



TI CTMS USER GUIDE v2.0

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VERSION HISTORY

Author	Revision	Date	Change History
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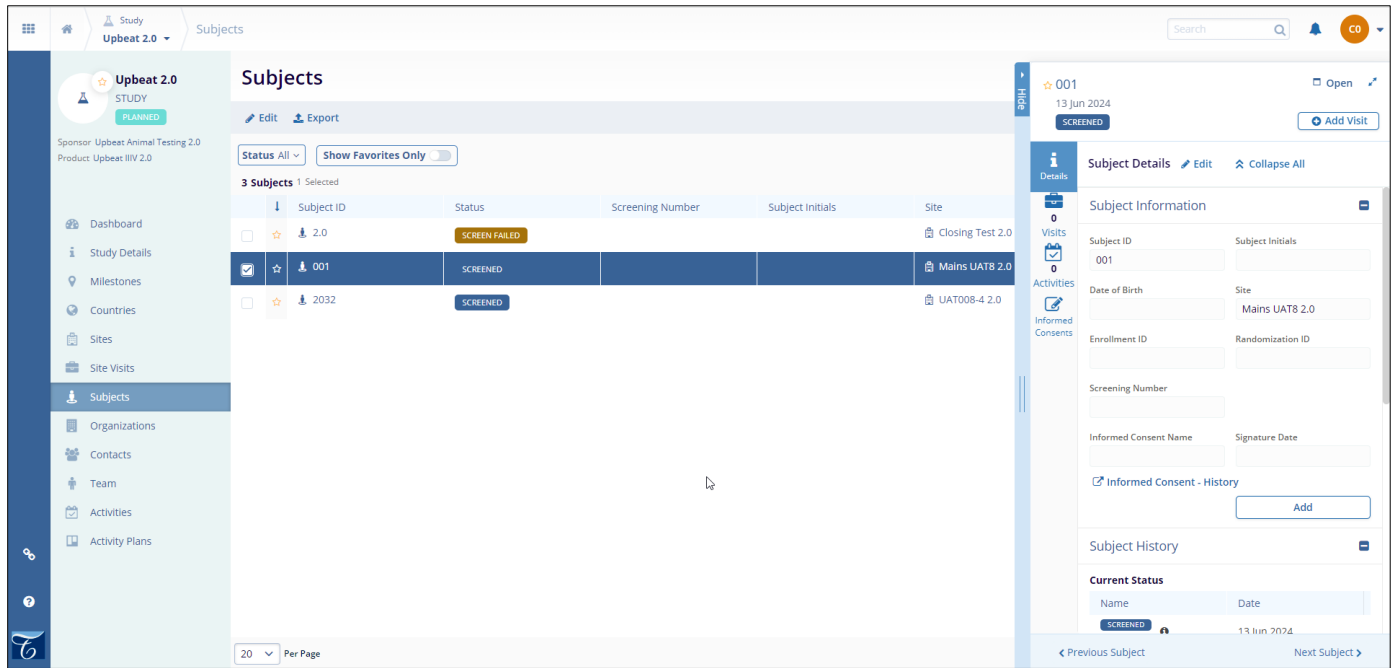
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What's New in CTMS v2.0?

Enhanced Subject Tracking

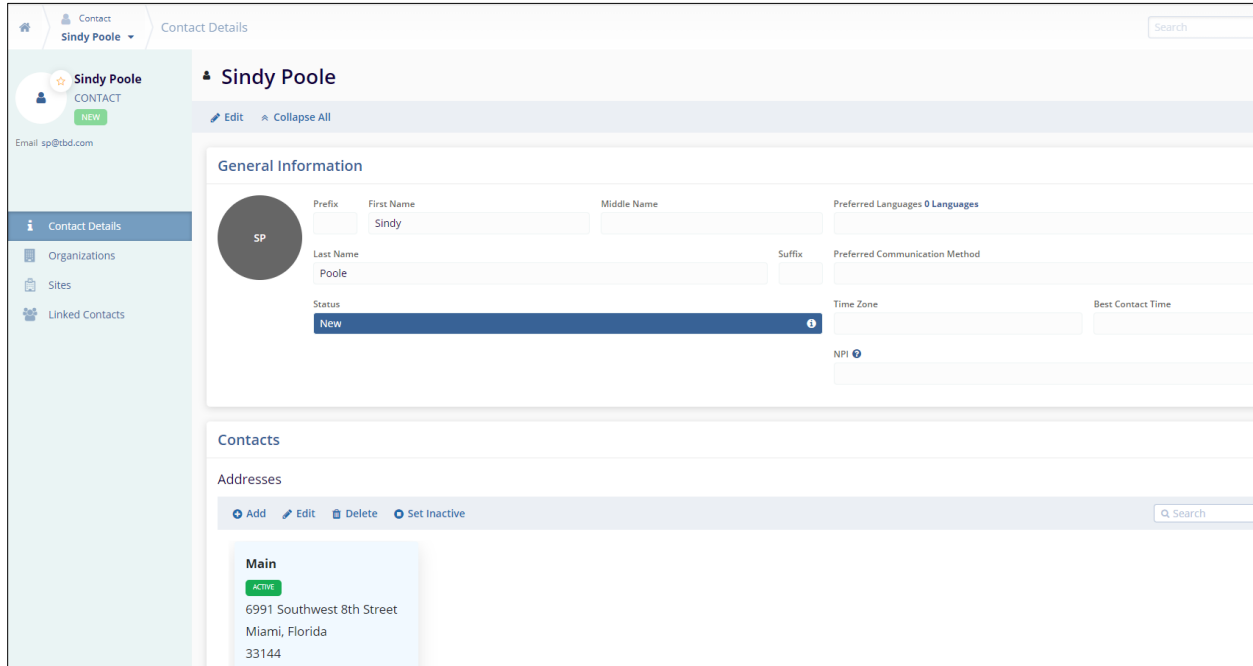
With the release of CTMS 2.0, we are enhancing the subject-tracking functionality to allow for more study-specific tracking capabilities. The aim is to maintain the core subject-tracking features while introducing expanded options for users who require more comprehensive tracking. Key improvements include:

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



New Financial Reference Data Tracking

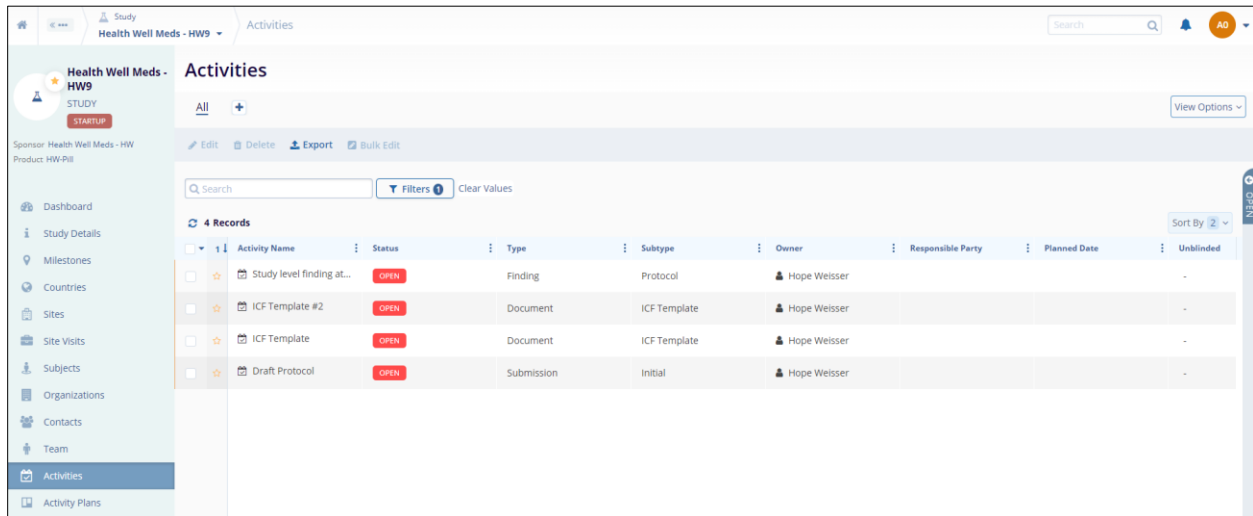
The goal of CTMS 2.0 is to enable the capture of essential financial reference data required for regulatory financial reporting. Regulatory bodies mandate the tracking of key financial information in clinical trials. CTMS 2.0 will allow users to capture and include valuable study-related financial details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



New Field Type - URL

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

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



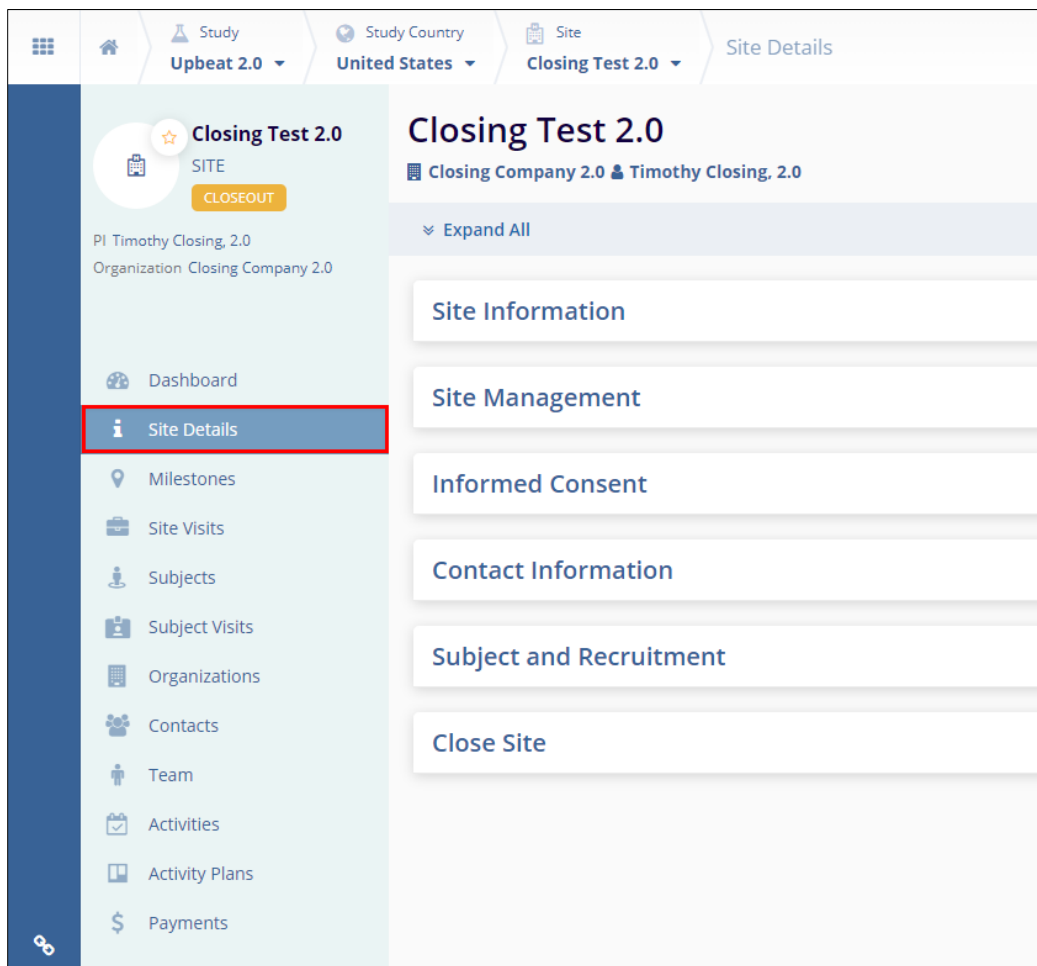
Enhanced Site Detail Tracking

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

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

- Email address
- Phone number
- Fax number

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



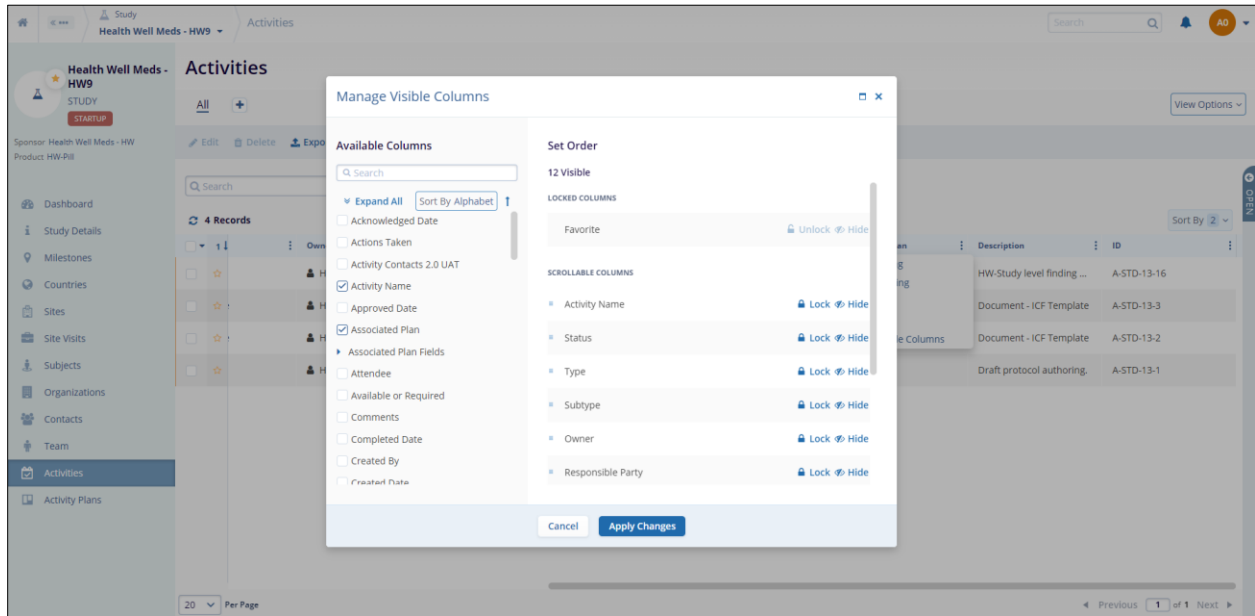
Expanded Custom Save View and Filters

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

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

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

- Global Contacts

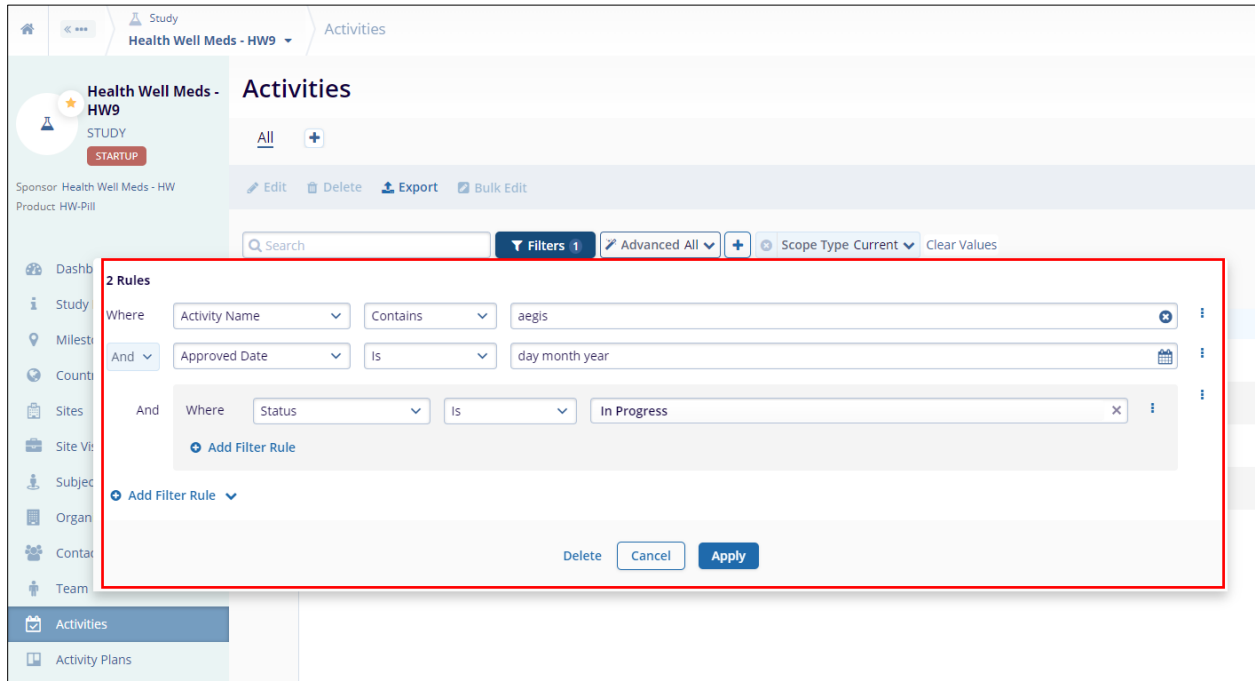


New Advanced Filtering Functionality

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

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

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

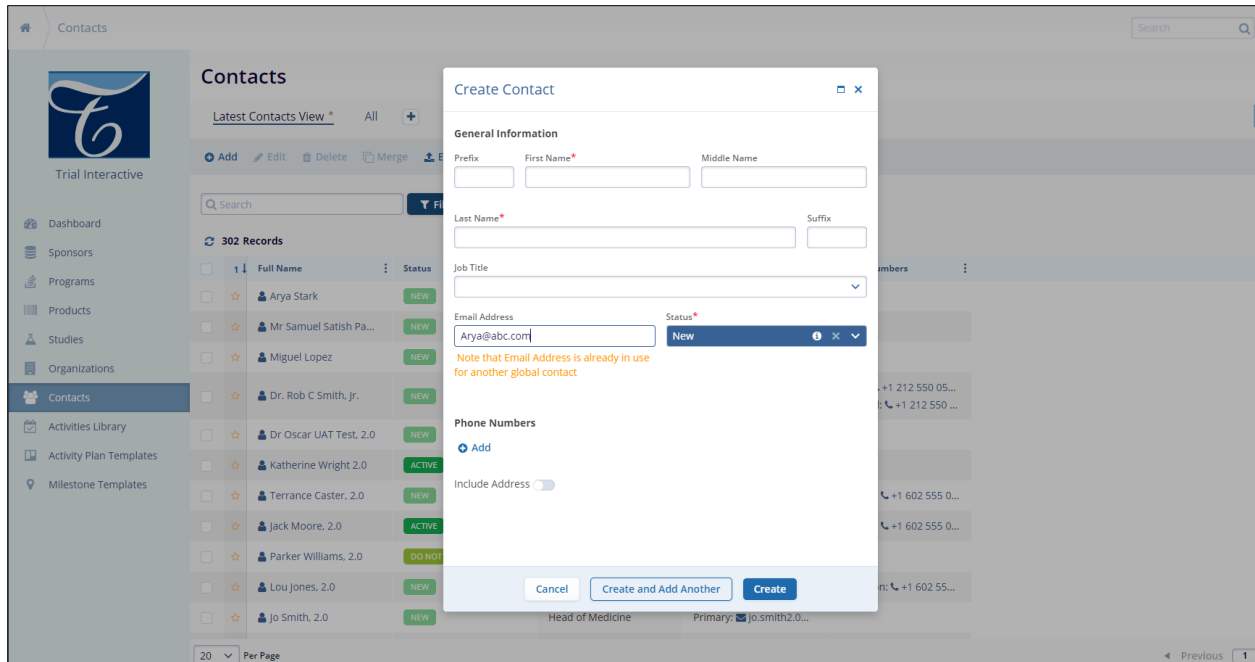


New Deduplication Functionality

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

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

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



Dashboard

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

Accessing Dashboard

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

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



Figure: Accessing Dashboard

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

Dashlets

Top Countries Dashlet

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

A user can perform the following actions on this dashlet.

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

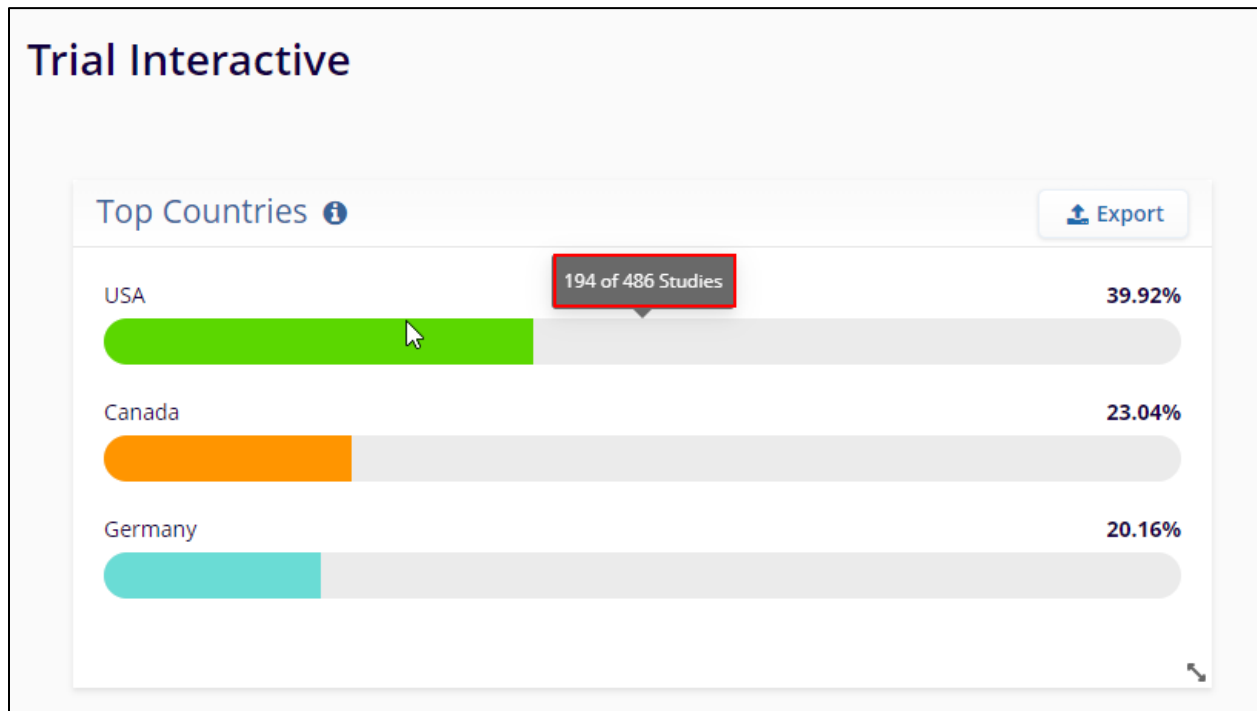


Figure: Top Countries

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

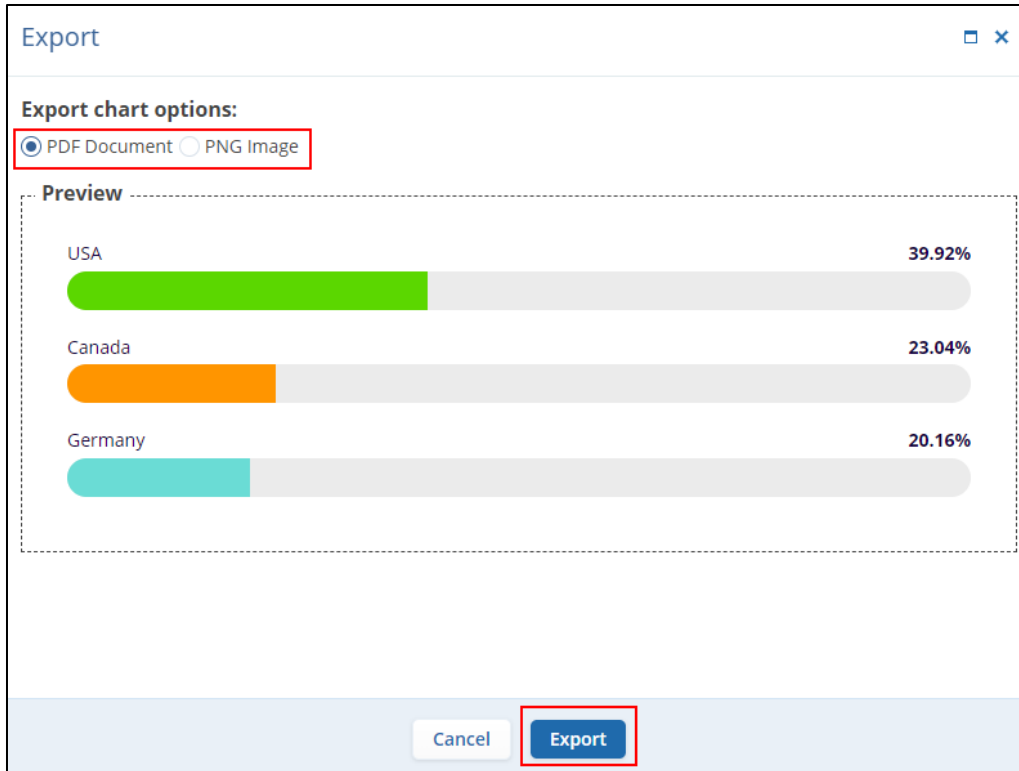


Figure: Export Chart Options

Portfolio Dashlet

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

A user can perform the following actions on this dashlet.

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

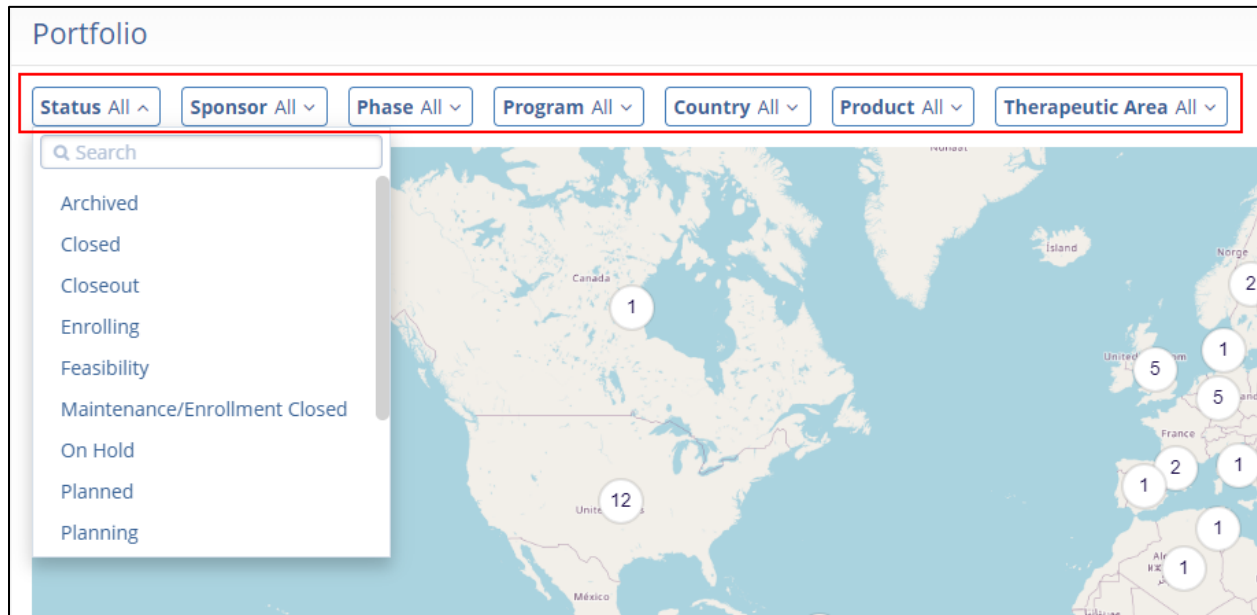


Figure: Portfolio dashlet filters

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

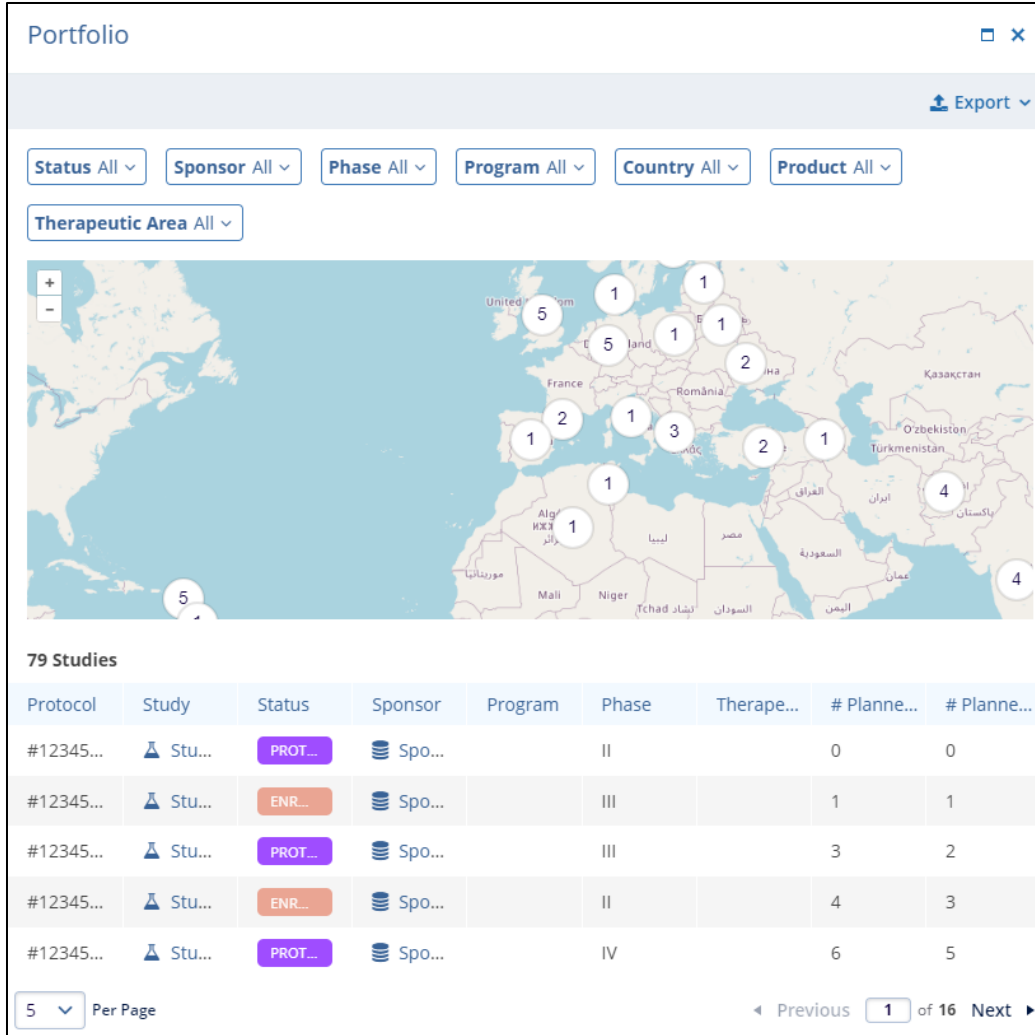


Figure: Expanded Portfolio screen

On this screen, perform the following.

- a. Apply filters by selecting the available options from the filters dropdown.
- b. Click on Export to retrieve an export of the portfolio screen in the Grid or Chart format.
 - i. **Export Grid:** The Export Grid option allows exporting the data in CSV or XLSX file format. Refer to the [Exporting Contacts](#) section to understand the export process in detail.
 - ii. **Export Chart:** The Export Chart option allows exporting the data in PDF Document or PNG Images. Refer to the [Top Countries Dashlet](#) section to understand the process.

Note:

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

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

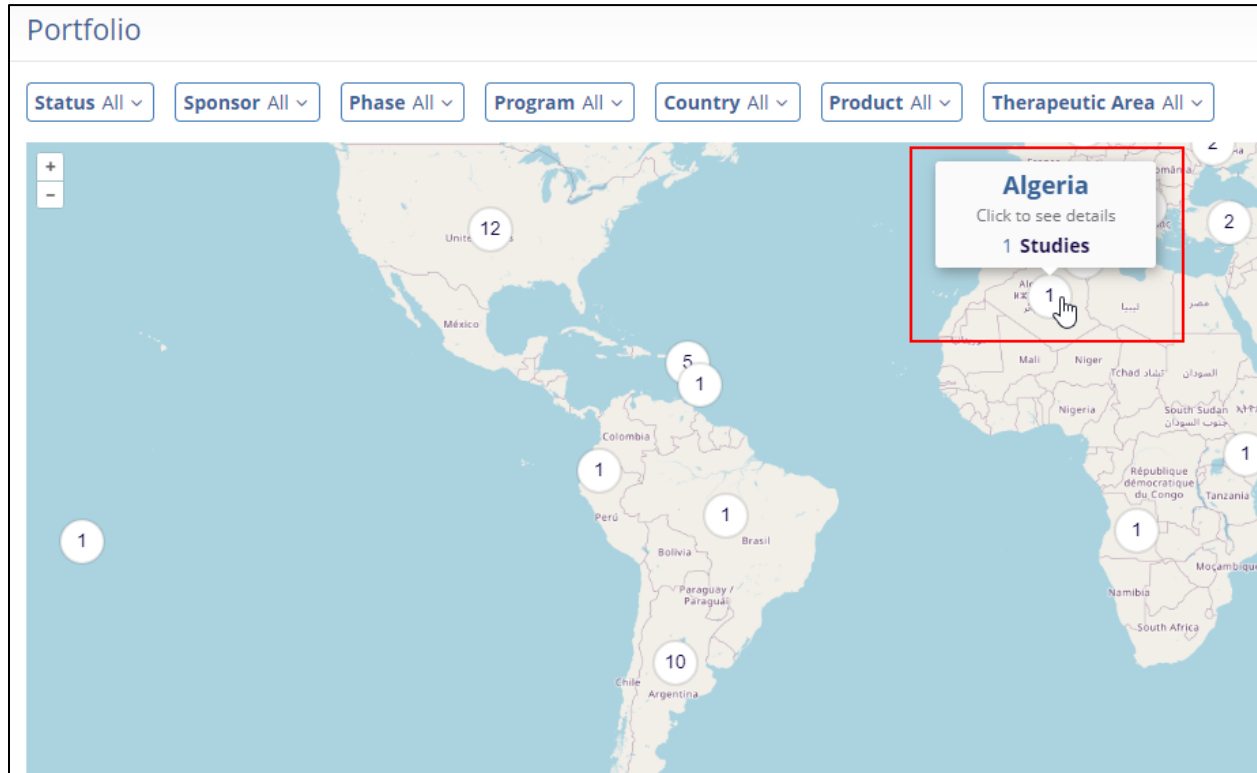


Figure: Country name and number of studies

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

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

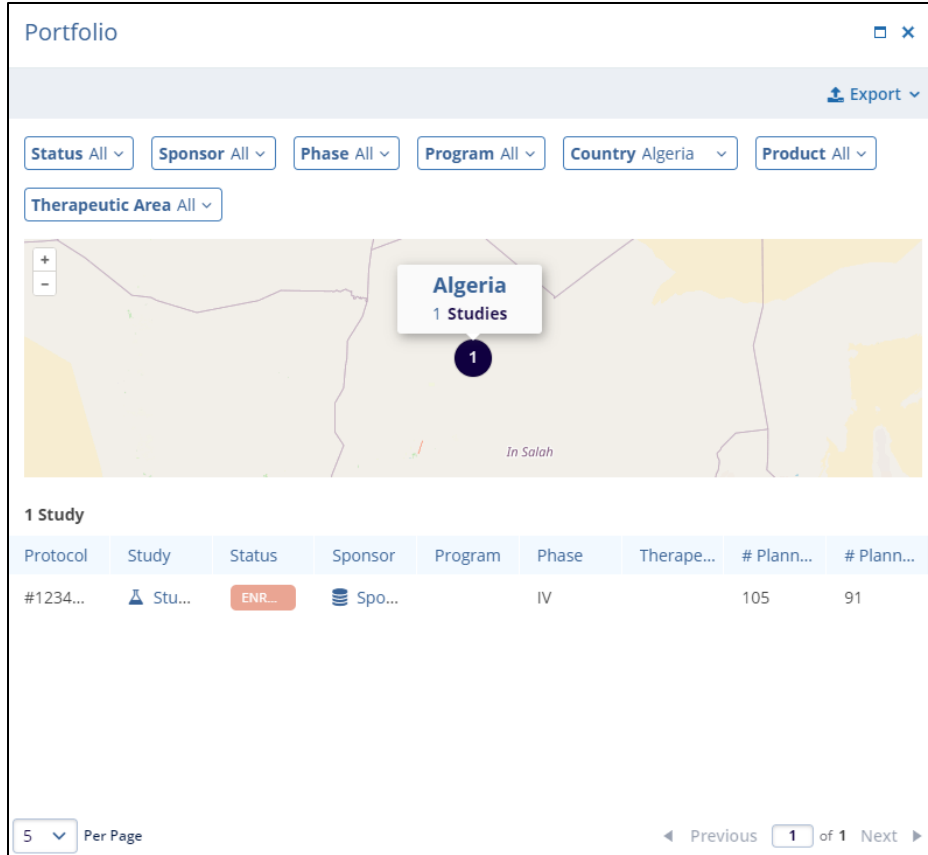


Figure: Study details by individual country

Studies Dashlet

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

A user can perform the following actions on this dashlet.

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

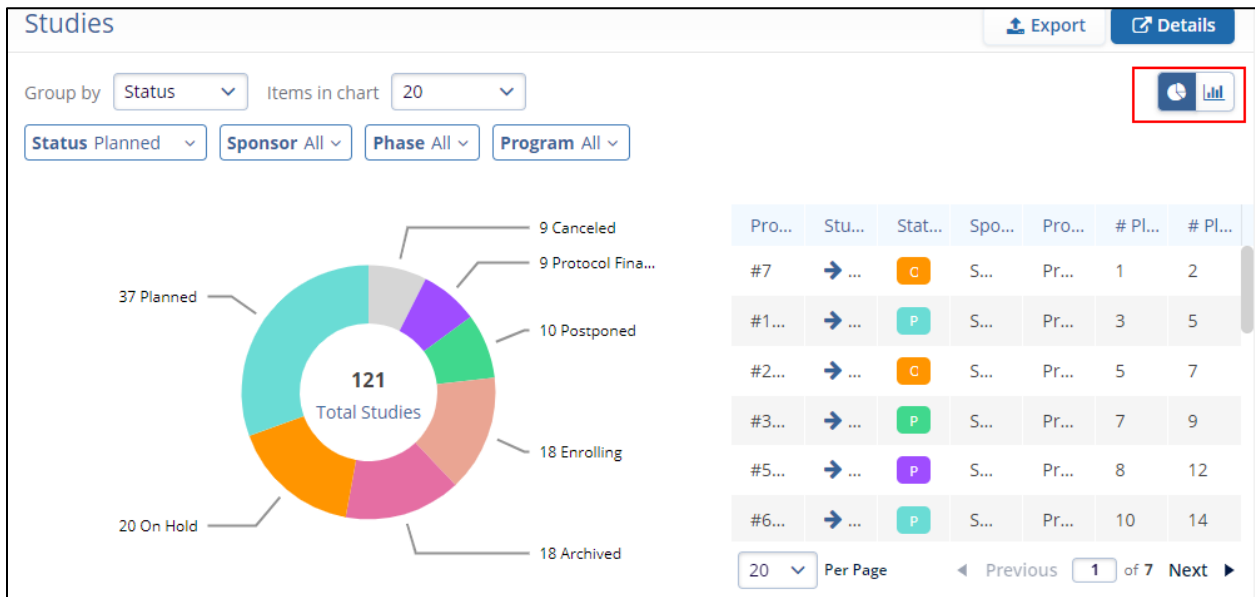


Figure: Select the data visualization type

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

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

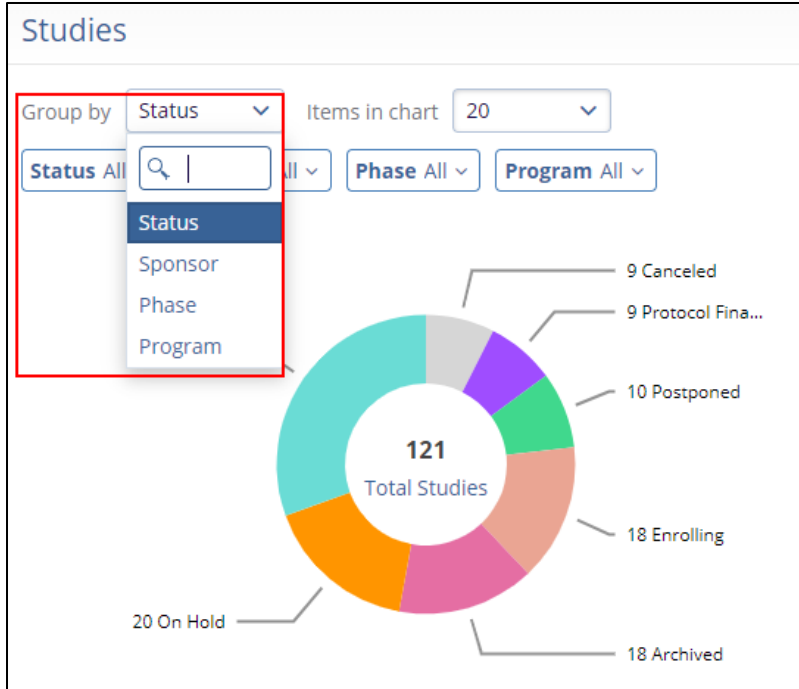


Figure: Grouping pie chart

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

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

Protocol	Study Name	Status	Sponsor	Program	# Planned Trial...	# Planned Subj...
#7	→ Study 0	ON HOLD	Sponsor 8	Program 1	1	2
#131	→ Study 1	PLANNED	Sponsor 1	Program 3	3	5
#255	→ Study 2	ON HOLD	Sponsor 2	Program 5	5	7
#379	→ Study 3	POSTPONED	Sponsor 3	Program 6	7	9
#503	→ Study 4	PROTOCOL F...	Sponsor 1	Program 2	8	12
#627	→ Study 5	PLANNED	Sponsor 3	Program 1	10	14
#751	→ Study 6	CANCELED	Sponsor 4	Program 7	12	16

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Figure: Sort data in ascending and descending order

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

Note:

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

CRA Visit Report Performance Dashlet

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

A user can perform the following on this dashlet.

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

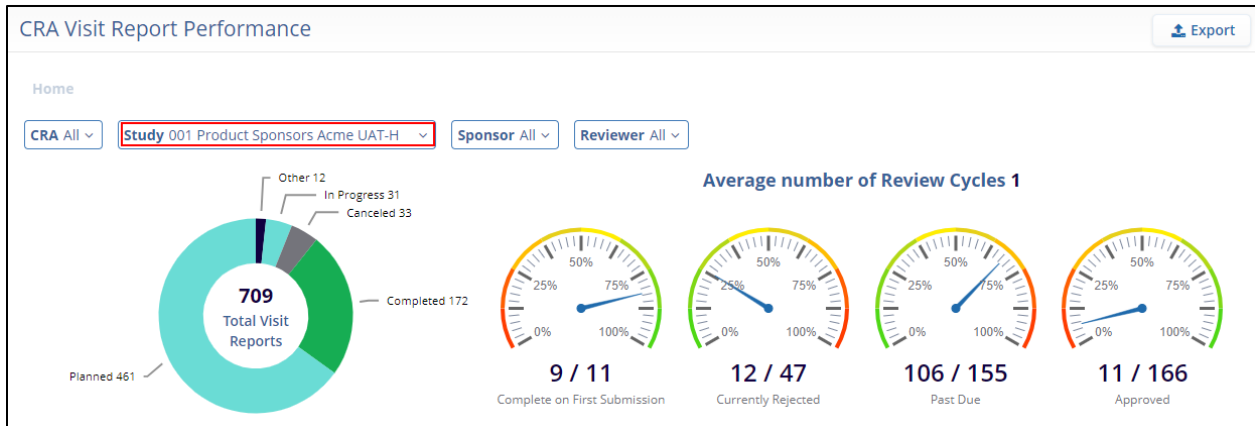
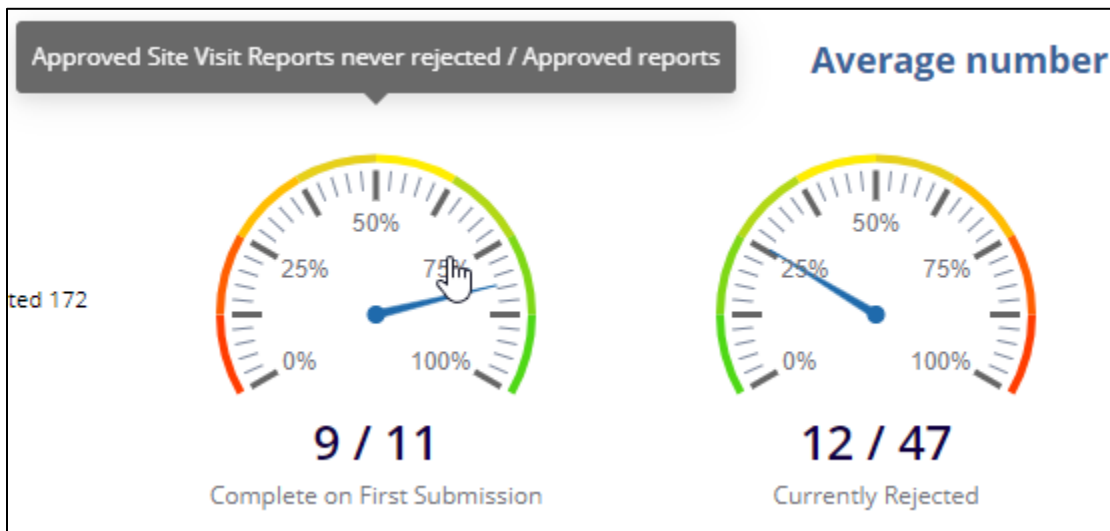


Figure: CRA Visit Report Performance filters

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



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

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

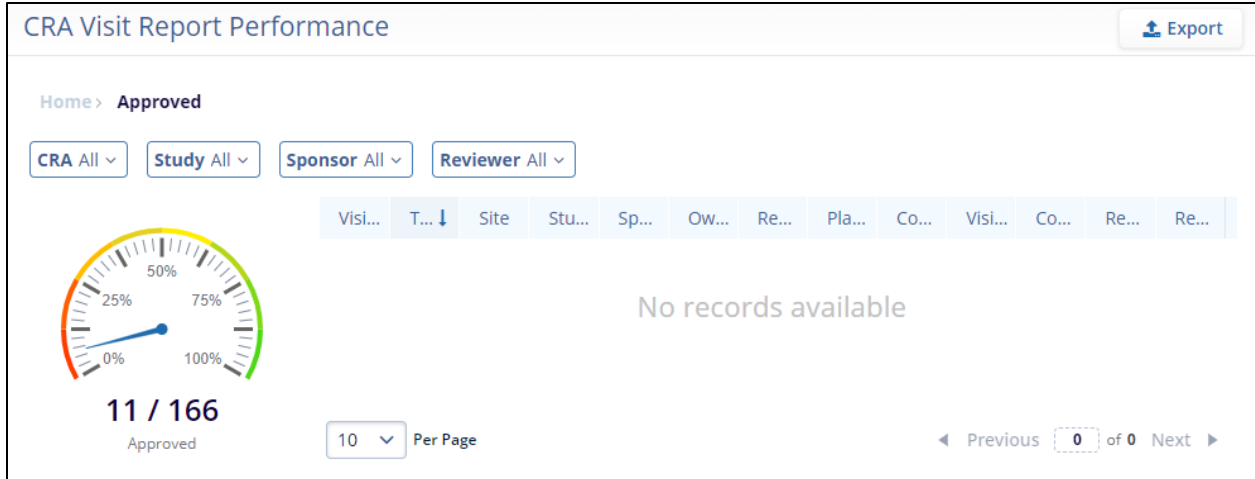


Figure: Tabular view for CRA visit reports

4. Click on the **Export** button to retrieve an export of the current or custom pages. Refer to the [Exporting Contacts](#) section to understand the export process.

Note:

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

Study Dashboards

To access the Study Dashboards, follow the steps below.

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

The Study Dashboard contains the following dashlets

Study Milestone

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



Figure: Study Milestones dashlet

Study Enrolment

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

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

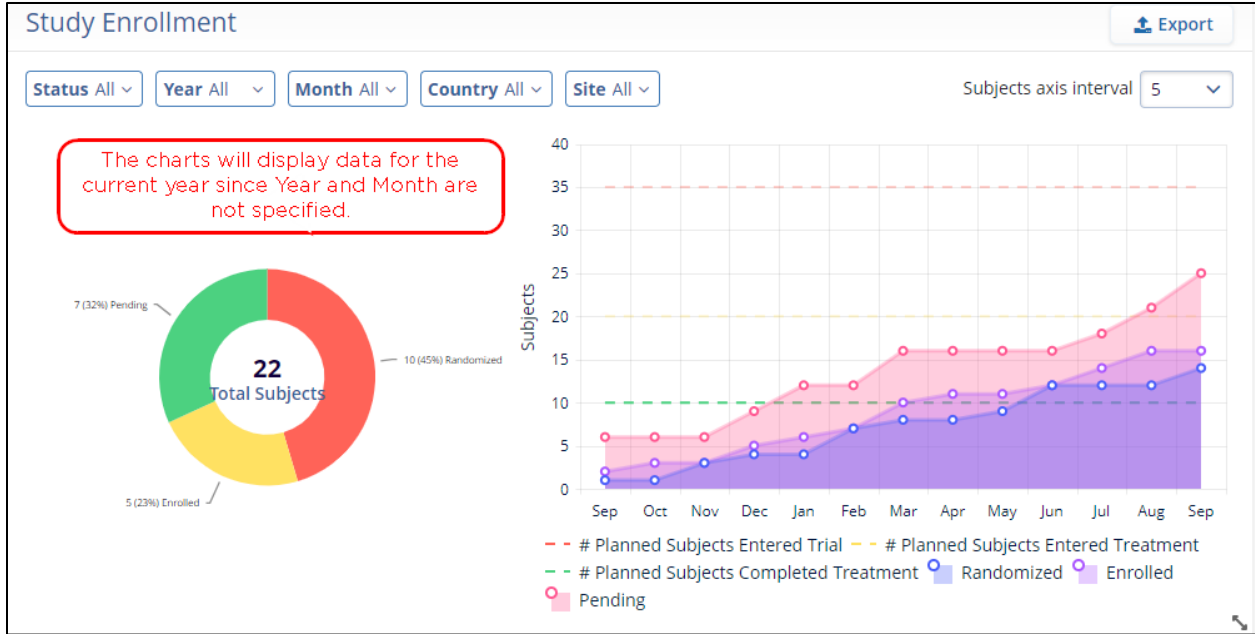


Figure: Study Enrollment dashlet

Study Timeline

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

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

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

3. The date range filters allow specifying a range of dates (From and To) and choosing a predefined viewing period (e.g., 1 week, 1 month, 3 months, 6 months, 1 year) for displaying data within that timeframe.
4. The **Status** and **Classification** filters allow to customize the chart per the filters applied.

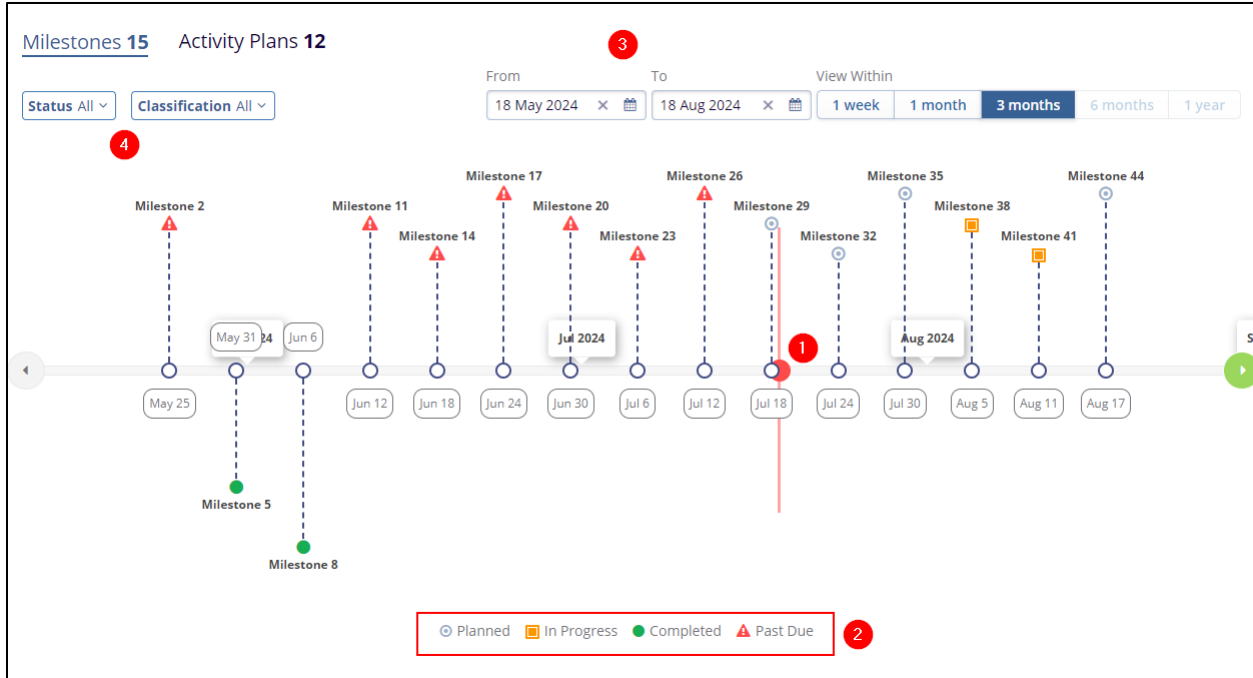


Figure: Study Timeline dashlet

Activities

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

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

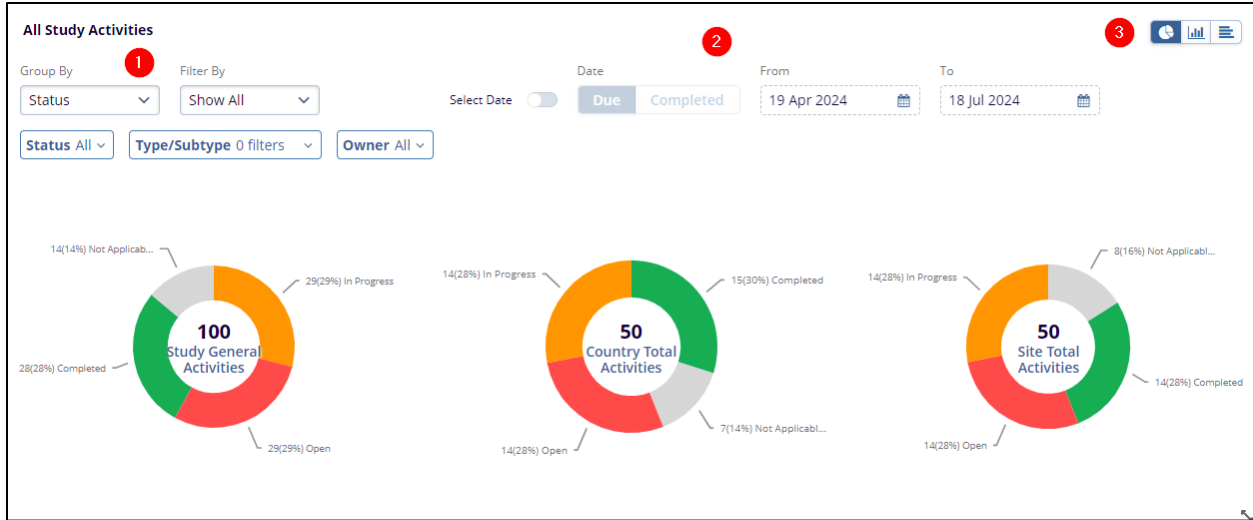


Figure: Activities dashlet

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

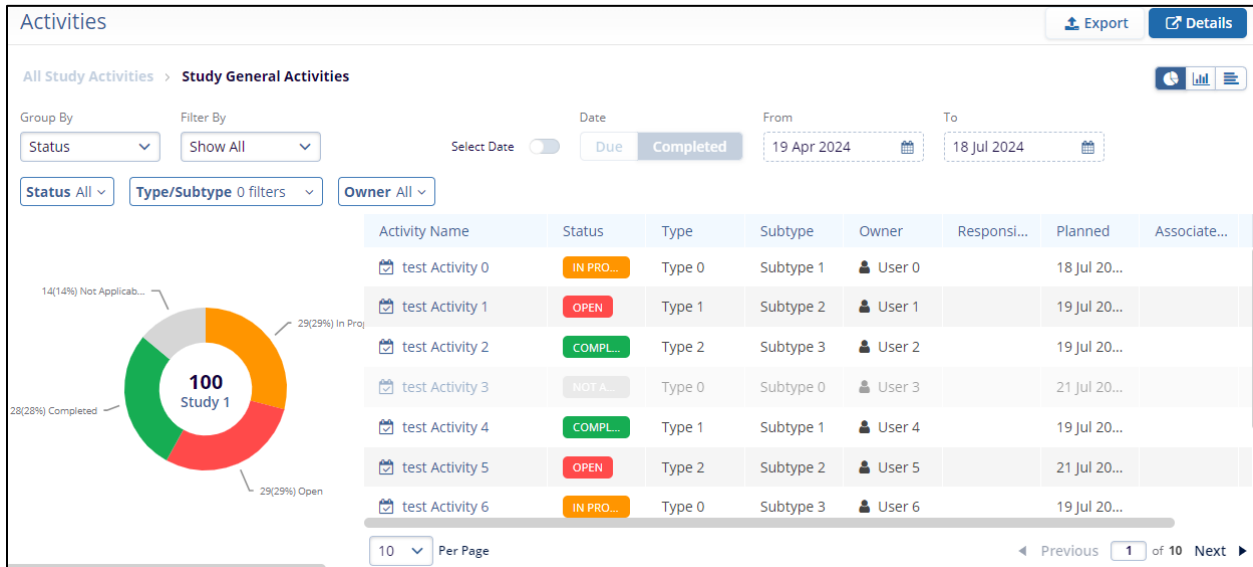


Figure: Study General Activities view

Note:

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

Countries Dashboard

To access the Countries Dashboard, follow the steps below.

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

Country Timeline

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

Refer to the [Study Timeline](#) dashlet which has similar functionalities to the Country Timeline dashlet.

Activities

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

Refer to the [Activities](#) dashlet which has similar functionalities to the Activities dashlet for countries.

Site Dashboard

To access the Countries Dashboard, follow the steps below.

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

Site Timeline

Refer to the [Study Timeline](#) dashlet having similar functionalities to the **Site Timeline** dashlet.

Activities

The Activities dashlet shows customizable visualization of **Sites**.

Refer to the [Activities](#) dashlet having similar functionalities to the Activities dashlet for sites.

Sponsors

Pre-Requisites

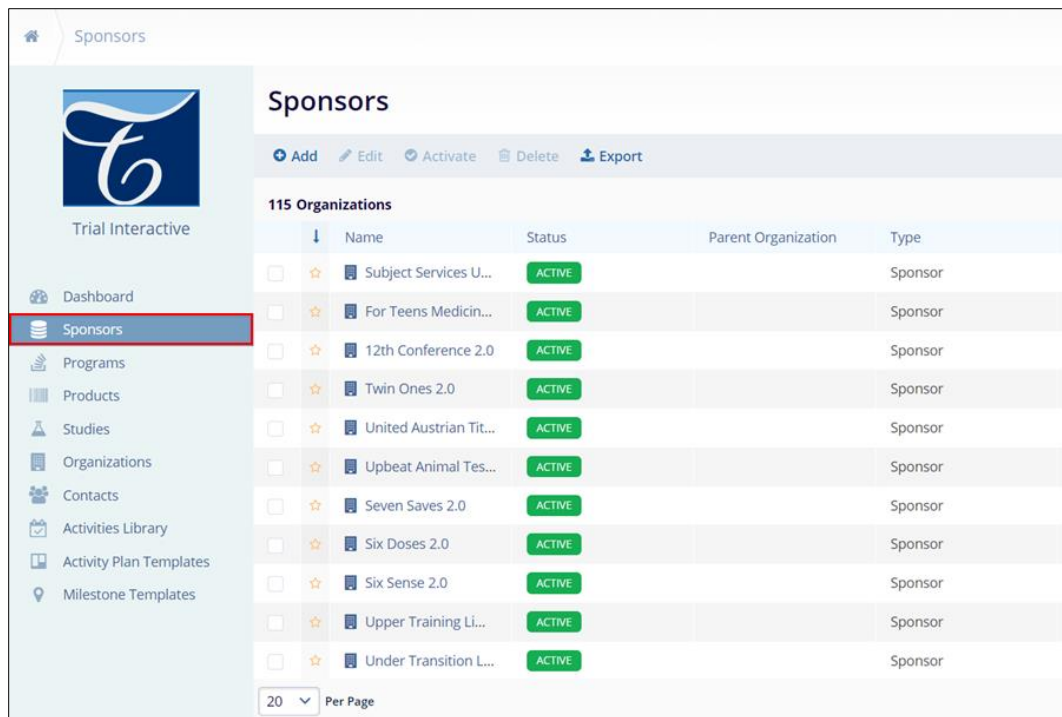
To perform any of the following actions, users must have an account with system access permissions that allow them to **Create, Edit, Activate, Deactivate, Delete, and Export** sponsors:

How to Create a Sponsor:

Navigate to the Sponsor list

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

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

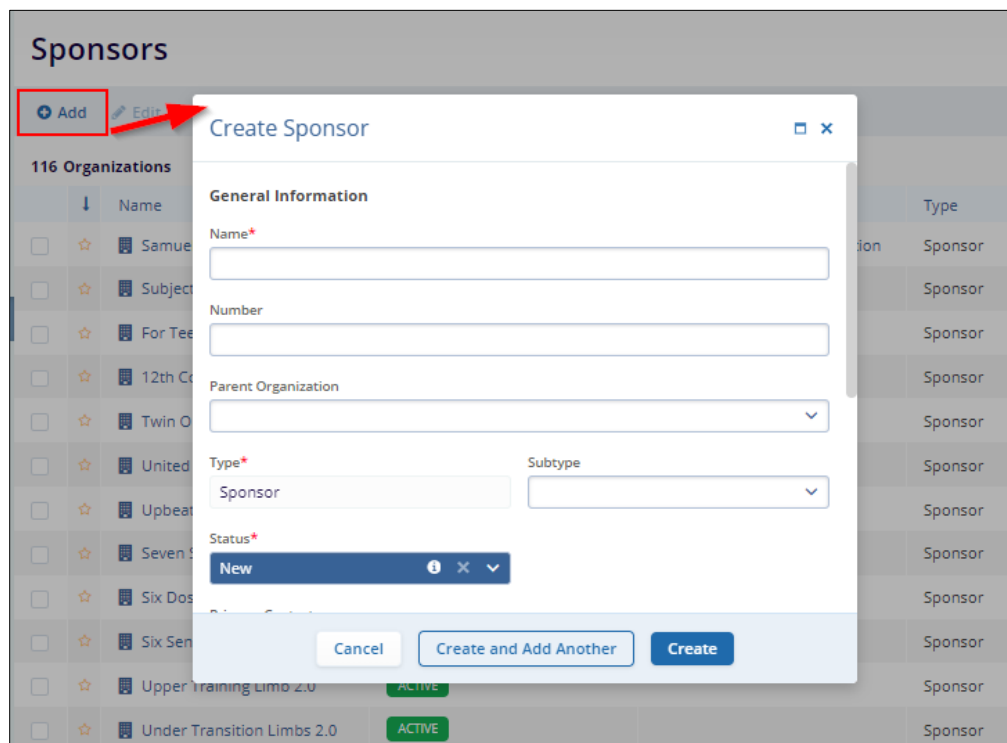


Steps to Add a New Sponsor

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



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



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

Step by Step All fields are explained below:

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

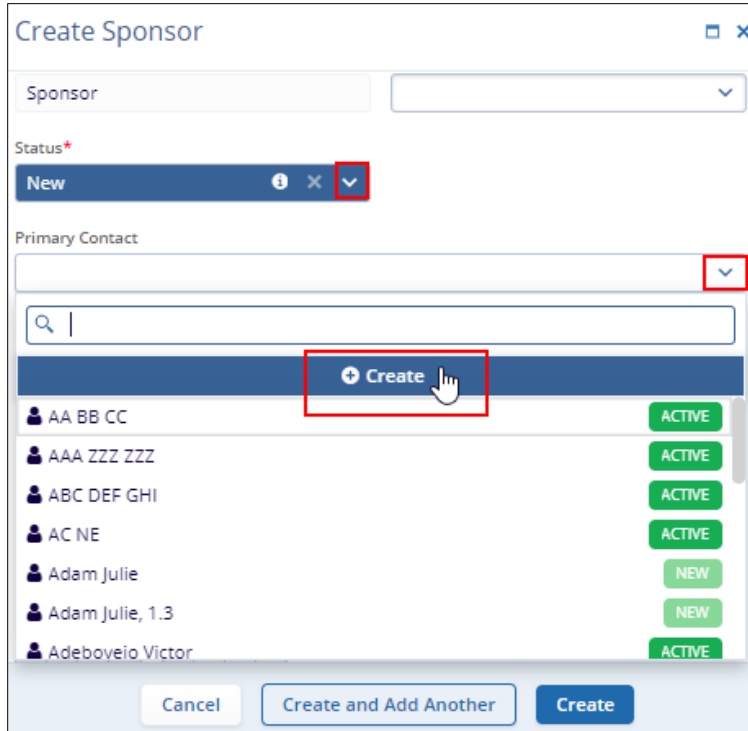
3. **Parent Organization field:** To add an organization to the sponsor, click on the drop-down arrow and select the appropriate organization from the list. To create a New organization, click on the “+Create” button. Refer to the screenshot below.

The screenshot shows a 'Create Sponsor' form with the following fields and elements:

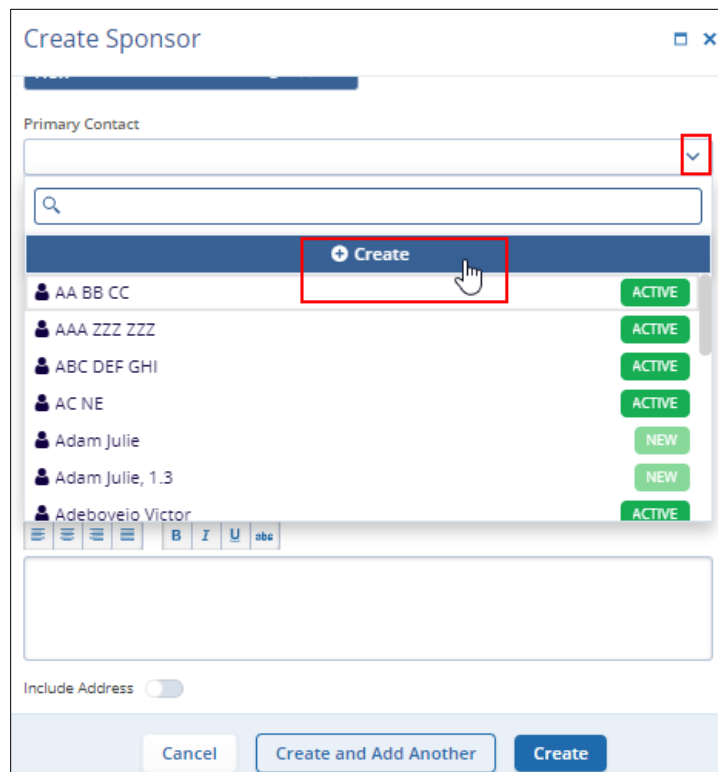
- Name***: Text input field containing 'Arya Stark'.
- Number**: Text input field containing '123456789'.
- Parent Organization**: A dropdown menu with a red box around the arrow icon.
- Search**: A search bar with a magnifying glass icon.
- Organization List**: A list of organizations with a red box around the '+ Create' button. The list includes:
 - 1.3 Therapeutics Clinic (ACTIVE)
 - 1.4 Therapeutics Clinic (ACTIVE)
 - 1.6 Therapeutics Clinic (ACTIVE)
 - 12th Conference 1.4 Sponsor (ACTIVE)
 - 12th Conference 1.5 Sponsor (ACTIVE)
- Buttons**: 'Cancel', 'Create and Add Another', and 'Create' buttons at the bottom.

Note: To learn How to Create an Organization. [Click here.](#)

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



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



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

The screenshot shows the 'Create Sponsor' form with the following fields and options:

- Phone:** A dropdown menu set to 'Primary', a country dropdown set to '+1', a text input field containing '123-456-7890', and an 'Ext' field.
- Emails:** A dropdown menu set to 'Primary' and a text input field containing 'Arya@.com'.
- Notes:** A rich text editor with a toolbar containing icons for bold (B), italic (I), underline (U), and text color (abc).
- Include Address:** A toggle switch currently turned off.
- Buttons:** 'Cancel', 'Create and Add Another', and 'Create'.

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

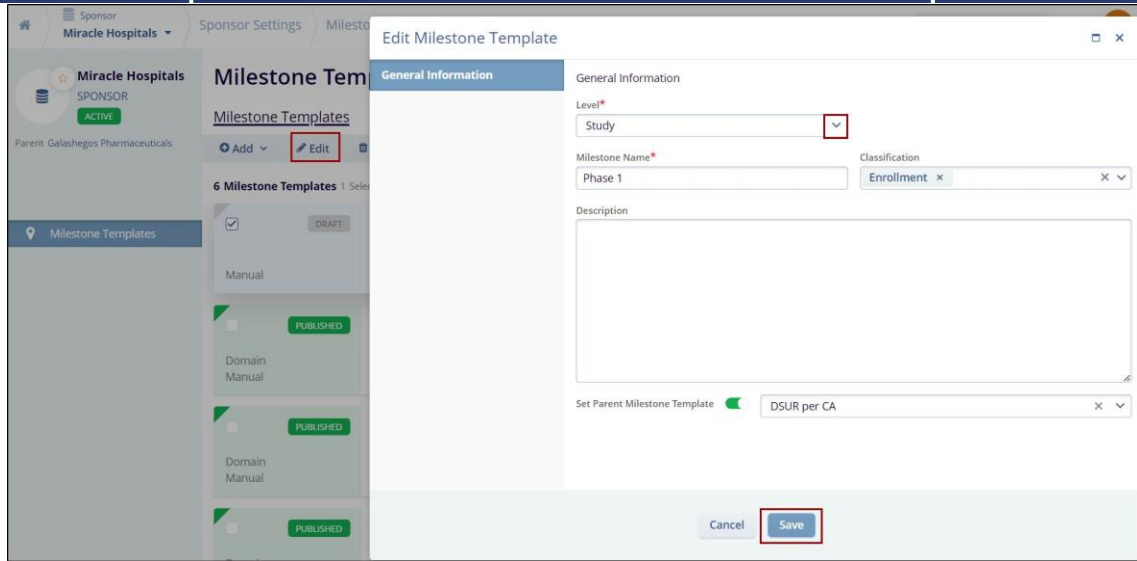
The screenshot shows the 'Create Sponsor' form with the 'Include Address' toggle turned on, revealing the following address-related fields:

- Address Information:** A dropdown menu set to 'Primary'.
- Search:** A search bar with the placeholder text 'Enter address and press Return'.
- Primary Address:** A text input field containing 'ABC Hill, Street 12345'.
- Address Line 2:** An empty text input field.
- Address Line 3:** An empty text input field.
- Town/City:** An empty text input field.
- Province/State:** An empty text input field.
- Country:** A dropdown menu set to 'India'.
- Postal Code:** A text input field containing '12345678'.
- Buttons:** 'Cancel', 'Create and Add Another', and 'Create'.

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

12. **Search Address:** Click on the search icon to search for the address and enter your address it will show you an auto-populated list.
13. After filling in all required fields, you have three options at the bottom of the form.
 - **Create:** Saves the new organization and closes the screen.
 - **Create and Add Another:** Saves the new organization and opens a new screen to add another organization.
 - **Cancel:** Discards the information and closes the screen.
14. When the user clicks on the “**Create**” button. This action will create a sponsor and it will display a successfully created pop-up. The created sponsor can also be seen in the grid. Refer to the screenshot below.

The screenshot shows a 'Sponsors' grid with a success message at the top right. The success message reads: 'Success The Record is successfully created'. The grid contains 117 organizations. The first row, 'Arya Stark', is highlighted with a red box. This record has a status of 'NEW', a parent organization of 'Star Plus Hospital', and a type of 'Sponsor'. Other records in the grid include 'Samuel Sponsor Testing', 'Subject Services UAT', 'For Teens Medicine 2.0', '12th Conference 2.0', 'Twin Ones 2.0', 'United Austrian Titrations ...', 'Upbeat Animal Testing 2.0', 'Seven Saves 2.0', 'Six Doses 2.0', 'Six Sense 2.0', 'Upper Training Limb 2.0', 'Under Transition Limbs 2.0', 'Research Inc. 2.0', 'United Talent for Medicine ...', 'Pro CRO', 'Sneha S J', 'Training Sponsor20', 'Lucrezia Cassetti', and 'Astra Whenecca'. The grid also shows columns for Name, Status, Parent Organization, Type, Subtype, and Primary Contact. At the bottom, there is a 'Per Page' dropdown set to 20 and a pagination control showing '1 of 6'.



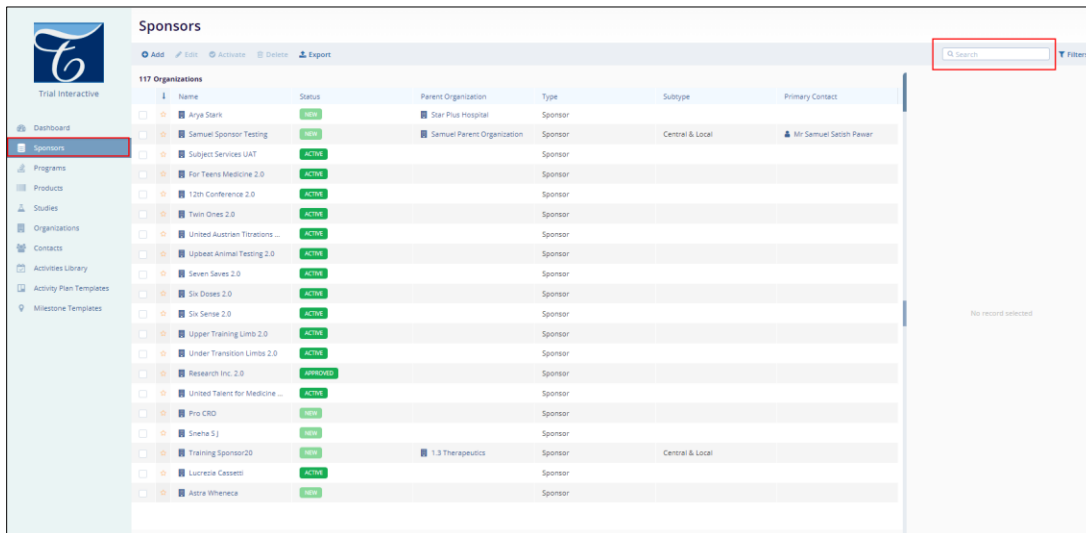
Note: Editing a sponsor follows the same process as editing an organization. Refer to the "How to Edit an Organization" section, To Edit a Sponsor. [Click here](#)

How to Search for a Sponsor

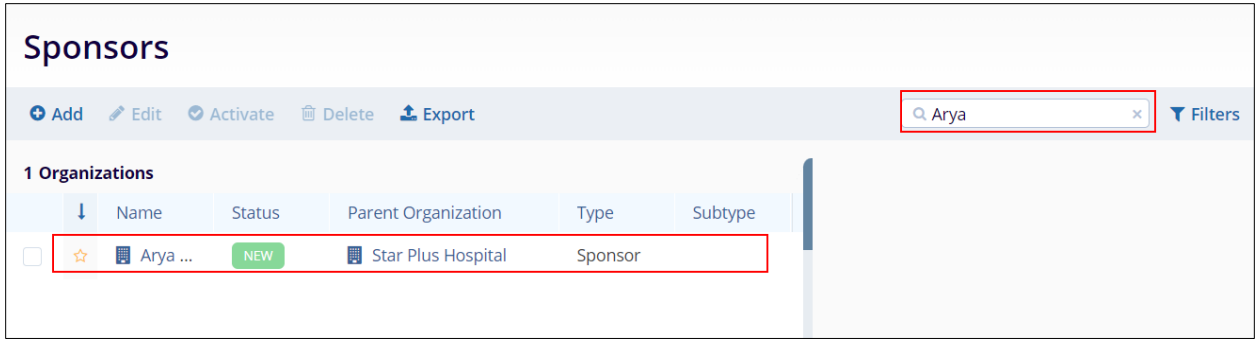
To learn how to navigate to the Sponsor list. [Click here](#)

Steps to search for a sponsor

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



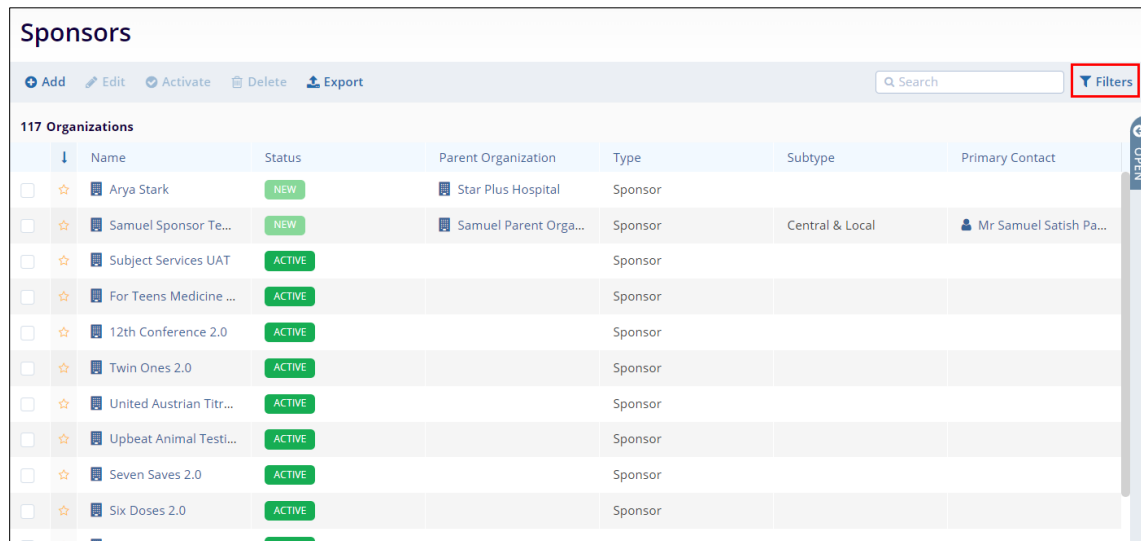
- To search for the sponsor, Enter the Sponsor's name or a related keyword into the search bar.
- The user does not need to press the enter button. It will automatically show all related results. Refer to the below screenshot.



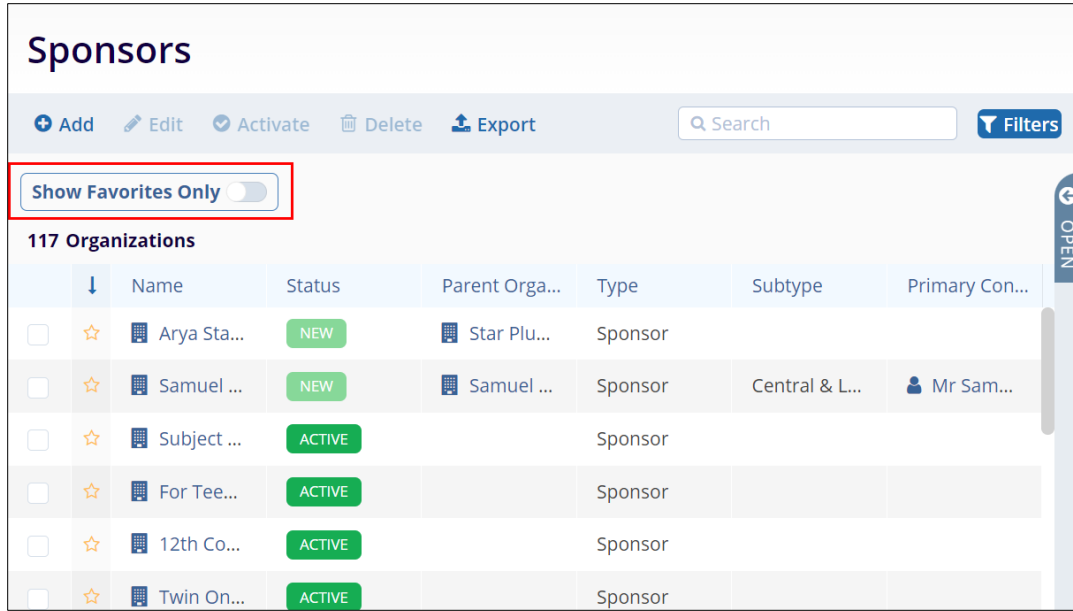
Steps to Apply Filter

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

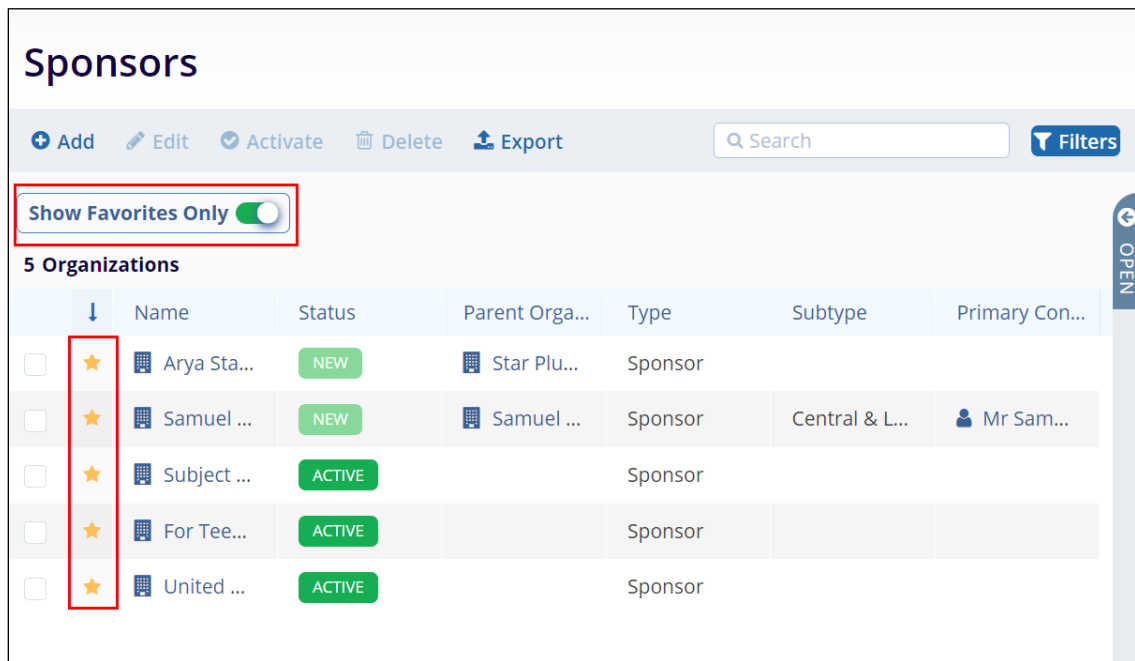
1. From the sponsor main menu in the top right corner, click on the “Filter” button to apply filters. Refer to the screenshot below.



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



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



How to Add and Remove Favorites

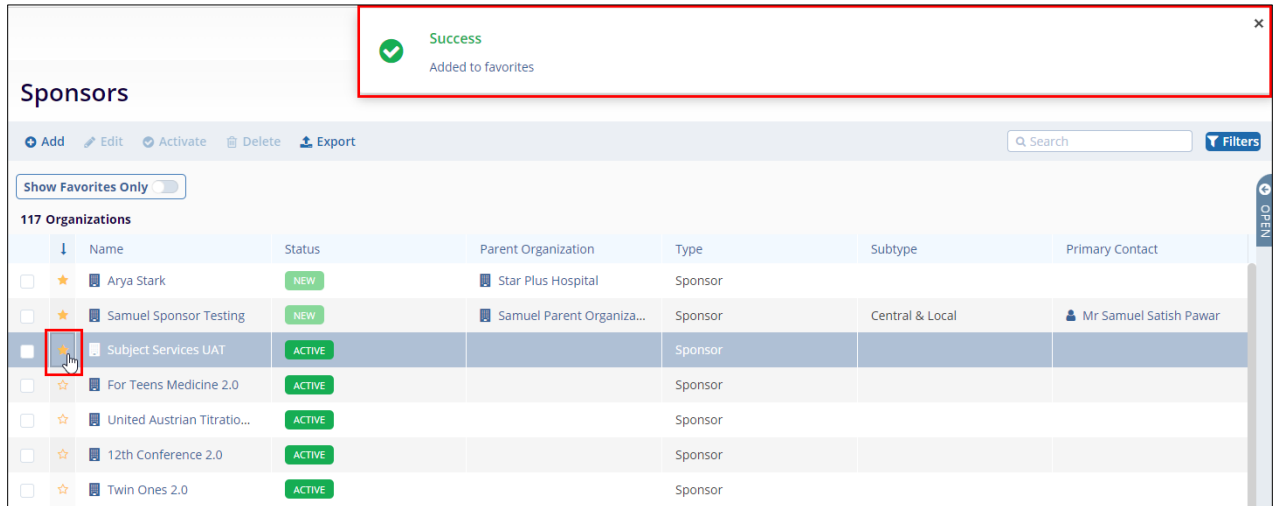
To learn how to navigate to the Sponsor list. [Click here](#)

Steps to add Favorites to the sponsors.

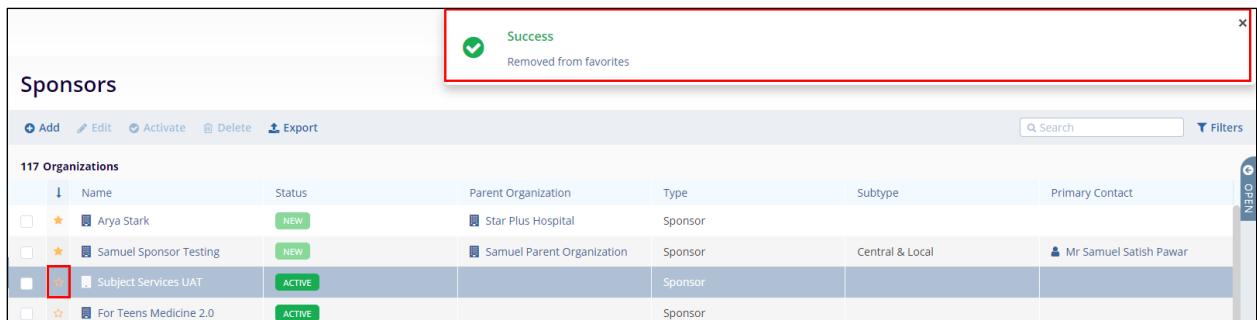
- Click the “Star” symbol next to the sponsor’s name to add a favorite to the sponsor. Refer to the screenshot below.



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



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



How to Activate A Sponsor

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

Steps to Activate a Sponsor

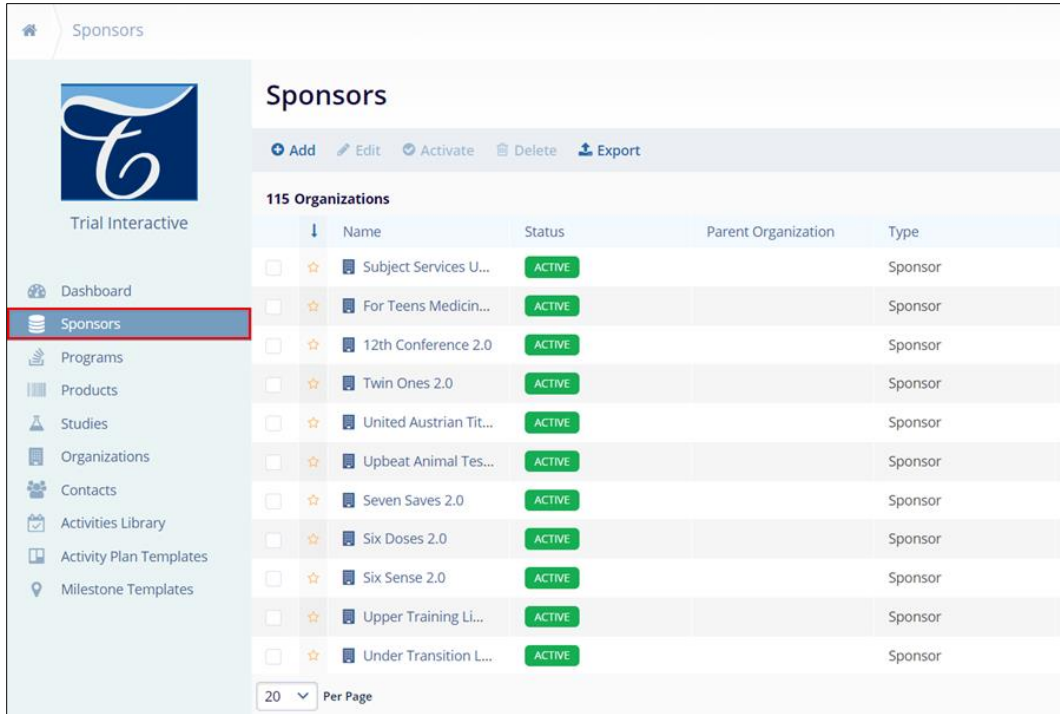
1. Select the sponsor, that the user needs to Activate the sponsor and click on the

Sponsors				
+ Add ✎ Edit 🔘 Activate 🗑 Delete 📄 Export				
117 Organizations 1 Selected				
	Name	Status	Parent Organization	Type
<input checked="" type="checkbox"/>	★ Arya Stark	NEW	Star Plus Hospital	Sponsor
<input type="checkbox"/>	★ Samuel Sponsor Testing	NEW	Samuel Parent Organization	Sponsor
<input type="checkbox"/>	★ Subject Services UAT	ACTIVE		Sponsor
<input type="checkbox"/>	★ For Teens Medicine 2.0	ACTIVE		Sponsor
<input type="checkbox"/>	★ 12th Conference 2.0	ACTIVE		Sponsor
<input type="checkbox"/>	★ Twin Ones 2.0	ACTIVE		Sponsor
<input type="checkbox"/>	★ United Austrian Titrations 10...	ACTIVE		Sponsor
<input type="checkbox"/>	★ Upbeat Animal Testing 2.0	ACTIVE		Sponsor
<input type="checkbox"/>	★ Seven Saves 2.0	ACTIVE		Sponsor
<input type="checkbox"/>	★ Six Doses 2.0	ACTIVE		Sponsor
<input type="checkbox"/>	★ Six Sense 2.0	ACTIVE		Sponsor

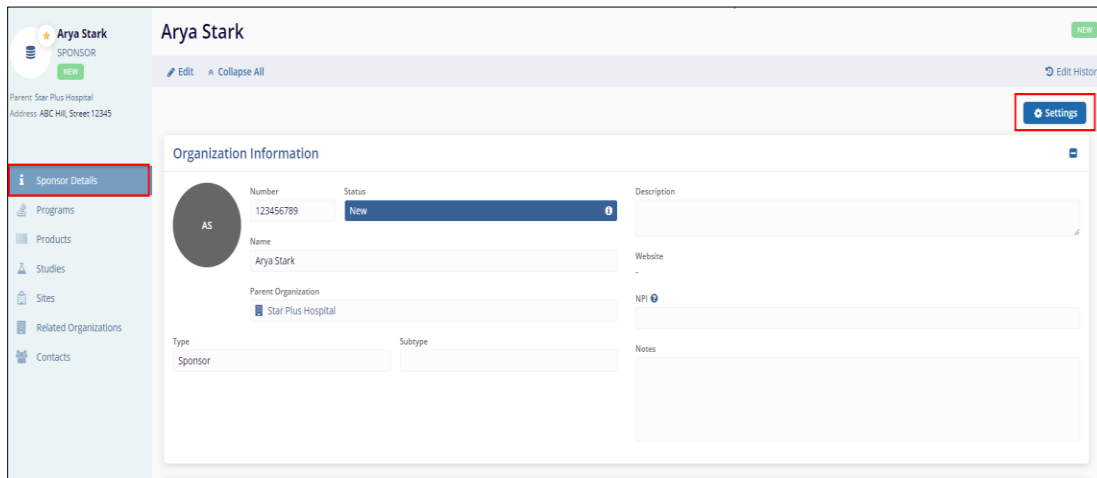
Defining Sponsor Settings

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

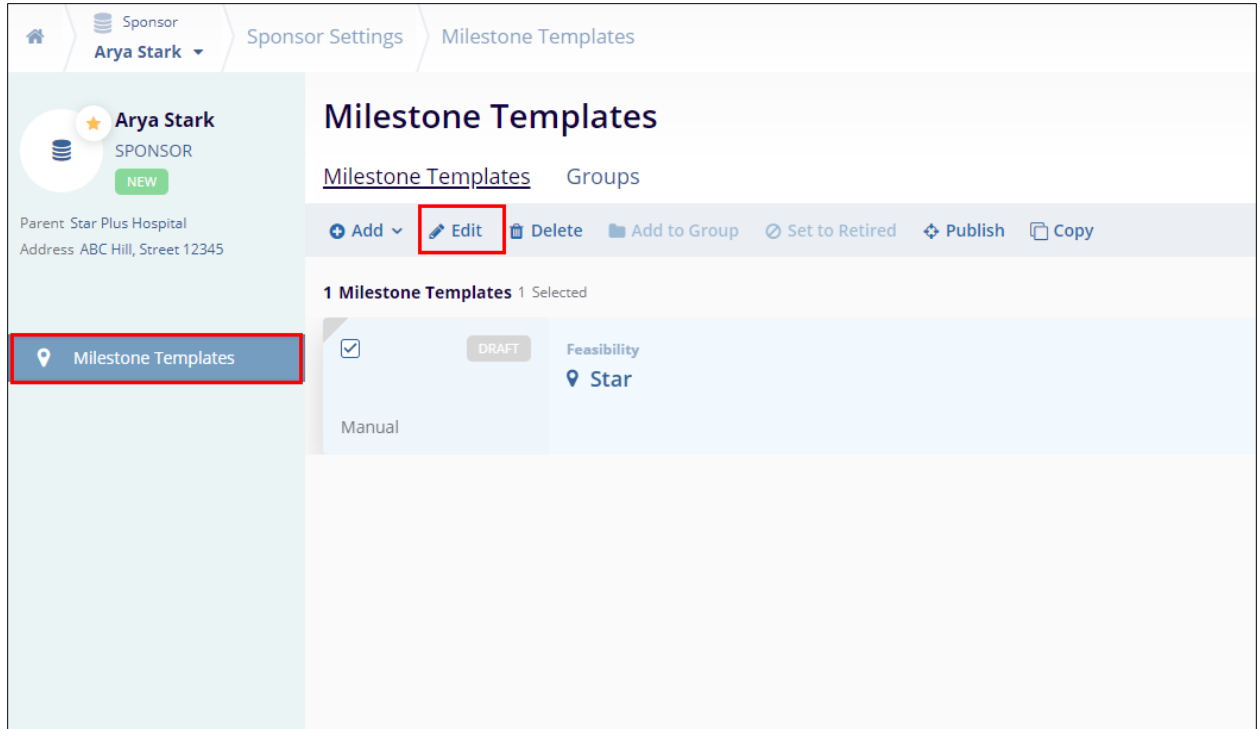
1. Click on the "Sponsor" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Sponsor" grid view where all Sponsors at the global level are displayed.



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

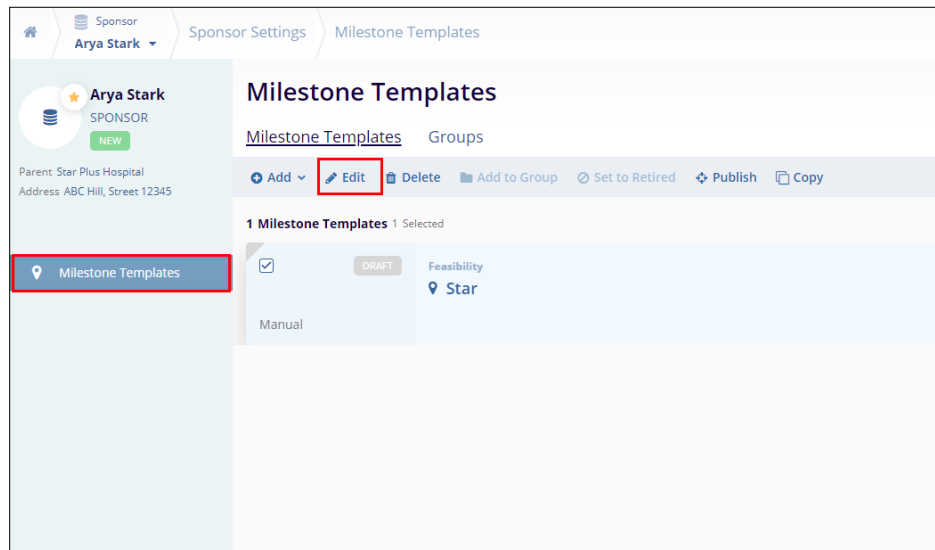


- Click on the "Setting" button in the top-right of the screen. This will redirect you to the "Sponsor Settings"-> Milestone Template's" screen.
- Click on the Edit button for the milestone you want to edit.



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

6. This opens the **Edit Milestone Template** window.



7. As per the requirement, the user can make necessary changes in the milestone templates.

8. Click **Save** for the changes to apply.

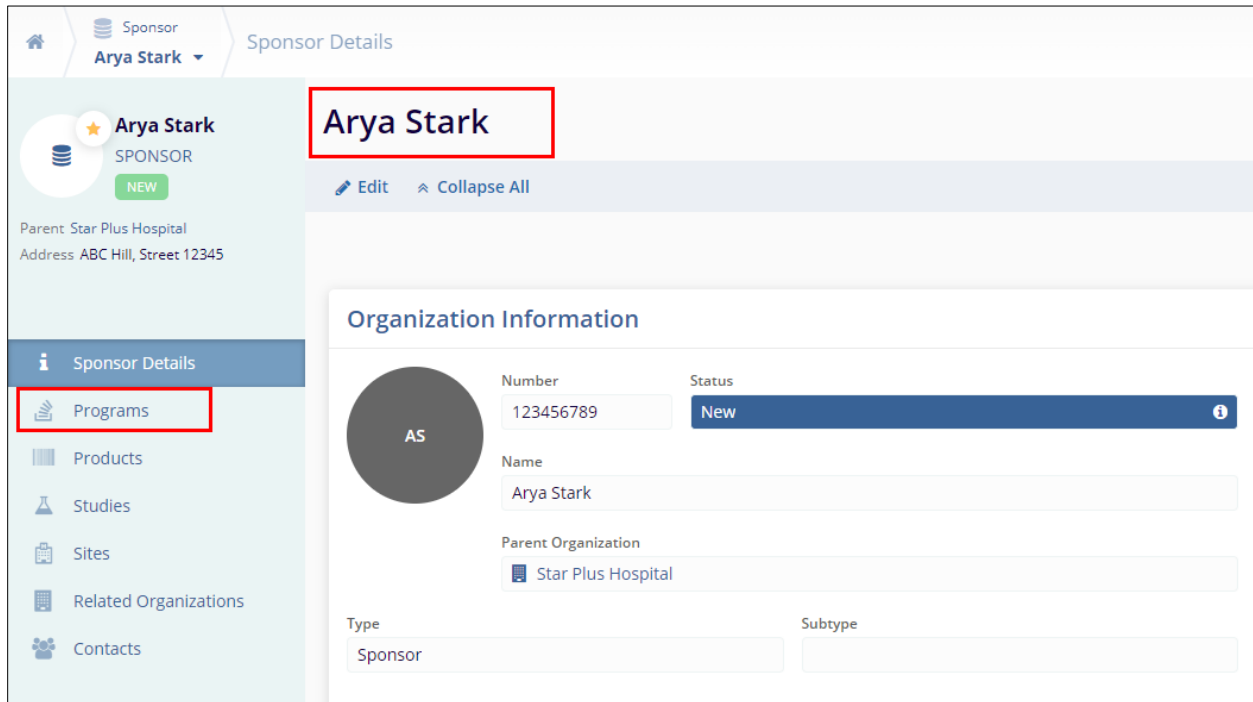
Note: To learn more about Milestone Templates functionality. For Example: How to Add, Delete, Publish, Copy and so on. Refer to the Milestone Template section. [Click Here.](#)

Creating a Product for a Sponsor

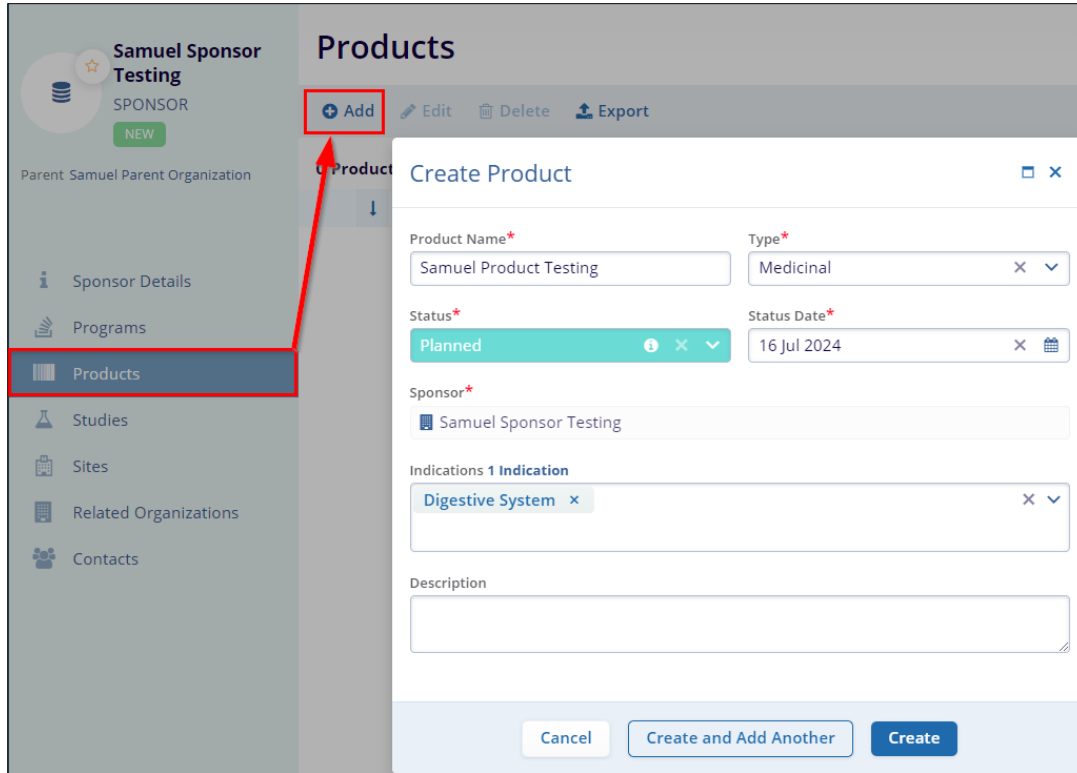
To learn how to navigate to the Sponsor list, [Click here](#)

Steps to create a product for a Sponsor

1. Click on the “**Sponsor name**”, It will redirect you to the Sponsor Details screen.



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



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

1. Fill in the Product Name

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

2. Select the Product Type

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

3. Set the Product Status

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

4. Specify the Status Date

- **Field:** Status Date
- **Description:** Enter or select the date corresponding to the product status. This is a mandatory field.
- **Example:** 16 Jul 2024

5. Assign a Sponsor

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

6. Indications

- **Field:** Indications
- **Description:** Select any relevant indications for the product. This is optional.
- **Example:** Choose from the dropdown menu if applicable.

7. Provide a Description

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

8. Save the Product

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

Notes:

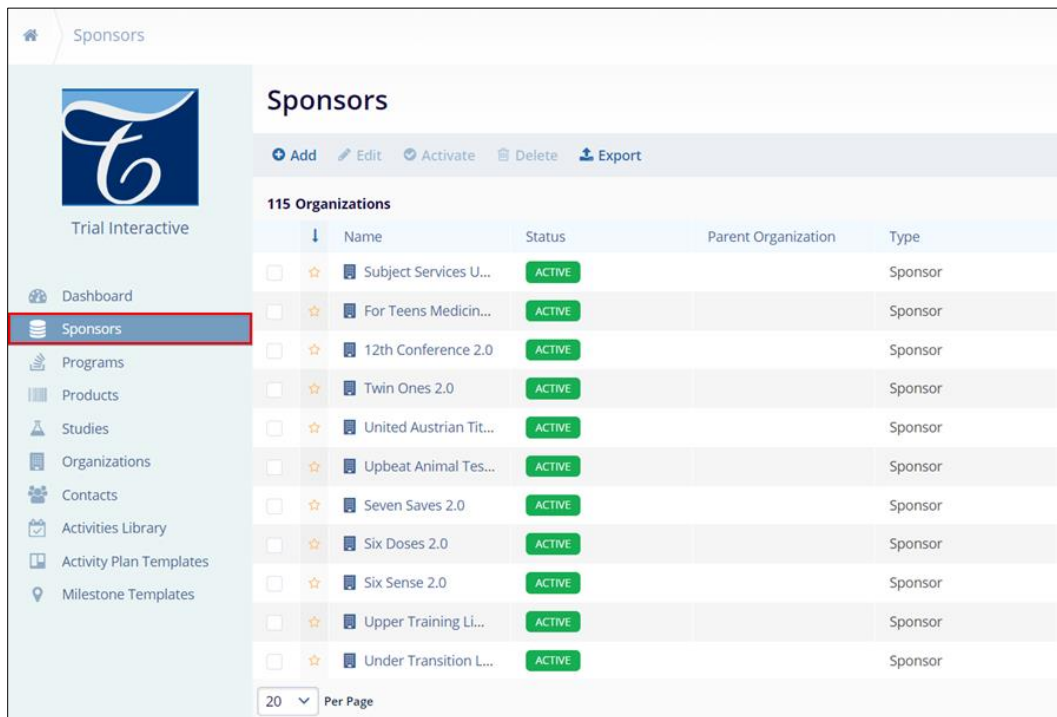
- Make sure all mandatory fields (marked with a red asterisk *****) are filled out before attempting to save the product.
- Use the calendar widget to easily select the status date.
- The **“Sponsor”** field is predefined and cannot be edited.
- Review all entered information for accuracy before clicking the **“Create”** button

9. Now user will be able to see this product is successfully associated with the sponsor.

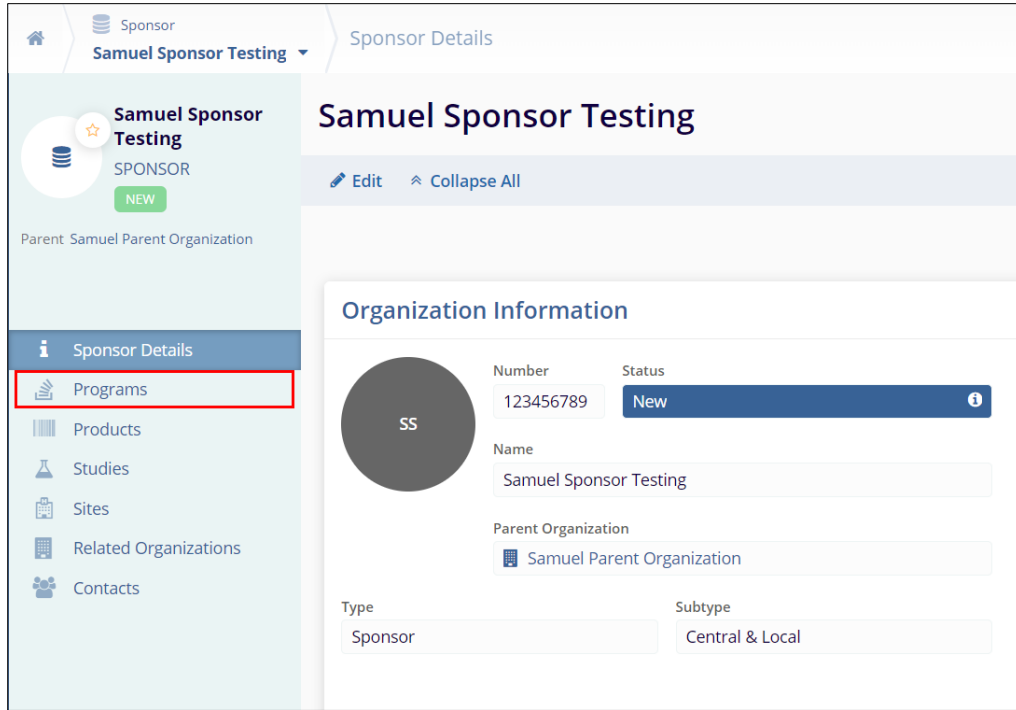
Creating a Program for a Sponsor

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

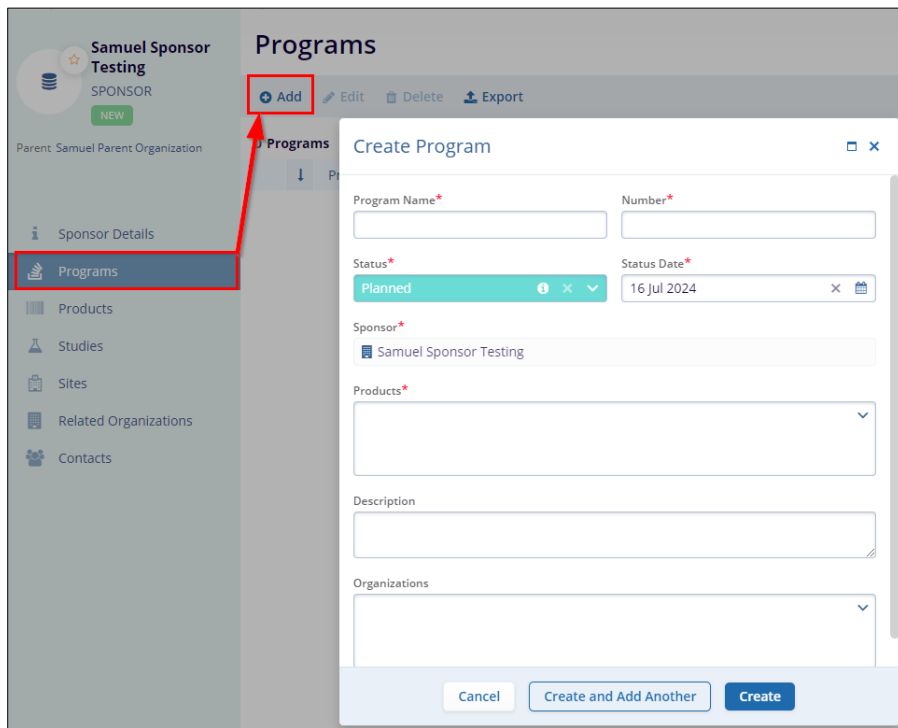
1. Click on the “**Sponsor**” tab located in the navigation panel on the left side of the screen.
2. This action will redirect you to the “**Sponsor**” page where all Sponsors at the global level will be displayed.



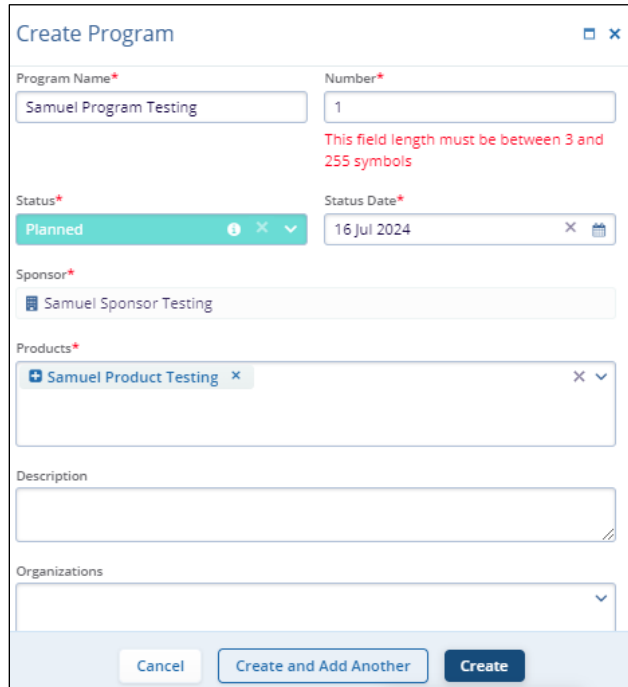
3. Click on the name of the sponsor to which you want to associate program. It will redirect you to the “**Sponsor Details**” page and click on the “**Program**” link in the Navigation menu on the left side of the screen.



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



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



1. Fill in the Program Name

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

2. Enter the Program Number

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

3. Set the Program Status

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

4. Specify the Status Date

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

- **Example:** 16 Jul 2024

5. Assign a Sponsor

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

6. Add Products

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

7. Provide a Description

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

8. List Organizations

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

9. Save the Program

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

Notes:

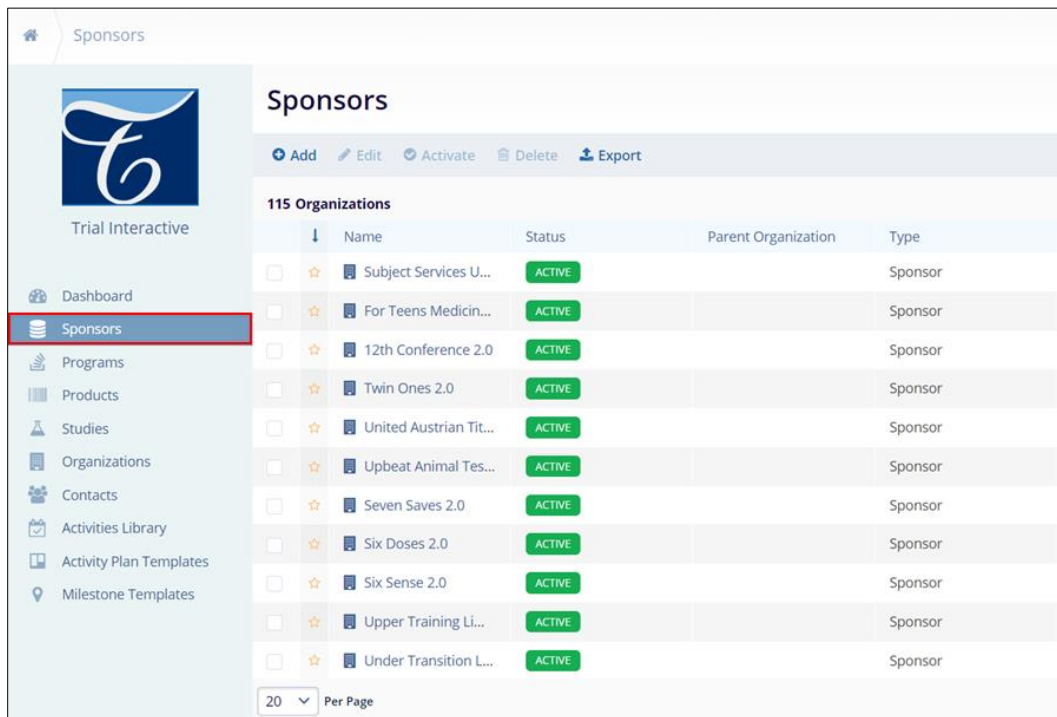
- Make sure all mandatory fields (marked with a red asterisk *****) are filled out before attempting to save the program.
- Use the calendar widget to easily select the status date.
- Review all entered information for accuracy before clicking the **"Create"** button.
- If the program number is too short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

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

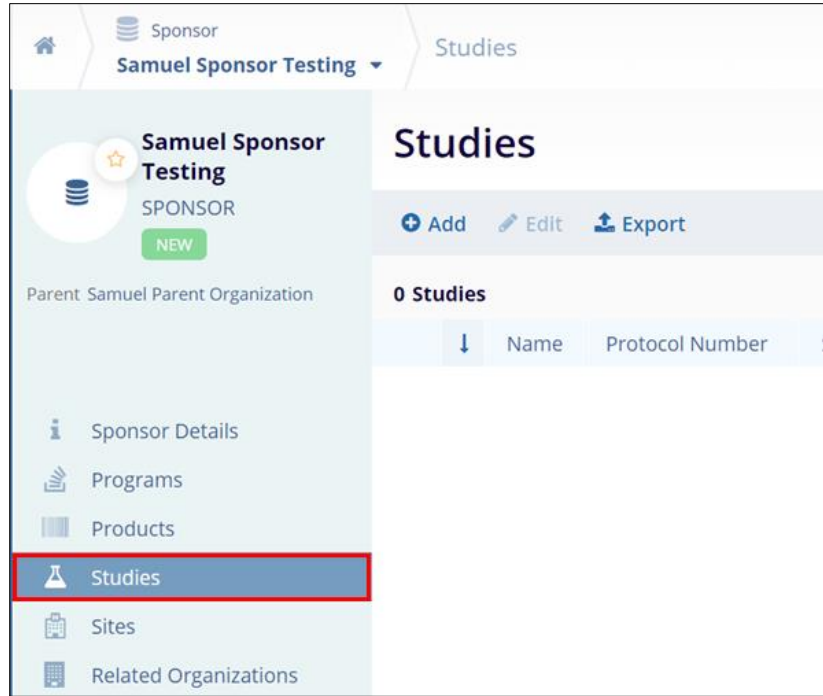
Creating a Study for a Sponsor

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

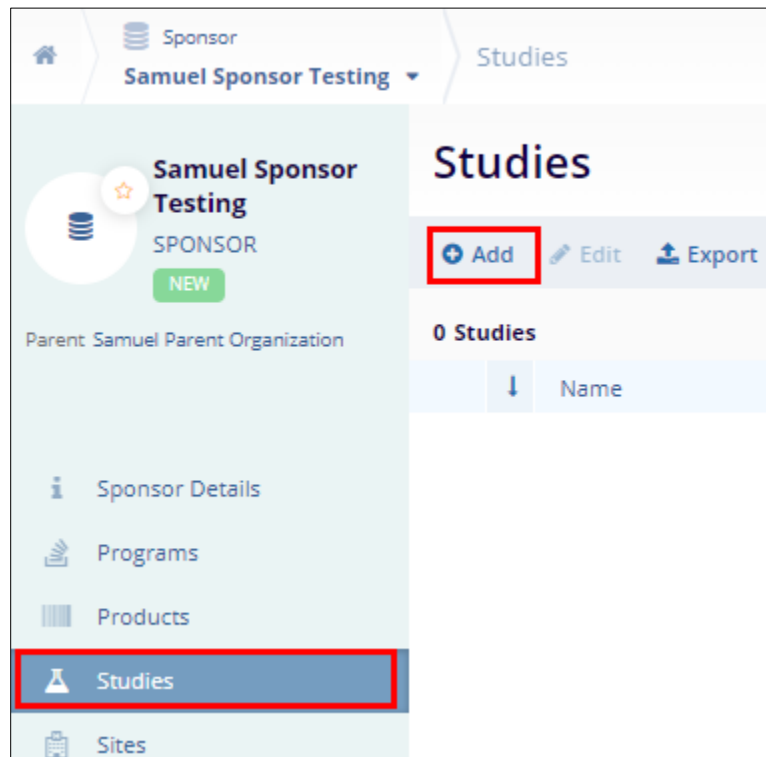
1. Click on the “**Sponsor**” tab located in the navigation panel on the left side of the screen.
2. This action will redirect you to the “**Sponsor**” page where all Sponsors at the global level will be displayed.



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



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

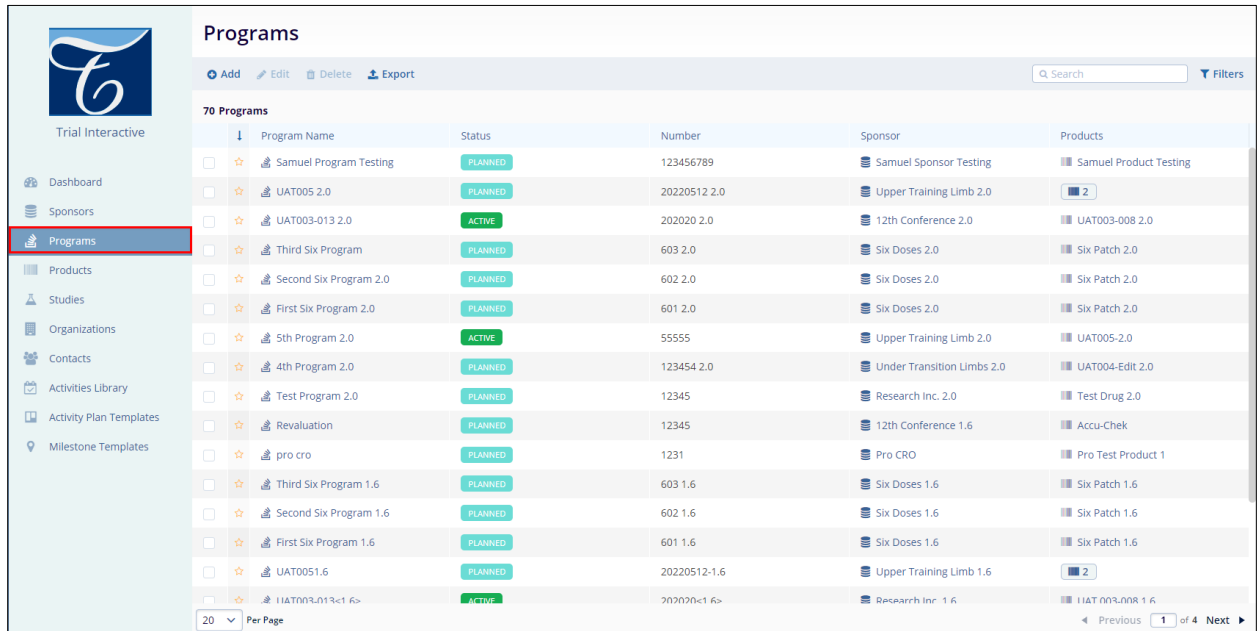


Program

Creating a Program

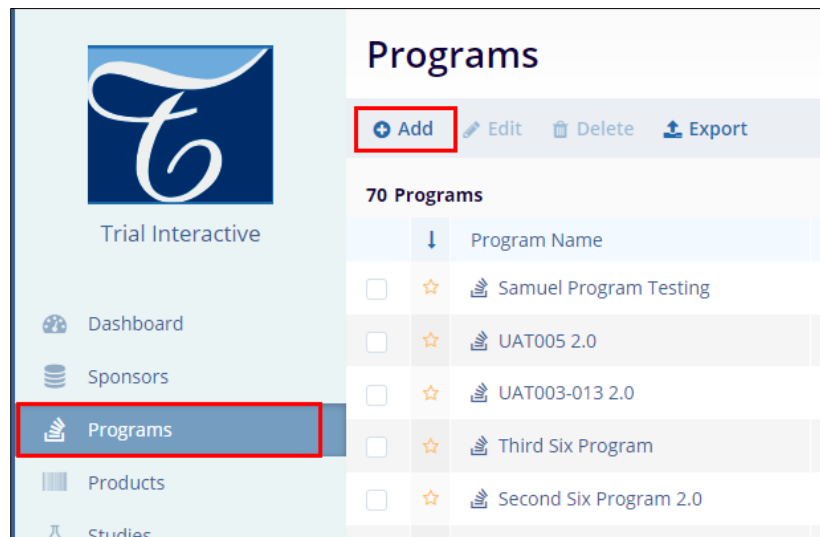
To navigate to the Program screen and view all the Program entries, follow the steps below.

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



Steps to add a new Program

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



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

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

Metadata field(s)	Description
Program Name	Enter a suitable name for the Program.
Number	Enter the unique number for the Program.
Status*	<p>Select a suitable status from the available dropdown options.</p> <ul style="list-style-type: none"> • Planned: The program is planned. • Active: The program is currently being actively used. • Approved: The program has been approved. • Archived: Program data has been archived • Cancelled: The Program has been cancelled. • Closed: The Program has reached the end and no additional data will be tracked. • Inactive: The inactive program. • Pending Approval: The Program is pending an approval.

	<ul style="list-style-type: none"> • Postponed: The program is postponed until a future date. • Rejected: Rejected program. <p>Note:</p> <ul style="list-style-type: none"> • The Status field will be displayed in a different color depending upon the status selected. • A tooltip showing the status description is visible after hovering over the icon.
Status Date	Enter the status date.
Sponsor	Select the sponsor's name from the available dropdown options.
Products	Select the product from the available dropdown options.
Description	Enter a suitable description for the Program.
Organization	Select the related organization.

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

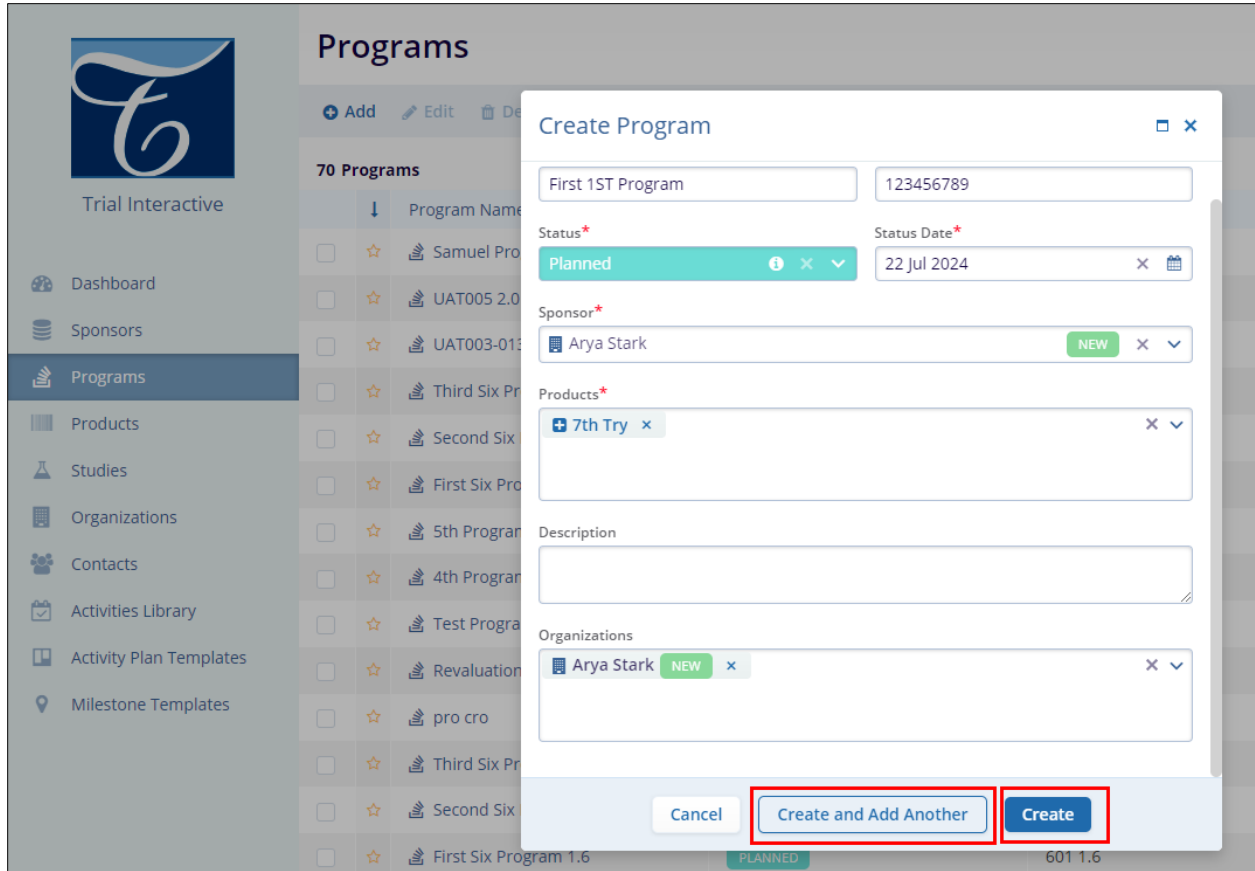


Figure: Create Program

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

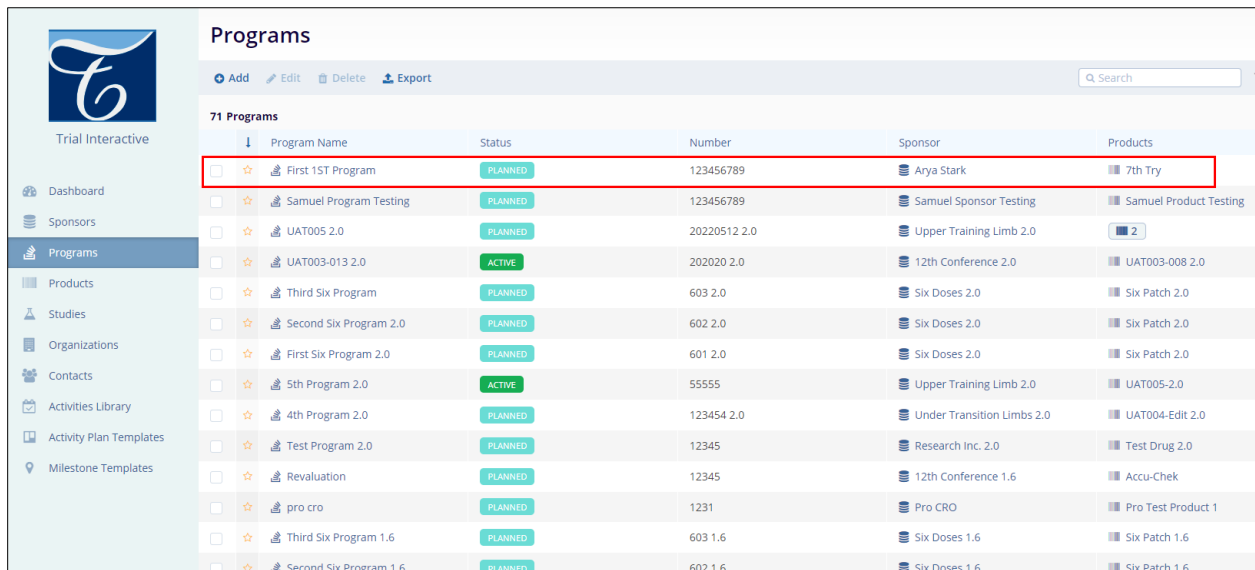


Figure: Newly created Program on the Program home screen

Important Behaviour of Create Program

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

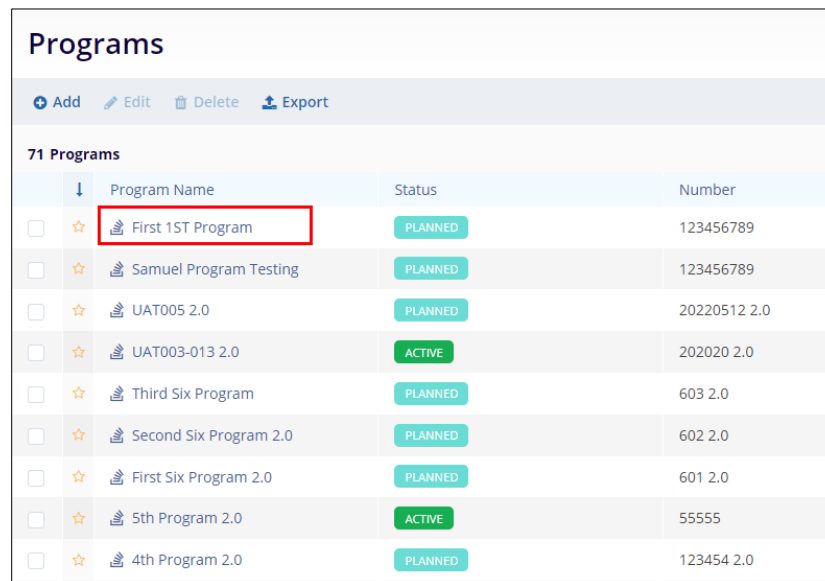
Editing and Reviewing a Program

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

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

Method 1

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



Programs			
+ Add ✎ Edit 🗑 Delete 📄 Export			
71 Programs			
	Program Name	Status	Number
<input type="checkbox"/>	First 1ST Program	PLANNED	123456789
<input type="checkbox"/>	Samuel Program Testing	PLANNED	123456789
<input type="checkbox"/>	UAT005 2.0	PLANNED	20220512 2.0
<input type="checkbox"/>	UAT003-013 2.0	ACTIVE	202020 2.0
<input type="checkbox"/>	Third Six Program	PLANNED	603 2.0
<input type="checkbox"/>	Second Six Program 2.0	PLANNED	602 2.0
<input type="checkbox"/>	First Six Program 2.0	PLANNED	601 2.0
<input type="checkbox"/>	5th Program 2.0	ACTIVE	55555
<input type="checkbox"/>	4th Program 2.0	PLANNED	123454 2.0

Figure: Select a Program to edit

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

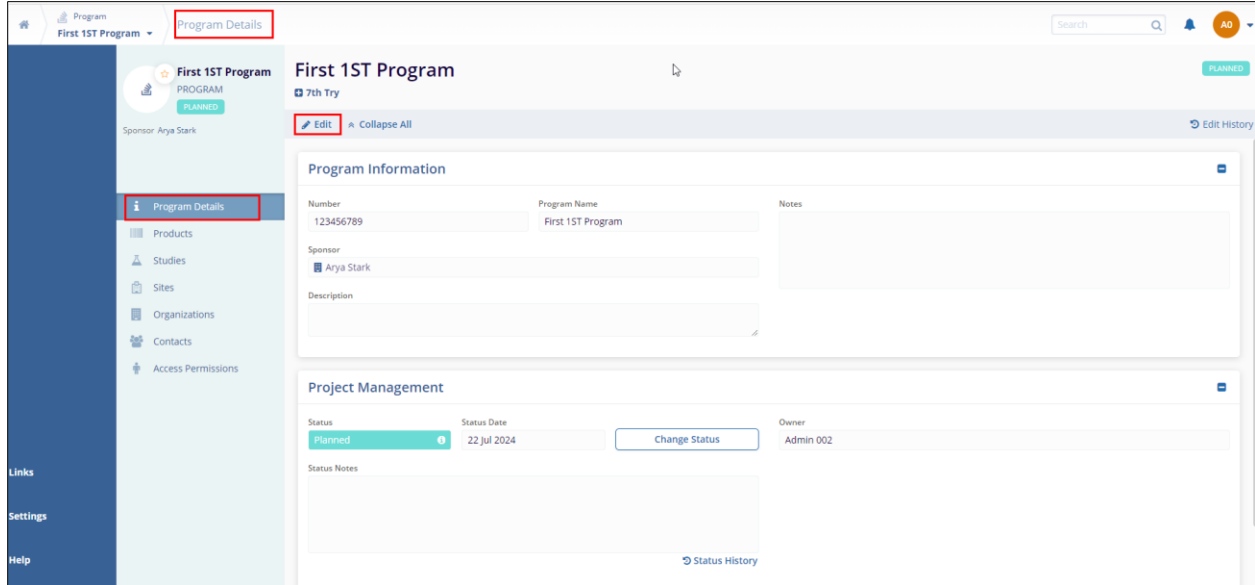


Figure: Program Details screen

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

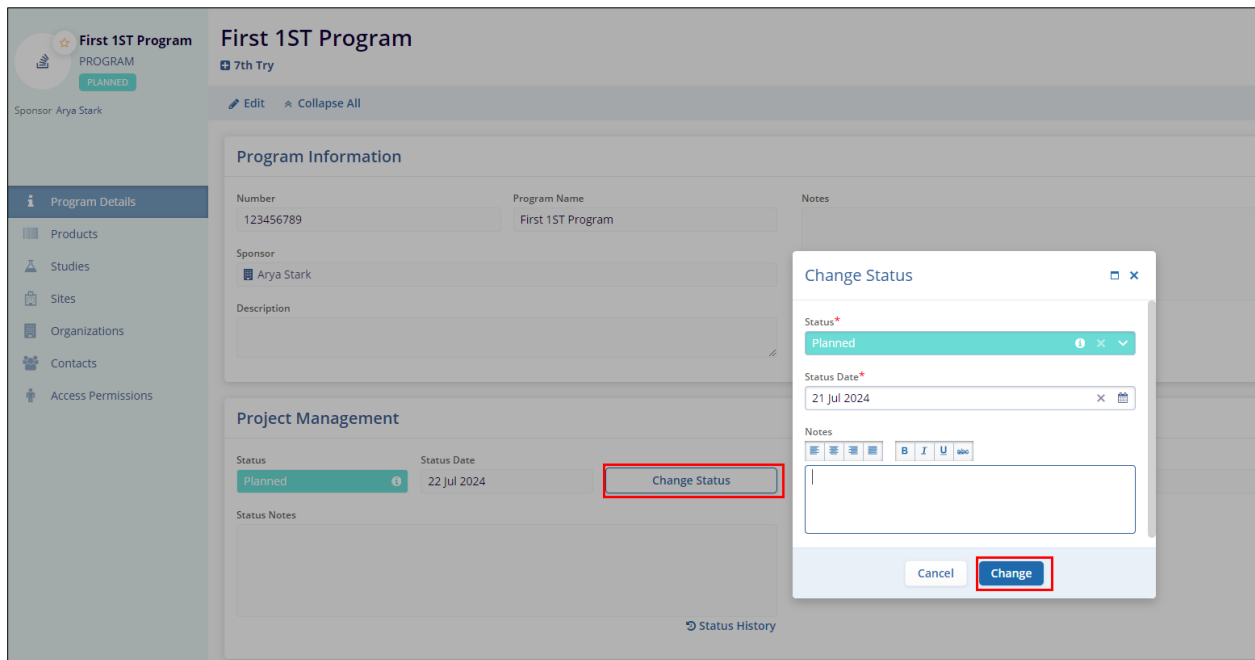


Figure: Change Status

b. Status History:

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

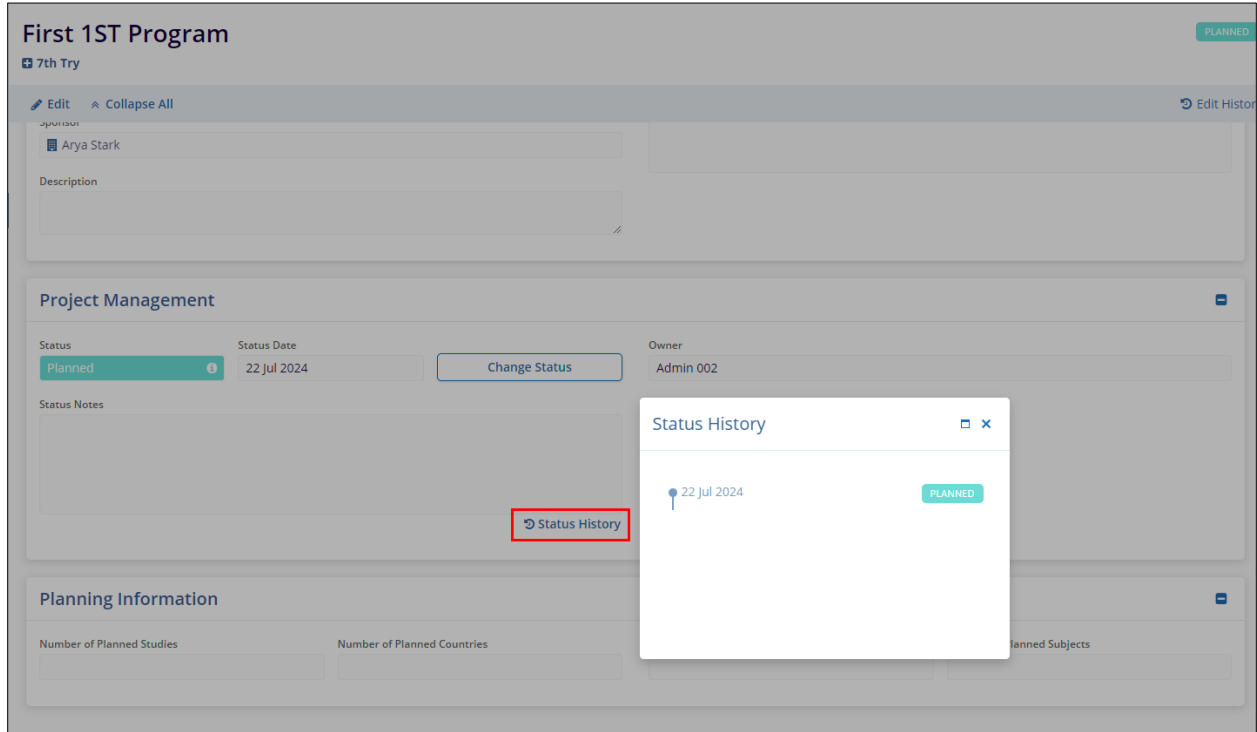


Figure: Status History

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

Programs

[Add](#)
[Edit](#)
[Delete](#)
[Export](#)

71 Programs 1 Selected

	Program Name	Status	Number
<input checked="" type="checkbox"/>	First 1ST Program	PLANNED	123456789
<input type="checkbox"/>	Samuel Program Testing	PLANNED	123456789
<input type="checkbox"/>	UAT005 2.0	PLANNED	20220512 2.0
<input type="checkbox"/>	UAT003-013 2.0	ACTIVE	202020 2.0
<input type="checkbox"/>	Third Six Program	PLANNED	603 2.0
<input type="checkbox"/>	Second Six Program 2.0	PLANNED	602 2.0
<input type="checkbox"/>	First Six Program 2.0	PLANNED	601 2.0
<input type="checkbox"/>	5th Program 2.0	ACTIVE	55555
<input type="checkbox"/>	4th Program 2.0	PLANNED	123454 2.0
<input type="checkbox"/>	Test Program 2.0	PLANNED	12345
<input type="checkbox"/>	Revaluation	PLANNED	12345
<input type="checkbox"/>	pro cro	PLANNED	1231

Method 2

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

Program Details

First 1ST Program

7th Try

Sponsor Anya Stark

Program Information

Number	Program Name	Notes
123456789	First 1ST Program	

Sponsor Anya Stark

Description

Project Management

Status	Status Date	Owner
Planned	22 Jul 2024	Admin 002

Status Notes

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

Deleting a Program

To delete a Program, follow the steps below.

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

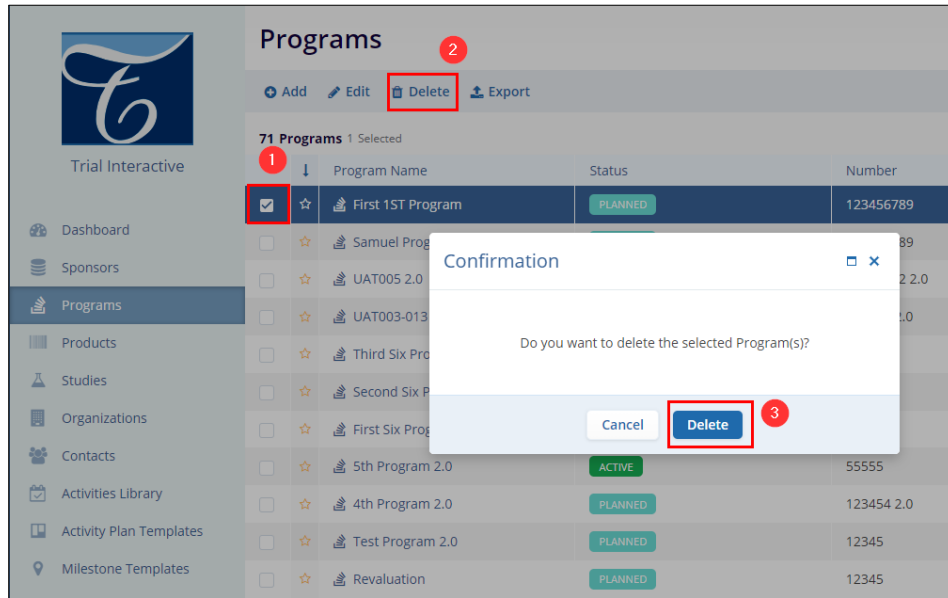


Figure: Delete Program

Exporting Program

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

Customizing Program screen

Filters

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

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

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

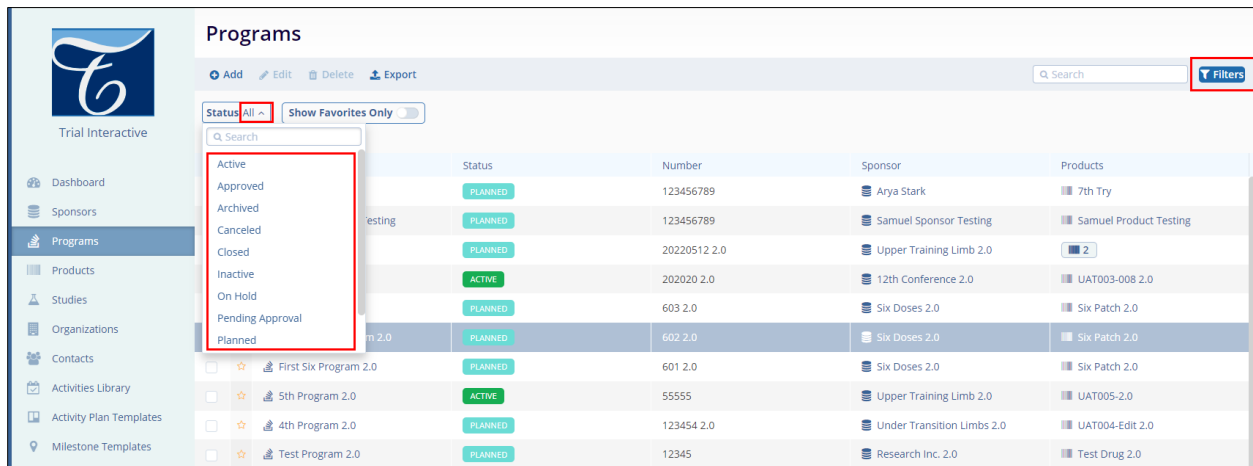


Figure: Apply Status filter

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

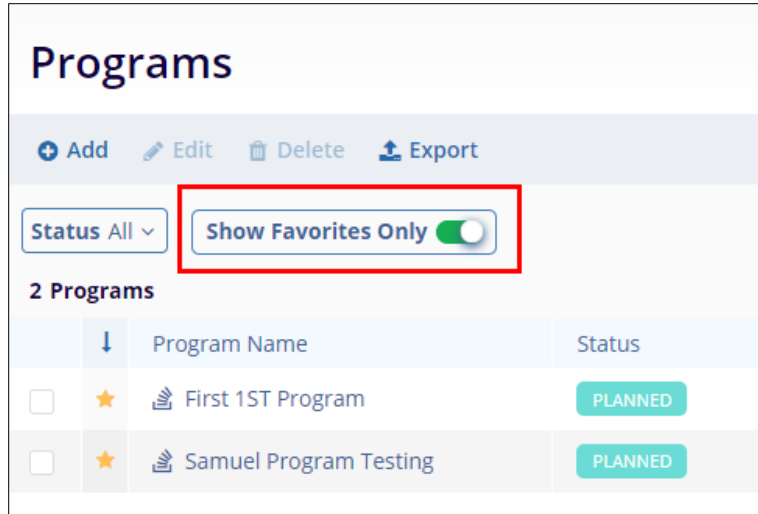


Figure: Show Favorites Only toggle

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

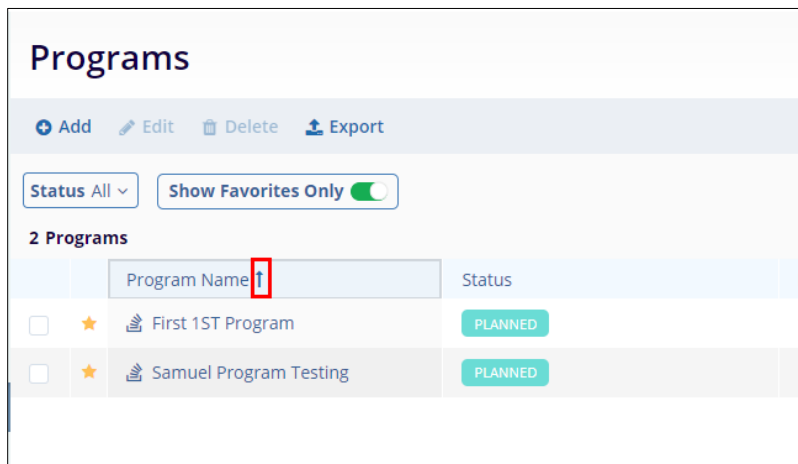


Figure: Sort column in ascending and descending order

Marking a Program as Favorite

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

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

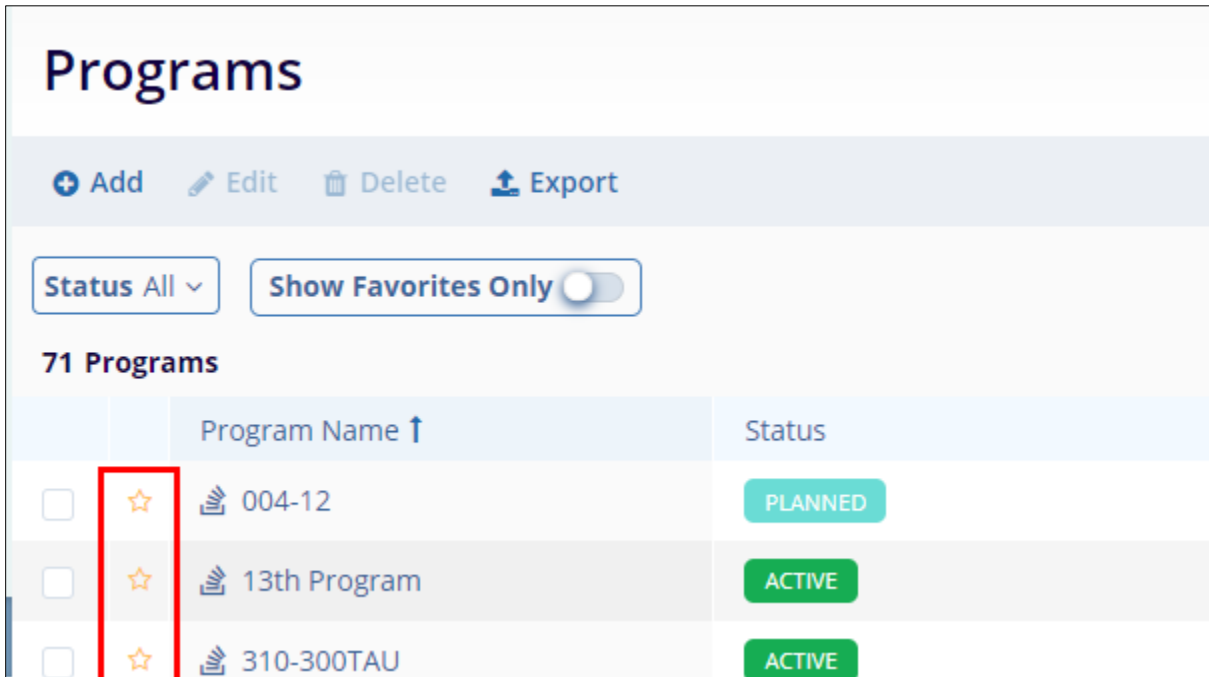


Figure: Mark as Favorite

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

Product

Creating a Product

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

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

Steps to add a new product

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

Metadata field(s)	Description
Product Name*	Enter a suitable name for the product.
Type*	Select the product type from the available dropdown options. <ul style="list-style-type: none"> Combination Custom Device Medicinal
Status*	Select a suitable status from the available dropdown options. <ul style="list-style-type: none"> Planned: Product is planned Active: Product is currently being actively used Approved: Product has been approved Archived: Product data has been archived Cancelled: The product has been canceled Closed: The product has reached the end and no additional data will be tracked In Use: Product is currently in use Inactive: Product is not currently in use Pending Approval: The product is pending an approval Postponed: Product is postponed until a future date Terminated: Product has been terminated <p>Note:</p> <ul style="list-style-type: none"> The Status field will be displayed in a different color depending upon the status selected. A tooltip showing the status description is visible after hovering over the icon.
Status Date*	Enter the status date

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

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

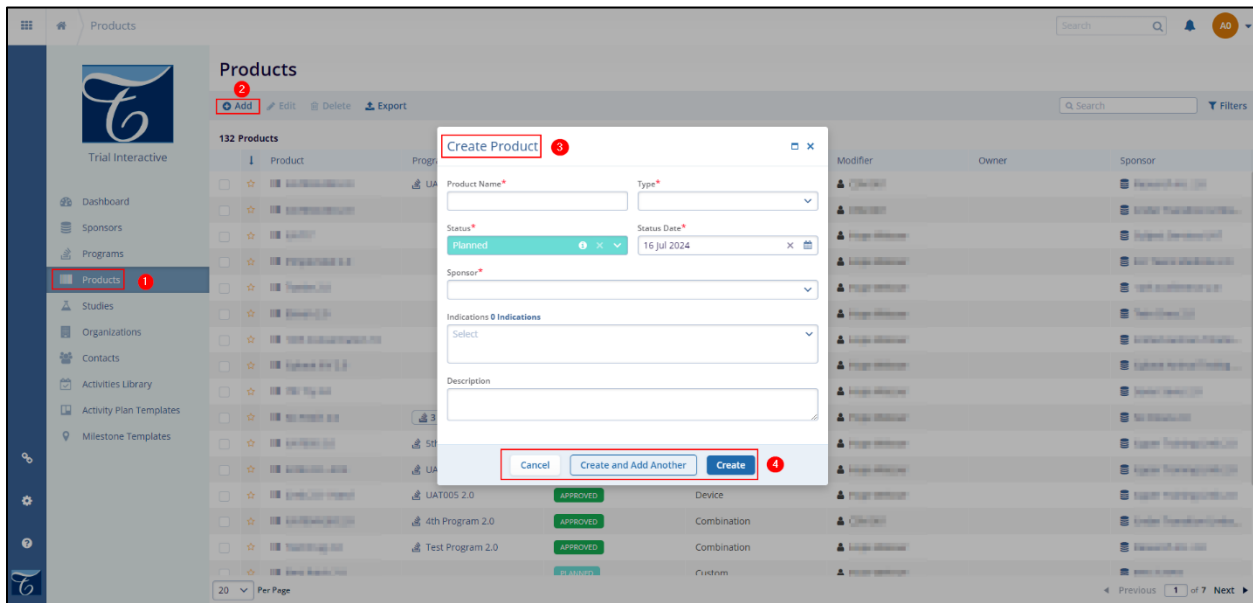


Figure: Create Product

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

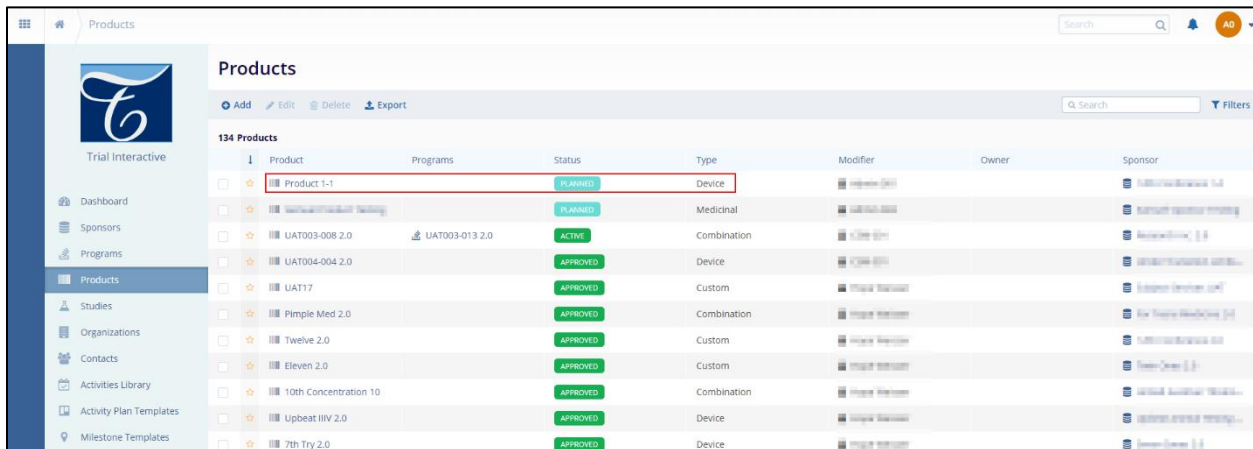


Figure: Newly created product on the Products home screen

Important Behaviour of Create Product

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

Editing and Reviewing a product

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

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

Method 1

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

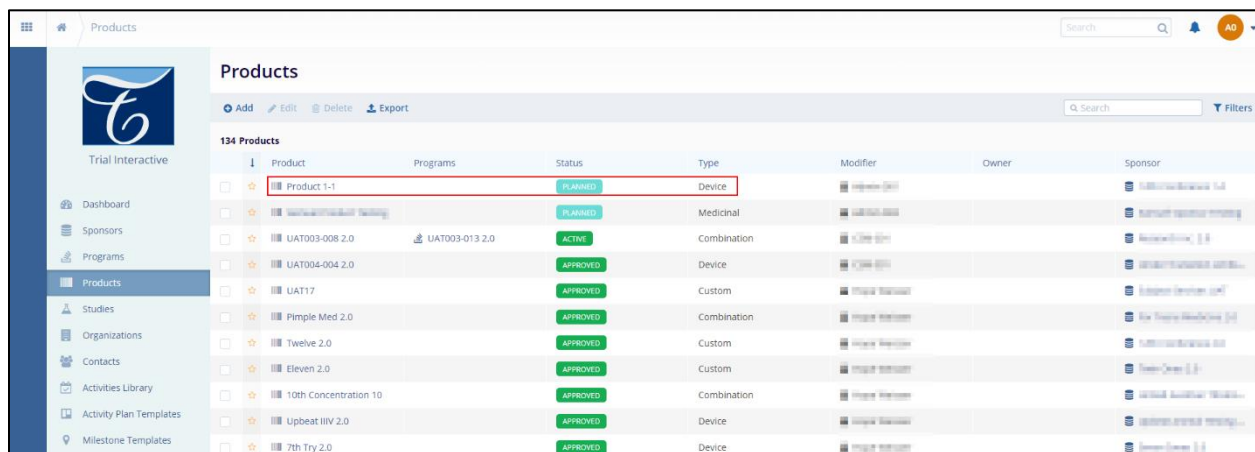


Figure: Select a product to edit

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

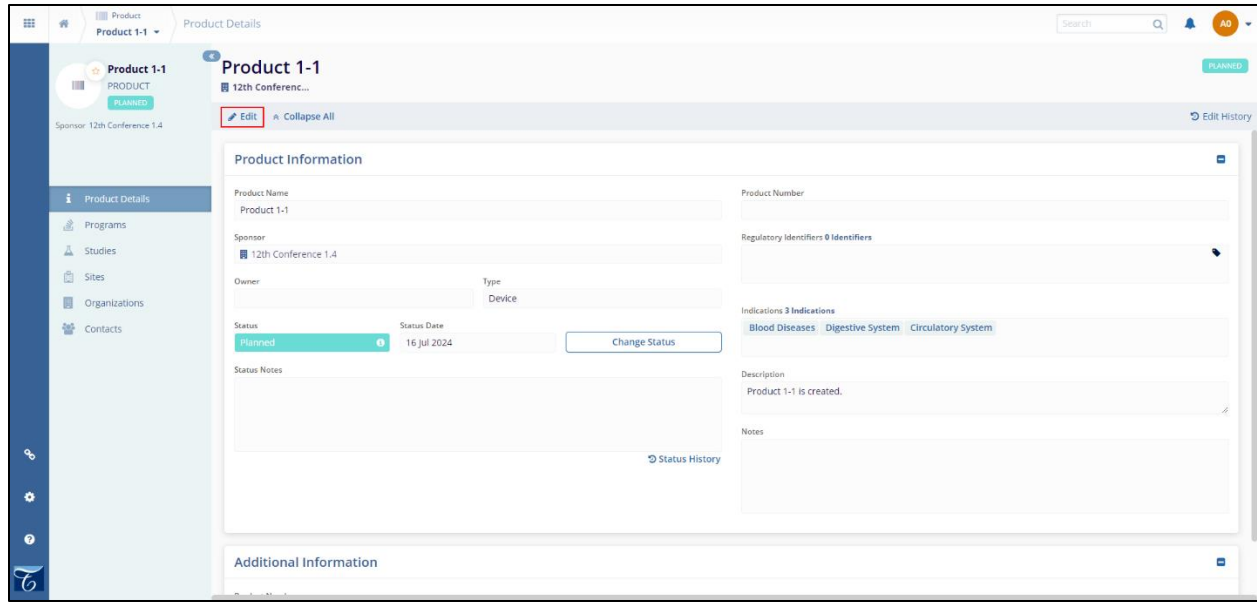


Figure: Product Details screen

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

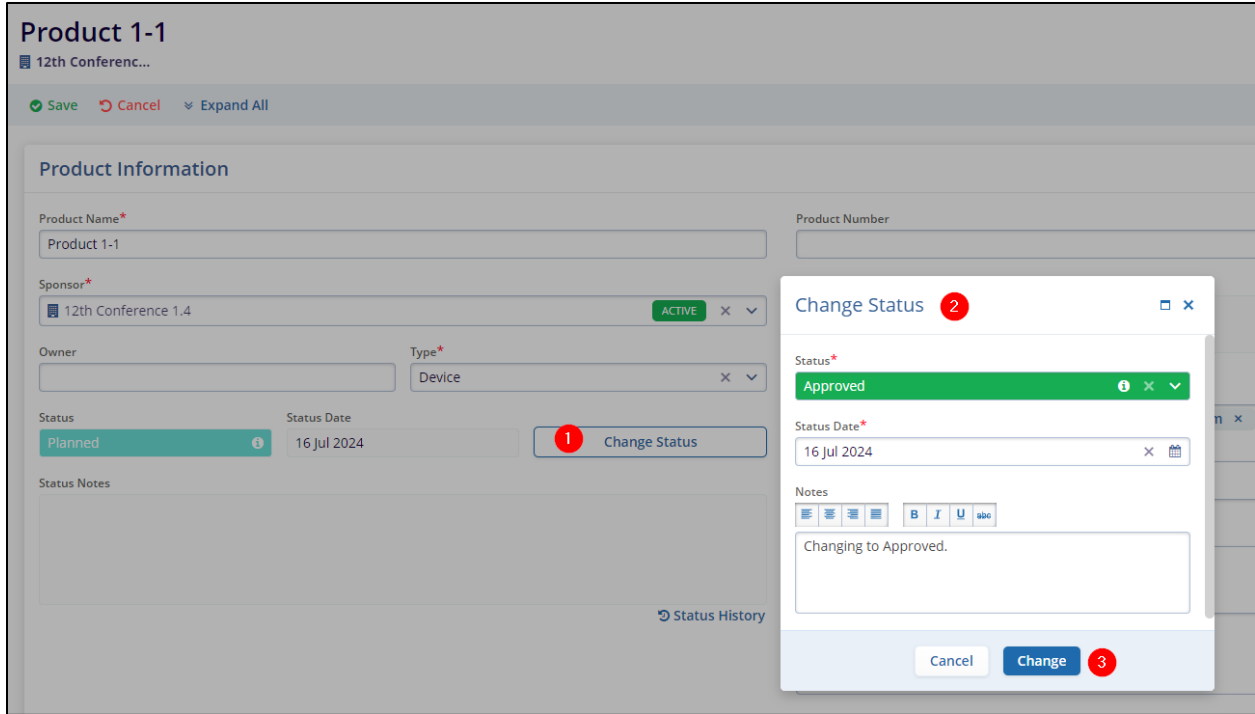


Figure: Change Status

b. Status History:

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

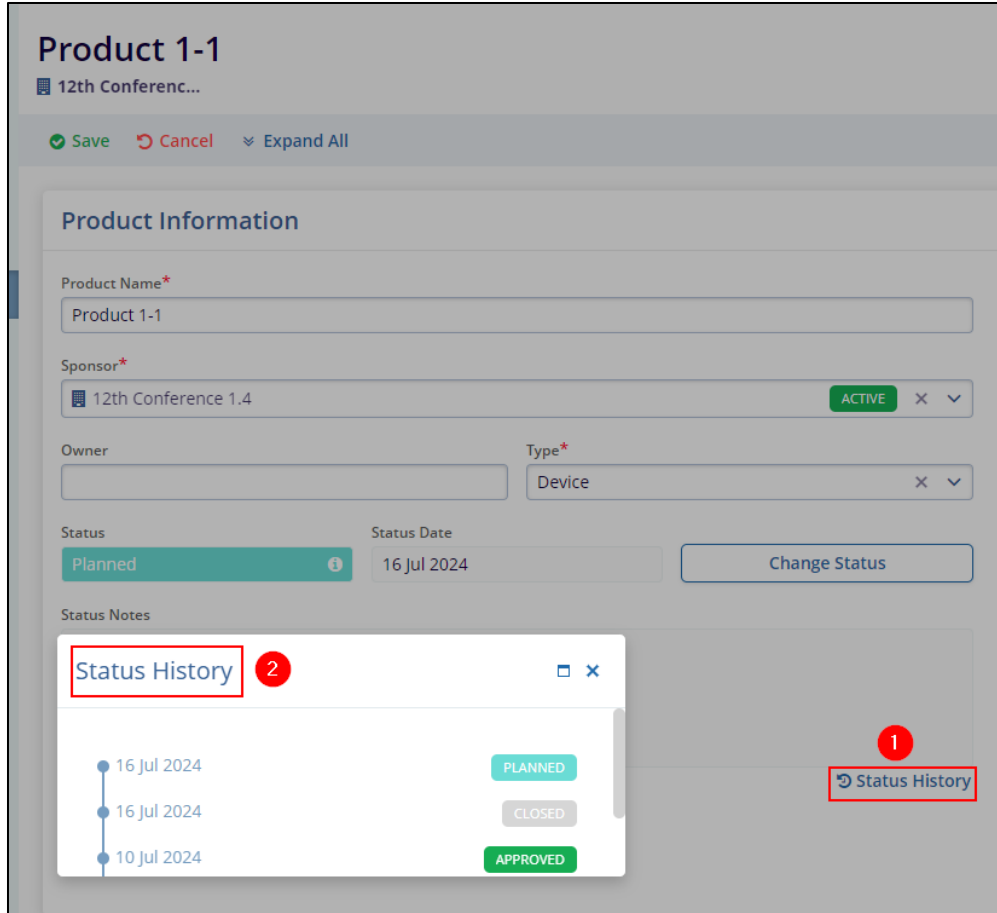


Figure: Status History

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

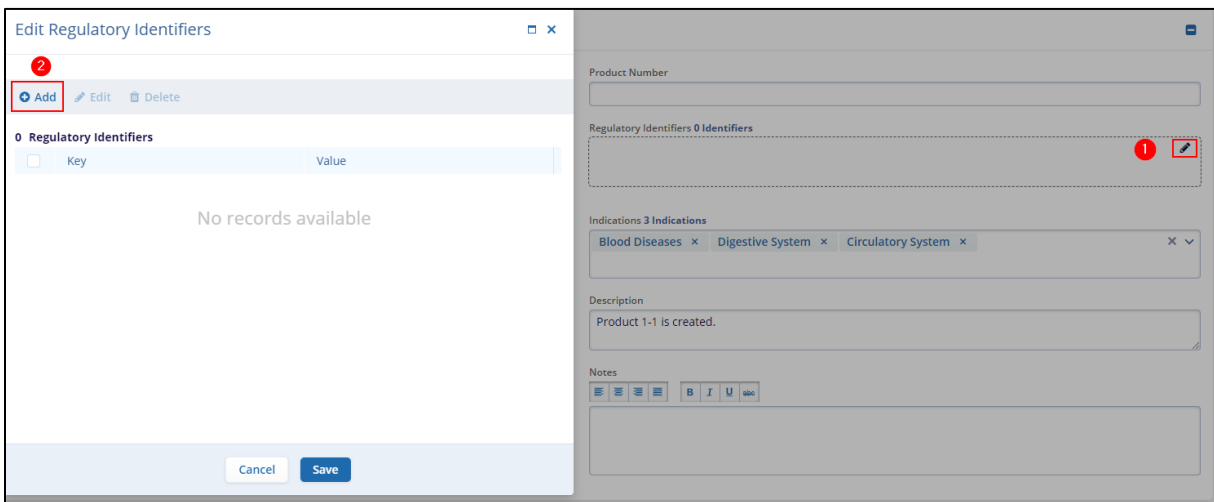


Figure: Add Regulatory identifiers

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

Figure: Add a value to the Key and Value fields

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

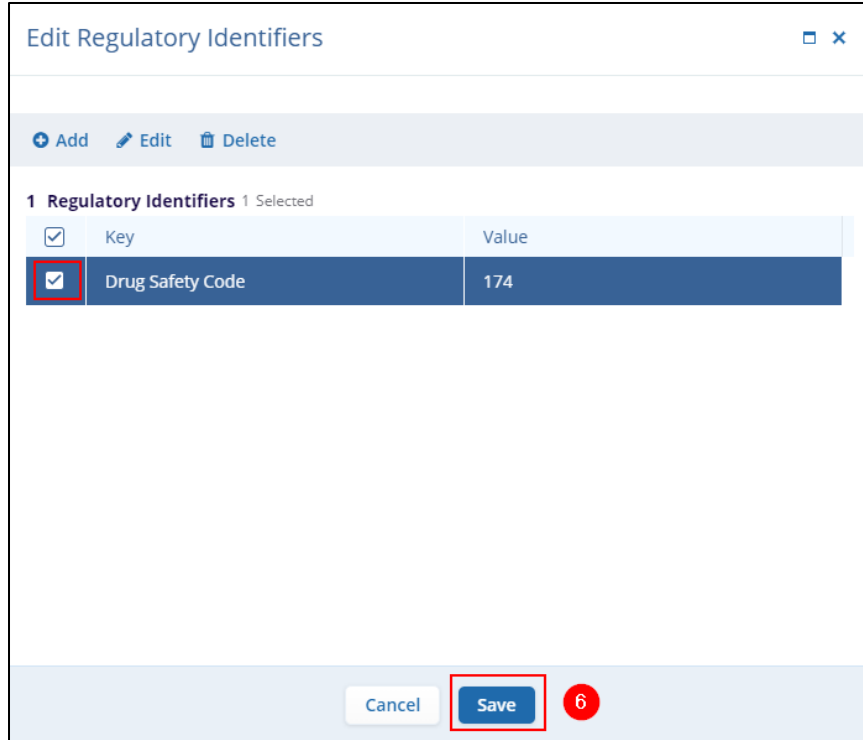


Figure: Save the new Regulatory Identifier

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

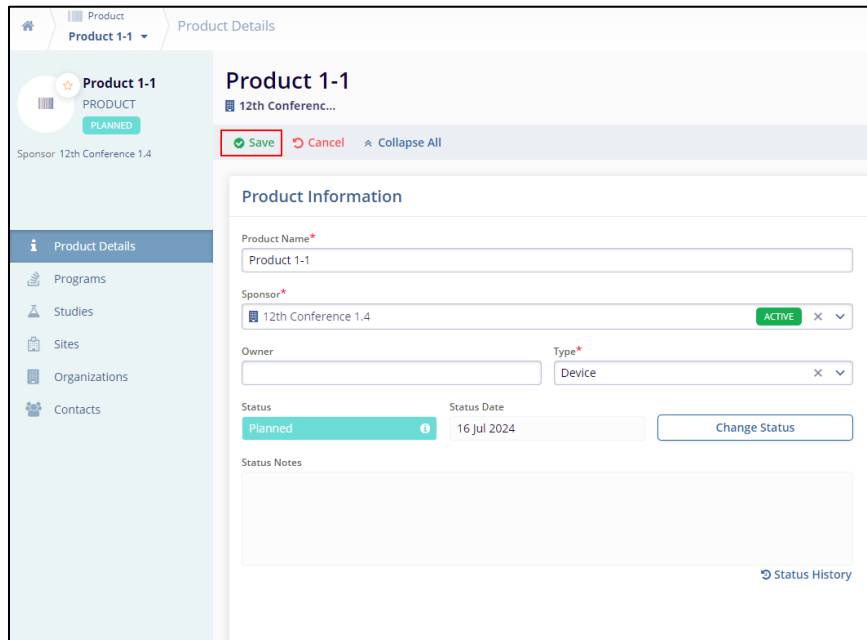


Figure: Save the edited/updated product details

Method 2

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

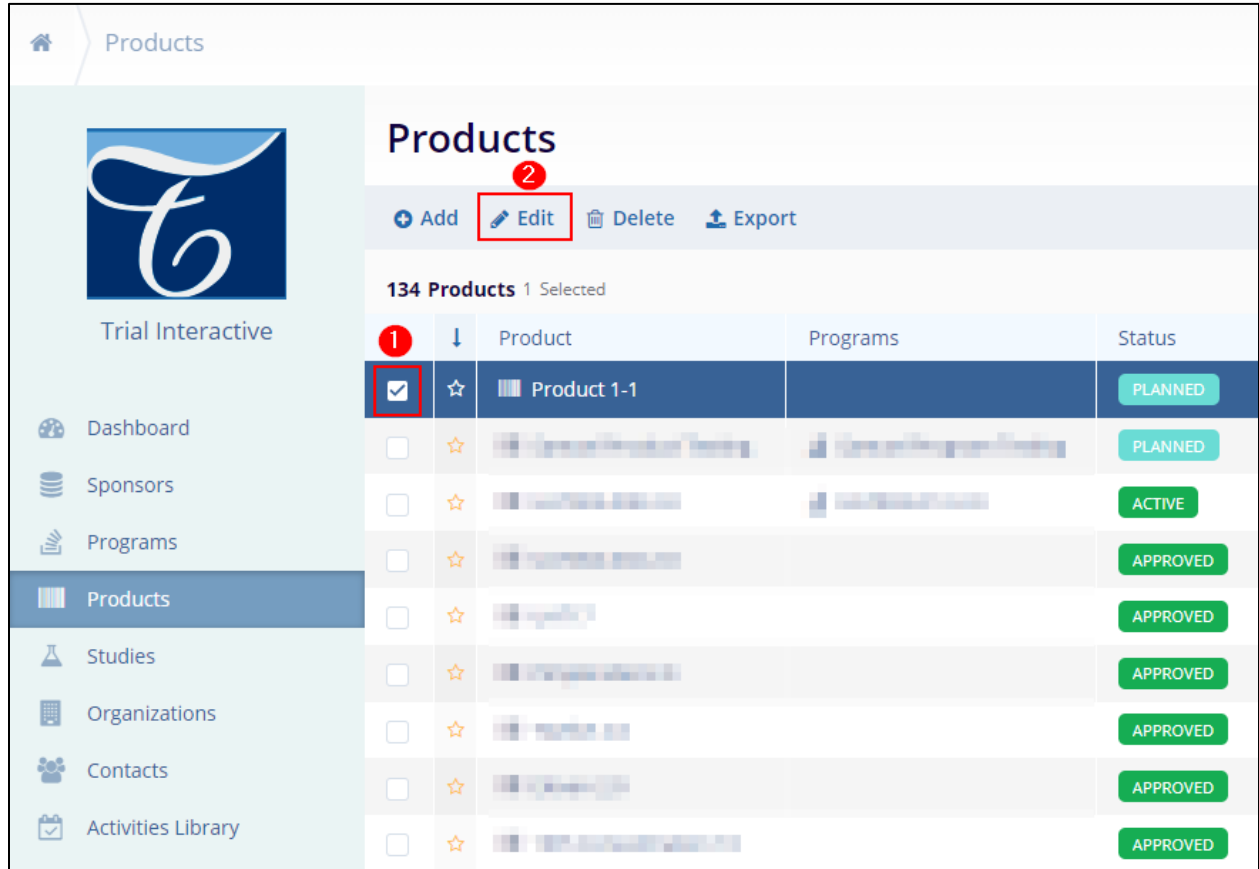


Figure: Edit Product details

Deleting a Product

To delete a product, follow the steps below.

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

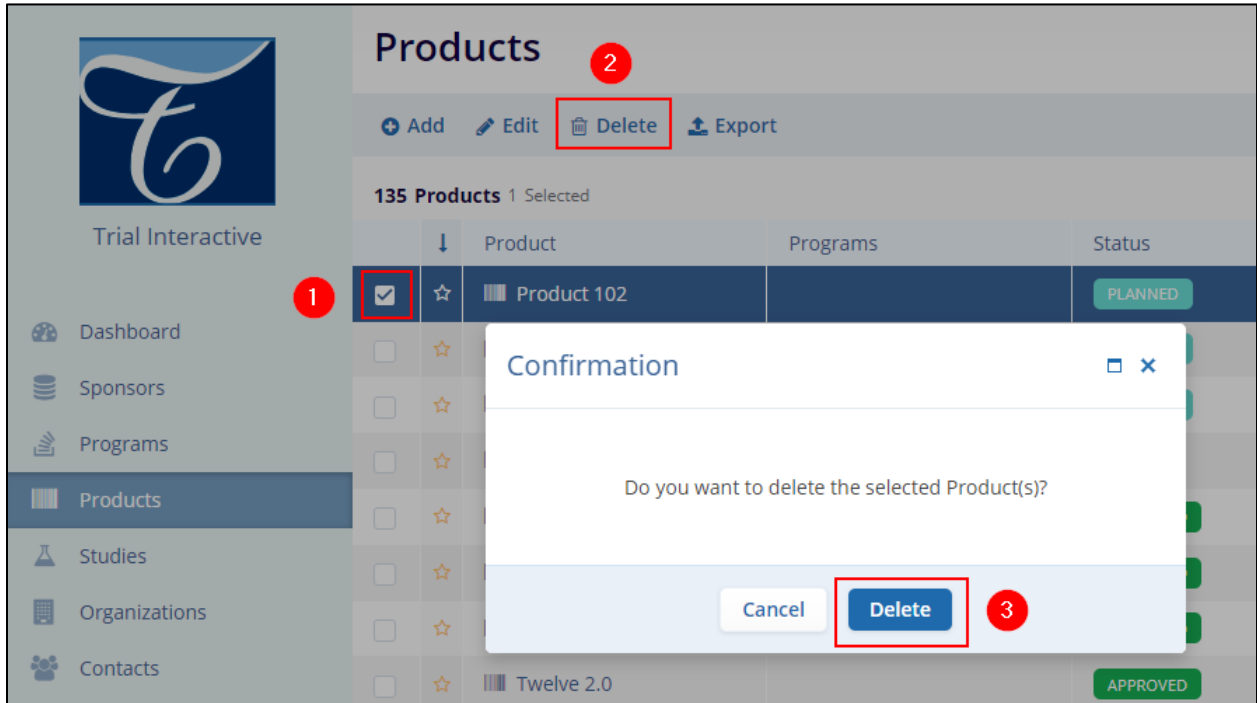


Figure: Delete product

Exporting Products

To export product details from CTMS, refer to the standard export steps detailed in the [Exporting Contacts](#) section.

Customizing Products screen

Filters

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

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

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

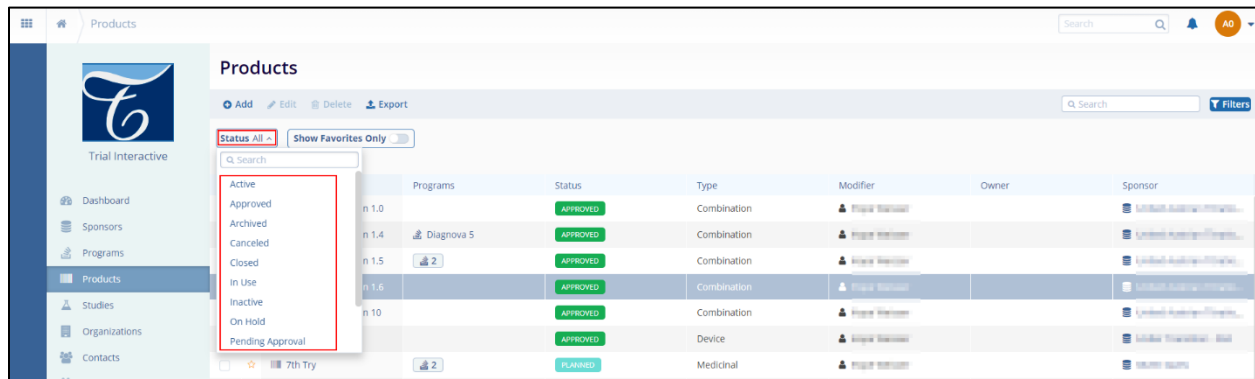


Figure: Apply Status filter

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

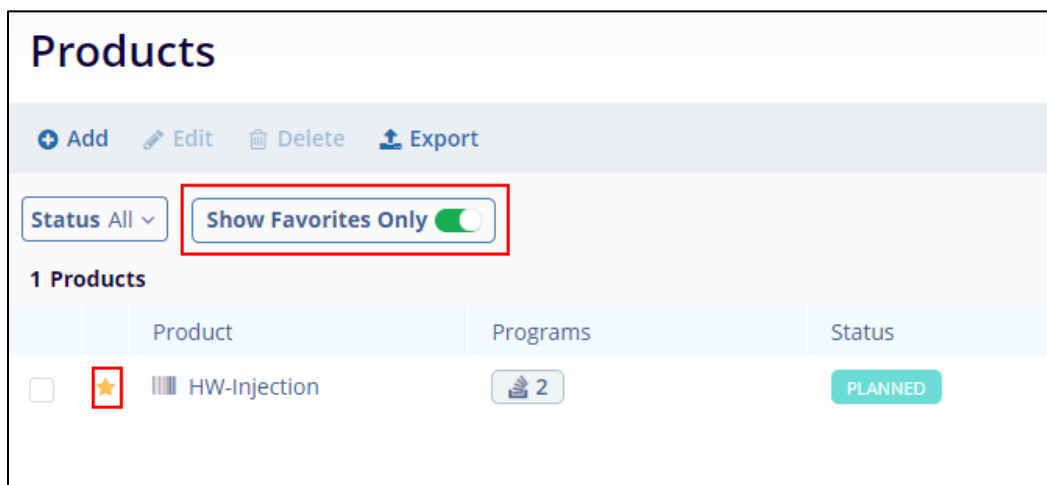


Figure: Show Favorites Only toggle

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

Products

+ Add ✎ Edit 🗑 Delete 📄 Export

Status All ▾ Show Favorites Only

135 Products

	Product ↓	Programs	Status
<input type="checkbox"/>	10th Concentration 1.0		APPROVED
<input type="checkbox"/>	10th Concentration 1.4	Diagnova 5	APPROVED
<input type="checkbox"/>	10th Concentration 1.5	2	APPROVED
<input checked="" type="checkbox"/>	10th Concentration 1.6		APPROVED
<input type="checkbox"/>	10th Concentration 10		APPROVED
<input type="checkbox"/>	400-400TAU		APPROVED
<input type="checkbox"/>	7th Try	2	PLANNED

Figure: Sort column in ascending and descending order

Marking a product as Favorite

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

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

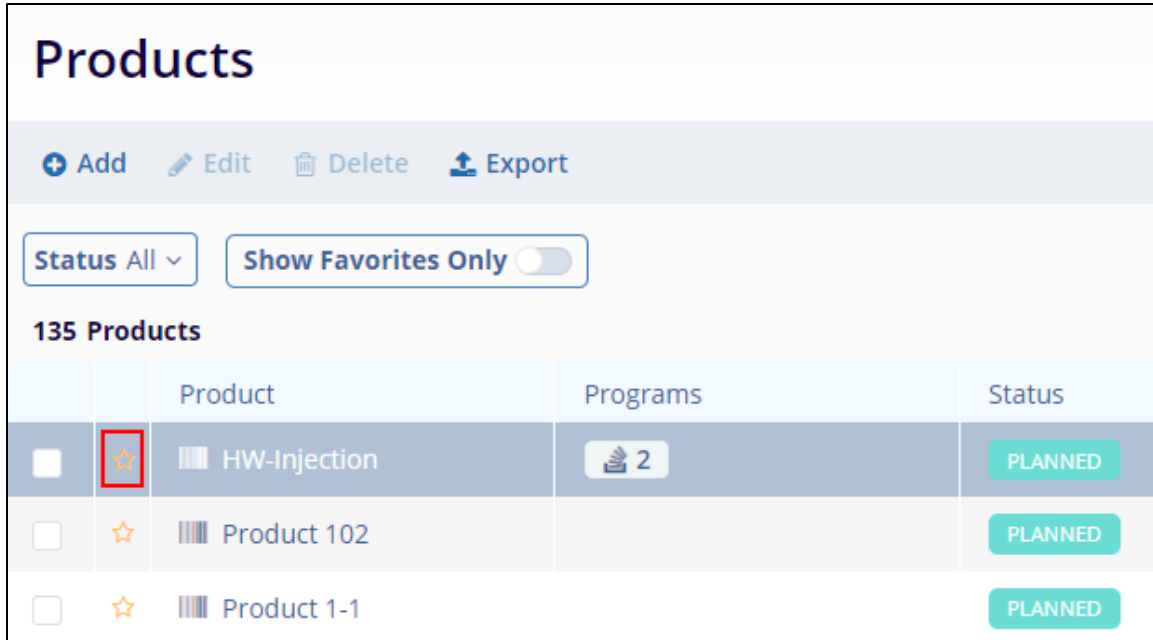


Figure: Mark as Favorite

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

Site Visit Documentation

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

Pre-Requisite

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

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

Site Visit Navigation

To navigate to the site visit, follow the steps below

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

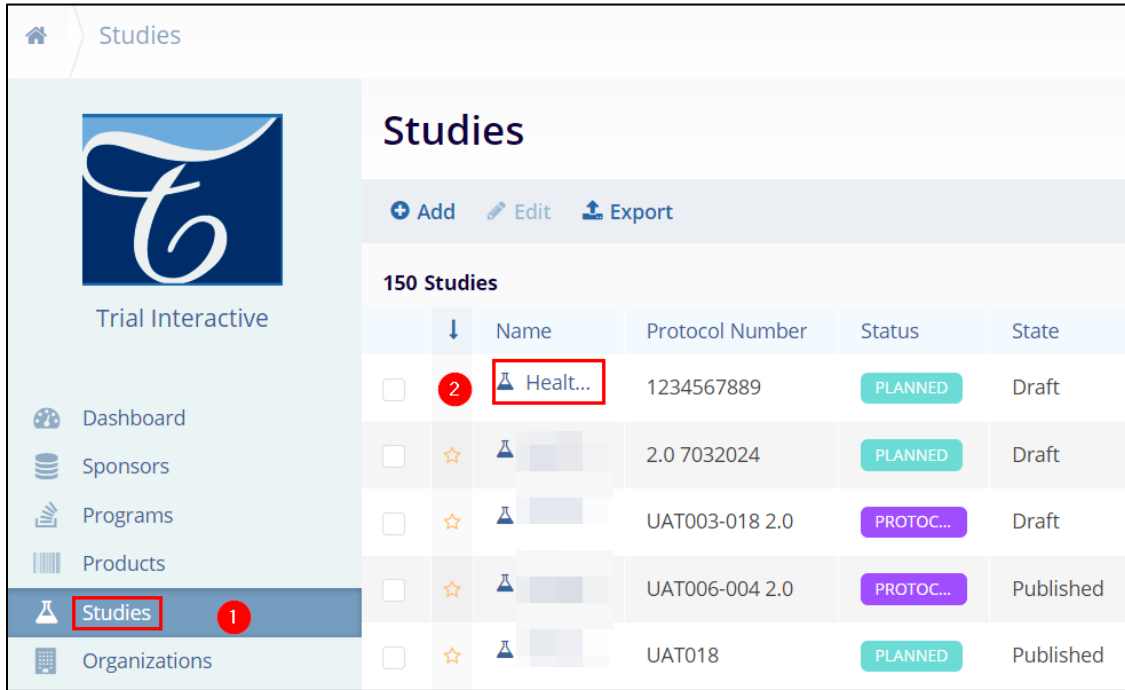


Figure: Select a Study and a study name

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

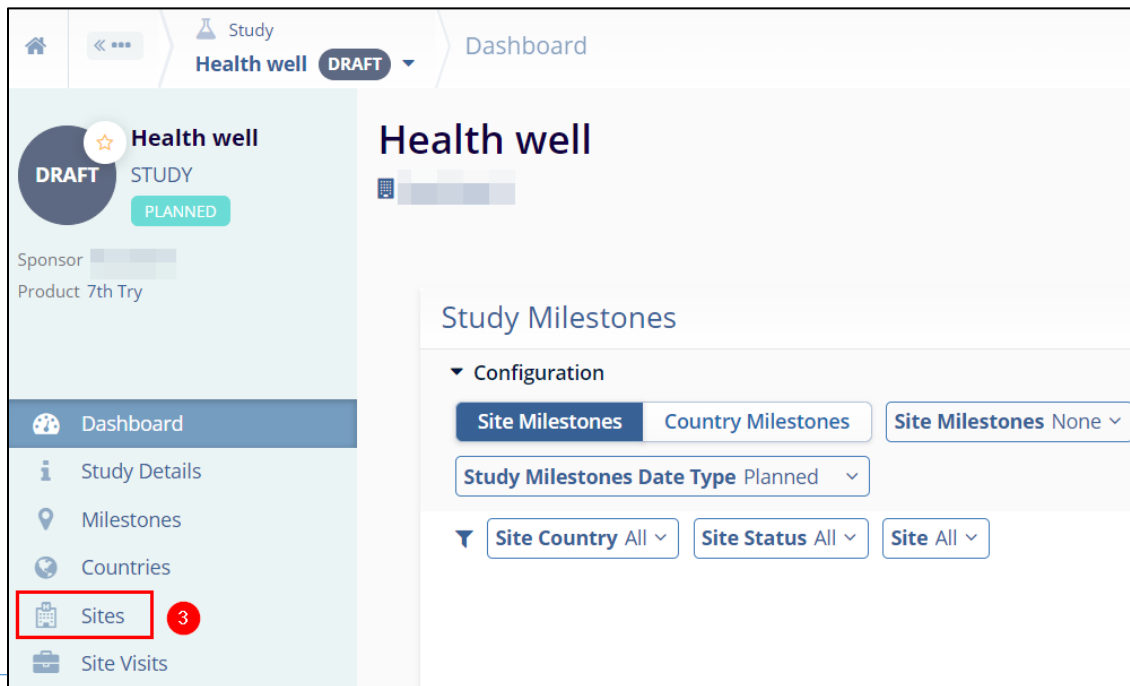


Figure: Select Sites from the Study Dashboard

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

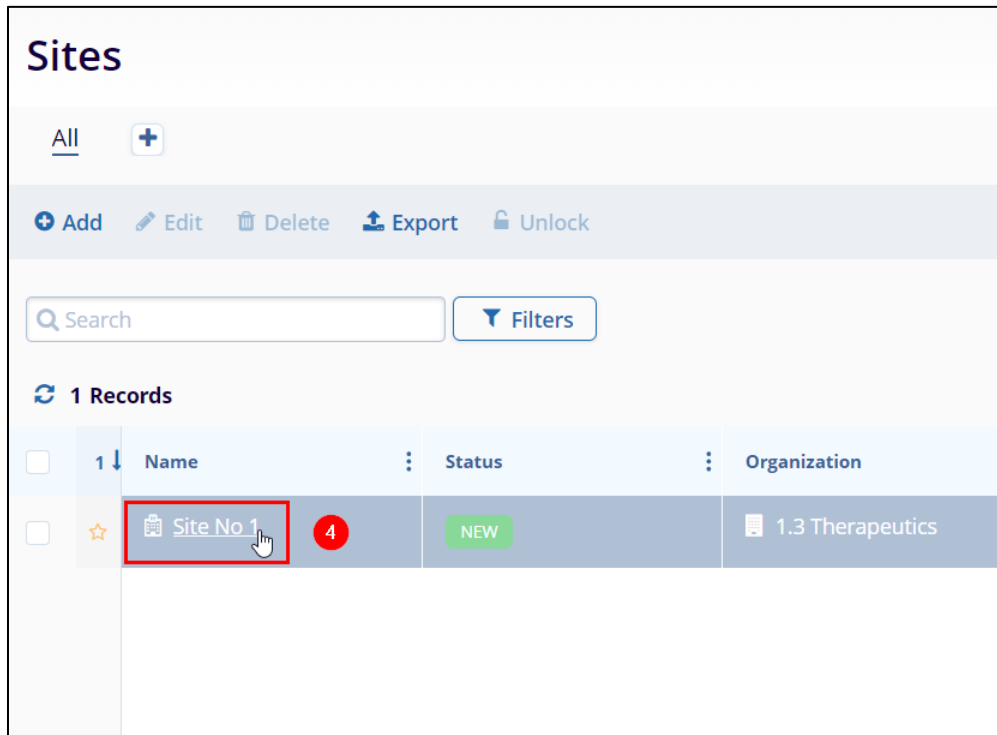


Figure: Select site

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

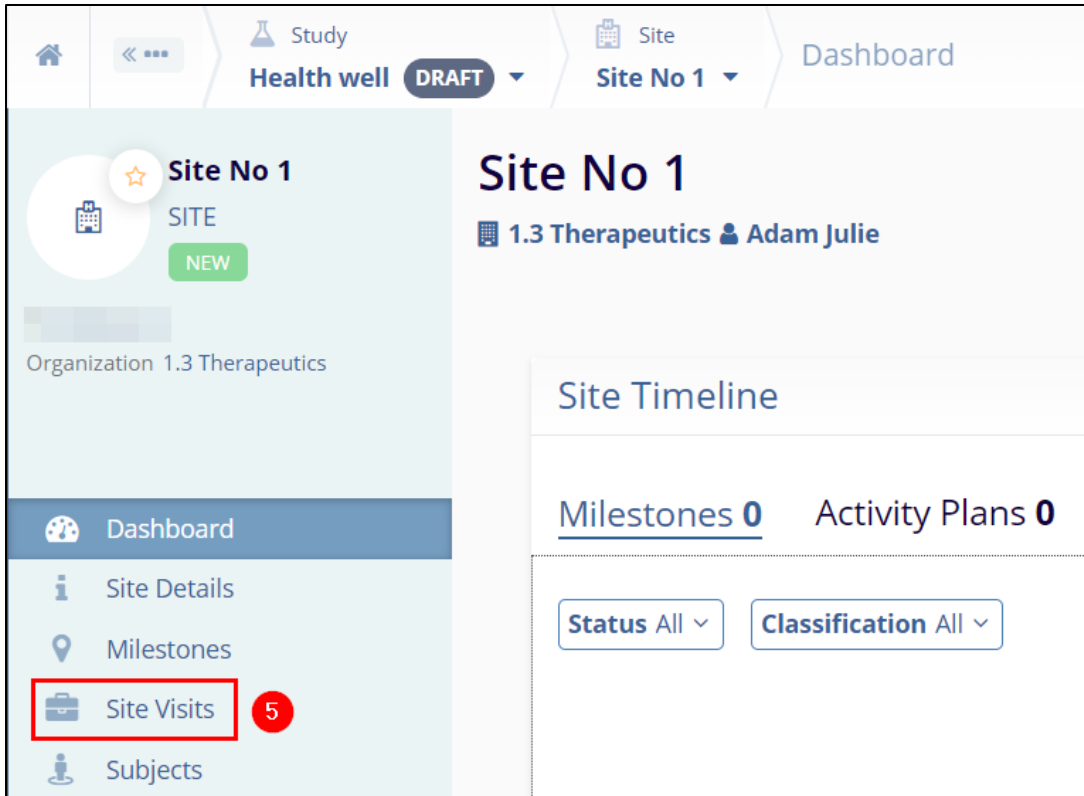


Figure: Select Site Visits

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

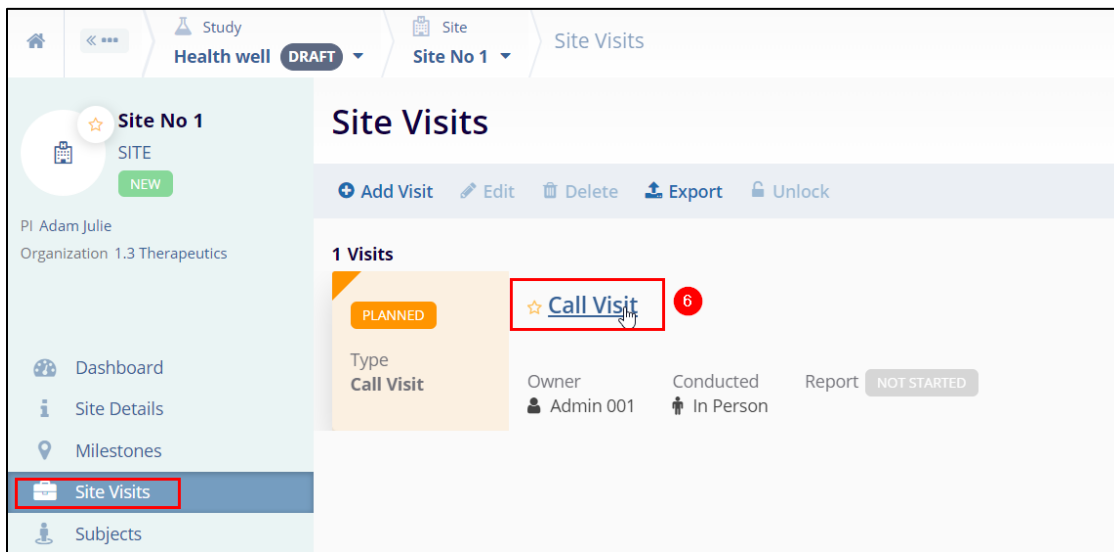


Figure: Select a visit

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

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

The screenshot shows the 'Call Visit' form with the following fields and values:

- Visit Type:** Call Visit
- Visit Status:** Planned
- Start Visit Time:** hour:minute AM/PM
- Duration:** Hours Days
- Visit Name:** Call Visit
- Visit Number:** (empty)
- Owner:** Admin 001
- Visit Planned Date:** 30 Jul 2024
- Co-Monitor:** (toggle off)
- General Comment:** (text area with rich text editor)
- Visit Start Date:** day month year
- Visit End Date:** day month year
- How Was The Visit Conducted:** In Person
- Visit Checklist Template:** (dropdown menu)

The bottom navigation bar includes buttons for: Previous Step, Add Activity, Discard Changes, Save (highlighted), Save and Next, and Next Step.

Figure: Updating site visit information

Site Visit Attendees

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

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

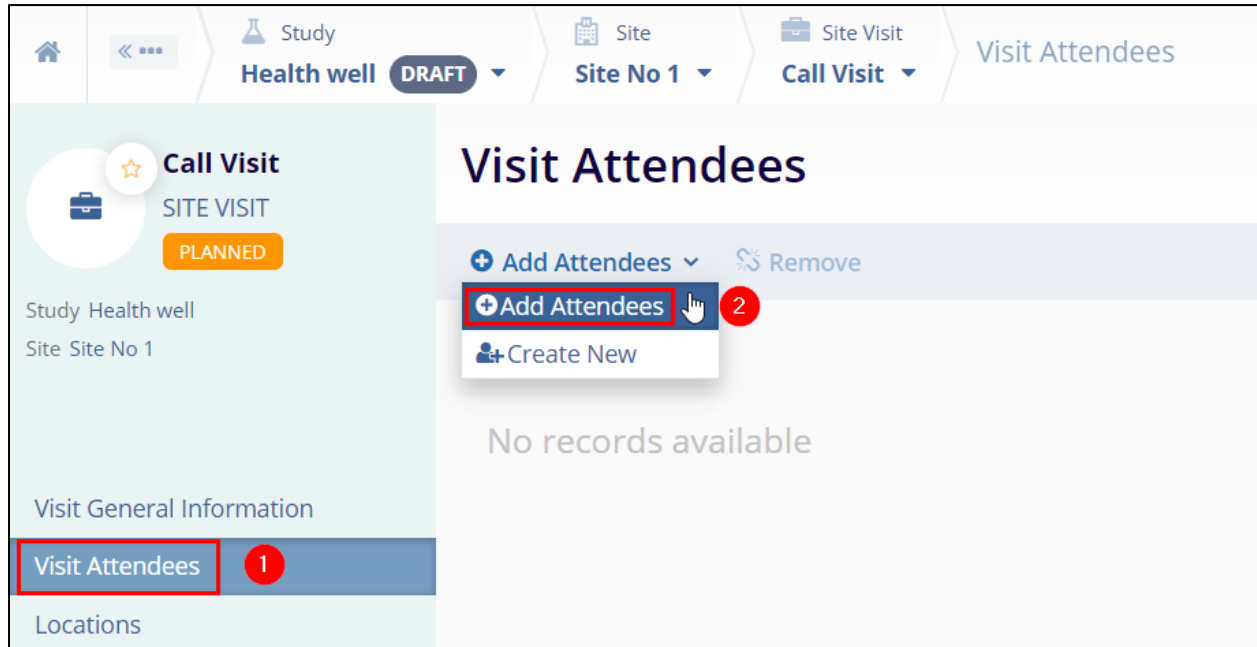


Figure: Add Attendees

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

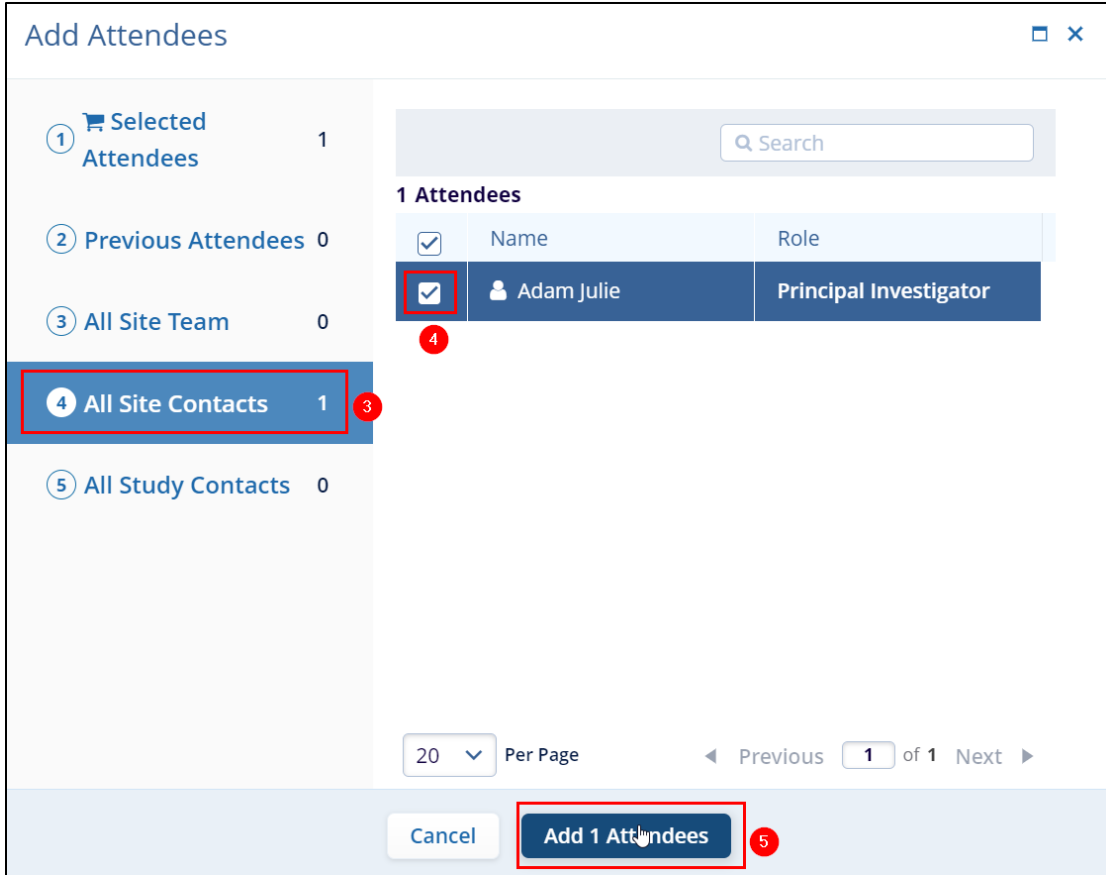


Figure: Add attendees from All Site Contacts

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

Site Visit Locations

To access Site Visit Locations, follow the steps below.

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

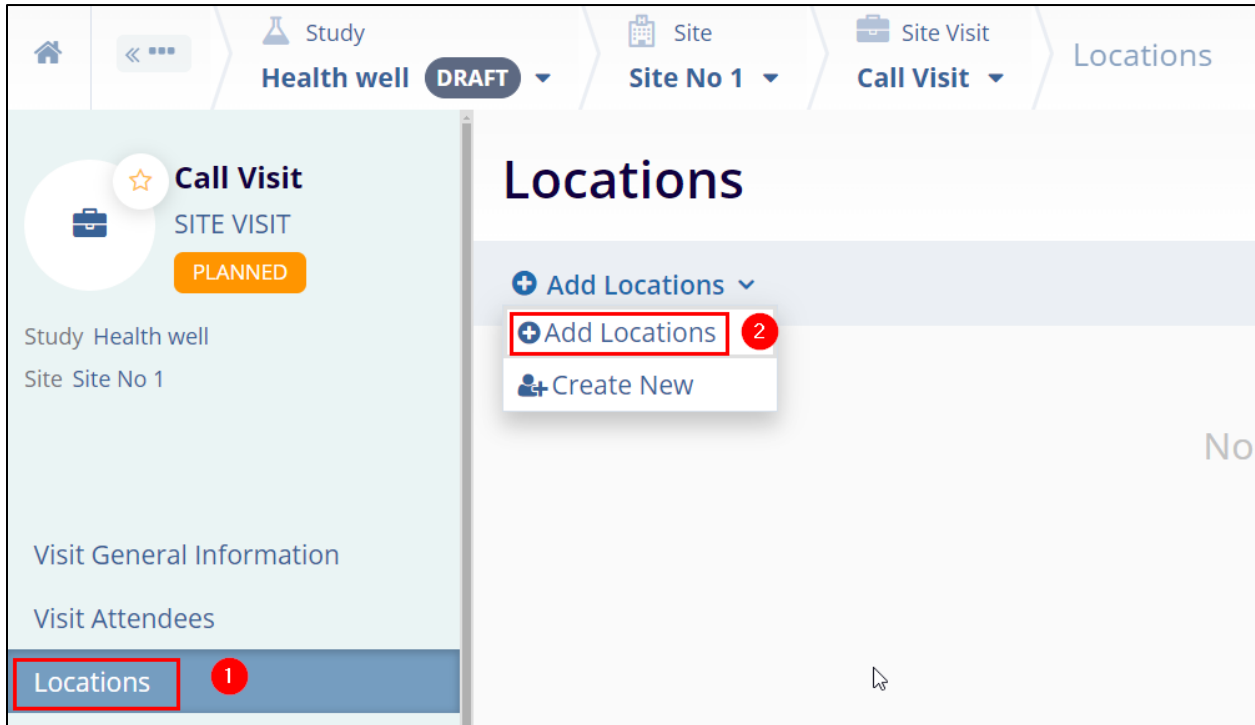


Figure: Add Locations

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

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

The screenshot shows the 'Add Locations' window with a sidebar on the left and a main table area. The sidebar contains three items: 'Selected Locations' (1), 'Previous Locations' (0), and 'All Site Locations' (1). The 'All Site Locations' item is highlighted with a red box and a red callout '3'. The main table area has a search bar and a table with one row. The table has columns: Organization Name, Status, Address Type, and Address. The row contains: 1.3 Therapeutics, ACTIVE, Primary, and 112 Main Street. A red callout '4' points to the selection checkbox in the first column of this row. At the bottom of the window, there are 'Cancel' and 'Add 1 Locations' buttons. The 'Add 1 Locations' button is highlighted with a red box and a red callout '5'. There is also a 'Per Page' dropdown set to 20 and pagination controls showing '1 of 1'.

Figure: Add location from All Site Locations

Site Visit Checklist

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

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

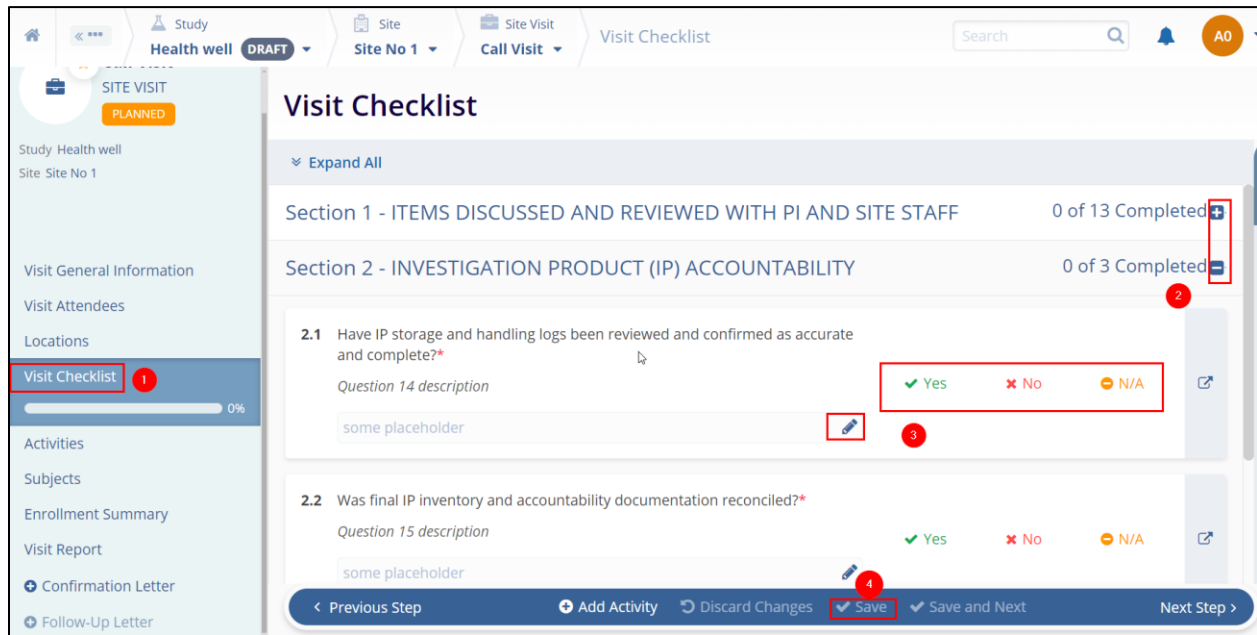


Figure: Visit Checklist

Note

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

Site Visit Activities

To access Site Visit Activities, follow the steps below.

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

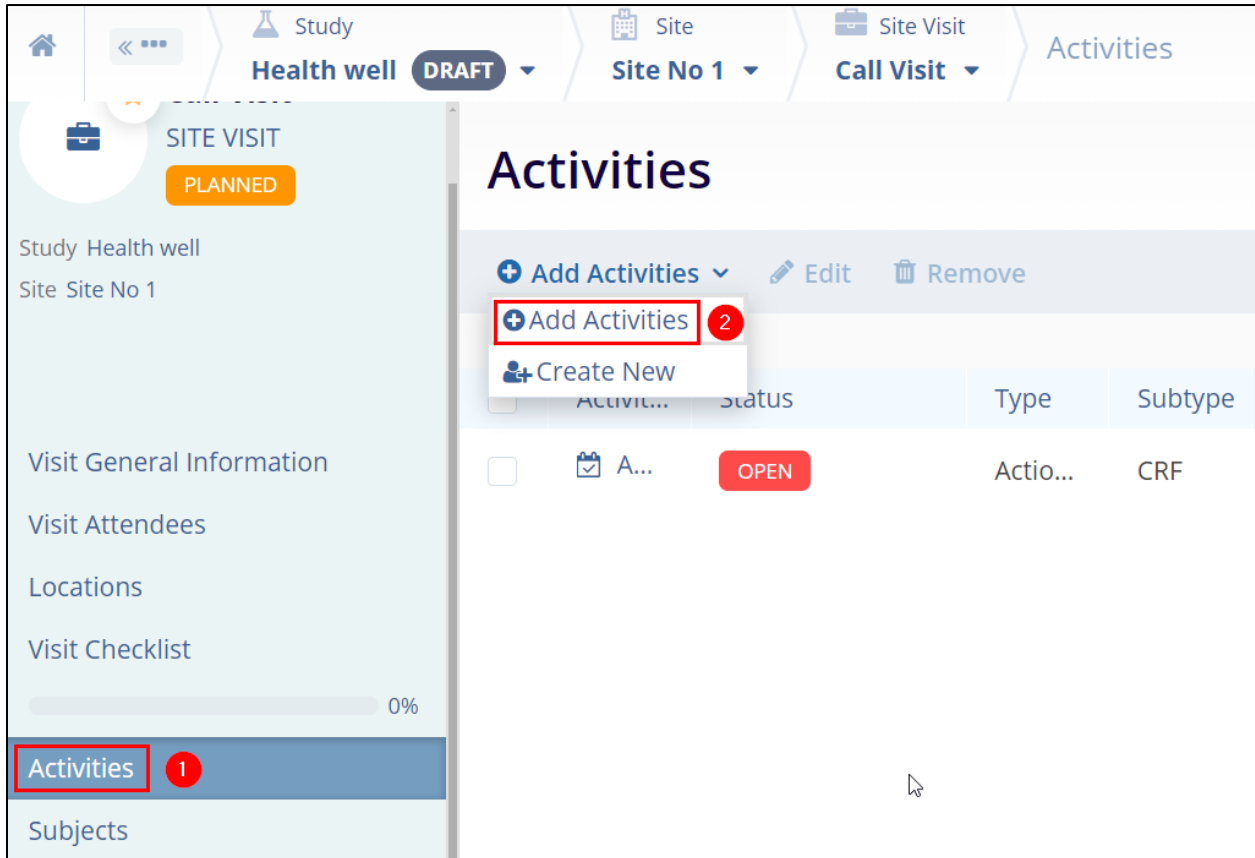


Figure: Add Activities

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

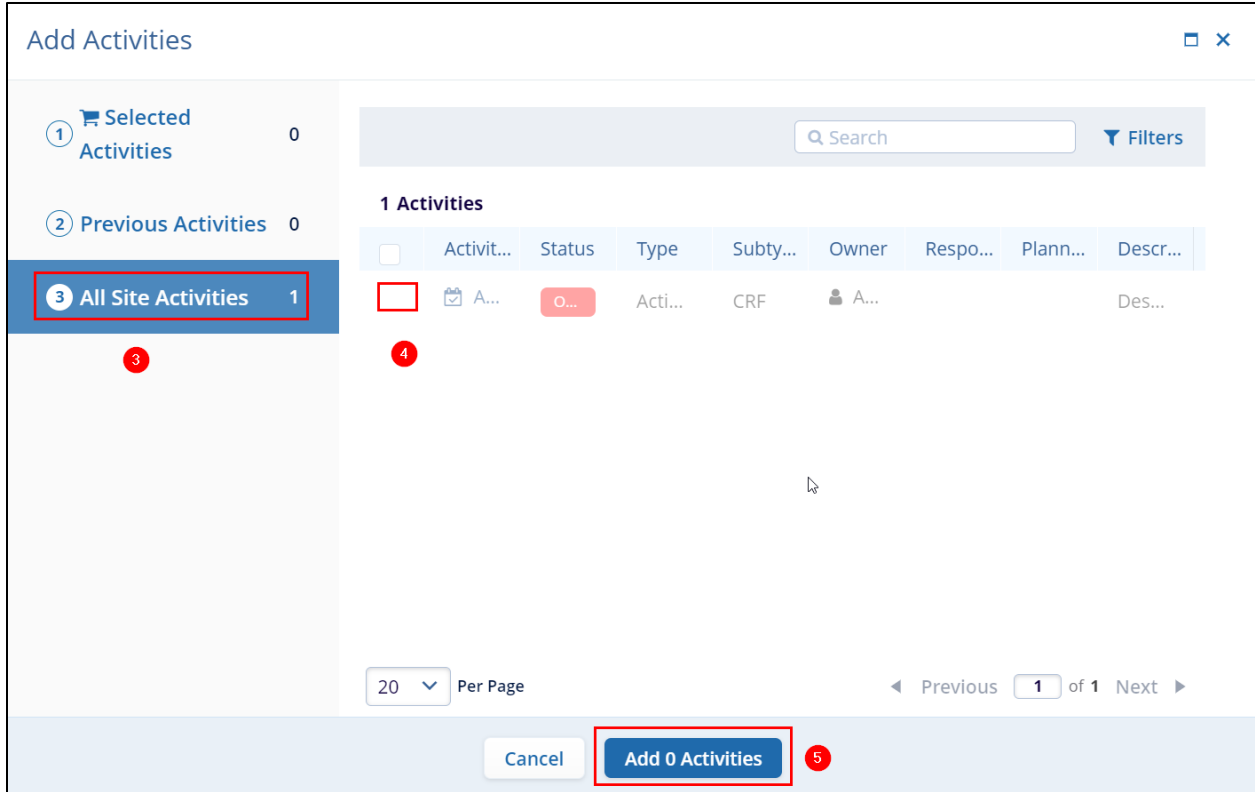


Figure: Add activities from All Site Activities

Site Visit Subjects

To access Site Visit Subjects, follow the steps below

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

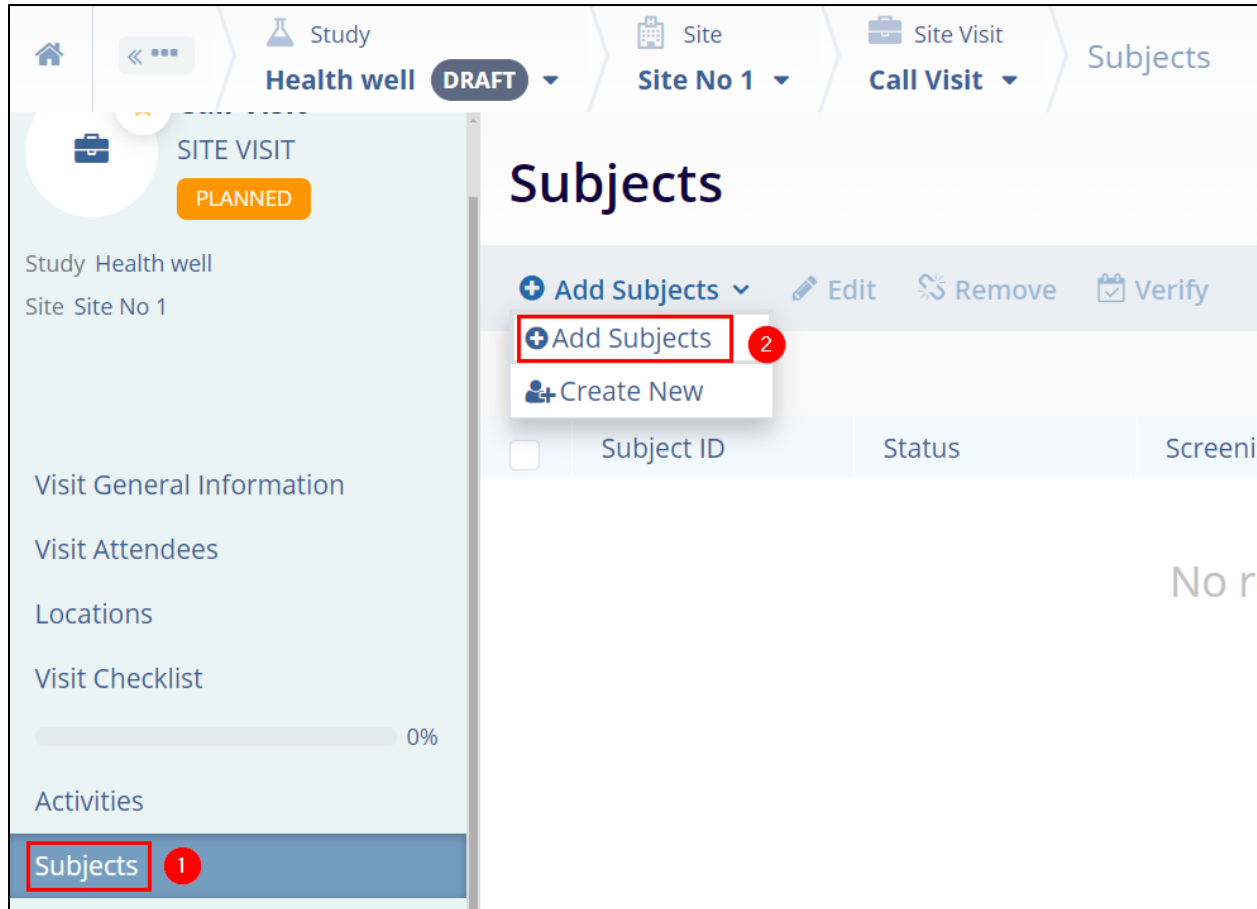


Figure: Add Subjects

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

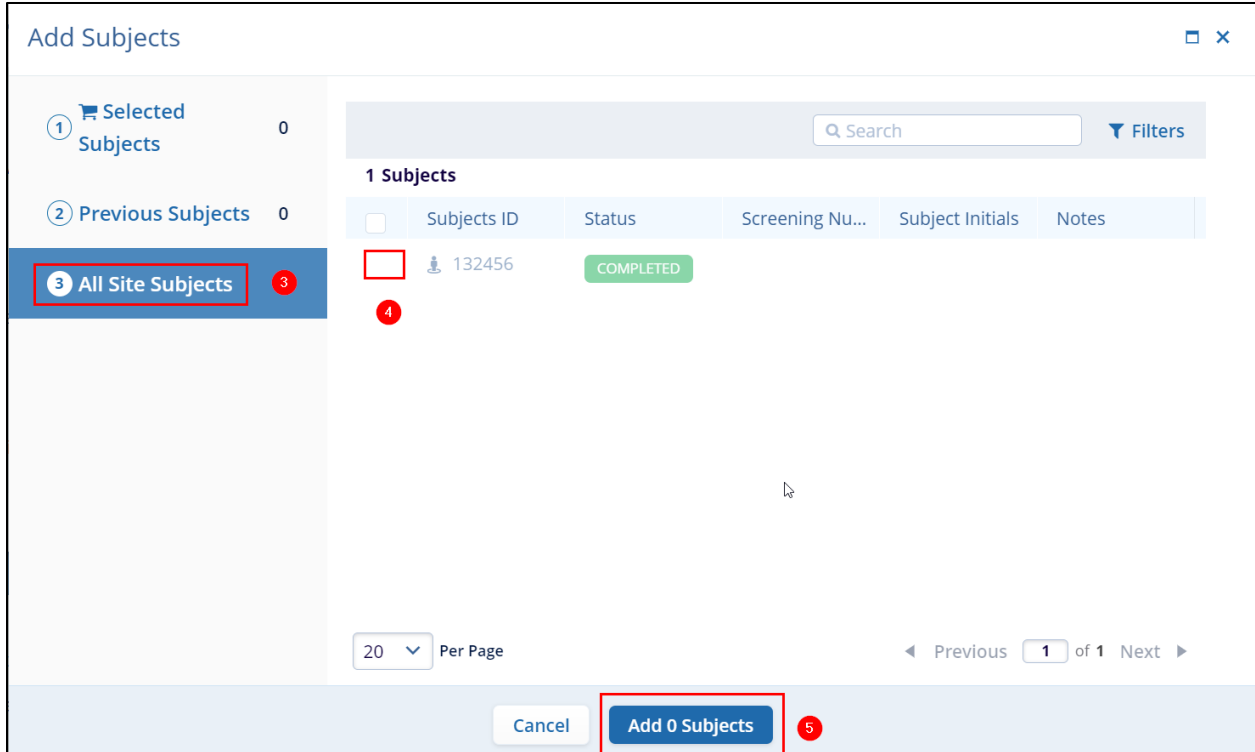


Figure: Adding subjects from All Site Subjects

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

Site Visit Enrollment Summary

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

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

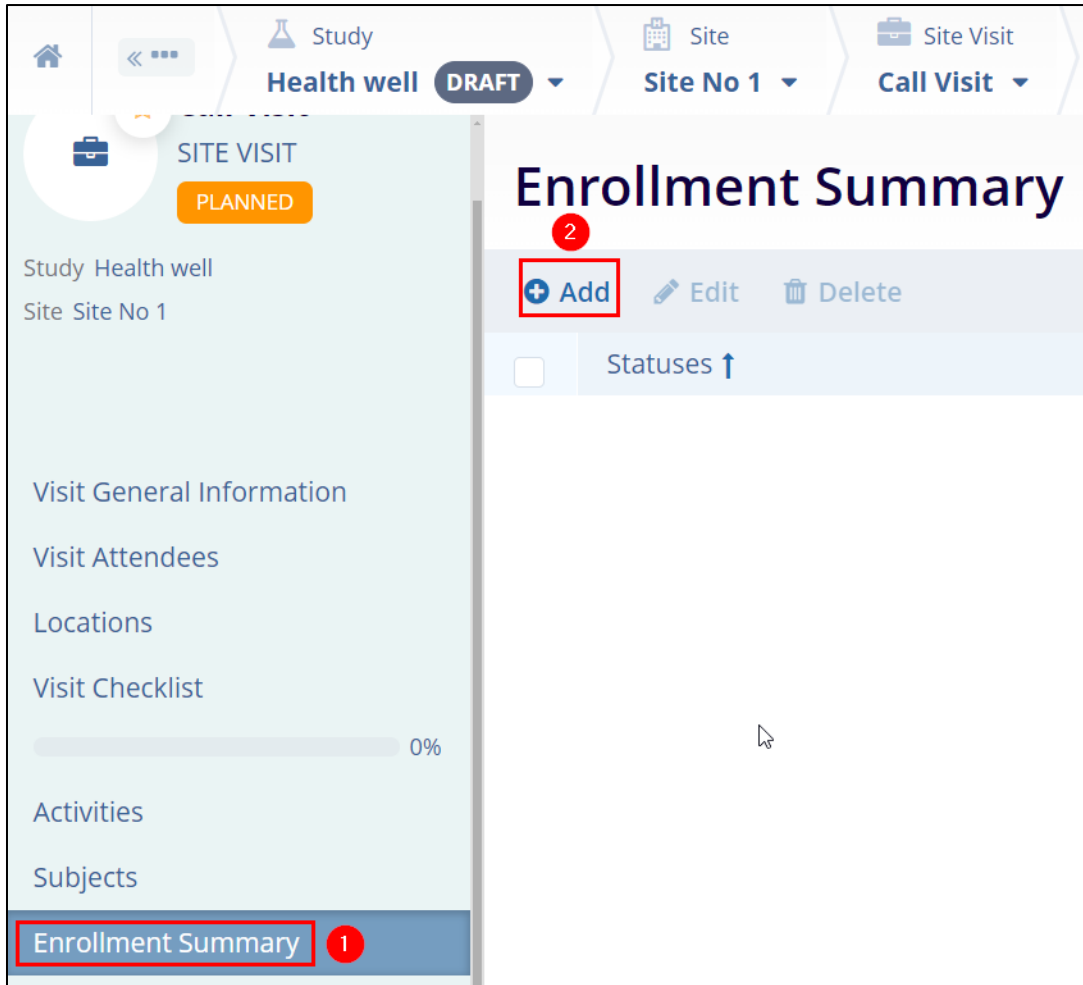


Figure: Add Enrollment Summary

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

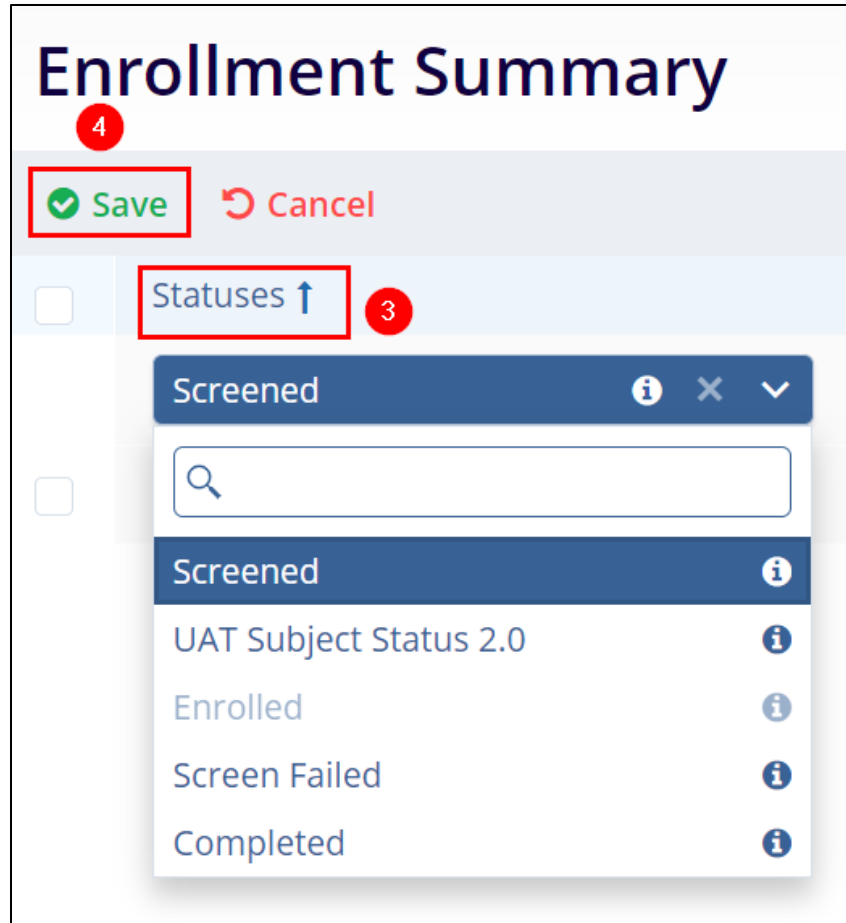


Figure: Select Summary Status

Note

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

Site Visit Confirmation Letter Creation

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

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

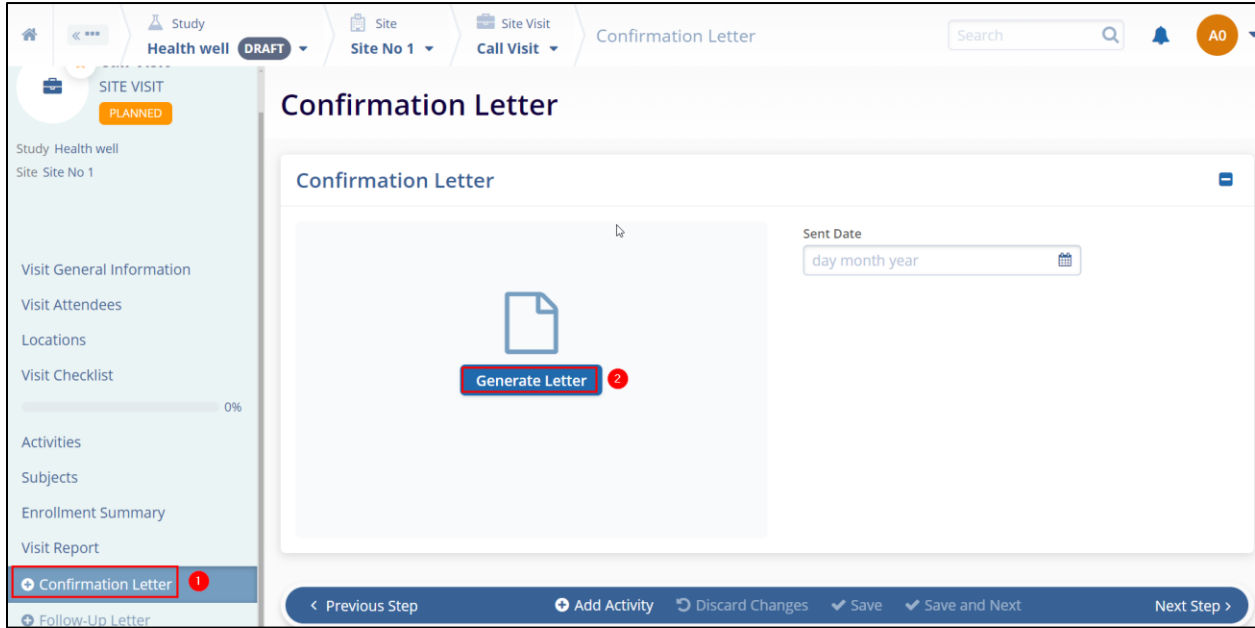


Figure: Generate Confirmation Letter

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

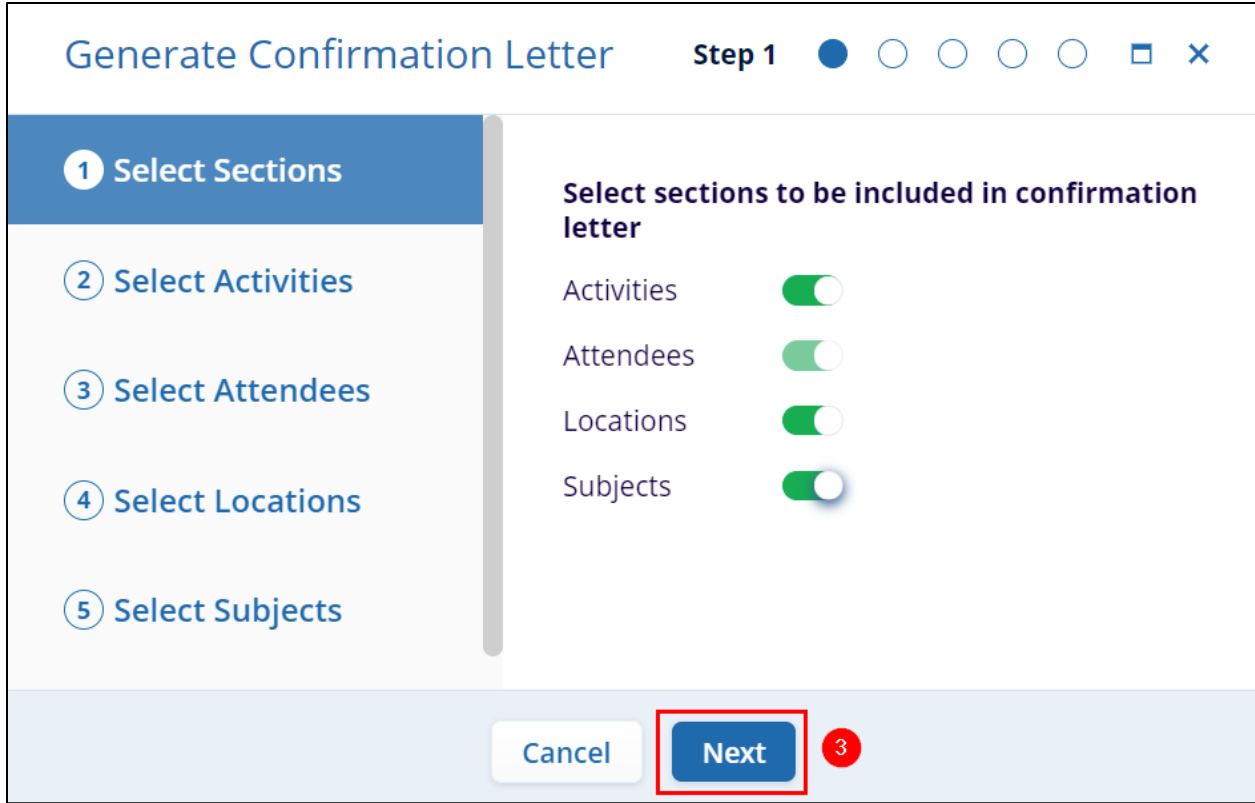


Figure: Generate Confirmation letter steps

Signing the Document and Workflow Approval

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

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

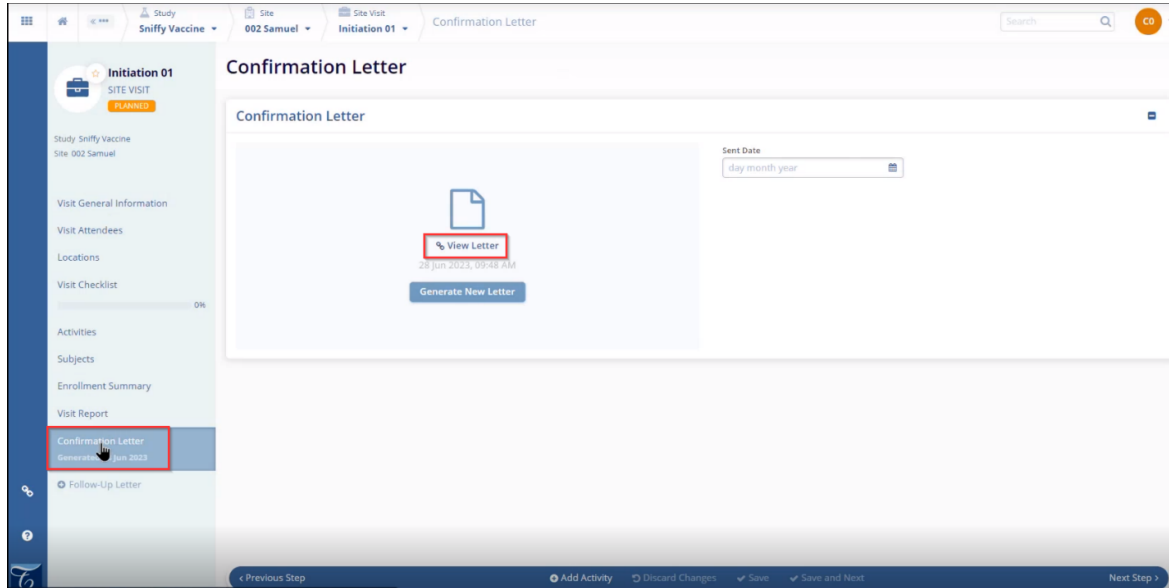


Figure: View Letter

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

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

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

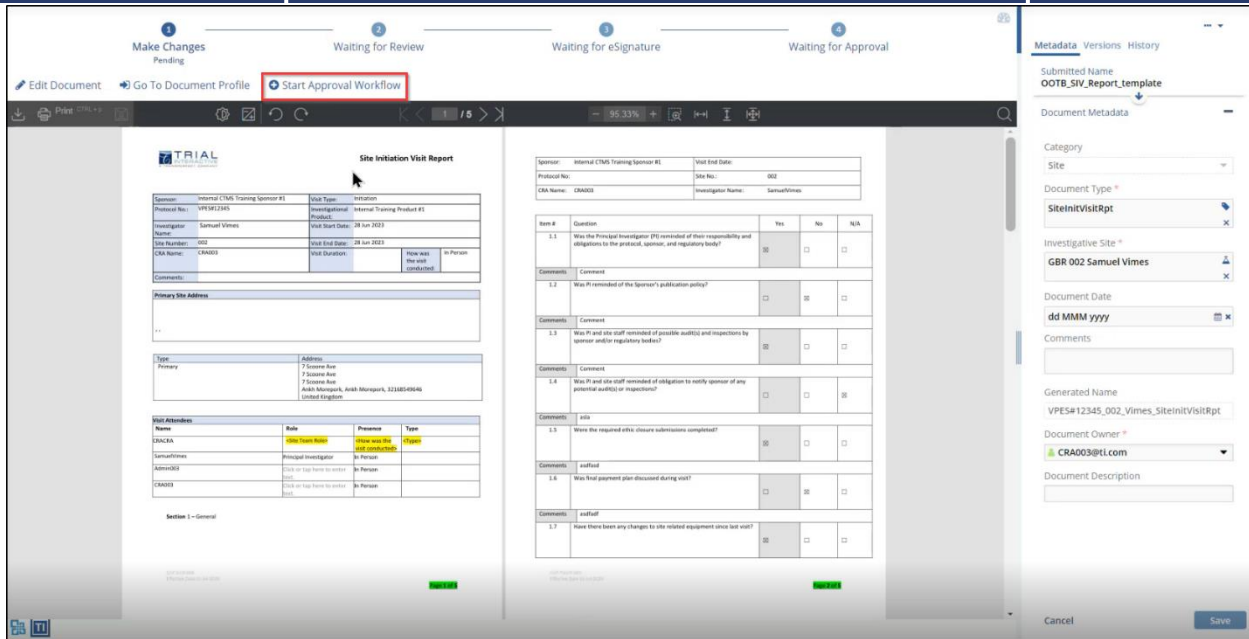


Figure: Start Approval Workflow

- A notification is displayed in the top right corner – Add document(s) to Monitoring Visit Workflow.

Note: The **Make Changes** stepper displayed in the top right corner shows a green tick mark with Complete status. Refer to the screenshot below.

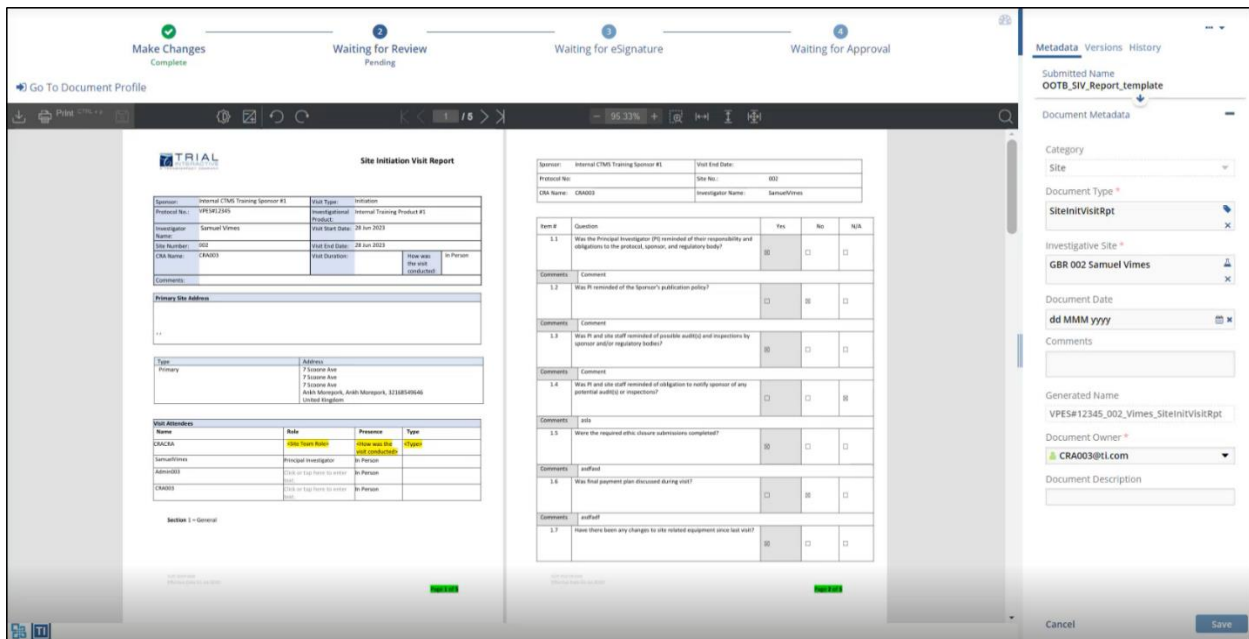


Figure: Add document(s) to monitoring

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

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

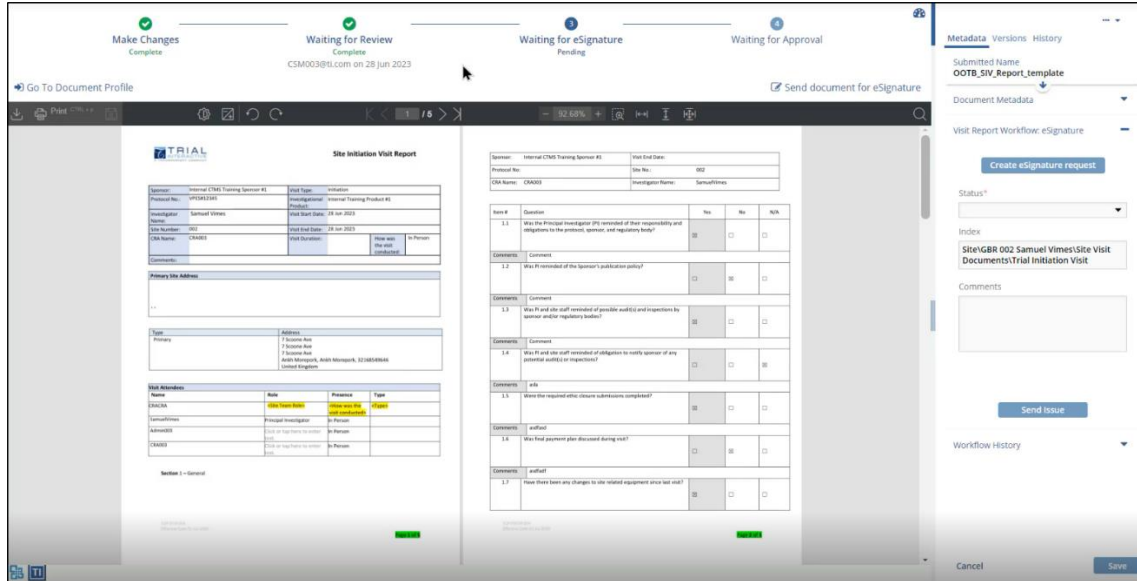


Figure: Waiting for Review

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

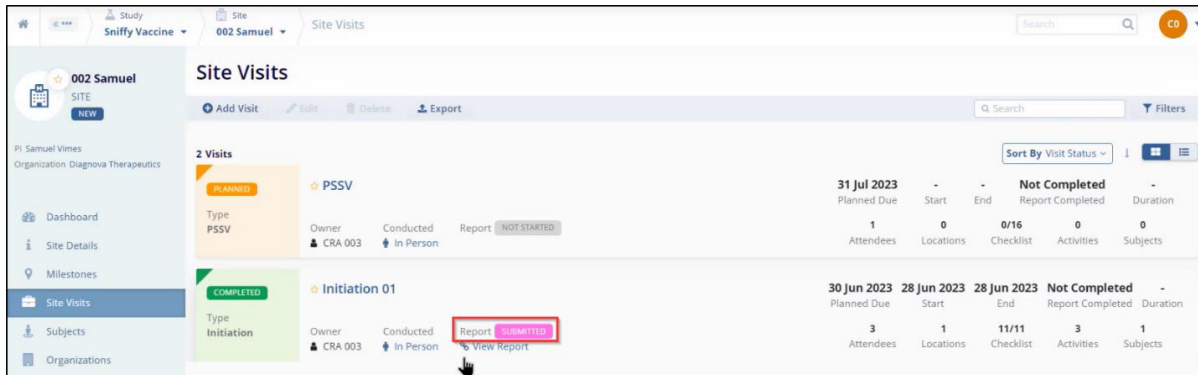


Figure: Status changed to Submitted

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

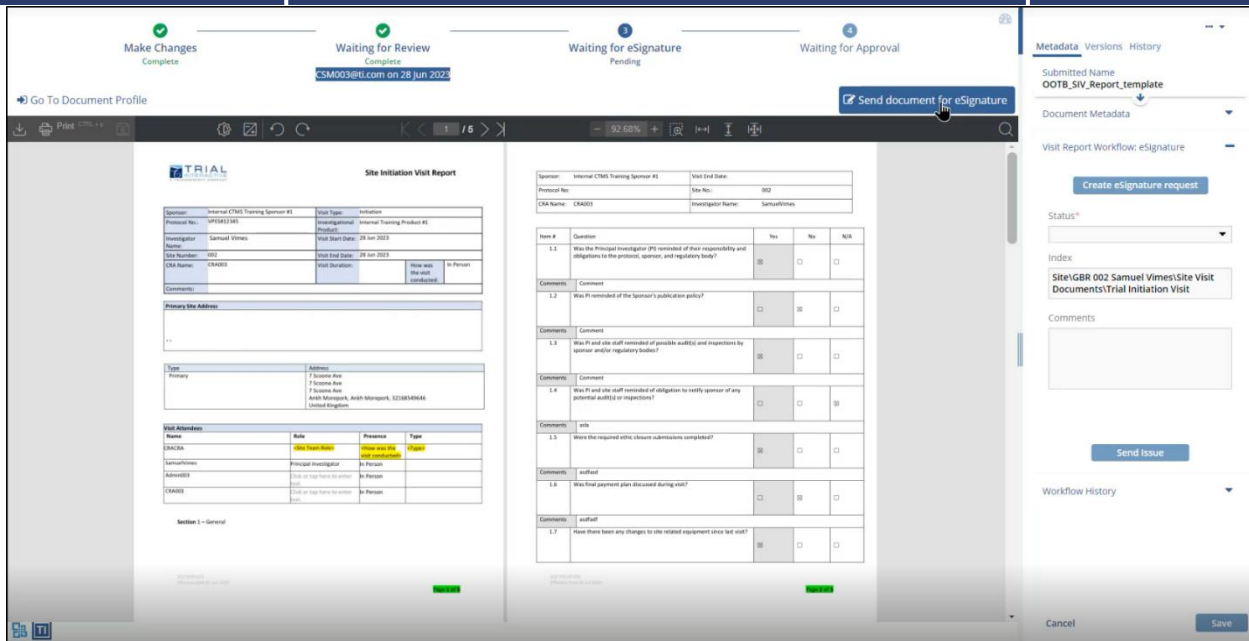


Figure: Send document for eSignature

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

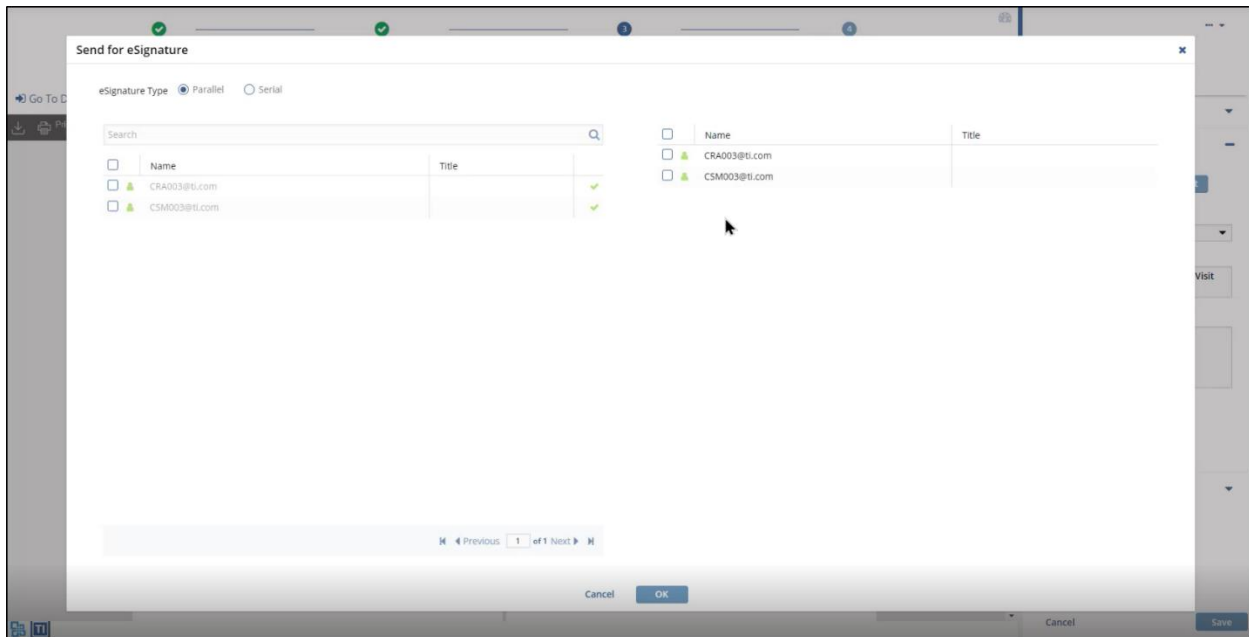


Figure: Send for eSignature screen

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

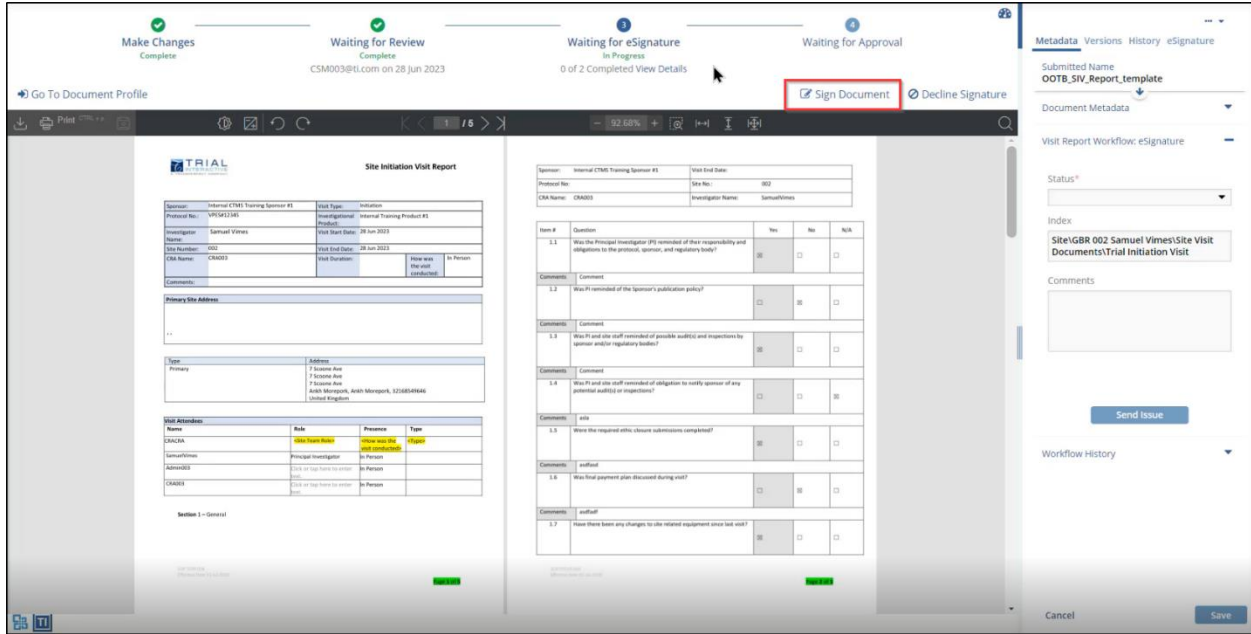


Figure: Sign Document option

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

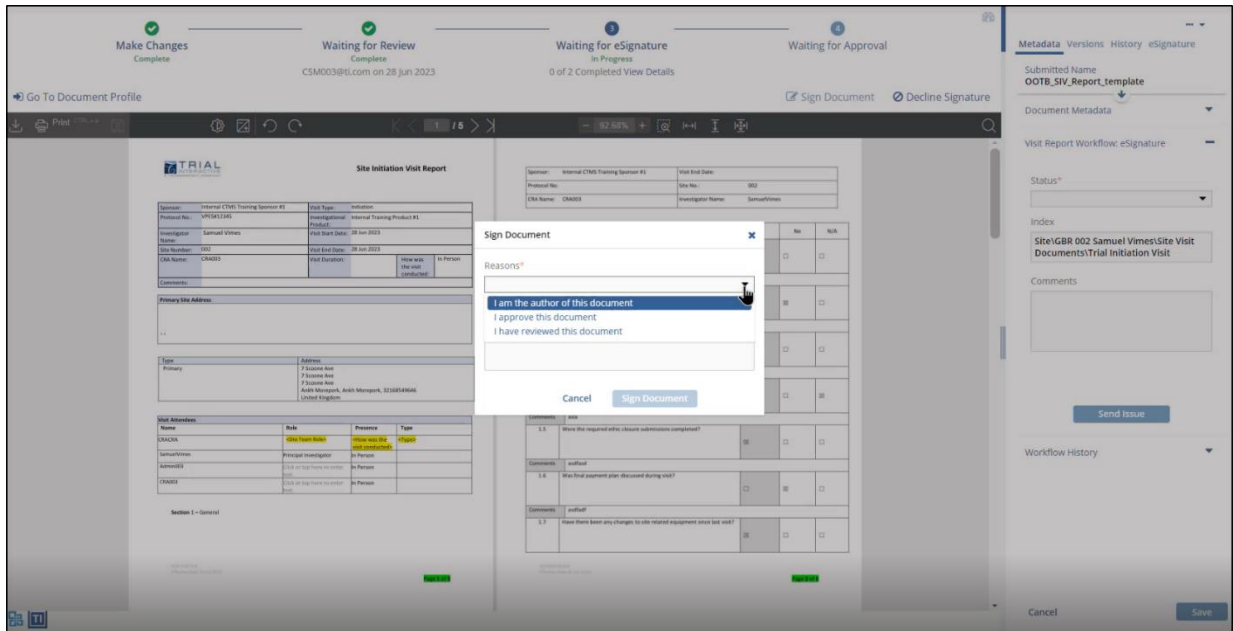


Figure: Sign Document screen

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

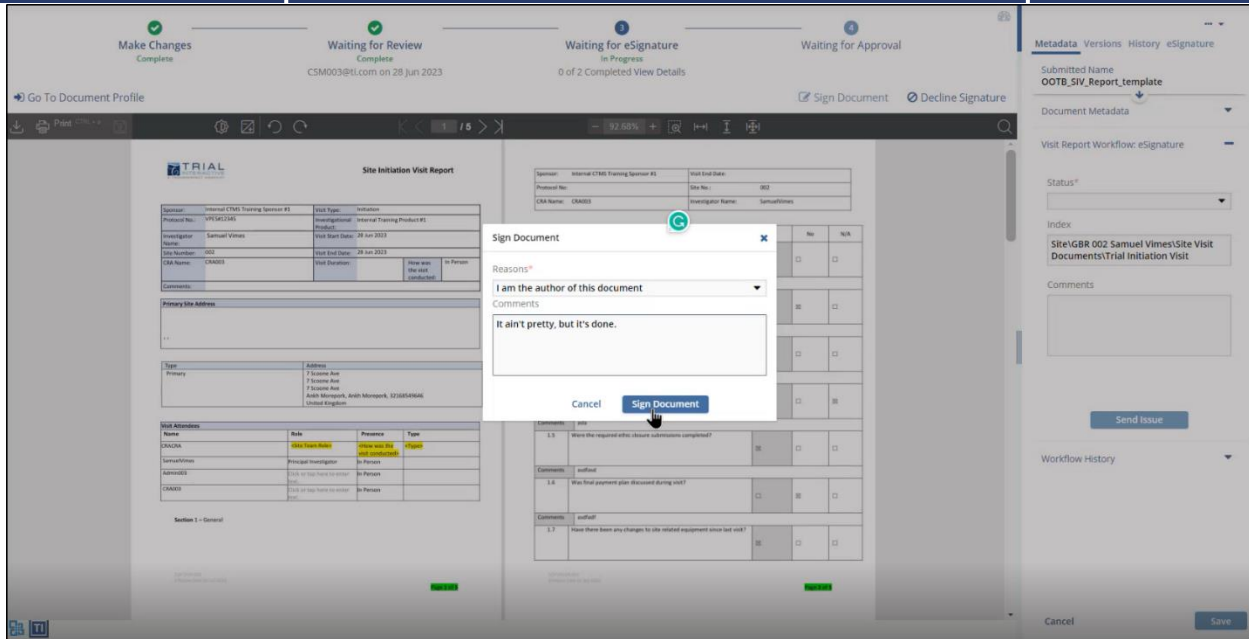


Figure: Entering comments

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

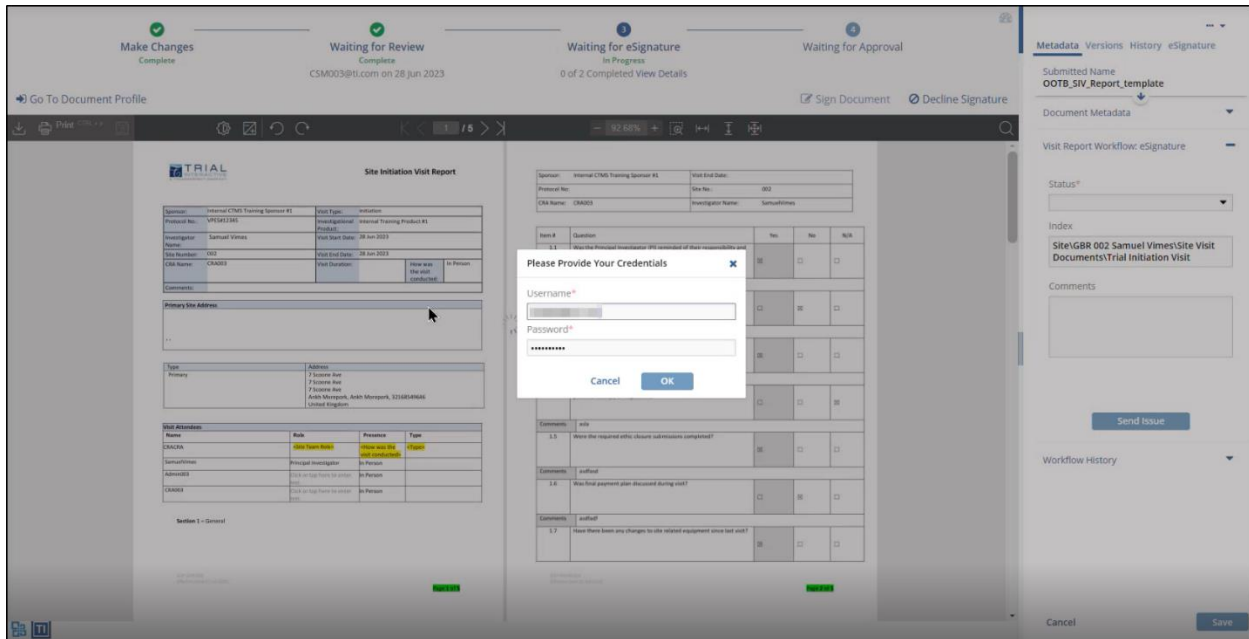


Figure: Please Provide Your Credentials screen

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

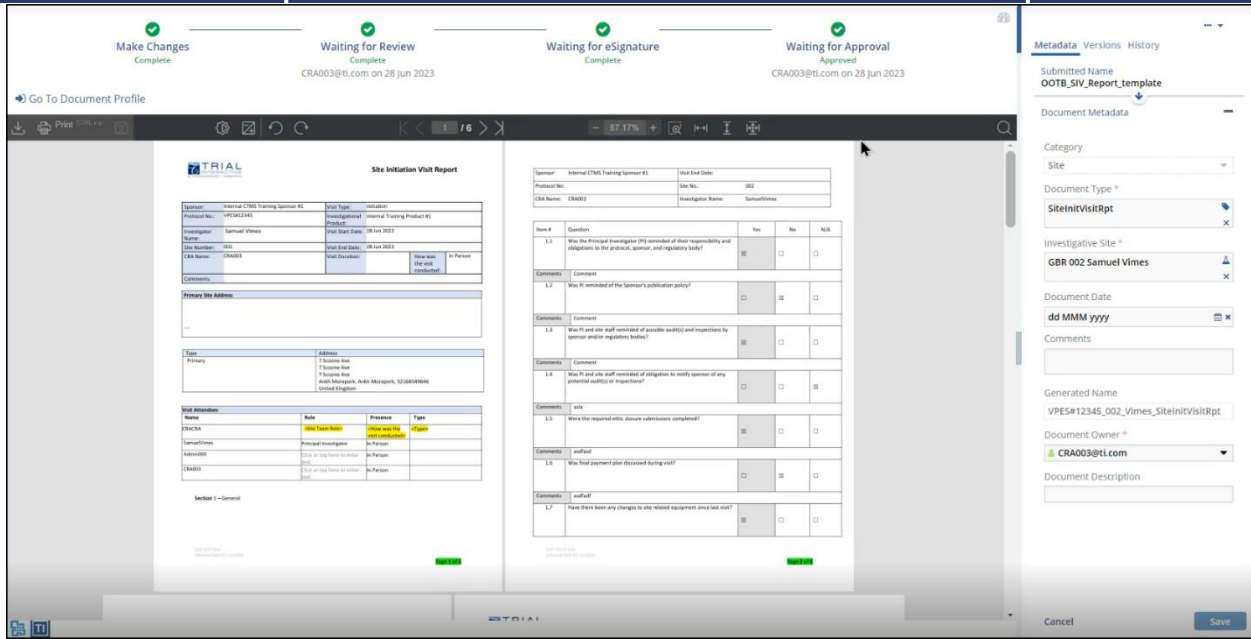


Figure: Approved and Signed Document

Site Visit Draft Report Generation

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

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

The screenshot shows the 'Visit Report' interface. On the left, there are two large buttons: 'Generate Report Preview' and 'Create Visit Report'. The 'Create Visit Report' button is highlighted with a red box. To the right of these buttons is a form with several fields: 'Report Status' (set to 'In Progress' and highlighted with a red box), 'Reviewer' (empty), 'Status Date' (7/25/2024), and 'Reason for Rejection' (empty text area).

Figure: Create Visit Report

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

Create Visit Report ✕

Completeness Check

- ✔ General Information
- ✔ Attendees **1 Items**
- ✔ Locations **1 Items**
- ✔ Visit Checklist **16 of 16 required completed**

Other Visit Info

- Activities **1 Items**
- Subjects **1 Items**
- Enrollment Summary **2 Items**

Reviewers

❗ There are **No Reviewers** defined for this report

Reviewers are captured within the Study Settings, Study Managers can process any required updates

Related Documentation

<input type="checkbox"/> All Site Milestones	<input type="checkbox"/> All Site Subjects
<input type="checkbox"/> All Site Contacts	<input type="checkbox"/> Subjects ICFs
<input type="checkbox"/> All Site ICFs	<input type="checkbox"/> Subjects Visits
<input type="checkbox"/> All Site Addresses	<input type="checkbox"/> Site Team
<input type="checkbox"/> All Site Organizations	

Cancel
Generate Report

Figure: Generate Report

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

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

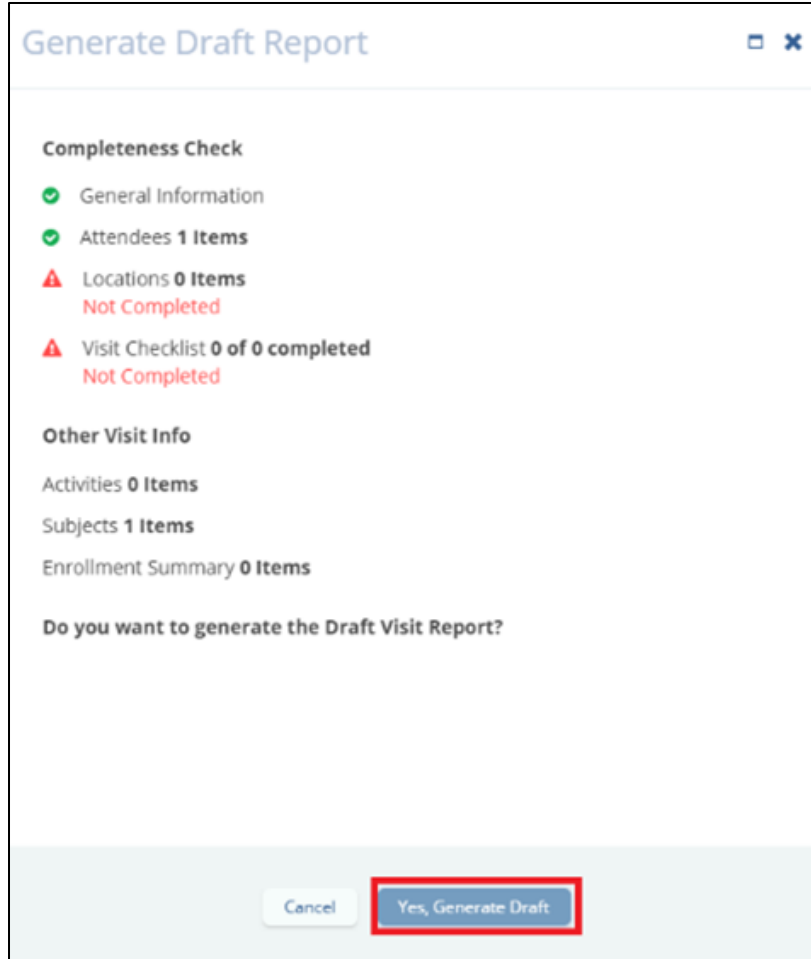


Figure: Yes Generate Draft option

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

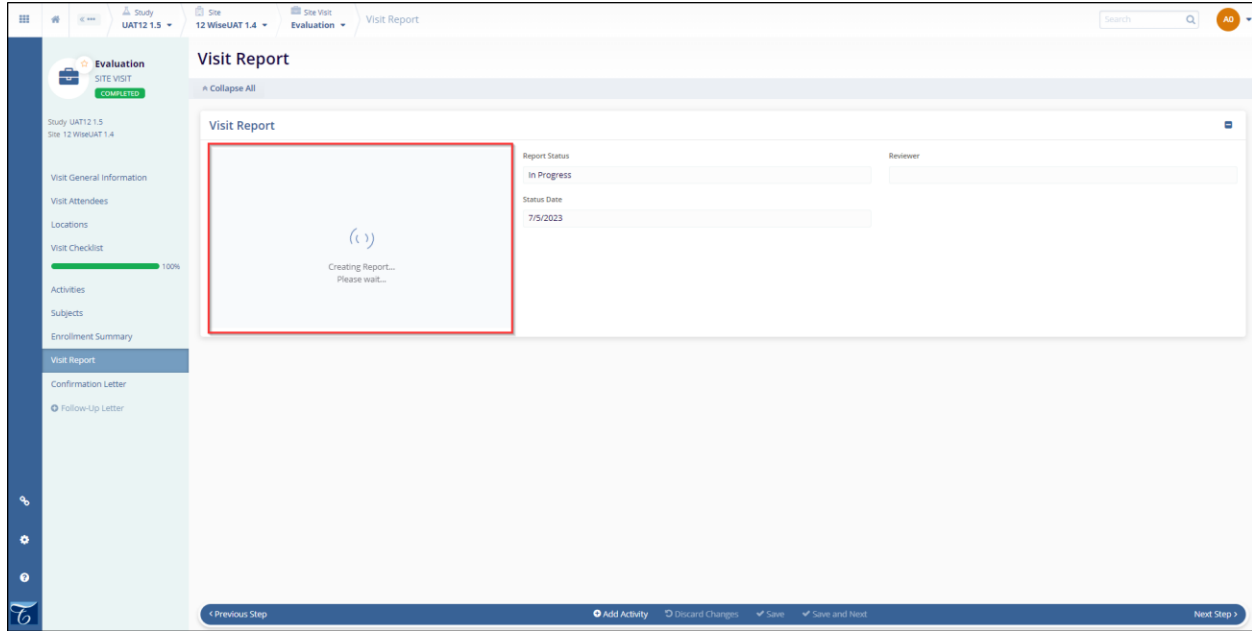


Figure: Generate Report notification

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

Site Visit Final Report Generation

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

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

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

Site Visit Follow-up Letter Creation

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

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

Access Permissions

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

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

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

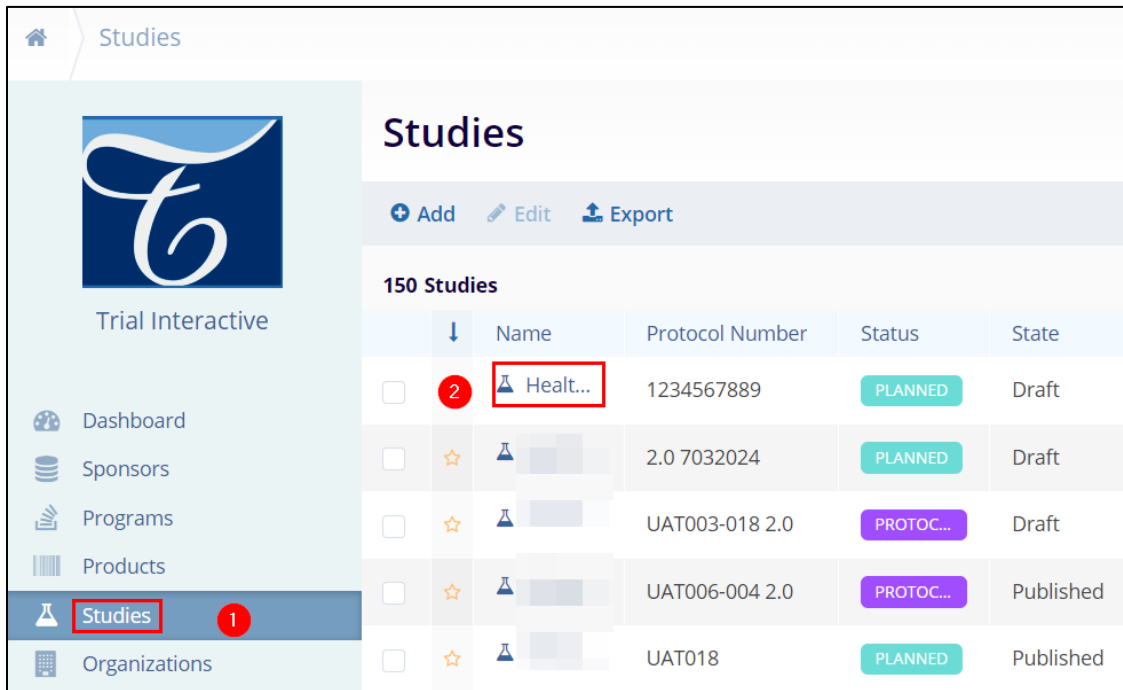


Figure: Select a Study and a study name

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

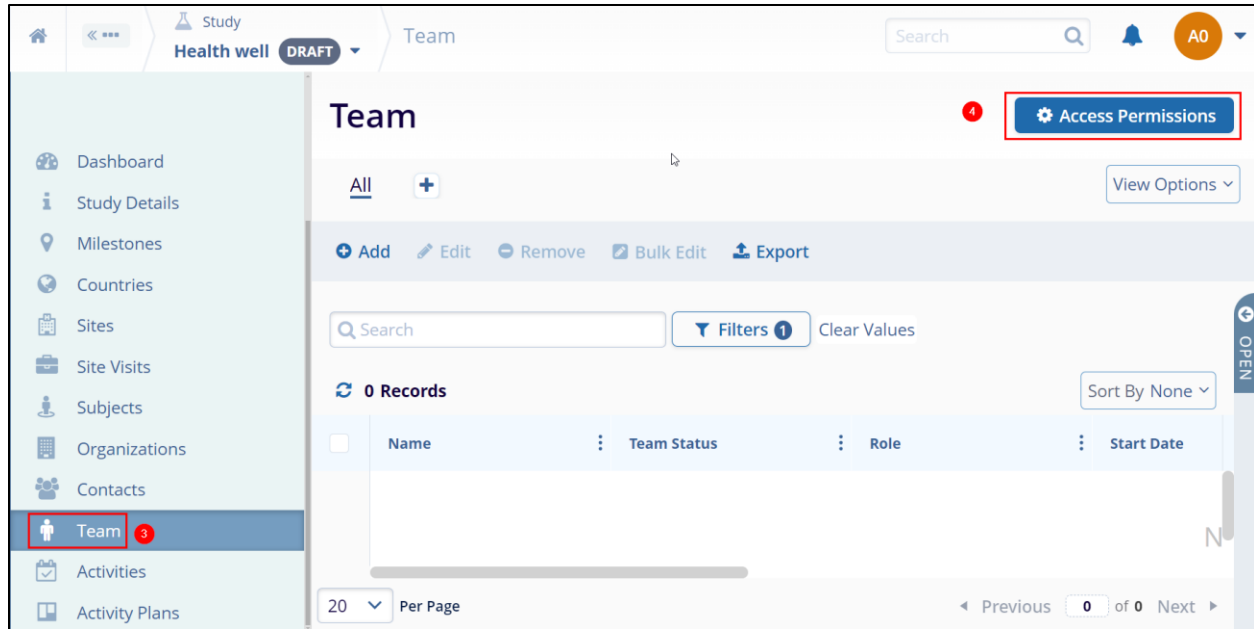


Figure Access Permissions

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

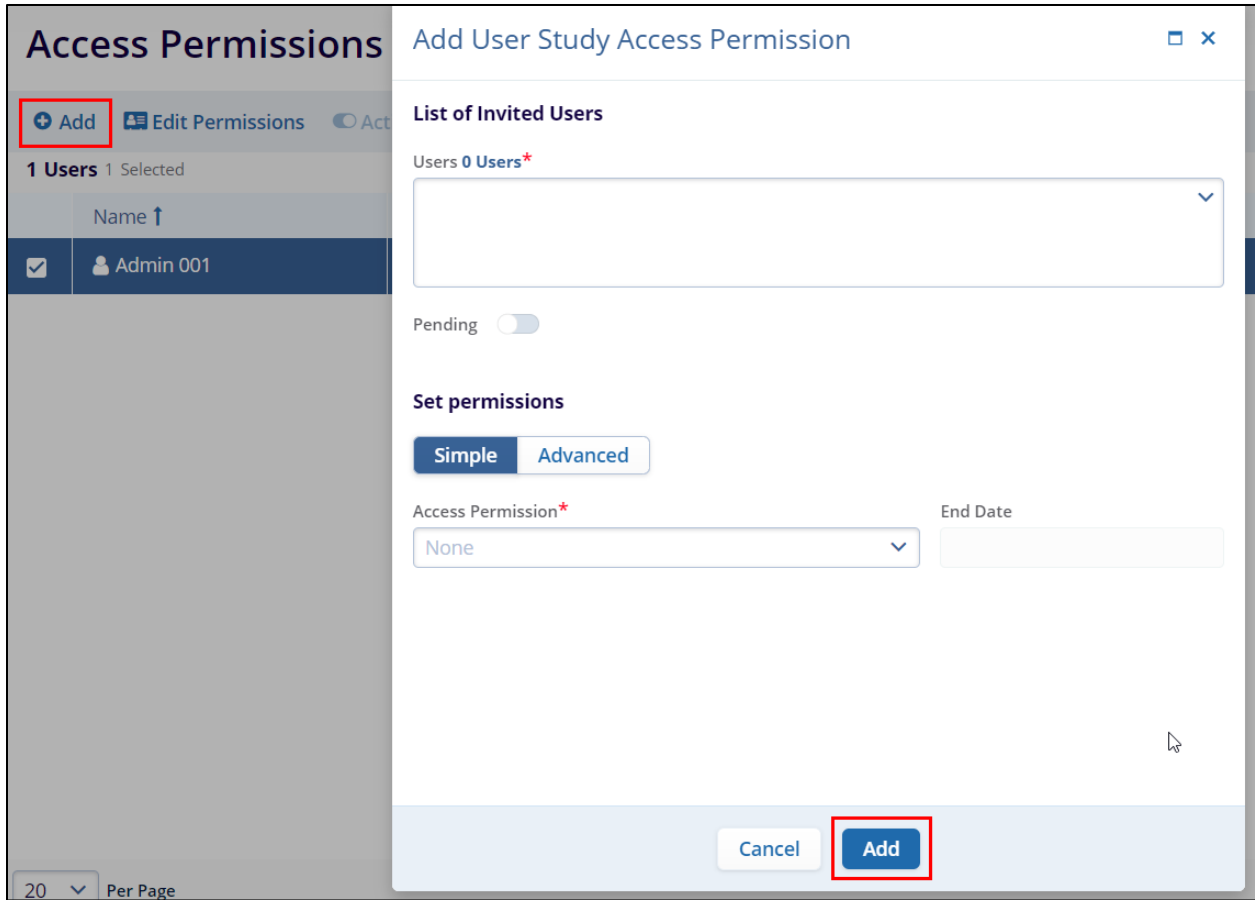


Figure: Add User

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

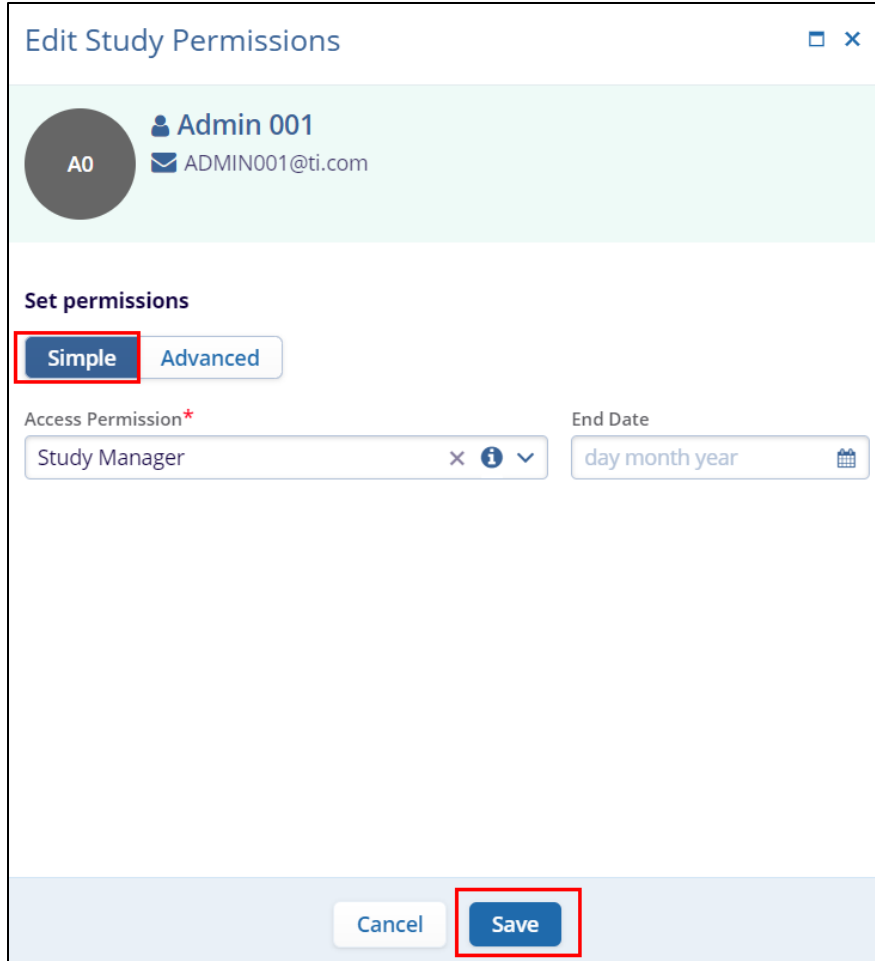


Figure: Edit Study Permissions-Simple

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

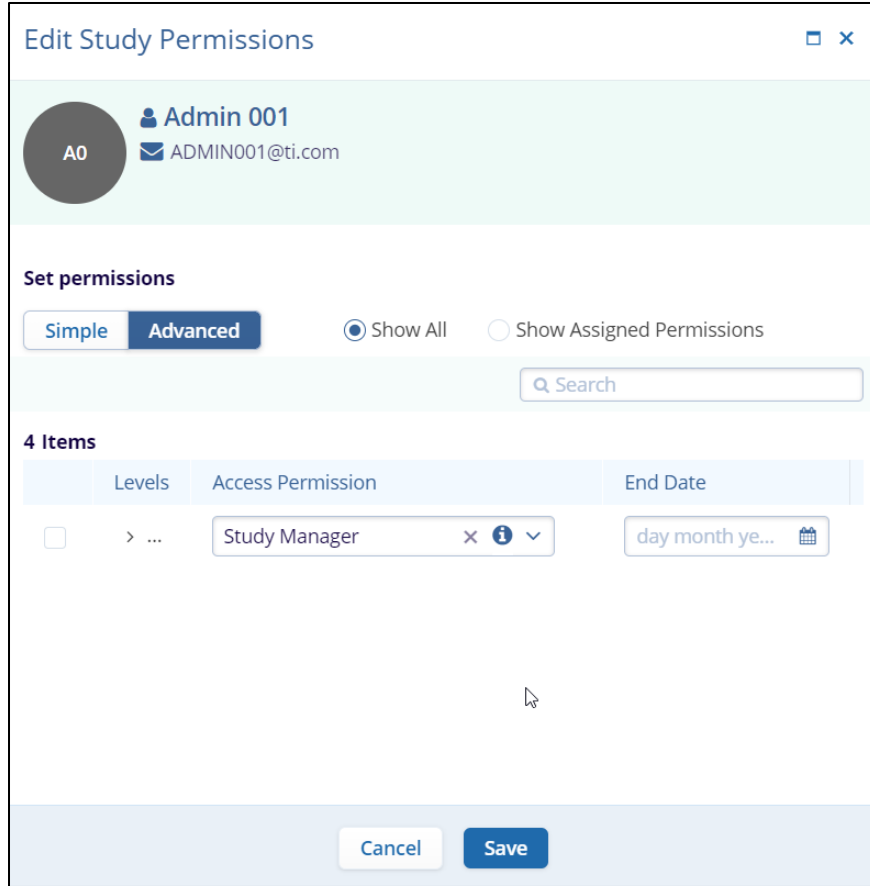


Figure: Edit Study Permissions-Advanced

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

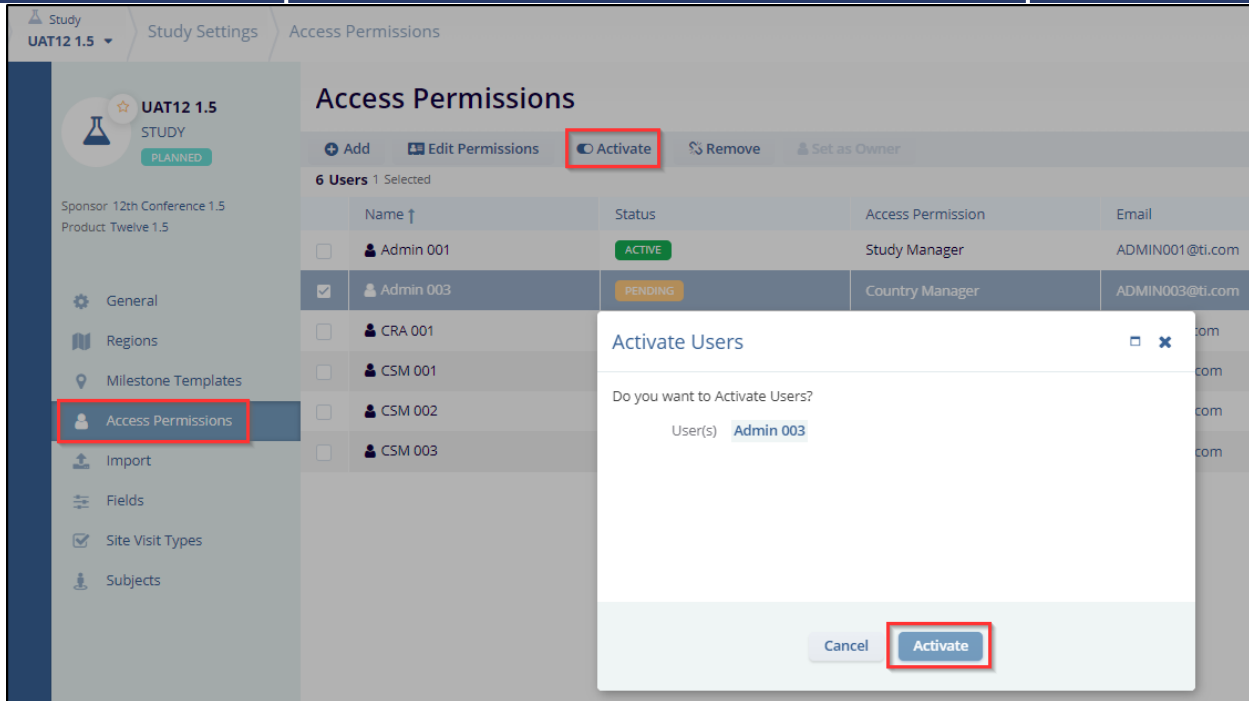


Figure: Activate users

d. Remove

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

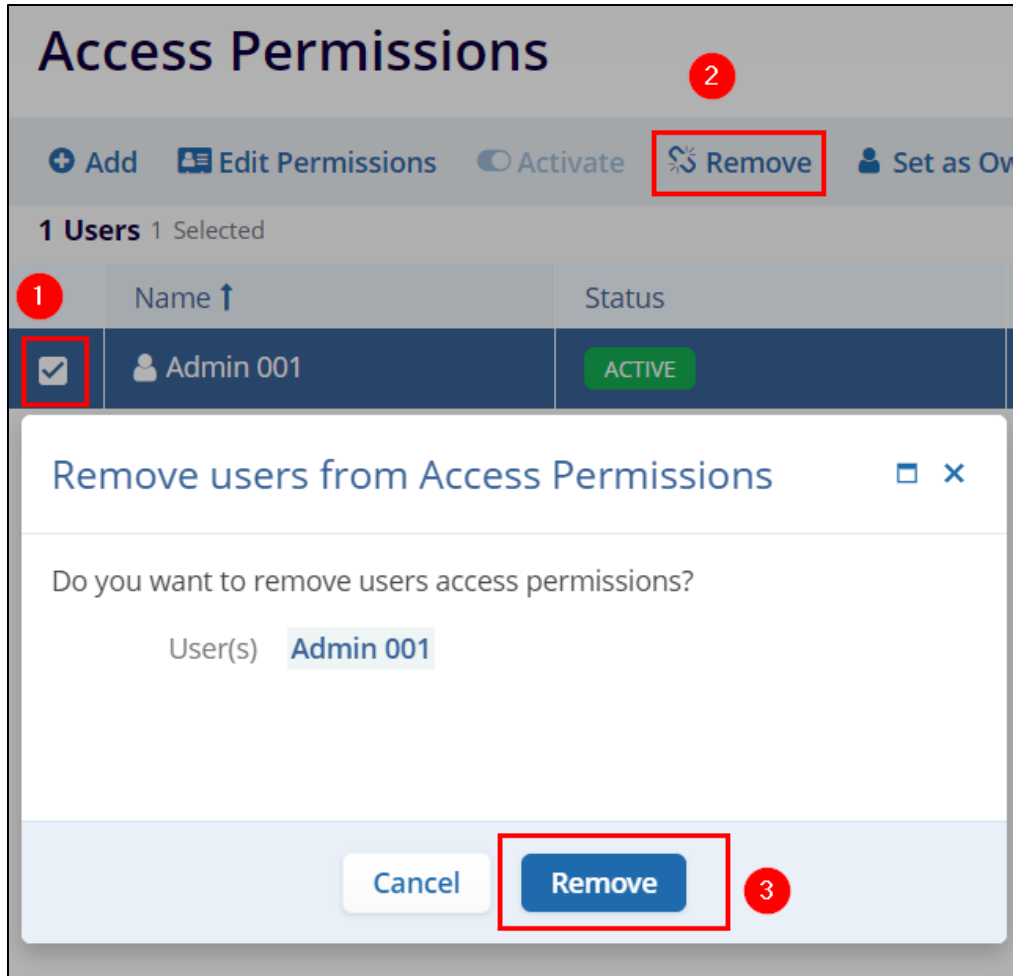


Figure: Remove the user

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

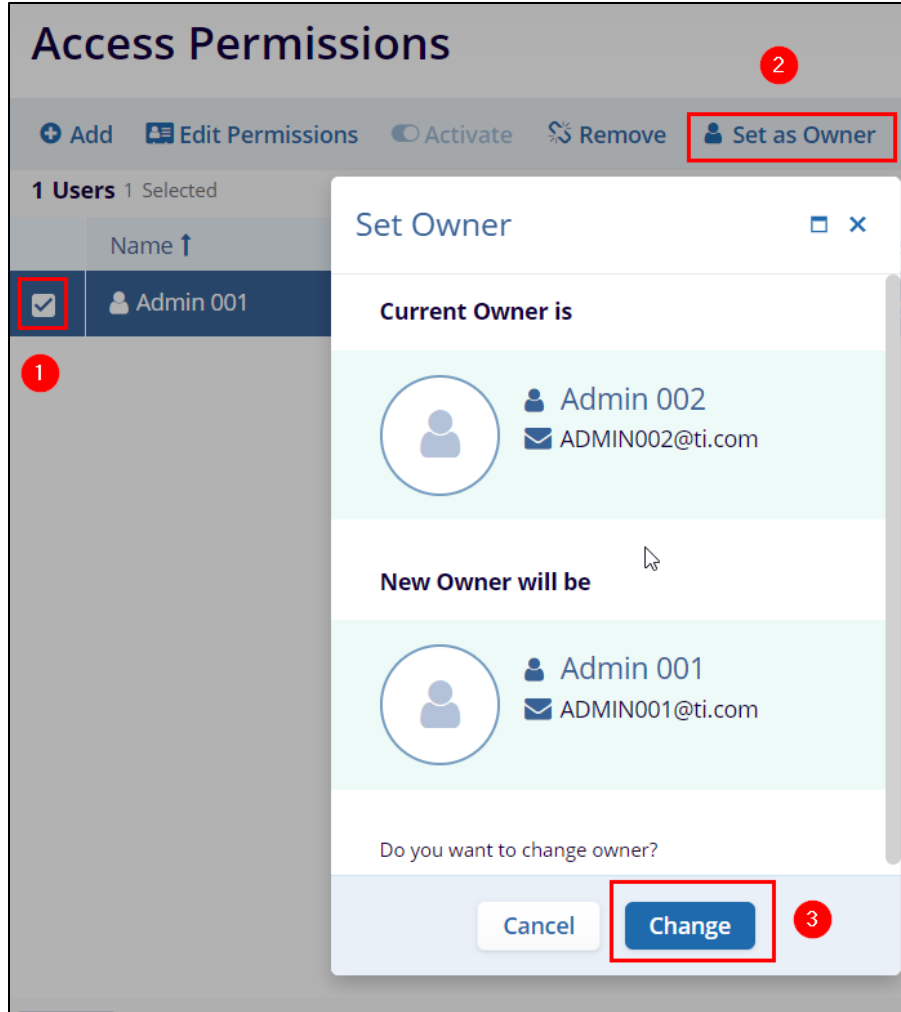


Figure: Set as Owner

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

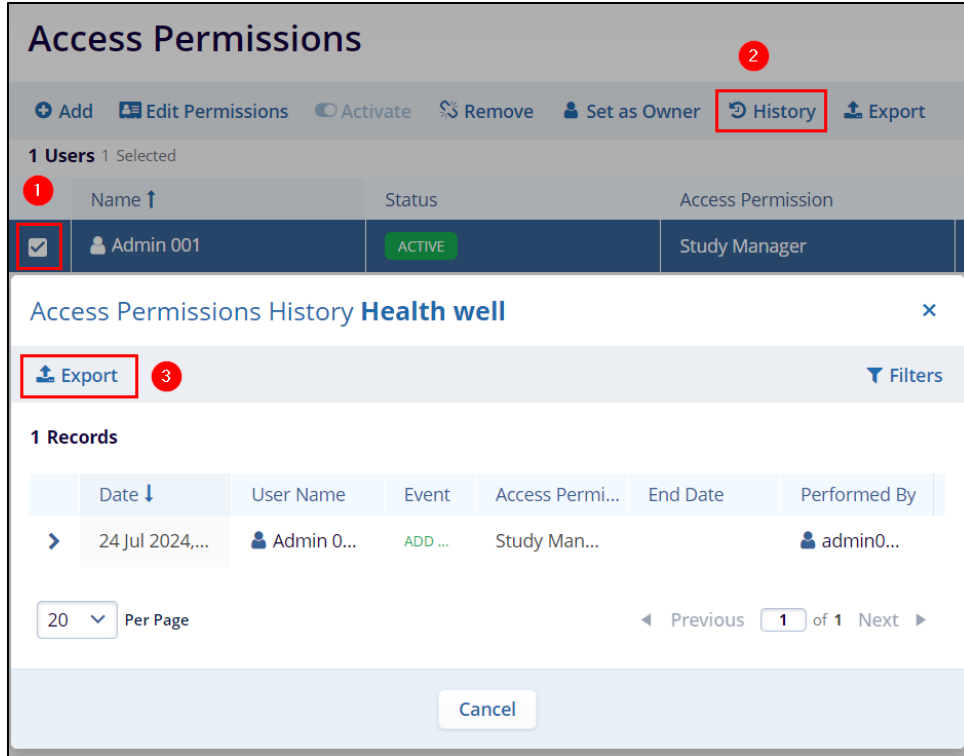


Figure: History

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

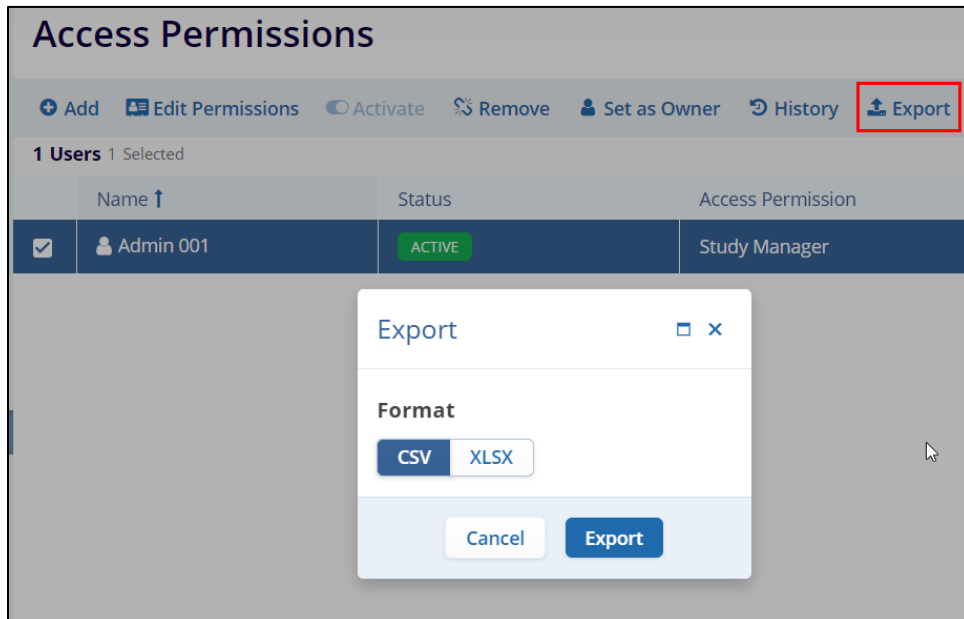


Figure: Export user details

Manage Visible Columns

To manage visible columns, follow the steps below.

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

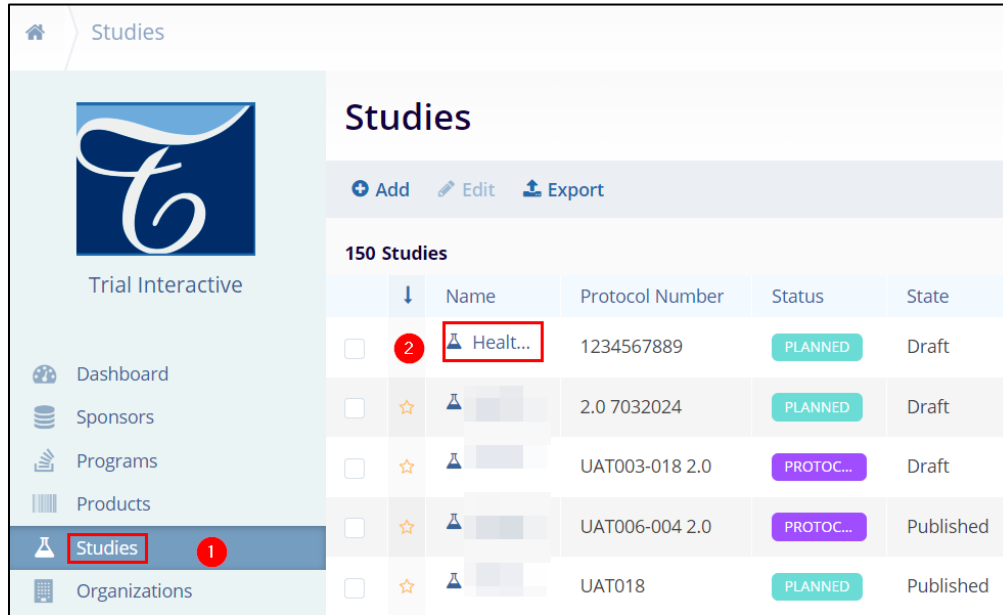


Figure: Select Study and Study name

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

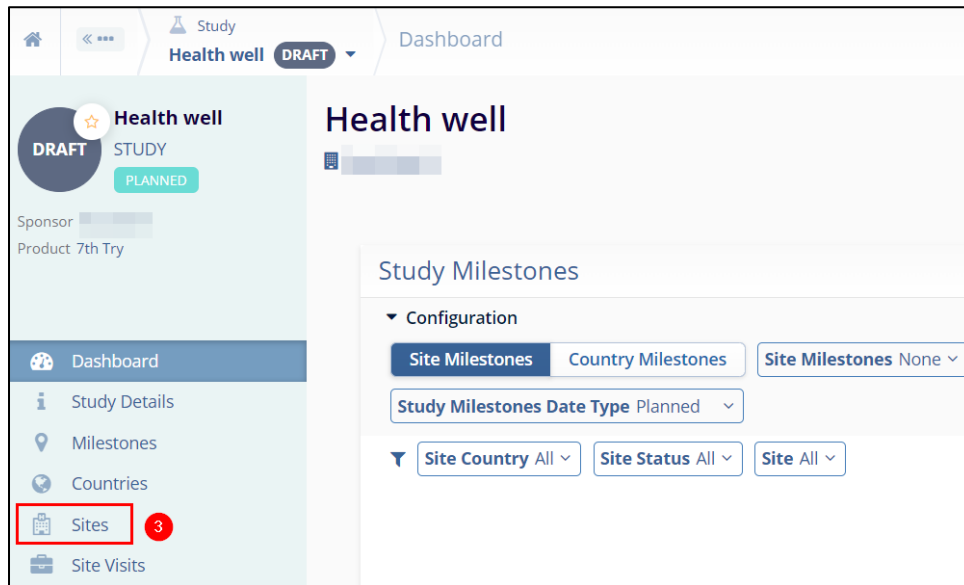


Figure: Select Sites

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

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

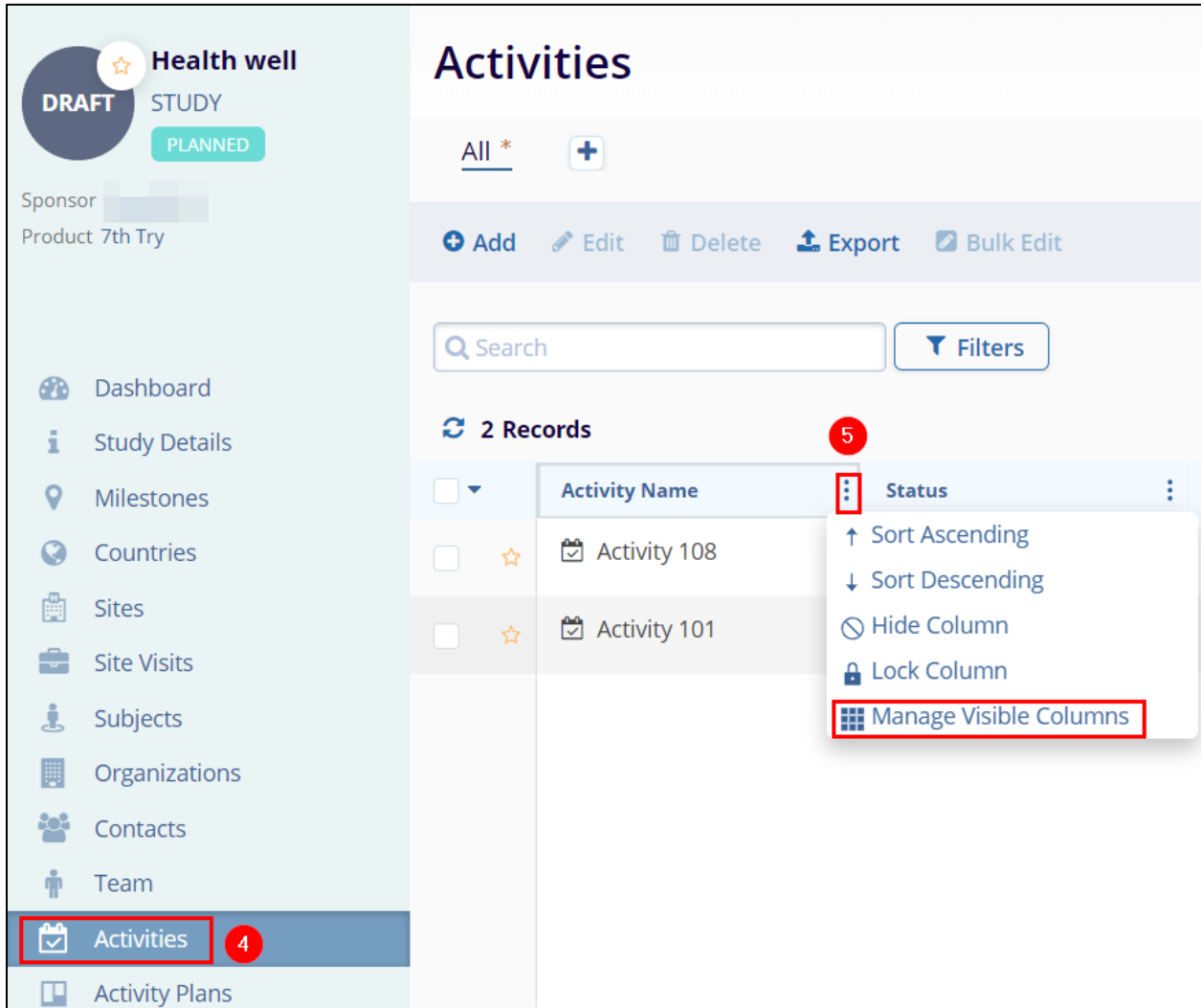


Figure: Manage Visible Columns

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

Create Contact Copy

To create a contact copy, follow the steps below.

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

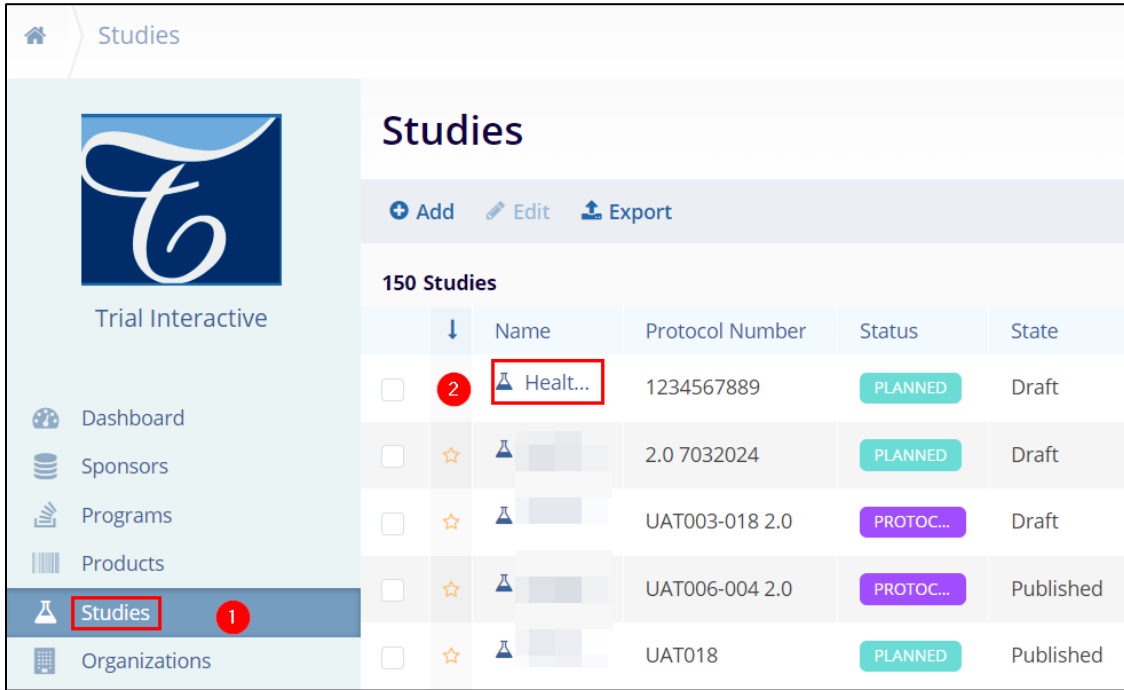


Figure: Select a Study and a study name

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

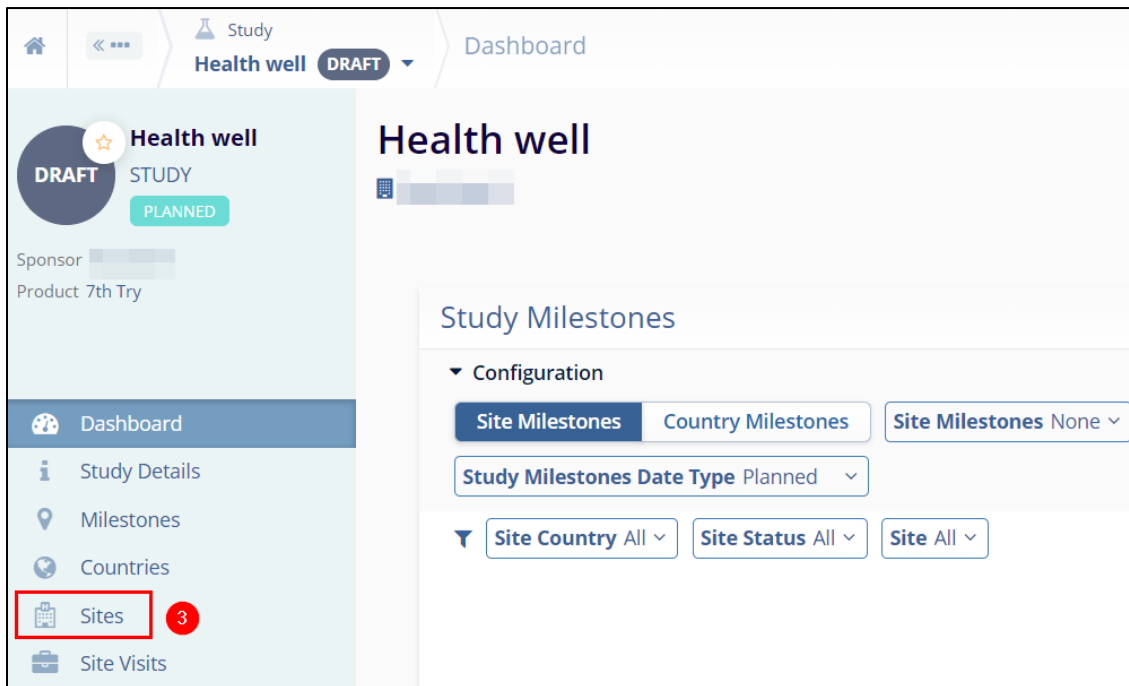


Figure: Select Sites from the Study Dashboard

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

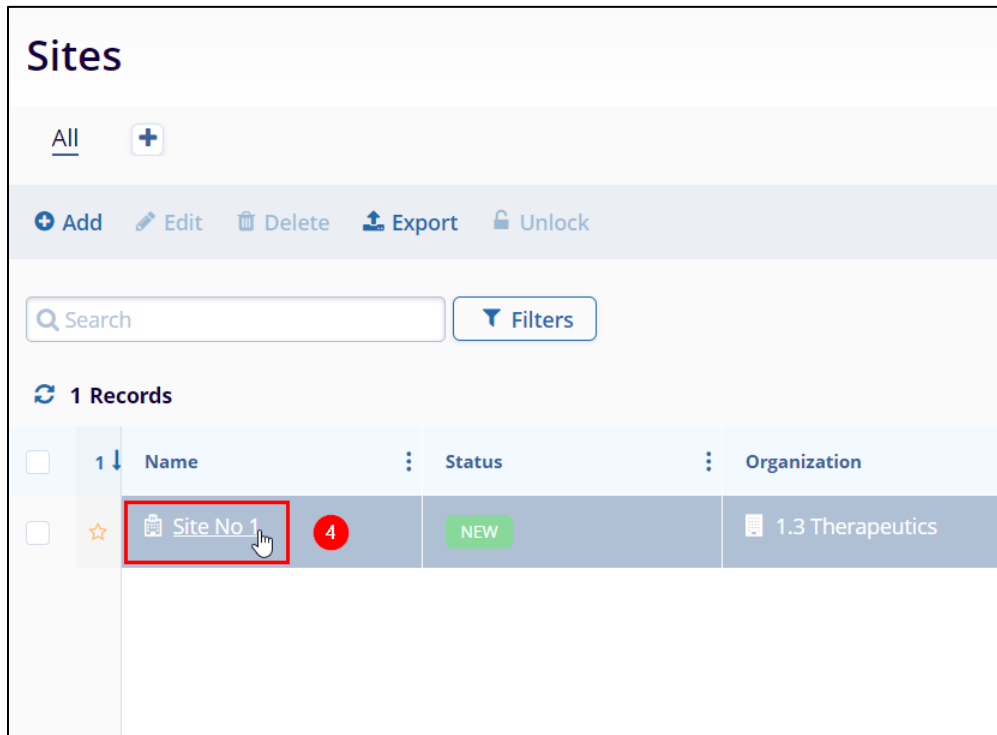


Figure: Select site

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

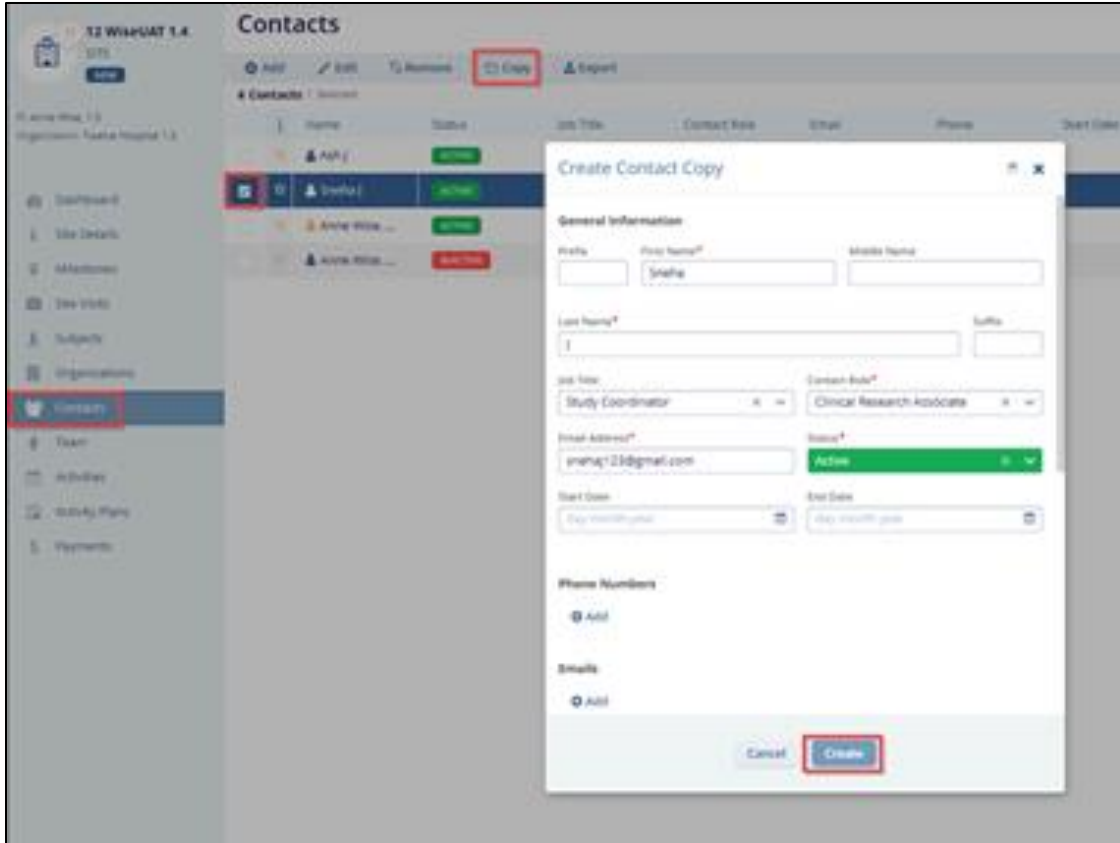


Figure: Create Contact Copy

User-Defined Site Visit Checklists

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

Creating a Site Visit Checklist

To create a Site Visit Checklist, follow the steps below

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

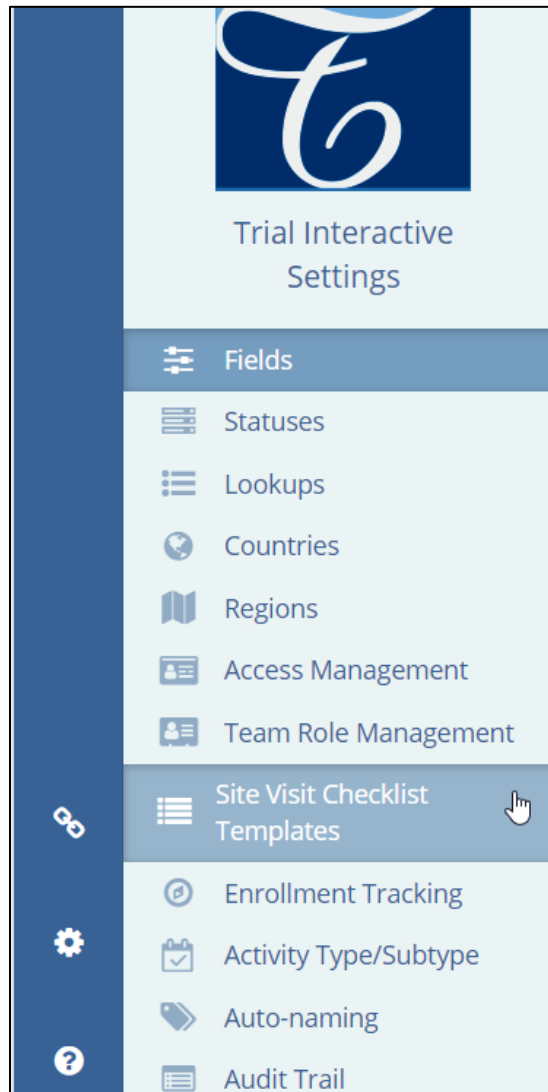


Figure: Site Visit Checklist Templates

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

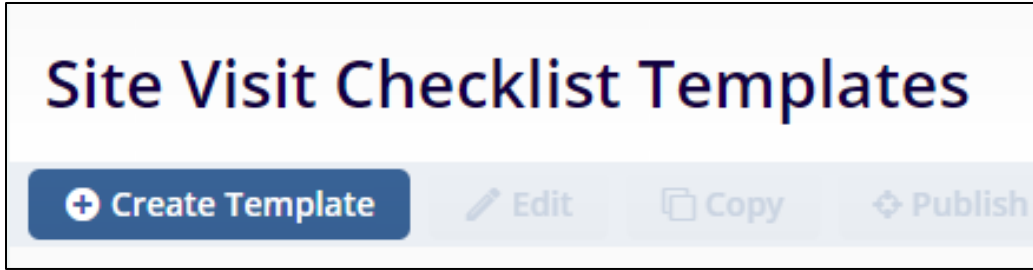


Figure: Create Template

- The 'Create Site Visit Checklist Template' window is displayed

Figure: Create Site Visit Checklist template

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

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

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

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

- Select the new checklist from the list.
- Click **Edit** from the menu bar at the top of the grid.

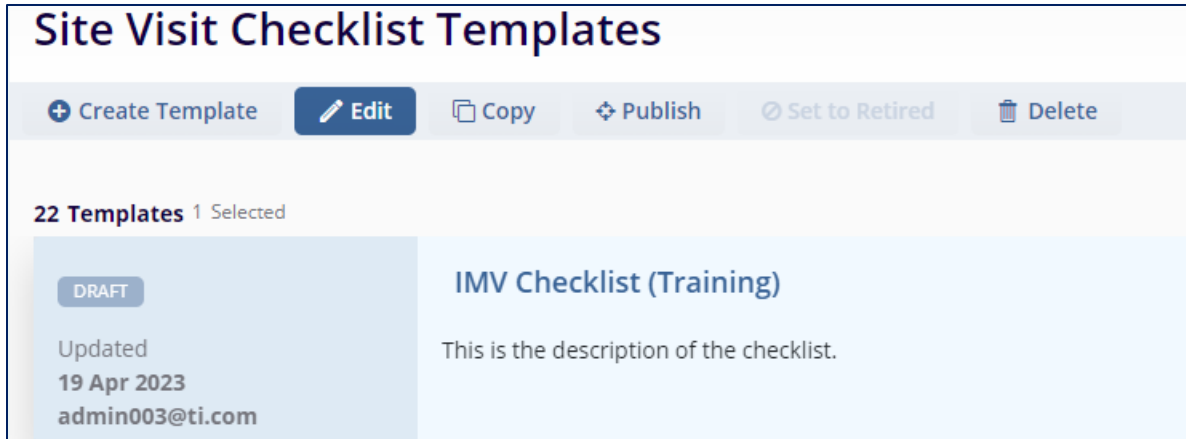


Figure: Edit Template

8. The checklist profile will load.

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

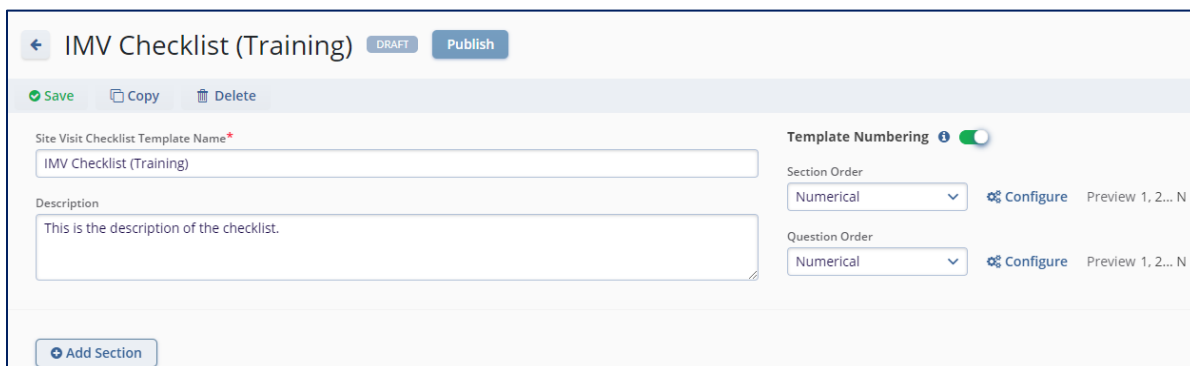


Figure: Checklist Profile

9. Using the toggle switch, indicate if the sections and questions in the checklist should be ordered and, if so, whether the ordering should be alphabetical or numerical.

10. Press **+Add Section** and a new section box will appear.

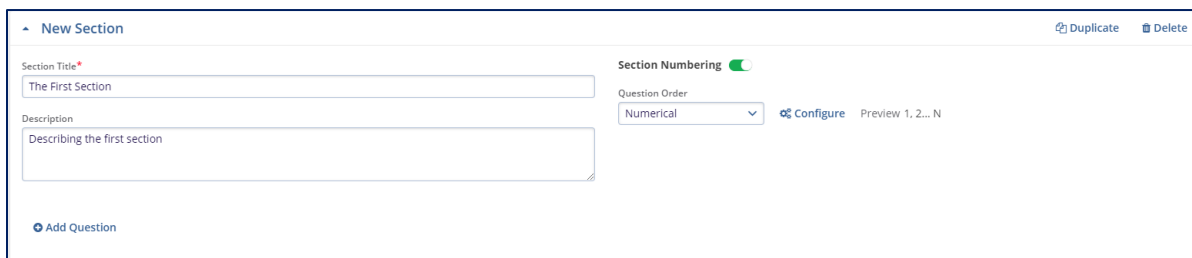


Figure: New Section

11. Give the section a title and, if desired, a description.

12. Press the **+Add Question** button in the new section.

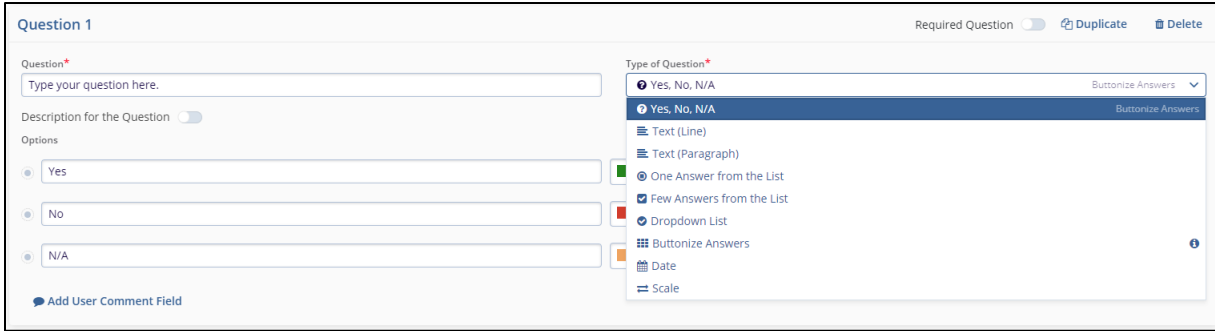


Figure: Add Question

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

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

14. When the question is ready, press the **Save** button in the menu bar at the top of the screen.

15. Continue adding sections and questions until the checklist is complete.

16. Press **Save**.

Publishing a Site Visit Checklist

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

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

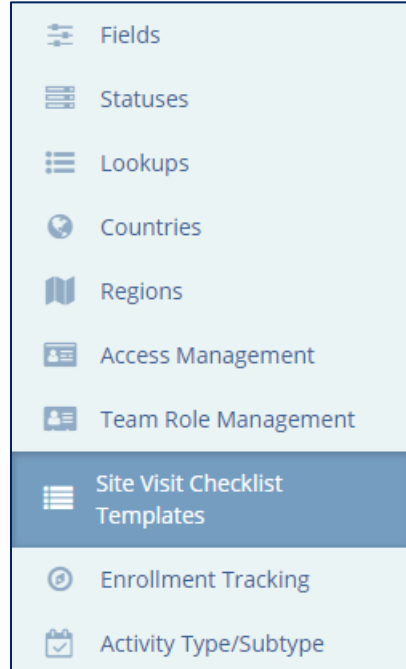


Figure: Site Visit Checklist Templates

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

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

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

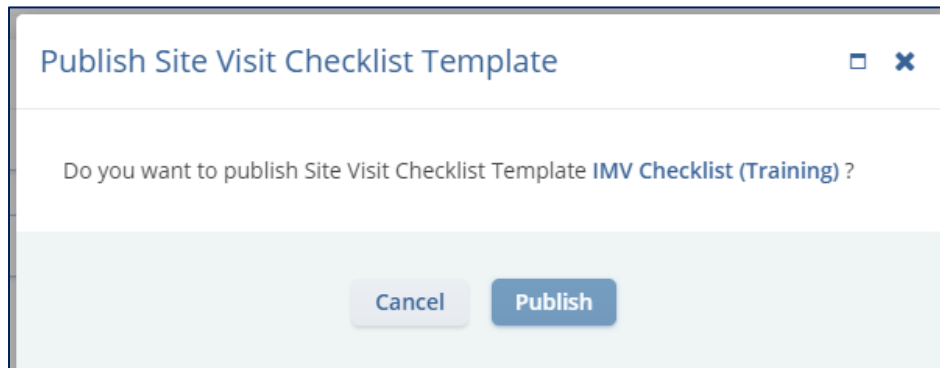


Figure: Publish Site Visit Template

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

Site Visit Checklist Templates

+ Create Template Edit Copy Publish Set to Retired Delete

22 Templates 1 Selected

PUBLISHED Updated 19 Apr 2023 admin003@ti.com	IMV Checklist (Training) This is the description of the checklist.
--	--

Figure: Published Template

Retiring a Site Visit Checklist

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

To Retire a Site Visit Checklist Template:

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

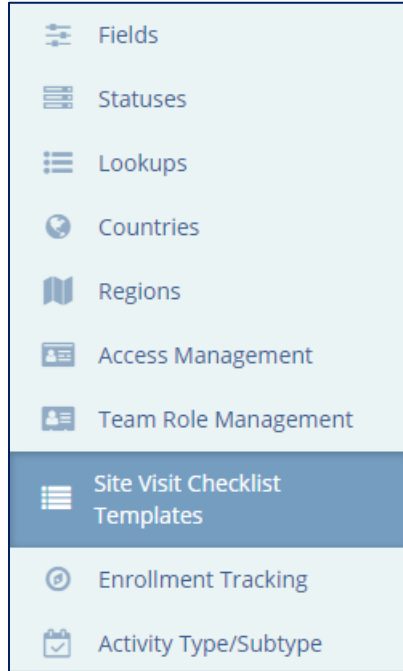


Figure: Site Visit Checklist Templates

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

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

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

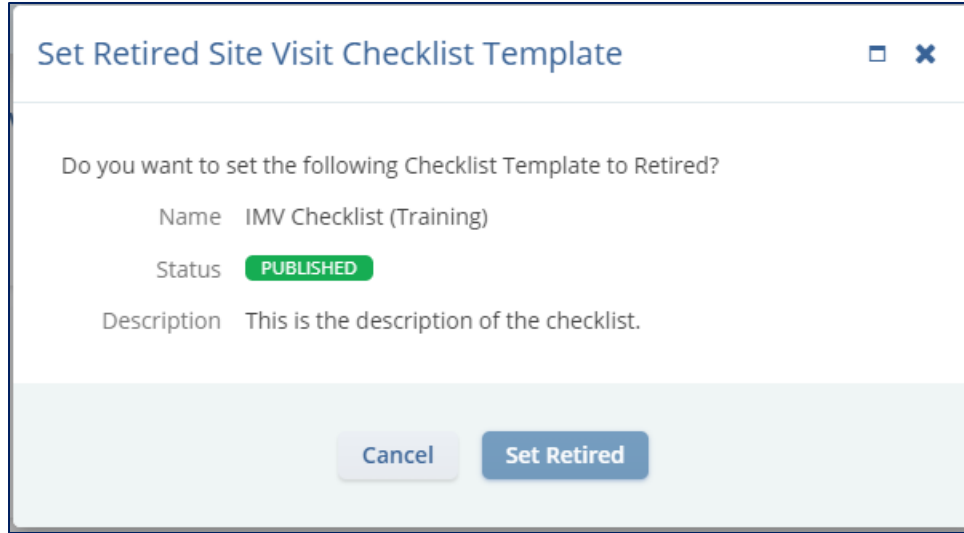


Figure: Set template as Retired

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

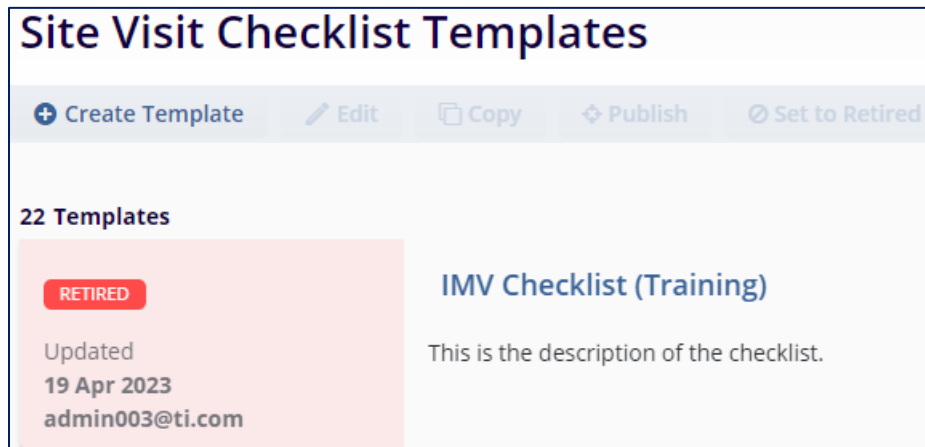


Figure: Retired Template

Deleting a Site Visit Checklist

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

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

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

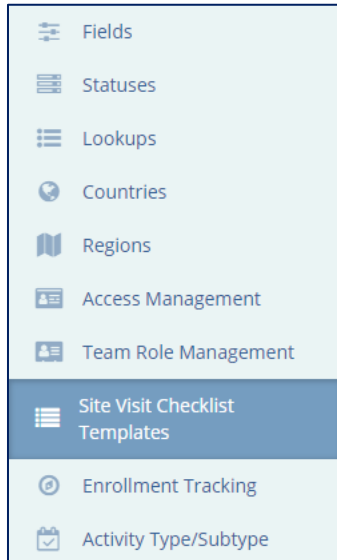
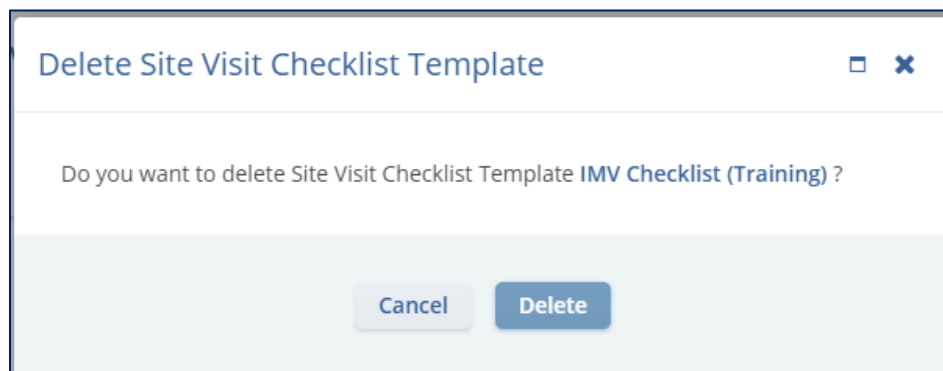


Figure: Site Visit Checklist Templates

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

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

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



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

Auto-Saving Answers for Site Visit Checklists

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

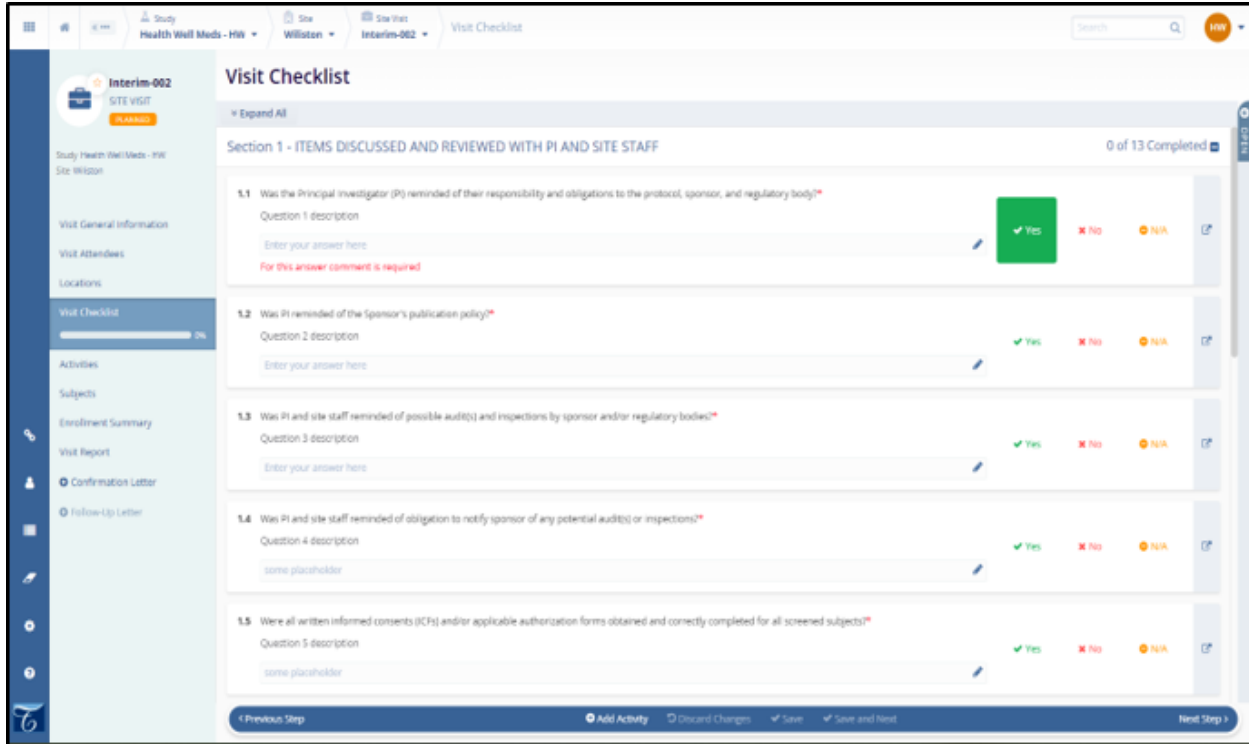


Figure: Auto Saving Answers

Unblinded Visit Type Naming Requirements

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

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

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

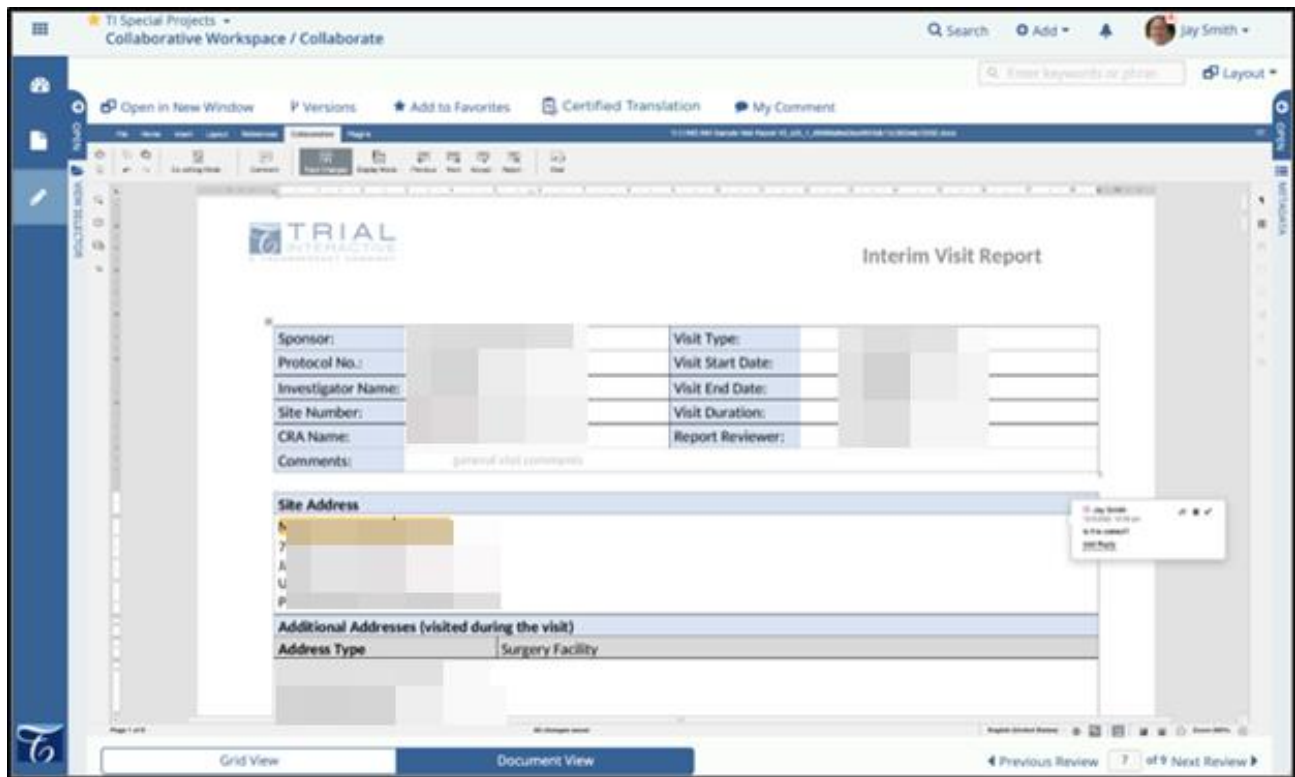


Figure: Unblinded Visit Type Naming Requirements

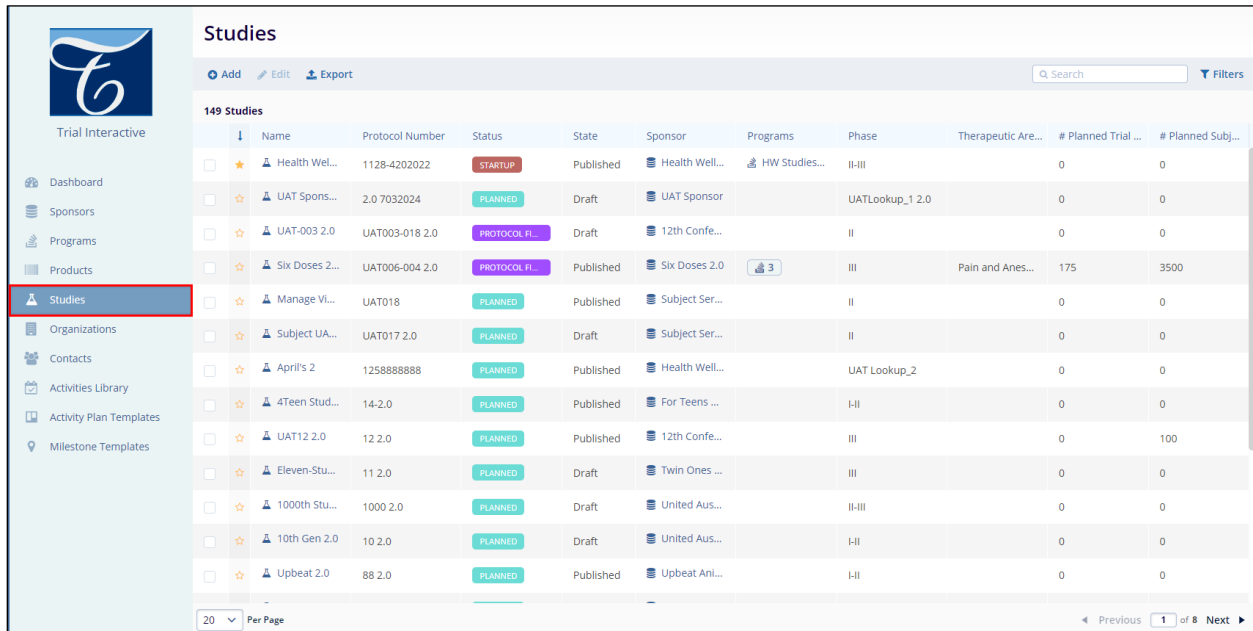
Studies

Pre-Requisites

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

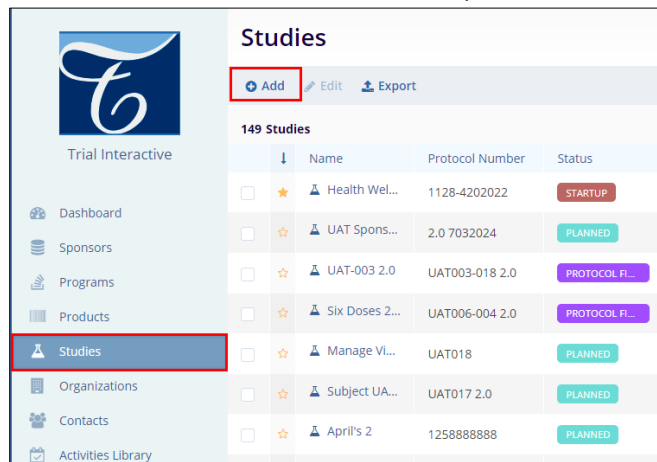
Navigate to Studies.

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

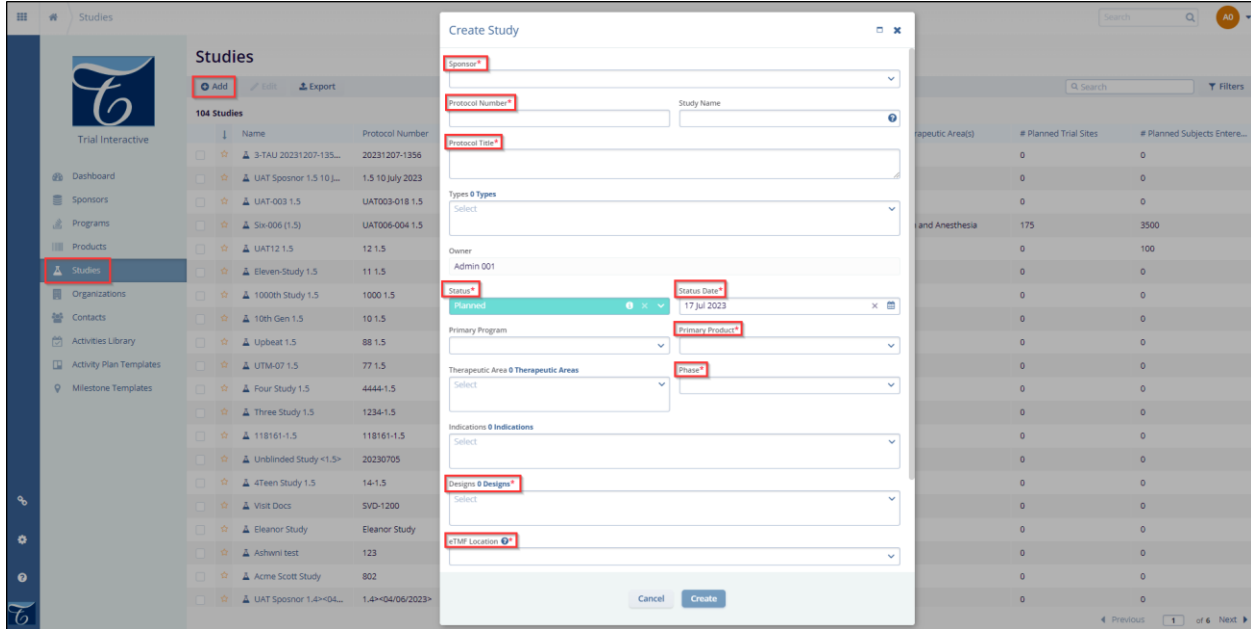


Steps to Add Studies

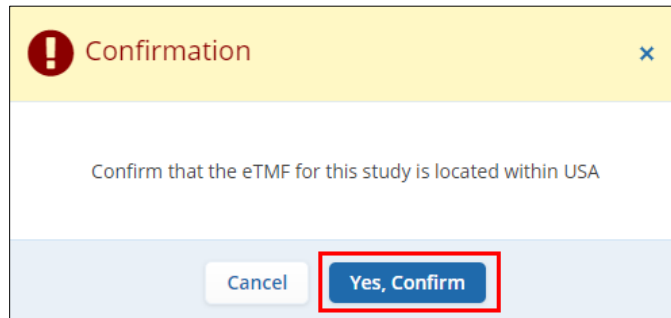
1. To add a study, click on the 'Add' button from the top main menu.



2. It opens the 'Create Study' window.



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



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

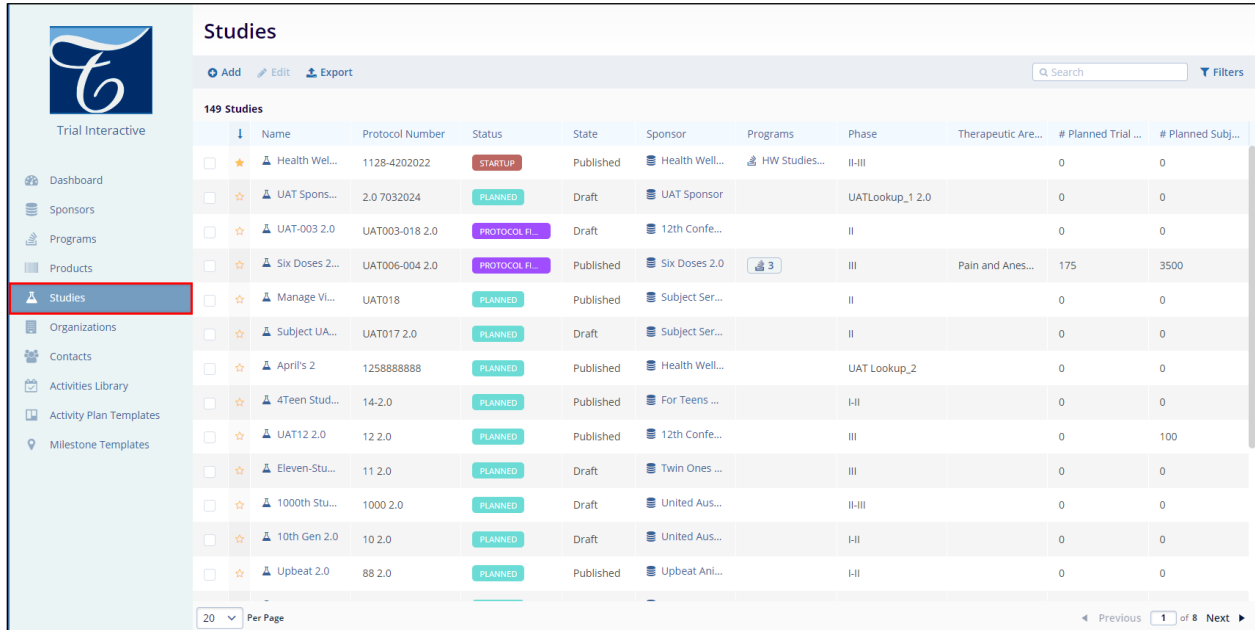
The screenshot displays the 'Studies' section of the TI CTMS interface. A success message is visible at the top: 'Success: The Record is successfully created'. Below this, a table lists 149 studies. The table columns include Name, Protocol Number, Status, State, Sponsor, Programs, Phase, Therapeutic Area, # Planned Trial, and # Planned Subject. The 'Status' column uses color-coded labels: STARTUP (red), PLANNED (green), and PROTOCOL P... (purple). The 'State' column includes values like Published, Draft, and Published. The 'Phase' column shows Roman numerals (II-III, II, III, II, I-II, III, III, II-III, I-II). The 'Therapeutic Area' column includes 'Pain and Anes...'. The '# Planned Trial' and '# Planned Subject' columns show numerical values, with one row showing 175 and 3500 respectively.

	Name	Protocol Number	Status	State	Sponsor	Programs	Phase	Therapeutic Are...	# Planned Trial ...	# Planned Subj...
<input type="checkbox"/>	Health Wel...	1128-4202022	STARTUP	Published	Health Wel...	HW Studies...	II-III		0	0
<input type="checkbox"/>	UAT Spons...	2.0 7032024	PLANNED	Draft	UAT Sponsor		UATLookup_1 2.0		0	0
<input type="checkbox"/>	UAT-003 2.0	UAT003-018 2.0	PROTOCOL P...	Draft	12th Confe...		II		0	0
<input type="checkbox"/>	Six Doses 2...	UAT006-004 2.0	PROTOCOL P...	Published	Six Doses 2.0	3	III	Pain and Anes...	175	3500
<input type="checkbox"/>	Manage Vi...	UAT018	PLANNED	Published	Subject Ser...		II		0	0
<input type="checkbox"/>	Subject UA...	UAT017 2.0	PLANNED	Draft	Subject Ser...		II		0	0
<input type="checkbox"/>	April's 2	1258888888	PLANNED	Published	Health Wel...		UAT Lookup_2		0	0
<input type="checkbox"/>	4Teen Stud...	14-2.0	PLANNED	Published	For Teens ...		I-II		0	0
<input type="checkbox"/>	UAT12 2.0	12 2.0	PLANNED	Published	12th Confe...		III		0	100
<input type="checkbox"/>	Eleven-Stu...	11 2.0	PLANNED	Draft	Twin Ones ...		III		0	0
<input type="checkbox"/>	1000th Stu...	1000 2.0	PLANNED	Draft	United Aus...		II-III		0	0
<input type="checkbox"/>	10th Gen 2.0	10 2.0	PLANNED	Draft	United Aus...		I-II		0	0
<input type="checkbox"/>	Upbeat 2.0	88 2.0	PLANNED	Published	Upbeat Ani...		I-II		0	0

How to Edit a Study

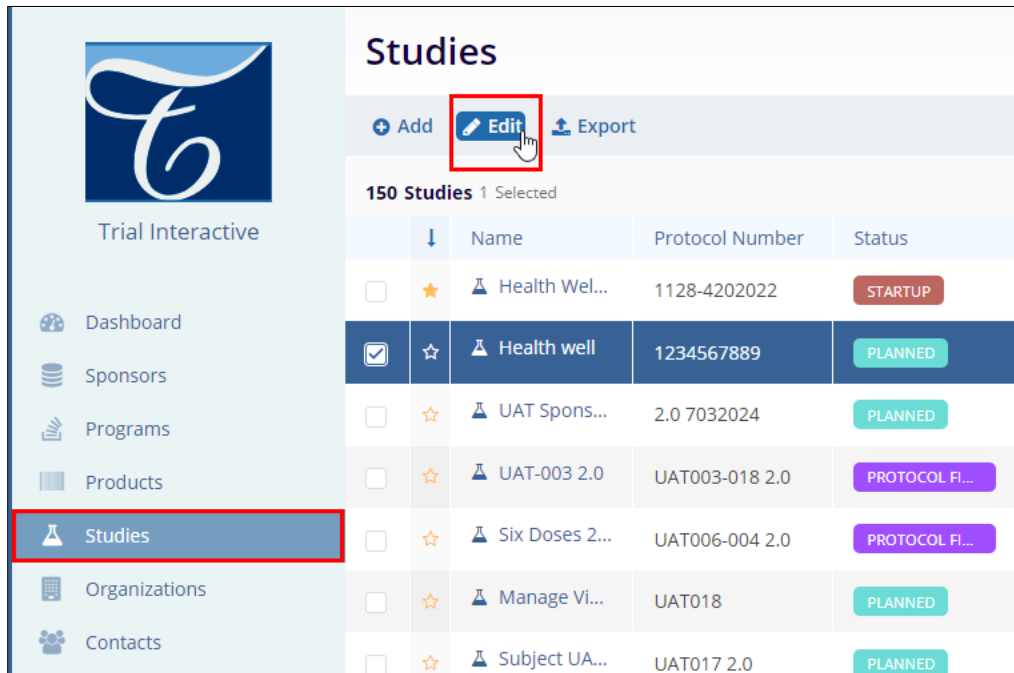
Navigate to Studies.

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

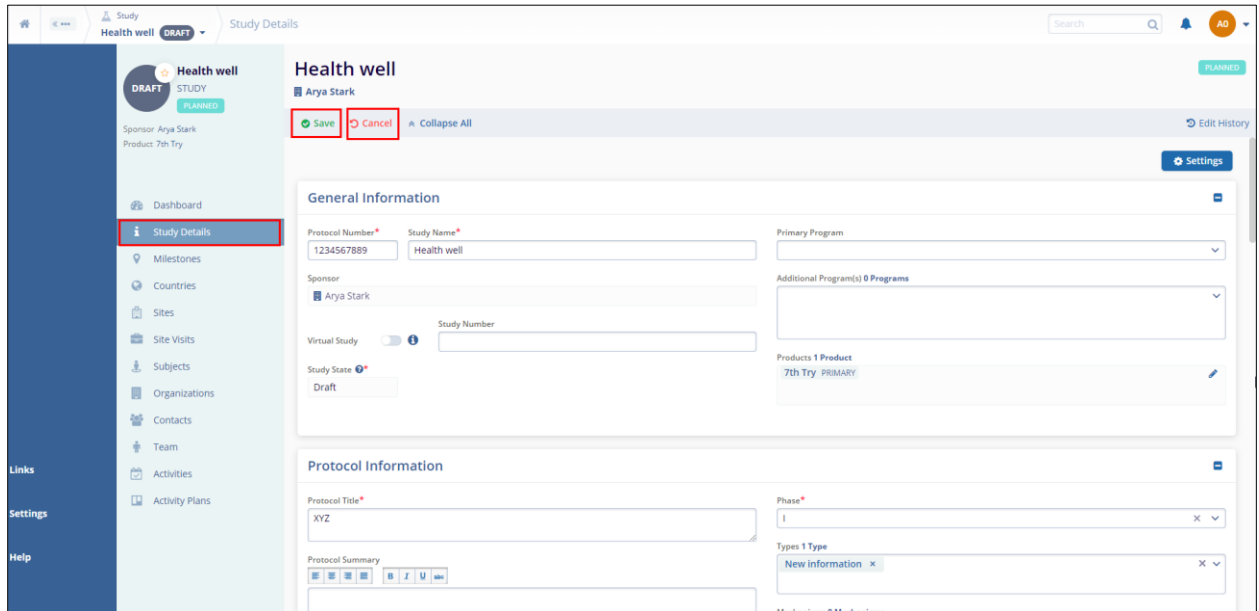


Steps to Edit Study

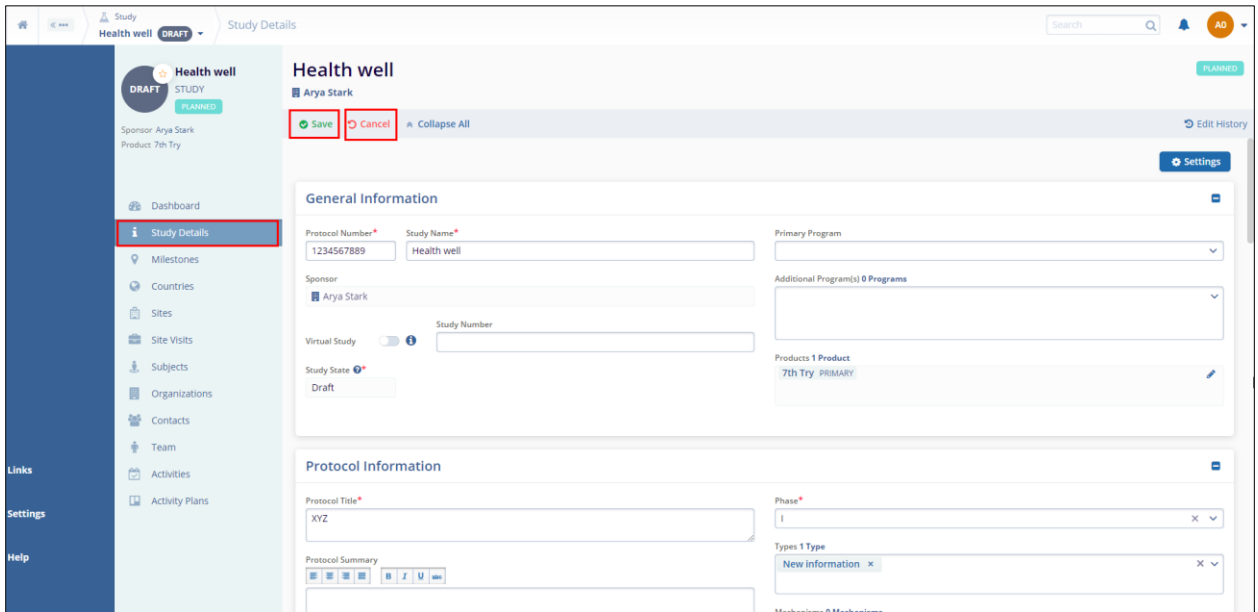
- Click on the check box next to the name of the study and click on the 'Edit' button from the top main menu. Refer to the screenshot below.



- The 'Study Details' window is displayed.



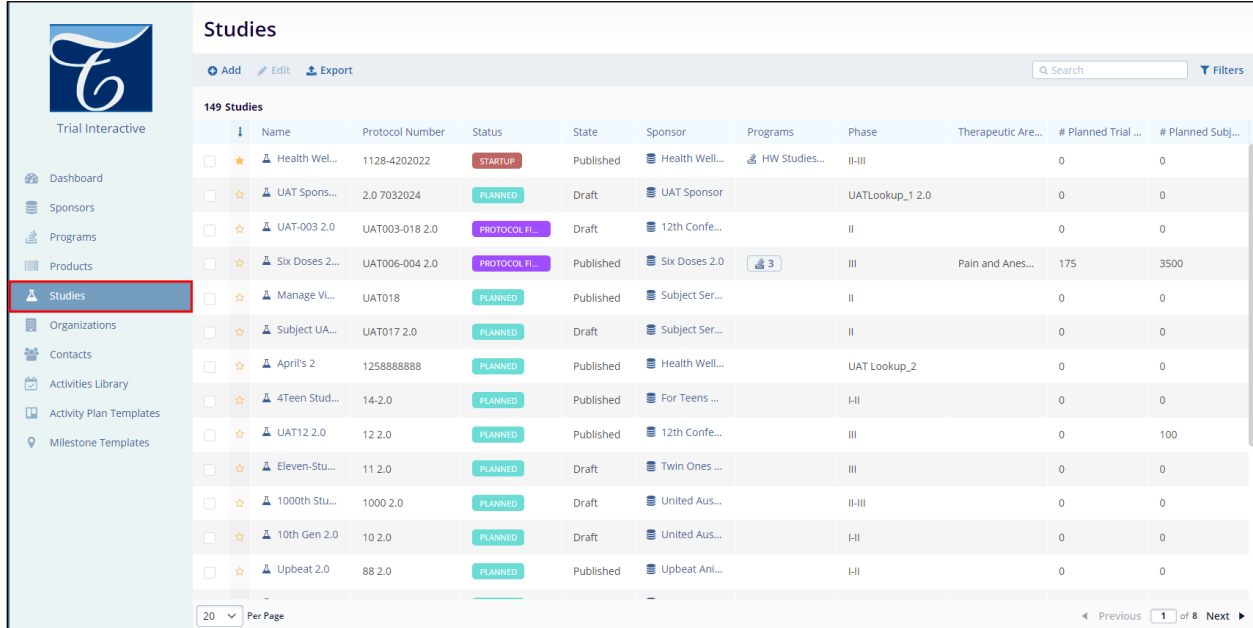
1. Make any necessary changes to the Study information.
2. Click the 'Save' button for the changes to apply or to discard the changes click on the 'Cancel' button.



Study Settings

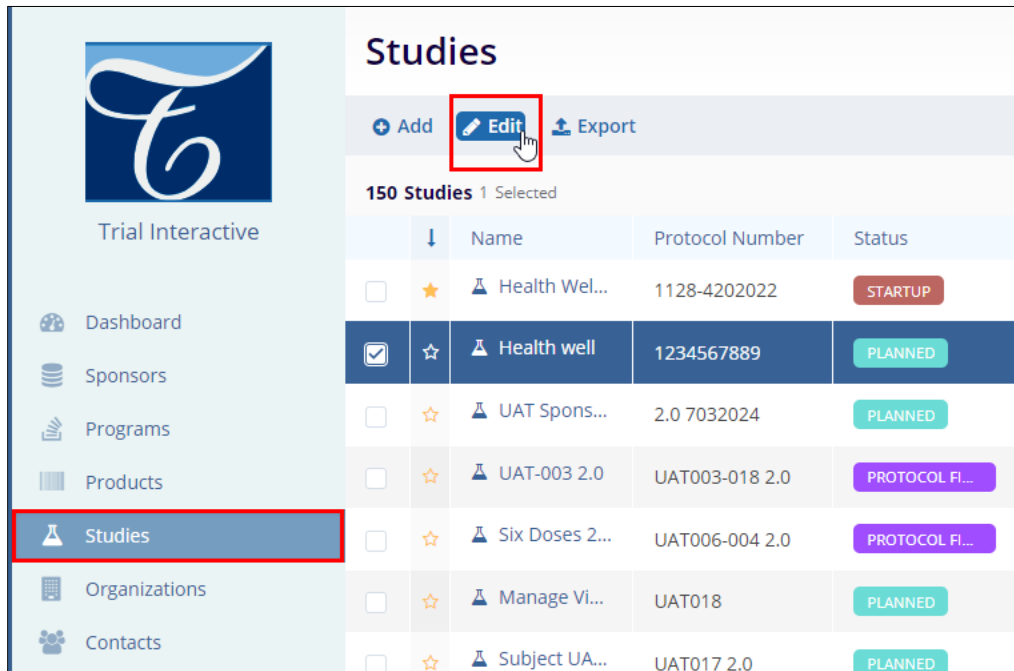
Navigate to Studies.

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

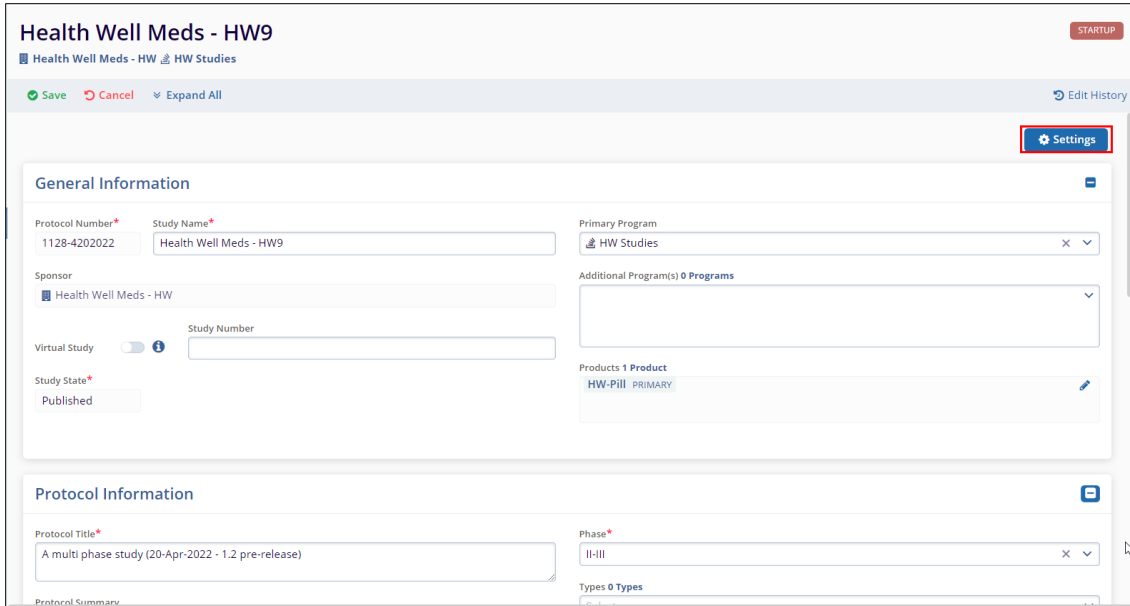


Steps to Manage Study Settings

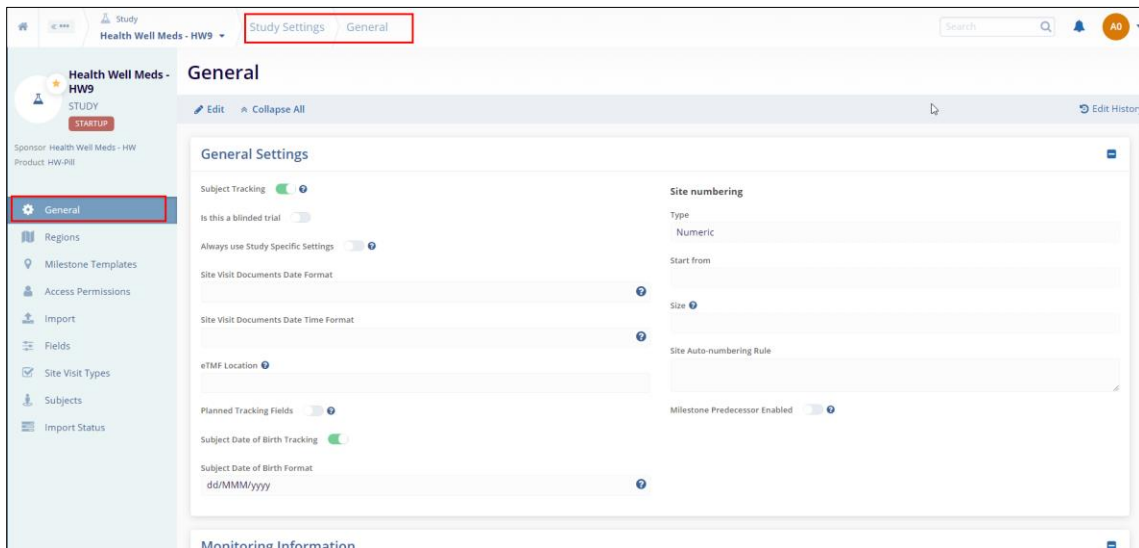
- Click on the check box next to the name of the study and click on the 'Edit' button from the top main menu. Refer to the screenshot below.



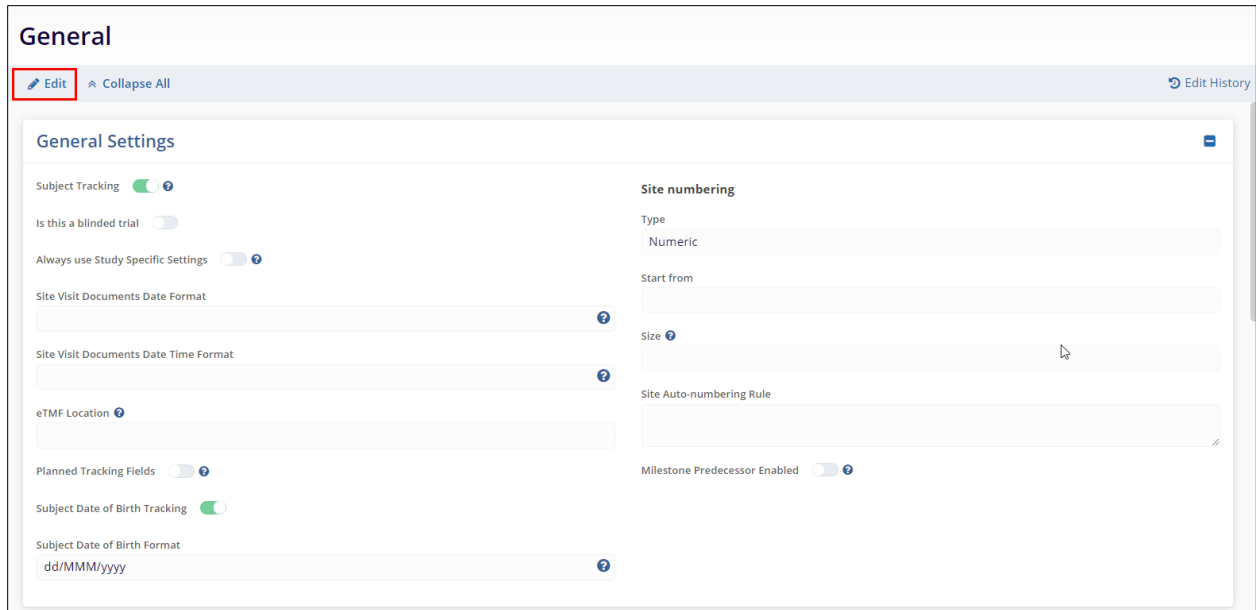
- The 'Study Details' window is displayed.



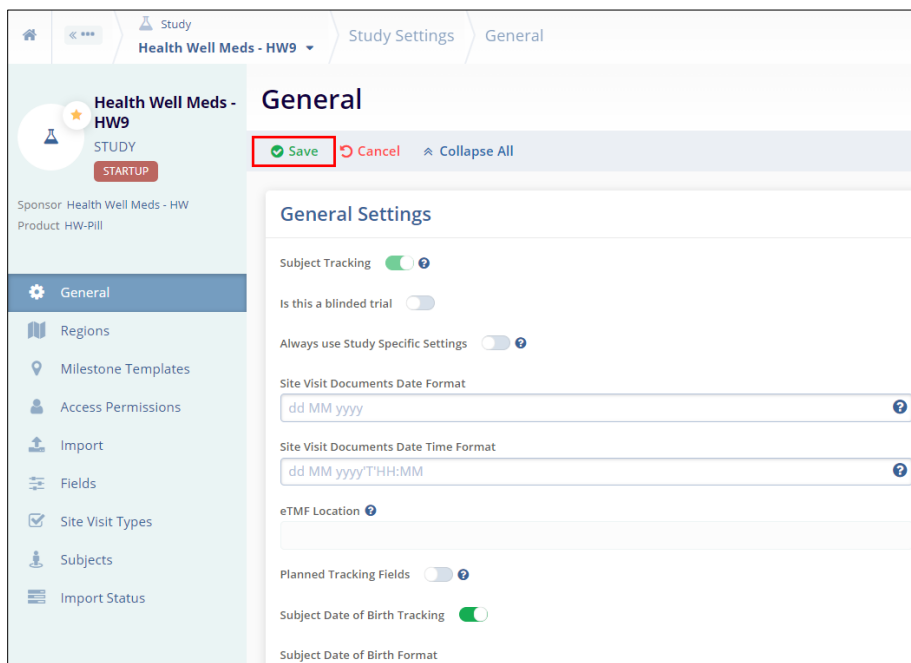
3. It will redirect you to the study general settings. Refer to the below screenshot.



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



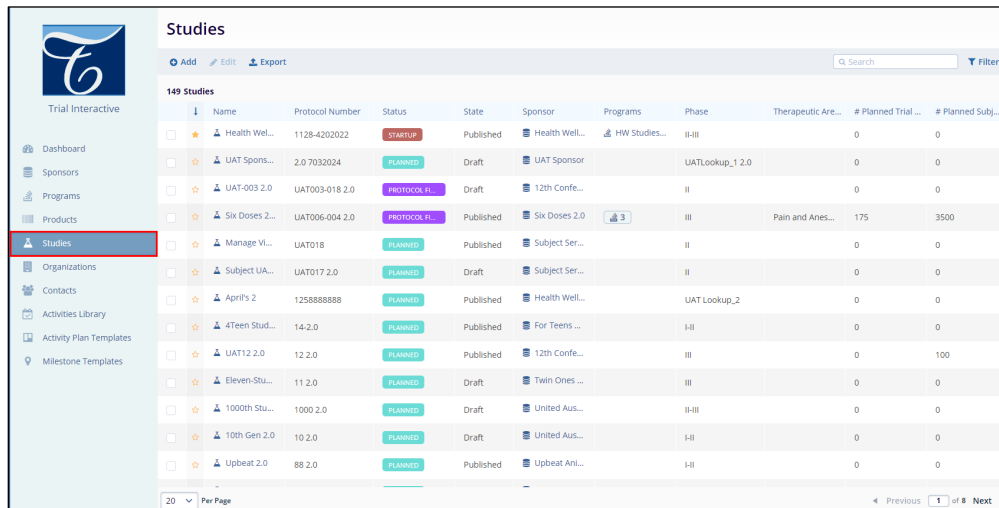
5. Make any necessary changes in the "Study Settings General" window.



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

Defining Study Partners

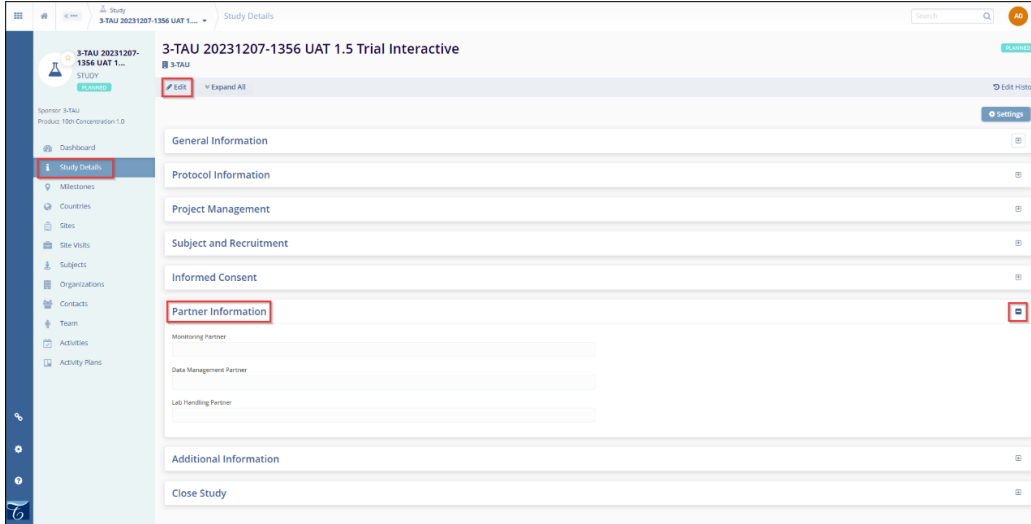
1. Click on the **Studies** link in the Navigation menu at the left side of the screen. This opens the “**Studies**” window and the study list is displayed.



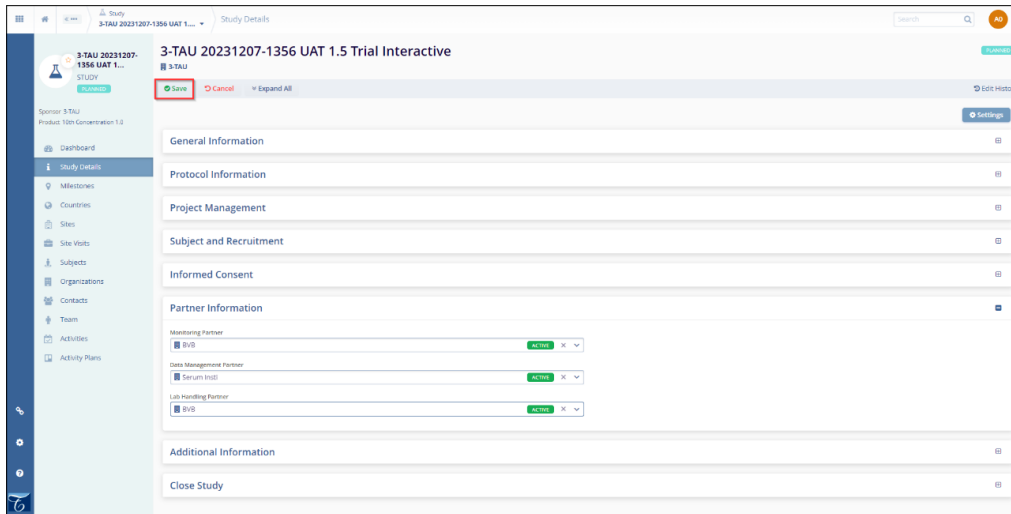
2. Click on the name of the study to which you want to add partner information. The dashboard for the study is displayed.



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



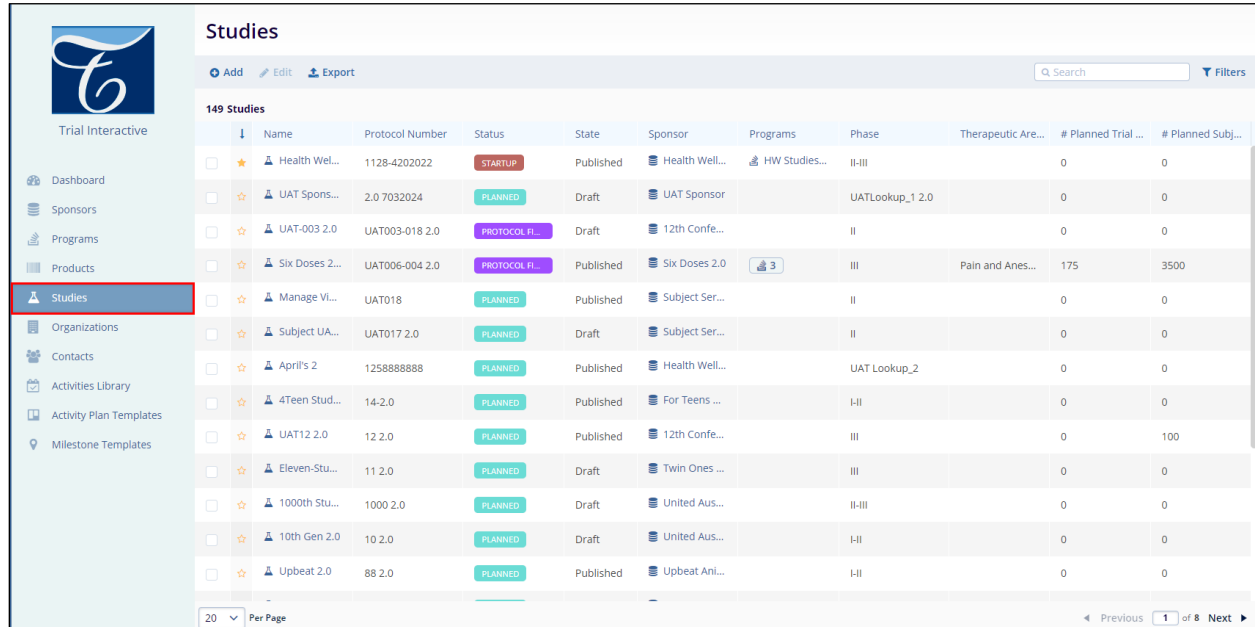
- 5 Make the necessary changes in the partner information section.
- 6 Click the Save button in the top-left of the screen.



Study Dashboard

Navigate to the Studies Dashboard

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

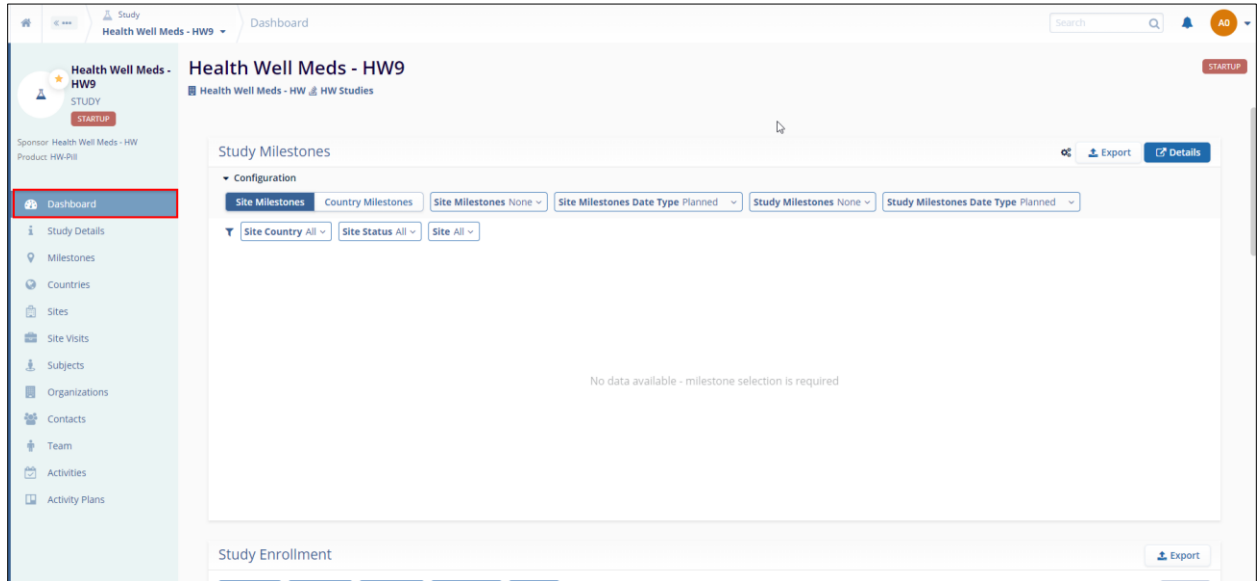


- Click on the check box next to the name of the study and click on the 'Edit' button from the top main menu or Directly click on the Study name. Refer to the screenshot below.

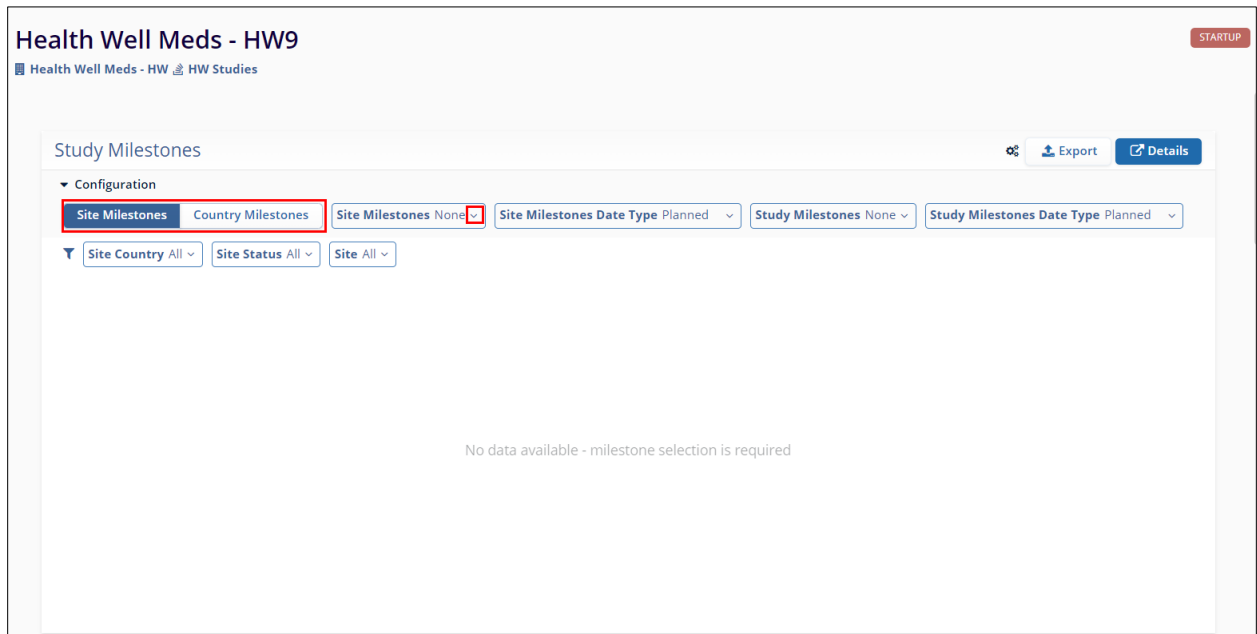


- It will redirect the user to the Study Details screen. From the navigation pane, Click on the Dashboard. It will redirect you to the Study's Dashboard.

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

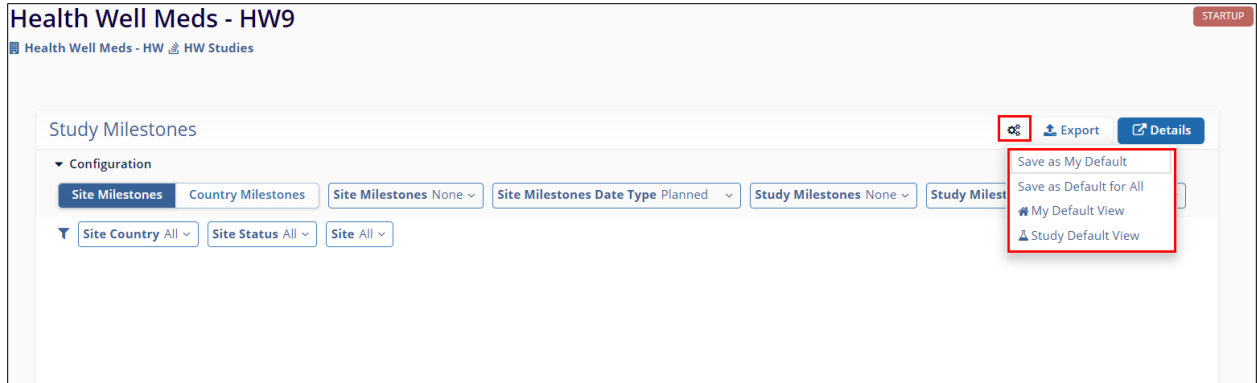


8. In the study dashboard we have **Study Milestone, Study Enrollment, Study Enrollment, and Study Activities.**
9. In the study milestone window, we have **Site Milestones and Country Milestones.** Users can click on the specific milestone as per the requirement. Refer to the below screenshots.

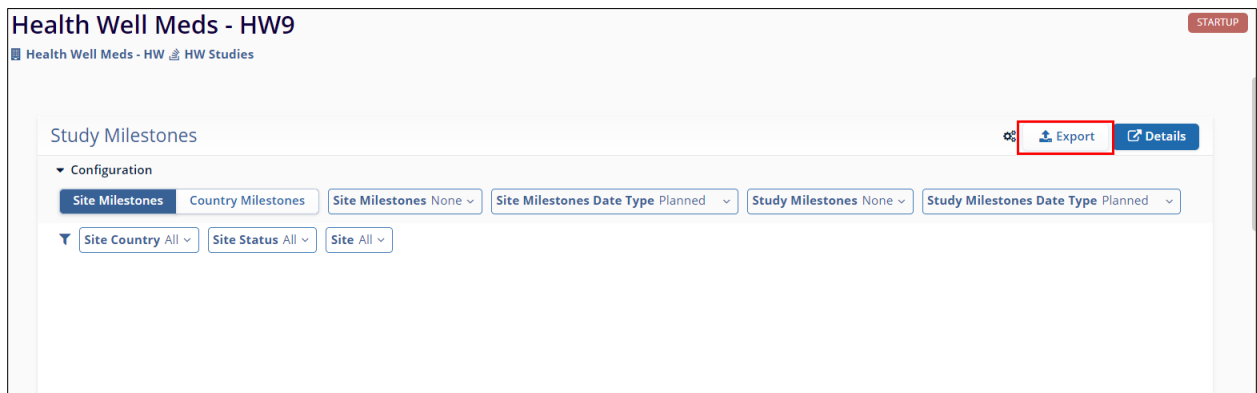


10. To apply filters, click on the drop-down arrow from the available fields and select the appropriate option as per the requirement.
11. To set up a default view, the user can click on the **Gear** icon from the top left corner. Users can customize the view as per the requirement. Refer to the below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

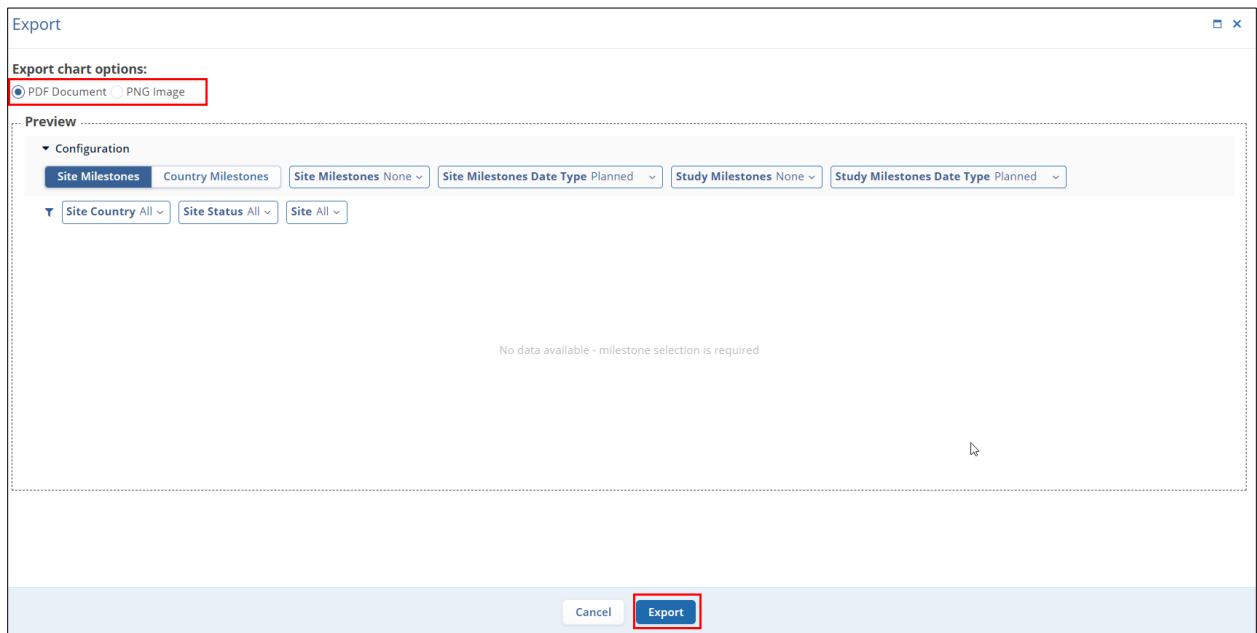
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To export the milestone view, click the "Export" button located at the top left side of the window.



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

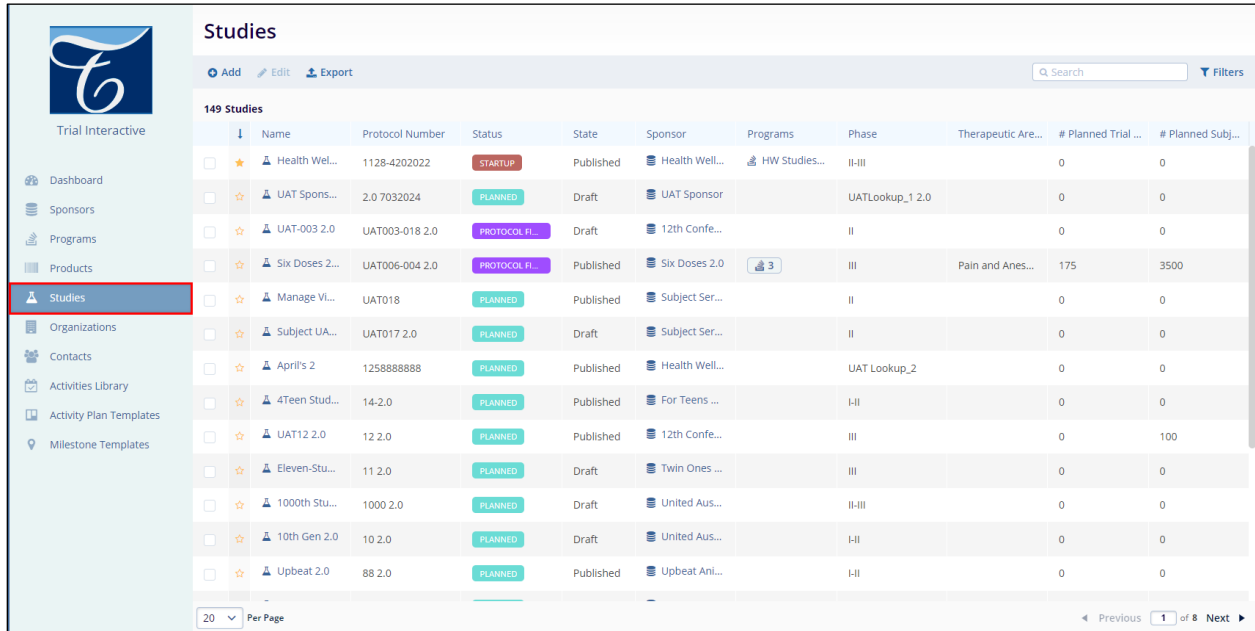


Note. For Study Enrollment, the Study Enrollment and Study Activities sections users can perform the same activities to view, export, apply filters, and so on.

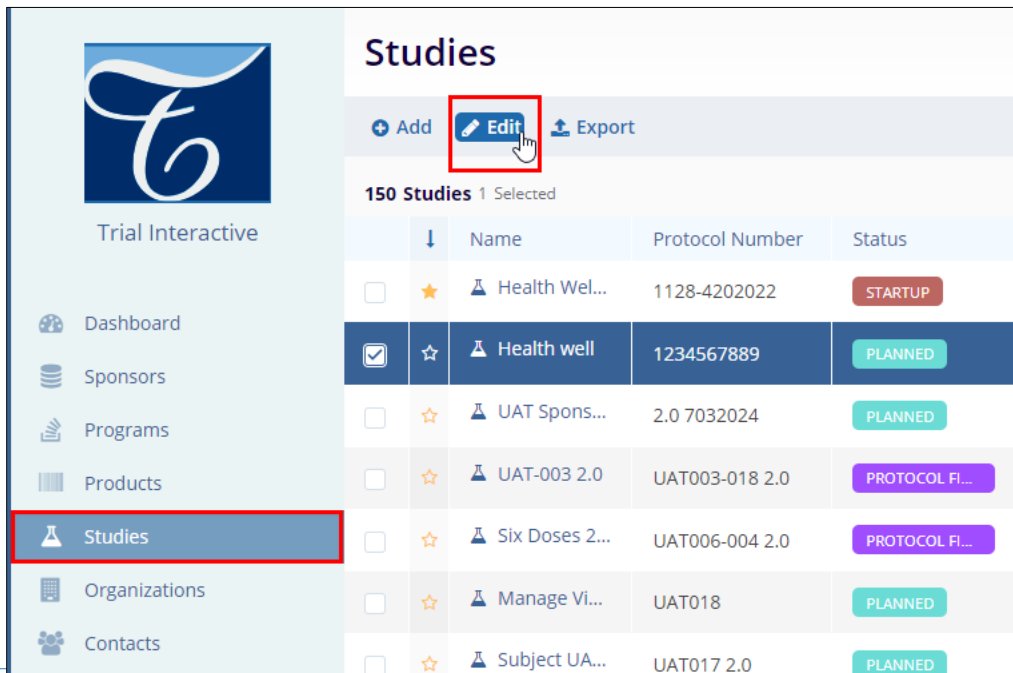
Study Milestones

Navigate to Study’s milestone

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

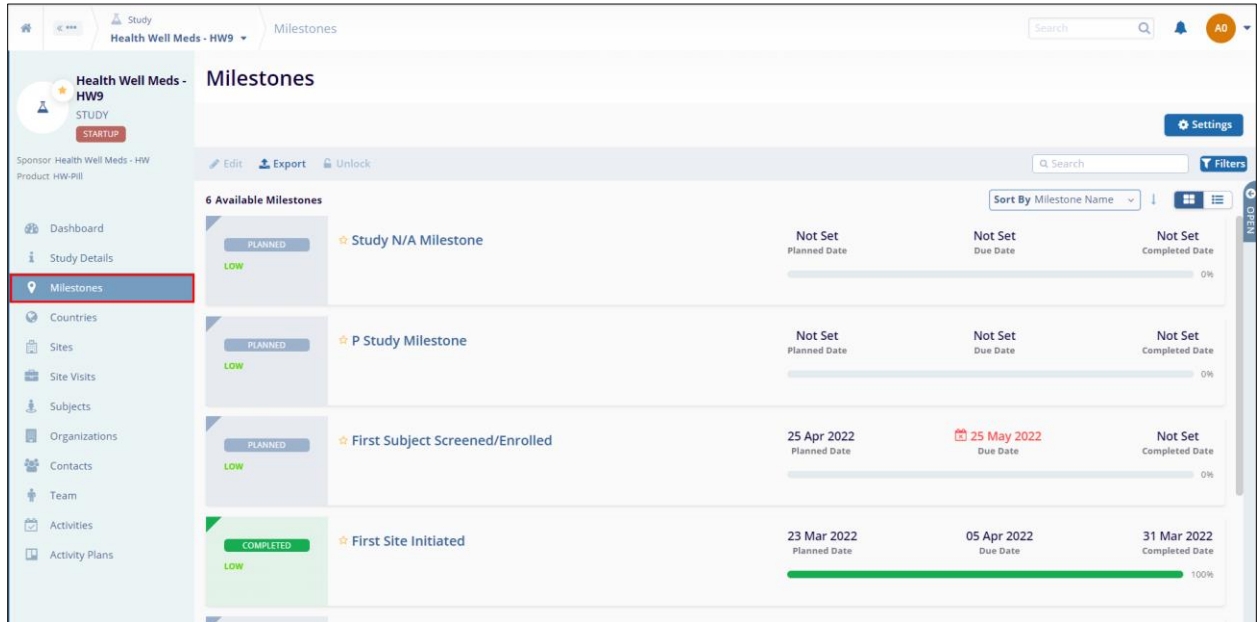


2. Click on the check box next to the name of the study and click on the ‘**Edit**’ button from the top main menu. Refer to the screenshot below.

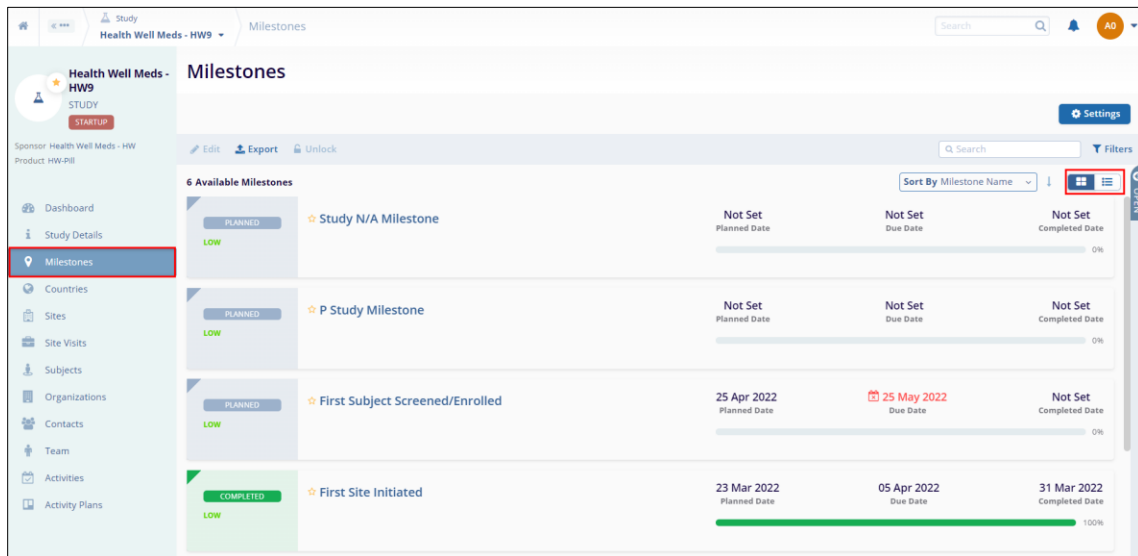


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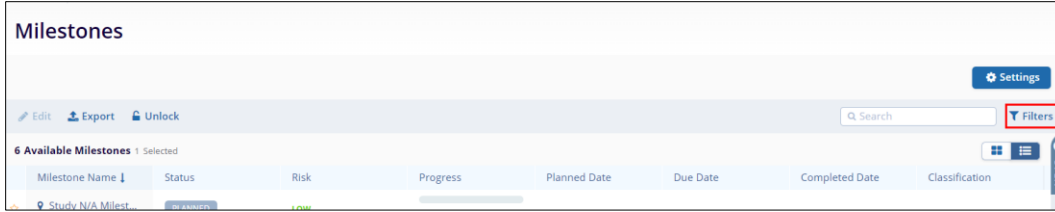
- It will redirect the user to the **Study Details** screen. From the navigation pane, Click on the **Milestone**. It will redirect the user to the **Study's Milestone**.



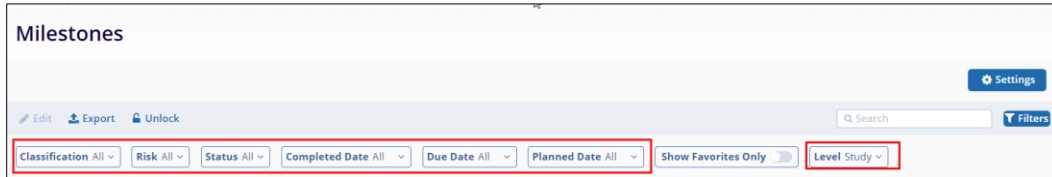
- Users have two options to view Milestone **Card view** and **List view**. Select the appropriate view at your convenience.



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



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



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

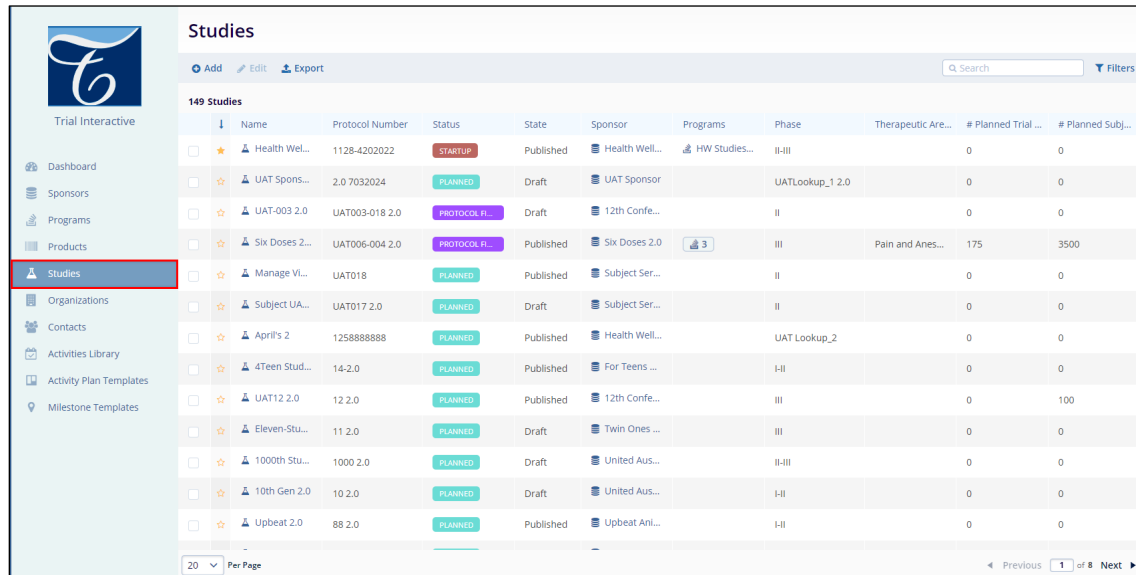
Note: Marking favorite and Exporting will be the same as Contact. To learn [How to mark favorite](#) and [export](#). Click the hyperlinks.

- To learn how to edit the Milestone, [click here](#).

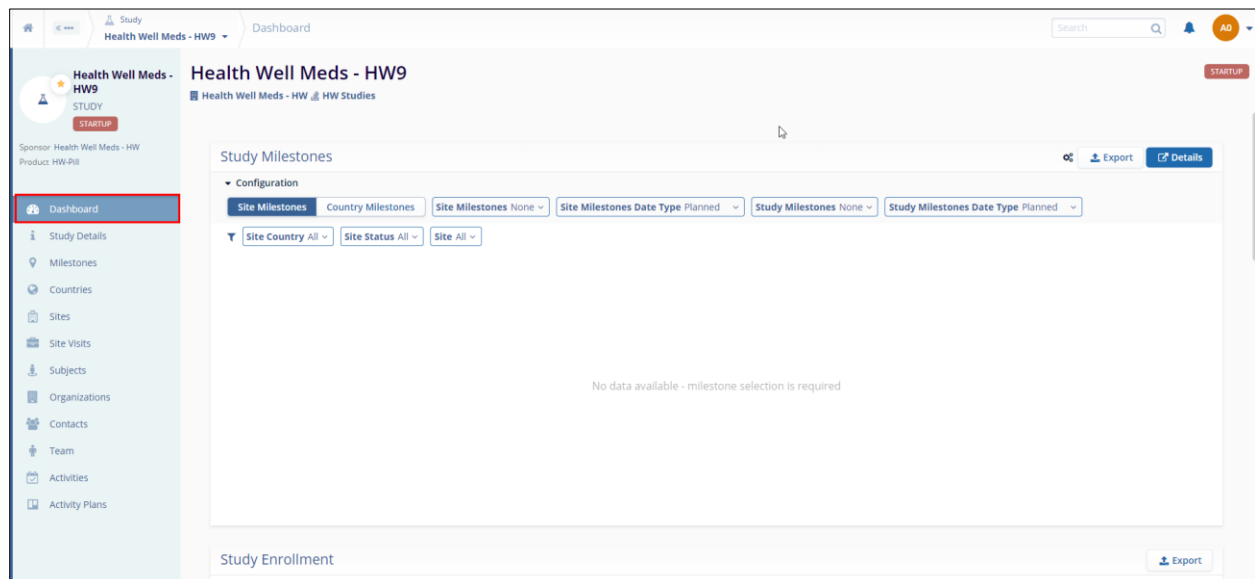
Study Countries

Defining and Editing Countries within a Study

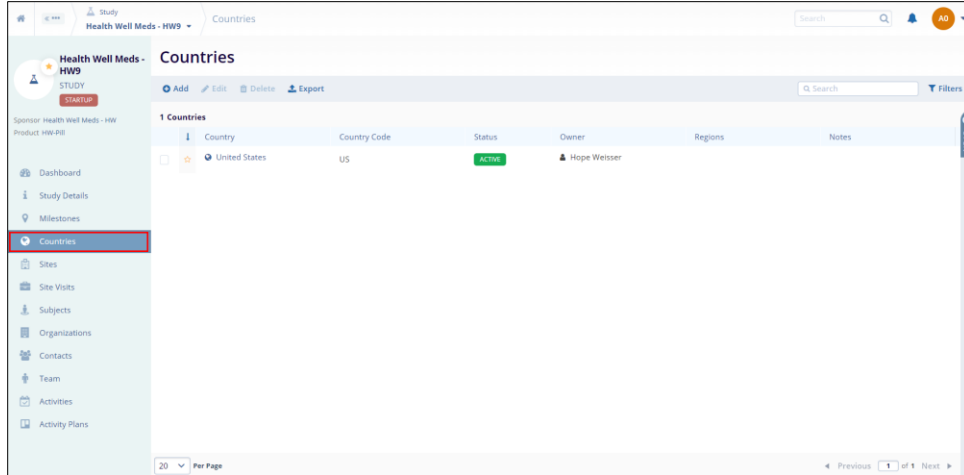
1. Click on **"Studies"** in the navigation menu on the left side of the screen. This opens the **"Studies"** window.



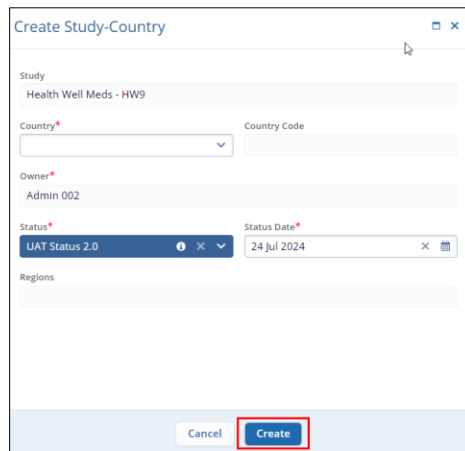
2. Click on the name of the study in which you want to define countries. This opens the study's dashboard.



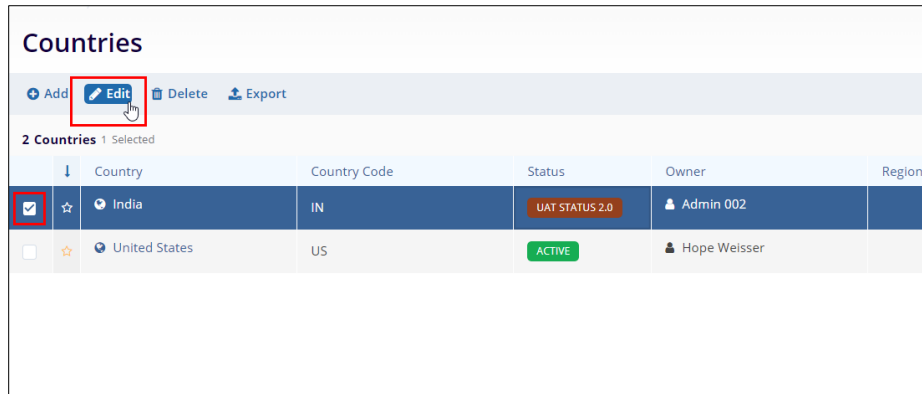
3. Click on the **"Countries"** link in the navigation menu on the left side of the screen. This opens the **"Countries"** window, and the countries list is displayed.



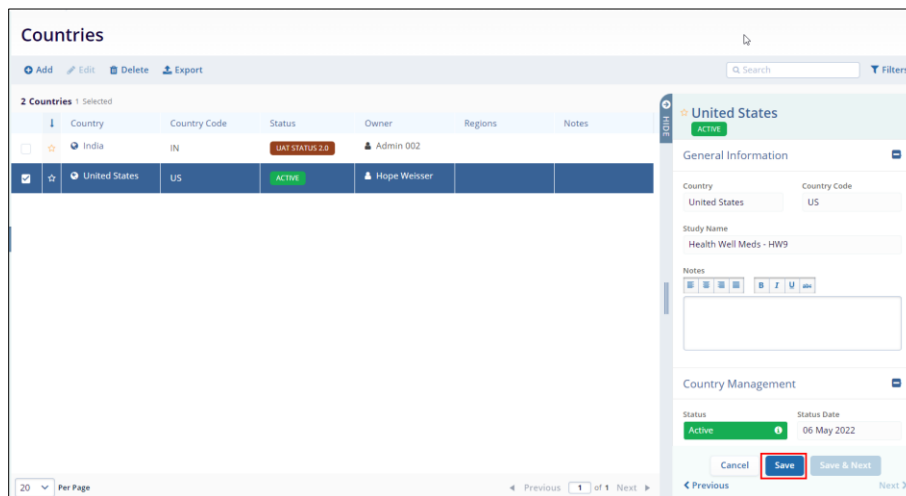
4. Click "Add" at the top-left of the screen. This opens the "Create Study-Country" window.



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



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



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

Reviewing and Tracking Country Details

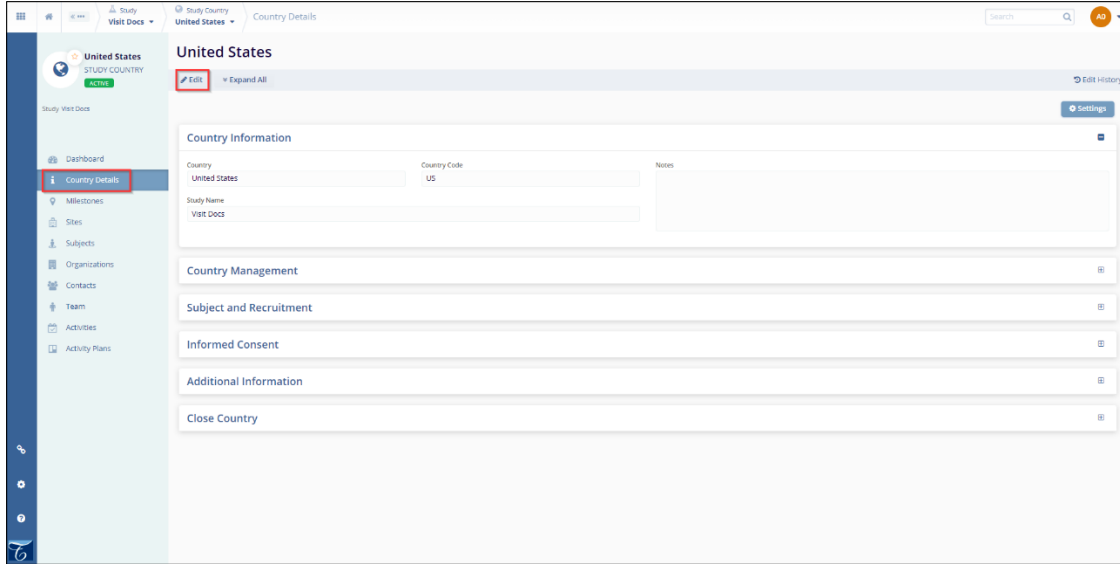
1. Click on "Studies" in the navigation menu on the left side of the screen. This opens the "Studies" window.

Name	Protocol Number	Status	State	Sponsor	Programs	Phase	Therapeutic Area	# Planned Trial	# Planned Subject
Health Well...	1128-4202022	STARTUP	Published	Health Well...	HW Studies...	II-III		0	0
UAT Spons...	2.0 7032024	PLANNED	Draft	UAT Sponsor		UATLookup_1 2.0		0	0
UAT-003 2.0	UAT003-018 2.0	PROTOCOL F...	Draft	12th Confe...		II		0	0
Six Doses 2...	UAT006-004 2.0	PROTOCOL F...	Published	Six Doses 2.0	3	III	Pain and Anes...	175	3500
Manage YL...	UAT018	PLANNED	Published	Subject Ser...		II		0	0
Subject UA...	UAT017 2.0	PLANNED	Draft	Subject Ser...		II		0	0
April's 2	1258888888	PLANNED	Published	Health Well...		UAT Lookup_2		0	0
4Teen Stud...	14-2.0	PLANNED	Published	For Teens ...		I-II		0	0
UAT12 2.0	12 2.0	PLANNED	Published	12th Confe...		III		0	100
Eleven-Stu...	11 2.0	PLANNED	Draft	Twin Ones ...		III		0	0
1000th Stu...	1000 2.0	PLANNED	Draft	United Aus...		II-III		0	0
10th Gen 2.0	10 2.0	PLANNED	Draft	United Aus...		I-II		0	0
Upbeat 2.0	88 2.0	PLANNED	Published	Upbeat Ani...		I-II		0	0

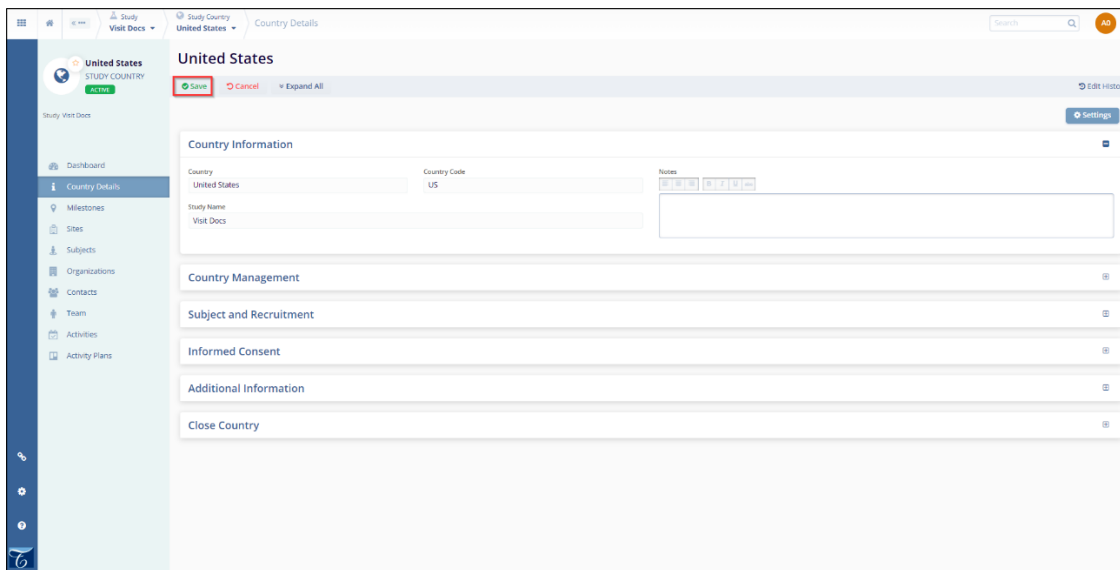
2. Click on the name of the study in which you want to define countries. This opens the study's dashboard.

The screenshot shows the study dashboard for 'Health Well Meds - HW9'. The left navigation menu has 'Dashboard' highlighted. The main area displays 'Study Milestones' configuration with dropdowns for 'Site Milestones', 'Country Milestones', 'Site Milestones None', 'Site Milestones Date Type Planned', 'Study Milestones None', and 'Study Milestones Date Type Planned'. Below this, there are filters for 'Site Country All', 'Site Status All', and 'Site All'. A message states: 'No data available - milestone selection is required'. At the bottom, there is a 'Study Enrollment' section with an 'Export' button.

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

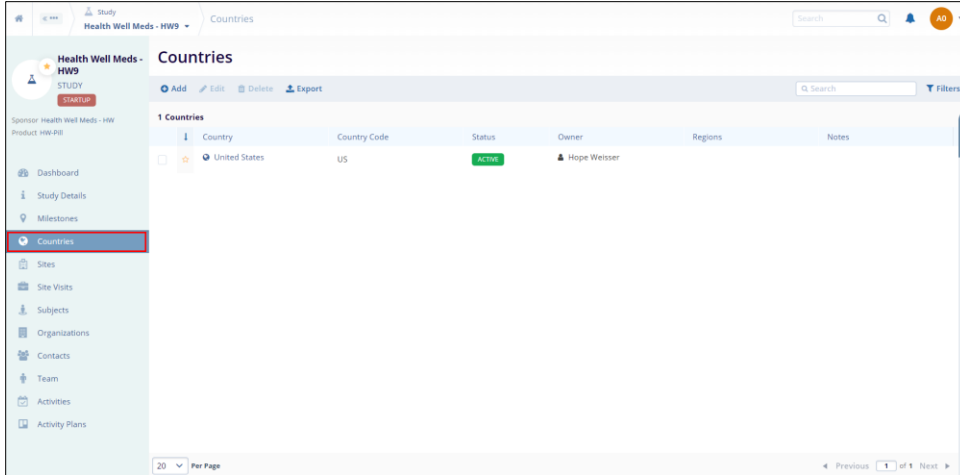


5. Click on the **Edit** button on the top-left of the screen to make any changes and before returning, click on the **Save** button for the changes to apply.

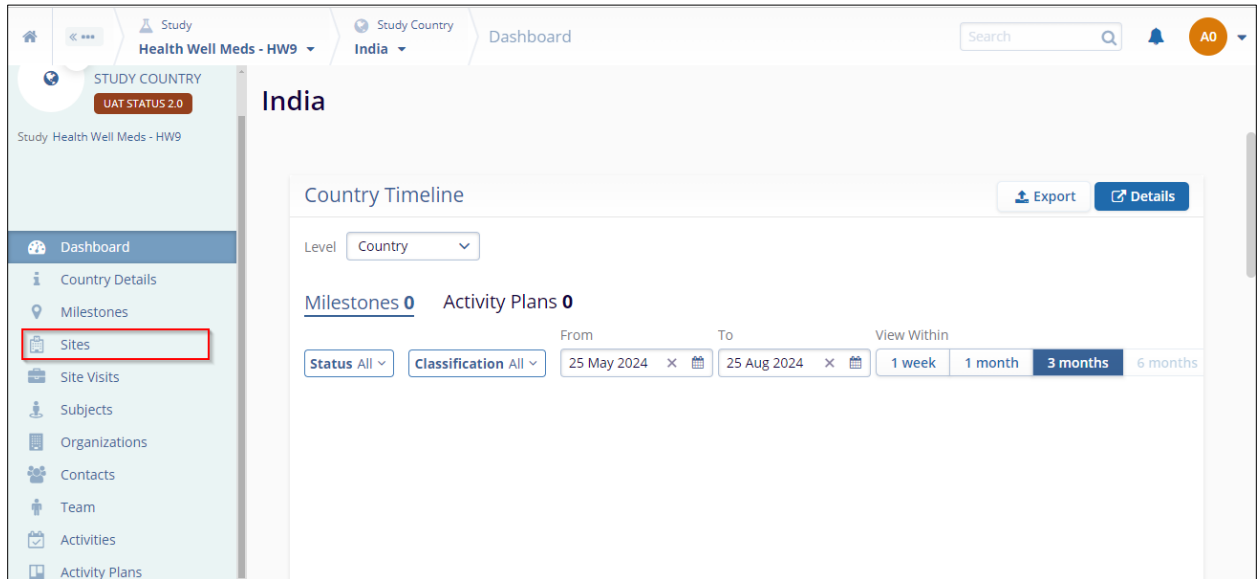


Creating a Site within a Country

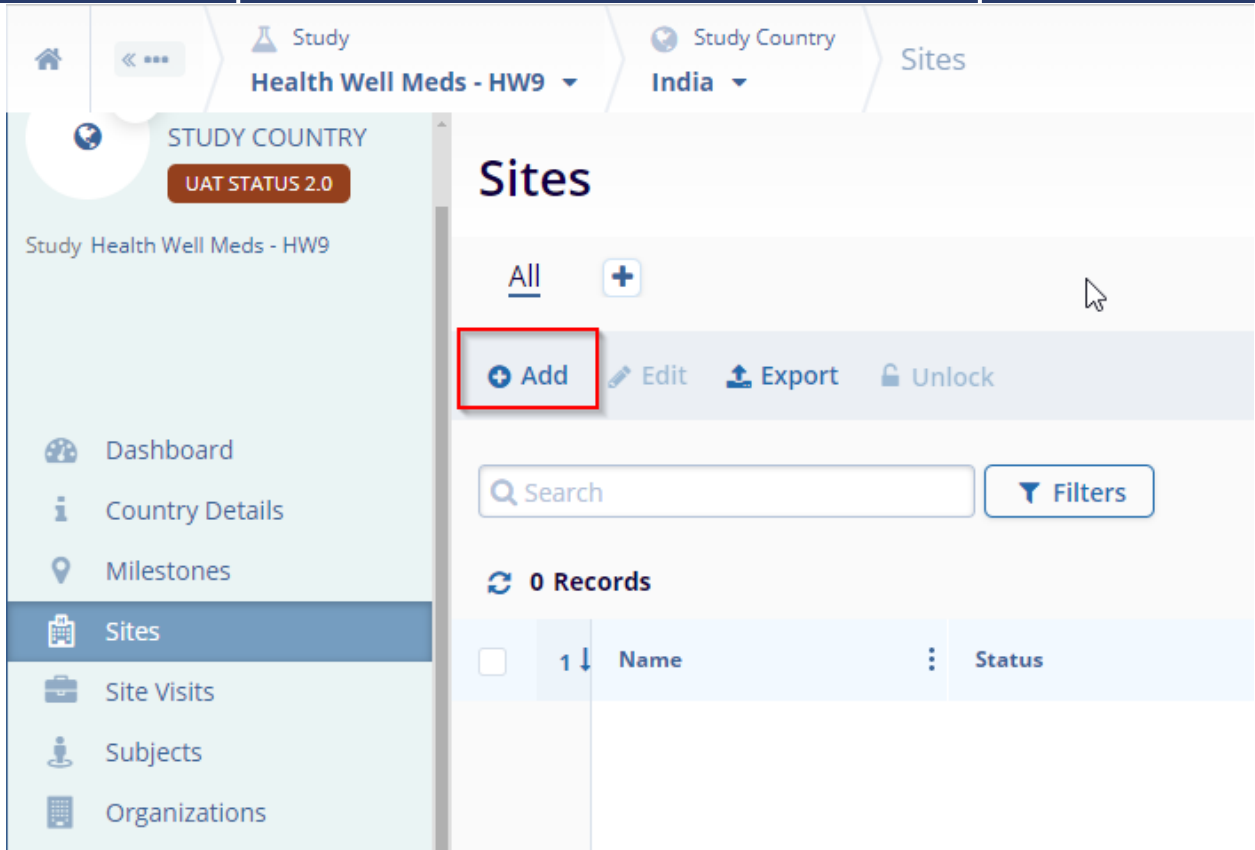
1. Click on **Countries** in the Navigation menu at the left side of the screen.



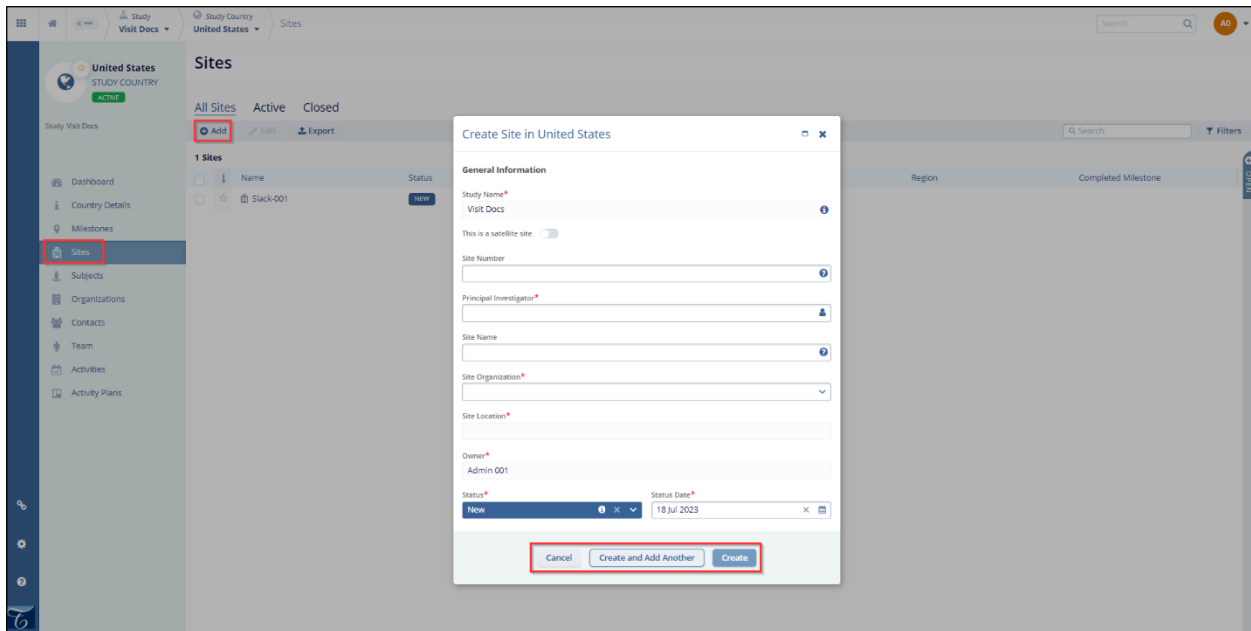
2. Navigate to the country in the list you want to edit and click on it. This opens the dashboard for the country.
3. Click on the **Sites** link in the Navigation menu at the left side of the screen.



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

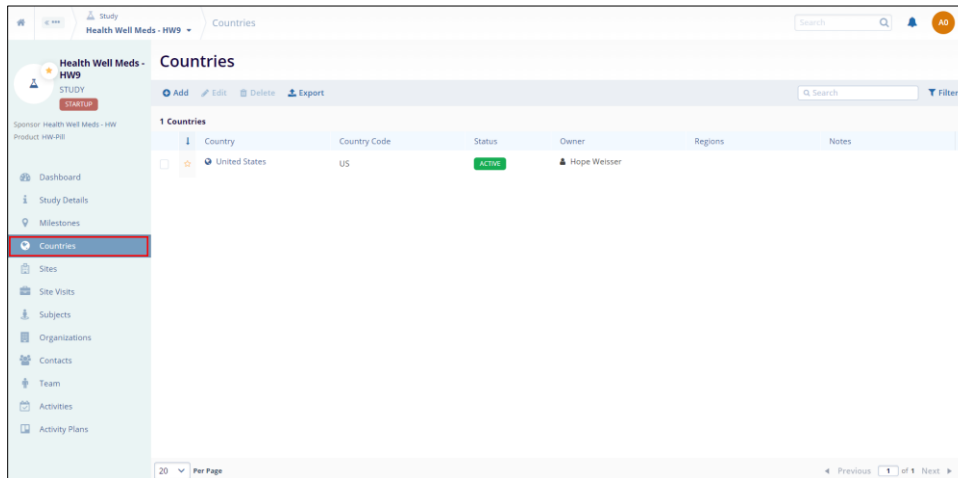


5. Fill in the required information and click Create.
 - a. More detailed instructions regarding this step can be found [here](#).

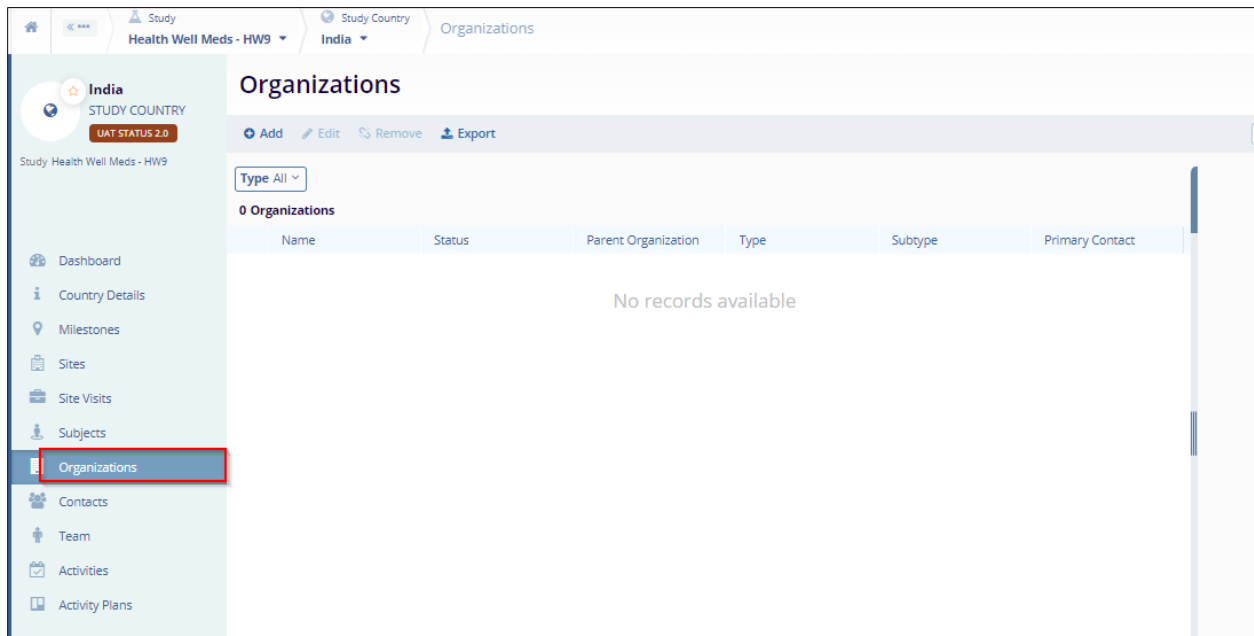


Associating an Organization with a Country

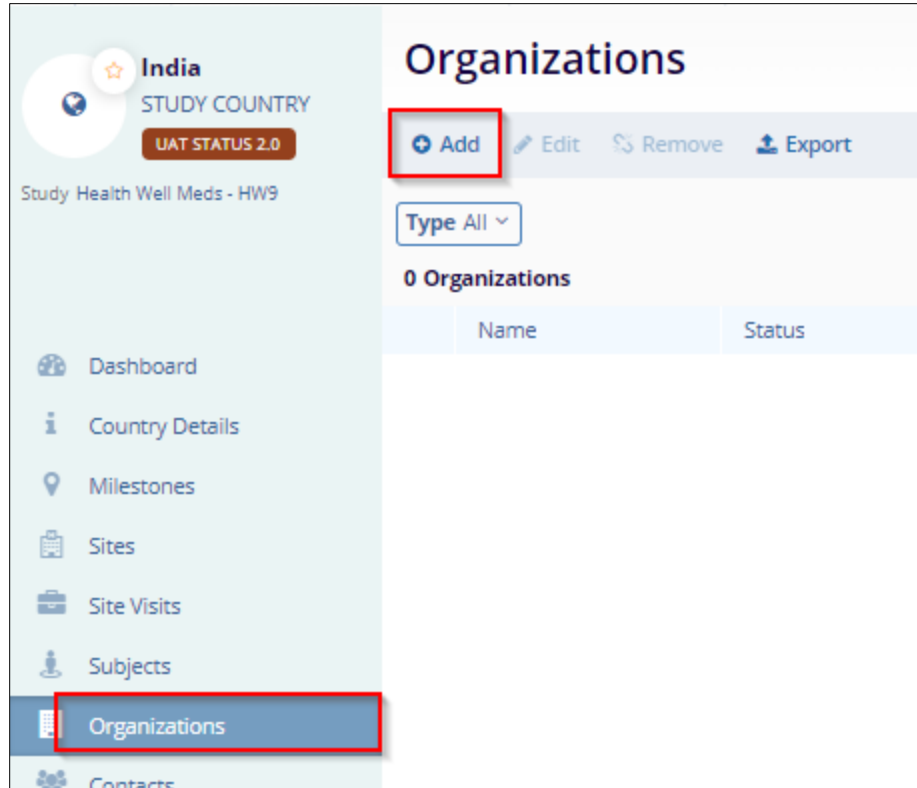
1. Select **Countries** from the menu on the left side of the screen and Click on the name of the country to which you wish to associate an organization.



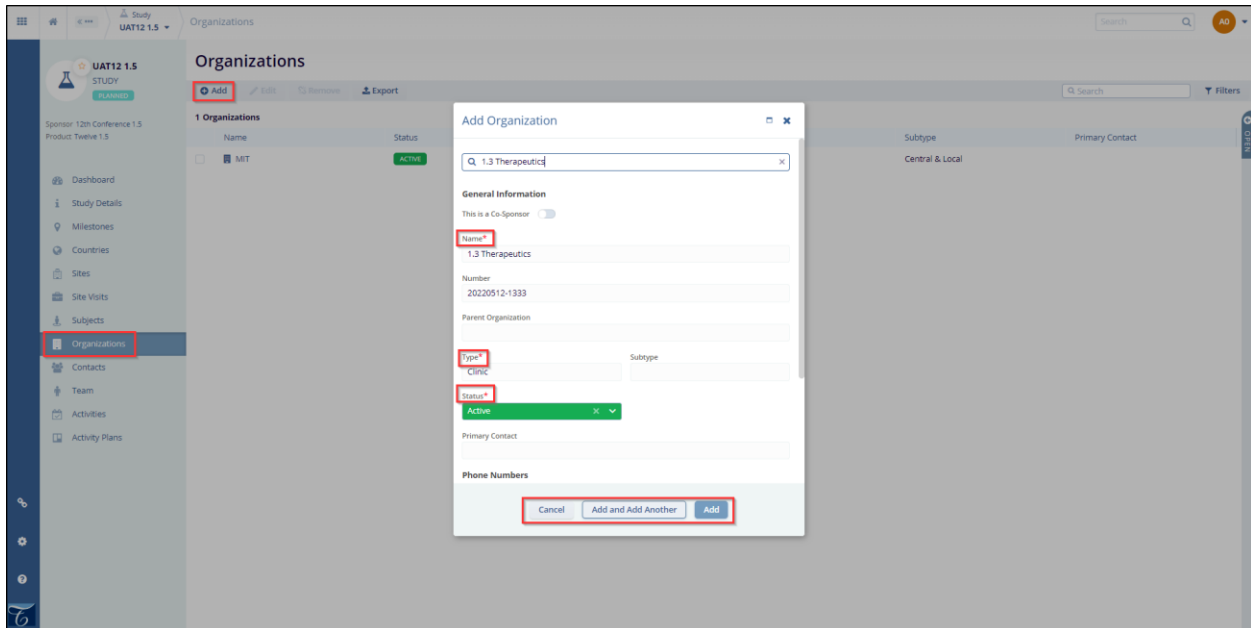
2. Click on the **Organizations** link in the Navigation menu at the left side of the screen. This opens the organization window, and the organization list is displayed.



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

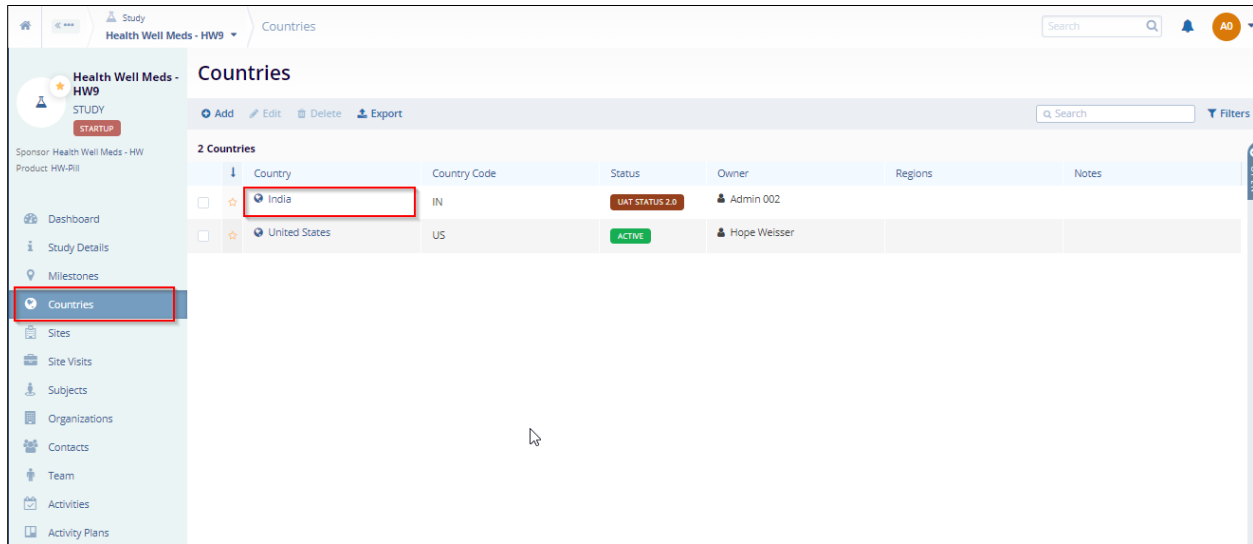


4. Search for an Organization or create a new one if necessary.
 - a. More detailed instructions for this step may be found [here](#).

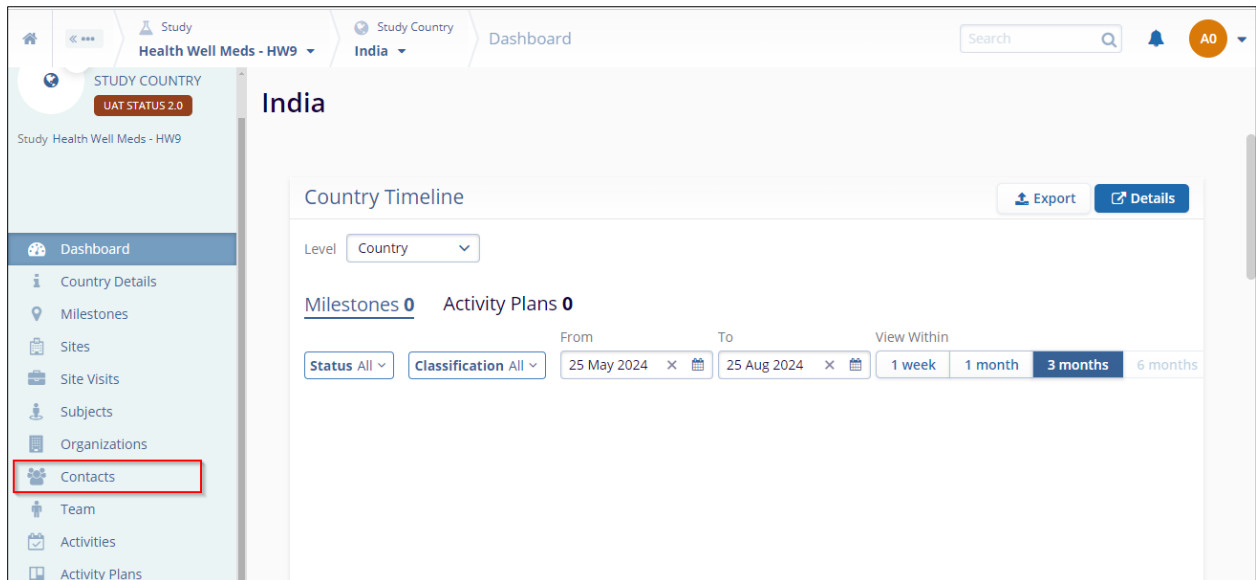


Associating Contacts with a Country

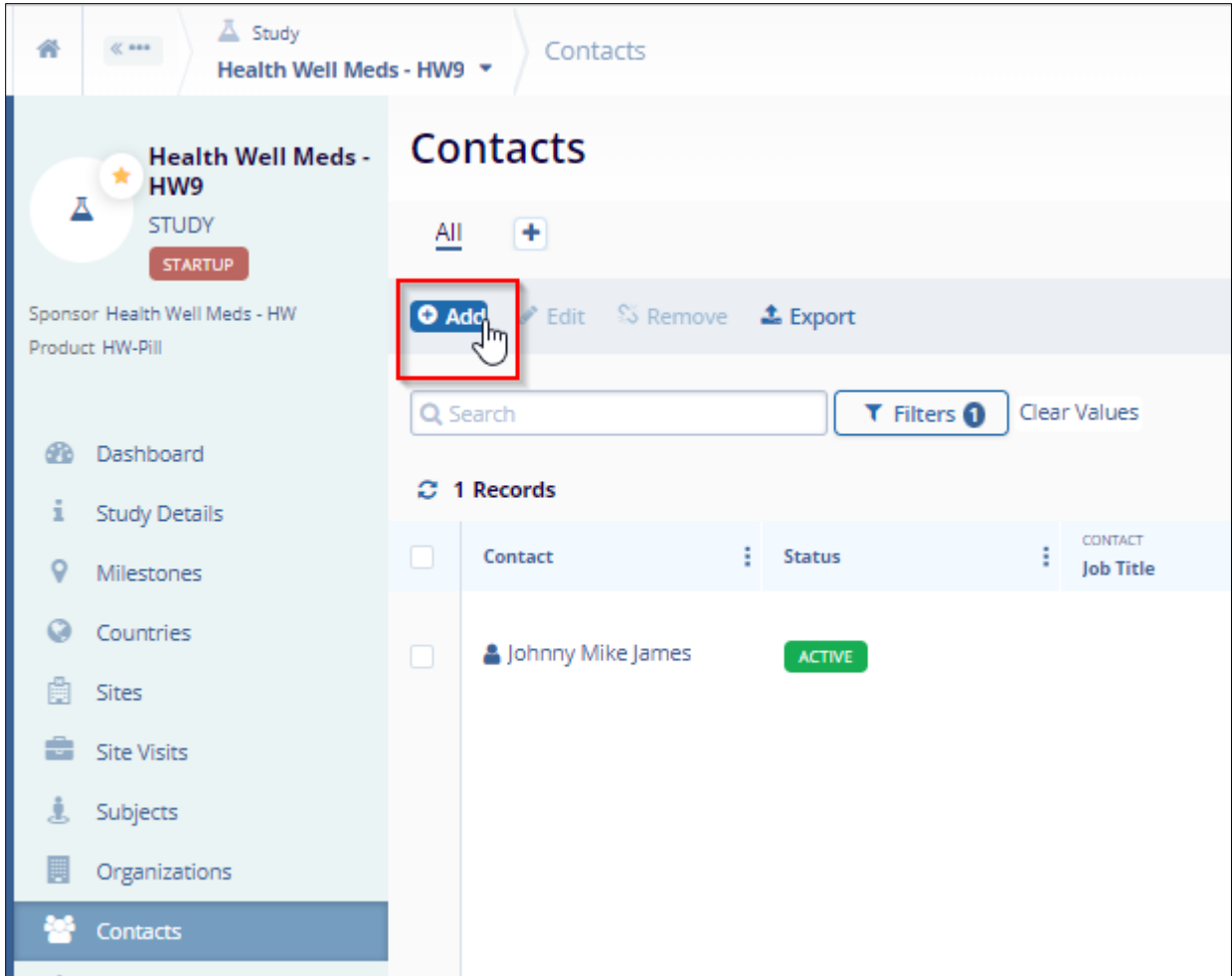
1. Navigate to the country to which you wish to associate a contact.
2. Click on the name of the country to which you wish to associate a contact.



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

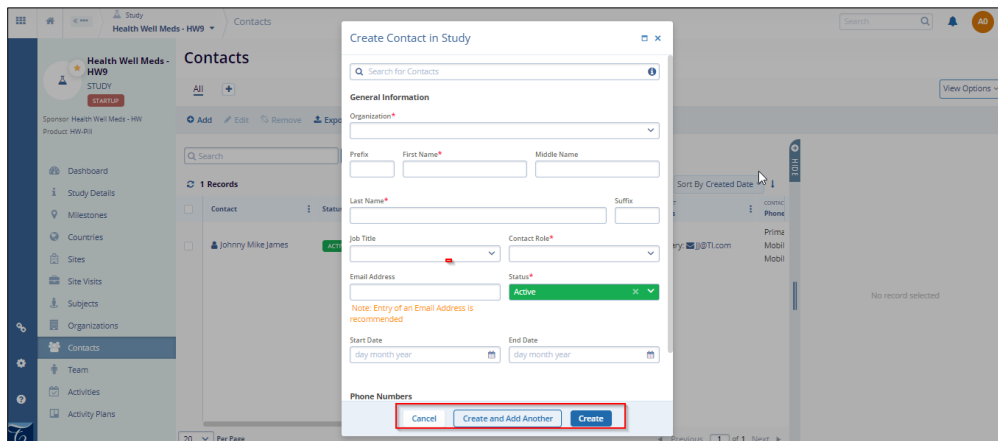


4. Click on the **Add** button in the top-left of the screen. This opens the "Create Contact in Country" window.

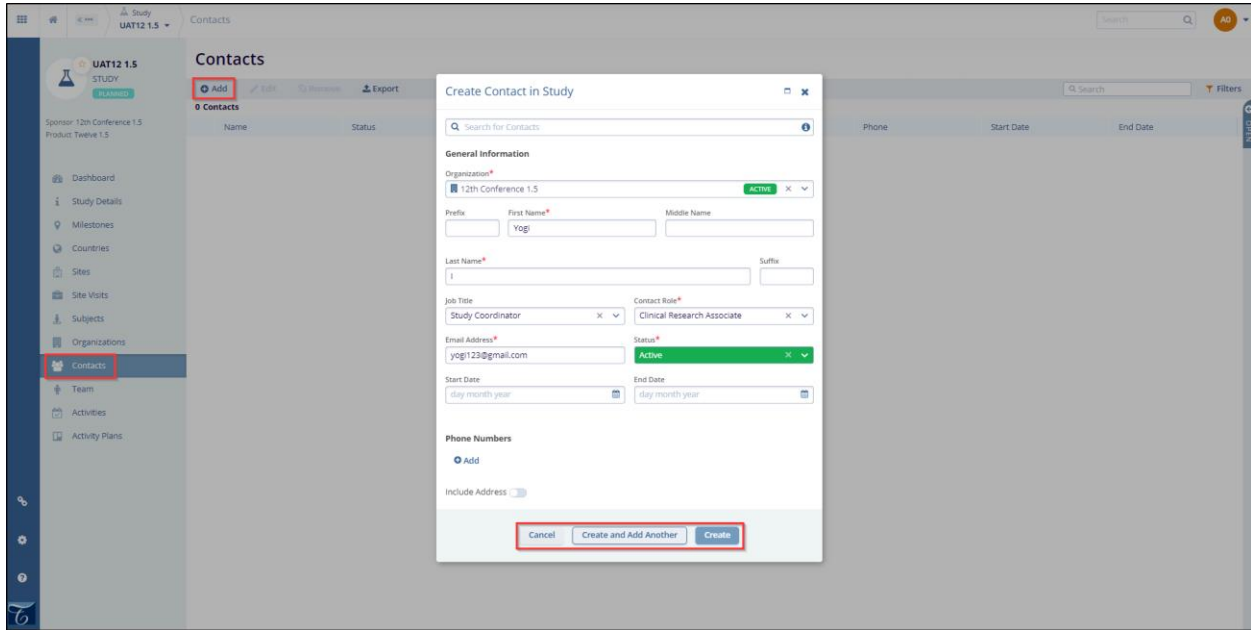


Note: The search field can be used to locate and select existing CTMS contacts.

- Here we need to enter the mandatory metadata to create a contact i.e., **Organization, First Name, Last Name, Contact Role, Email Address, and Status**, as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.



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



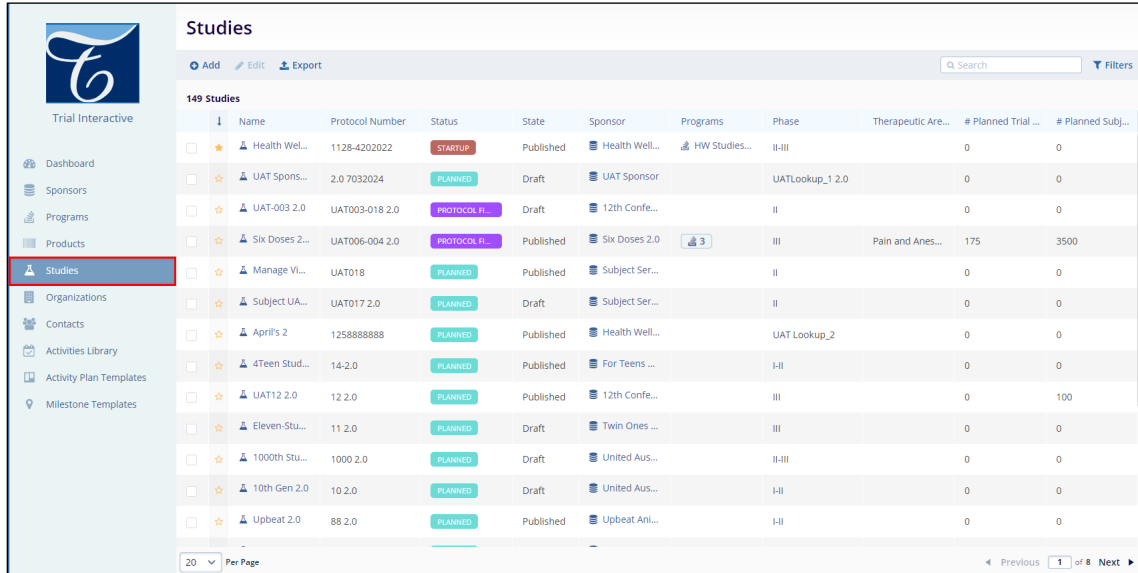
Study Sites

Study Sites Pre-Requisites

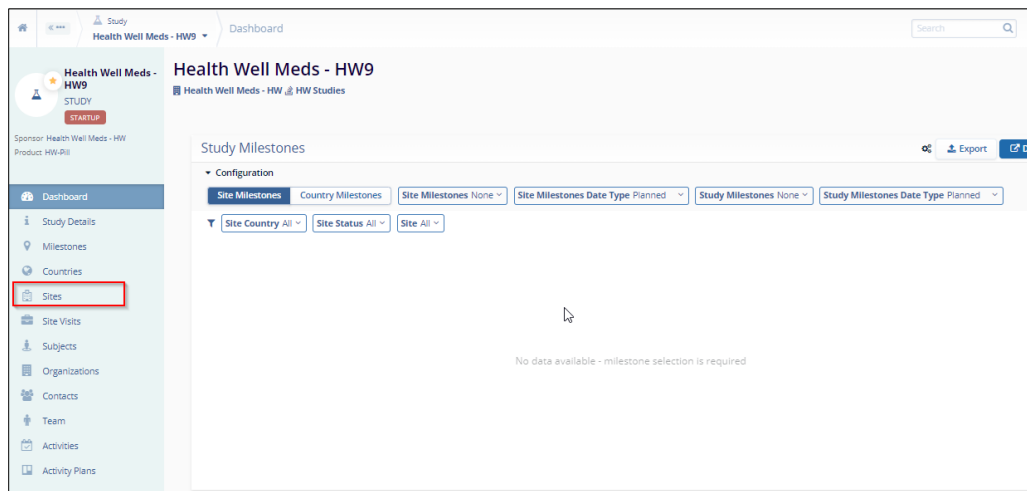
The user who is responsible for creating or managing sites in any study should have **CRA** user access. Company administrators will need to assign **CREATE, UPDATE, EDIT** and **DELETE** permissions/privileges to users' accounts so that they can perform these steps.

Associating Sites within Study

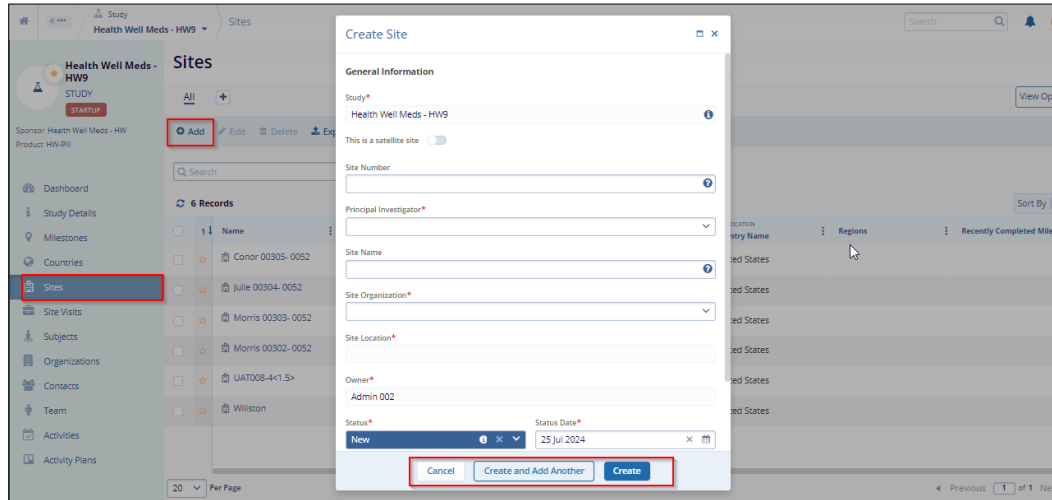
1. Click on the **Studies** link in the Navigation menu at the left side of the screen. This opens the "Studies" window and the study list is displayed.



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

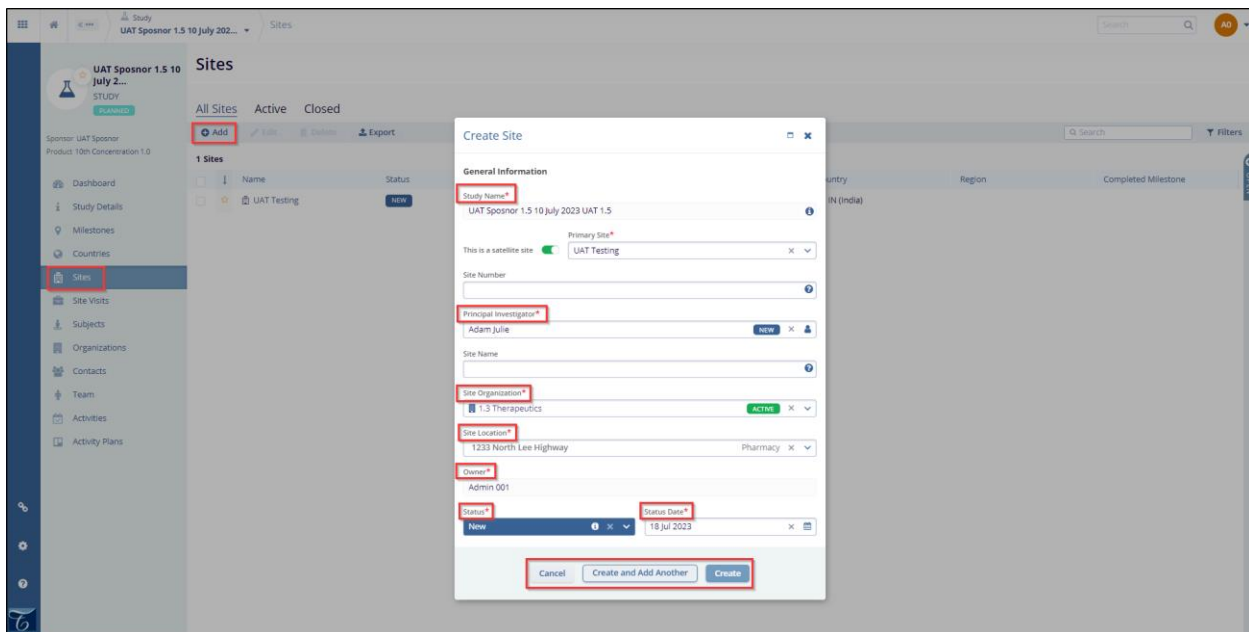


- Click on the **Add** button at the top-left of the screen. This opens the **Create Site** window.



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

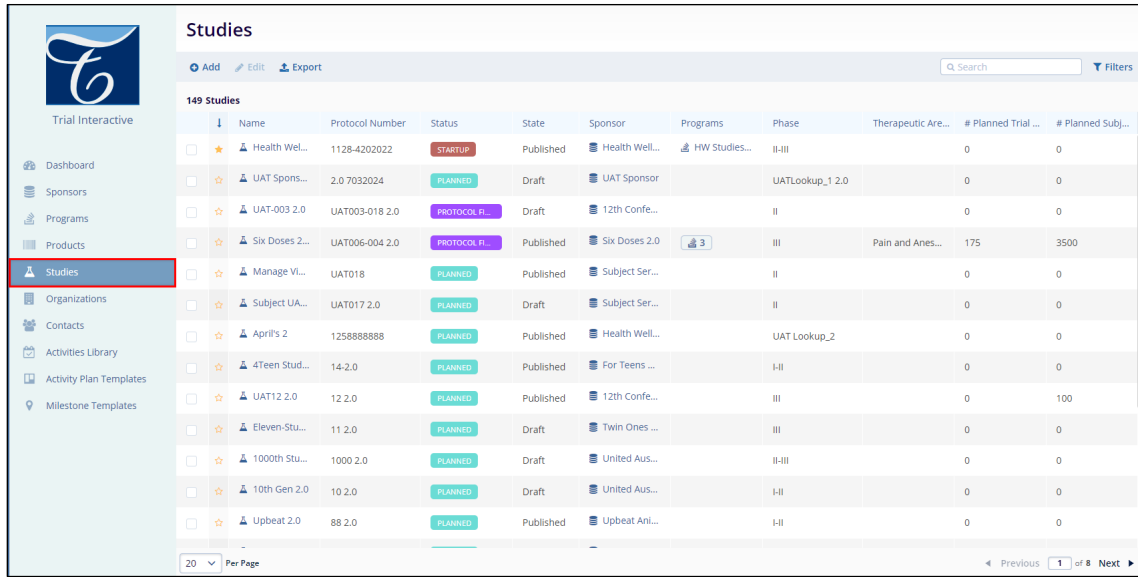
Note: The **Site Number** field is limited to 5 characters. Satellite sites can either have a unique site number or they can use the same number as the parent site.



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

Editing a Site in a Study

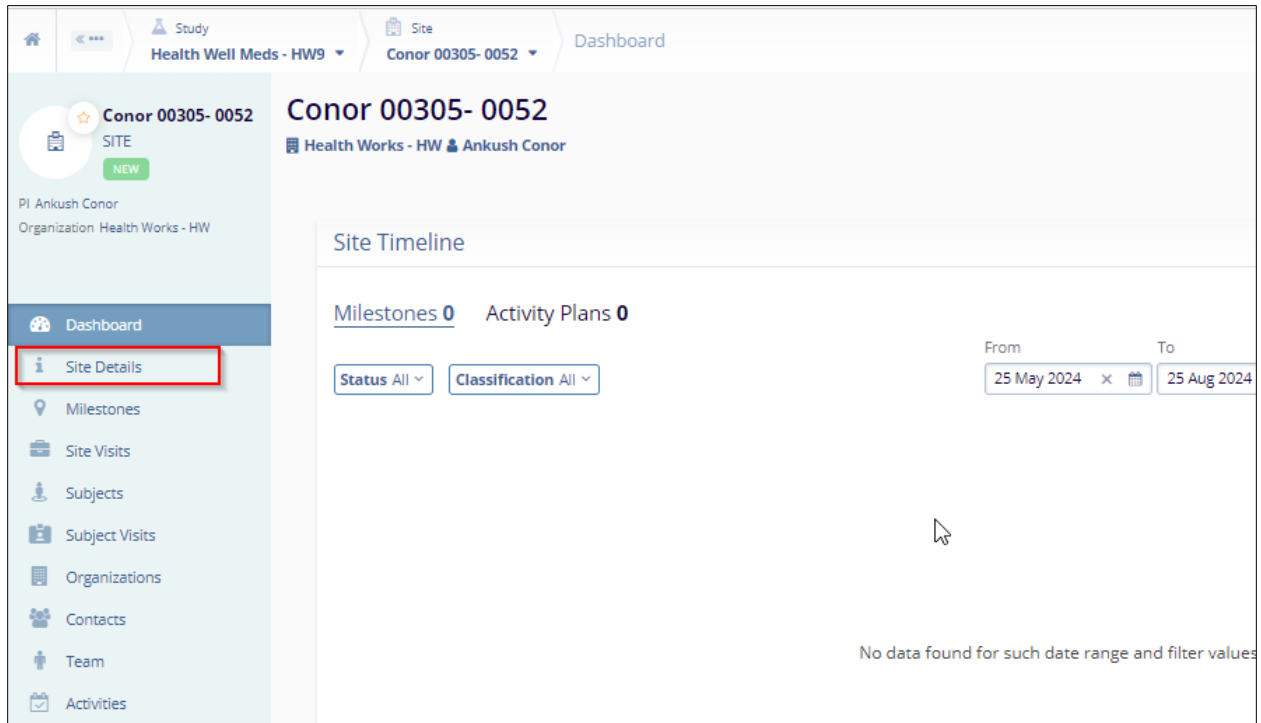
1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
2. Navigate to the study you want to access.



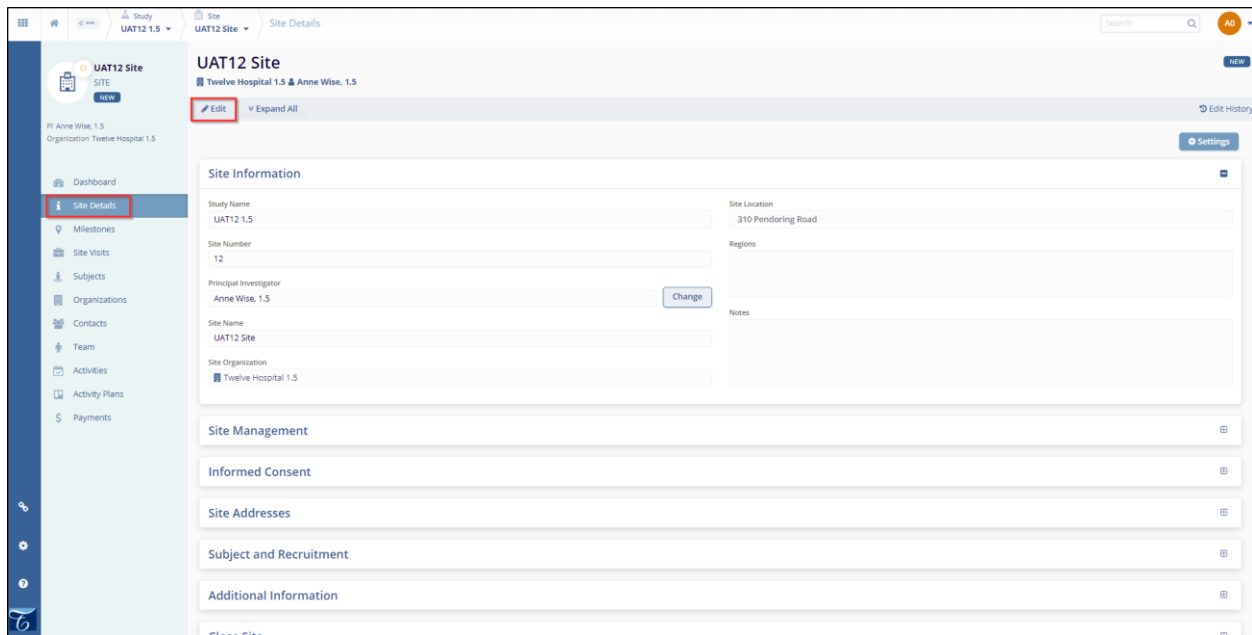
3. Click on **Sites** in the Navigation menu at the left side of the screen. This opens the “Study Site” window and the study site list is displayed.



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



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



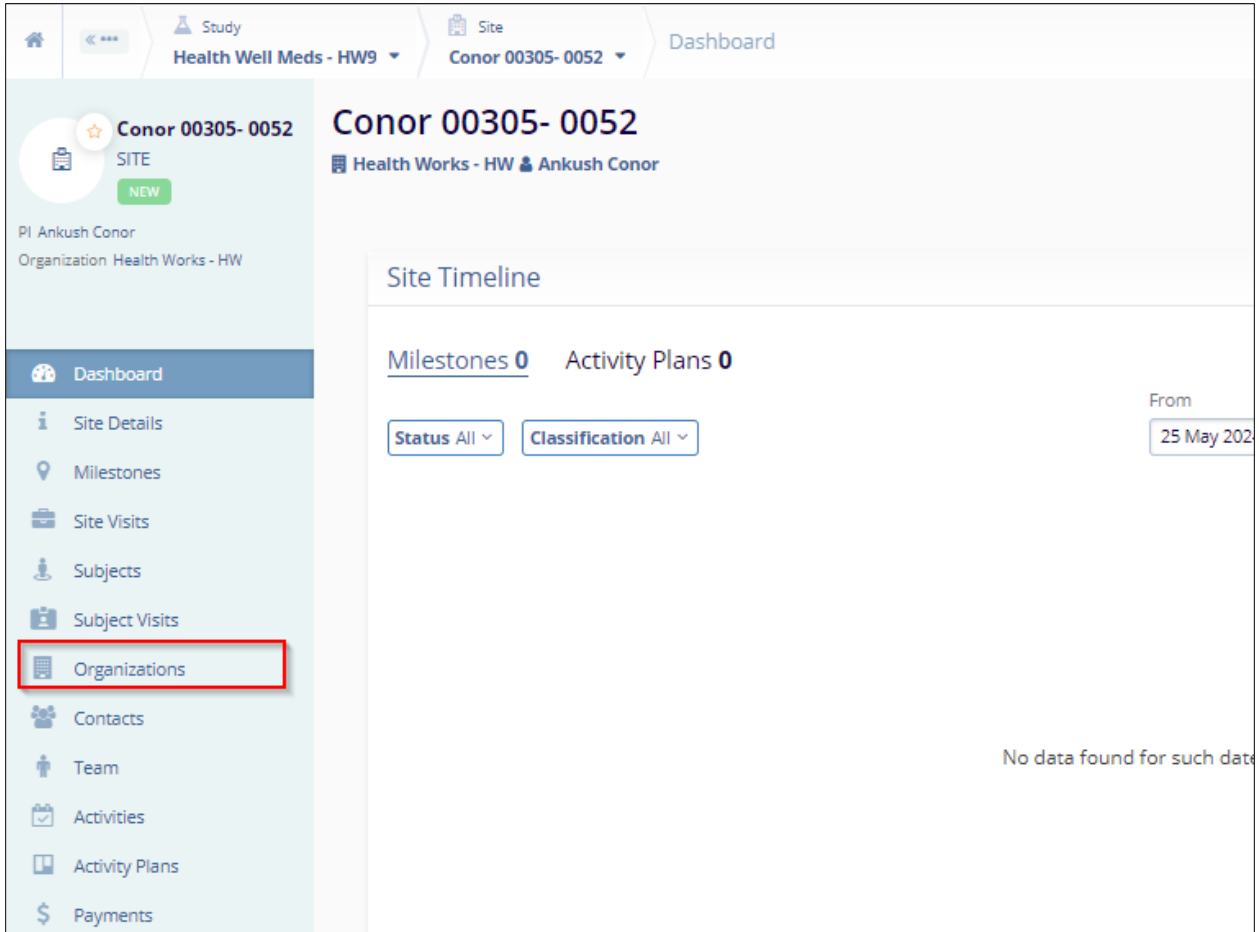
7. Make the required changes in the site details window.

8. Click on the **Save** button at the top-left of the screen for the changes to apply.

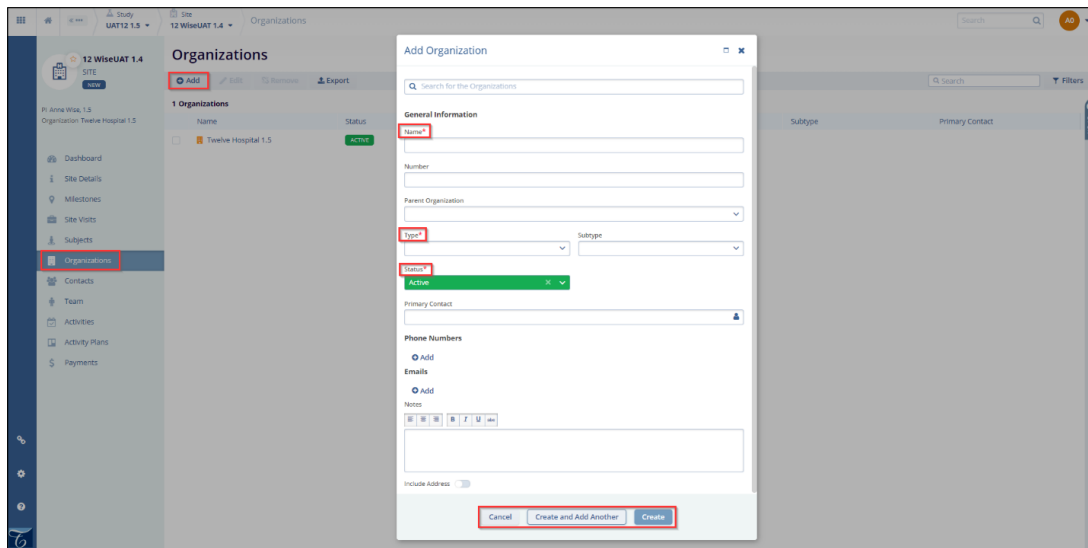
The screenshot shows the 'Site Details' page for site 'Conor 00305-0052'. The navigation menu on the left includes 'Dashboard', 'Site Details', 'Milestones', 'Site Visits', 'Subjects', 'Subject Visits', and 'Organizations'. The main content area displays the site name 'Conor 00305-0052', the study name 'Health Well Meds - HW9', and the principal investigator 'Ankush Conor'. Below this, there are buttons for 'Save', 'Cancel', and 'Collapse All'. The 'Save' button is highlighted with a red box. The 'Site Information' section includes fields for 'Study Name' (Health Well Meds - HW9), 'This is Satellite Site' (toggle), 'Site Number' (00305-0052), and 'Principal Investigator*'. The 'Organizations' link in the navigation menu is highlighted in blue.

Associating an Organization with a site

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



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



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

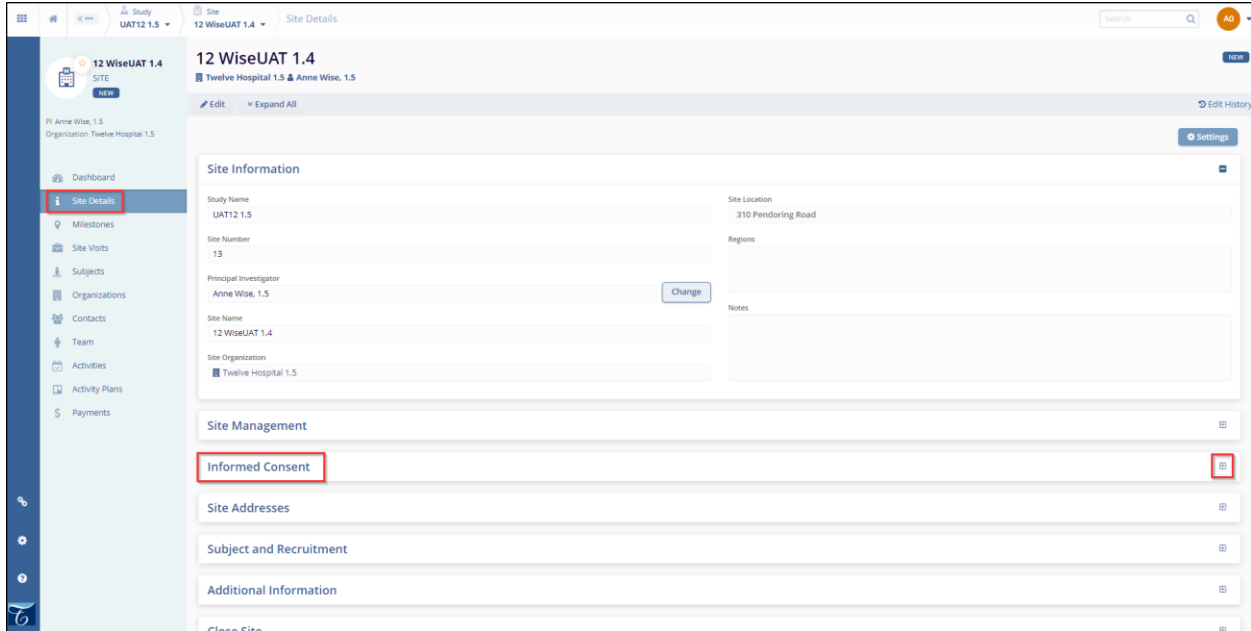
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Managing Site Contacts

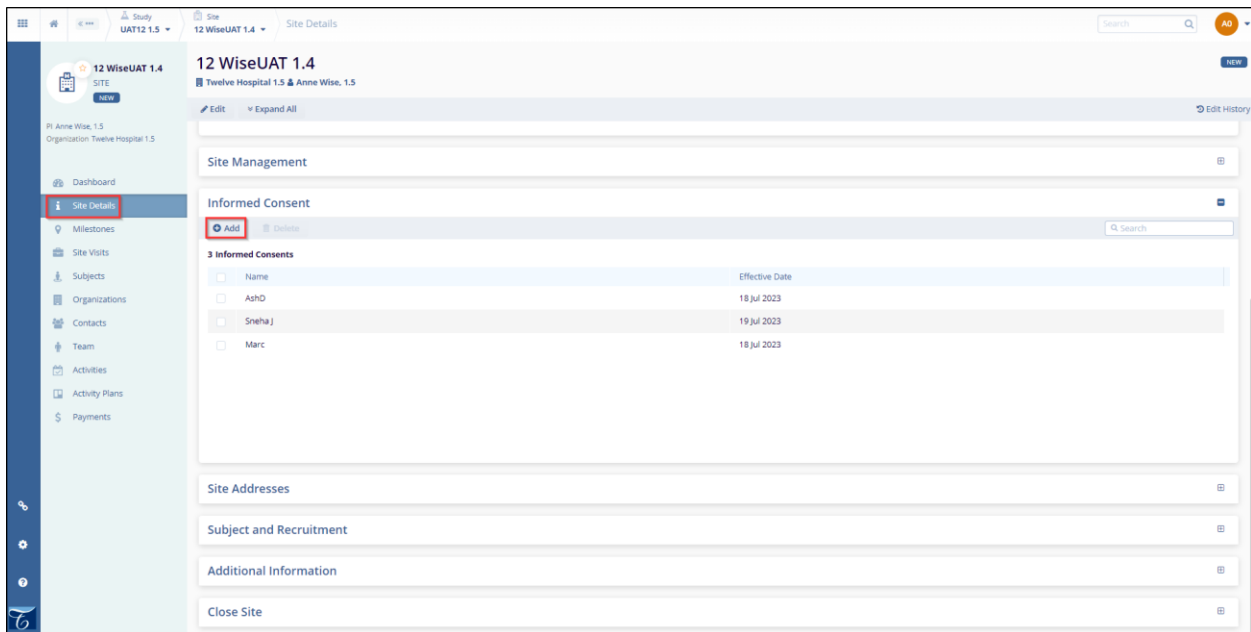
The functionality here is similar to the improvements described above in the section about managing the study team. Each contact can have multiple entries as needed to indicate the various roles that they may play at the site. Importantly, to enter the same person more than once, there is now a 'Copy'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

Tracking Informed Consents (ICFs) for a Site

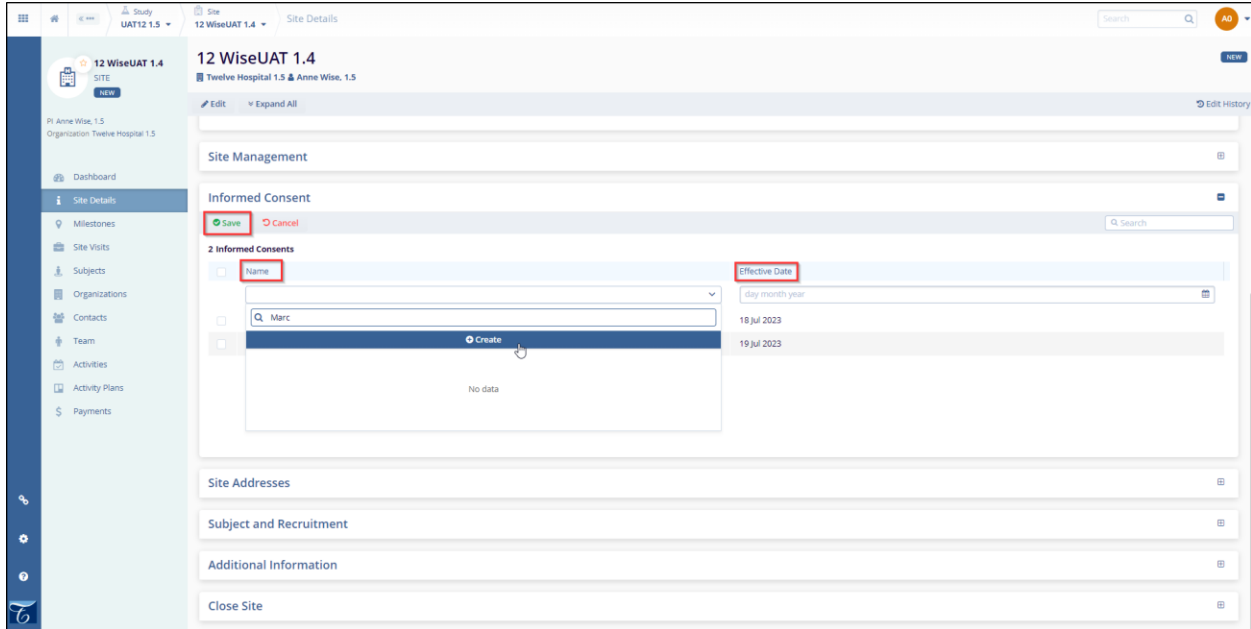
1. Navigate to the Site Details area for the related site. The necessary steps are found [here](#).
2. Click on the [+] sign next to the Informed Consent to expand that section.



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



5. Enter site-specific **Name** and **Effective Date**.

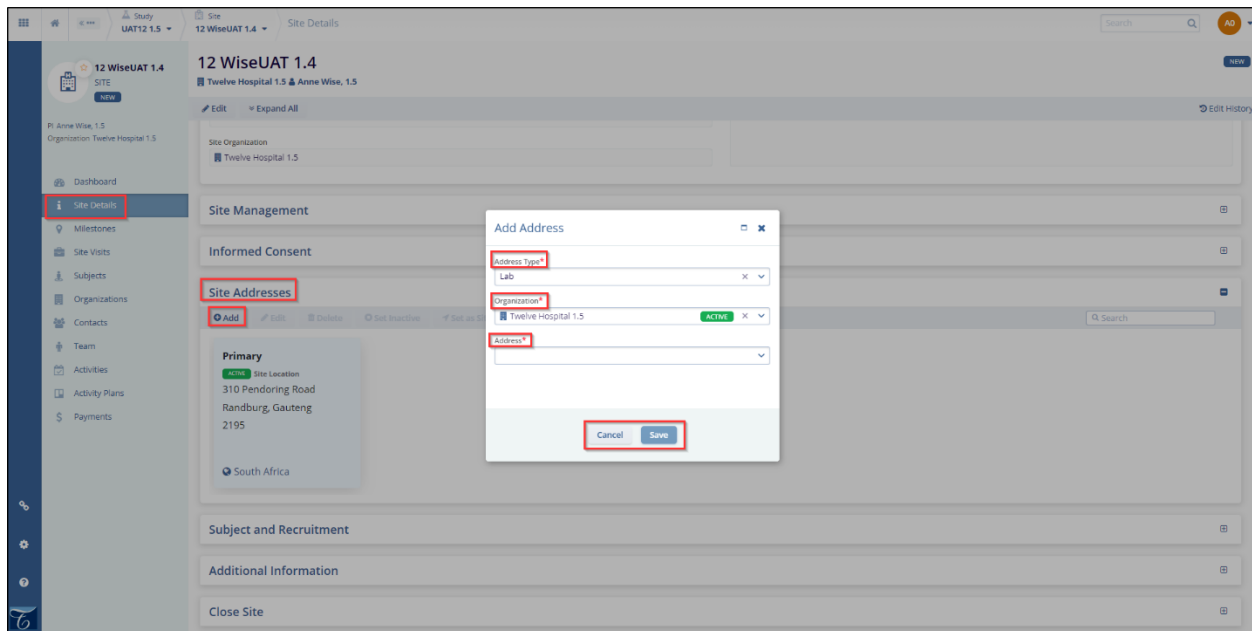


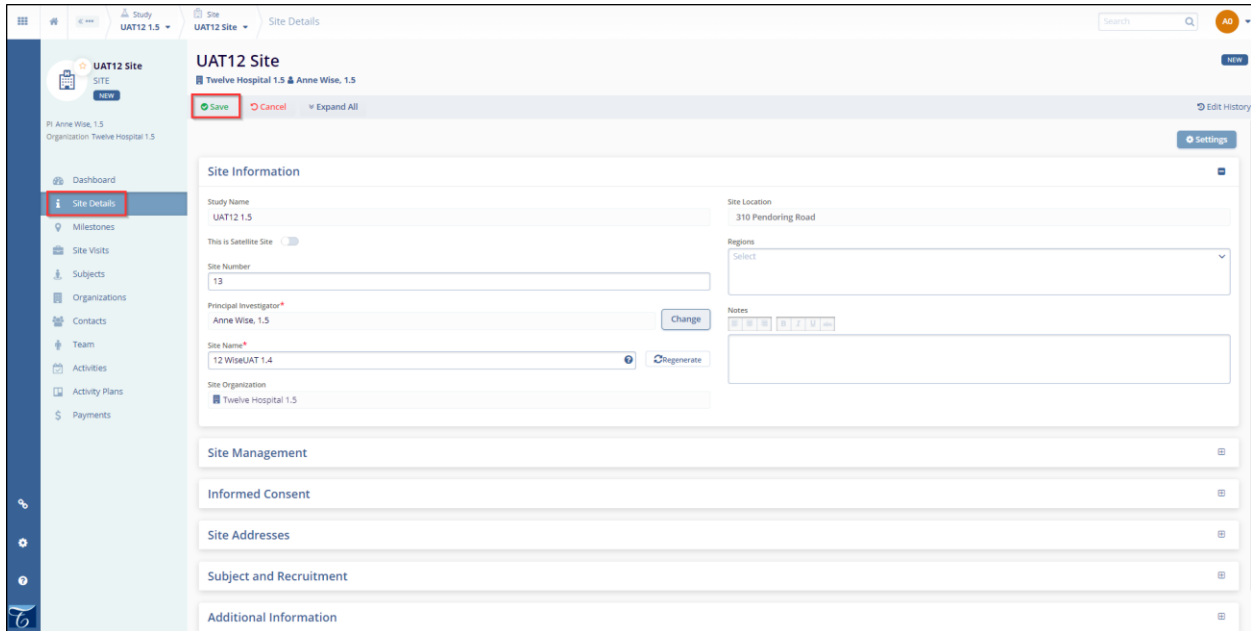
6. Click **Create**.
7. Click on the **Save** button in the informed consent section to save the record. This creates site-level ICF for the site.

Tracking Site Addresses

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

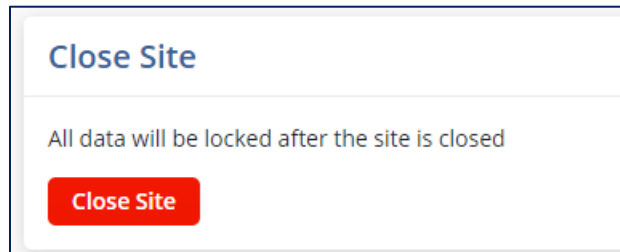
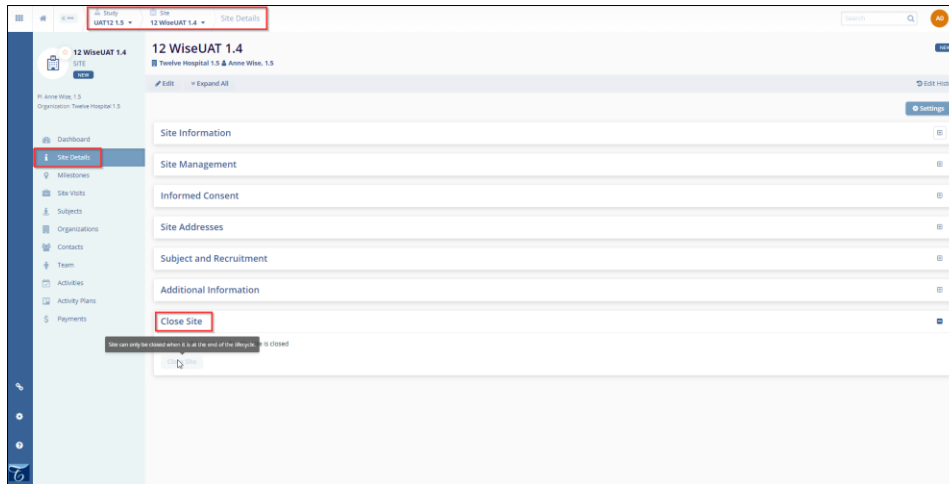
Note: Only addresses associated with the selected site organization are available for selection.





Closing a Site

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

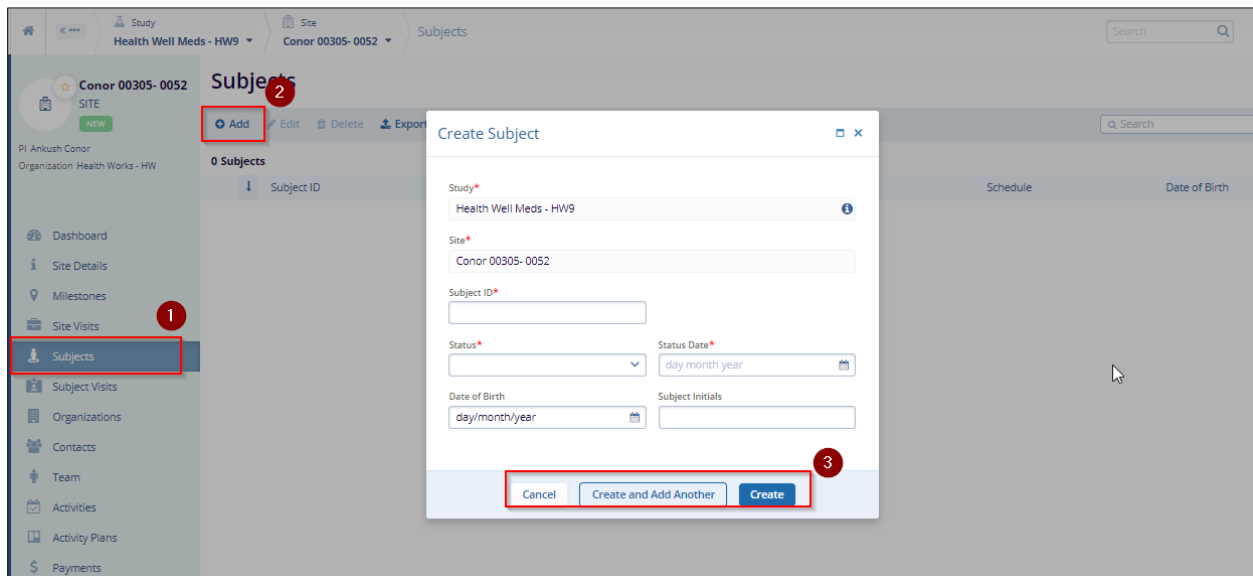


Note :Once that button is pressed, a Site Health Card window is displayed indicating the completion status of the site-related Milestones, Site Visits, Subjects, Activities, and Activity Plans. This gives the user a chance to locate and deal with any unresolved items before they become locked.

Study Subjects

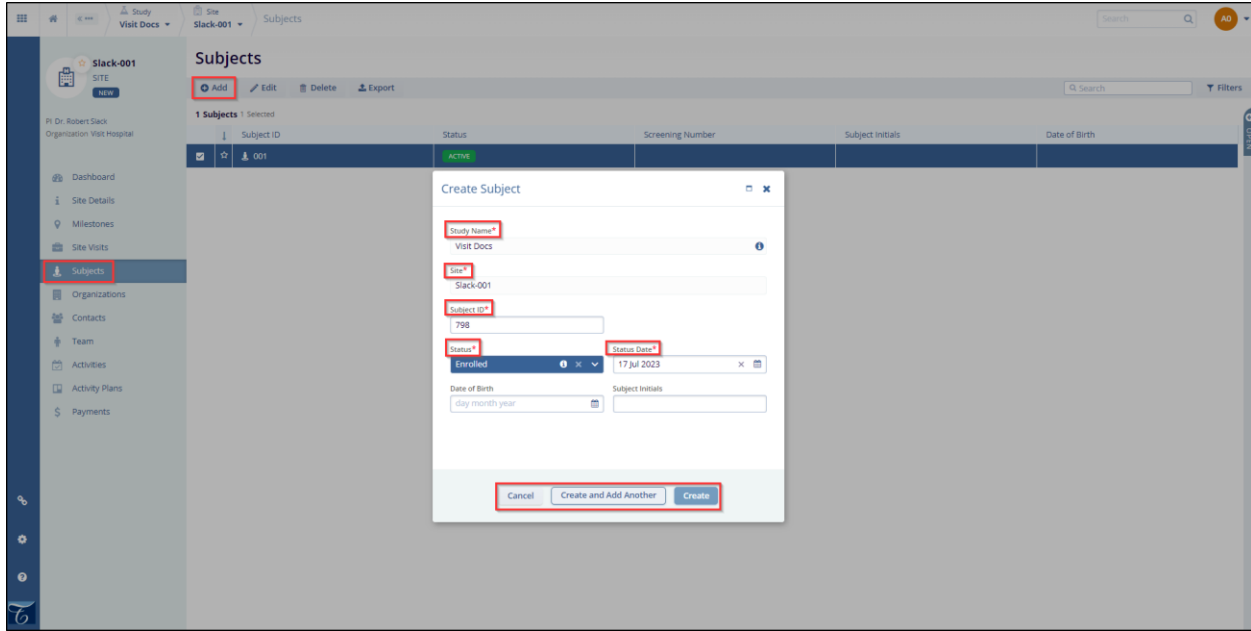
Tracking Subjects

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



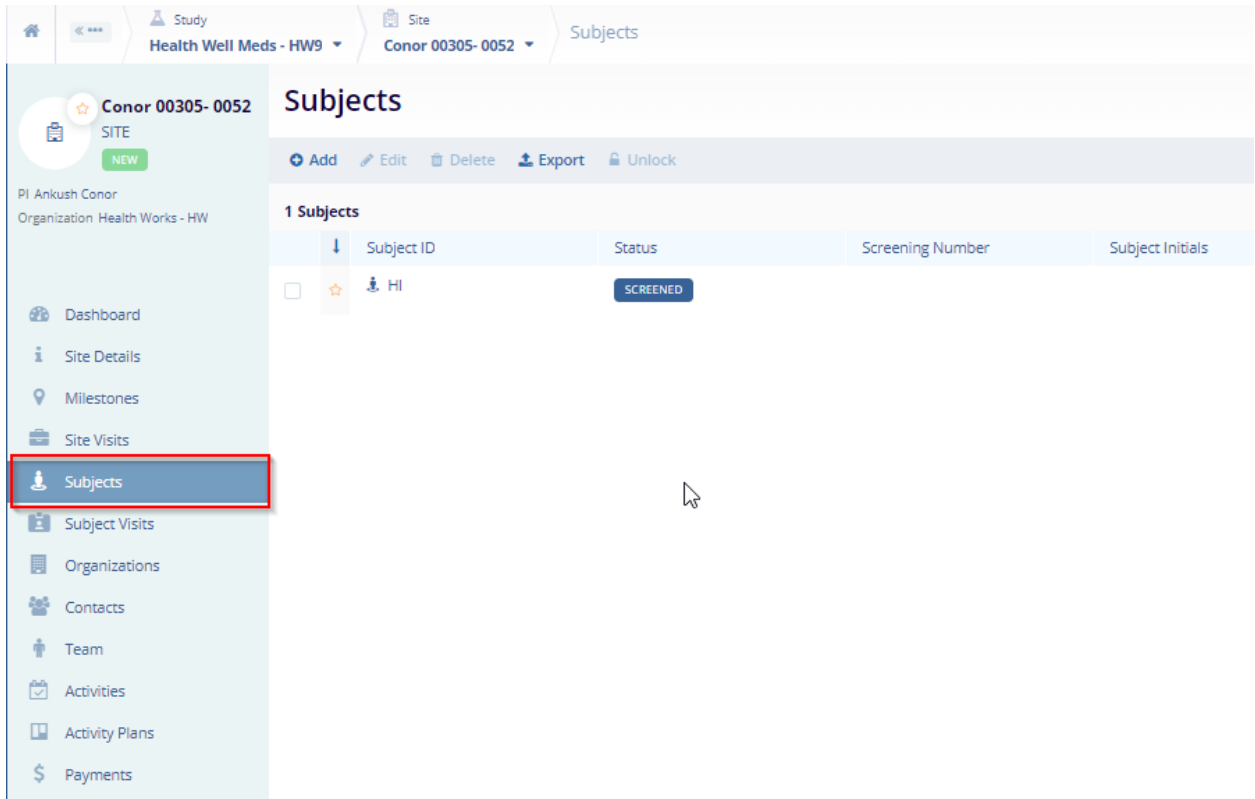
3. Click on the **Add** button at the top-left of the screen and This opens the **Create Subject** window.
4. Here we need to enter the mandatory metadata to create a Subject i.e., **Study Name, Site, Subject ID, Status, Status Date** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a subject successfully.
6. Finally, before clicking **Create**, verify all the fields are entered correctly in the Create subject window.
 - a. **Create Subject window** closes, and the subject record is created and displayed in the list.
7. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another subject right away.

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

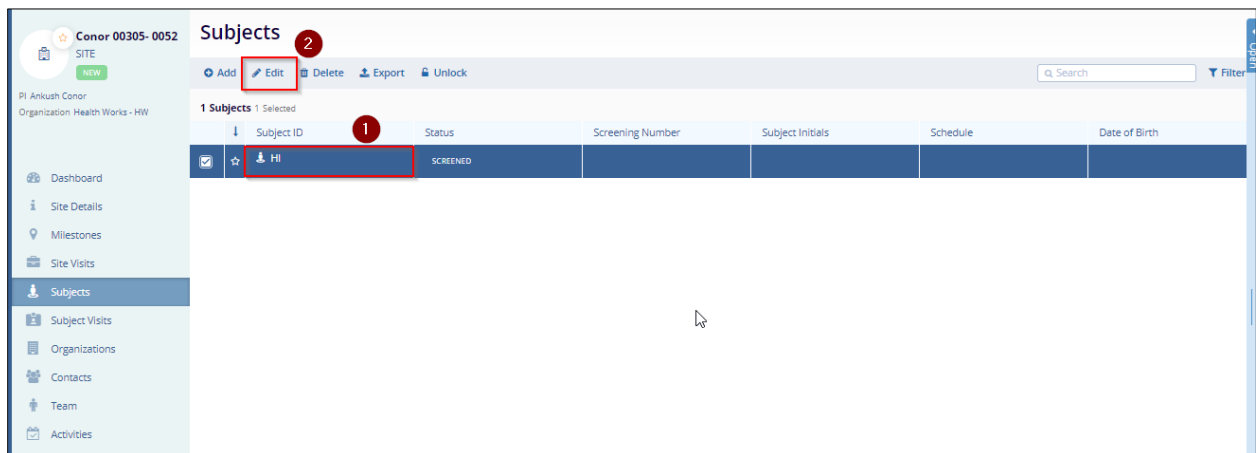


Editing a Subject

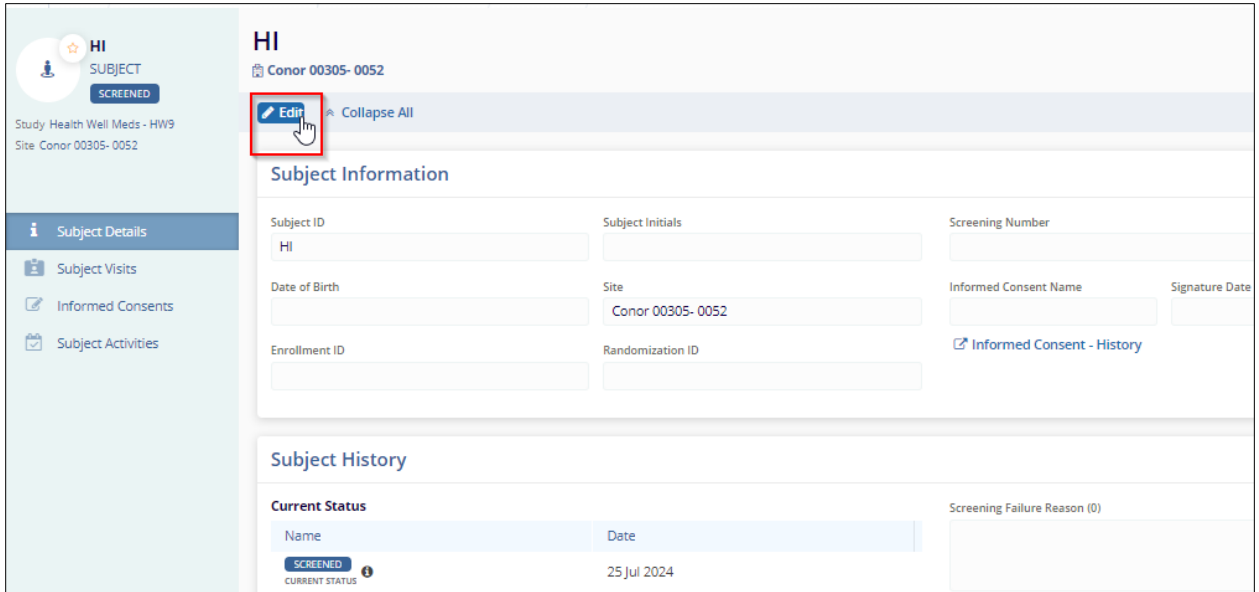
1. Click on the **Subjects** in the Navigation menu at the left side of the screen. This opens the “Subjects” window.



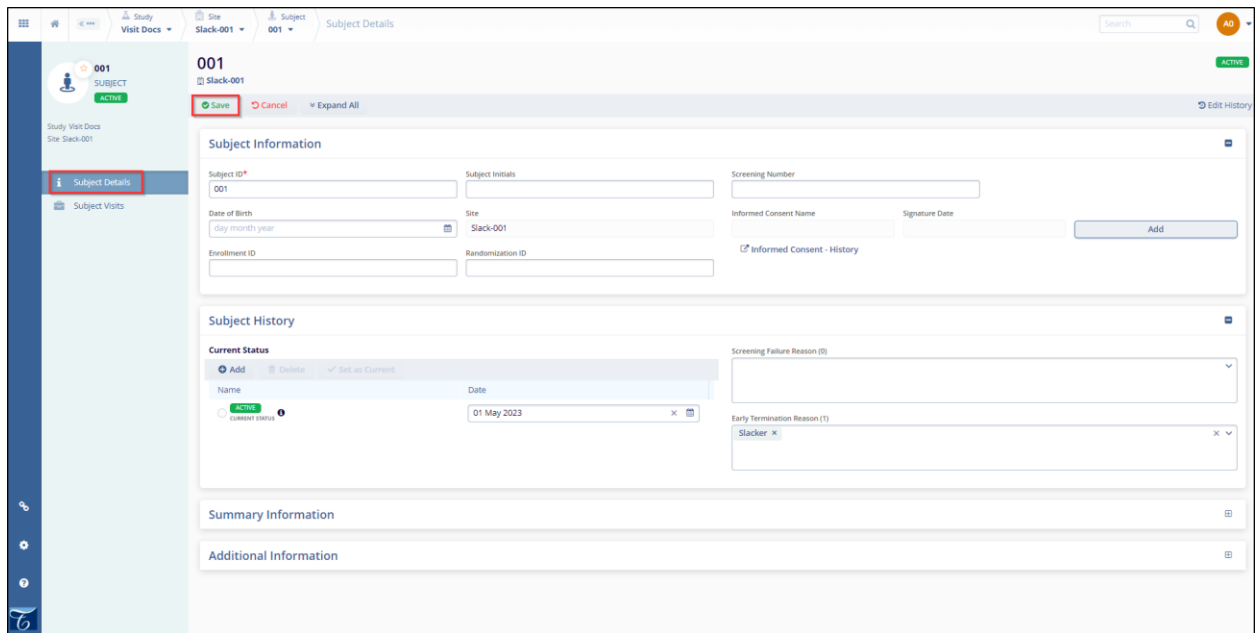
2. Click on the checkbox before the Subject name or the edit button. A quick view panel will display on the right side of the screen.



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



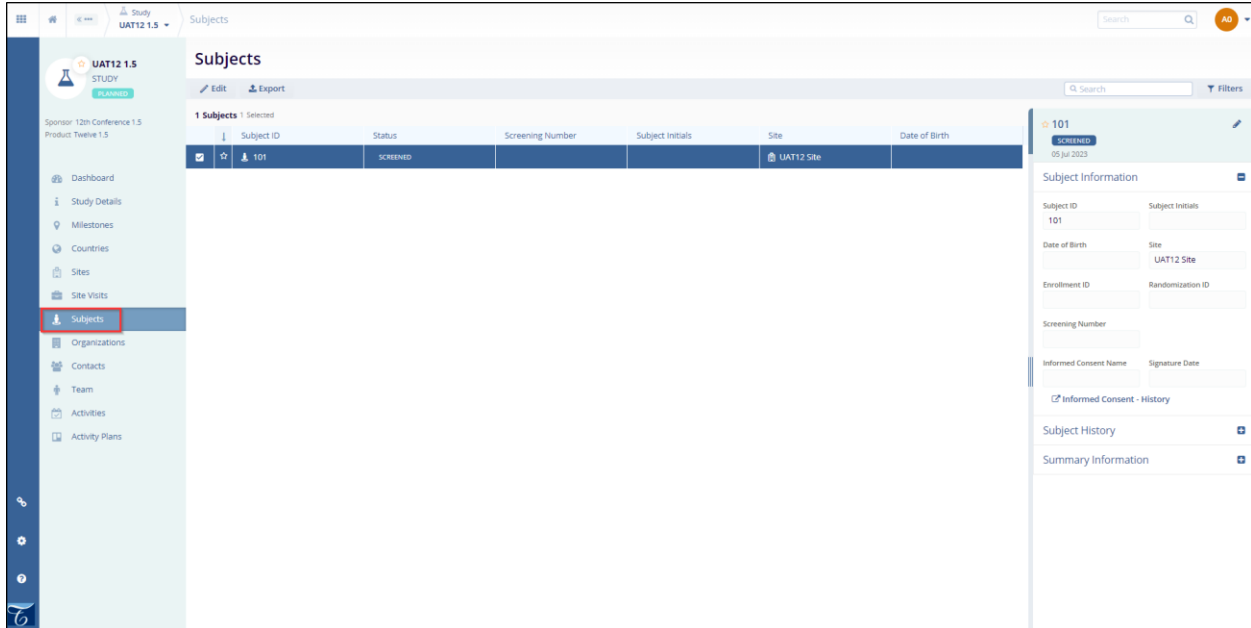
4. Make any necessary changes to the subject information.
5. Click on the Save button at the top-left of the screen.



Reviewing Subjects Within a Study

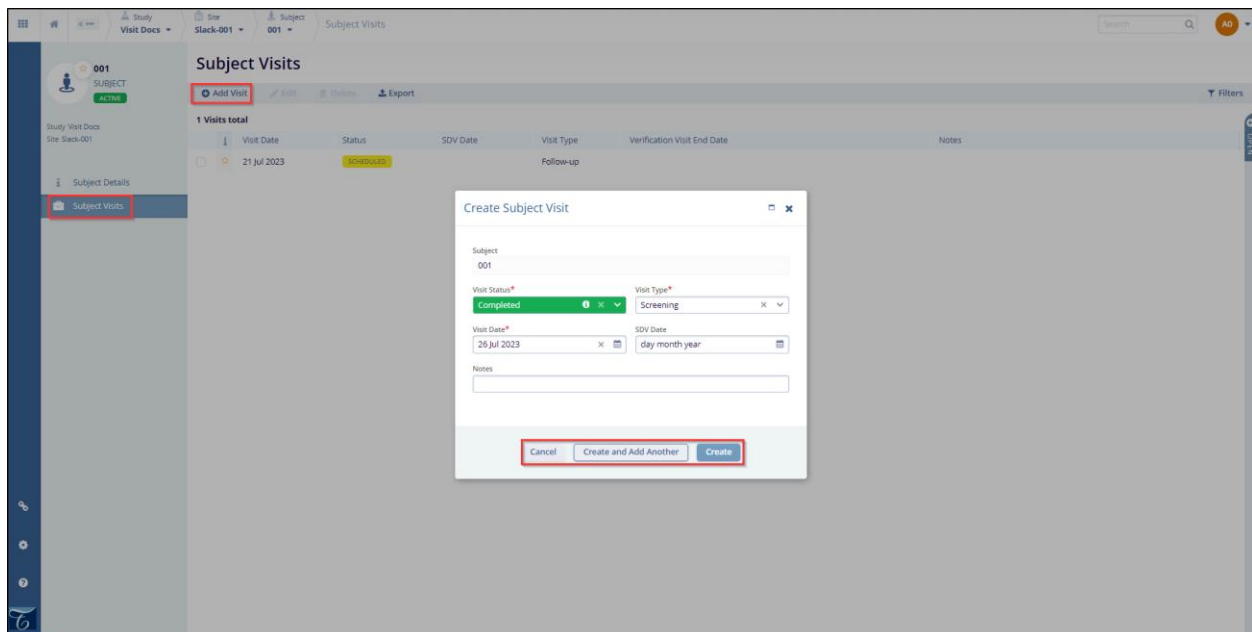
Note: Subjects is only available if the study is tracking subjects within CTMS. This list will be populated with the current list of subjects for the study.

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



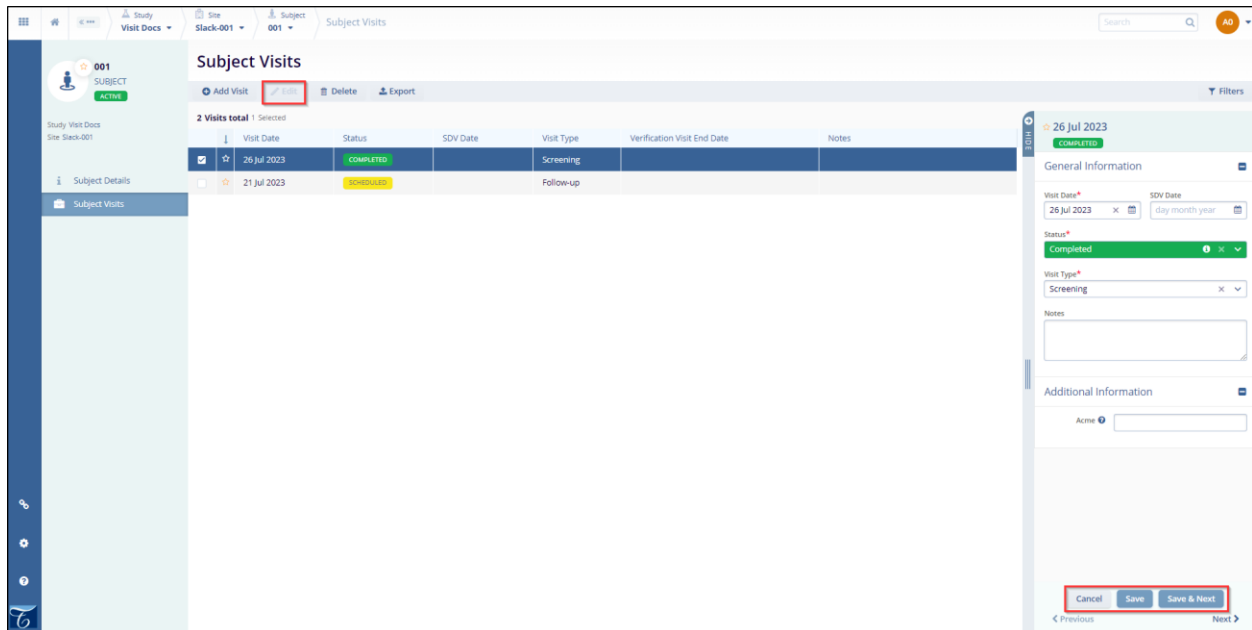
Tracking Subjects Visits

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



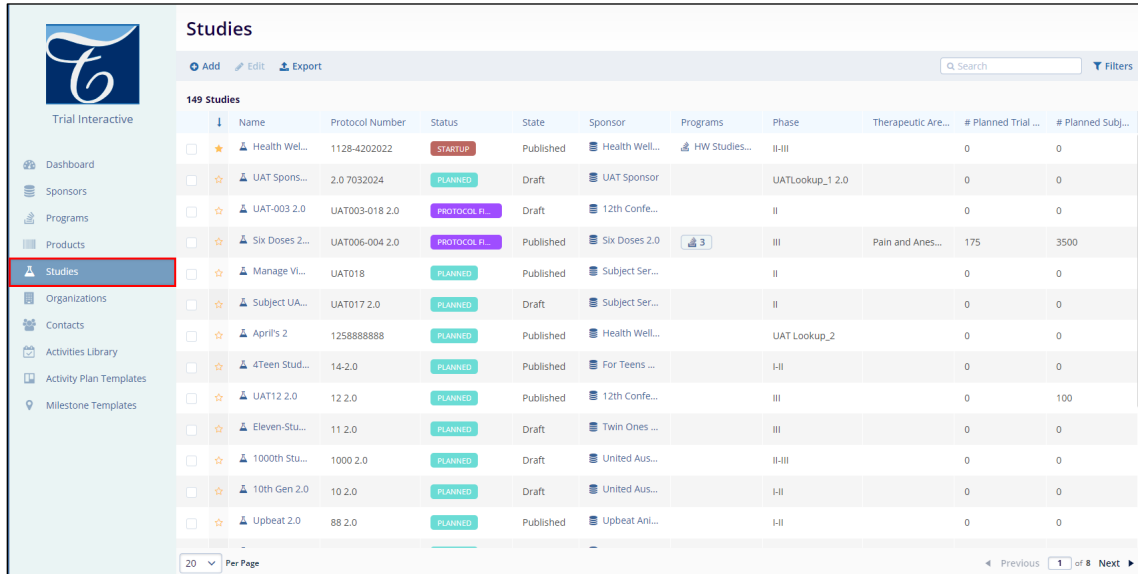
Editing a Subject Visit

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



Study Organization

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



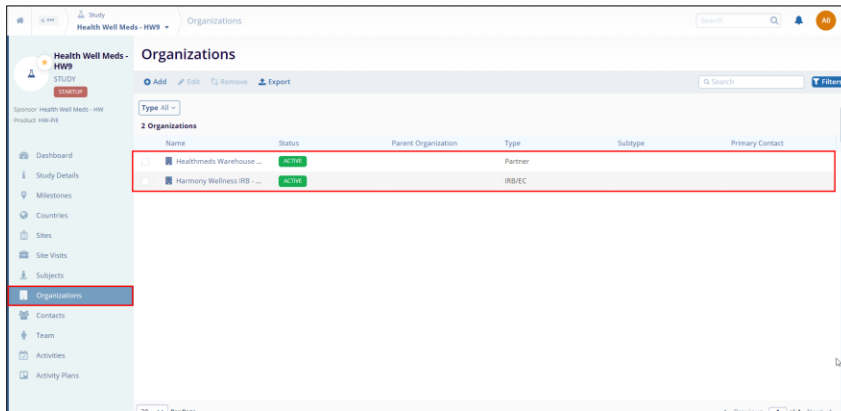
2. Locate the study to which you want to associate an organization and click on it. This opens the dashboard for that study.



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



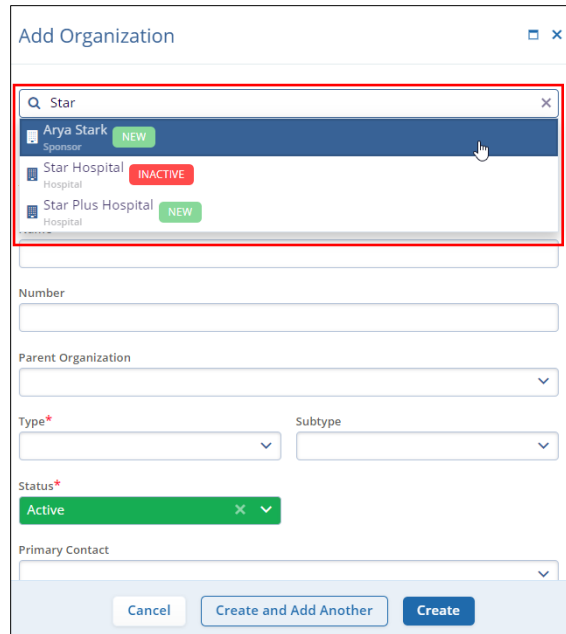
- This opens the "Organization" window, displaying organizations associated with the study.



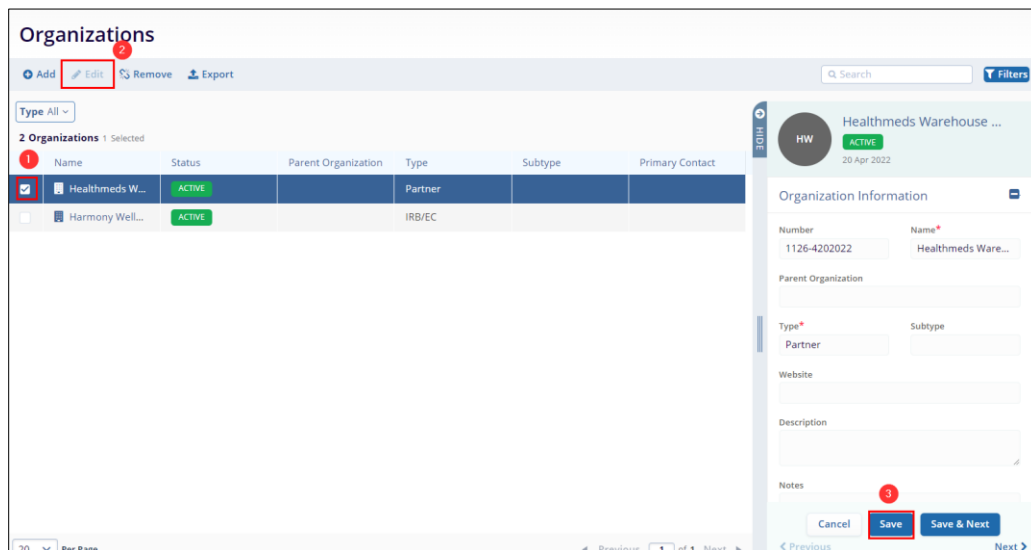
- Click the "Add" button at the top-left of the screen.



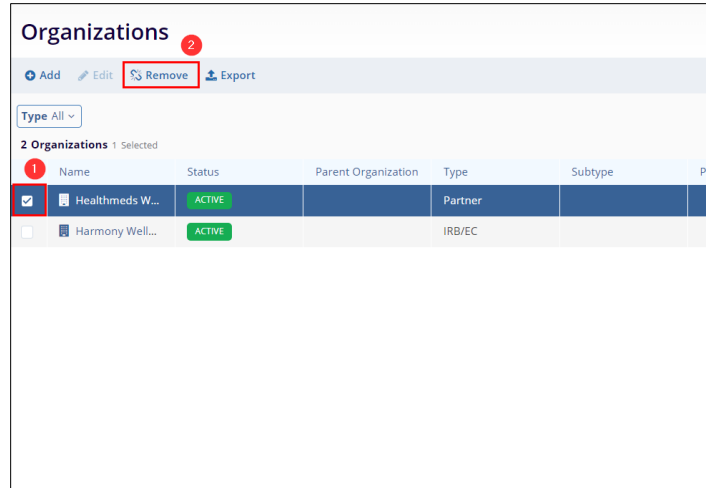
- It will open the Create organization window. To learn How to create organization [click here](#).
- If the organization has already been created, use the search area to locate and select the organization.



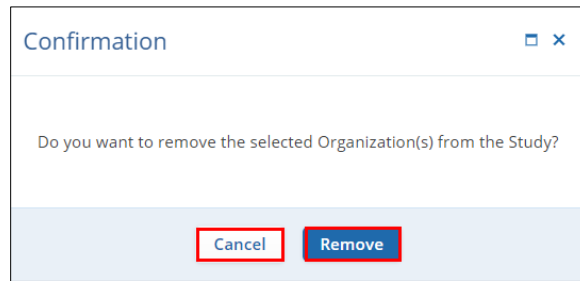
8. Click "Create" or "Create and Add Another" depending on whether the user needs to associate another organization with this study.
6. To edit an organization, select the organization and click the "Edit" button from the top menu. A quick view panel is displayed on the right side of the screen. Make any necessary changes in the quick view panel. Click "Save" at the bottom of the quick view panel. Refer to the screenshot below.



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



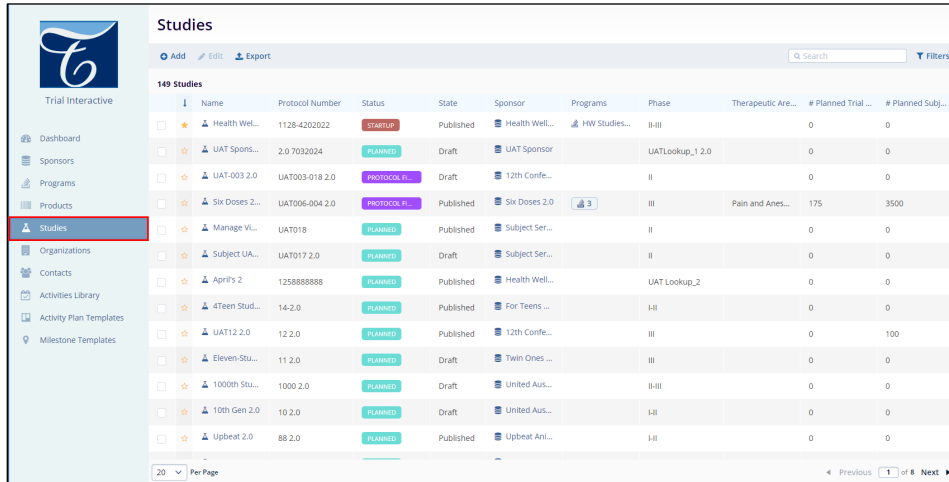
10. The user will receive the confirmation pop-up, To proceed further click on the 'Remove' button or click on 'Cancel' to discard it.



11. To learn how to export the organization, [click here](#).

Study Contacts

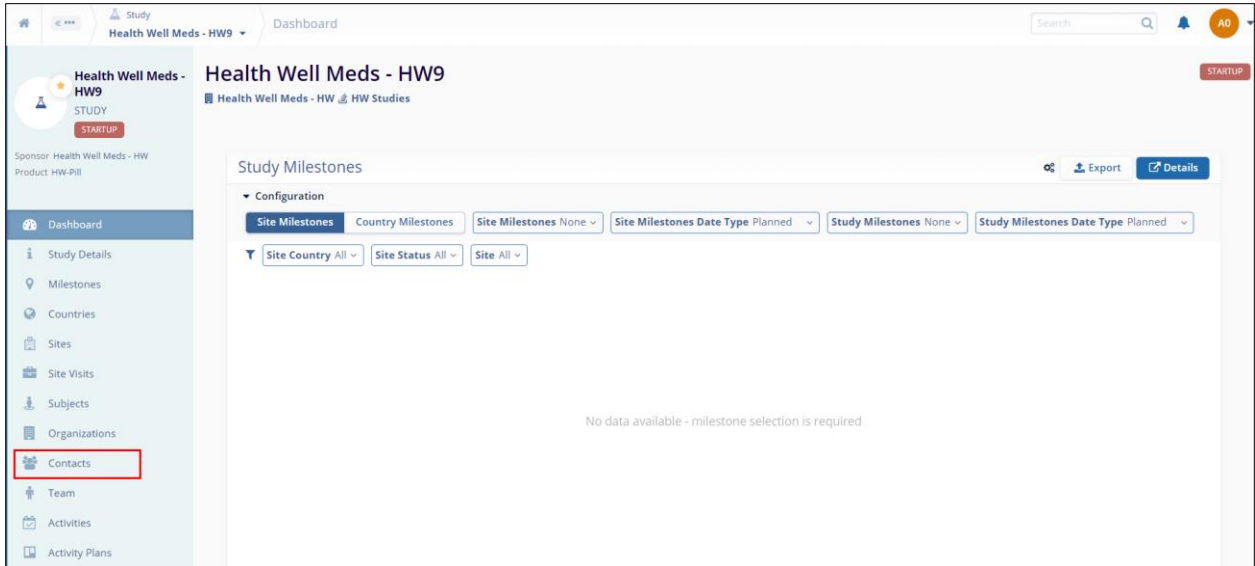
1. Click on the "Studies" link in the navigation menu on the left side of the screen. This opens the "Studies" window and displays the study list.



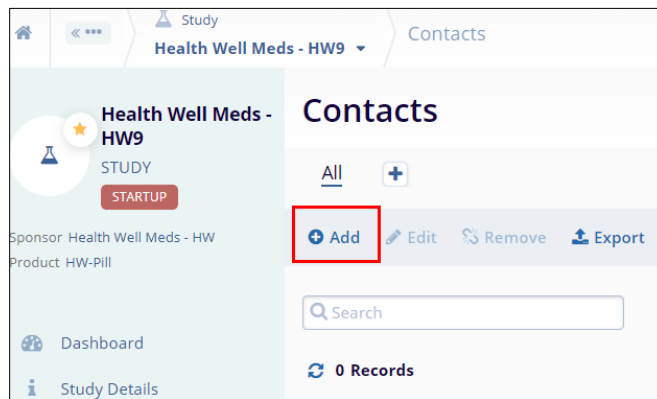
2. Click on the name of the study to which you want to associate contacts. The dashboard for the study will be displayed.



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



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



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

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

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

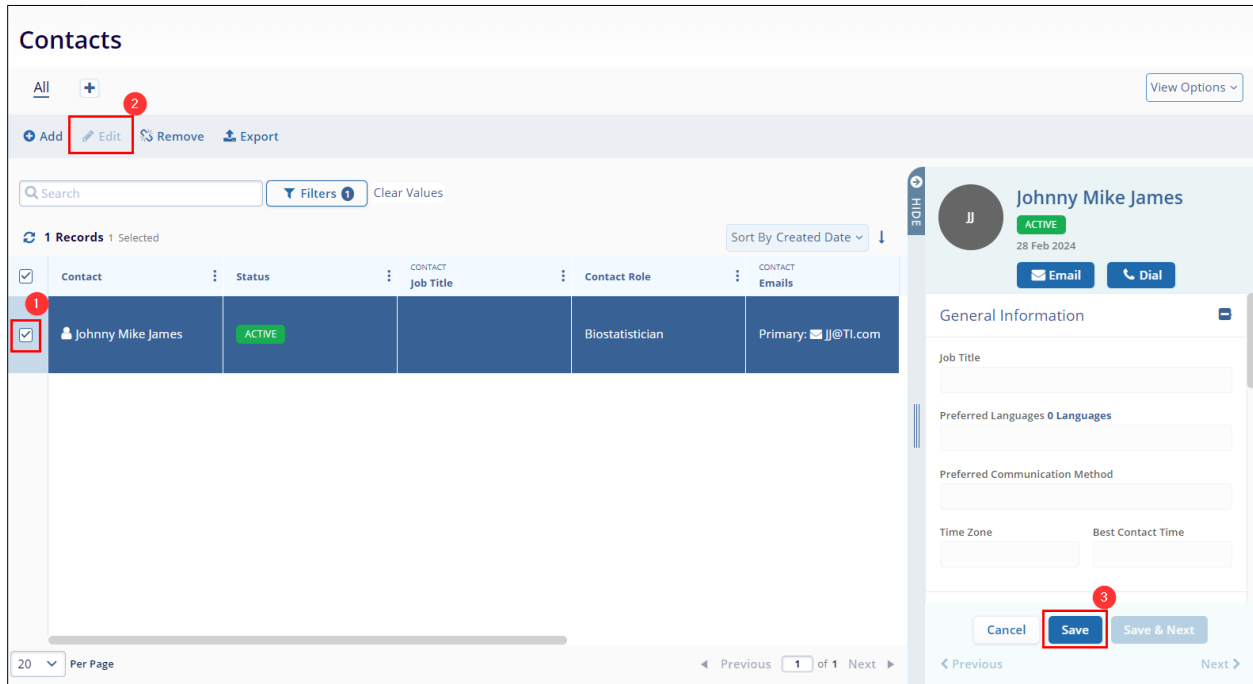
7. To learn how to create a contact, [click here](#).

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

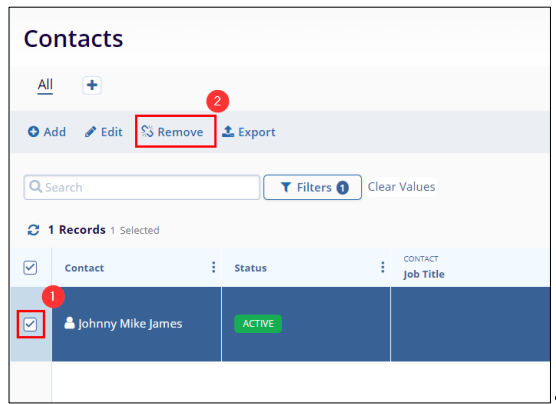
8. Before clicking "Create," verify that all fields are entered correctly in the "Create Contact in the Study" window.
9. Click "Create" or "Create and Add Another" depending on whether you intend to create another contact immediately.

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

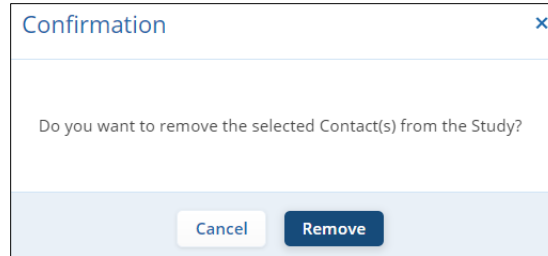
10. When editing a contact record from the list, only data that is contextual to the study can be updated.
11. To edit a contact, select the contact and click the “Edit” button from the top menu. A quick view panel is displayed on the right side of the screen. Make any necessary changes in the quick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



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



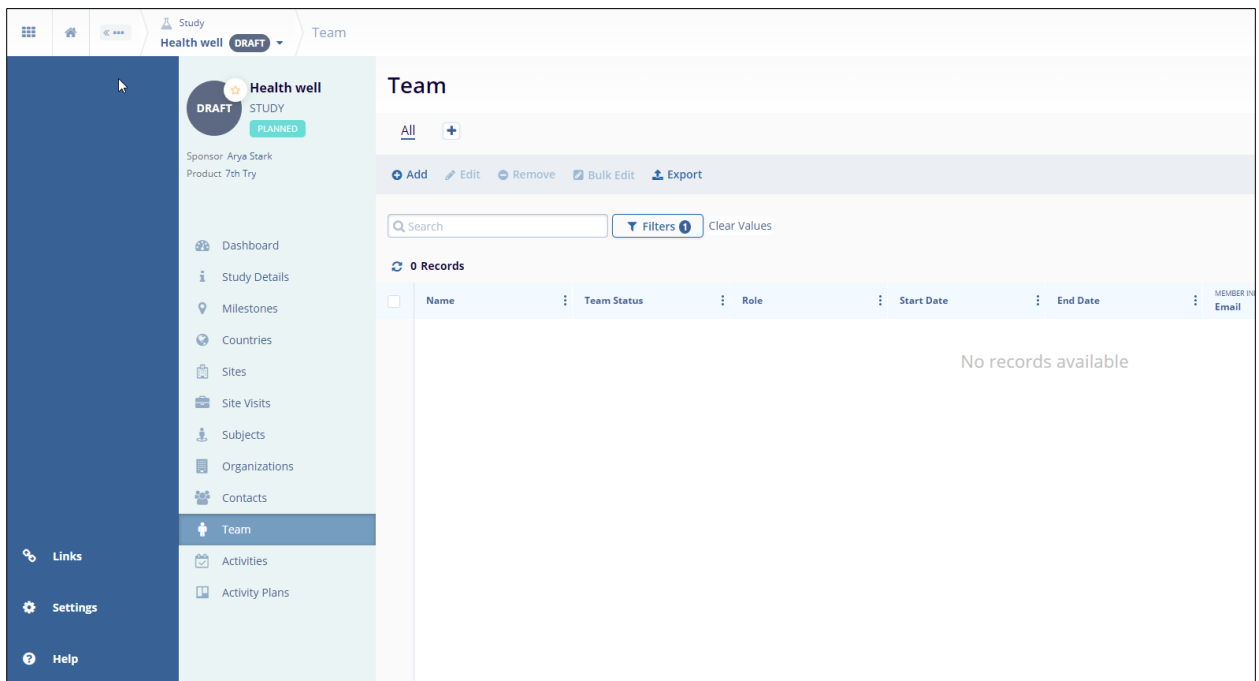
13. The user will receive the confirmation pop-up, To proceed further click on the ‘Remove’ button or click on ‘Cancel’ to discard it.



14. To learn how to export the organization, [click here](#).

Study Team vs Access Permissions

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

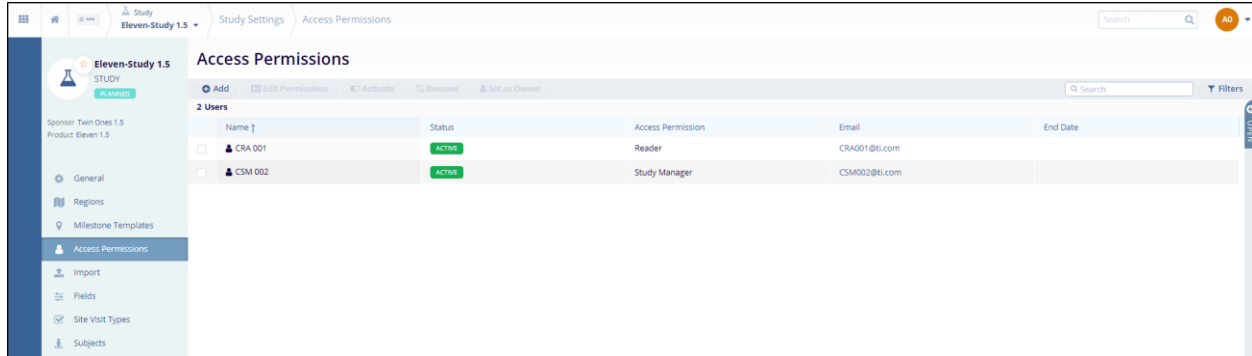


Some important points to note about managing study team members are:

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

Managing Study Access Permissions

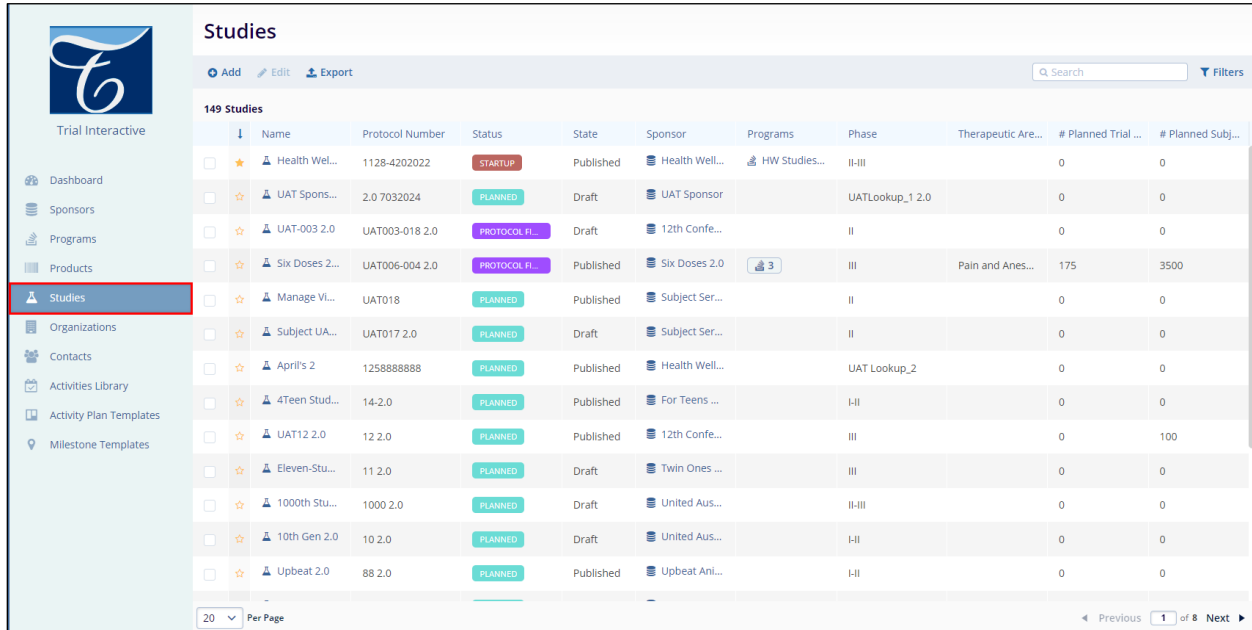
Users will see an 'Access Permissions' button at the top-right of the Study Team area. Clicking on that button will take you to the Site or Study Settings area as appropriate and the Access Permissions menu. Users can also navigate directly thereby accessing the settings area directly.



Entering Study Settings

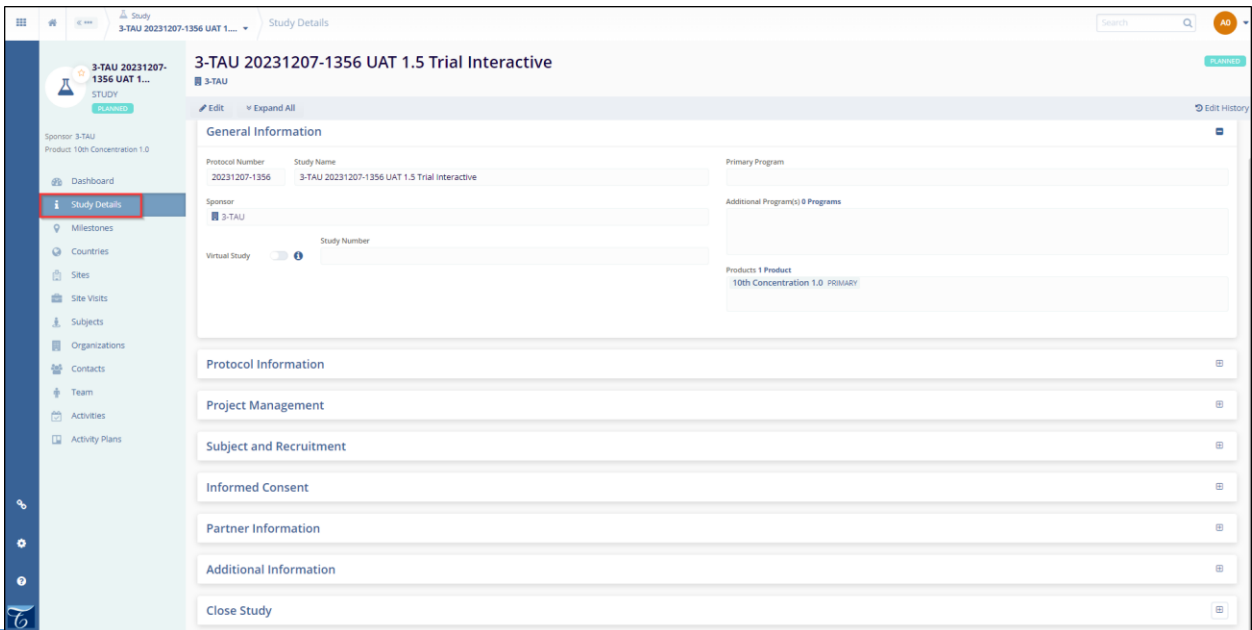
Navigate to Studies.

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

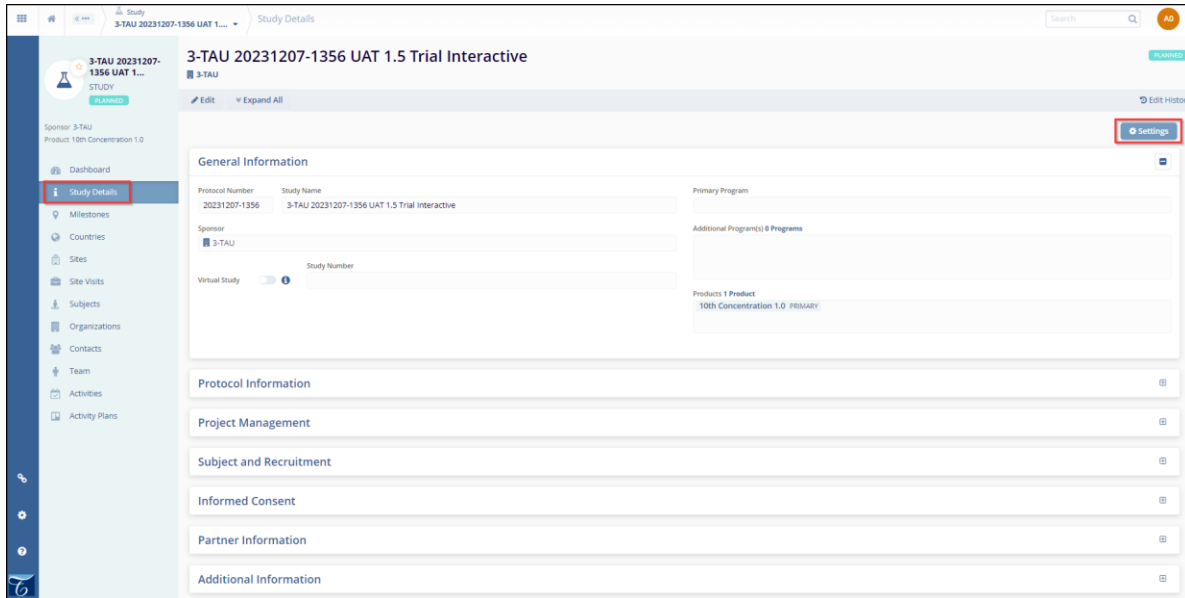


Steps to Manage Study Settings

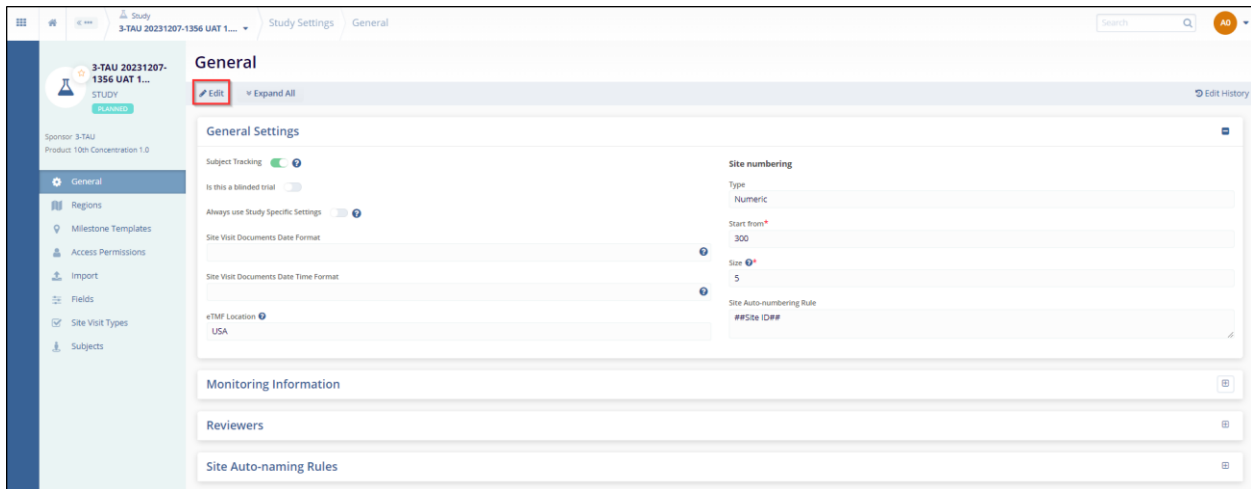
1. Click on the name of the study in the list.
 - a. The dashboard for the study is displayed.
2. Click on the **Study Details** in the Navigation menu at the left side of the screen.
 - a. The “Study Details” window is displayed.



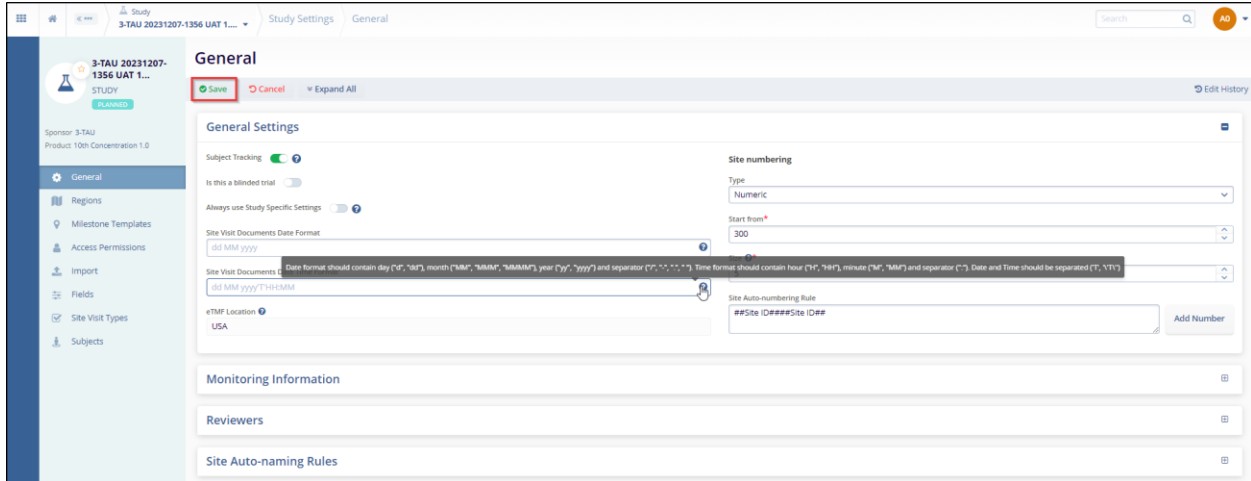
3. Click **Settings** in the top-right corner of the **study details** window. This opens the **Study Settings General** window.



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



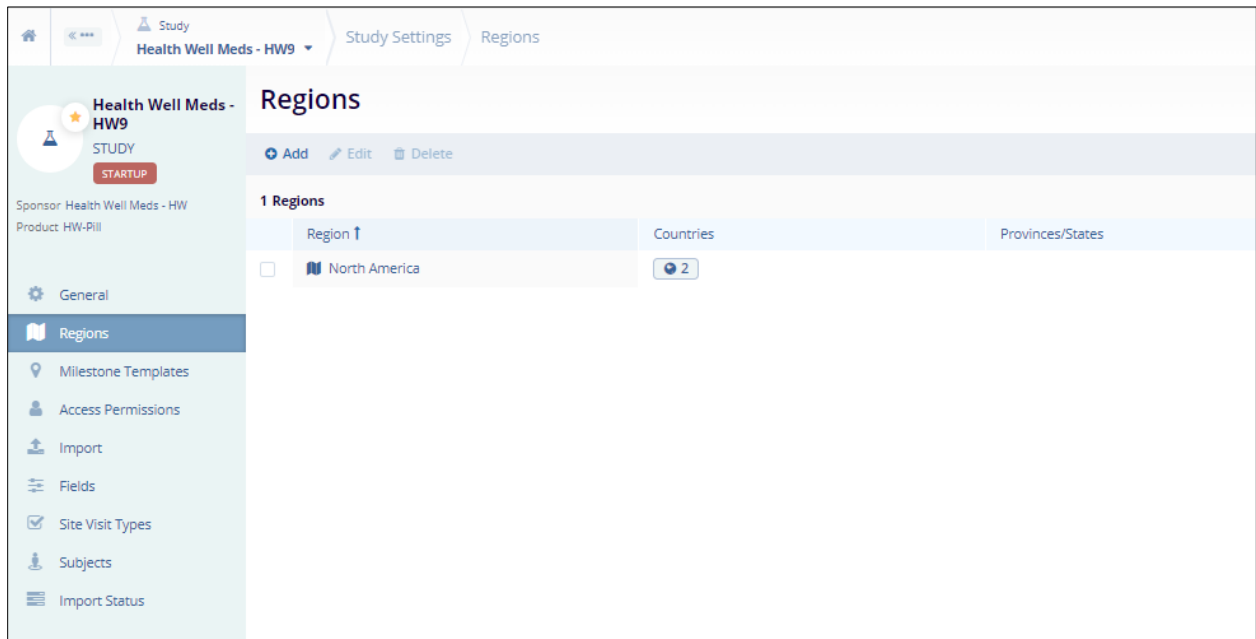
5. Make any necessary changes in the **Study Settings General** window.
6. Click on **Save** at the top-left of the window.



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

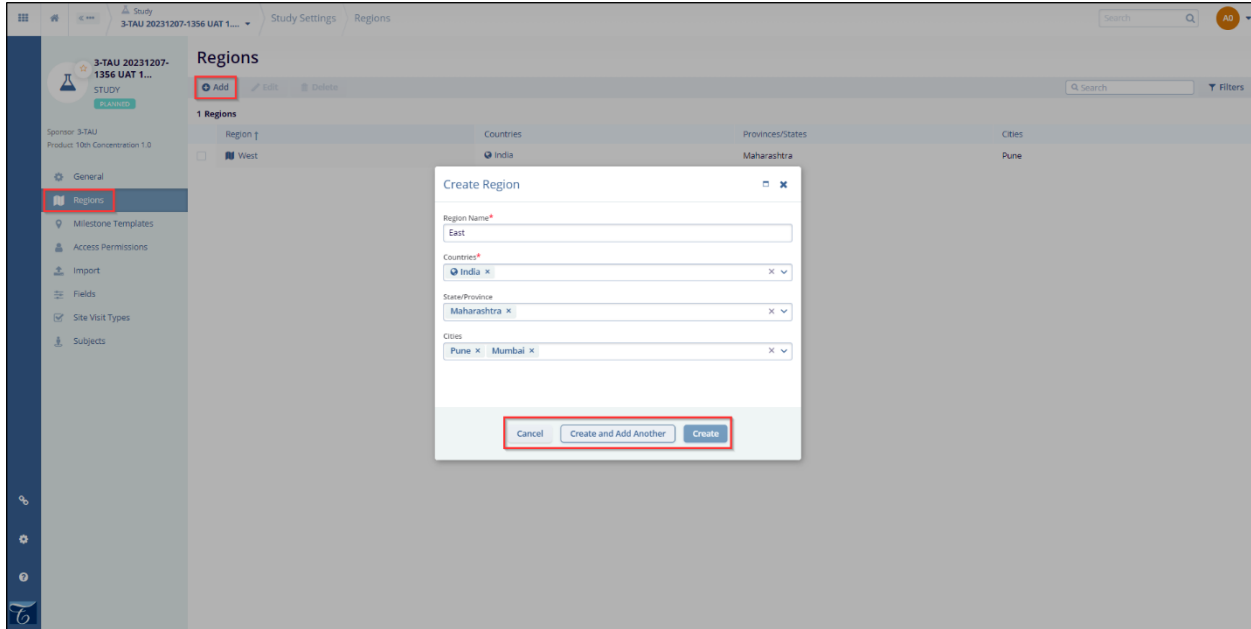
Defining Study-Specific Regions

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



3. Click on the **Add** button at the top-left of the screen. This opens the “Create Region” Window.
4. Here we need to enter the mandatory metadata to create a Region i.e., **Region Name**, **Countries** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.

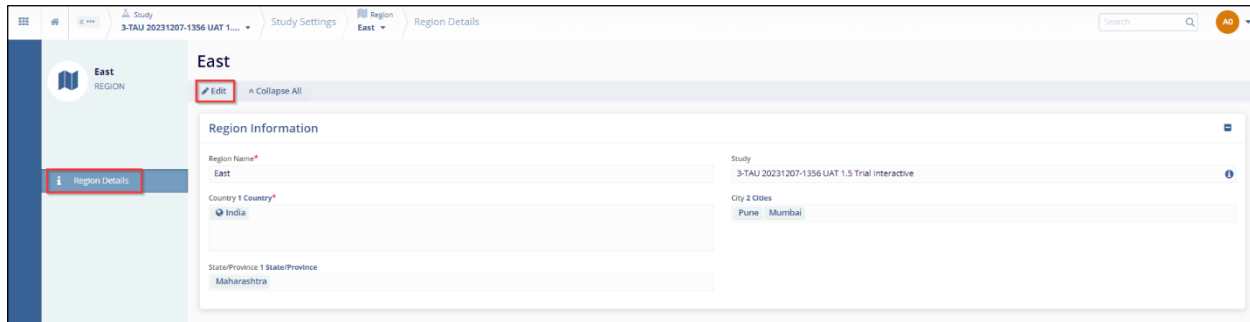
5. Click **Create** or **Create and Add Another** depending on whether you intend to create another Region right away.



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

Editing Study Regions

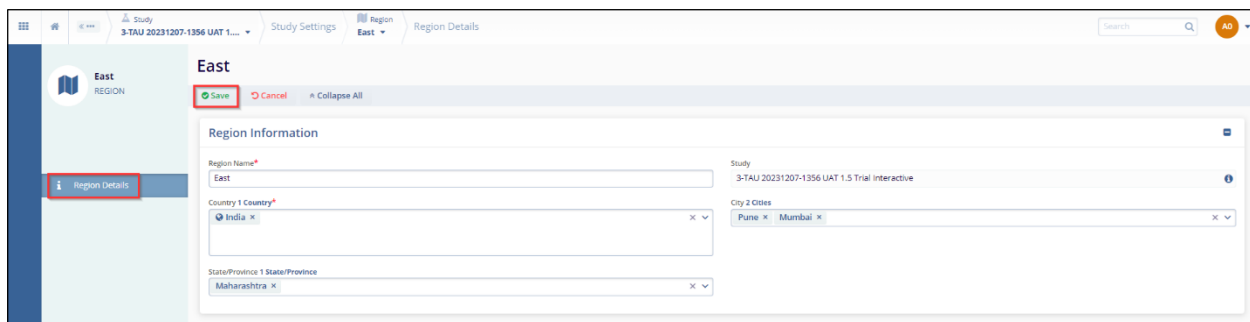
1. Navigate to the Regions area for the study you wish to edit.
 - a. The necessary steps are found [here](#).
2. Click on the region name from the list you want to Edit.
 - a. This opens the “Region Details” window.
3. Click on the **Edit** button in the top-left corner.



The screenshot shows the 'Region Details' window for the 'East' region. The 'Edit' button is highlighted with a red box. The form contains the following fields:

- Region Name:** East
- Country 1:** India
- State/Province:** Maharashtra
- City 2:** Pune, Mumbai

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



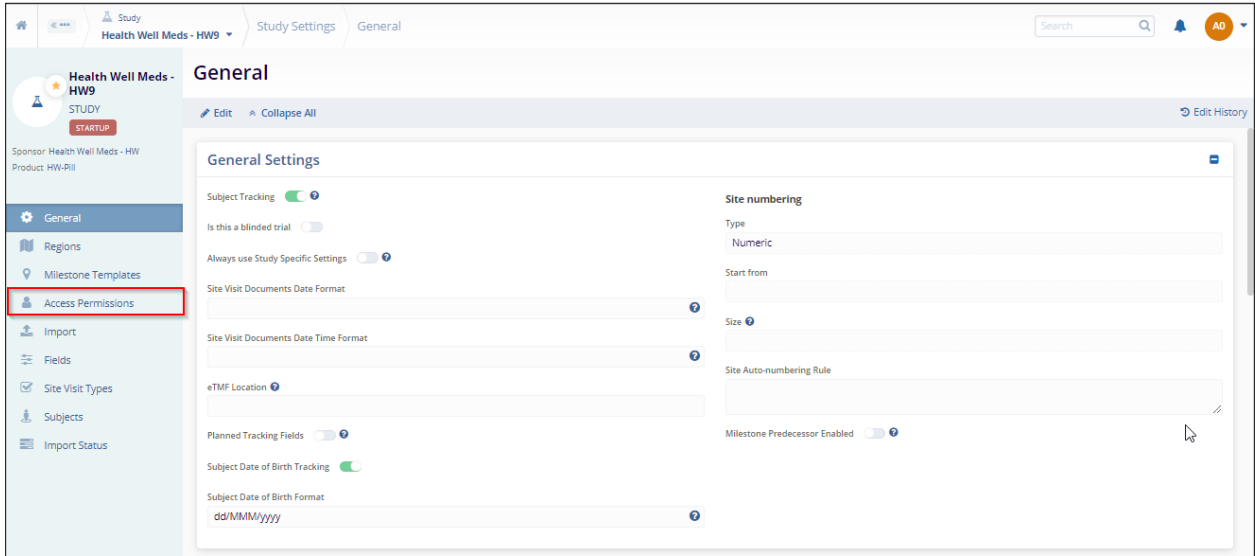
The screenshot shows the 'Region Details' window for the 'East' region. The 'Save' button is highlighted with a red box. The form contains the following fields:

- Region Name:** East
- Country 1:** India
- State/Province:** Maharashtra
- City 2:** Pune, Mumbai

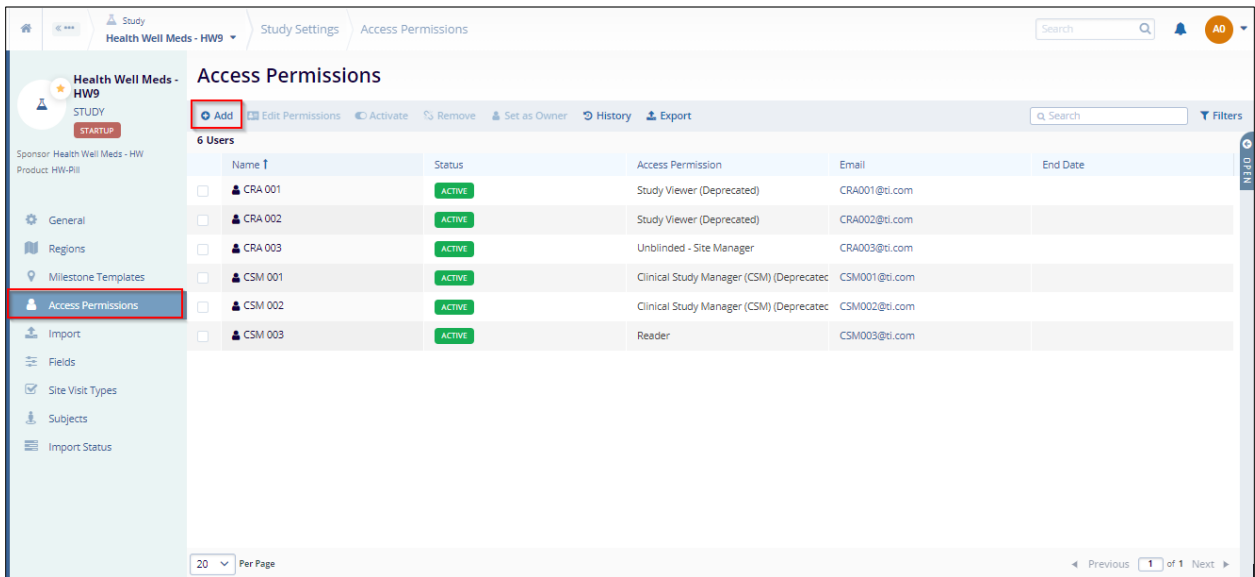
Access Permission in Study Settings

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

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



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



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

Add User Study Access Permission

List of Invited Users

Users 0 Users*

Pending

Set permissions

Simple Advanced

Access Permission* None End Date

Cancel Add

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

Success
The Record is successfully created

Access Permissions

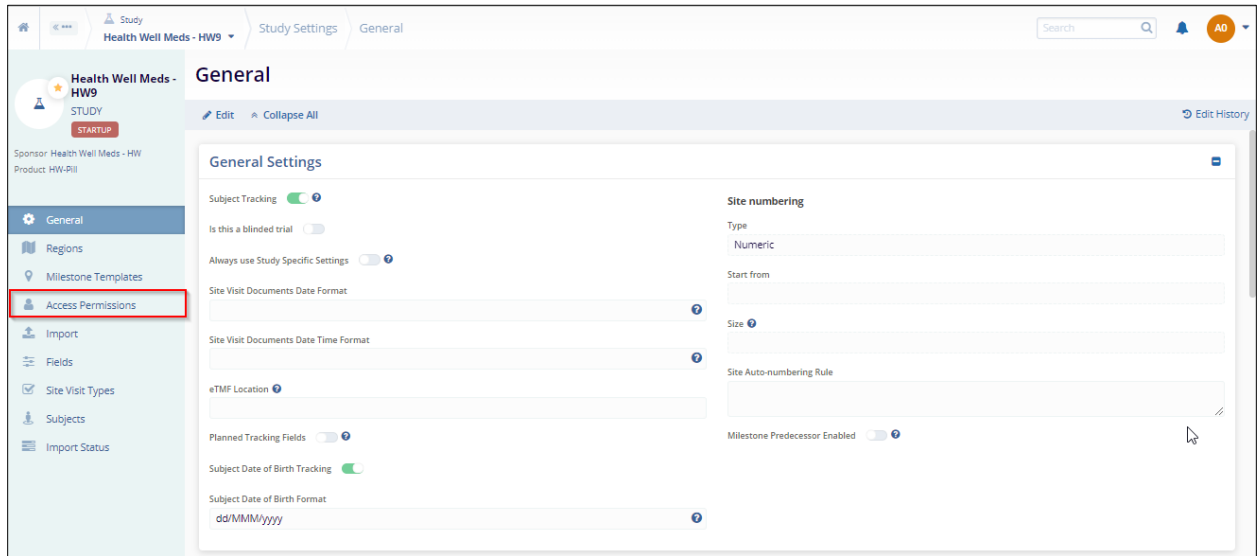
7 Users

Name	Status	Access Permission	Email	End Date
Admin 001	ACTIVE	Country Manager	ADMIN001@ti.com	27 Jul 2024, 12:00 AM
CRA 001	ACTIVE	Study Viewer (Deprecated)	CRA001@ti.com	
CRA 002	ACTIVE	Study Viewer (Deprecated)	CRA002@ti.com	
CRA 003	ACTIVE	Unblinded - Site Manager	CRA003@ti.com	
CSM 001	ACTIVE	Clinical Study Manager (CSM) (Deprecated)	CSM001@ti.com	
CSM 002	ACTIVE	Clinical Study Manager (CSM) (Deprecated)	CSM002@ti.com	
CSM 003	ACTIVE	Reader	CSM003@ti.com	

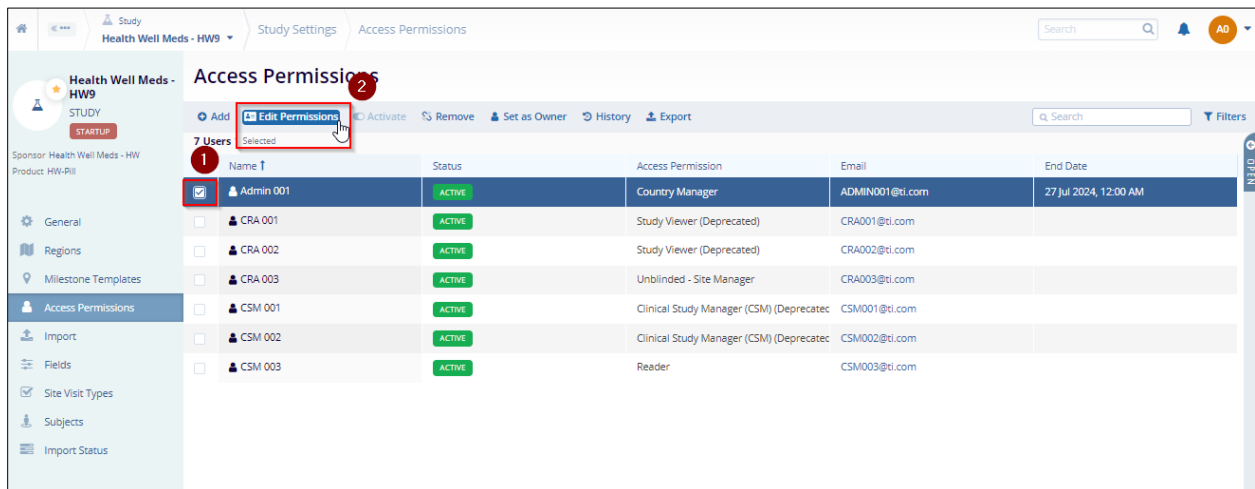
Steps to Edit a User Permission

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

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



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



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

Edit Study Permissions

Admin 001
ADMIN001@ti.com

Set permissions

Simple Advanced

Access Permission* Country Manager x ⓘ v End Date 27 Jul 2024 x 📅

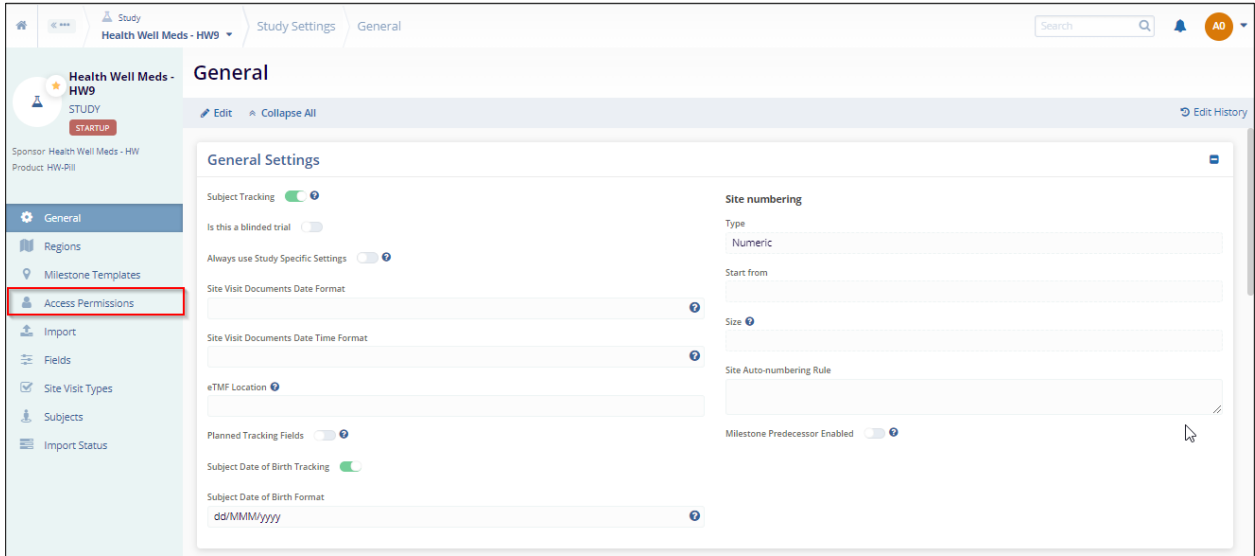
Cancel Save

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

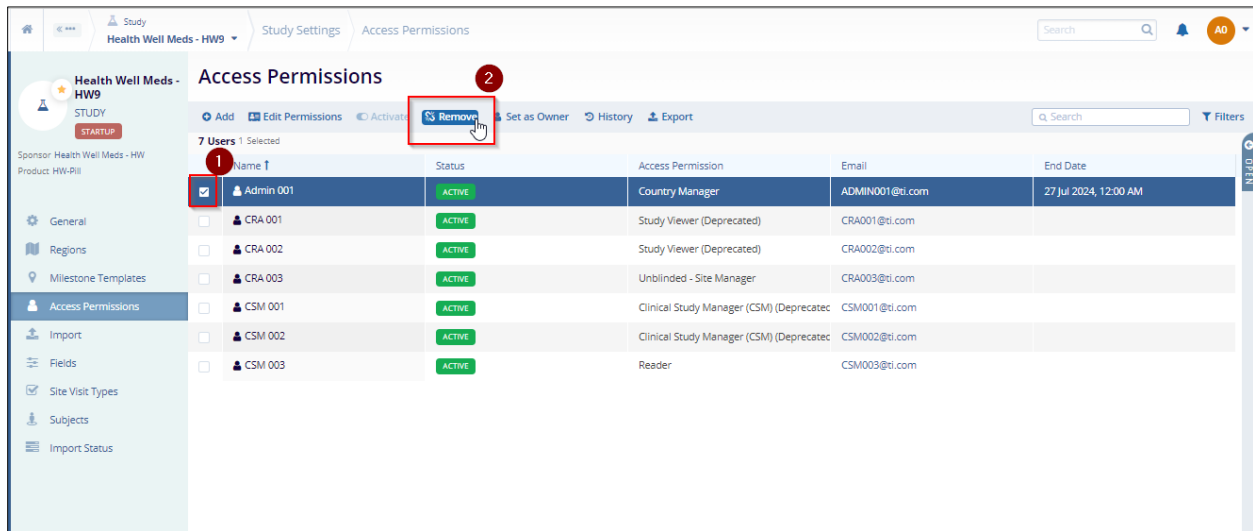
Remove user permission

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

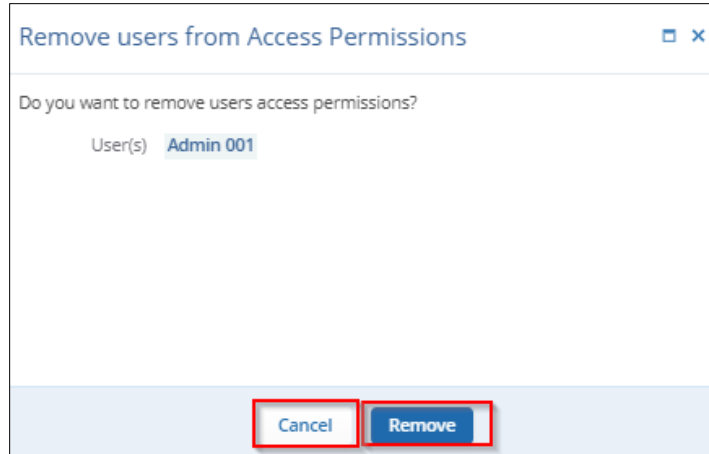
1. Once the user is on the **Study Setting** screen, Click on the **Access Permission** tab from the navigation pane.



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



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

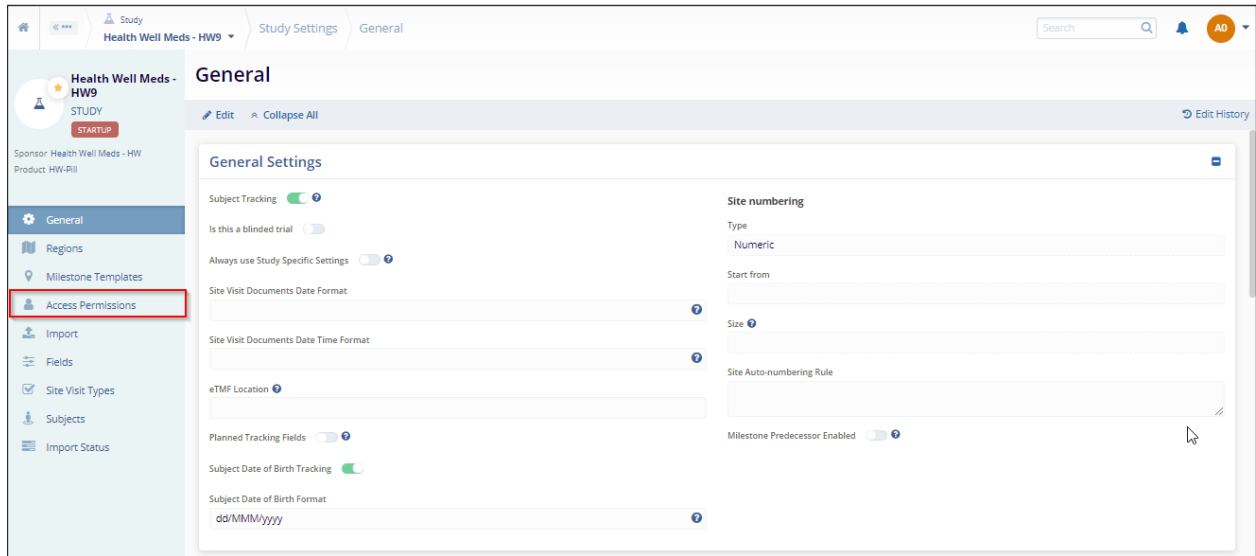


4. After clicking the Remove button, the user will receive a successful removal pop-up and will disappear from the grid.

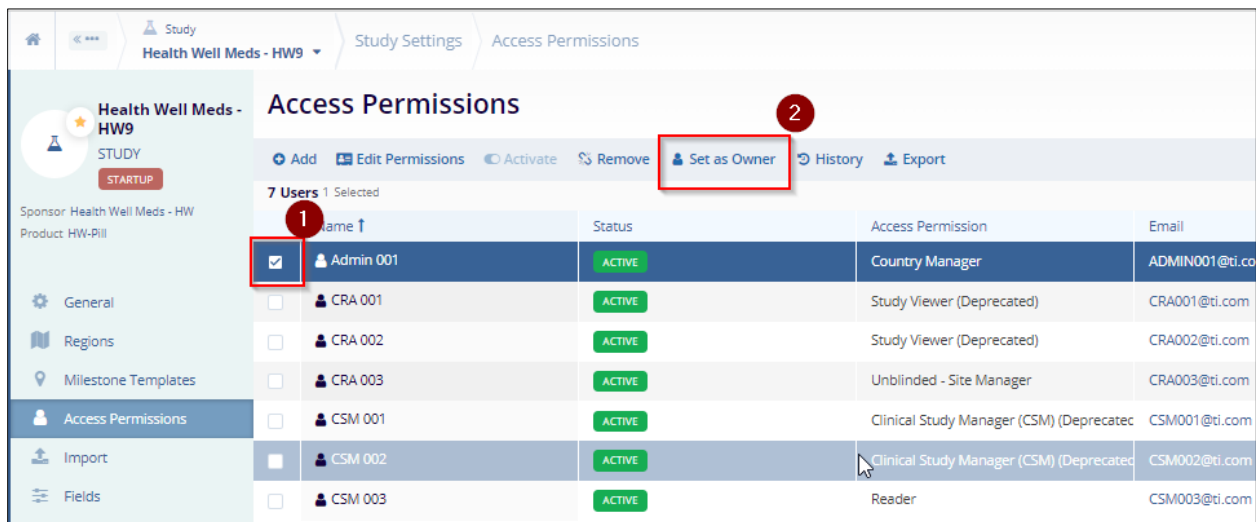
Set as Owner in Access Permission

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

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



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



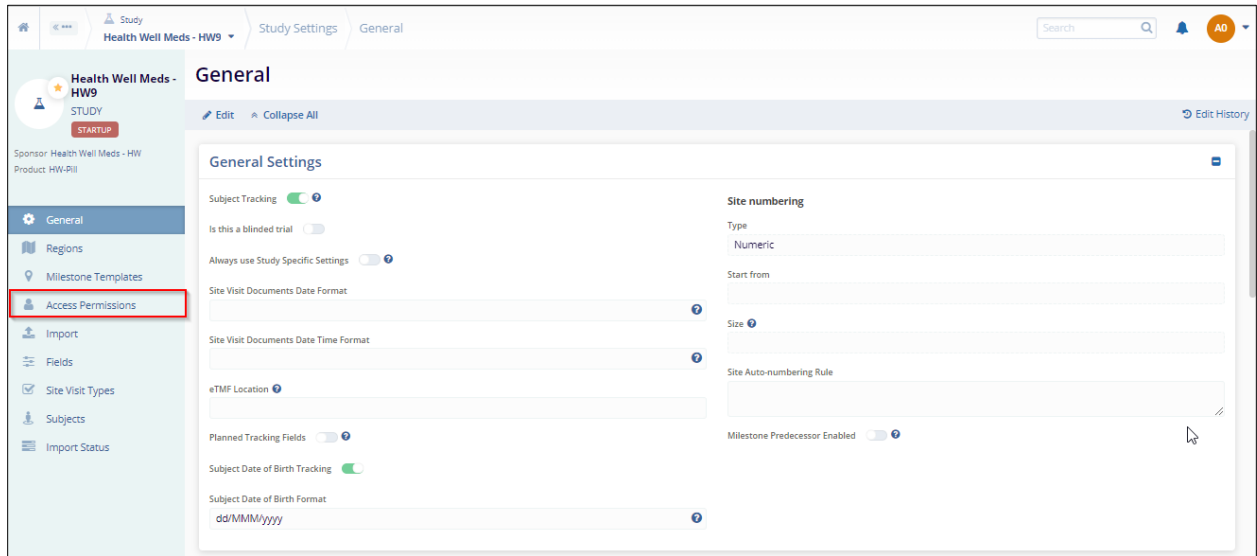
3. The user will receive a pop-up with who the current owner is and who will be the new owner. To add the new owner click on the **Confirm** button.

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

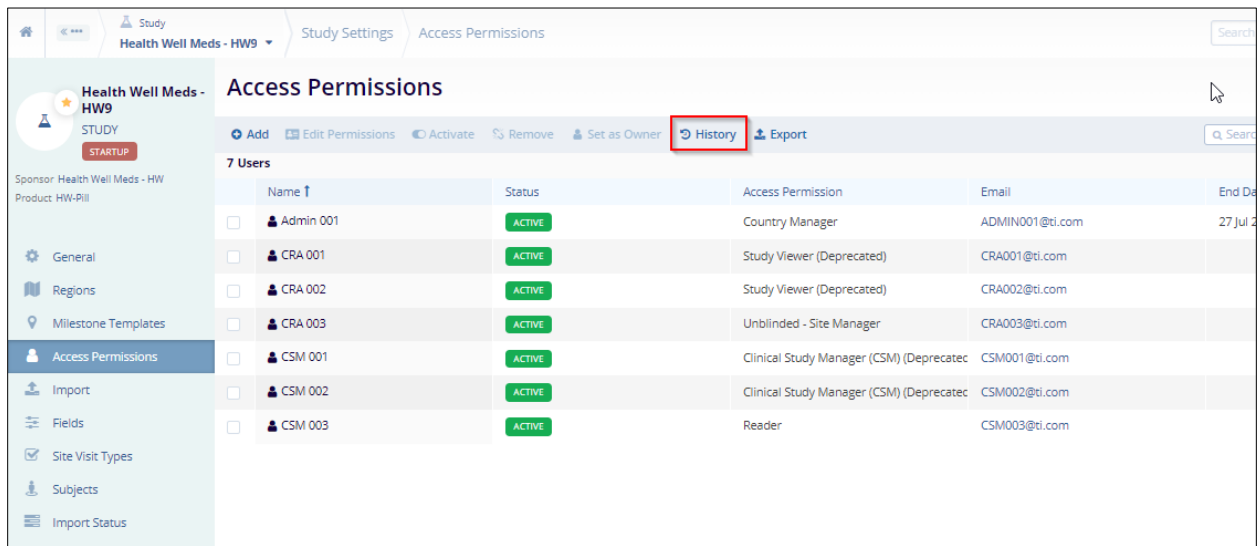
History of Access Permission

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

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



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



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

Access Permissions History **Health Well Meds - HW9**

Export Filters

7 Records

Date ↓	User Name	Event	Access Permission	End Date	Performed By
> 26 Jul 2024, 12:07 PM	Admin 001	ADD MEMBER	Country Manager	27 Jul 2024, 12:00 AM	admin002@ti.com
> 11 Aug 2023, 09:32 PM	CSM 003	UPDATE	Reader		csm001@ti.com
> 16 May 2022, 09:10 PM	CRA 002	ADD MEMBER	Study Viewer		Admin001@ti.com
> 16 May 2022, 09:10 PM	CRA 001	ADD MEMBER	Study Viewer		Admin001@ti.com
> 16 May 2022, 09:10 PM	CRA 003	ADD MEMBER	Study Viewer		Admin001@ti.com
> 16 May 2022, 09:09 PM	CSM 002	ADD MEMBER	Clinical Study Manager (CSM)		Admin001@ti.com
> 16 May 2022, 09:09 PM	CSM 003	ADD MEMBER	Clinical Study Manager (CSM)		Admin001@ti.com

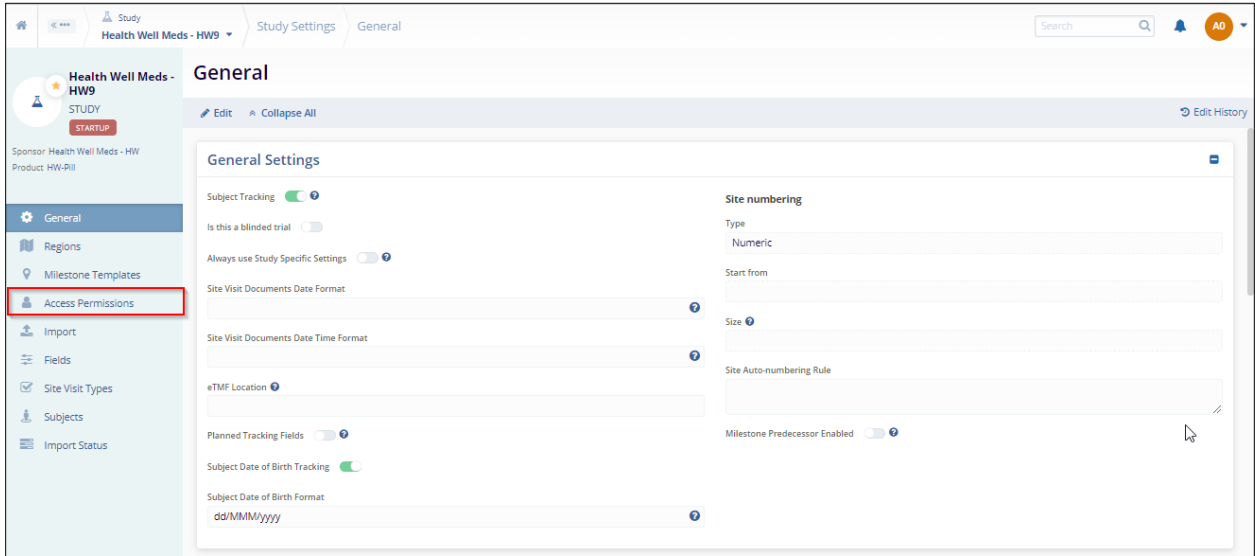
20 Per Page Previous 1 of 1 Next

Cancel

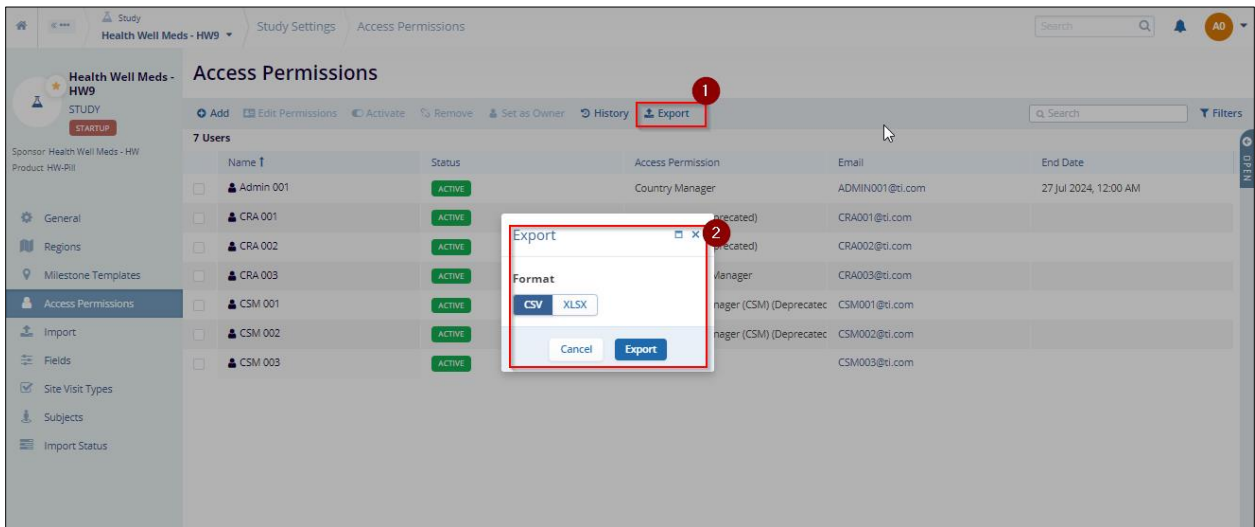
Access Permission Export

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

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

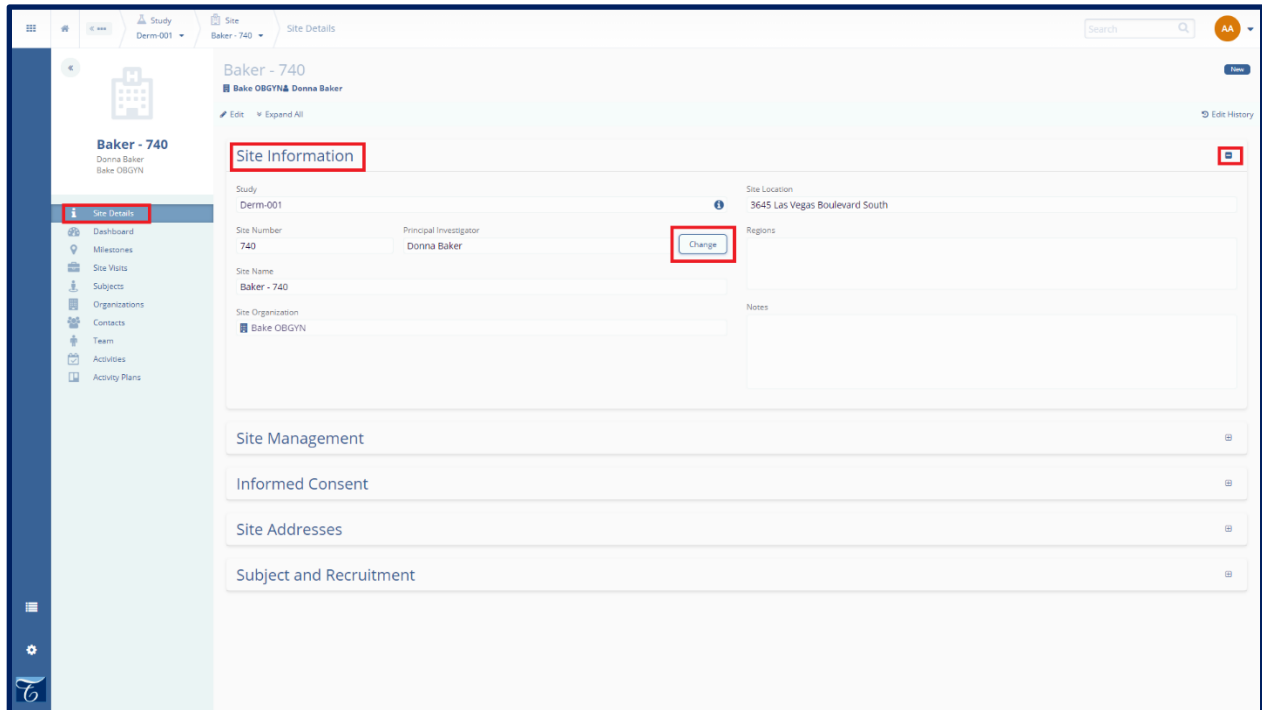


2. It will open the access permission screen. Users can export the data. Click on the export button. Refer to the screenshot below.



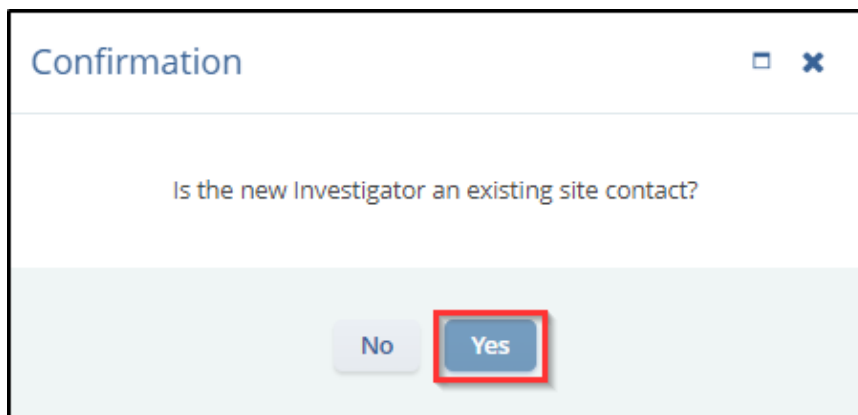
Change of Principal Investigator (PI)

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

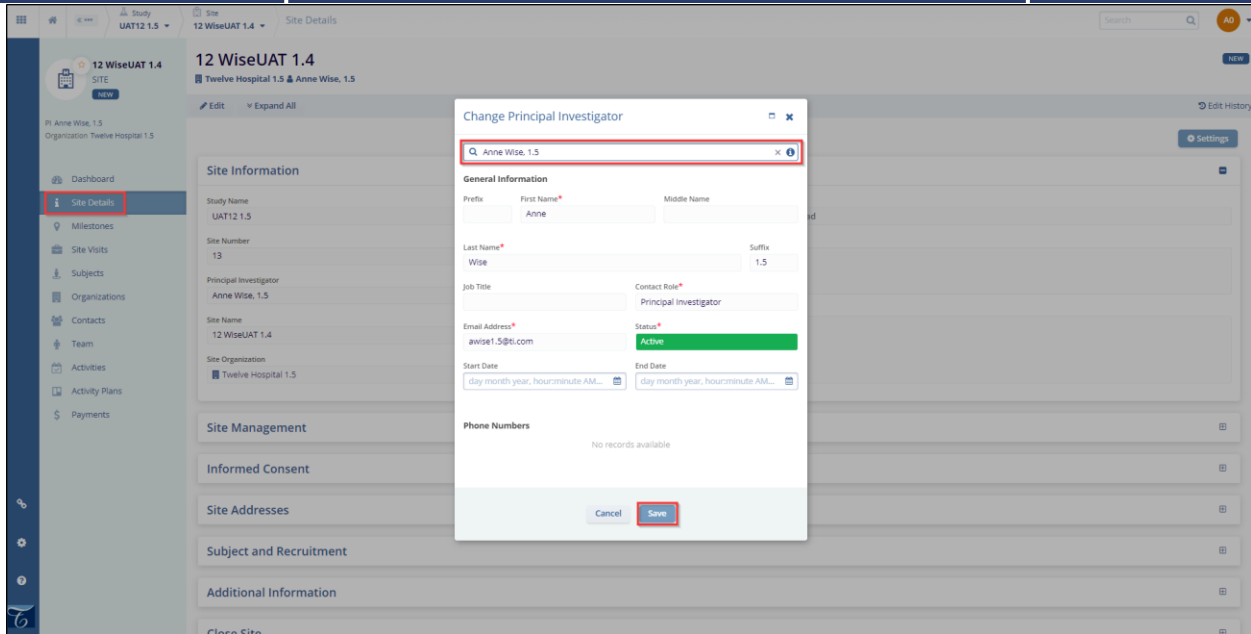


6. A confirmation window is popped up, select **Yes** in the confirmation window.
 - a. This opens the “Change Principal Investigator” window.

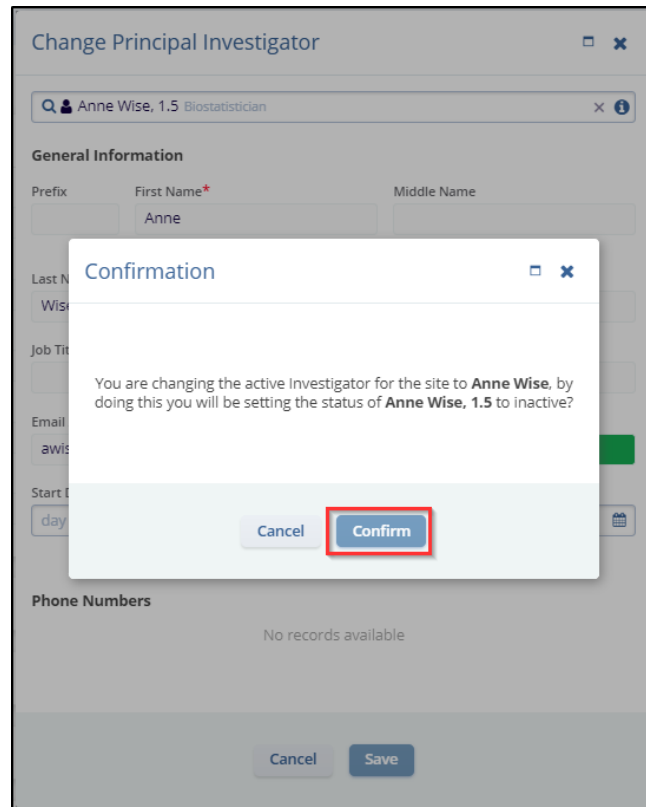
Note: Use the search box to find the contact.



7. Click on the **Save** button.

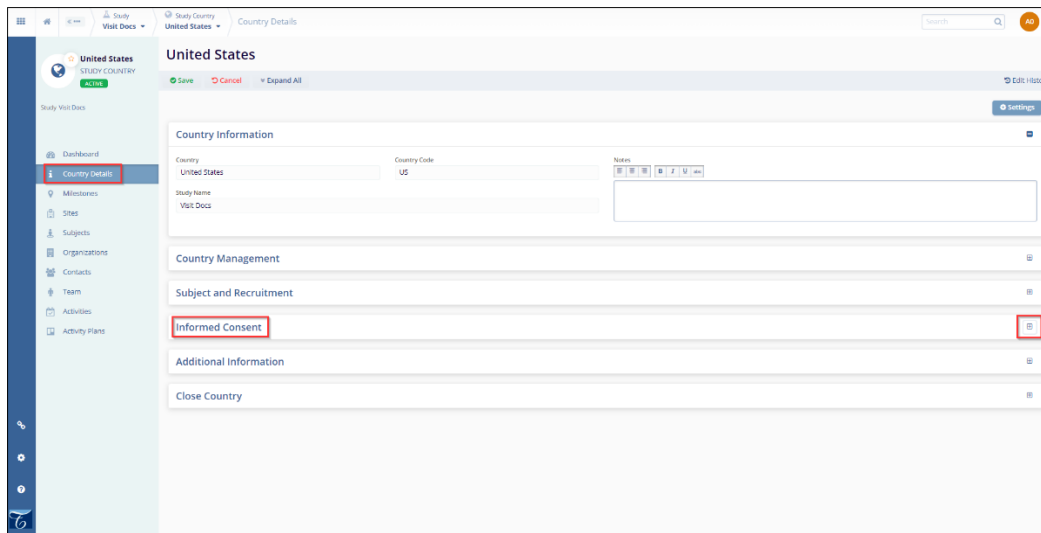


8. Click **Confirm** in the Confirmation popup window to save the changes.

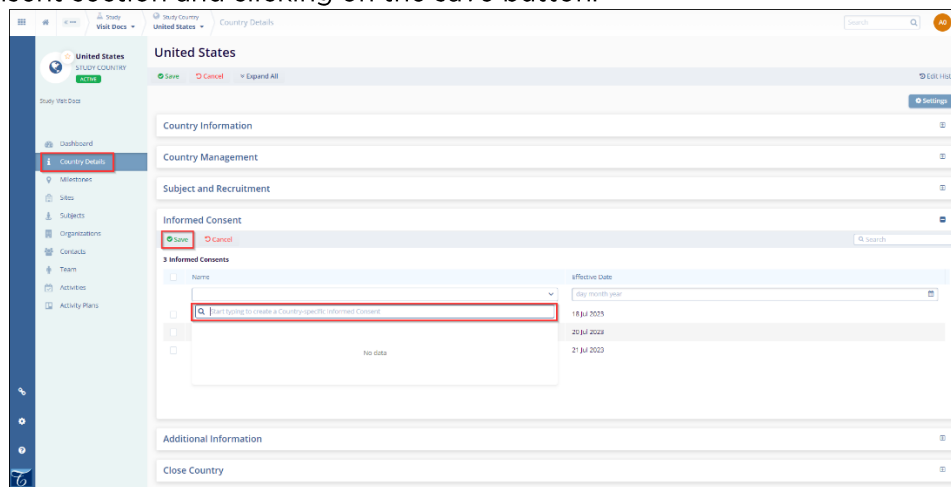


Tracking Country Informed Consents (ICFs)

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

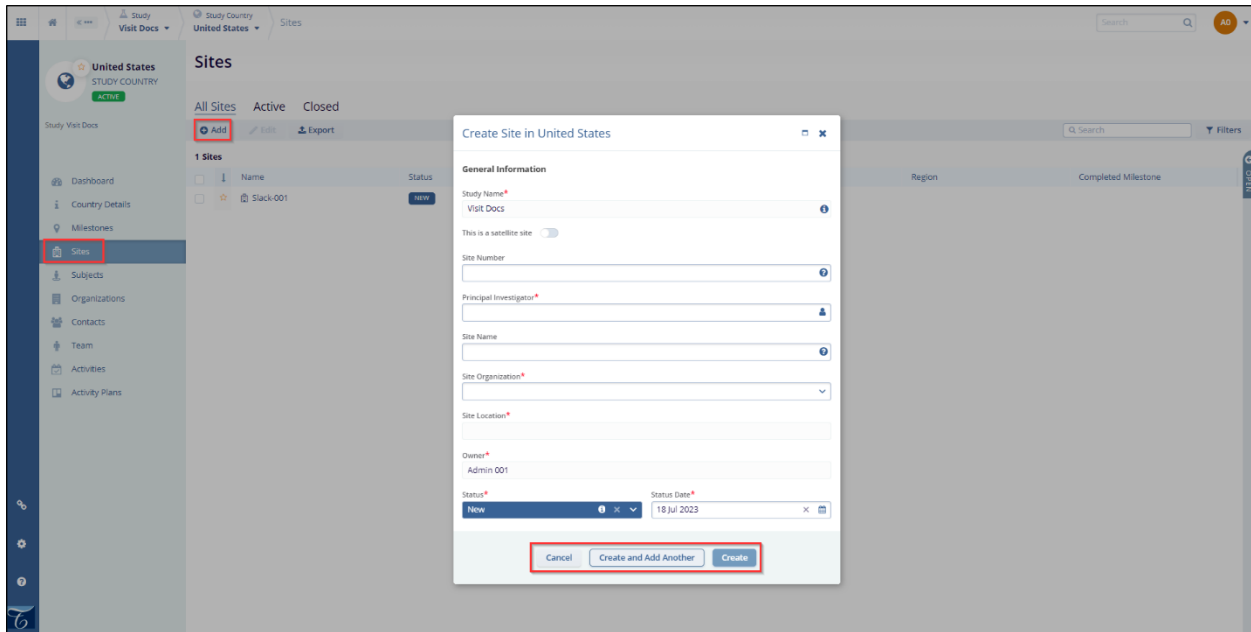


7. Select the study ICF from the list and click on the **Save** button in the informed consent section.
8. You can add country-level ICF by adding the name and effective date in the informed consent section and clicking on the save button.



Creating a Site within a Country

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



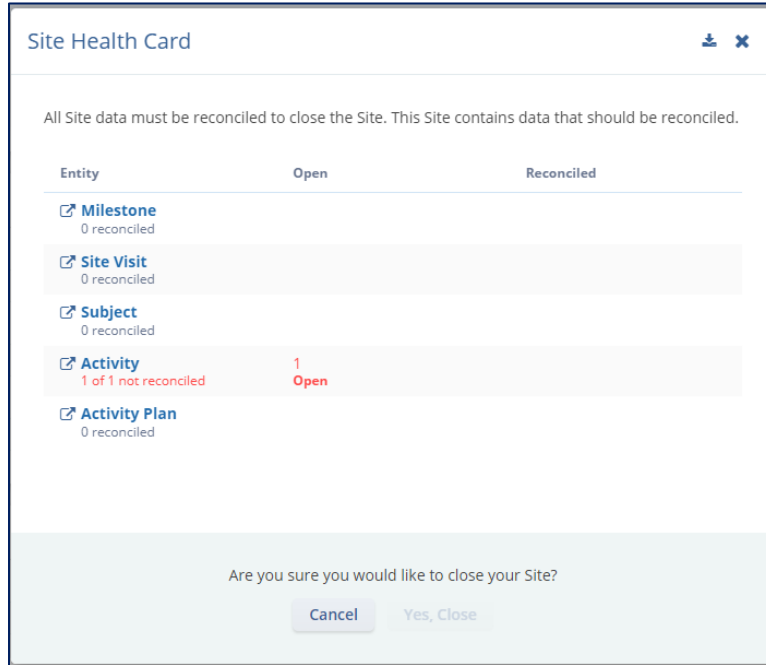
Integrated Payments View

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

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

1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
2. Navigate to the study you want to access.
3. Click on **Sites** in the Navigation menu at the left side of the screen.
 - a. This opens the “Study Site” window and study site list is displayed.
4. Click on the name of the site you want to view the payments.
 - a. This opens the dashboard window for the site.
5. Click the **Payments** link displayed in the left side of the screen.
 - a. This opens the Payments window in the center of the screen.
6. The user can apply filters to view the required payments for ‘Awaiting QC’ and ‘New Request’.
7. The user can also search for a payment ‘Payee Name’ and ‘Invoice Number’. Refer to the screenshot below.

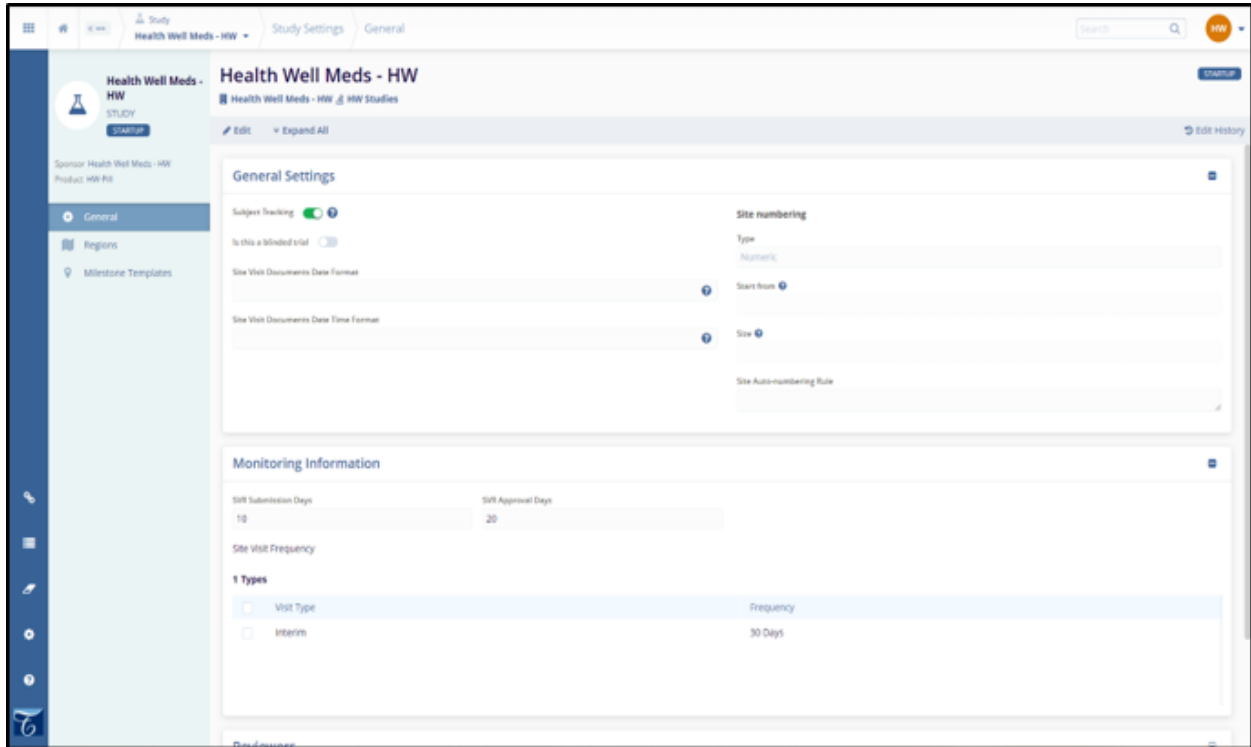
Payment Status	Payee Name	Invoice Number	Payee ID	Payment Method	Payment Type	Payment ID	Payment Amount	Payment Currency	Payment Status	Payment Status D...	Invoice Number	Invoice Date
Awaiting QC			Armand Thomas	electronic deposit	Visit		9,056.70	USD	Awaiting QC	2022-07-11	951	2023-01-18
New Request			Lobortis Class Inc.	electronic deposit	Visit		4,568.50	USD	Awaiting QC	2023-10-04	51	2022-12-12
			Hannah Middle...	electronic deposit	Invoiceable		7,516.30	USD	New Request	2023-07-14	139	2022-11-16
			Elementum Inc.	electronic deposit	Invoiceable		7,215.40	USD	New Request	2024-02-05	162	2023-05-17
			Xenos Cunningh...	electronic deposit	Visit		7,037.90	USD	Awaiting QC	2022-04-24	507	2023-08-15
			Ledger Run, Inc.	electronic deposit	Visit		1,788.30	USD	Awaiting QC	2022-04-08	949	2023-07-28
			Ezra Velez	electronic deposit	Invoiceable		8,171.10	USD	New Request	2023-11-05	458	2022-05-16
			Radiology Assoc...	electronic deposit	Invoiceable		4,762.70	USD	New Request	2022-09-18	300	2023-04-16
			Jamalia Brooks	electronic deposit	Visit		6,042.90	USD	Awaiting QC	2023-05-19	185	2022-05-03
			Nullam Ut LLP	electronic deposit	Visit	E3BA	9,993.20	USD	Awaiting QC	2022-12-31	871	2022-07-18
			Robert Beard	electronic deposit	Invoiceable	50715347	378.50	USD	New Request	2023-01-21	210	2023-02-09
			Quis Accumsan ...	electronic deposit	Invoiceable		9,232.40	USD	New Request	2023-02-10	874	2023-01-08
			Burke Mccray	electronic deposit	Visit		1,806.60	USD	Awaiting QC	2022-10-20	842	2023-10-11
			Quisque Ornare...	electronic deposit	Visit		3,015.80	USD	Awaiting QC	2023-07-11	395	2023-01-19
			Stacey James	electronic deposit	Invoiceable		2,567.00	USD	New Request	2023-04-04	706	2023-01-30
			Sit Amet Limited	electronic deposit	Invoiceable		9,692.30	USD	New Request	2023-03-10	915	2022-10-27
			Kimberly Shaw	electronic deposit	Visit		324.20	USD	Awaiting QC	2023-12-29	265	2023-02-07
			Pharetra Nam A...	electronic deposit	Visit		2,555.60	USD	Awaiting QC	2024-02-17	380	2023-11-26
			Medgia Farmer	electronic deposit	Invoiceable		2,174.80	USD	New Request	2022-08-27	518	2022-03-10
		



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

Study Specific Settings

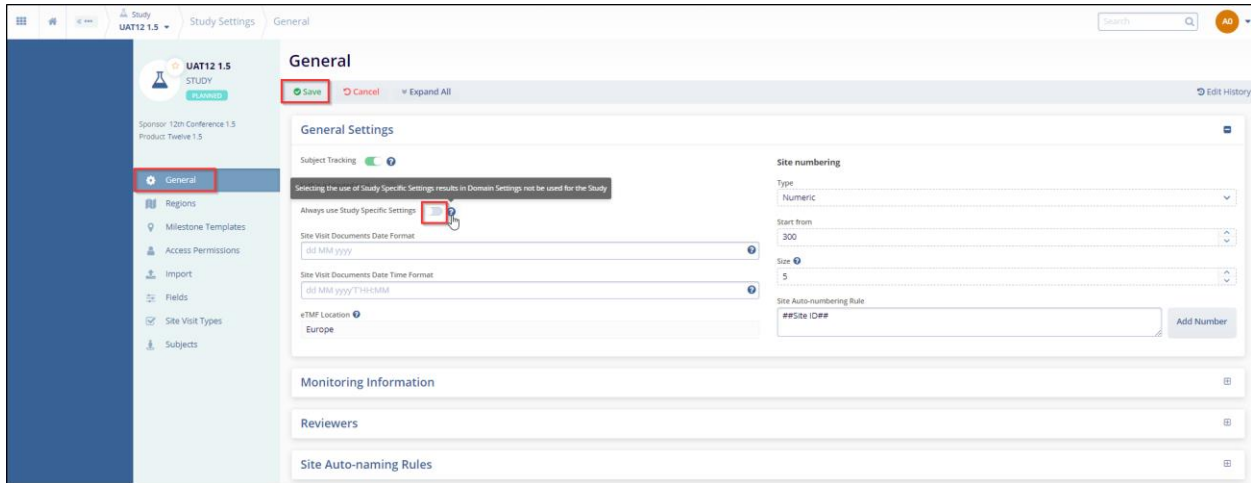
CTMS v1.5 makes clear to the user when the system/domain level settings are being utilized or study-defined settings are in use. This improvement ensures the study managers are always aware of what data is available to users within their study and the impact on the available data within the study if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



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

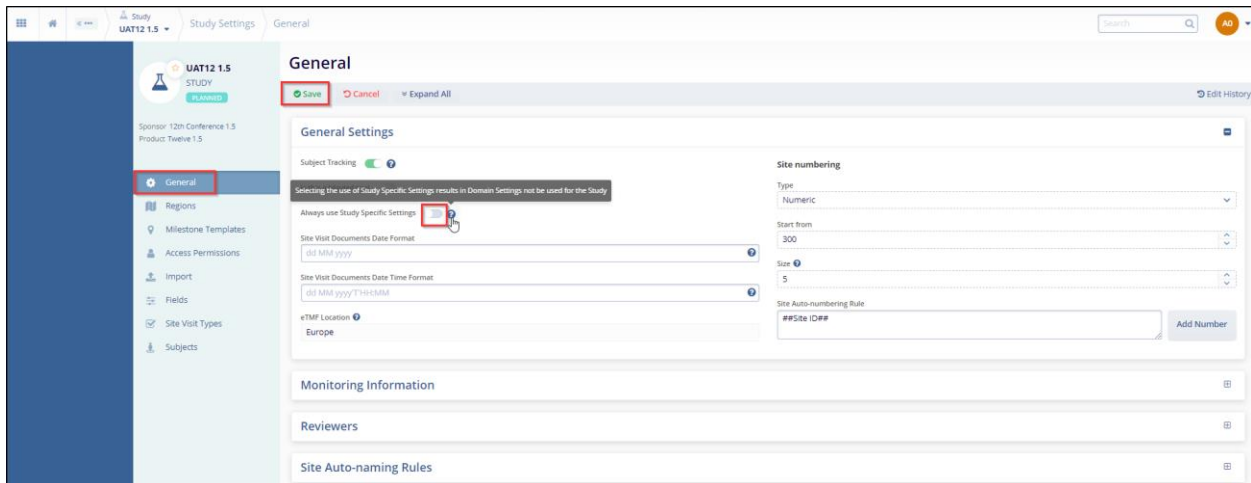
1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the “Studies” window and study list is displayed.
2. Click on the name of the study to which you want to add partner information.
 - a. The dashboard for the study is displayed.
3. Click on the **Study Details** in the Navigation menu at the left side of the screen.
 - a. The “Study Details” window is displayed.
4. Click on the **Settings** button displayed in the top right corner.
 - a. This opens the ‘Study Settings – General’ window.
5. Expand the General settings window by clicking the + icon on the right side of the screen.

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



7. Click the **Always use Study Specific Settings** toggle button.

8. Hover the mouse over the ? icon to view the tooltip.

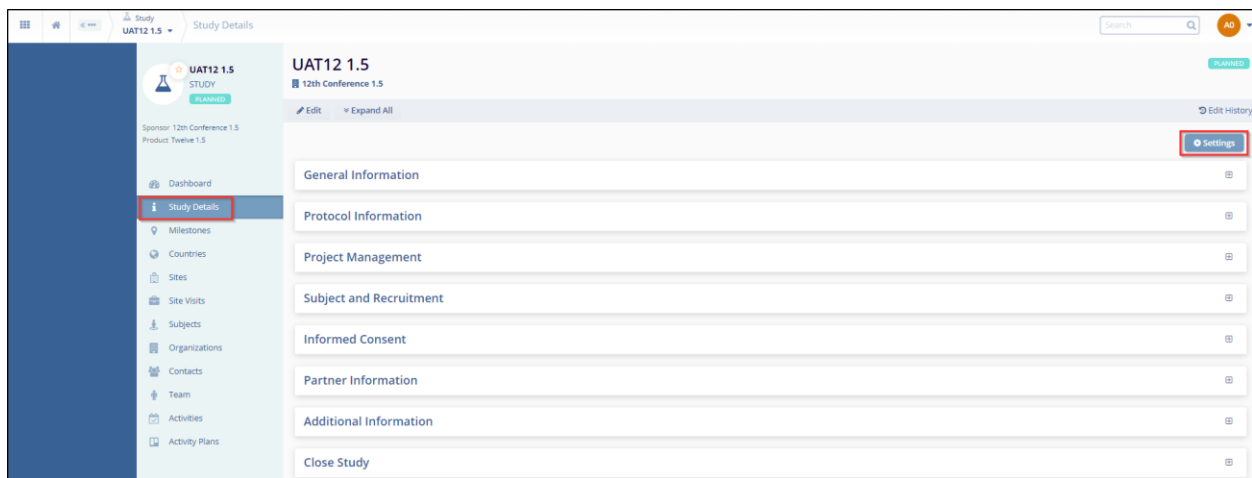


9. Selecting this toggle button helps the user to not add any custom fields.

Fields

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

1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the “Studies” window and the study list is displayed.
2. Click on the name of the study to which you want to add partner information.
 - a. The dashboard for the study is displayed.
3. Click on the **Study Details** in the Navigation menu at the left side of the screen.
 - a. The “Study Details” window is displayed.
4. Click on the **Settings** button displayed in the top right corner.
 - a. This opens the ‘Study Settings – General’ window.

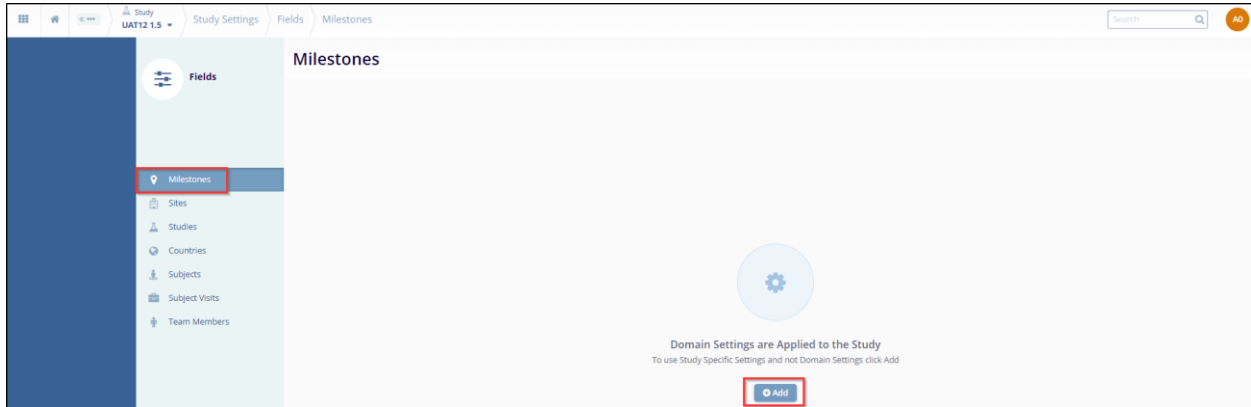


5. The left side navigation menu displays new added fields – **Fields, Site Visit Types and Subjects.**

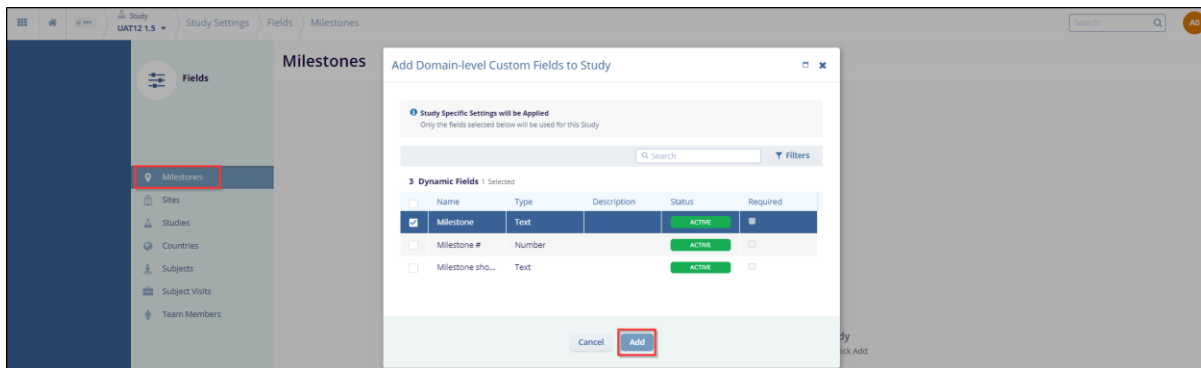


6. Click the **Fields** link.
 - a. This opens the ‘Study Settings – Fields’ window.
7. Click on the **Milestones** link from the center of the window.
 - a. This opens the Study Settings – Fields – Milestones window.

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



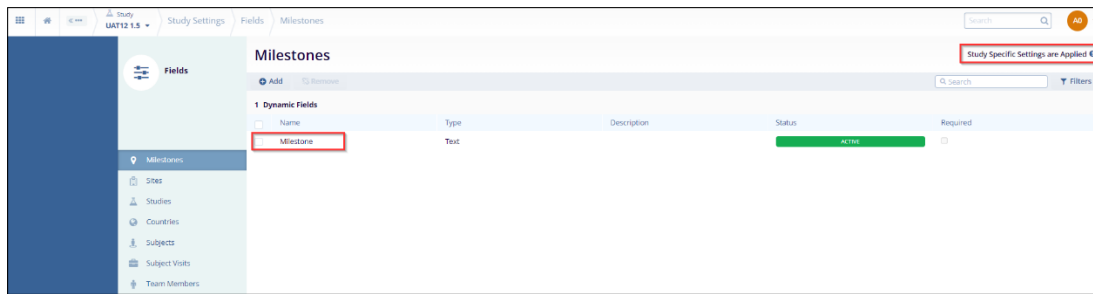
- a. This opens the Add Domain-level Custom Fields to Study window.
9. Select the checkbox(s) before the Name field and click **Add** button.



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



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



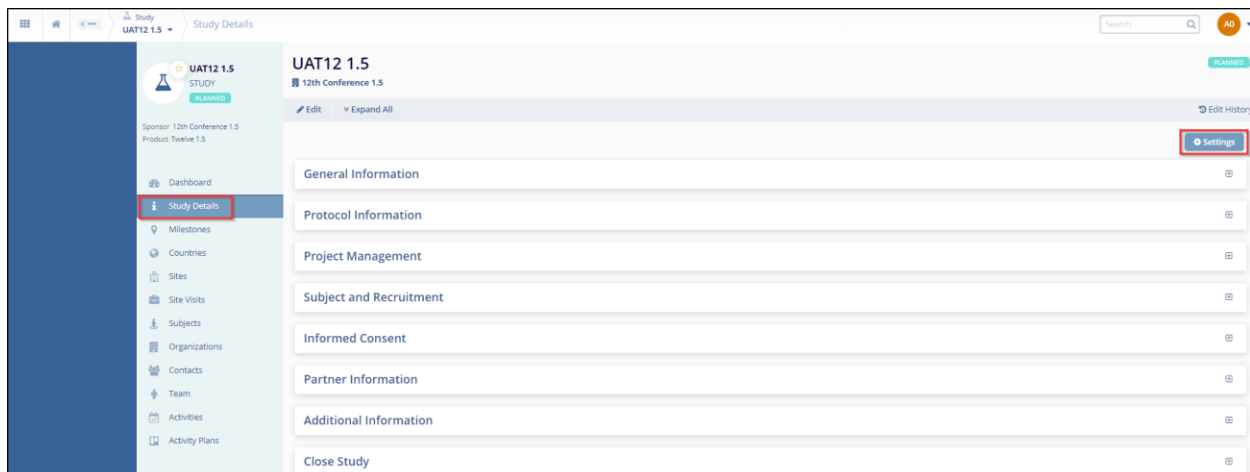
12. Select the checkbox of the added dynamic field.
13. This enables the Remove button. Click the **Remove** button to delete the dynamic field.

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

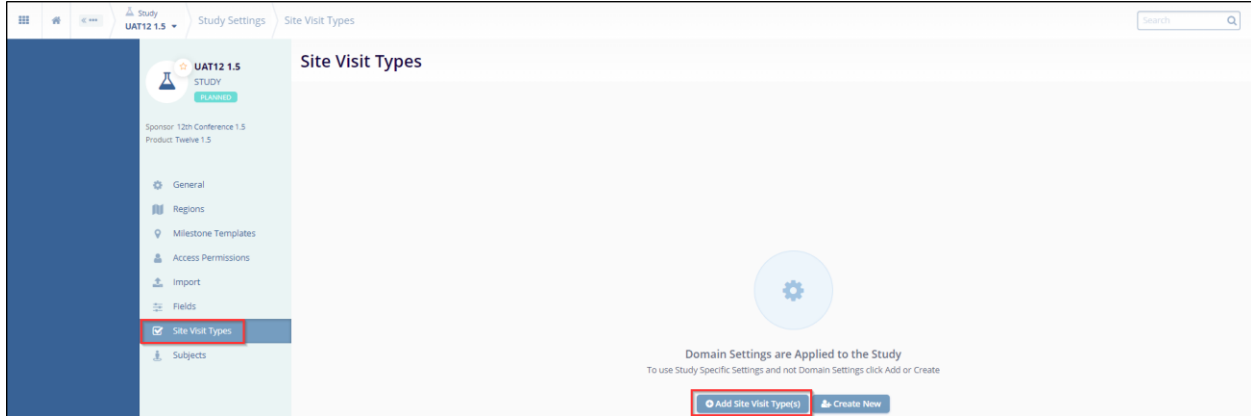
Site Visit Types

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

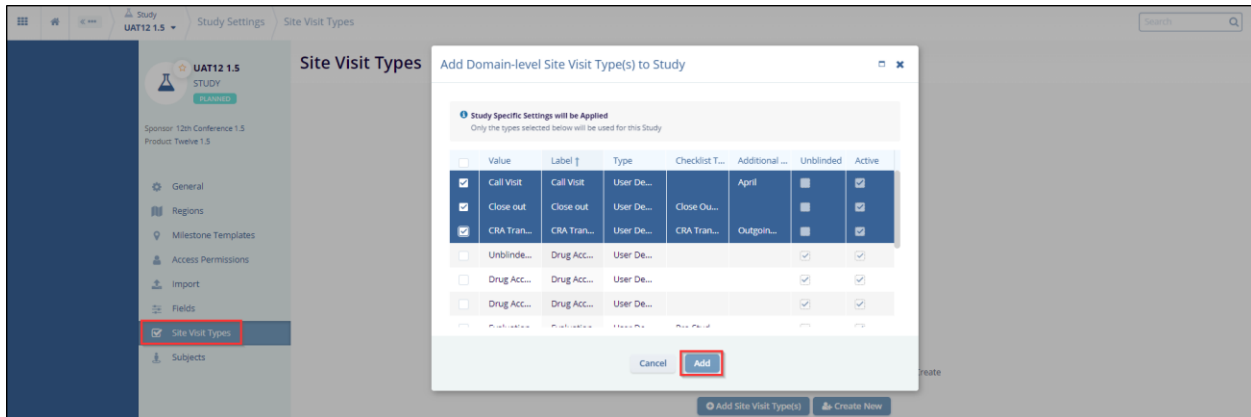
1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the “Studies” window and the study list is displayed.
2. Click on the name of the study to which you want to add partner information.
 - a. The dashboard for the study is displayed.
3. Click on the **Study Details** in the Navigation menu at the left side of the screen.
 - a. The “Study Details” window is displayed.
4. Click on the **Settings** button displayed in the top right corner.
 - a. This opens the ‘Study Settings – General’ window.



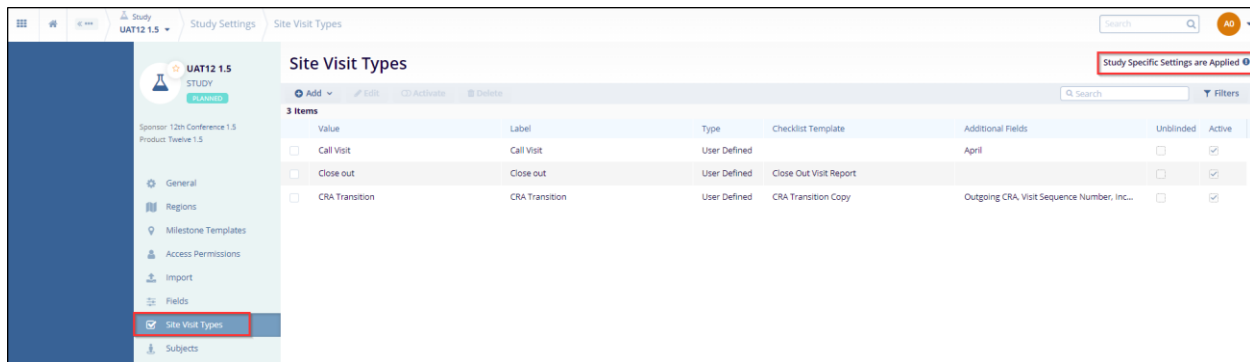
5. Click the **Site Visit Types** option in the navigation menu at the left side of the screen.
 - a. This opens the ‘Study Settings – Site Visit Types’ window.
6. Click the **Add Site Visit Type(s)** button.
 - a. This opens the ‘Add Domain-level Site Visit Type(s) to Study window.



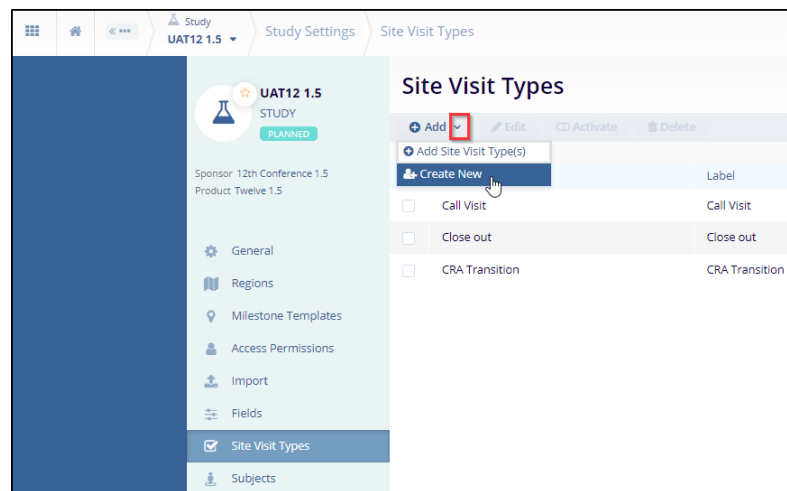
7. Select a checkbox(s) before the value column and click **Add** button.



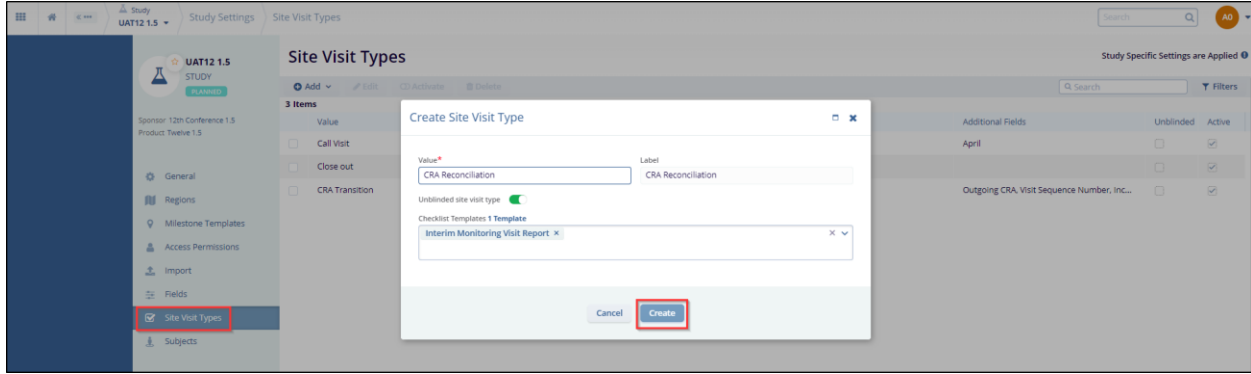
8. A notification of Success is displayed in the top right corner of the screen.
9. The dynamic added field is displayed in the center of the screen and ‘Study Specific Settings are Applied’ is displayed in the top right corner of the screen.



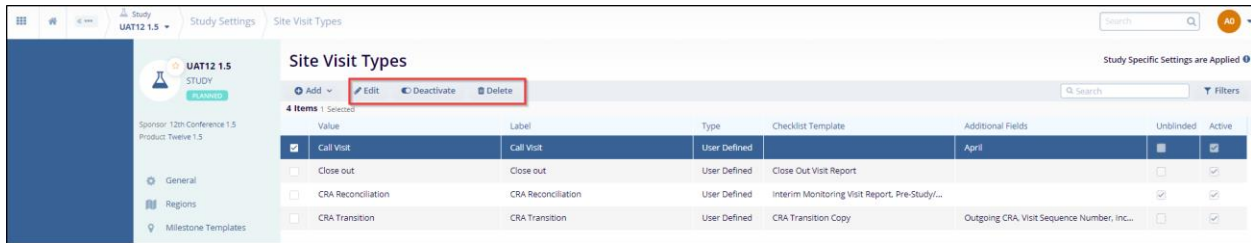
10. Notice that the 'Create New button' is disappeared and is now displayed below the '+ Add' dropdown menu.
11. Click the **Create New** option from the +Add Dropdown menu.



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



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

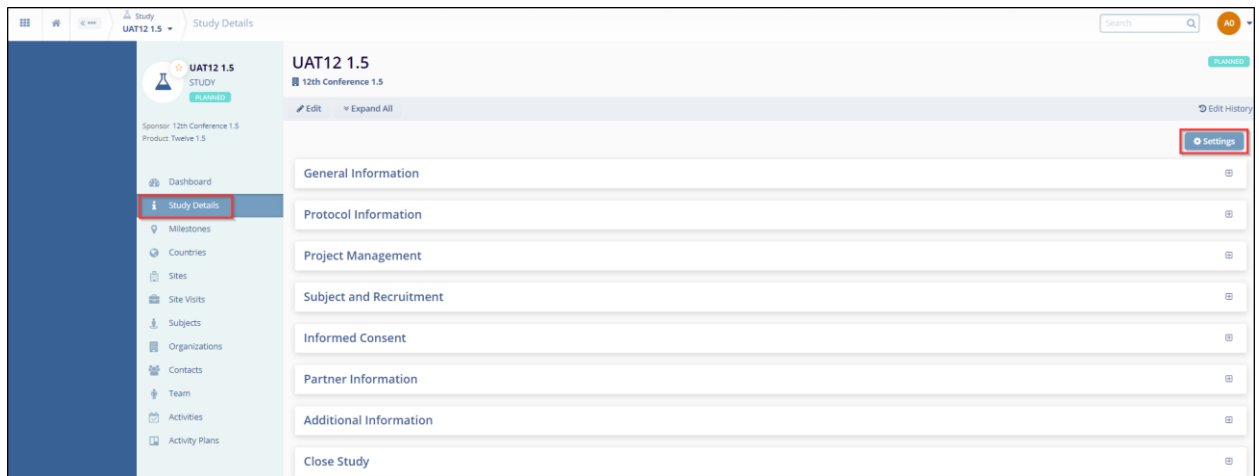


20. Perform the required action.

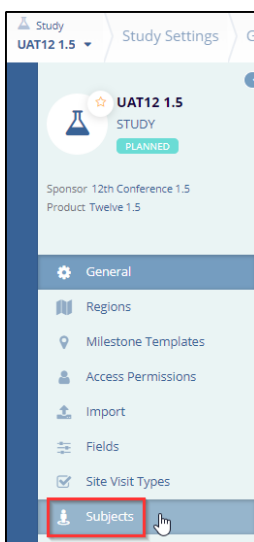
Subjects

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

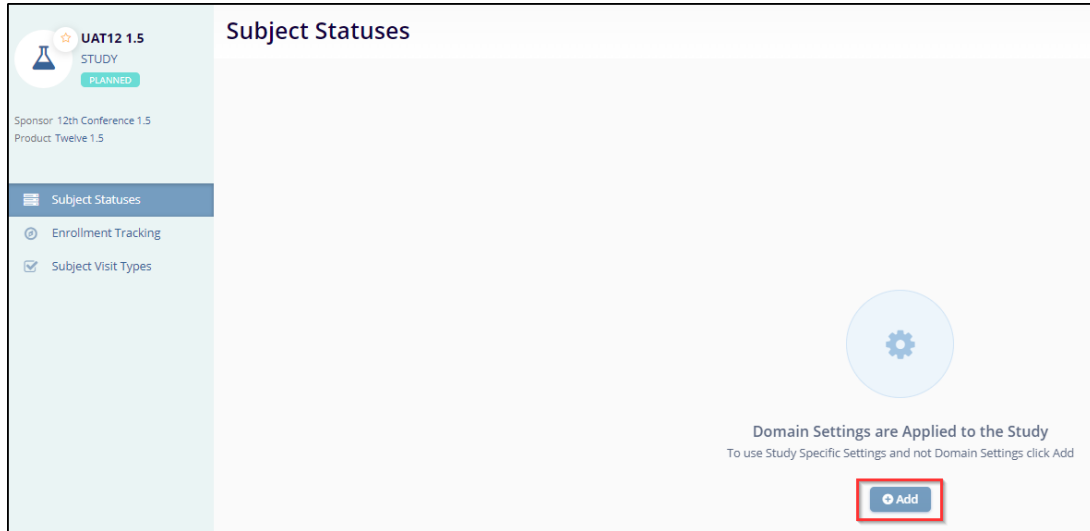
1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the “Studies” window and the study list is displayed.
2. Click on the name of the study to which you want to add partner information.
 - a. The dashboard for the study is displayed.
3. Click on the **Study Details** in the Navigation menu at the left side of the screen.
 - a. The “Study Details” window is displayed.
4. Click on the **Settings** button displayed in the top right corner.
 - a. This opens the ‘Study Settings – General’ window.



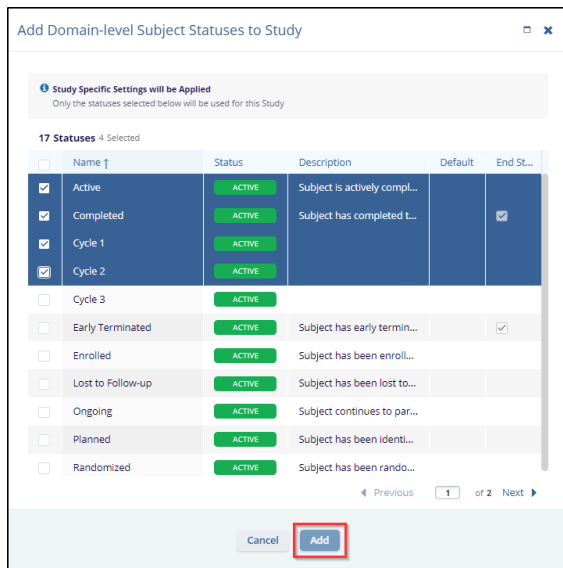
5. Click the **Subjects** option in the navigation menu at the left side of the screen.



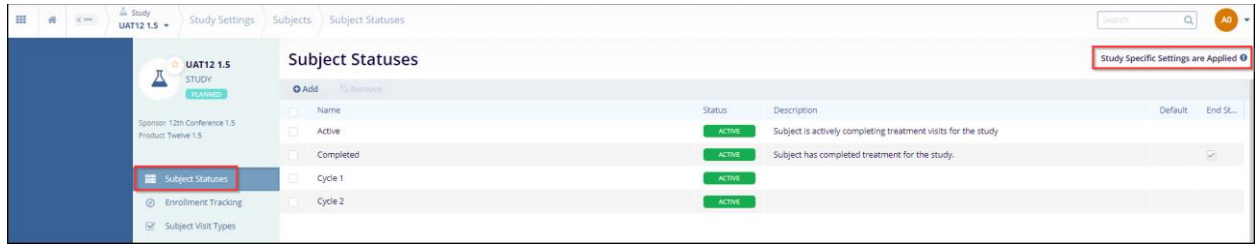
- a. This opens the ‘Subjects – Subject Statuses’ window.
6. Click the **Add** button displayed in the center of the screen.



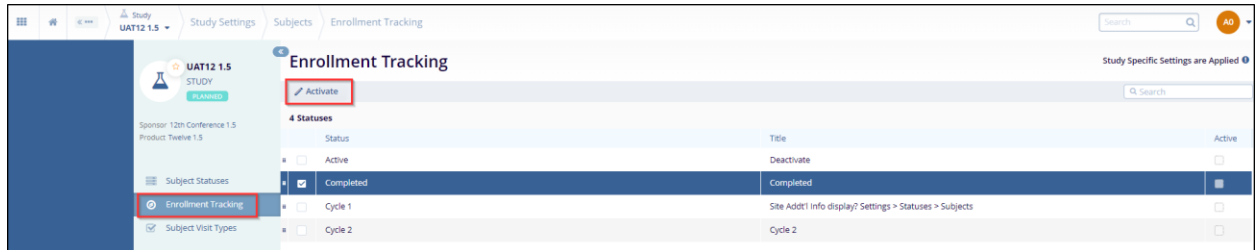
- a. This opens the Add Domain-level Subject Statuses to Study window.
7. Select a checkbox(s) before the value column and click **Add** button.



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



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



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

Organizations

Pre-requisites

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

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

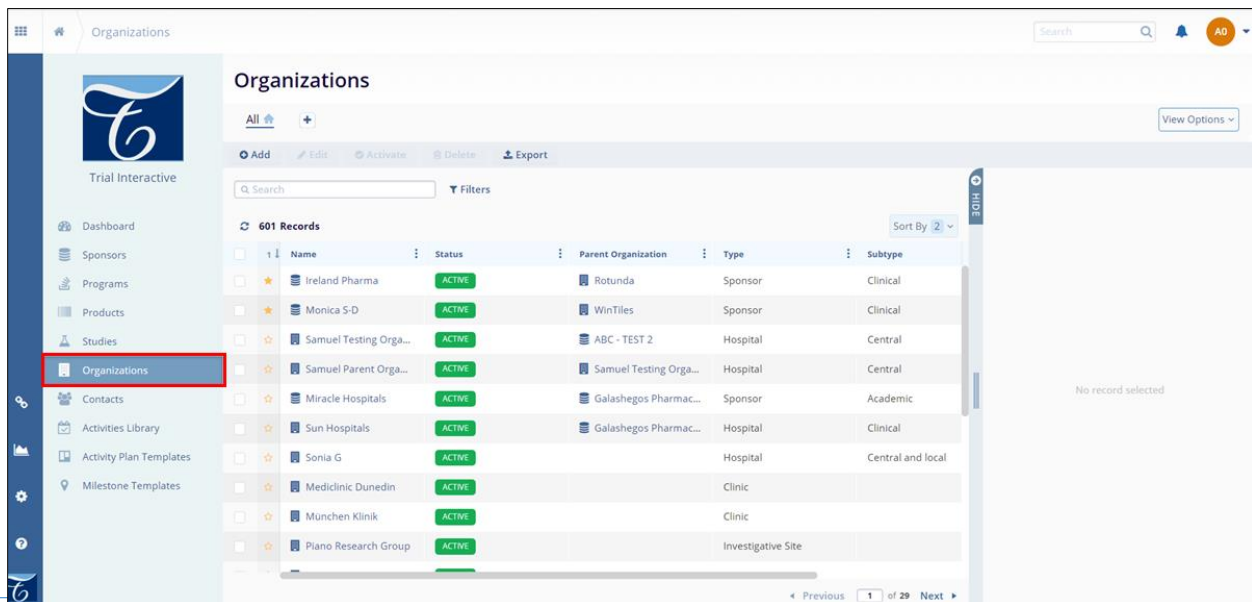
Users with system access permissions can perform the following actions:

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

Creating an Organization

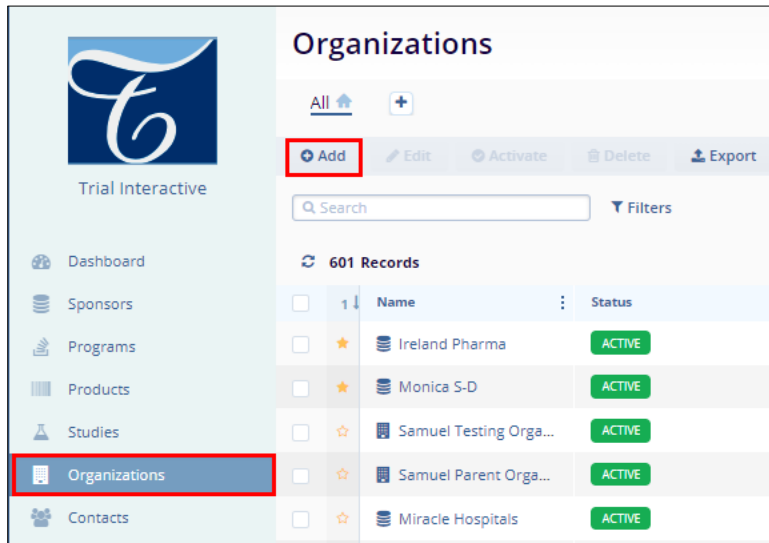
To navigate to the organization list and view all global organizations, follow these steps:

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

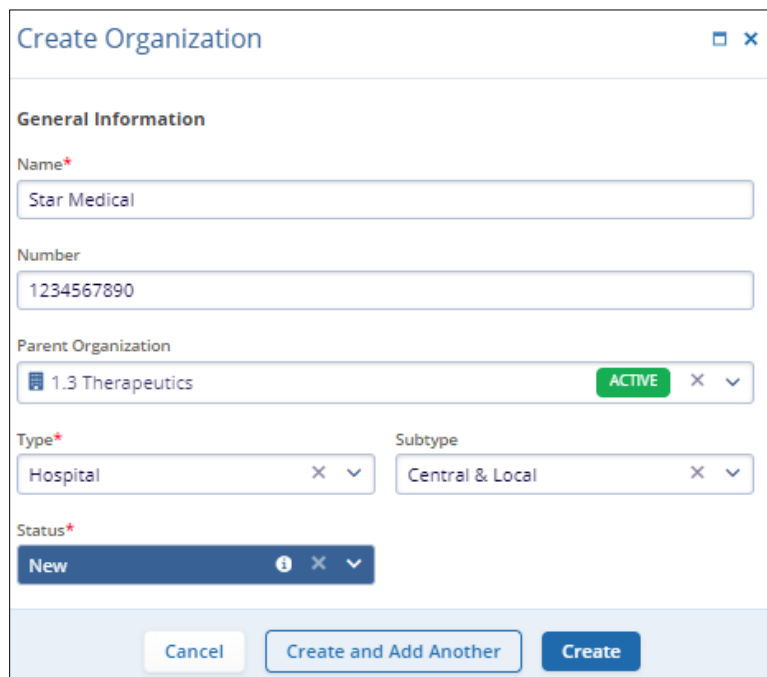


Steps to Add a New Organization

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



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



Create Organization

General Information

Name*
Star Medical

Number
1234567890

Parent Organization
1.3 Therapeutics ACTIVE

Type*
Hospital

Subtype
Central & Local

Status*
New

Buttons: Cancel, Create and Add Another, Create

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

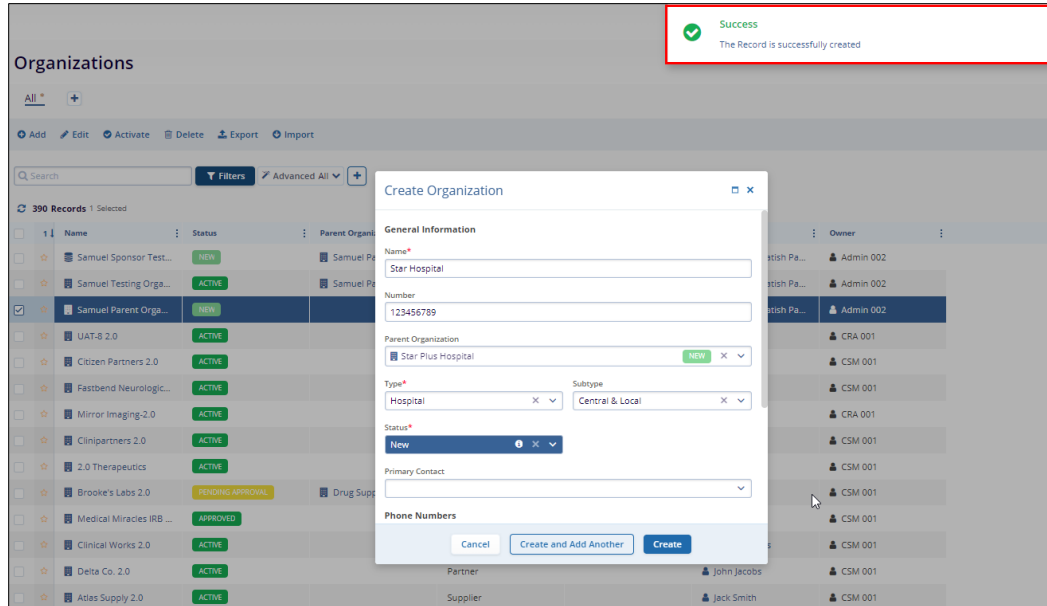
Step by Step All fields are explained below:

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

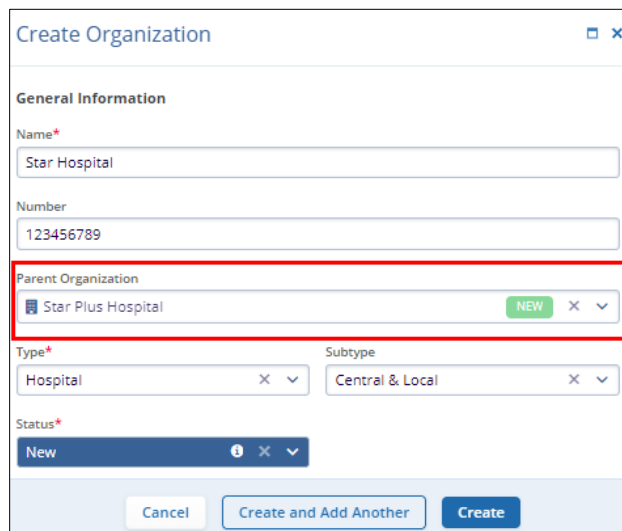
18. When the user click on the "Create" button, the screen opens on the same child organization. To prevent confusion, move the form to one side of your screen and fill in the information accordingly.

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

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



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

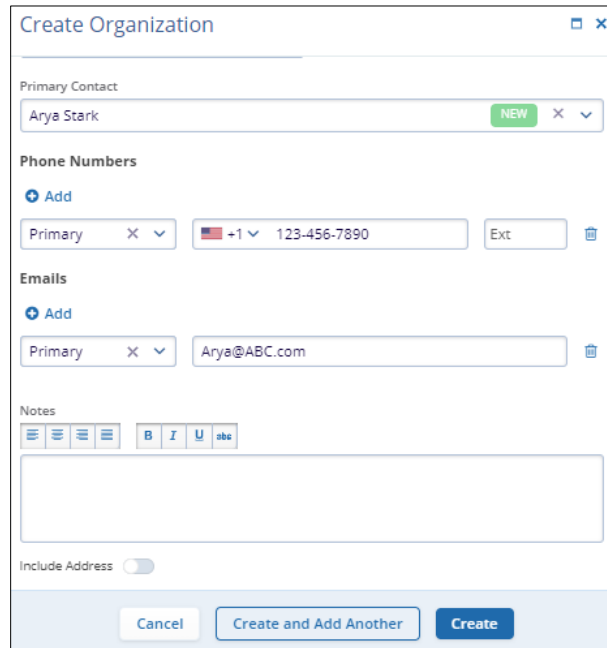
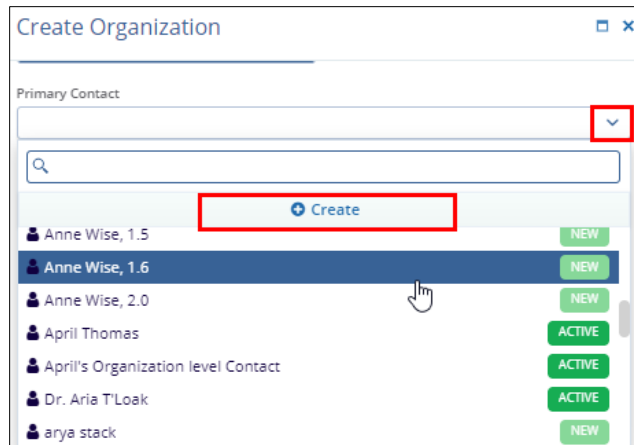


- Type:** Select the type of organization from the dropdown menu.

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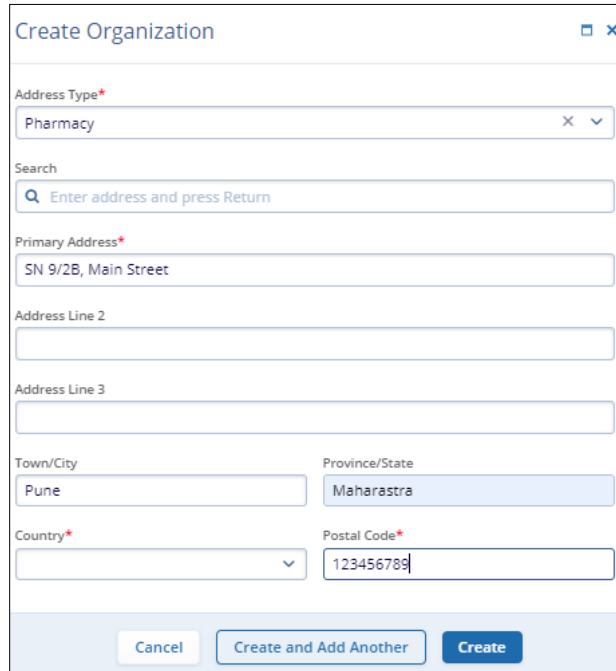
- 22. **Subtype:** Select the subtype that best describes the Organization.
- 23. **Status:** Choose the status as your requirement.

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



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

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



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

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

Success
 The Record is successfully created

Organizations

[Add](#) | [Edit](#) | [Activate](#) | [Deactivate](#) | [Export](#) | [Import](#)

[Filter](#) | [Advanced All](#)

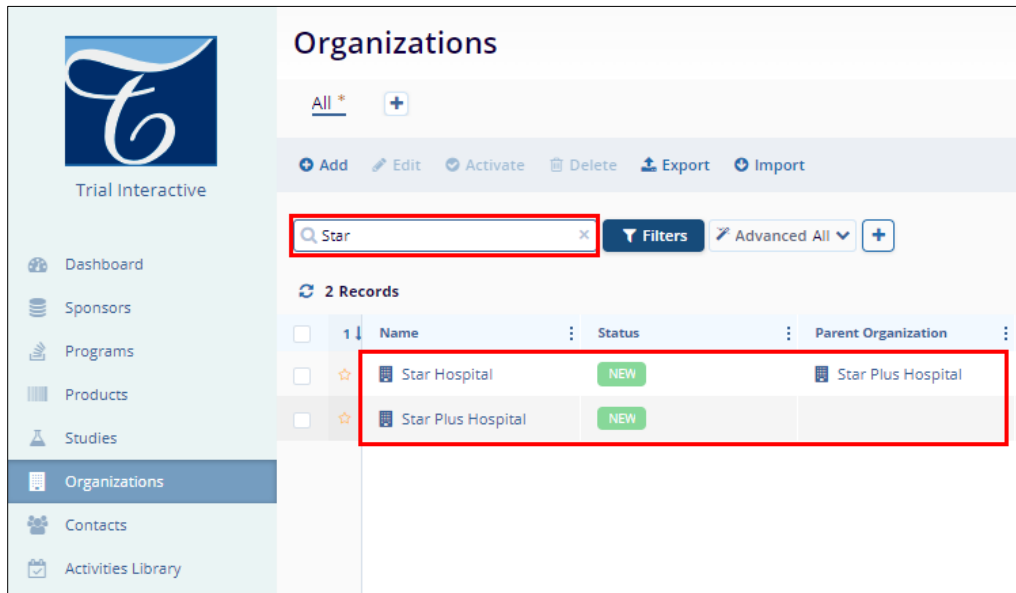
311 Records Sort By

ID	Name	Status	Parent Organization	Type	Subtype	Primary Contact	Owner
1	Star Plus Hospital	Active		Hospital			Admin 002
2	Samuel Spinal Test	Active	Samuel Parent Orga...	Spencer	Central & Local	Mr Samuel Satish Pa...	Admin 002
3	Samuel Testing Orga...	Active	Samuel Parent Orga...	Hospital	Central & Local	Mr Samuel Satish Pa...	Admin 002
4	Samuel Parent Orga...	Active		Hospital	Central & Local	Mr Samuel Satish Pa...	Admin 002
5	UAT# 2.0	Active		Clinic			CSA 001
6	Citizen Partners 2.0	Active		Partner			CSM 001
7	Fastbind Neurologi...	Active		Investigative Site			CSA 001
8	Minor Imaging 2.0	Active		Partner			CSA 001
9	Clinpartners 2.0	Active		Lab			CSM 001
10	2.0 Therapeutics	Active		Clinic			CSM 001
11	Brown's Labs 2.0	Active	Drug Supply v2.0	Partner			CSM 001
12	Medical Miracles IRB...	Active		Partner		Erin Garner	CSM 001
13	Clinical Wares 2.0	Active		IRB-EC		Jacob Roberts	CSM 001
14	Delta Co. 2.0	Active		Partner		John Jacobs	CSM 001
15	Atlas Supply 2.0	Active		Supplier		Jack Smith	CSM 001
16	Acme Inc 2.0	Active		Partner			CSM 001
17	Acme Inc 2.0	Active		Investigative Site		Barbra Martin	CSM 001
18	Prostate Services I&T	Active		Resource			House Warner

How to Search for an Organization

Steps to Search for an Organization

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



Customizing Organization Screen

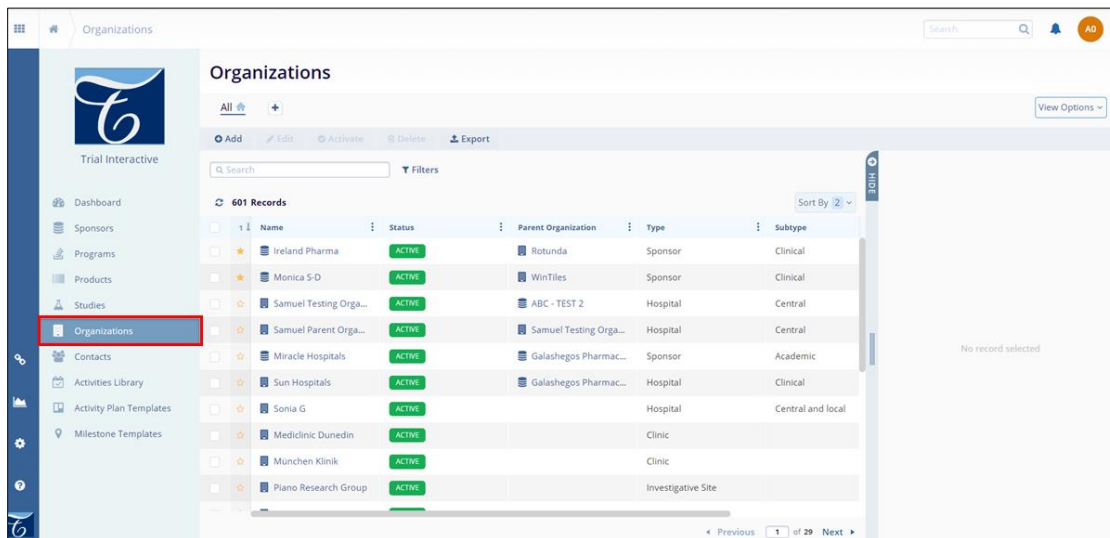
The procedure to perform the mentioned actions is standard across Organizations and Contacts.

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

Editing an Organization

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

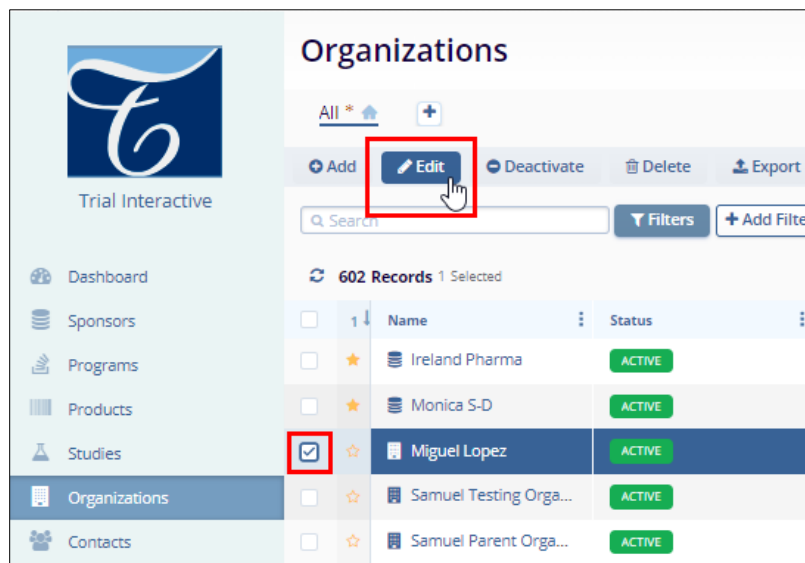
1. Click on the **"Organizations"** tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the **"Organizations"** page where all organizations at the global level will be displayed.



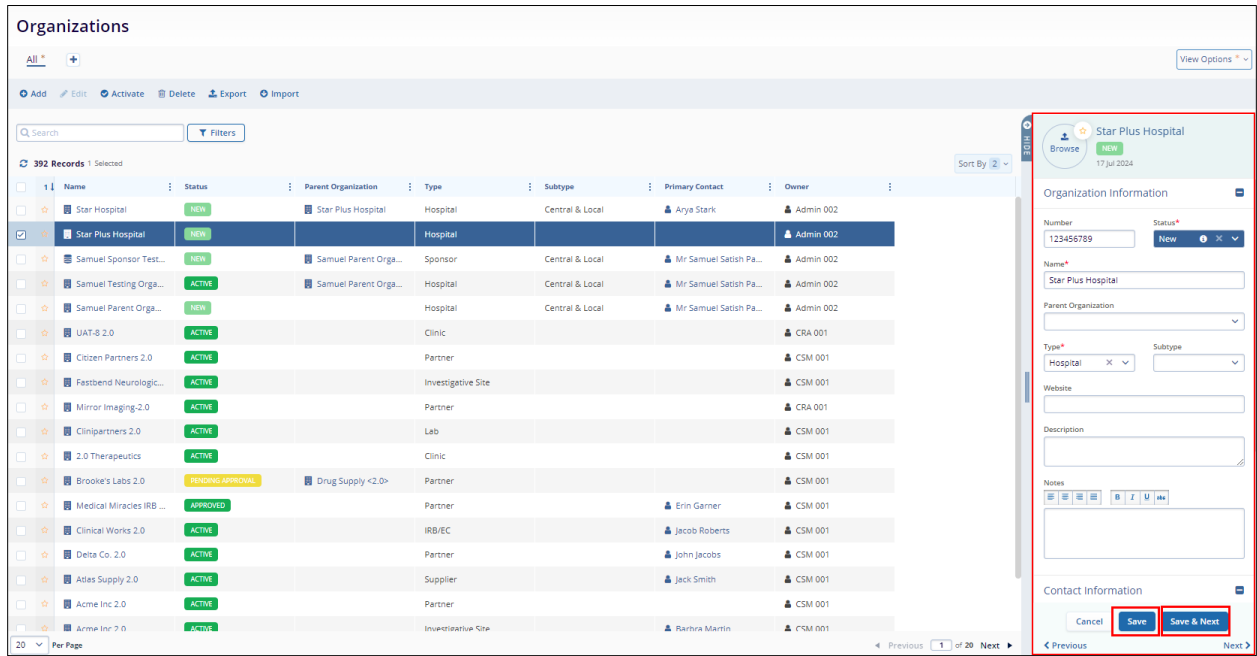
Steps to Edit an Organization:

There are two ways to Edit an Organization explained below.

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



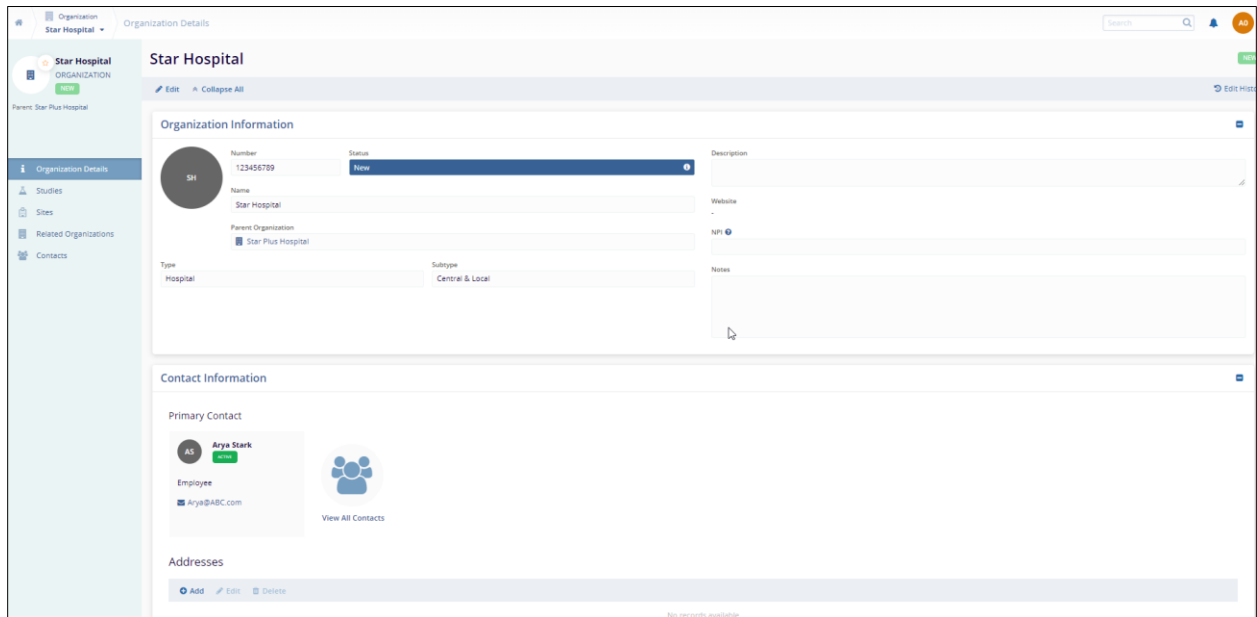
2. The Quick View panel will display in the editable stage on the right side of the screen.



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

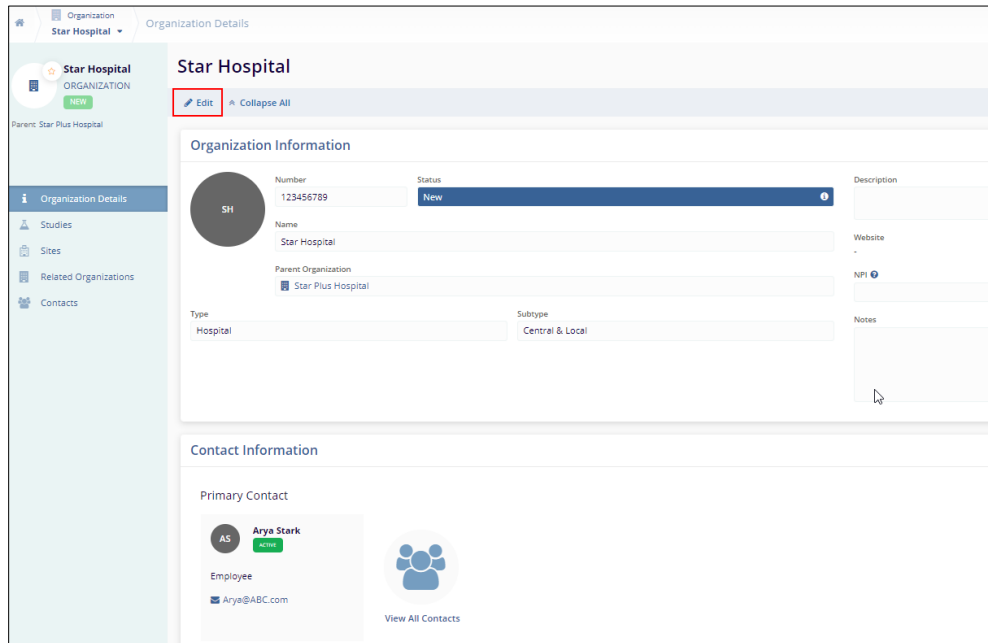
Second method to edit an Organization

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

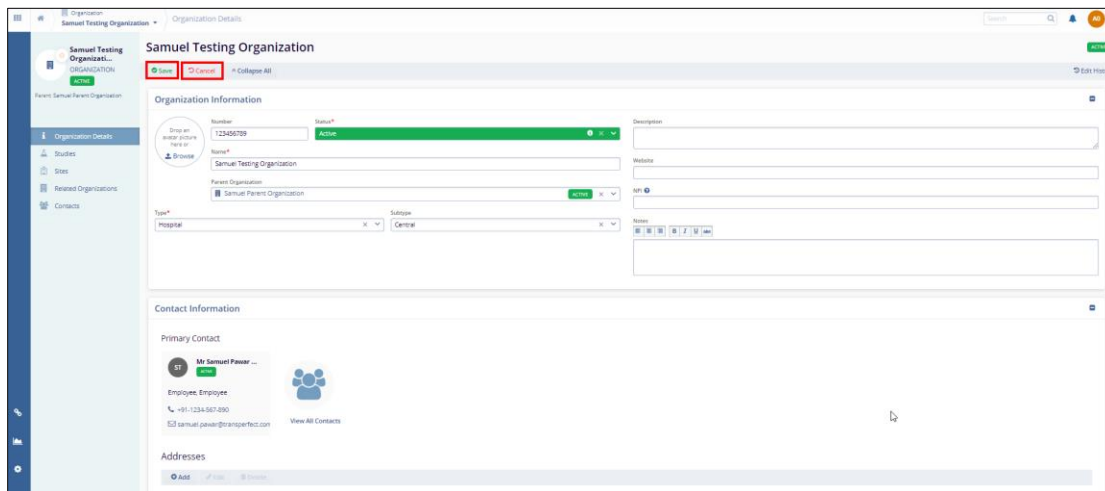


2. **Note:** The "Organization Details" page contains additional fields that are not available within the quick-view panel (For Example: NPI, Website, etc.)

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



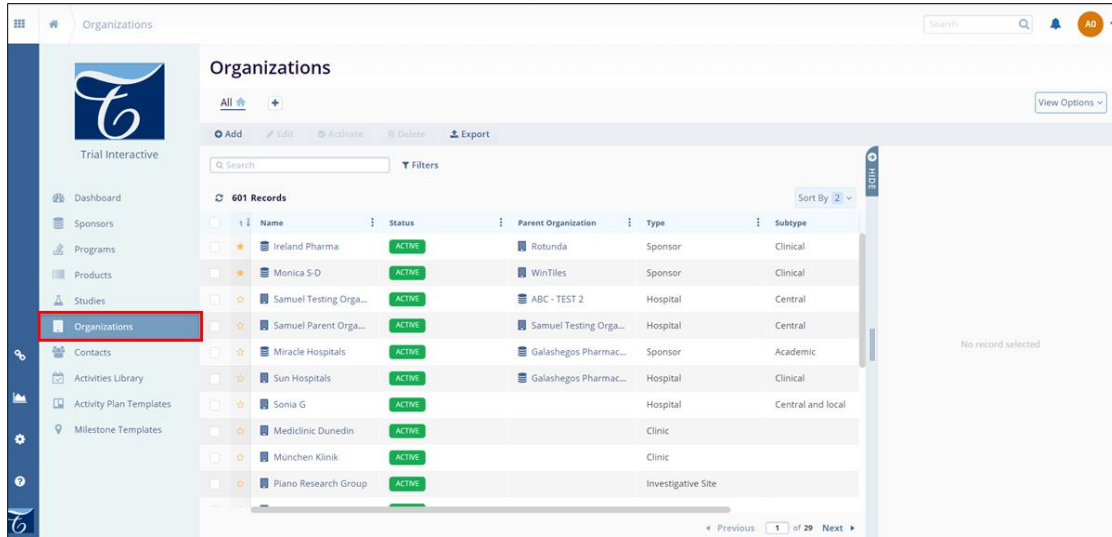
- Once the changes are made, click the "Save" button to save the updates, or click the "Cancel" button to discard them.



How to Activate Organizations

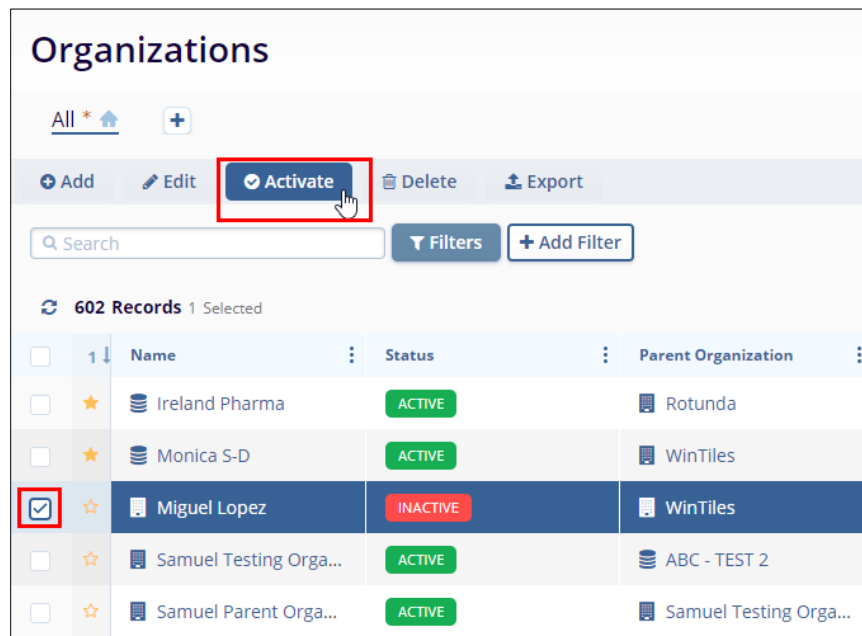
To navigate to the organization list and view all global organizations, follow these steps:

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

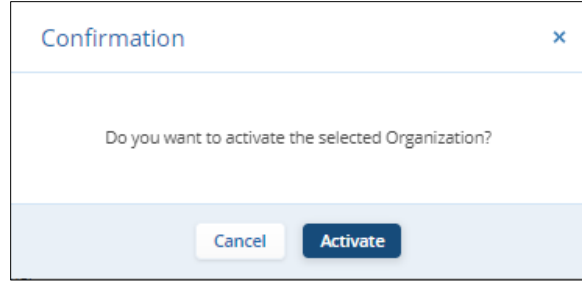


Steps to Activate Organization:

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



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

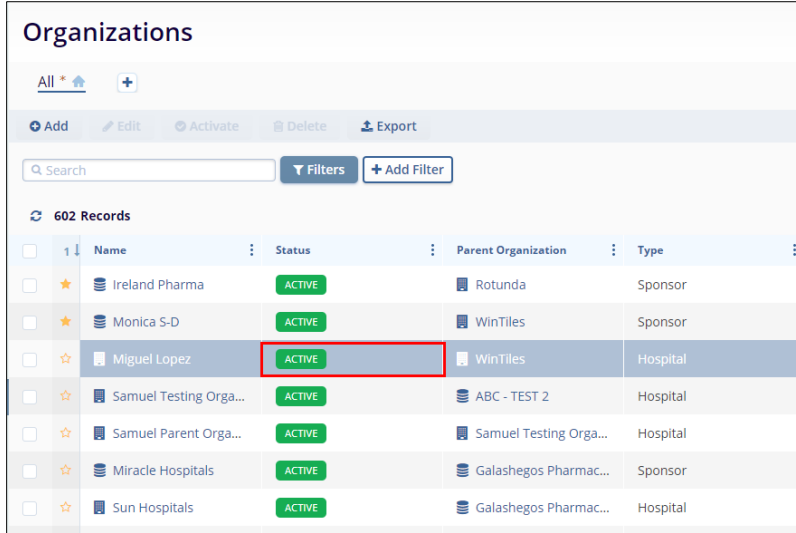


2. Upon successful activation, you will receive a success notification at the top right corner of the screen.

The screenshot shows the "Organizations" management interface. At the top right, a success notification is displayed: "Success The Record is successfully updated". Below this, the "Organizations" section includes a search bar, filters, and a table of records. The table has columns for Name, Status, Parent Organization, Type, Subtype, Primary Contact, and Owner. The first row, "Star Hospital", is selected and highlighted. To the right of the table, a sidebar shows the "Organization Information" for "Star Hospital", including details like Number (123456789), Status (New), Name, Parent Organization (Star Plus Hospital), Type (Hospital), Subtype (Central & Local), Website, Description, and Notes. The Primary Contact is also listed.

Name	Status	Parent Organization	Type	Subtype	Primary Contact	Owner
Star Hospital	NEW	Star Plus Hospital	Hospital	Central & Local	Arya Stark	Admin 002
Star Plus Hospital	NEW		Hospital			Admin 002
Samuel Sponsor Test...	NEW	Samuel Parent Orga...	Sponsor	Central & Local	Mr Samuel Satish Pa...	Admin 002
Samuel Testing Orga...	ACTIVE	Samuel Parent Orga...	Hospital	Central & Local	Mr Samuel Satish Pa...	Admin 002
Samuel Parent Orga...	NEW		Hospital	Central & Local	Mr Samuel Satish Pa...	Admin 002
UAT-8 2.0	ACTIVE		Clinic			CRA 001
Citizen Partners 2.0	ACTIVE		Partner			CSM 001
Fastbend Neurologic...	ACTIVE		Investigative Site			CSM 001
Mirror Imaging 2.0	ACTIVE		Partner			CRA 001
Clinipartners 2.0	ACTIVE		Lab			CSM 001
2.0 Therapeutics	ACTIVE		Clinic			CSM 001
Brooke's Labs 2.0	PENDING APPROVAL	Drug Supply <2.0>	Partner			CSM 001
Medical Miracles IRB ...	APPROVED		Partner		Erin Garner	CSM 001
Clinical Works 2.0	ACTIVE		IR/REC		Jacob Roberts	CSM 001
Delta Co. 2.0	ACTIVE		Partner		John Jacobs	CSM 001
Atlas Supply 2.0	ACTIVE		Supplier		Jack Smith	CSM 001
Acme Inc 2.0	ACTIVE		Partner			CSM 001
Arma Inc 2.0	ACTIVE		Investigative Site		Ranva Martin	CSM 001

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



	Name	Status	Parent Organization	Type
<input type="checkbox"/>	Ireland Pharma	ACTIVE	Rotunda	Sponsor
<input type="checkbox"/>	Monica S-D	ACTIVE	WinTiles	Sponsor
<input type="checkbox"/>	Miguel Lopez	ACTIVE	WinTiles	Hospital
<input type="checkbox"/>	Samuel Testing Orga...	ACTIVE	ABC - TEST 2	Hospital
<input type="checkbox"/>	Samuel Parent Orga...	ACTIVE	Samuel Testing Orga...	Hospital
<input type="checkbox"/>	Miracle Hospitals	ACTIVE	Galashegos Pharmac...	Sponsor
<input type="checkbox"/>	Sun Hospitals	ACTIVE	Galashegos Pharmac...	Hospital

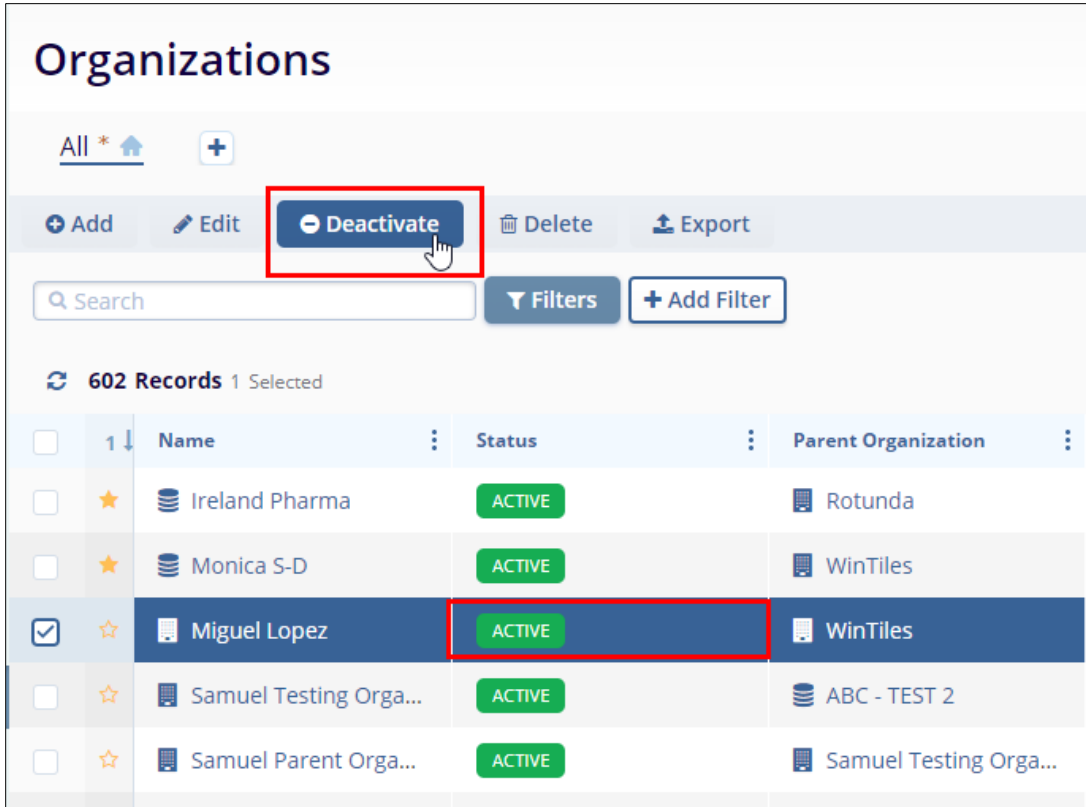
How to Deactivate Organisations

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

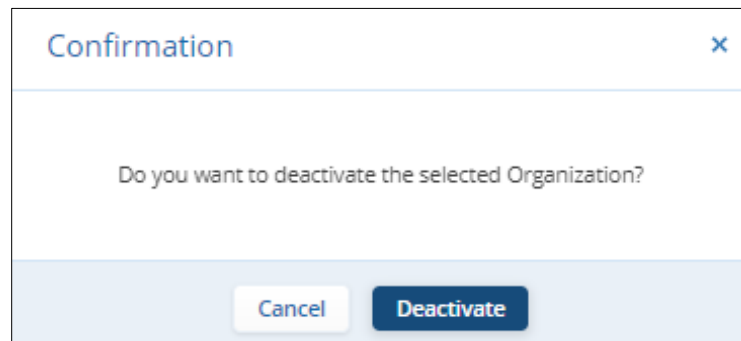
- Click on the "Organizations" tab located in the navigation link on the left side of the screen.
- This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.

Steps to Deactivate Organization:

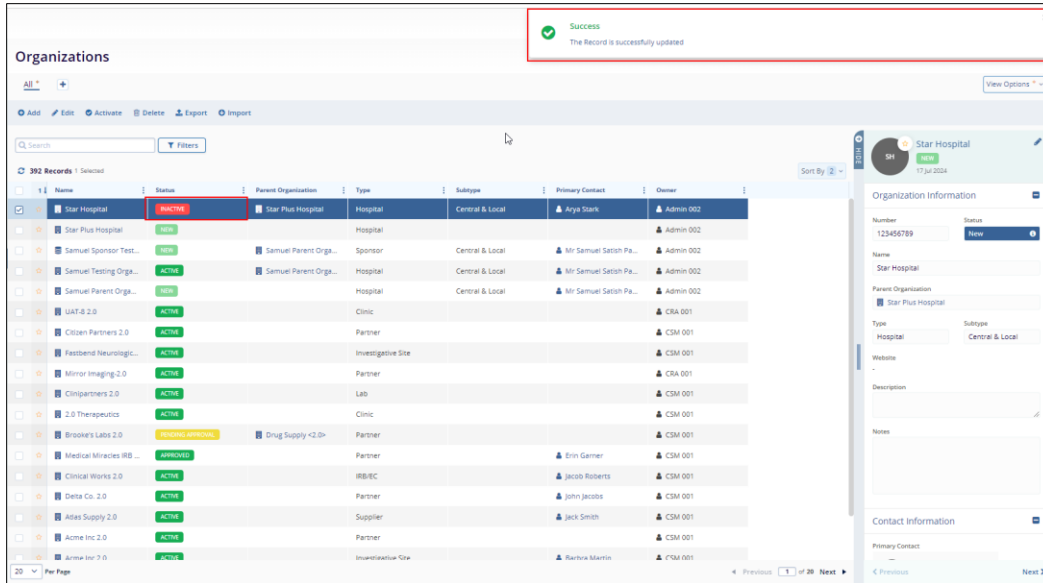
- Select the organization by clicking the checkbox next to its name. Then, click the "Deactivate" button at the top of the grid to initiate the activation process.



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



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

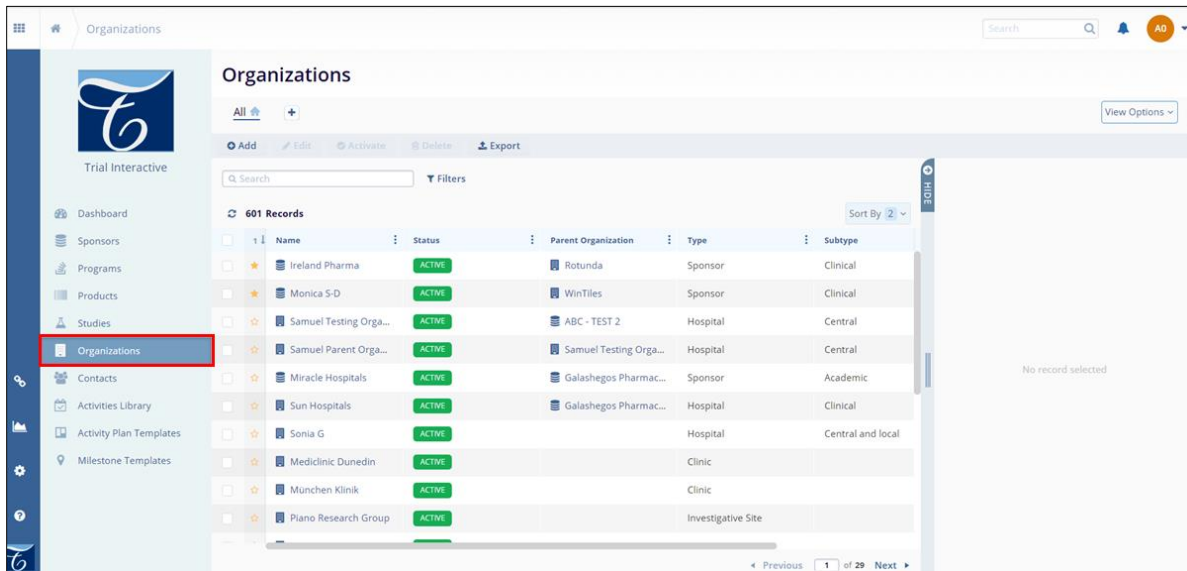


- The status of the organization will now be updated to "Inactive" and displayed in the status field of the grid.

Associating an Address to an Organization

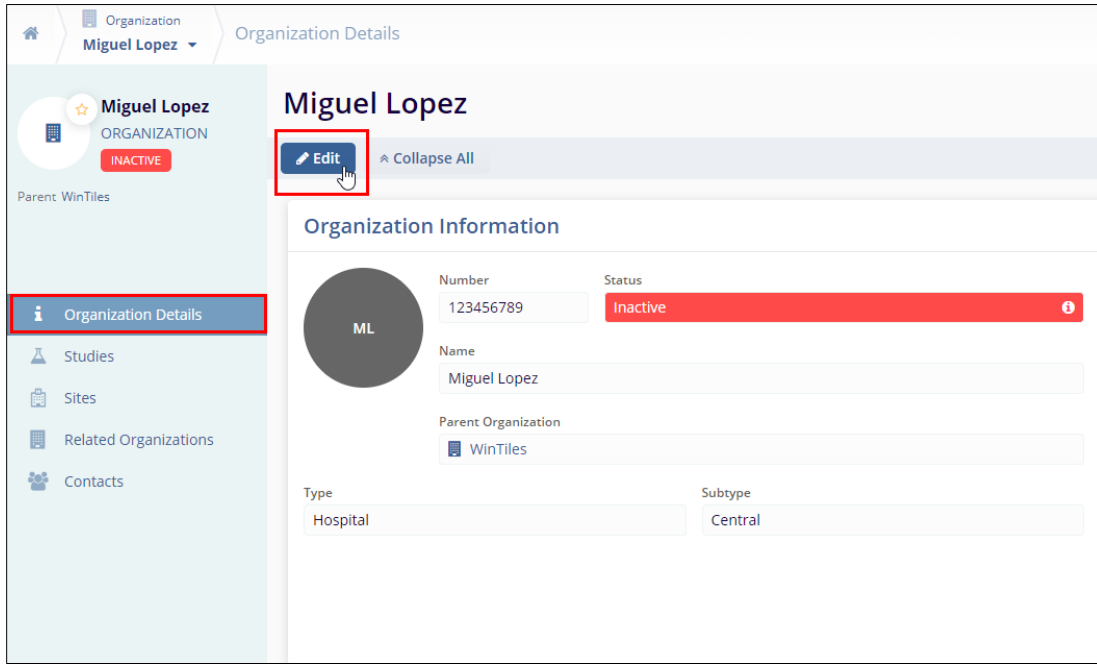
To navigate to the organization list and view all global organizations, follow these steps:

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

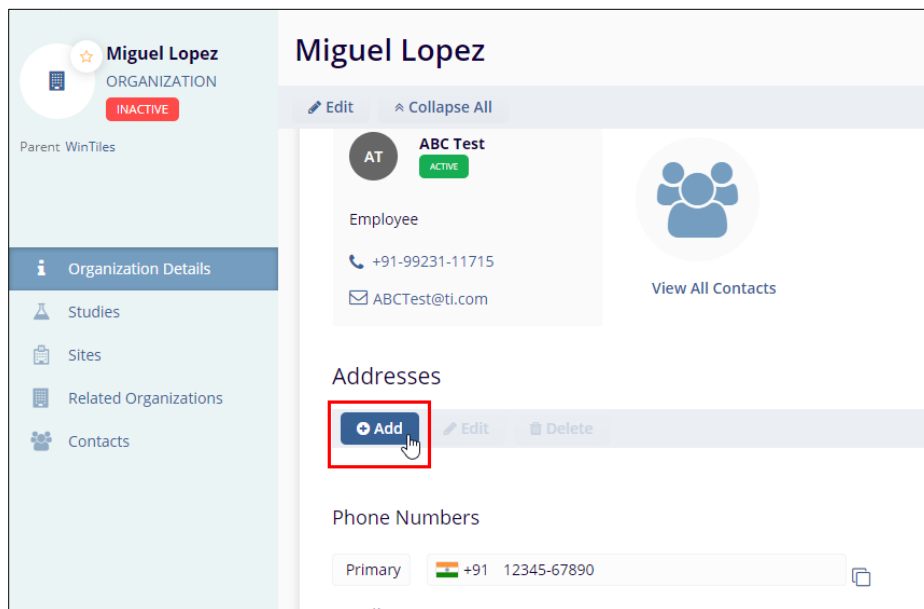


Steps to Associate an address to an Organization.

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



3. Click on the “+Add” button in the Addresses section.



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

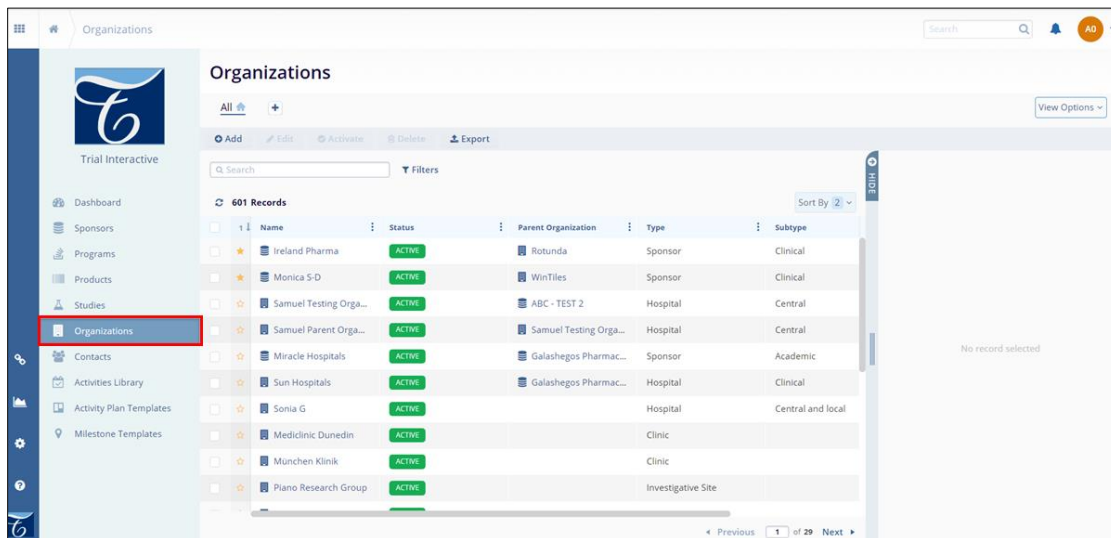
which has an asterisk (*) symbol next to the field title. Enter any additional information, as per your requirement.

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

Associating an Organization to a Parent Organization

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

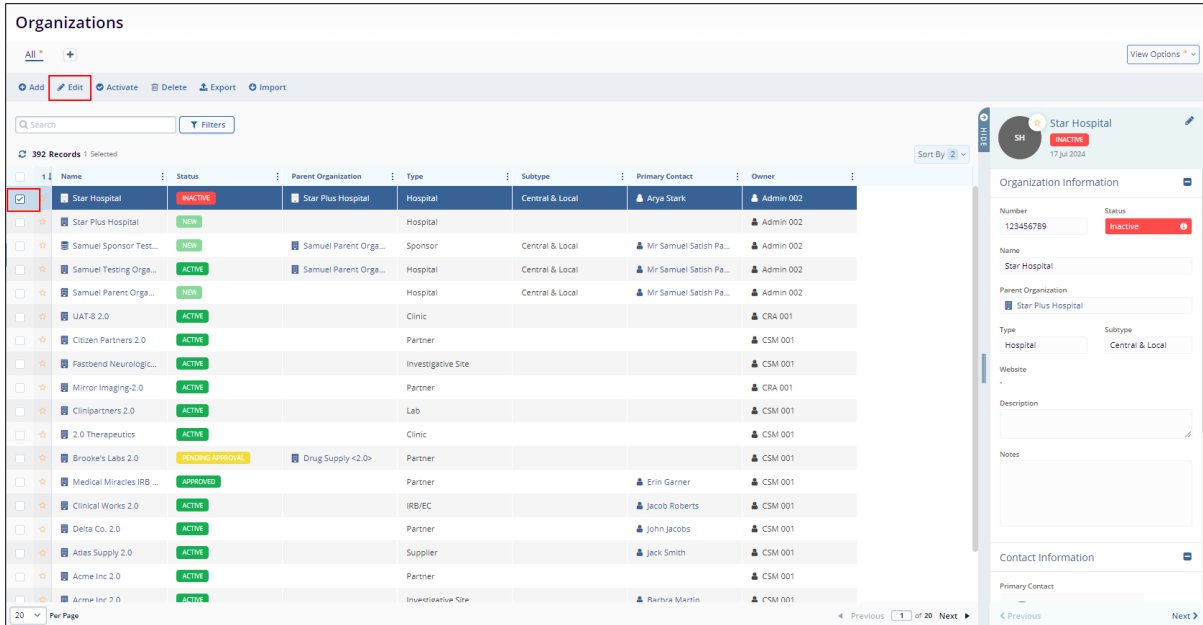
1. Click on the **"Organizations"** tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the **"Organizations"** page where all organizations at the global level will be displayed.



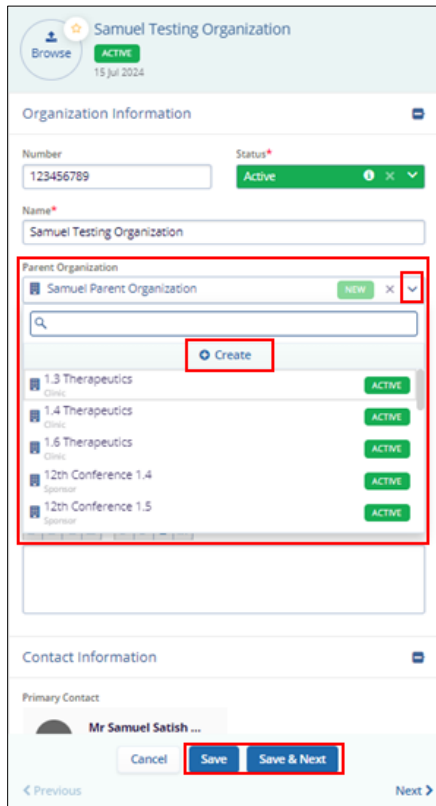
Steps to associate an organization with a parent organization, follow the steps below:

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

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



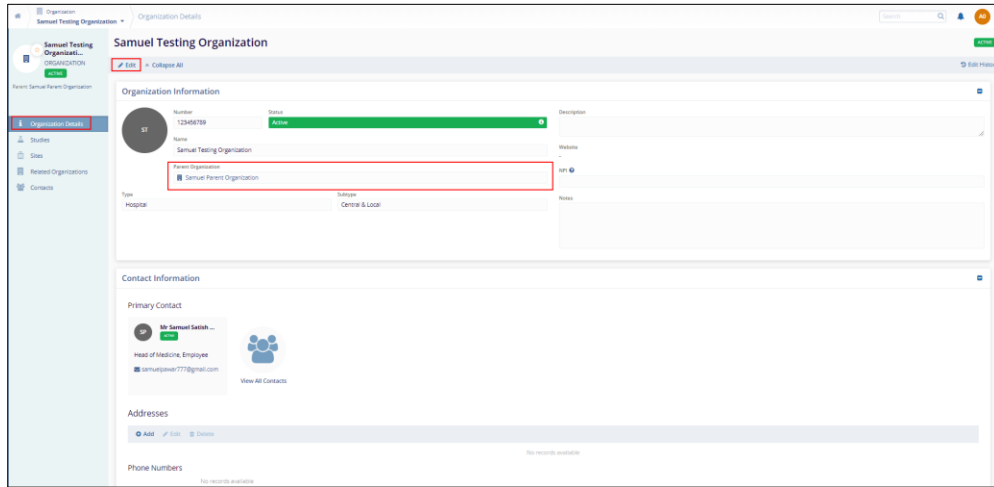
2. Click the drop-down arrow displayed in the parent organization field, and select the appropriate parent organization.
3. If you need to create a new parent organization, please refer to this link to learn “[How to create a Parent Organization](#)”.



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

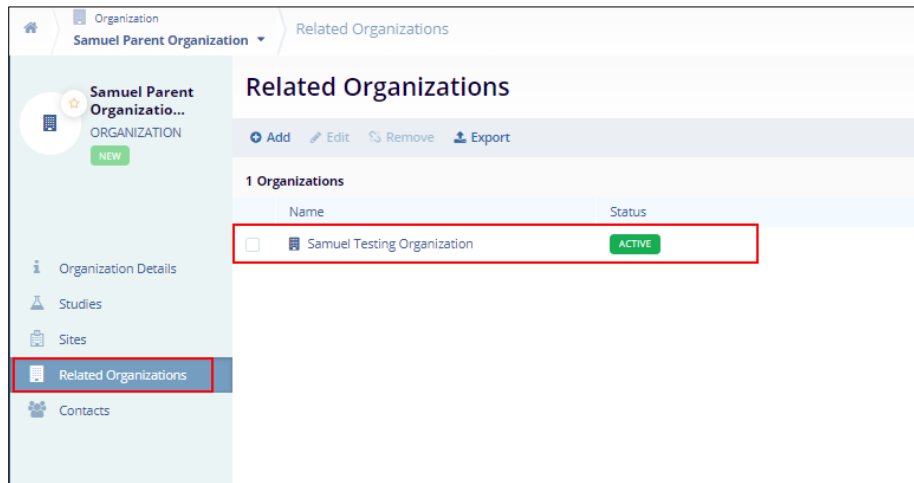
The second method of associating a parent organization.

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



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

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

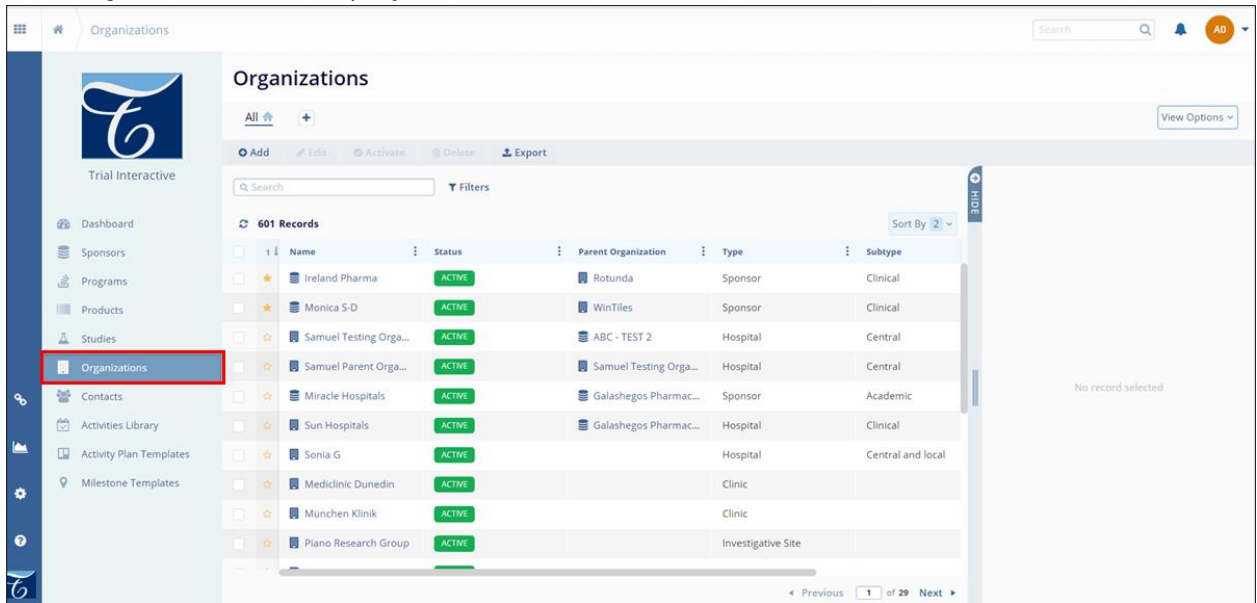


Reviewing Studies Associated with an Organization

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

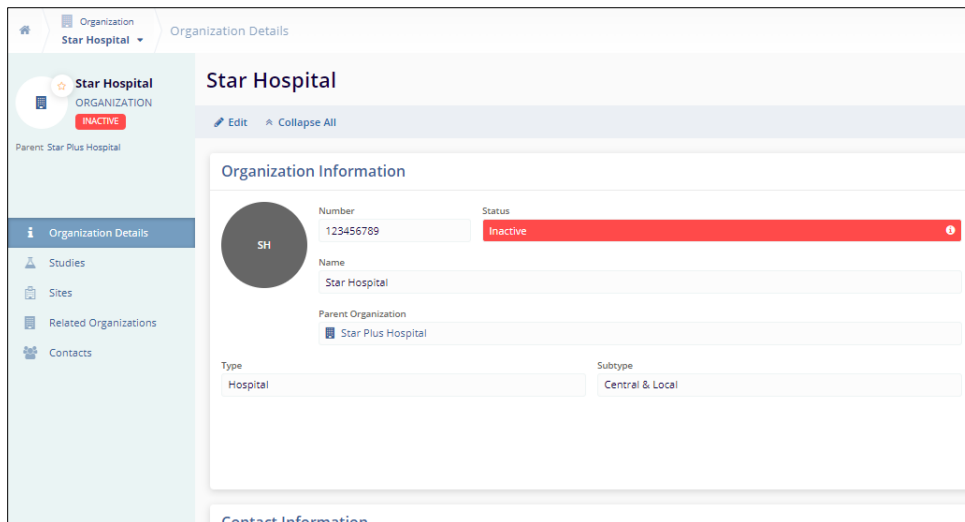
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1. Click on the **"Organizations"** tab located in the navigation link panel on the left side of the screen.
2. This action will redirect you to the **"Organizations"** list where all organizations at the global level are displayed.

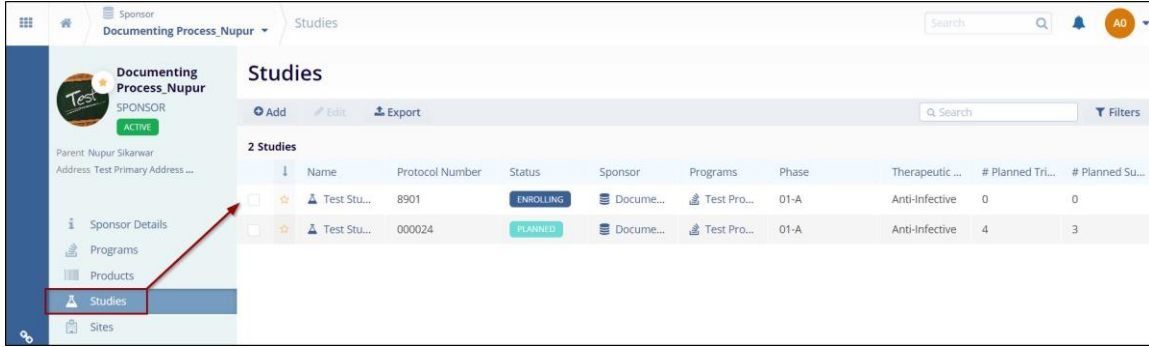


To review the studies associated with an organization follow the below steps.

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



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

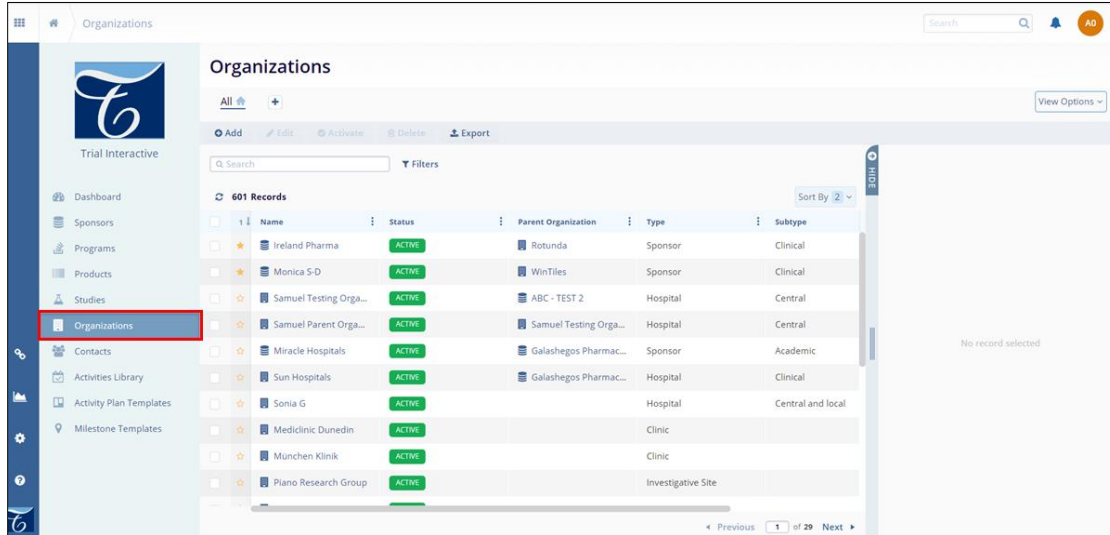


Note: To review sites associated with an organization, follow the same process. However, instead of clicking on the 'Studies' tab from the navigation link on the left side of the screen, click on the 'Site' tab to view all associated sites.

Customized Data Export

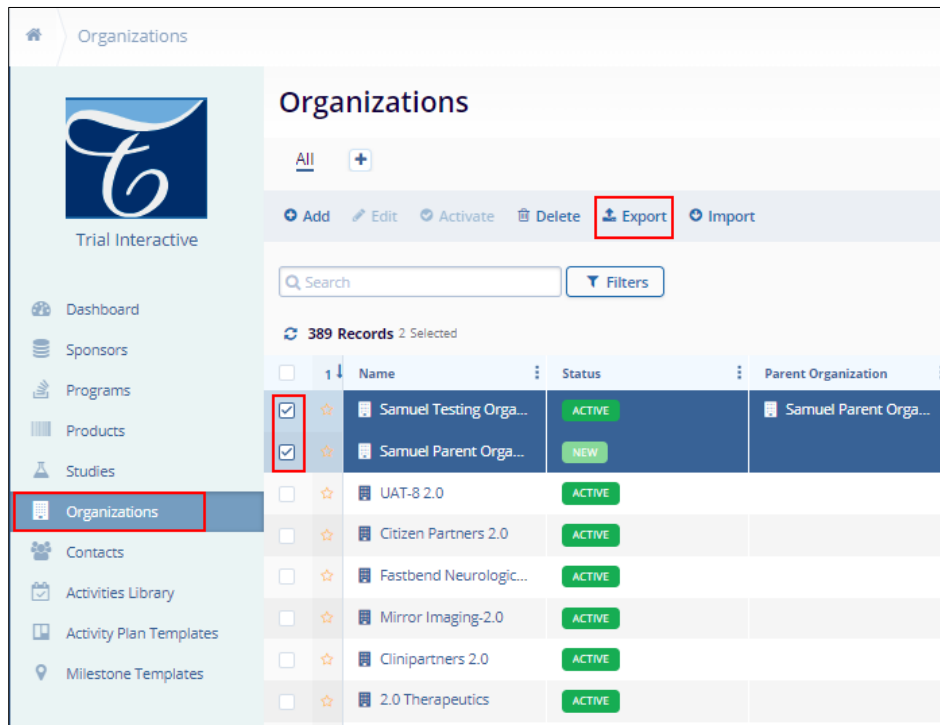
To navigate to the organization list and view all global organizations, follow these steps:

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



To Customized Data Export, Follow the below steps:

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

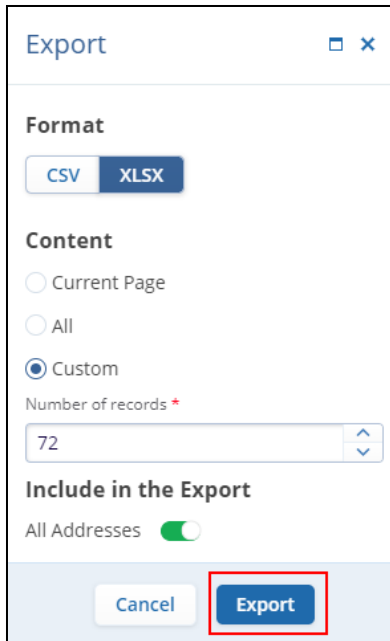


- On the **Export** dialog box, select the file format to export the contacts data. Users can export Organization in either **CSV** or **XLSX** file formats.
For the **CSV** or **XLSX** file formats, select either of the following:

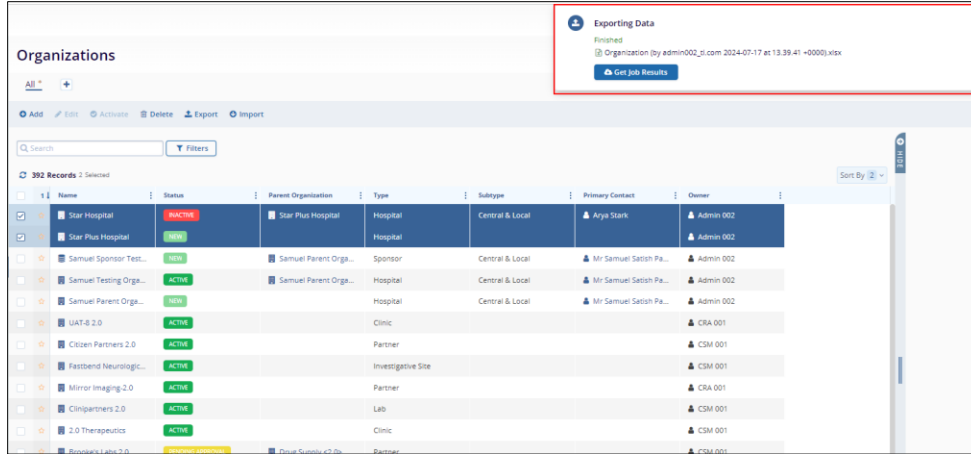
- **Current Page:** This option will export data on the existing page of the organization screen.
- **All:** This option will consider all the contact data.
- **Custom:** Here, specify the number of records to be exported by either clicking on the up and down arrows or entering the number of records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

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

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



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

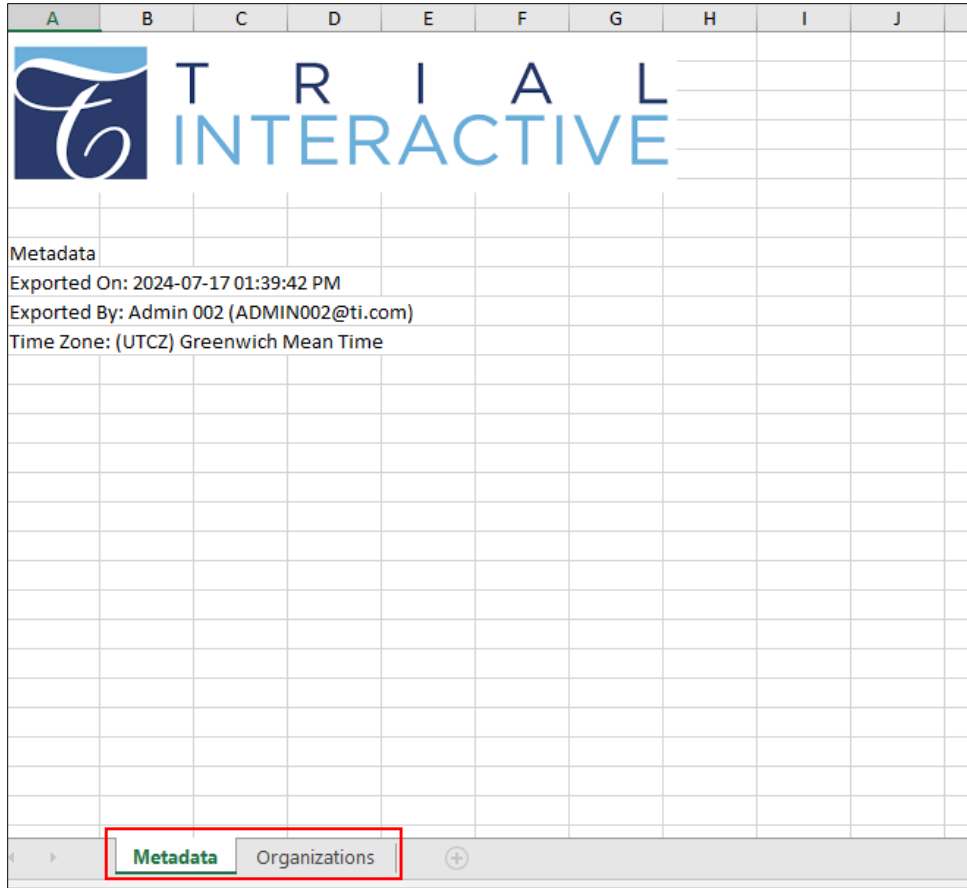


- The files will be downloaded to the local systems and will display the file formats.
 - The CSV file will display, just one tab with the contact details.

Favorite	Name	Status	Parent Org	Type	Subtype	Primary Contact	Owner
No	Star Hospital	Inactive	Star Plus Hospital	Hospital	Central & Local	Arya Stark	Admin 002
No	Star Plus Hospital	New		Hospital			Admin 002
No	Samuel Sponsor Test...	New	Samuel Parent Orga...	Sponsor	Central & Local	Mr Samuel Satish Pa...	Admin 002
No	Samuel Testing Orga...	Active	Samuel Parent Orga...	Hospital	Central & Local	Mr Samuel Satish Pa...	Admin 002
No	Samuel Parent Orga...	New		Hospital	Central & Local	Mr Samuel Satish Pa...	Admin 002
No	UAT-8 2.0	Active		Clinic			CRA 001
No	Citizen Partners 2.0	Active		Partner			CSM 001
No	Fastbend Neurologi...	Active		Investigative Site			CSM 001
No	Mirror Imaging 2.0	Active		Partner			CRA 001
No	Clinipartn 2.0	Active		Lab			CSM 001
No	2.0 Therapeutics	Active		Clinic			CSM 001
No	Brooke's Lab 2.0	Pending Approval	Drug Support	Partner			CSM 001
No	Medical M	Approved		Partner		Erin Garne	CSM 001
No	Clinical W	Active		IRB/EC		Jacob Rob	CSM 001
No	Delta Co. ;	Active		Partner		John Jacob	CSM 001
No	Atlas Supp	Active		Supplier		Jack Smit	CSM 001
No	Acme Inc ;	Active		Partner			CSM 001
No	Acme Inc ;	Active		Investigative Site		Barbra M	CSM 001
No	Subject Se	Active		Sponsor			Hope Weisser
No	Subject Ce	Active		Clinic			Hope Weisser

The XLSX file will display the following two tabs:

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

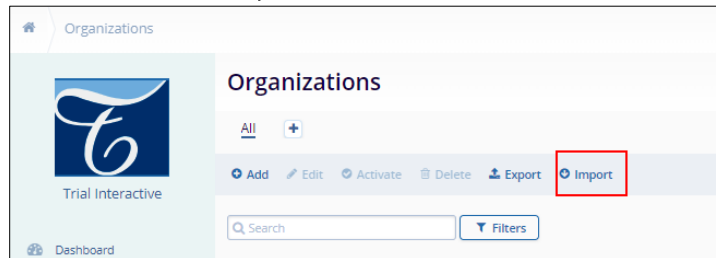


- **Organization:** This tab has the organization details.

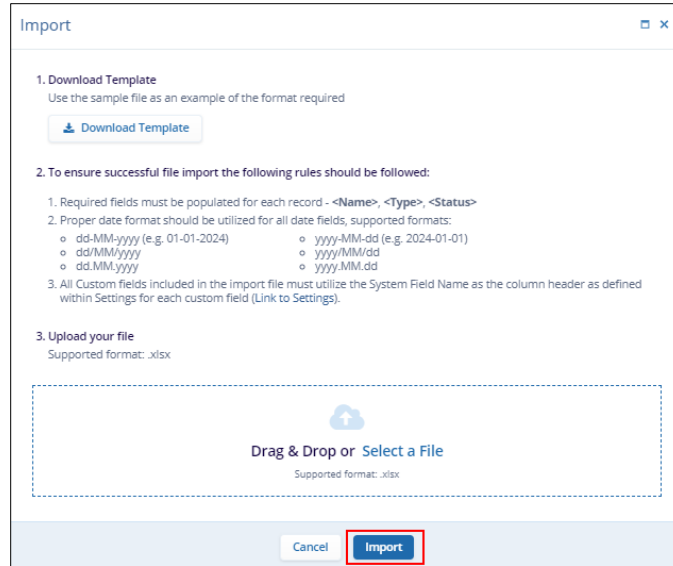
Import Data

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

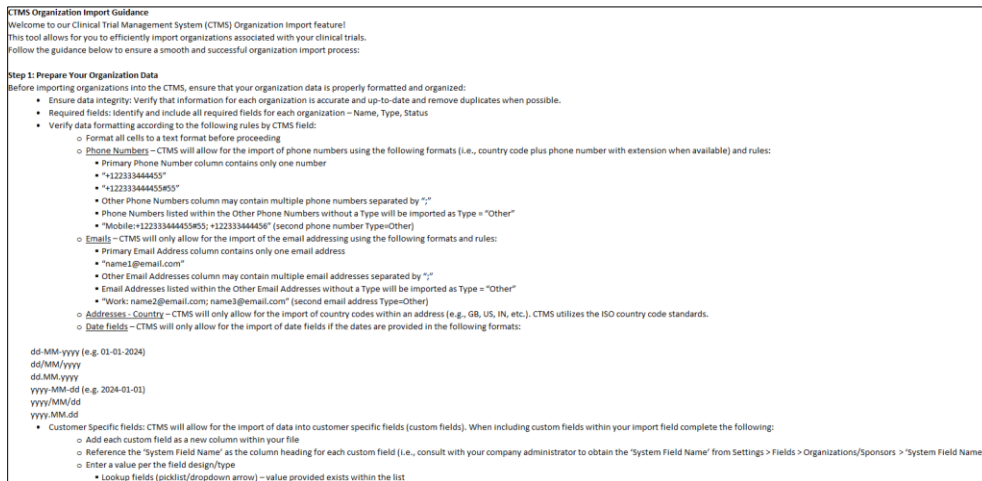
1. Click on the "Organizations" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Organizations" page where all organizations at the global level will be displayed.
3. To import the data, Click on the import button.



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



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



6. Click the “Import” button.

Contacts

Pre-requisites

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

Levels of Contact Creation in the Application

There are multiple levels of creating and managing a contact.

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



Creating a Contact

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

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

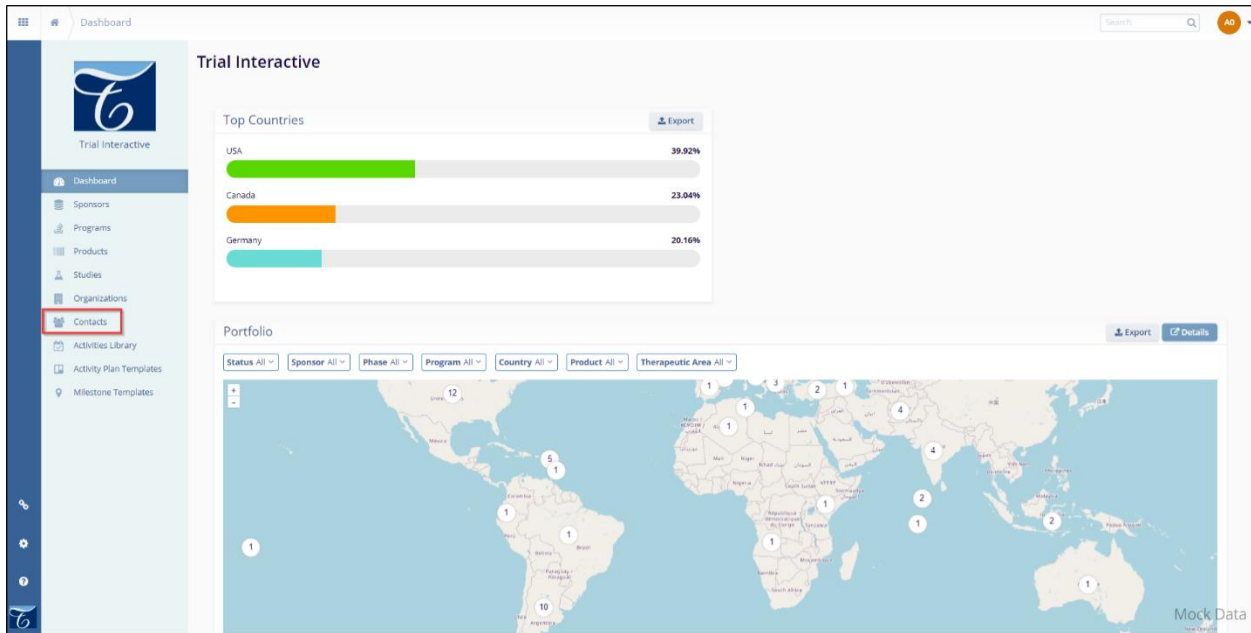


Figure: Select Contacts

Steps to create a contact

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

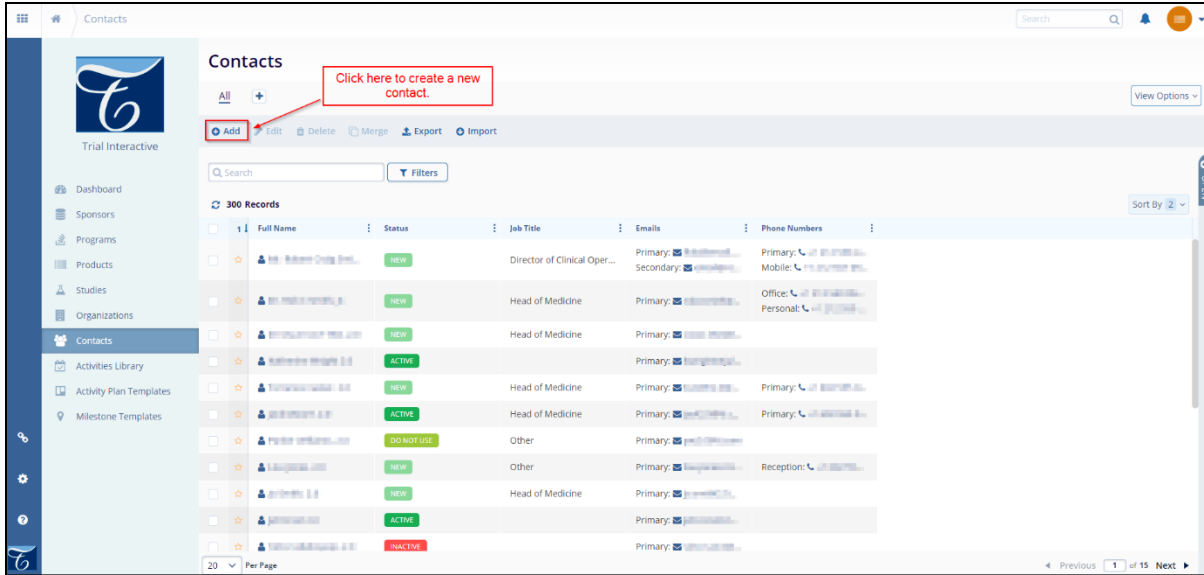


Figure: Create a new contact

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

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

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

Figure: Add contact details

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

Contacts

All +

Add Edit Delete Merge Export Import

Search Filters

301 Records

<input type="checkbox"/>	1 ↓	Full Name	Status	Job Title	Emails	Phone Numbers
<input type="checkbox"/>	☆	Miguel Lopez	NEW			
<input type="checkbox"/>	☆	Dr. Robert [Redacted]	NEW	Director of Clinical Oper...	Primary: [Redacted] Secondary: [Redacted]	Primary: [Redacted] Mobile: [Redacted]
<input type="checkbox"/>	☆	Dr. [Redacted]	NEW	Head of Medicine	Primary: [Redacted]	Office: [Redacted] Personal: [Redacted]
<input type="checkbox"/>	☆	Dr. [Redacted]	NEW	Head of Medicine	Primary: [Redacted]	
<input type="checkbox"/>	☆	[Redacted]	ACTIVE		Primary: [Redacted]	
<input type="checkbox"/>	☆	[Redacted]	NEW	Head of Medicine	Primary: [Redacted]	Primary: [Redacted]
<input type="checkbox"/>	☆	[Redacted]	ACTIVE	Head of Medicine	Primary: [Redacted]	Primary: [Redacted]
<input type="checkbox"/>	☆	[Redacted]	DO NOT USE	Other	Primary: [Redacted]	
<input type="checkbox"/>	☆	[Redacted]	NEW	Other	Primary: [Redacted]	Reception: [Redacted]
<input type="checkbox"/>	☆	[Redacted]	NEW	Head of Medicine	Primary: [Redacted]	

Figure: New Contact

Editing a Contact

To edit a Contact, follow the steps below.

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

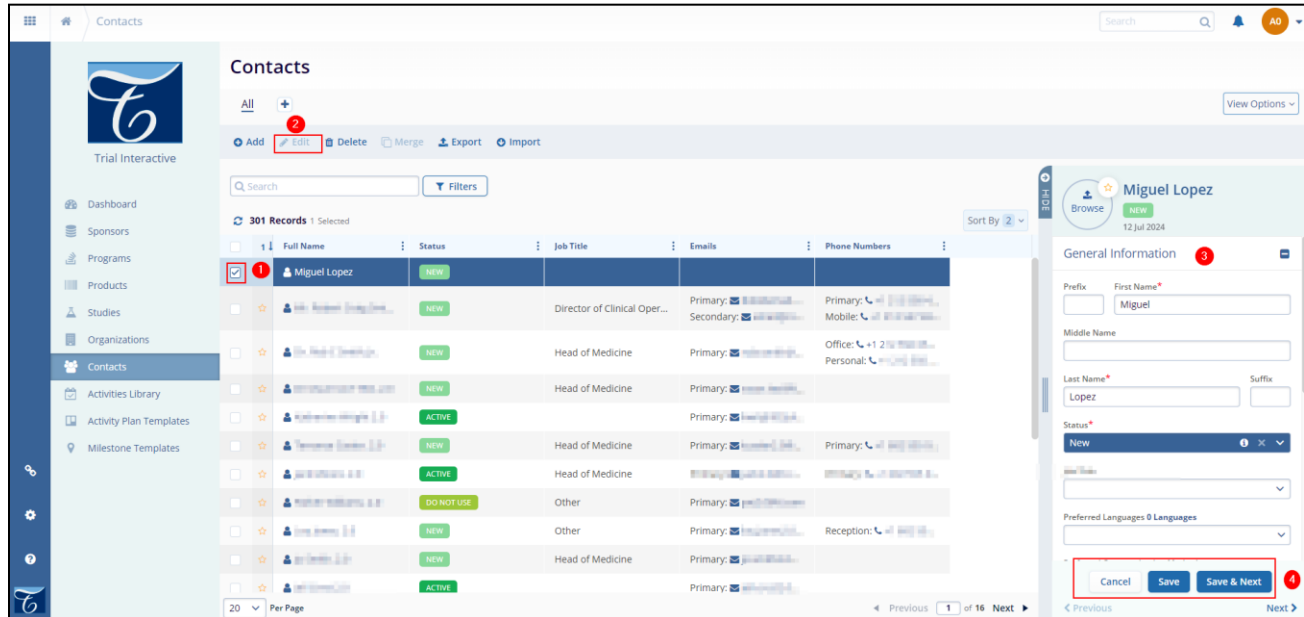


Figure: Editing a Contact

Note:

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

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

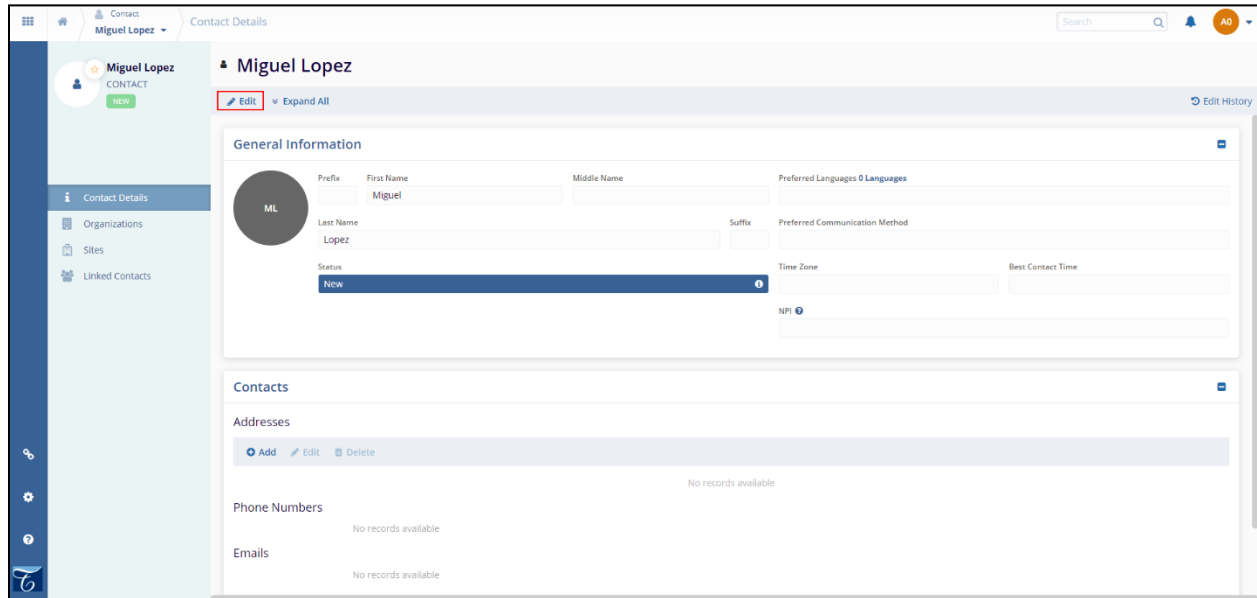
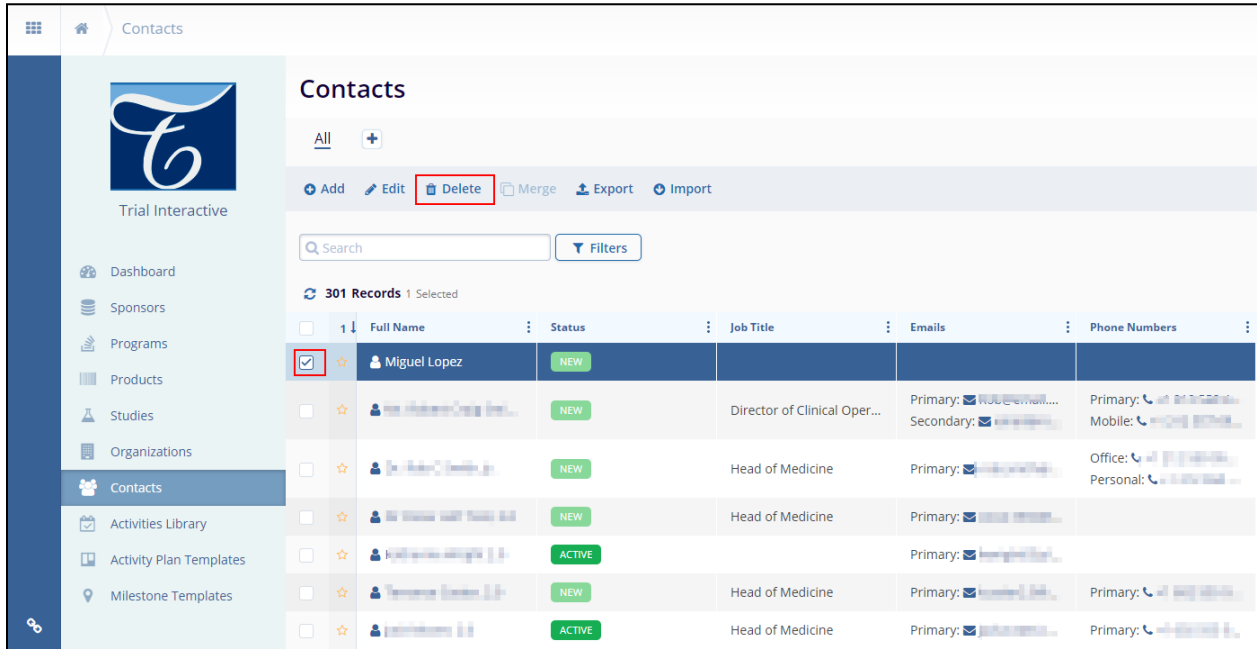


Figure: Edit contact on the Contact Details page

Deleting a Contact

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

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



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

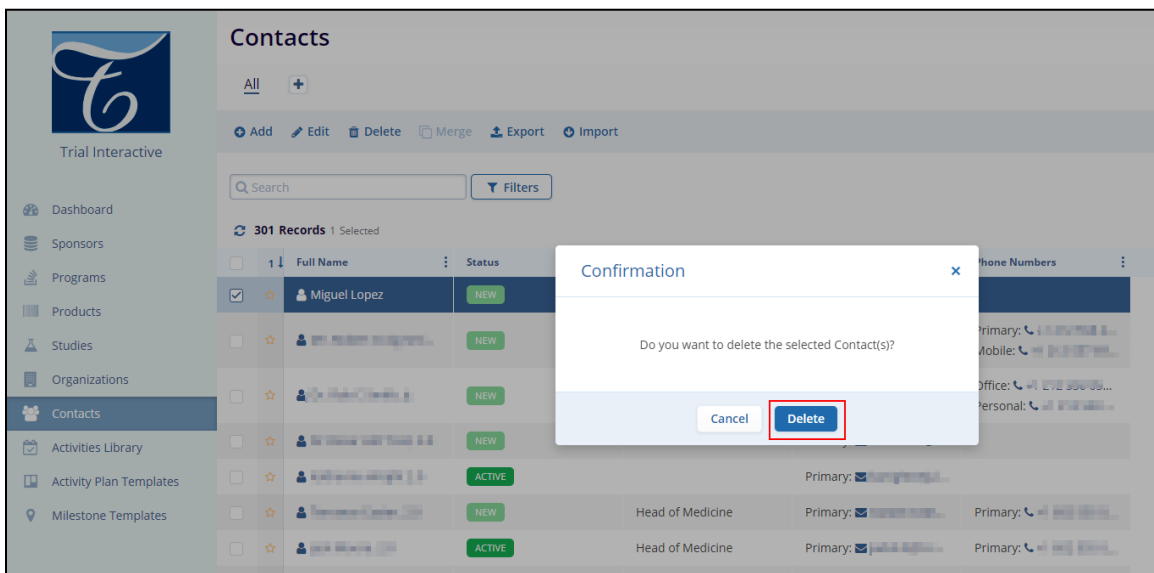


Figure: Contact deletion confirmation message

Merging Contacts

To merge contacts, follow the steps below.

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

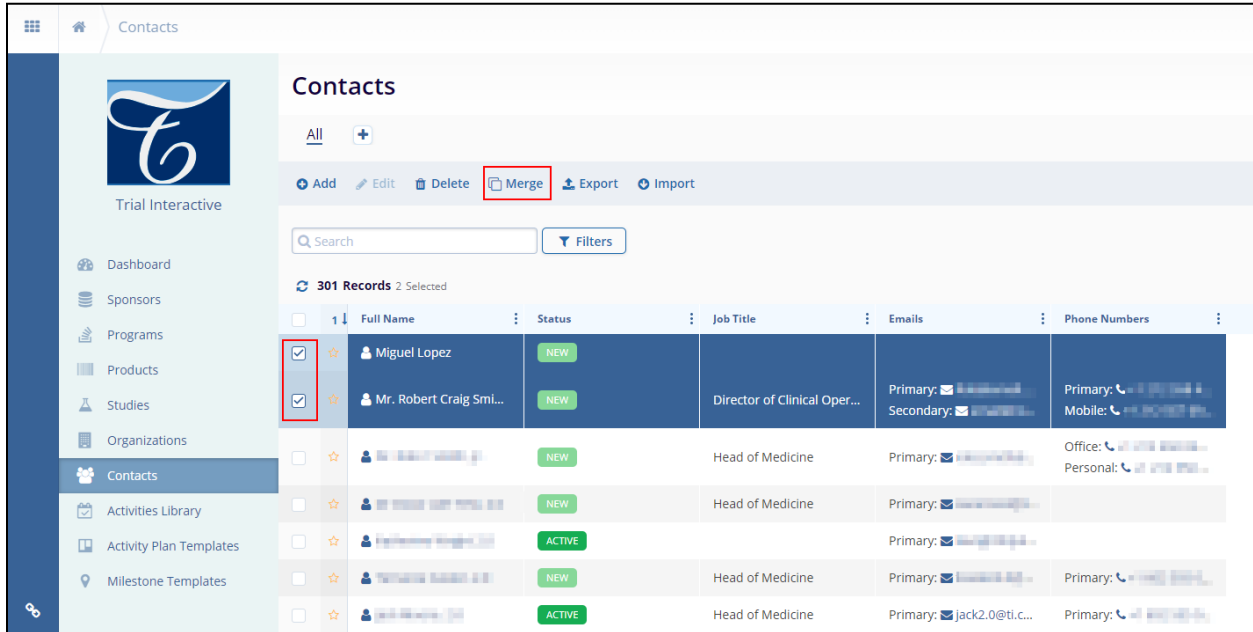


Figure: Merge Contacts

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

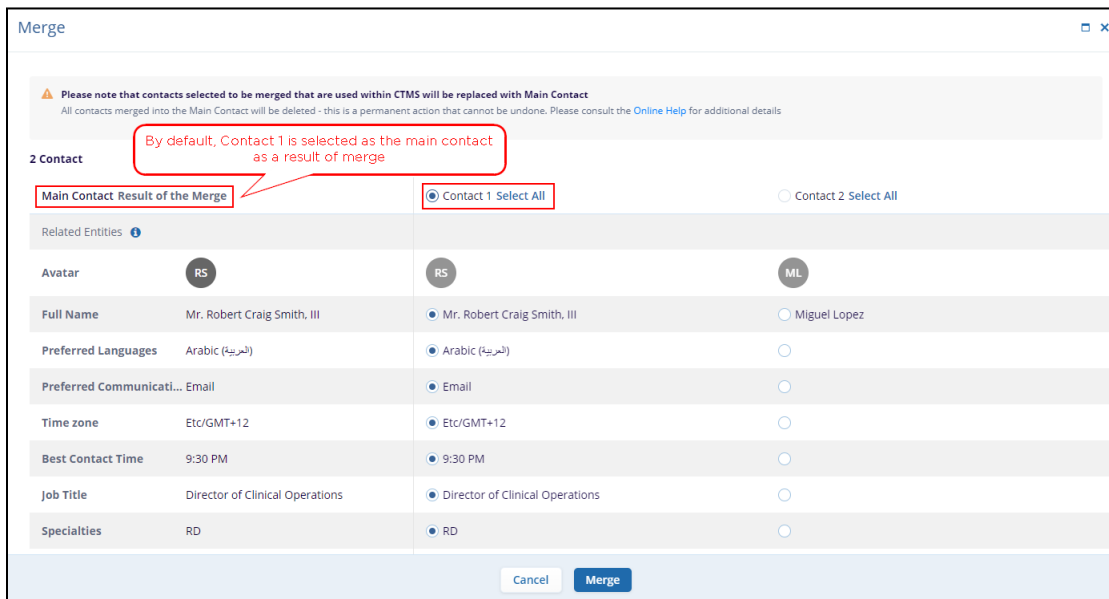


Figure: Contact 1 as the main contact

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

The screenshot shows a 'Merge' dialog box with a warning message: 'Please note that contacts selected to be merged that are used within CTMS will be replaced with Main Contact. All contacts merged into the Main Contact will be deleted - this is a permanent action that cannot be undone. Please consult the Online Help for additional details.' Below this, there are two columns representing 'Contact 1' and 'Contact 2'. At the top, 'Main Contact Result of the Merge' is set to 'Contact 1 Select All'. The 'Full Name' field for Contact 2 is highlighted with a red box, showing 'Miguel Lopez' selected. Other fields like 'Preferred Languages' and 'Preferred Communicati... Email' are also visible. At the bottom, there are 'Cancel' and 'Merge' buttons.

Figure: Merge individual entries from Contact 2

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

This screenshot is similar to the previous one, but now 'Contact 2 Select All' is selected under 'Main Contact Result of the Merge'. A red callout box points to the 'Select All' radio button with the text: 'Select All will consider all entries from Contact 2'. The 'Merge' button at the bottom is also highlighted with a red box.

Figure: Merge all entries from contact 2

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

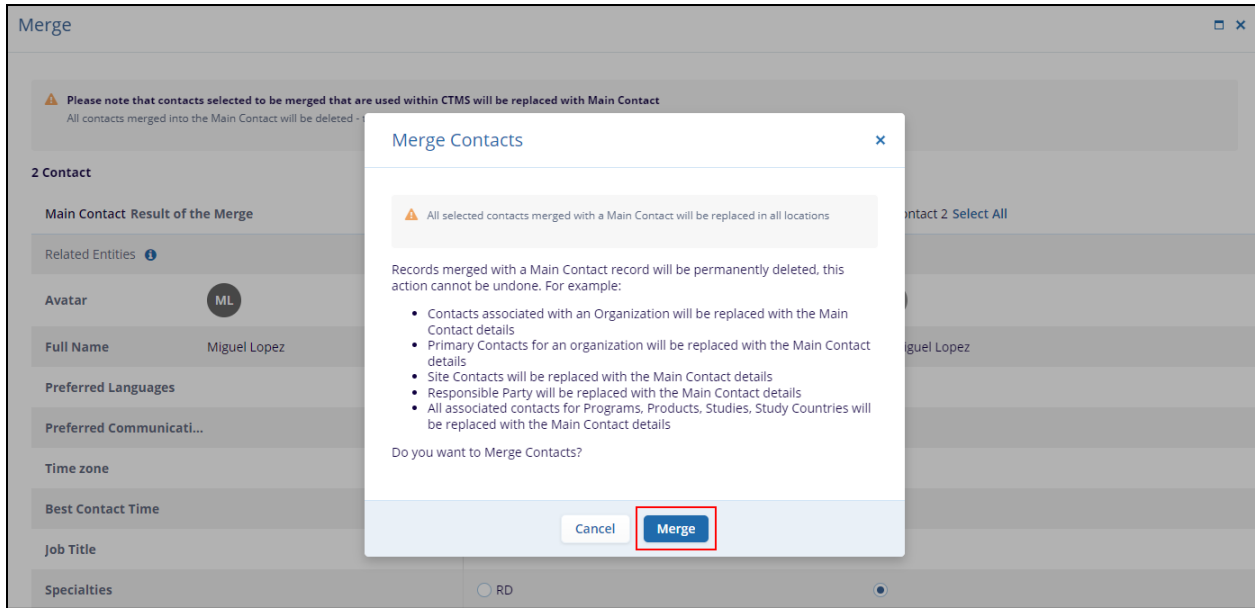


Figure: Merge Contacts confirmation popup

Exporting Contacts

To export contacts, follow the steps below.

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

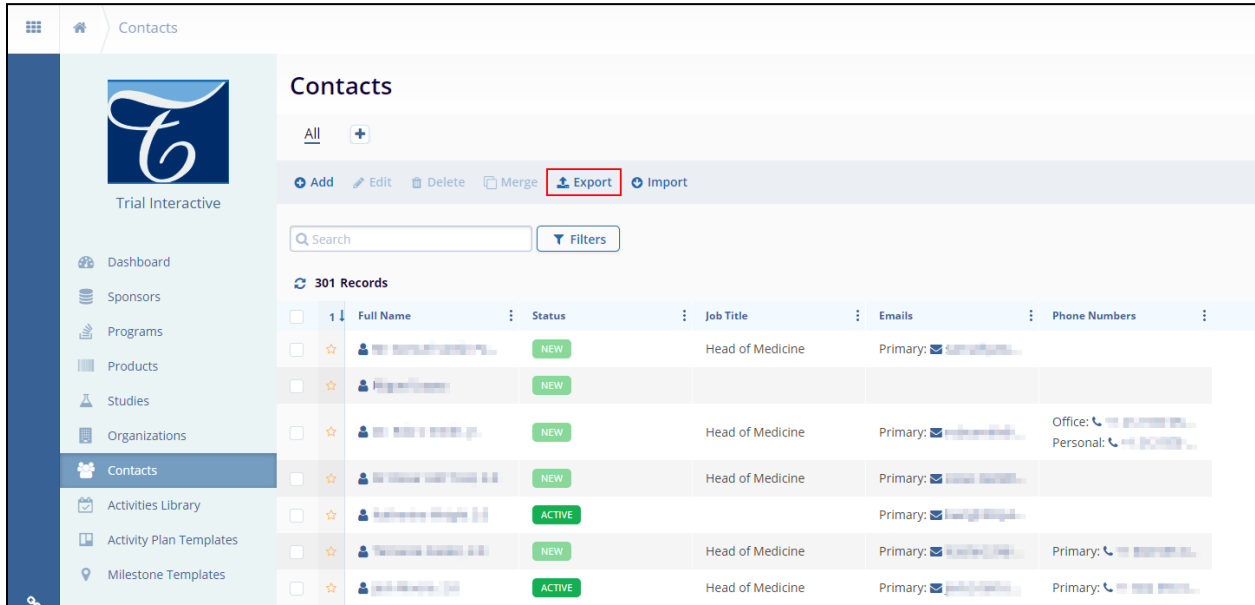


Figure: Select Export

- On the **Export** dialog box, select the file format to export the contacts data. Users can export contacts in either **CSV** or **XLSX** file formats.
- For the **CSV** or **XLSX** file formats, select either of the following:
 - Current Page:** This option will export data on the existing page of the Contacts screen.
 - All:** This option will consider all the contact data.
 - Custom:** Here, specify the number of records to be exported by either clicking on the up and down arrows or entering the number of records since it is a free text field.
 - Include in Report:** Click on the **All Addresses** toggle button to include addresses in the exported file.

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

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

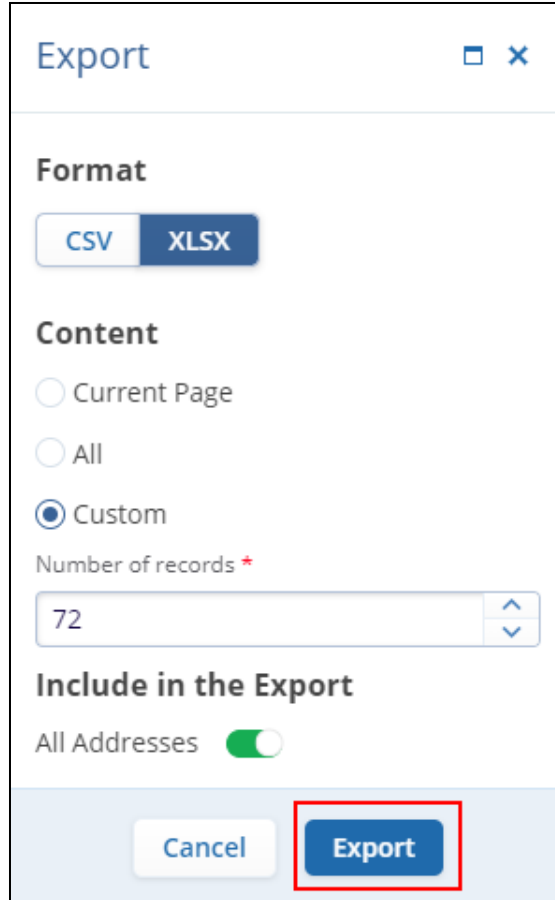


Figure: Export contacts file formats

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

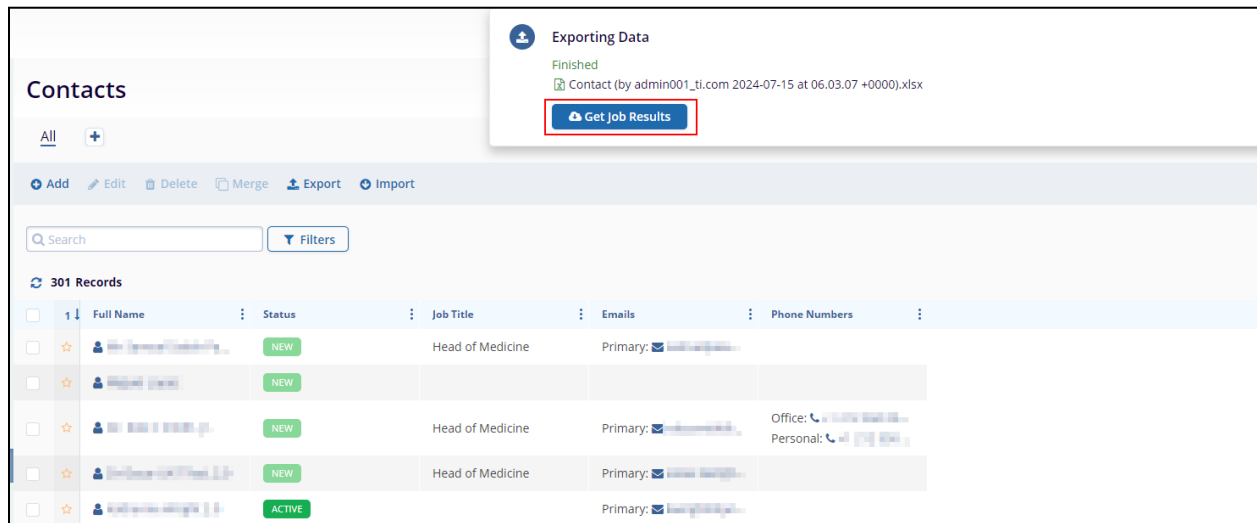


Figure: Get Job Results

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

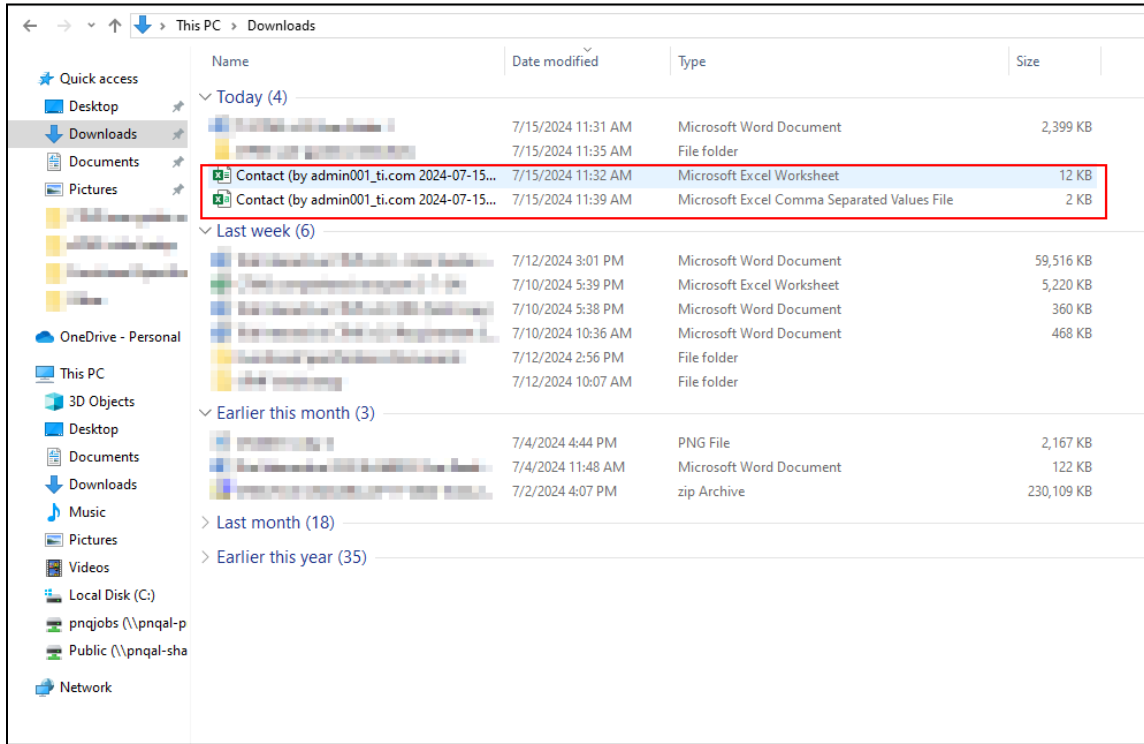


Figure: Exported files in CSV and XLSX file format

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

	A	B	C	D	E	F	G	H	I	J	K
1	Favorite	Full Name	Status	Job Title	Emails	Phone Numbers	Site Name	Site Num	Study Num	Study Number	
2	No	[REDACTED]	New	Head of Medicine	[REDACTED]						
3	No	[REDACTED]	New								
4	No	[REDACTED]	New	Head of Medicine	[REDACTED]	[REDACTED]					
5	No	[REDACTED]	New	Head of Medicine	[REDACTED]						
6	No	[REDACTED]	Active		[REDACTED]						
7	No	[REDACTED]	New	Head of Medicine	[REDACTED]	[REDACTED]					
8	No	[REDACTED]	Active	Head of Medicine	[REDACTED]	[REDACTED]					
9	No	[REDACTED]	Do not use	Other	[REDACTED]						
10	No	[REDACTED]	New	Other	[REDACTED]	[REDACTED]					
11	No	[REDACTED]	New	Head of Medicine	[REDACTED]						
12	No	[REDACTED]	Active		[REDACTED]						
13	No	[REDACTED]	Inactive		[REDACTED]						
14	No	[REDACTED]	Active		[REDACTED]						
15	No	[REDACTED]	Active		[REDACTED]						
16	No	[REDACTED]	Active		[REDACTED]						
17	No	[REDACTED]	New		[REDACTED]	[REDACTED]					
18	No	[REDACTED]	New		[REDACTED]						
19	No	[REDACTED]	New		[REDACTED]	[REDACTED]					
20	No	[REDACTED]	New		[REDACTED]	[REDACTED]					
21	No	[REDACTED]	New	Director of Clinical Operations	[REDACTED]	[REDACTED]					
22											
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37											

Figure: CSV file export

The XLSX file will display the following two tabs:

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

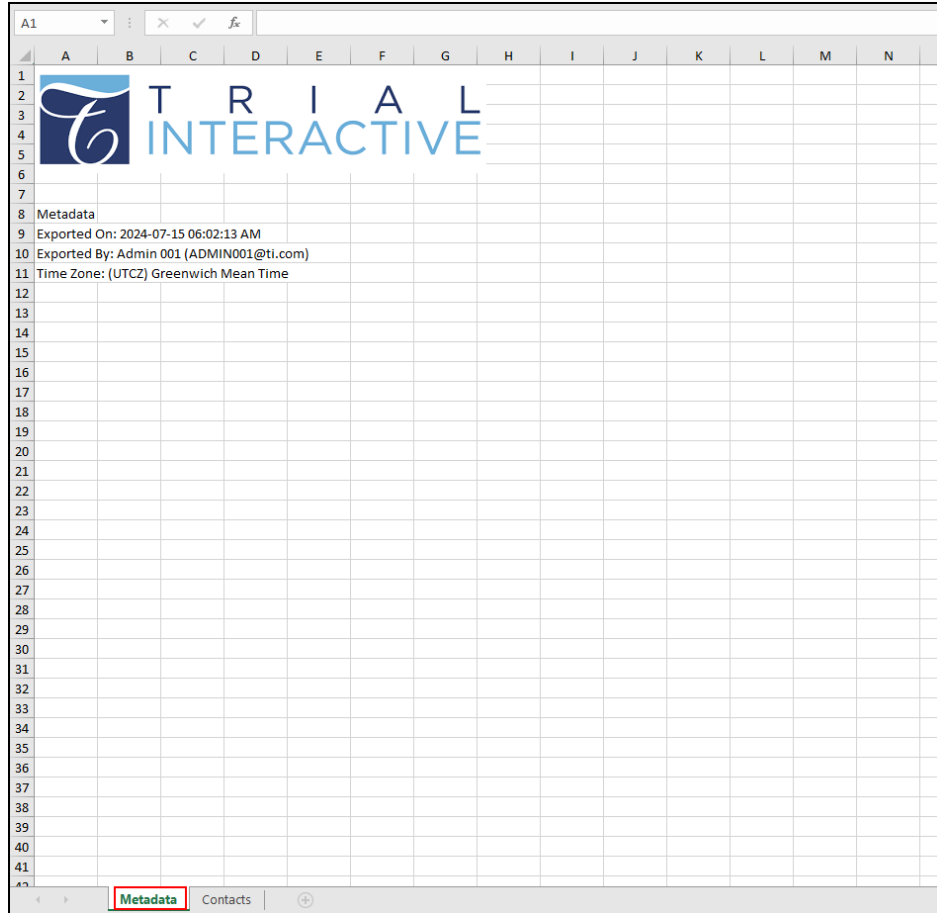


Figure: XLSX file-Metadata tab

- **Contacts:** This tab has the contact details.

	A	B	C	D	E	F	G	H	I	J
1	Favorite	Full Name	Status	Job Title	Emails	Phone Numbers	Site Name	Site Number	Study Name	Study Number
2	No	[Redacted]	New	Head of Medicine	[Redacted]					
3	No	[Redacted]	New		[Redacted]					
4	No	[Redacted]	New	Head of Medicine	[Redacted]	[Redacted]				
5	No	[Redacted]	New	Head of Medicine	[Redacted]					
6	No	[Redacted]	Active		[Redacted]					
7	No	[Redacted]	New	Head of Medicine	[Redacted]	[Redacted]				
8	No	[Redacted]	Active	Head of Medicine	[Redacted]	[Redacted]				
9	No	[Redacted]	Do not use	Other	[Redacted]					
10	No	[Redacted]	New	Other	[Redacted]	[Redacted]				
11	No	[Redacted]	New	Head of Medicine	[Redacted]					
12	No	[Redacted]	Active		[Redacted]					
13	No	[Redacted]	Inactive		[Redacted]					
14	No	[Redacted]	Active		[Redacted]					
15	No	[Redacted]	Active		[Redacted]					
16	No	[Redacted]	Active		[Redacted]					
17	No	[Redacted]	New		[Redacted]	[Redacted]				
18	No	[Redacted]	New		[Redacted]					
19	No	[Redacted]	New		[Redacted]	[Redacted]				
20	No	[Redacted]	New		[Redacted]	[Redacted]				
21	No	[Redacted]	New	Director of Clinical Operations	[Redacted]	[Redacted]				
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Figure: XLSX file-Contacts tab

Importing Contacts

To import contacts in CTMS, follow the steps below.

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

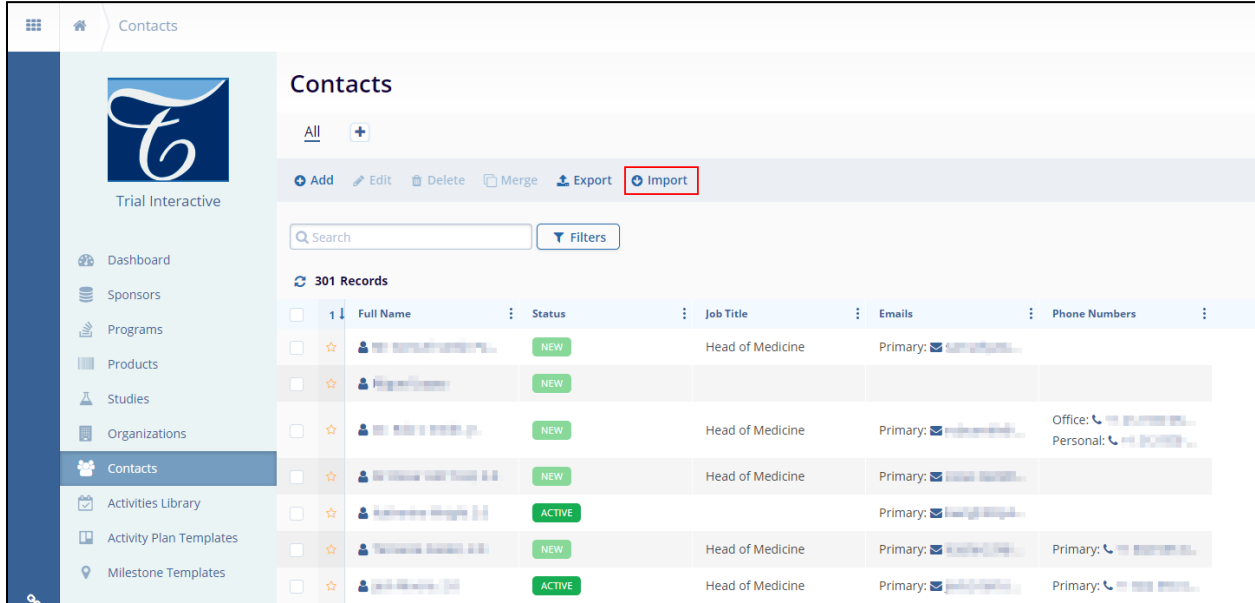


Figure: Select Import

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

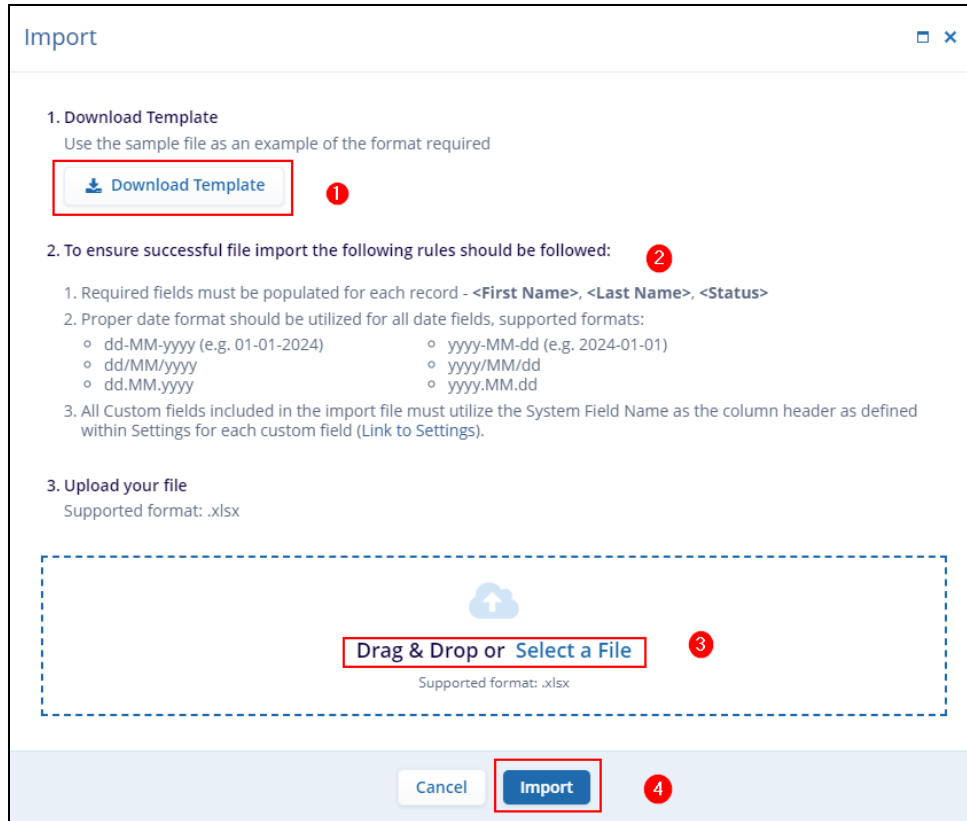


Figure: Import contacts process

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

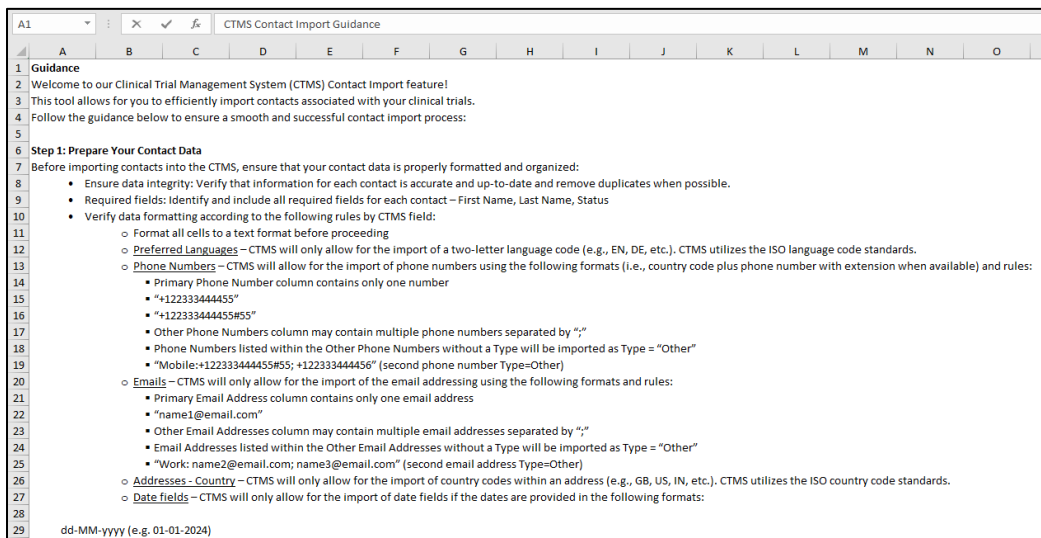


Figure: Contacts import template-Import Guidance

	A	B	C	D	E	F	G	H	I
1	Prefix	First Name	Middle Name	Last Name	Suffix	Status	Preferred Languages	Preferred Communication Method	NPI
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
22									
23									
24									

Figure: Contacts import template-Contacts

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

Contacts Views

Creating a Contact View

To create a Contact View, follow the steps below.

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

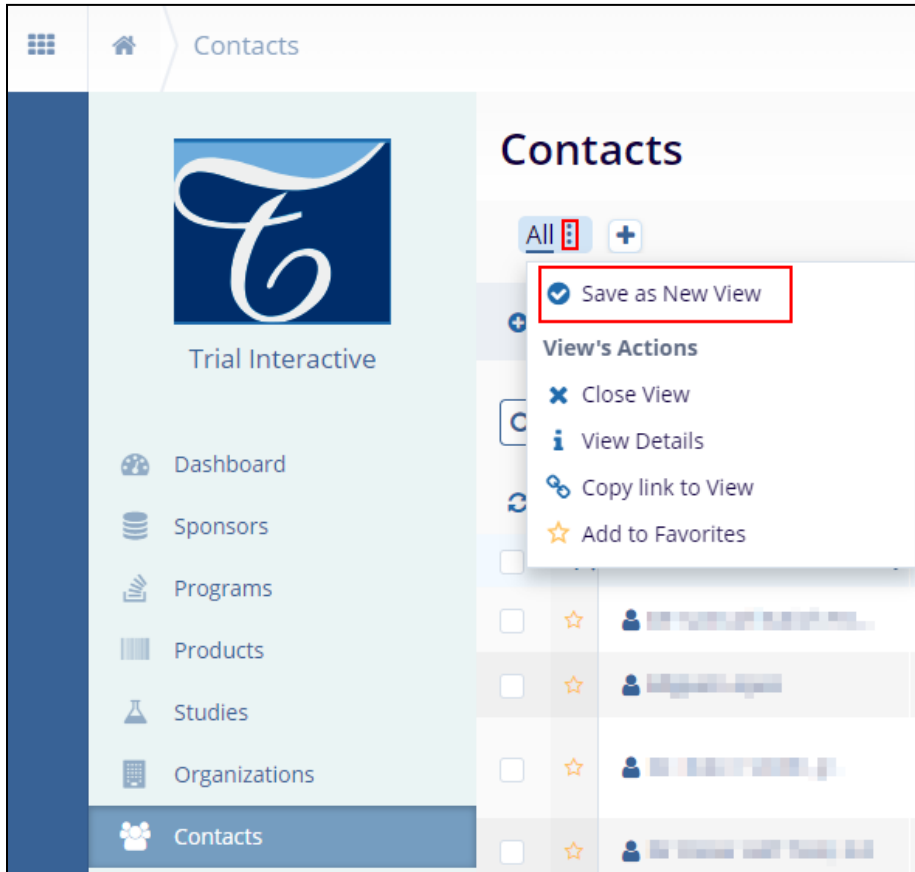


Figure: Save as New View

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

Save as New View
✕

View saves Filters, Column Customization, and Content View by default (list or card) if there are any

View Name*

Description

Latest Contacts view for reference.

Sharing Options

Private
Only I can see and use this view

Public
Anyone can see and use this view

Set as Default

Figure: Save as New View Configuration

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

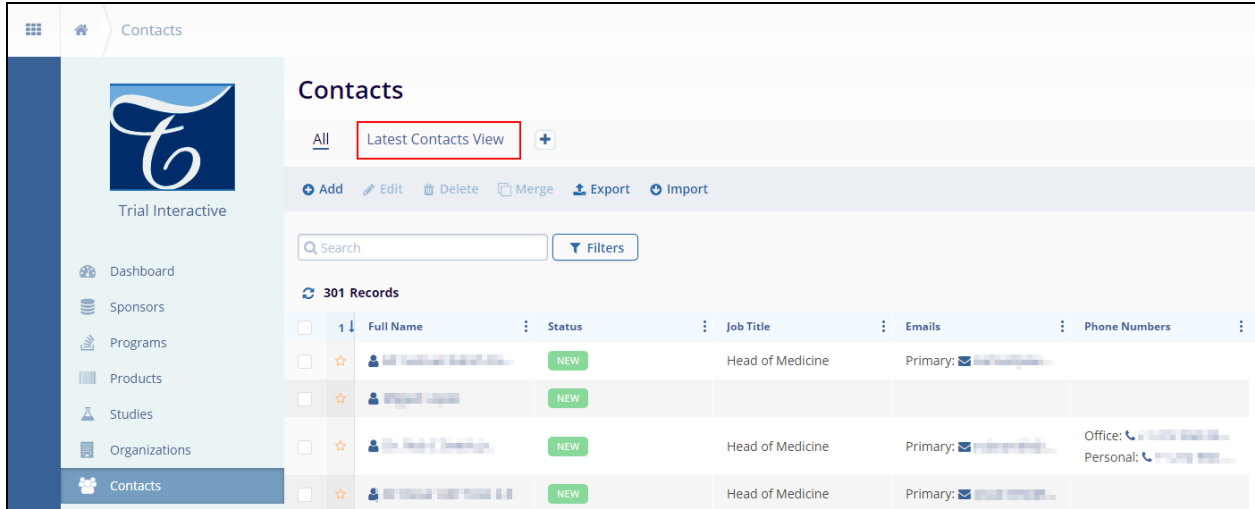


Figure: New contacts view on the home screen

Accessing View's Actions

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

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

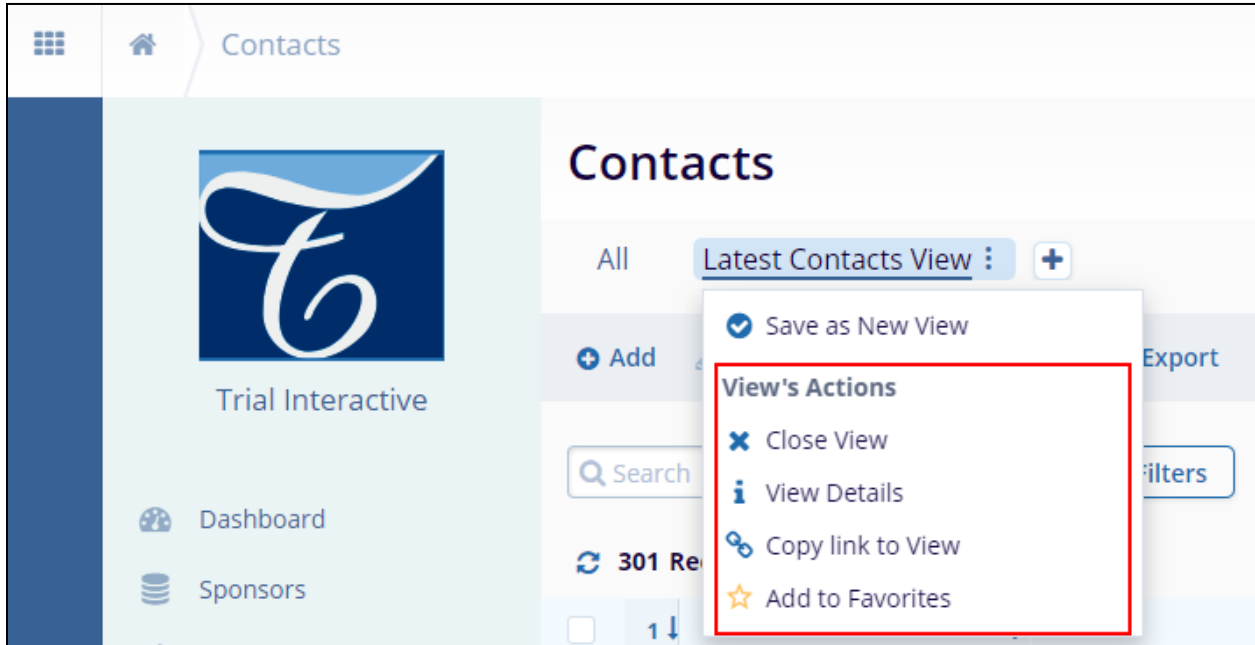


Figure: Accessing View's Actions

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

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

Adding a View

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

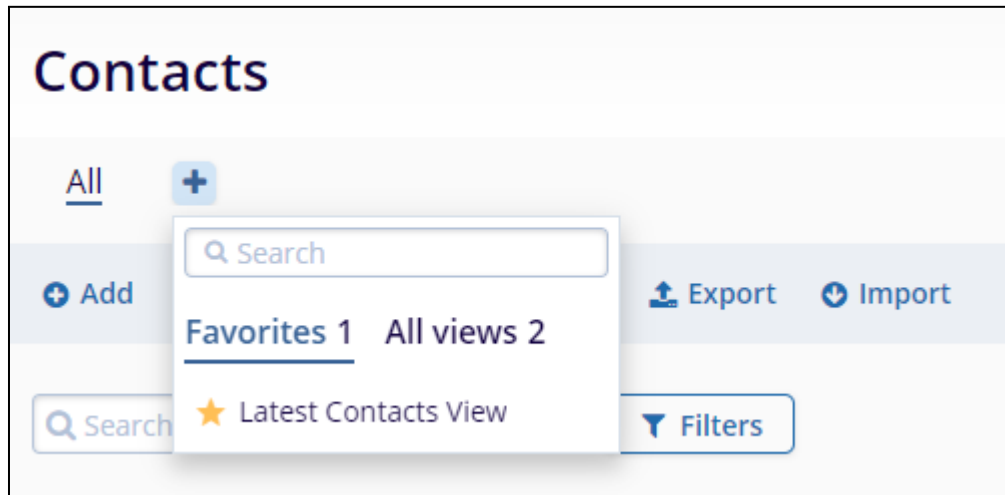


Figure: Adding a new

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

All View's Actions

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

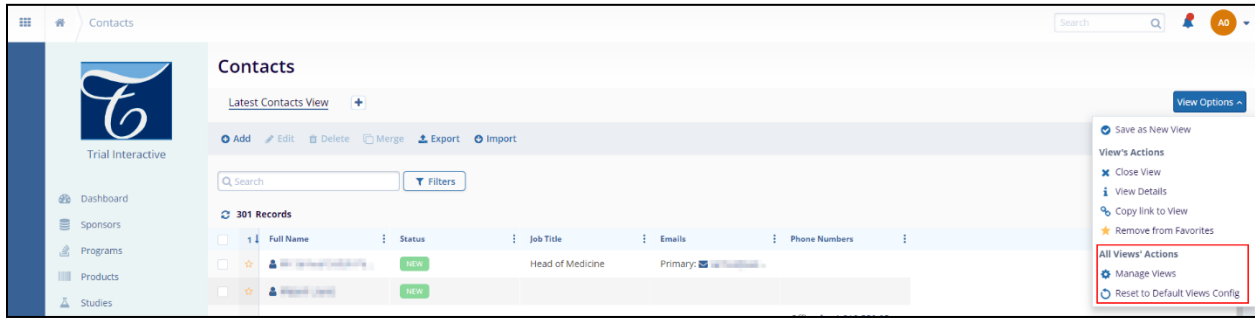


Figure: All View's Actions

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

1. **Manage Views:** The Manage View's screen displays views bifurcated by **All Views, Favorites, Created By Me, and Default**. On this screen, perform the following actions.
 - a. Access all the **View's Actions** by selecting an individual view.
 - b. Filter the records by applying the **Created By, Share Options, and Add to Page** filters.
 - c. Click on **+Add** to add the view on the Contacts home page.
 - d. Sort the data in Ascending and Descending order by applying different sorting criteria.

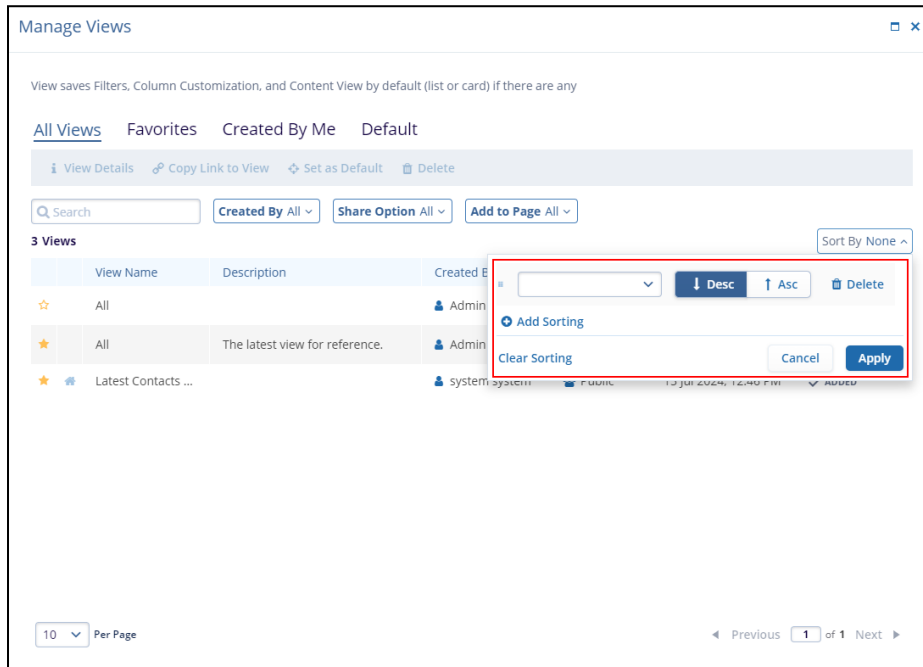


Figure: Sort views

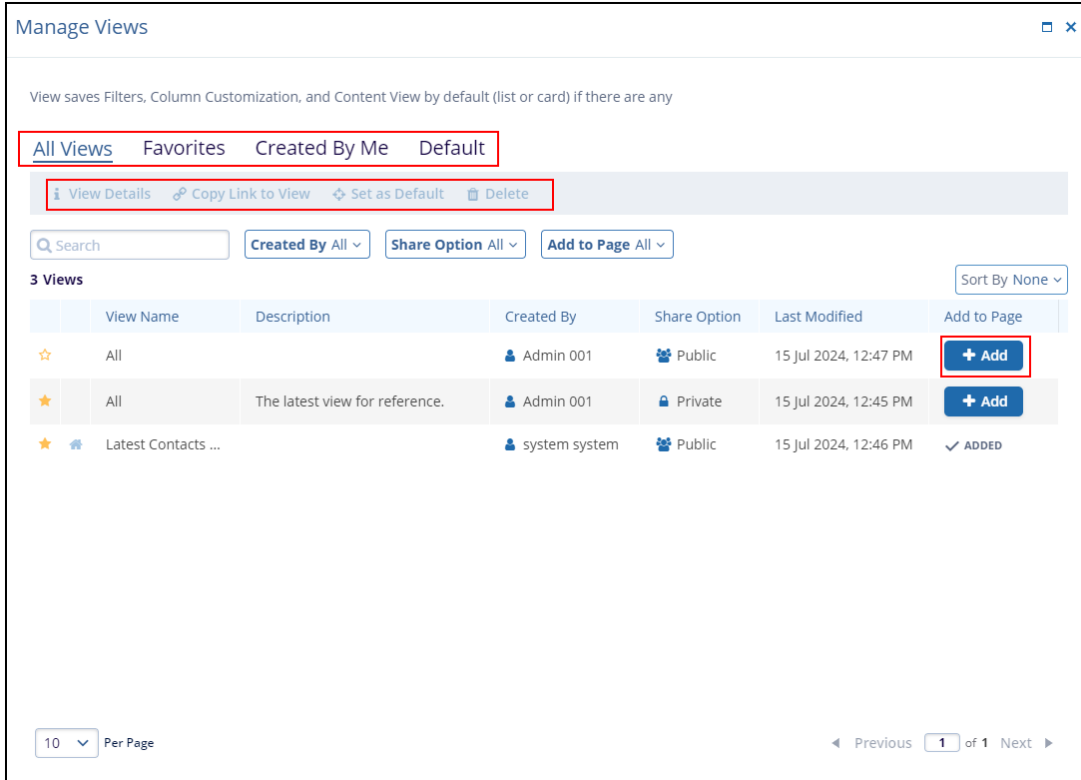


Figure: Manage Views

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

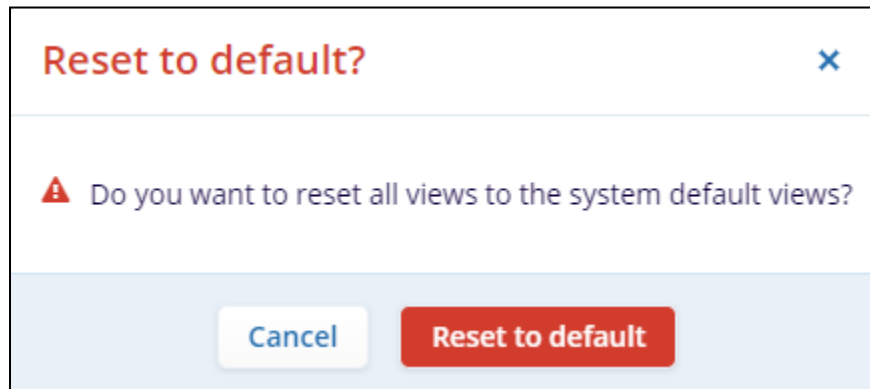


Figure: Reset to Default Views Config

Customizing Contacts screen

Filters

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

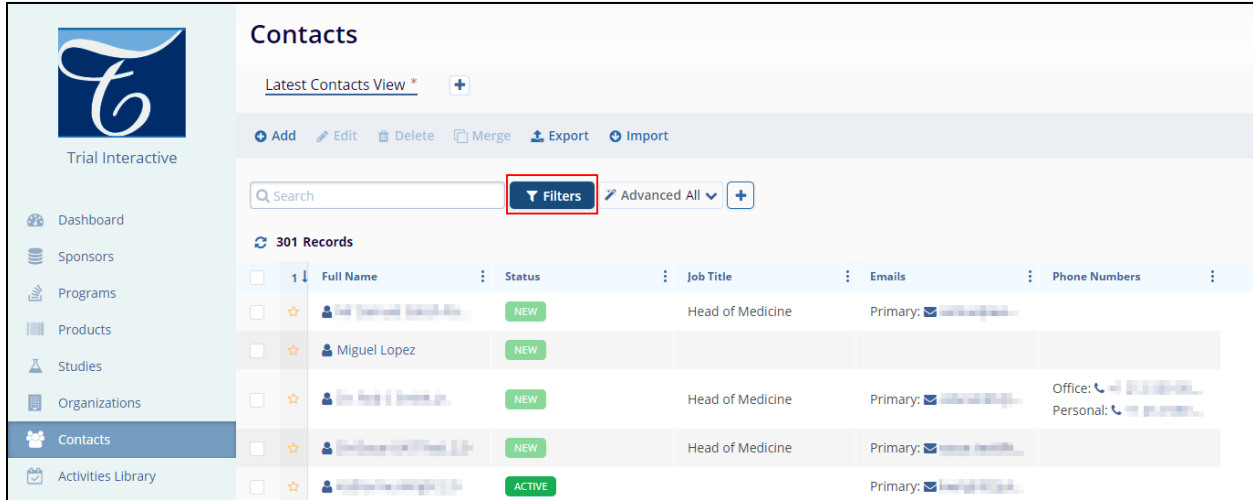


Figure: Add Filters

Standard Filters

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

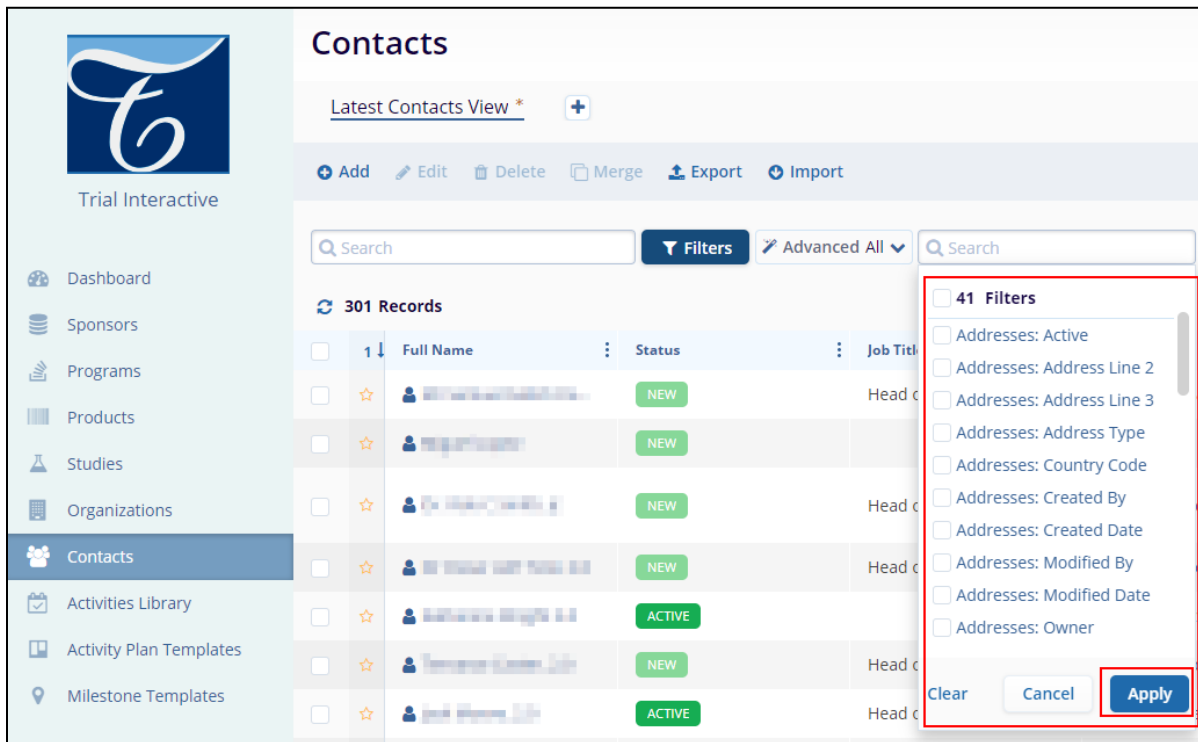


Figure: Apply standard filters

Advanced Filters

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

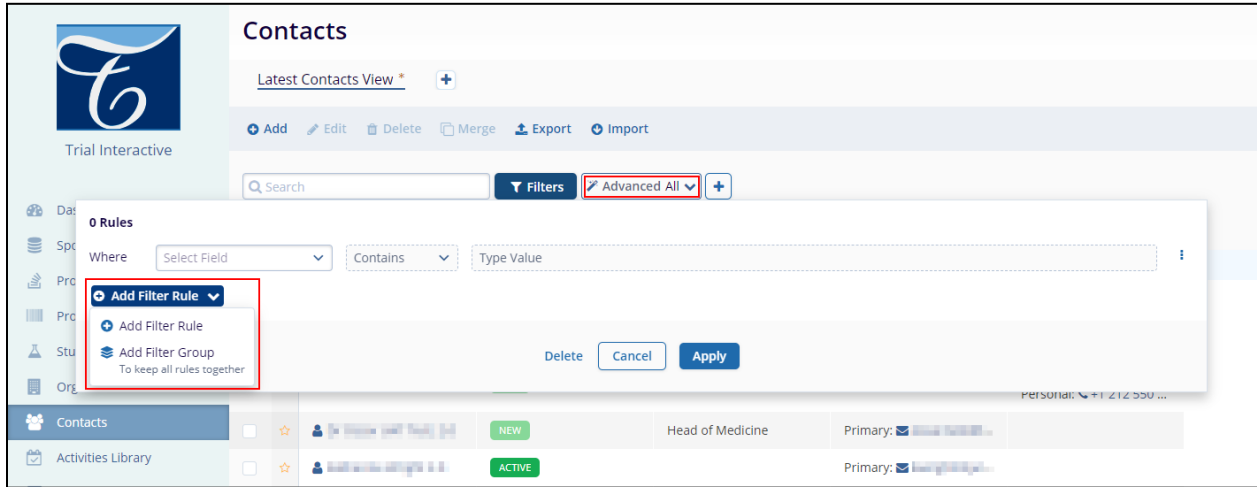


Figure: Apply Advanced Filters

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

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

Important

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

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

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

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

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

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

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

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

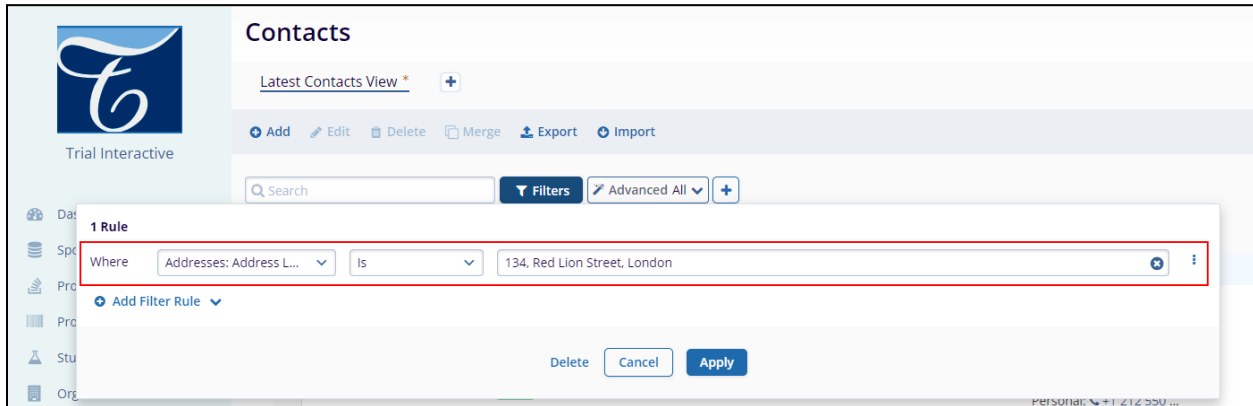


Figure: Configure Advanced filters

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

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

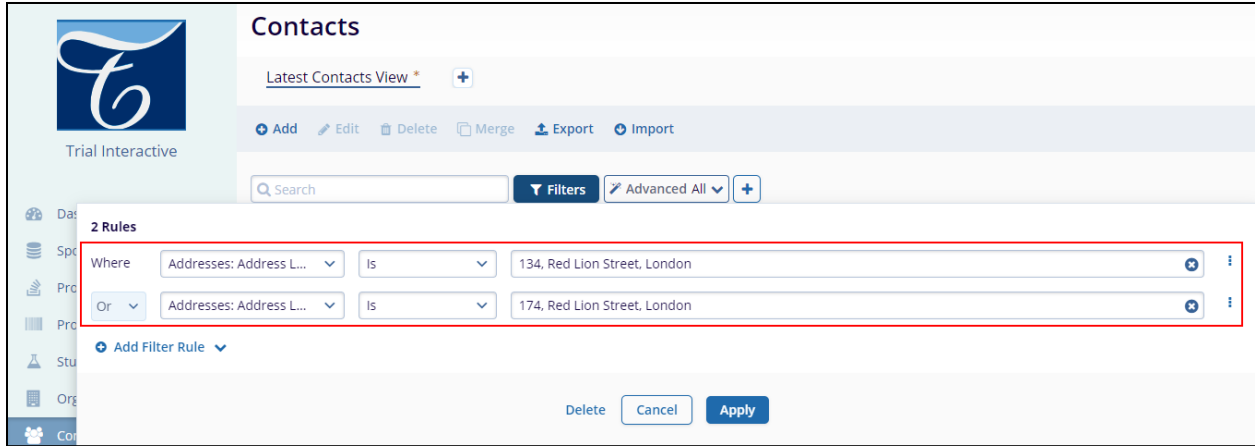


Figure: Advanced filters with And/Or conditions

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

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

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

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

Customize Columns

Hide Column

To hide a column, follow the steps below.

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

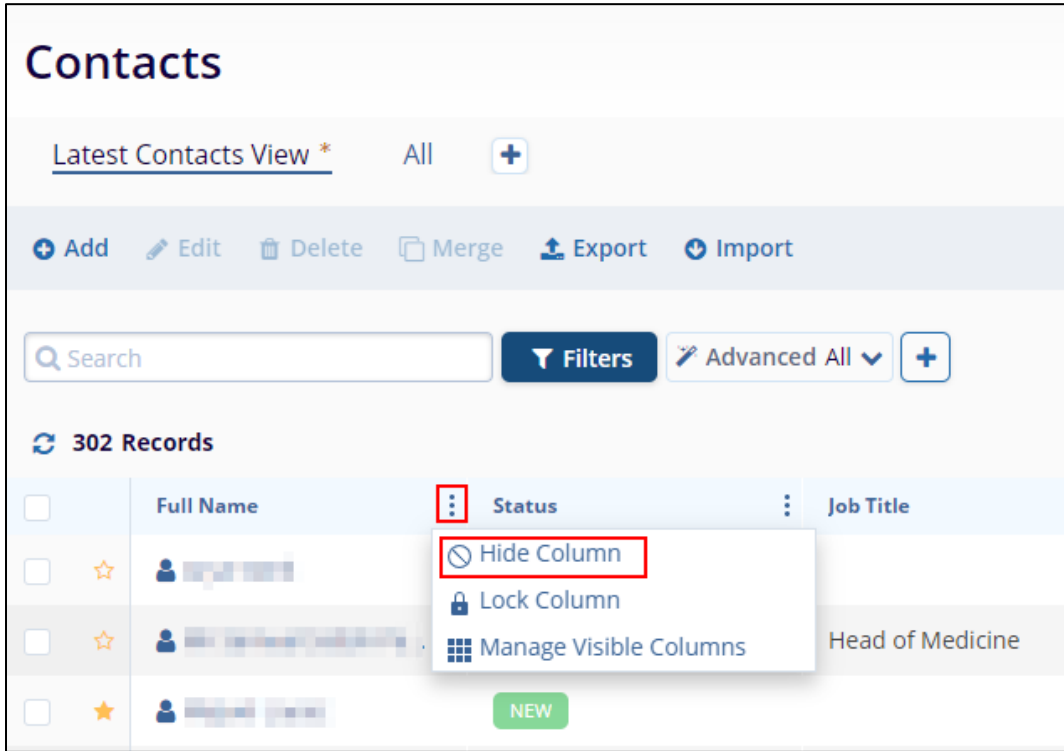


Figure: Hide Column

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

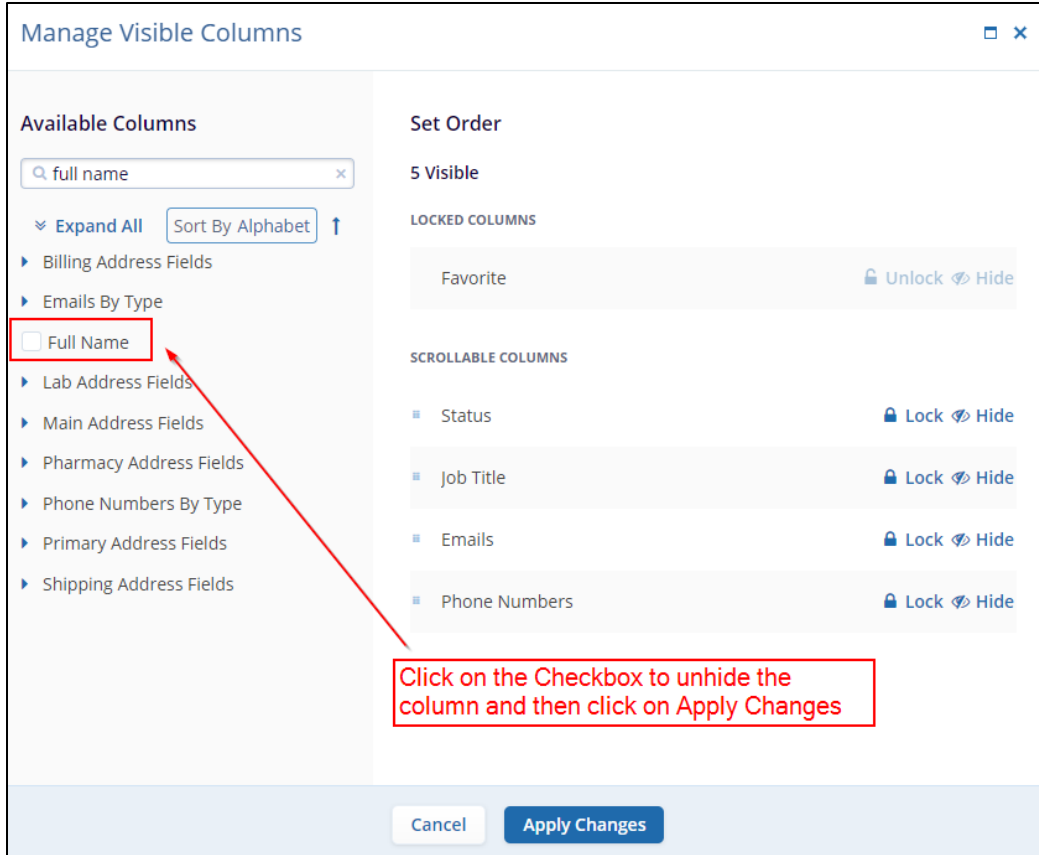


Figure: Unhide column

Lock Column

To lock a column, follow the steps below.

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

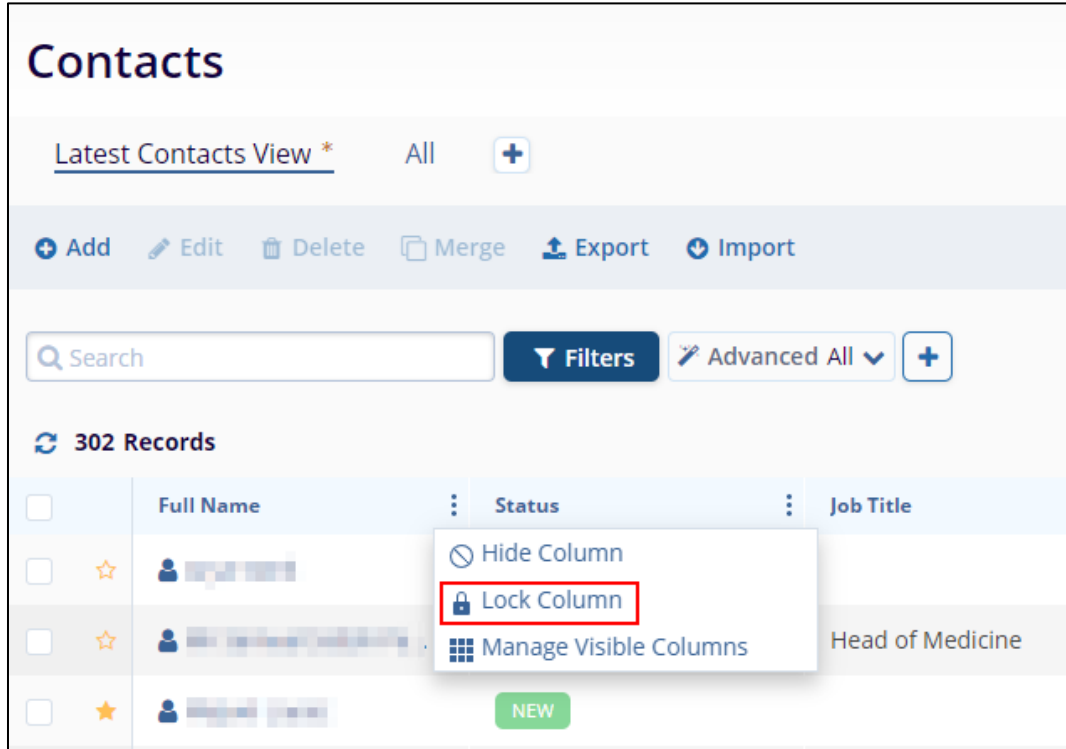


Figure: Lock Column

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

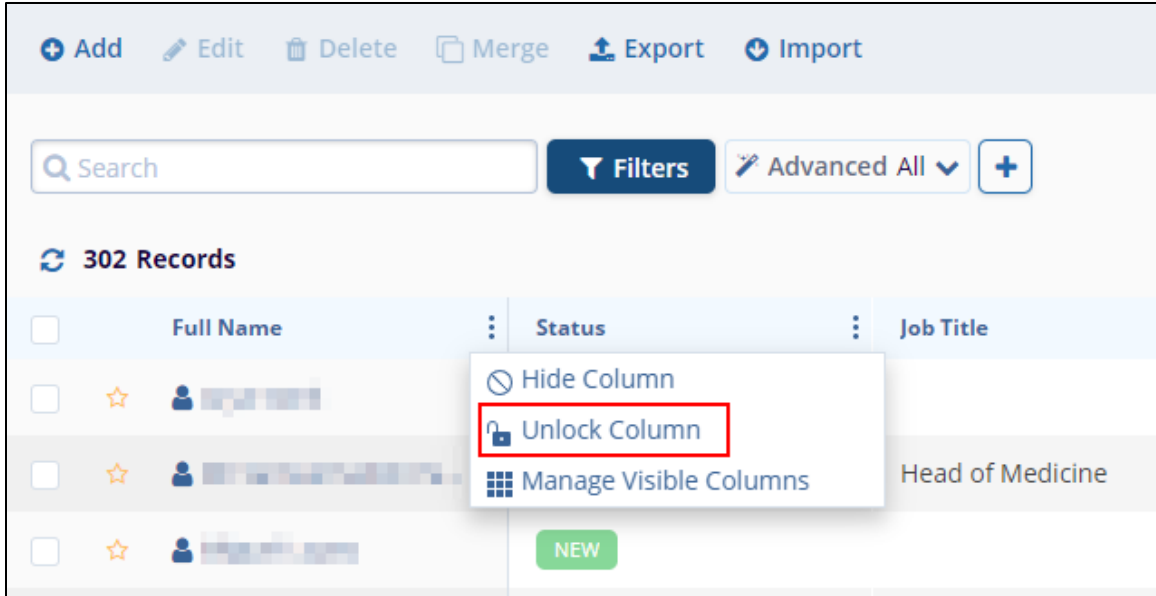


Figure: Unlock Column

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

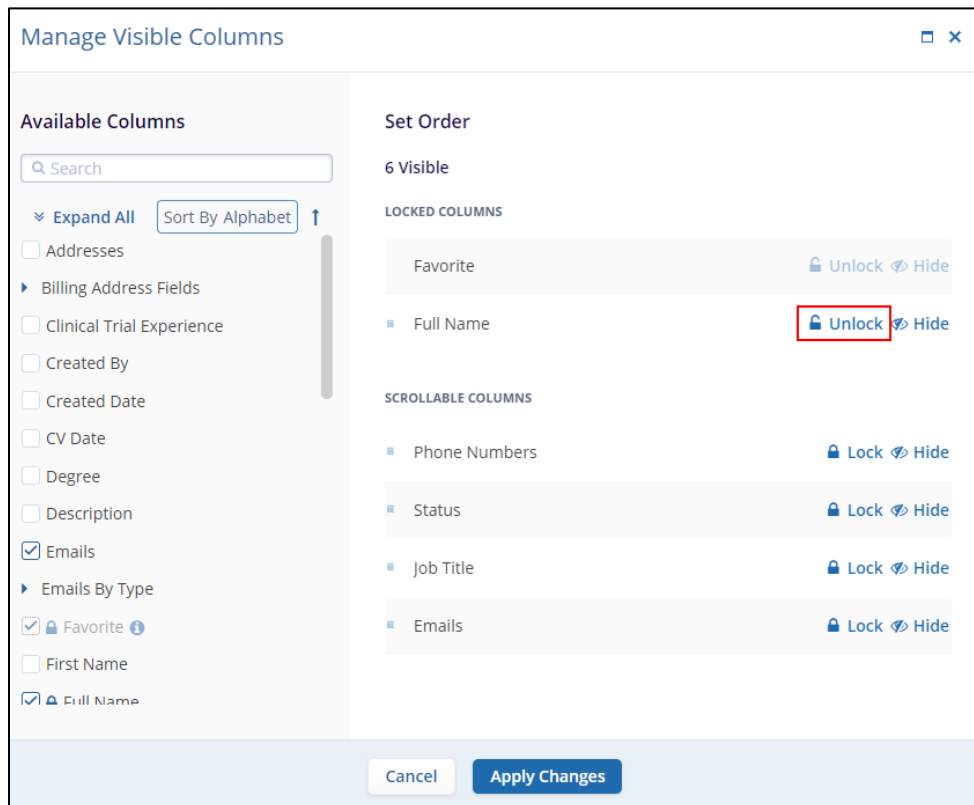


Figure: Unlock column through Manage Visible Columns

Manage Visible Columns

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

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

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

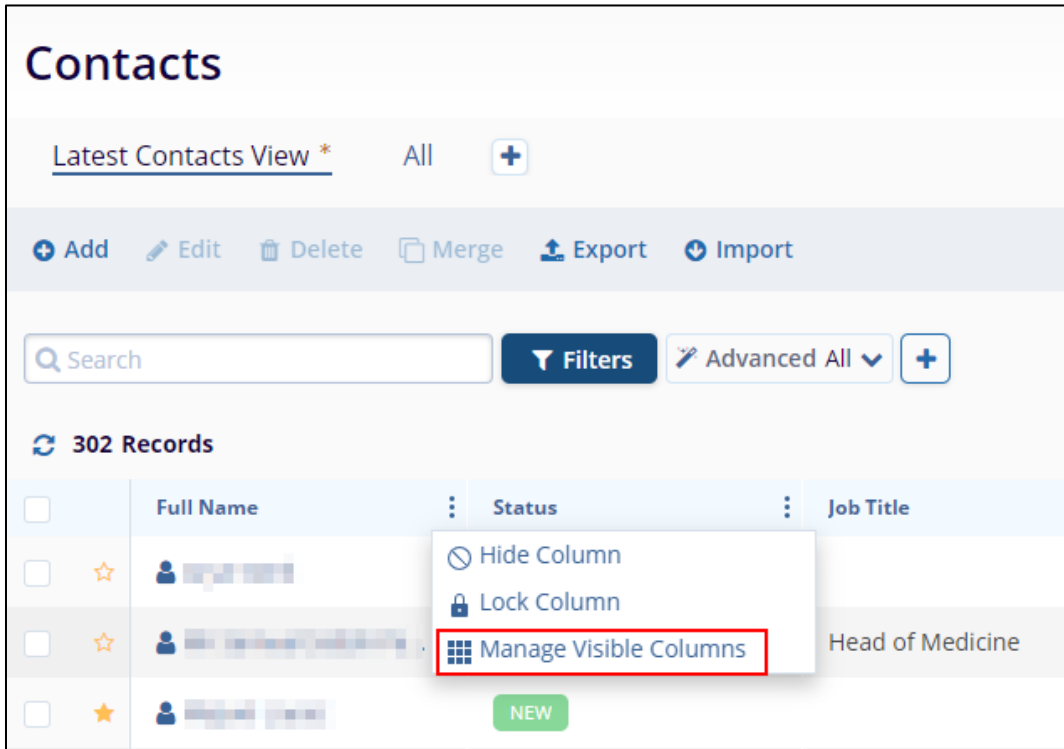


Figure: Manage Visible Columns

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

The screenshot shows the 'Manage Visible Columns' dialog box. It is divided into two main sections: 'Available Columns' on the left and 'Set Order' on the right. The 'Available Columns' section has a search box, an 'Expand All' button, and a 'Sort By Alphabet' button. Below these are several checkboxes for different fields, including 'Favorite', 'Full Name', 'Phone Numbers', 'Status', 'Job Title', and 'Emails'. The 'Set Order' section shows a list of columns currently visible on the screen, with 'Favorite' and 'Full Name' under 'LOCKED COLUMNS' and 'Phone Numbers', 'Status', 'Job Title', and 'Emails' under 'SCROLLABLE COLUMNS'. Each column in the 'Set Order' section has 'Lock' and 'Hide' icons. Red callout boxes provide instructions: one points to the search box, another to the 'Unlock' and 'Hide' icons for 'Full Name', a third to the 'Lock' and 'Hide' icons for 'Phone Numbers', and a fourth to the checkboxes in the 'Available Columns' section. At the bottom are 'Cancel' and 'Apply Changes' buttons.

Figure: Manage Visible Columns options

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

Sorting Columns

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

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

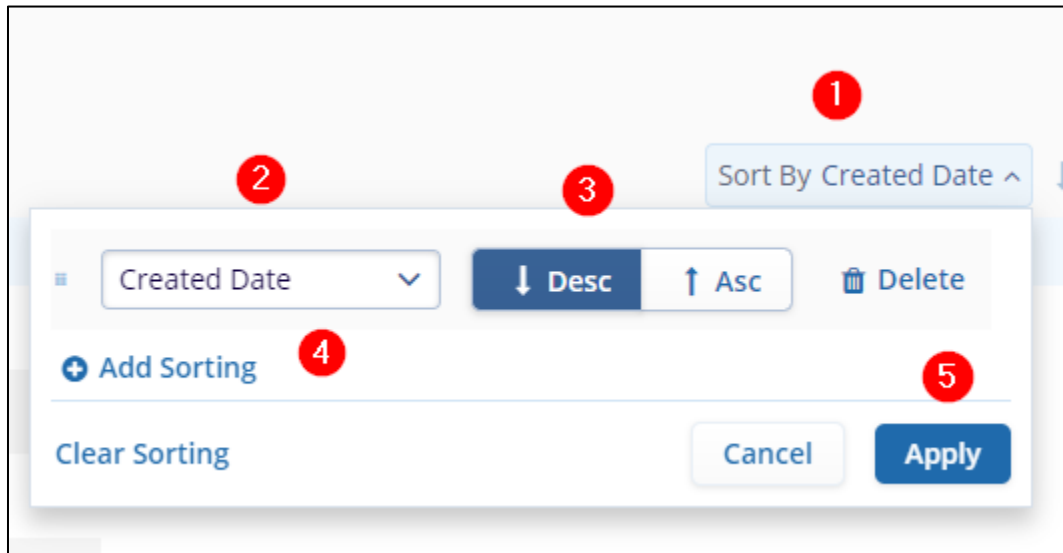


Figure: Apply sorting criteria

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

Mark a contact as a favorite

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

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

The screenshot displays the 'Contacts' management interface. A success notification is visible in the top right corner, indicating that a contact has been successfully added to favorites. The notification includes a green checkmark icon, the text 'Success', and 'Added to favorites', with a red circle containing the number '2' next to it. Below the notification, the 'Contacts' section is visible, showing a search bar, filter options, and a table of 302 records. The table has columns for 'Full Name', 'Status', 'Job Title', 'Emails', and 'Phone Numbers'. The first three rows of the table are partially visible, showing contact names, 'NEW' status, and email addresses. The third row shows a contact named 'Miguel Lopez' with a 'NEW' status. A red circle with the number '1' is positioned over the star icon in the first column of the 'Miguel Lopez' row, indicating the step to click the star icon to mark the contact as a favorite.

Activities Library

Accessing Activities

To access the Activities Library, follow the steps below.

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

The screenshot shows the 'Activities Library' page. On the left is a navigation menu with 'Activities Library' highlighted. The main area displays a table of 94 activities. The table has columns for 'Activity Name', 'Status', 'Type', and 'Subtype'. The first few rows are:

	↓	Activity Name	Status	Type	Subtype
<input type="checkbox"/>	★	📅 Reports	ACTIVE	Document	ICF Template
<input type="checkbox"/>	★	📅 Demo Reports 2	ACTIVE	Action Item	CRF
<input type="checkbox"/>	★	📅 UAT010 Step14 ...	ACTIVE	Acknowledgement	IRB/EC
<input type="checkbox"/>	★	📅 Step 7 UAT010 2.0	ACTIVE	Site Visit	Issue/Action
<input type="checkbox"/>	★	📅 UAT010 Step 6 2.0	ACTIVE	Protocol	Deviation
<input type="checkbox"/>	★	📅 AP2 Activity 2.0	ACTIVE	Communication	Email
<input type="checkbox"/>	★	📅 UAT10 Act1 2.0	INACTIVE	Acknowledgement	IRB/EC
<input type="checkbox"/>	★	📅 Approval 2.0	ACTIVE	Approval	Annual Renewal
<input type="checkbox"/>	★	📅 10 Acknowledge...	ACTIVE	Acknowledgement	IRB/EC

Figure: Accessing Activities Library

Creating Domain Library Activity Records

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

1. On the Activities Library screen, click on the **Add** button in the top-left of the screen.
2. On the Create Activity screen, we need to enter the mandatory metadata to create an Activity.

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

- a. **Activity**
 - b. **Type**
 - c. **Sub Type**
 - d. **Description**
3. Click on the **Create** button once all the mandatory details are filled.

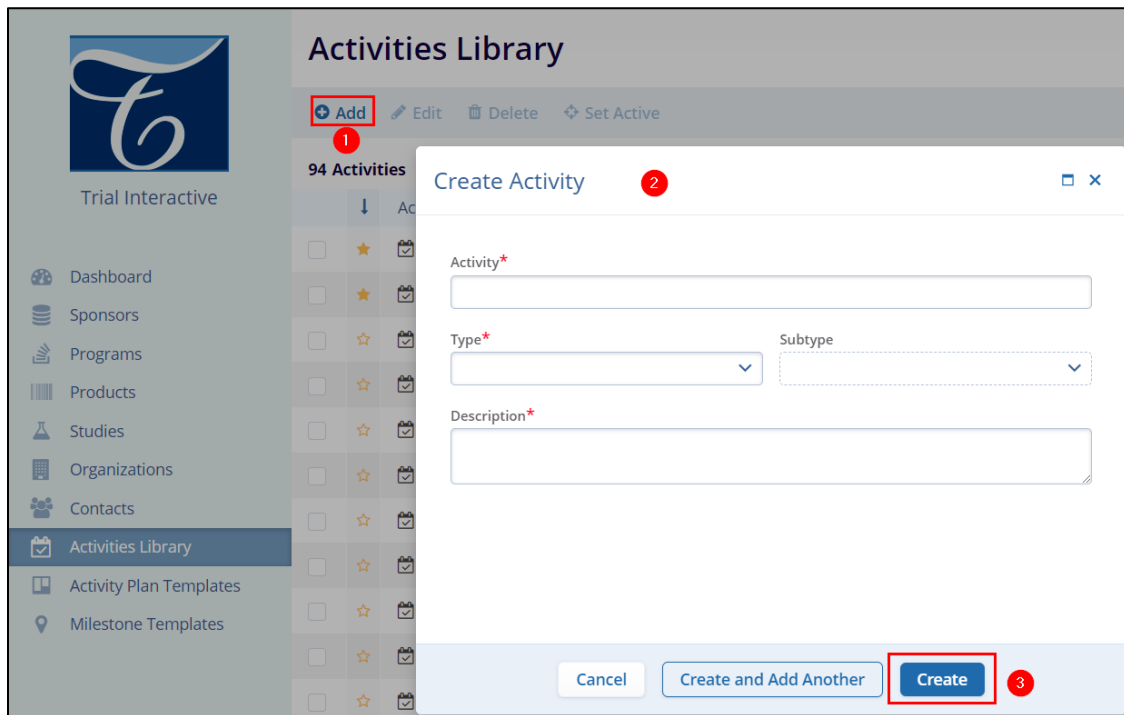


Figure: Creating Domain Library Activity Records

Note:

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

Editing Domain Library Activity Records

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

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

The screenshot displays the TI CTMS interface for editing activity records. At the top, there is a menu bar with 'Add', 'Edit', 'Delete', and 'Set Inactive' buttons. Below this is a search bar and a 'Filters' button. A table lists 94 activities with columns for 'Activity Name', 'Status', 'Type', 'Subtype', 'Description', 'Modified', and 'Modifier'. The first row is selected, and its checkbox is checked. To the right, a 'General Information' panel is open, showing fields for 'Activity', 'Type', 'Subtype', and 'Description'. The 'Save' button in the bottom right of the panel is highlighted.

Activity Name	Status	Type	Subtype	Description	Modified	Modifier
Repo...	ACTIVE	Document	ICF Tem...	This is re...	20 Jul 2023	Admi...
Dem...	ACTIVE	Action It...	CRF	This is m...	20 Jul 2023	Admi...
UAT0...	ACTIVE	Acknowl...	IRB/EC	UAT010 ...	03 Jul 2024	Admi...
Step ...	ACTIVE	Site Visit	Issue/Ac...	UAT010 ...	03 Jul 2024	Admi...
UAT0...	ACTIVE	Protocol	Deviation	UAT010 ...	03 Jul 2024	Admi...
AP2 ...	ACTIVE	Commu...	Email	AP2 Acti...	14 Jun 2024	Admi...
UAT1...	INACTIVE	Acknowl...	IRB/EC	UAT010 ...	03 Jul 2024	Admi...
Appr...	ACTIVE	Approval	Annual ...	UAT Scri...	14 Jun 2024	Hope ...
10 A...	ACTIVE	Acknowl...	IRB/EC	UAT Scri...	14 Jun 2024	Hope ...
Man...	ACTIVE	Commu...	Email	Commu...	30 Jan 2024	Admi...

Figure: Editing Domain Library Activity Records

Deleting Domain Activity Records

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

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

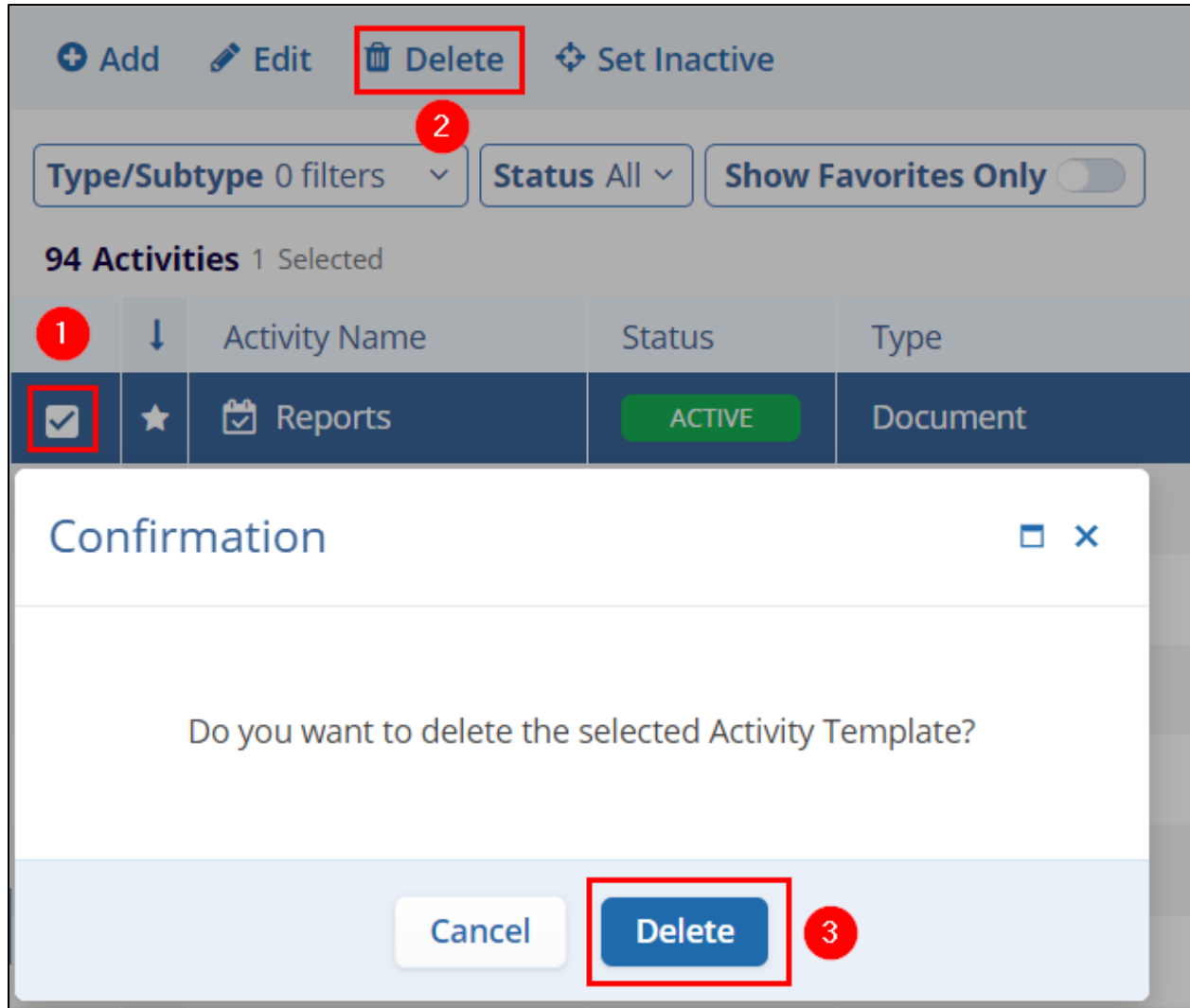


Figure: Deleting Domain Activity Records

Setting Domain Activity Records to Inactive

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

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

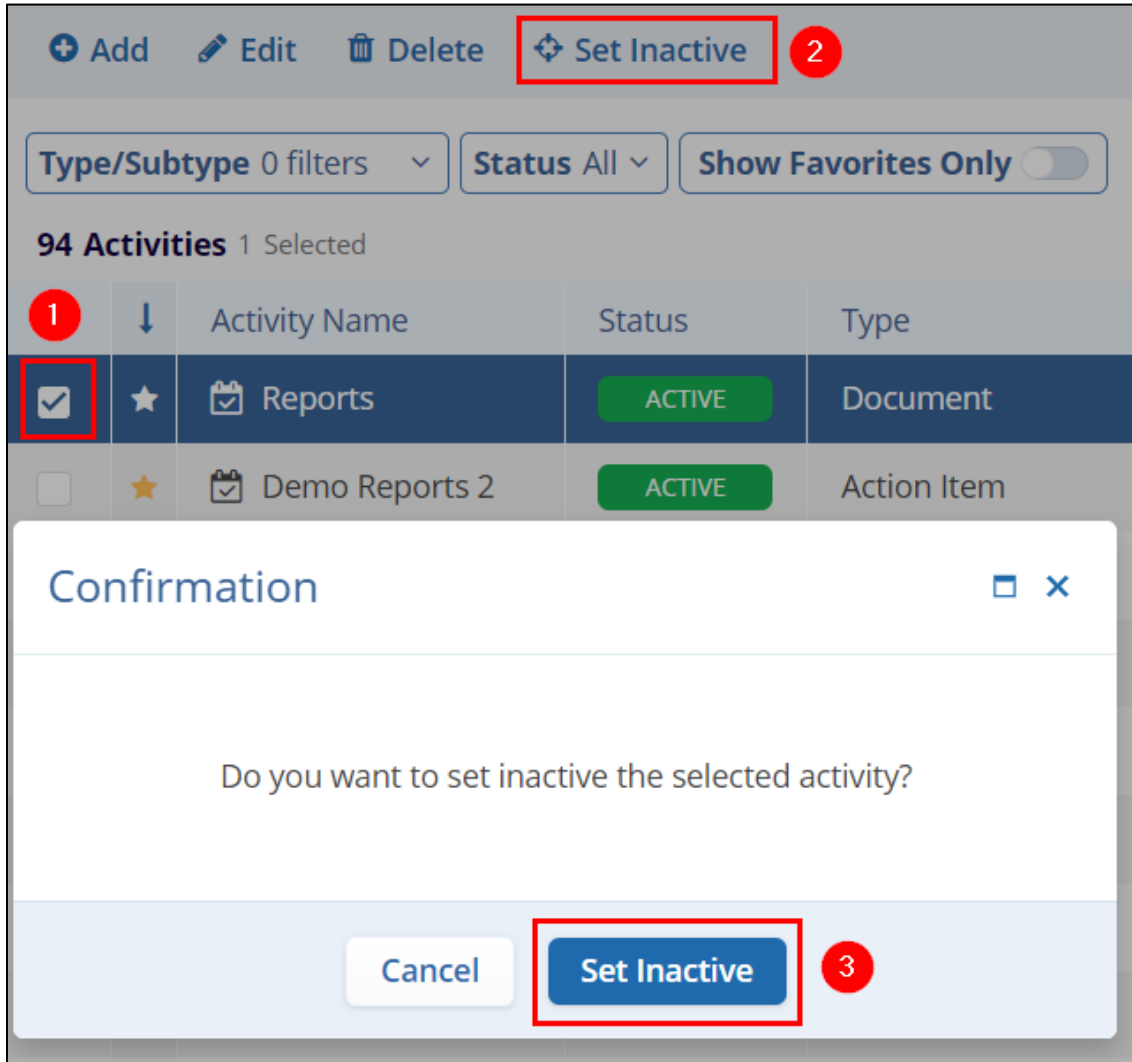


Figure: Change activity record status to Inactive

Customizing Activities Library screen

Filters and Sorting

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

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

Marking an activity as a favorite

To mark an activity as a favorite follow the standard steps detailed in [Mark a contact as a favorite](#) section.

Activity Plan Templates

Accessing Activity Plan Templates

To access Activity Plan Templates, follow the steps below.

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

The screenshot displays the 'Activity Plan Templates' interface. On the left, a navigation menu lists various system components, with 'Activity Plan Templates' highlighted in blue and a red box around the text. The main content area features a header with the 'Activity Plan Templates' title and a toolbar with actions like 'Create Template', 'View', 'Copy', 'Publish', 'Set to Retired', and 'Delete'. Below the toolbar are filter buttons for 'Status All', 'Level All', and 'Classification All'. A summary indicates '61 Activity Plan Templates' with '1 Selected'. A table lists the templates with their respective statuses and classifications.

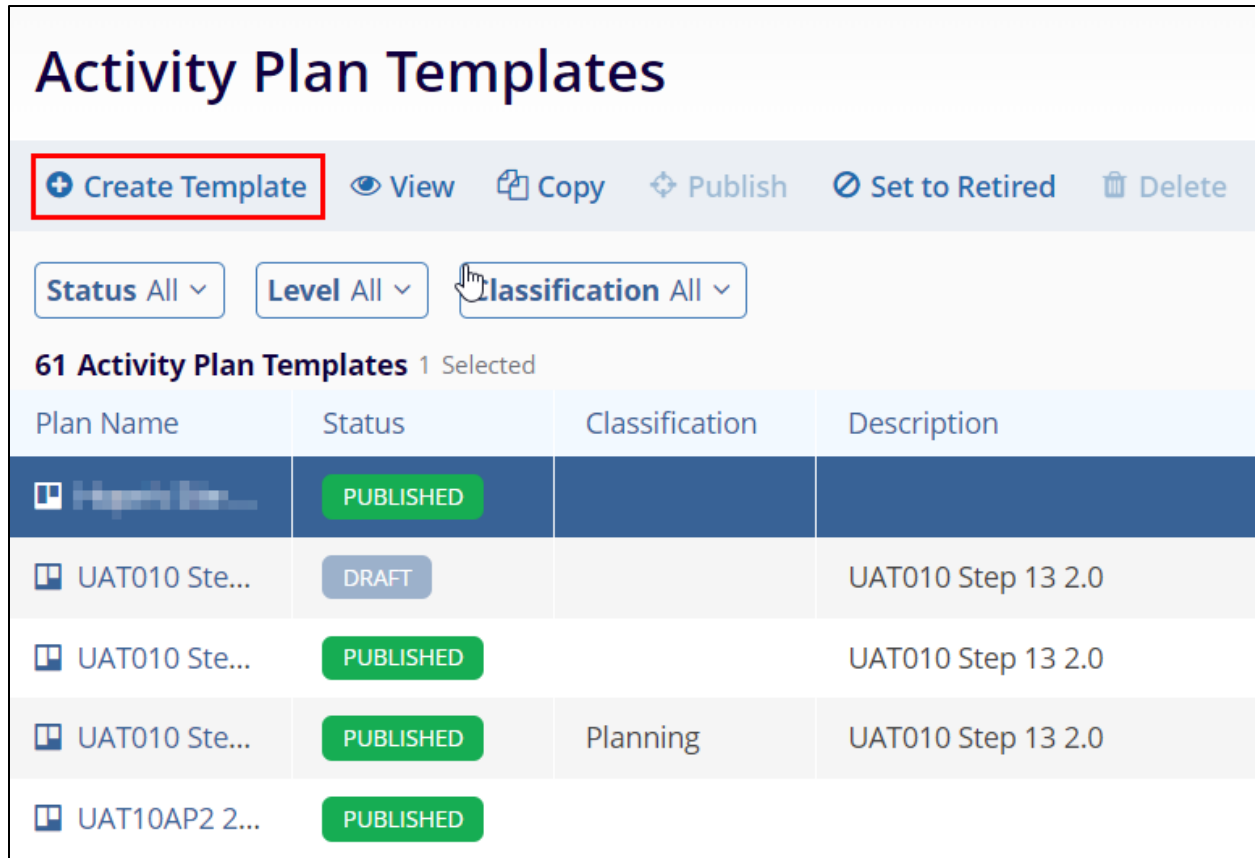
Plan Name	Status	Classification	Description
Hope's Site ...	PUBLISHED		
UAT010 Ste...	DRAFT		UAT010 Step 13 2.0
UAT010 Ste...	PUBLISHED		UAT010 Step 13 2.0
UAT010 Ste...	PUBLISHED	Planning	UAT010 Step 13 2.0
UAT10AP2 2...	PUBLISHED		
UAT10AP 2.0	RETIRED		
UAT10AP 2.0	DRAFT		2
UAT10AP 2.0	DRAFT	Amendment	
Site Docum...	PUBLISHED	Planning	

Figure: Accessing Activity Plan Templates

Creating Domain Library Activity Template

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

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



Activity Plan Templates

61 Activity Plan Templates 1 Selected

Plan Name	Status	Classification	Description
[blurred]	PUBLISHED		
UAT010 Ste...	DRAFT		UAT010 Step 13 2.0
UAT010 Ste...	PUBLISHED		UAT010 Step 13 2.0
UAT010 Ste...	PUBLISHED	Planning	UAT010 Step 13 2.0
UAT10AP2 2...	PUBLISHED		

Figure: Create Domain Library Activity Template

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

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

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

Create Activity Plan Template Step 1

1 General Information

General Information

Activity Plan Name* 213 Level* Study

Classification Select

Description

Status Draft

Select Parent Plan Parent Plan*

Cancel **Create, Next Add Activities**

Figure: Domain Library Activity Template-General Information

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

Create Activity Plan Template Step 2

2 Associated Activities

Associated Activities

Search Library / Quick Select **1** **Browse Activities Library** **2**

+ Create **3** **Remove** **4**

0 Activities

	Activity Na...	Type	Subtype	Description	Modified	Modifier
No records available.						

Cancel Previous **Save Activities**

Figure: Domain Library Activity Template-Associated Activities

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

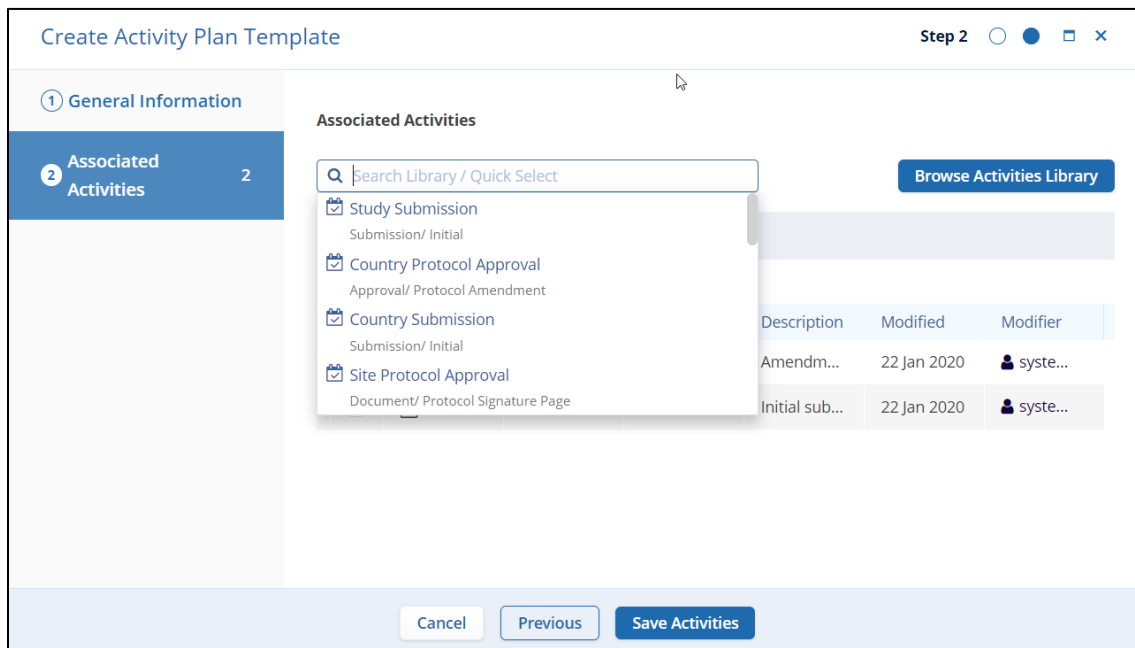


Figure: Search Library and Quick Select

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

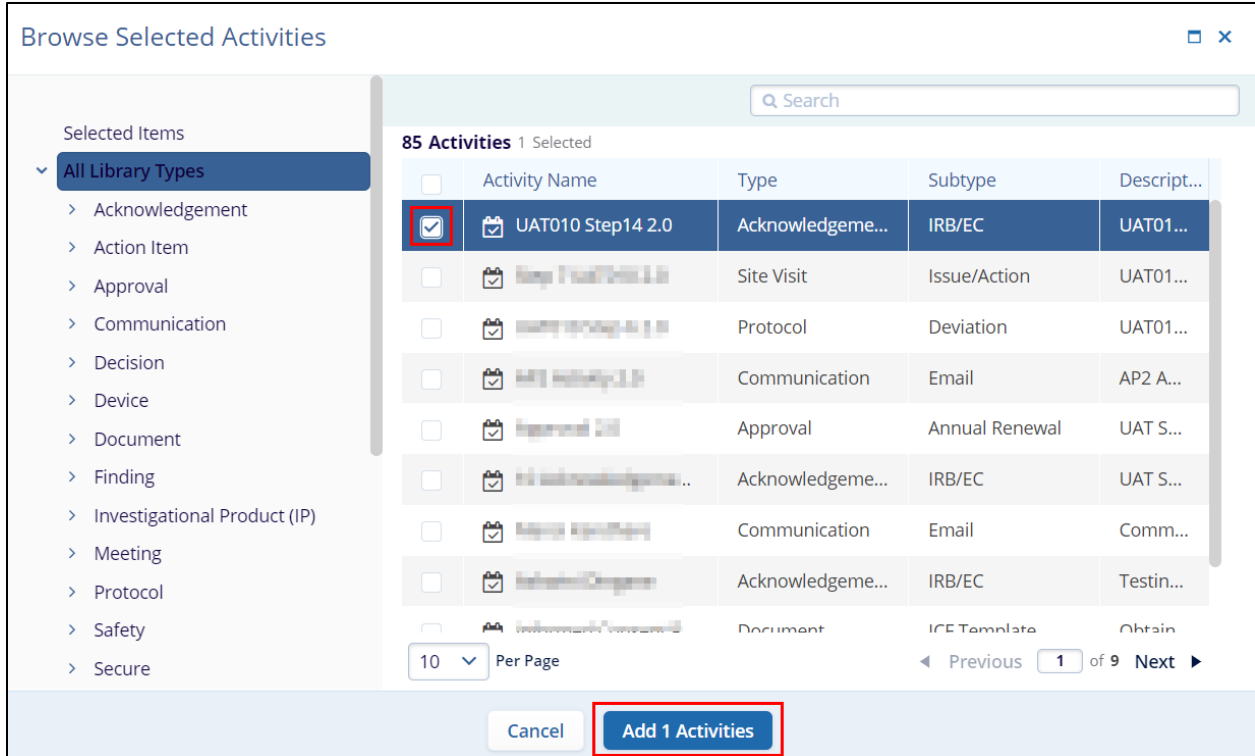


Figure: Browse Activities Library

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

Create Activity □ ×

Activity*

Type* **Subtype**

Description*

Cancel
Create and Add Another
Create

Figure: Create New Activity

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

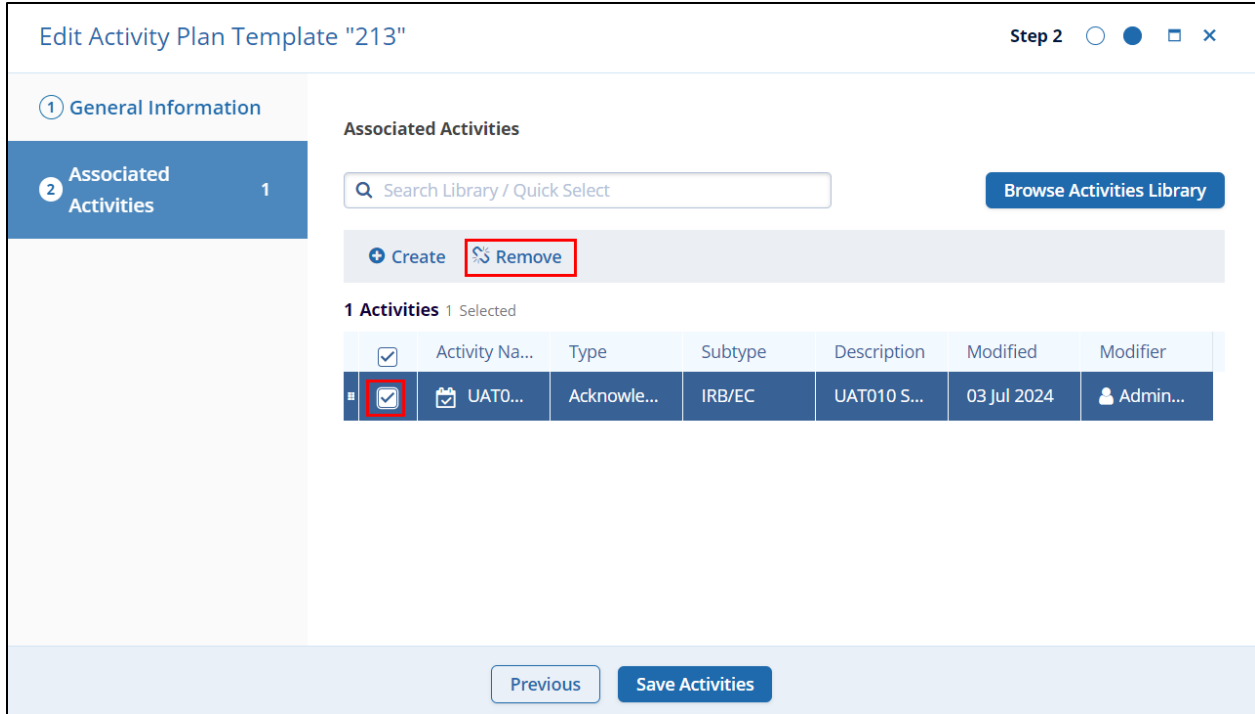


Figure: Remove Activities

- Once all the details are entered click on **Save Activities**.

View Published Template Details

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

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

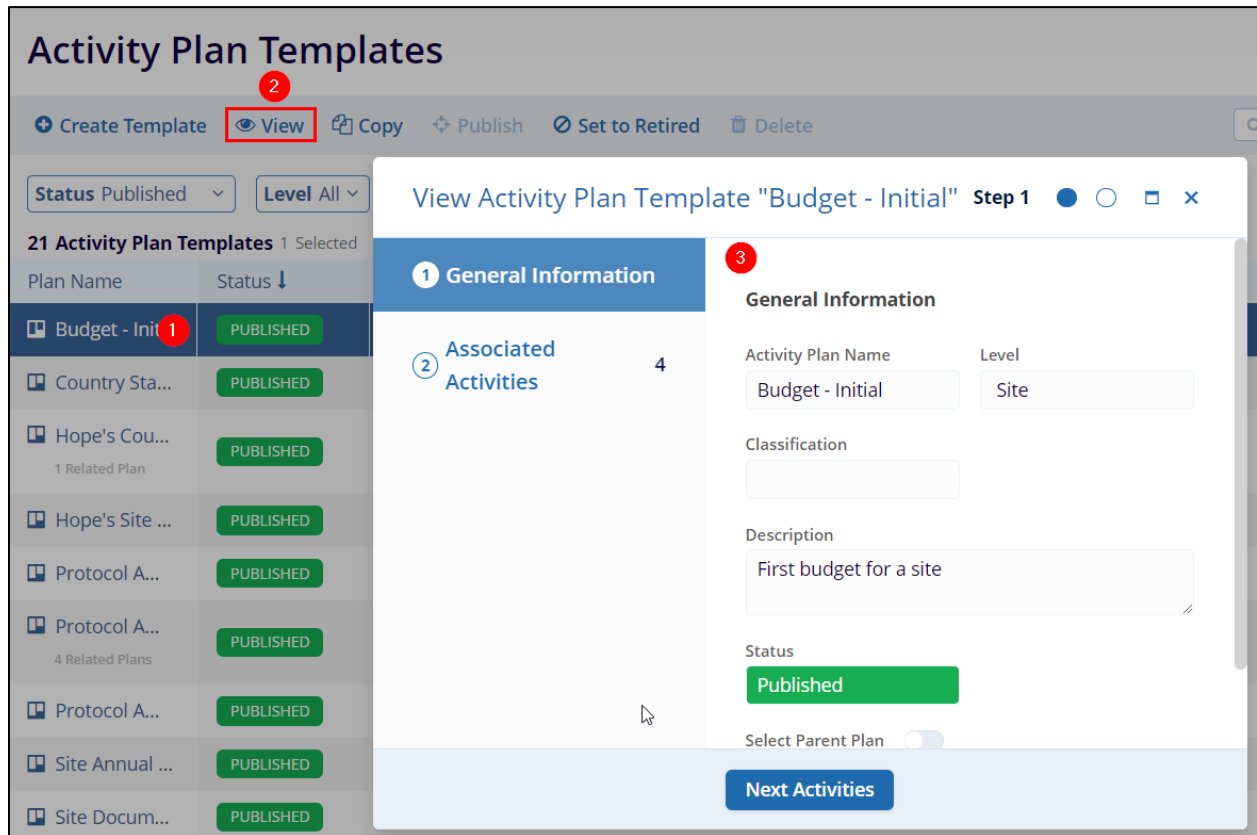


Figure: View Activities Plan Template

Editing Activity Plan Templates

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

Method 1

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

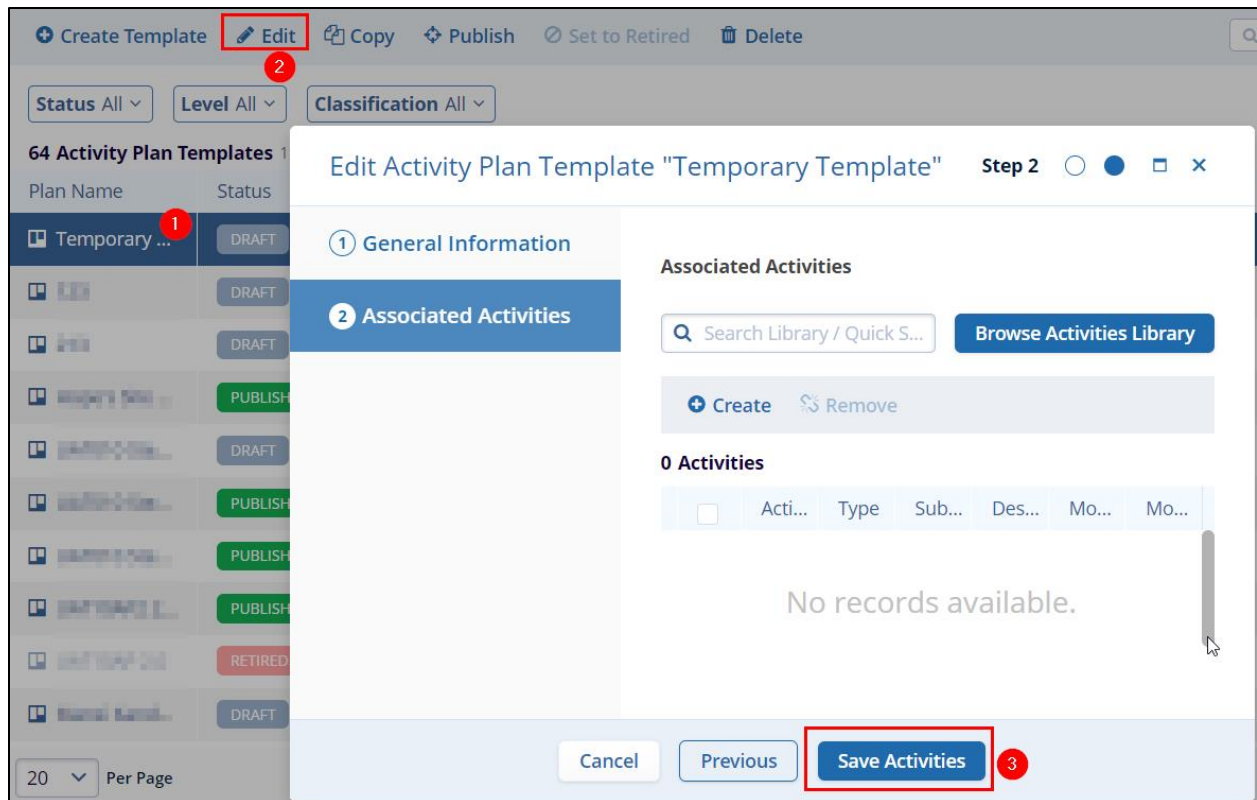


Figure: Edit Activity Plan Template-Method 1

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

Method 2

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

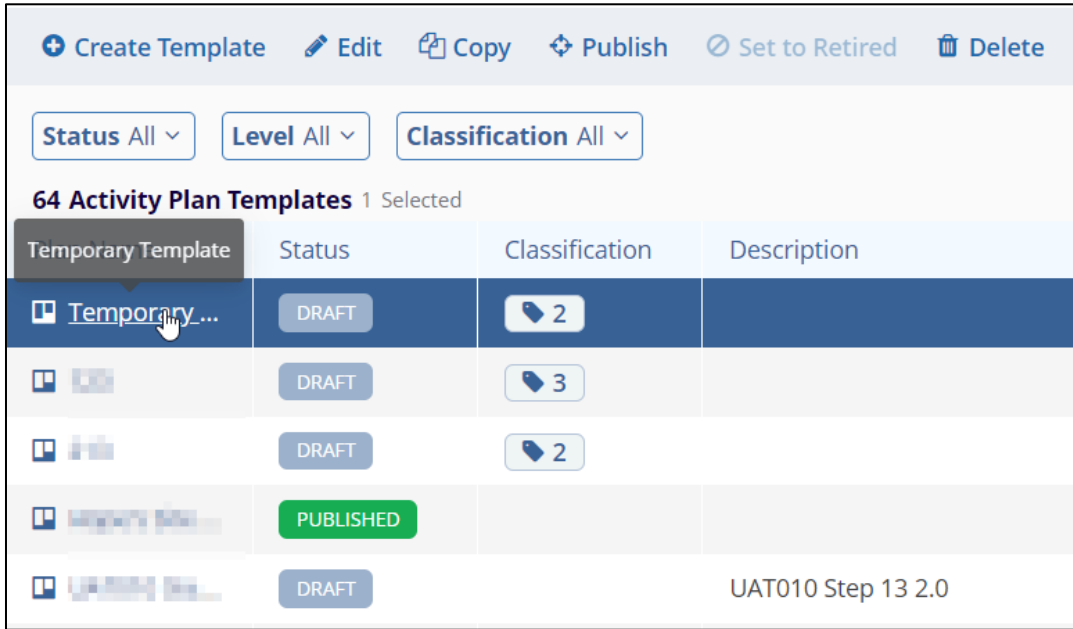


Figure: Select plan name

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

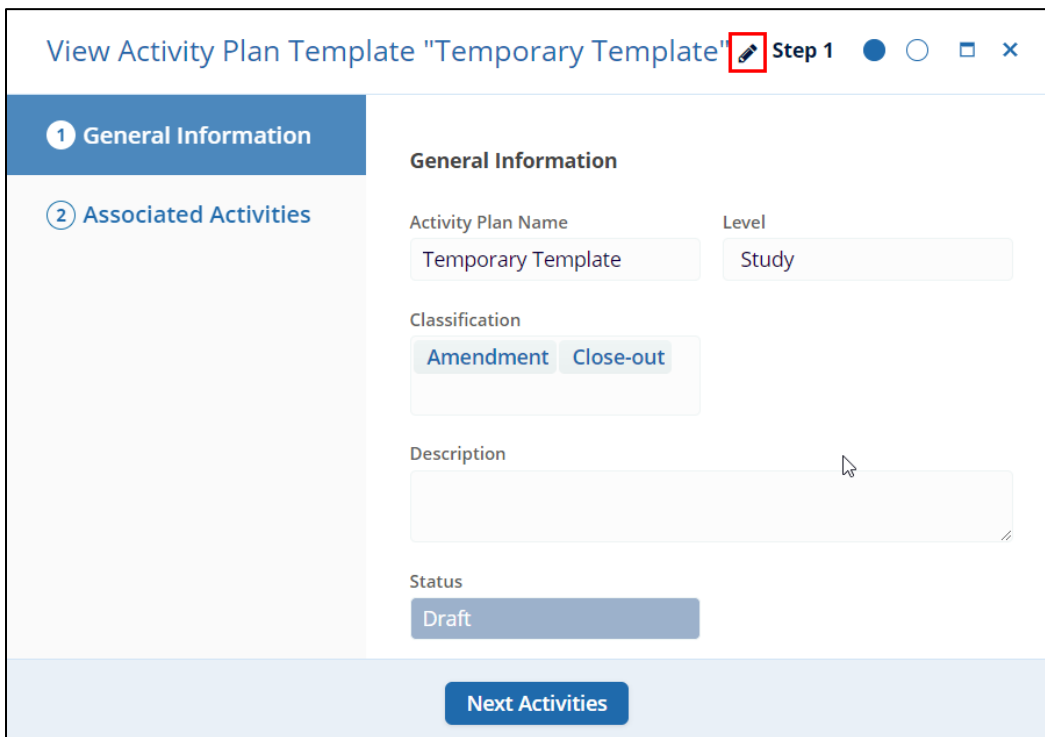


Figure: Select the Edit icon

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

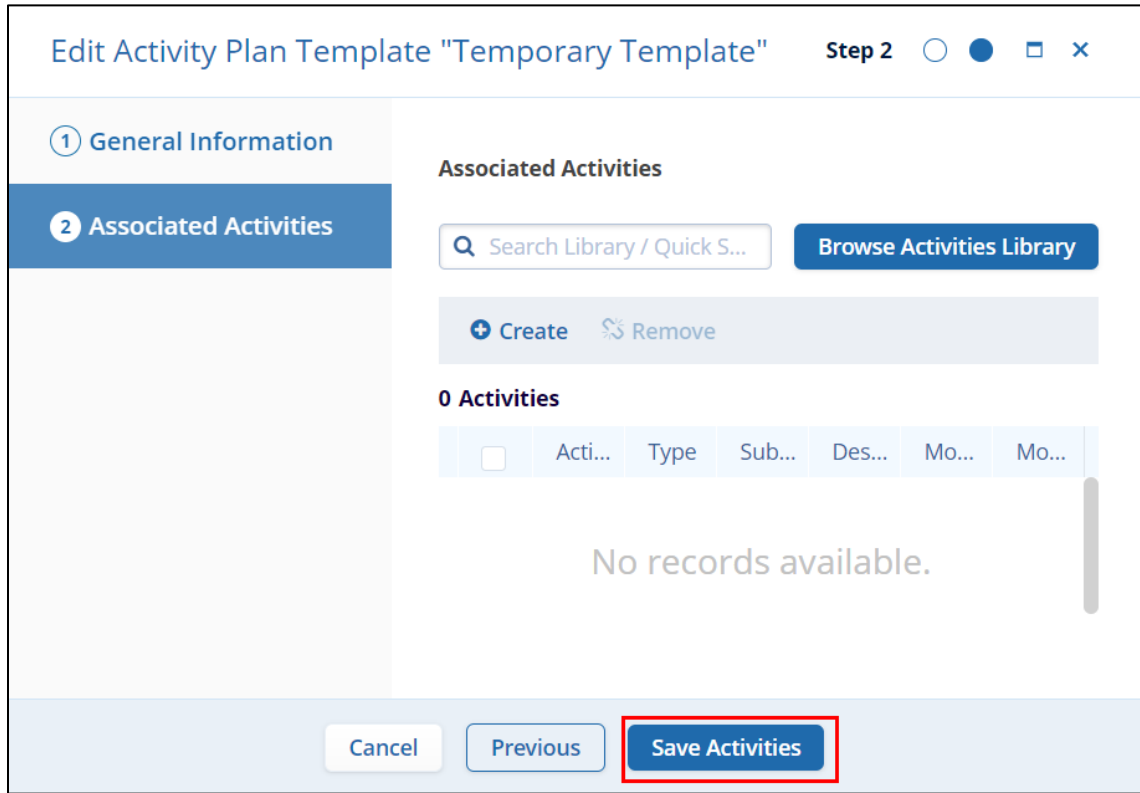


Figure: Edit Activity Plan Template-Method 2

Publishing Activity Plan Templates

To publish an activity plan, follow the steps below.

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

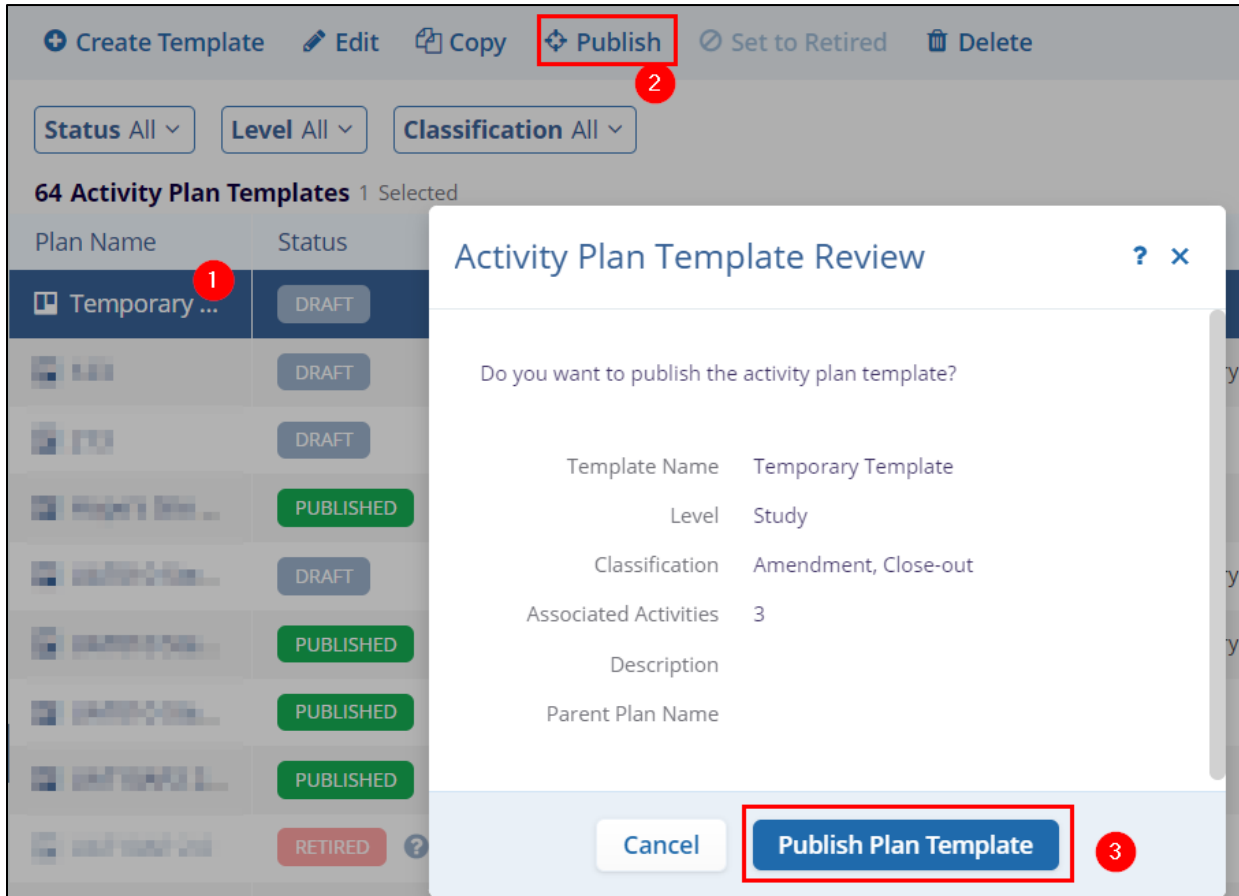


Figure: Publishing Activity Plan Template

Note

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

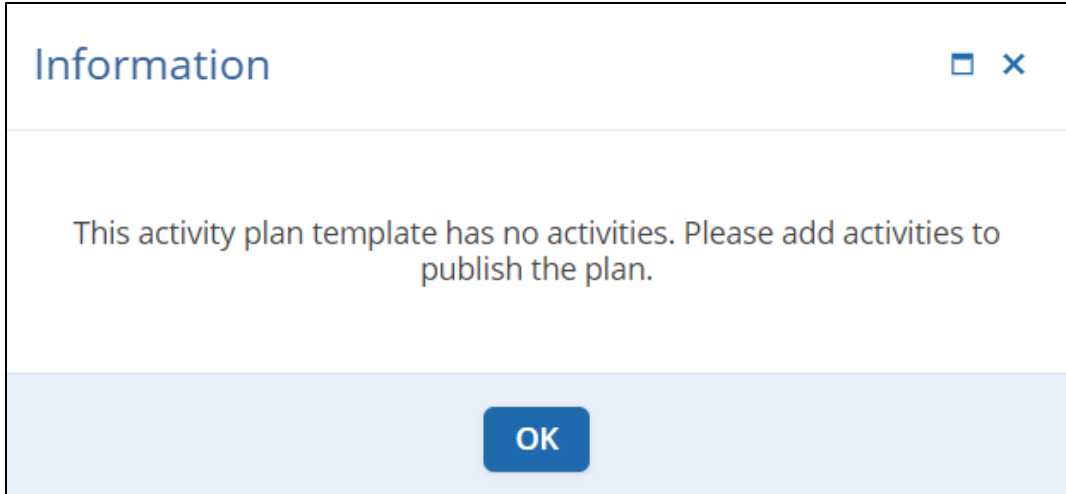


Figure: Information popup prompting to add templates

Retire Activity Plan Templates

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

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

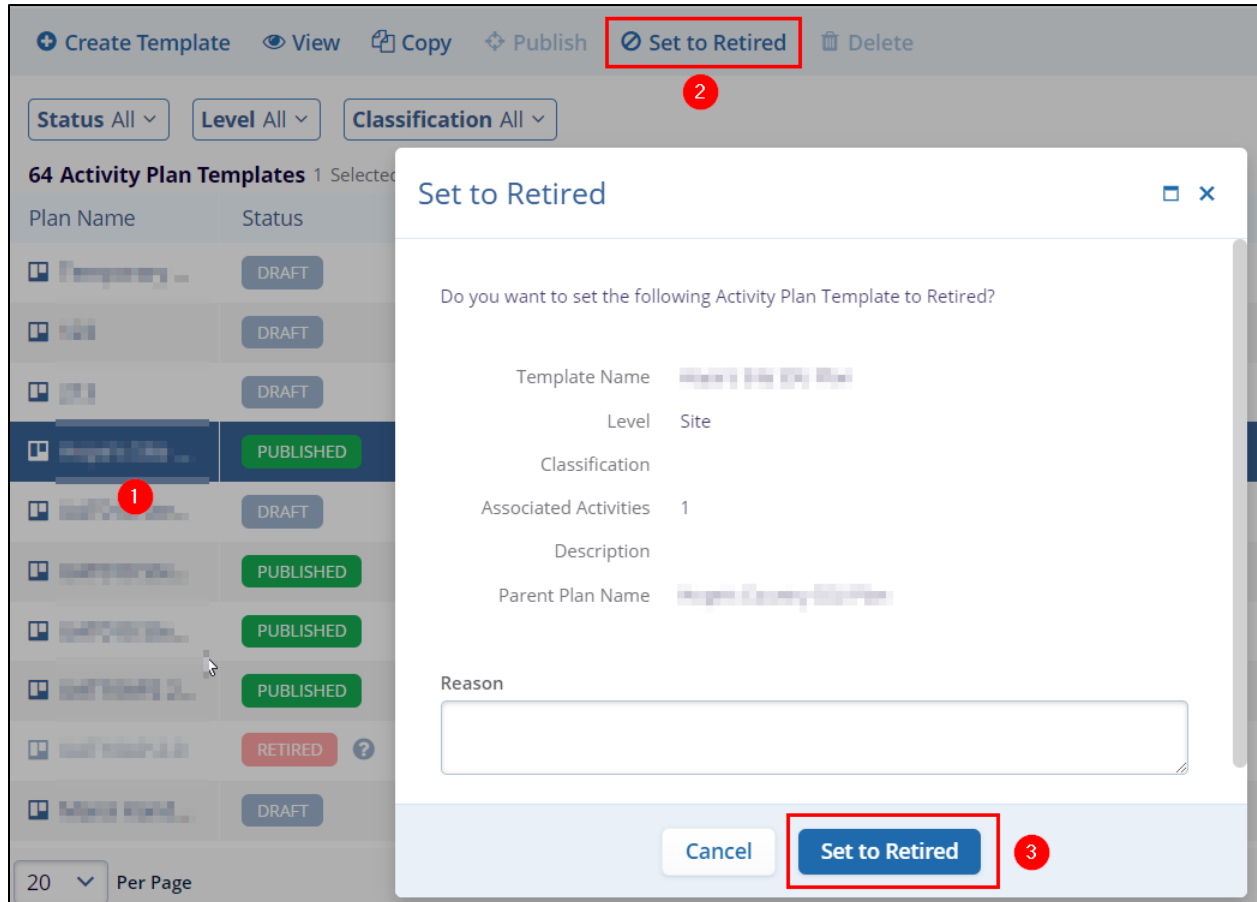


Figure: Retire Activity Plan Template

Note:

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

Copying Activity Plan Templates

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

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

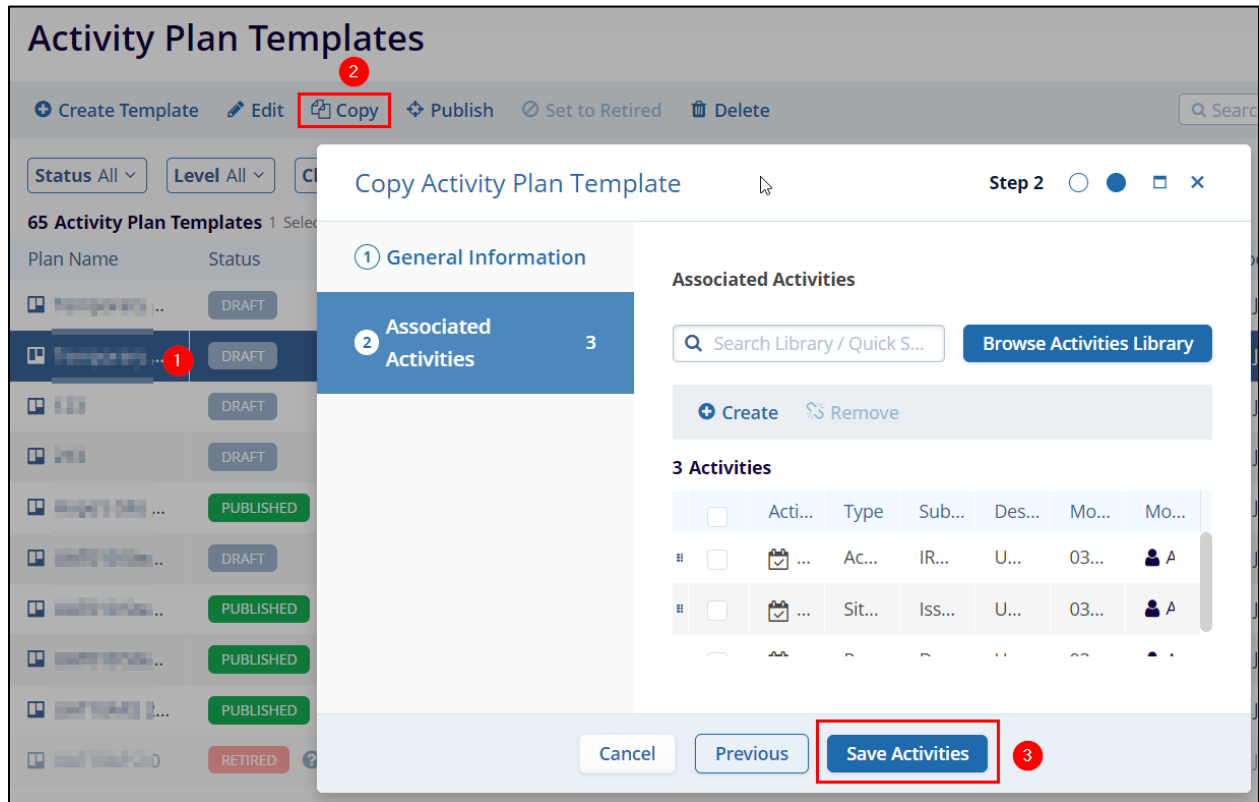


Figure: Copy Activity Plan Templates

Associating Activity Plan Templates to a Study

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

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

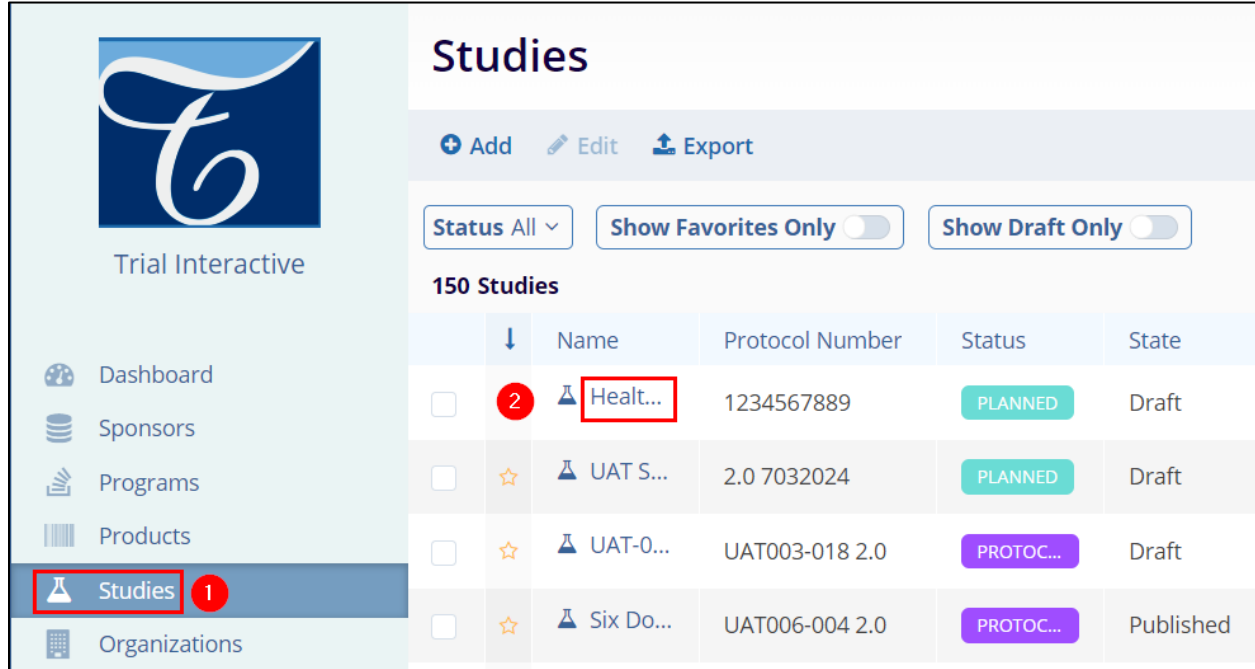


Figure: Selecting a Study

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

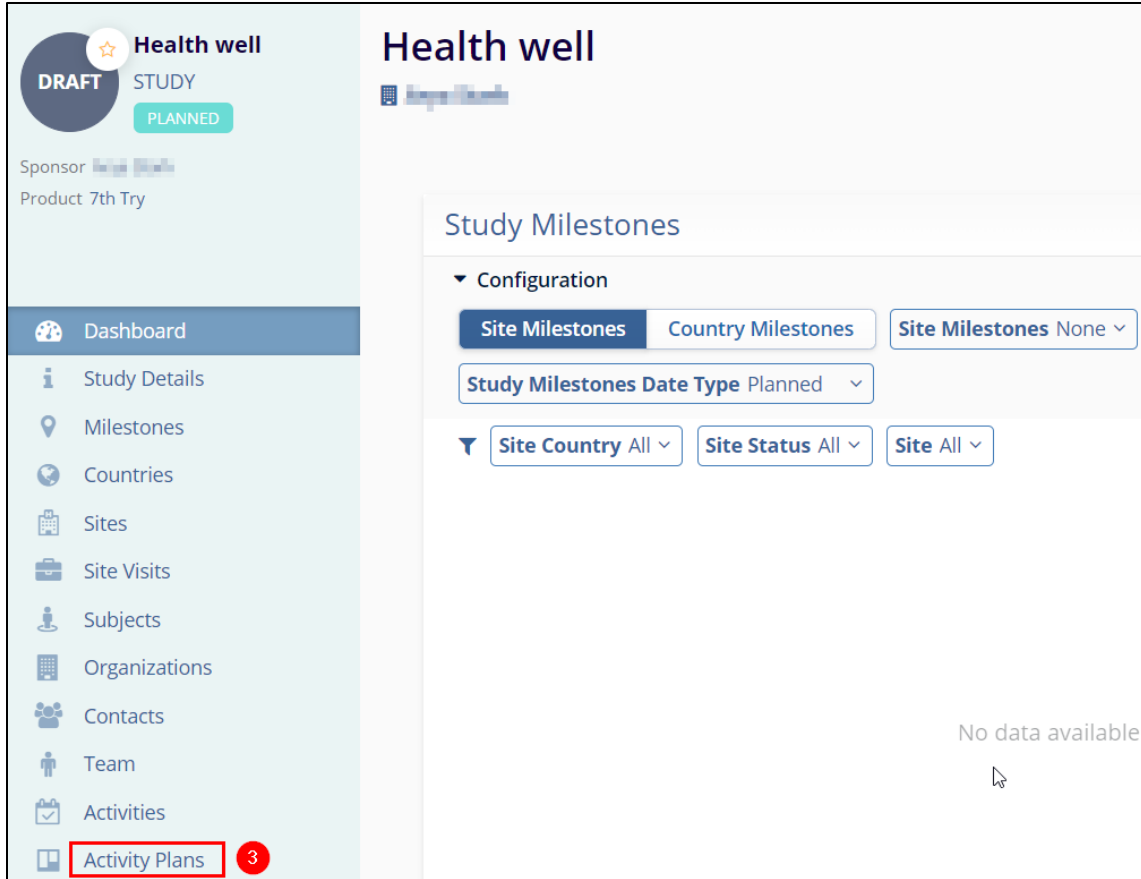


Figure: Select Activity Plans

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

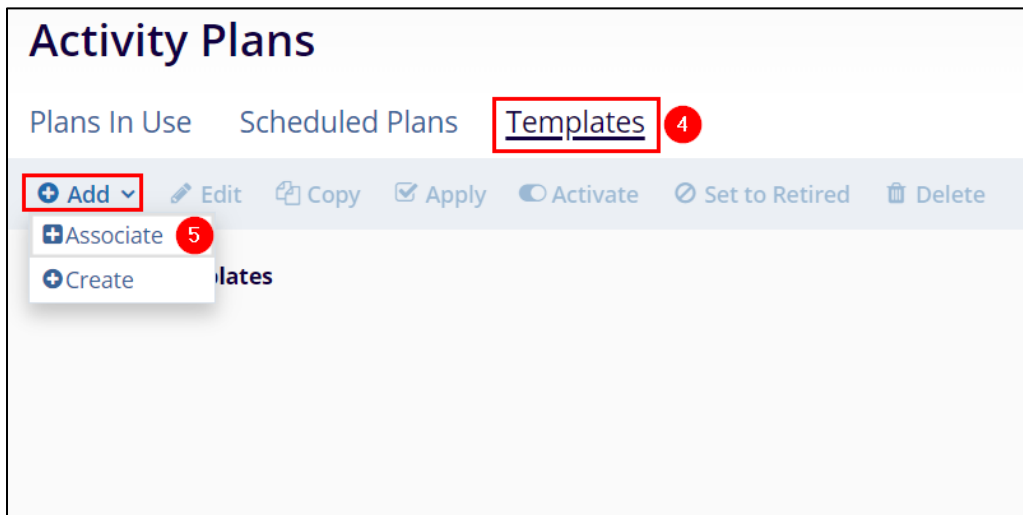


Figure: Select the Templates tab and access the Add and Associate buttons

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

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

Associate Activity Plan Templates to Study "Health well" ✕

Select the activity plan templates you would like to use for the study

Selected plan templates

Impersonate Site Plan ✕
UAT010 Step 13 2.0 ✕
✕

Level All ▾
Classification All ▾

21 Activity Plan Templates 2 Selected - this number includes any related activity plans

	Plan Name	Classification	Description	Level	Activities
6	<input checked="" type="checkbox"/> Impersonate Site Plan			Site	1
	<input checked="" type="checkbox"/> UAT010 Step 13 2.0		UAT010 Step 13 2.0	Country	1
	<input type="checkbox"/> UAT010 Step 13 2.0	Planning	UAT010 Step 13 2.0	Study	2
	<input type="checkbox"/> UAT10AP2 2.0			Study	1

20 ▾ Per Page
◀ Previous 1 of 2 Next ▶

Cancel
Associate
7

Figure: Associate Activity Plan Template to Study Screen

Scheduling Activity Plans

To schedule Activity plans, follow the steps below.

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

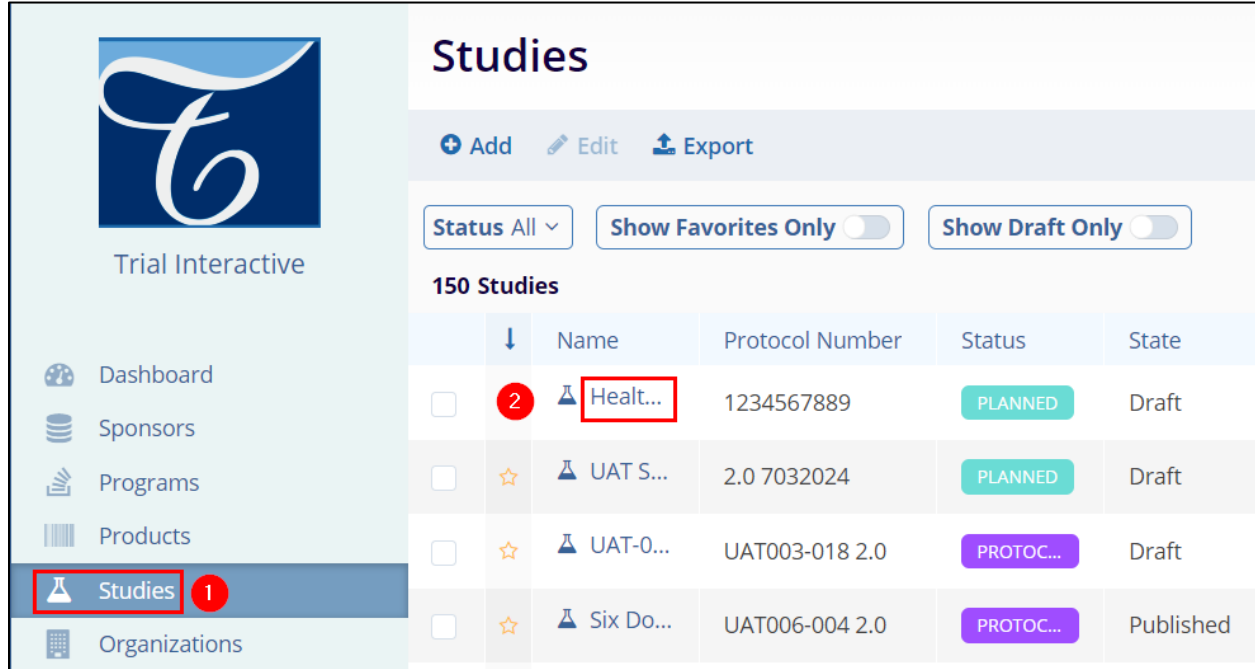


Figure: Selecting a Study

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

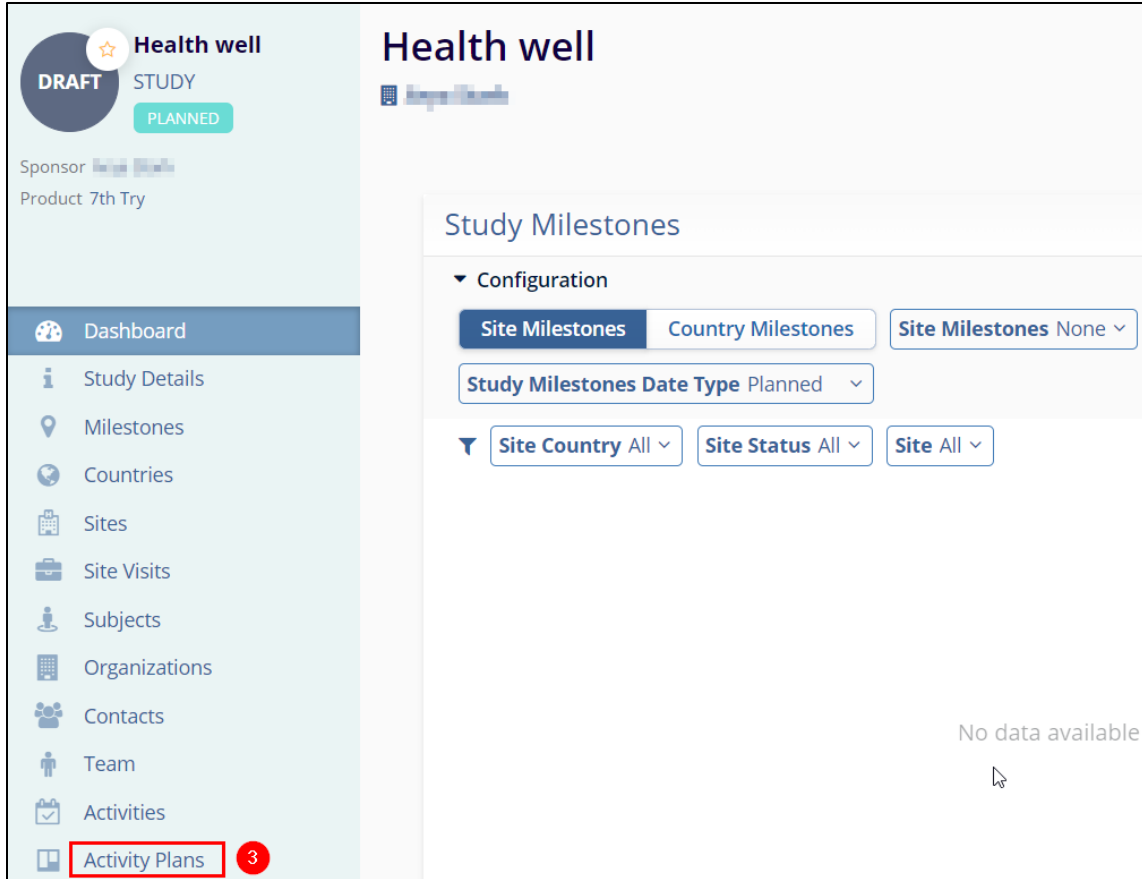


Figure: Select Activity Plans

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

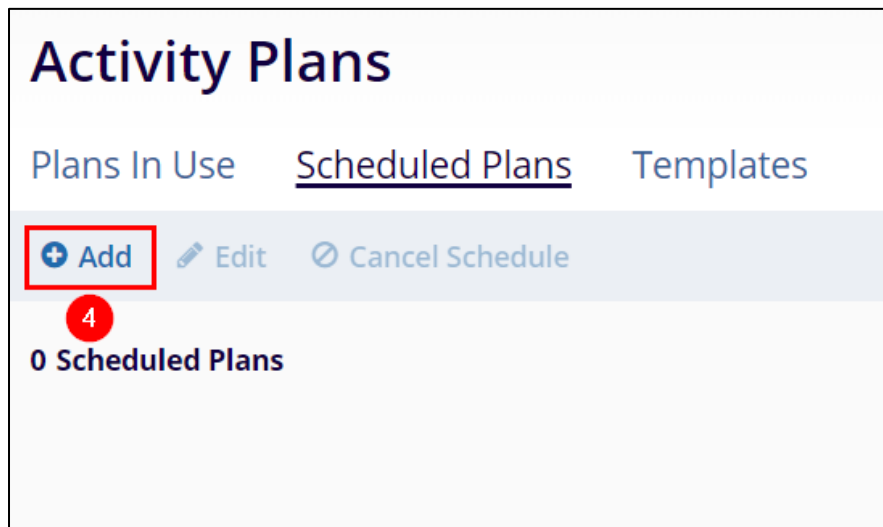


Figure: Scheduled Plans tab

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

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

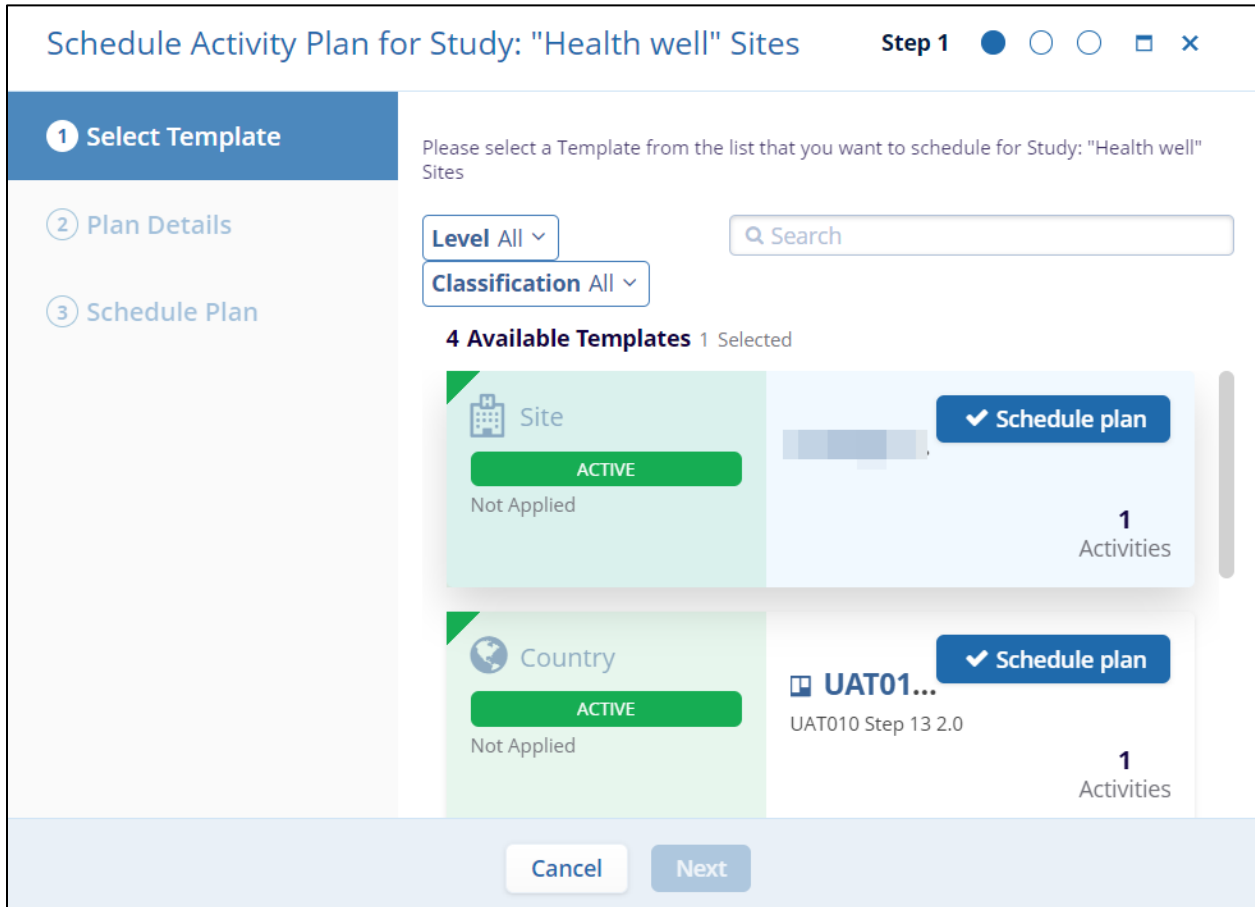


Figure: Schedule Activity Plan for Study-Select Template

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

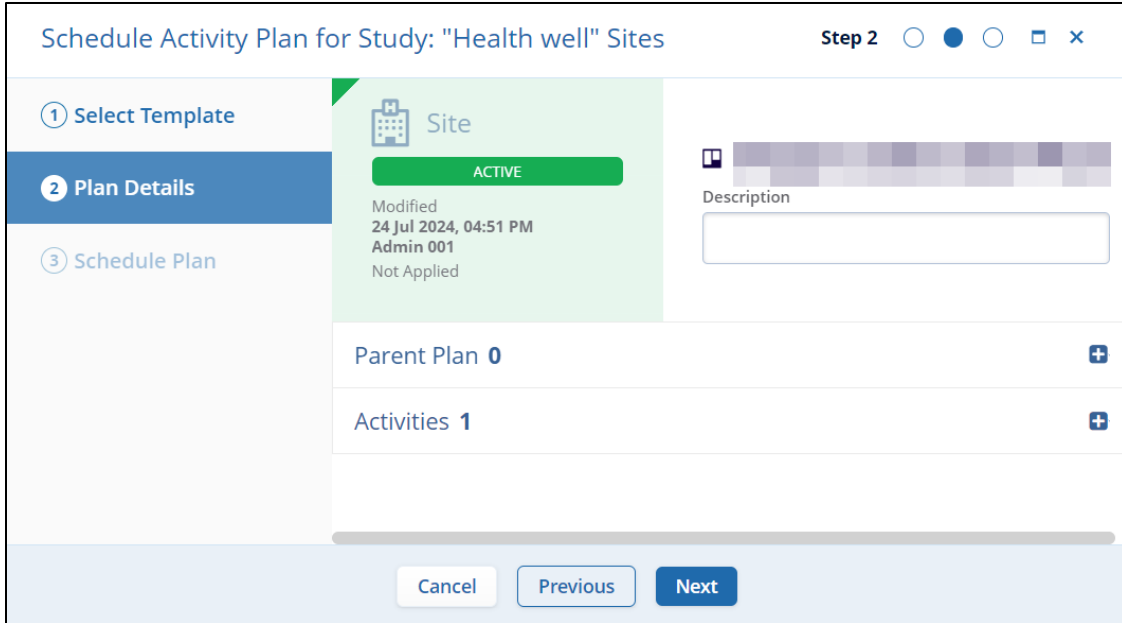


Figure: Schedule Activity Plan for Study-Plan Template

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

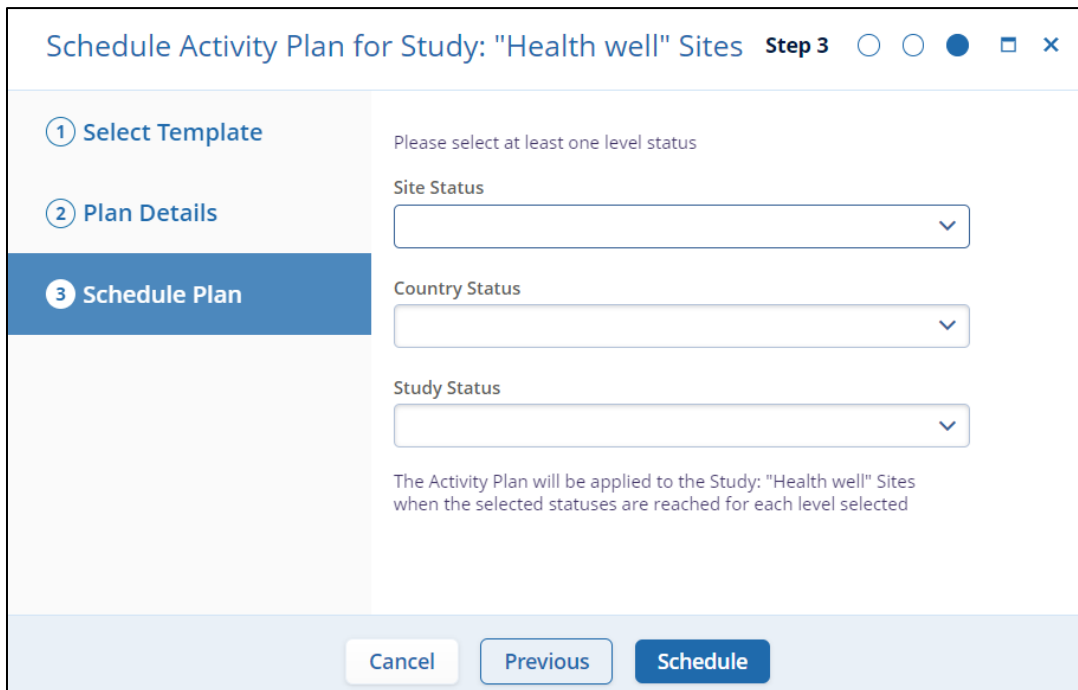


Figure: Schedule Activity Plan for Study-Schedule Plan

Tracking Activities Outside of Activity Plans

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

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

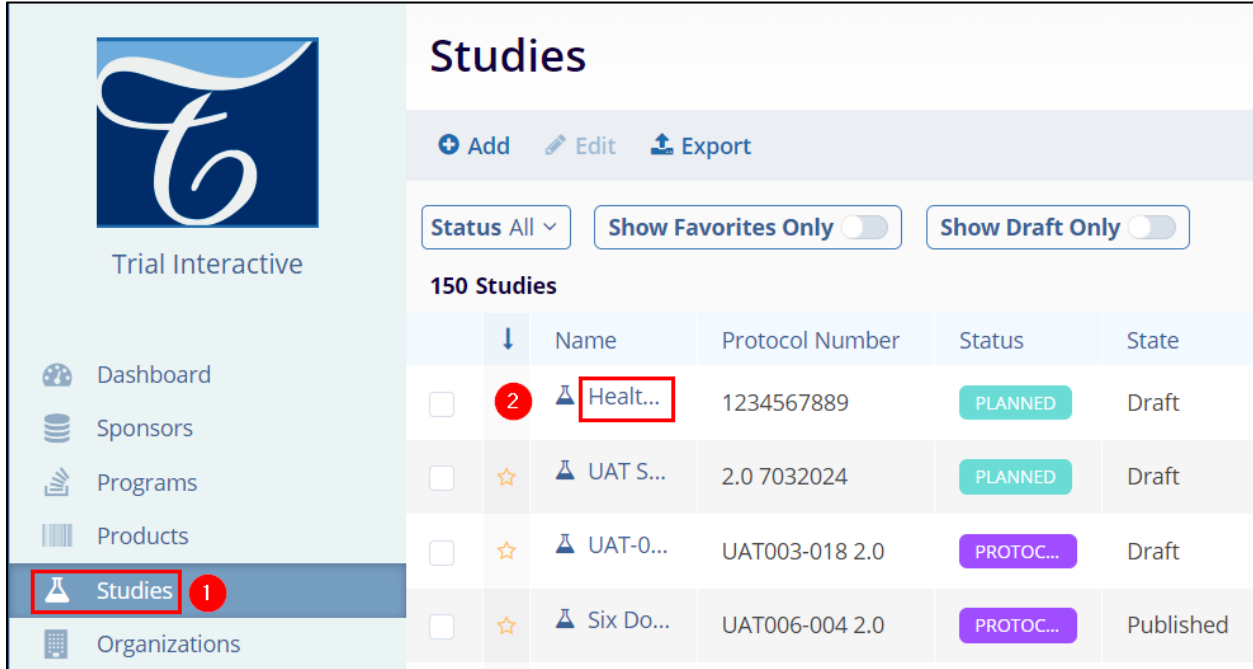


Figure: Selecting a Study

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

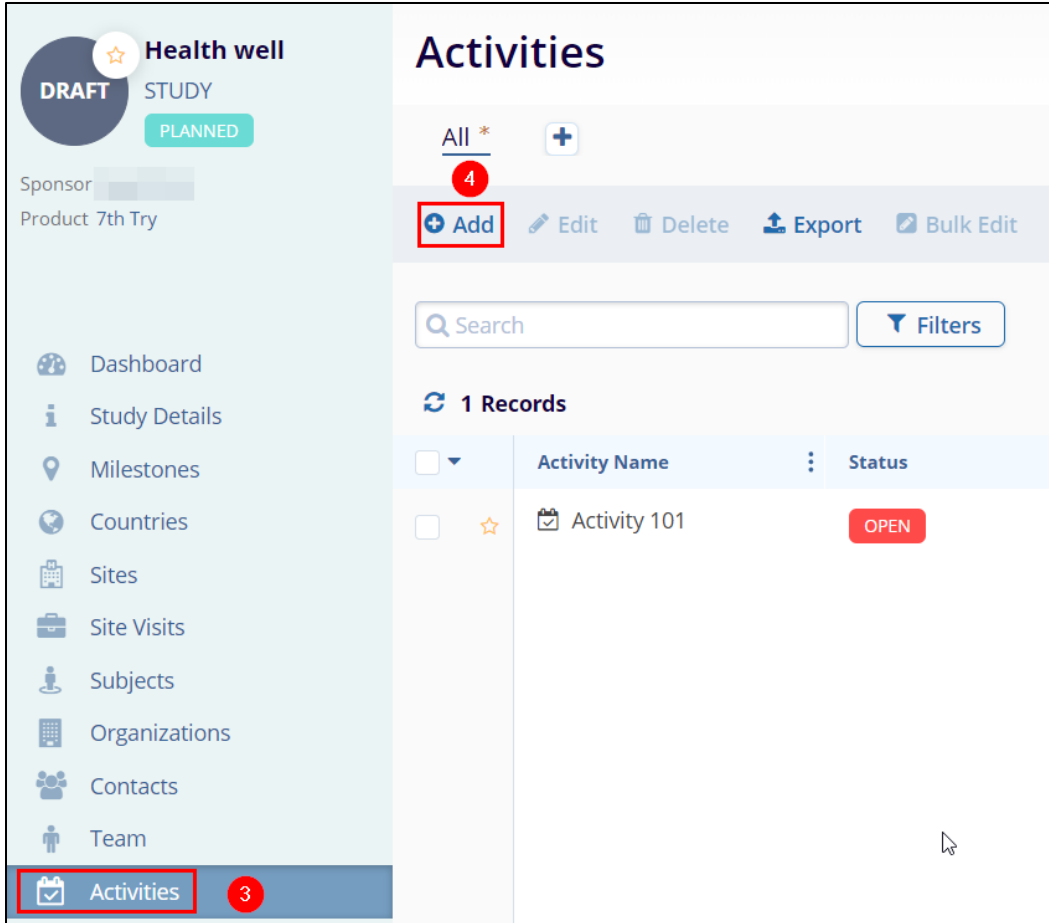


Figure: Select Add Activities

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

Create Activity 5

Activity Name*

Type* Subtype

Description*

Cancel Create and Add Another Create 6

Figure: Tracking Activities

To edit any activity, follow the steps below

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

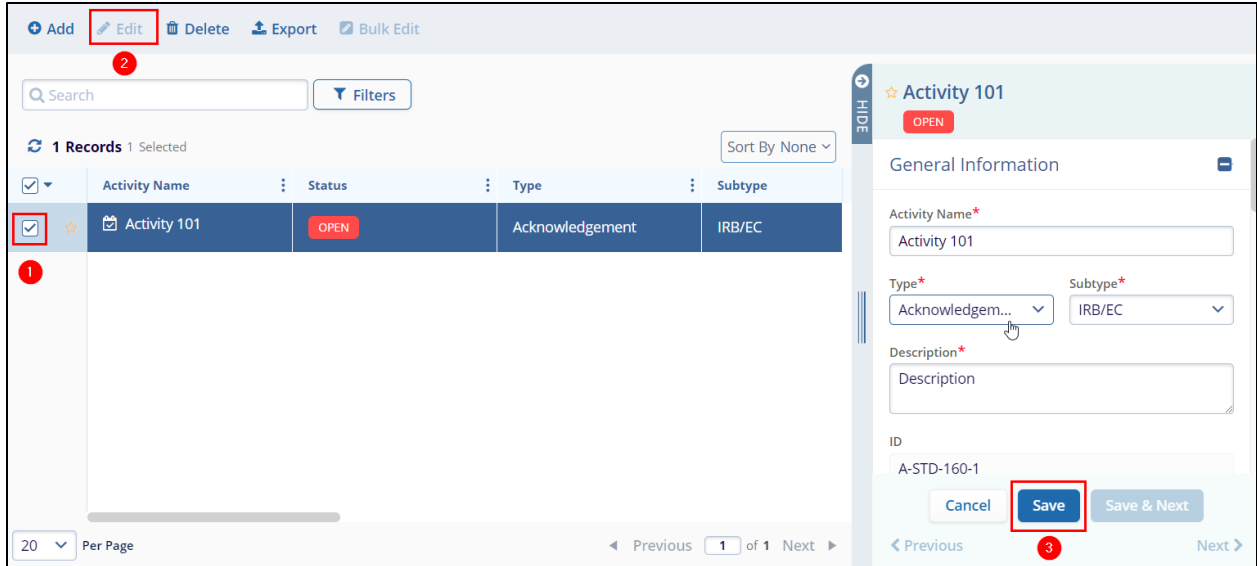


Figure: Editing Activities outside of the Activity Plan

Tracking Actions Towards Activity Completion

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

To track activity completion actions follow the steps below.

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

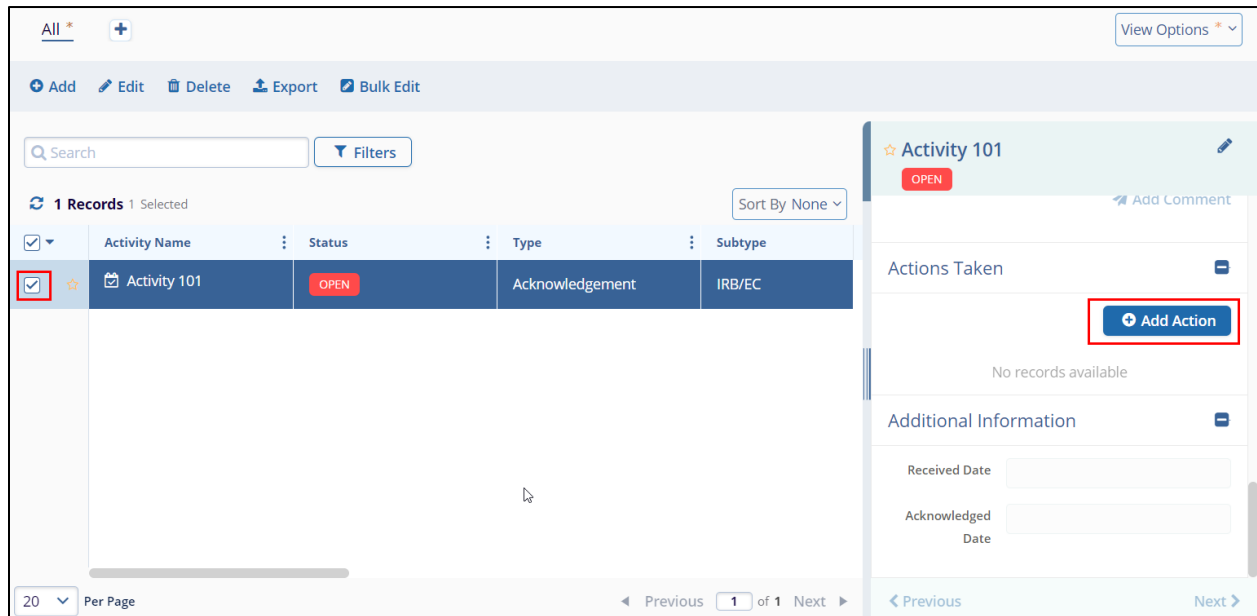


Figure: Actions Taken on quick view panel

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

Add Action [Close]

Action Date*
31 Jul 2024 [Calendar Icon]

Description*
Action Date is added

Cancel Add

Figure: Add Action screen

Customizing Activity Plan Templates screen

Filters

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

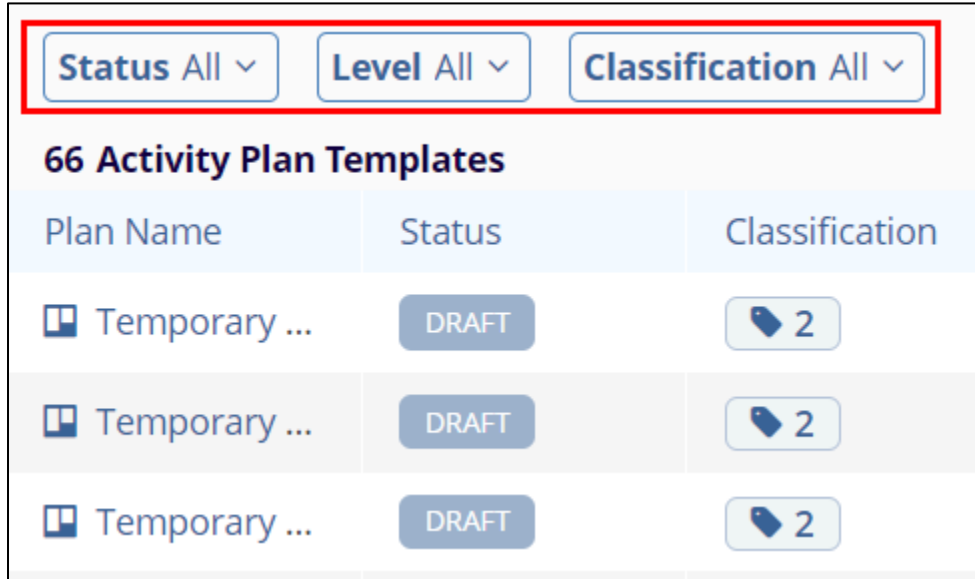


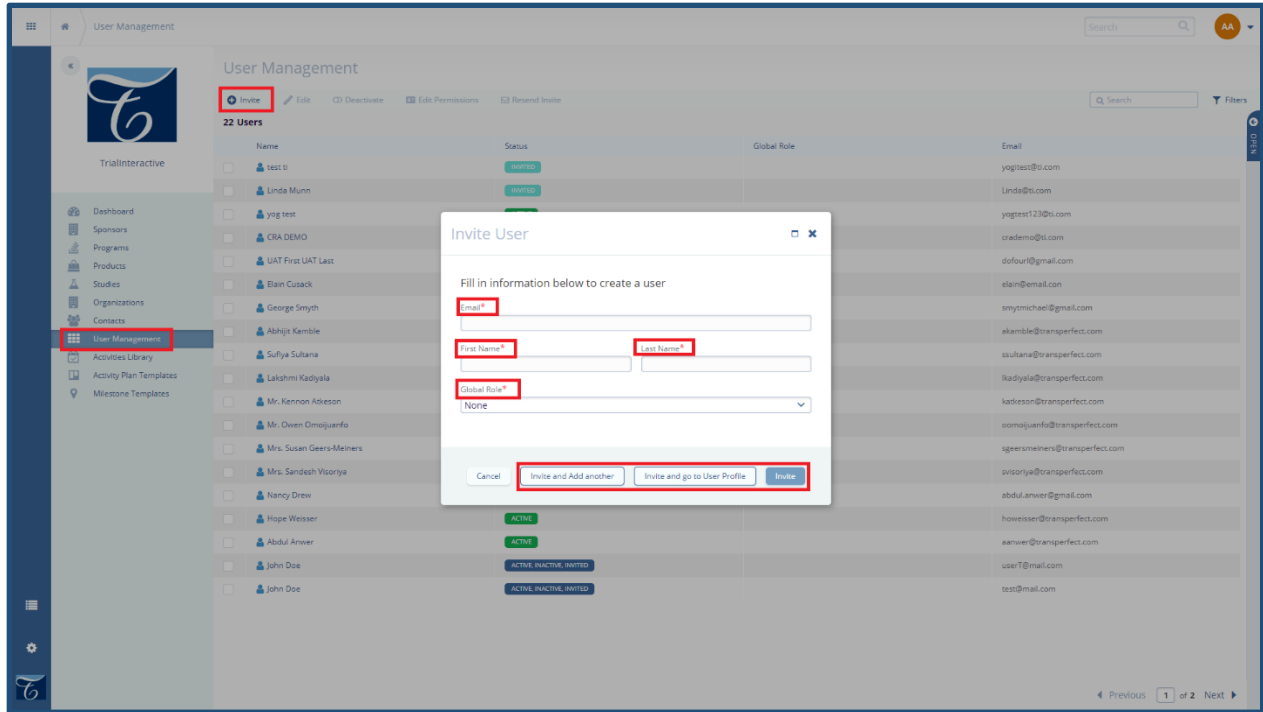
Figure: Activity Plan Templates screen filters

Team Management

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

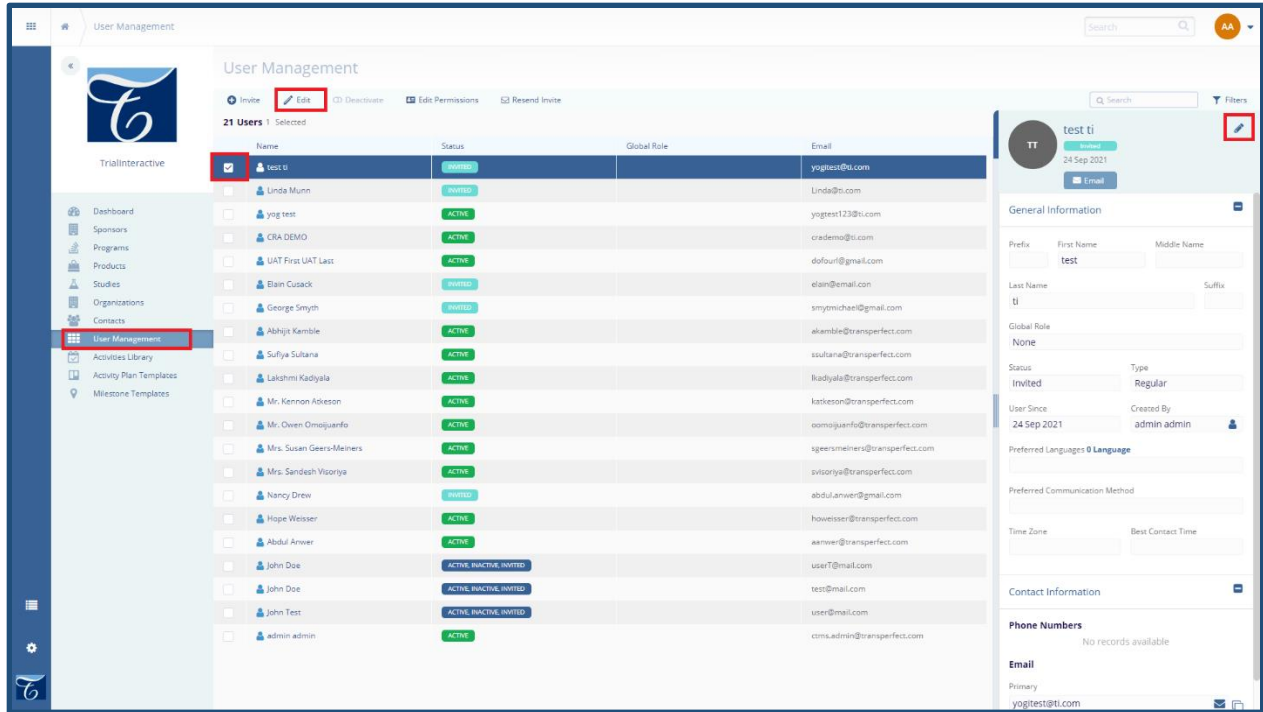
Creating Users

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



Editing a User

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

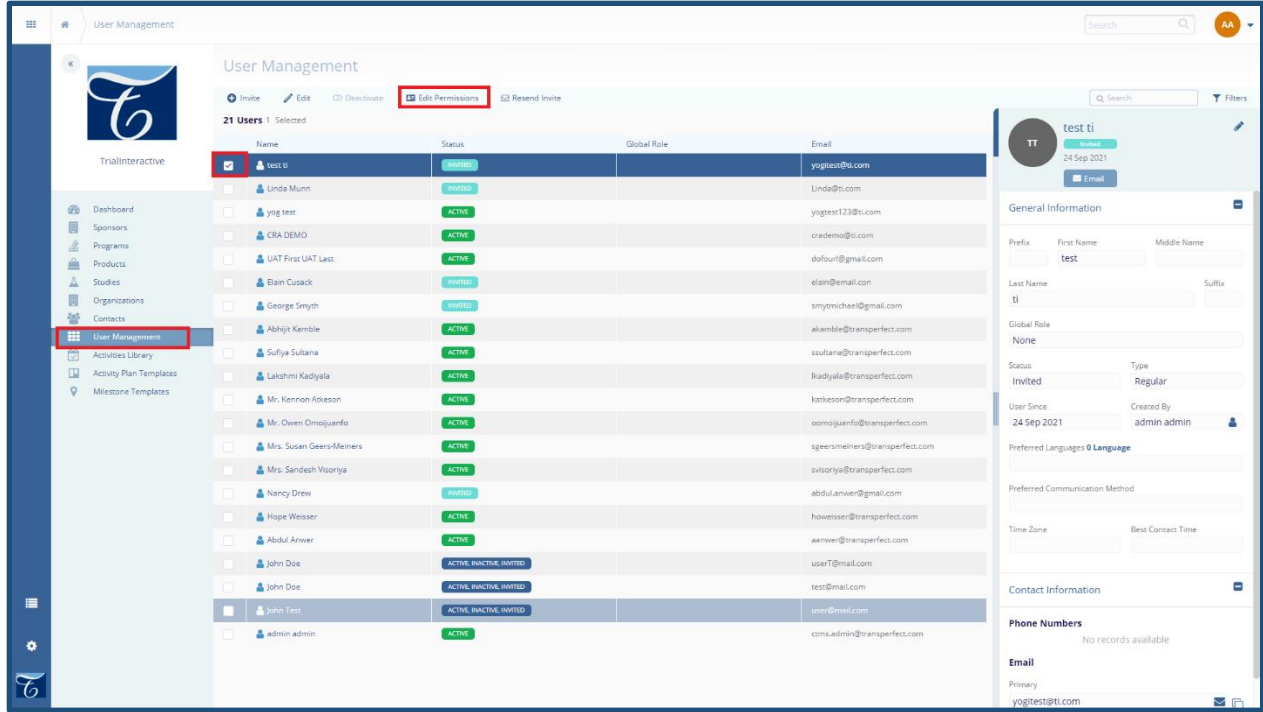


5. Click on the **Save** button in the bottom right of the screen, for the changes to apply to the user account.

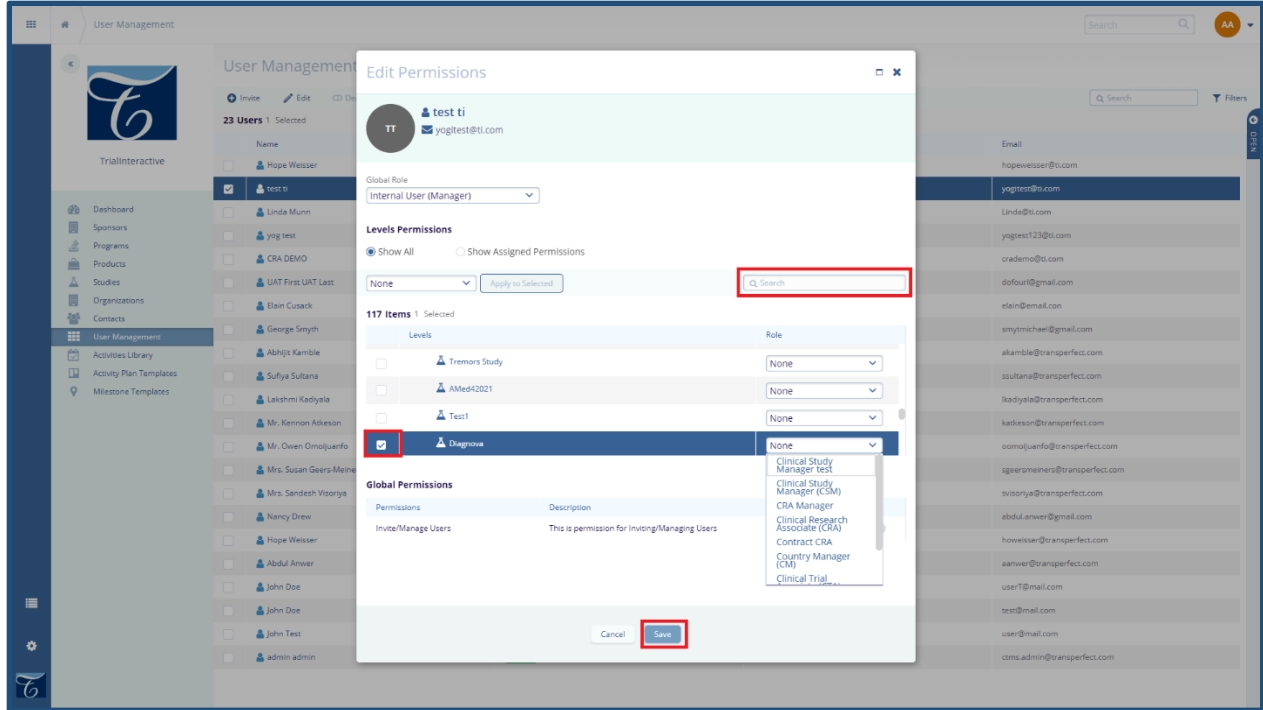
Editing a User's Permissions

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

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



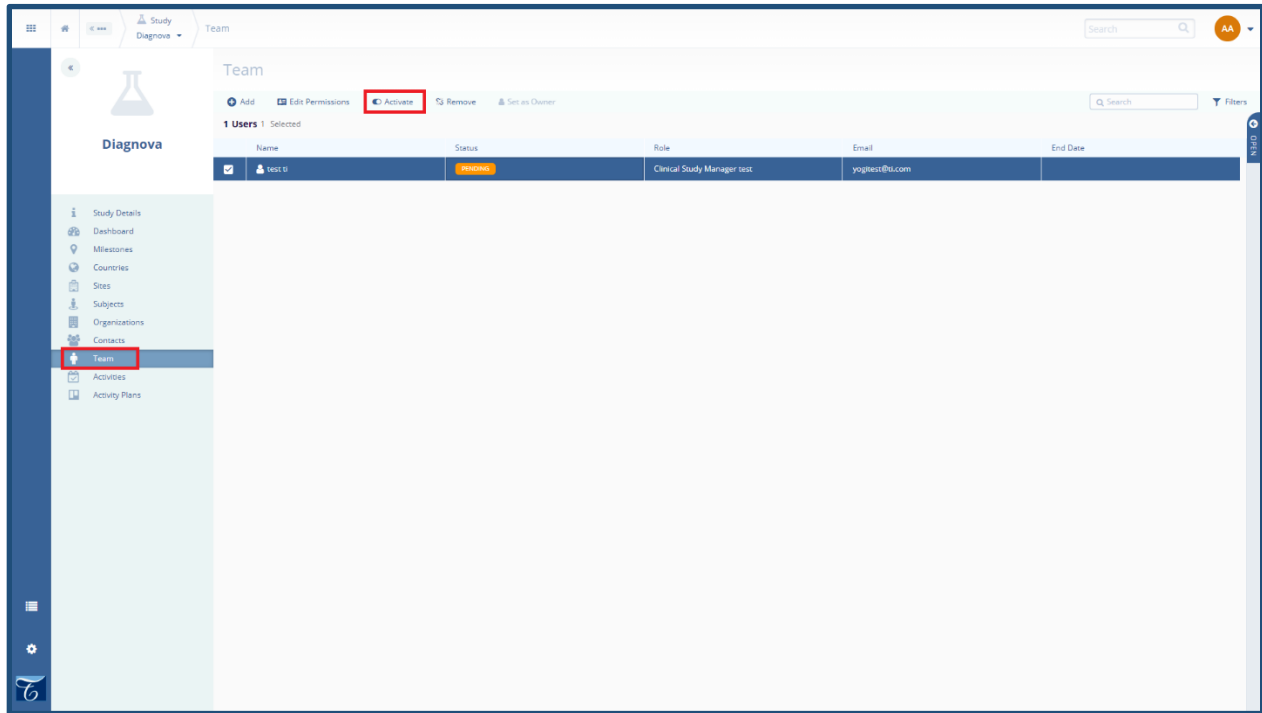
4. Navigate through the list of organizations below or use the search box to find the sponsor.
5. Expand the selected organization and select the appropriate product or study.
6. Assign the user a specific role associated with that product or study.
7. Click on the Save button the bottom of the edit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



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

Study Team Management

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

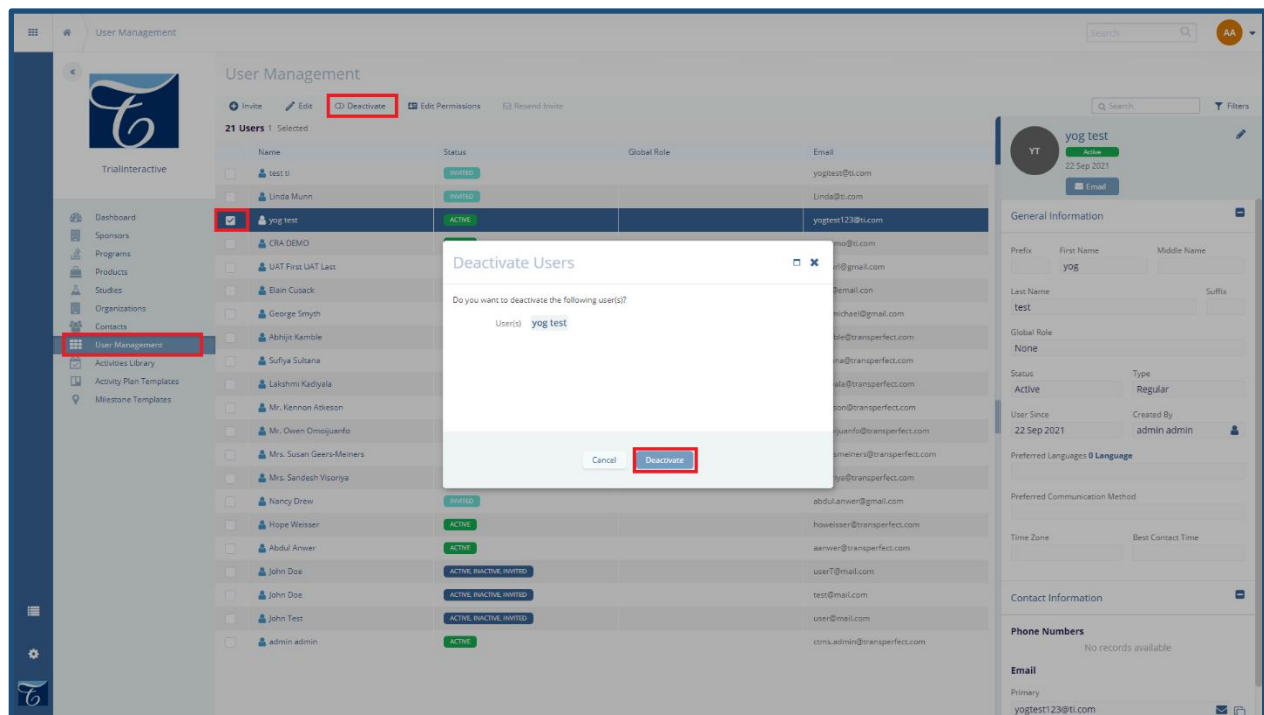


Please note that only study team members listed as Unblinded team members will be able to see unblinded study data where applicable. An Unblinded Clinical Study Manager may assign study team members to Unblinded roles but a Blinded Clinical Study Manager cannot.

Deactivating a User Account

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

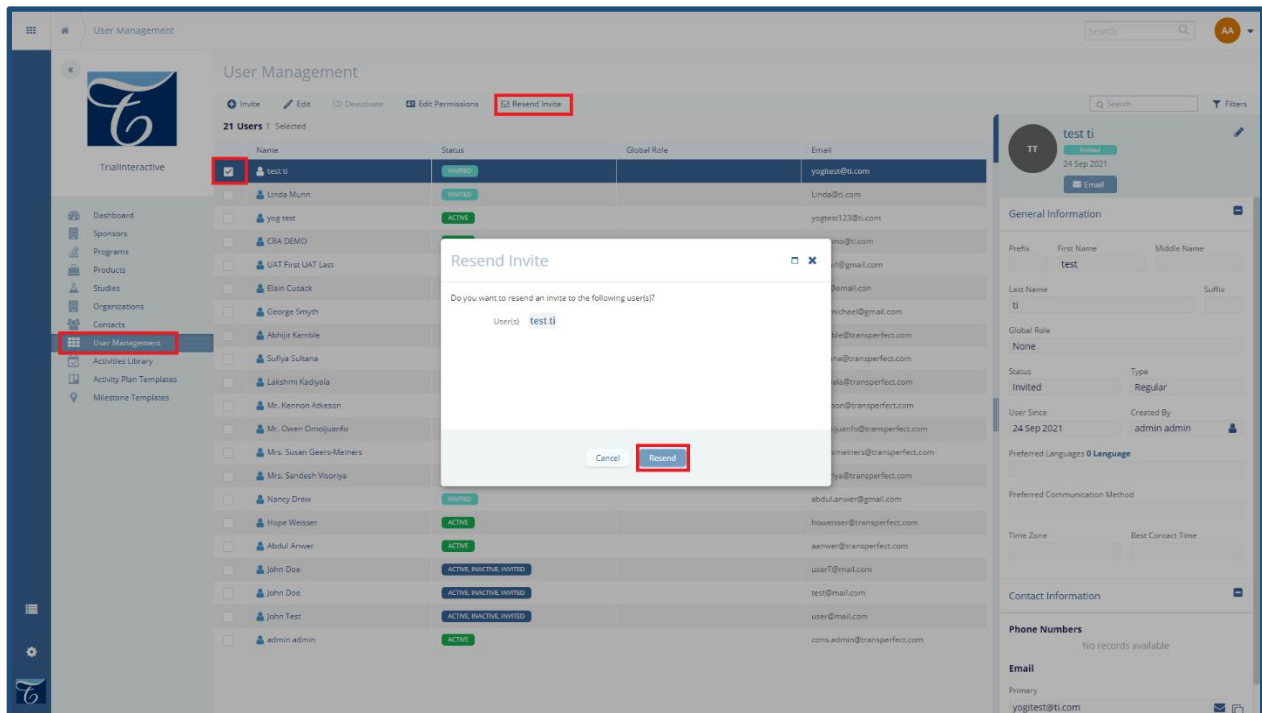
Note: The reverse of this action can be done to activate a user.



Resending a User's Invite

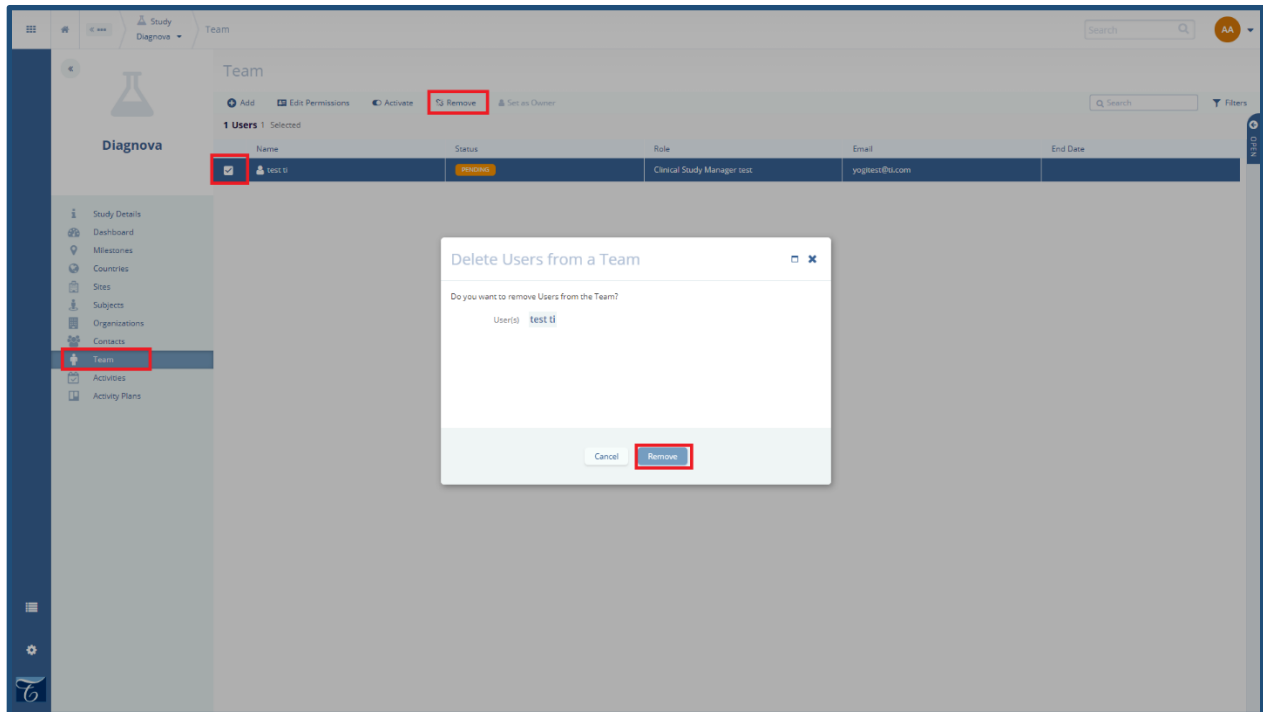
1. Click on the **User Management** link in the Navigation menu at the left side of the screen.
 - a. This opens the **User Management** screen.
2. Navigate to the user whose invitation you want to resend and click the check box.
 - a. This opens the quick view on the right side of the screen.
3. Click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

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



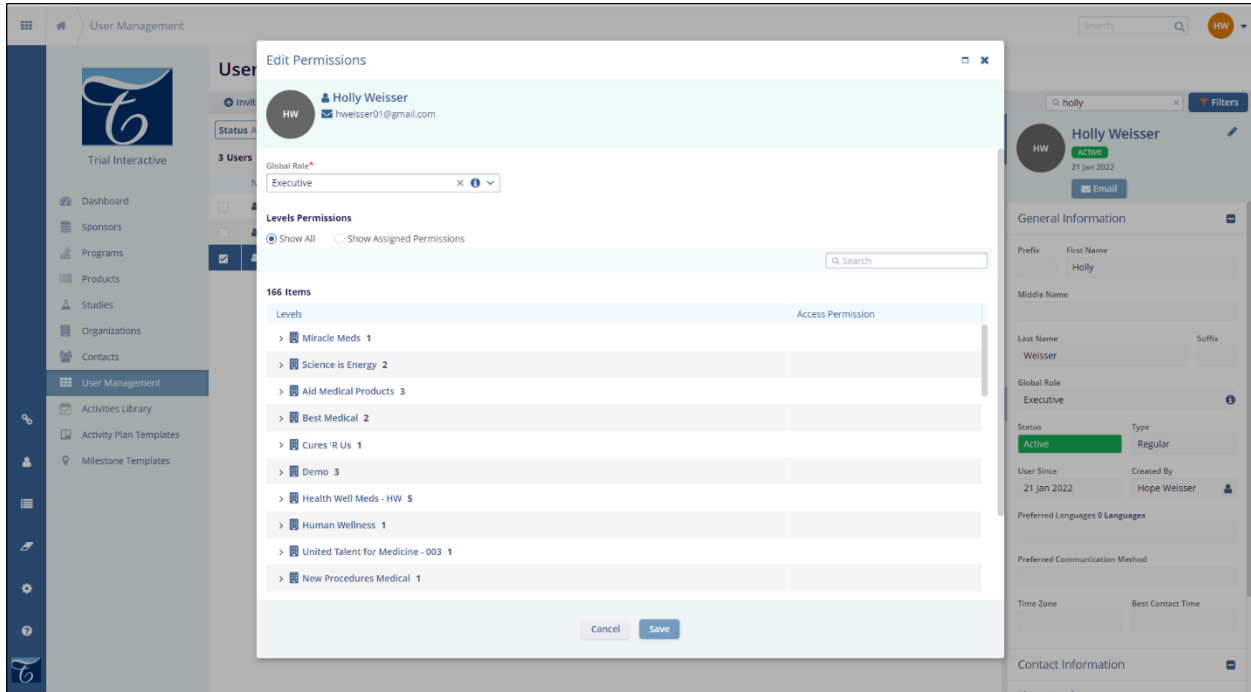
Removing Users from a Team list

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



Access Management

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



Milestones

This section describes about Milestones module in the application.

Important

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

Pre-Requisites

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

Creating Domain Library Milestone Template

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

1. From the left-hand navigation links, click on the **Milestone Templates** which opens the Milestone Templates window.
2. Click the **+Create** button at the top-left of the screen.
3. On the **Create Milestone** template, enter the following metadata details.

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

 - a. **Level***: Specify whether the milestone is to be created at a Study, Site, or Country level by selecting the option from the dropdown.
 - b. **Milestone Name***: Enter a name for the milestone template.
 - c. **Classification**: Select the classification criteria from the available dropdown options.
 - d. **Description**: Enter a suitable description for the template
 - e. **Set Parent Milestone Template**: Turn on the **Set Parent Milestone Template** toggle to add a parent template for the current template. Select a template from the available dropdown options.
 - f. **Countries**: The **Countries** field is only visible if the template is created at the **Site** or **Country** level. Select the countries from the available dropdown options.
4. Click on **Create** once all the necessary details are entered in the respective fields.

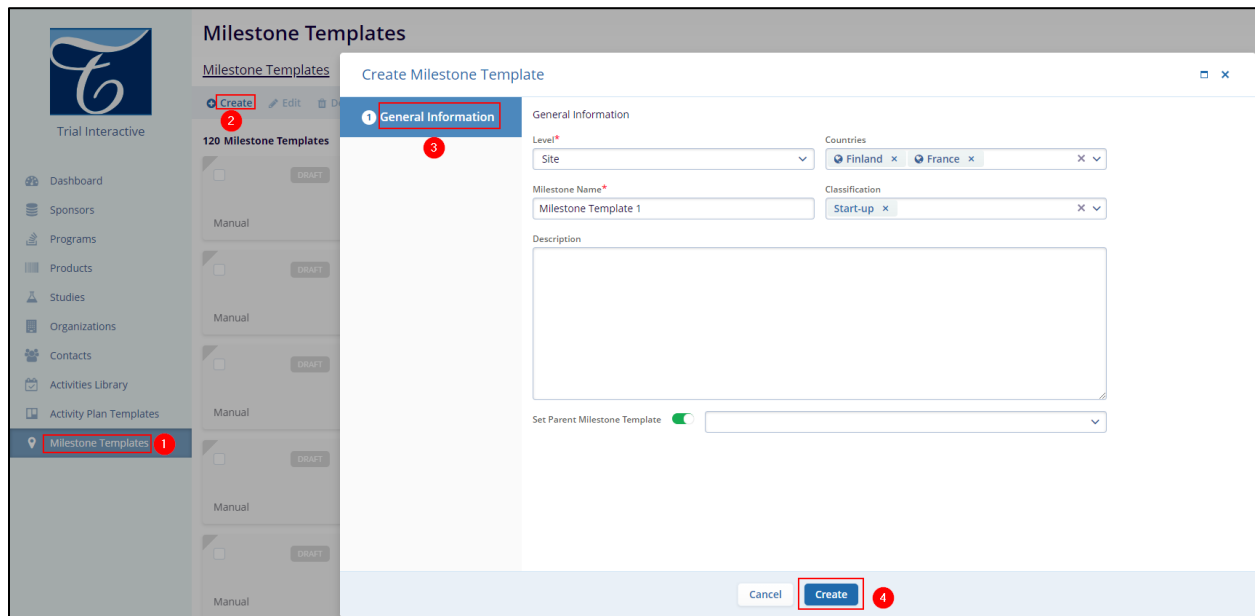


Figure: Creating Domain Library Milestone Template

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

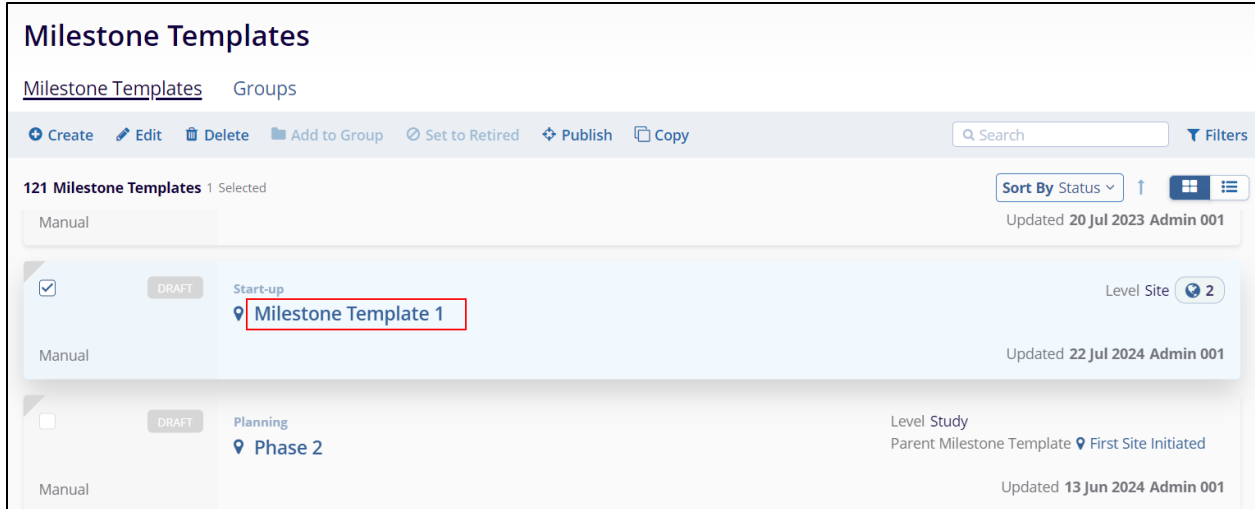


Figure: Newly created milestone template

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

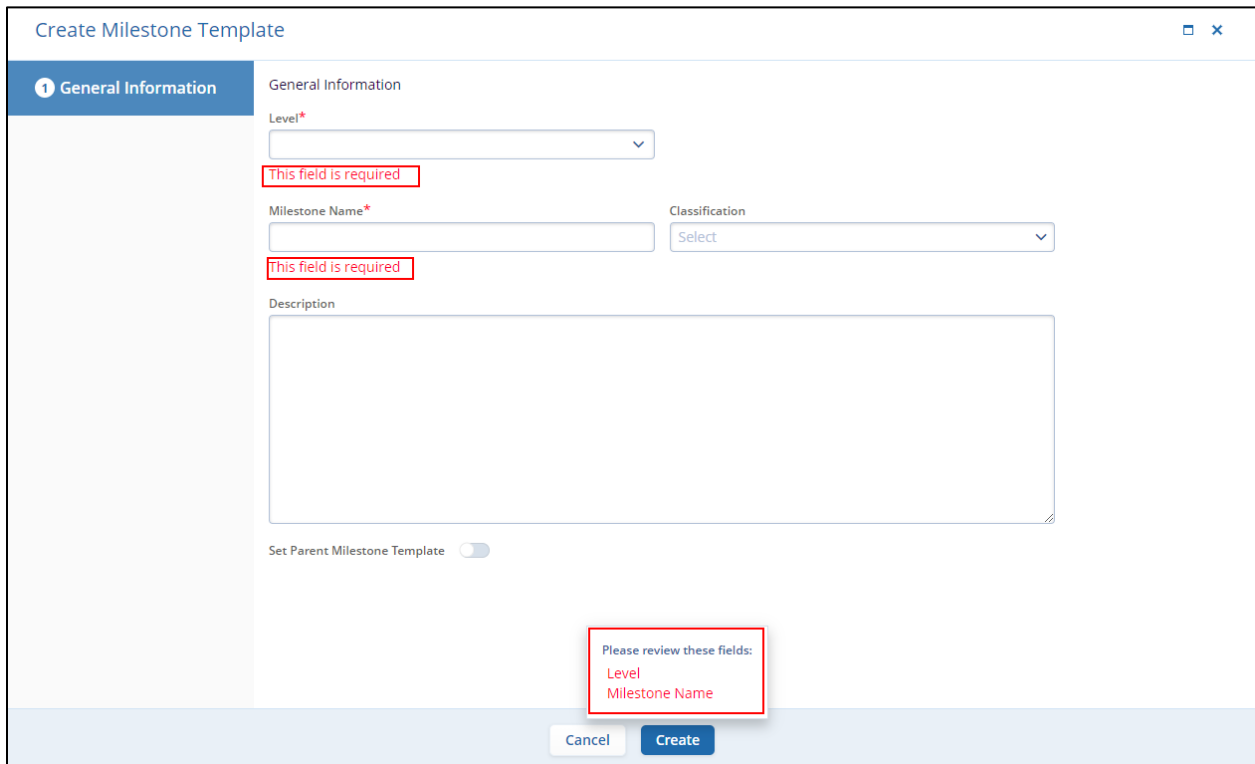


Figure: Mandatory fields error

Creating a Study Milestone from a Template

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

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

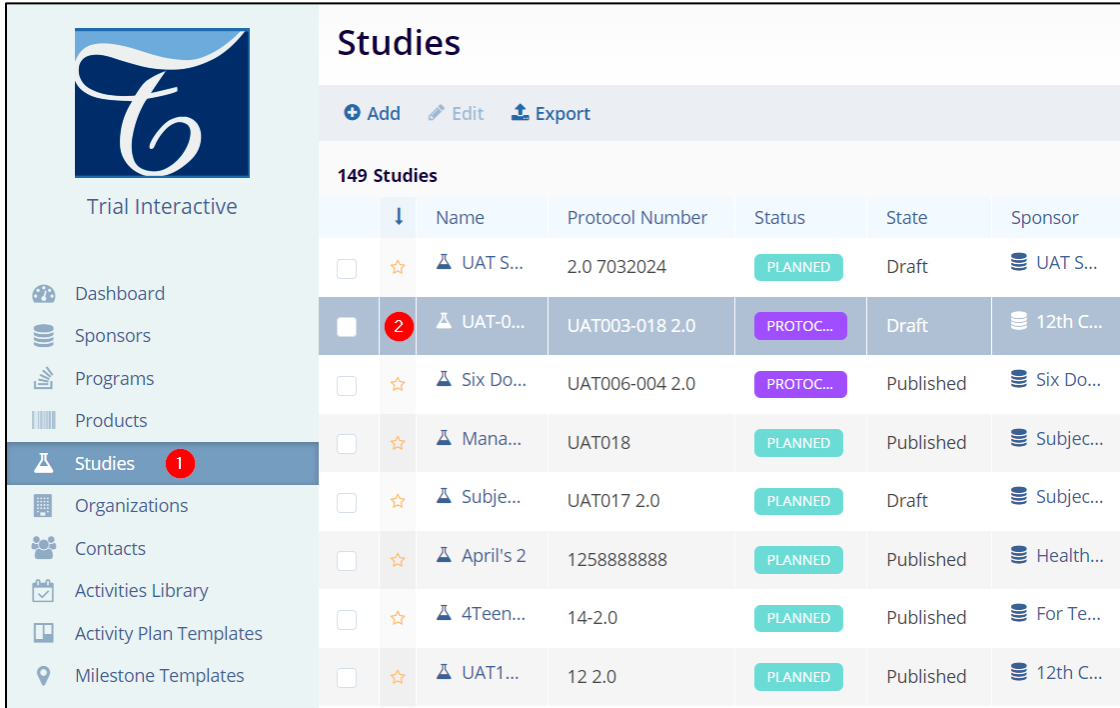


Figure: Selecting a study

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

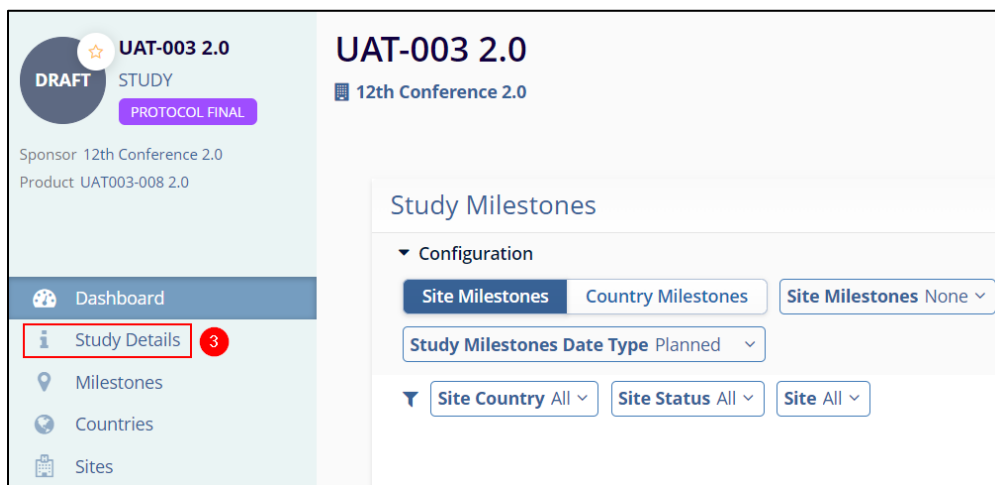


Figure: Select Study Details

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

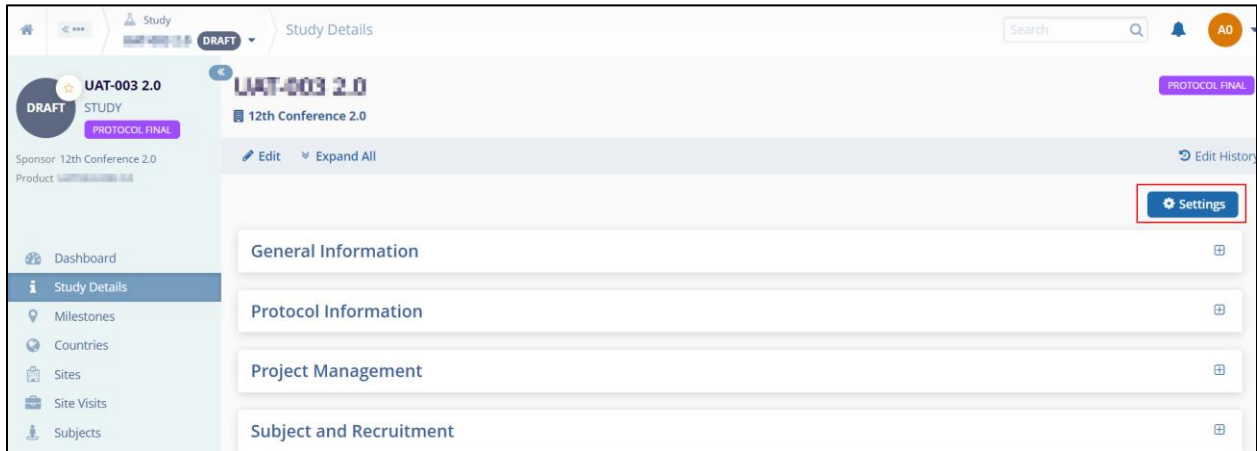


Figure: Select Settings on the Study Details screen

- Click on the **Milestone Templates** link in the Navigation menu at the left side of the screen.
- Click on the **+Add** button on the on the top-left of the screen.
- Click on **Add From Sponsor**.

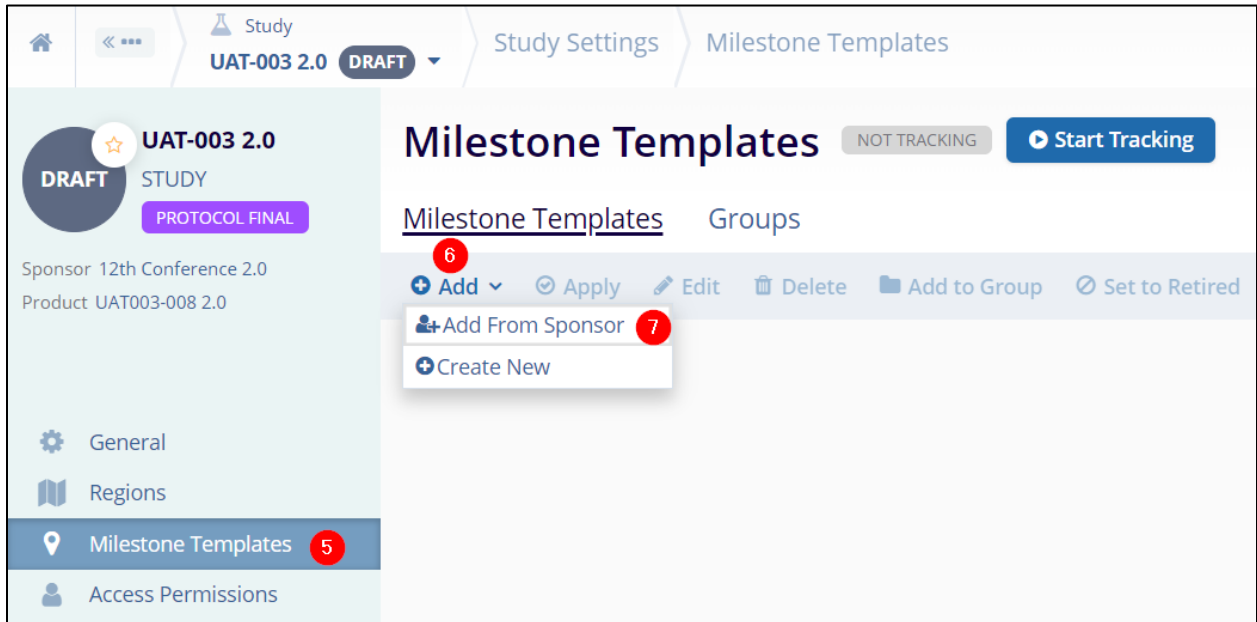


Figure: Select Add From Sponsor

- On the Add Milestone Template From Sponsor screen, select the milestone template.
- Click on the Add button.

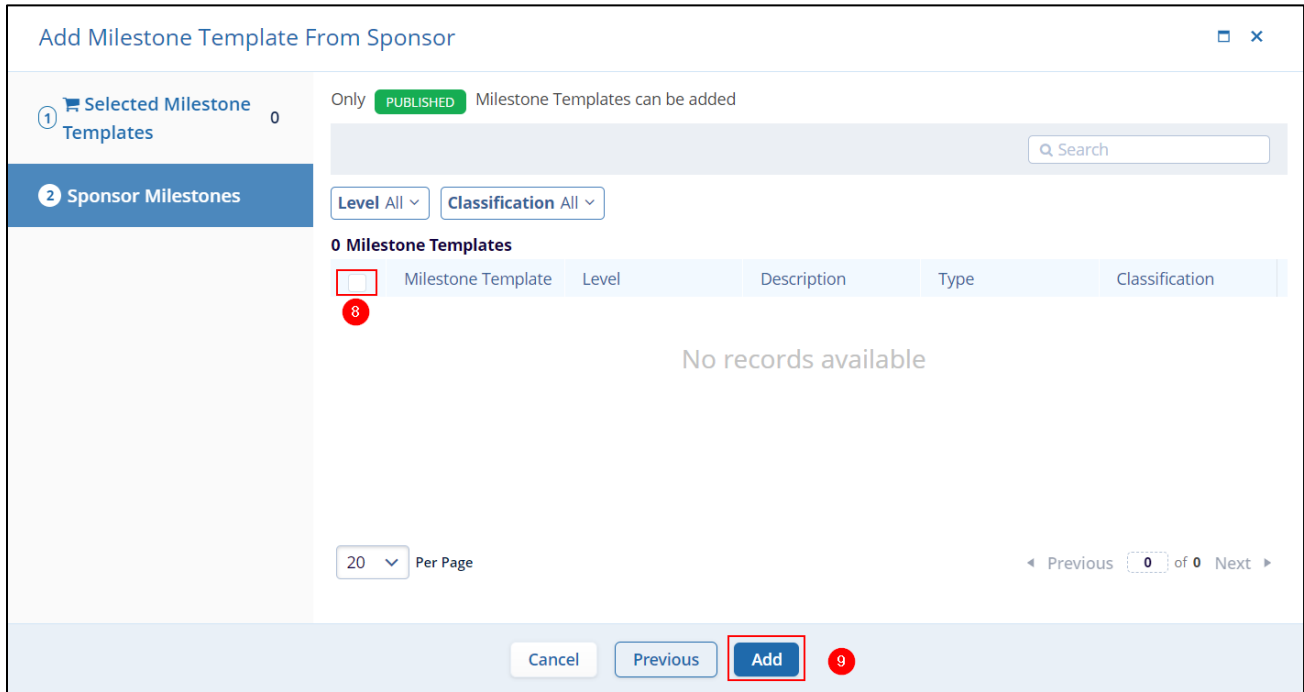


Figure: Add Milestone Template From Sponsor

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

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

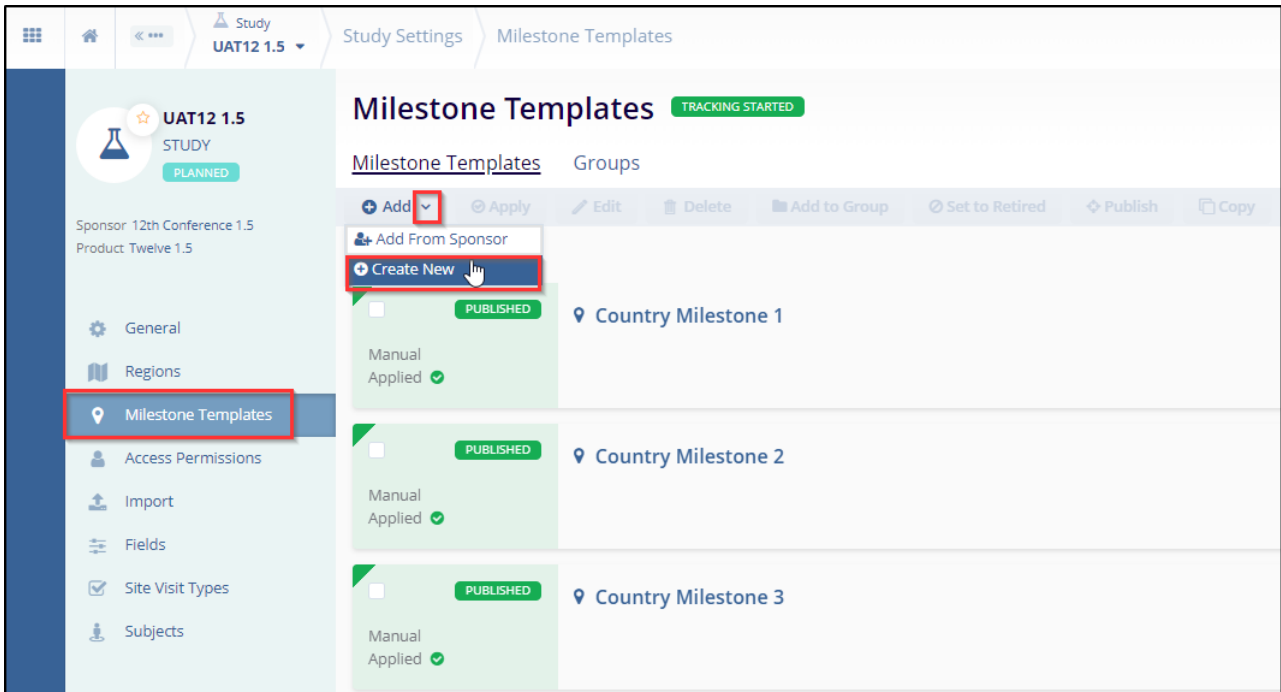


Figure: Create a New Template

2. Fill in the mandatory metadata to create a milestone template i.e., **Level**, **Template Name** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information as necessary.
3. Click on Create once all the details are entered.

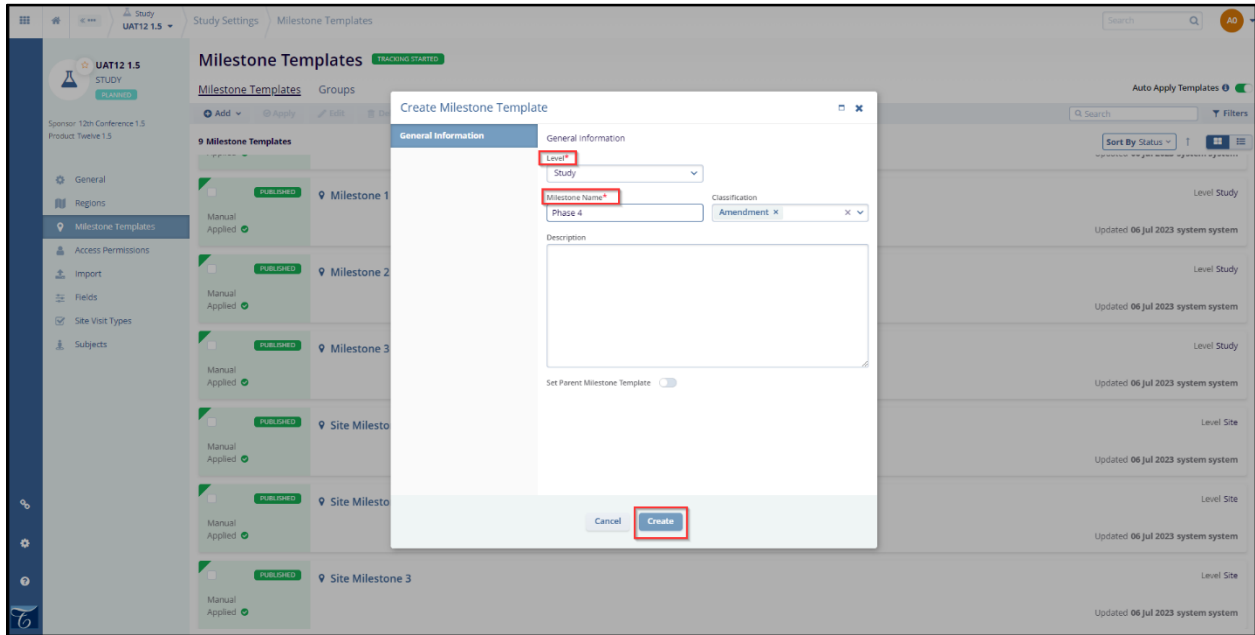


Figure: Save the new template

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

Editing Domain Milestone Templates

To edit Domain Milestone Templates, follow the steps below.

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

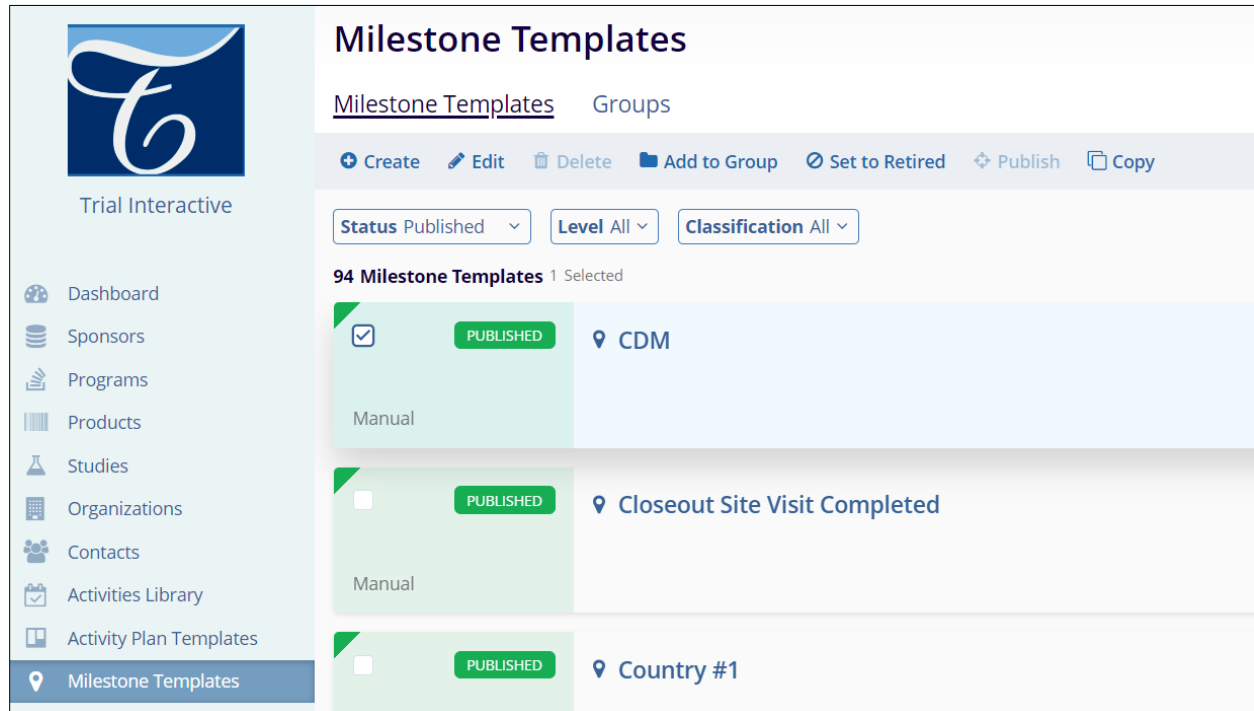


Figure: Select a template to edit

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

Figure: Edit Milestone Template

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

Deleting Domain Milestone Templates

To delete Domain Milestone Templates, follow the steps below.

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

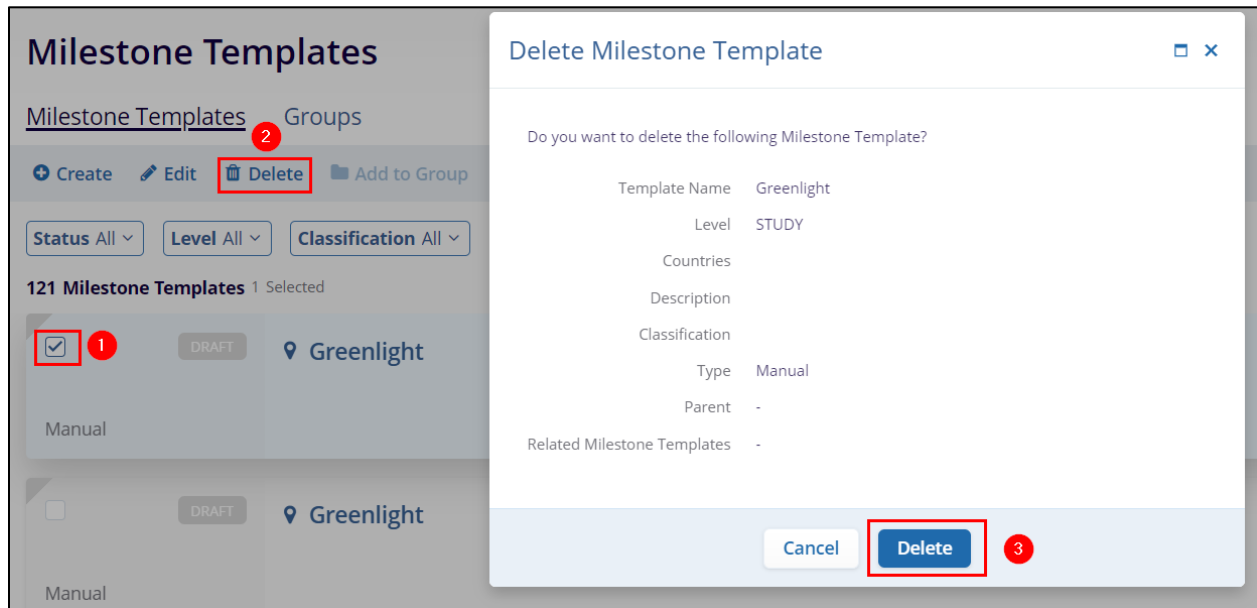


Figure: Deleting Milestone Template

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

Publishing Milestone Templates

To publish Milestone Templates, follow the steps below.

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

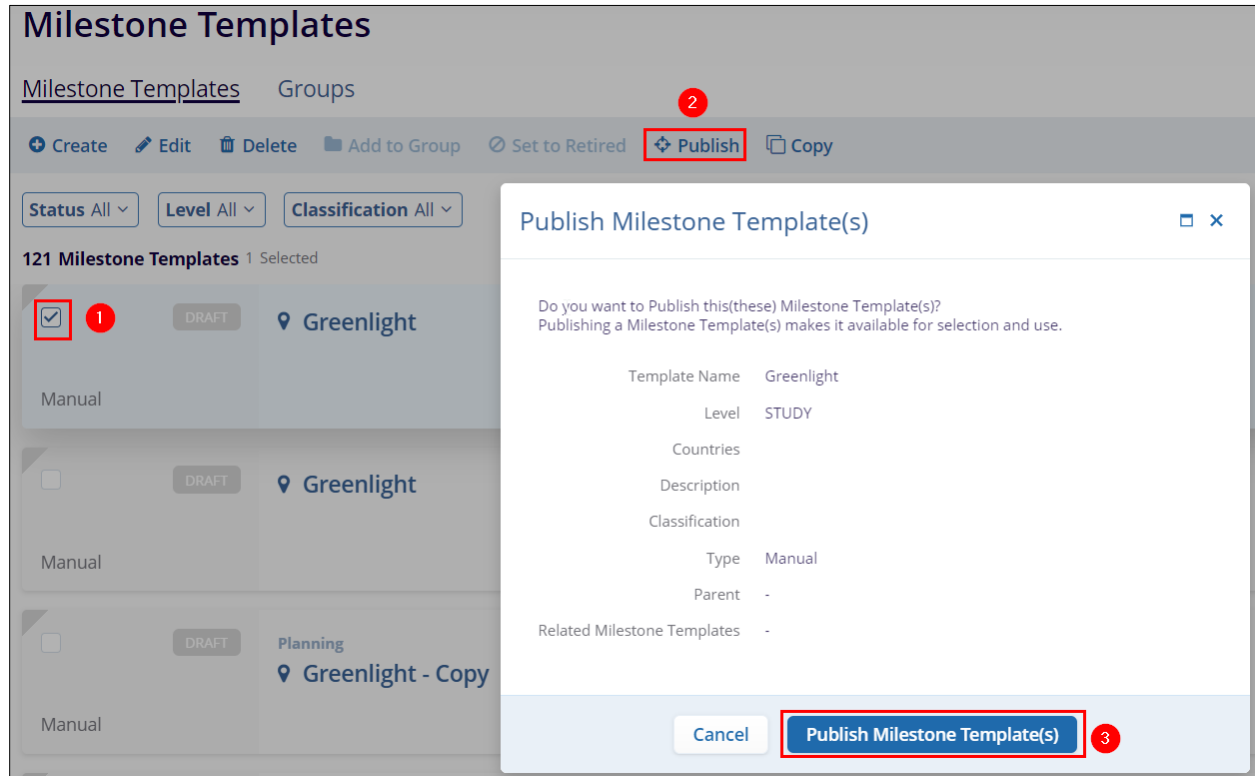


Figure: Publishing Milestone templates

Note: Milestone Templates with **Draft** status can be published.

Retiring Milestone Templates

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

To retire a Milestone Template, follow the steps below.

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

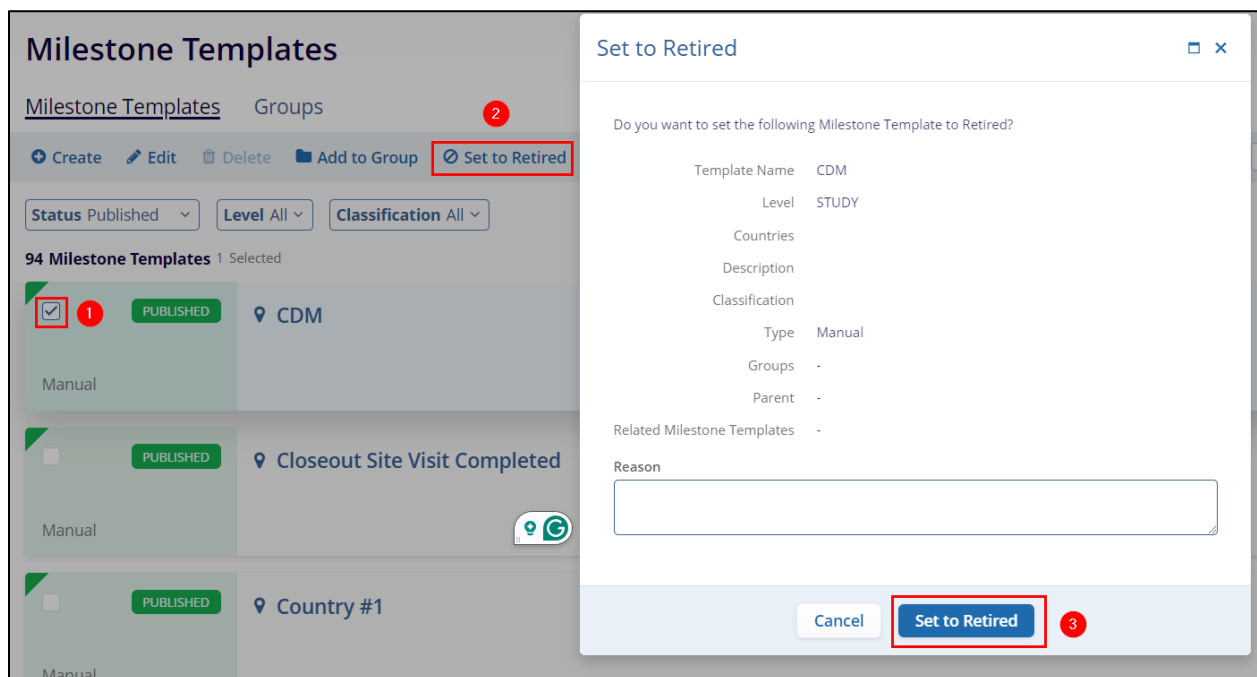


Figure: Retiring Milestone Template

Copying Milestone Templates

To copy Milestone Templates, follow the steps below.

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

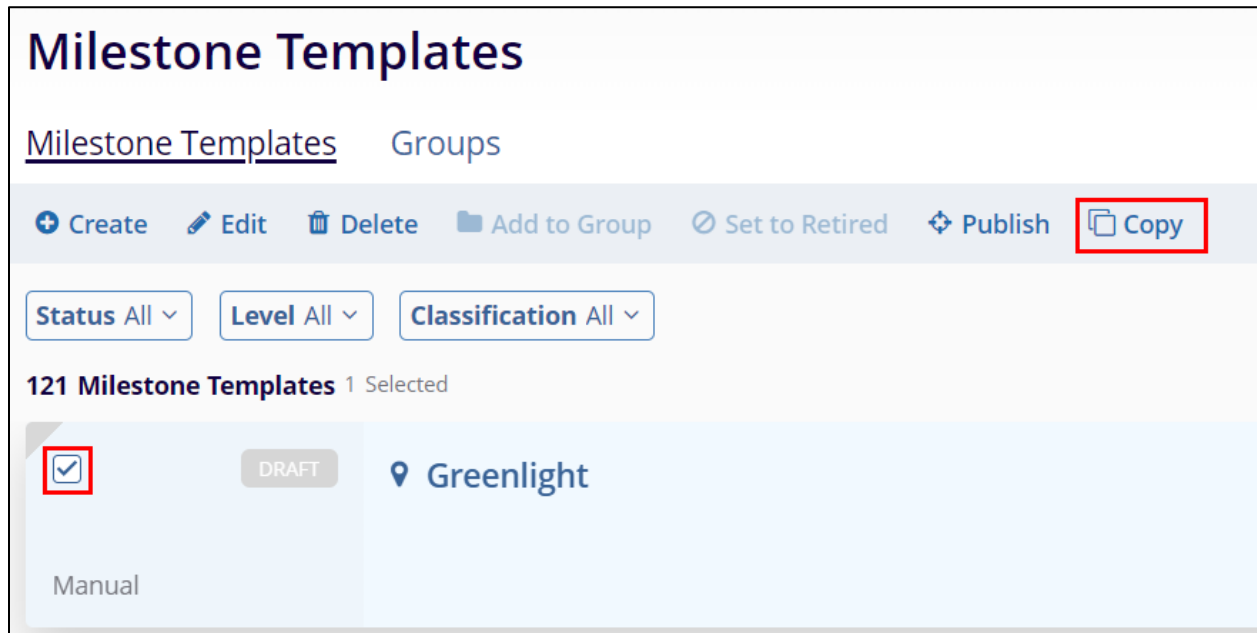


Figure: Copying a milestone template

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

Associating Milestone Templates to a Sponsor

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

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

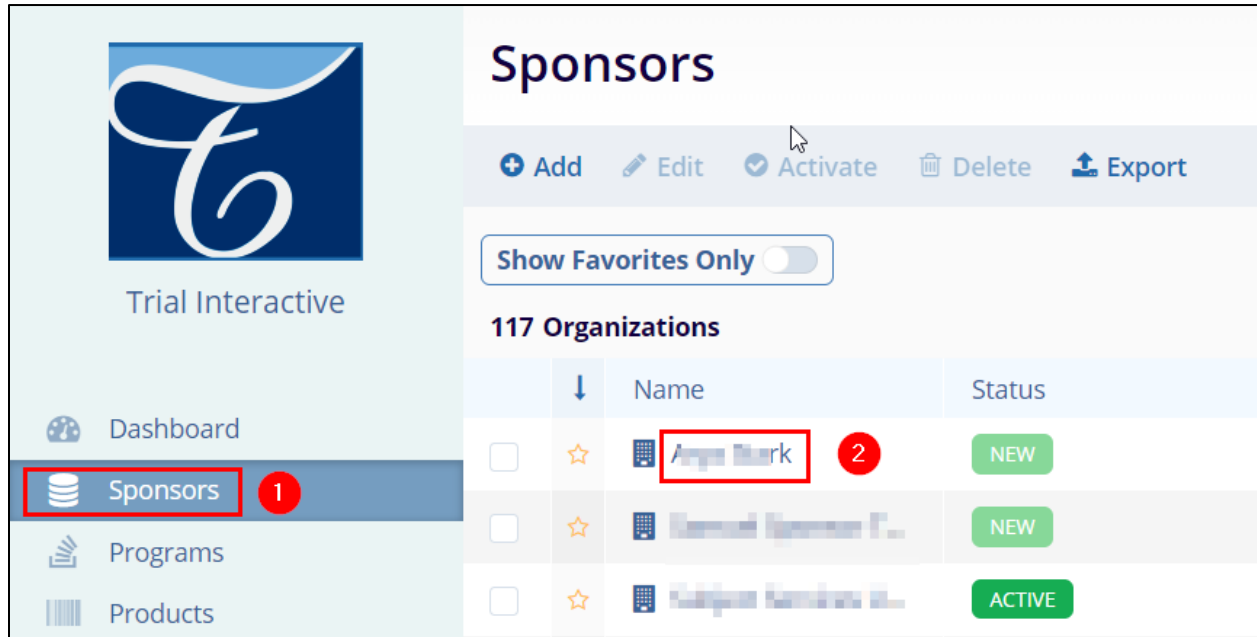


Figure: Select Sponsors

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

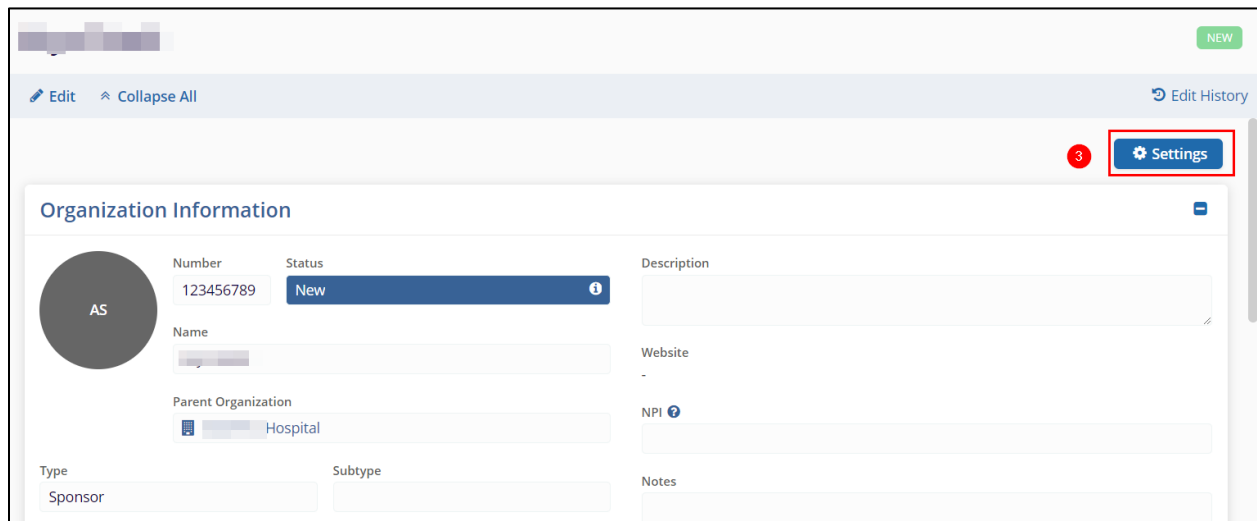


Figure: Access Setting on the Sponsor Details screen

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

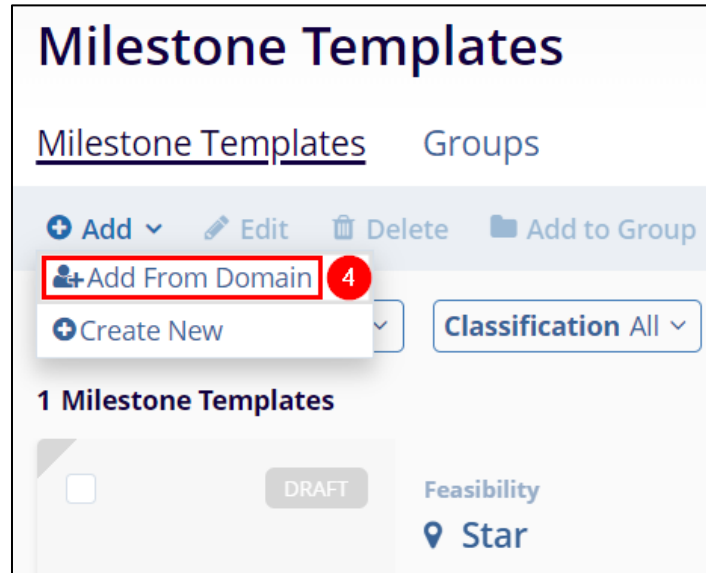


Figure: Add Template From Domain

- On the Add Milestone Template from the Domain window, select one of the milestone templates by clicking on the milestone templates checkbox.
- Click on the Add button once all the required templates are selected.

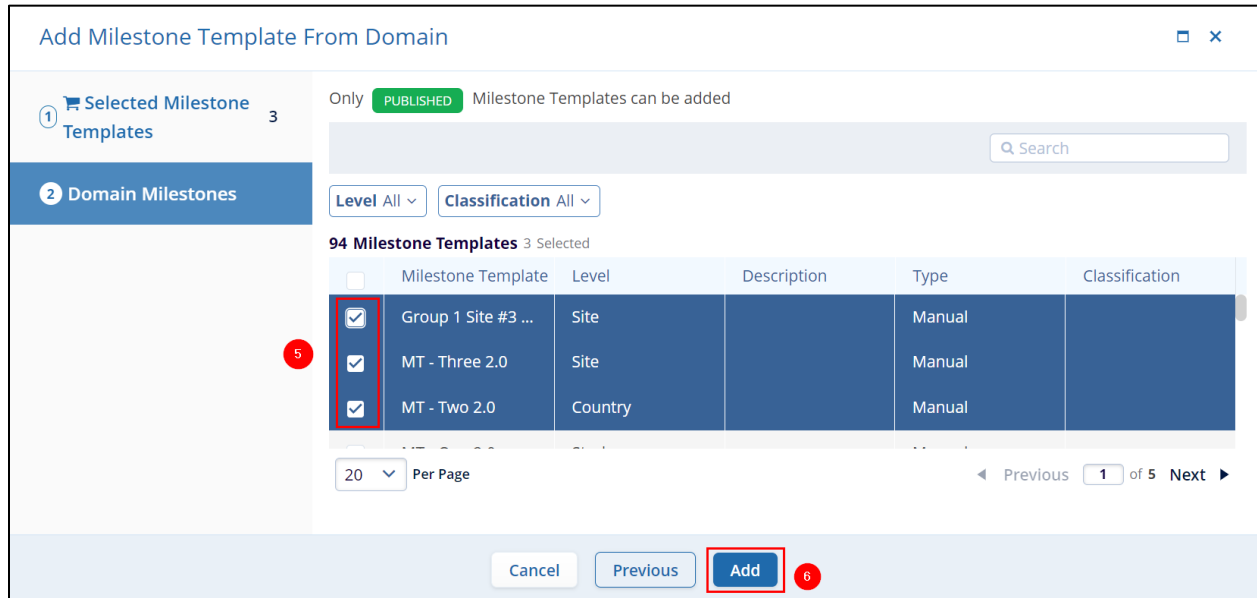


Figure: Add Milestone From Domain screen

Defining Sponsor-Specific Milestone Templates

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

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

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

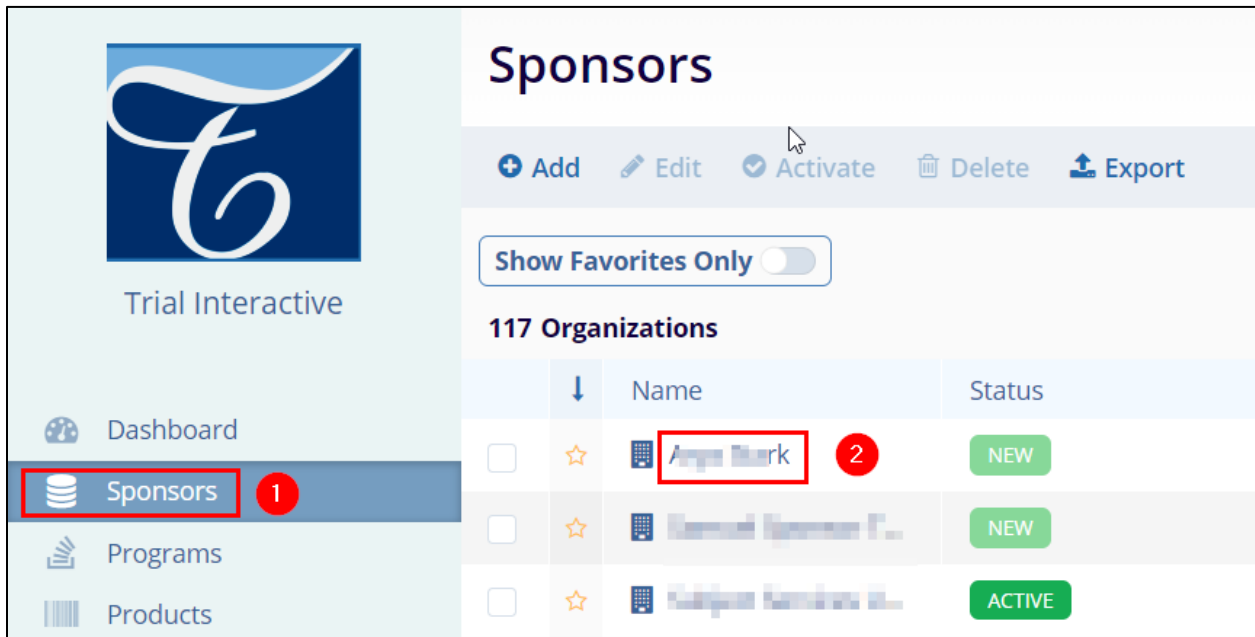


Figure: Select Sponsors

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

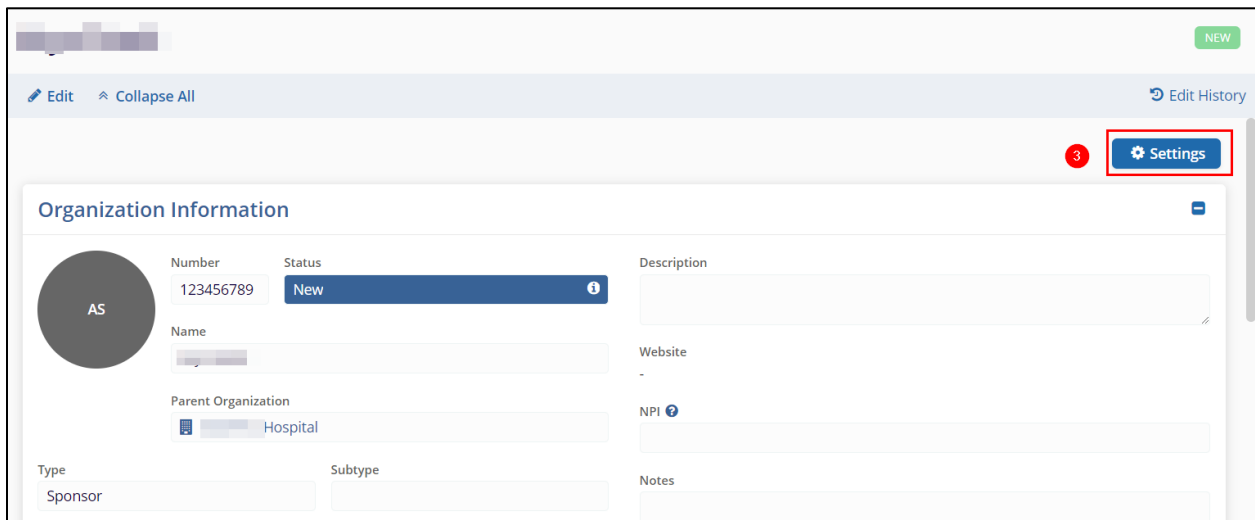


Figure: Access Setting on the Sponsor Details screen

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

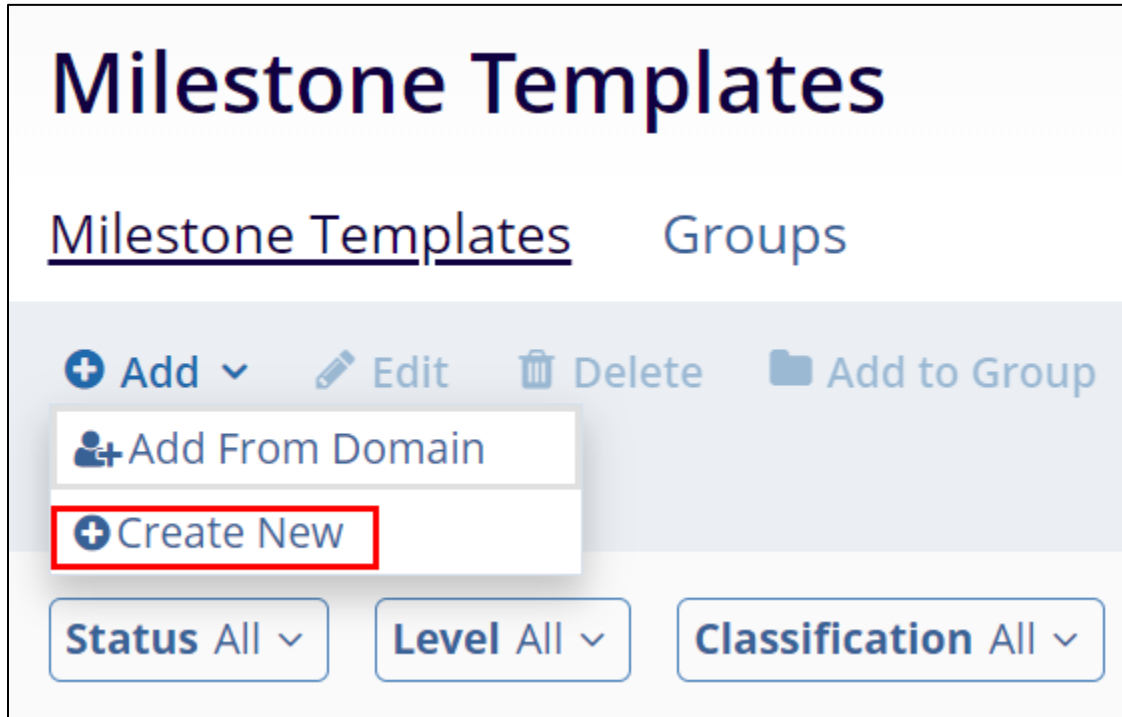


Figure: Create new milestone template for the sponsor

- On the **Create Milestone Template from the Domain** window, add all the mandatory details.
- Click on the **Add** button once all the mandatory details are entered.

Create Milestone Template
☐ ✕

1 General Information

General Information 5

Level*

Milestone Name*

Classification

Description

Set Parent Milestone Template

Cancel
Create
6

Figure: Creating new milestone template for sponsor

Tracking Milestones

To track milestones, follow the steps below.

1. From the left-hand navigation links click on the **Studies**.
2. On the Studies window, click on the name of the study.
3. On the selected studies window, navigate to the left-hand navigation links and click on the **Study Details**.
4. On the Study Details screen, click on the **Settings** button in the top-right of the screen.
5. Click on **Start Tracking** in the top-left of the screen. This opens the **Start Tracking** confirmation window.
6. Click on the **Yes, start tracking** button which will result in all milestones to be applied and start tracking, not just the selected milestone.

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

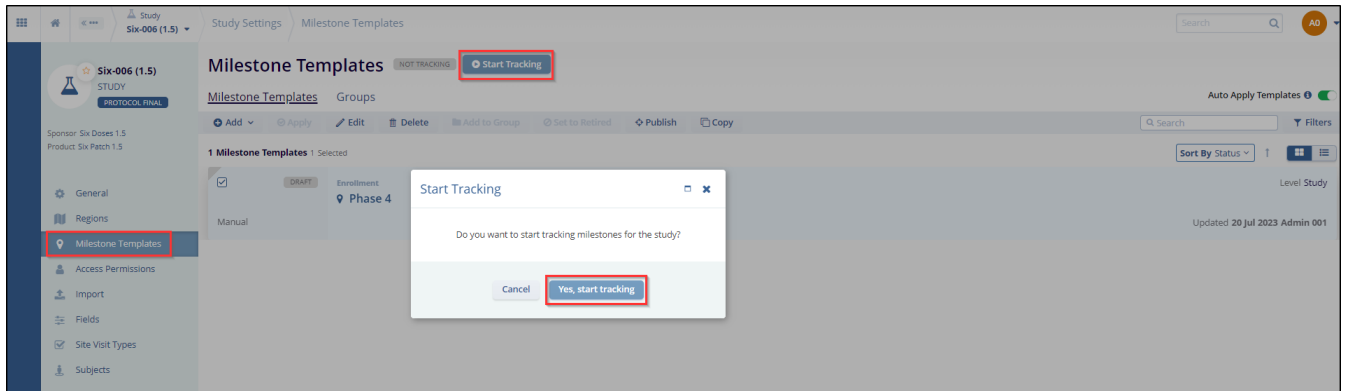


Figure: Tracking Milestones

Auto Apply

It can be difficult, at times, to remember to apply a newly added or created milestone to a study. The **Auto Apply Templates** toggle switch at the top-right corner of the Milestone Templates screen at the study level. This way, Study Managers can indicate whether or not milestones should be applied manually, as needed, or automatically once they are published and added to a study.

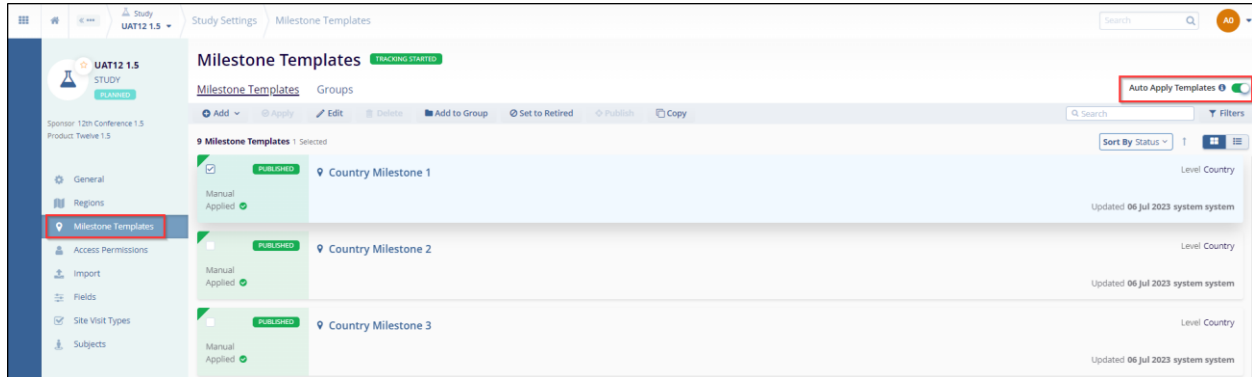


Figure: Auto Apply Templates

Note: This would not apply the template to sites created after this switch is activated. For future sites, it is recommended to use the scheduler for activity plans.

Milestone Groups

Users can create and apply groups of milestone templates as needed. Only published milestone templates may be added to a group. Milestone groups may be set up at the Global or Study level by users with sufficient access to either level of data.

Creating Milestone Groups

To create Milestone Groups, follow the steps below. Refer to the screenshot and steps for the sequence.

1. From the left-hand navigation links, select Milestone Templates.
2. Click on **Groups** on the Milestone Templates screen.

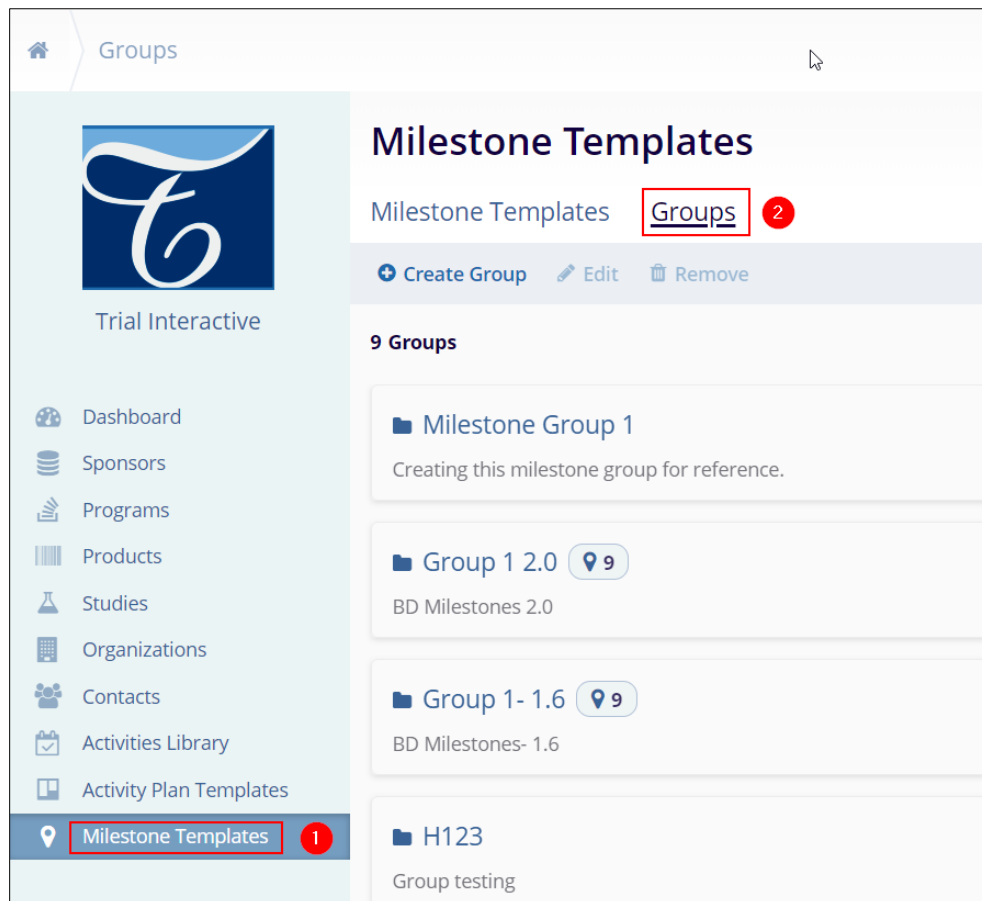


Figure: Milestone Groups

3. Click on **+Create Group**.
4. On the **Create a Group** screen, fill in the following details.
 - a. **Title***: Enter a suitable title for the group
 - b. **Description***: Enter the necessary description for the group.
5. Click on Create once all the necessary details are entered.

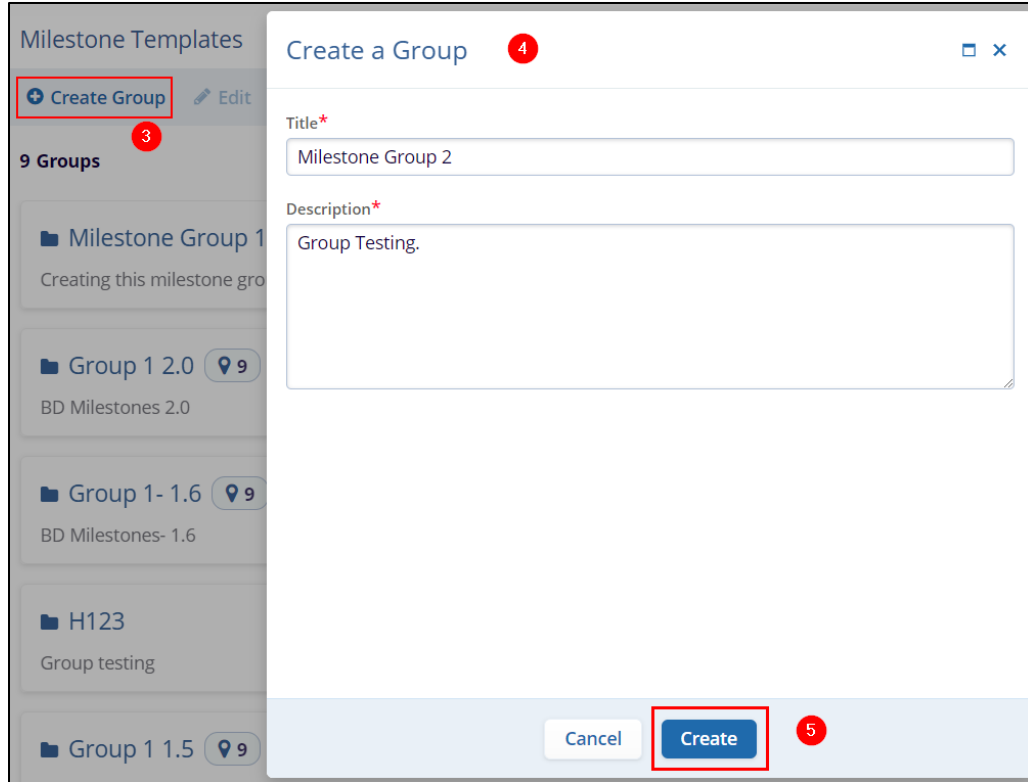


Figure: Create a Group

- Once the record is successfully created, users will get a success message and the newly created group will appear on the **Groups** screen.

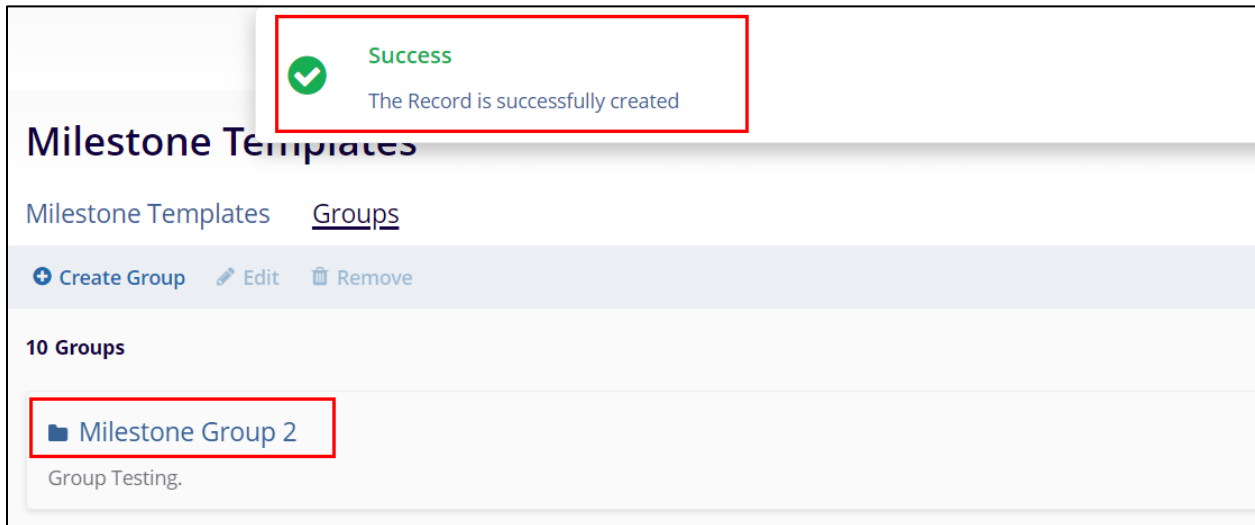


Figure: Success notification for the newly created group.

Adding Template to a Milestone Group

To add templates to a Milestone Group, follow the steps below

1. Click on the Milestone Group name (Milestone Group 2)

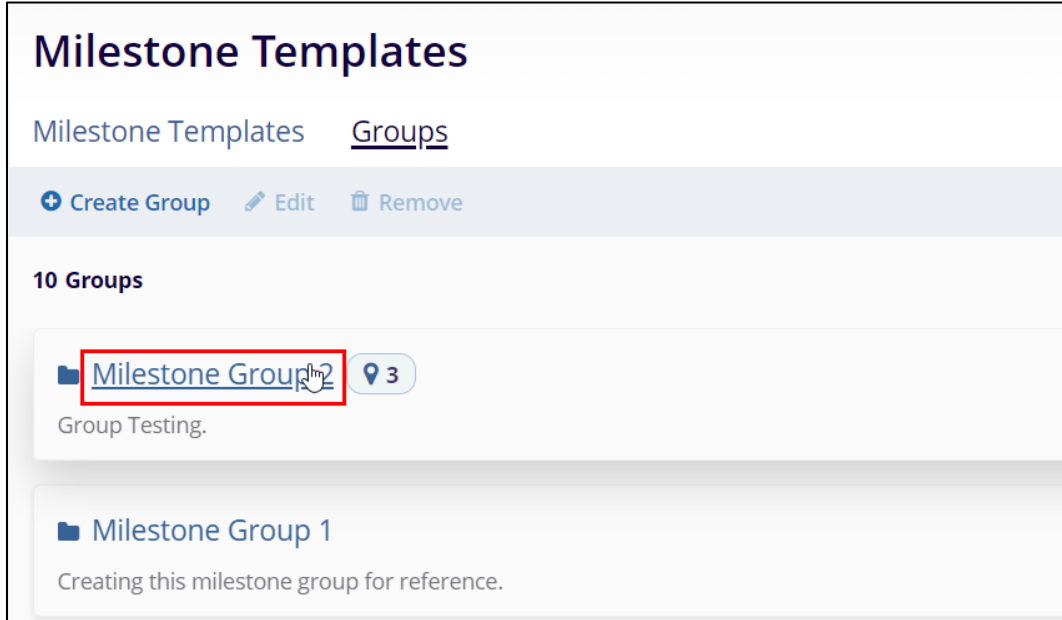


Figure: Adding Template to a Milestone Group

2. On that Milestone Groups screen, templates that are added to that group are visible. To add more templates, click on **+Add**.



Figure: Group Details

3. Click on the respective templates checkboxes to select the templates and then click on **Add**.

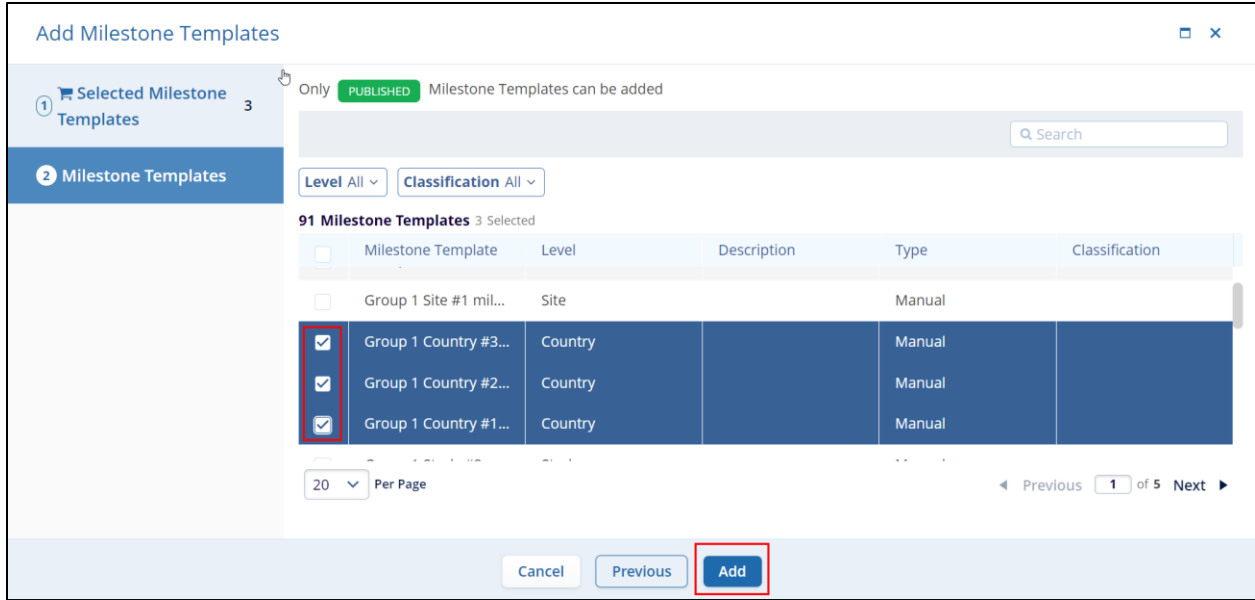


Figure: Select and Add milestone templates to groups

- The screen displays a success notification once templates are added to the groups. The Group Details screen displays the total number of templates associated with that group.

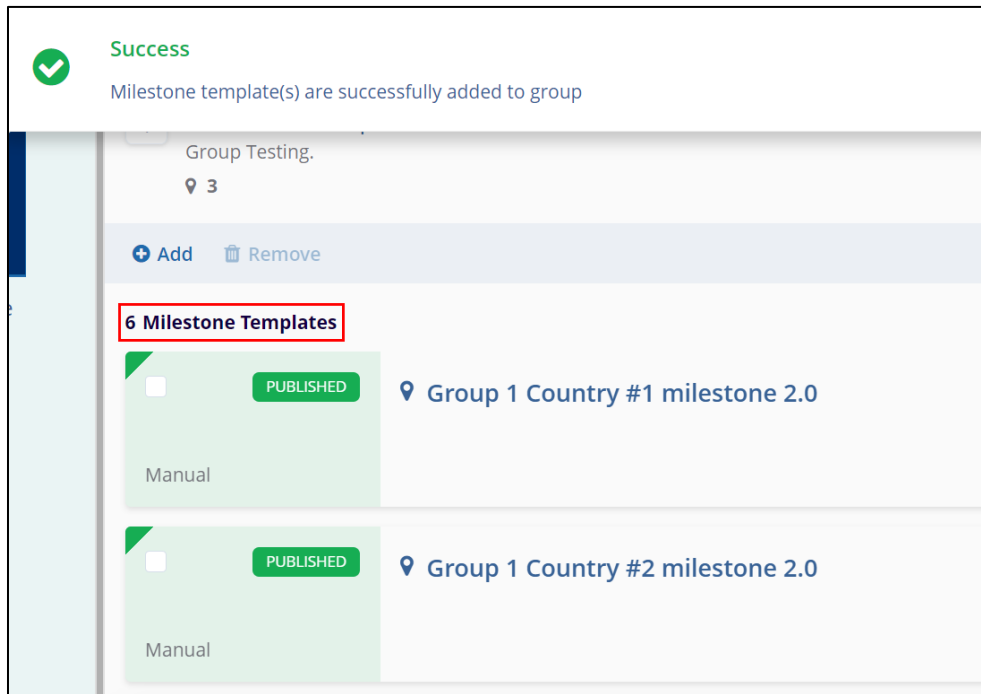


Figure: Milestone template success notification

Removing Templates from Milestone Groups

To remove templates from a Milestone Group, follow the steps below. Refer to the screenshot for the sequence.

1. Select a template by clicking on that particular template checkbox.
2. Click on the Remove button from the top menu bar
3. On the **Remove From Group** confirmation popup, click on the **Remove** button.

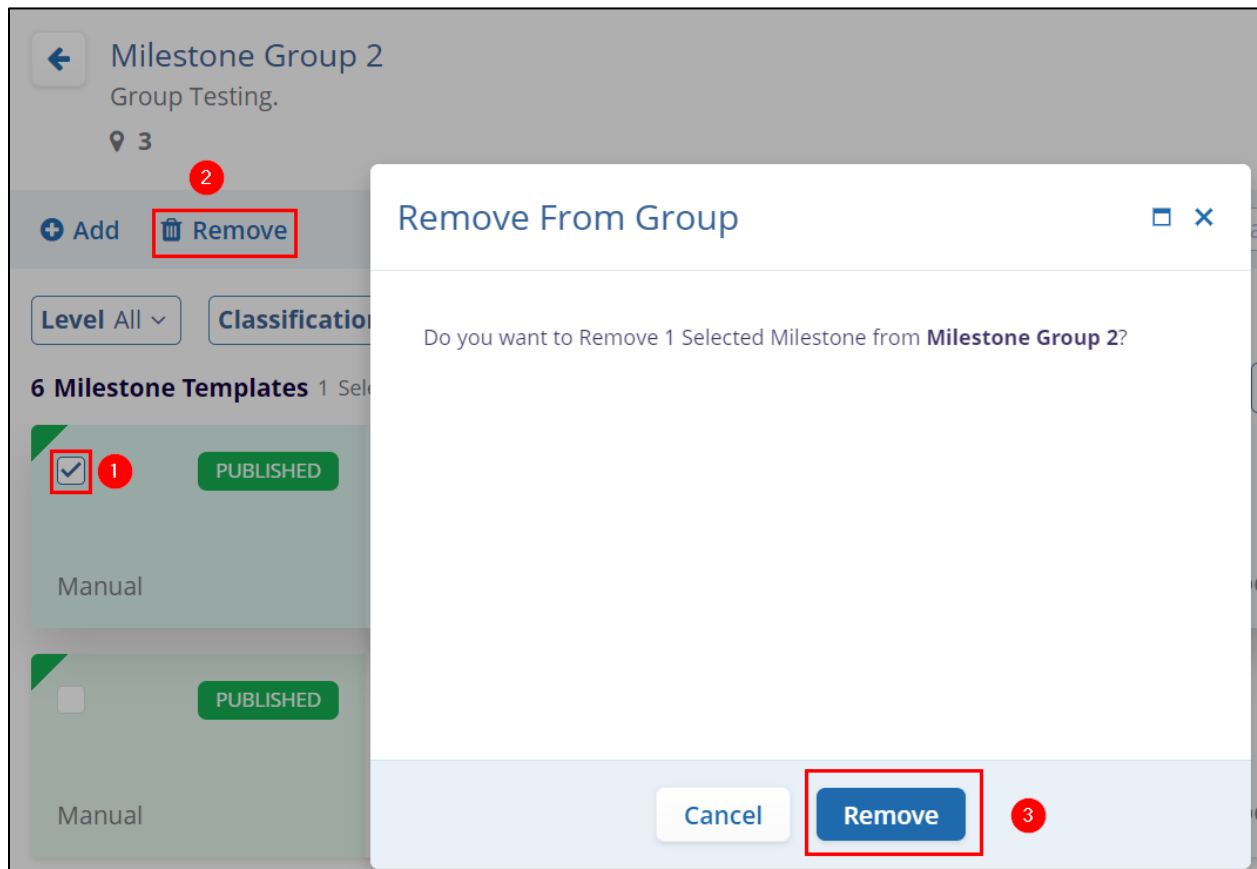


Figure: Removing templates from group

Customizing Milestone Groups screen

Users can apply filters and sorting criteria, as well as customize the screen view of the selected milestone group.

Filters

To apply filters, follow the steps below

1. Click on **Filters** situated beside the search box.
2. By default the screen displays milestones created at a **Country, Site, and Study** level. Click on the **Level** dropdown and select the appropriate option.
3. Click on the **Classification** dropdown and select the required option.



Figure: Filters

Sorting

To sort the screen, follow the steps below

1. Click on the **Sort By** dropdown and select the appropriate sorting criteria. By default, the **Status** sorting criteria are applied.
2. Click on the arrow to sort the screen in ascending or descending order.

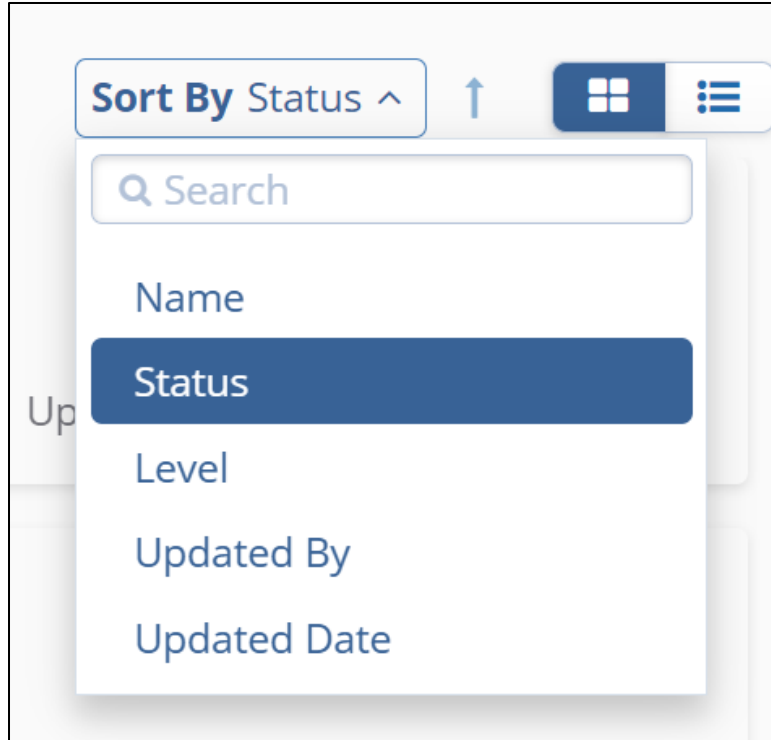


Figure: Sorting criteria

View

To customize the screen view, follow the steps below

1. Navigate to the screen customization icons situated beside Sort By dropdown.
2. Select either Grid View or List View.

Note: By default, Grid View is selected.

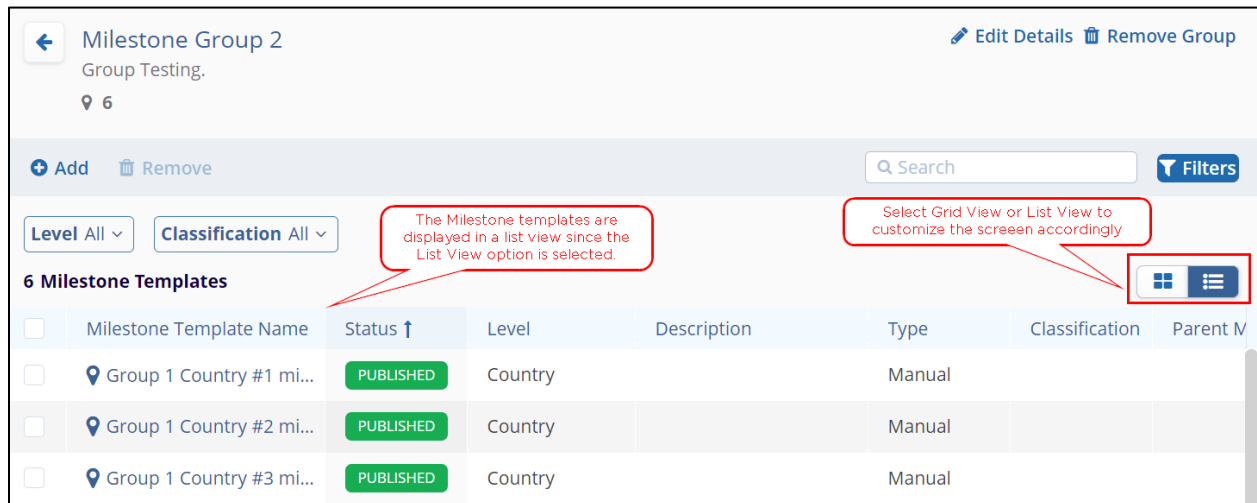


Figure: Grid View or List View

Editing Group

To edit the group, follow any one of the two methods listed below

Method 1

1. From the left-hand navigation links, select **Milestone Templates > Groups**
2. Select a group by clicking on the group tile.
3. Click on the **Edit** icon from the top menu bar.

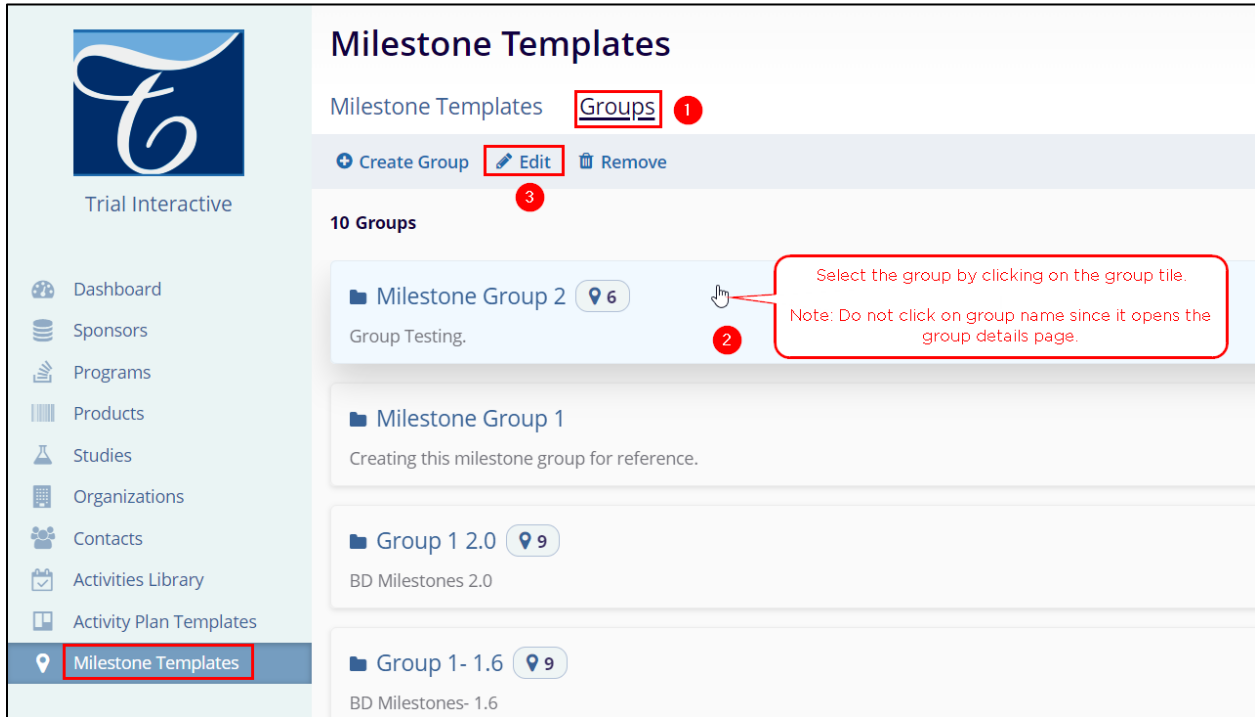


Figure: Editing Group

4. On the Edit Group Details page, make the required changes to the Title* or Description*.
5. Click on the **Edit** button, which will become accessible when edits are made, once the required details are updated.

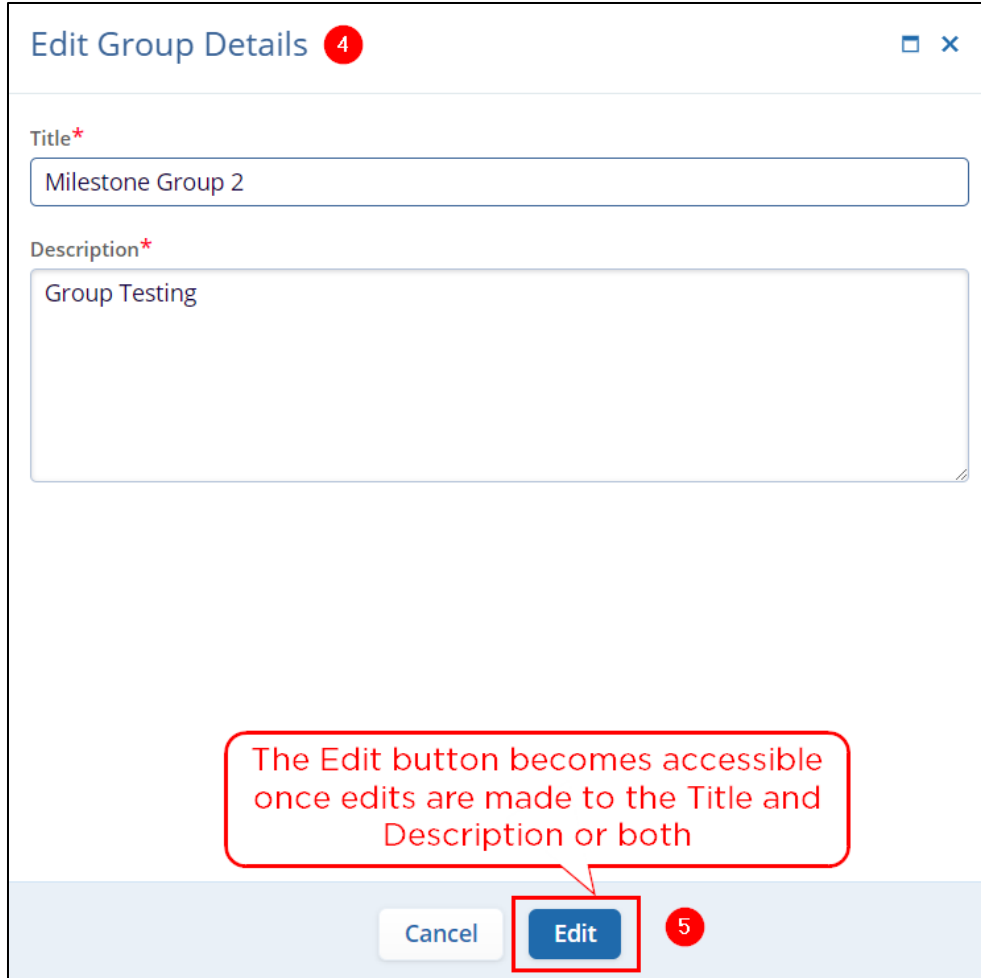


Figure: Edit Group Details screen

Method 2

1. From the left-hand navigation links, select **Milestone Templates > Groups**
2. Click on the name of a group that needs to be edited which will then open that particular group's screen.

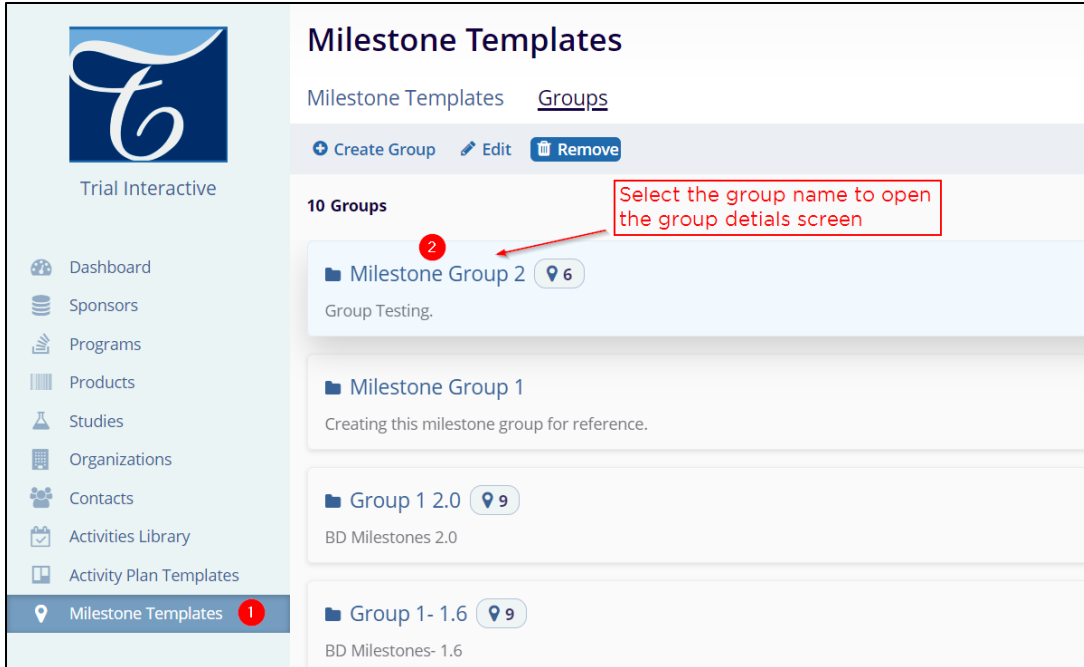


Figure: Select the group name

3. Click on Edit Details,
4. Make the required changes on the **Edit Group Details** screen, and select **Edit**.

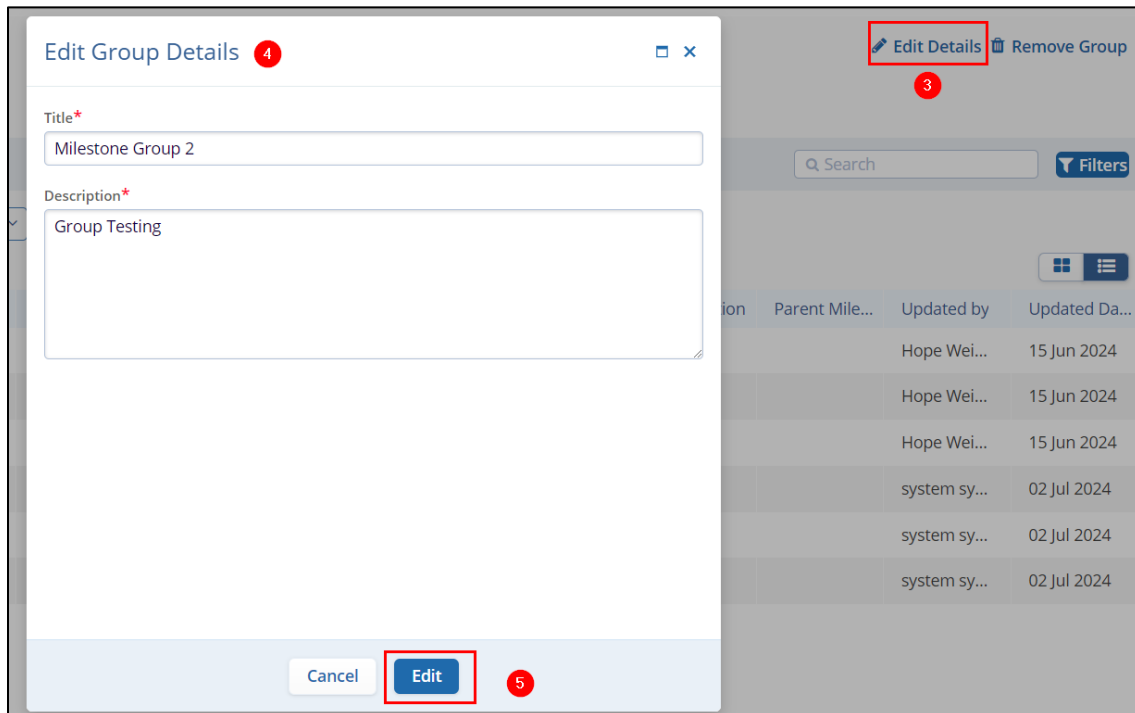


Figure: Edit Group Details-method 2

Removing Group

Method 1

1. From the left-hand navigation links, select **Milestone Templates > Groups**.
2. Select a group by clicking on the group tile.
3. Click on the **Remove** icon from the top menu bar.

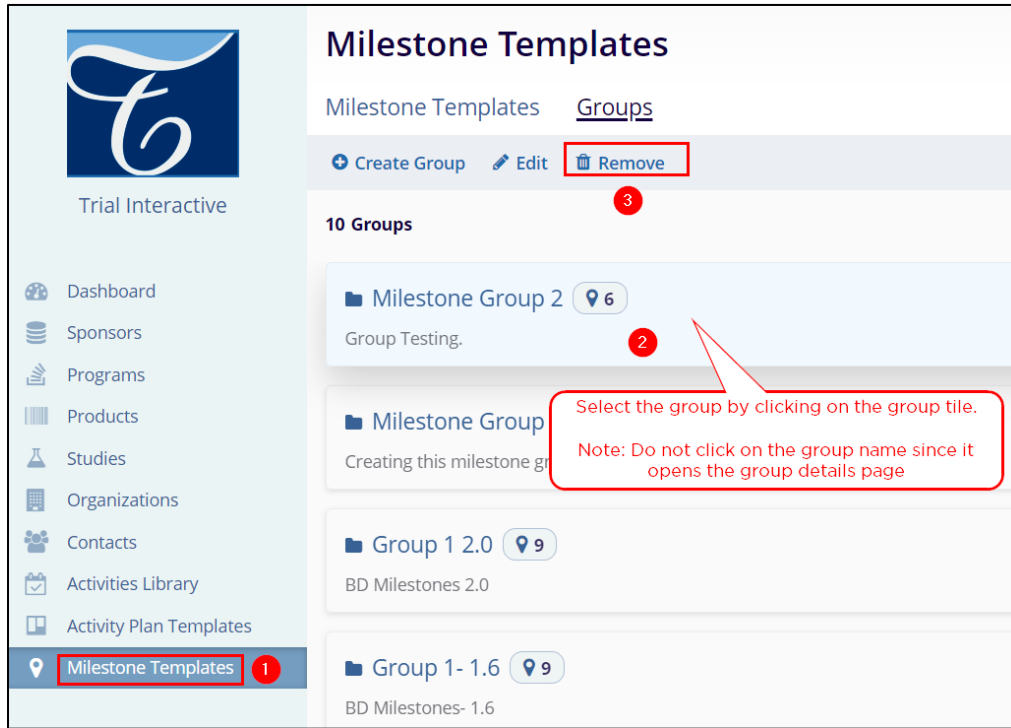
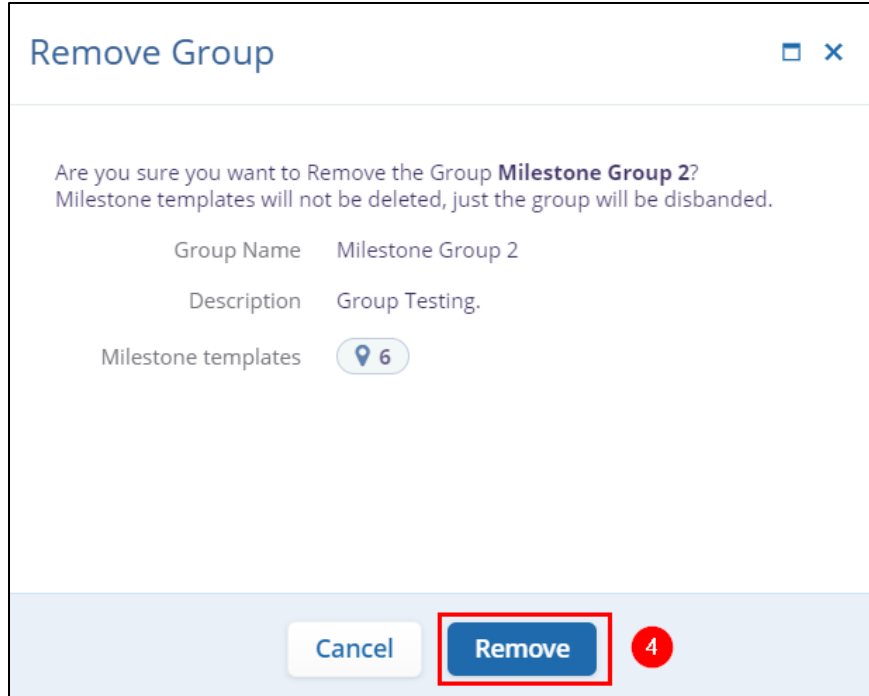


Figure: Removing Group-method 1

4. Click on the **Remove** button on the **Remove Group** screen.



Method 2

1. From the left-hand navigation links, select **Milestone Templates > Groups**
2. Click on the name of a group that needs to be edited which will then open that particular group's screen.

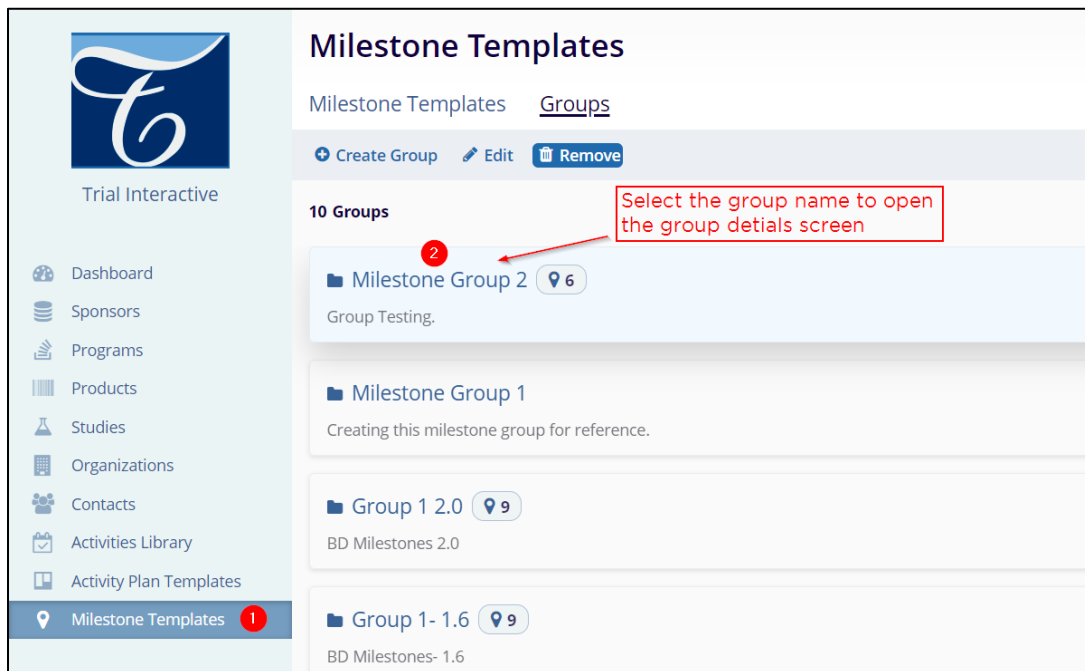


Figure: Select the group name

3. Click on the **Remove Group** button.

4. Click on the **Remove** button on the **Remove Group** screen.

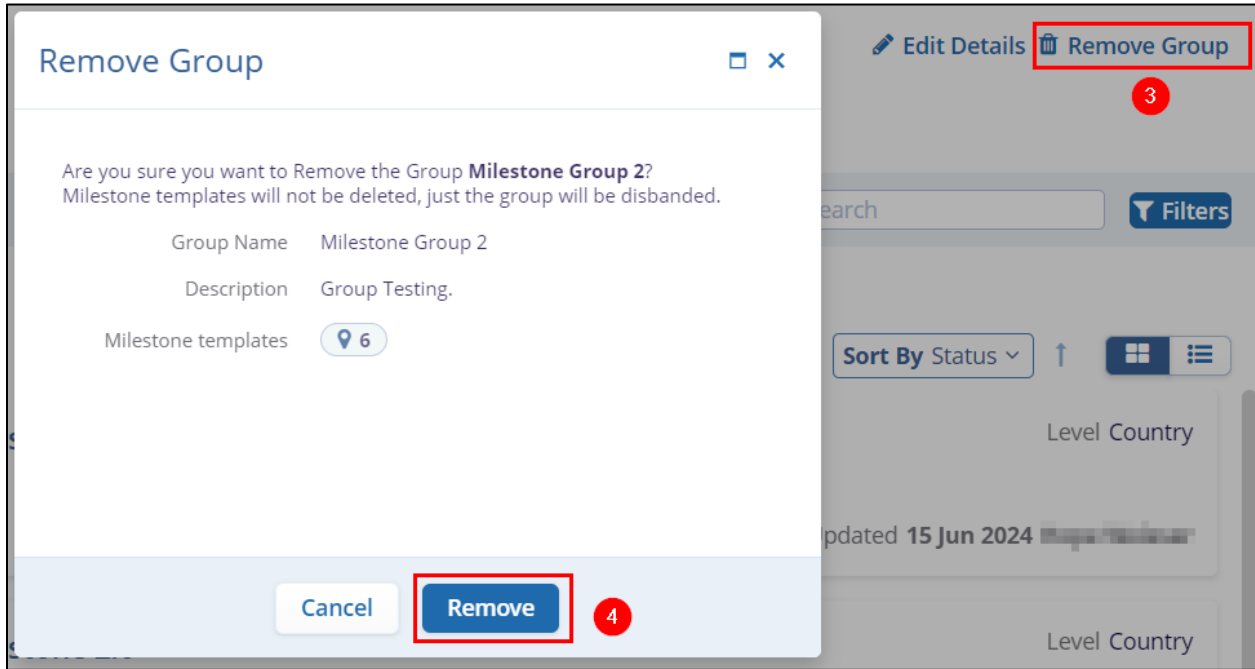


Figure: Remove Group-method 2

Accessing Platform Links

To access all the Platform Links, follow the steps below.

1. Click on the waffle icon to expand the side menu bar and select Links.
2. Select the required link
3. Click on the required platform links from the available options and it will open the specific platforms page.

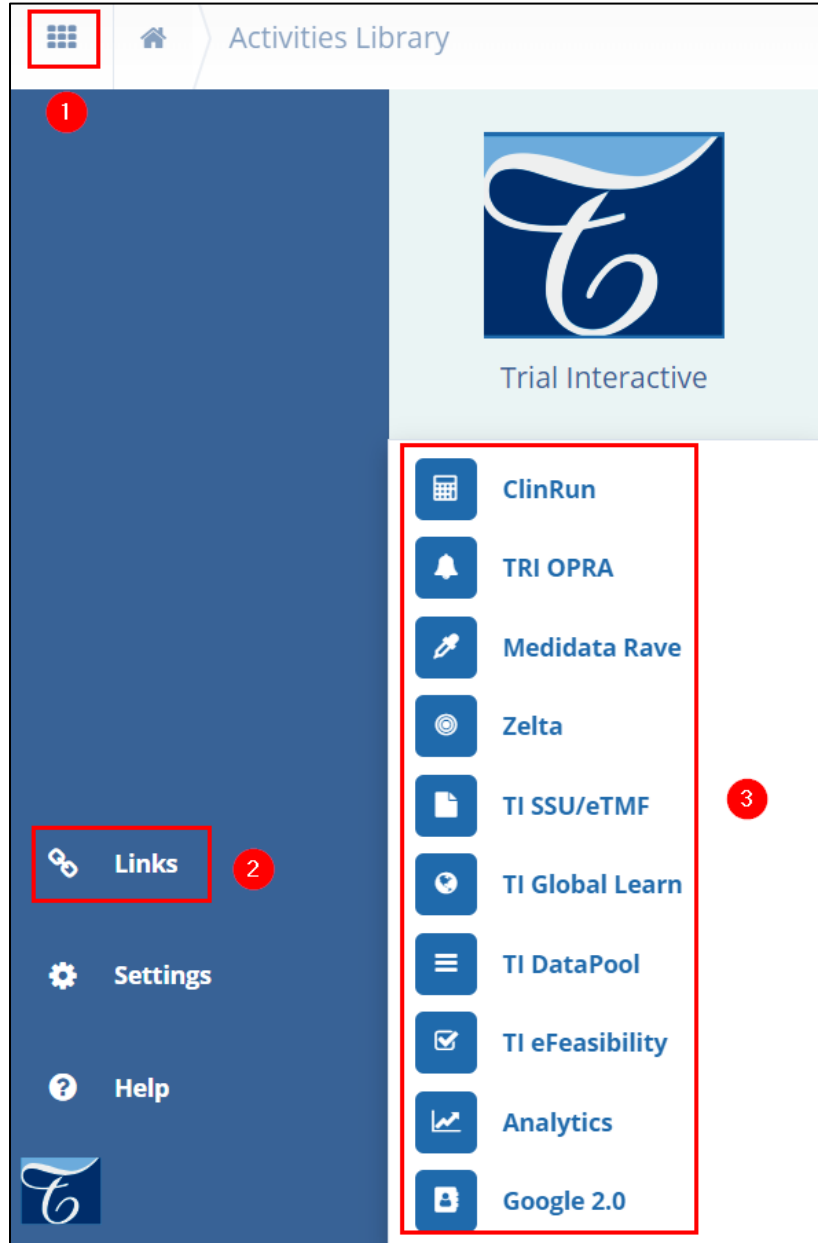


Figure: Accessing Platform links

Settings

Users with Company Administrator access to the CTMS will be able to make changes to settings which impact all users.

Company Name and Logo

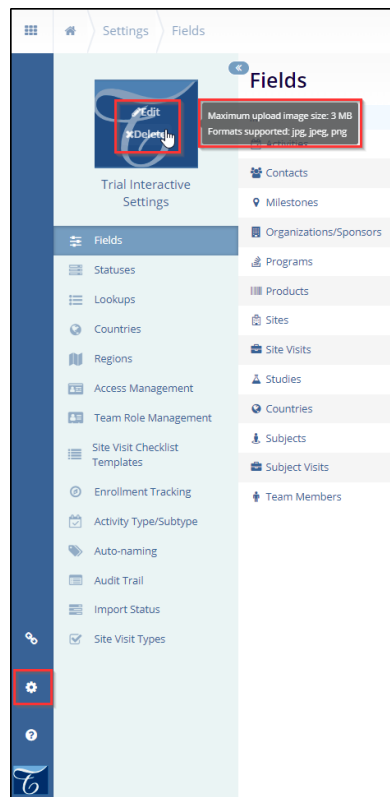
Users can change the name and logo associated with their CTMS environment in order to keep up with the changes that happen over the course of a company’s lifetime.

To do this, users will need to navigate to the **Settings** area.

To change the Company Logo:

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

Note: The maximum size of the image and the formats supported are displayed after hovering the image. Refer to the screenshot below.



To change the company’s name:

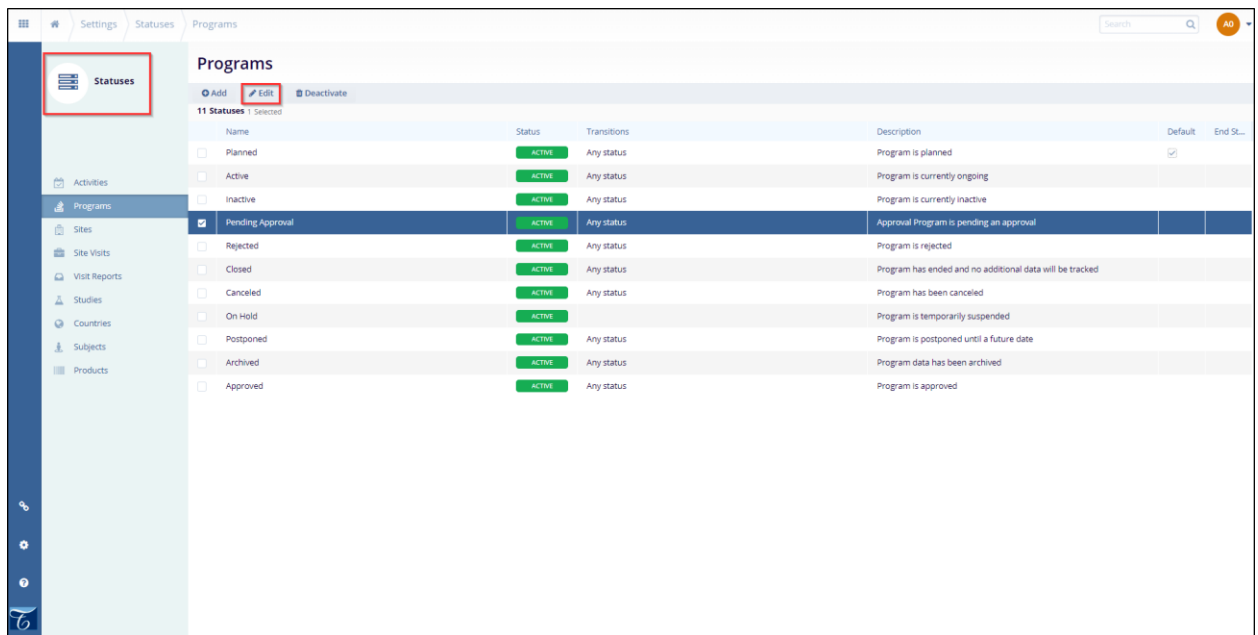
1. Navigate to the **Settings** area and to the **General** menu.
2. Click the ‘**Edit**’ button in the menu ribbon at the top of the menu.
 - a. The menu will become editable.
3. Type a new name for the organization into the “**Client Name**” field.
4. Press ‘**Save**’ in the menu ribbon at the top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

Final Statuses

Users have the ability to indicate which of the available statuses is considered a Final or ‘End’ status.

To set an ‘End’ status:

1. Navigate to the **Settings** area and click the **Statuses** menu.
2. Select the particular area of interest (Programs, Sites, etc.)
 - a. **Note:** This is not available for all areas.
3. Select the status which should be indicated as an ‘End’ or ‘Final’ status using the checkbox.
4. Press the ‘**Edit**’ button in the menu above the list.
5. Check the box in the ‘Is End’ column (or uncheck the box to indicate a status as non-final)
6. Press the ‘**Save**’ button in the menu above the list.



Custom Fields for Milestones

To create a custom field:

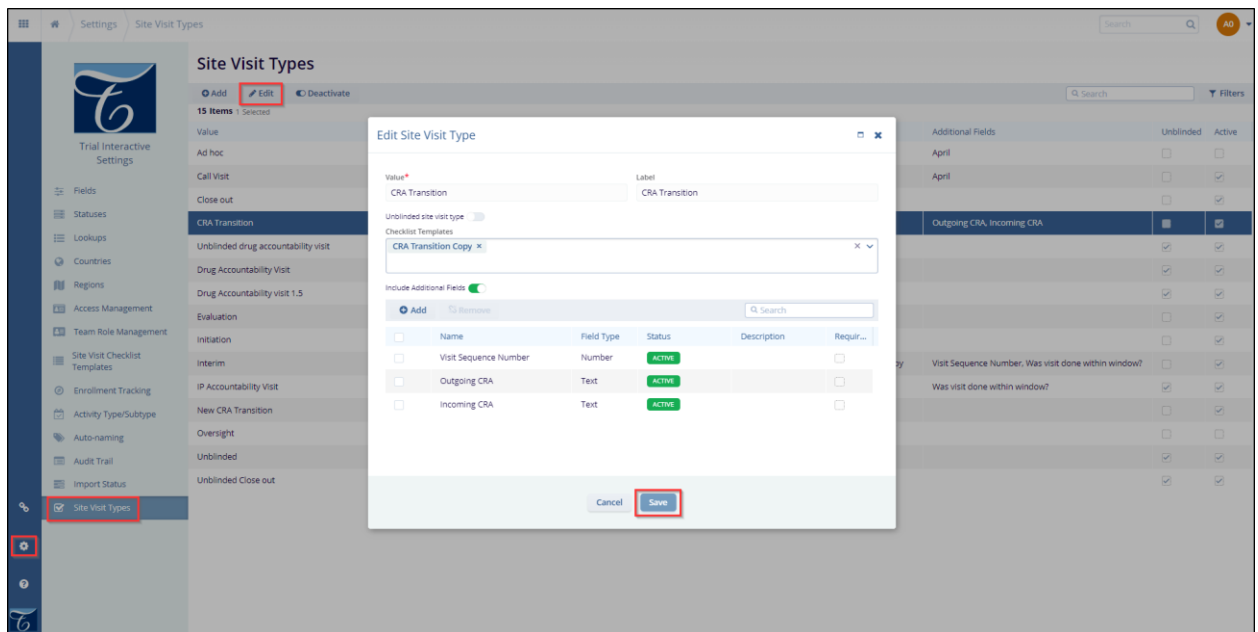
1. Navigate to the **Settings** area and select the **Fields** menu.
2. Select the sub-type (Activities, Contacts, etc.)
3. Press the **'Add Field'** button in the menu above the list of fields.
 - a. The **'Add Custom Field'** window will open.
4. Select the type of field
 - a. Please note that the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

Site Visit Custom Fields related to Visit Types

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

To apply a custom field to a site visit type:

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

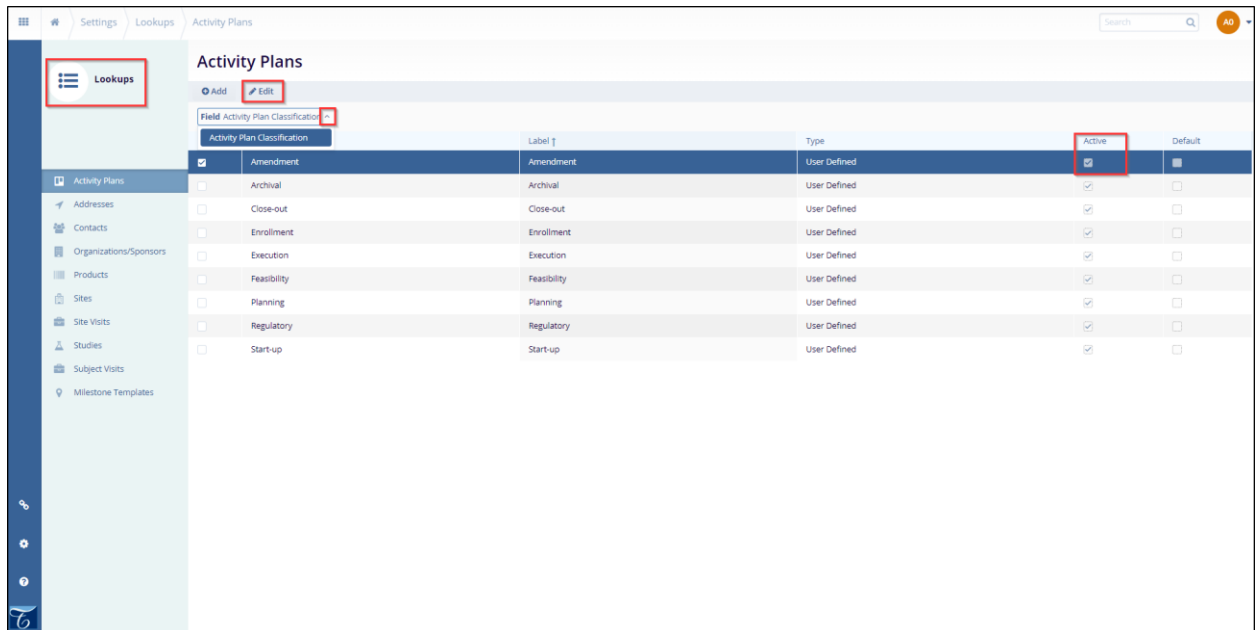


Lookups Field

The term ‘Lookups’ refers to the options found in various dropdown menus throughout the system. If your group is upgrading to a new version of CTMS which includes additional standard values, in order to avoid impacting current study data, these values will be added in an ‘inactive’ status and will need to be manually updated if desired.

To activate a lookup value:

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



Favorites

CTMS has the ability for a user to denote a record as a favorite. Users now have the ability to define a record as a personal favorite within the CTMS or via myTI, and have the indication displayed within both applications.

The ability to designate a record as a favorite provides users with the ability to quickly locate items within lists without having to create specific “filtered” views. Favorites can be used when sorting lists to reduce the number of relevant records displayed.

The user can select the following fields as favorites:

- Sponsors
- Programs
- Products
- Studies
- Organizations
- Contacts and
- Activities Library

Click the **star** icon to turn it yellow. The selected field is added to favorites with a notification displayed in the top right corner. Refer to the screenshots below.

