TRIAL INTERACTIVE

TI CTMS V3.0 - USER GUIDE V1.0

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APPROVALS

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CONTENTS

VERSION HISTORY

Author	Revision	Date	Change History
Salil Joshi	1.0	20-Jun-2025	Document Finalized.

ABOUT THIS USER GUIDE

This guide provides a comprehensive overview of the features and components of the TI CTMS v3.0 application, enabling users to work efficiently and securely manage their tasks within the platform.

It includes detailed instructions on the user interface, step-by-step processes, and visual aids to enhance understanding and ease of use. This guide is exclusively designed for clients who have purchased the Trial Interactive platform.

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CHAPTER 1. NEW FEATURES IN TI CTMS V3.0

Automate: Study creation powered by AI

Leverage Automate's large language model (LLM) to accelerate study setup by uploading protocol documents directly into CTMS. Automate scans the document and extracts key data to assist in creating a study profile, reducing manual user entry, improving efficiency, and ensuring data consistency.

Key Benefits

- Streamlines Study Profile Creation: Automate reduces setup time by pre-populating study fields using protocol content.
- Reduces Manual Data Entry Errors: AI-driven data extraction minimizes the risk of inconsistencies
- Supports Standardization Across Studies: Ensure consistent data entry from protocol to system fields.

My Page: A Centralized and Informative Landing Page

The introduction of 'My Page' transforms the way users interact with the CTMS by providing an intuitive, centralized cross-study landing page to view upcoming events, reminders, and empowering users to work smarter, faster, and more efficiently.

Key Benefits

- Centralized Location: Access all key updates in one place, including upcoming activities, milestones, and site visits, without needing to navigate multiple menus.
- Quick Links: Direct links guide users to pending milestones, upcoming visits, or overdue activities, saving time.
- Global Search: Global search makes locating associated data across the application easy.
- Dashlets: Configure and view the important data through dashlets for Activities, Milestones, Site Visits, and Site Visit Calendar.

Importing: Activities, Sites, and Site Contacts

CTMS now supports the import of activity records, sites, and site contacts using structured templates. This enhancement simplifies data entry and speeds up the population of records across multiple studies.

Key Benefits

- Accelerates Data Entry: Import templates allow users to quickly load large volumes of structured data.
- Improves Data Accuracy: Standardized formats reduce the likelihood of manual entry errors.
- Enables Cross-Study Efficiency: Supports bulk updates and centralized data management across studies.

CHAPTER 2: HOW TO USE CTMS

This User Guide is intended to provide general guidance on a SaaS system's functionality and features. All scenarios, job names, workflows, and terminology used within this guide are based on generic industry standards and may not reflect the specific configurations or naming conventions used by individual customers.

Customers may need to update or modify this guide to align with their unique operational requirements, organizational structures, and regulatory considerations. If customization is required, we recommend working with your internal teams or CTMS support representatives to ensure the documentation accurately reflects your implementation.

This guide is subjected to updates and enhancements as the system evolves. Please refer to the latest version for the most current information.

For optimal user experience, data should be entered in CTMS according to the following data flow:

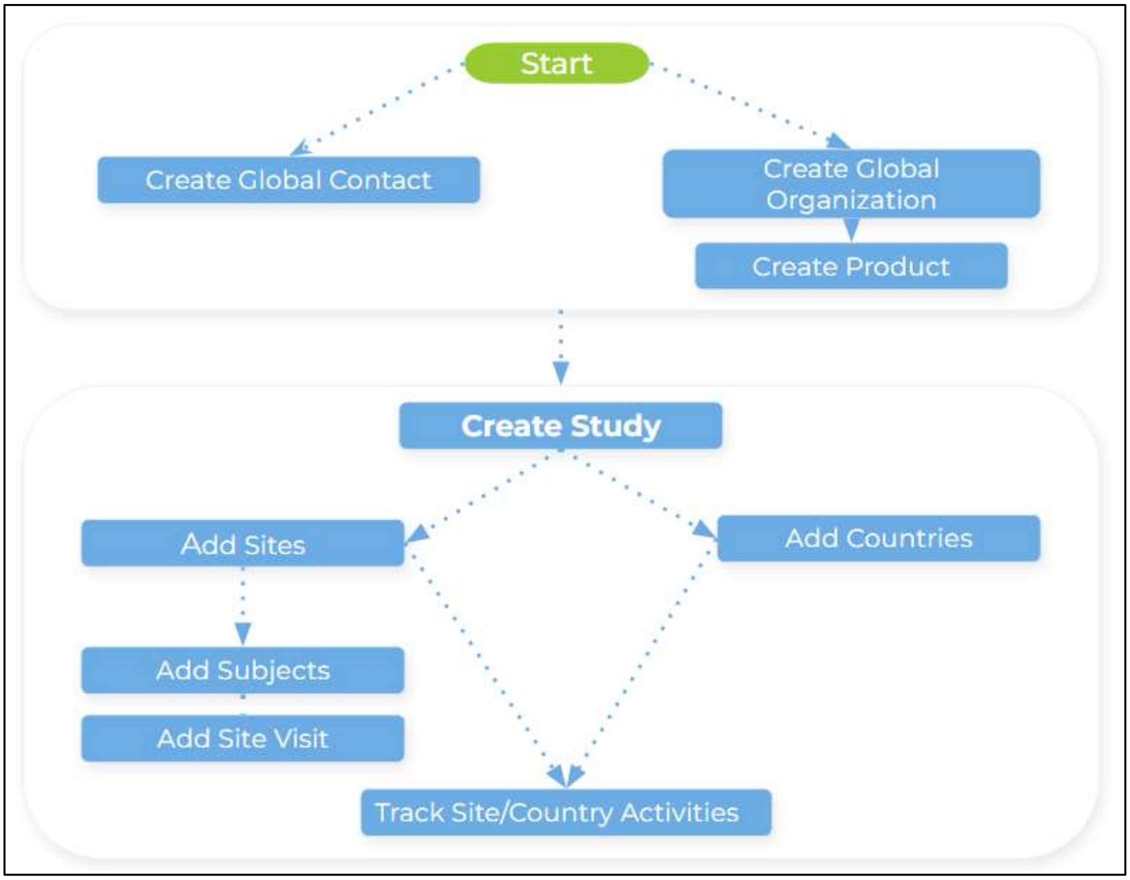


Figure: CTMS Data Flow

Note: Users should create and maintain data according to the established workflow diagram to ensure successful system utilization.

Key System Functions for Study Managers (SM) include:

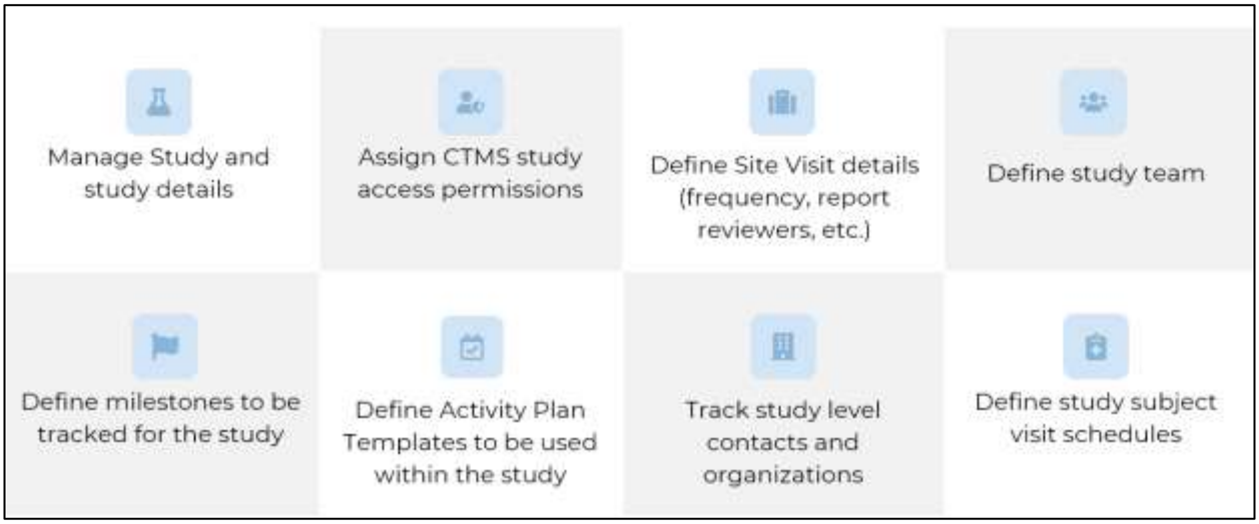


Figure: System Functions for Study Managers

- Performance Monitoring: Access dashboards and analytics to review study and user performance metrics
- Directory Management: Create and maintain Contact and Organization records in the global-level directory
- Product Administration: Create and maintain Product records for study use
- Program Management: Create and maintain Program records
- Study Administration: Create and maintain Study records, including associated Countries and Sites.

Key System Functions for Clinical Research Associates (CRA) include:

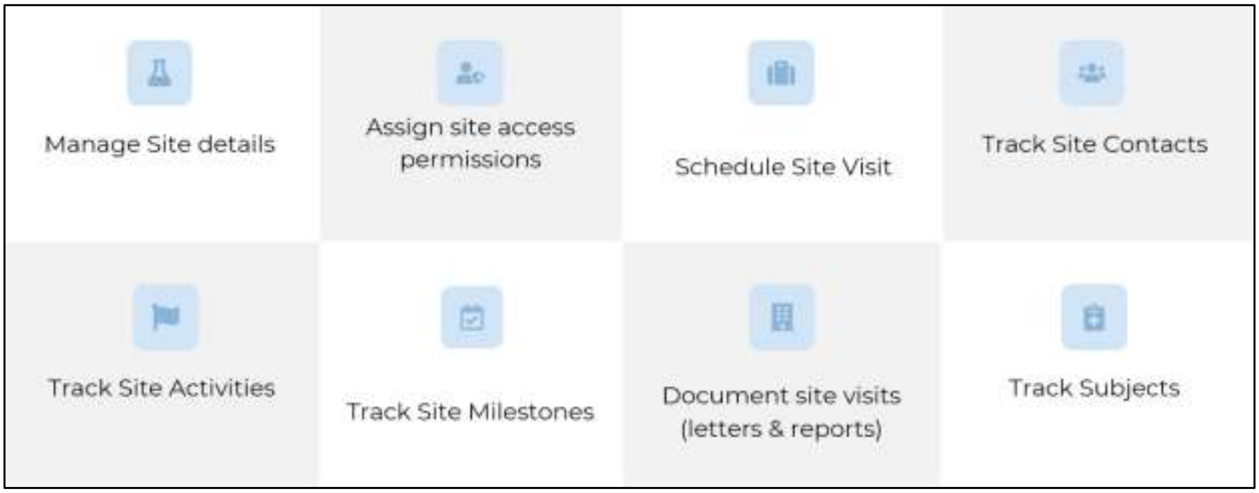


Figure: System Functions for CRAs

- Site Management: Maintaining site records including associated activities, subjects, and site visits
- Subject Management: Maintaining subject records including subject details, visits, ICFs, and subject related activities
- Site Visit Management: Creating, updating, and completing of site visits
- Site Visit Documentation Creation: Creating site visit related confirmation and follow-up letters, creation and finalization of site visit reports.

Note: Reference 'SM' and 'CRA' reference notations on tasks to easily find tasks perform by each key function.

CHAPTER 3. DASHBOARD SM

Global-level dashboard provide a clear overview of the organization's performance across studies, countries, and sites. They help users track progress, identify trends, and visualize overall performance. With intuitive charts and filters, users can quickly access key information and focus on important details. The Global-level dashboard consists of multiple dashlets:

- Top Countries dashlet: The Top Country Dashboard highlights the countries with the most study activity, providing a quick view of global study distribution.

- Portfolio dashlet: A world map provides a visual representation of study activity by highlighting the number of studies in each country.

- Site Visit Report Review Status dashlet: The Site Visit Report Review Status Dashlet provides a comprehensive overview of the status of site visit reports across studies and sites as well as CRA visit assignment. It allows users to track the progress of reports through various stages, such as review and approval, ensuring that site visit documentation is completed in a timely manner.
  The visibility of tabs within this dashlet depends on user roles. All users can access the "Visit Owners" tab to review site visits by CRA across studies, helping them determine which CRAs are conducting site visits within a specific location on particular dates.
  Users designated as site visit report reviewers for any study will have access to additional tabs for reviewing and managing site visit report statuses. With this dashlet, users can easily identify reports that are pending review, unassigned, or overdue after initial submission. Customizable filtering options allow users to focus on specific studies, sites, CRAs, or timeframes, helping them stay on top of outstanding actions and ensure timely completion of site visit documentation.

- Studies dashlet: The Studies Dashlet provides a clear breakdown of all studies by their current status using a pie chart and a list view. This allows users to quickly see the overall study count categorized by status. The pie chart offers a visual representation of study distribution, while the list view provides detailed information on each study's status. Users can easily track the progress of studies and gain insights into the distribution of study statuses across their portfolio.

- CRA Visit Report Performance dashlet: The CRA Visit Report Performance Dashlet offers a comprehensive view of site visit report statuses across studies. It includes a pie chart that visually breaks down the total number of site visit reports by their current status, providing an at-a-glance overview of report progress. Additional visuals displaying key performance metrics: completed on first submission, currently rejected, past due, and approved, allowing users to easily track report performance. Additionally, the dashlet shows the average number of review cycles across all studies, helping users monitor the efficiency of the review process and potentially identifying areas for improvement.

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 tabs

    a. My Page
    b. Analytics

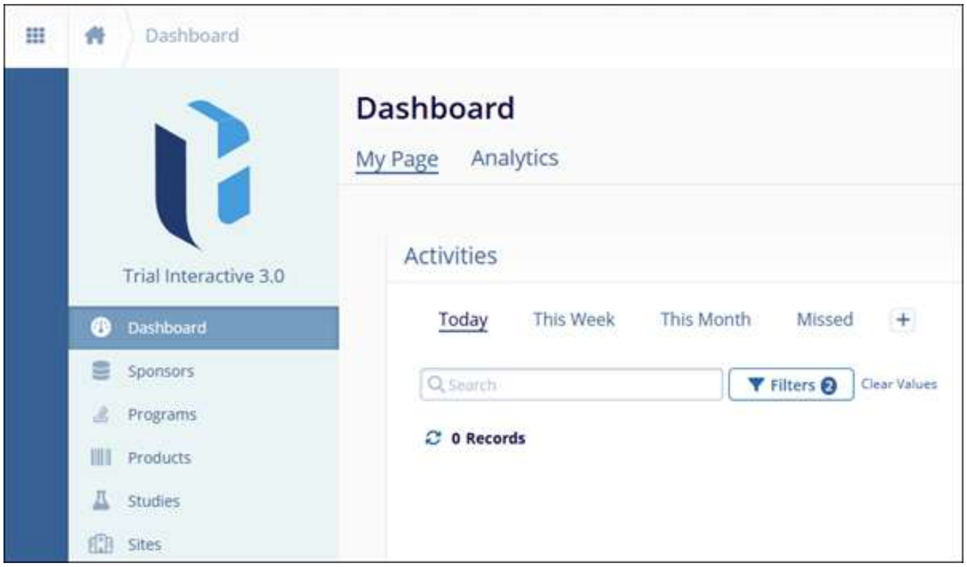


Figure: Accessing Dashboard

My Page

The 'My Page' with the domain level dashboard is a centralized and informative landing page that provides a centralized location for users to view relevant notifications associated to key information such as:

- Upcoming Activities
- Milestones
- Site Visits

Activities

The Activities dashlet provides users a centralized location to view relevant notifications associated to key information related to activities. i.e., Upcoming and Past Due Activities. The Activity records are displayed when the logged-in user is an 'Activity Owner'.

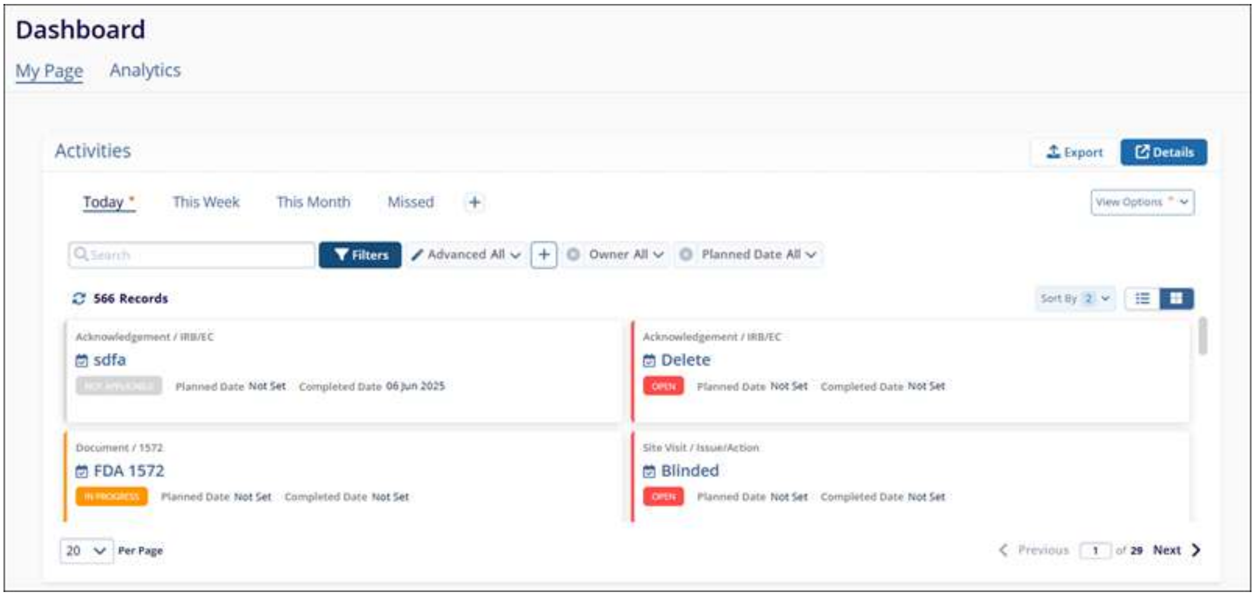


Figure: Activities Dashlet

Activity Views

To add an activity view to the dashlet, follow the steps below.

1. Click on the '+' icon on the Activities dashlet.
2. Select a view from the available dropdown list.
3. Click on the star icon to mark a view as favorite and access the 'Favorites' tab to see all views marked as favorites.
4. The newly added view appears as a tab on the activities dashlet.

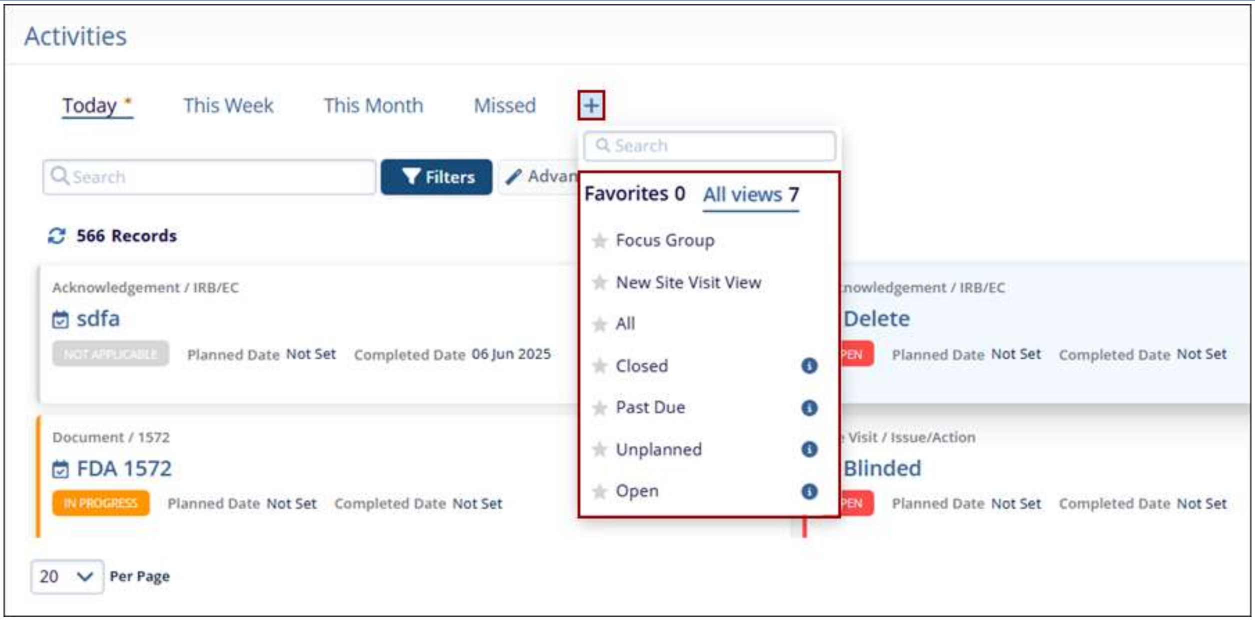


Figure: Activity Views

5. To configure a view, either click the hamburger icon next to the desired view or click on the 'View Options' dropdown.

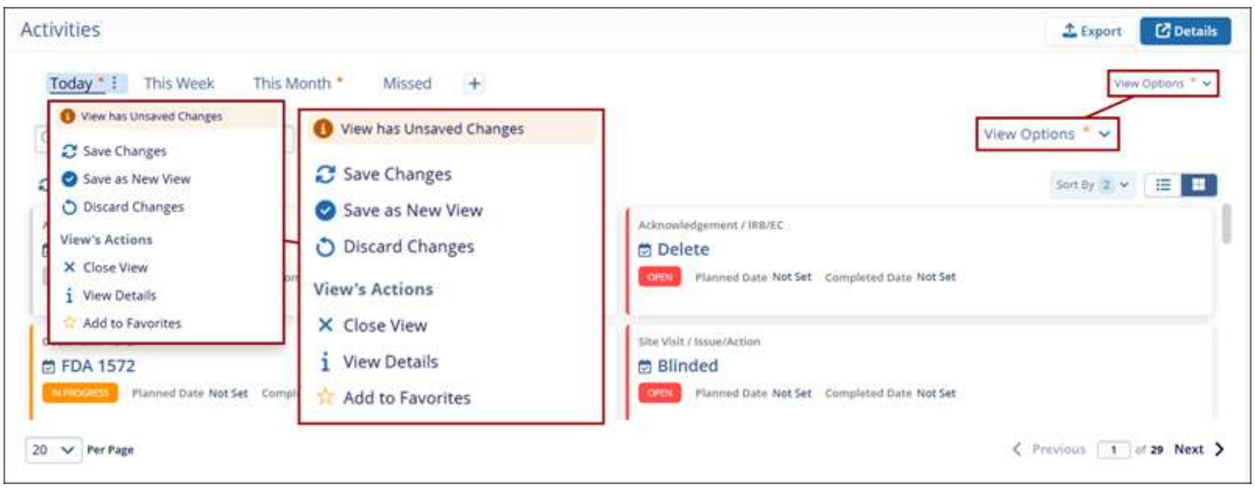


Figure: Configure Activity Views

Export Activities

To export activities dashlet data from My Page, follow the steps below.

1. Within the Activities dashlet on My Page, click on the Export button.
2. Select either CSV or XLSX as file formats.
3. Select either Current Page, All or Custom by clicking on the radio buttons. If Custom option is selected, specify the number of records.
4. Click on the Export button once all the details are specified.

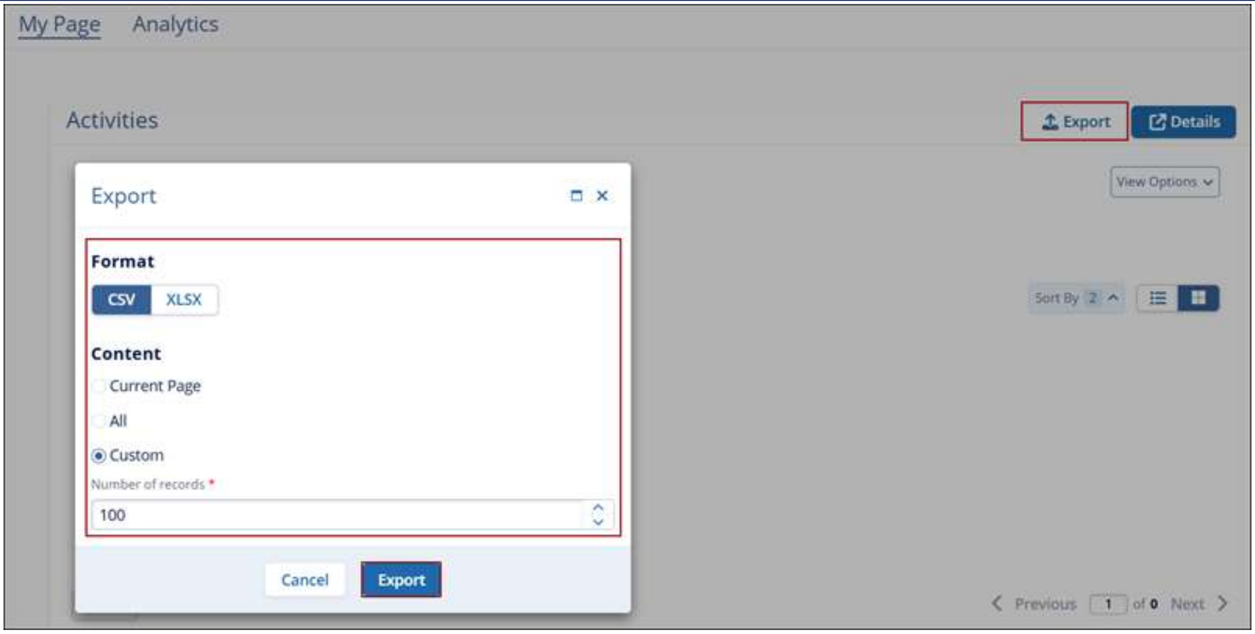


Figure: Export Activities

Activity Details

To open the list of activities in a different modal window, click on the 'Details' button on the Activities dashlet.

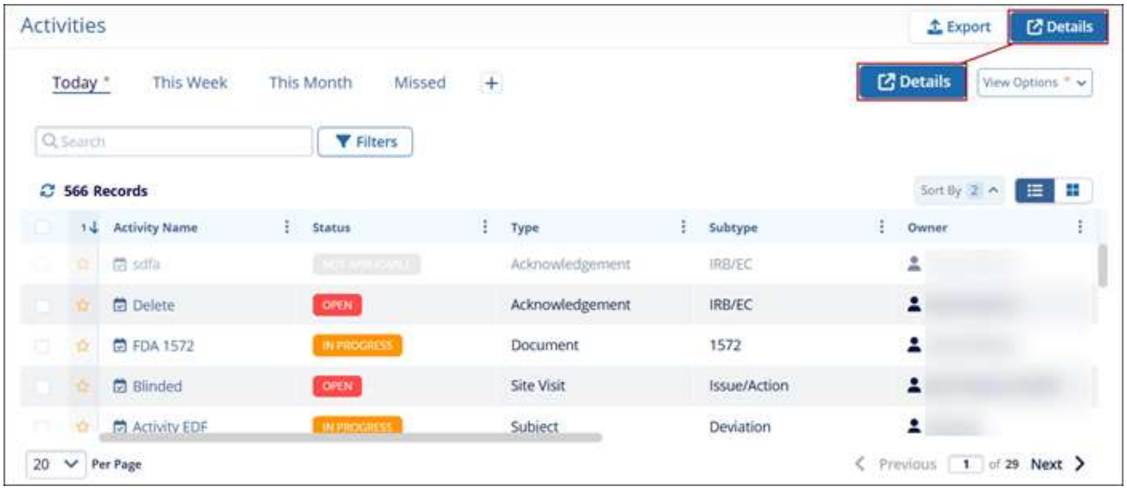


Figure: Activity Details

Activity Filters

To filter the Activities dashlet, follow the steps below.

1. Click on the Filters button to add the advanced and standard filters.
2. Click on the '+' icon, select filter options from the available list and click on the Apply button.

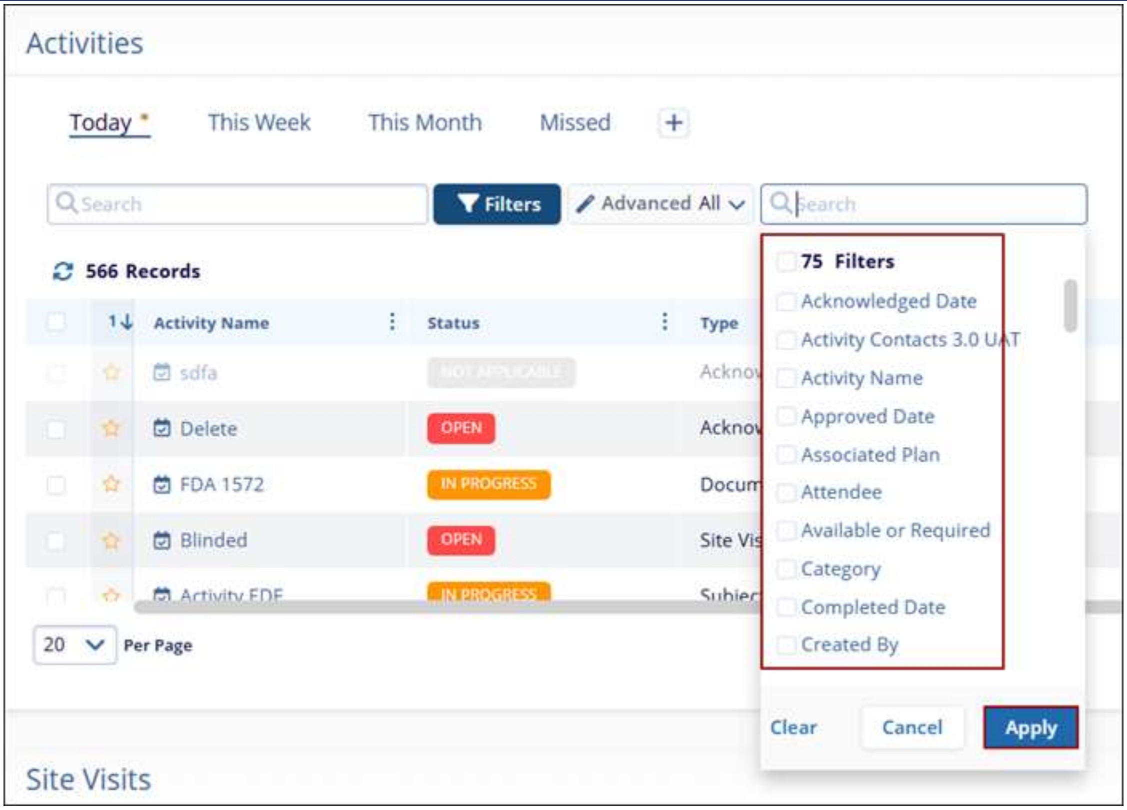


Figure: Activities dashlet – standard filters

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

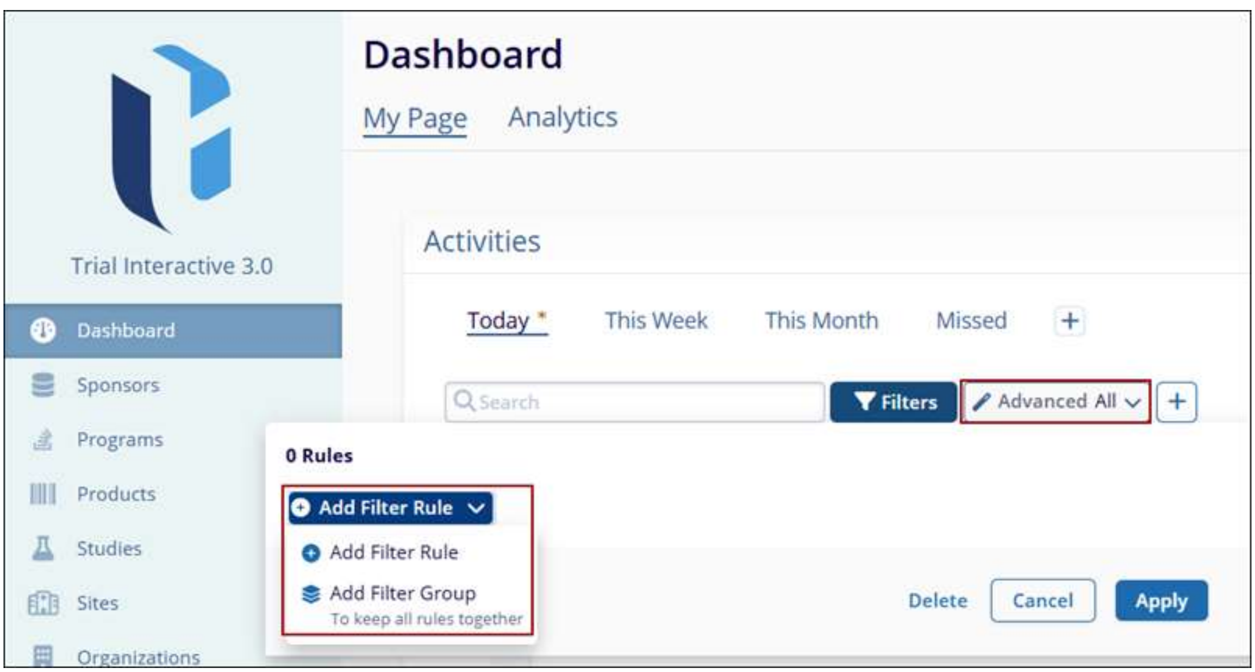


Figure: Activities Dashlet – Advanced Filter

4. To configure the filter rules, enter a criterion in the 'Where' field, choose a logical operator, provide a corresponding value and click on the Apply button.

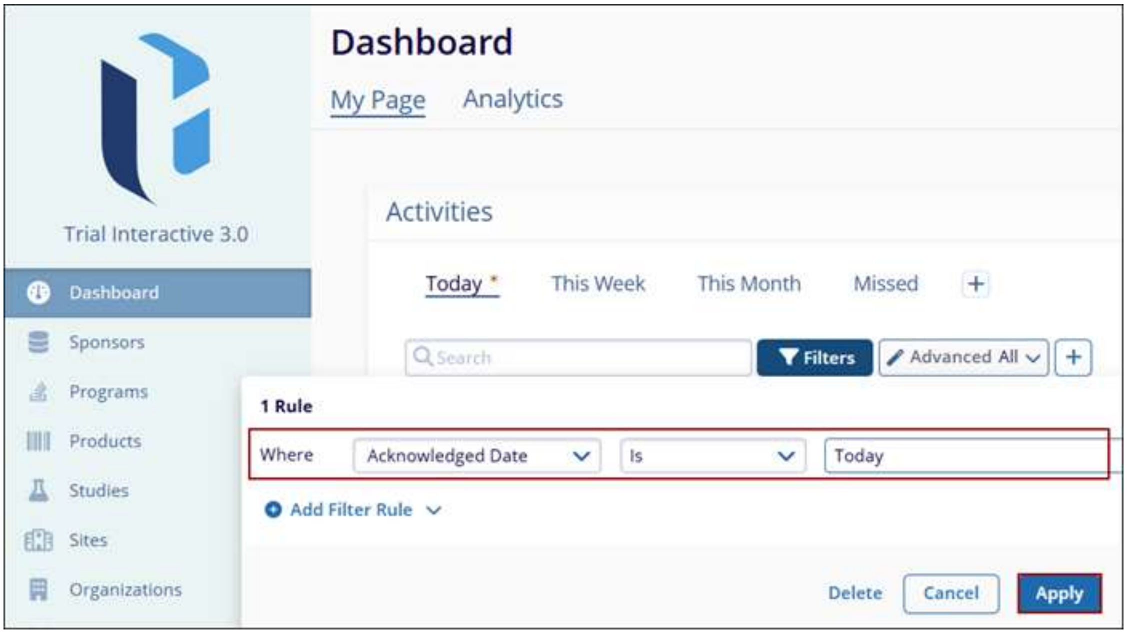


Figure: Apply filter rules

In the above example, the Activities dashlet will show only those activities where 'Acknowledge Date' is 'Today' i.e., Current Date etc. as per the filter applied.

Site Visits

The Site Visits dashlet provides users a centralized location to view the list of site visits where the user is a Site Visit Owner. Additionally, users can perform the following on the Milestones dashlet.

- Access and review a cross-study site visit listing.
- Apply filters within the cross-study site visit list.
- Pull in custom fields within the cross-study site visits view.
- Retrieve an export of all records from the cross-study site visits view.

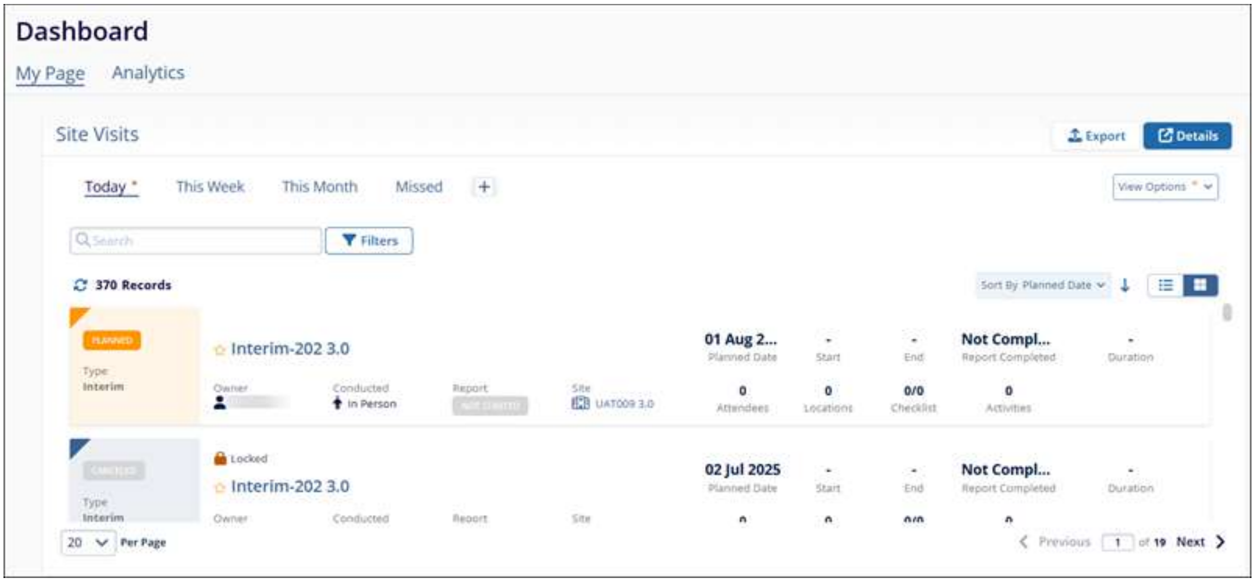


Figure : Site Visits Dashlet

Site Visits Views

To add a view to the Site Visits dashlet, follow the steps below.

1. Click on the '+' icon on the Site Visits dashlet.
2. Select a view from the available dropdown list.
3. Click on the star icon to mark a view as favorite and access the 'Favorites' tab to see all views marked as favorites.
4. The newly added view appears as a tab on the Site Visits dashlet.

Figure: Site Visit Views

5. To configure a view, either click the hamburger icon next to the desired view or click on the ‘View Options’ dropdown.

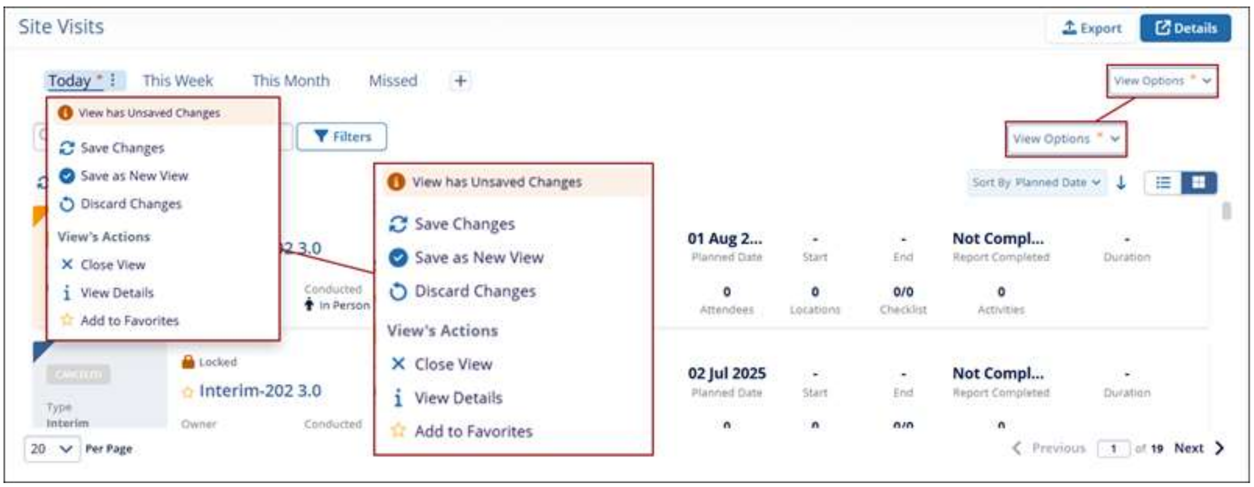


Figure : Configure Site Visits Views

Export Site Visits

To export the Site Visits dashlet details, click on the ‘Export’ buttons and refer to the standard steps detailed in the Export Activities section above.

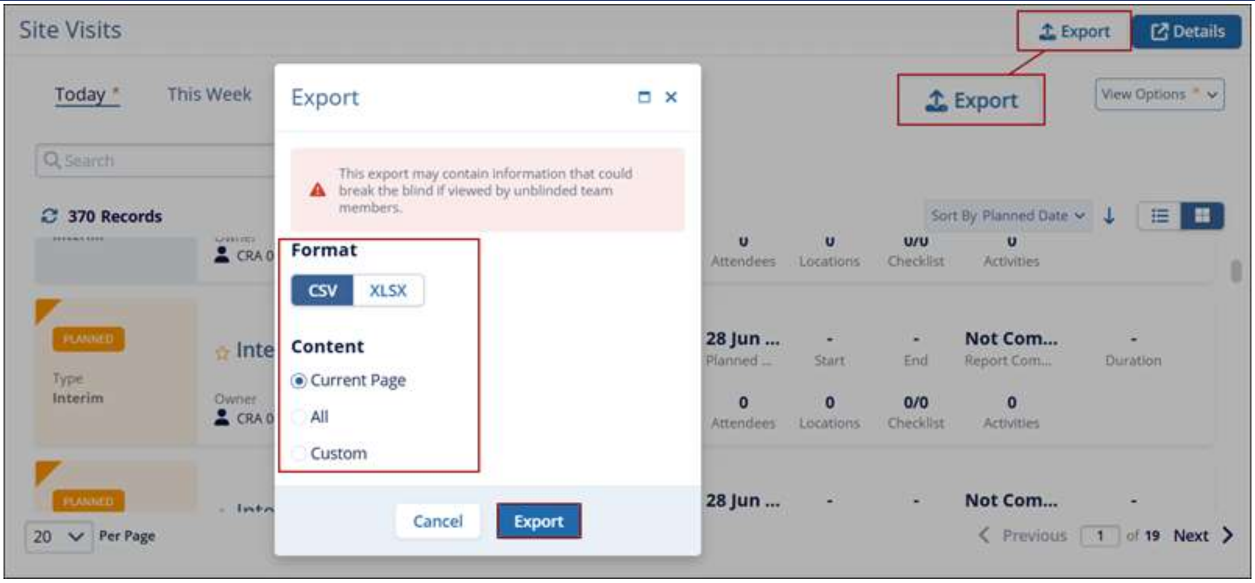


Figure: Export Site Visits

Site Visit Details

To open the list of Site Visits in a different modal window, click on the 'Details' button on the Site Visits dashlet.

Figure: Site Visit Details

Site Visit Filters

To filter the Site Visits dashlet, refer to the standard steps detailed in the Filter Activities section above to apply standard and advanced filters.

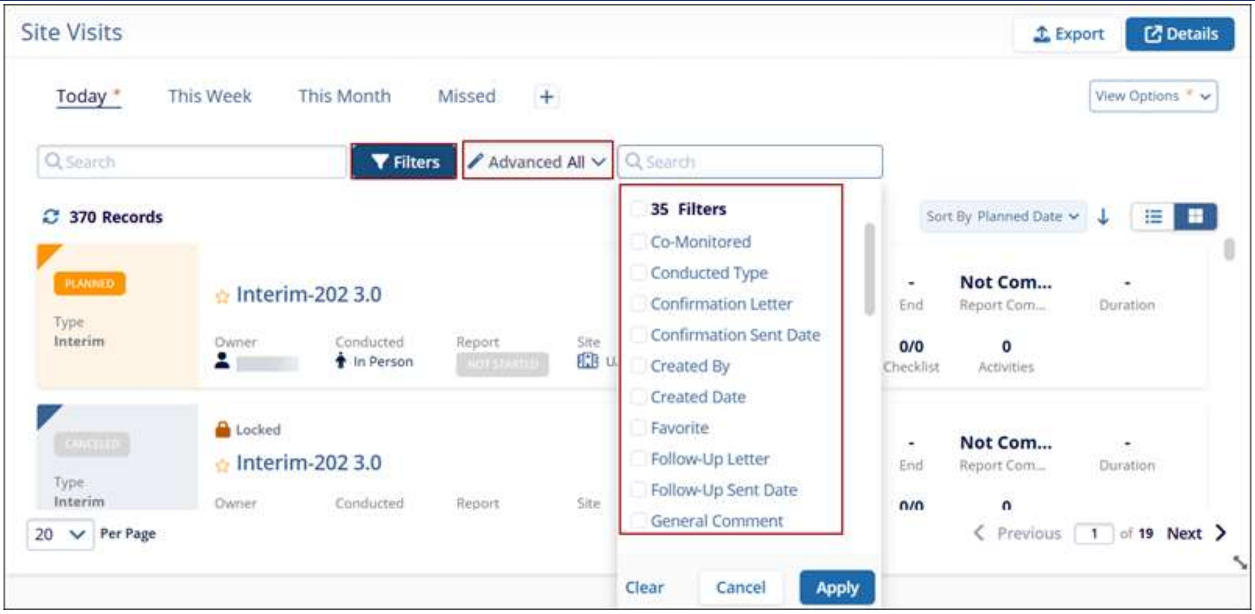


Figure : Site Visit Filters

Site Visits Calendar

The cross-study ‘Site Visits Calendar at the domain-level on the ‘My Page’ dashboard, enables users to view site visits in a calendar format. This calendar offers functionality similar to the study-level site visits calendar, while providing sufficient details to identify the associated study and site for each visit.

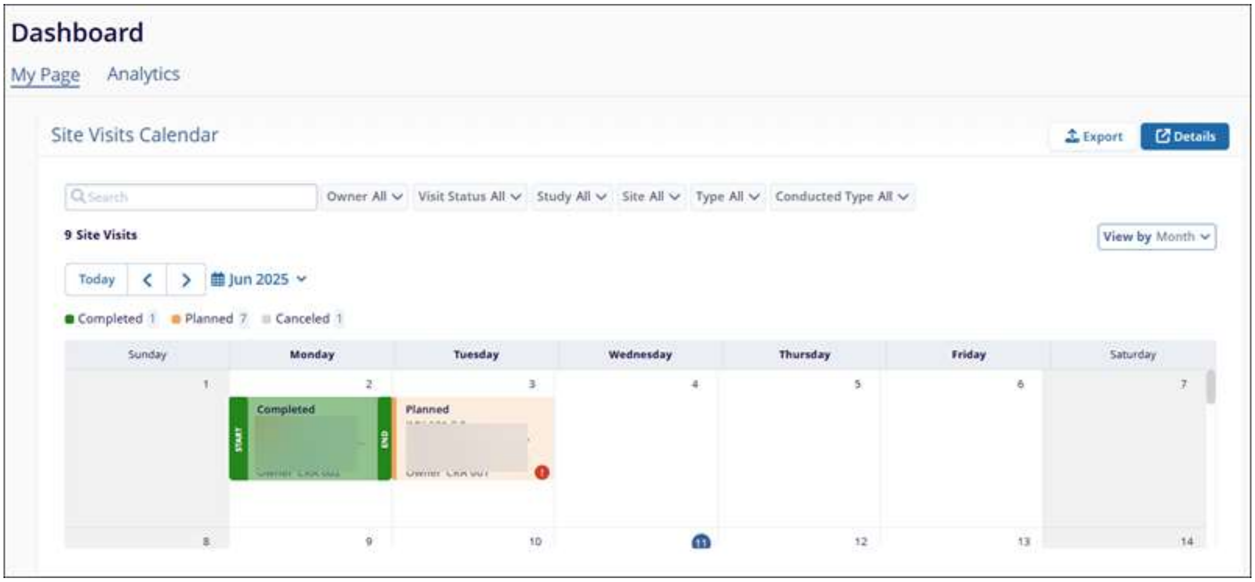


Figure : Site Visits Calendar dashlet

Site Visit Calendar Views

To configure the views on the Site Visit Calendar dashlet, follow the steps below.

1. Click on the calendar icon and set the dates.

Figure: Site Visits Calendar – Set dates

2. Click on the ‘View By’ dropdown and select either Day, Week, Month, Quarter, or Year.

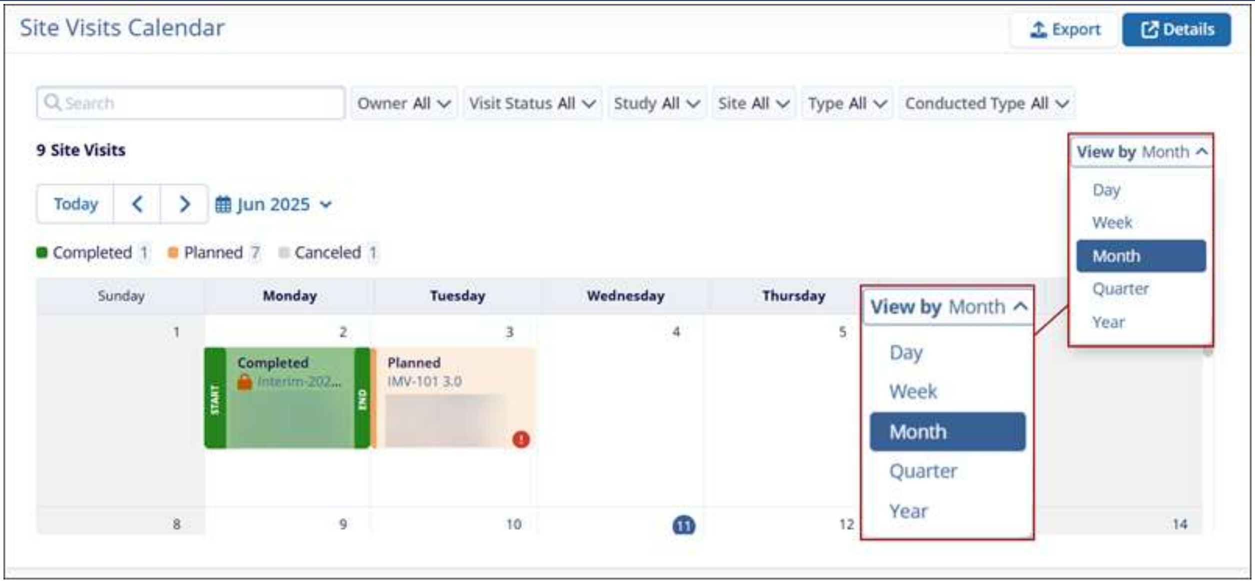


Figure: Site Visits Calendar – View by options.

Export Site Visits Calendar

To export the Site Visits Calendar dashlet, follow the steps below.

1. On the Site Visits Calendar dashlet, click on the 'Export' button.

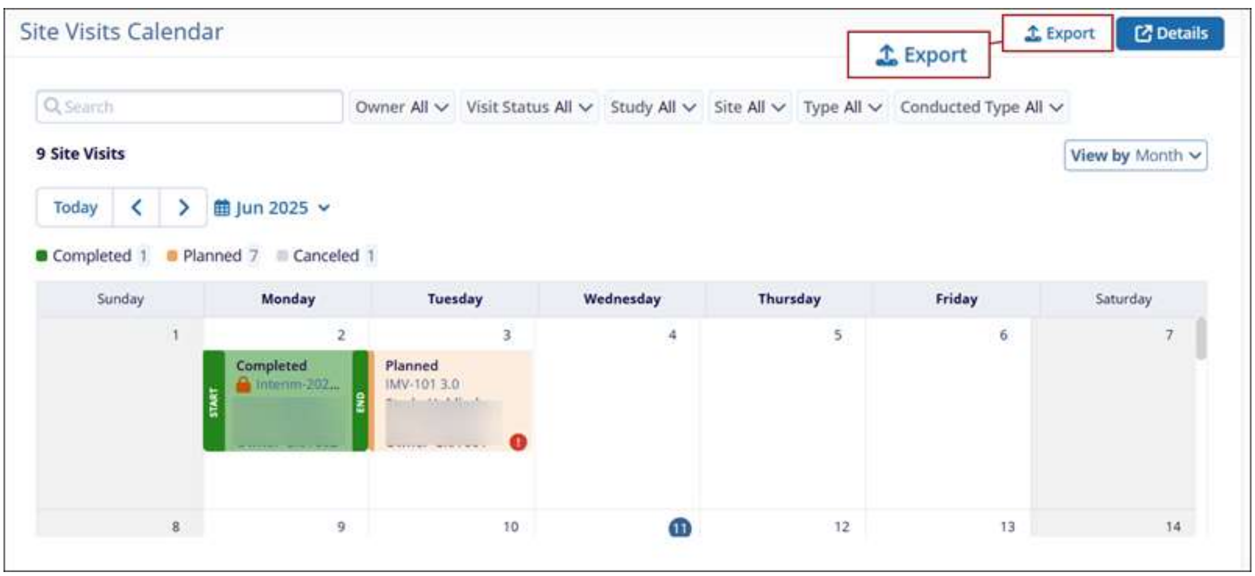


Figure: Export Site Visits Calendar

2. On the Export window, select either PDF Document or PNG Image option and click on the Export button.

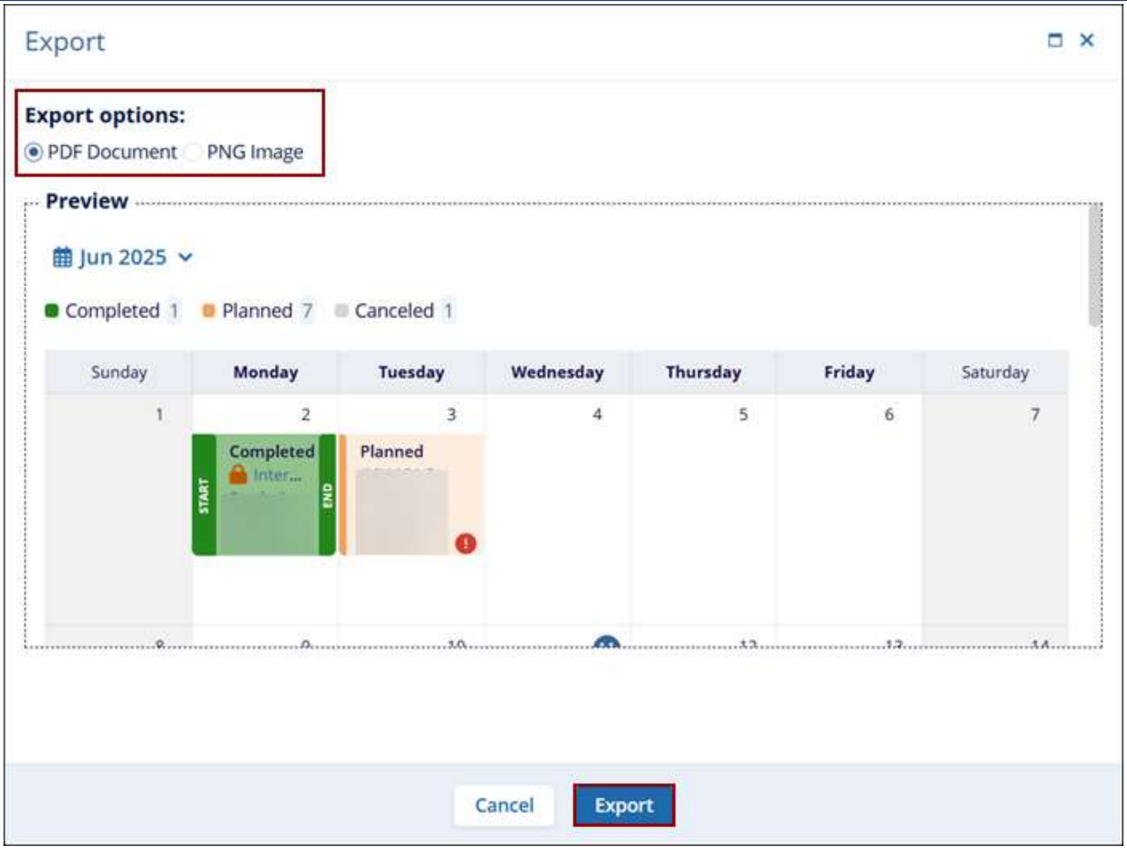


Figure: Export in PDF or PNG format

Site Visit Calendar Details

To open the list of Site Visits Calendar details in a different modal window, click on the 'Details' button on the Site Visits dashlet.

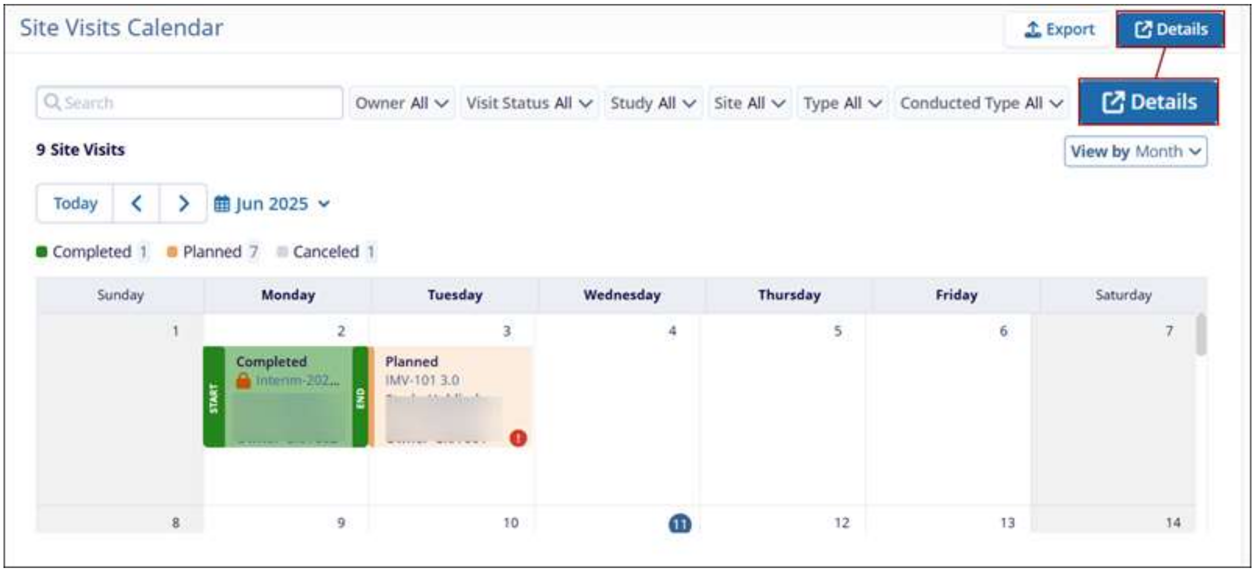
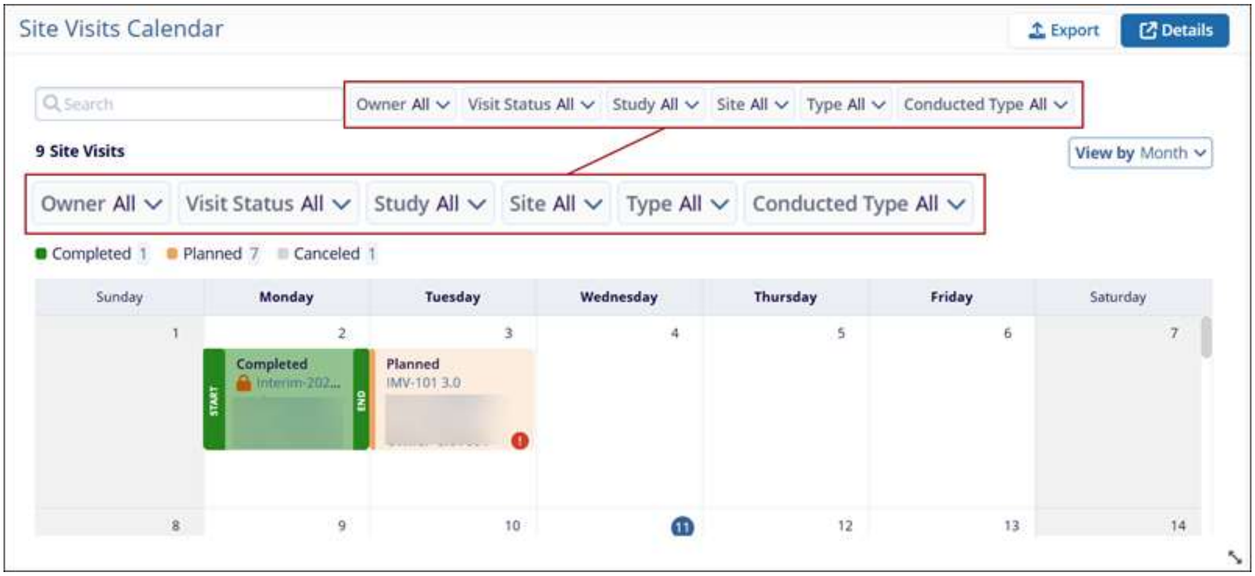


Figure: Site Visit Calendar Details

Site Visit Filters

To filter the Site Visits Calendar dashlet, click on the following filter dropdowns and select the necessary filter criteria.

- Owner
- Visit Status
- Study
- Site
- Type
- Conducted Type



Milestones

The Milestones dashlet on the My Page allows users to access and review a cross-study milestones listing. Additionally, users can perform the following on the Milestones dashlet.

- Apply filters within the cross-study milestones list, i.e., create a milestone listing with custom fields, etc.
- Pull in custom fields within the cross-study milestones view.
- Configure and save a custom cross-study milestones view.
- Retrieve an export of all records from the cross-study milestones view.

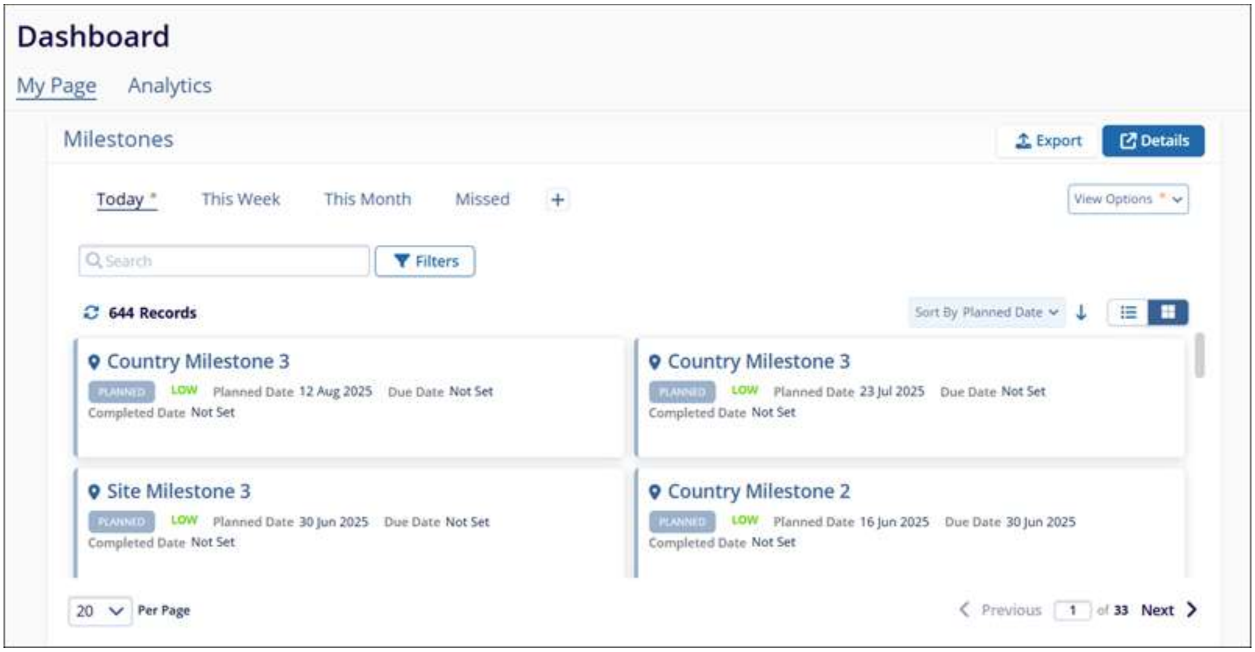


Figure: Milestones dashlet

Milestones Views

To add a milestone view to the dashlet, follow the steps below.

1. Click on the '+' icon on the Milestones dashlet.
2. Select a view from the available dropdown list.
3. Click on the star icon to mark a view as favorite and access the 'Favorites' tab to see all views marked as favorites.
4. The newly added view appears as a tab on the Milestones dashlet.

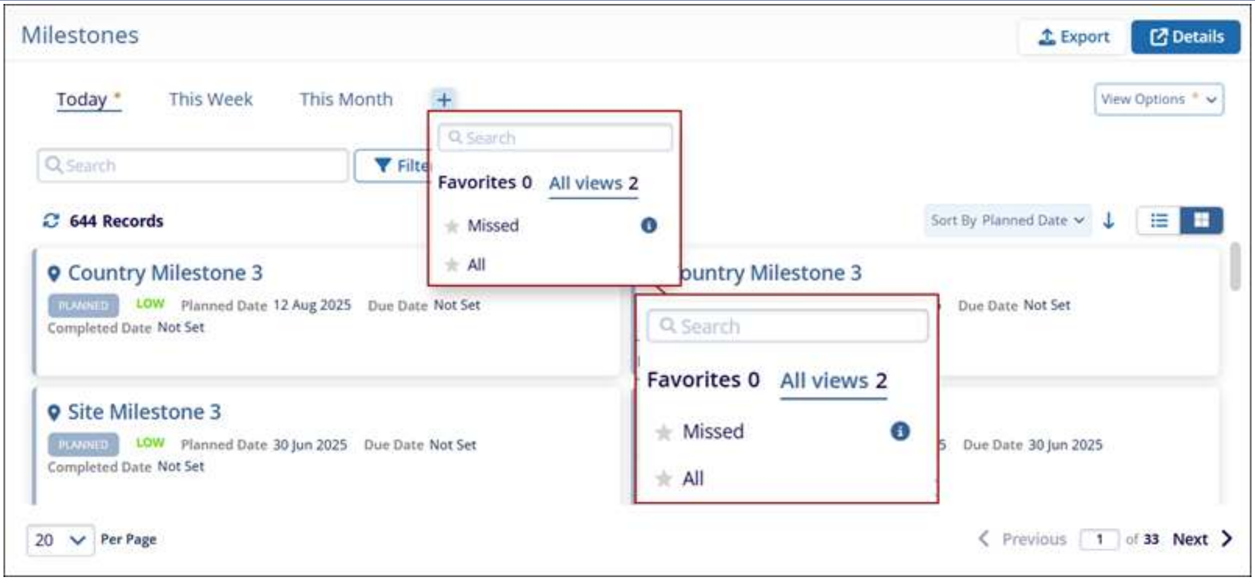


Figure: Milestone Views

5. To configure a view, either click the hamburger icon next to the desired view or click on the 'View Options' dropdown.

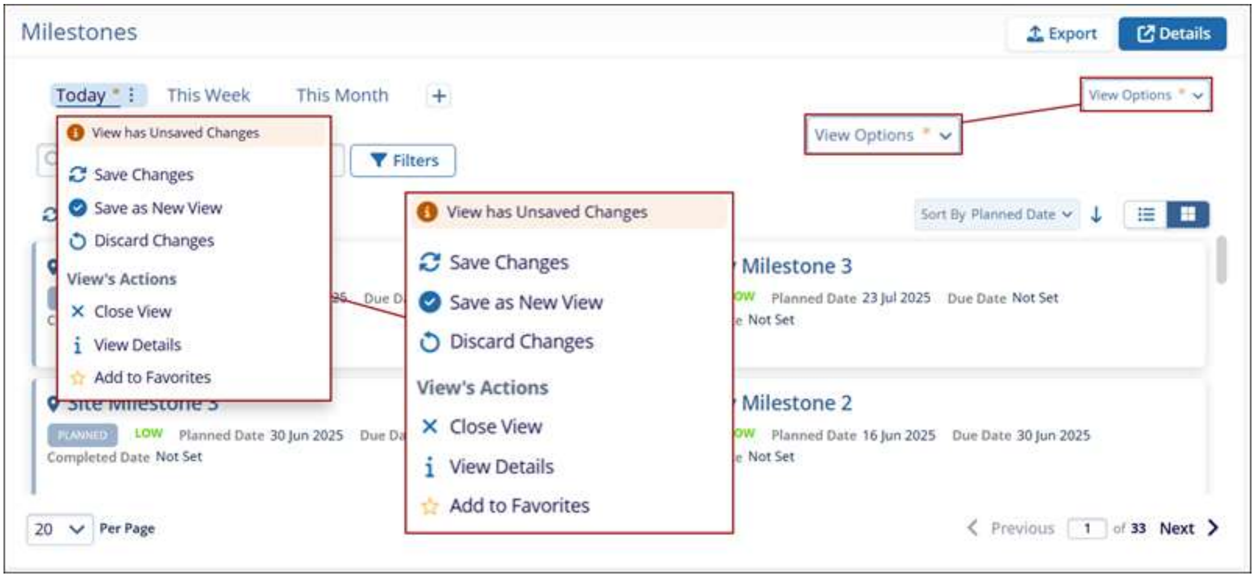


Figure: Configure Milestone Views

Export Milestones

To export the Milestone dashlet details, click on the 'Export' button and refer to the standard steps detailed in the Export Activities section above.

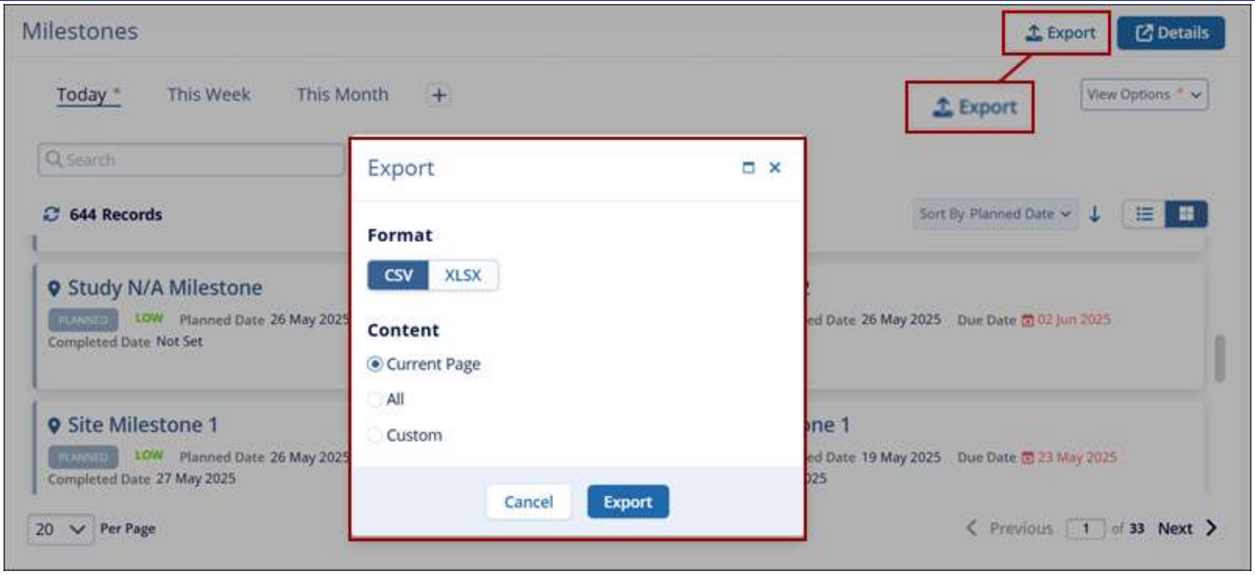
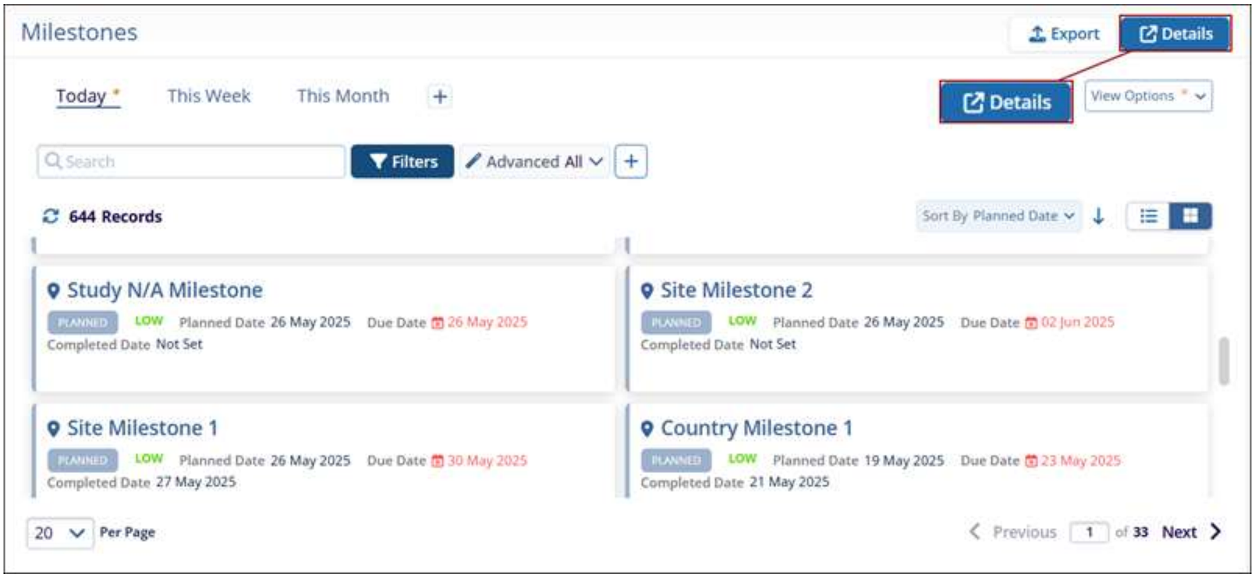


Figure: Export Milestones

Milestone Details

To open the list of Milestone details in a different modal window, click on the ‘Details’ button on the Milestones dashlet.



Milestone Filters

To filter the Milestones dashlet, refer to the standard steps detailed in the Filter Activities section above to apply standard and advanced filters.

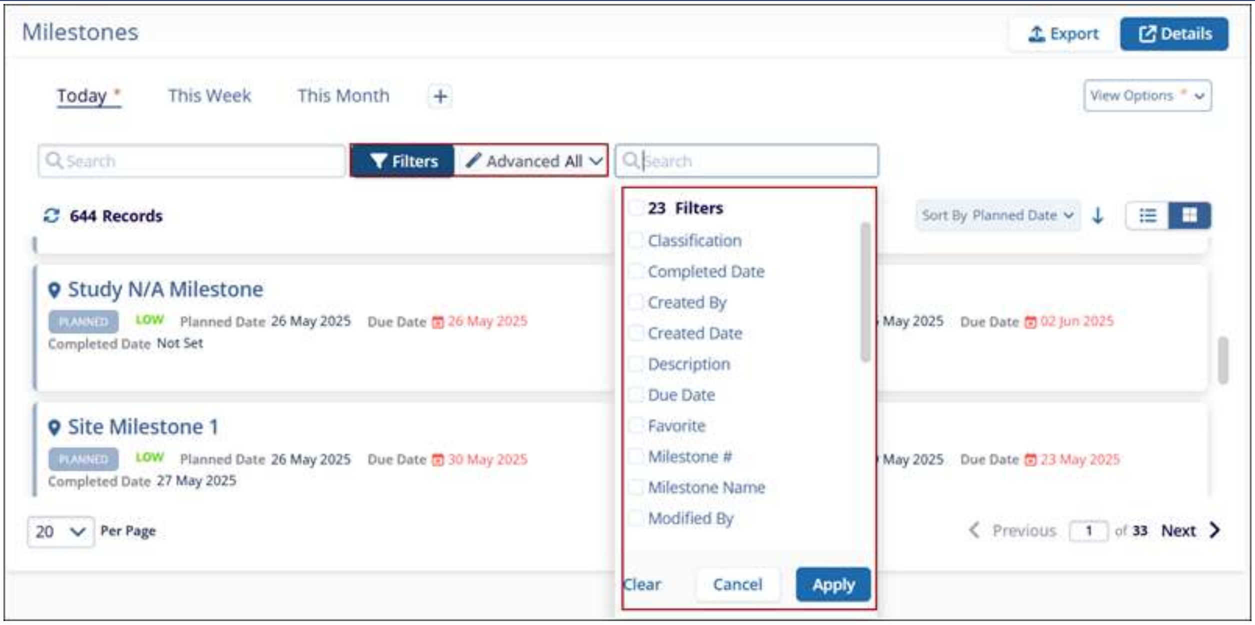


Figure: Milestone dashlet filters

Analytics

This section describes the various dashlets within the Analytics section of the Dashboard.

Top Countries Dashlet

The Top Countries dashlet within the Portfolio dashboard displays the three countries with the highest percentage of studies that include at least one site in each country. Each study is counted once per country, regardless of the number of sites it has in that country (e.g., a study with 1 site in Germany and another with 100 sites in the U.S. will count equally toward each country's total).

This dashboard offers a quick snapshot of study distribution by geography, helping users to easily identify where the clinical trials are most commonly conducted. Percentages are calculated based on the presence of site locations across all studies tracked within CTMS.

Users can use this view to:

- Understand geographical trends in the study portfolio
- Support strategic planning and resource allocation
- Identify regions with high clinical trial activity for further analysis

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.

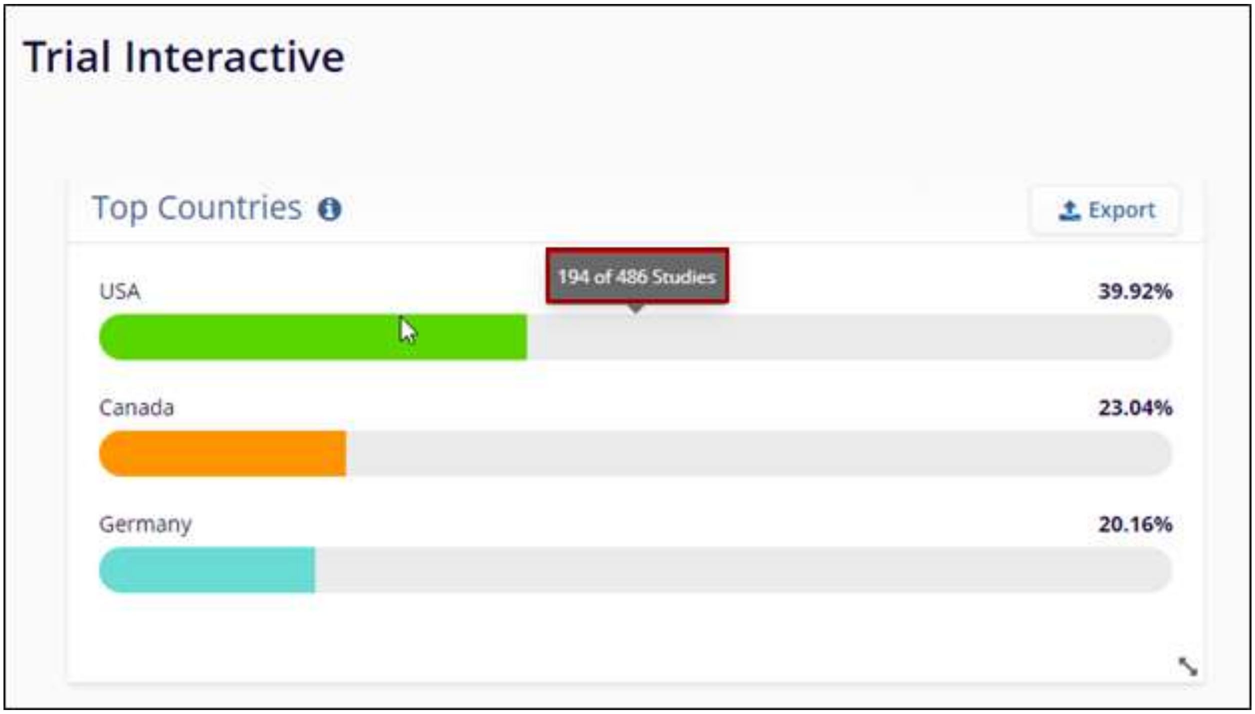


Figure: Top Countries

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.

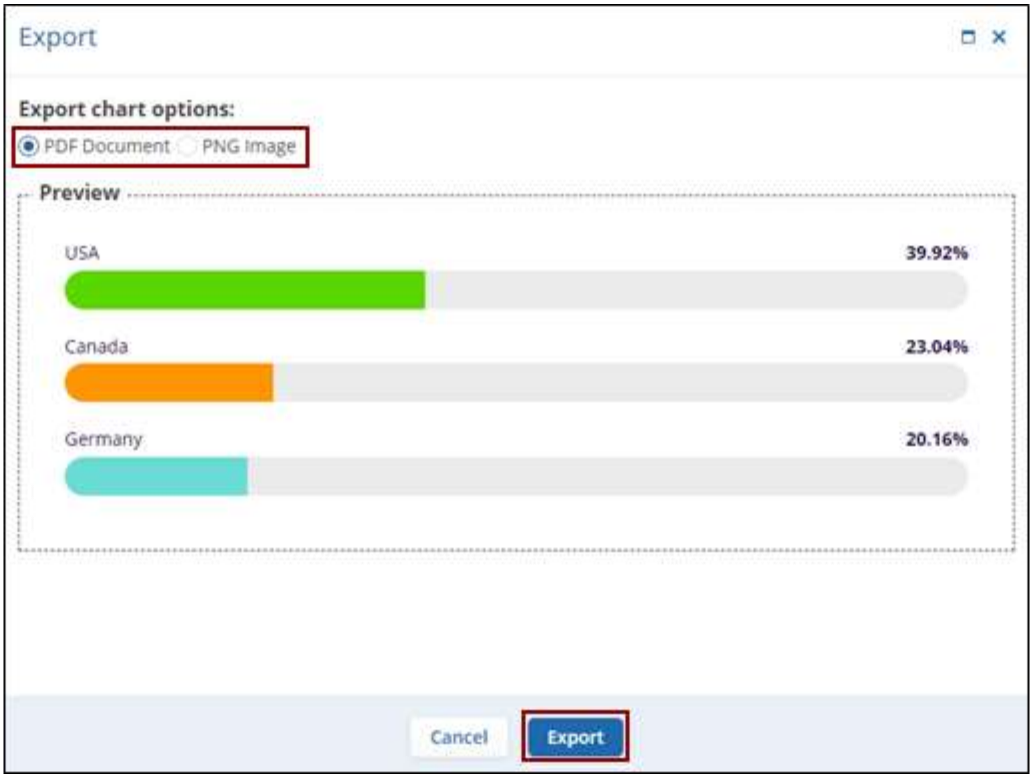


Figure: Export Chart Options

Portfolio Dashlet

The Portfolio dashlet provides a global view of the clinical study activity. Displayed as an interactive world map, this dashlet highlights the number of studies associated with each country, offering a high-level snapshot of the geographic trial distribution.

Users can tailor the map to focus on specific data by applying filters available in the dropdown menu. Filters include:

- Status
- Sponsor
- Phase
- Program
- Country
- Product
- Therapeutic Area

These filters allow users to quickly refine the view to focus on targeted aspects of the portfolio, supporting data-driven insights and strategic decision-making.

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

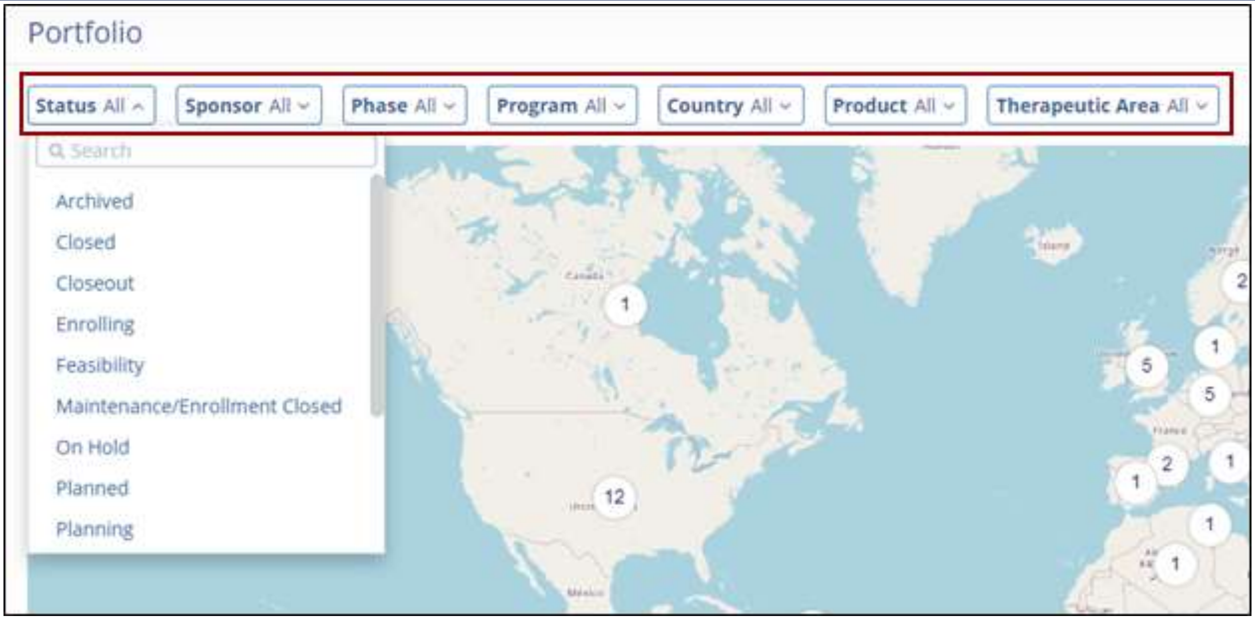


Figure: Portfolio dashlet filters

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

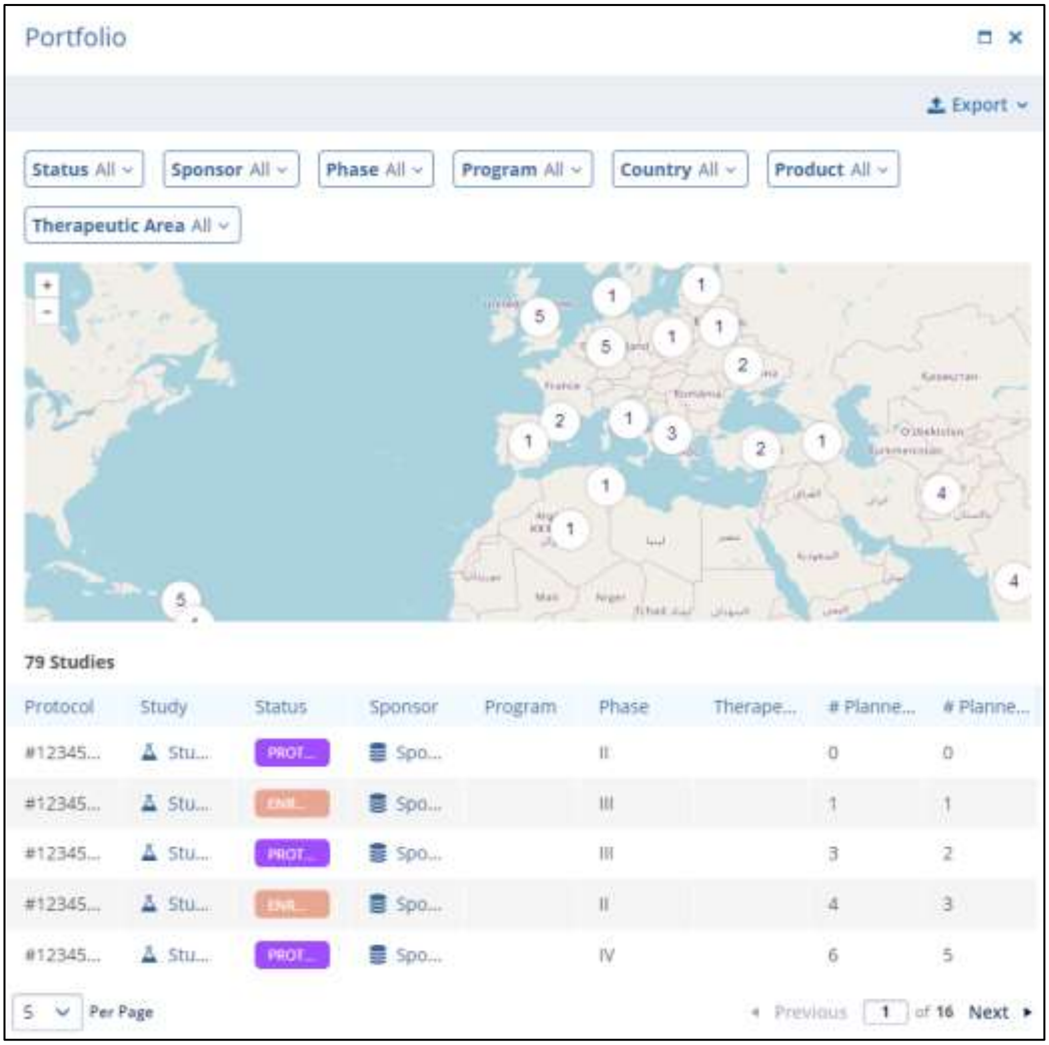


Figure: Expanded Portfolio screen

3. On the portfolio screen, perform the following.
    - Apply filters by selecting the available options from the filter's dropdown.
    - Click on Export to retrieve an export of the portfolio screen in the Grid or Chart format.
        - Export Grid: The Export Grid option allows data to be exported in CSV or XLSX file format. Refer to the Exporting Contacts section to understand the export process in detail.
        - Export Chart: The Export Chart option allows users to export the data in PDF Documents or PNG Images. Refer to the Top Countries Dashlet section to understand the process.

Note:

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

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

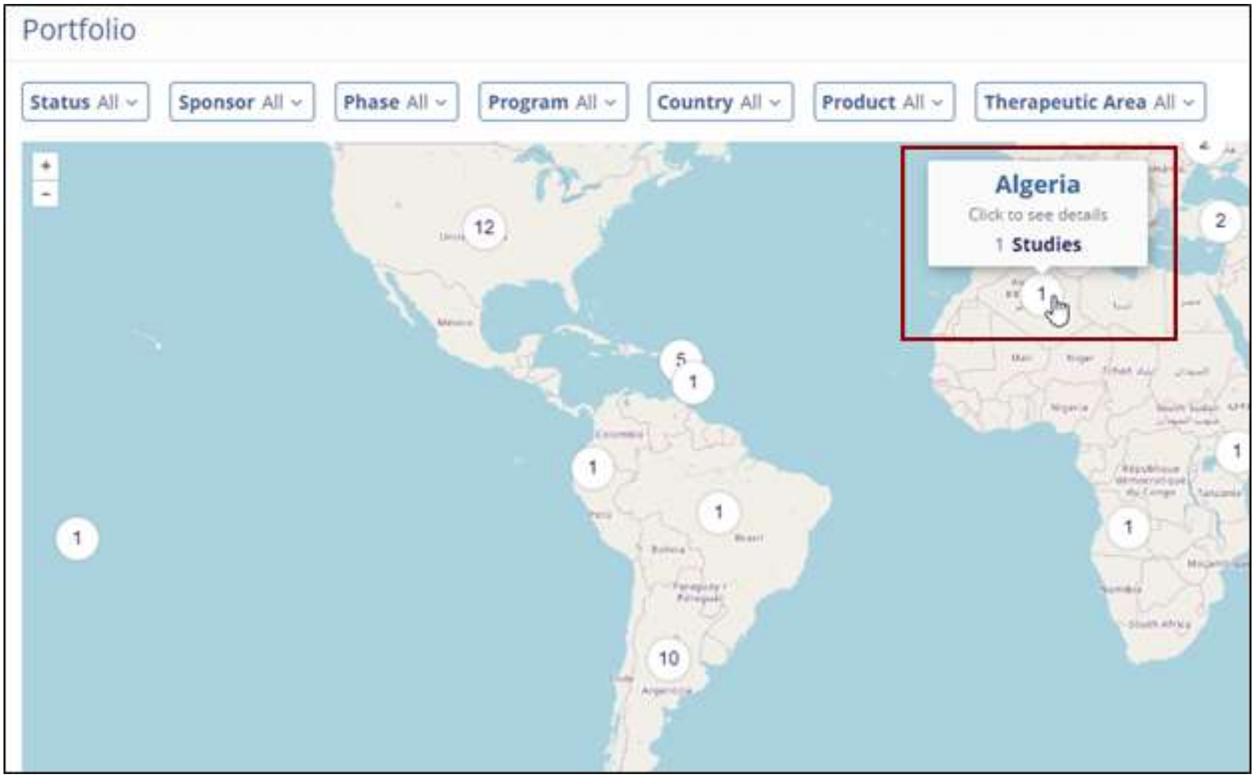


Figure: Country name and number of studies

5. Additionally, click on the number to get additional details associated with that particular study.
6. 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.

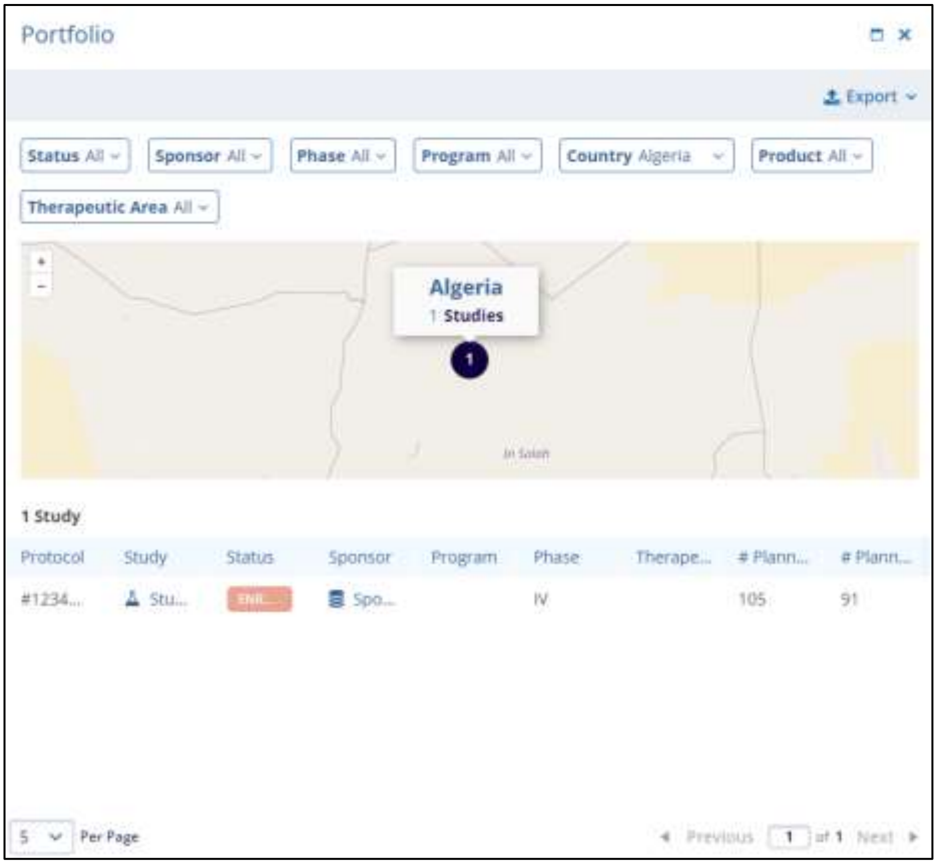


Figure: Study details by individual country

Site Visit Report Review Status

The Site Visit Report Review Status dashlet provides visibility into site visit activity and report review status across studies. It helps reviewers stay on top of their assigned reports and monitor the review pipeline across their studies. Access to this dashlet varies based on the logged in user's role:

- Users defined as site visit report reviewers within any study will see three additional tabs, each showing only submitted site visit reports for their studies:
    - Assigned to Me – displays submitted reports currently assigned to the logged-in reviewer
    - All – shows all submitted reports, regardless of reviewer
    - No Reviewer – lists submitted reports that have not yet been assigned to any reviewer
- Users who are not defined as site visit report reviewers will only see the Visit Owner section, which displays a list of site visit details.
- For the Assigned to Me, All, and No Reviewer tabs, users can further refine the data using the following filters:
    - All – shows all submitted reports in the tab
    - Past Due – highlights report that are overdue for review
    - Approaching Due – displays reports with upcoming due dates, with 'approaching' defined by default as within the next 3 days
- For the Visit Owner tab, users can further refine the data using the following filters:
    - Study – shows all study names for the studies associated to the user
    - Protocol Number
    - Site Status
    - Site Visit Owner
    - Visit Type
    - Visit Planned Date
    - Visit Start Date
    - Visit End Date
    - Conducted Type
    - Visit Status
    - Site Location
    - Report Status

This dashlet is designed to support efficient workload management and timely review completion for site visit reports and site visit resource assignments.

Users can use this dashlet to:

- Monitor the status of submitted site visit reports
- Focus on reviews assigned to the user.
- Identify overdue or soon-to-be-due reports
- Ensure visibility and accountability across the team's review process
- Identify site visit resources by date/time and location as well as study

A user can perform the following actions on this dashlet.

1. Click on the Assigned to Me, All, No Reviewer and Visit Owner tabs to view the visit data accordingly.

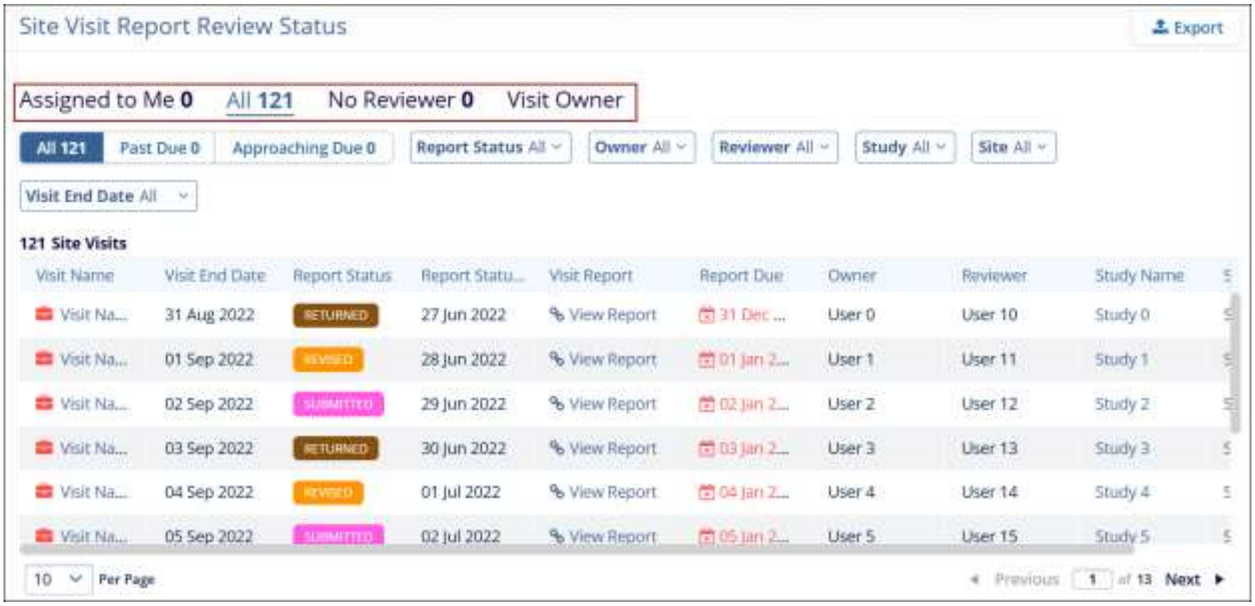


Figure: Site Visit Report Review Status - tabs

2. Apply the following filters on the Assigned to Me, All and No Reviewer tabs.
    a. All
    b. Past Due
    c. Approaching Due
    d. Report Status
    e. Owner
    f. Study
    g. Site
    h. Visit End Date

3. Apply the following filters on the Visit Owner tab.
    a. Study
    b. Protocol Number
    c. Site Status
    d. Site Visit Owner
    e. Visit Type
    f. Visit Planned Date
    g. Visit Start Date
    h. Visit End Date
    i. Conducted Type
    j. Visit Status
    k. Site Location
    l. Report Status
    m. Submission Due Date
    n. Confirmation Letter Sent Date
    o. Follow-up Letter Sent Date

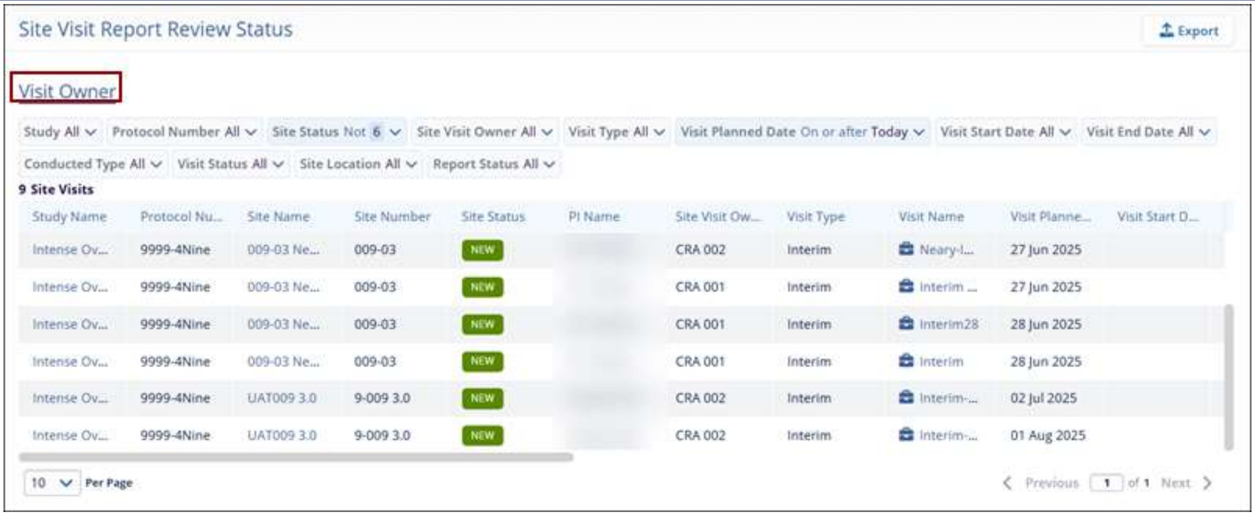


Figure: Site Visit Report Review Status – Visit Owner tab

4. Click on the Export button to export the dashlet data into the CSV or XLSX file format. Refer to the Exporting Contacts section for the standard steps for exporting data in CSV or XLSX file format.

Important

- Only site visit report reviewers can view the Assigned to Me, All, and No Reviewer tabs within the dashlet.
- CRAs can view only the Visit Owner tab within the dashlet.

Studies Dashlet

The Studies dashlet provides a visual and detailed overview of the study portfolio. It features a customizable chart, either pie or bar, alongside a study list displayed in a clear table format, offering both high-level insights and granular data.

Users can interact with the dashlet in the following ways:

1. Toggle Chart Type: Click the Pie or Bar Chart icons to switch between visualization styles based on the preferences.
2. Group and Display: Click on Group by to select the preferred grouping criteria (e.g., by status, phase, sponsor, or program). The chart will automatically update based on the selected grouping. Users can also click on the number of items to control how many categories are displayed in the chart.
3. Apply Filters: Use the available filters to further refine the data shown in the chart and table, ensuring the view reflects exactly what is needed.

This combination of visual summaries and detailed listings helps users analyze study distribution and quickly drill into areas of interest.

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.

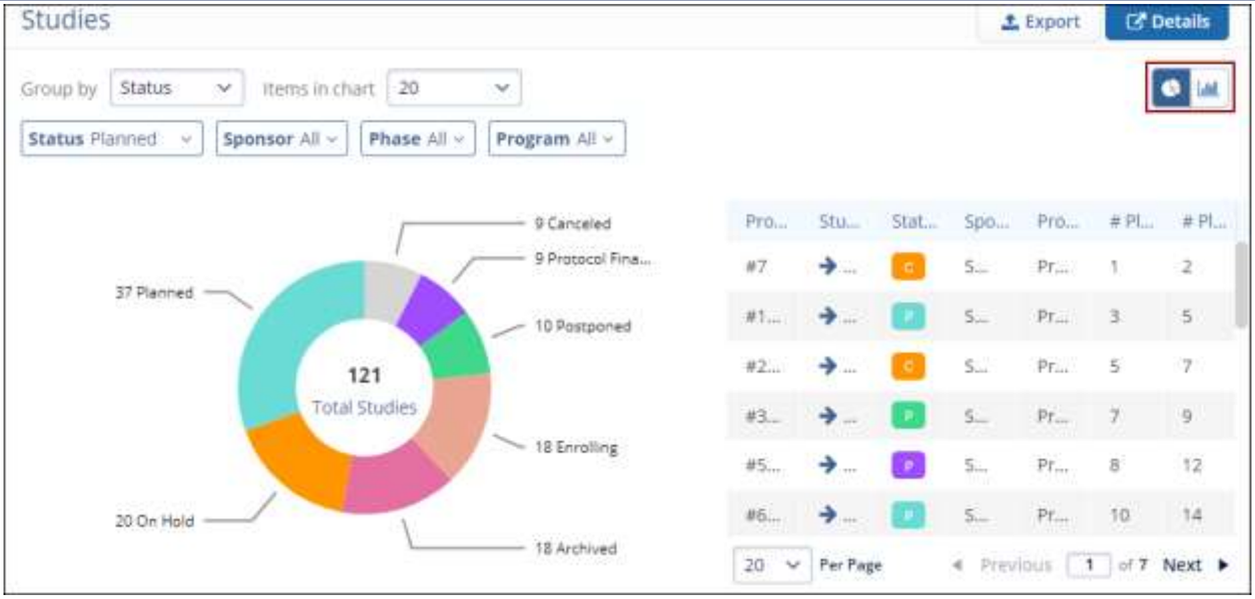


Figure: Select the data visualization type

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. Click on 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.

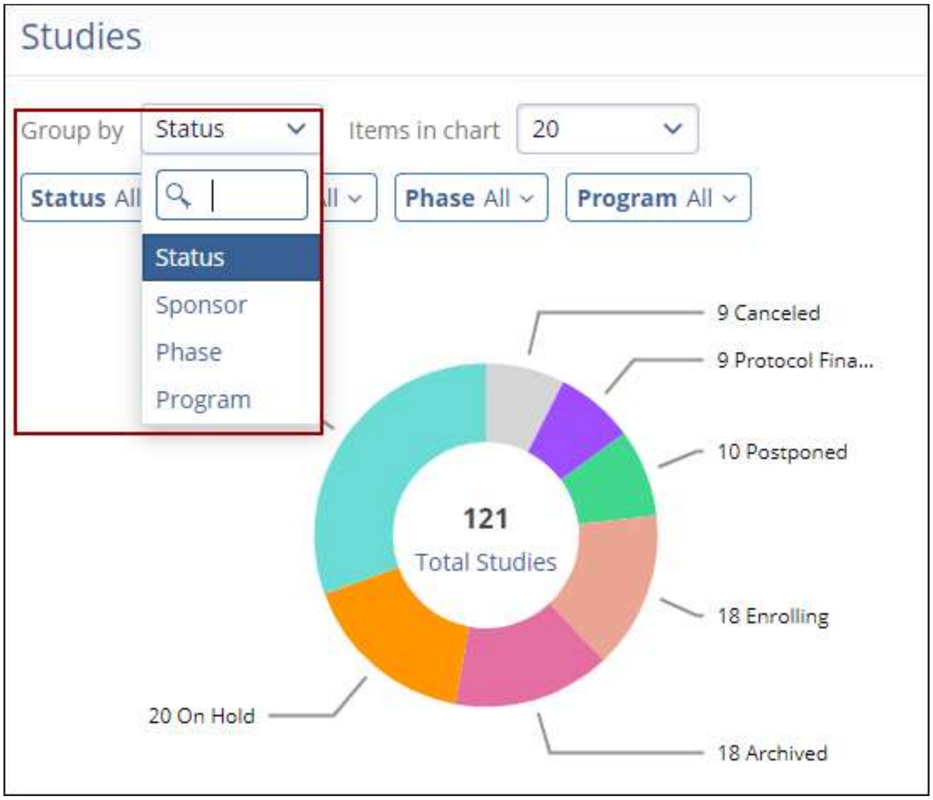


Figure: Grouping pie chart

3. Select and apply the filters to customize the pie chart.

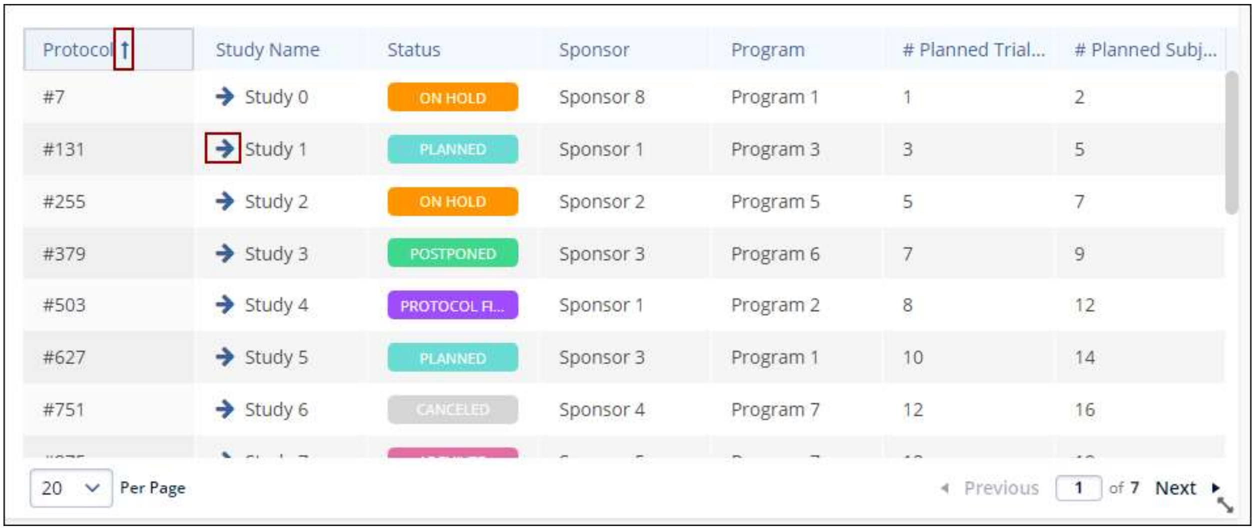
a. Status

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 FI...	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.

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 provides insight into site visit report activity and efficiency. The visuals help users to quickly assess report progress and performance across studies. It features two visual components:

- A pie chart showing the total number of site visit reports broken down by their current status
- Tachometer graphs displaying percentage of site visit reports:
  - Complete on First Submission
  - Currently Rejected
  - Past Due
  - Approve
- A numeric display of the average number of review cycles for submitted reports

Users can use this dashlet to:

- Monitor the volume and status of visit reports
- Track average review cycle counts for process efficiency
- Filter performance metrics by study, reviewer, CRA, or sponsor
- Identify bottlenecks or delays in the review process

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 tachometer graphs show the site visit reports categorized by their statuses. Hovering over the dials reveals a brief description of the chart statistics.

Figure: CRA Visit Report Performance – Categorization by status

In the above image, the Complete on First Submission tachometer 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.

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

1. Site Visit Report Review Status
2. Study Milestones
3. Study Enrollment
4. Study Timeline
5. Activities

Site Visit Report Review Status

Refer to the [Site Visit Report Review Status](#) section.

Study Milestone

The Study Milestones dashlet helps users track study progress by comparing site or country level milestones against overall study milestones. This allows teams to quickly identify whether individual sites or countries are on track to meet key study deadlines.

Figure: Study Milestones dashlet

Study Enrolment

The Study Enrollment dashlet provides a visual overview of actual enrollment progress compared to planned enrollment targets at the study level. It enables users to monitor enrollment performance over time and identify potential risks to meeting study goals.

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 key at the bottom of the dashlet defines the Milestone or Activity Plan statuses.

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.

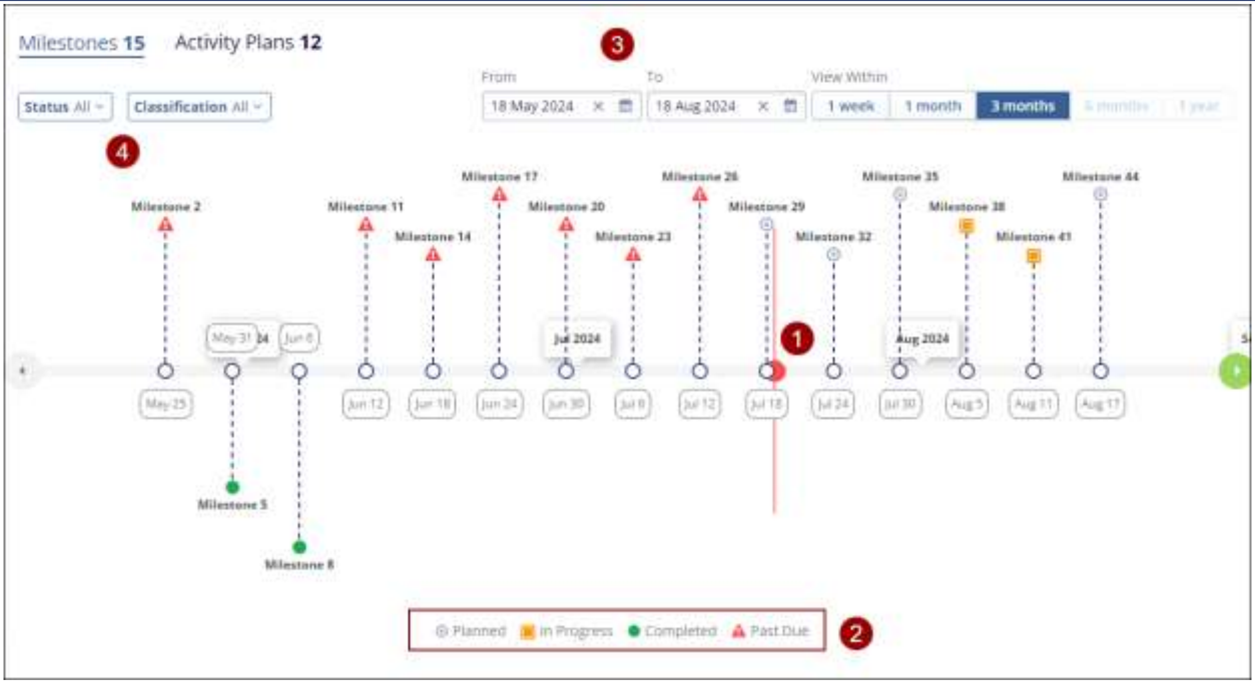


Figure: Study Timeline dashlet

Activities

The Activities dashlet displays a high-level summary of activities grouped by status for study, country, and site level activities. Users can apply filters to view activities by type and other criteria. Each chart provides a visual breakdown, and clicking a segment opens a detailed grid view for deeper analysis. 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.

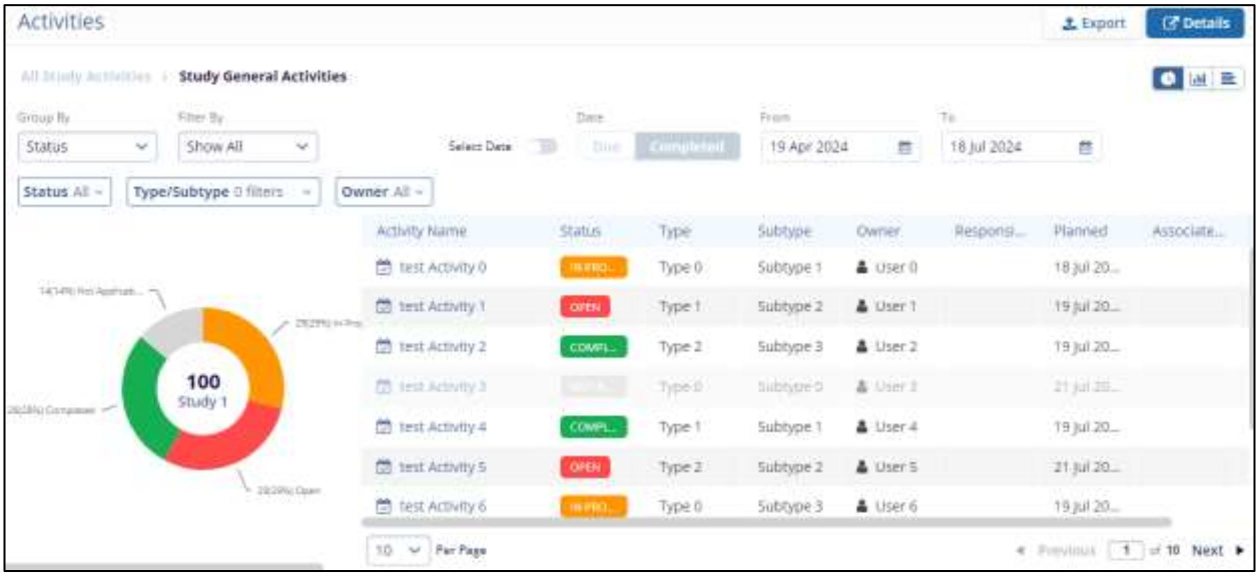


Figure: Study General Activities view

Note:

- The Export functionality is similar across all the dashboards. Refer to any one of the sections where Export functionality is detailed.
- The functionality to switch to Details 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.

Side Bar Navigation

The sidebar navigation menu enables users to access, platform links, settings, and online help options. Users with Company Administrator access to the CTMS can access all the options from the sidebar.

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 that impact all users.

Company Name and Logo

Users can change the name and logo associated with their CTMS environment to keep up with the changes that happen throughout a company's lifetime.

To change the company name and logo, follow the steps below.

1. Click on the waffle menu and select the Settings option.
2. From the left-hand navigation pane, hover over the logo at the top-left of the screen and select one of the available options: Edit or Delete.
3. Deleting the existing file will remove it from the company environment.
4. 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.

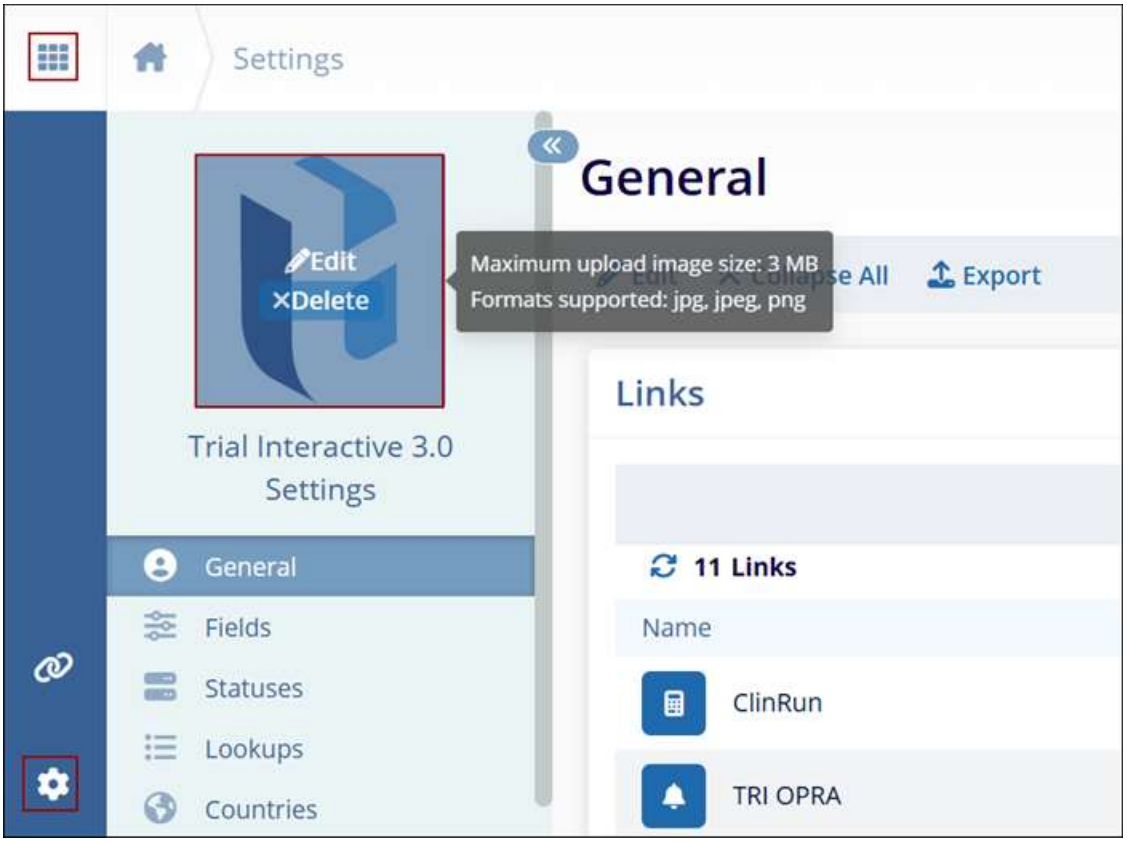


Figure: Edit Company Logo

Note: The maximum size of the image and the formats supported are displayed after hovering over the image.

General

The General Settings section allows Admin users to define links, breadcrumb performance, and the display of mock data.

<u>Links</u>

To configure the links, follow the steps below.

1. Select the General tab from the settings menu and click on the Edit button from the top menu bar.

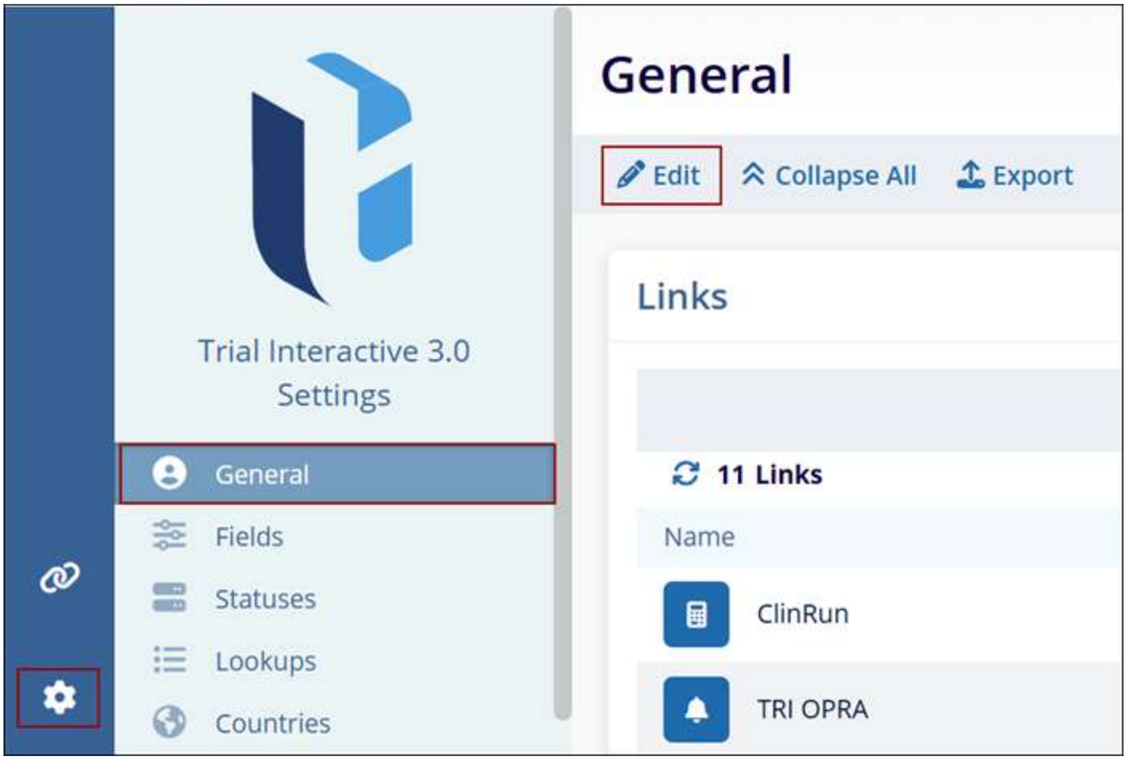


Figure: General Settings – Edit Links

2. Click on the +Create button within the Links section.
3. On the Create Link from, select an icon from the dropdown list, specify the link name, add the URL and click on the Create button.

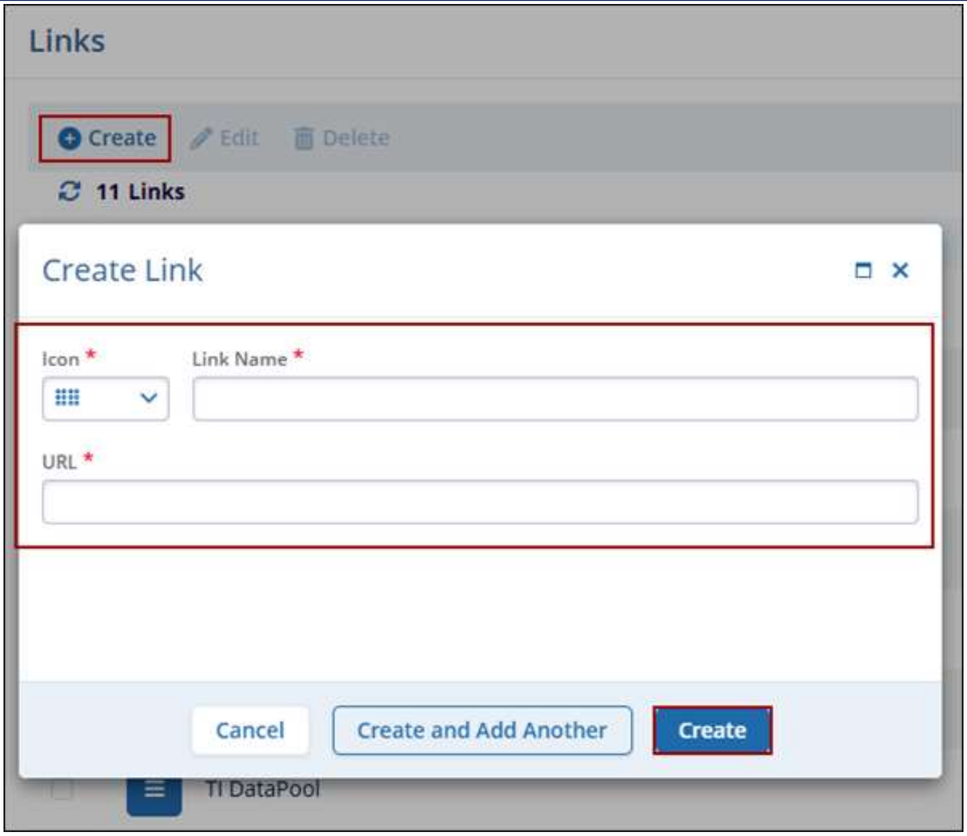
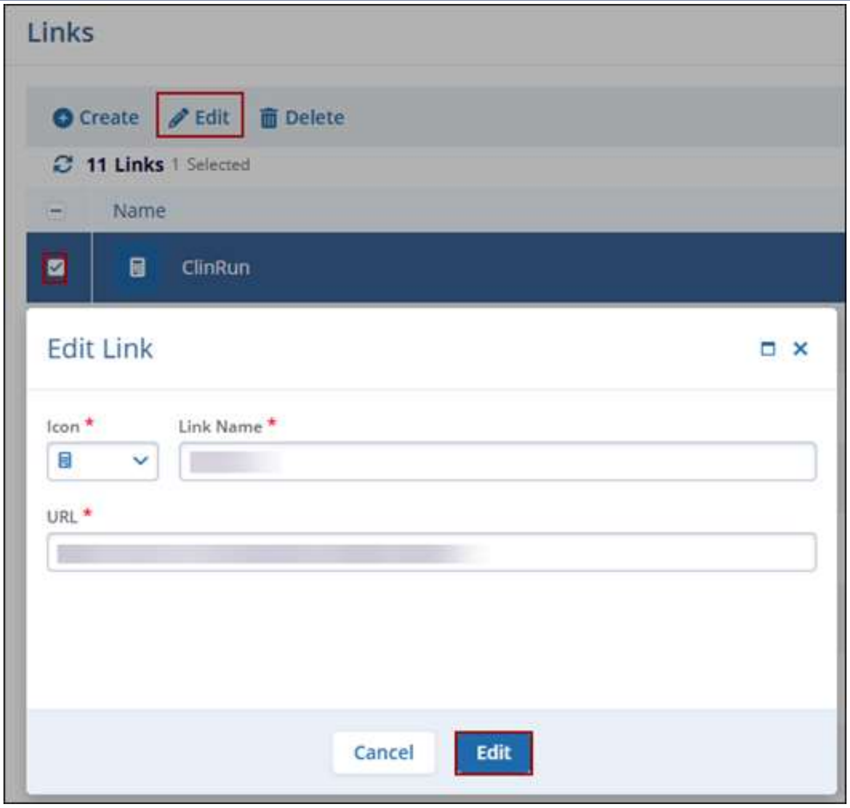


Figure: Create Link

4. To edit a link, select a link and click on the Edit button from the top menu bar.
5. On the Edit Link popup, make the required changes and click on the Edit button.



6. To delete a link, select a link and click on the Delete button from the top menu bar.
7. On the confirmation popup, click on the Delete button.

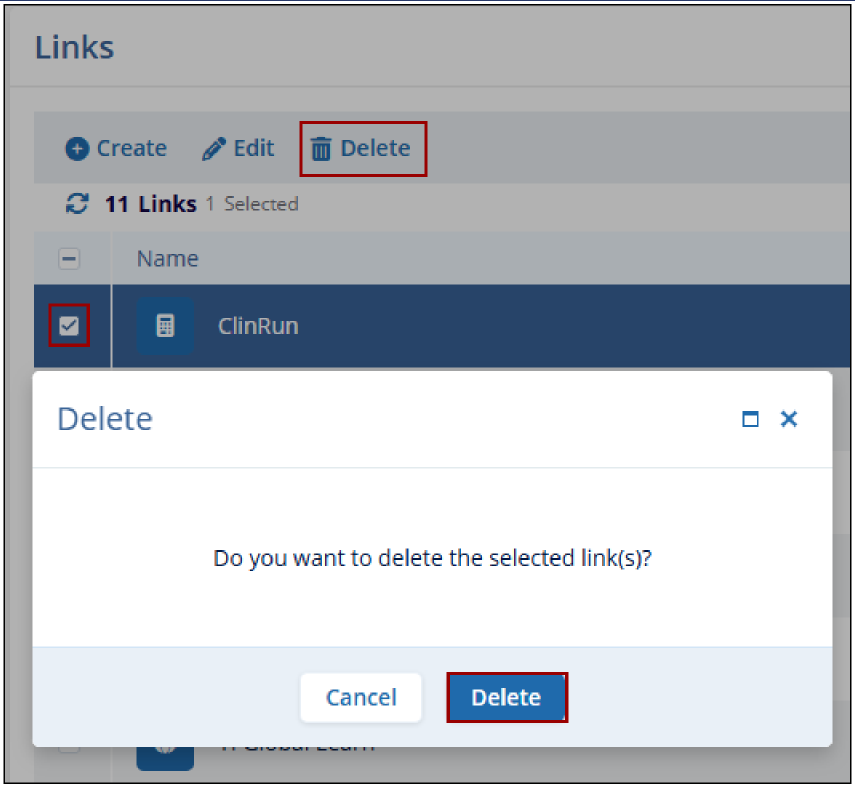


Figure: Delete Links

<u>Breadcrumbs</u>

To configure the breadcrumbs, go to the ‘Breadcrumbs’ section under General Settings, select or clear the desired checkboxes to adjust breadcrumb visibility, and then click the ‘Save’ button.

- Show Sponsor in Breadcrumbs
- Show Program in Breadcrumbs
- Show Product in Breadcrumbs

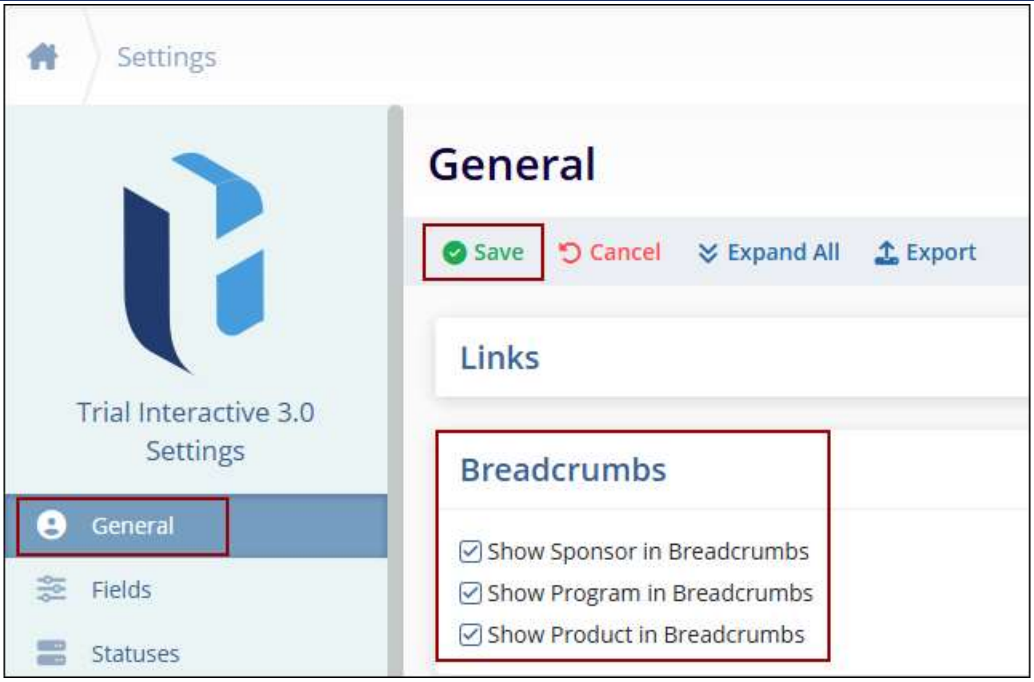


Figure: General Settings – Breadcrumbs

Mock Data

To configure the Mock Data setting, enable or disable the 'Use mock data for dashboards' toggle switch and click on the 'Save' button.

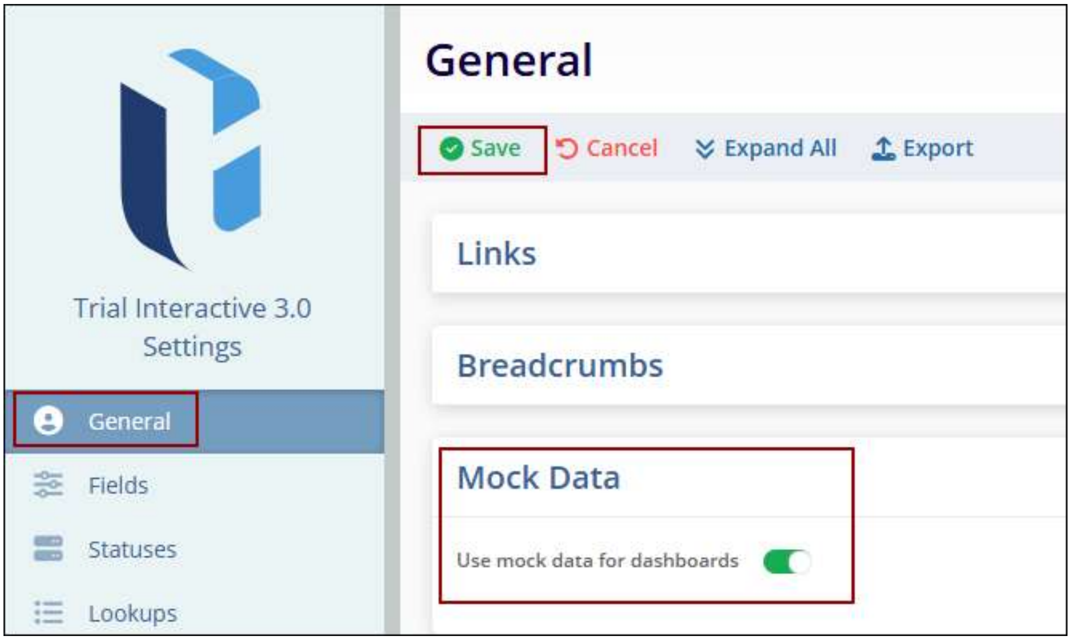


Figure: General Settings – Mock Data

Export

To export the General Settings data, follow the steps below

1. Click on the 'Export' button from the top menu bar.
2. Click on the Export button on the 'Export' popup to download a XLSX file with the General setting details.

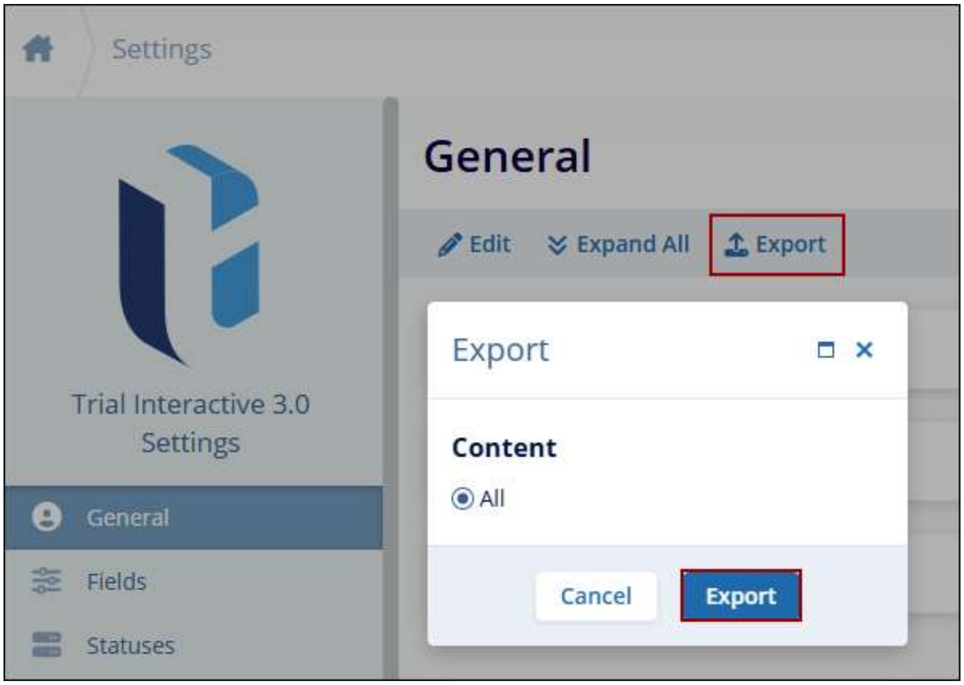


Figure: Export General Settings

Fields

Add New Custom Field

To create a custom field, follow the steps below.

1. Navigate to the Settings area and select the Fields menu.
2. Select the sub-type. For example, Activities.

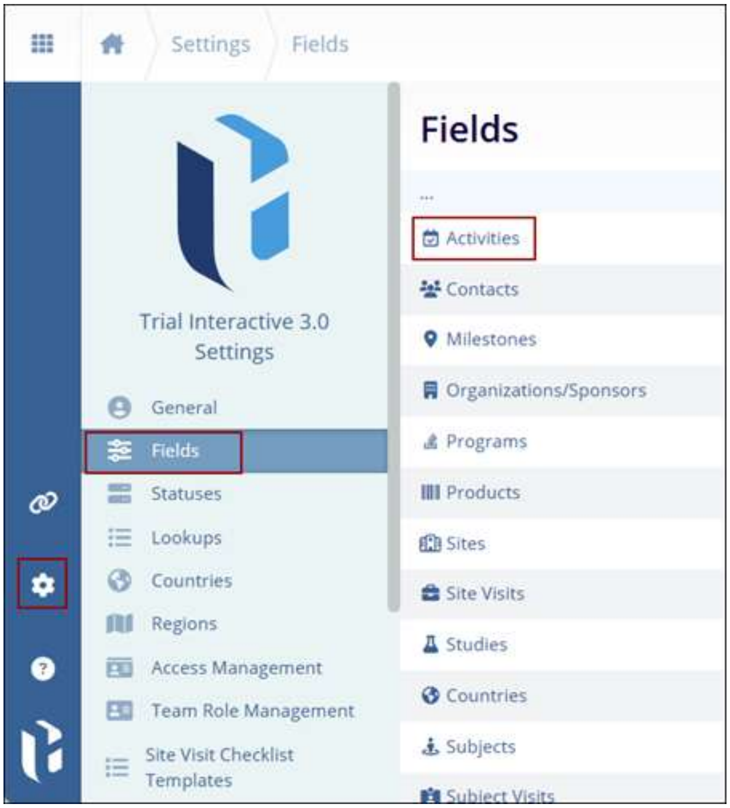


Figure: Fields

3. On the Activities screen, click on the +Add Field button.

Figure: Add Field

4. In step 1 of 'Add Custom Field' form, select the custom field type from the available options and click on the Next button.

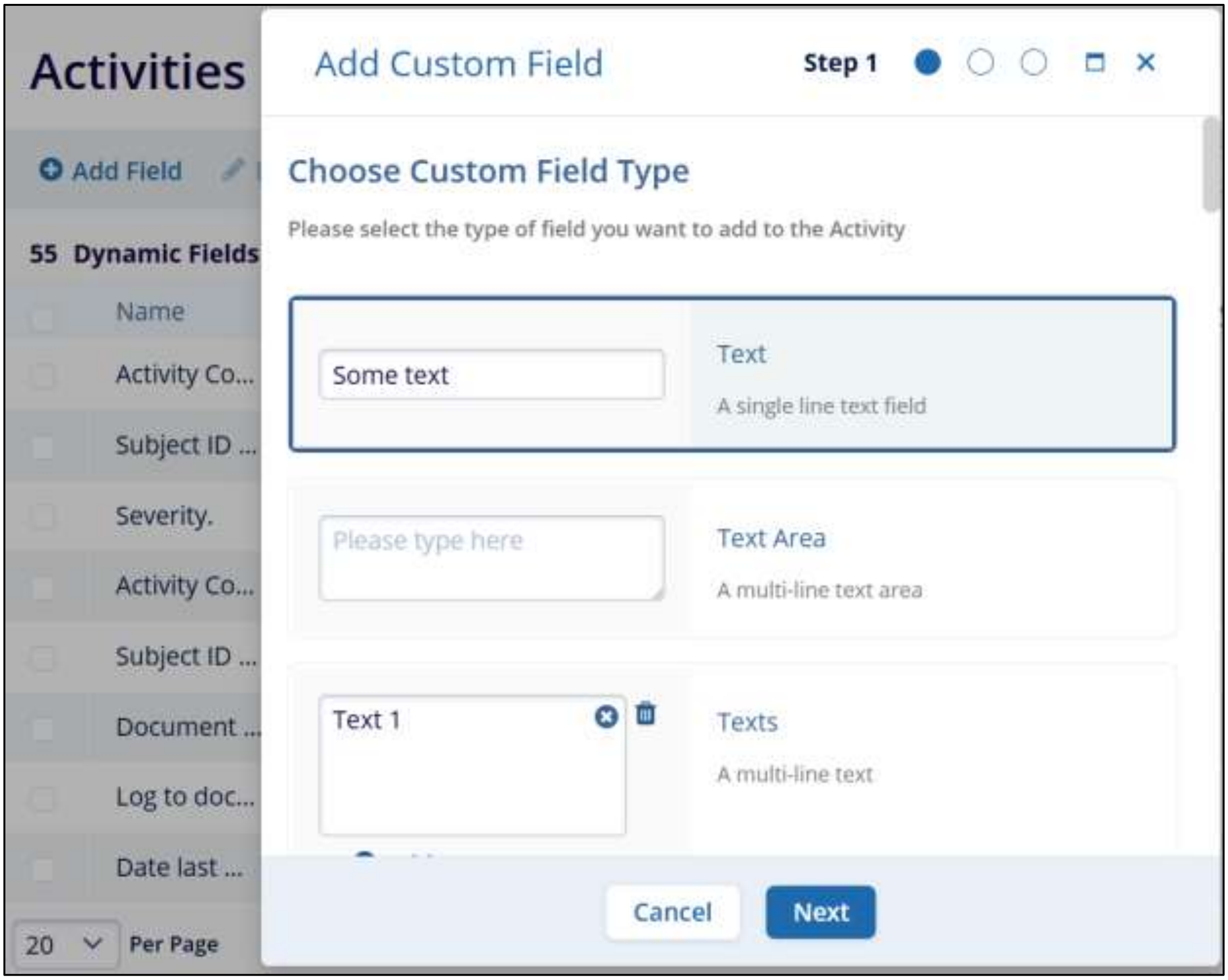


Figure: Add Custom Field

5. In Step 2, mandatorily add a name for the field. Optionally add description and select whether the field in Optional, Required, or Read-only. Click on the Next button.

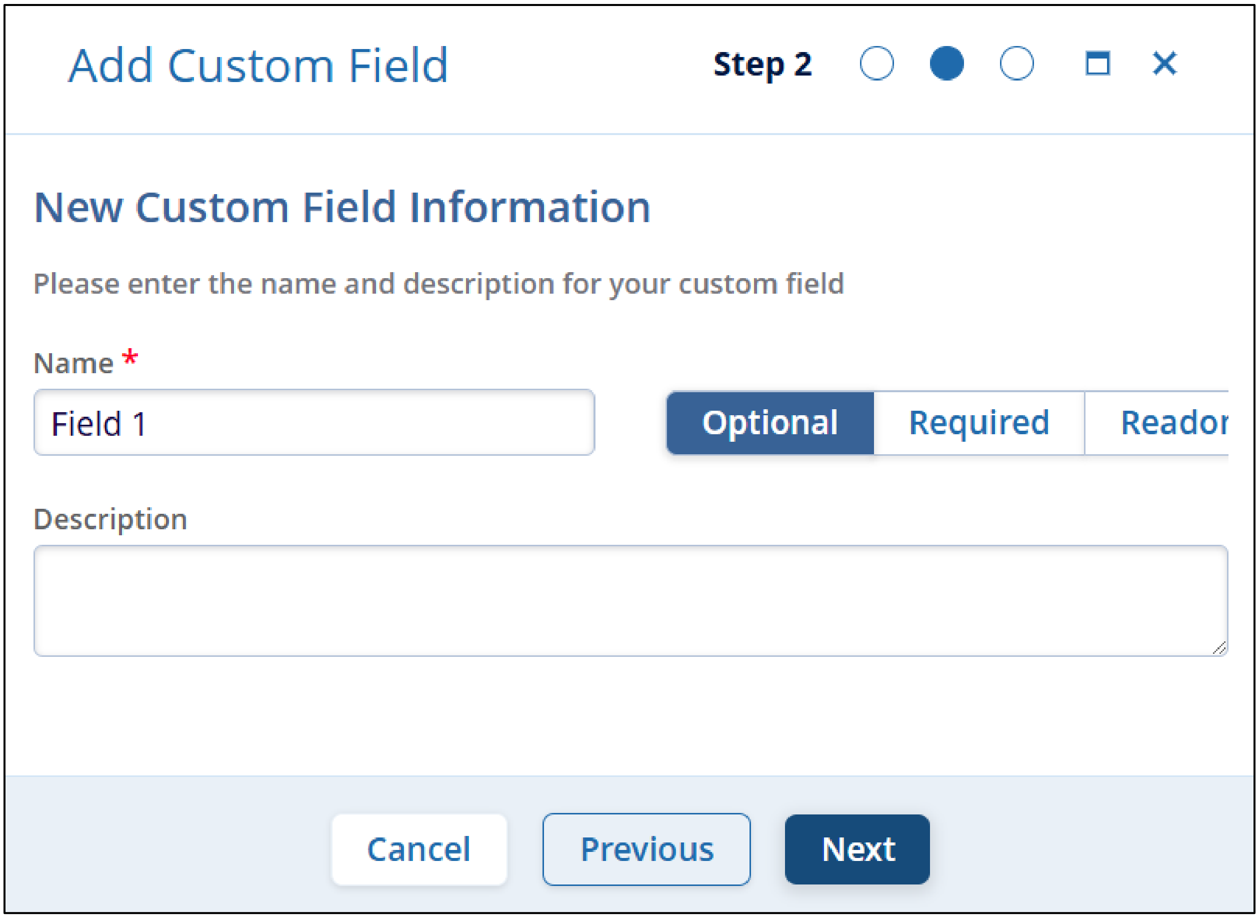


Figure: New Custom Field Information

6. In Step 3, add the field validation value by accessing the dropdown options and click on the Create button.

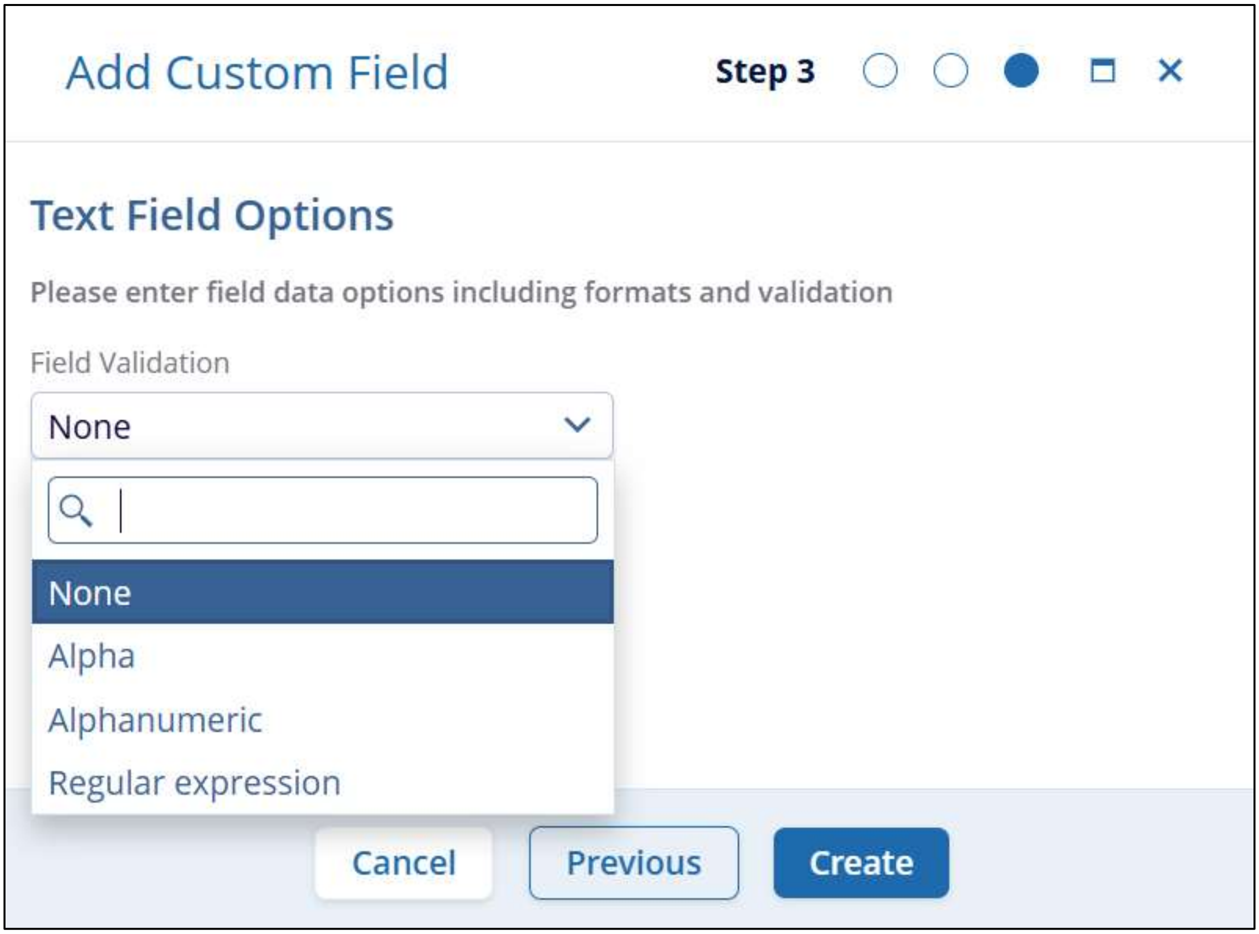


Figure: Add Custom Field

Note

- Follow the similar steps for other sub-types. i.e., Organizations, Milestones, and others etc.
- The steps below may vary slightly depending on the type of field chosen.
- A tooltip is displayed explaining the meaning of the 'Regular Expression' option selected as a Field Validation type which improves clarity by helping users understand the purpose of 'Regular Expression' when configuring custom text fields within a domain.

Edit Custom Field

To edit a custom field, follow the steps below.

1. Select a custom field by clicking on the checkbox.
2. Click on the Edit Field button from the top menu bar.
3. On the Modify Custom Field window, make the necessary edits within the Field Information section.
4. Click on the Save button.

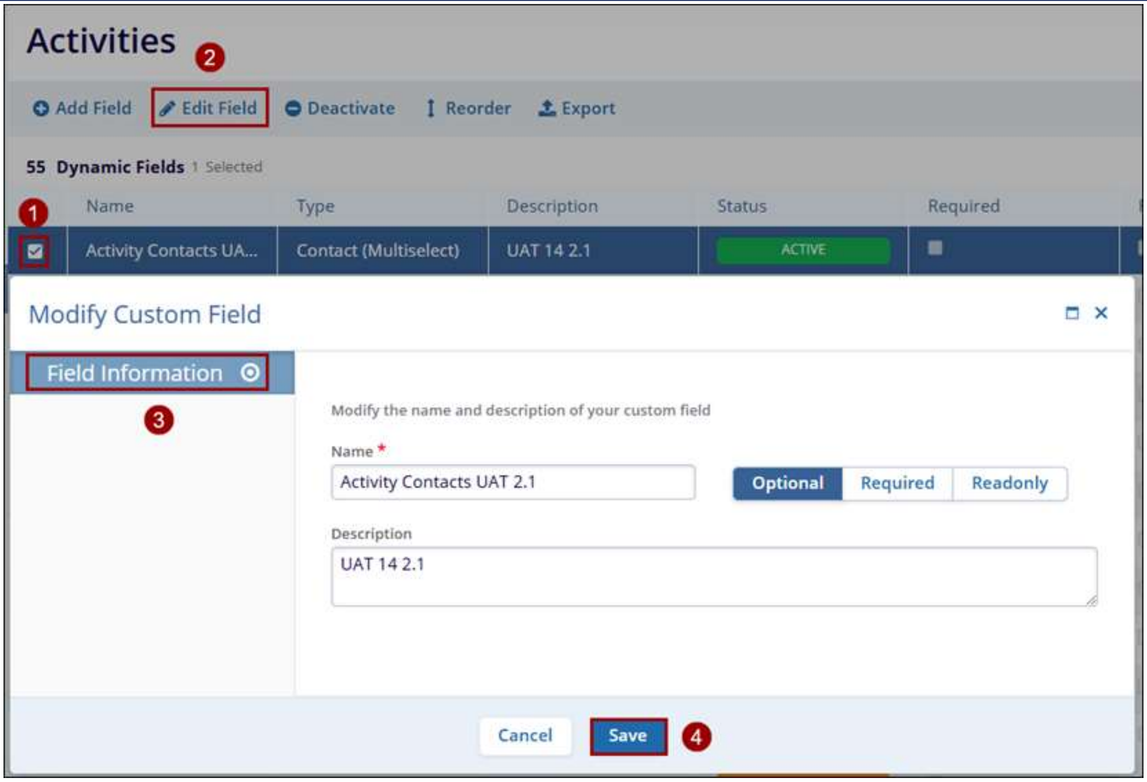


Figure: Edit custom field

Activate Custom Field

To activate a custom field, follow the steps below.

1. Select a custom field by clicking on the checkbox.
2. Click on the Activate button from the top menu bar.
3. On the 'Deactivate' confirmation popup, click on the '**Deactivate'** button.

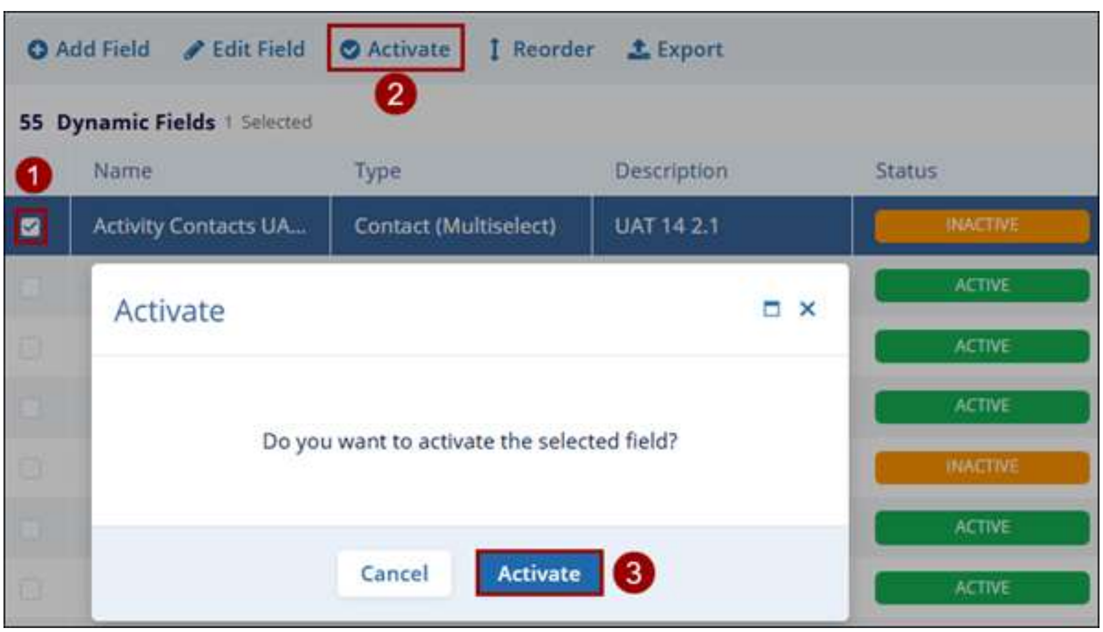


Figure: Activate Custom Field

Deactivate Custom Field

To deactivate a custom field, follow the steps below.

4. Select an active custom field by clicking on the checkbox.
5. Click on the Deactivate button from the top menu bar.
6. On the ‘Deactivate’ confirmation popup, click on the ‘**Deactivate’** button.

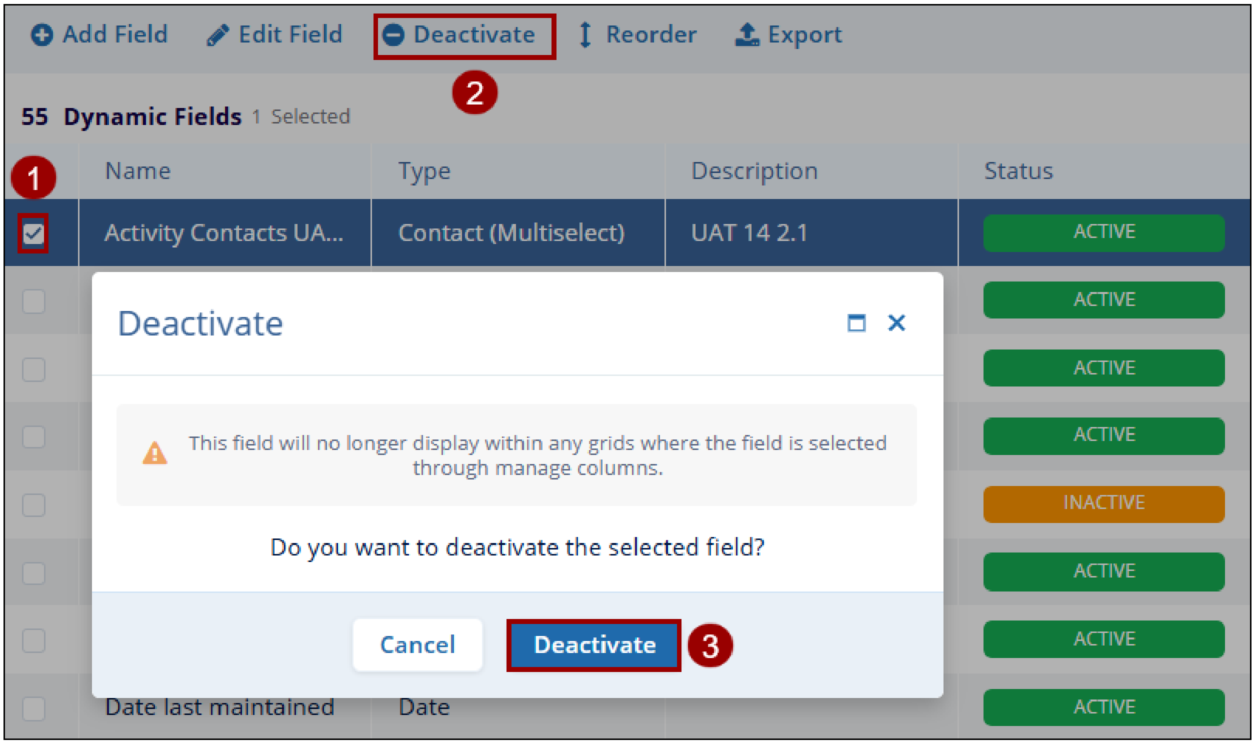


Figure: Deactivate Custom Field

Reorder

To reorder the custom field list, follow the steps below.

1. Click on the Reorder button from the top menu bar.
2. Place the fields in the desired position using the drag & drop functionality.

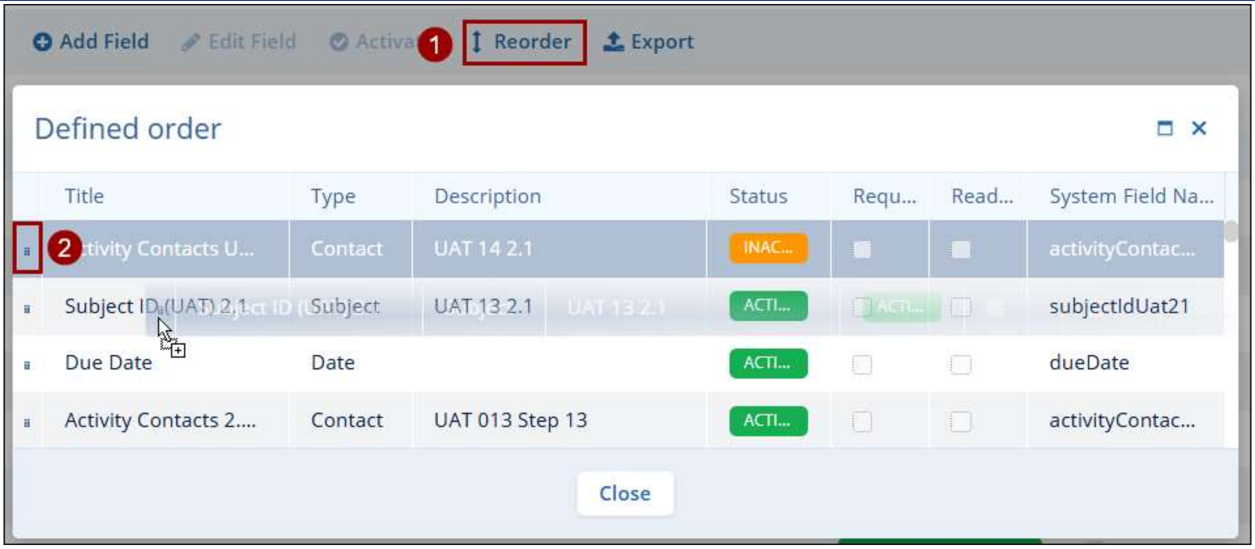


Figure: Reorder custom fields

Export

To export the custom fields list, click on the Export button and follow the standard steps detailed in the Exporting Contacts section.

Statuses

Users can 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 module (Programs, Sites, etc.)
3. Select the status that 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.

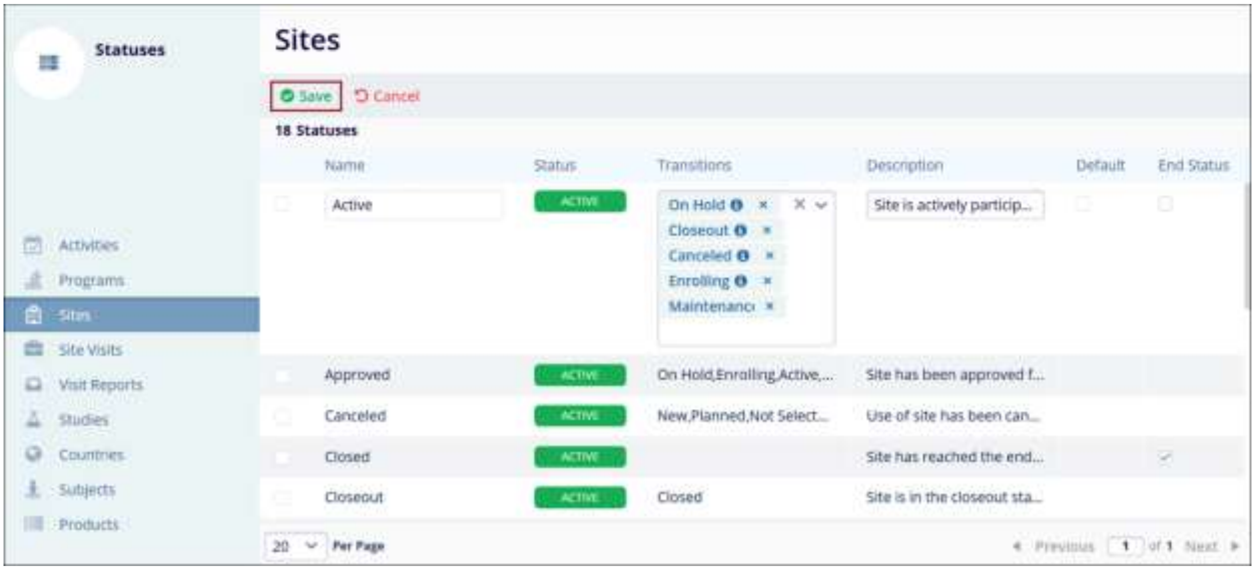


Figure: Settings - Statuses

Note:

- The end status is not available for all areas.

Lookups

The term '**Lookups'** refer to the options found in various dropdown menus throughout the system. If the group is upgrading to a new version of CTMS which includes additional standard values, 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. Click on the +Add button to create a new lookup value and click on the Active and Default checkboxes as required.
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' or Required column
6. Press 'Save'.

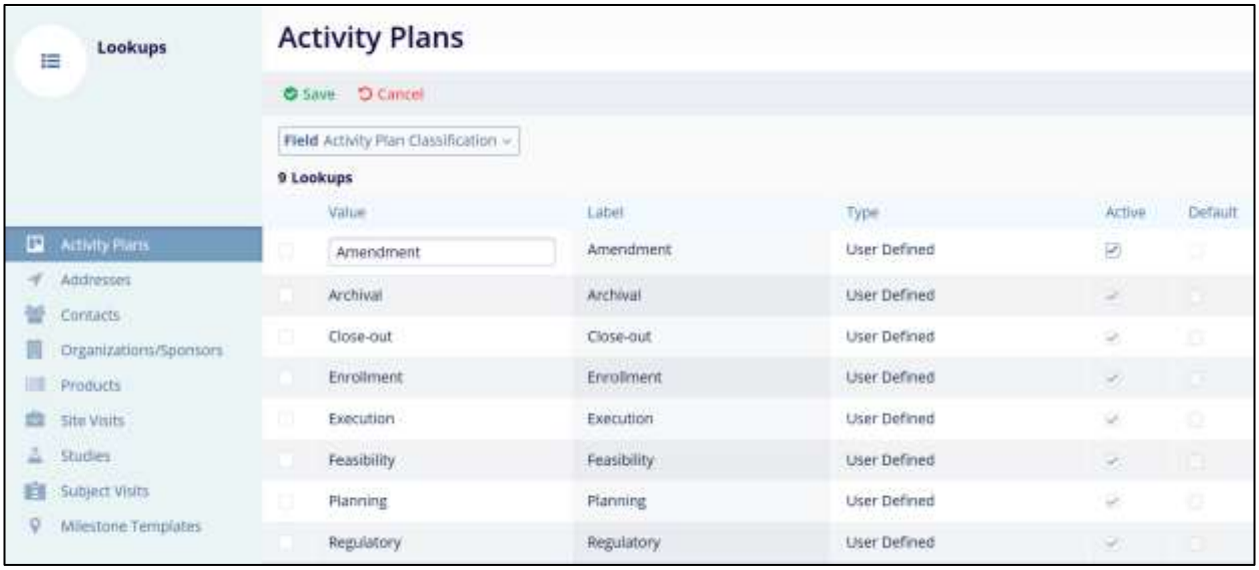


Figure: Settings - Lookups

Countries

Activate a Country

To activate a country, follow the steps below.

1. Click on the waffle menu and select Settings.
2. Click on the checkbox of a country with the inactive status.
3. Click on the Activate button from the top menu bar.

Figure: Settings – Activate Countries

Deactivate a Country

1. To deactivate a country, select the country by clicking on the checkbox.
2. Click on the Deactivate button from the top menu bar.

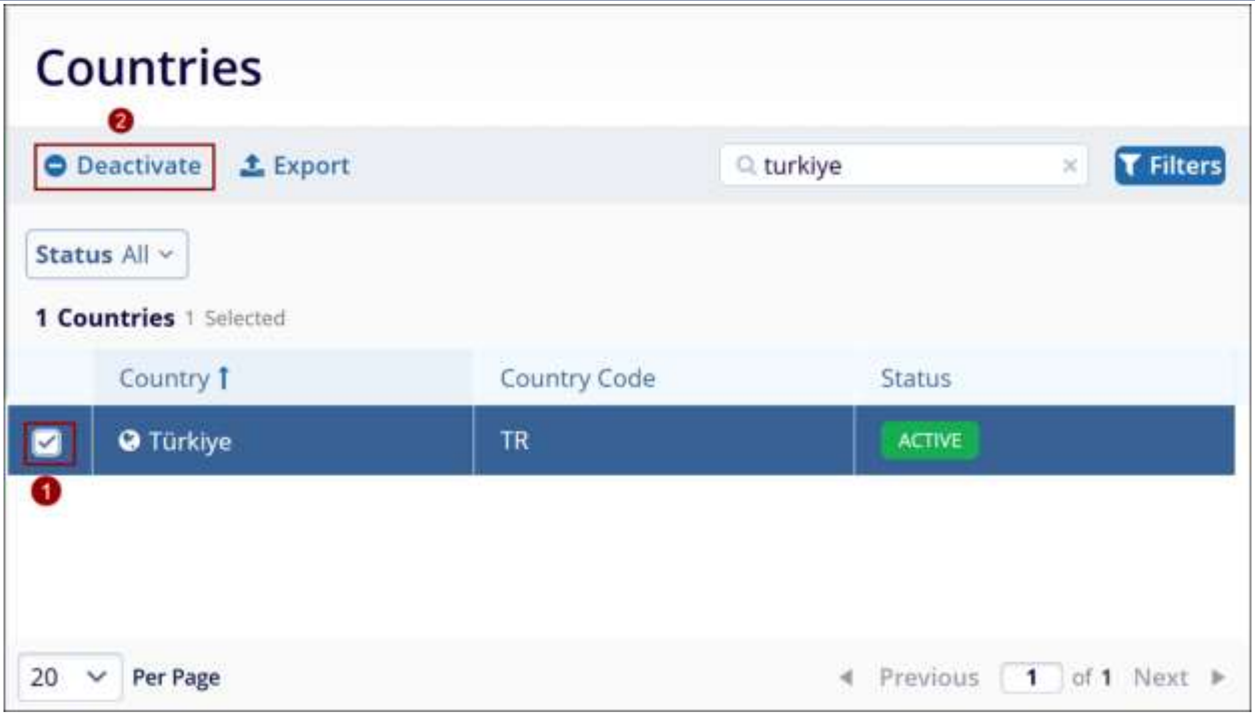


Figure: Settings – Deactivate country

3. Click on the Export button to export the data in an XLSX or CSV file format.

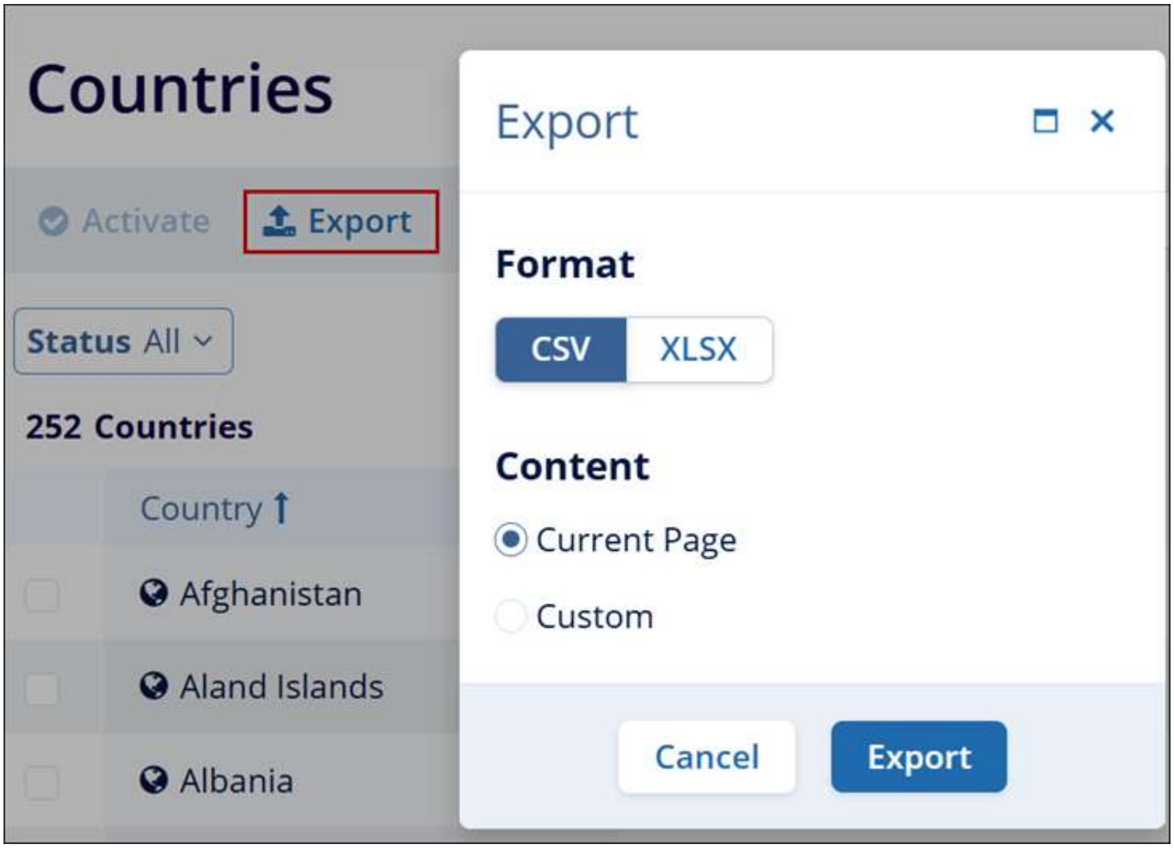


Figure: Settings – Export Countries Data

Regions

To create a new region, follow the steps below.

1. Navigate to the Settings area and select the Regions menu.
2. On the Regions screen, click on the +Add button.
3. On the Create Region screen, mandatorily enter the Region Name and Countries
4. Click on the Create button.

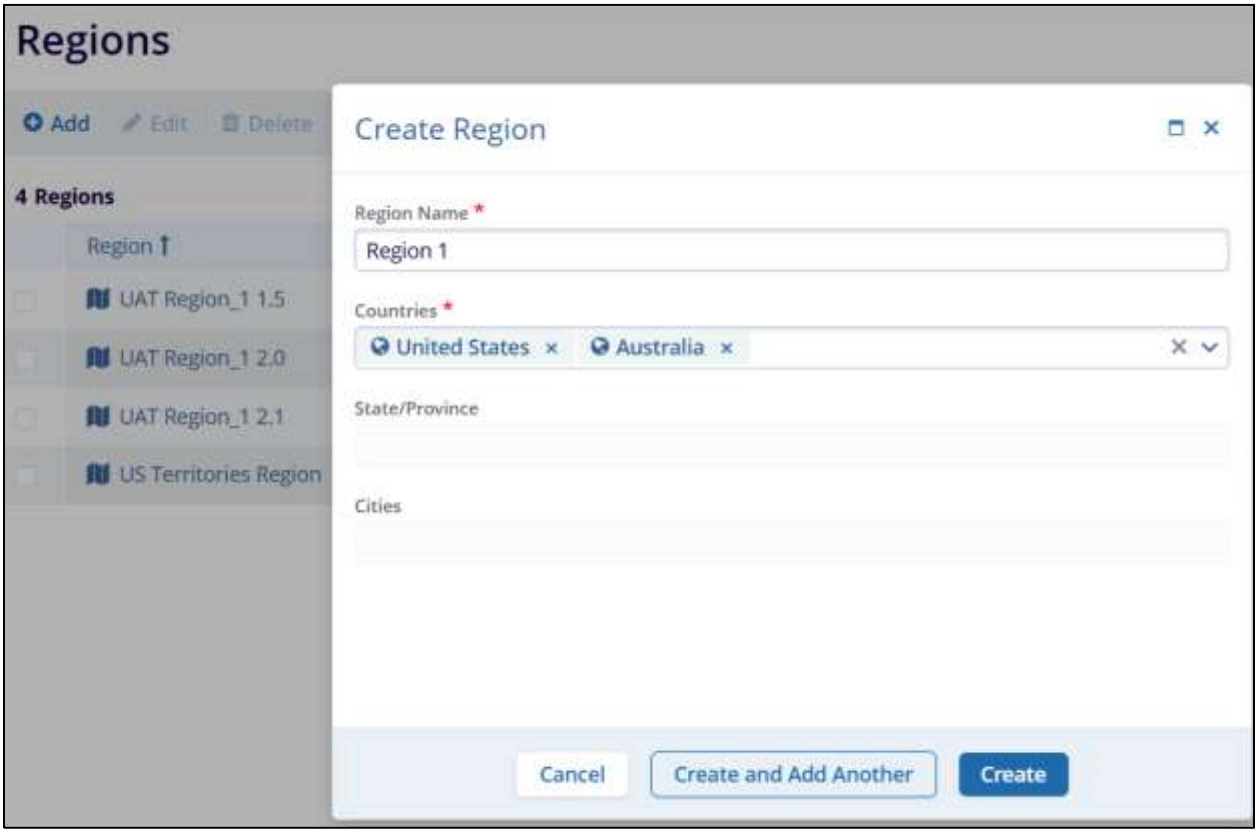


Figure: Settings – Add Region

Edit Region

To edit a region, follow the steps below.

1. Select the region and click on the Edit button from the top menu bar.
2. On the Region Details screen, make the required edits and click on the Save button.

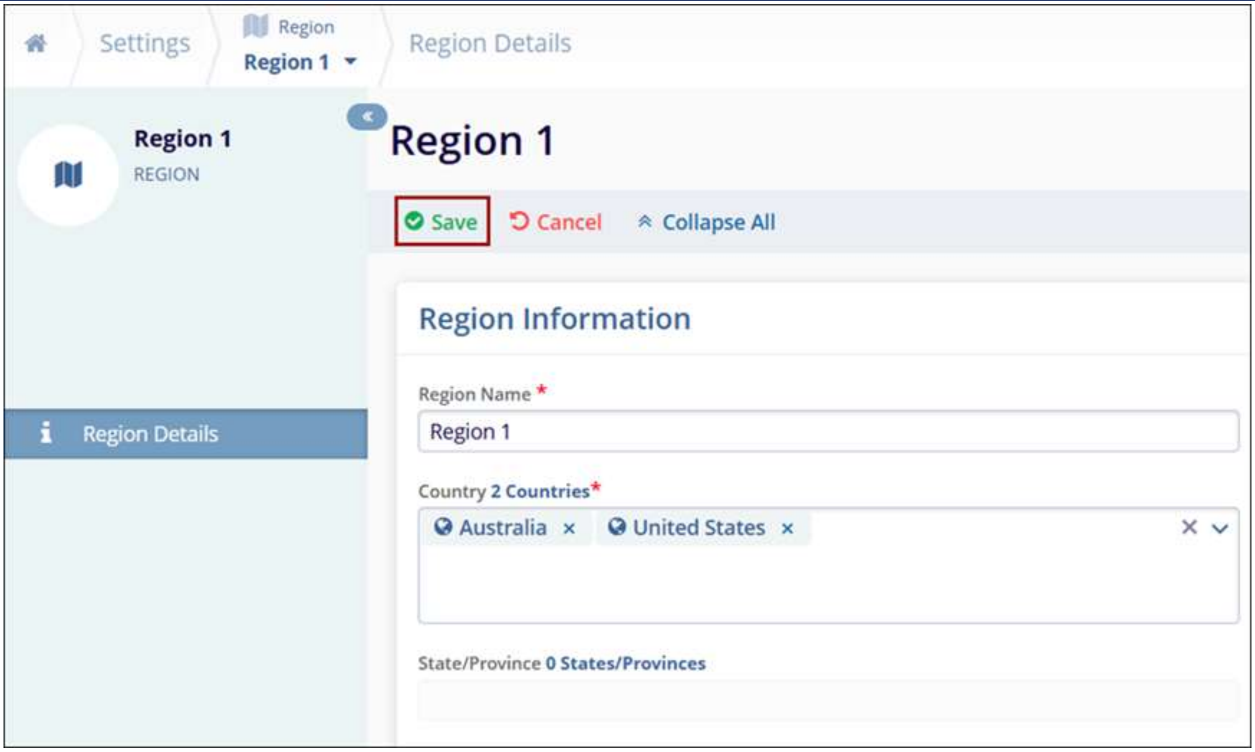


Figure: Settings – Edit Region

Delete Region

To delete a region, follow the steps below.

1. Select the region by clicking on the checkbox
2. Click on the Delete button from the top menu bar.
3. Click on the Delete button on the Confirmation popup.

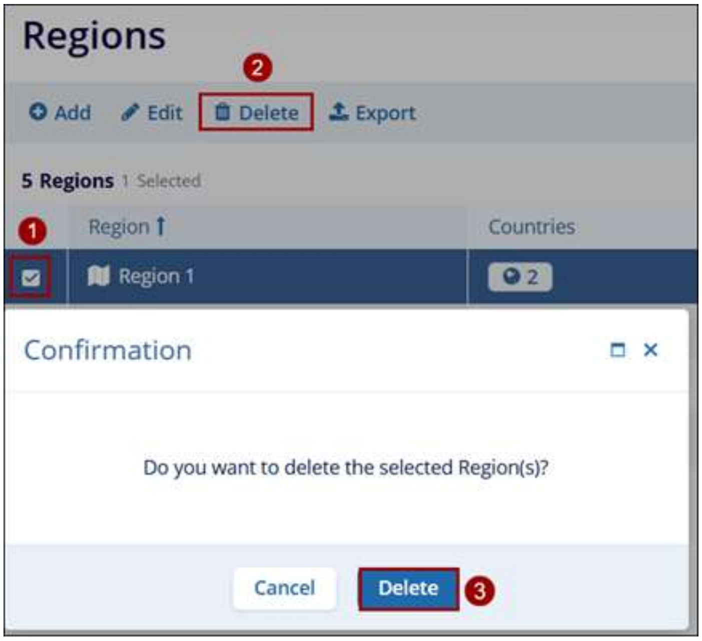


Figure: Delete Region

4. Click on the Export button to retrieve the region's data in XLSX or CSV file formats.

Access Management

To view the Access Management, follow the steps below.

1. Navigate to the Settings area and select the Access Management menu.
2. Select a record by clicking on the checkbox and click on the View button.
3. The View Access Permissions screen displays the permissions for the particular role.

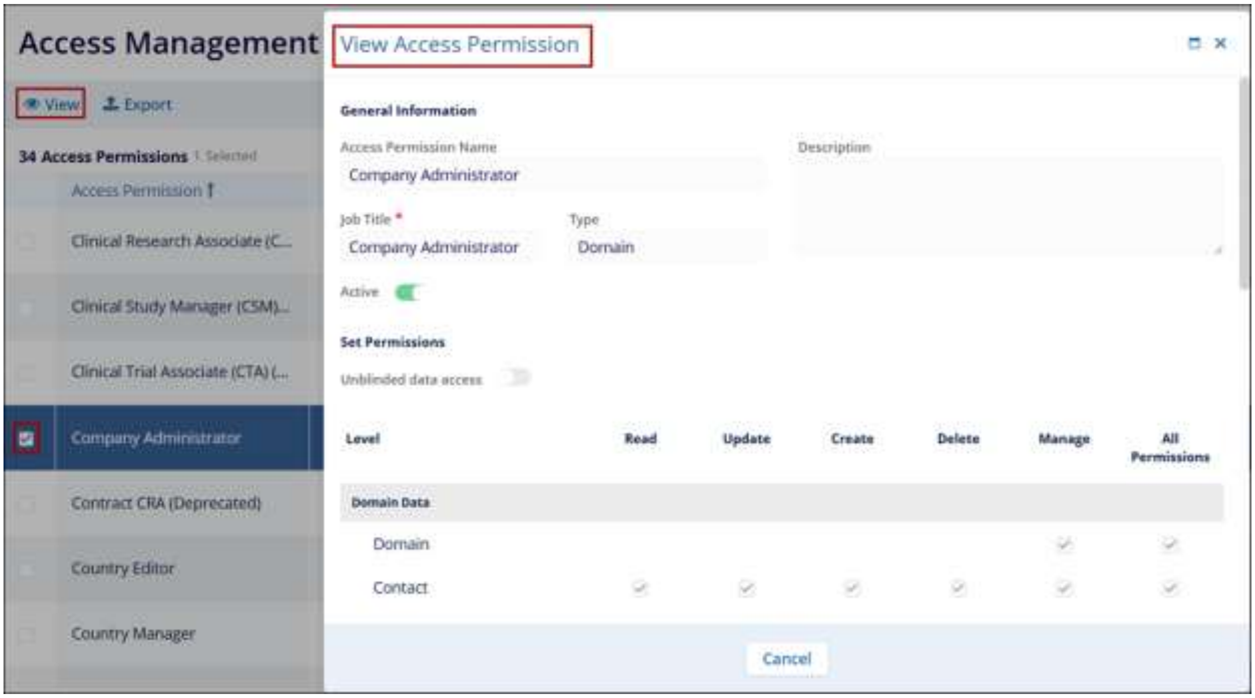


Figure: Access Management

4. Click on the Export button to export the Access Management list in CSV or XLSX file formats.

Team Role Management

Add Team Role

To access the Team Role Management settings and add a team role, follow the steps below.

1. Navigate to the Settings area and select the Team Role Management menu.
2. Click on the +Add button to add a new role.
3. Mandatorily fill in the Name* and Level* fields.
4. Click on the Create button.

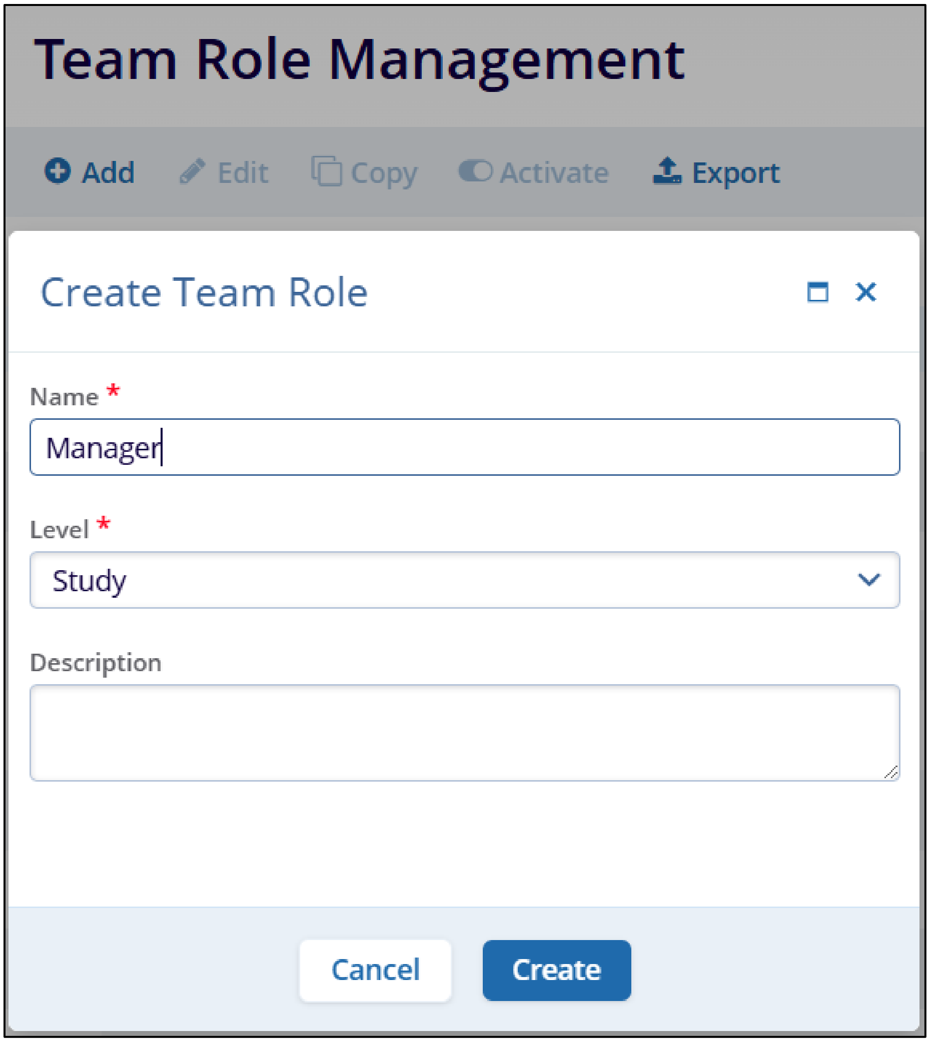


Figure: Create Team Role

<u>Edit Team Role</u>

To Edit a Team Role, follow the steps below.

1. Select a role to edit by clicking on the checkbox.
2. Click on the Edit button from the top menu bar.
3. On the Edit Team Role window, make the required edits and click on the Edit button.

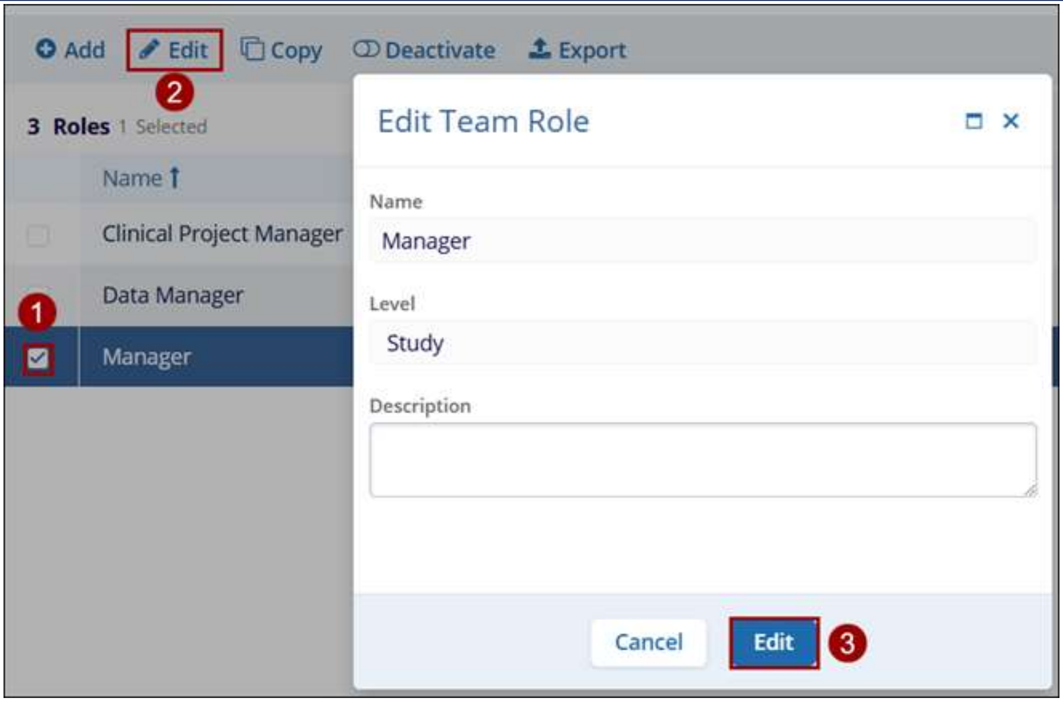


Figure: Edit Team Role

Copy Team Role

To copy a team role, follow the steps below.

1. Select a role by clicking on the checkbox.
2. Click on the Copy button from the top menu bar.
3. On the Copy Team Role screen, make the required changes and click on the Create button.

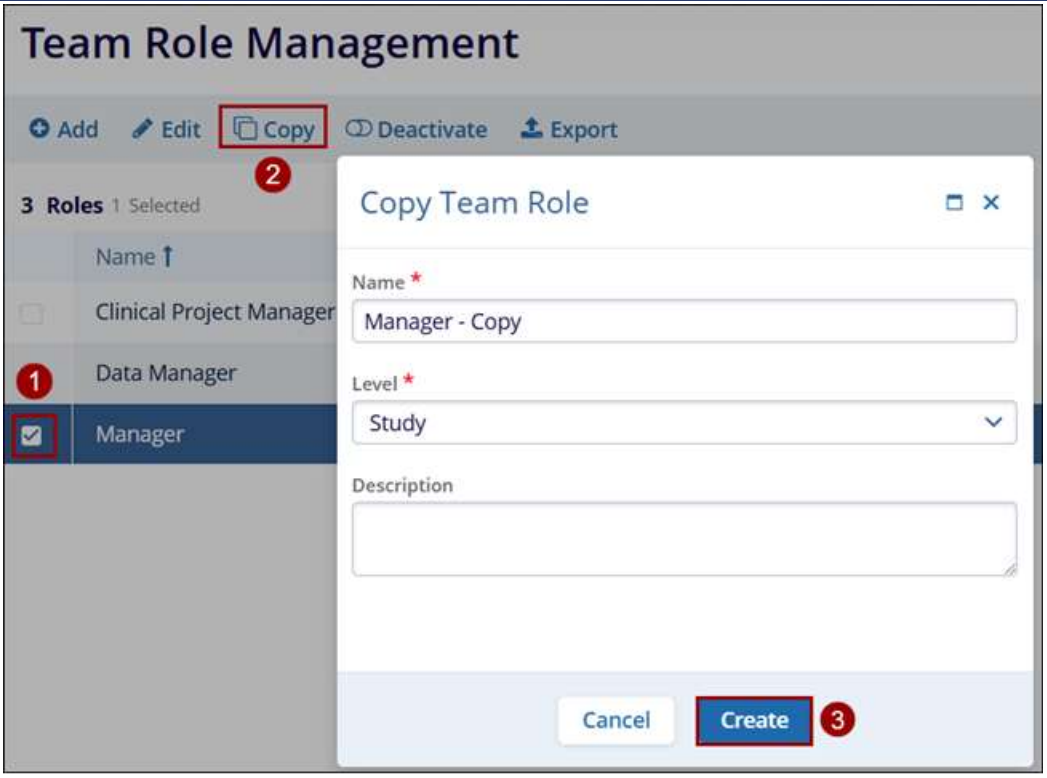


Figure: Copy Team Role

Deactivate team role

To deactivate a team role, follow the steps below.

1. Select an active user by clicking on the checkbox.
2. Click on the Deactivate button from the top menu bar.
3. Click on the Deactivate button on the Confirmation popup.

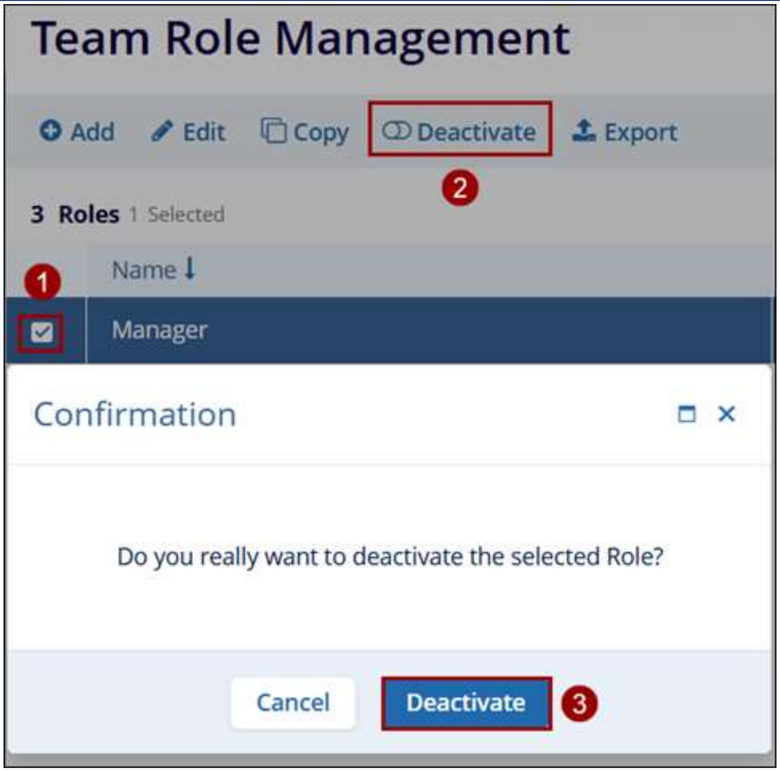


Figure: Deactivate role

Activate Team Role

To activate a team role, follow the steps below.

1. Select an inactive role by clicking on the checkbox
2. Click on the Activate button from the top menu bar.
3. Click on the Activate button on the Confirmation popup.

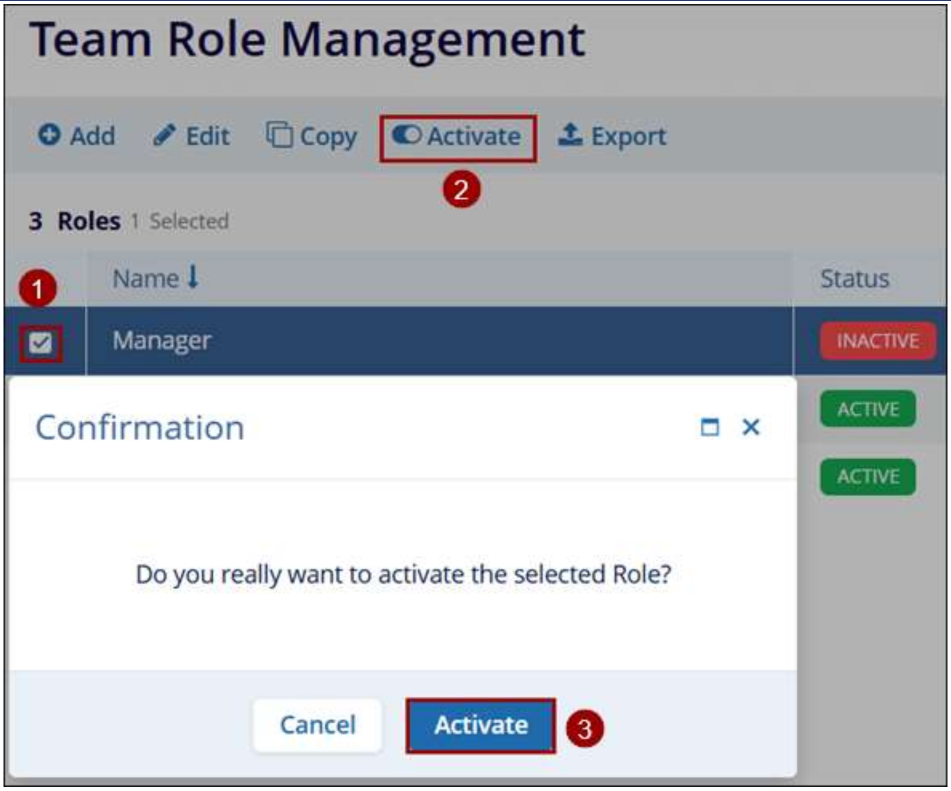


Figure: Activate role

Site Visit Checklist Templates

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.
2. Click on the +Create Template button at the top of the grid area.
3. On the ‘Create Site Visit Checklist Template’ screen, mandatorily enter the following details
    a. Site Visit Checklist Template Name*
    b. Description

4. Click on the Create button.

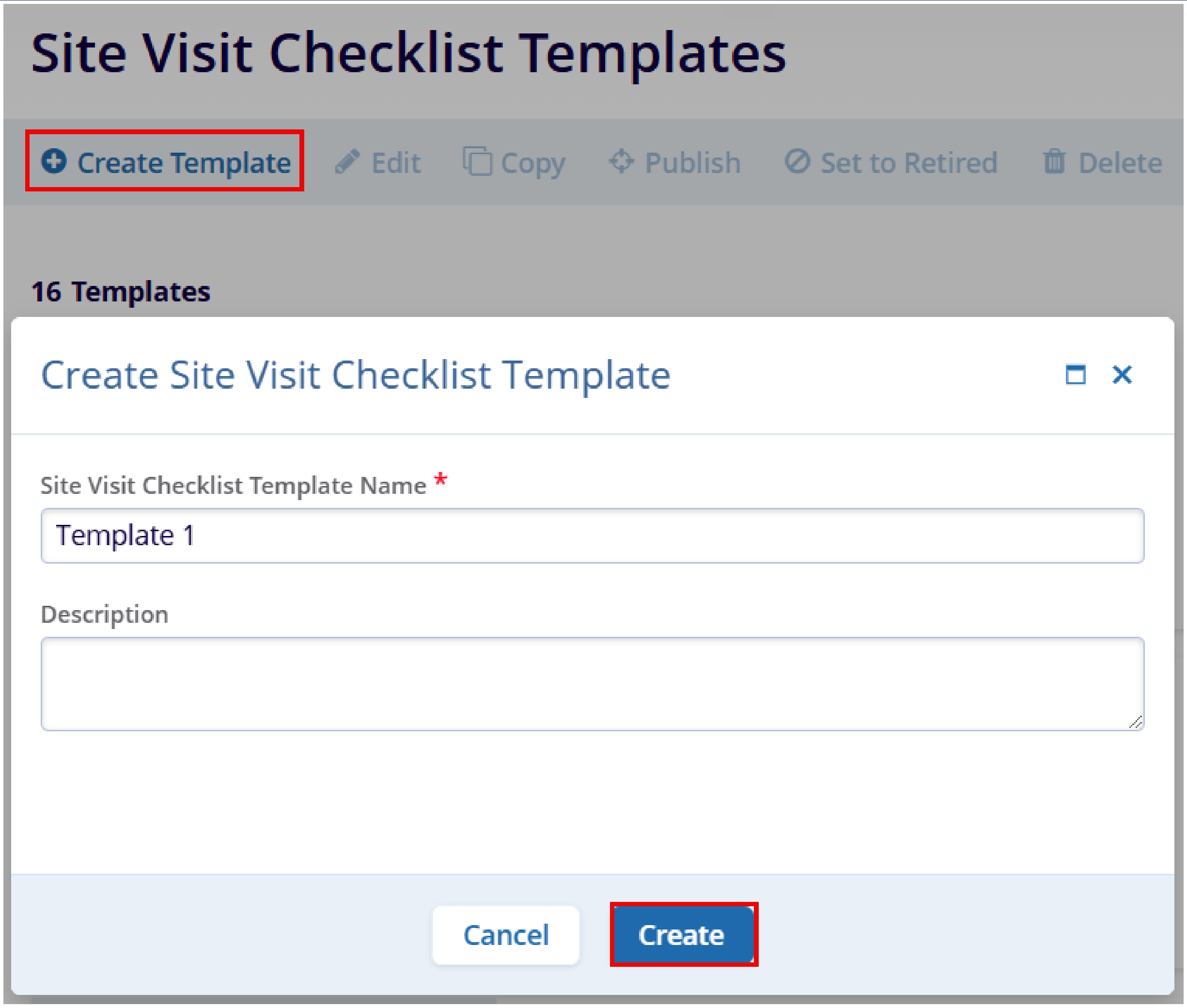


Figure: Create Site Visit Checklist template

Note:

- Providing a description is recommended whenever possible, especially when multiple similar checklist templates may exist. The description helps in ensuring that the correct checklist is applied when needed.
- The checklist will initially remain in Draft status, as questions still need to be added before it can be published for use.

<u>Edit Site Visit Checklist Template</u>

1. Select the new checklist template from the list.
2. Click Edit from the menu bar at the top of the grid.

Figure: Edit Template

3. On the site visit screen, make the required edits to the section title and description.
4. 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.
5. Press the +Add Section button and a new section box will appear.

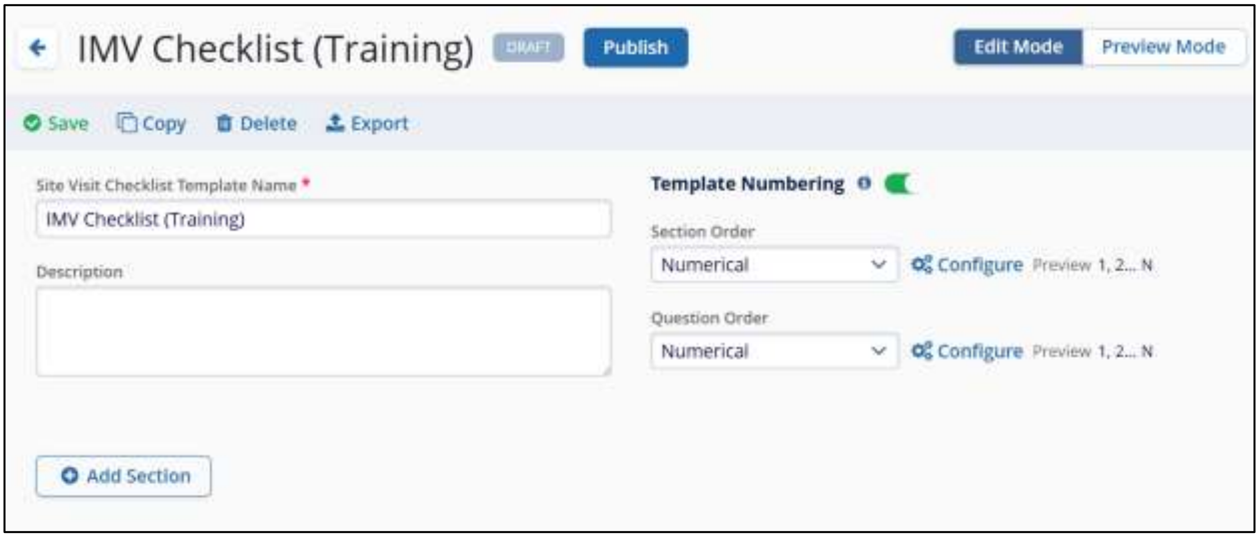


Figure: Checklist Profile

6. Give the section a title and a description.
7. Press the +Add Question button in the new section.

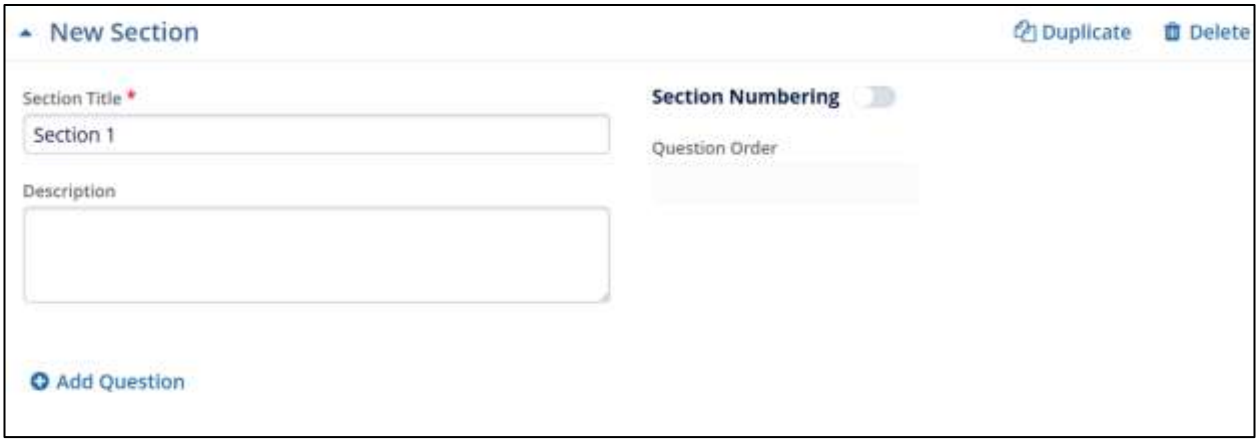


Figure: New Section

8. Type in the question and select the type of question from the dropdown menu.
9. Continue adding sections and questions until the checklist is complete.
10. Enable the 'Required Question' toggle switch to make the question mandatory.
11. Click on the Duplicate button to make a copy of the question.
12. Click on the Delete button to remove the question.

Figure: Add Question

13. When all the edits are made, click on the Save button from the top menu bar.

Copying a Site Visit Checklist

To copy a site visit checklist, follow the steps below.

1. Select a Visit Checklist Template and click on the Copy button from the top menu bar.
2. On the 'Create Site Visit Checklist Template enter the details and click on the Create button.

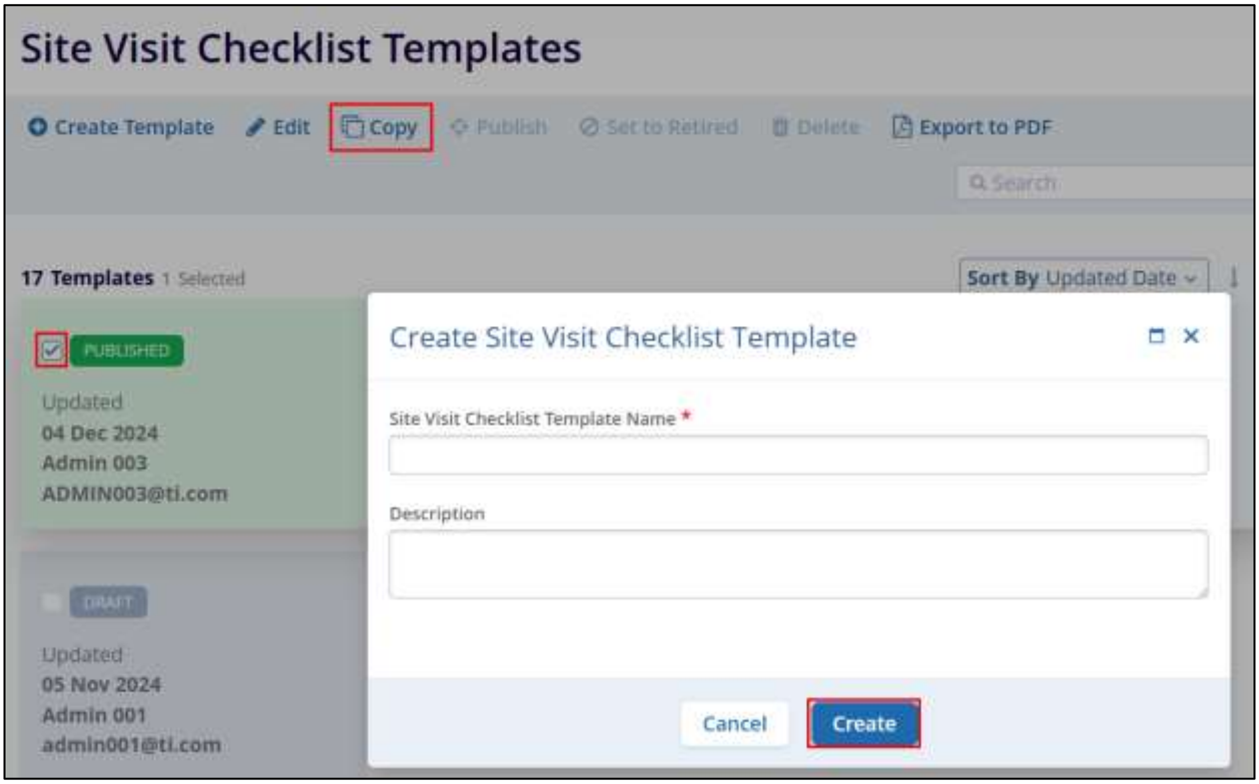


Figure: Copy Site Visit Checklist Template

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.
2. Select the checklist from the list displayed.
3. Press the Publish button in the menu bar at the top of the screen.
4. Click Publish on the confirmation popup.

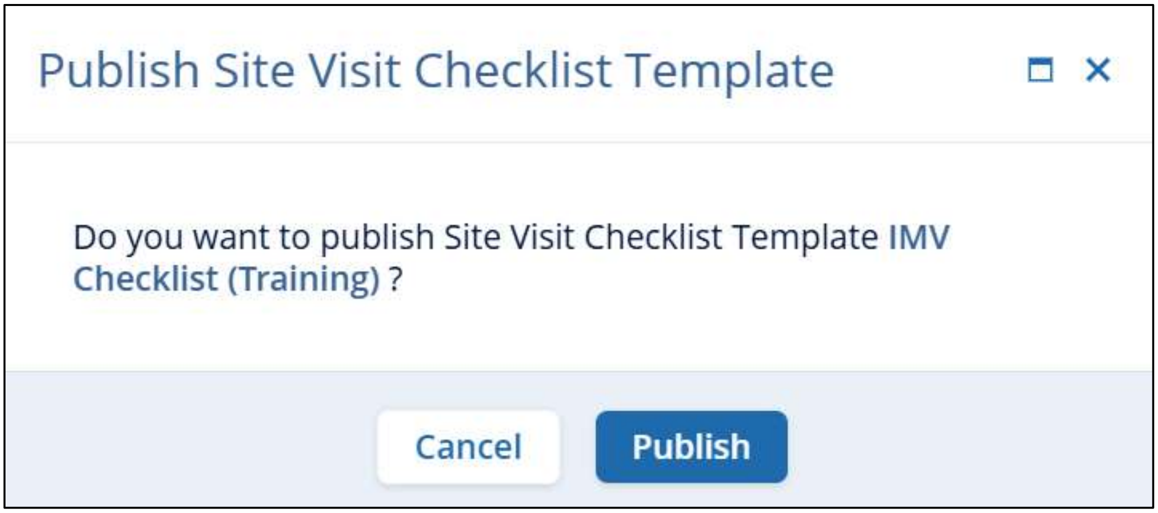


Figure: Publish Site Visit Template

5. The checklist will be displayed with the Published status in the list.

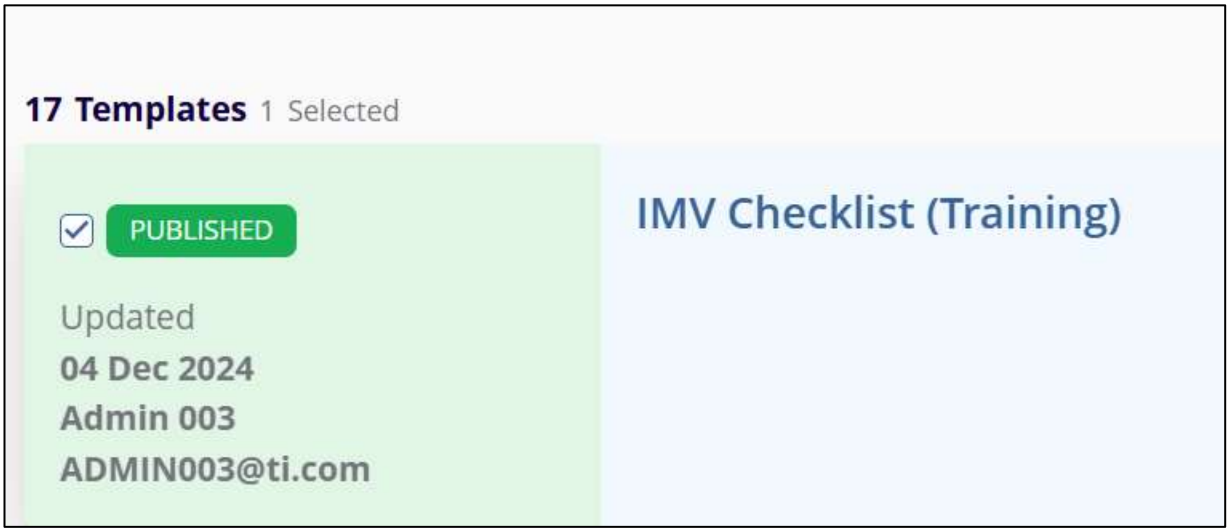


Figure: Published Template

Retiring a Site Visit Checklist

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.
2. Click on the checklist name from the list displayed.
3. Click the Set to Retired button in the menu bar at the top of the screen.
4. On the confirmation popup, click on the Set Retired button.

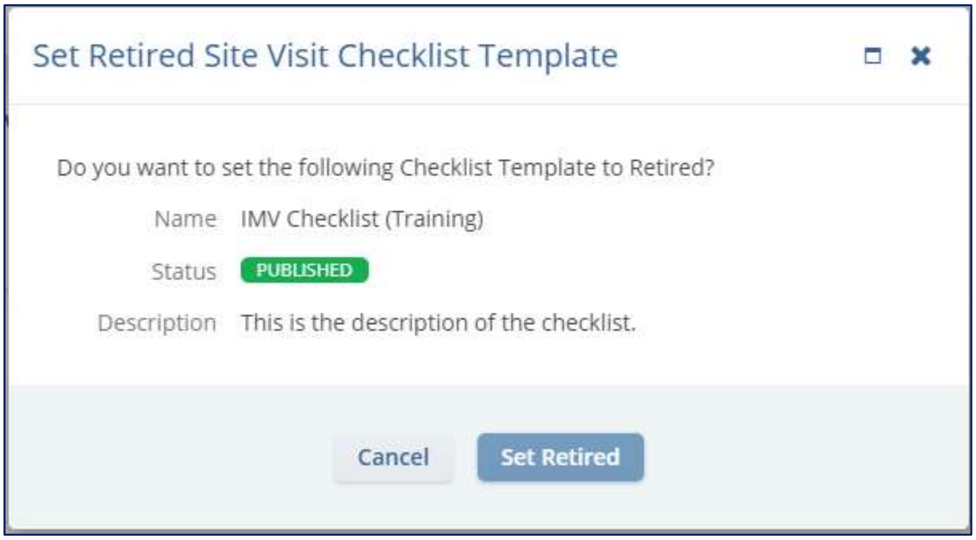


Figure: Set template as Retired

5. The checklist will be displayed as Retired.

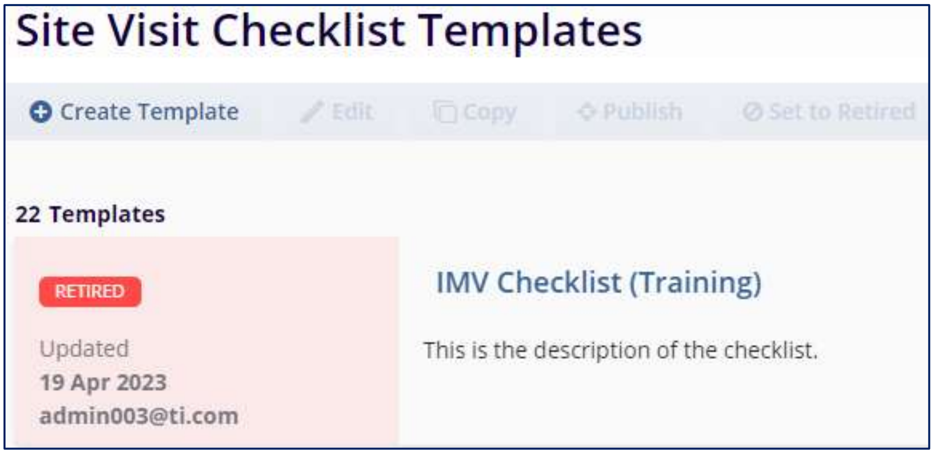


Figure: Retired Template

Note: Once a Site Visit Checklist has been retired, it cannot be re-published. It is recommended to copy the checklist and publish the new copy to use the checklist again.

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 Delete 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.
2. Select the checklist from the list displayed.
3. Click on the Delete button in the menu bar at the top of the screen.
4. On the 'Delete Site Visit Checklist Template' confirmation popup, click on the Delete button.

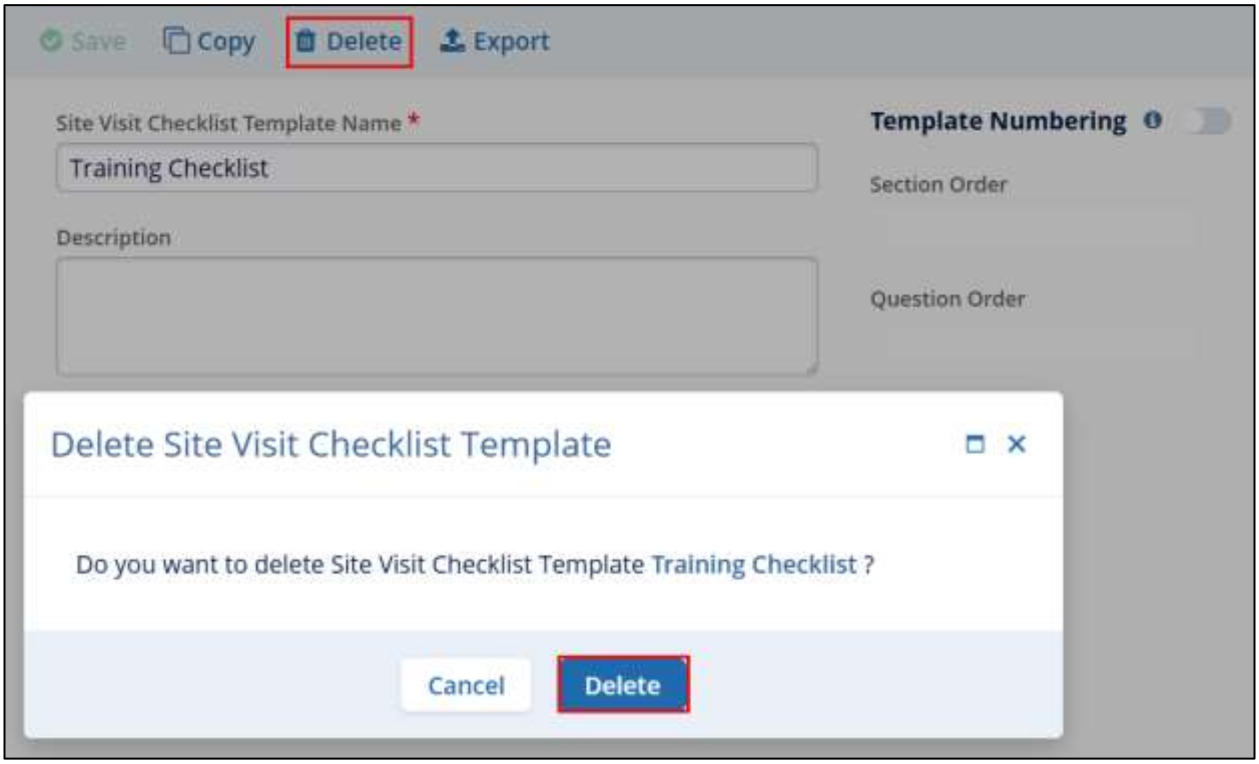


Figure: Delete Site Visit Checklist template

Export to PDF

To export Checklist details as a PDF, follow the steps below.

1. Select a Checklist Template and click on the Export to PDF button.

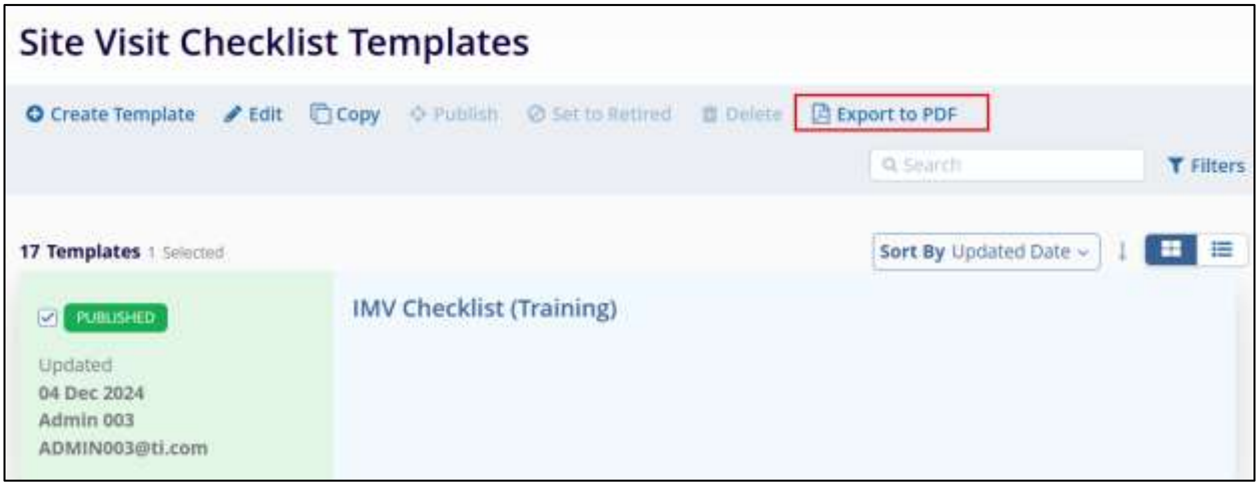


Figure: Export to PDF

2. Click on the Export button on the 'Export Site Visit Checklist Template'.

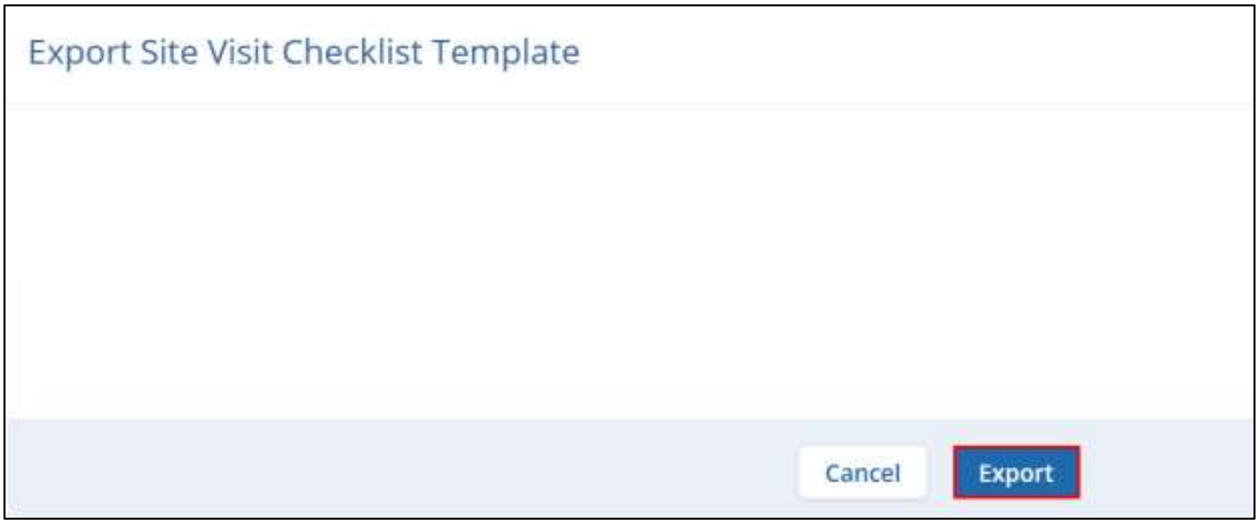


Figure: Export Site Visit Checklist Template

Enrollment Tracking

Add Enrollment Tracking

To add an enrollment tracking record, follow the steps below.

1. Navigate to the Settings area and select the Enrollment Tracking option.
2. Click on the +Add button from the top menu bar.
3. Select a status that has not been added yet.
4. Click on the Add button.

Note: Previously selected statuses are grayed out and cannot be selected.

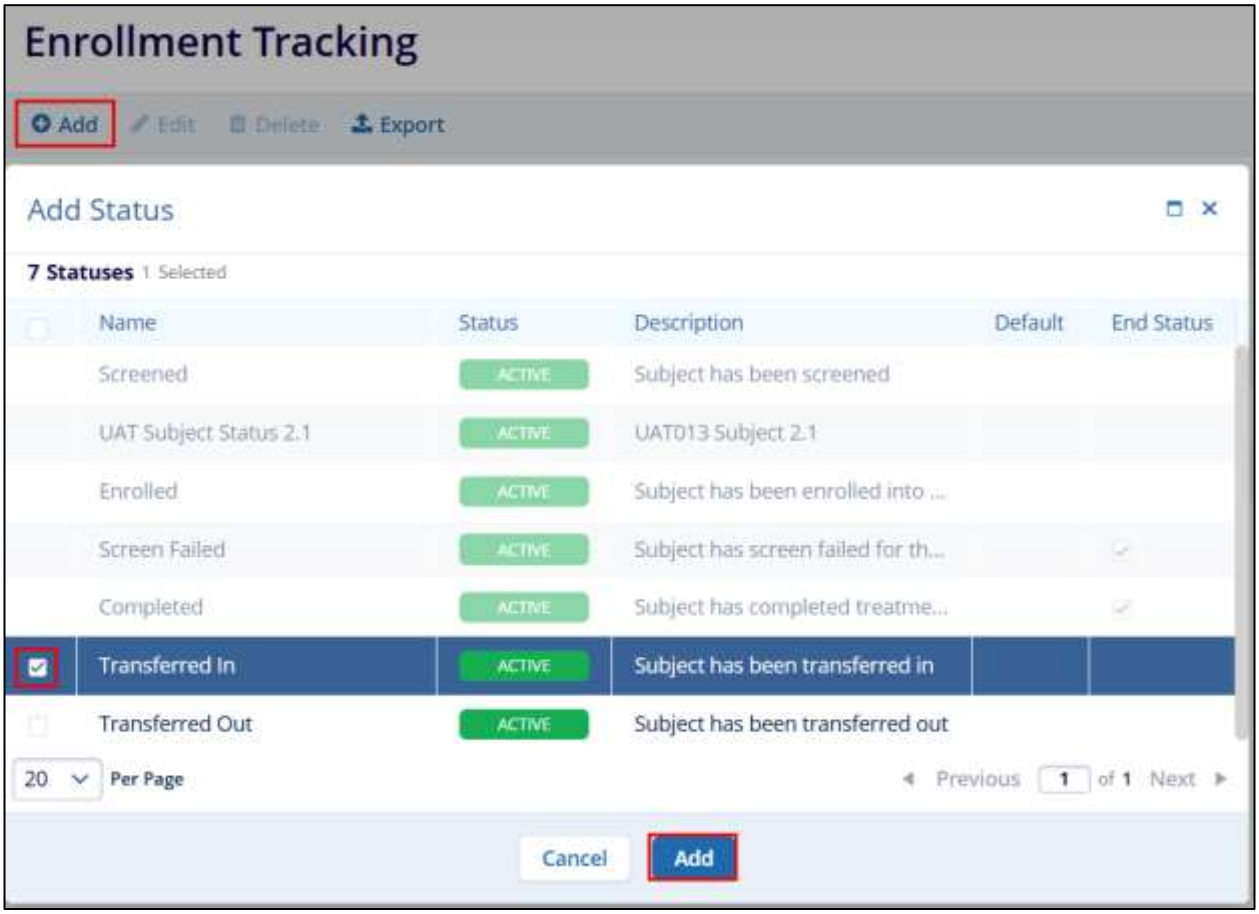


Figure: Add Enrollment Tracking

Edit Enrollment Tracking Record

To Edit an enrollment tracking record, follow the steps below.

1. Select a status by clicking on the checkbox
2. Click on the Edit button from the top menu bar.

Figure: Edit enrollment status tracking record

3. Make the required button and click on the Save button.

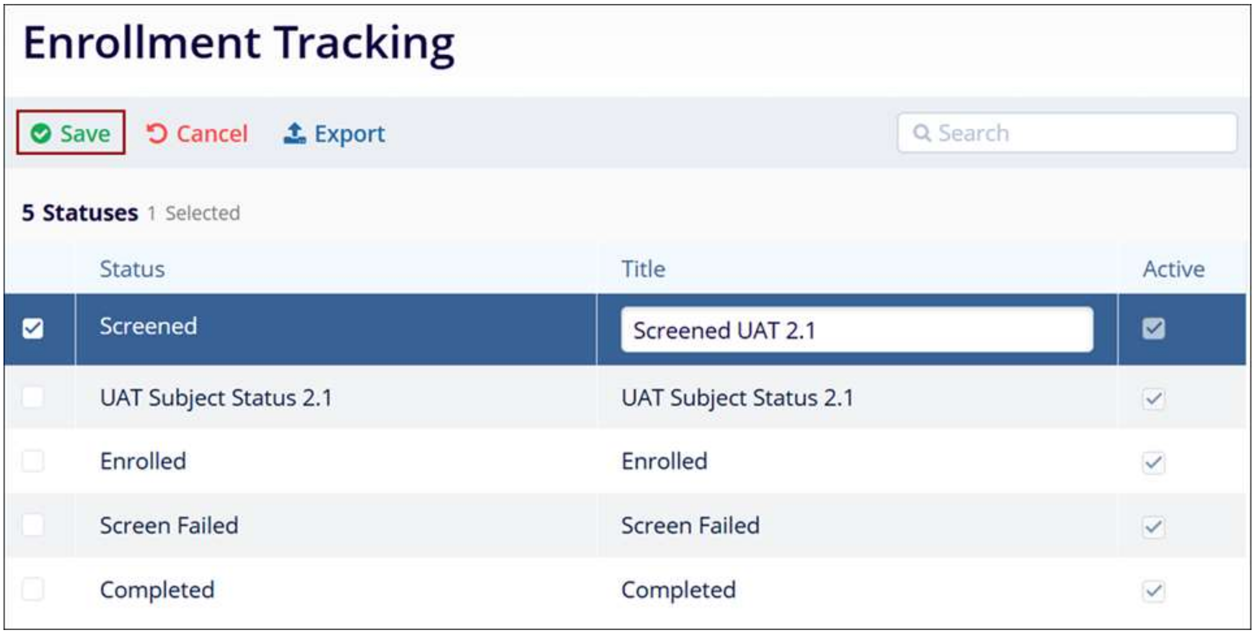


Figure: Edit Enrollment Tracking Status

Delete Enrollment Tracking record

To delete enrollment tracking record, follow the steps below.

1. Select a status to delete by clicking on the checkbox
2. Click on the Delete button from the top menu bar.
3. Click on the Yes button on the Confirmation popup.

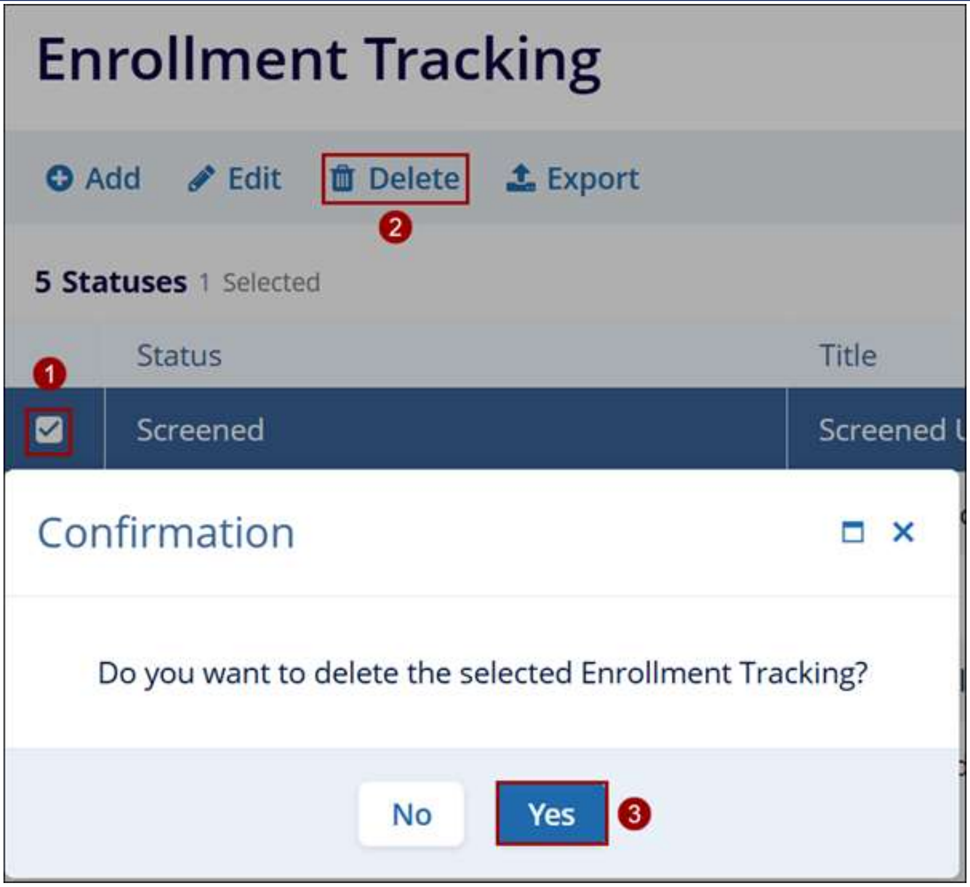


Figure: Delete enrollment tracking status

<u>Export enrollment tracking records</u>

To export the records, click on the Export button to retrieve the enrollment tracking data in an XLSX or CSV file format.

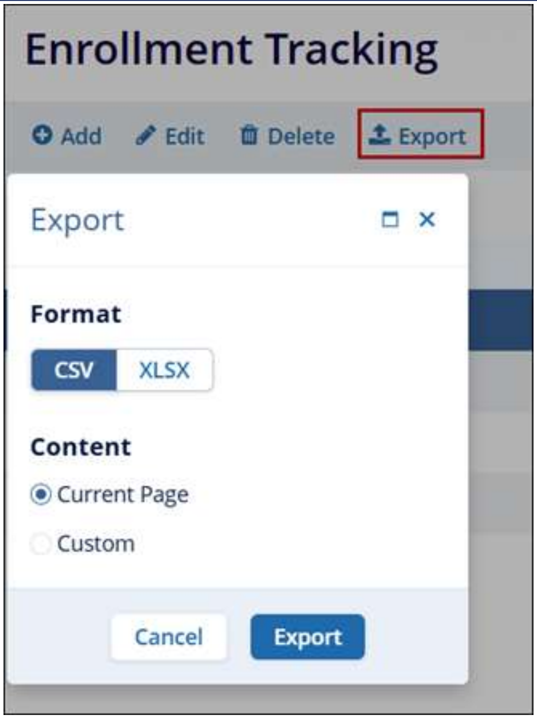


Figure: Export Enrollment Tracking Data

Activity Type/Subtype

Add Activity Type/Subtype

To add, activity types/subtypes, follow the steps below.

1. Navigate to the Settings area and select the Activity Type/Subtype option.
2. On the Activity Type/Subtype screen, click on the +Add button.
3. Mandatory enter the Type field and optionally enter the Subtype field and enable the Subject Activity Tracking toggle switch.
4. Enable the Include Additional Field toggle switch to add additional fields.
5. Enter the required details and click on the Save button.

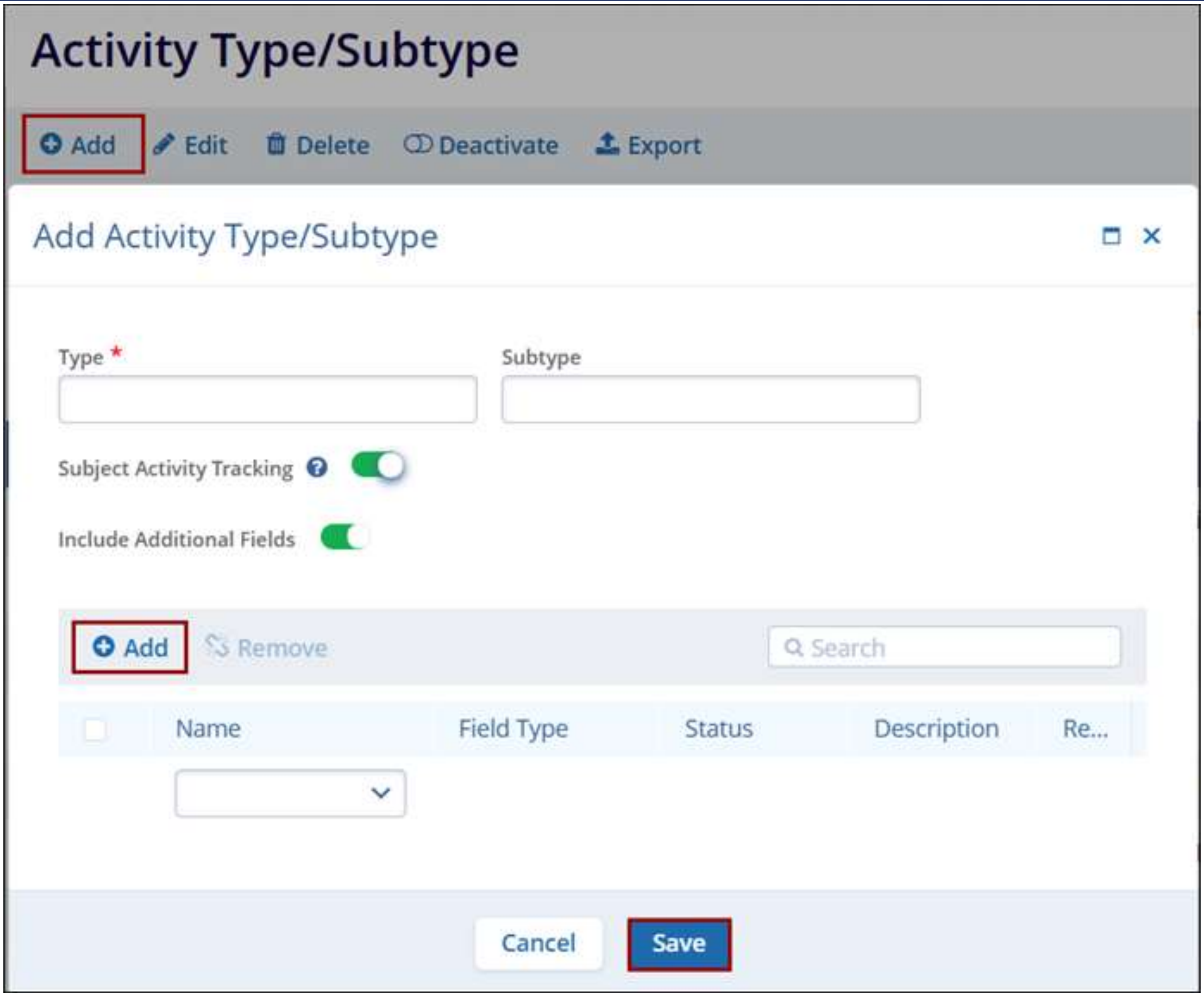


Figure: Add Activity Type/Subtype

<u>Edit Activity Type/Subtype</u>

To edit, select an activity type/subtype, follow the steps below.

1. Select a record to edit by clicking on the tile.
2. Click on the Edit button from the top menu bar.
3. Make the required edits on the 'Edit Activity Type/Subtype' window and click on the Save button.

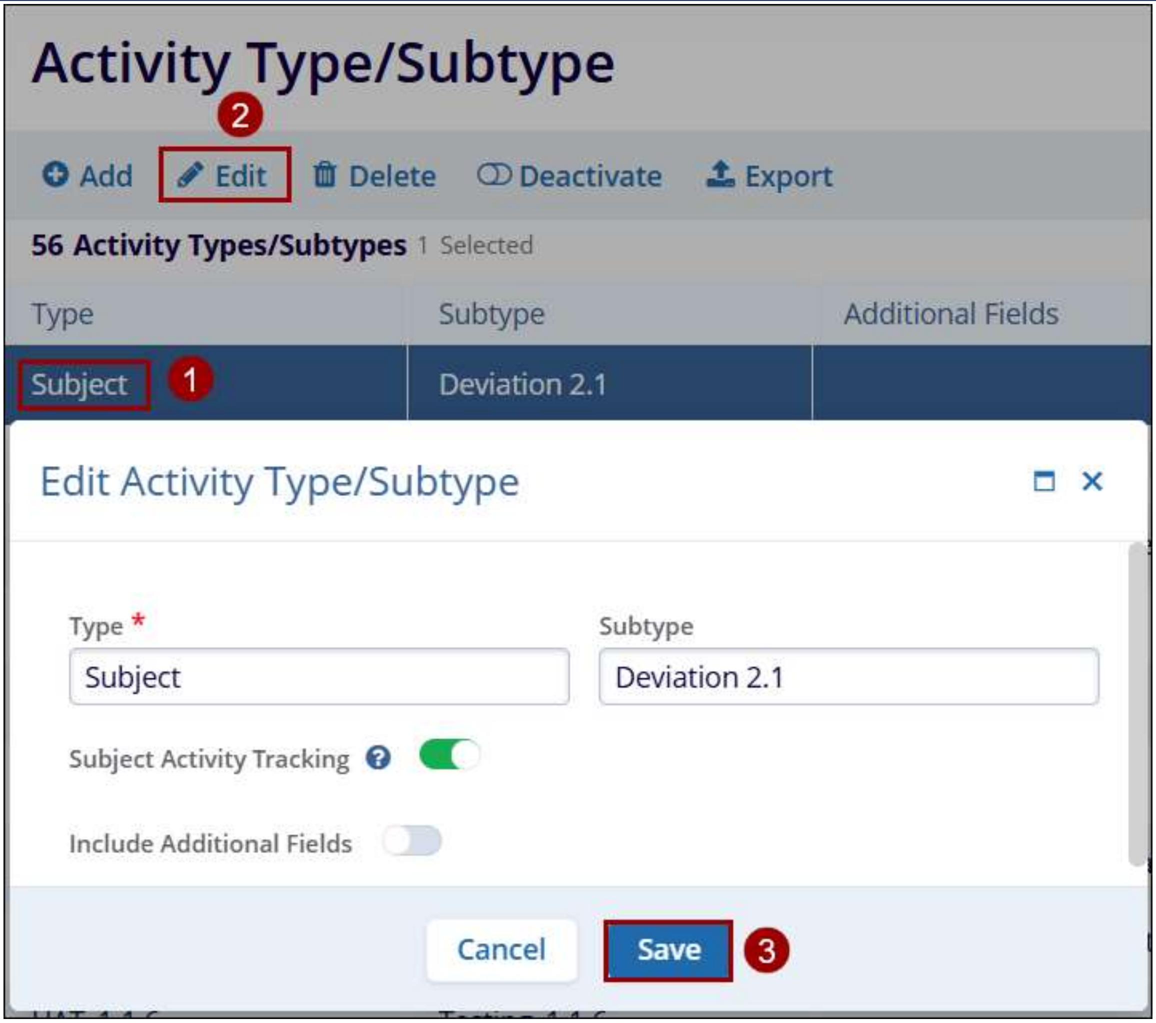


Figure: Edit Activity Type/Subtype

<u>Delete Activity Type</u>

To delete an activity type, follow the steps below.

1. Select a subject by clicking on the checkbox
2. Click on the Delete button from the top menu bar.
3. Click on the Delete button on the Confirmation popup.

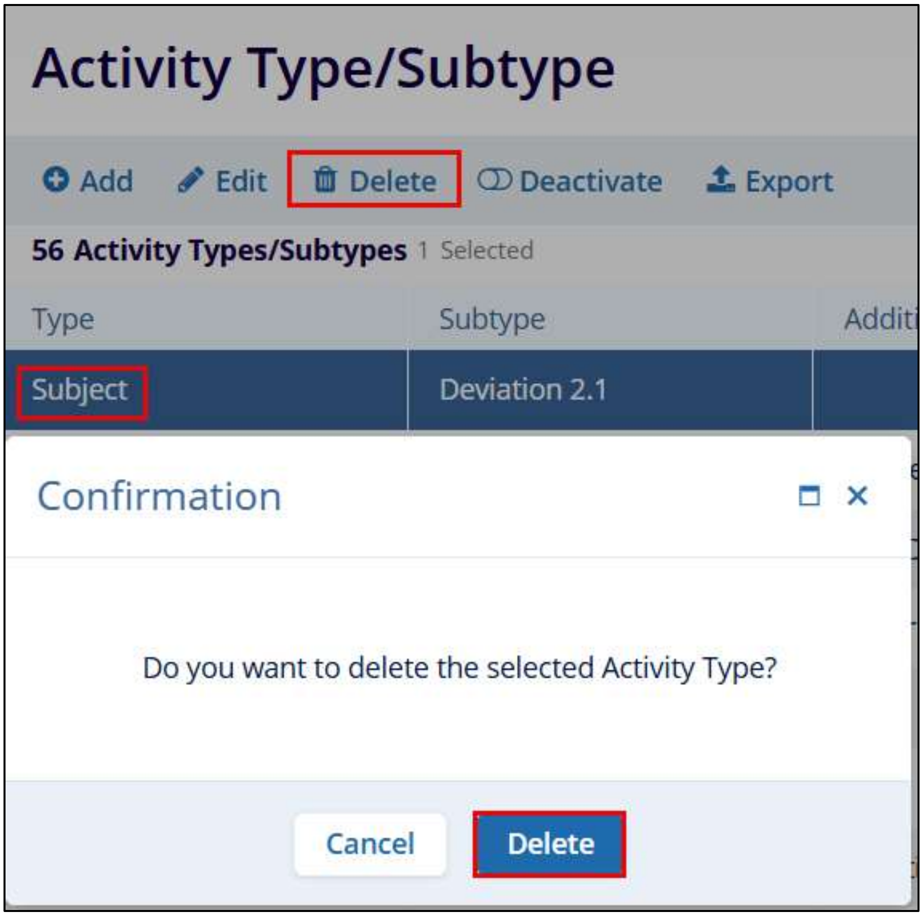


Figure: Delete activity type/subtype

Deactivate Activity Type

To deactivate an activity type, follow the steps below.

1. Select an active record by clicking on the tile.
2. Click on the Deactivate button from the top menu bar.

Figure: Deactivate activity type/subtype

Activate Activity Type

To activate an activity type, follow the steps below.

1. Select an inactive record by clicking on the tile

2. Click on the Activate button from the top menu bar.

Figure: Activate activity type/subtype

Auto-naming

To configure the auto-naming settings, follow the steps below.

1. Navigate to the Settings area and select the Auto-naming option.
2. On the Auto-naming screen, click on the Edit button from the top menu bar.
3. Make the required edits to the General Settings, Study Auto-naming Rules, and Site Auto-naming Rules.
4. Click on the Save button once all the changes are made.

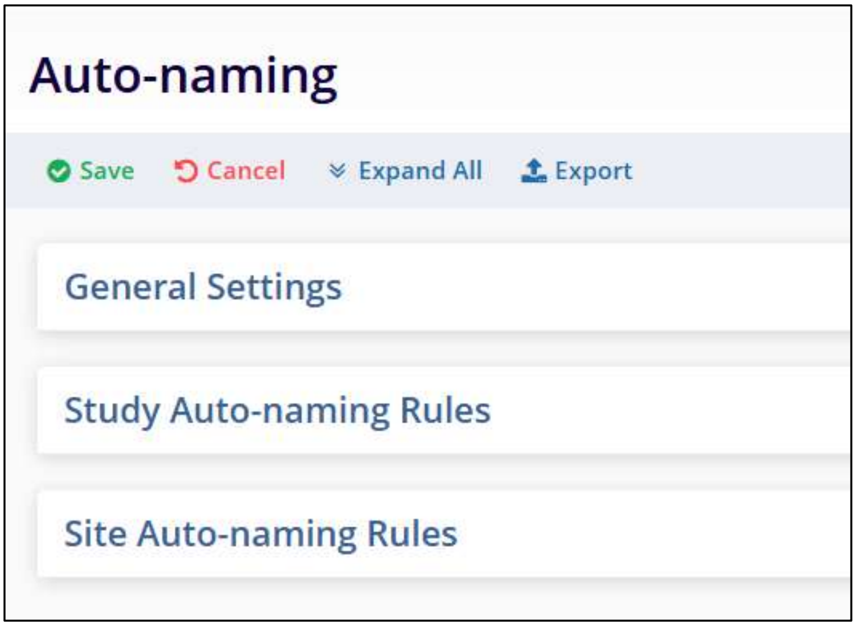


Figure: Auto-naming

Audit Trail

To retrieve the audit trail, follow the steps below.

1. Navigate to the Settings area and select the Audit Trail option.
2. Click on the Export button
3. Select Current Page or Custom.
4. Specify the number of records for Custom.
5. Click on the Export button.
6. Once the export is completed, an XLSX file is downloaded into the system.

Note: Refer to the Exporting Contacts section for the standard detailed process.

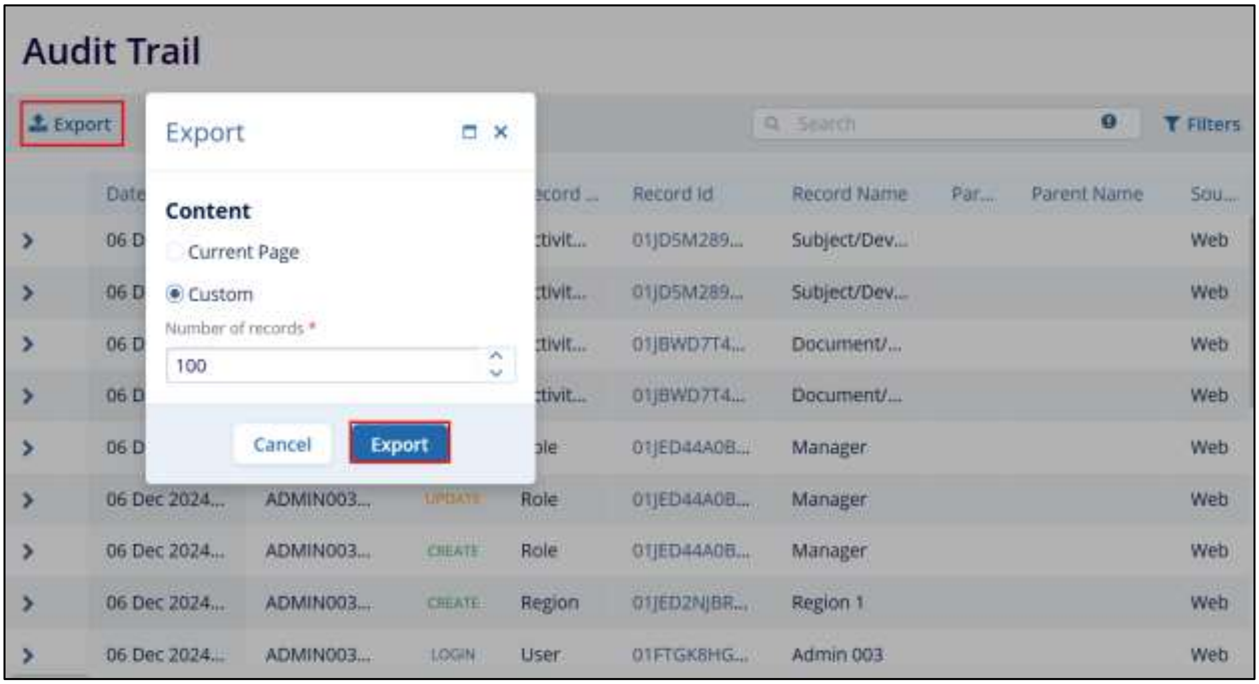


Figure: Audit Trail

Import Status

To retrieve the import status records, follow the steps below.

1. Navigate to the Settings area and select the Import Status option.
2. Click on the Export button.
3. Select the format – CSV or XLSX
4. Specify whether the records to export shall be from the '**Current Page'** or 'All **Records'** or '**Custom'**
5. Specify the number of records if Custom is selected.
6. Enable the 'All Failure' Reasons toggle switch if required. (Only for XLSX)
7. Click on the Export button.

Note: Refer to the Exporting Contacts section for the standard detailed process.

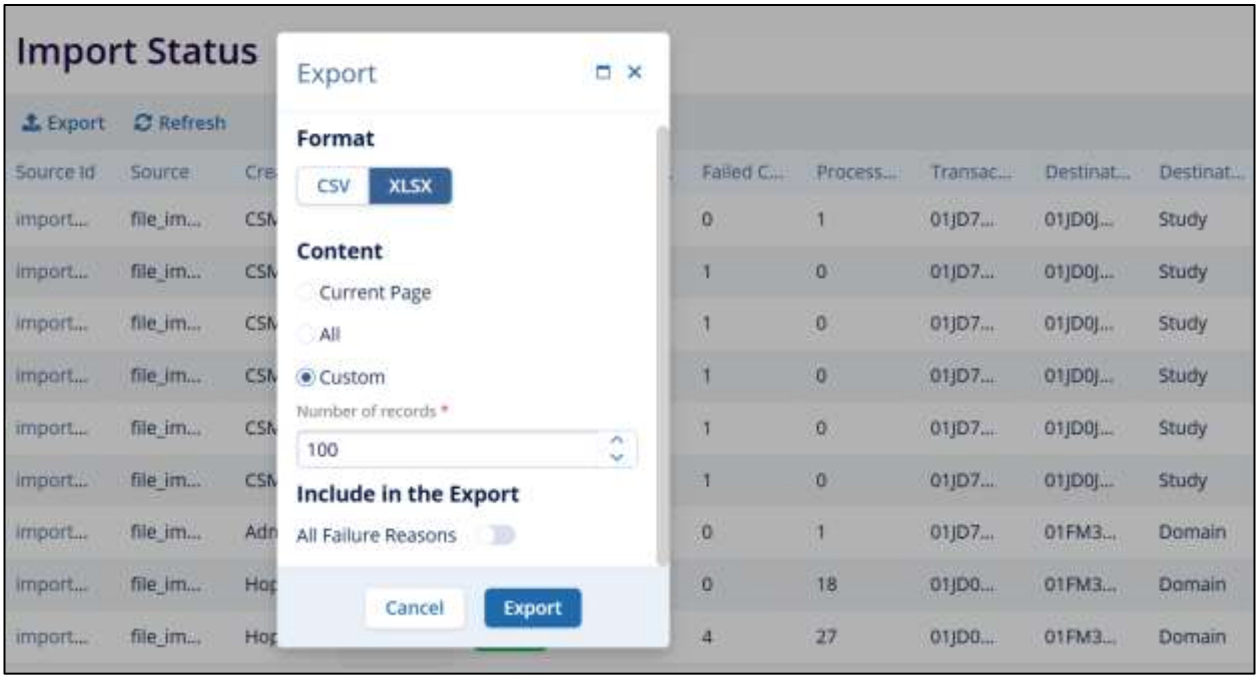


Figure: Export Import Status Records

8. Click on the Get Job Results button.

Figure: Get Job Results

Site Visit Types

Add Site Visit Types

To add a site visit type, navigate to the Settings area and go to the Site Visit Types option and follow the steps below.

1. On the Site Visit Types screen, click on the +Add button
2. Add a name in the Value* field.
3. Optionally enable the 'Unblind**ed site visit type'** toggle switch and add Checklist Templates from the available dropdown options.
4. To associate a custom field, enable the '**Include Additional Fields'** toggle switch.
5. Click on the +Add button and select the appropriate field from the dropdown options.
6. Click on the Save button.

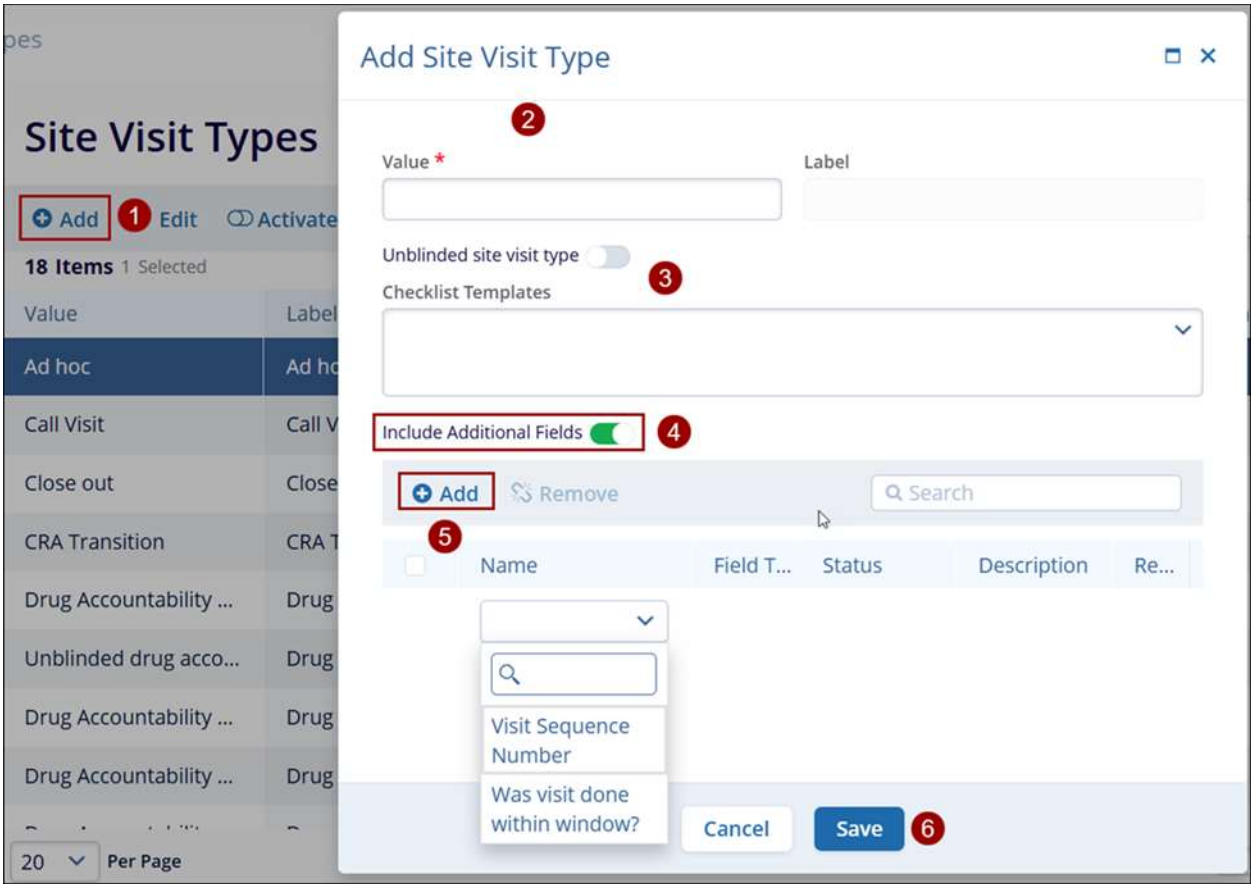


Figure: Site Visit Types

Important

- Creating a custom site visit field does not automatically make it available for all visit types. Since most fields are relevant only to specific visit types, users can customize the field list by navigating to the Site Visit Types in Settings. After creating a new field, users must manually associate it with the relevant visit types to ensure it is applied.
- Only active custom fields can be added as additional fields.
- To edit, activate, deactivate, and export the Site Visit Type details, follow the steps mentioned in the relevant sections above.
- 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
    - Unblinded activities/actions.

Accessing Online Help

To access online help, follow the steps below.

1. Click on the waffle menu, and select the Help **'?'** icon.

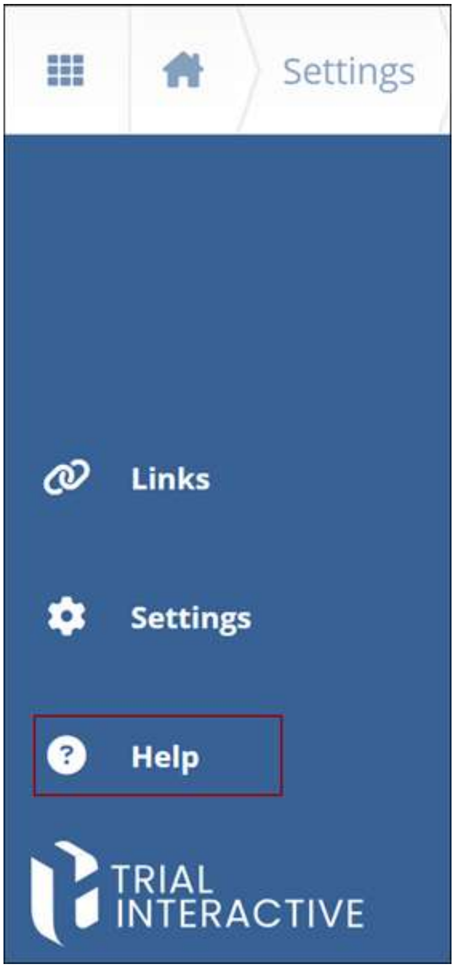


Figure: Accessing Online Help

2. A new tab opens containing all the online help links.

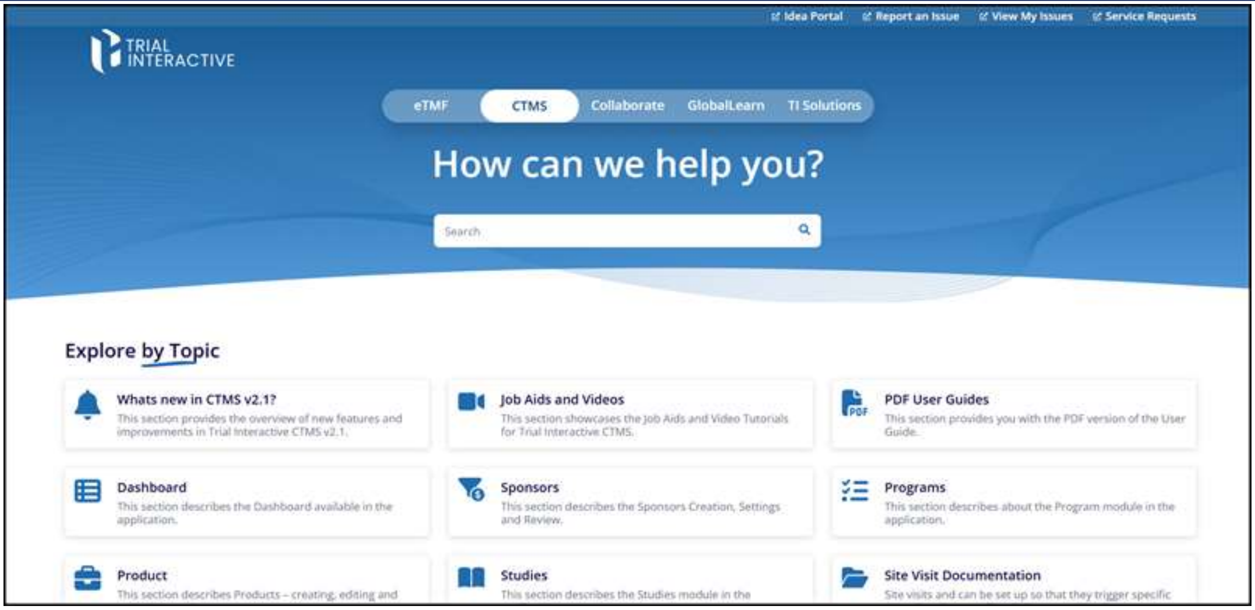


Figure: Online Help Webpage

CHAPTER 4. SPONSORS

This section describes the Sponsors module in CTMS.

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:

Creating a Sponsor

To navigate to the 'Sponsor' list, view all Global-level sponsors, and create a new sponsor, follow the steps below.

1. From the left-hand navigation links, select Sponsors. The Sponsors screen opens where all sponsors at the global level are displayed.
2. Click the '+Add' button from the menu bar above the grid to add a new sponsor.

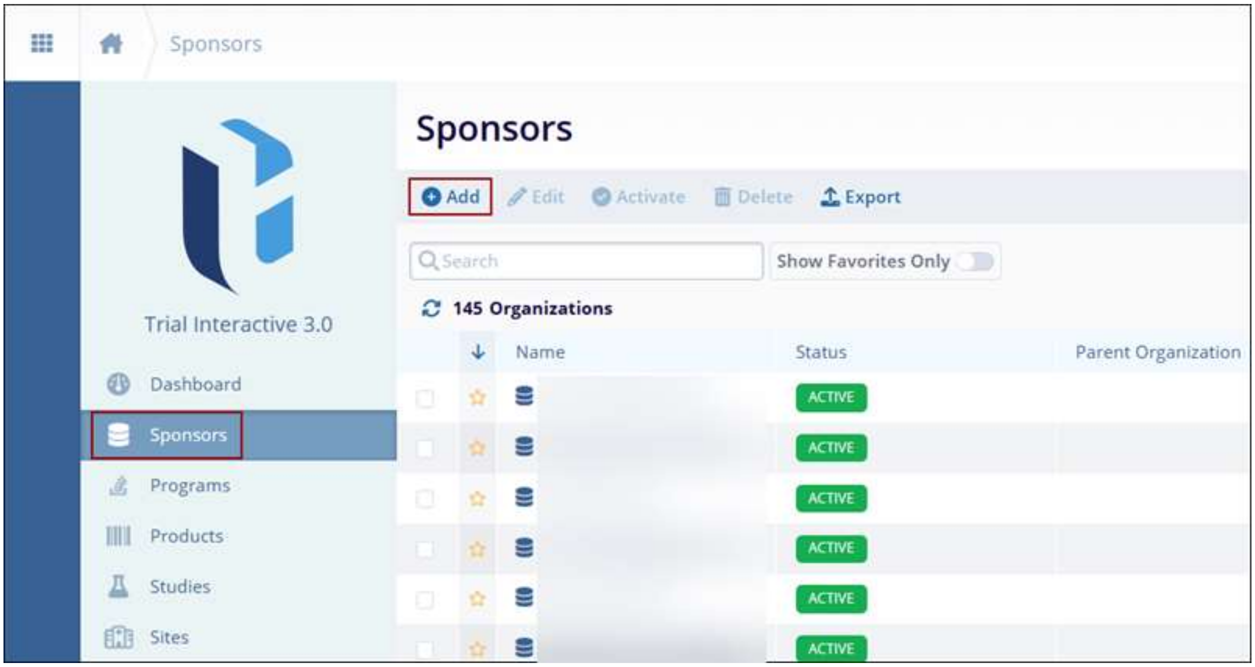


Figure: Accessing Sponsors

3. On the 'Create Sponsor' screen, add the following fields into their respective sections.

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

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

General Information

- Name*: Enter a name for the sponsor.
- Number: Enter the unique number for a sponsor.
- Parent Organization: To add an existing 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.

Note: To Create an organization, refer to Chapter 8. Organizations section.

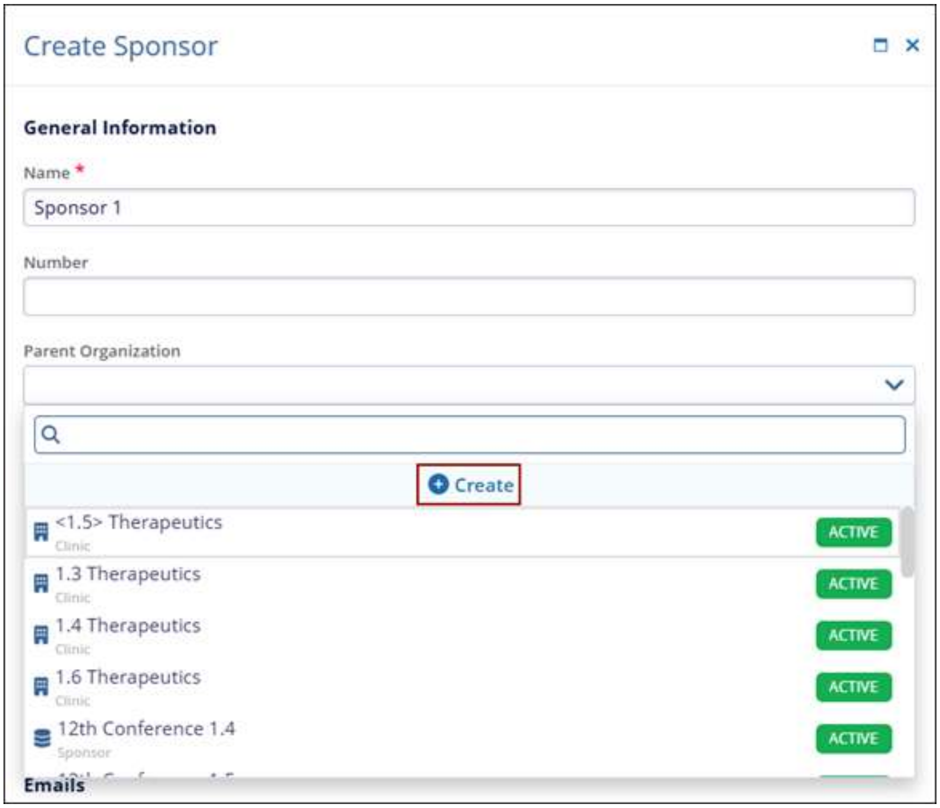


Figure: Create Sponsors

- Type: This field is pre-filled as 'Sponsor' and is not editable.
- Subtype: Select the appropriate subtype from the drop-down menu.
- Status: By default, the user can see '**New'** Status. To add a different status, click on the drop-down arrow and select the status.

- 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.

Note: To add a new contact, refer to the Creating a Contact section.

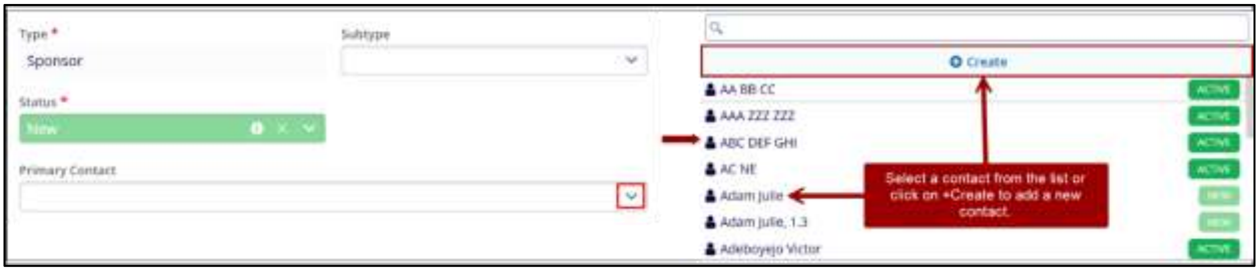


Figure: Create primary contact

Phone Numbers

- Click on '+Add' to input phone numbers and enter the phone number in the provided field.
- Specify the phone number type i.e., Work, Mobile, Office, or Fax.
- Select the Country Code.
- Click on the 'Set as Primary' checkbox.
- Click on the Delete icon to remove the phone number.

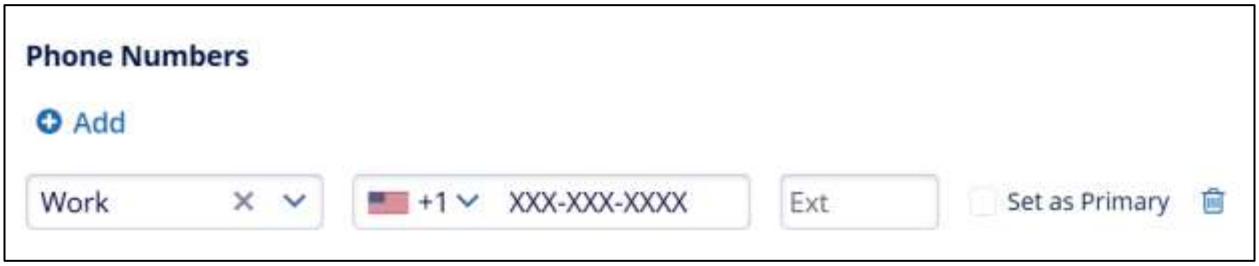


Figure: Add Phone Numbers in Sponsors

Emails

- Click on the '+Add' button and enter the email address in the provided field.
- Enter any additional notes regarding the Sponsor in the 'Notes' field.
- Click on the 'Set as Primary' checkbox.
- Click on the Delete icon to remove the email address.

Figure: Add email addresses in Sponsors

Include Address:

- Toggle the switch to include an address and enter the mandatory details into the respective fields.
- To include an address, enter the following mandatory fields highlighted with a red asterisk (*) mark.
  - Address Type
  - Primary Address
  - Country
  - Postal code
- Add details to the optional fields if required.
  - Address Line 2
  - Address Line 3
  - Town/City
  - Province/State
- Additionally, enter the address in the search box to view an auto-populated list based on the search term.

4. After filling in all required fields, select an option from 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.

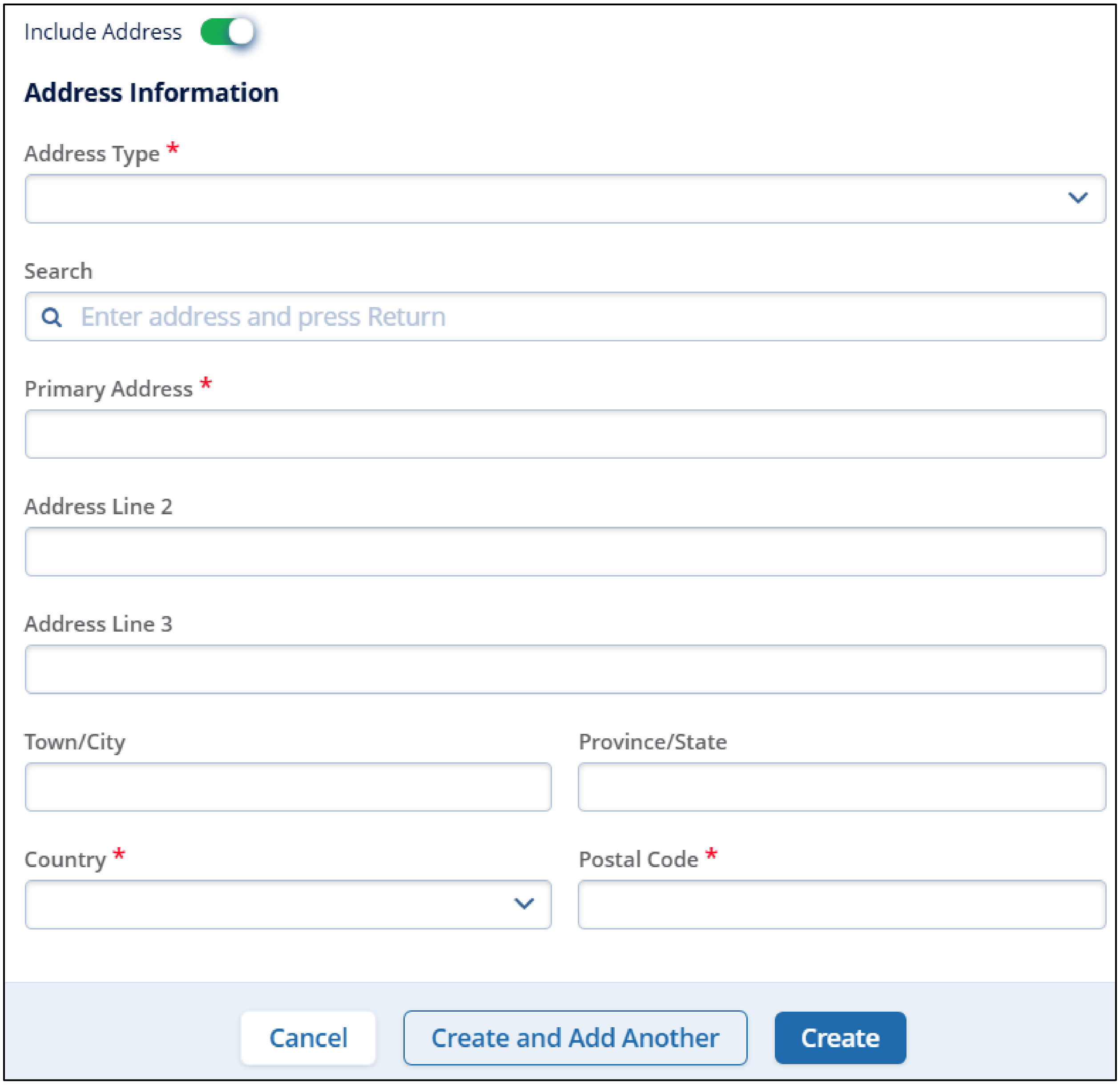


Figure: Include Address in Sponsors

5. Click on the 'Create' button and it displays the success message.

Figure: Sponsor Creation Success Notification

Editing a Sponsor

To edit a sponsor, follow the steps below.

1. Select a sponsor by clicking on the checkbox.
2. Click on the Edit button.
3. On the metadata panel, make the required edits by accessing each section.
4. Click on the Save button.

Note: Click on the Save & Next button to edit another sponsor from the list.

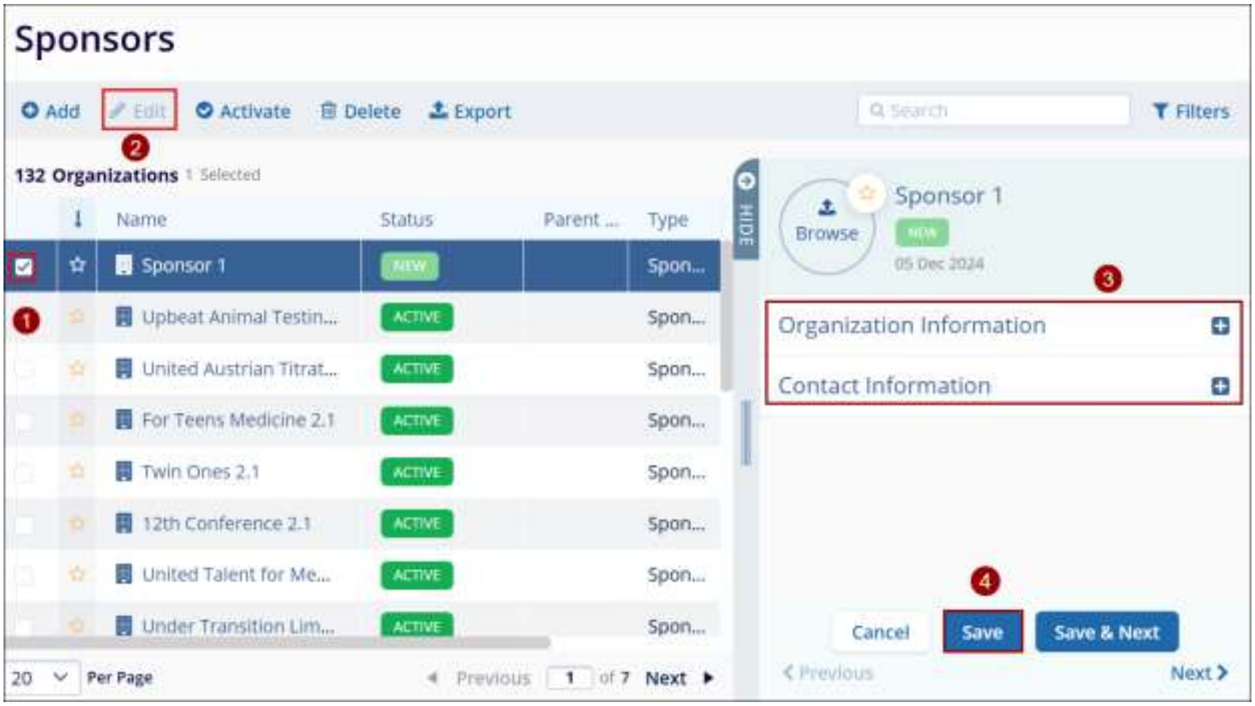


Figure: Editing a Sponsor

Activating a Sponsor

To activate a sponsor, follow the steps below

1. Select a sponsor by clicking on the checkbox.
2. Click on the Activate button from the top menu bar.
3. On the Confirmation popup, click on the Activate button.

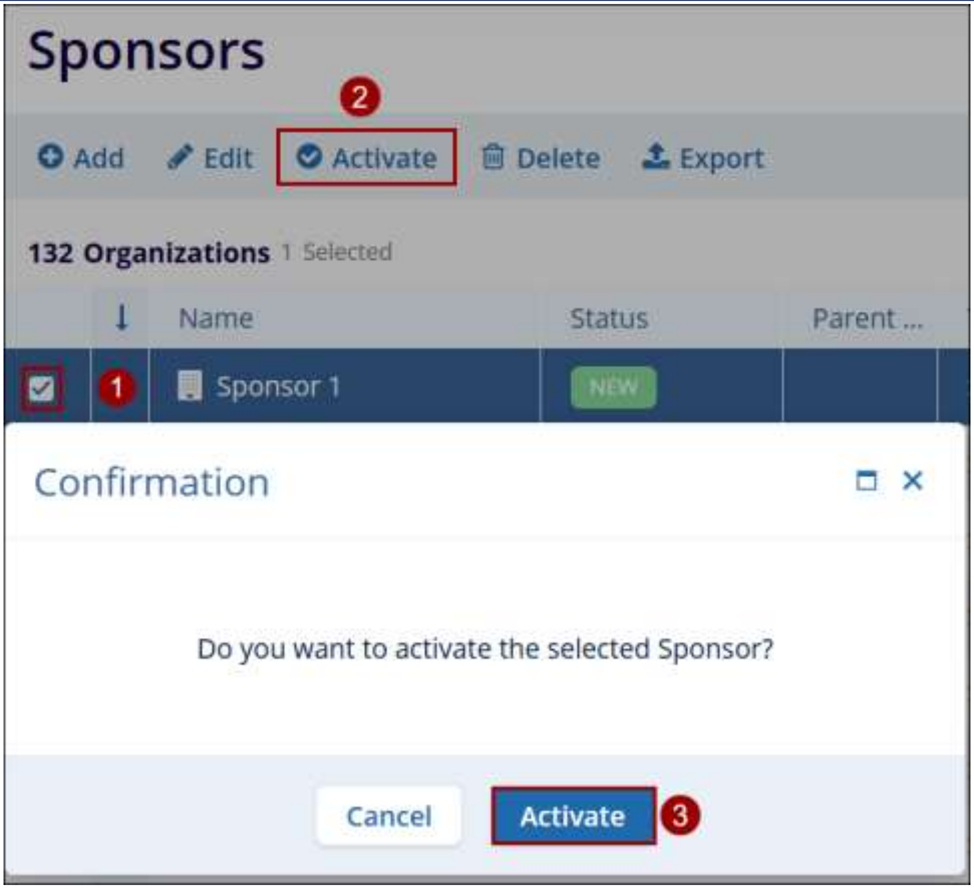


Figure: Activate a Sponsor

Deleting a Sponsor

To delete a sponsor, follow the steps below.

1. Select a sponsor by clicking on the checkbox.
2. Click on the Delete button.
3. On the confirmation popup, click on the Delete button.

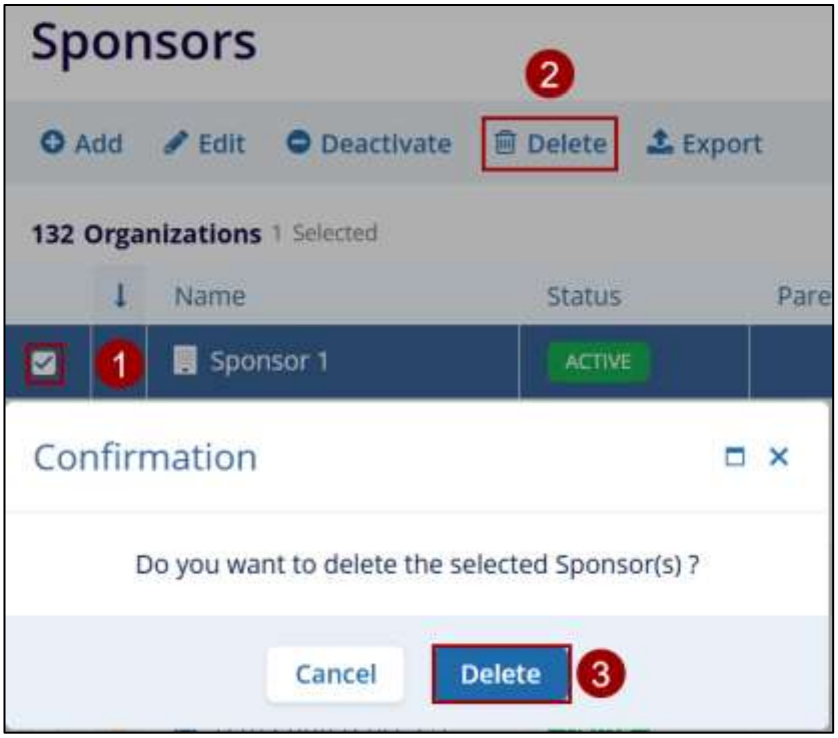


Figure: Deleting a Sponsor

Exporting Sponsors

To export sponsors, click on the Export button and follow the standard steps detailed in the [Exporting Contacts](#) section.

Search and Filter

To search for a sponsor, follow the steps below.

Search

1. Click on the 'Magnifying Glass' icon or the 'Search' textbox and enter the Sponsor's name or a related keyword into the search bar.
2. The list will automatically show all related results based on the search term entered.

Figure: Search Sponsors

Filter

1. On the Sponsors screen, click on the 'Filter' button to apply filters.
2. Enable the 'Show Favorites Only' toggle switch.
3. Sponsors marked as favorites will be displayed.

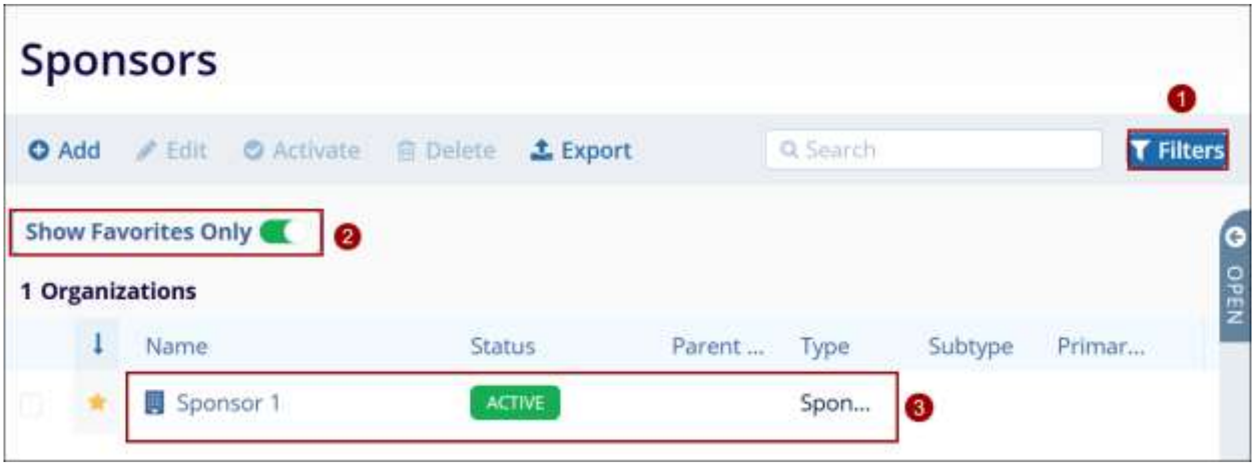


Figure: Filter Sponsors

Add and Remove Favorites

To add or remove favorites, follow the steps below.

1. Click the '**Star'** symbol next to the sponsor's name to add a favorite to the sponsor.
2. To mark the sponsor as unfavorite, click that solid Star. The screen displays the success notifications accordingly.

Figure: Add and Remove Favorites

Defining Sponsor Settings

To define sponsor settings, follow the steps below.

1. From the left-hand navigation links, select 'Sponsors'. The Sponsors screen opens with a list of sponsors at a global level.
2. Click on the Sponsor name.

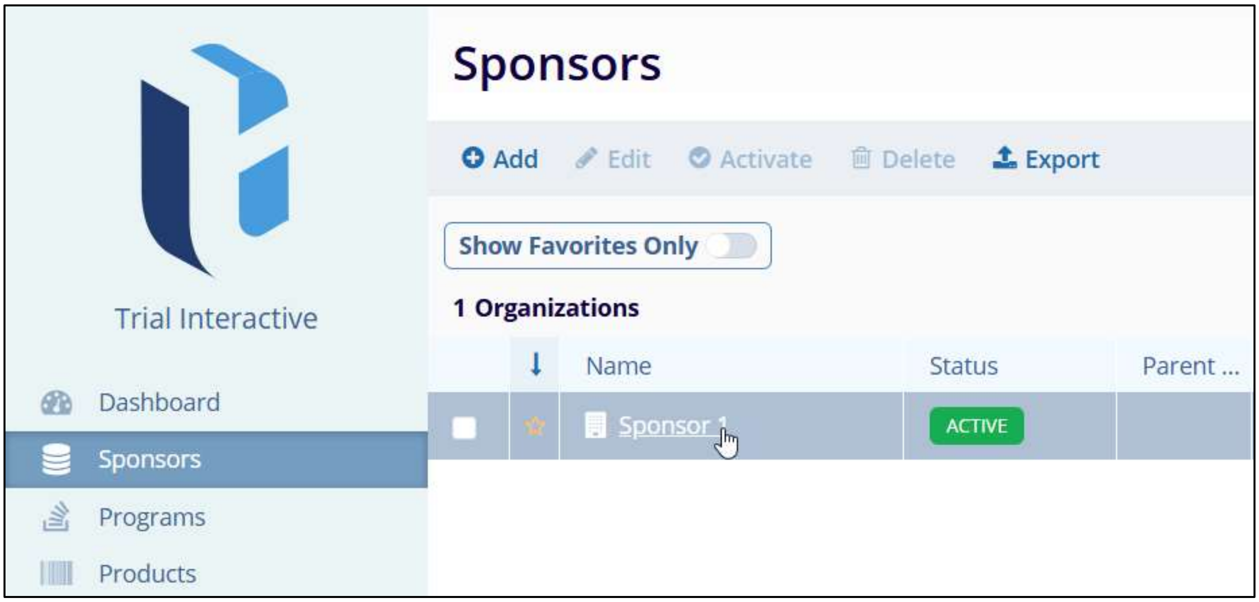


Figure: Define Sponsor Settings

3. On the Sponsor Details screen, click on the '**Setting'** button in the top-right of the screen. This opens the '**Sponsor Settings'-> Milestone Template's'** screen.

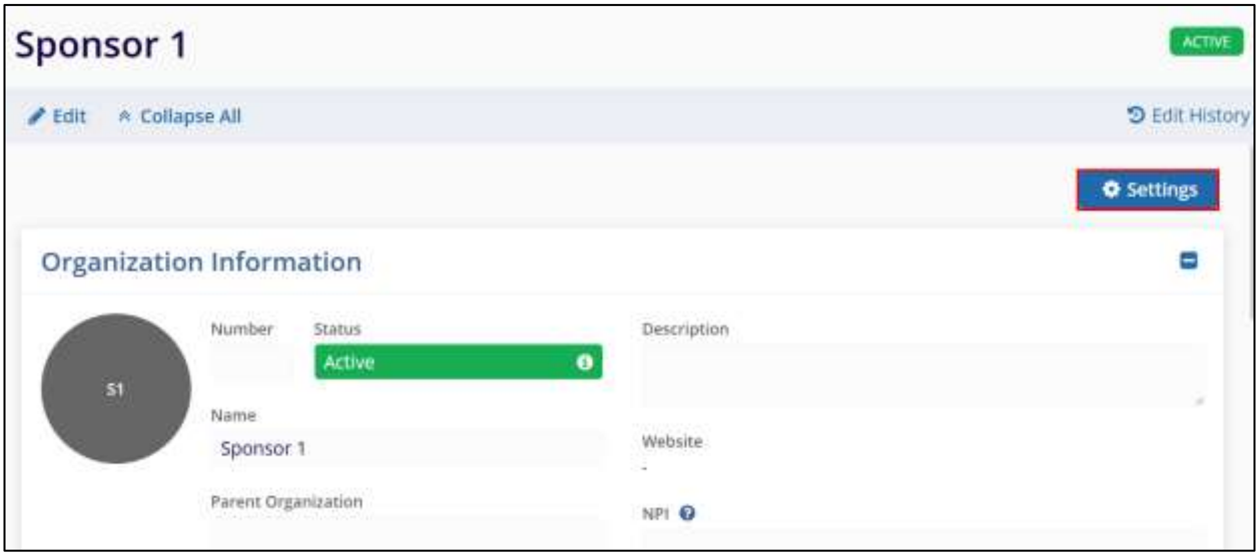


Figure: Access Sponsor level settings

Note: To learn more about Milestone Templates functionality. For Example, Add, Delete, Publish and Copy Refer to [Chapter 13. Milestones] section.

Creating a Product for a Sponsor

To create a product at sponsor level, follow the steps below.

1. Click on the Sponsor name, The Sponsor Details screen opens.

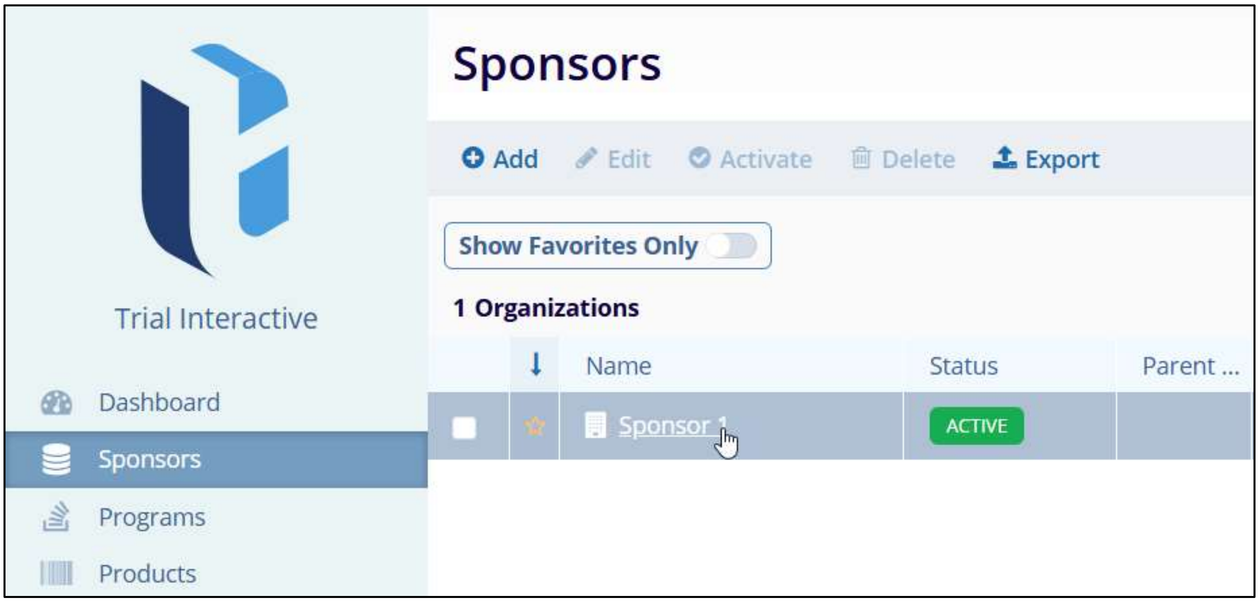


Figure: Create Product for Sponsor – Access sponsor

2. Click on Products from the navigation link to the left side of the screen. This opens the product screen at the Sponsor level.

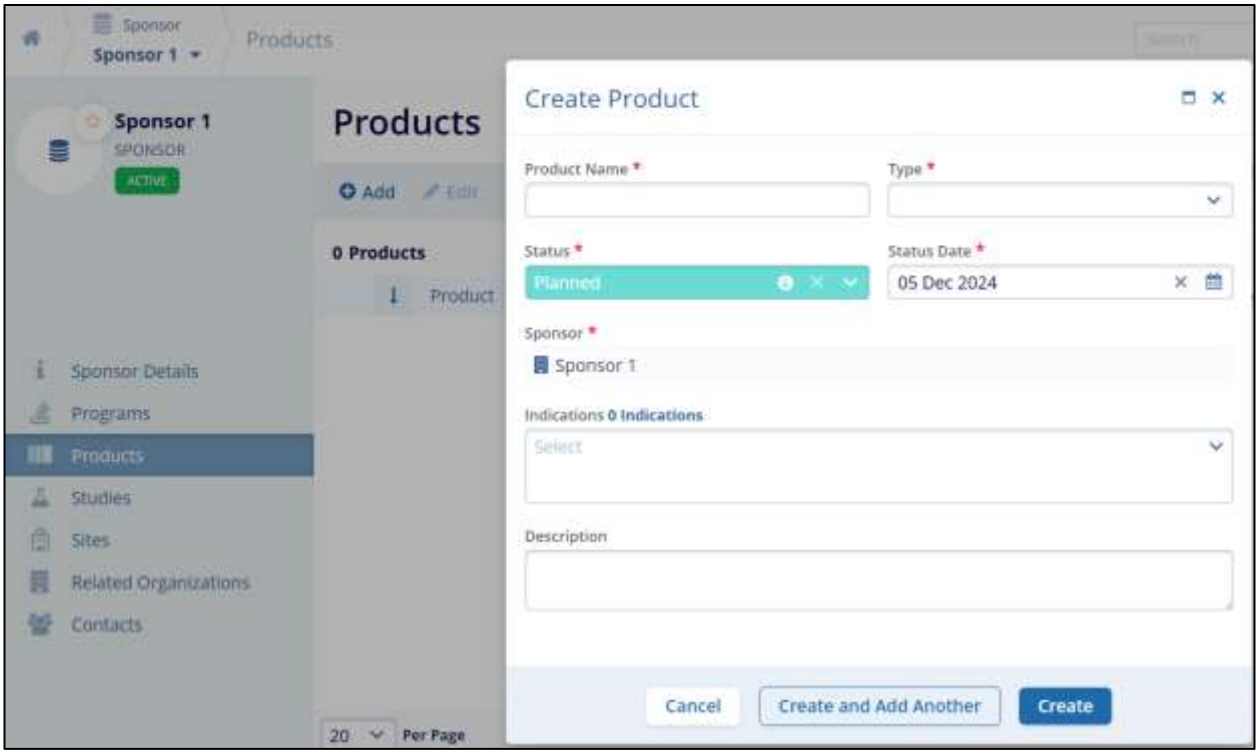


Figure: Create a new product at the sponsor level

3. To create a new product and the associated actions, refer to Chapter 5. Product section.

Notes:

- Ensure all mandatory fields (marked with a red asterisk (*) are filled out before attempting to save the product.
- The '**Sponsor'** field is pre-filled and cannot be edited.

Creating a Program for a Sponsor

To create a program at sponsor level, follow the steps below.

1. On the Sponsors screen, click on the sponsors' name.

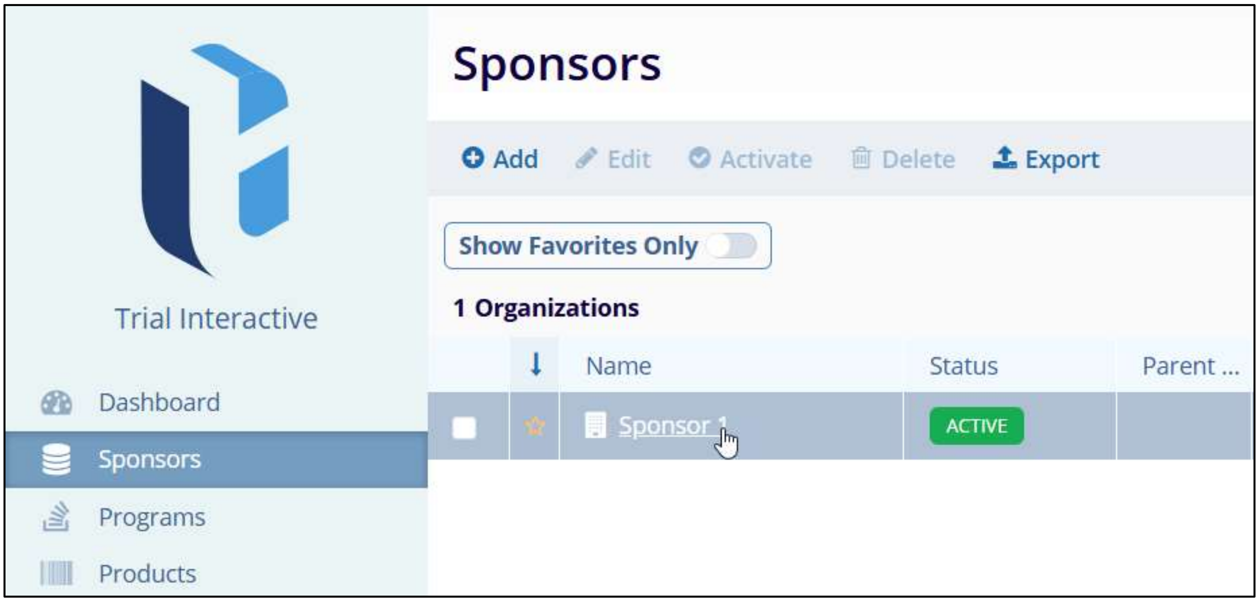


Figure: Create a Program for the sponsor

2. On the 'Sponsor Details' screen, click on the Program link from the left-hand Navigation menu.
3. On the Program Details screen, click on the +Add button at the top of the grid.

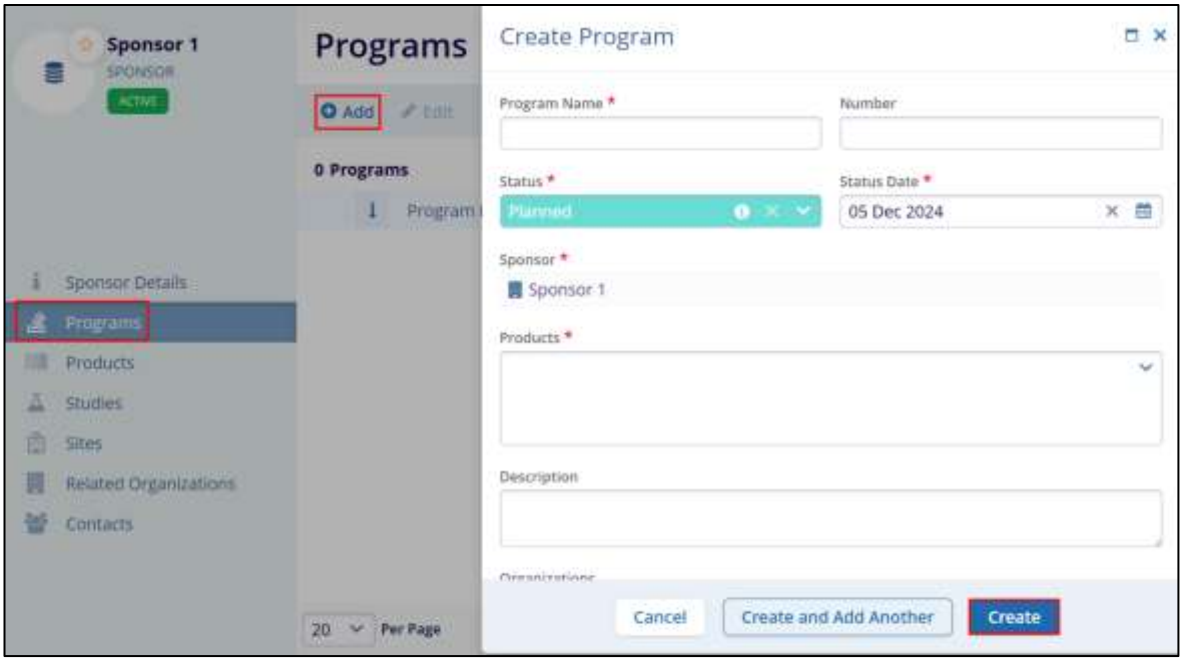


Figure: Create a Program at the Sponsor level

4. To create a new program and the associated actions, refer to [Chapter 4. Programs](#) section.

Note:

- Ensure 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.

Creating Study for a Sponsor

To create a study at a sponsor level, follow the steps below.

1. On the Sponsors screen, select the sponsors name.

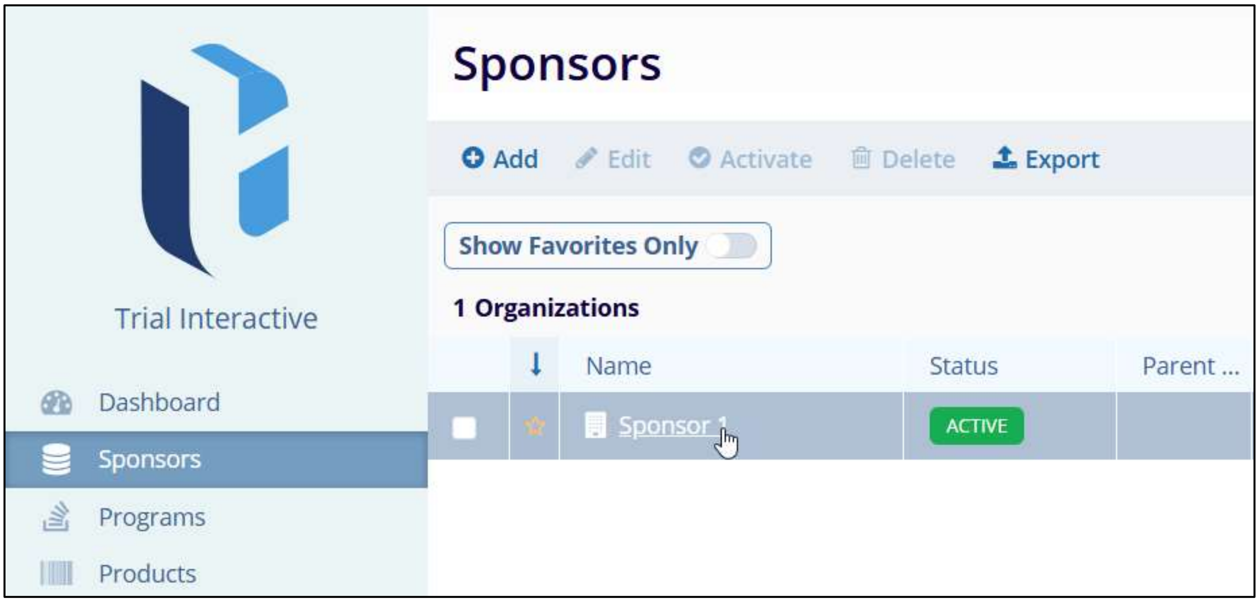


Figure: Create a Study for the sponsor

2. On the '**Sponsor Details'** screen, click on the Studies link from the left-hand Navigation menu.
3. On the Studies screen, click on the +Add button to add a new study at the sponsor level.

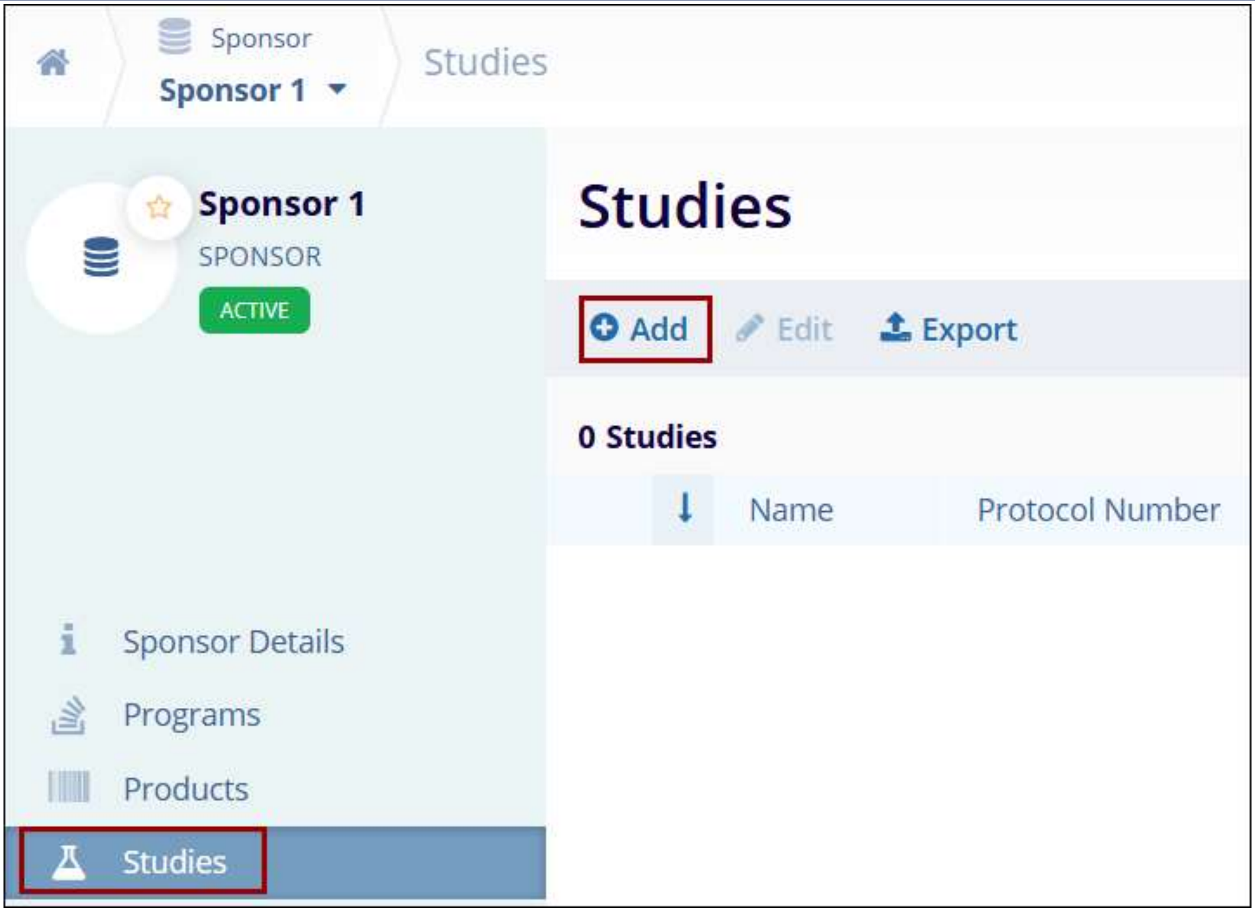


Figure: Add Study to Sponsor

4. To create a study and the associated actions, refer to [Chapter 6. Studies](#) section.

Editing Sites within a Sponsor

To edit a site within a sponsor, follow the steps below.

1. On the Sponsors screen, select the sponsor's name.

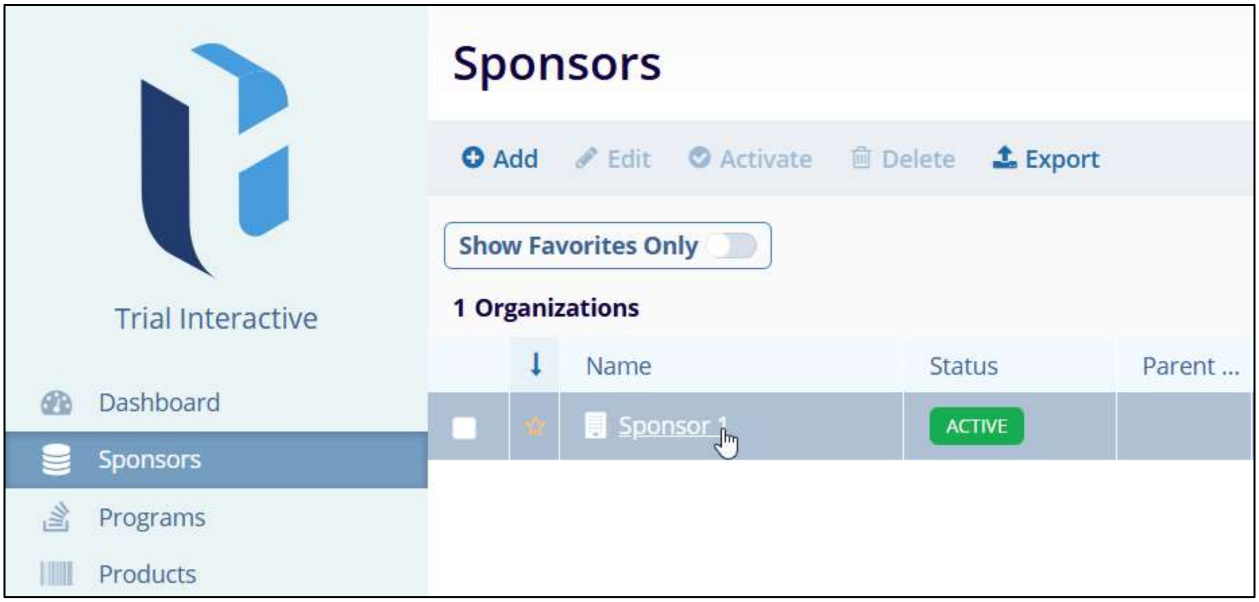


Figure: Edit a Site within a sponsor

2. Follow the steps detailed in the Editing a Site in a Study to edit the site details.

Creating Organization within a sponsor

To create an organization at the sponsor level, follow the steps below.

1. On the Sponsors screen, select the sponsor's name.

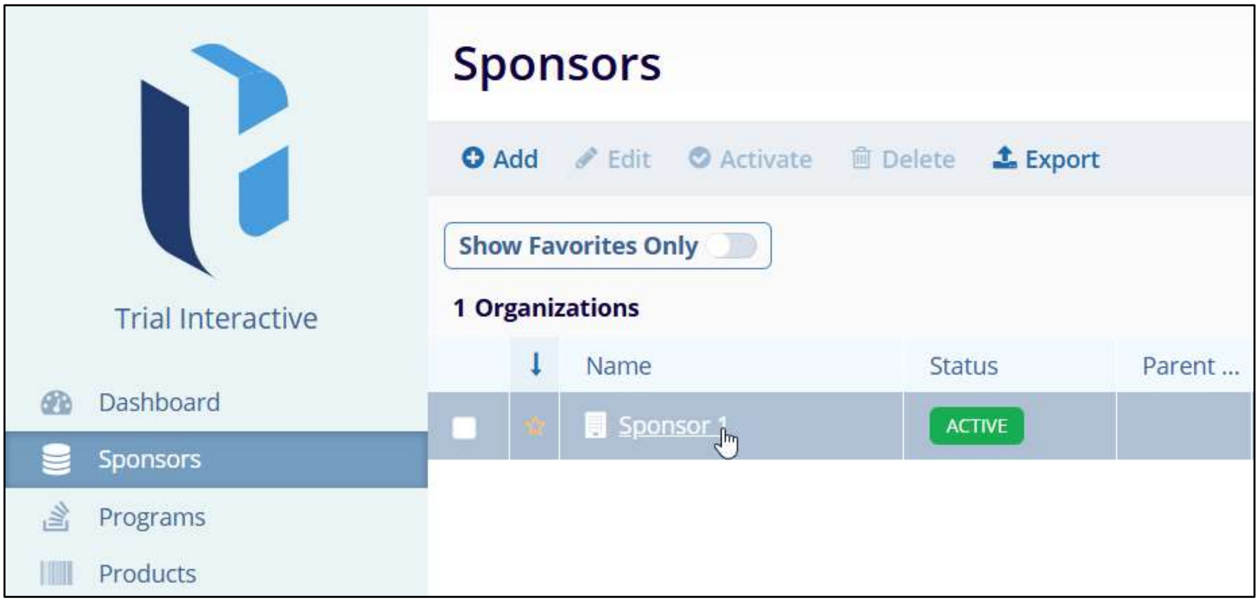


Figure: Add an organization within a sponsor

2. On the Sponsor details screen, select 'Related Organizations' from the left-hand navigation pane.

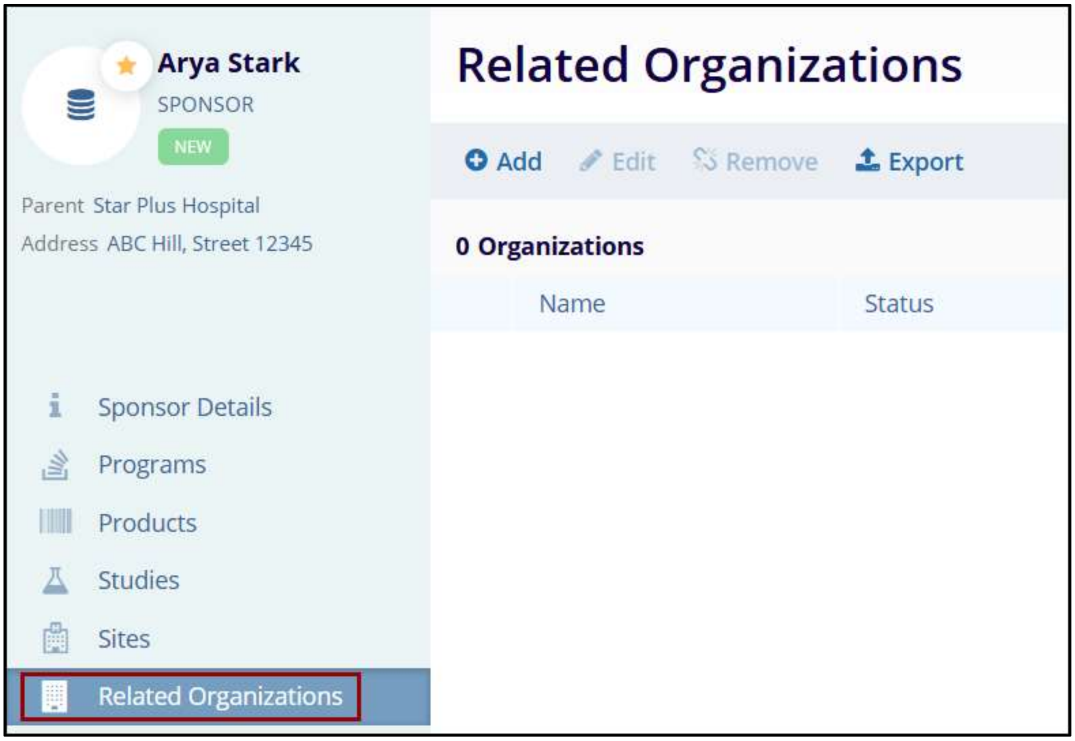


Figure: Add Related Organization within a sponsor

3. Follow the steps detailed in the relevant sections of [Chapter 8. Organizations](#) to add, edit, remove and export organizations.

Creating Contacts within sponsors

To create contacts at the sponsor level, follow the steps below.

1. On the sponsor's screen, click on the sponsors' names.

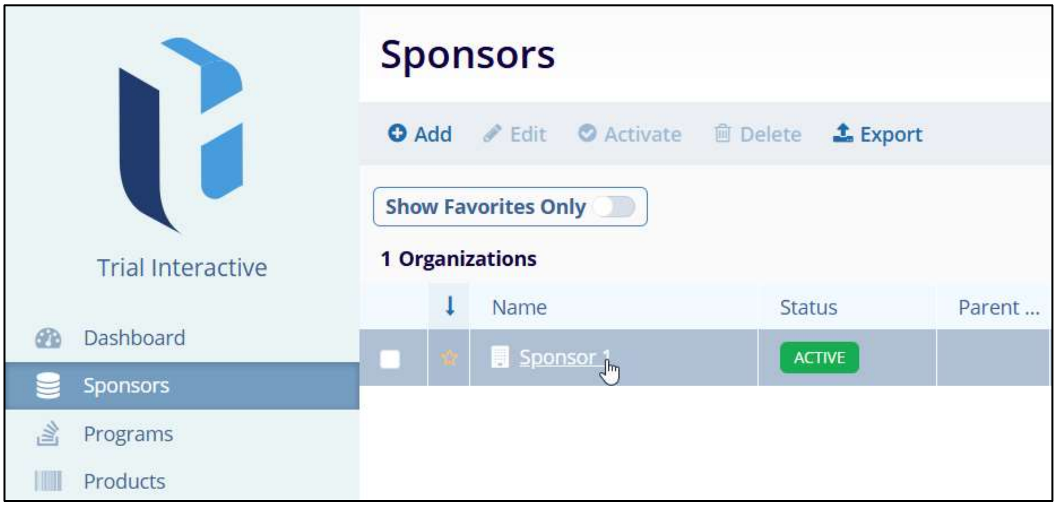


Figure: Add Contacts at the sponsor level

2. On the Sponsor details screen, select Contacts from the left-hand navigation menu.

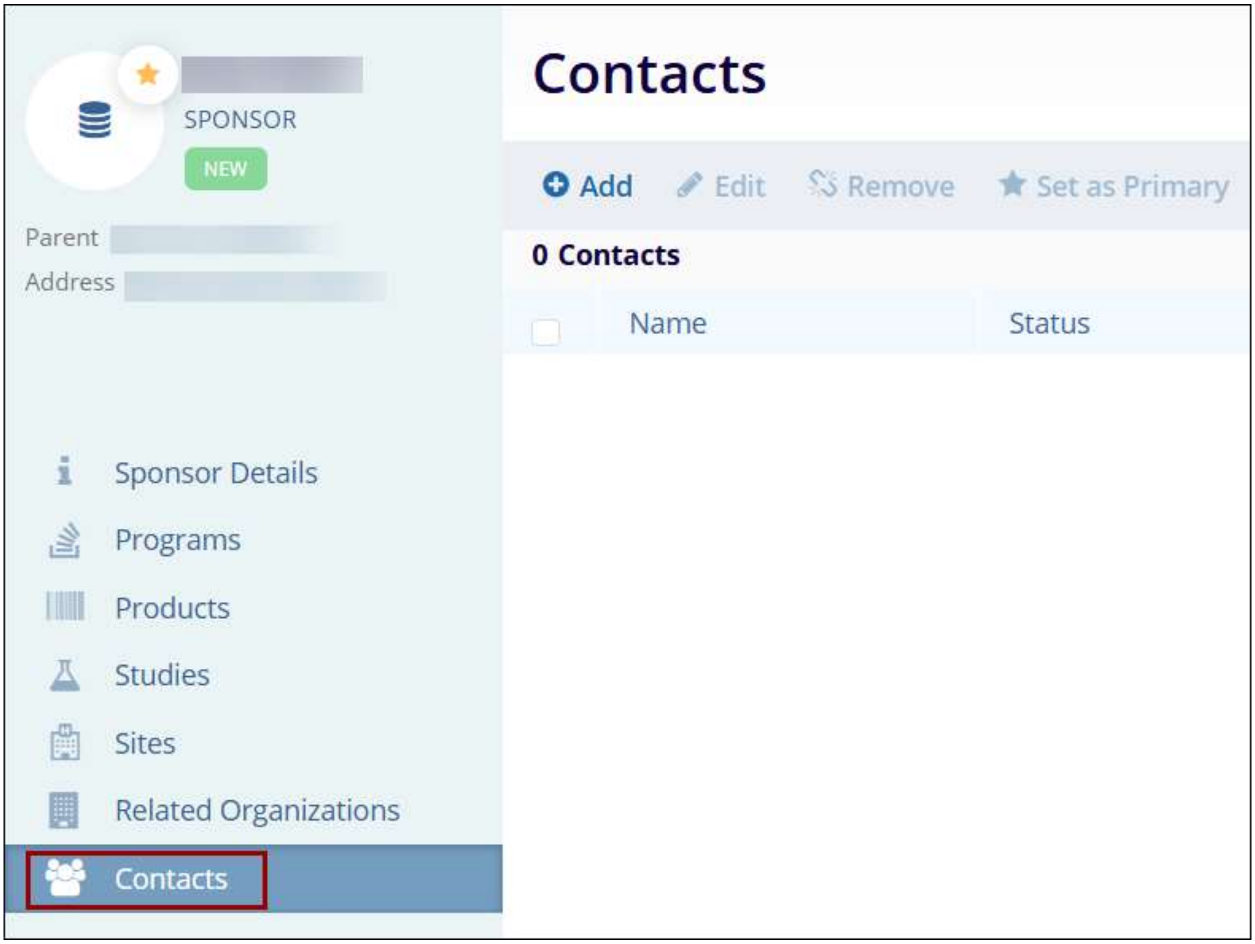


Figure: Add Contacts at Sponsor Level

3. Follow the steps detailed in the relevant sections of the [Chapter 9. Contacts](#) to add, edit, remove, and set as primary contact.

CHAPTER 5. PROGRAMS SM

This section explains the Programs module in CTMS.

Creating a Program

To navigate to the Program screen, view all the Program entries, and create a new program, follow the steps below.

1. From the left-hand navigation pane, select Programs. This opens the Program screen with a list of existing Programs.
2. Click on +Add from the top menu bar.
3. On the Create Program window, fill in all the mandatory metadata.
4. Once all the mandatory metadata fields are entered and reviewed, click on the Create button.

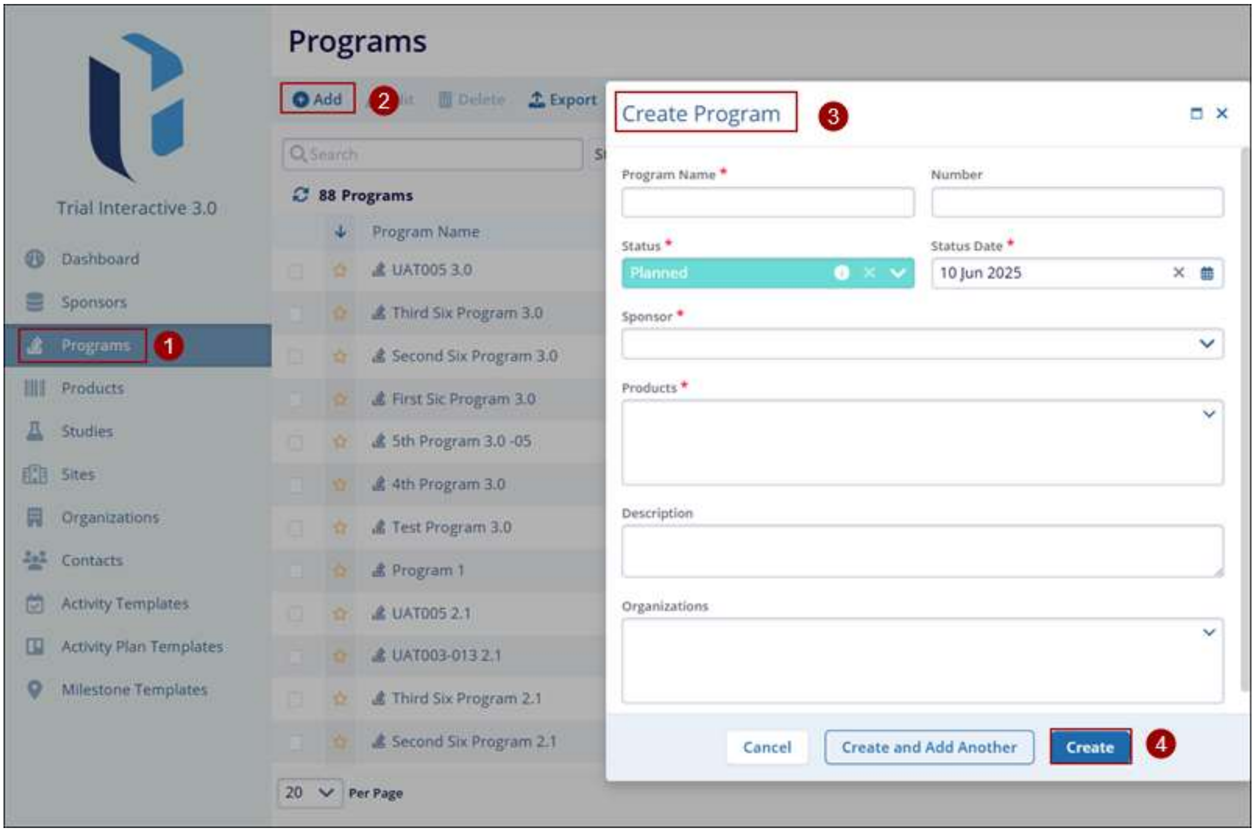


Figure: Create Program

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

Metadata field(s)	Description
Program Name*	Enter a suitable name for the Program.
Number	Enter the unique number for the Program.
Status*	Select a suitable status from the available dropdown options. • Planned: The program is planned. • Active: The program is currently being actively used. • Approved: The program has been approved. • Archived: Program data has been archived • Cancelled: The Program has been canceled. • Closed: The Program has reached the end and no additional data will be tracked. • Inactive: The inactive program. • Pending Approval: The Program is pending an approval. • Postponed: The program is postponed until a future date. • Rejected: Rejected program. Note: • The Status field will be displayed in a different color depending upon the status selected. • A tooltip showing the status description is visible after hovering over the icon.
Status Date*	Enter the status date.
Sponsor*	Select the sponsor's name from the available dropdown options.
Products*	Select the product from the available dropdown options.
Description	Enter a suitable description for the Program.
Organization	Select the related organization.

Important Behavior of Create Program

- An error appears if the user clicks on the Create button and any one of the mandatory metadata fields is blank.
- If the user selects Create and Add Another, the system saves the initially created Program and enables creating a new Program.
- If the user selects Cancel, the system discards 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 Programs. This opens the Program screen with a list of existing Programs.
2. There are two methods to edit the Program details.

Method 1

1. On the Programs screen, click on a 'Program Name'.

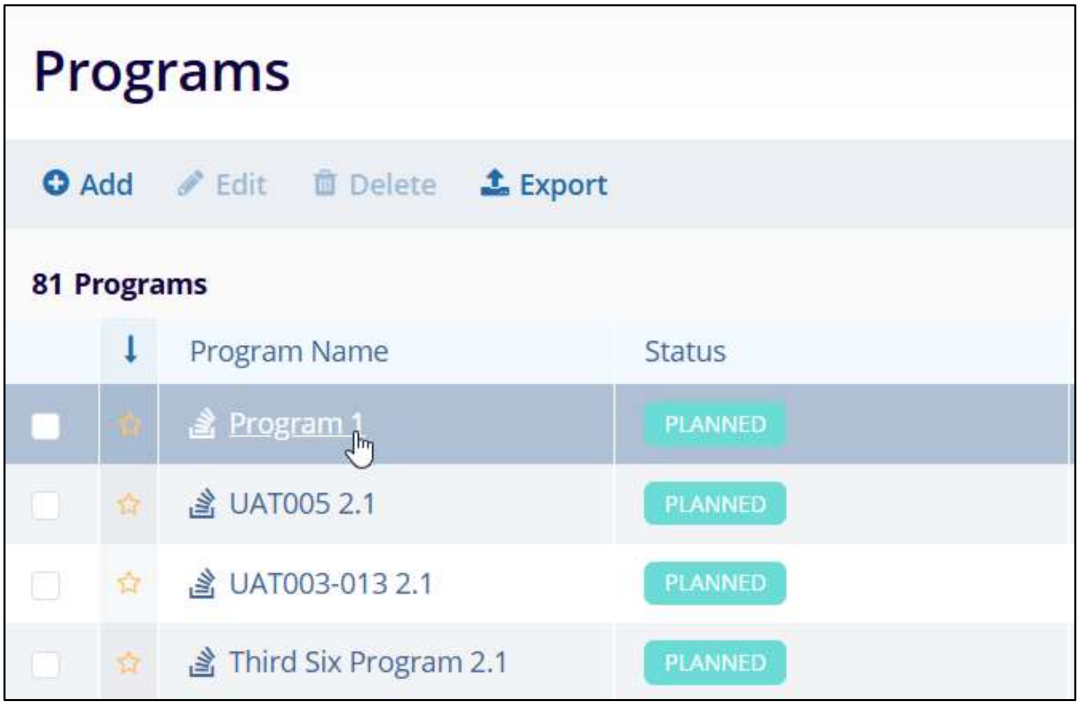


Figure: Select a Program to edit

2. On the Program Details screen, click on the Edit (pencil) icon.

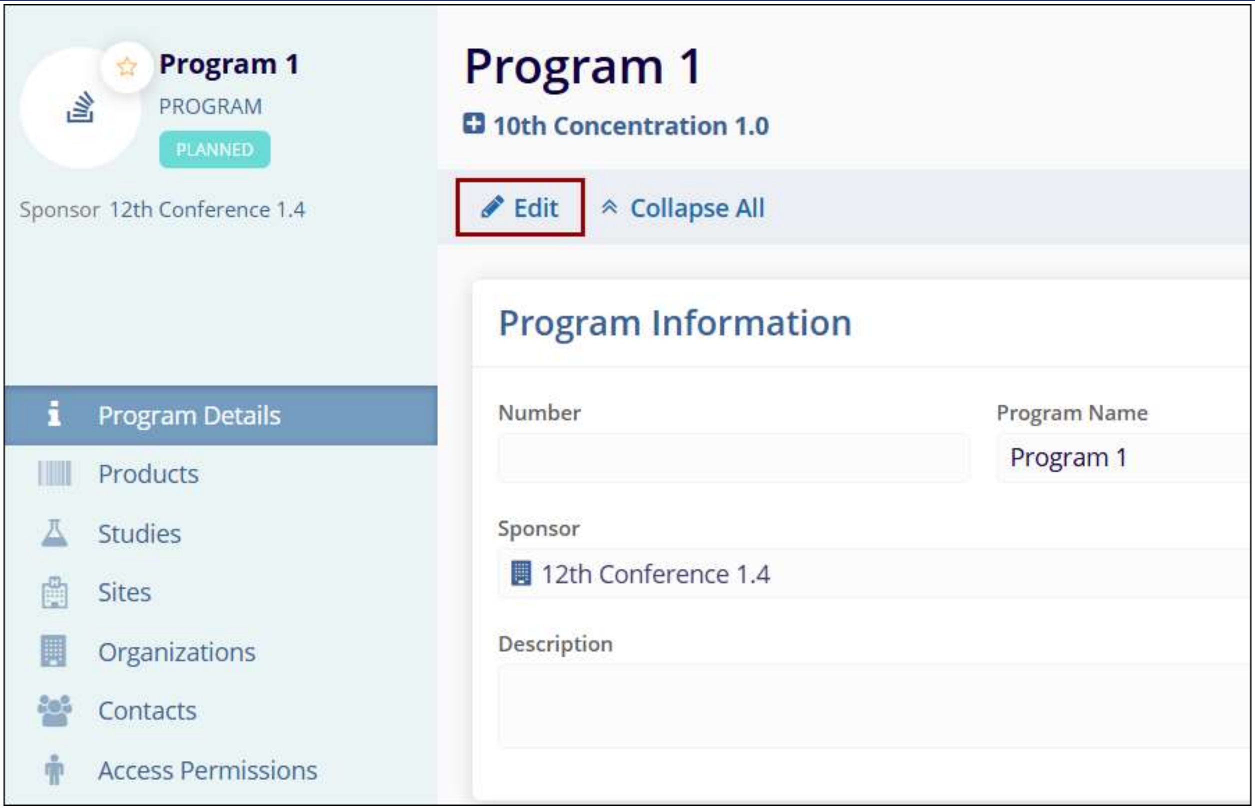


Figure: Program Details screen

3. Make the required edits in the Program Information, Project Management and Planning Information section.

4. In the Program Information section perform the following.
   a. Edit the Number, Program Name, Sponsor, Notes and Description.

5. On the Project Management screen, perform the following.
   a. Change Status:
      i. Click on the Change Status button.
      ii. On the Change Status screen, update the Status*, Status Date* and enter notes if required.
      iii. Once the required changes are made, click on the '**Change' button.** The respective status-related field will be updated with the latest status, date, and notes if any.

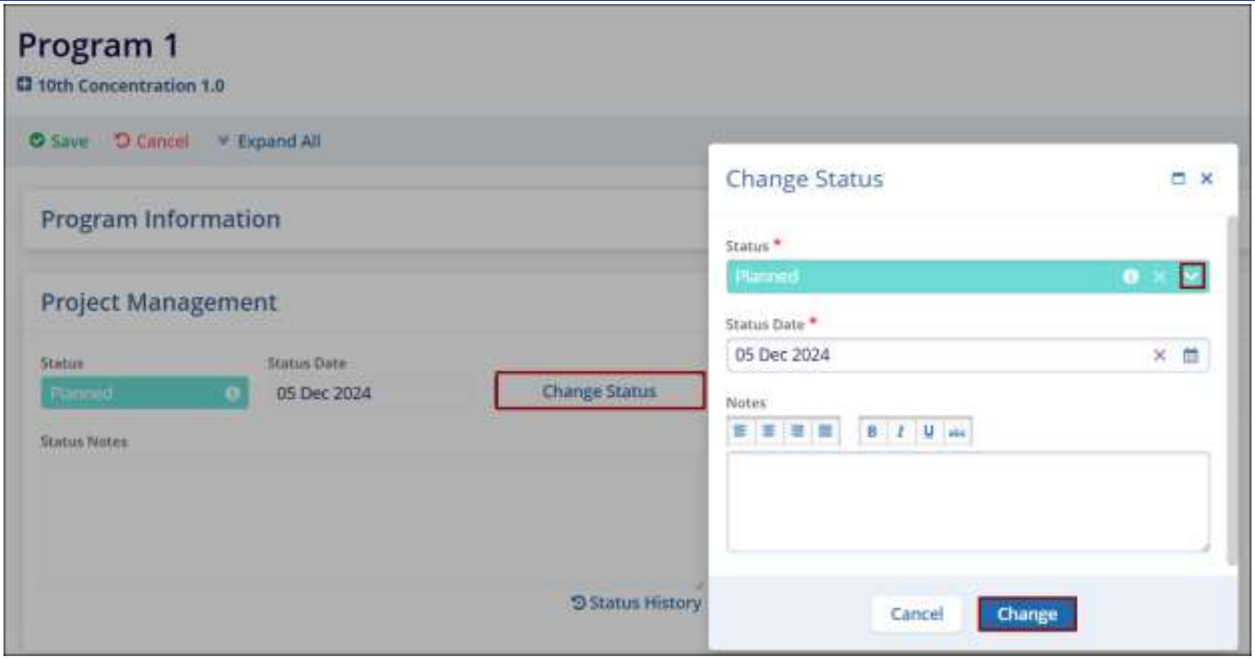


Figure: Change Status

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

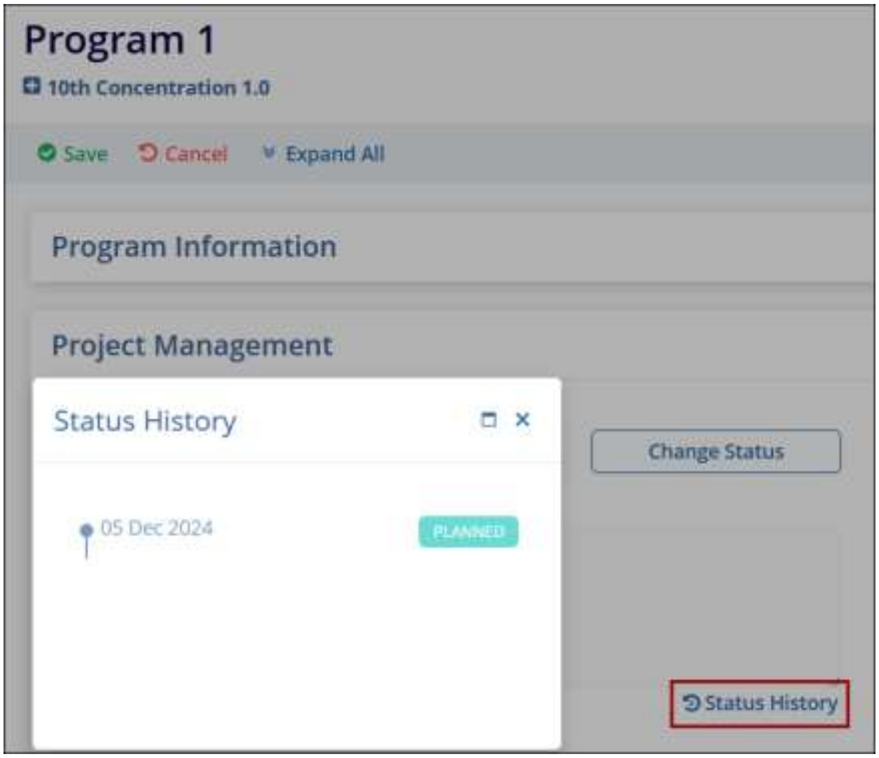


Figure: Status History

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

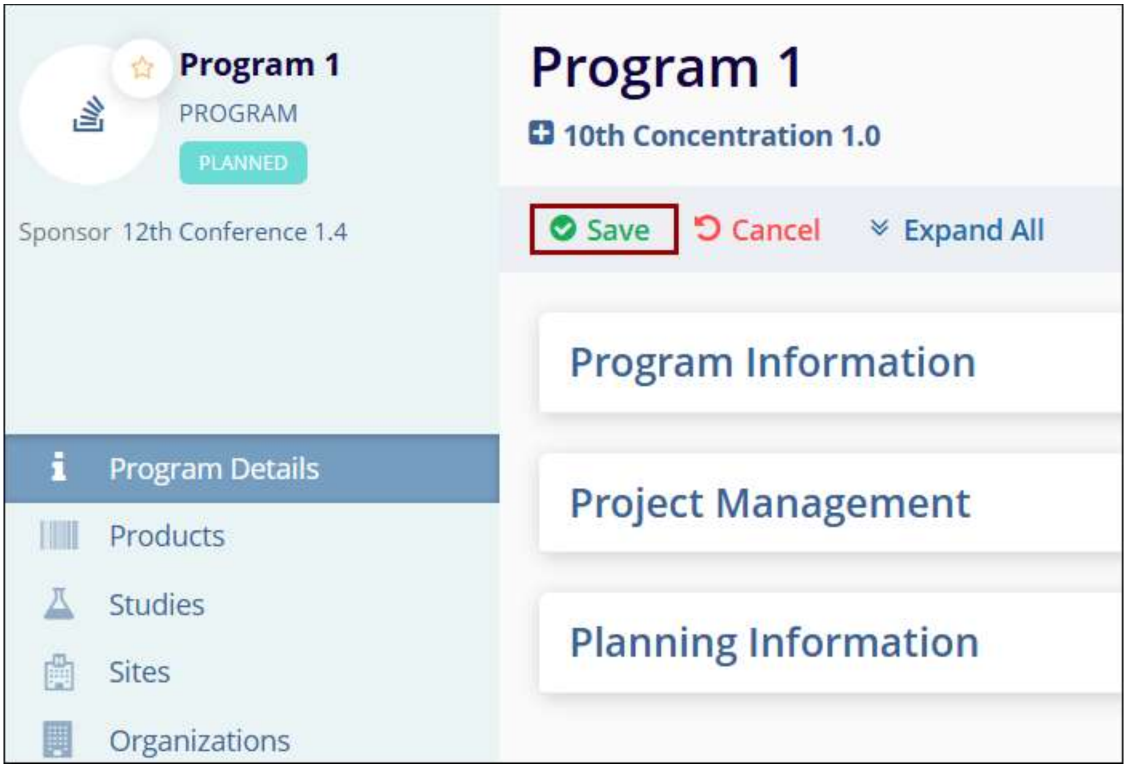


Figure: Save edits

Method 2

1. On the Programs screen, click on the checkbox for the particular Program.
2. Click on the Edit (pencil) icon to edit. This opens the 'Program details' screen.
3. Follow the steps detailed in Method 1 to edit and save all the Program-related details.

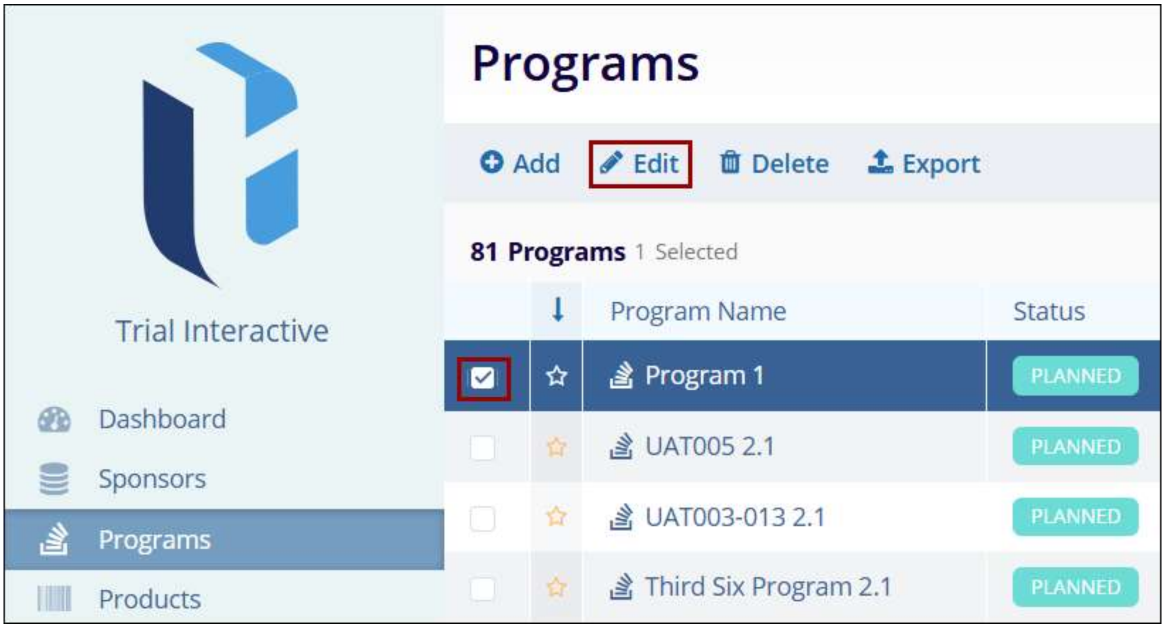


Figure: Edit Program – Method 2

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.

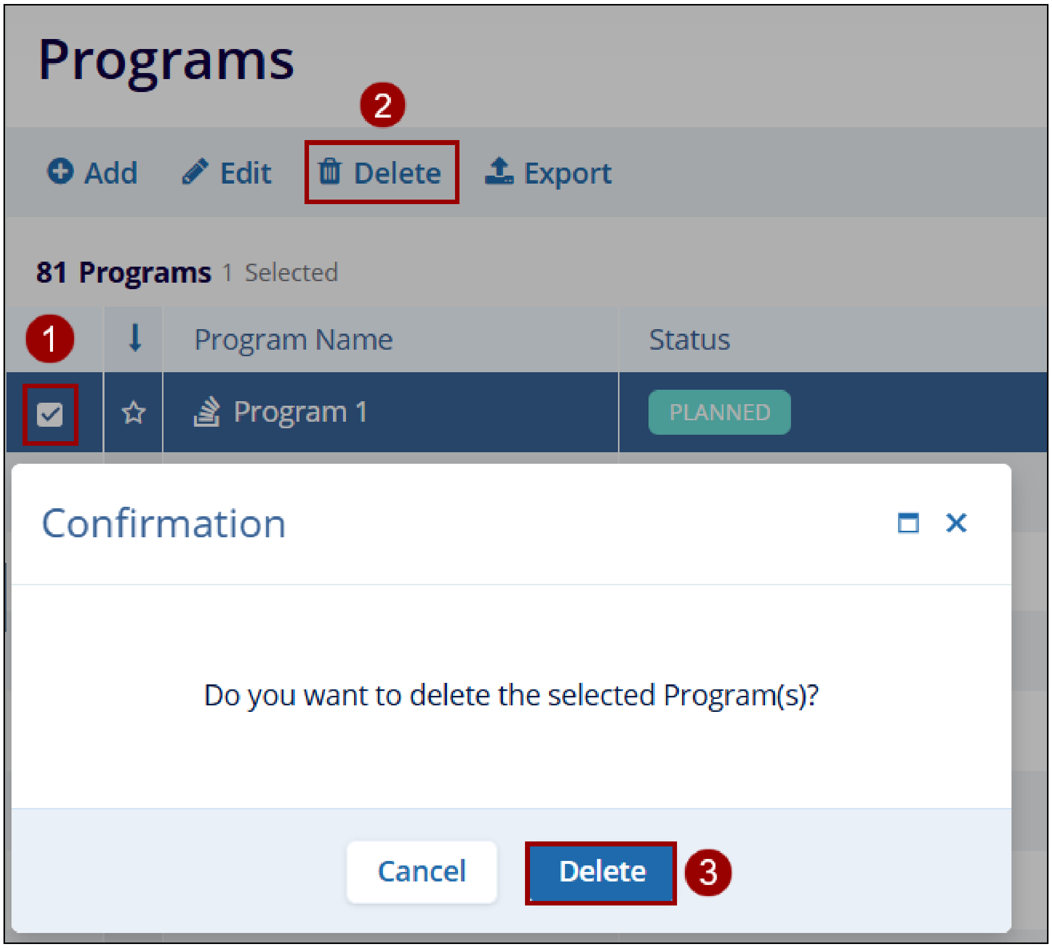


Figure: Delete Program

Exporting Program

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

Customizing Program screen

Users can customize the programs screen by applying filters, searching for a specific program and marking a program as favorite.

Filters

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

1. 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.

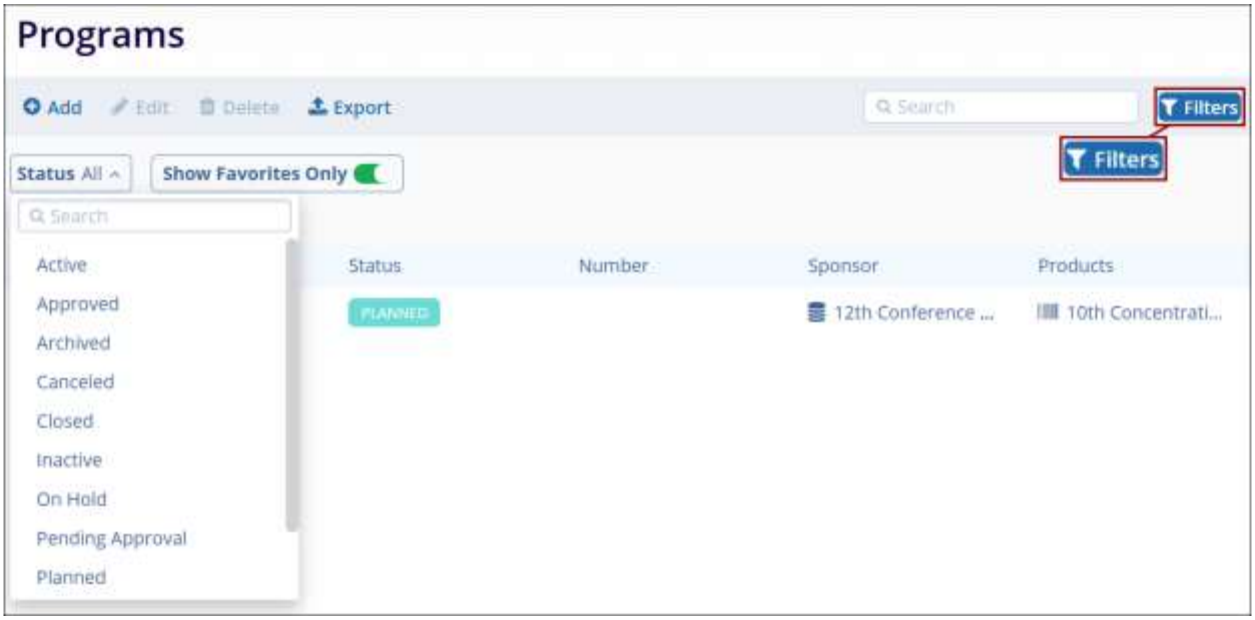


Figure: Apply Status filter

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

3. Switch the 'Show Favorites Only' toggle button to display records marked as favorites.

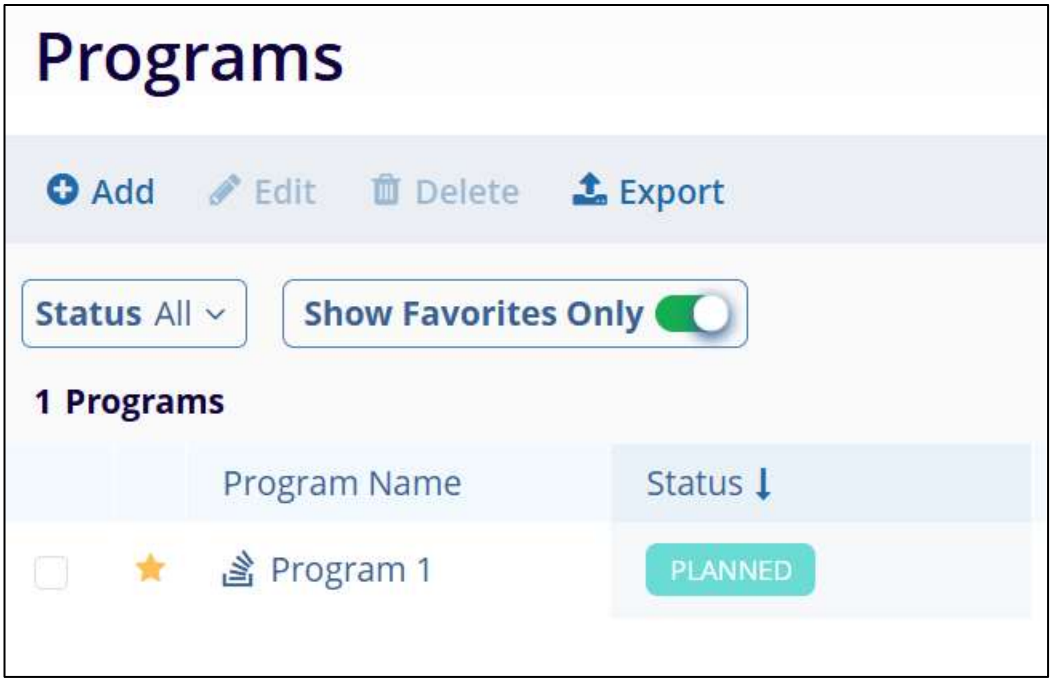


Figure: Show Favorites Only toggle

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

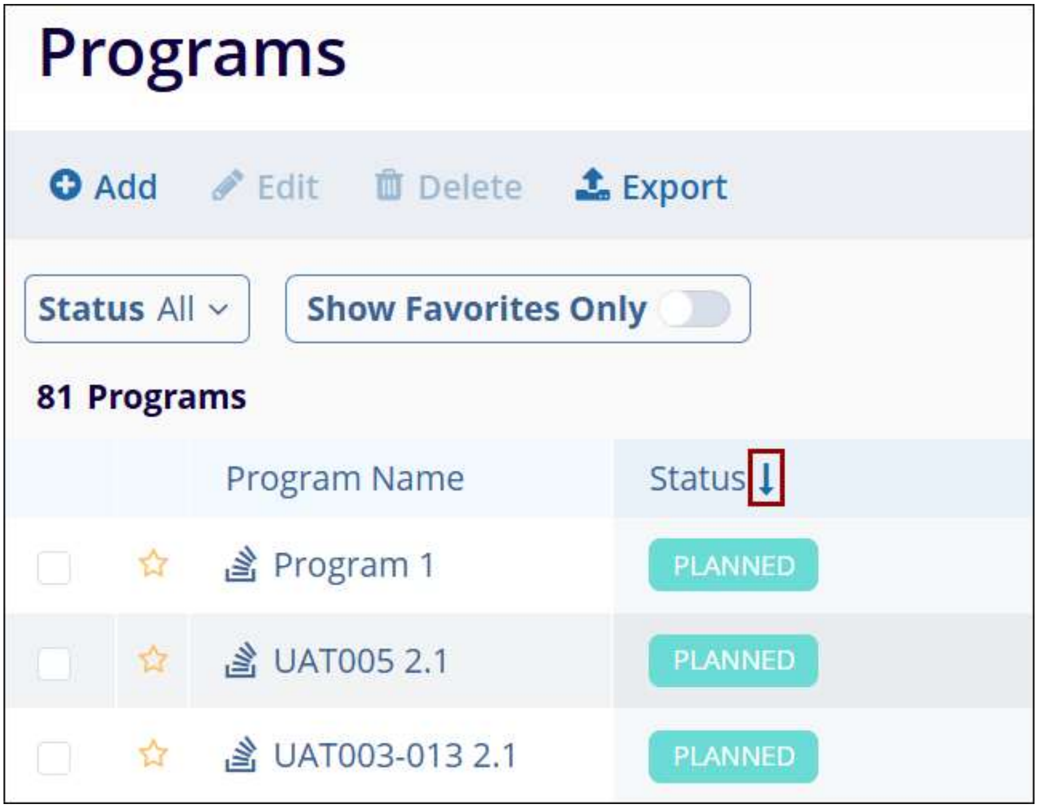


Figure: Sort column in ascending and descending order

Marking a Program as Favorite

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

1. On the Programs screen, click on the star icon next to the Program Name.

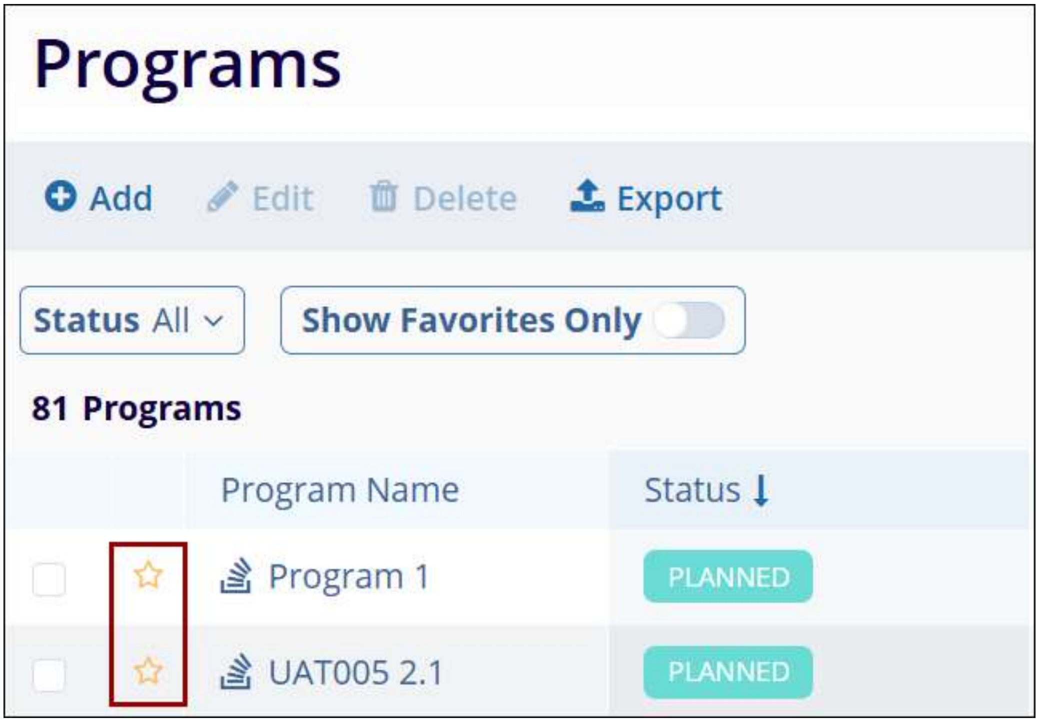


Figure: Mark as Favorite

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

Product at a Program Level

To add a product at a program level, follow the steps below.

1. On the Programs screen, select a program by clicking on the product name. This opens the Program Details screen.
2. Click on 'Products' from the left-hand navigation menu.
3. On the Products screen, click on the +Add button.
4. On the Add Product screen, select a product from the available dropdown options.
5. Click on the '**Add'** button once the required product record is selected.

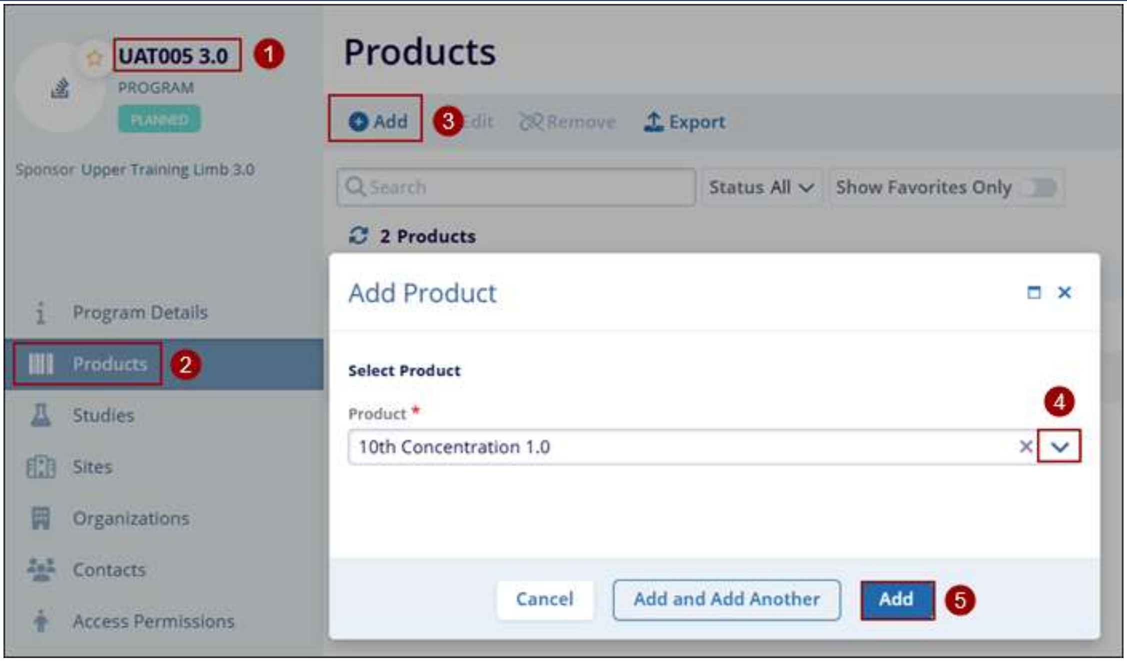


Figure: Add Product at a Program level

Studies at a Program Level

Studies linked to a specific program are displayed on the Studies screen within that program. To make a study visible within a program, it must first be associated with the study during the study creation process.

To edit a study associated at a program level, follow the steps below.

1. On the products screen, select a program by clicking on the program name. This opens the Program Details screen.
2. Click on '**Studies'** from the left-hand navigation menu.
3. Select the particular study by clicking on the checkbox and click on the Edit button.
4. Refer to the Edit Studies section for a detailed process of editing study information.

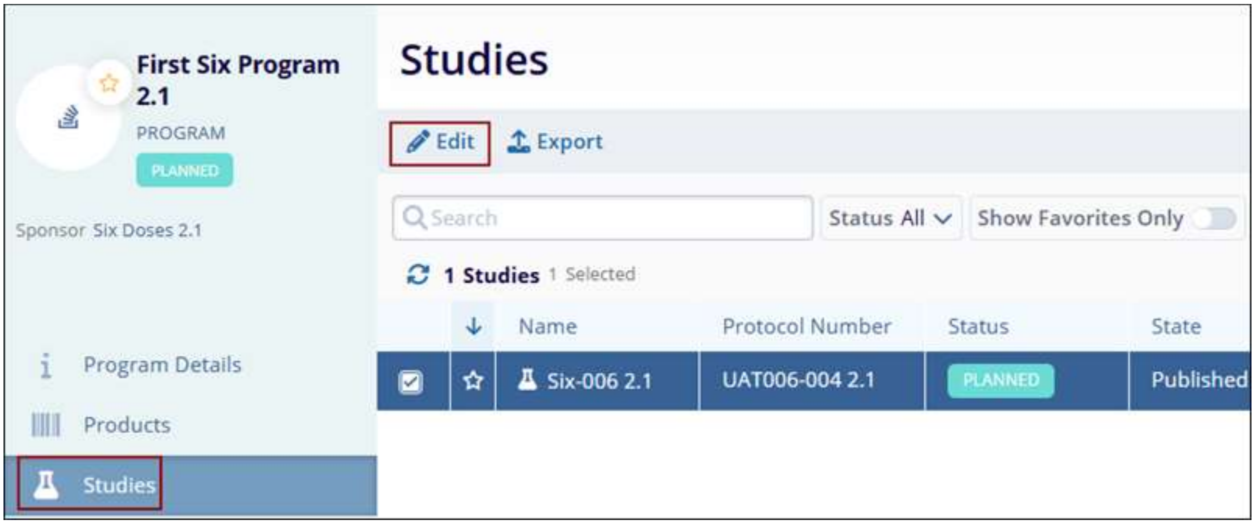


Figure: Edit Study at the program level

Sites at the program level

Sites associated with the Study are automatically added at the program level.

To edit the site details, follow the steps below.

1. On the programs screen, select a program by clicking on the program name. This opens the Program Details screen.
2. Click on '**Sites'** from the left-hand navigation menu.
3. Select the particular site by clicking on the checkbox and click on the Edit button.
4. Refer to the Editing a Site in Study section for a detailed process of editing study information.

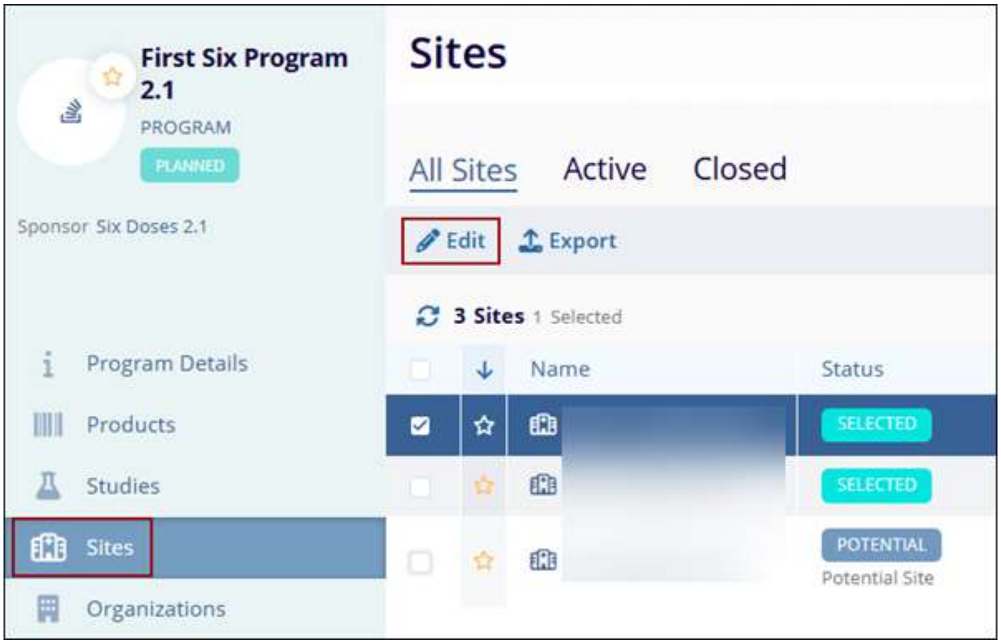


Figure: Edit Site at the Program level

Organization at the Program Level

To add an organization at the program level, follow the steps below.

1. Navigate to the Program Details screen by selecting an individual program.
2. Click on 'Organizations' from the left-hand navigation menu.
3. On the Organization screen, click on the +Add button.

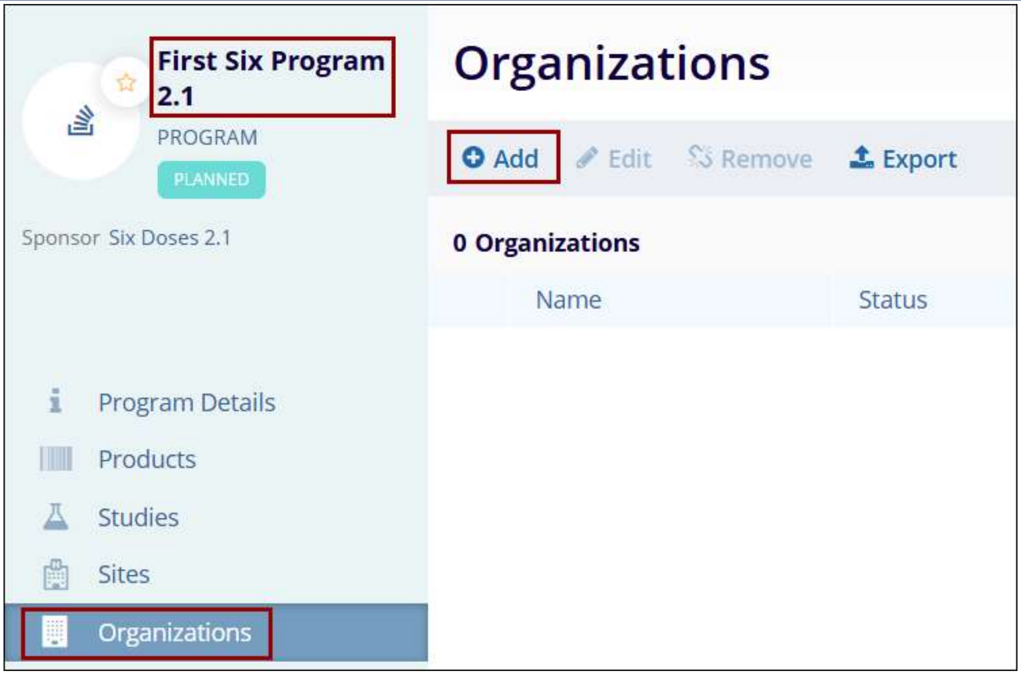


Figure: Add Organization at the program level

4. To add an existing organization, click on the '**Search for the Organizations'** search box and select an organization from the available options and click on the Add button.

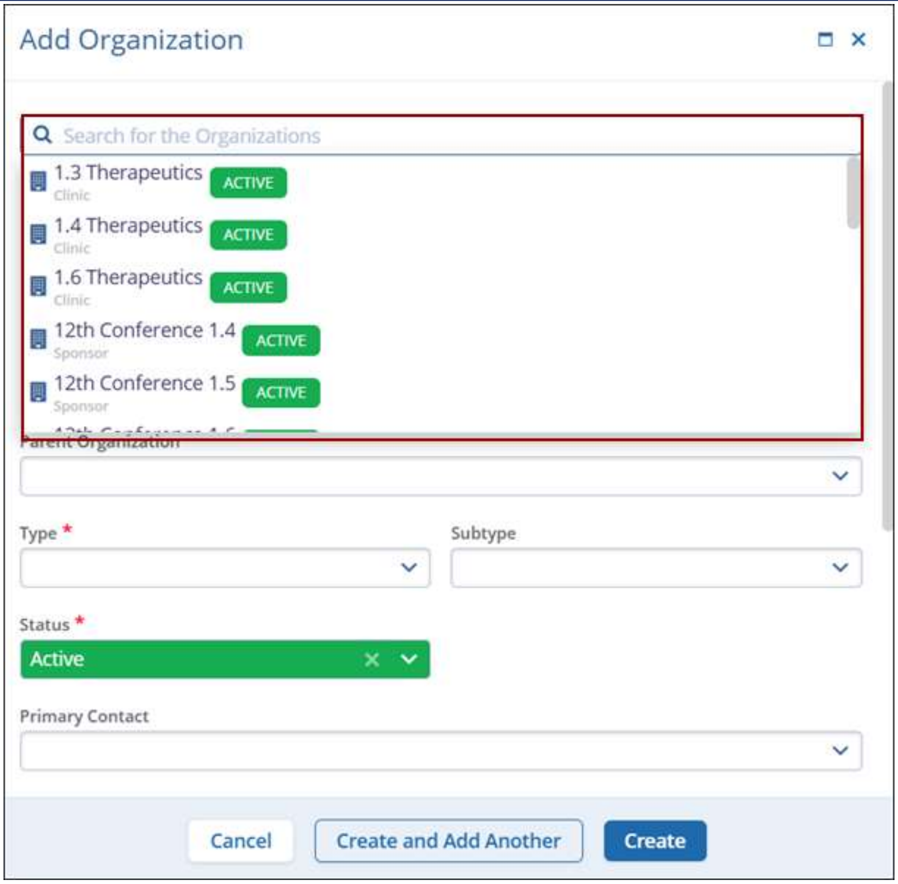


Figure: Add existing organization

5. To Create, Edit, Remove, and Export organization details, refer to the relevant subsections in [Chapter 8. Organizations.](#)

Contacts at Program Level

To add contacts at a program level, follow the steps below.

1. Navigate to the Program Details screen by selecting an individual program.
2. Click on ‘Contacts’ from the left-hand navigation menu.
3. On the Contacts screen, click on the +Add button.

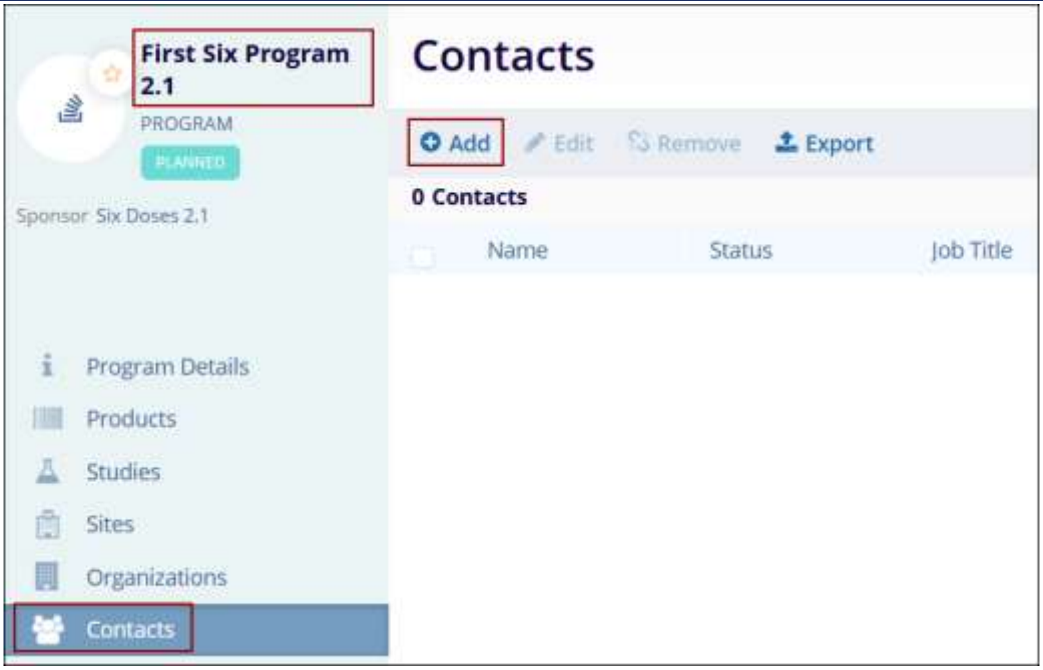


Figure: Add Contacts at Program Level

4. To add an existing contact, click on the '**Search for Contacts'** search box and select a contact from the available options and click on the Add button.

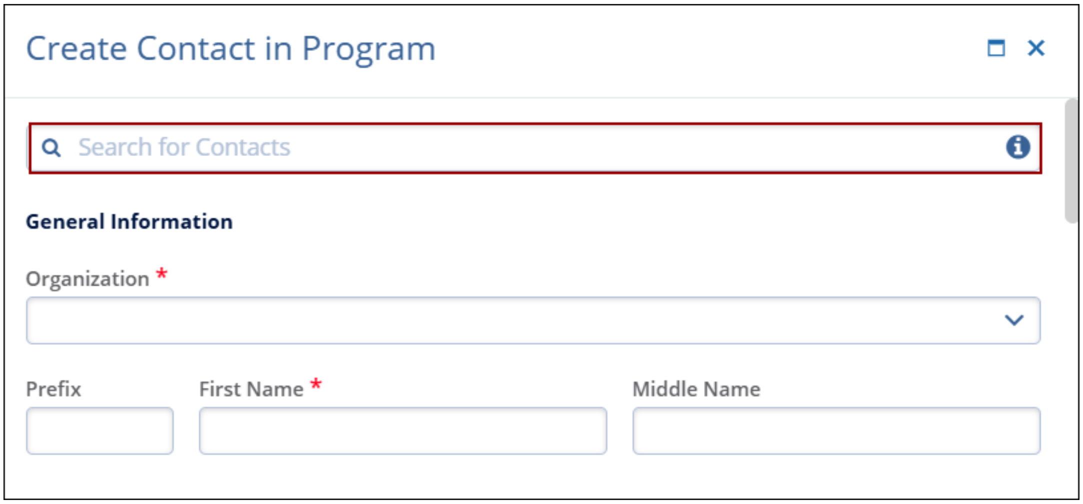


Figure: Add Existing Contact

Note: Only Contacts from organizations associated to the program are included in this list.

5. To Create a new contact, Edit, Remove and Export the contact details, refer to the relevant sections from Chapter 9. Contacts.

Access Permissions

To manage the access permissions at the Program level, follow the steps below.

1. Navigate to the Program Details screen by selecting an individual program.
2. Click on 'Access Management' from the left-hand navigation menu.
3. On the 'Access Management' screen, click on the +Add button.

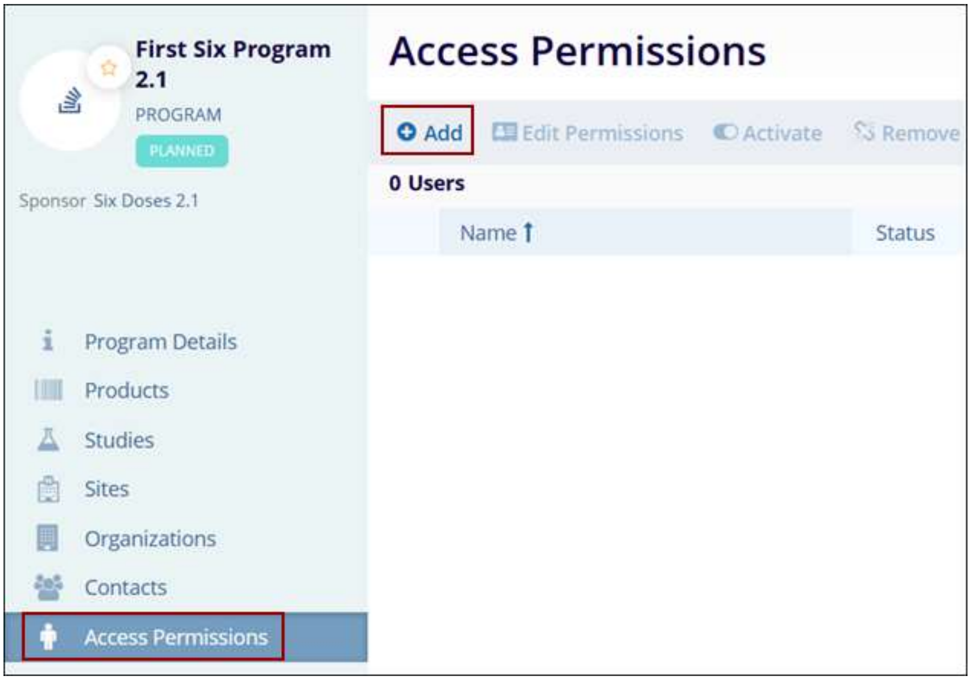


Figure: Access Permissions at Program Level

4. On the 'Add User Program Access Permission' screen, add the required number of users by from the dropdown list.
5. Optionally enable the 'Pending' toggle switch.
6. Within the 'Set Permissions' section, click on the 'Simple' option and select the permissions from the dropdown options.

<u>Edit Access Permissions</u>

To edit access permissions, follow the steps below.

1. Select a user by clicking on the checkbox.
2. Click on the Edit Permissions button from the top menu bar.

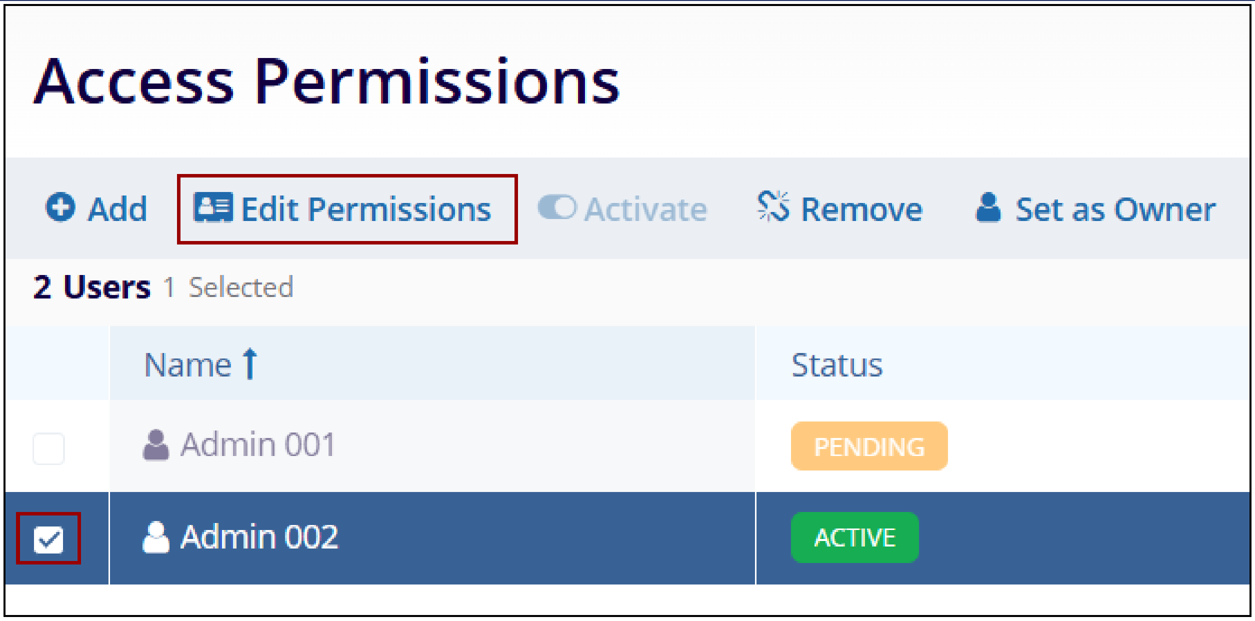


Figure: Edit Access Permissions

3. On the Edit Programs Permissions screen, make the required edits
4. Click on the Save button.

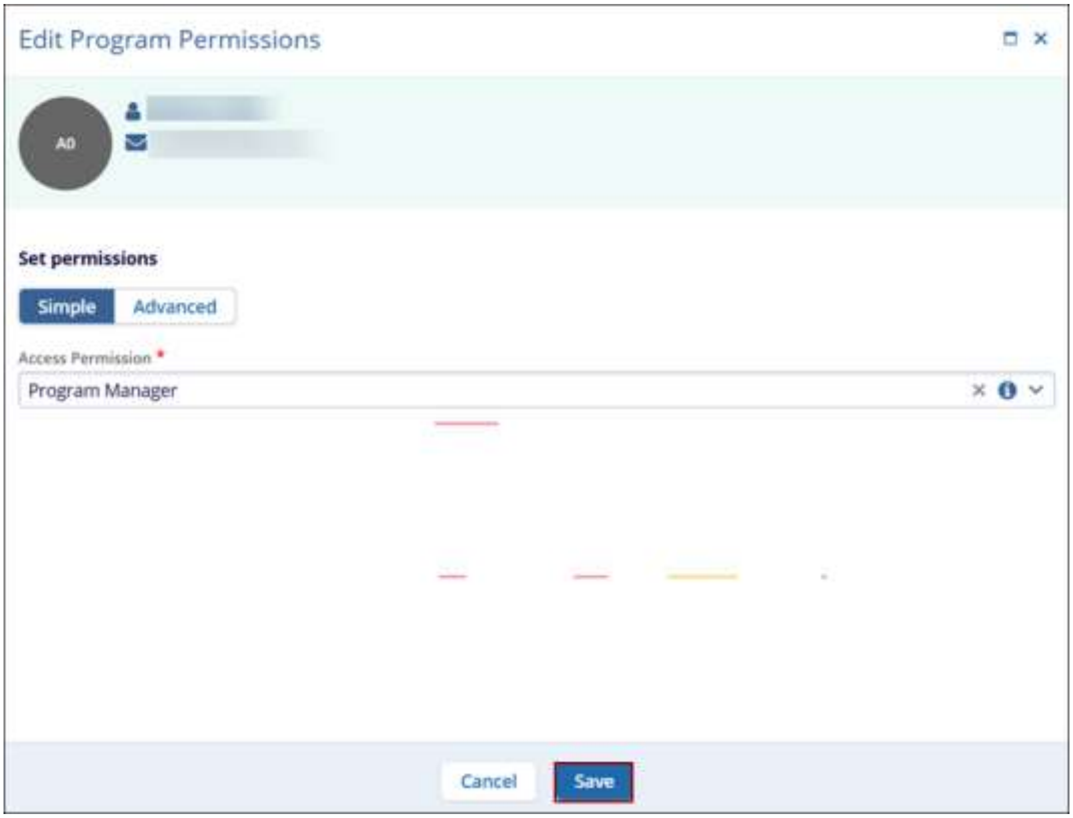


Figure: Edit Program Permissions

Activate

1. Select a user with Pending status by clicking on the checkbox.

2. Click the 'Activate' toggle switch from the top menu bar.
3. Click on the 'Activate' button on the confirmation popup.

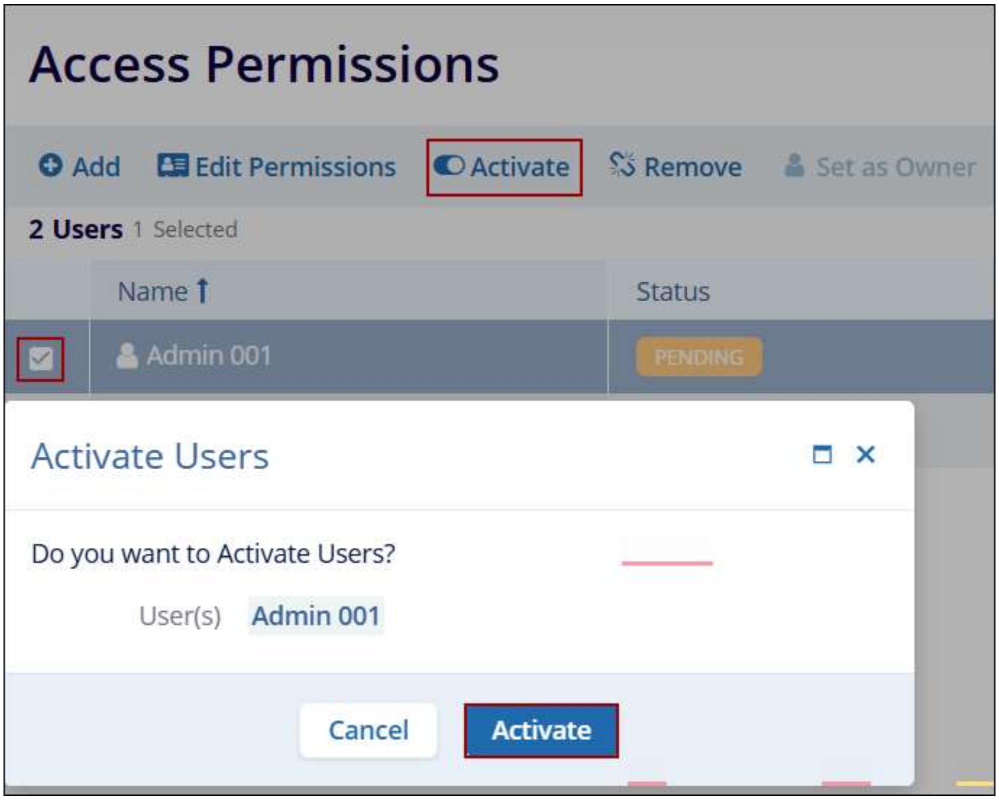


Figure: Activate Users

Remove

1. Select a user by clicking on the checkbox.
2. Click on the Remove button from the top menu bar
3. Click on the Remove button on the 'Remove Users from Access Permissions' confirmation popup.

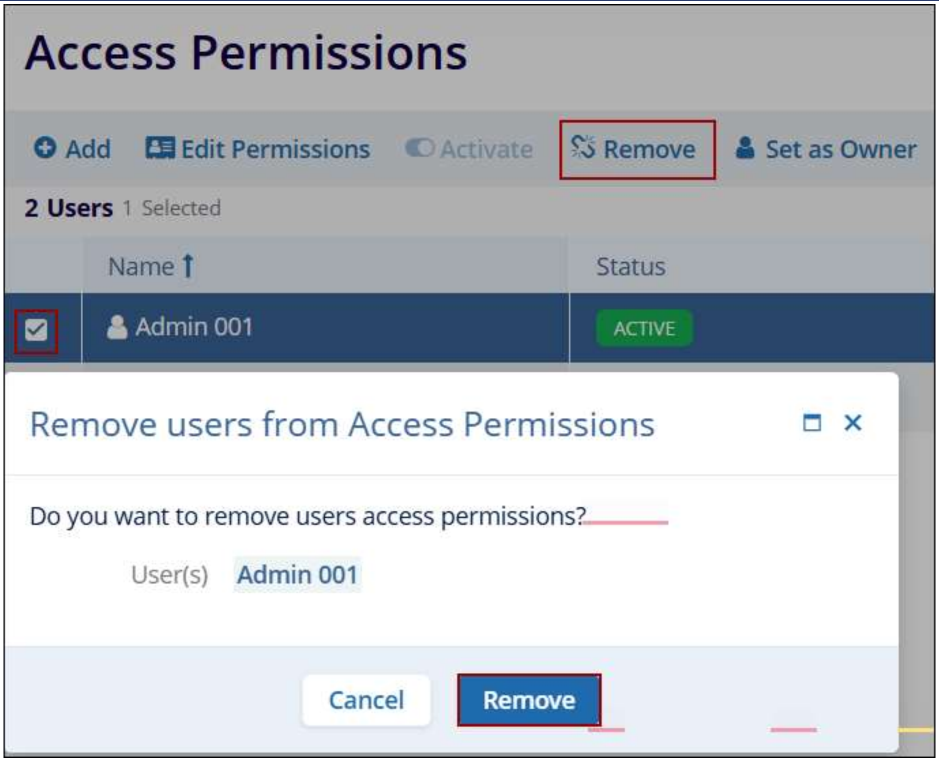


Figure: Remove Users from Access Permissions

<u>Set as Owner</u>

1. Select a user by clicking on the checkbox.
2. Click on the Set as Owner from the top menu bar
3. Click on the Change button on the confirmation popup.

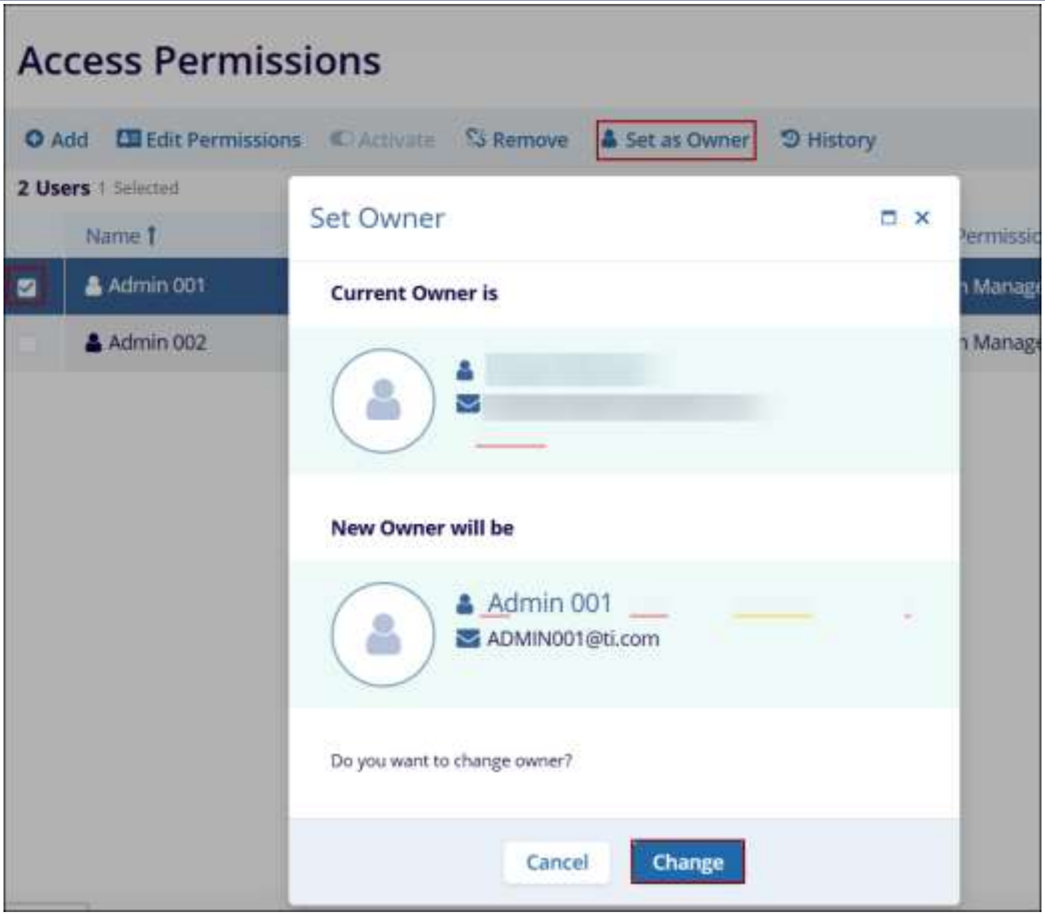


Figure: Set as Owner

History

1. Select a user by clicking on the checkbox.
2. Click on the History from the top menu bar
3. On the History screen, click on Export to retrieve the Access Permission History details of the program.

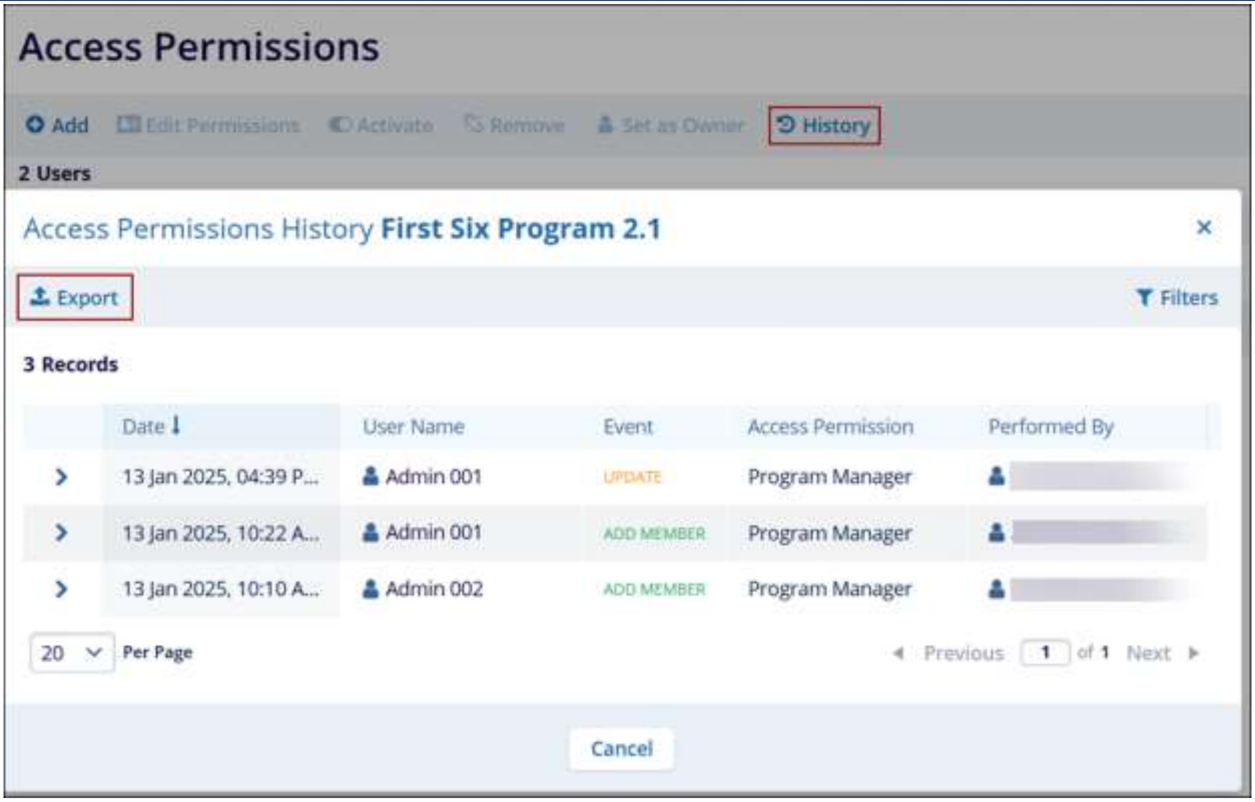


Figure: Program Access Permissions History

CHAPTER 6. PRODUCT SM

This section describes the Product module in CTMS.

Creating a Product

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

1. From the left-hand navigation links, select Product which will open the Products screen with a list of existing products.
2. Click on +Add from the top menu bar.
3. On the Create Product window, fill in all the mandatory metadata.

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

	Note: • The Status field will be displayed in a different color depending upon the status selected. • A tooltip showing the status description is visible after hovering over the icon.
Status Date*	Enter the status date
Sponsor*	Select the sponsor's name from the available dropdown options.
Indications	Select one or more indications from the available dropdown options. NOTE: The Indications differ from client to client and are configured by Super Admin users.
Description	Enter a suitable description for the product.

4. Once all the mandatory metadata fields are entered and reviewed, click on Create and the newly created product appears on the Products home screen.

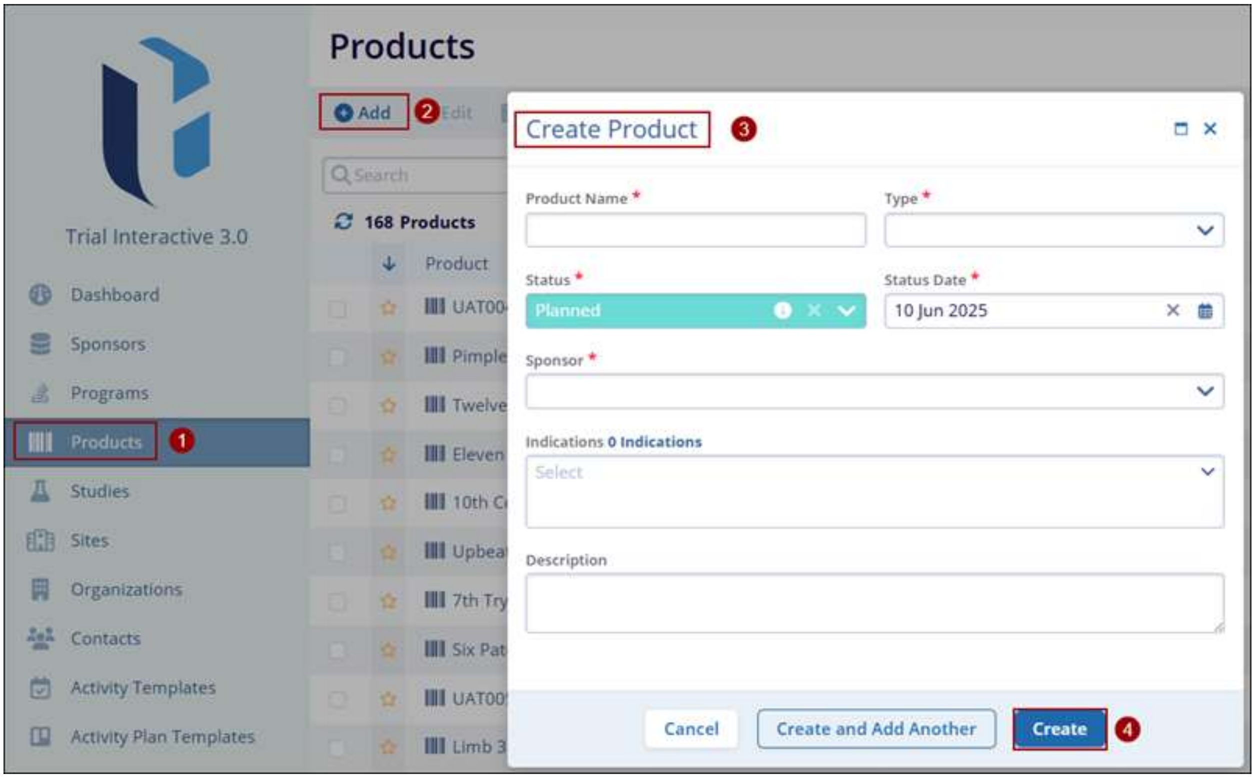


Figure: Create Product

Important Behavior of Creating a Product

- An error appears 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 saves the initially created product and enable creating a new product right away.
- If the user selects Cancel, the system discards all the changes made to the Create Product window.

Editing and reviewing a product

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

1. From the left-hand navigation links, click on the Products. This opens the Products screen with a list of existing products.
2. There are two methods to edit the product details.

Method 1

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

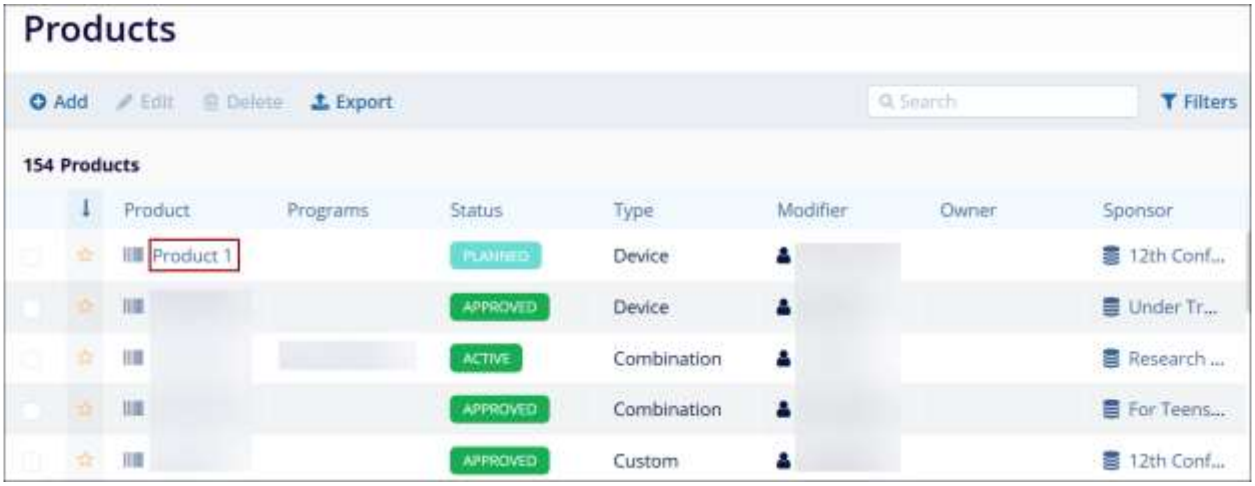


Figure: Select a product to edit

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

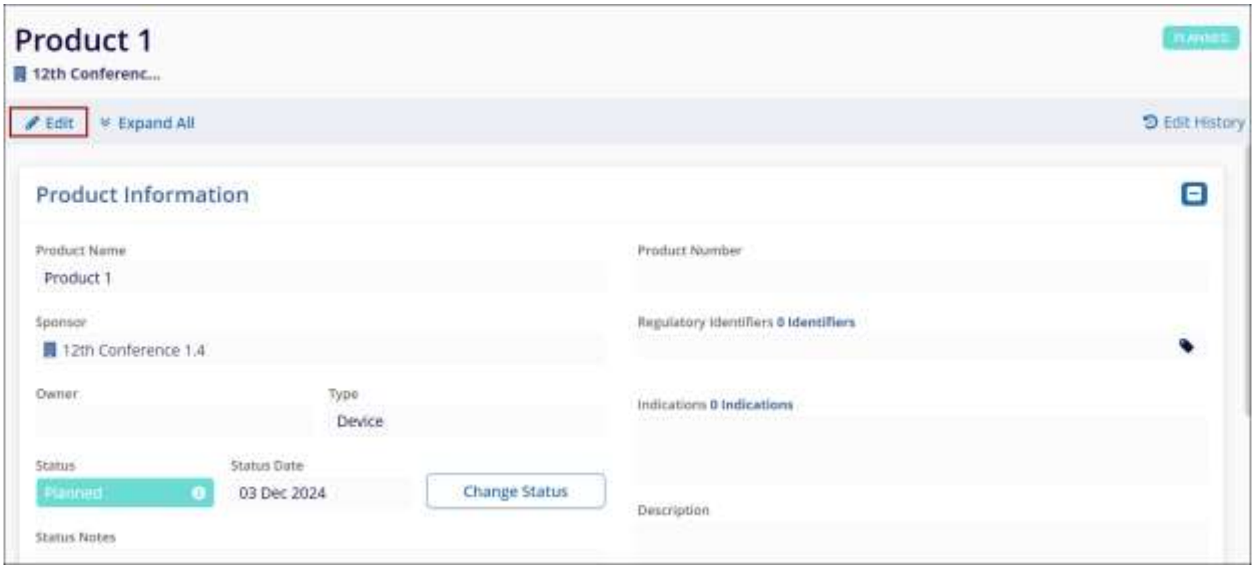


Figure: Product Details screen

3. Make the required edits in the Product Information section along with the following.

   a. Change Status:

      i. Click on the Change Status button.

      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 the Change button. The respective status-related field will be updated with the latest status, date, and notes if any.

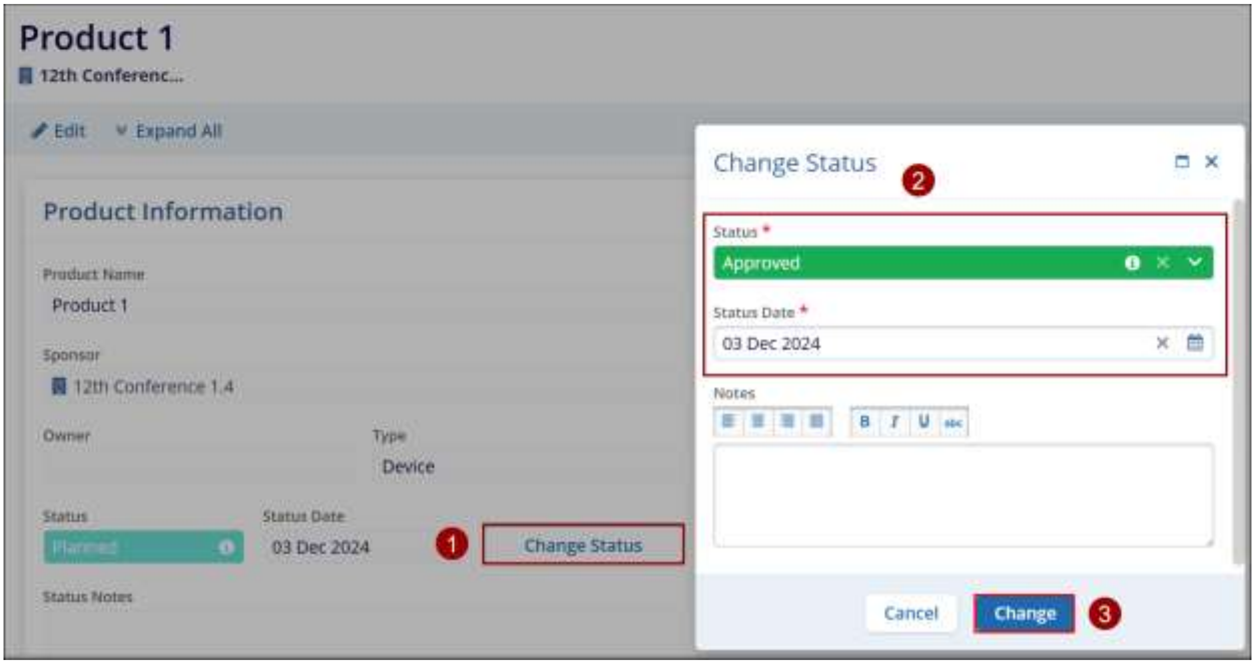


Figure: Change Status

   b. Status History:

      i. Click on the Status History icon.

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

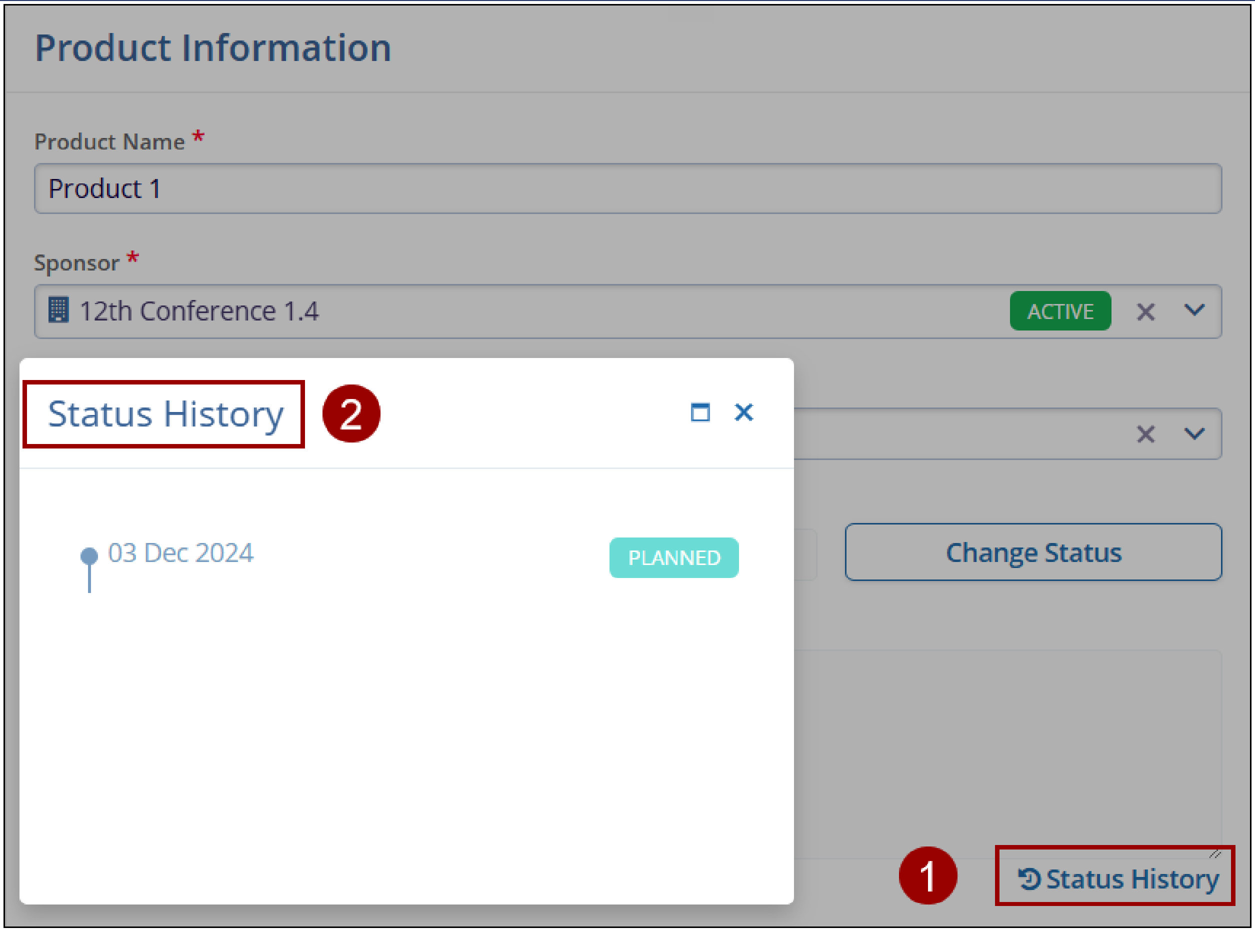


Figure: Status History

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

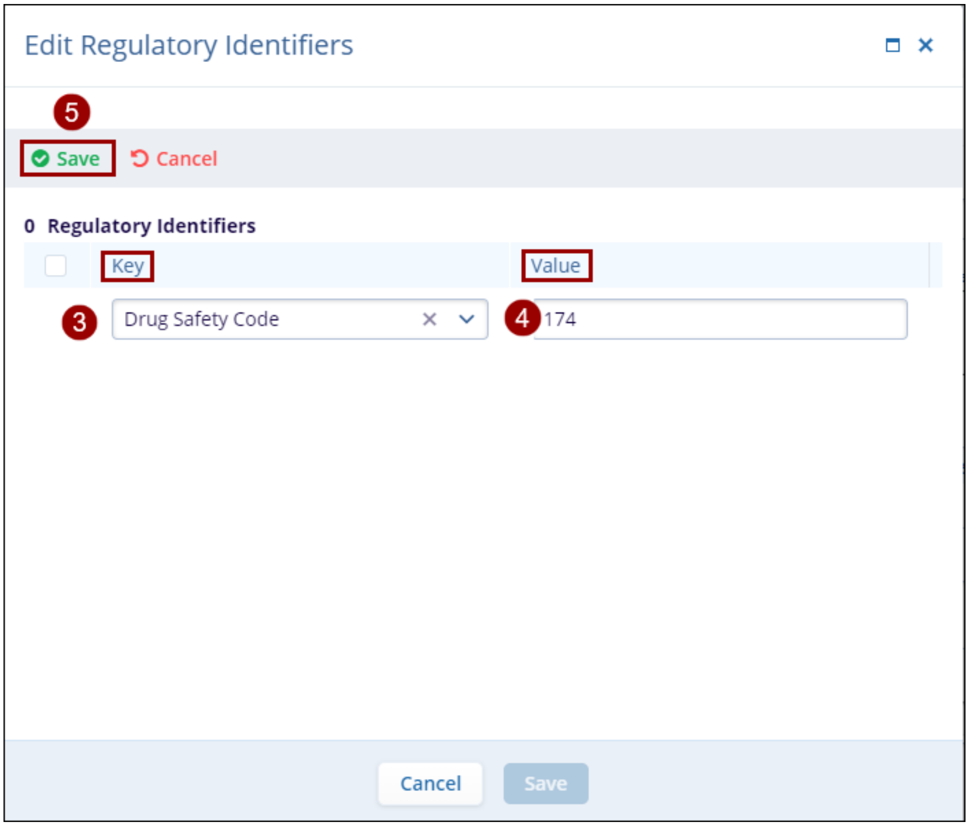


Figure: Add a value to the Key and Value fields

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

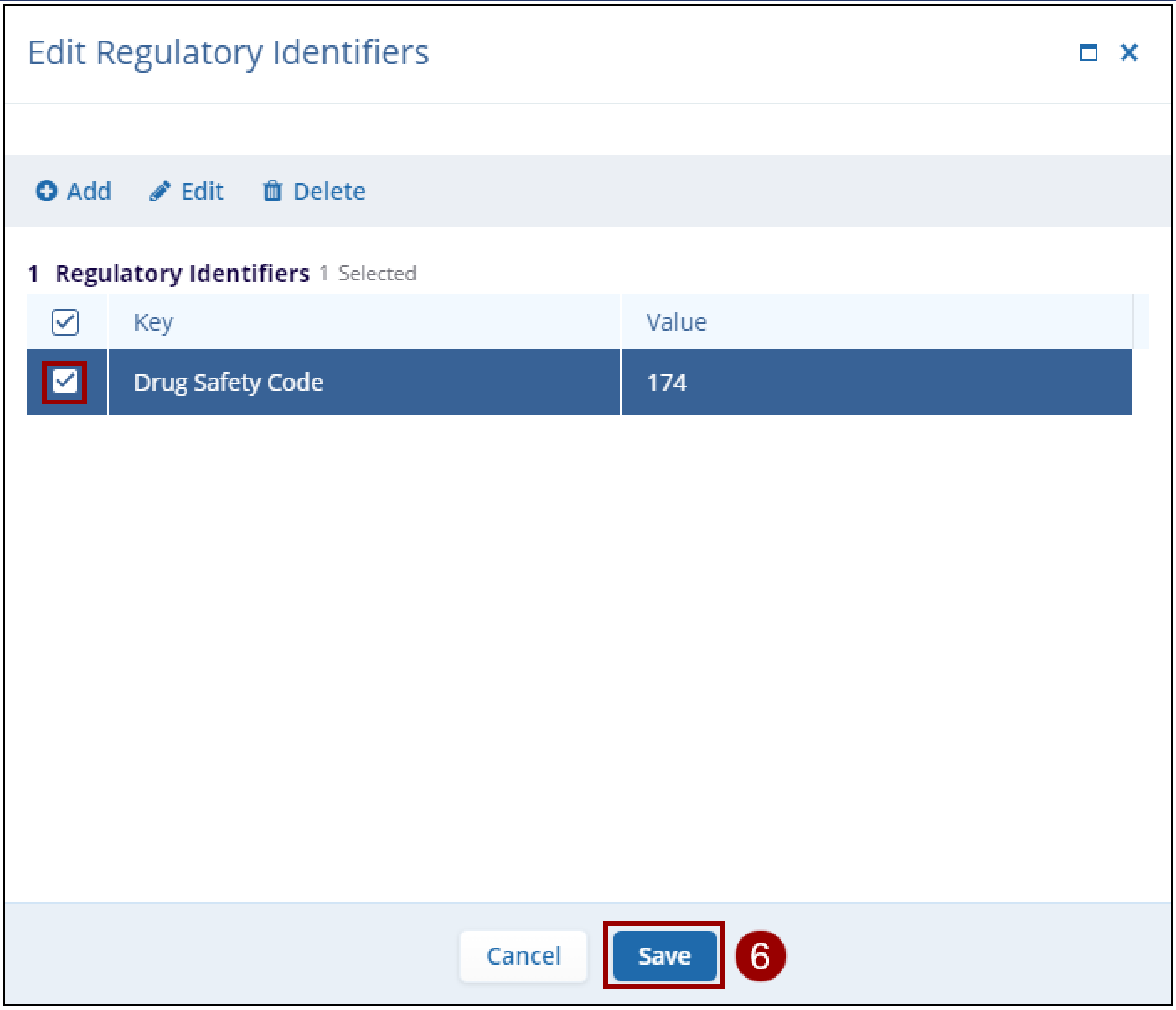


Figure: Save the new Regulatory Identifier

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

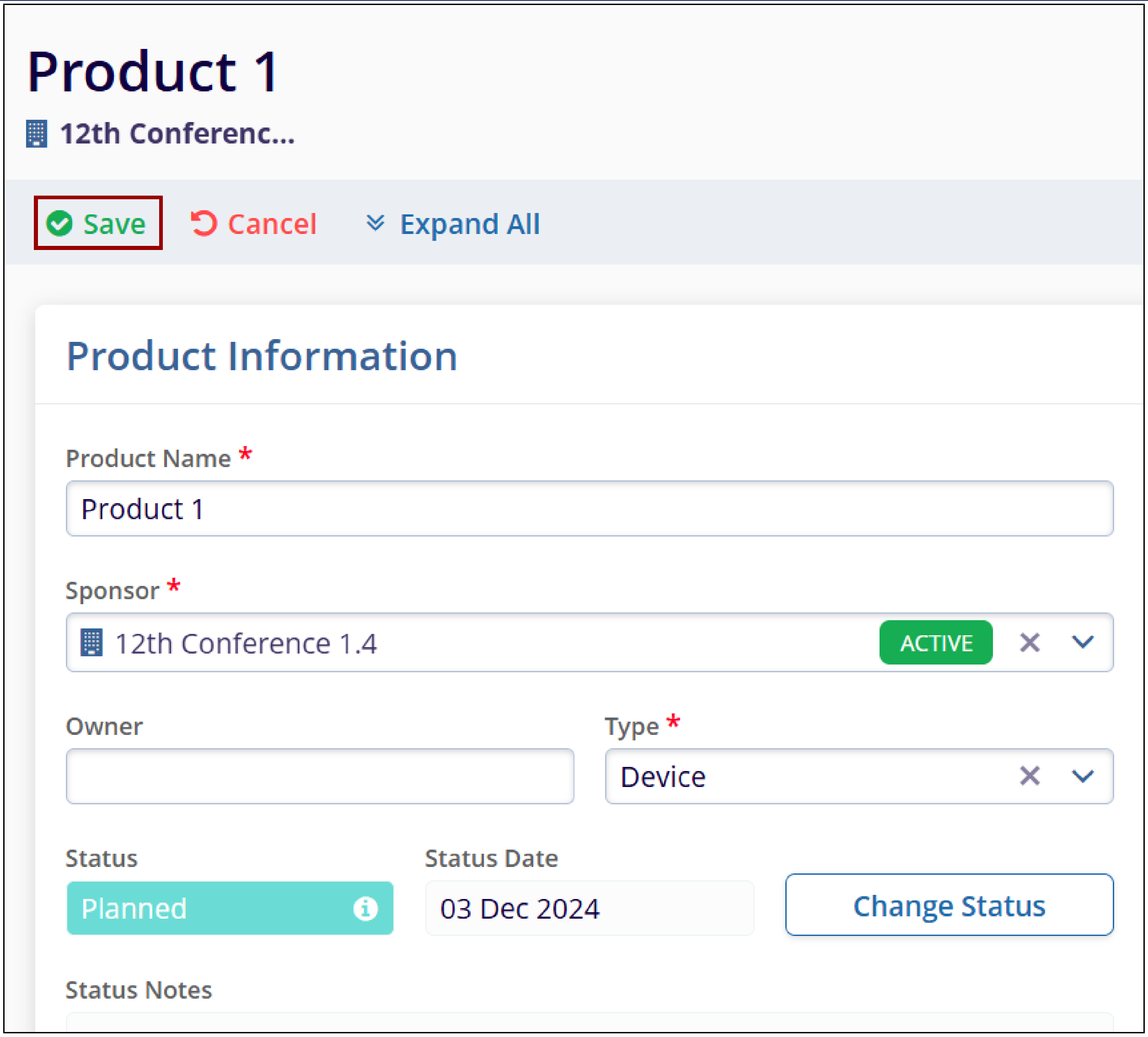


Figure: Save the edited product details

Method 2

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

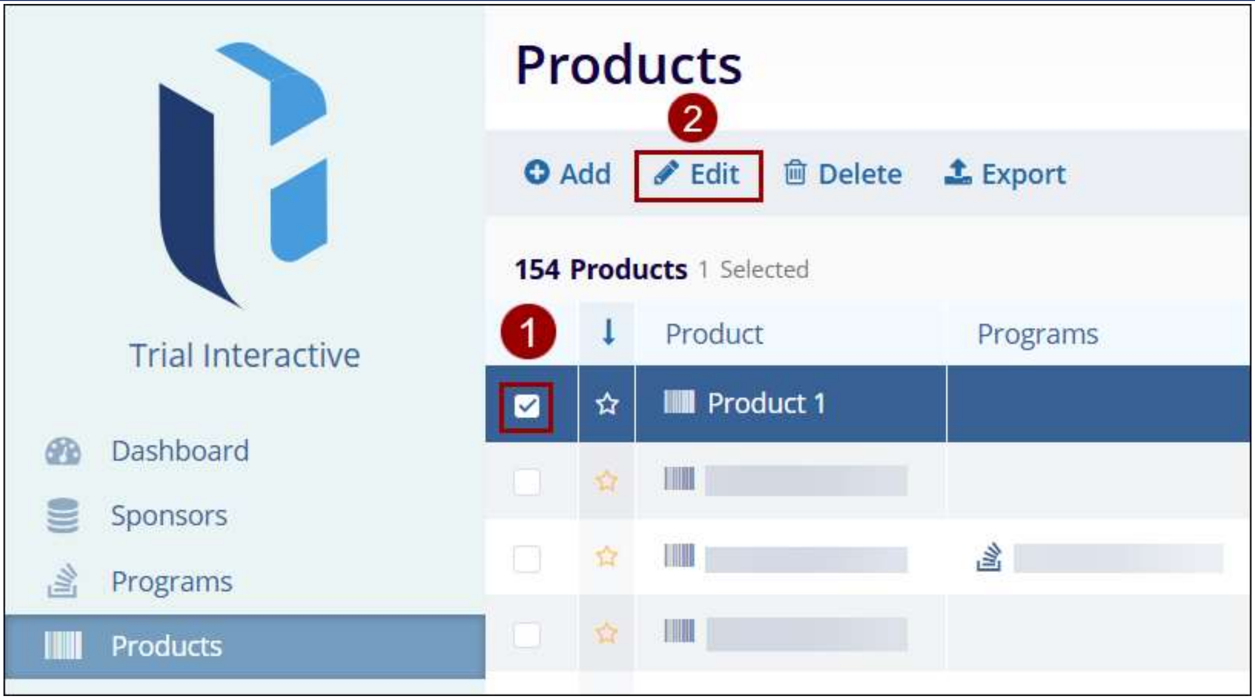


Figure: Edit Product details

Deleting a Product

To delete a product, follow the steps below.

1. Select a product (s) by clicking on that product checkbox.
2. Click on the Delete icon in the top menu bar.
3. On the Confirmation popup, click on Delete to confirm the product deletion.

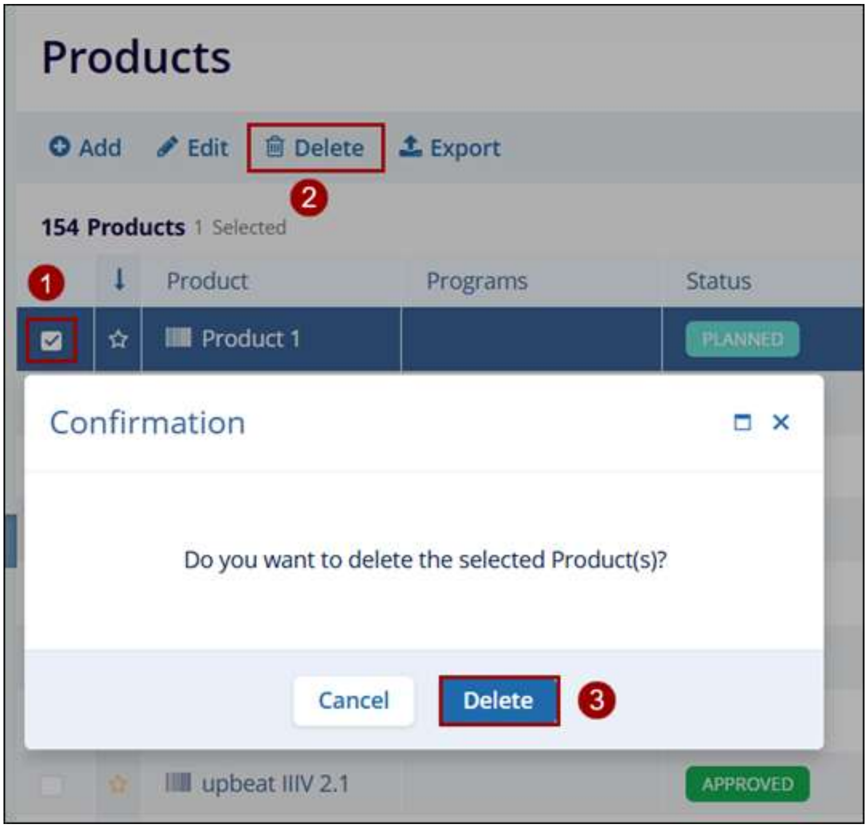


Figure: Delete product

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 Products screen, follow the steps below.

1. To apply filters to the Products screen, click on Filters situated on the right-hand side of the Products screen.
2. Click on the All filters 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.

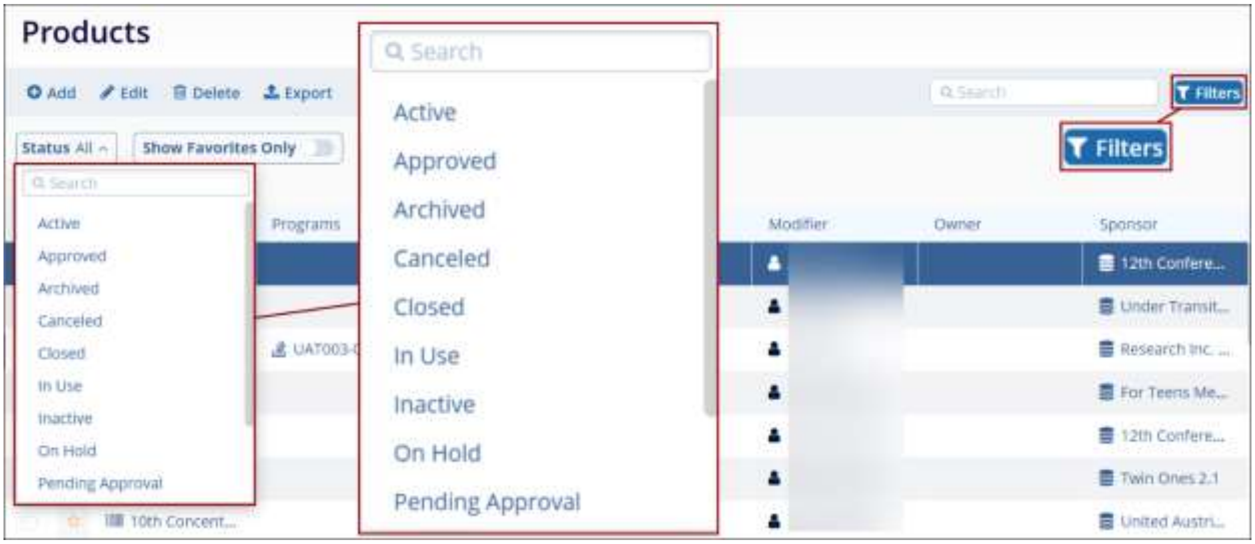


Figure: Apply Status filter

3. Switch the Show Favorites Only toggle button to display records marked as favorites.

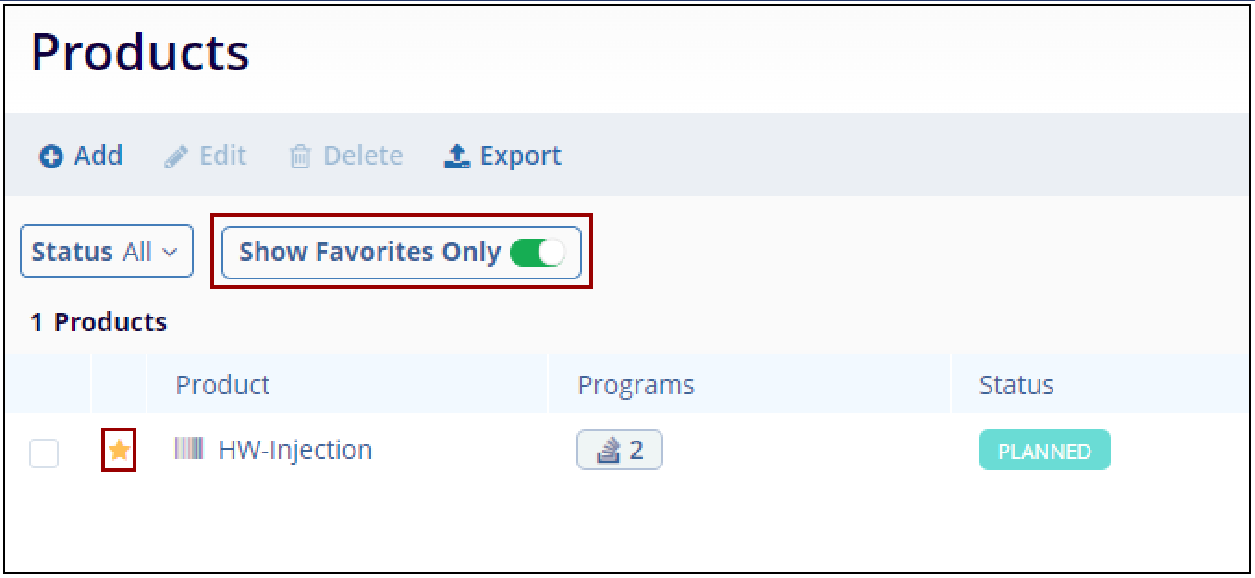


Figure: Show Favorites Only toggle

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

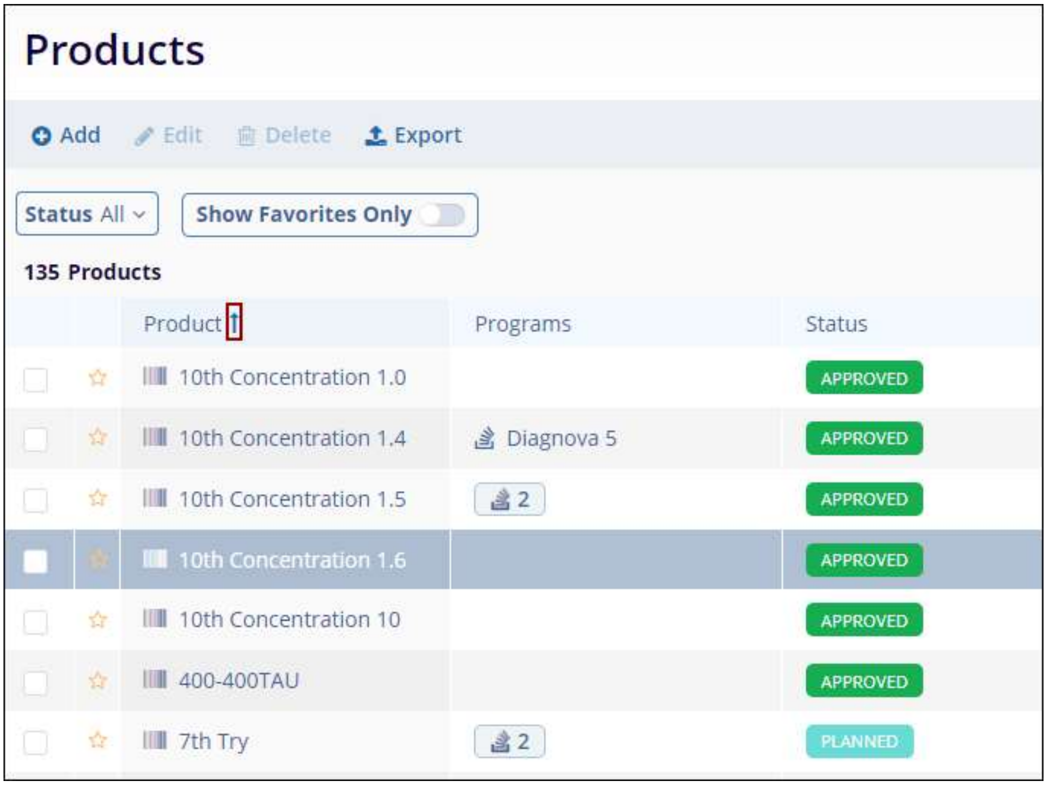


Figure: Sort column in ascending and descending order

Marking a product as Favorite

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

1. Click on the star icon next to the product to mark it as favorite.

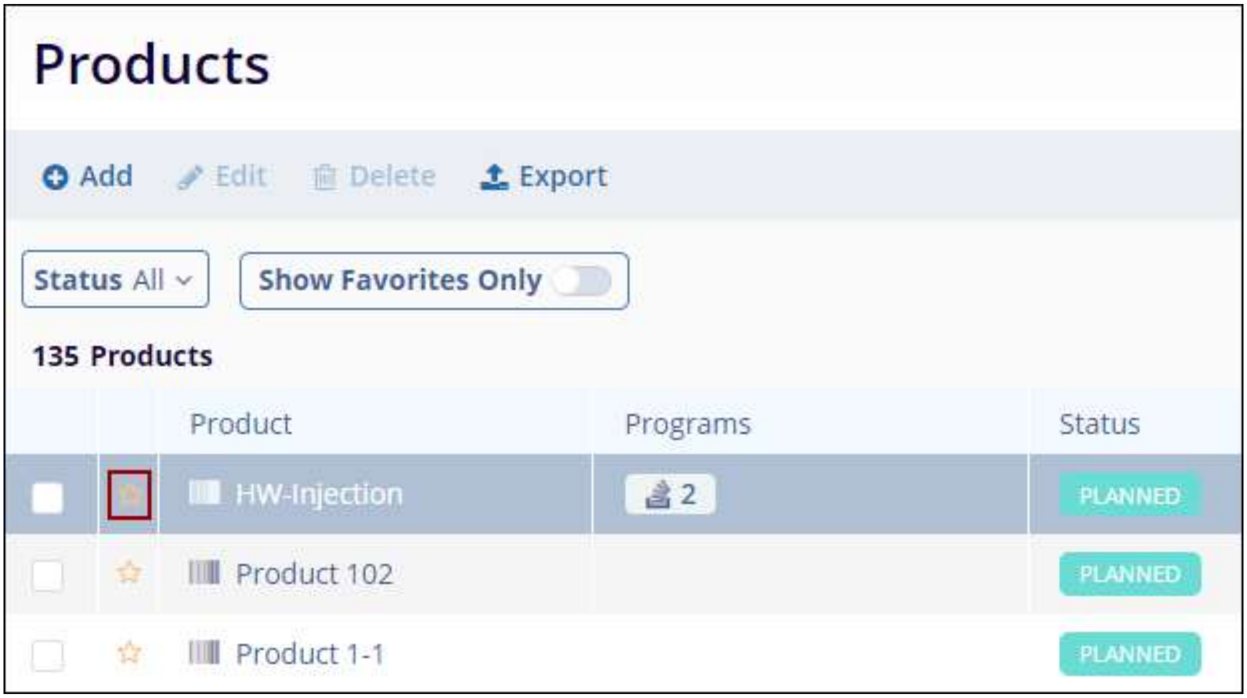


Figure: Mark as Favorite

2. Click on the same icon again to remove that product from the favorites list. Enable the Show Favorites Only toggle switch to display products marked as favorites.

Important

Users can add Programs, Studies, Sites, Organizations and Contacts at a product level by accessing the Product Details screen.

To access the product details screen, follow the steps below.

1. On the Products screen, click on the product name.

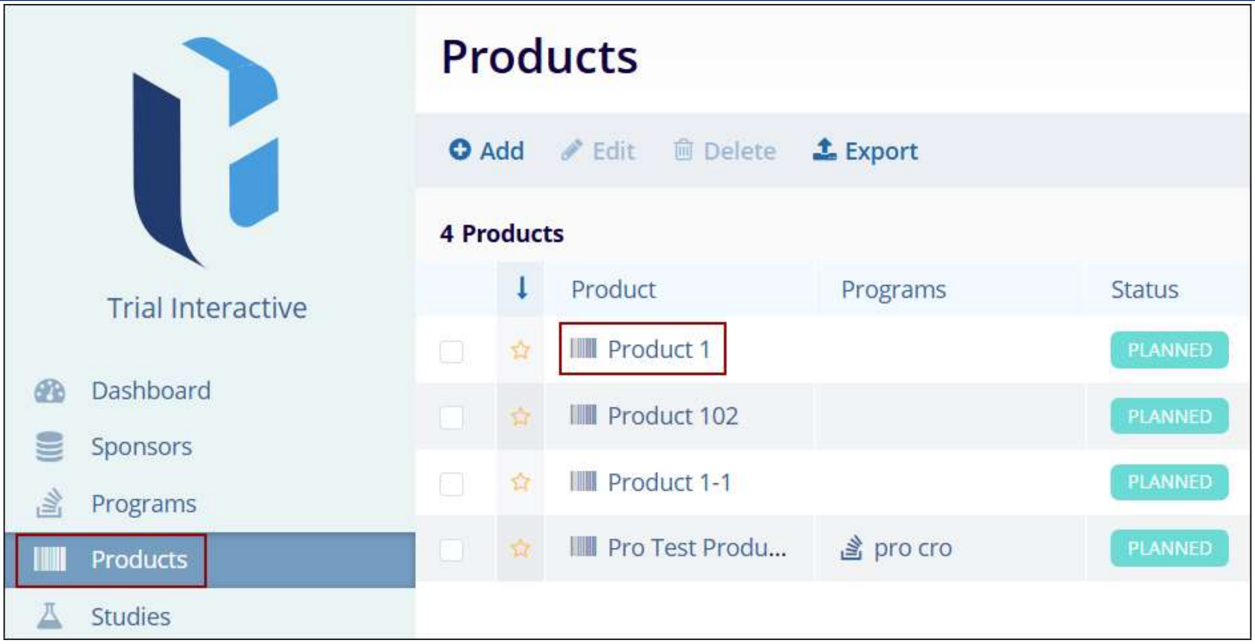


Figure: Select Product

2. On the Product Details screen, select the relevant links from the left-hand navigation menu.

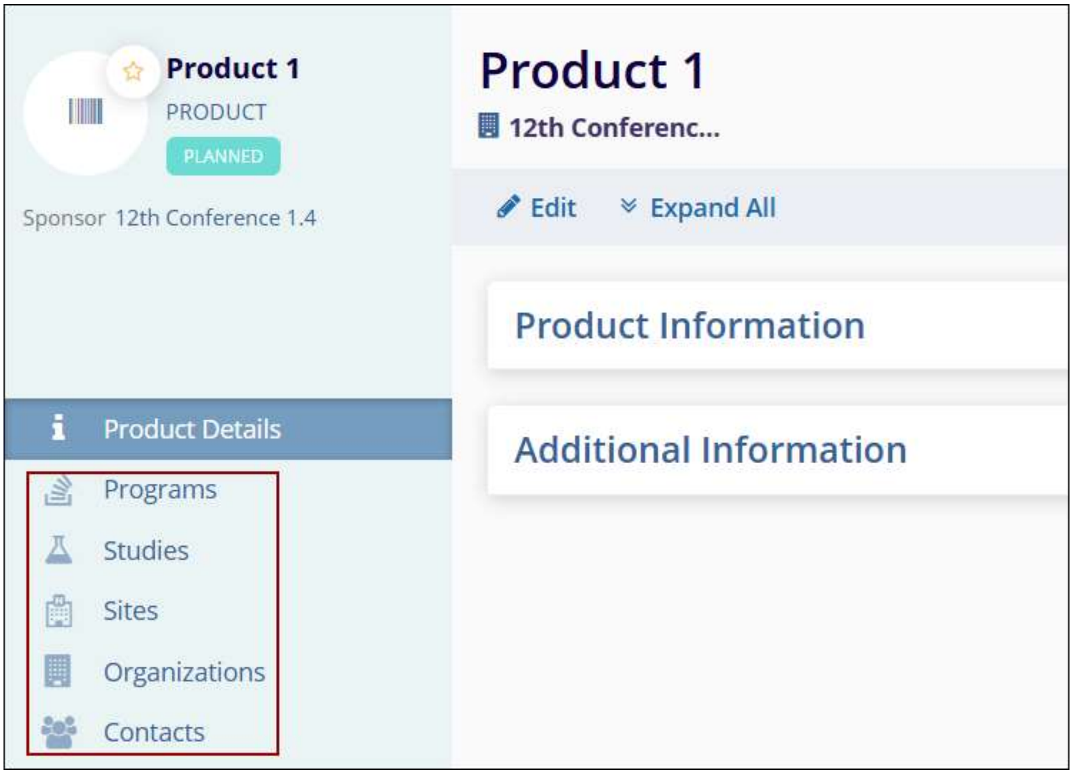


Figure: Product Details

Note: Refer to the relevant sections in this document to add programs, studies, sites, organizations and contacts within a product.

CHAPTER 7. STUDIES SM

This section describes the Studies module in CTMS.

Pre-Requisites

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

Navigation

To navigate to the studies module, follow the steps below.

1. From the left-hand navigation pane, click on the Studies link. This opens the Studies screen with a list of existing studies in CTMS.

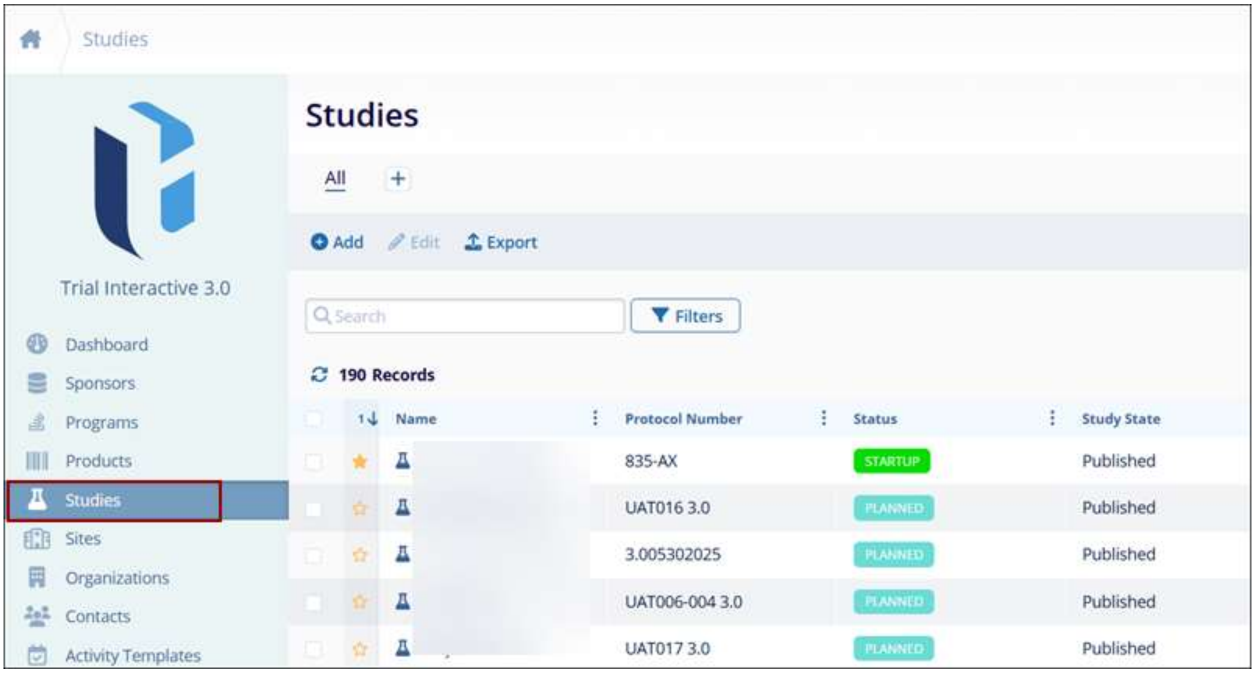


Figure: Navigate to Studies

Add Studies

To add a new study, follow the steps below.

1. Click on the '**Add'** button from the top menu bar.

Figure: Add Studies

2. Enter data in the following fields in the Create Study window.
   a. Sponsor*: Select a sponsor from the dropdown list
   b. Protocol Number*: Add a protocol number to the study.
   c. Study Name: Provide a name to the study. The study name is automatically generated when left blank.
   d. Protocol Title*: Enter the protocol title.
   e. Types: Select multiple records from the available dropdown options.
   f. Owner: This field is not editable and displays the name of the user creating a study.
   g. Status*: Select a status from the dropdown menu. The dropdown menu displays the statuses configured in the Settings section for Studies.
   h. Status Date*: Add the status date.

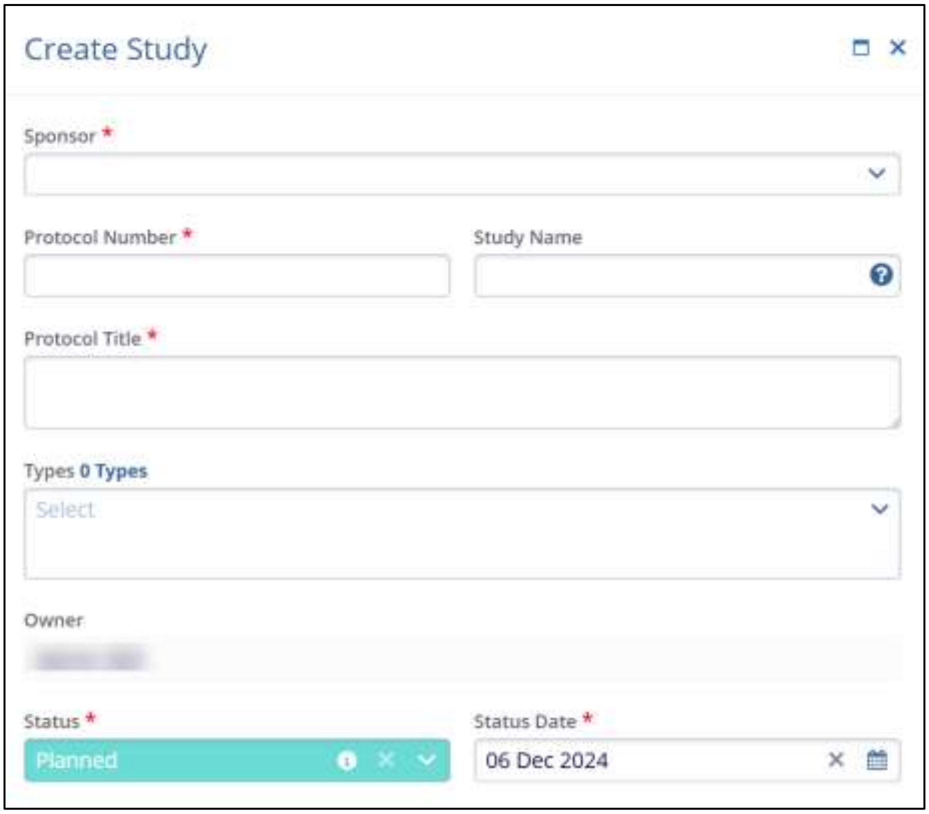


Figure: Create a Study

i. Primary Program: Select a program from the available dropdown options. The Primary Program dropdown displays all programs created at the domain level.
j. Primary Product*: Select a product from the available dropdown options. The Primary Product dropdown displays all products created at the domain level.
k. Phase*: Select the phase from the available dropdown options.
l. Design*: Select designs from the available dropdown options.
m. eTMF Location*: Select eTMF location from the available dropdown options.

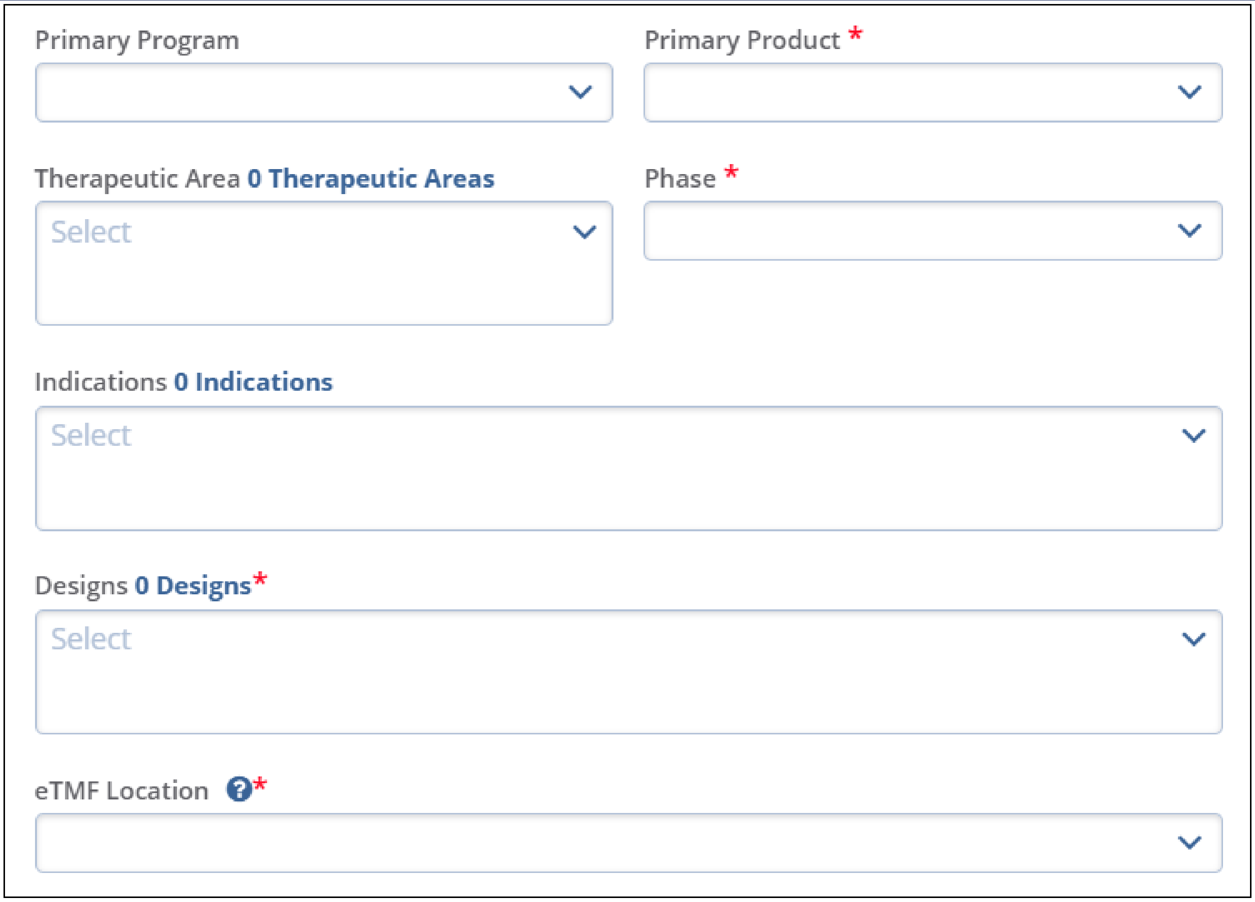


Figure: Additional Study Information

3. Click the ‘**Toggle’** buttons for Virtual Study, Subject Tracking, and Is this a blinded trial. These fields are optional.
4. To create a study, click the ‘**Create’** button.

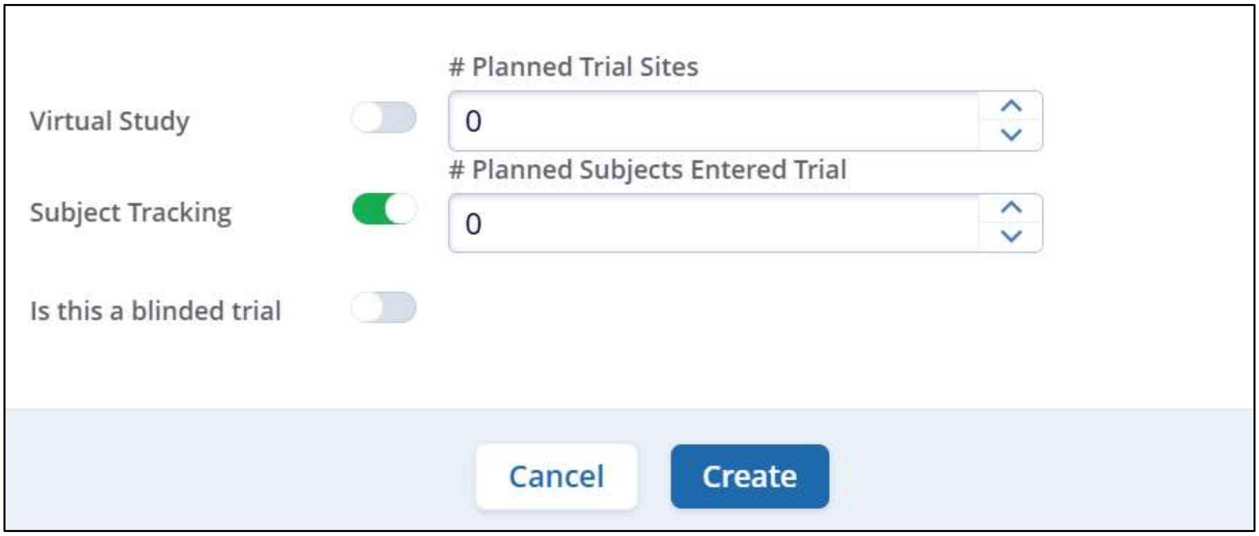


Figure: Create Study Fields

5. 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.

Figure: Create Study confirmation message

6. 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.

Important

- Indicate whether this is a blinded trial on the Study Details page. Although users can update this information after the study has been created, this is the first opportunity to specify that the study will include a blinded component.
- If any mandatory fields are missing, an error message appears when the user clicks the 'Create' button, listing the fields that require mandatory updates.

Edit Studies

To edit studies, follow the steps below.

1. Click on the check box next to the name of the study.
2. Click on the '**Edit'** button from the top main menu.

Figure: Edit Study

3. Make any necessary changes to the Study Details by expanding the following sections.
4. General Information:
    a. Protocol Number
    b. Study Name
    c. Sponsor
    d. Primary Program
    e. Virtual Study
    f. Study Number
    g. Additional Program(s)
    h. Study State
    i. Products

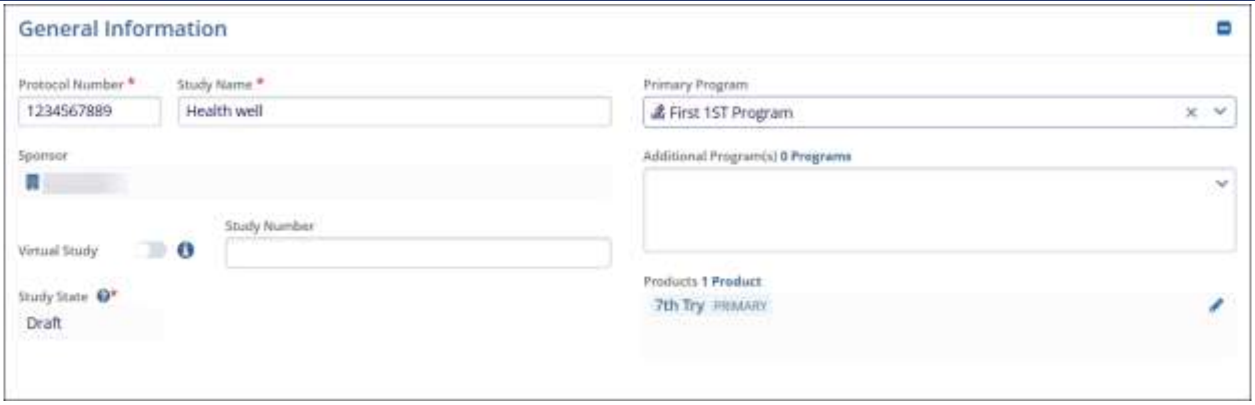


Figure: Study Details – General Information

5. Protocol Information

    a. Protocol Title*
    b. Protocol Summary
    c. Indications
    d. Phase*
    e. Types
    f. Mechanisms
    g. Objectives
    h. Designs*

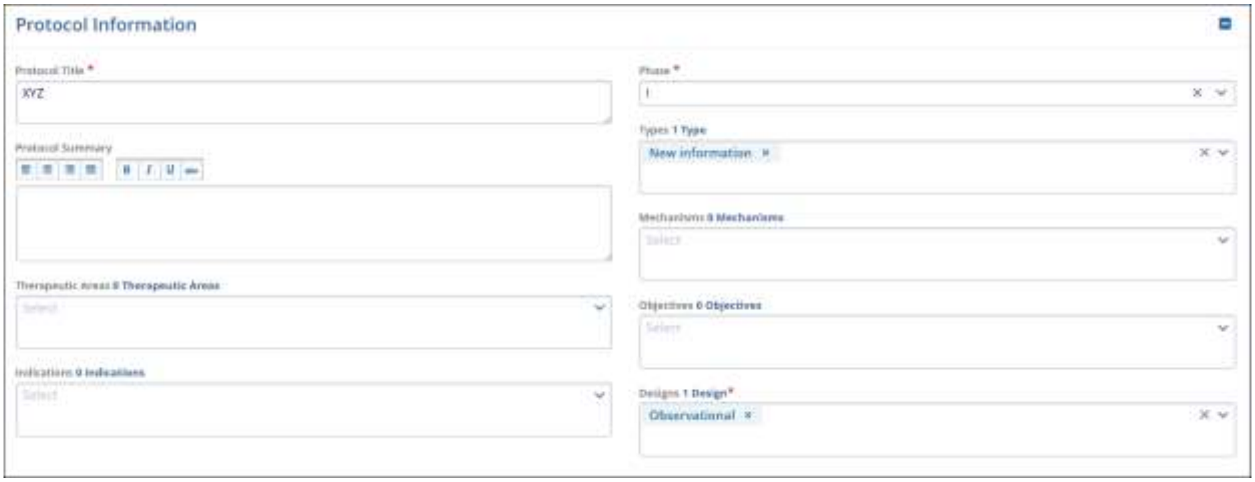


Figure: Study Details _Protocol Details

6. Project Management
    a. Status
    b. Status Date
    c. Status Notes
    d. Recently Completed Milestone
    e. Projected Start Date
    f. Projected End Date
    g. Actual End Date
    h. Owner

i. Database Lock Date
j. Recruitment Months
k. Site Recruitment Deadline
l. Subject Recruitment Deadline

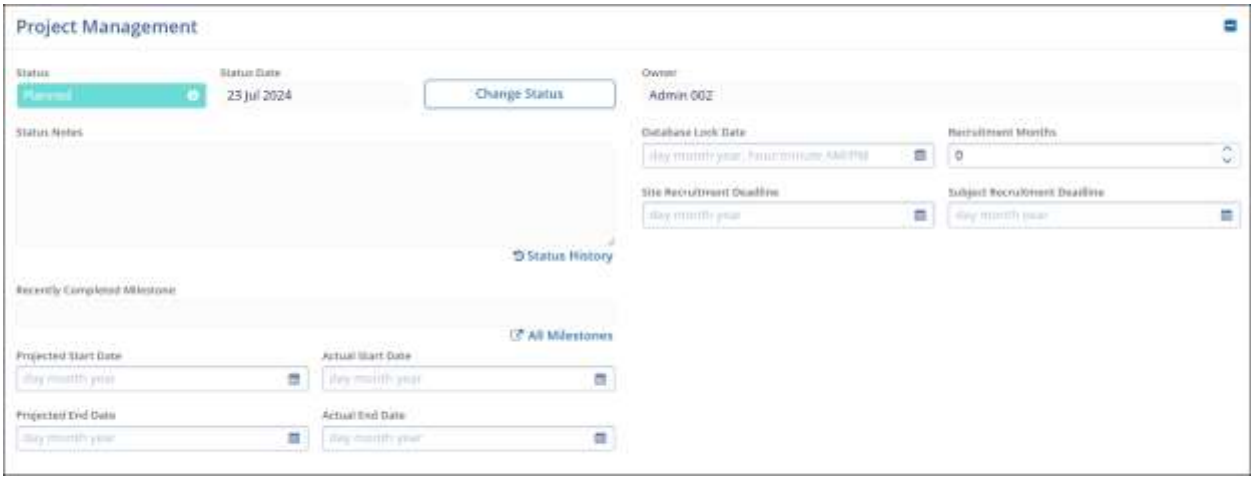


Figure: Study Details – Project Management

7. Subject and Recruitment
   a. # Planned Trial Sites
   b. 1st Site Activated
   c. # Planned Subjects Entered Trial
   d. # Planned Subjects Entered Treatment
   e. # Planned Subjects Completed Treatment
   f. Actual Screened
   g. Actual Enrolled
   h. Actual Screen Failed
   i. Actual Completed.

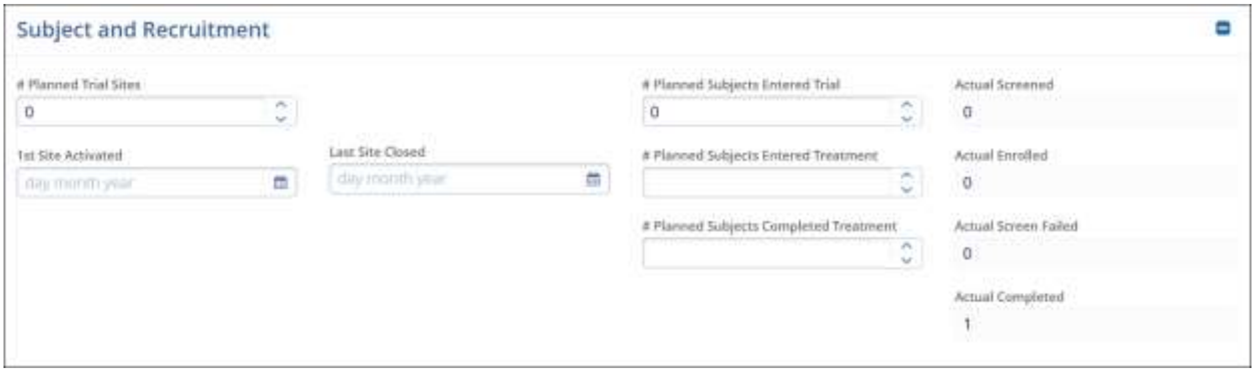


Figure: Study Details - Subject and Recruitment

<u>Informed Consent</u>

Add Informed Consent

To add informed consent, follow the steps below

1. Click on the +Add button within the Informed Consent section.

Figure: Add Informed Consent

2. Enter the Name and Effective Date into the respective fields.
3. Click on the Save button.

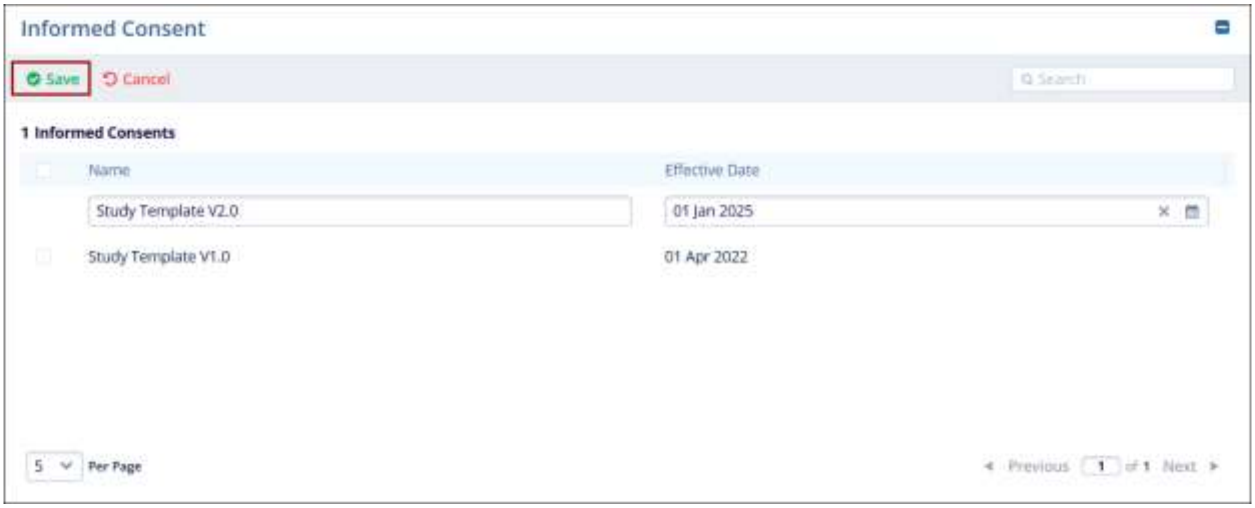


Figure: Save Informed Consent

Delete Informed Consent

To delete an informed consent, follow the steps below.

1. Select a record from the Informed Consent section to delete
2. Click on the Delete button.
3. On the confirmation popup, click on the Delete button.

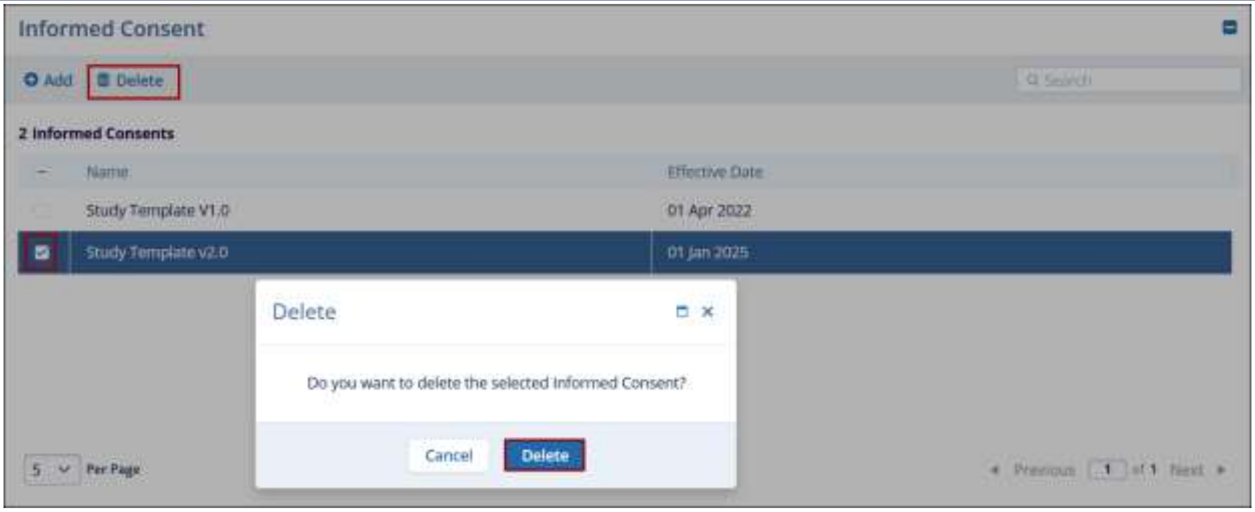


Figure: Delete Informed Consent

Additional Information

The Additional Information section displays the custom fields configured via Settings > Fields > Studies. The displayed fields vary based on the configurations set in the Settings section.

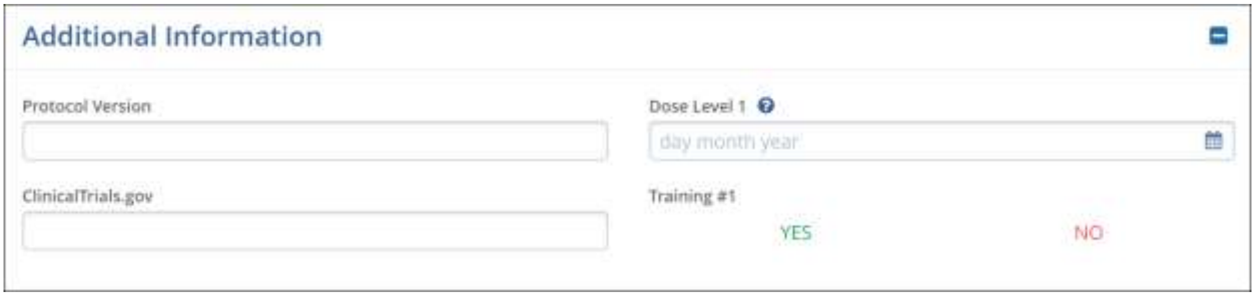


Figure: Study Details – Additional Information

Close Study

The Close Study Section enables users to close a study when it is at the end of the life cycle.

Figure: Study Details- Close Study

8. Click the ‘**Save’** button for the changes to apply.

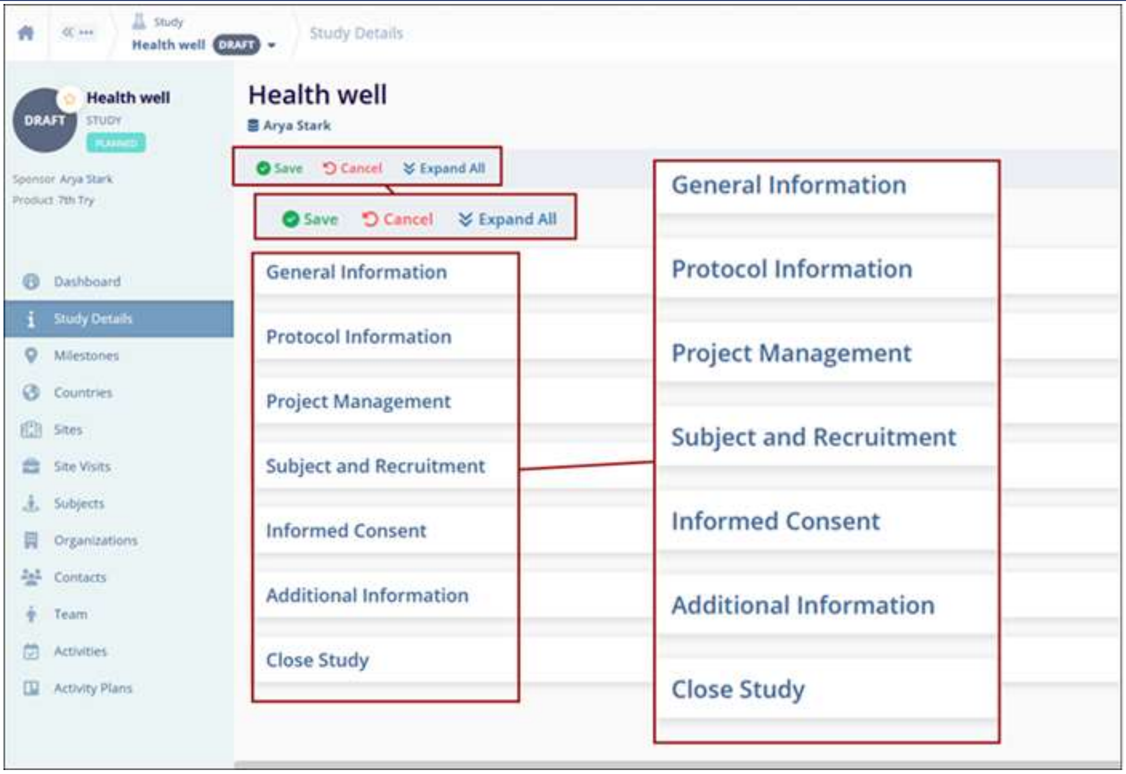


Figure: Study Details

Study Settings

To manage the study settings, follow the steps below.

1. Click on the check box next to the name of the study.
2. Click on the '**Edit'** button from the top main menu.

Figure: Edit study to access settings

3. On the Study Details screen, click on the Settings button.

Figure: Study-specific settings

4. On the General Settings screen, click on the Edit button from the top menu bar.

Figure: Edit Study Settings

5. Configure the following settings by accessing them through the left-hand navigation pane.

    a. General
    b. Regions
    c. Milestone Templates
    d. Access Permissions
    e. Import
    f. Fields
    g. Site Visit Types
    h. Subjects
    i. Import Status

General

To configure the General Settings, follow the steps below.

1. Navigate to the Study Settings screen and click on the 'General' link from the left-hand navigation pane.
2. Click on the Edit button from the top menu bar.
3. Expand the following sections and configure the necessary settings.
4. General Settings: On the General Settings screen, configure the following settings.
    a. Subject Tracking
    b. Is this a blinded trial
    c. Always use Study Specific Settings
    d. Site Visit Documents Date Format
    e. Site Visit Documents Date Time Format
    f. eTMF Location
    g. Planned Tracking Fields
    h. Subject Date of Birth Tracking
    i. Subject Date of Birth Format
    j. Site numbering
    k. Type
    l. Start from
    m. Size
    n. Site Auto-numbering Rule

Note: Hover over the tooltip of each field to view its meaning and instructions related to that specific field.

Figure: Study Settings – General Settings

5. Publish Study: The Publish Study section allows users to publish a study in a draft state. To publish a study, click on the Publish Study button. On the confirmation popup click on the Publish button. Once the study is published, users cannot edit study information like Protocol Number, Study State, and Subject DOB definition.

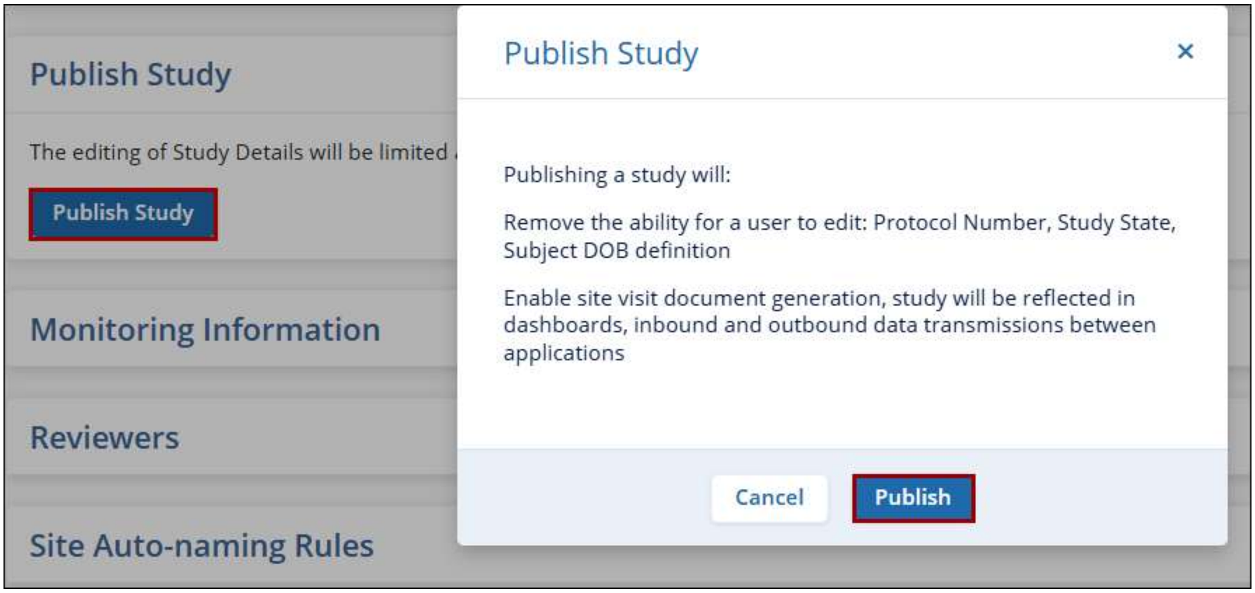


Figure: Study Settings-Publish Study

6. Monitoring Information: Configure the following settings within the Monitoring Information section.

    a. SVR Submission Dates
    b. SVR Approval Days
    c. Site Visit Frequency

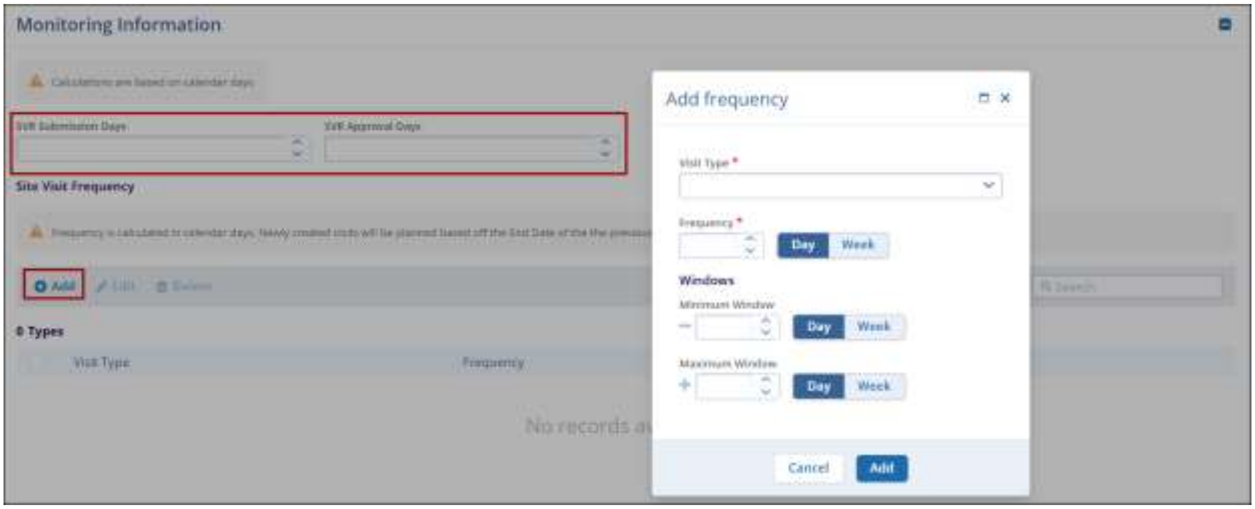


Figure: Study Settings – Monitoring Information

7. Reviewers: To add blinded and unblinded reviewers, click on the +Add button and select the reviewers from the available list.

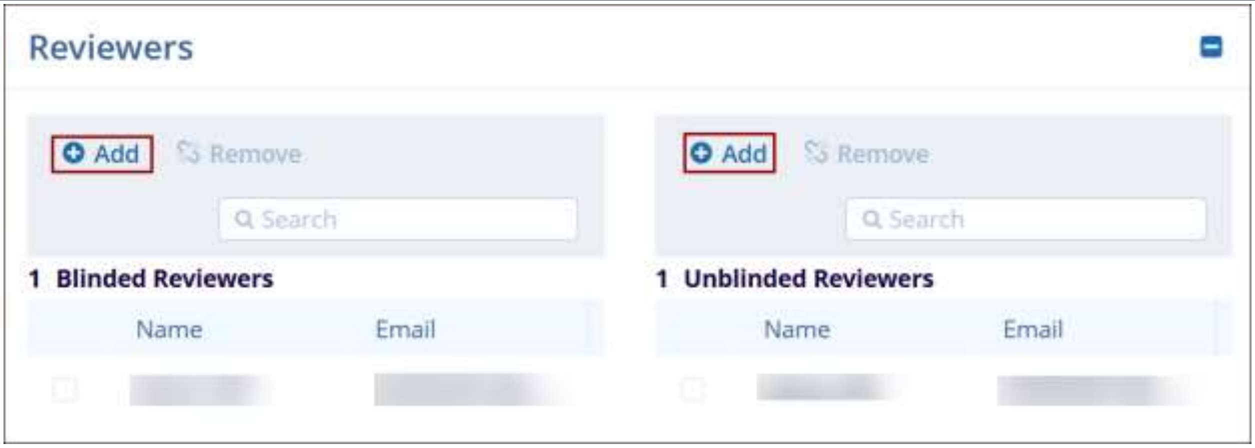


Figure: Study Settings – Reviewers

8. Site Auto Naming Rules: To configure the site auto naming rules, double on a value to select from the list of available fields.

Figure: Study Settings-Site Auto naming rules

9. Once all the changes are made, click on the 'Save' button at the top-left of the window.

Figure: Save settings.

Regions

Within the Regions settings, users can add, edit, delete, and export regions created at the study level.

Add Study Regions

To add regions within a study, follow the steps below.

1. Navigate to the Study Settings by following the steps detailed in the Study Settings section.
2. From the left-hand navigation pane, click on the Regions.
3. On the Regions screen, click on the +Add button.
4. On the Create Regions enter the following details.
   a. Region Name*
   b. Countries*
   c. State/Province
   d. Cities
5. Click on the Create button.

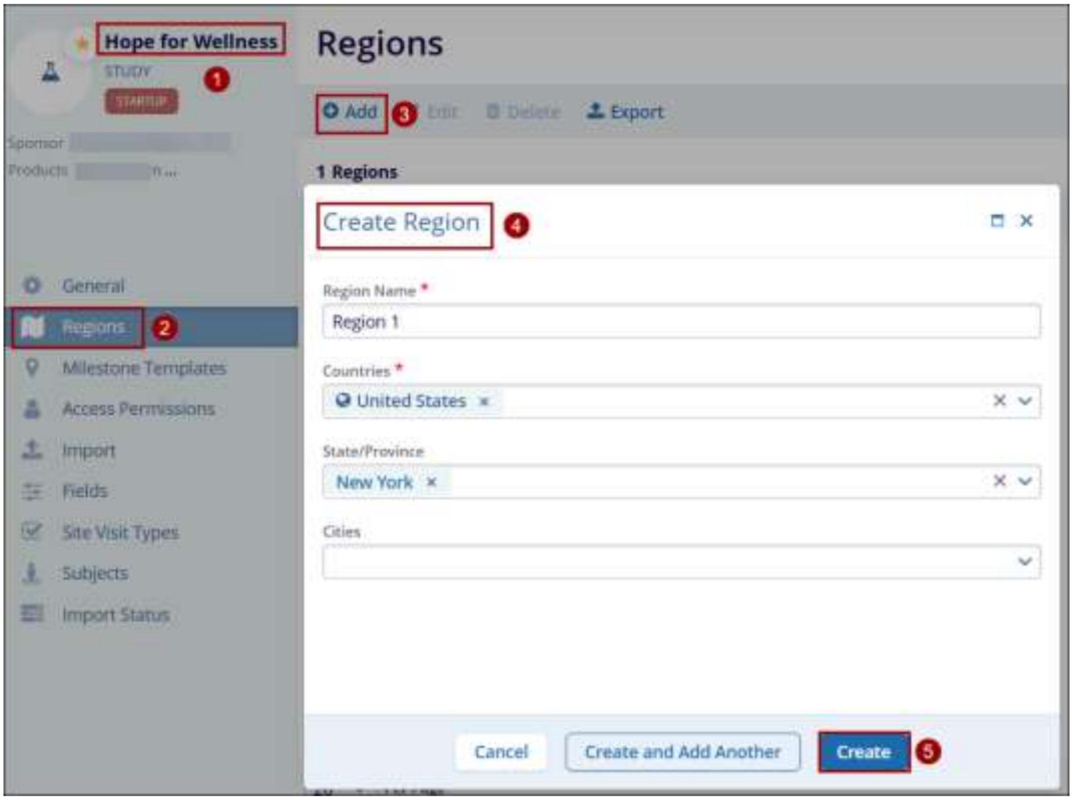


Figure: Create a Region at a Study level

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

Editing Study Regions

To edit regions associated with a study, follow the steps below.

1. Select the region by clicking on the checkbox.
2. Click on the Edit button.

Figure: Edit Region within a study

3. On the Region Details screen, make the required edits and click on the Save button.

Figure: Save changes to Region Details

Milestone Templates

To define Milestone Templates within the Study Settings, follow the steps below.

1. Navigate to the Study Settings by following the steps detailed in the Study Settings section.
2. Click on the Milestone Templates link from the left-hand navigation pane.
3. Refer to Chapter 13. Milestones to perform the standard actions associated with the Milestone Templates.

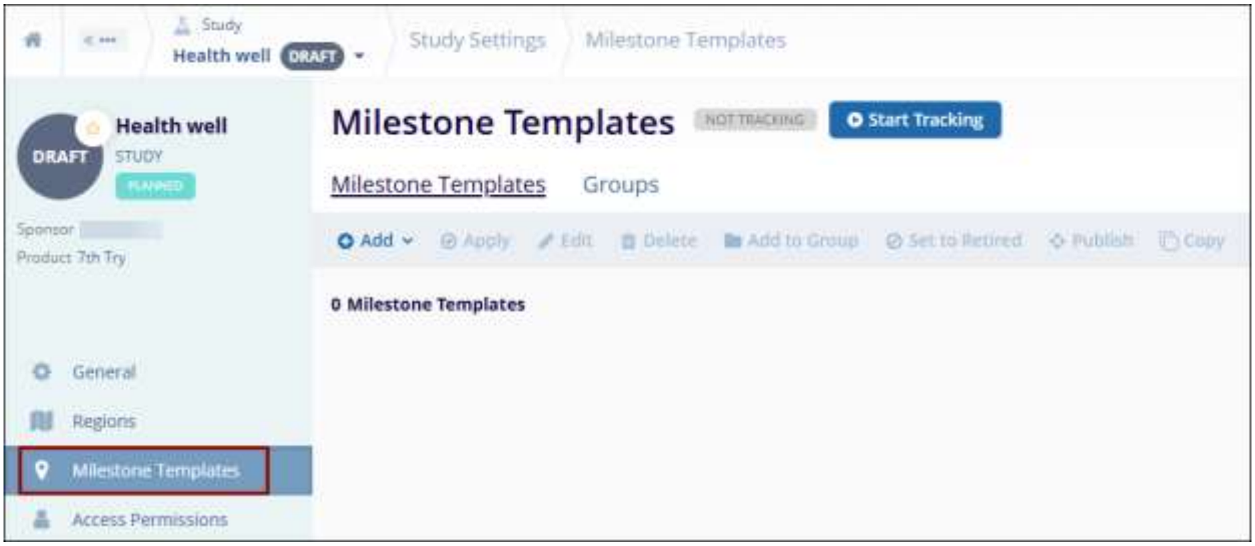


Figure: Milestone Templates

Access Permissions

To manage the access permissions from the Study Settings, follow the steps below.

1. Navigate to the Study Settings by following the steps detailed in the Study Settings section.
2. Click on the Access Permissions link from the left-hand navigation pane.
3. Refer to the Managing Study Access Permissions section to understand the standard steps.

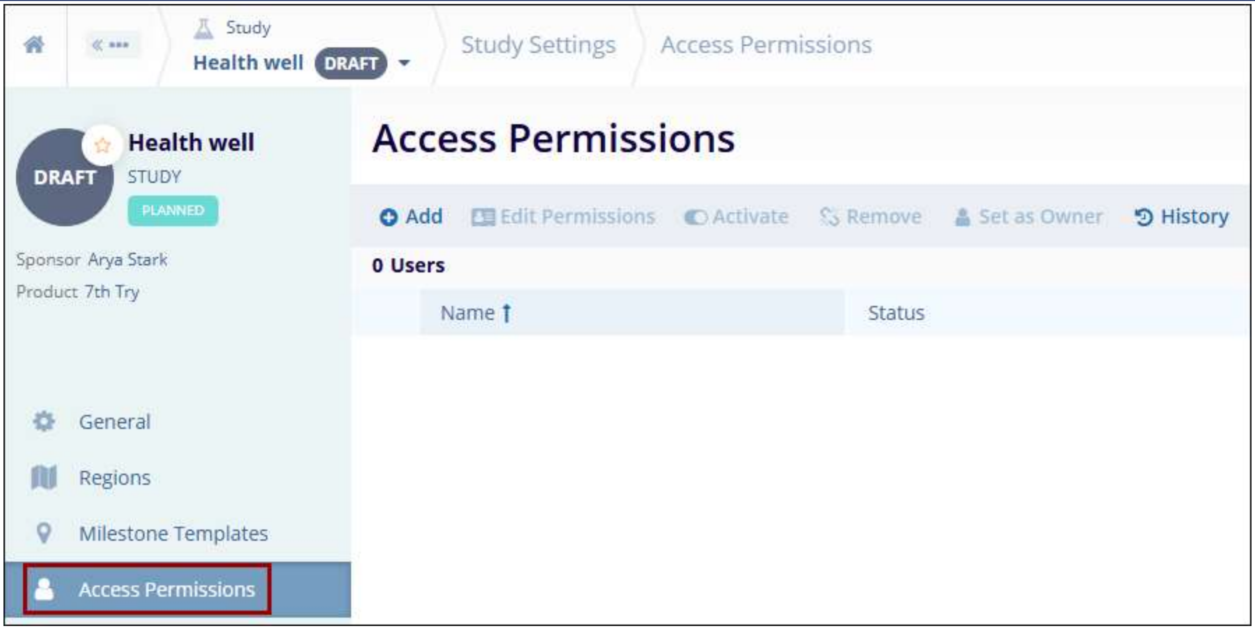


Figure: Study Settings - Access Permissions

Import

The Import functionality within the Study Settings allows users to import subject records through a pre-defined template.

To import the subject records, follow the steps below.

1. Navigate to the Study Settings by following the steps detailed in the Study Settings section.
2. Click on the Import link from the left-hand navigation pane.
3. Expand the '**Templates'** section and click on the **'Download Subjects Import** Template' button to download the template.

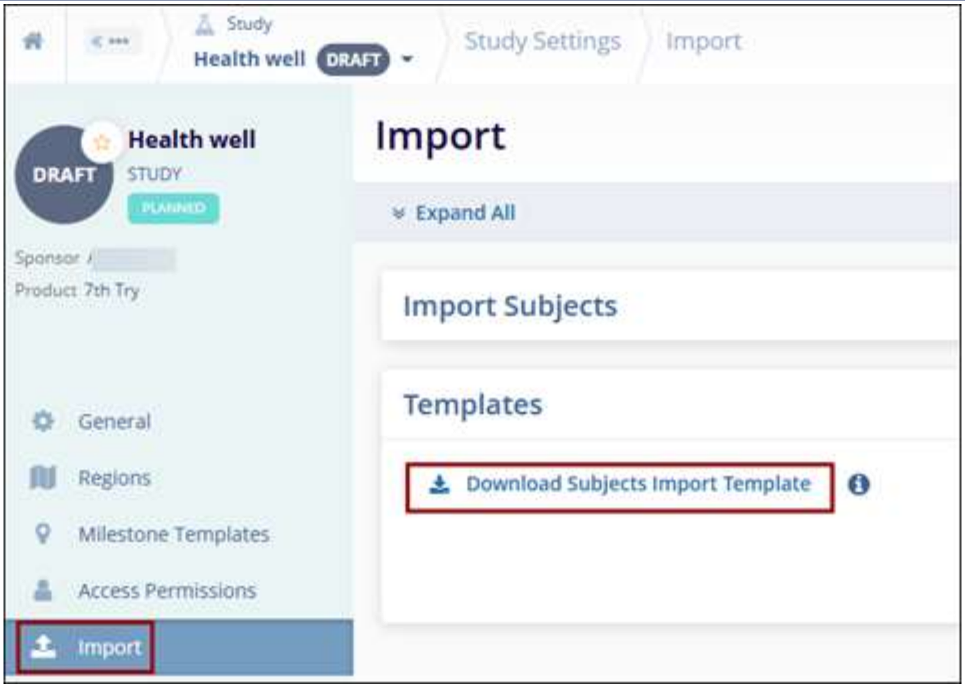


Figure: Study Settings - Import

4. Save the template as a Microsoft Excel Worksheet.

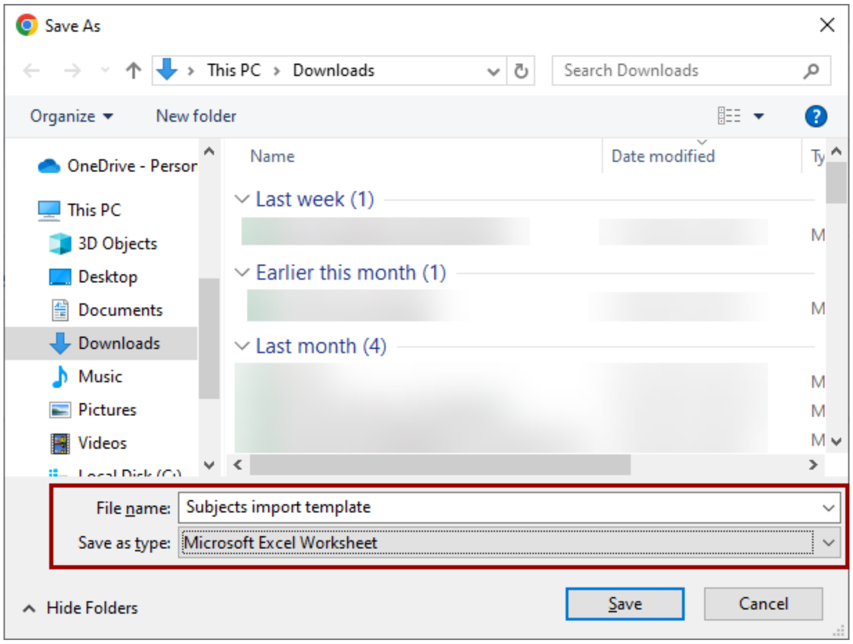


Figure: Subjects Import Template

5. In the downloaded template, fill in the following information within the Subjects tab.

   a. Subject ID
   b. Randomization ID
   c. Screening Number
   d. Enrollment ID
   e. Subject Initials

f. Date of Birth
g. Site Number
h. Screening Failure Reasons
i. Early Termination Reasons
j. Subject Outcome
k. Notes
l. Current Status
m. Screened Status Date
n. Screen Failed Status Date
o. Run-in Status Date
p. Randomized Status Date
q. Enrolled Status Date
r. Treated Status Date
s. Early Terminated Status Date
t. Lost to Follow-up Status Date
u. Completed Status Date
v. Withdrawn Status Date

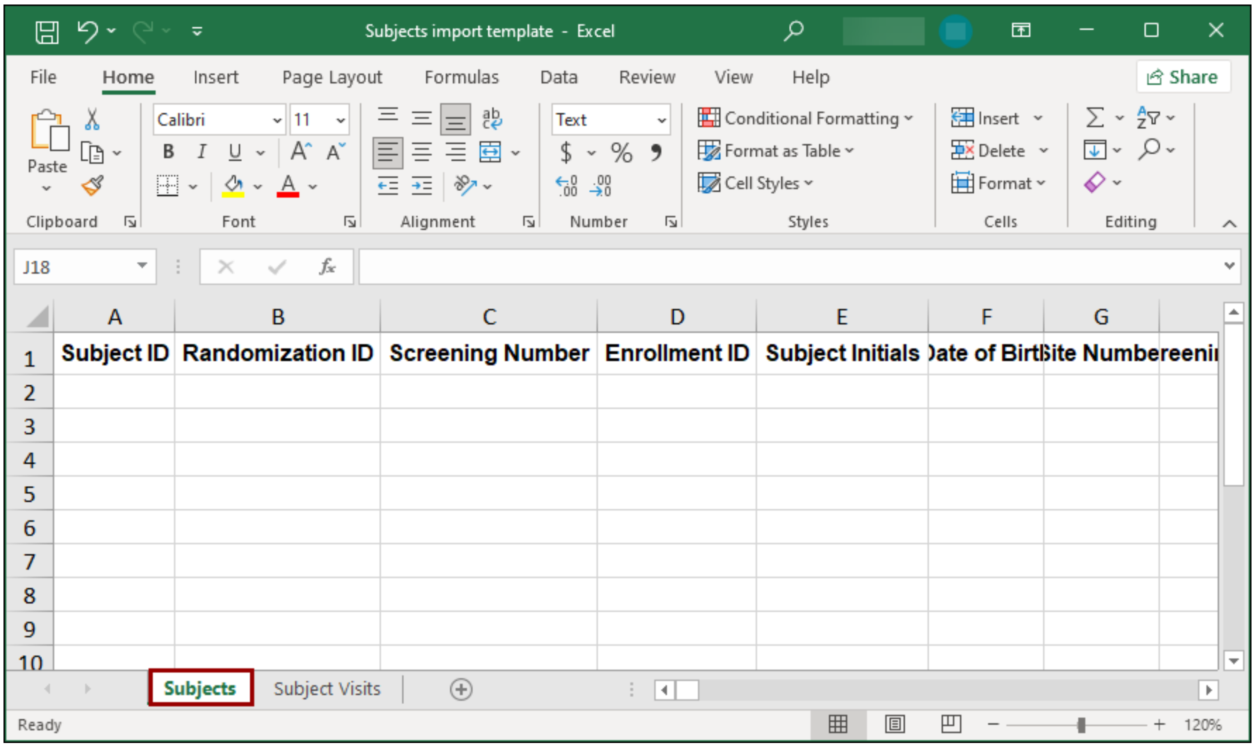


Figure: Subjects

6. Fill in the following details in the Subject Visits tab.
   a. Subject ID
   b. Site number
   c. Status
   d. Visit Date
   e. Type
   f. SDV Date
   g. Notes
   h. Visit Name
   i. Visit Reference

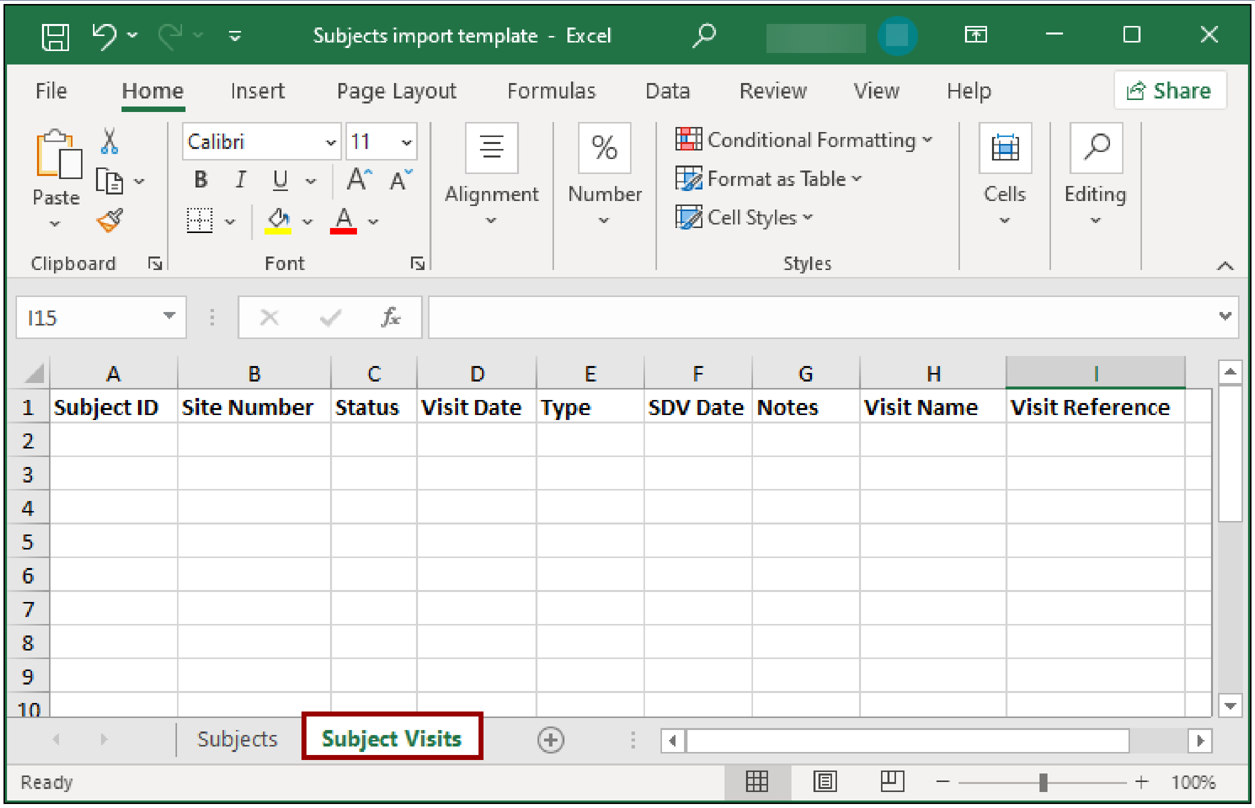


Figure: Subject Visits tab

7. Within the Study Settings > Import screen, expand the Import Subjects section and upload the file by using the Drag & Drop or manual upload functionality.

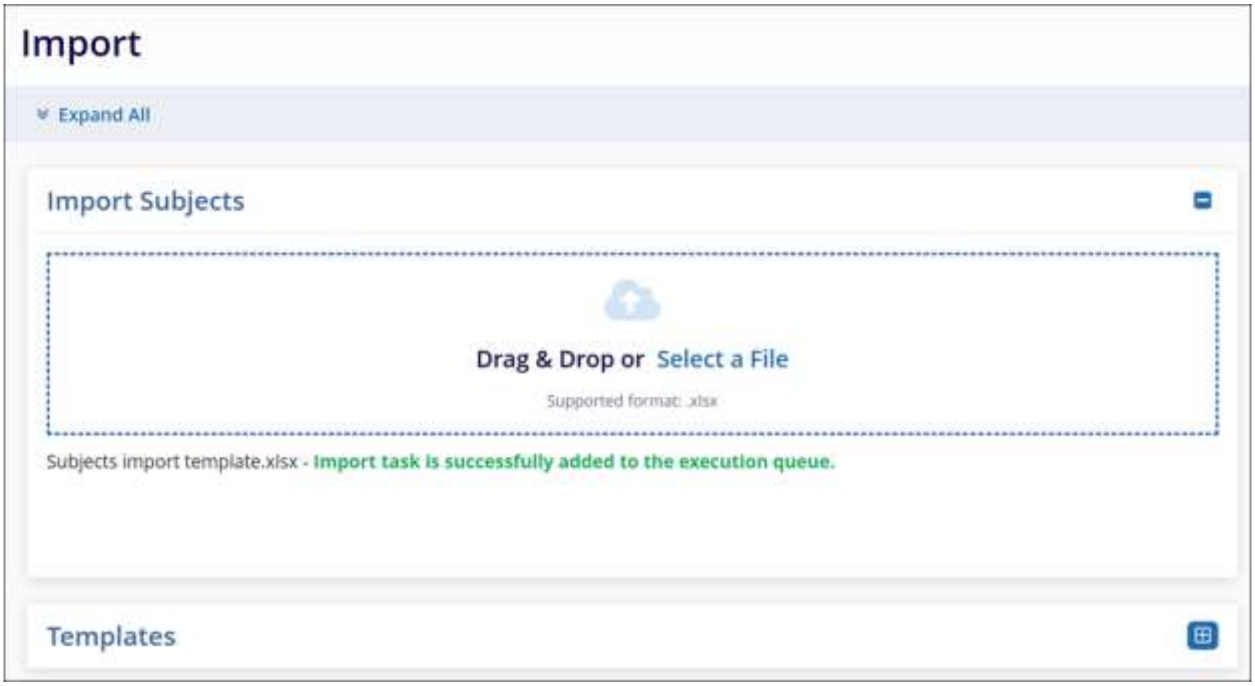


Figure: Import Subjects

8. Click on the notifications (bell) icon and select the ‘Get Job Results’ button.

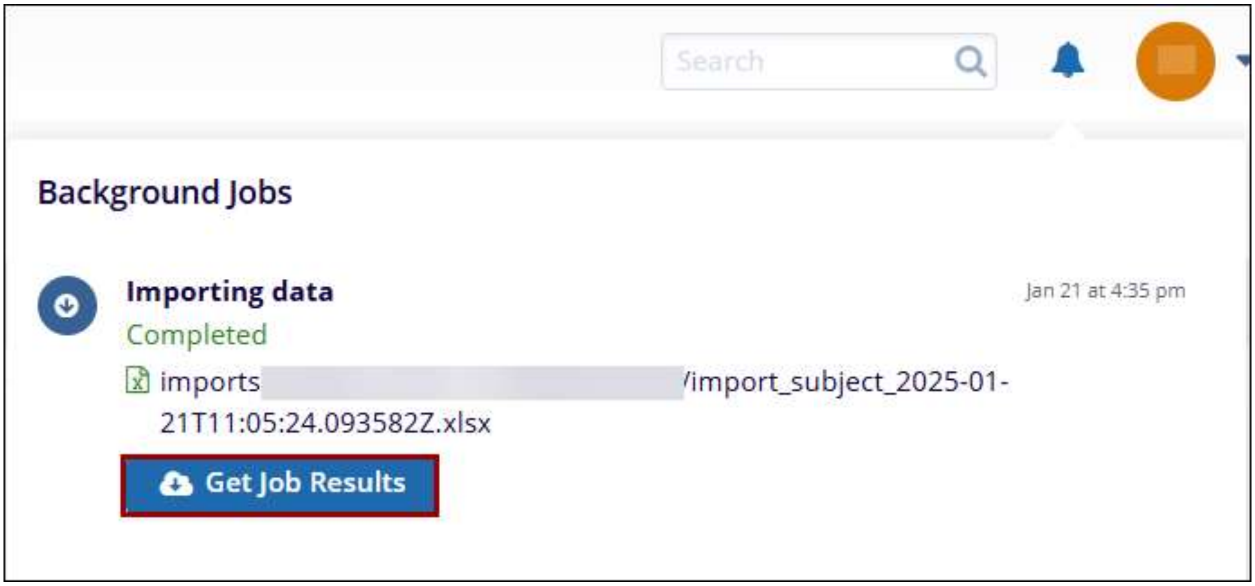


Figure: Get Job Results

9. On the ‘Failure Reason’ screen, view the number of successful and failed records.

Figure: Failure Reason

Fields

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

1. To access the Study Settings section, follow the steps detailed in the Study Settings section.
2. On the Study Settings screen, click on the Fields option from the left-hand navigation pane.
3. Select an option from the list. For example - Milestones

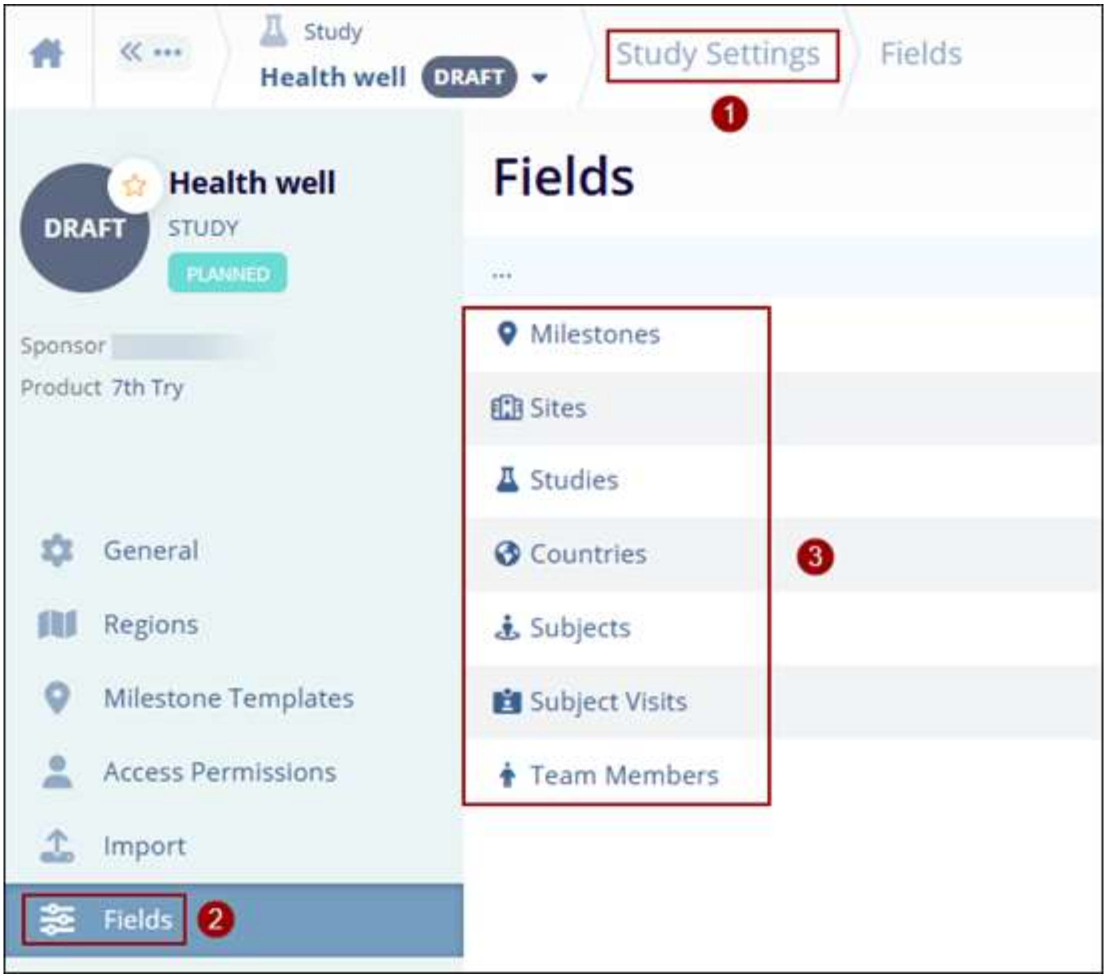


Figure: Define Fields at the Study level

4. On the Milestones field, click on the +Add button.
5. Select the required number of records by clicking the respective checkboxes.
6. Click on the Add button.

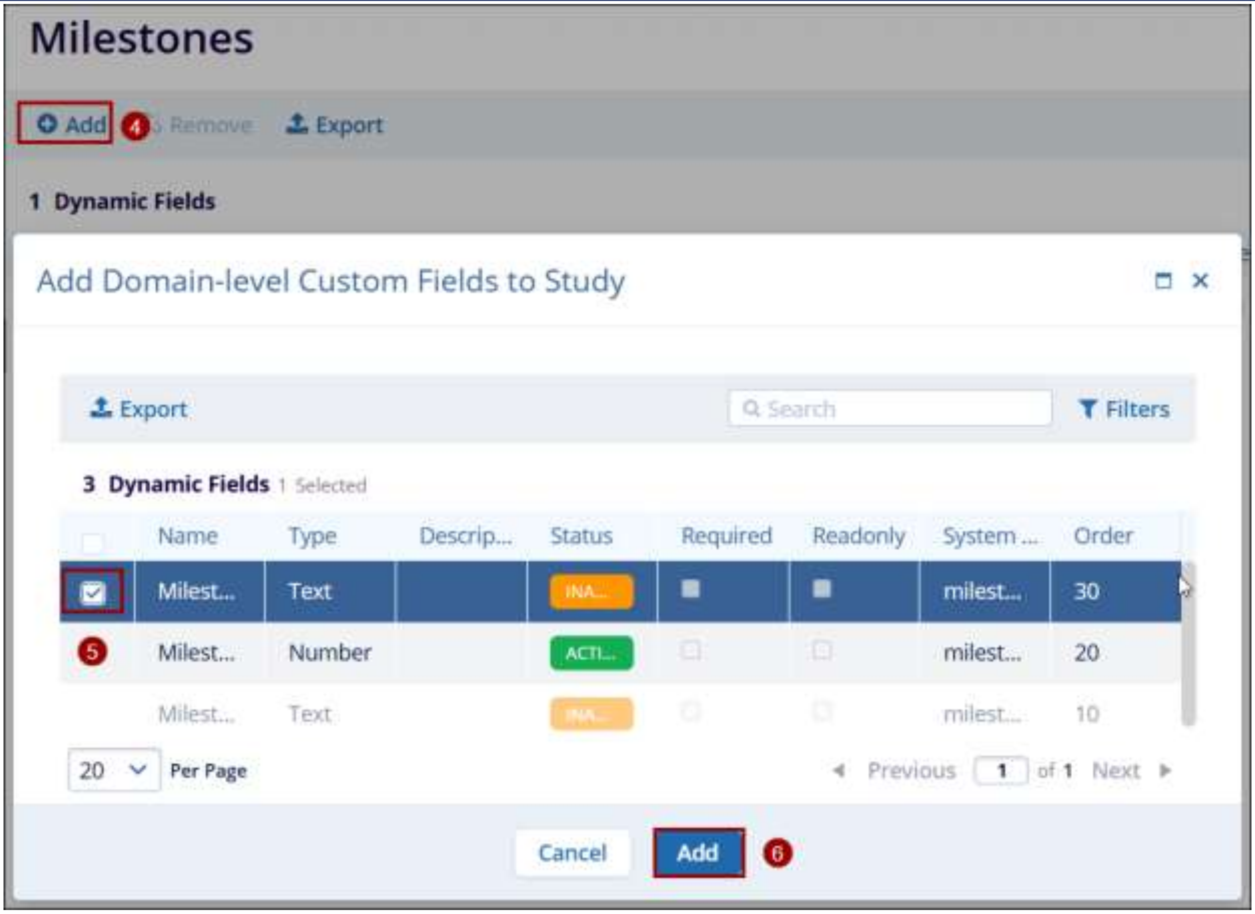


Figure Add Domain-level Custom Fields to Study

Note: Likewise, the user can apply Domain Settings 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. To access the Study Settings section, follow the steps detailed in the Study Settings section.
2. On the Study Settings screen, click on the Site Visit Types option from the left-hand navigation pane.
3. Click on the +Add button and select the +Add Site Visit Type(s) option.

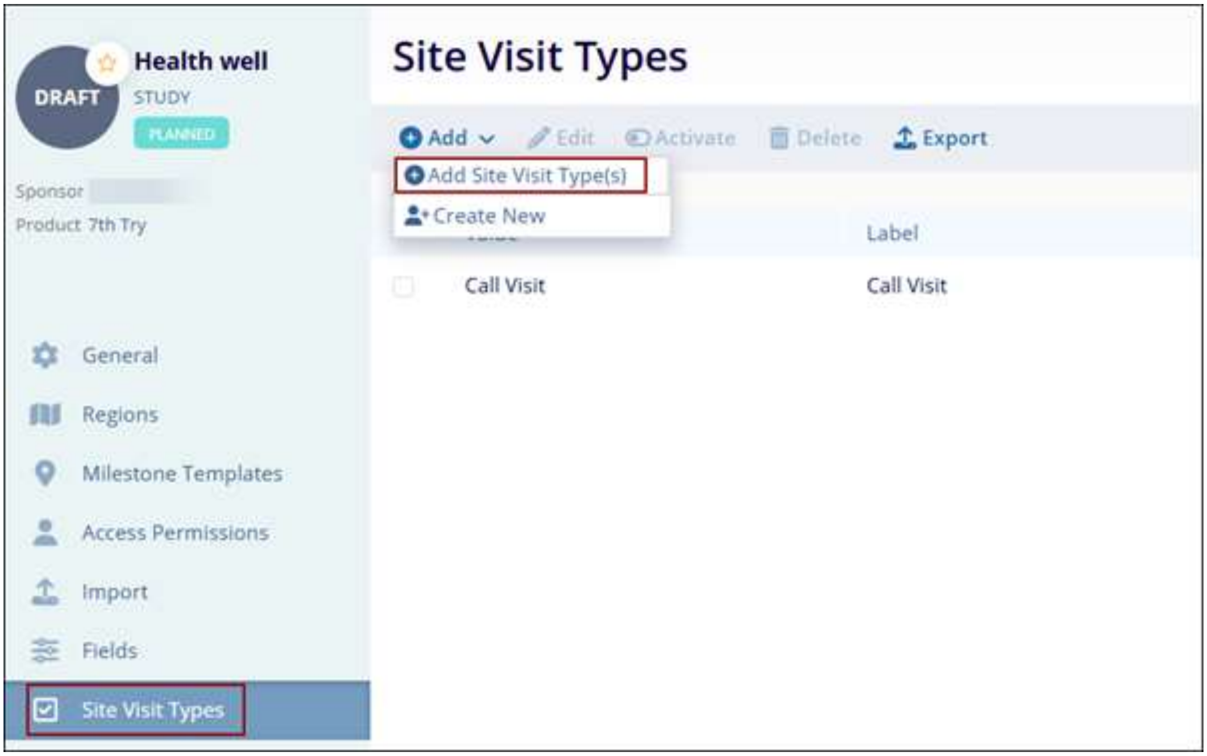


Figure: Add Site Visit Types

4. Select the values by clicking on the respective checkboxes and clicking on the Add button.

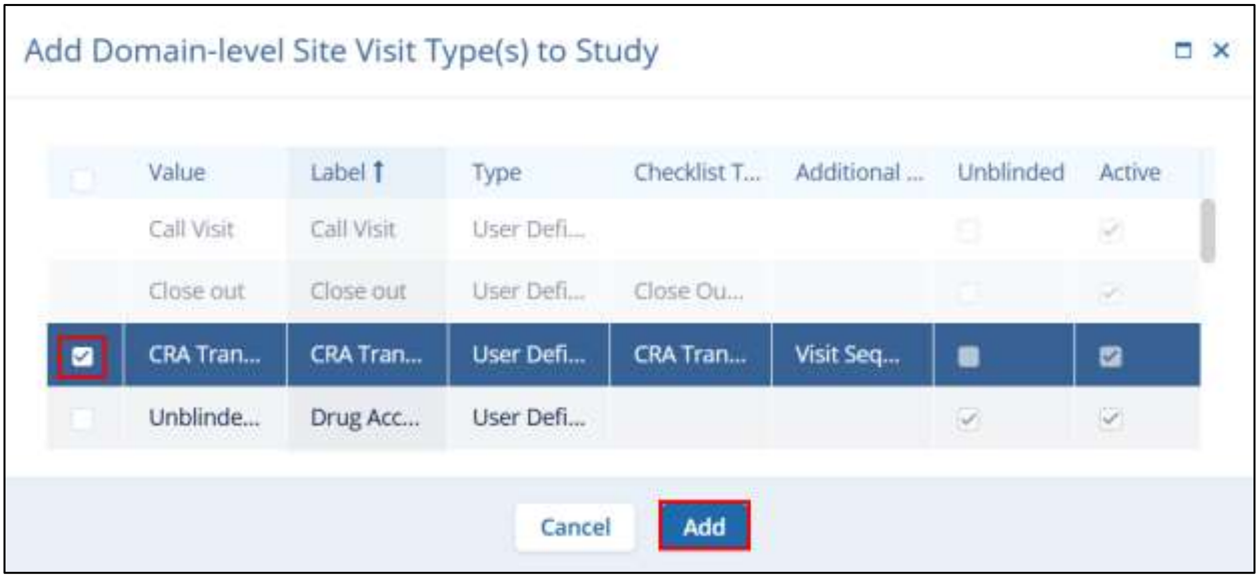


Figure: Select and Add site visit type fields

5. To create a new site visit type, click on the +Add button and select the +Create New option.
6. On the Create Site Visit Type screen, enter the mandatory details and click on the Create button.

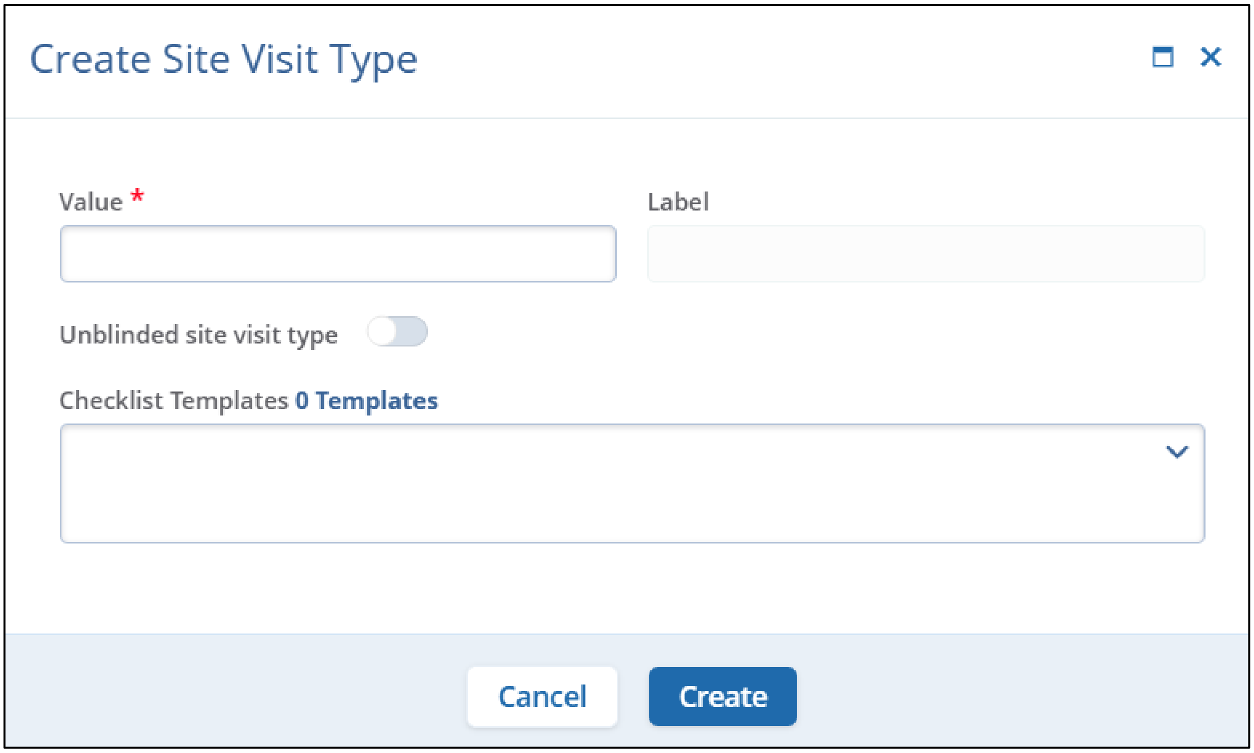


Figure: Create Site Visit Type

Site Visit Cancellation Reason

The Stie Visit Cancellation Reason section allows users to specify the domain level subject visit cancellation reason or create a new subject visit cancellation reason.

Add Subject Visit Cancellation Reason

To add subject visit cancellation reason, follow the steps below.

1. To access the Study Settings section, follow the steps detailed in the [Study Settings](#) section.
2. On the Study Settings screen, click on the Site Visit Cancellation Reason option from the left-hand navigation pane.
3. Click on the +Add Subject Visit Reason Cancellation button.

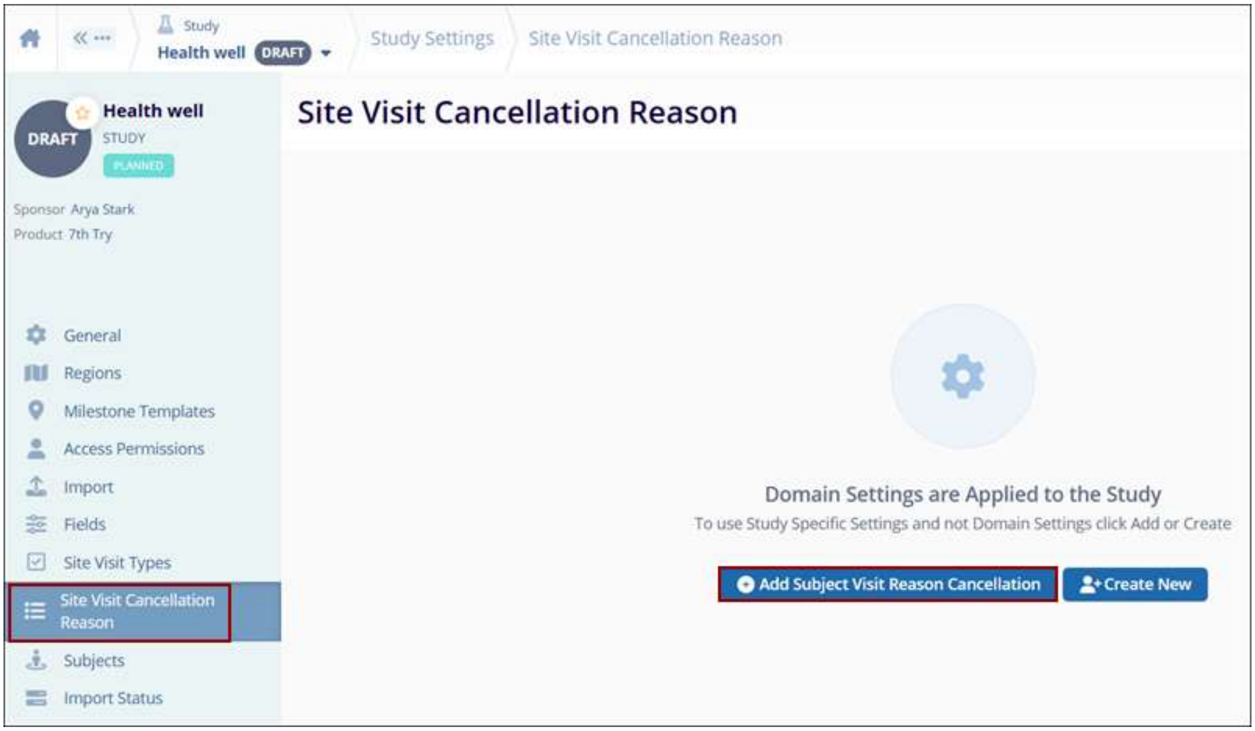


Figure: Site Visit Cancellation Reason

4. Select a reason from the available options and click on the ‘Add’ button.

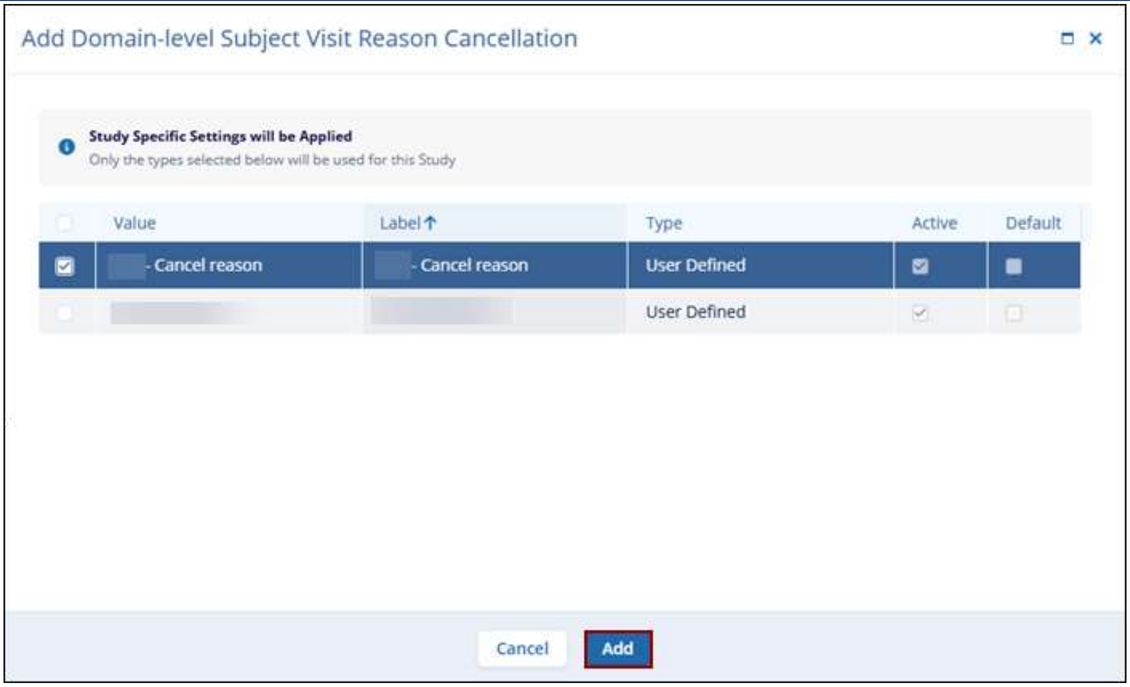
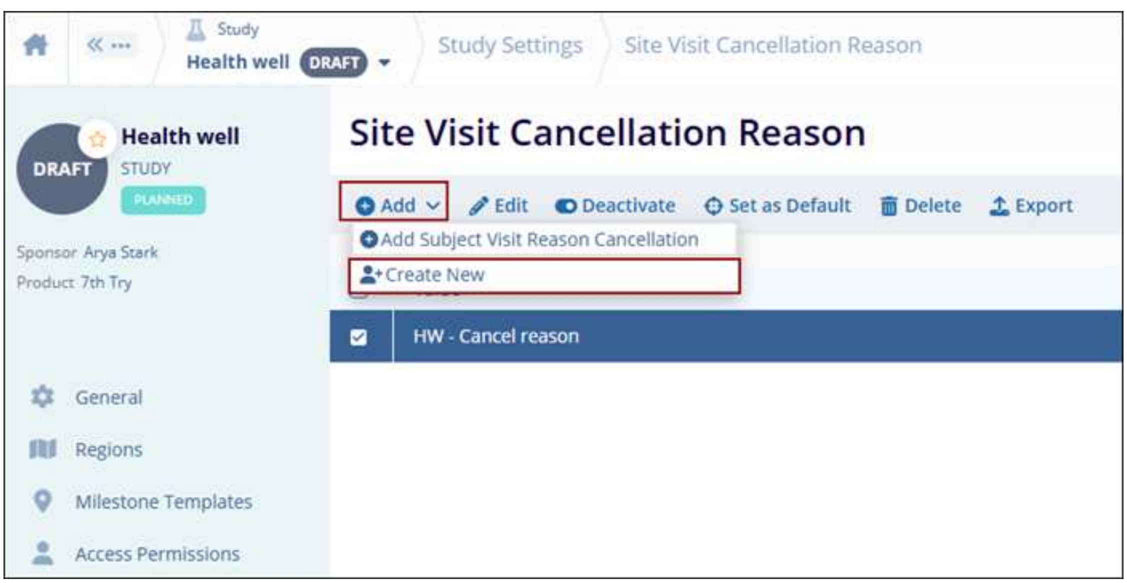


Figure: Add Domain-level Subject Visit Cancelation Reason

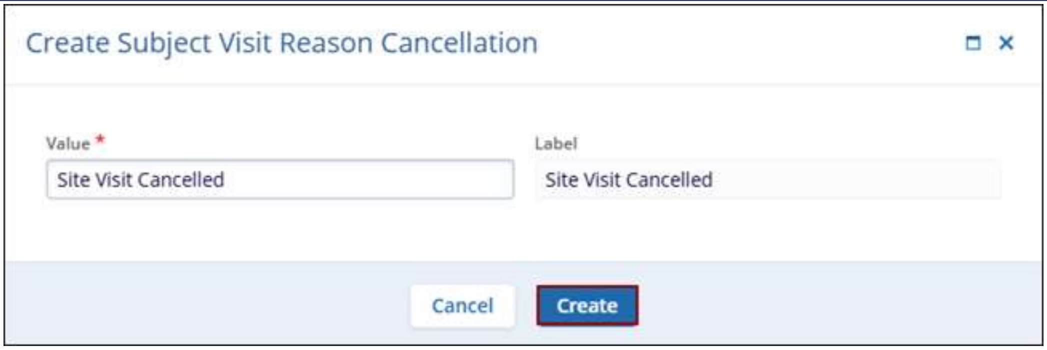
Create New Cancellation Reason

To create a new cancellation reason, follow the steps below.

1. On the Site Visit Cancellation screen, click on the '+Add' button and select the '+Create New' option.



2. On the 'Create Subject Visit Reason Cancellation' modal, specify the value and click on the 'Create' button.


Create Subject Visit Reason Cancellation
Value *
Site Visit Cancelled
Label
Site Visit Cancelled
Cancel
Create

Subjects

Users 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. To access the Study Settings section, follow the steps detailed in the Study Settings section.
2. On the Study Settings screen, click on the Site Visit Types option from the left-hand navigation pane.
3. Click on the +Add button and select the +Add Site Visit Type(s) option.

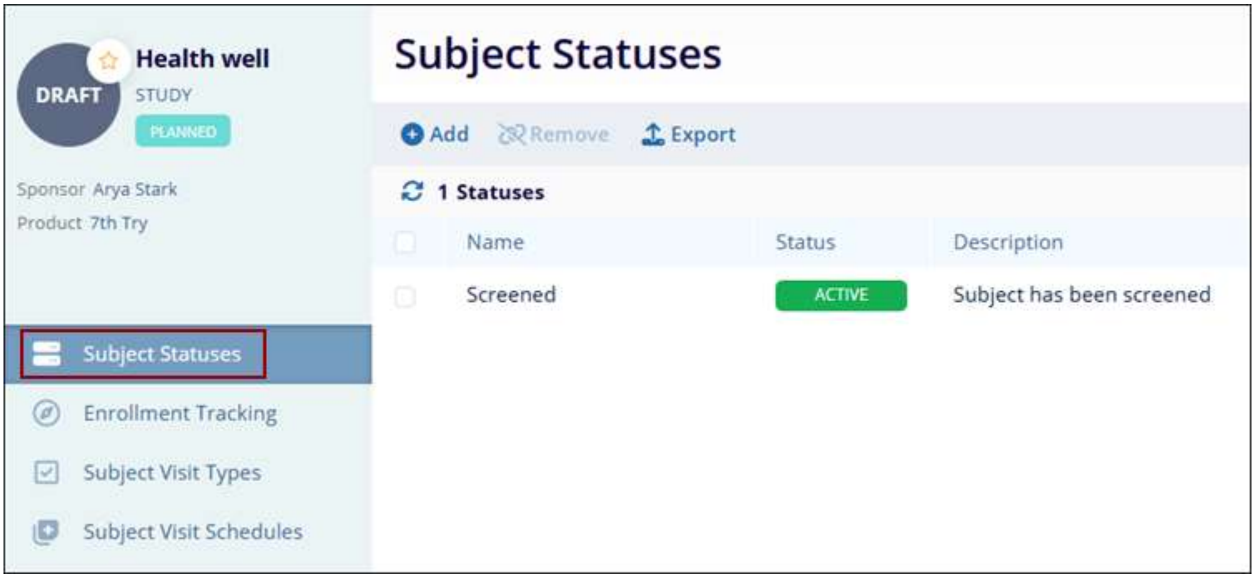


Figure: Define Subject Statuses at the Subject Level

4. On the 'Add Domain-level Subject Statuses to Study' screen, select the required number of statuses and click on the Add button.

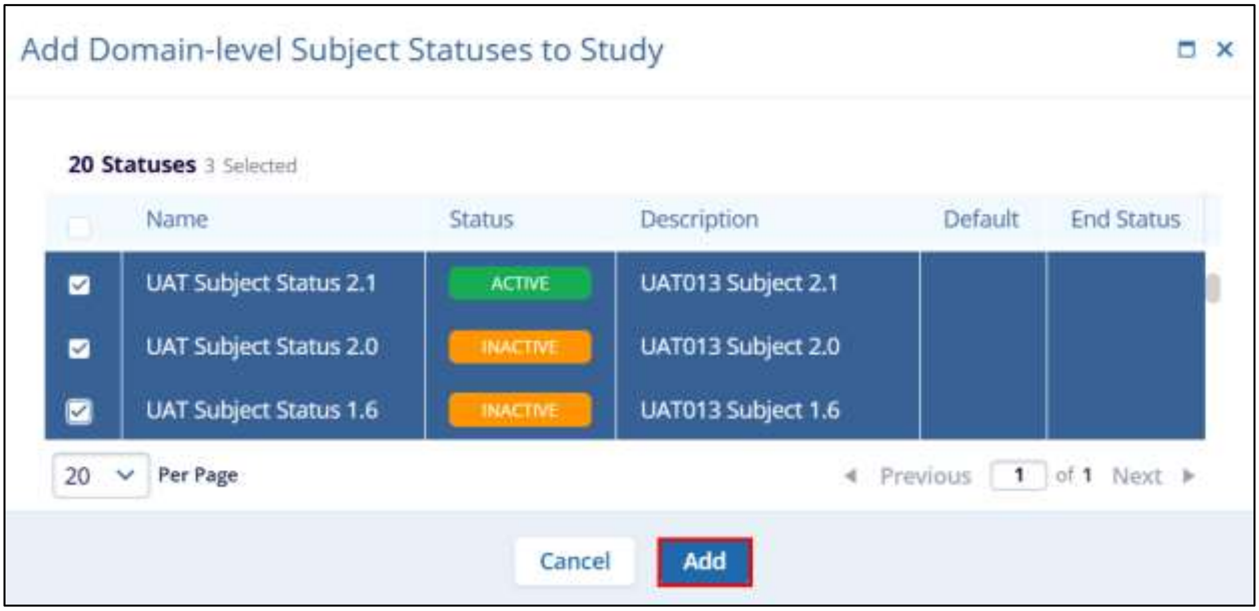


Figure: Add Domain Level Subject Statuses to Study

5. On the Subject Statuses screen, select the records and click on the Remove button from the top menu bar.
6. On the confirmation popup, click on the Remove button.

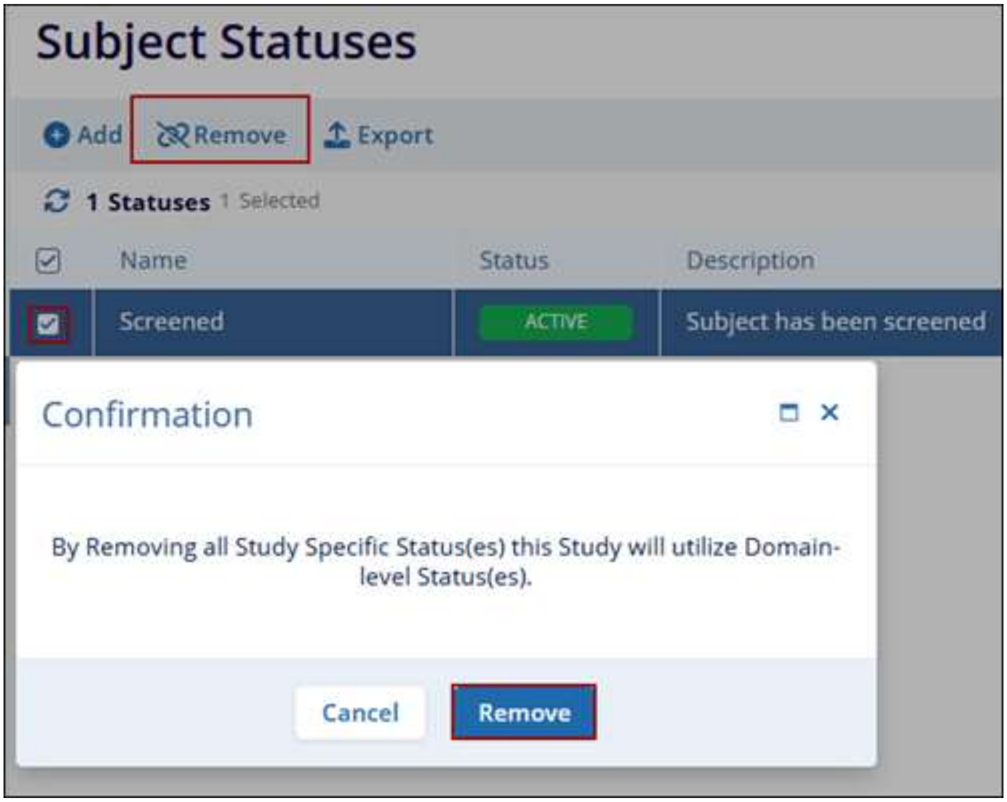


Figure: Remove Subject Statuses

7. Click on the Enrollment Tracking option and add, delete, and export the required details.

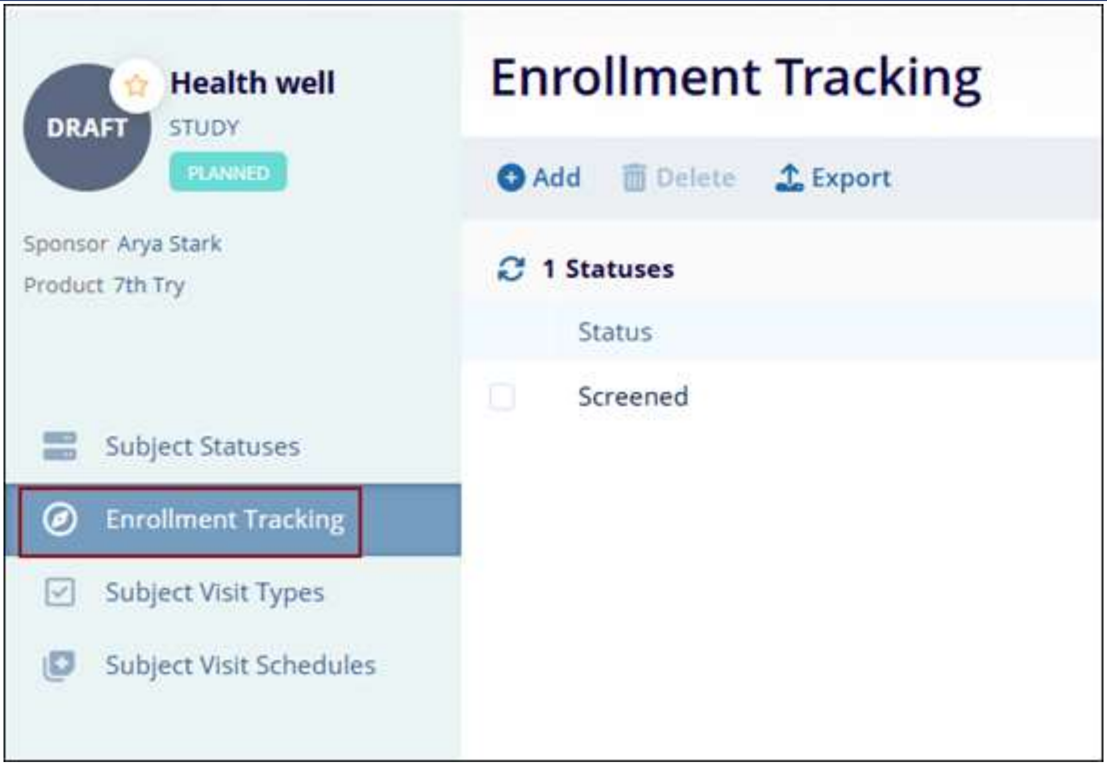


Figure: Enrollment Tracking

8. Click on the Subject Visit Types and Add, Edit, Delete, Set as Default, Delete, or Export the required details.

Figure: Subject Visit Types

9. Click on the Subject Visit Schedules and Add, Edit, Copy, Set to Retired, Publish, and Delete the required records.

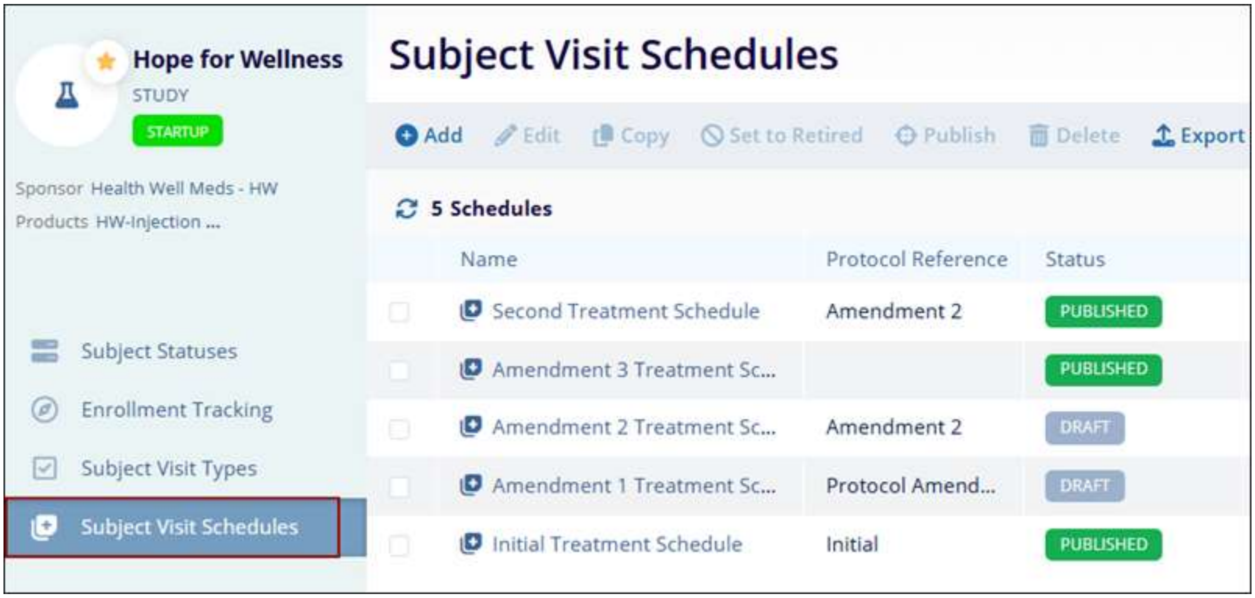


Figure: Subject Visit Schedules

Import Status

The ‘Import Status’ page allows users to view the Import Statuses.

To view the import statuses, follow the steps below.

1. To access the Study Settings section, follow the steps detailed in the Study Settings section.
2. On the Study Settings screen, click on the Import Status option from the left-hand navigation pane.
3. Click on the Export button to export the import status record and the ‘Refresh’ button to view the latest import records.

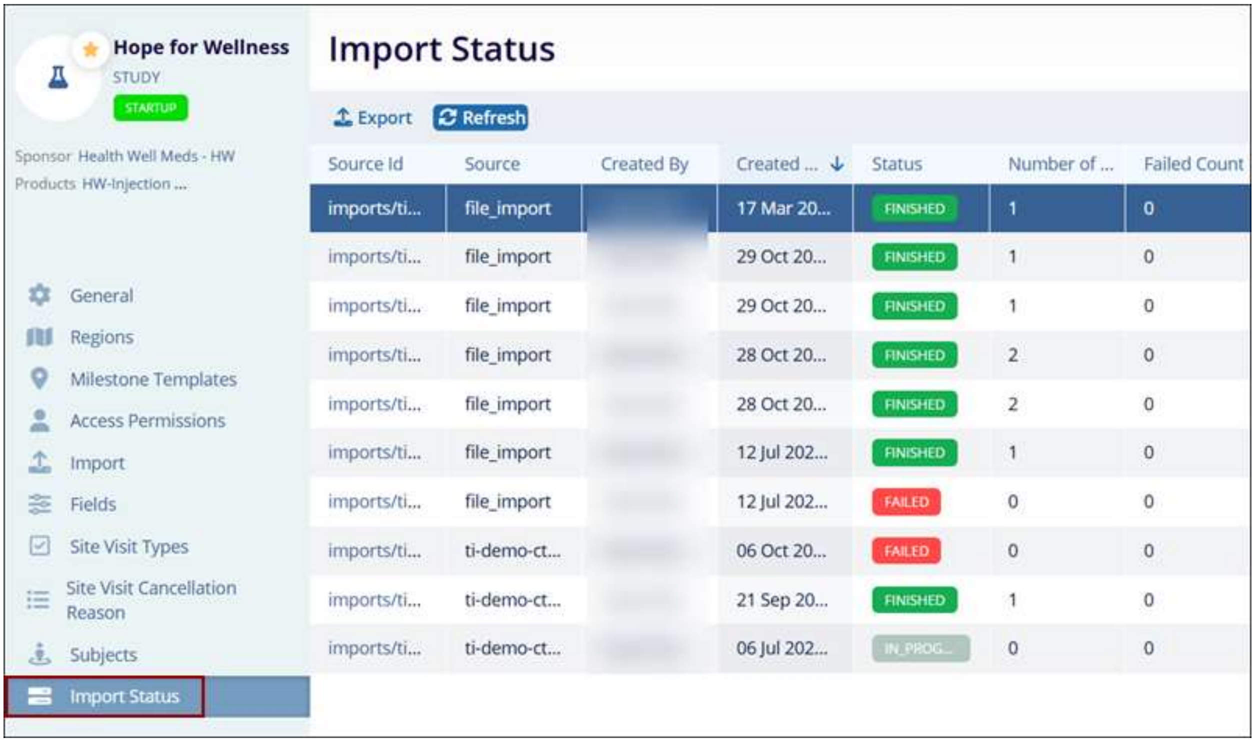


Figure: Import Status

Study Dashboard

To access dashboards associated with a study, follow the steps below.

1. To navigate a Studies Dashboard, click on the '**Studies'** link in the Navigation menu at the left side of the screen.
2. Click on a Study Name which opens the Study Details screen.
3. From the left-hand navigation pane, click on the Dashboard link which displays the dashboards associated with the study.
4. Refer to Chapter 2. Dashboard section.

Study Milestones

To access the Study Milestones, follow the steps below.

1. To navigate a Studies Dashboard, click on the '**Studies'** link in the Navigation menu at the left side of the screen.
2. Click on a Study Name which opens the Study Details screen.
3. From the left-hand navigation pane, click on the Milestones.
4. Select the Card or List View to customize the milestone template's view.
5. To apply a filter, click on the Filter dropdowns displayed on the screen.
6. It will display all fields with the drop-down, click on the drop-down arrow and select the appropriate option as per the requirement.
7. As per the applied filter, users will able to see the results in the grid.

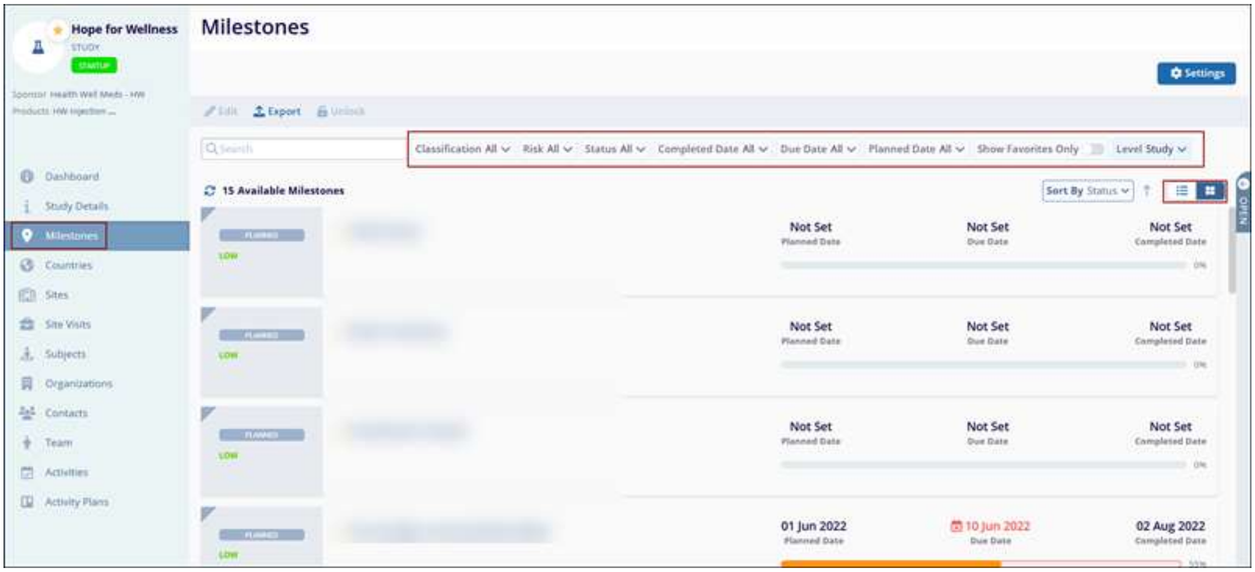


Figure: Milestones at Study Level

Note: Refer to Chapter 13. Milestones section for detailed information on Milestones.

Study Countries SM

Adding Countries within a Study

To add countries within a study, follow the steps below

1. From the left-hand navigation pane, select the Studies link.
2. On the Studies screen, click on the study name.

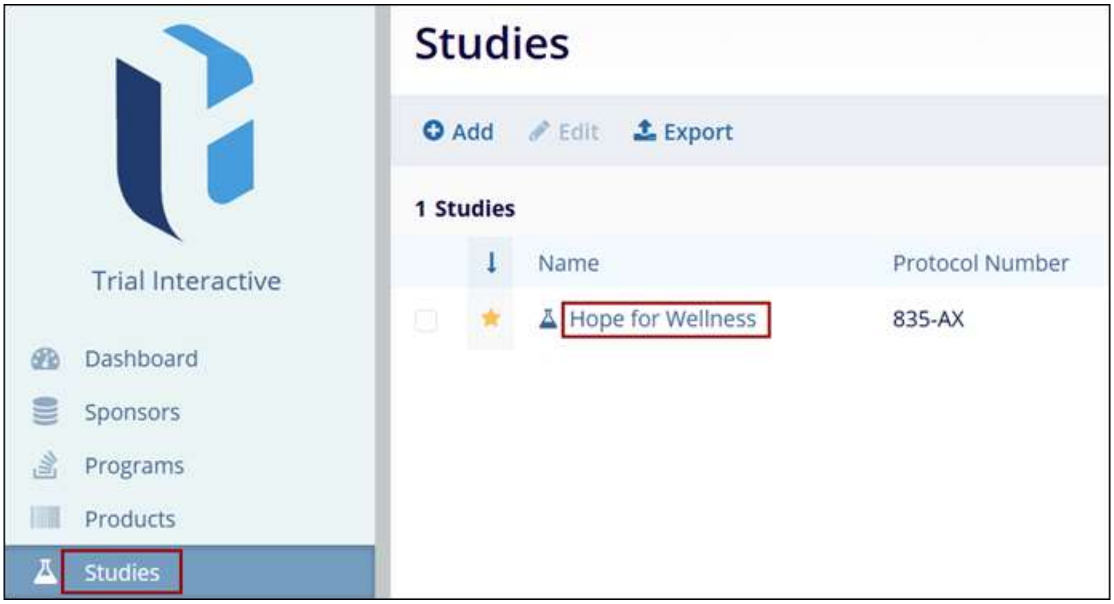


Figure: Select a study to associate a country

3. On the Study screen, click on Countries from the left navigation pane.
4. On the Countries screen, click on the +Add button.

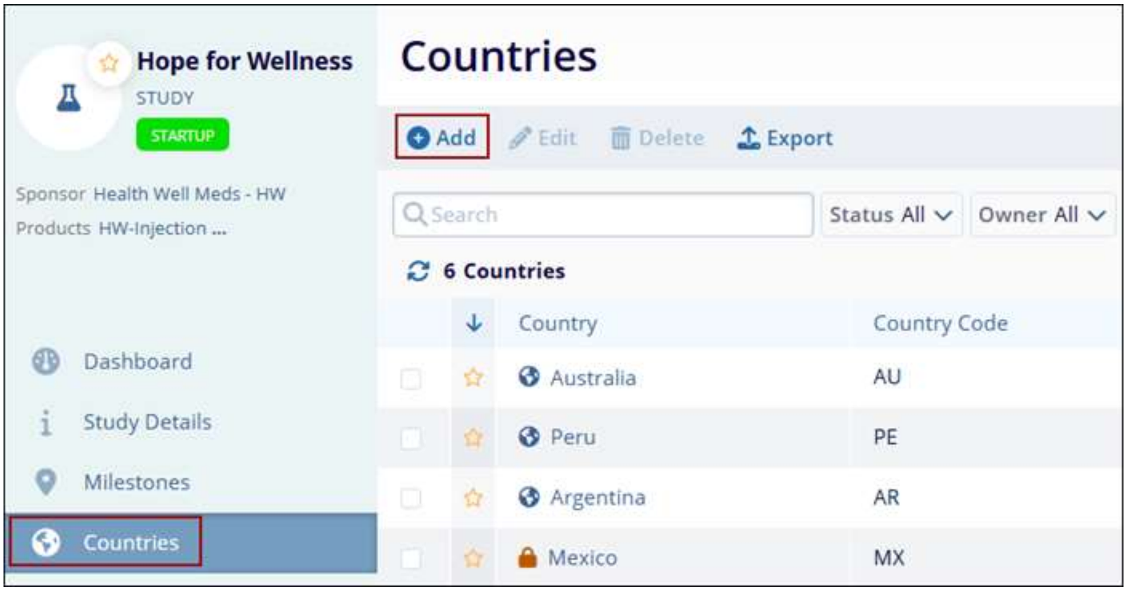


Figure: Add Country

5. On the Create Study-Country form, enter the mandatory metadata into the respective fields.
    a. Country*
    b. Owner*
    c. Status*
    d. Status Date*
    e. Region

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

6. Click on the 'Create' button.

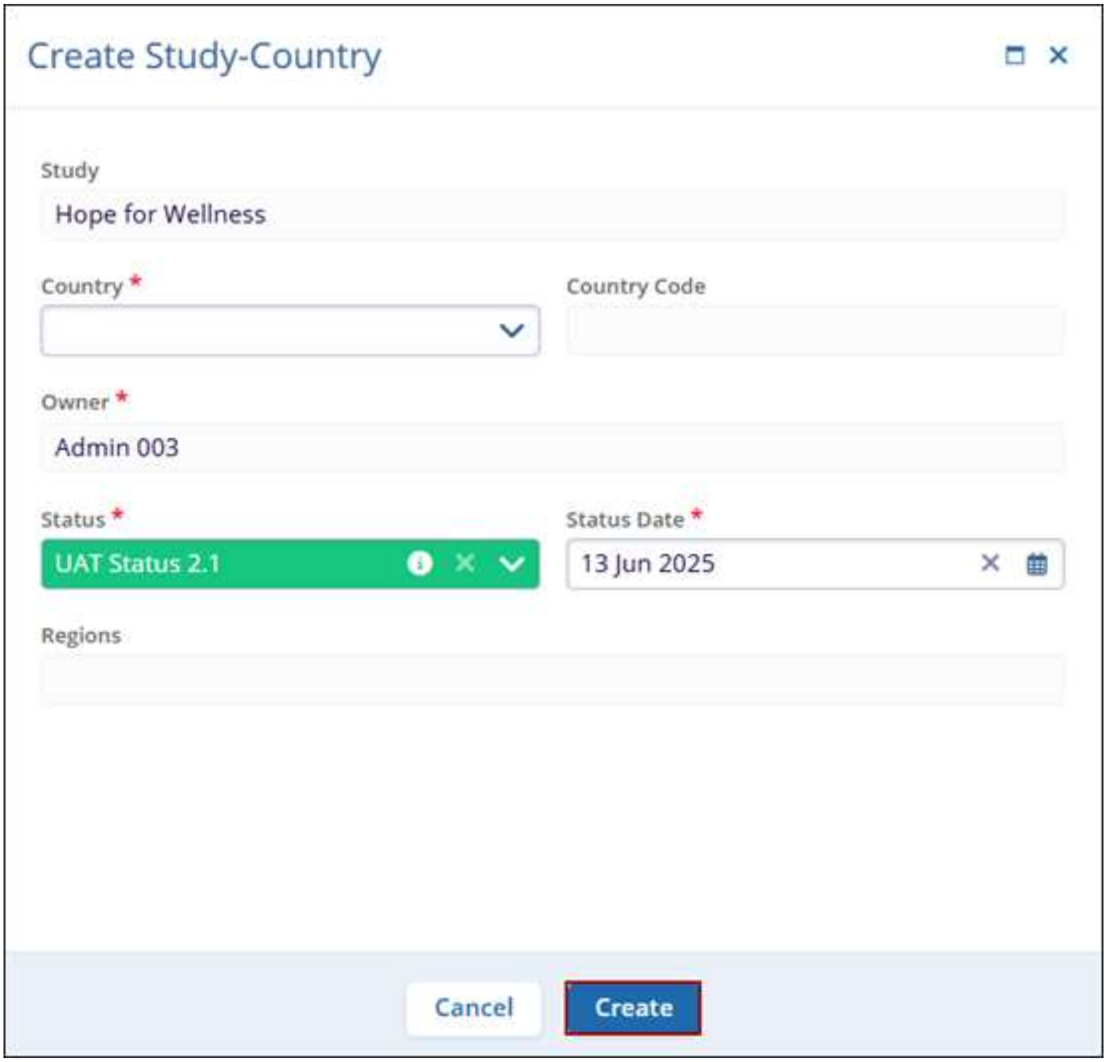


Figure: Create Study Country form

Edit Country Details

To edit country details, follow any one of the methods below.

Method 1

1. Click on a Country name in the countries tab within a Study.

Figure: Review and Track Countries within a Study

2. Click on the Country Details tab.
3. Click on the Edit button.

Figure: Access Country Details

4. Make the required changes by expanding each section and clicking on the Save button.

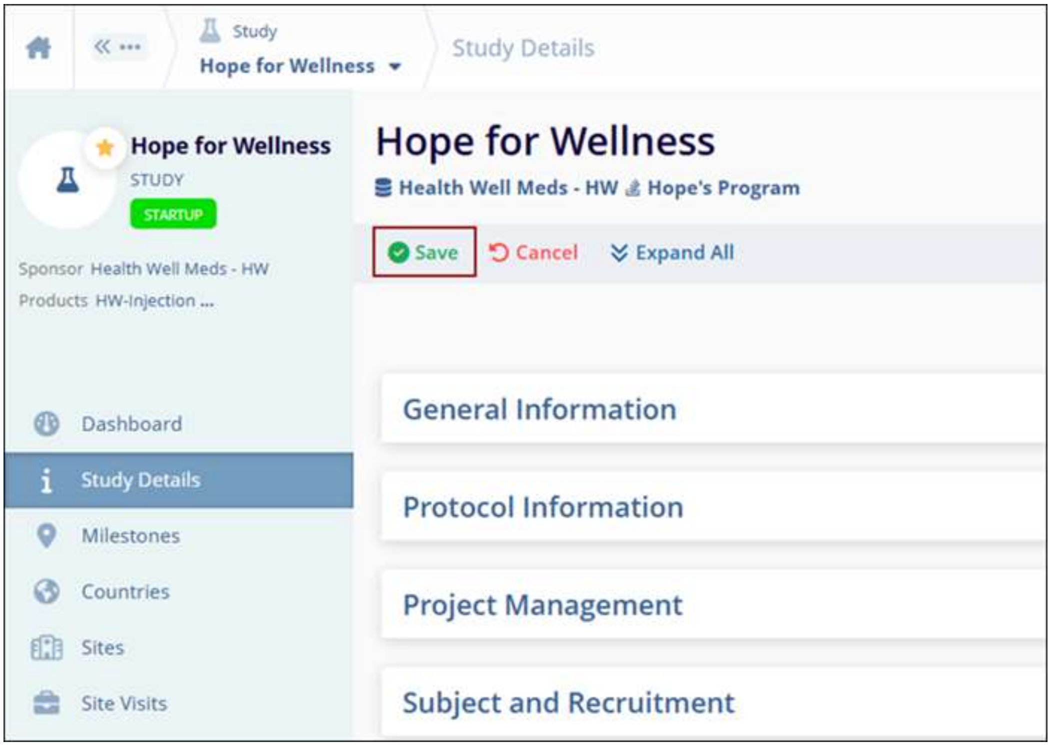


Figure: Save changes to country details

Method 2

1. Click the checkbox next to the name of the country to edit
2. Click on the Edit button from the top-left menu bar.
3. Make any necessary changes in the quick view panel on the right-hand side of the screen.
4. Click on the '**Save'** button at the bottom of the quick view panel.

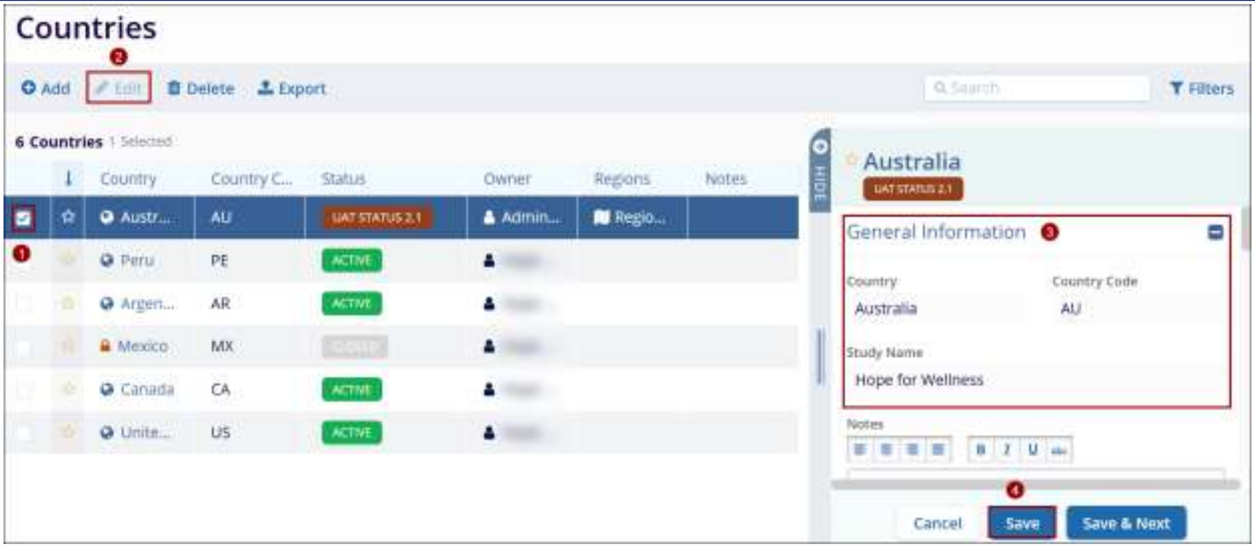


Figure: Edit Countries within a Study

Creating a Site within the Country

To create a site within a country, follow the steps below.

1. Click on Countries in the Navigation menu on the left side of the screen.
2. Navigate to the country to edit and click on the country name. This opens the dashboard for the country.

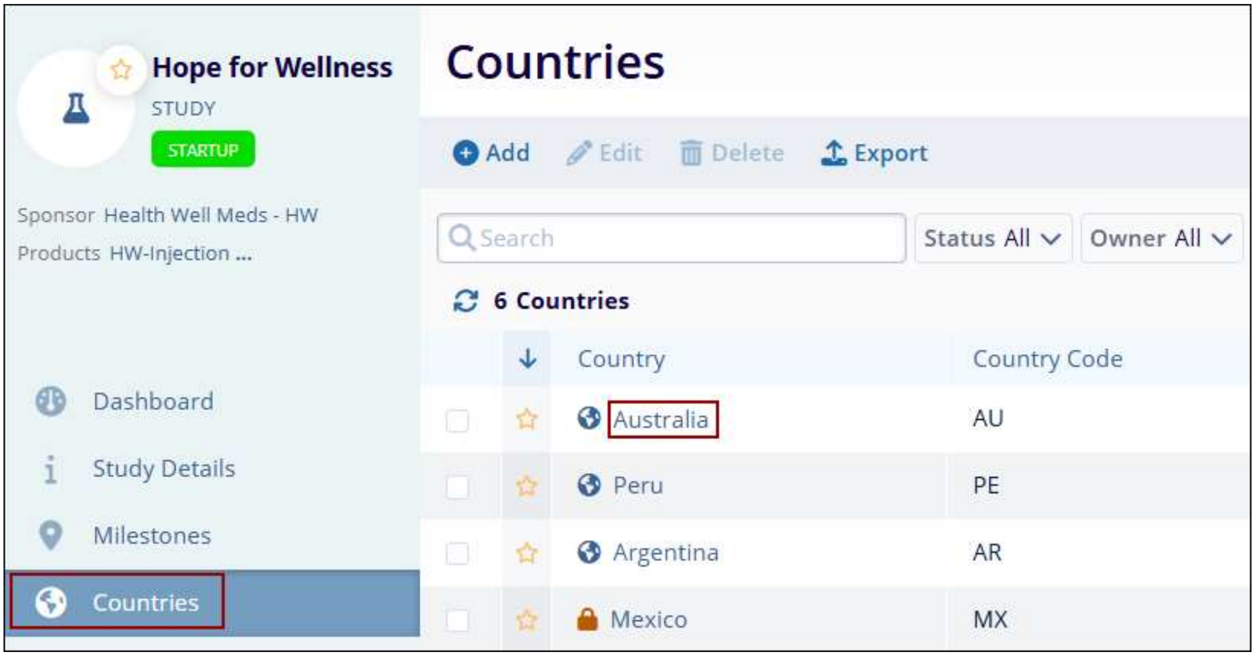


Figure: Select country to add a site within

3. Click on the Sites link in the Navigation menu on 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.

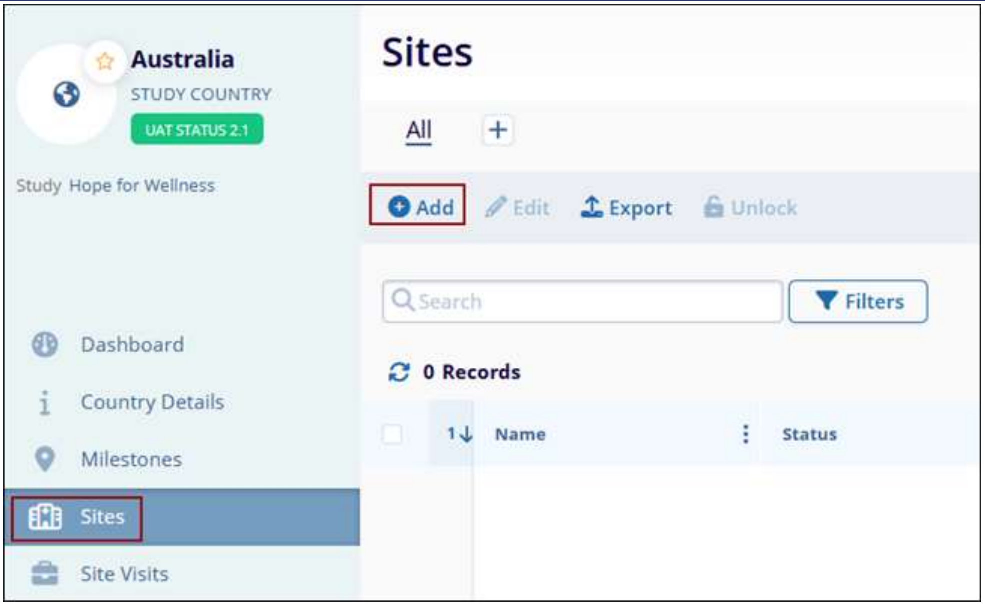


Figure: Add Site to Country

5. Fill in the required information and click Create.

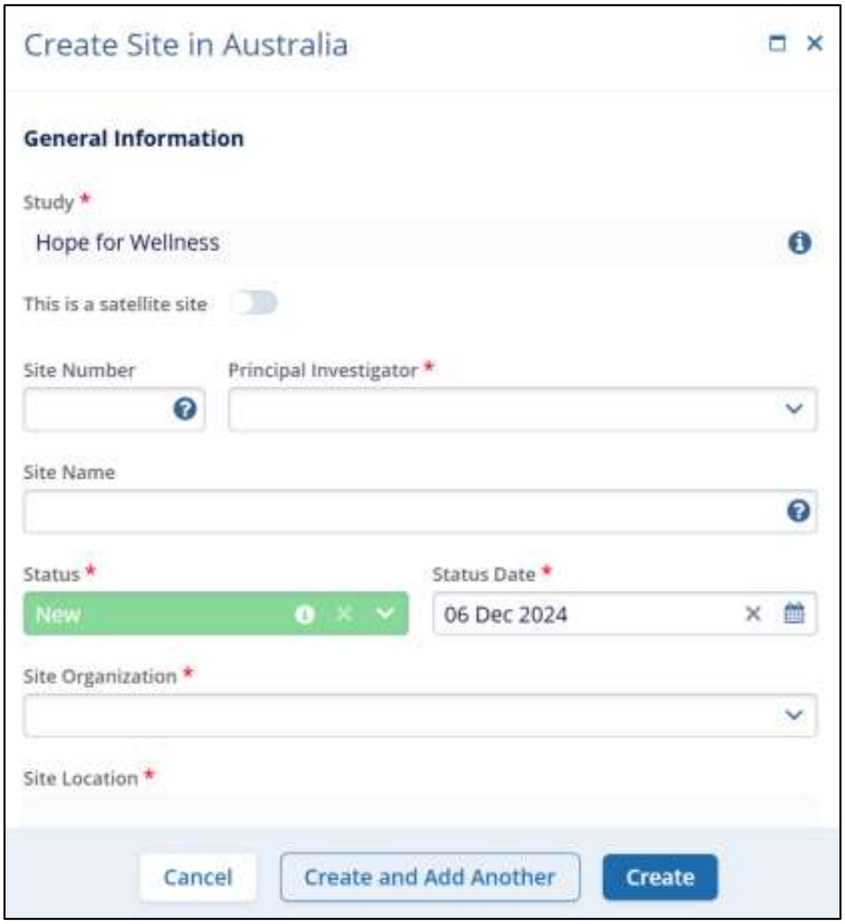


Figure: Create Site form

Associating an Organization with a Country

To associate an organization with a study, follow the steps below.

1. Click on a Country name in the countries tab within a Study.

Figure: Select a country to associate an organization to

2. From the left-hand navigation pane, select Organizations.
3. On the Organization tab within the country, click on the +Add button.

Figure: Add Organization within a Country

4. On the Add Organization screen, fill in the required details and click on the Create button. Refer to Chapter 8. Organizations for detailed information.

Associating Contacts with a Country

1. Navigate to the country to associate a contact with.
2. Click on the name of the country.

Figure: Select a country to associate contact with

3. Click on the Contacts link in the Navigation menu on the left side of the screen. This opens the 'Contacts' window, and the contacts list is displayed.
4. Click on the +Add button to create a contact within a study.
5. Refer to Chapter 9. Contacts and associated subsections.

Study Sites

This section explains to associate sites in studies.

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.

Adding Sites within the Study

1. From the left-hand navigation pane, click on the Studies link This opens the Studies screen, and the study list is displayed.
2. Click on a study name. The dashboard for the study is displayed.

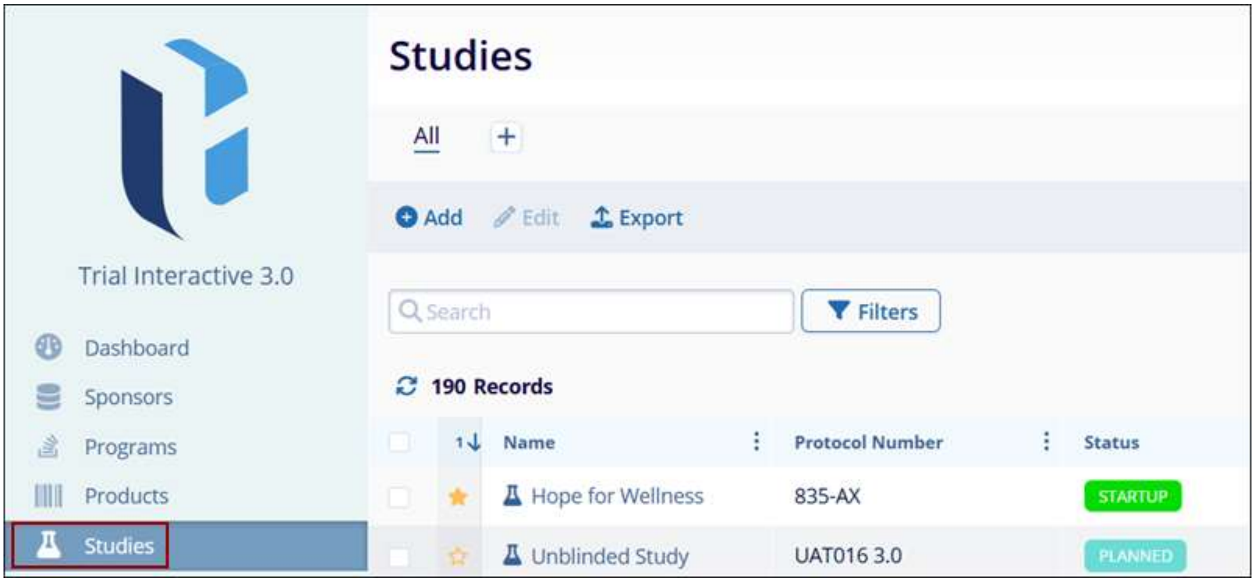


Figure: Select a Study to associate a site

3. From the left-hand navigation menu, click on the Sites link.
4. On the Sites screen, click on the +Add button from the top menu bar. This opens the Create Site form.

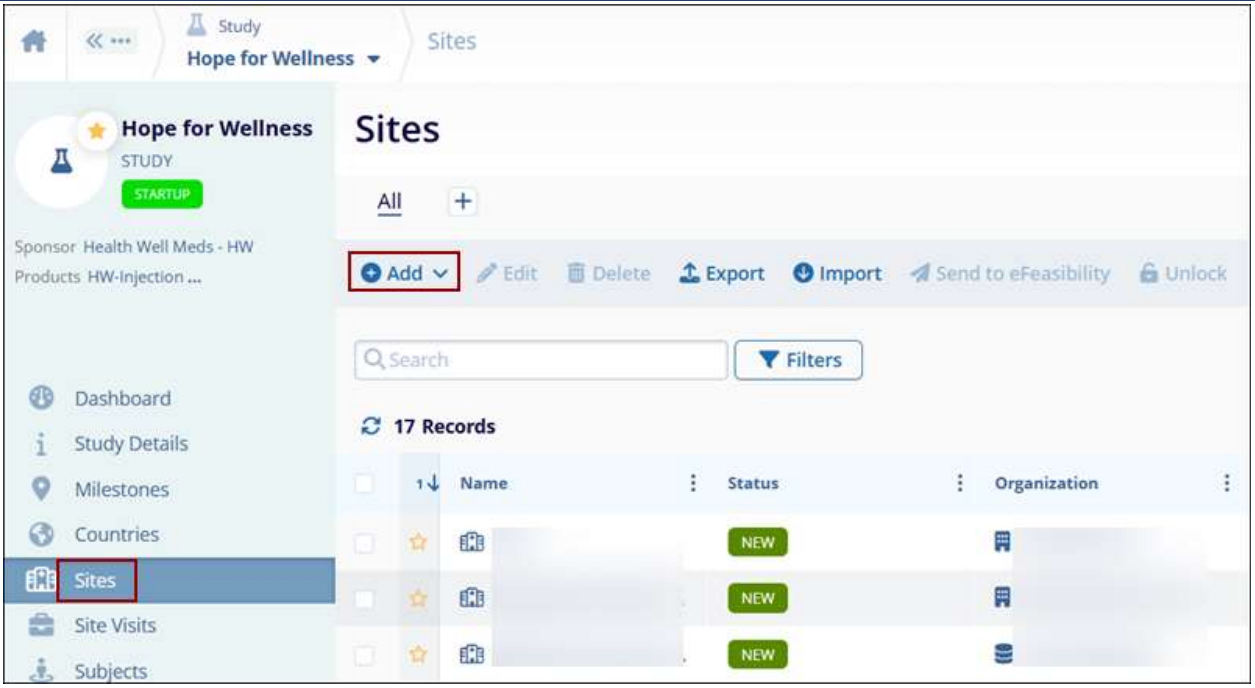


Figure: Add Site within a Study

5. On the Create Site form, add the following mandatory metadata to create a site.

    a. Primary Site* (If This is a Satellite Site toggle switch is enabled)
    b. Principal Investigator*
    c. Site Organization*
    d. Site Location*
    e. Owner*
    f. Status*
    g. Status Date*

6. Enter the following optional metadata, if required.
    a. Site Number
    b. Site Name
    c. Phone Numbers
    d. Emails

7. Click Create or Create and Add Another depending on whether to create another site.

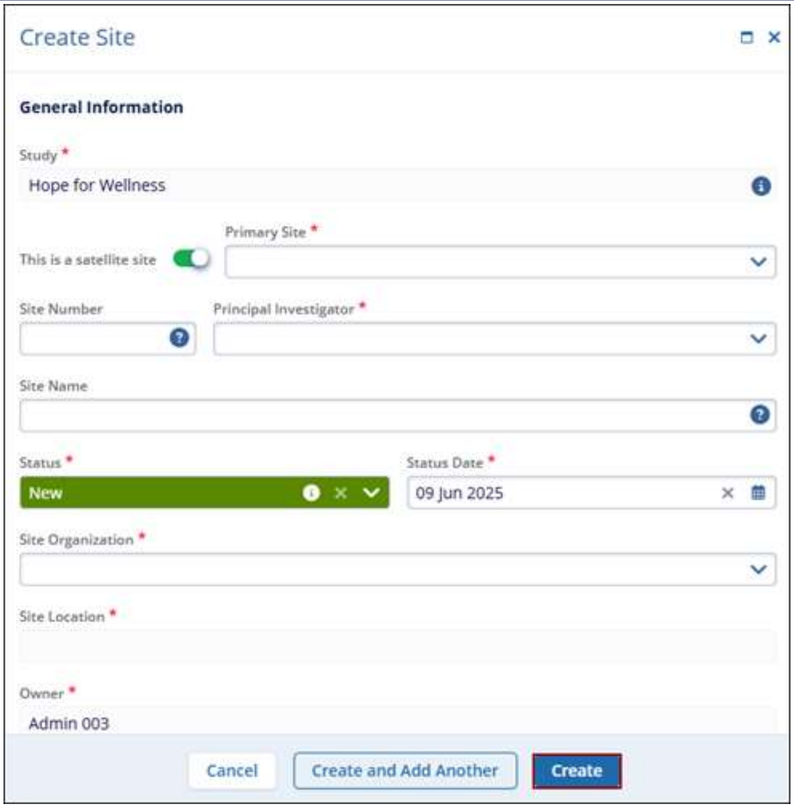


Figure: Create Site form

8. Once the site is successfully created users can click on the Site name to access the site and the required settings.

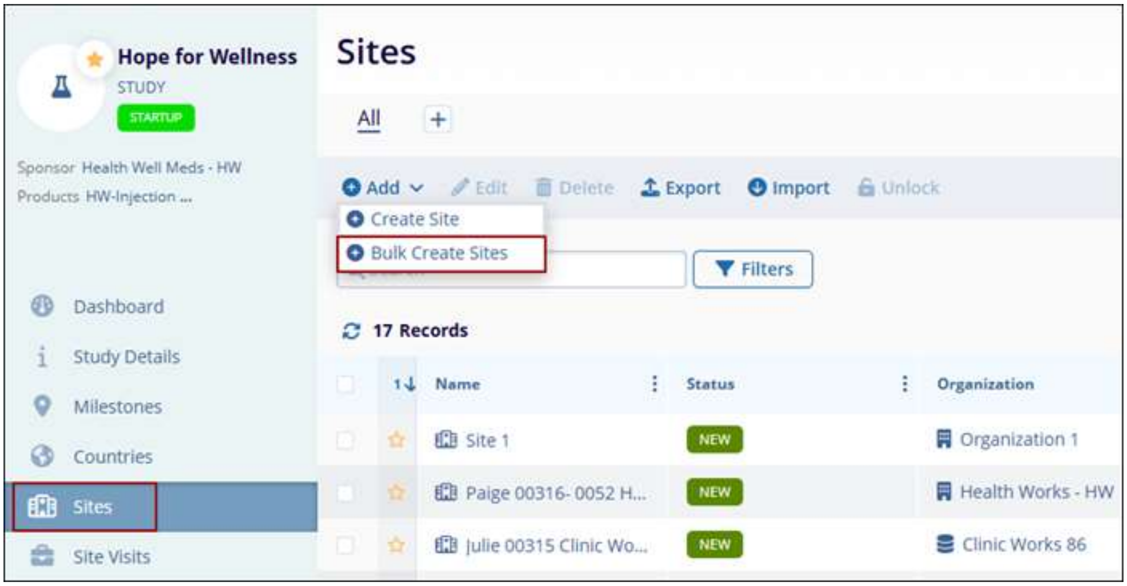
Note:

- If the site is a satellite site, it is mandatory to associate the parent site. The parent site will need to already be created and associated with the study before identifying a site as a satellite site.
- 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.
- If Site Number and Site Name are automatically generated if left blank.

Bulk Create Sites

To bulk create sites, follow the steps below.

1. On the Sites screen, click on the +Add button from the top menu bar and select the '+Bulk Create Sites' option.



2. On the Create Potential Sites modal window, select the required number of Global Contacts and click on the Next button.

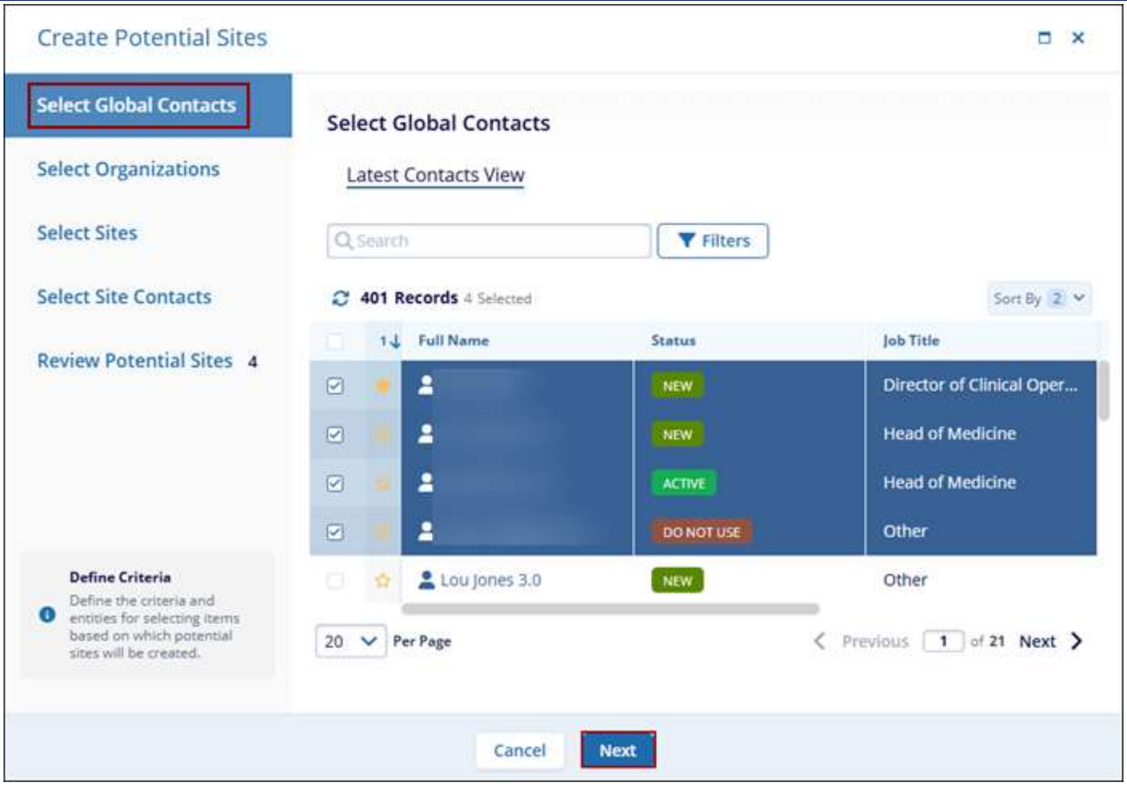


Figure: Create Potential Sites – Select Global Contacts

3. Select the required number of organizations and click on the Next button.

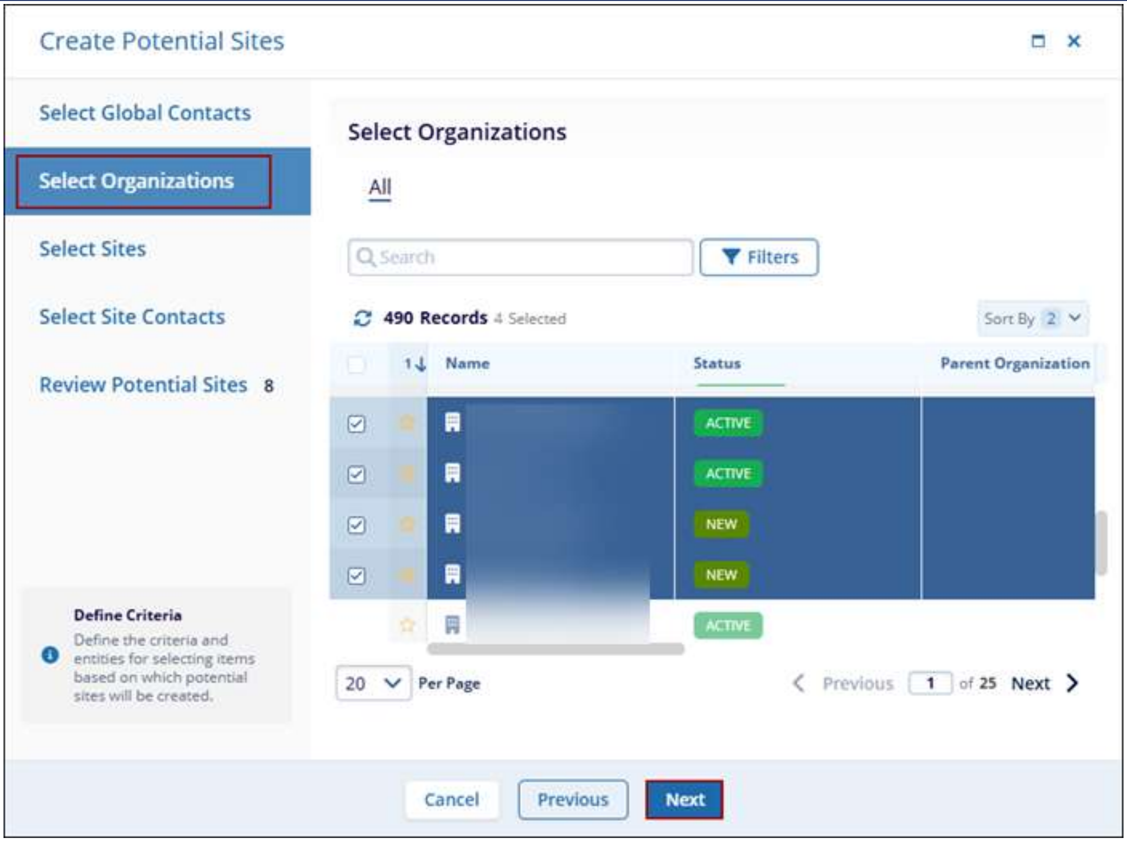


Figure: Create Potential Sites – Select Organizations

4. Select the required number of sites and click on the Next button.

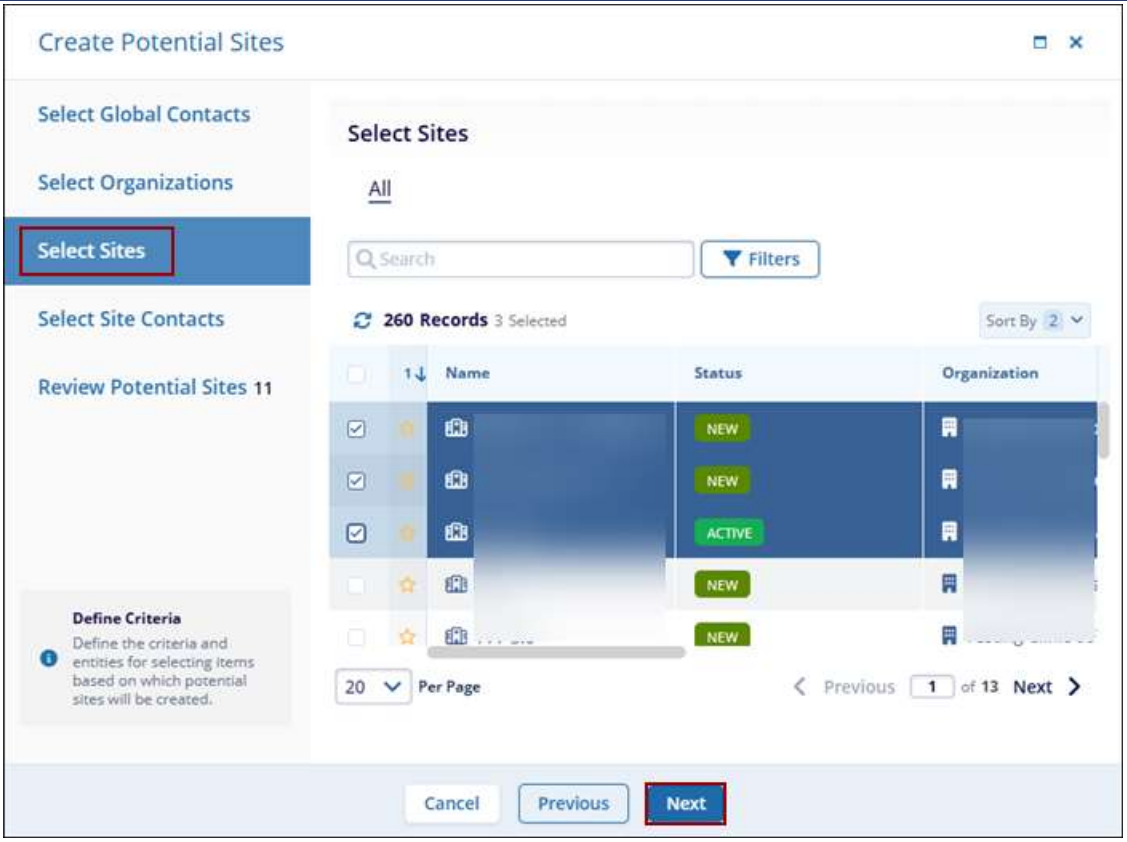


Figure: Create Potential Sites – Select Sites

5. Select the required number of site contacts and click on the Next button.

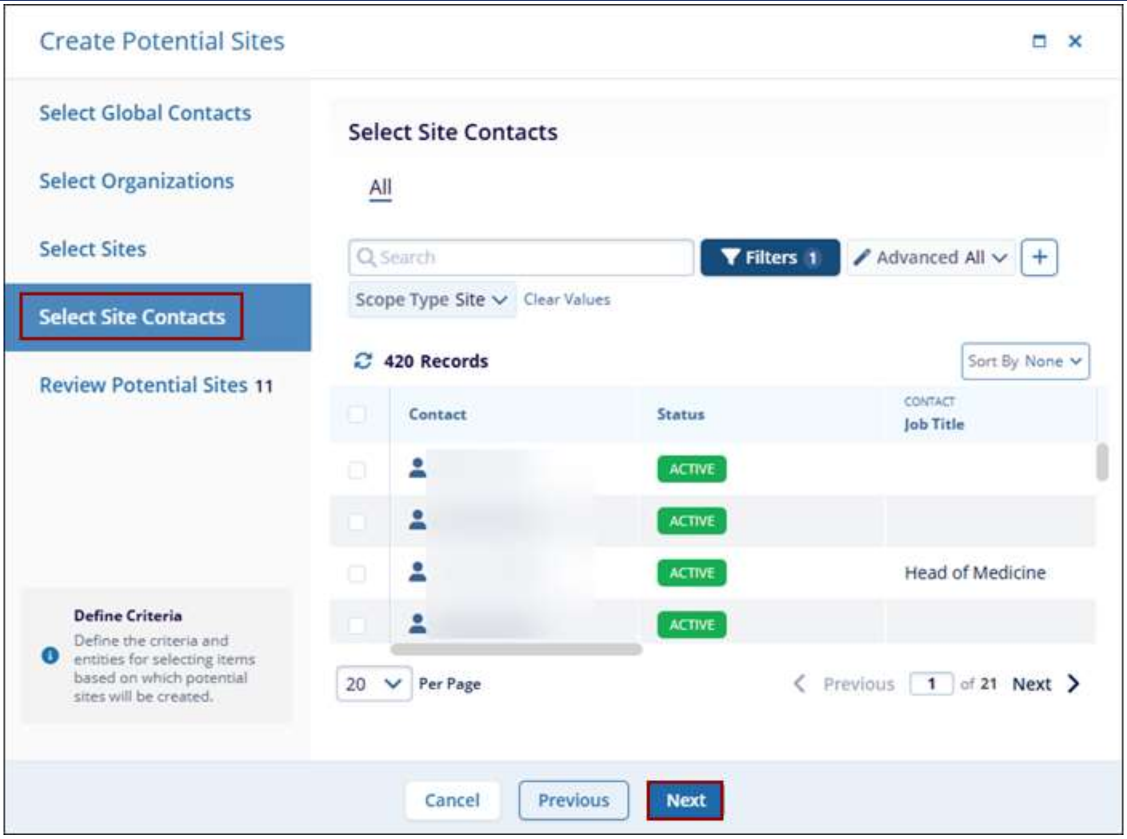
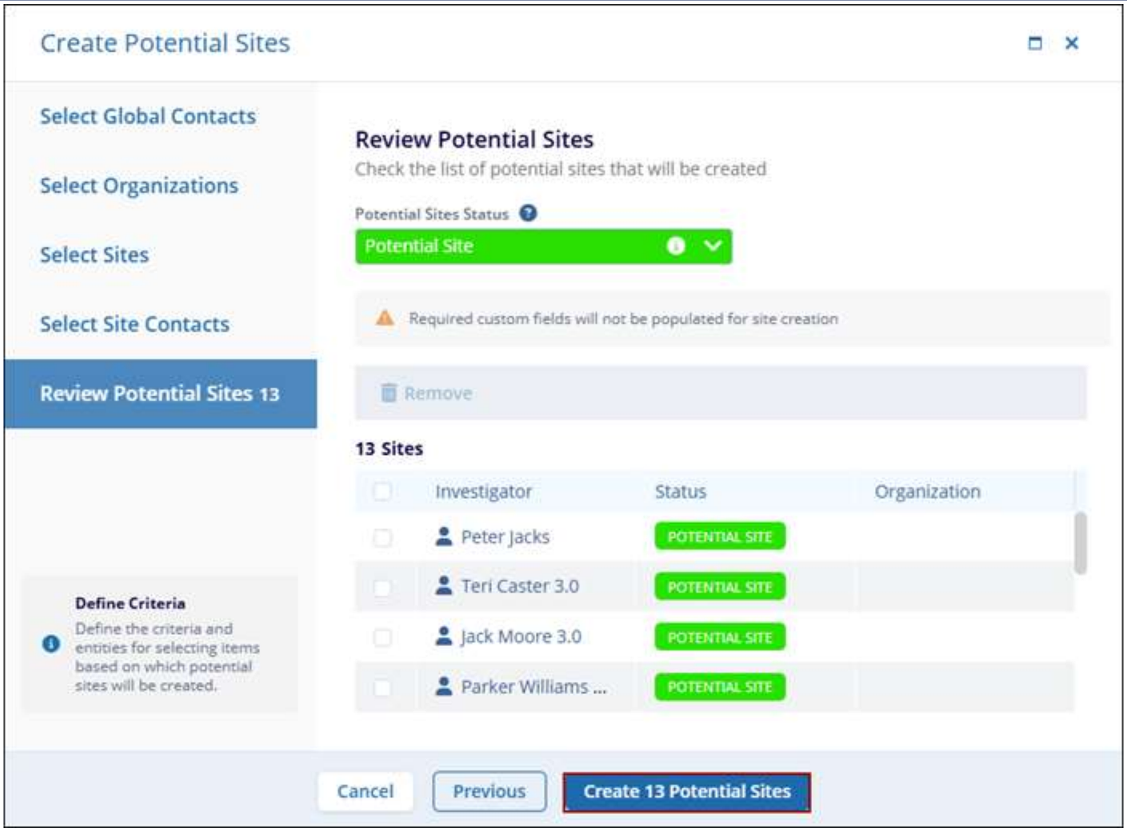


Figure: Create Potential Sites – Select Site Contacts

6. On the 'Review Potential Sites' section, view the list of potential sites that will be created and click on the 'Create (number) Potential Sites button.


Create Potential Sites
Select Global Contacts
Select Organizations
Select Sites
Select Site Contacts
Review Potential Sites 13
Define Criteria
Define the criteria and entities for selecting items based on which potential sites will be created.
Review Potential Sites
Check the list of potential sites that will be created
Potential Sites Status
Potential Site
Required custom fields will not be populated for site creation
Remove
13 Sites
Investigator
Status
Organization
Peter Jacks
POTENTIAL SITE
Teri Caster 3.0
POTENTIAL SITE
Jack Moore 3.0
POTENTIAL SITE
Parker Williams ...
POTENTIAL SITE
Cancel
Previous
Create 13 Potential Sites

Editing a Site in a Study CRA

To edit a site in a study, follow the steps below

1. To access a site created with a study, follow the navigation steps detailed in the [Adding Sites within the Study](#) section.
2. Select a site by clicking on the checkbox and click on the Edit button from the top menu bar.

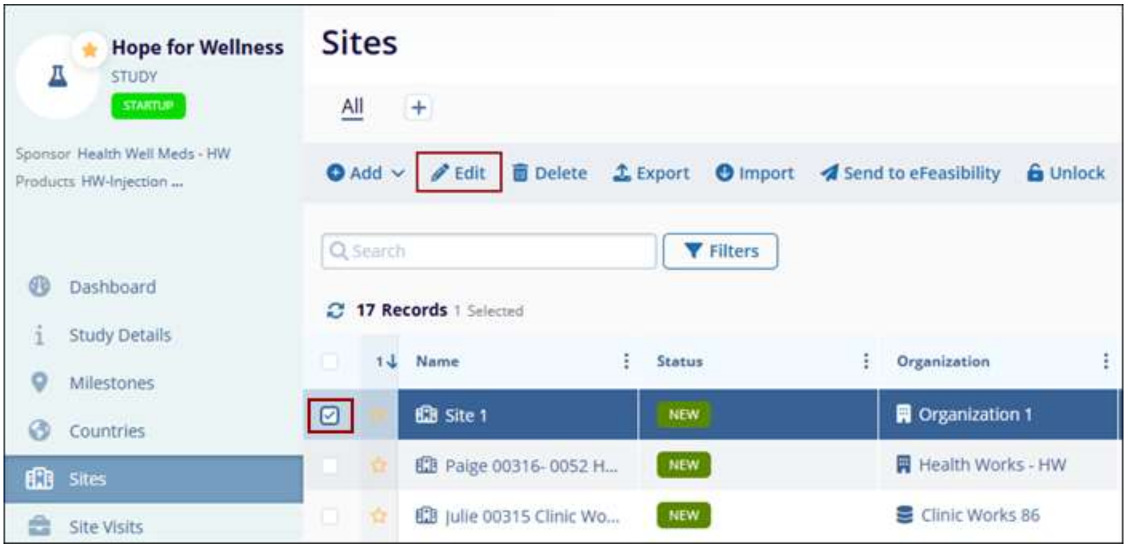


Figure: Edit Site details

3. Make the required changes in the site details window and click on the Save button at the top-left of the screen for the changes to apply.

Figure: Save changes to site details

The following sections describe the site-related details users can edit.

<u>Site Information</u>

Within the Site Information section, make the following changes.

- Change the Principal Investigator and Site Organization by clicking on the Change button.
- Click on the Regenerate button to generate a new site name
- Enable the 'This is a Satellite Site' toggle switch to make the site a satellite site.
- Add Regions and notes if required.

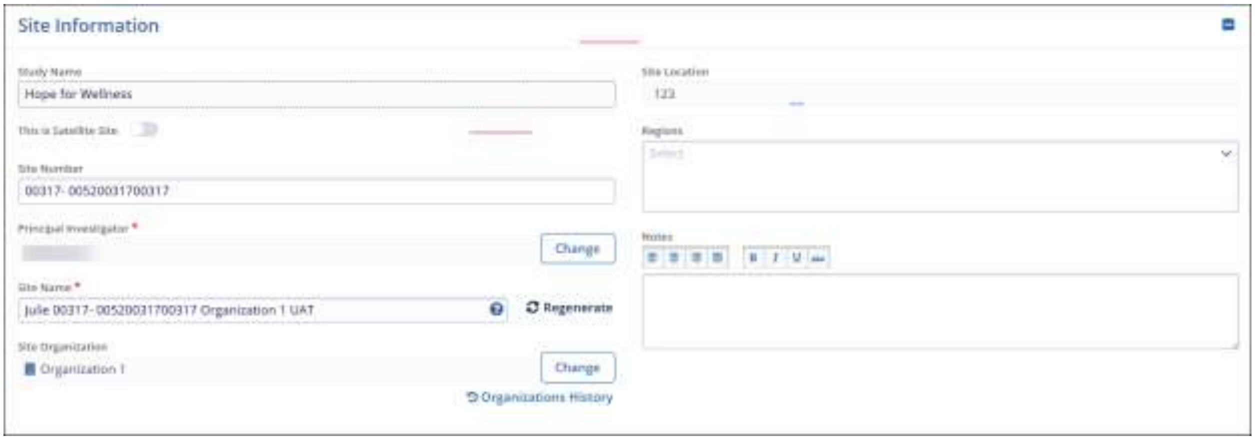


Figure: Edit Study – Site Information

Note: Study Name and Site Location are non-editable.

Change of Principal Investigator (PI)

To change the principal investigator, follow the steps below.

1. Navigate to the Site Details screens by following the steps in the [Editing a Site in a Study] section.
2. On the Site Details screen, expand the Site information screen and click on the Change button in front of the Principal Investigator field.

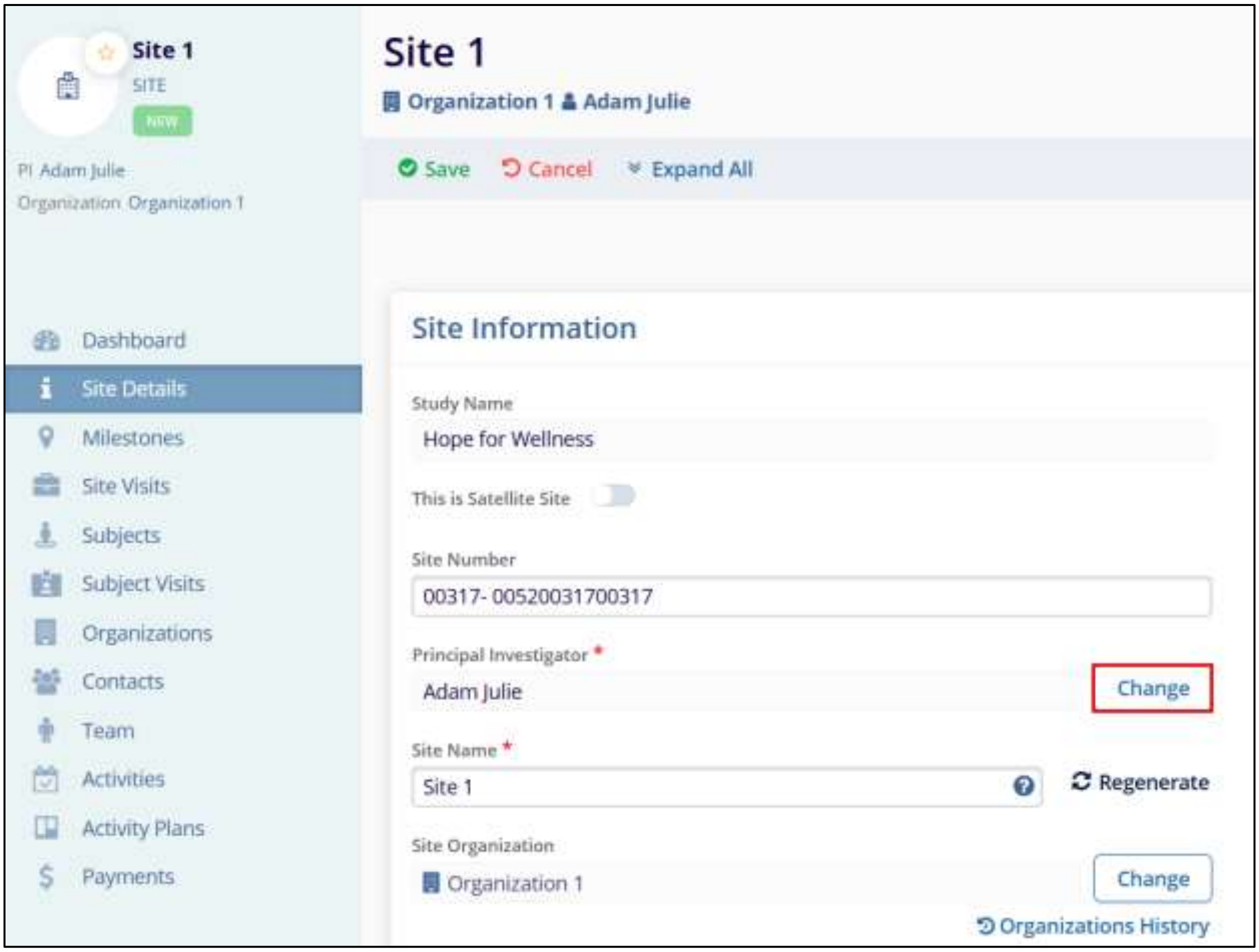


Figure: Change Principal Investigator

3. On the Confirmation popup, click on the Yes button.

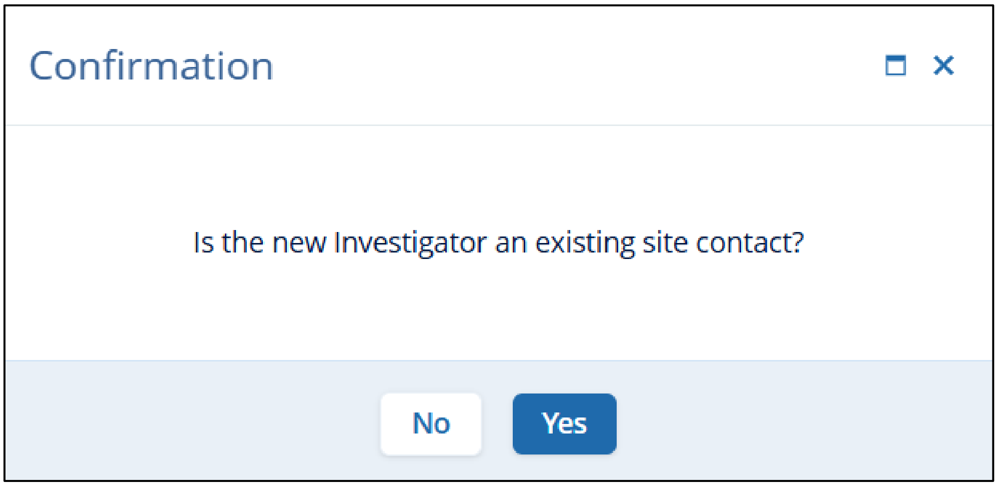


Figure: Confirmation popup

4. On the ‘Change Principal Investigator screen, make the required edits and click on the Save button.

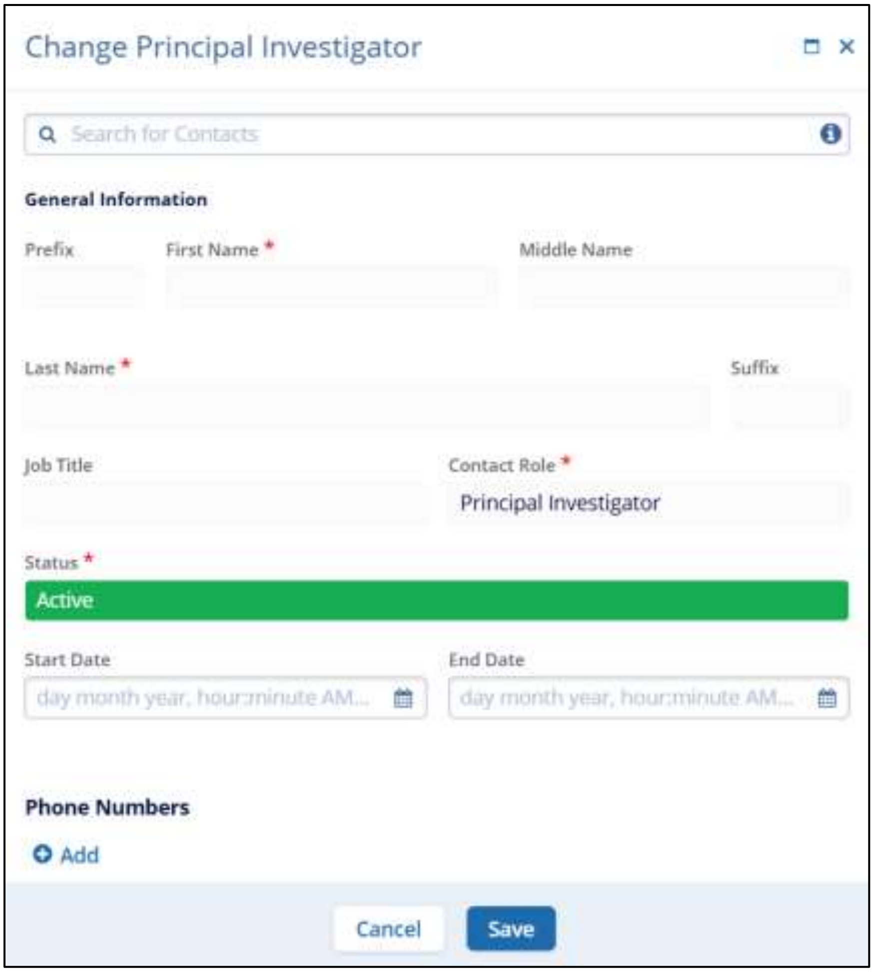


Figure: Change Principal Investigator form

Site Management

Within the Site Information section, make the following changes.

- Click on the Change Status button to modify the Status and Status Date.

Figure: Site Management

Informed Consents

To track informed consents (ICFs) for a site, follow the steps below.

1. Navigate to the Site Details screen by following the steps detailed in the [Associating Sites within the Study](#) section.
2. Expand the Informed Consent section.
3. Click on the +Add button.

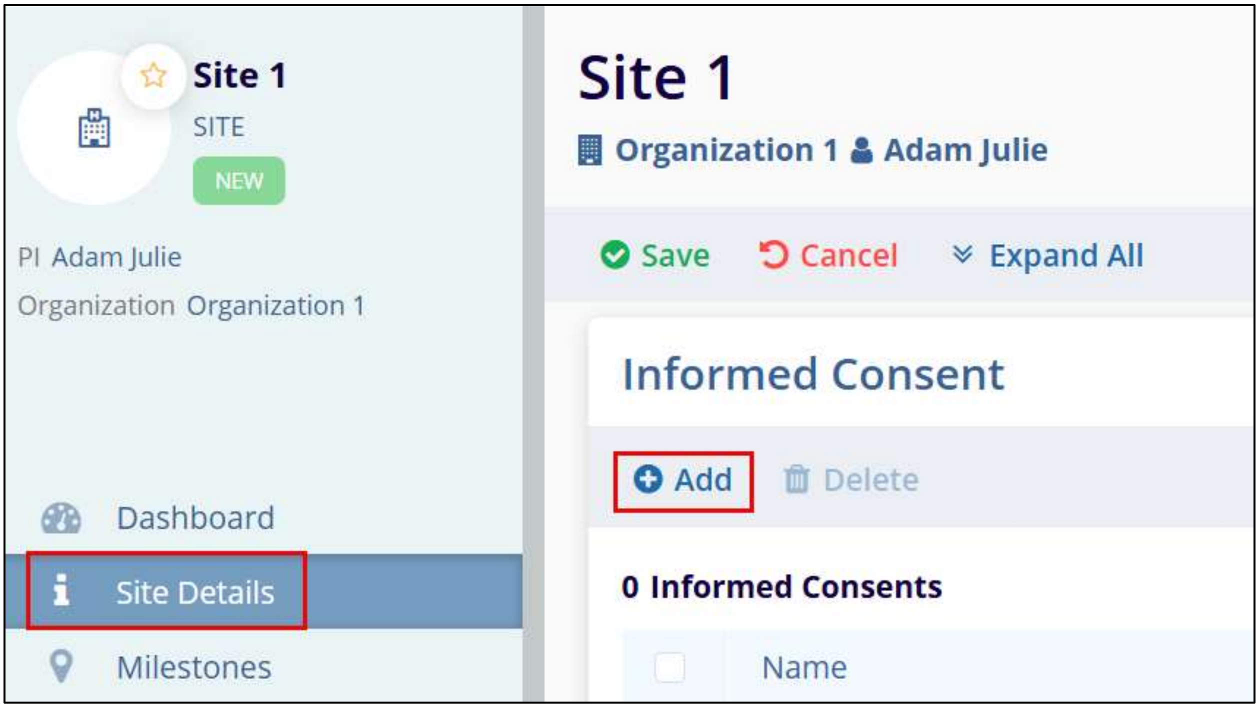


Figure: Add Informed Consents

4. Enter the site-specific Name and Effective Date.
5. Click on the Save button in the informed consent section to save the record. This creates site-level ICF for the site.

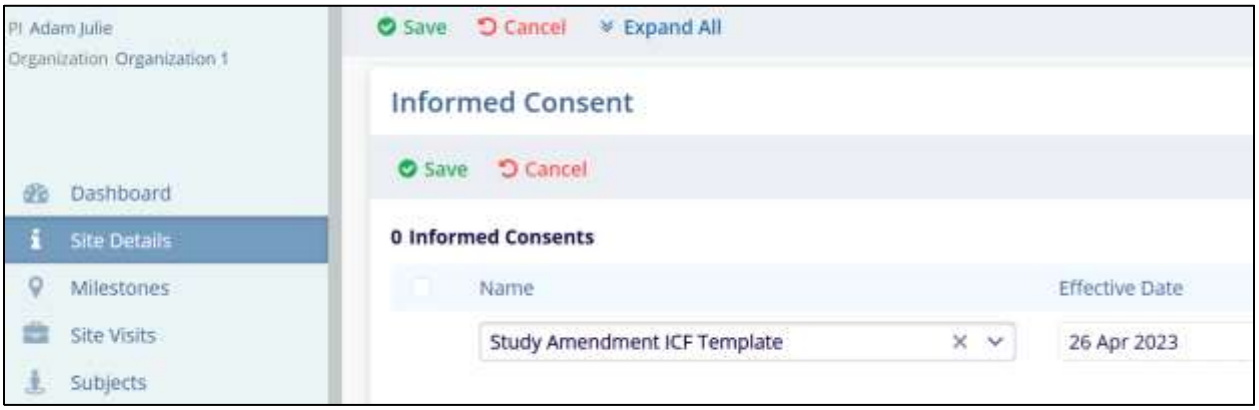


Figure: Save newly created informed consents

Contact Information

To edit the Contact information, follow the steps below.

1. Navigate to the Site Details screen by following the steps detailed in the [Associating Sites within the Study](#) section.
2. Expand the Contact Information section.

3. Site Location is listed as a primary address for the site.
4. Click on the Add button under the Site Addresses section. This opens the Add Address window.
5. 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.
6. Click on the Save button.

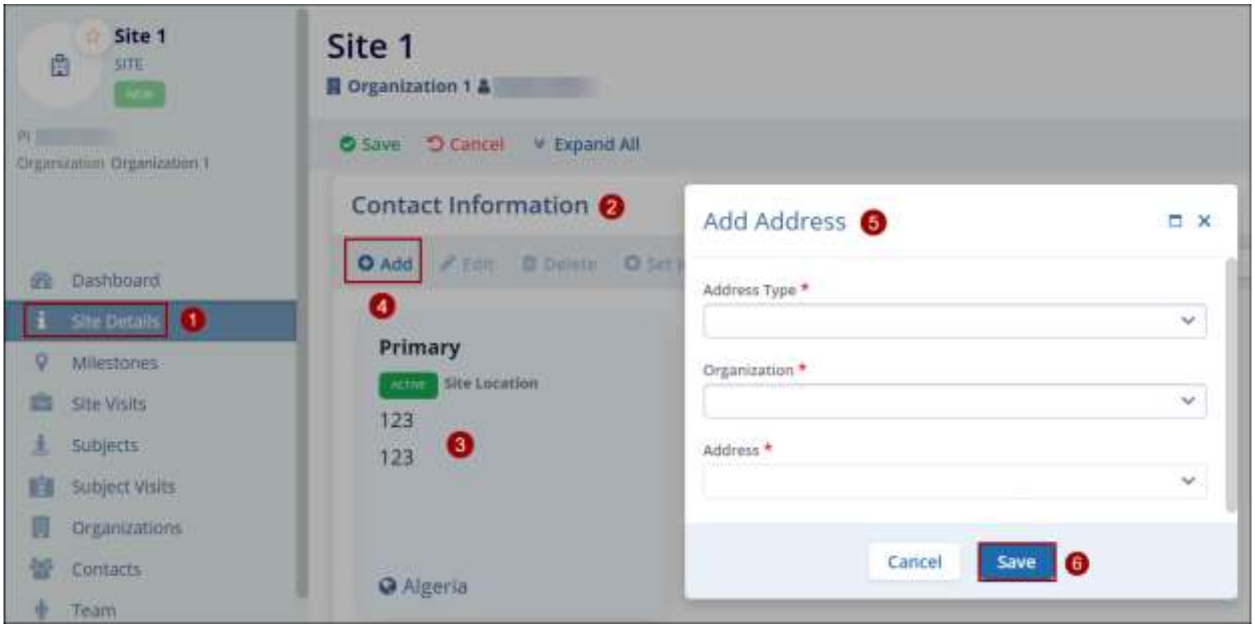


Figure: Site Details – Contact Information

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

<u>Subject and Recruitment</u>

Update the following fields by accessing the number input icon of each field to adjust the numerical values.

- Planned Subjects Entered Trial
- Planned Subjects Entered Treatment
- Planned Subjects Completed Treatment
- Planned Withdrawn
- Planned Screened
- Planned Active
- Planned Enrolled
- Planned Screen Failed
- Planned Completed
- Planned Lost to Follow-up
- Planned Randomized

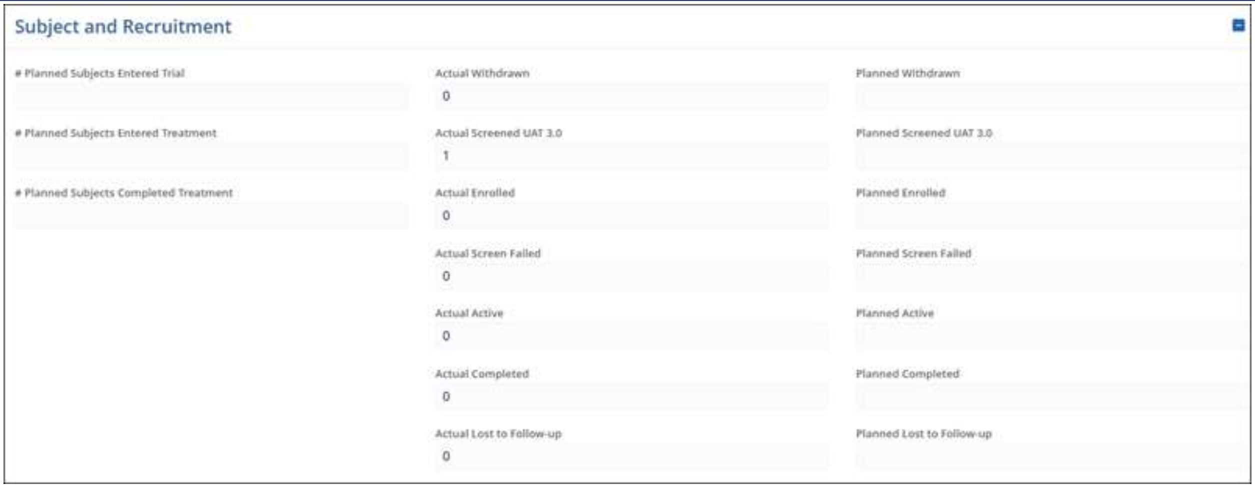


Figure: Edit Study – Subject and Recruitment

Additional Information

Expand the Additional Information section to access additional fields. The Additional Information section displays active fields configured under Settings > Fields > Sites.

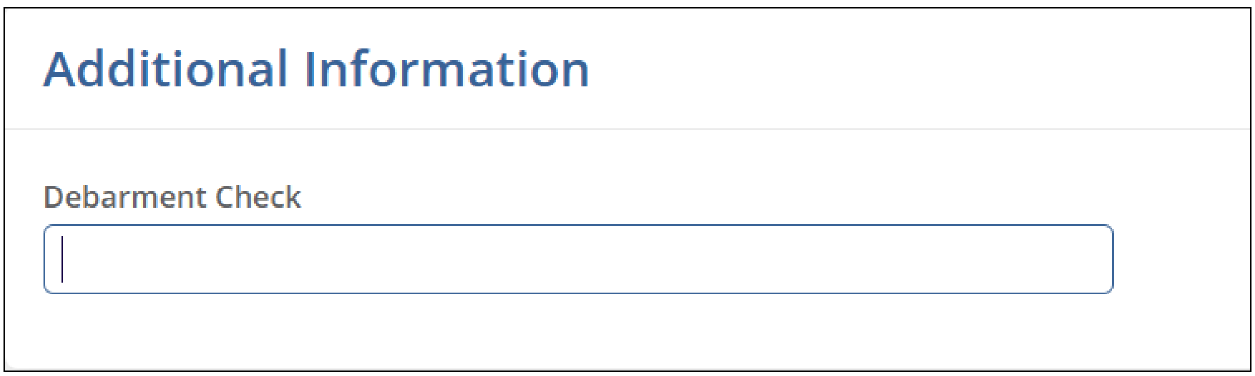


Figure: Edit Site – Additional Information

Close Site

To close a site, follow the steps below.

1. Navigate to the Site Details screen by following the steps detailed in the Adding Sites within the Study section.
2. Expand the Close Site section.

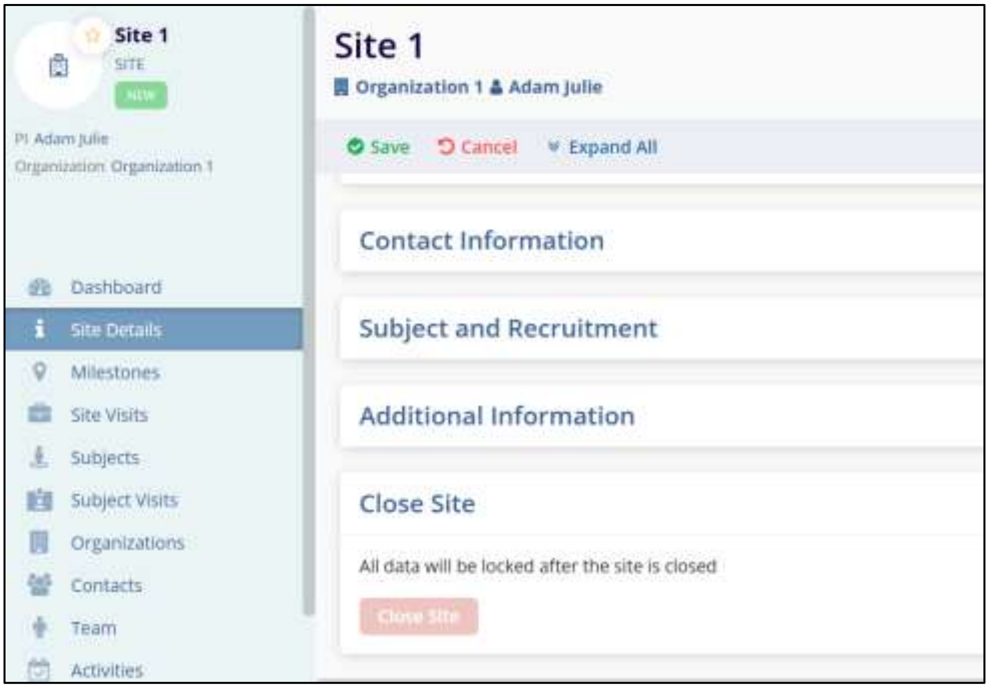


Figure: Accessing Close Site setting

3. Click on the Close Site button

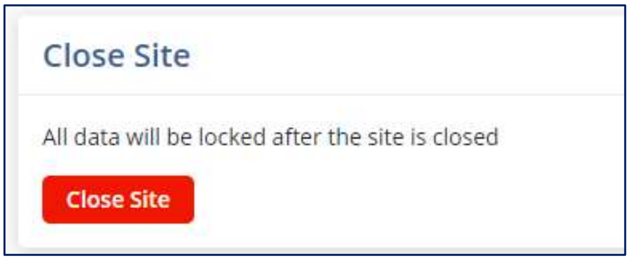


Figure: Close a Site

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.

Deleting a Site

To delete a site, follow the steps below.

1. On the Sites screen, select a site by clicking on the checkbox.
2. Click on the Delete button, from the top menu bar.
3. Click on the Delete button on the confirmation popup.

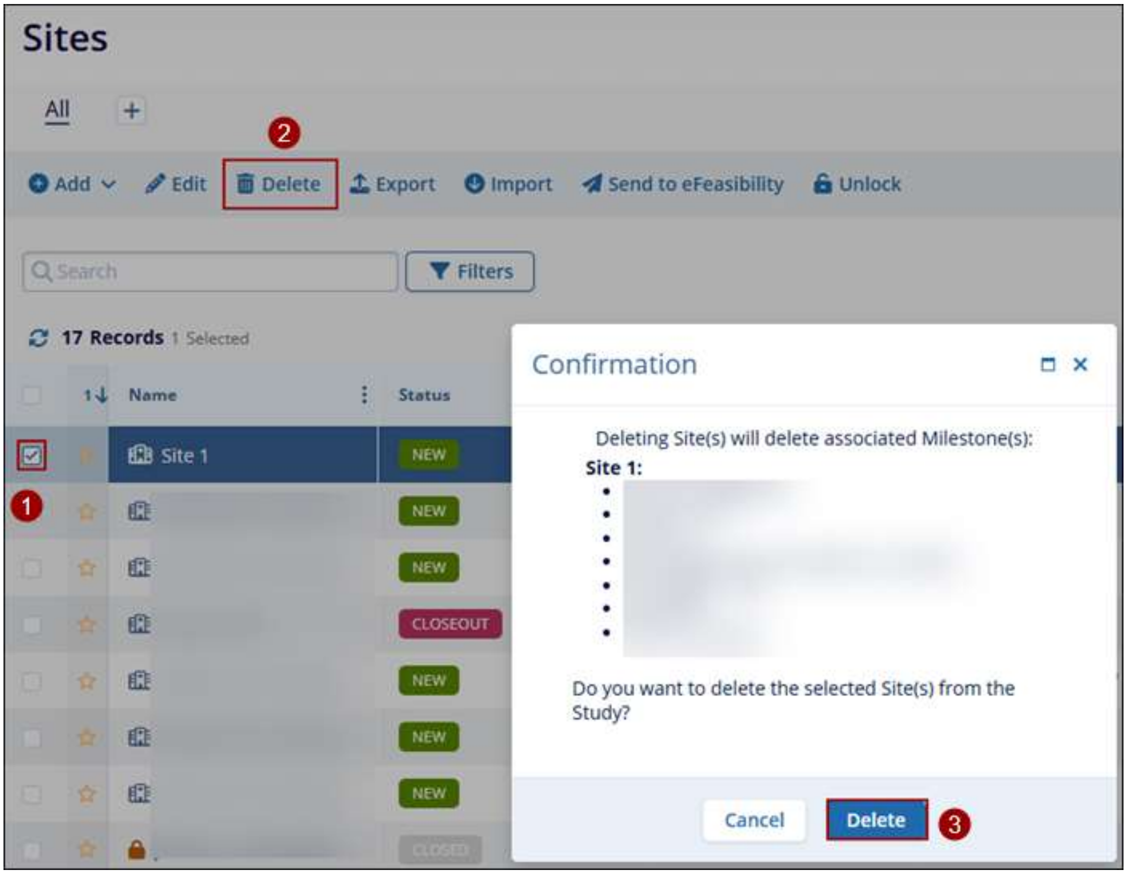


Figure: Delete Site

Export Sites

To export sites, follow the steps below.

1. Click on the 'Export' button from the top menu bar on the Sites screen within a Study profile.

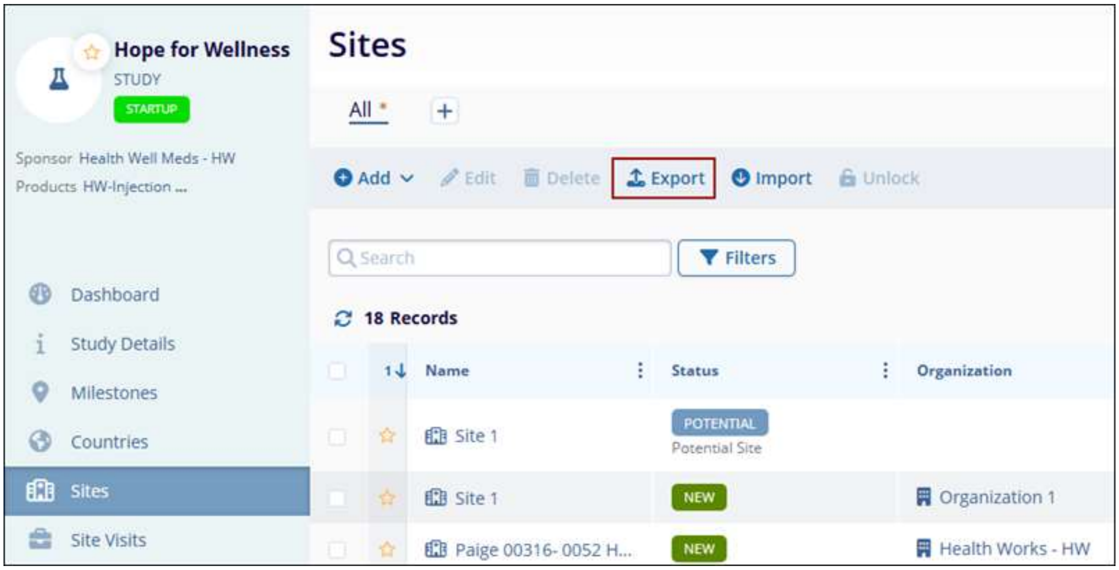


Figure: Export Sites

2. On the 'Export' dialog, select the format i.e., CSV or XLSX, define the number of records and click on the 'Export' button.

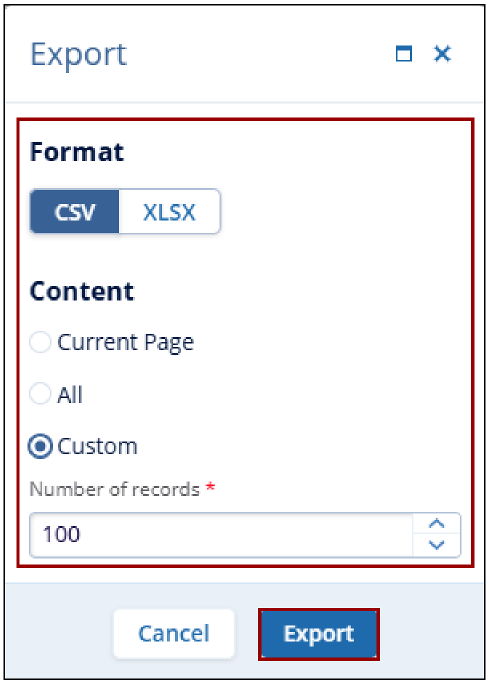


Figure: Export Sites – Format and Content

3. Click on the 'Get Job Results' button and download the file into the system.

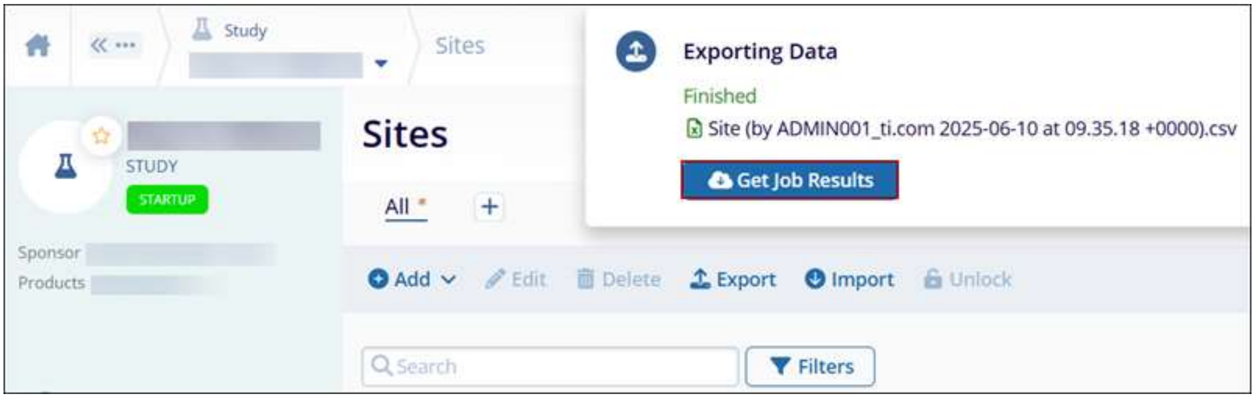


Figure: Export Sites – Get Job Results

4. Open the downloaded file and access the 'Site' tab to view the site details.

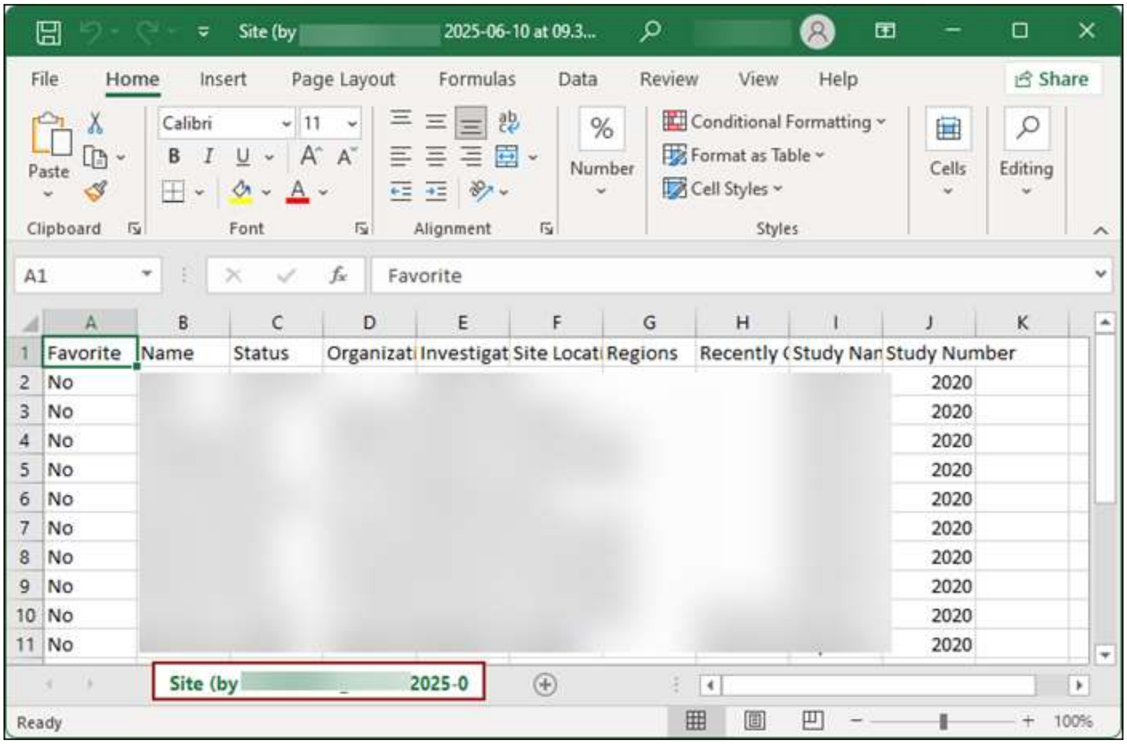
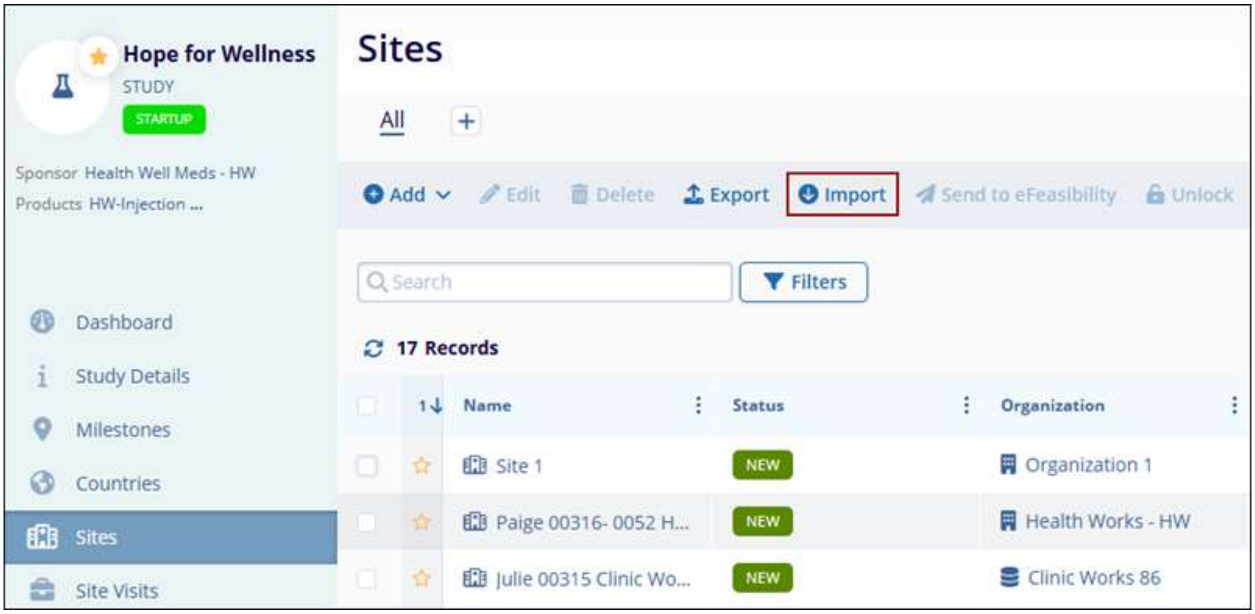


Figure: Site export file

Import Sites

To import sites, follow the steps below.

1. Click on the 'Import' button from the top menu bar on the Sites screen.



2. On the 'Import Sites' modal window, click on the 'Download Template' button.

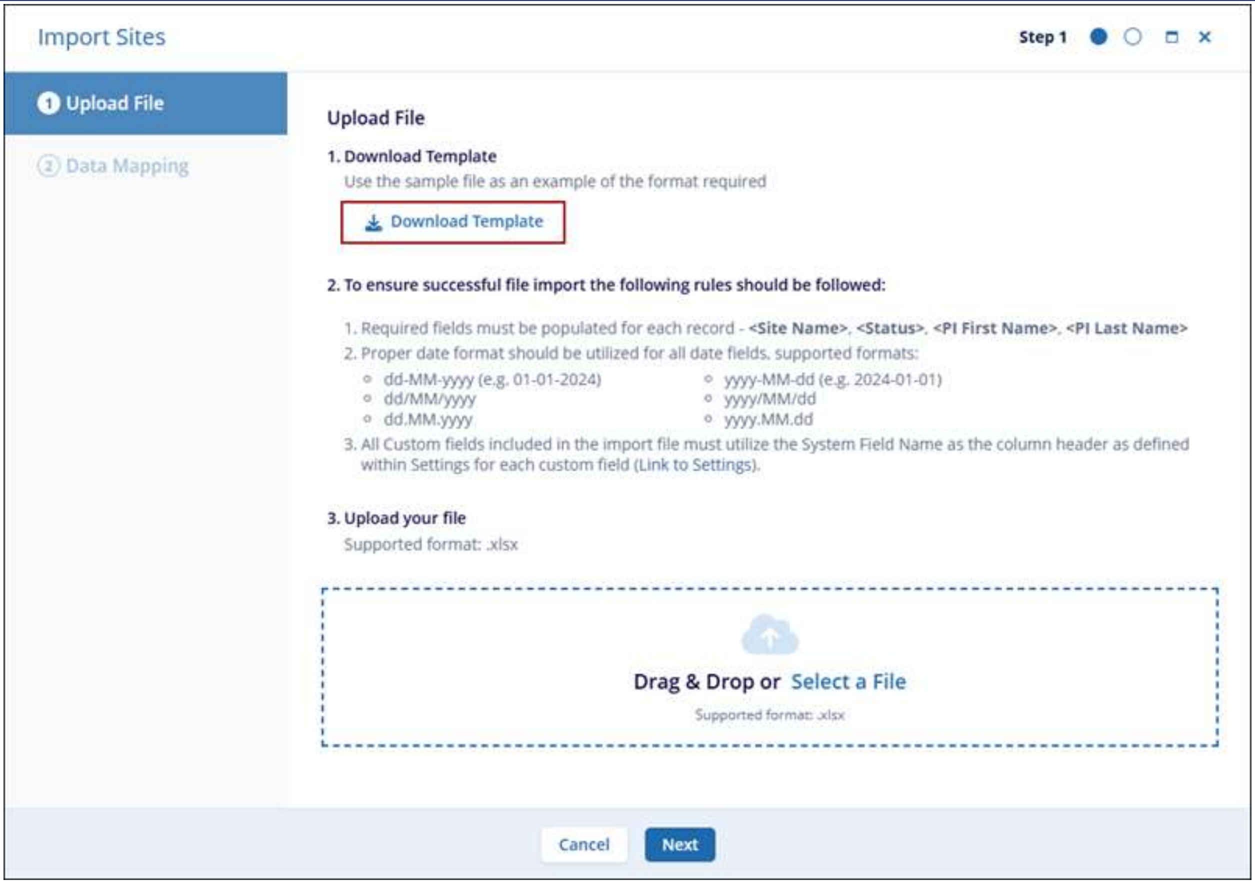


Figure: Download Site Import Template

3. Within the downloaded template fill in the necessary information in the 'Sites' tab.

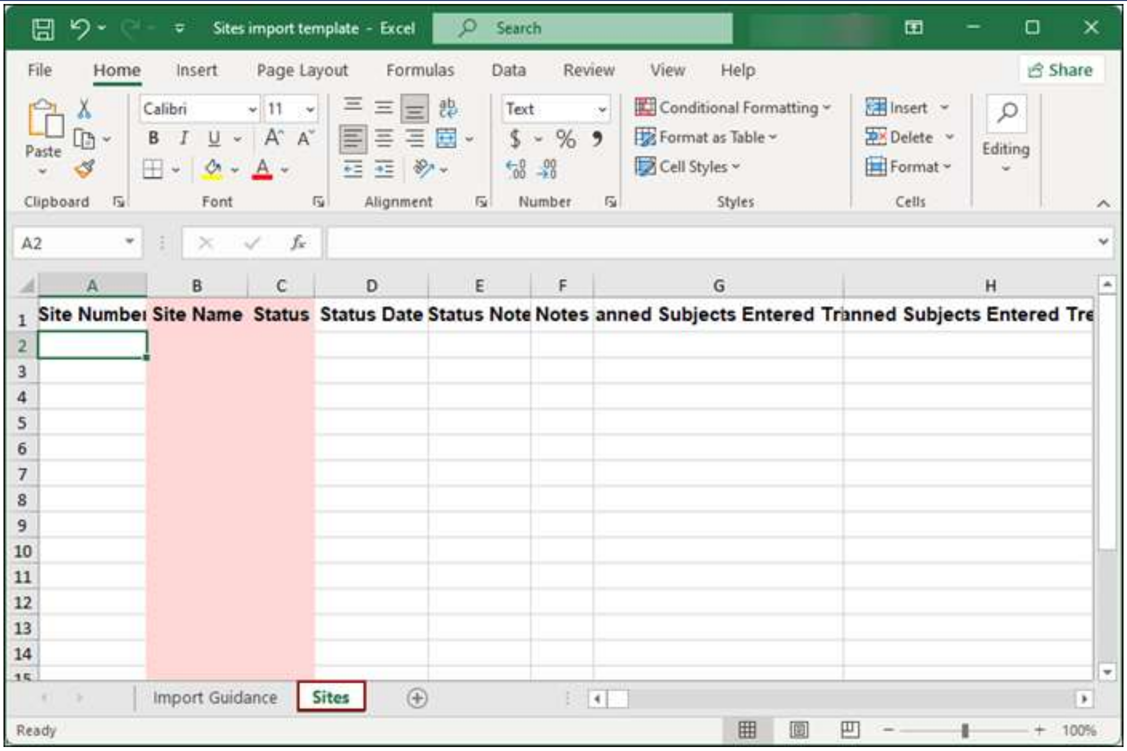
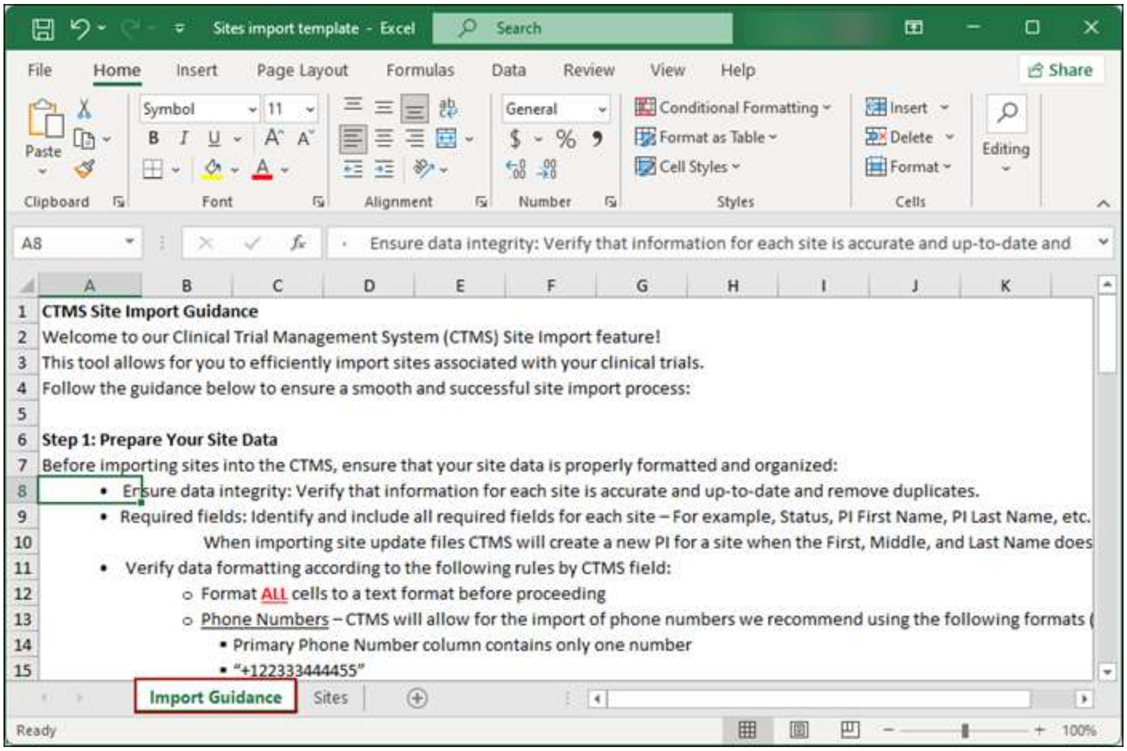


Figure: Site Import Template – Sites tab

4. For detailed instructions on the import process, click on the 'Import Guidance' tab.



5. Upload the template file in XLSX file format by using the Drag & Drop or manual upload functionality and click on the 'Next' button.

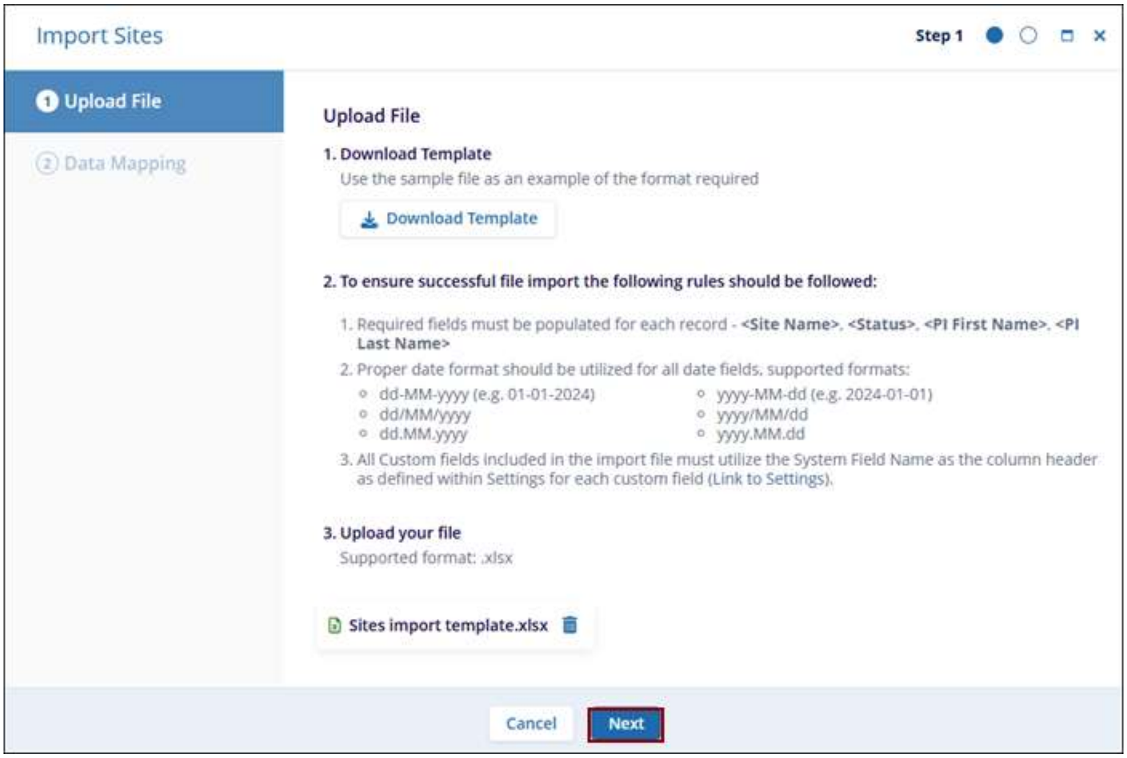


Figure: Upload Template File

6. On the 'Data Mapping' screen, specify the unique identifiers for the Organization, the default value for the Organization Type and Status columns and click on the 'Import' button.

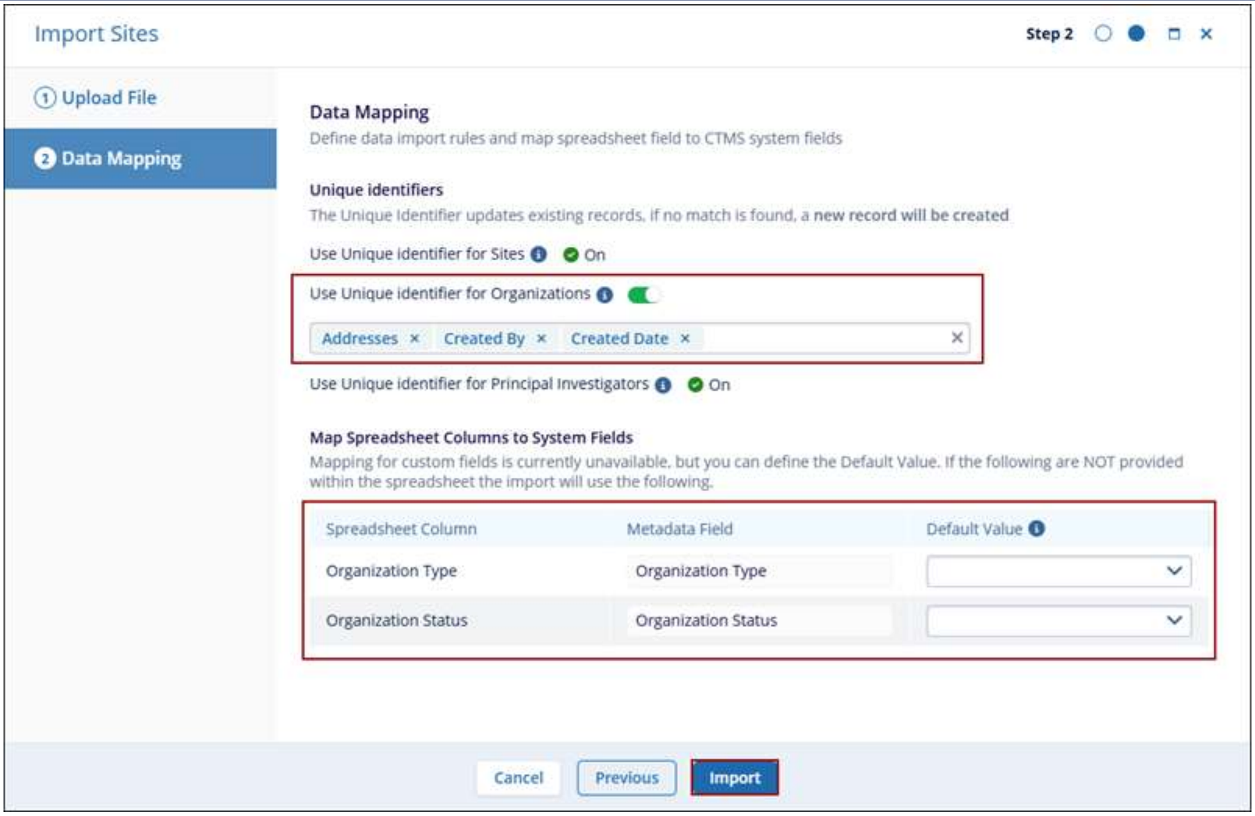


Figure: Site Import – Data Mapping

Important: To import activities, users must have the 'Create' and 'Update' permissions enabled for Sites from Settings > Access Permissions.

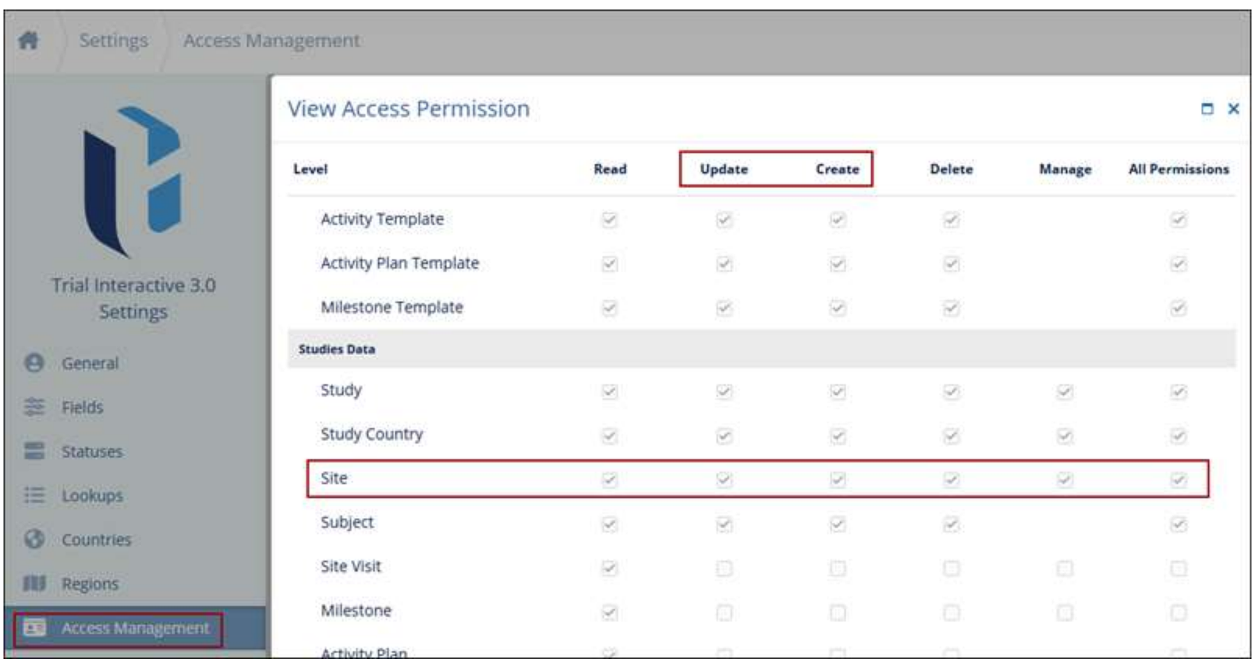


Figure: Site Import Access Management

Send to eFeasibility

Users can share 'Potential' sites list from CTMS to eFeasibility, from the Sites grid within a study profile, ensuring the reduction of duplicate efforts for site entries across multiple applications.

To send sites to eFeasibility, follow the steps below.

1. Select sites with 'Potential' status from the Sites grid within a Study profile.
2. Click on the 'Send to eFeasibility' button.

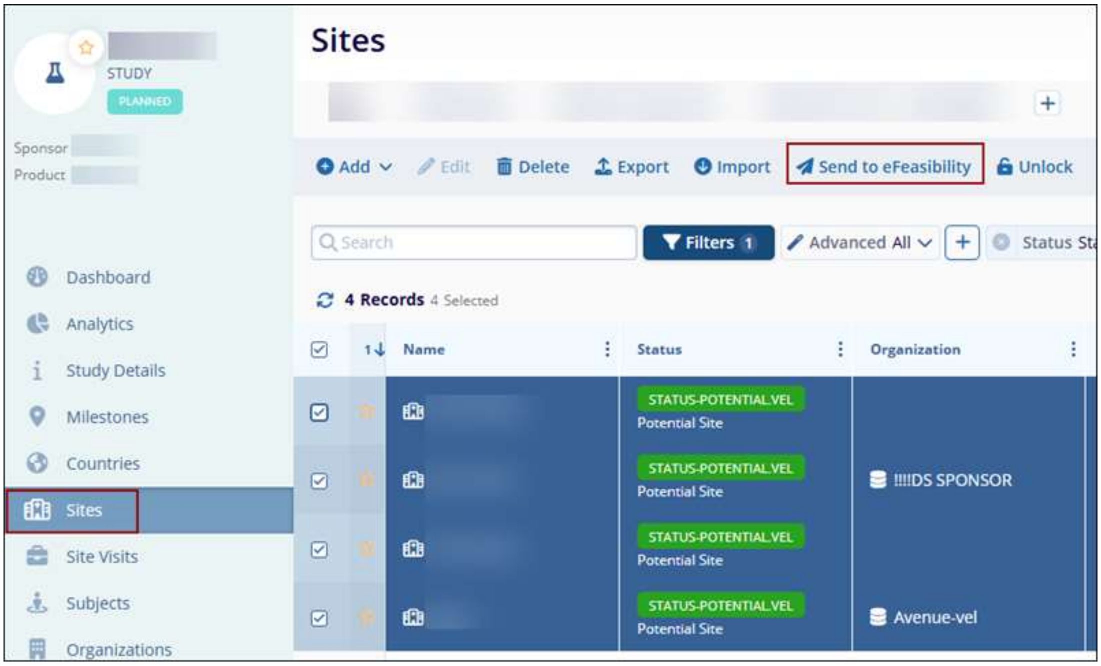


Figure: Send to eFeasibility

3. On the 'Send to eFeasibility' confirmation popup, click on the 'Send (number) Sites' button.

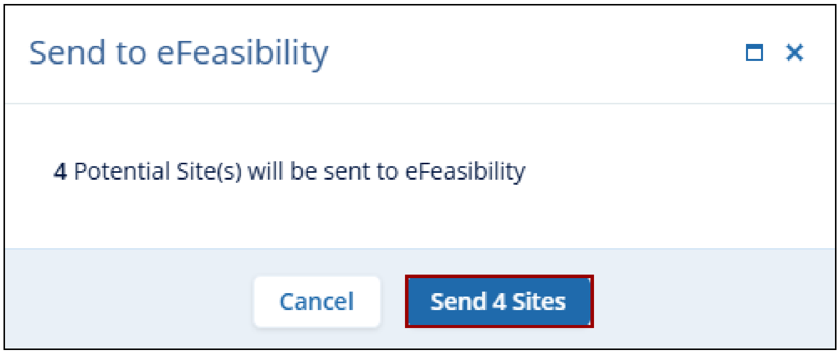
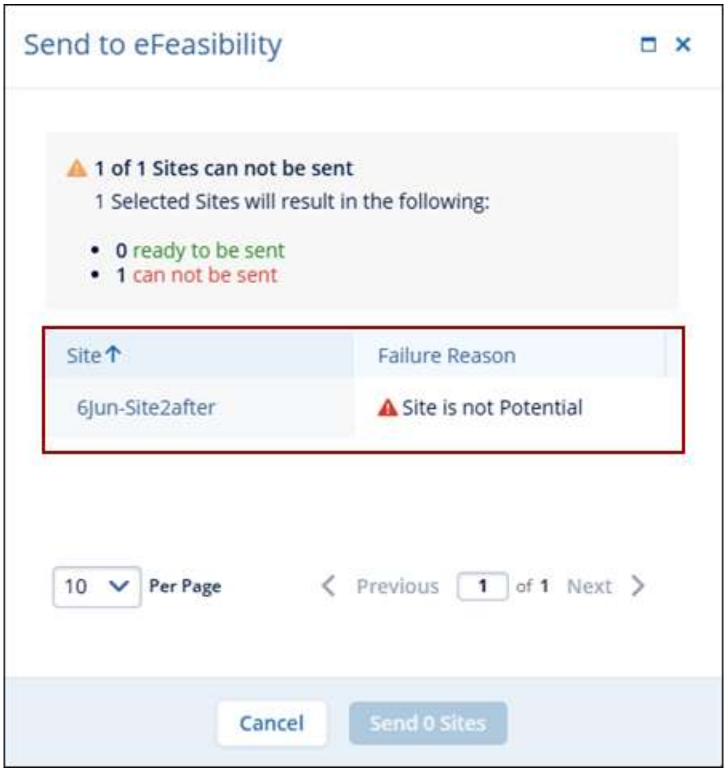


Figure: Send to eFeasibility confirmation

Important: The 'Send to eFeasibility' dialog box displays the failure message incase the selected sites does not match the requirements.

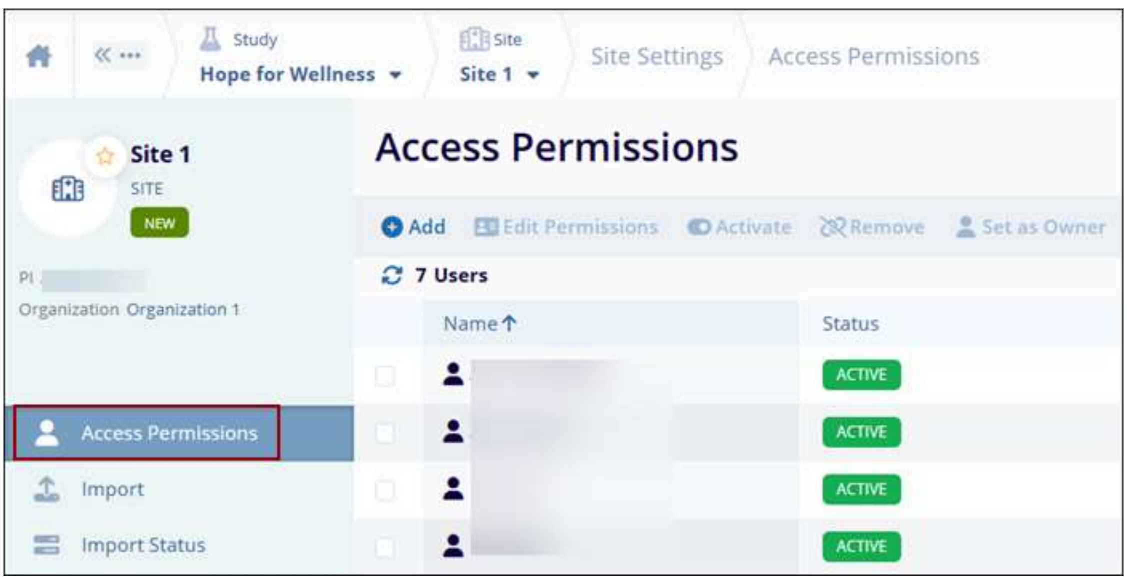


Site Settings

To access the site settings, follow the steps below.

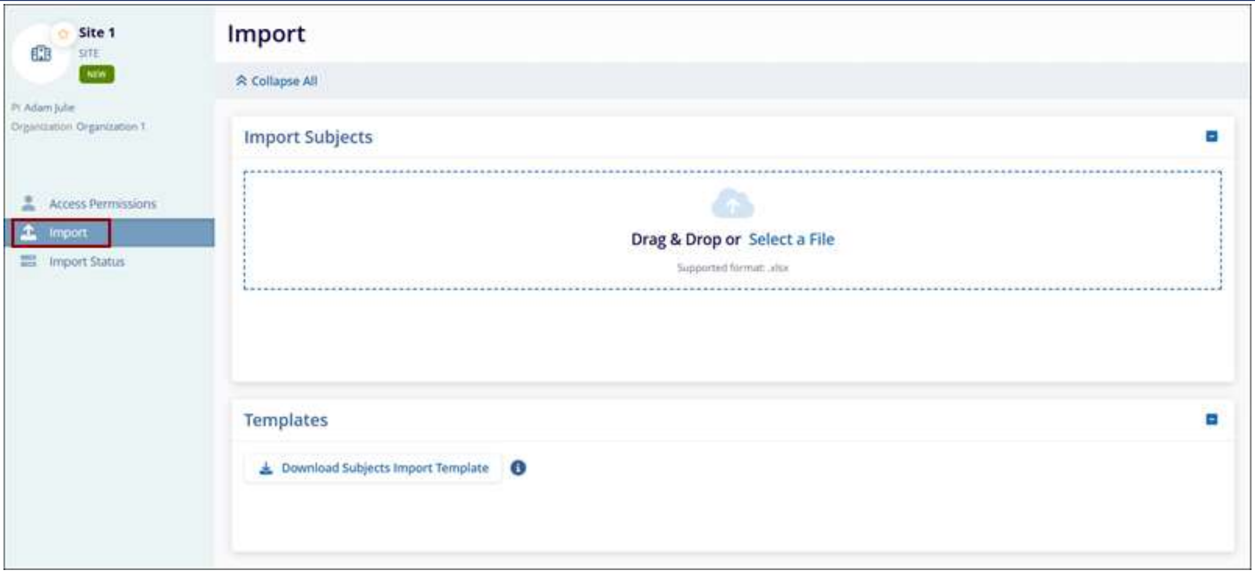
1. On the Site Details screen, click on the Settings button.

2. On the Access Permissions screen, provide access to the intended users at the site level.



Note: Refer to the standard steps detailed Study Level access permissions to manage the access permissions at the site level.

3. On the Import screen, import the subjects at the site level using a pre-defined template.



Note: Refer to the standard import steps detailed Study Level to import subject within a site.

Associating an organization with a site CRA

1. Navigate to the Site to associate an organization with.
2. Click on the Organization link in the Navigation menu on 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.

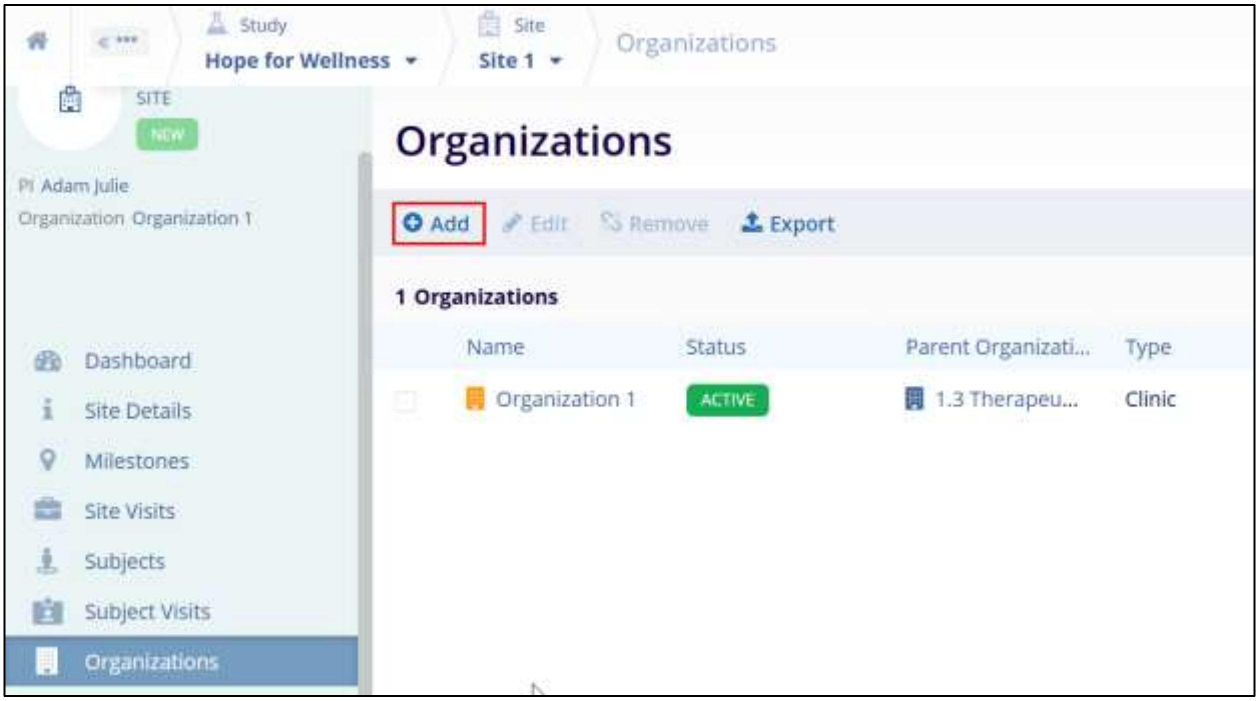


Figure: Add Organization within a Site

4. Fill the required metadata to create an organization with an address. Refer to Chapter 8. Organizations for detailed information on adding organizations and other associated actions.

Managing Site Contacts CRA

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 the user intends to create another record for the same person, especially if the user is doing so to change some detail of their information (for example, someone's last name might have changed).

Add Contact

To add a contact within a site, follow the steps below.

1. Click on the Contacts link from the left-hand navigation menu within a site.
2. Click on the +Add button.
3. On the 'Create Contact in Stie' form select an existing contact by accessing the '**Search for Contacts'** or create a new contact by adding the necessary details.

4. Click on the Create button once all the necessary details are added.

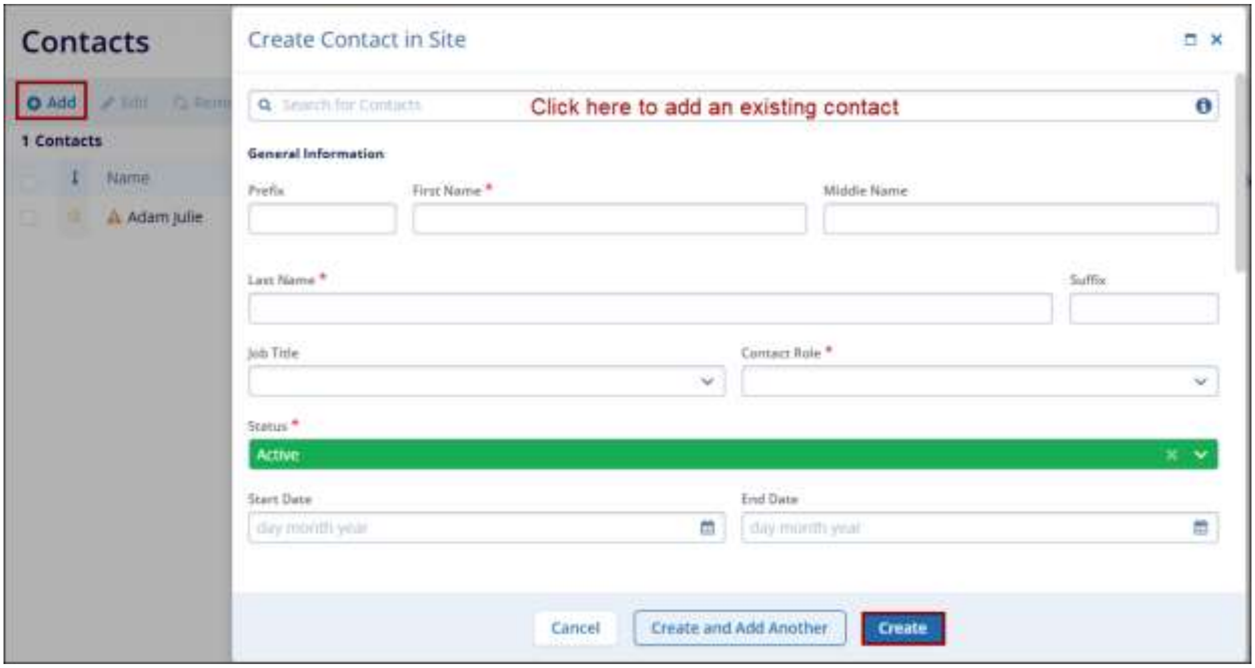


Figure: Create Contact in Site

Promote to Global Contact

To promote a contact to global level, follow the steps below.

1. Select a newly created contact within the site.
2. Click on the Promote to Global Contact button from the top menu bar.

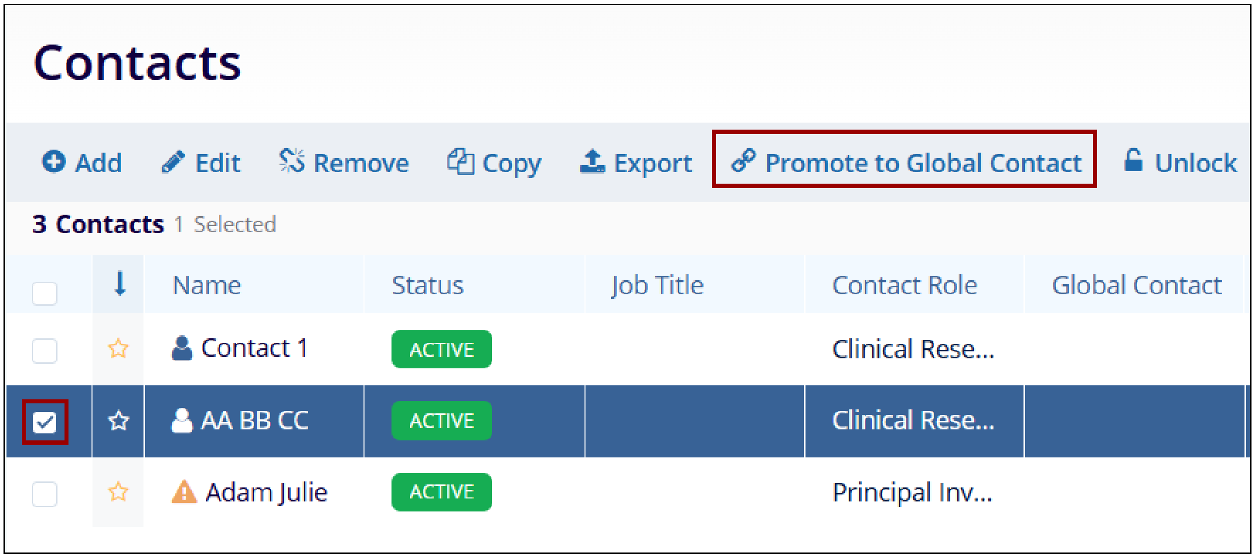


Figure: Promote to Global Contact

3. The Promote to Global Contact screen displays the potential contact matches. Select the contact and click on the Link with Selected button.

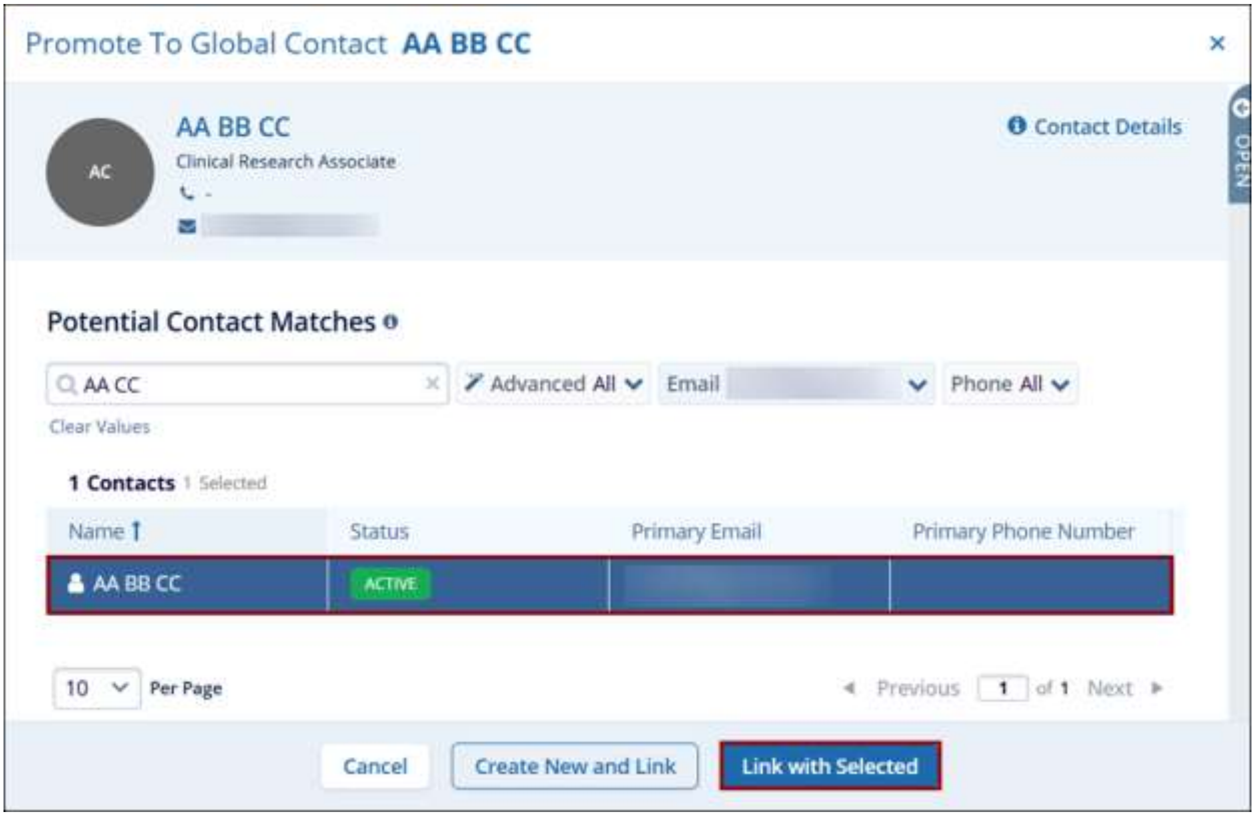


Figure: Link with Selected contact

Note: To edit, remove, copy, or export records, follow the standard steps outlined in the respective modules.

Import Site Contacts

To import site contacts, follow the steps below.

1. On the Contacts screen within a site, click on the 'Import' button from the top menu bar.

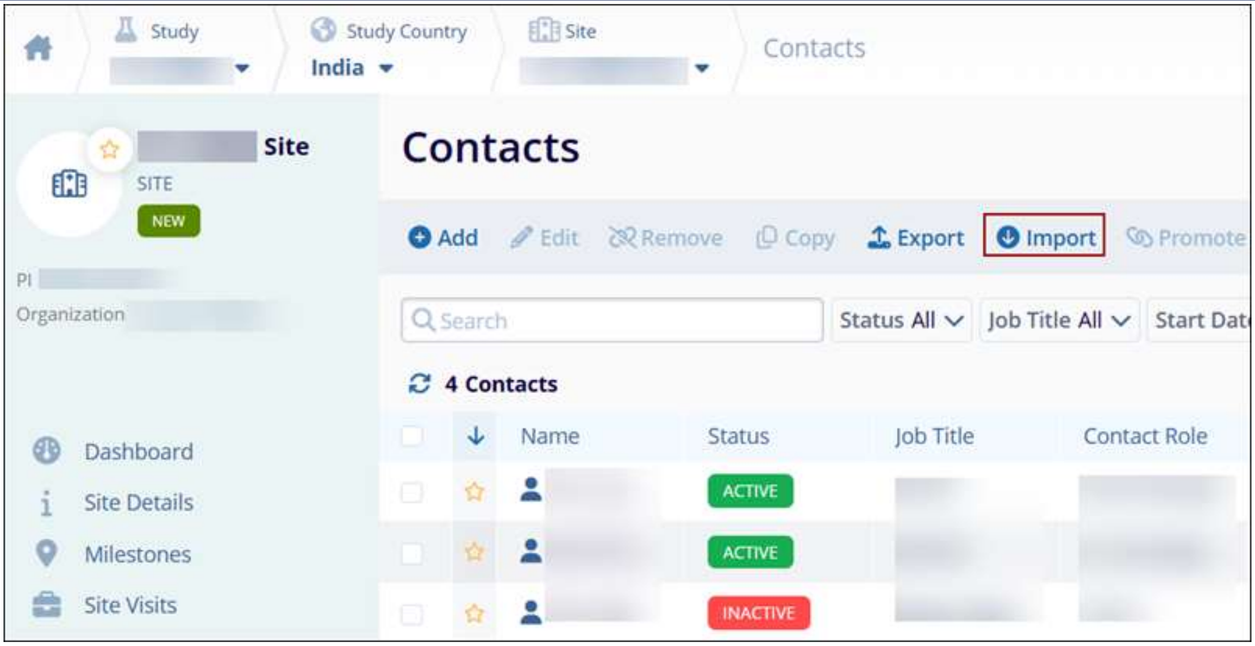


Figure: Import Site Contacts

2. Refer to the standard import steps detailed in the Import Sites section.

Integrated Payments View

TI CTMS has the ability for a user to review high-level payment details when 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 payment-related information.

1. Navigate to the Site Details screens by following the steps in the Editing a Site in a Study section.
2. Click the Payments link displayed on the left side of the screen.
   a. This opens the Payments window in the center of the screen.
3. The user can apply filters to view the required payments for ‘Awaiting QC’ and ‘New Request’.
4. The user can also search for a payment ‘Payee Name’ and ‘Invoice Number’.

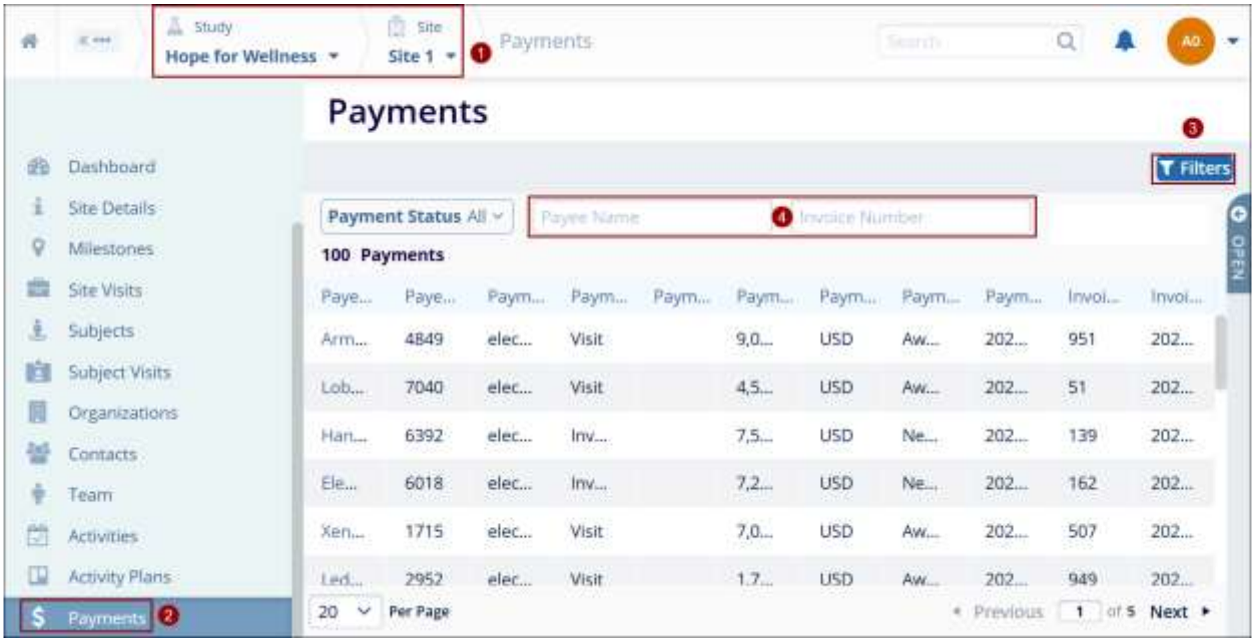


Figure: Payments View

Important: Additionally, users can define Milestones, Subjects, Subject Visits, Team (Access Permissions), Activities, and Activity Plans at the Site level. For standard steps and procedures, refer to the Study-level associations of these parameters.

Study Subjects CRA

The subjects created within all sites that are associated with the particular study are displayed within the subject's tab at the Study level.

Edit Subjects Within a Study

To view and edit subjects at a study level, follow any one of the methods below.

Method 1

1. Navigate to the Study Details screen of a particular study to edit.
2. Click on the Subjects link from the left-hand navigation pane.
3. Select a subject by clicking on the Subject ID.
4. Click on the Edit button, from the top menu bar.
5. Within the Quick View panel on the right-hand side of the screen, navigate to each tab i.e., Details, Visits, Activities, Informed Consents, etc., and make the necessary changes in the relevant sections.
6. Click on the +Add Visit button to create a subject visit record.
7. Once all the changes are made, click on the Save button.

Figure: Edit Subjects within the study

Method 2

1. On the Subjects screen within the Study, click on the Subject ID.

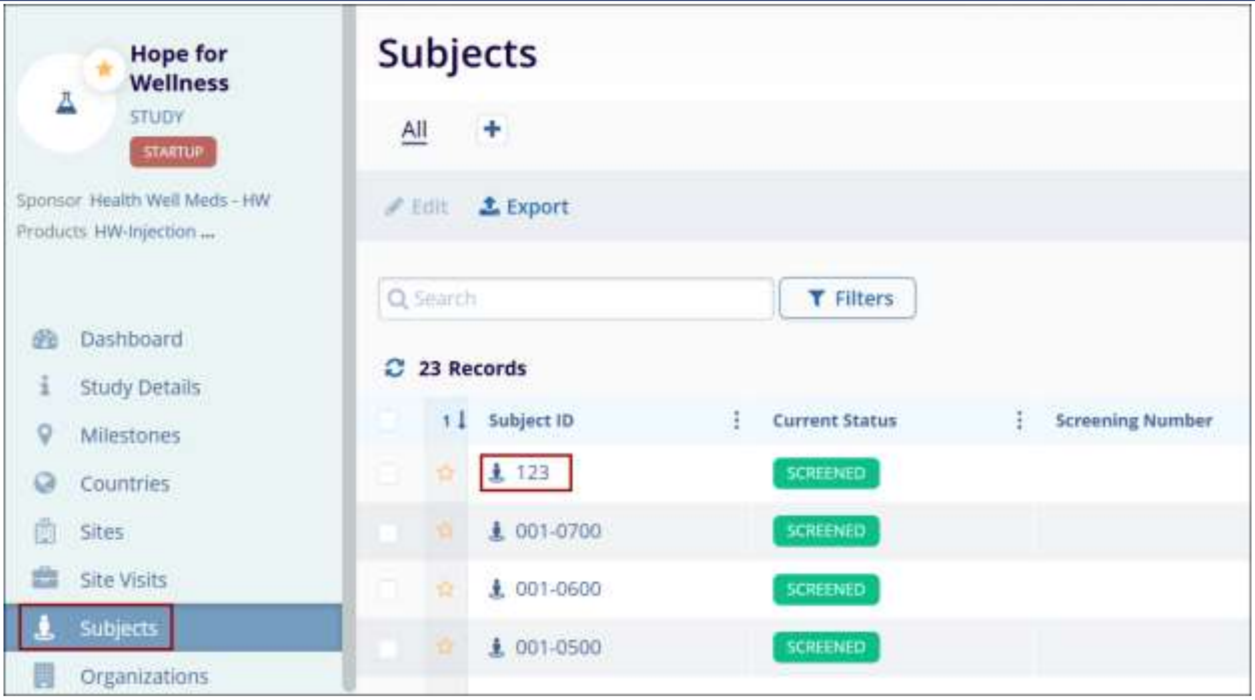


Figure: Study Subjects – Select subject

2. On the Subject Details screen, click on the Edit button, from the top menu bar.
3. Expand the following sections and make the required edits.
4. Click on the Save button once all the changes are made.

Figure: Subject Details.

5. Click on the Studies link in the Navigation menu on the left side of the screen This opens the 'Studies' window and the study list is displayed.
6. Click on the name of the study. The dashboard for the study is displayed.

7. Click on the Subjects link in the Navigation menu on the left side of the screen. This displays all the subjects for the study.

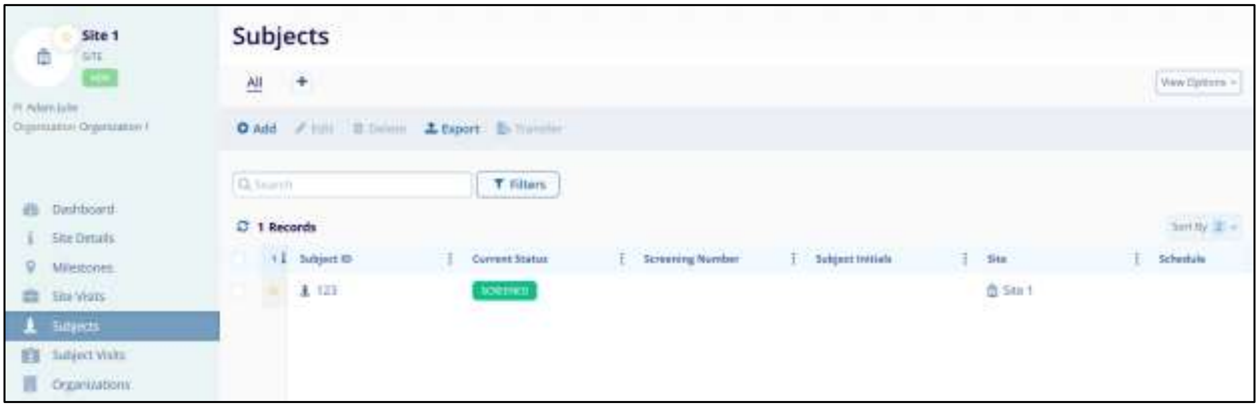


Figure: Review Subjects within the study

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

Subject Visits

Add Subject Visits

To add subject visits, follow the steps below.

1. Navigate to the Subject Details screen, by clicking on the Subject ID.
2. Click on the Subjects Visits in the Navigation menu on the left side of the screen.
3. Click on the Add Visit button.

Figure: Add Subject Visit

4. 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.
5. Click on the Create button.

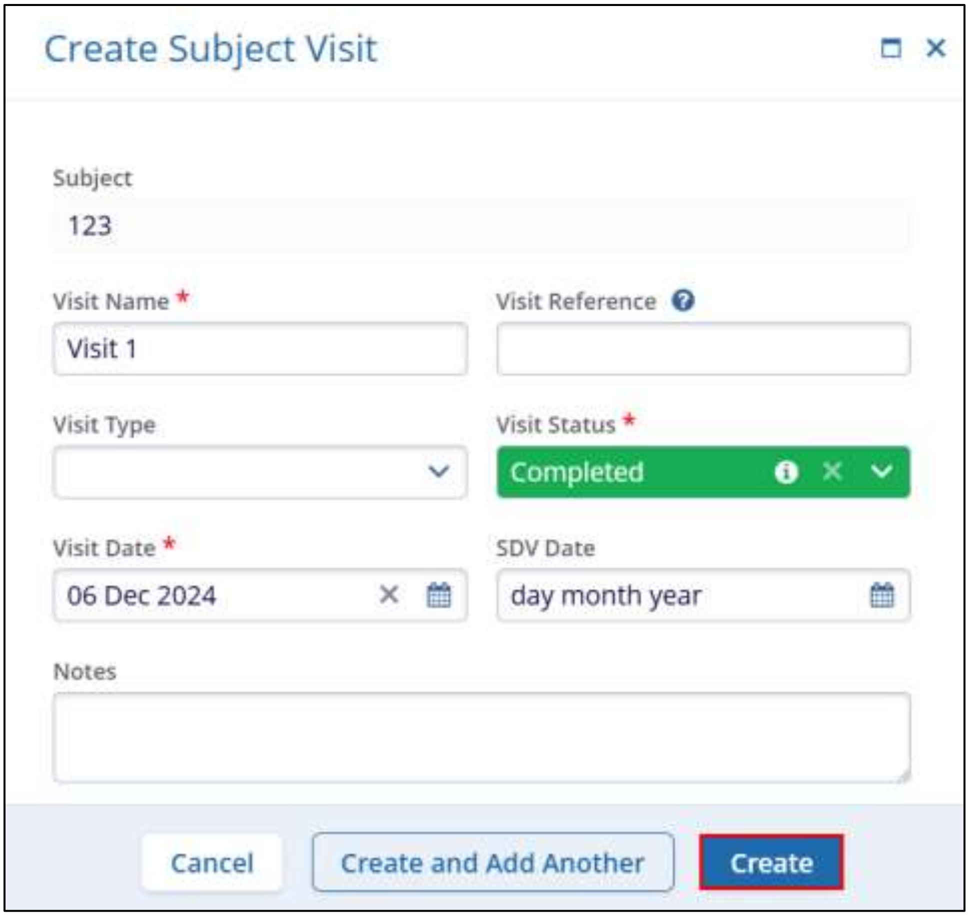


Figure: Create Subject Visit form

Editing a Subject Visit

To edit a subject visit, follow the steps below.

1. On the Subject Visits screen, select a visit by clicking on the checkbox.
2. Click on the Edit button from the top menu bar.
3. On the Quick View panel on the right-hand side, make the required changes.
4. Click on the Save button.

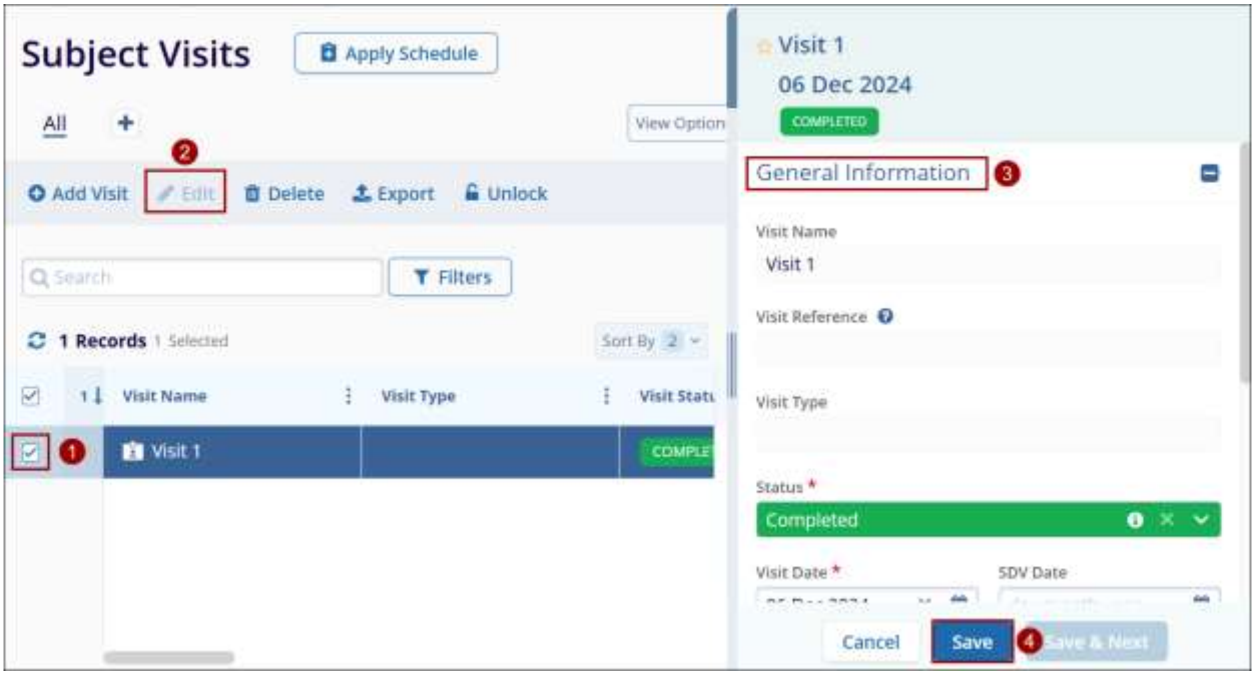


Figure: Edit Subject Visit

Note: Delete, Export, and Filters functionalities are similar across other modules.

Informed Consents

Add Informed Consents

To add informed consent, follow the steps below.

1. On the Subject Details screen, click the 'Informed Consents' link from the left-hand navigation pane.
2. Click on the +Add button from the top menu bar.
3. On the Add Informed Consent form, fill in the following mandatory details
   a. Informed Consent Name*
   b. Signature Date*
4. Click on the Save button.

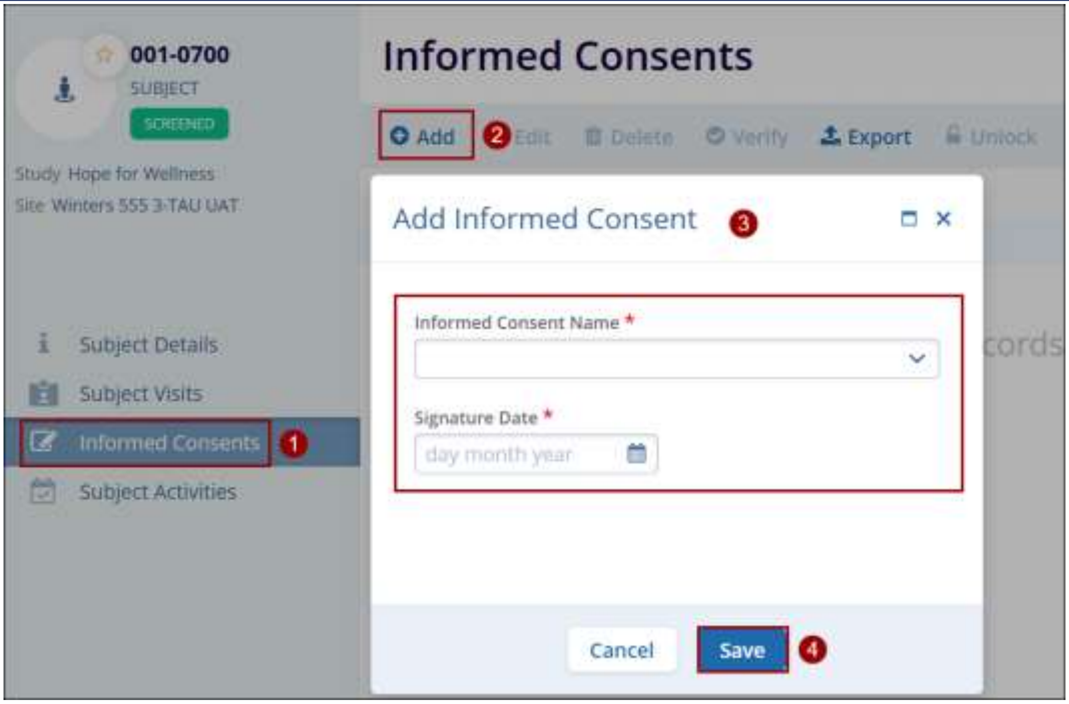


Figure: Add Informed Consent

Verify Informed Consent

To verify informed consent, follow the steps below.

1. Select the informed consent by clicking on the checkbox.
2. Click on the Verify button from the top menu bar.
3. On the **'Verify Informed Consent'** popup enter the Verification Date*
4. Click on the '**Verify'** button.

Figure: Verify Informed Consent

Note: The Edit, Delete, and Export functionalities are similar across other modules.

Subject Activities

The Subject Activities allows users to define activities at the subject level.

To add an activity at a subject level, follow the steps below.

1. Click on the Subject Activities link from the left-hand navigation pane.
2. Click on the +Add button from the top menu bar.
3. On the Create Activity form, enter the mandatory details and click on the Create button.

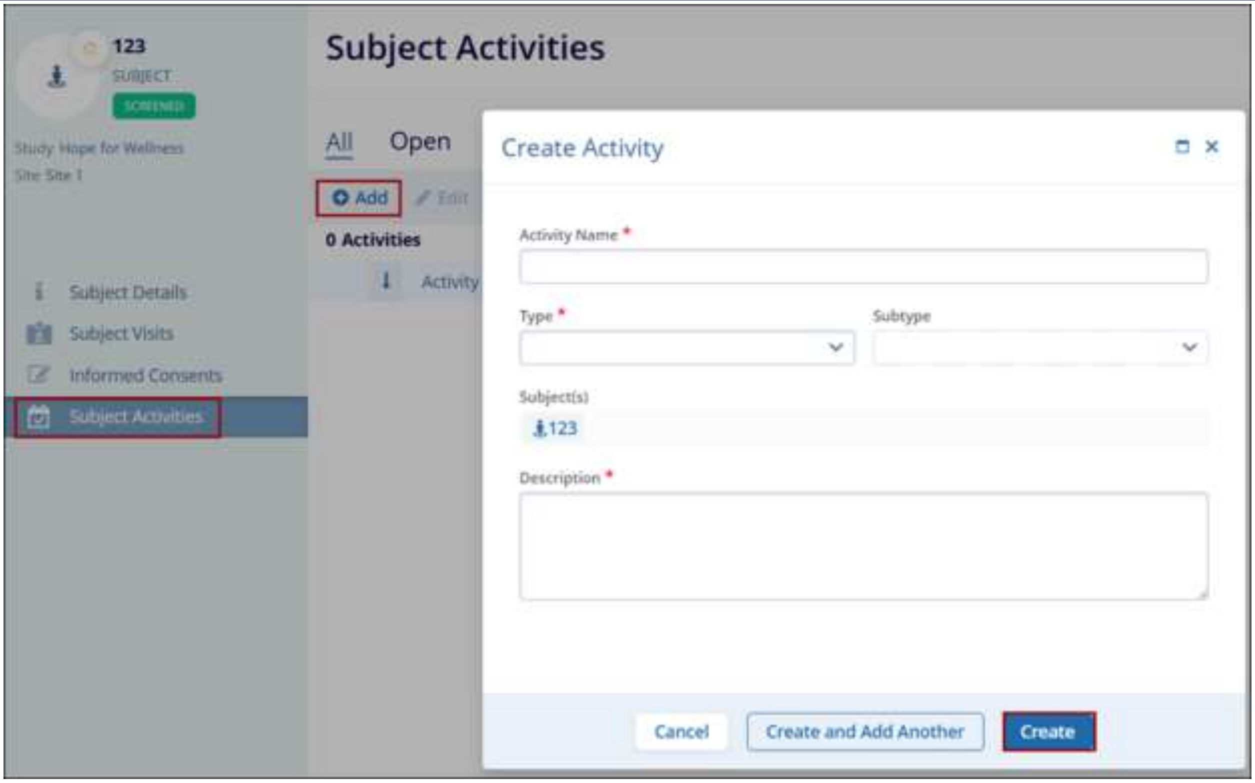


Figure: Add Subject Activities

Note

- Subject Name is auto-populated into the respective field and is non-editable.
- The Edit, Delete and Export functions are standard as mentioned in the other modules.

Study Organization

To configure organizations within a study, follow the steps below.

1. From the left-hand navigation pane, select the Studies link.
2. On the Studies screen, click on the study name.

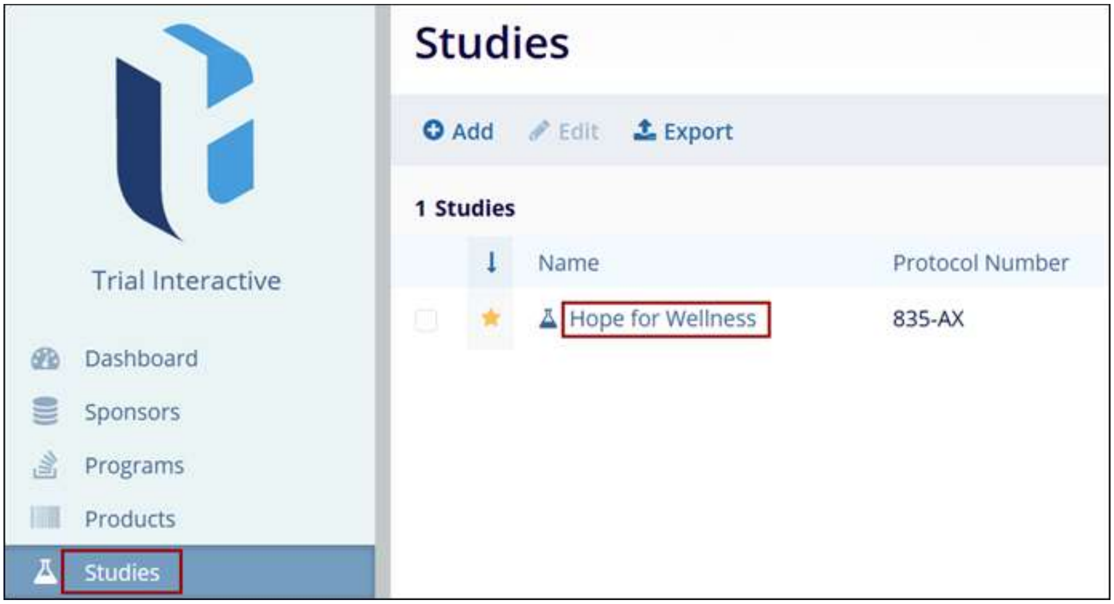


Figure: Access Study to add organization

3. On the Study screen, click on Organizations from the left navigation pane.
4. On the Organizations screen, click on the +Add button to create a new organization within a study.

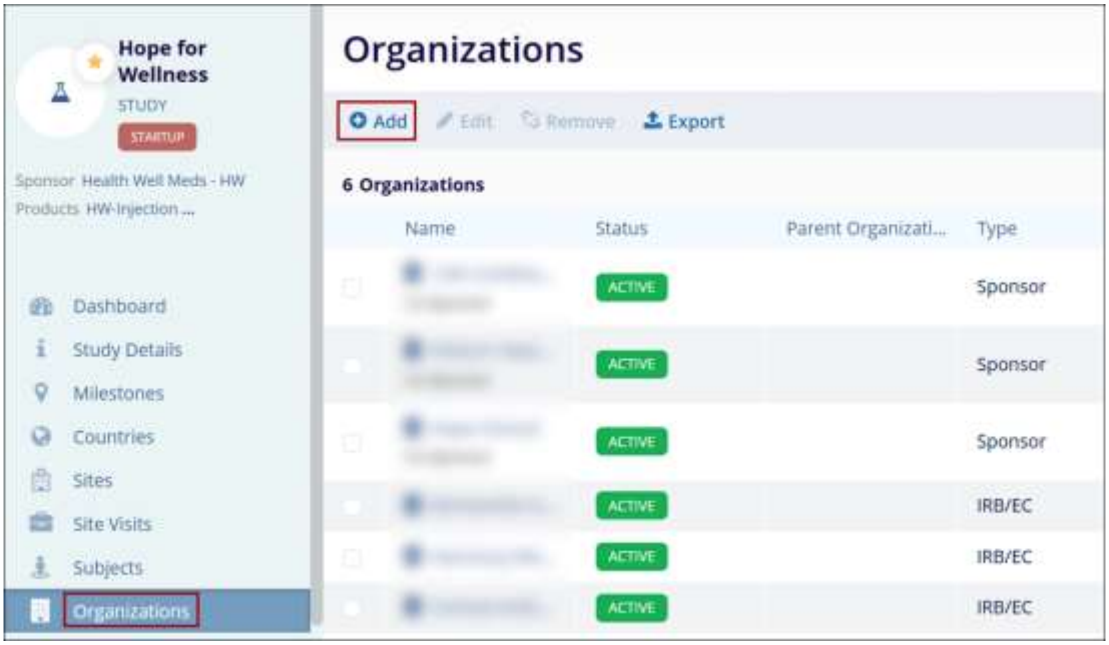


Figure: Add Organization within a study

5. Refer to the Chapter 8. Organizations for standard steps to add, edit, remove, and export organizations.

Study Contacts SM

To configure contacts within a study, follow the steps below.

1. From the left-hand navigation pane, select the Studies link.
2. On the Studies screen, click on the study name.

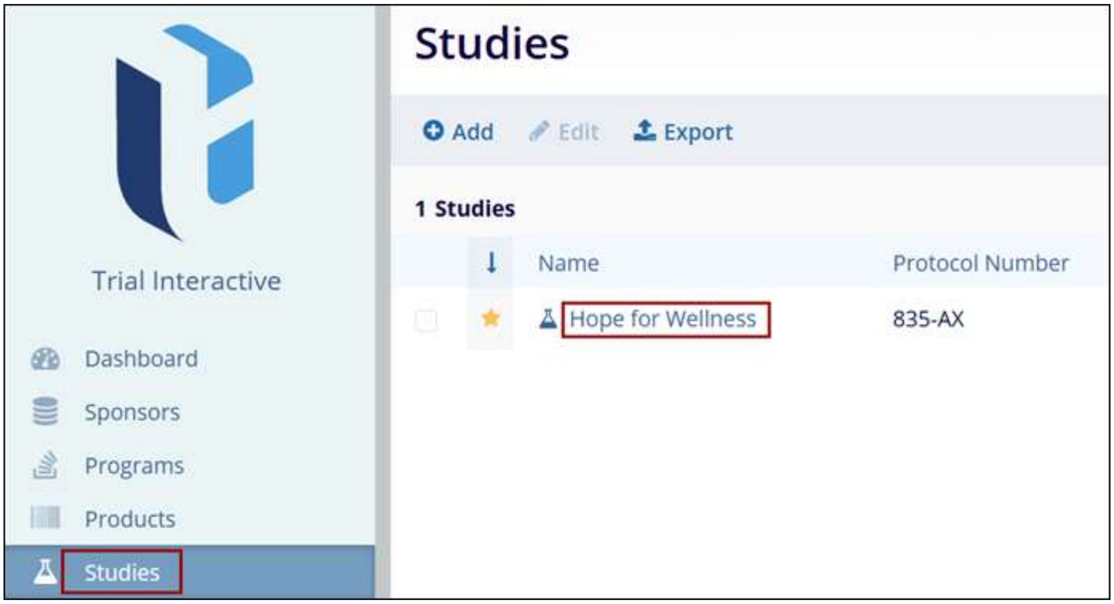


Figure: Access Study to add contacts

3. On the Study screen, click on Contacts from the left navigation pane.
4. On the Contacts screen, click on the +Add button to create a new organization within a study.

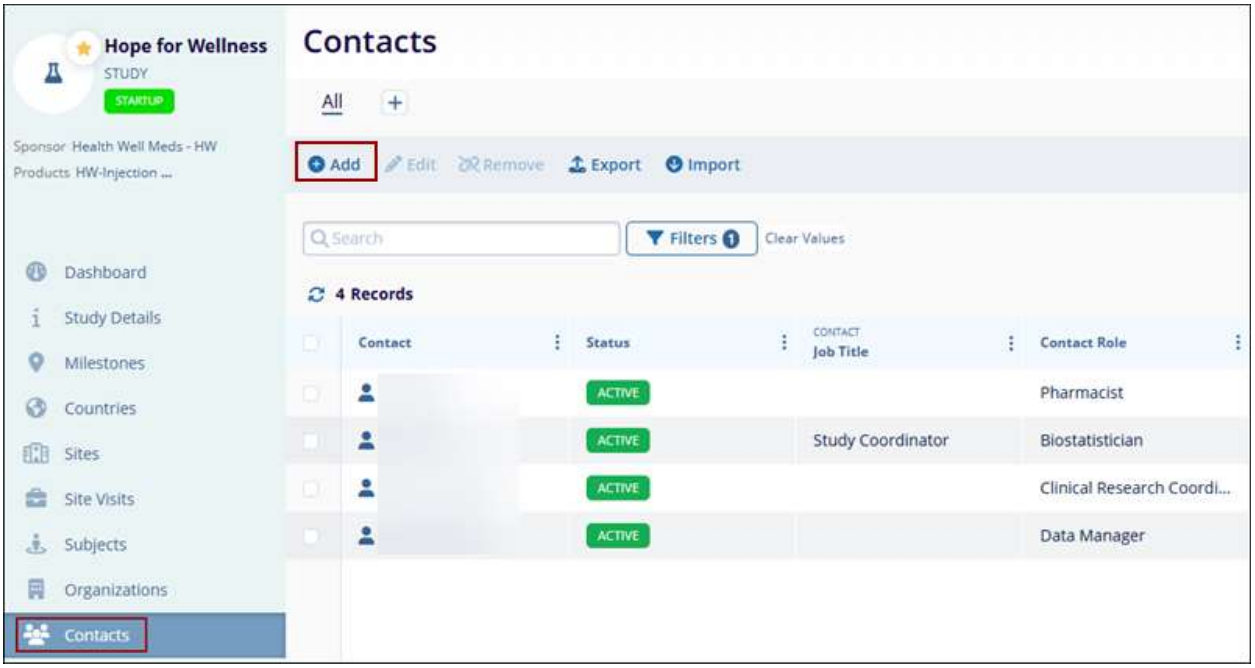


Figure: Add Contacts to Studies

5. Refer to the [Chapter 9. Contacts](#) for detailed information on creating contacts and associated functionalities.

Team

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.

Add Team Member

To add a member to the team, follow the steps below.

1. Select a study to add a team member.
2. From the left-hand navigation pane, select the Team option.
3. Click on the Add button.
4. On the Add Team Members screen, enter the mandatory details highlighted with a red asterisk mark.
5. Click on Add once all details are entered.

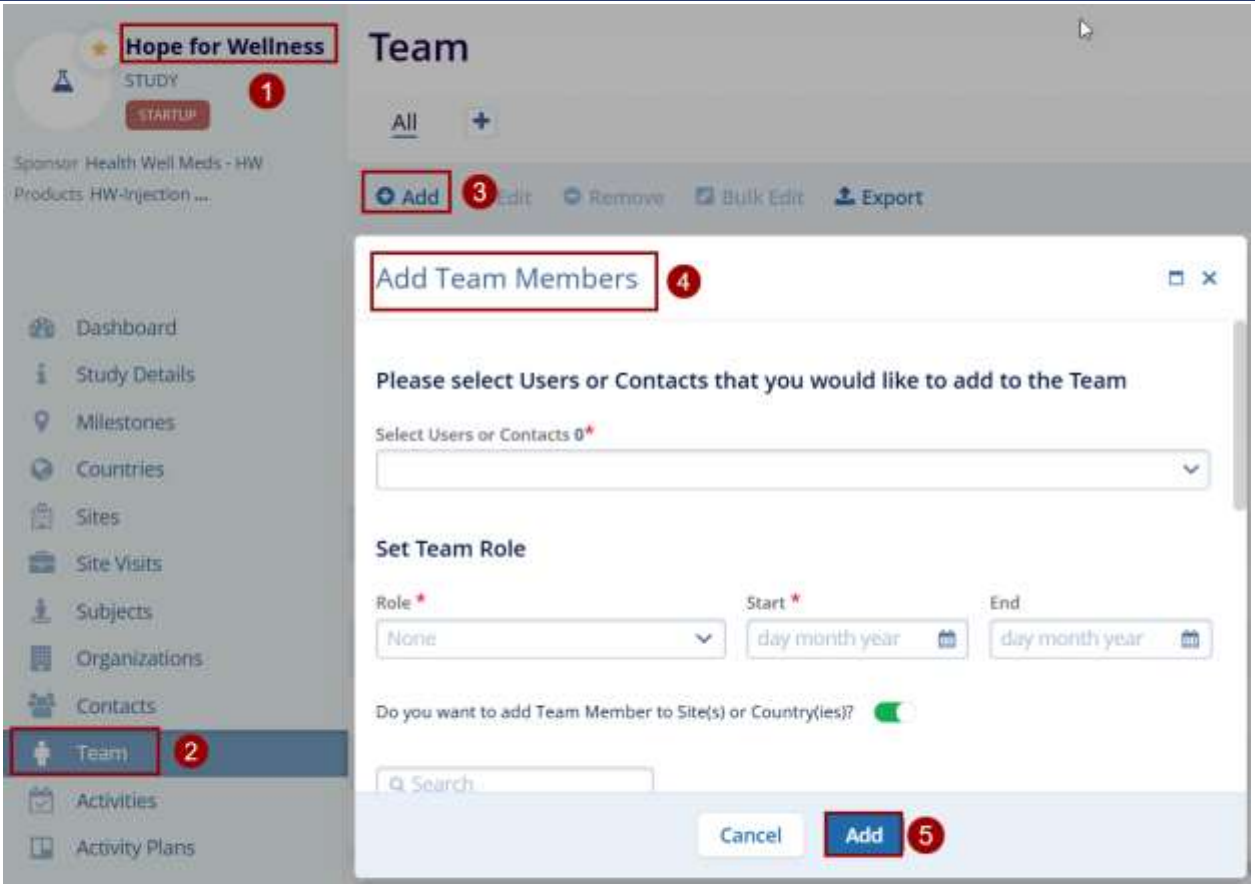


Figure: Add Team members within a study

Edit team member details

To edit team member details, follow the steps below.

1. Select a record by clicking on the checkbox.
2. Click on the Edit button from the top menu bar.
3. Make changes in the Quick View panel on the right-hand side.
4. Click on the Save button.

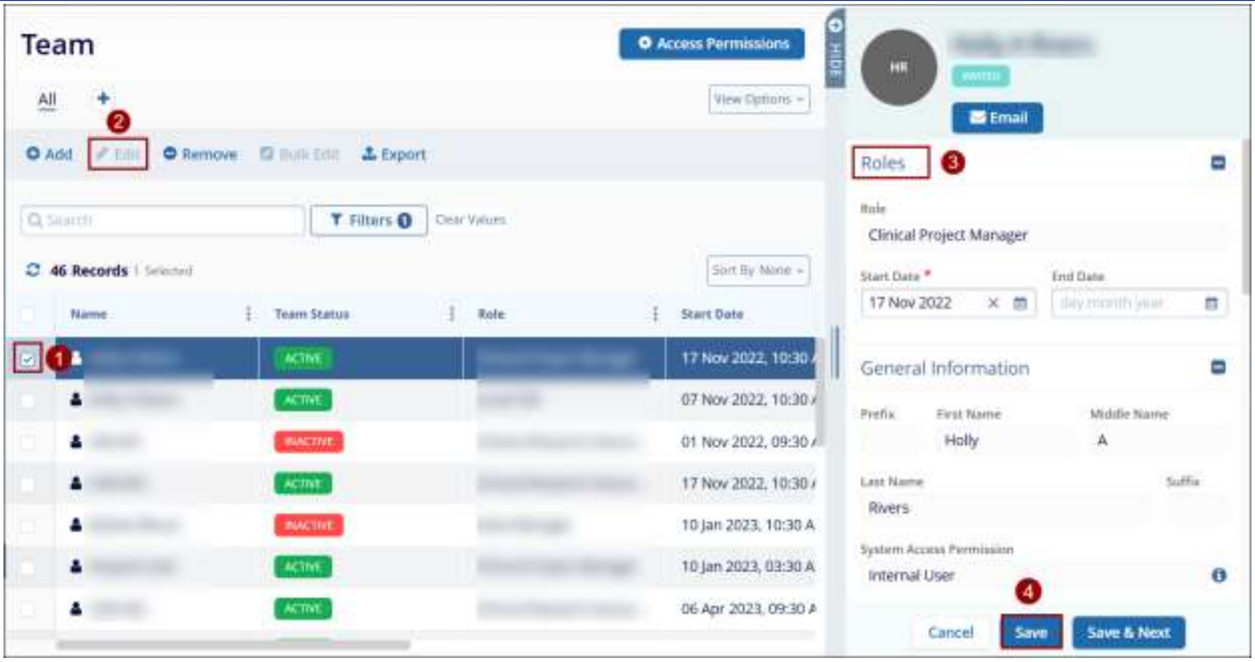


Figure: Edit Team member details

Remove team member

To remove a team member, follow the steps below.

1. Select a record by clicking on the checkbox.
2. Click on the Remove button from the top menu bar.
3. On the confirmation popup, click on the Remove button.

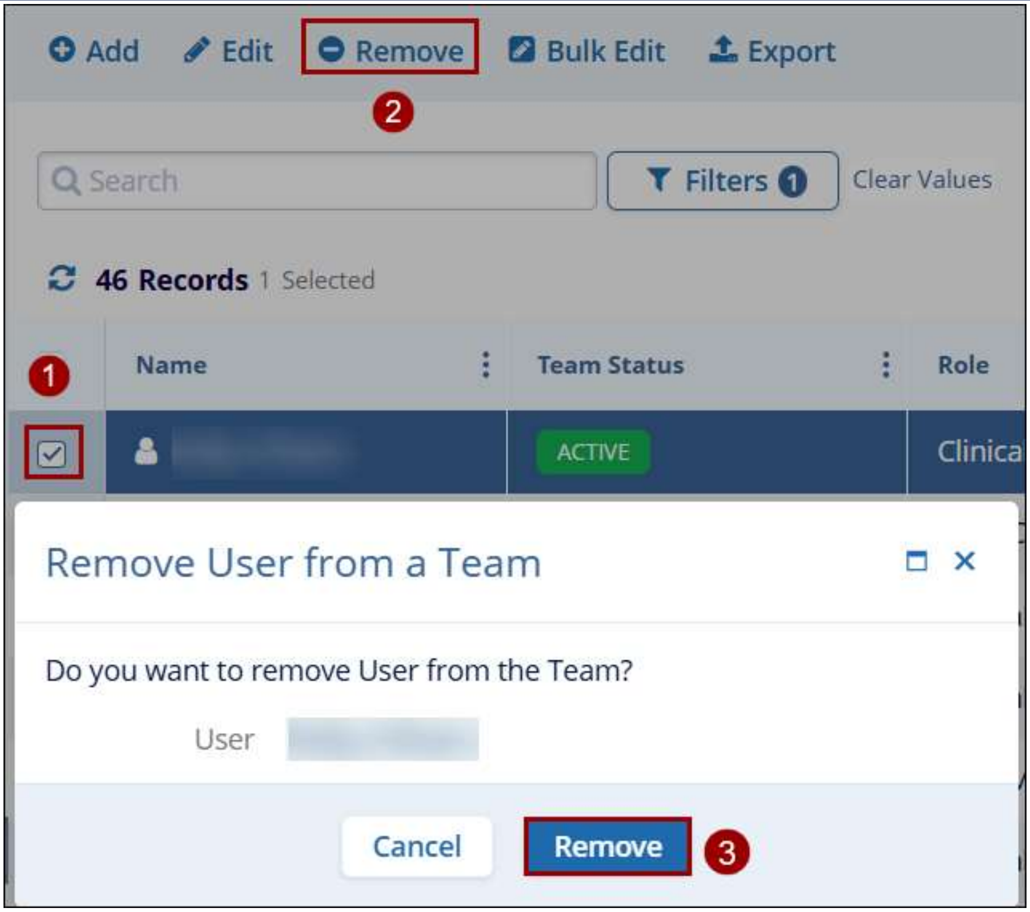


Figure: Remove Team Member

Bulk Edit

To bulk edit records, follow the steps below.

1. Select multiple records
2. Click on the Bulk Edit option from the top menu bar.
3. Make edits on the Quick View panel opened on the right-hand side.
4. Click on the ‘Edit (number of records) button.

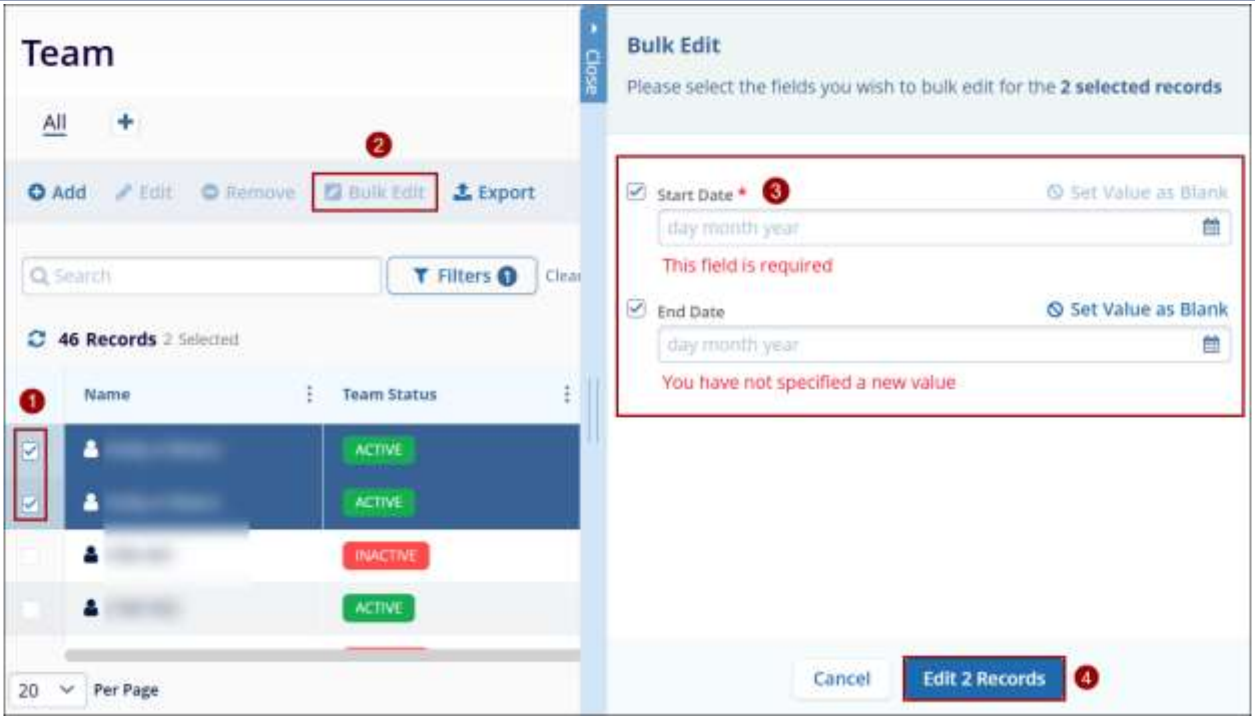


Figure: Bulk Edit Team Member details

Export

To export Team member details, refer to the standard export process detailed in various sections of this guide.

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 there is an error, 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 navigate 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.

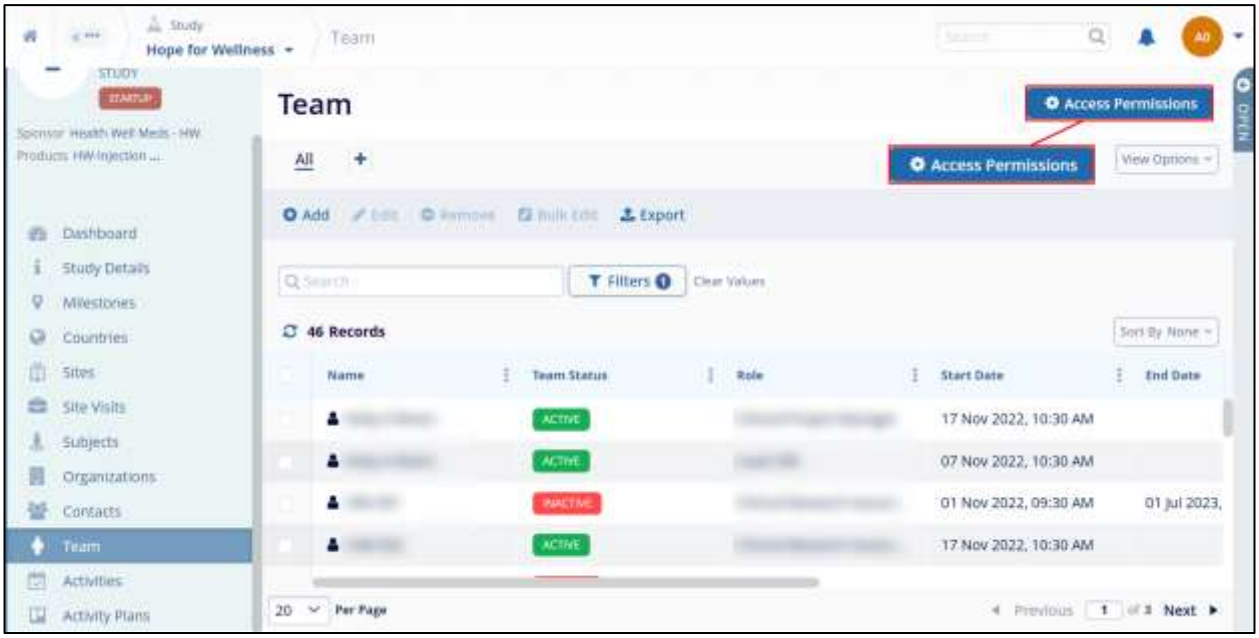


Figure: Manage access permissions

<u>Add users to study access permissions</u>

To add users, follow the steps below.

1. On the Access permissions screen, click on the +Add button.
2. Add the users and provide them access permissions.
3. Click on the Add button.

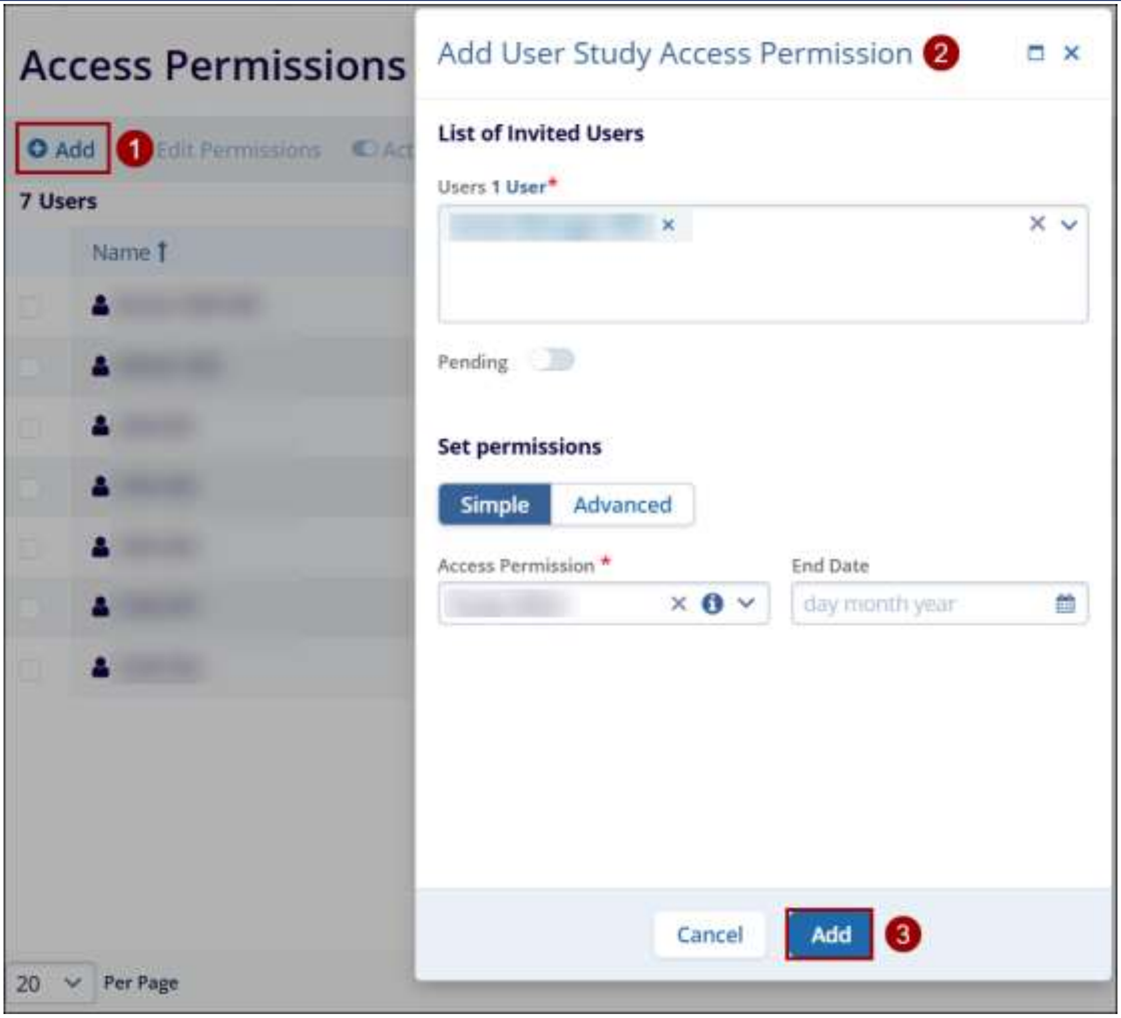


Figure: Add Users Study Access Permissions

Edit Permissions

To edit permissions, follow the steps below.

1. Select a user by clicking on the checkbox.
2. Click on the Edit Permissions button.
3. Make the required changes and click on the Save button.

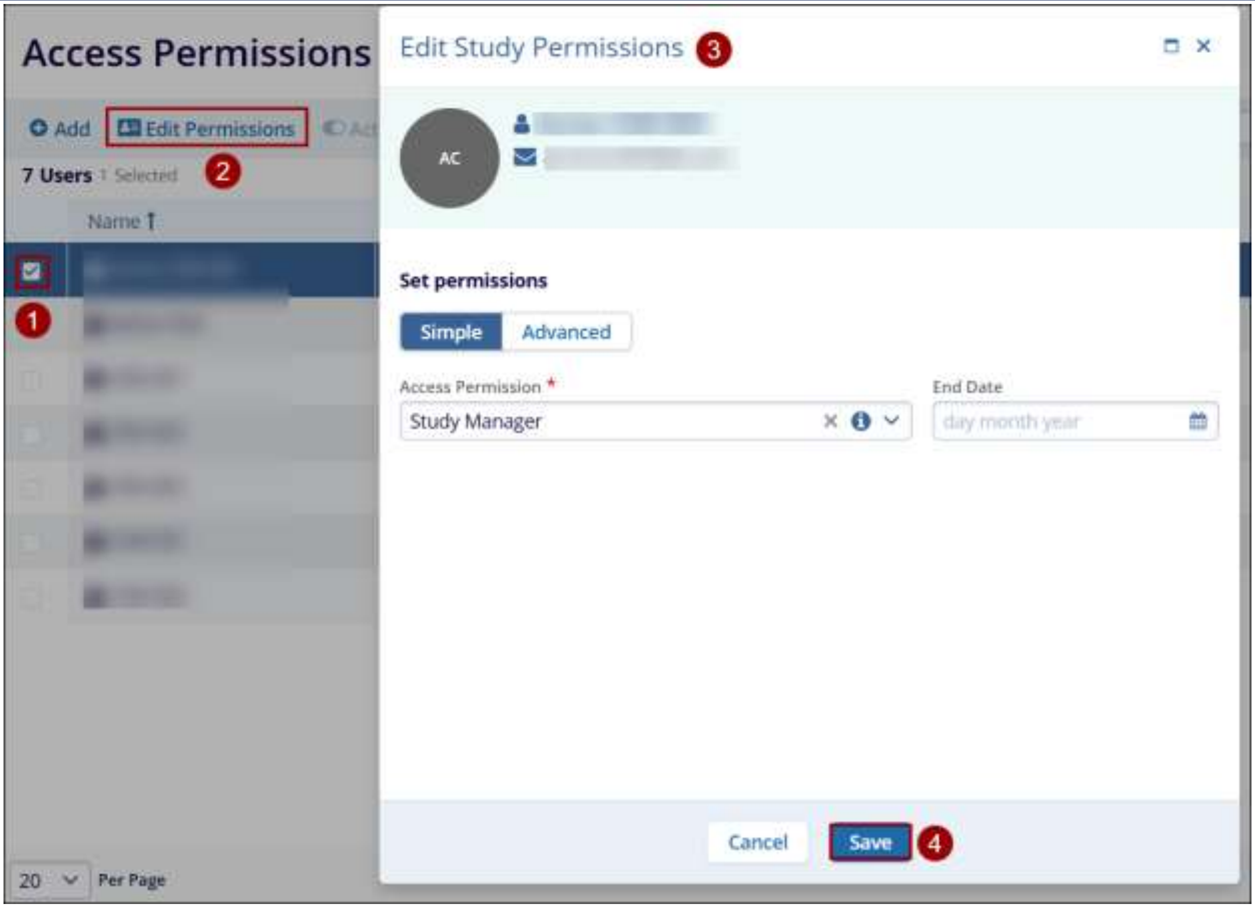


Figure: Edit Study Permissions

Remove

To remove a user from access permissions, follow the steps below.

1. Select a user by clicking on the checkbox.
2. Click on the Remove button.
3. On the confirmation popup, click on the Remove button.

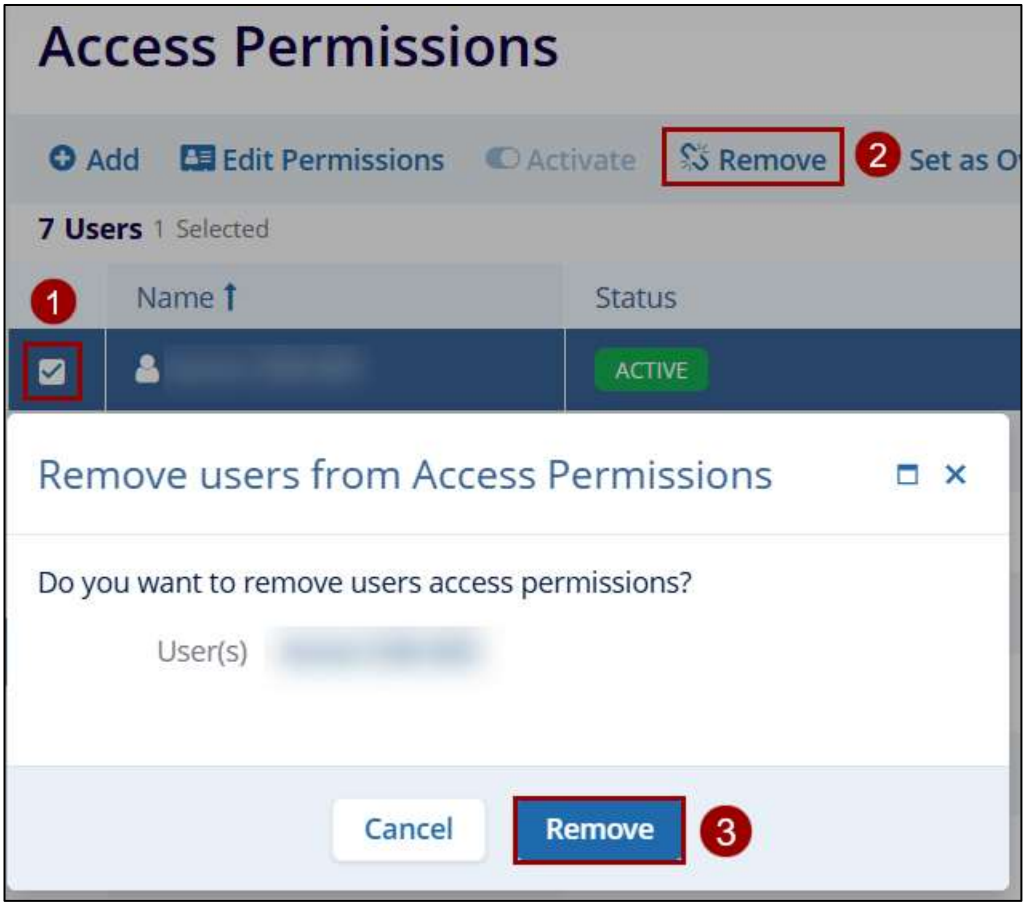


Figure: Edit Permissions

Set as Owner

To set a user as owner, follow the steps below.

1. Select a user by clicking on the checkbox.
2. Click on the Set as Owner button.
3. Click on the Change button.

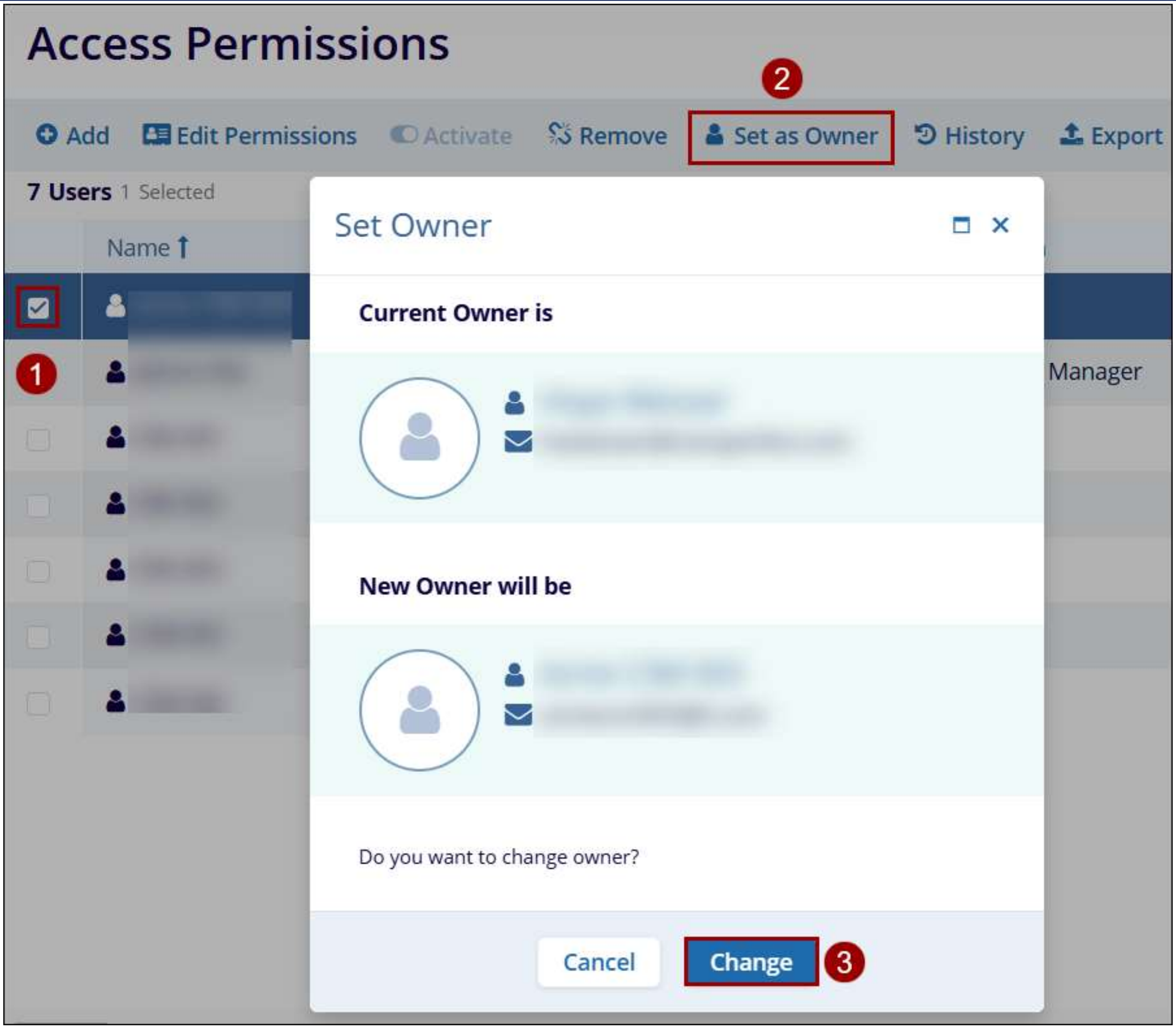


Figure: Set as Owner

History

To view history, follow the steps below.

1. Click on the History button from the top menu bar.

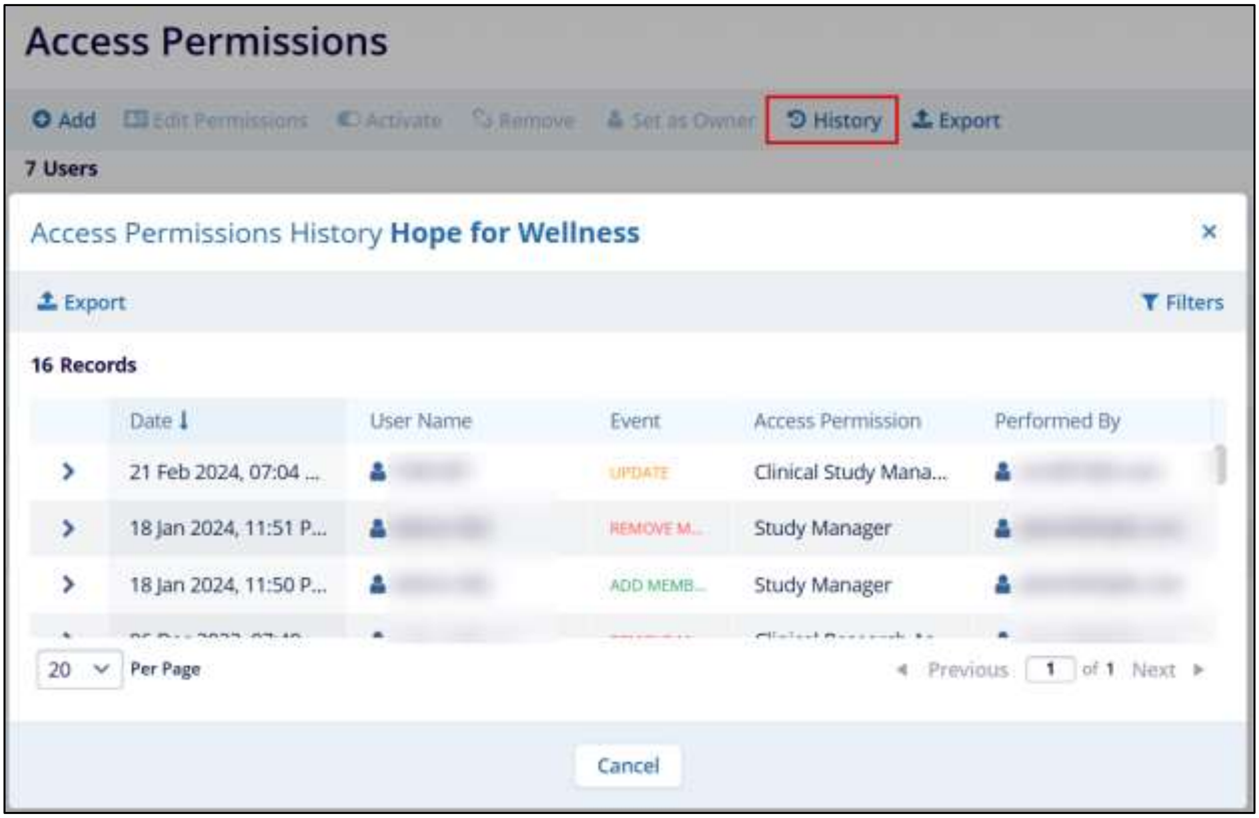


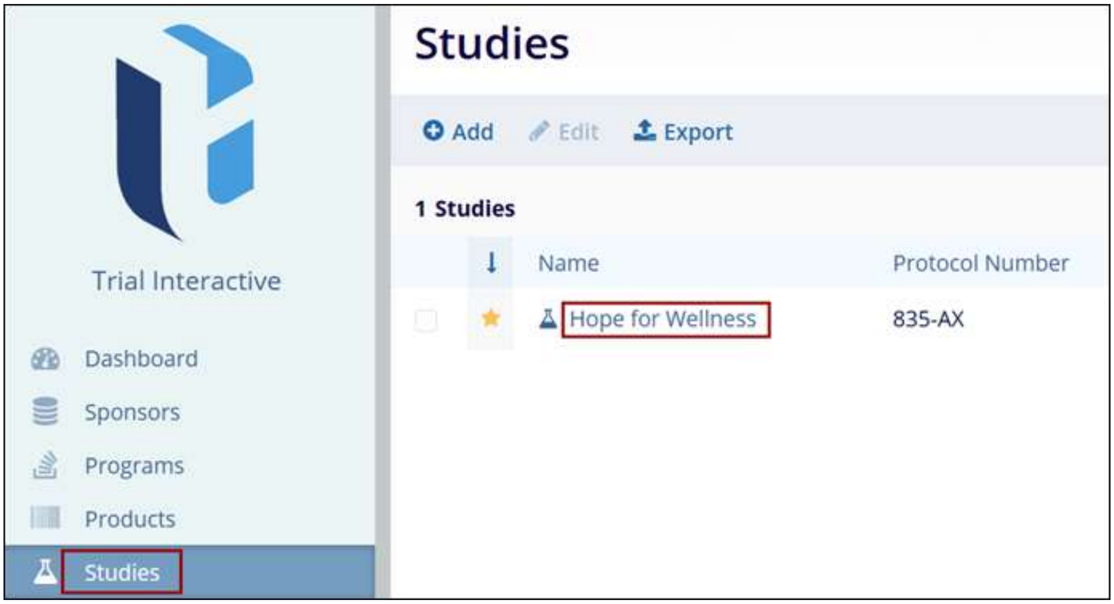
Figure: Retrieve History

Study Activities

CTMS enables users to define activities at the Study level.

To access the activities associated with the study follow the steps below.

1. From the left-hand navigation pane, select the Studies link.
2. On the Studies screen, click on the study name.



3. On the Study screen, click on Activities from the left navigation pane.

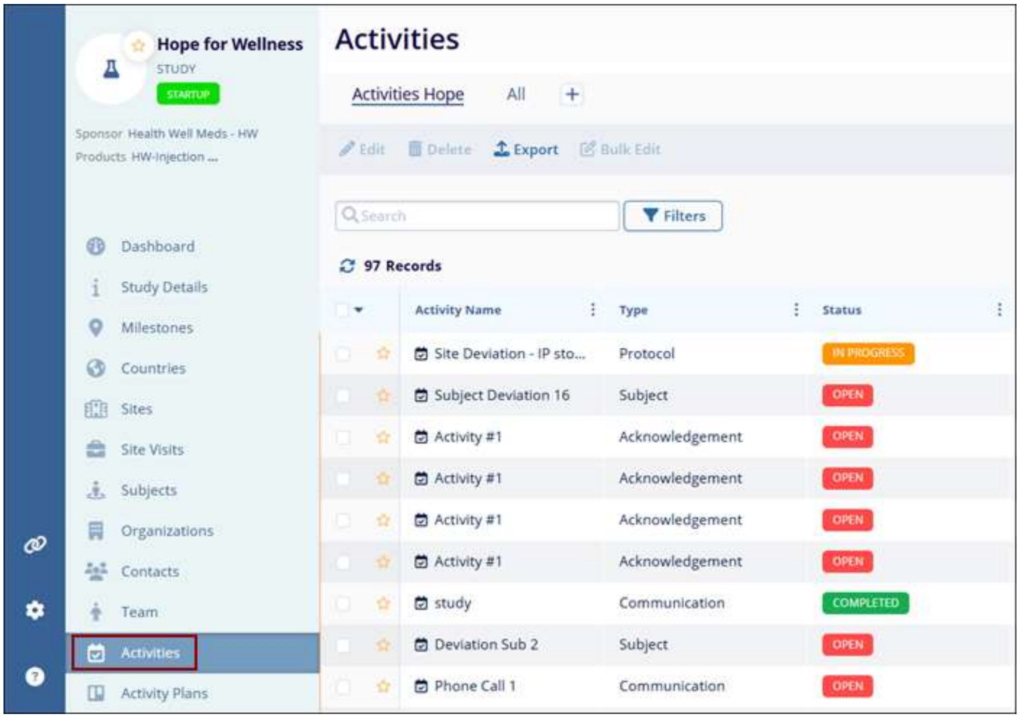


Figure: Study Activities

4. Refer to the Creating Domain Activity Template Records section to understand the standard steps of creating an activity and other associated actions.

Import Activities

To import activities at the study level, follow the steps below.

1. Within the Activities tab of a Study profile, click on the 'Import' button from the top menu bar.

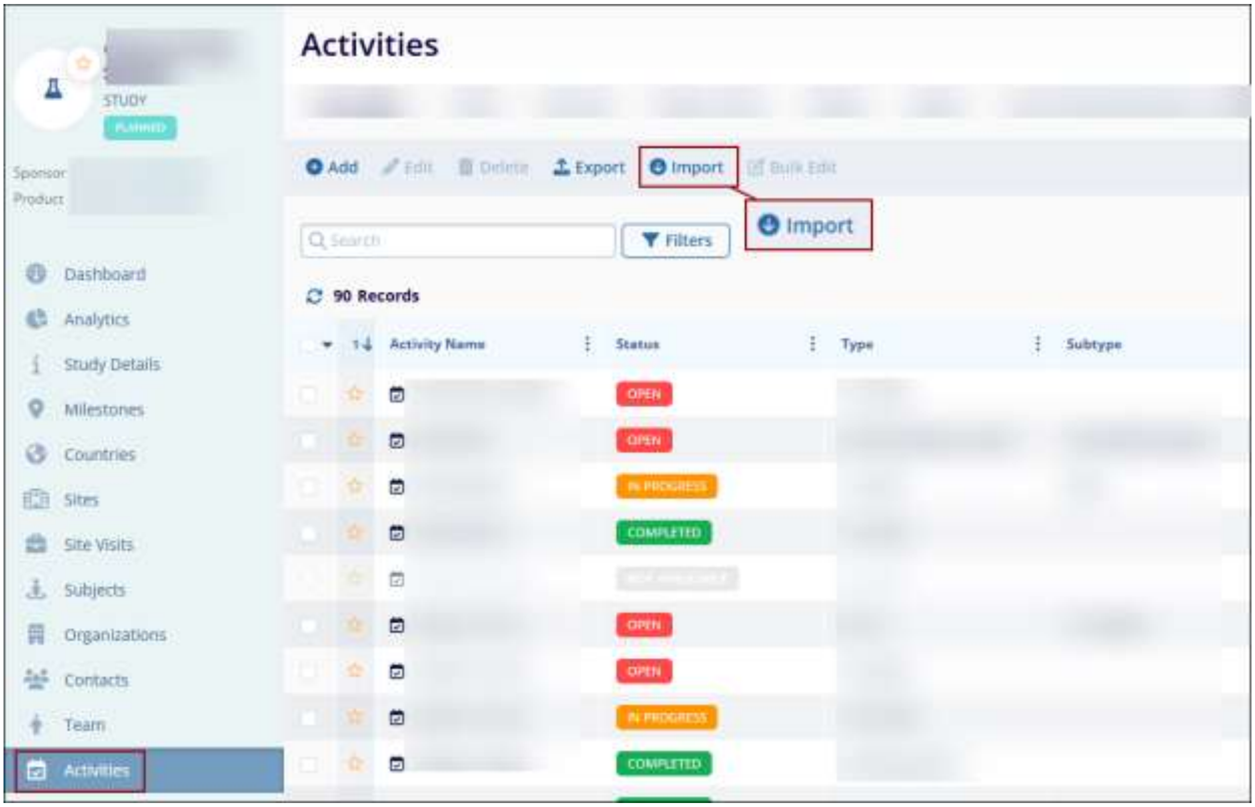


Figure: Import Activities

2. On the 'Import Activities' modal window, click on the 'Download Template' button.

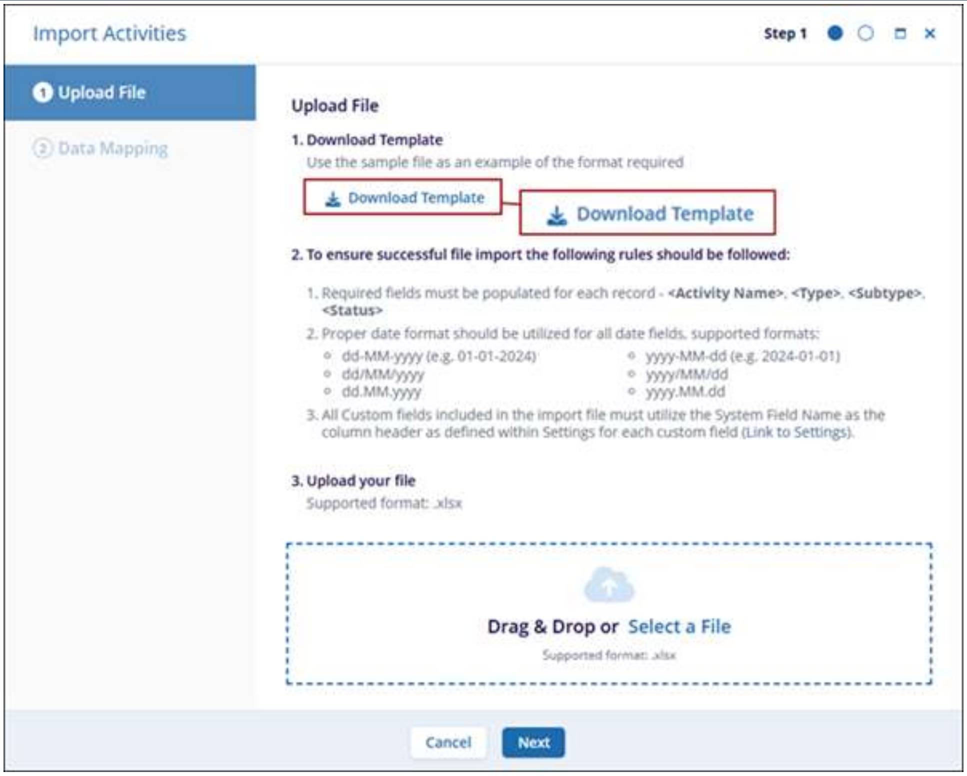


Figure: Import Activities Download Template

3. Within the downloaded template, fill in the necessary information in the 'Activities tab' tab.

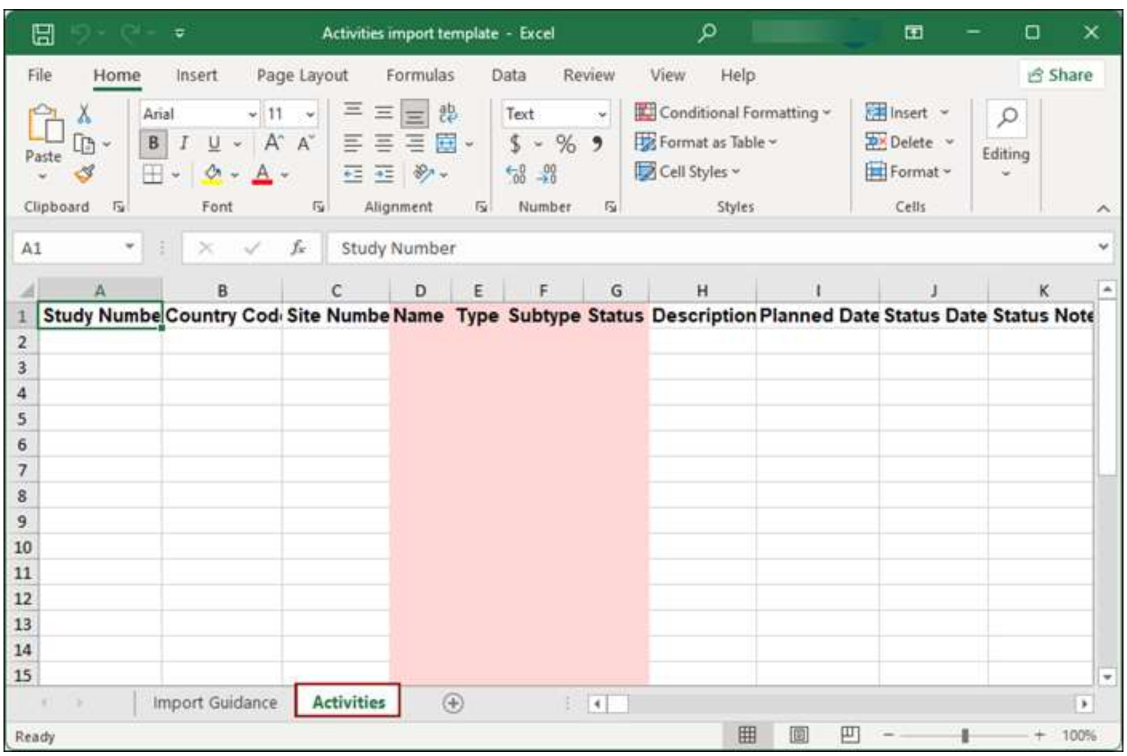


Figure: Activity Import Template – Activities tab

4. For detailed instructions on the import process, click on the ‘Import Guidance’ tab.

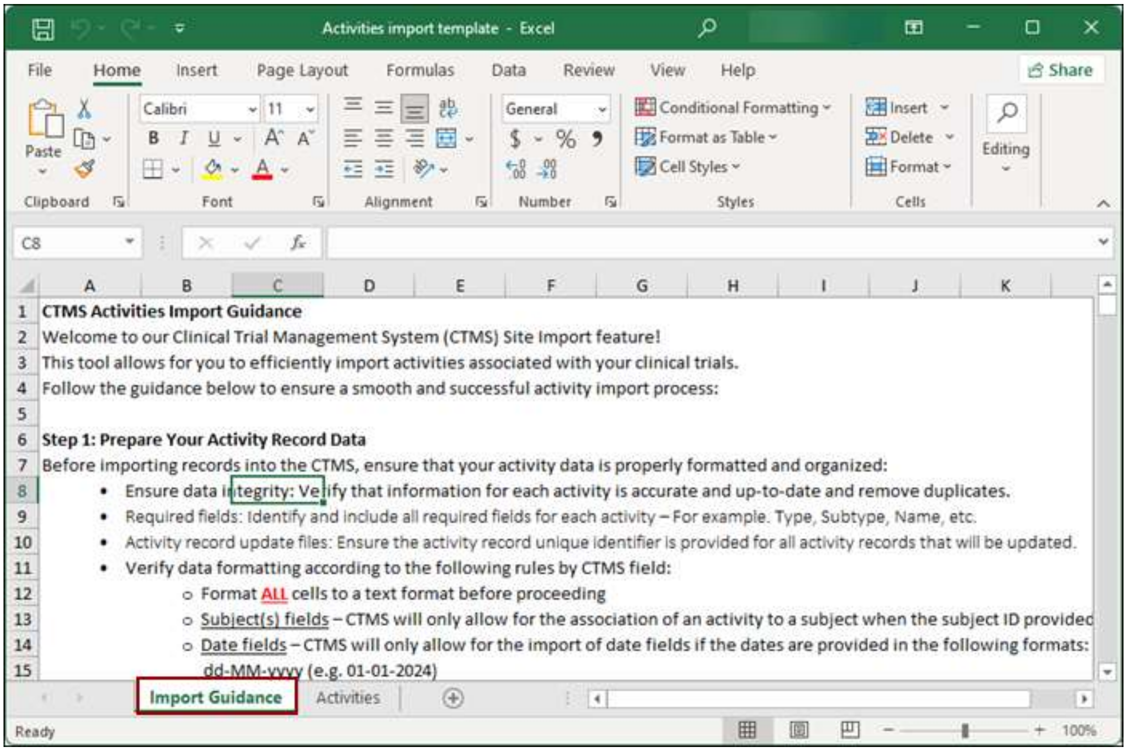


Figure: Activity Import Template – Import Guidance tab

5. Upload the template file in XLSX file format by using the Drag & Drop or manual upload functionality and click on the ‘Next’ button.

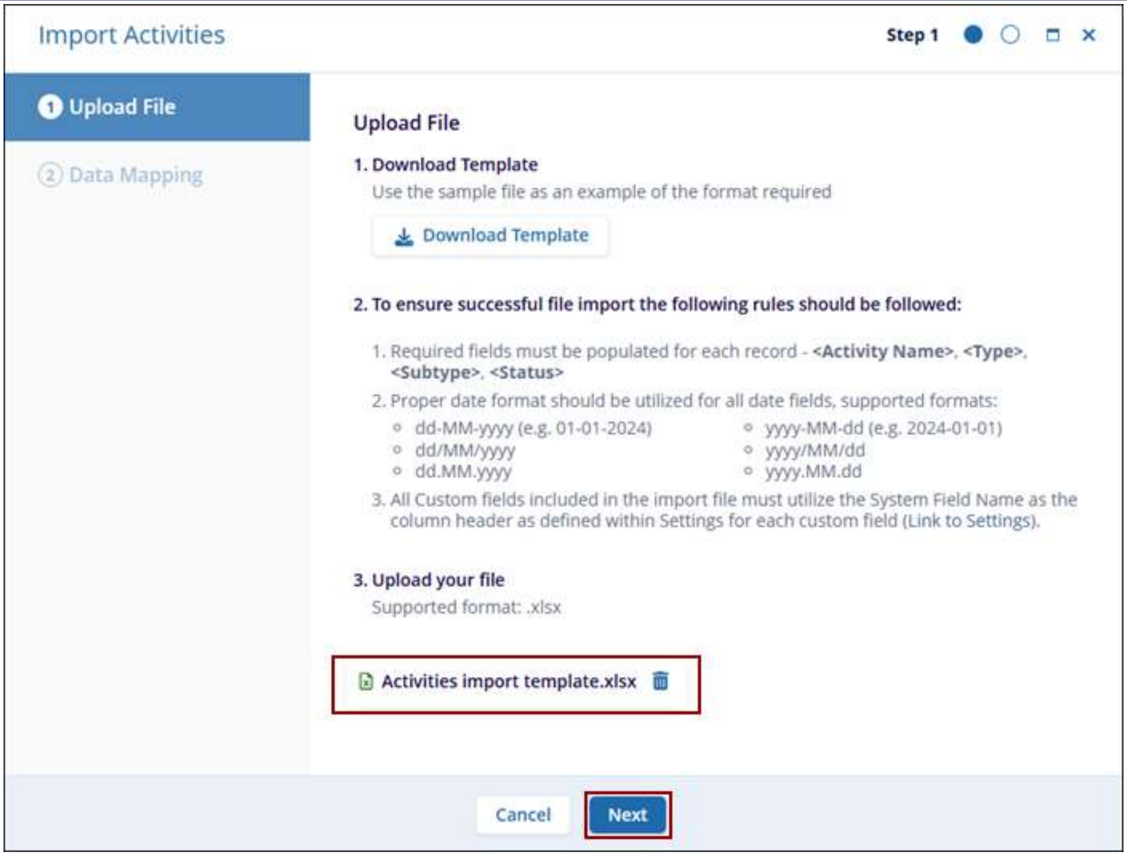


Figure: Upload Activity Template file

6. On the 'Data Mapping' screen, define the data import rules and map spreadsheet field to CTMS system fields.

    a. Choose the level at which the activity should be imported i.e., Study, Study Country and Site.
    b. Enable the 'Use Unique identifier for Activities' toggle switch and add the unique identifiers.
    c. Select either Override or Merge option that define the relationship behavior between spreadsheet and metadata field column.

7. Click on the Import button once the data import rules are defined.

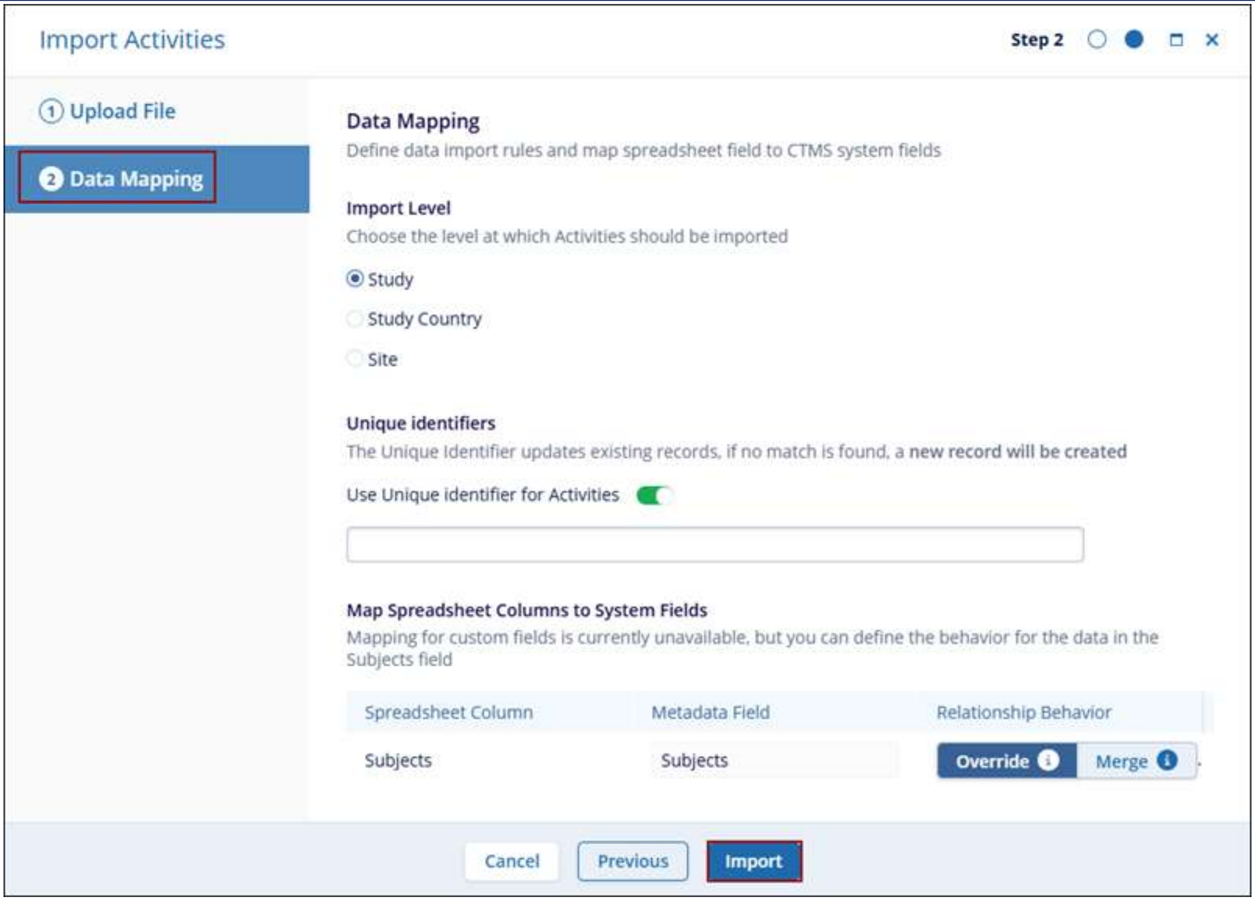


Figure: Activity Import – Data Mapping

Important: To import activities, users must have the 'Create' and 'Update' permissions enabled for Activities from Settings > Access Permissions.

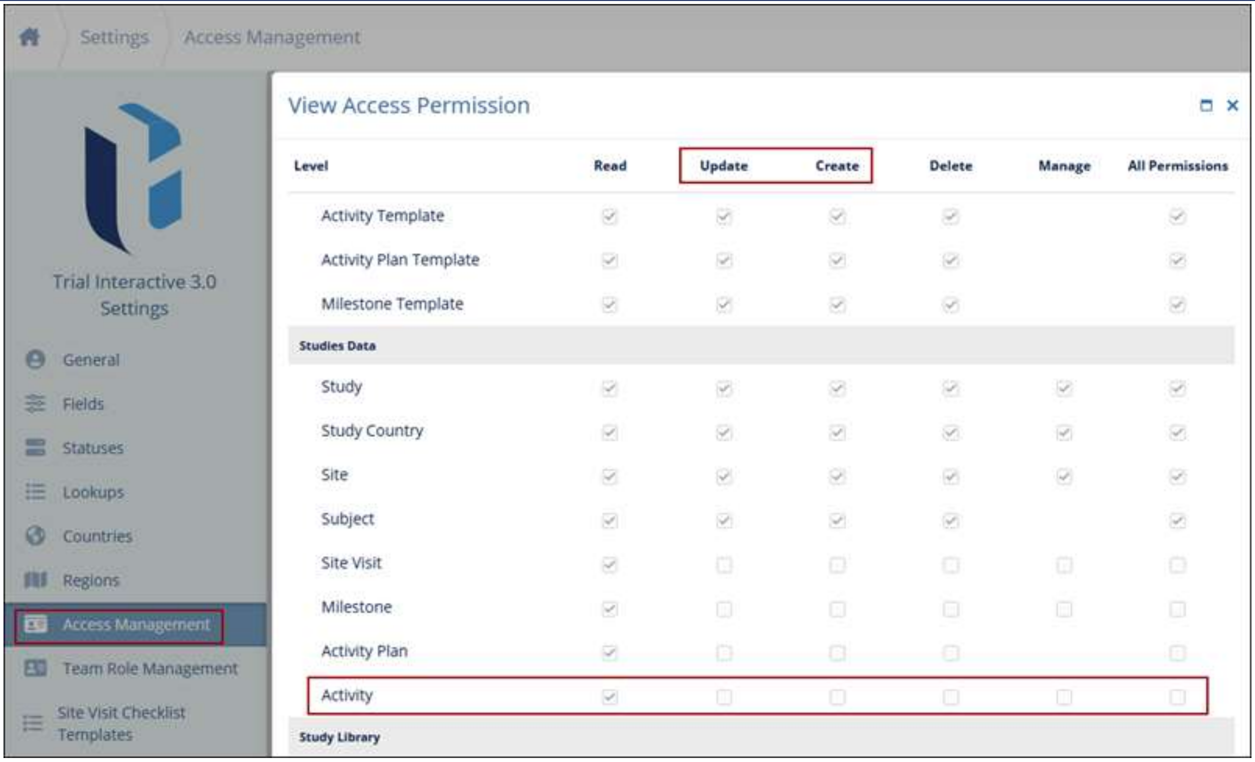


Figure: Activity Import Access Management

Study Activity Plans

Users with Admin, CRA, and CSM access can apply activity plans to studies. Users have the ability to associate and existing plan or create a new plan directly within the study.

To access Study Activity Plans, follow the steps below.

1. From the left-hand navigation pane, select the Studies link.
2. On the Studies screen, click on the study name.

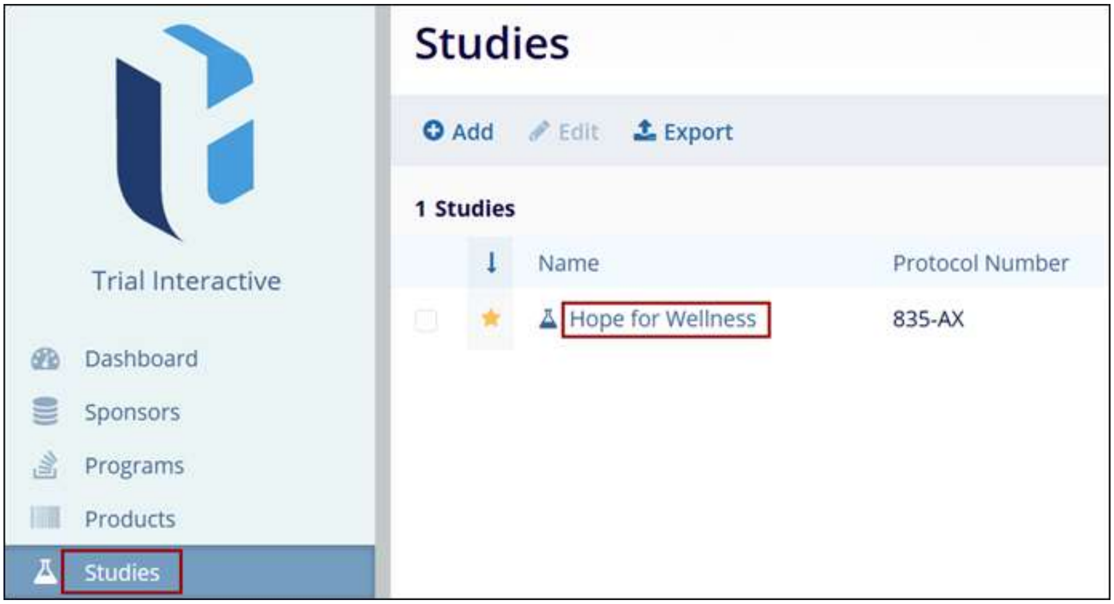


Figure: Accessing Study Details

3. On the Study Details screen, click on the Activity Plans from the left navigation pane.
4. The Activity Plans screen displays the following tabs.
    a. Plans in Use
    b. Scheduled Plans
    c. Templates

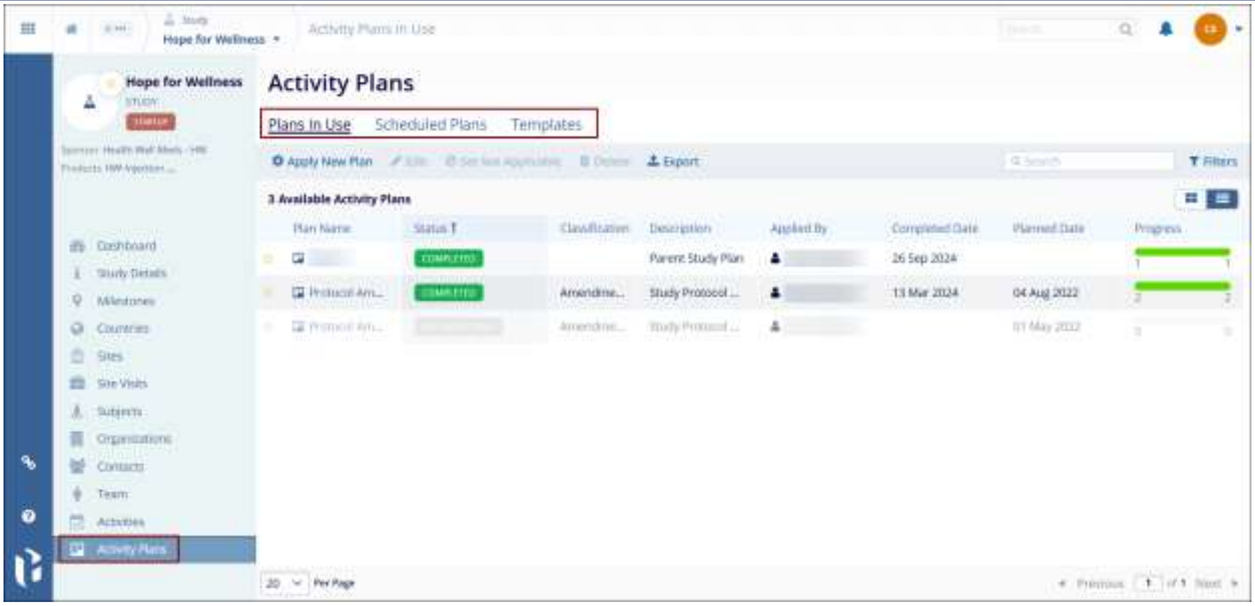


Figure: Activity Plans at Study level

Plans In Use

Apply New Plan

To apply a new plan, follow the steps below.

1. Click on the +Apply New Plan button from the top menu bar.

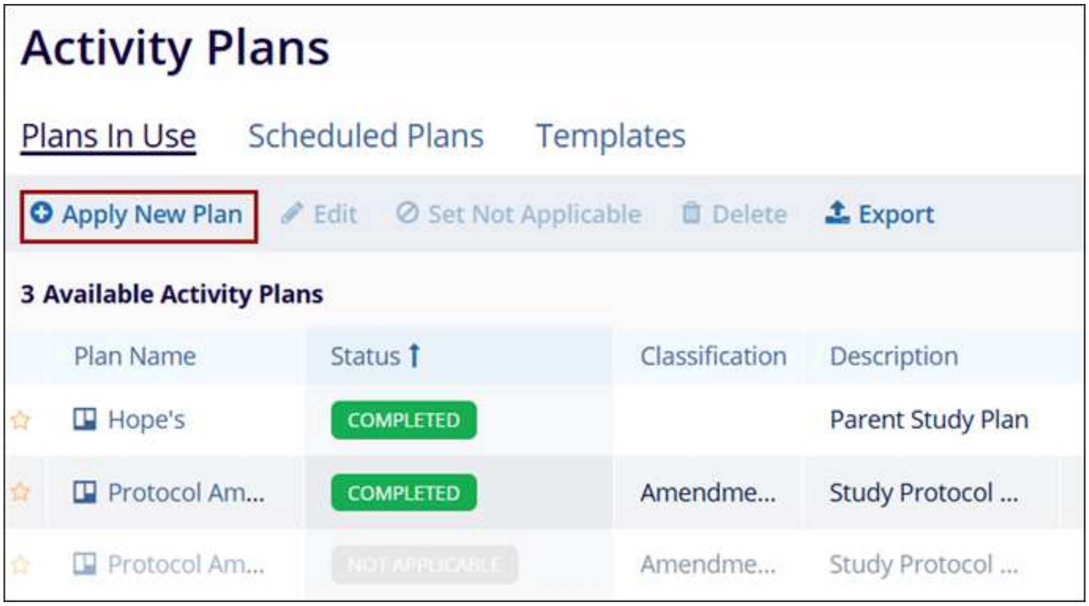


Figure: Apply New Plan

2. On the 'Apply Activity Plan for Study' screen in Step 1, either click the Apply Plan button for a specific plan or select a plan and click the Next button.

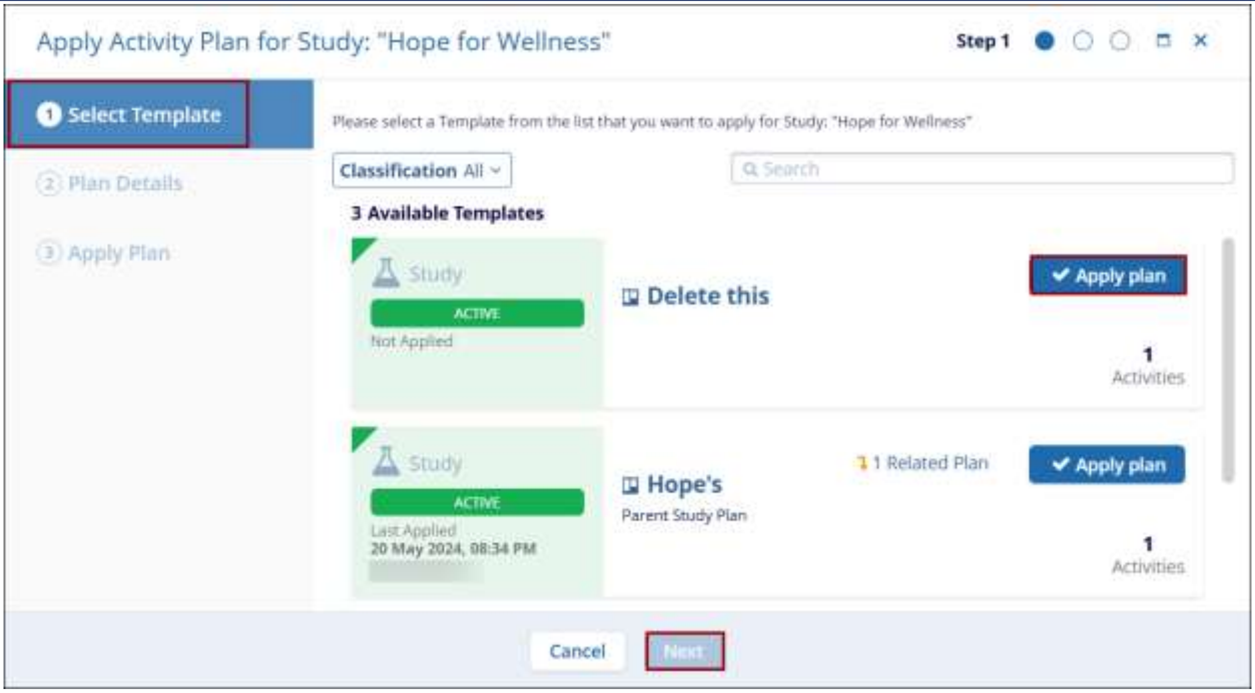


Figure: Apply Activity Plan – Select Template

3. On the 'Plan Details' screen in Step 2, verify the details and click on the Next button.

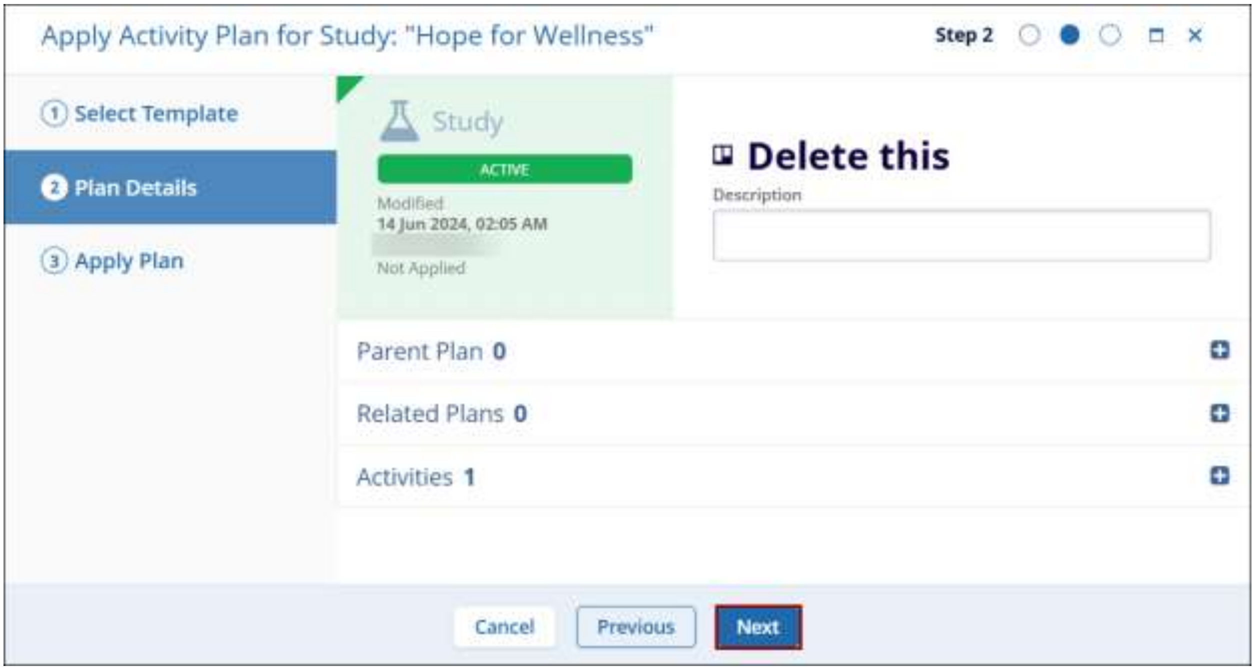


Figure: Apply Activity Plans – Plan Details

4. On the 'Apply Plan' screen in Step 3, select the planned date and click on the Apply button.

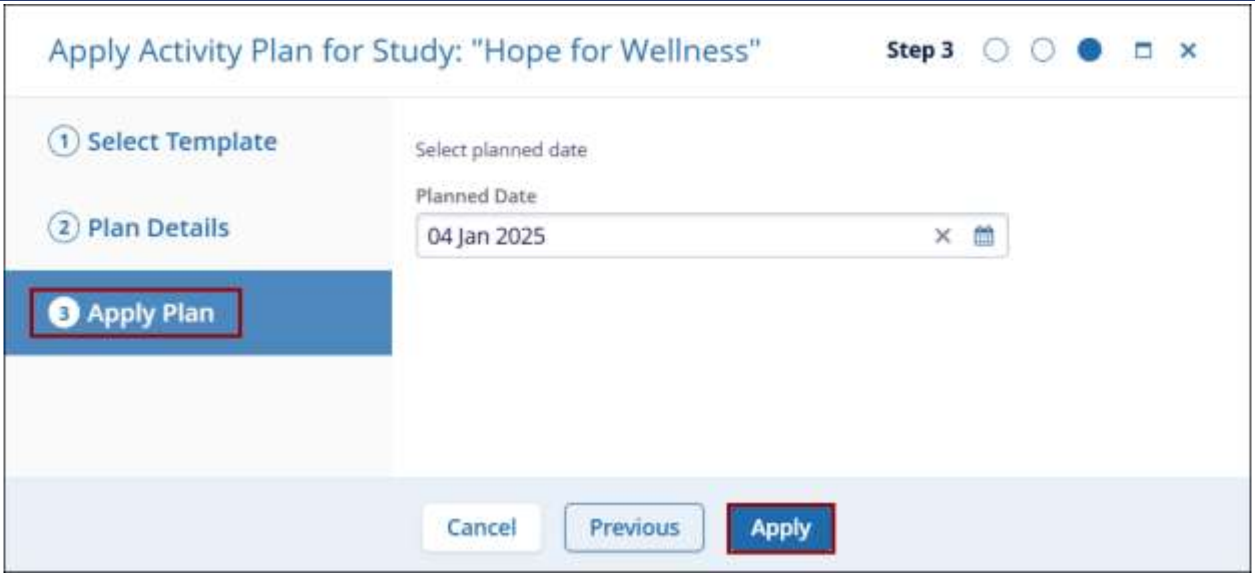


Figure: Apply Activity Plan – Apply Plan

Note: The Edit, Set Not Applicable, Delete and Export functionalities are standard across the relevant modules.

Scheduled Plans

Add Scheduled Plans

1. Click on the +Add button.

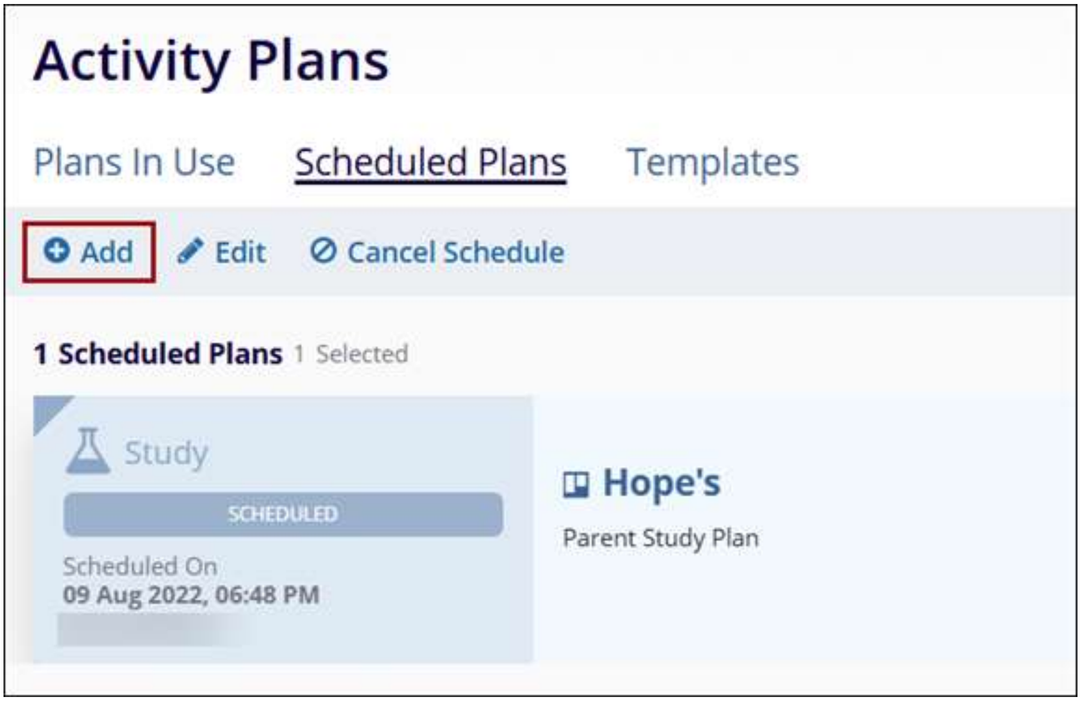


Figure: Add Scheduled Plans

2. Follow the similar steps detailed in the '**Plans in Use'** section to complete adding a Scheduled Plan.
3. Click on the Edit button to the modify the plan details.

Cancel Schedule

To cancel a scheduled plan, follow the steps below.

1. Select a plan by clicking on the tile.
2. Click on the 'Cancel Schedule' button from the top menu bar.
3. On the 'Cancel Schedule' screen, mandatorily enter a reason and click on the Confirm button.

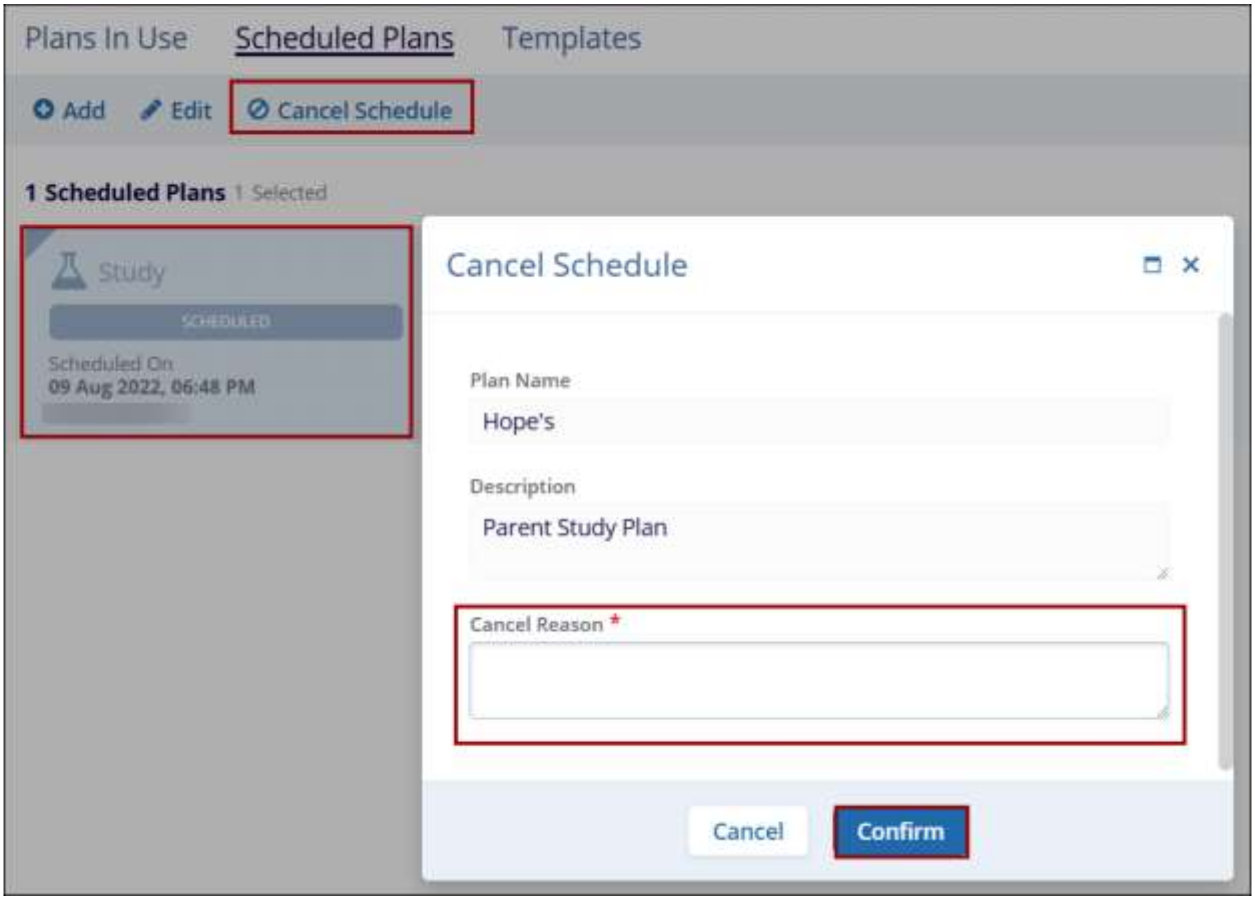


Figure: Cancel Schedule

Templates

To associate an existing template, follow the steps below.

1. On the Templates tab, click on the +Add button and select +Associate option.

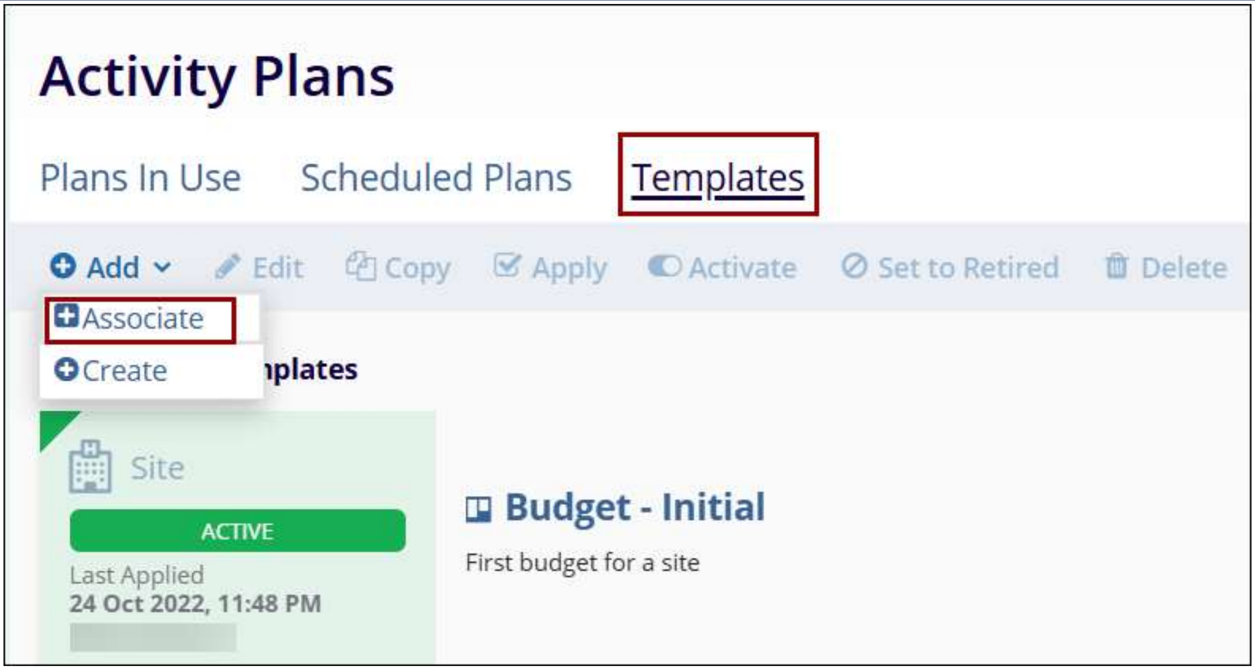


Figure: Associate Template

2. On the 'Associate Activity Plan Templates to Study' screen, select the plans and click on the 'Associate' button.

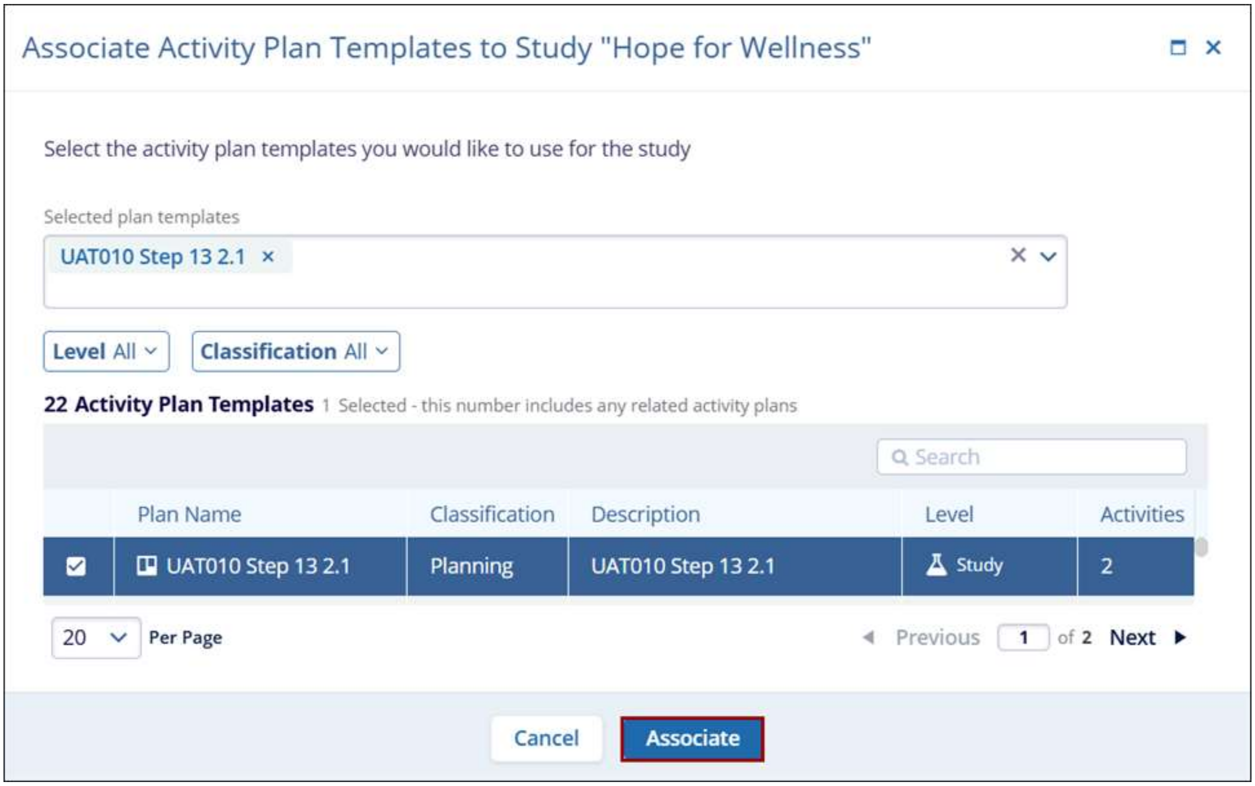


Figure: Associate Activity Plan

Note: Refer to Chapter 12. Activity Plan Templates for standard steps to create new template, edit, copy, apply, activate, set to retired and delete activity plan template records.

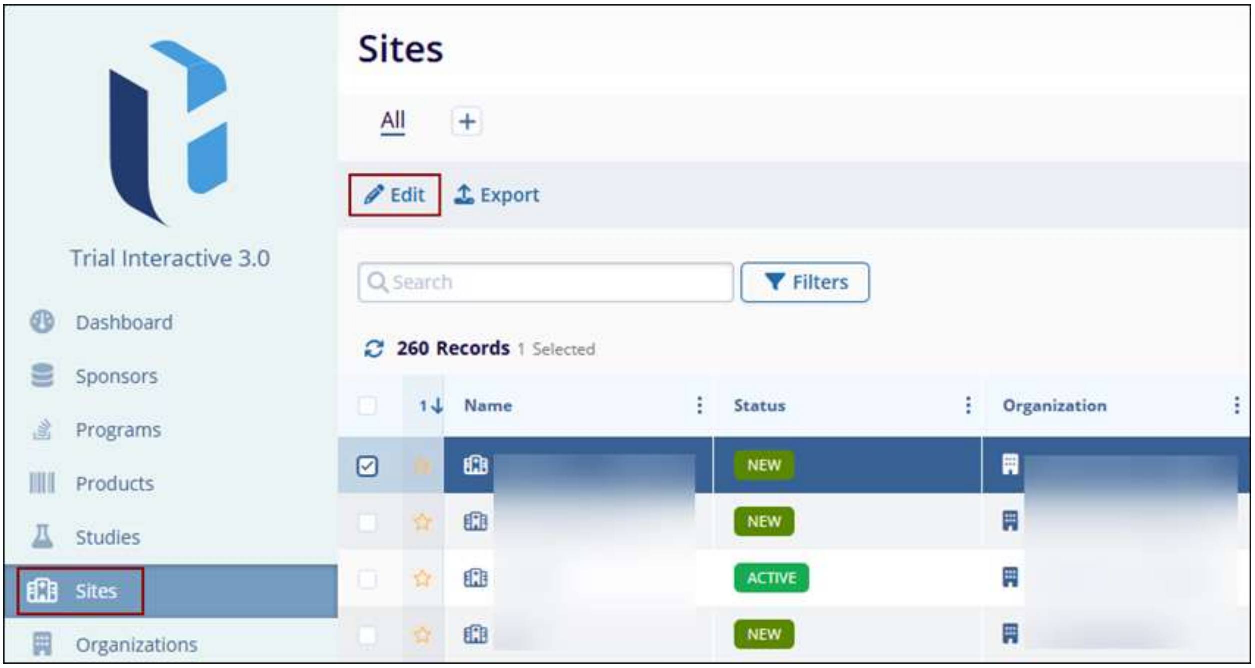
CHAPTER 8: SITES

Users can view a cross-study sites list at the domain level where the system applies the domain settings rather than study-specific settings for the cross-study site listing. Additionally, users can export a cross-study site list based on the defined views.

Edit Site at domain level

To edit sites, follow the steps below.

1. From the left-hand navigation pane, select Sites.
2. Select a site and click on the Edit button from the top menu bar.



3. Follow the standard steps to edit a site detailed in the Editing a Site in a Study section.

Export Sites at domain level

To export sites, follow the steps below.

1. From the left-hand navigation pane, select Sites.
2. Select a site and click on the Export button from the top menu bar.

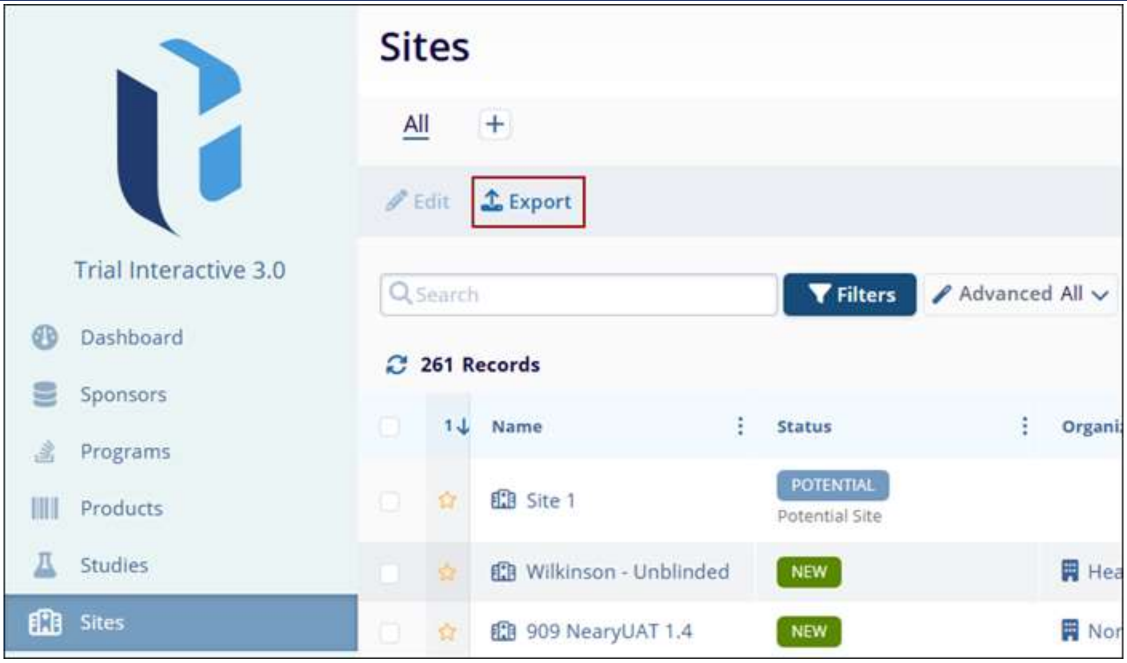


Figure: Export sites across studies

3. Follow the standard steps to edit a site detailed in the Export Sites section.

CHAPTER 9. SITE VISIT DOCUMENTATION

Site visits can be set up to 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 Clinical Research Associate (CRA) user responsible for creating and managing Site Visit Documentation in a Site must have the 'Site & Visit Editor' permission.

Refer to the Managing Study Access Permissions section for the steps to assign user access permissions.

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

Important

- Any details created within a site visit type designated as Unblinded will be restricted from view by users who do not have an unblinded access permission for the Study or Site.
- Unblinded designation on site visits is typically limited to only site visits where users want to restrict the visibility of potentially confidential restricted data (e.g., activities)
- If there are no site visit report templates designated as Unblinded, and the visit is of an unblinded type, users will not be able to generate documents without configuration changes/updates. Those changes have to go through the change management process.
- Unblinded site visit document will only auto-file to an unblinded eTMF.
- The 'Open' Label is not the same as Unblinded in TI CTMS designations.

Site Visit Navigation CRA

To navigate to the site visit, follow the steps below

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

Figure: Select a Study and a study name

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

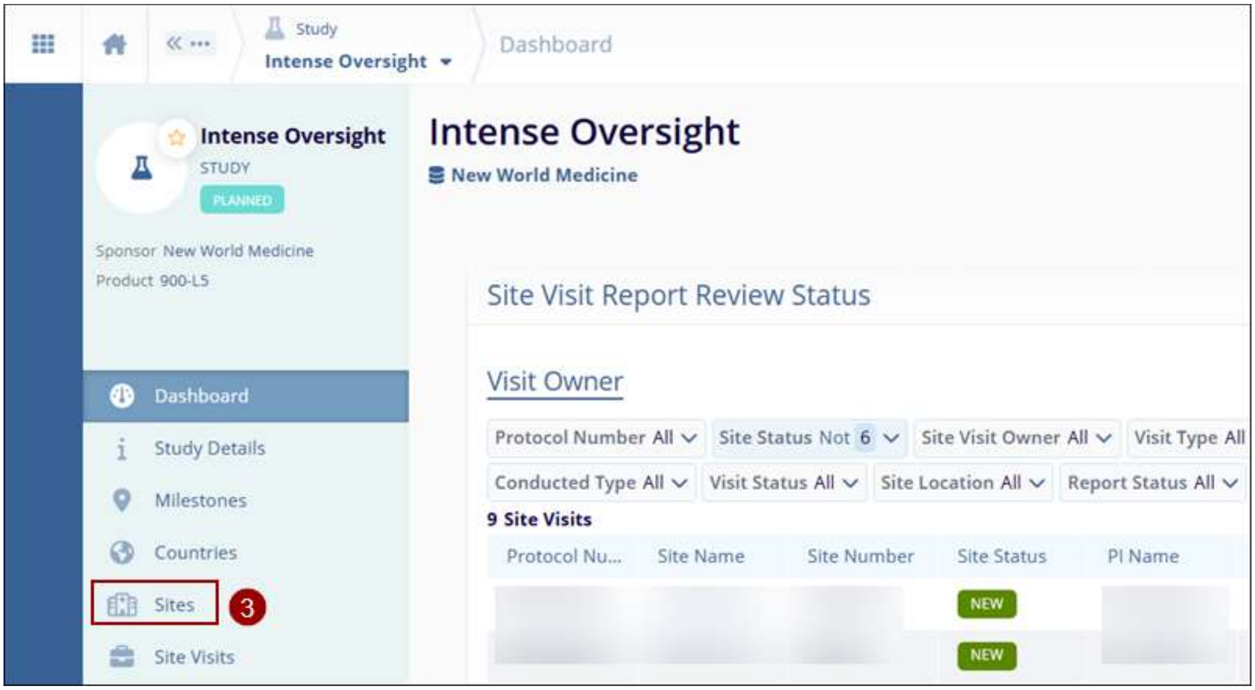


Figure: Select Sites from the Study Dashboard

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

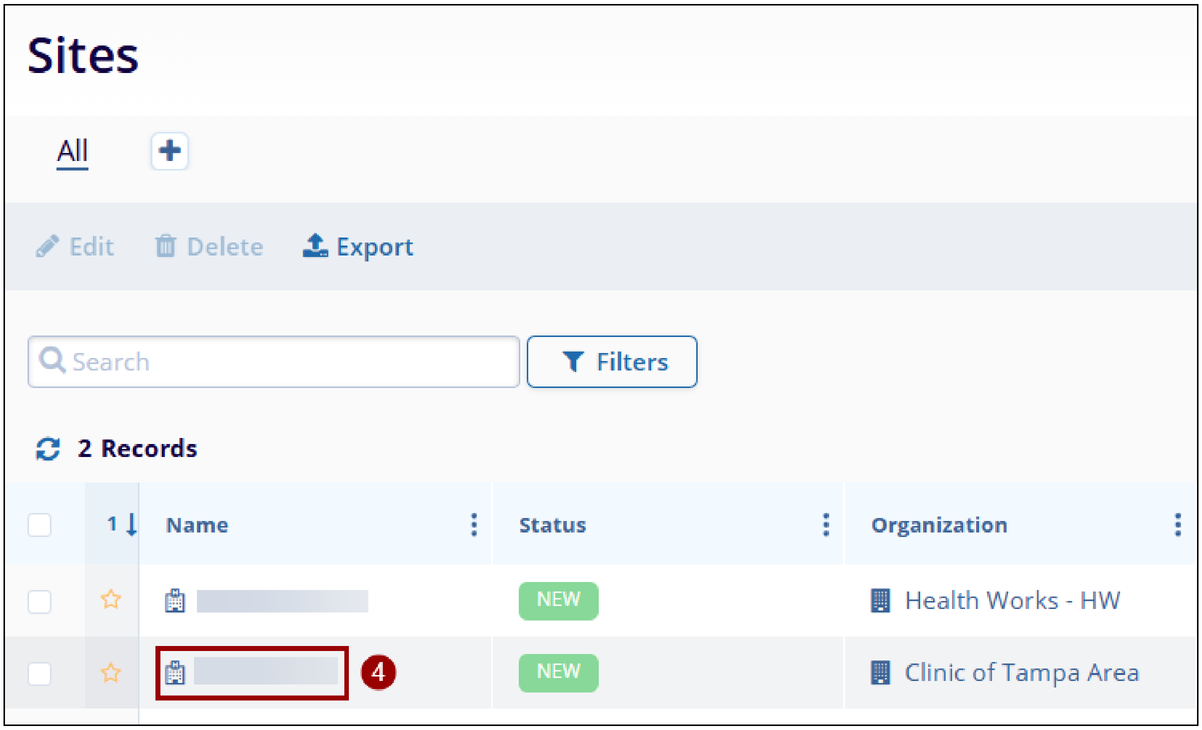


Figure: Select site

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

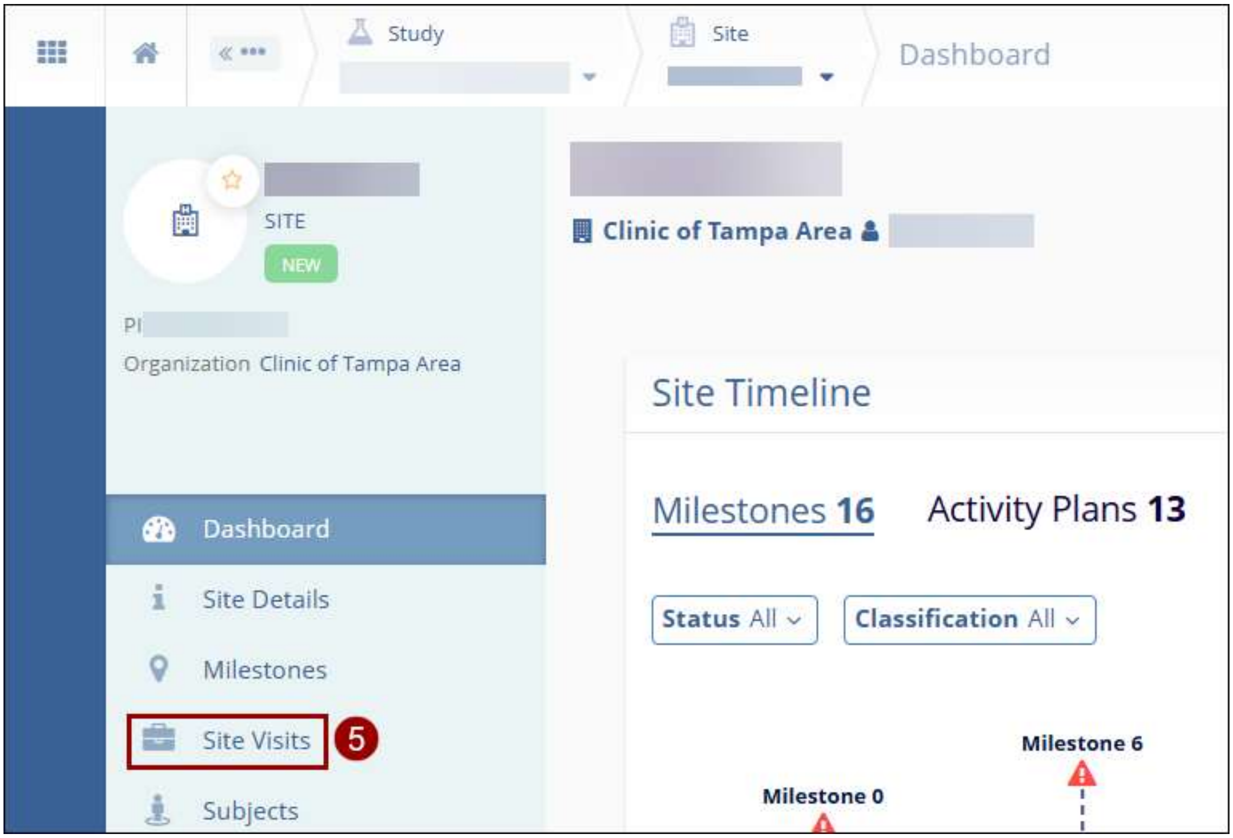


Figure: Select Site Visits

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

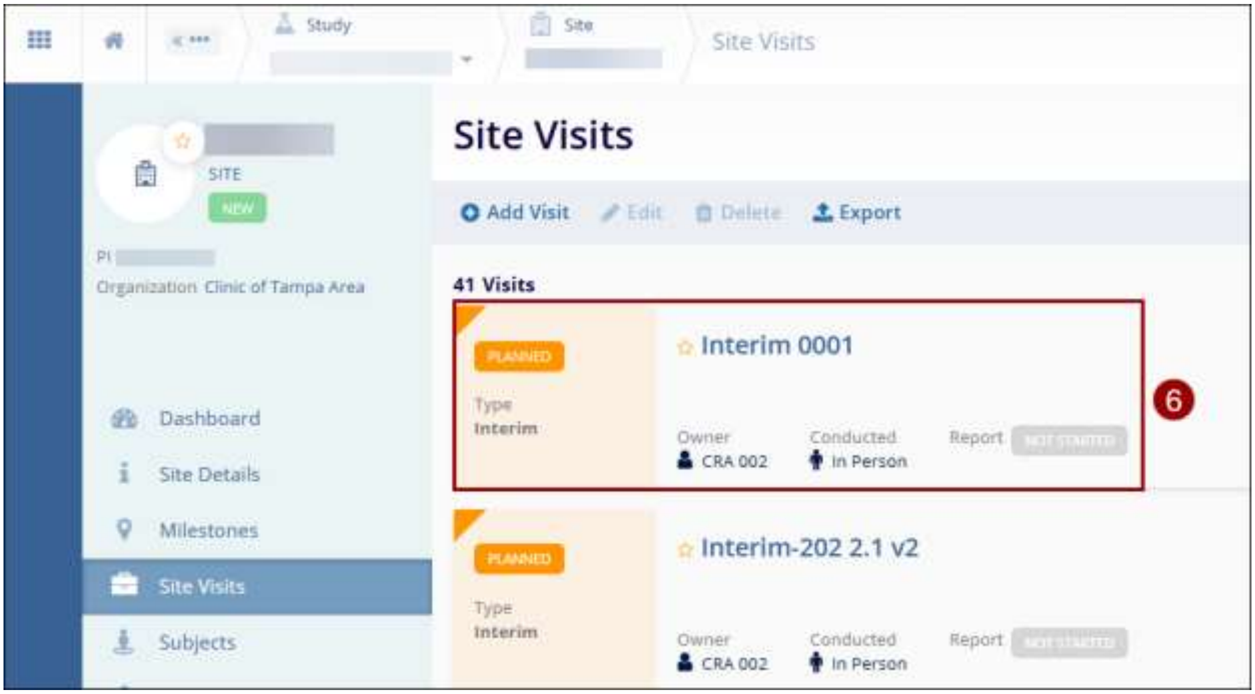


Figure: Select a visit

7. On the Site Visit General Information window, review the visit details, make the required changes if any, and click on the following buttons.
    a. Add Activity: Refer to the Creating Domain Activity Template Records section to add an activity.
    b. Discard Changes: Click on Discard Changes to remove any changes made.
    c. Save: Click on the Save button to save the changes made
    d. Click on the Save and Next button to save the changes on the current activity and move on to the other activity.
    e. Next Step: Clicking on Next Step will display a confirmation popup and clicking on Yes will display further details regarding the site visit.

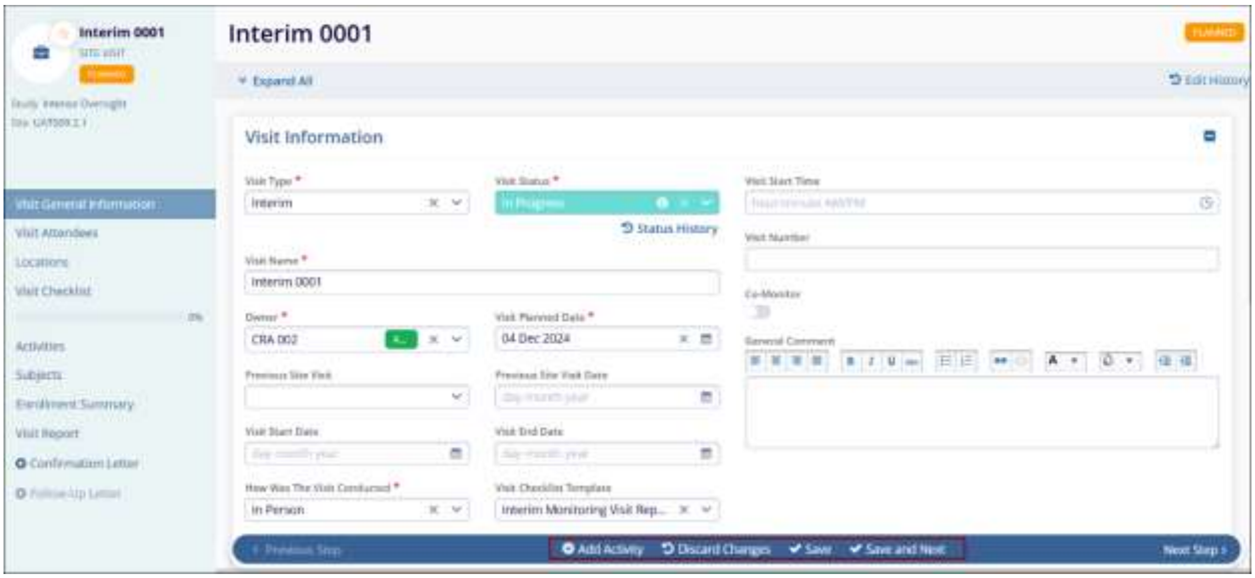


Figure: Updating site visit information

Add, Edit, Delete, and Export Site Visits CRA

To add, edit, and delete a site visit follow the steps below.

<u>Create Site Visit</u>

1. Navigate to the Site Visit screen by following the steps in the Site Visit Navigation.
2. Click on the +Add Visit button.
3. On the Create Site Visit form, add the required details
4. Click on the Create button.

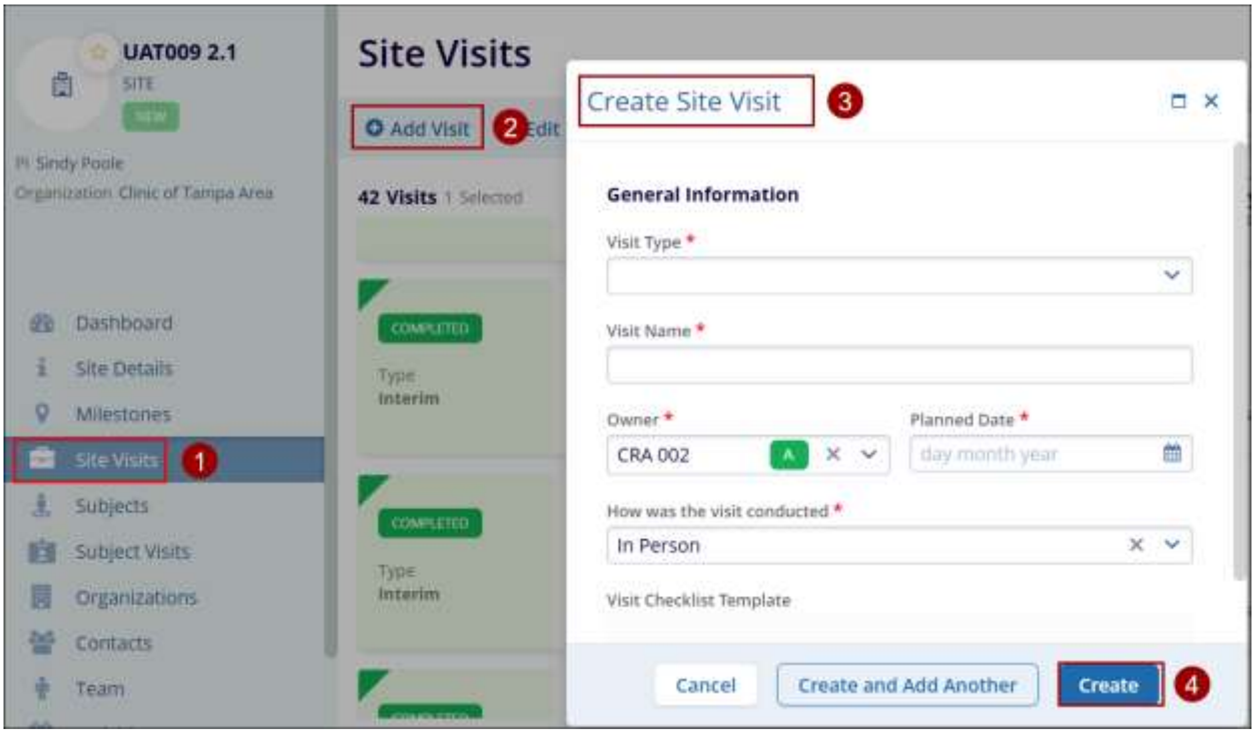


Figure: Create Site Visit

<u>Edit Site Visit</u>

To edit the site visit, follow the steps below.

1. Click on the Site Visit.
2. Click on the Edit button from the top menu bar.

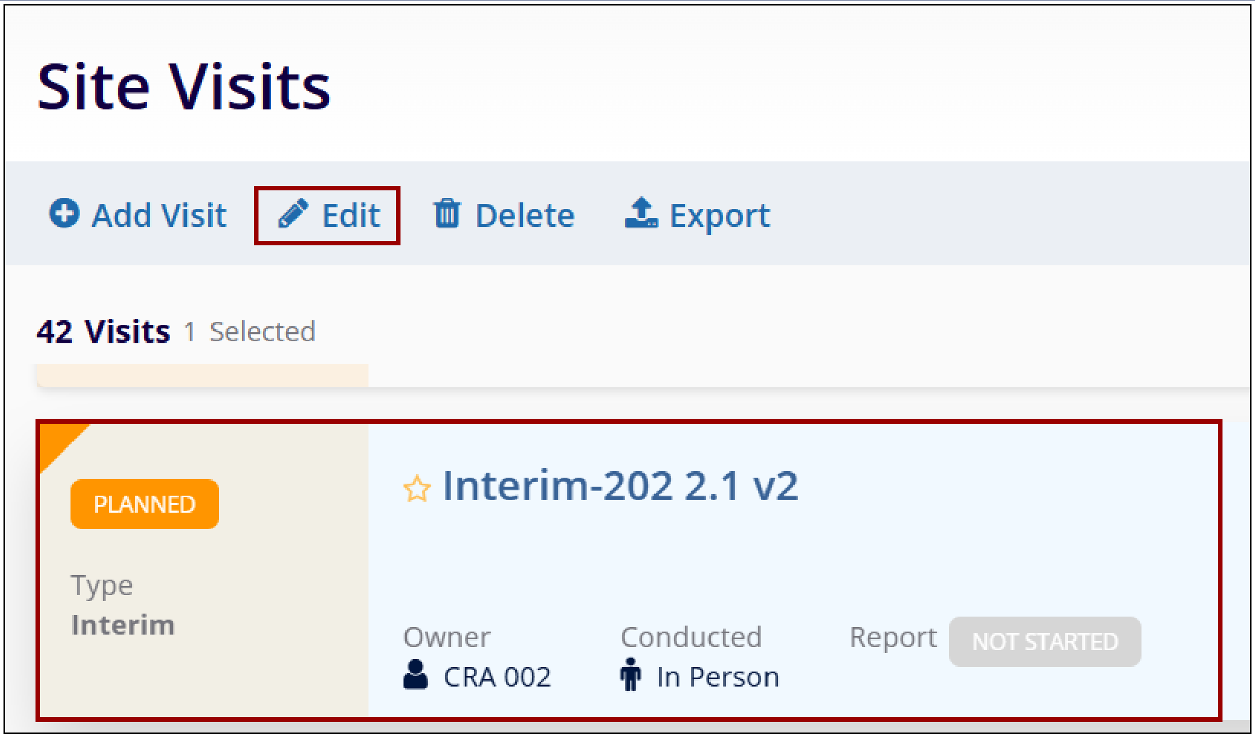


Figure: Edit Site Visit

3. On the Visit General Information screen, make the required edits and click on the Save button.

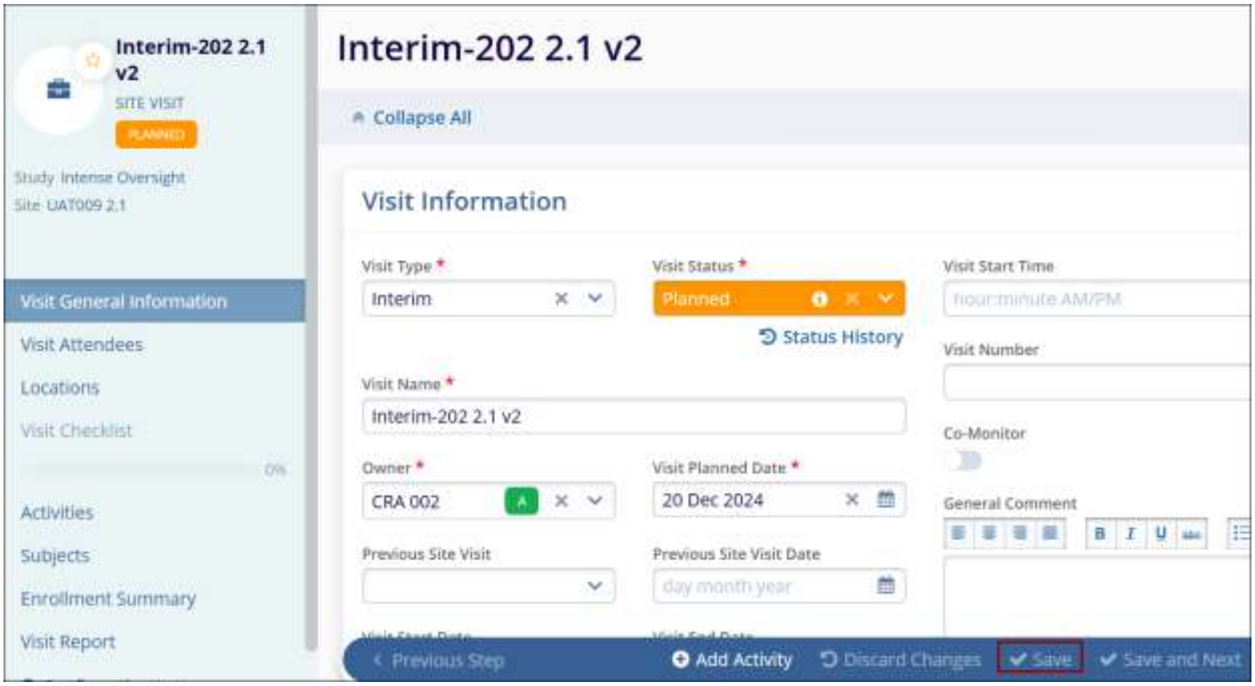


Figure: Visit General Information

<u>Delete a Site Visit</u>

To delete a site visit, follow the steps below

1. Select a site visit Planned or Draft status.
2. Click on the Delete button.
3. On the Confirmation popup, click on the Delete button.

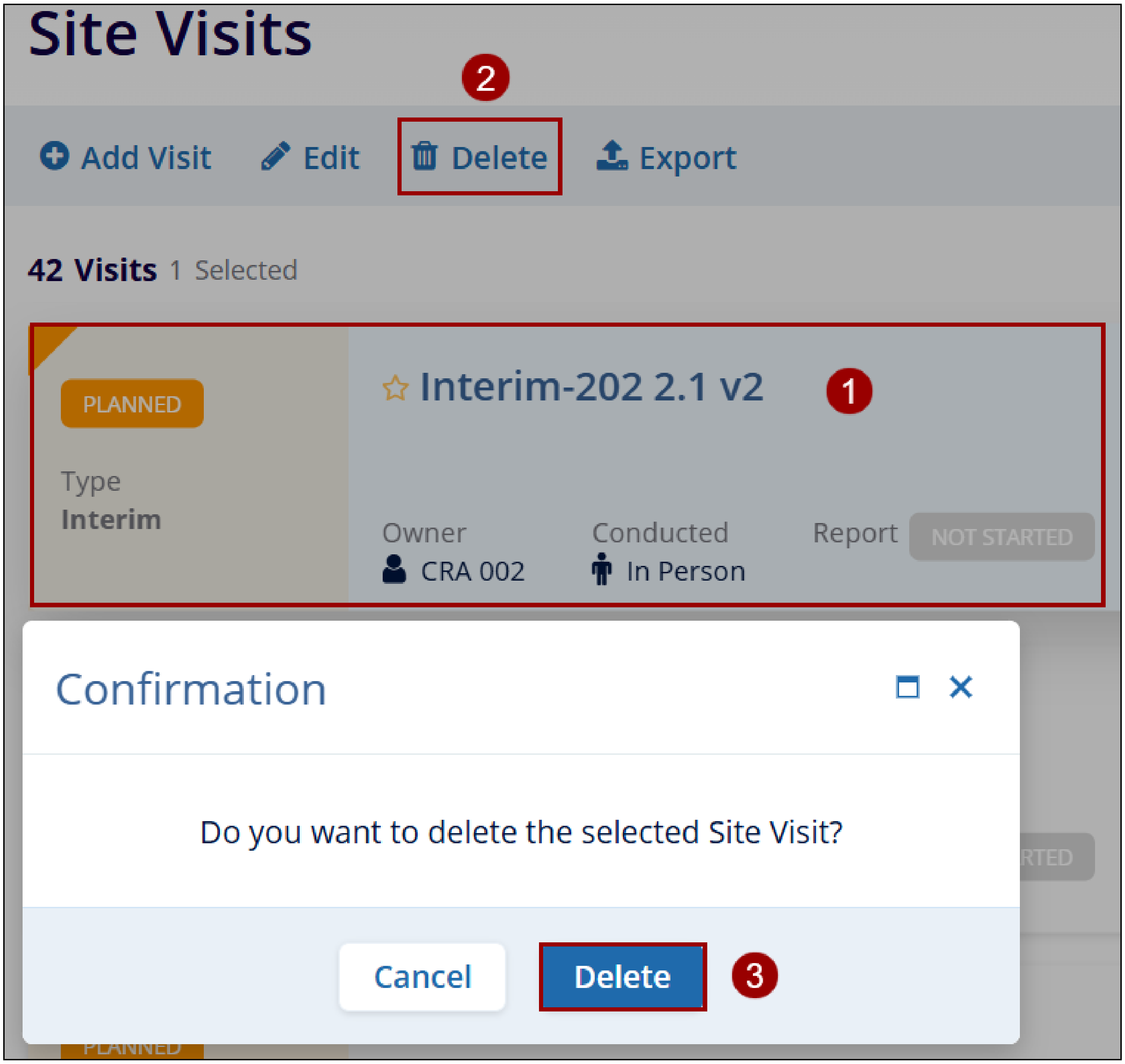


Figure: Delete Site Visit

<u>Export</u>

To export the site visit data from List and Card views, click on the Export button and follow the standard steps detailed in the Exporting Contacts section.

To export the data in Calendar View, follow the steps below.

1. On the Site Visits screen, click on the Calendar View icon and click on the Export button from the top menu bar.
2. Select the ‘Export Calendar’ option.

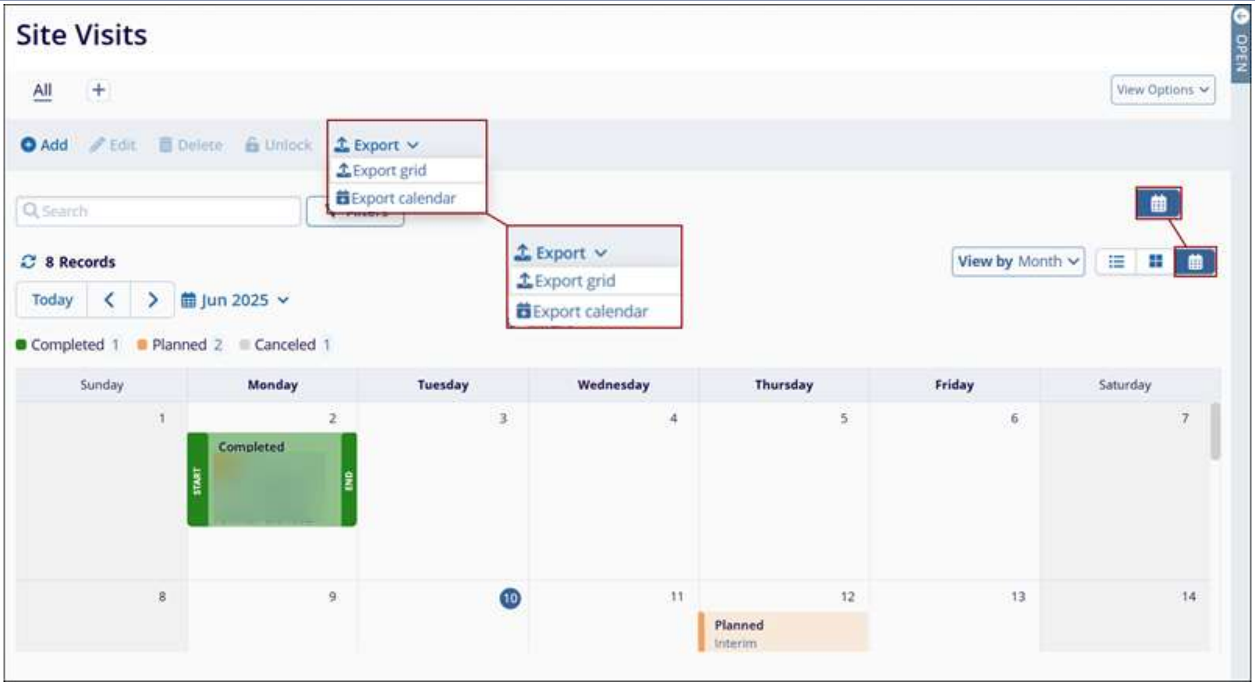


Figure: Export Calendar View

3. On the Export window, select either PDF Document or PNG Image as export options and click on the Export button.

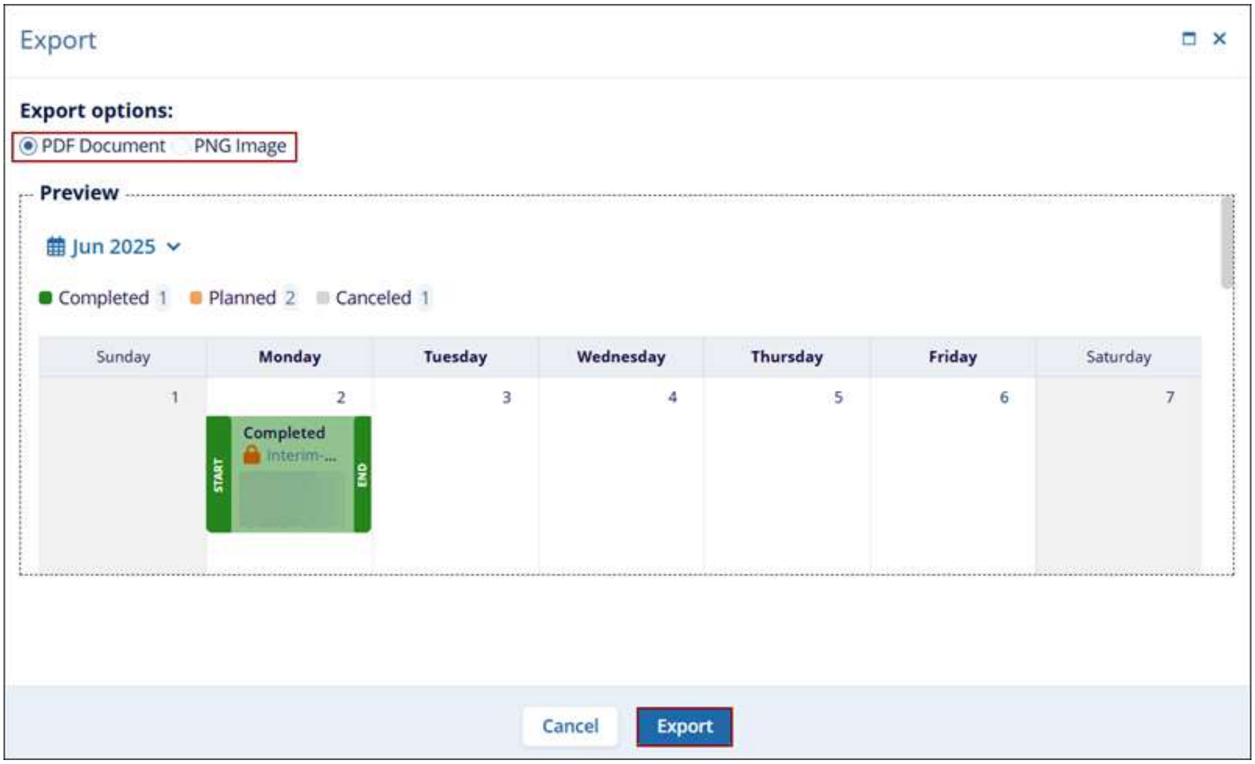


Figure: Export Calendar as PDF or PNG

Customize Site Visit screen SM

Users can customize the site visit screen by applying filters, sorting criteria, changing views, and exporting the site visit data.

Filters

To apply filters, follow the steps below.

1. Navigate to the Site Visit screen by following the steps in the [Site Visit Navigation.](#)
2. Click on the Filters button and apply the following filters by accessing the dropdown options.
3. Additionally, enable the ‘Show Favorites Only’ toggle switch to display visits marked as favorites.

Figure: Site Visit Filters

Sort

To sort the site visit data, follow the steps below.

1. Click on the Sort By button.
2. Select a Sort Criteria.
3. Click on the Up and Down arrow.

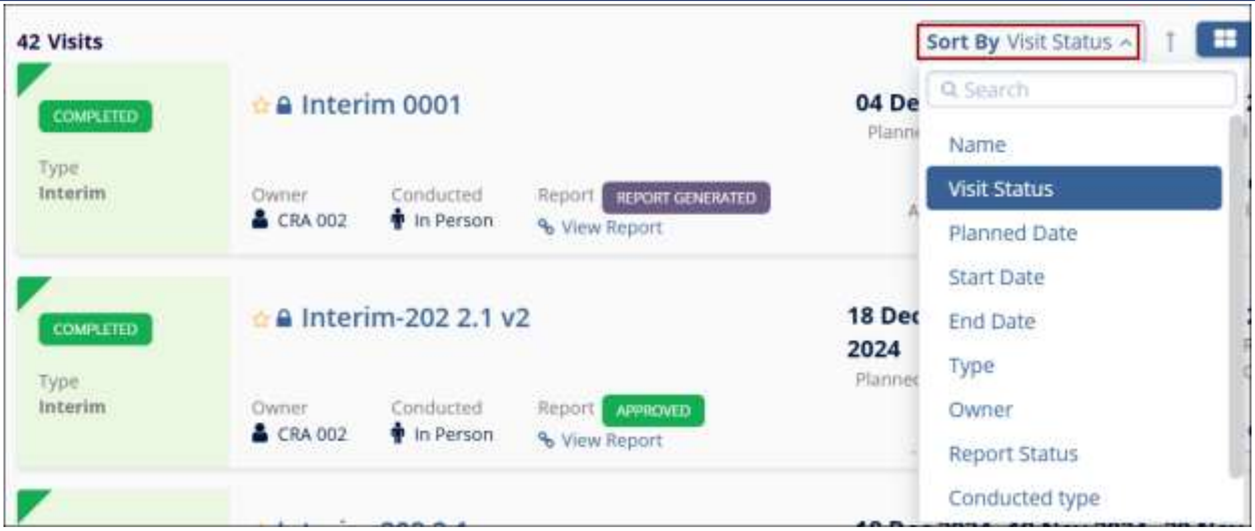


Figure: Sort Site Visits

Views

To customize the Site Visit screen view, follow the steps below.

1. Click on the Card View button to display all site visits in a tile format.

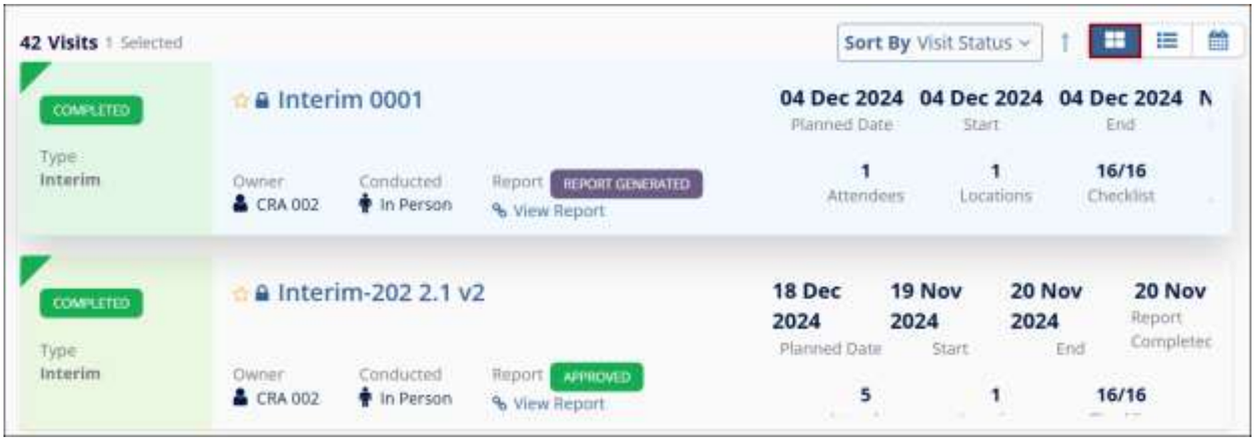


Figure: Card View

2. Click on the List view button to view all the site visits in a list format.

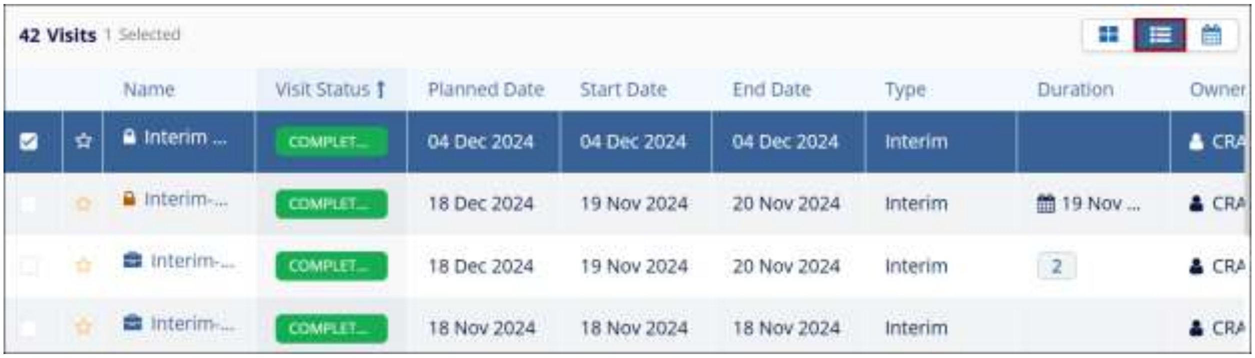


Figure: List View

3. Select the Calendar View button to display all site visits in a Day, Week, Month, Quarter, or Year format within a calendar layout.

Figure: Calendar View

Site Visit Attendees CRA

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.

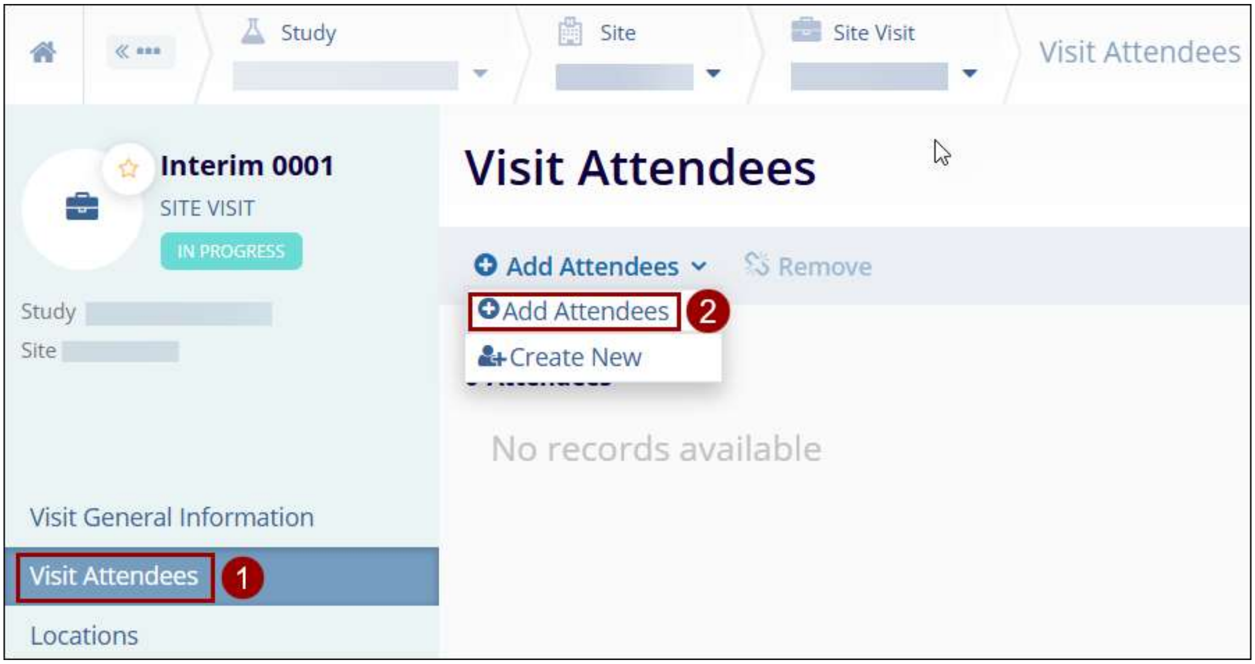


Figure: Add Attendees

3. On the Add Attendees screen, navigate to the Previous Attendees, All Site Team, All Site Contacts, and All Study Contacts tabs.
4. Select attendees by clicking on the checkbox.
5. Once the attendees are selected, click on the Add Attendees button.

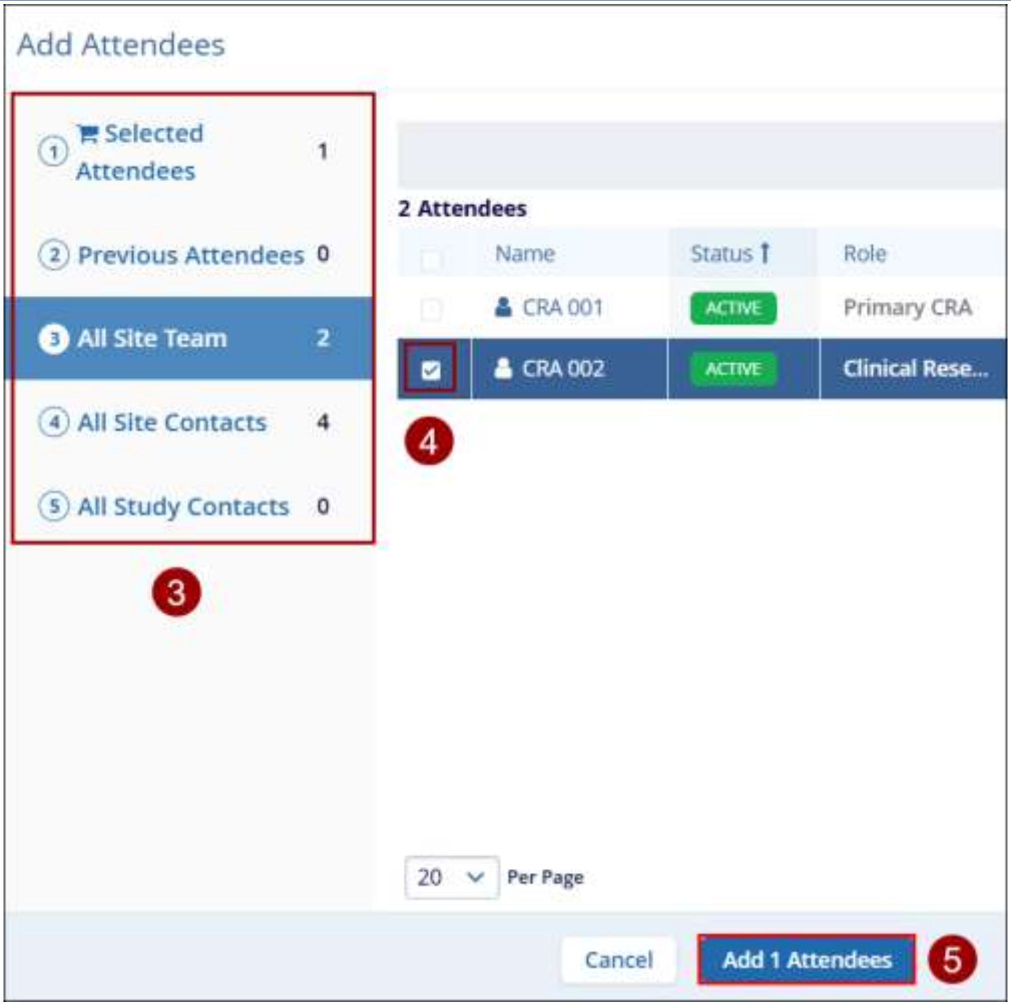


Figure: Add attendees from All Site Contacts

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

Site Visit Locations CRA

To access Site Visit Locations, follow the steps below.

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

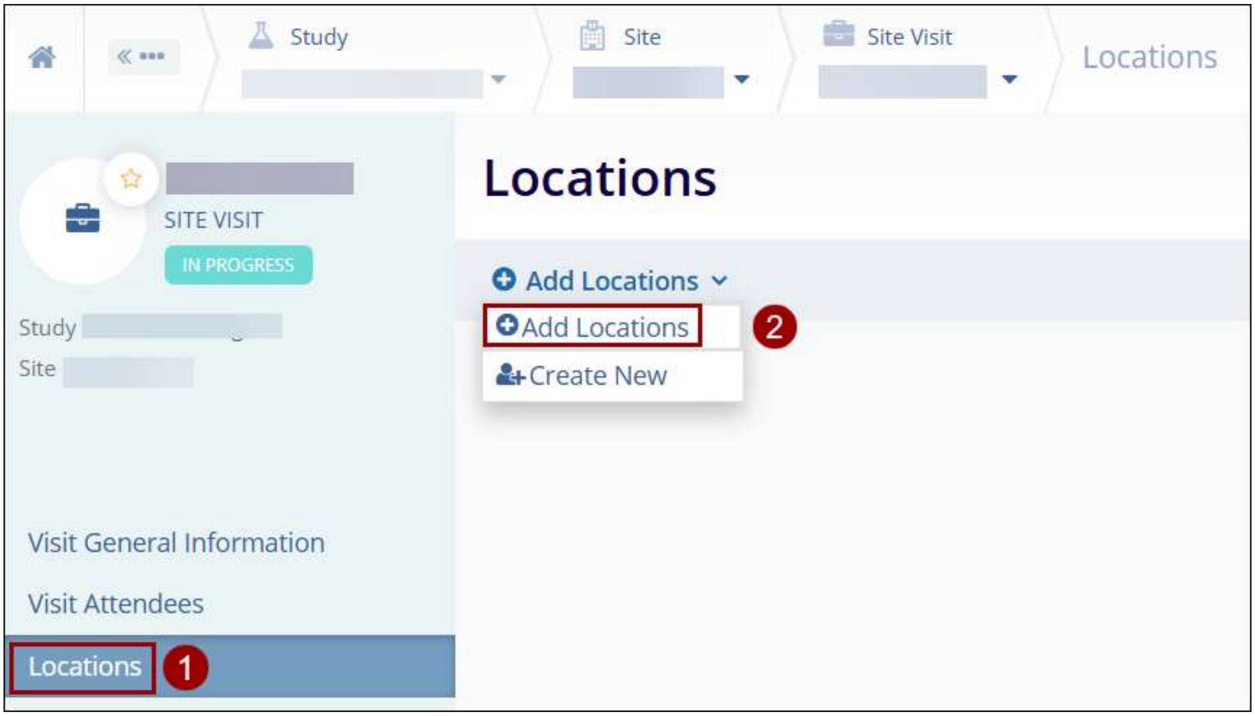


Figure: Add Locations

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

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

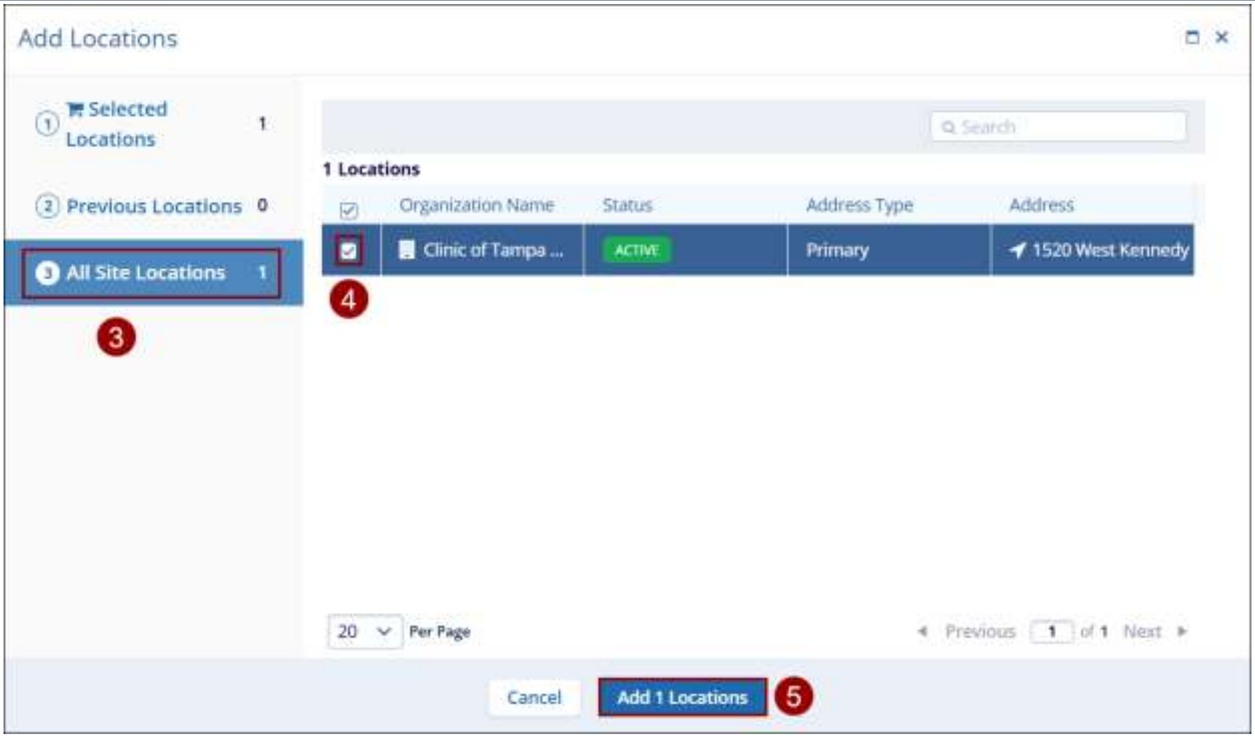


Figure: Add location from All Site Locations

Site Visit Checklist CRA

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 Visit 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.

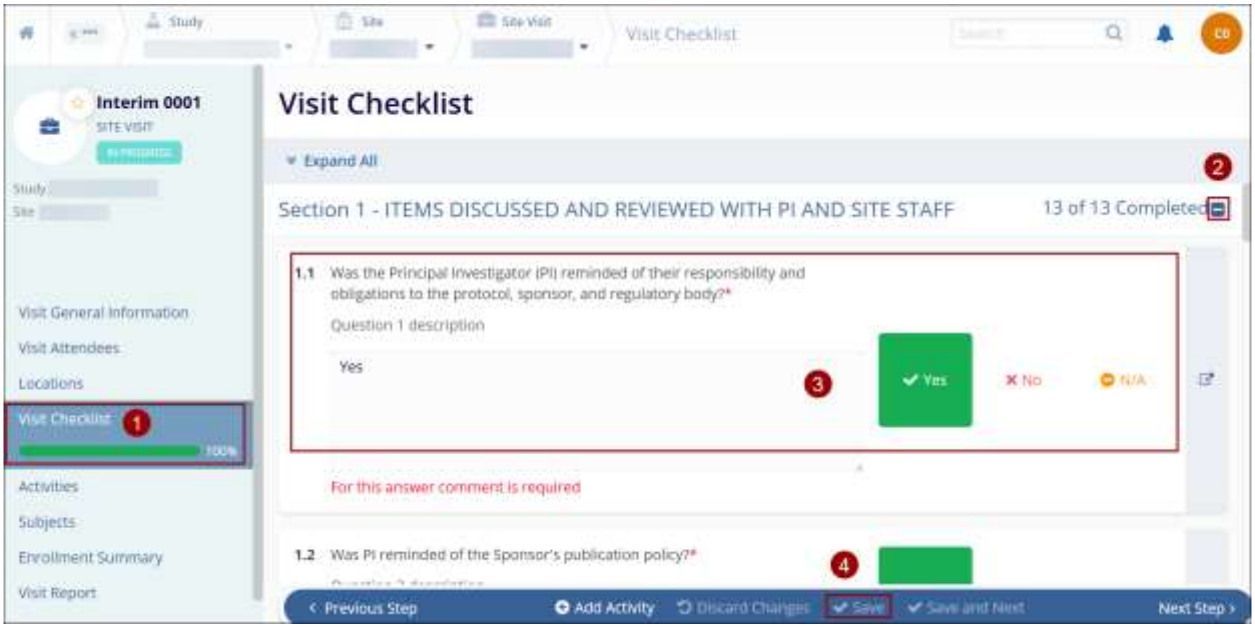


Figure: Visit Checklist

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.
- 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.

Site Visit Activities CRA

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.

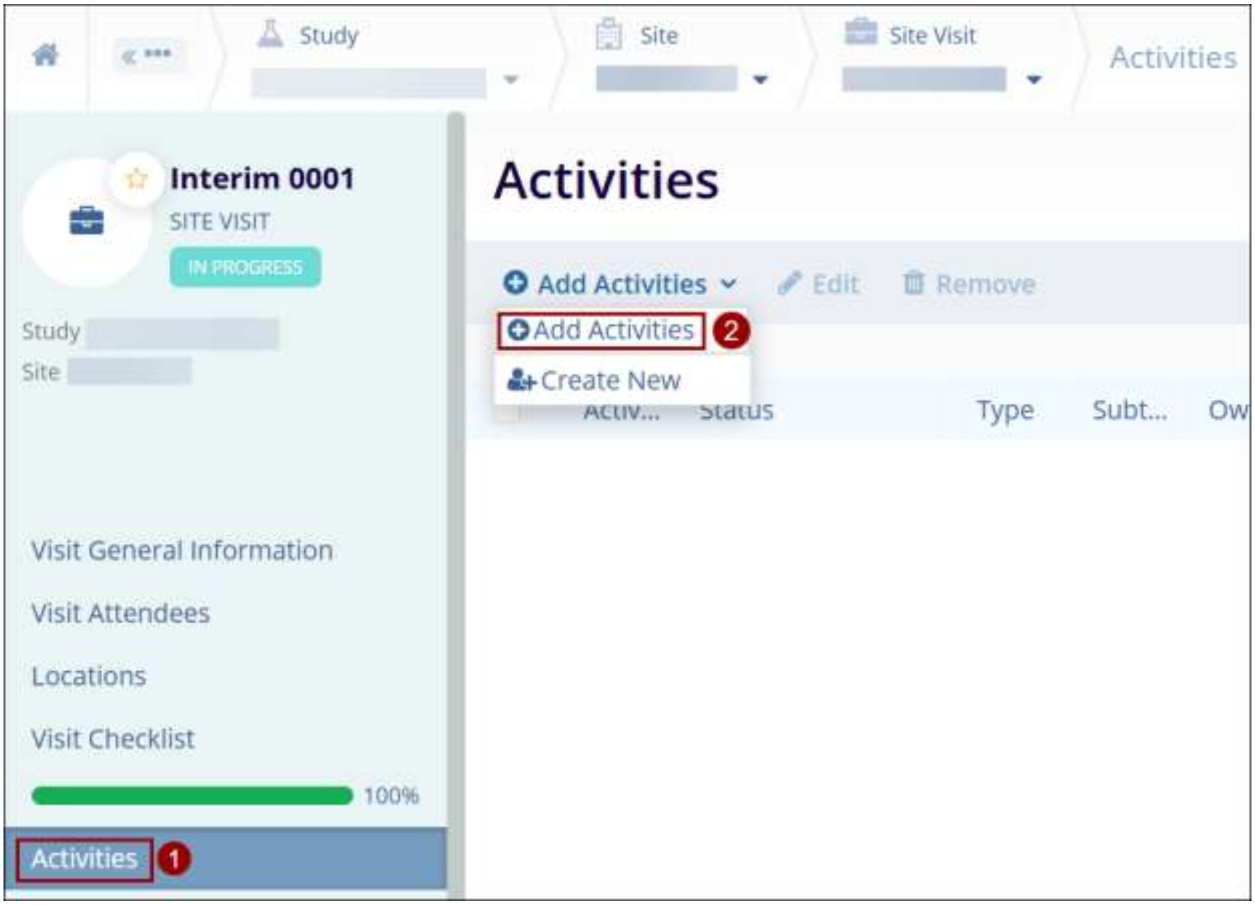


Figure: Add Activities

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.

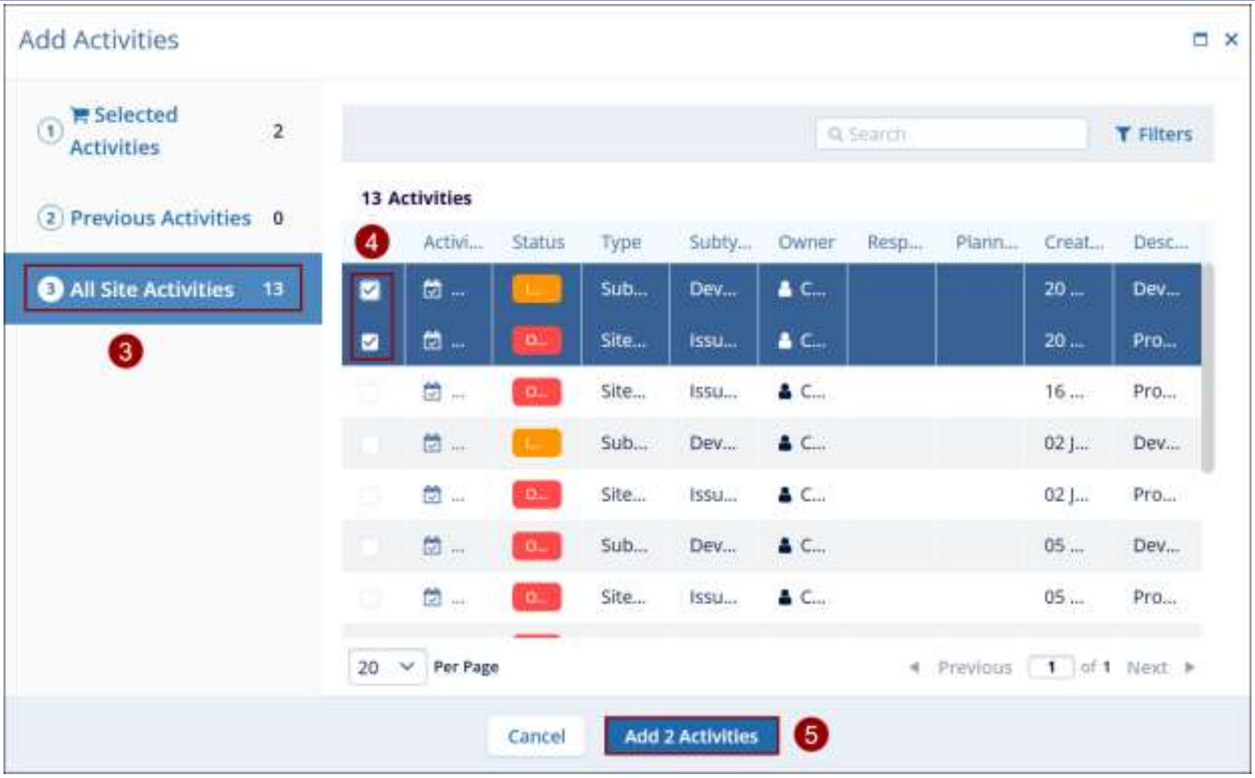


Figure: Add activities from All Site Activities

Site Visit Subjects CRA

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.

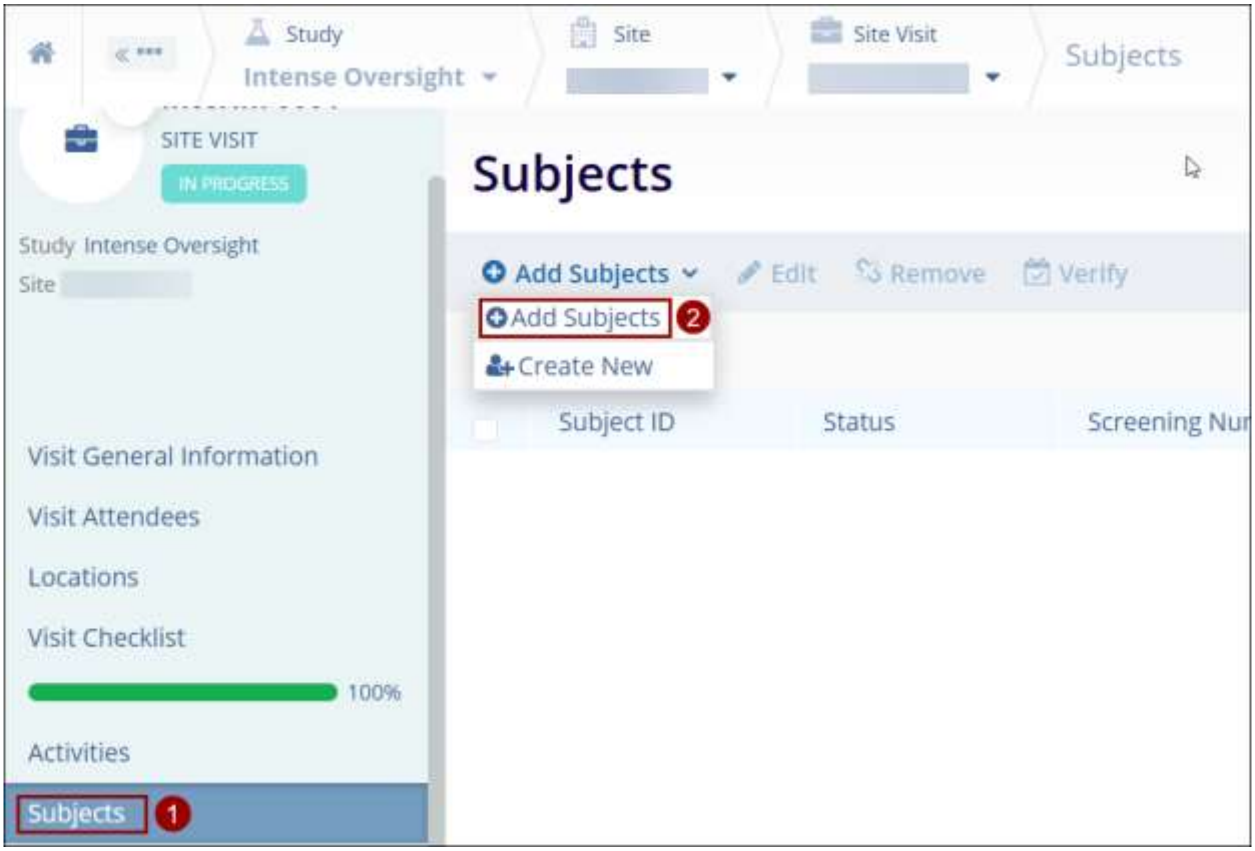


Figure: Add Subjects

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.

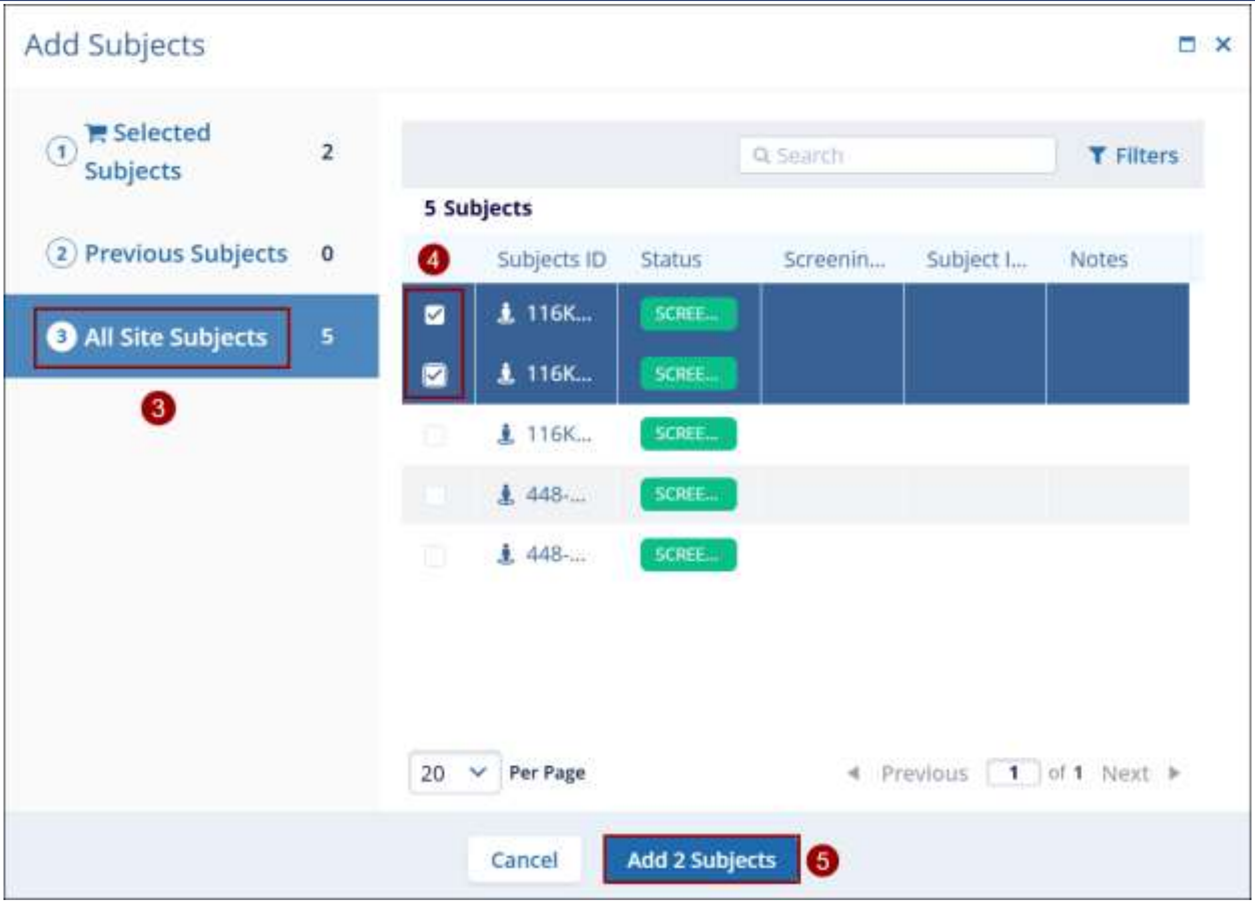


Figure: Adding subjects from All Site Subjects

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 CRA

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

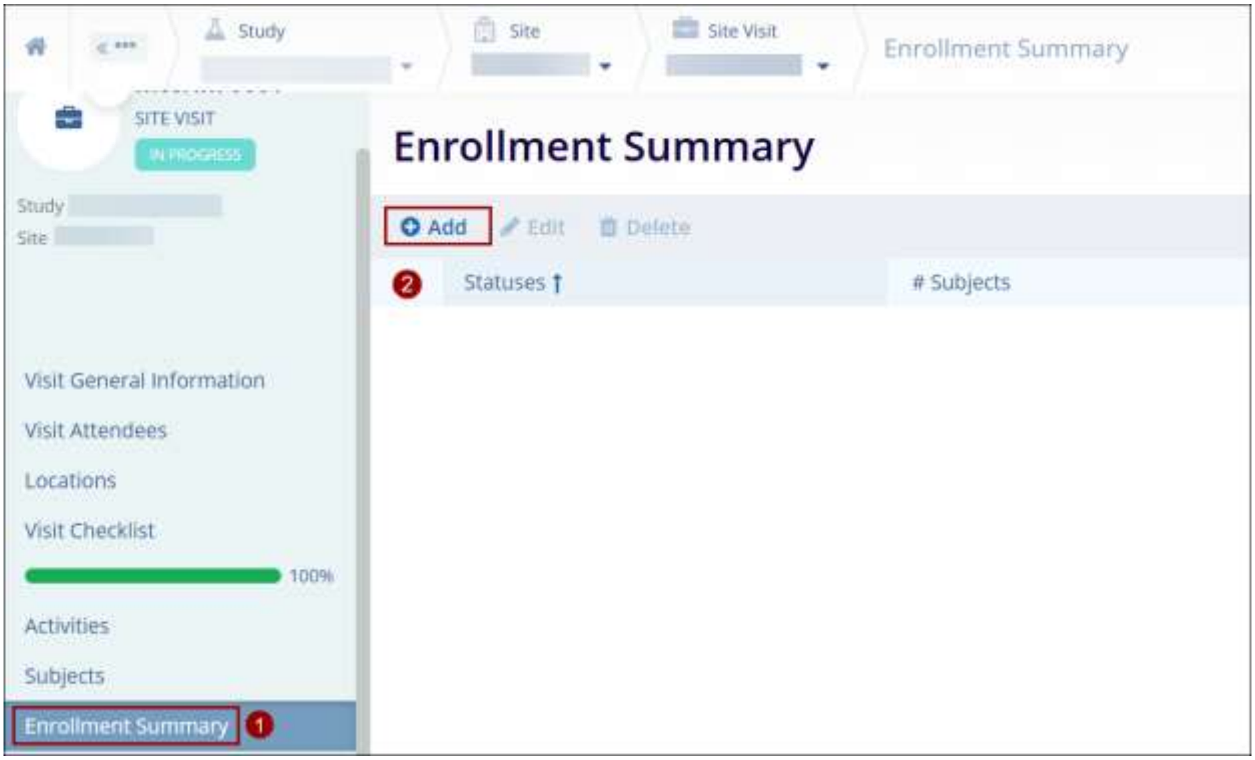


Figure: Add Enrollment Summary

3. Select the required option from the Statuses dropdown,
4. Enable the Calculated by System toggle switch to automatically consider the subjects. Disable the toggle switch to manually add the subjects.

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 CRA

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.

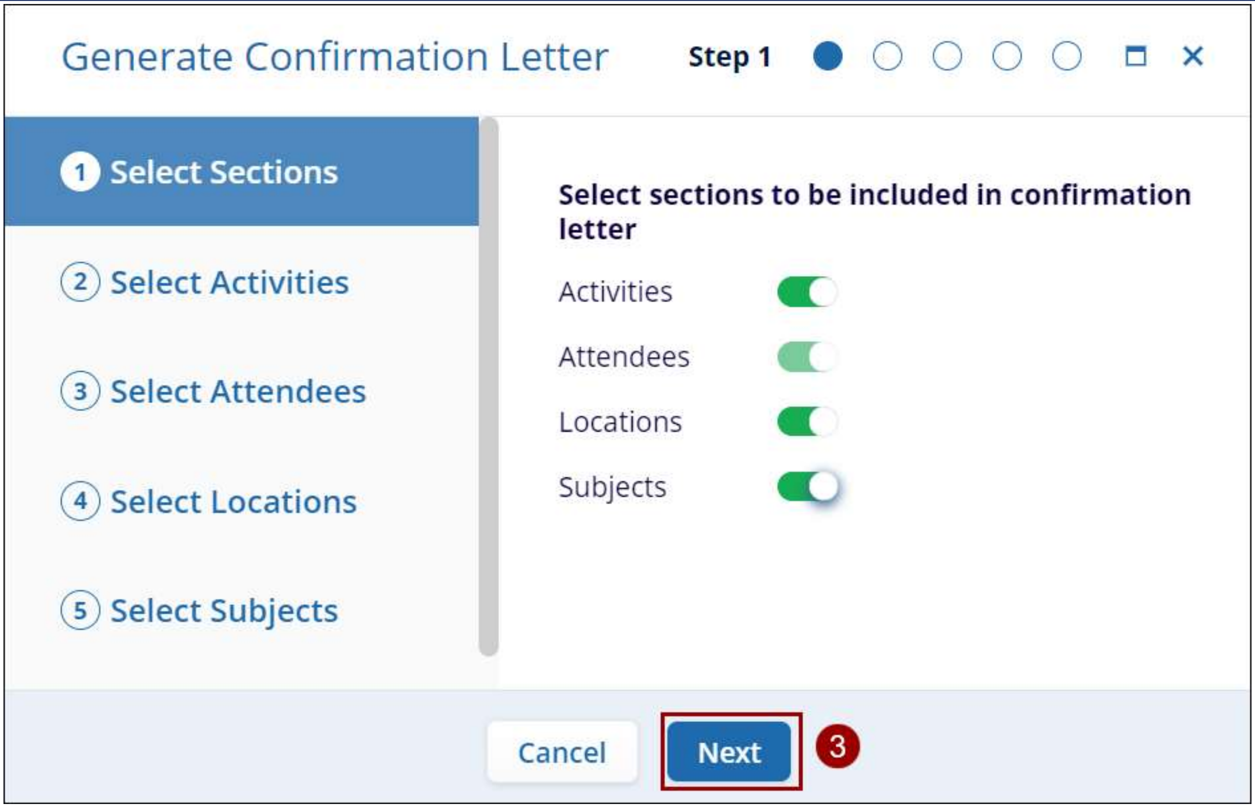


Figure: Generate Confirmation letter steps

4. Once all the steps have been completed, the confirmation letter is generated and can be viewed on the Confirmation Letter screen.

Note: CRAs can create confirmation letter at any point of time and specify any date as the 'Sent Date'.

Signing the Document and Approval Workflow CRA

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

1. Click the View Letter hyperlink.

Figure: View Letter

2. On the TI viewer of the Trial Interactive Collaborative Room, opened in a new tab of the browser, click the Edit Document button displayed in the top left corner.

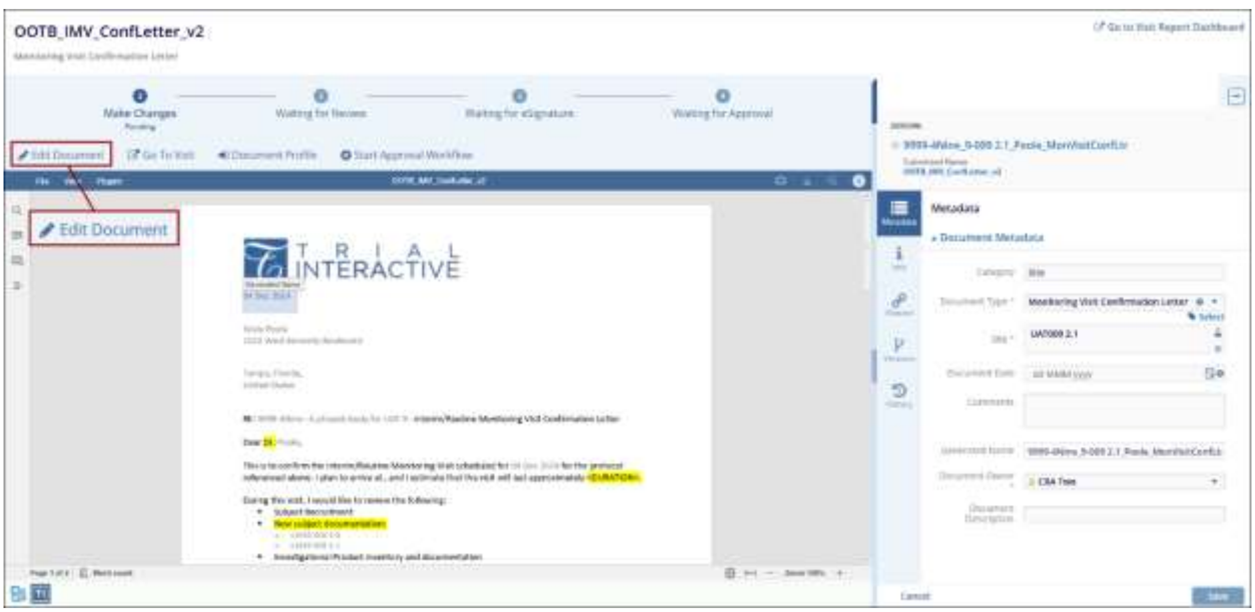


Figure: Edit Document

3. Make the required changes in the document and click on the Save Changes button.

4. On the Commit Changes popup window, enter the comments and click on the Save button.

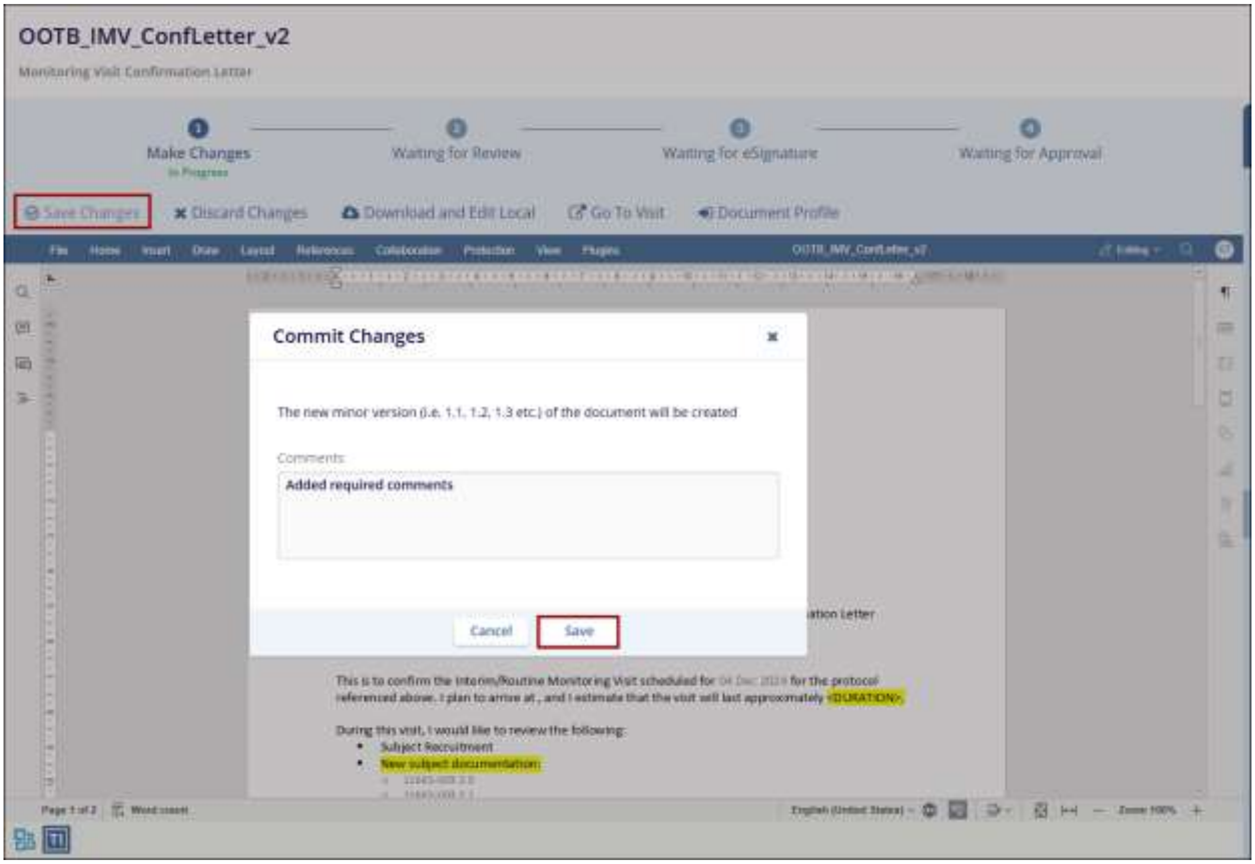


Figure: Save Changes

Note:

- The page is refreshed and all the values that are entered in the Visit Report Checklist are displayed in the document.
- Once the changes are saved, the Make Changes step shows 'Pending Status'

5. Click the Start Approval Workflow button.

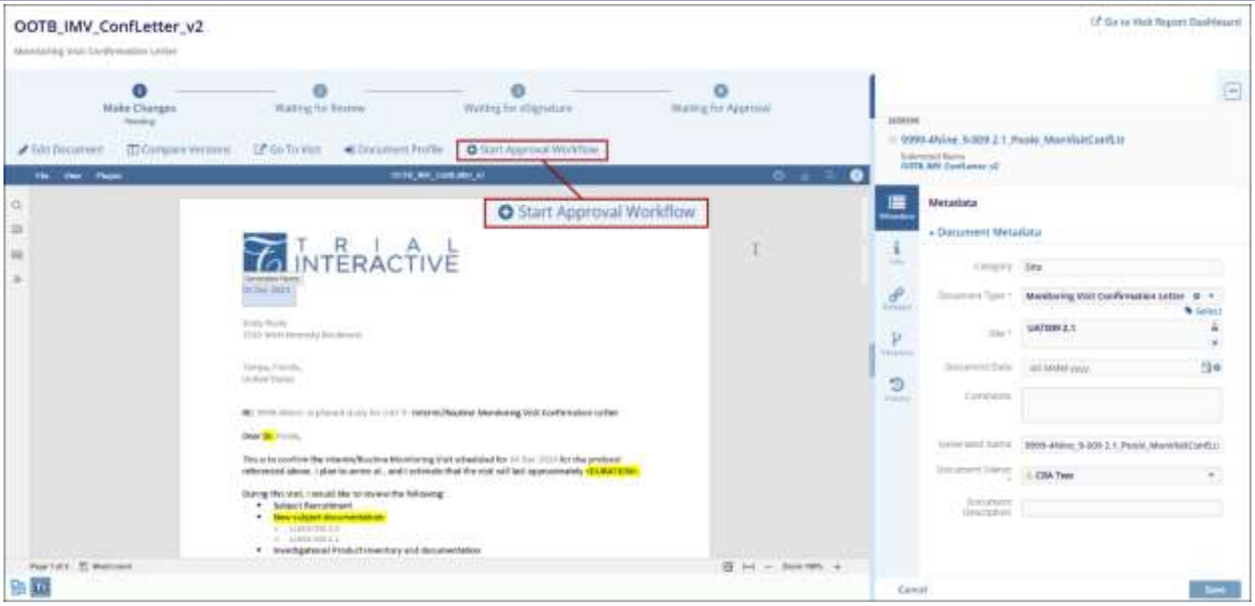


Figure: Start Approval Workflow

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

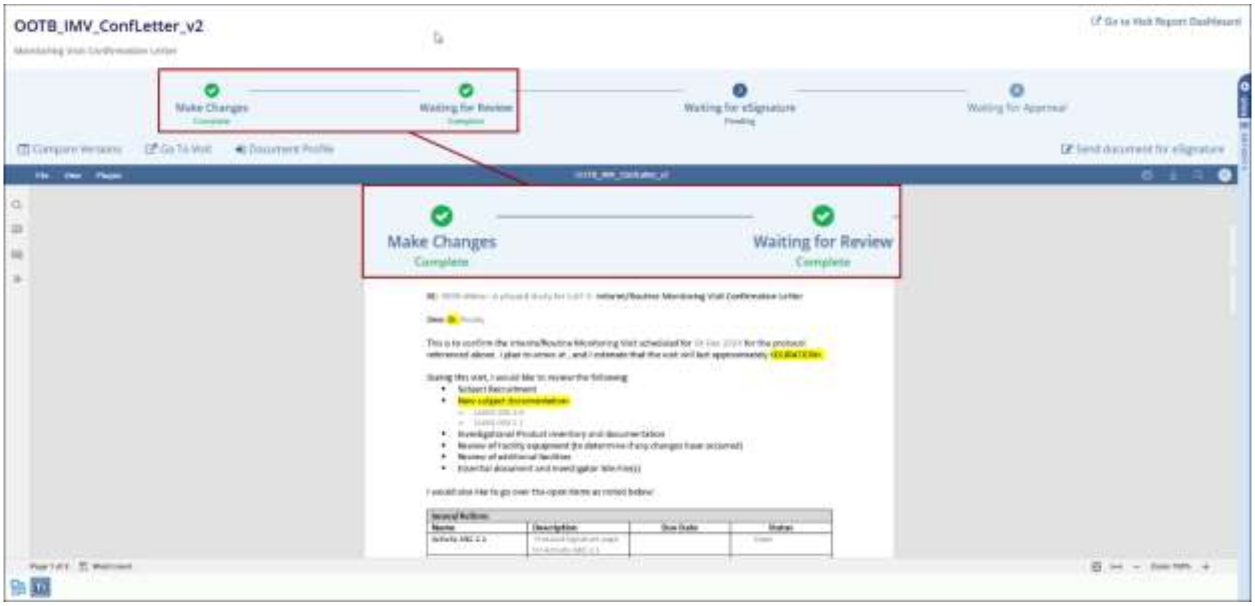


Figure: Add document(s) to monitoring

Note:

- The Make Changes stepper displayed in the top right corner shows a green tick mark with Complete status.
- If the one-step workflow is enabled, the Waiting for Review steeper also shows the Completed status.
- If a two-step workflow is enabled, the reviewer user (probably the CSM user) has to complete that step.

- When the Reviewer signs/approves the review, 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.

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

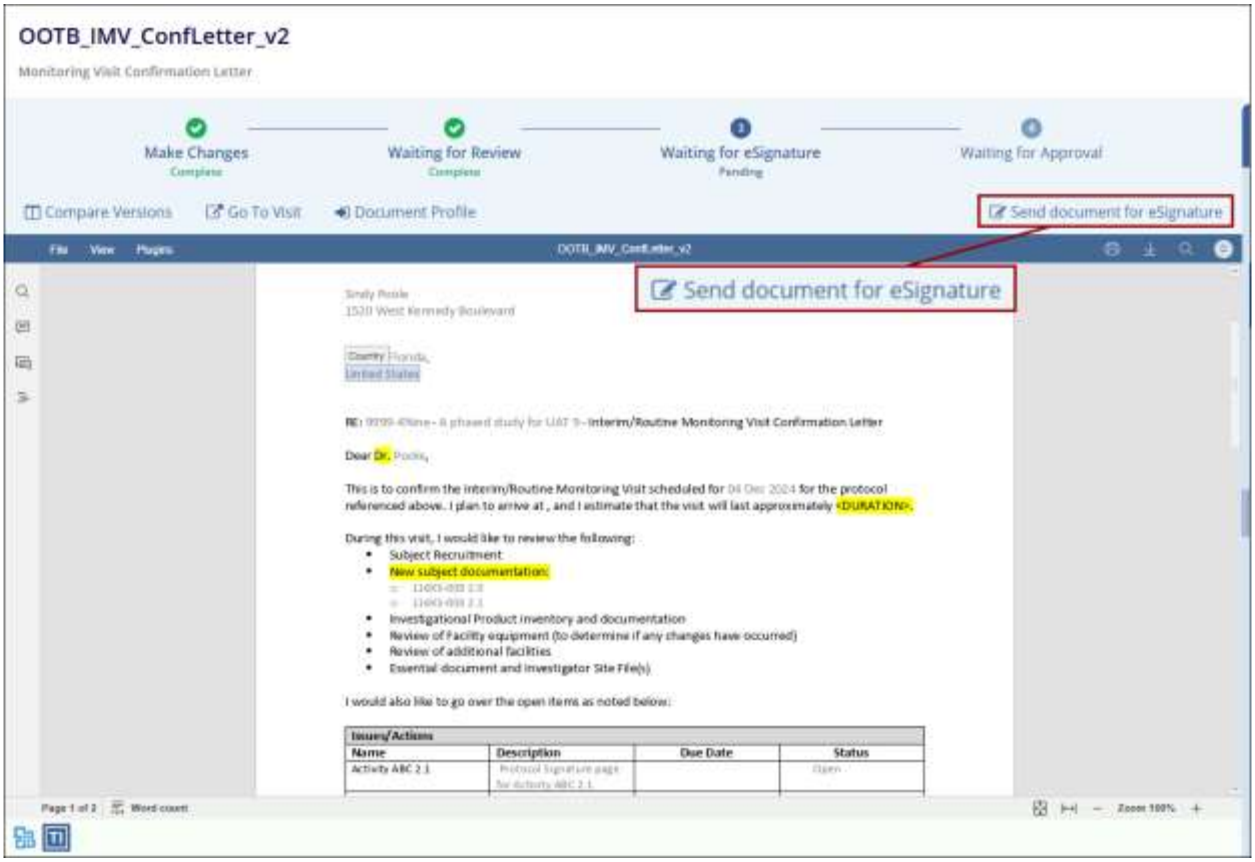


Figure: Send document for eSignature

8. On the eSignature screen, select a radio button for eSignature Type – Parallel or Serial.
9. Select the checkbox(s) displayed in front of the email IDs and mention the ‘Signer Role’ by accessing the dropdown options.
10. Click OK at the bottom of the screen. The document needs to be signed by the number of users mentioned in the ‘Send for ESignature’ window.

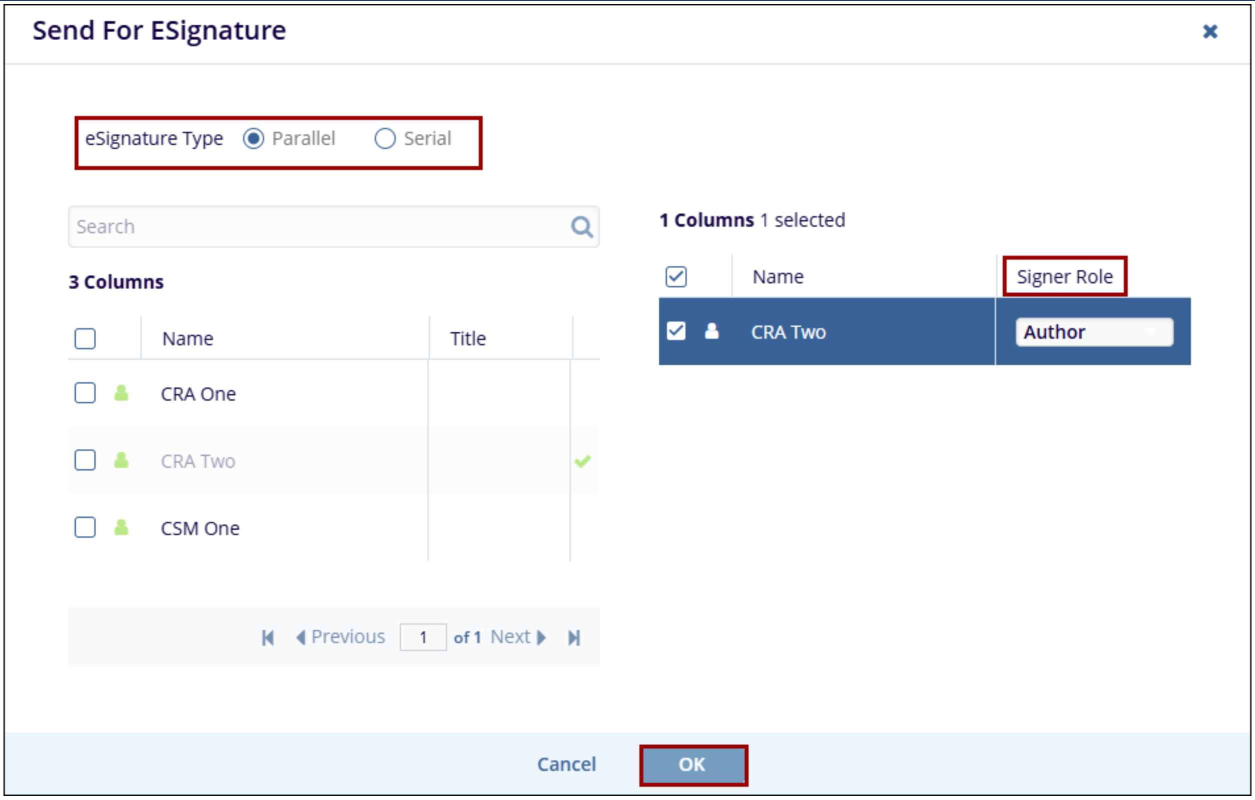


Figure: Send for eSignature screen

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 on the View Details to check the eSignature status for the letter.
13. Click on the Sign Document button.

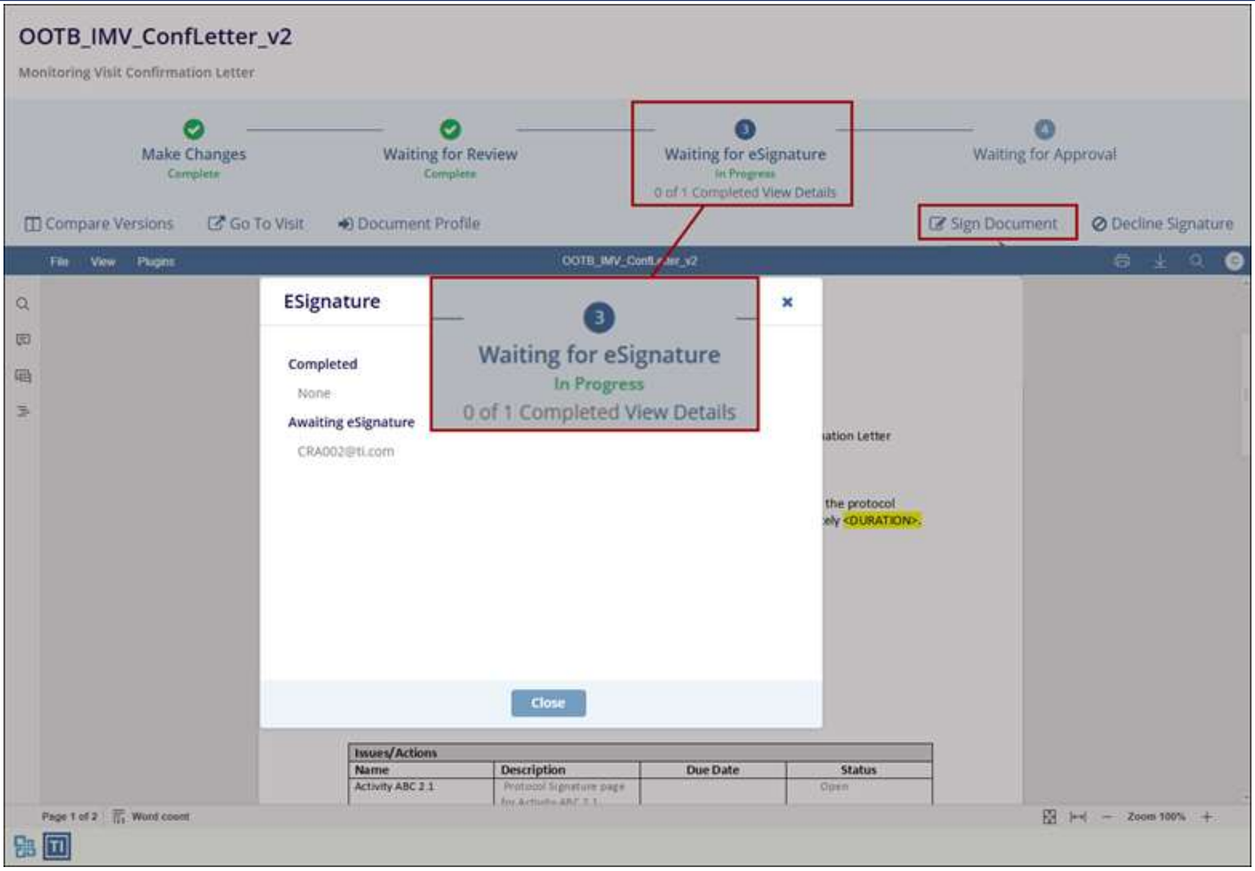


Figure: Sign Document option

14. On the Sign Document screen, select a reason from the ‘Reasons’ dropdown menu, add the required comments in the ‘Comments’ section, and click in the Sign Document button.

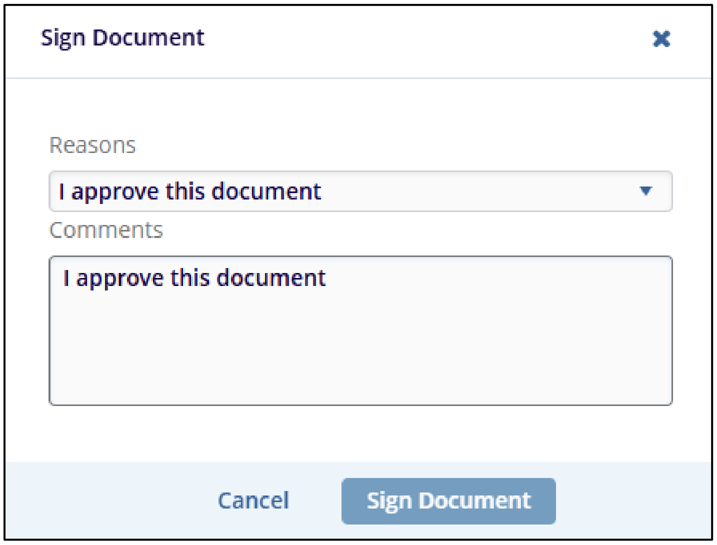


Figure: Sign Document screen

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

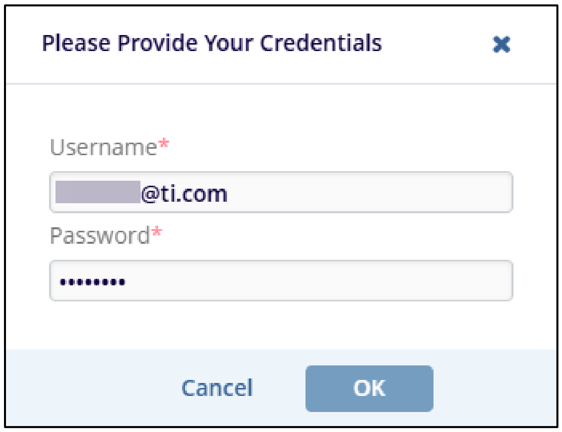


Figure: Please Provide Your Credentials screen

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

17. Refresh the page and navigate to the last page of the document to view the signature.

Figure: Approved and Signed Document

Site Visit Report Preview Generation CRA

To generate a Site Visit Report Preview, 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 to In Progress
3. Click on the Generate Report Preview button.

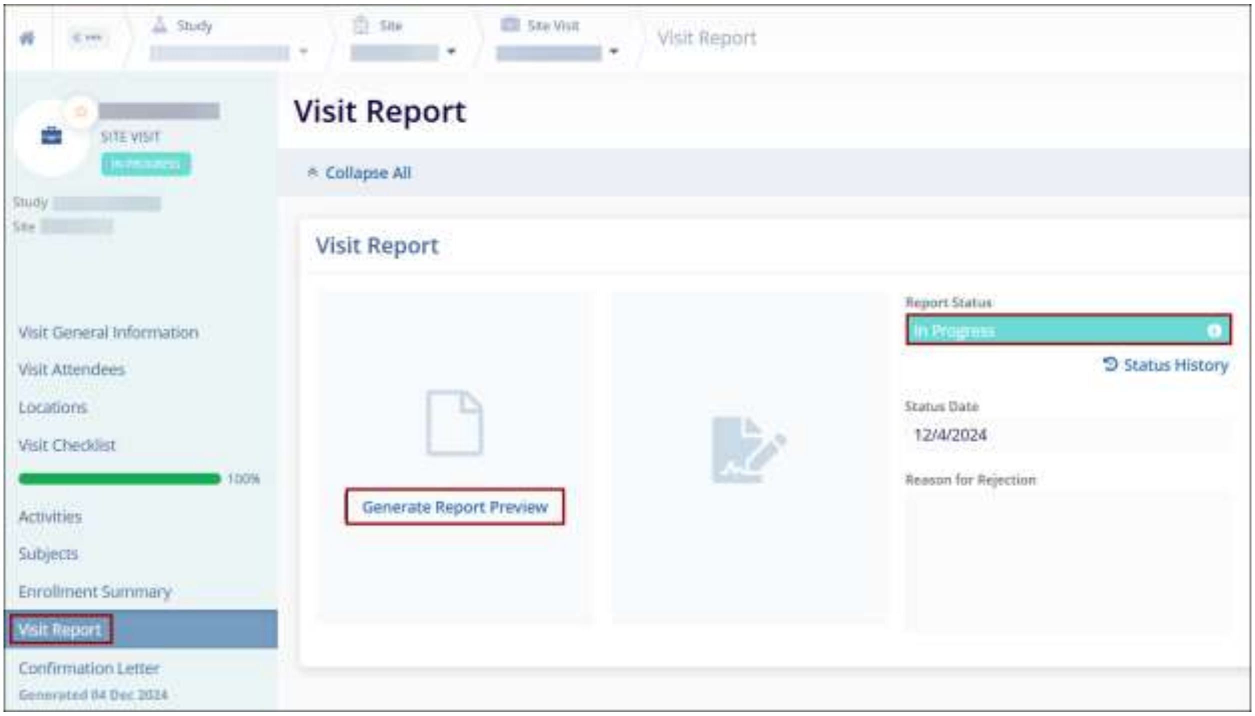


Figure: Generate Report Preview

4. On the 'Generate Report Preview' window, click on the Generate Preview button.

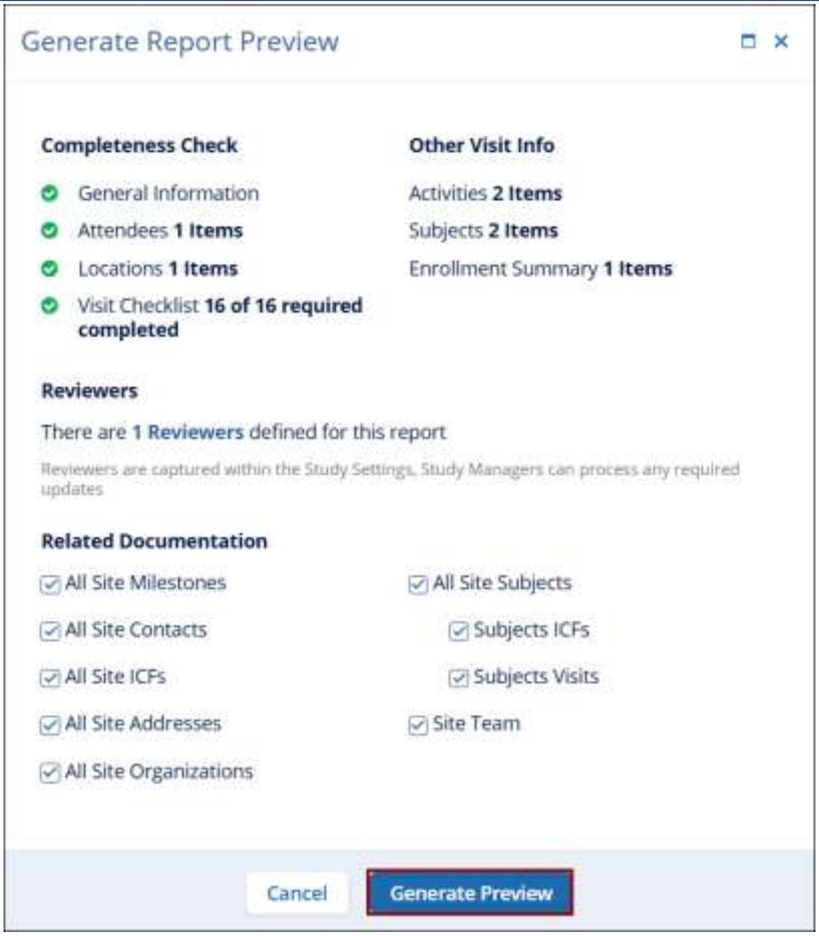


Figure: Confirm preview generation

5. Once the report is generated, click on the View Report Preview button.

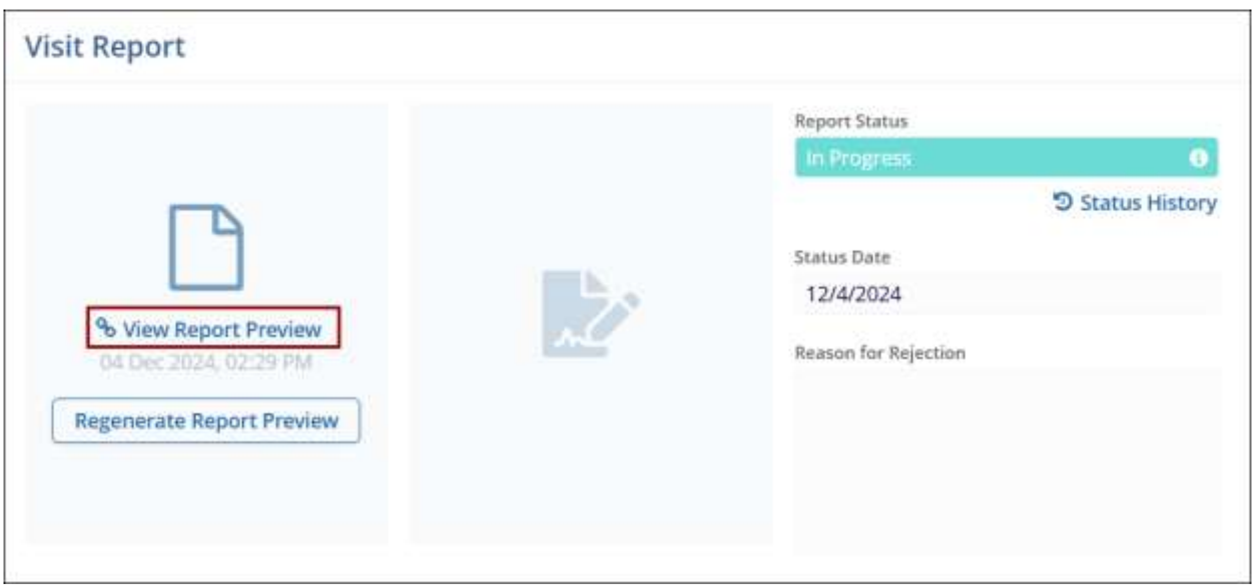


Figure: View Report Preview

Site Visit Final Report Generation CRA

To generate the Site Visit Final Report, follow the steps below. Ensure that the visit status is completed.

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 Create Visit Report.

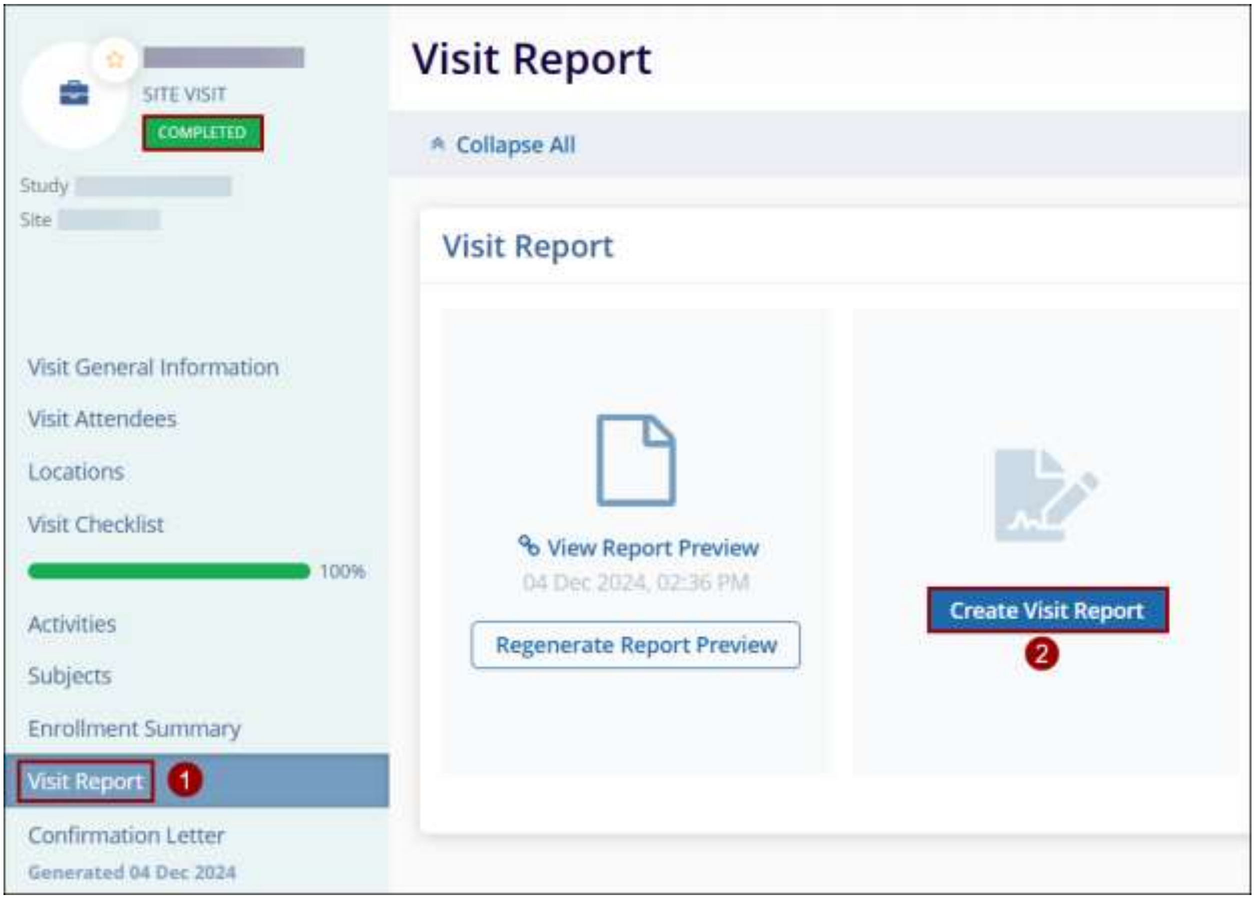


Figure: Create Visit Report

3. On the Create Visit Report window, click on the Generate Report button.

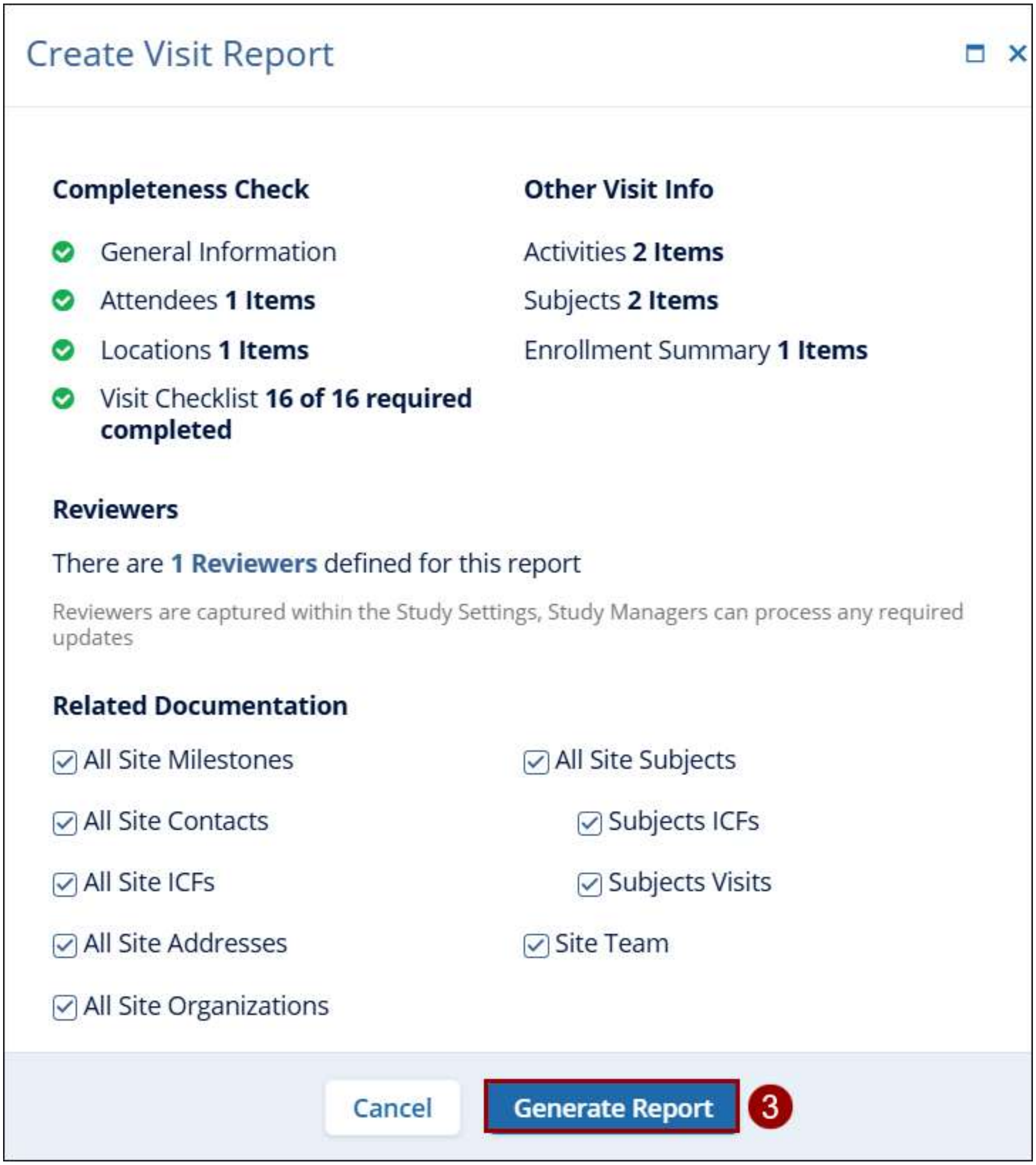


Figure: Generate Visit Report

4. On the Visit Report screen, click on the View Report link.

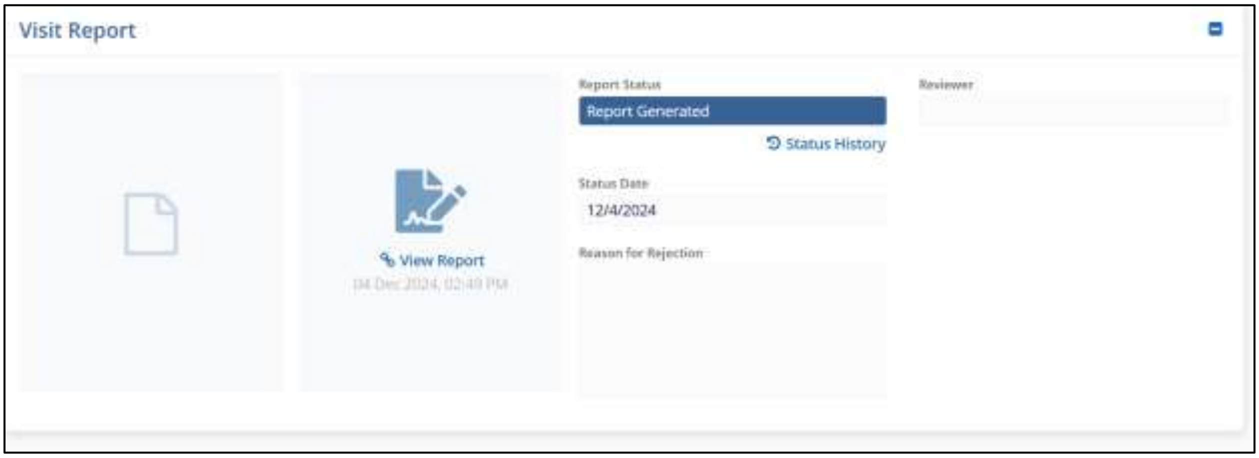


Figure: View Report

5. On the TI Document Viewer, opened in a separate tab, follow the standard steps of review and approval detailed in the Site Visit Confirmation Letter Creation section.

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

Site Visit Follow-up Letter Creation CRA

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 Letter screen, click on the Generate Letter button.

Figure: Generate Follow up letter

3. On the Generate Follow-Up Letter screen, configure each step and click on the Next button until the last step.
4. On the last step, click on the Create button.

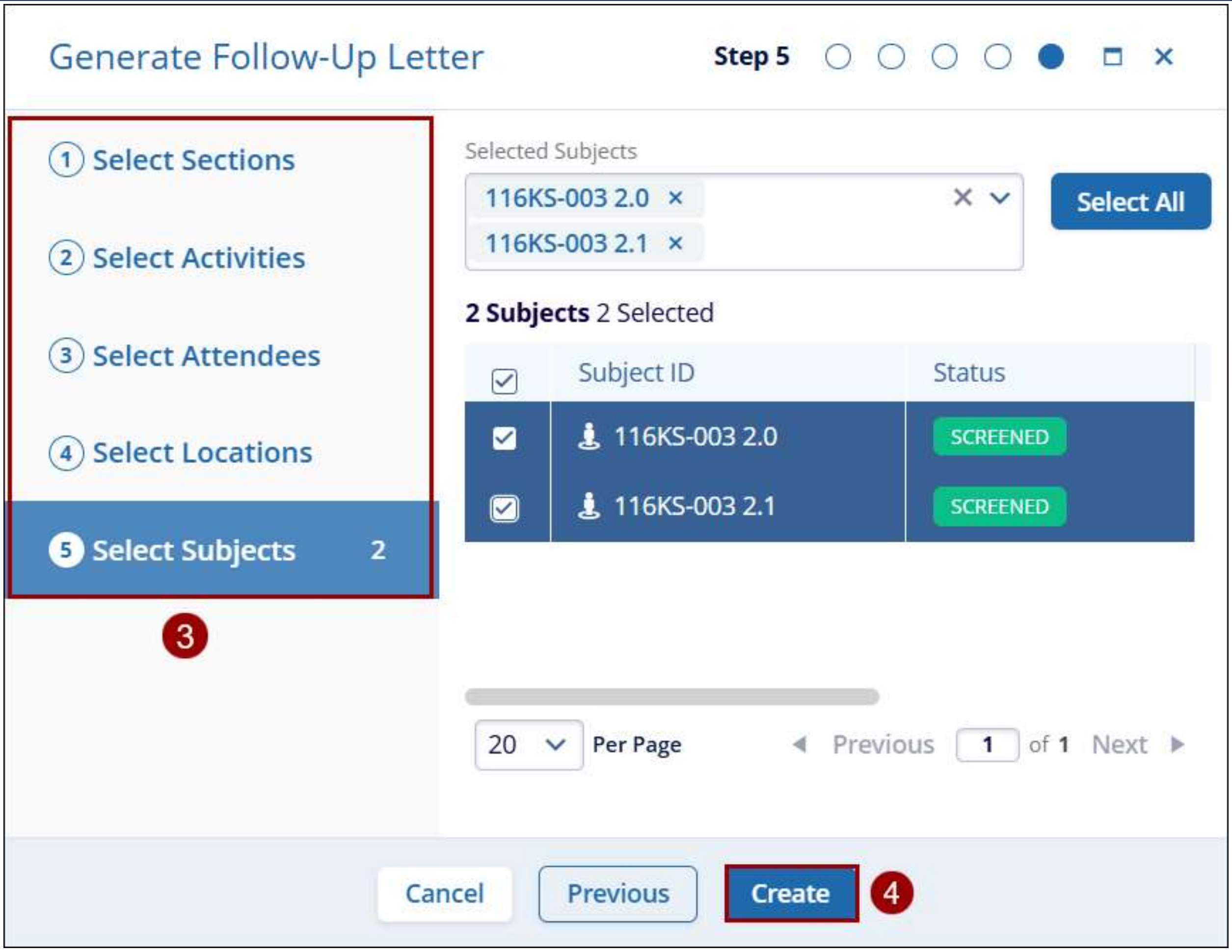


Figure: Generate Follow Up Letter

5. On the Follow-Up Letter screen, click on the View Letter link.

Figure: View Letter

6. A Follow-up letter is generated, and TI Viewer is opened displaying the letter.

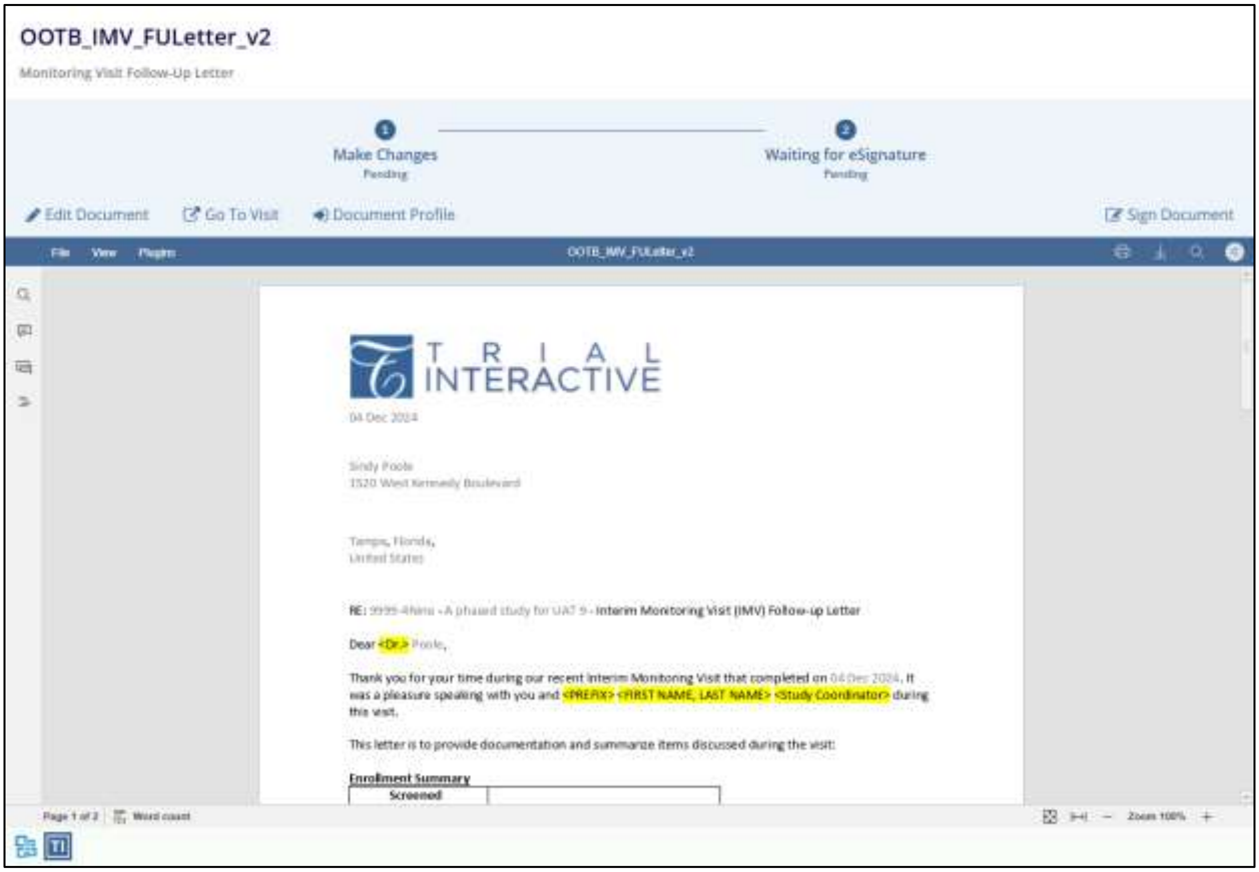


Figure: Follow-Up Letter in TI Document Viewer

Note:

- To electronically sign the follow-up letter, follow the standard steps detailed in the Signing the Document and Approval Workflow section.
- CRAs can generate a follow-up letter immediately after a site visit is created and specify any 'Sent Date'.

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.

Refer to the Site Visit Checklist Templates section for detailed information.

CHAPTER 10. ORGANIZATIONS

Organizations can be created at multiple levels in CTMS i.e., Study, Country, or Site. Organizations created at a global level can be associated with the lower levels in the data hierarchy without having to re-enter the information.

Pre-requisites

Users must have an account with Admin 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 create an organization, follow the steps below.

1. Click on the '**Organizations'** link from the left-hand navigation pane. This opens the 'Organizations' screen where all organizations at the Global level are displayed.

2. Click on the '**+Add'** button from the top menu bar.

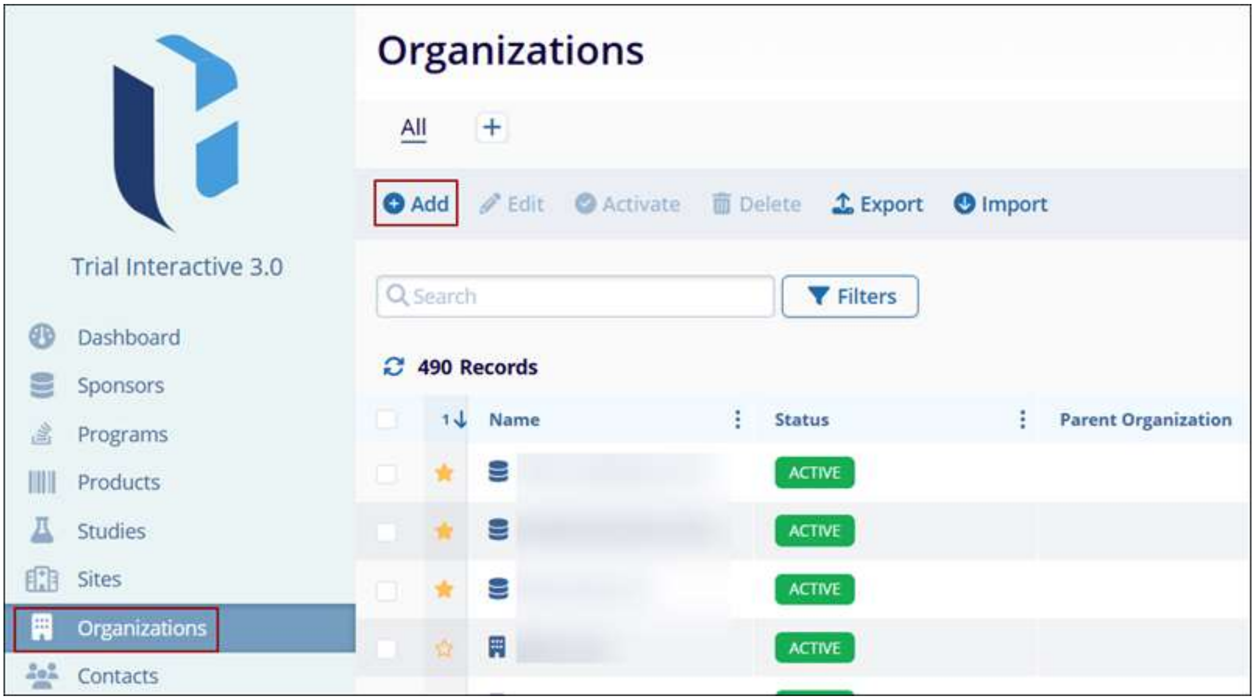


Figure: Add Organization

3. On the Create Organization screen, fill in the mandatory details, highlighted with a red (*) asterisk mark, in the respective sections.

   <u>General Information</u>

- Name*: Enter a name for the organization.
- Number: Enter the unique number for the organization.
- 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.

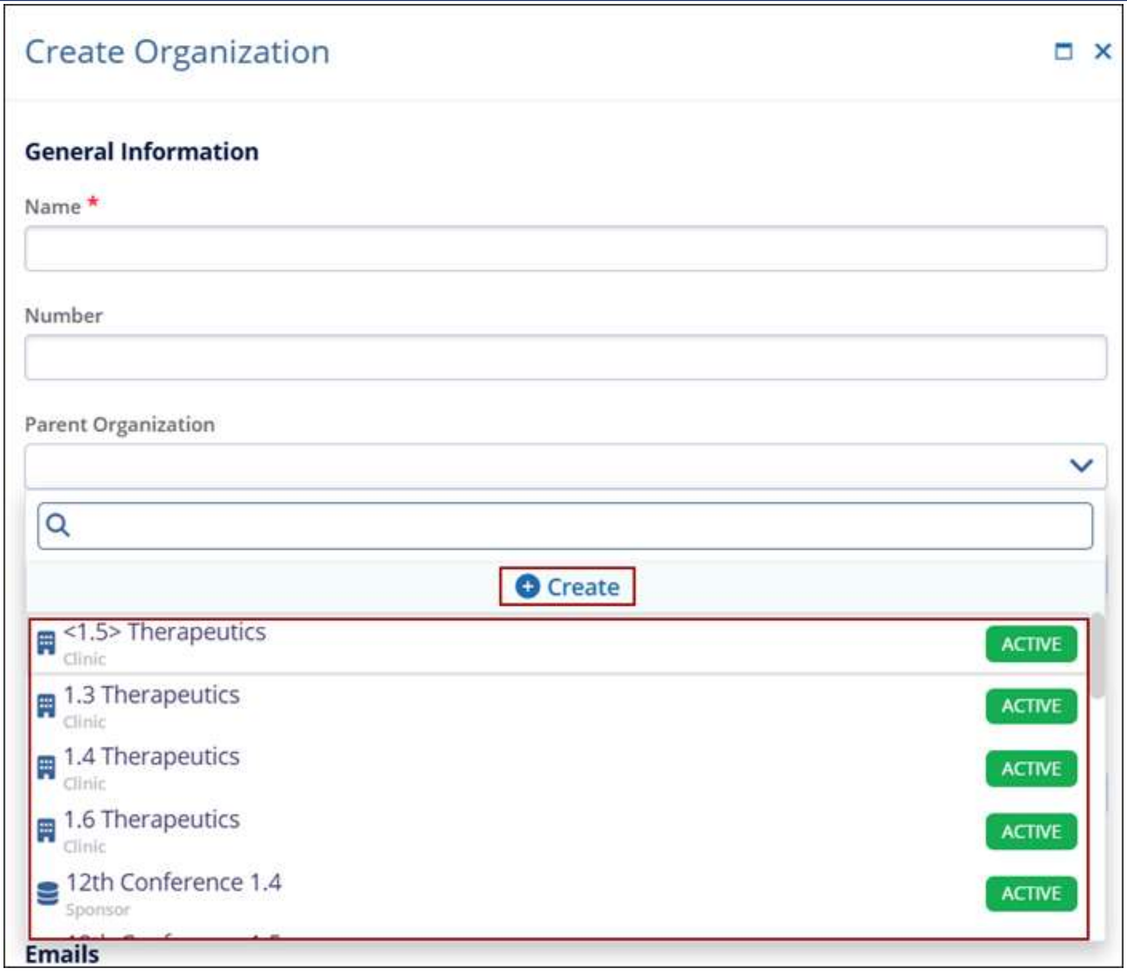


Figure: Create Organization form

Note:

- When the user clicks on the ‘Create’ button, the screen opens on the same child organization. To prevent confusion, move the form to one side of the screen and fill in the information accordingly.
- To create a Parent Organization, it is mandatory fields Name, Type, and Status which are marked with an asterisk (*) next to the field title. Other fields are optional.
- The parent organization will now be automatically populated in the parent field of the child organization.

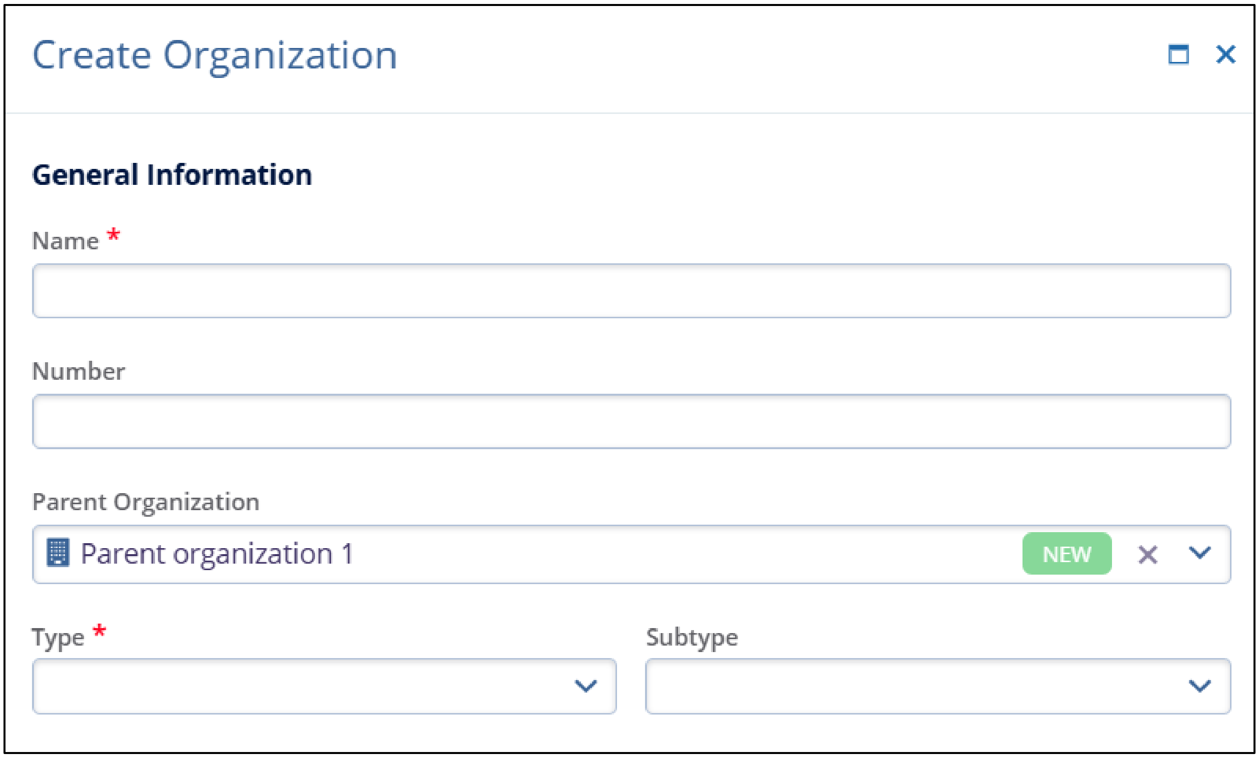


Figure: Create Organization – General Information

- Type*: Select the type of organization from the dropdown menu.
- Subtype: Select the subtype that best describes the Organization.
- Status*: Choose the status as per requirement.
- 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 [Creating a Contact.](#)

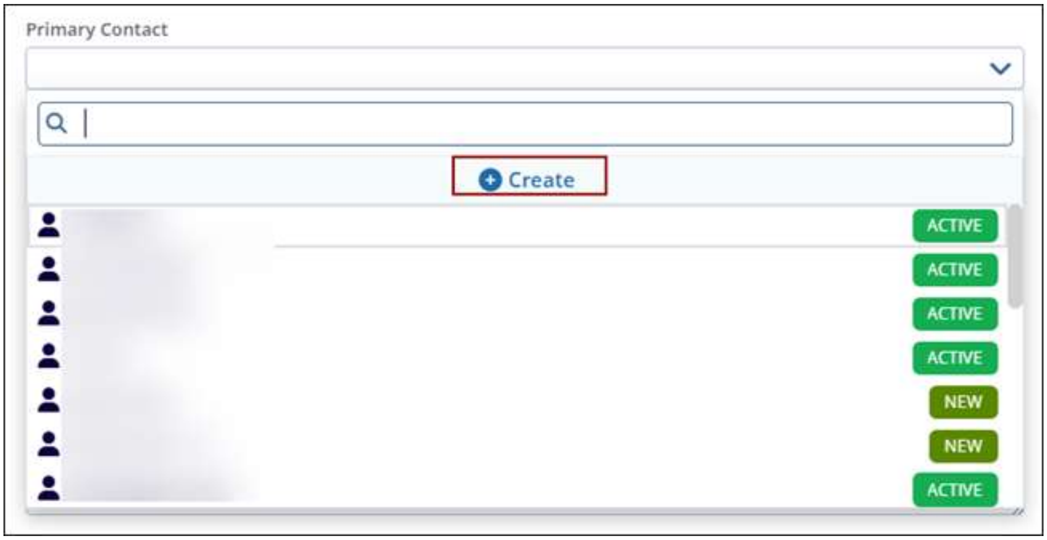


Figure: Create Primary Contact

Phone Numbers

- Click on the +Add button to add phone numbers. Enter the phone number in the provided field.
- Specify the phone number type i.e., Work, Mobile, Office, or Fax.
- Select Country Code
- Optionally click on the 'Set as Primary' checkbox.

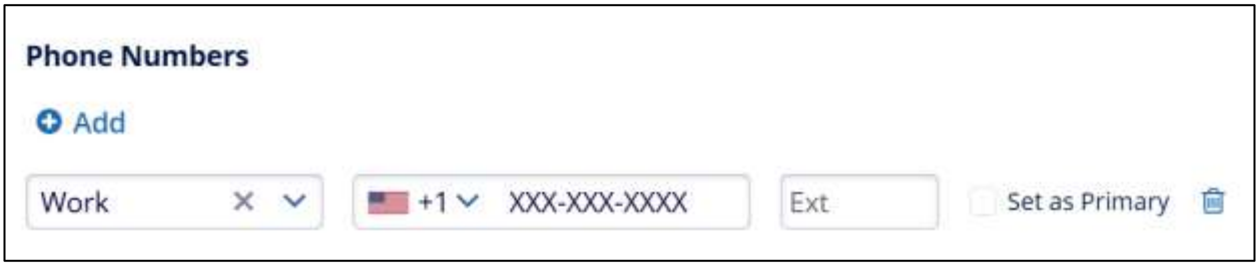


Figure: Add Phone Numbers

Emails

- In the Emails section, click on the '**+Add'** and enter the email address in the provided field.
- Notes Message Box: Enter any additional notes regarding the Sponsor in the 'Notes' field.

Figure: Add Emails

Include Address:

- Enable the '**Include Address'** toggle switch to include an address and enter the mandatory details into the respective fields to create an address.
    - Address Type*
    - Primary Address
    - Country
    - Postal Code
- Add other optional fields as required.

- Click on the search icon to search for a specific address
    - After filling in all required fields, click on the Create button.

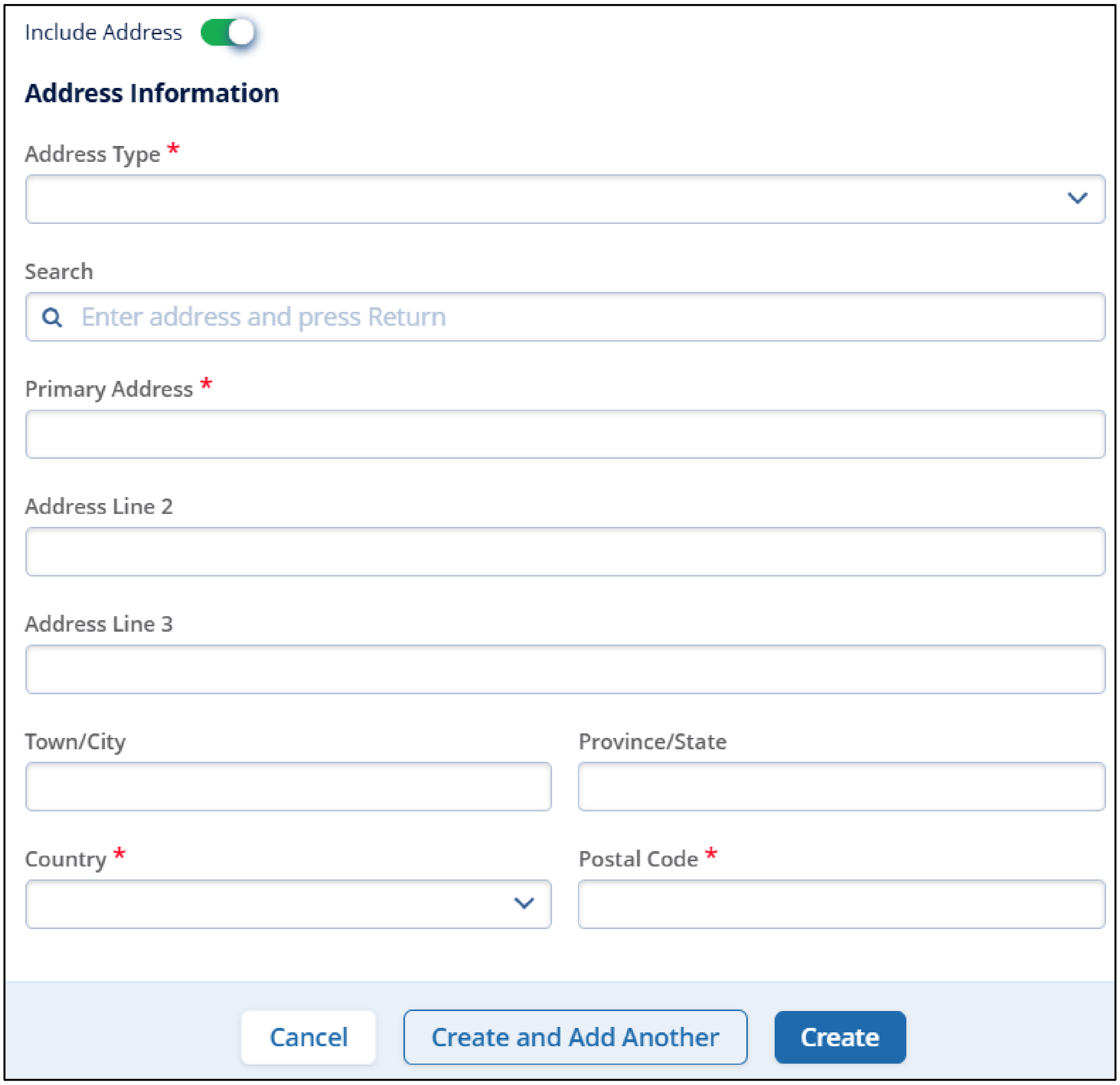


Figure: Include Address

4. When the user clicks on the 'Create' button, it creates a sponsor and it will display a successfully created pop-up.

Figure: Success Message

Editing an Organization

To edit an organization, follow the steps below.

Method 1

1. Click the checkbox next to the organization name. Then, click the 'Edit' button (pencil icon).
2. click the 'Edit' button (pencil icon).
3. On the Quick View panel, make the required edits.
4. Click on the Save button.

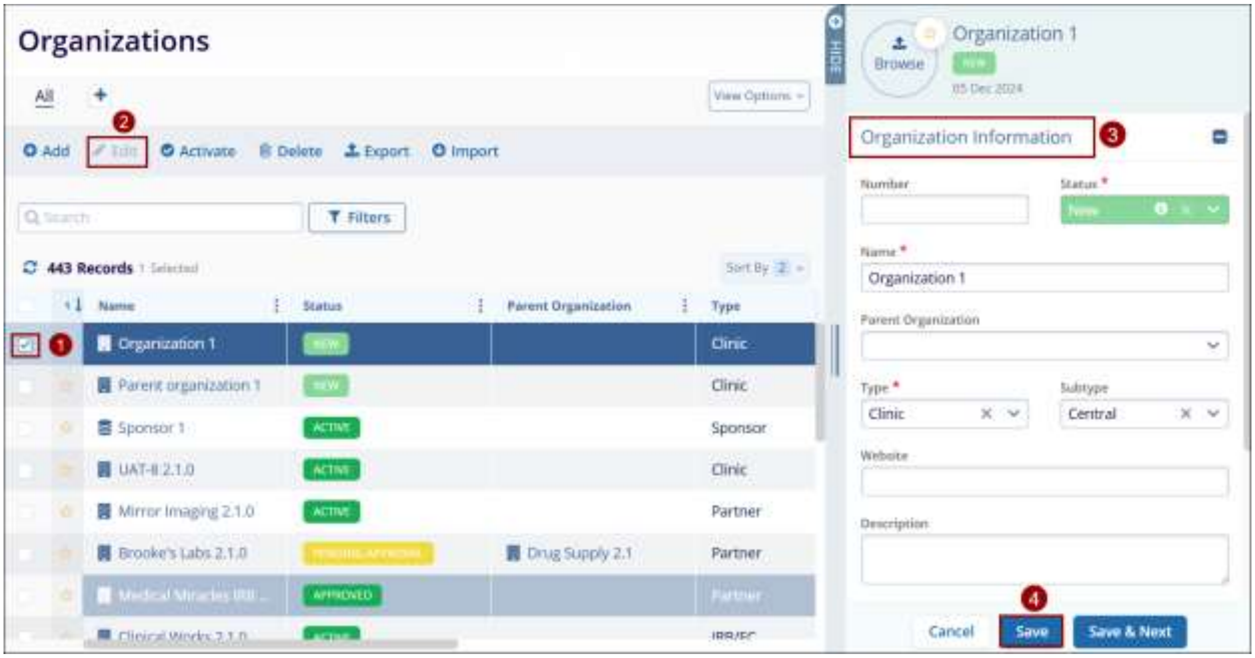


Figure: Edit Organization – Method 1

Method 2

1. Click on the Organization name to open the Organization Details screen.
2. Click on the Edit button and make the required changes to the organization.

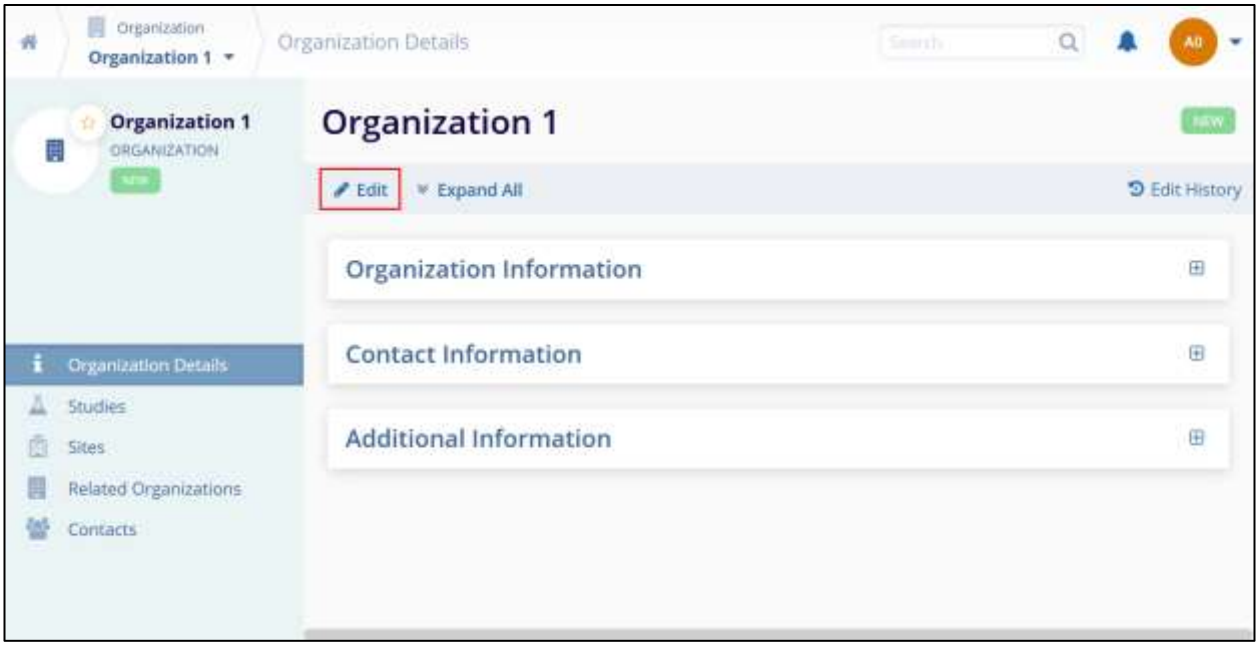


Figure: Edit Organization – Method 2

3. Make changes to the Organization, Contact, and Additional Information sections and click on the Save button.

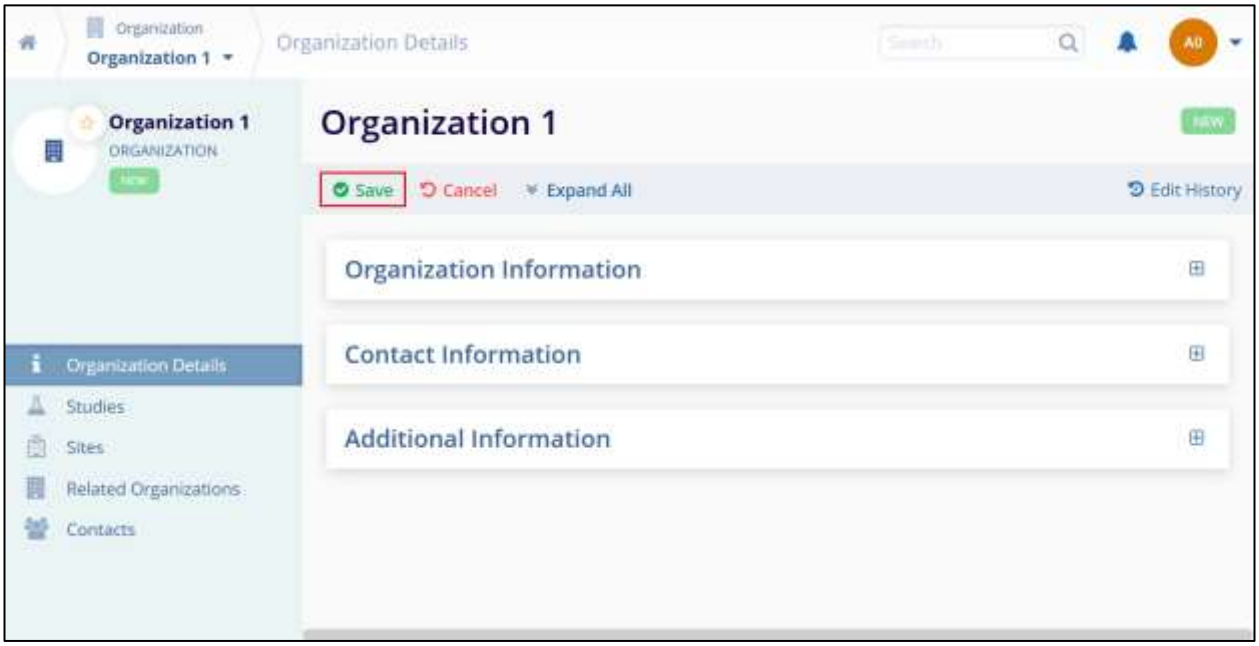


Figure: Save changes to Organization Details

Activating and Deactivating an Organization

To activate and deactivate an organization, follow the steps below.

1. Select the organization by clicking the checkbox next to its name.
2. Click the '**Activate'** button at the top of the grid to initiate the activation process.
3. A confirmation pop-up window will appear. Click the '**Activate'** button to proceed with activation or '**Cancel**' to discontinue.

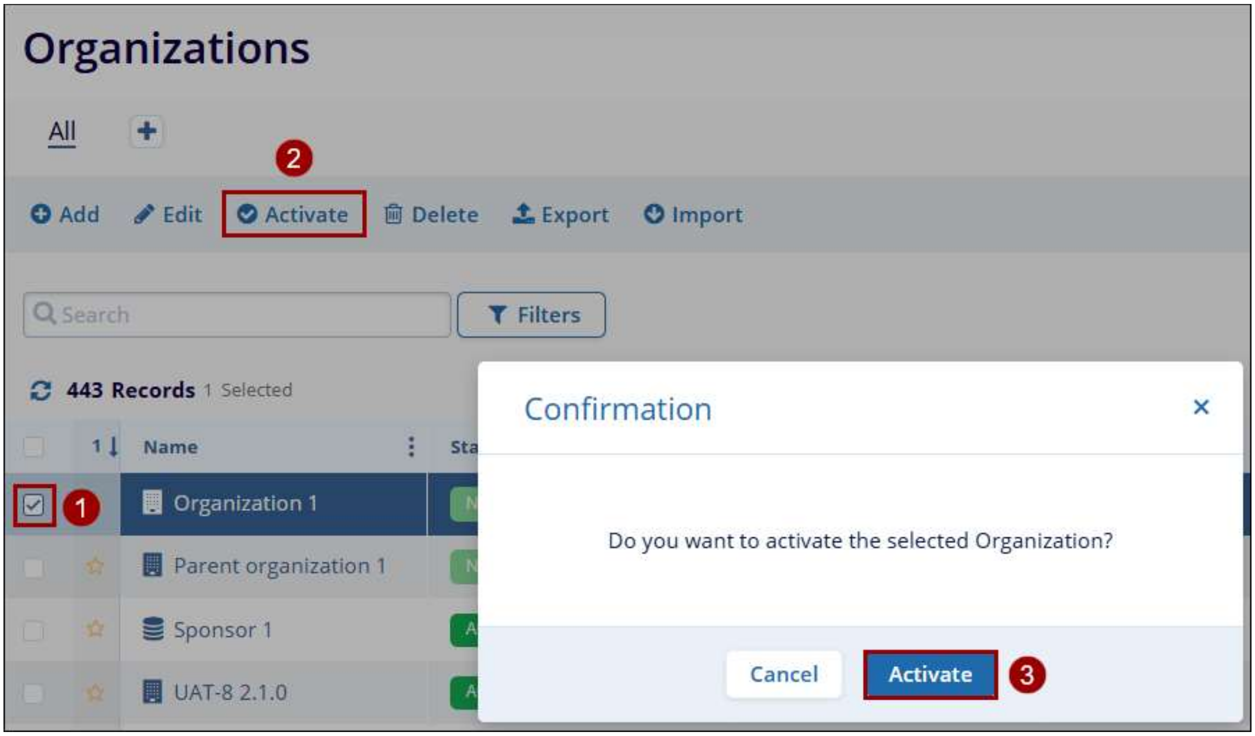


Figure: Activate Organization

4. Select the organization by clicking the checkbox next to its name.
5. Click the '**Deactivate'** button at the top of the grid to initiate the activation process.
6. A confirmation pop-up window appears. Click the '**Deactivate'** button to proceed with activation or '**Cancel'** to discontinue.

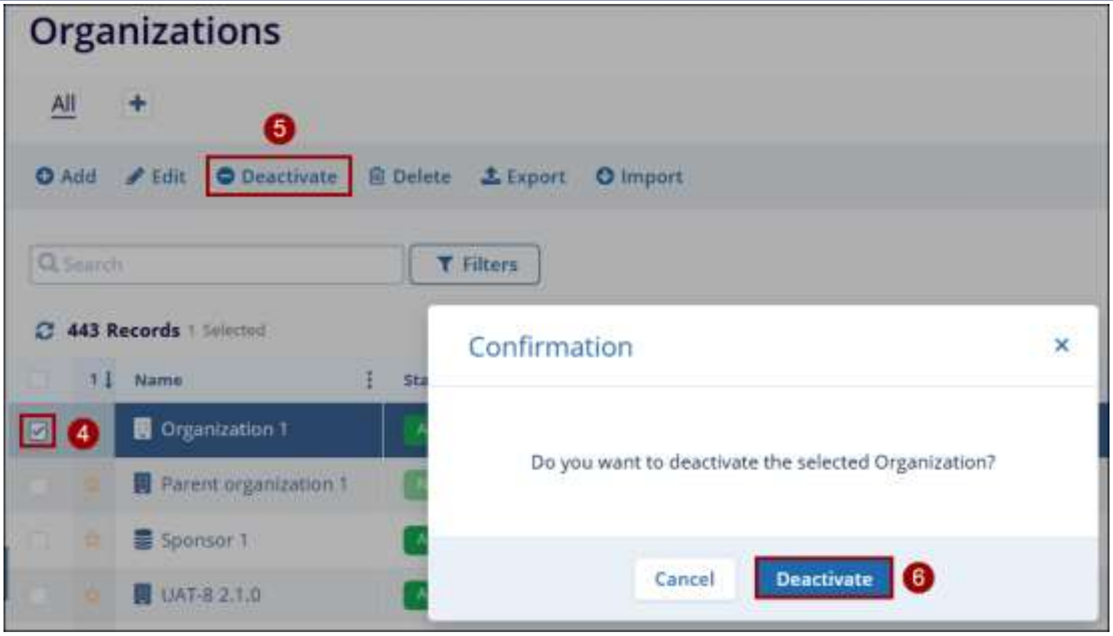


Figure: Deactivate Organization

Deleting an Organization

To delete an organization, follow the steps below.

1. Select the organization by clicking the checkbox next to its name.
2. Click on the Delete button from the top menu bar.
3. Click on the Delete button on the Confirmation popup.

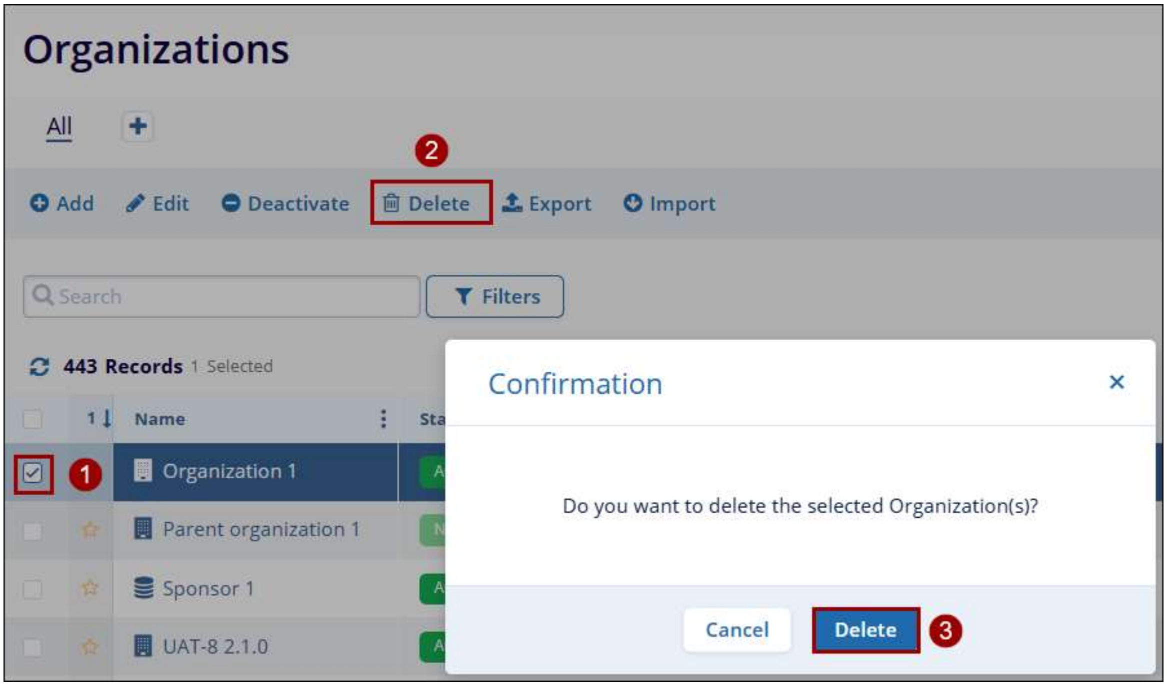


Figure: Delete Organization

Exporting Organizations

To export organizations, follow the steps below.

1. On the Organizations tab, click on the Export button from the top menu bar.
2. Refer to the standard exporting data steps detailed in the Exporting Contacts section.

Importing Organizations

To import organizations, follow the steps below.

1. On the Organizations tab, click on the Import button from the top menu bar.
2. Refer to the standard importing steps detailed in the Importing Contacts section.

Search for an Organization

To search for a specific organization, follow the steps below.

1. Click on the 'Magnifying Glass' icon or the 'Search' textbox.
2. Enter the organization's name or a related keyword into the search bar.

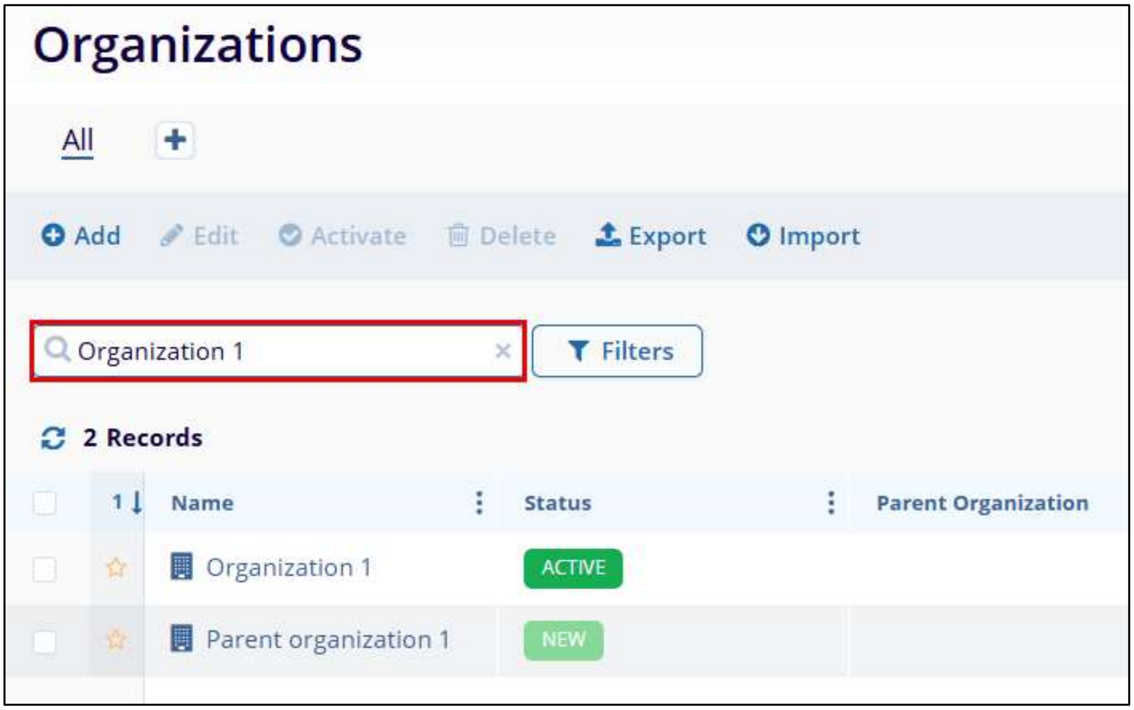


Figure: Search for Organization

Customizing Organization Screen

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

1. Filters: Refer to the Filters section to apply standard and advanced filters to the 'Organizations' screen.
2. Favorite: Refer to the Mark a contact as a favorite section and follow the standard steps of marking an organization as a favorite.
3. Customize Columns: Refer to the Customizing columns on the Contacts screen section and follow the standard steps to Hide, Lock, Manage Visible Columns, and Sort Columns.
4. Views: Refer to the Contacts Views section and follow the standard steps to set a view and access different view options.

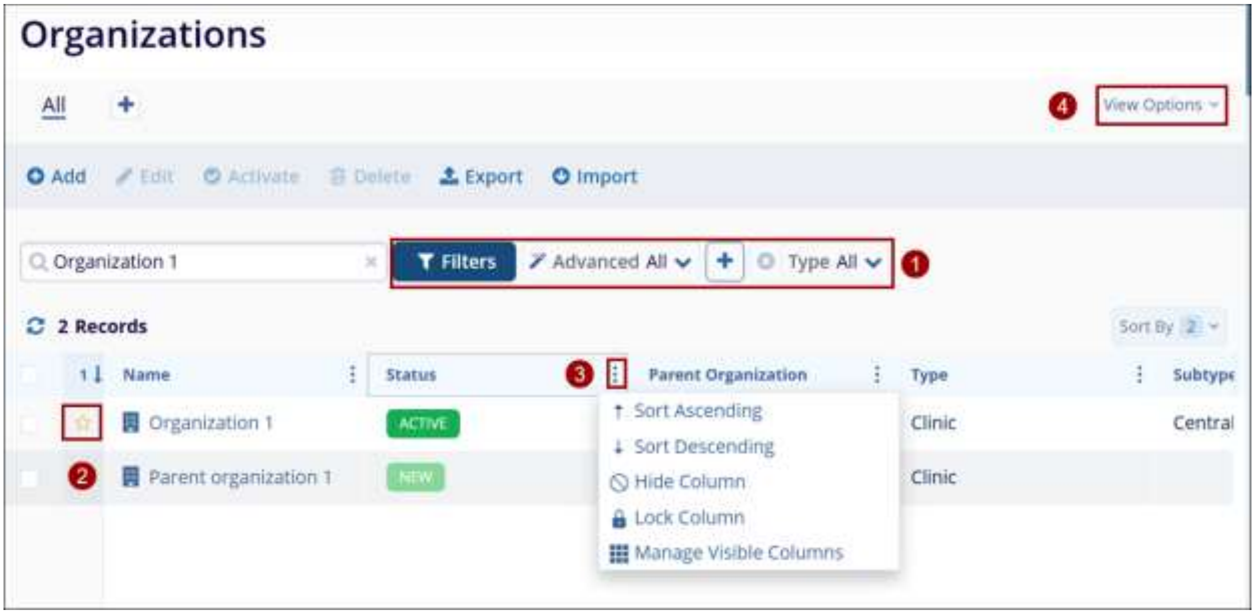


Figure: Organization filters

Organization Details

The Organization Details screen enables users to view and edit the initially configured organization details.

Associating an Address to an Organization

To associate an address with the organization, follow the steps below.

1. Click on the '**Organizations'** tab located in the navigation link on the left side of the screen.
2. On the organization tabs, locate the organization to associate an address with and click on the organization's name.

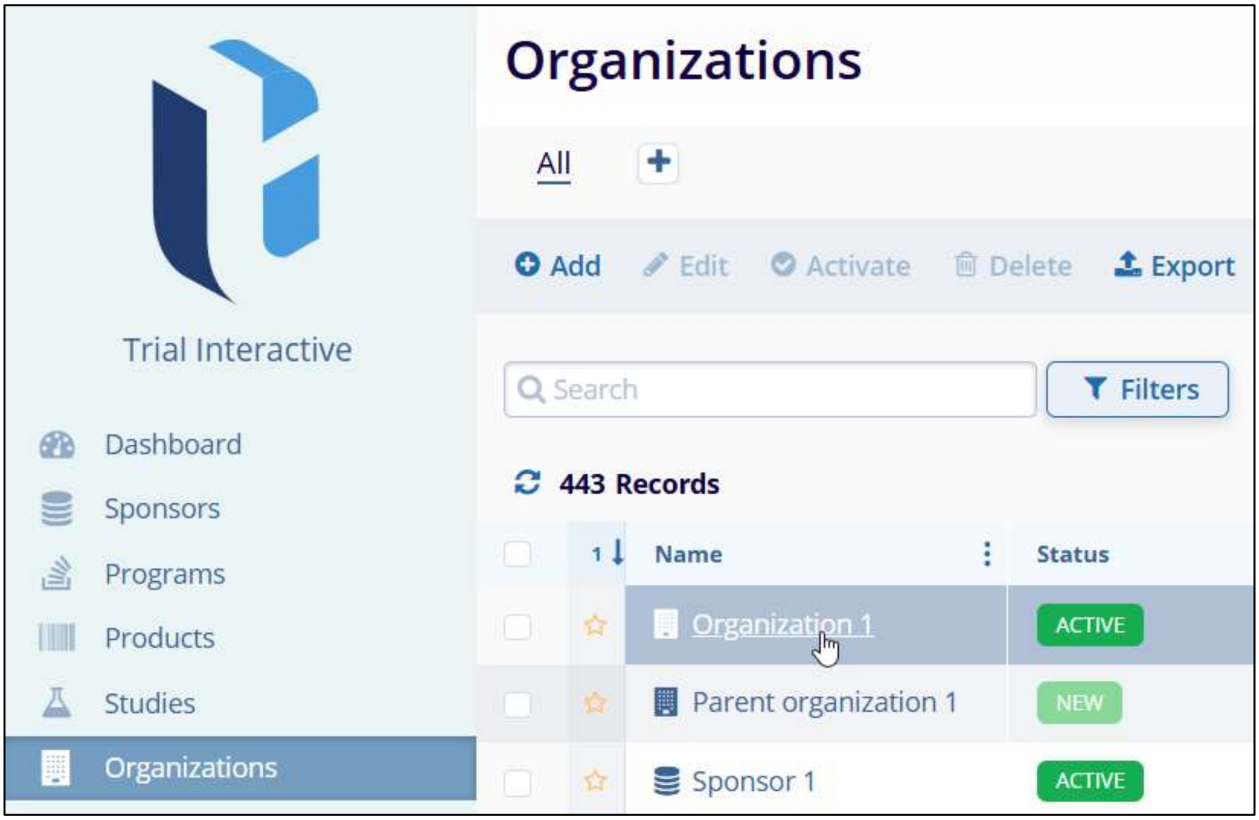


Figure: Associate Address to organization

3. Access the Contact Information section and click the '**Edit'** button on the Organization detail page.

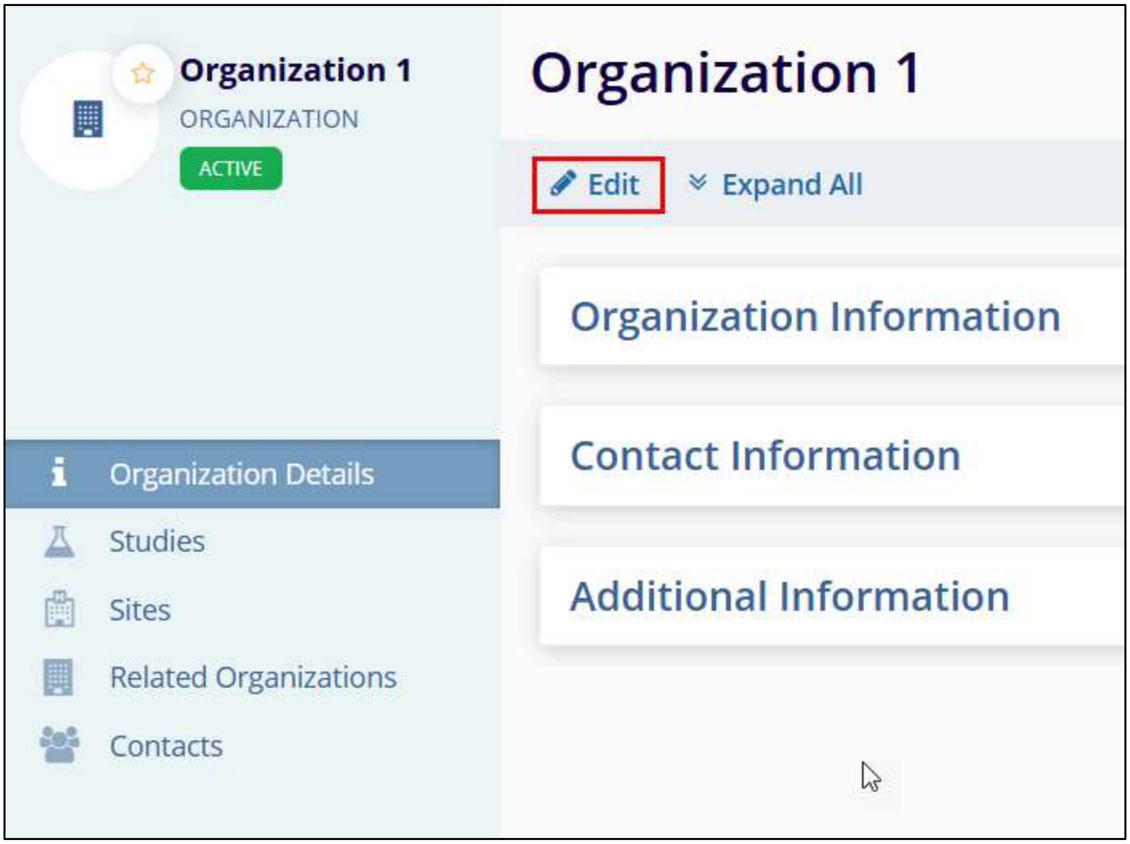


Figure: Organization Details

4. Click on the '**+Add'** button in the Addresses section.
5. Enter 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 the requirement.
6. Here, there are two options to add addresses:
   - Add and Create Another: This option allows adding the current address and immediately start creating another one.
   - Add Address: This option allows creating only the address you are currently working on.
7. Click on the Save button once the address is added.

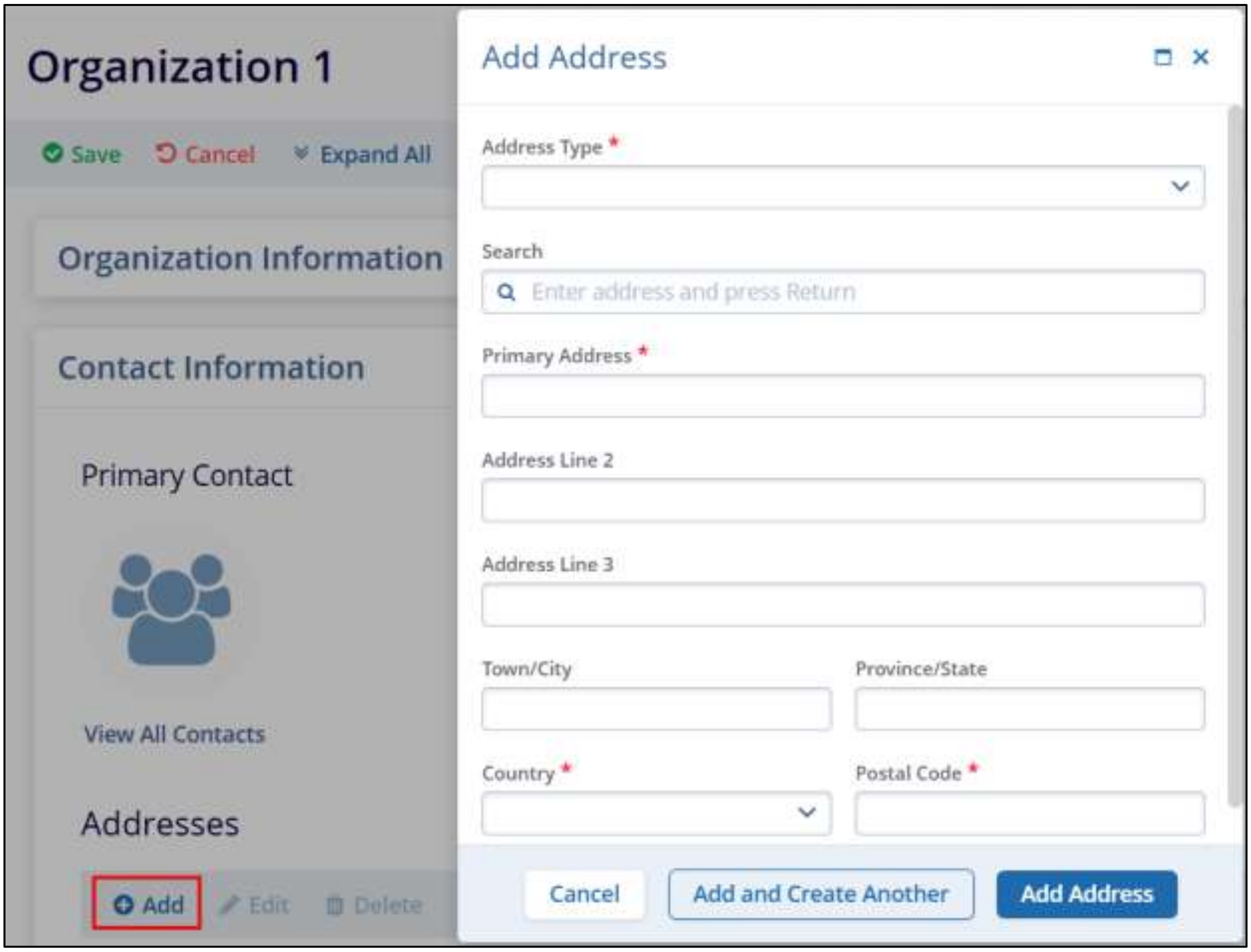


Figure: Add Address to organization

Associating an Organization to a Parent Organization

To associate an organization with a parent organization, follow these steps.

Method 1

1. Click the checkbox next to the organization name. Then, click the 'Edit' button (pencil icon).
2. click the 'Edit' button (pencil icon).
3. On the Quick View panel, associate a parent organization by accessing the dropdown options and either adding an existing one or creating a new one.
4. Click on the Save button.

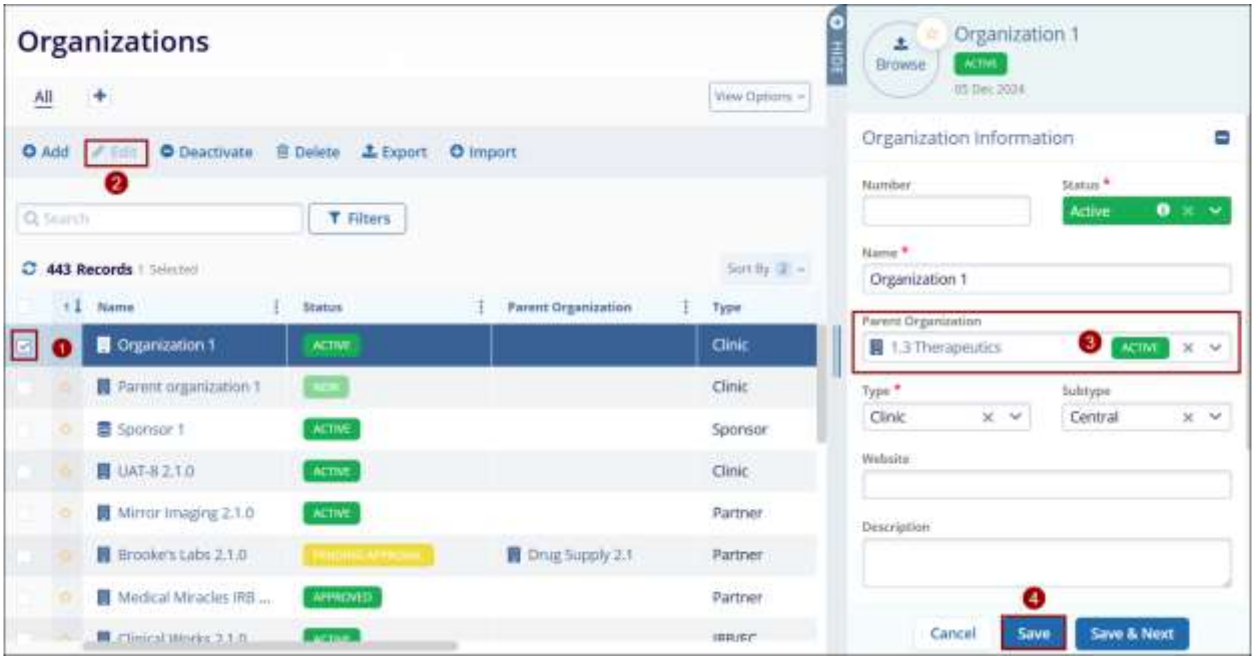


Figure: Associate Organization to a parent organization

Method 2

1. Locate the organization to associate a parent organization with and click on the organization's name.
2. On the Organization Details screen, click on the Edit button.
3. Access the Parent Organization dropdown and associate an existing or create a new parent organization.
4. Click on the Save button.

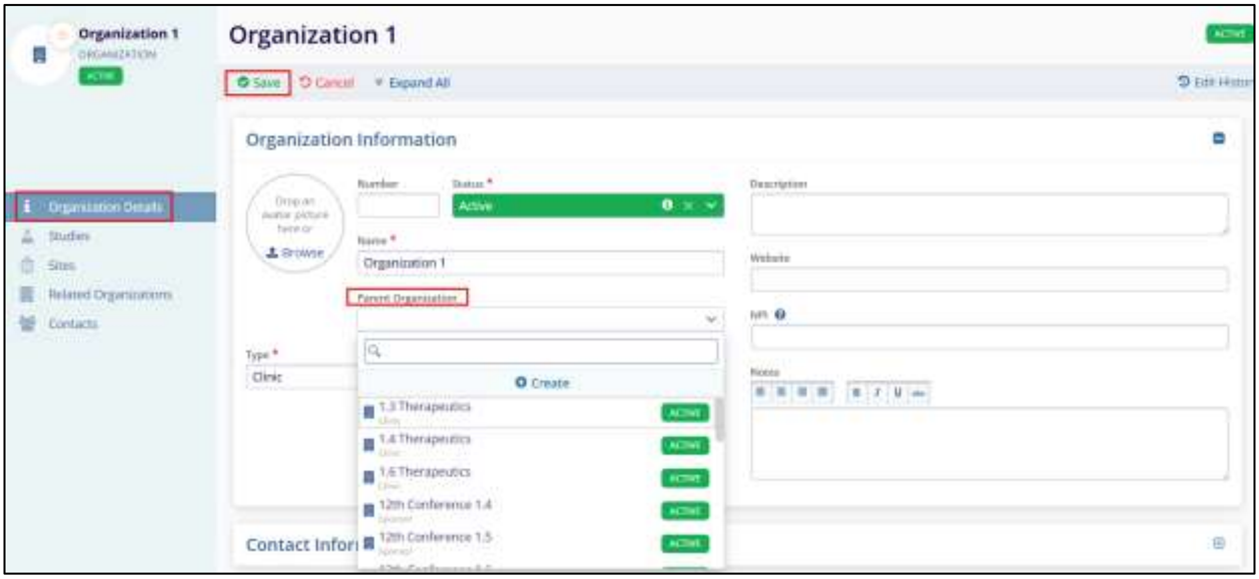


Figure: Add organization to parent organization

Note:

- The '**Organization Details'** view contains additional fields not available within the quick-view panel i.e., NPI, Website, etc.
- Refer to the [Creating an Organization](#) section to understand how to create a parent organization.
- From the Parent Organization details page, users can view associated child organizations under the '**Related Organizations'** tab.

Figure: View Parent Organization

Studies and Sites Associated at the Organizational level

To review studies and sites associated with an organization, follow these steps.

1. On the Organizations, tab click on the organization name.
2. On the Organization Details screen, click on the '**Studies'** from the left-hand navigation links.
3. This opens the '**Studies'** window which displays a list of studies associated with the organization.
4. To Edit the study details, select a study and click on the Edit button from the top menu bar.
5. Similarly, to export the Studies list, click on the Export button.

Figure: Reviewing Studies and Sites in Organization

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 'Sites' link to view all associated sites.

Related Organizations

The 'Related Organizations' screen displays all the child organizations associated with the parent organization.

Add Related Organization

To add a child organization, follow the steps below.

1. On the Organizations, tab click on the organization name.
2. On the Organization Details screen, click on the '**Related Organizations'** from the left-hand navigation links.
3. Click on the +Add button.
4. Refer to the Creating an Organization section for the standard steps to create an organization.

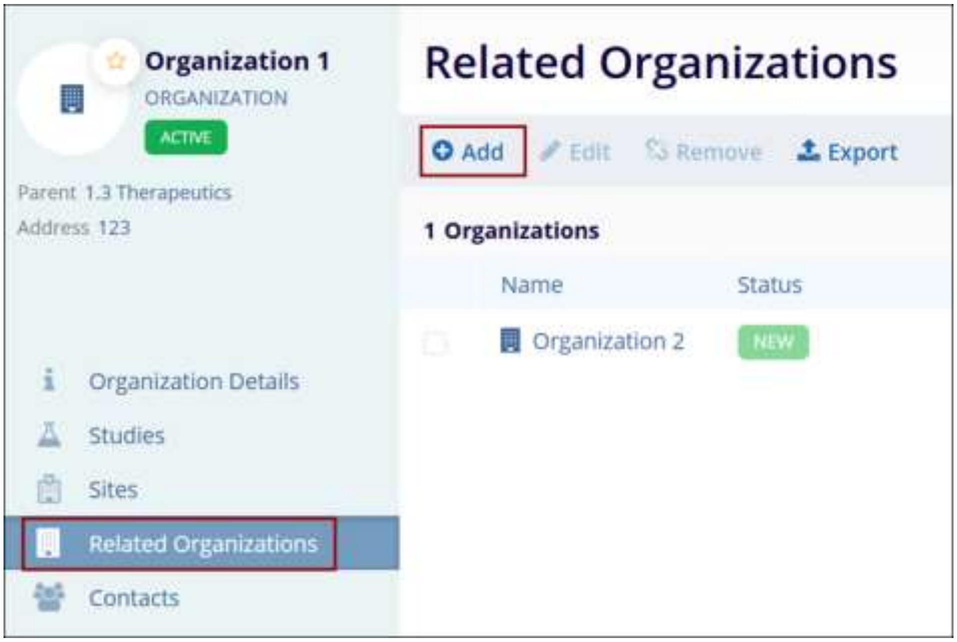


Figure: Add Related Organization

Note: The 'Parent' Organization' field is pre-populated in the 'Create Organization' form.

Edit Related Organization

To edit a related organization, follow the steps below.

1. On the 'Related Organizations' screen, select an organization to edit.
2. Click on the Edit button from the top menu bar.
3. Make the necessary edits to the Organization and Contact Information sections in the Quick View panel.
4. Click on the Save button.

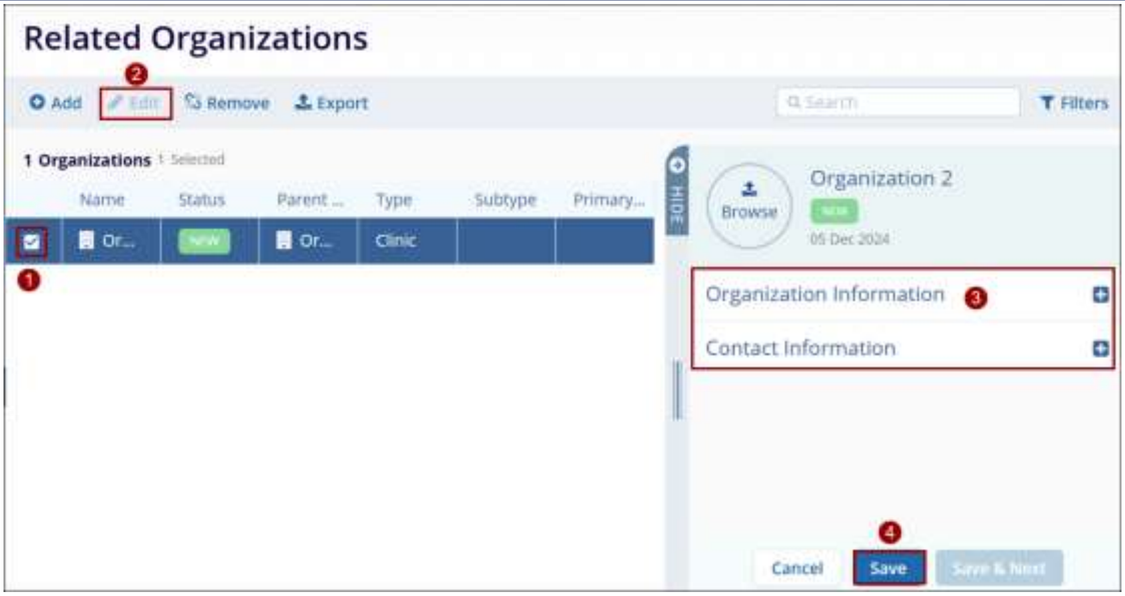


Figure: Edit Related Organization

<u>Remove Related Organization</u>

To remove a Related Organization, follow the steps below.

1. On the 'Related Organizations' screen, select an organization to remove.
2. Click on the Remove button from the top menu bar.
3. On the Confirmation popup, click on the Remove button.

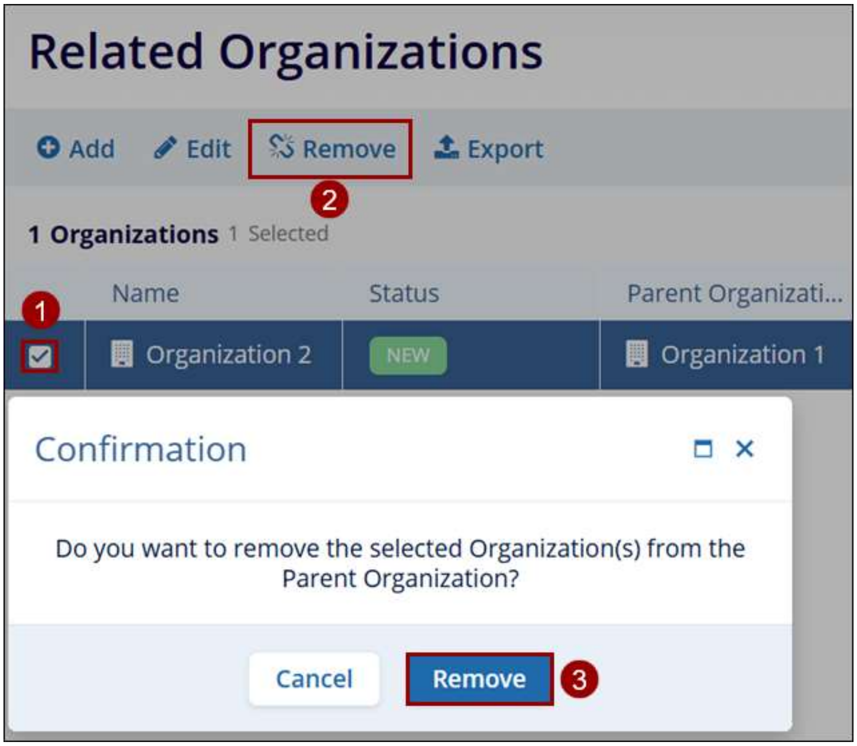


Figure: Remove Related Organization

Export Related Organizations

To export the Related Organizations, follow the steps below.

1. On the Related Organizations screen, click on the 'Export' button.
2. Follow the standard steps to retrieve exports detailed in the Exporting Contacts section.

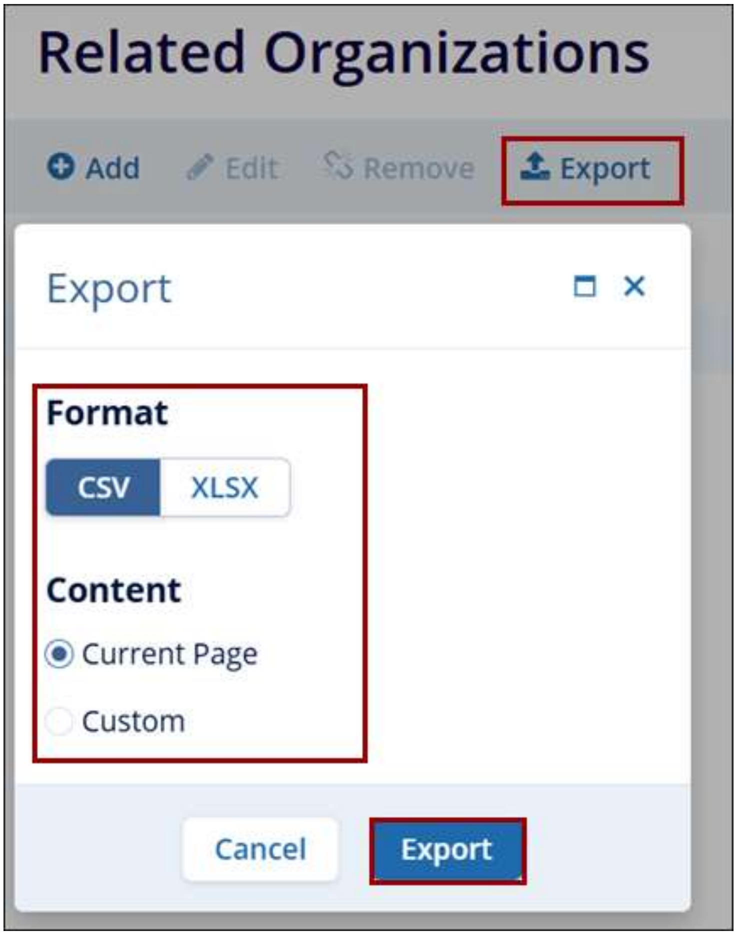


Figure: Export Related Organizations

Contacts at the Organization Level

Add Contact in the Organization

To add contacts at the organization level, follow the steps below.

1. On the Organization Details screen, click on the '**Contacts'** from the left-hand navigation links.
2. On the Contacts screen, click on the +Add button.
3. Add the necessary information to the mandatory fields on the 'Create Contact in Organization' form.
4. Refer to the Creating an Organization section for the detailed steps.

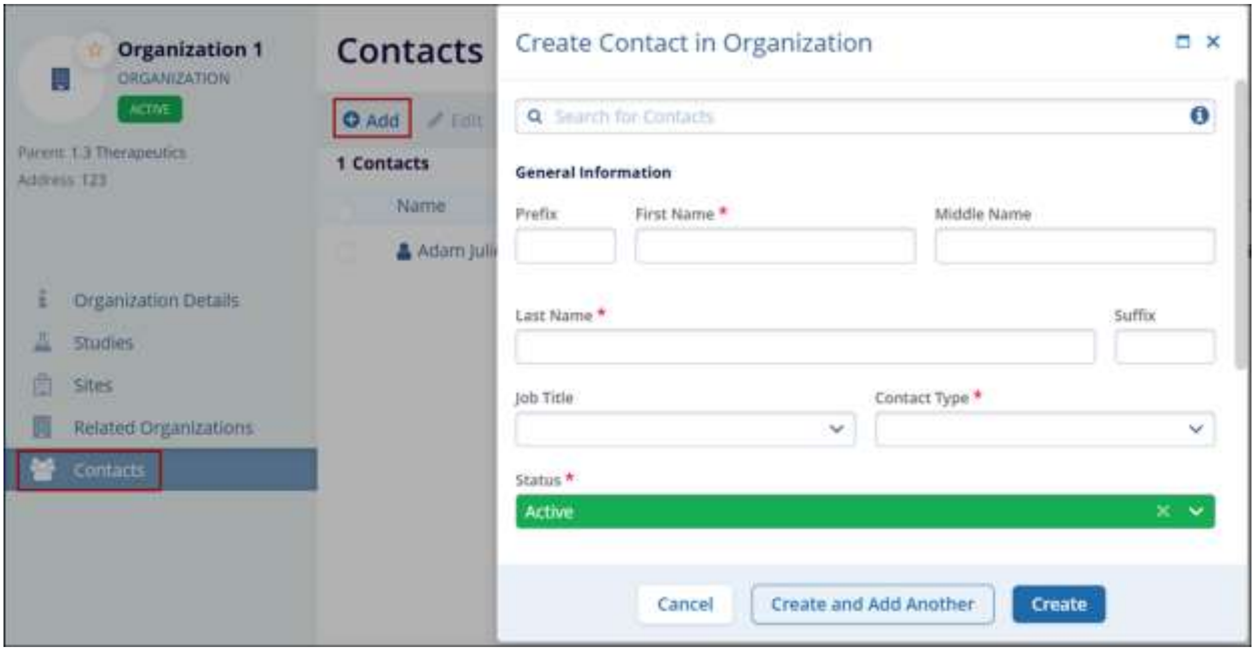


Figure: Create Contact in Organization

Edit Contacts in Organization

To edit contacts in an organization, follow the steps below.

1. Select a contact to edit.
2. Click on the Edit button from the top menu bar.
3. Make changes to the General Information, Contact Relation, and Contact Information sections.
4. Click on the Save button.

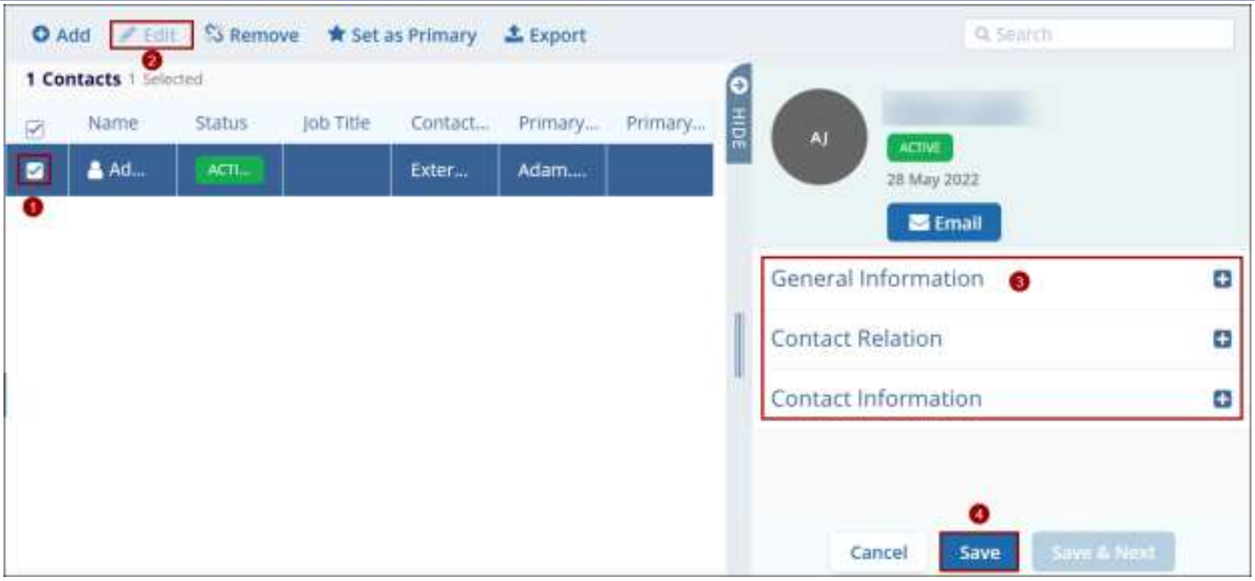


Figure: Edit Contact in Organization

<u>Remove Contact</u>

To remove a contact, follow the steps below.

1. Select a contact to remove.
2. Click on the Remove button from the top menu bar.
3. Click on the Remove button on the confirmation popup.

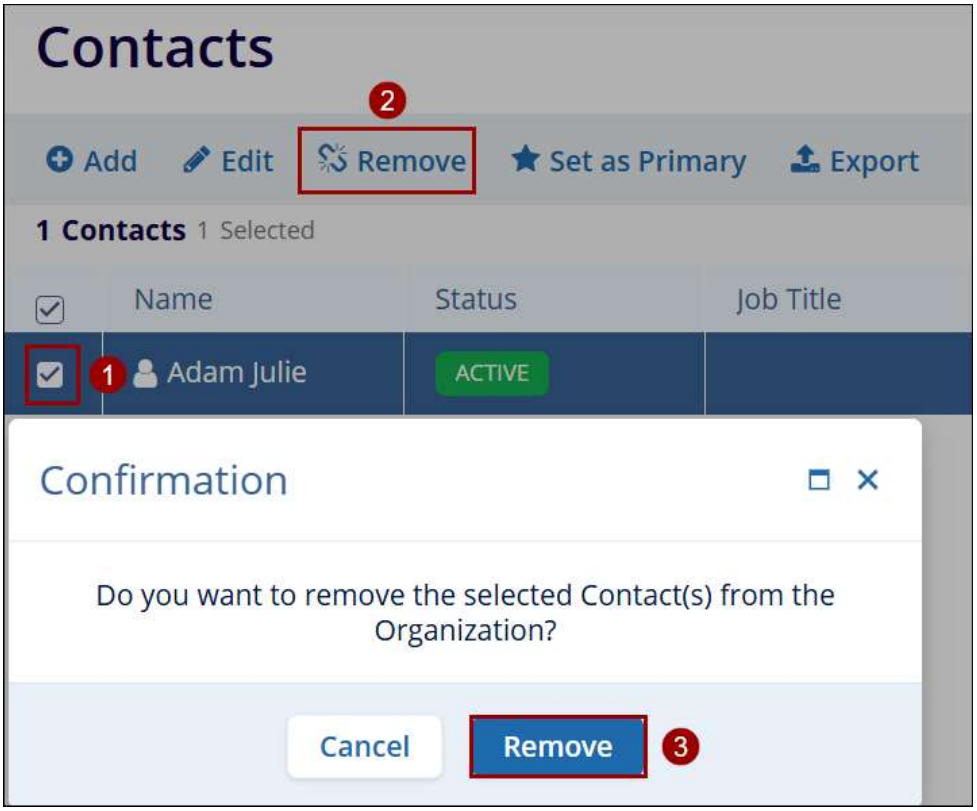


Figure: Remove Contact in Organization

Set as Primary

To set a contact as primary, follow the steps below.

1. Select a contact to set as a primary.
2. Click on the 'Set as Primary' button from the top menu bar.
3. The contact name displays a primary contact.

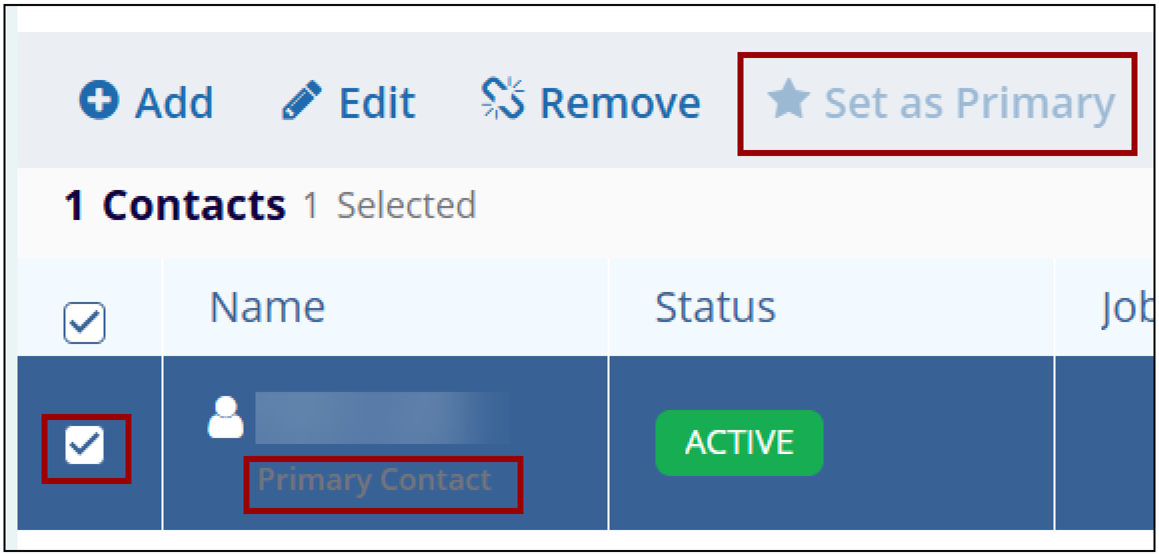


Figure: Set as Primary

Export

To export the Related Organizations, follow the steps below.

1. On the Contacts screen, click on the 'Export' button.
2. Follow the standard steps to retrieve exports detailed in the Exporting Contacts section.

CHAPTER 11. CONTACTS SM

Pre-requisites

Users with Company Administrator and Study Manager roles have 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 a global 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.

Refer to the flowchart below for a better understanding.

Global Information

Contact	Sponsor	Organization

↓

Clinical Study Information

↓

Product

Create	Manage

↓

Program

Create	Manage

↓

Study

Create	Manage	Tracking

↓

Country

Create	Manage	Tracking

↓

Site

Create	Manage	Tracking	Subjects	Site Visits	Visit Docs

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. The Contacts screen opens where contacts are displayed at a global level.

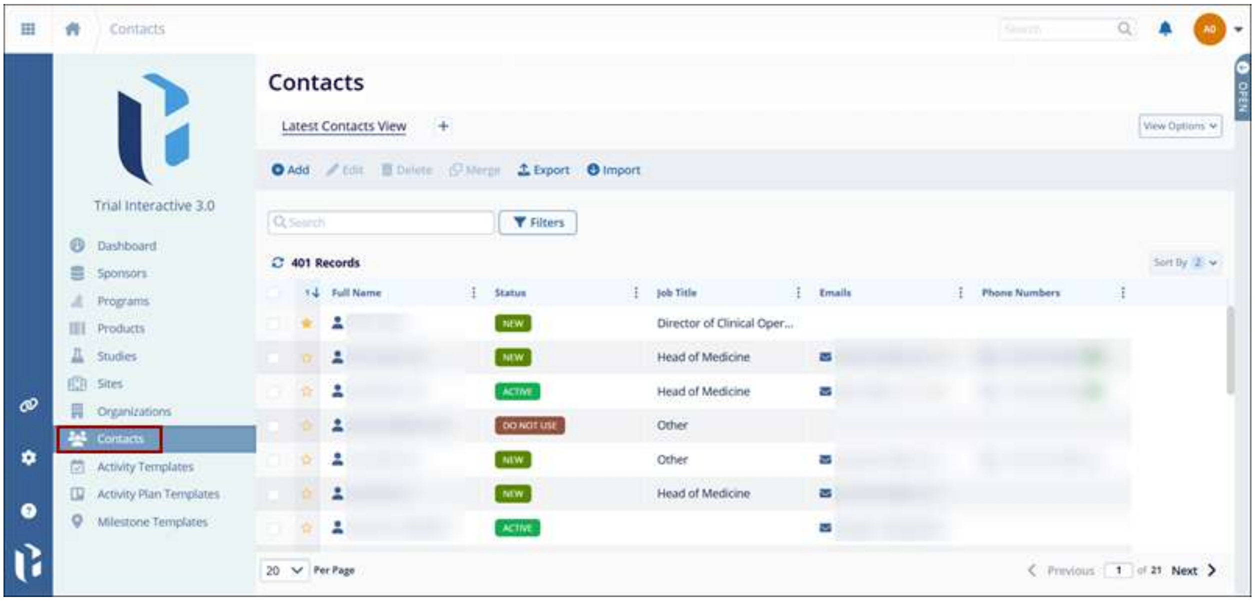


Figure: Select Contacts

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

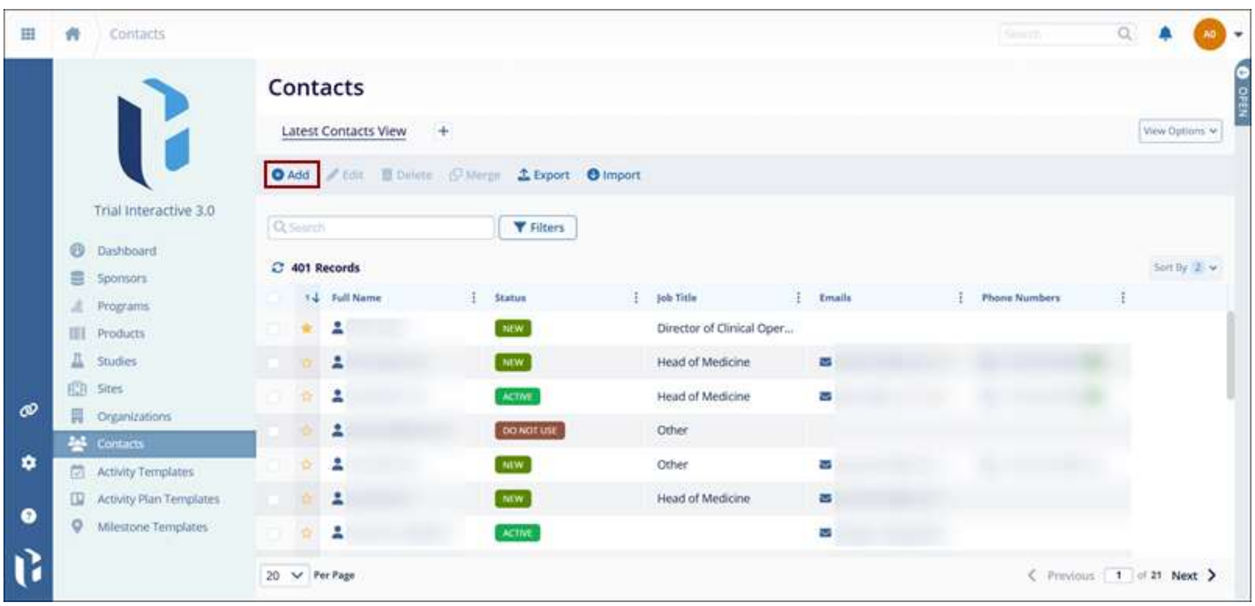


Figure: Create a new contact

3. 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.

    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

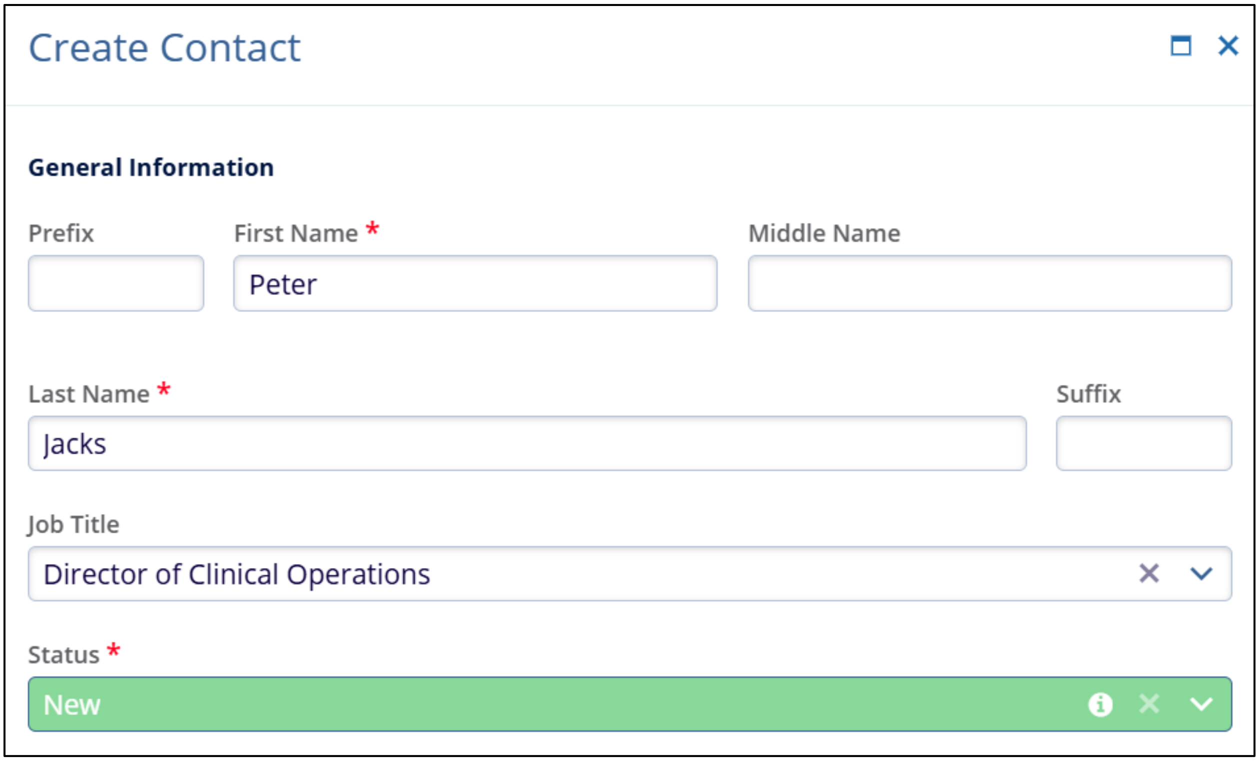


Figure: Create Contact form

i. Phone Numbers: Click on the +Add button to include phone numbers for the contact. Set a contact type by accessing the dropdown options. Click on the checkbox to set the number as a primary contact.

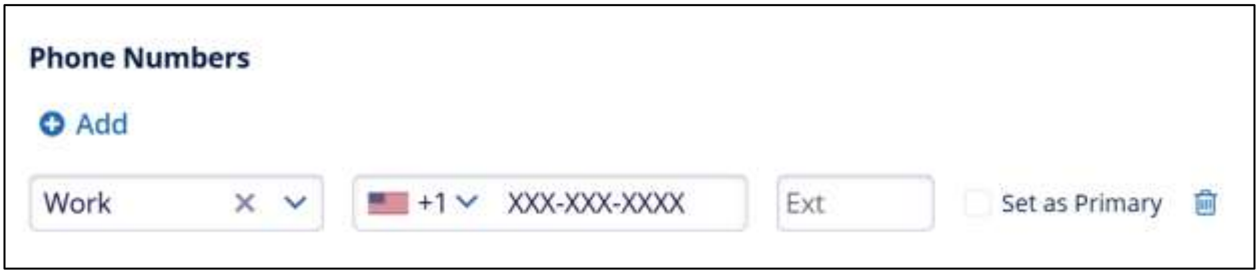


Figure: Phone Numbers

j. Emails: Click on the +Add button to add a new email address. Click on the checkbox to set the email address as a primary email address.

Figure: Add Emails

k. Include Address: Toggle the switch to include the address of the contact. Enter the address details if the switch is turned on.

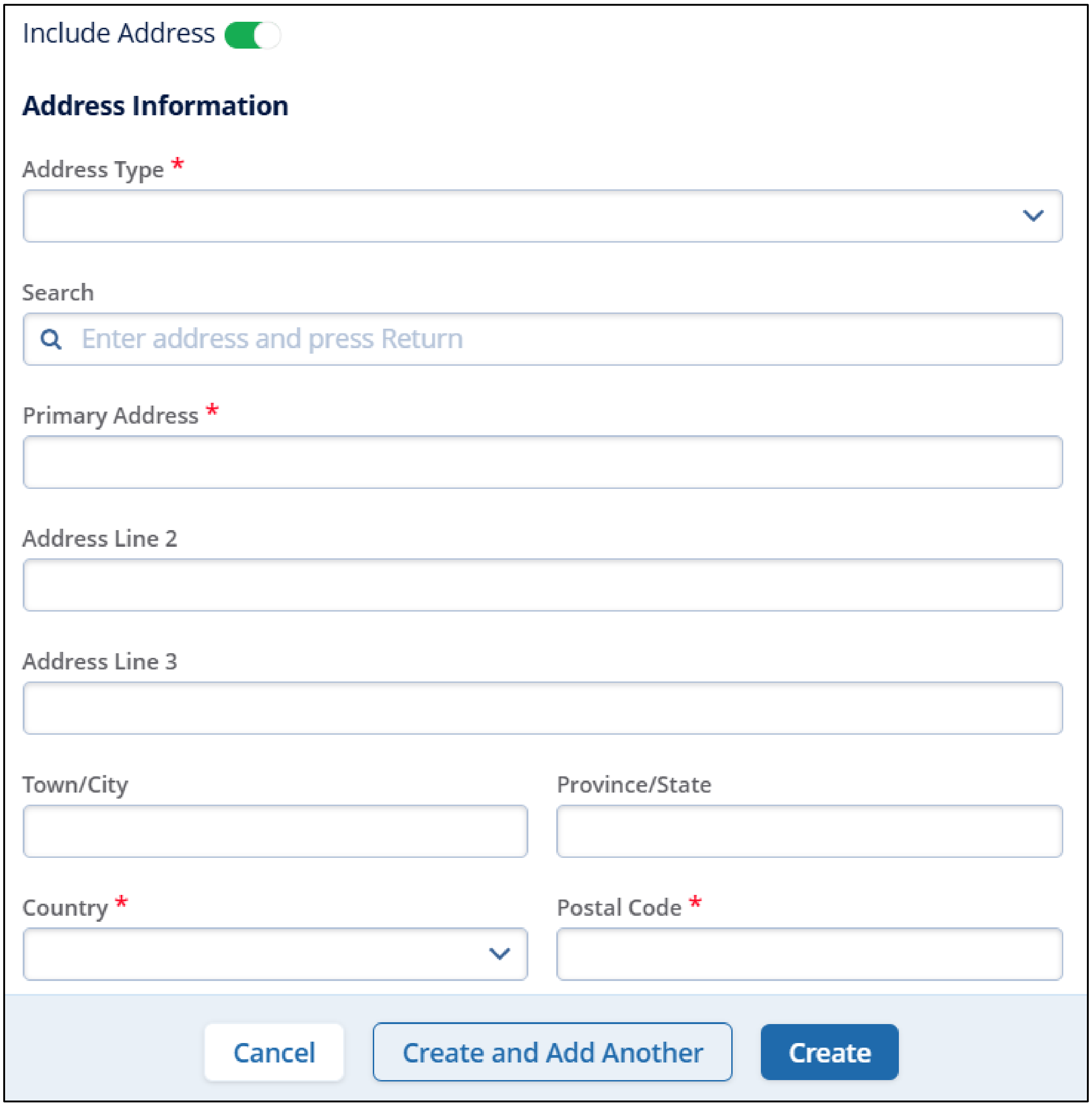


Figure: Add contact details

4. 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.
5. Once the contact is successfully created, it appears on the Contacts screen.

Figure: New Contact

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

Editing a Contact

Method 1

To edit a Contact, follow the steps below.

1. Click on the checkbox before the contact's 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.

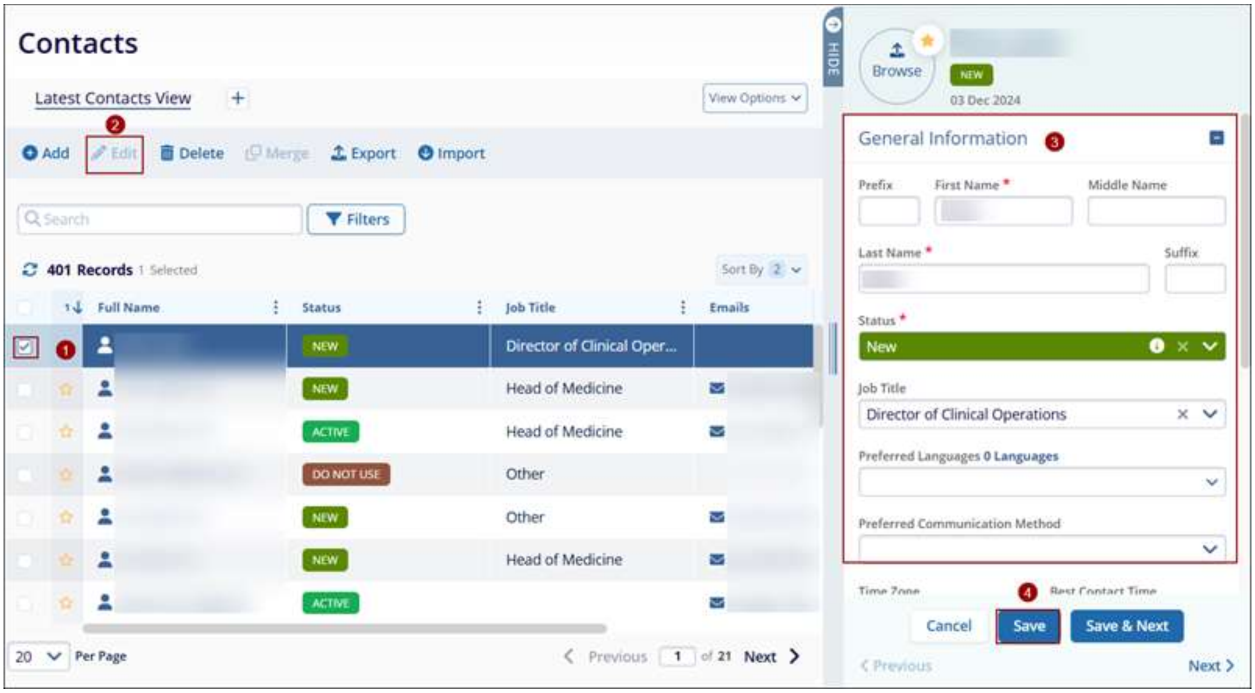


Figure: Editing a Contact

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, discards all the edits.

Method 2

Additionally, the contact details can also be edited through the Contact details page.

1. Click on a contact name which will open the Contact Details page.
2. On the Contact Details page, click on the Edit button from the top menu bar.

Figure: Edit contact on the Contact Details page

3. Expand the '**General Information'**, '**Contacts'**, Experience Information', and 'Additional Information' sections and make the required changes.
4. Click on the Save button once all changes are made.
5. Click on the Edit History button to view the contact edit history.

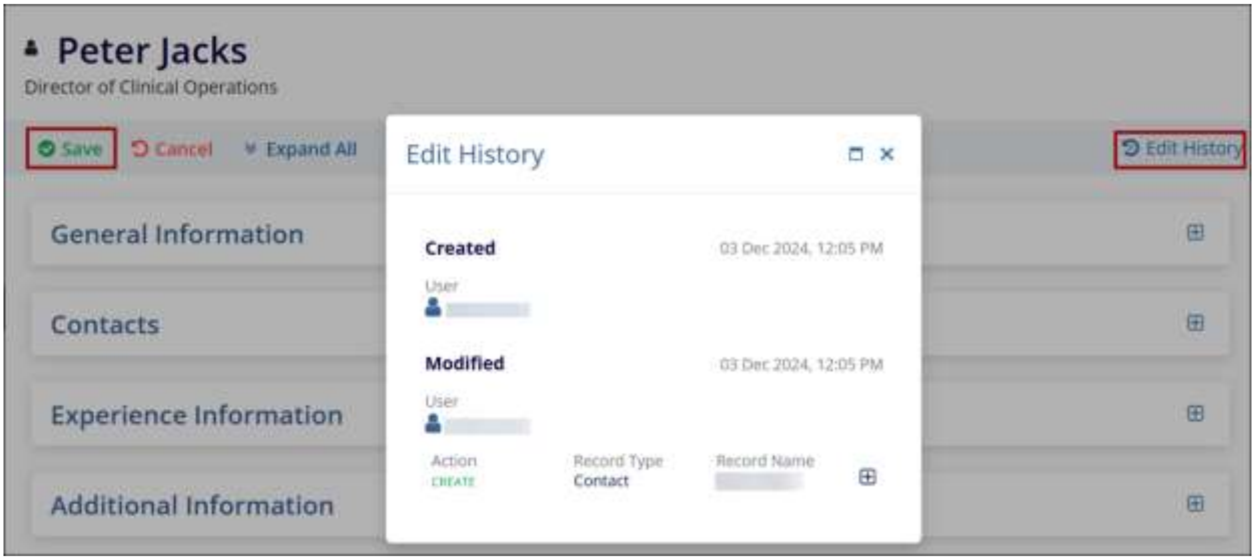


Figure: Edit History

Important

- Select the Organizations link from the left-hand navigation pane to view and associate organizations with the contact.
- Select the Sites link from the left-hand navigation pane to view the sites associated with the contact and manage site configurations within the contact.
- Select the Linked Contacts link from the left-hand navigation pane to view all contacts associated with the contact.

Deleting a Contact

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

1. Click on the checkbox beside the contact's 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.

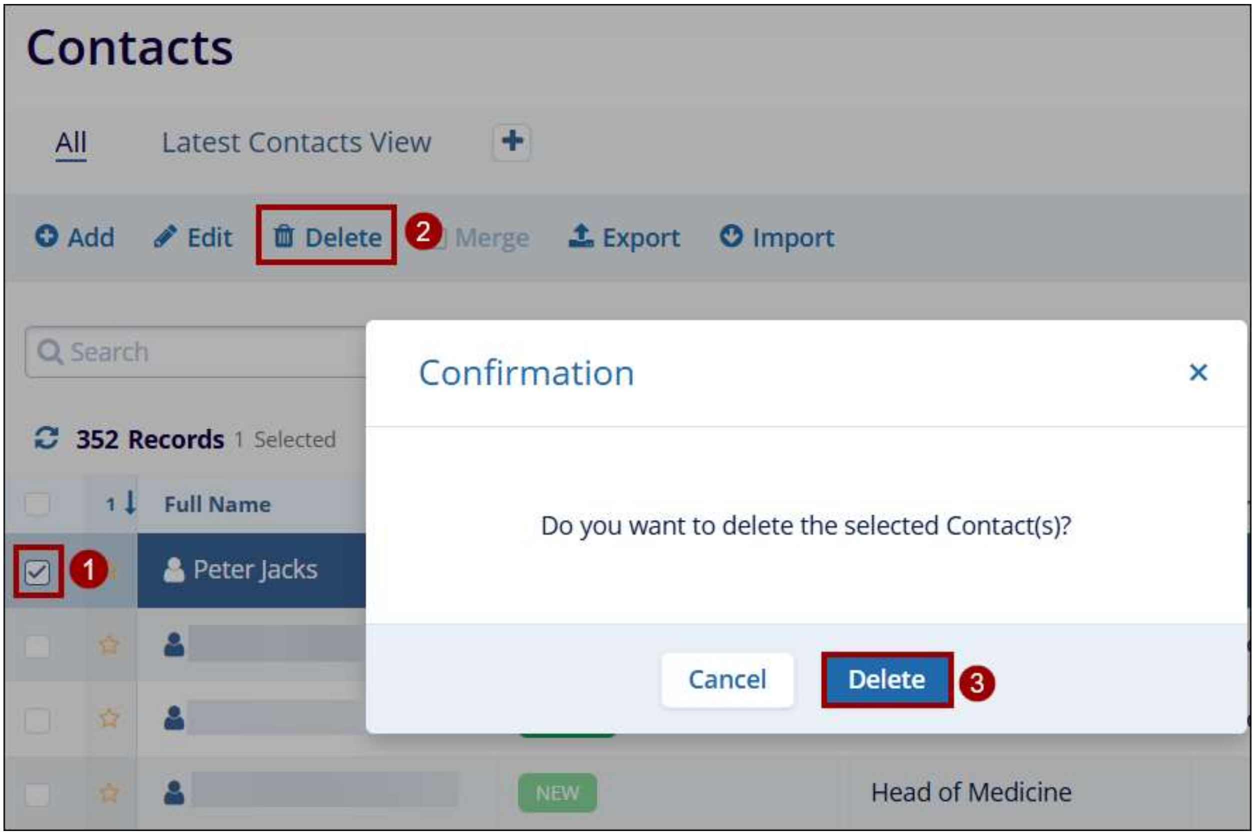


Figure: Contact deletion confirmation message

Merging Contacts

Duplicate contact entries exist due to their creation at various levels within the system's data hierarchy, each containing partial information. The Merge Contacts functionality empowers users to consolidate these entries into a single, comprehensive global contact record, ensuring all pertinent information is accurately unified.

To merge contacts, follow the steps below.

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

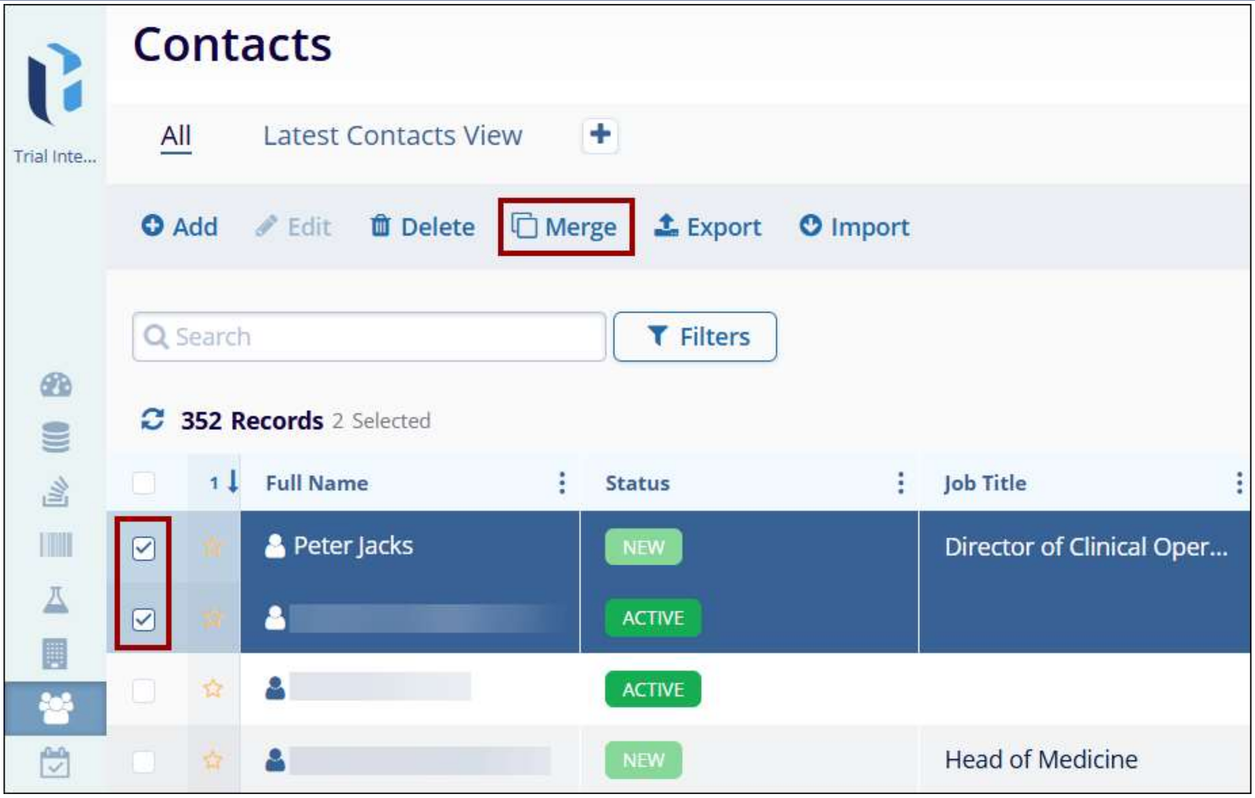


Figure: Merge Contacts

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

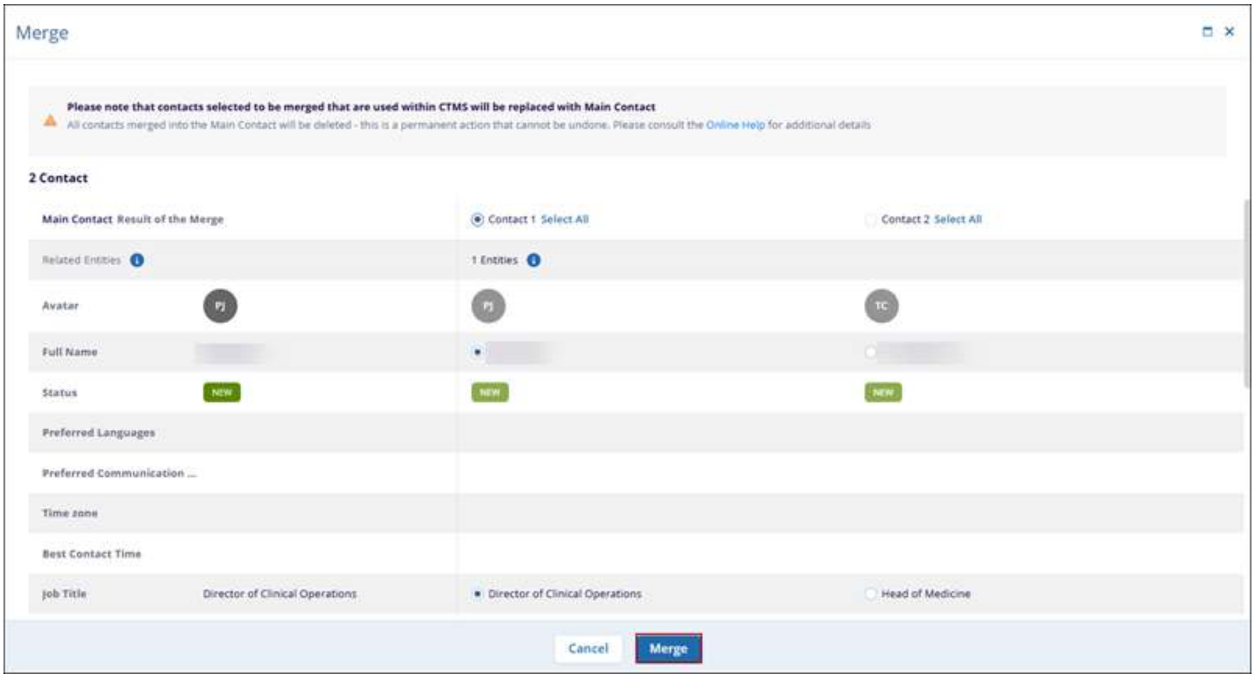


Figure: Contact 1 as the main contact

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

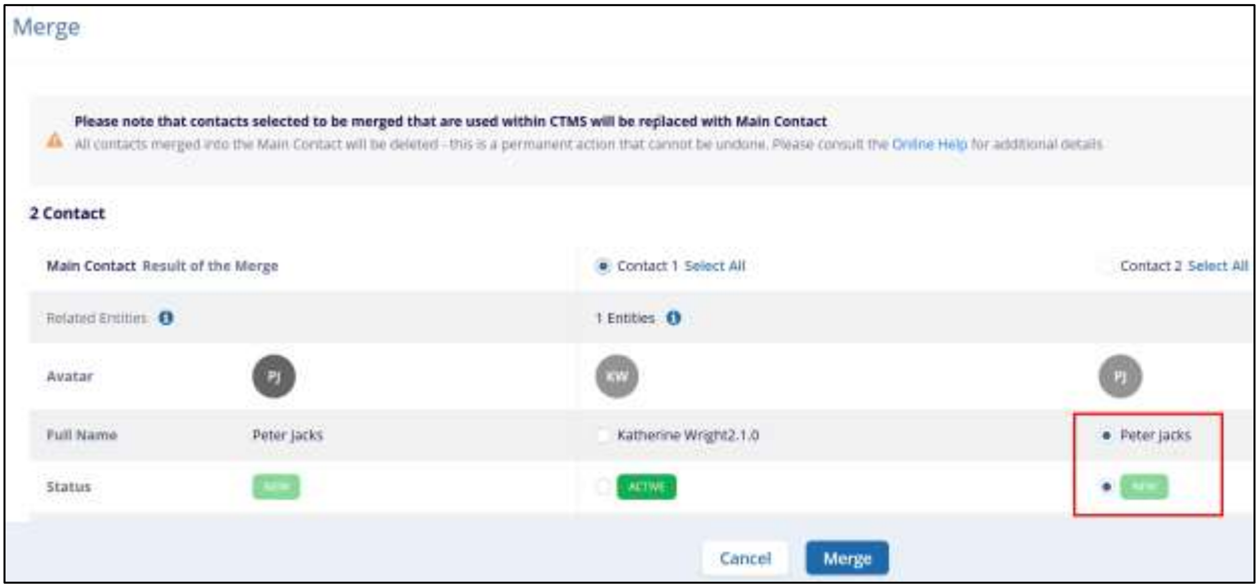


Figure: Merge individual entries from Contact 2

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

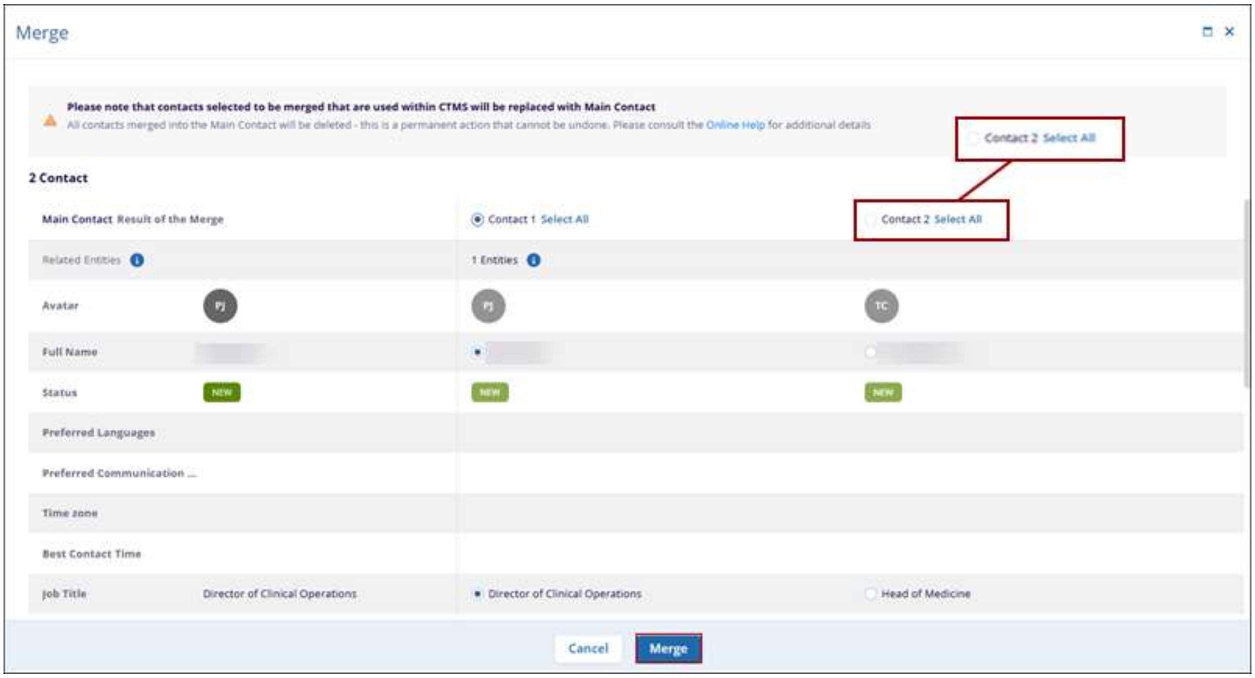


Figure: Merge all entries from contact 2

6. Once the user selects Merge, the Merge Contacts confirmation popup displays certain actions that cannot be undone and prompts the user to read those before confirmation. (Refer to the image below to read all actions that cannot be undone)

7. Click on Merge once all the details about actions that cannot be undone are read and confirmed.

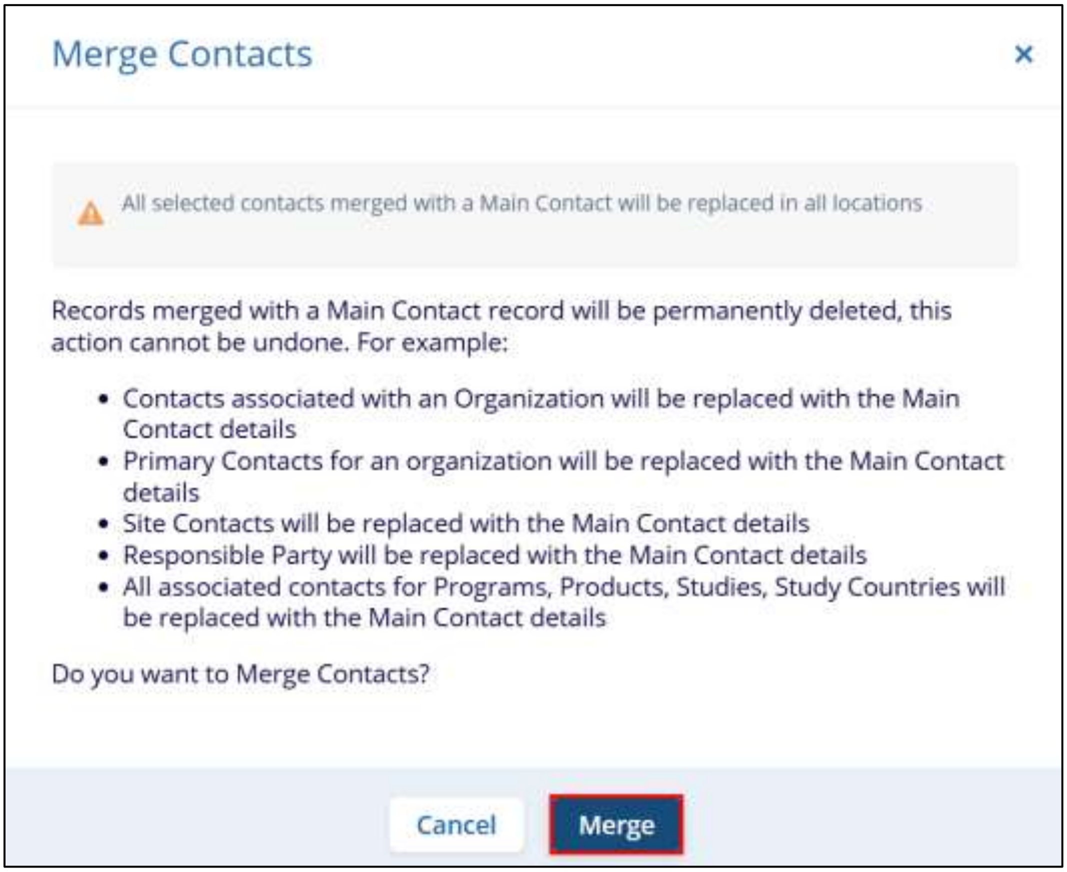


Figure: Merge Contacts confirmation popup

Exporting Contacts

To export contacts, follow the steps below.

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

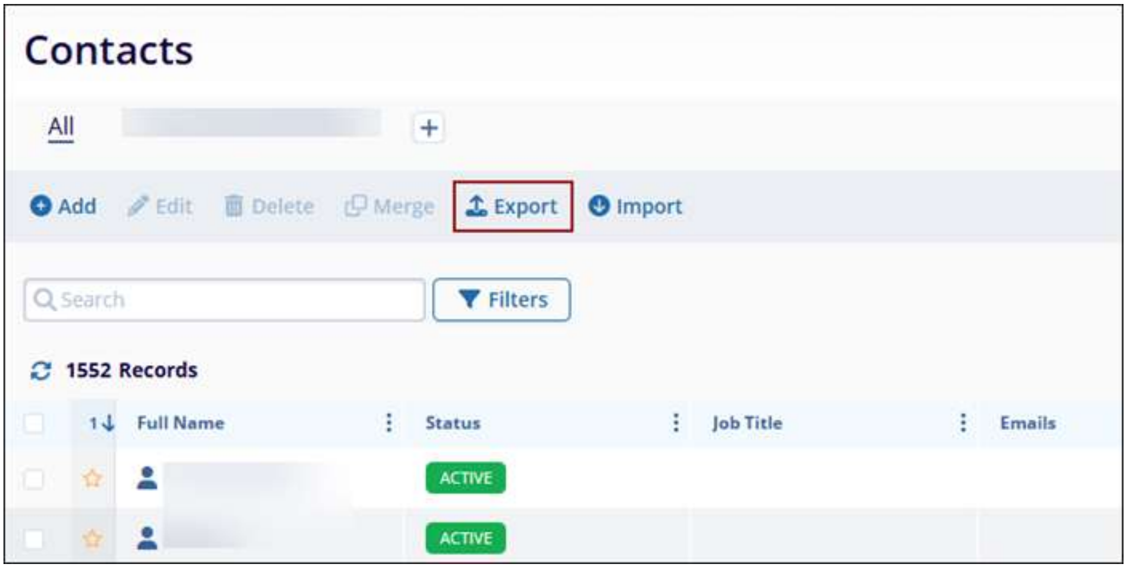


Figure: Select Export

2. 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.

3. 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.

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

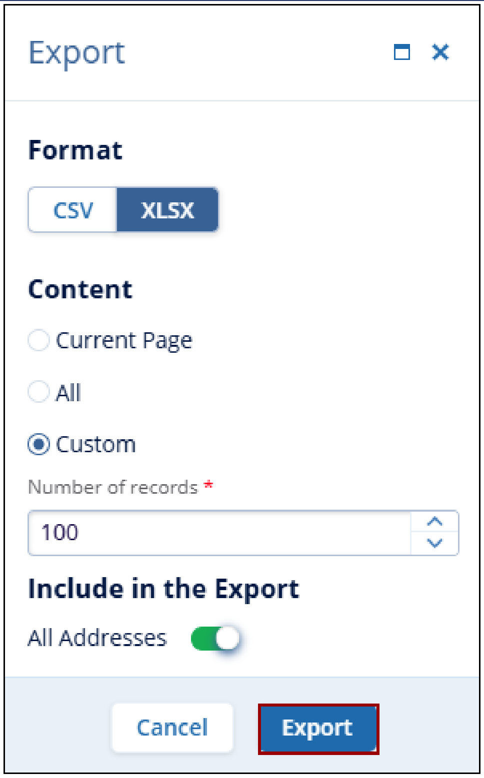


Figure: Export contacts file formats

5. Once the export is finished, the system displays 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.

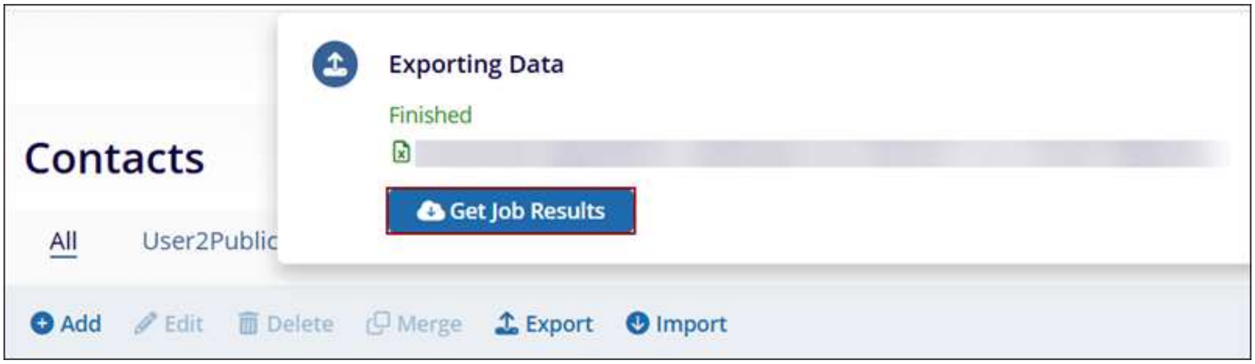


Figure: Get Job Results

6. The files will be downloaded to the local system and will display the file formats.

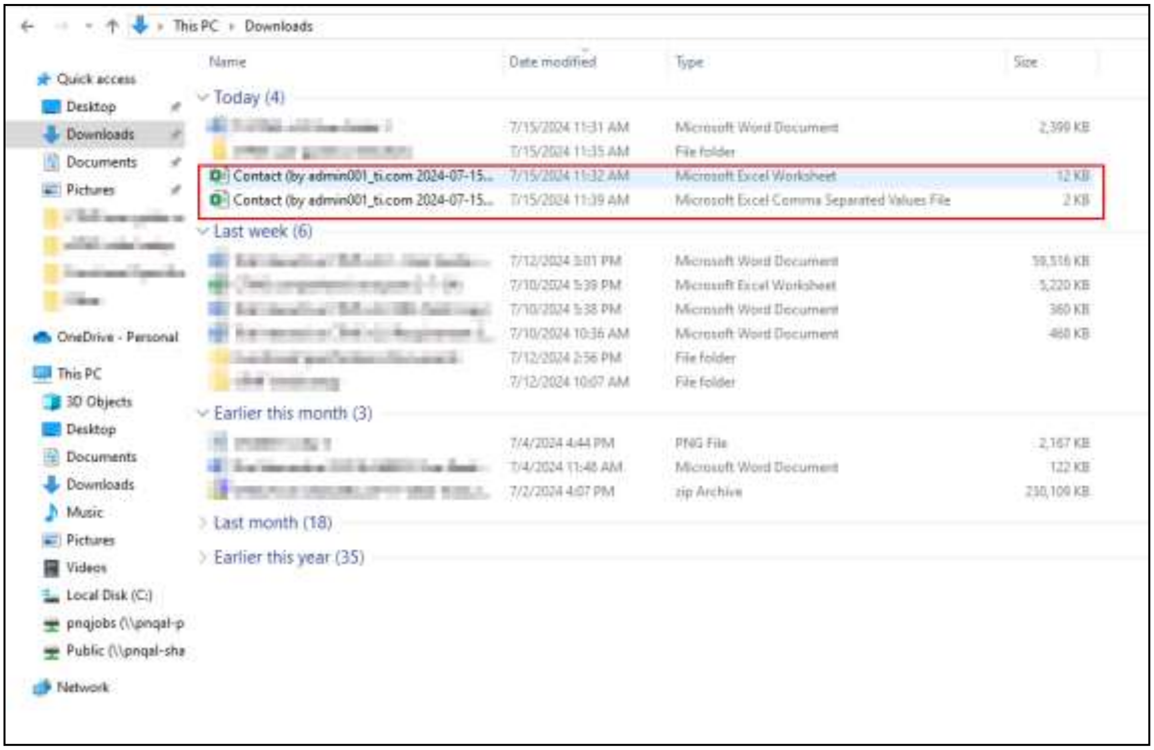


Figure: Exported files in CSV and XLSX file format

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

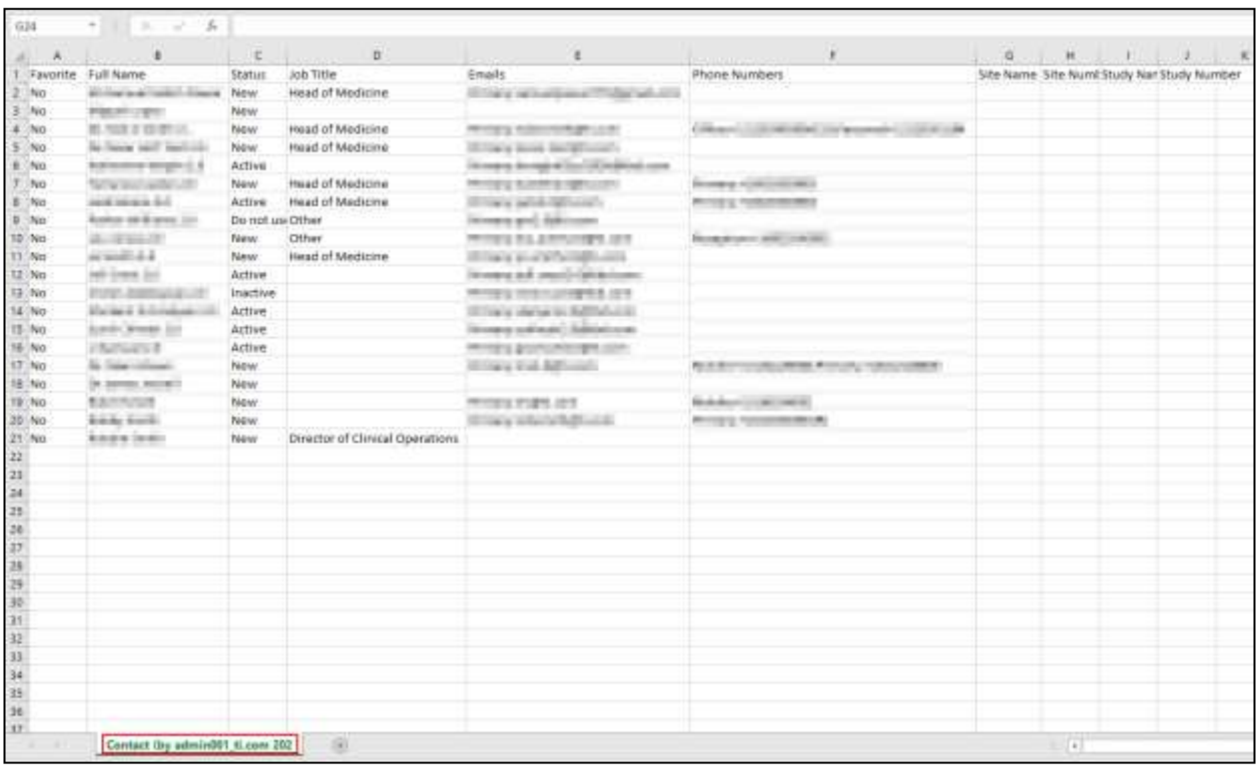


Figure: CSV file export

8. 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.

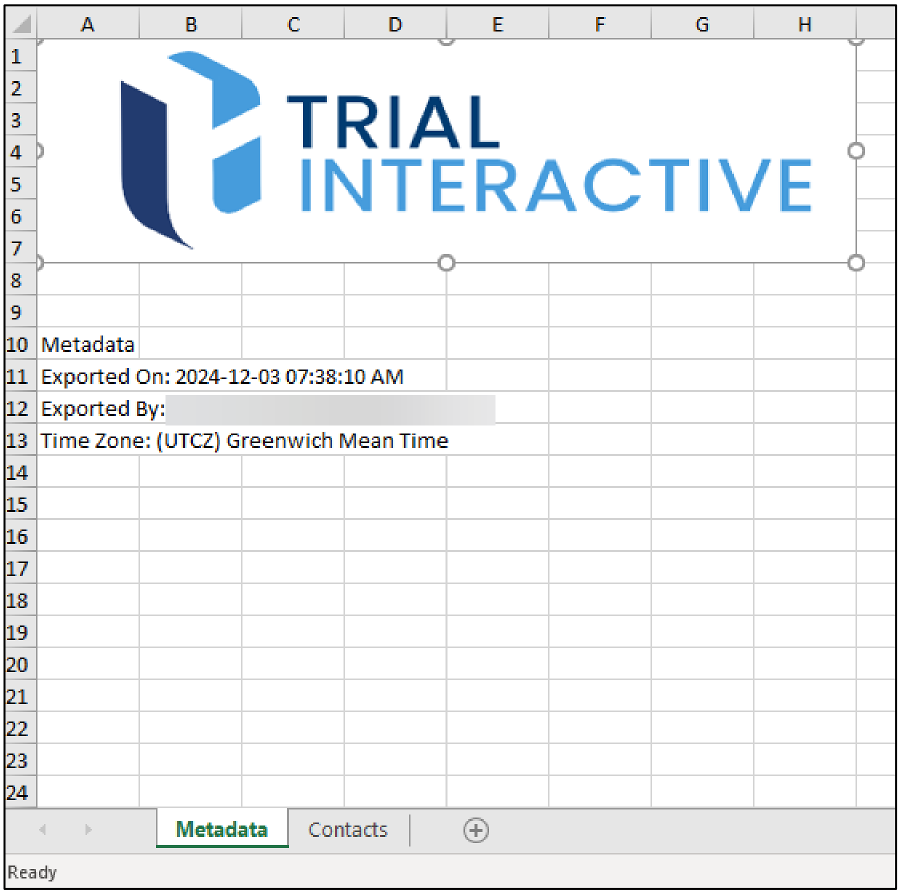
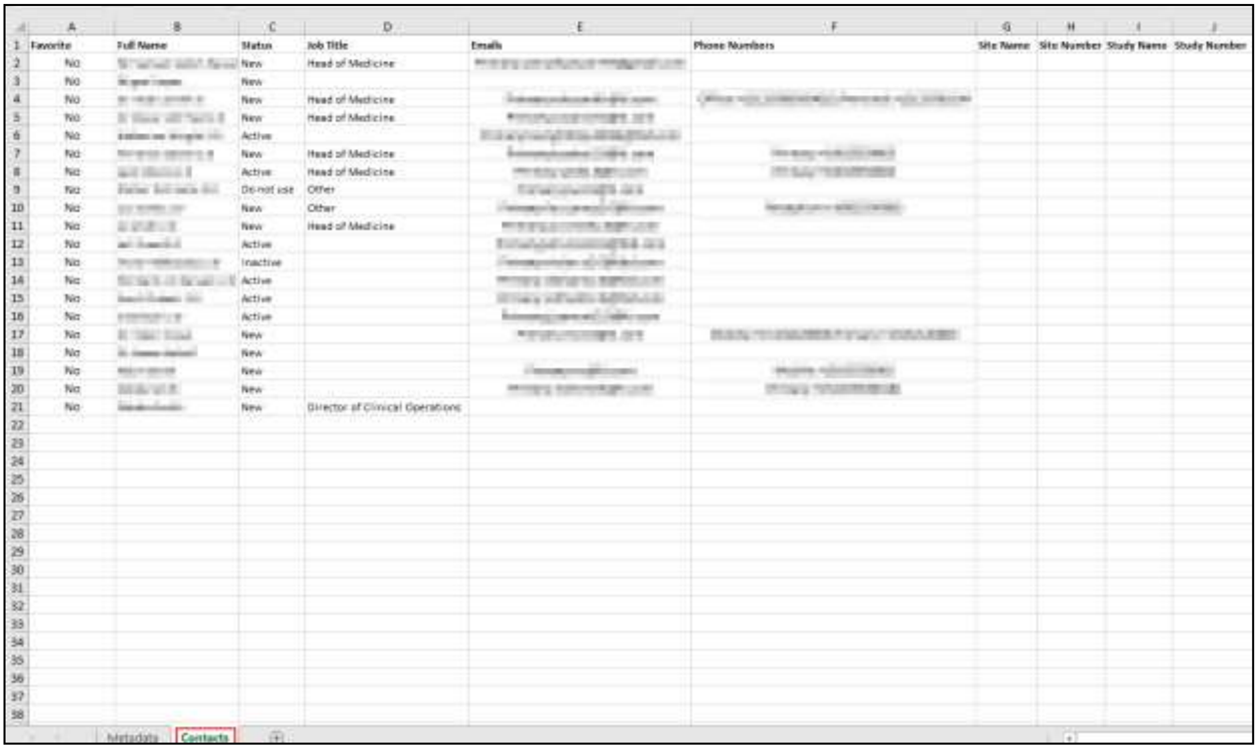


Figure: XLSX file-Metadata tab

- 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	[illegible]	New	Head of Medicine	[illegible]					
3	No	[illegible]	New							
4	No	[illegible]	New	Head of Medicine	[illegible]	[illegible]				
5	No	[illegible]	New	Head of Medicine	[illegible]					
6	No	[illegible]	Active		[illegible]					
7	No	[illegible]	New	Head of Medicine	[illegible]	[illegible]				
8	No	[illegible]	Active	Head of Medicine	[illegible]	[illegible]				
9	No	[illegible]	Do not use	Other	[illegible]					
10	No	[illegible]	New	Other	[illegible]	[illegible]				
11	No	[illegible]	New	Head of Medicine	[illegible]					
12	No	[illegible]	Active		[illegible]					
13	No	[illegible]	Inactive		[illegible]					
14	No	[illegible]	Active		[illegible]					
15	No	[illegible]	Active		[illegible]					
16	No	[illegible]	Active		[illegible]					
17	No	[illegible]	New		[illegible]	[illegible]				
18	No	[illegible]	New							
19	No	[illegible]	New		[illegible]	[illegible]				
20	No	[illegible]	New		[illegible]	[illegible]				
21	No	[illegible]	New	Director of Clinical Operations						

Metadata | Contacts

Figure: XLSX file-Contacts tab

Importing Contacts

To import contacts in CTMS, follow the steps below.

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

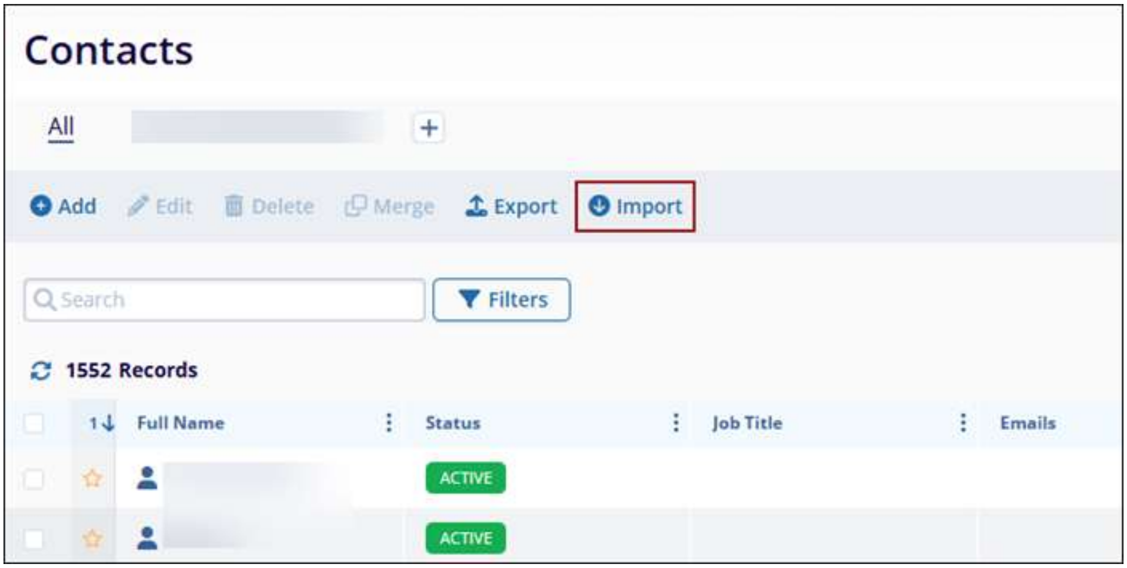


Figure: Select Import

2. On the Import screen, perform the following

   a. Click on the Download Template button to get a specimen of the required format.

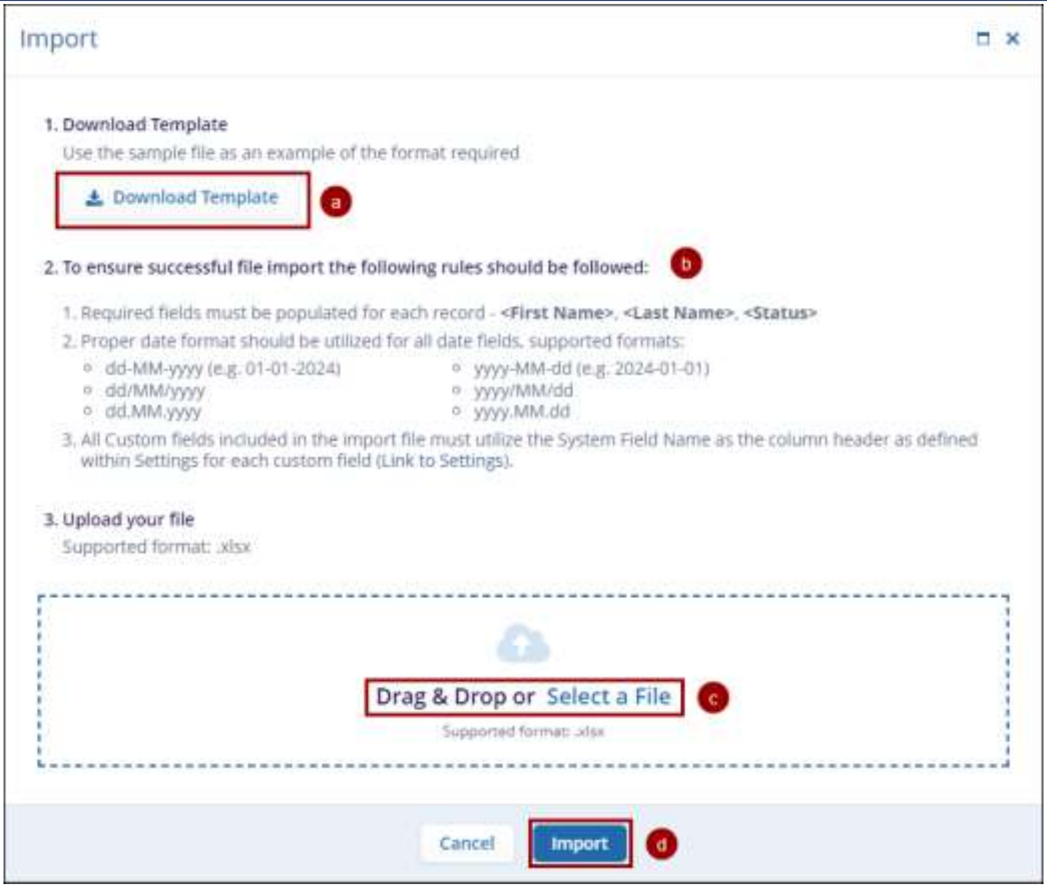


Figure: Import contact's process

b. 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.

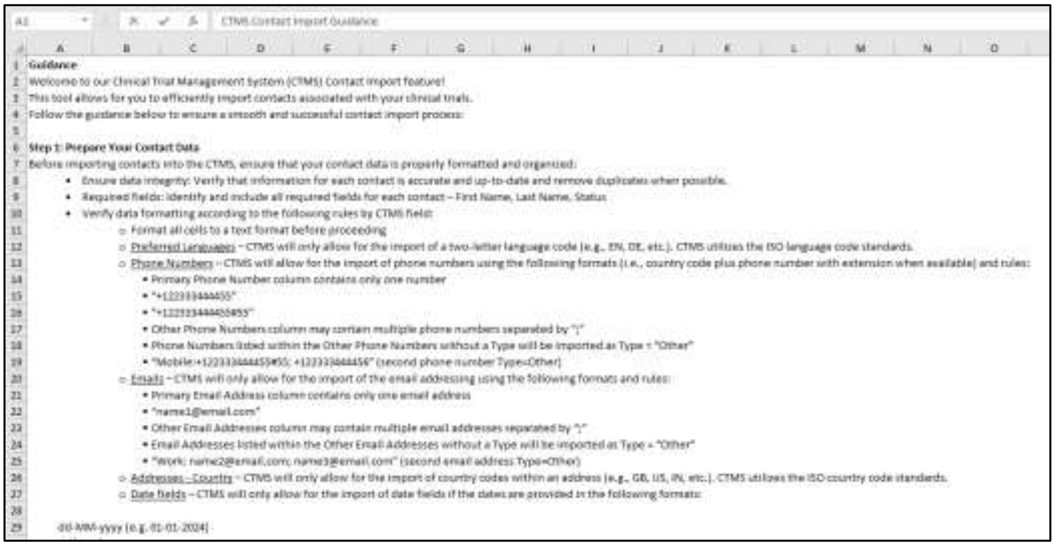
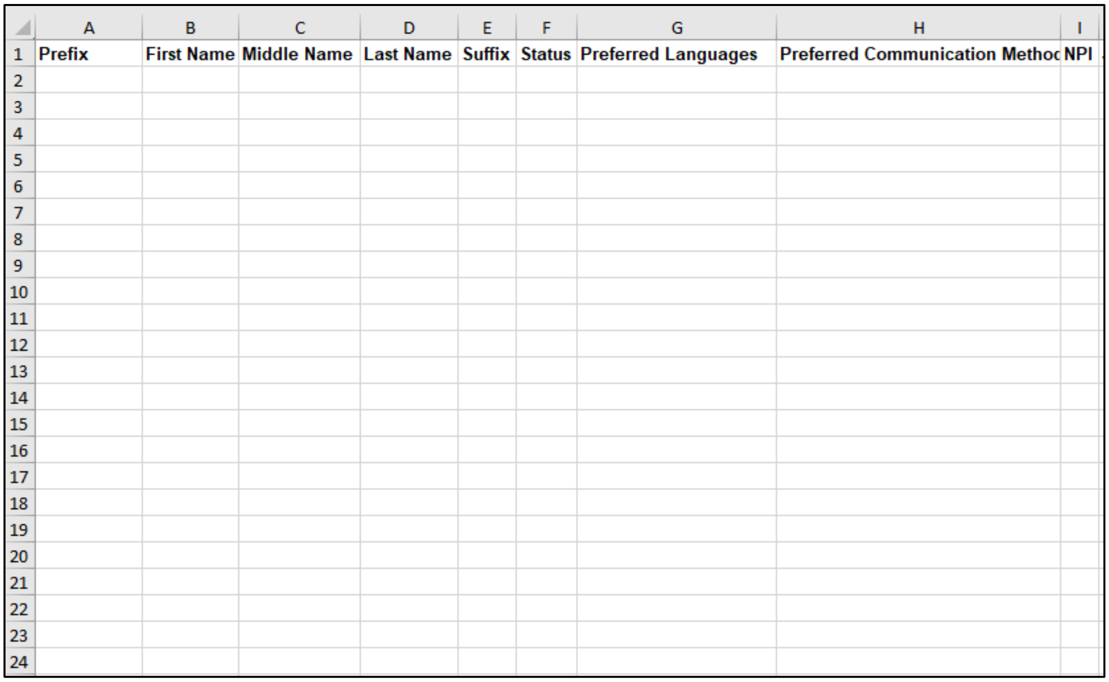


Figure: Contacts import template-Import Guidance



	A	B	C	D	E	F	G	H	I
1	Prefix	First Name	Middle Name	Last Name	Suffix	Status	Preferred Languages	Preferred Communication Methoc	NPI

Figure: Contacts import template-Contacts

c. Upload the file in .xlsx file format either by selecting the file or using the Drag & Drop functionality.

d. Click on the Import button 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.

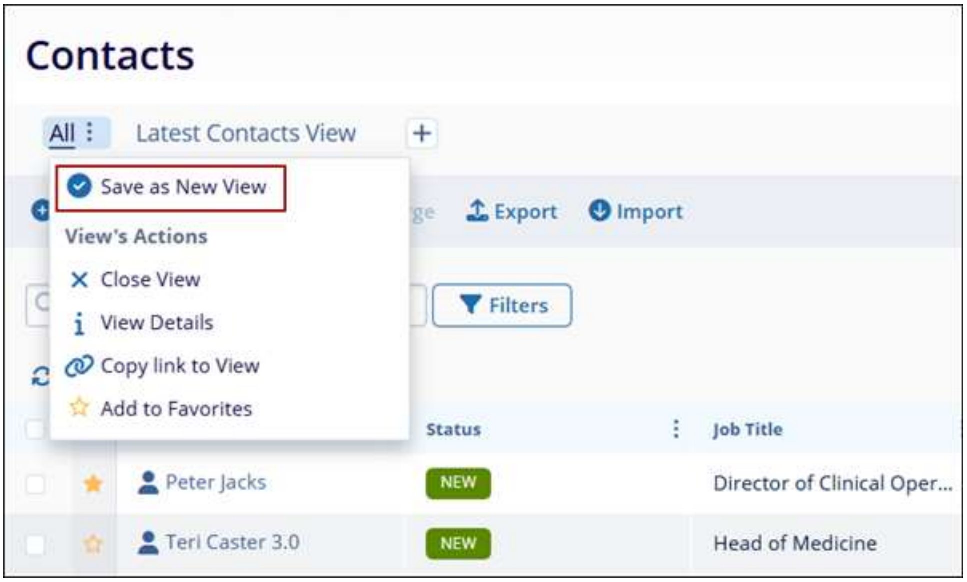


Figure: Save as New View

2. On the 'Save as New View' screen, specify View Name, Description, and Sharing Options-Private or Public. For the '**Public' option**, it is possible to set it as a default view by enabling the Set as Default toggle button.
3. Once all the details are entered and configured click on the Save View button.

Figure: Save as New View Configuration

4. Once successfully saved, it appears on the Contacts home screen.

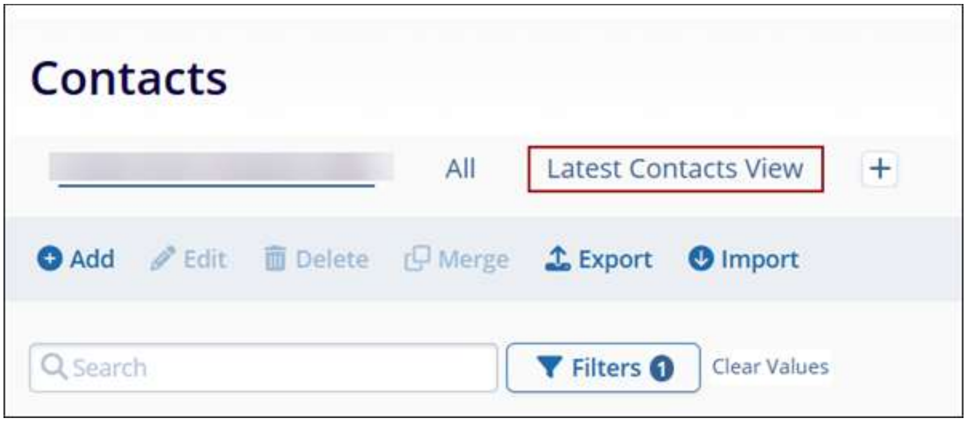


Figure: New contacts view on the home screen

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.

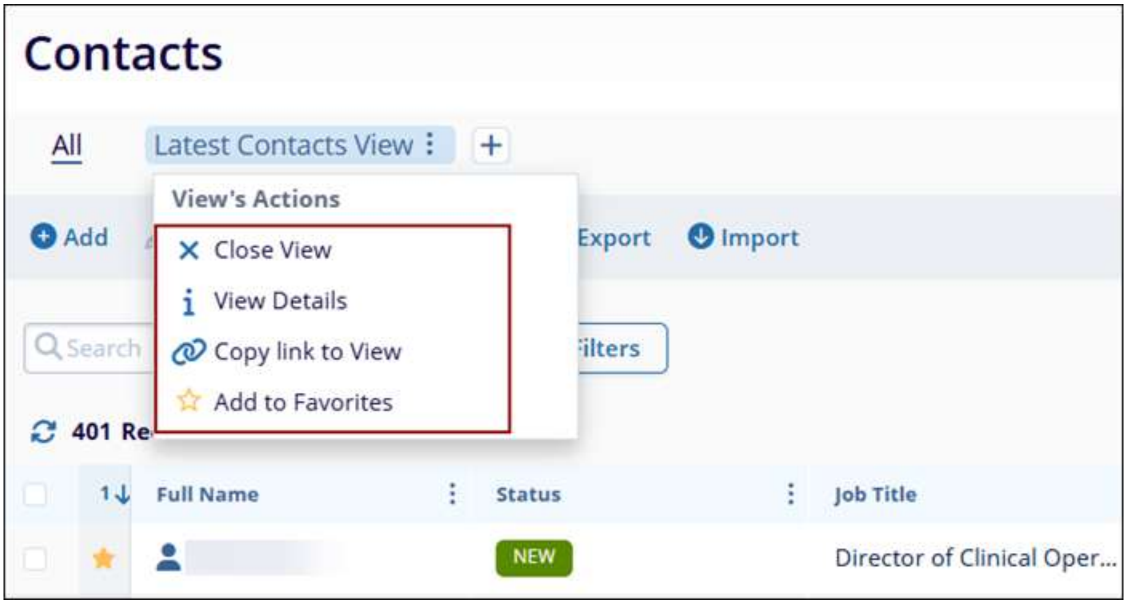


Figure: Accessing View's Actions

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

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

Adding a View

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

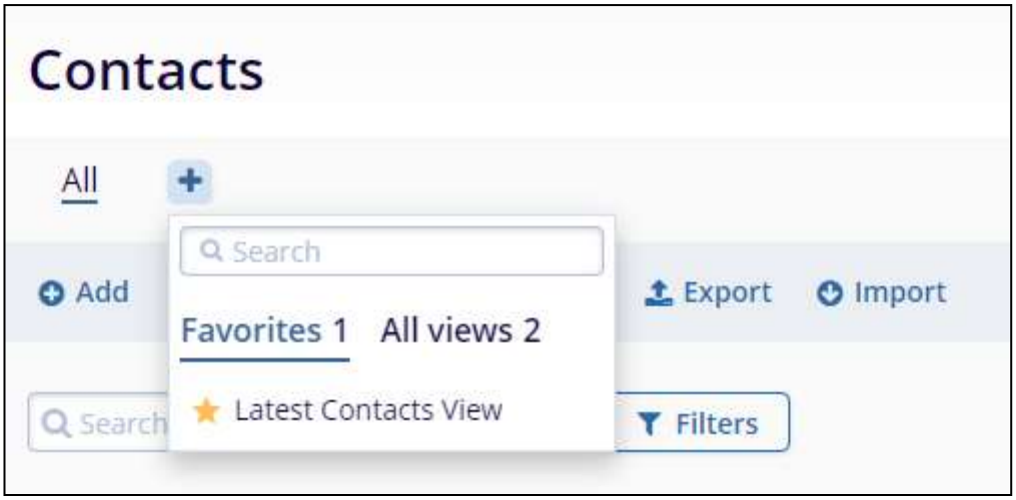


Figure: Adding a new

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

All View's Actions

To access All View's Actions, from the left-hand navigation links, 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 screen displays views bifurcated by All Views, Favorites, Created By Me, and Default. On this screen, perform the following actions.

    a. Navigate between the All Views, Favorites, Created by Me, and Default tabs to select the desired view.

    b. Select an individual view.

    c. Navigate to the top menu bar to access 'View Details,' Copy Link to View, Set/Unset as Default and Delete, etc.

    d. Filter the records by applying the Created By, Share Options, and Add to Page filters.

    e. Sort the data in Ascending and Descending order by applying different sorting criteria.

    f. Click on +Add to add the view on the Contacts home page.

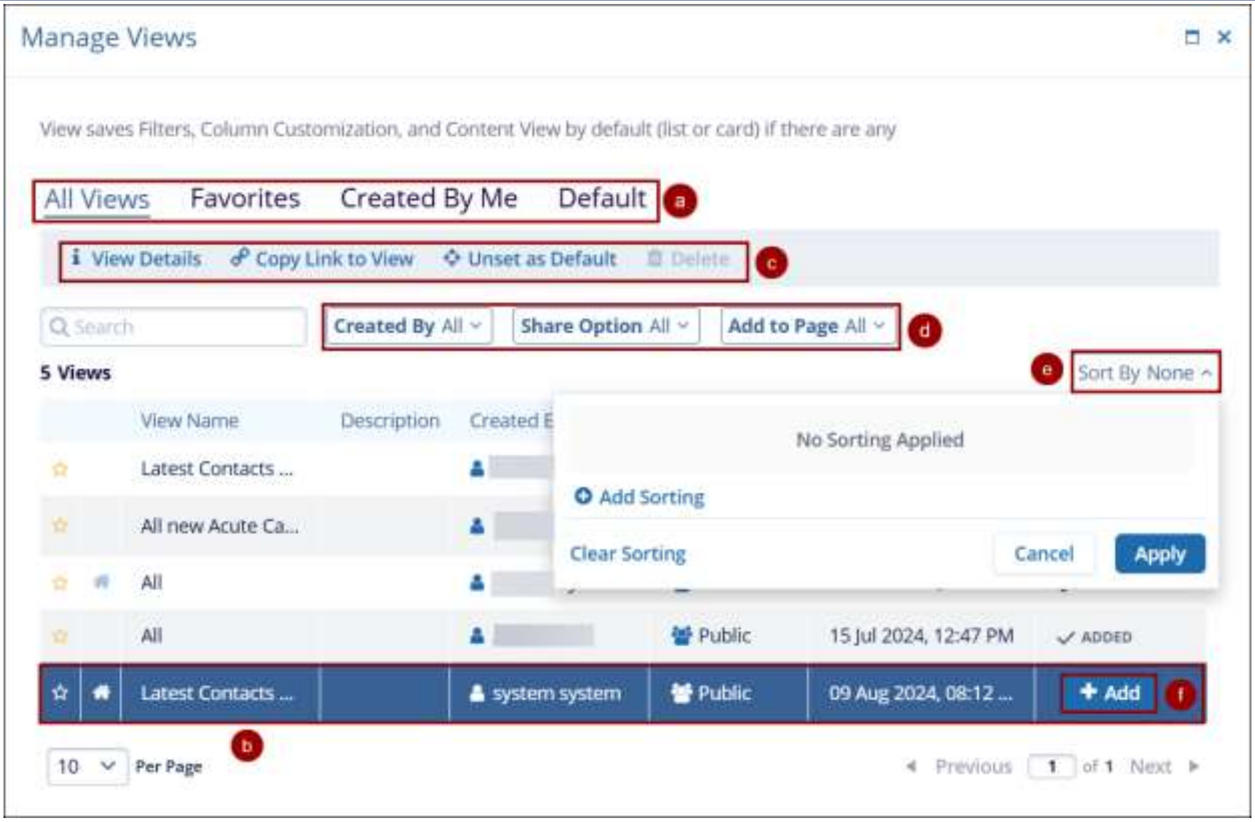


Figure: Manage Views

2. Set as Default View: Selecting this option will set the selected view as a default view. Once this option is selected, click on Unset as default on the confirmation popup.

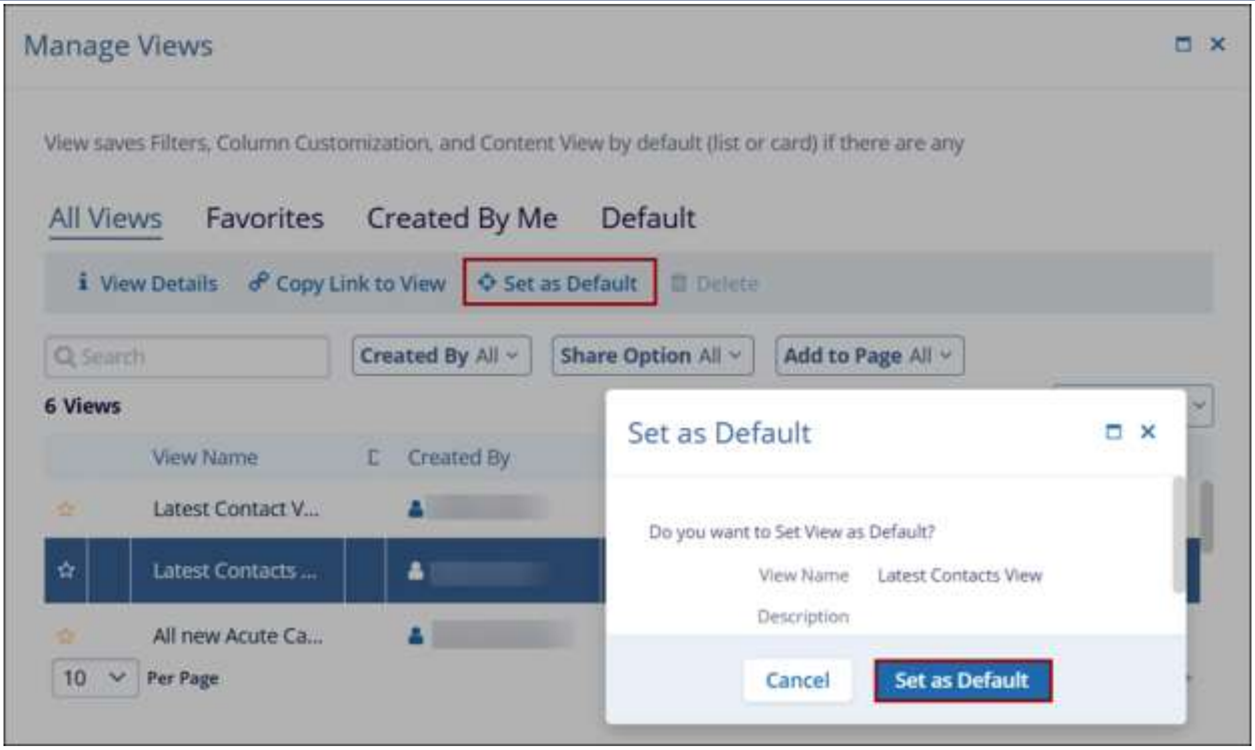


Figure: Set as Default view

3. Unset as Default View: Selecting this option will unset the initially selected view as a default. Once this option is selected, click on Unset as default on the confirmation popup.

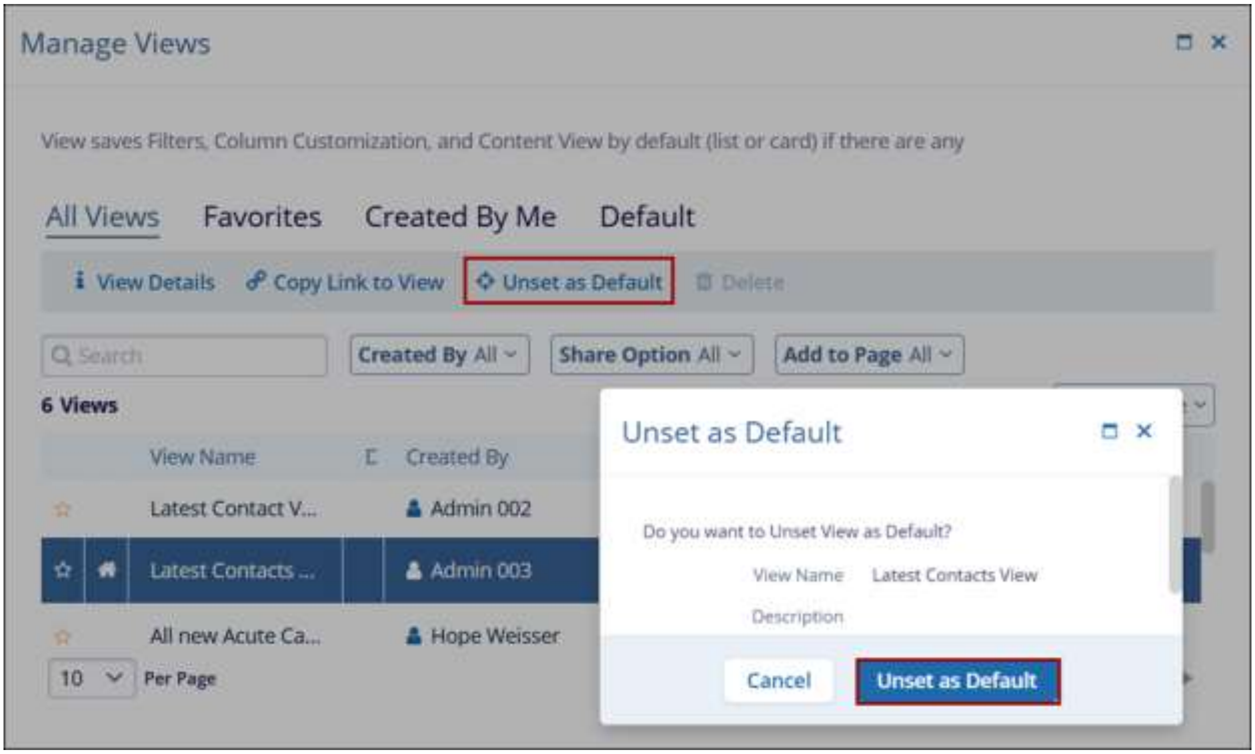


Figure: Reset to Default Views Config

4. Reset to Default Views Config: Selecting this option will reset all views to the system default views.

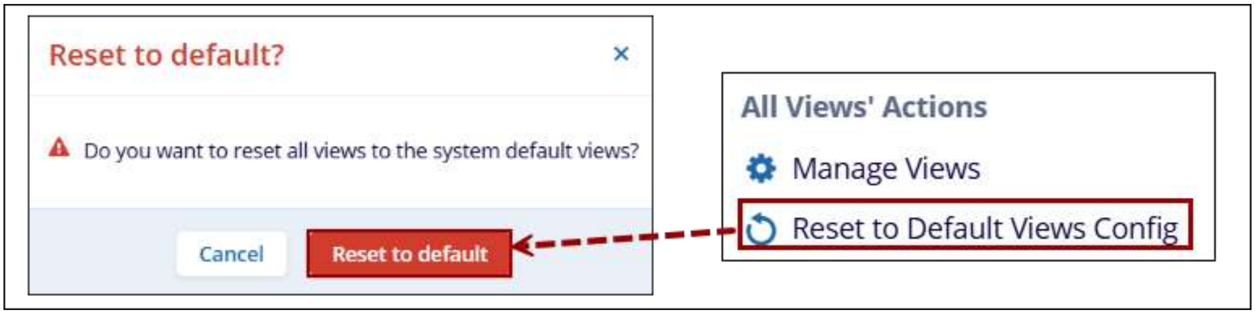


Figure: Reset to default

Customizing Contacts screen

The Contacts screen can be customized by performing the following:

Filters

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

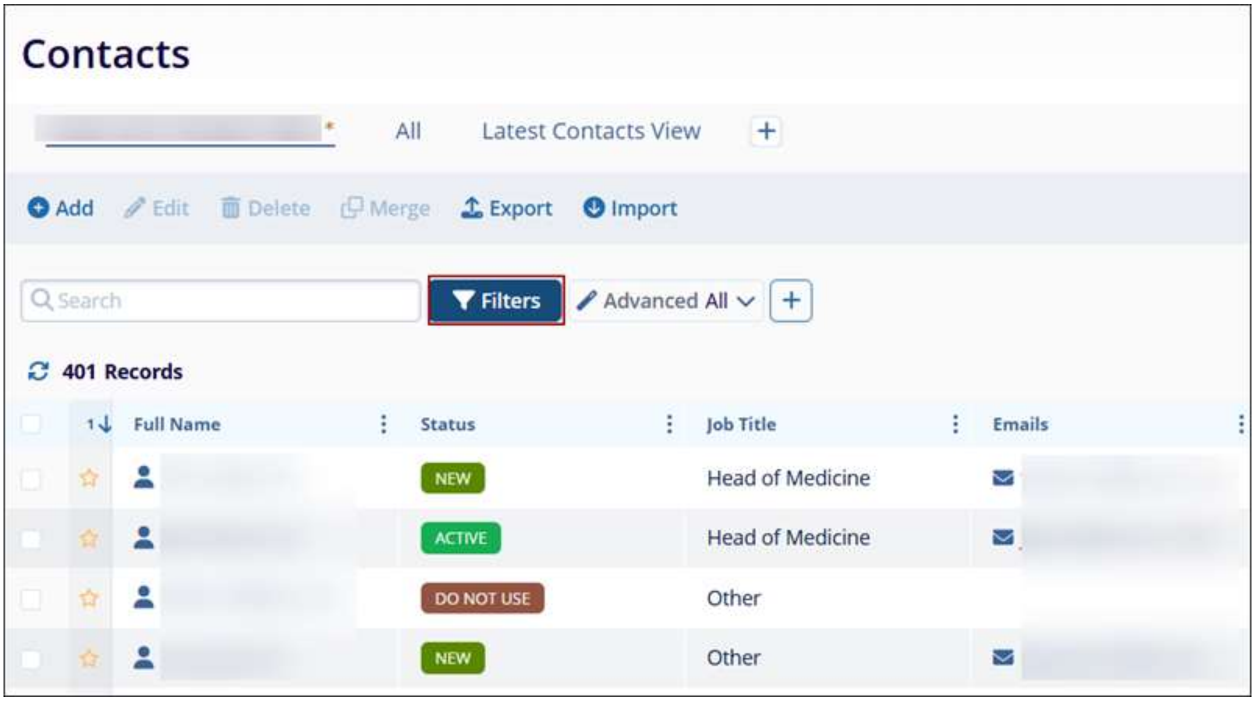


Figure: Add Filters

Standard Filters

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

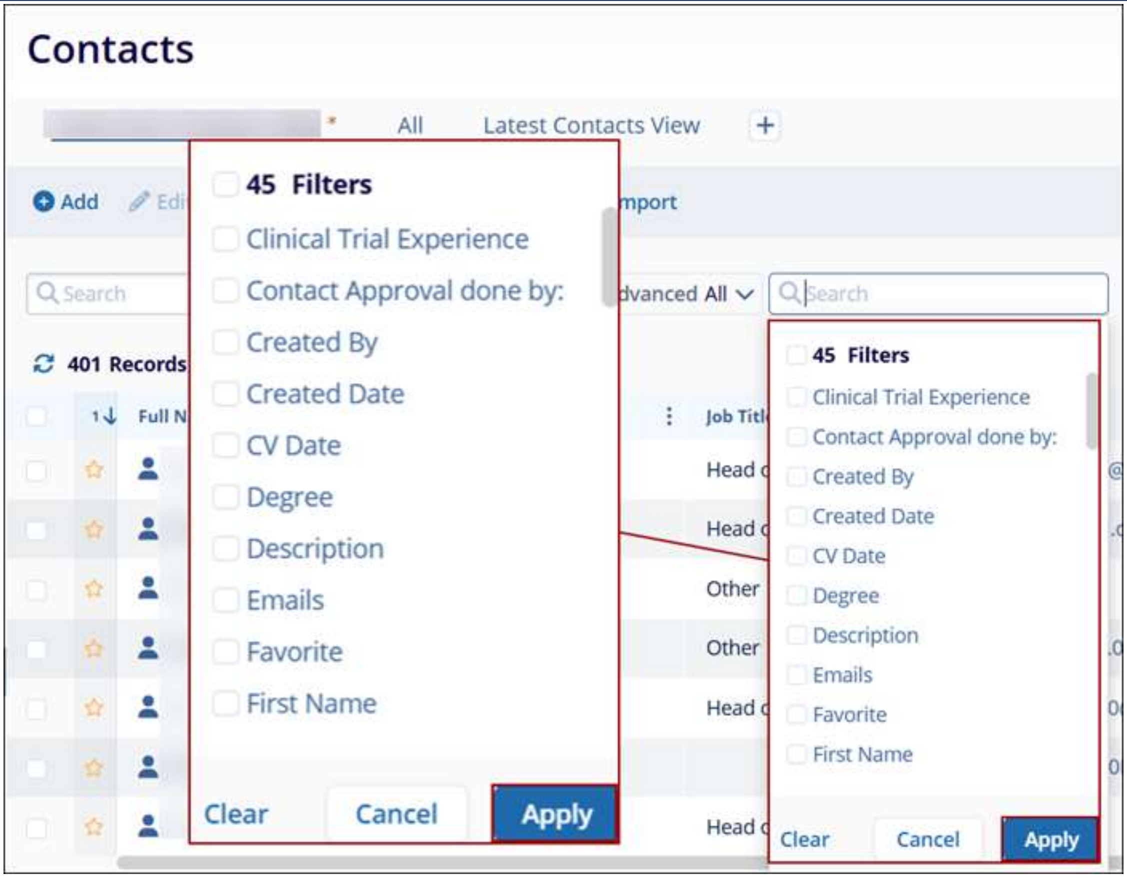


Figure: Apply standard filters

Advanced Filters

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

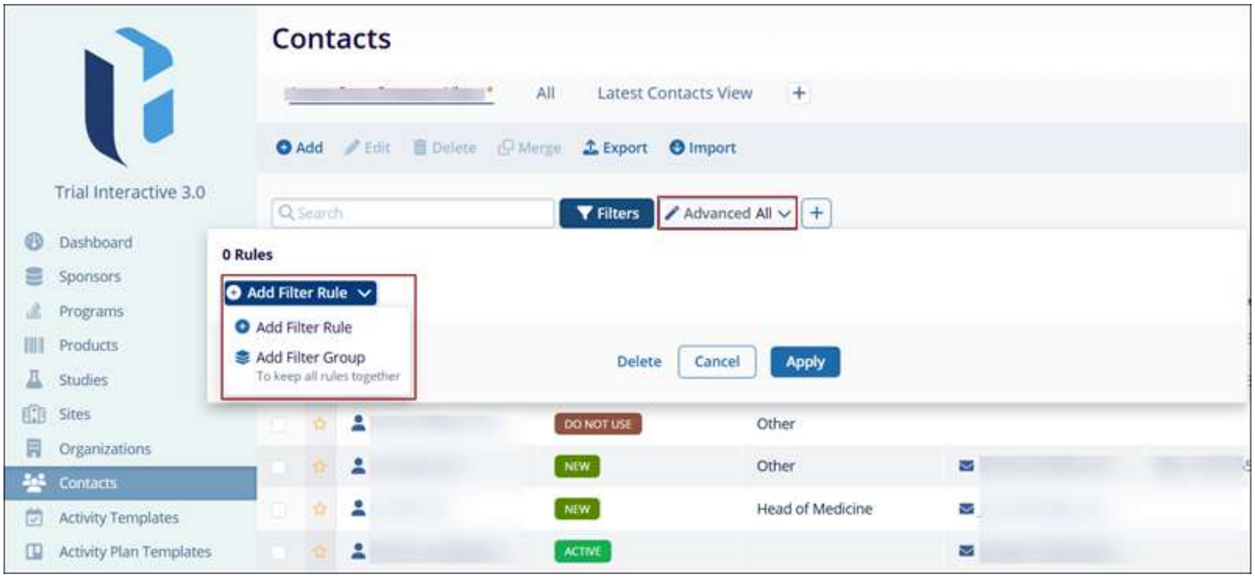


Figure: Apply Advanced Filters

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 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 2
- Operator: Is
- Text: 134, Red Lion Street, London

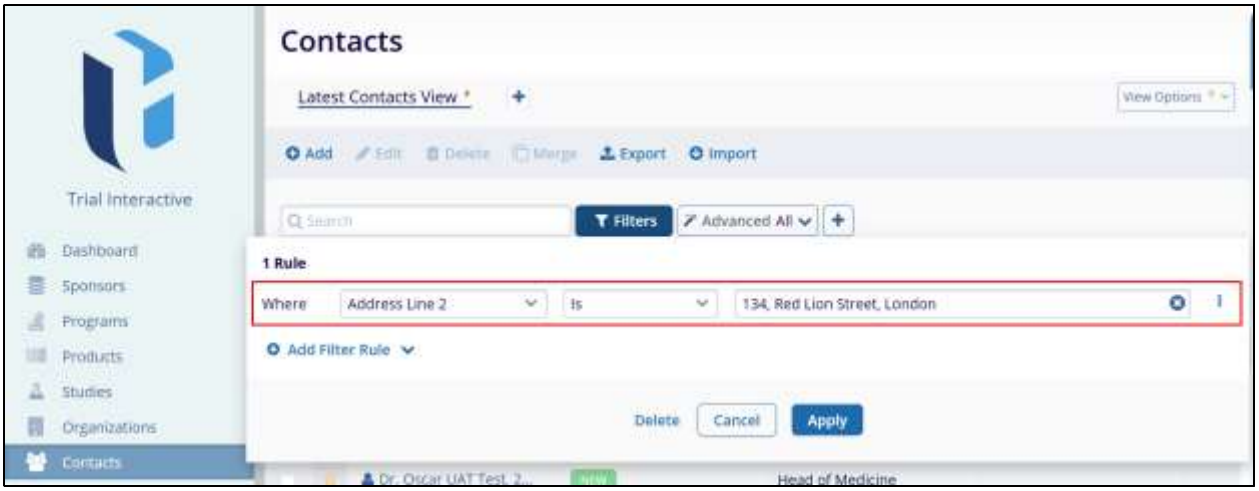


Figure: Configure Advanced filters

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.

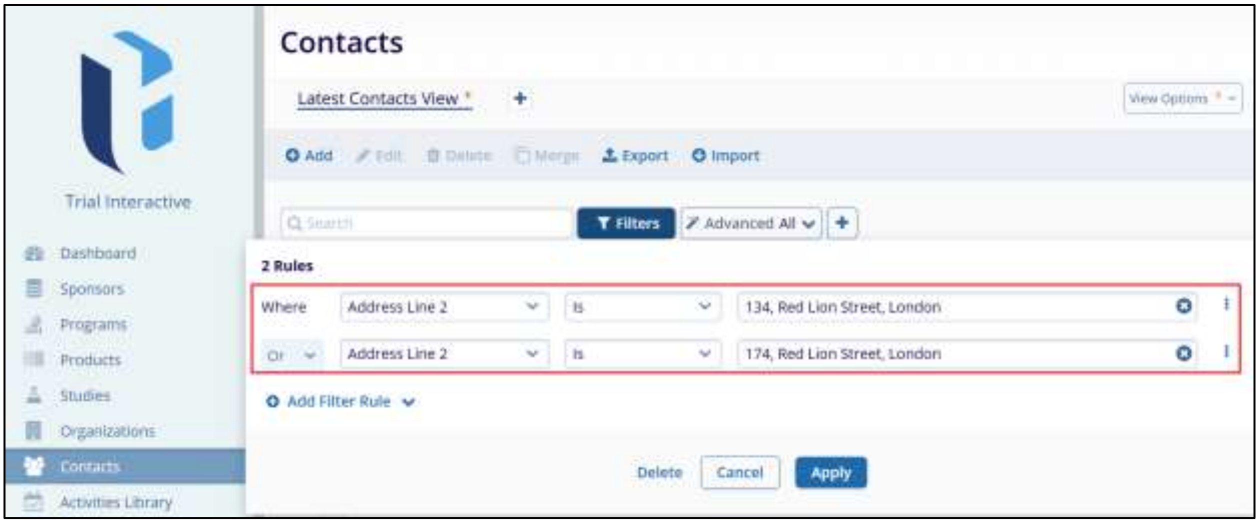


Figure: Advanced filters with And/Or conditions

Now, if the 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.

Customizing columns on the Contacts screen

To customize the contacts screen, the user can perform the following

- Marking a contact as a favorite
- Hiding a column
- Locking a column
- Managing the visibility of the columns.
- Sorting in ascending or descending order

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.

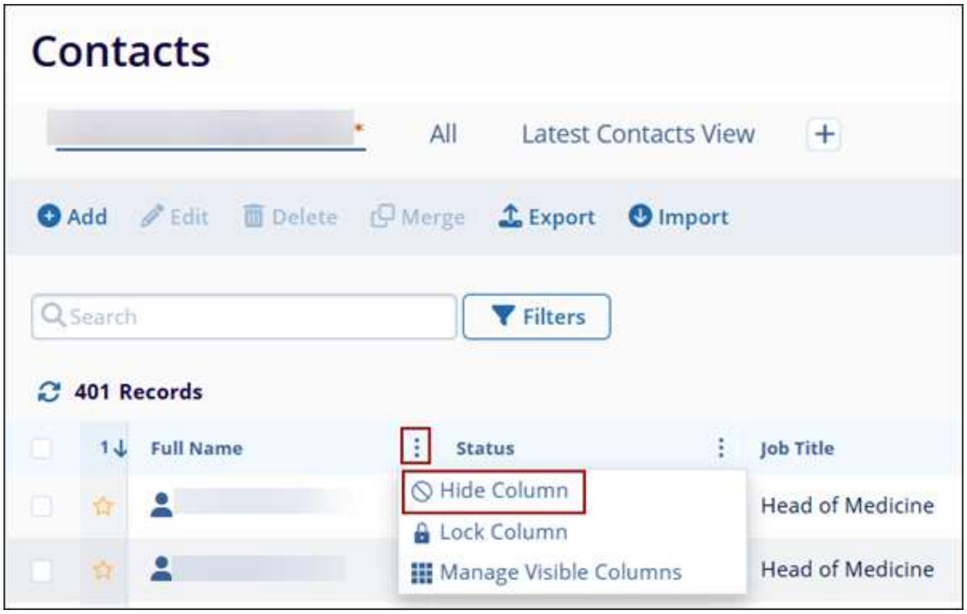


Figure: Hide Column

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. Click on the check box to unhide the column and click on the Apply Changes button.

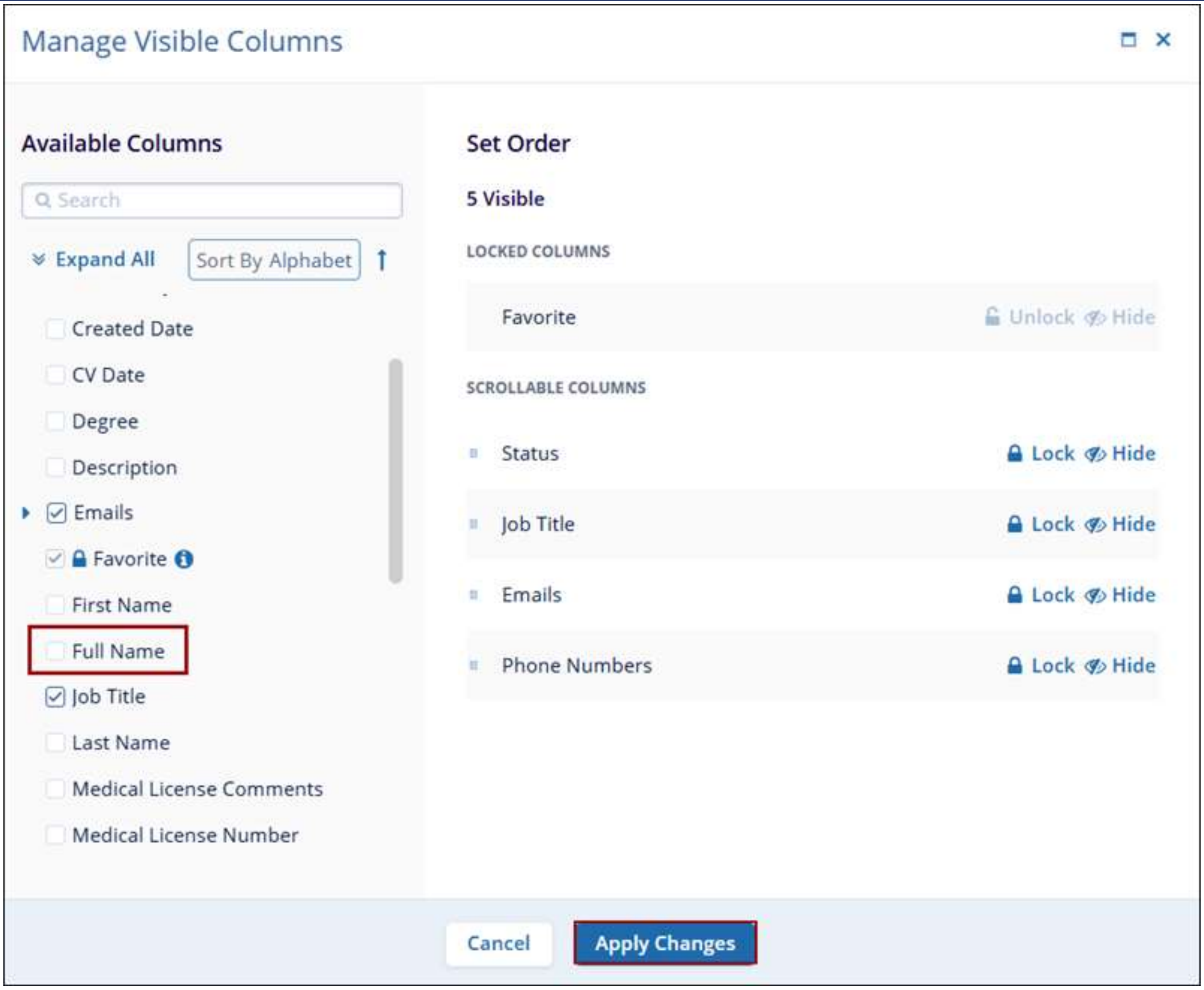


Figure: Unhide column

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.

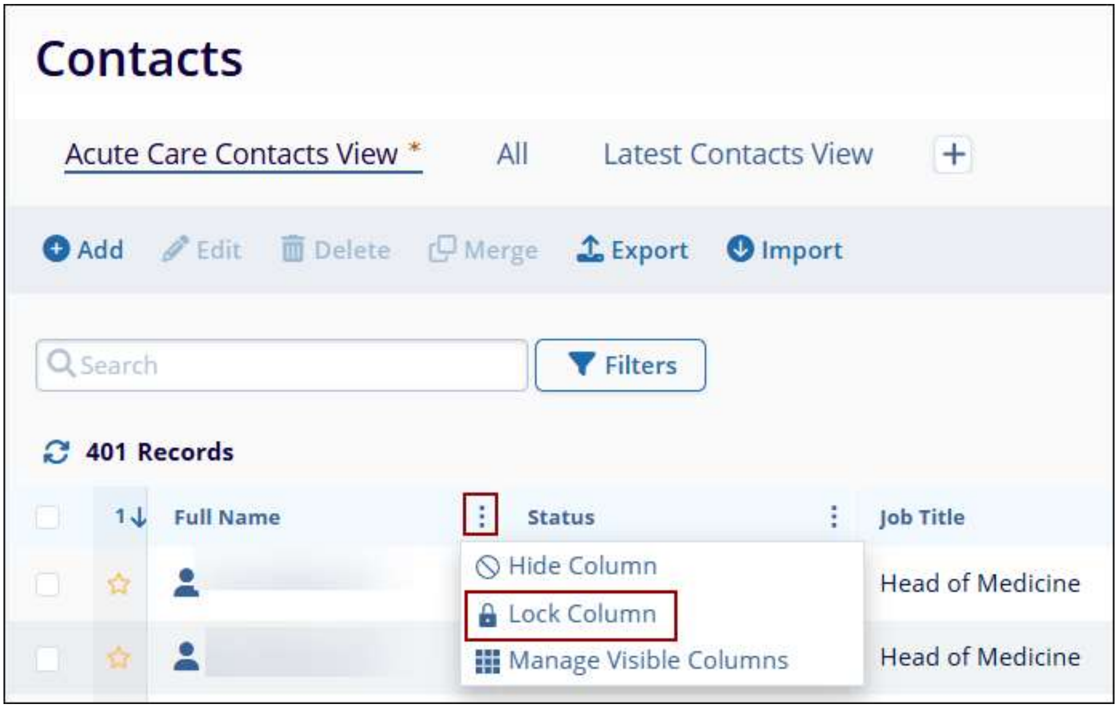


Figure: Lock Column

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

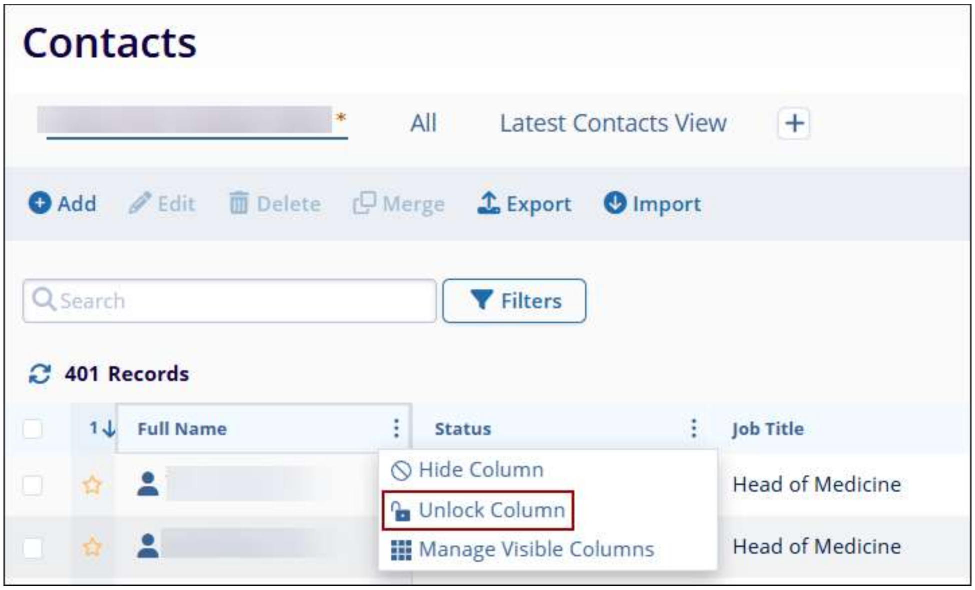


Figure: Unlock Column

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

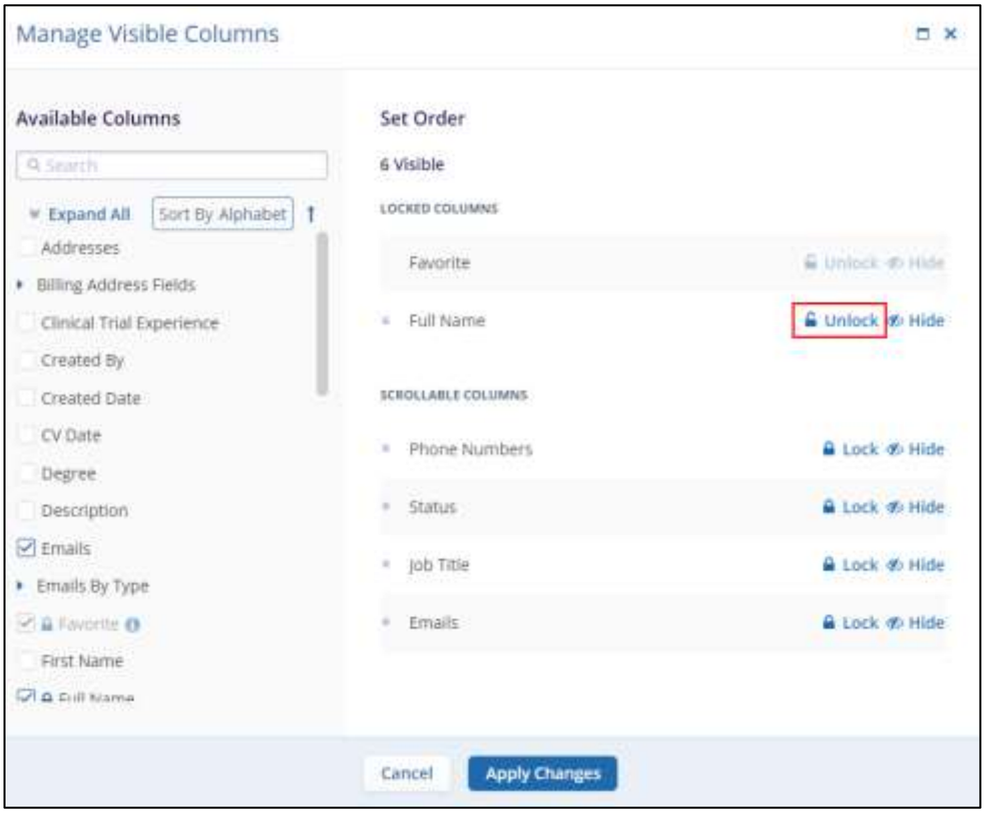


Figure: Unlock column through Manage Visible Columns

Manage Visible Columns

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

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

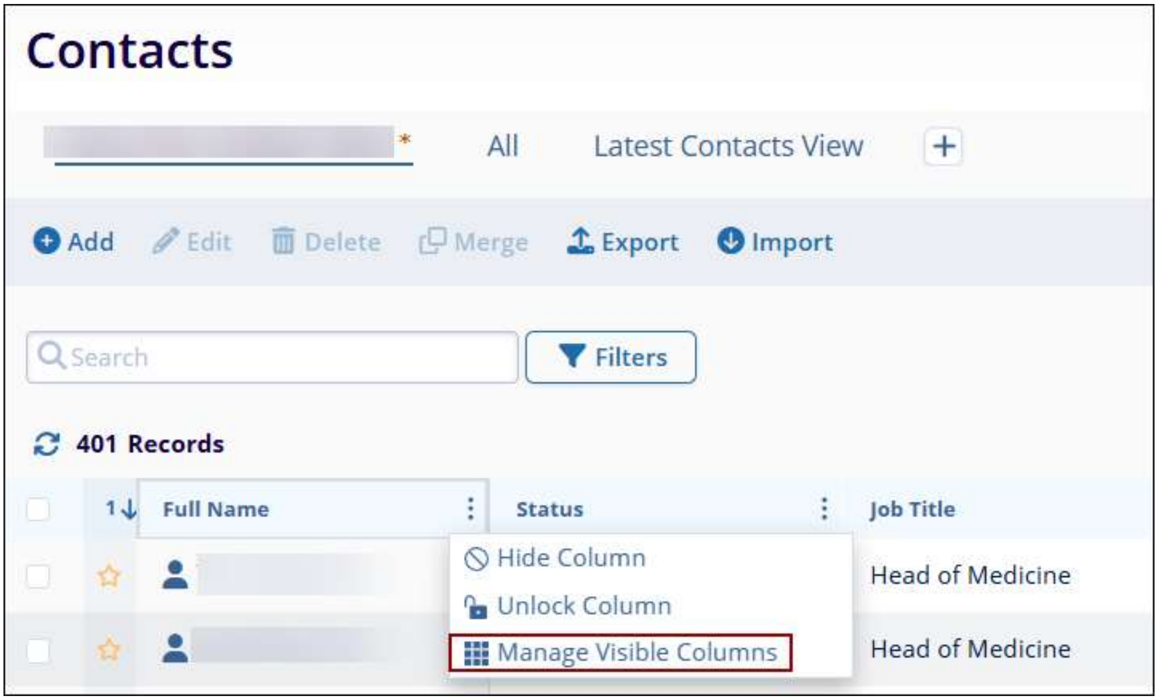


Figure: Manage Visible Columns

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

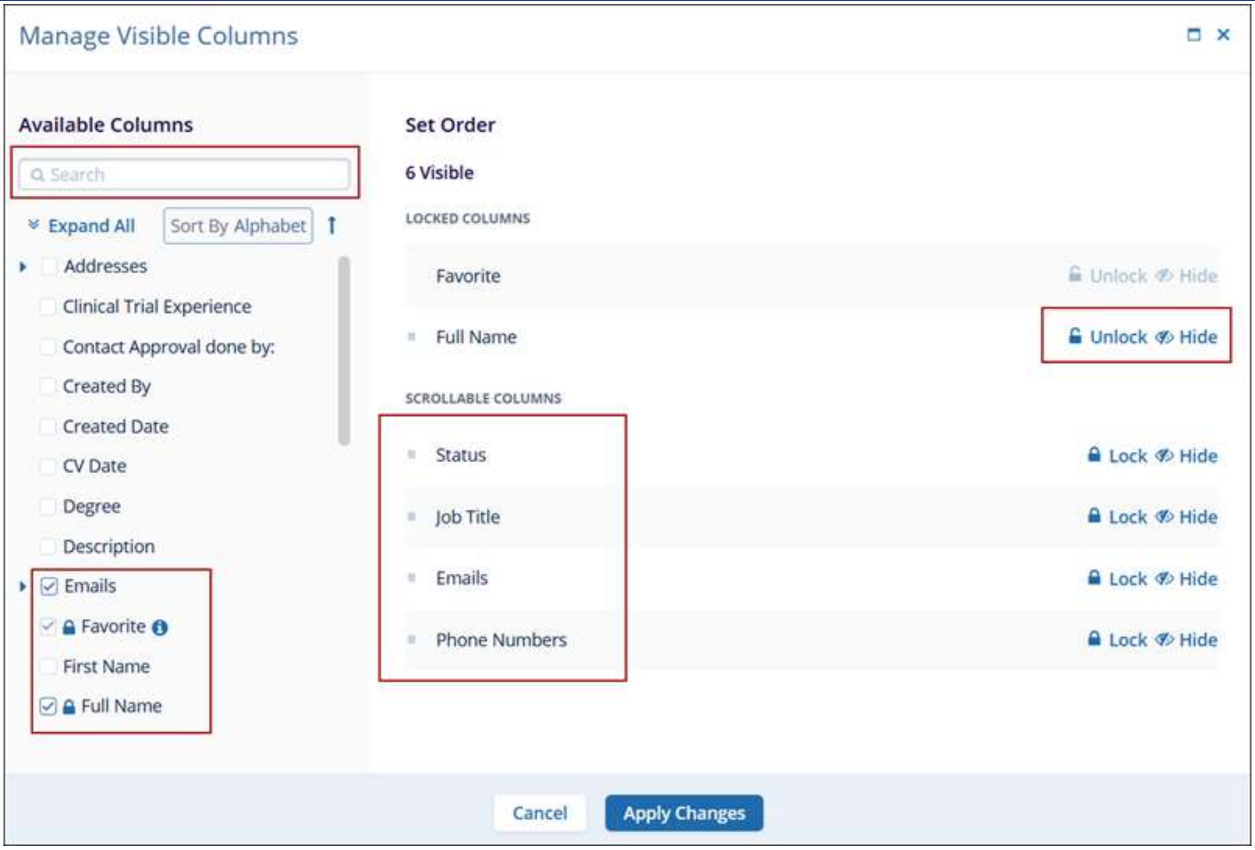


Figure: Manage Visible Columns options

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

Sort Ascending and Descending

The Sort Ascending and Descending options are available only for the Status and Job Title columns.

To sort the columns in ascending order, follow the steps below.

1. Click on the ellipsis (vertical three dots) icon present beside each header field and select Sort Ascending or Sort Descending.

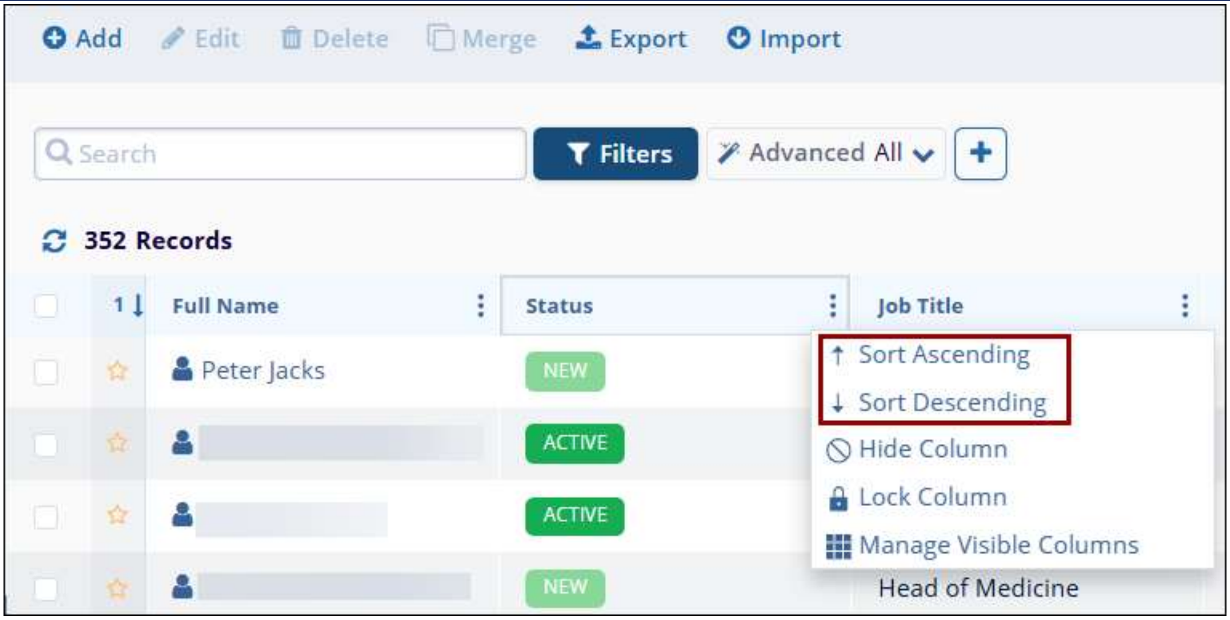


Figure: Sort Ascending and Descending

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 criterion 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.
6. Click on the Clear Sorting button to remove all the sort criteria.
7. Click on the Delete button to delete a specific sort criterion.

Figure: Apply sorting criteria

Important

Only when the sorting criteria are applied to a particular column, the ellipses (three vertical dots) icon will display Ascending and Descending options.

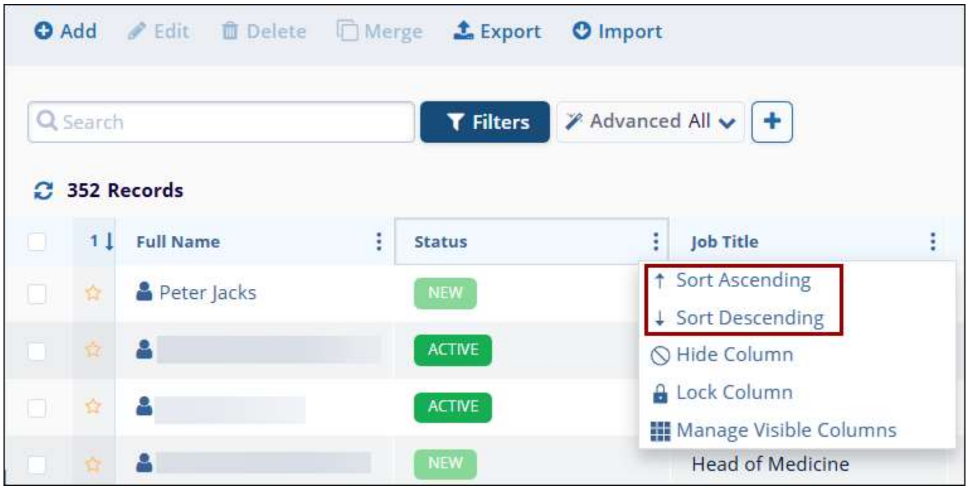


Figure: Sort Ascending and Descending

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.

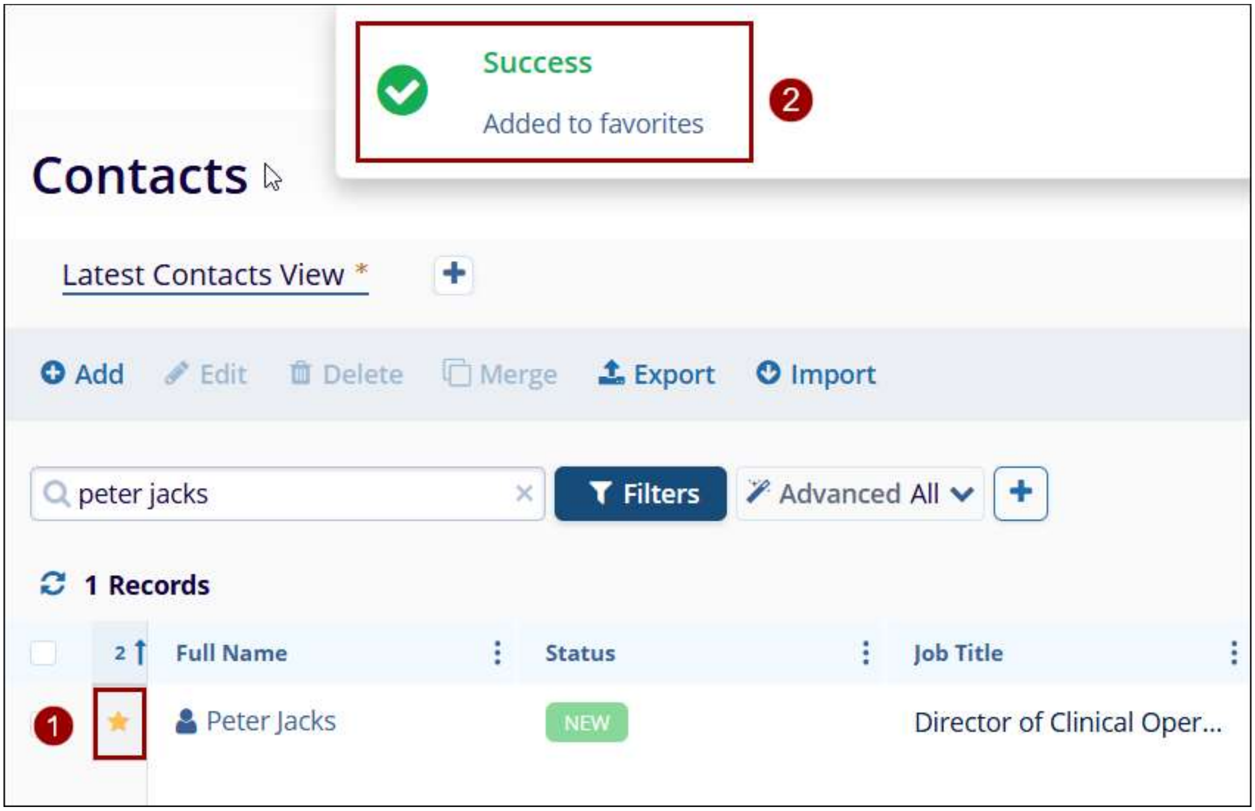


Figure: Mark a contact as a favorite

Note: Click on the same icon to remove the contact as a favorite.

CHAPTER 12. USER MANAGEMENT

This section describes the process of managing users in CTMS.

Note: Currently, only Super Administrators can access the User Management module.

Invite User

To create a new user in CTMS, follow the steps below.

1. Select the User Management link, from the left-hand navigation pane.
2. On the User Management screen, click on the +Invite button.

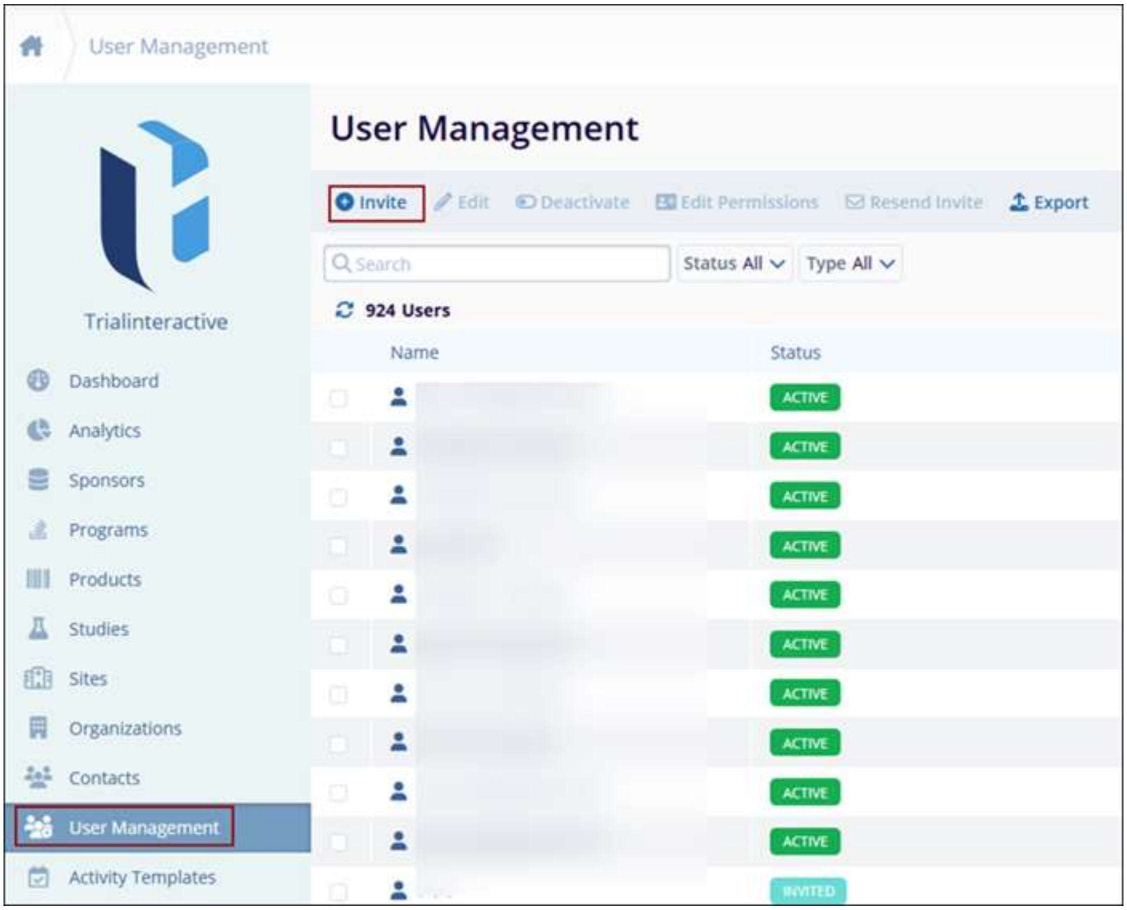


Figure: Invite Users

3. On the Invite User screen, fill in the following information.
   a. Email*
   b. Prefix
   c. First Name
   d. Middle Name
   e. Last Name
   f. Suffix
   g. System Access Permission*
4. Click on the Invite button.

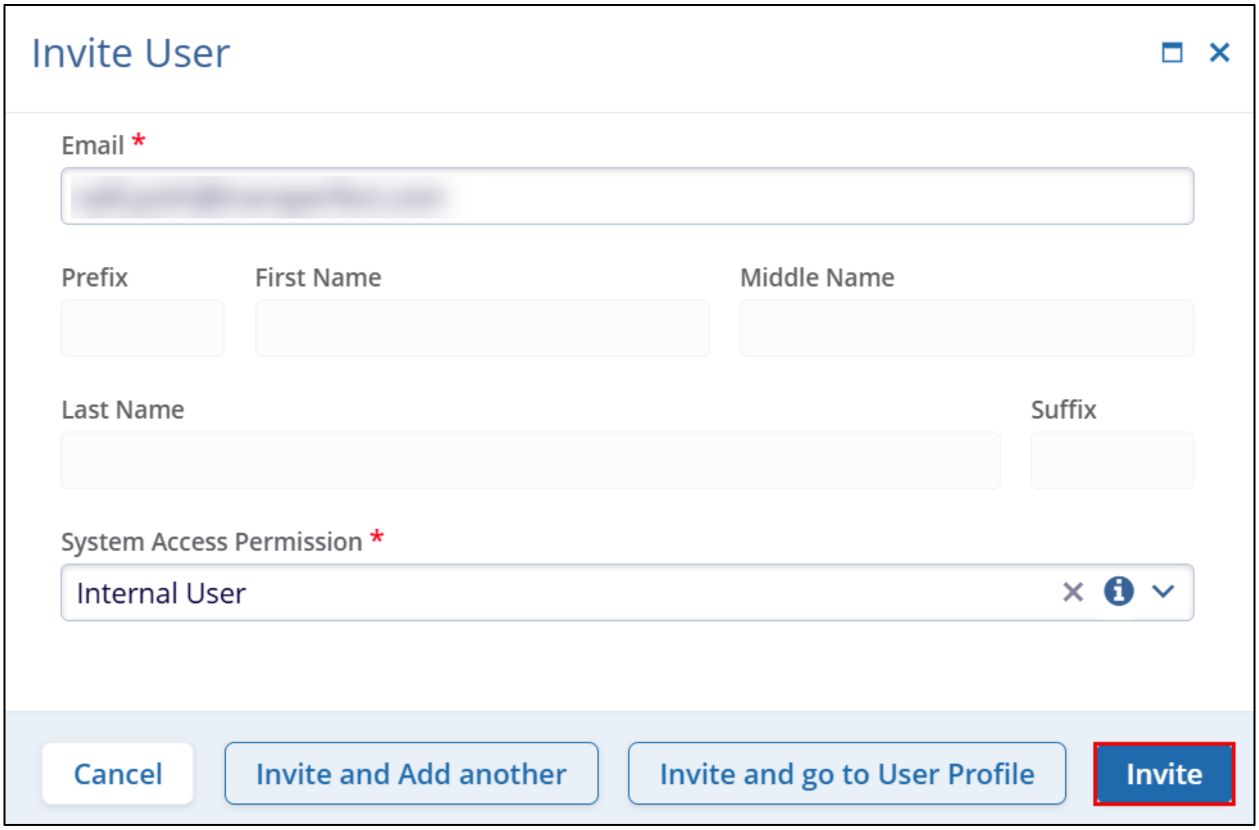


Figure: Invite User fields

Edit User

To edit the user, follow the steps below.

1. Select a user by clicking on the checkbox.
2. Click on the Edit button from the top menu bar.
3. Make the required edits to the user details on the Quick View panel on the right-hand side of the screen.

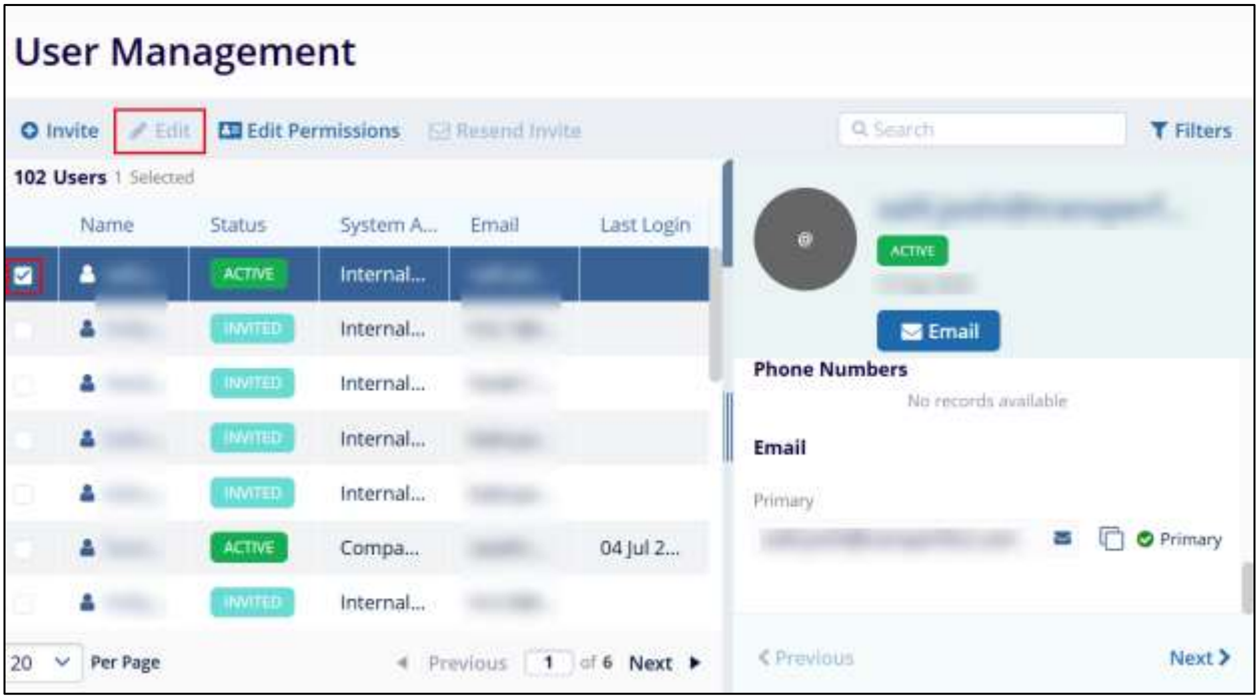


Figure: Edit User

Edit Permissions

To edit user permissions, follow the steps below.

1. On the User Management screen, select a user by clicking on the checkbox.
2. Click on the Edit Permissions button from the top menu bar.

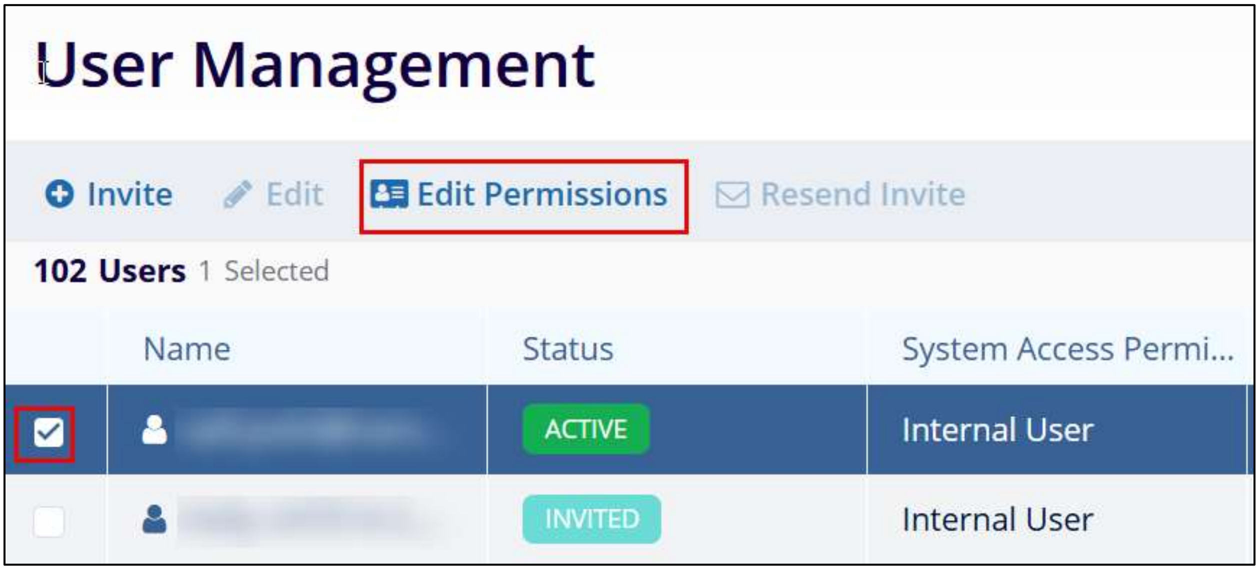


Figure: Edit Permissions

3. On the Edit Permissions screen, click on the System Access Permission dropdown and select a user role.

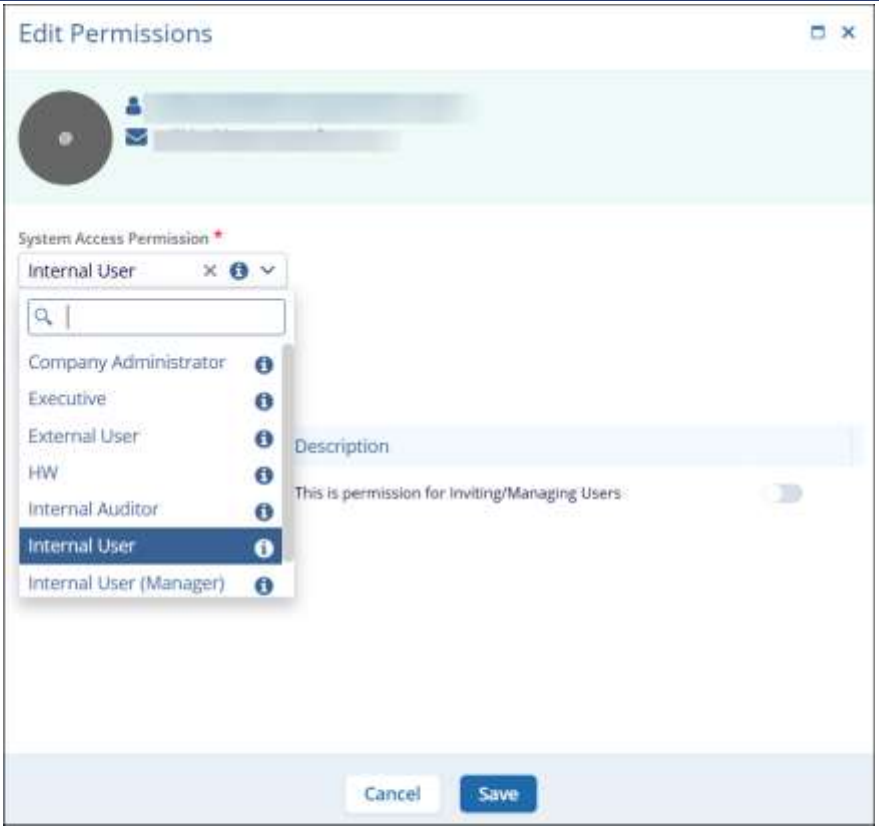


Figure: System Access Permissions

4. Enable the ‘Global Permissions’ toggle switch to grant the ‘Invite/Manage User’ access to the user.
5. Click on the Show Level Permissions button to manage user access at Organization, Program and Study Levels.

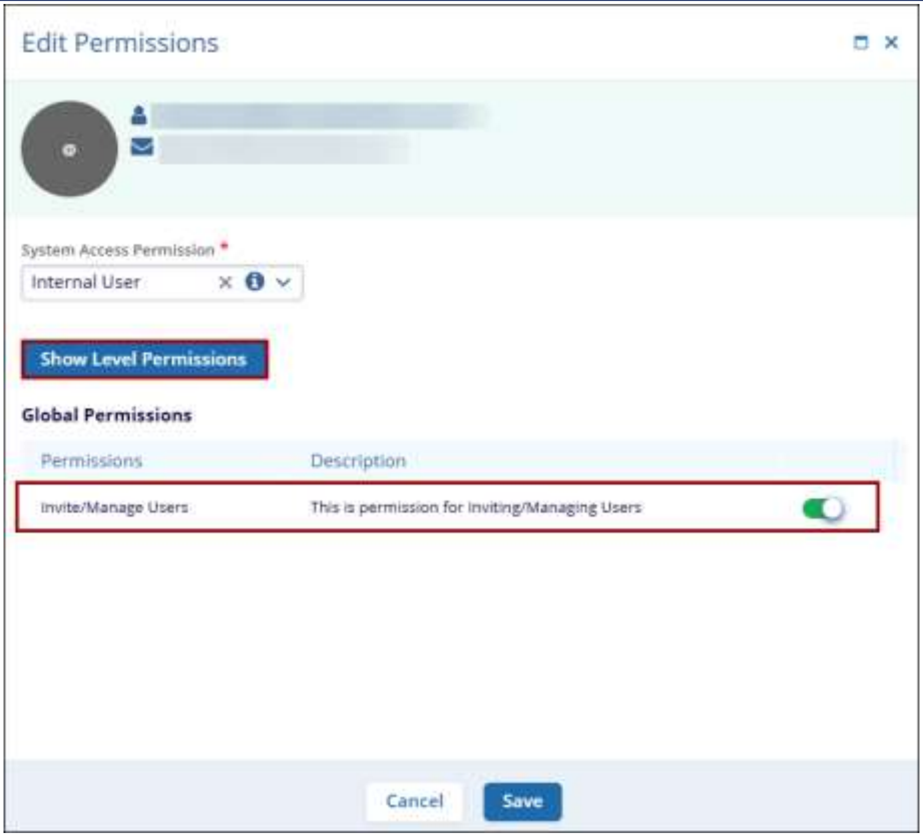


Figure: Global Permissions

6. Within the Level Permissions section, click on the 'Show All' radio button, expand each option and select an option from the Access Permission dropdown.
7. Select the 'Show Assigned Permissions' radio button to view the already assigned permissions at the study level.
8. Click on the Save button once all the access permissions are updated.

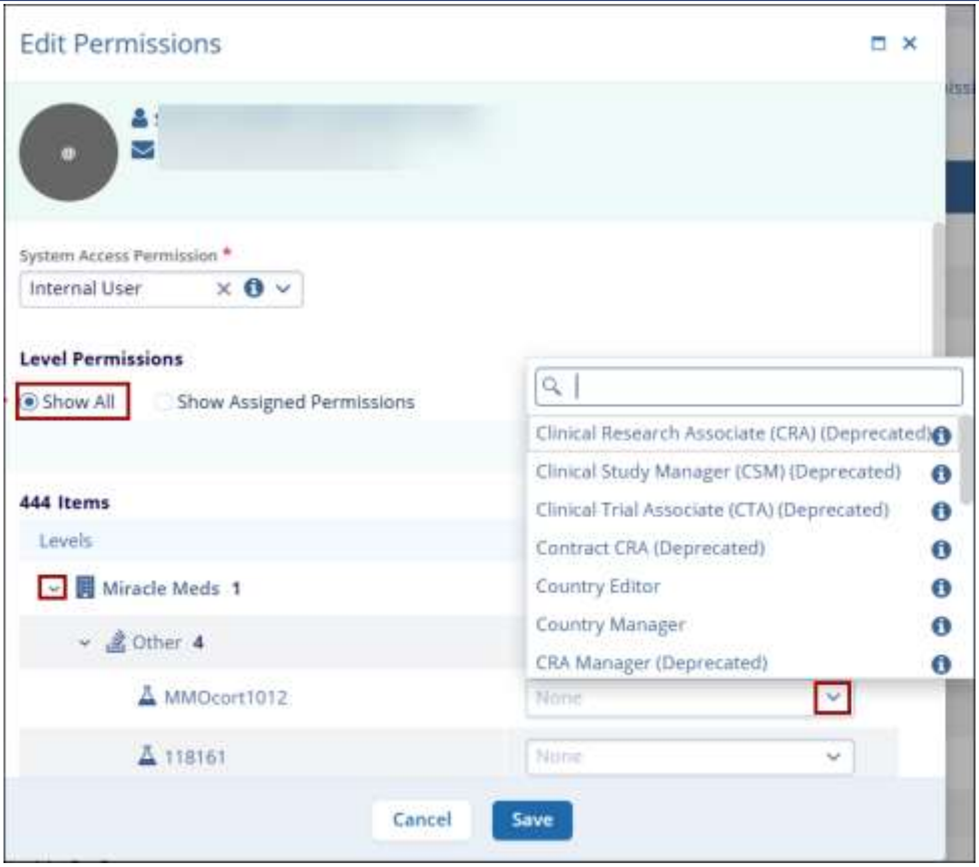


Figure: Level Permissions

Resend Invite

To resend the invite to users, follow the steps below.

1. Select a user with Invited status.
2. Click on the Resend Invite.
3. Click on the Resend button on the confirmation popup.

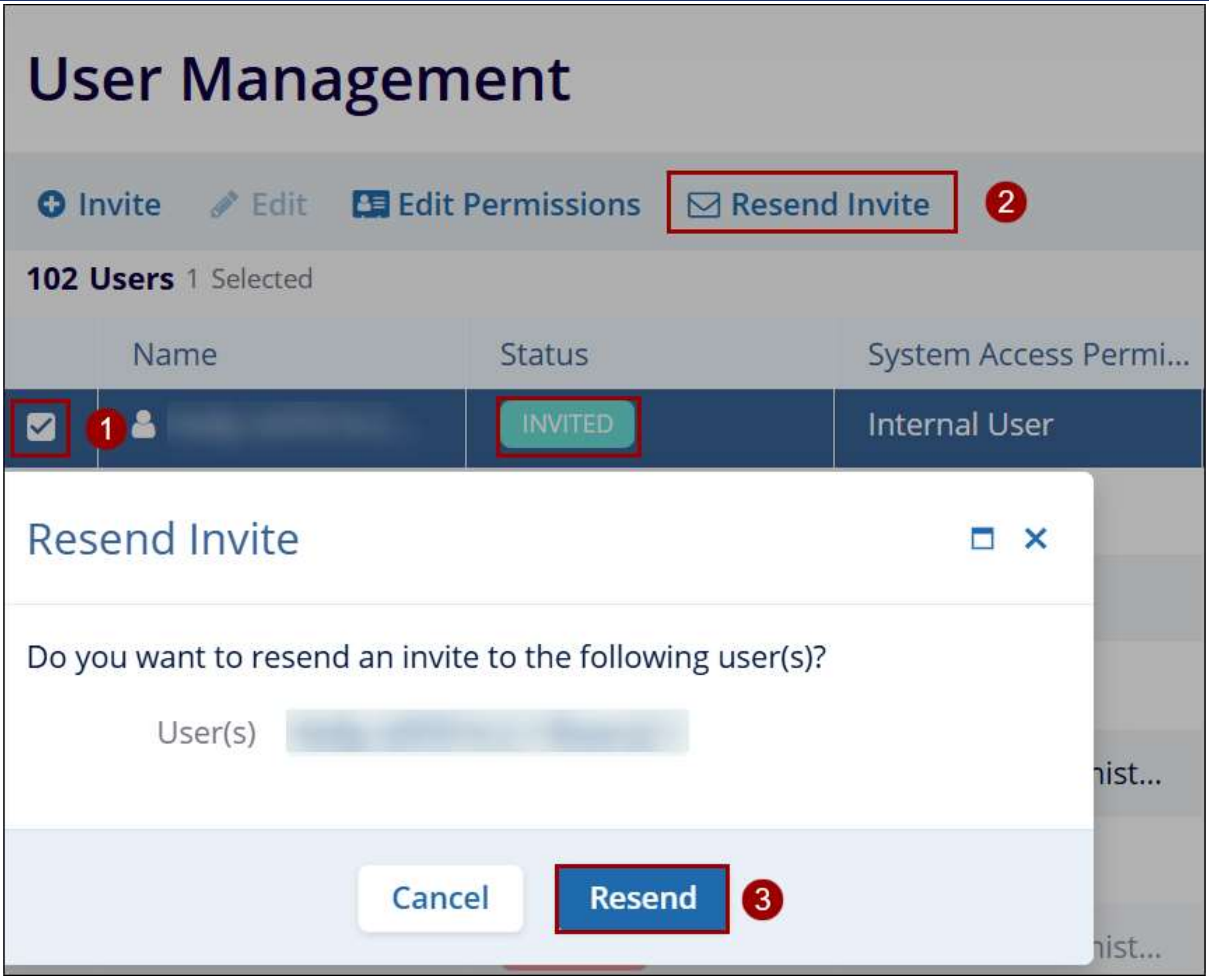


Figure: Resend Invite

4. Once the invitation is successfully sent to the user, the success message is displayed.

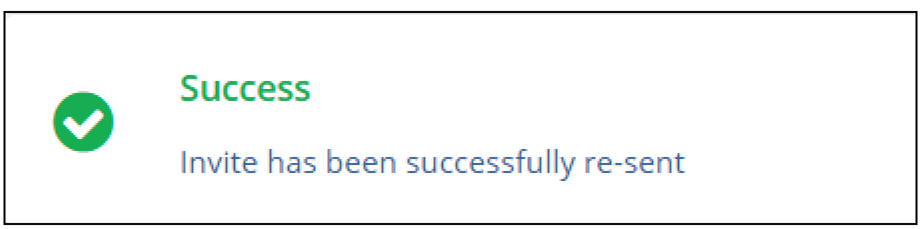


Figure: Resend Invite success message

CHAPTER 13. ACTIVITY TEMPLATES

This section describes the Activity Plan Templates module in the application.

Accessing Activity Templates

To access the Activity Templates, follow the steps below.

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

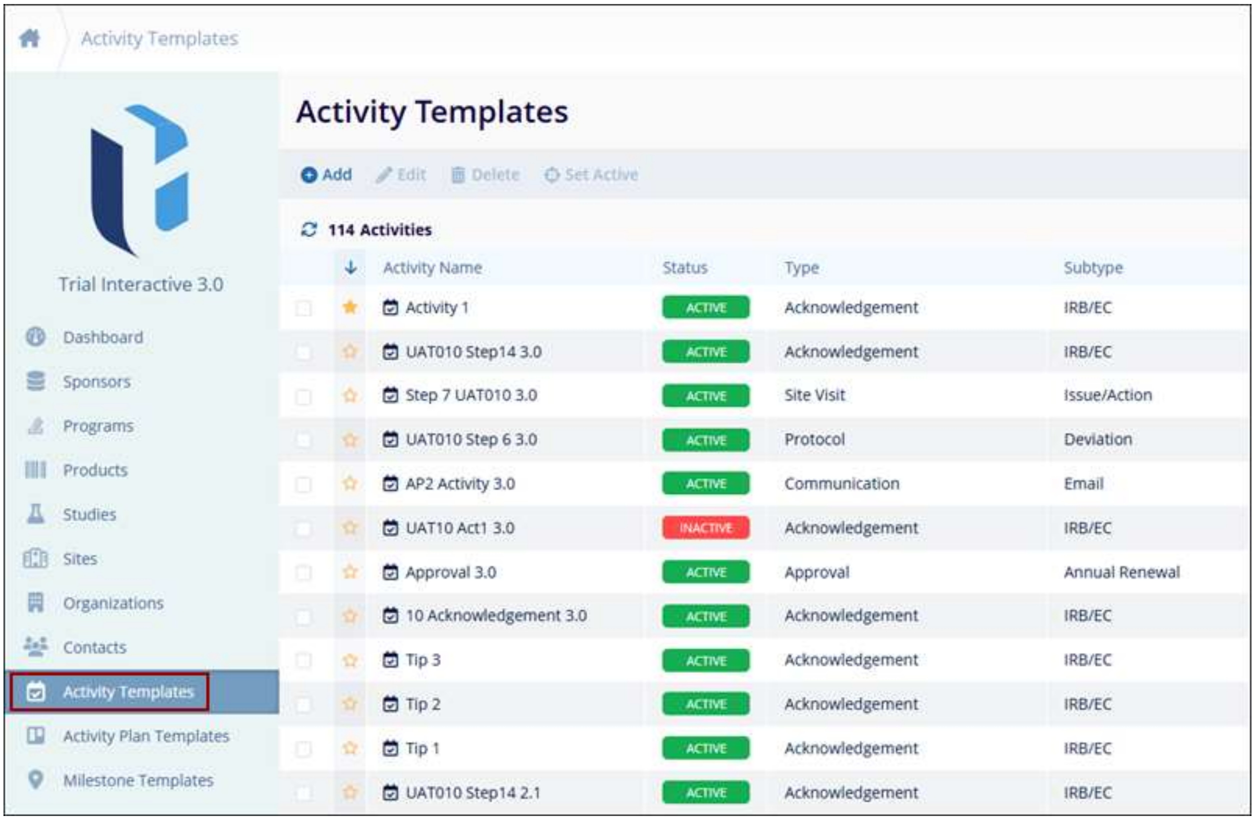


Figure: Accessing Activity Templates

Creating Domain Activity Template Records

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

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

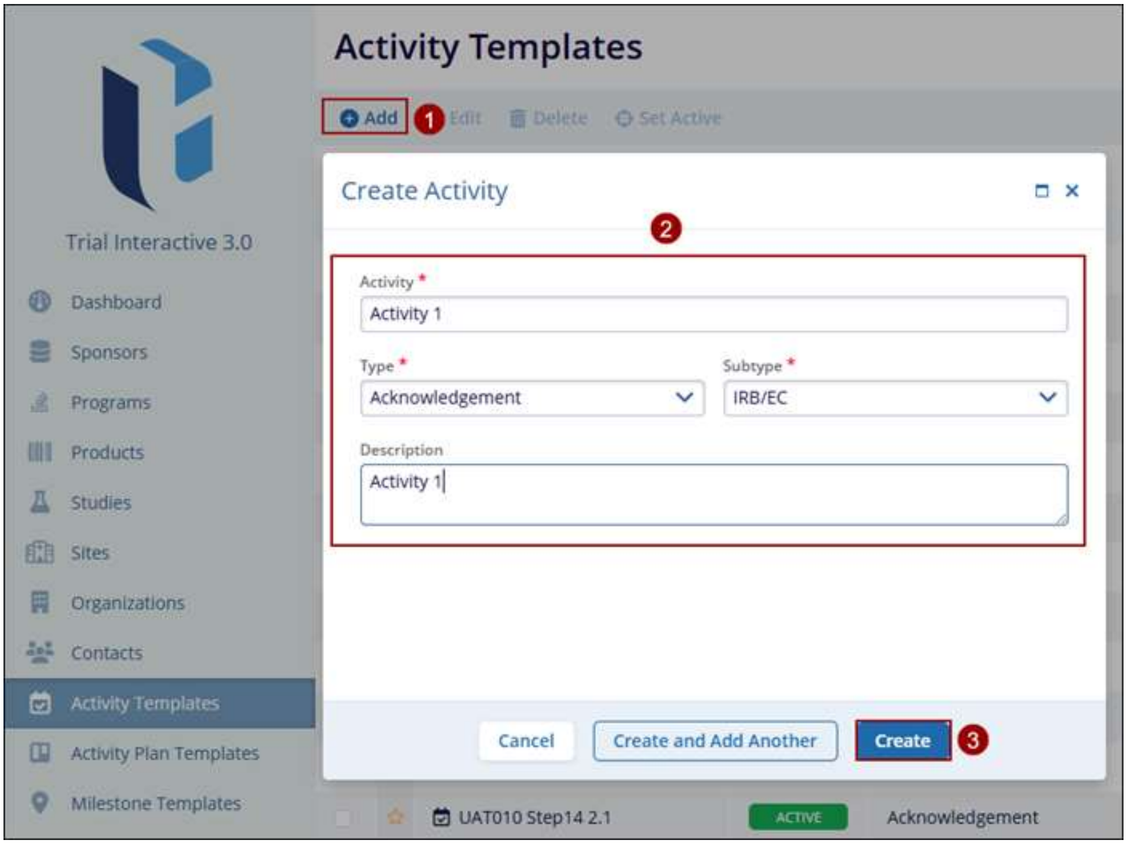


Figure: Creating Domain Activity Template Records

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 Activity Template Records

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

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

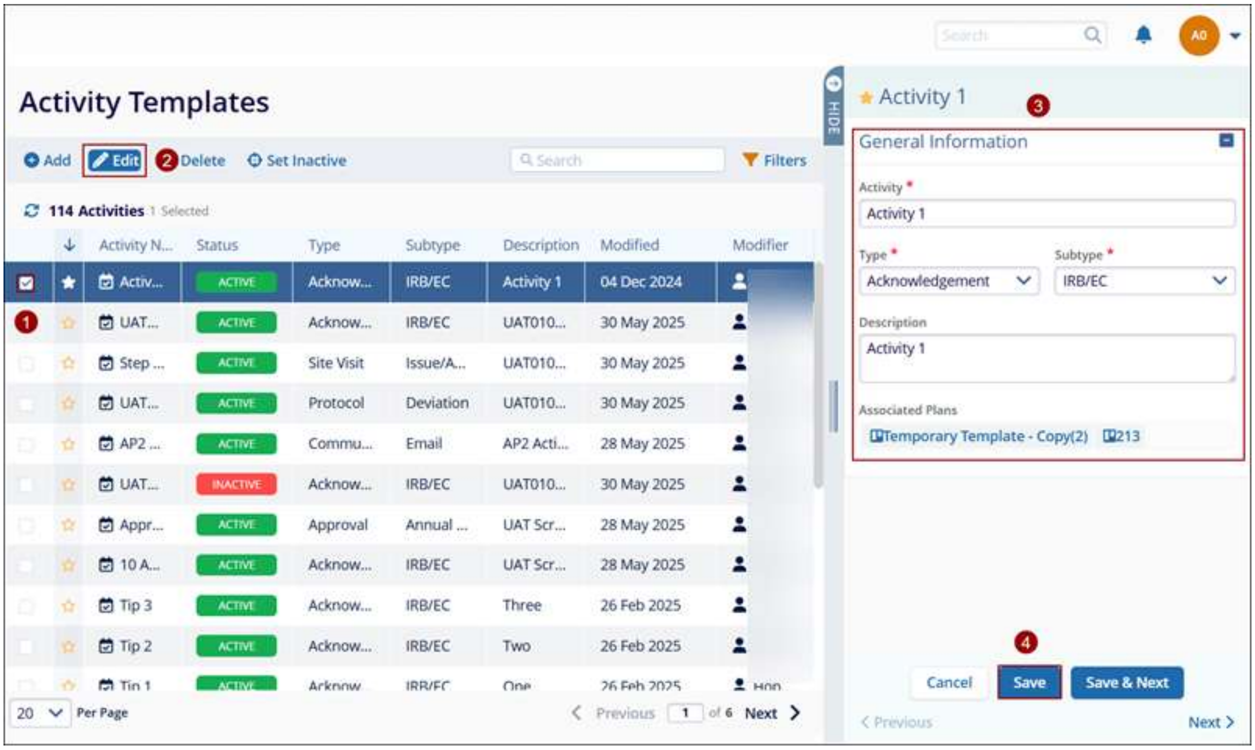


Figure: Editing Domain Activity Template Records

Deleting Domain Activity Records

To delete Domain Activity Template 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.

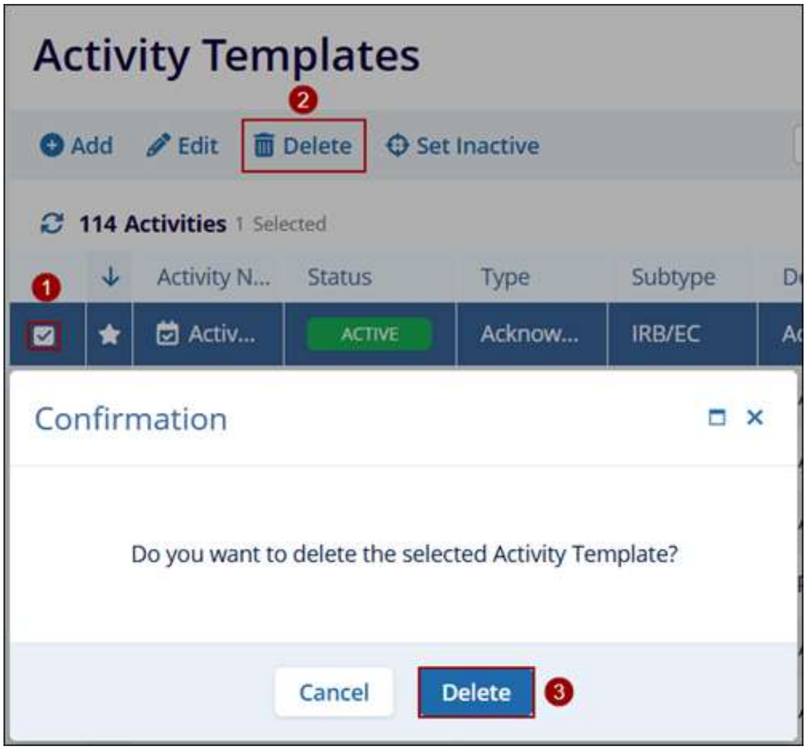


Figure: Deleting Domain Activity Records

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.

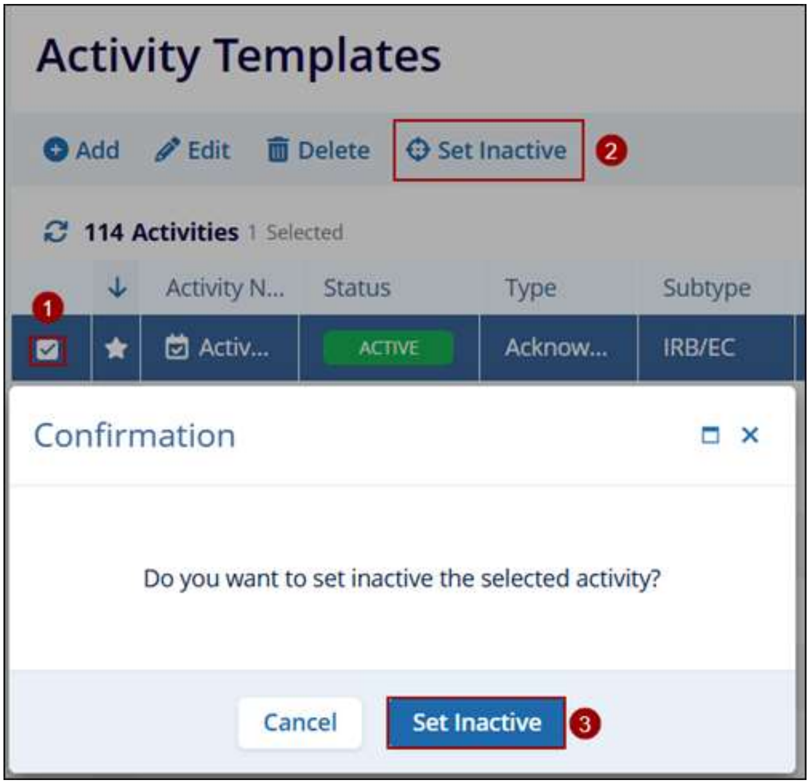


Figure: Change activity record status to Inactive

Setting Domain Activity Template Records to Active

To set an activity template record as active, follow the steps below.

1. Click the checkbox of the activity name with an Active status.
2. Click on the Set Active button from the top menu bar.
3. On the Confirmation popup, click on the Set Active button.

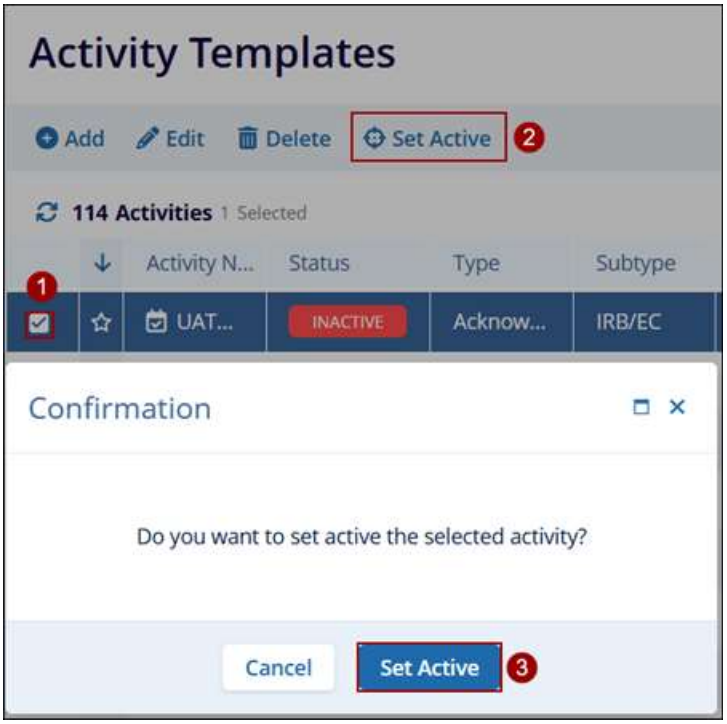


Figure: Change activity record status to active

Customizing Activity Templates screen

Filters and Sorting

To apply filters and sort columns, 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 favorite column header.

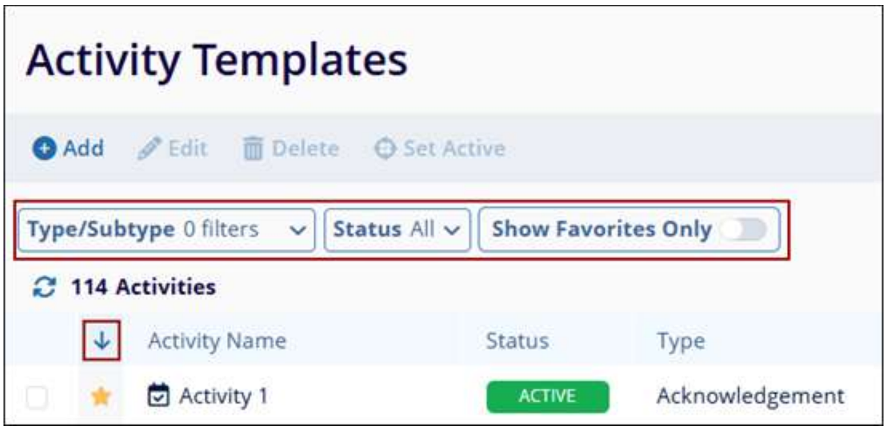


Figure: Activity Templates - Filters

Marking an activity as a favorite

To mark an activity as a favorite, click on the star icon beside the Activity Name.

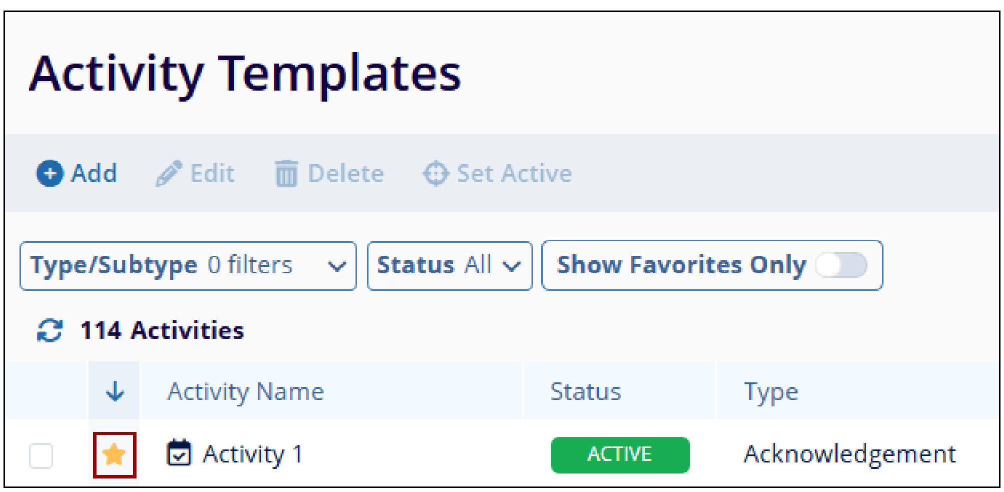


Figure: Activity Templates – Mark as favorite

CHAPTER 14. ACTIVITY PLAN TEMPLATES

Accessing Activity Plan Templates

To access Activity Plan Templates, follow the steps below.

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

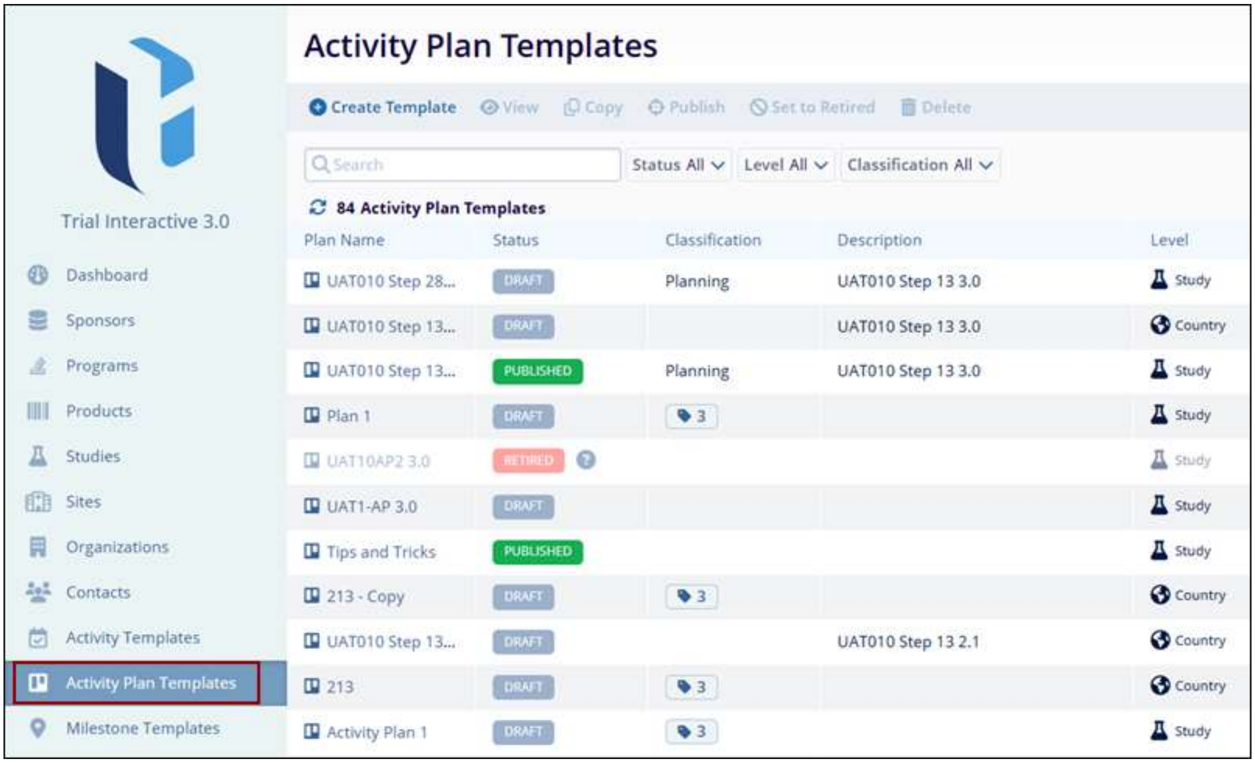


Figure: Accessing Activity Plan Templates

Creating Domain Activity Plan Template

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

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

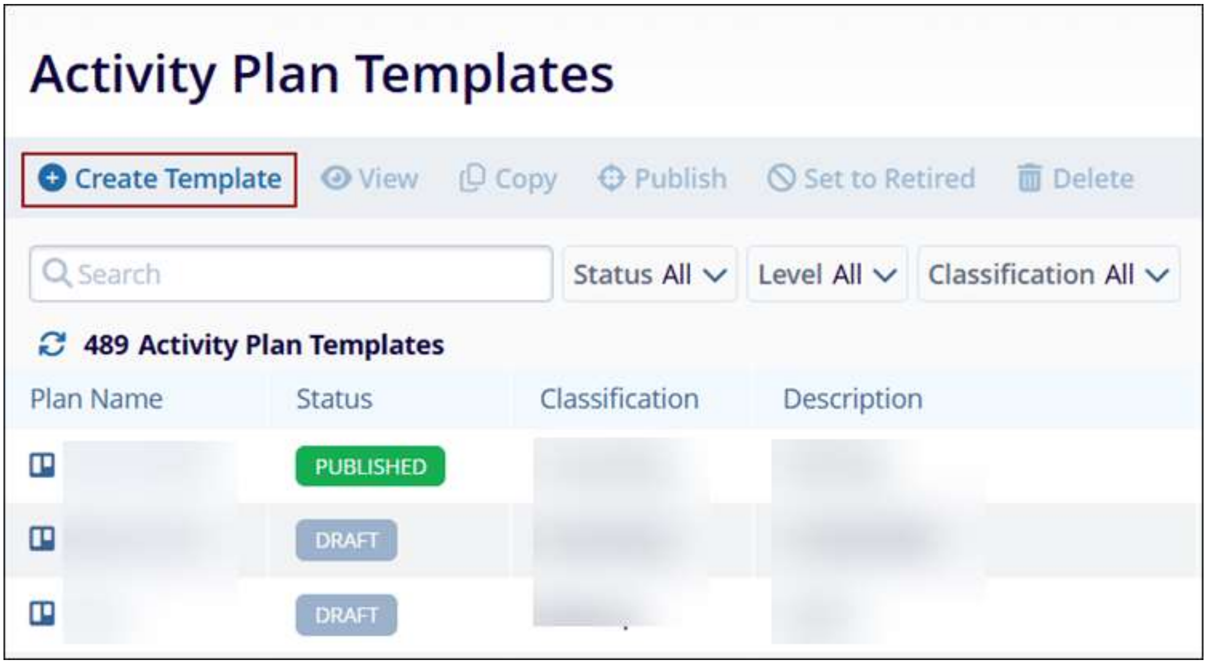


Figure: Create Domain Library Activity Template

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

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

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

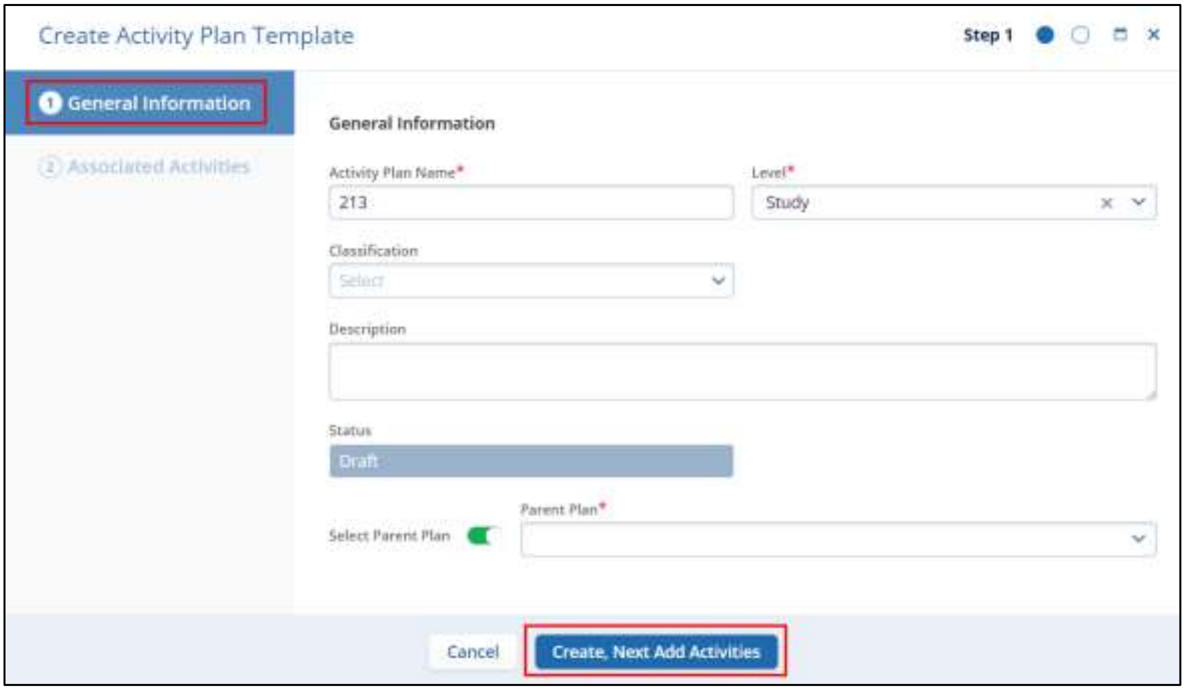


Figure: Domain Library Activity Template-General Information

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

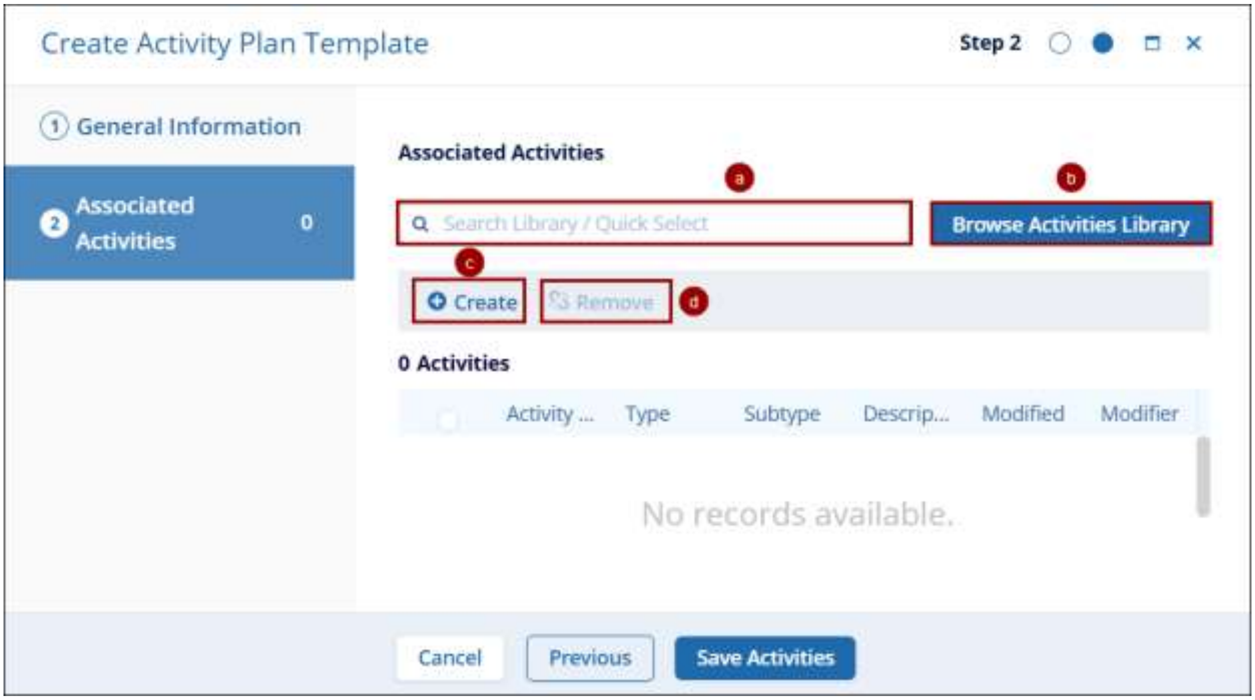


Figure: Domain Library Activity Template-Associated Activities

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

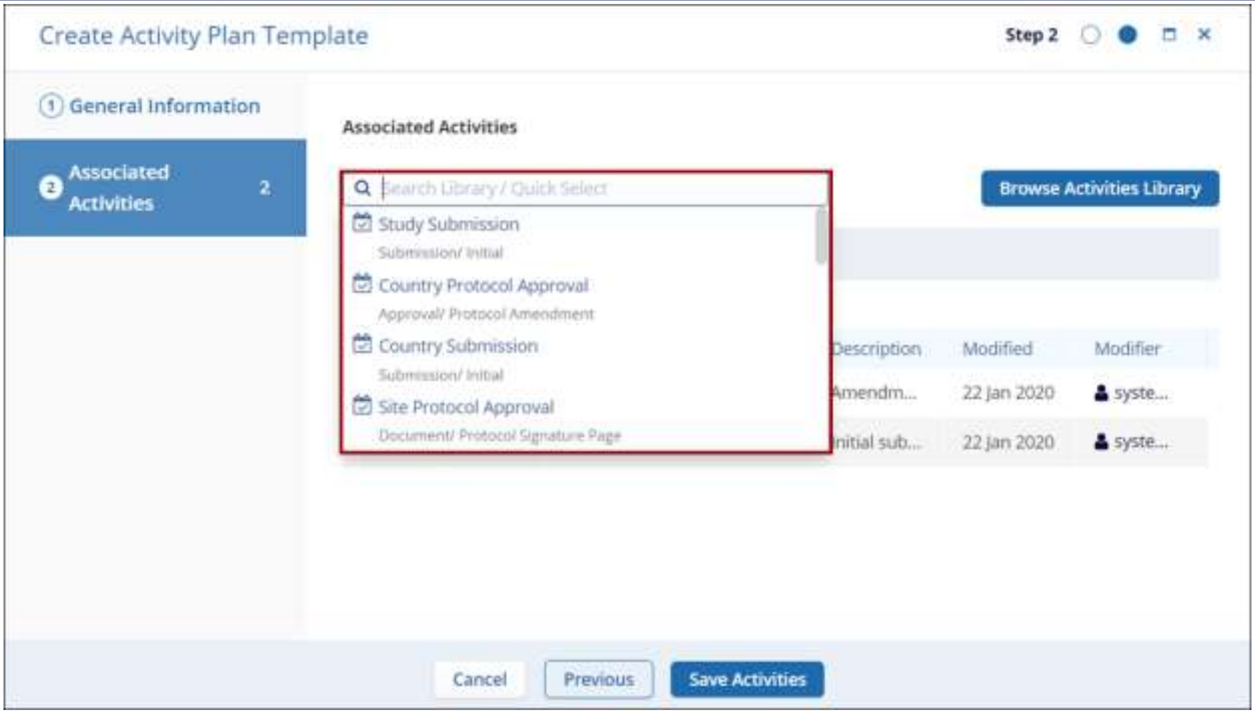


Figure: Search Library and Quick Select

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 (number of activities) Activities button.

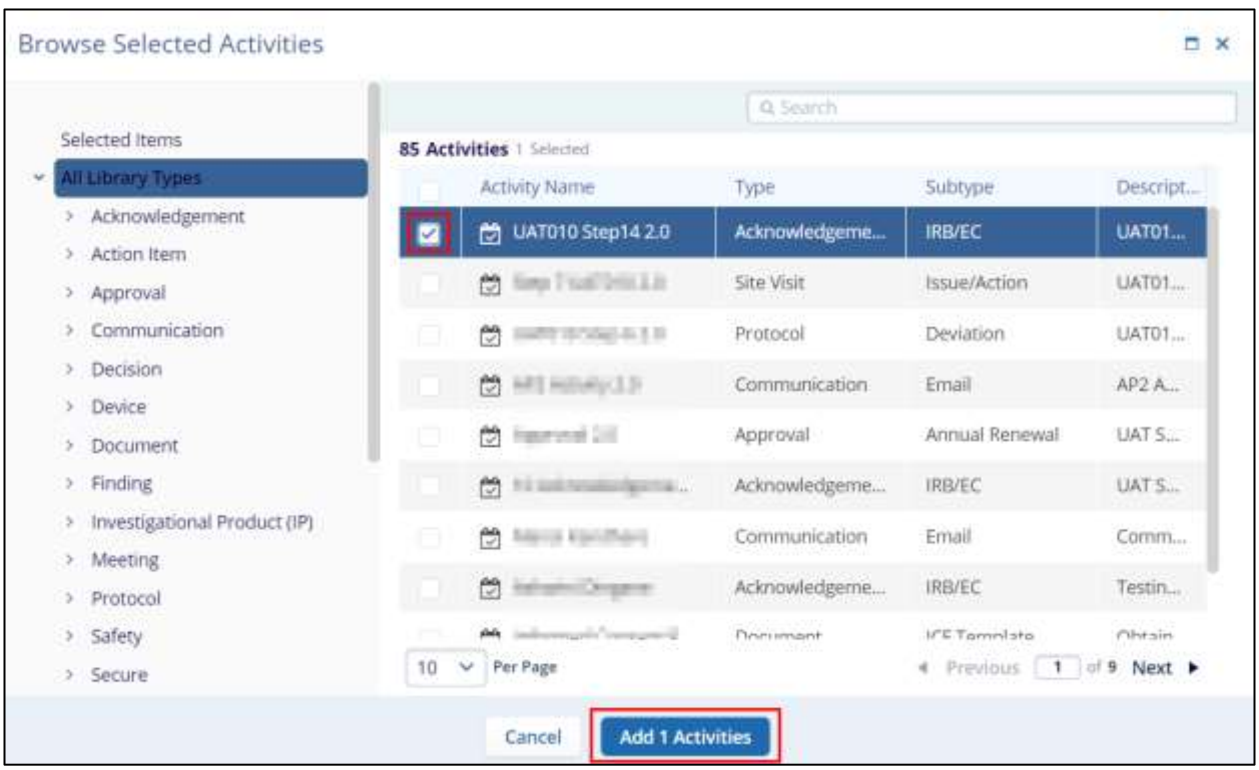


Figure: Browse Activities Library

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

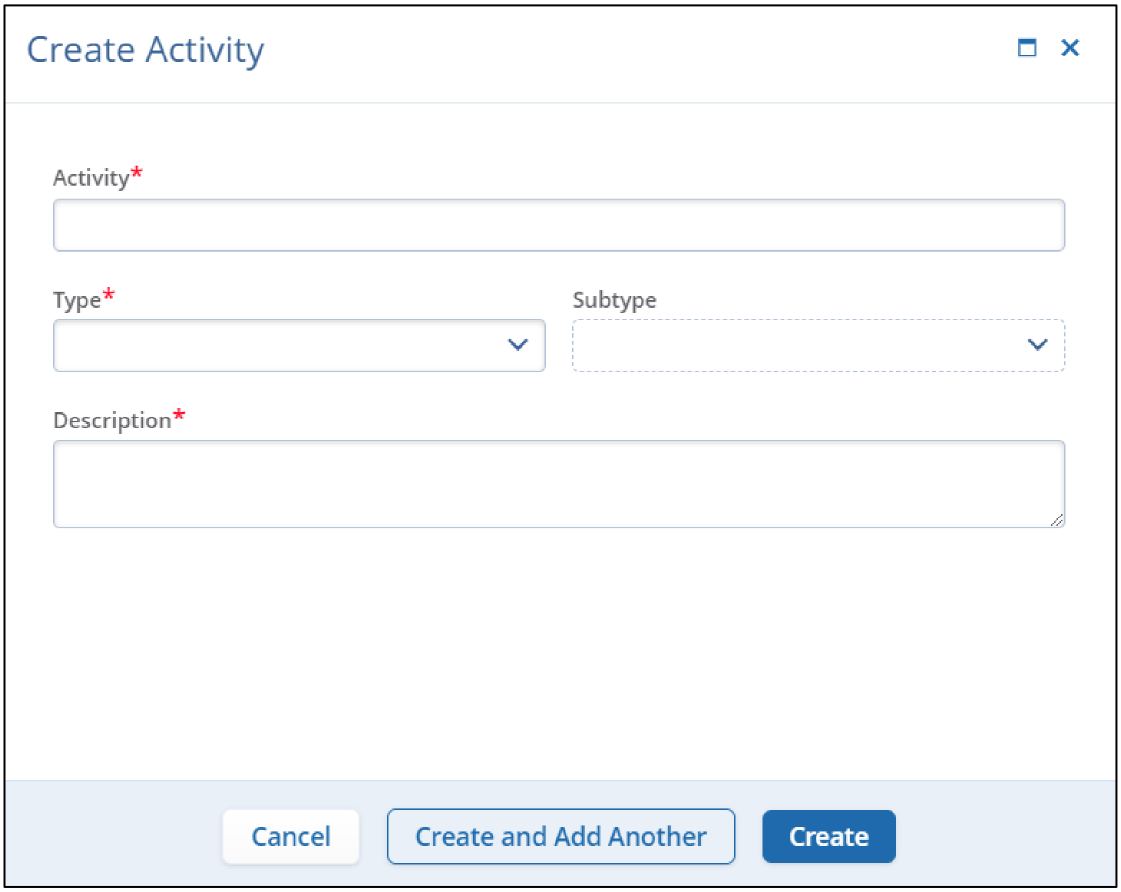


Figure: Create New Activity

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

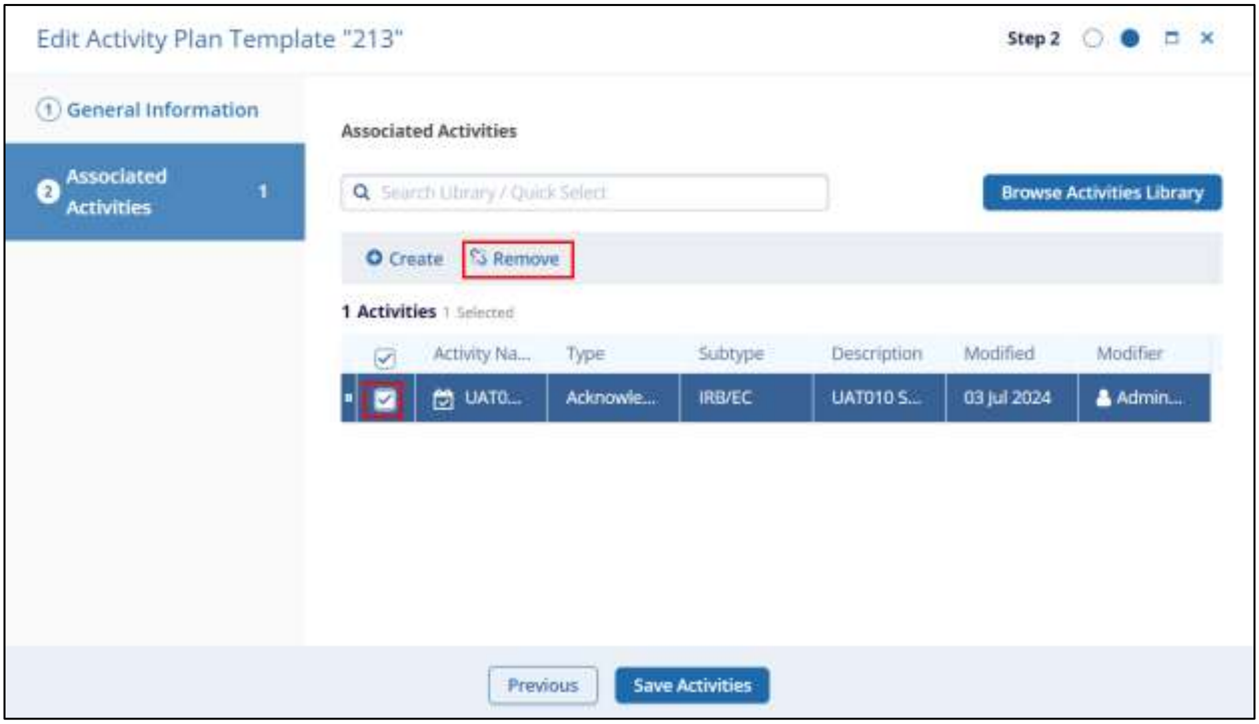


Figure: Remove Activities

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

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.

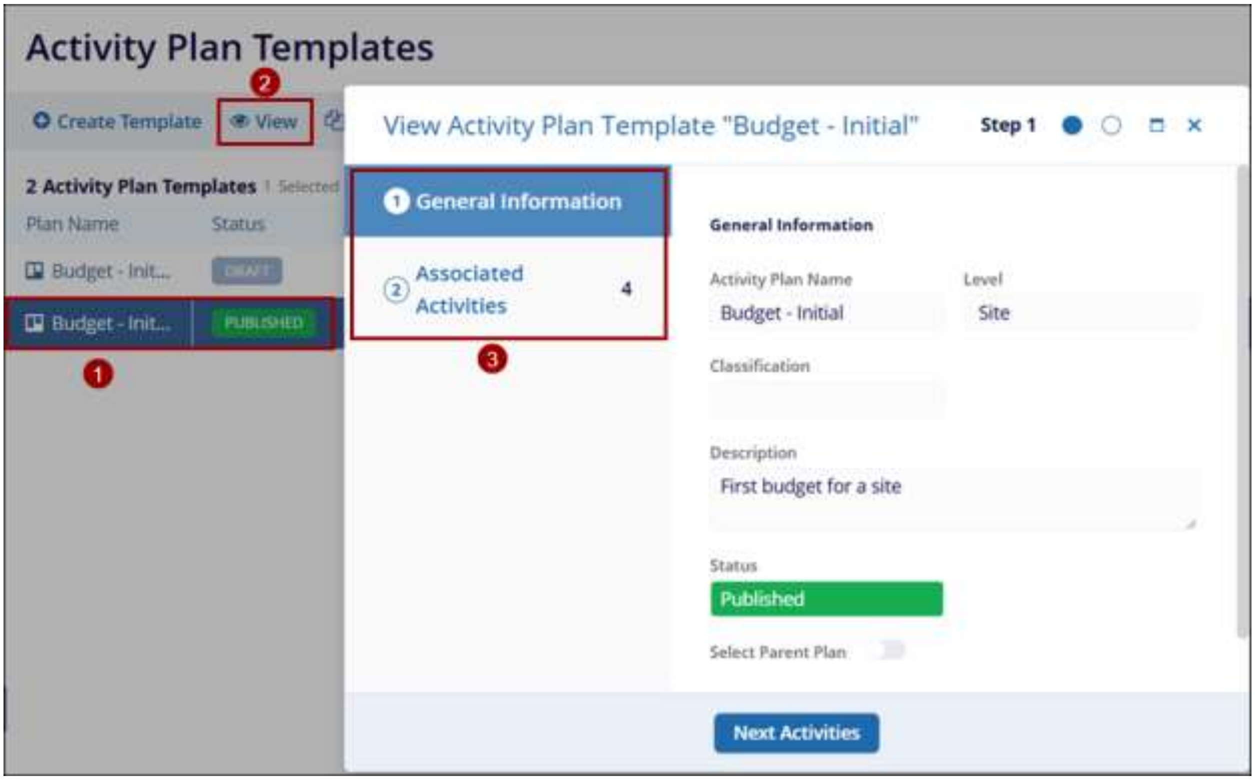


Figure: View Activities Plan Template

Editing Activity Plan Templates

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

Method 1

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

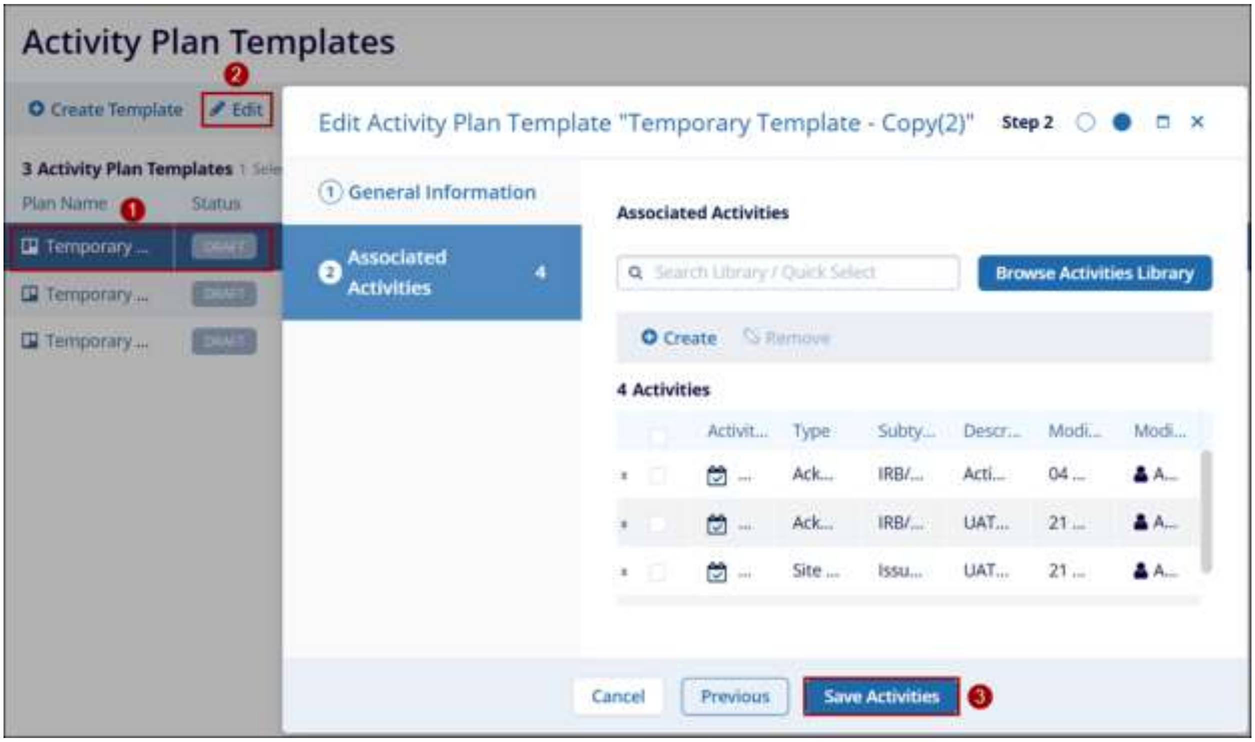


Figure: Edit Activity Plan Template-Method 1

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

Method 2

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

Figure: Select plan name

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

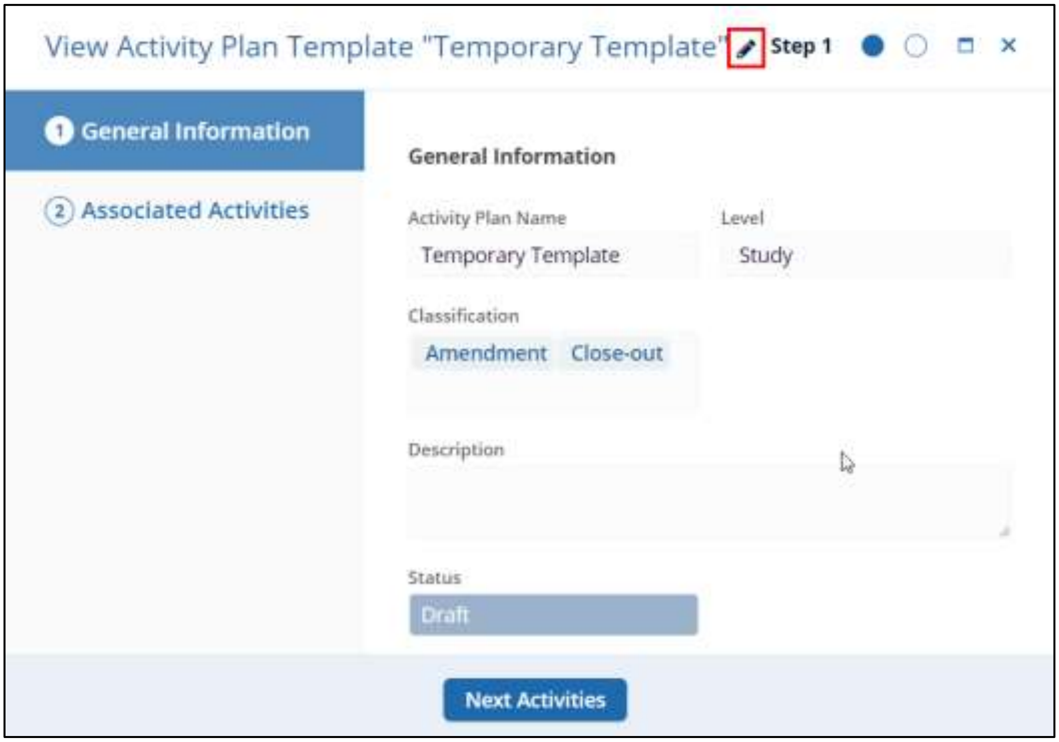


Figure: Select the Edit icon

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

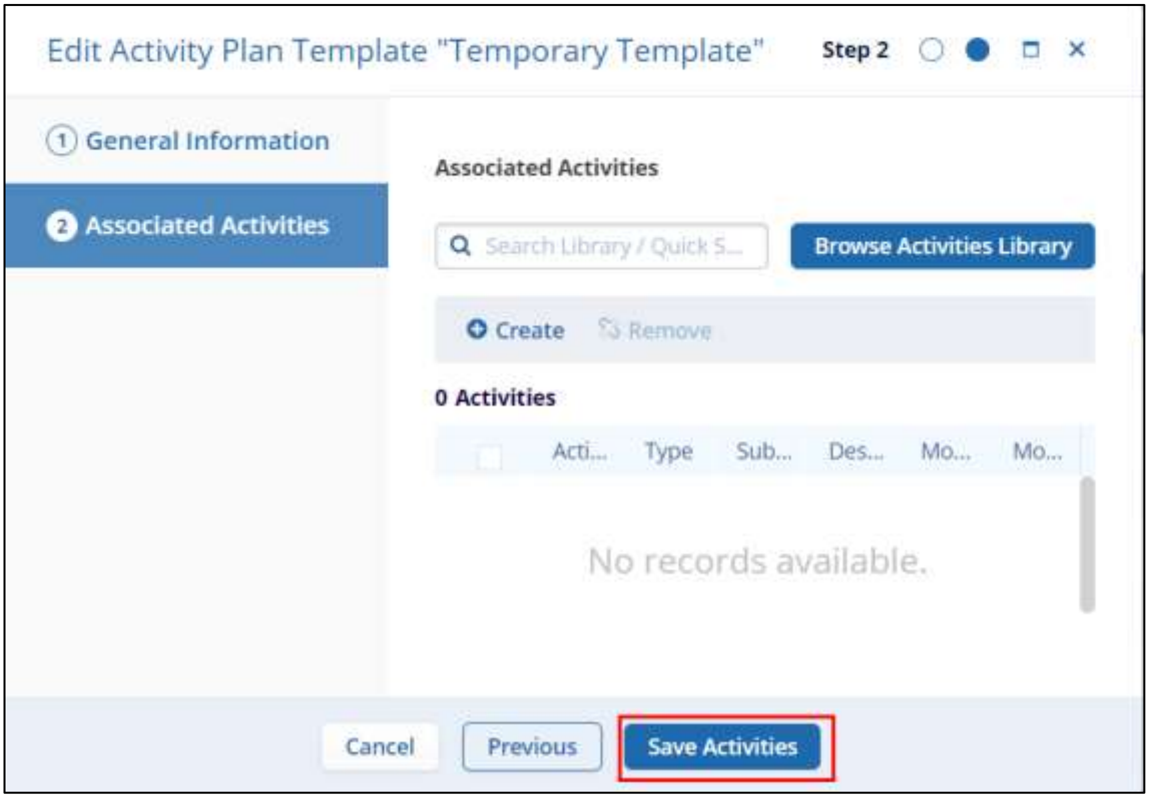


Figure: Edit Activity Plan Template-Method 2

Publishing Activity Plan Templates

To publish an activity plan, follow the steps below.

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

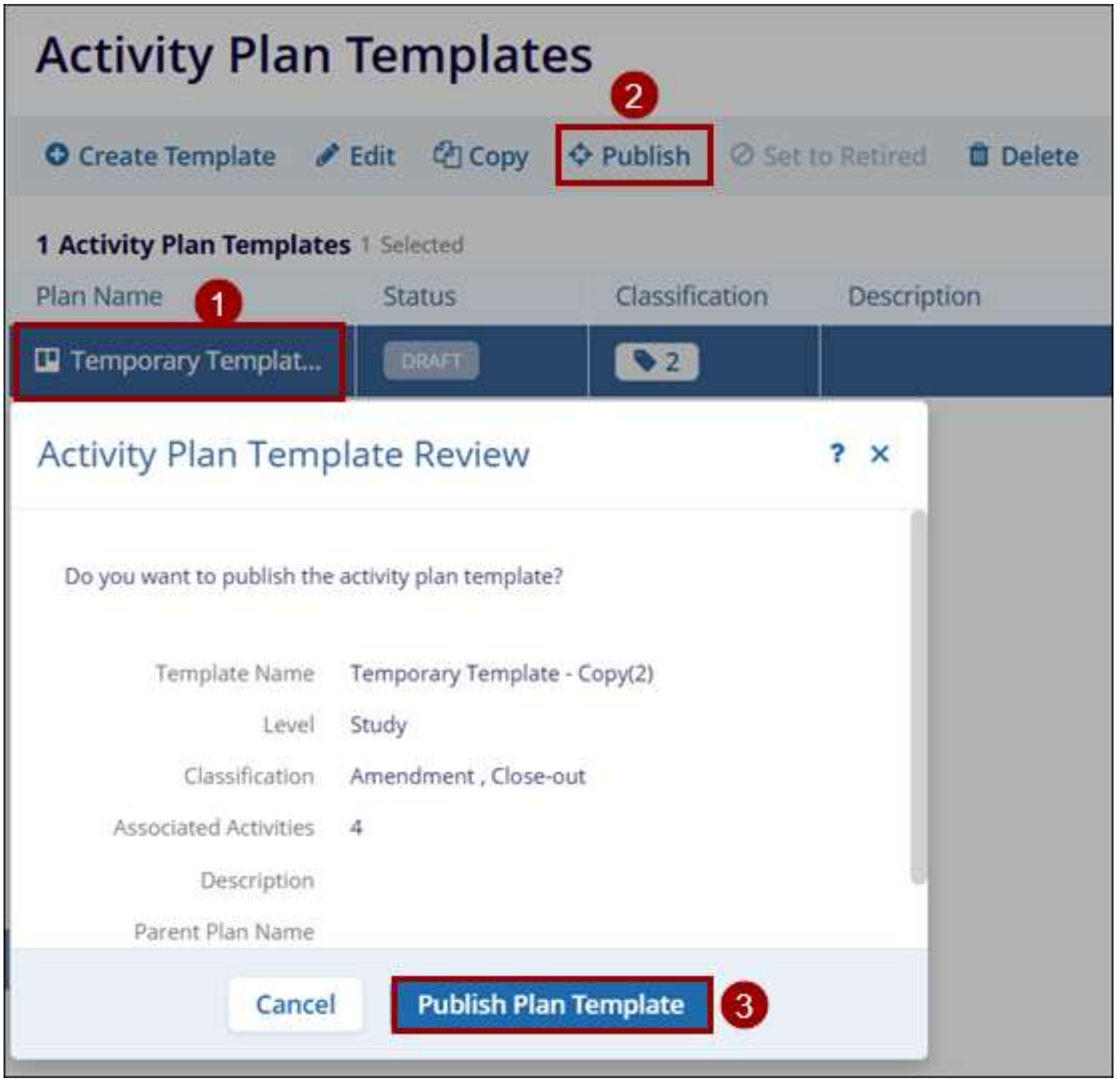


Figure: Publishing Activity Plan Template

Note

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

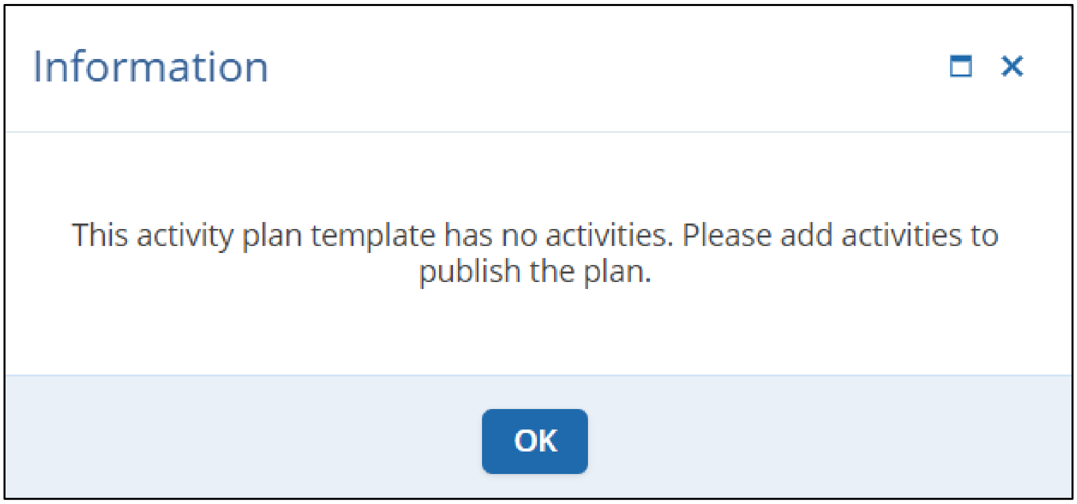


Figure: Information popup prompting to add templates

Retire Activity Plan Templates

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

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

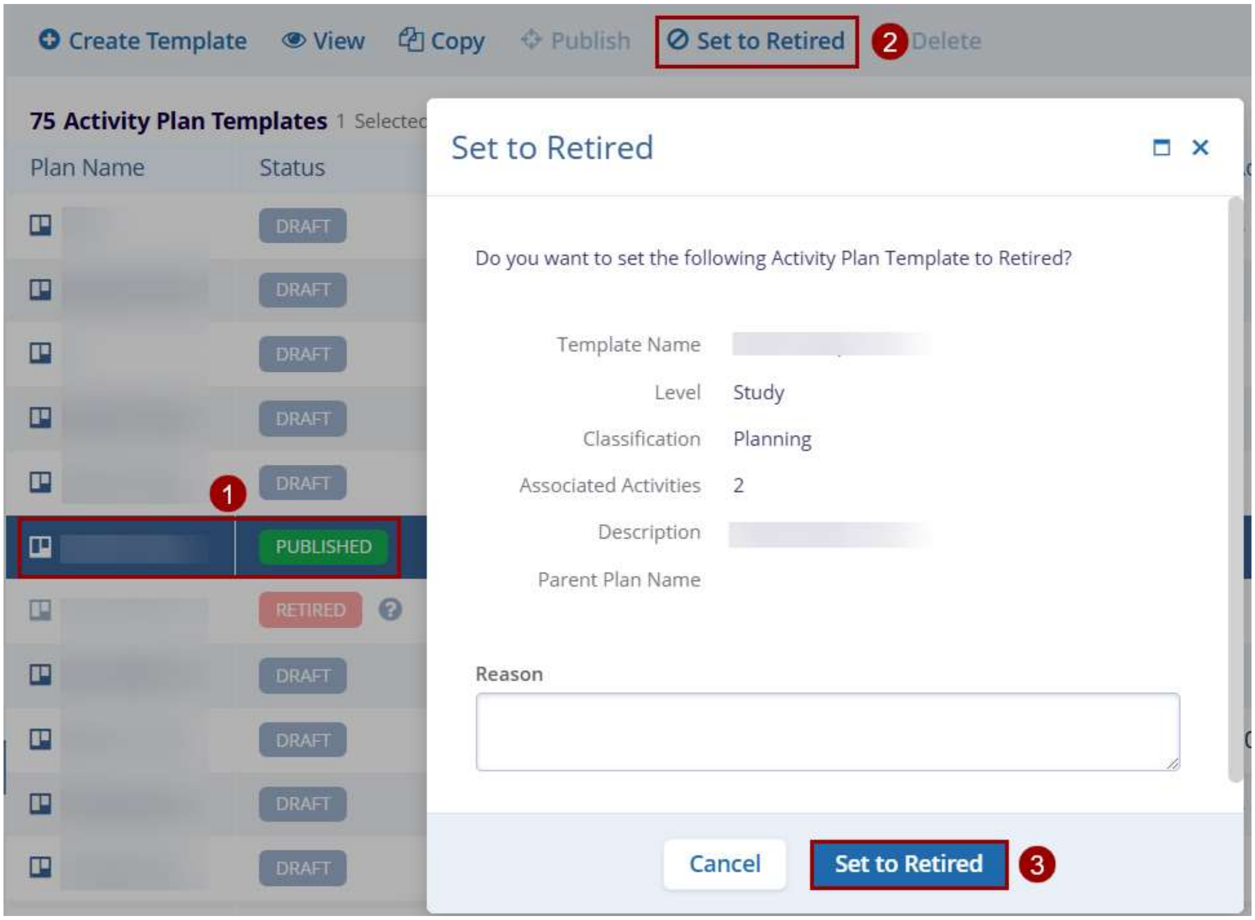


Figure: Retire Activity Plan Template

Note: Only Activity Plan Templates with Published status can be retired.

Copying Activity Plan Templates

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

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

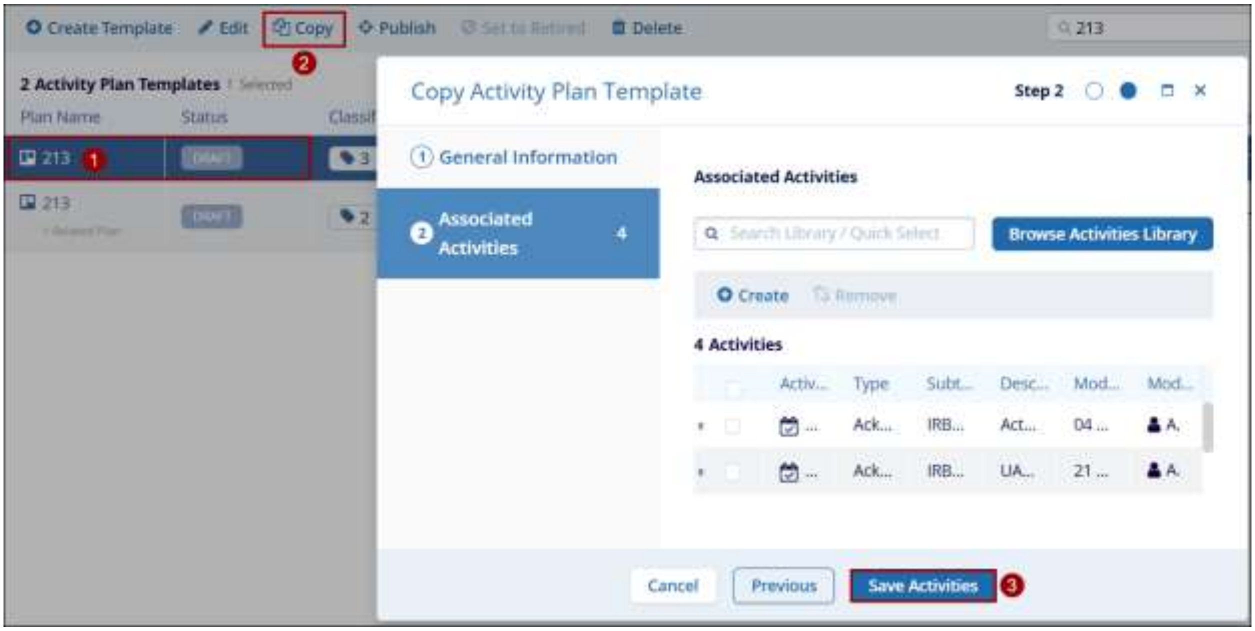


Figure: Copy Activity Plan Templates

Associating Activity Plan Templates to a Study

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

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

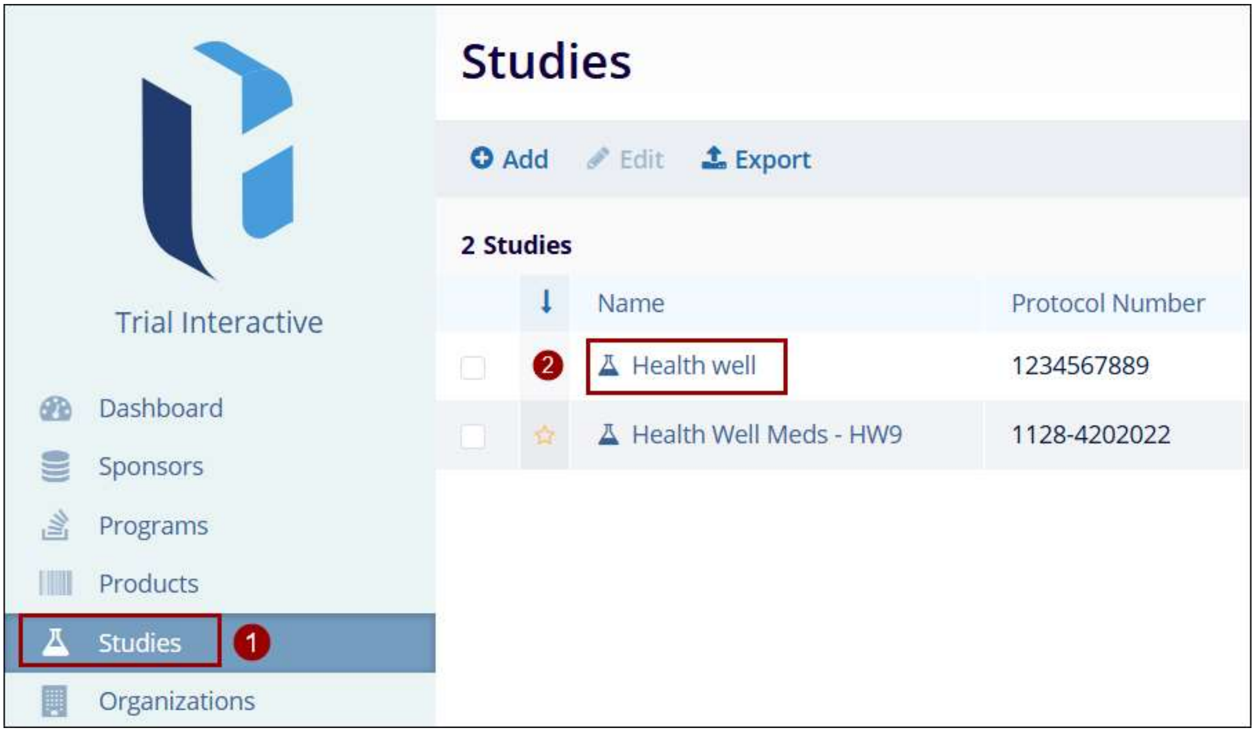


Figure: Selecting a Study

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

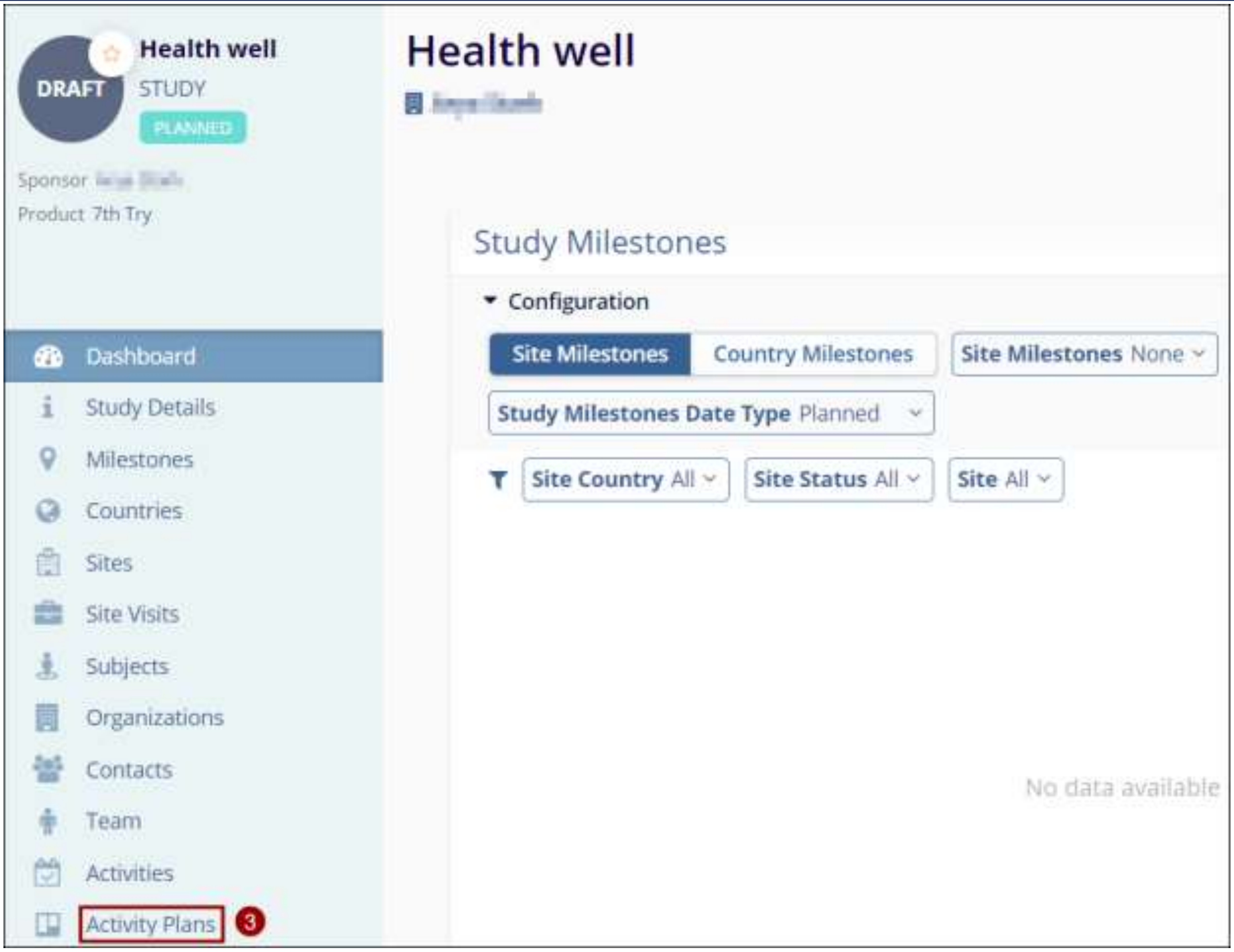


Figure: Select Activity Plans

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

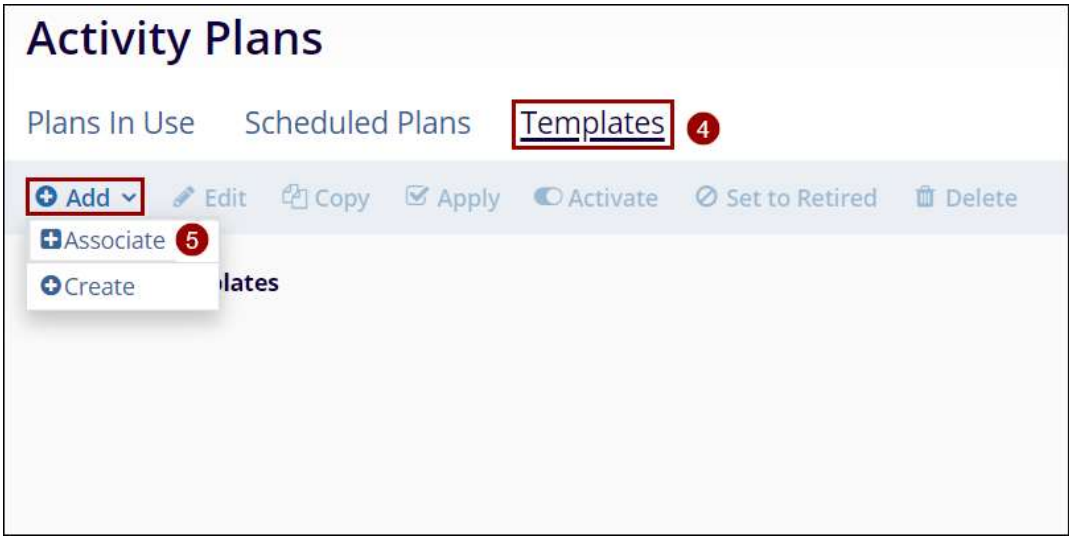


Figure: Select the Templates tab and access the Add and Associate buttons

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

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

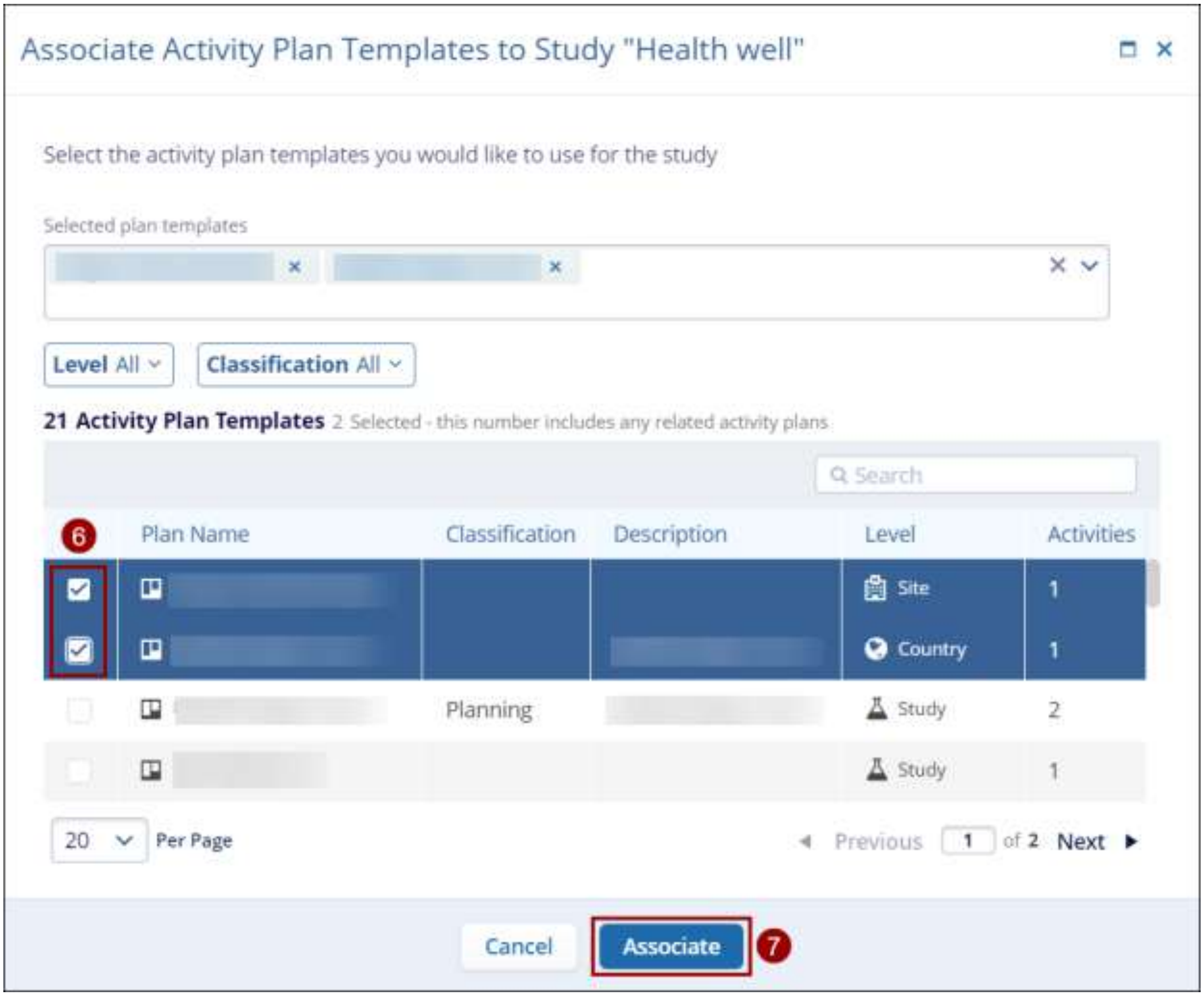


Figure: Associate Activity Plan Template to Study Screen

Scheduling Activity Plans

To schedule Activity plans, follow the steps below.

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

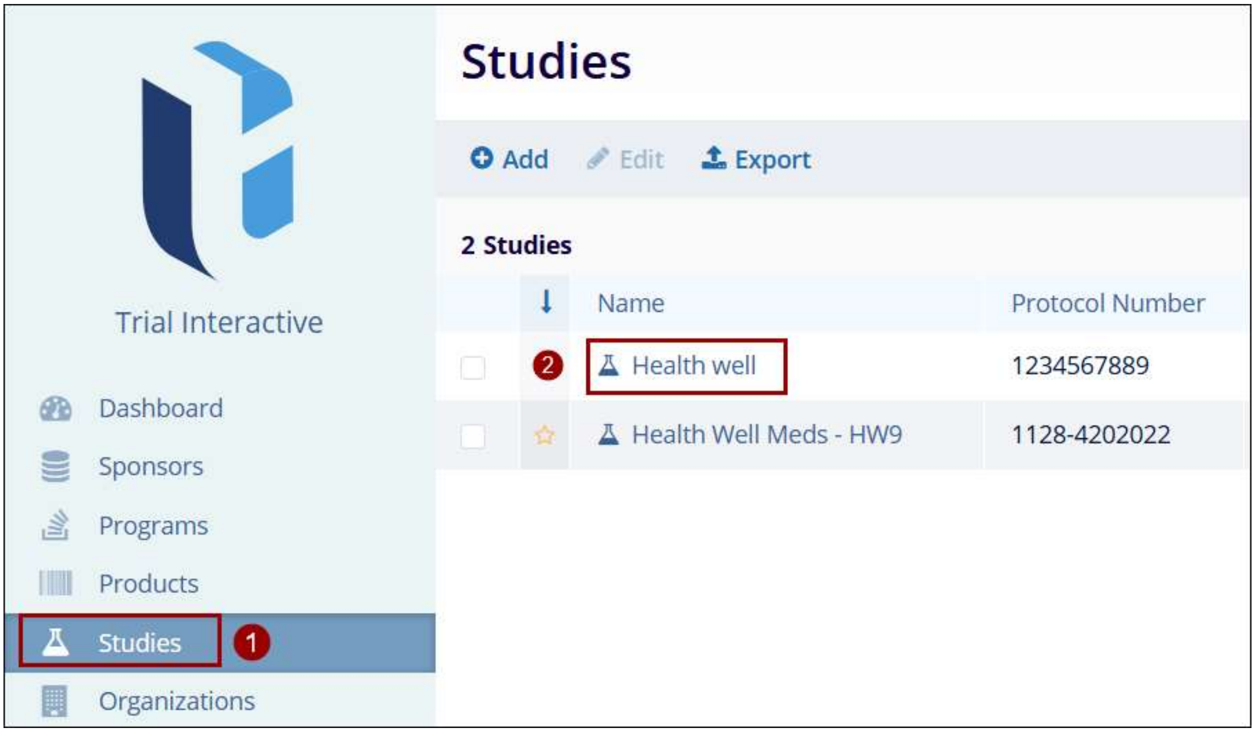


Figure: Selecting a Study

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

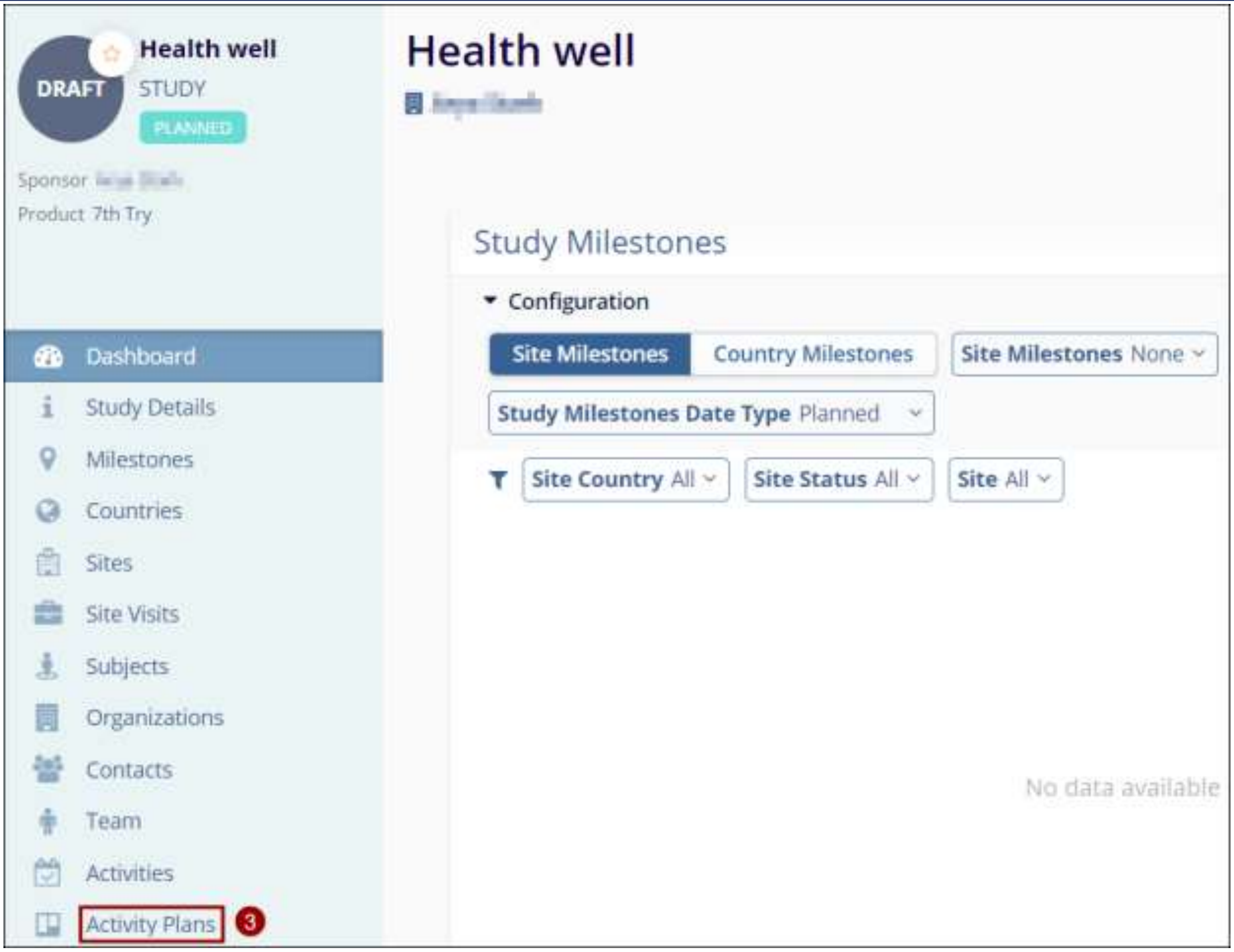


Figure: Select Activity Plans

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

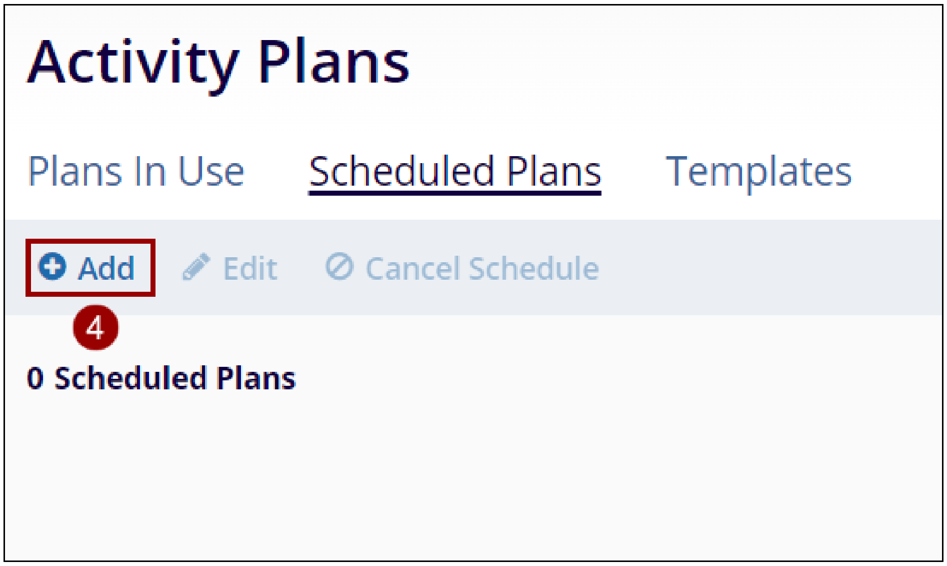


Figure: Scheduled Plans tab

5. On the Schedule Activity Plans for Study screen, perform the following.
    a. Select Templates: Click on Schedule plan or the templates tile to select the template and click on the Next button.

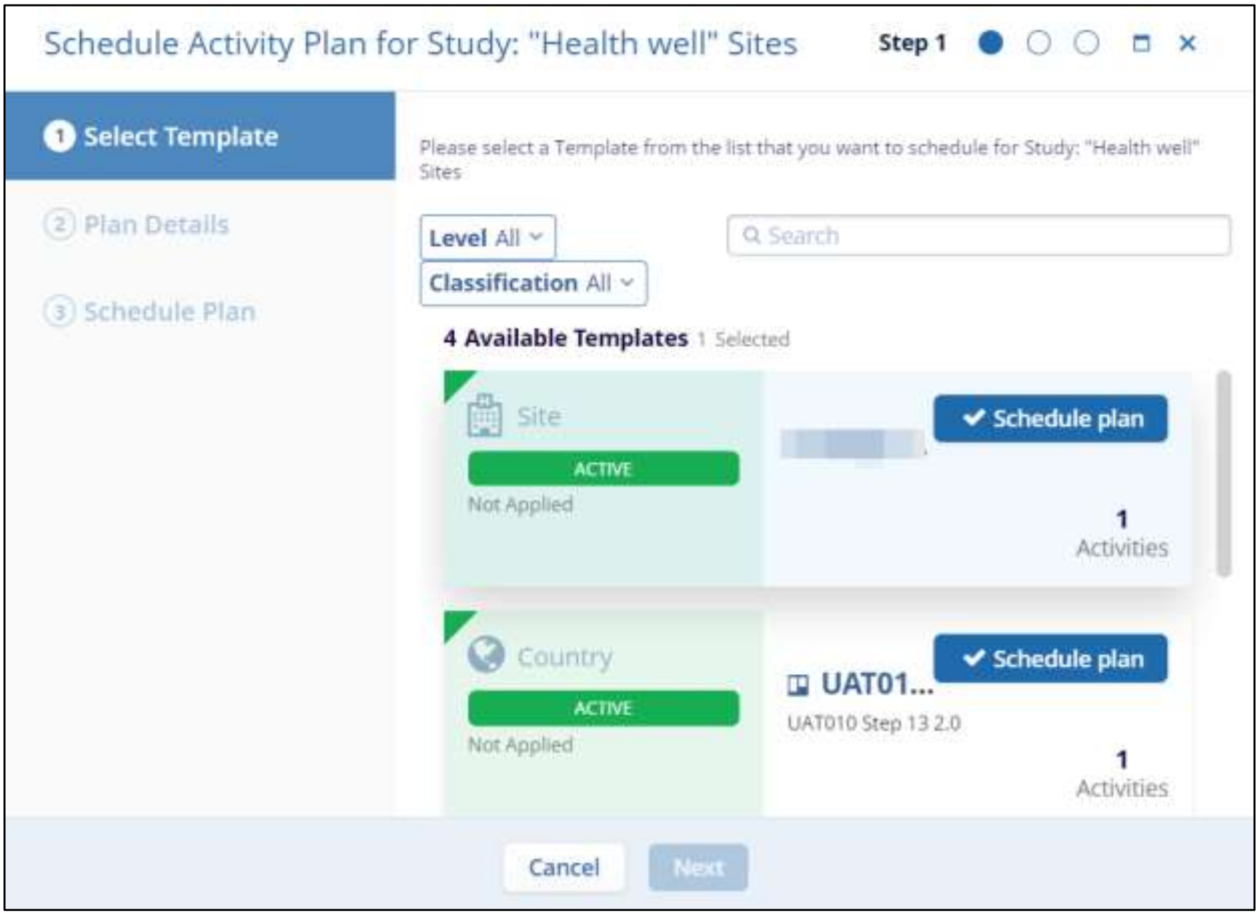


Figure: Schedule Activity Plan for Study-Select Template

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

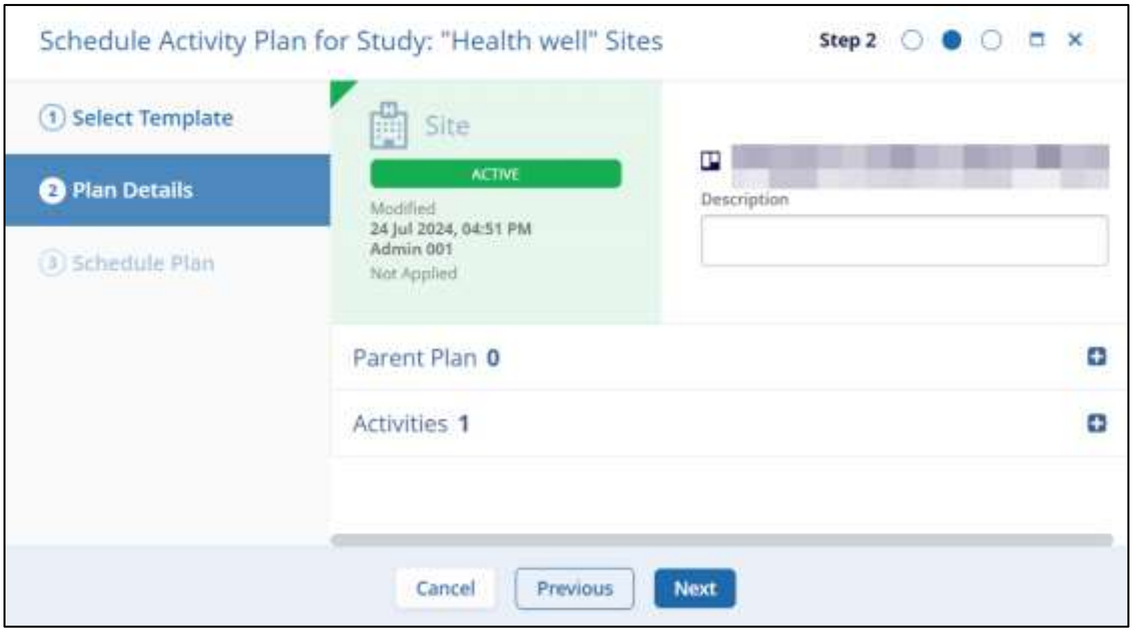


Figure: Schedule Activity Plan for Study-Plan Template

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

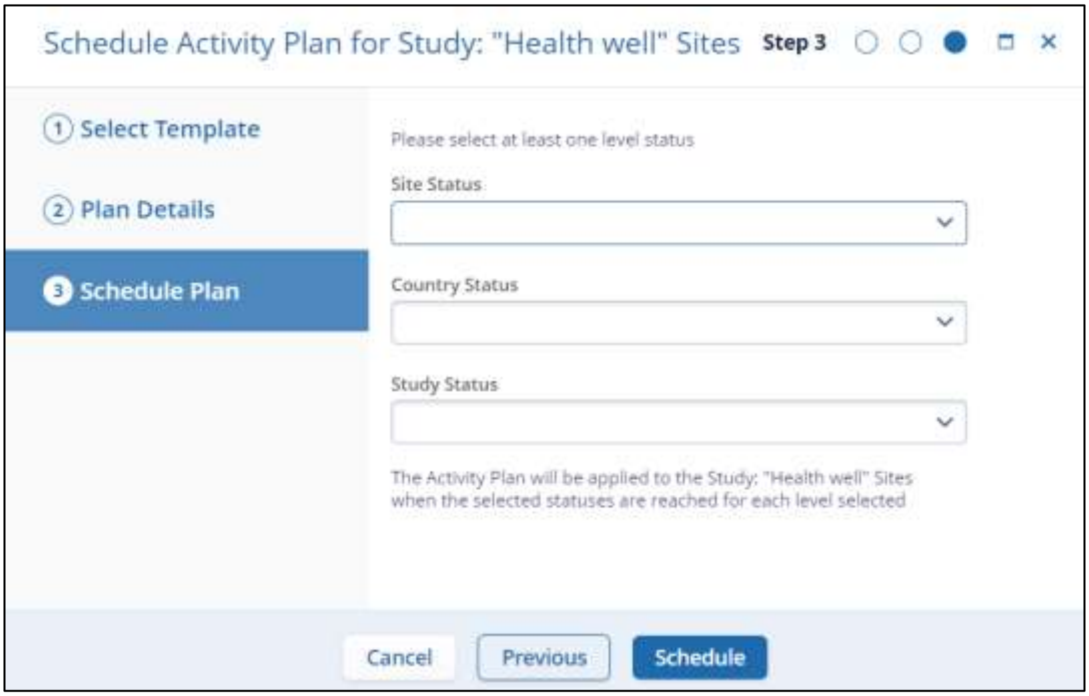


Figure: Schedule Activity Plan for Study-Schedule Plan

Tracking Activities Outside of Activity Plans

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

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

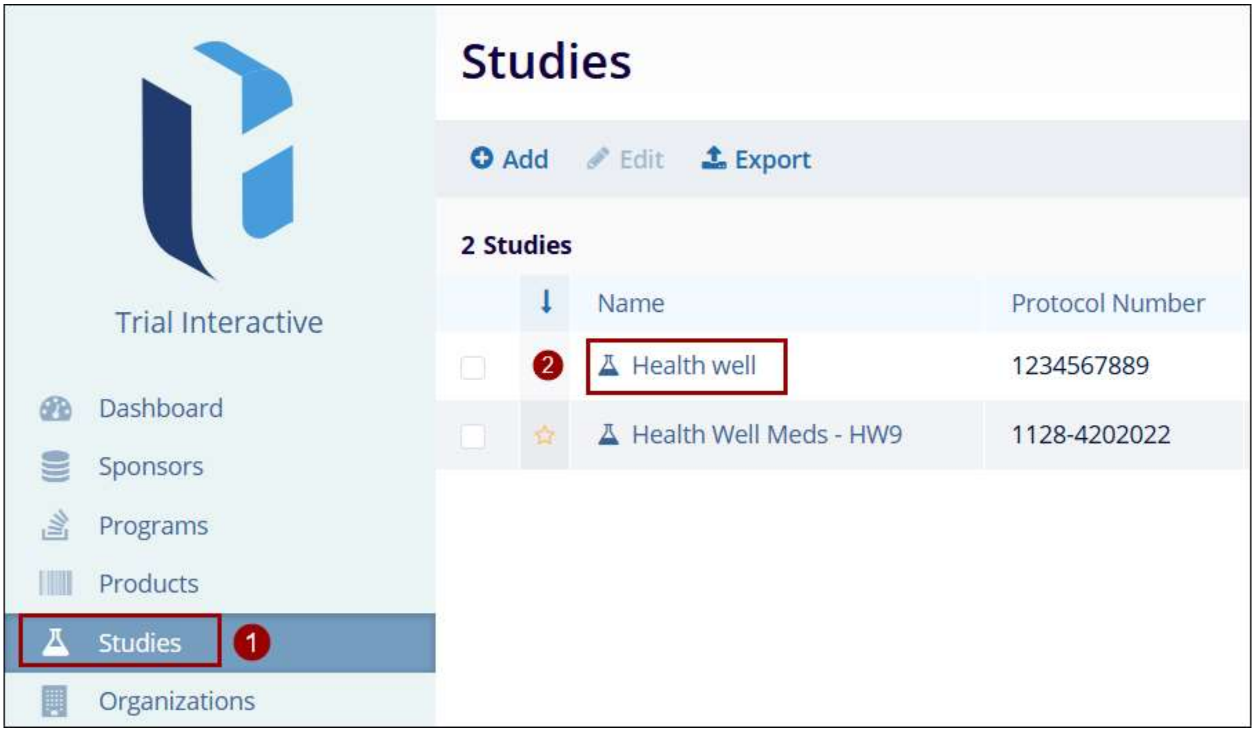


Figure: Selecting a Study

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

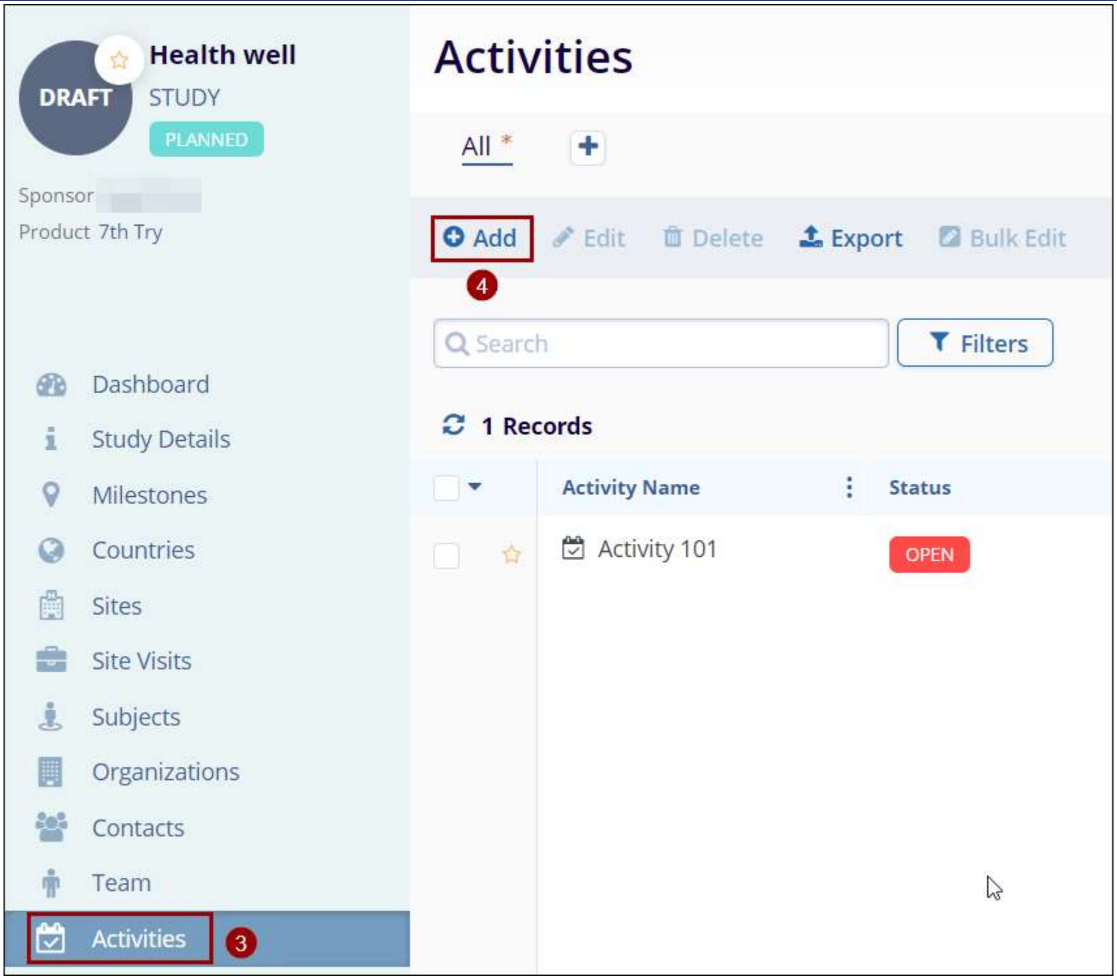


Figure: Select Add Activities

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

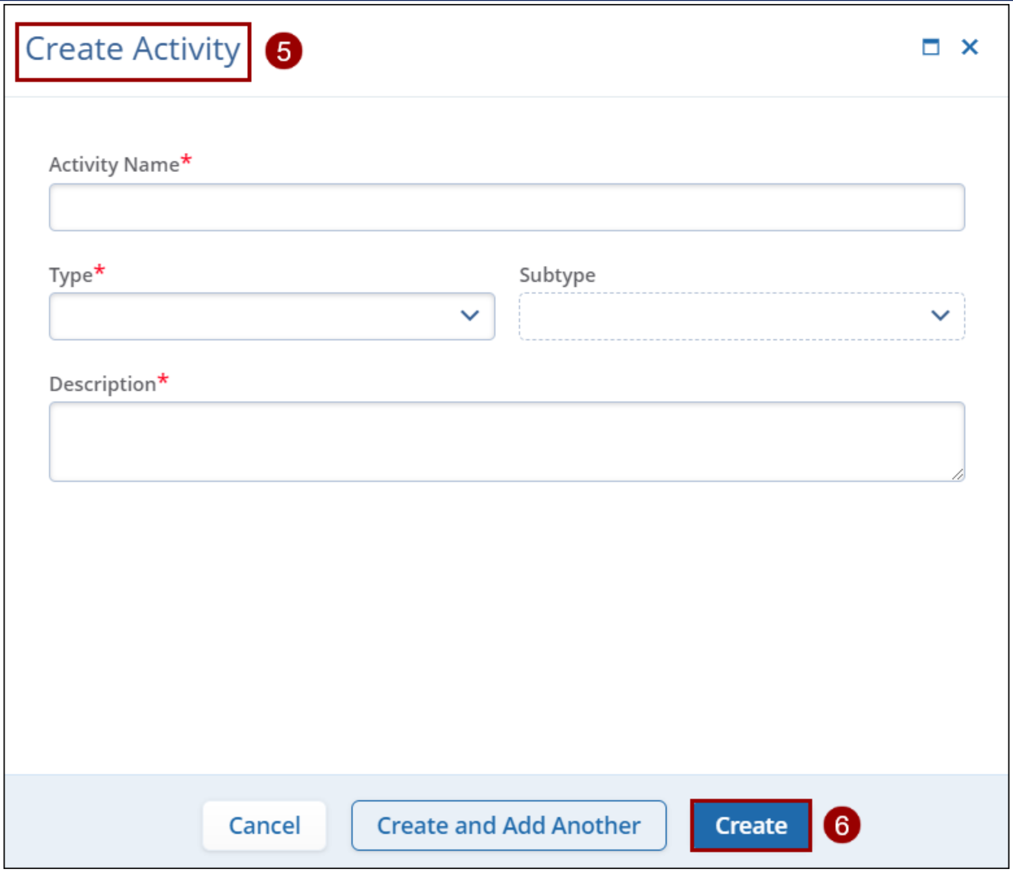


Figure: Tracking Activities

To edit any activity, follow the steps below

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

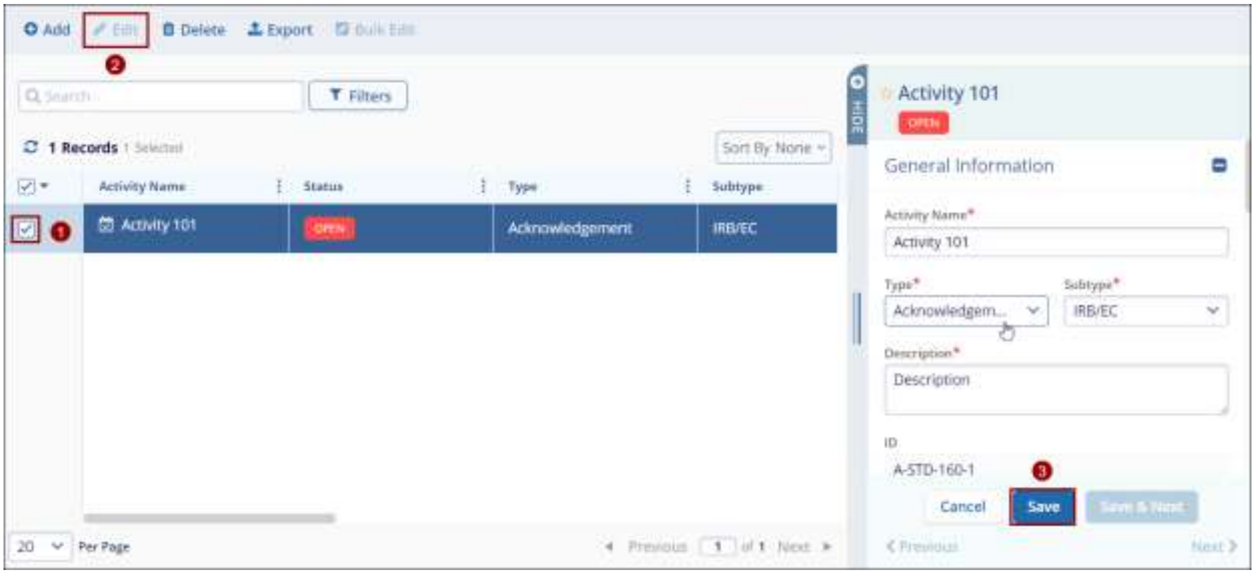


Figure: Editing Activities outside of the Activity Plan

Tracking Actions Towards Activity Completion

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

To track activity completion actions, follow the steps below.

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

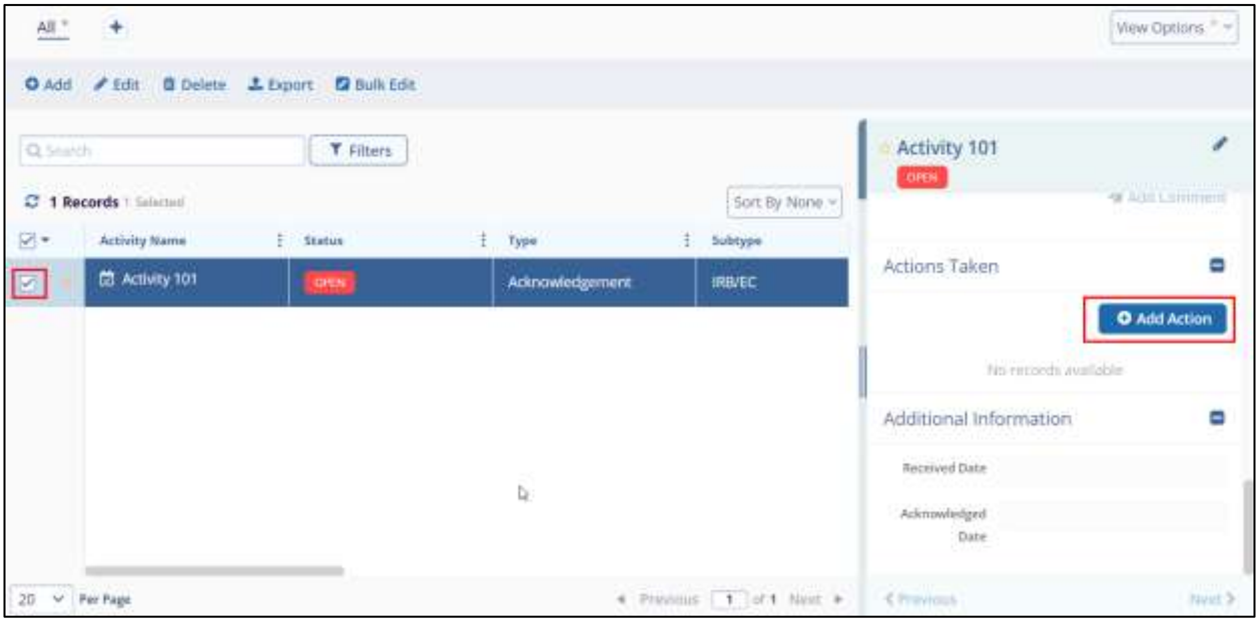


Figure: Actions Taken on Quick View panel

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

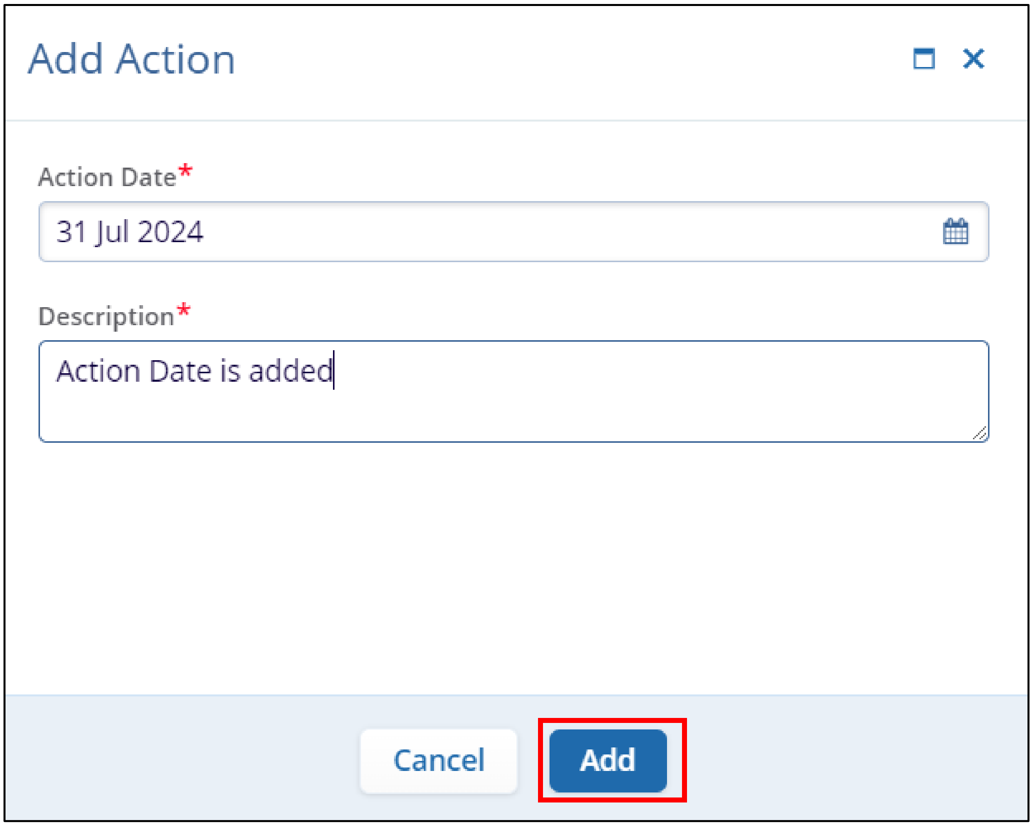


Figure: Add Action screen

Customizing Activity Plan Templates screen

Filters

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

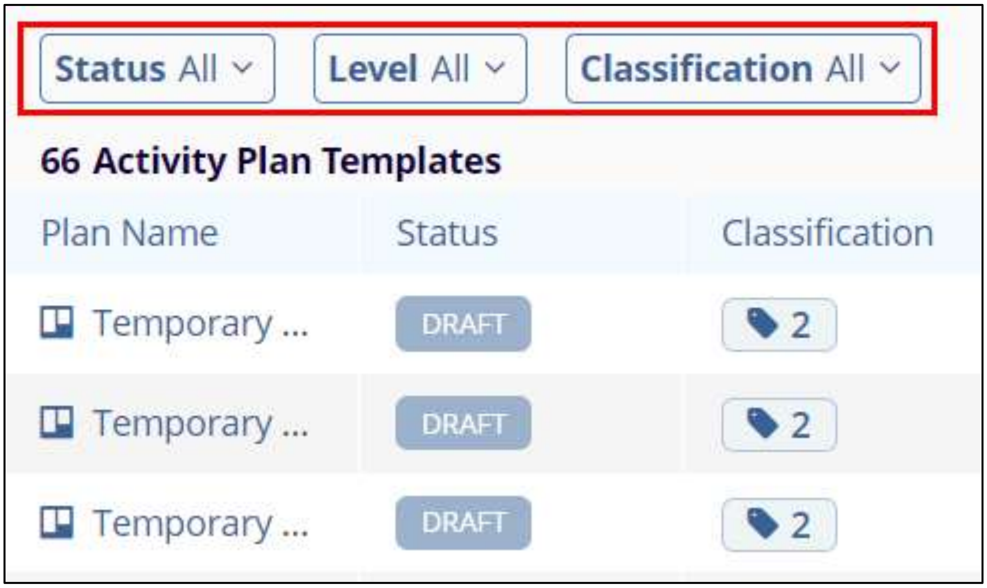


Figure: Activity Plan Templates screen filters

CHAPTER 15. MILESTONES

This section describes the Milestones module in the application.

Important

- 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 user who is 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.

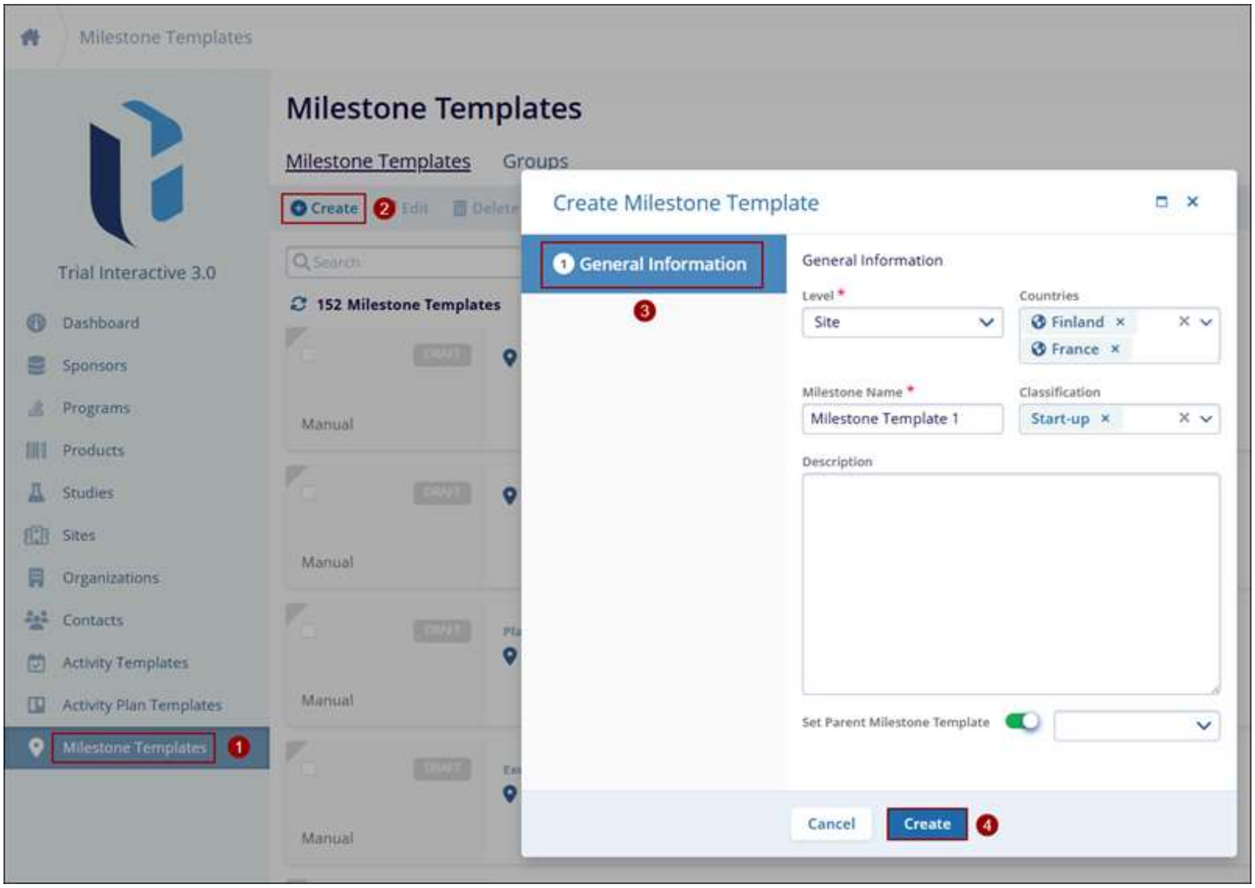


Figure: Creating Domain Library Milestone Template

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

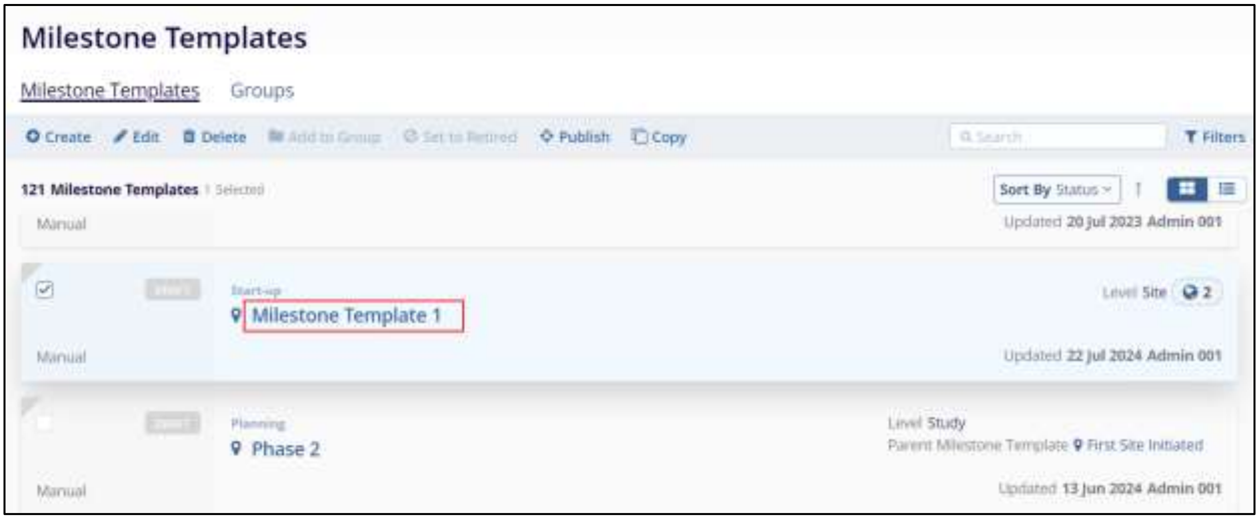


Figure: Newly created milestone template

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.

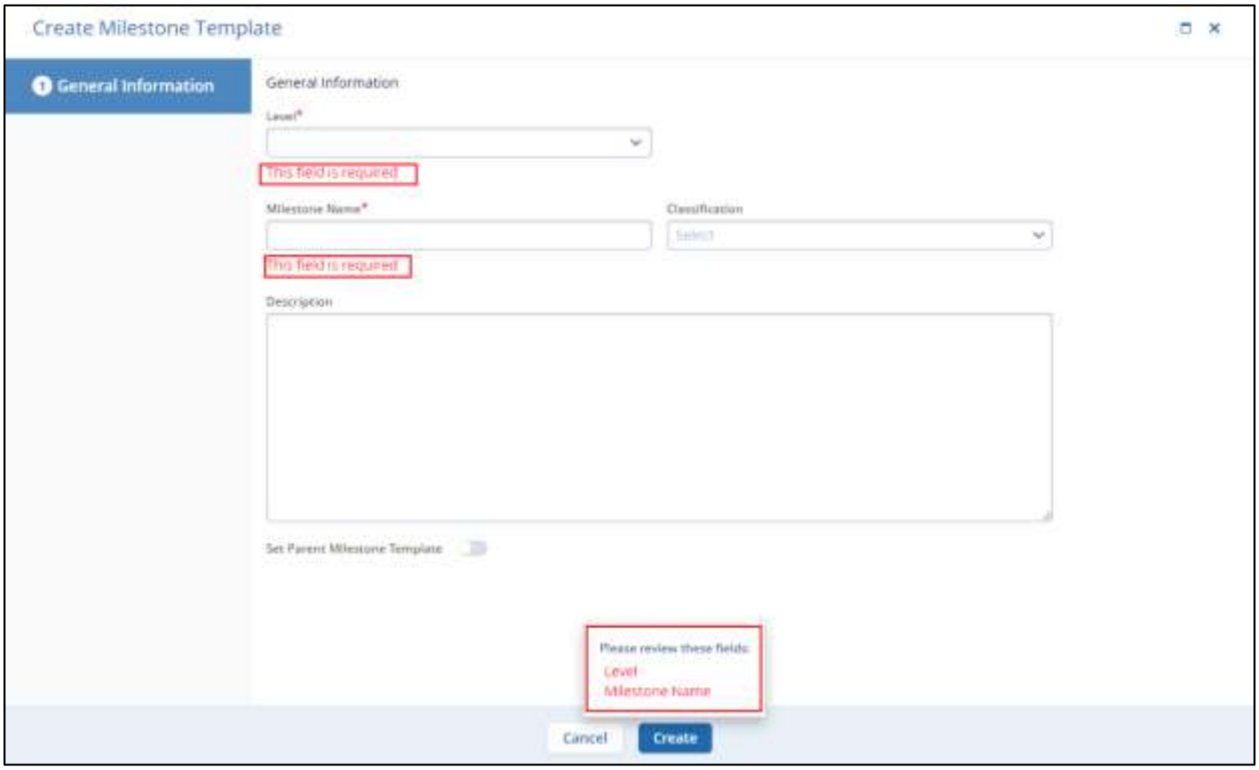


Figure: Mandatory fields error

Creating a Milestone Template at Study Level

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

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

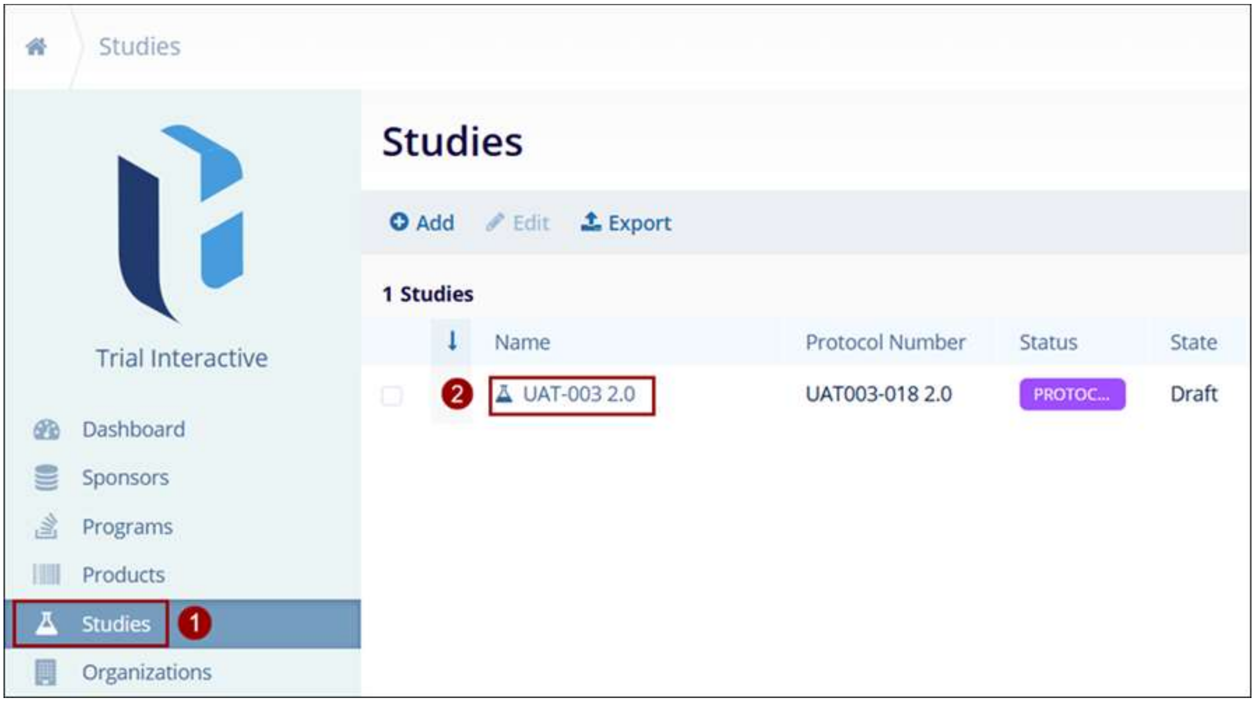


Figure: Selecting a study

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

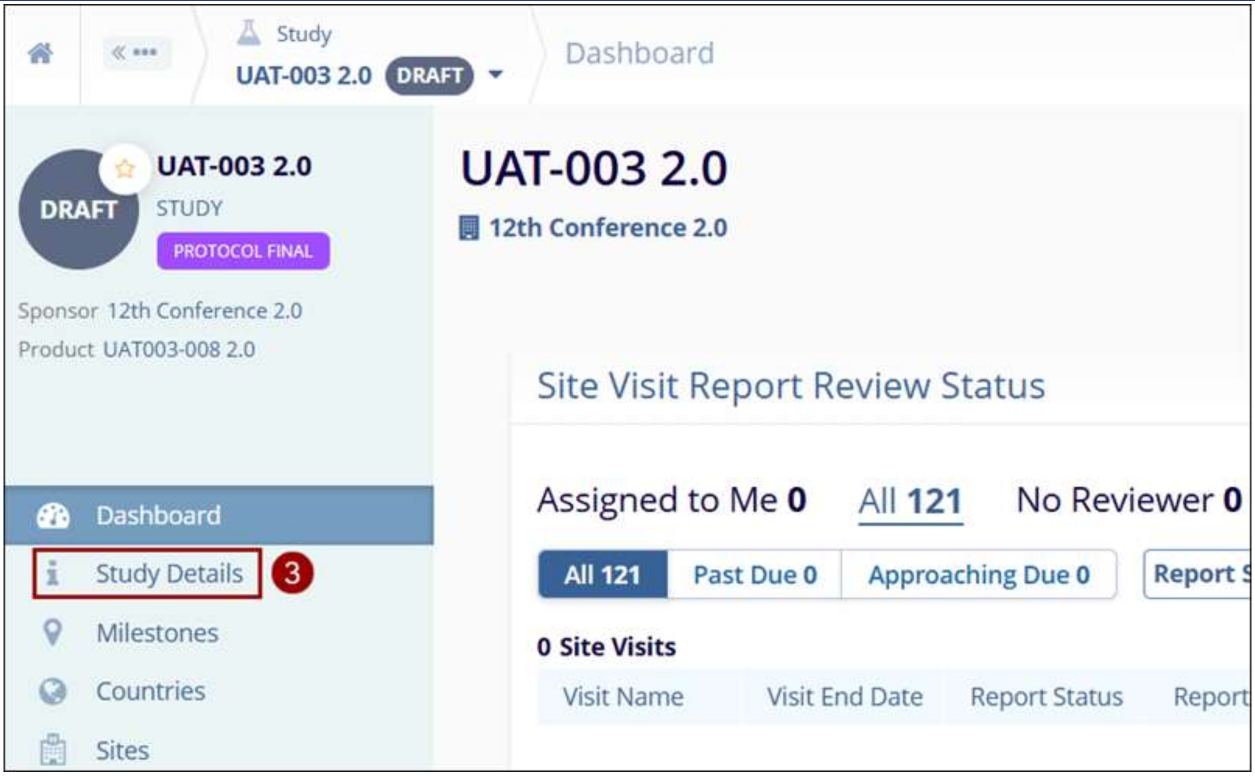


Figure: Select Study Details

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

Figure: Select Settings on the Study Details screen

5. Click on the Milestone Templates link in the Navigation menu at the left side of the screen.
6. Click on the +Add button on the on the top-left of the screen.
7. Click on Add From Sponsor option.

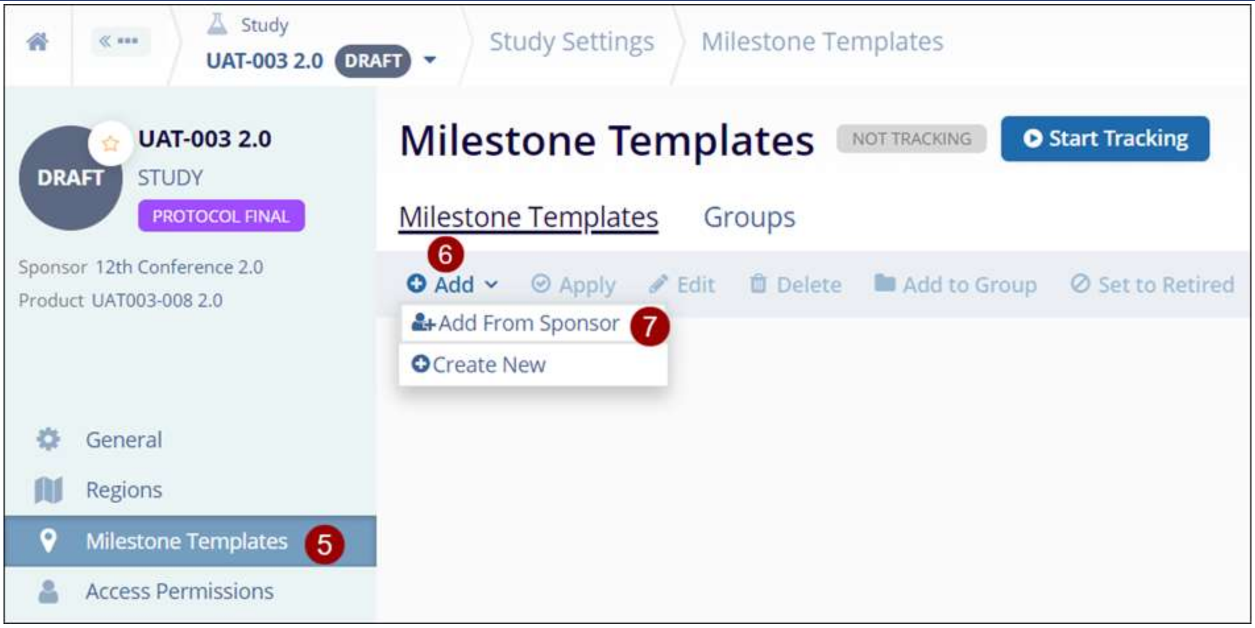


Figure: Select Add From Sponsor

8. On the Add Milestone Template From Sponsor screen, select the milestone template.
9. Click on the Add button.

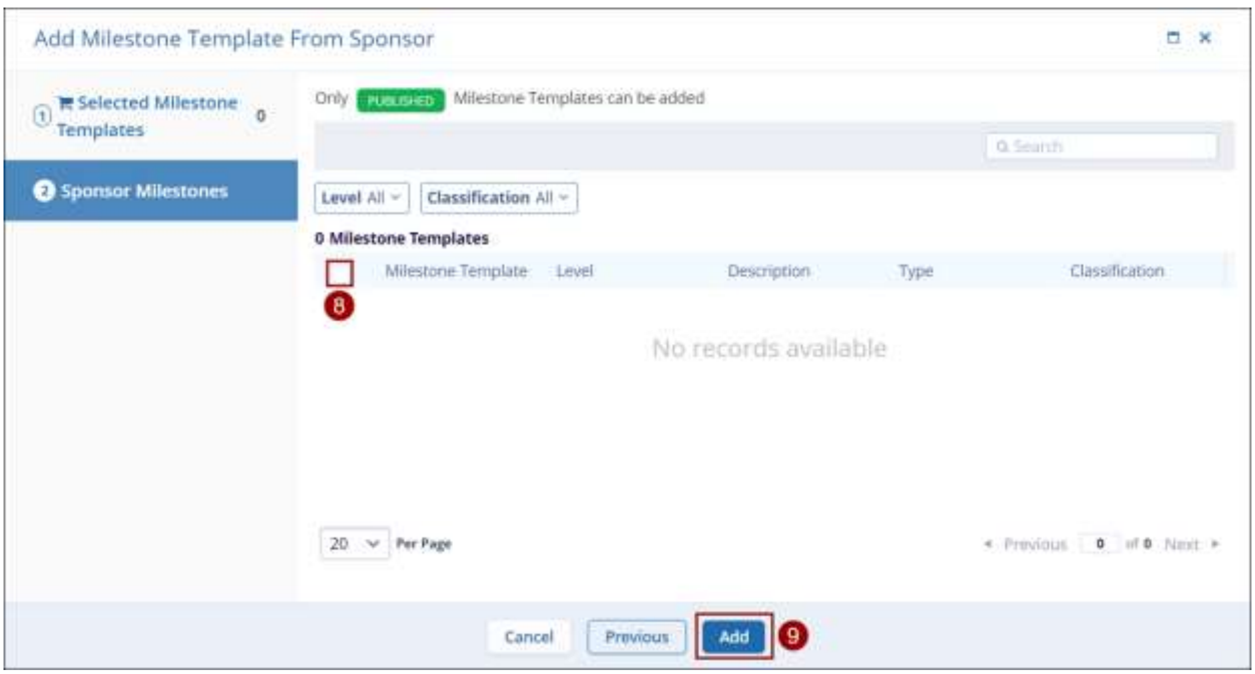


Figure: Add Milestone Template From Sponsor

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

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

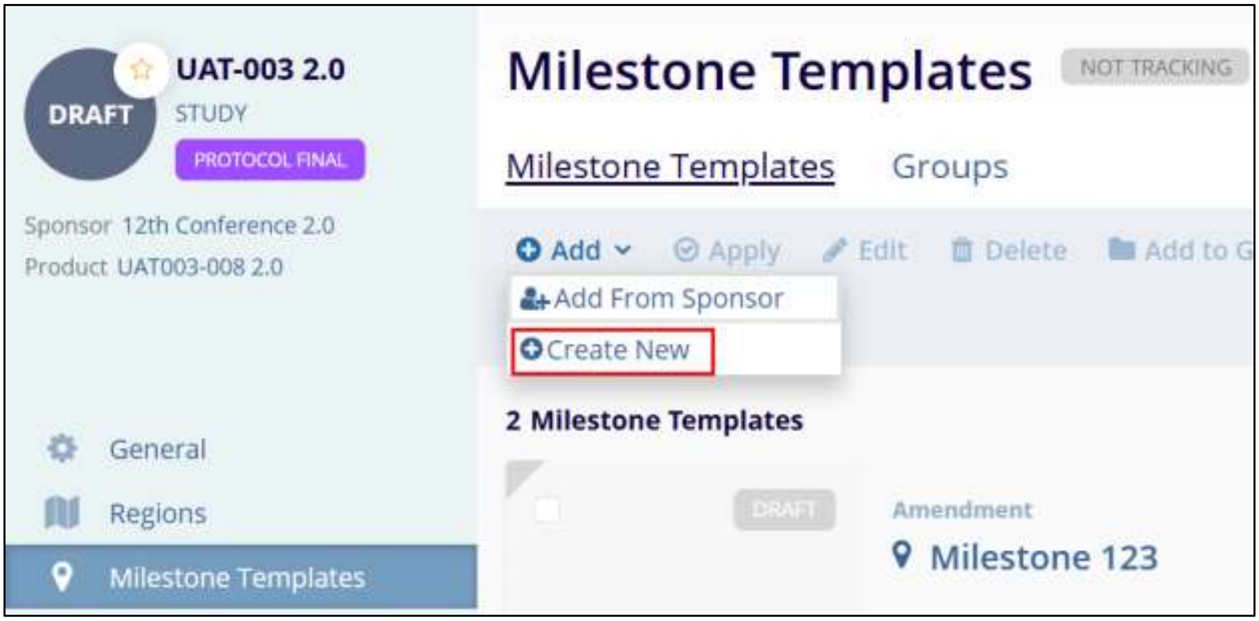


Figure: Create a New Template

2. Fill in the mandatory metadata to create a milestone template i.e., Level, Template Name as indicated by an asterisk (*) symbol next to the field title. Enter any additional information as necessary.

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

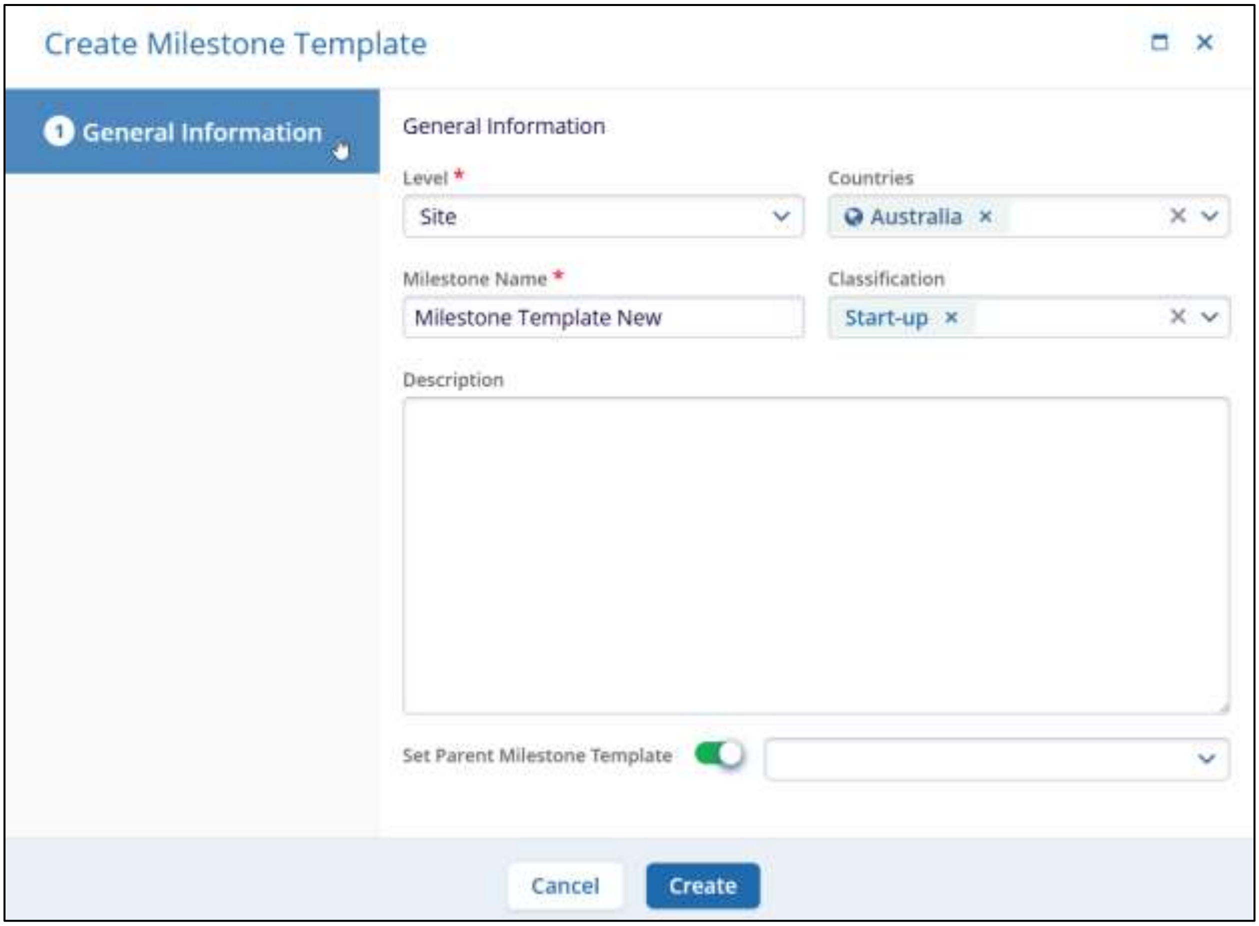


Figure: Save the new template

Note: If any of the required fields are missing, an error will appear when users click on the Create button. The error displays the fields that must 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.

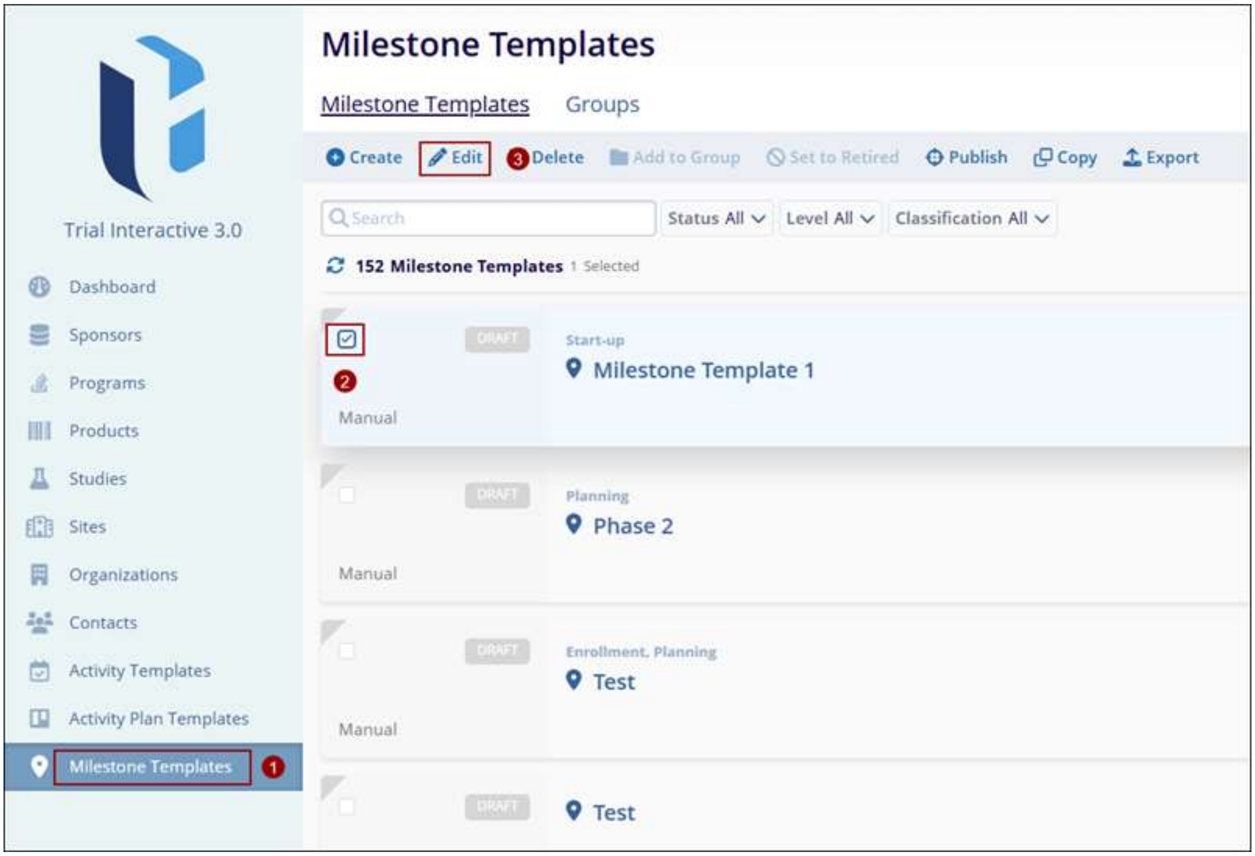


Figure: Select a template to edit

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

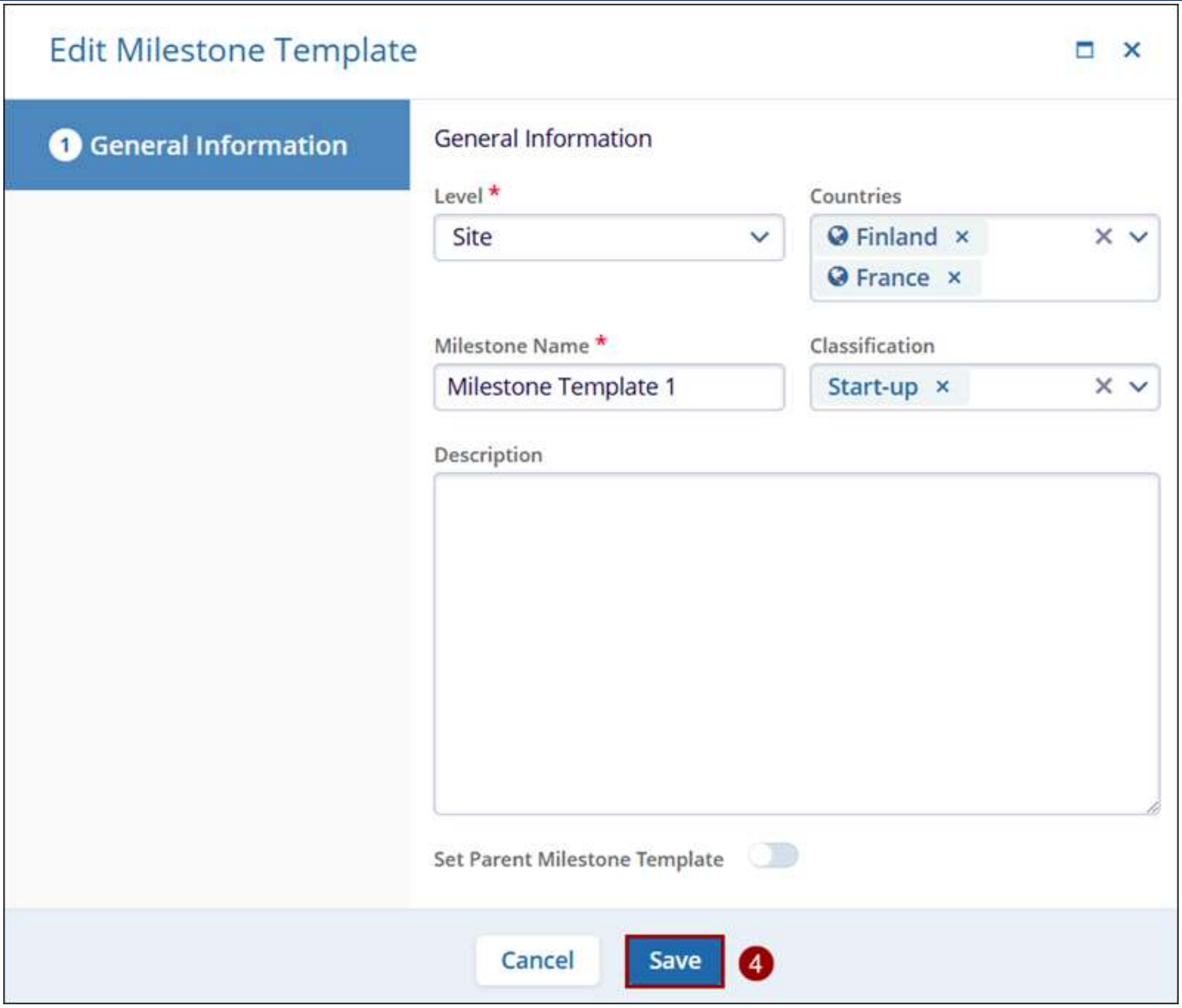


Figure: Edit Milestone Template

Note: Users can only edit templates with a Draft 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.

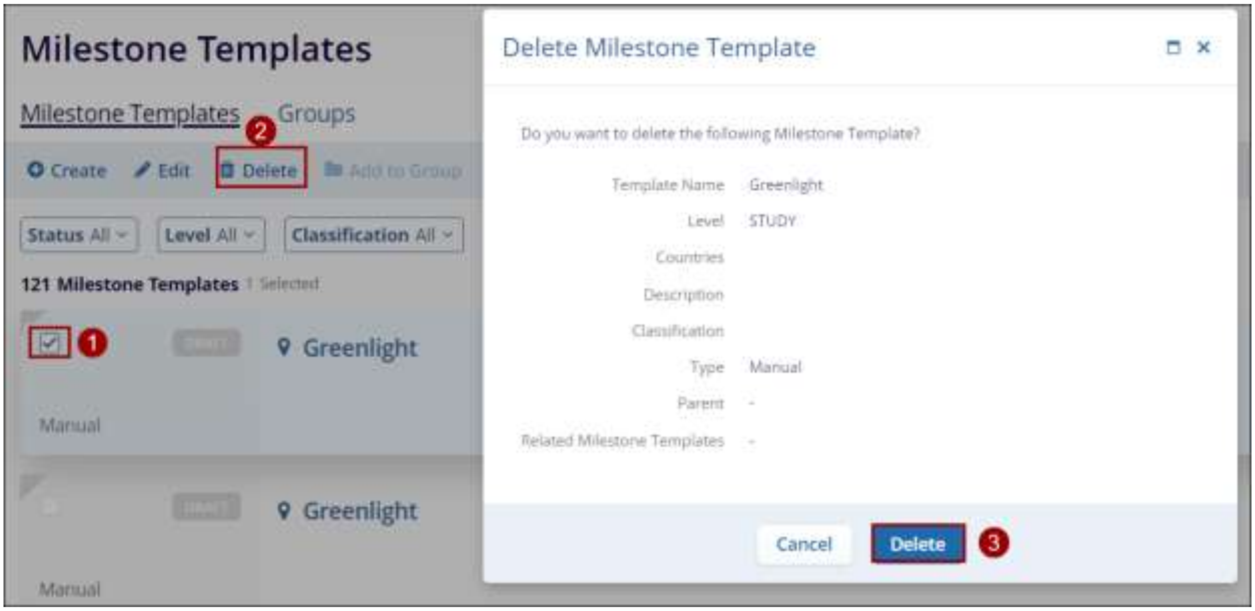


Figure: Deleting Milestone Template

Note: Users can edit templates only with the Draft status.

Adding Domain Milestone Templates to Group

To add domain milestone templates to groups, follow the steps below.

1. Select published template(s) by clicking on the checkbox.
2. Click on the 'Add to Group' option from the top menu bar.
3. On the 'Add to Group' screen select one or multiple groups by clicking on their respective checkboxes.
4. Click on the 'Add to (number of groups) Groups' button.

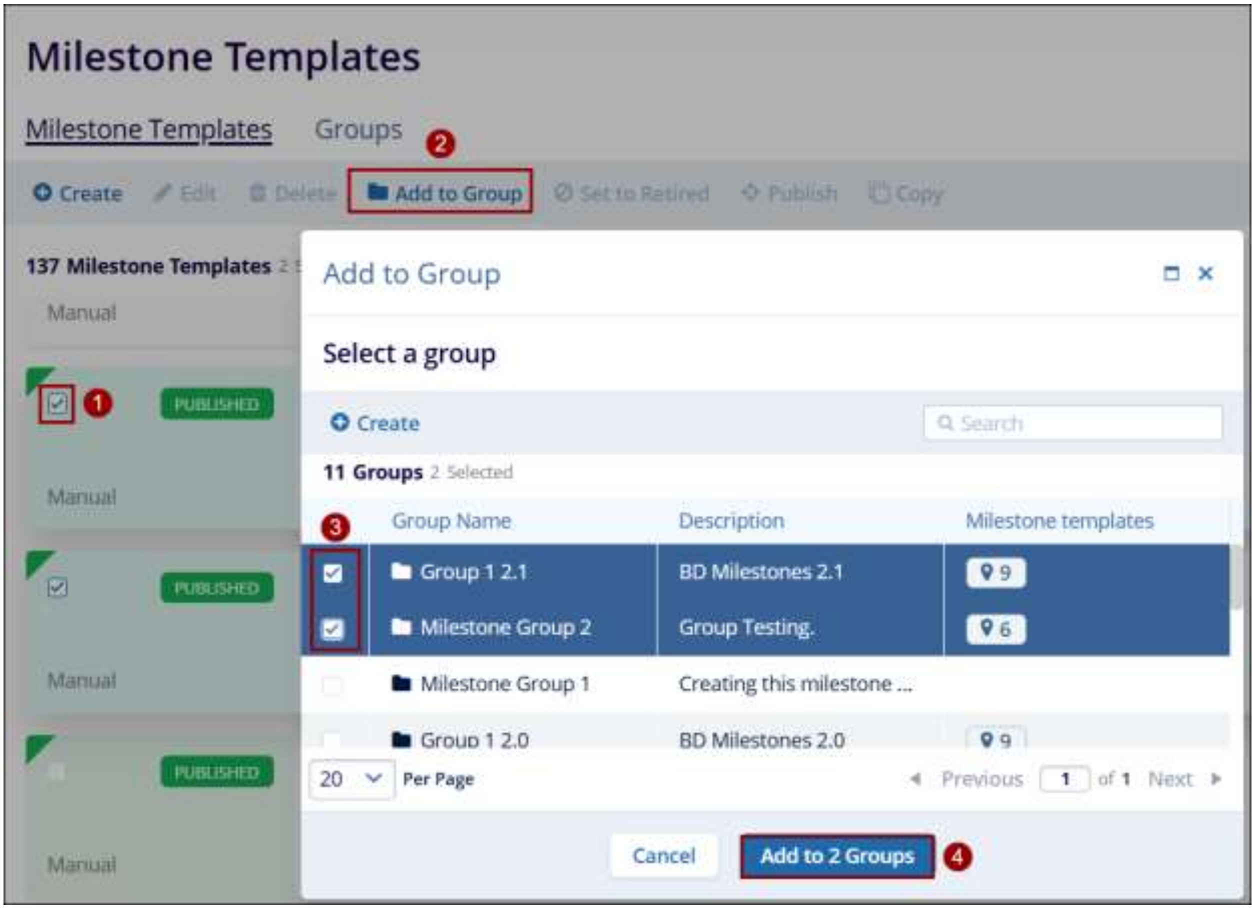


Figure: Add to Group

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.

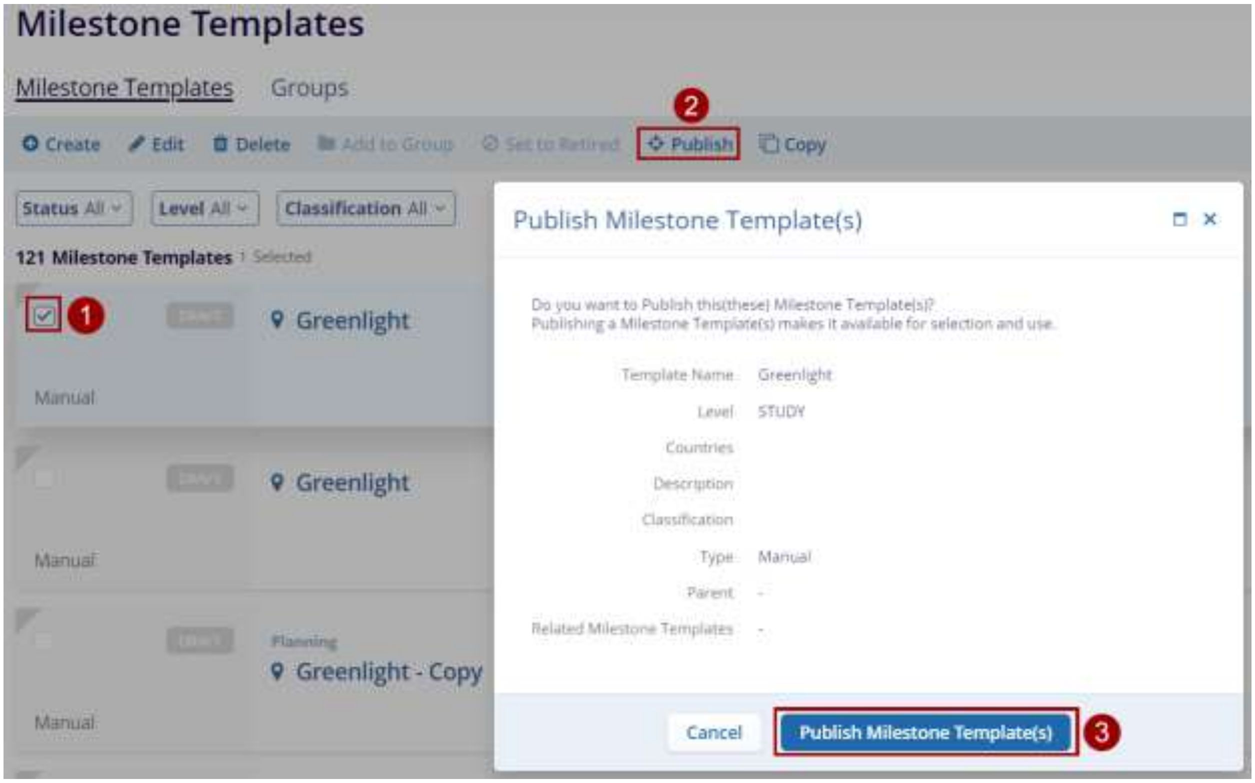


Figure: Publishing Milestone templates

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.

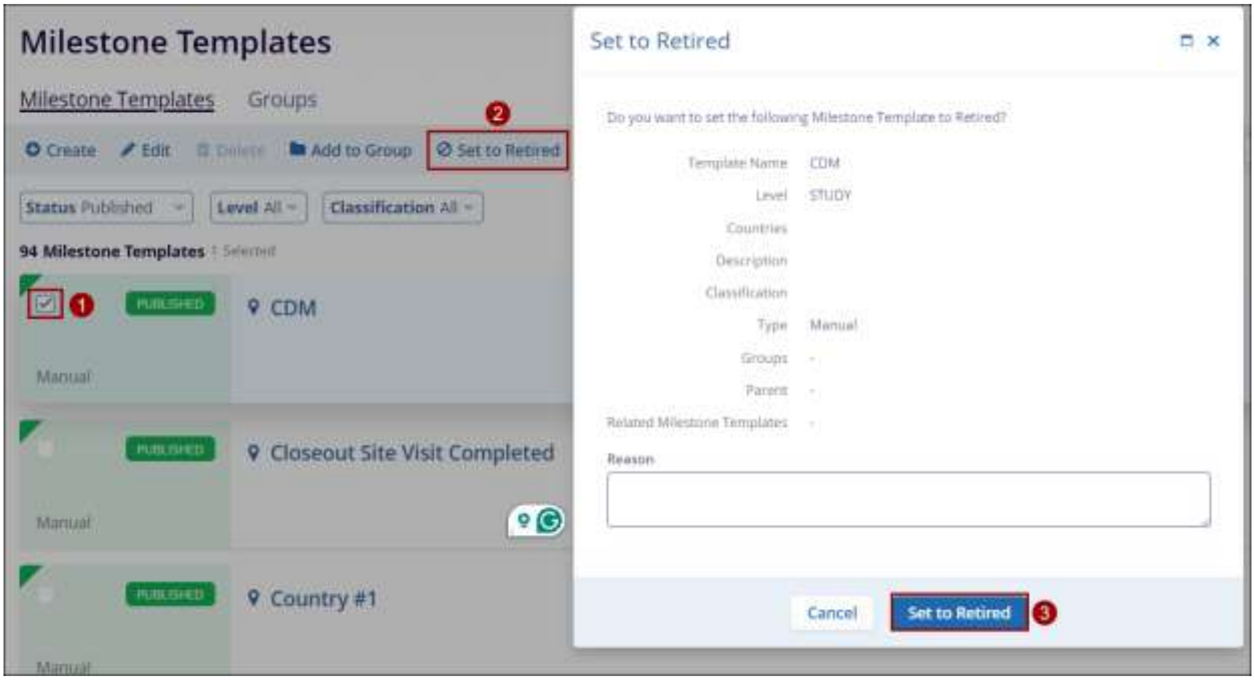


Figure: Retiring Milestone Template

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.

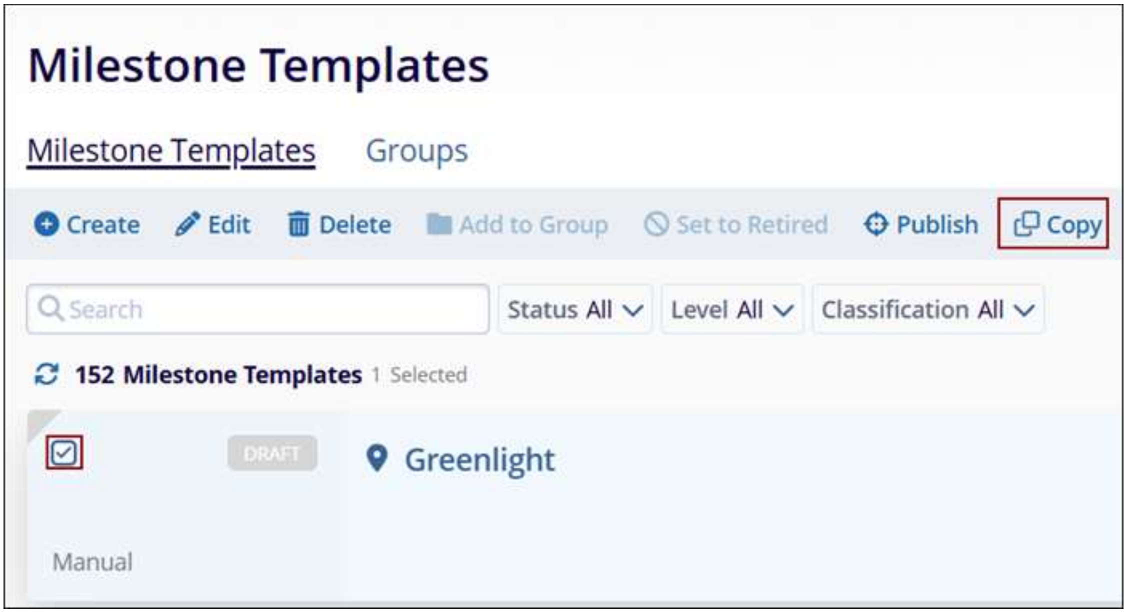


Figure: Copying a milestone template

3. On the Copy Milestone Template screen, click on the Create button.

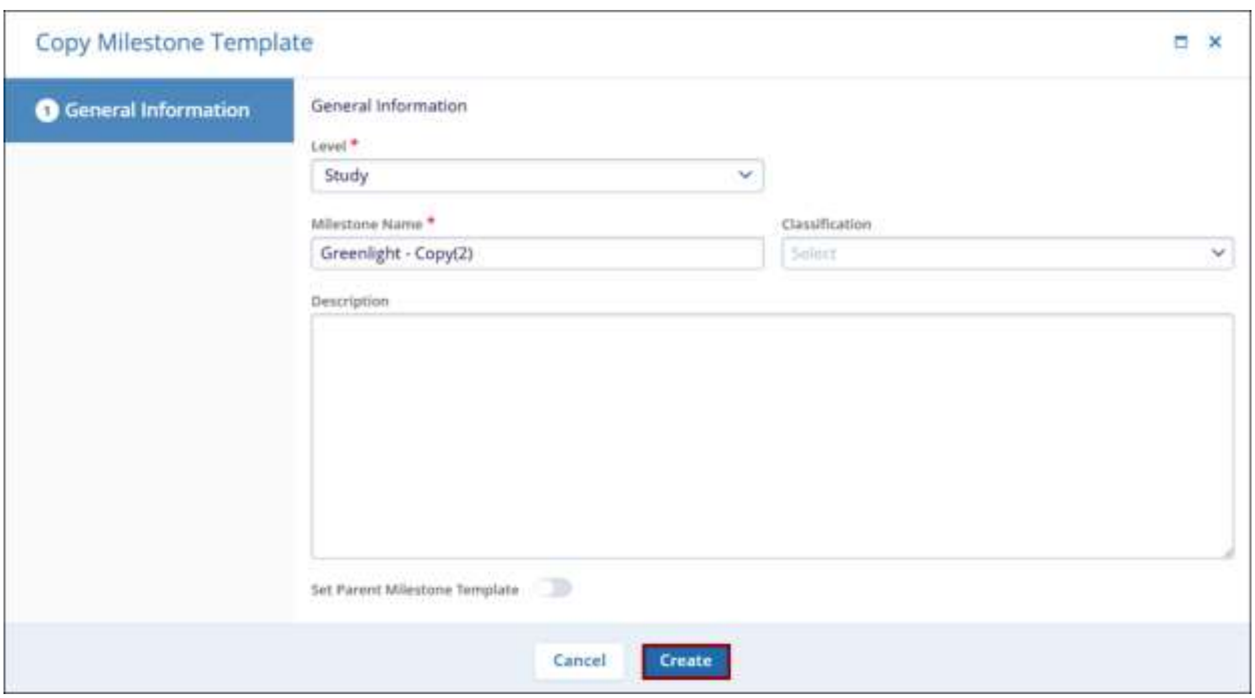


Figure: Create a milestone template copy

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

Associating Milestone Templates to a Sponsor

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

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

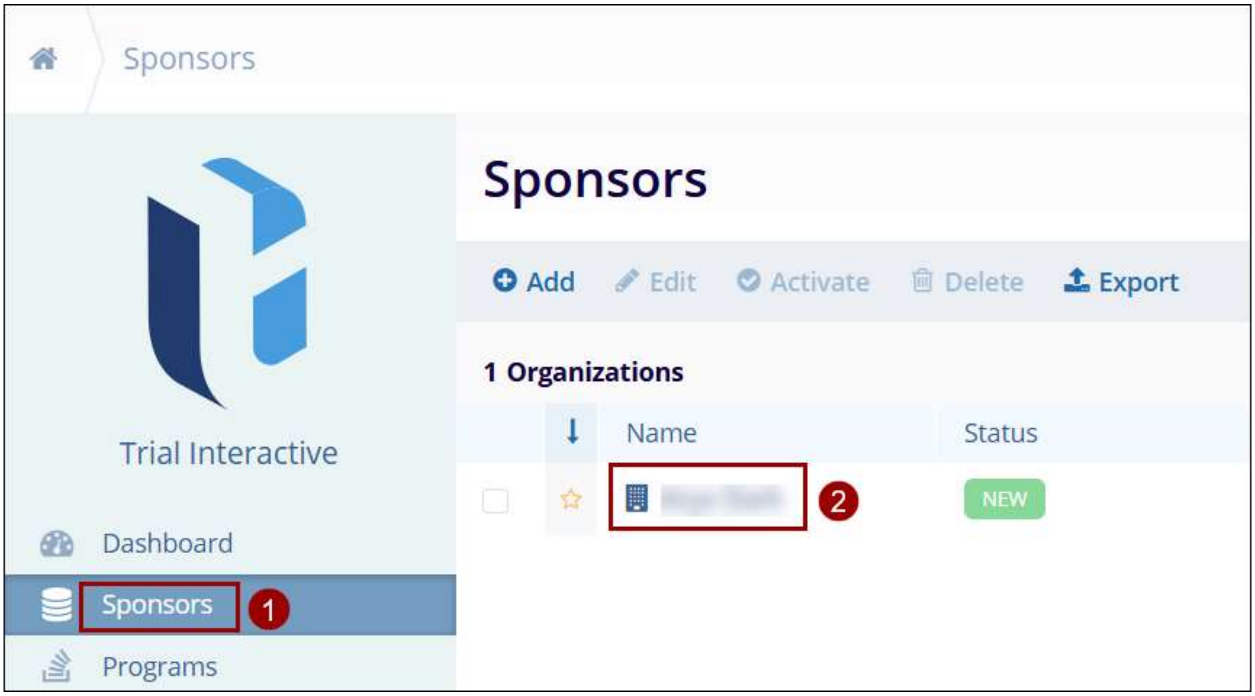


Figure: Select Sponsors

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

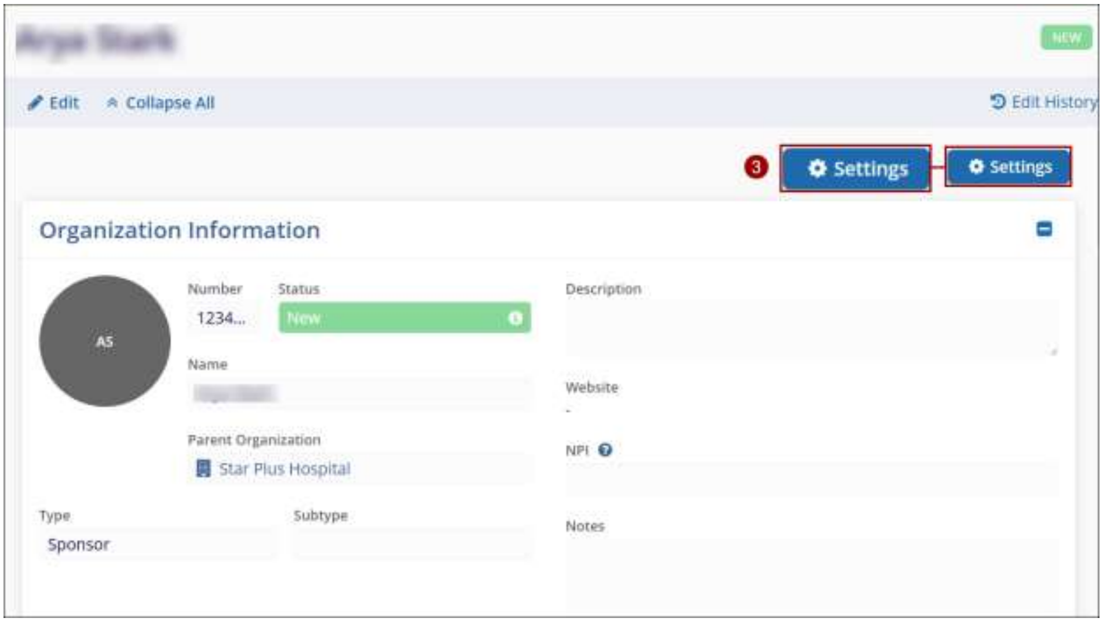


Figure: Access Setting on the Sponsor Details screen

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

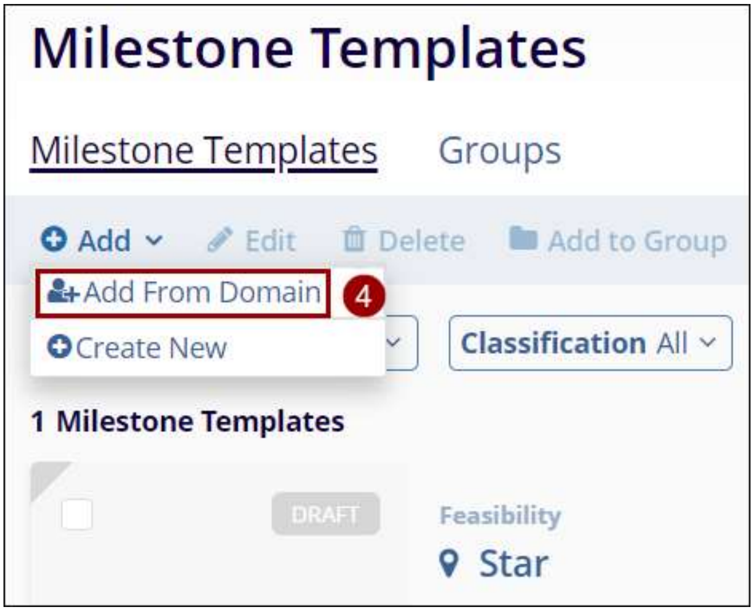


Figure: Add Template From Domain

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

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

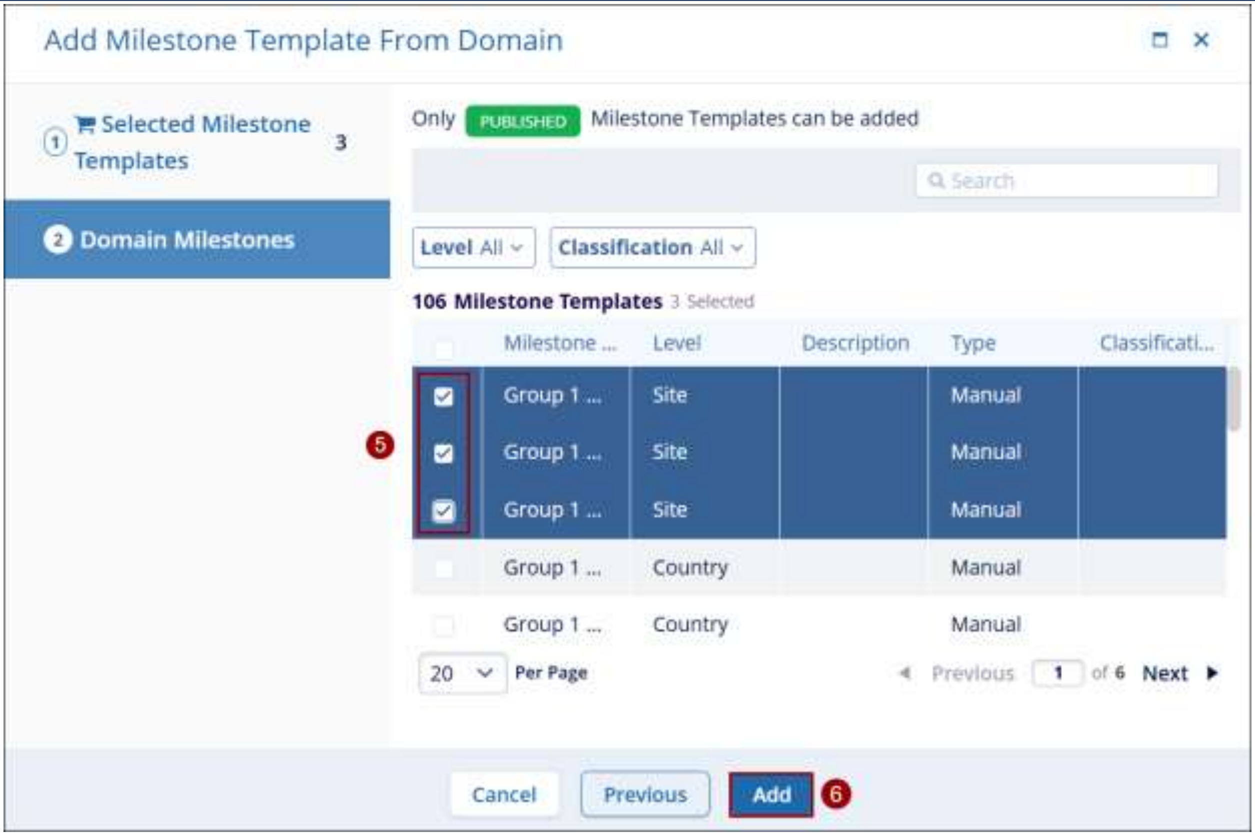


Figure: Add Milestone From Domain screen

Defining Sponsor-Specific Milestone Templates

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

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

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

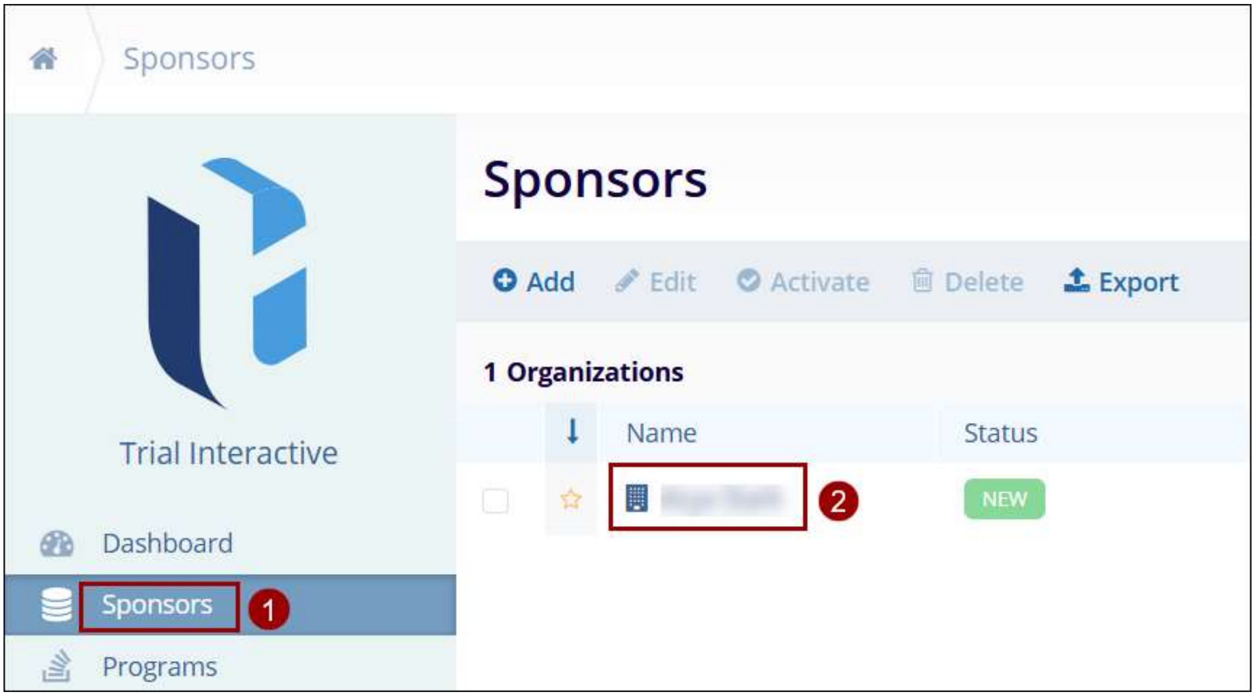


Figure: Select Sponsors

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

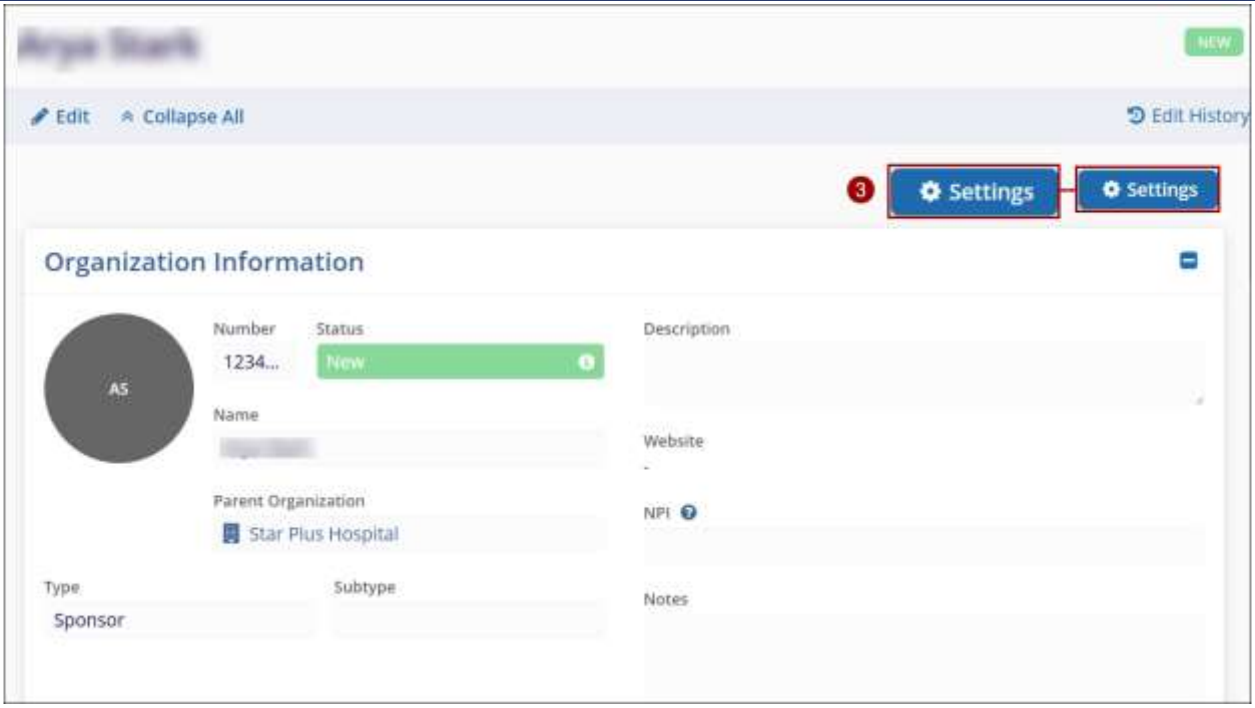


Figure: Access Setting on the Sponsor Details screen

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

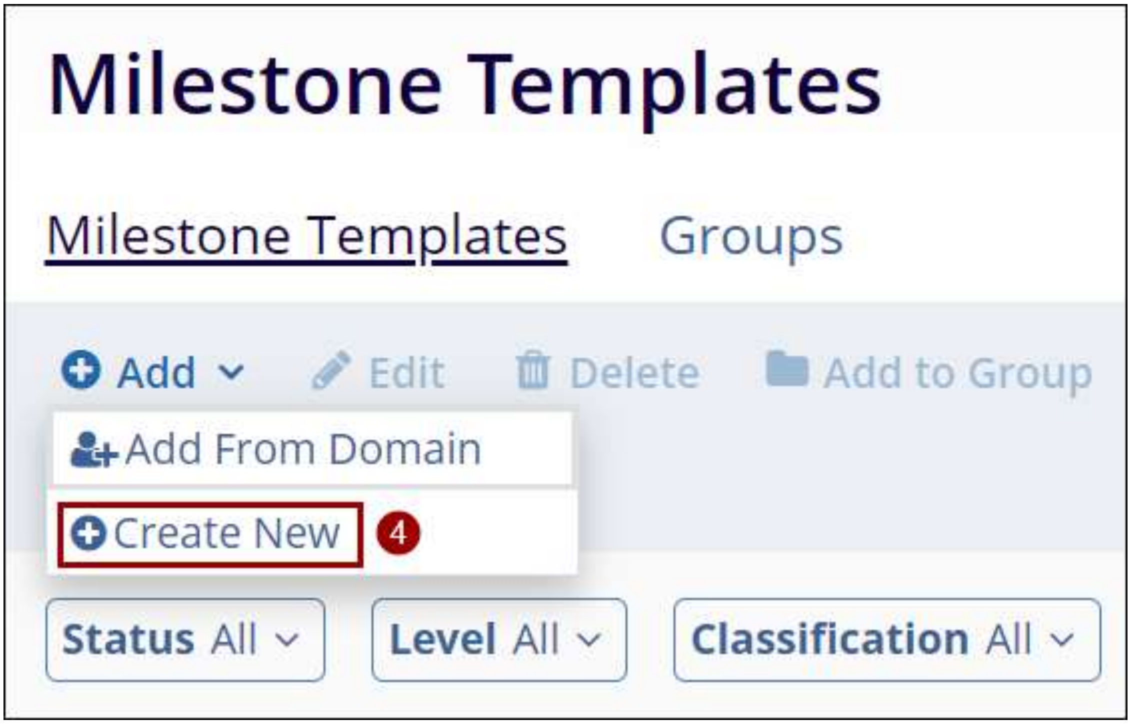


Figure: Create a new milestone template for the sponsor

5. On the Create Milestone Template from the Domain window, add all the mandatory details.

6. Click on the Add button once all the mandatory details are entered.

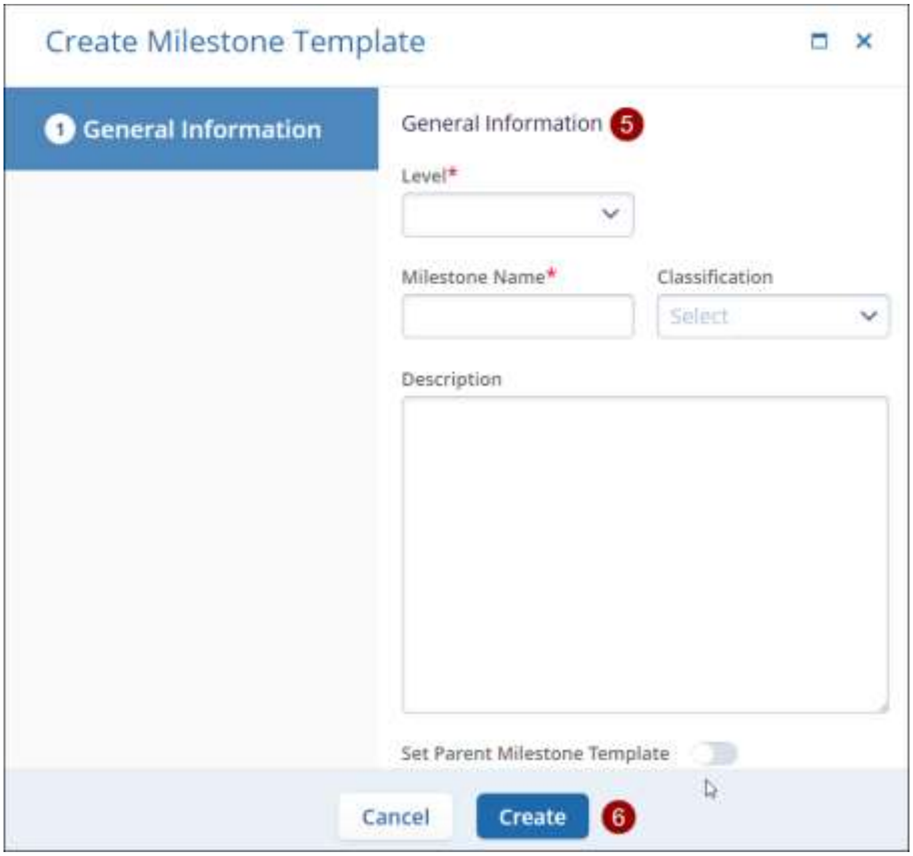


Figure: Creating new milestone template for sponsor

Tracking Milestones

To track milestones, follow the steps below.

1. From the left-hand navigation links click on the Studies.
2. On the Studies window, click on the name of the study.
3. On the selected studies window, navigate to the left-hand navigation links and click on the Study Details.
4. On the Study Details screen, click on the Settings button in the top-right of the screen.
5. Click on Start Tracking in the top-left of the screen. This opens the Start Tracking confirmation window.
6. Click on the Yes, start tracking button which will result in all milestones to be applied and start tracking, not just the selected milestone.

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

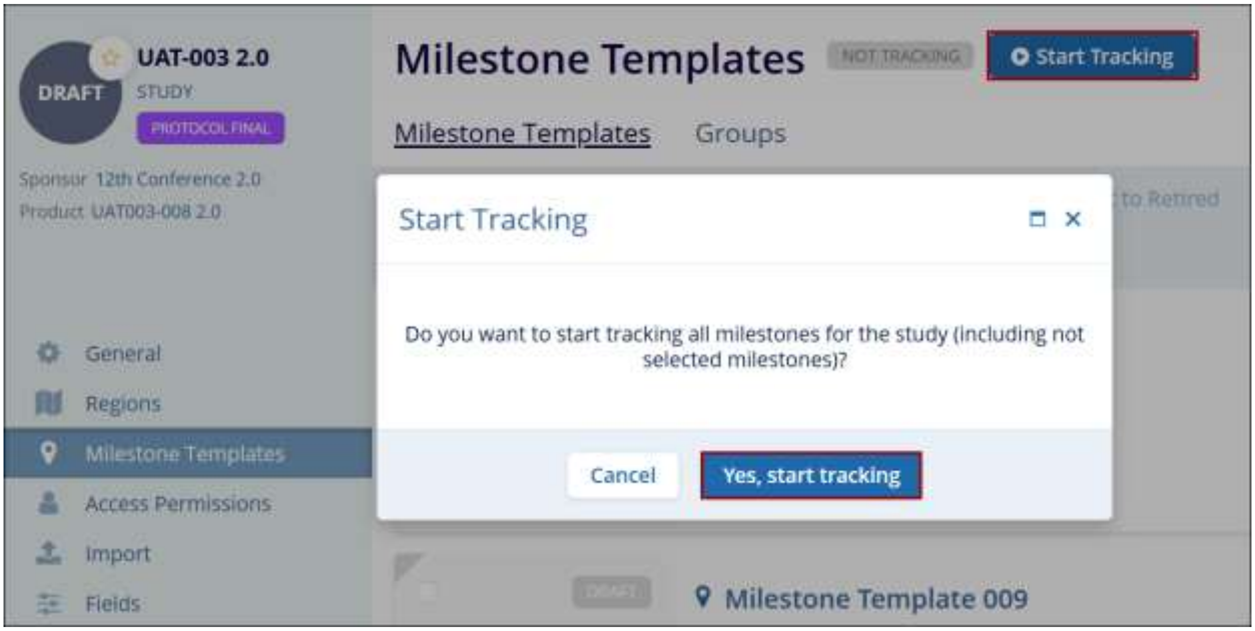


Figure: Tracking Milestones

Auto Apply

It can be difficult, at times, to remember to apply a newly added or created milestone to a study. Users can enable the Auto Apply Templates toggle switch at the top-right corner of the Milestone Templates screen at the study level. This way, Study Managers can indicate whether or not milestones should be applied manually, as needed, or automatically once they are published and added to a study.

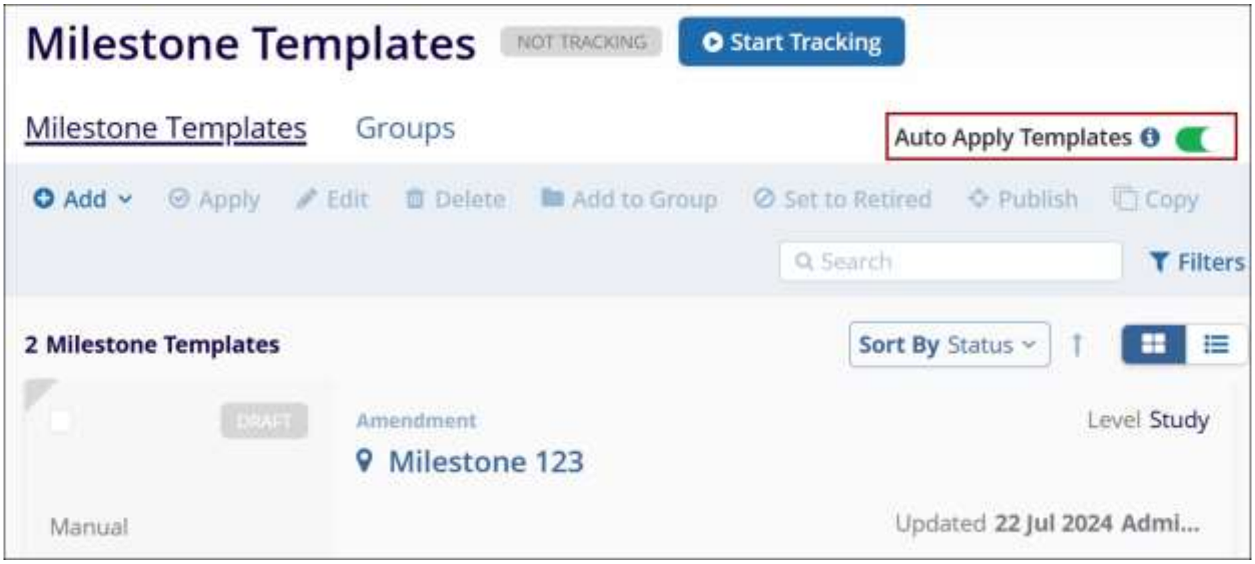


Figure: Auto Apply Templates

Note: This would not apply the template to sites created after this switch is activated. For future sites, it is recommended to use the scheduler for activity plans.

Milestone Groups

Users can create and apply groups of milestone templates as needed. Only published milestone templates may be added to a group. Milestone groups may be set up at the Global or Study level by users with sufficient access to either level of data.

Creating Milestone Groups

To create Milestone Groups, follow the steps below. Refer to the screenshot and steps for the sequence.

1. From the left-hand navigation links, select Milestone Templates.
2. Click on Groups on the Milestone Templates screen.

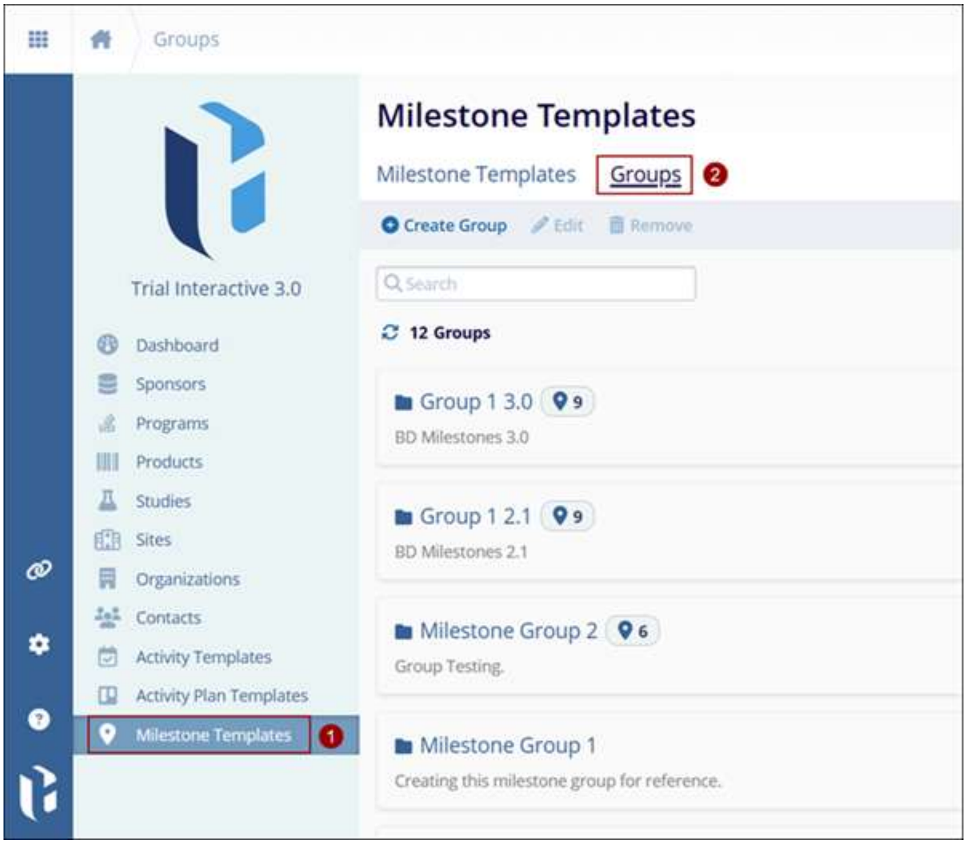


Figure: Milestone Groups

3. Click on +Create Group.
4. On the Create a Group screen, fill in the following details.
    a. Title*: Enter a suitable title for the group
    b. Description*: Enter the necessary description for the group.
5. Click on Create once all the necessary details are entered.

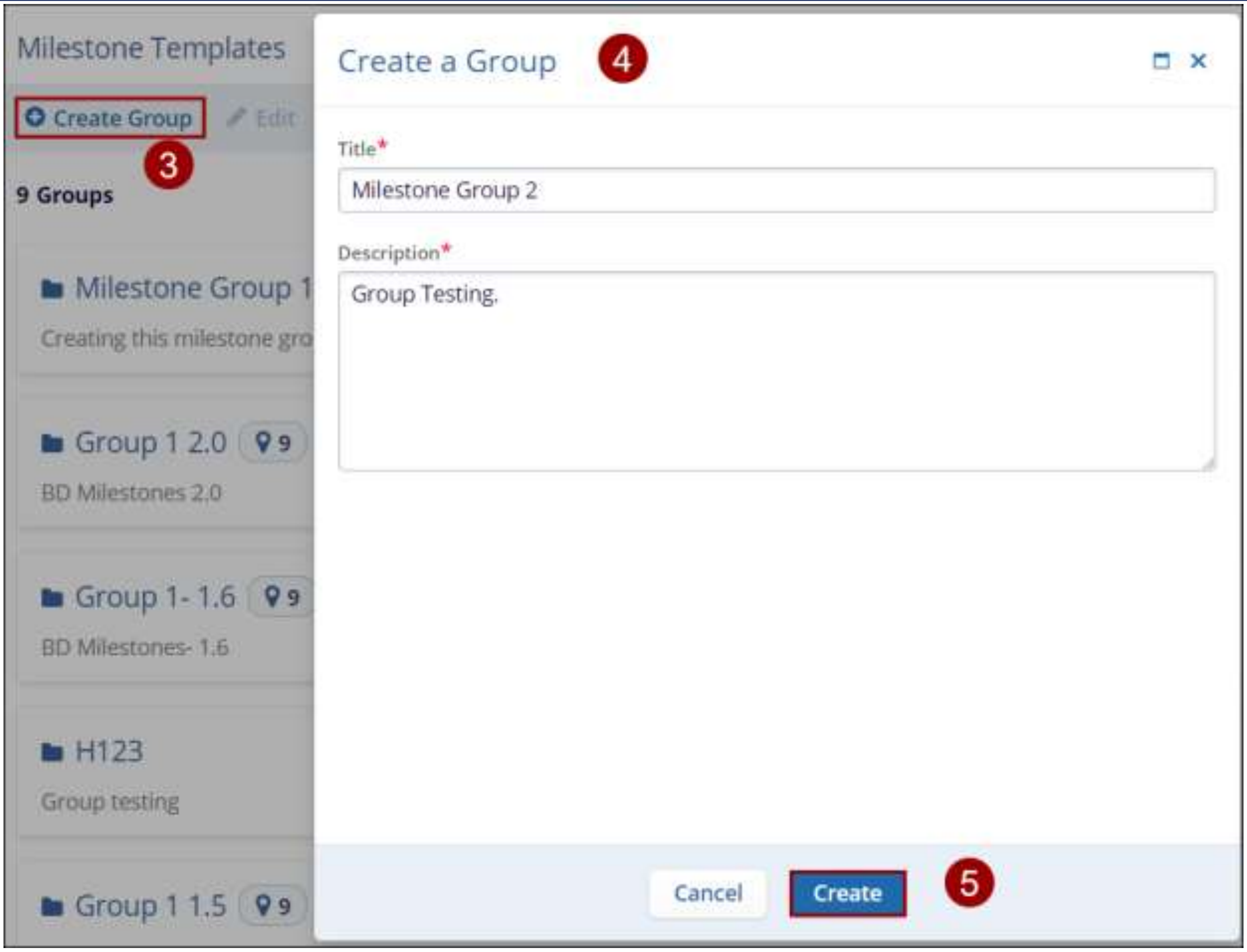


Figure: Create a Group

6. Once the record is successfully created, users will get a success message and the newly created group will appear on the Groups screen.

Figure: Success notification for the newly created group.

Adding Template to a Milestone Group

To add templates to a Milestone Group, follow the steps below

1. Click on the Milestone Group name (Milestone Group 2)

Figure: Adding Template to a Milestone Group

2. On that Milestone Groups screen, templates that are added to that group are visible. To add more templates, click on +Add.

Figure: Group Details

3. Click on the respective templates checkboxes to select the templates and then click on Add.

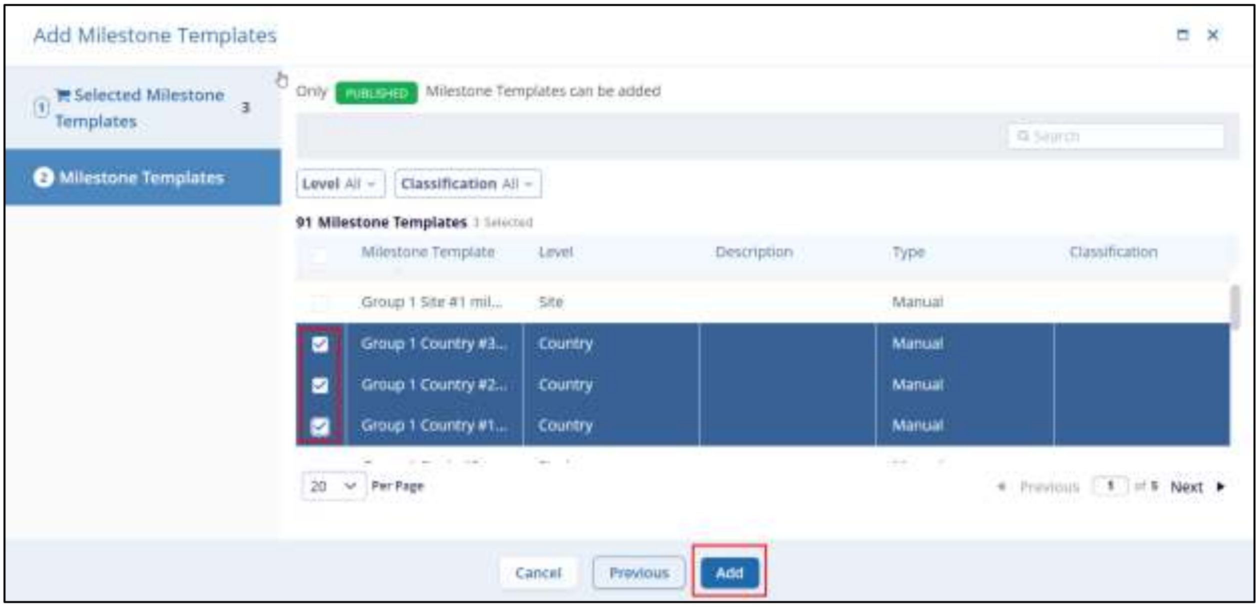


Figure: Select and Add milestone templates to groups

4. The screen displays a success notification once templates are added to the groups. The Group Details screen displays the total number of templates associated with that group.

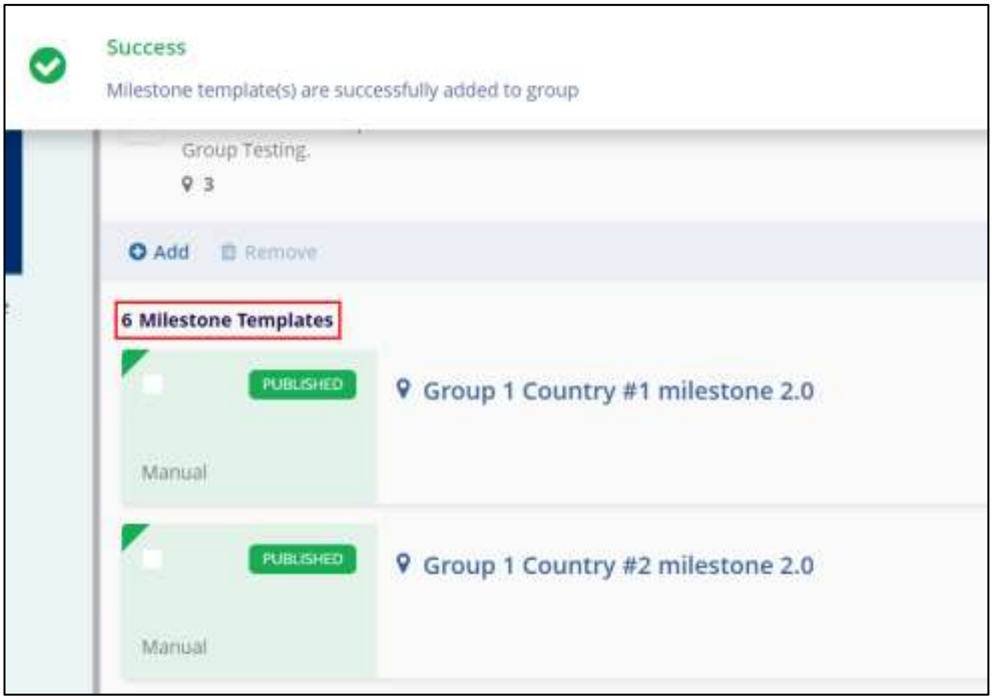


Figure: Milestone template success notification

Removing Templates from Milestone Groups

To remove templates from a Milestone Group, follow the steps below. Refer to the screenshot for the sequence.

1. Select a template by clicking on that particular template checkbox.
2. Click on the Remove button from the top menu bar
3. On the Remove from Group confirmation popup, click on the Remove button.

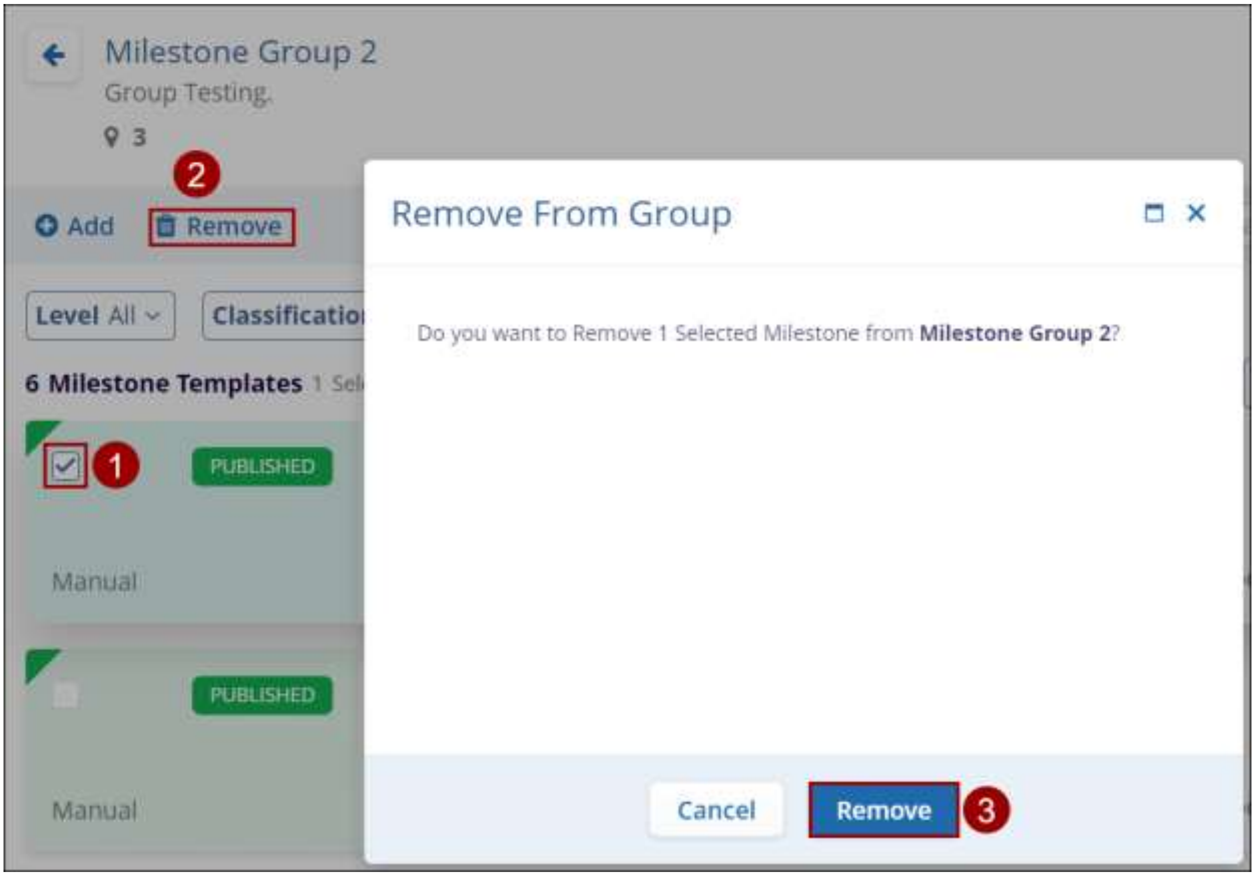


Figure: Removing templates from group

Customizing Milestone Groups screen

Users can apply filters and sorting criteria, as well as customize the screen view of the selected milestone group.

Filters

To apply filters, follow the steps below

1. Click on Filters situated beside the search box.
2. By, default the screen displays milestones created at a Country, Site, and Study level. Click on the Level dropdown and select the appropriate option.
3. Click on the Classification dropdown and select the required option.

Figure: Filters

Sorting

To sort the screen, follow the steps below

1. Click on the Sort By dropdown and select the appropriate sorting criteria. By default, the Status sorting criteria are applied.
2. Click on the arrow to sort the screen in ascending or descending order.

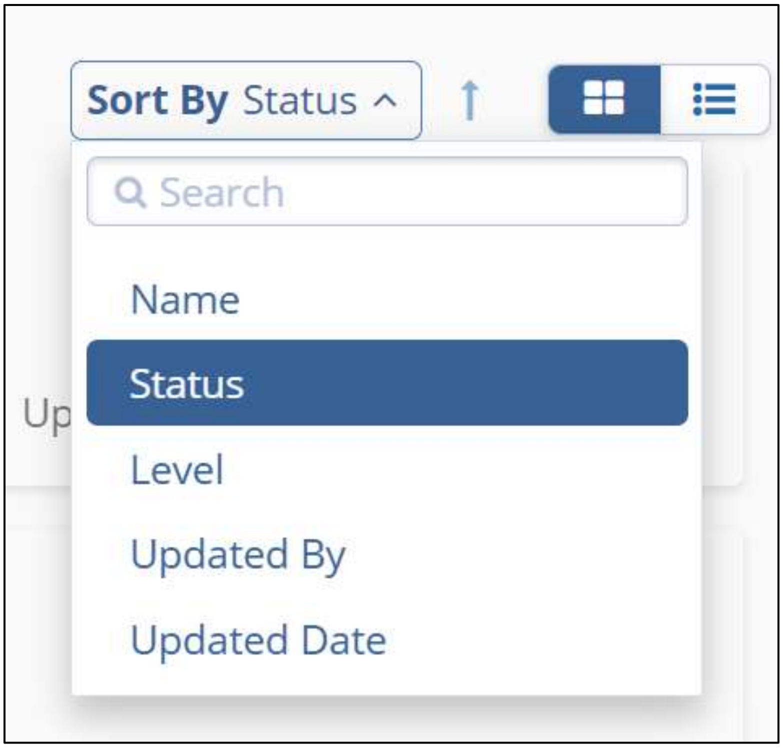


Figure: Sorting criteria

View

To customize the screen view, follow the steps below

1. Navigate to the screen customization icons situated beside Sort By dropdown.
2. Select either Grid View or List View.

Note: By default, Grid View is selected.

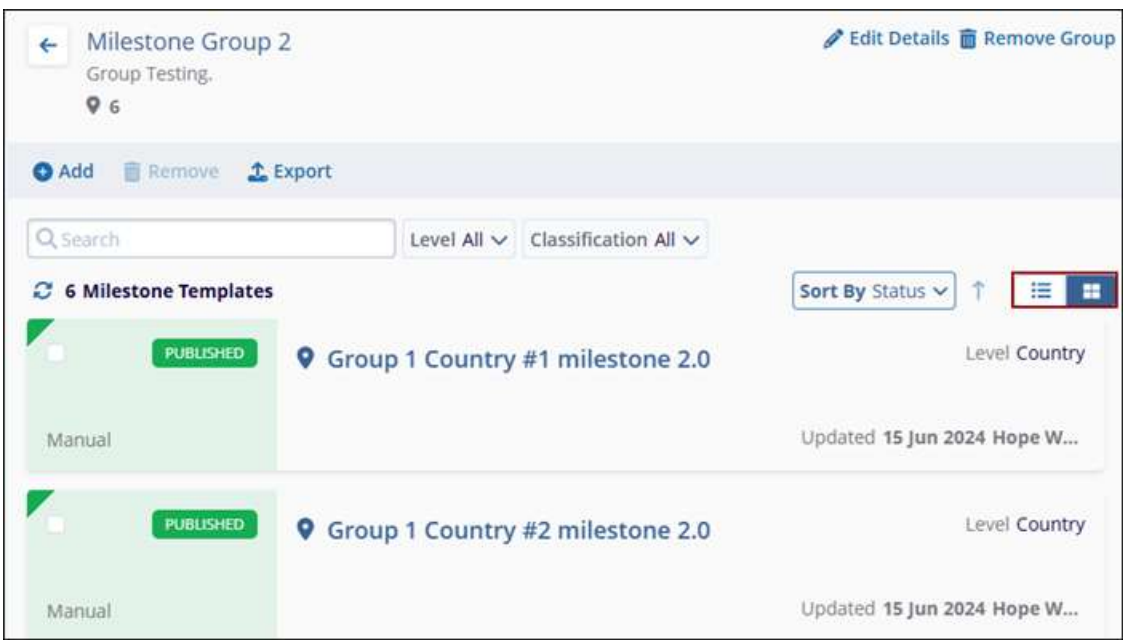


Figure: Grid View or List View

Editing Group

To edit the group, follow any one of the two methods listed below

Method 1

1. From the left-hand navigation links, select Milestone Templates > Groups
2. Select a group by clicking on the group tile.
3. Click on the Edit icon from the top menu bar.

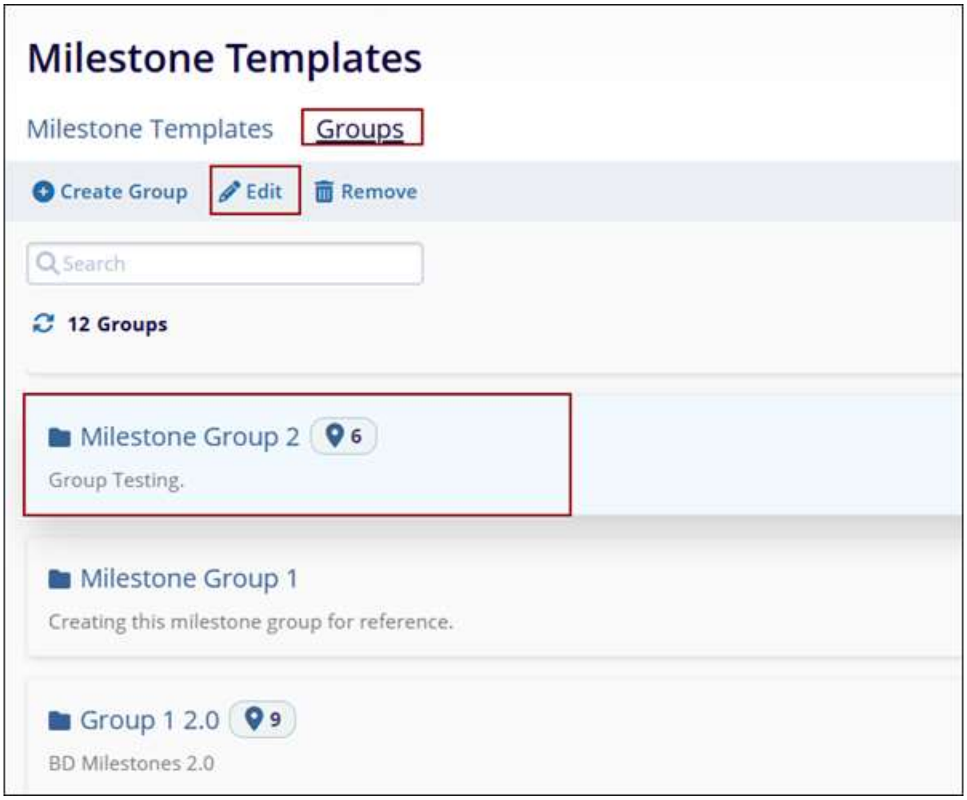


Figure: Editing Group

4. On the Edit Group Details page, make the required changes to the Title* or Description*.
5. Click on the Edit button, which will become accessible when edits are made, once the required details are updated.

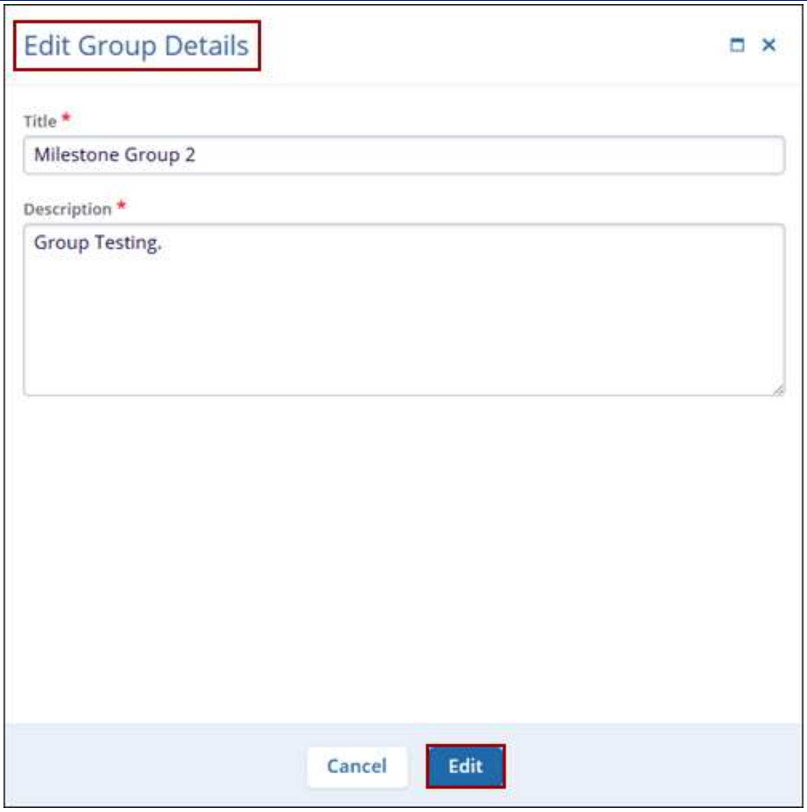


Figure: Edit Group Details screen

Method 2

1. From the left-hand navigation links, select Milestone Templates > Groups
2. Click on the name of a group that needs to be edited which will then open that particular group's screen.

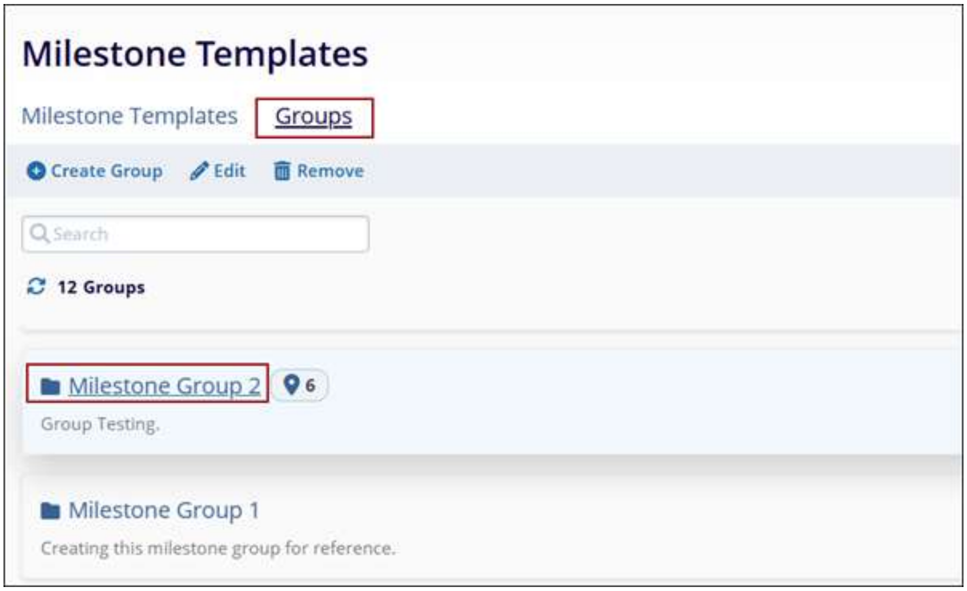


Figure: Select the group name

3. Click on Edit Details,
4. Make the required changes on the Edit Group Details screen, and select Edit.

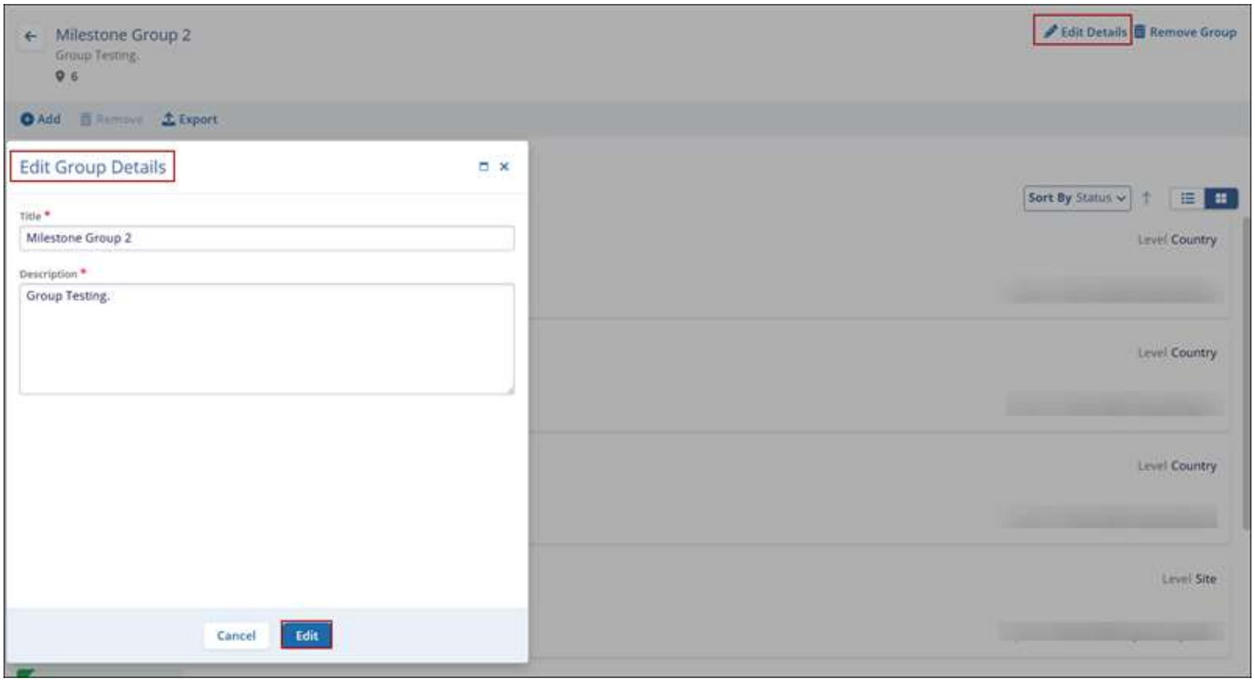


Figure: Edit Group Details-method 2

Removing Group

Method 1

1. From the left-hand navigation links, select Milestone Templates > Groups.
2. Select a group by clicking on the group tile.
3. Click on the Remove icon from the top menu bar.

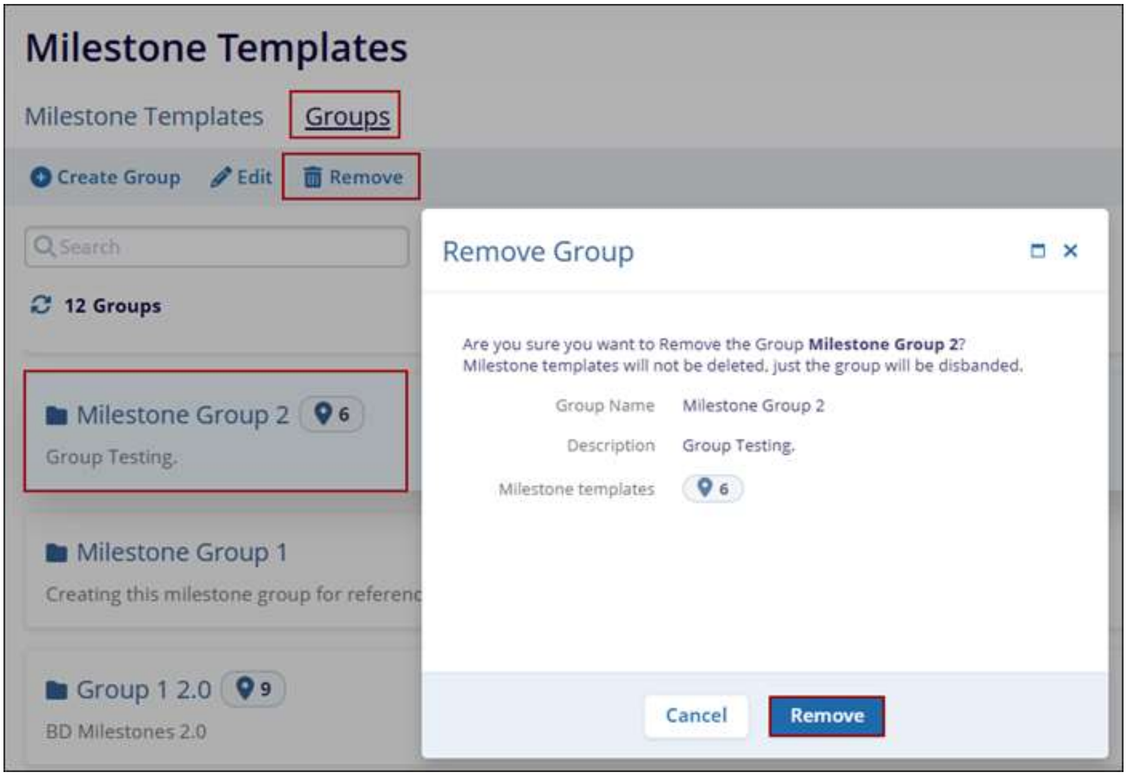


Figure: Removing Group-method 1

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.

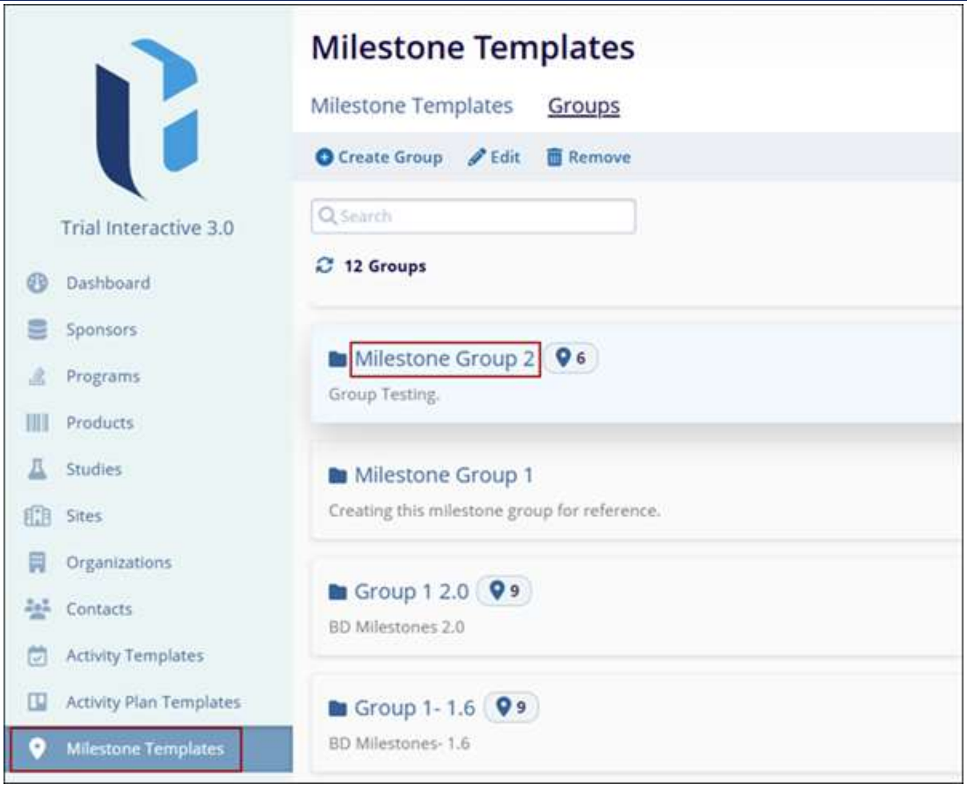


Figure: Select the group name – method 2

3. Click on the Remove Group button.
4. Click on the Remove button on the Remove Group screen.

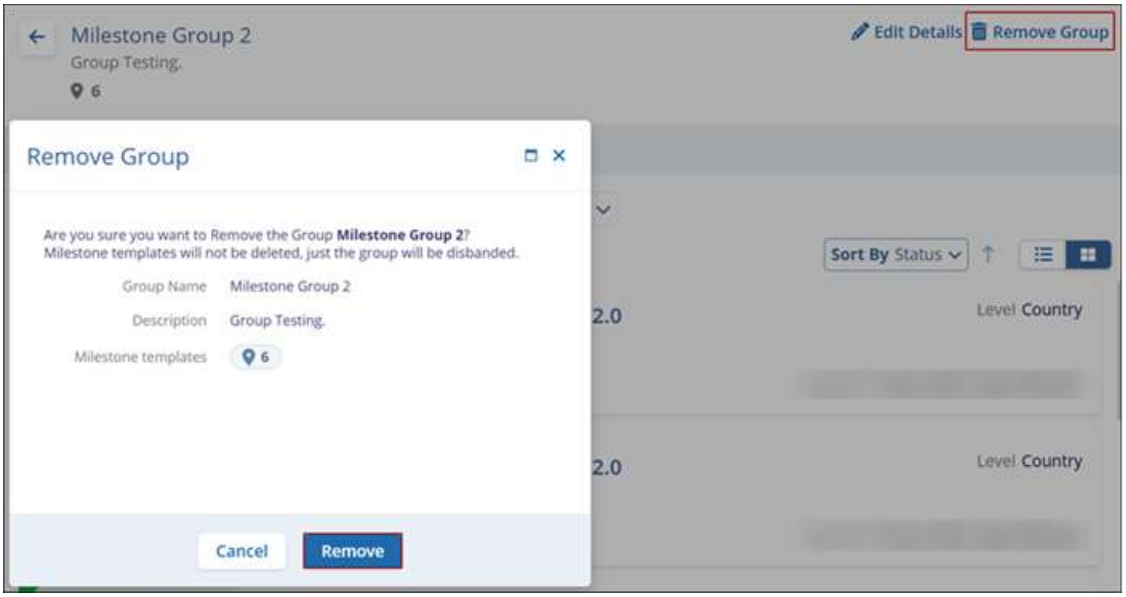


Figure: Remove Group-method 2

CHAPTER 16. ANALYTICS

The Analytics module is an integration of CTMS data with the TI Analytics tool, providing users with seamless access to comprehensive study data directly from the CTMS interface. Users can now utilize TI Analytics to track key study metrics, monitor site performance, and gain insights into trial outcomes with dynamic, customizable visualizations.

Note: The Analytics module needs to be explicitly enabled for users at the domain level and the study level.

Analytics at the Domain Level

1. From the left-hand navigation pane, select the Analytics module.
2. The Analytics module page displays the welcome message. Click on the link to access the dashboards and dashlets.

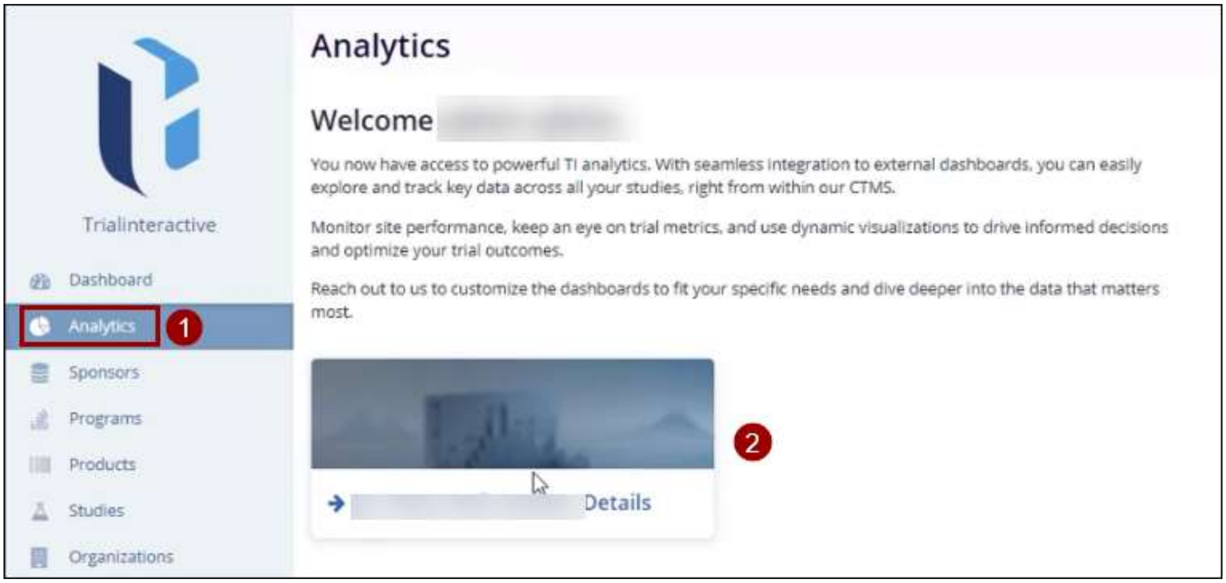


Figure: Access Analytics module

Dashboards at the Domain level

The customizable dashboards in TI Analytics enable users to monitor site performance, check the trial metrics, use dynamic visualizations to drive informed decisions and optimize trial outcomes.

The TI Analytics module displays the following dashboards at the domain level.

Study Team Assignment

The Cross Study Team Assignment dashboard displays a comprehensive, domain-level view of study team assignments across all studies within the customer's domain/CTMS. The dashboard consolidates data from multiple studies and displays it in one place.

To access the Cross Study Team Assignment dashboard, follow the steps below

1. Click on the Study Team Assignment dashboard tab.
2. Click on the ellipsis (vertical three dots) icon, and select the Export to CSV or Export to Excel option to retrieve the dashboard data into the respective file formats.
3. Expand the filters section and apply the filters to view data as per selected criteria.

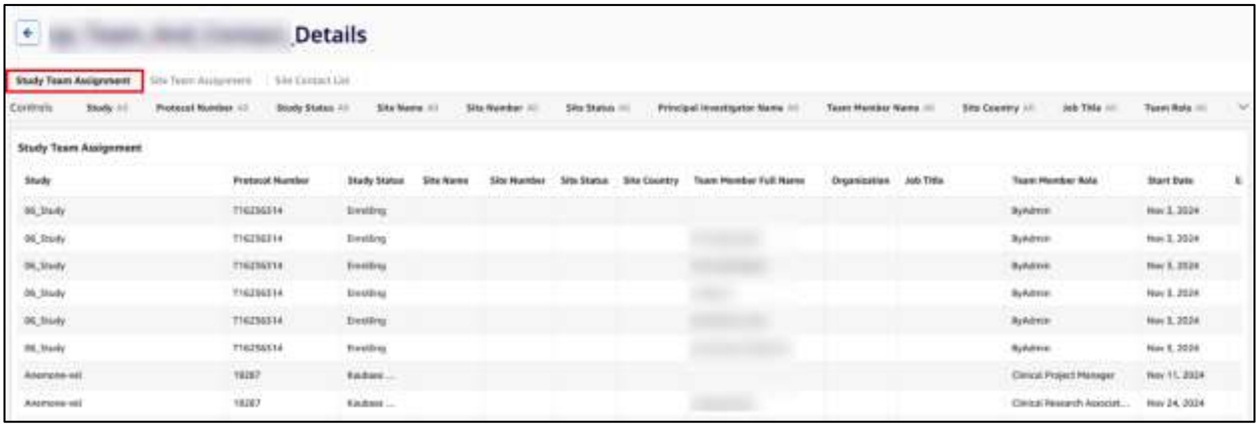


Figure: Study Team Assignment

Site Team Assignment

The Site Team Assignment dashboard offers comprehensive insights into site team assignments across studies.

To access the Site Team Assignment dashboard, follow the steps below.

1. Click on the Site Team Assignment Dashboard tab.
2. Click on the ellipsis (vertical three dots) icon, and select the Export to CSV or Export to Excel option to retrieve the dashboard data into the respective file formats.
3. Expand the filters section and apply the filters to view data as per selected criteria.

Figure: Site Team Assignment

Site Contact List

The Site Contact List dashboard displays all site contacts across all studies.

To access the Site Team Assignment dashboard, follow the steps below.

1. Click on the Site Contact List Dashboard tab.
2. Click on the ellipsis (vertical three dots) icon, and select the Export to CSV or Export to Excel option to retrieve the dashboard data into the respective file formats.
3. Expand the filters section and apply the filters to view data as per selected criteria.

Figure: Site Contact List

Analytics at a Study level

To access the TI Analytics dashboard at a study level, follow the steps below.

1. From the left-hand navigation pane, select Studies.
2. On the Studies screen, click on a Study Name.
3. On the Study Details screen, click on Analytics from the left-hand navigation pane.

Study Overview Dashboard

The Study Overview Dashboard displays the following dashlets.

Site by Status

The Sites by Status dashlet at the Study-level dashboard in TI Analytics, is designed to provide users with a comprehensive view of site status across a study. By default, the dashlet displays all site records, including Potential Sites, which can be filtered out as needed based on user preferences.

<u>Key features include:</u>

- Default Comparison: The dashlet automatically compares site status data from today with 30 days ago, giving users insight into changes in site statuses over the past month. This comparison can be adjusted by selecting specific date ranges.
- Group by Status: The system groups sites by their current status, allowing users to quickly view and assess site progress within the study.
- Advanced Filtering: Users can filter sites by Dates (From-To) for the statuses (e.g., only show sites with a current status within X and Y date) (date range)
- Export Capabilities: Export deviation data to Excel, CSV, or PDF formats, for easy sharing and reporting.

<u>Key Benefits</u>

- Status Progress Monitoring: The dashlet allows users to track site progress over time, comparing site statuses between two points to identify trends and improvements.
- Customizable Insights: Users can apply flexible filters, narrowing down the data by dates and statuses to focus on the most relevant information for their study.
- Easy Reporting: Exporting allows for seamless sharing of data and charts with stakeholders.

Deviation Activities

This release introduces the Protocol Deviation Dashlets to the Study-level dashboard in TI Analytics, providing users with powerful tools to monitor and analyze protocol deviations across their study. These dashlets include advanced filtering options, customizable data views, and comprehensive export capabilities for efficient deviation management.

Key Features:

- Deviation Records by Default: Automatically displays activity records where Subtype = Deviation, offering immediate visibility into protocol deviations.
- Potential Sites Included by Default: Potential Sites are included in the default site list, with the option for users to filter them out.
- Advanced Filtering: Users can filter data by fields such as Type, Status, Due Date, Severity, Identified Date, Occurrence Date, and Responsible Party, enabling precise deviation tracking.
- Date Range Filtering: Narrow results to deviations that occurred within a specified date range for more focused analysis.
- Export Capabilities: Export deviation data to Excel, CSV, or PDF formats, for easy sharing and reporting.
- Side-by-Side Site Comparison: Review individual site deviations side by side within the dashboard, using customizable category filters to enable detailed analysis with a detailed deviation listing.

Issue Action Activities

The Issue/Actions Activities Dashlet at the Study-level dashboard in TI analytics, provides users with powerful tools to monitor and analyze study-related issues/actions across their study.

Key features:

- Issue/Action Activity Records by Default: Automatically displays activity records where the subtype equals ‘Issue/Action’.
- Potential Site Included by Default: The dashlet organizes issue/action records by status and highlights open issues/actions by site, including Potential Sites, which can be filtered out.
- Advanced Filtering: Users can filter records by Status, Due Date, Severity, Identified Date, Date It Occurred, and Responsible Party, enabling precise issue/action tracking.
- Date Range Filtering: Narrow results to issues/actions that occurred within a specified date range for more focused analysis.
- Export Capabilities: Export deviation data to Excel, CSV, or PDF formats, for easy sharing and reporting.

Key Benefits

- Efficient Tracking: Users can easily monitor issues/actions by status, site, and customized filters.
- Flexible Reporting: Exporting data and charts enables streamlined reporting, and side-by-side comparison provides deeper insights across sites.