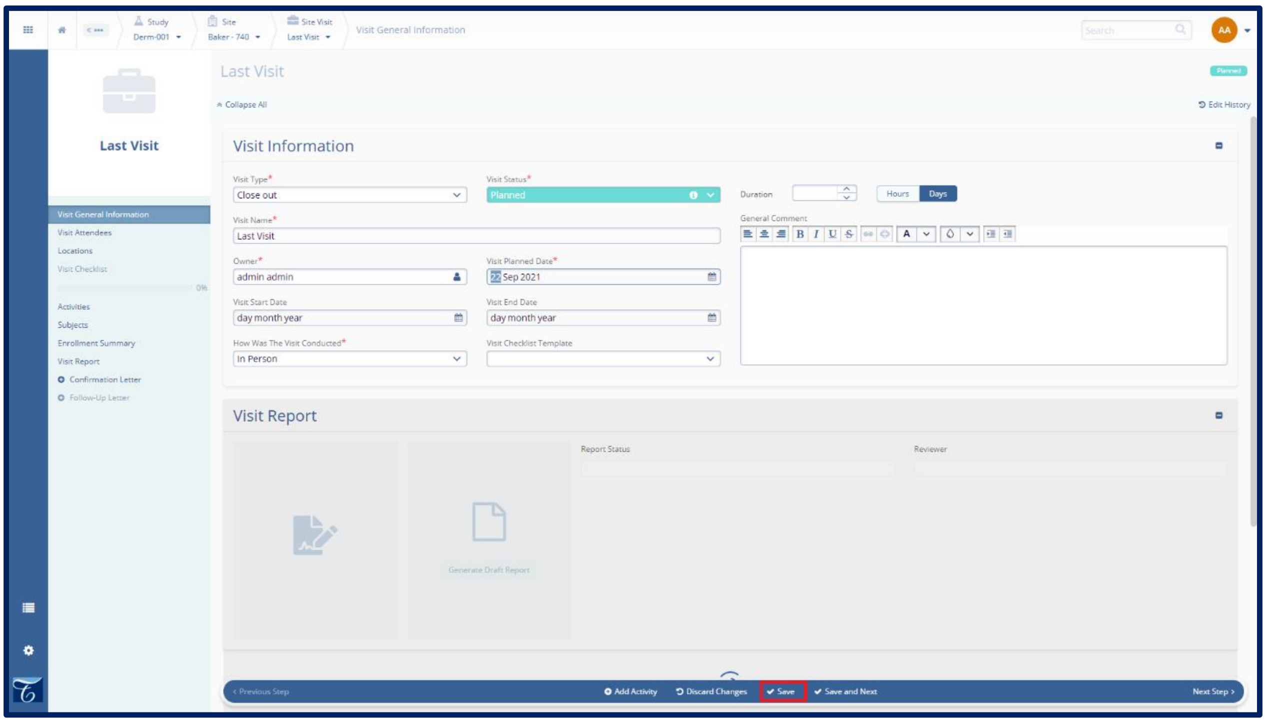
5.20 Creating Site Visits

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



5.21 Updating a Site visit

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

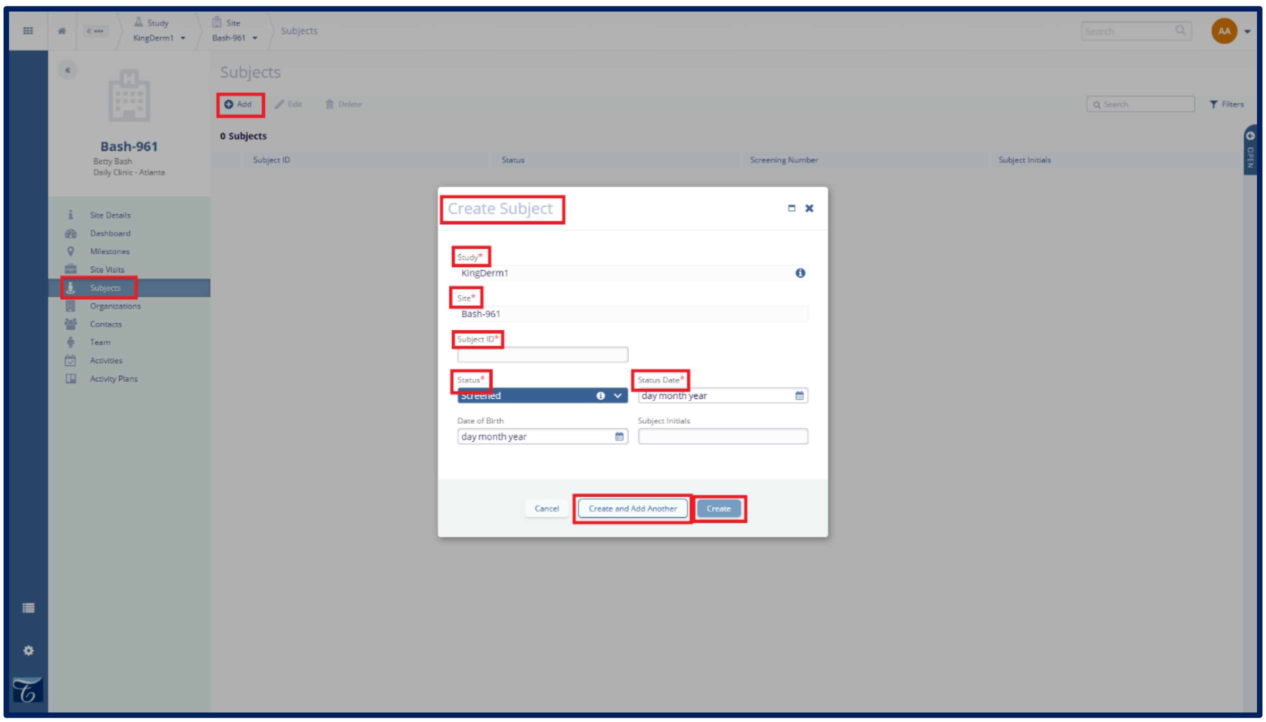


5.22 Tracking Subjects

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

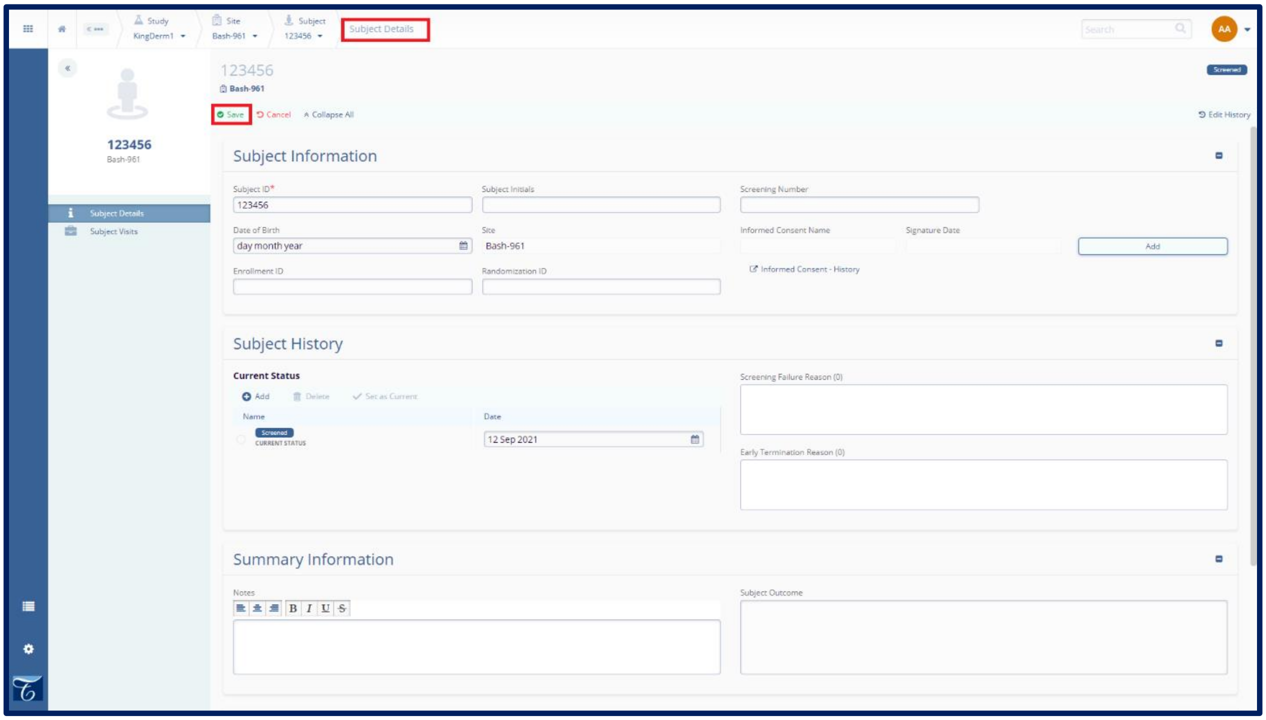
5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a subject successfully.
6. Finally, before clicking **Create**, verify all the fields are entered correctly in the create subject window.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

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



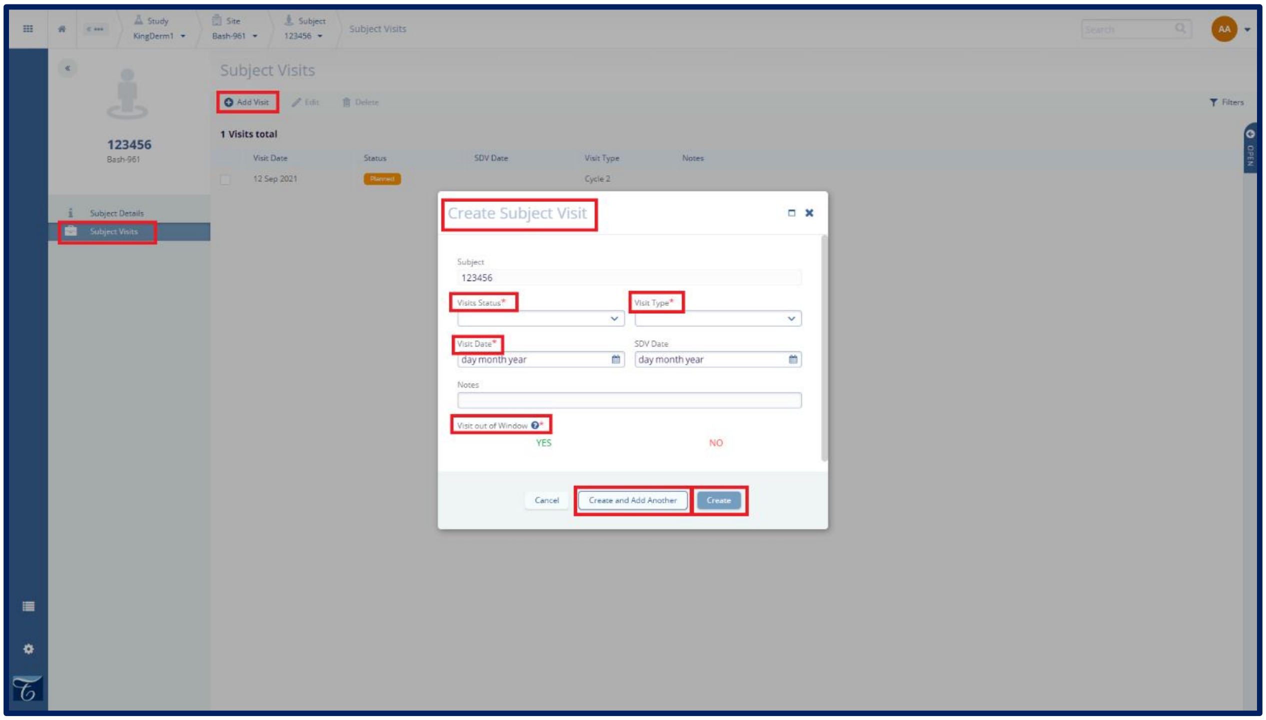
5.23 Editing a Subject

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



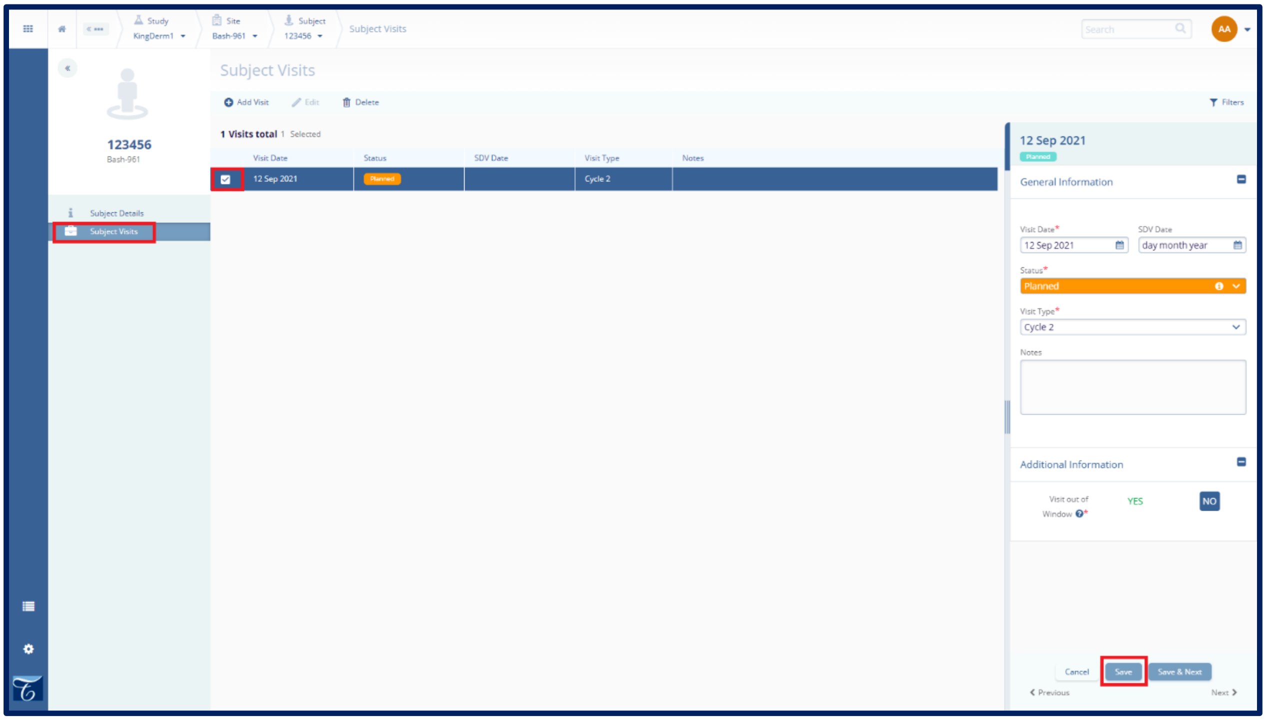
5.24 Tracking Subjects Visits

1. Navigate to the site in question.
2. Click on the **Subjects** in the Navigation menu at the left side of the screen.
   a. This opens the “Subjects” window.
3. Navigate to the subject name you want to access and click on it.
4. Click on the **Subjects Visits** in the Navigation menu at the left side of the screen.
   a. This opens “Subject Visits” window.
5. Click on the **Add Visit** button in the top-left of the screen.
   a. This opens **Create Subject Visit** window.
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 which need to be filled to create a subject successfully.
8. Finally, before clicking **Create**, verify all the fields are entered correctly in the create subject visit window.
   a. Create Subject Visit window closes, subject visit record is created and displayed in the list.
9. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another subject visit right away.



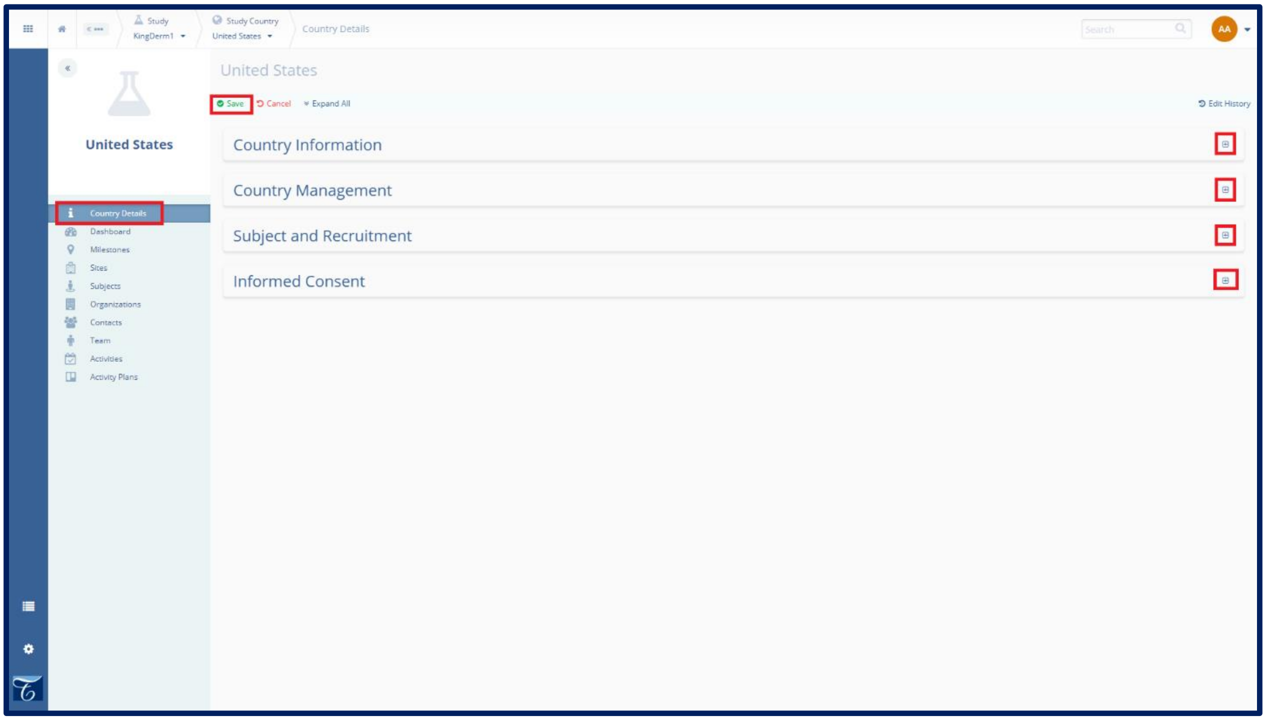
5.25 Editing a Subject Visit

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 “Subject Visits” window.
5. Navigate to the Subject visit record you want to edit and Click on the checkbox before the Subject visit name.
   a. A quick view panel will display on the right side of the screen.
6. Now, click on the **Edit** button (pencil icon) in the top-right of the screen.
7. Make any necessary changes to the subject visit information.
8. Click on the **Save** button in the right bottom of the screen.



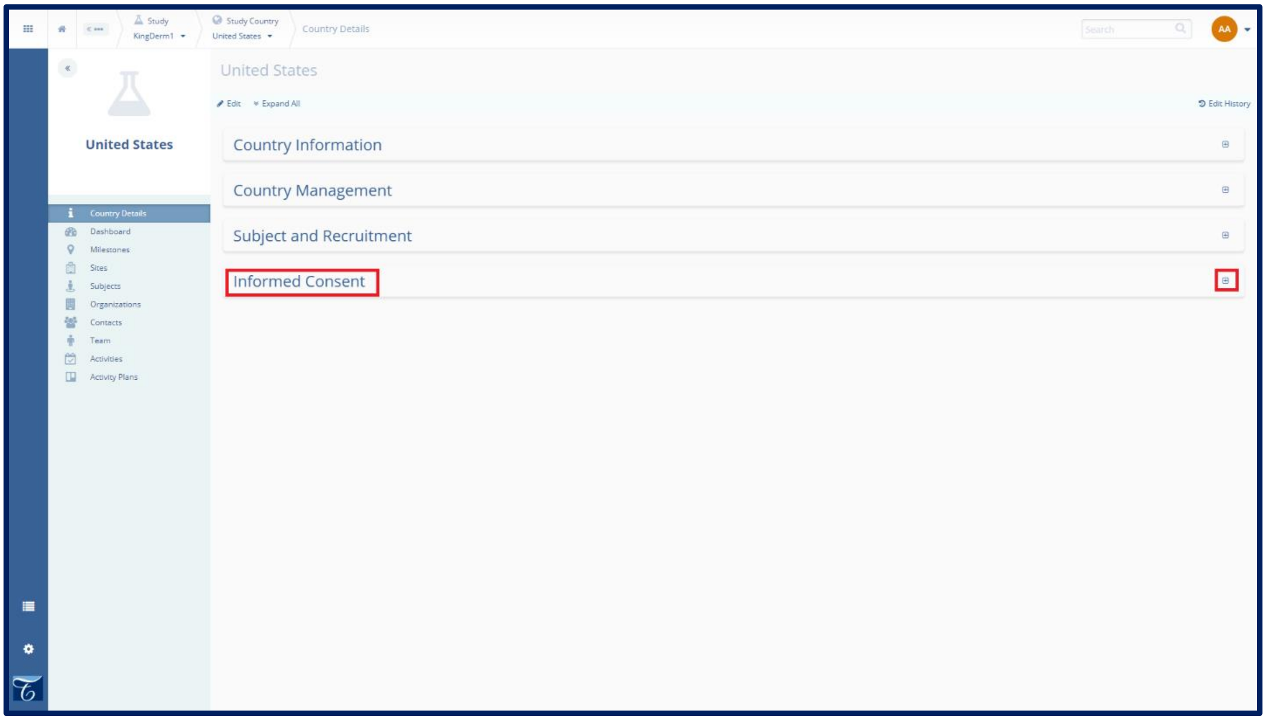
5.26 Reviewing and Tracking Country Details

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

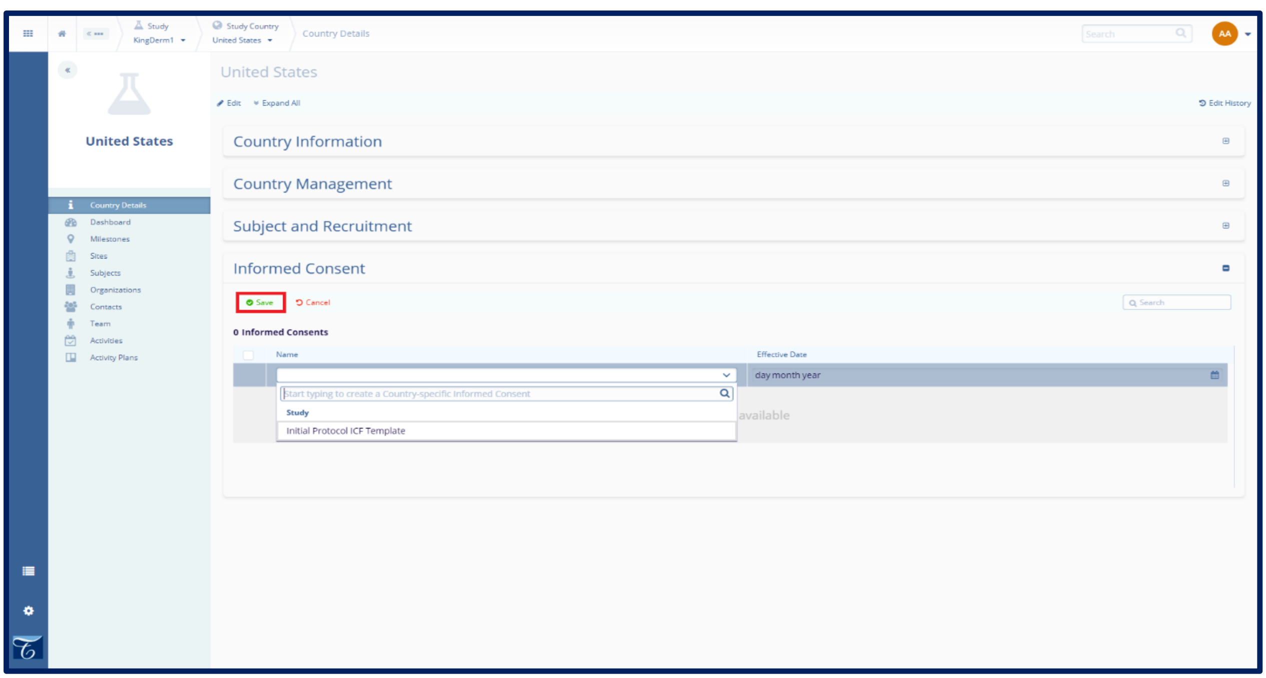


5.27 Tracking Country Informed Consents (ICFs)

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

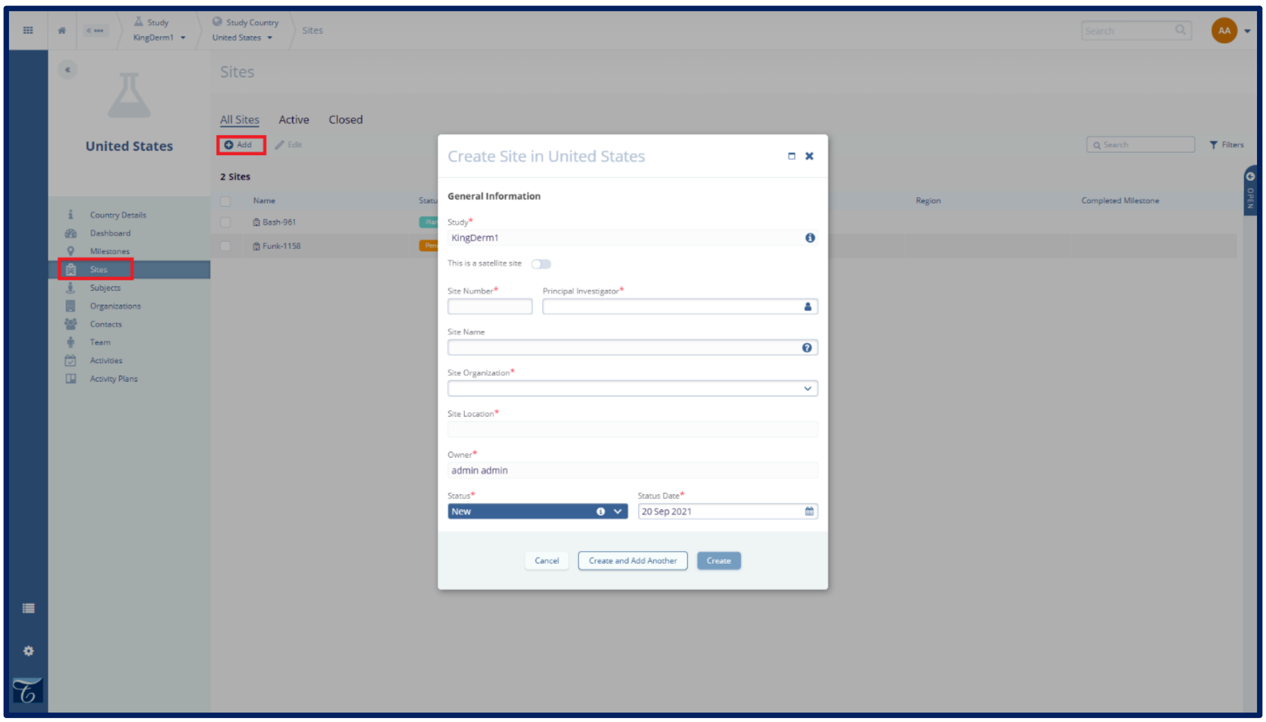


7. Select the study ICF from the list and click on the save button in the informed consent section.
8. You can add country level ICF by adding name and effective date in the informed consent section and click on the save button.



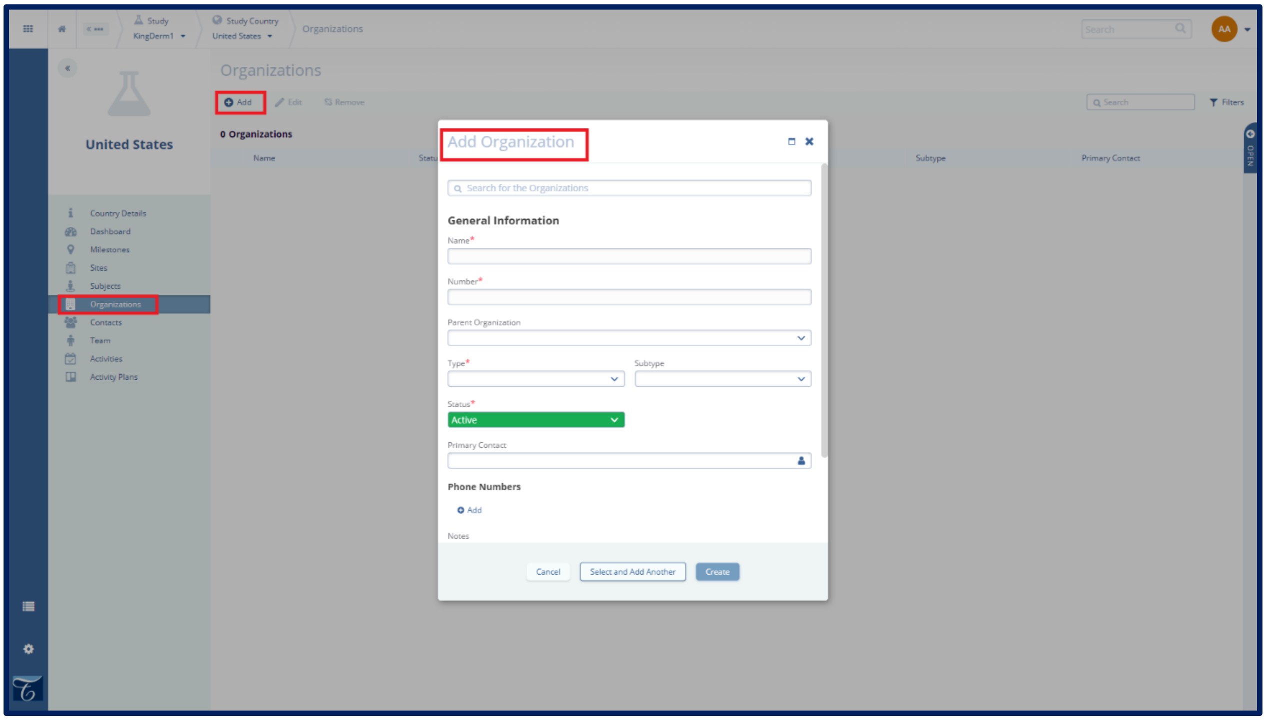
5.28 Creating Site within a Country

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



5.29 Associating an Organization with a Country

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

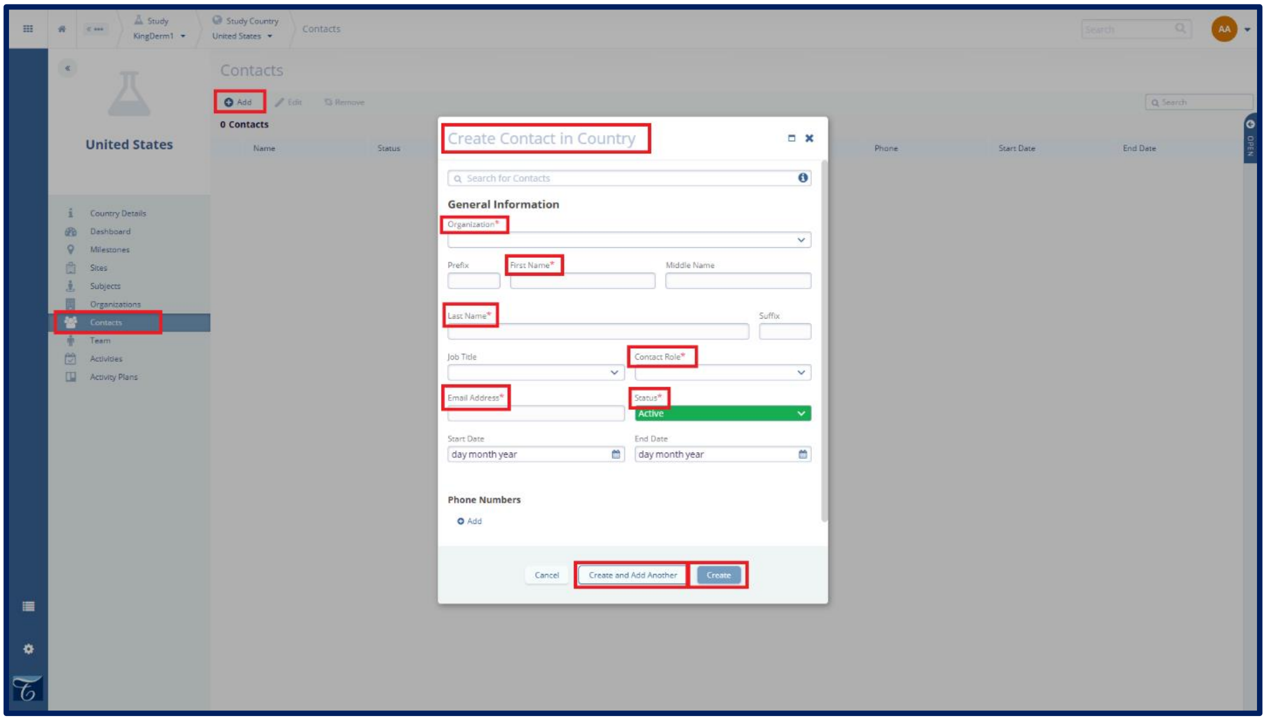


5.30 Associating Contacts with a Country

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.
   a. This opens the “Contacts” window, and contacts list is displayed.
4. Click on the **Add** button in the top-left of the screen.
   a. This opens the “Create Contact in Country" window.

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

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



6 Site Visit Documentation

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

6.1 Pre-Requisite

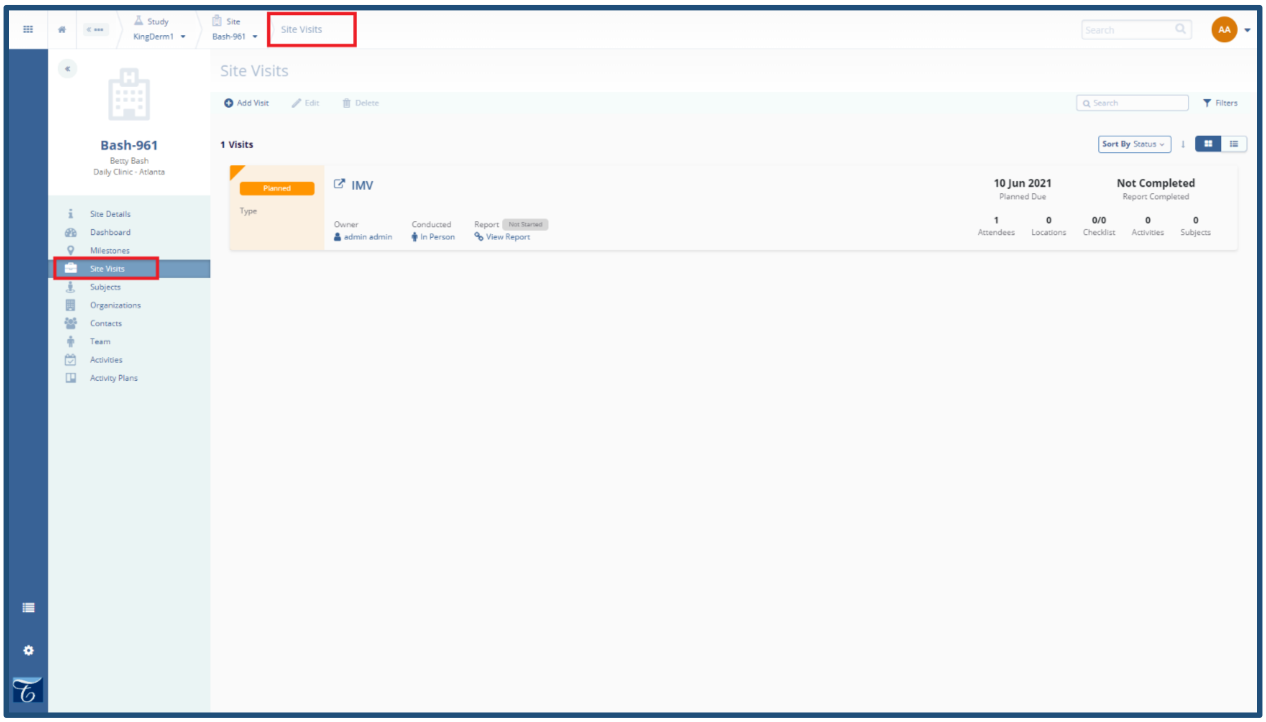
The user who is responsible for creating and managing **Site Visit Documentation** in an **Organization** must have **Clinical Regulatory Associate** user access.

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

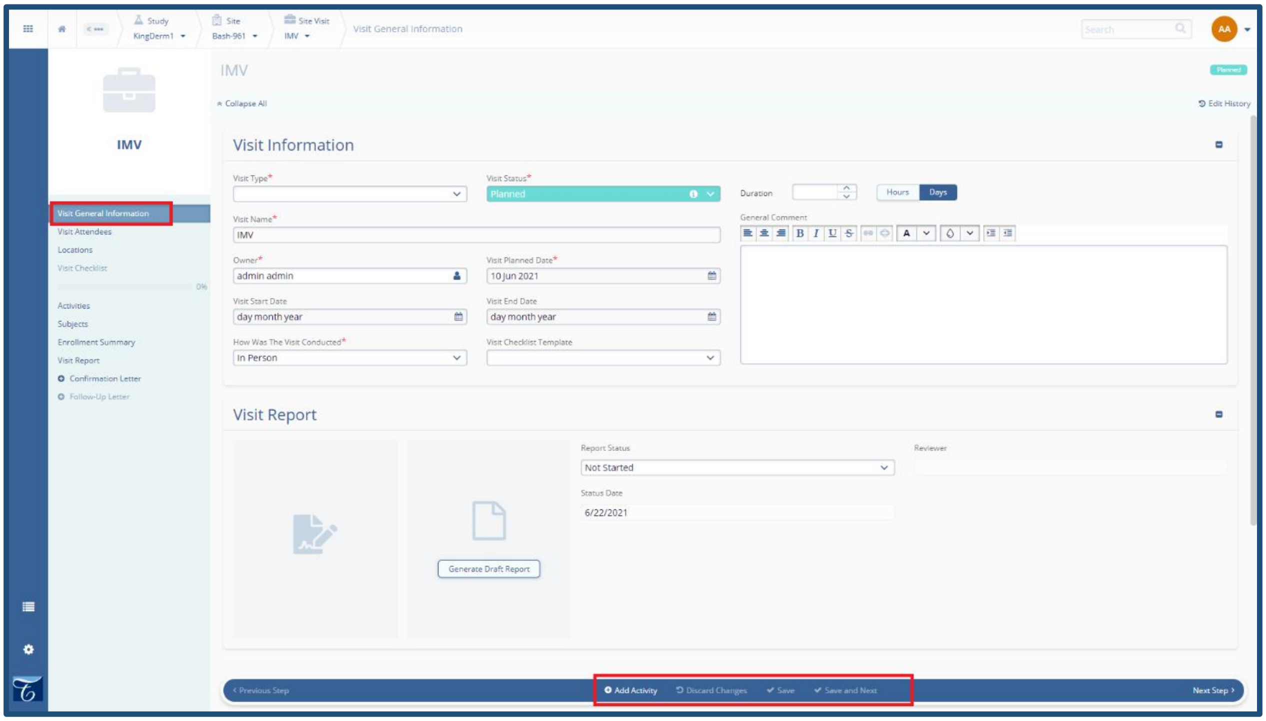
6.2 Navigation to Site Visit

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

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



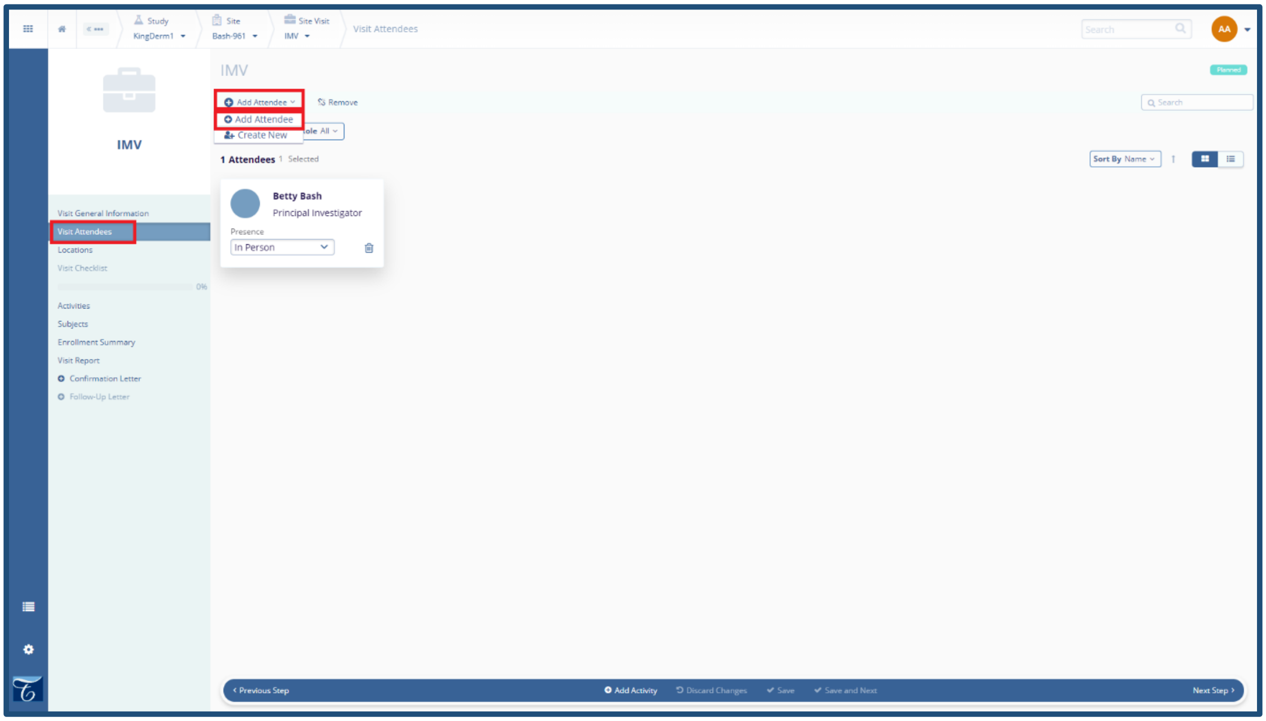
6. Navigate to the Visits you want to review and click on it.
   a. This opens the **Visit General Information** window.
7. Review the site visit information and make any necessary changes if required and click on the **Save** button in the bottom of the screen, for the changes to apply.



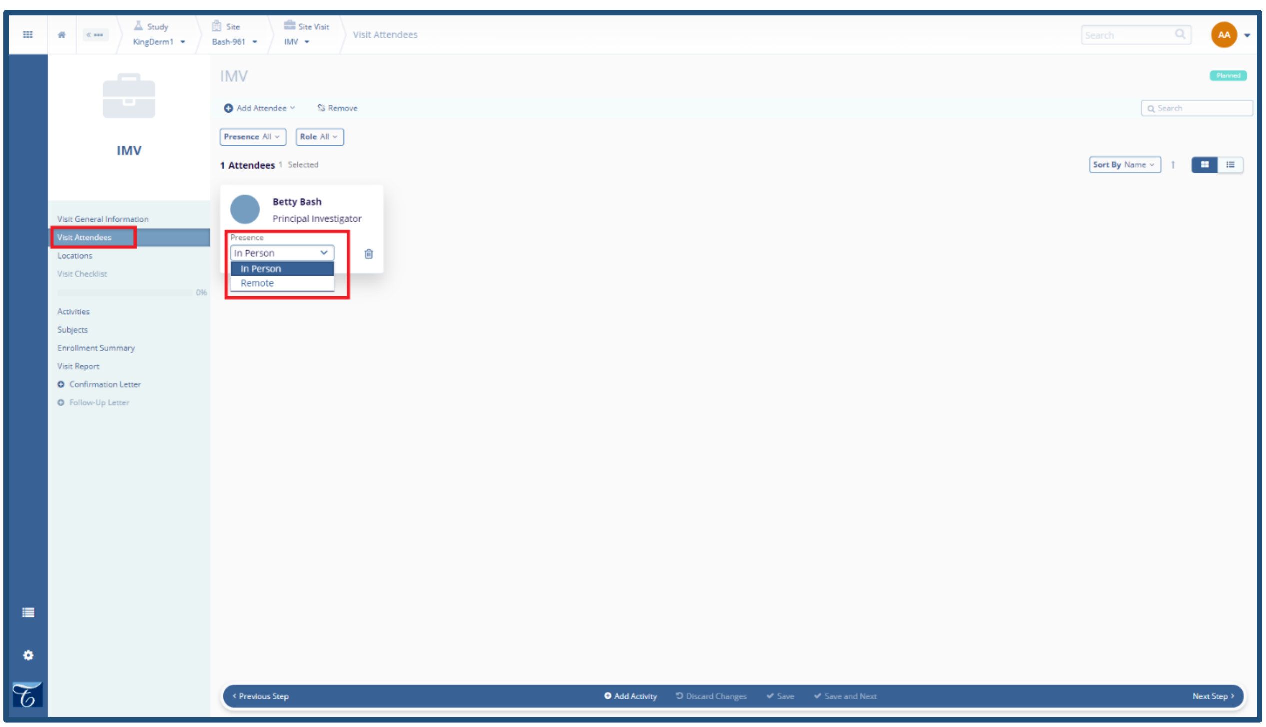
6.3 Site Visit Attendees

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

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



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



6.4 Site Visit Locations

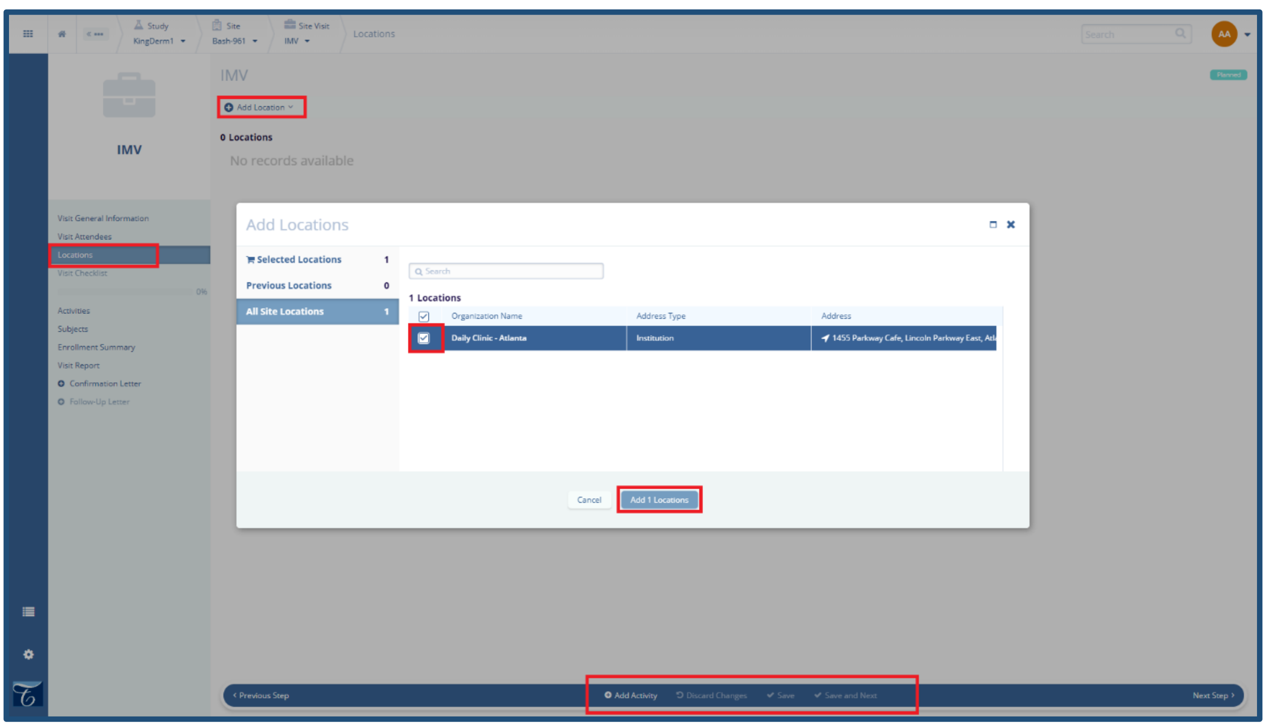
1. Navigate to the Site Visit area for the related site.
   a. More detailed instructions on this step can be found here.
2. Click on the **Locations** link in the Navigation menu at the left side of the screen.
   a. This opens the “Locations” window.

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

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

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

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

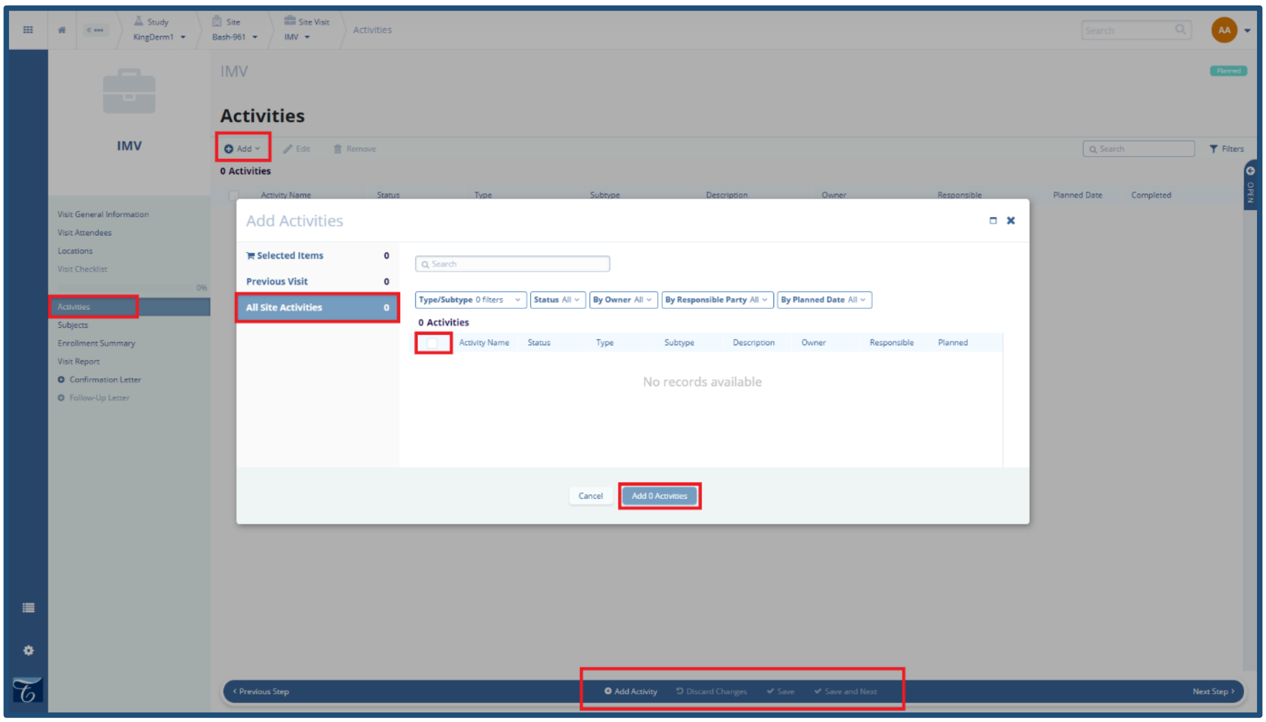


6.5 Site Visit Activities

1. Navigate to the Site Visit area for the related site.
   a. More detailed instructions on this step can be found here.

2. Click on the **Activities** link in the Navigation menu at the left side of the screen.
   a. This opens the "Activities" window.
3. Click on the **Add** button in the top-left of the screen
4. Click on the **Add Activities** from the dropdown of the Add button.
   a. This opens the "Add Activities" window.
5. Select an existing site activity from the list of **All Site Activities**.
6. Click on the **Add** button in the Add Activities window.

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



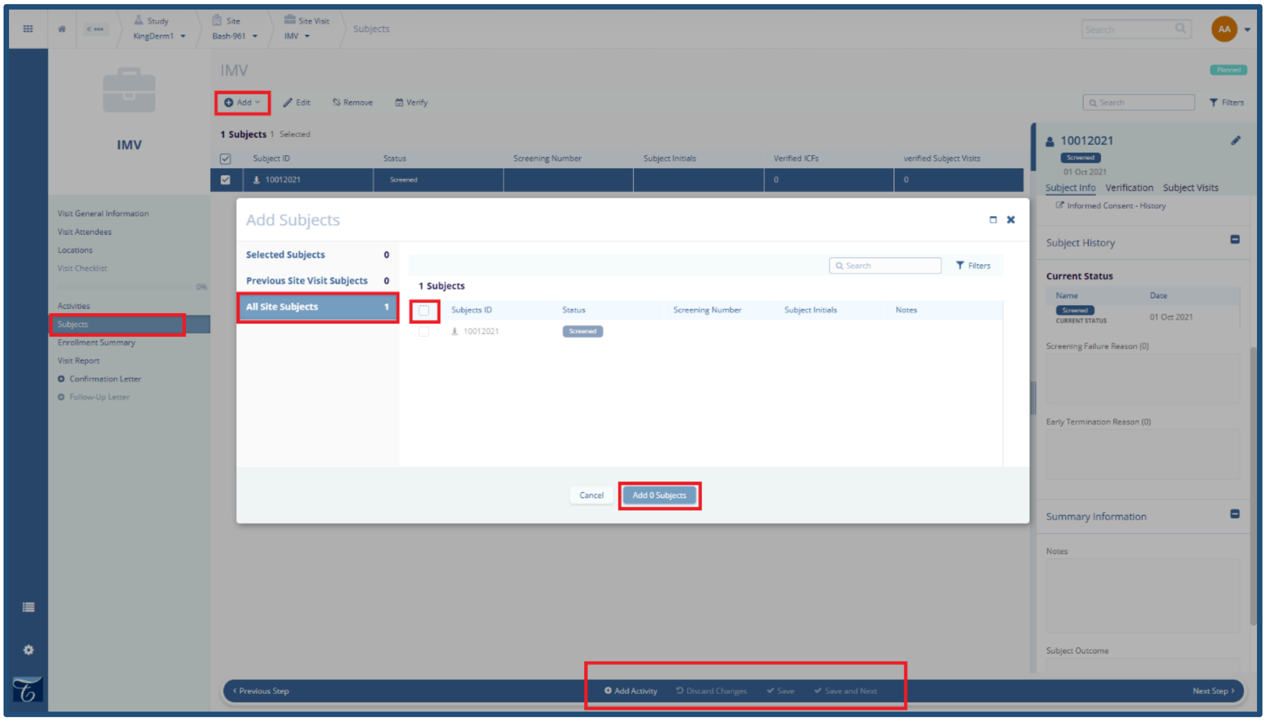
Note: When a previous visit has occurred a user can select **Previous Visit** to select Activities that were associated with the previous visit report.

6.6 Site Visit Subjects

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

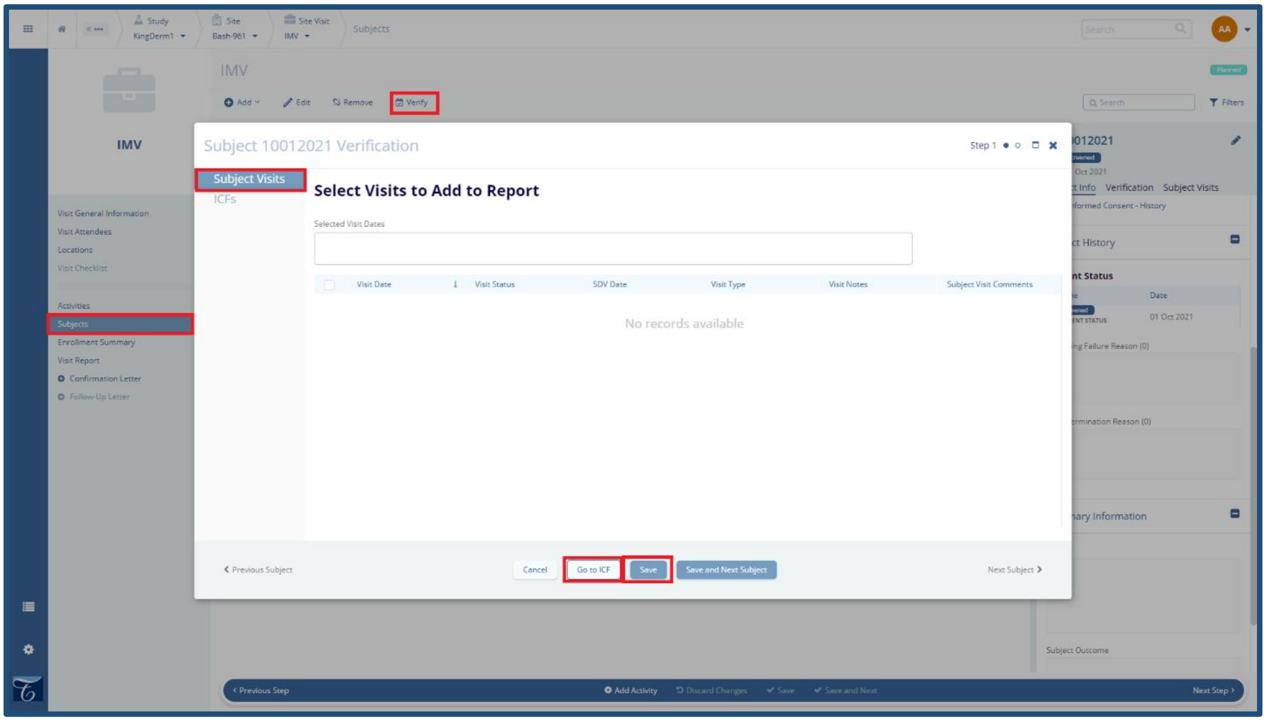
5. Select an existing site subject from the list of **All Site Subjects**.
6. Click on the **Add** button in the **Add Subjects** window.

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



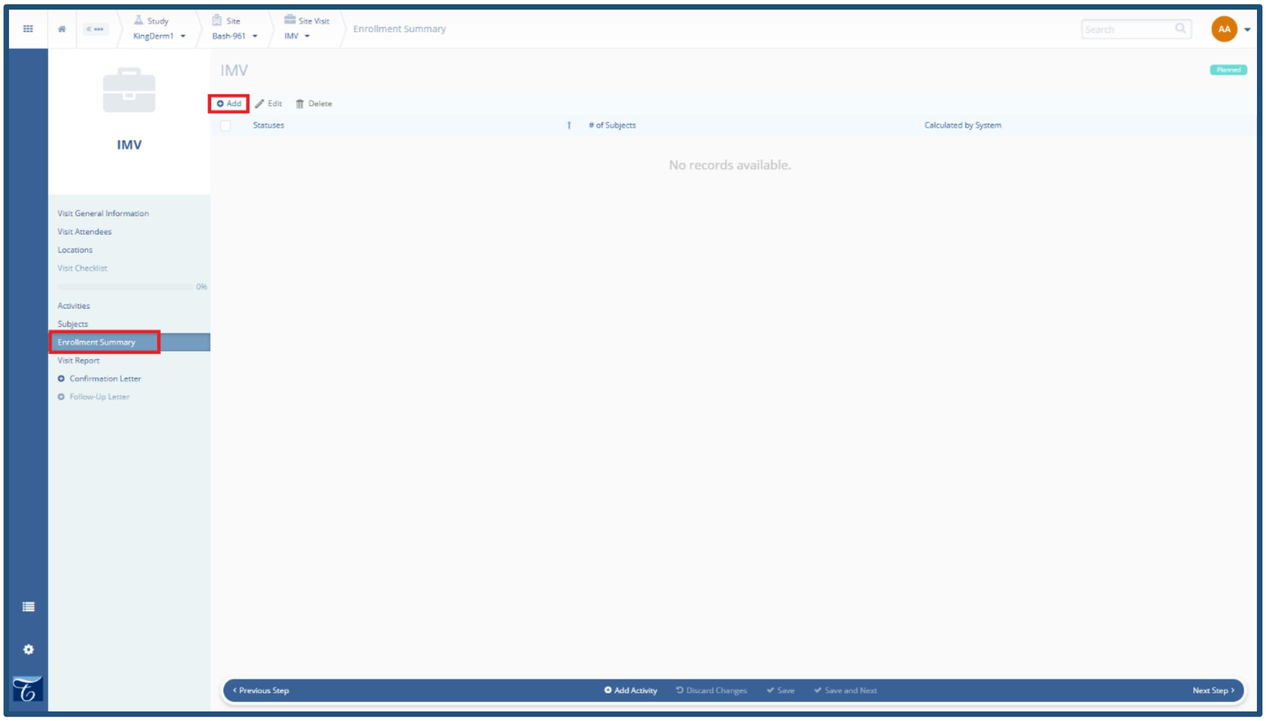
   Note: When a previous visit has occurred a user can select **Previous Visit** to select subjects that were associated with the previous visit report.

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

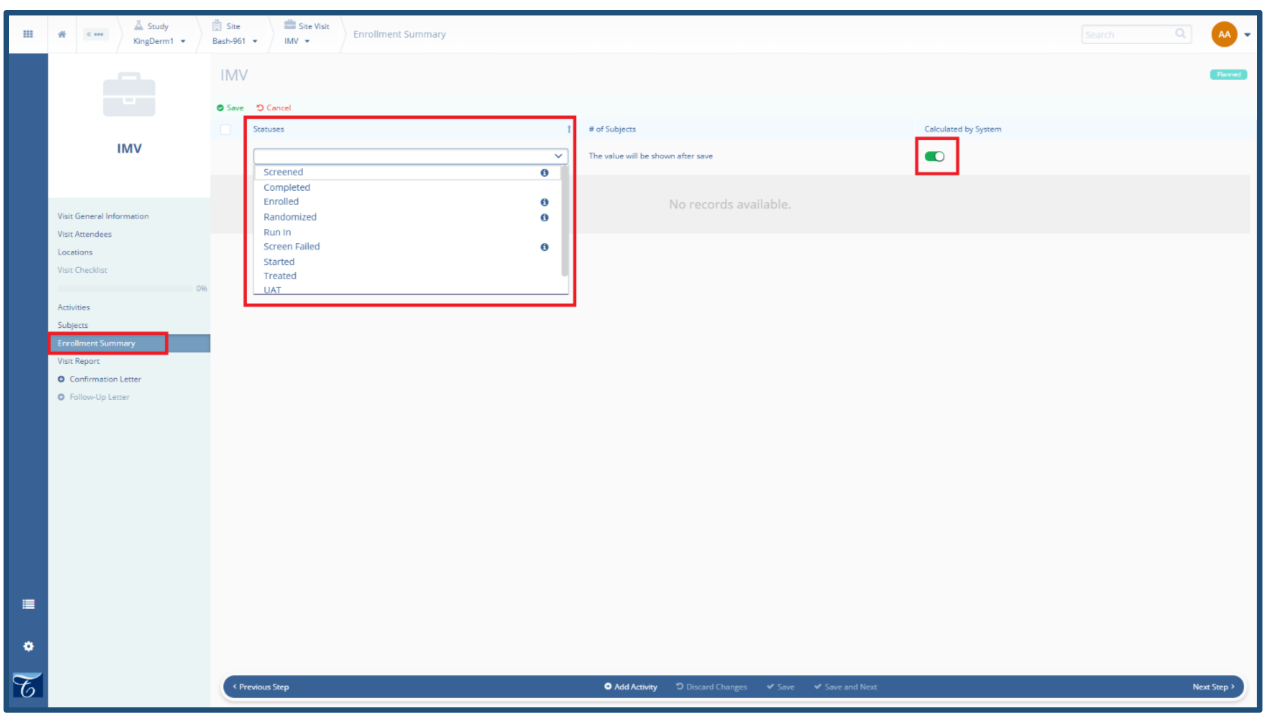


6.7 Site Visit Enrollment Summary

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



4. Select the subject Statuses from the dropdown.
5. Indicate if the system should calculate the enrollment statistic or should it be manually entered by the visit report author.



6. Click on the **Save** button in the top-left of the screen.

   Note: By turning off **Calculated by System**, the system will allow the user to manually enter the site's enrollment statistics for the site at the time of the site visit.

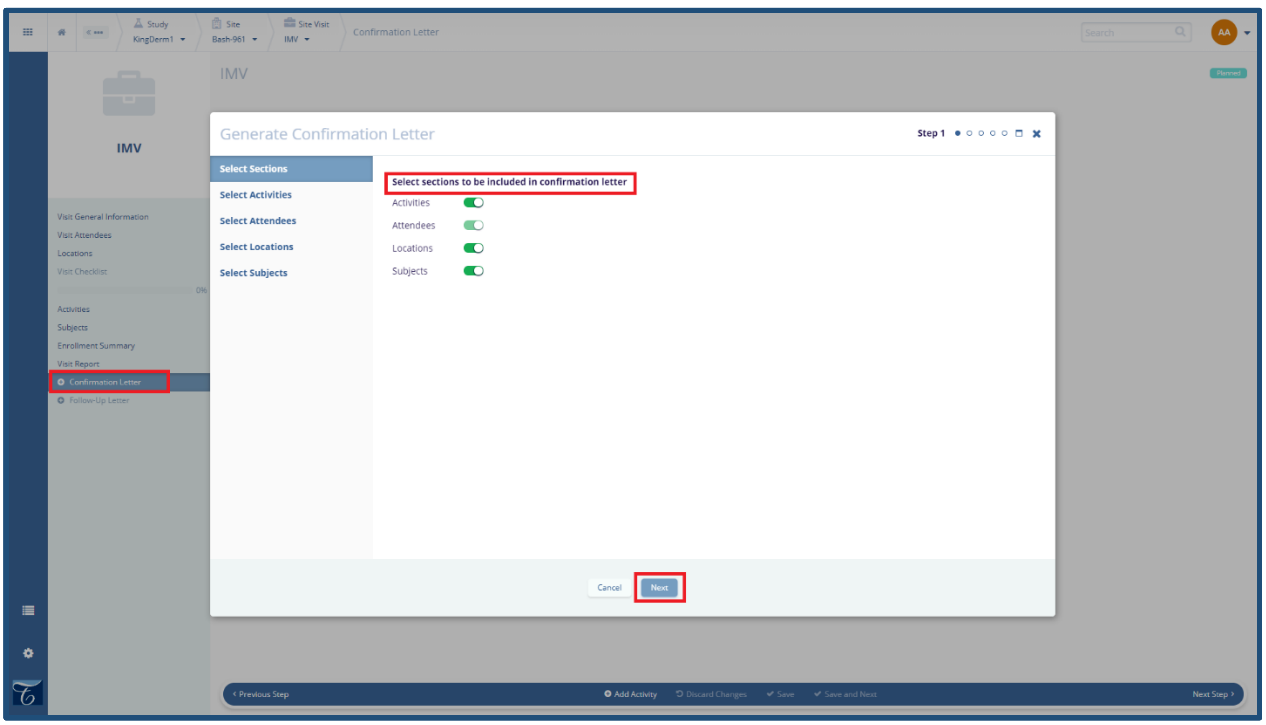
6.8 Site Visit Confirmation Letter Creation

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

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

3. Review the sections within the confirmation letter that are relevant
4. Click on the **Next** button in the bottom of the **Generate Confirmation Letter** window.

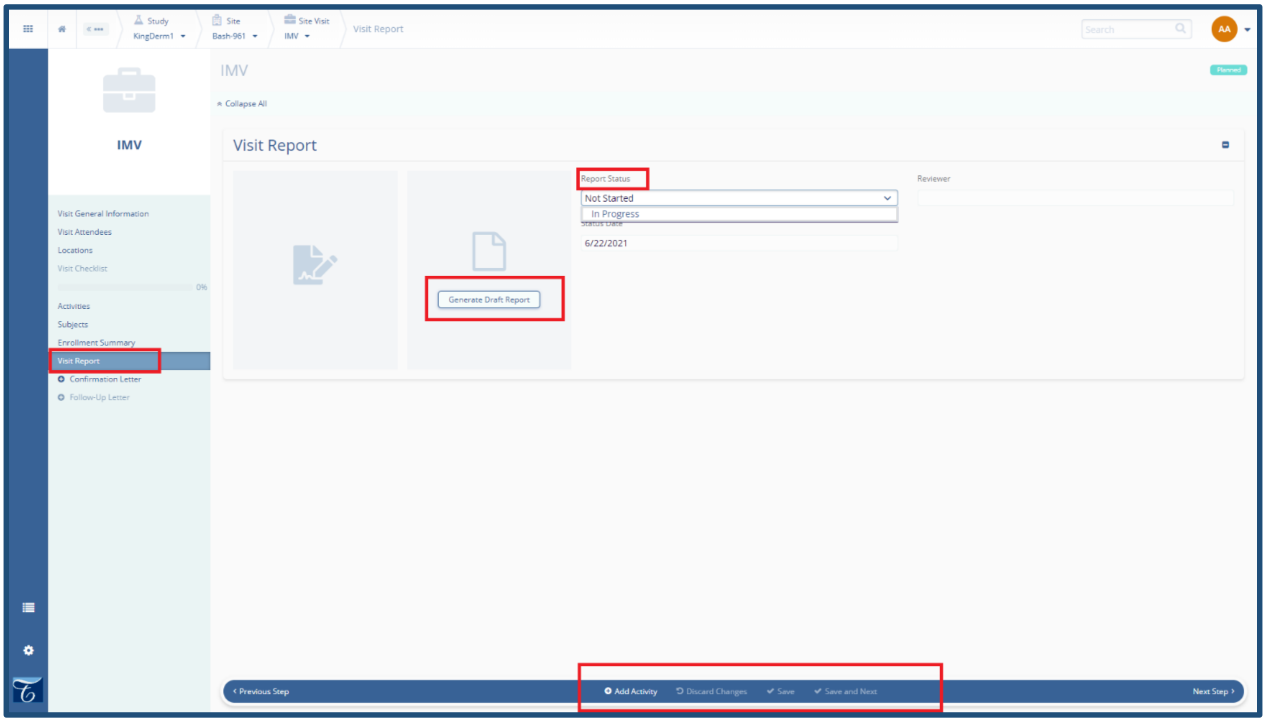
   Note: A user can turn off any section that is not relevant to a visit related confirmation letter. Regardless of user selection/incorporation a letter will only display content that there is a location within the template to display that data.



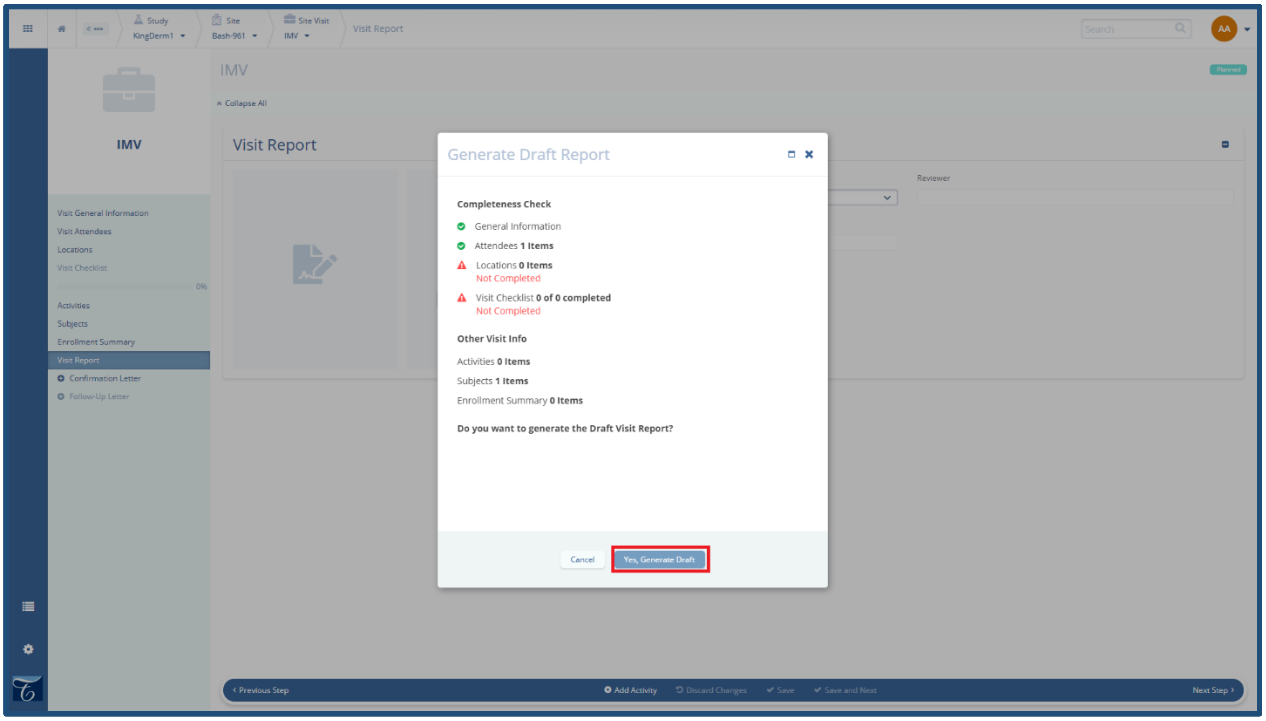
5. Click on the **Create** button in the bottom of the **Generate Confirmation Letter** window, once all the selections are made for the letter.
6. This generates the site visit confirmation letter as per our selections.

6.9 Site Visit Draft Report Generation

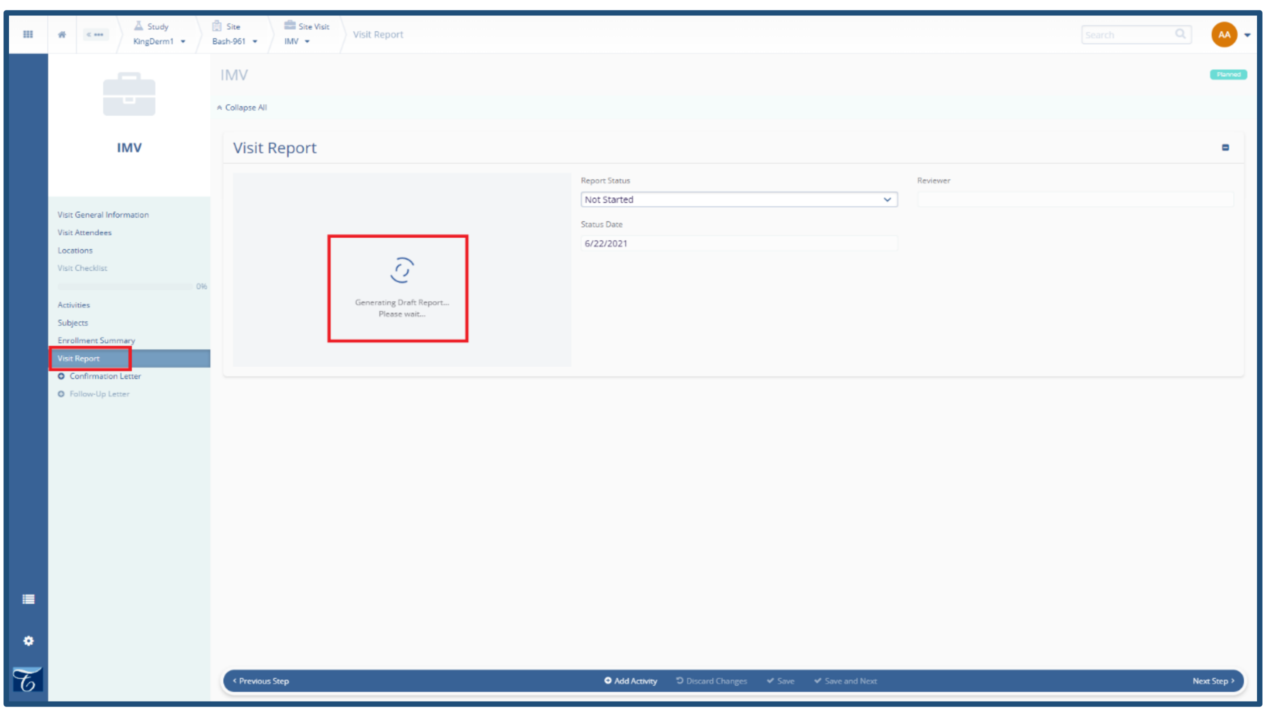
1. Navigate to the Site Visit area for the related site.
   a. More detailed instructions on this step can be found here.
2. Click on the **Visit Report** link in the Navigation menu at the left side of the screen.
   a. This opens the "Visit Report" window.
3. You can update the **Report Status** to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



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



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



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

6.10 Site Visit Final Report Generation

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

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

6.11 Site Visit Follow-up Letter Creation

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

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

3. Review the sections within the confirmation letter that are relevant.
4. **Generate Follow-up Letter** window displays the selected sections and the selected content from the final report
5. Click on the **Next** button on the screen.

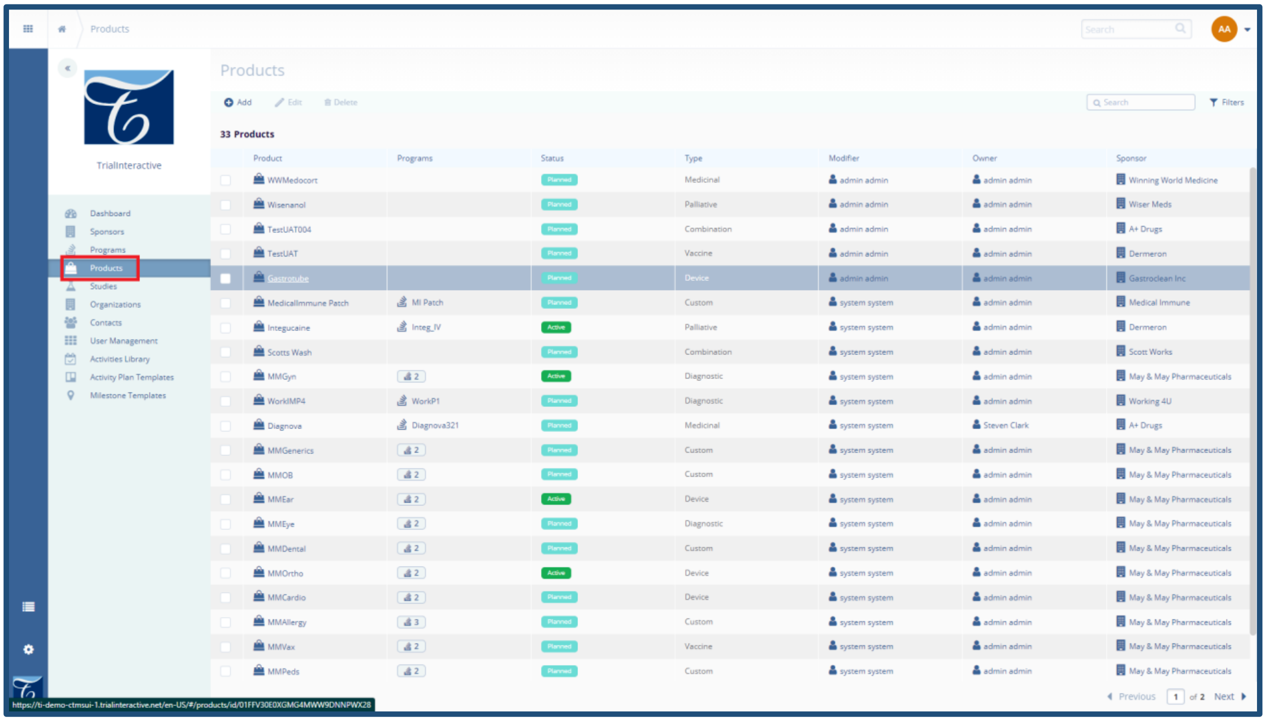
Note: A user can turn off any section that is not relevant to a visit related follow-up letter. Regardless of user selection/incorporation a letter will only display content that there is a location within the template to display that data.

6. Click on the Create button of the window.
7. Follow-up letter is generated, and origami is opened displaying the letter

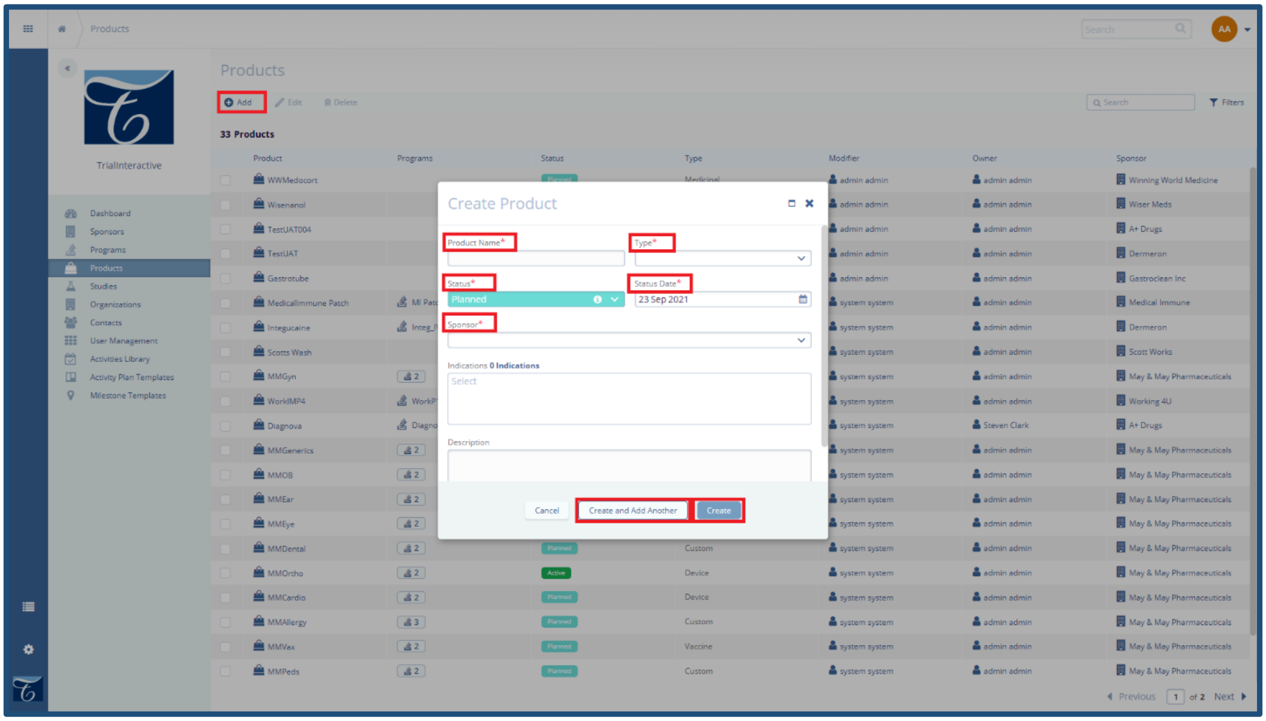
7 Product

7.1 Creating a Product

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

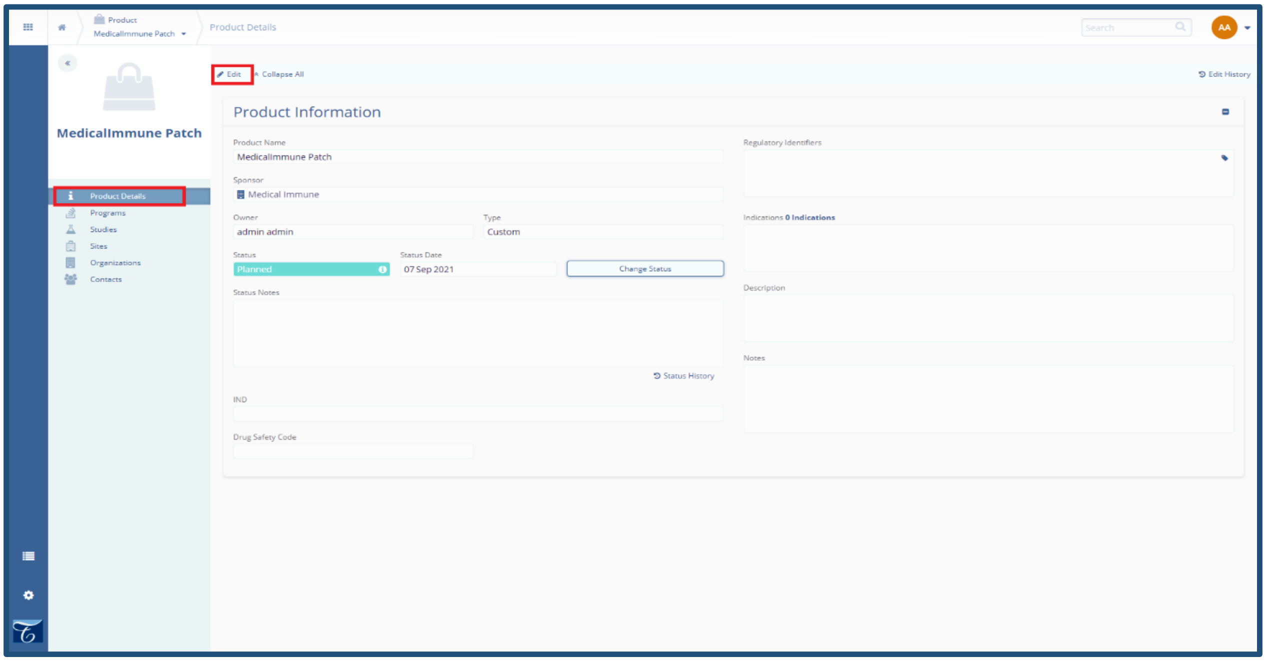


2. Click on the **Add** button in the top-left of the screen.
    a. This opens the “Create Product” Window.
3. Here we need to enter the mandatory metadata to create a product i.e., **Product Name, Type, Status, Status Date, Sponsor** as indicated by an asterisk (*) symbol next to the field title. Enter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

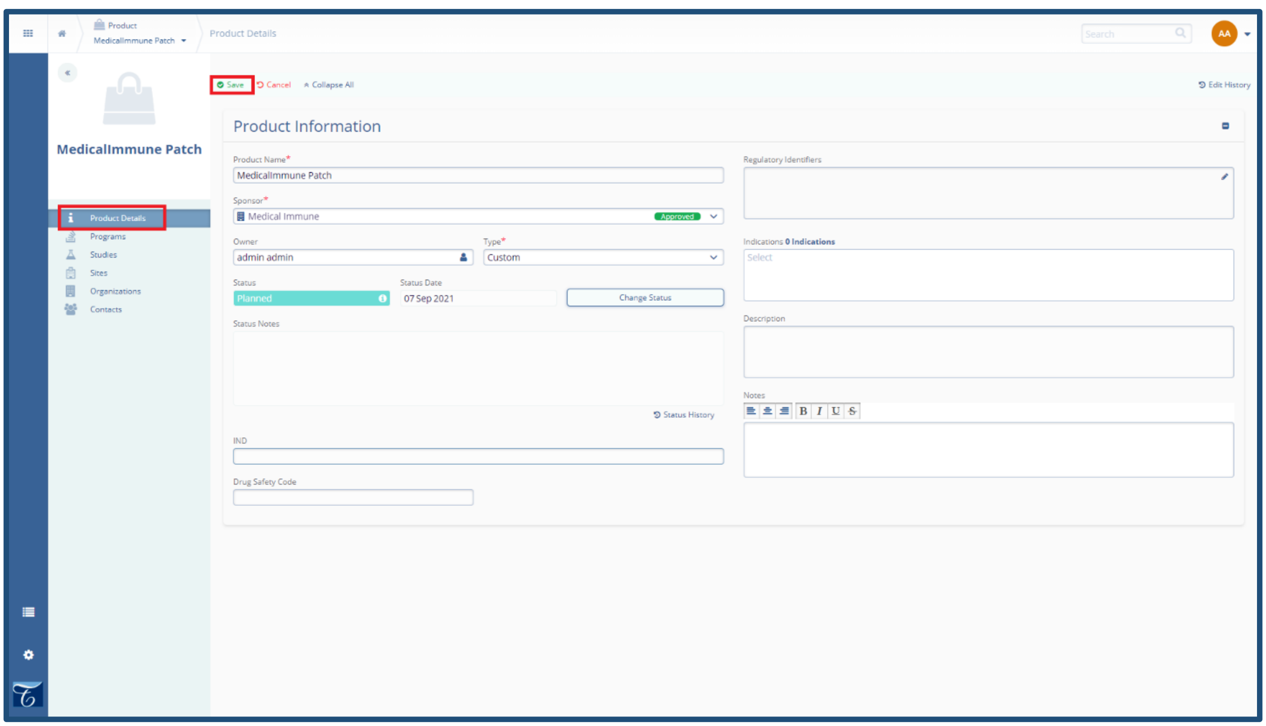


7.2 Reviewing and Editing a Product

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

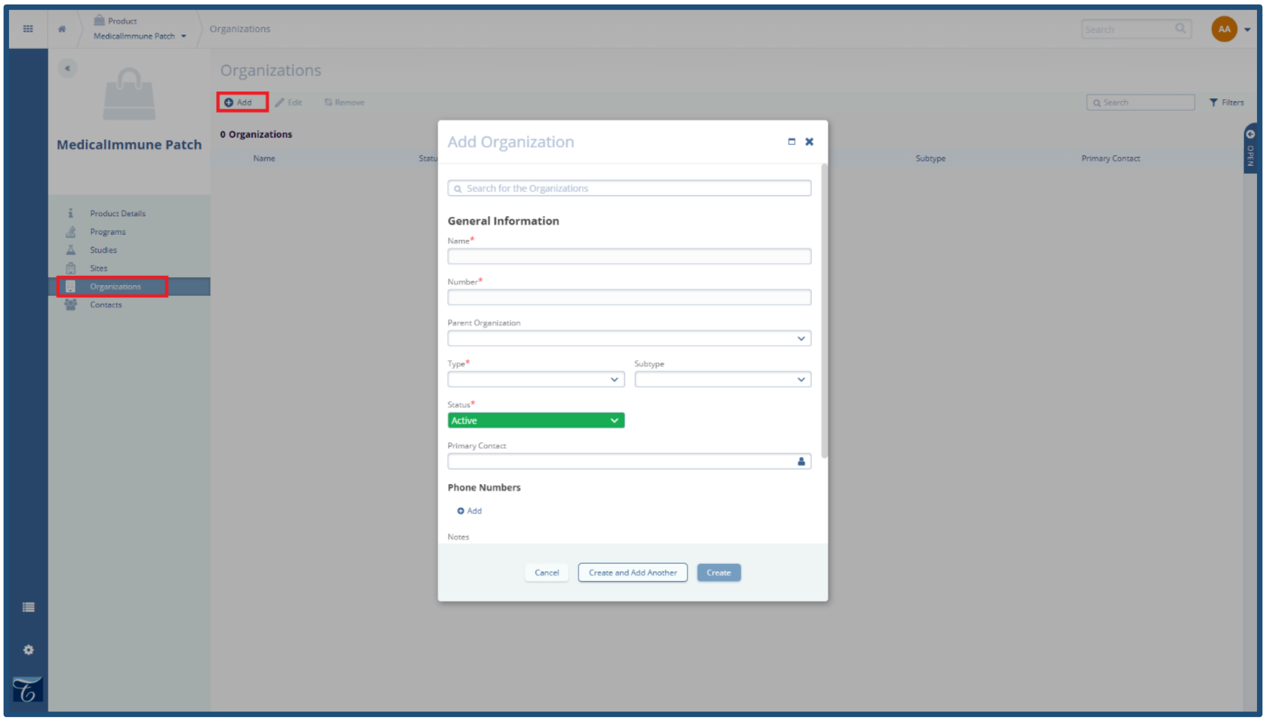


4. Make the necessary changes in the product details window.
5. Click on the **Save** button in the top-left of the screen.



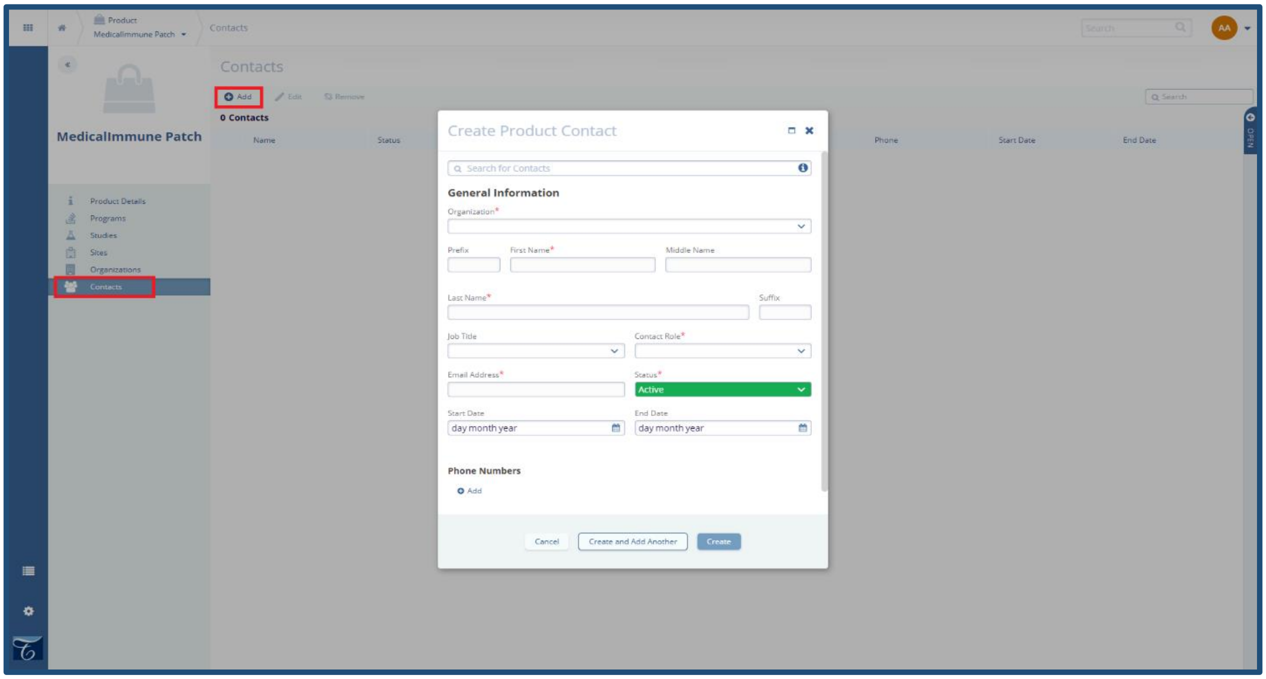
7.3 Associating an Organization to a Product

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



7.4 Associating a Contact to a Product

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



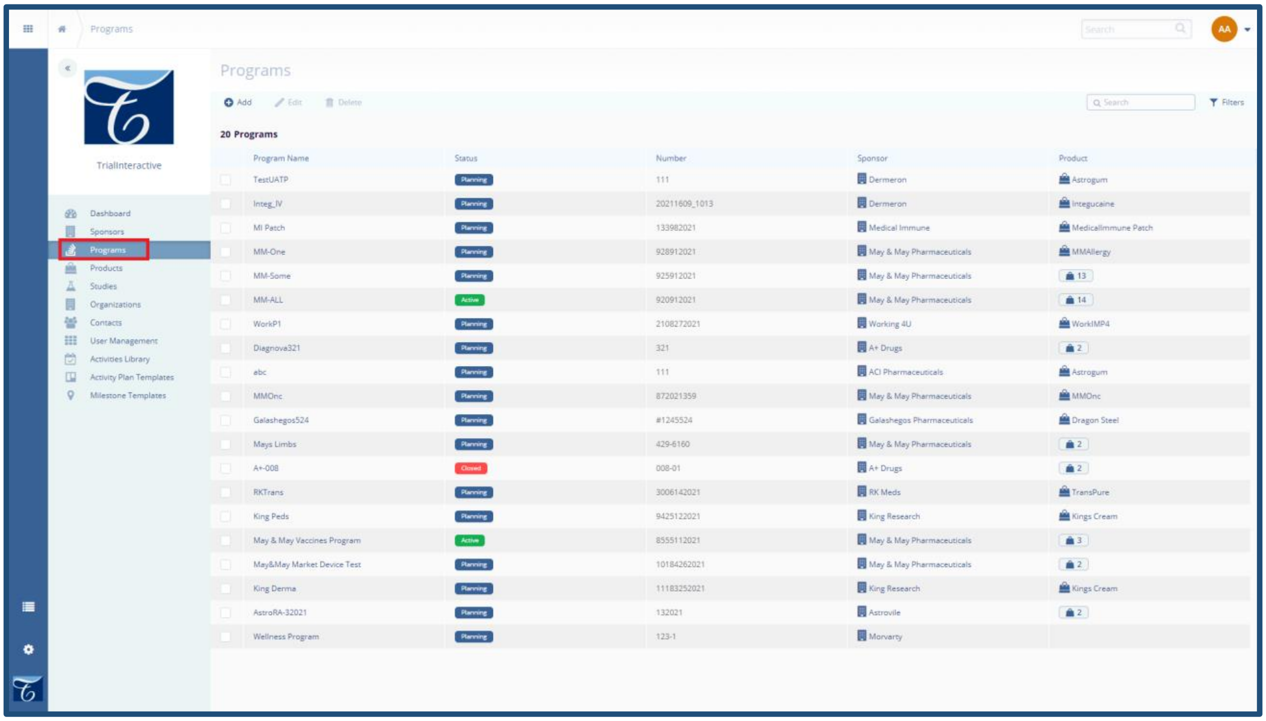
8 Program

8.1 Pre-Requisites

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

8.2 Create a Program

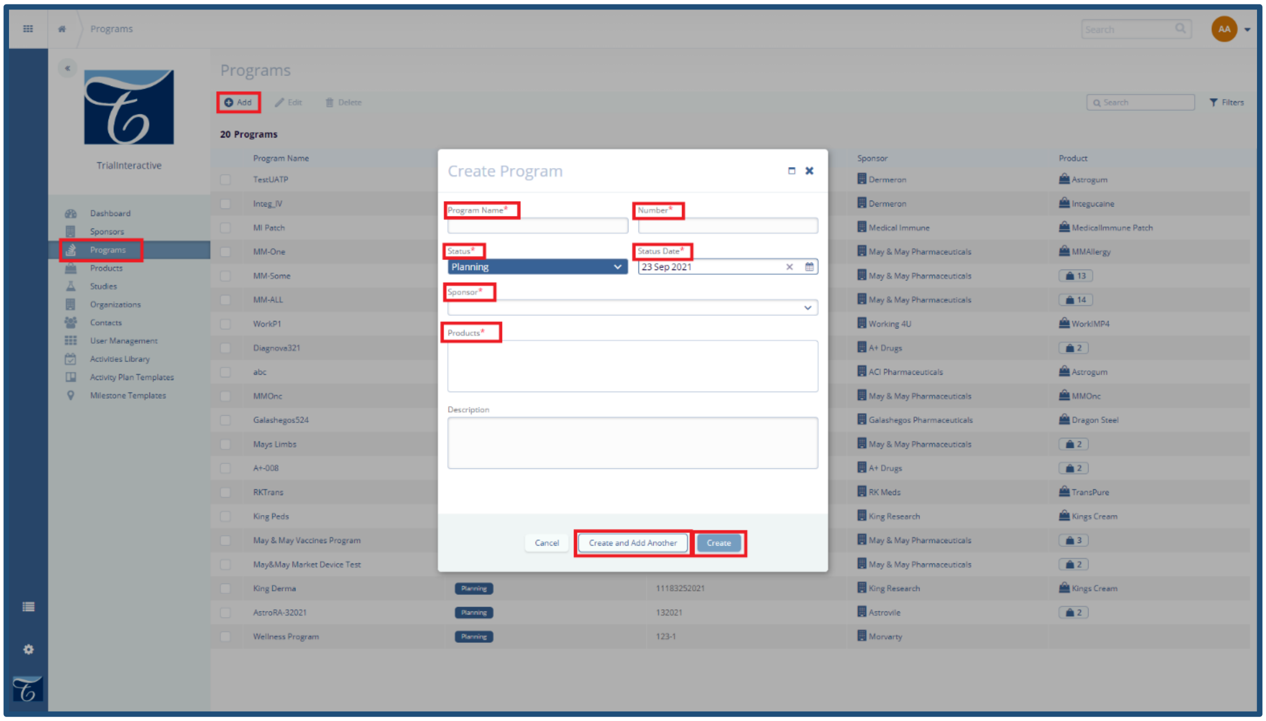
1. Click on the **Programs** link in the Navigation Menu at the left side of the screen.
   a. This opens the "Programs" window, and the programs list is displayed.



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

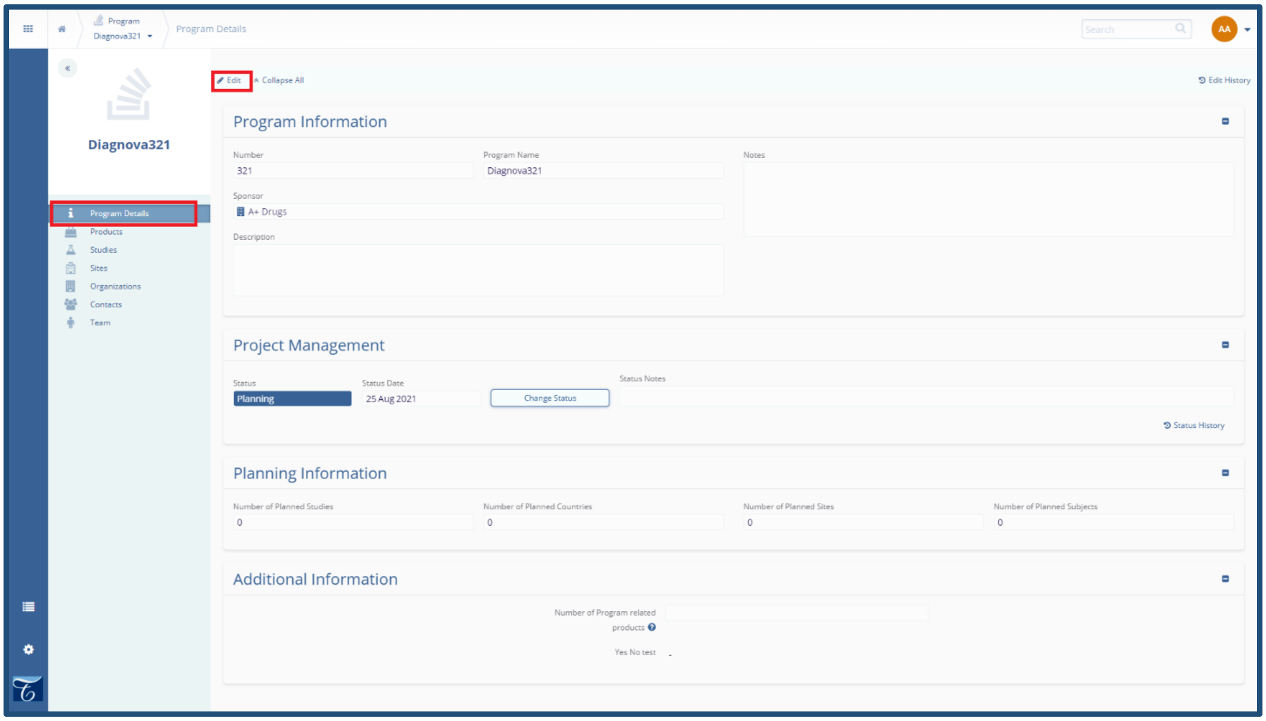
Note: Program records can be created in multiple locations within the system:

1. Programs
2. Sponsors → Programs
3. Product → Programs

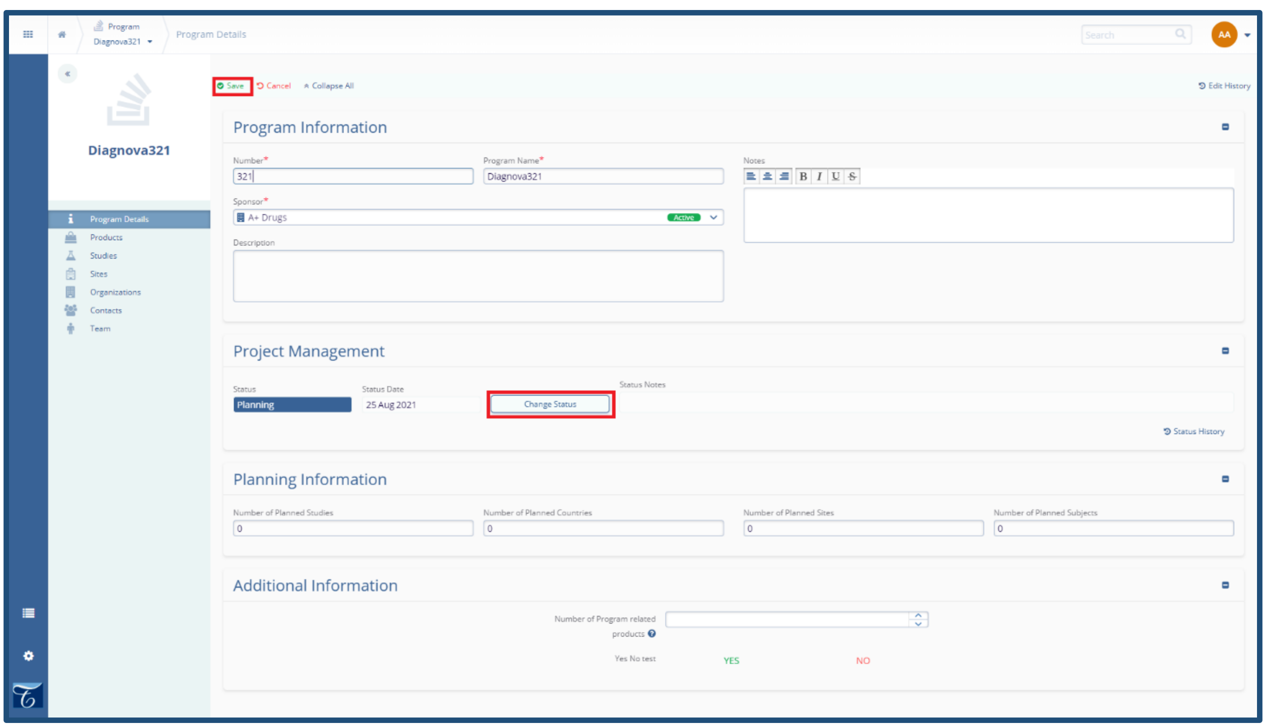


8.3 Reviewing and Editing a Program

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

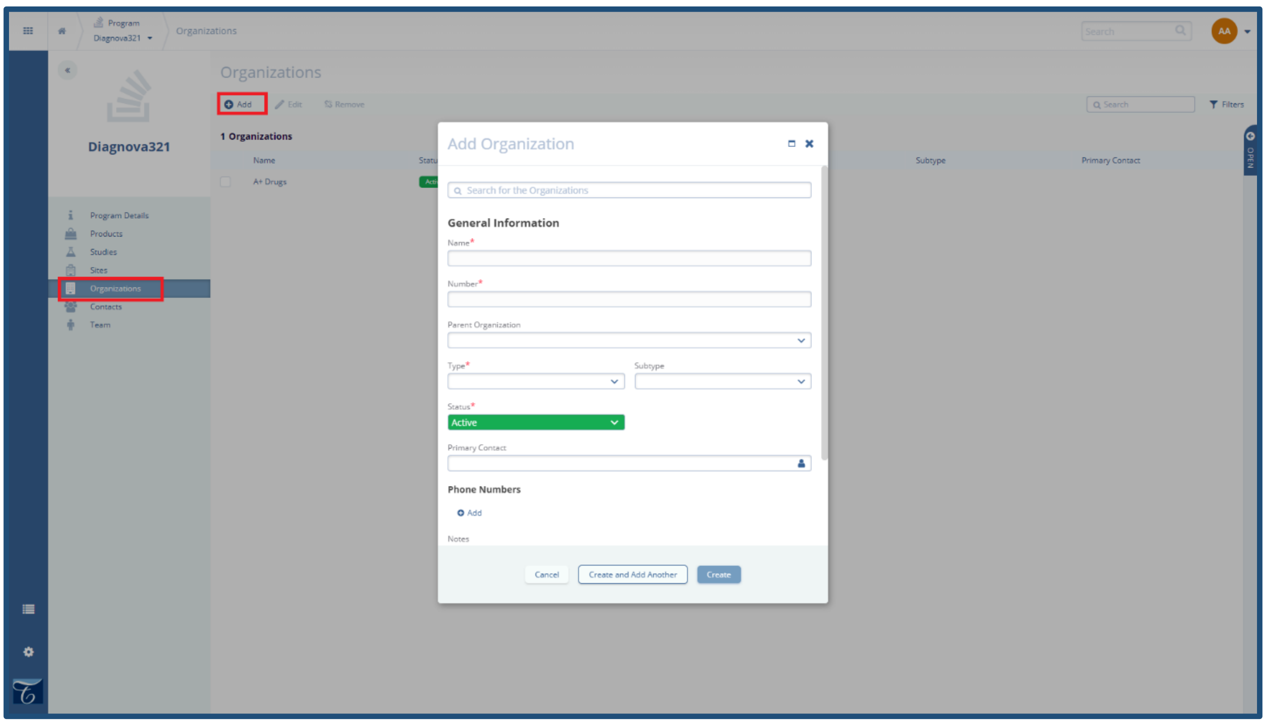


4. Make any necessary changes in the sections you want.
5. Click on the **Save** button on the top-left of the screen, for the changes to apply.



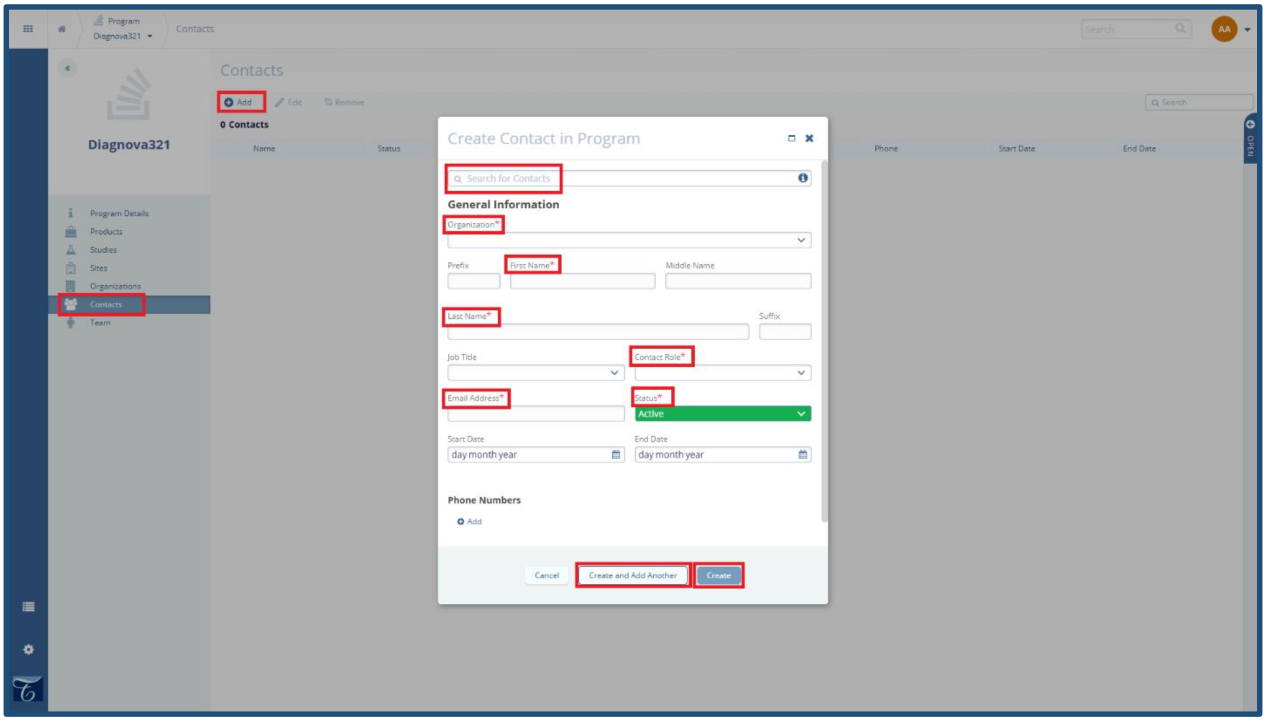
8.4 Associating an Organization to a Program

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



8.5 Associating a Contact to a Program

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



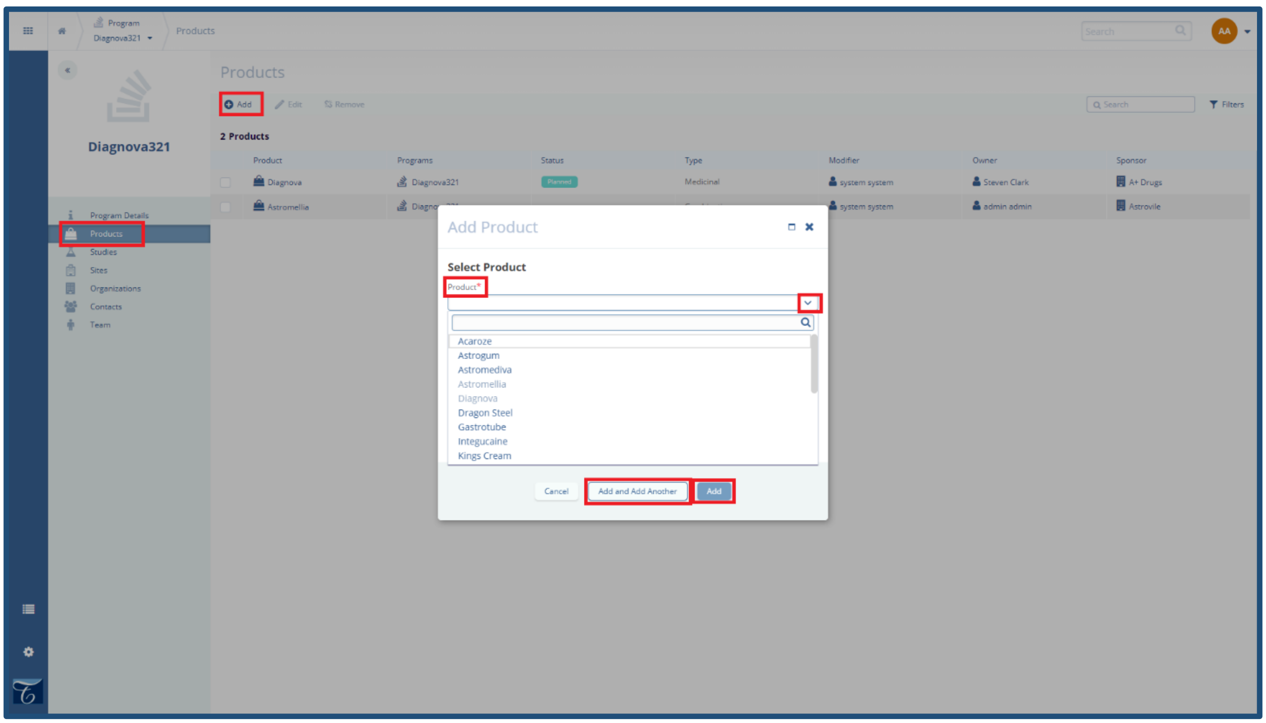
5. Here we need to enter the mandatory metadata to create a Contact i.e., **Organization, First Name, Last Name, Contact Role, Email Address, Status, Include Address** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
6. If any of the required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

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

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

8.6 Associating a Product to a Program

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

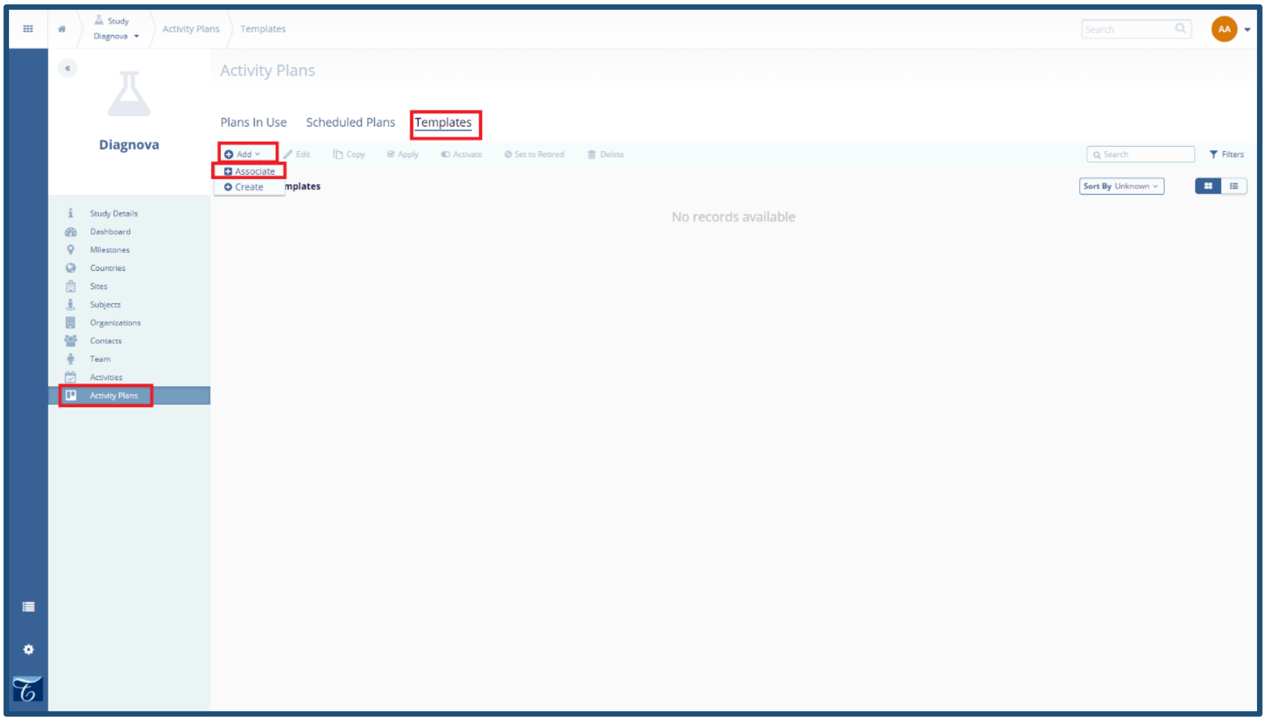


9 Activities

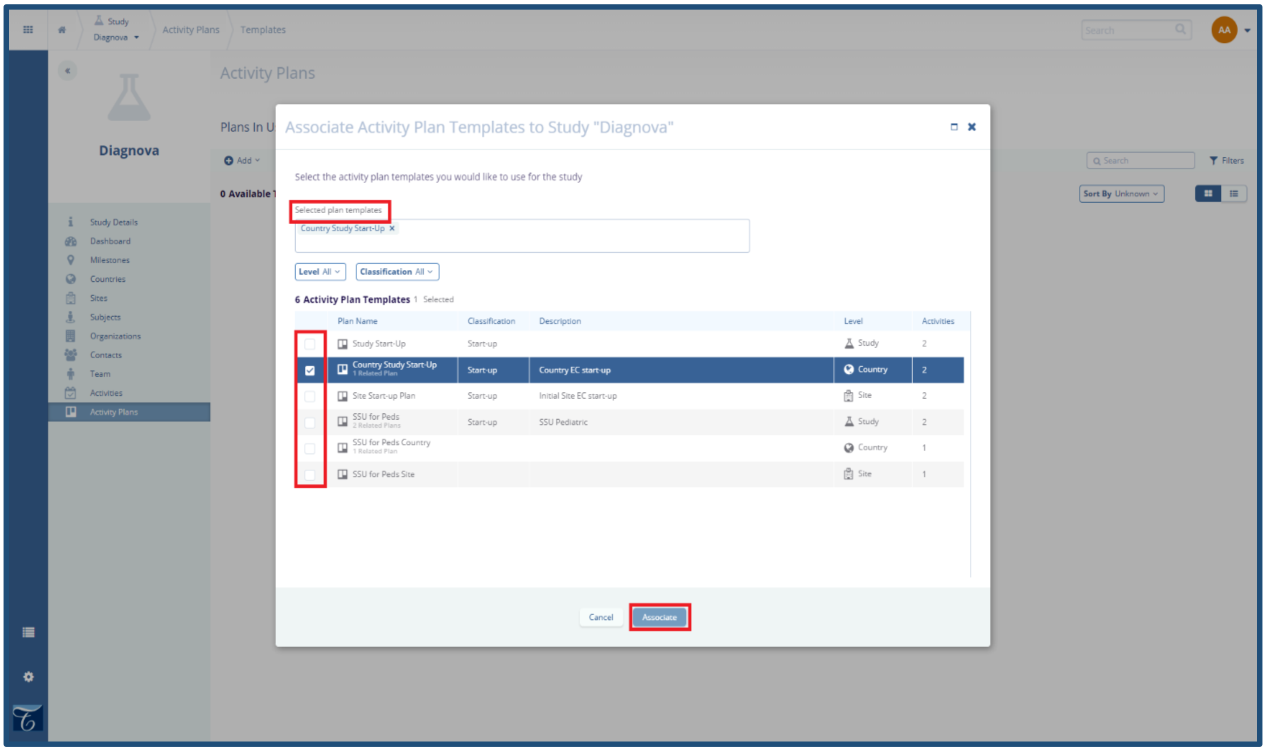
9.1 Associating Domain library Activity Records to a Study

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

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



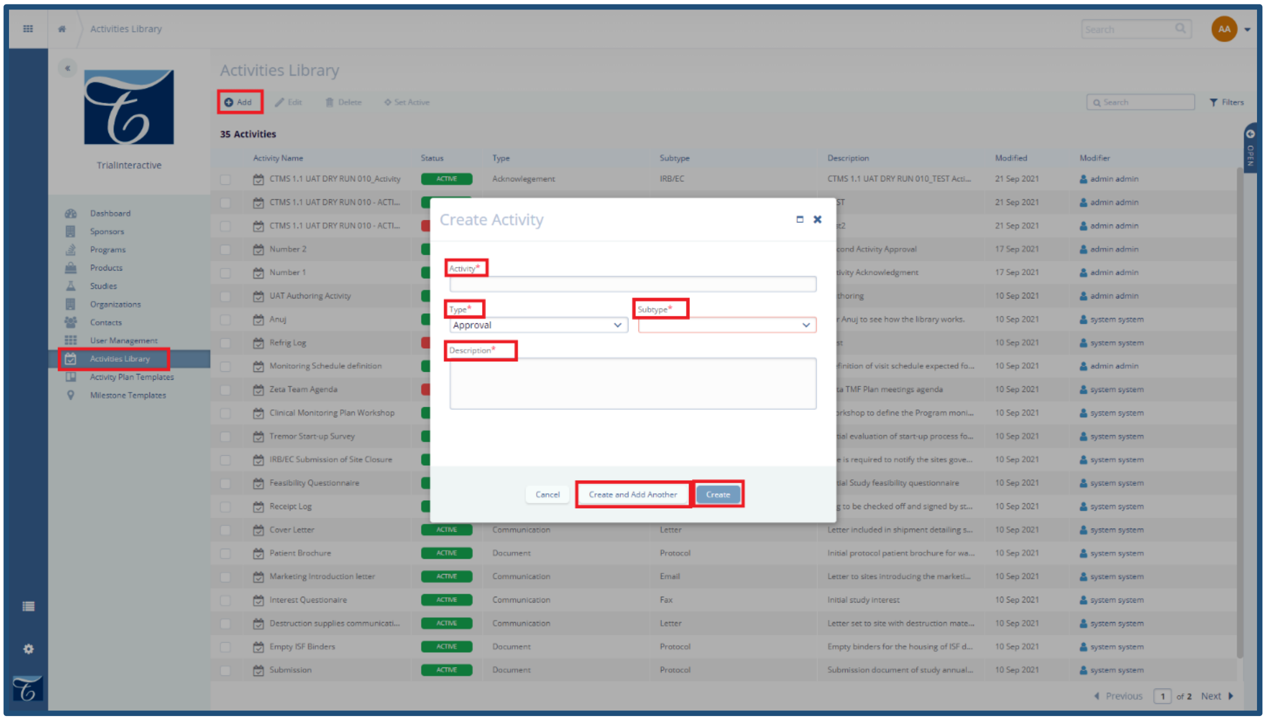
6. This opens the **Associate Activity Plan Templates to study** “Study name is displayed”.



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

9.2 Creating Domain library Activity Records

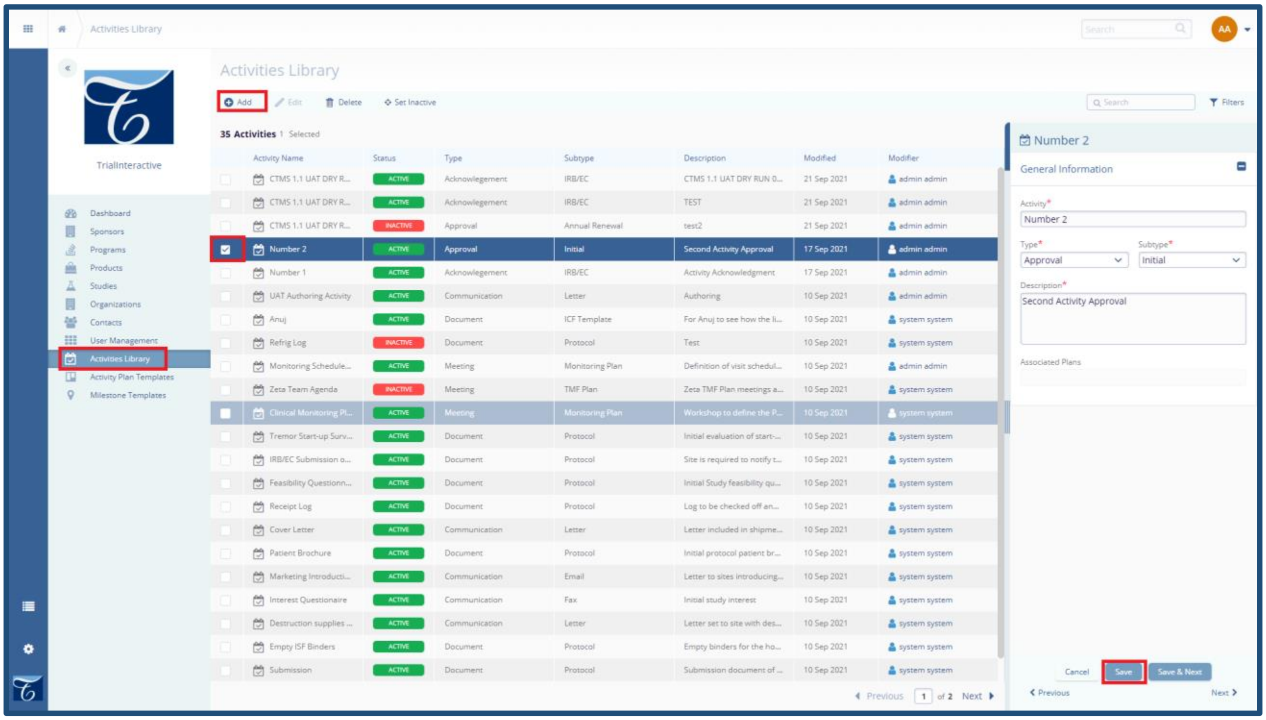
1. Click on the **Activities Library** link in the Navigation menu at the left side of the screen.
   a. This opens the “Activities Library” window.
2. Click on the **Add** button in the top-left of the screen.
   a. This opens the **Create Activity** window.
3. Here we need to enter the mandatory metadata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



9.3 Editing Domain Library Activity Records

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

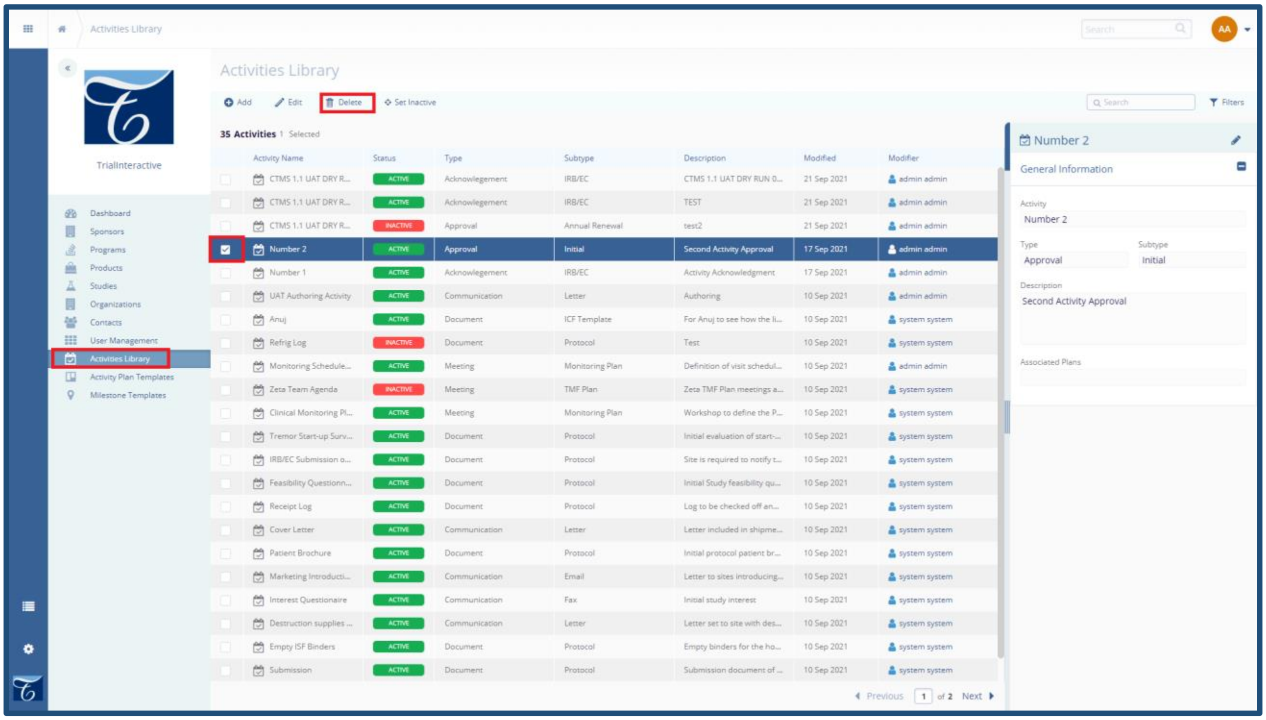
Note: Updates to an activity record will not be reflected within activity plans already actively applied or tracking. Updated activity records will be used for any new application or tracking of an activity plan containing the updated record.



9.4 Deleting Domain Activity Records

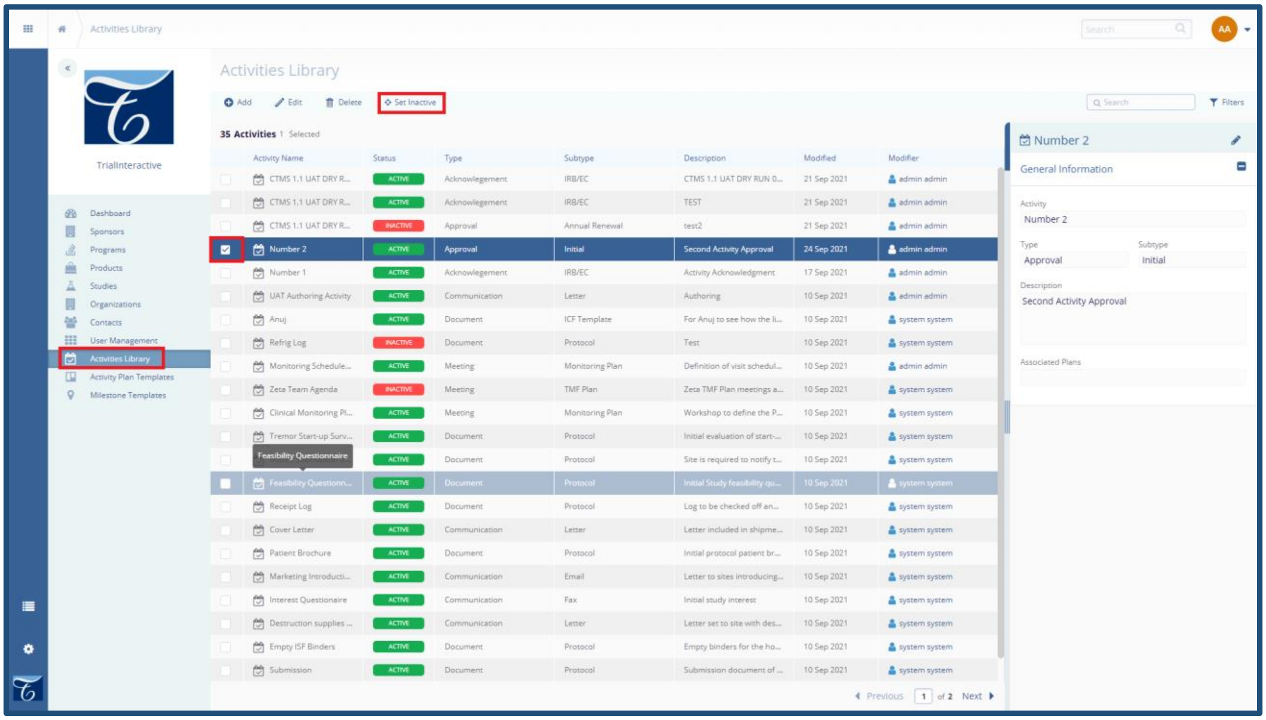
1. Click on the **Activities Library** link in the Navigation menu at the left side of the screen.
   a. This opens the "Activities Library" window.
2. Navigate to the activity name you want to delete and click the check box before the activity name or click directly on the activity name.
3. Click on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

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



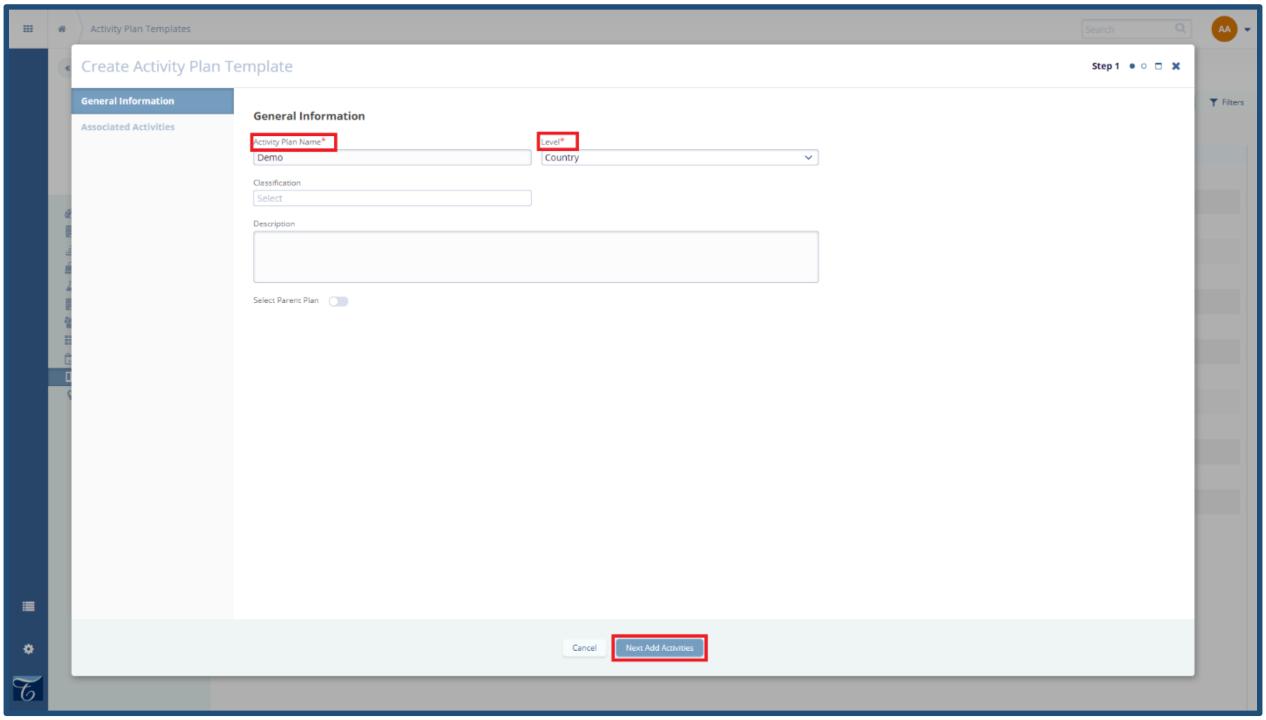
9.5 Inactivating Domain Activity Records

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



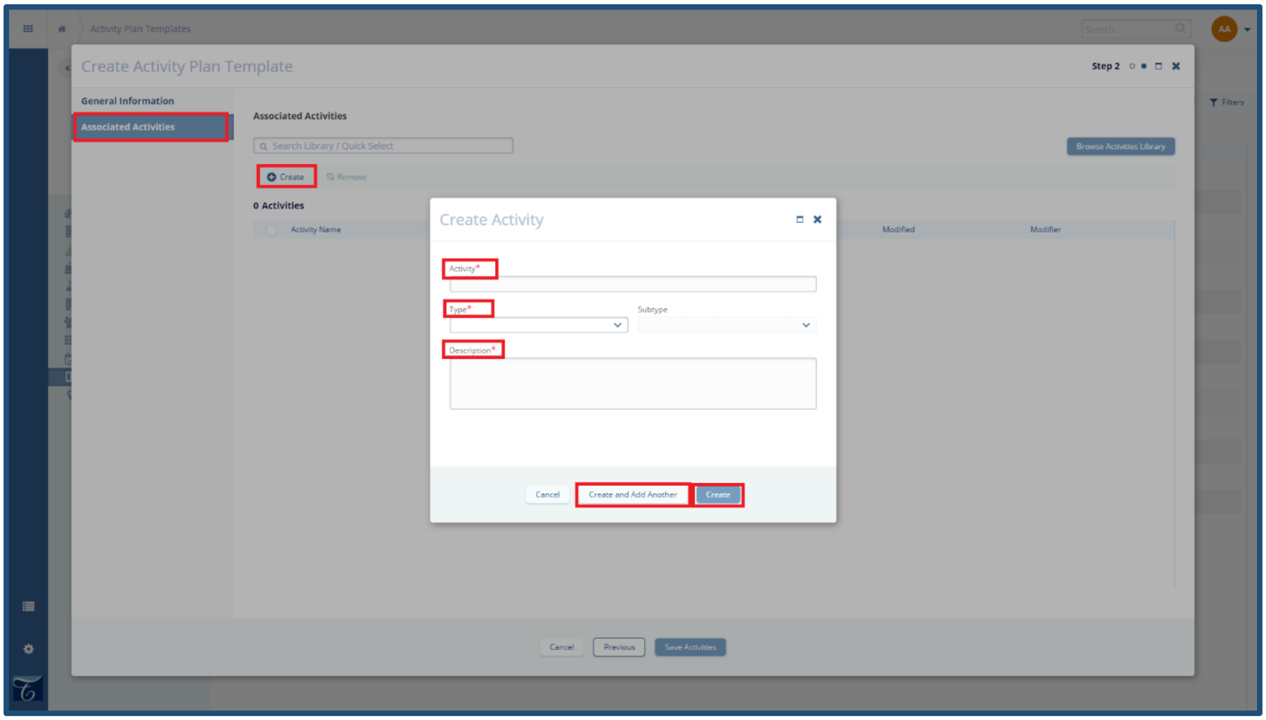
9.6 Creating Domain Library Activity Plans

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



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

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

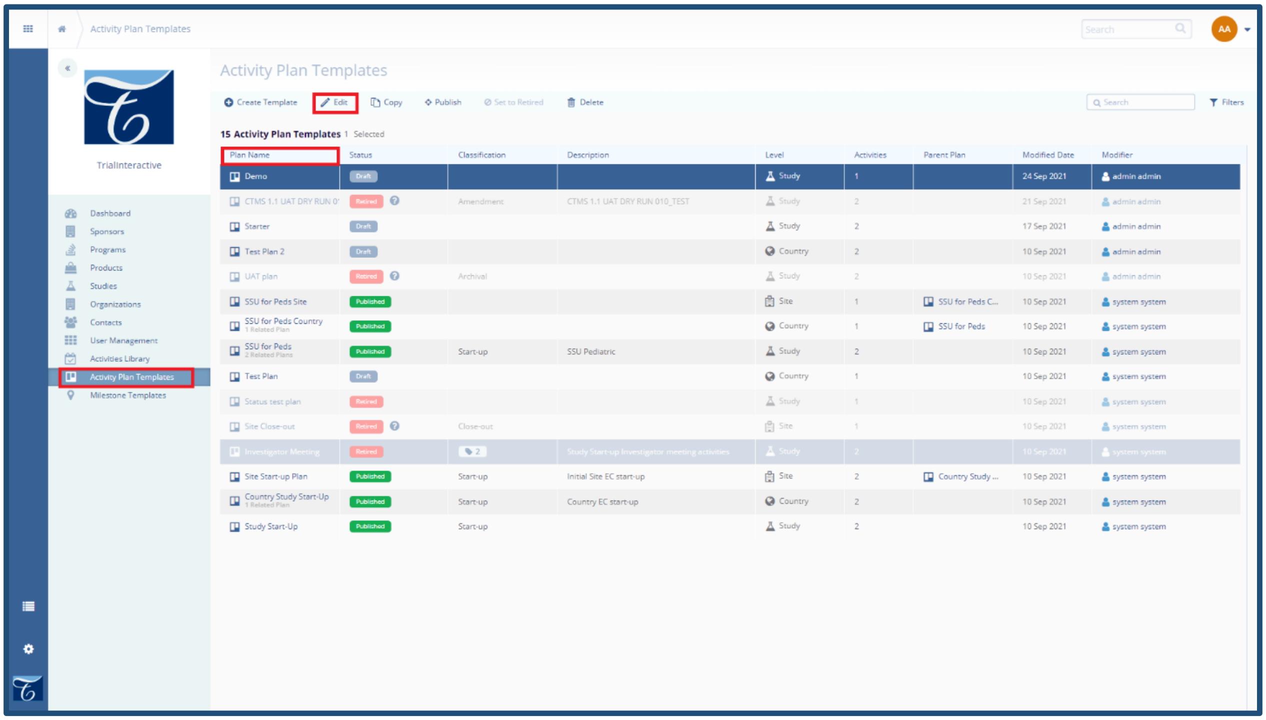


11. Click on the **Save Activities** button in the create activity plan template window.
    a. The create activity plan template closes and a template is created.

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

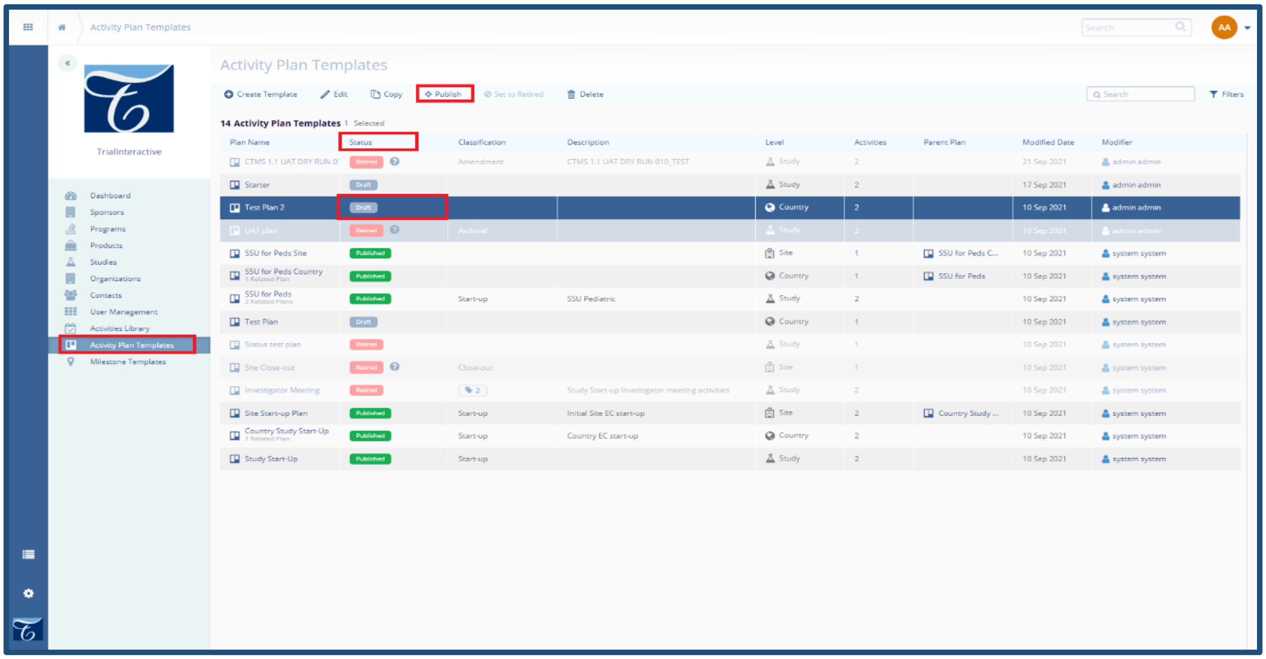
9.7 Editing Draft Activity plans

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



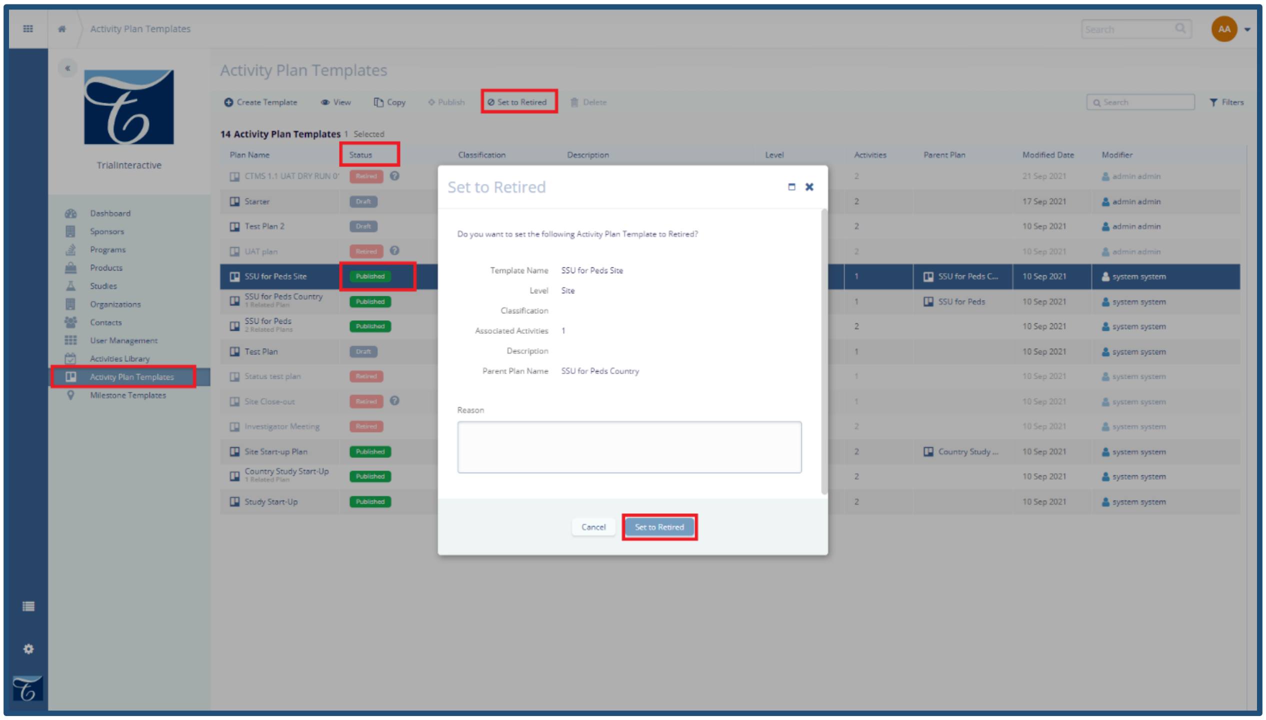
9.8 Publishing Activity Plans

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



9.9 Retiring Activity Plans

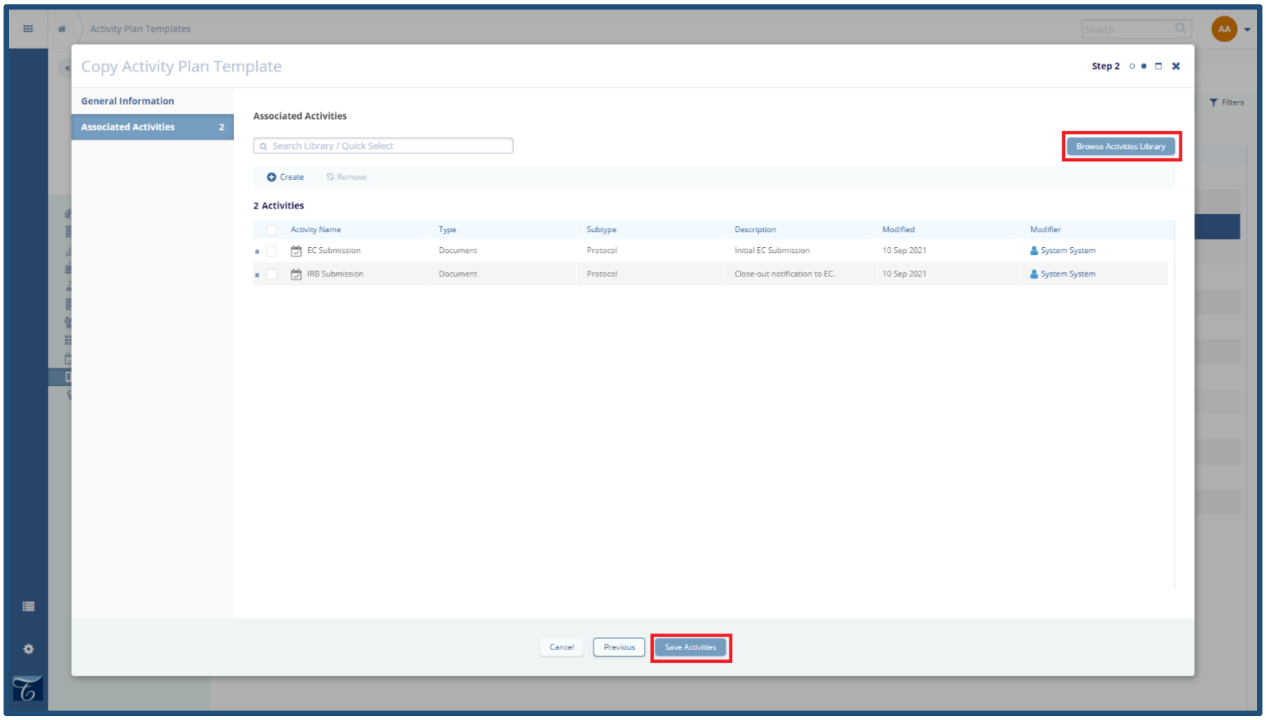
1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
   a. This opens the **Activity Plan Templates** window.
2. Navigate to the plan name which is in **Published** status you want to retire and click on it.
3. Click on the **Set to Retired**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



9.10 Copying Activity Plans

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

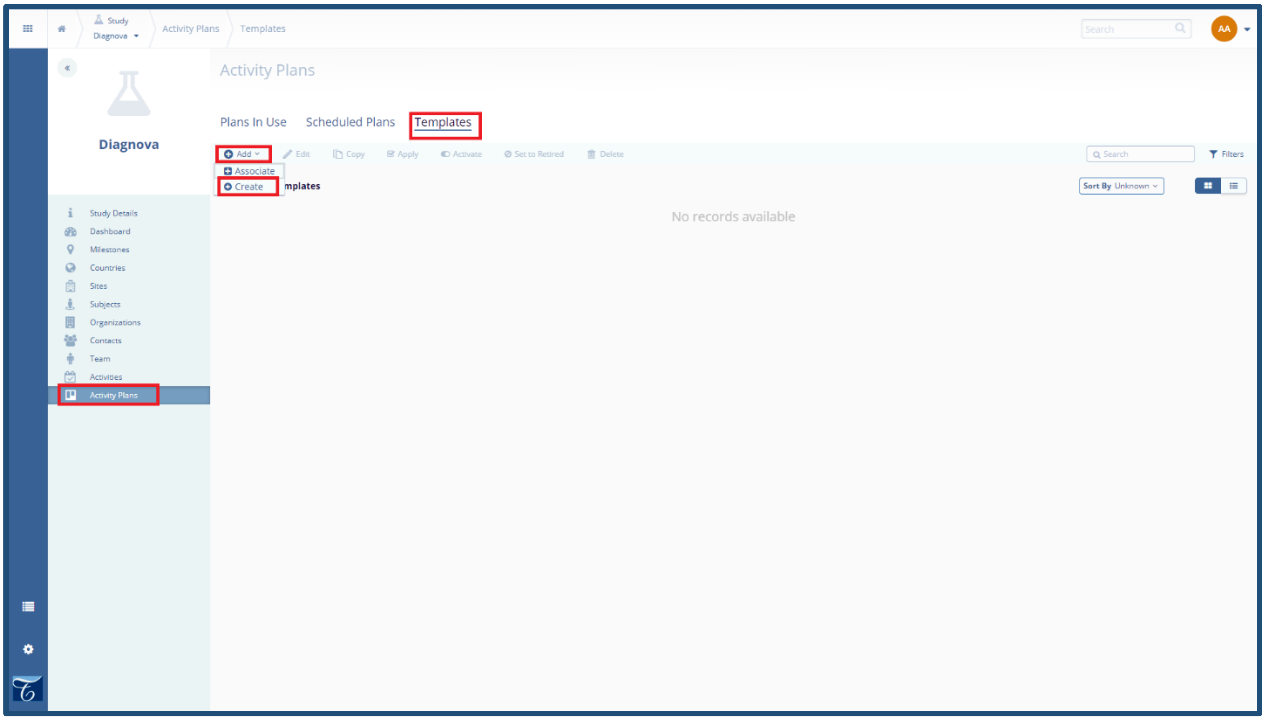
Note: Draft and Retired activities are not available for selection for any entity.



9.11 Associating Activity Plan Templates to a Study

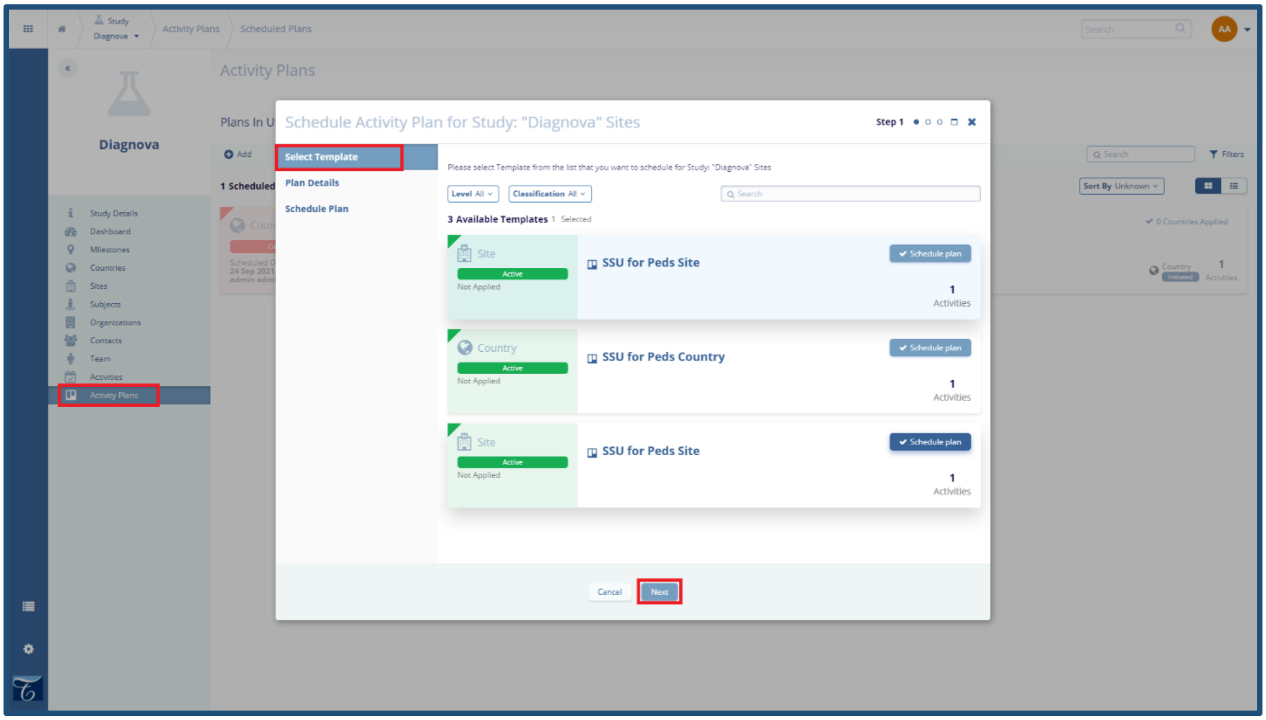
1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
   a. This open the "Studies" window and the studies list is displayed.
2. Navigate to the study you want to associate to an activity plan template and click on it.
   a. This opens the dashboard for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

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

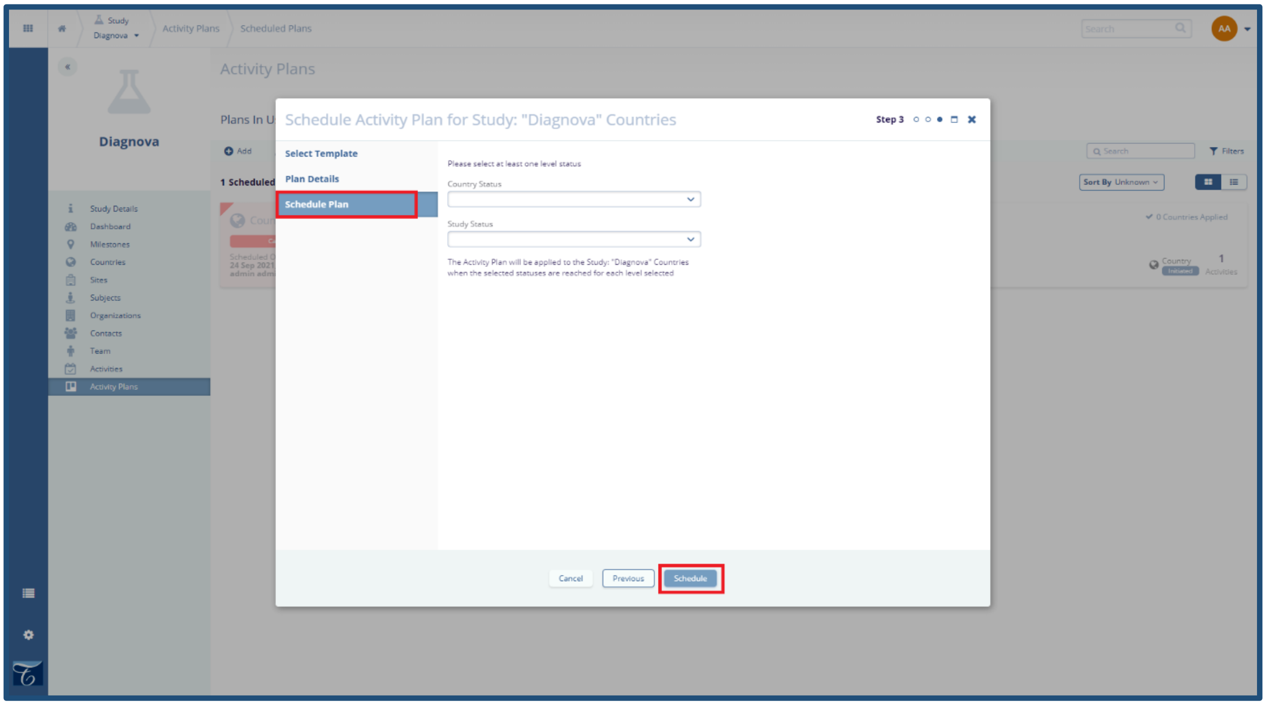


9.12 Scheduling Activity Plans

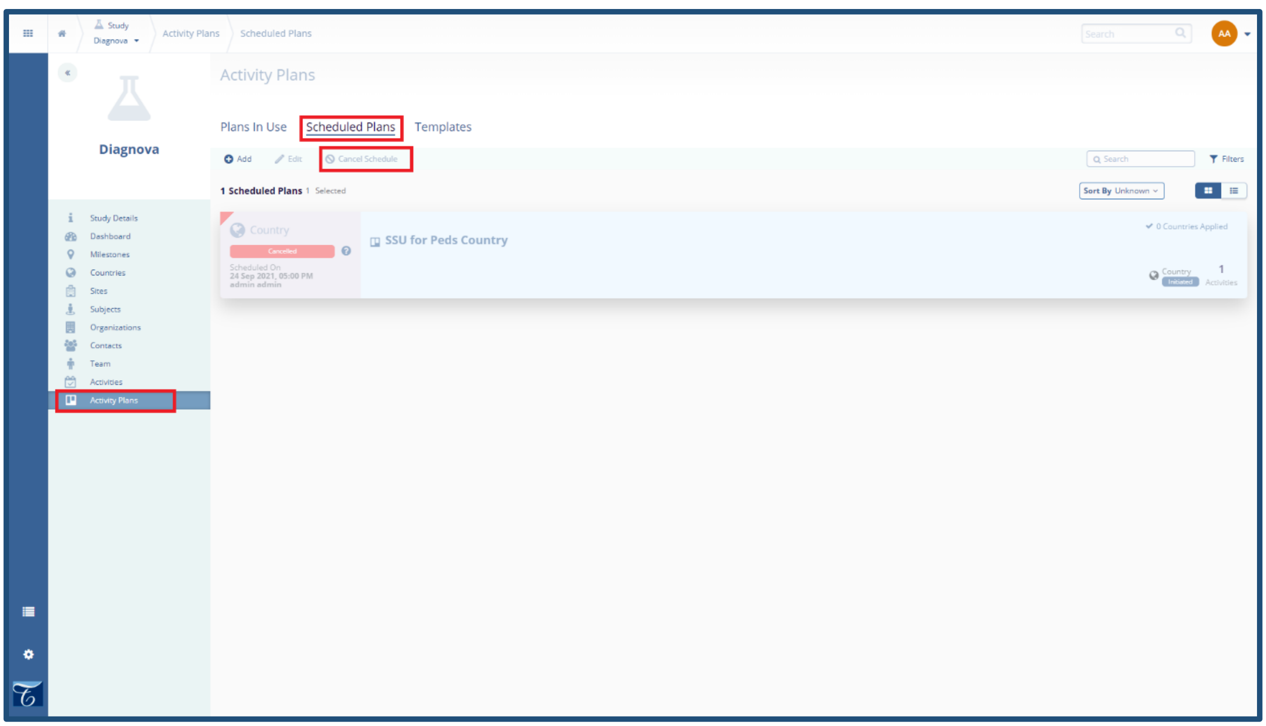
1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
   a. This open the studies window and studies list is displayed.
2. Click on the name of the study to which you want to associate an activity plan template.
   a. This opens the **dashboard** for the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



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

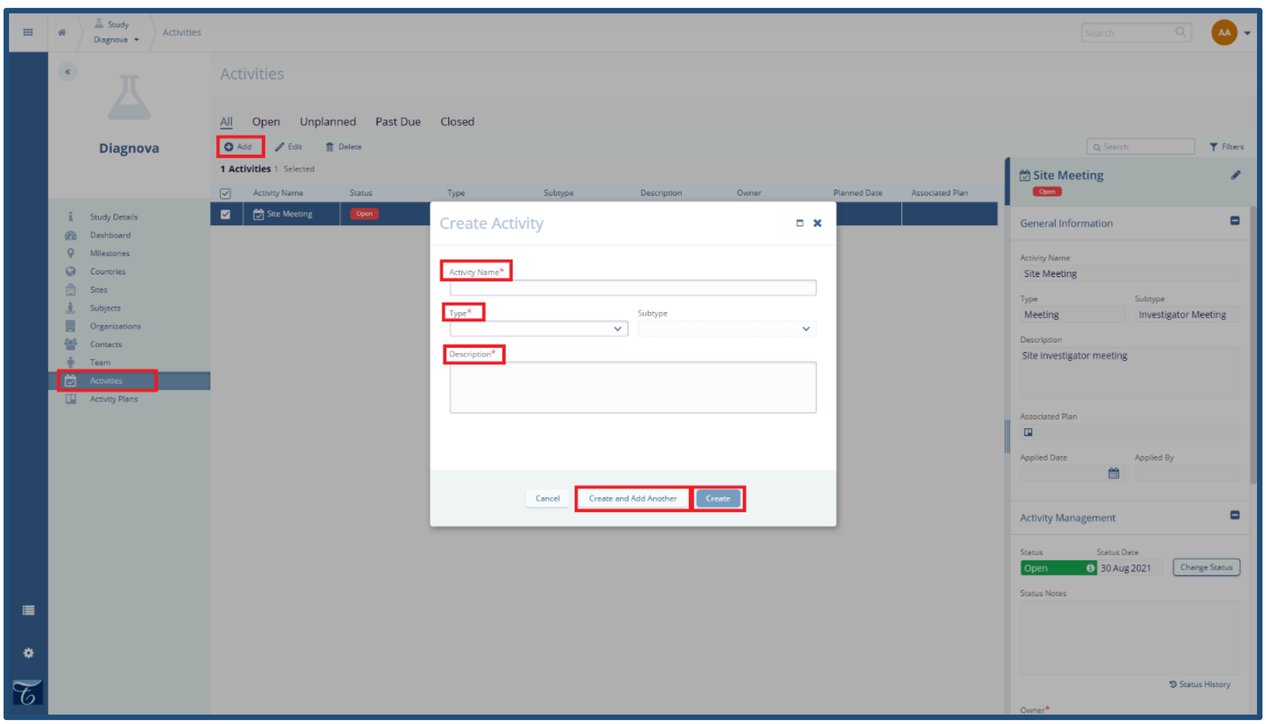


10. If you want to cancel the scheduled plans which was scheduled.
11. Navigate to scheduled plans window and click on the scheduled activity plan you want to cancel.
12. Click on the **Cancel Schedule** button in the top-left of the screen.

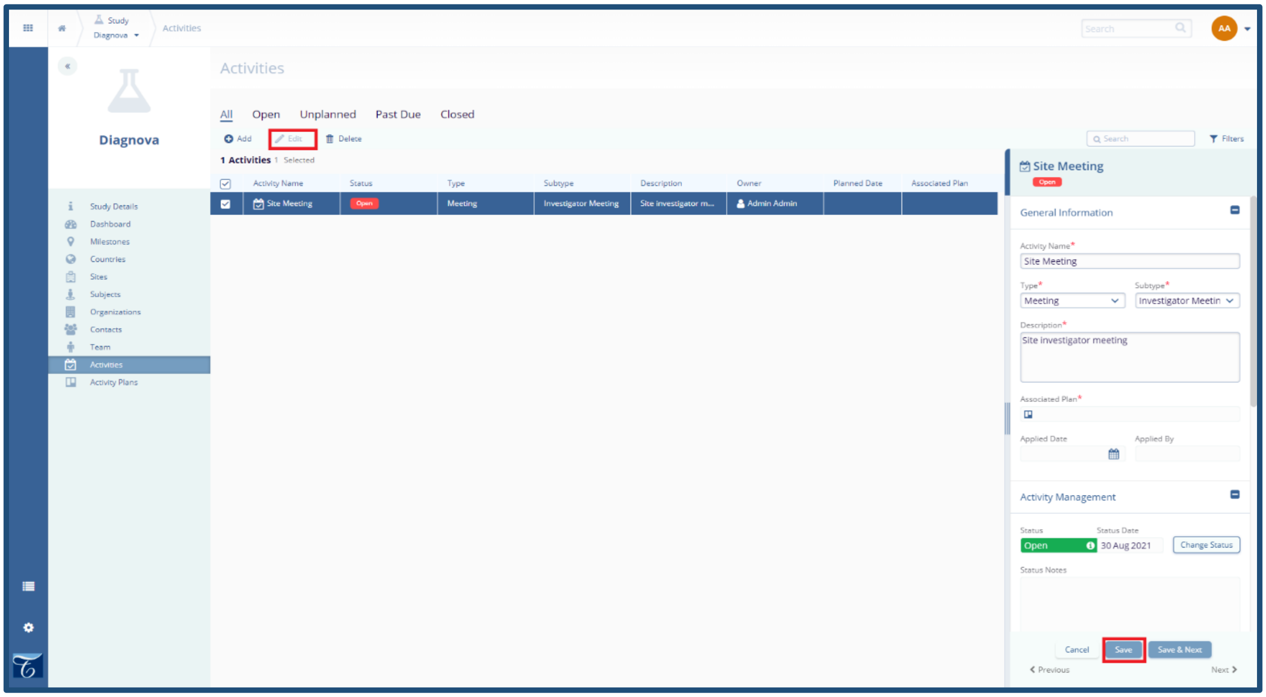


9.13 Tracking Activities Outside of Activity plans

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



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



9.14 Tracking Actions Taken Toward Activity Completion

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

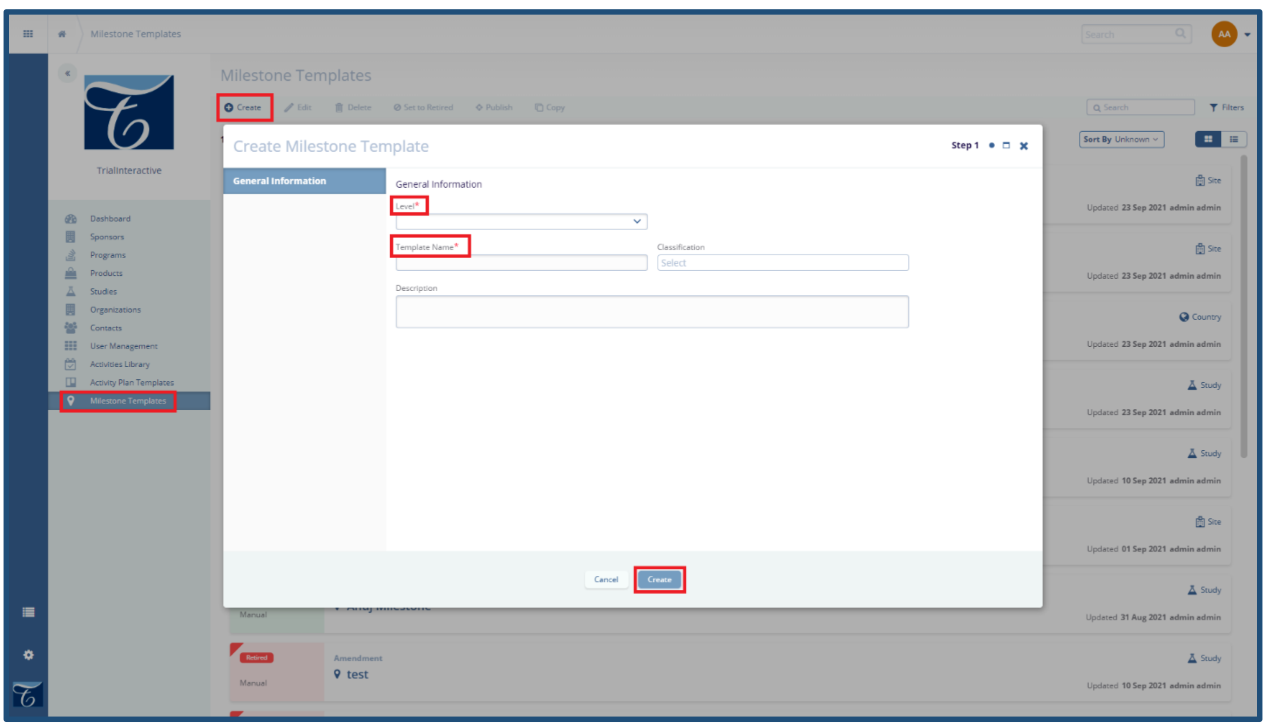
10 Milestones

10.1 Pre-Requisites

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

10.2 Creating Domain Library Milestone Template

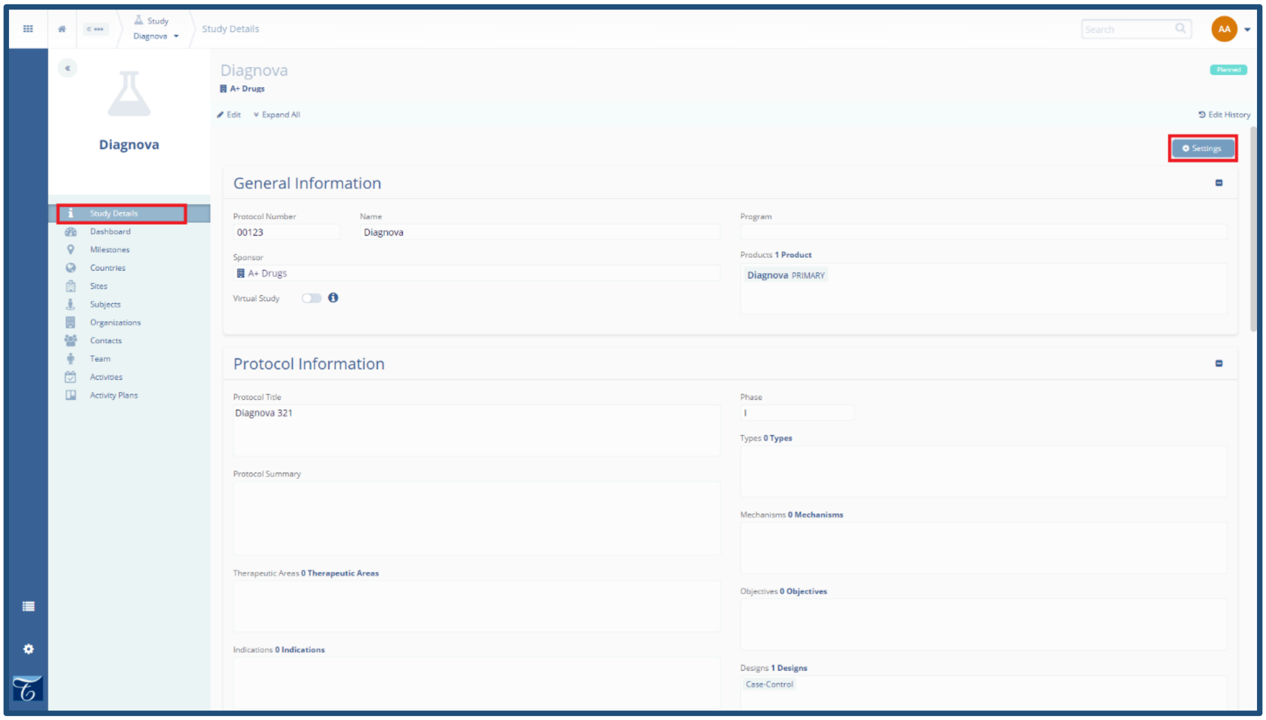
1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
   a. This opens the "Milestone Templates" window.
3. Click the **Create** button in the top-left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



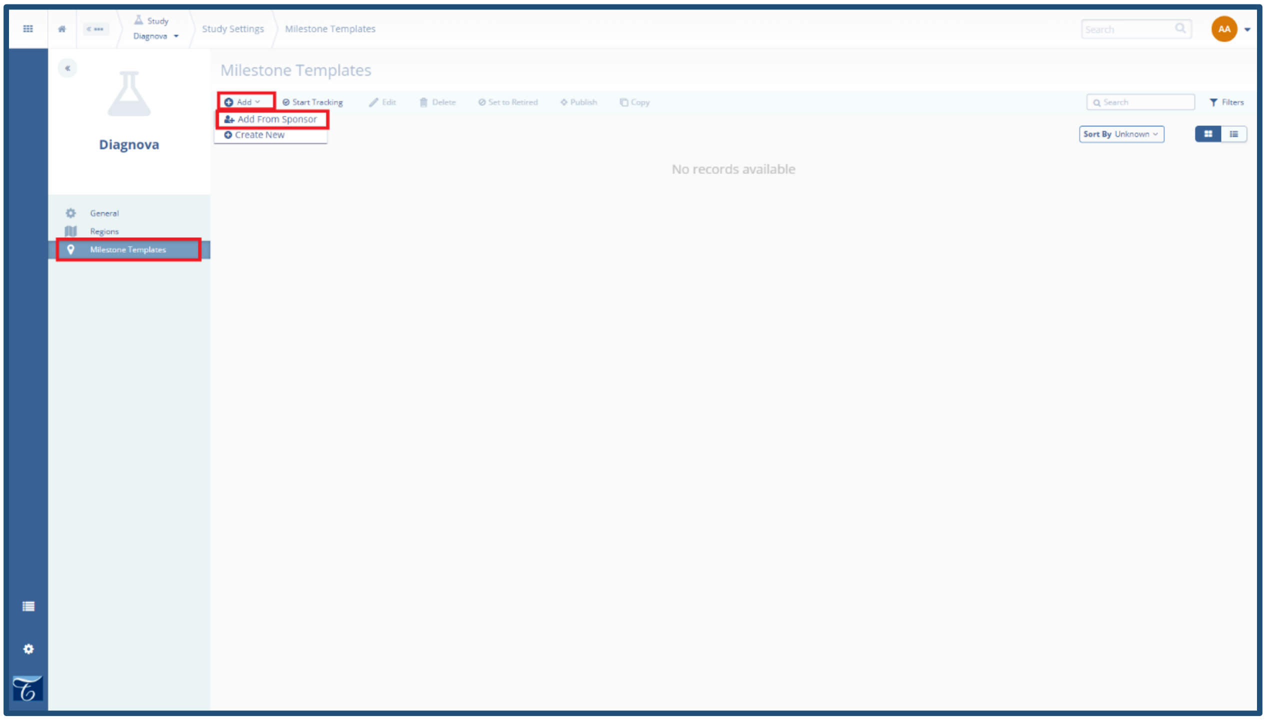
6. The **Create Milestone Template** window will close, and milestone template will be displayed.

10.3 Creating a Study Milestone from a Template

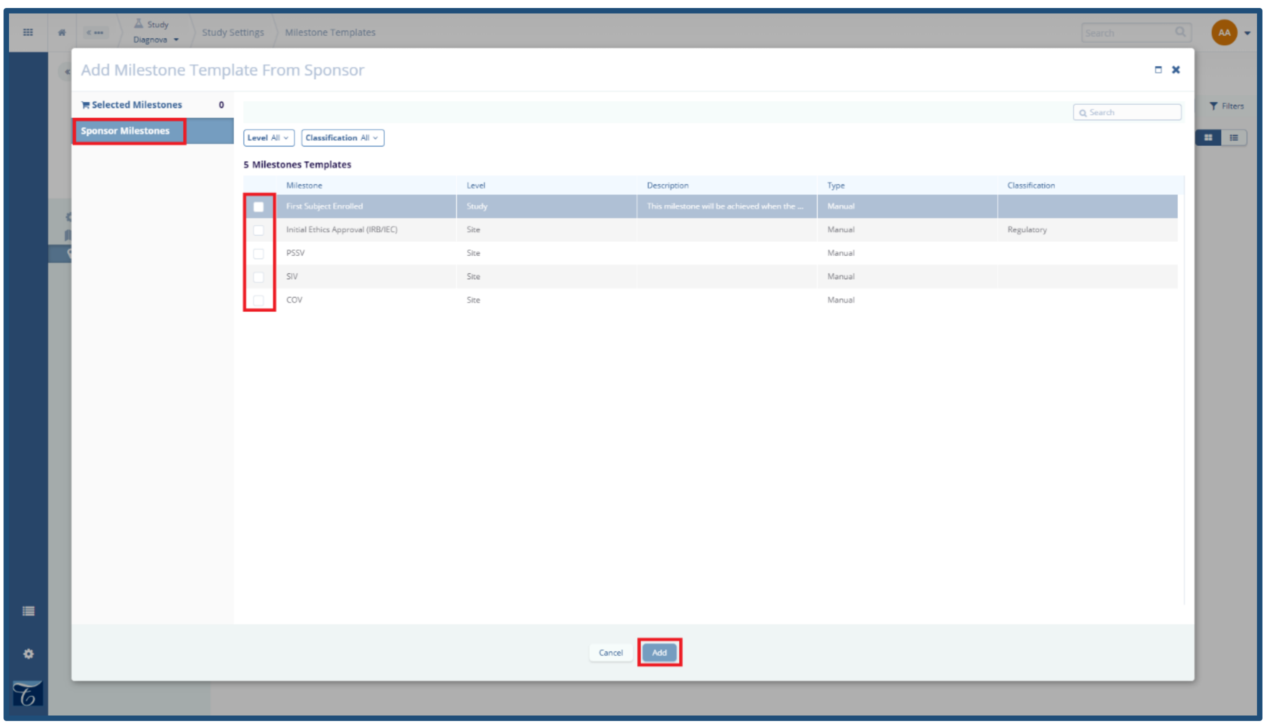
1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
   a. This opens the "Studies" window, and study list is displayed.
2. Click on the name of the study for which you want to create a milestone.
   a. This opens the study.
3. Click on the **Study Details**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



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



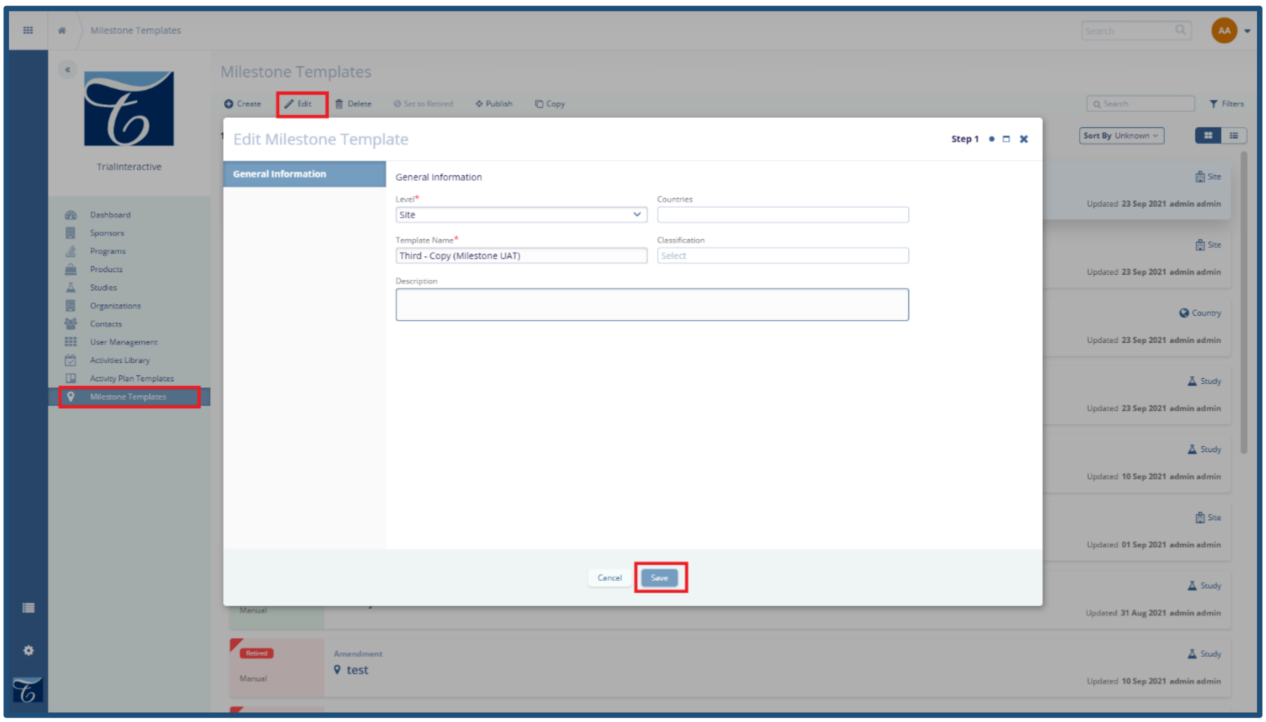
8. Click on the **Add** button in the **Add Milestone Template from Sponsor** window.



10.4 Editing Domain Milestone Templates

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

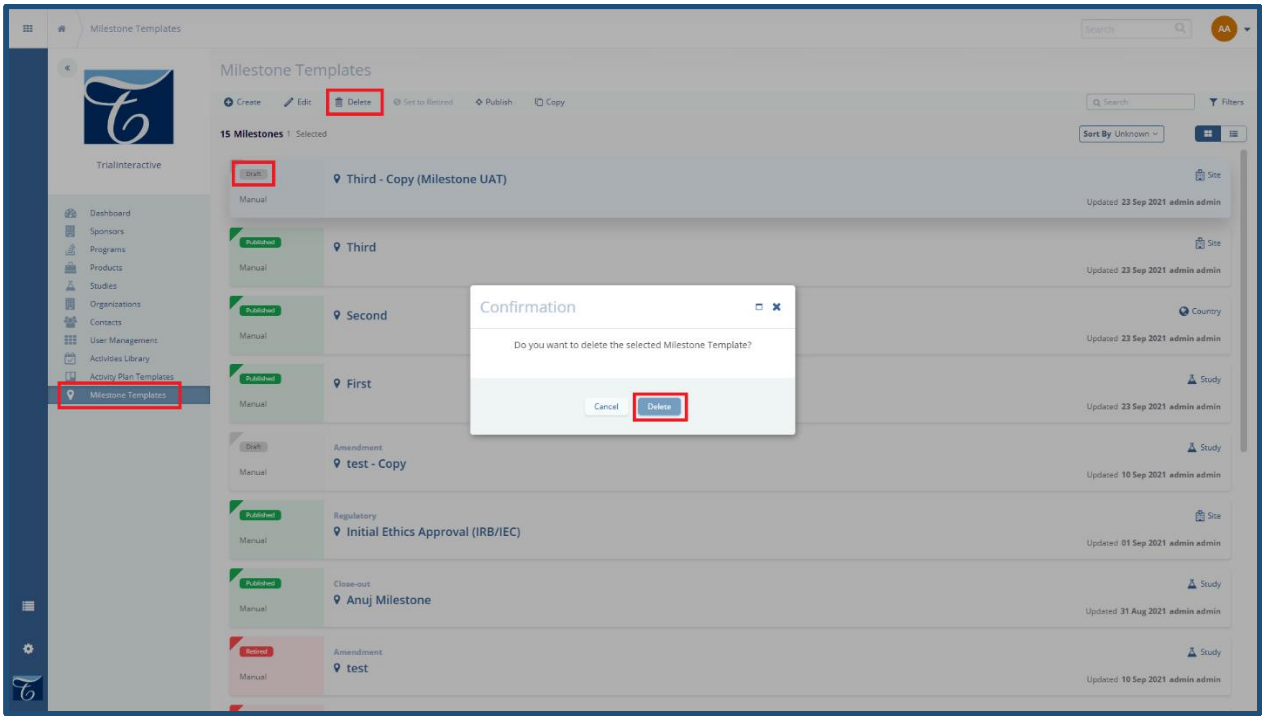
Note: You can edit only milestone templates with **Draft** status.



10.5 Deleting Domain Milestone Templates

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

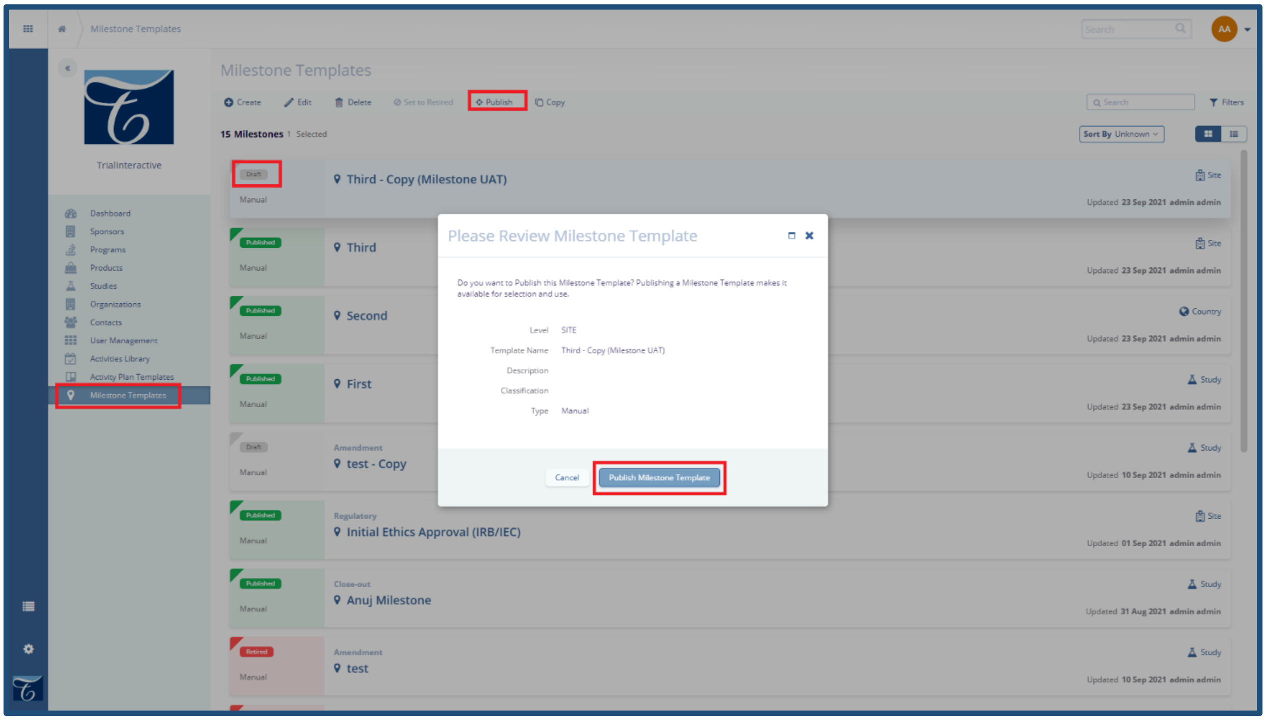
4. Click on the **Delete** button in the top-left of the screen.
    a. This opens the “Confirmation” window.
5. Click on the **Delete** button in the confirmation page.
6. The Milestone Template will be **Deleted** from the list.



10.6 Publishing Milestone Templates

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

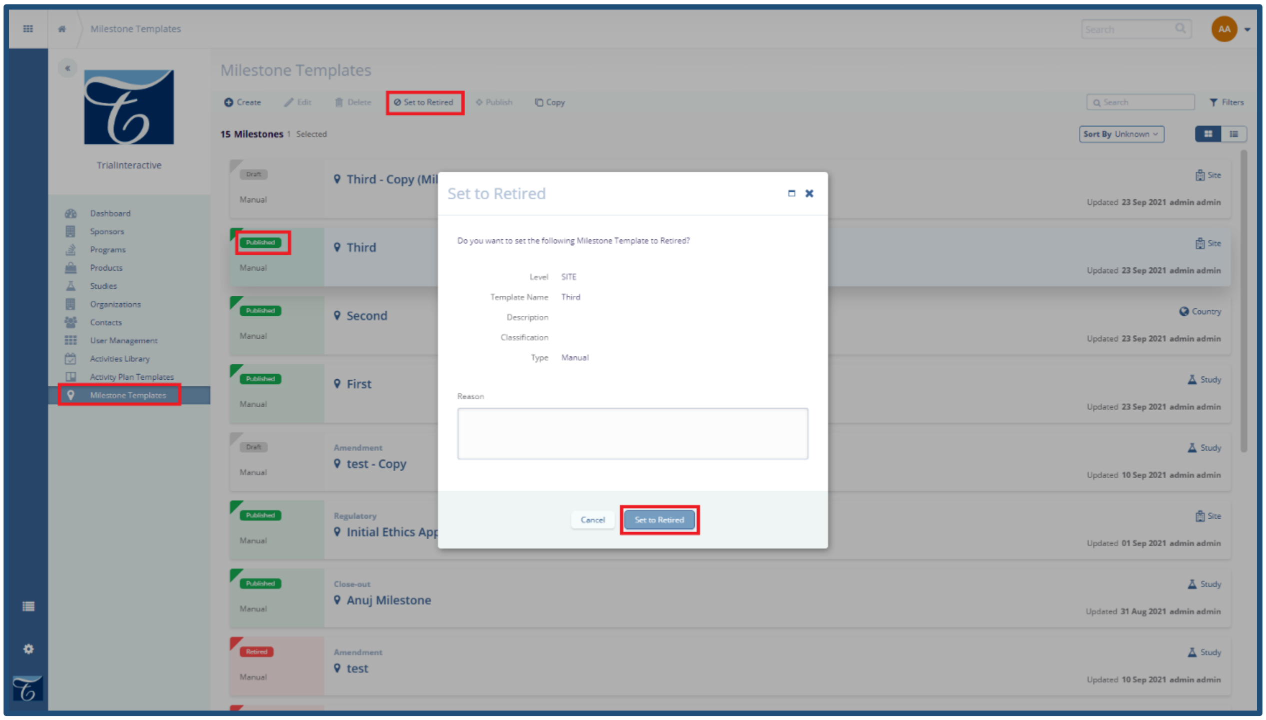
Note: Milestone Templates are not available for selection by the user community until **Published**.



10.7 Retiring Milestone Templates

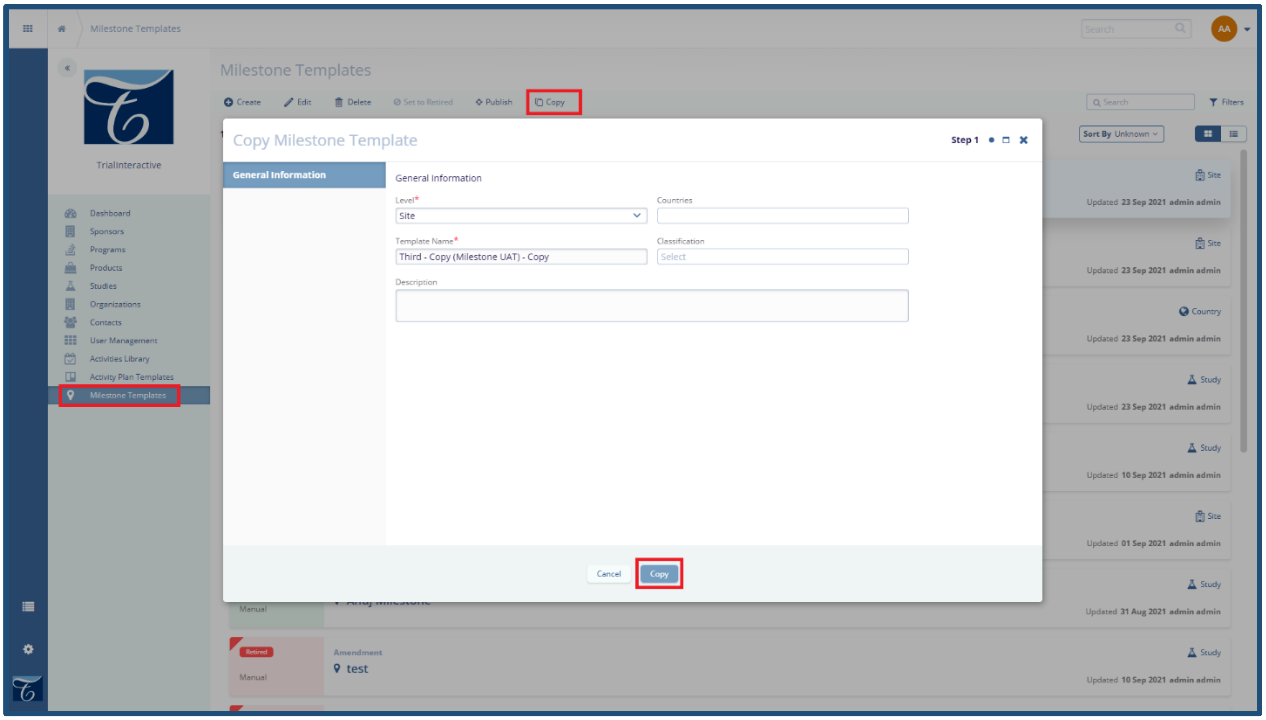
1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
    a. This opens the “Milestone Templates” window.
3. Navigate to the milestone template you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

Note: Only **Published** templates can be **Retired**.



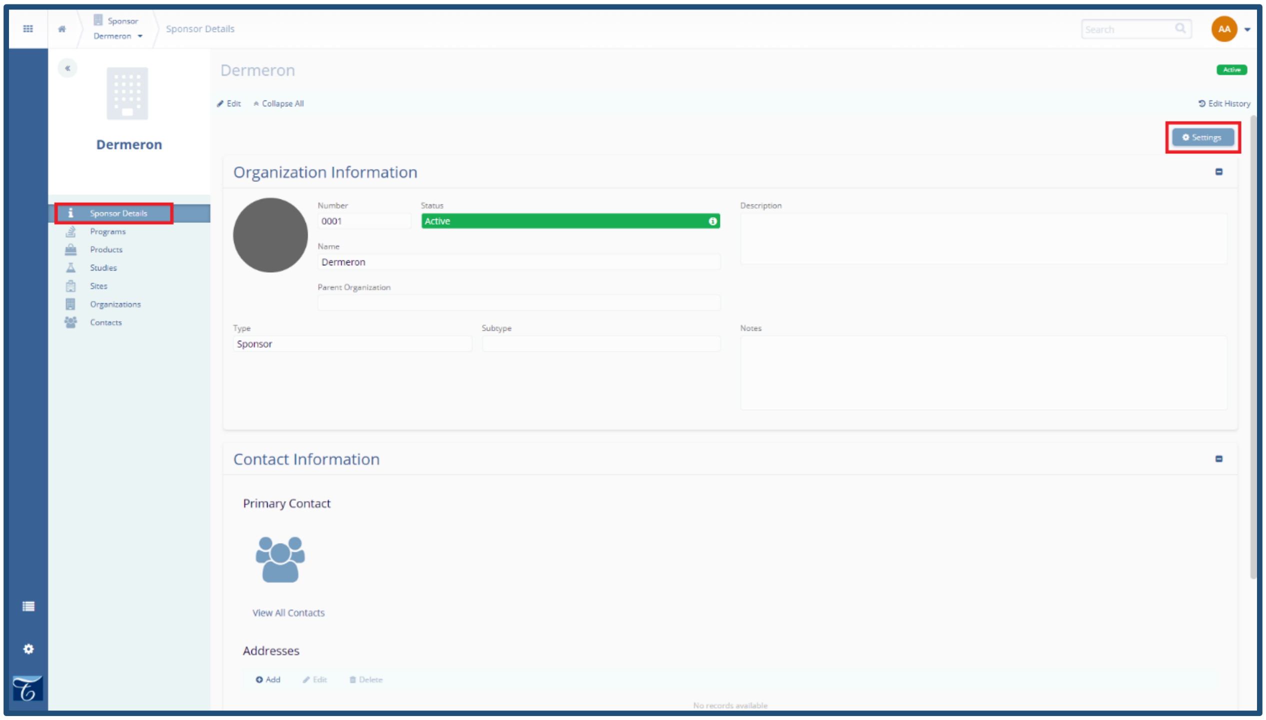
10.8 Copying Milestone Templates

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

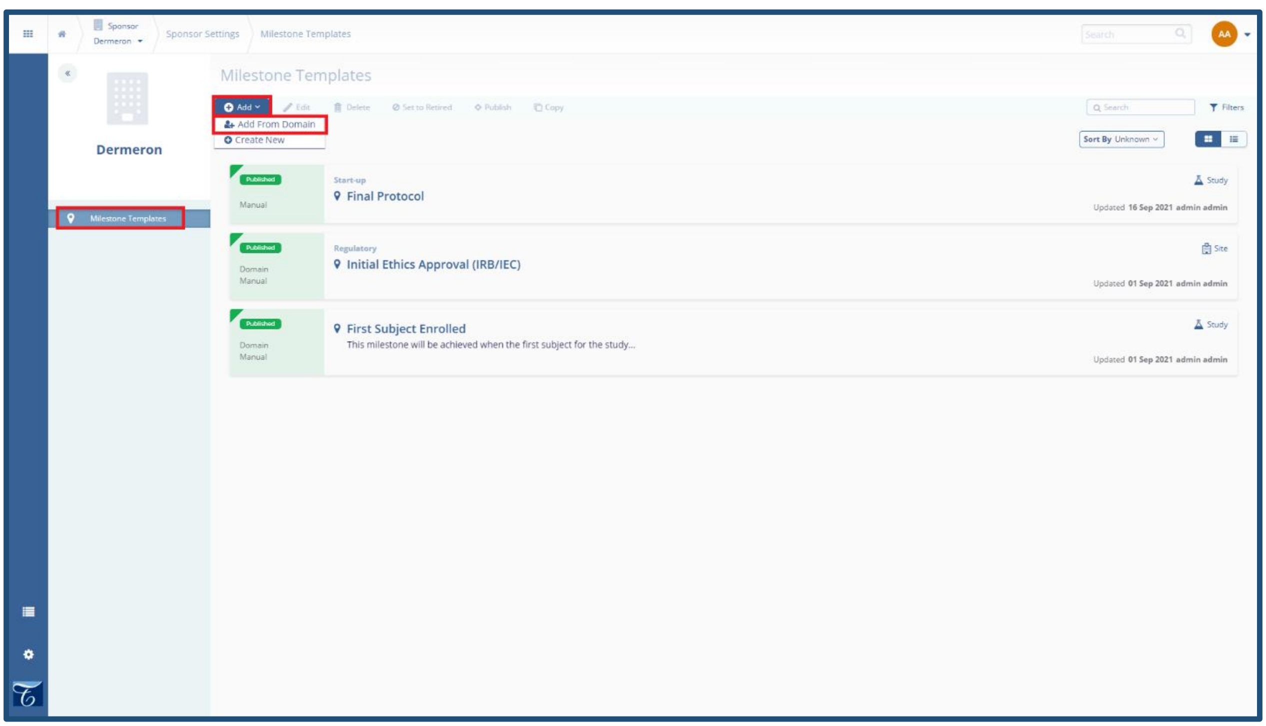


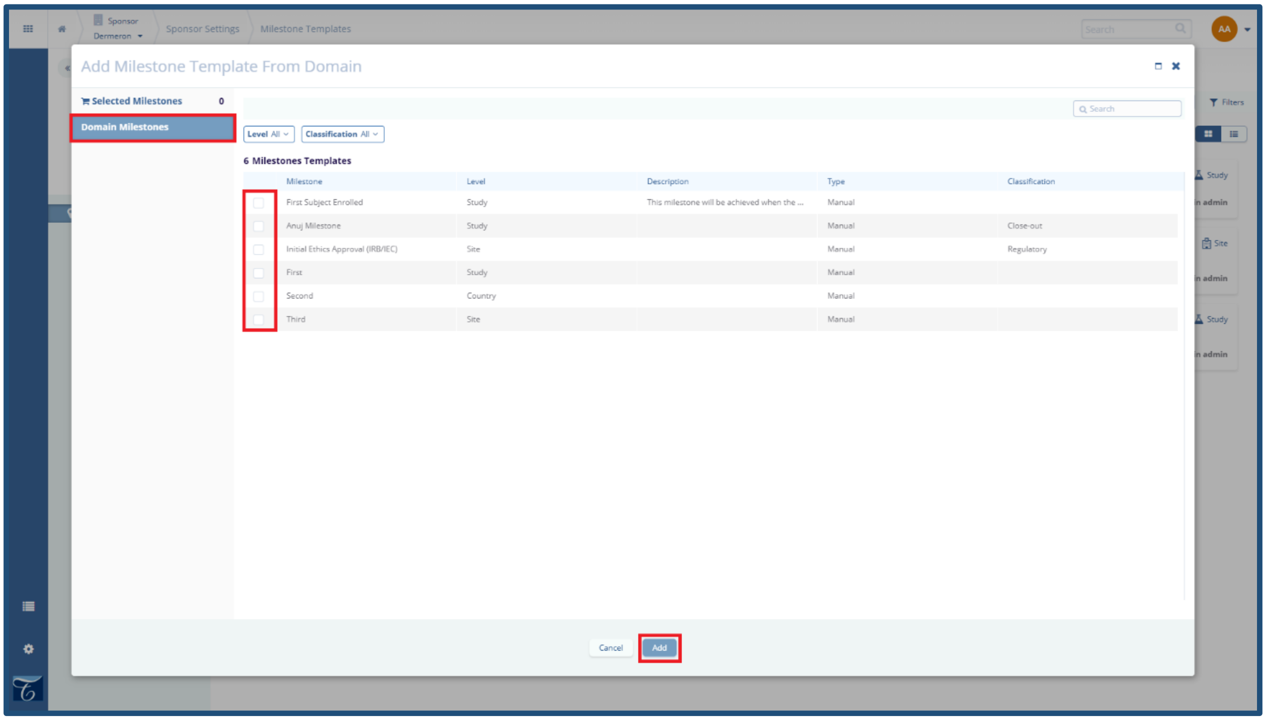
10.9 Associating Milestone Templates to a Sponsor

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



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

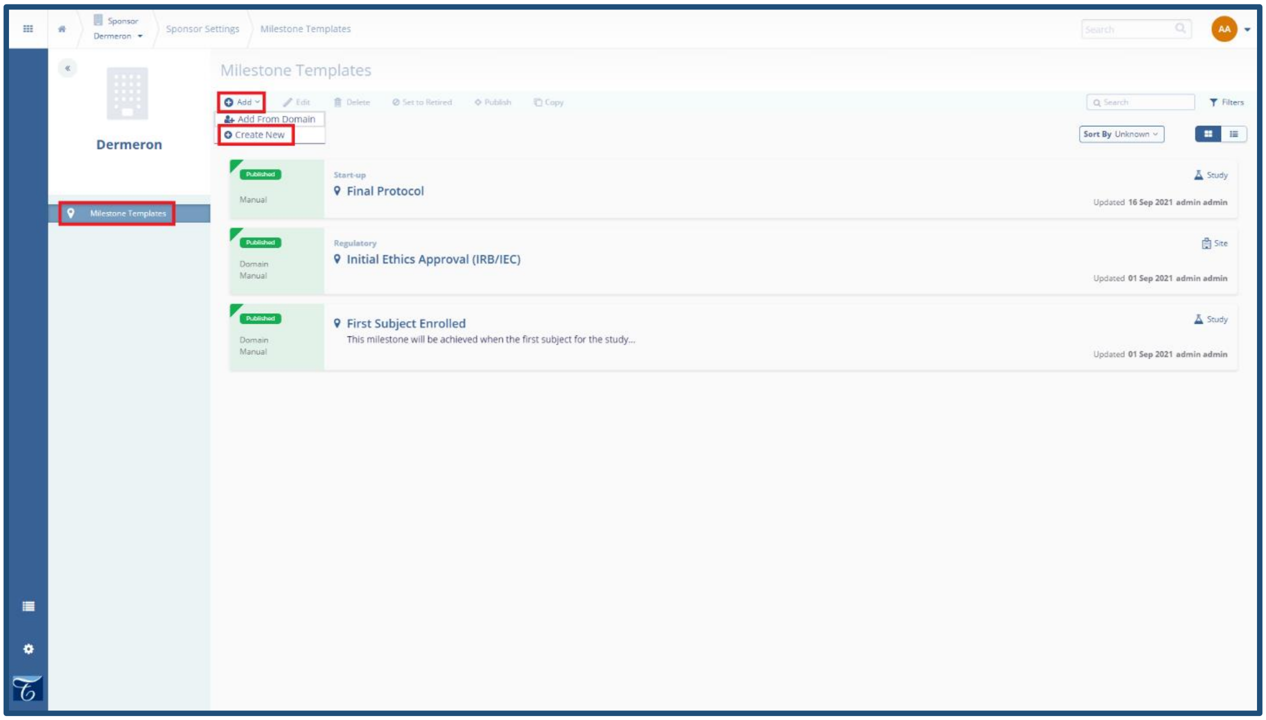




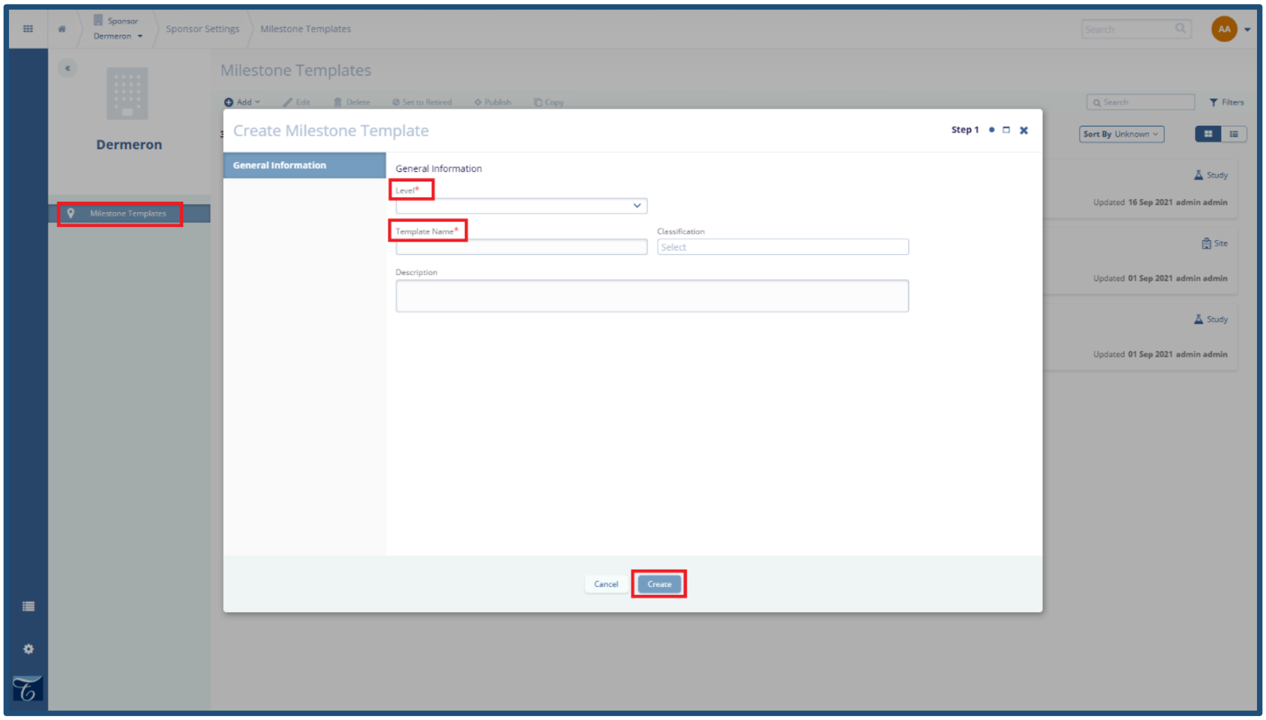
7. This opens the **Add Milestone Template from Domain** window.
8. Select one of the milestone templates from the list and click on the **Add** button.
9. The Milestone Template is added to the list.

10.10 Defining Sponsor-Specific Milestone Templates

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

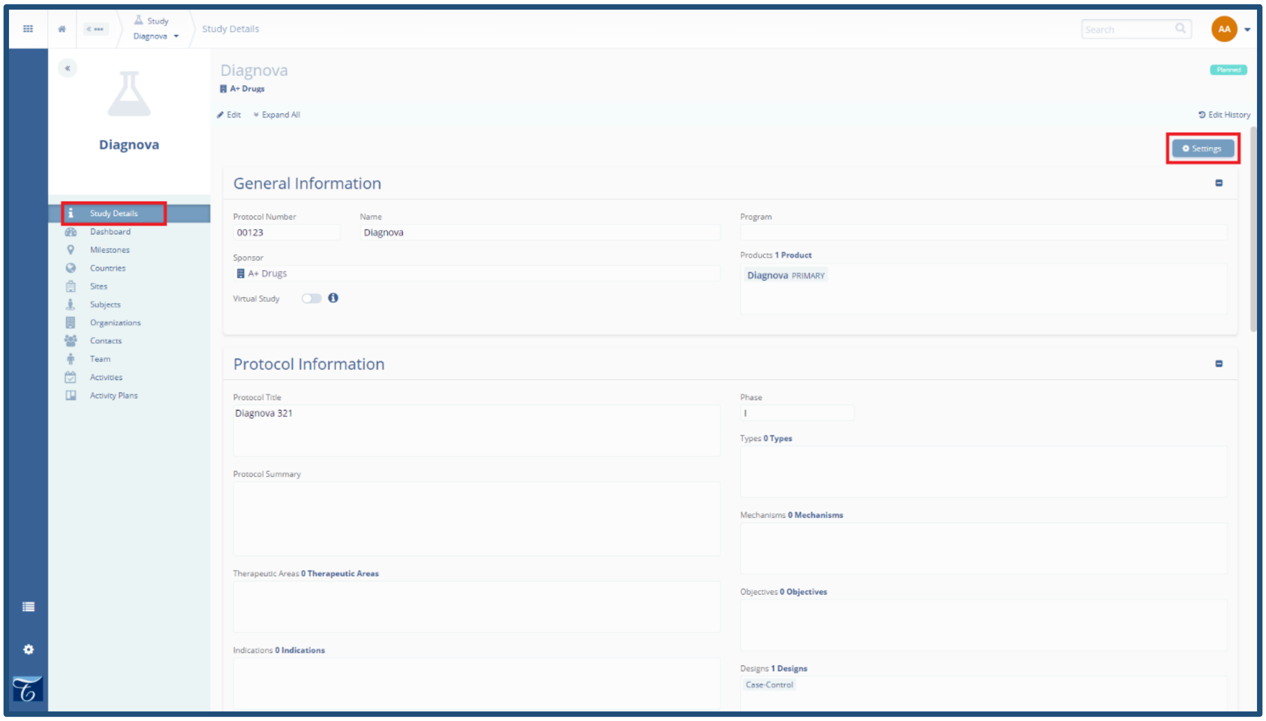


7. This opens the **Create Milestone Template** window.
8. Here we need to fill the mandatory metadata to create milestone template i.e., **Level, Template Name** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information as necessary.
9. If any of the required fields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

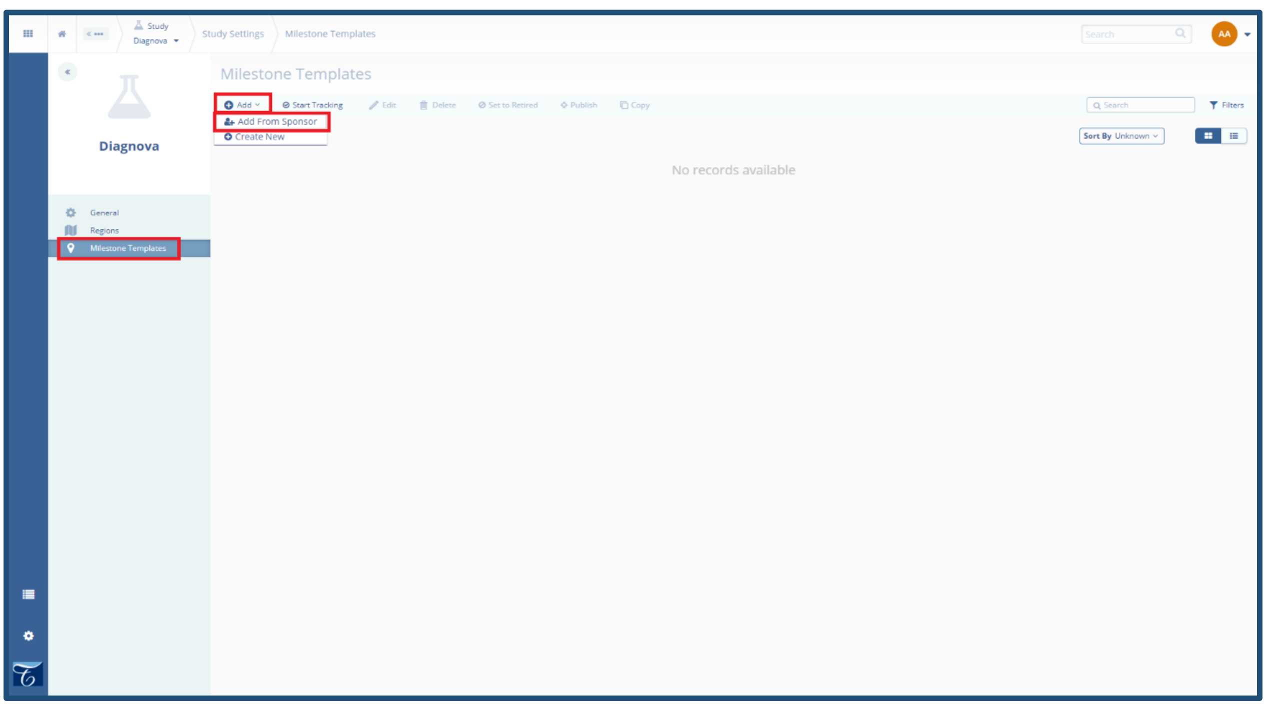


10.11 Defining Study Milestone Templates (New)

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

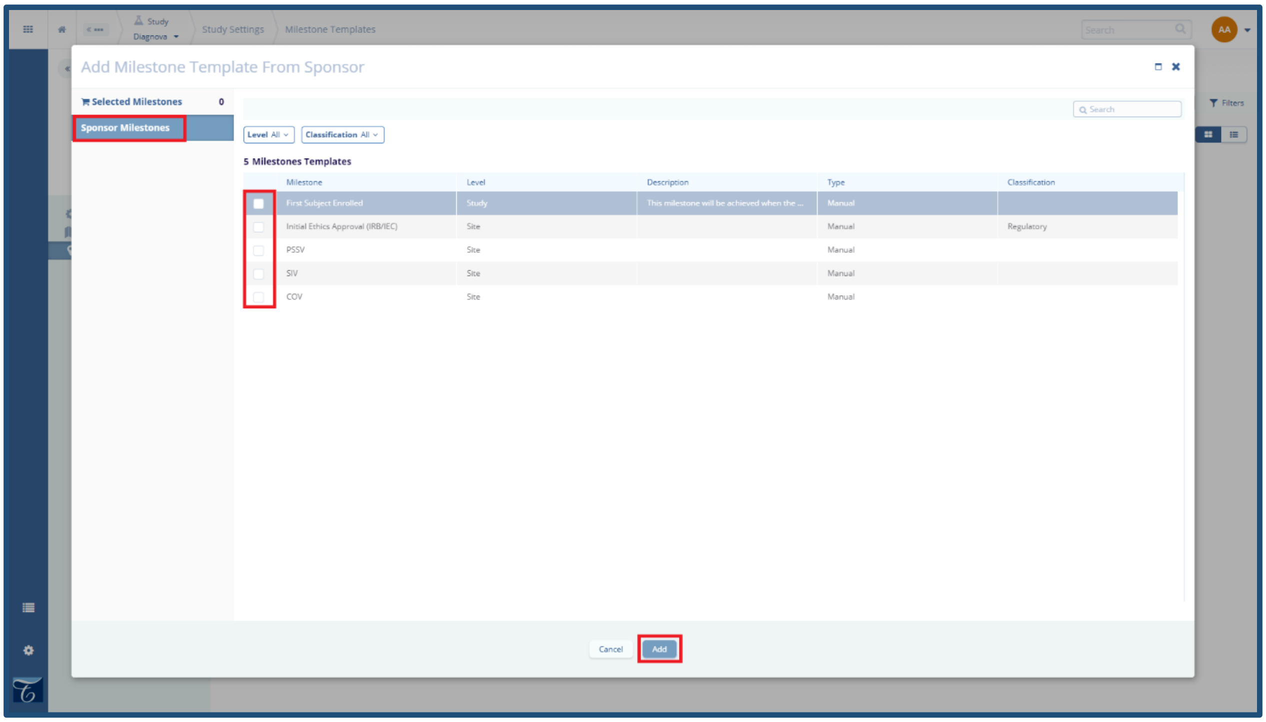


5. Click on the **Milestone Template** link in the Navigation menu at the left side of the screen.
    a. This opens the “Milestone Template” window.
6. Click on the **Add** button in the top-left of the screen.
7. Click on **Add from Sponsor** from the dropdown.



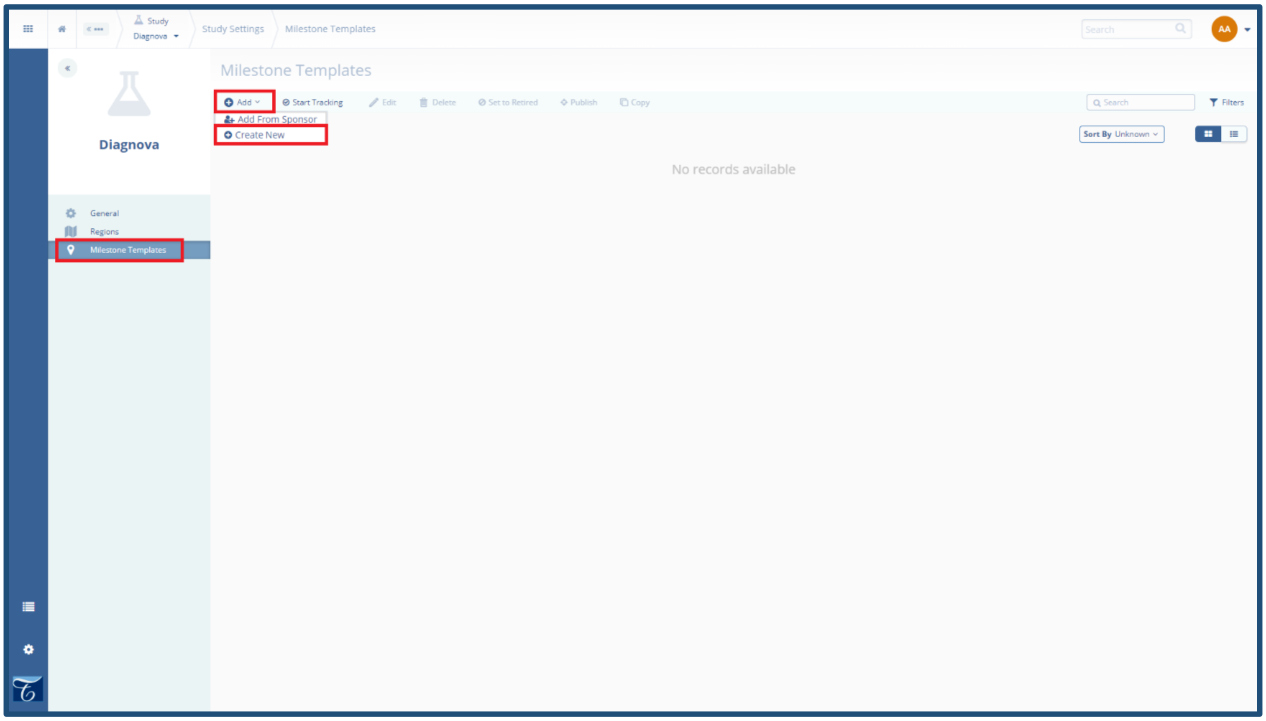
Note: Clicking Add from Sponsor will allow for the selection of a milestone template that is already associated to your study sponsor.

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

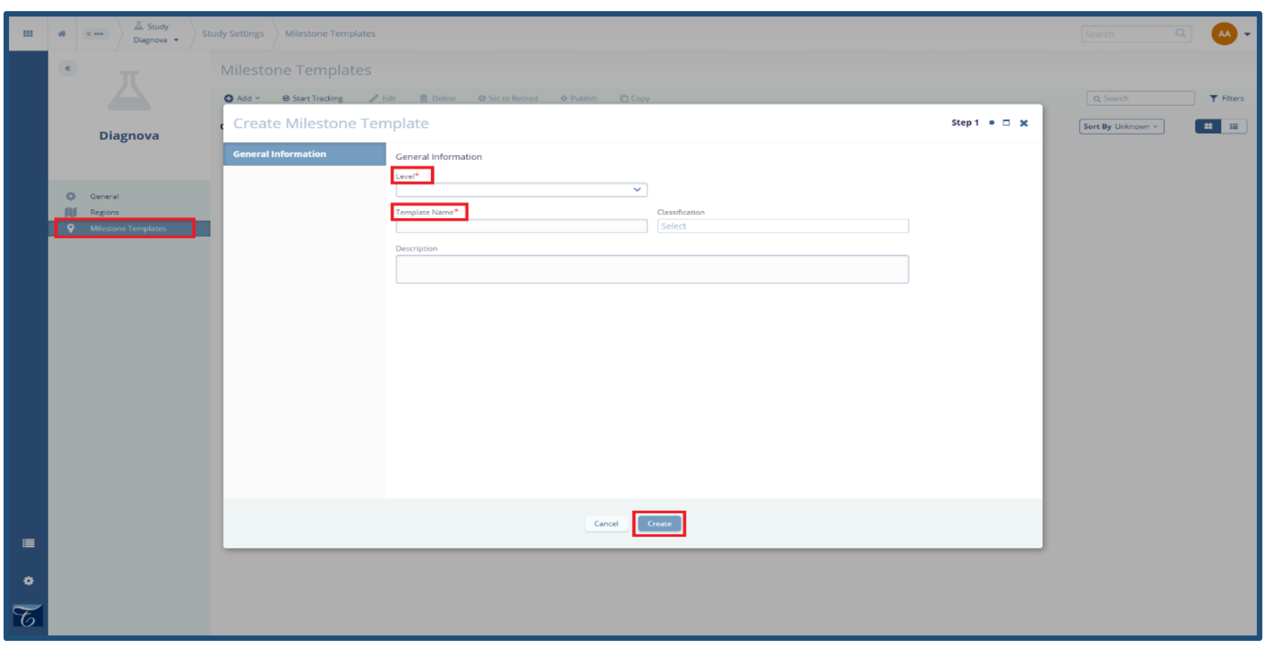


11. To create a new **Milestone Template**, follow these steps.
12. Click on the **Add** button in the top-left of the screen.
13. Click on the **Create New** button form the dropdown list.

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



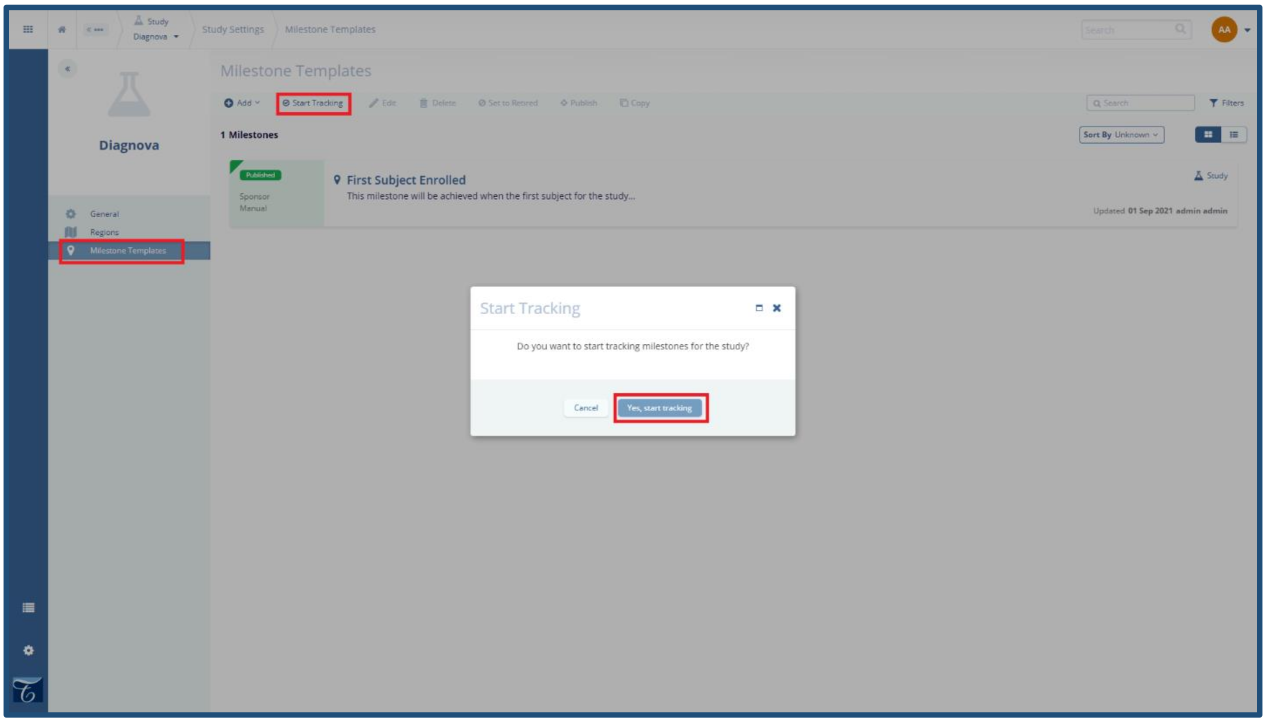
14. Here we need to fill the mandatory metadata to create a milestone template i.e., **Level, Template Name** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information as necessary.
15. If any of the required fields are missing, an error will appear when we click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



10.12 Tracking Milestones

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

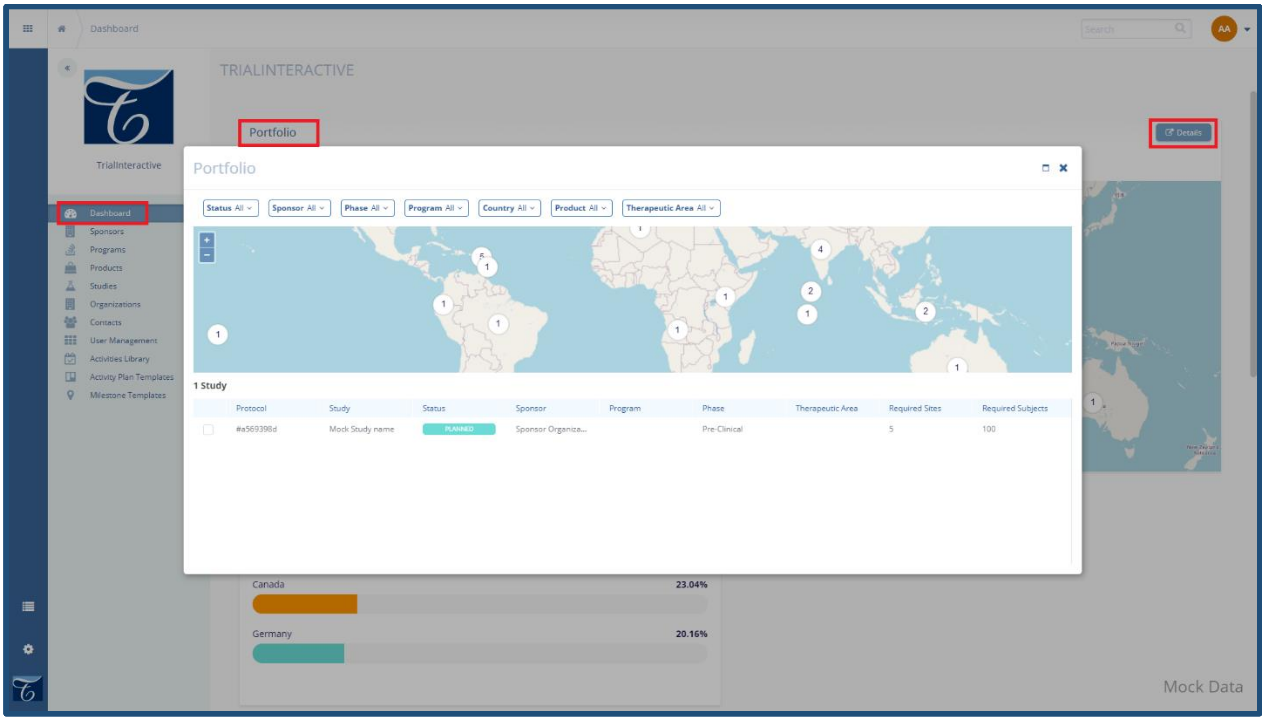
   Note: The milestone will not be displayed for tracking at any level until Start Tracking is clicked for the desired milestone.



11 Dashlets

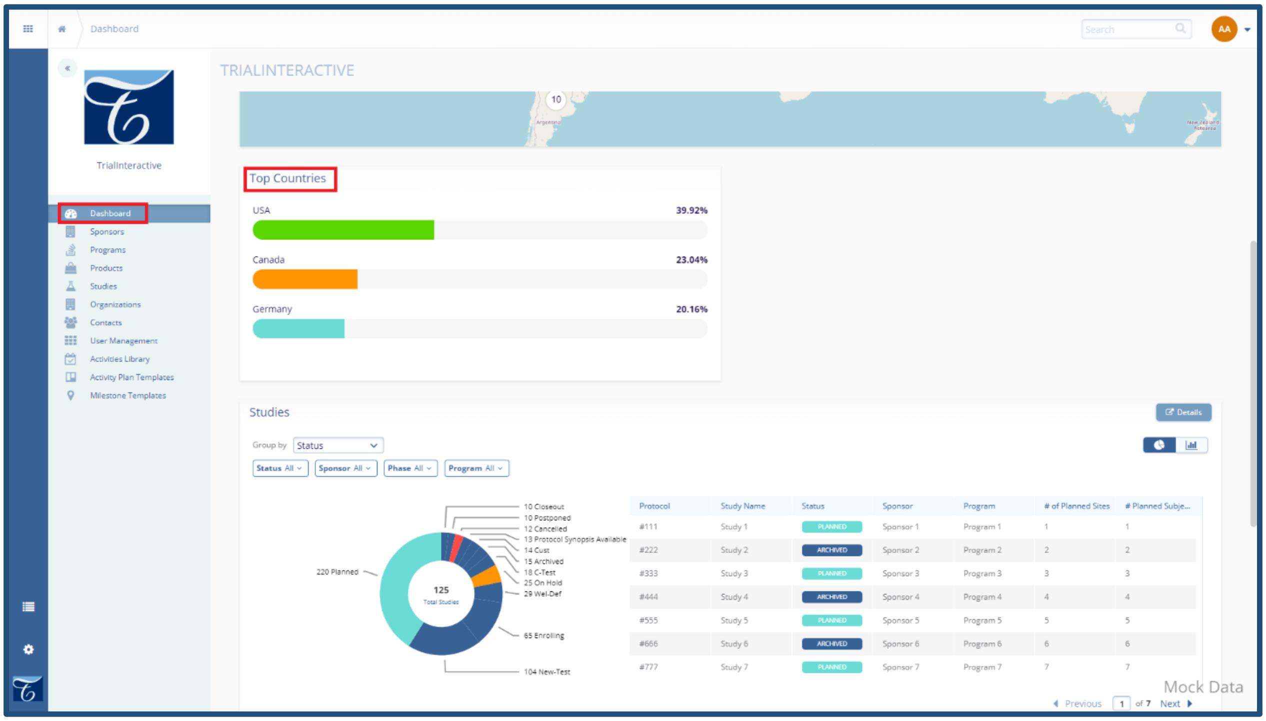
11.1 The Portfolio Dashlet

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



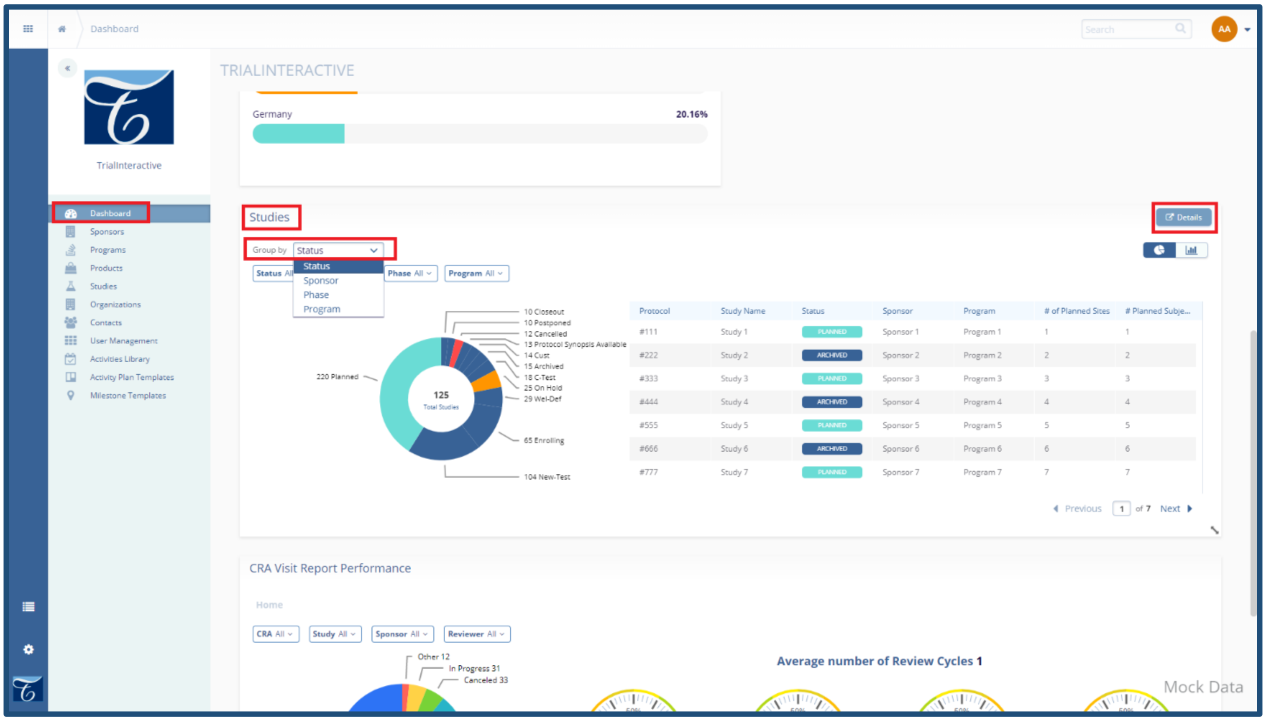
11.2 The Top Countries Dashlet

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



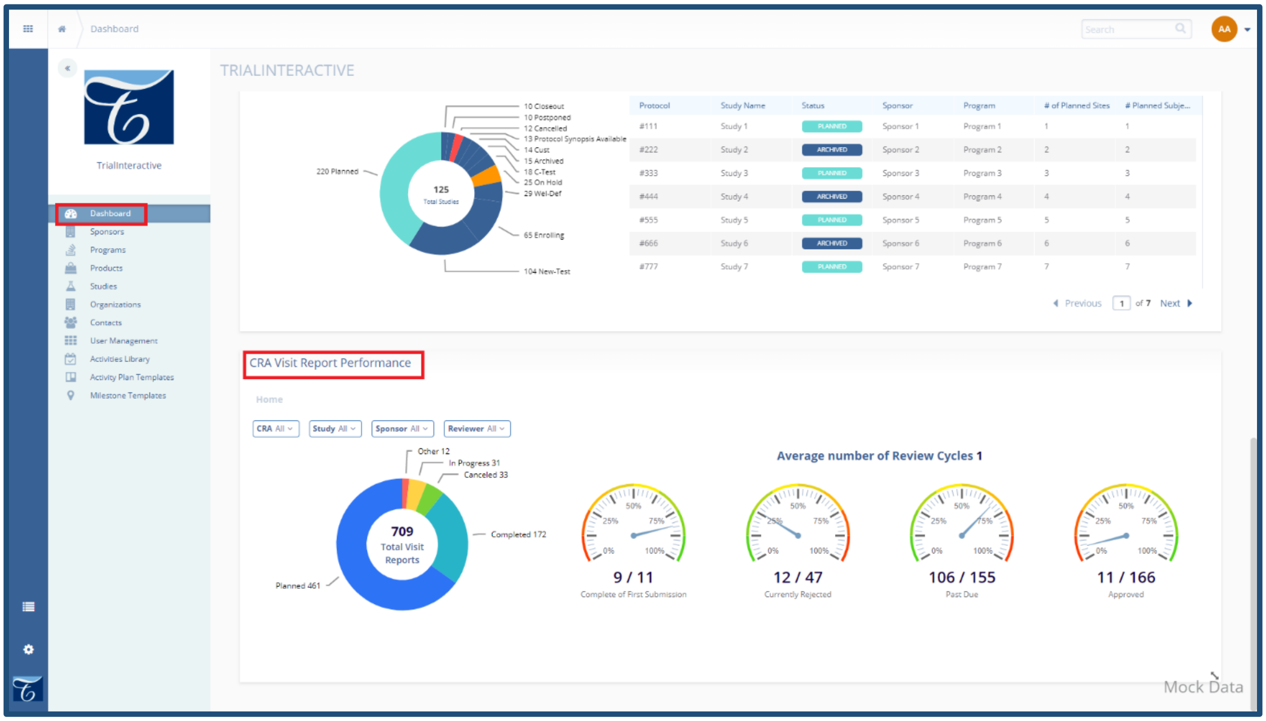
11.3 The Studies Dashlet

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



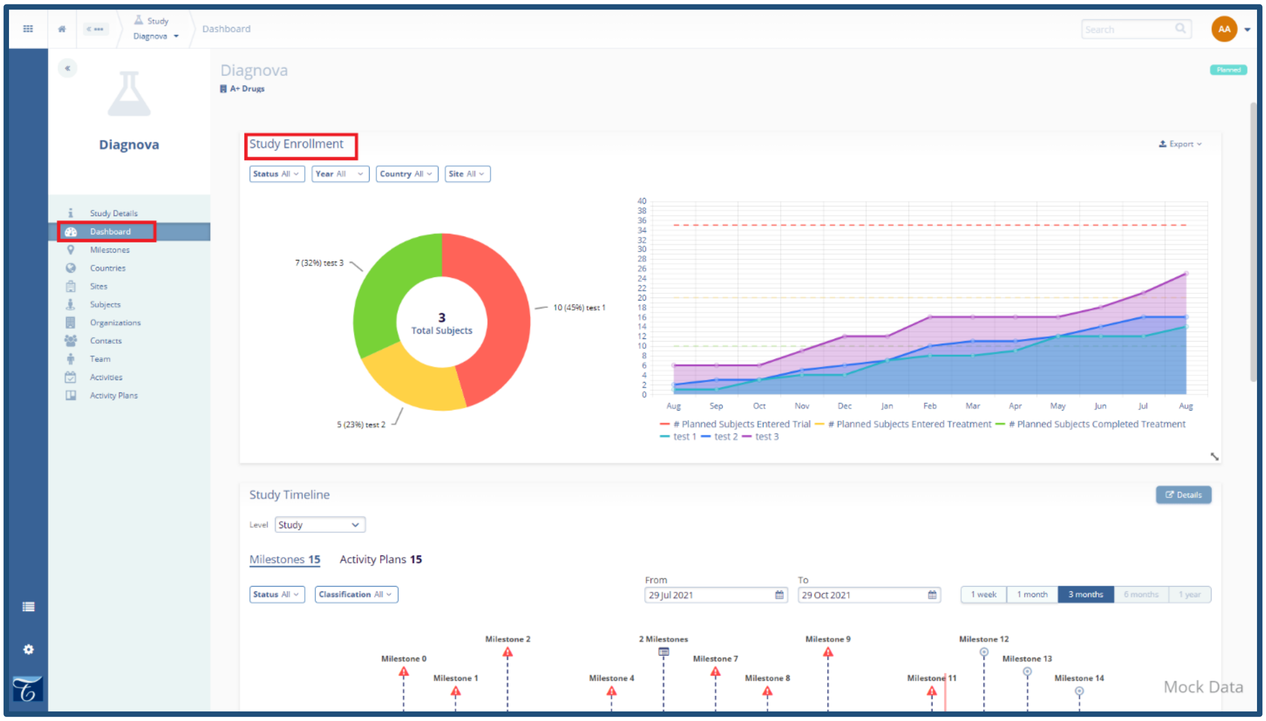
11.4 The CRA Visit Report Performance Dashlet

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

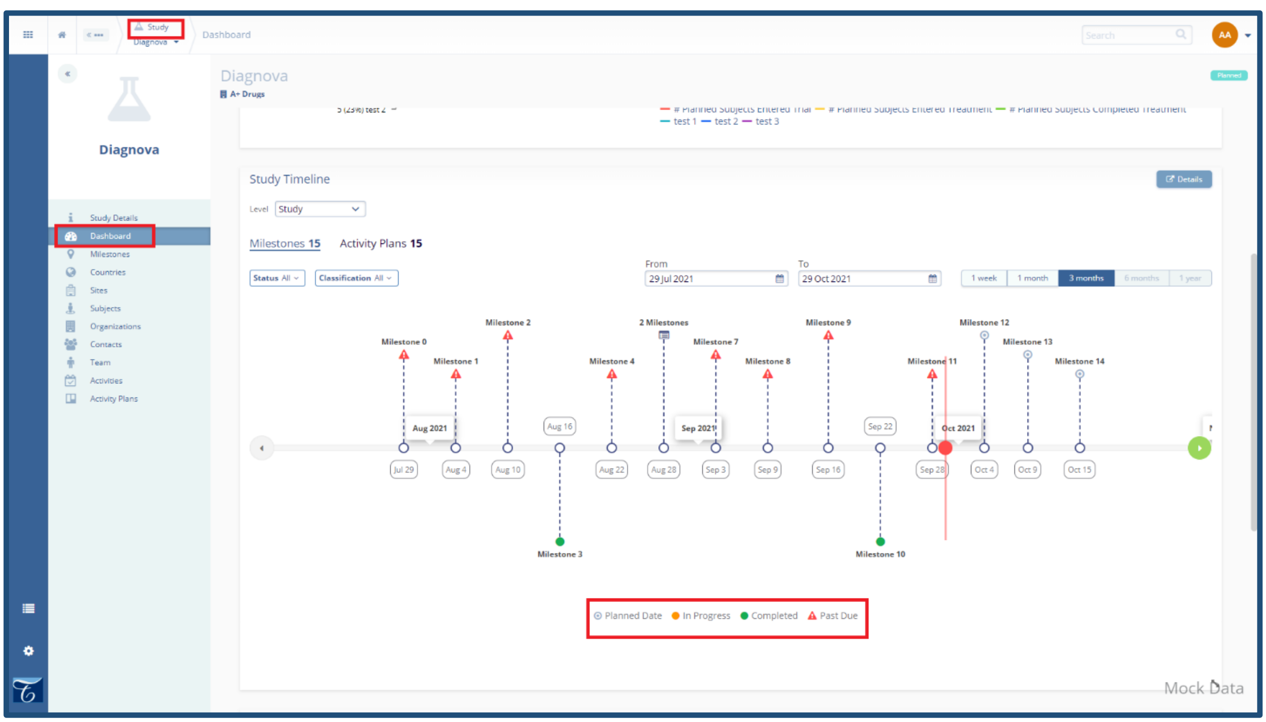


11.5 Reviewing Studies via their Dashboard

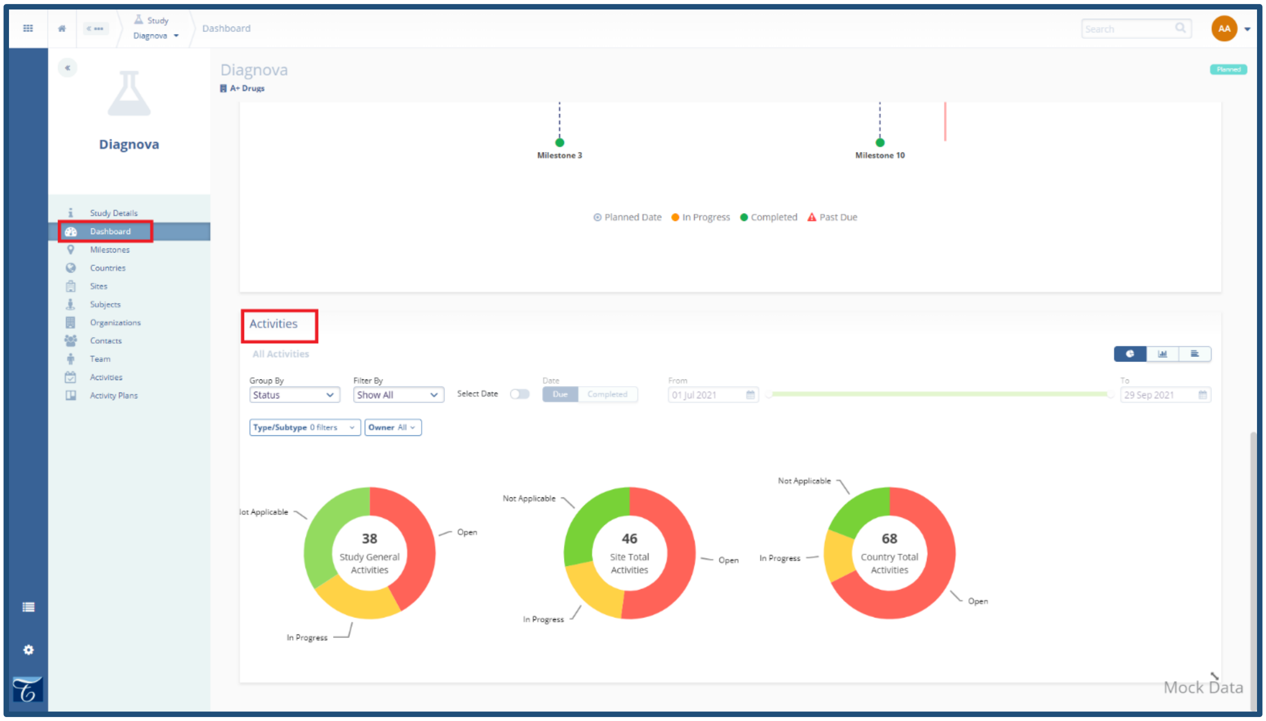
1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
    a. This opens the “Studies” window.
2. Navigate to the study you want to review.
3. **Study Enrollment, Study Timeline, and Activities** dashlets are displayed.
4. Navigate to **Study Enrollment** in the dashboard.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



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

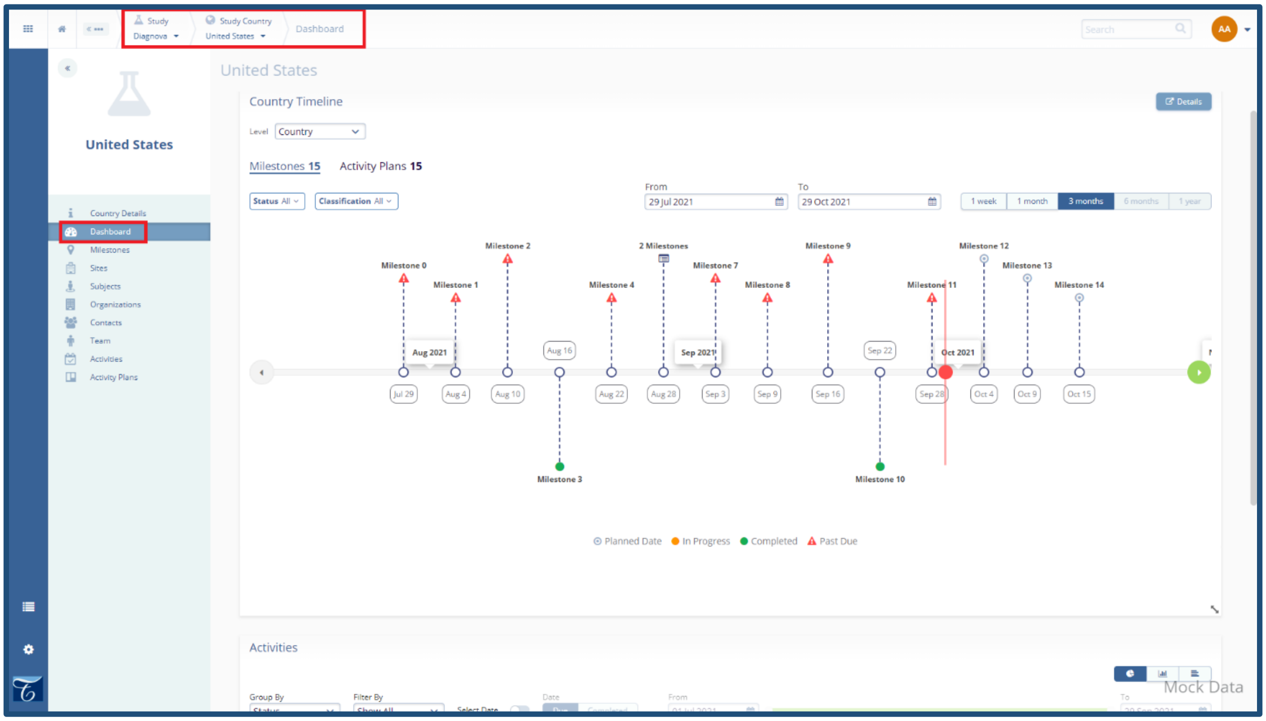


7. Navigate to **Activities** on the dashboard.
8. This shows data for **Study General Activities, Site Total Activities, Country Total Activities** in pie chart, that can be changed to a bar graph if preferred.



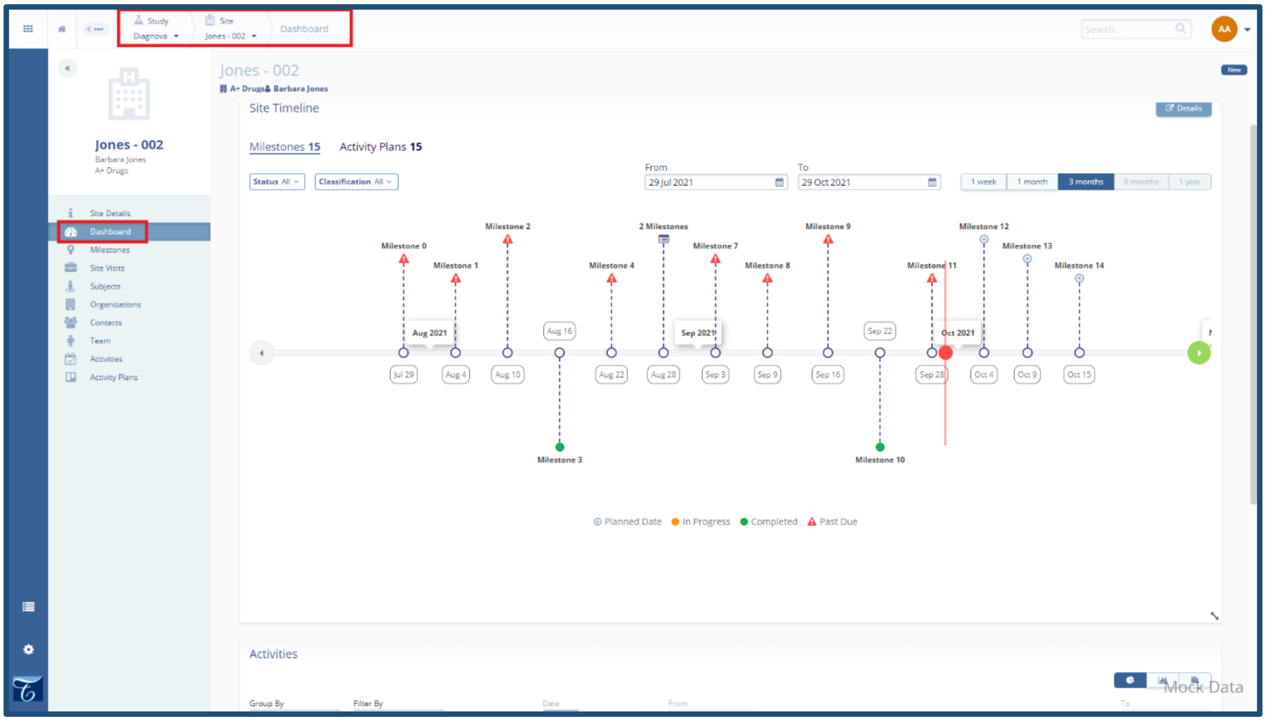
11.6 Reviewing Countries via their Dashboard

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



11.7 Reviewing Site Dashboard

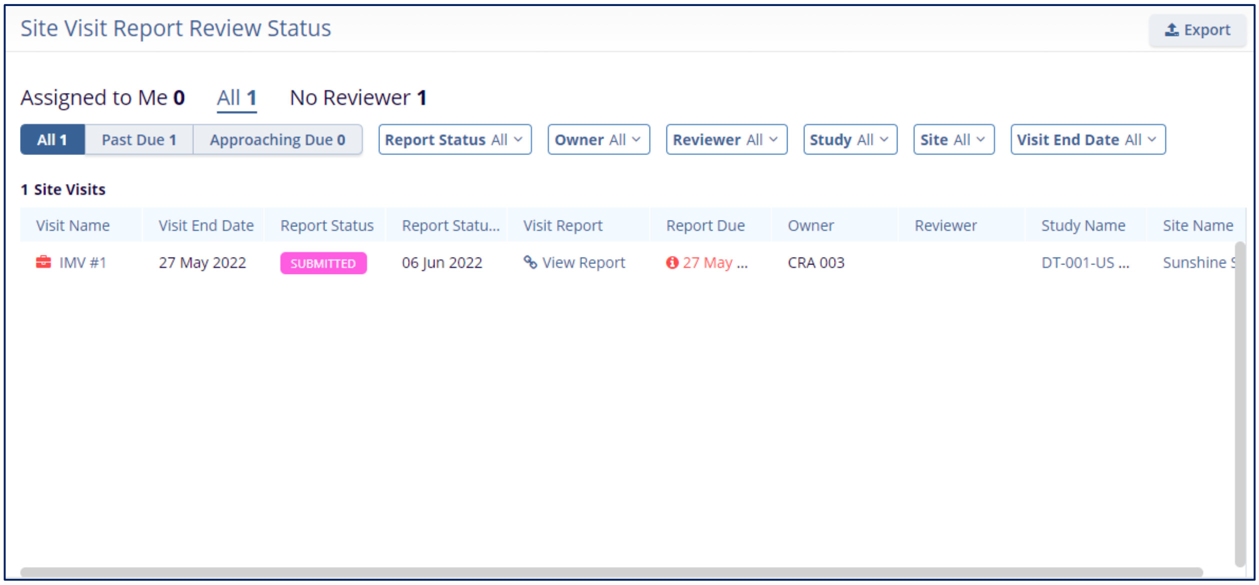
1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
    a. This opens the "Studies" window.
2. Click on the name of the study you want to review.
    a. This opens the dashboard for the study.
3. Click on the **Sites** link in the Navigation menu at the left side of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



11.8 Site Visit Report Review Status Dashlet

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

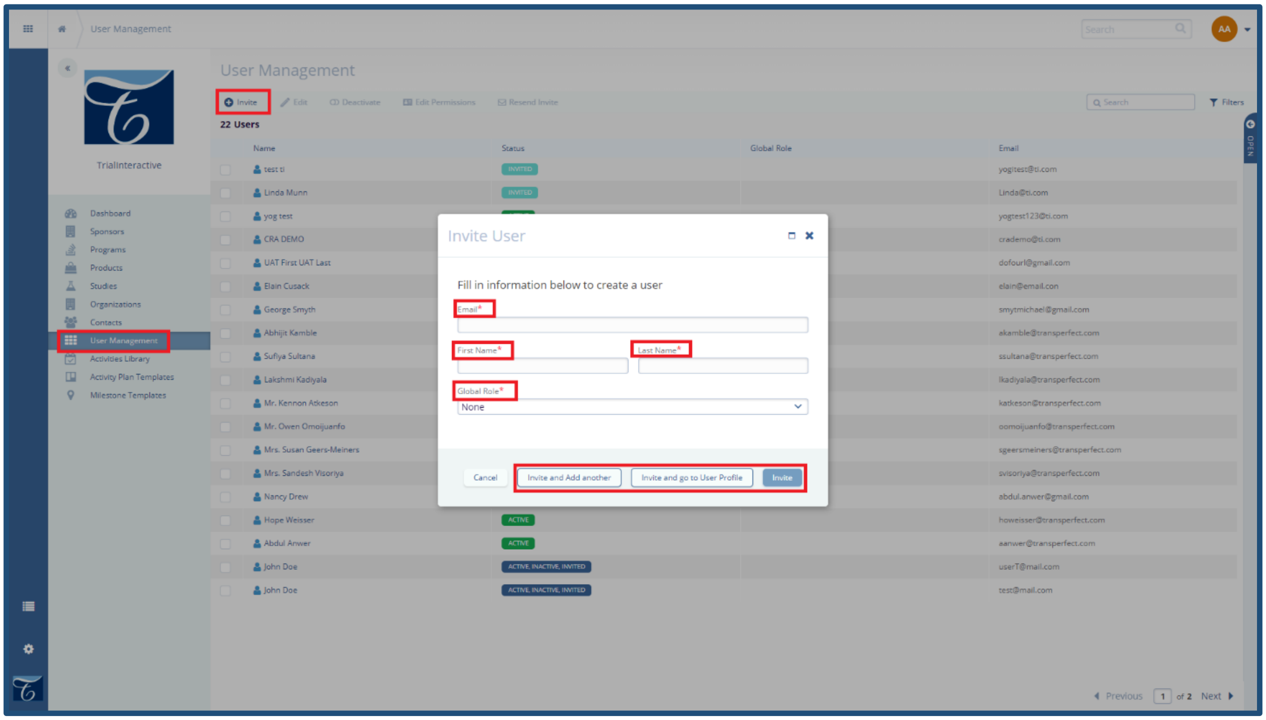
Users can navigate directly to the Site Visit in question by clicking on the name of the visit as shown in the grid or they can navigate directly to the report to be reviewed by clicking on the “View Report” link in the grid.



12 User and Team Management

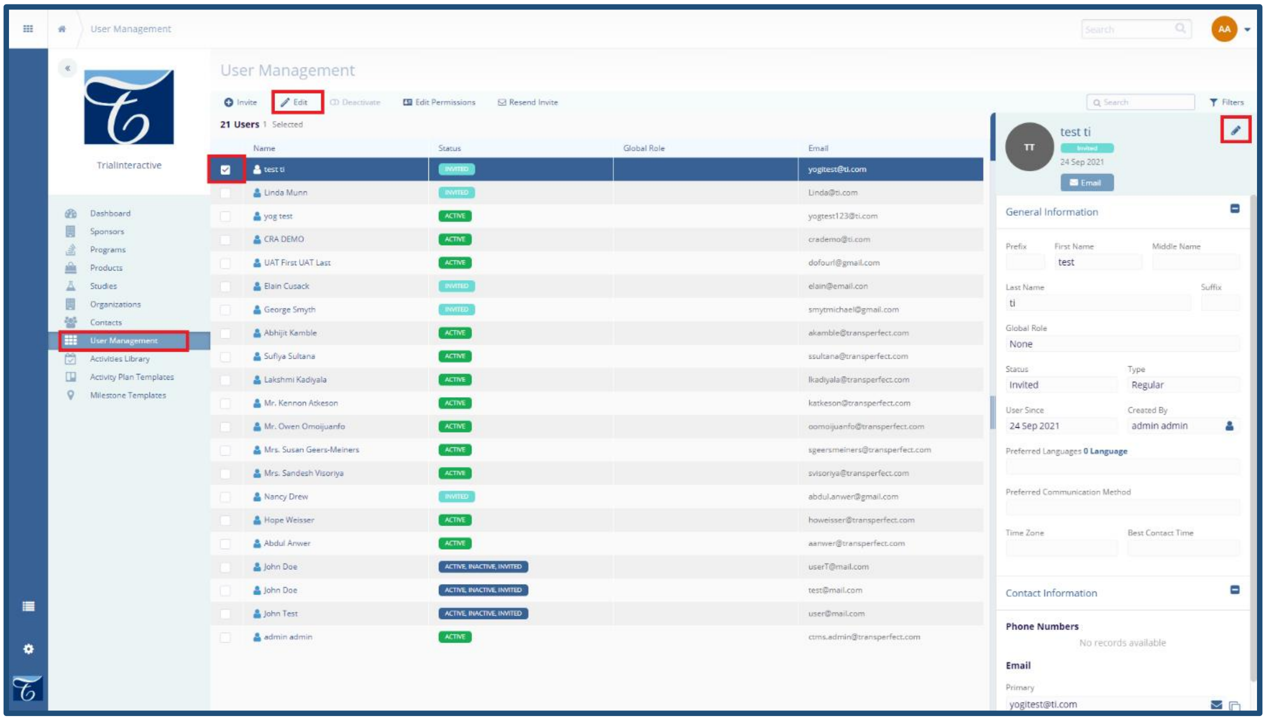
12.1 Creating Users

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



12.2 Editing a User

1. Click on the **User Management** link in the Navigation menu at the left side of the screen.
   a. This opens the **User Management** screen.
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.

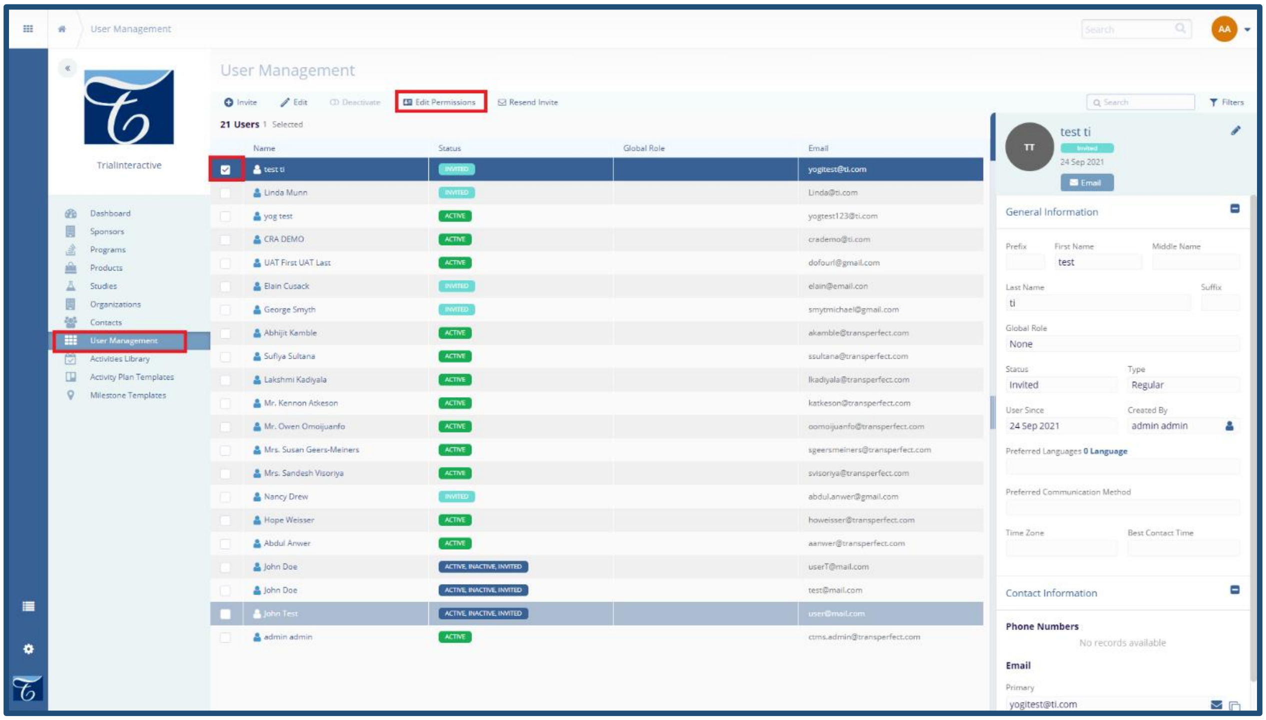


5. Click on the **Save** button in the bottom right of the screen, for the changes to apply to the user account.

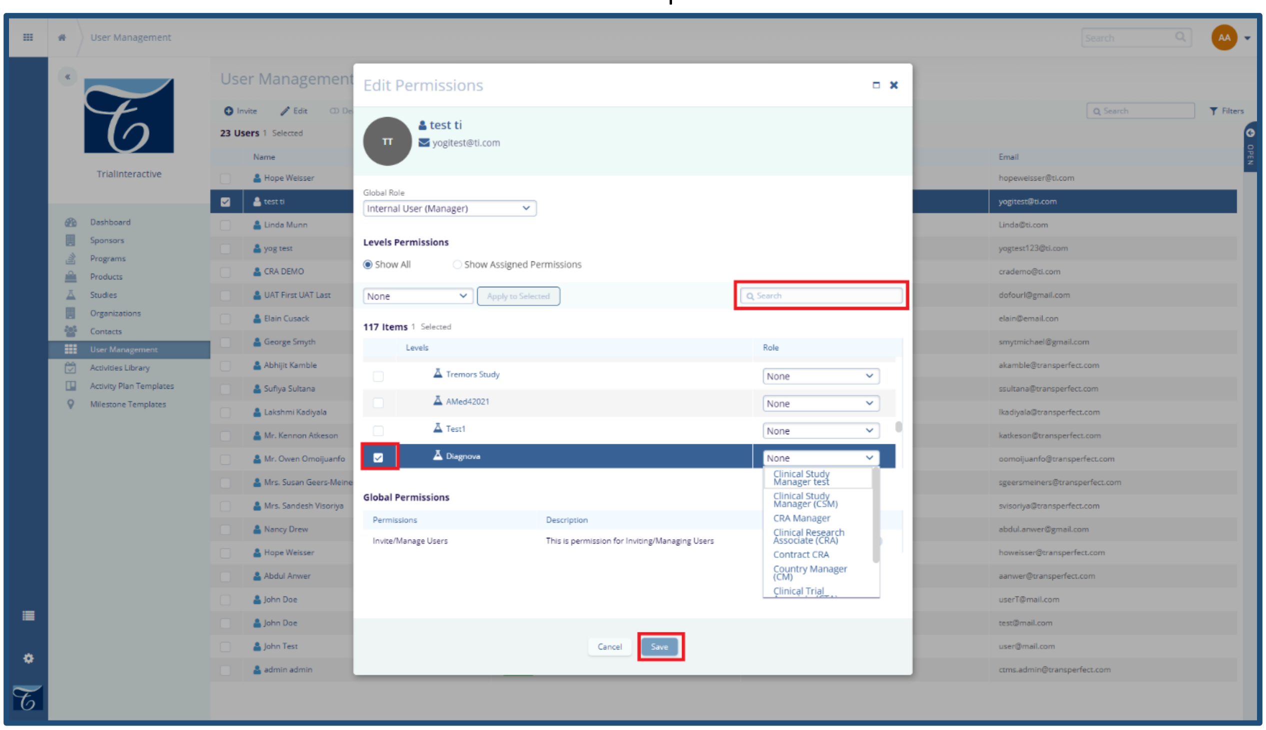
12.3 Editing a User's Permissions

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.



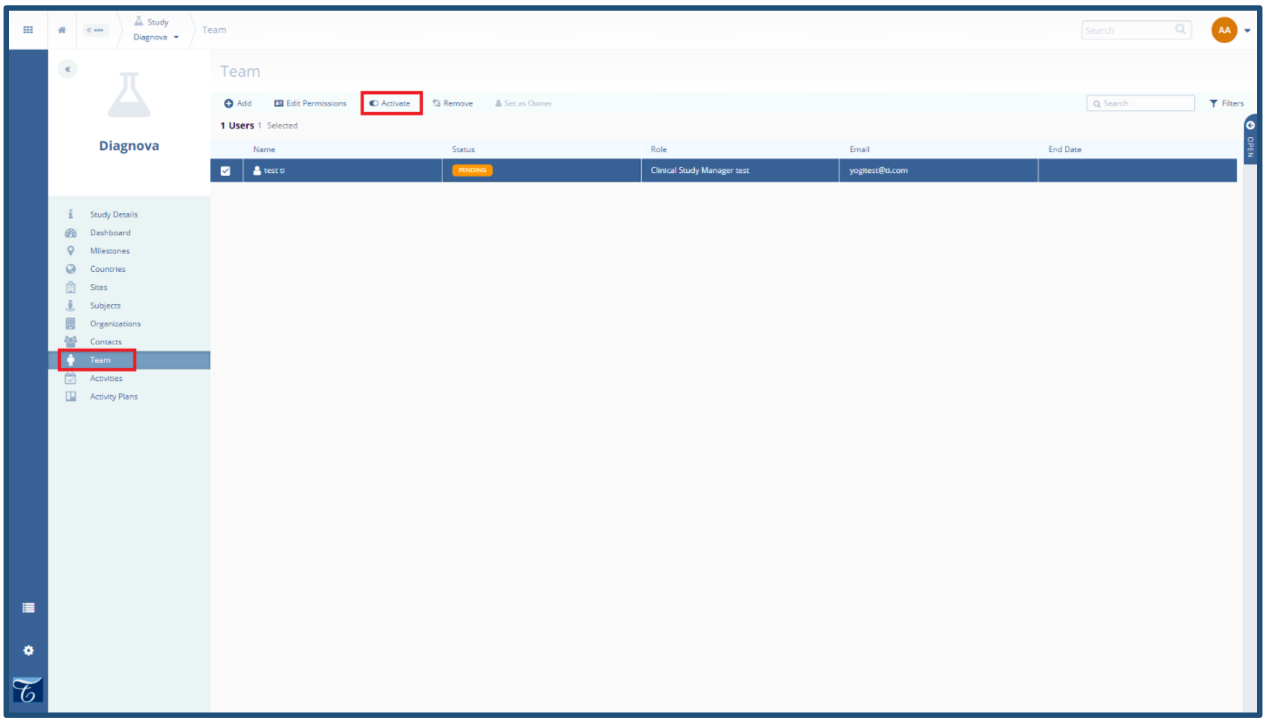
4. Navigate through the list of organizations below or use the search box to find the sponsor.
5. Expand the selected organization and select the appropriate product or study.
6. Assign the user a specific role associated with that product or study.
7. Click on the **Save** button the bottom of the edit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



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

12.4 Study Team Management

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



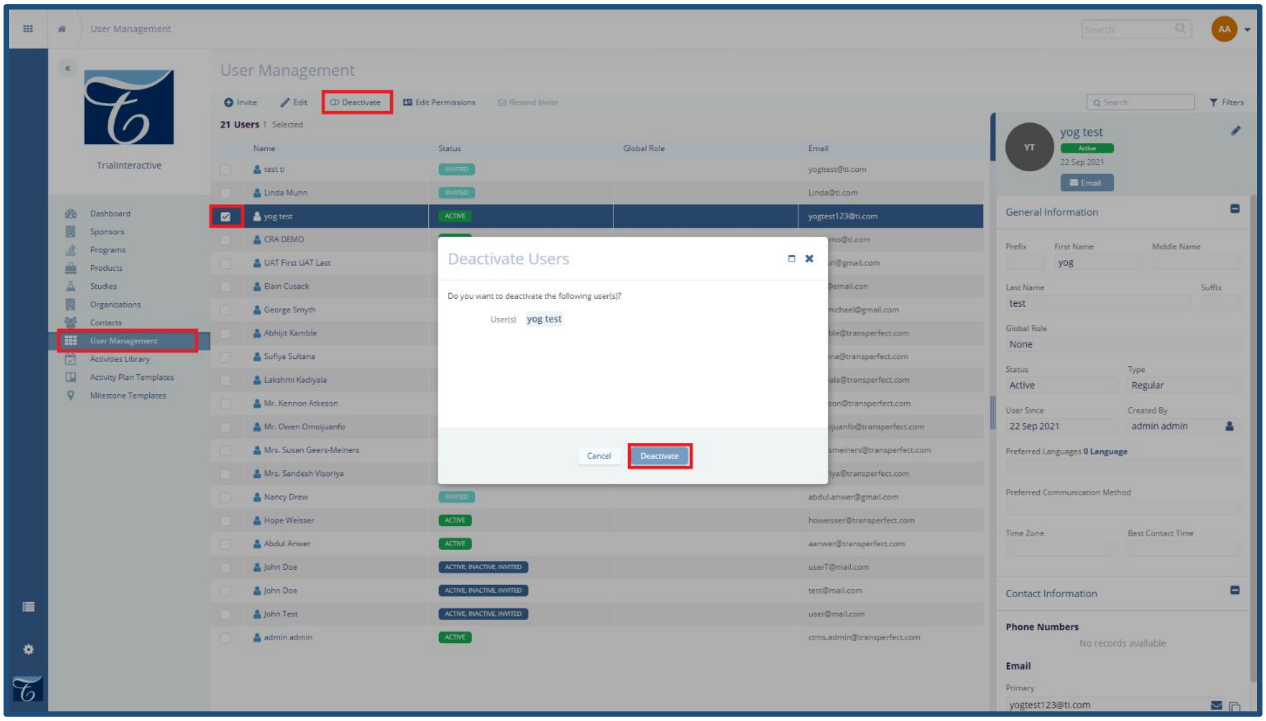
Please note that only study team members listed as Unblinded team members will be able to see unblinded study data where applicable. An Unblinded Clinical Study Manager may assign study team members to Unblinded roles but a Blinded Clinical Study Manager cannot.

12.5 Deactivating a User Account

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

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

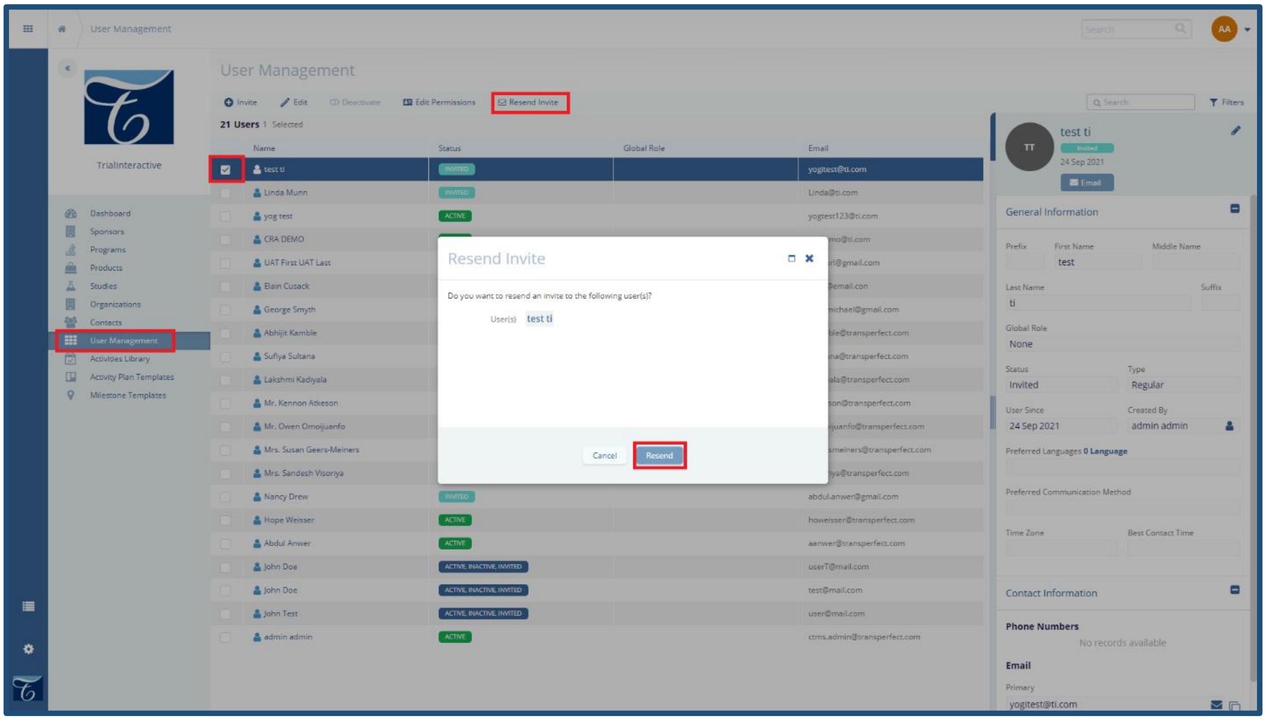
   Note: The reverse of this action can be done to activate a user.



12.6 Resending a User's Invite

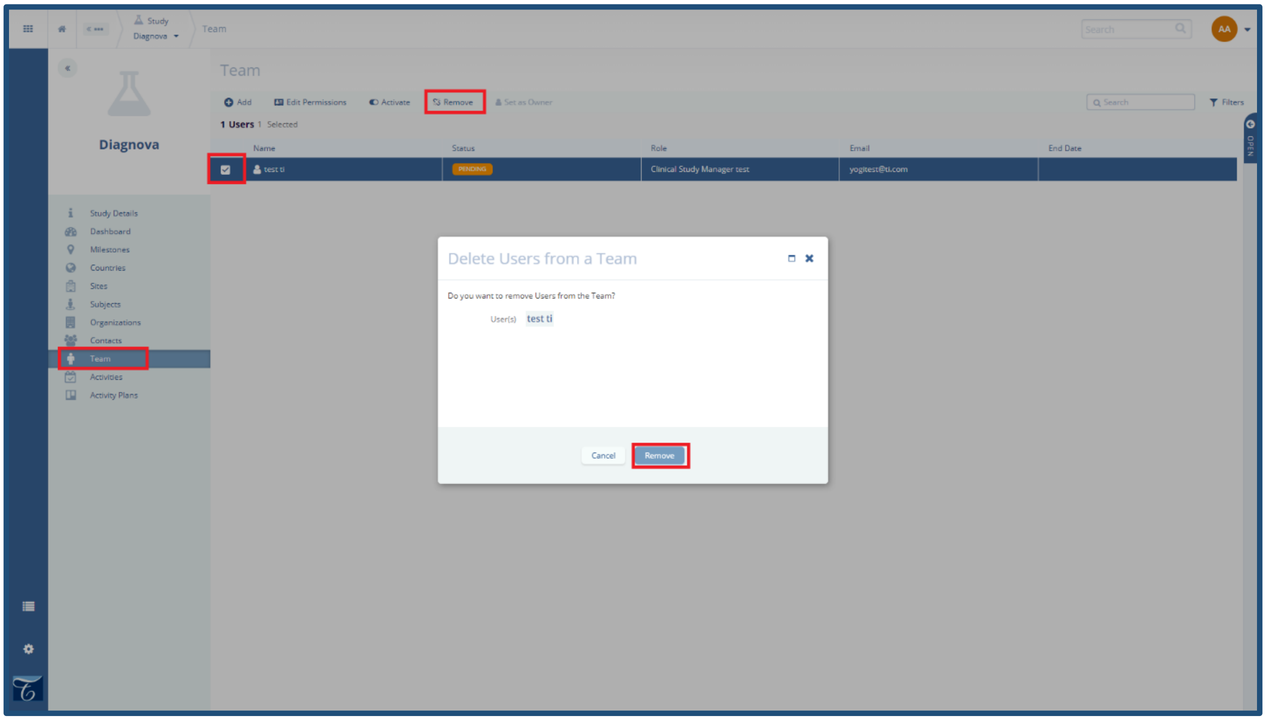
1. Click on the **User Management** link in the Navigation menu at the left side of the screen.
   a. This opens the **User Management** screen.
2. Navigate to the user whose invitation you want to resend and click the check box.
   a. This opens the quick view on the right side of the screen.
3. Click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

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



12.7 Removing Users from a Team list

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


Team
Add
Edit Permissions
Activate
Remove
Set as Owner
1 Users 1 Selected
Name
Status
Role
Email
End Date
test ti
PENDING
Clinical Study Manager test
yogitest@ti.com
Diagnova
Study Details
Dashboard
Milestones
Countries
Sites
Subjects
Organizations
Contacts
Team
Activities
Activity Plans
Delete Users from a Team
Do you want to remove Users from the Team?
User(s) test ti
Cancel
Remove