TRIAL INTERACTIVE

TI CTMS V2.1 - USER GUIDE V1.0

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LIFE SCIENCES

APPROVALS

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VERSION HISTORY

Author	Revision	Date	Change History
Salil Joshi	1.0	13-Dec-2024	Initial version finalized.

ABOUT THIS USER GUIDE

This guide provides a comprehensive overview of the features and components of the TI CTMS v2.1 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 V2.1

Subject Transfer Between Study Sites with Comprehensive Data Tracking

This feature introduces the ability to transfer subjects between sites within the same study, ensuring seamless tracking of subject details and visit histories while maintaining data integrity across sites.

What's New:

- Subject Transfer: Users with the appropriate permissions can transfer subjects from one study site to another, transferring key data such as subject details, status history, and visit history.
- Data Integrity: Subject-related activities, ICFs, and visit schedules will not be transferred, ensuring a clear distinction between sites.
- Visual Identification & Quick Links: Transferred subjects are visually identified, with references and quick links to both the original and new sites available on the Subject Details page and Subject Quick View.
- Status Handling: Subject statuses "Transferred In" and "Transferred Out" will be automatically set when the subject transfer action is performed. The system ensures the subject's data from the originating site is locked and cannot be edited post-transfer. However, Super Admins can unlock the original site data if necessary.
- Status Counting & Enrollment Summary: Statuses achieved at each site are only counted for that site's enrollment metrics, preventing duplication in summary numbers.
- Transfer Notifications: Clear notifications are displayed during transfers, alerting users to the data being transferred and ensuring users understand which data can be viewed but not edited.
- Filtering & Subject Management: Users can filter subjects by "Transferred In" and "Transferred Out" statuses to better manage tracked subjects.
- Status Messaging: When adding a duplicate status (a status previously recorded before the transfer – historical status), the system warns users of potential double counting before they finalize the action.

Business Value: This feature allows studies to seamlessly transfer subjects between sites without losing valuable data, ensuring continuity in subject tracking even when participants move locations. By maintaining the integrity of subject statuses and visits, while offering clarity on editable and non-editable data, this enhancement helps prevent data duplication and ensures accurate reporting of study metrics across multiple sites.

Potential Site Management

This feature introduces the ability to manage and track potential sites as well as active study sites, providing greater control over site statuses and ensuring accurate site data management throughout the study lifecycle.

What's New:

- Potential Site Status Definition: The system allows users to define a site status as

"Potential" in Settings > Statuses > Sites and to visually identify potential site statuses within the site status list.

- Potential Site Criteria: To create a potential site, the system requires the Principal Investigator's:
  - Last Name
  - First Name
  - Email address
- Restrictions on Potential Sites: For sites marked as potential, subject creation and importing are restricted, ensuring potential sites do not track subjects or impact subject management. The system will display clear messaging to users when attempting to create or import subjects for potential sites.
- Potential Site Dashboards and Analytics: Site visit documentation for potential sites will appear in the Site Visit Report Review Status and CRA Performance Dashboards. Potential sites will not be included by default in all CTMS or Analytics dashboards.
- Site Number Assignment: Potential sites will not be automatically assigned a site number. A site number will only be assigned once the site status is changed to a non-potential (active) status and an organization with a physical address is assigned to the site.
- Site Status Transition: The system supports the transition from a potential site status to a non-potential site status. A confirmation message will notify users of the transition, and the system will ensure all necessary information (organization, physical address) is captured before the status change.
- Bulk Status Updates: The system provides clear messaging during bulk status updates if certain sites cannot be transitioned to a non-potential site status, explaining the reasons (e.g., missing organization or address).
- Restricted Reversion to Potential Status: Sites that have transitioned to a non-potential site status cannot revert back to a potential site status without a support ticket submission.

Business Value: This enhancement enables organizations to manage potential sites as well as active sites, ensuring that data related to potential sites is properly tracked and available for future use. By restricting subject management for potential sites and ensuring accurate site information before transitioning to active site statuses, the system improves data integrity and resource planning while allowing for historical reference of sites.

New Feature: Site Visit Windows

This feature offers users more insight into site visit compliance. In combination with the existing CTMS feature of site visit forecasting, site visit windows will allow for the user to easily identify site visits that occur in or out of the window. Users will be able to define visit frequencies with an allowable range of days, ensuring visits align with the study's monitoring plan.

- Users can currently set visit frequencies, for example "+ 30 days," allowing for tailored scheduling of next visits to accommodate study needs.
- With this release the system will now allow for the configuration of acceptable visit windows, giving teams the flexibility to plan visits within a defined timeframe around the planned visit date, "+30 days within -/+ 5 days".
- As part of the upgrade, existing customers with month-based visit frequency settings will automatically transition to a 30-day frequency. "Month" value will no longer be

available for selection.
- Site Visits with a status of Planned or In Progress at the time of window definition Initial Entry will have a window calculated within dashboards
- Site Visits with a status of Planned or In Progress at the time of window definition Editing will have a window re-calculated within dashboards

Business Value: This enhancement simplifies visit planning, boosts operational efficiency, and unlocks new reporting and analytic features.

New Dashlet: TI Analytics - Protocol Deviation Dashlets

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.

Business Value: This dashlet provides powerful insights into protocol deviations, enabling users to track, analyze, and manage deviations more effectively. With customizable filtering, side-by-side comparison, and export capabilities, users can gain greater control over deviation management, improving study oversight and decision-making. By including potential sites by default, users also maintain comprehensive site visibility, while still having the flexibility to filter out unnecessary data.

Site Visit Report Status Synchronization

This enhancement ensures better alignment between the site visit document state (within the CCR) and the status reflected within the Report Status field within the site visit (within CTMS). It introduces new automated statuses and refines existing ones for more accurate and timely tracking of site visit reports, improving overall workflow efficiency and reporting accuracy.

What's New:

- Report Generated: Automatically set when a report/document is successfully created.
- In Review: Automatically set when a reviewer begins the site visit report/document review.

- Revised: Now set only after a rejected report is regenerated and the document approval workflow is started (within the CCR.)

Additionally, the Report Generated and In Review statuses will be added to the Site Visit Report Review Status dashboard and the CRA Visit Report Performance dashboard, improving visibility and performance tracking.

Phone Number Primary Indication

This release introduces the ability for users to set any phone number type as the primary number for contacts, organizations, or site records. The system ensures that only one phone number can be assigned as the primary phone number at any time. Users can easily reassign the primary indication to any additional phone numbers.

To streamline the process for existing records, the system will automatically assign the "Primary" indication to any phone number records that are currently marked with a type equal to "Primary." After the release of v2.1 the "Primary" value will no longer be available for selection. The system will now default to "Work".

Additionally, the system now refers to this primary indication when enabling the Dial button within the quick view of contact records, ensuring that communication options are tied to the primary phone number.

Key Benefits

- Flexibility: Users can designate any phone number, regardless of type (e.g., office, personal), as the primary contact number, providing more control over how contacts are reached.
- Efficiency: The ability to reassign the primary phone number without needing to create new entries simplifies record management.
- Improved User Experience: The system intelligently enables key communication features based on the primary phone number, reducing manual steps for users.
- Record Management: Users can now easily manage primary phone numbers and reassign them without adding new entries. Existing records have been automatically updated.

This enhancement is available immediately across all contact, organization, and site records.

Export Functionality for Site Visit Checklists

This improvement introduces the ability to export site visit checklists directly from the Site Visit Checklist Templates library, offering users the ability to produce documented verification of their checklists. Users can now easily export checklist details and questions in a professional format that aligns with their compliance needs and reporting requirements.

Key Benefits:

- Export individual or multiple site visit checklists in a single action.

- Export format will be .pdf, ensuring the output mirrors the checklist preview mode.
- The exported documents can be easily filed in eTMF or other document repositories for streamlined compliance and record-keeping.

TI Analytics - CTMS Data Integration

This feature introduces 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.

Upon navigating to TI Analytics, users will be greeted with a landing page message that outlines the capabilities of this integration.

This integration allows users to leverage advanced data visualization and reporting capabilities for efficient study management, with the option to further customize dashboards based on specific trial needs.

TI Analytics - Issue/Actions Activities Dashlet

This release introduces the Issue/Actions Activities Dashlet to the Study-level dashboard in TI analytics, providing 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.

TI Analytics – Sites by Status Dashlet

This release introduces the Sites by Status dashlet to the Study-level dashboard in TI Analytics, 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.

Key features include:

- 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.

Key Benefits

- 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.

TI Analytics – Cross-Study Team Assignment Dashboard

This release introduces a Cross-Study Team Assignment Dashboard in TI Analytics, providing users with 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, offering powerful filtering and export capabilities to streamline team assignment management. The dashboard provides extensive details for each study team member.

Users can filter the dashboard by Team Role, including any custom roles (e.g., Primary CRA) created by the customer. Additionally, the dashboard supports filtering by various other metadata points, such as study name, protocol number, study status, etc. Users can export the dashboard data into Excel, CSV, or PDF formats for reporting purposes.

This enhancement offers a centralized, detailed view of team assignments across studies, flexible filtering options, and streamlined reporting capabilities, allowing users to focus on relevant data and generate reports quickly and efficiently.

TI Analytics - Site Contact List Dashboard

This release introduces a Site Contact List Dashboard in TI Analytics, displaying contact information across studies from the customer's domain/CTMS.

Users can filter by various metadata points, such as study, site name, country, status, job title, role, etc. Data can be exported in Excel, CSV, or PDF formats.

This feature helps customers track site contacts and generate updated lists for vendors, as well as view team hierarchies and roles within studies, all in one centralized system. It simplifies reporting and contact management, previously done manually in external spreadsheets.

TI Analytics - Cross-Study Site Team Assignment Dashboard

This release introduces a new Cross-Study Site Team Assignment Dashboard that offers comprehensive insights into site team assignments across studies. The dashboard enables users to filter and export critical site data, ensuring streamlined management of team roles and statuses.

Key Features:

The dashboard provides a complete view of site team members, including key details such as Study Name, Protocol Number, Study Status, Site Name, etc.

Users can filter data by Study, Protocol Number, Study Status, Site Name, Site Status, Principal Investigator Name, Job Title, Team Role, Site Country, and team member Start/End Dates.

- Filters also allow for precise role-based viewing, including custom roles like Primary CRA.
- Filtering by Study, Site, and Country status ensures users can exclude closed, on-hold, or canceled sites.

The dashboard supports data export for easy reporting and external analysis. Data can be exported in Excel, CSV, or PDF formats.

This feature empowers customers to efficiently manage and track site team assignments across multiple studies. By including detailed filtering and export capabilities, users gain control over site-specific data, improving decision-making and oversight of team roles and statuses. Additionally, customizable filters help users focus on the most relevant data, ensuring they can exclude irrelevant or inactive sites and teams from their views.

Site Visit Report Review Cycle Definition at Domain Level

This release introduces the ability for customers to define what the site visit report review cycles will be based on at the domain level, allowing for greater flexibility in choosing between calendar or business days for report submission and approval timelines.

Key Enhancements:

- Day Definition Flexibility: Customers can now set the site visit report day definition as either calendar days or business days for all studies within a domain.
- Domain-Level Consistency: The day definition is applied at the domain level, ensuring uniformity across all studies. Individual studies cannot define their own day settings, ensuring consistency and avoiding negative impacts on analytics.
- Business Day Support: The system defines business days = 5 days per week and does not account for holidays.
- Calendar Day Support: Similarly, the system will support calendar days for the same timelines if the customer chooses this option.
- Default to Calendar Days: By default, the system will use calendar days for site visit report day definitions unless specified otherwise.
- Tool Tip Clarification: The Monitoring Information portlet within Study Settings > General will display a tooltip reflecting the domain-level day definition, ensuring users can easily identify the report review cycle settings (either business days or calendar days).
- Fixed Definition: Once set, the day definition cannot be edited by users. However, changes can be made by submitting a ticket to the service desk.

Enhanced Phone Number Import Handling

This improvement introduces the ability for the system to handle and import phone numbers in any format, reducing the need for manual data reformatting and simplifying the import process.

Key Enhancements:

- Flexible Phone Number Import: The system now supports the import of phone numbers in any format, allowing users to import data from various systems removing the need to reformat phone number fields.
- Format Validation on Editing: While imports are more flexible, the system ensures phone numbers that are reused are saved in the correct format. Suppose a phone number is imported and the associated record is edited and contains an invalid phone number format. In that case, the system will prevent the save action of any record edits until the phone number is corrected.
- User-Friendly Error Messages: When users attempt to save a record with an incorrectly formatted phone number, a clear and user-friendly error message will appear, guiding them to correct the phone number format to save changes.

This enhancement significantly reduces the time and effort required by customers who receive phone number data from external systems that use free text fields. By allowing flexible imports and providing clear validation and messaging during record edits, this feature streamlines data handling and improves user experience.

The ‘Created Date’ Field Added to Site Visit Activities

This improvement enhances the Site Visit > Activities data set by adding the 'Created Date' field, improving the ability to track and filter activity records for site visits.

Key Enhancements:

- 'Created Date' Display: The system now ensures that the 'Created Date' field is visible within the activities grid when adding existing activity records to a site visit.
- Record Selection View: The 'Created Date' field is also displayed in the activity record selection window, making it easier for users to view and select relevant records.
- Date-Based Filtering: Users can now filter available activity records by 'Created Date' when selecting activities for inclusion in a site visit, providing more flexibility in managing and organizing activity records based on a point in time.

Study Level Overview Dashboard with Multiple Dashlets

This release introduces a comprehensive Study Overview Analytics Dashboard that consolidates multiple dashlets into a single view, providing users with streamlined access to key study metrics and activities.

Key Enhancements:

- Multiple Dashlets Displayed: The system now displays the following dashlets within the Study Overview Dashboard: Site by Status, Deviation Activity by Type, Deviation Activity by Site, Deviations Grid, Issue/Action Activities by Status, Issue/Action Activities by Site, Issue/Action Activities Grid
- Common Filters: Users can filter the data across all dashlets within this dashboard using common filters, including Site Name, Site Status, Principal Investigator, Site Number, Owner, Start Date, End Date, etc.

Domain-Level Cross-Study Dashboards

This release introduces the ability to display multiple cross-study dashboards at the domain level, providing users with enhanced visibility into the study and site team assignments as well as site contact lists for improved resourcing and management.

Key Enhancements:

- Multiple Cross-Study Dashboards: The system now supports the display of multiple domain-level dashboards, each focused on specific areas of study and site management: Cross-Study Team Assignment, Cross-Study Site Team Assignment, and Site Contact List.
- Individual Dashboard Tabs: Each of these dashboards will be individual tabs at the domain level.

These dashboards serve specific resourcing purposes, giving users a clear, organized view of team assignments and contact information across multiple studies. By separating these critical dashboards into individual tabs, teams can manage resources more effectively and streamline operations across studies within a domain.

CHAPTER 2. DASHBOARD

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

Accessing Dashboard

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

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

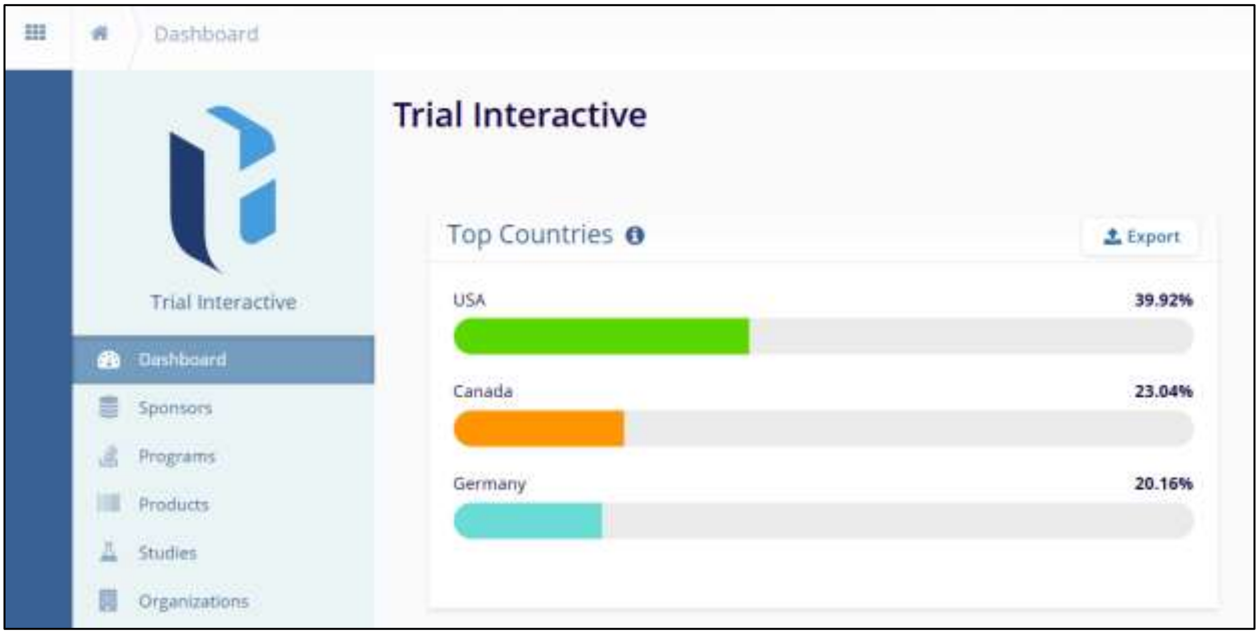


Figure: Accessing Dashboard

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

Dashlets

Top Countries Dashlet

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

A user can perform the following actions on this dashlet.

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

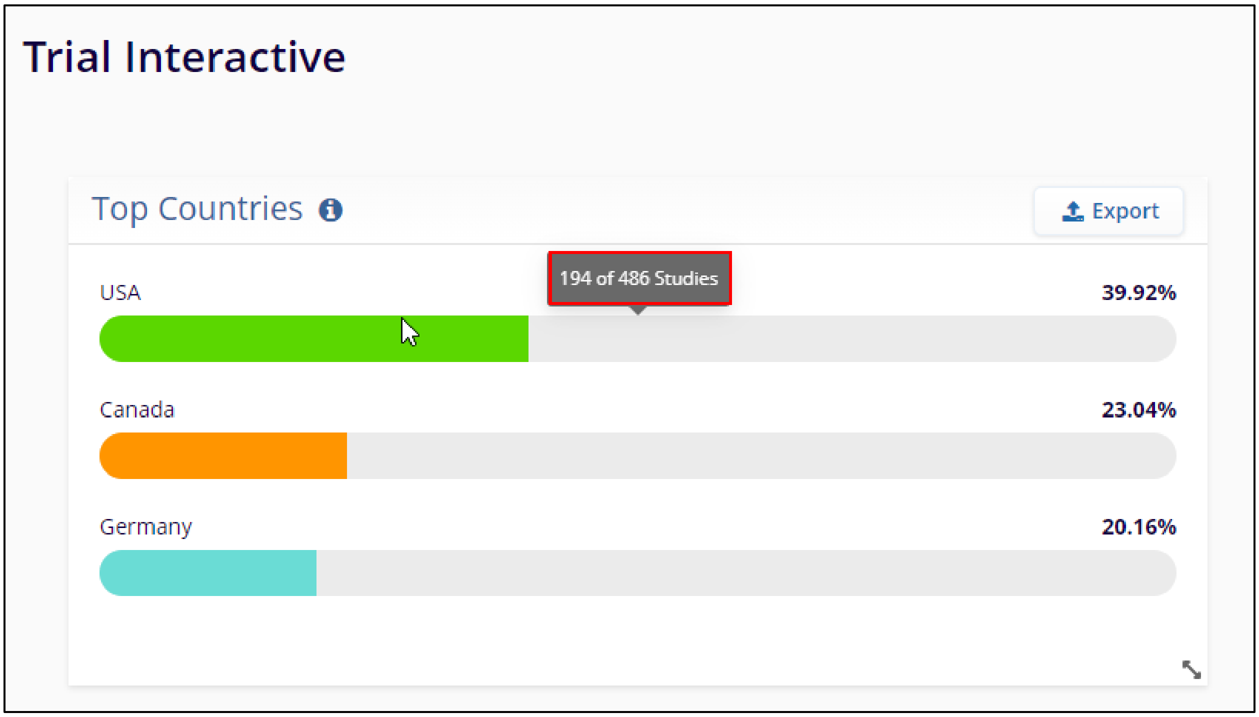


Figure: Top Countries

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

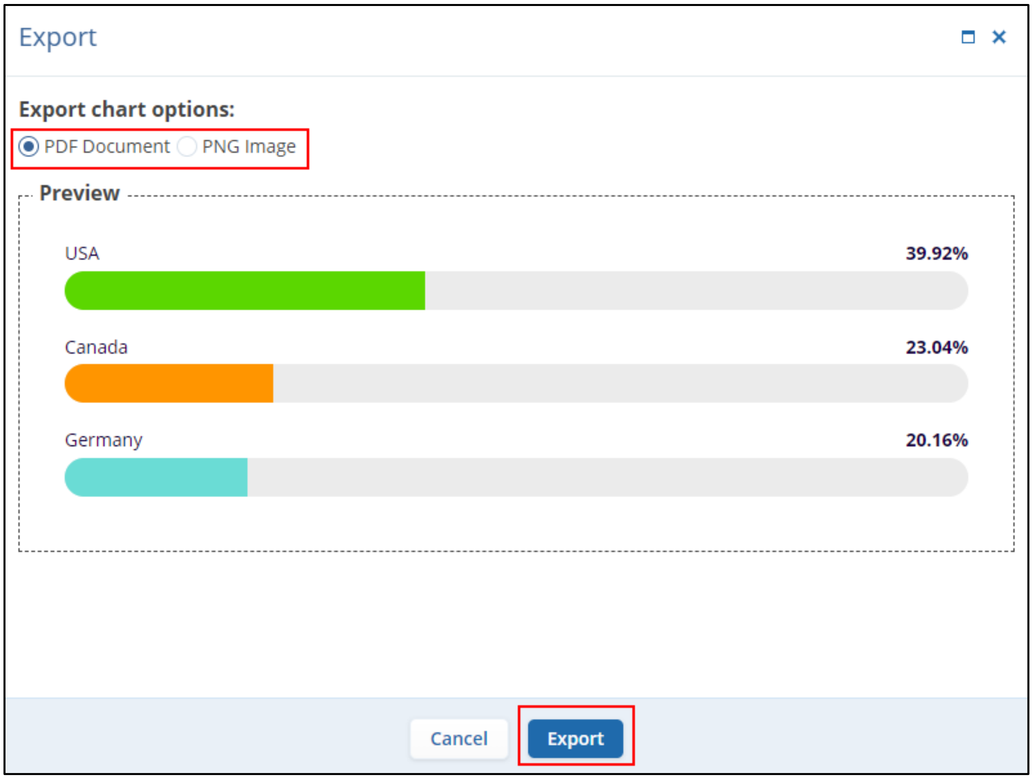


Figure: Export Chart Options

Portfolio Dashlet

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

A user can perform the following actions on this dashlet.

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

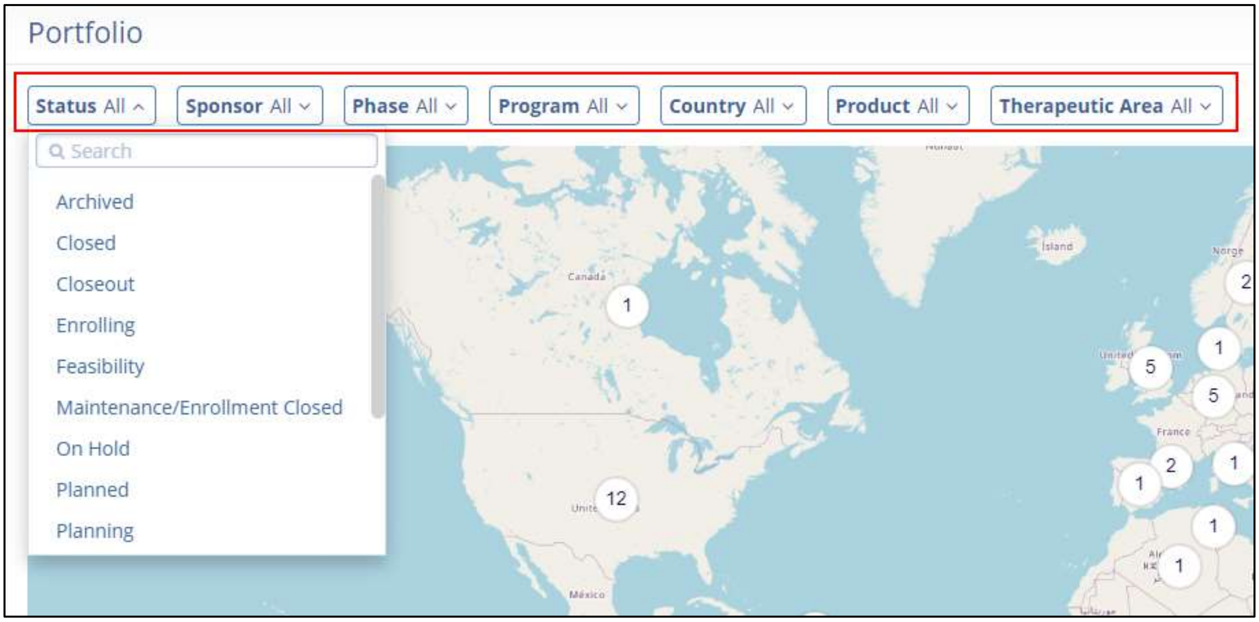


Figure: Portfolio dashlet filters

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

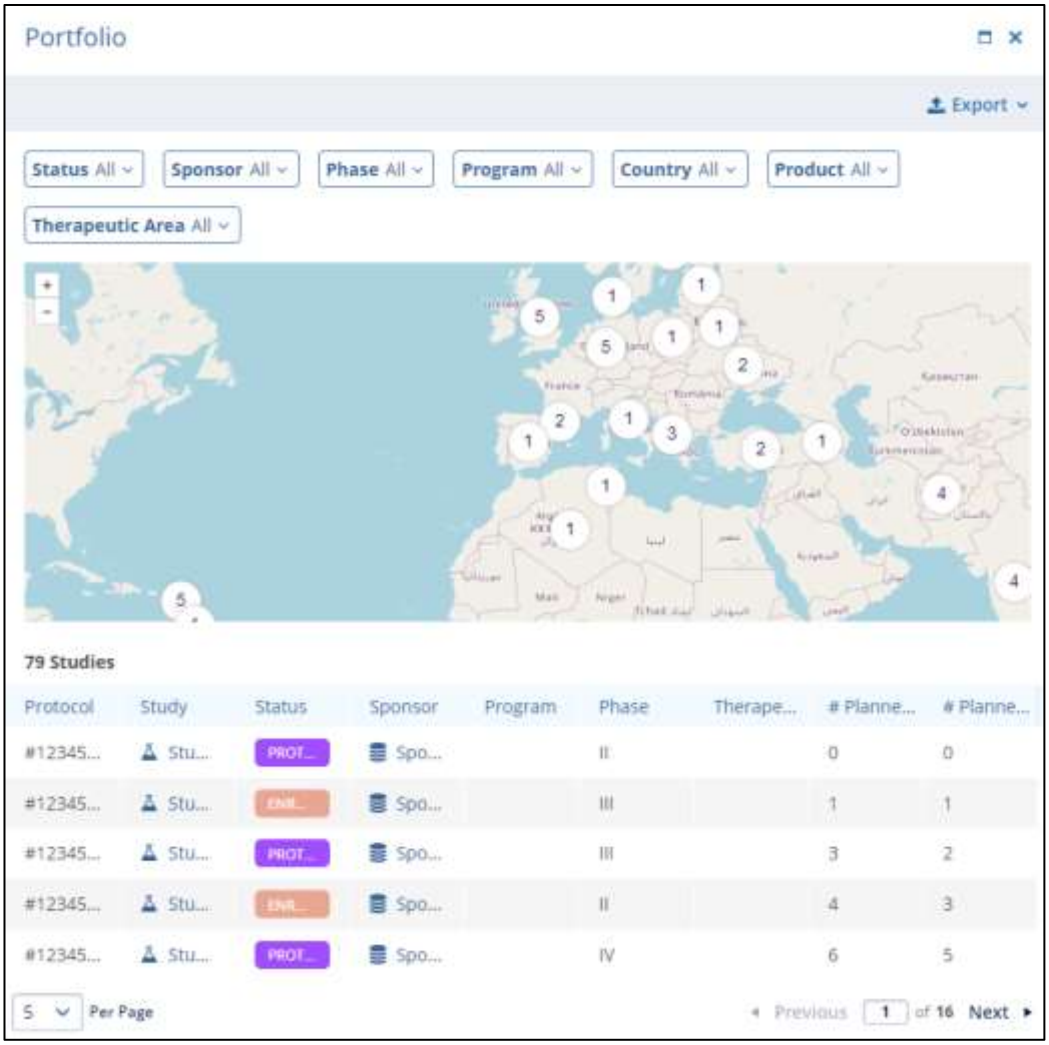


Figure: Expanded Portfolio screen

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 Exporting Contacts.
- 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.

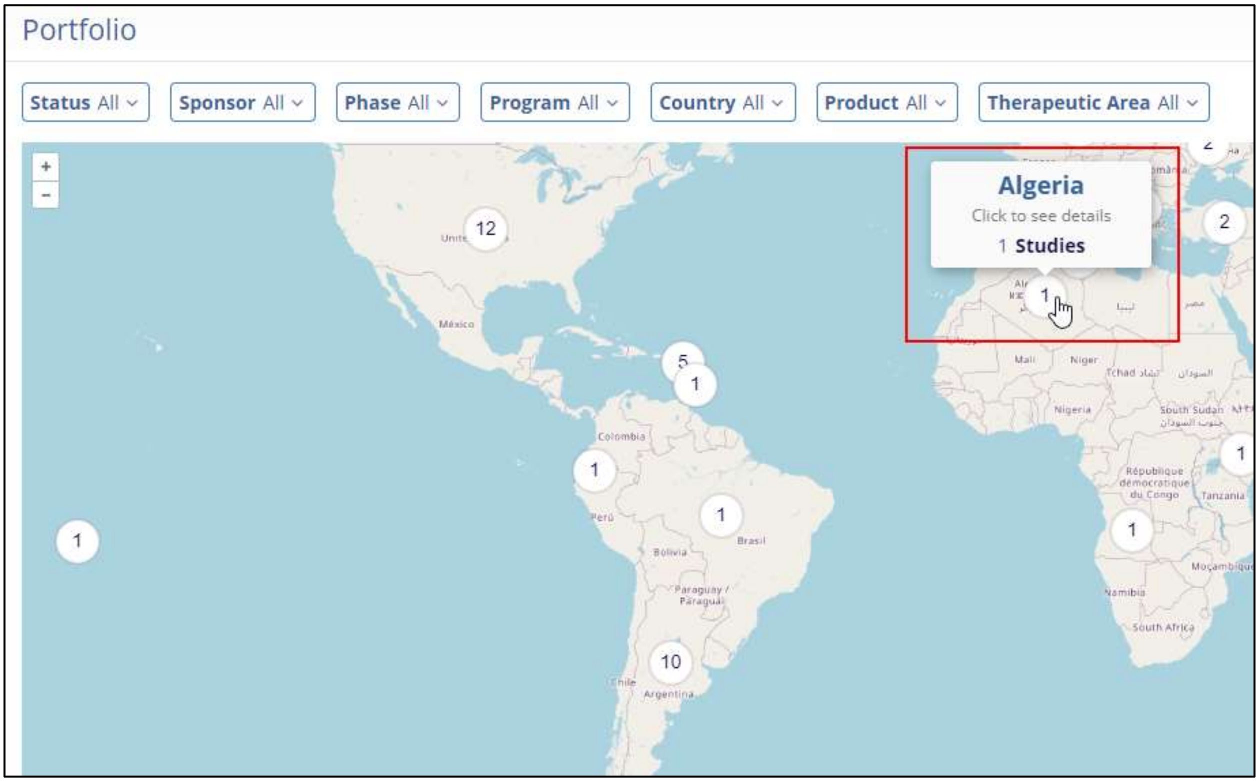


Figure: Country name and number of studies

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.

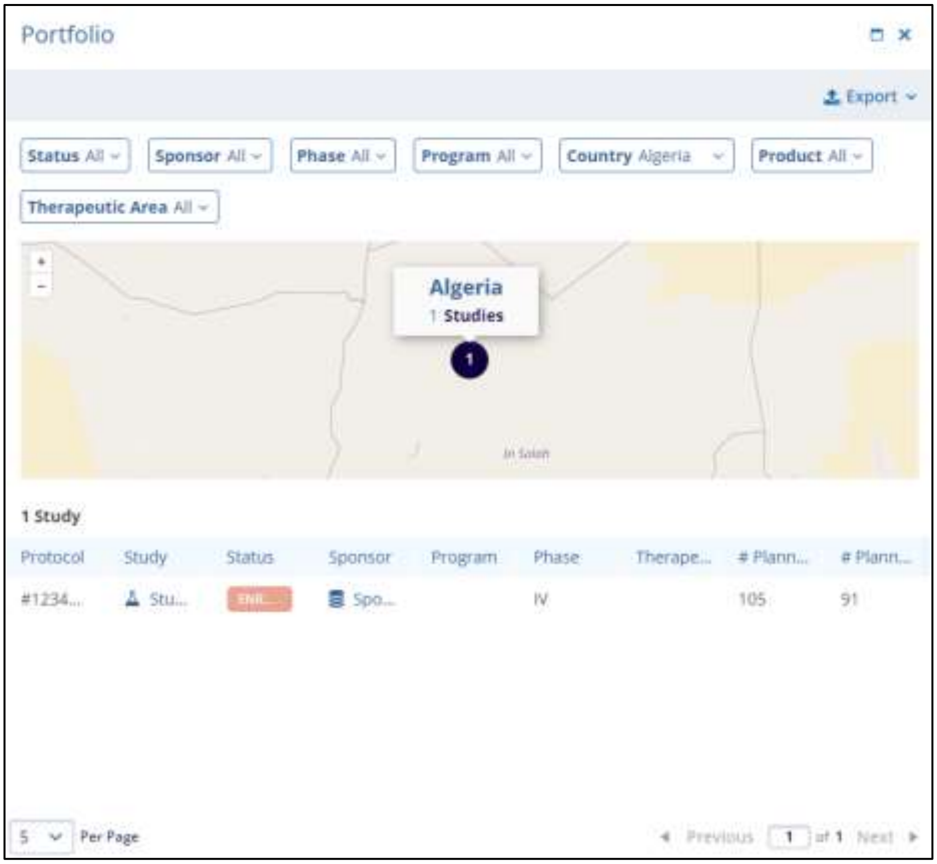


Figure: Study details by individual country

Site Visit Report Review Status

The Site Visit Report Review Status dashlet displays the cross-study site visit ownership data. Users can view the past, present, and future visits associated with a selected visit owner.

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.

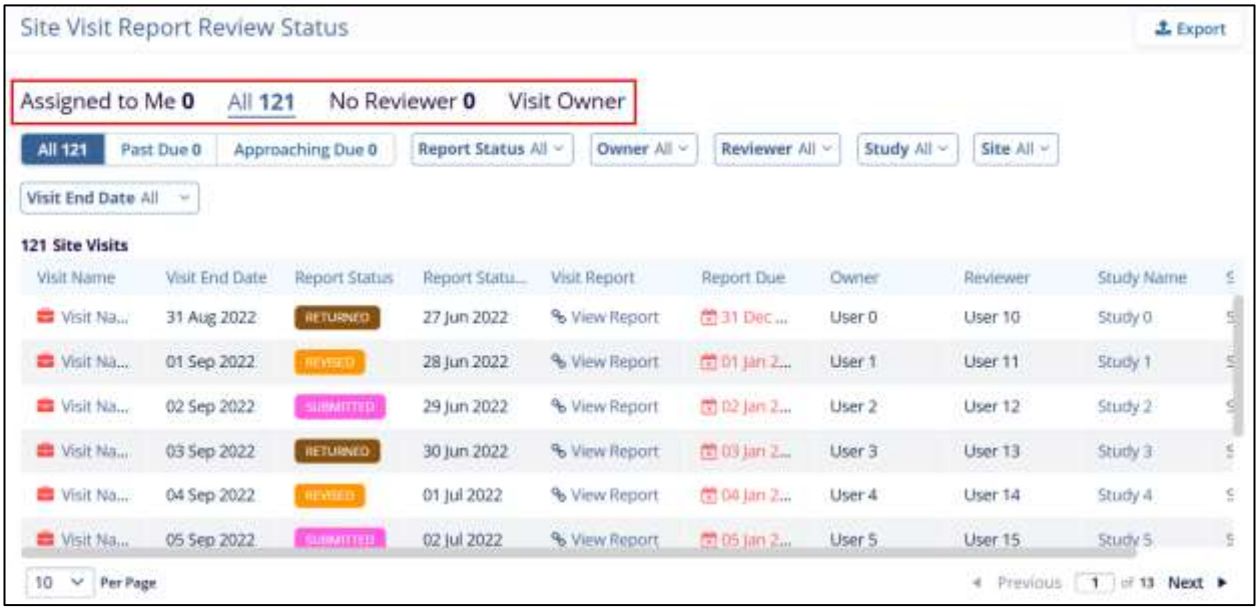


Figure: Site Visit Report Review Status - tabs

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

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

A user can perform the following actions on this dashlet.

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

Figure: Select the data visualization type

2. Click on Group by and select the required grouping criteria from the available options. The pie chart details will be populated as per the selected grouping criteria. 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.

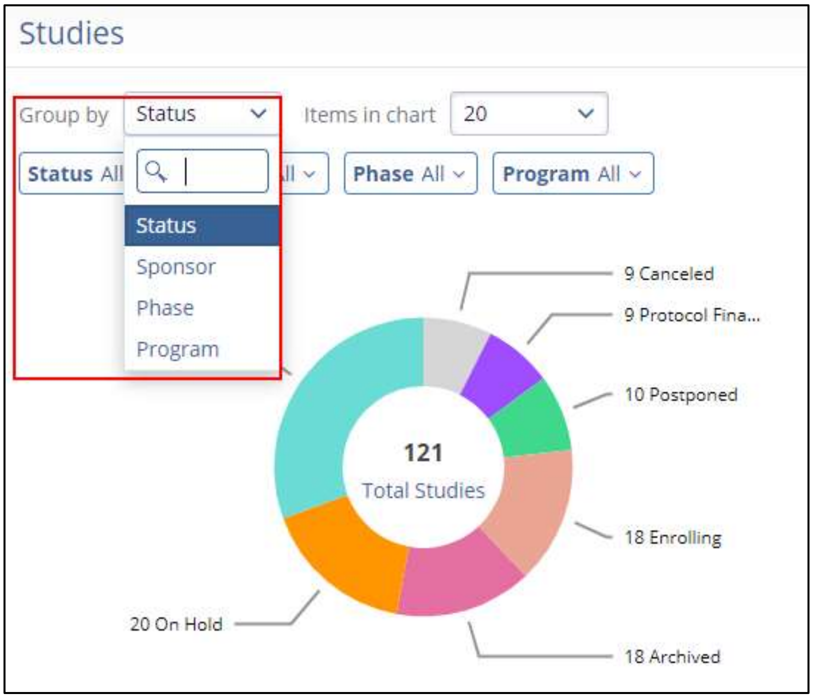


Figure: Grouping pie chart

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.

Figure: Sort data in ascending and descending order

5. Additionally, click on the arrow pinned to the study name to open the Study details page.

6. Click on the Details button to open the modal view of the Studies and perform the similar functions as listed above.

7. Additionally click on Export on the Regular and Modal view to retrieve an export of the Studies data.
    a. Refer to the Exporting Contacts section to understand the Export Grid process.
    b. Refer to the Top Countries Dashlet section to understand the Export Chart process.

Note:

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

CRA Visit Report Performance Dashlet

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

A user can perform the following on this dashlet.

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

Figure: CRA Visit Report Performance filters

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

Figure: CRA Visit Report Performance – Categorization by status

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

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

Figure: Tabular view for CRA visit reports

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

Note:

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

Study Dashboards

To access the Study Dashboards, follow the steps below.

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

The Study Dashboard contains the following dashlets

Site Visit Report Review Status

Refer to the Site Visit Report Review Status section.

Study Milestone

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

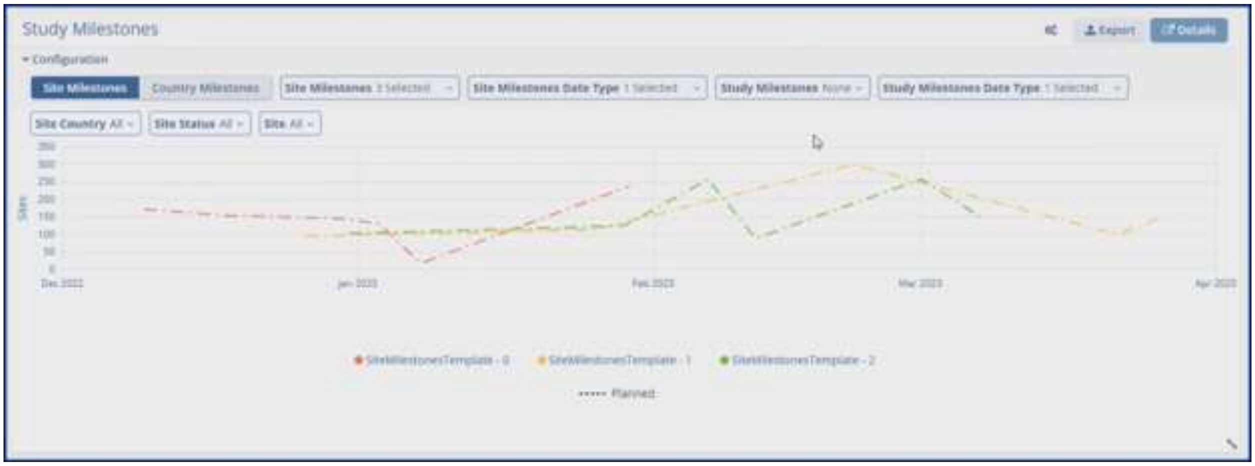


Figure: Study Milestones dashlet

Study Enrolment

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

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

Figure: Study Enrollment dashlet

Study Timeline

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

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

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

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

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

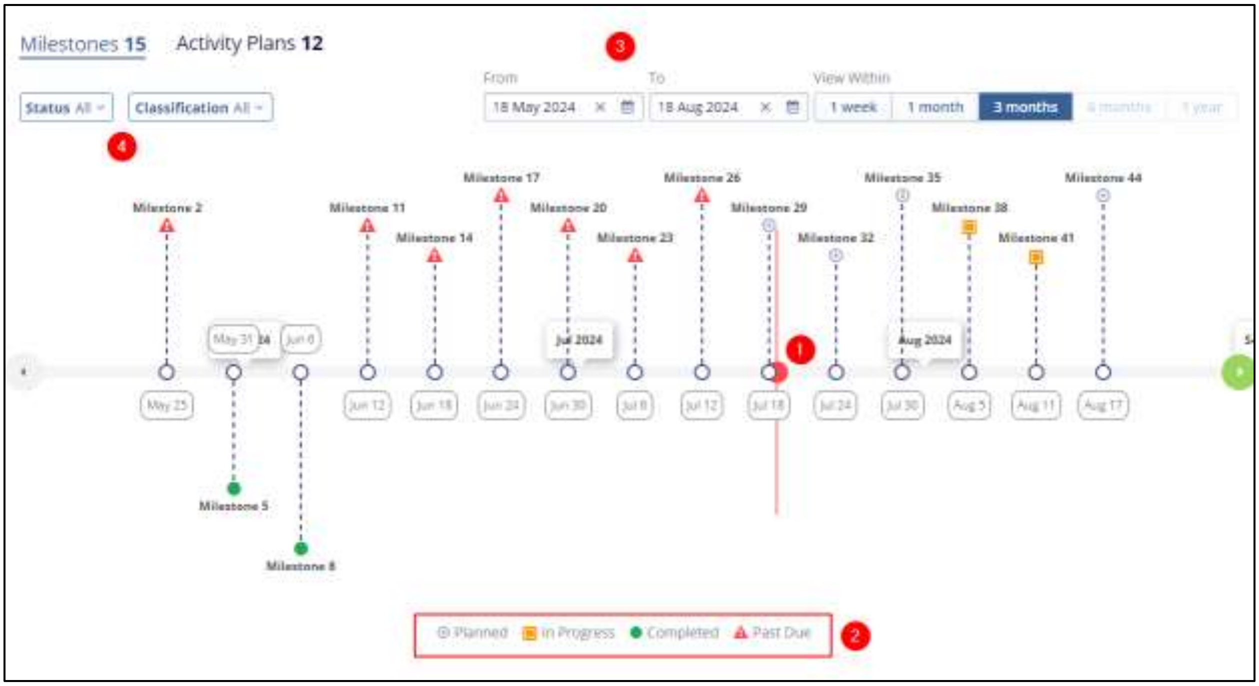


Figure: Study Timeline dashlet

Activities

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

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

Figure: Activities dashlet

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

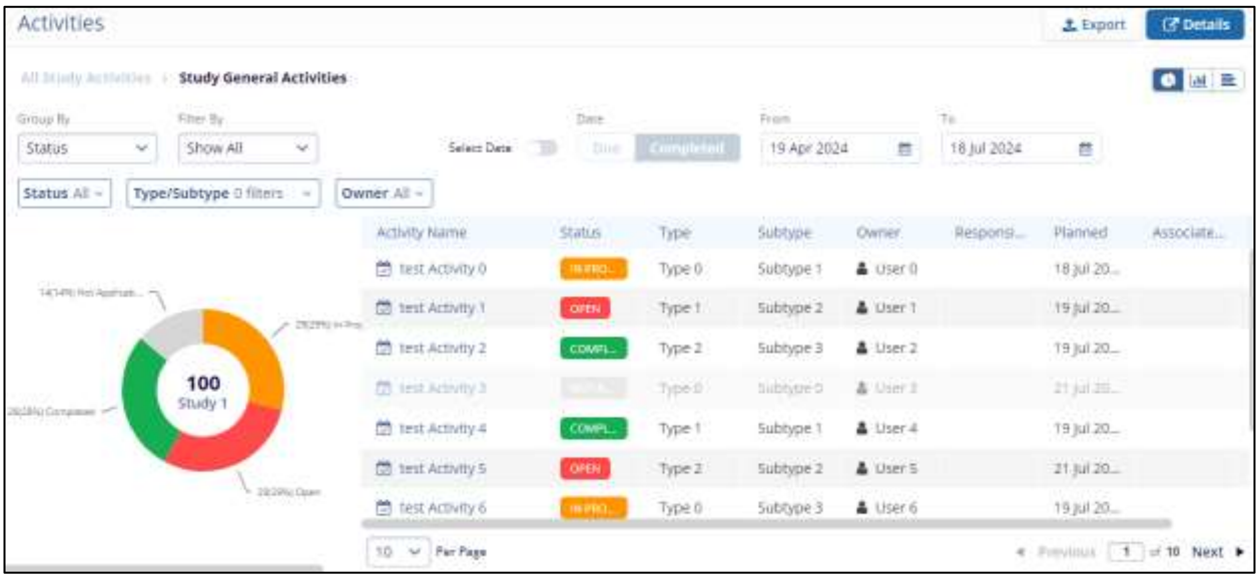


Figure: Study General Activities view

Note:

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

Countries Dashboard

To access the Countries Dashboard, follow the steps below.

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

Country Timeline

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

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

Activities

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

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

Site Dashboard

To access the Countries Dashboard, follow the steps below.

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

Site Timeline

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

Activities

The Activities dashlet shows customizable visualization of Sites.

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

CHAPTER 3. SPONSORS

Pre-Requisites

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

How to Create a Sponsor

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

1. Click on the "Sponsor" tab located in the navigation link on the left side of the screen.
2. This action will redirect you to the "Sponsor" page where all Sponsors at the global level are displayed.
3. click the "+Add" button from the menu bar above the grid to add a new organization.

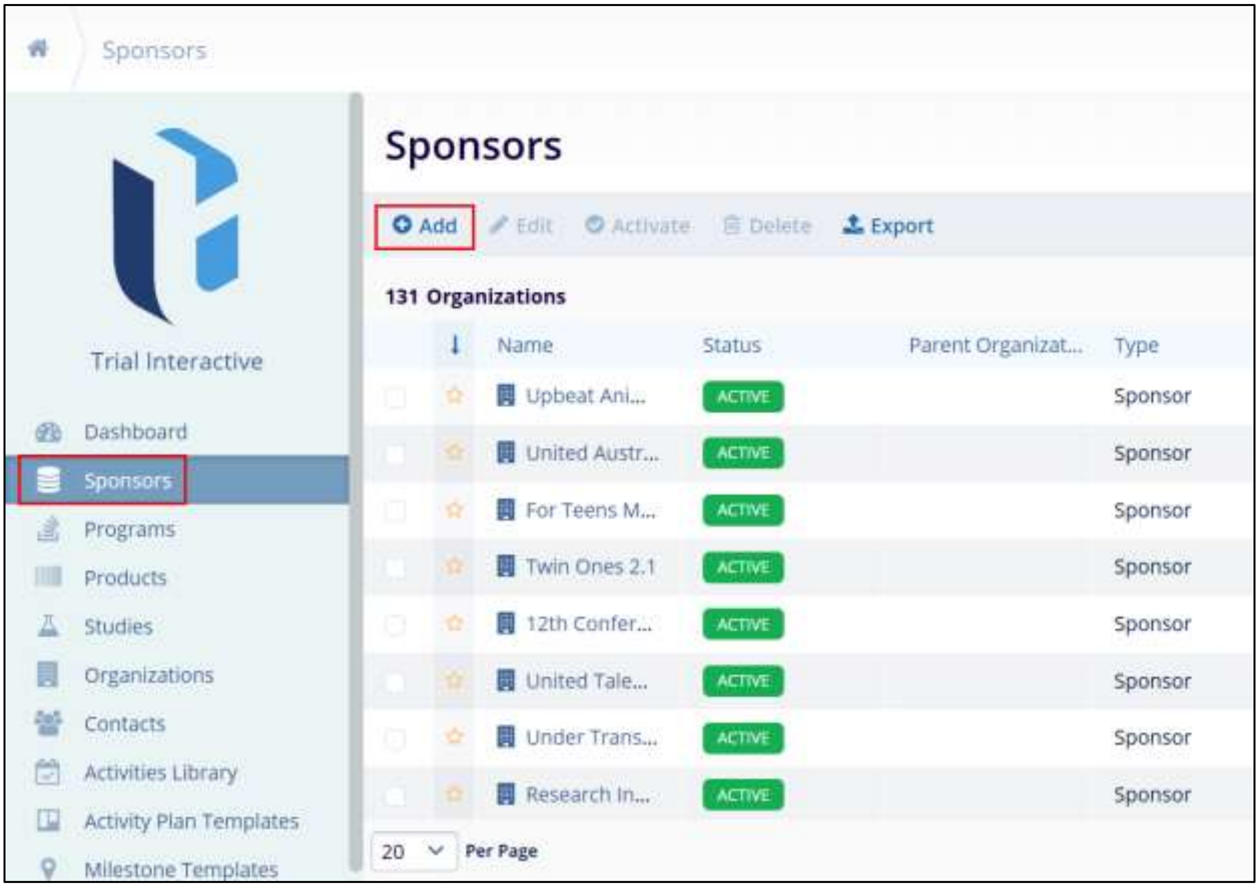


Figure: Accessing Sponsors

4. 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.

Step by Step All fields are explained below:

General Information

- Name: Enter the sponsor's name in the "Name" field.
- Number: Enter the unique number for a sponsor.
- Parent Organization field: To add an organization to the sponsor, click on the drop-down arrow and select the appropriate organization from the list. To create a new organization, click on the "+Create" button.

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

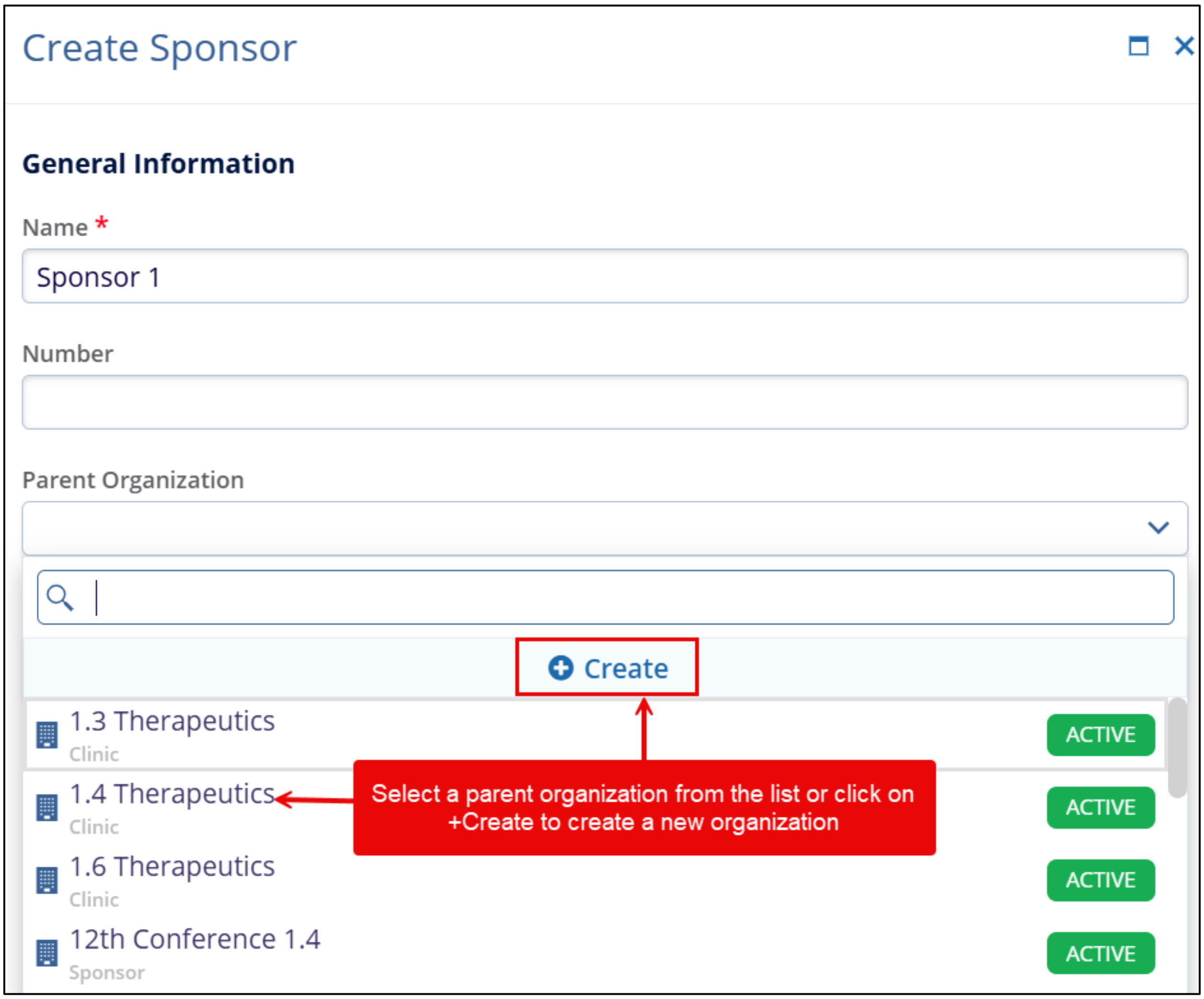


Figure: Create Sponsors

- Type: As we are creating the sponsor this field is pre-selected as "Sponsor" and it's not editable.
- Subtype: Select the appropriate subtype from the drop-down menu.

- Status: By default, the user will be able to "New" Status. To add the status to the sponsor, click on the drop-down arrow and select the status as per your requirement.

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

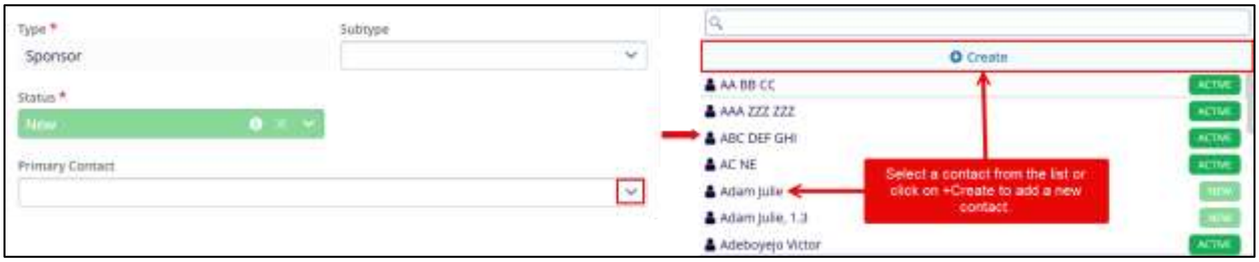


Figure: Create primary contact

Phone Numbers

- Click on "+Add" to input 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.

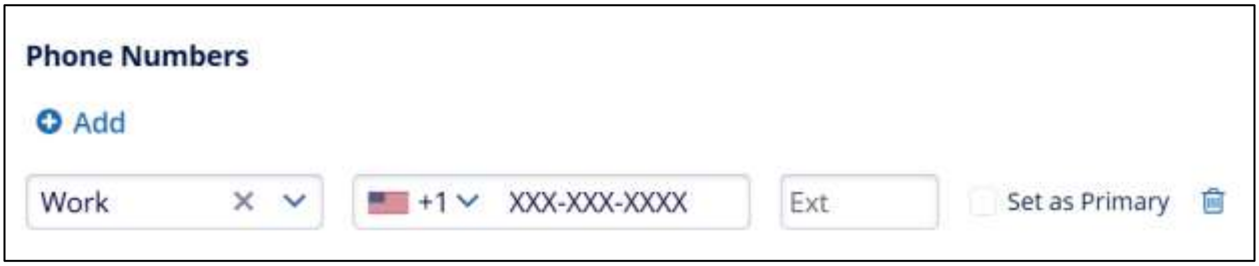


Figure: Add Phone Numbers in Sponsors

Emails

- Click on "+Add" to enter email addresses. Enter the email address in the provided field.
- Notes Message Box: Enter any additional notes regarding the Sponsor in the "Notes" field.

Figure: Add email addresses in Sponsors

Include Address:

- Toggle the switch if you want to include an address and enter the mandatory details into the respective fields.
- To include an address, you must enter the mandatory fields Address Type, Primary Address, and Country and Postal code which are marked with an asterisk (*) next to the field title. Other fields are optional.
- Search Address: Click on the search icon to search for the address and enter your address it will show you an auto-populated list.
- After filling in all required fields, you have three options at the bottom of the form
    - Create: Saves the new organization and closes the screen
    - Create and Add Another: Saves the new organization and opens a new screen to add another organization.
    - Cancel: Discards the information and closes the screen.

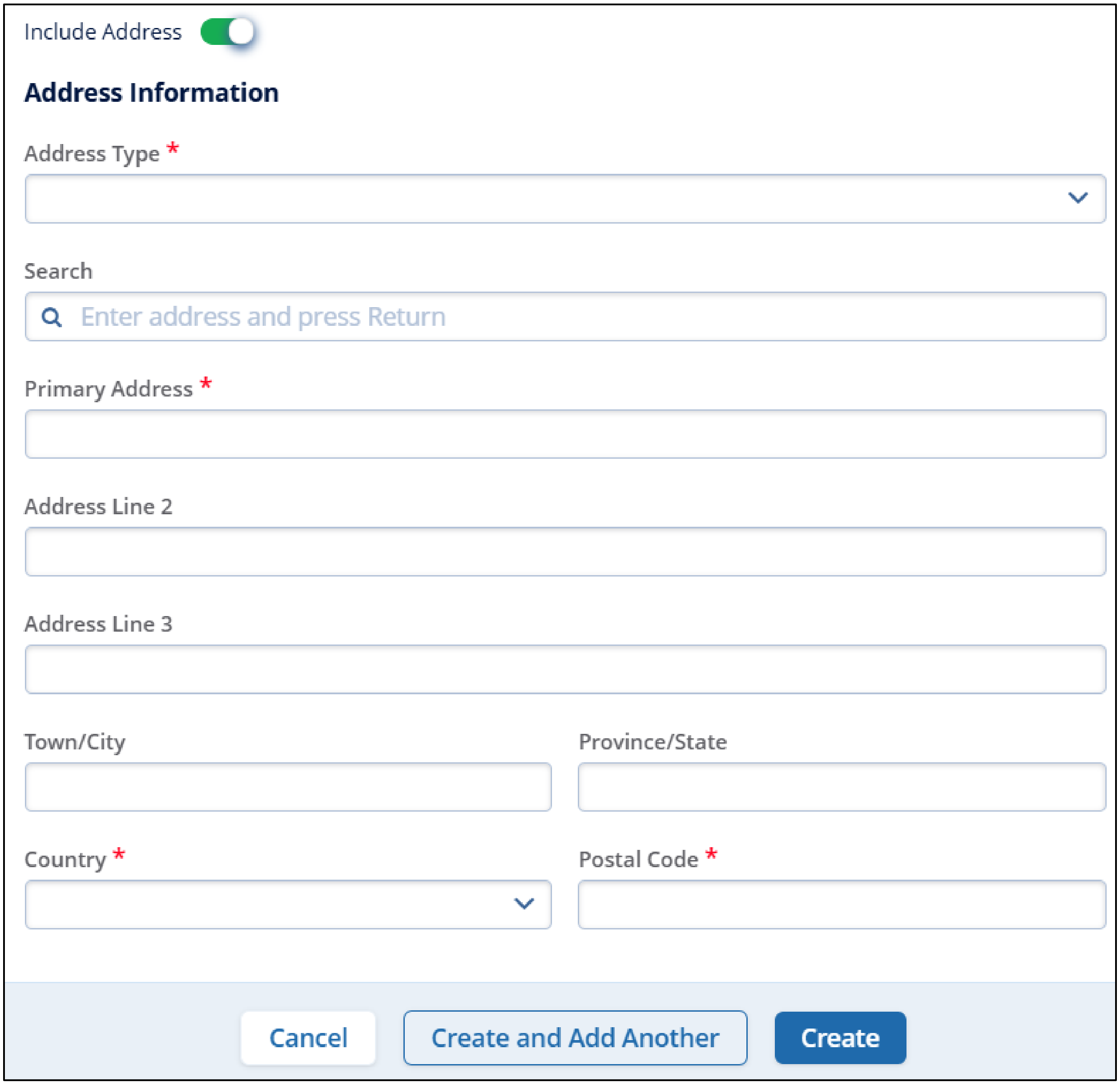


Figure: Include Address in Sponsors

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

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.

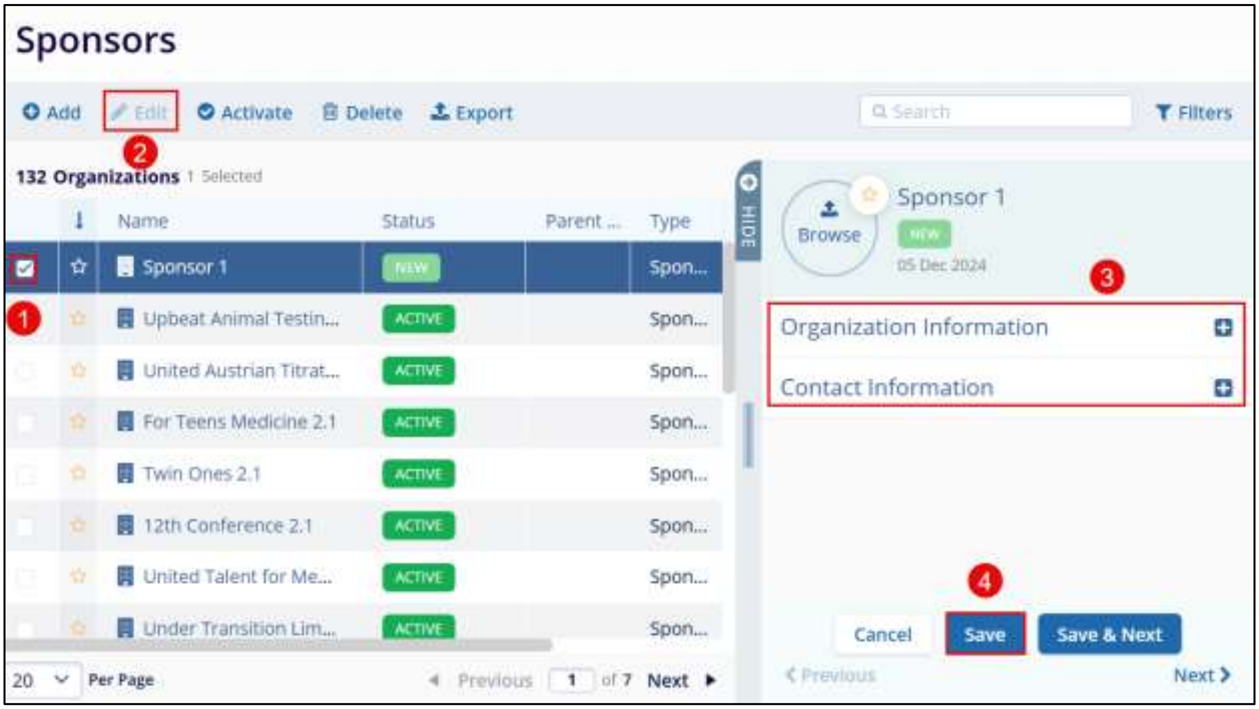


Figure: Editing a Sponsor

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.

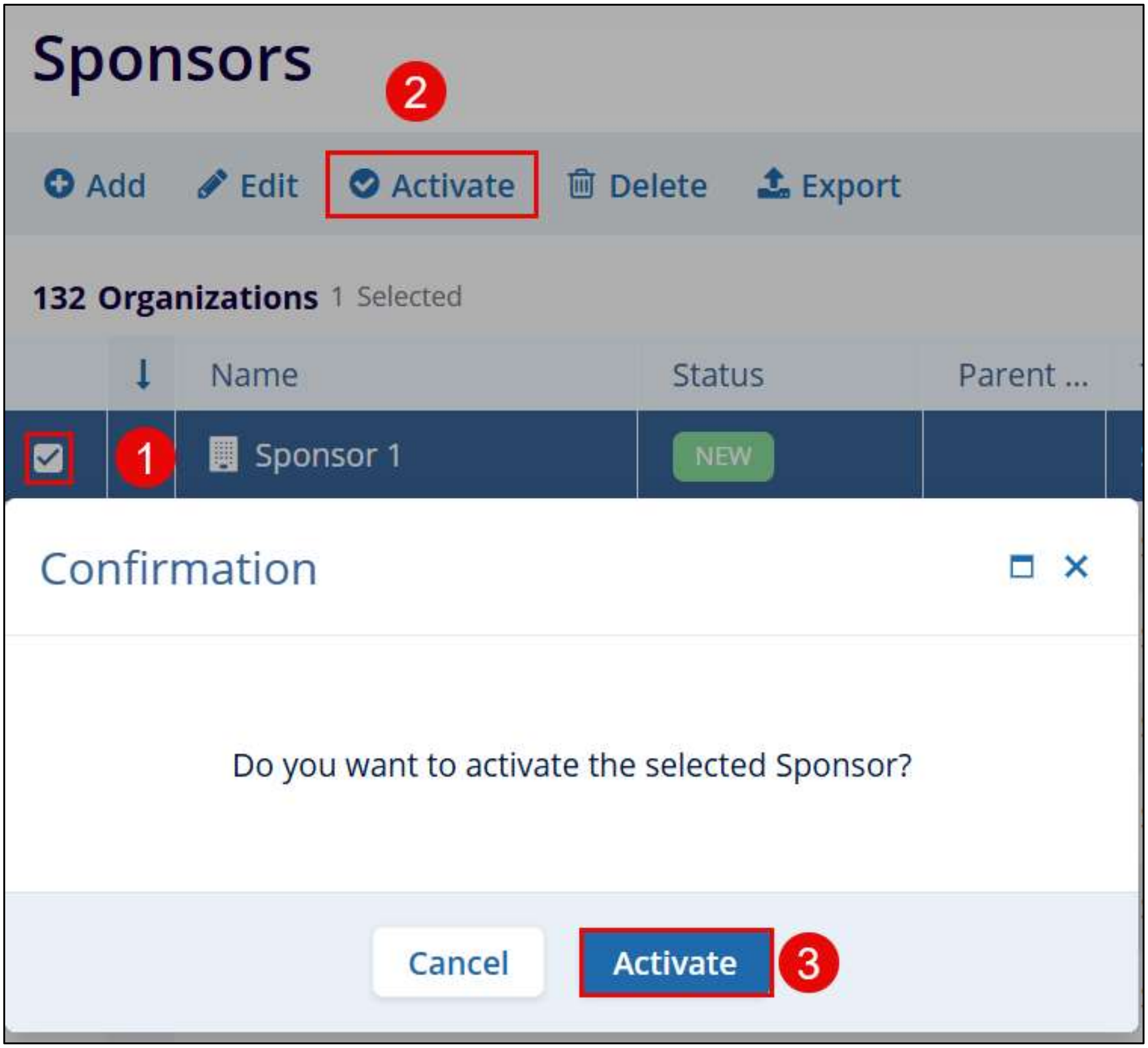


Figure: Activate a Sponsor

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.

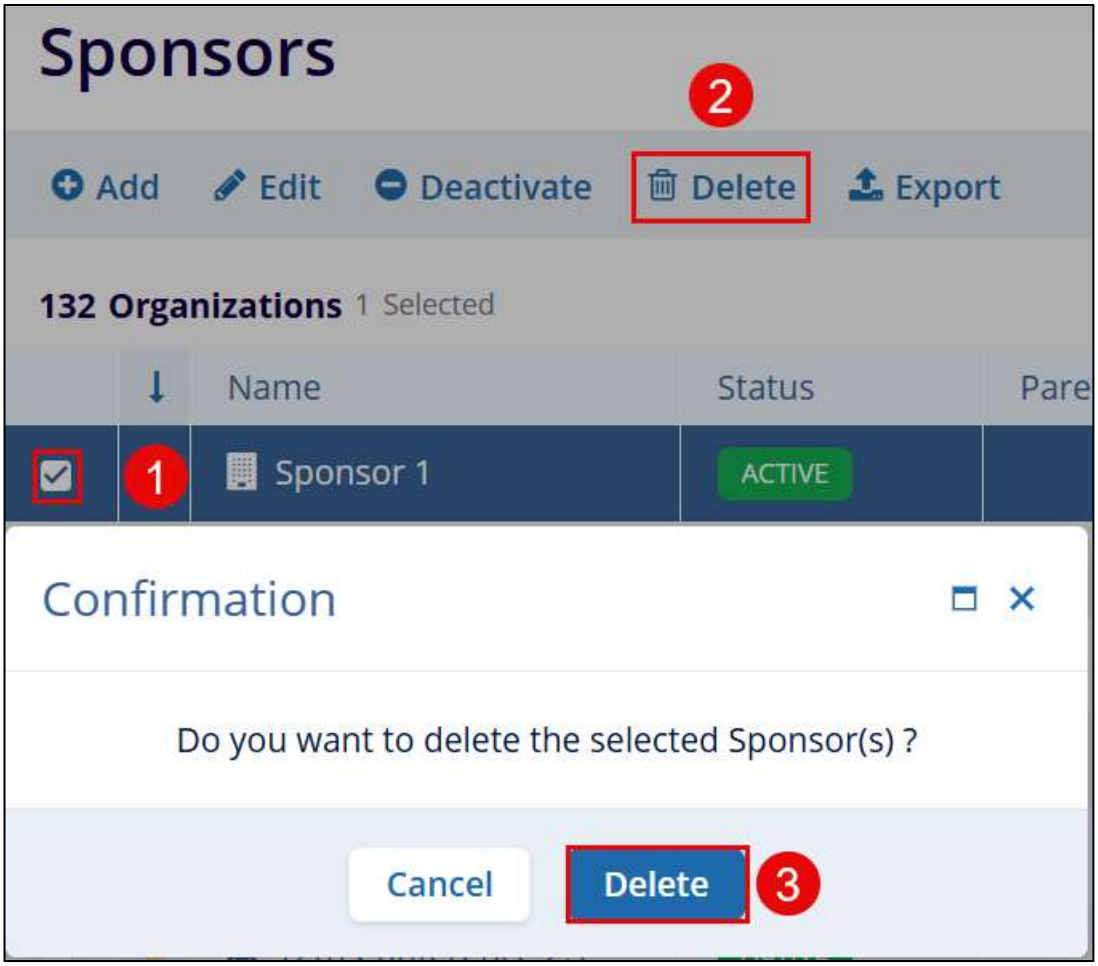


Figure: Deleting a Sponsor

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 user does not need to press the enter button. It will automatically show all related results.

Figure: Search Sponsors

Filter

1. From the sponsor main menu in the top right corner, click on the "Filter" button to apply filters.
2. To view all your favorite sponsors, click the switch button.
3. All favorite sponsors will then appear in the grid.

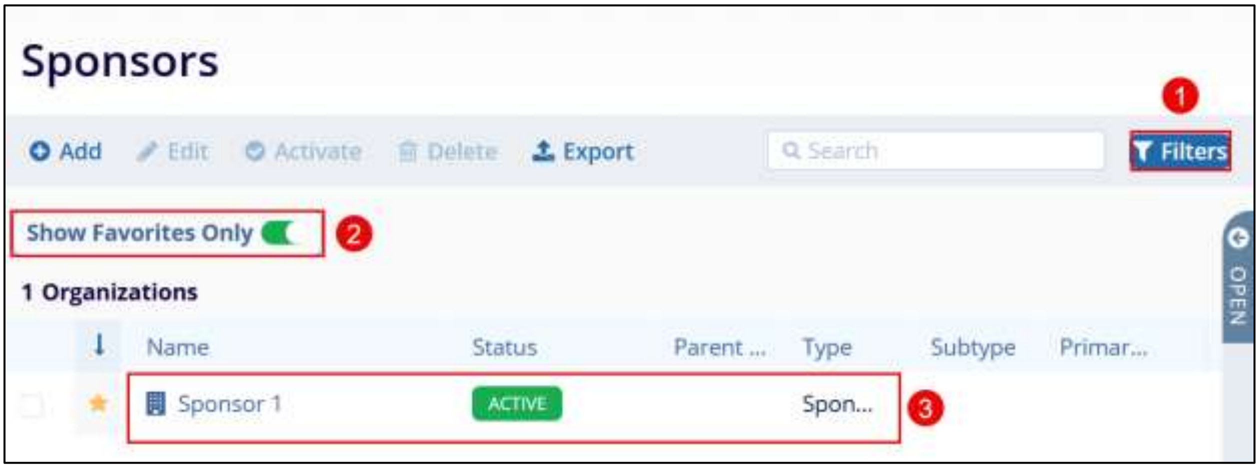


Figure: Filter Sponsors

How to 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. You have successfully marked your sponsor as unfavorite and the user will receive a notification as successful.

Figure: Add and Remove Favorites

Defining Sponsor Settings

To define sponsor settings, follow the steps below.

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

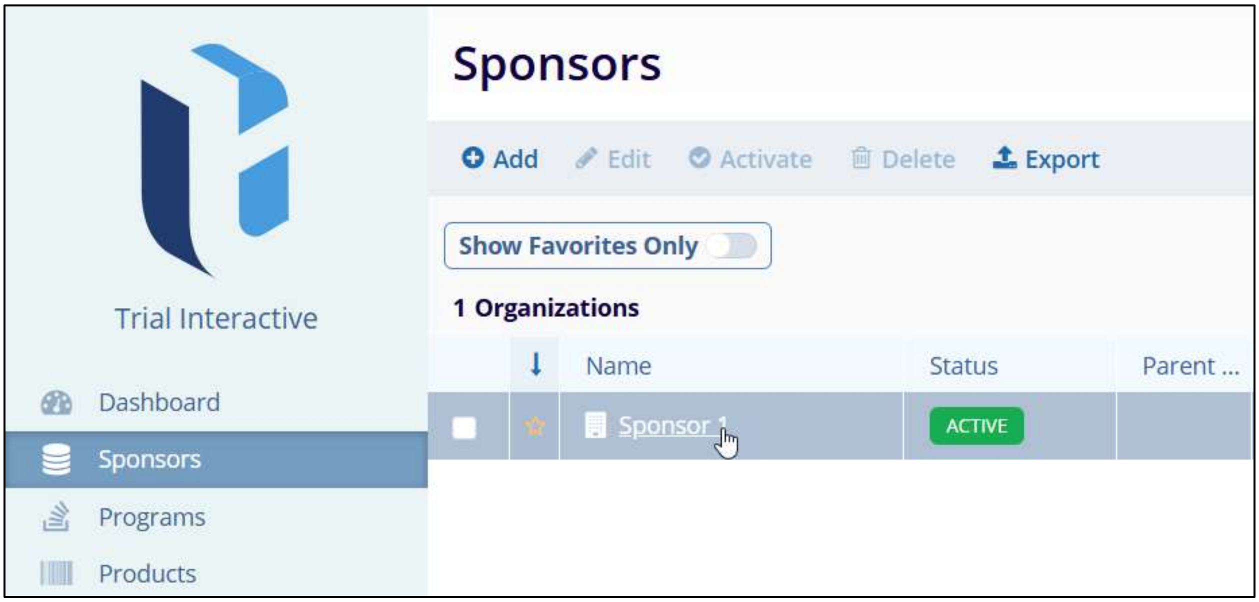


Figure: Define Sponsor Settings

3. On the Sponsor Details screen, click on the “**Setting”** button in the top-right of the screen. This will redirect you to the “**Sponsor Settings”-> Milestone Template’s”** screen.

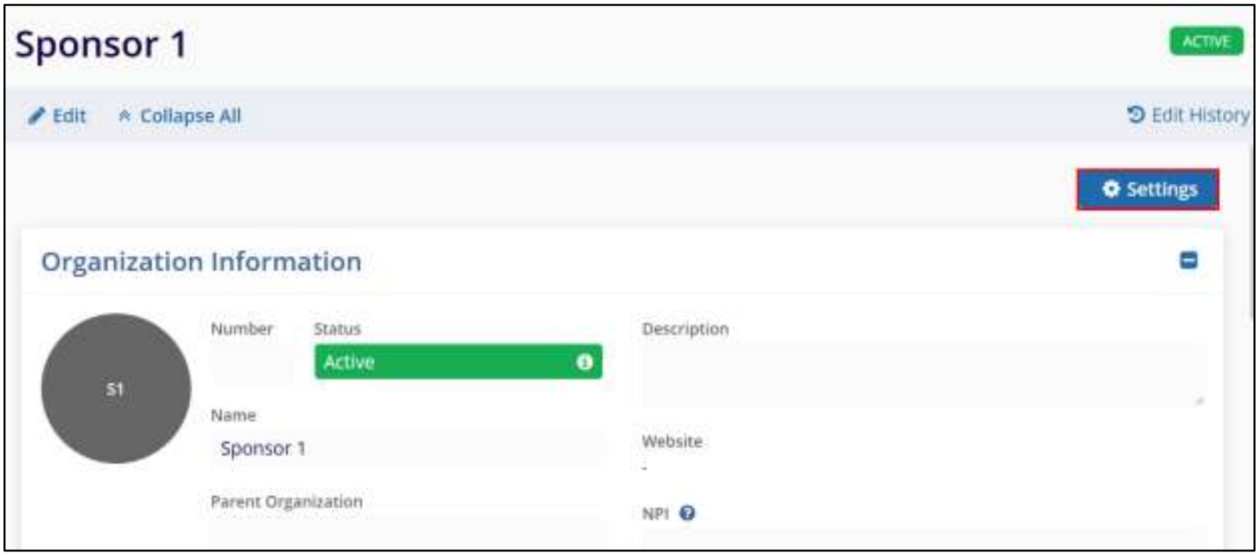


Figure: Access Sponsor level settings

Note: To learn more about Milestone Templates functionality. For Example: How to Add, Delete, Publish, Copy, and so on. Refer to [Chapter 11. Milestones]() section.

Creating a Product for a Sponsor

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

Steps to create a product for a Sponsor

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

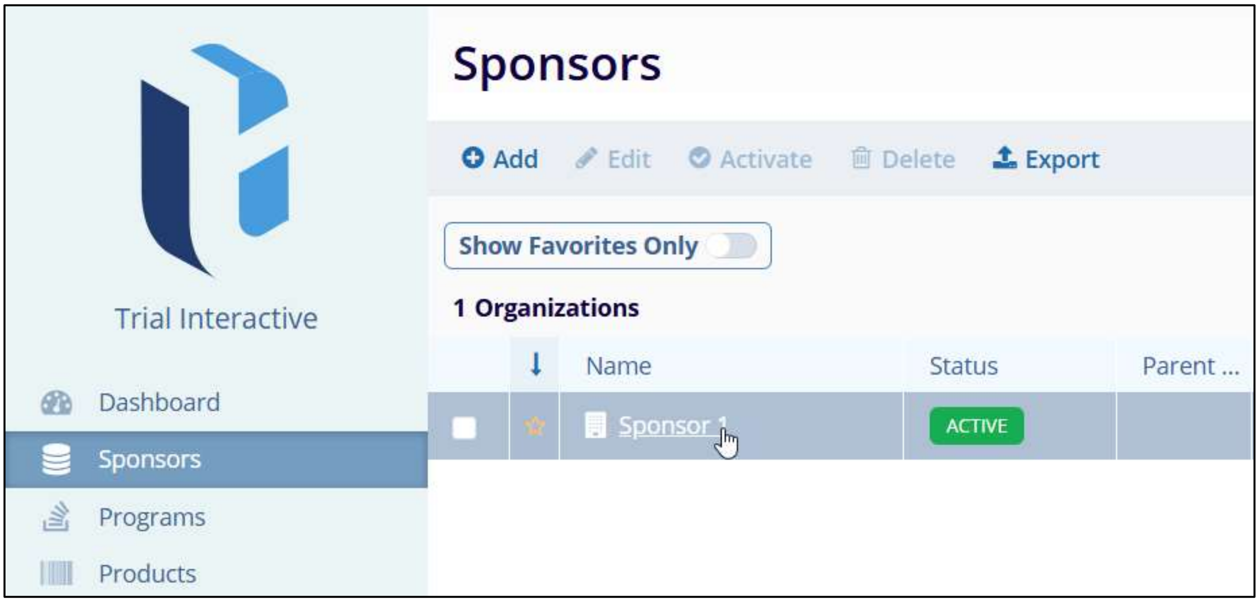


Figure: Create Product for Sponsor – Access sponsor

2. Click on "**Products**" from the navigation link to the left side of your screen. It will redirect you to the "Products" screen.

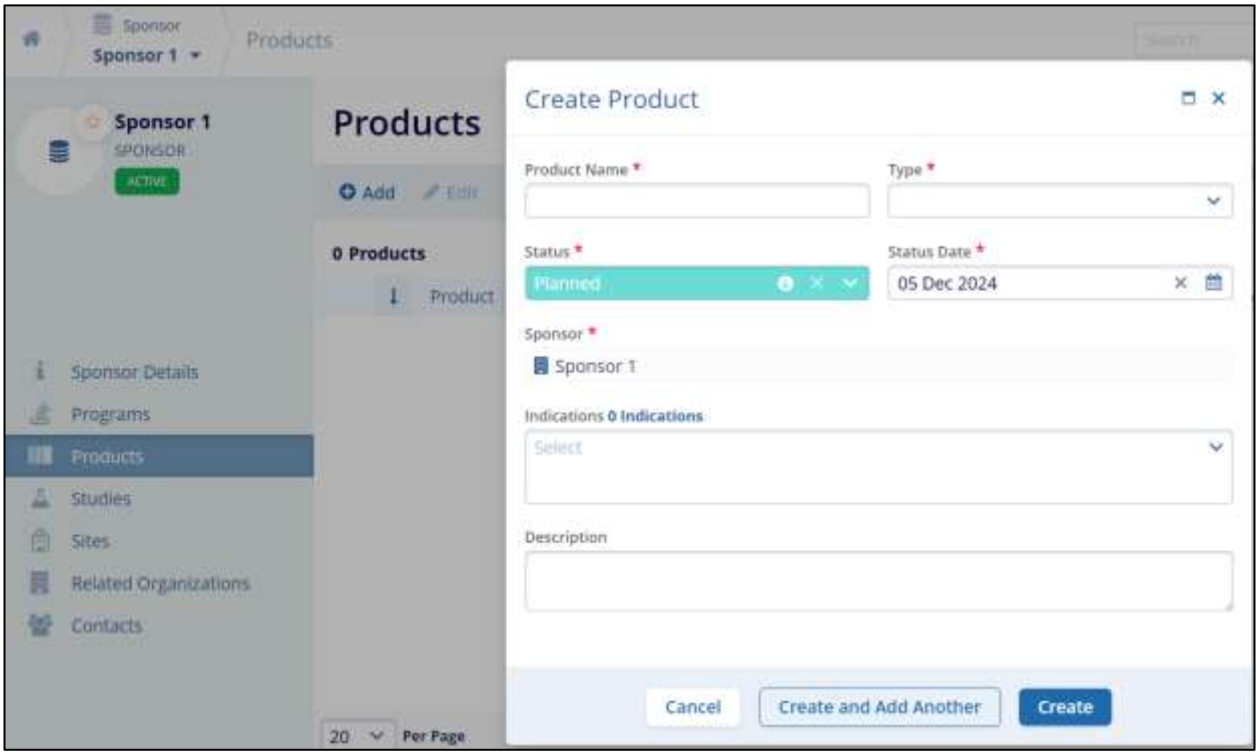


Figure: Create a new product at the sponsor level

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

Notes:

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

Creating a Program for a Sponsor

To create a program for a sponsor, follow the steps below.

1. Click on the name of the sponsor to which you want to associate program.

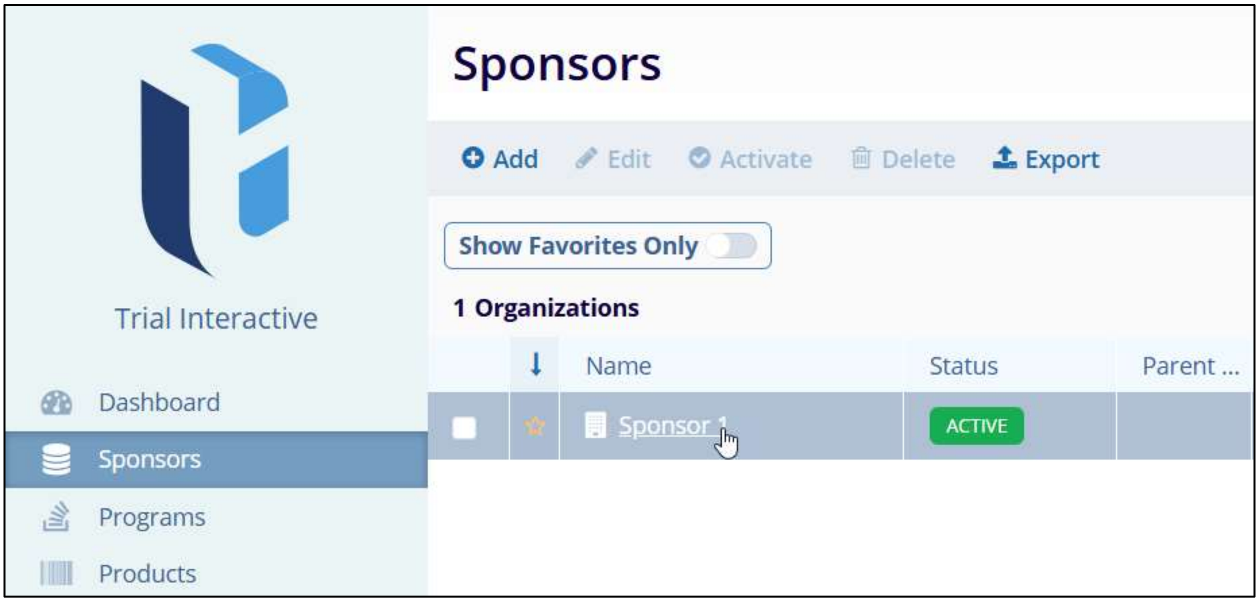


Figure: Create a Program for the sponsor

2. On the "Sponsor Details" page, click on the "**Program"** link in the Navigation menu on the left side of the screen.
3. You will be able to see the "Program Details" Page. To create the program, click on the **"+Add"** button at the top of the grid.

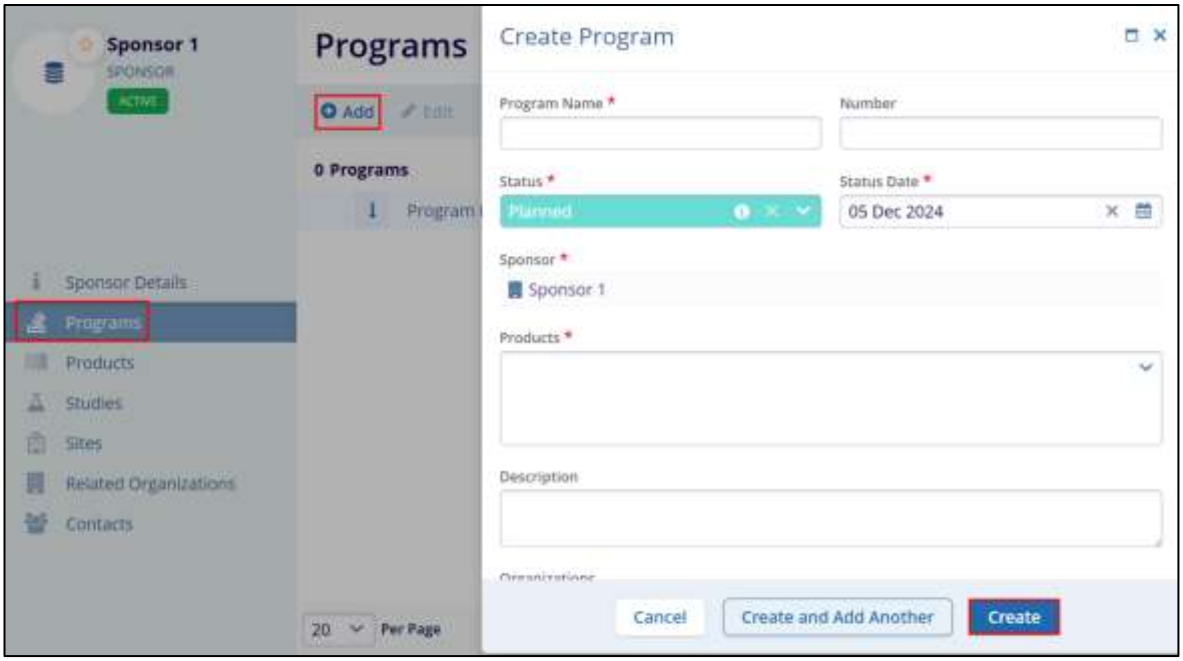


Figure: Create a Program at the Sponsor level

4. To create a new program and the associated actions, refer to Chapter 4. Programs section.

Notes:

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

CHAPTER 4. PROGRAMS

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 Program which will open 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 Create

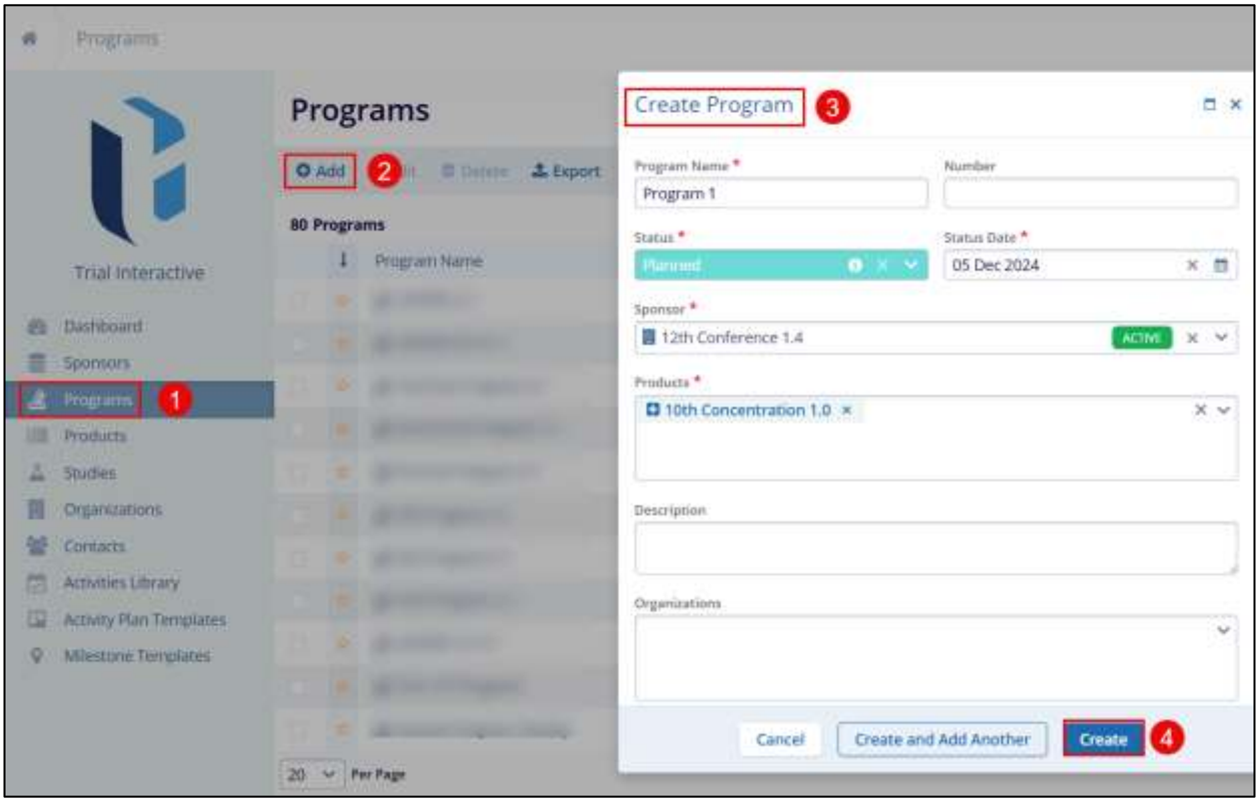


Figure: Create Program

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

Editing and Reviewing a Program

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

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

Method 1

1. Click on the "Program Name".

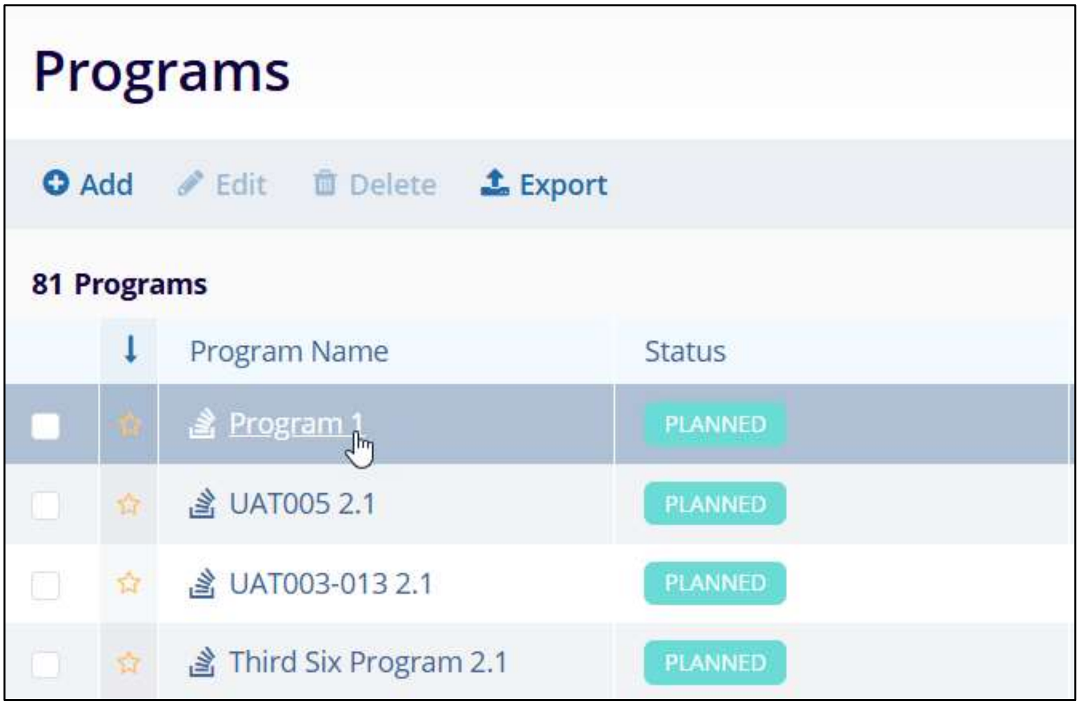


Figure: Select a Program to edit

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

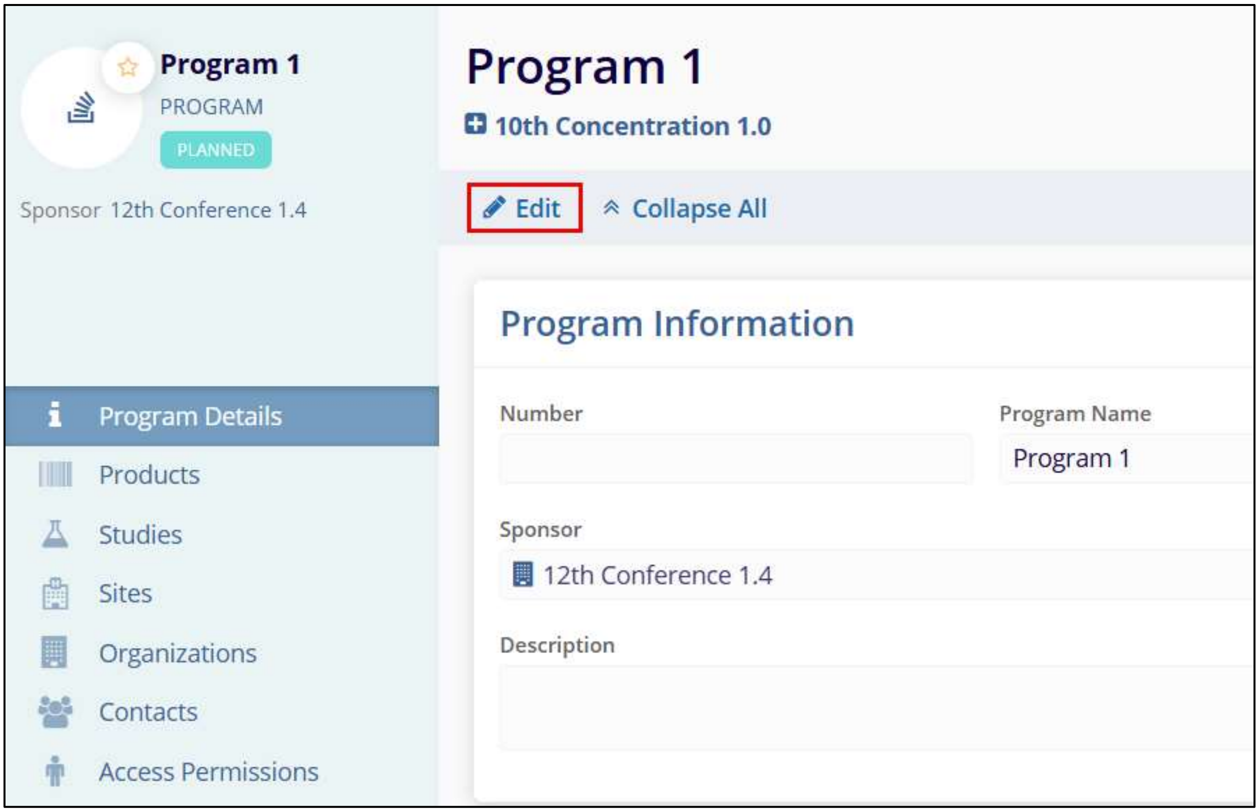


Figure: Program Details screen

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

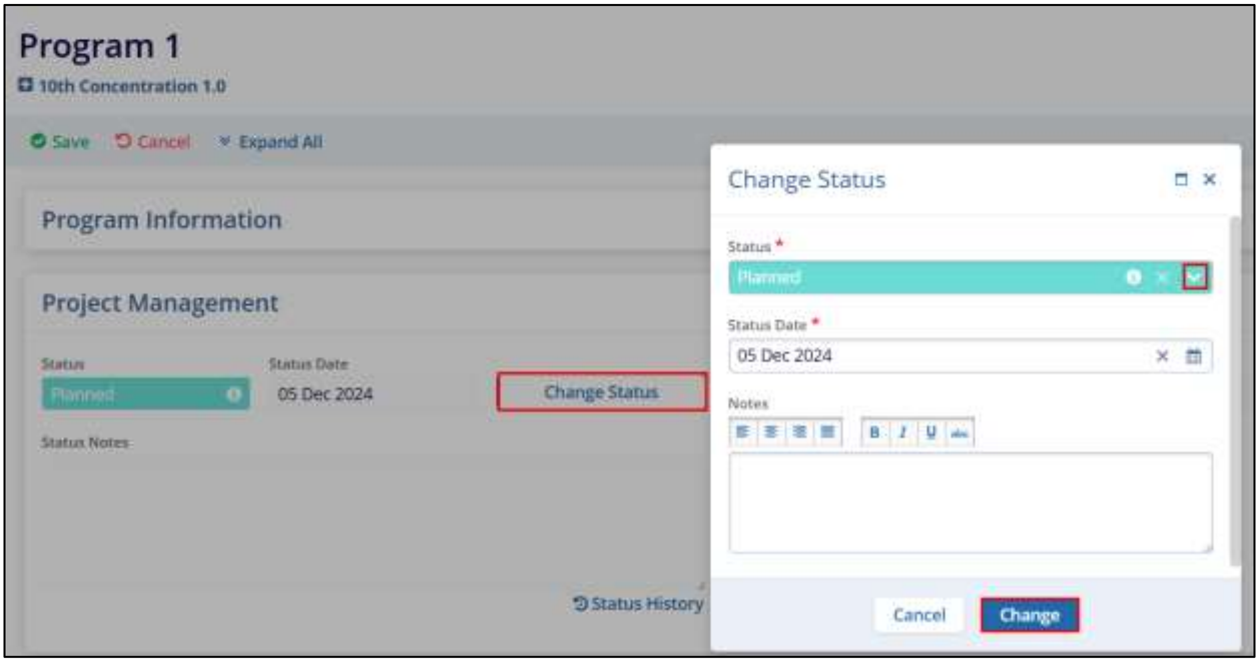


Figure: Change Status

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

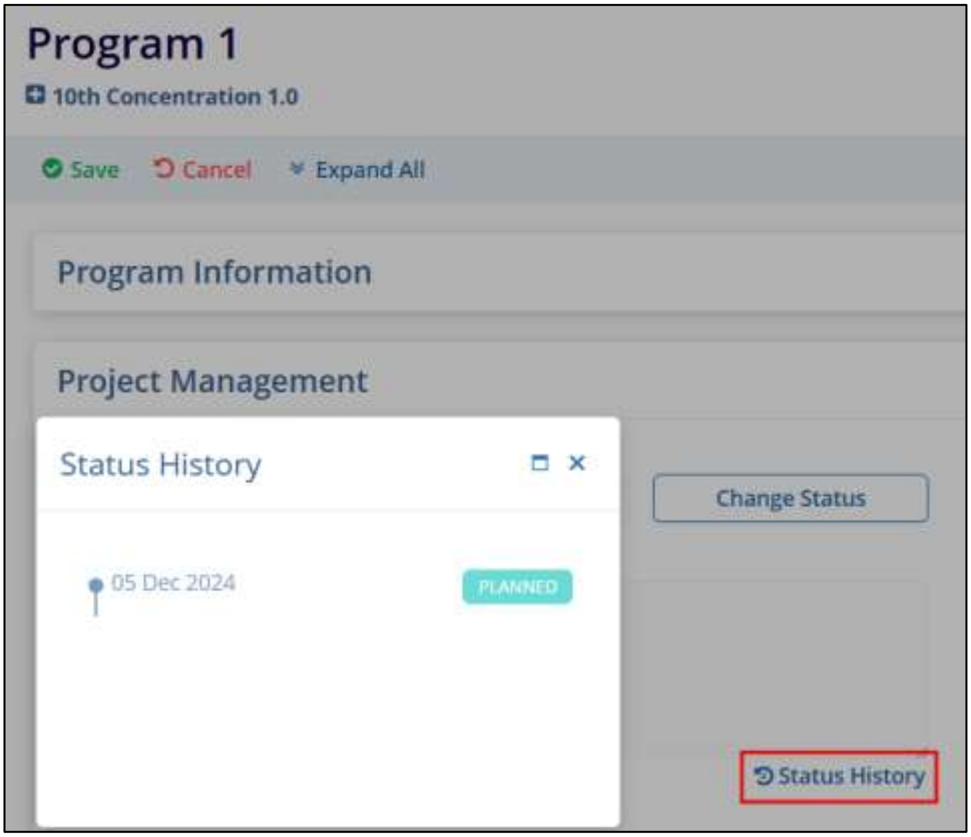


Figure: Status History

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

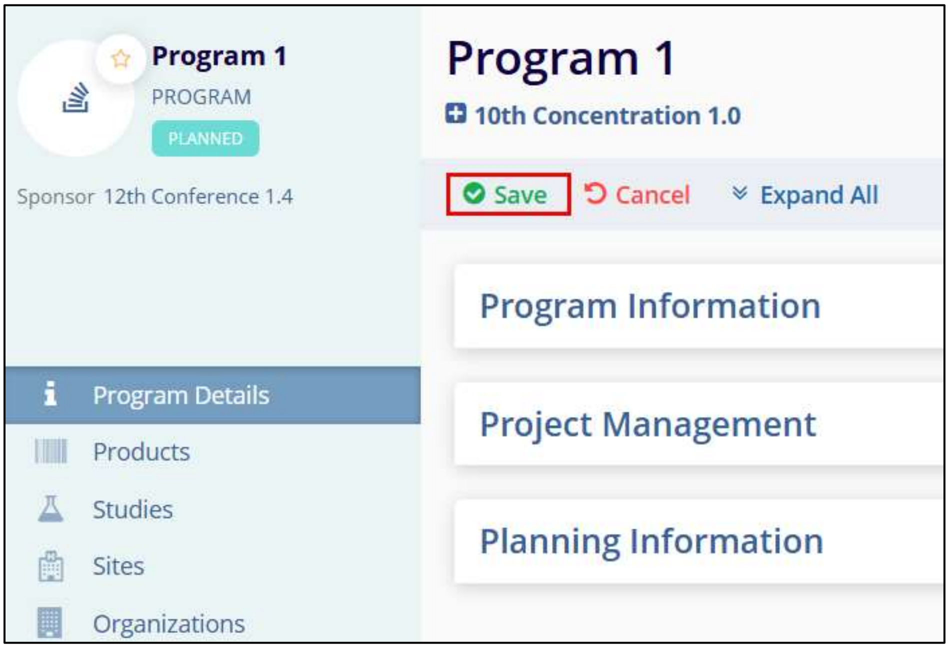


Figure: Save edits

Method 2

1. Click on the checkbox for the particular Program.
2. Click on the Edit (pencil) icon to edit, it will redirect you to the "Program details" screen.
3. Follow the steps detailed in Method 1 to edit and save all the Program-related details.

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.

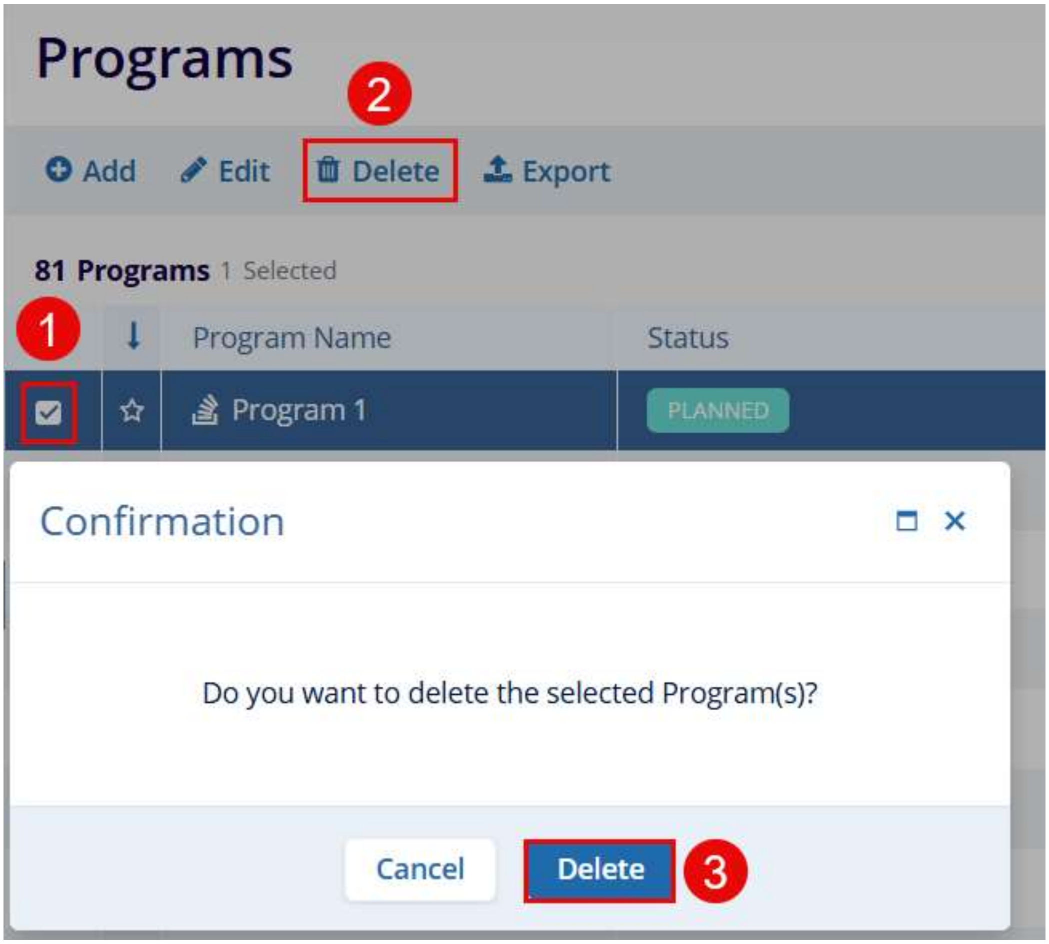


Figure: Delete Program

Exporting Program

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

Customizing Program screen

Filters

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

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

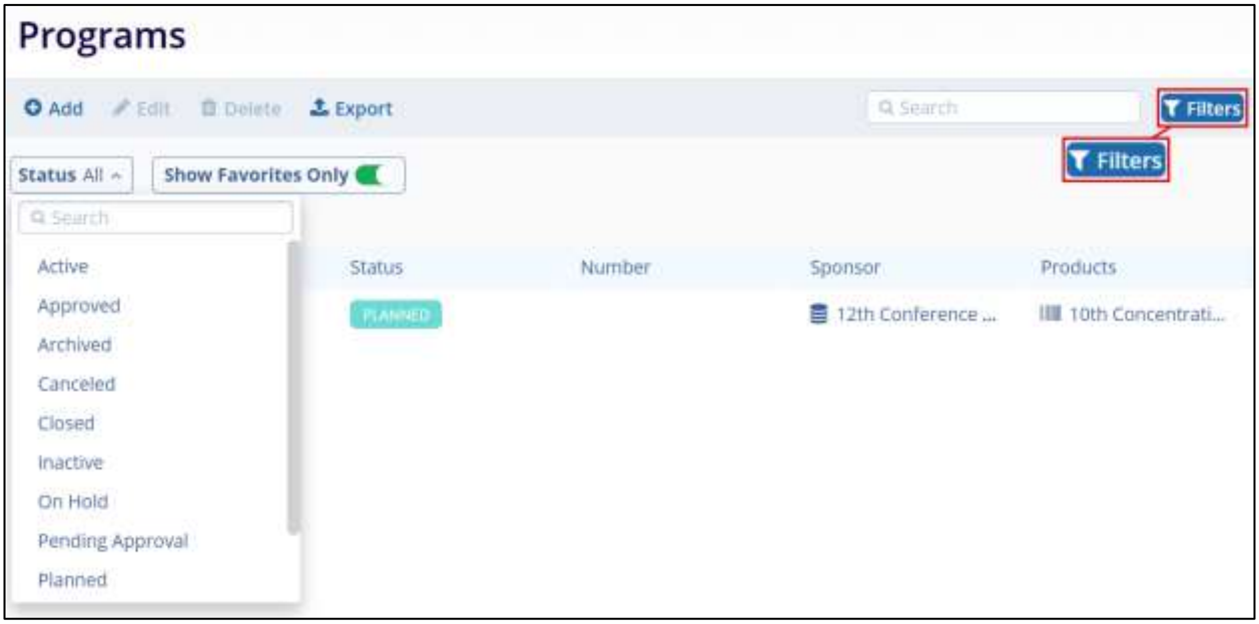


Figure: Apply Status filter

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.

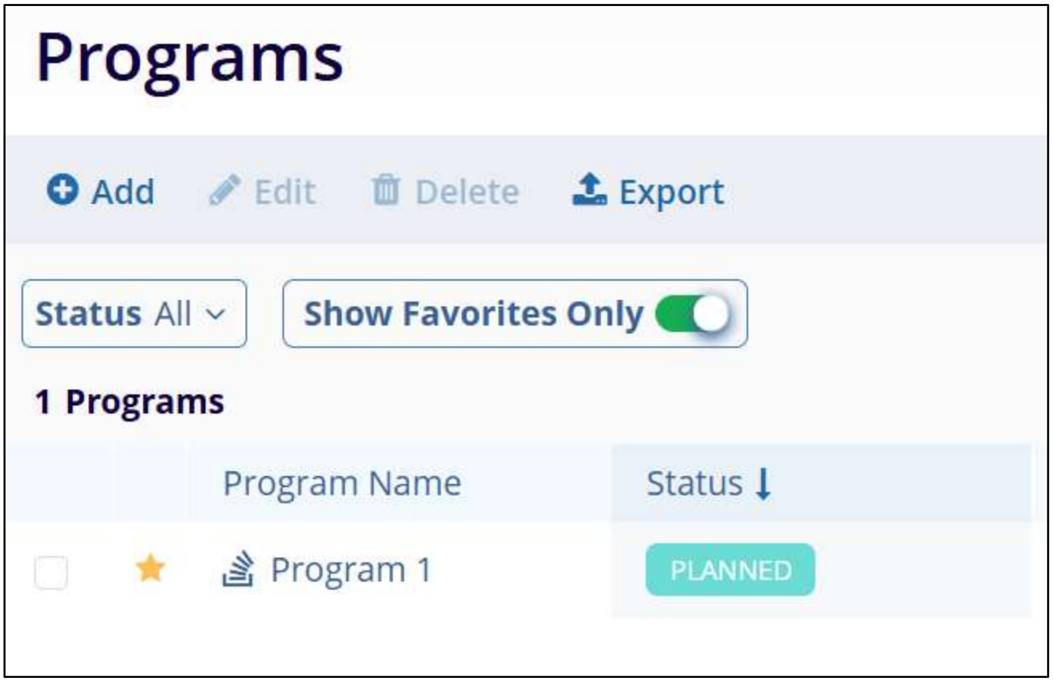


Figure: Show Favorites Only toggle

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

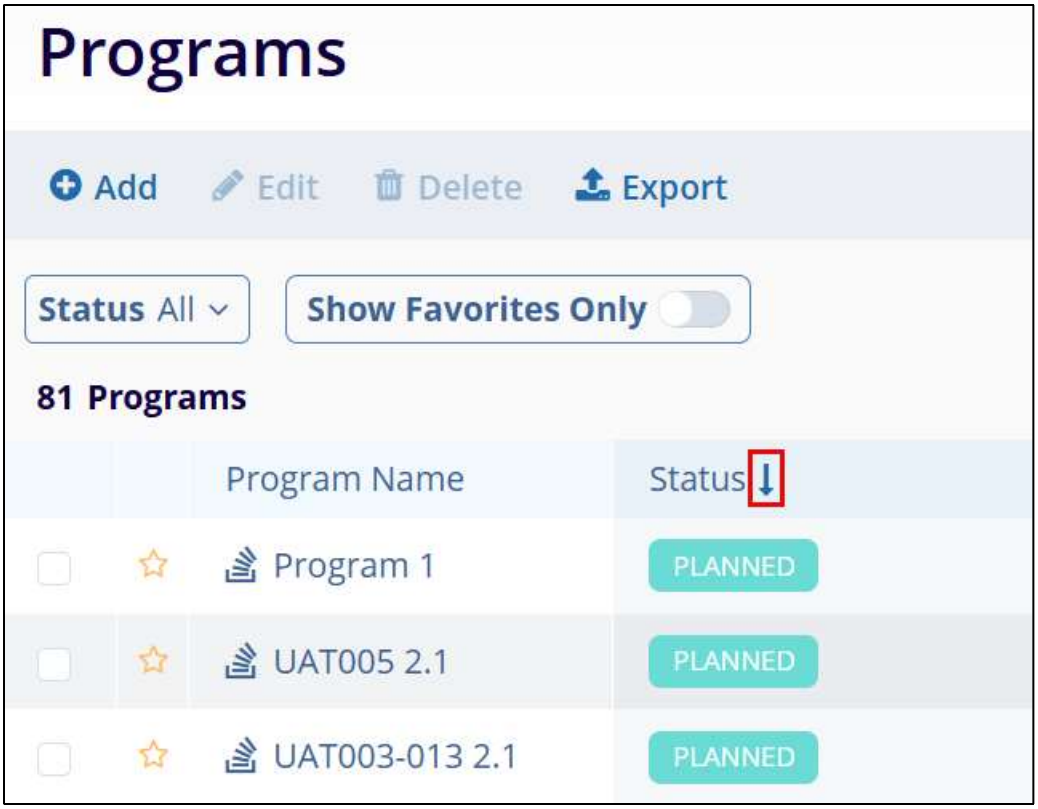


Figure: Sort column in ascending and descending order

Marking a Program as Favorite

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

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

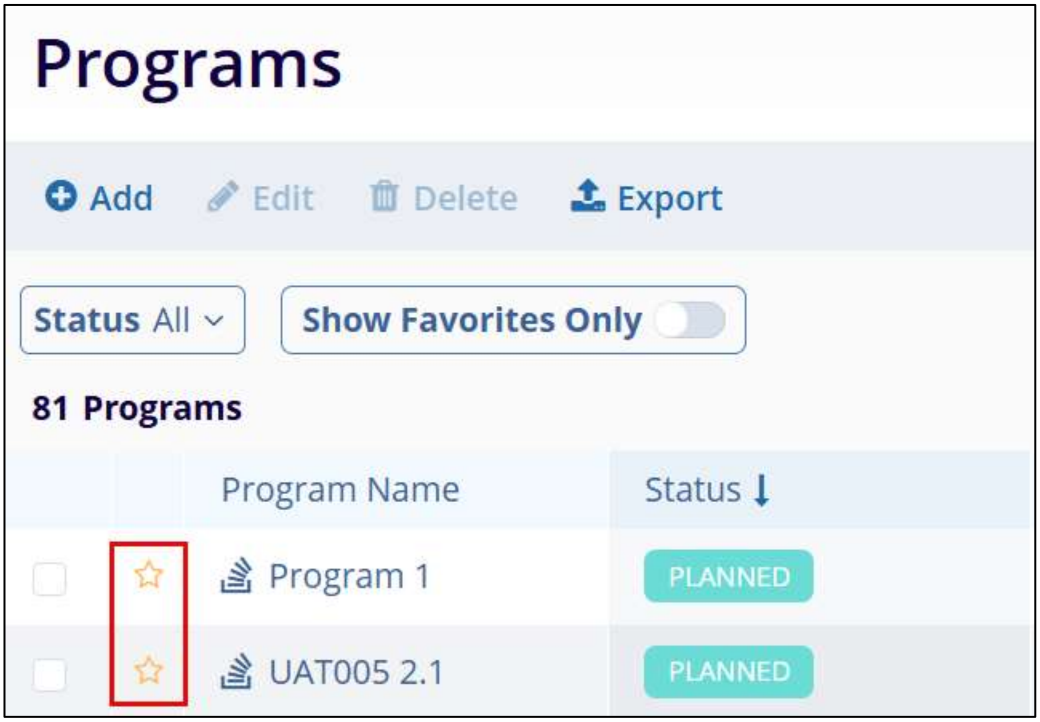


Figure: Mark as Favorite

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

CHAPTER 5. PRODUCT

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.

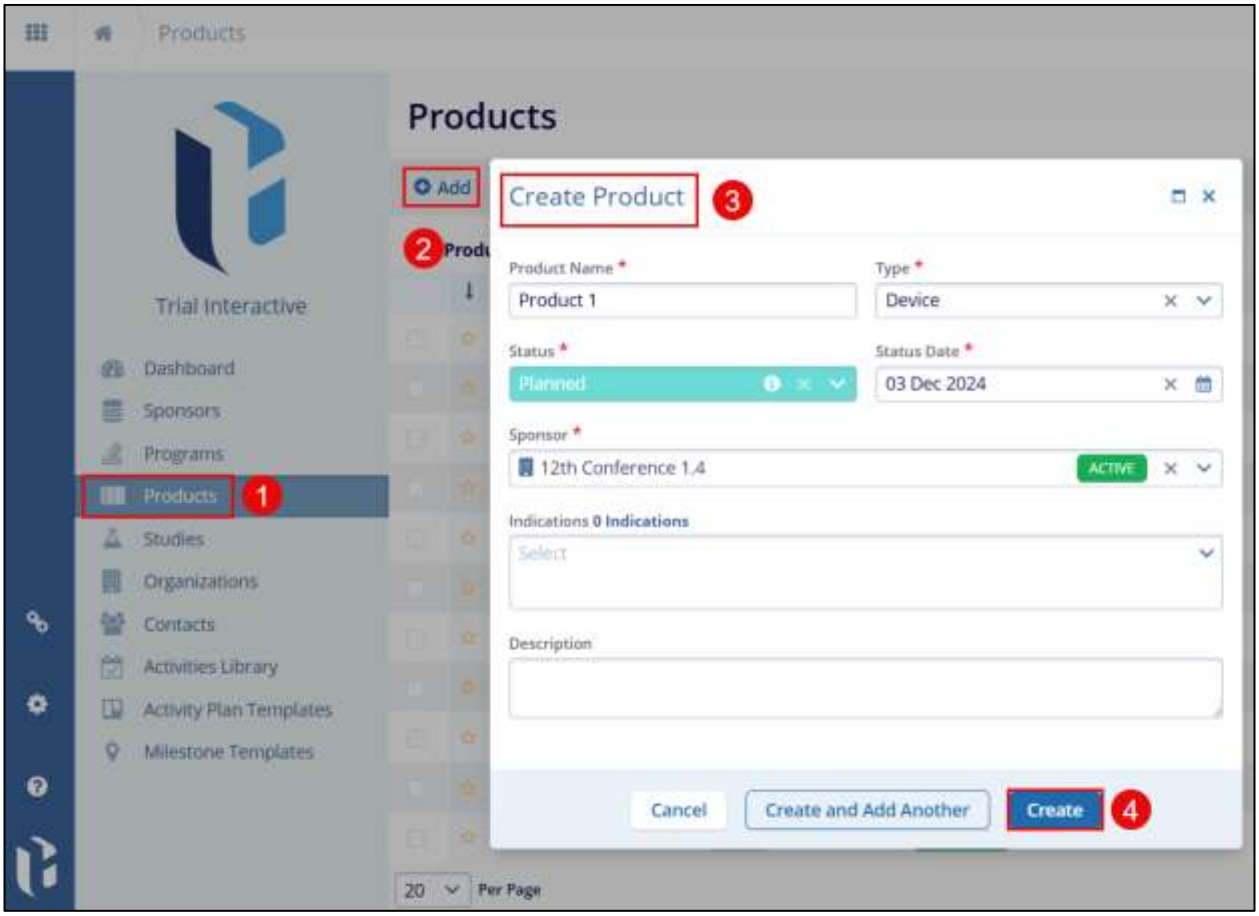


Figure: Create Product

Important Behavior of Creating a Product

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

Editing and reviewing a product

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

3. From the left-hand navigation links, click on the Products which will open the Products screen with a list of existing products.

4. There are two methods to edit the product details.

Method 1

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

Figure: Select a product to edit

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

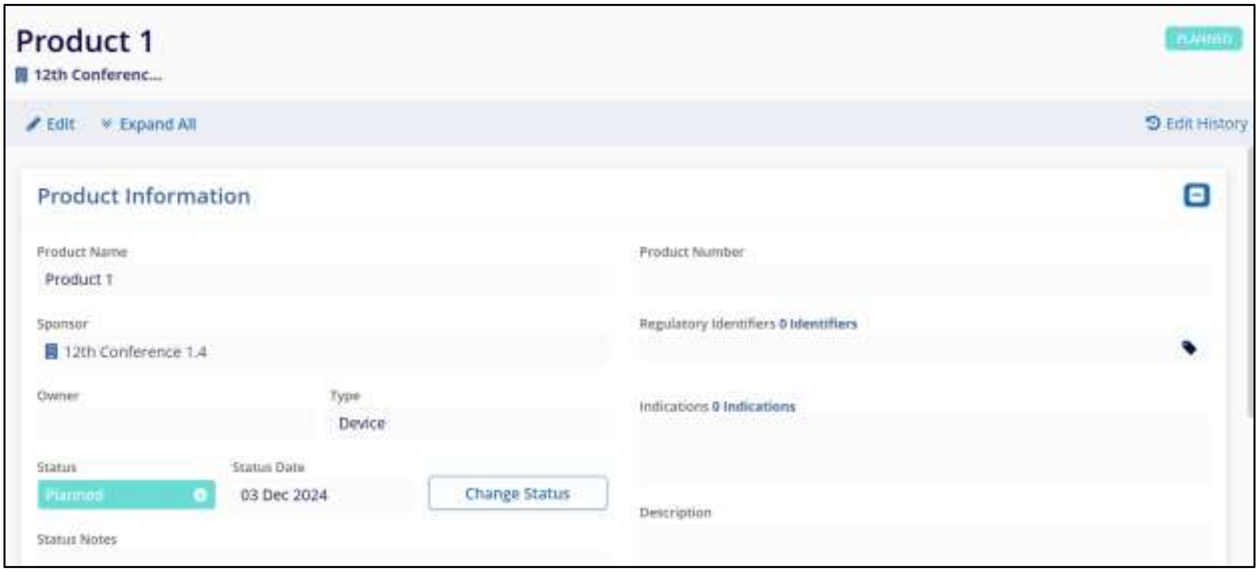


Figure: Product Details screen

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

   a. Change Status:

      i. Click on Change Status.

      ii. On the Change Status screen, update the Status*, and Status Date* and enter notes if required.

      iii. Once the required changes are made, click on Change and the respective status-related field will be updated with the latest status, date, and notes if any.

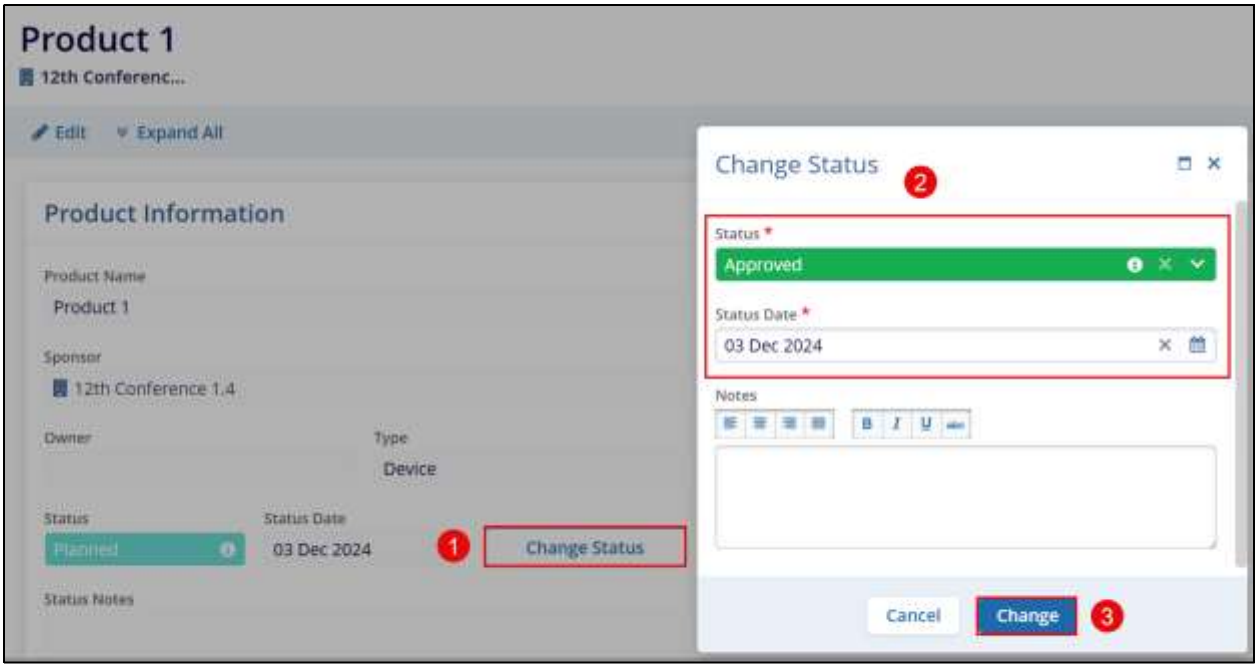


Figure: Change Status

   b. Status History:

      i. Click on the Status History icon.

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

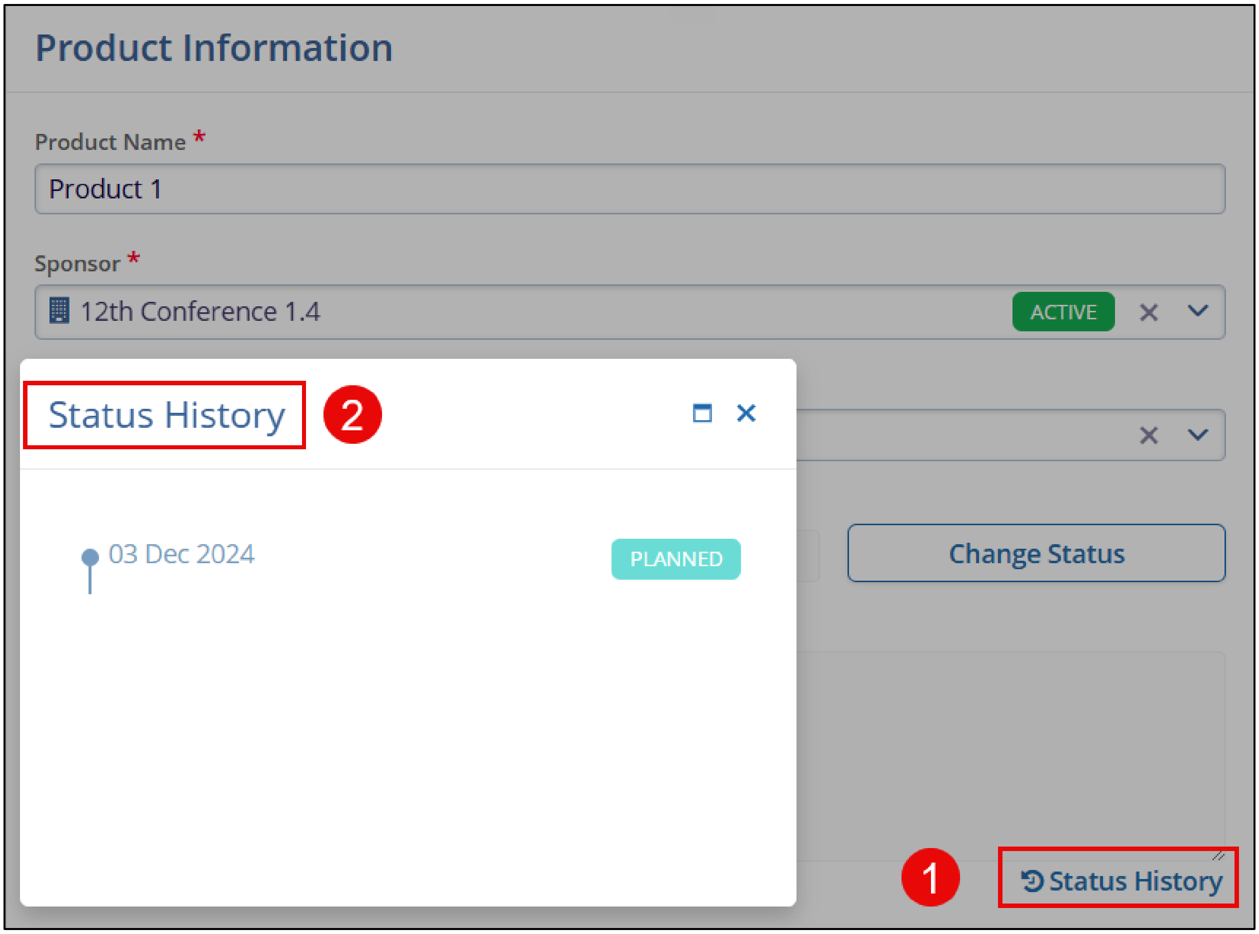


Figure: Status History

c. Regulatory Identifiers

i. Click on the Regulatory Identifier edit (pencil) icon

ii. Click on +Add to add a new Regulatory identifier

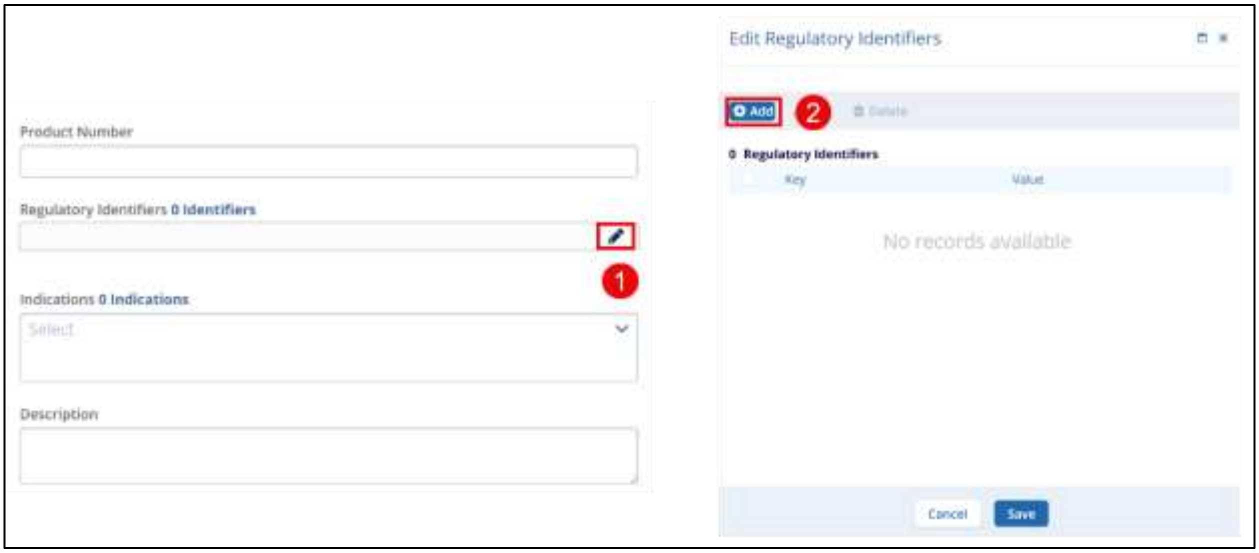


Figure: Add Regulatory identifiers

iii. In the Key field, select the required value from the available dropdown options.

iv. Enter the suitable value in the Value field.

v. Once the required details are added, click on Save

Figure: Add a value to the Key and Value fields

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

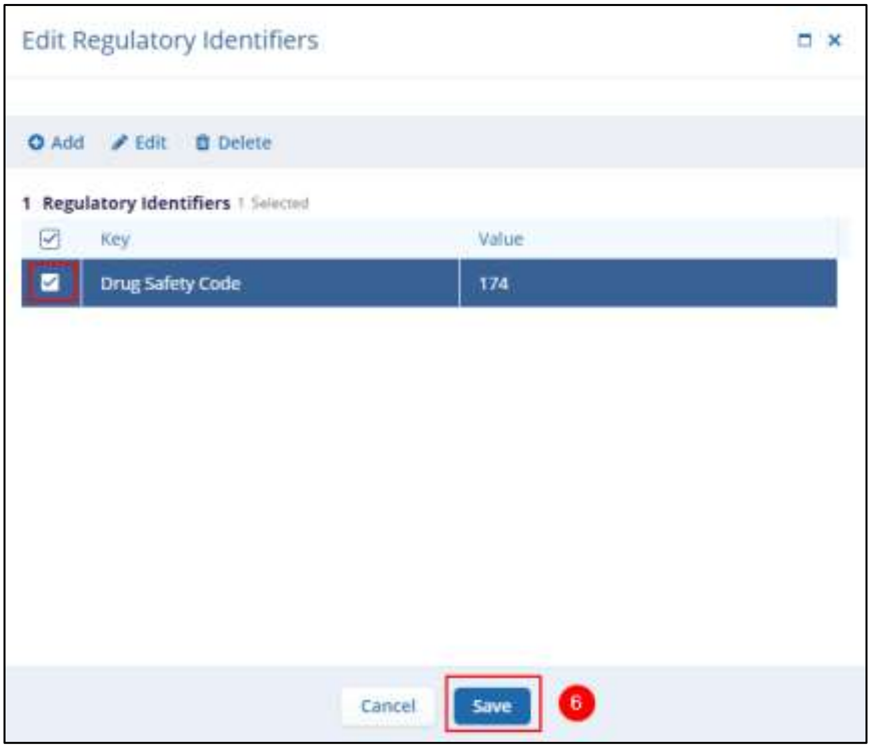


Figure: Save the new Regulatory Identifier

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

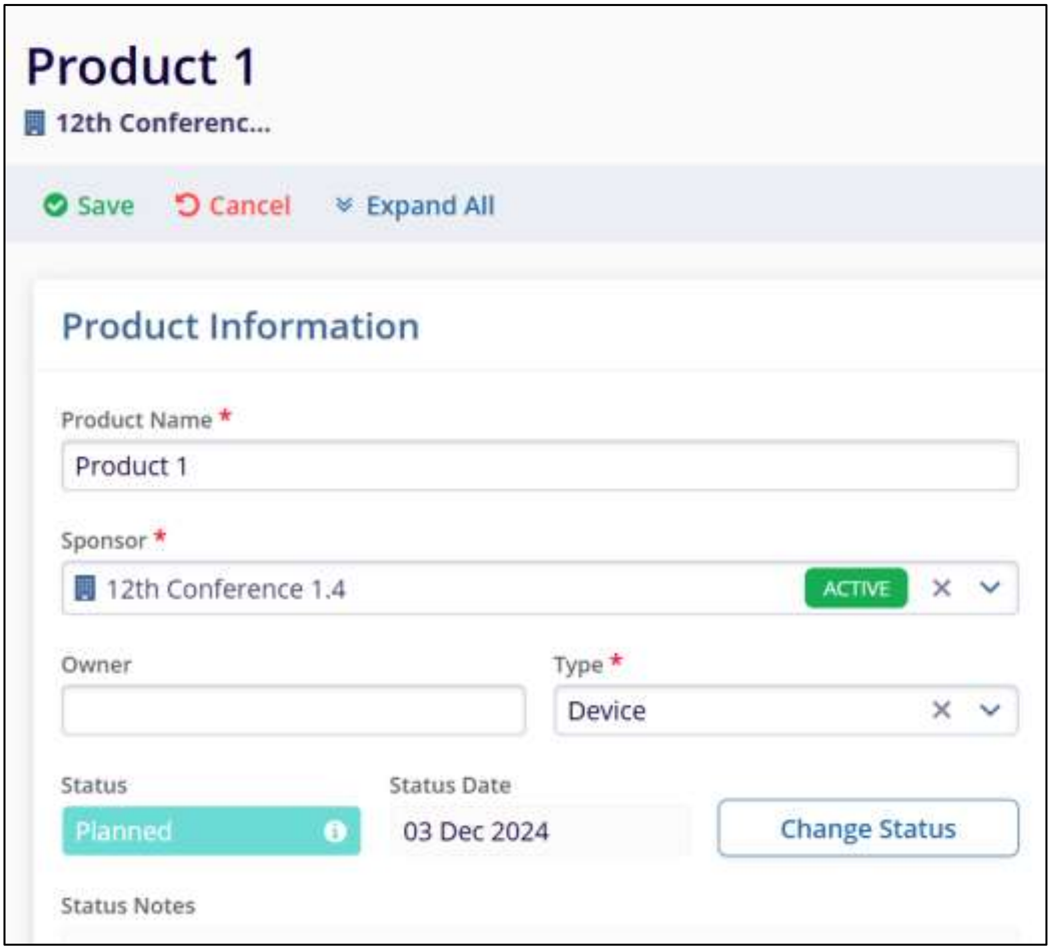


Figure: Save the edited product details

Method 2

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

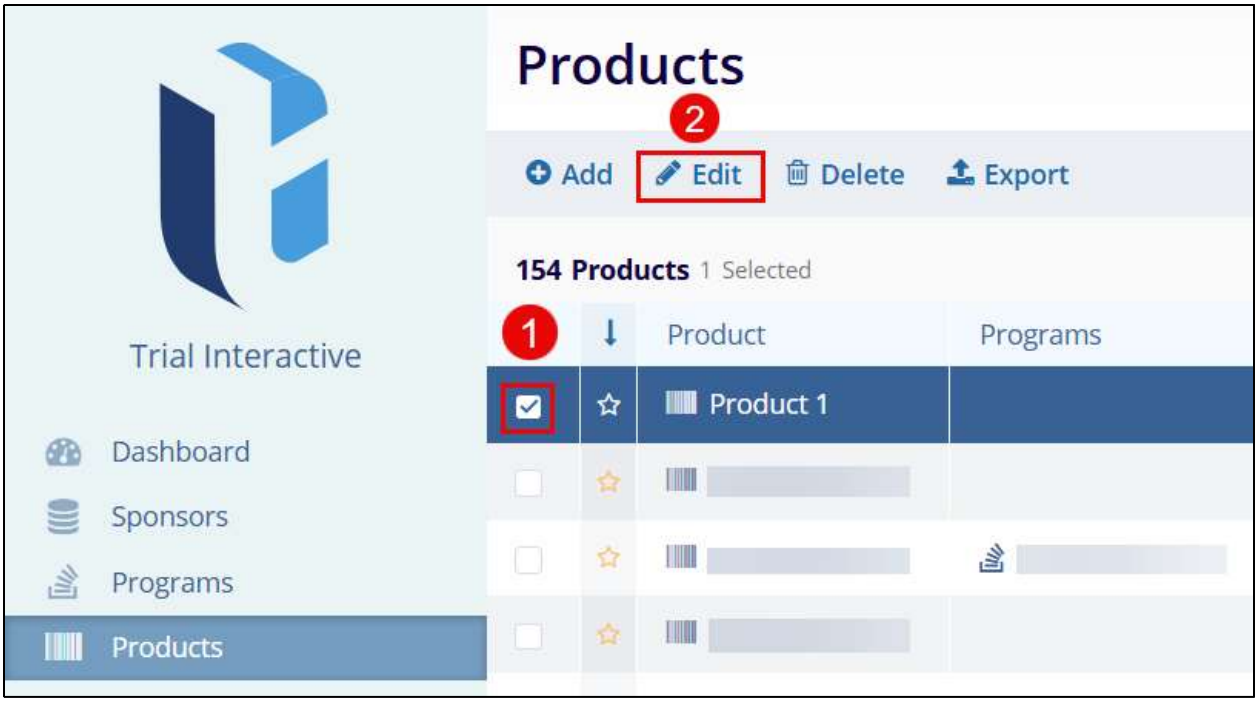


Figure: Edit Product details

Deleting a Product

To delete a product, follow the steps below.

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

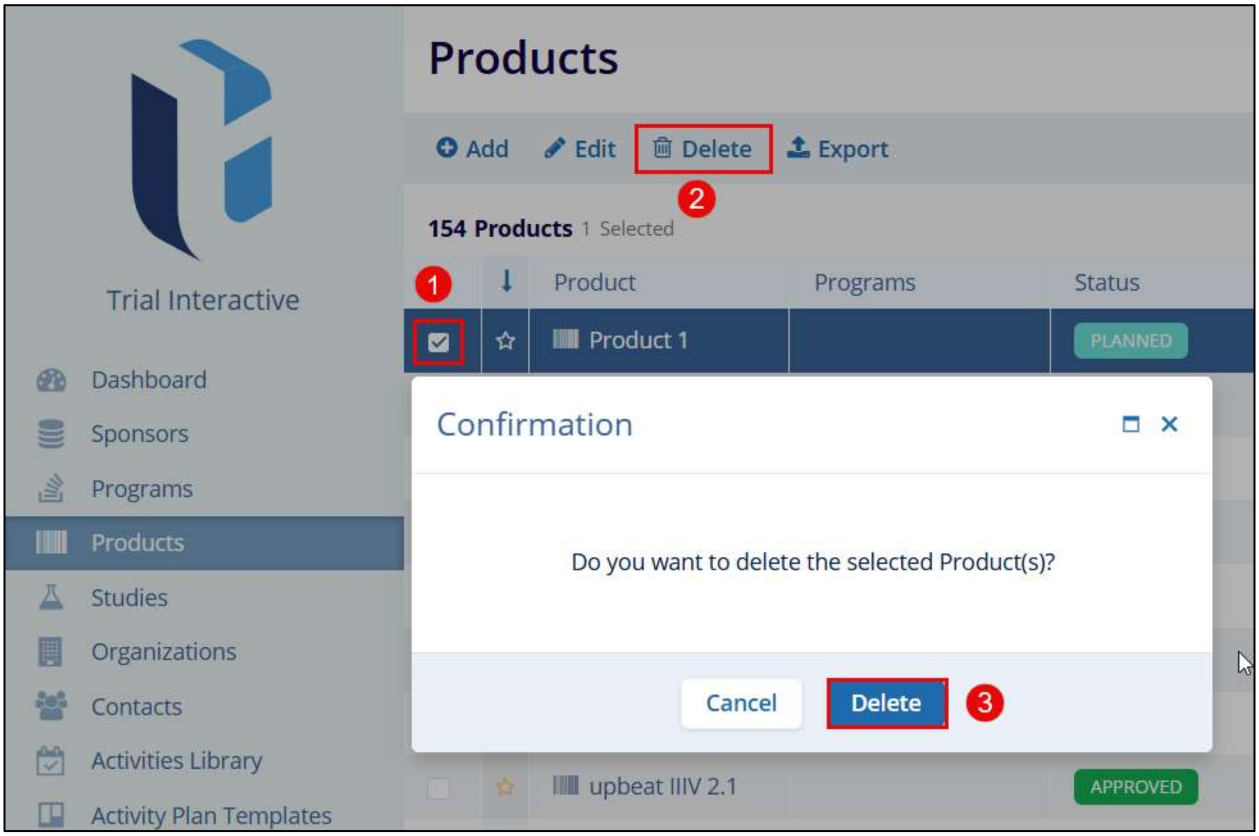


Figure: Delete product

Exporting Products

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

Customizing Products screen

Filters

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

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

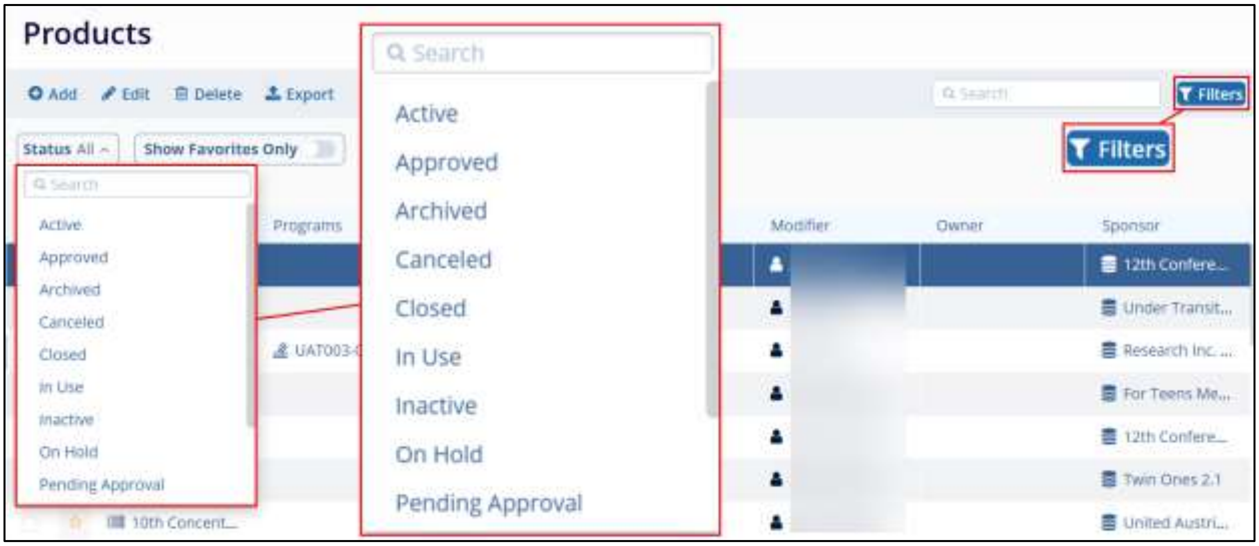


Figure: Apply Status filter

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

Figure: Show Favorites Only toggle

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

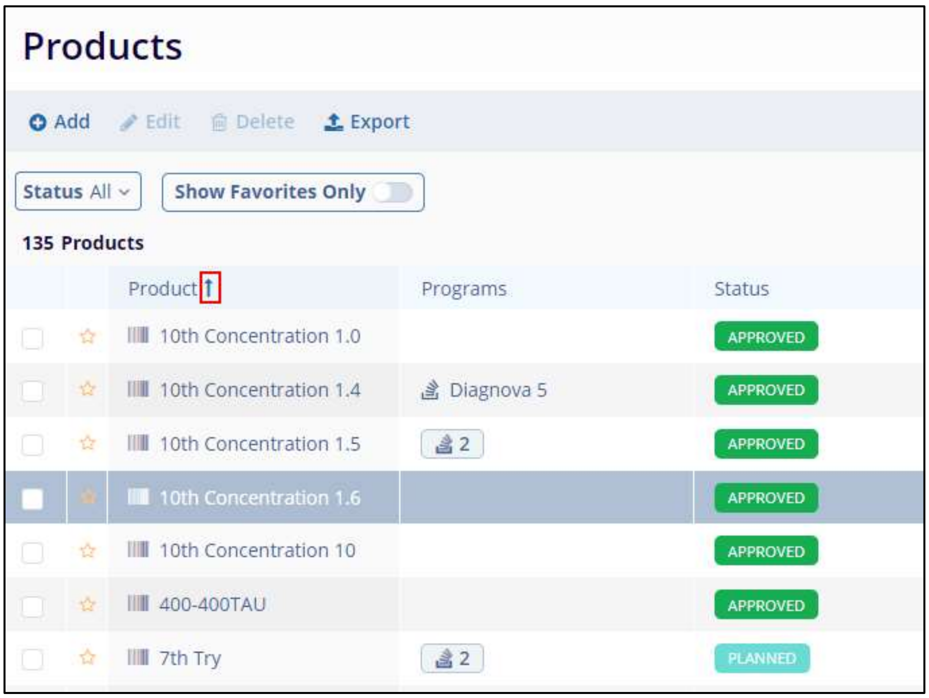


Figure: Sort column in ascending and descending order

Marking a product as Favorite

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

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

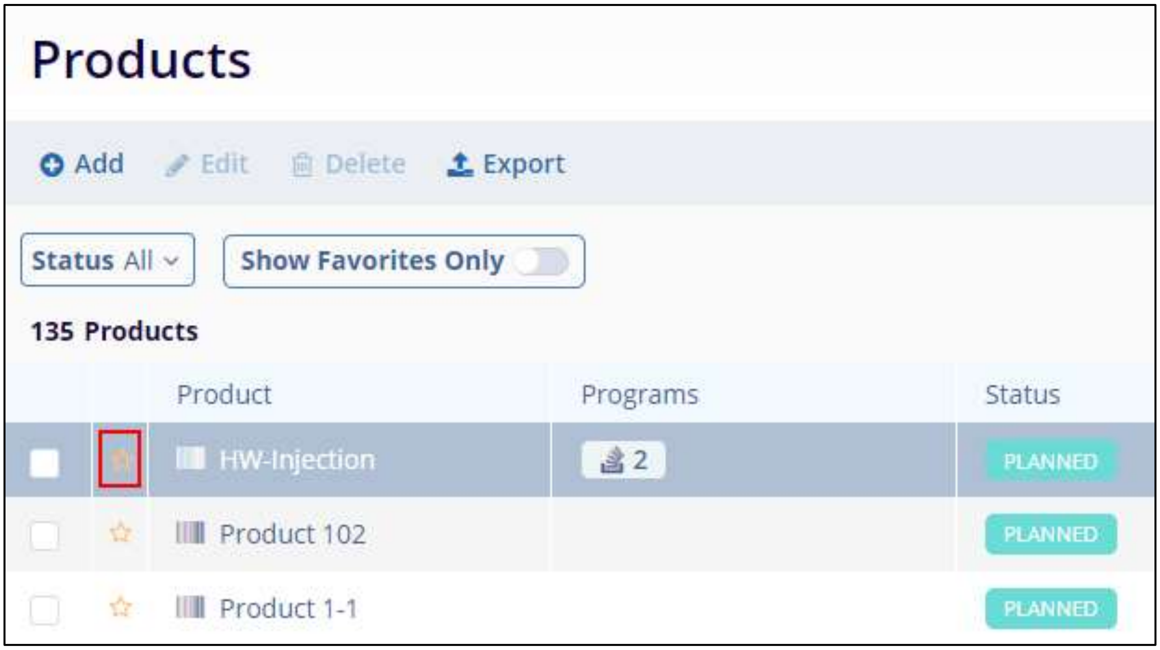


Figure: Mark as Favorite

4. 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.

CHAPTER 6. STUDIES

Pre-Requisites

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

Navigate to Studies

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

1. Click on the Studies link in the Navigation menu on the left side of the screen. It will open the Studies screen.

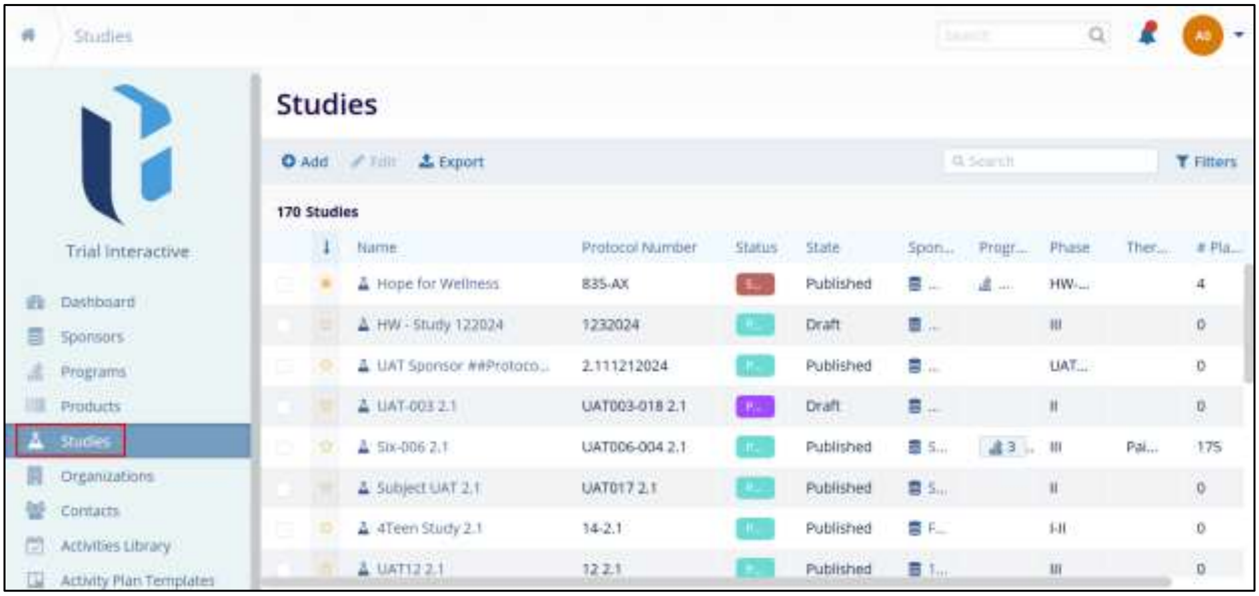


Figure: Navigate to Studies

Add Studies

To add a study, follow the steps below.

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

Figure: Add Studies

2. On the ‘Create Study’ window, enter the mandatory metadata to create a study (Sponsor, Protocol Number, Protocol Title, Status, Status Date, Primary Product, Phase, Design, and eTMF Location). These fields are marked with an asterisk (*) next to the field title. You may also enter any additional information as necessary.

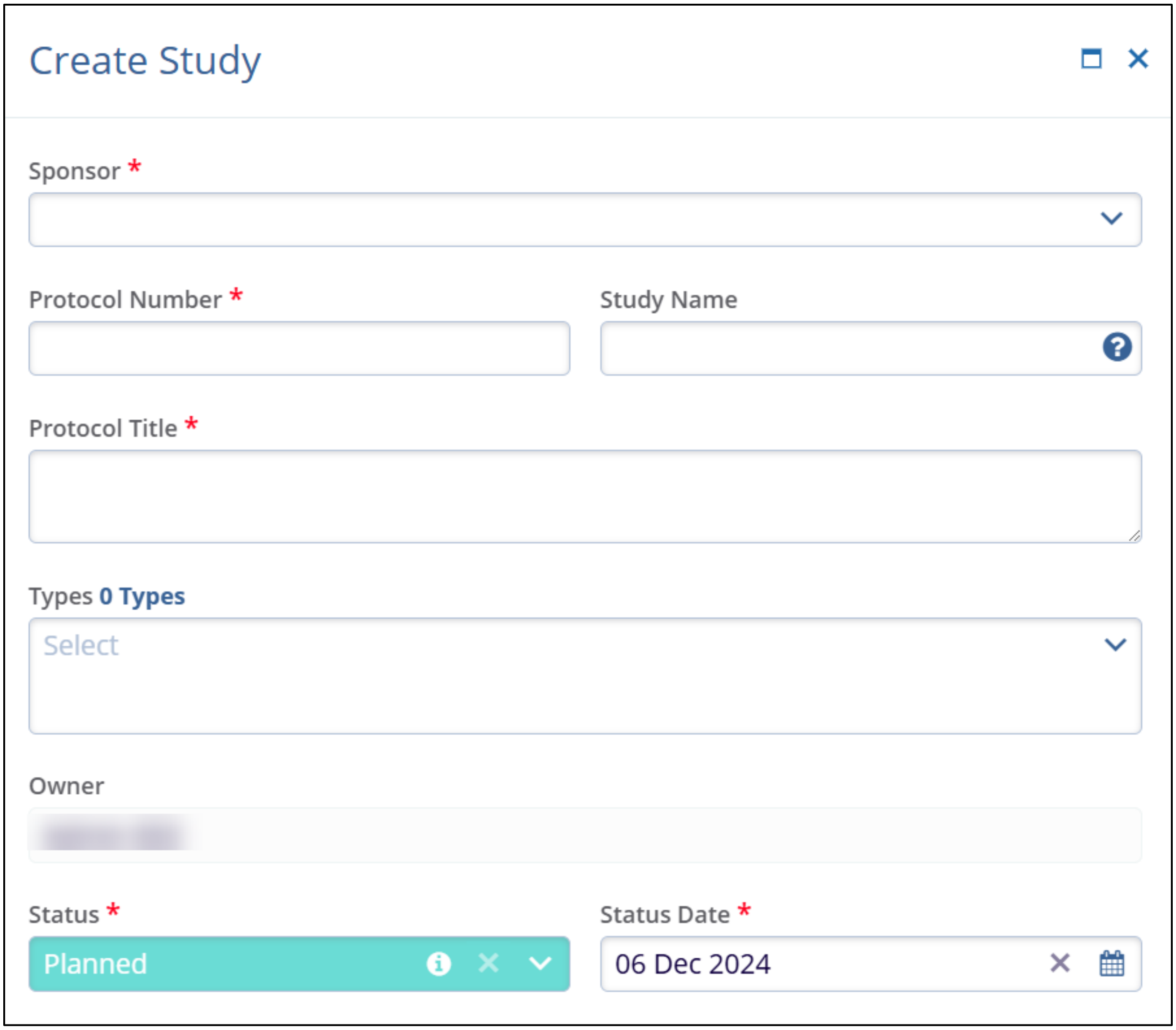


Figure: Create a Study

3. Indicate whether this is a blinded trial on the Study Details page. Although you can update this information after the study has been created, this is your first opportunity to specify that the study will include a blinded component.
4. If any required fields are missing, an error message will appear when the user clicks the 'Create' button, listing the fields that need to be filled to create the study successfully.
5. Click the '**Toggle'** buttons for Virtual Study, Subject Tracking, and Is this a blinded trial. These fields are optional.
6. To create a study, click the '**Create'** button. If you wish to cancel the study creation, click the 'Cancel' button.

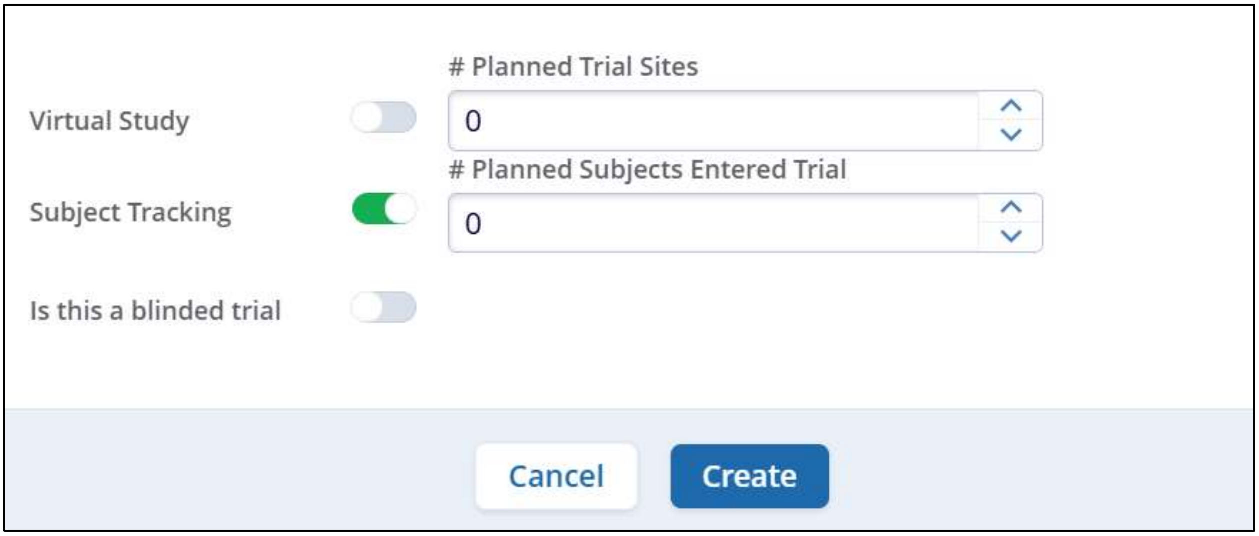


Figure: Create Study Fields

7. 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.

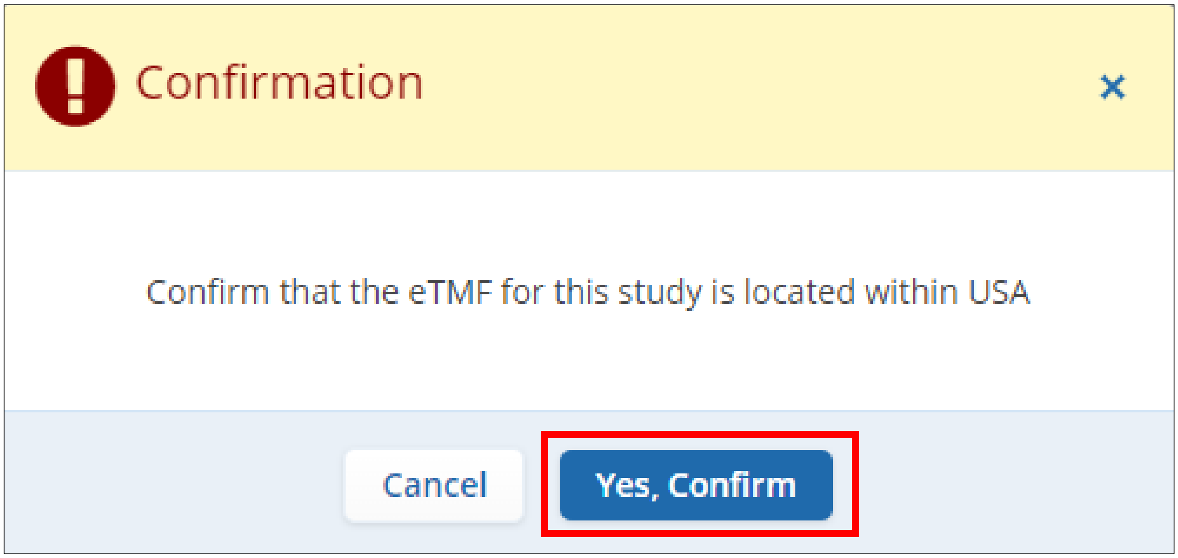


Figure: Create Study confirmation message

8. 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.

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.

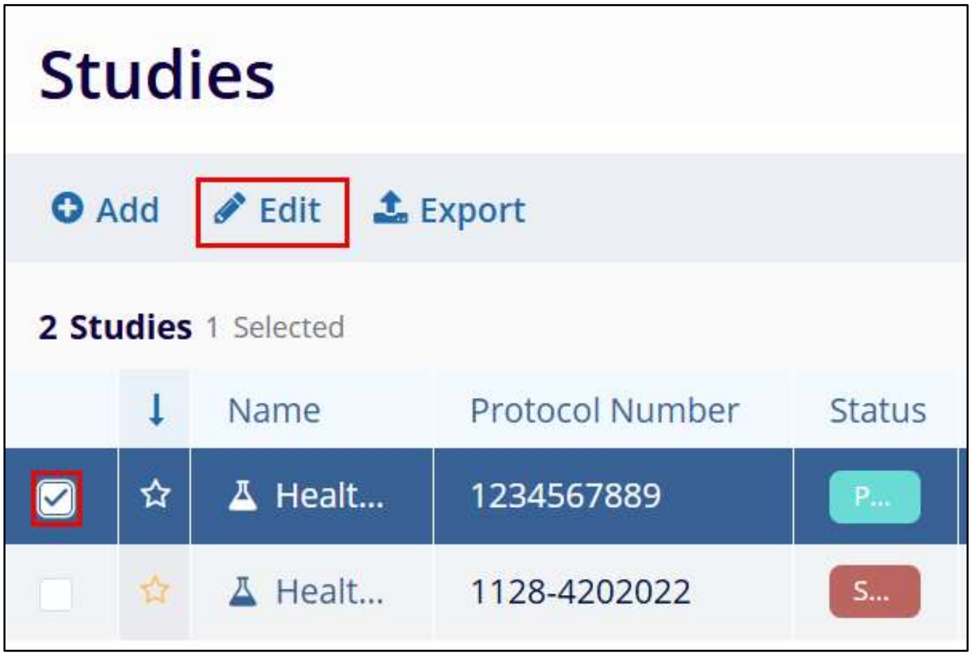


Figure: Edit Study

3. Make any necessary changes to the Study Details by expanding the sections.
4. Click the '**Save'** button for the changes to apply or to discard the changes click on the '**Cancel'** button.

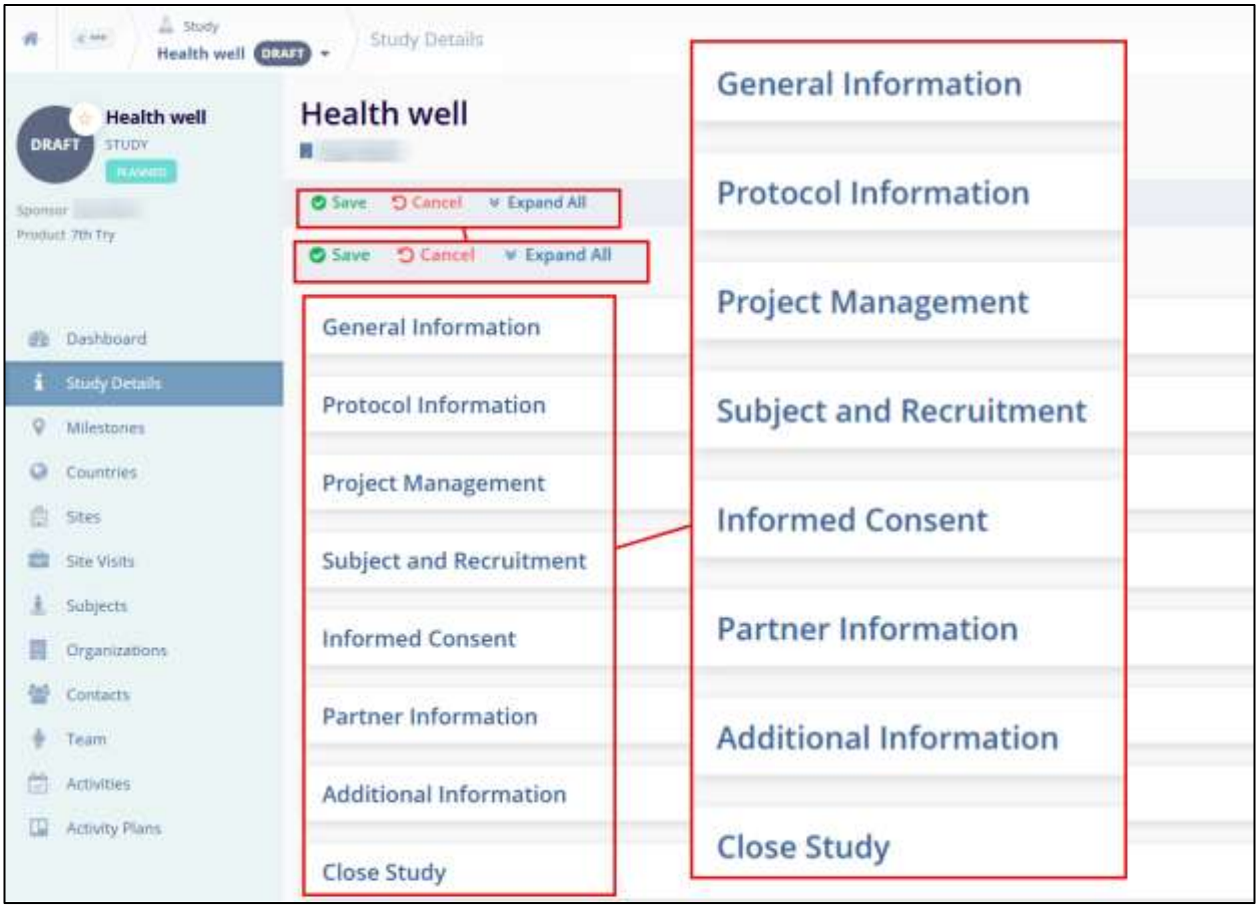


Figure: Study Settings

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.

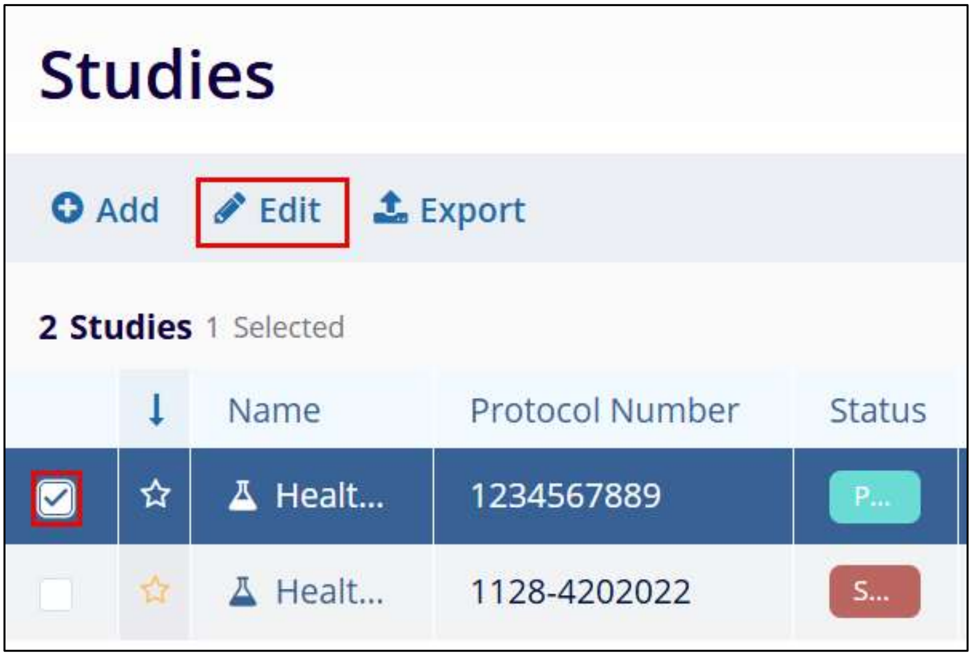


Figure: Edit study to access settings

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

Figure: Study-specific settings

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

Figure: Edit Study Settings

5. Make any necessary changes in the "Study Settings General" window by expanding the sections and click "Save" at the top-left of the window.

Figure: Save settings.

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

Defining Study Partners

To define study partners, follow the steps below.

1. Follow the steps to access the Study Details mentioned in the Edit Studies sections.
2. Click on the Study Details in the Navigation menu on the left side of the screen. The "Study Details" window is displayed.
3. Click on the [+] sign next to the '**Partner Information'** to expand that section. Click on the Edit button in the top-left of the screen. Refer to the below screenshot.
5 Make the necessary changes in the partner information section.
6 Click the Save button in the top-left of the screen.

Figure: Study Settings – Partner Information

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. It will redirect you to the studies screen.
2. Click on the Study Name and It will redirect the user to the Study Details screen. From the navigation pane, Click on the Dashboard. It will redirect you to the **Study's** Dashboard.
3. Refer to Chapter 2. Dashboard section.

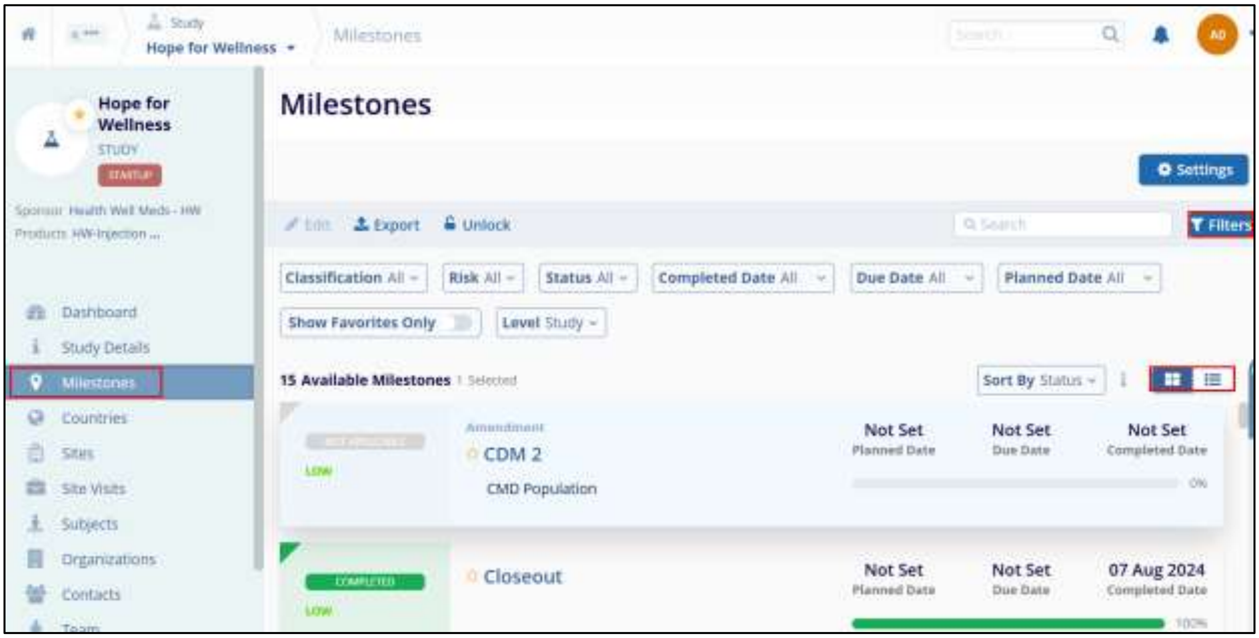
Study Milestones

To access the Study Milestones section, follow the steps below.

1. To navigate a Studies Milestone, click on the '**Studies'** link in the Navigation menu at the left side of the screen. It will redirect you to the studies screen.
2. Click on the Study Name and It will redirect the user to the Study Details screen. From the navigation pane, click on the Milestones.

   Note: Refer to Chapter 12. Milestones section for detailed information on Milestones.

3. Users have two options to view Milestone Card view and List view. Select the appropriate view at your convenience.
4. To apply a filter, click on the Filter button from the top left side of the screen. Refer to the below screenshot.
5. It will display all fields with the drop-down, click on the drop-down arrow and select the appropriate option as per the requirement.
6. As per the applied filter, users will able to see the results in the grid.



Study Countries

Defining and Editing Countries within a Study

To define and edit 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.

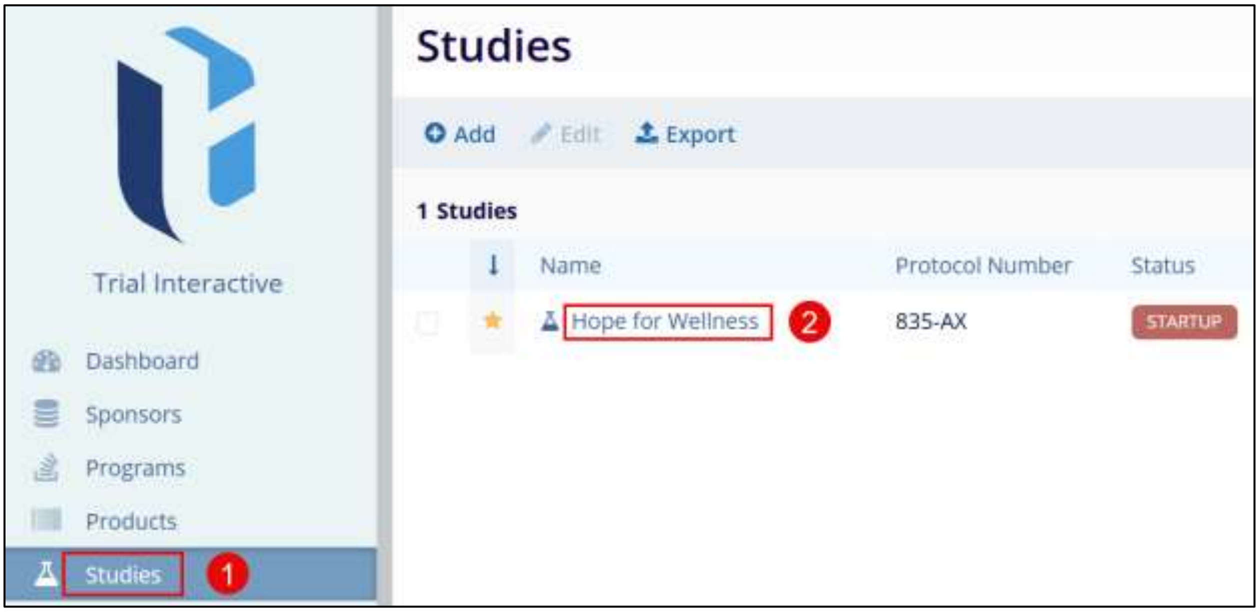


Figure: Select a study to associate a country

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

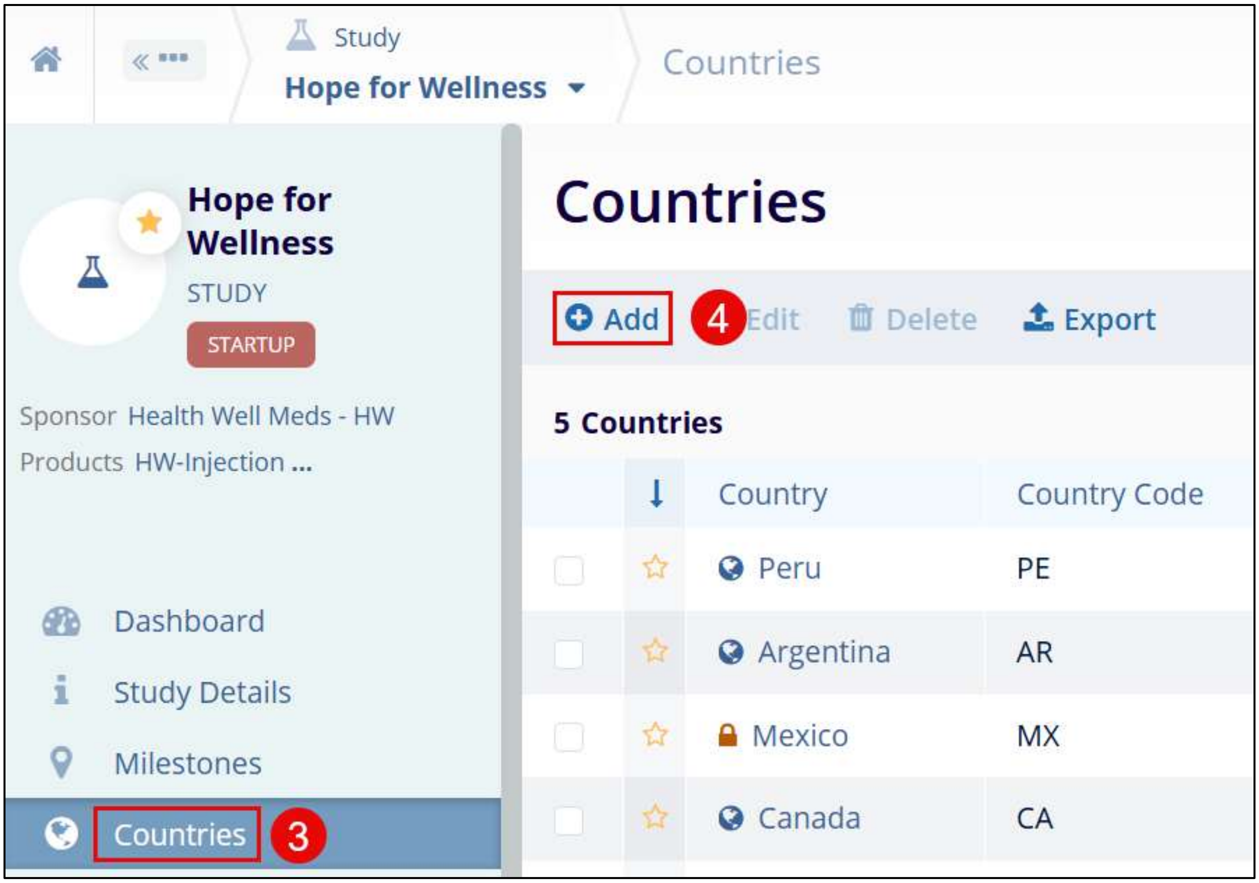


Figure: Add Country

5. On the Create Study-Country window, enter the mandatory metadata required to create a region, such as
    a. Country,
    b. Owner,
    c. Status, and
    d. Status Date. These fields are indicated by an asterisk (*) next to their titles. Enter any additional information, as necessary.

6. Click the "Create" button. The country is created, and the "Create Study-Country" window is closed.

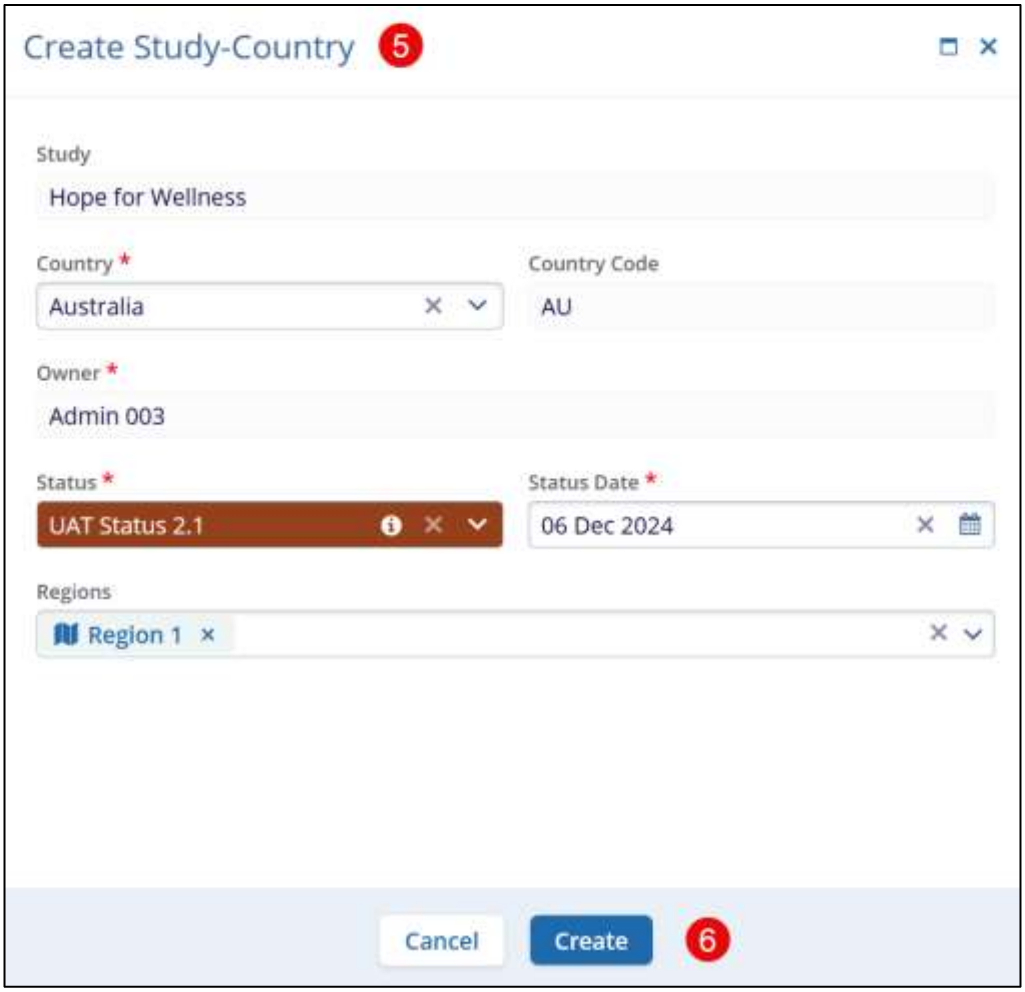


Figure: Create Study Country form

7. To edit a country, click the checkbox next to the name of the country you want to edit and Click "Edit" at the top-left of the screen.
8. A quick view panel is displayed on the right side of the screen. Make any necessary changes in the quick view panel.
9. Click "Save" at the bottom of the quick view panel.

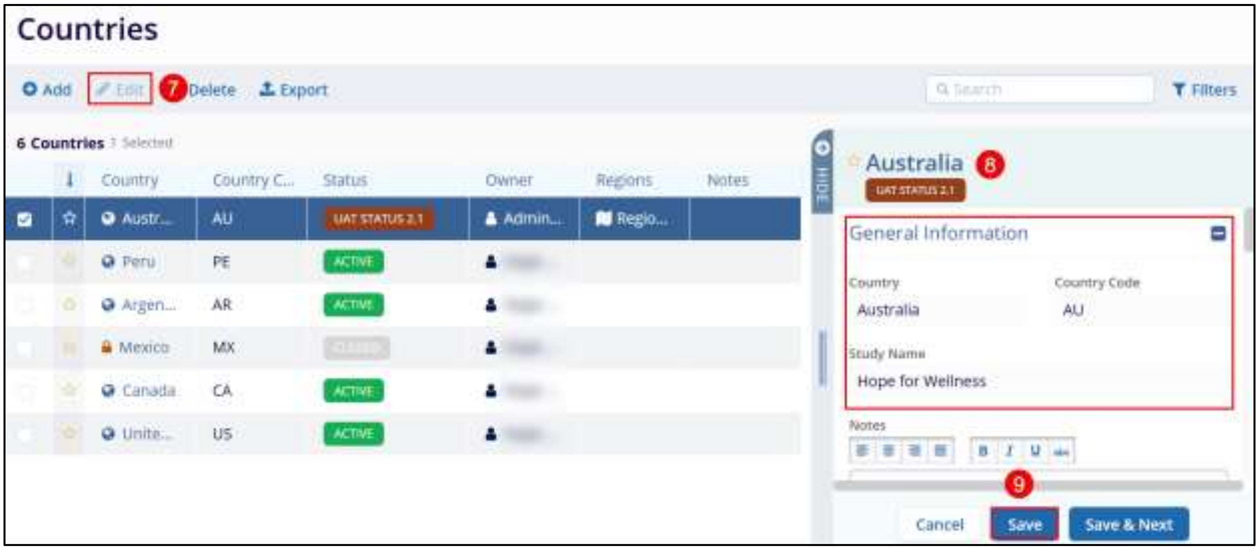


Figure: Edit Countries within a Study

Reviewing and Tracking Country Details

To Review and track country details, follow the steps below.

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.

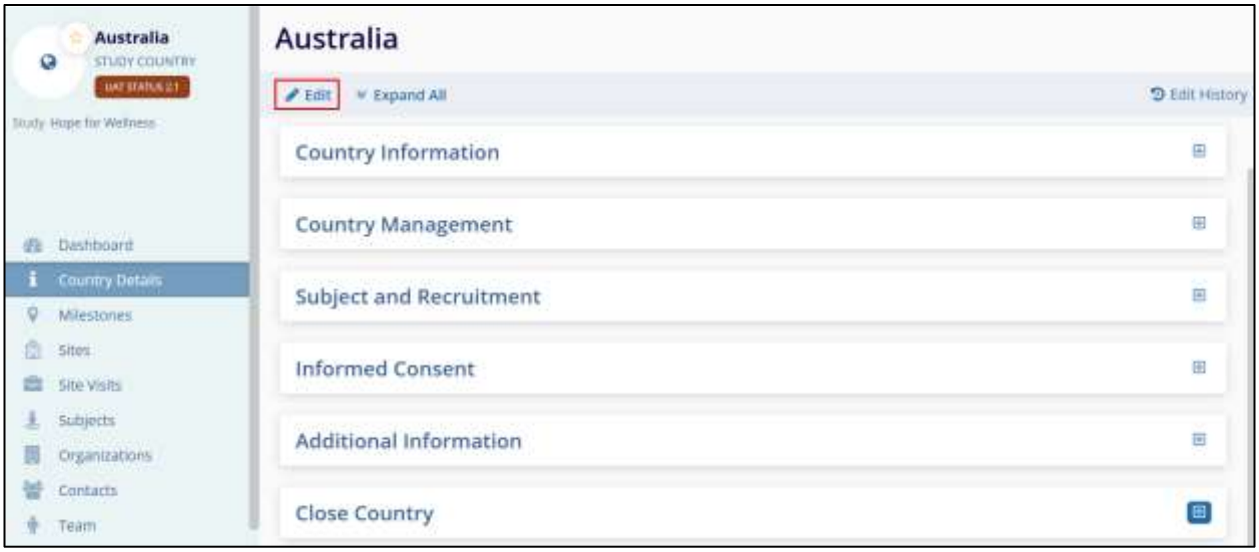


Figure: Access Country Details

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

Figure: Save changes to country details

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 in the list you want to edit and click on it. 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.

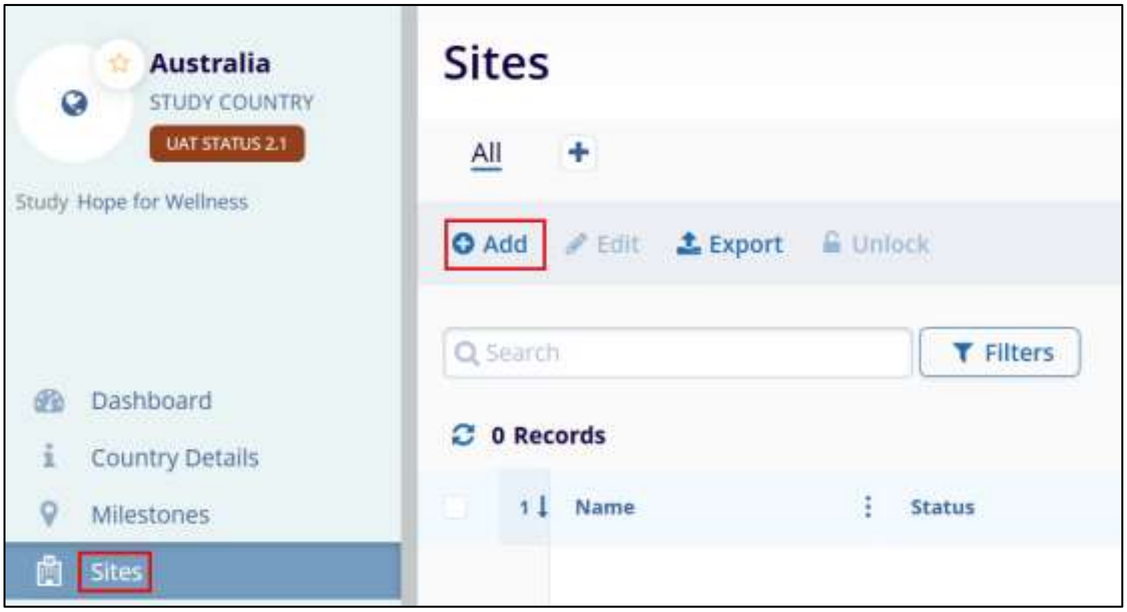


Figure: Add Site to Country

5. Fill in the required information and click Create.

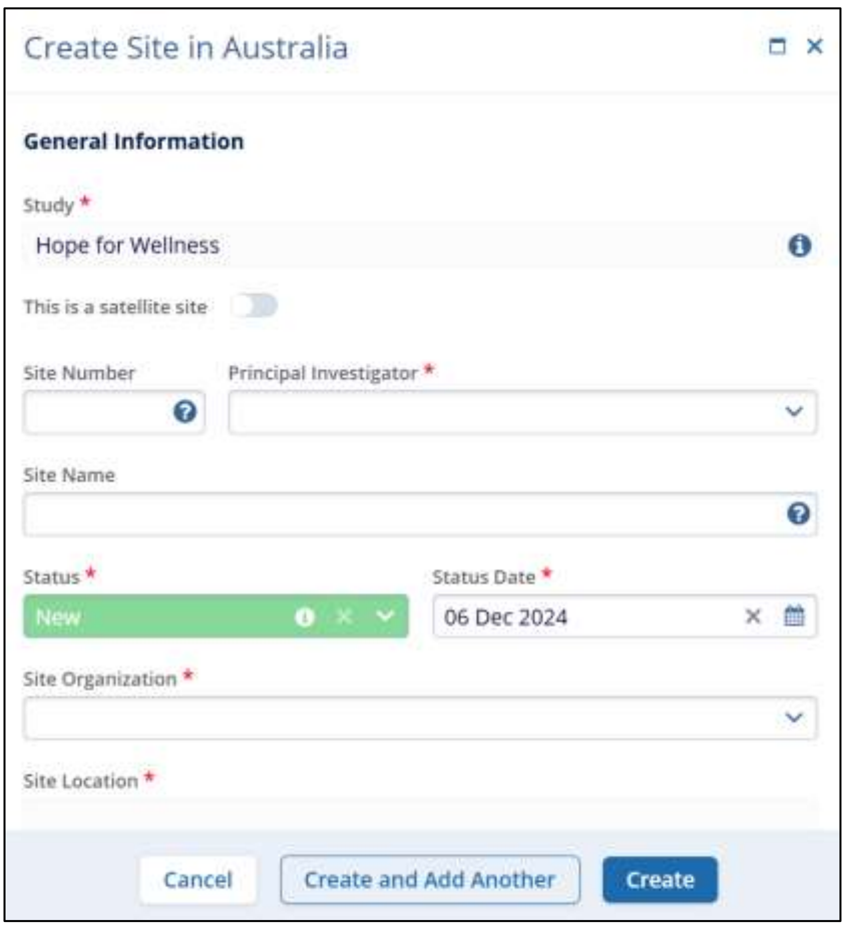


Figure: Create Site form

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.

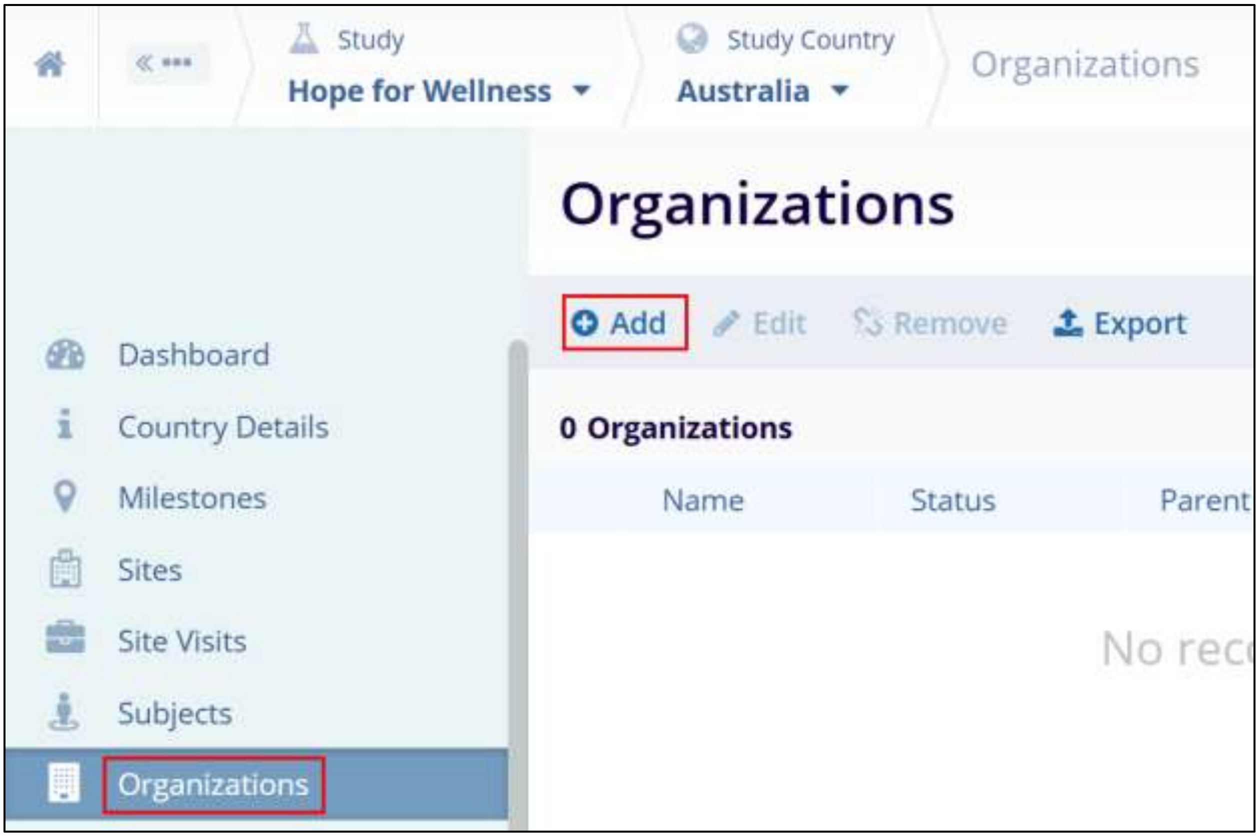


Figure: Add Organization within a Country

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

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. Refer to Chapter 9. Contacts.

Study Sites

Study Sites Pre-Requisites

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

Associating Sites within the Study

1. 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.
2. Click on the study name to which you want to add Sites. The dashboard for the study is displayed.

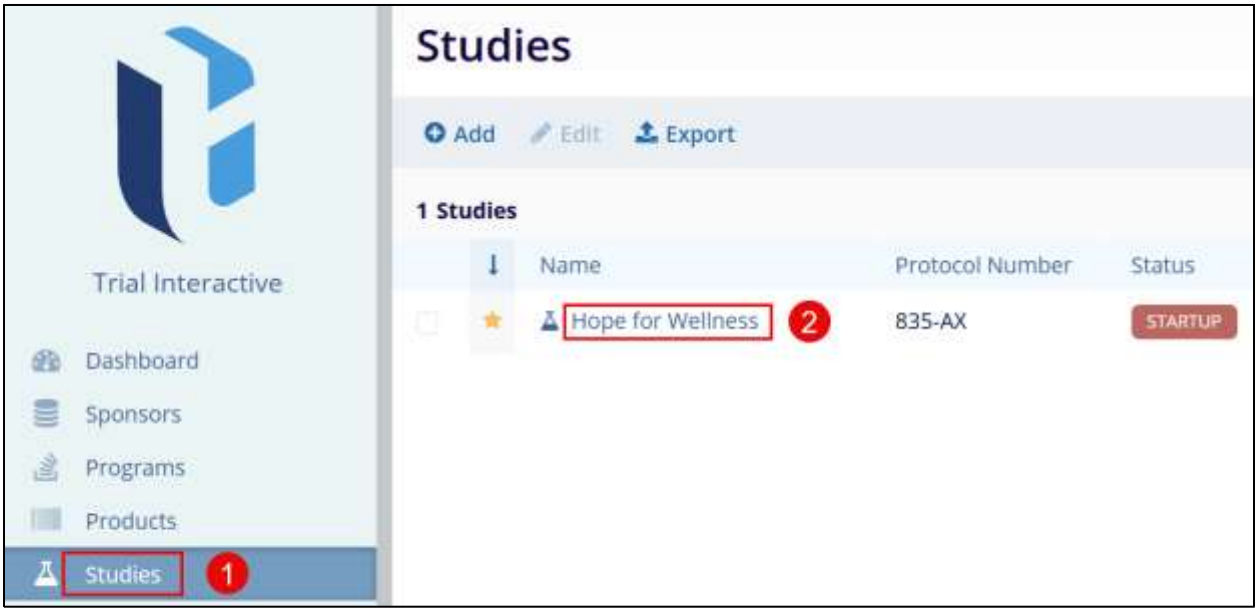


Figure: Select a Study to associate a site

3. Click on the Sites link in the Navigation menu on the left side of the screen. This opens the "Sites" window, and all the sites are listed for the study.
4. Click on the Add button at the top-left of the screen. This opens the Create Site window.

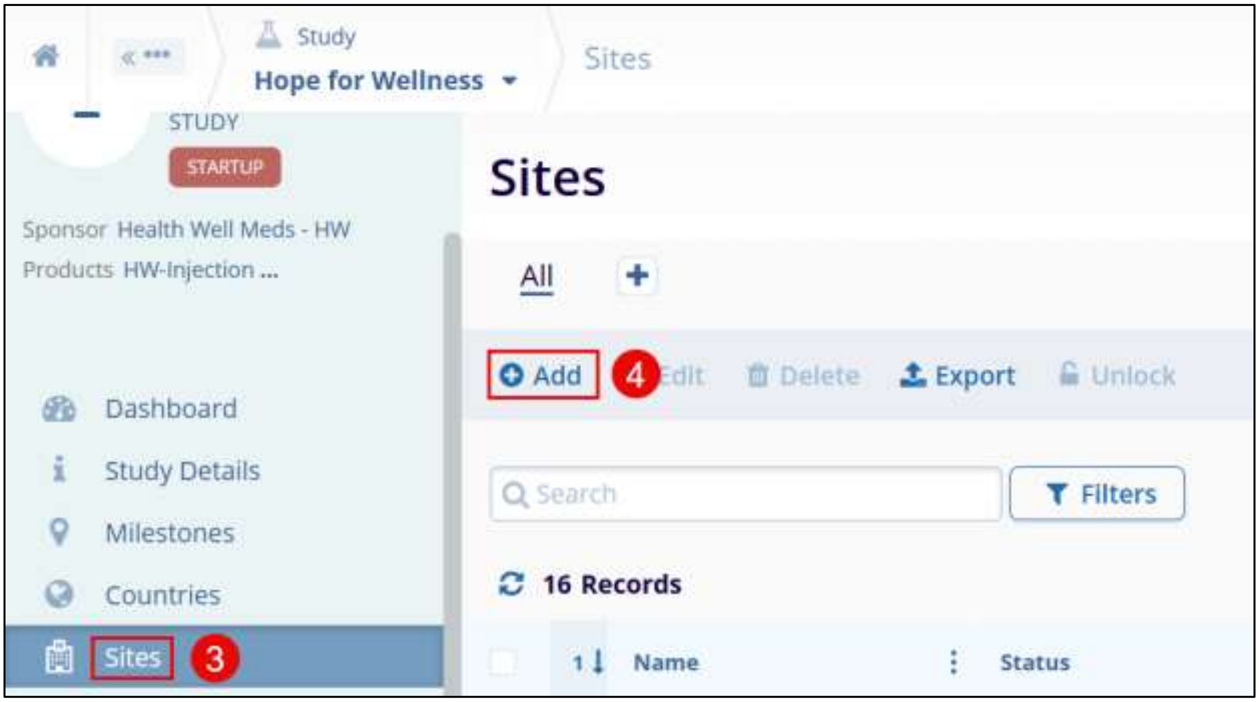


Figure: Add Site within a Study

5. Enter the mandatory metadata to create a site i.e., Site Number, Principal Investigator, Site Organization, Site Location, Owner, Status, and Status Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.

   a. If the site is a satellite site, this is also where you would identify the parent site. Please note that the parent site will need to already be created and associated with the study before identifying a site as a satellite site.
   b. Select the Primary Site from the dropdown menu displayed next to the toggle button as indicated by an asterisk (*).

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

6. Click Create or Create and Add Another depending on whether you intend to create another site.

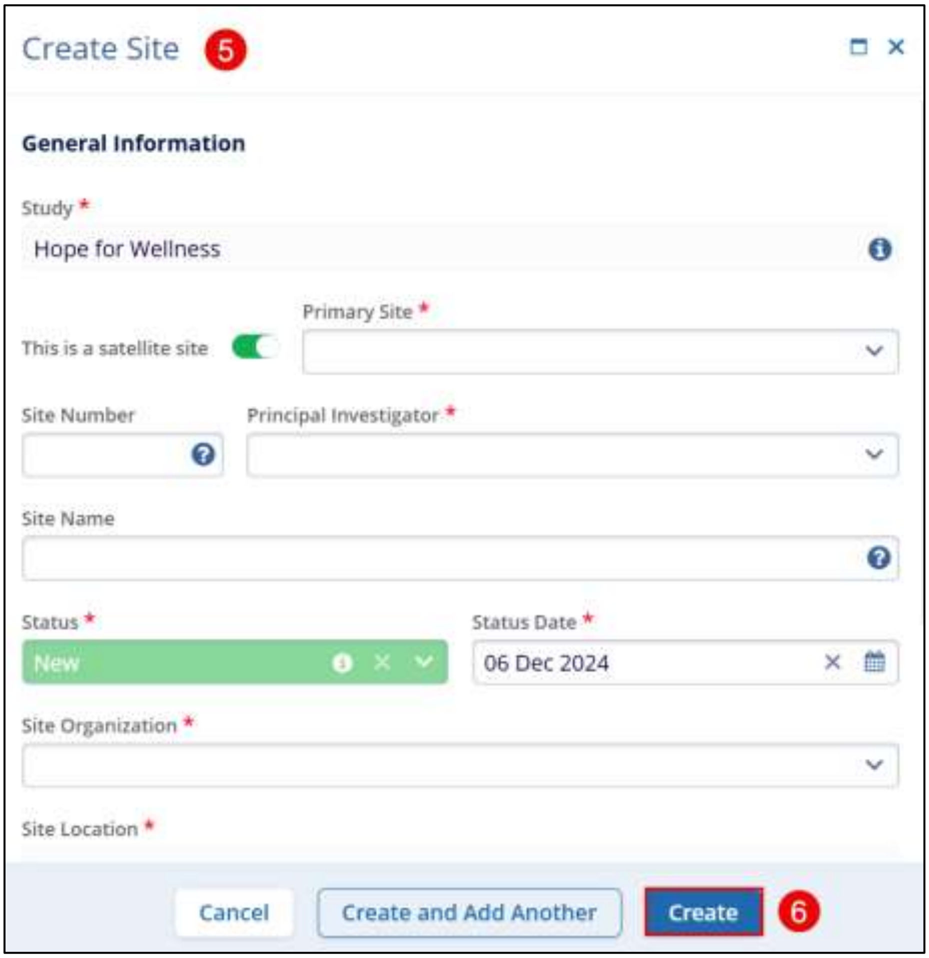


Figure: Create Site form

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

Editing a Site in a Study

To edit a site in a study.

1. To access a site created with a study, follow the navigation steps detailed in the [Associating 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.

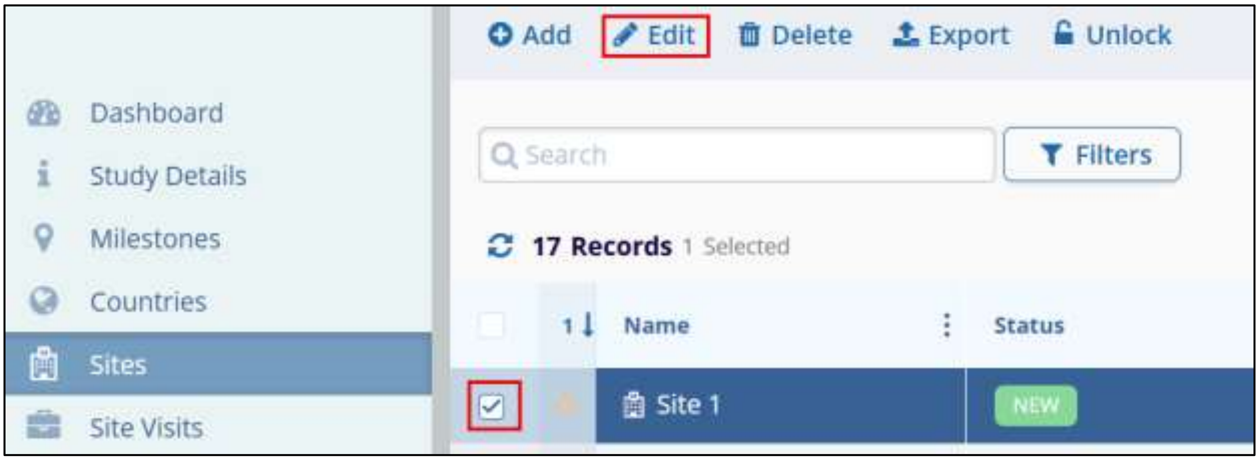


Figure: Edit Site details

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

Associating an organization with a site

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

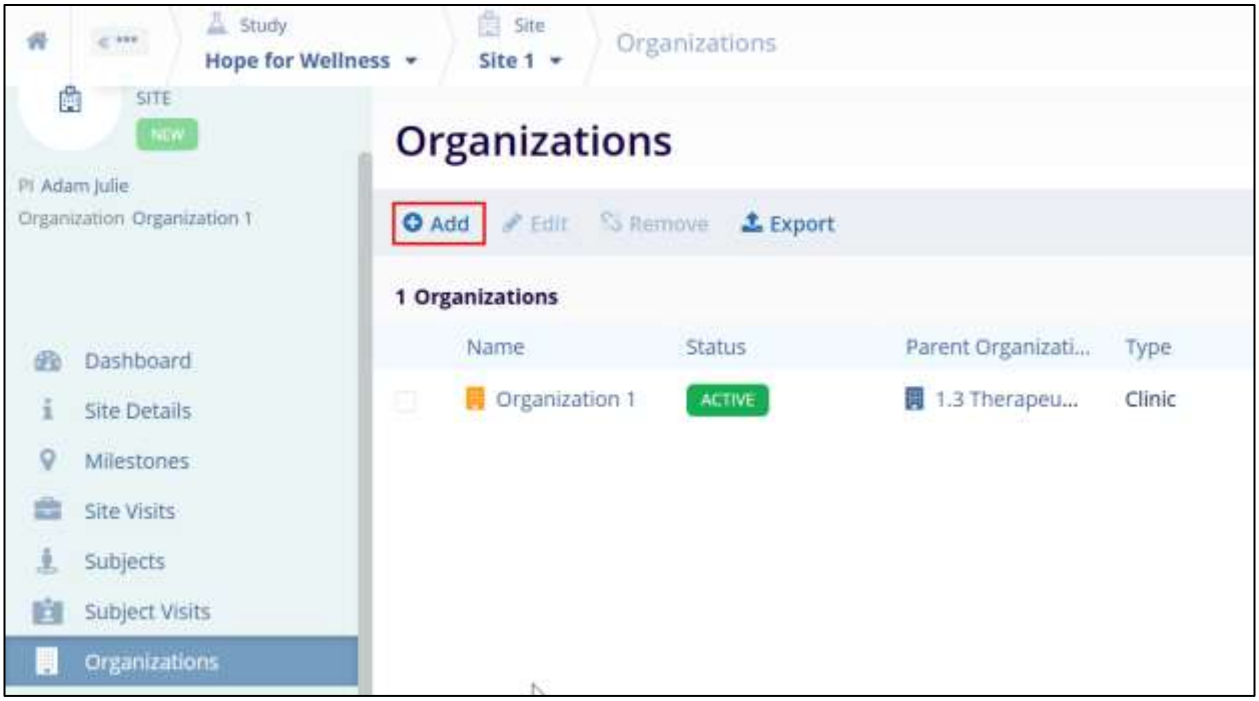


Figure: Add Organization within a Site

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

Managing Site Contacts

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

Tracking Informed Consents (ICFs) for a Site

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.

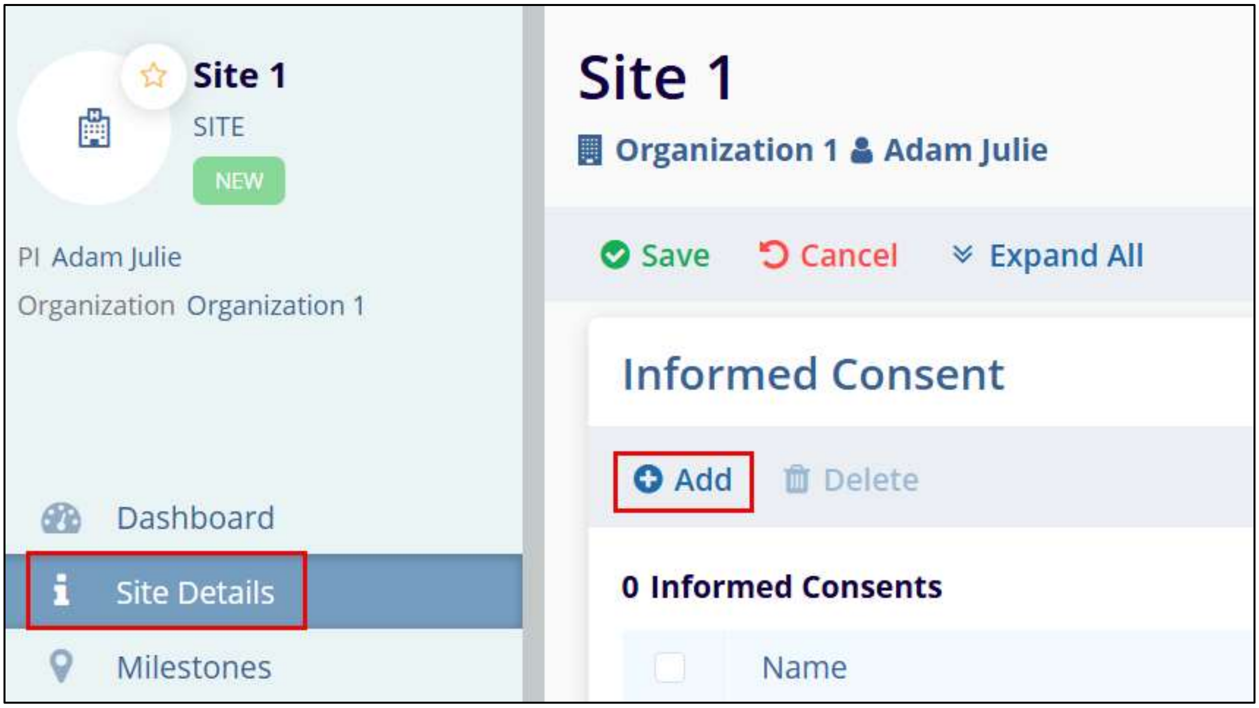


Figure: Add Informed Consents

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.

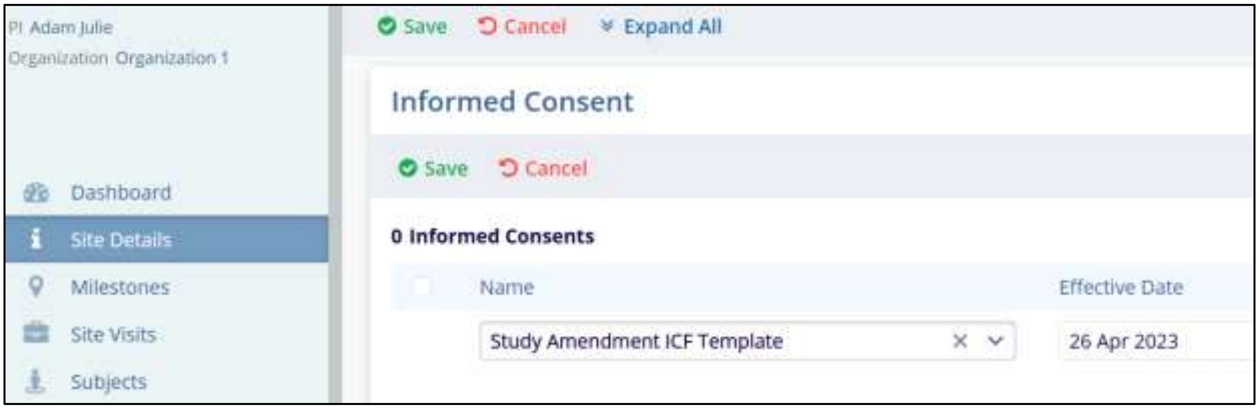


Figure: Save newly created informed consents

Tracking Site Addresses

To track site addresses, 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.

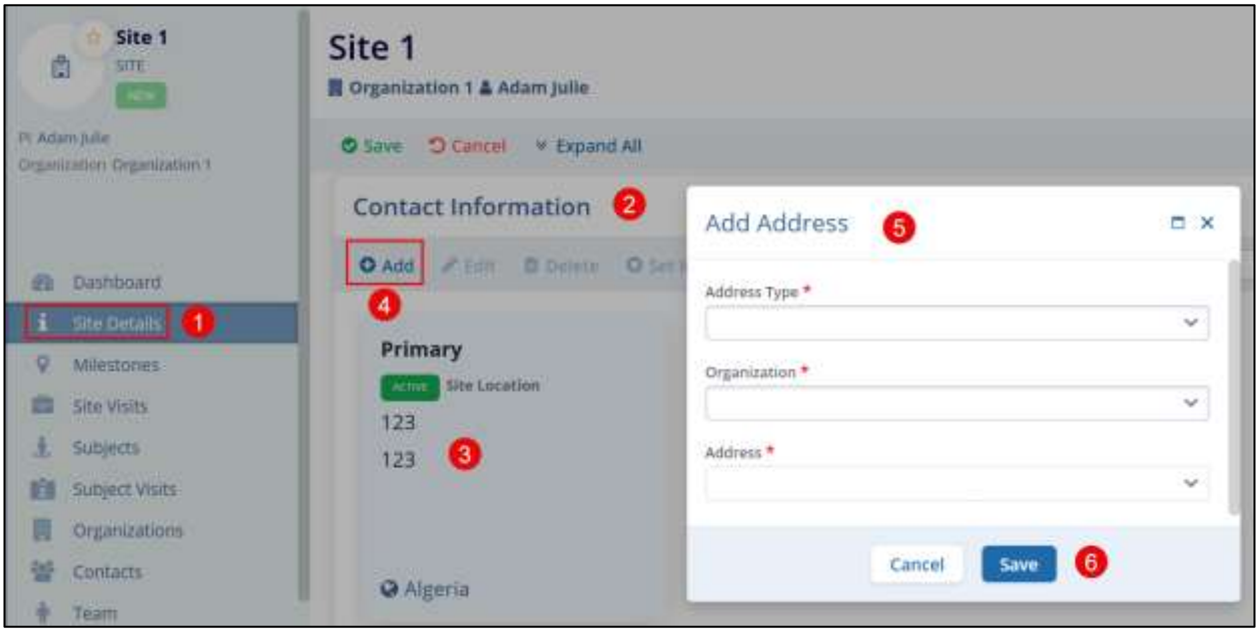


Figure: Site Details – Contact Information

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

Closing a Site

To close 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 Close Site section.

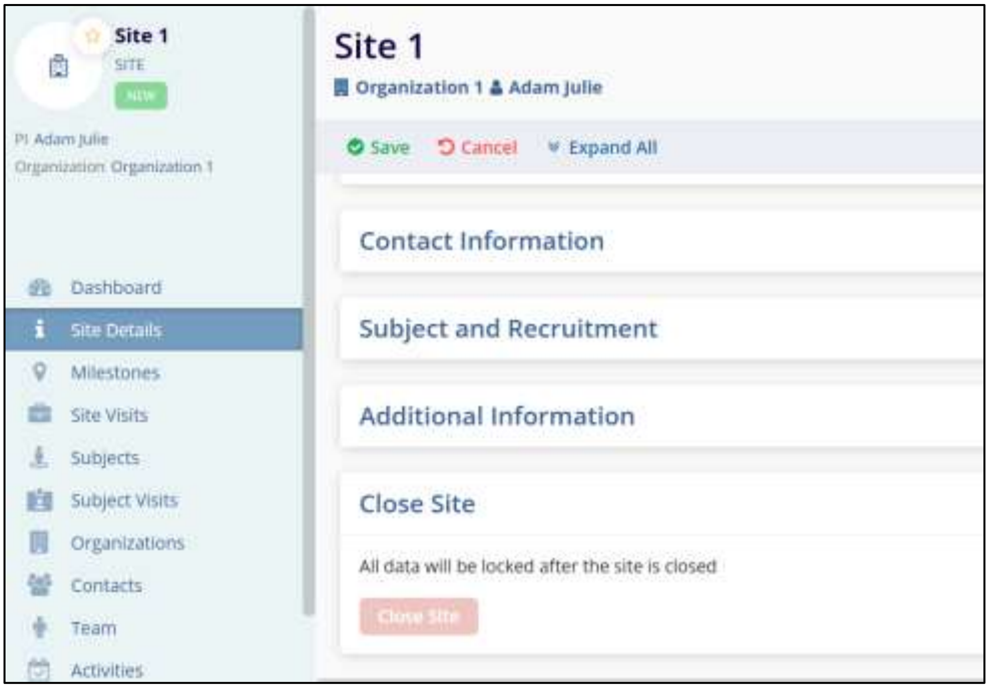


Figure: Accessing Close Site setting

3. Click on the Close Site button

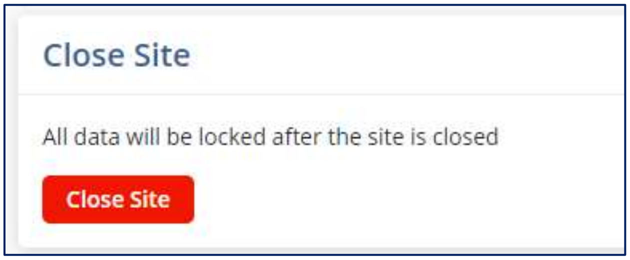


Figure: Close a Site

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.

Study Subjects

Tracking Subjects

1. To access a site created with a study, follow the navigation steps detailed in the Associating Sites within the Study section.
2. Click on Subjects in the Navigation menu at the left side of the screen. This opens the "Subjects" window.
3. Click on the Add button at the top-left of the screen and This opens the Create Subject window.

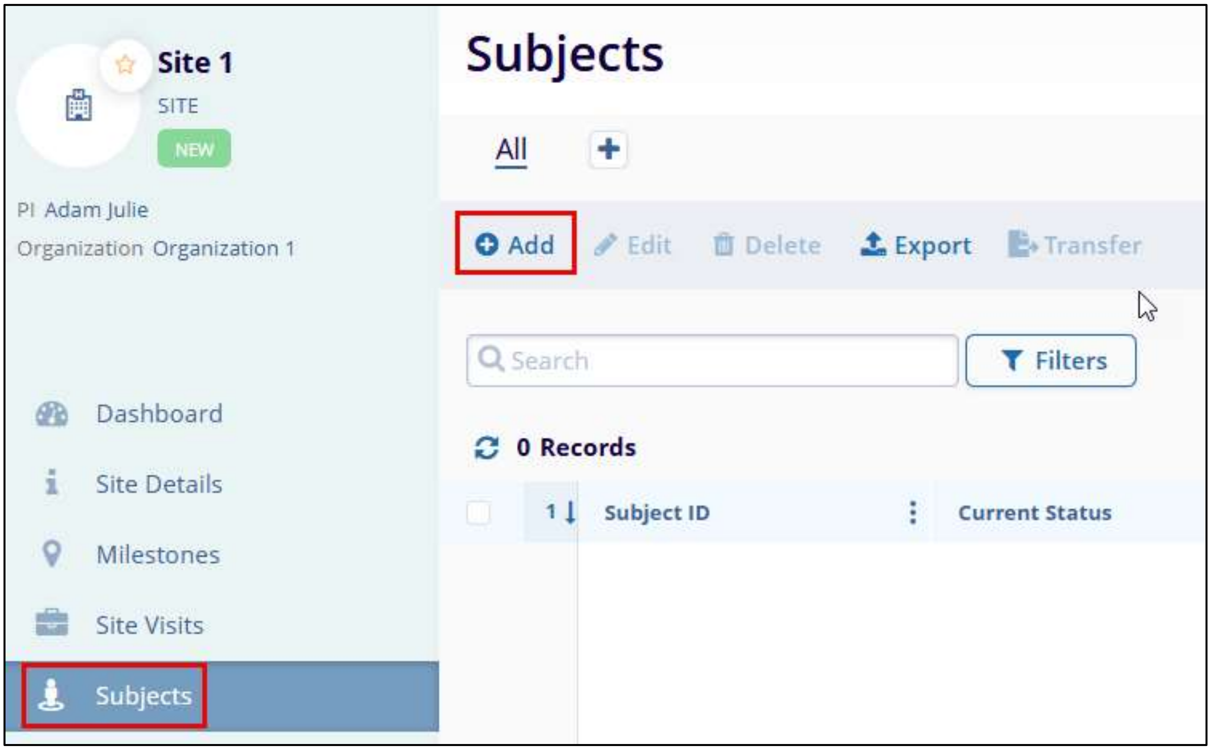


Figure: Add Subjects at a Study level

4. Enter the mandatory metadata to create a Subject i.e., Study Name, Site, Subject ID, Status, and Status Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
5. Click on the Create button.
6. (Optional) Click Create or Create and Add Another depending on whether you intend to create another subject right away.

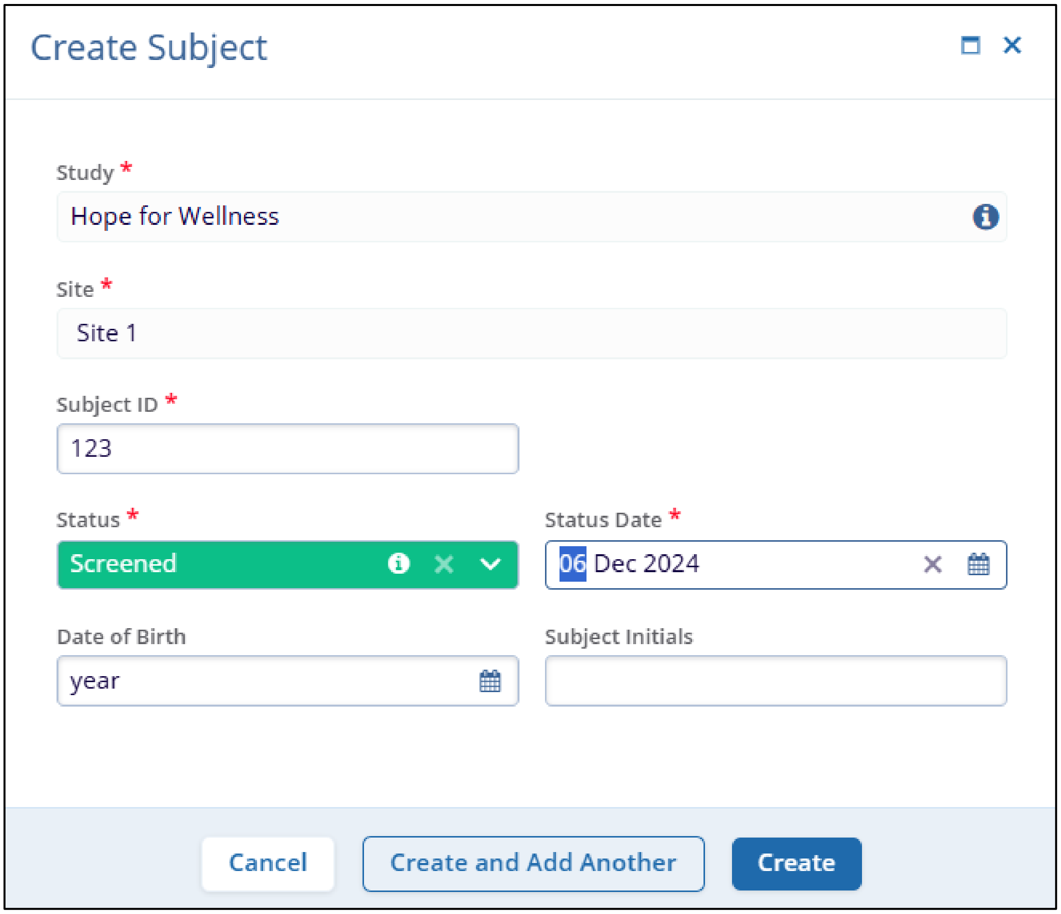


Figure: Create Subject form

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

Editing a Subject

To edit a subject, follow the steps below.

1. Click on the Subjects in the Navigation menu at the left side of the screen. This opens the "Subjects" window.
2. Click on the checkbox before the Subject name or the edit button. A quick view panel will display on the right side of the screen.
3. Click on the Edit button.
4. Make the required changes and click on the Save button.

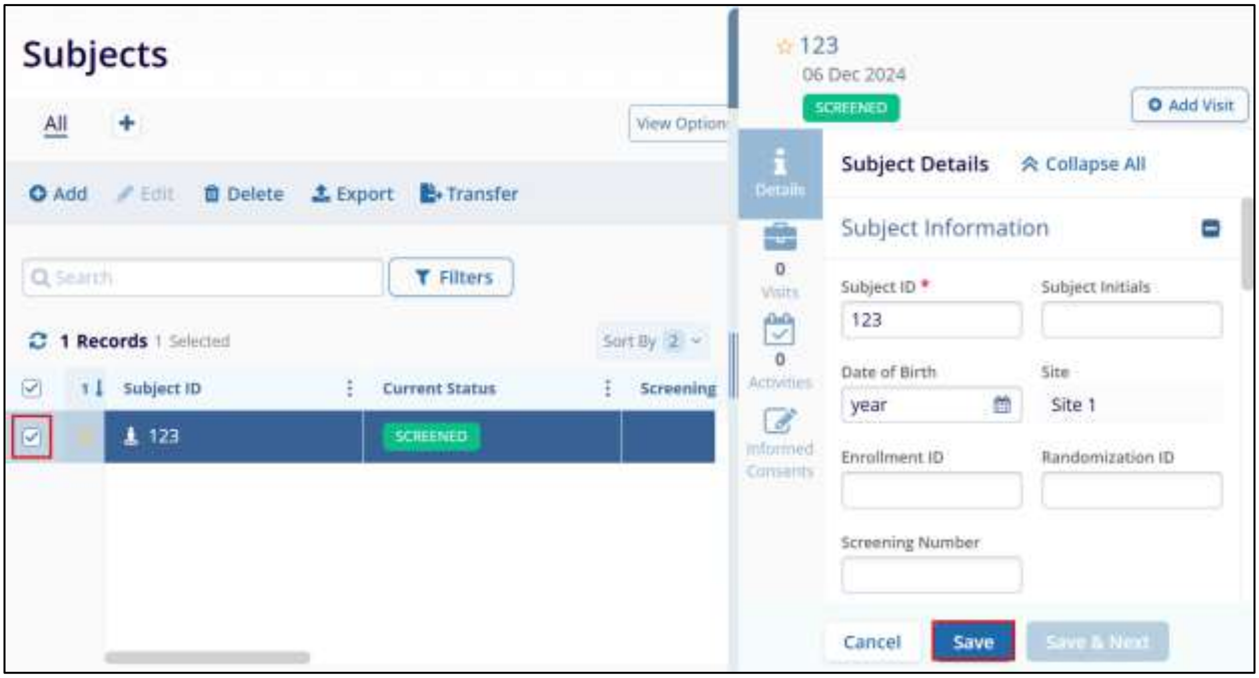


Figure: Edit Subjects – Method 1

To edit a subject using another method, follow the steps below.

1. Click on the subject name.

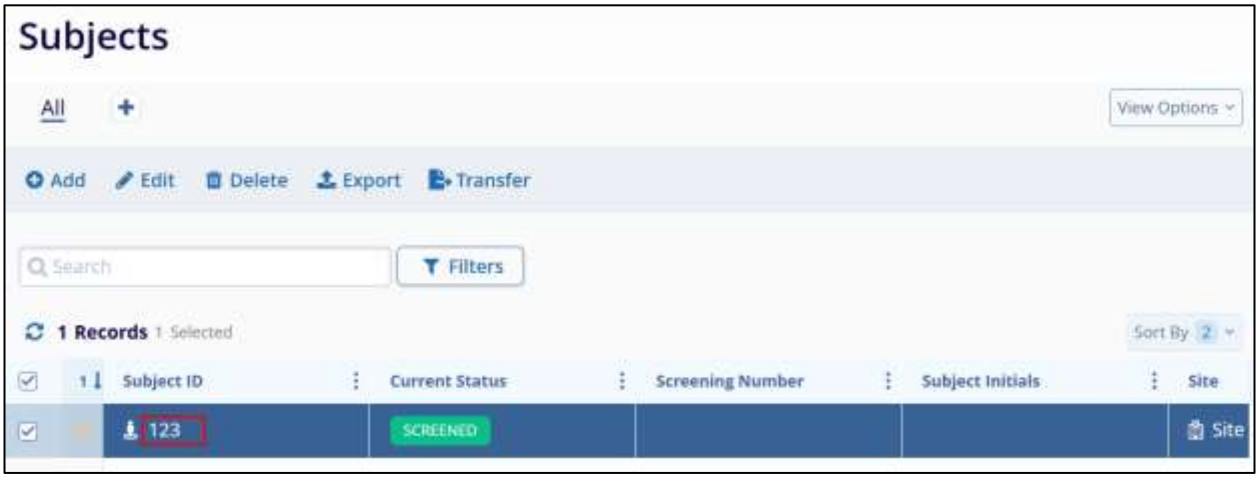


Figure: Edit Subjects – Method 2

2. Click on the Edit button.

Figure: Subject Details screen

3. Expand each section and make the required changes.
4. Click on the Save button.

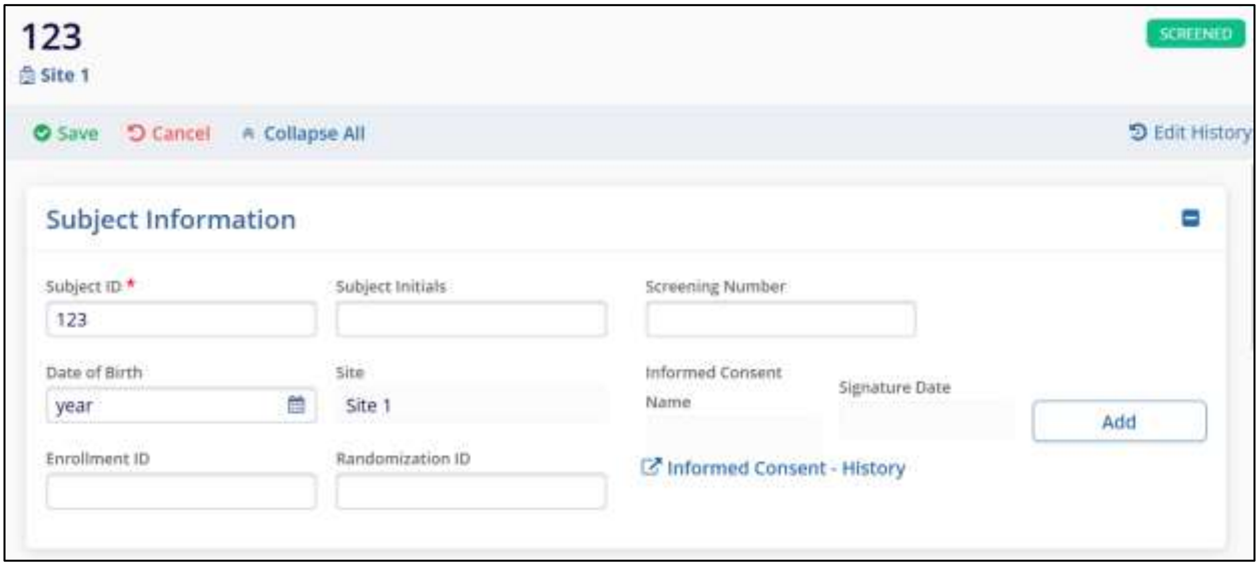


Figure: Save edits made to subject information

Reviewing Subjects Within a Study

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

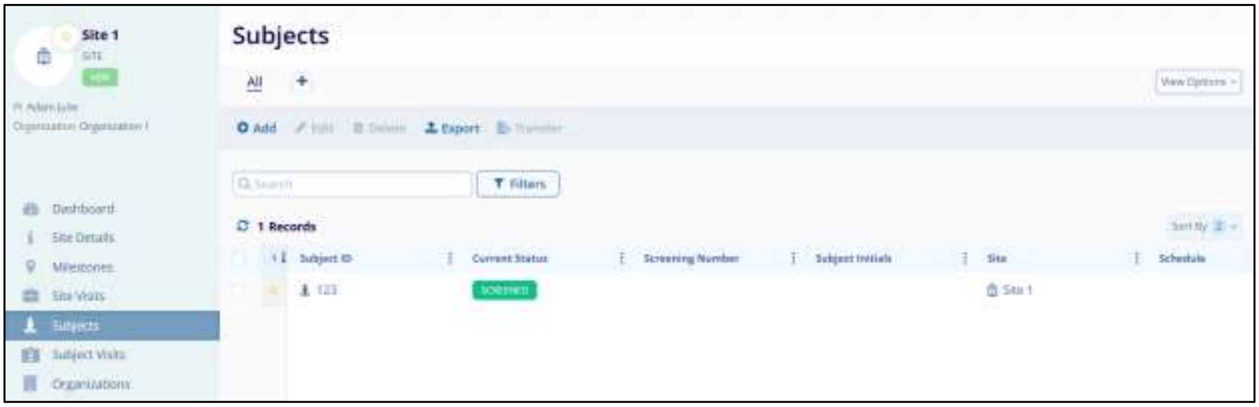


Figure: Review Subjects within the study

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.

Tracking Subjects Visits

To add or edit subject visits, follow the steps below.

1. To access a site created with a study, follow the navigation steps detailed in the Associating Sites within the Study section.
2. Click on Subjects in the Navigation menu on the left side of the screen. This opens the "Subjects" window.
3. Navigate to the subject name to access and click on it.
4. Click on the Subjects Visits in the Navigation menu on the left side of the screen.
5. Click on the Add Visit button.

Figure: Add Subject Visit

6. Enter the mandatory metadata to create a subject visit i.e., Visit Status, Visit Type, Visit Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
7. Click on the Create button.

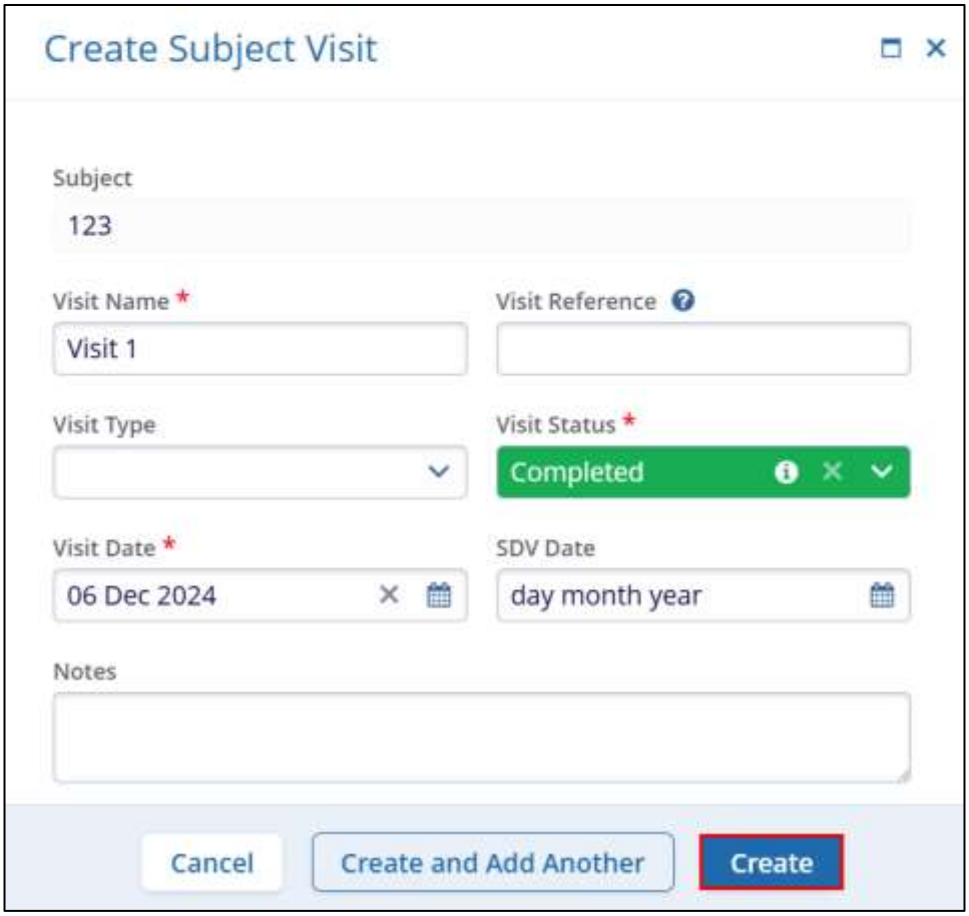


Figure: Create Subject Visit form

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.

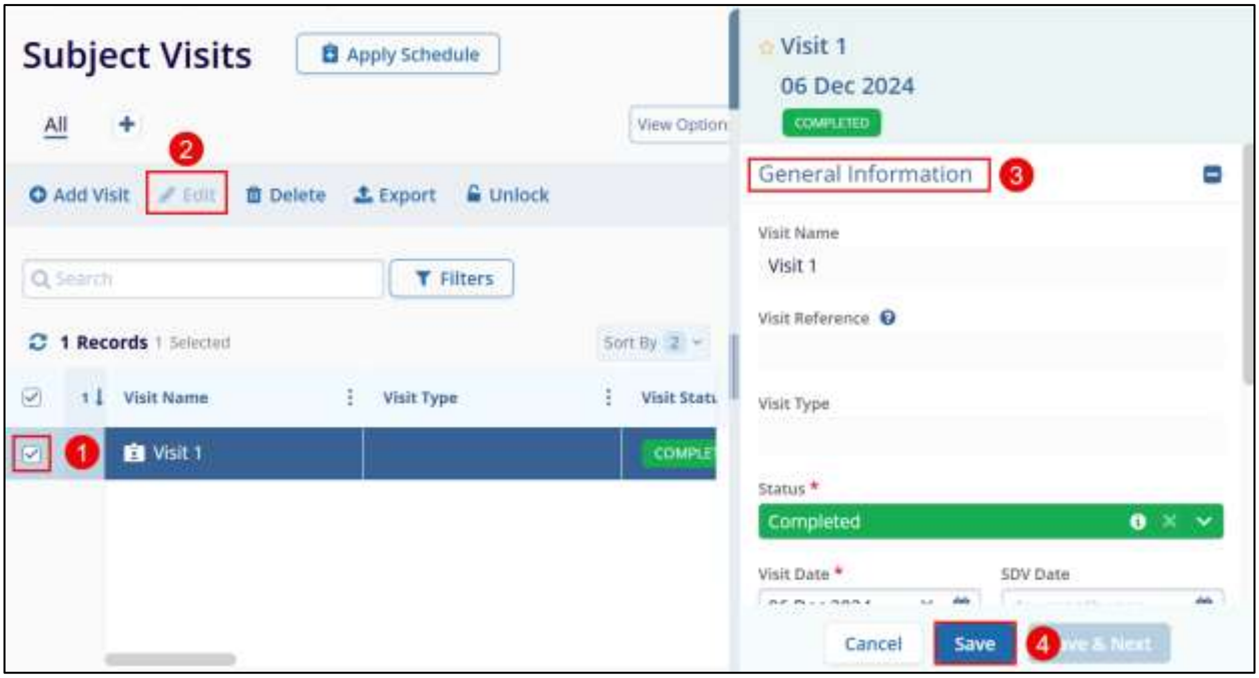


Figure: Edit Subject Visit

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

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.

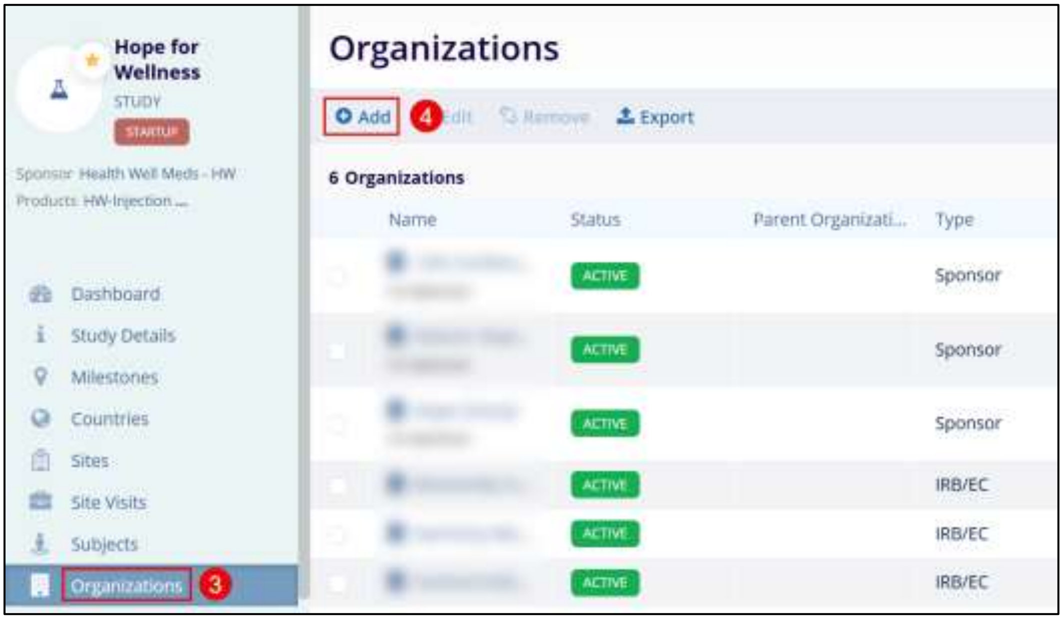


Figure: Add Organization within a study

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

Study Contacts

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.

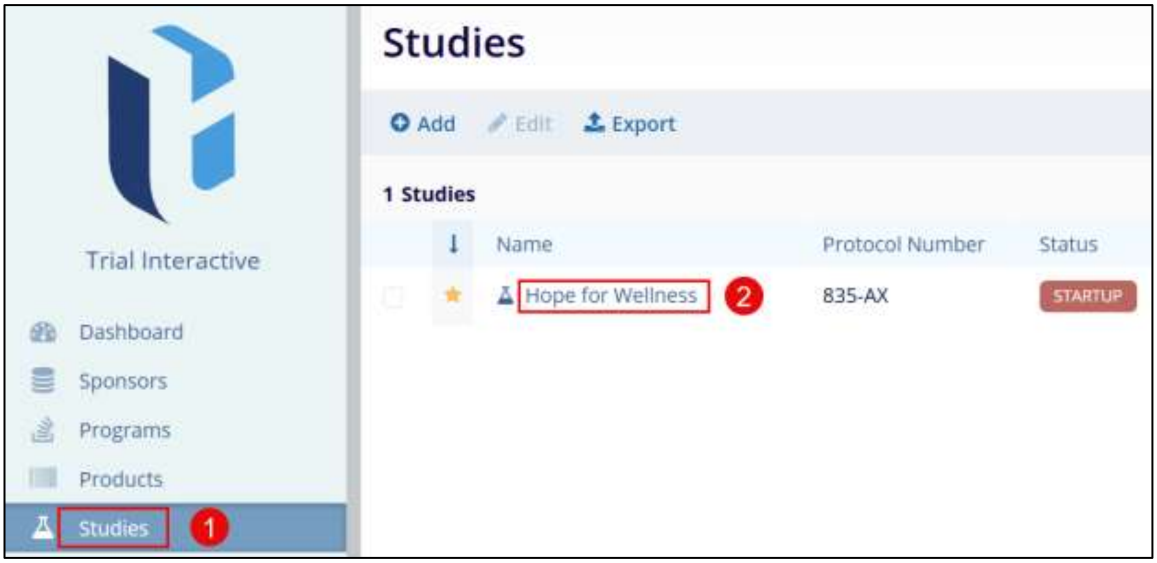


Figure: Access Study to add contacts

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.

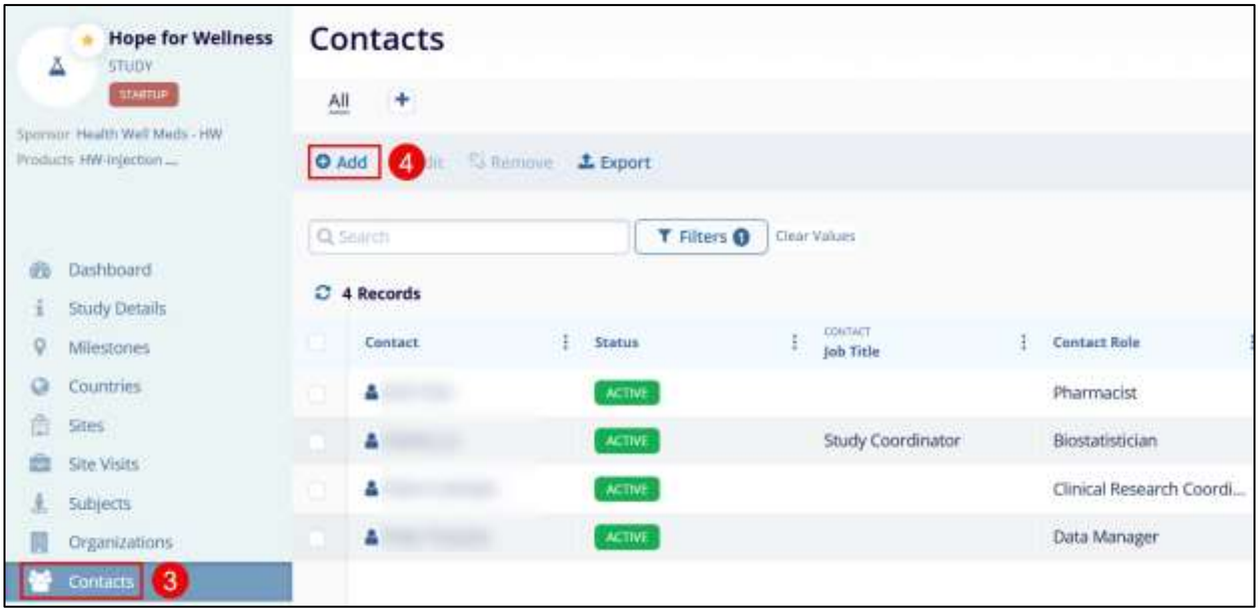


Figure: Add Contacts to Studies

5. Refer to the Chapter 9. Contacts for detailed information on creating contacts and associated functionalities.

Study Team vs Access Permissions

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

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.

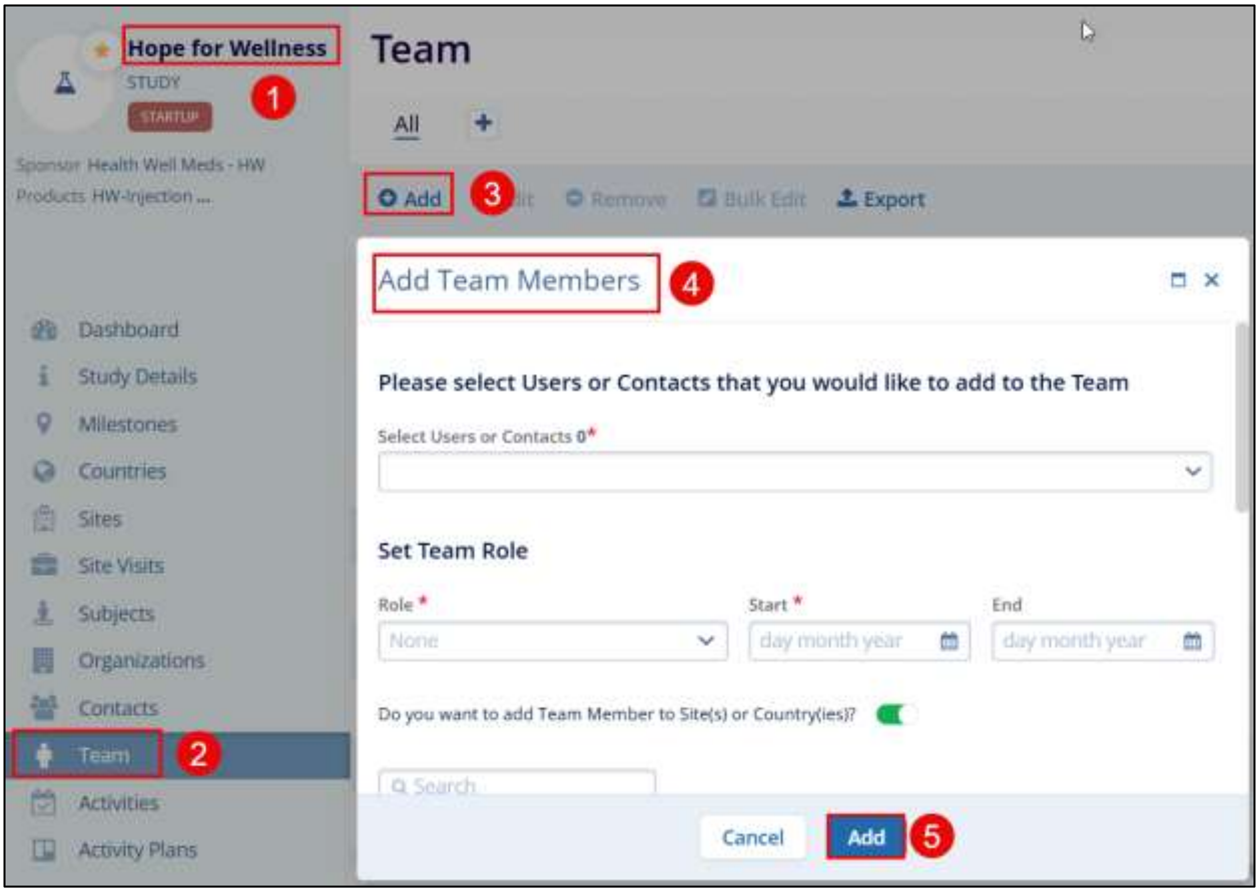


Figure: Add Team members within a study

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.

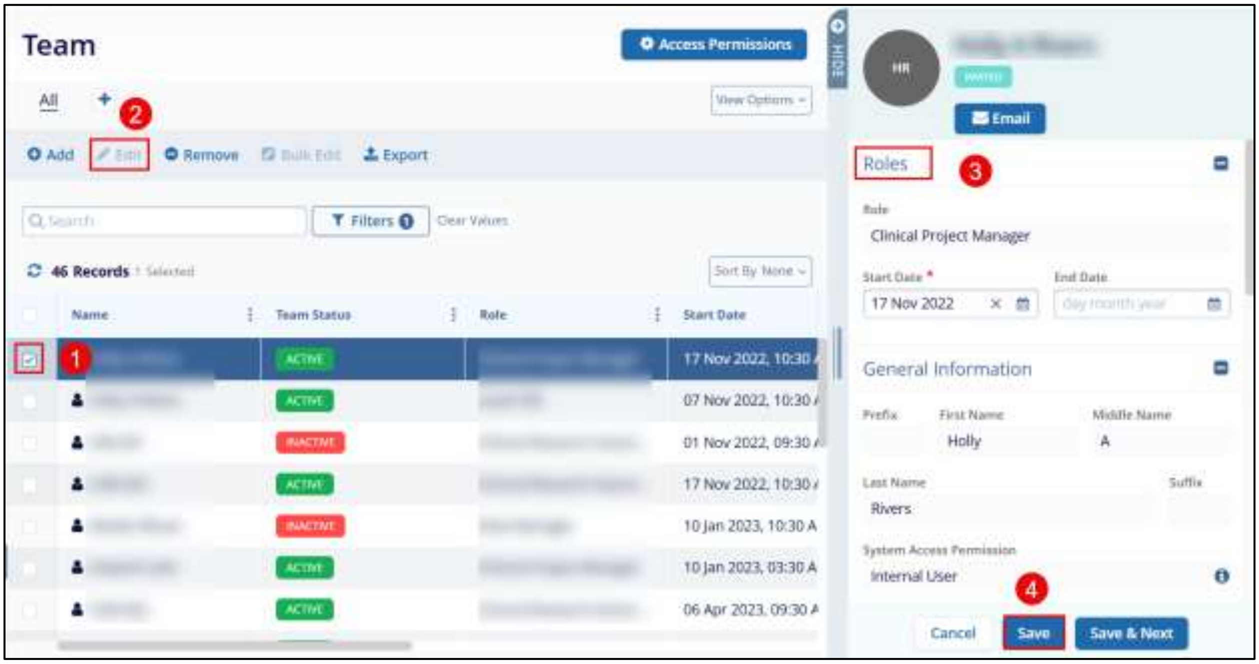


Figure: Edit Team member details

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.

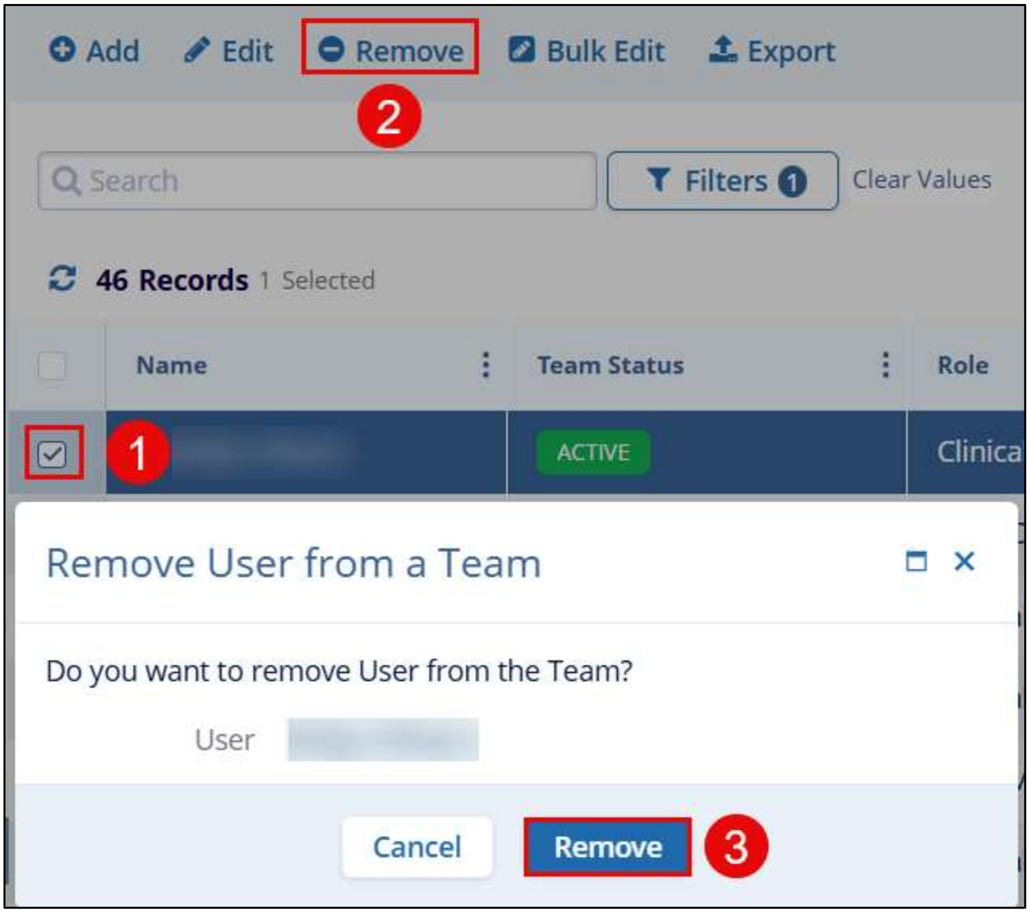


Figure: Remove Team Member

<u>Bulk Edit</u>

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.

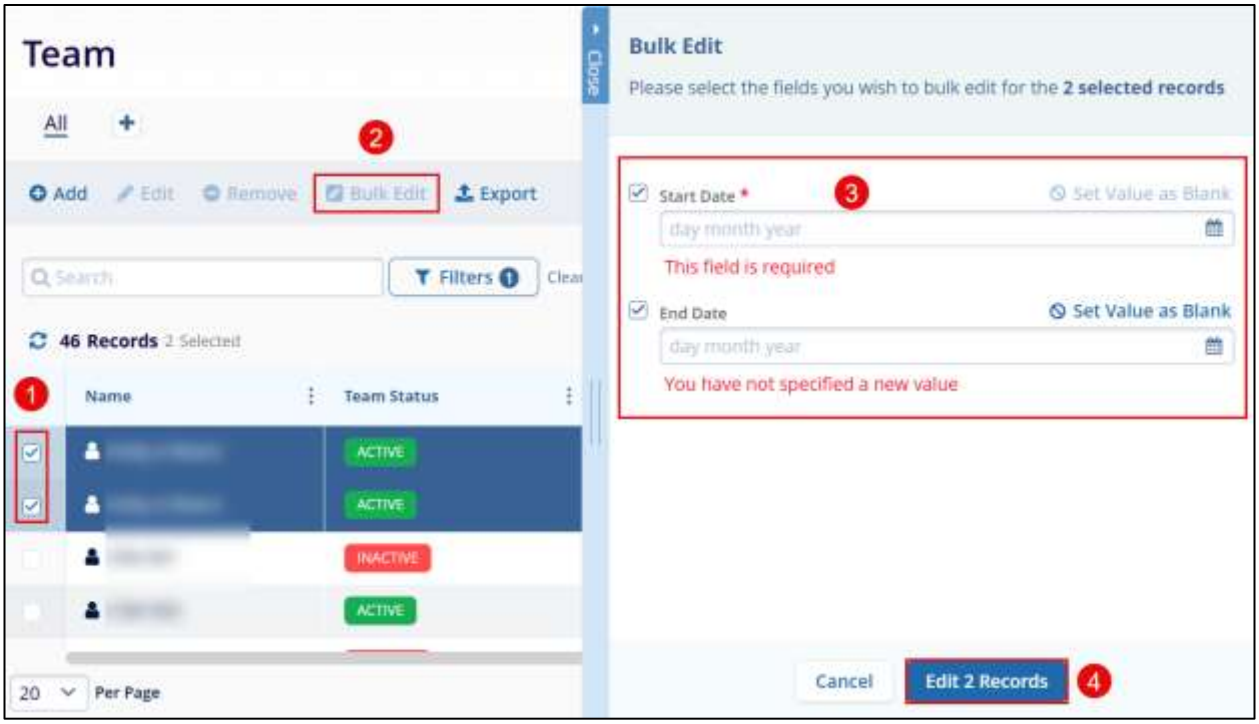


Figure: Bulk Edit Team Member details

Export

To export Team member details, refer to the 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 you have made an error, you will need to delete the entry and create a new one. For correct entries, if a team member moves on to a new role within the study, the study manager should enter an end date for the old role and create a new entry for the new role. This is to aid in providing tracking for each study team member and the roles that they may play throughout a study.

Managing Study Access Permissions

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

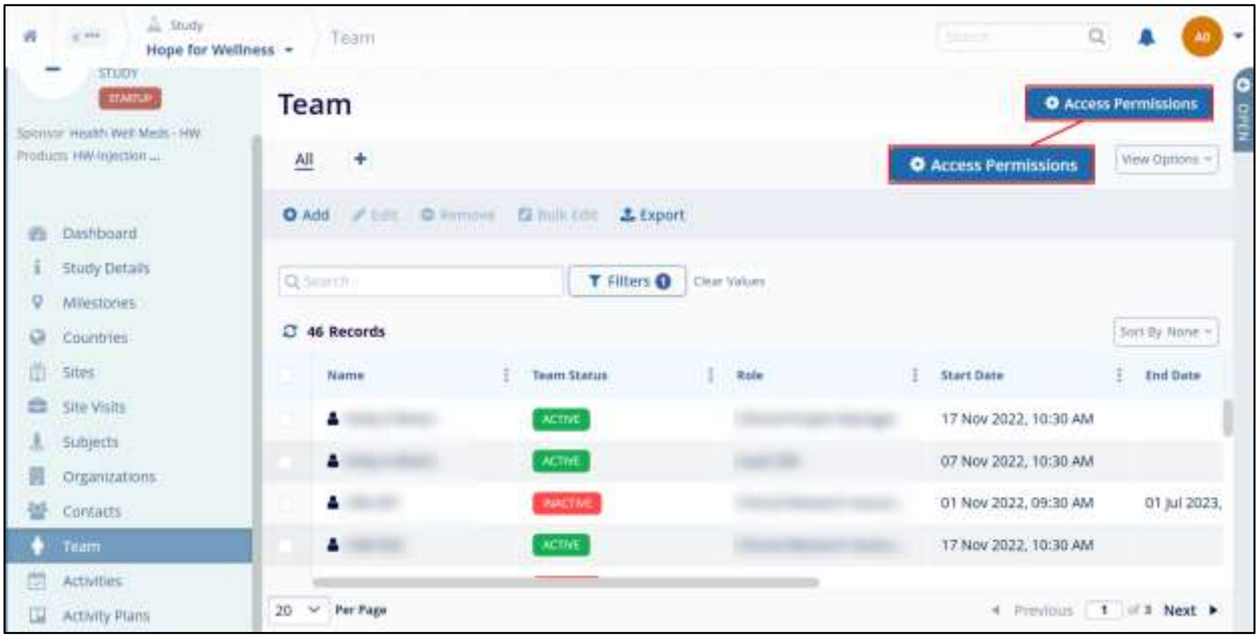


Figure: Manage access permissions

Add users to study access permissions

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.

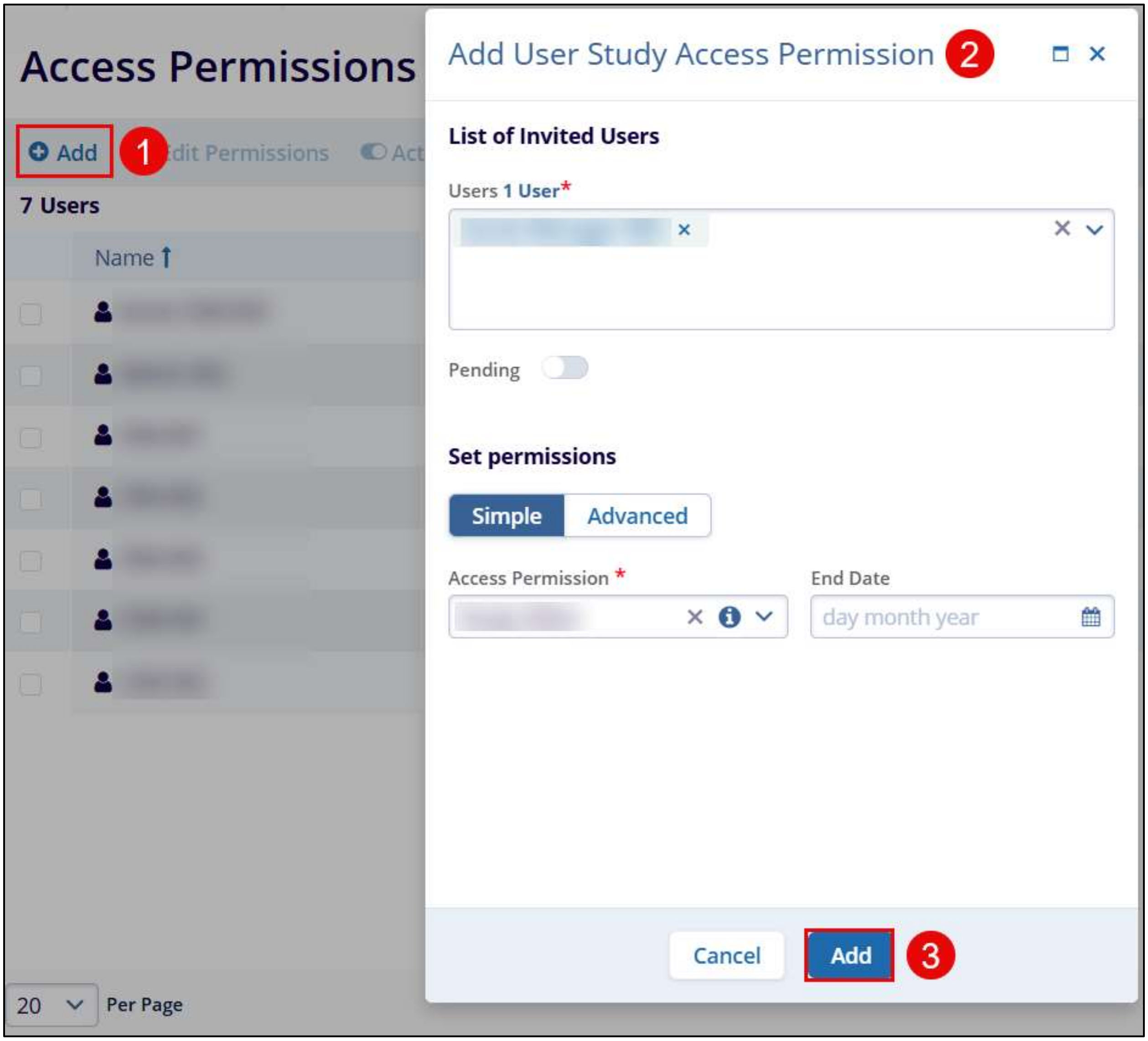


Figure: Add Users Study Access Permissions

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.

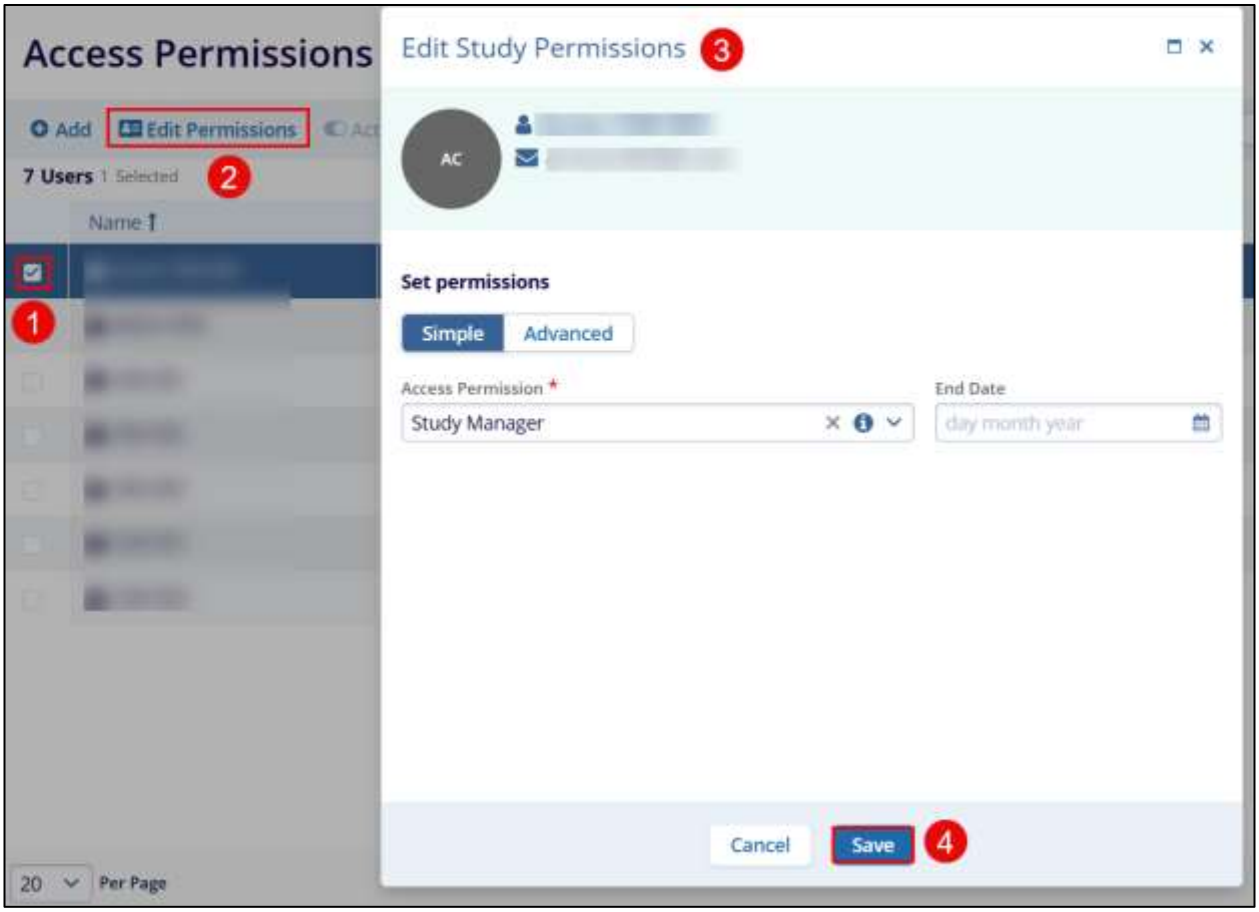


Figure: Edit Study Permissions

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.

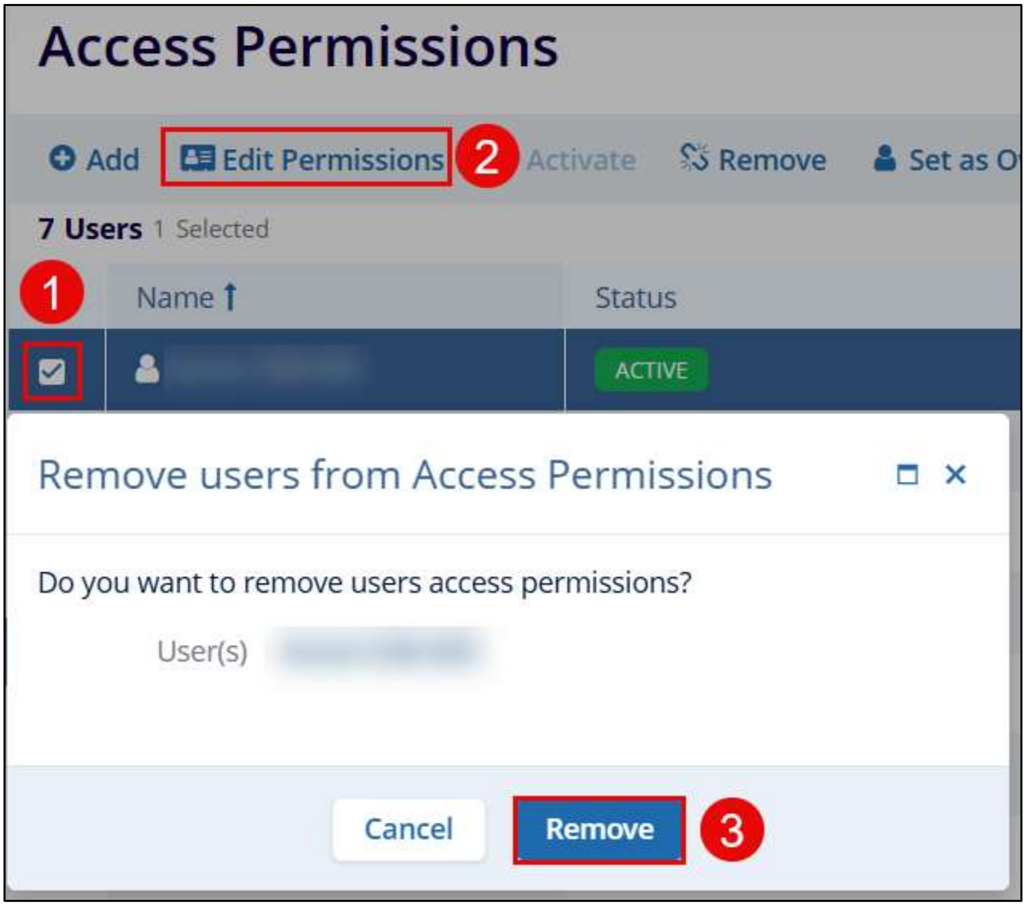


Figure: Edit Permissions

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.

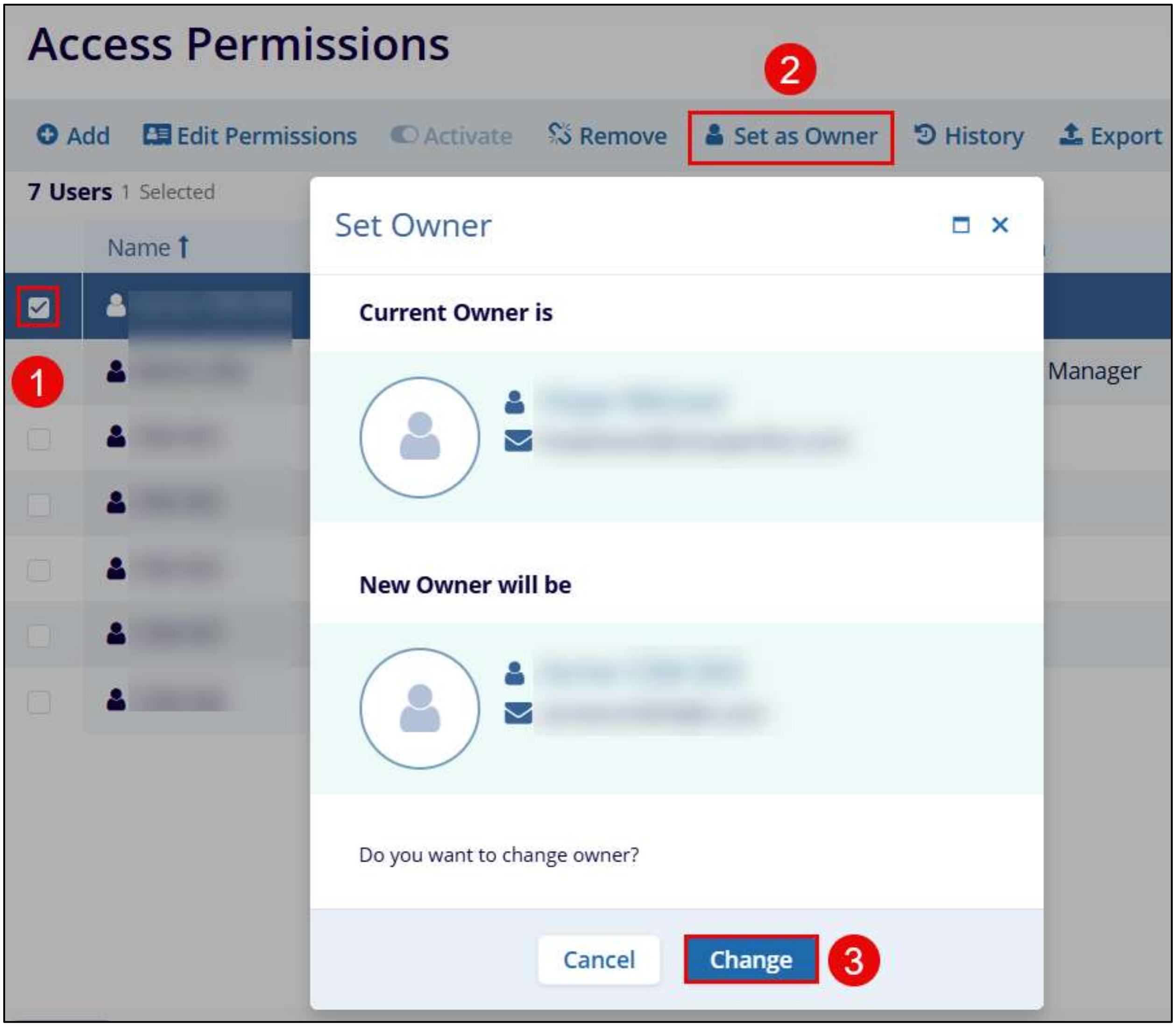


Figure: Set as Owner

History

To view history, follow the steps below.

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

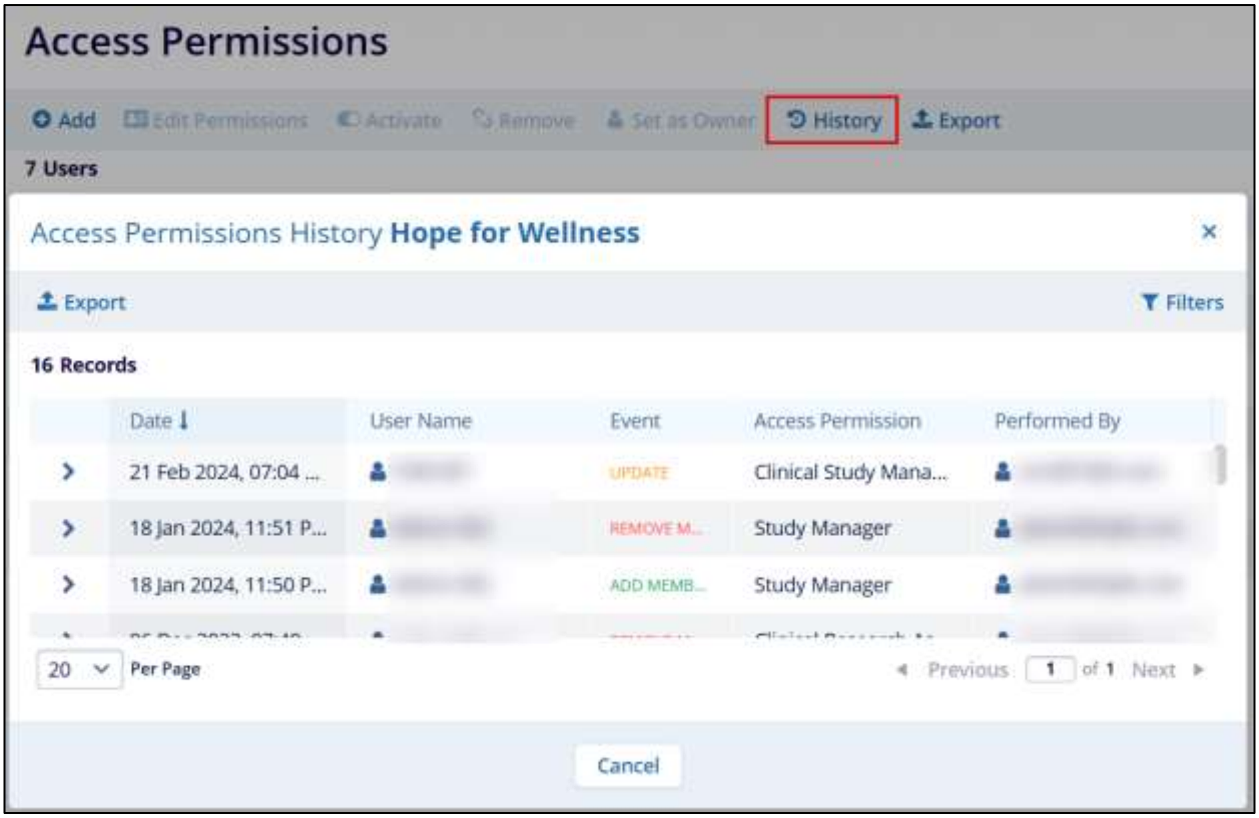


Figure: Retrieve History

Defining Study-Specific Regions

To configure 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.

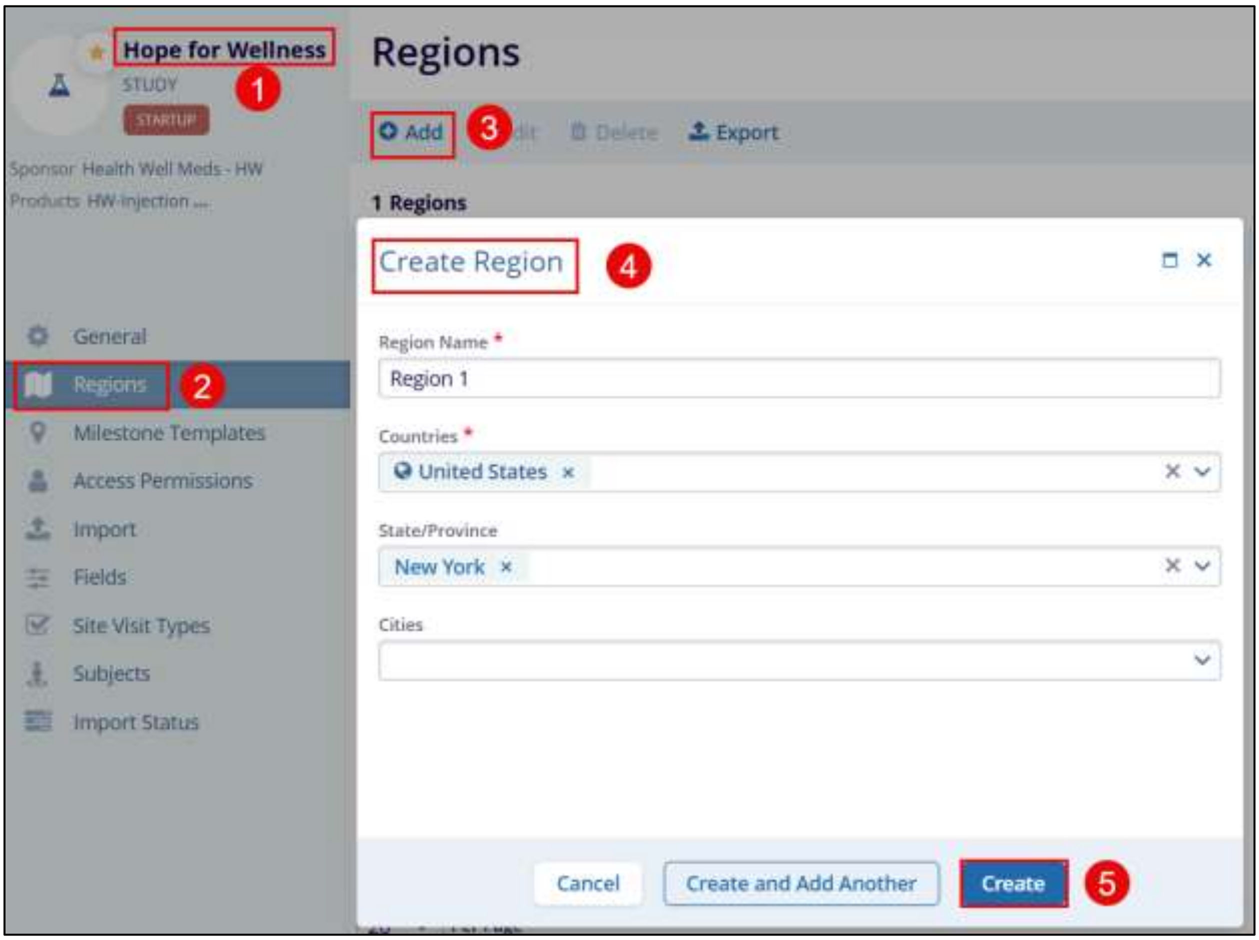


Figure: Create Region at a Study level

Note: To enter the State/Province and Cities values you must 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.

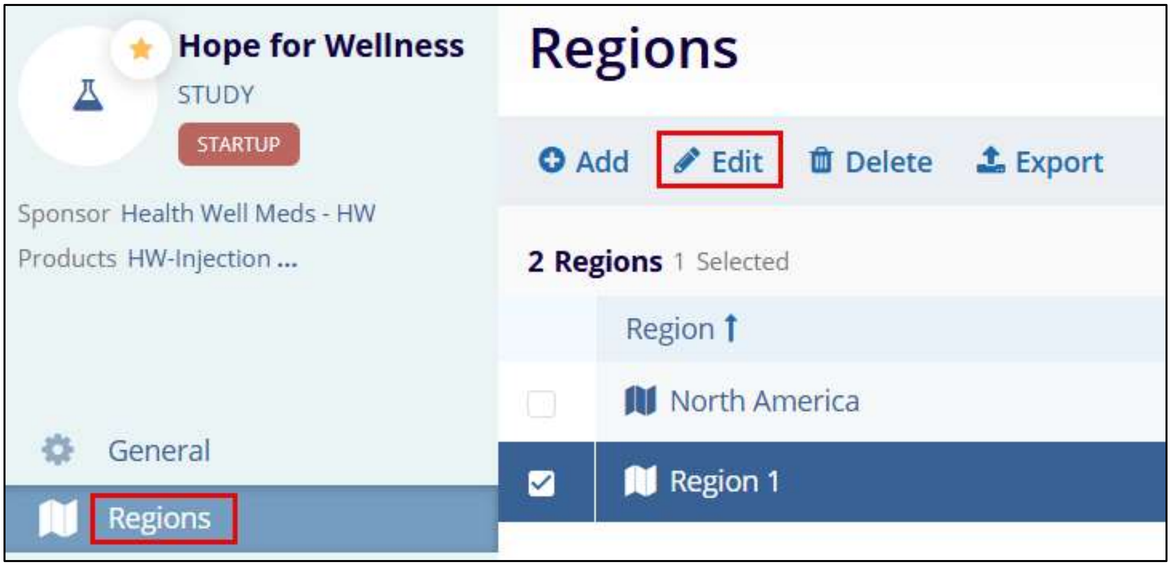


Figure: Edit Region within a study

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

Figure: Save changes to Region Details

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.

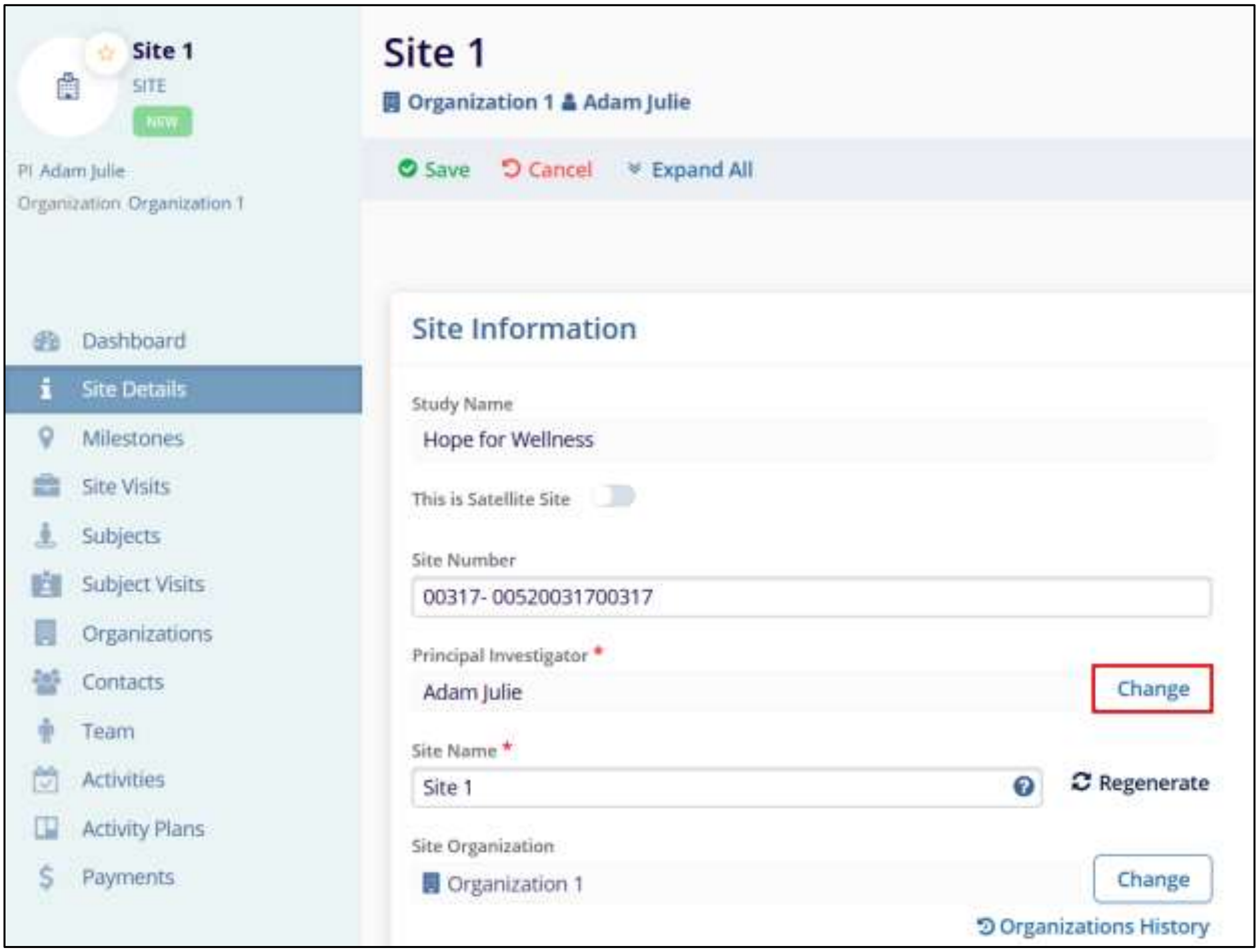


Figure: Change Principal Investigator

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

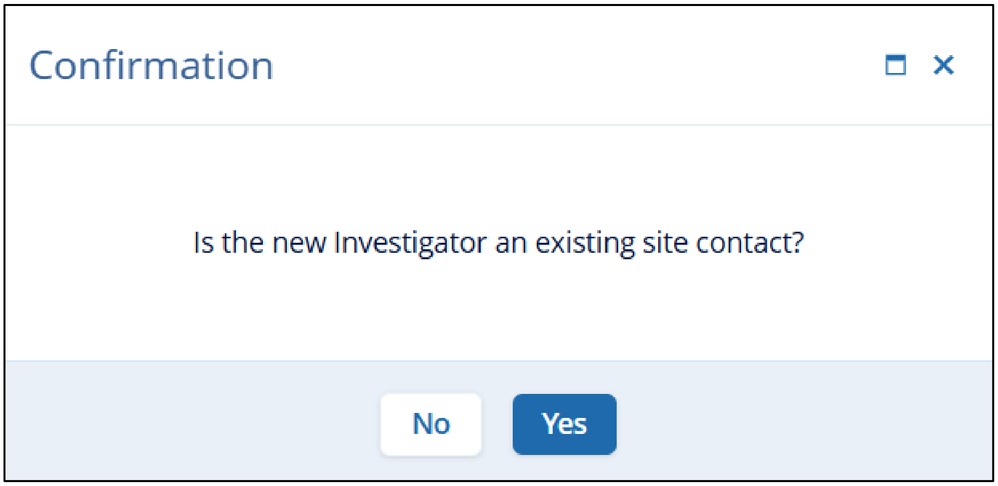


Figure: Confirmation popup

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

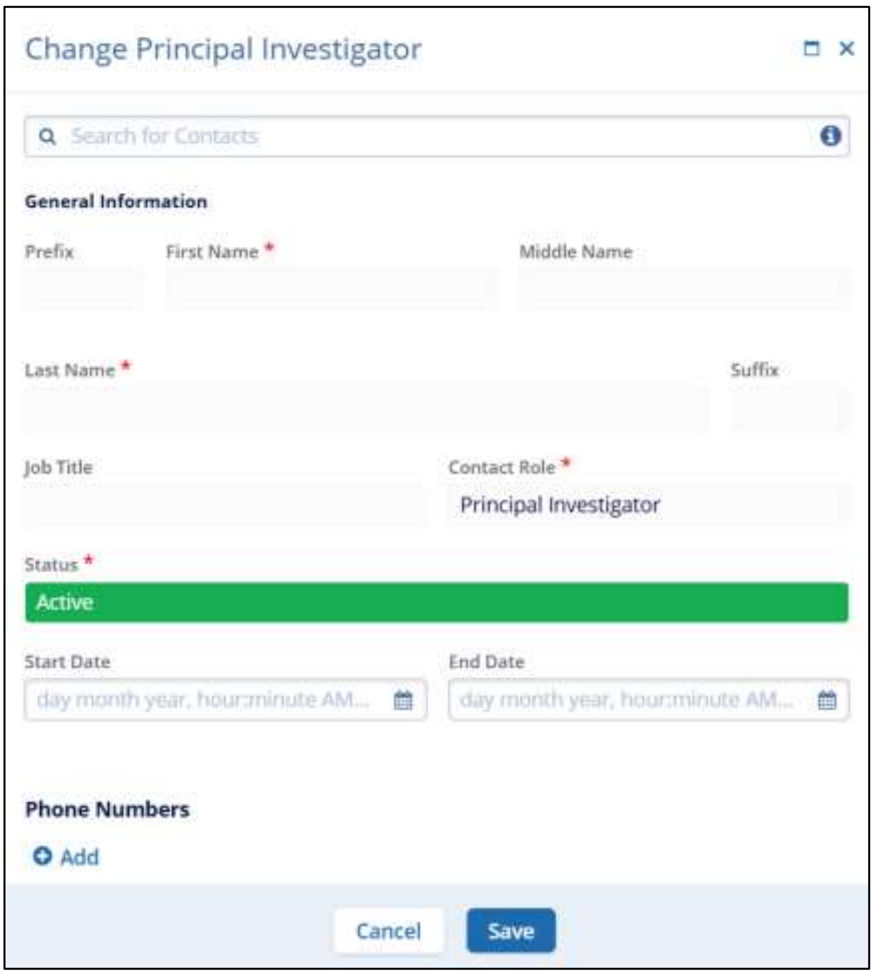


Figure: Change Principal Investigator form

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'.

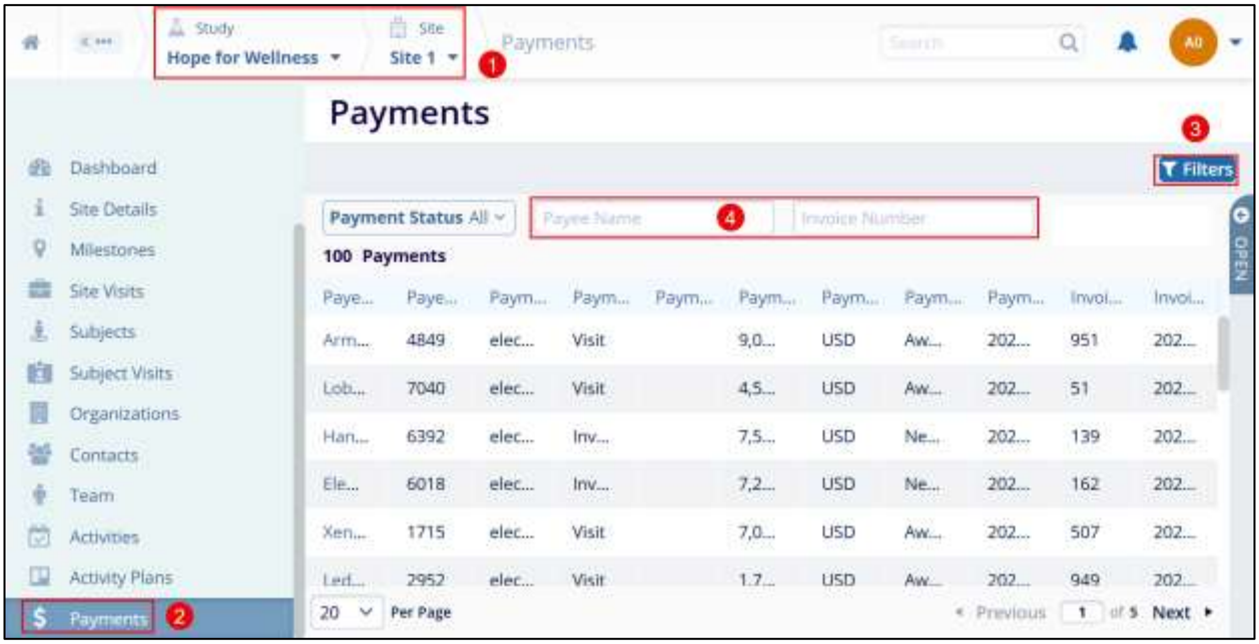


Figure: Payments View

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

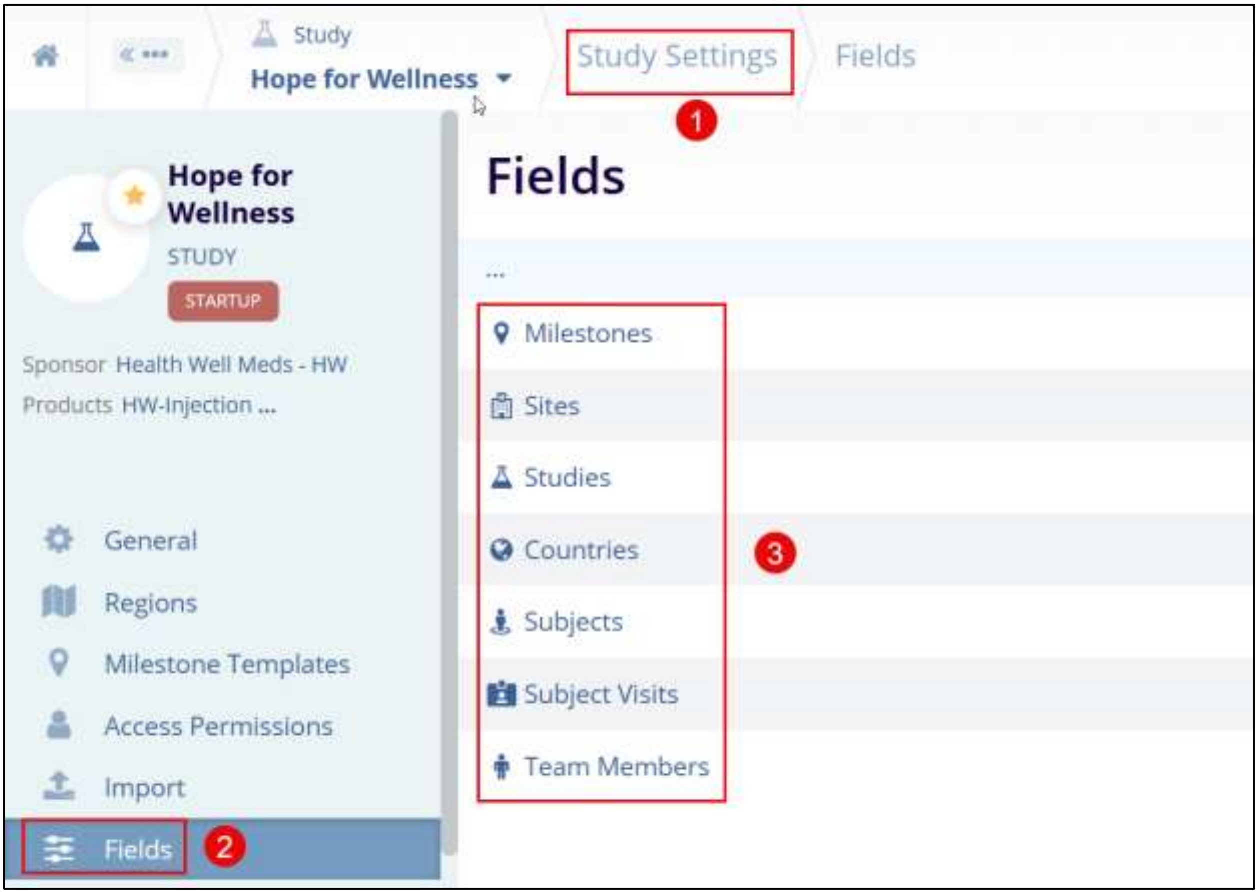


Figure: Define Fields at the Study level

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

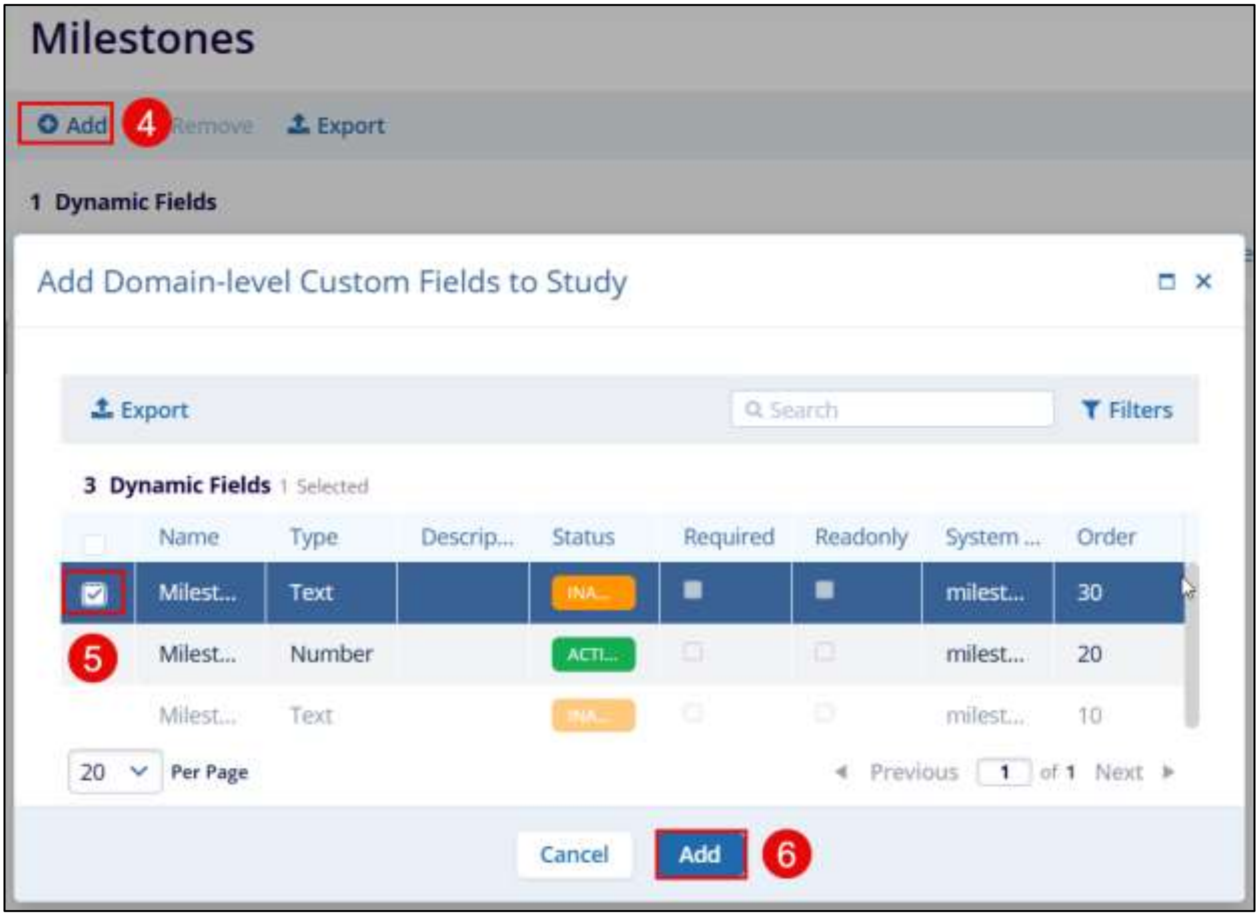


Figure Add Domain-level Custom Fields to Study

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

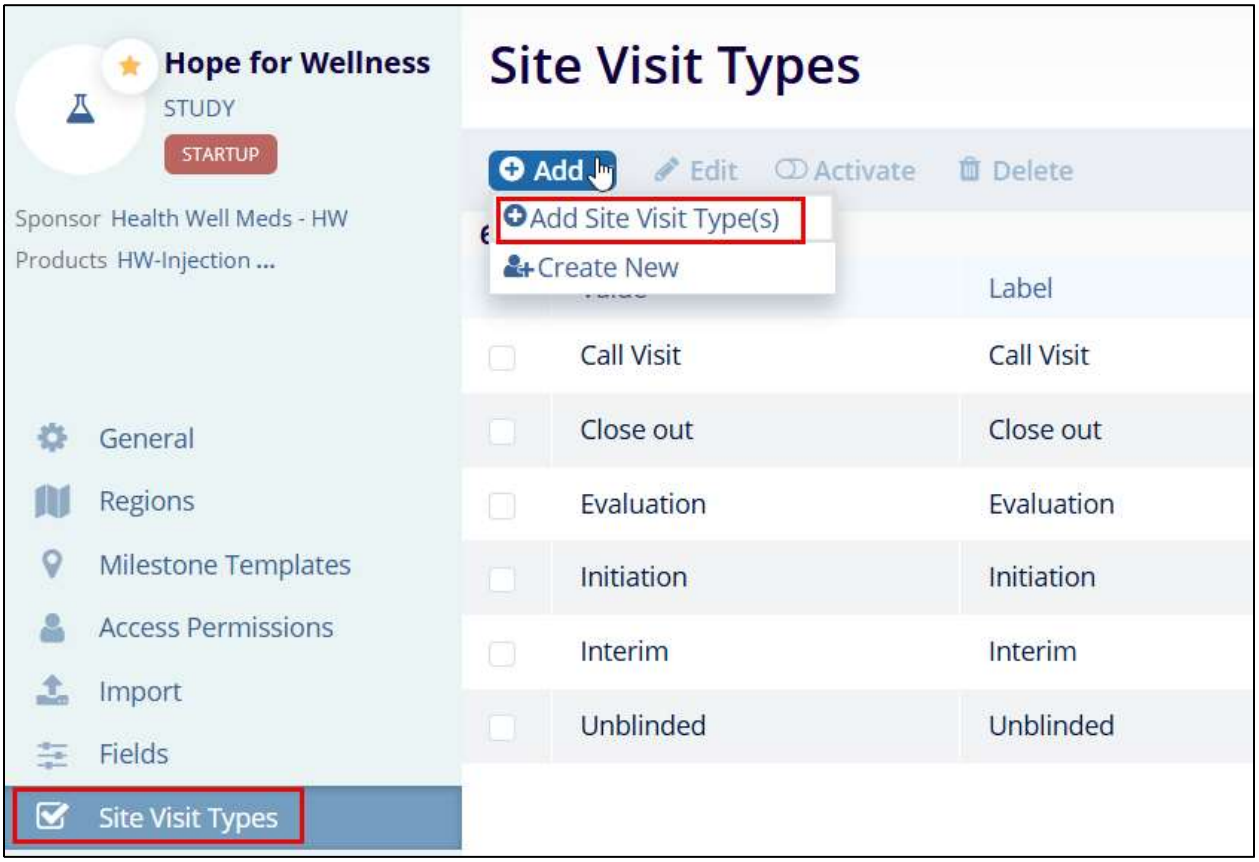


Figure: Add Site Visit Types

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

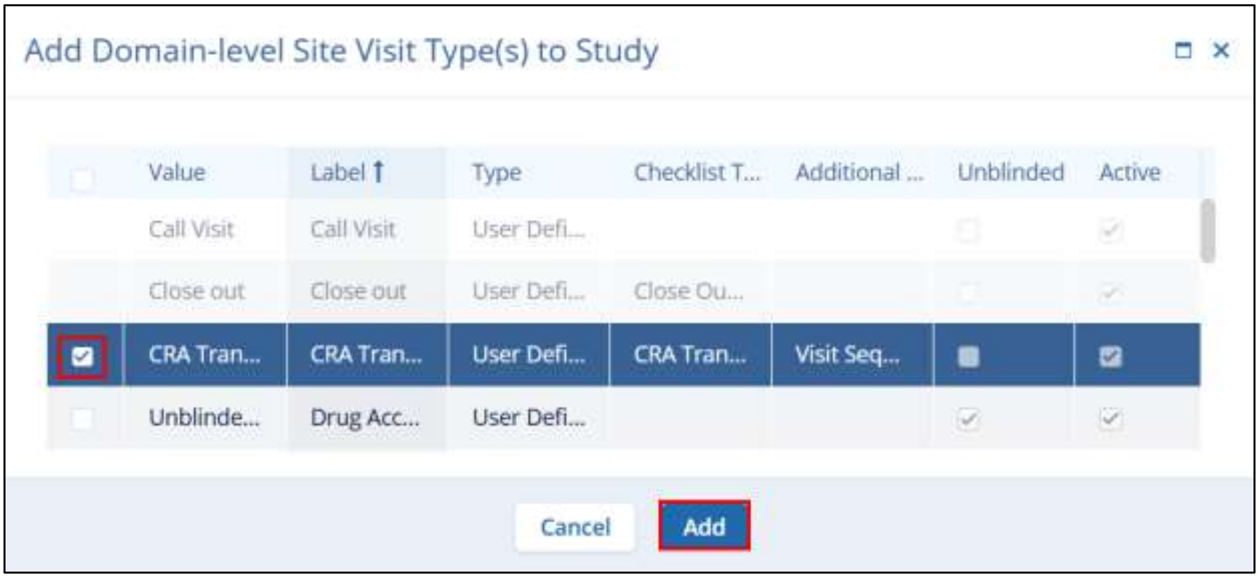


Figure: Select and Add site visit type fields

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 required details and click on the Create button.

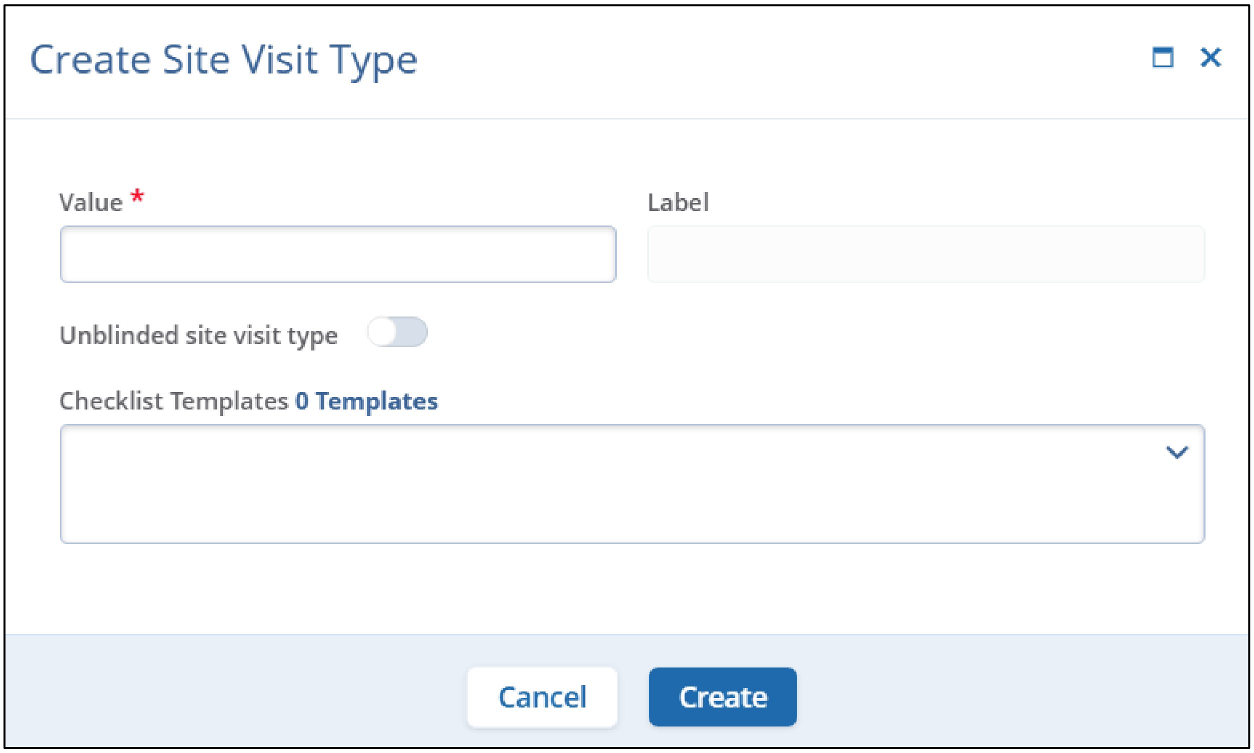


Figure: Create Site Visit Type

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.

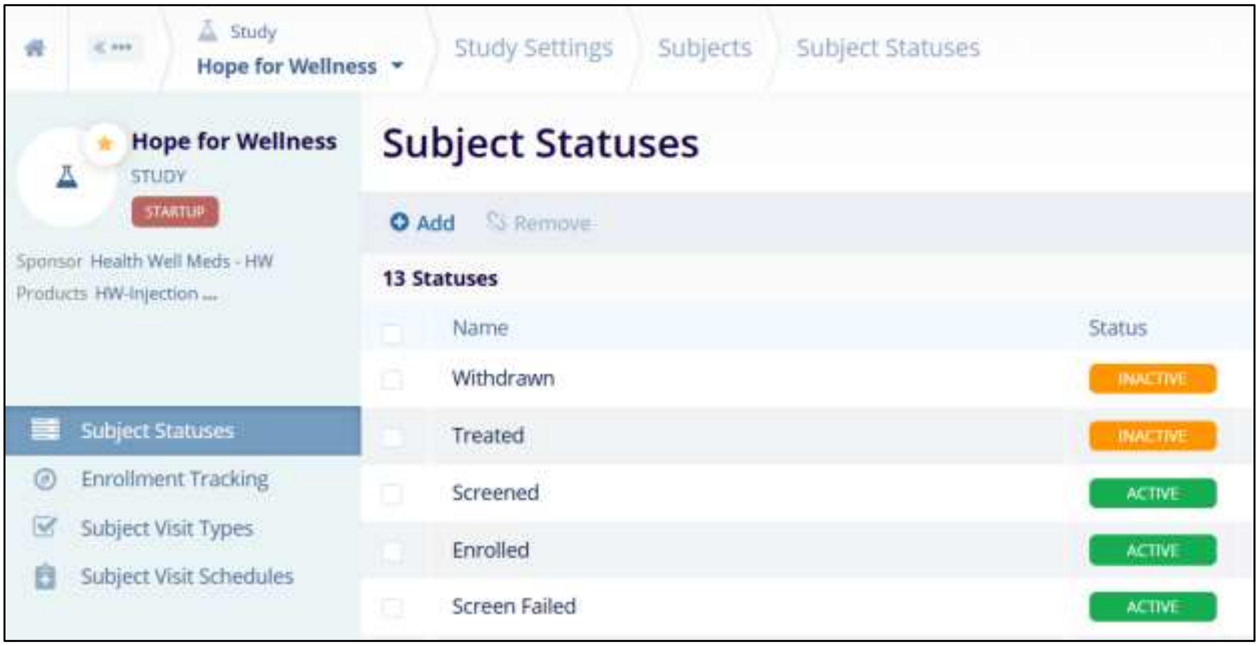


Figure: Define Subject Statuses at the Subject Level

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

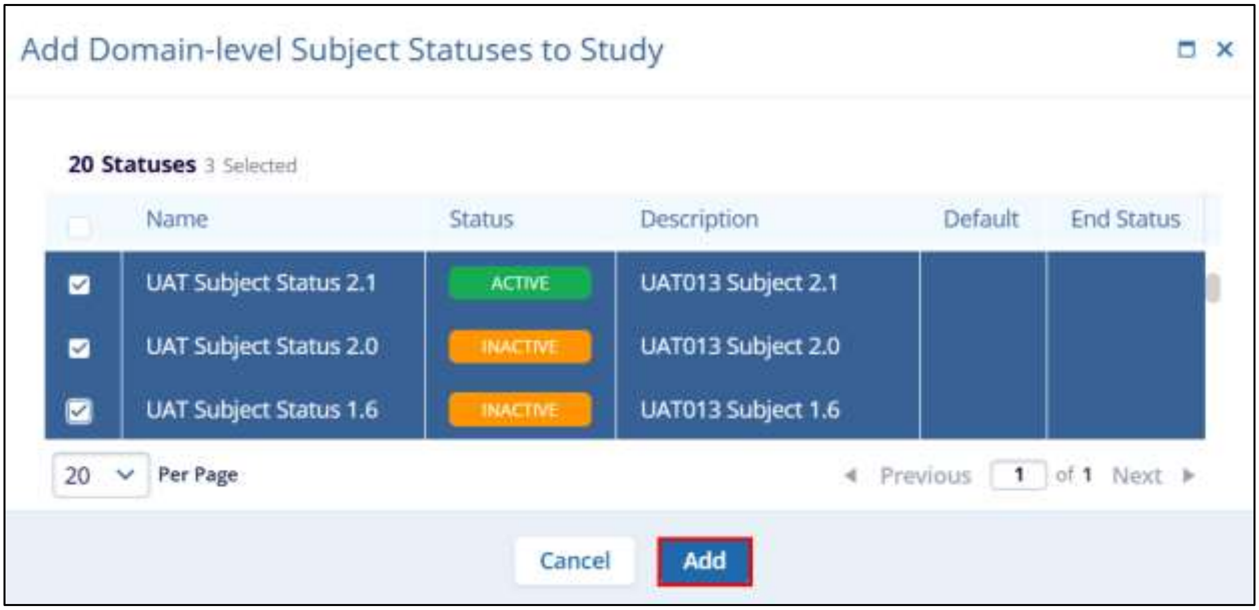


Figure: Add Domain Level Subject Statuses to Study

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.

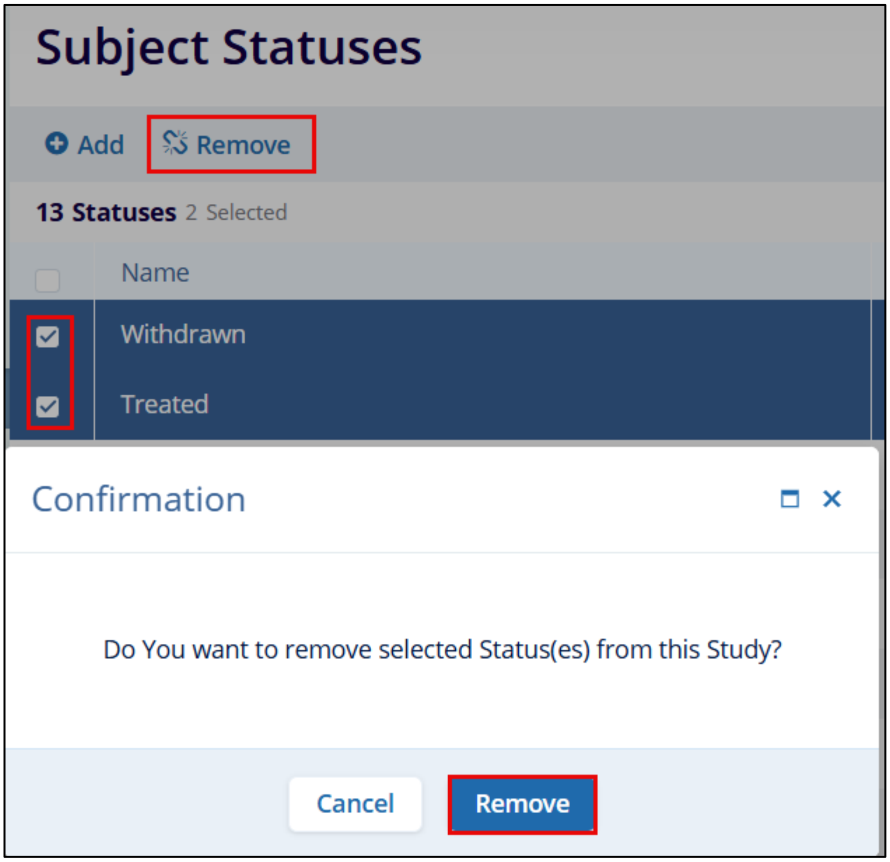


Figure: Remove Subject Statuses

7. Click on the Enrollment Tracking option and Add, Delete as well as Export the required details.

Figure: Enrollment Tracking

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

CHAPTER 7. SITE VISIT DOCUMENTATION

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

Pre-Requisite

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

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

Site Visit Navigation

To navigate to the site visit, follow the steps below

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

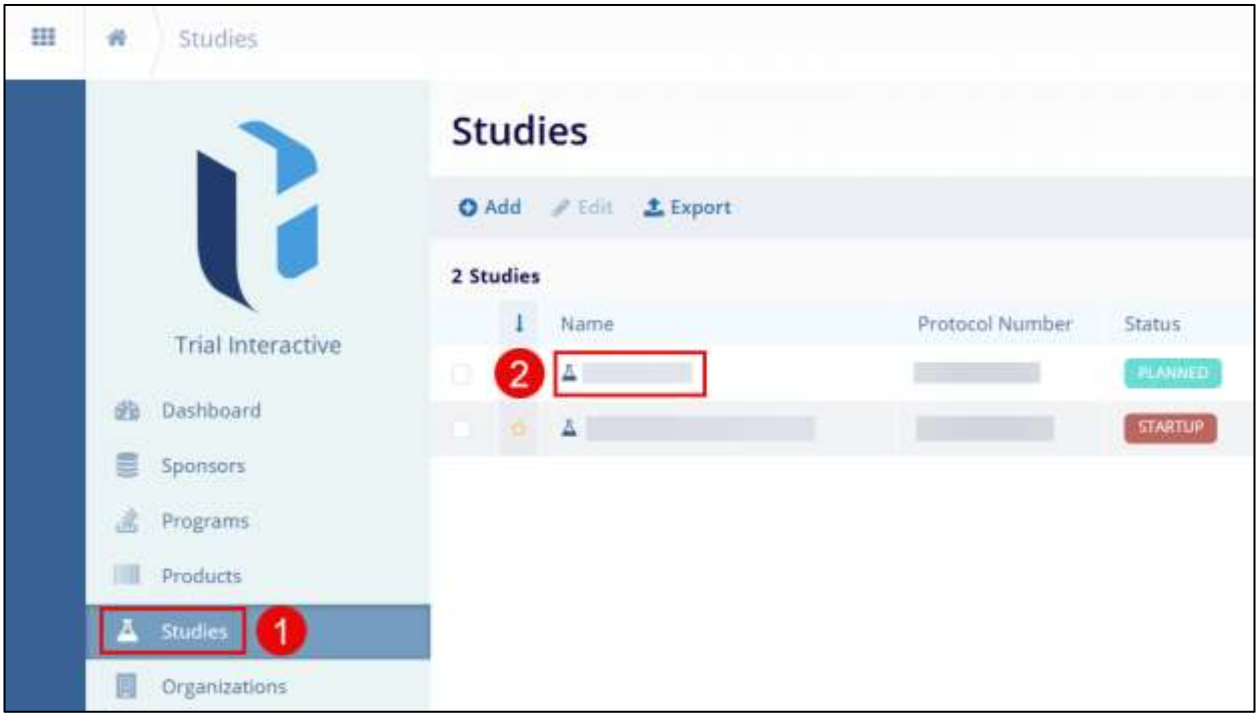


Figure: Select a Study and a study name

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

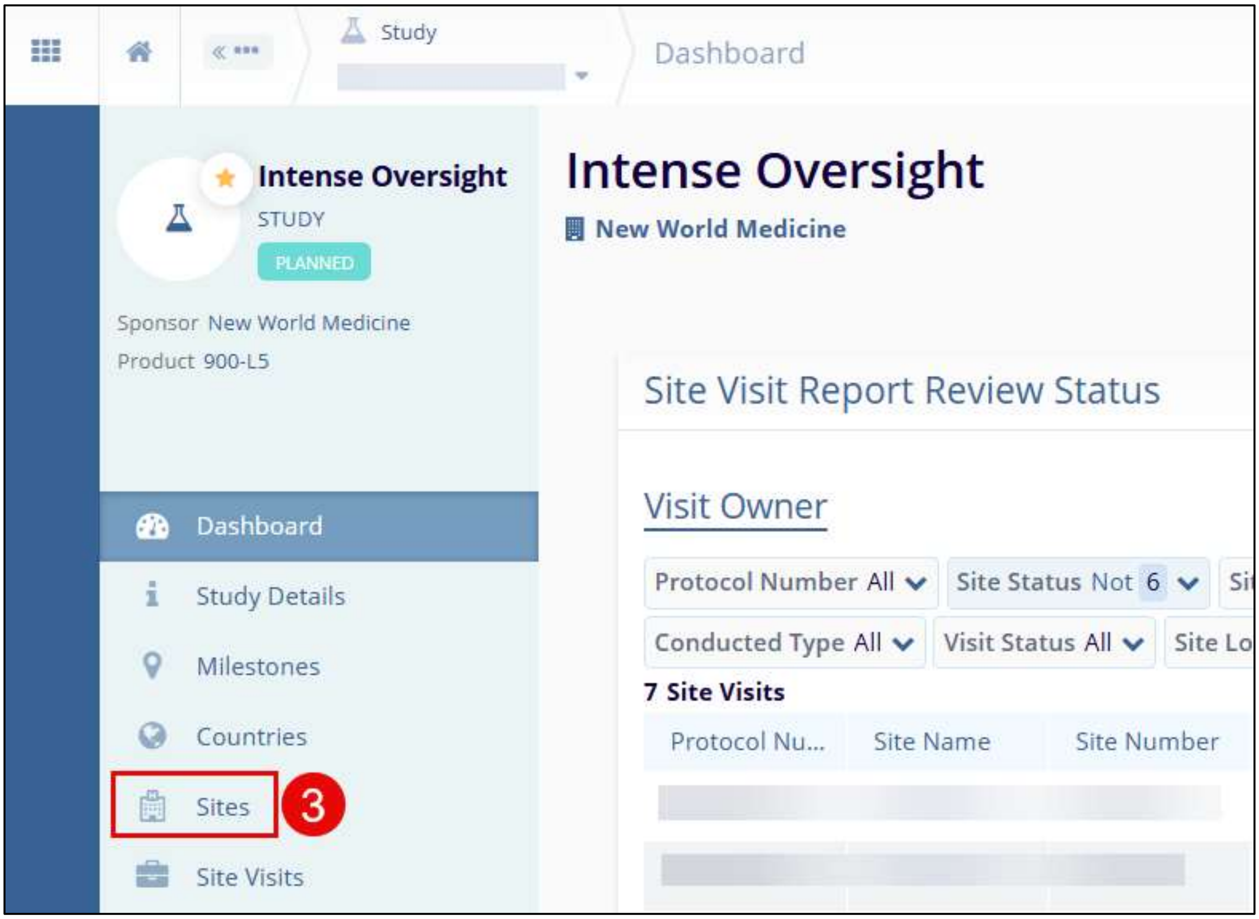


Figure: Select Sites from the Study Dashboard

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

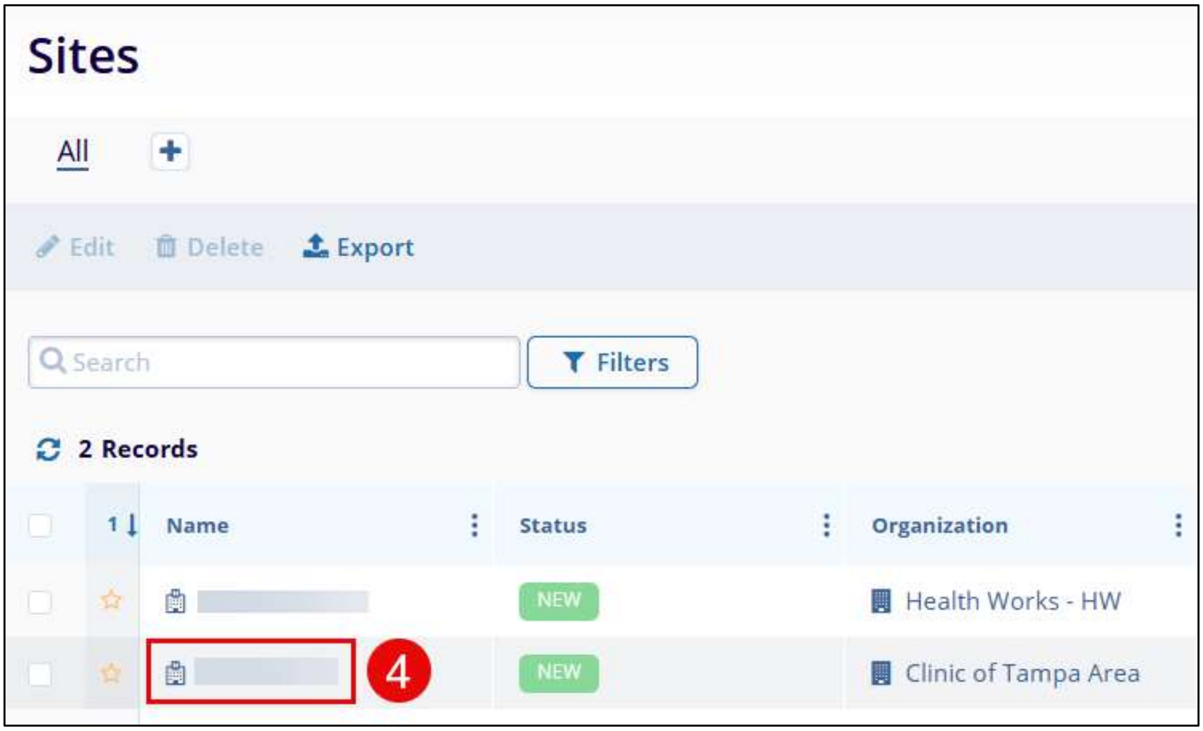


Figure: Select site

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

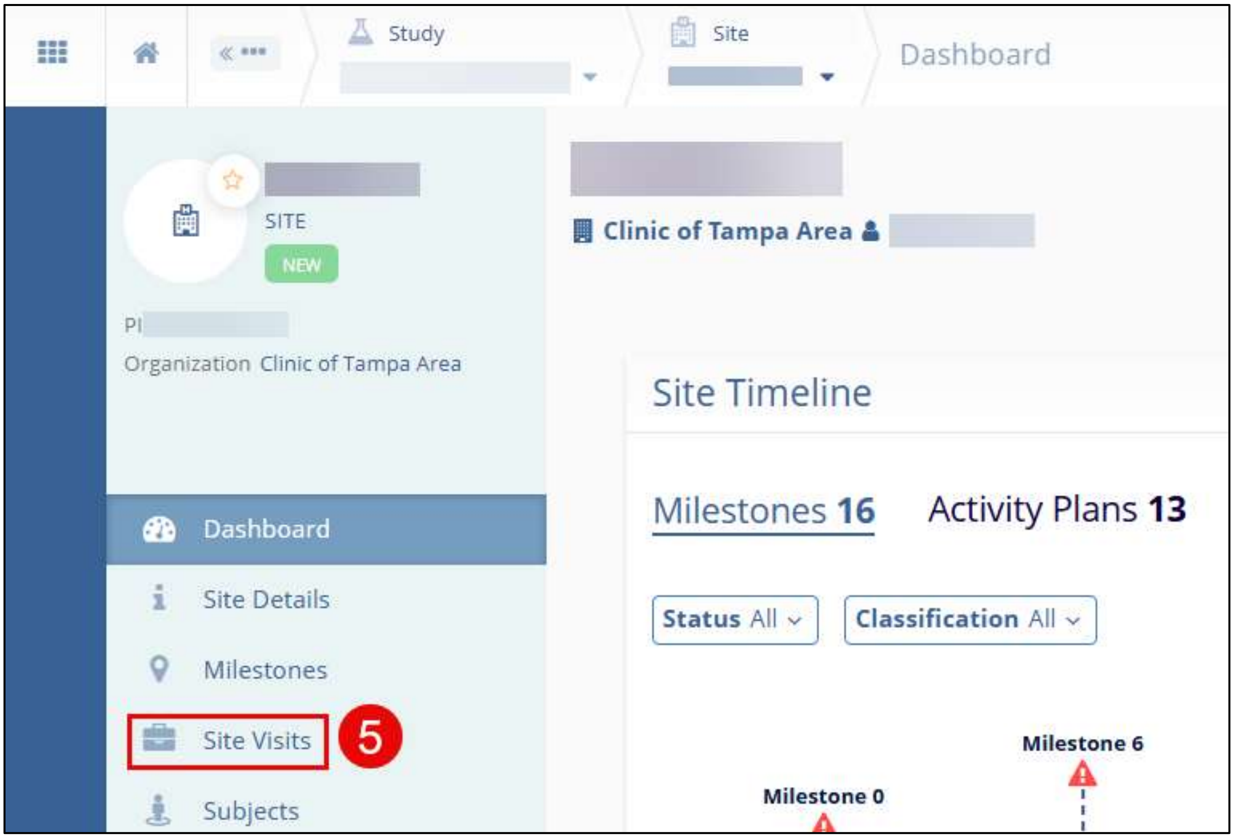


Figure: Select Site Visits

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

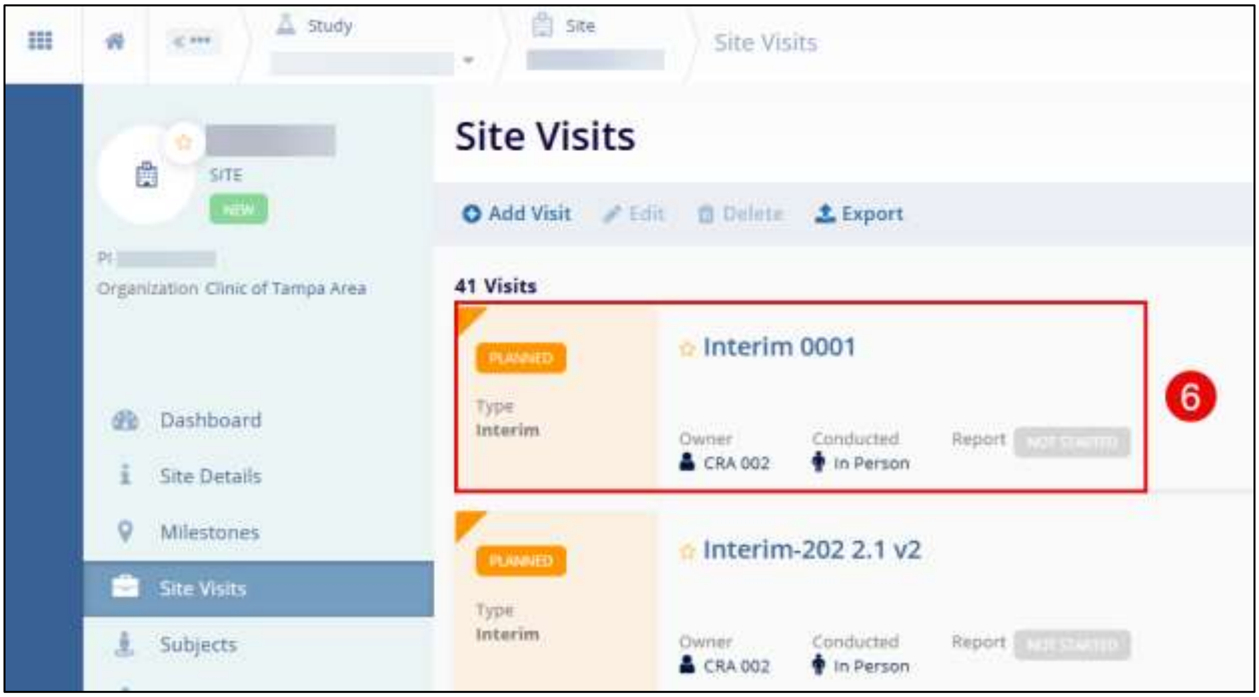


Figure: Select a visit

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

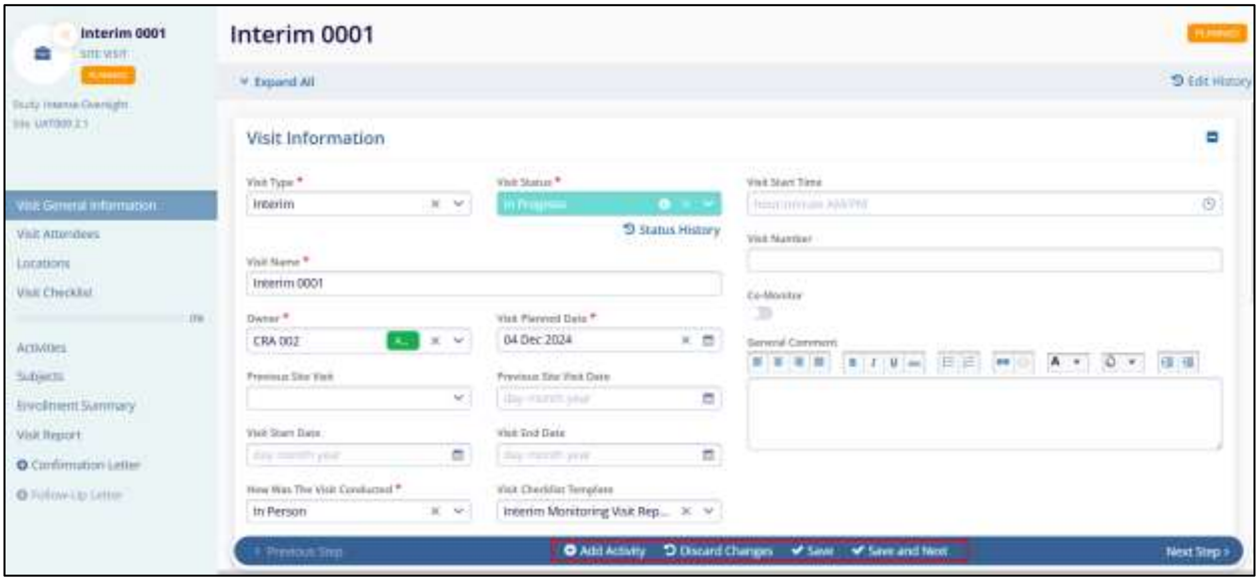


Figure: Updating site visit information

Add, Edit, Delete, and Export Site Visits

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

Create Site Visit

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.

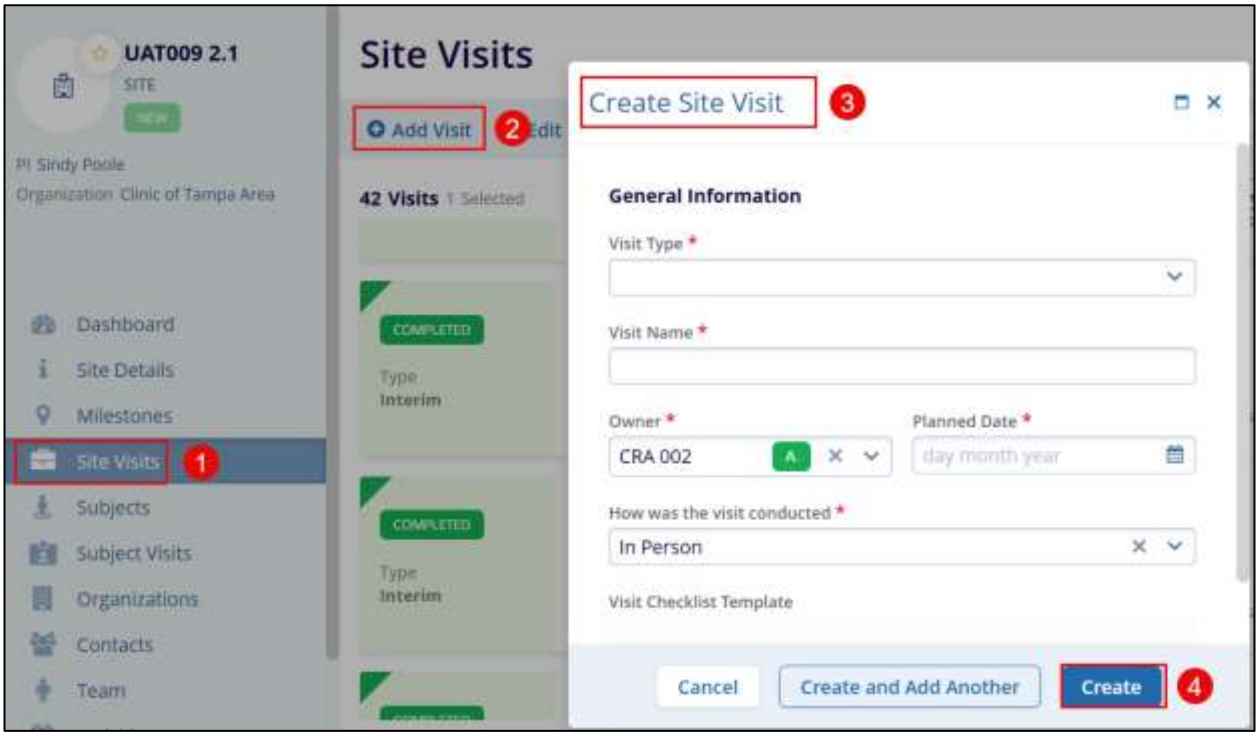


Figure: Create Site Visit

Edit Site Visit

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.

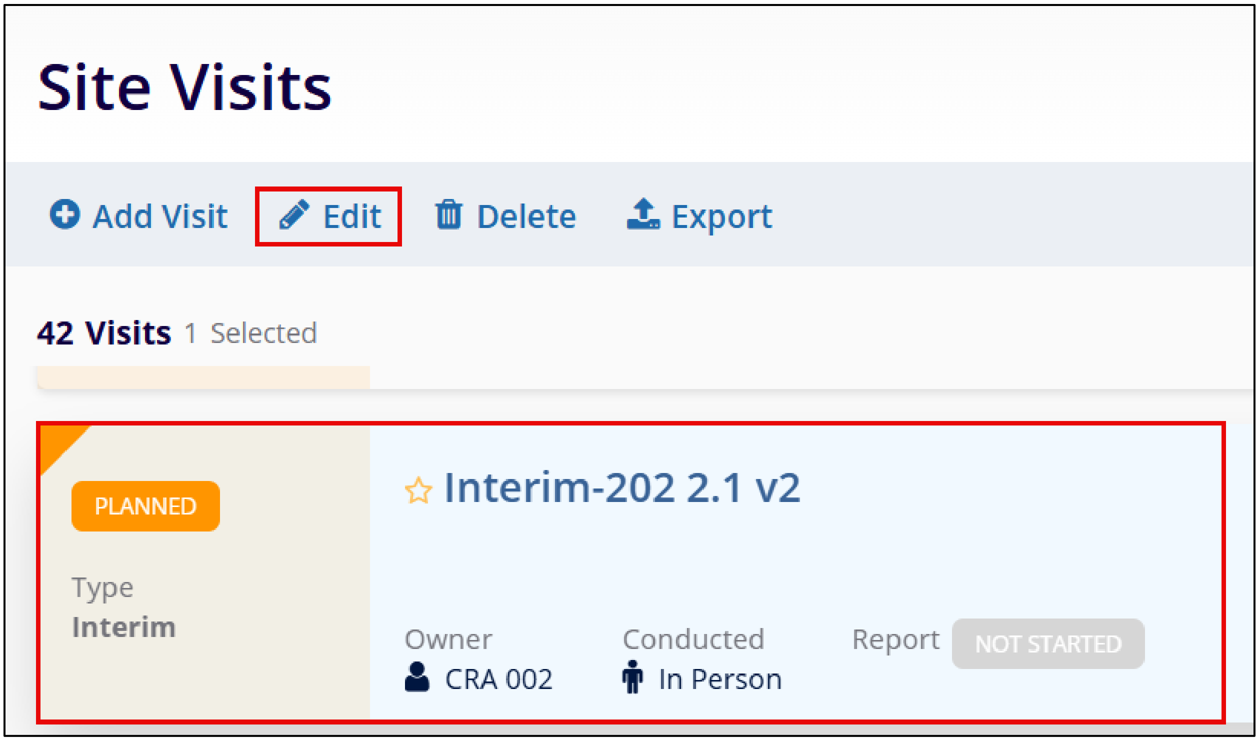


Figure: Edit Site Visit

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

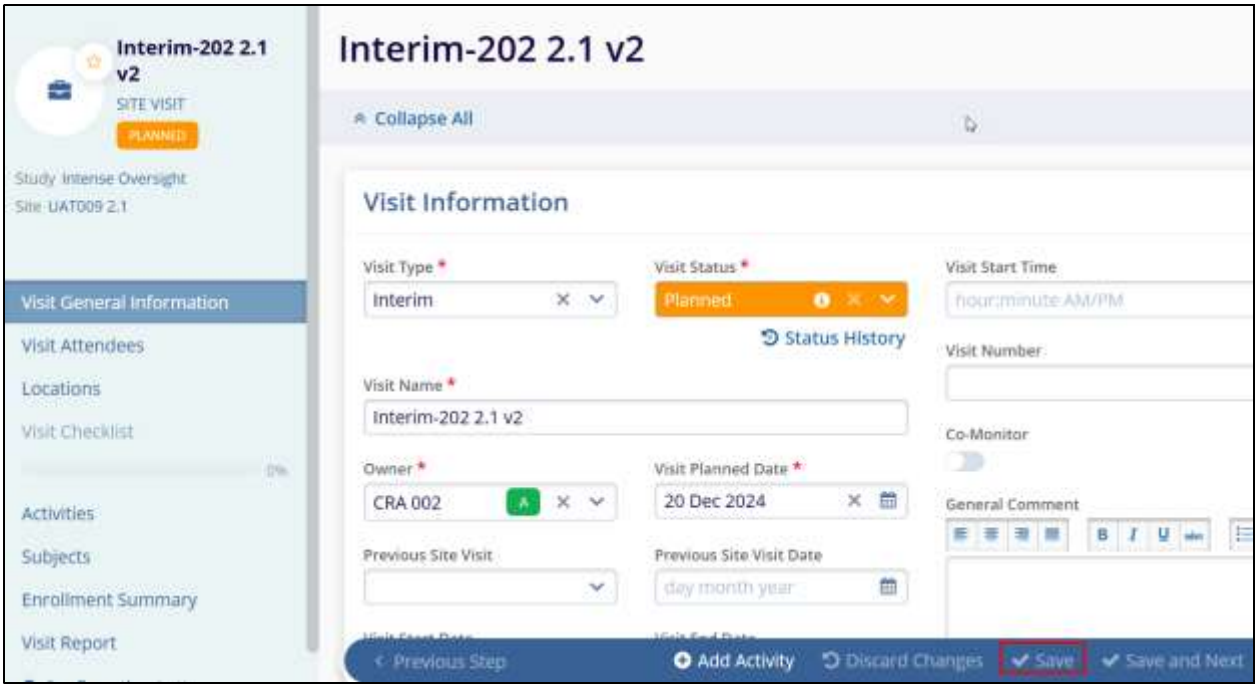


Figure: Visit General Information

Delete a Site Visit

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.

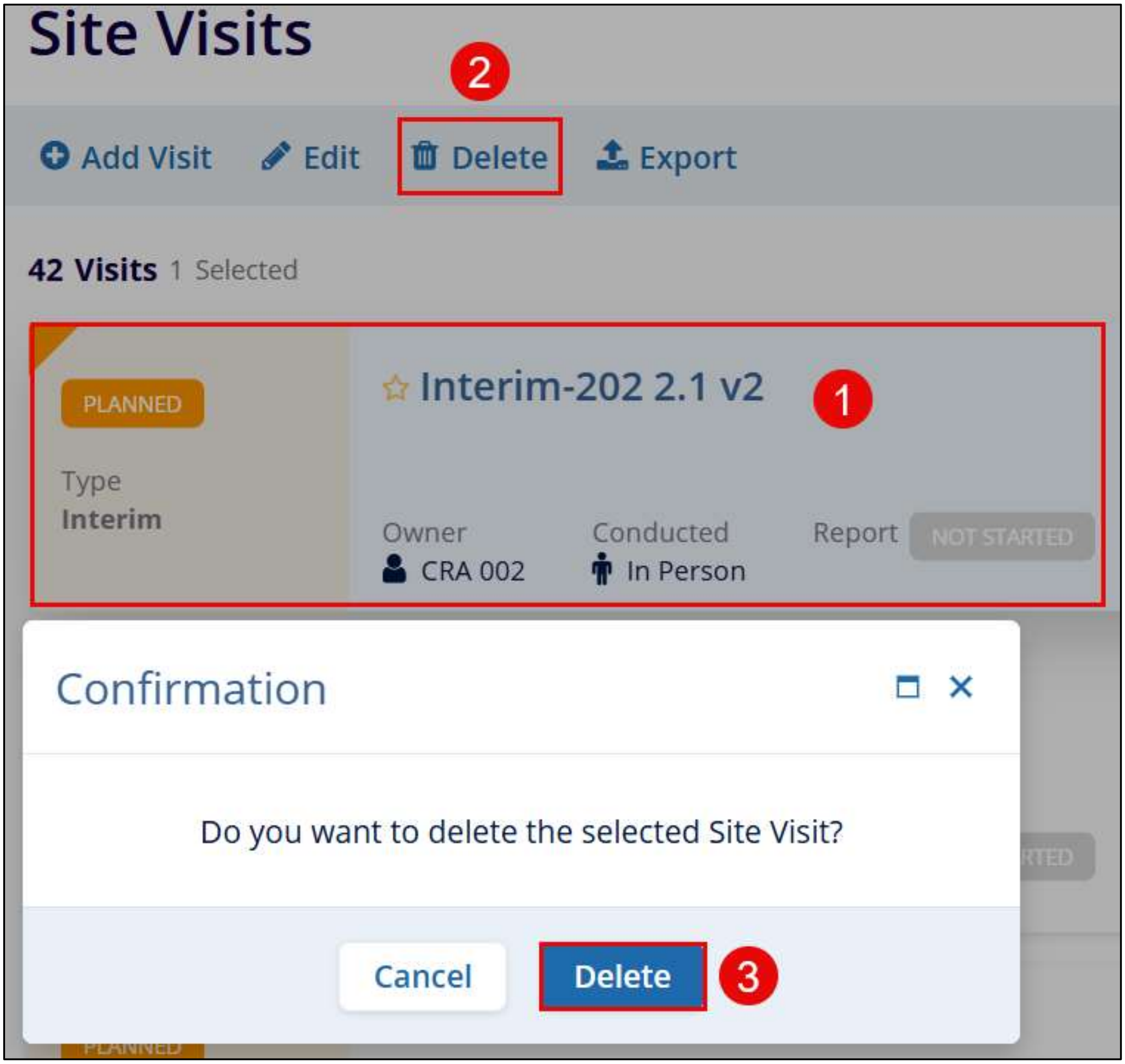


Figure: Delete Site Visit

<u>Export</u>

To export the site visit data into different views, click on the Export button and follow the standard steps detailed in the Exporting Contacts section,

Customize Site Visit screen

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.

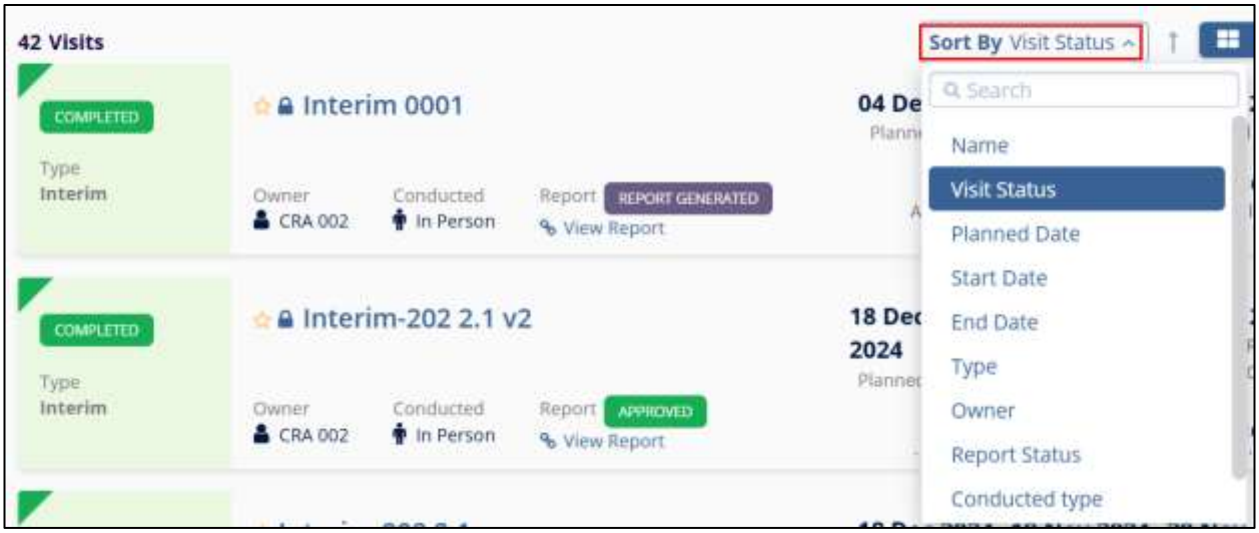


Figure: Sort Site Visits

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.

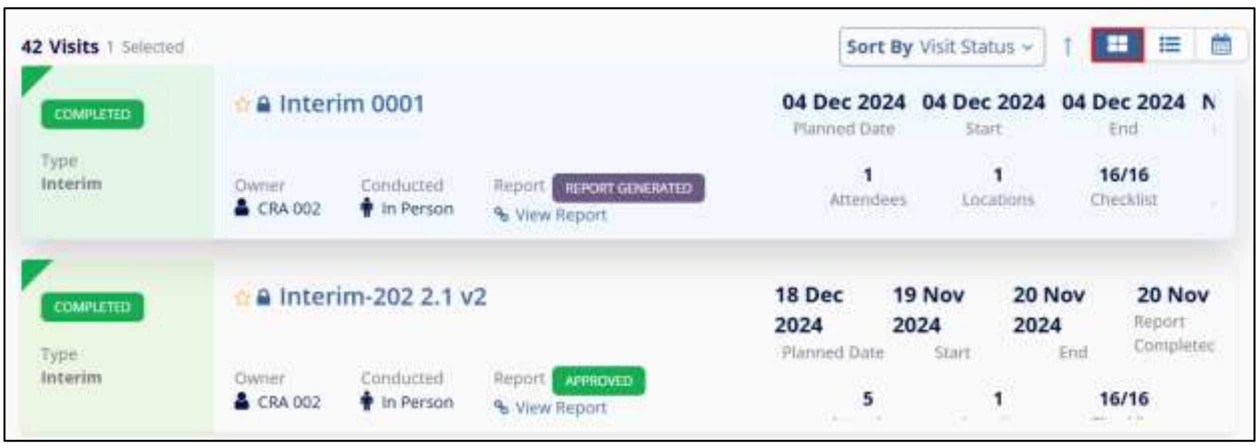


Figure: Card View

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

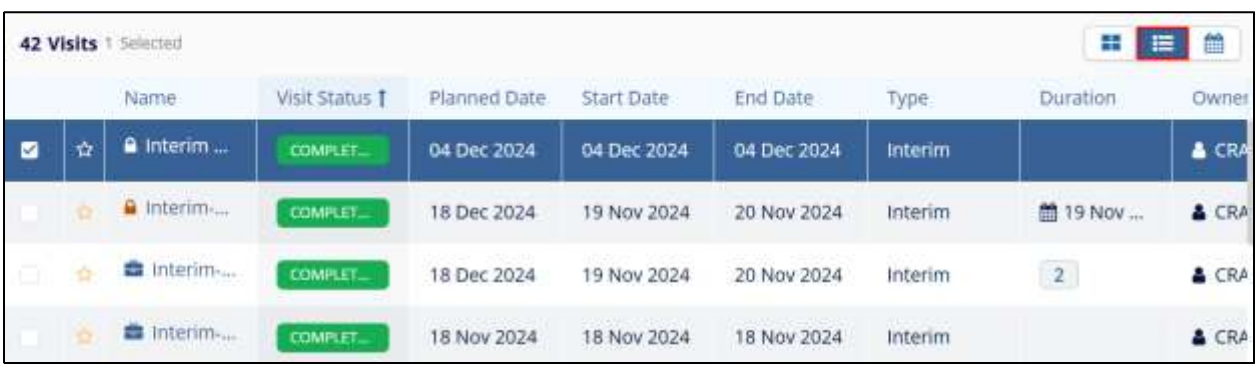


Figure: List View

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

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.

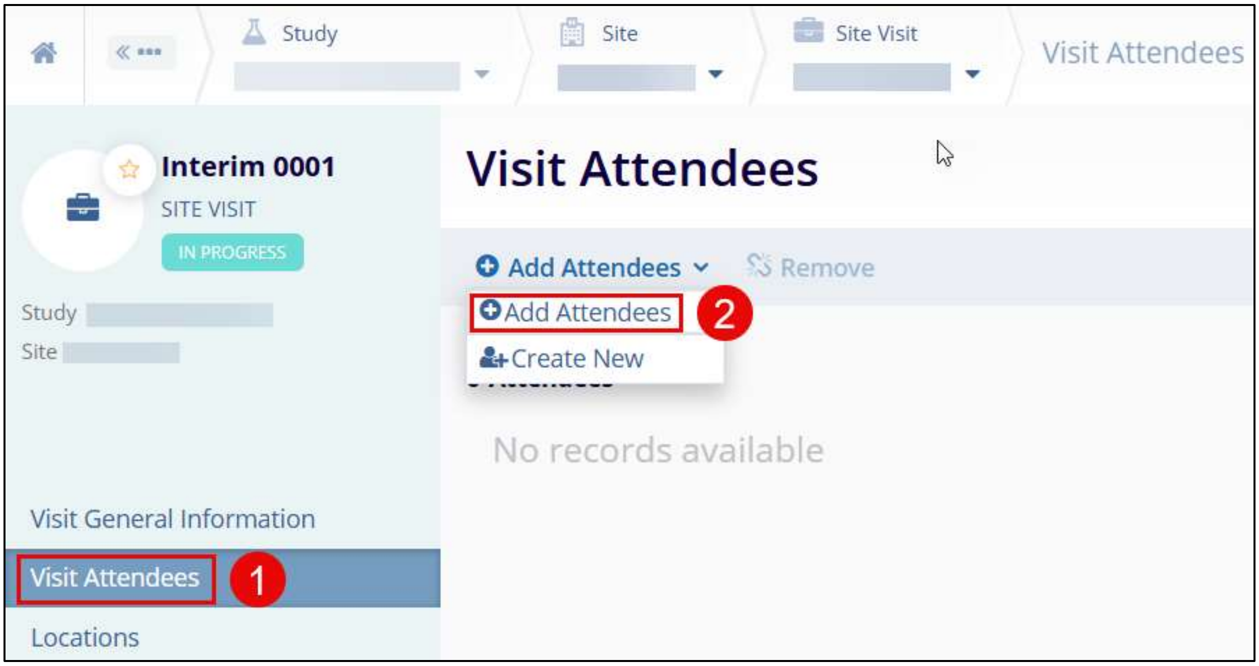


Figure: Add Attendees

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.

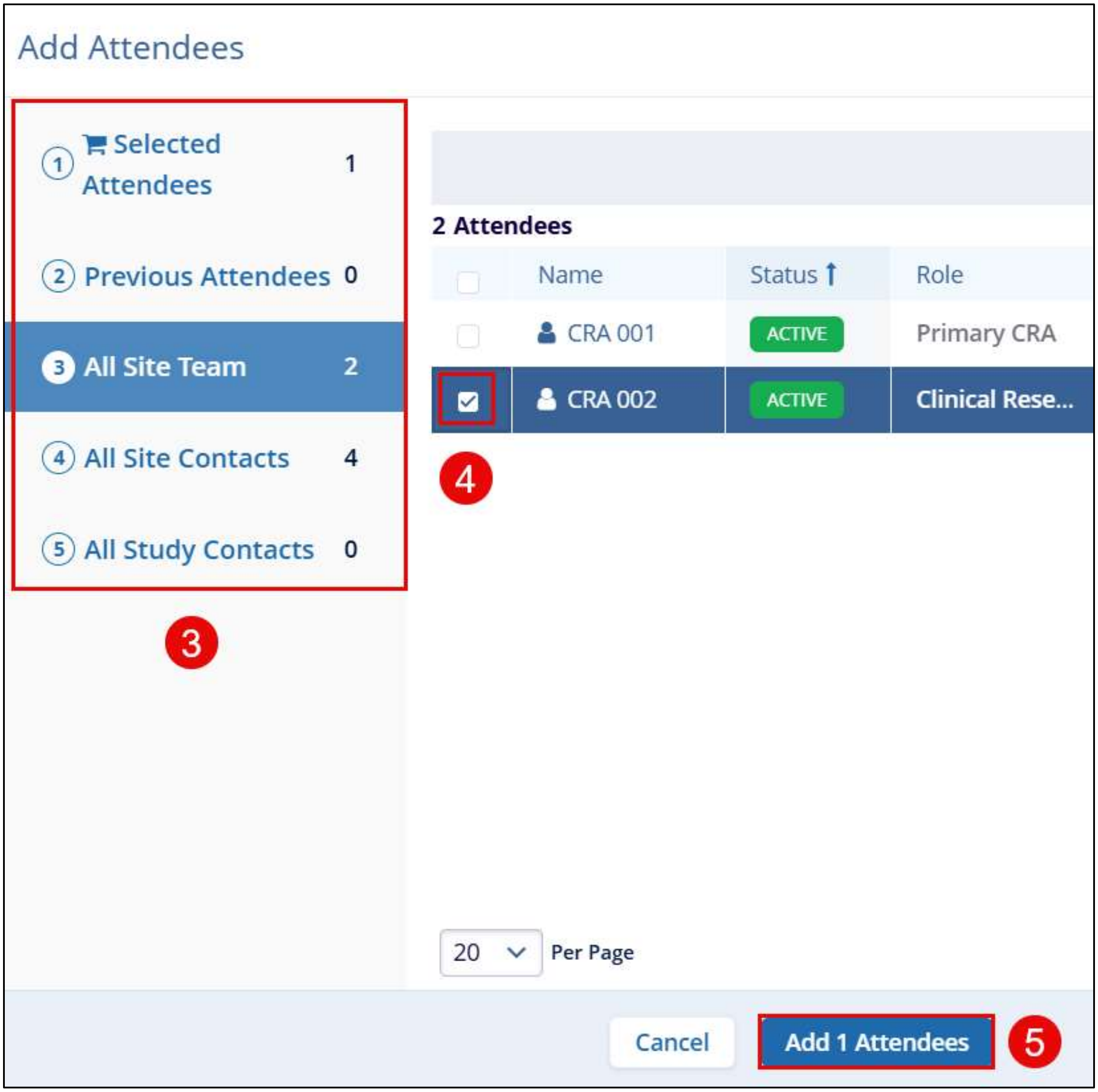


Figure: Add attendees from All Site Contacts

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

Site Visit Locations

To access Site Visit Locations, follow the steps below.

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

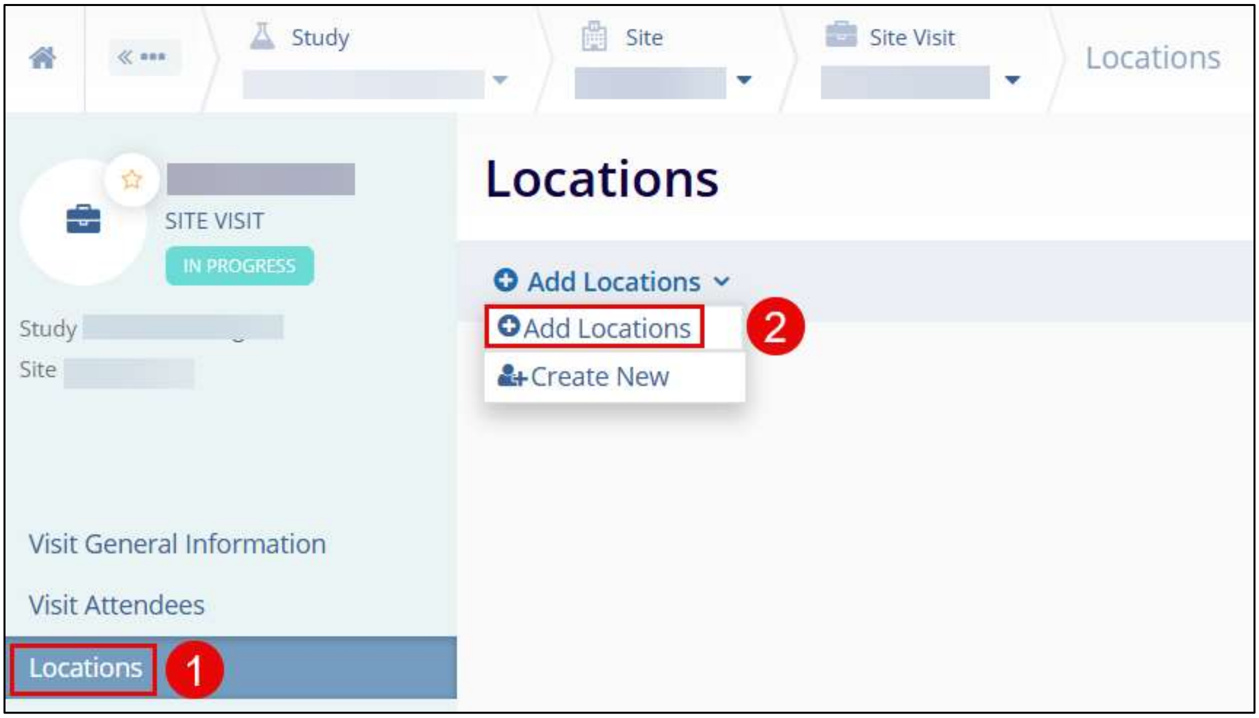


Figure: Add Locations

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

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

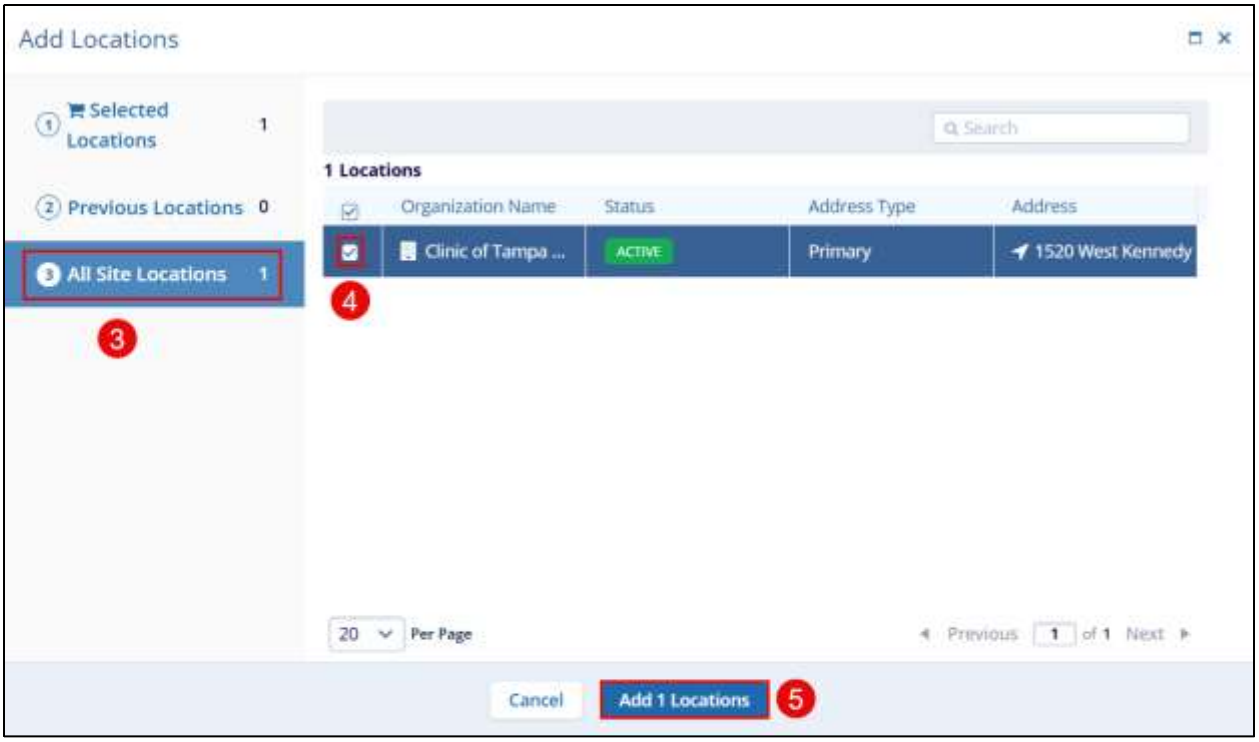


Figure: Add location from All Site Locations

Site Visit Checklist

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

1. Navigate to the Site Visit General Information screen by following the steps detailed in the Site Visit Navigation section and click on the Visit Checklist link.
2. On the 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.

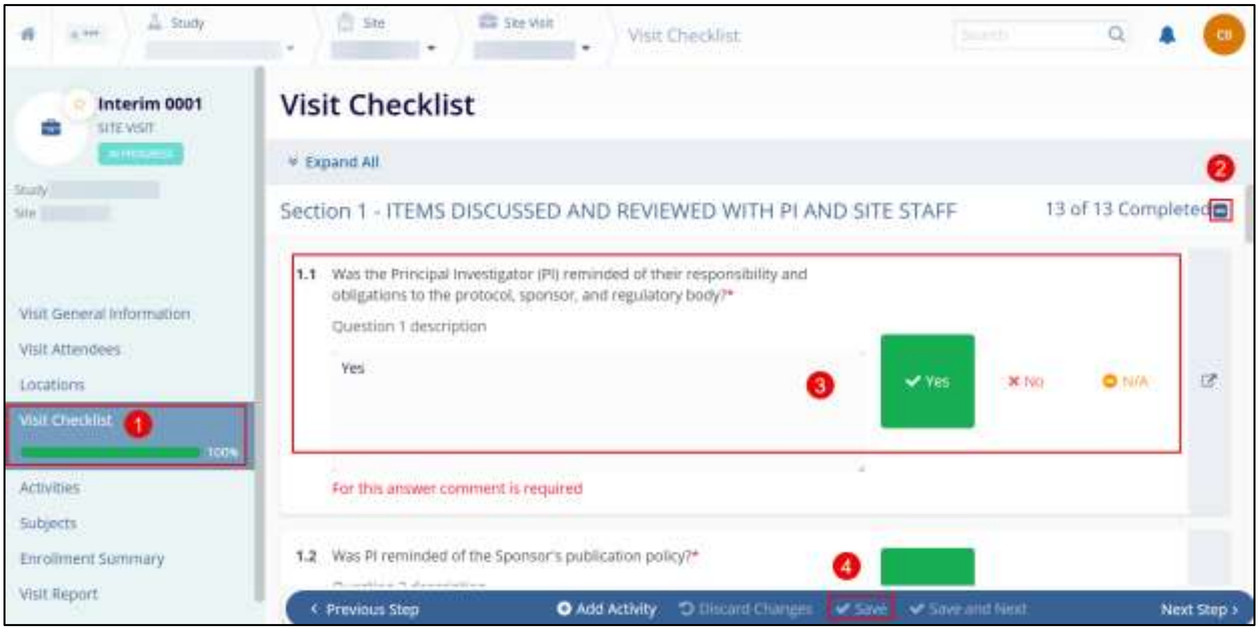


Figure: Visit Checklist

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.

Site Visit Activities

To access Site Visit Activities, follow the steps below.

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

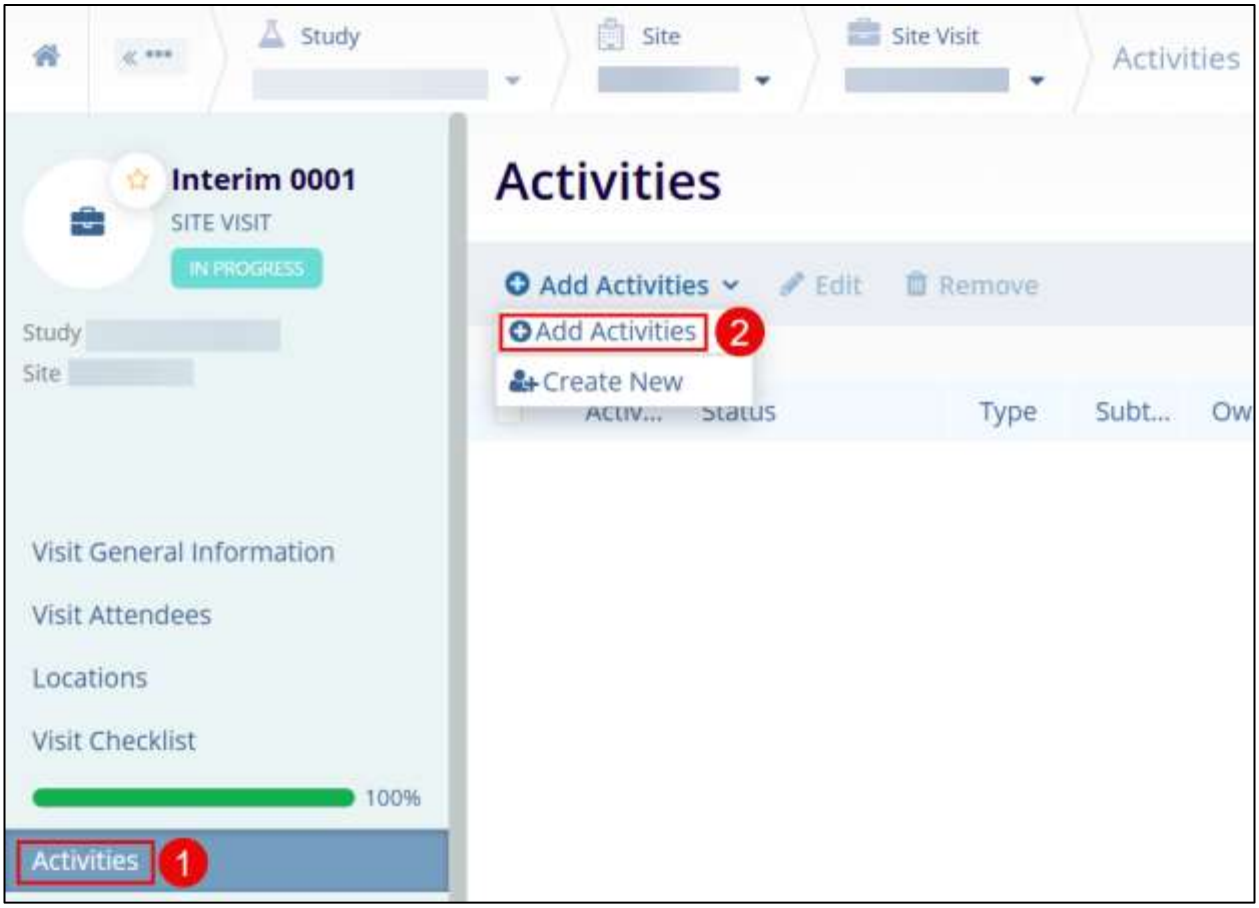


Figure: Add Activities

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

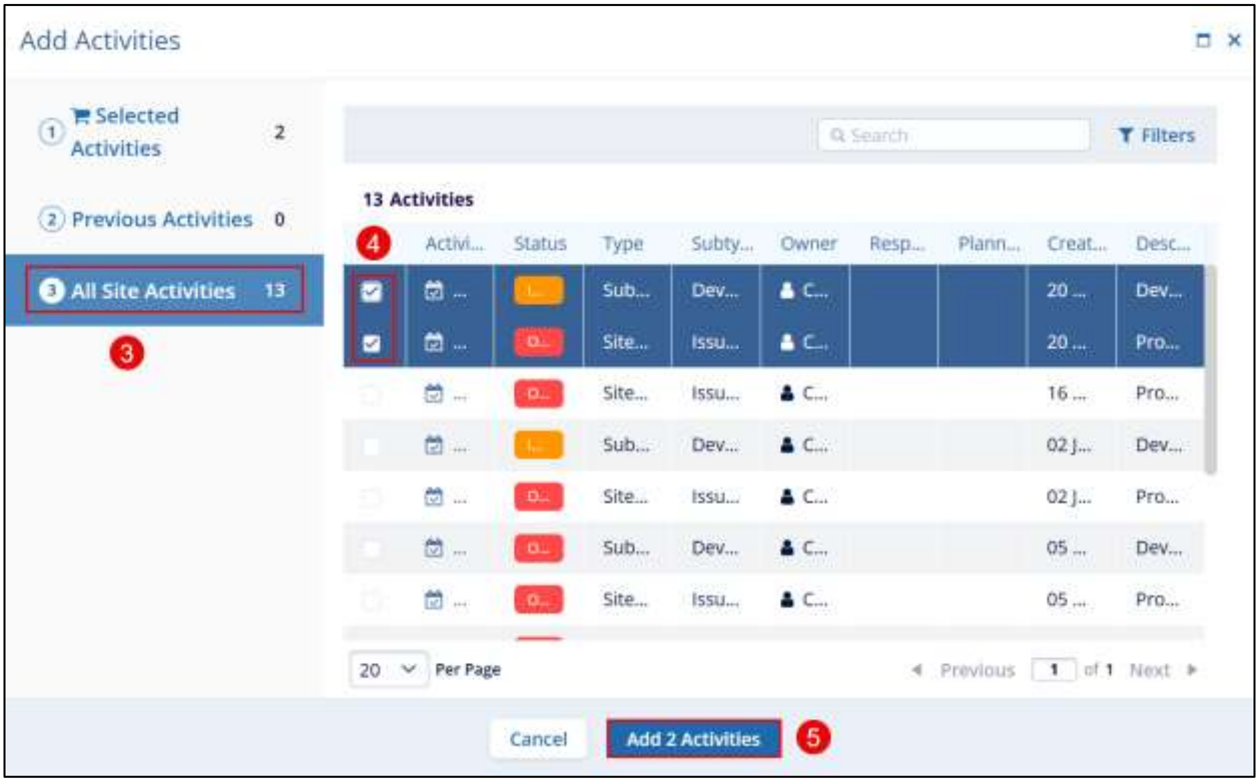


Figure: Add activities from All Site Activities

Site Visit Subjects

To access Site Visit Subjects, follow the steps below

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

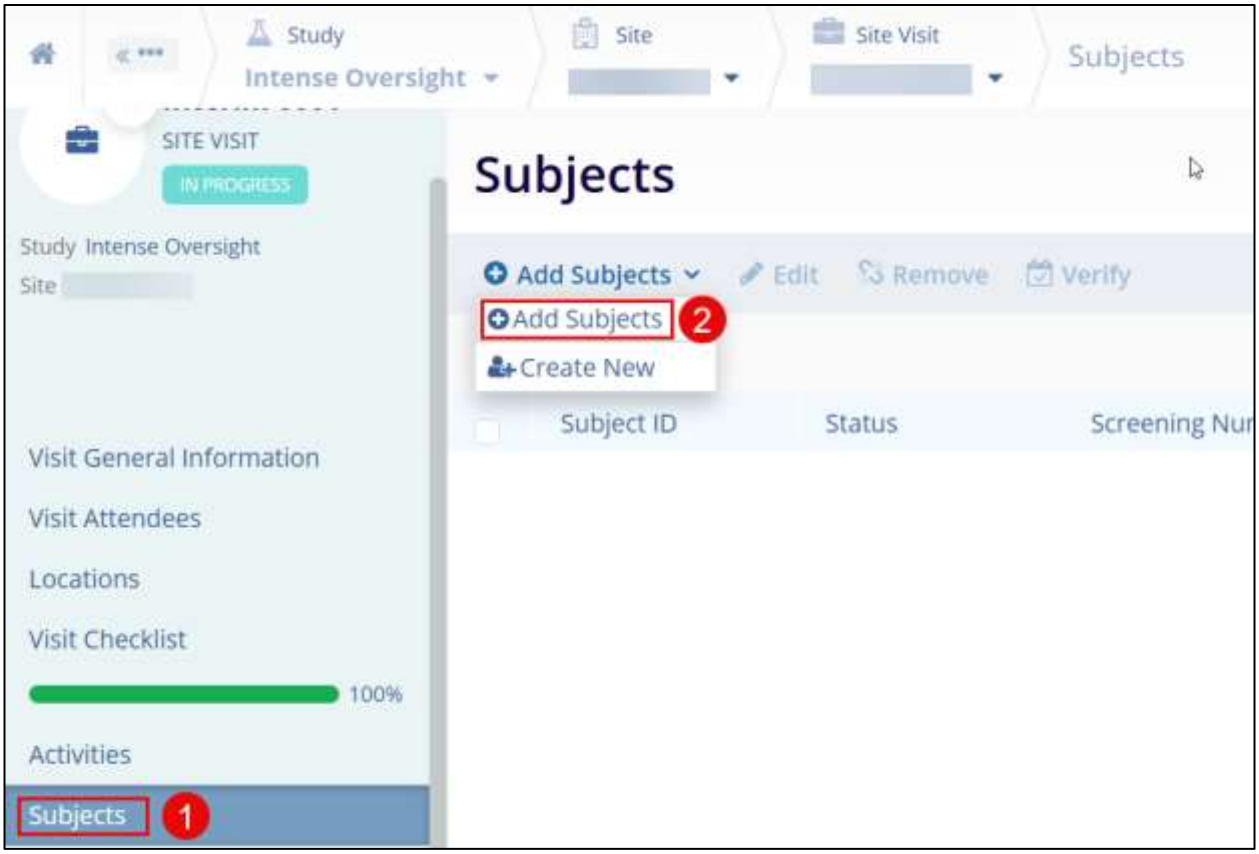


Figure: Add Subjects

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

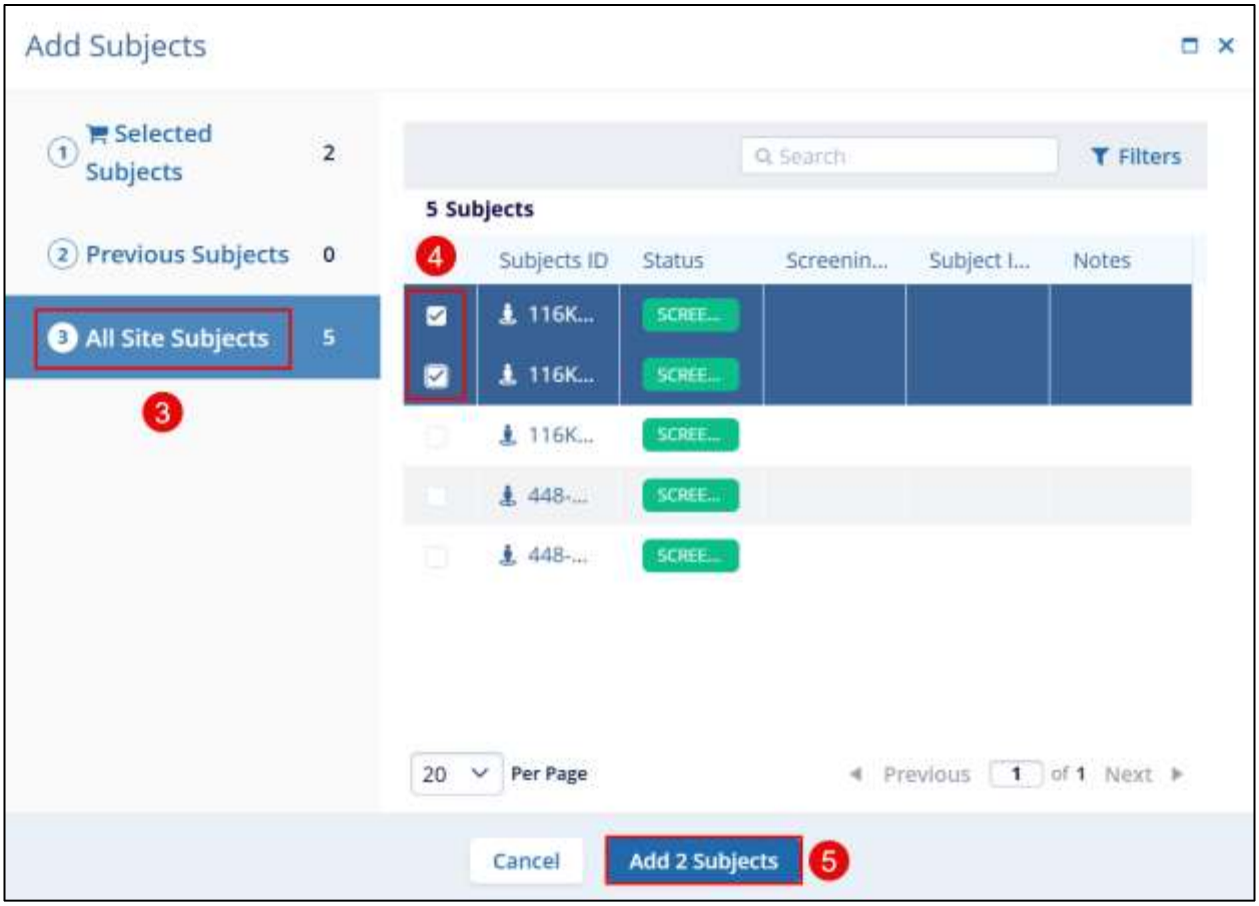


Figure: Adding subjects from All Site Subjects

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

Site Visit Enrollment Summary

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

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

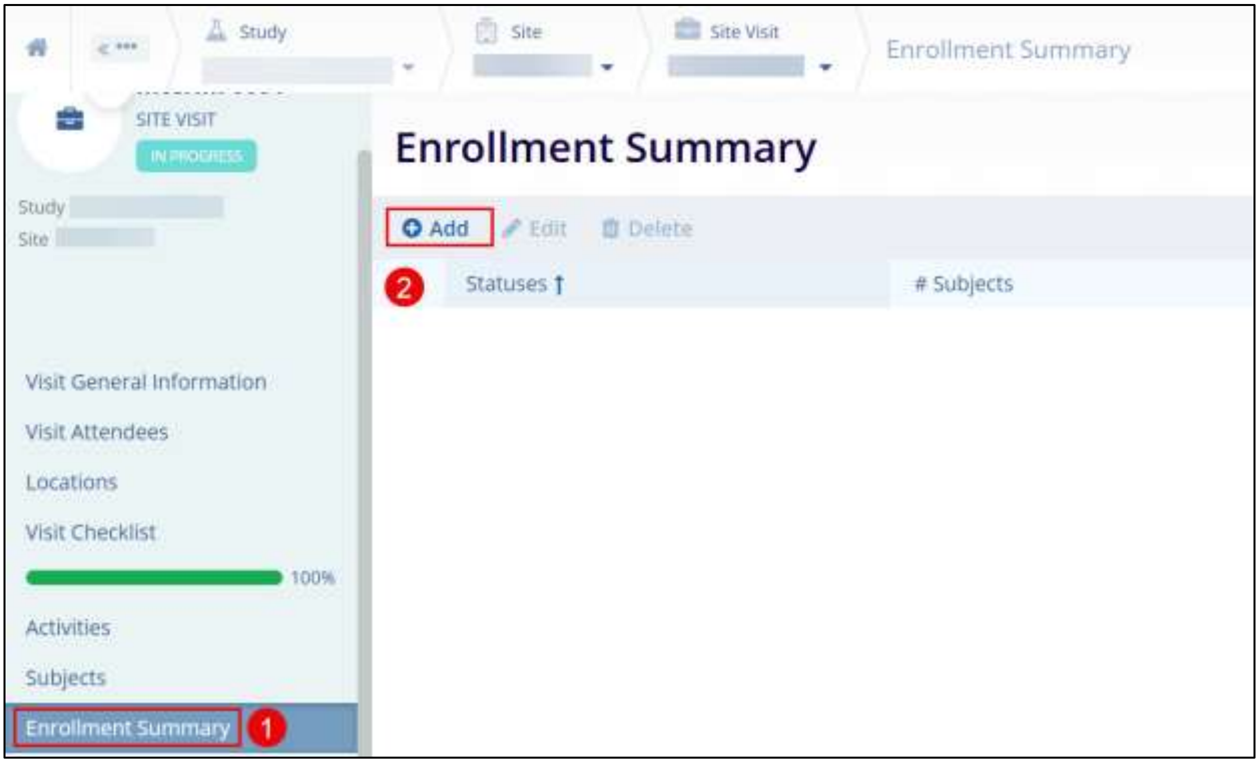


Figure: Add Enrollment Summary

3. Select the required option from the Statuses dropdown,
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

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.

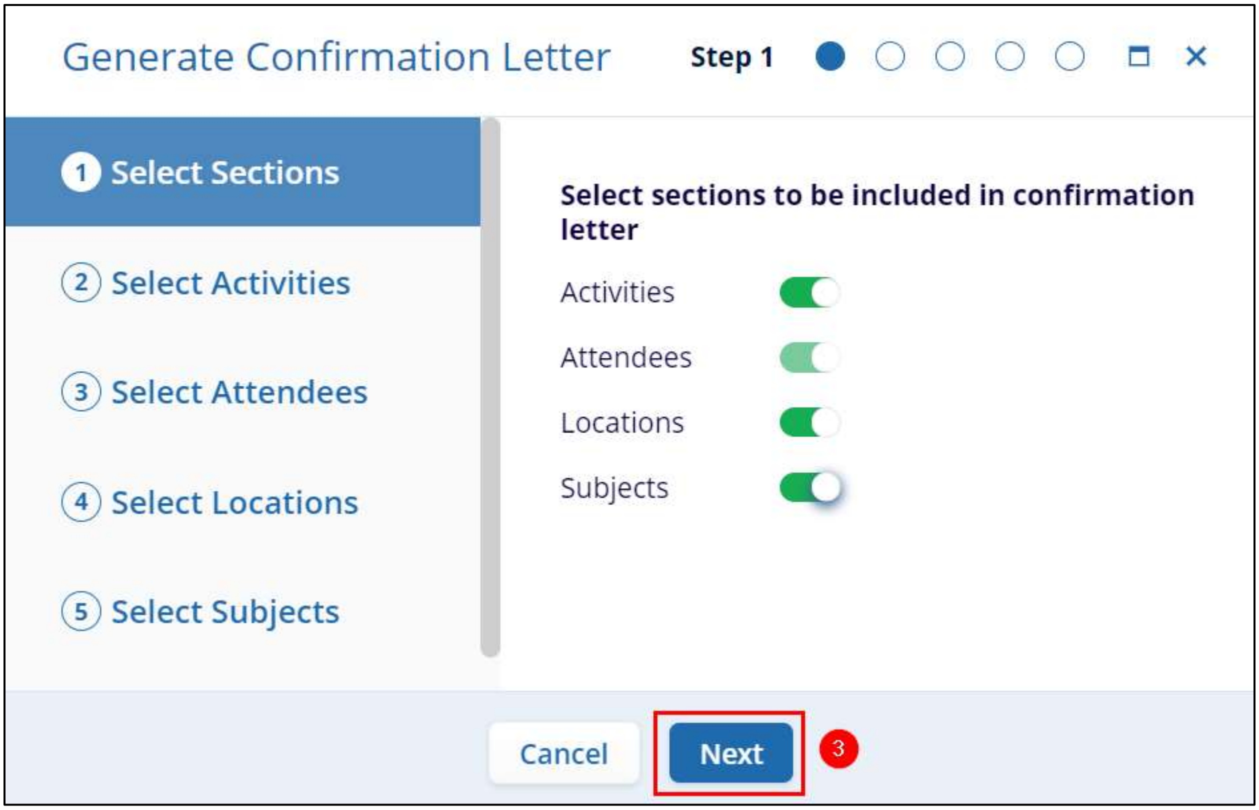


Figure: Generate Confirmation letter steps

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

Signing the Document and Approval Workflow

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

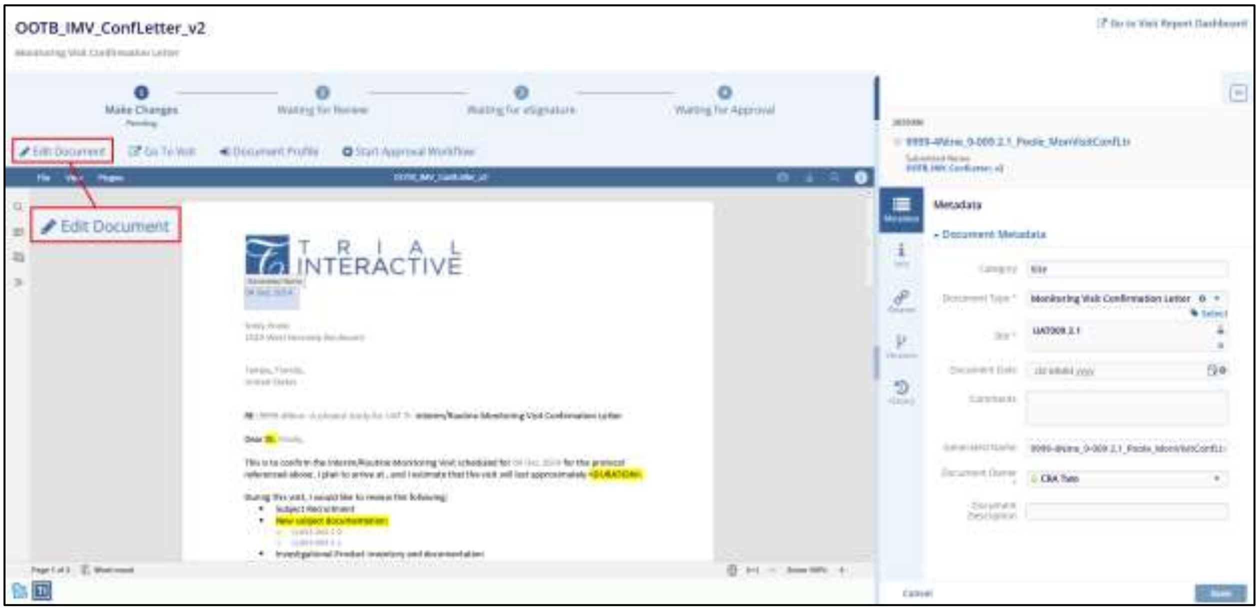


Figure: Edit Document

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.

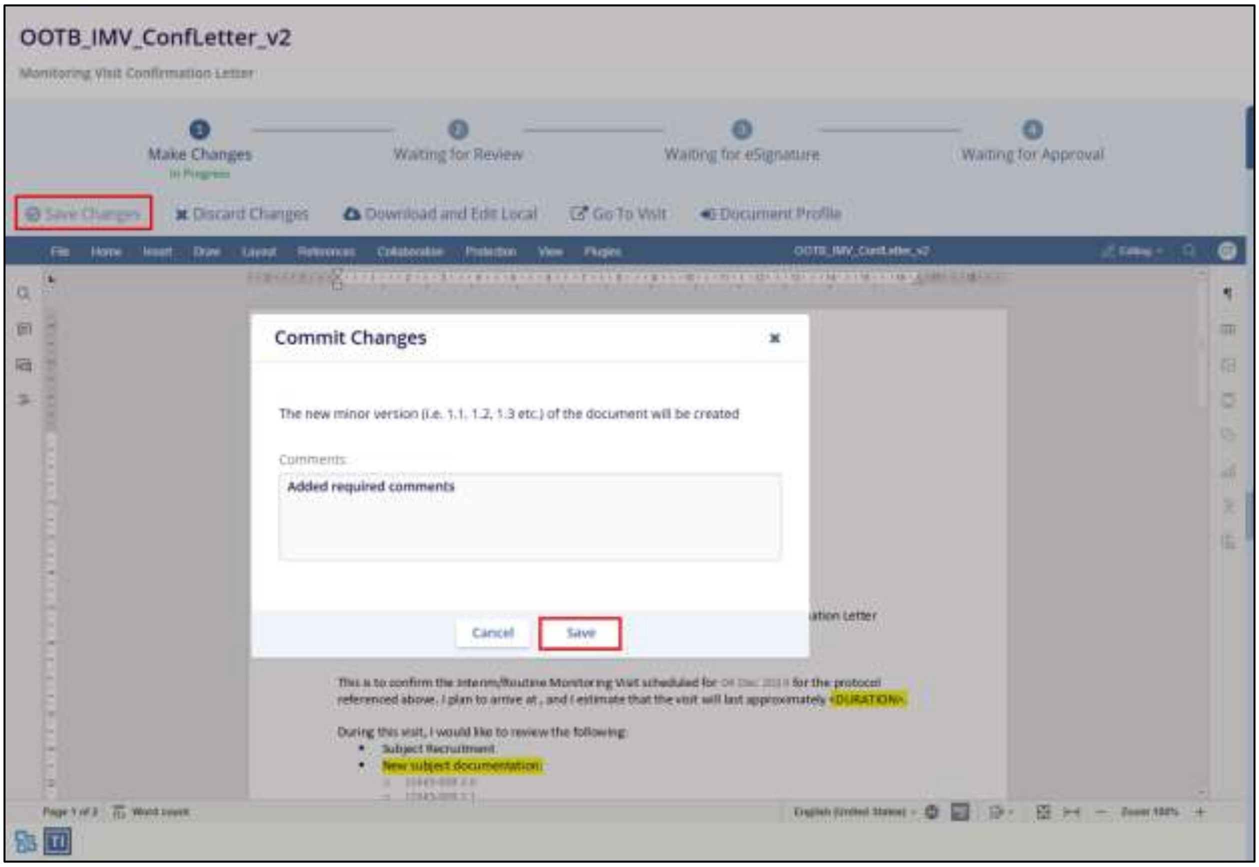


Figure: Save Changes

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.

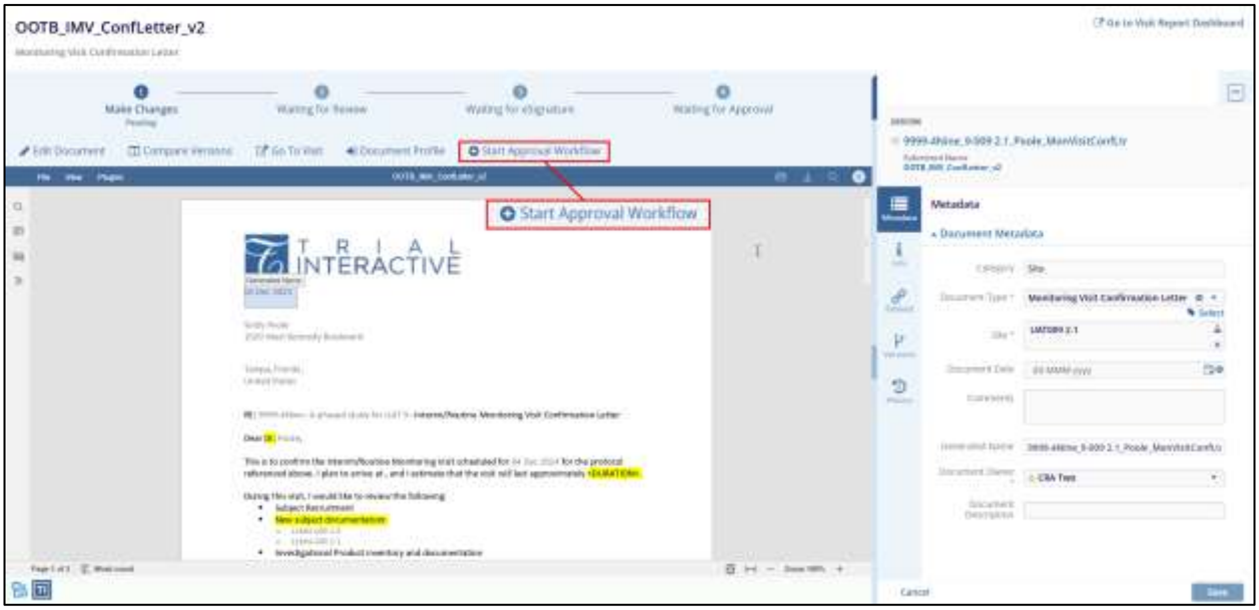


Figure: Start Approval Workflow

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

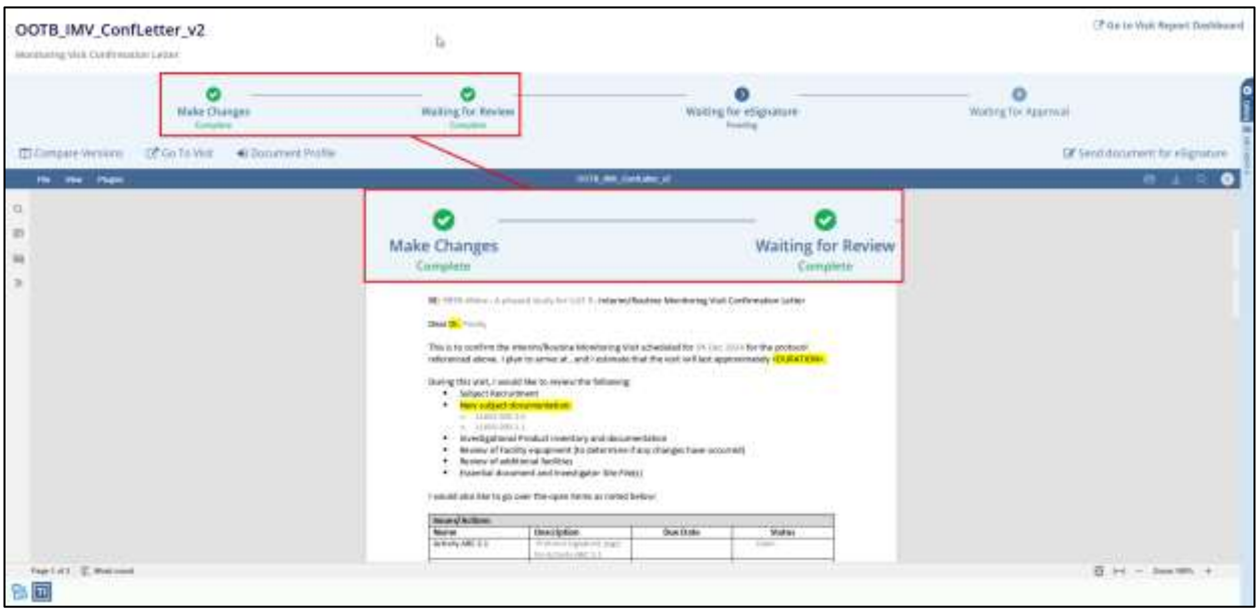


Figure: Add document(s) to monitoring

Note:

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

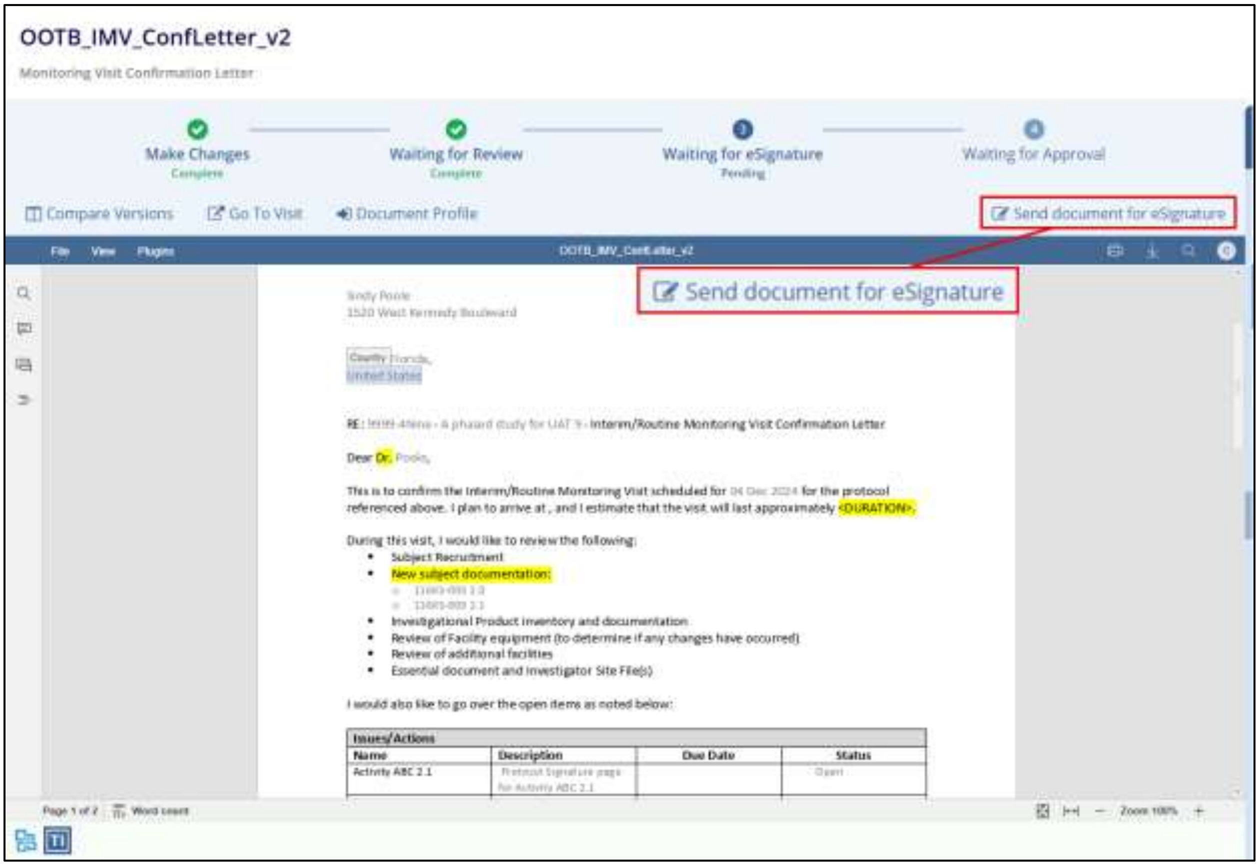


Figure: Send document for eSignature

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.

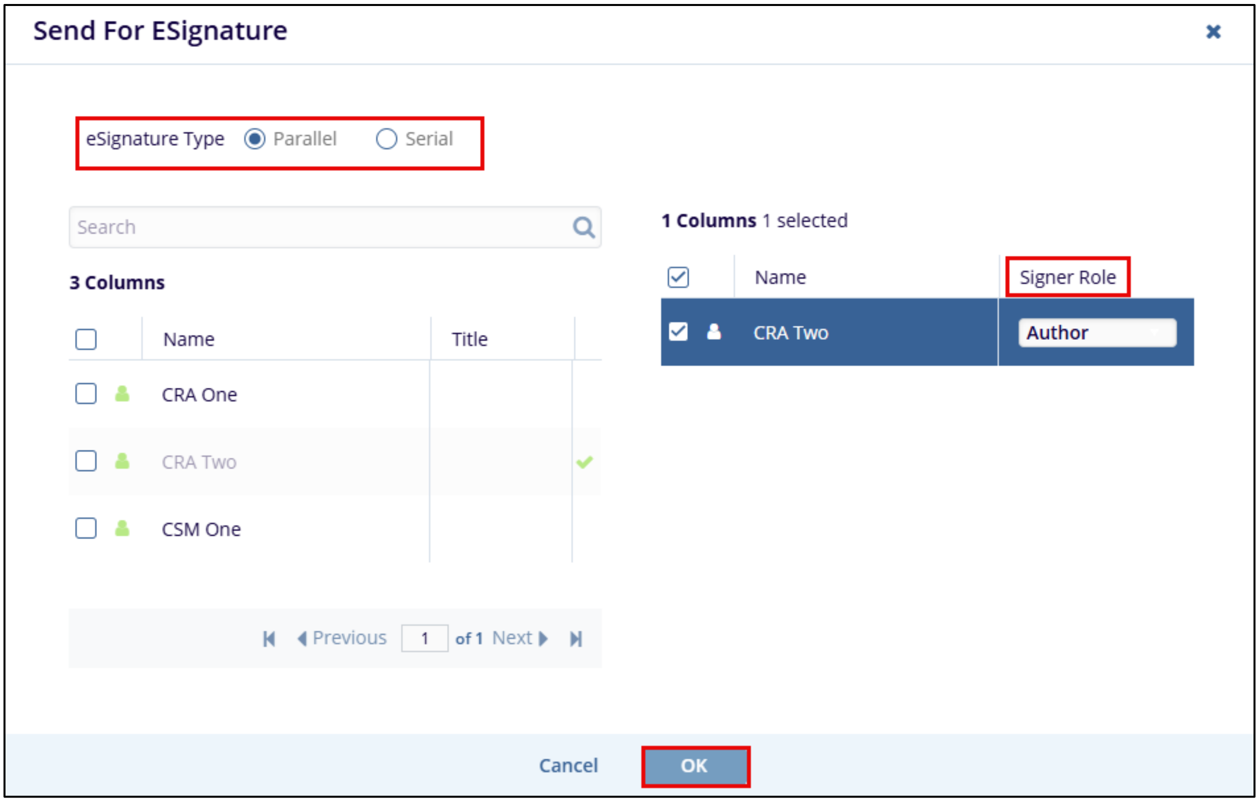


Figure: Send for eSignature screen

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 the Sign Document button.

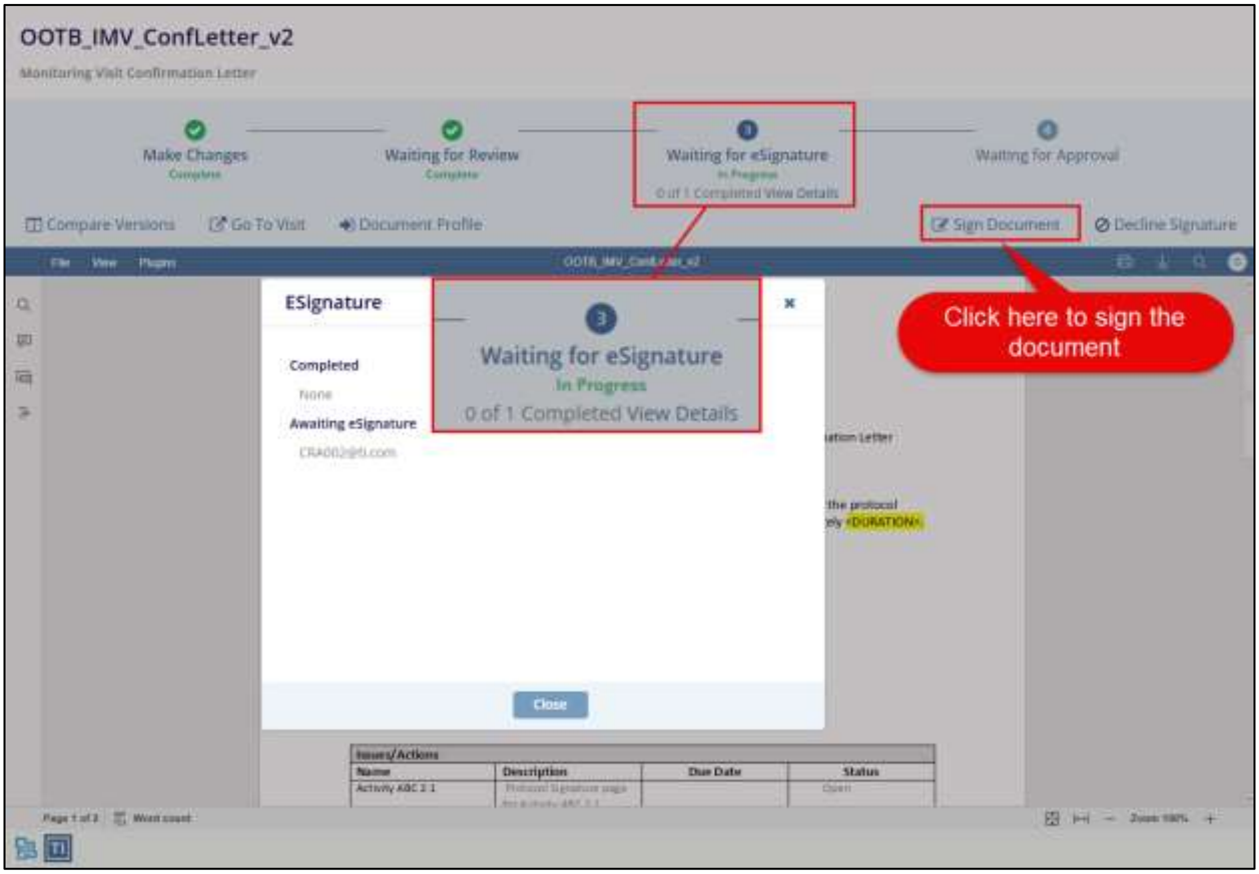


Figure: Sign Document option

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.

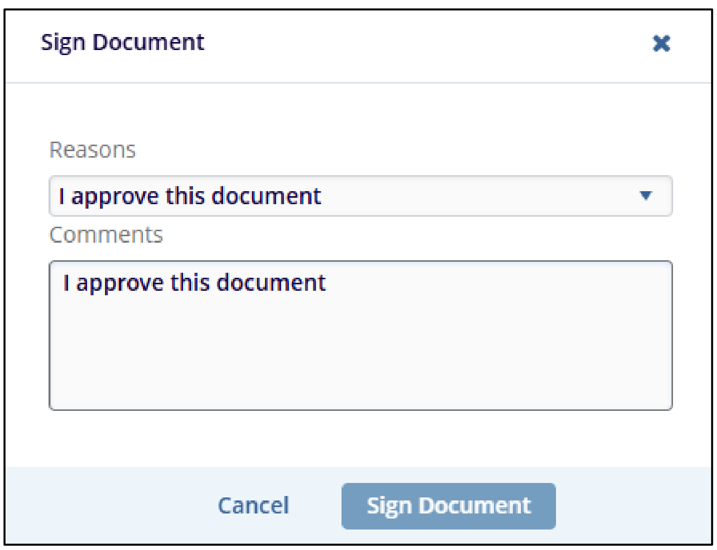


Figure: Sign Document screen

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

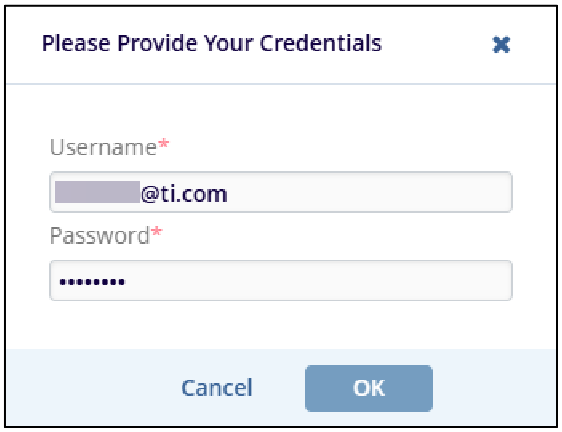


Figure: Please Provide Your Credentials screen

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.

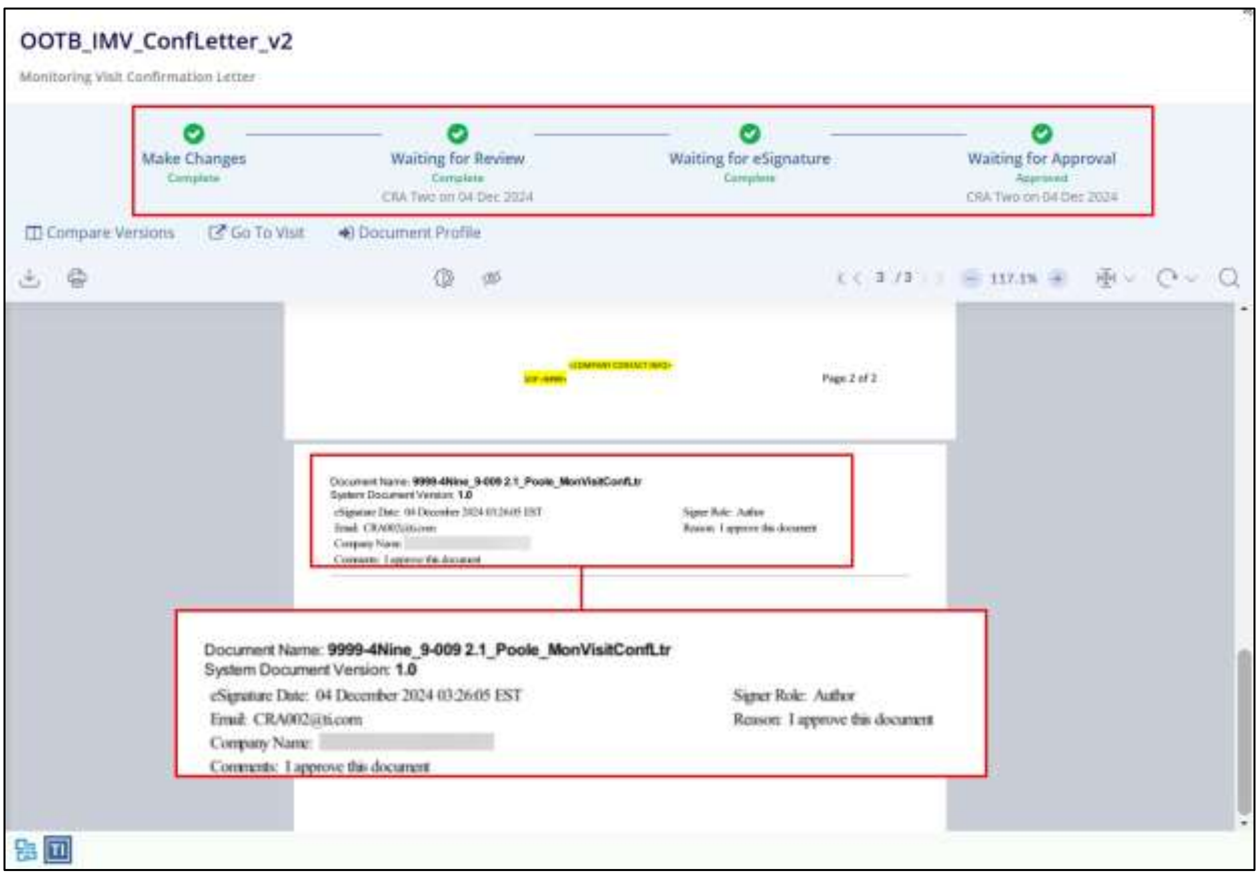


Figure: Approved and Signed Document

Site Visit Report Preview Generation

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.

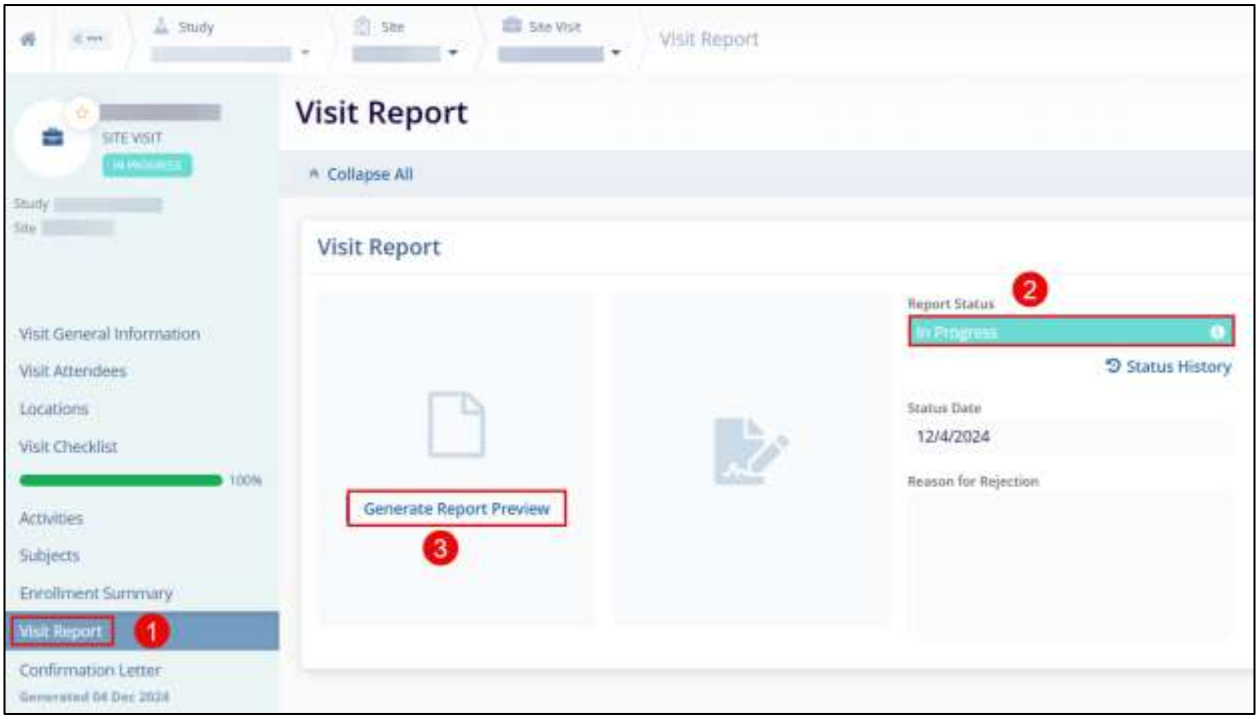


Figure: Generate Report Preview

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

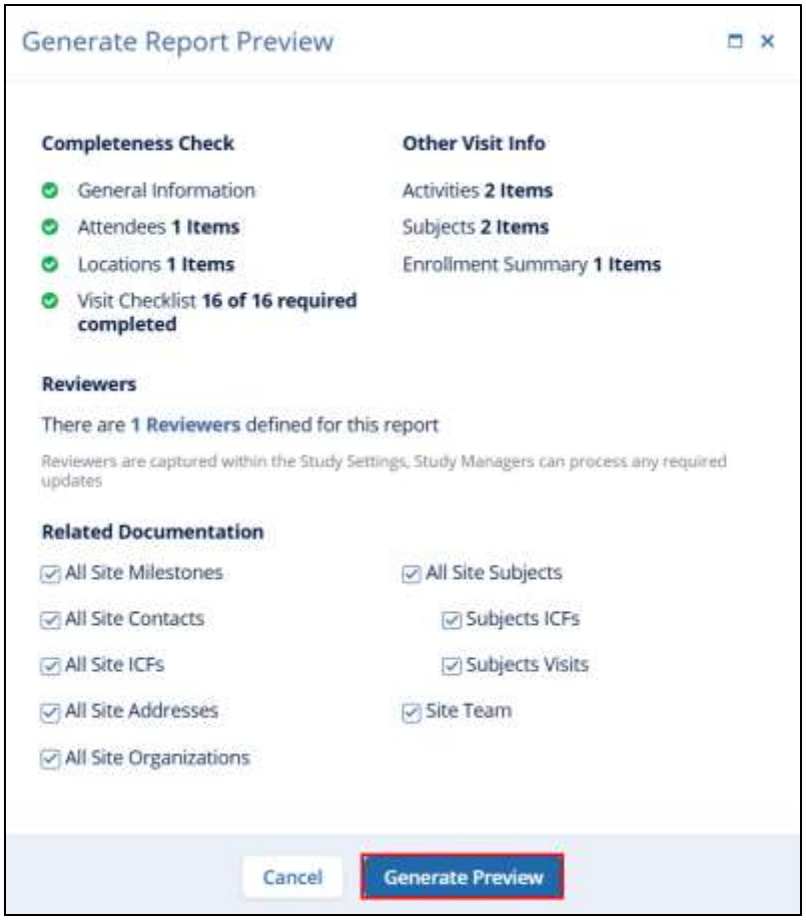


Figure: Confirm preview generation

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

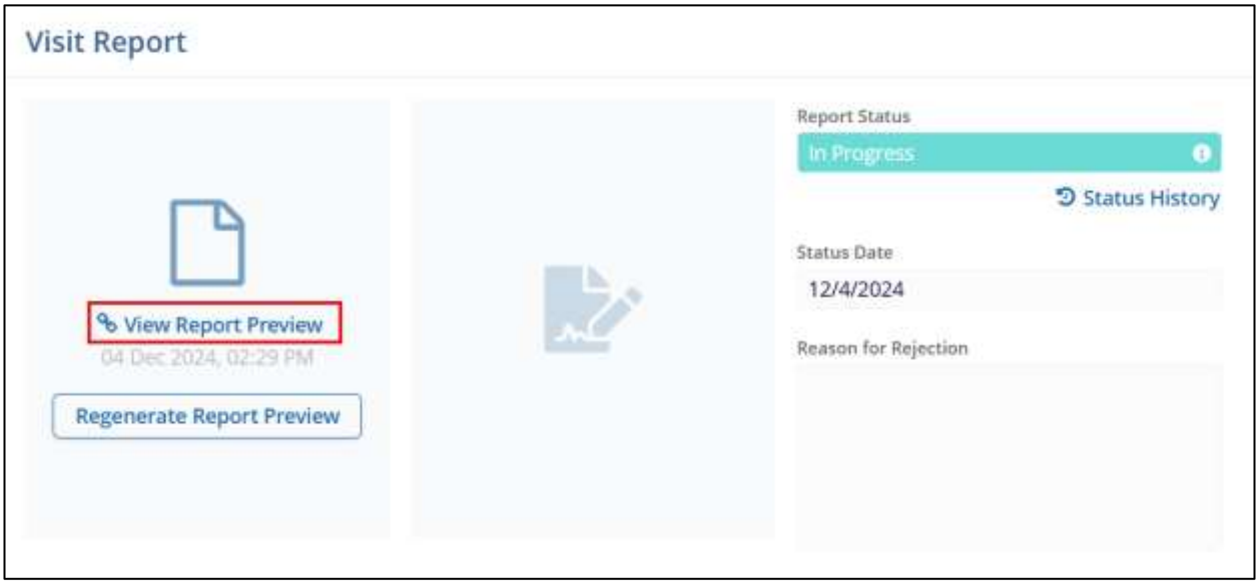


Figure: View Report Preview

Site Visit Final Report Generation

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.

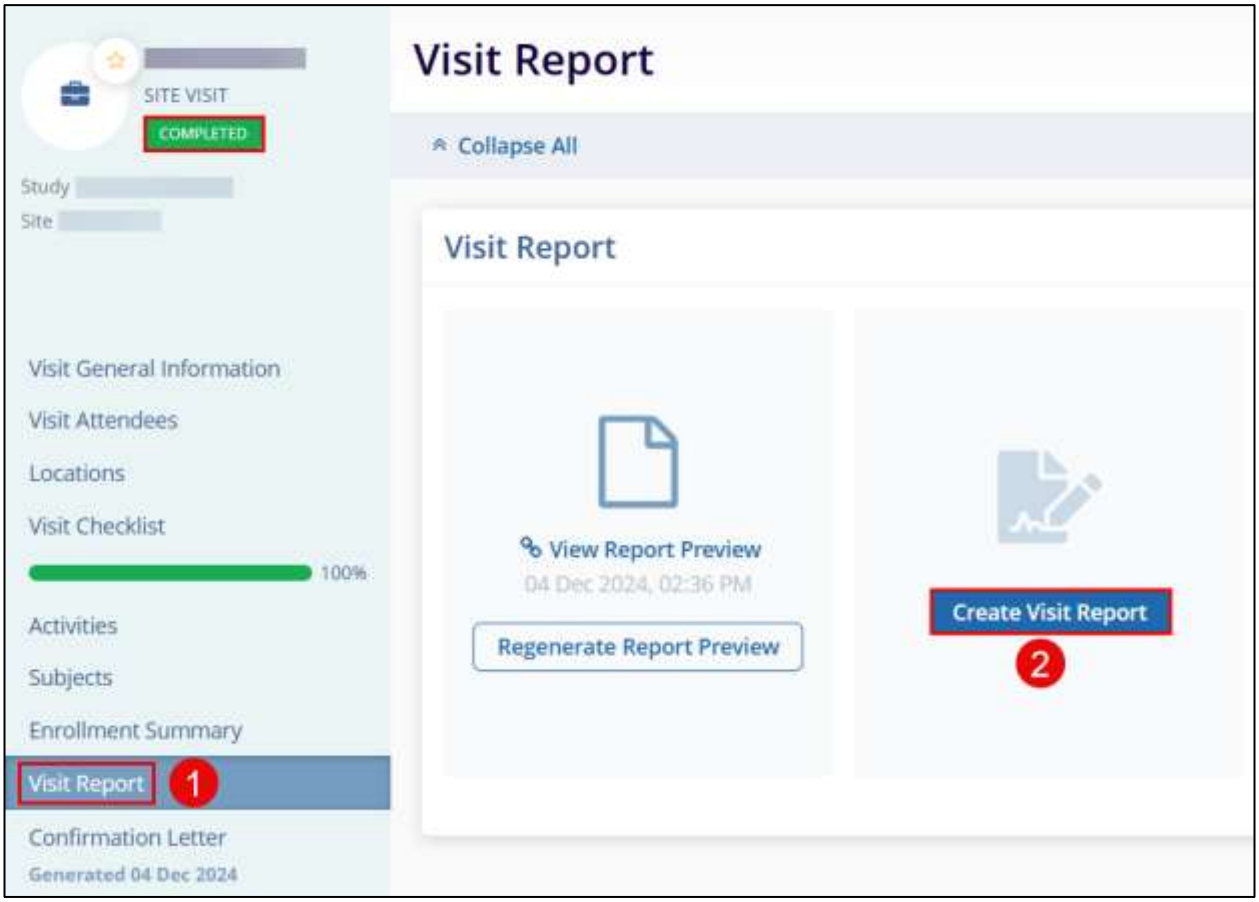


Figure: Create Visit Report

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

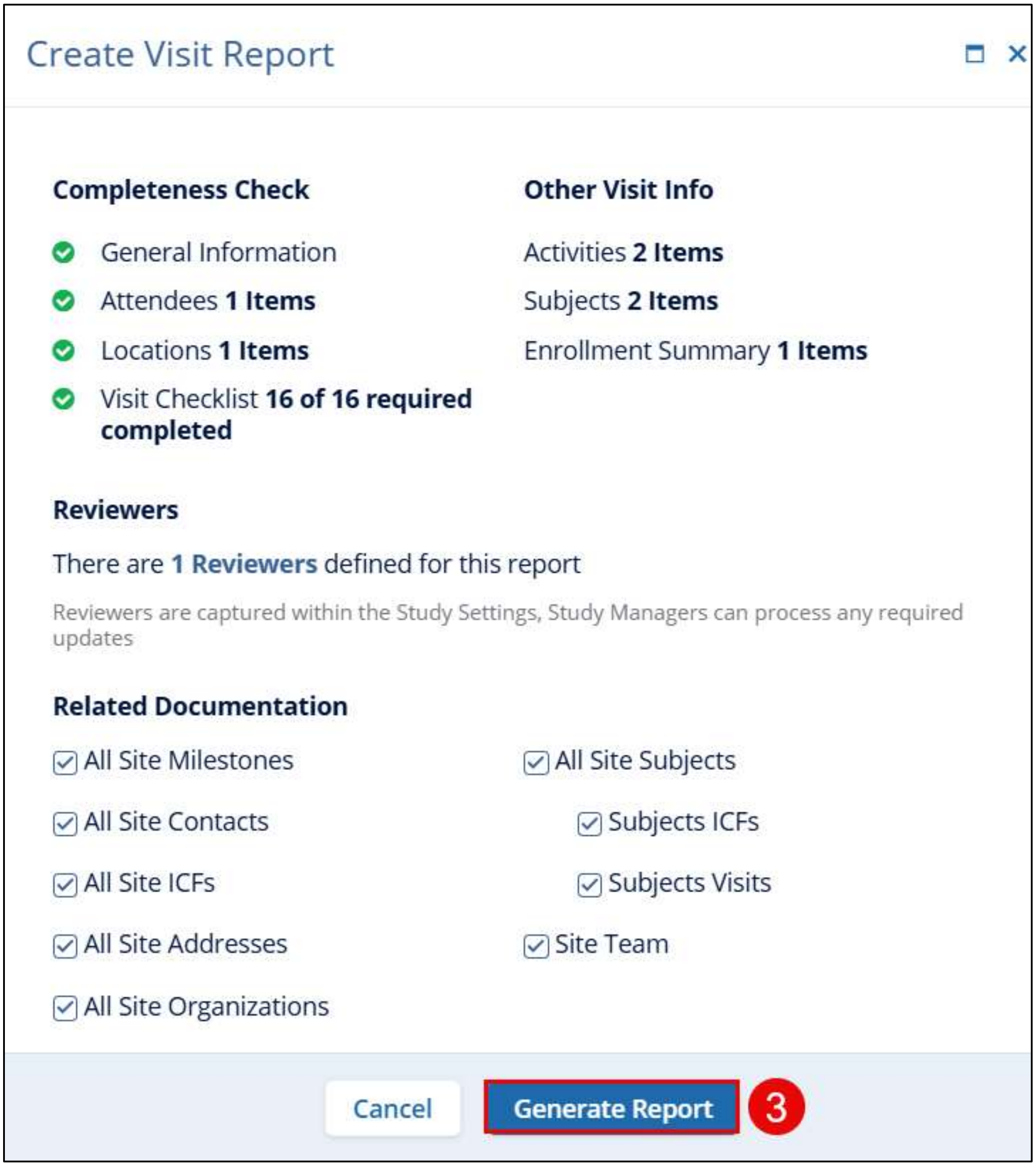


Figure: Generate Visit Report

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

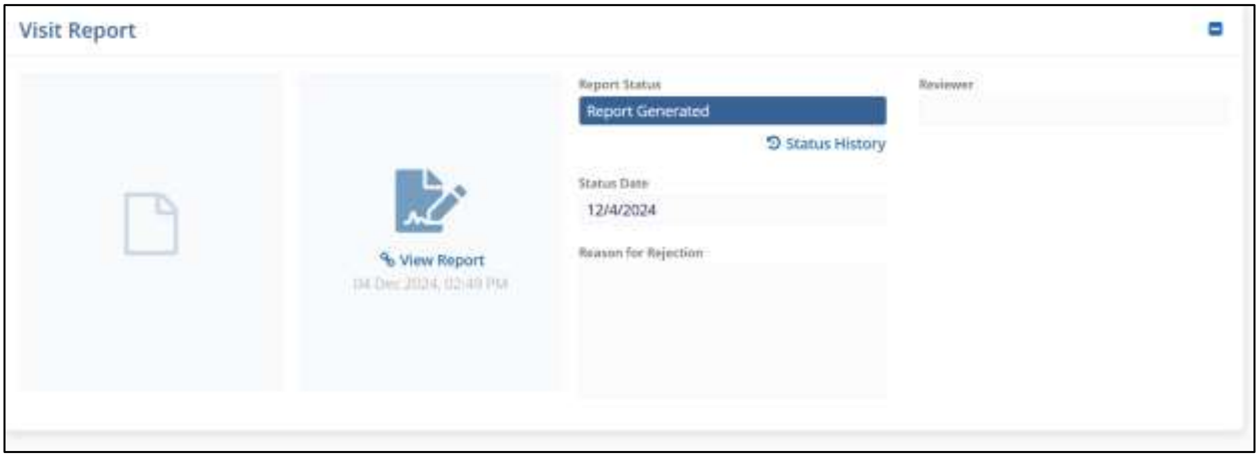


Figure: View Report

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

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.

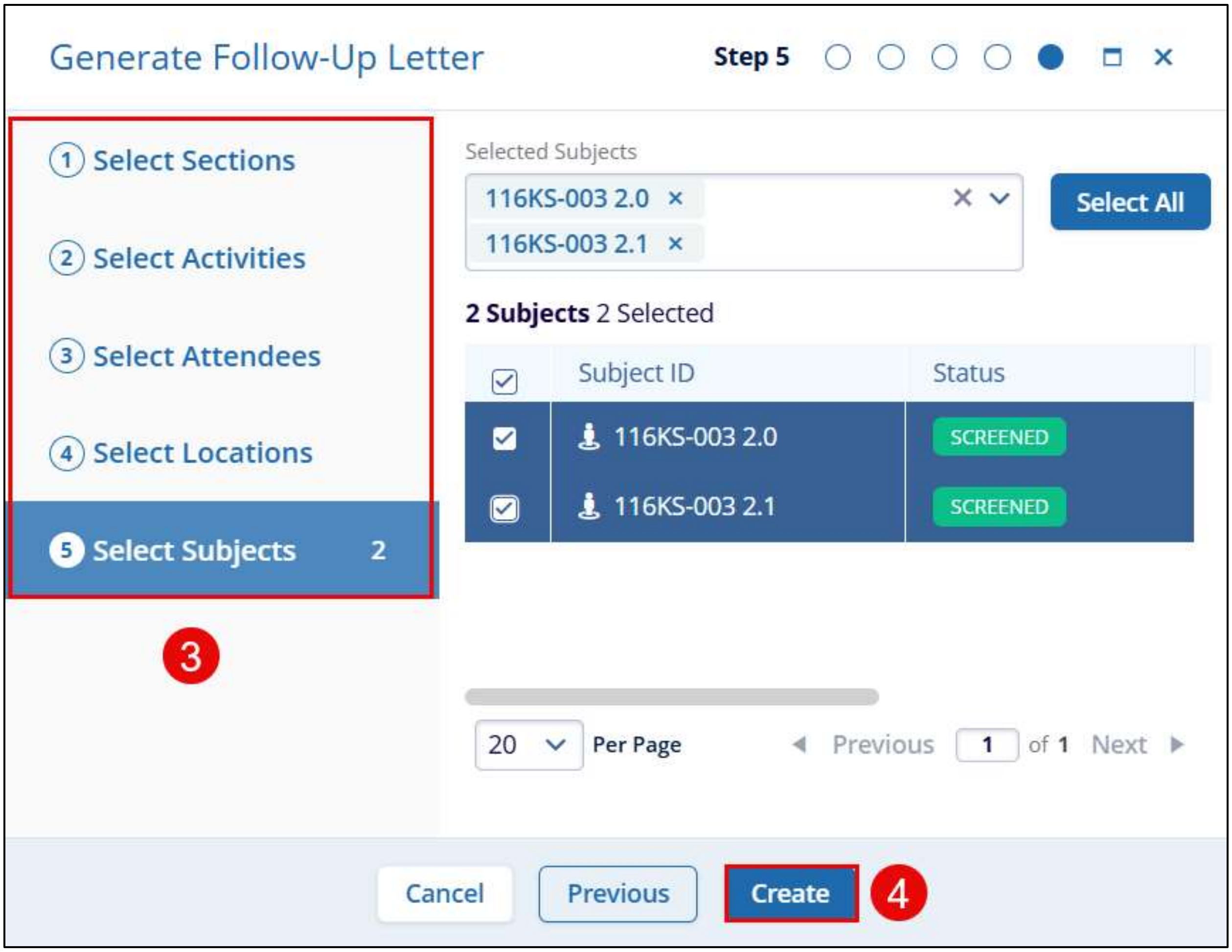


Figure: Generate Follow Up Letter

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.

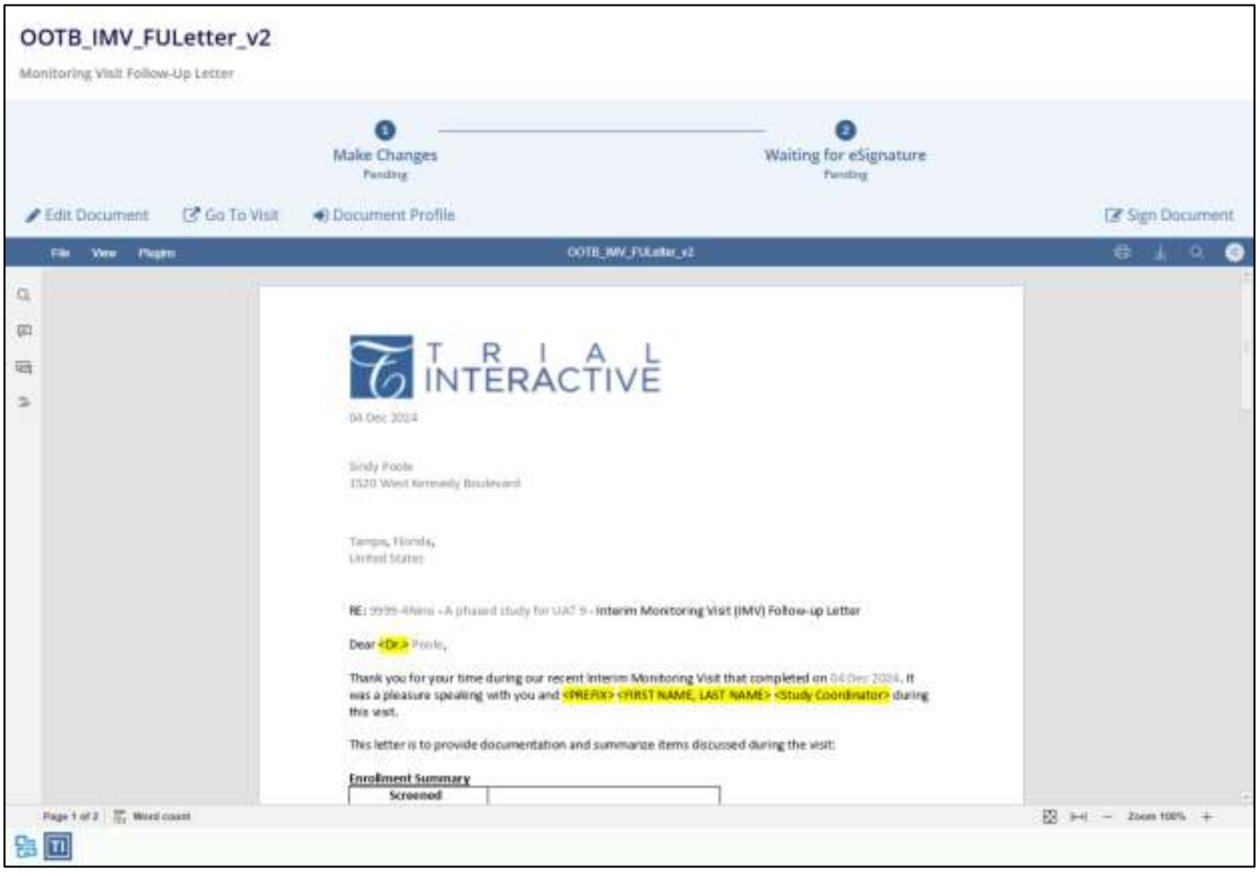


Figure: Follow-Up Letter in TI Document Viewer

Note: To electronically sign the follow-up letter, follow the standard steps detailed in the [Signing the Document and Approval Workflow](#) section.

Access Permissions

The Access Permissions feature helps the user add, edit, activate, and remove access permissions for other users. Users with Company Administrator access can modify the access permissions for other users.

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

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

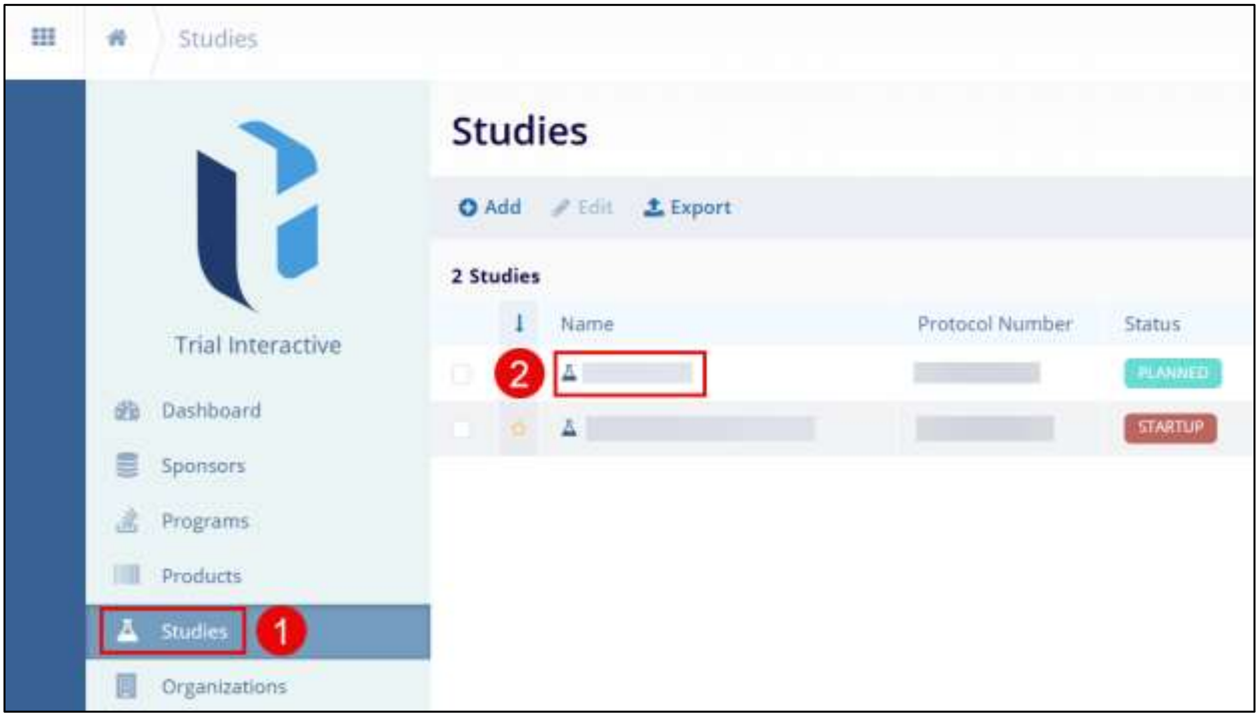


Figure: Select a Study and a study name

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

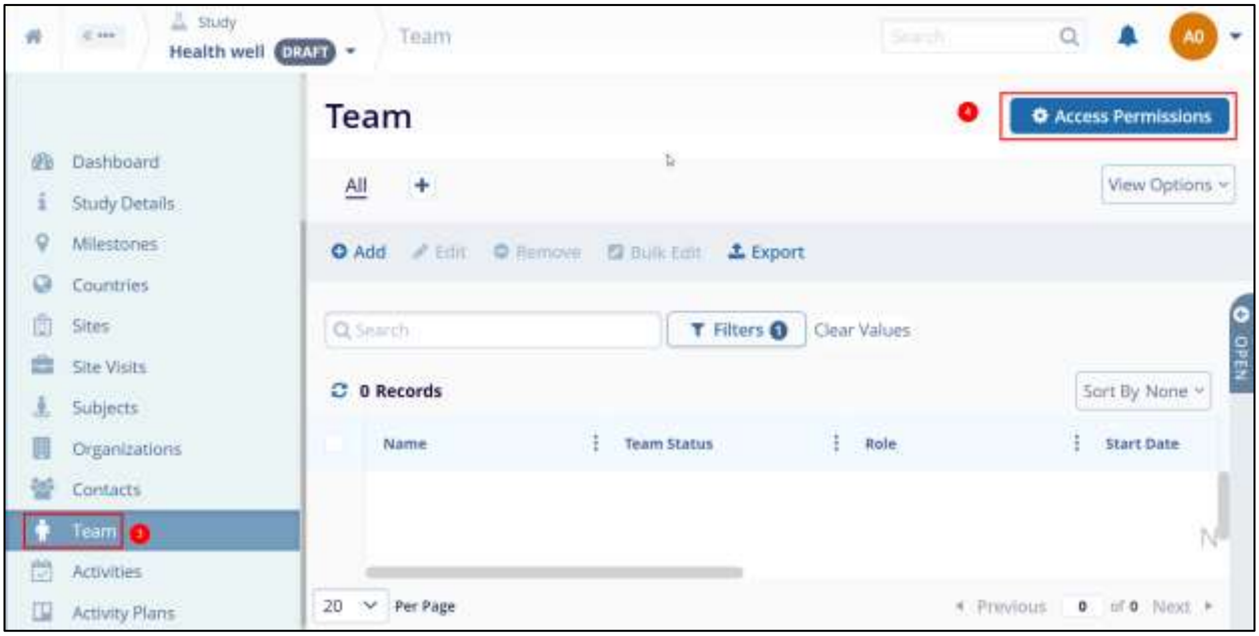


Figure Access Permissions

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

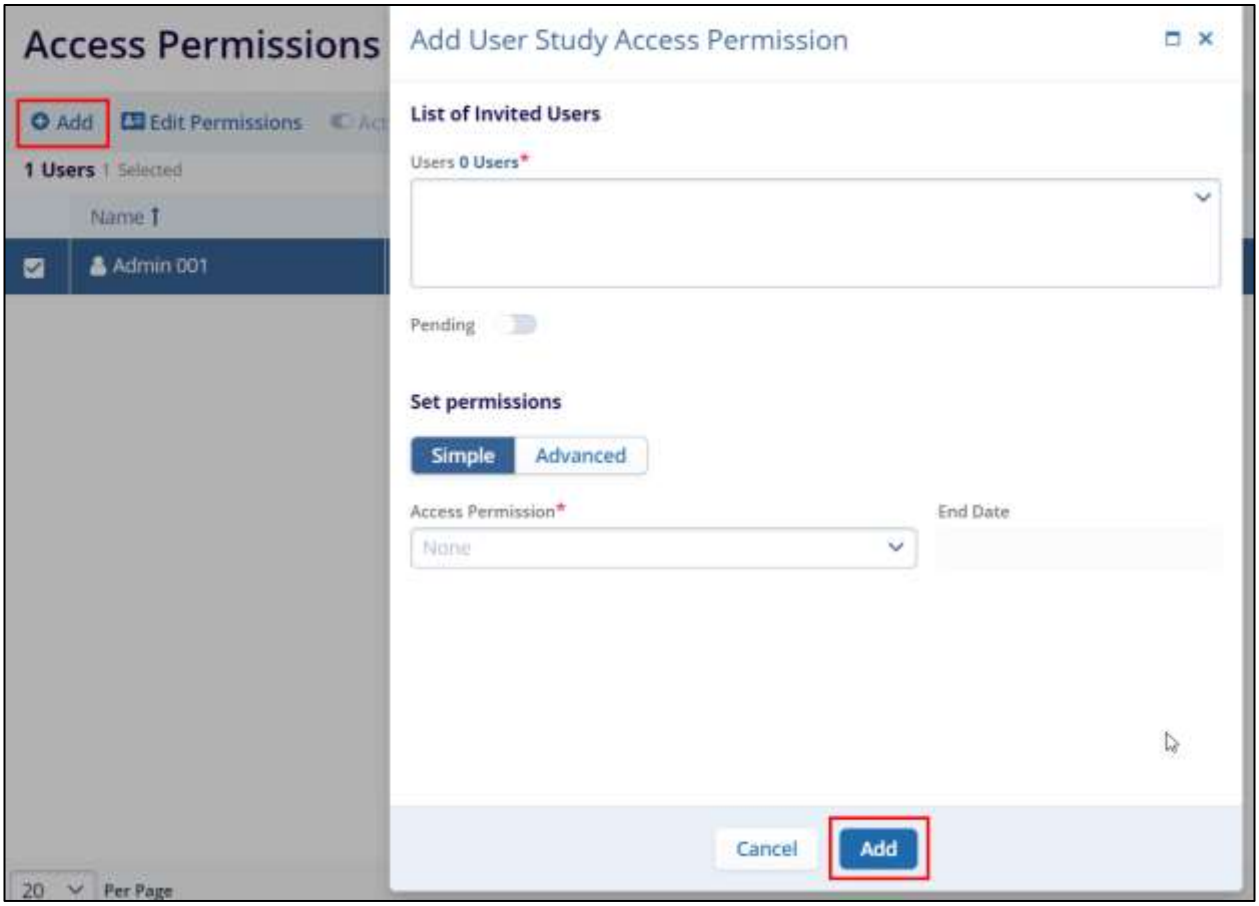


Figure: Add User

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

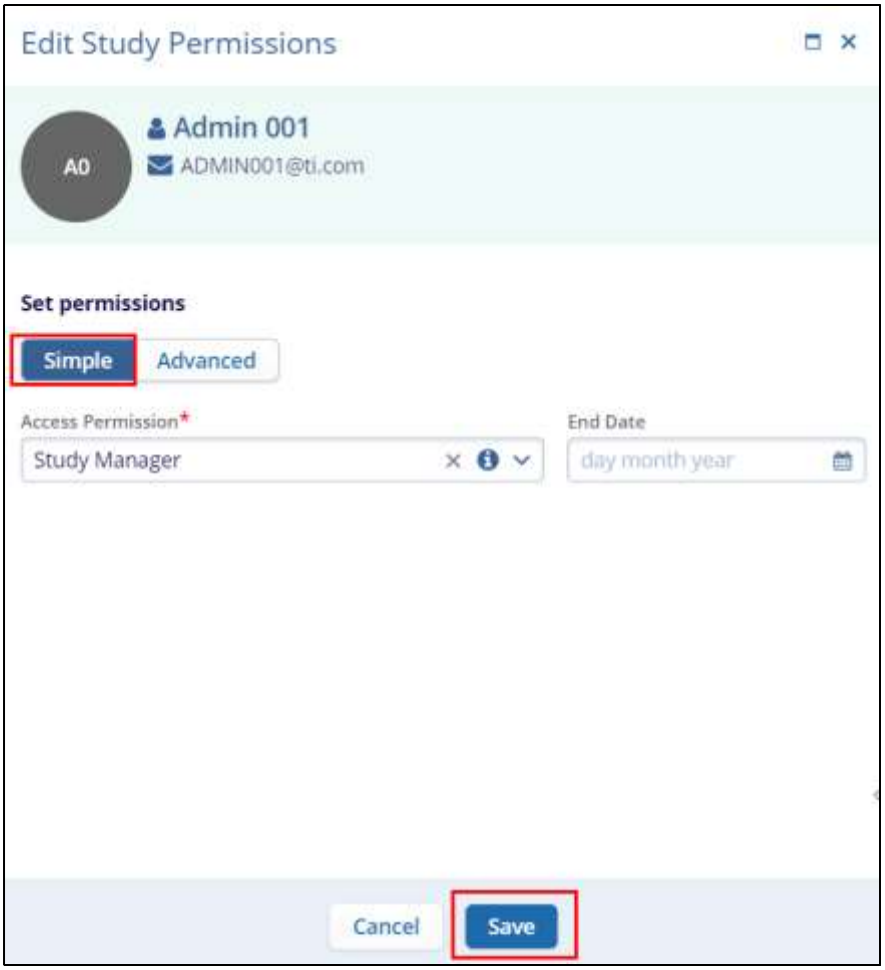


Figure: Edit Study Permissions-Simple

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

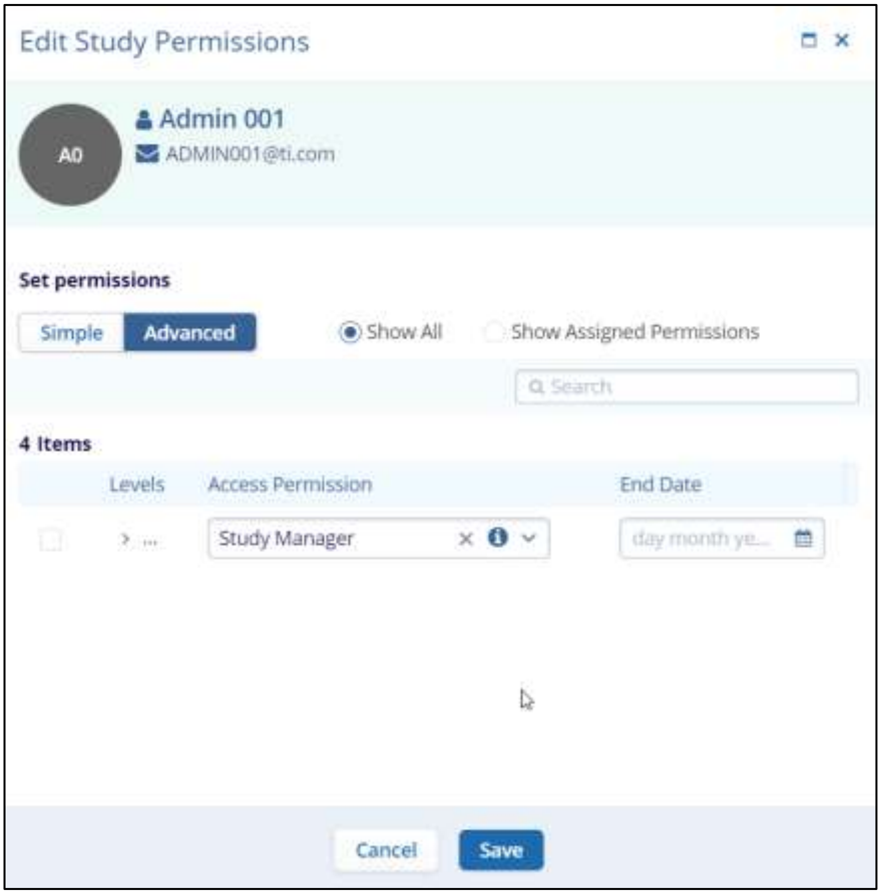


Figure: Edit Study Permissions-Advanced

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

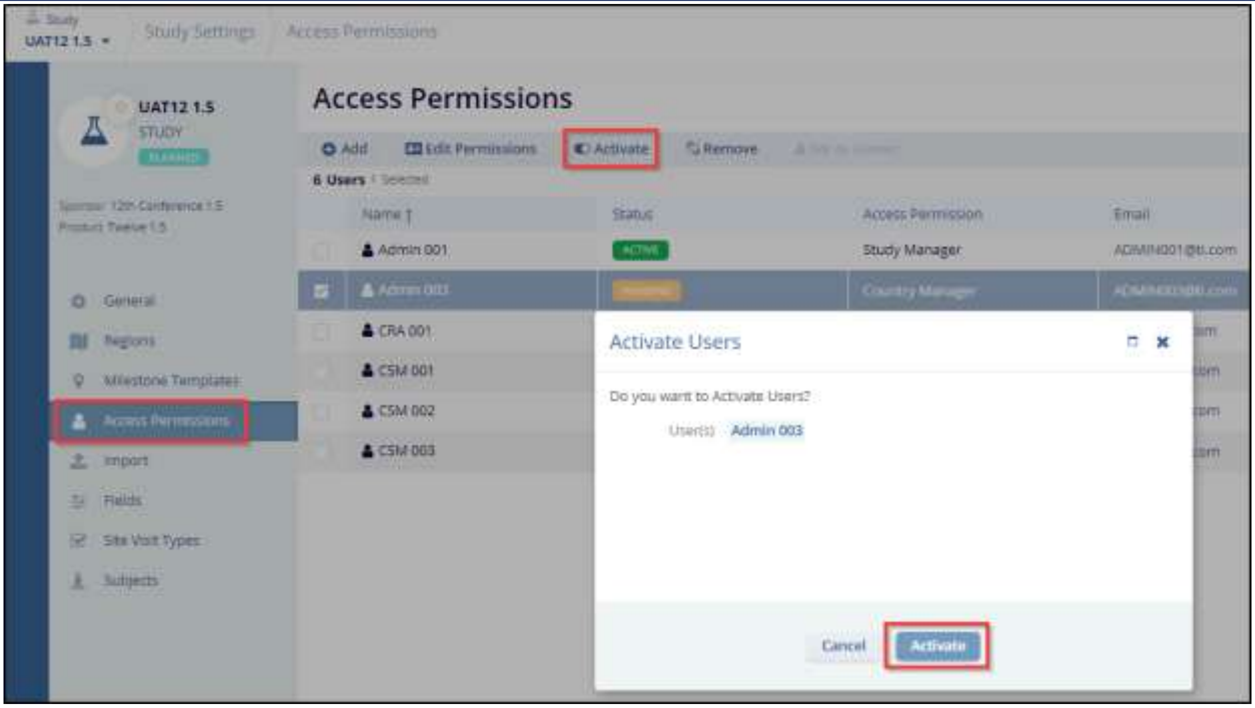


Figure: Activate users

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

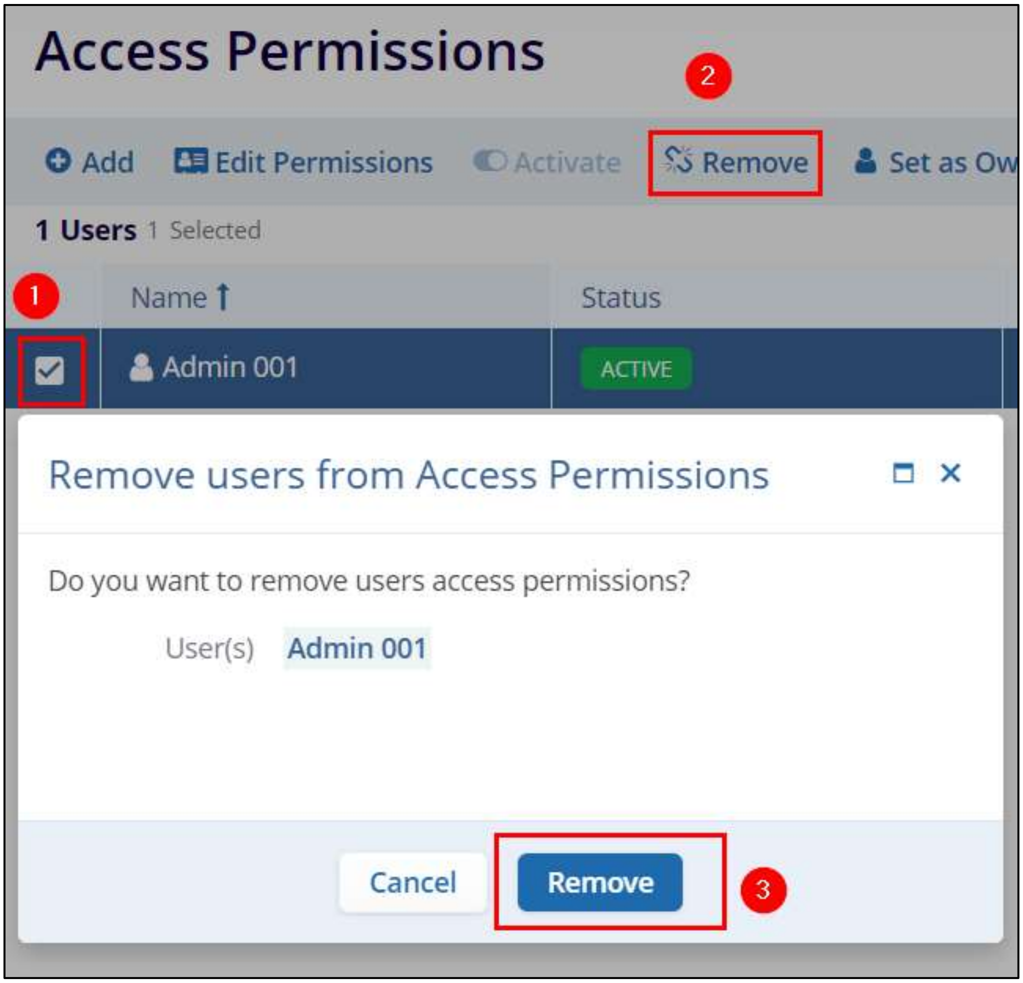


Figure: Remove the user

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

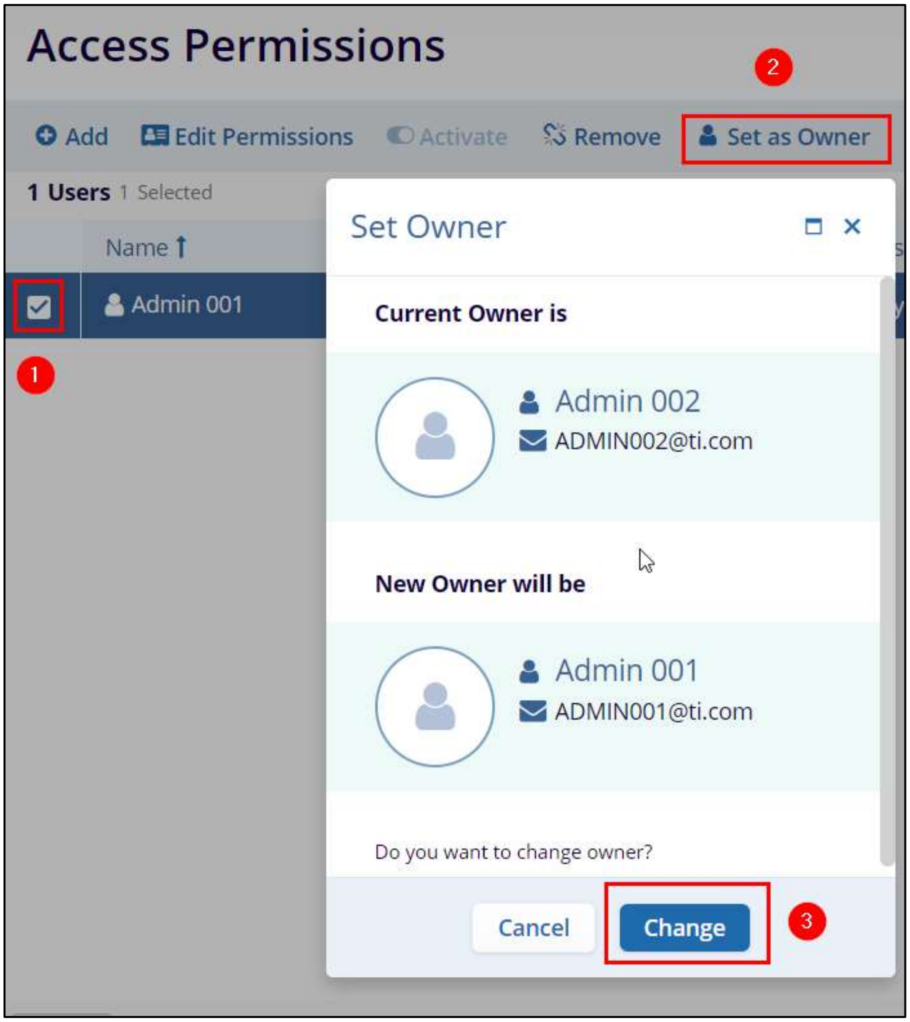


Figure: Set as Owner

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

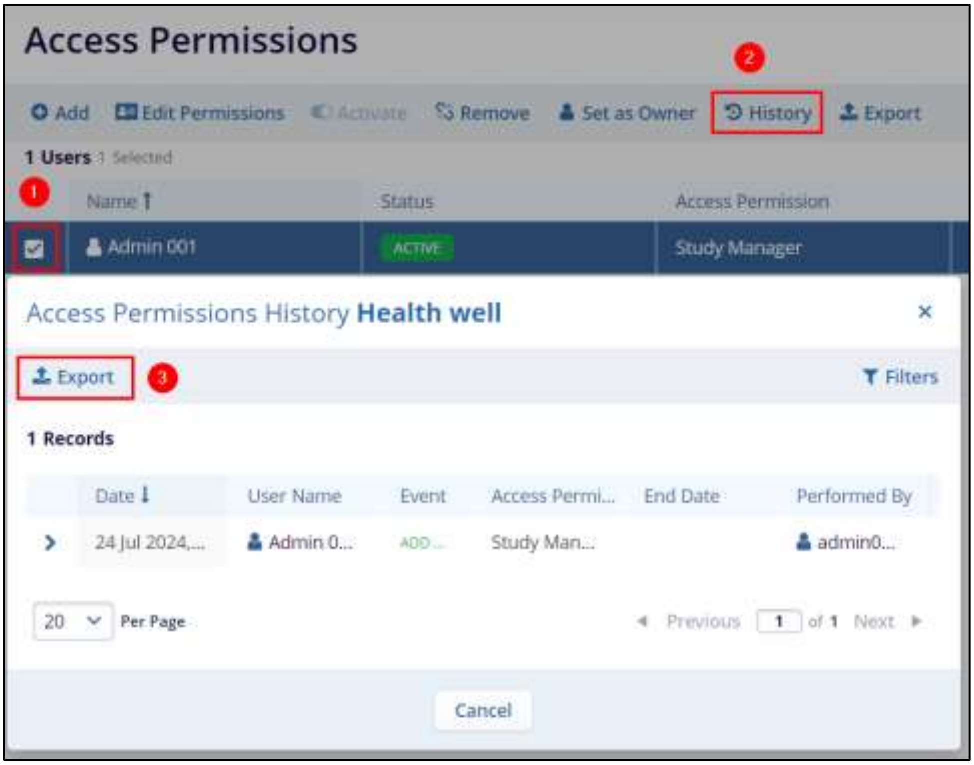


Figure: History

g. Export

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

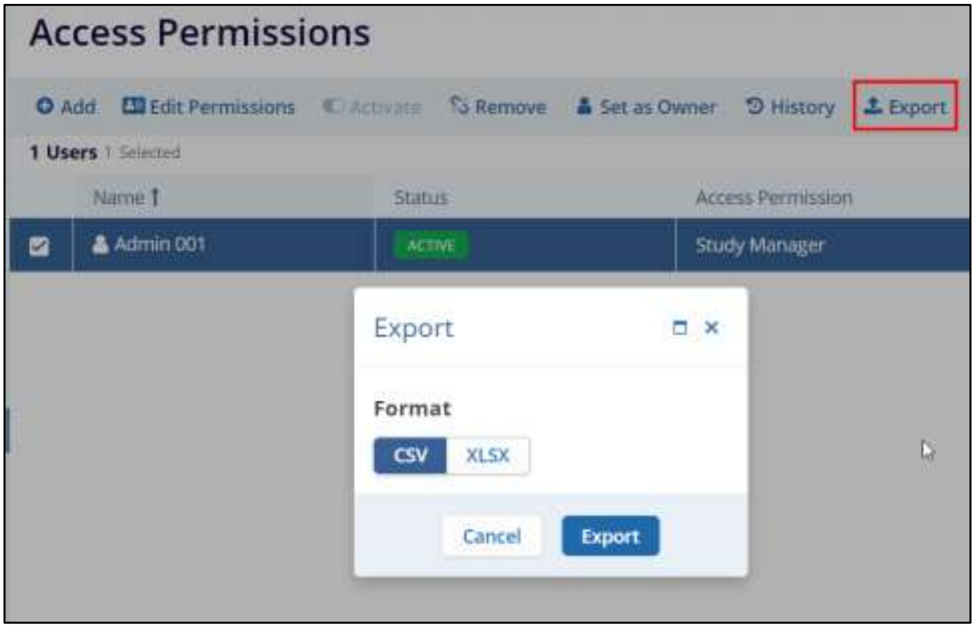


Figure: Export user details

Manage Visible Columns

To manage visible columns, follow the steps below.

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

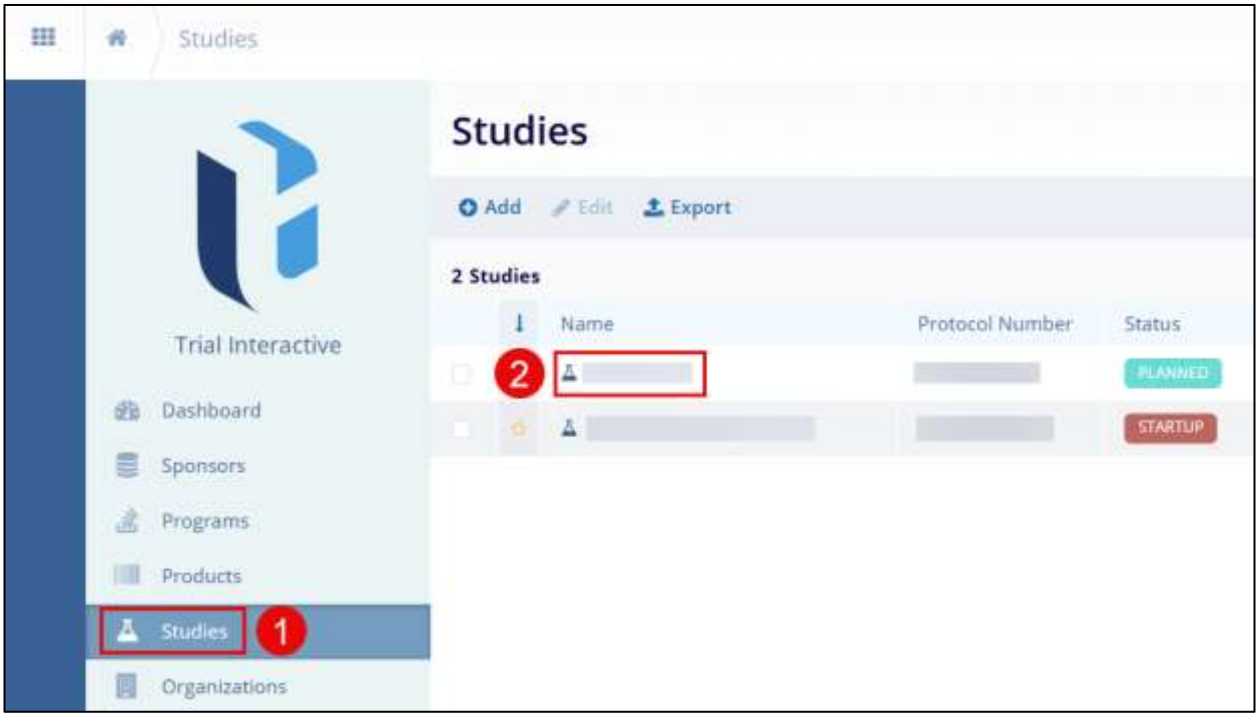


Figure: Select Study and Study name

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

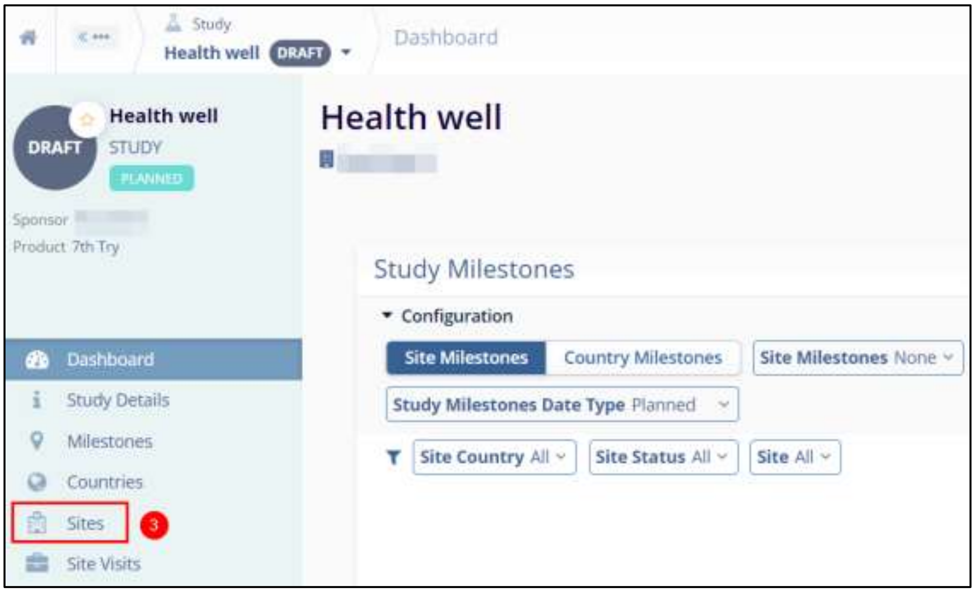


Figure: Select Sites

4. On the Site screen, navigate to the left-hand navigation links and select Activities.
5. Click on the Ellipsis (three-dot menu) displayed next to the Activity Name column.

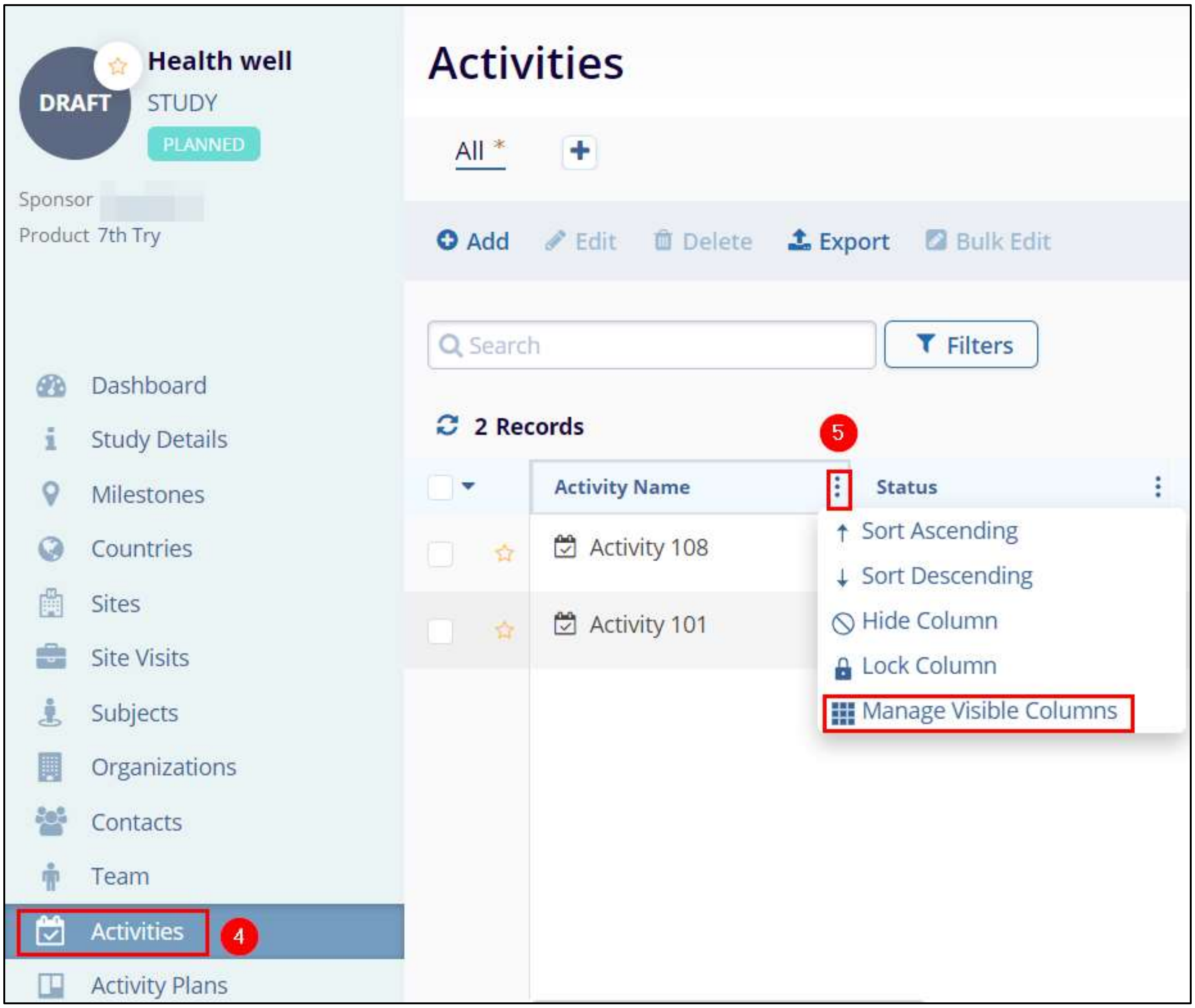


Figure: Manage Visible Columns

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

Create Contact Copy

To create a contact copy, follow the steps below.

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

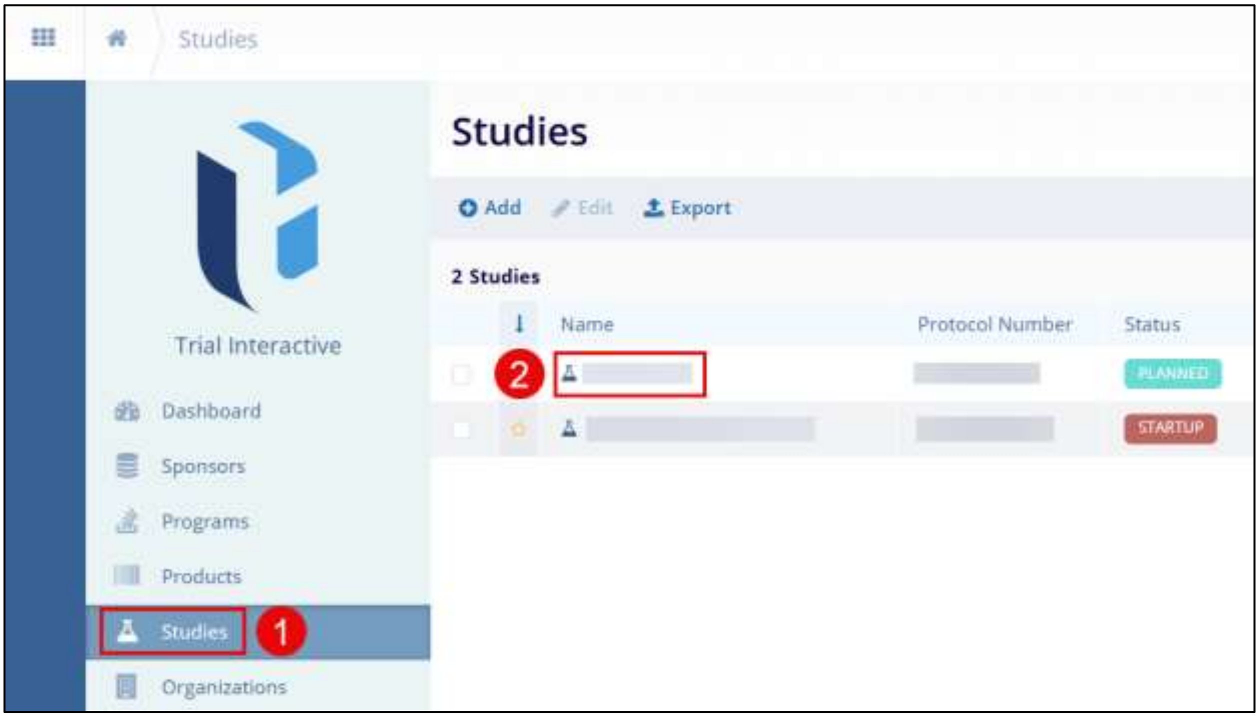


Figure: Select a Study and a study name

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

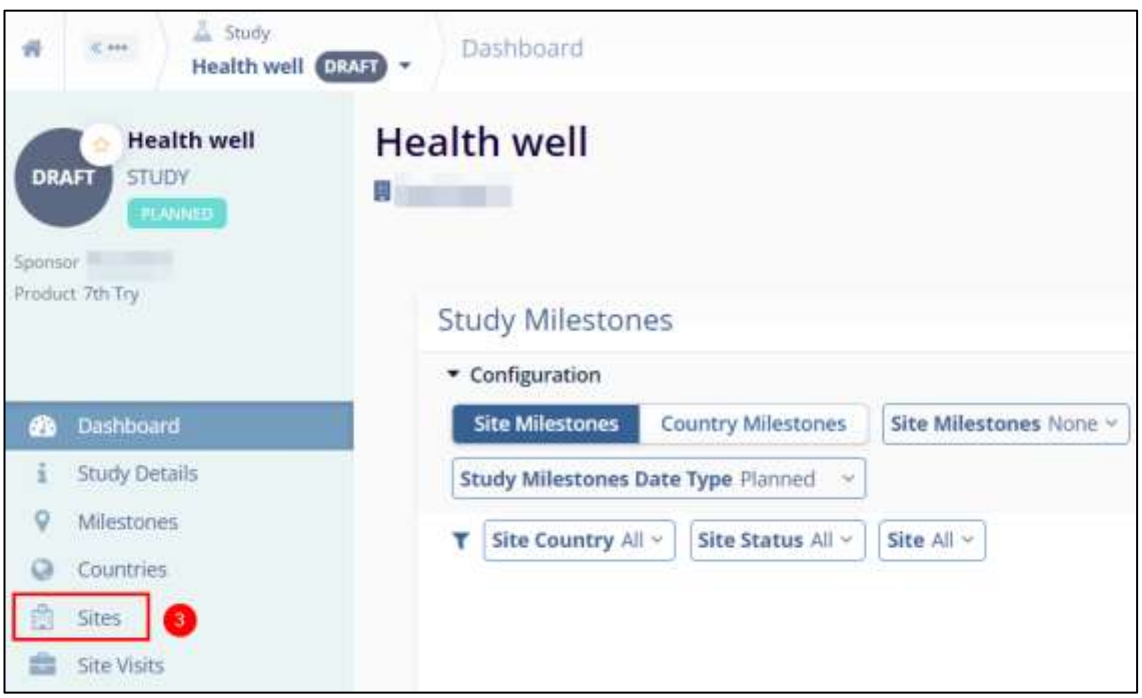


Figure: Select Sites from the Study Dashboard

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

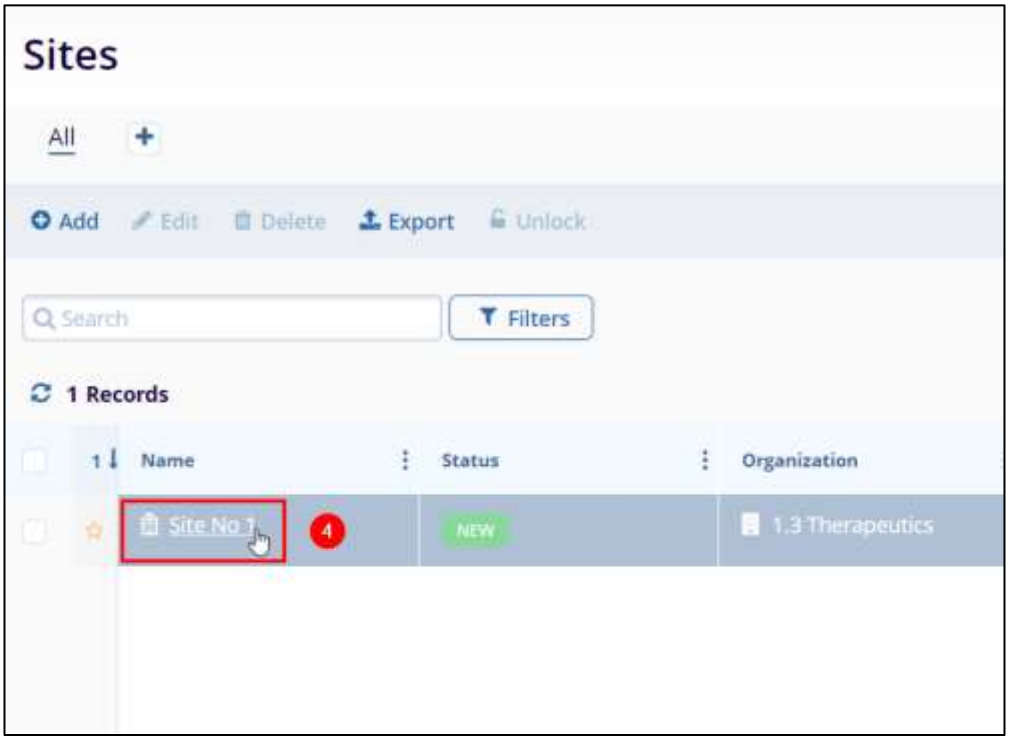


Figure: Select site

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

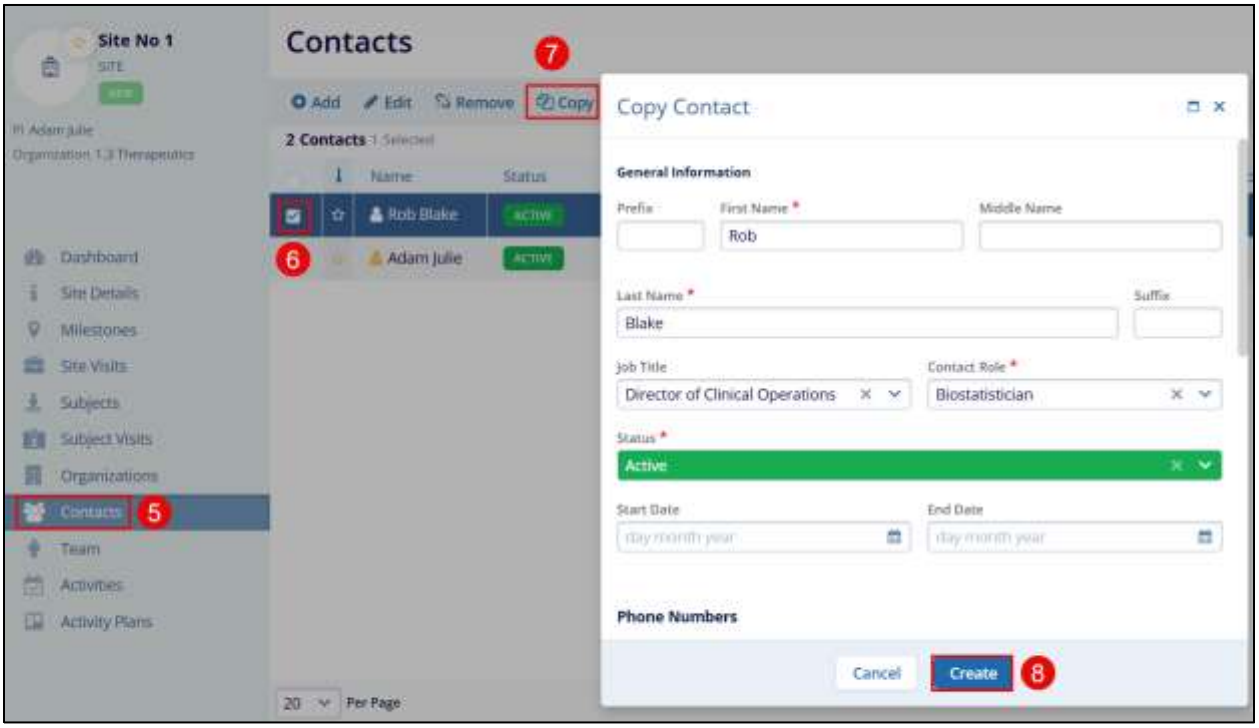


Figure: Create Contact Copy

User-Defined Site Visit Checklists

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

Creating a Site Visit Checklist

To create a Site Visit Checklist, follow the steps below

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

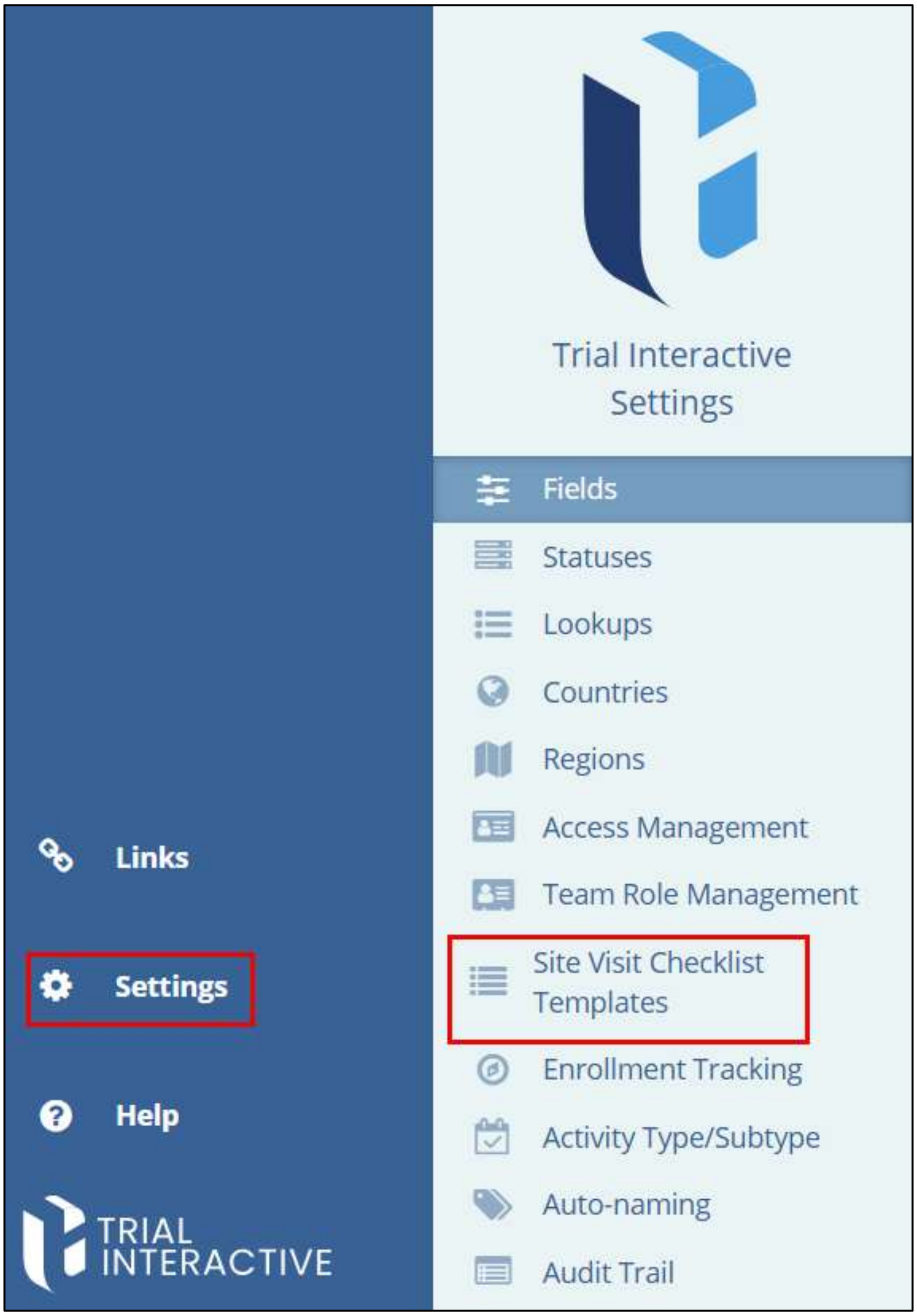


Figure: Site Visit Checklist Templates

2. Click on the +Create Template button at the top of the grid area.
   If users are creating a new template as a copy of an existing template, first, select the existing template and then press the Copy button.
3. On the 'Create Site Visit Checklist Template' screen, mandatorily enter the site visit checklist template name and optionally enter the description into their respective fields.
4. Click on the Create button

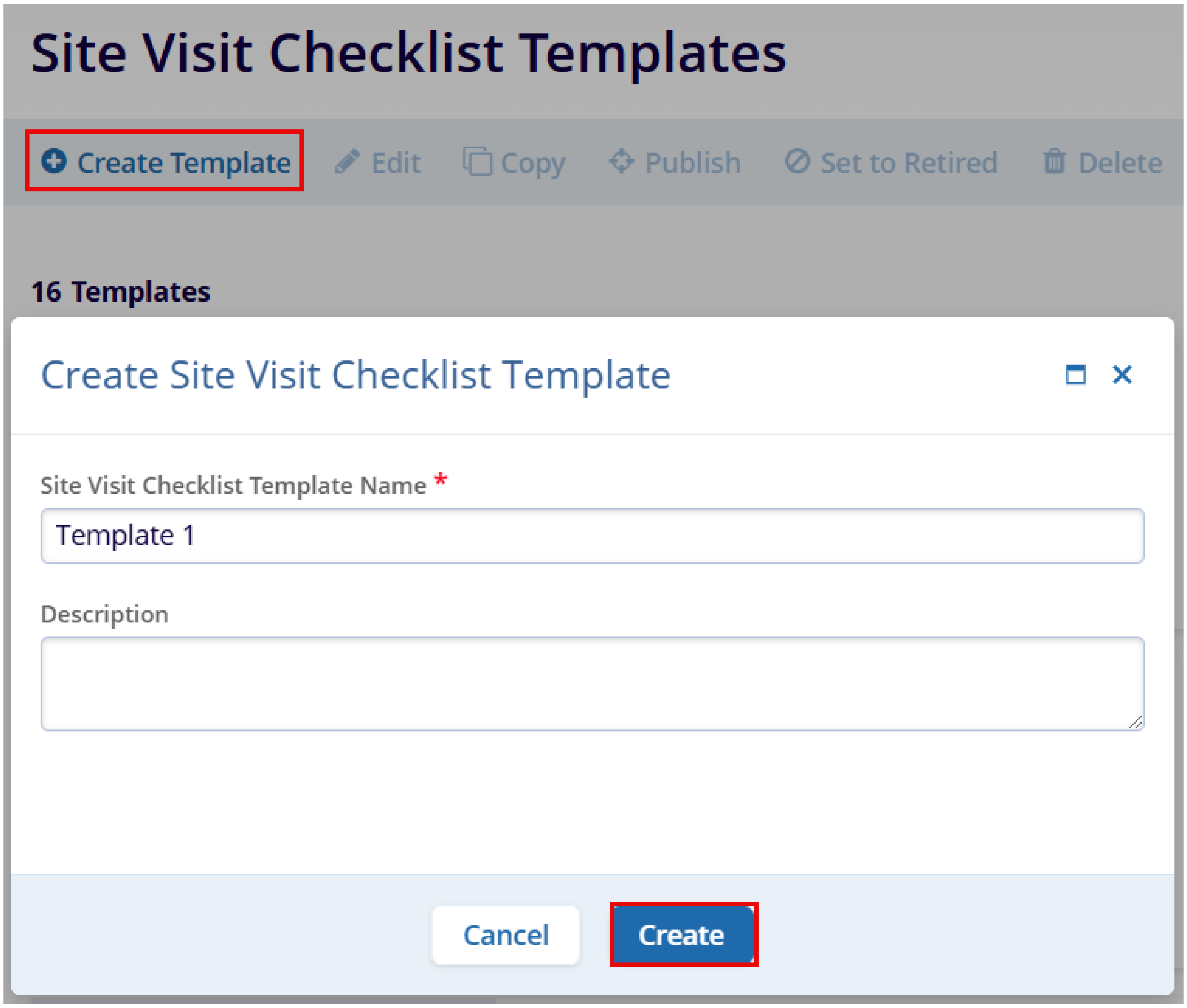


Figure: Create Site Visit Checklist template

Note:

- We recommend providing a description whenever possible, especially when you may have multiple similar checklist templates. The description can assist you in applying the correct checklist when needed.
- The checklist will be in Draft status initially because we still need to add questions to the checklist before publishing it for use.

5. Select the new checklist from the list.

6. Click Edit from the menu bar at the top of the grid.

Figure: Edit Template

7. On the site visit screen, make the required edits to the section title and description.
8. 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.
9. Press the +Add Section button and a new section box will appear.

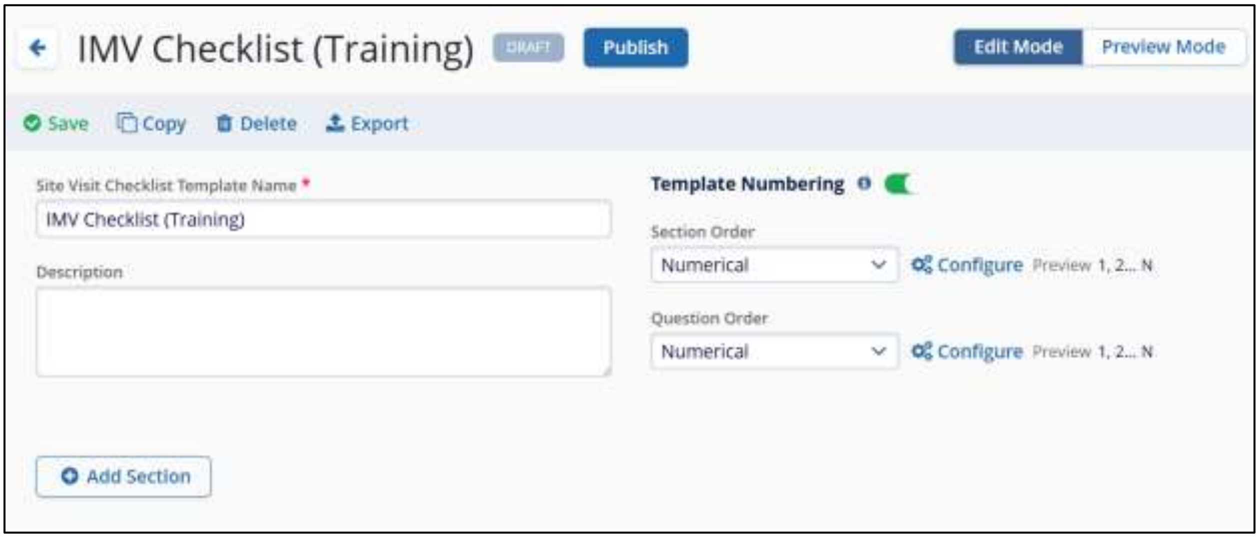


Figure: Checklist Profile

10. Give the section a title and a description.
11. Press the +Add Question button in the new section.

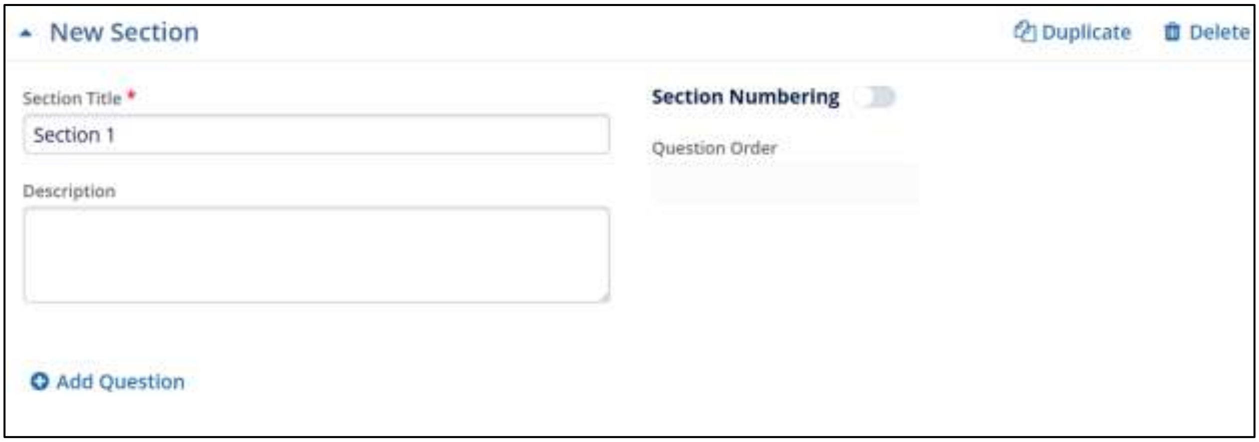


Figure: New Section

12. Type in the question and select the type of question from the dropdown menu.
13. Continue adding sections and questions until the checklist is complete

Figure: Add Question

14. 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.

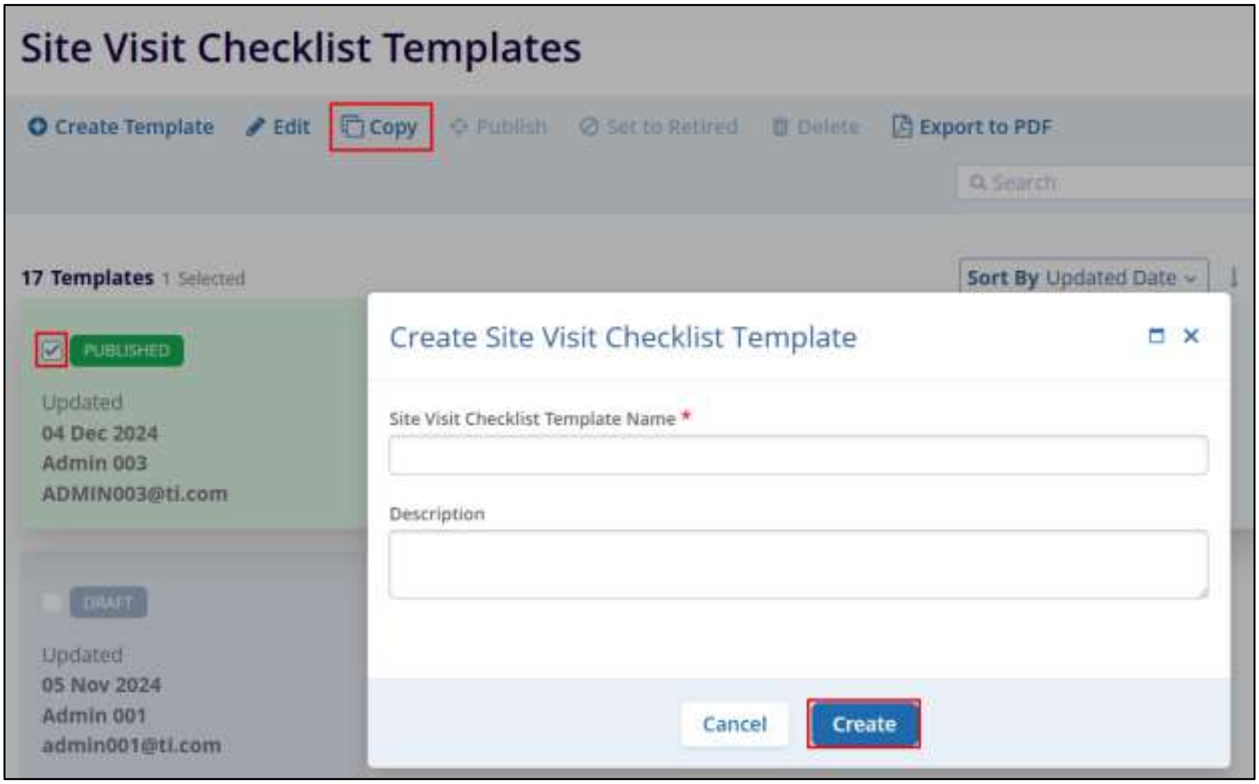


Figure: Copy Site Visit Checklist Template

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

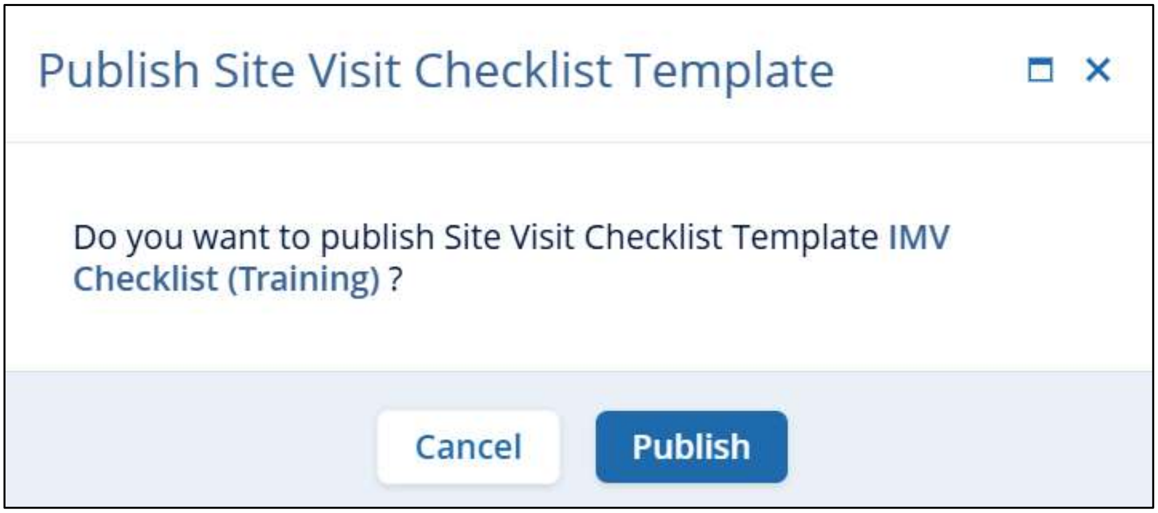


Figure: Publish Site Visit Template

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

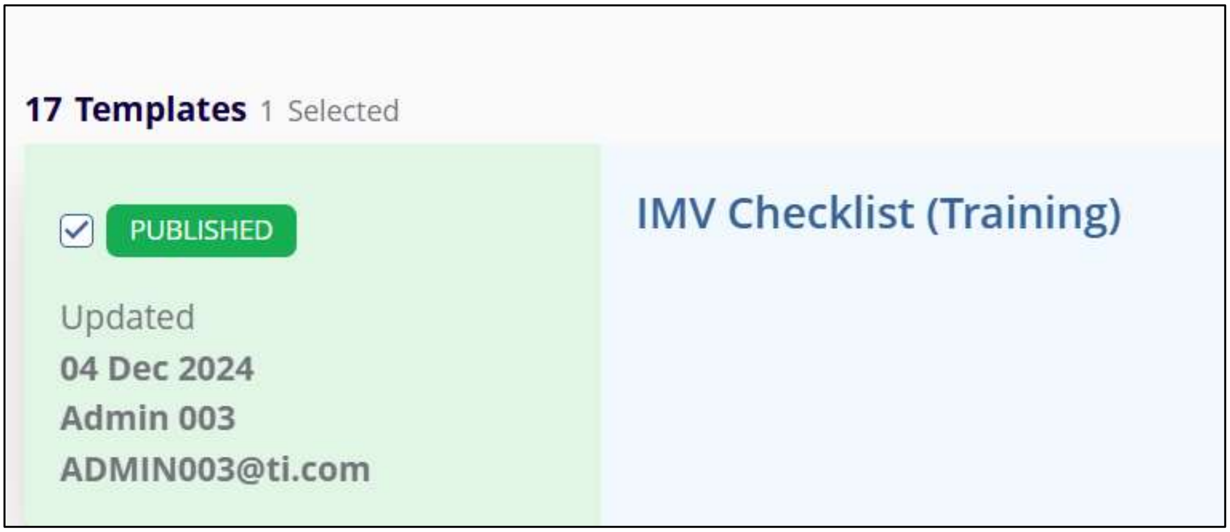


Figure: Published Template

Retiring a Site Visit Checklist

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

To Retire a Site Visit Checklist Template:

1. Navigate to the Settings area and select the Site Visit Checklist Templates option from the navigation links at the left side of the screen.
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, and the checklist will be displayed as Retired.

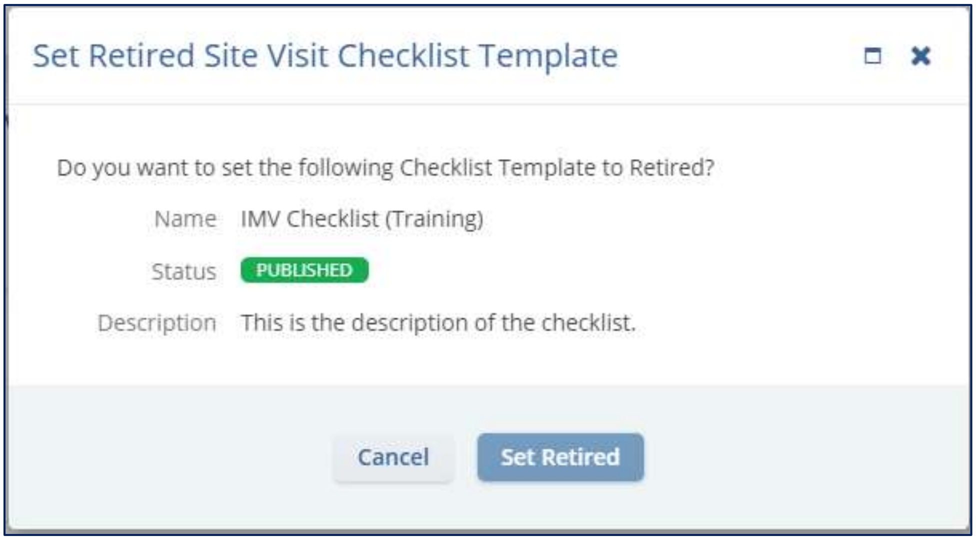


Figure: Set template as Retired

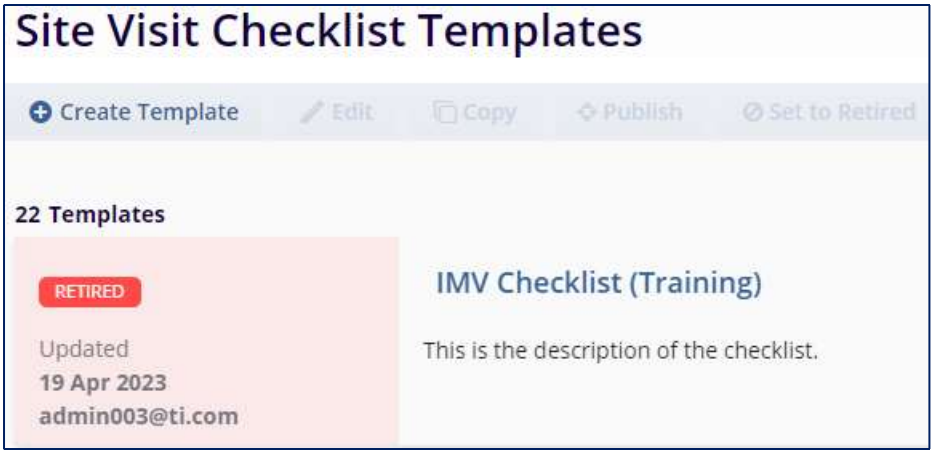


Figure: Retired Template

Deleting a Site Visit Checklist

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

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

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

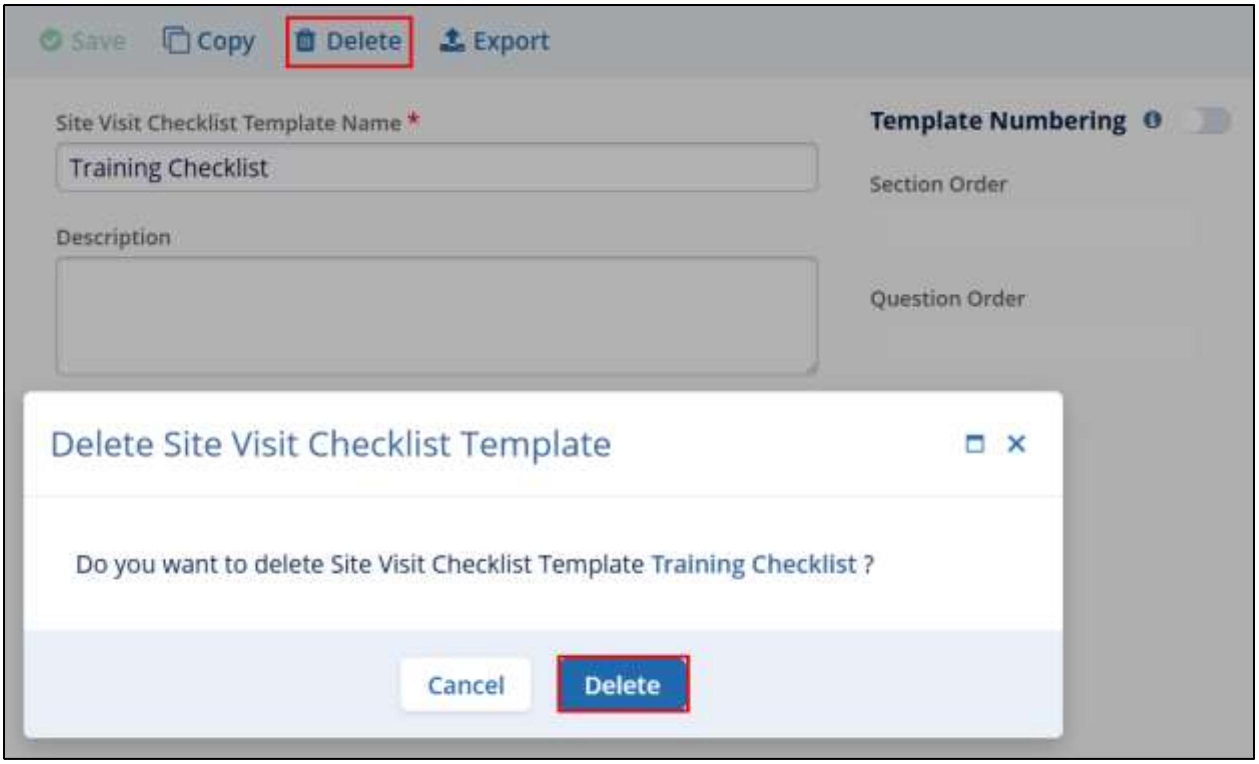


Figure: Delete Site Visit Checklist template

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.

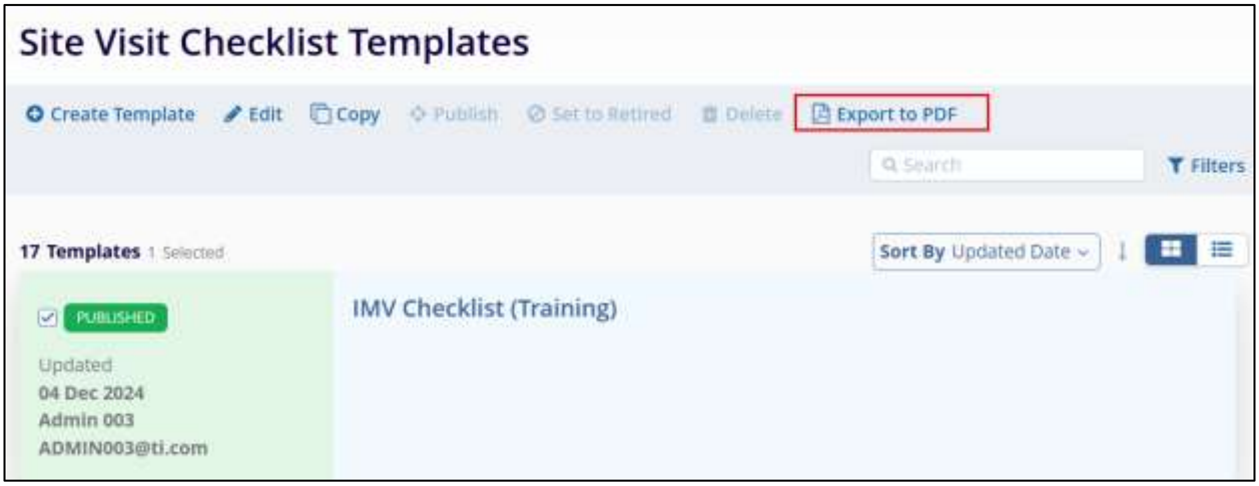


Figure: Export to PDF

2. Click on the Export button on the ‘Export Site Visit Checklist Template’.

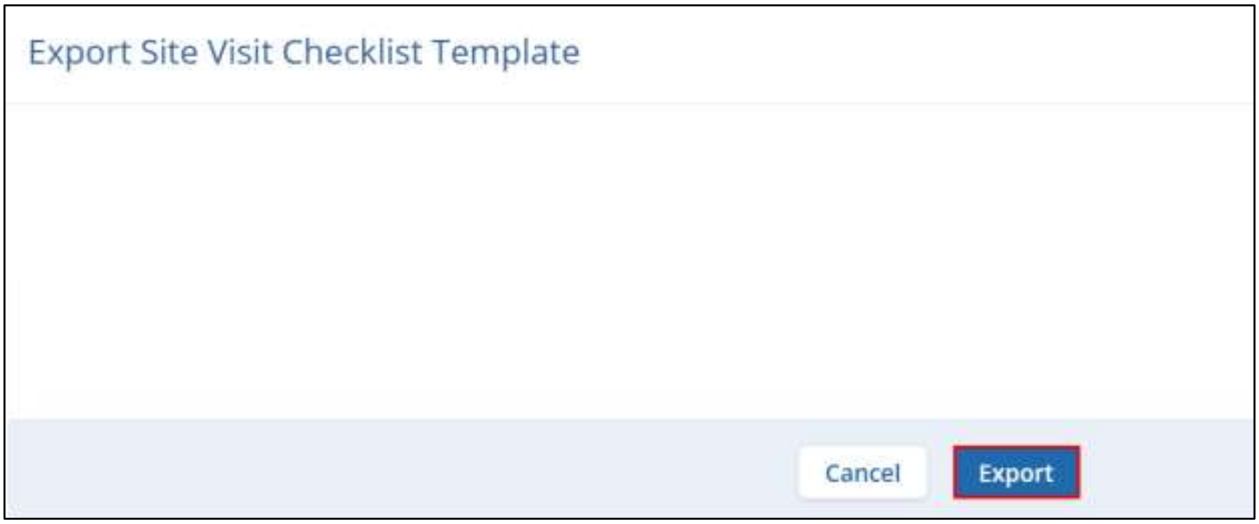


Figure: Export Site Visit Checklist Template

Auto-Saving Answers for Site Visit Checklists

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

Unblinded Visit Type Naming Requirements

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

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

- Site Visits,
- Site Visit Reports,
- Visit Report Content (responses),
- Subject related comments, and

Unblinded activities/actions.

CHAPTER 8. ORGANIZATIONS

Pre-requisites

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

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

Users with system access permissions can perform the following actions:

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

Creating an Organization

To create an organization, follow the steps below.

1. Click on the "Organizations" located in the navigation link on the left side of the screen. This action will redirect you to the "Organizations" list where all organizations at the Global level are displayed.
2. To add a new organization, click the "+Add" button from the menu bar above the grid.

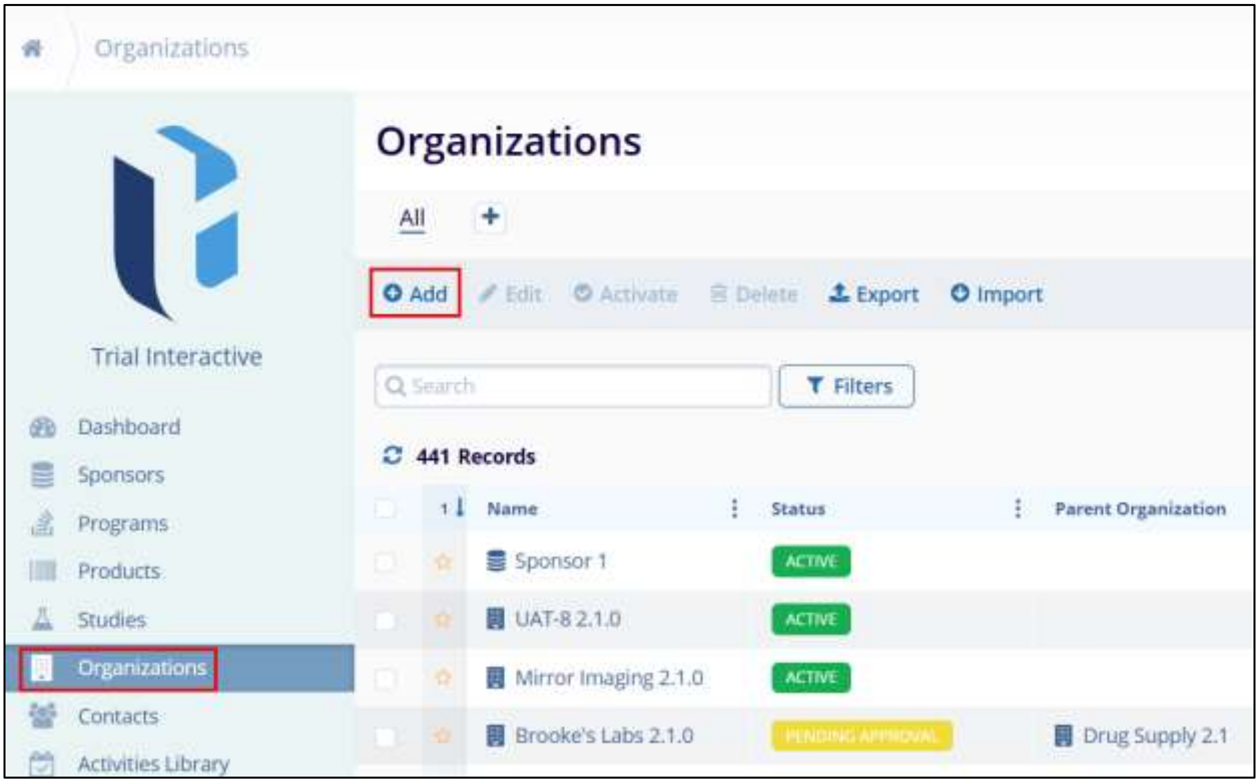


Figure: Add Organization

3. On the Create Organization screen, fill in the necessary details in the respective sections.

General Information

- Name: Enter the name of the organization in the "Name" field.
- Number: Enter the unique number for an 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. Refer to the screenshot below.

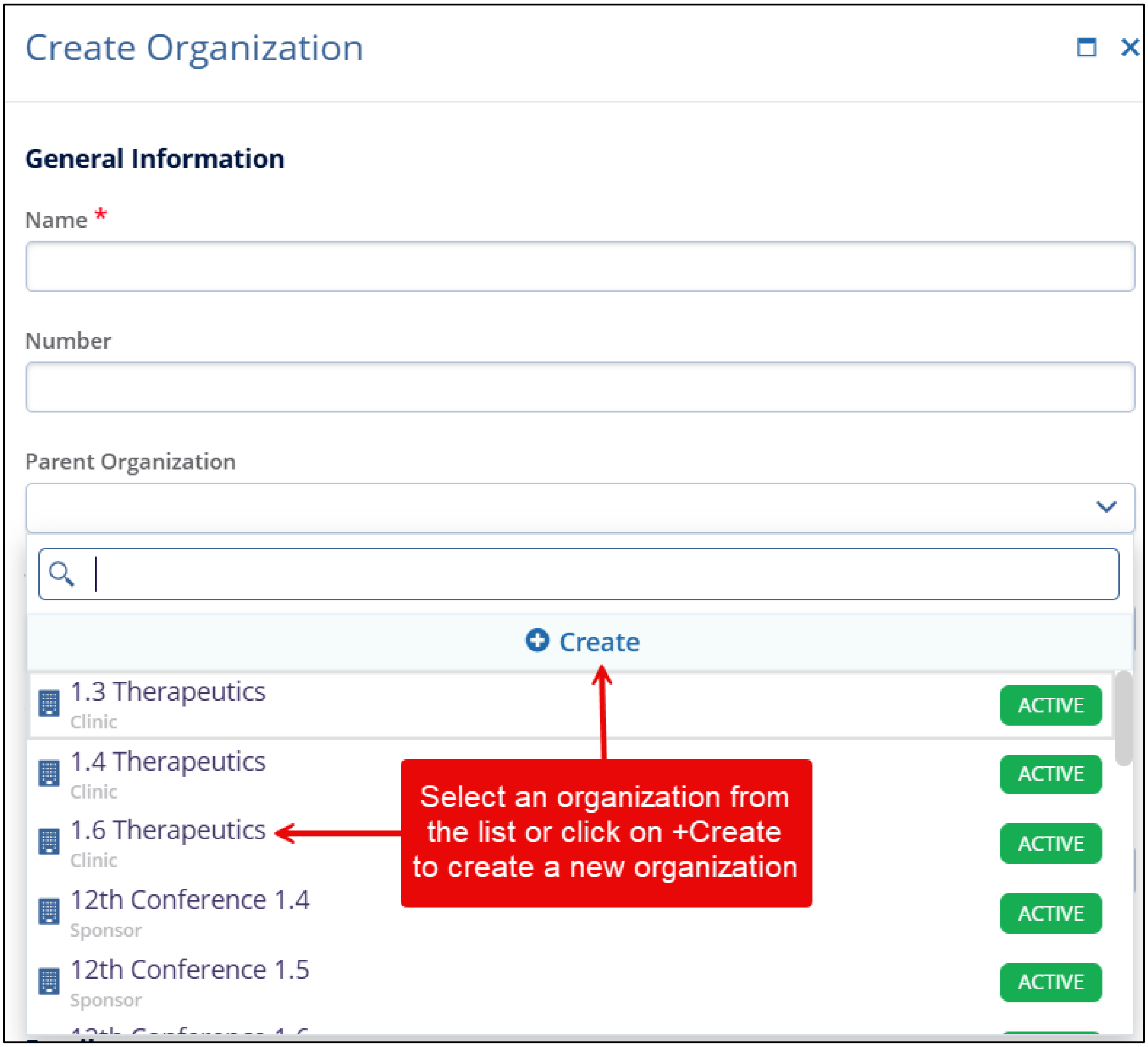


Figure: Create Organization form

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 your screen and fill in the information accordingly.
- To create a Parent Organization, you must enter the mandatory fields Name, Type, and Status which are marked with an asterisk (*) next to the field title. Other fields are optional.
- The parent organization will now be automatically populated in the parent field of the child organization. Please refer to the screenshot below.

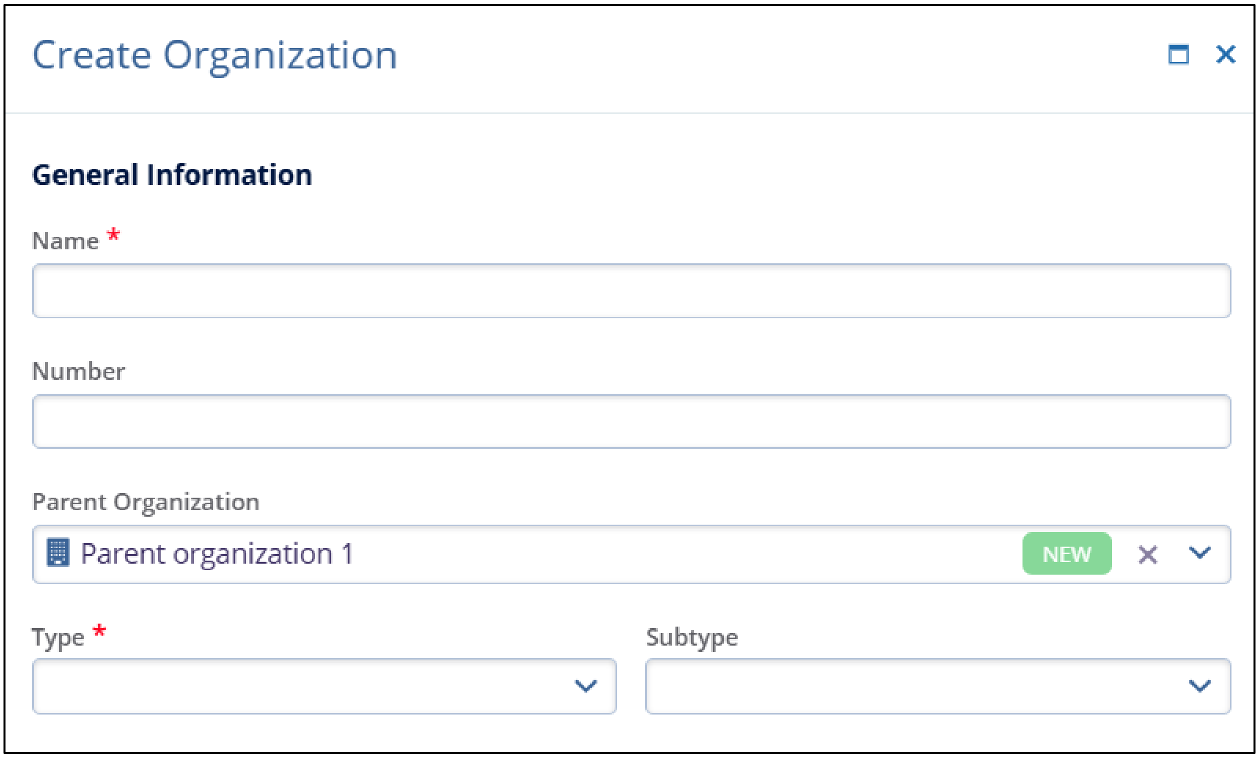


Figure: Create Organization – General Information

- Type: Select the type of organization from the dropdown menu.
- Subtype: Select the subtype that best describes the Organization.
- Status: Choose the status as your 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 [How to Create a Contact.]()

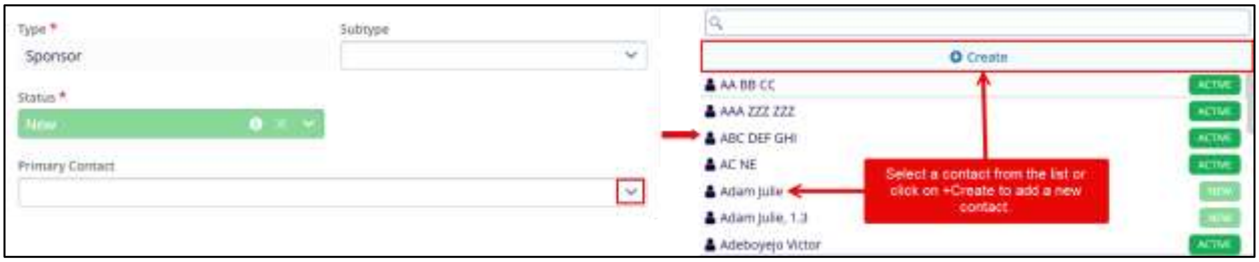


Figure: Create Primary Contact

Phone Numbers

- Click on "+Add" to input 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.

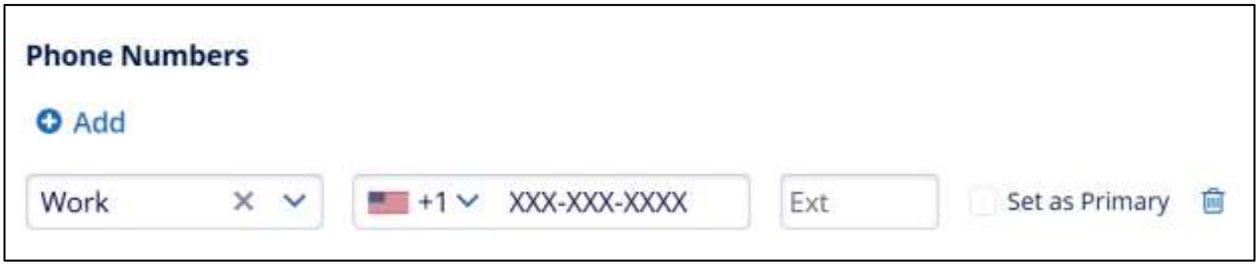


Figure: Add Phone Numbers

Emails

- Click on "+Add" to enter email addresses. 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:

- Toggle the switch if you want to include an address and enter the mandatory details into the respective fields.
- To include an address, you must enter the mandatory fields Address Type, Primary Address, and Country and Postal code which are marked with an asterisk (*) next to the field title. Other fields are optional.
- Search Address: Click on the search icon to search for the address and enter your address it will show you an auto-populated list.
- After filling in all required fields, you have three options at the bottom of the form
  - Create: Saves the new organization and closes the screen
  - Create and Add Another: Saves the new organization and opens a new screen to add another organization.
  - Cancel: Discards the information and closes the screen.

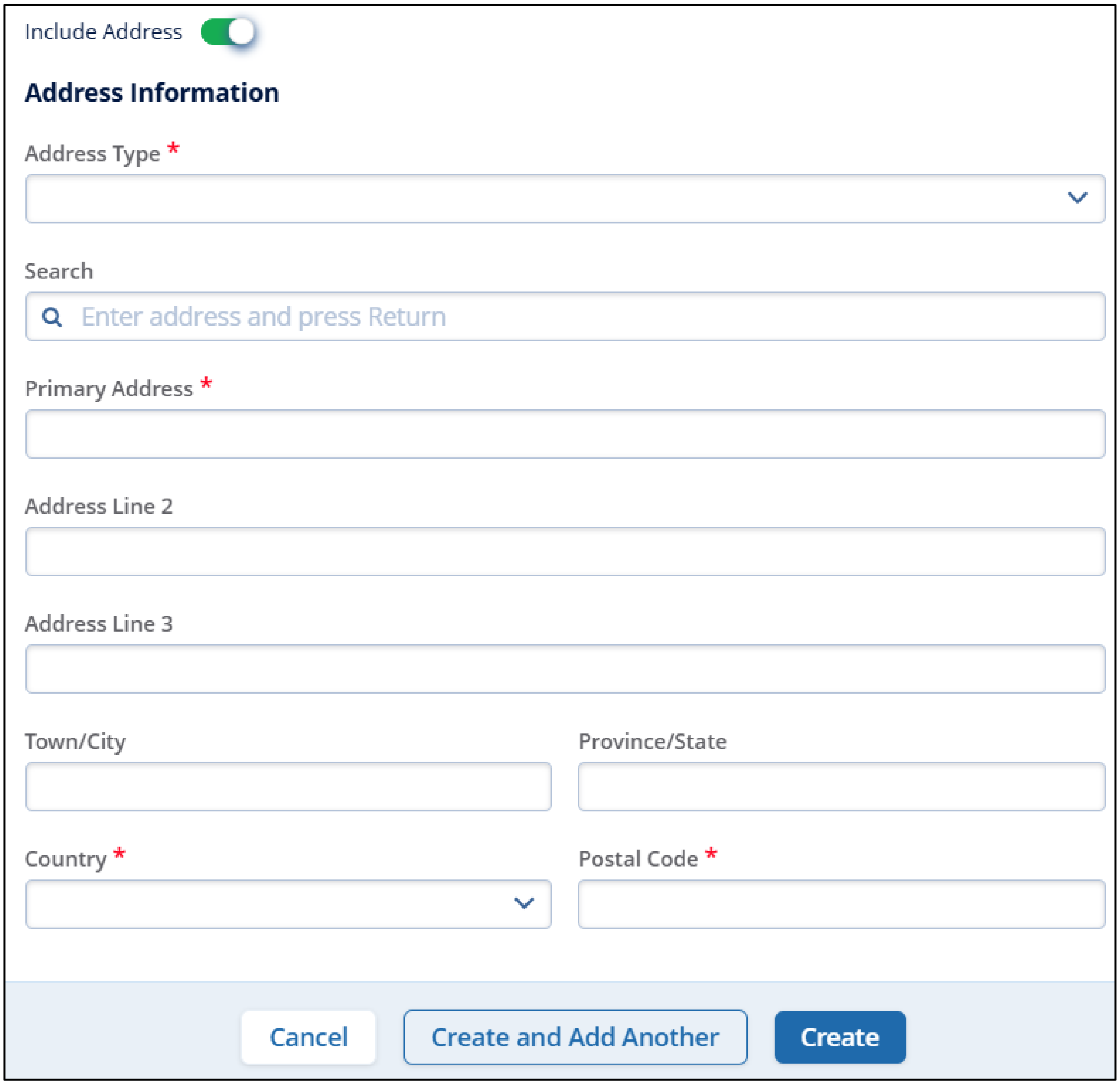


Figure: Include Address

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

Figure: Success Message

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

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.

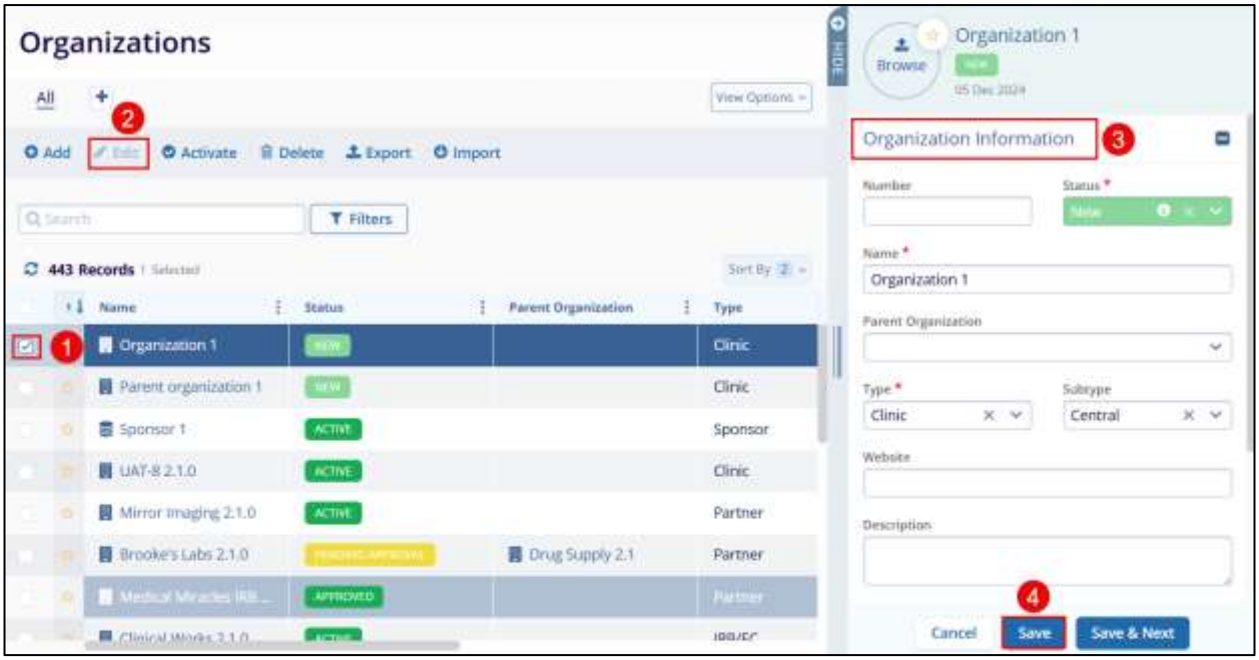


Figure: Edit Organization – Method 1

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.

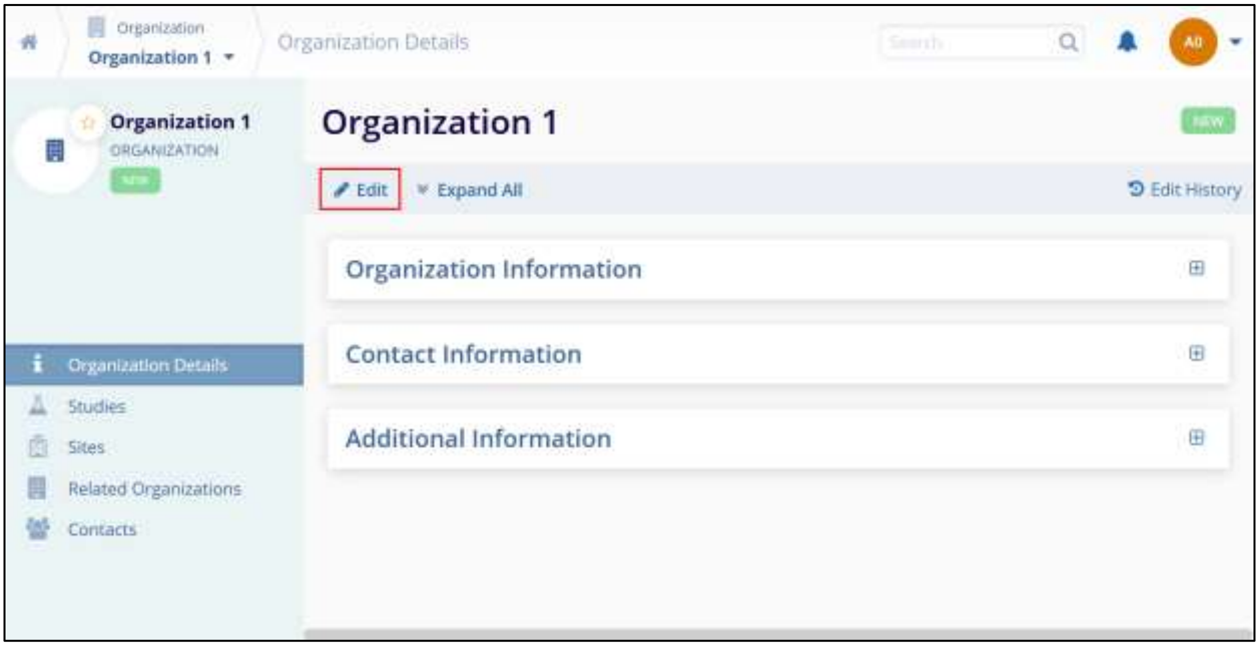


Figure: Edit Organization – Method 2

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

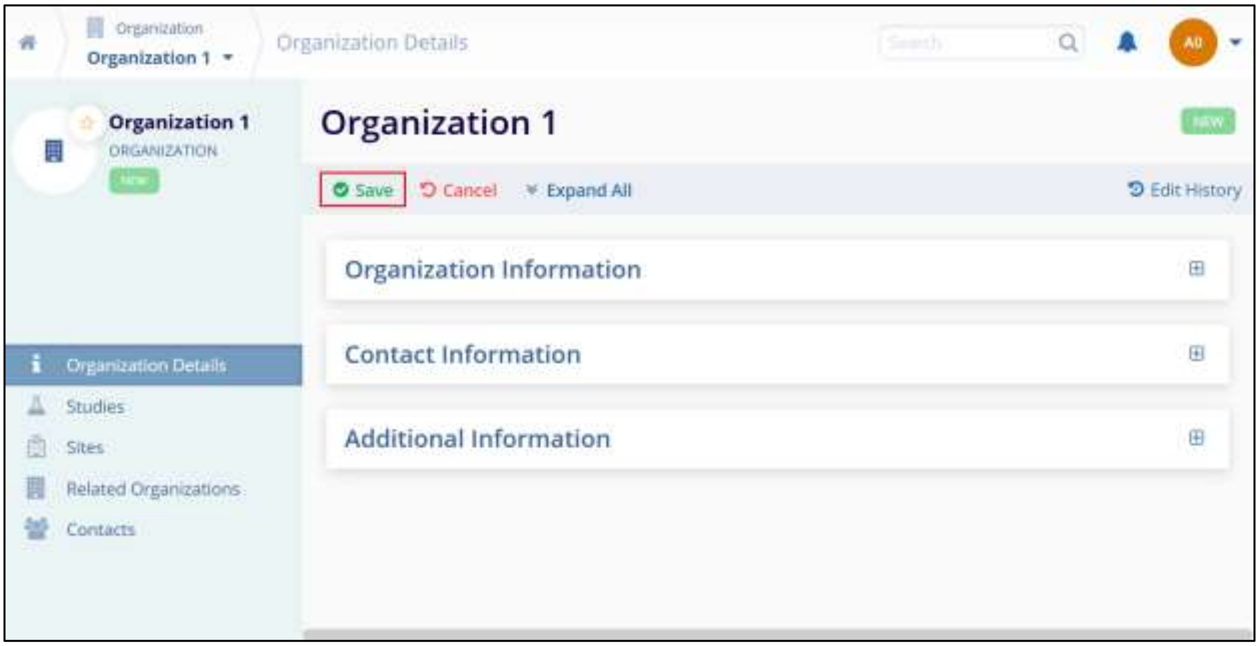


Figure: Save changes to Organization Details

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.

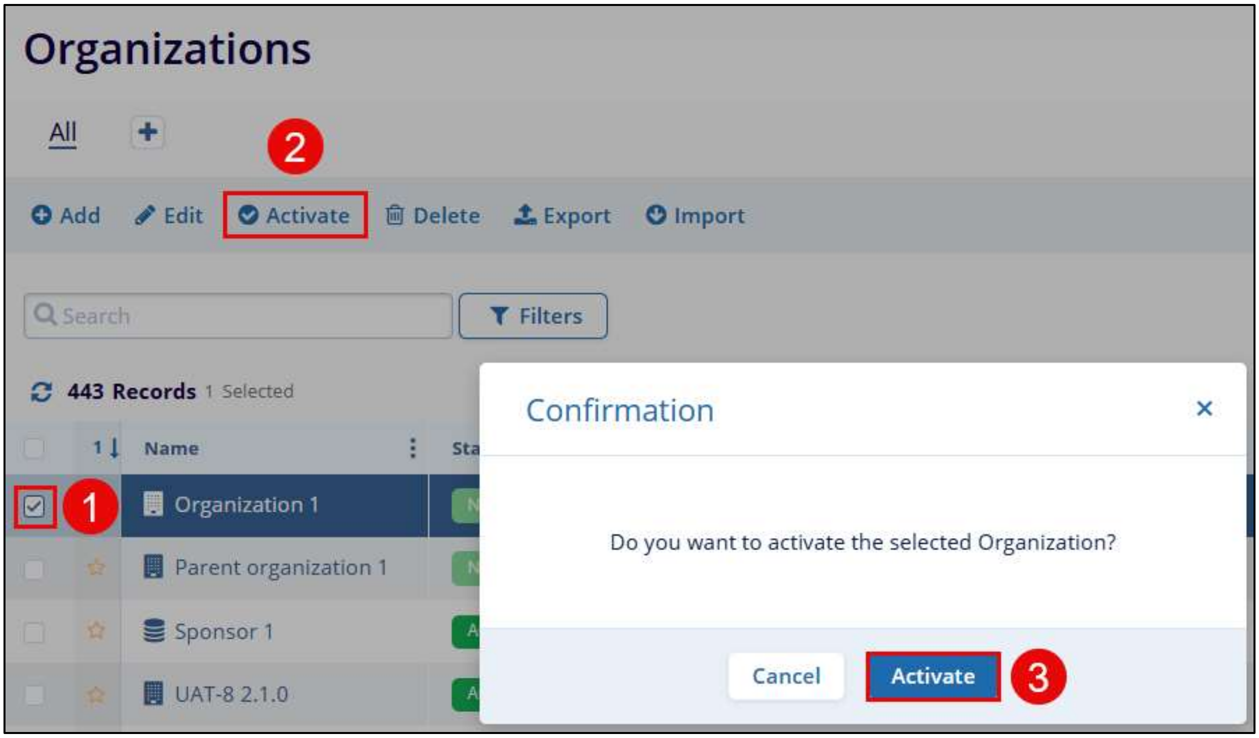


Figure: Activate Organization

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 will appear. Click the "Deactivate" button to proceed with activation or "Cancel" to discontinue.

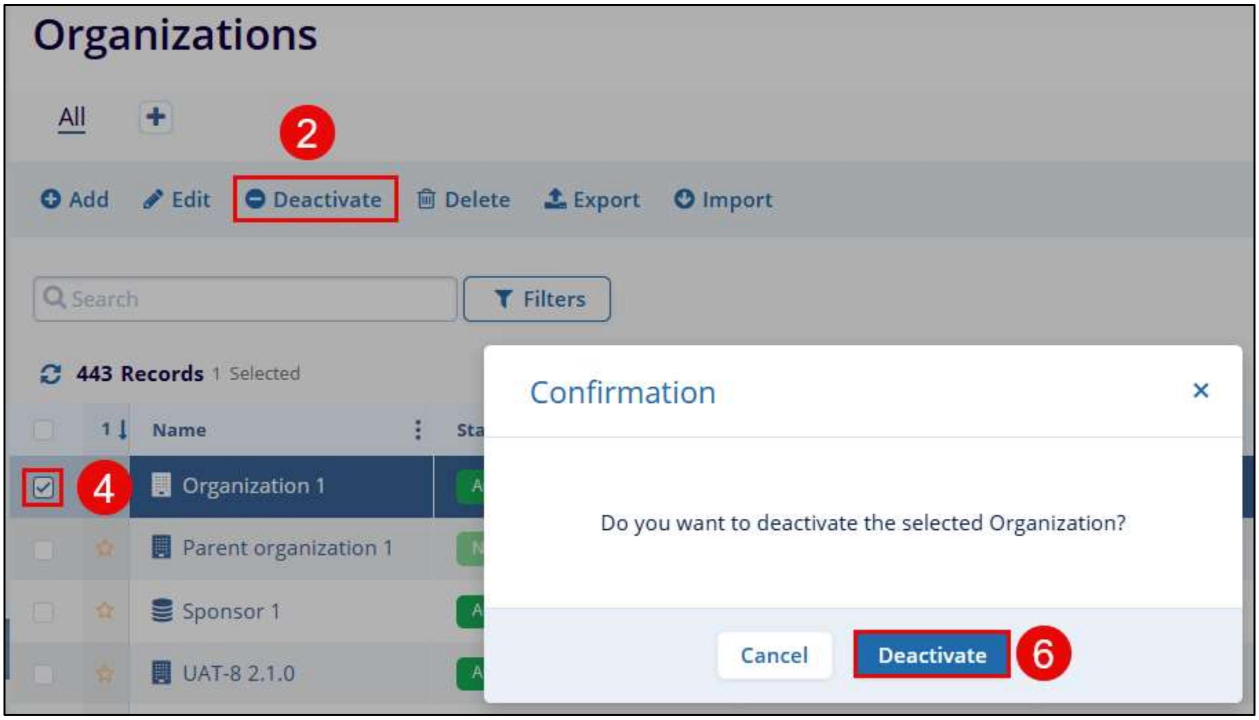


Figure: Deactivate Organization

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.

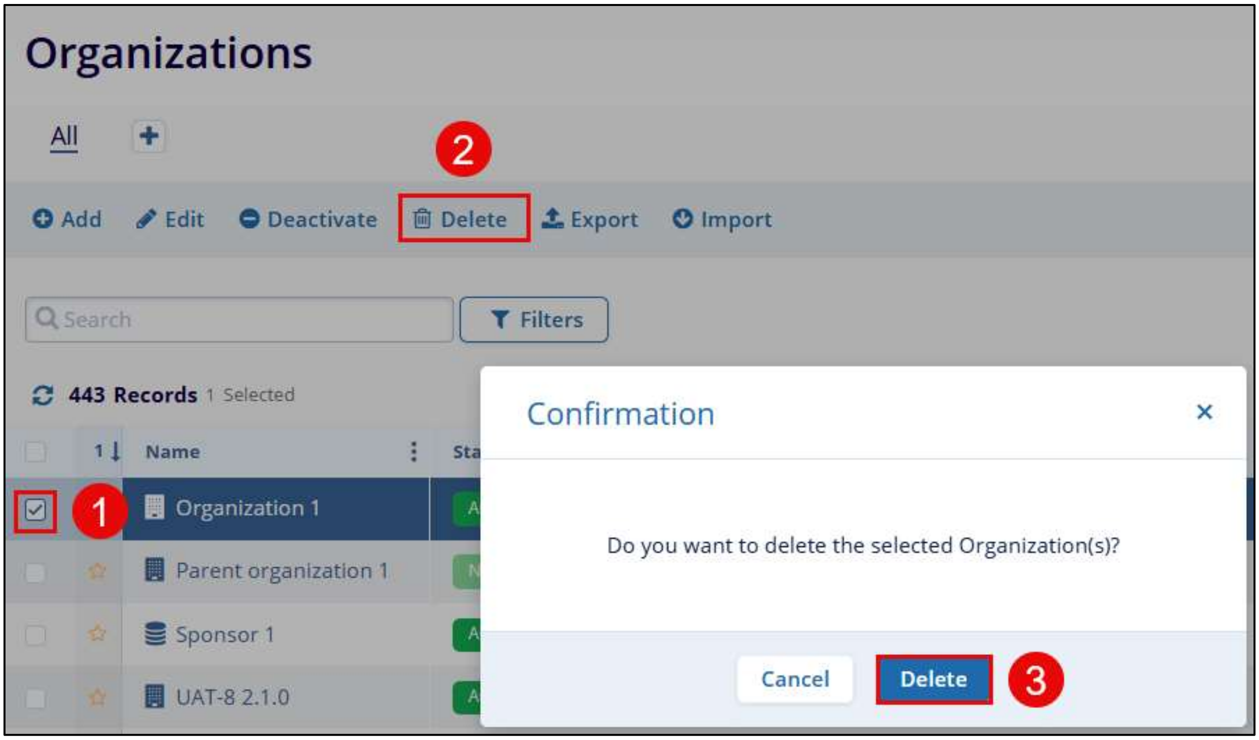


Figure: Delete Organization

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.

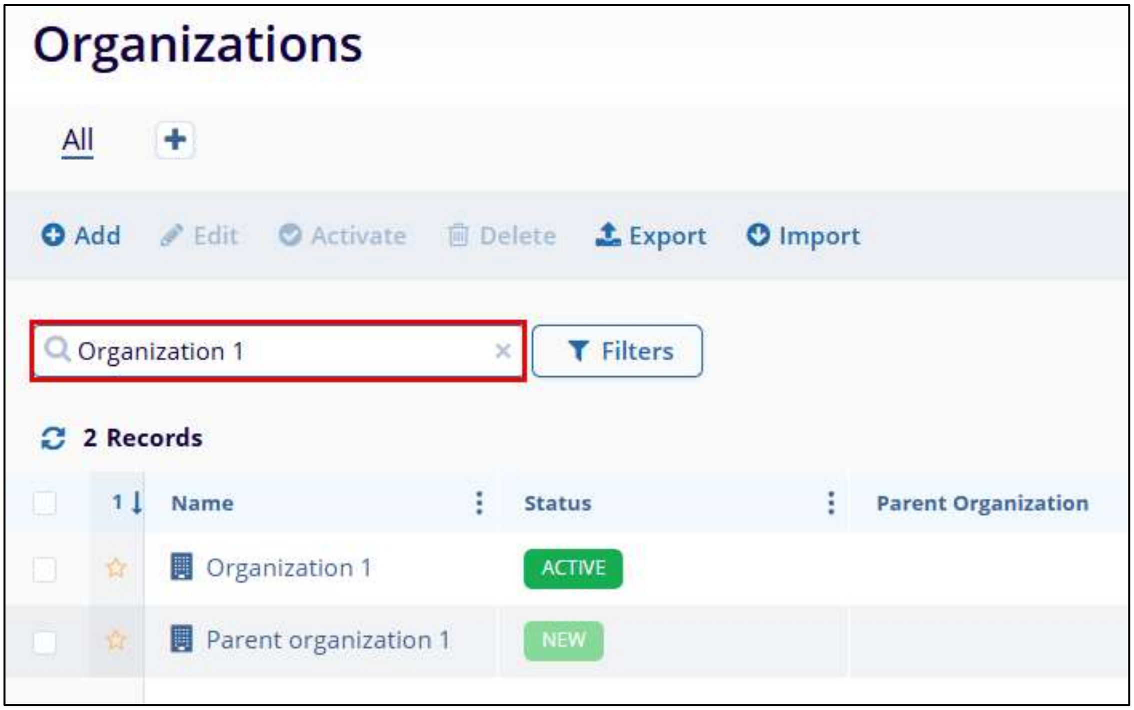


Figure: Search for Organization

Customizing Organization Screen

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

1. Filters: To learn how to apply standard and advanced filters, refer to the Filters section.
2. Favorite: To learn how to mark an organization as Favorite, refer to the Mark a contact as a favorite section.
3. Customize Columns: To learn how to Hide, Lock, Manage Visible Columns, and Sort Columns, refer to the Customizing columns on the Contacts screen section.
4. Views: To set a view and access different view options, refer to the Contacts Views section.

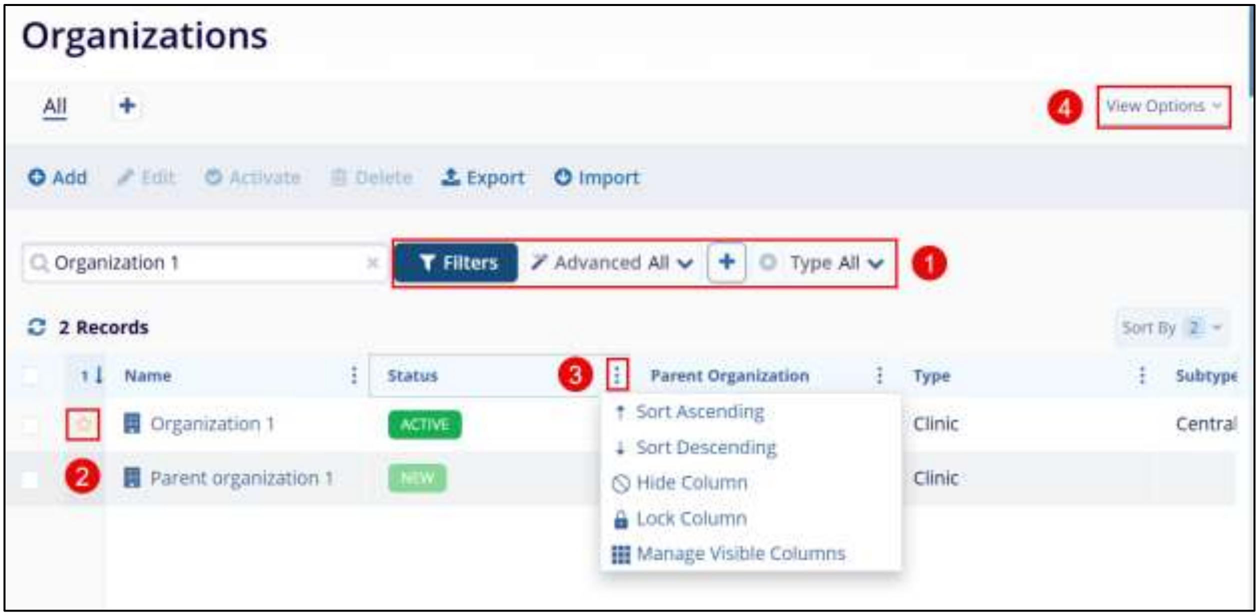


Figure: Organization filters

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 which you want to associate an address and click on the organization's name.

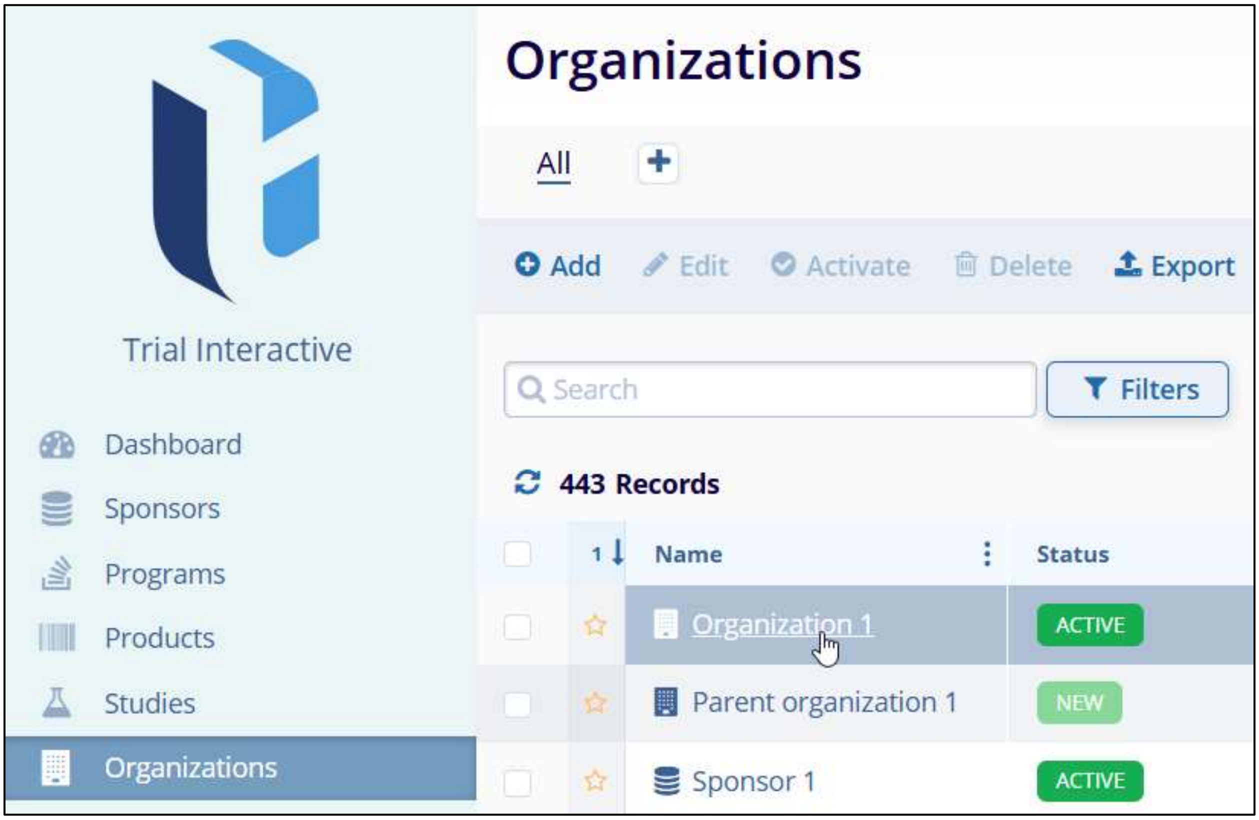


Figure: Associate Address to organization

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

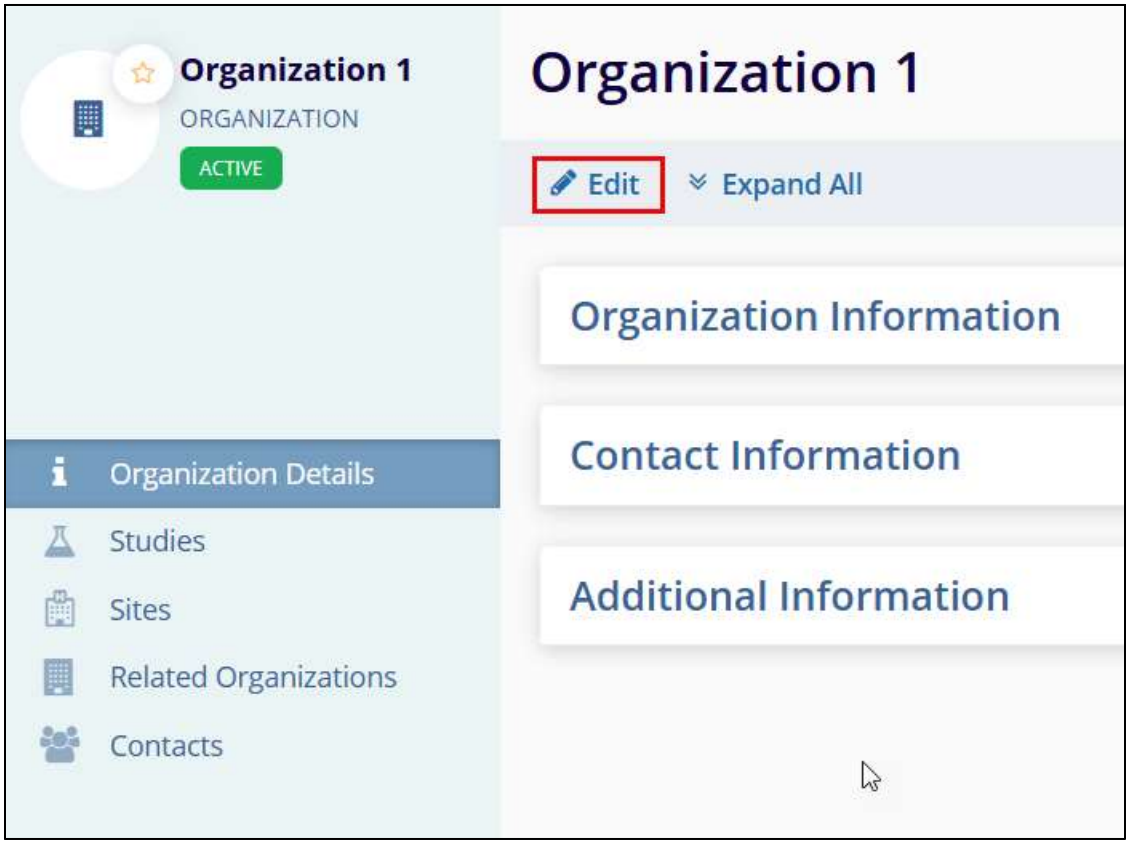


Figure: Organization Details

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 you to add the current address and immediately start creating another one.
    - Add Address: This option allows you to create only the address you are currently working on.
7. Click on the Save button once the address is added.

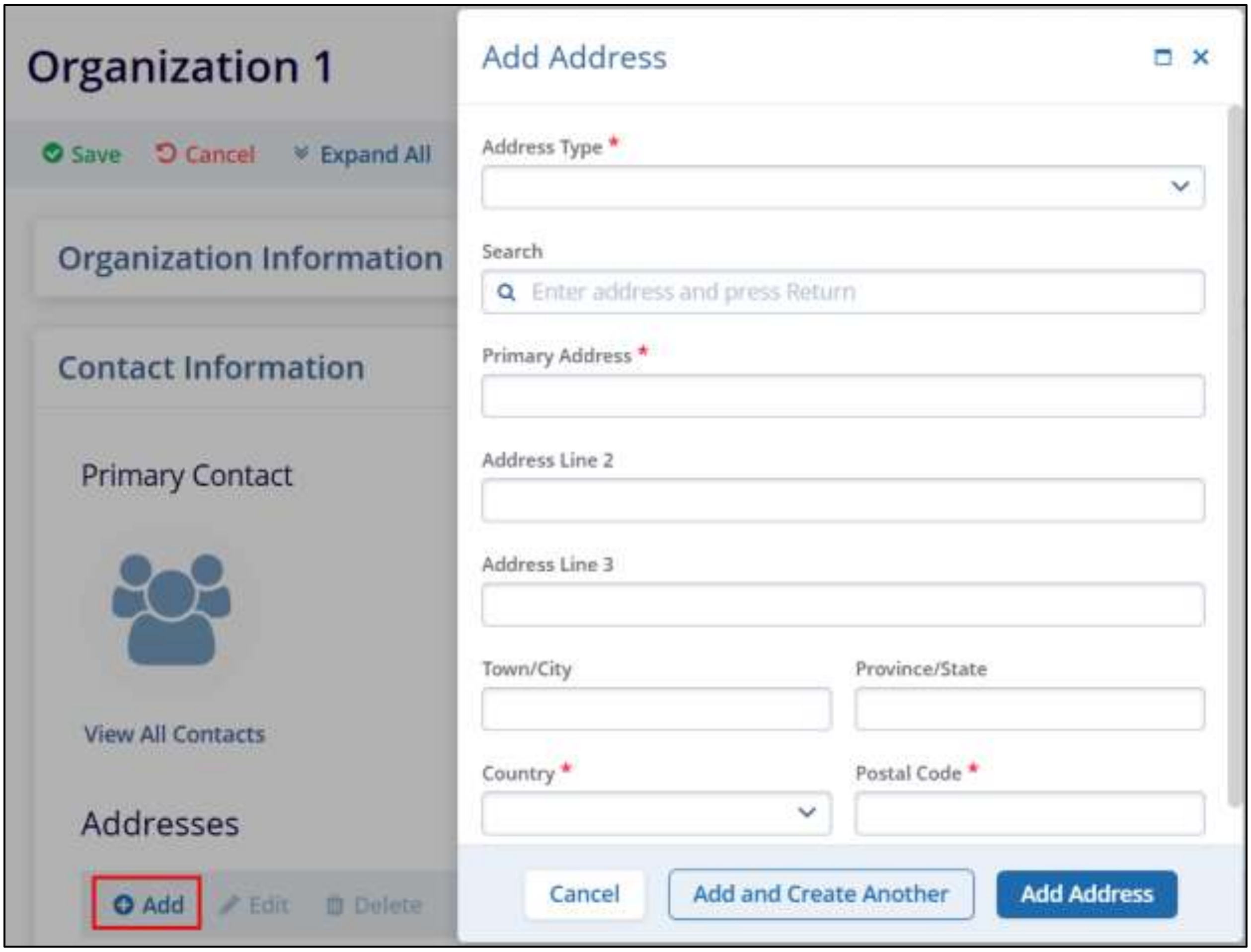


Figure: Add Address to organization

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.

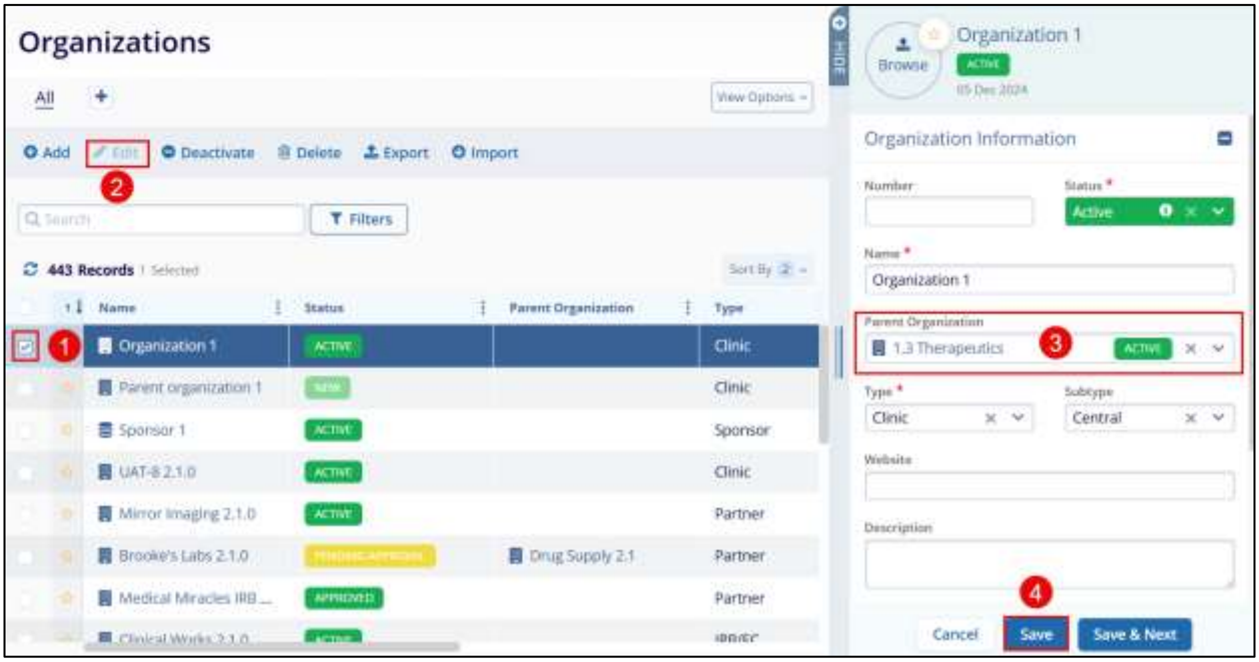


Figure: Associate Organization to a parent organization

Method 2

1. Locate the organization to which you want to associate a parent organization 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.

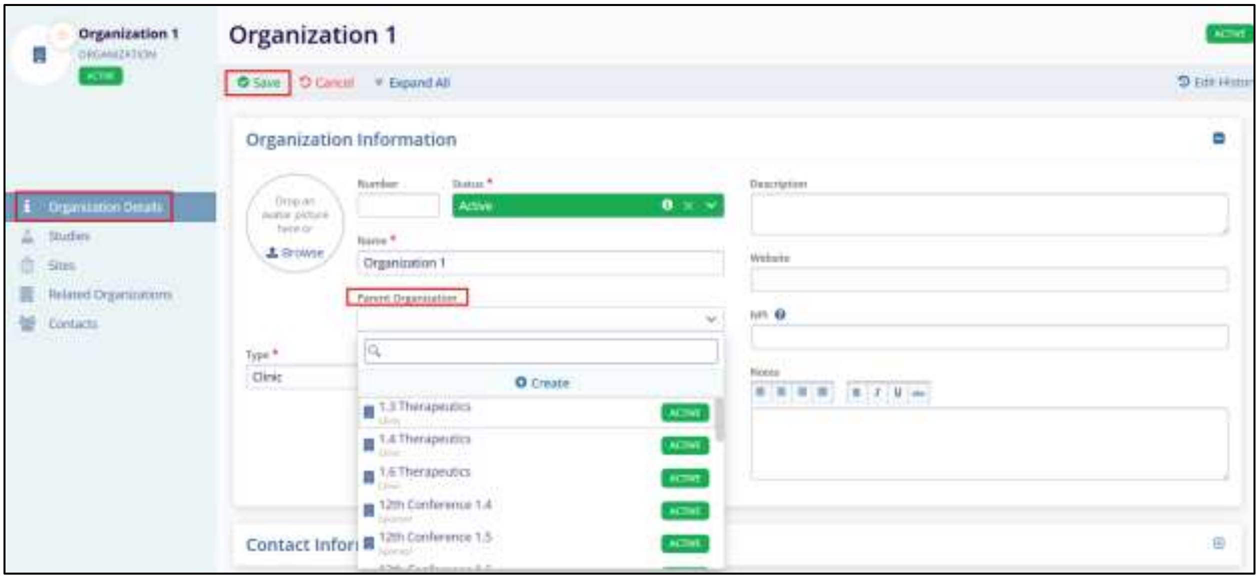


Figure: Add organization to parent organization

<u>Note:</u>

- The "**Organization Details"** view contains additional fields that are not available within the quick-view panel (For Example: 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" tab.

Figure: View Parent Organization

Reviewing Studies and Sites Associated with an Organization

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, click on the "Studies" from the Navigation link on the left side of the screen.
3. This opens the "Studies" window.

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 'Site' tab to view all associated sites.

CHAPTER 9. CONTACTS

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.
2. It directs the user to the Contacts screen where contacts are displayed at a global level.

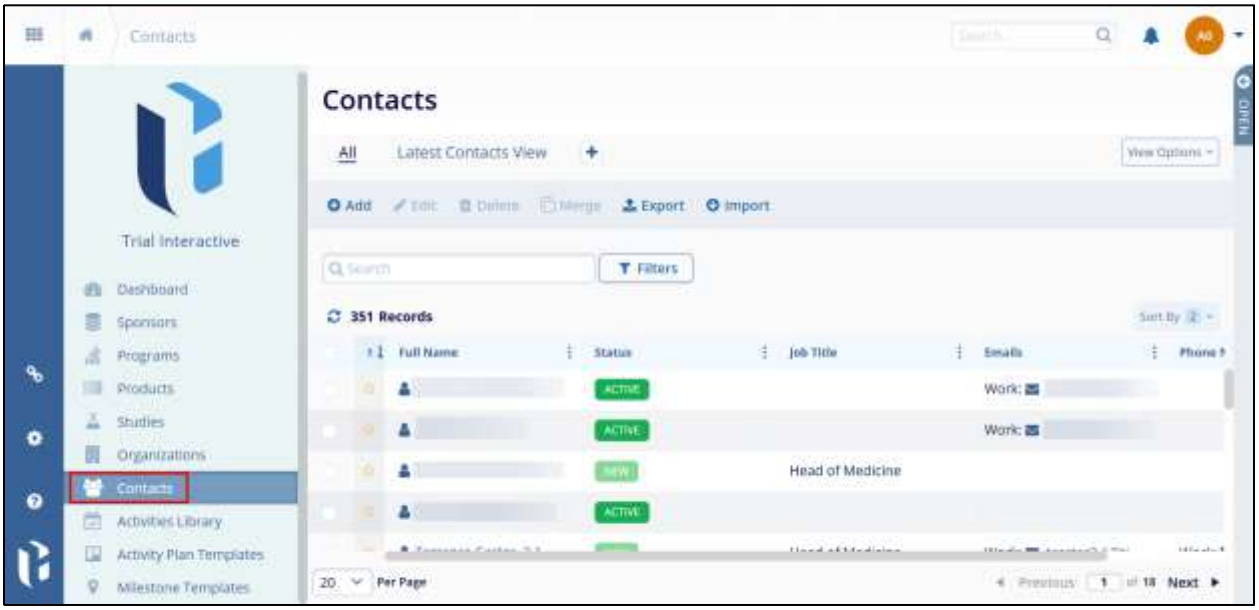


Figure: Select Contacts

Steps to create a contact

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

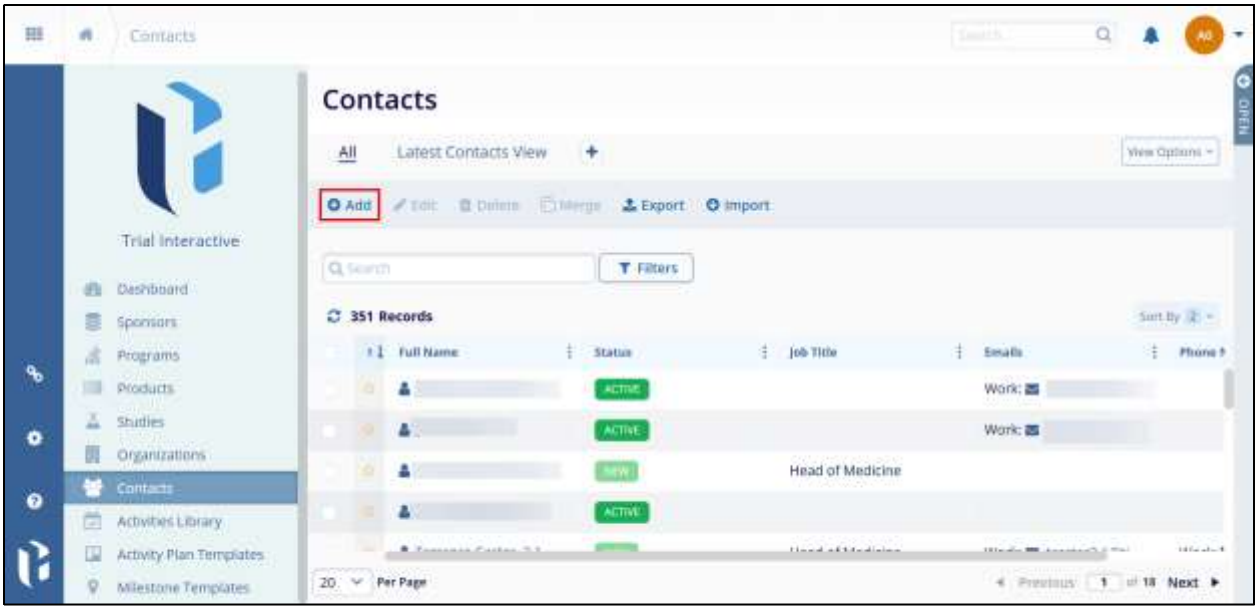


Figure: Create a new contact

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

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

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

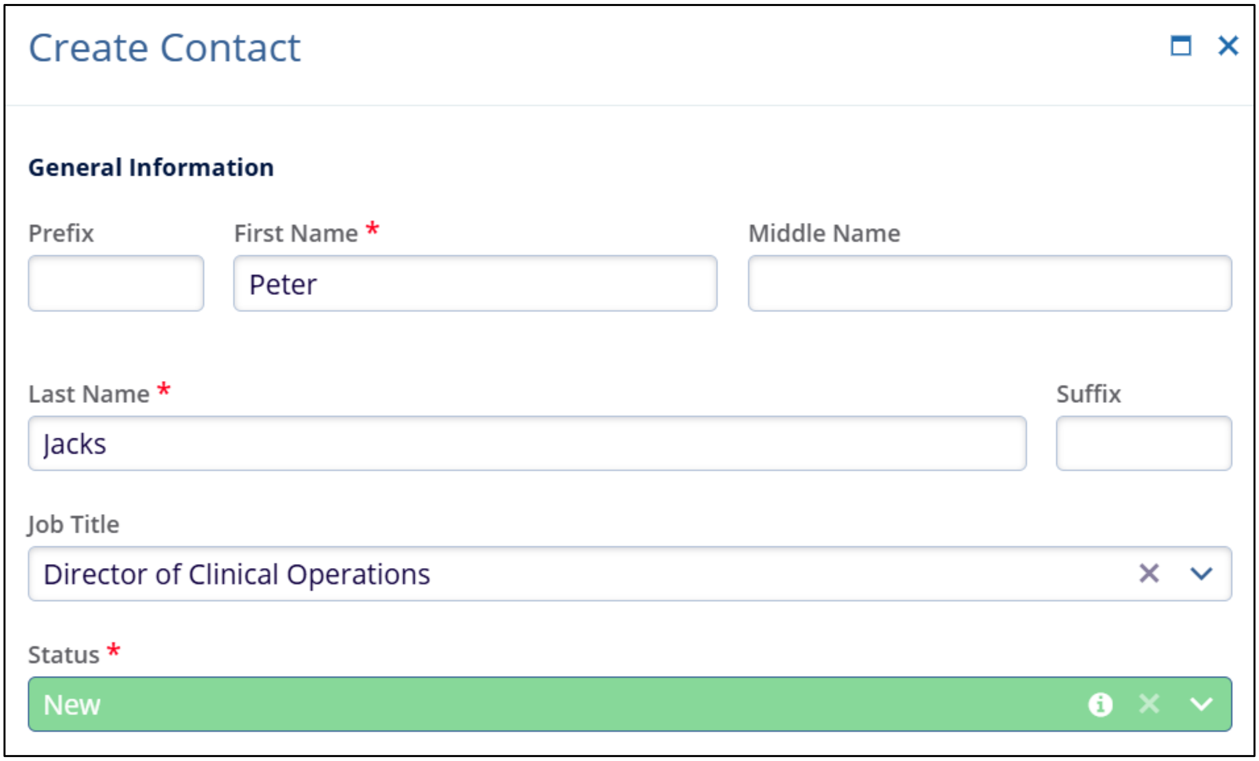


Figure: Create Contact form

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.

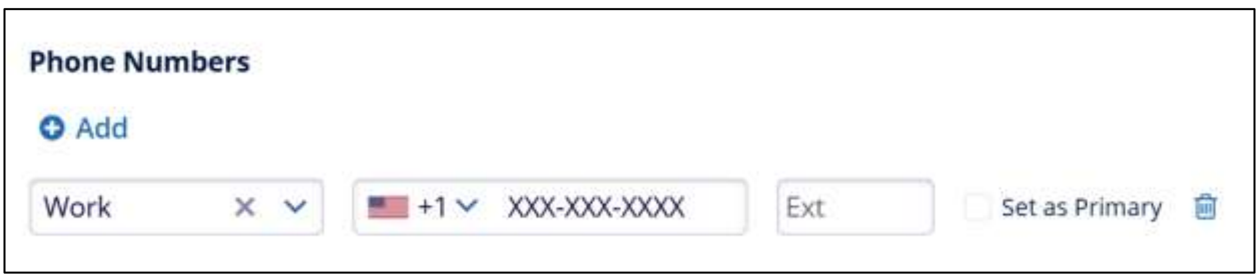


Figure: Phone Numbers

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.

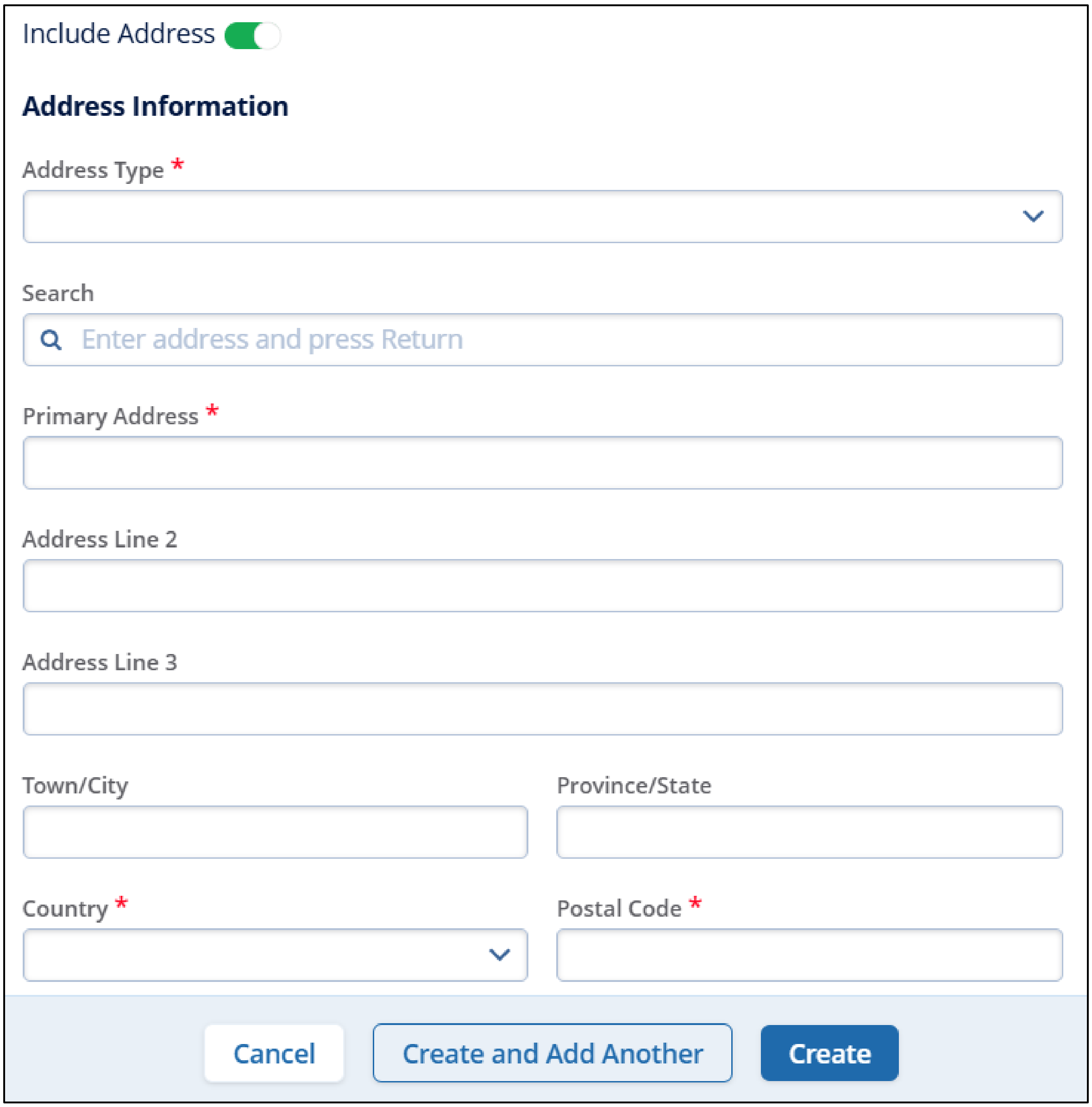


Figure: Add contact details

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

Figure: New Contact

Editing a Contact

To edit a Contact, follow the steps below.

1. Click on the checkbox before the contact'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.

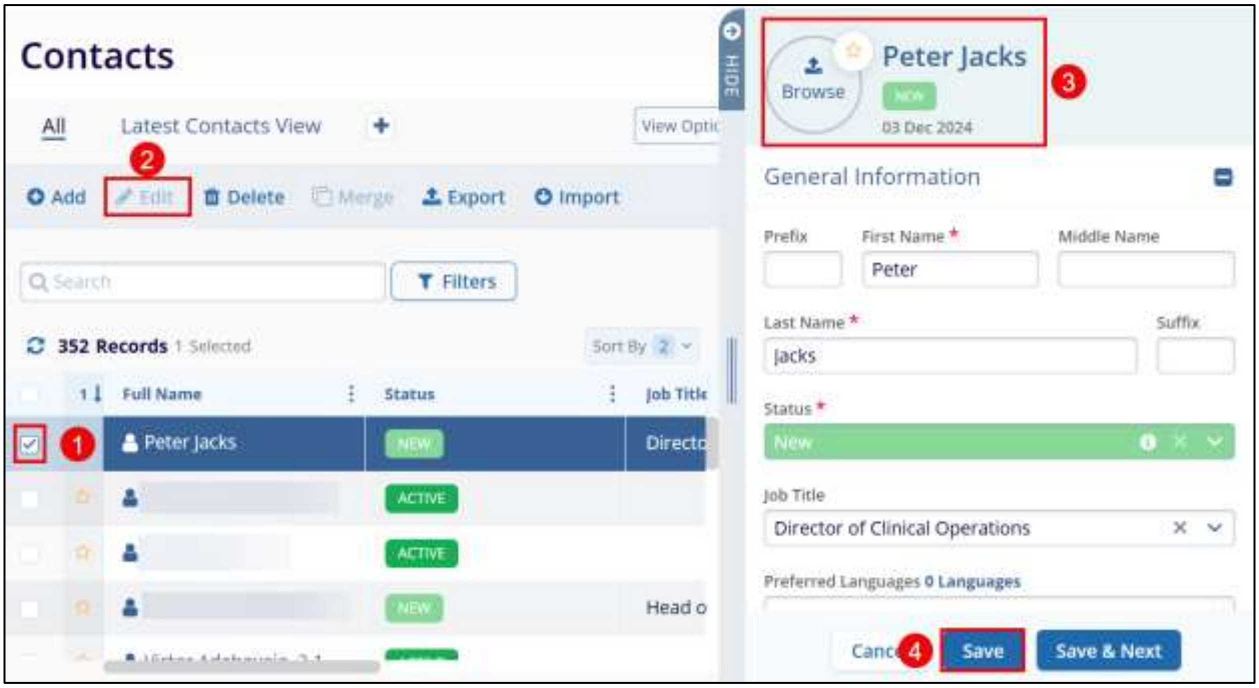


Figure: Editing a Contact

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, will discard all the edits.

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

Figure: Edit contact on the Contact Details page

Important

- Click on the Organizations link from the left-hand navigation pane to view the organizations associated with the user.
- Click on the Sites link from the left-hand navigation pane to view the sites associated with the user.
- Click on the Linked Contacts link from the left-hand navigation pane to view all the contacts associated with the user.

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.

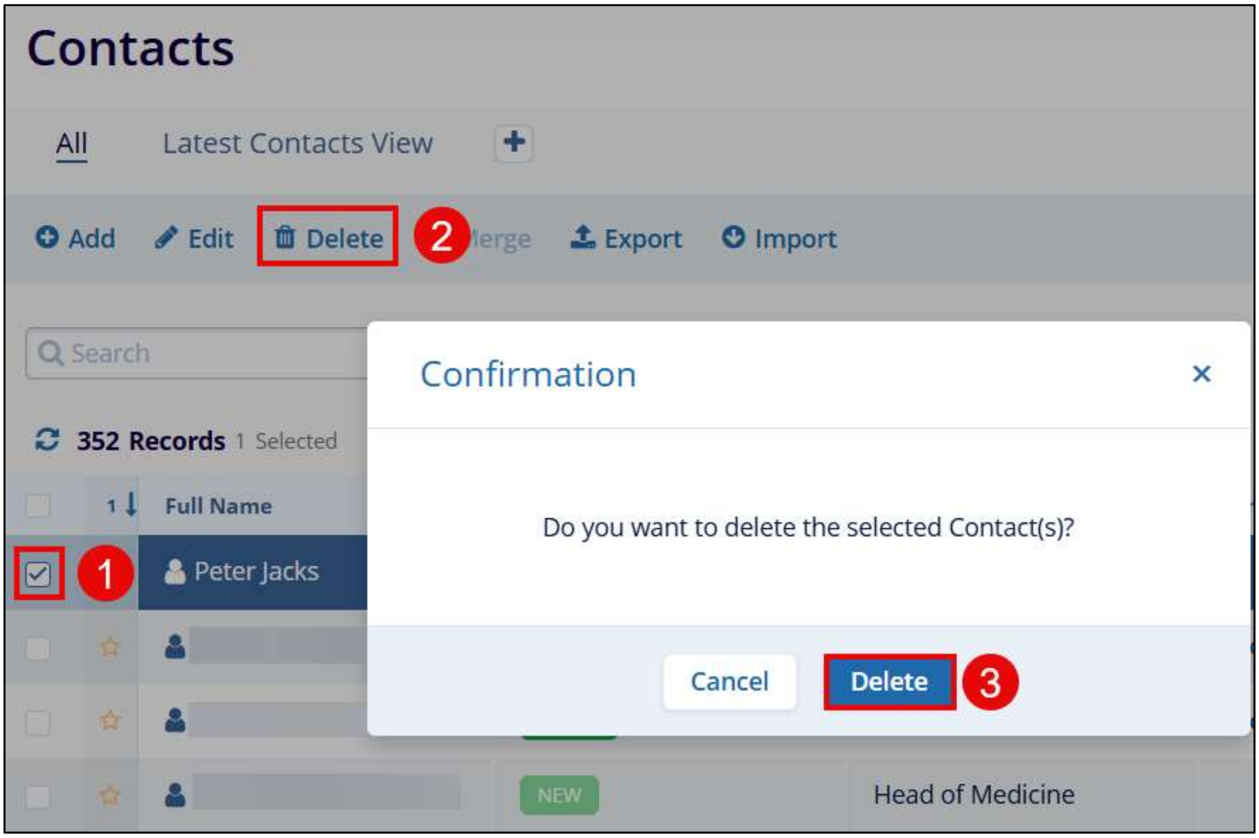


Figure: Contact deletion confirmation message

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.

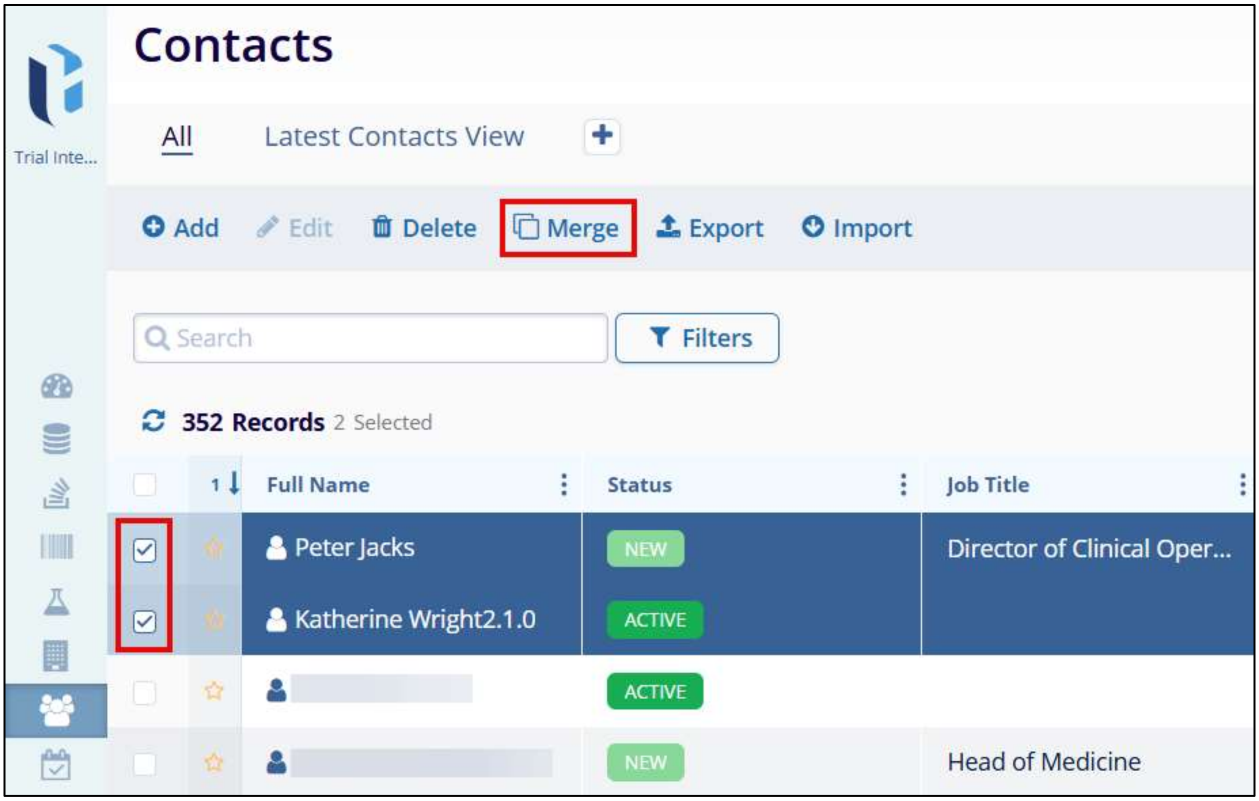


Figure: Merge Contacts

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.

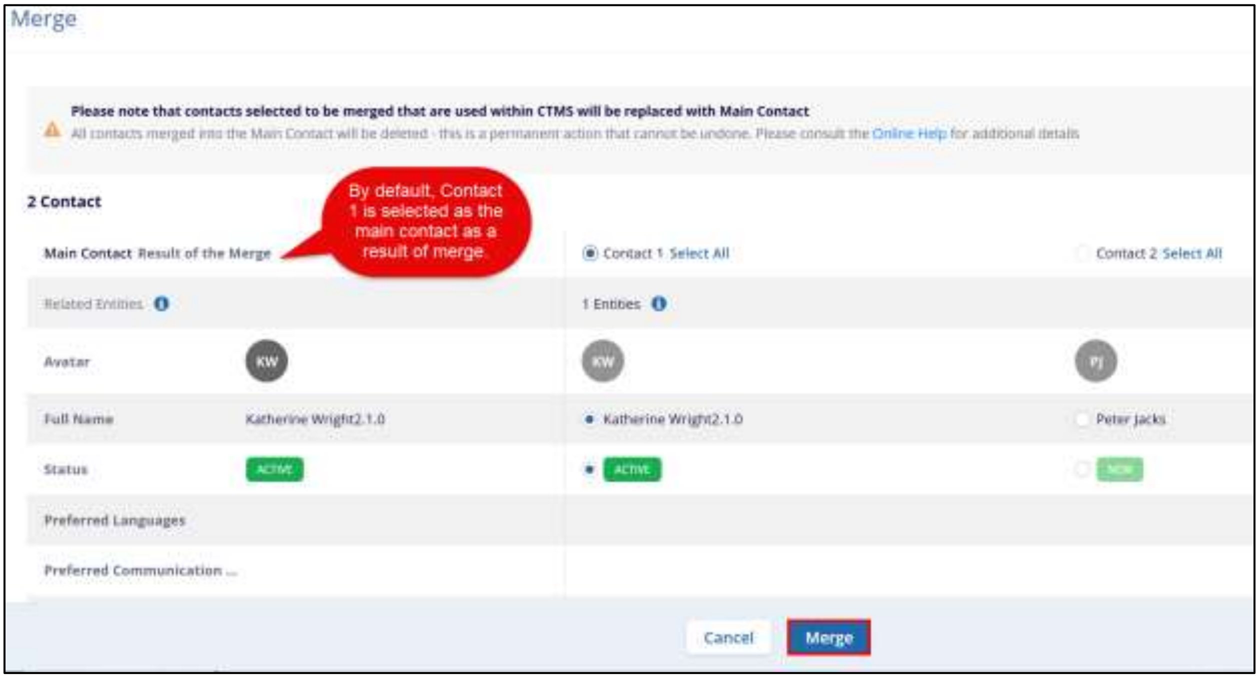


Figure: Contact 1 as the main contact

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

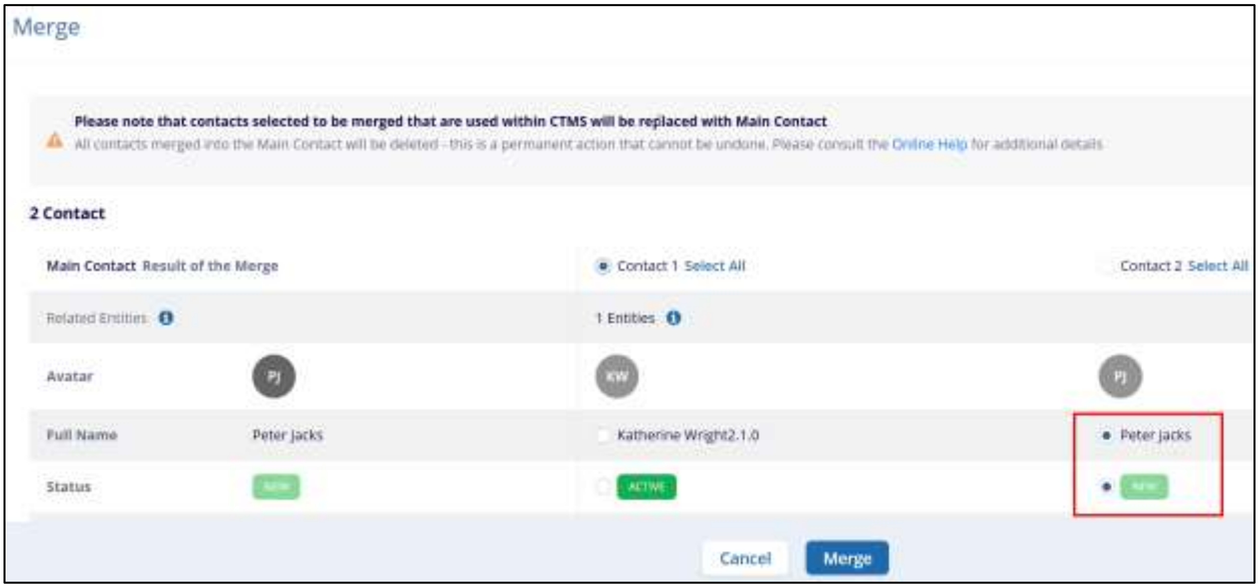


Figure: Merge individual entries from Contact 2

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.

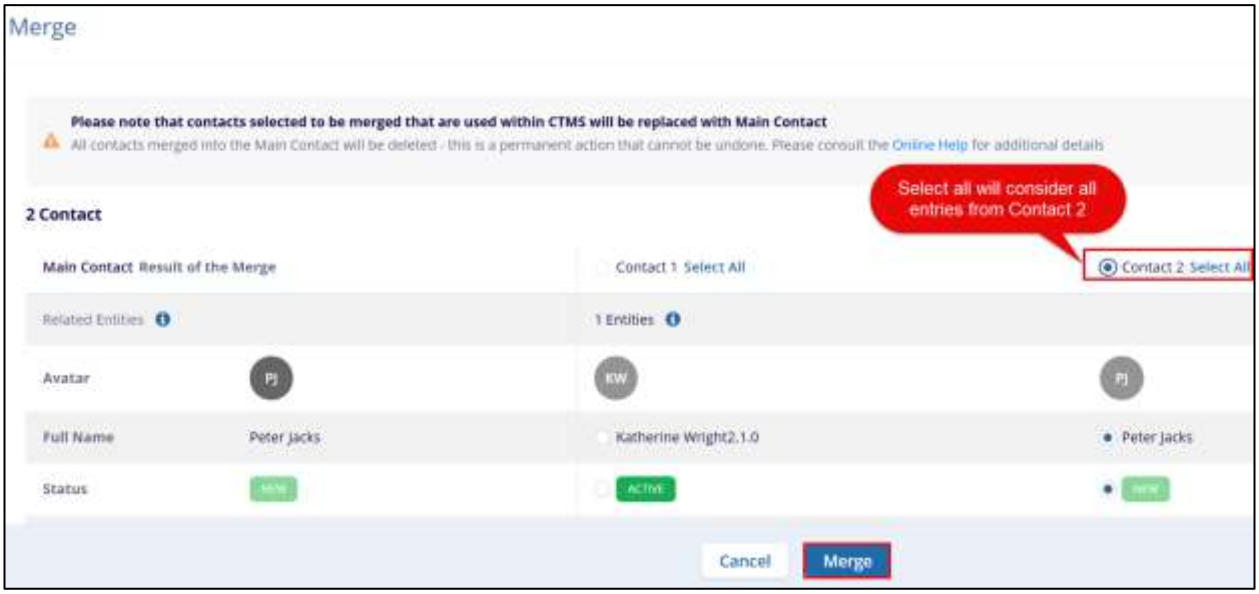


Figure: Merge all entries from contact 2

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.

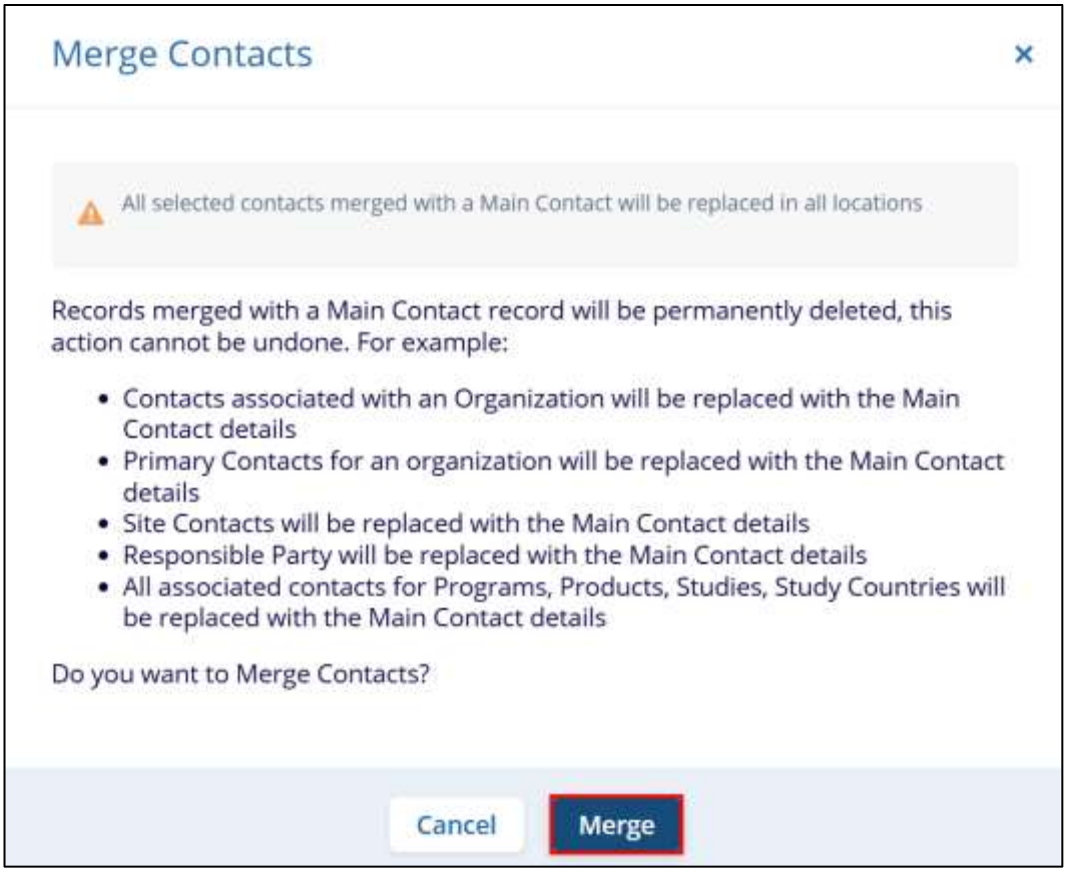


Figure: Merge Contacts confirmation popup

Exporting Contacts

To export contacts, follow the steps below.

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

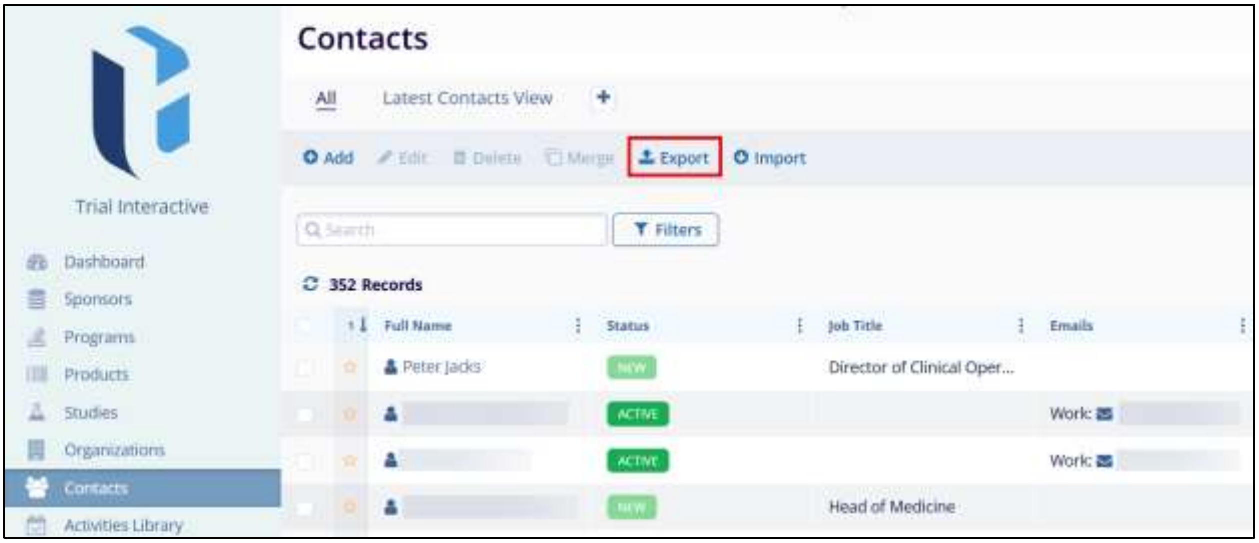


Figure: Select Export

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.

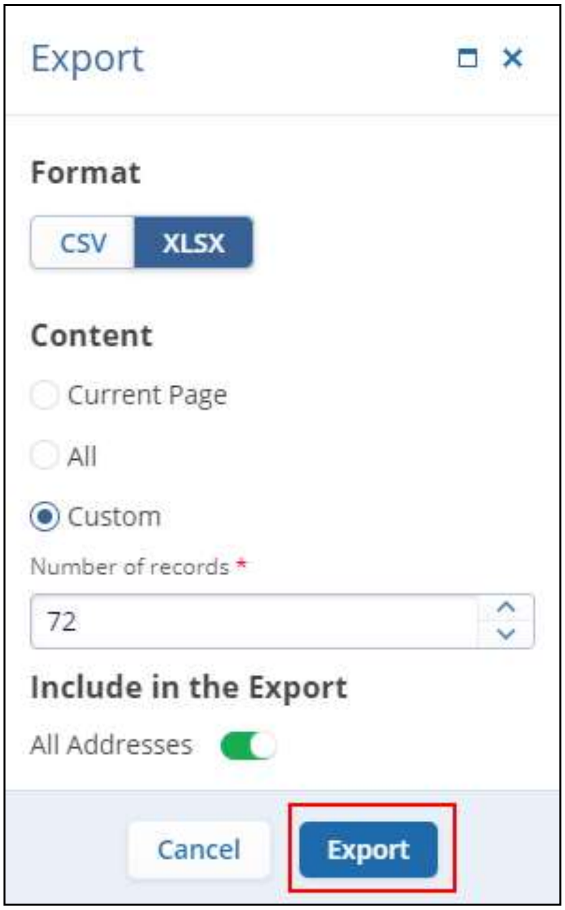


Figure: Export contacts file formats

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

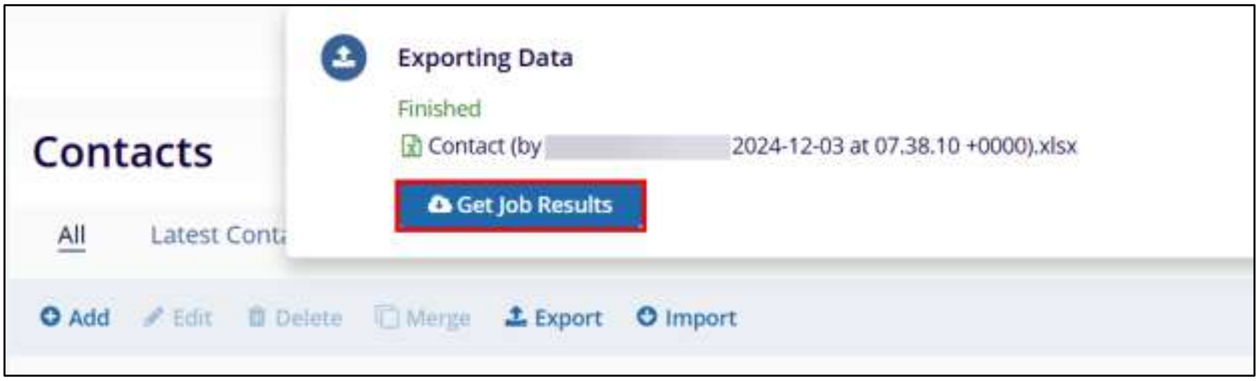


Figure: Get Job Results

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

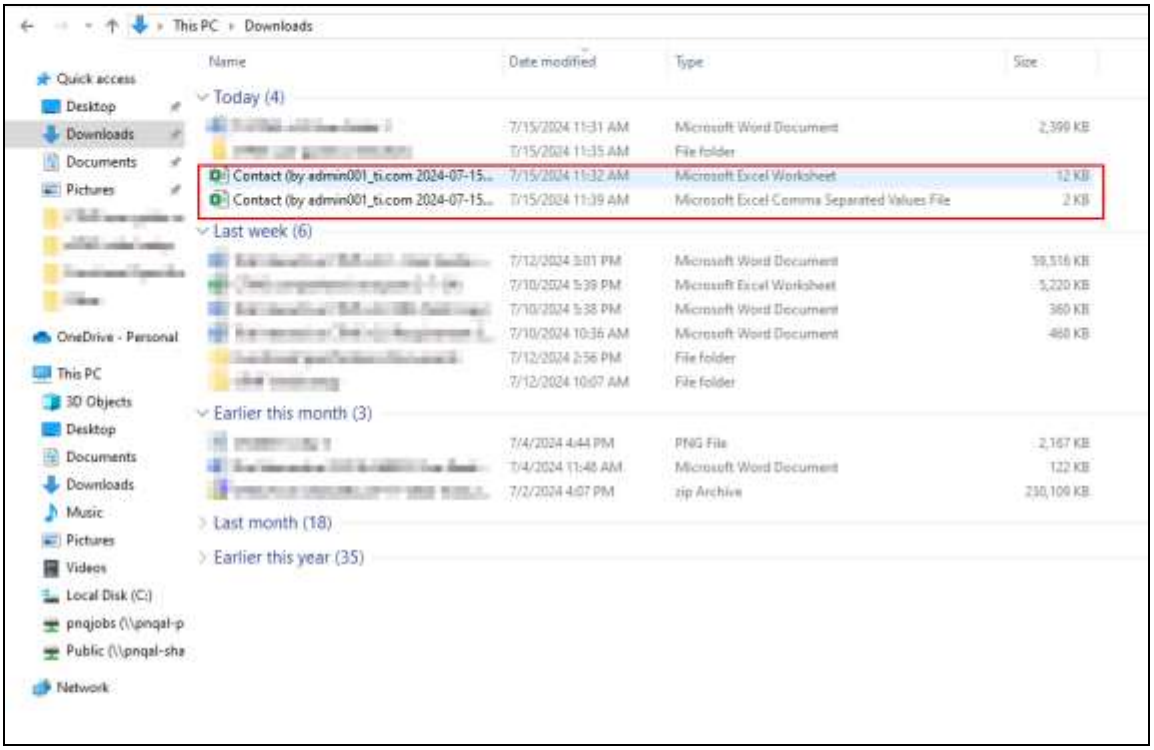


Figure: Exported files in CSV and XLSX file format

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

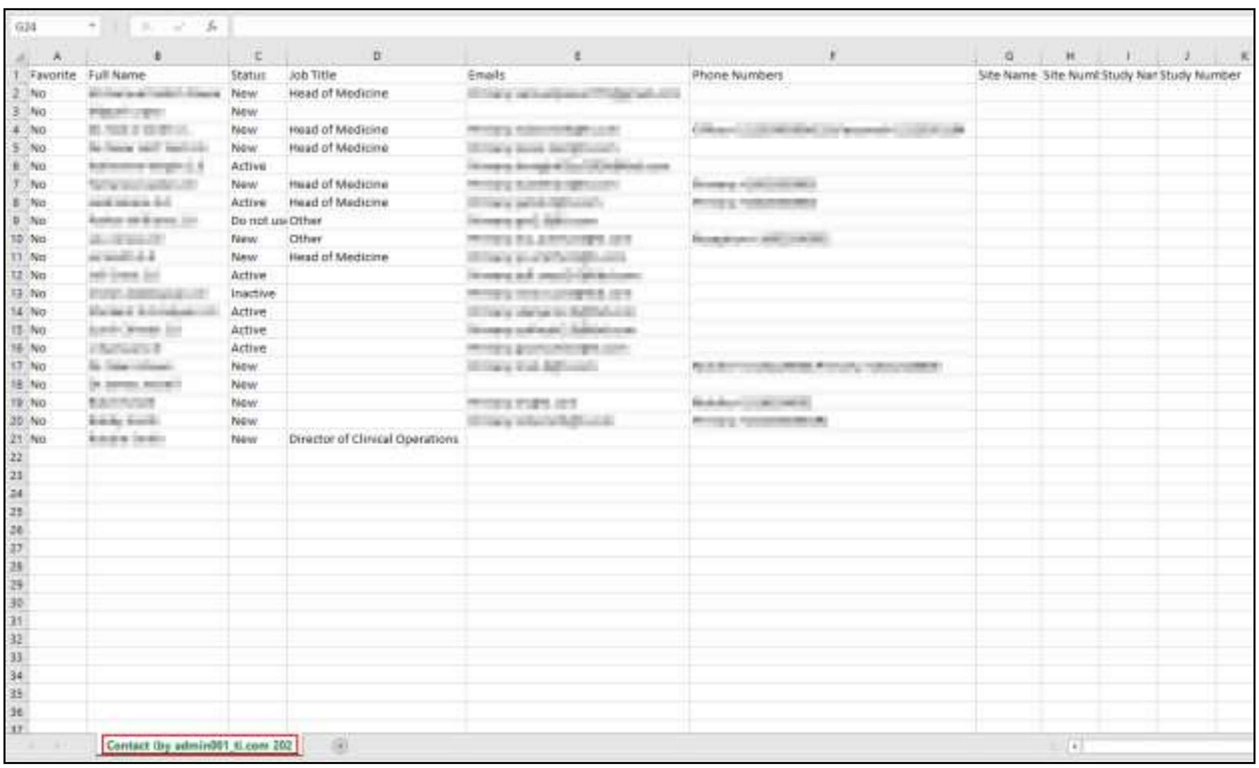


Figure: CSV file export

The XLSX file will display the following two tabs:

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

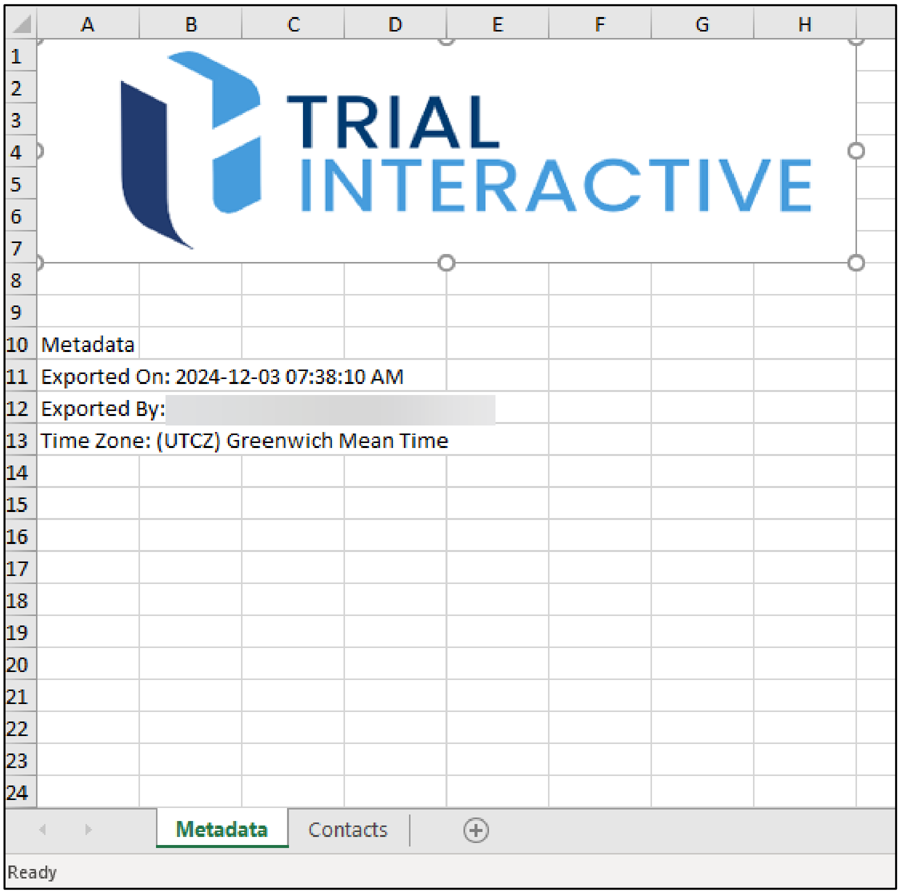
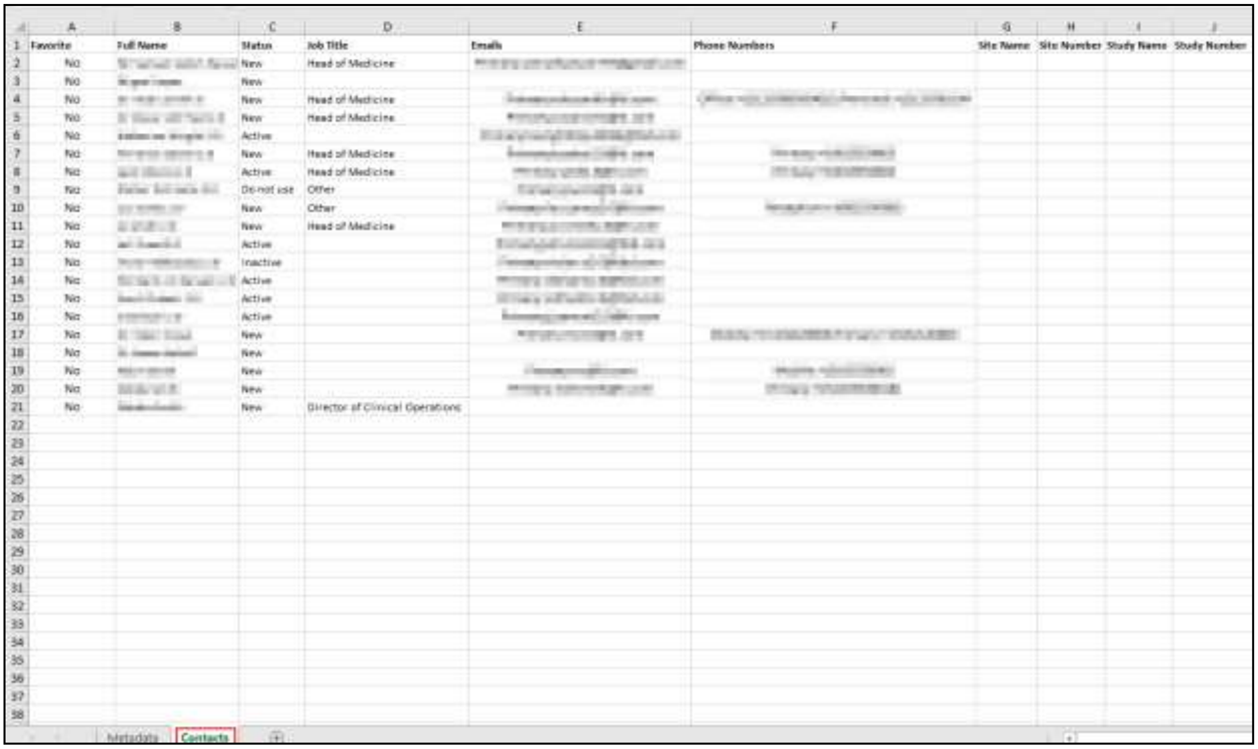


Figure: XLSX file-Metadata tab

- Contacts: This tab has the contact details.



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

Metadata | Contacts

Figure: XLSX file-Contacts tab

Importing Contacts

To import contacts in CTMS, follow the steps below.

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

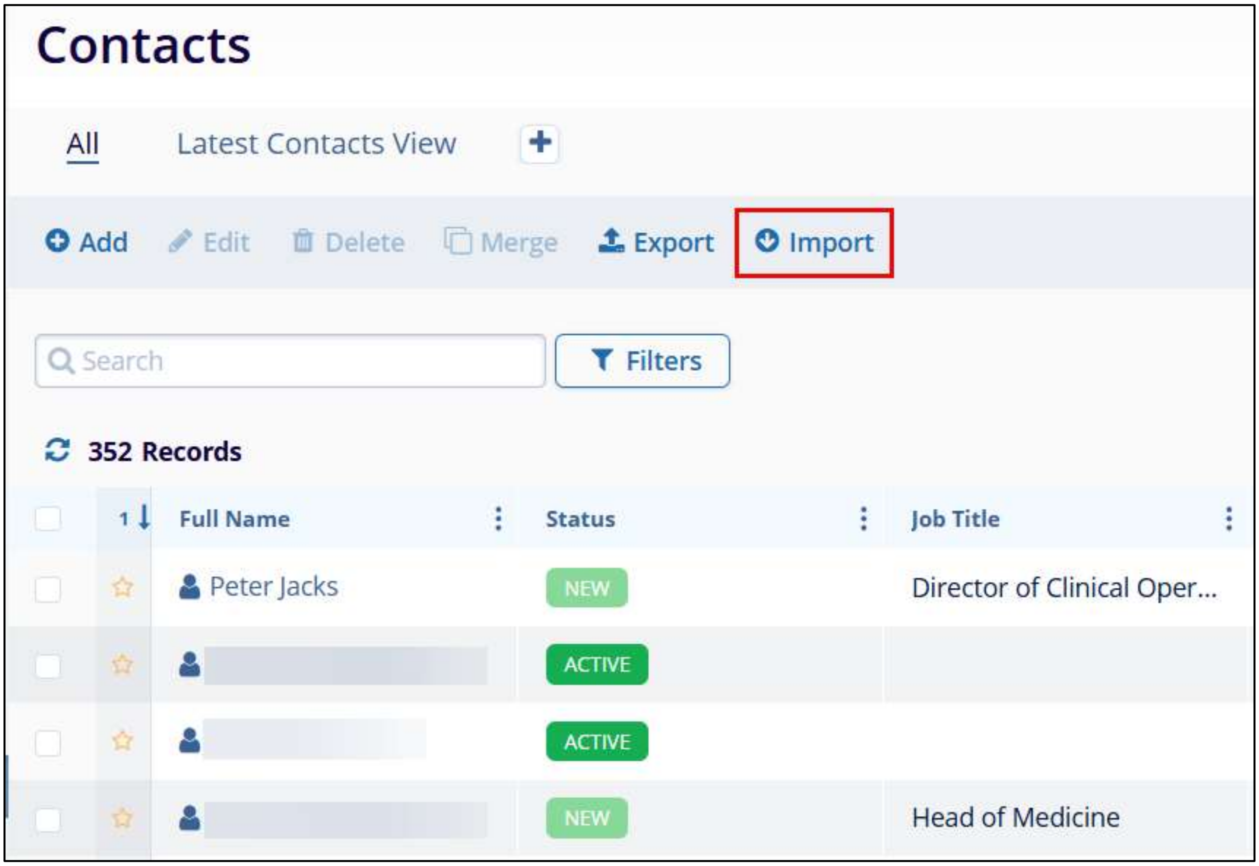


Figure: Select Import

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

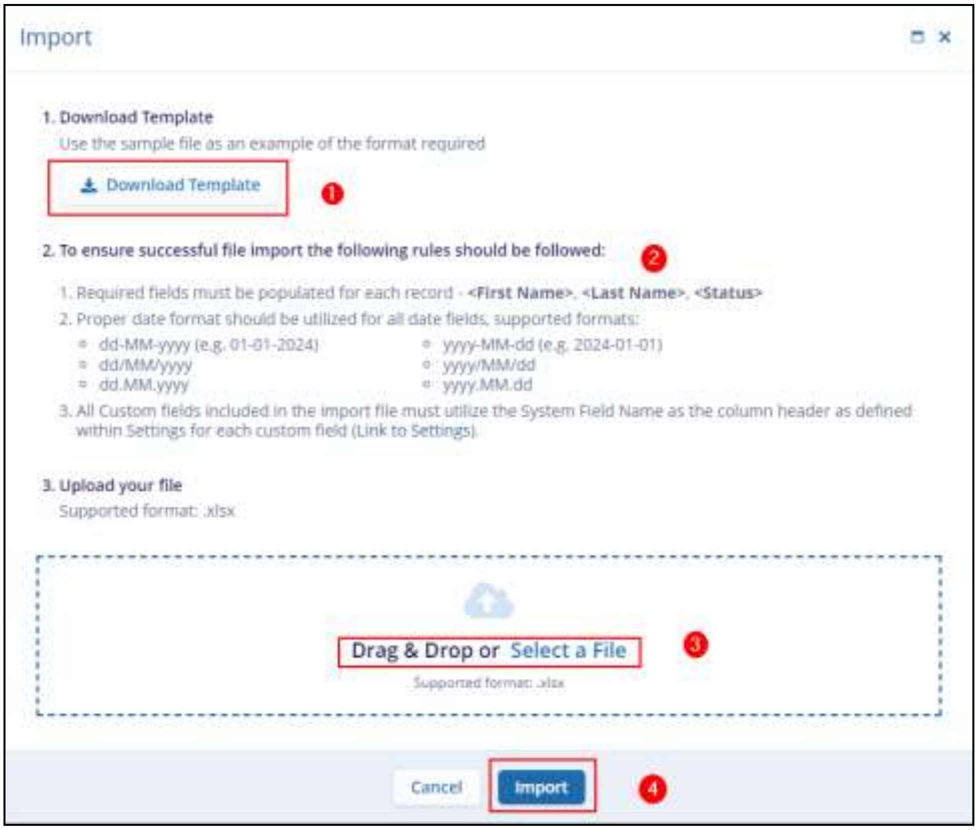


Figure: Import contact's process

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

2. Enter the required details into each column by adhering to the naming convention, date, and custom field-related rules. Refer to the steps detailed in the Contacts import template.

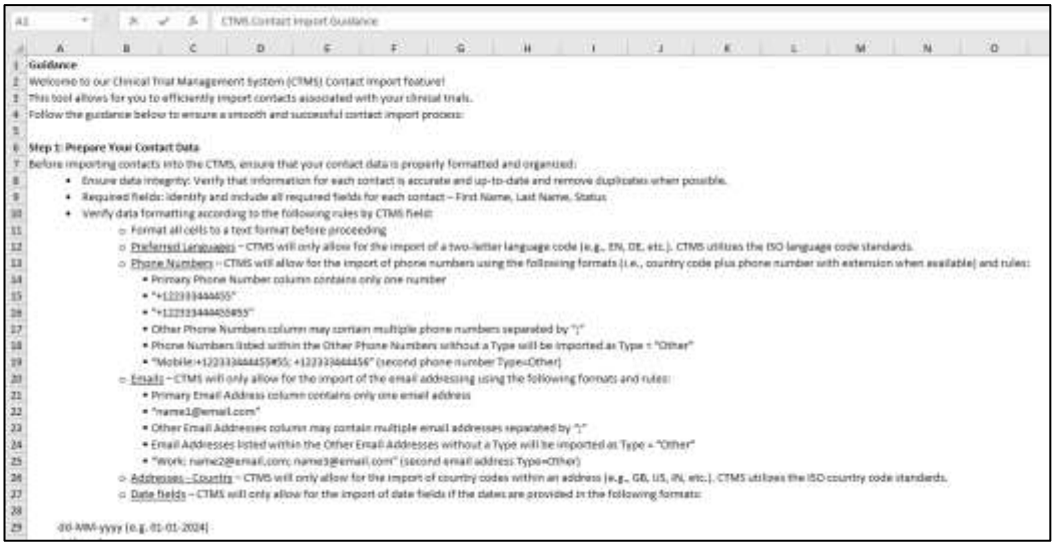
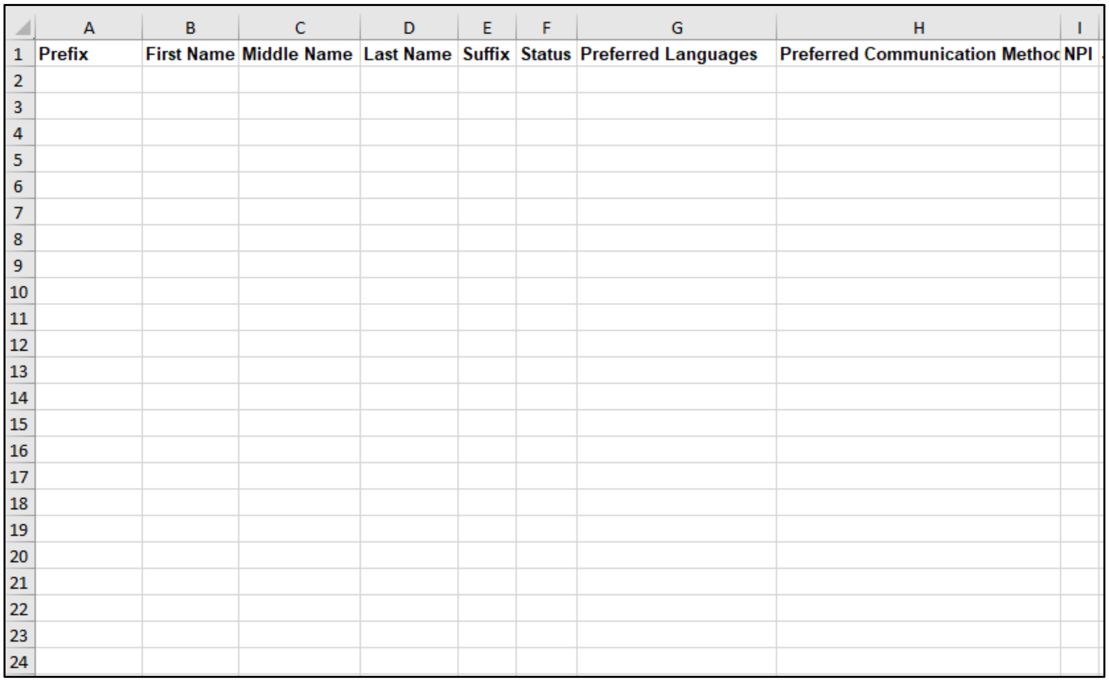


Figure: Contacts import template-Import Guidance



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

Figure: Contacts import template-Contacts

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

Contacts Views

Creating a Contact View

To create a Contact View, follow the steps below.

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

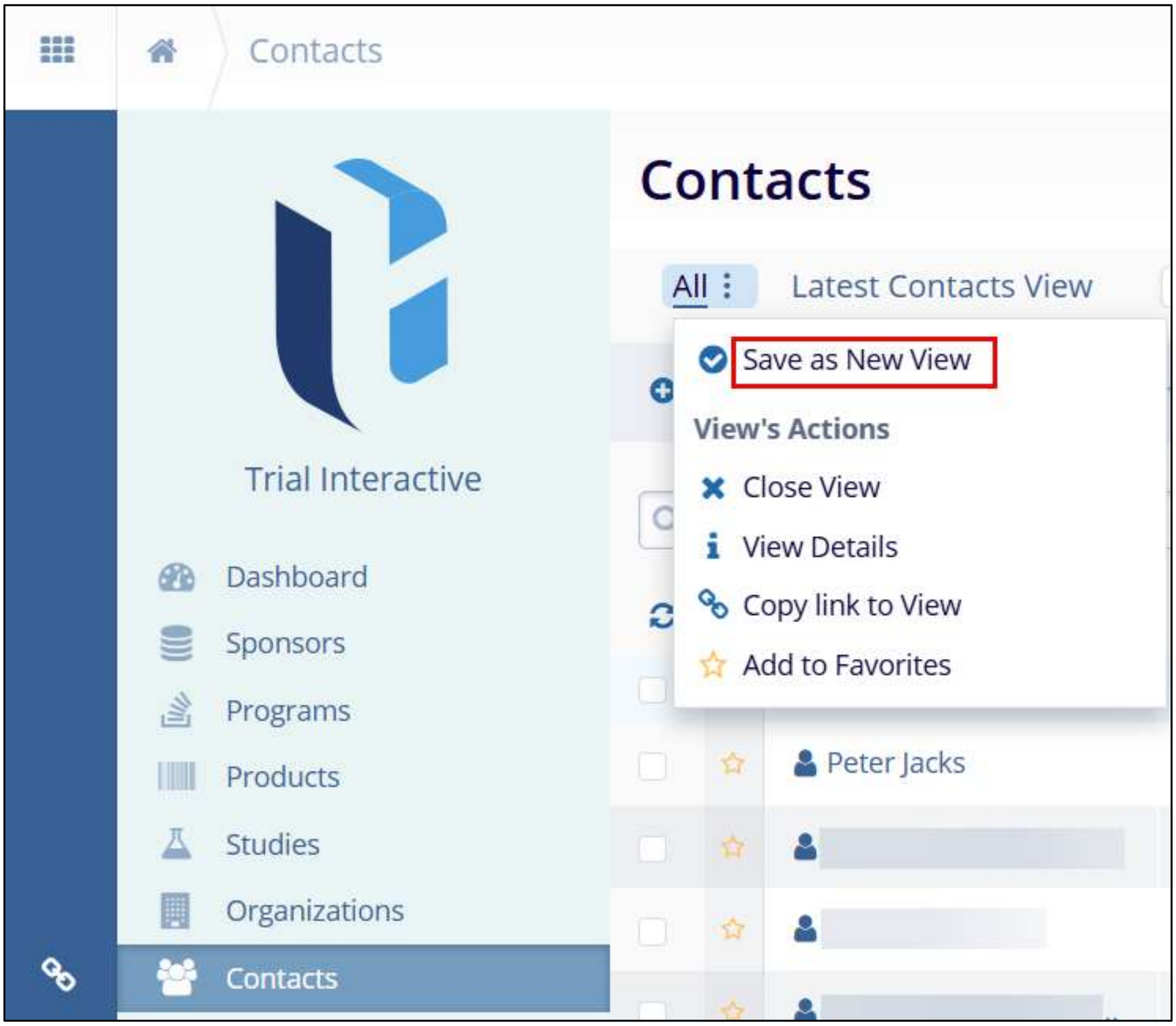


Figure: Save as New View

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

Figure: Save as New View Configuration

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

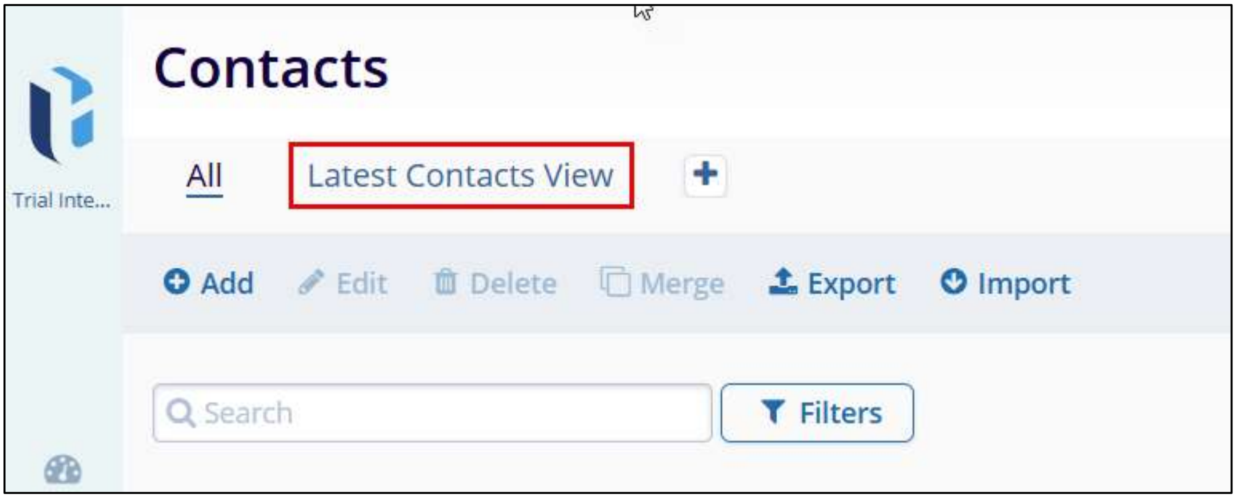


Figure: New contacts view on the home screen

Accessing View's Actions

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

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

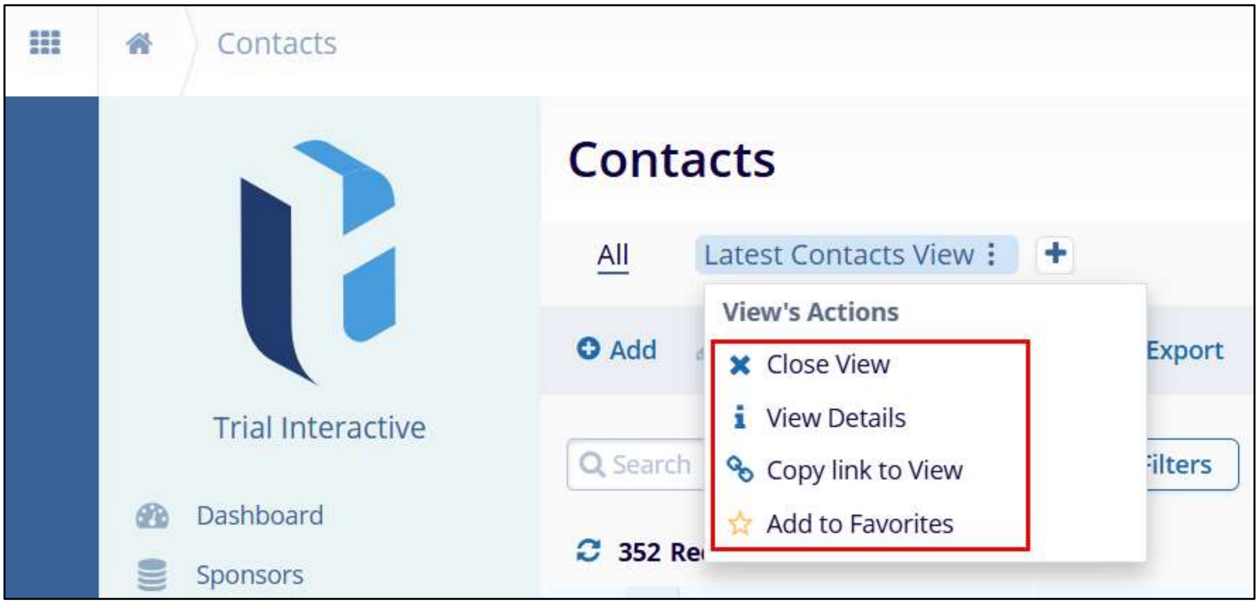


Figure: Accessing View's Actions

The following **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.

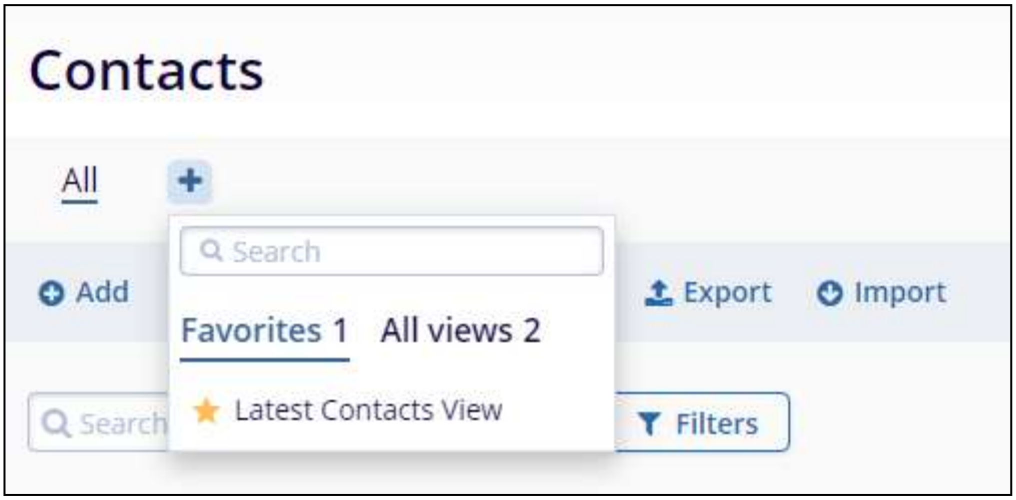


Figure: Adding a new

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.

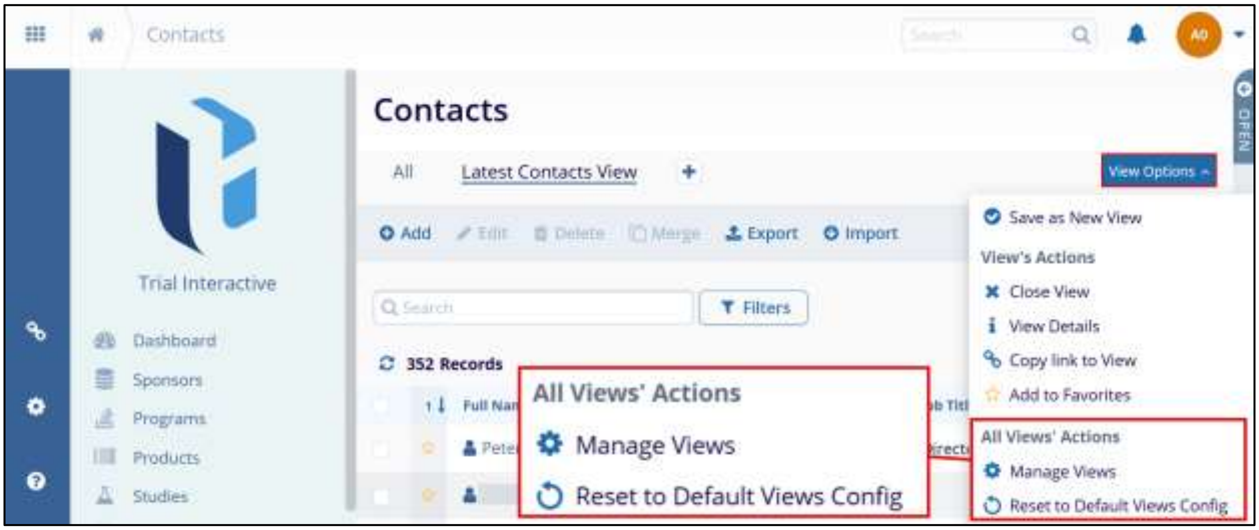


Figure: All View's Actions

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.

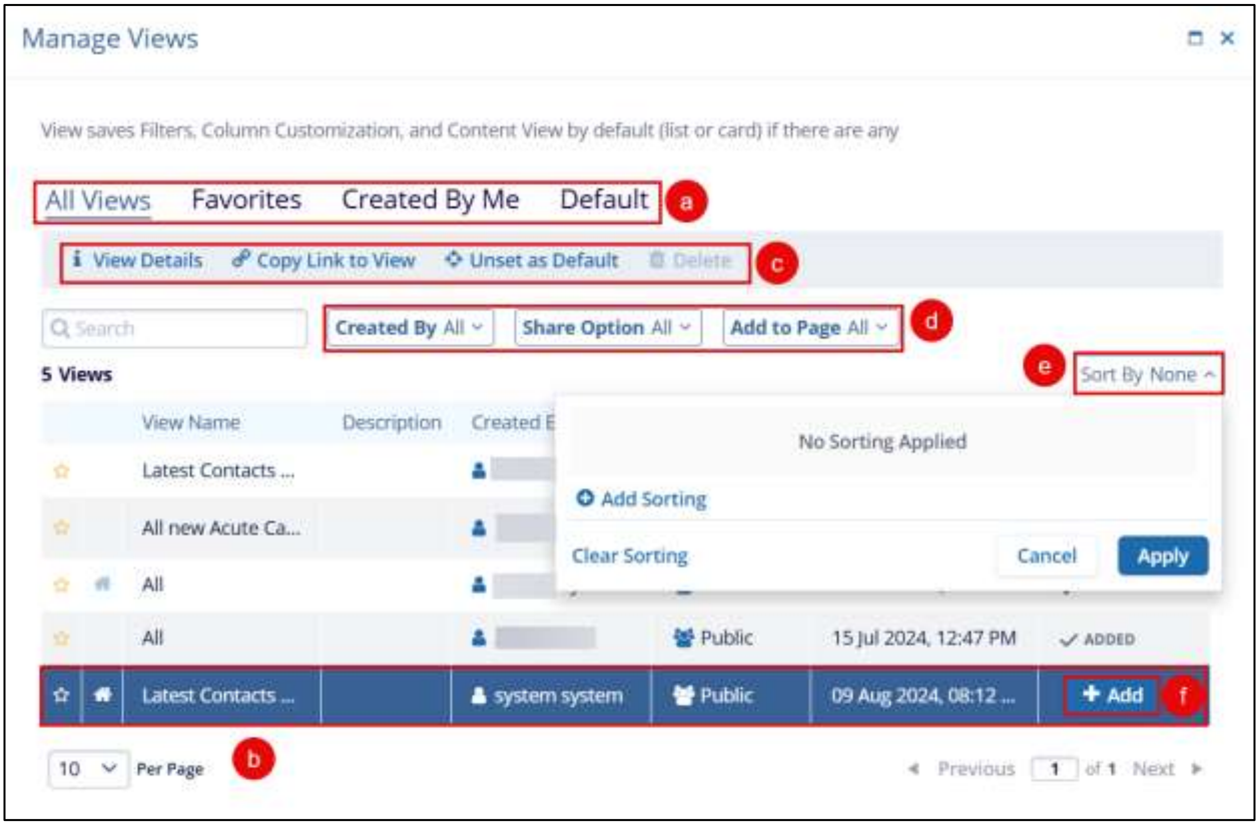


Figure: Manage Views

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

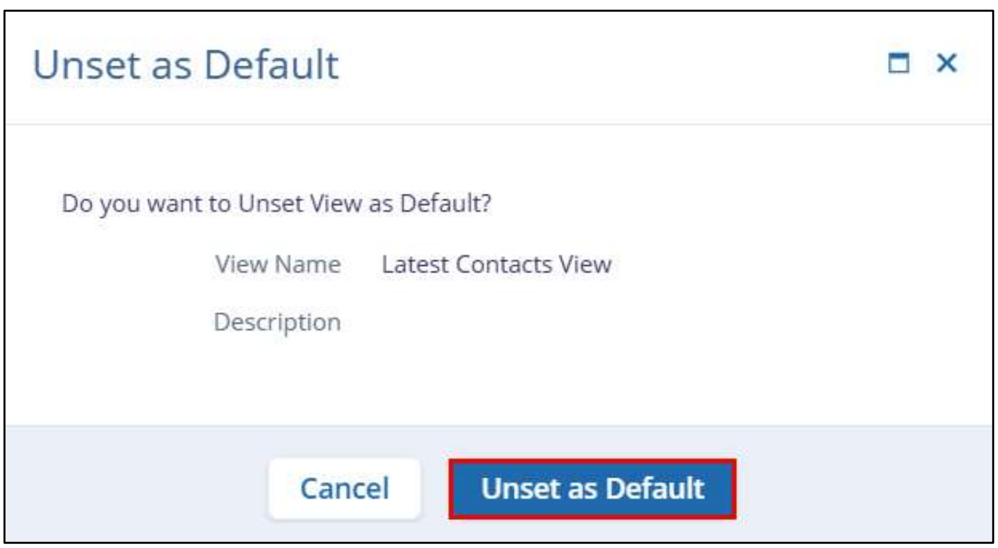


Figure: Reset to Default Views Config

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.

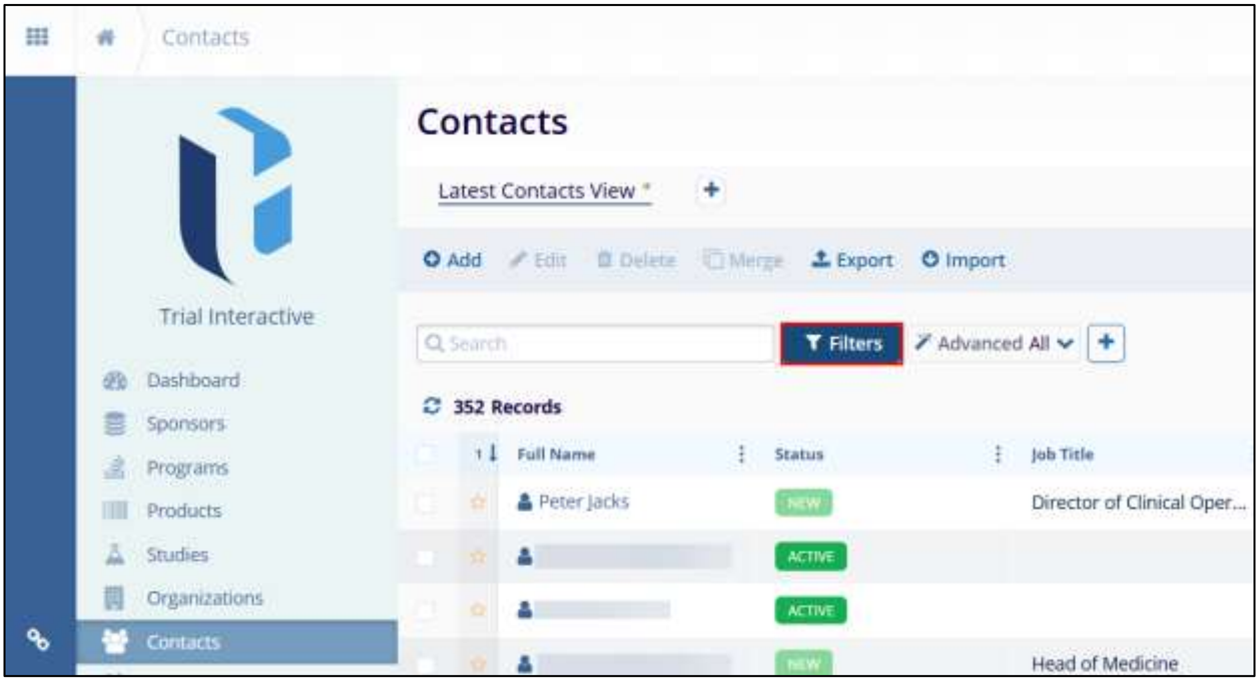


Figure: Add Filters

Standard Filters

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

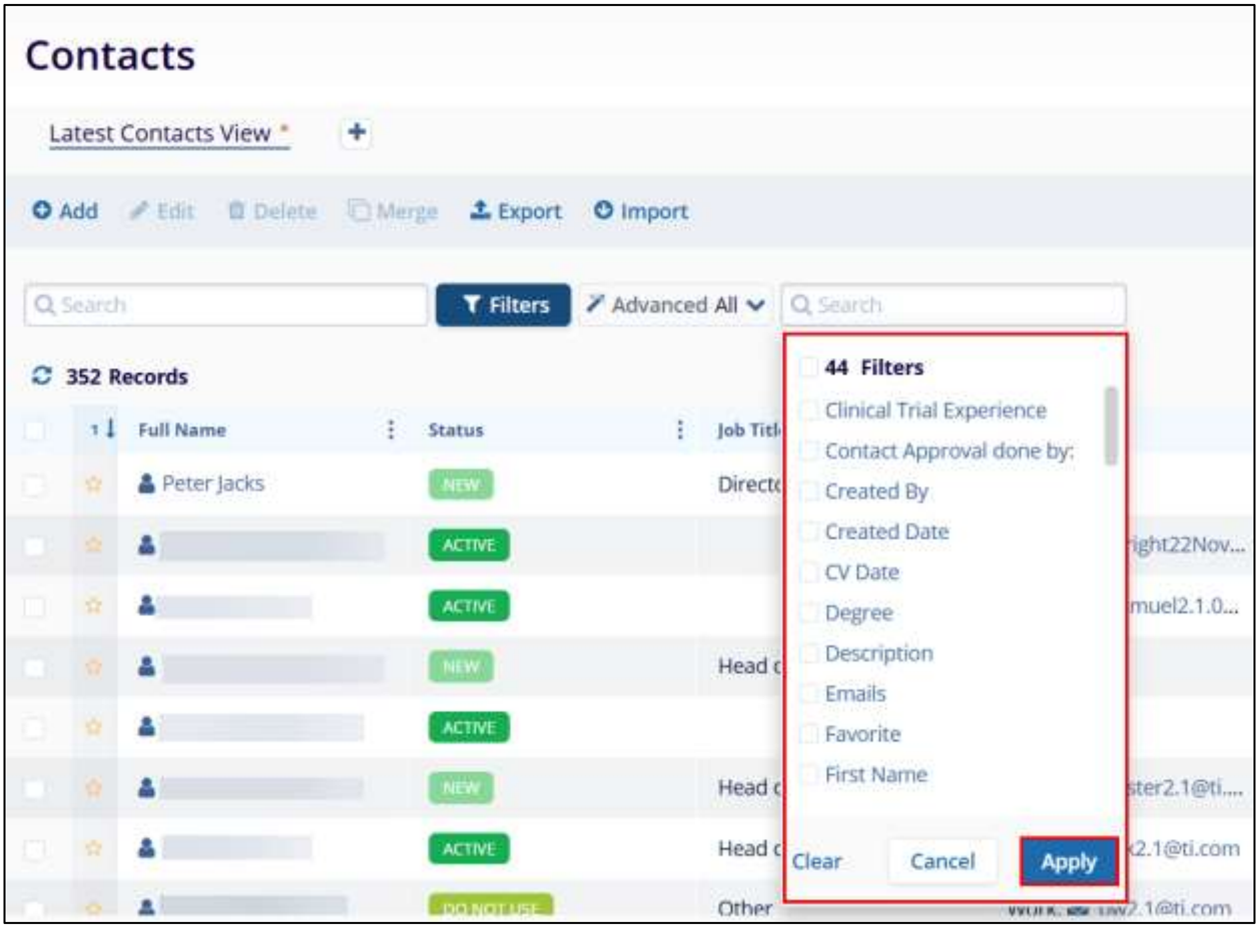


Figure: Apply standard filters

Advanced Filters

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

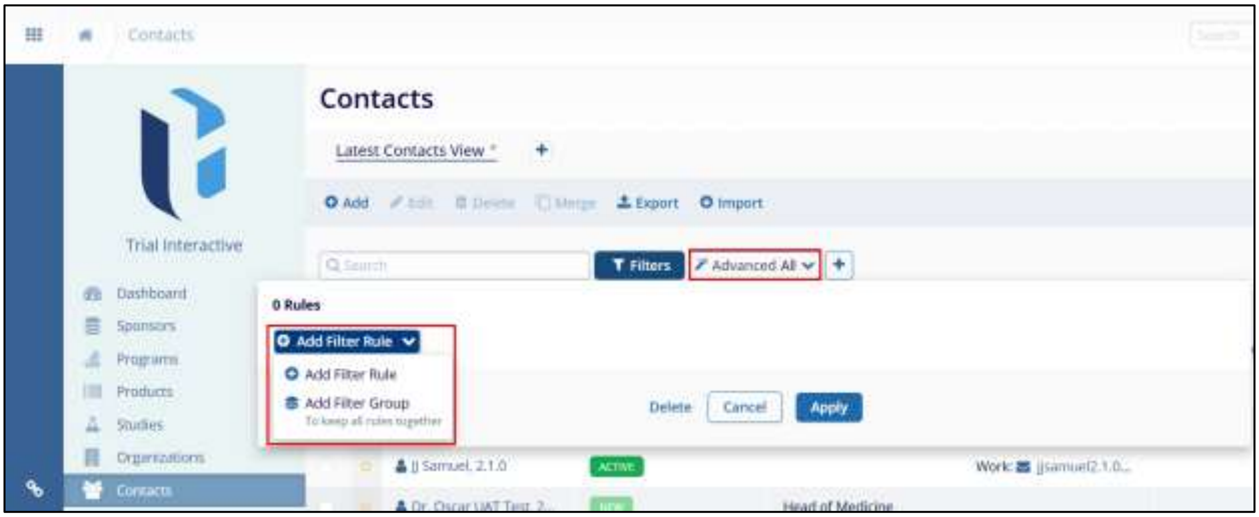


Figure: Apply Advanced Filters

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

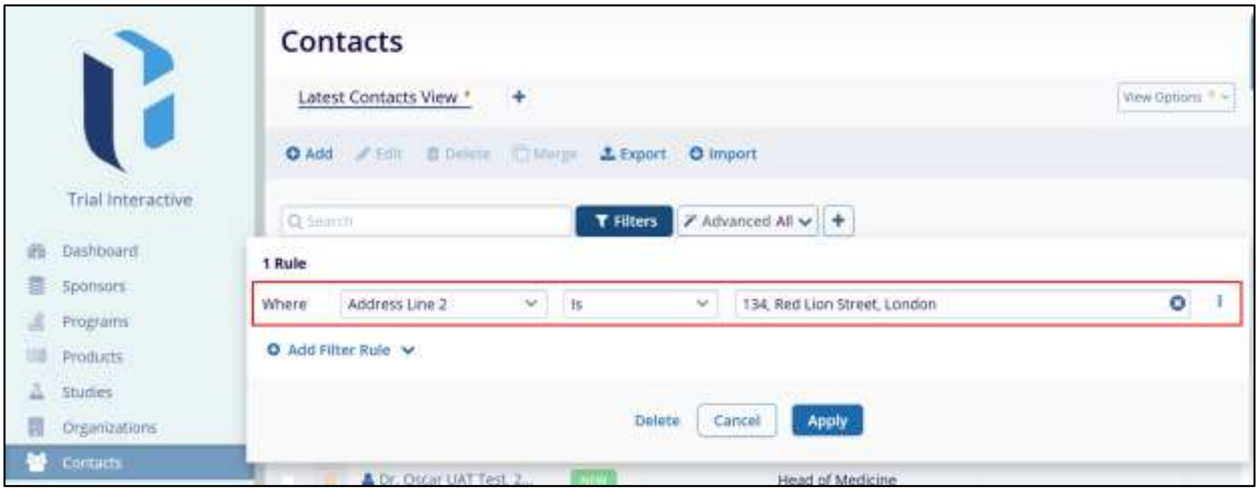


Figure: Configure Advanced filters

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.

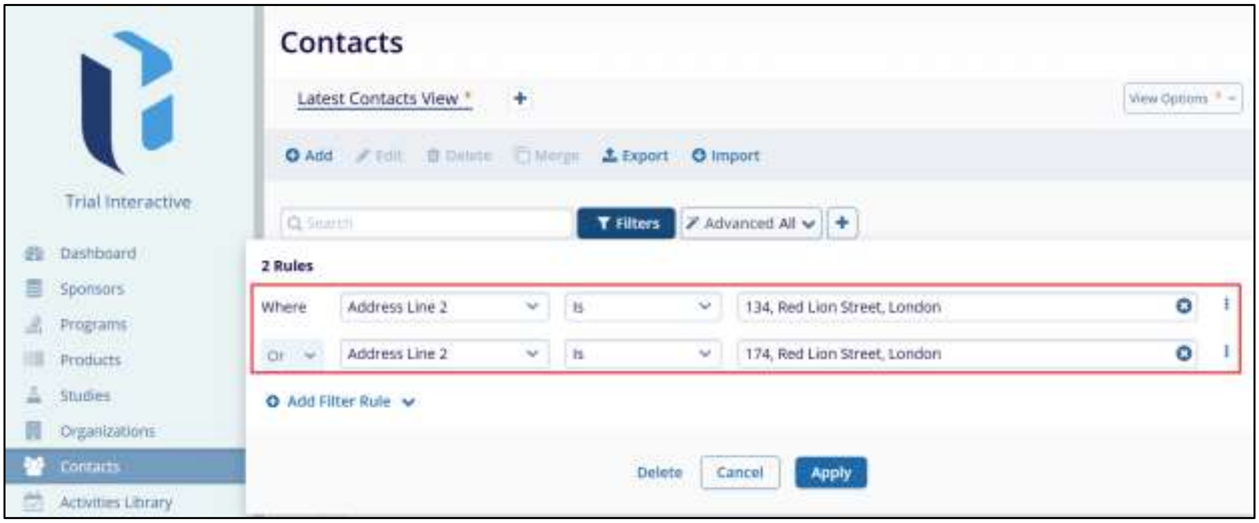


Figure: Advanced filters with And/Or conditions

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.

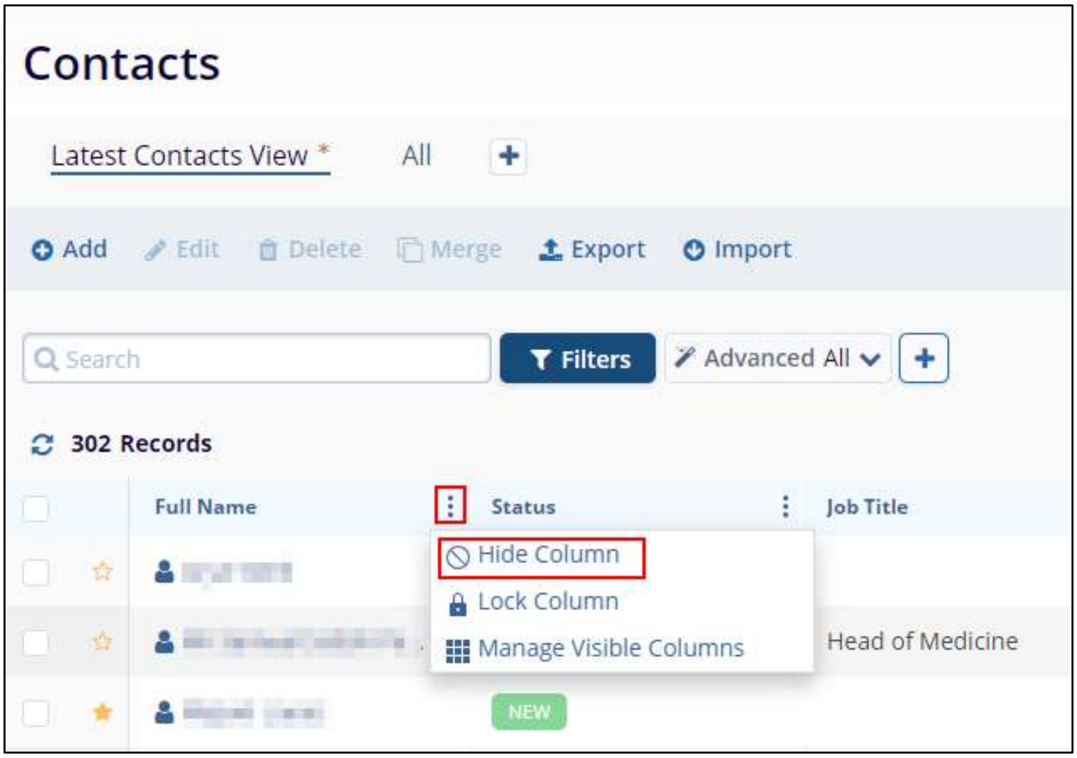


Figure: Hide Column

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.

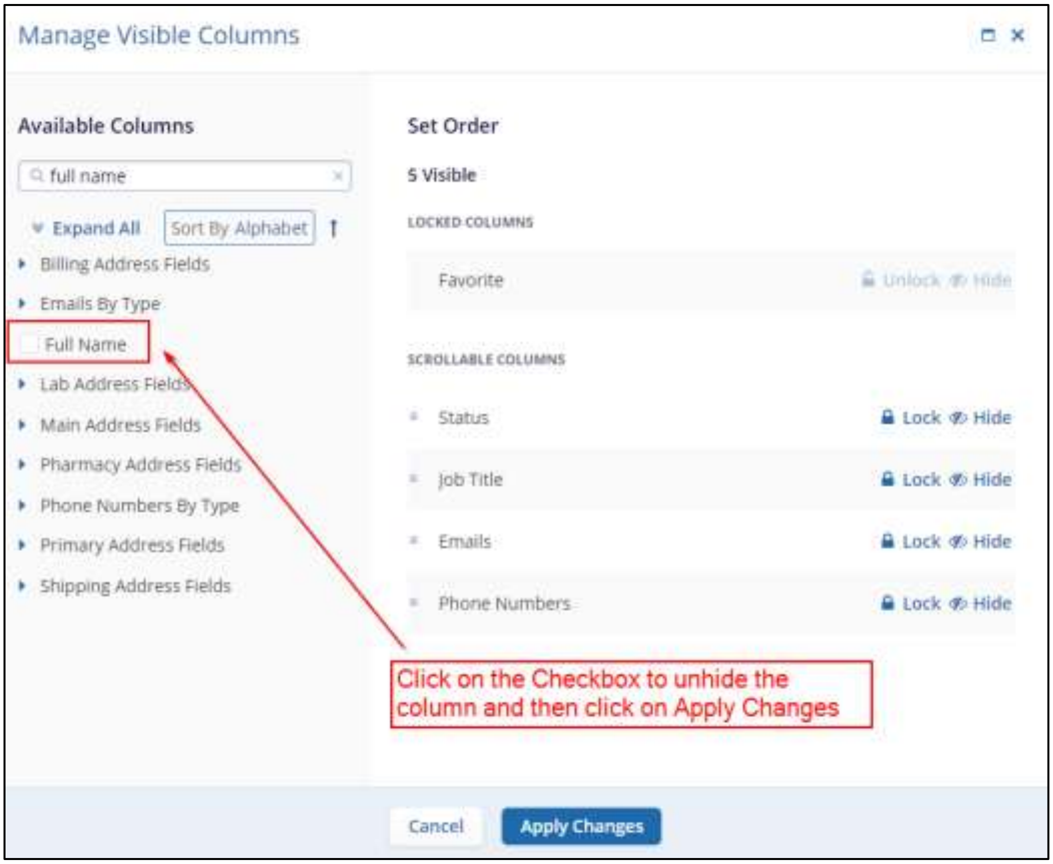


Figure: Unhide column

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.

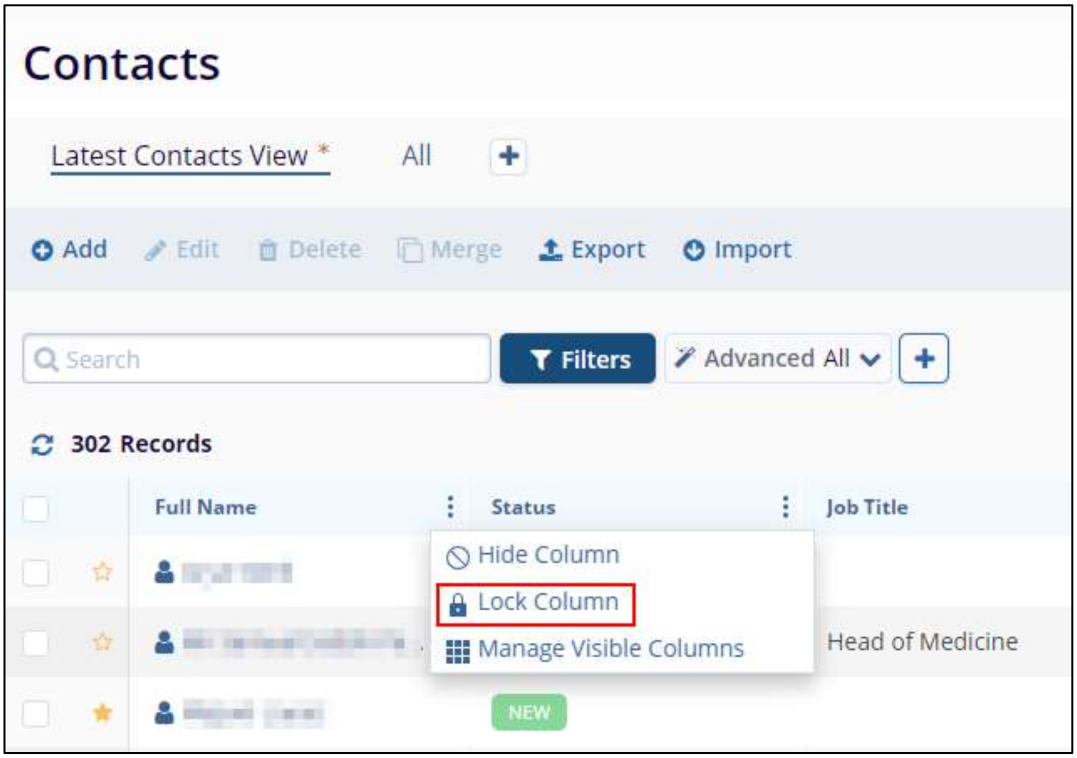


Figure: Lock Column

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.

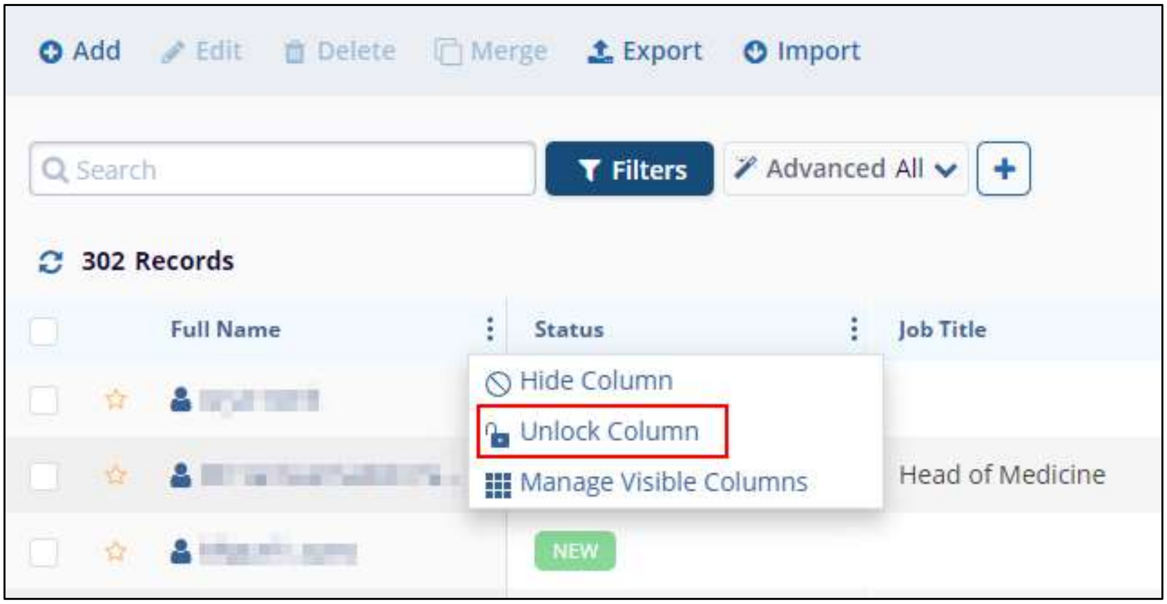


Figure: Unlock Column

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

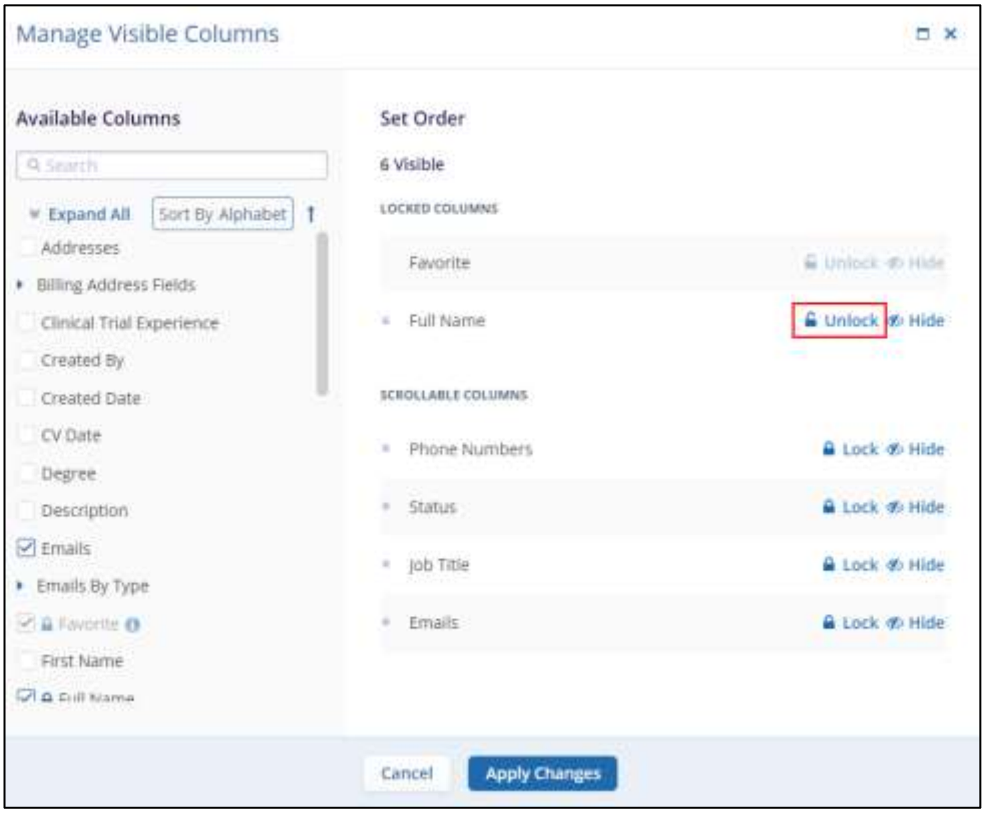


Figure: Unlock column through Manage Visible Columns

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.

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

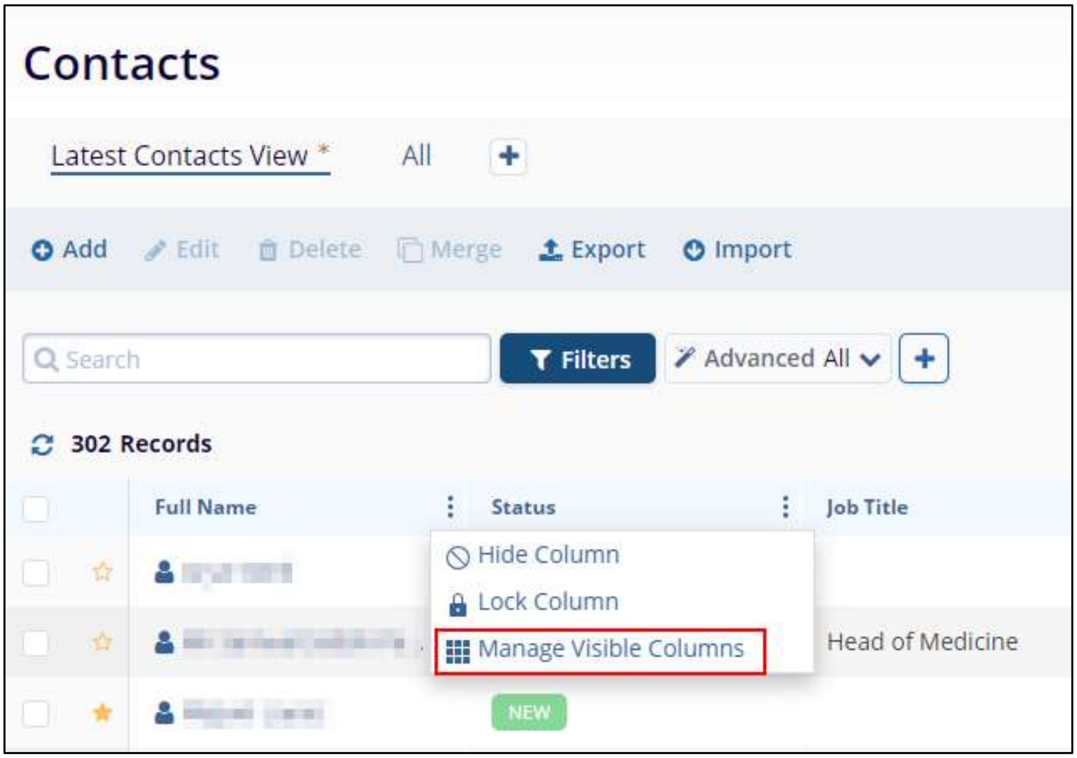


Figure: Manage Visible Columns

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

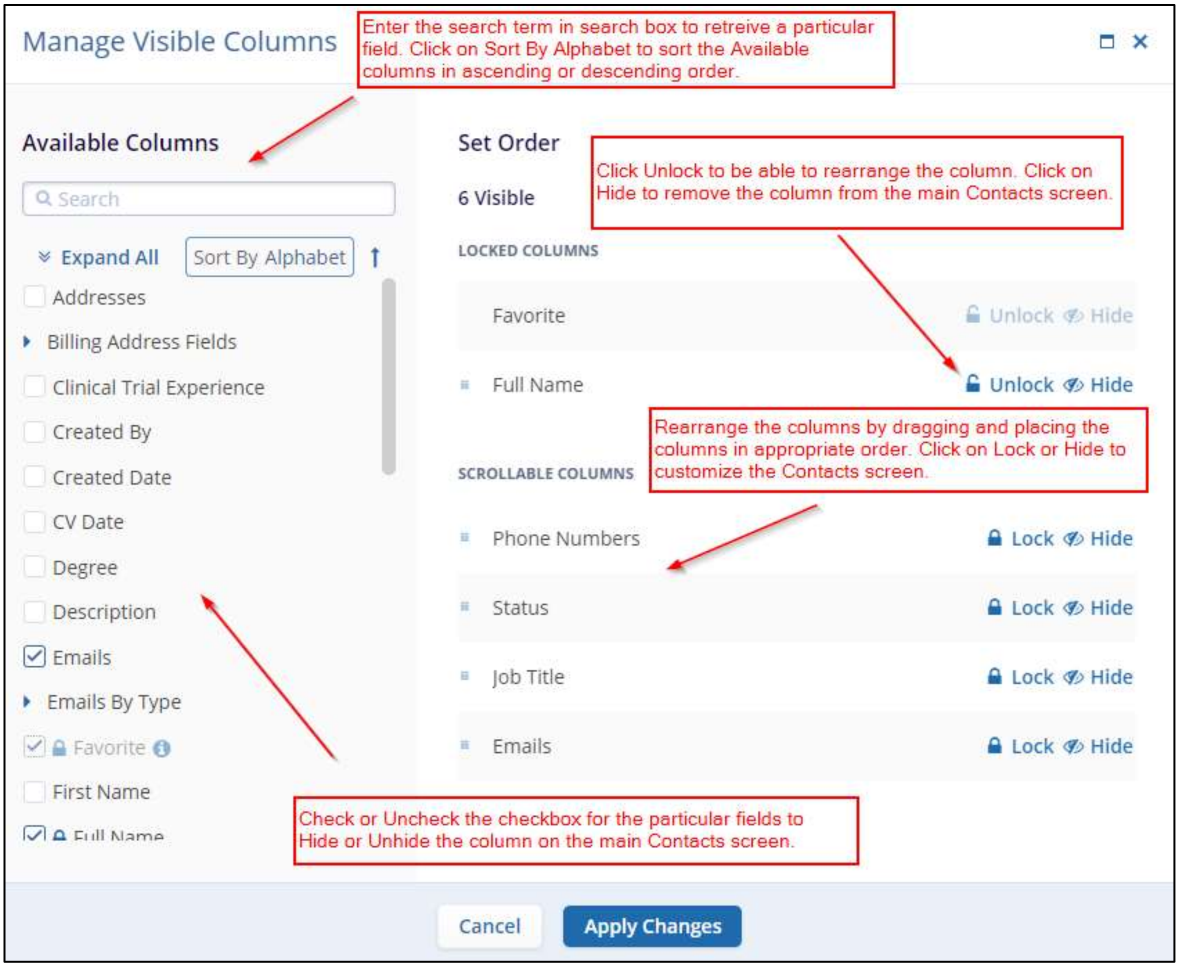


Figure: Manage Visible Columns options

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

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.

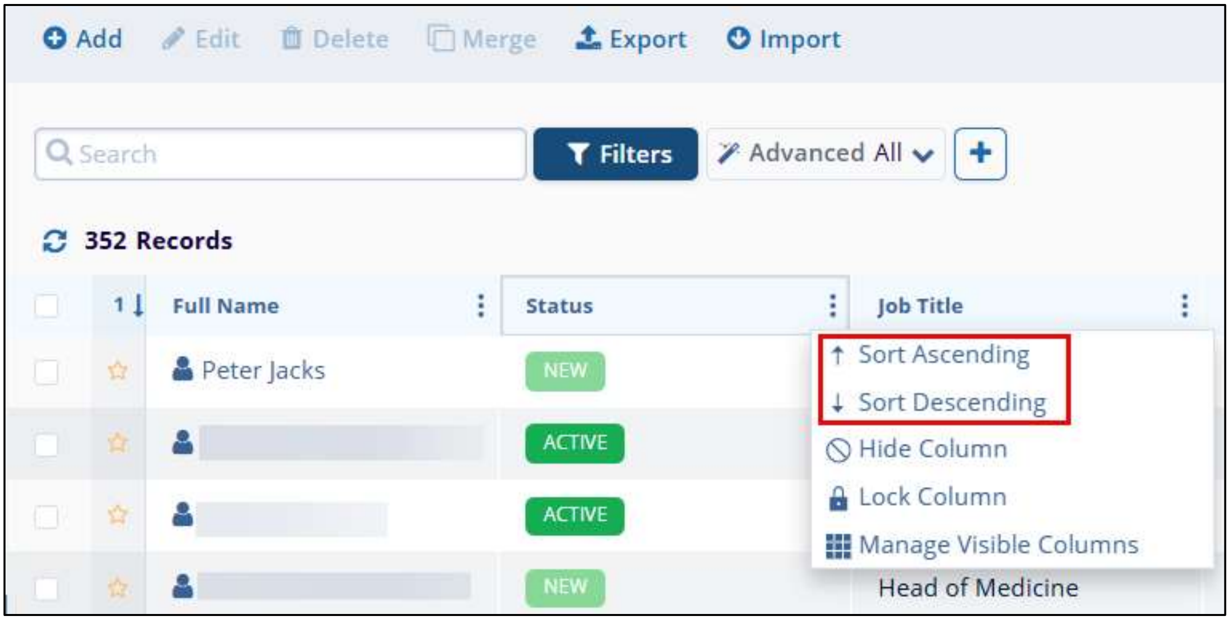


Figure: Sort Ascending and Descending

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.

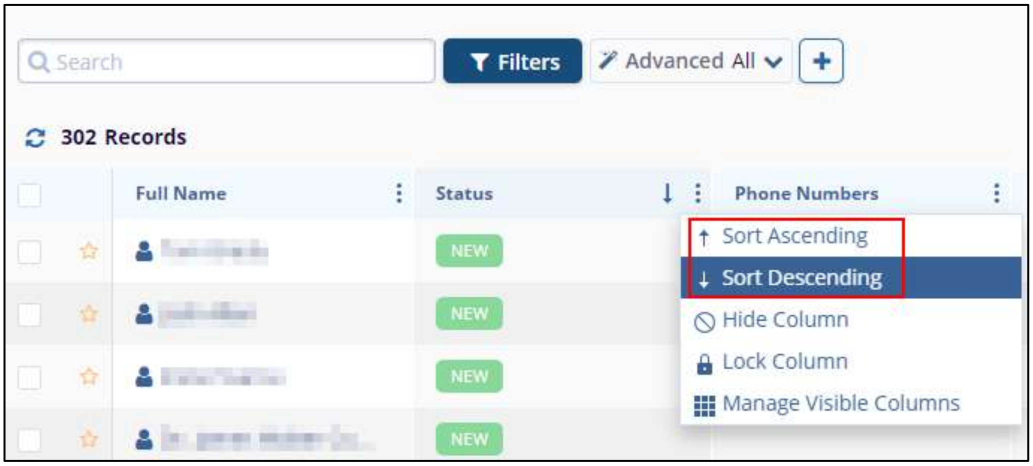


Figure: Sort Ascending and Descending

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.

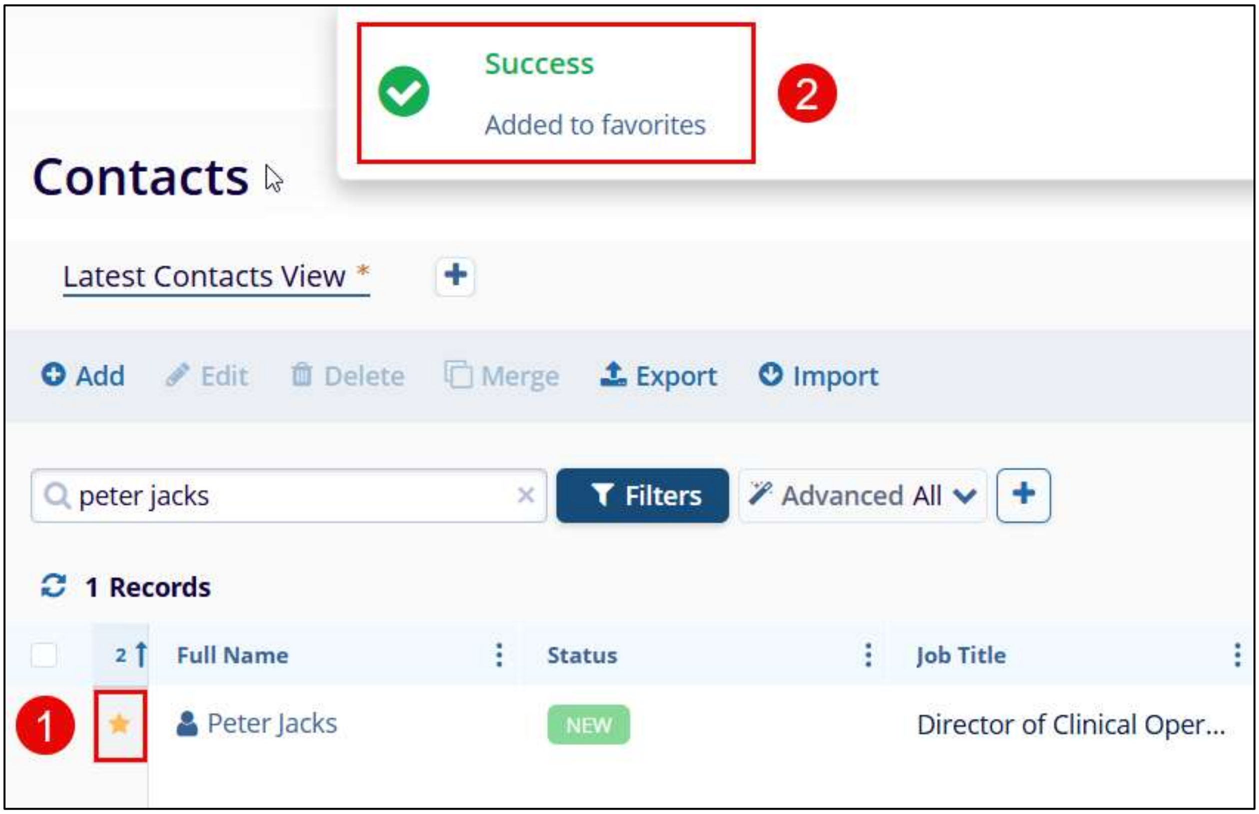


Figure: Mark a contact as a favorite

CHAPTER 10. USER MANAGEMENT

This section describes the process of managing users in CTMS.

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.

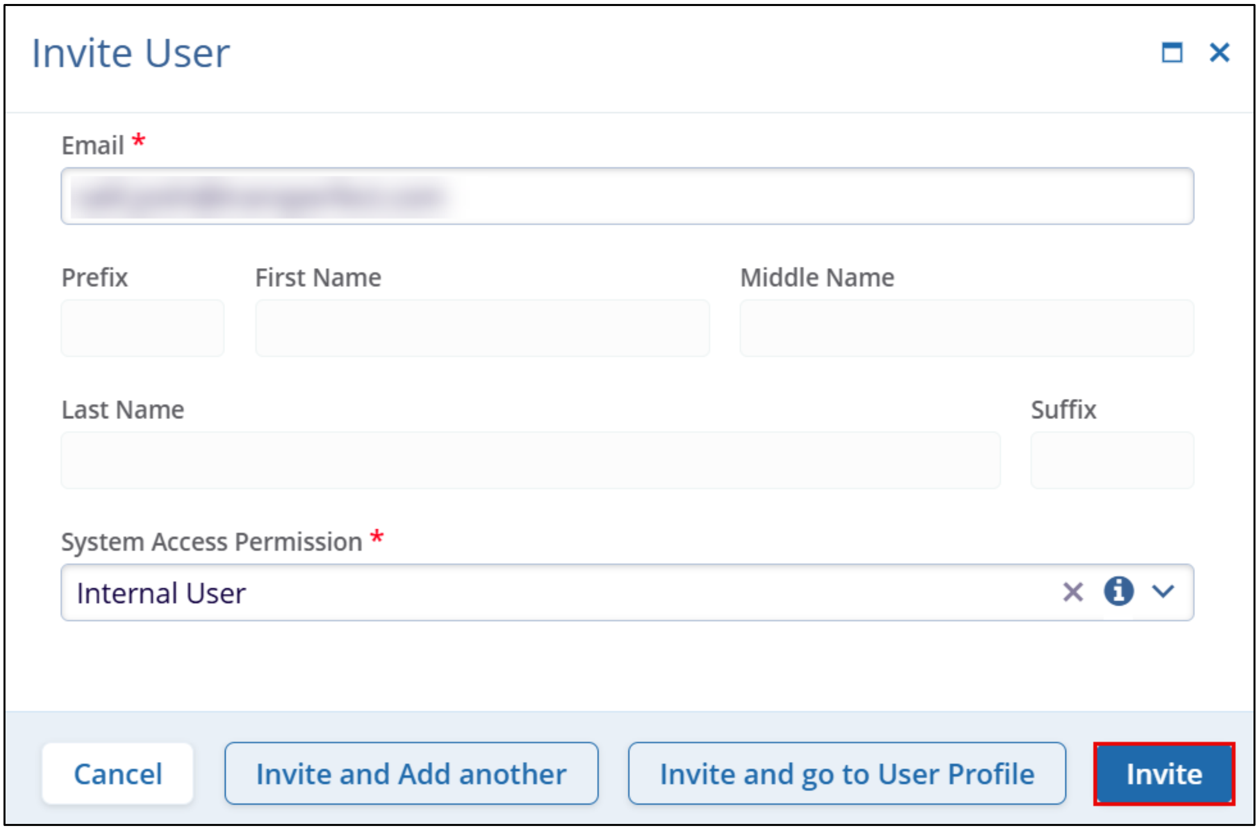


Figure: Invite User fields

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.

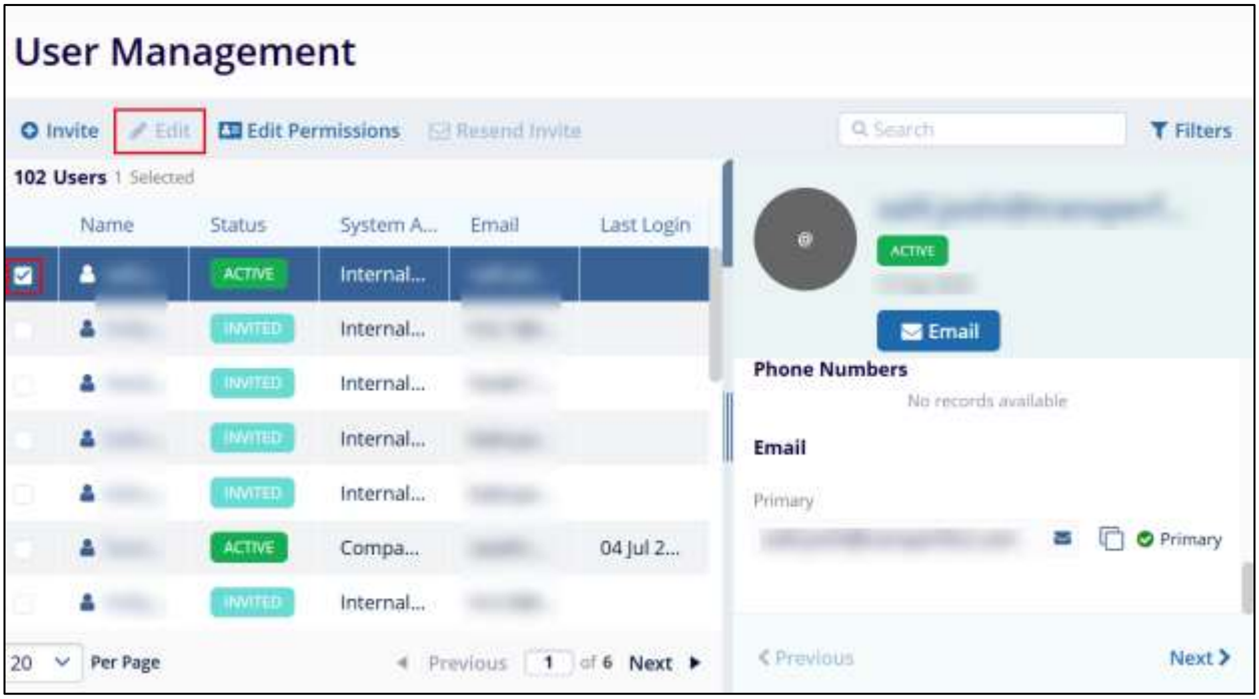


Figure: Edit User

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.

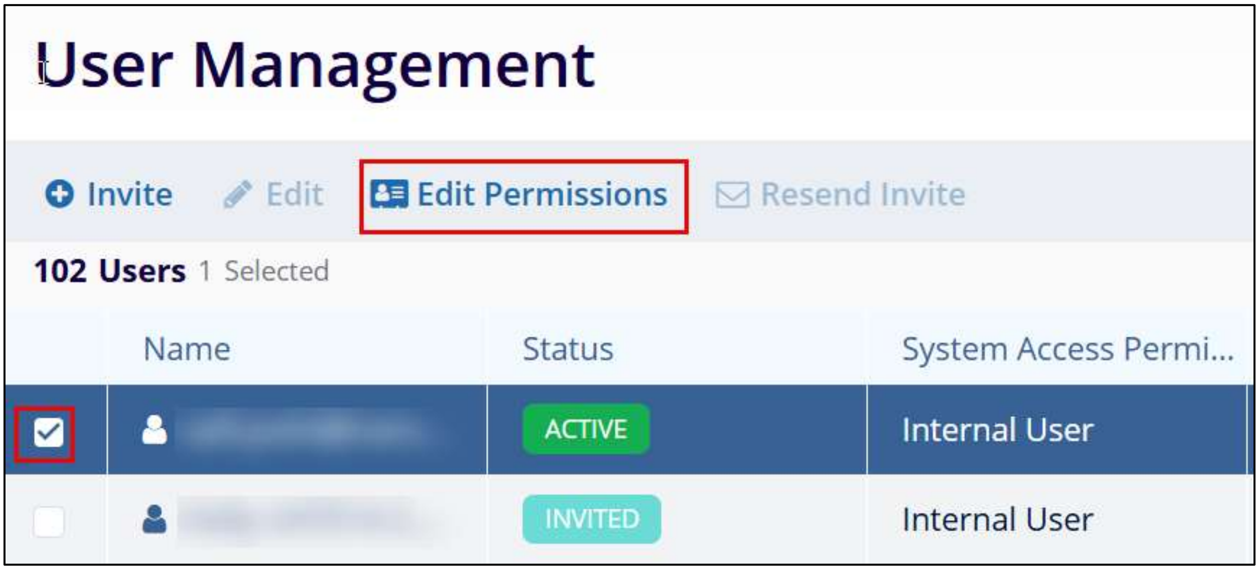


Figure: Edit Permissions

3. On the Edit Permissions screen, click on the System Access Permission dropdown and select a user role.
4. Click on the Show Level Permissions button to manage user access at Organization, Program and Study Levels.

5. Expand each option and select an option from the Access Permission dropdown.
6. Enable the Invite/Manage Users toggle switch, to allow users to add other users into the system.

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.

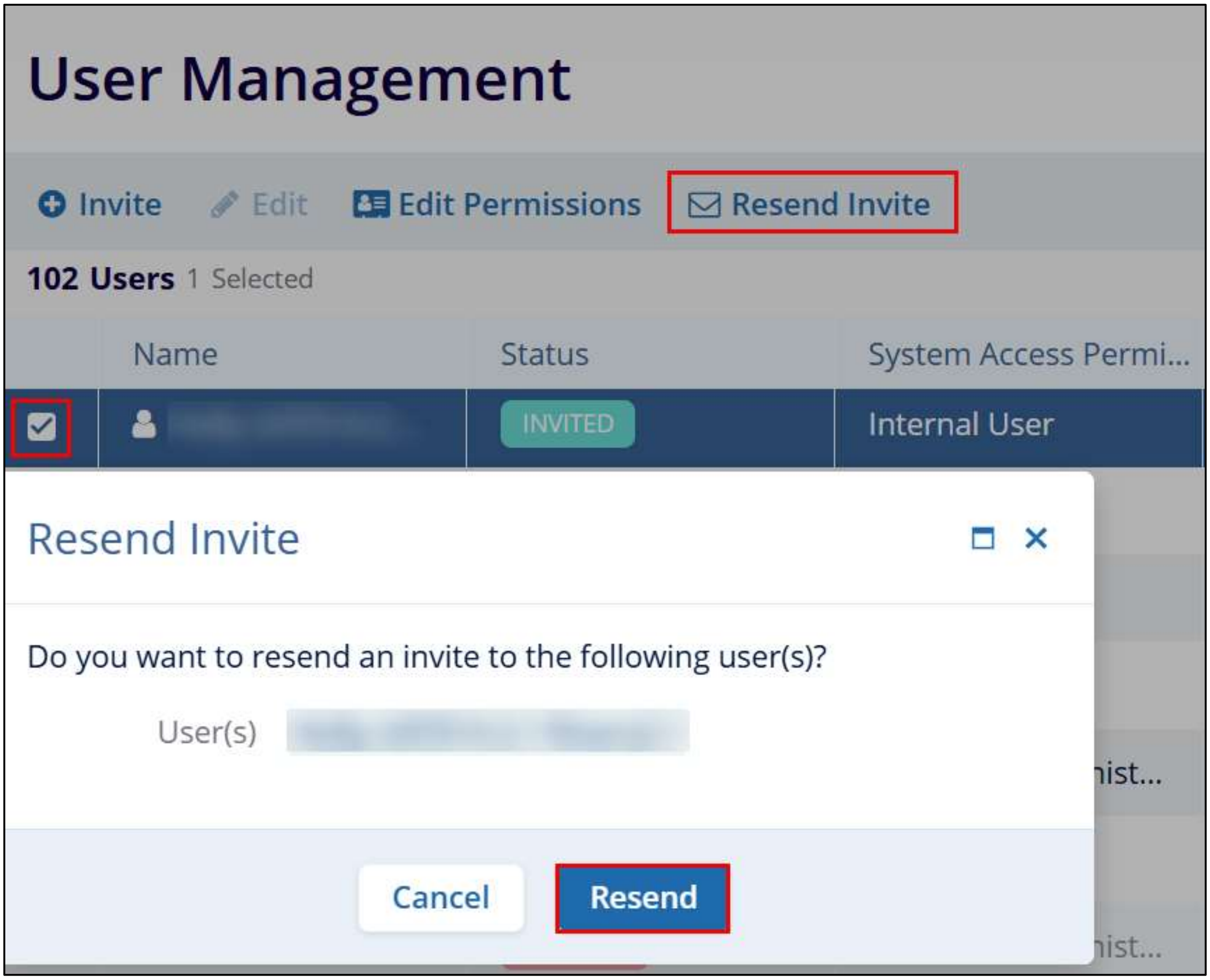


Figure: Resend Invite

CHAPTER 11. ACTIVITIES LIBRARY

Accessing Activities Library

To access the Activities Library, follow the steps below.

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

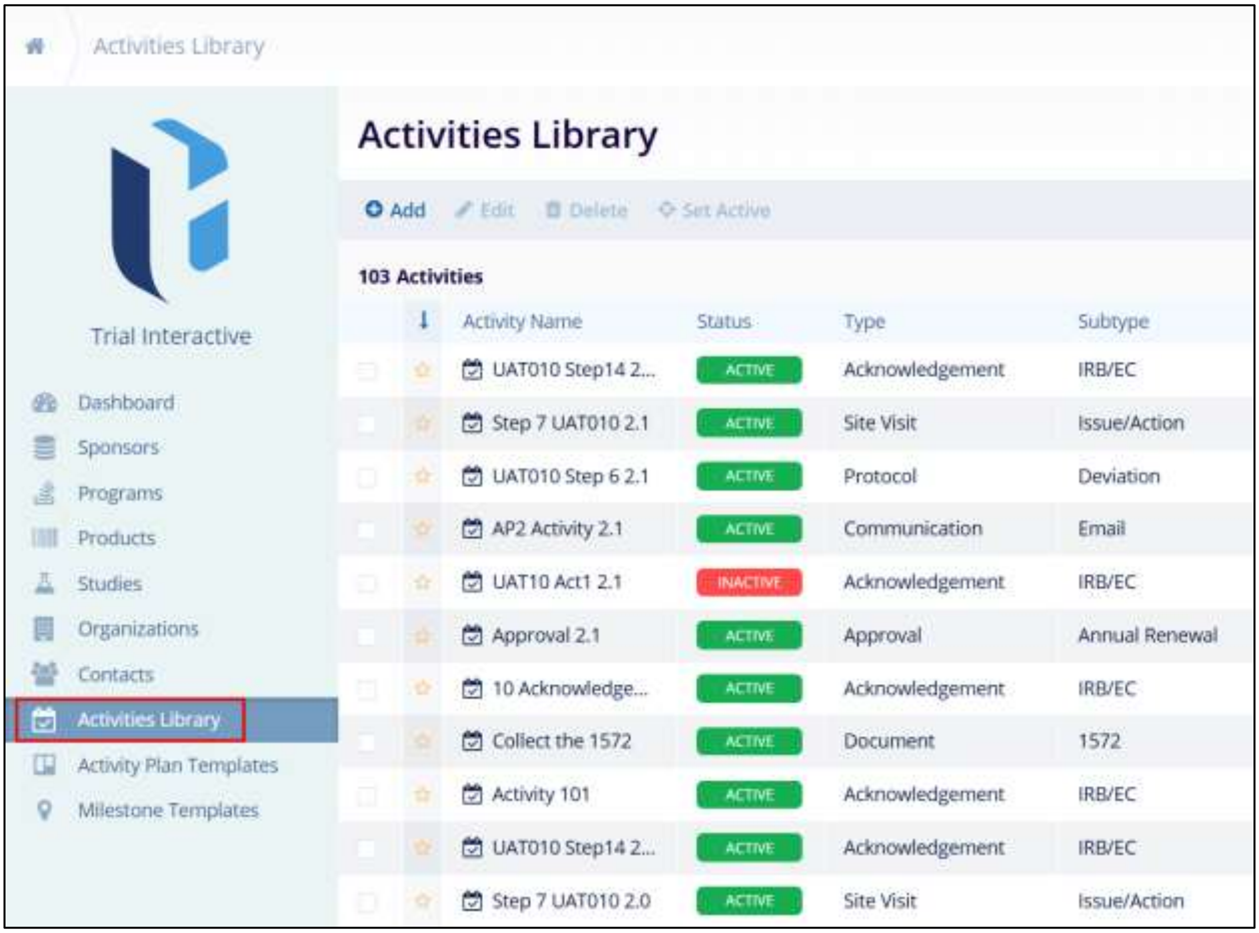


Figure: Accessing Activities Library

Creating Domain Library Activity Records

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

1. On the Activities Library screen, click on the Add button in the top-left of the screen.
2. On the Create Activity screen, 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.

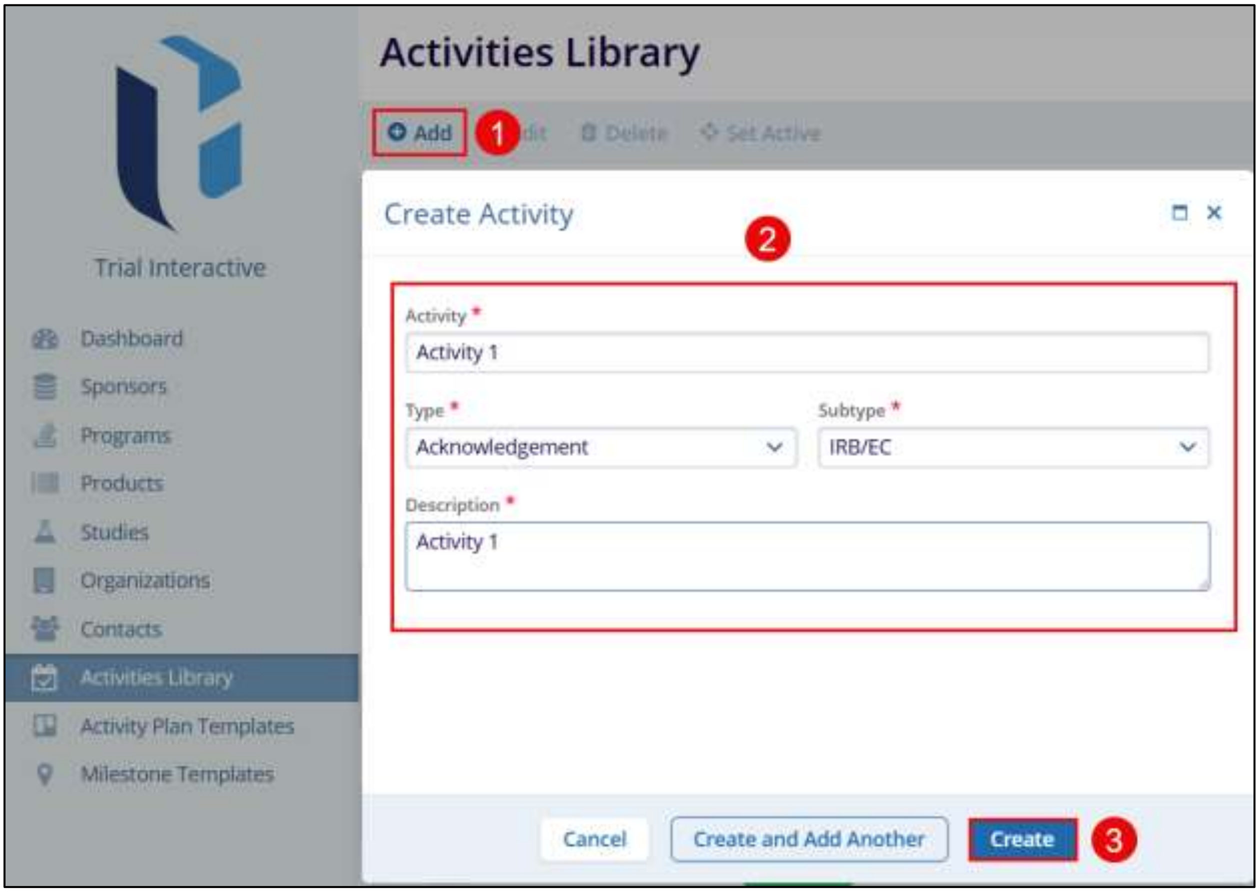


Figure: Creating Domain Library Activity Records

Note:

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

Editing Domain Library Activity Records

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

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

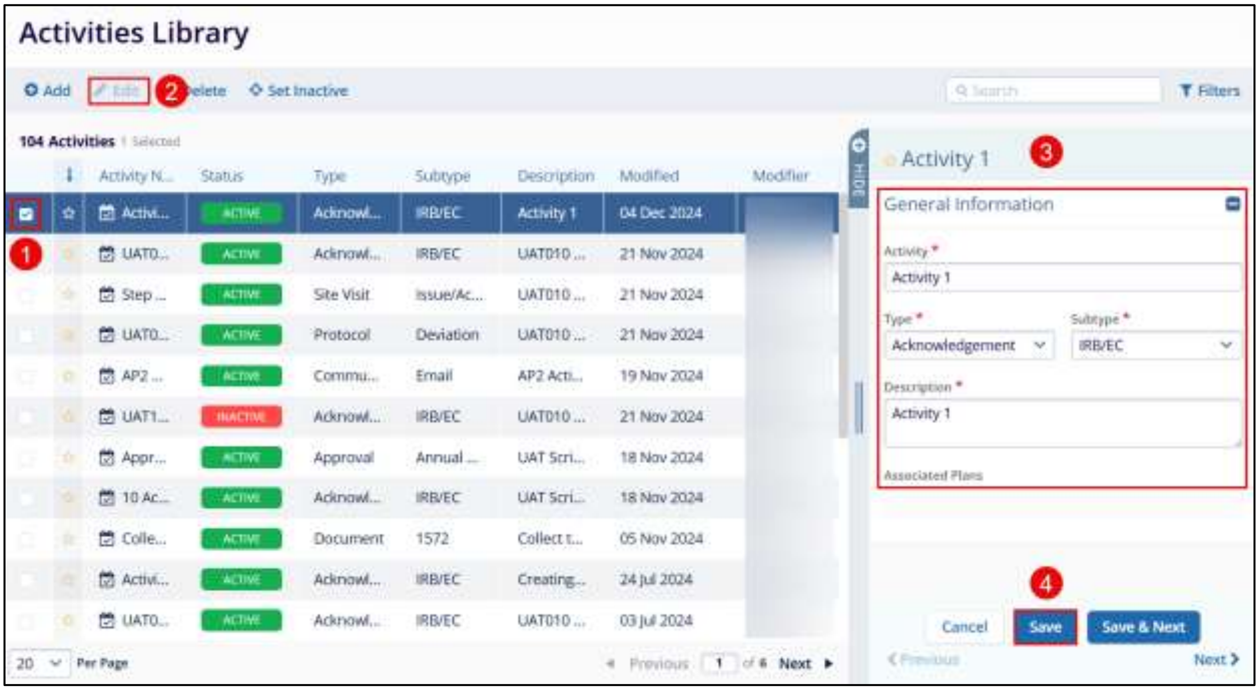


Figure: Editing Domain Library Activity Records

Deleting Domain Activity Records

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

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

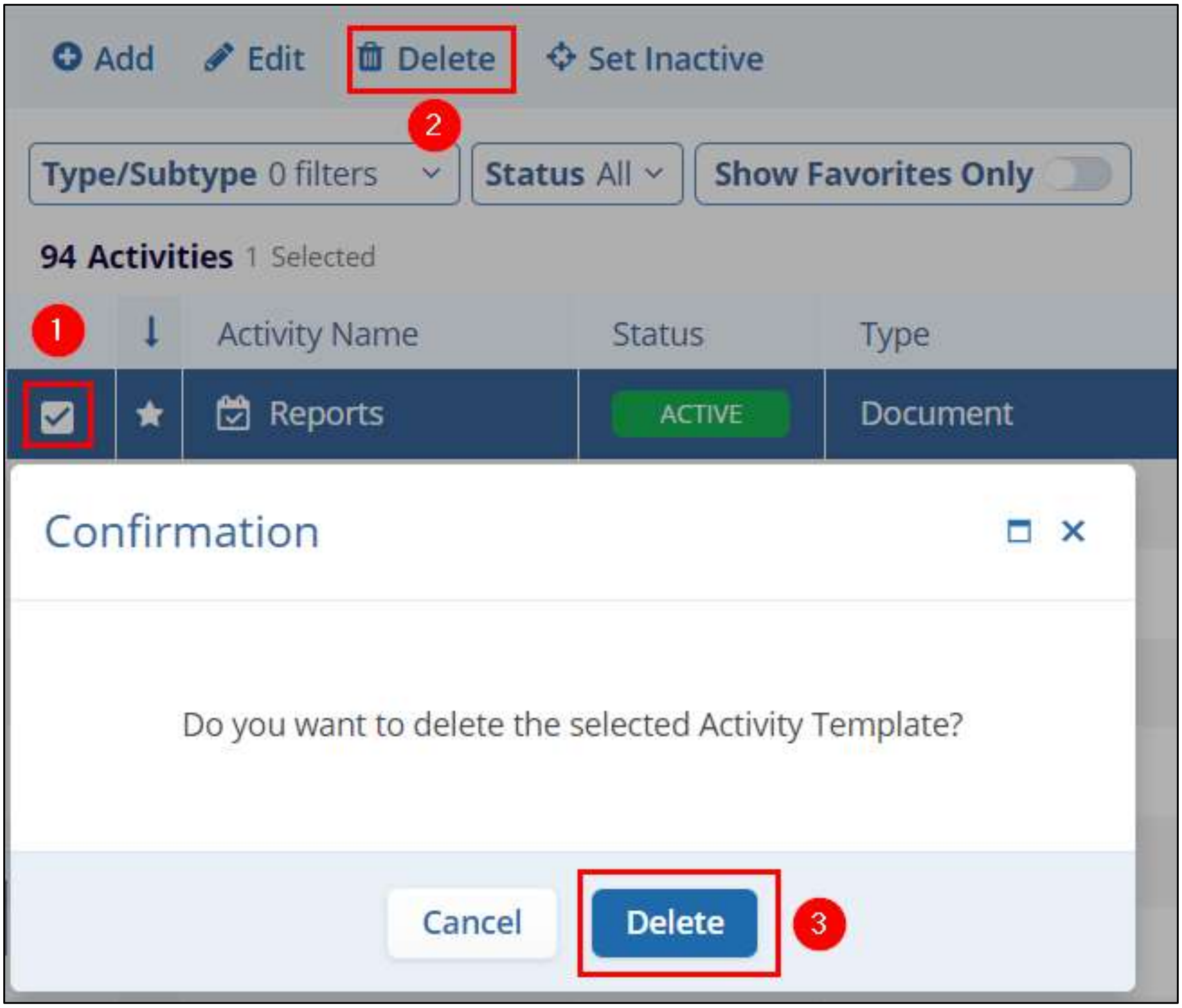


Figure: Deleting Domain Activity Records

Setting Domain Activity Records to Inactive

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

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

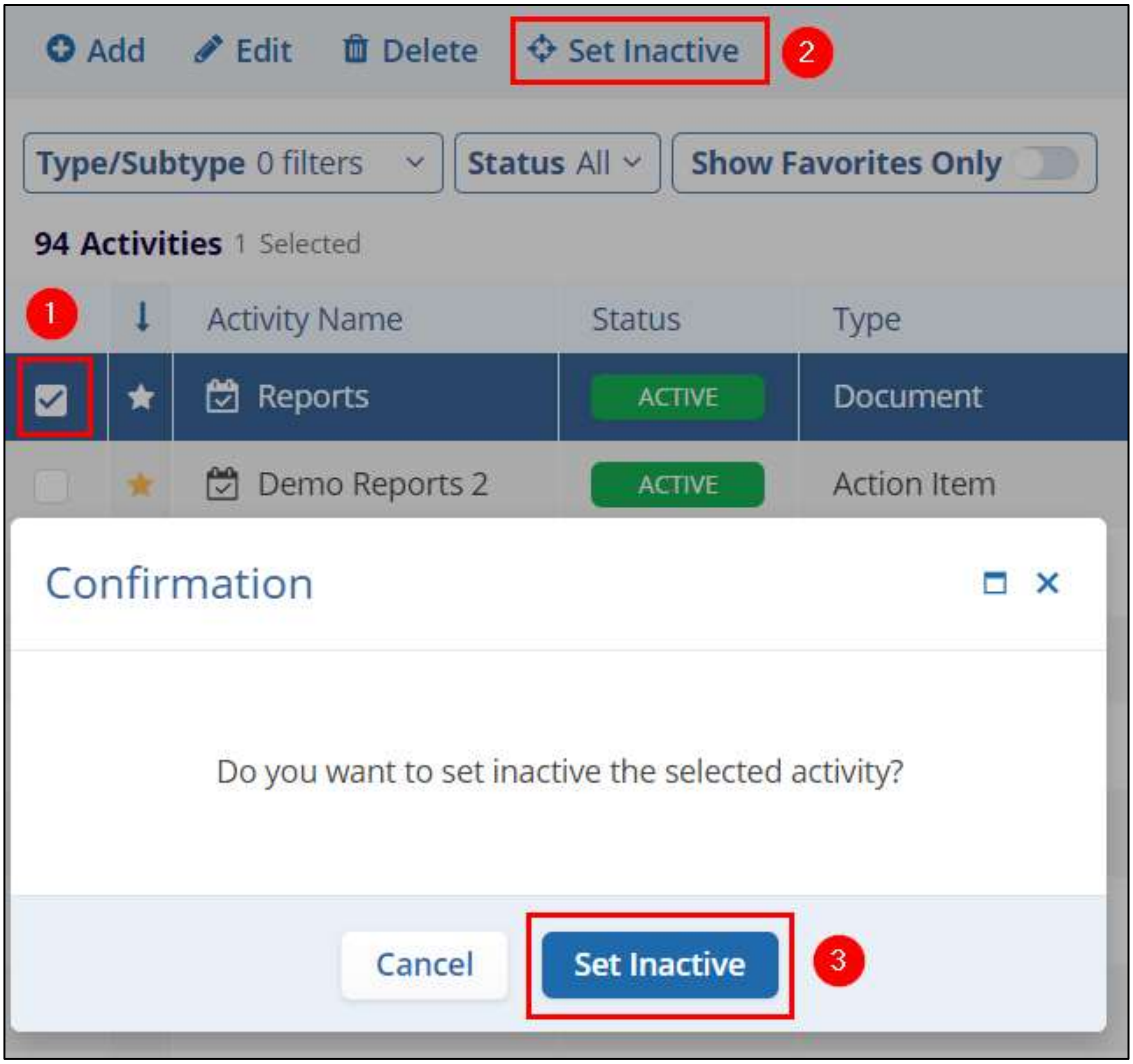


Figure: Change activity record status to Inactive

Customizing Activities Library screen

1. 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.

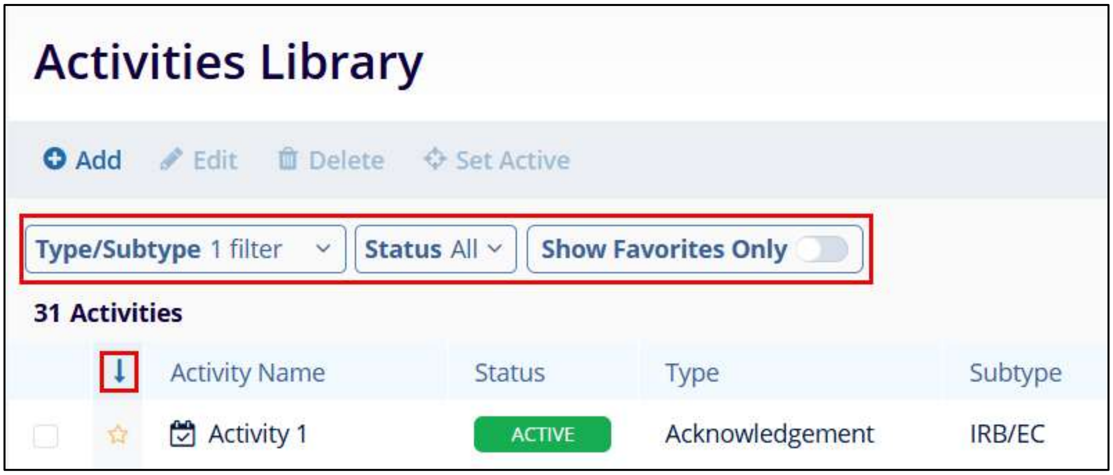


Figure: Activities Library - Filters

2. Marking an activity as a favorite

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

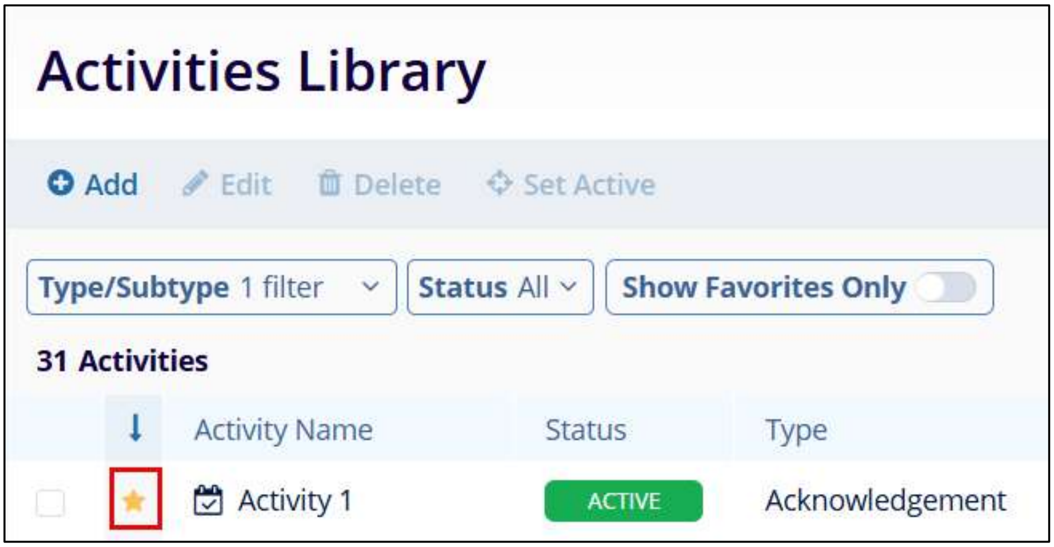


Figure: Activities Library – Mark as favorite

CHAPTER 12. ACTIVITY PLAN TEMPLATES

Accessing Activity Plan Templates

To access Activity Plan Templates, follow the steps below.

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

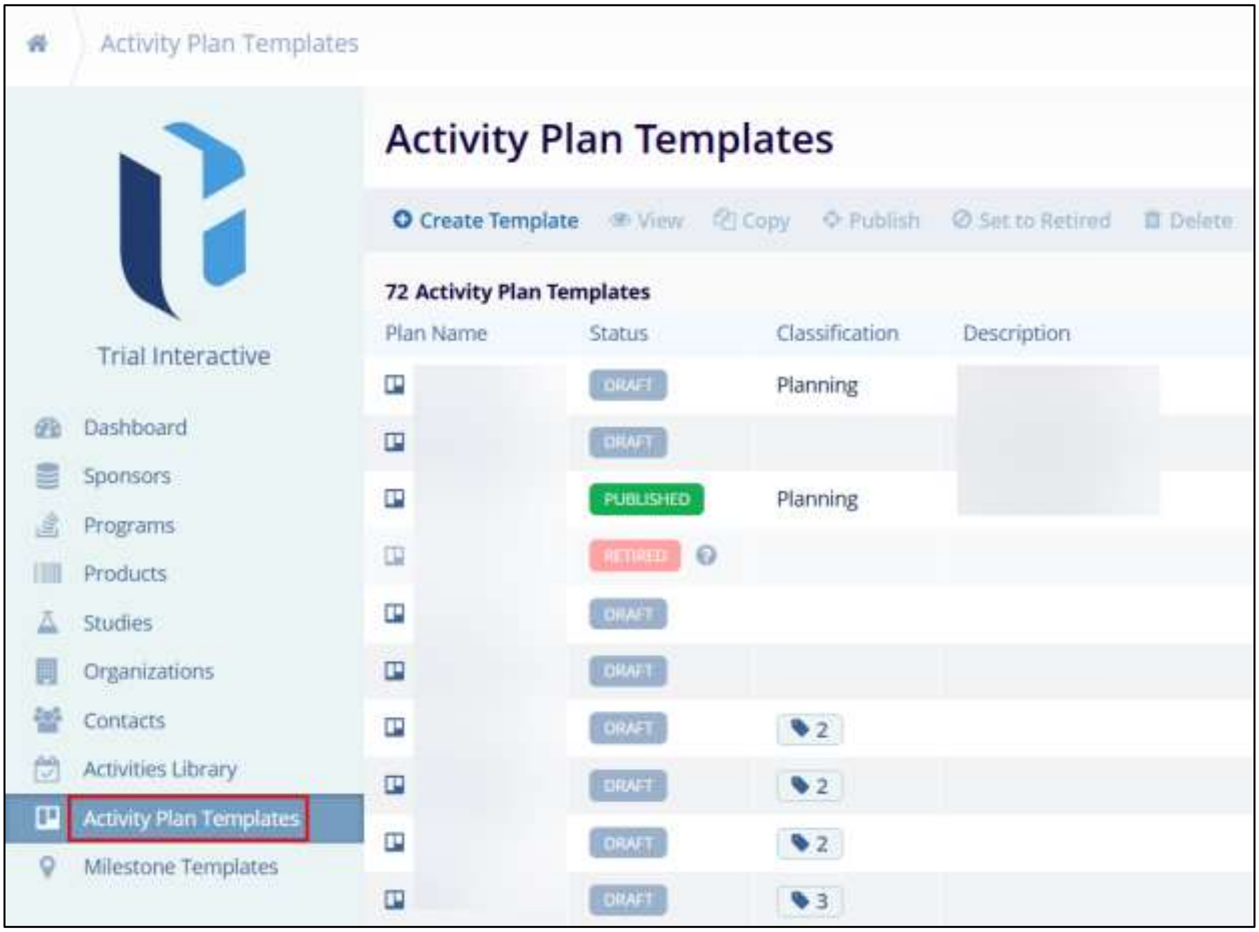


Figure: Accessing Activity Plan Templates

Creating Domain Library Activity Template

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

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

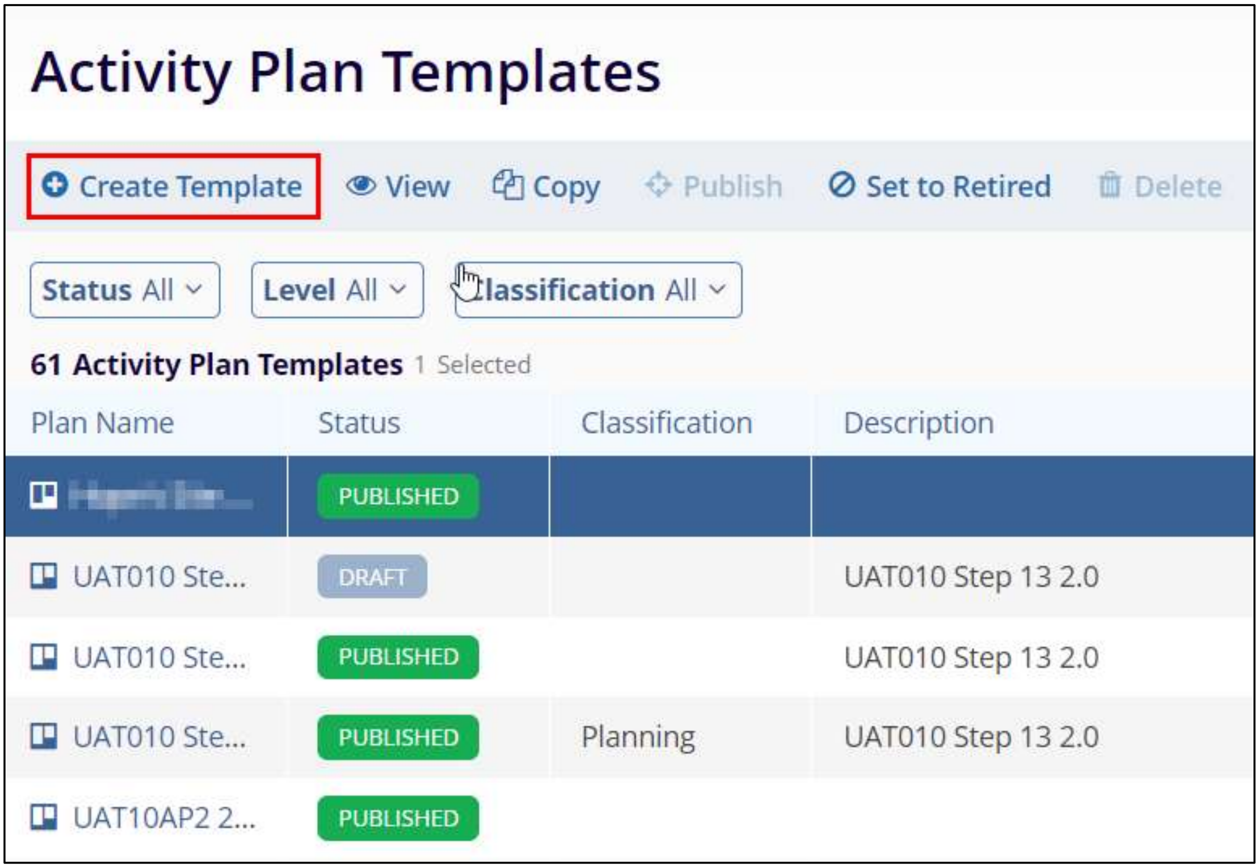


Figure: Create Domain Library Activity Template

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

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

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

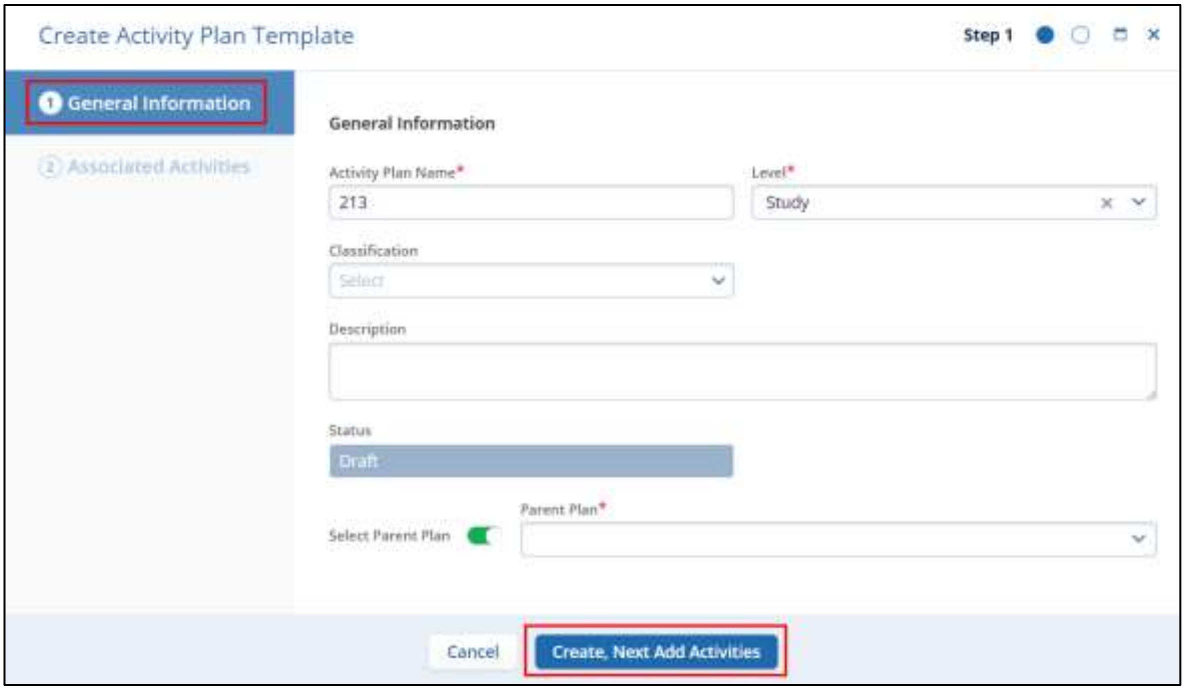


Figure: Domain Library Activity Template-General Information

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

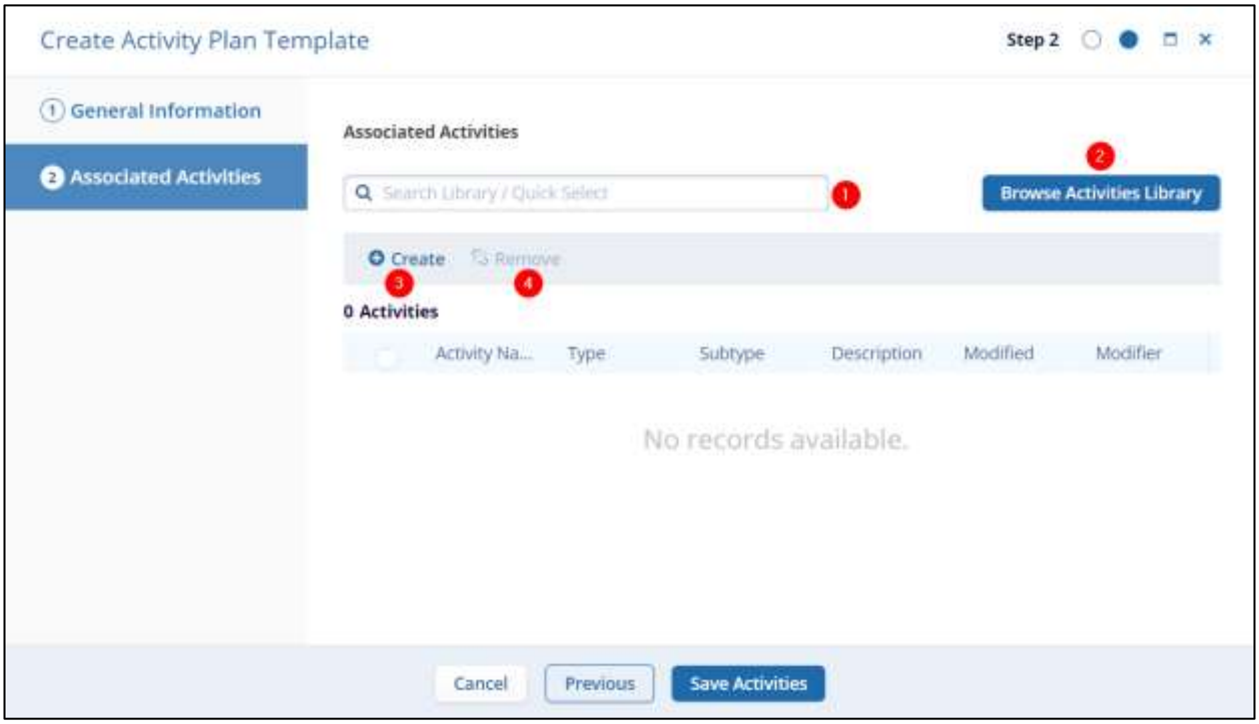


Figure: Domain Library Activity Template-Associated Activities

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

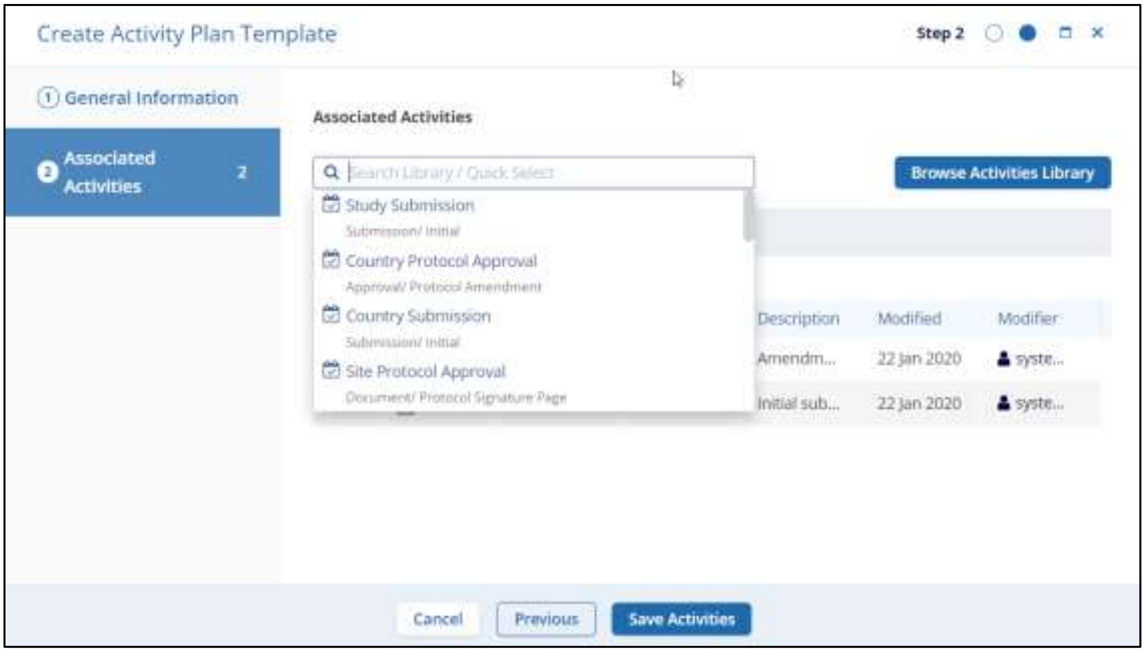


Figure: Search Library and Quick Select

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

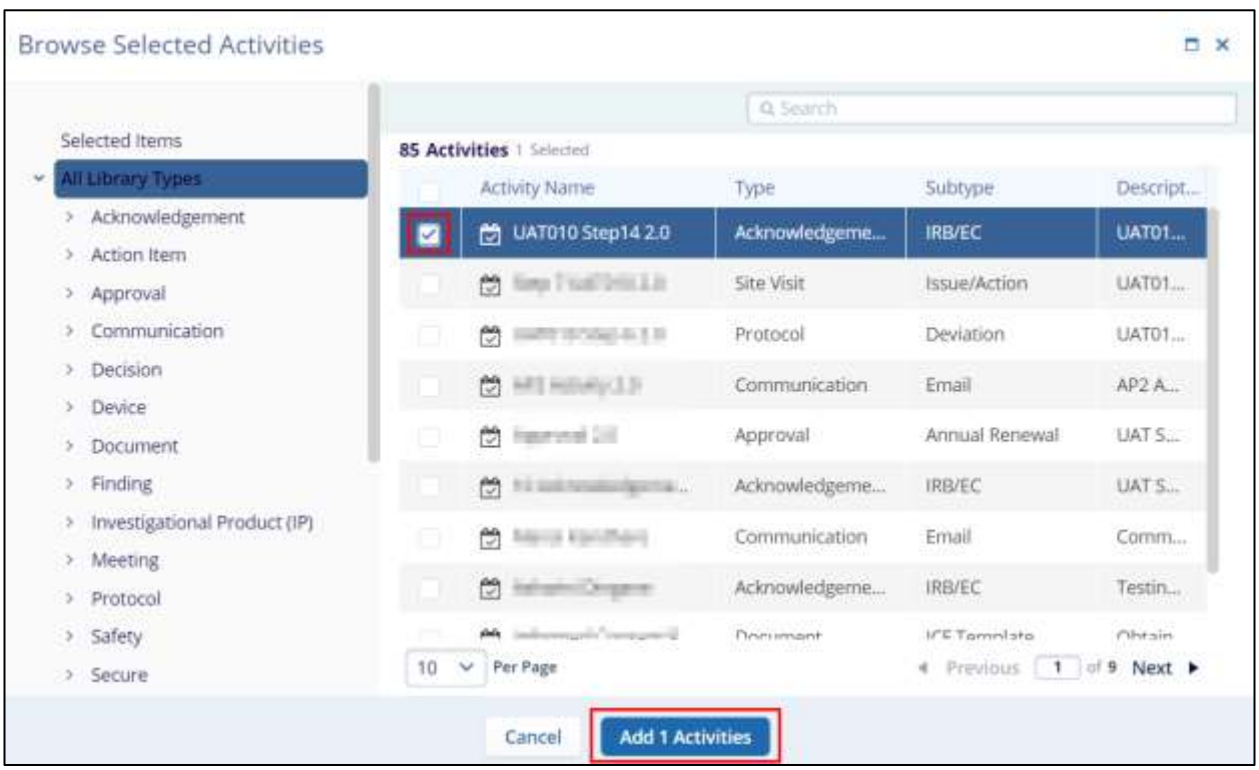


Figure: Browse Activities Library

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

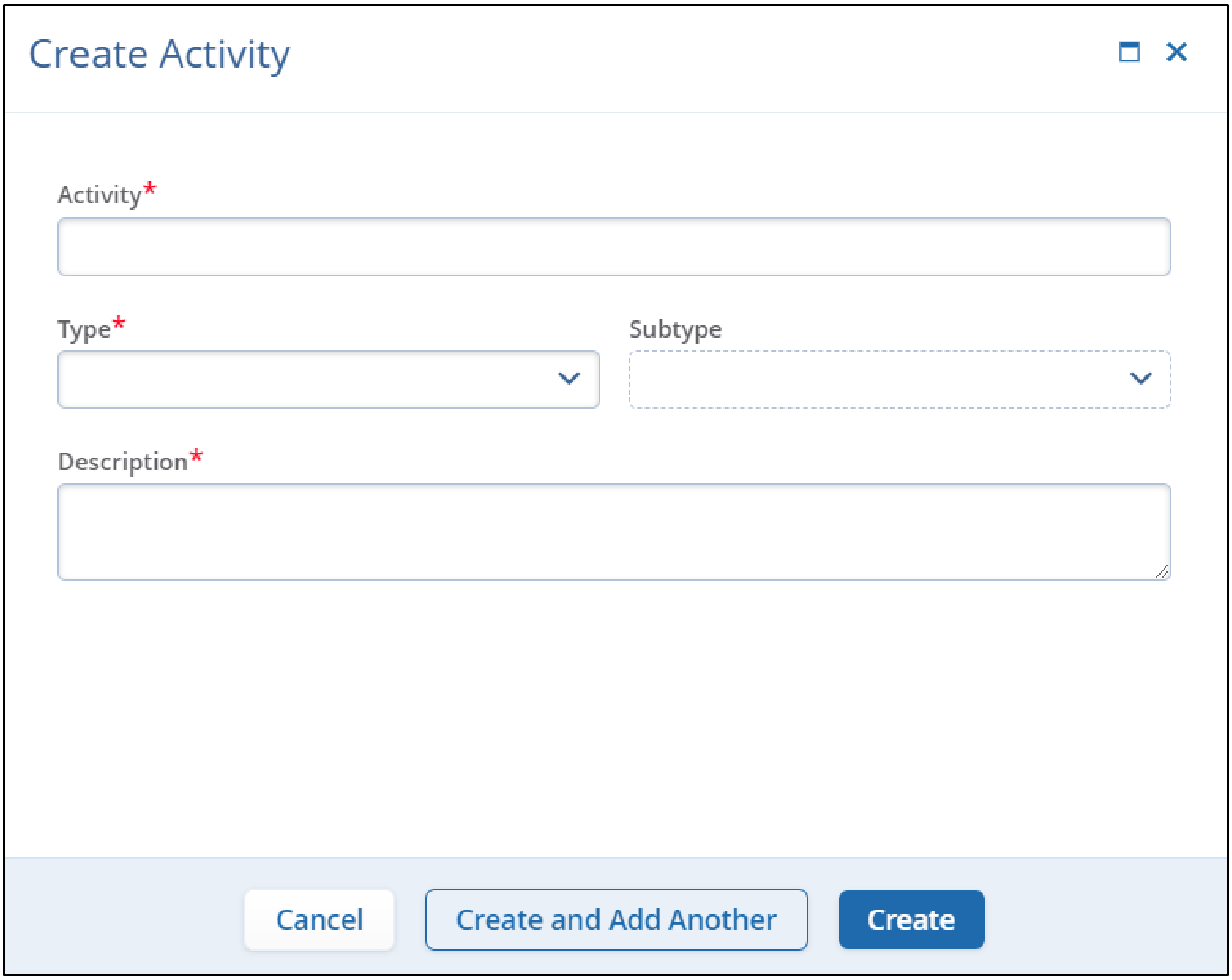


Figure: Create New Activity

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

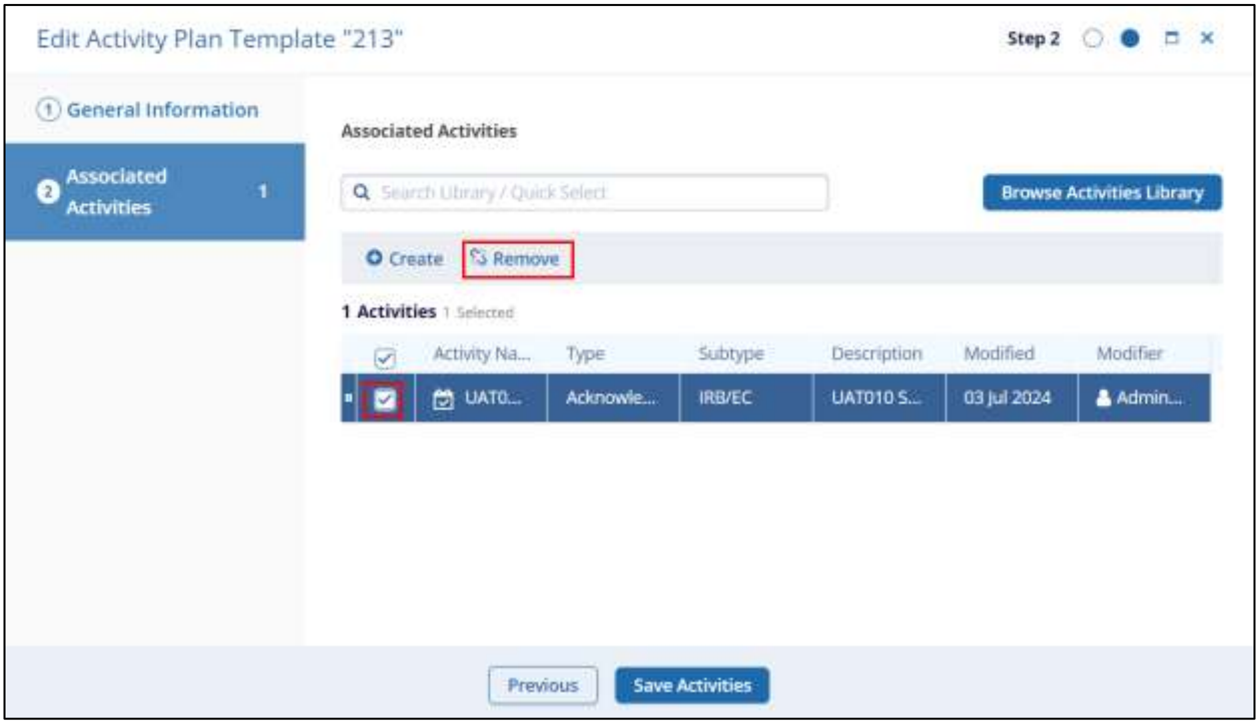


Figure: Remove Activities

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

View Published Template Details

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

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

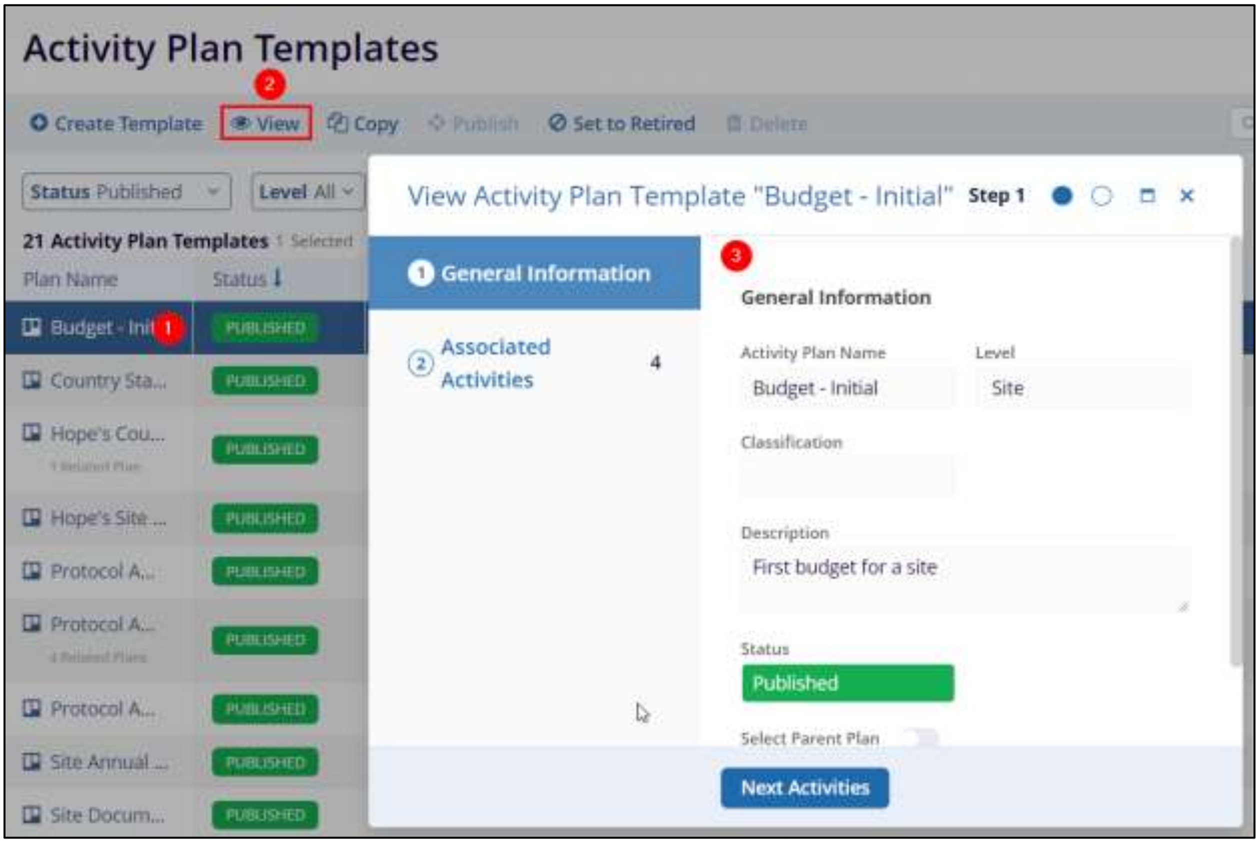


Figure: View Activities Plan Template

Editing Activity Plan Templates

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

Method 1

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

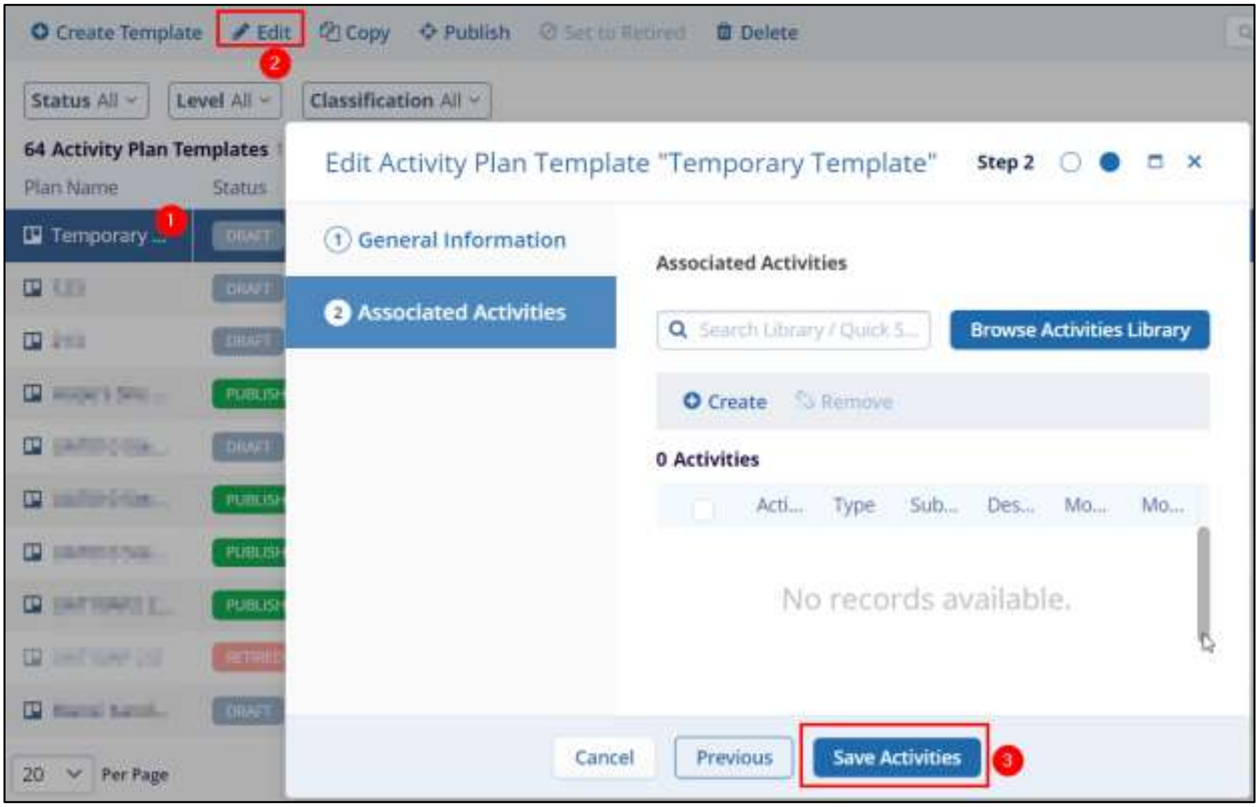


Figure: Edit Activity Plan Template-Method 1

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

Method 2

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

Figure: Select plan name

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

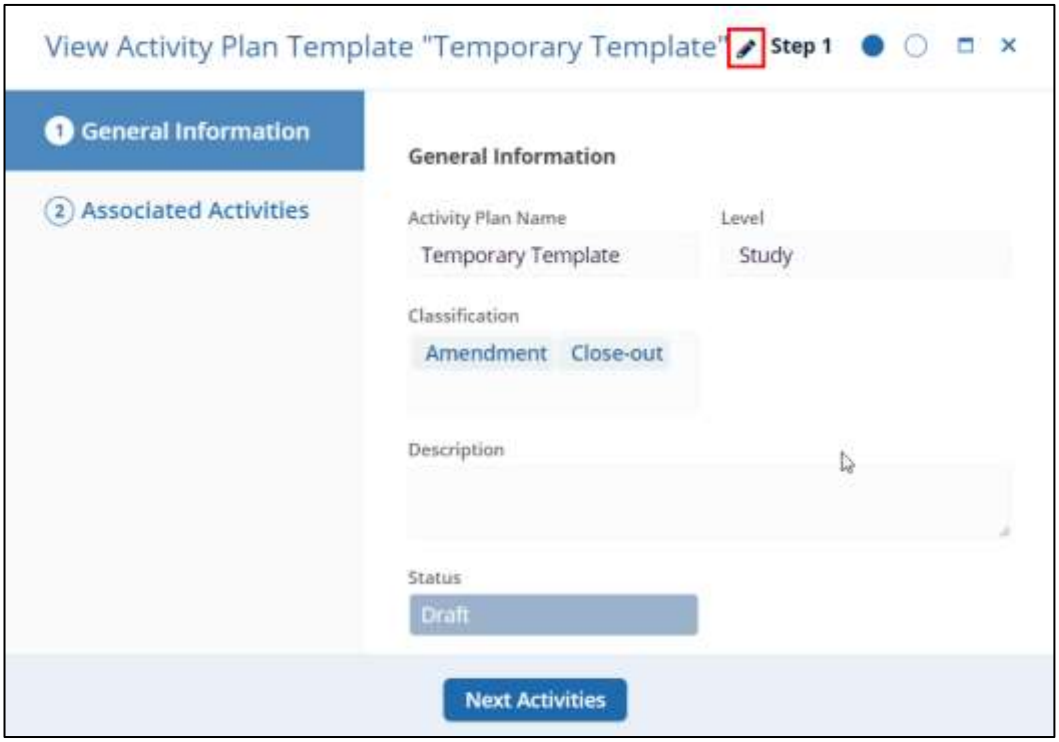


Figure: Select the Edit icon

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

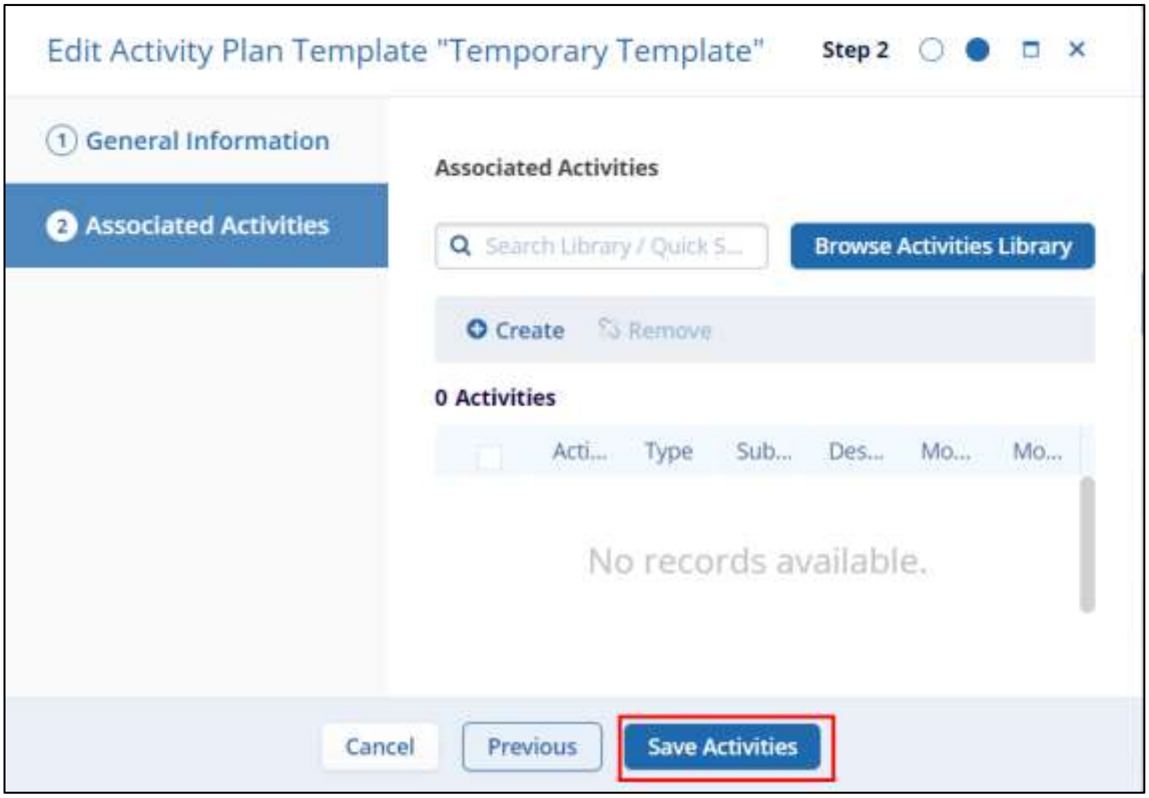


Figure: Edit Activity Plan Template-Method 2

Publishing Activity Plan Templates

To publish an activity plan, follow the steps below.

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

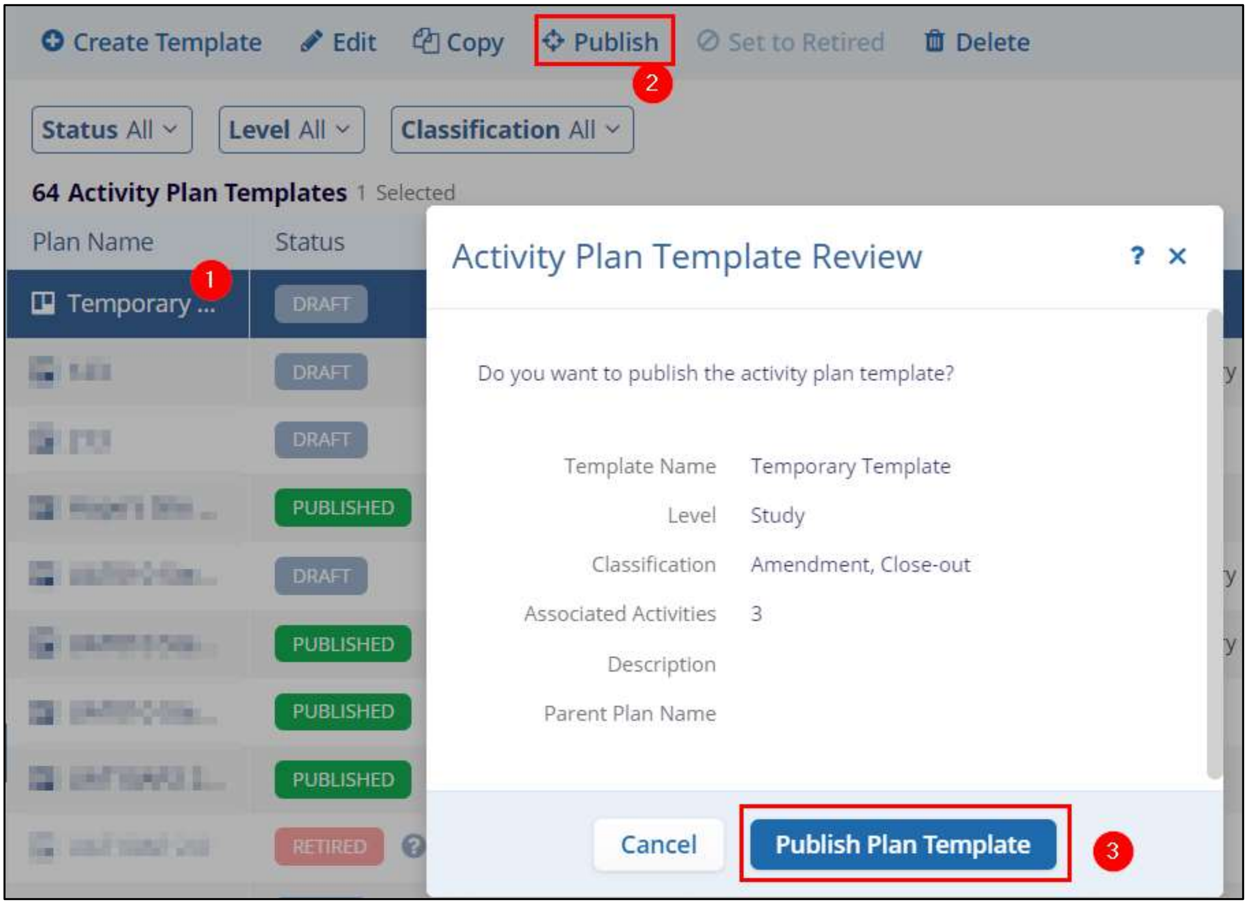


Figure: Publishing Activity Plan Template

Note

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

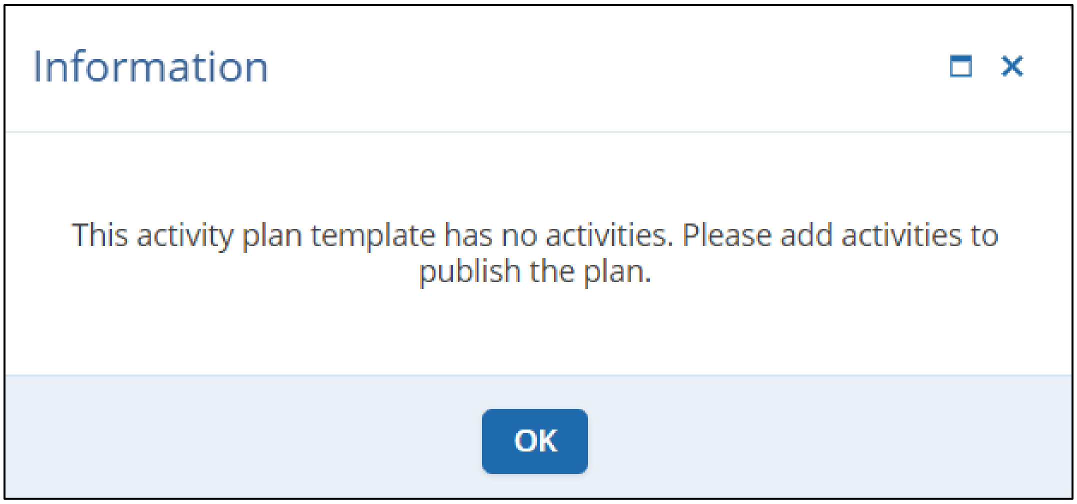


Figure: Information popup prompting to add templates

Retire Activity Plan Templates

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

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

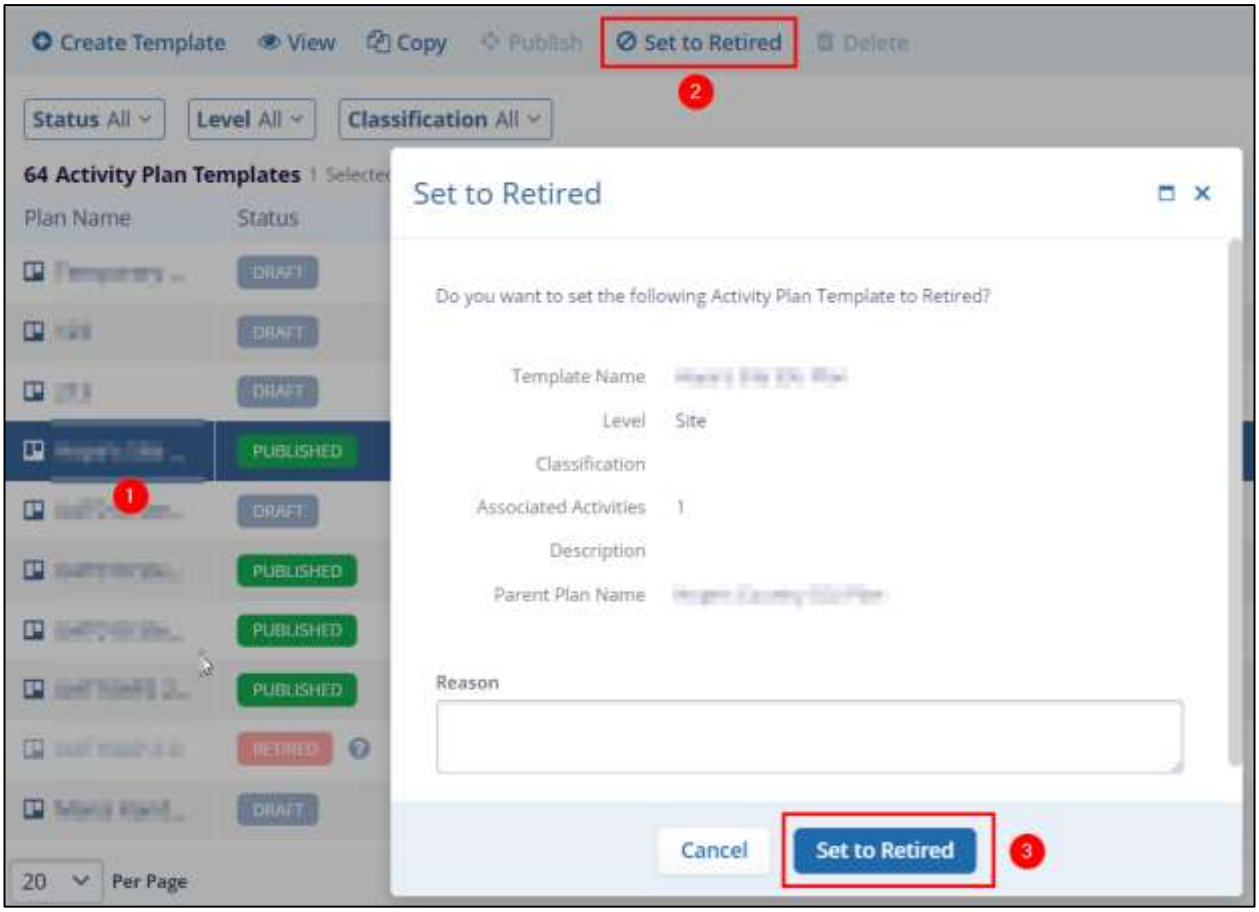


Figure: Retire Activity Plan Template

Note:

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

Copying Activity Plan Templates

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

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

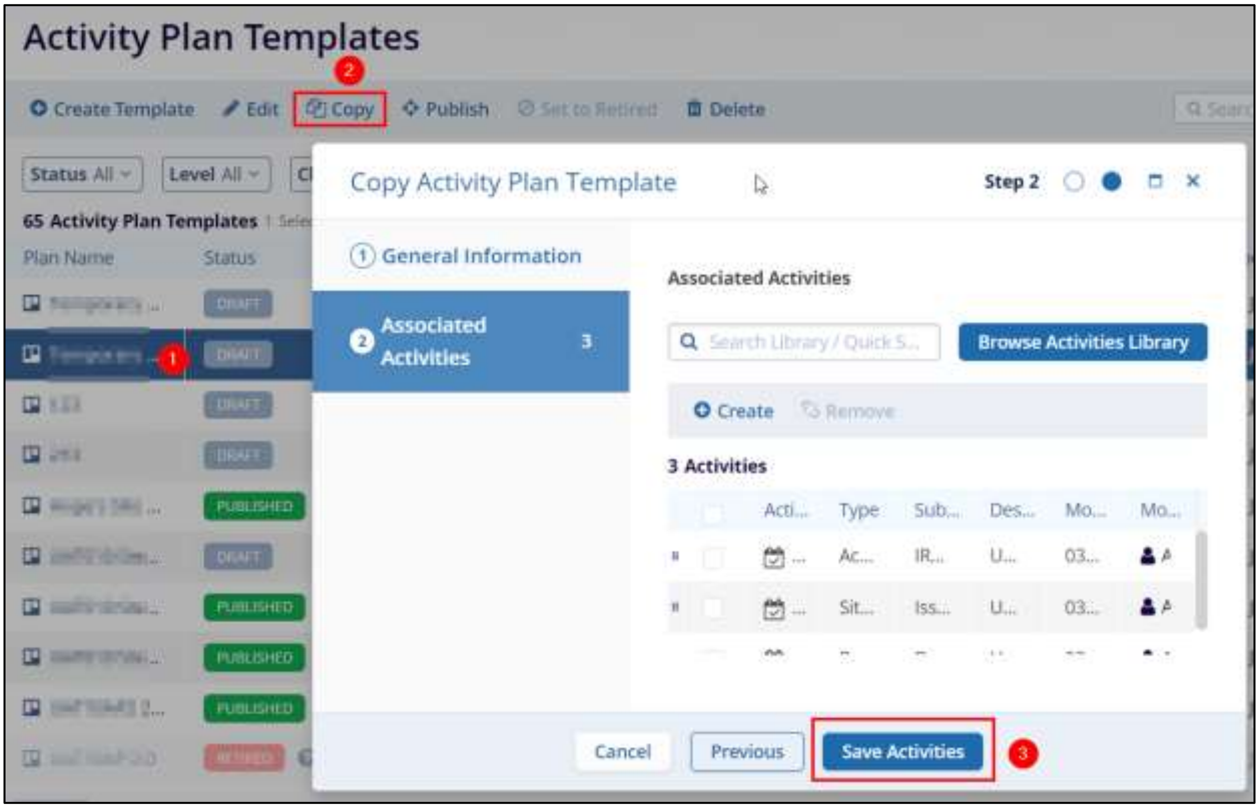


Figure: Copy Activity Plan Templates

Associating Activity Plan Templates to a Study

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

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

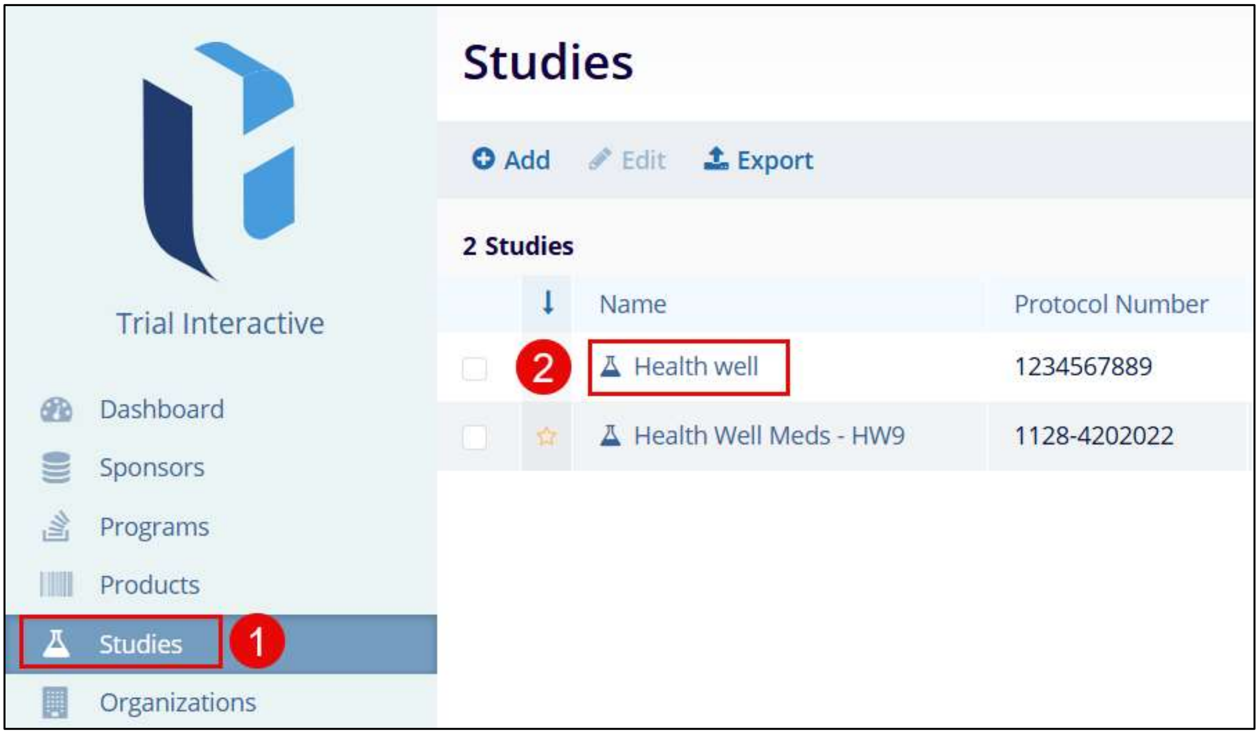


Figure: Selecting a Study

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

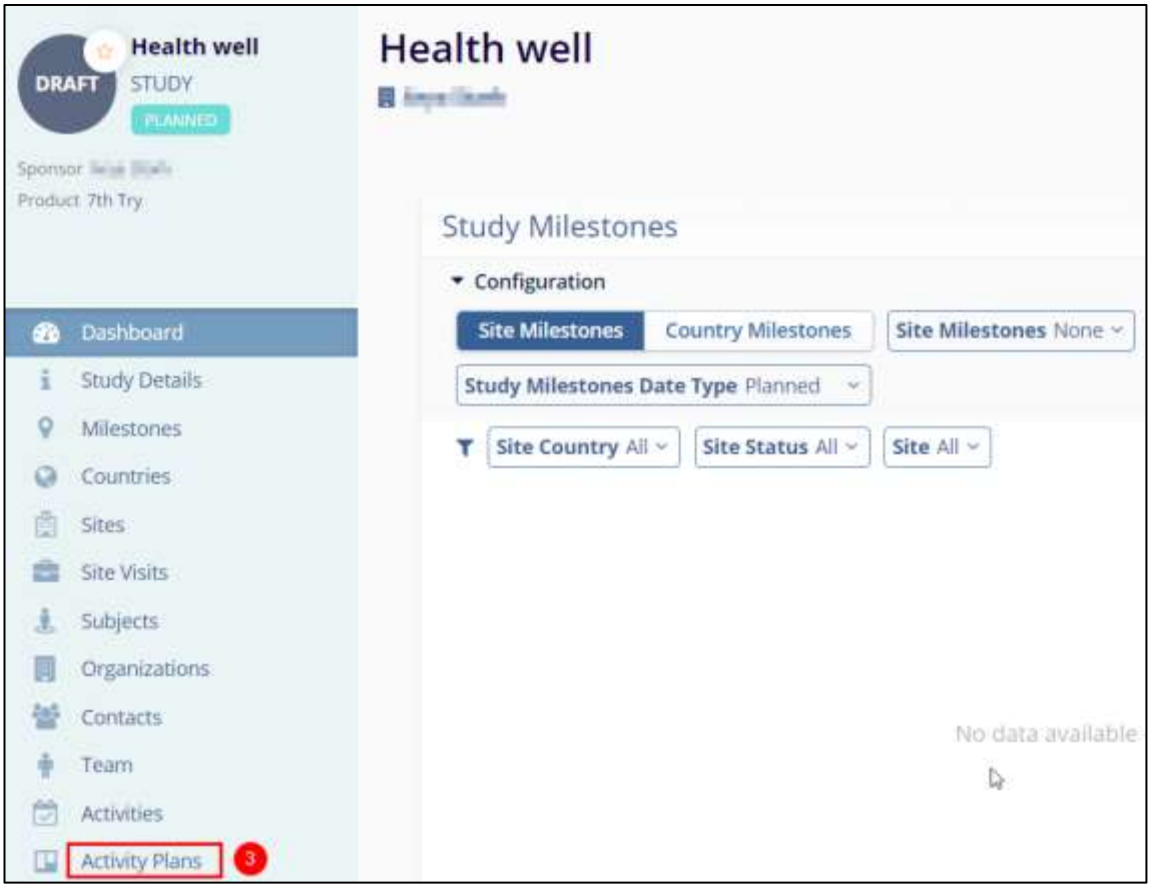


Figure: Select Activity Plans

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

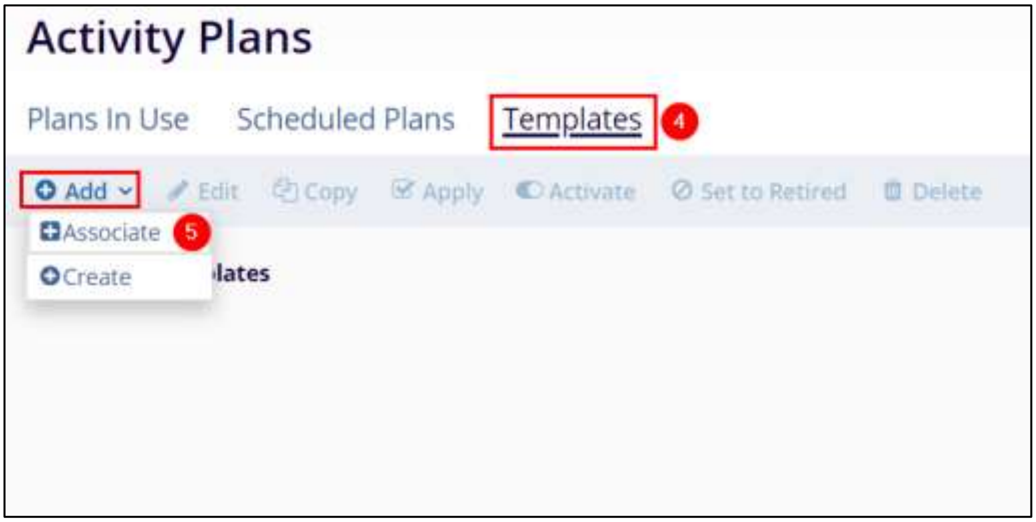


Figure: Select the Templates tab and access the Add and Associate buttons

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

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

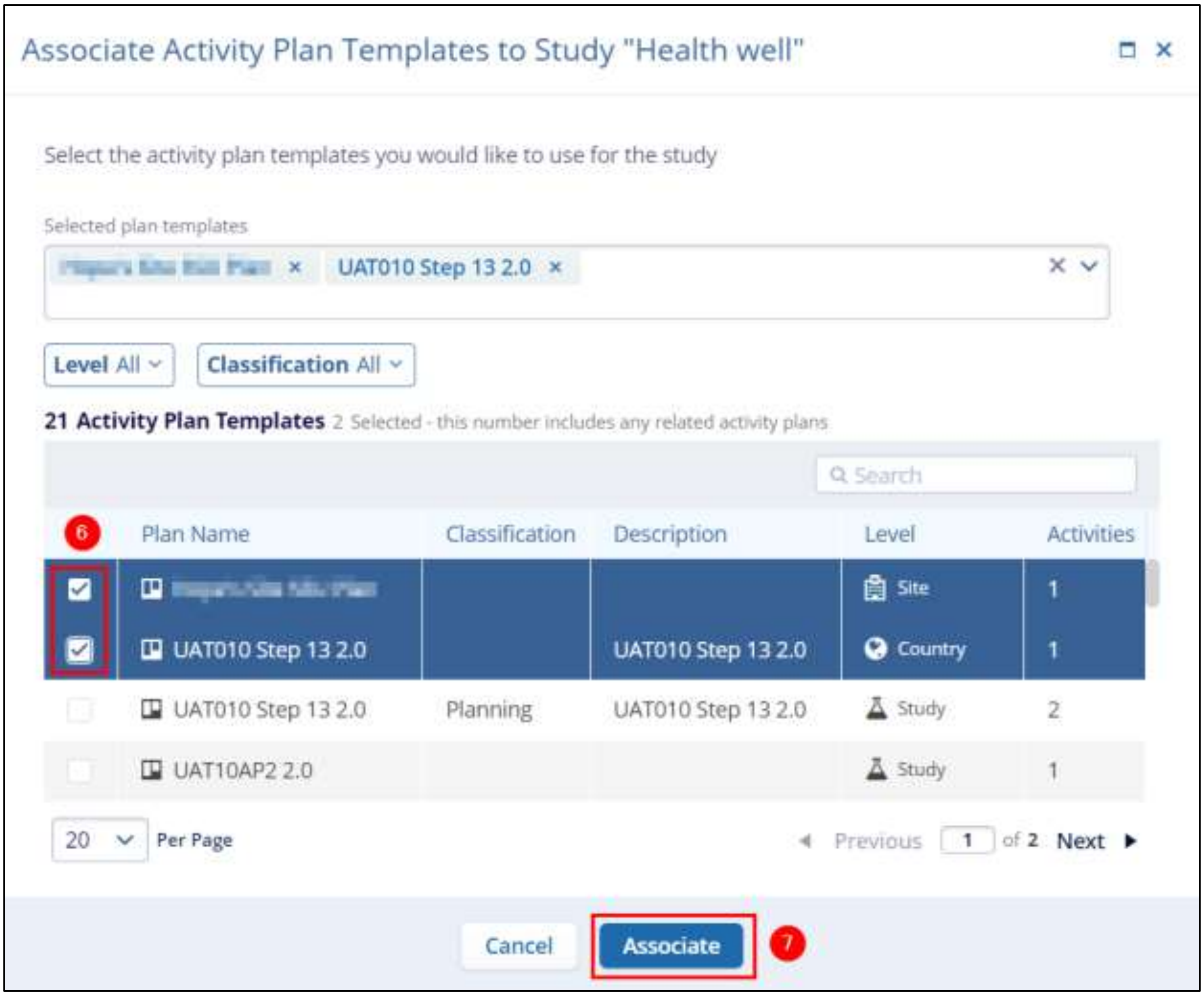


Figure: Associate Activity Plan Template to Study Screen

Scheduling Activity Plans

To schedule Activity plans, follow the steps below.

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

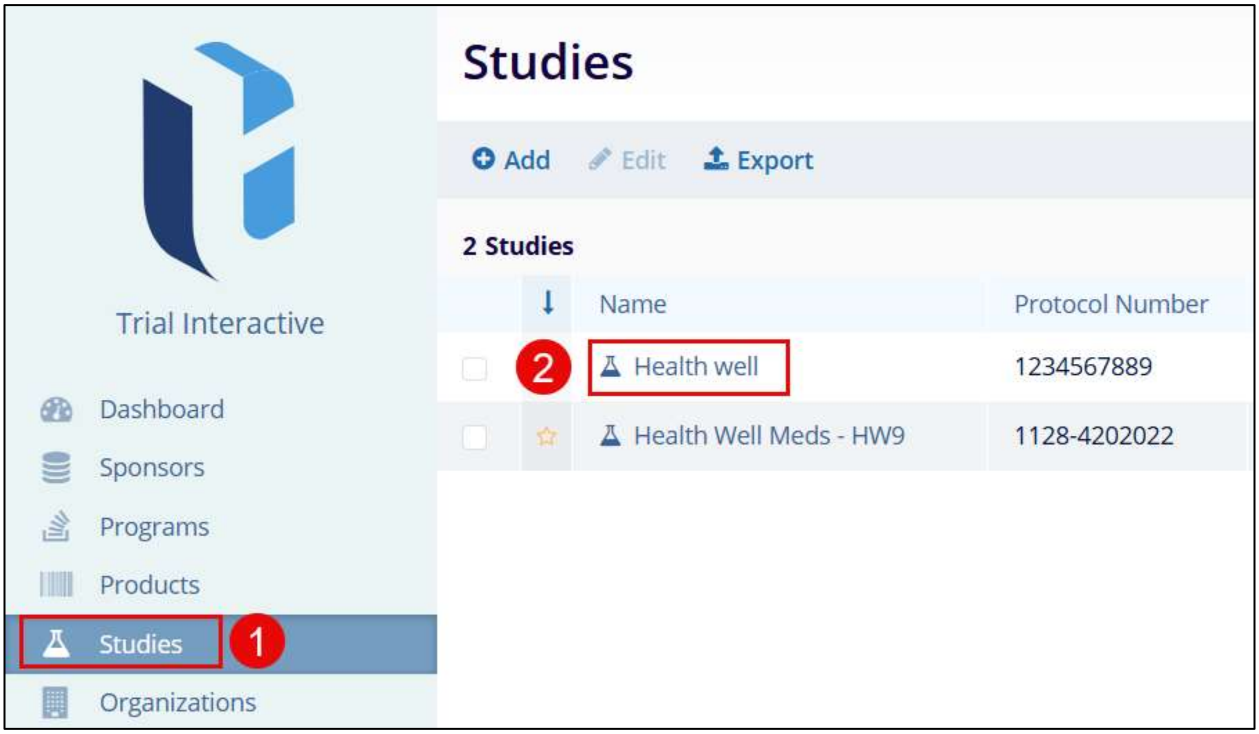


Figure: Selecting a Study

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

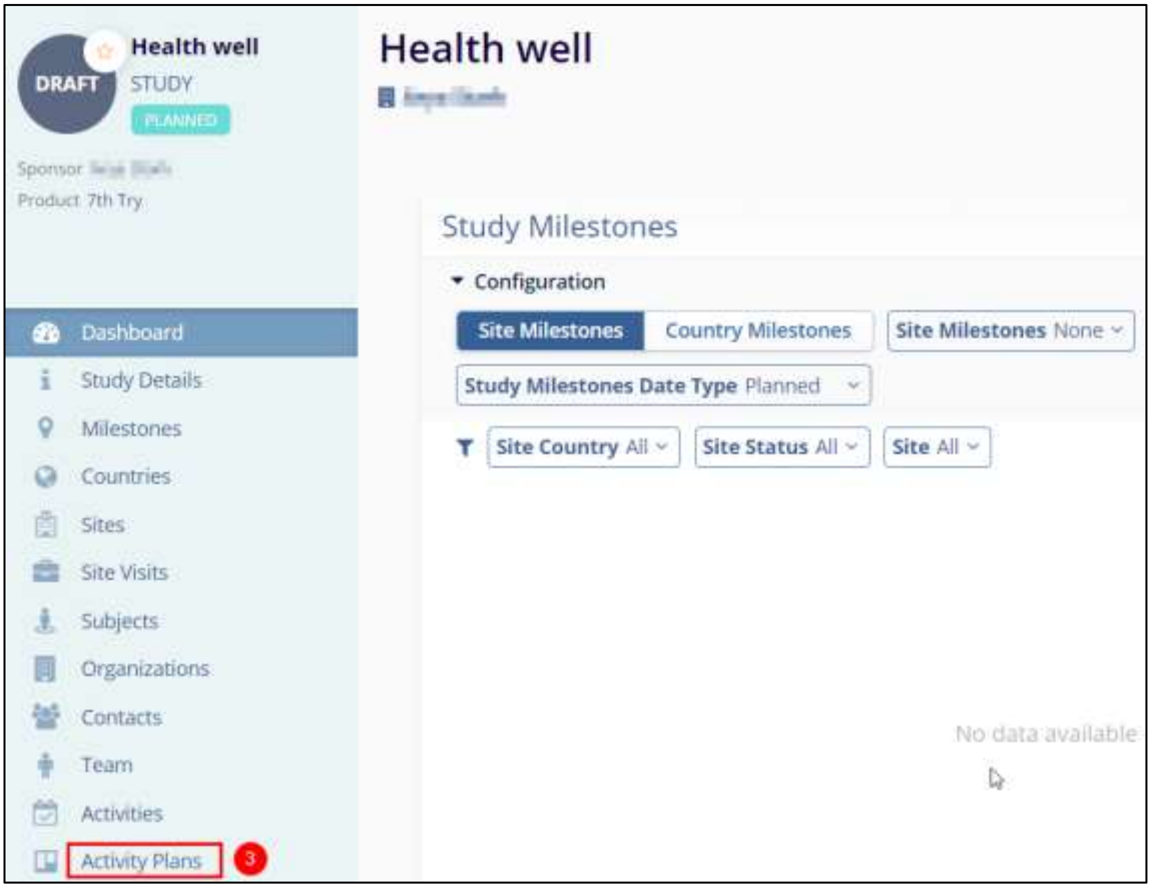


Figure: Select Activity Plans

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

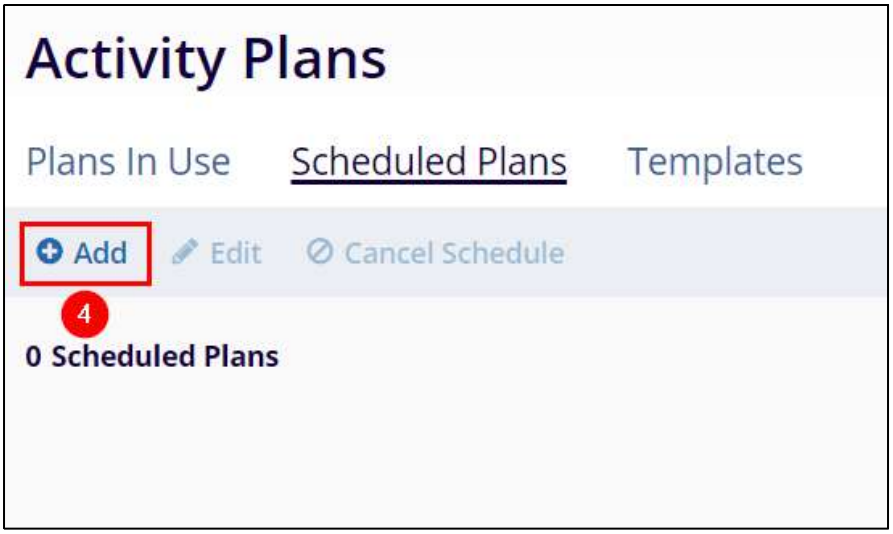


Figure: Scheduled Plans tab

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

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

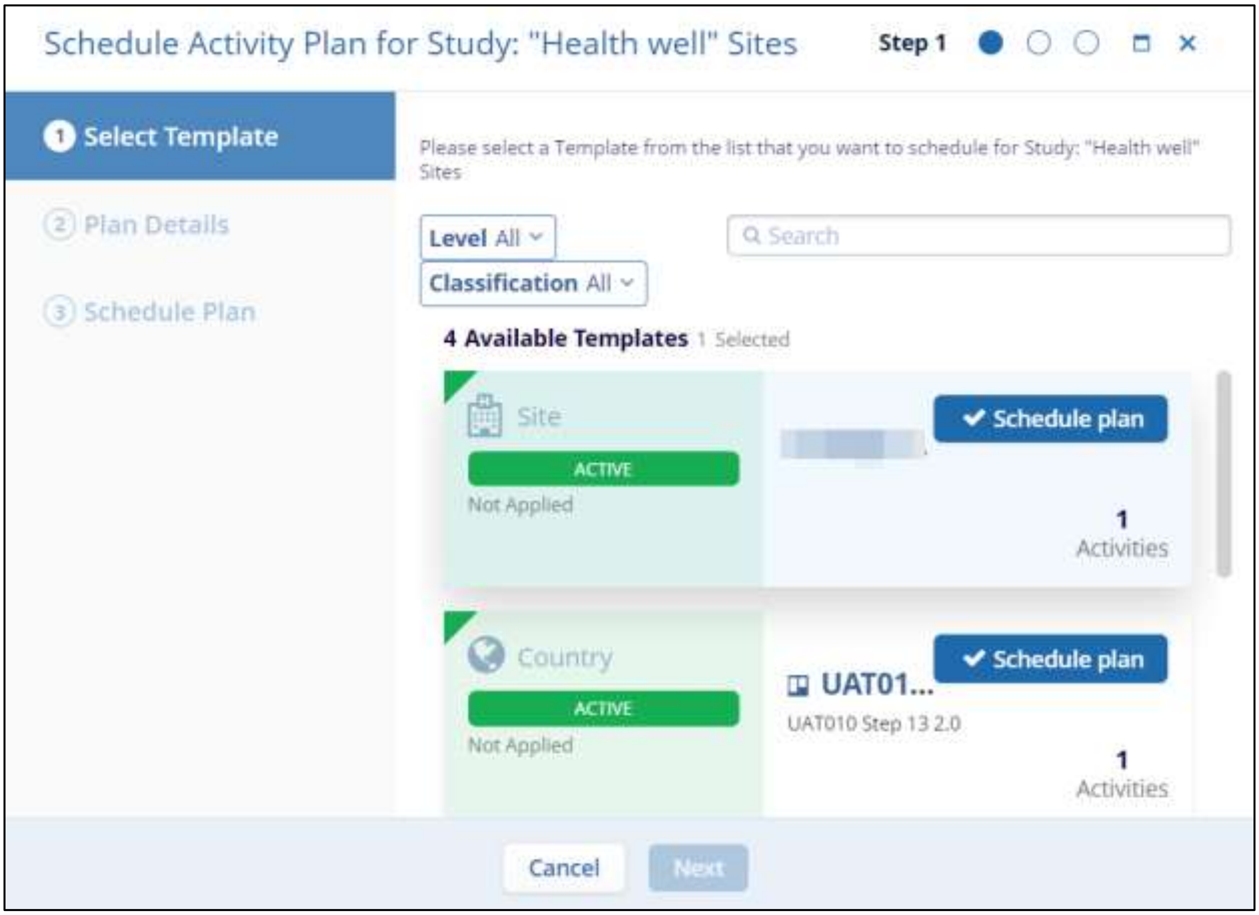


Figure: Schedule Activity Plan for Study-Select Template

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

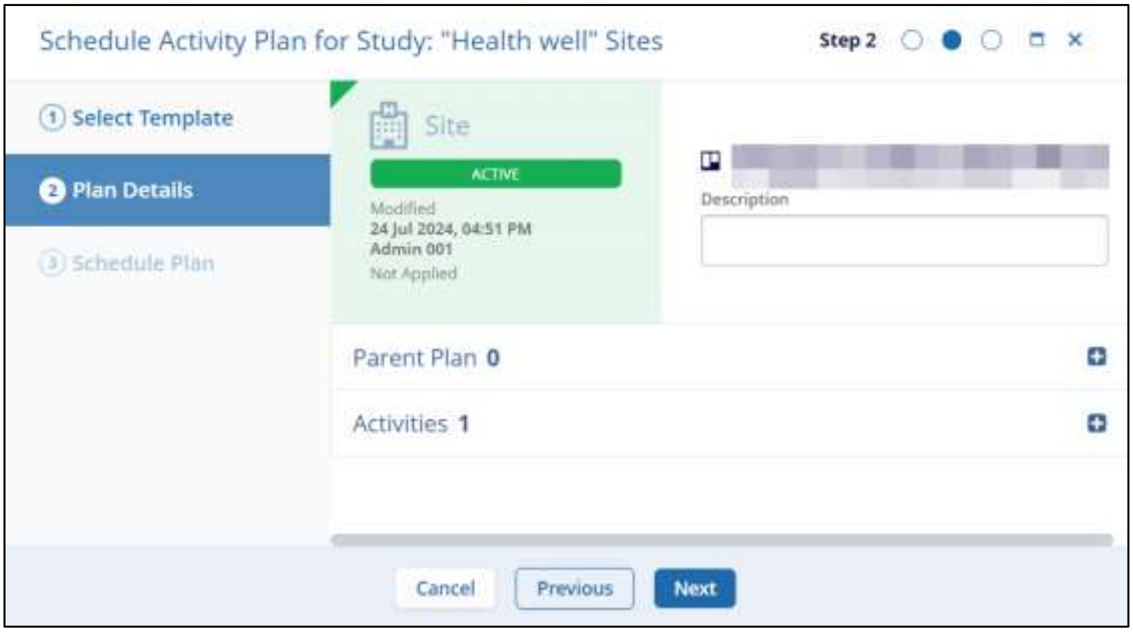


Figure: Schedule Activity Plan for Study-Plan Template

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

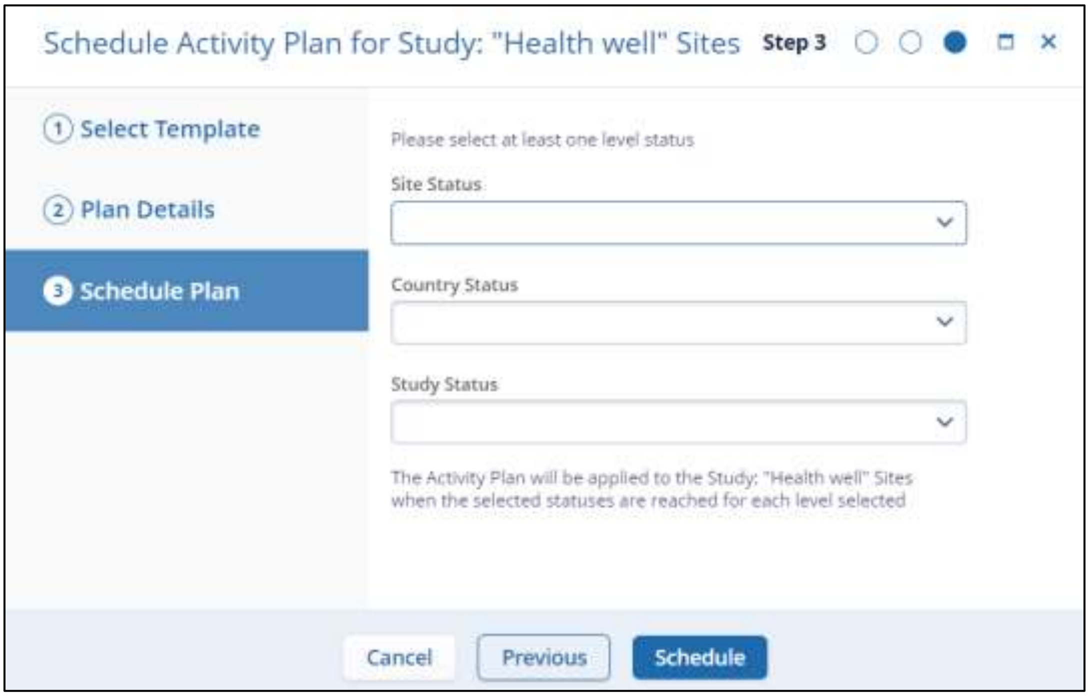


Figure: Schedule Activity Plan for Study-Schedule Plan

Tracking Activities Outside of Activity Plans

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

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

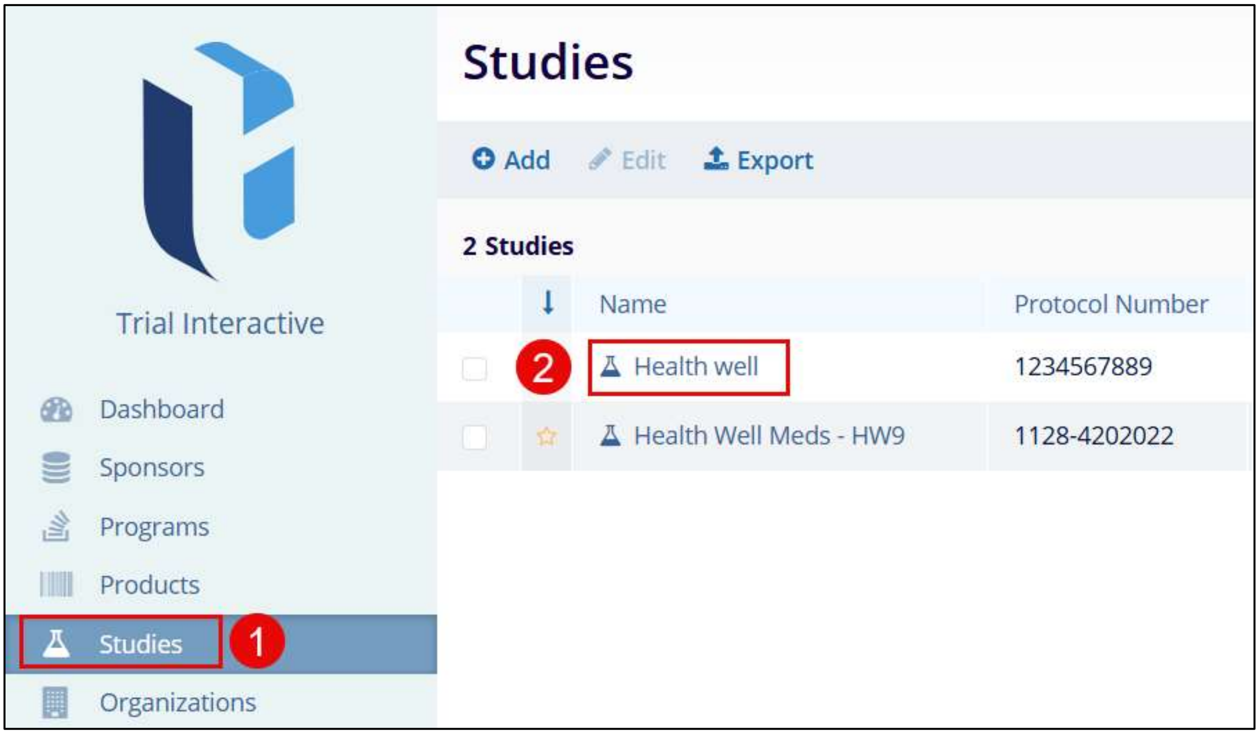


Figure: Selecting a Study

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

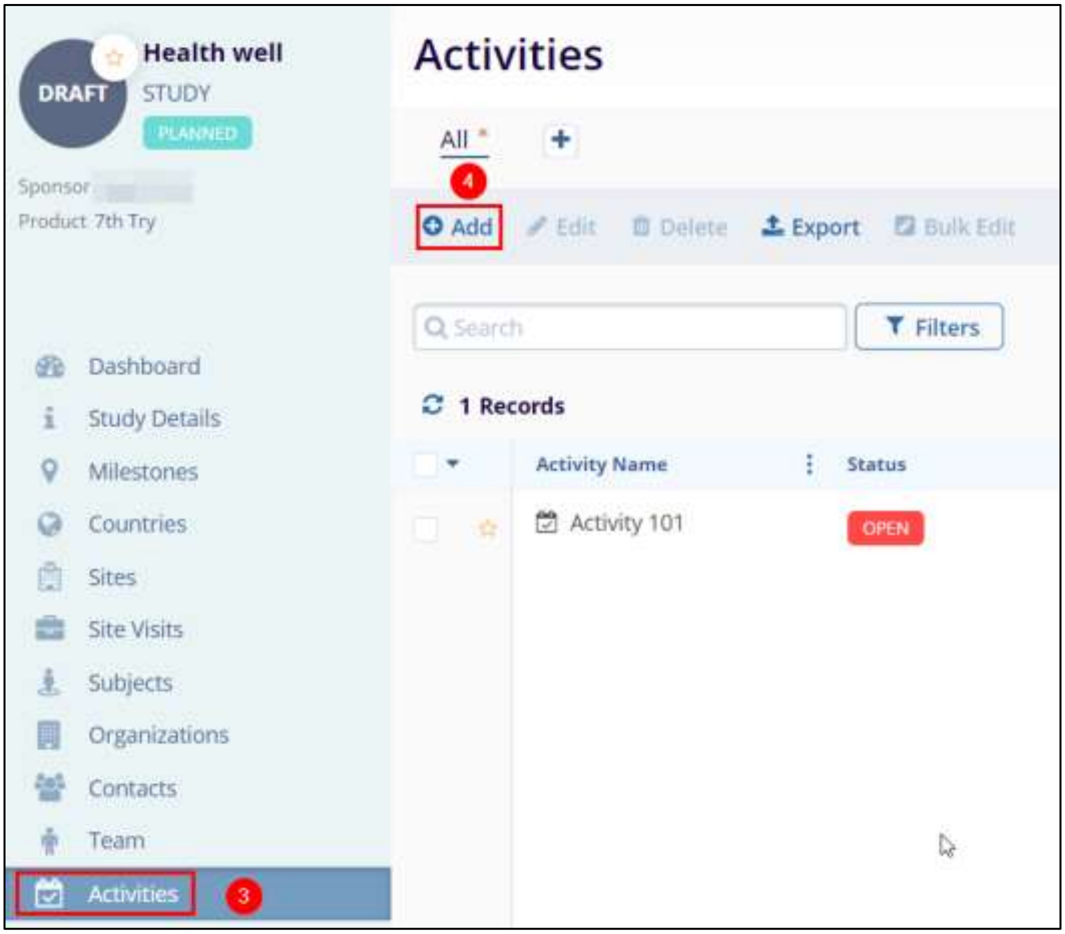


Figure: Select Add Activities

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

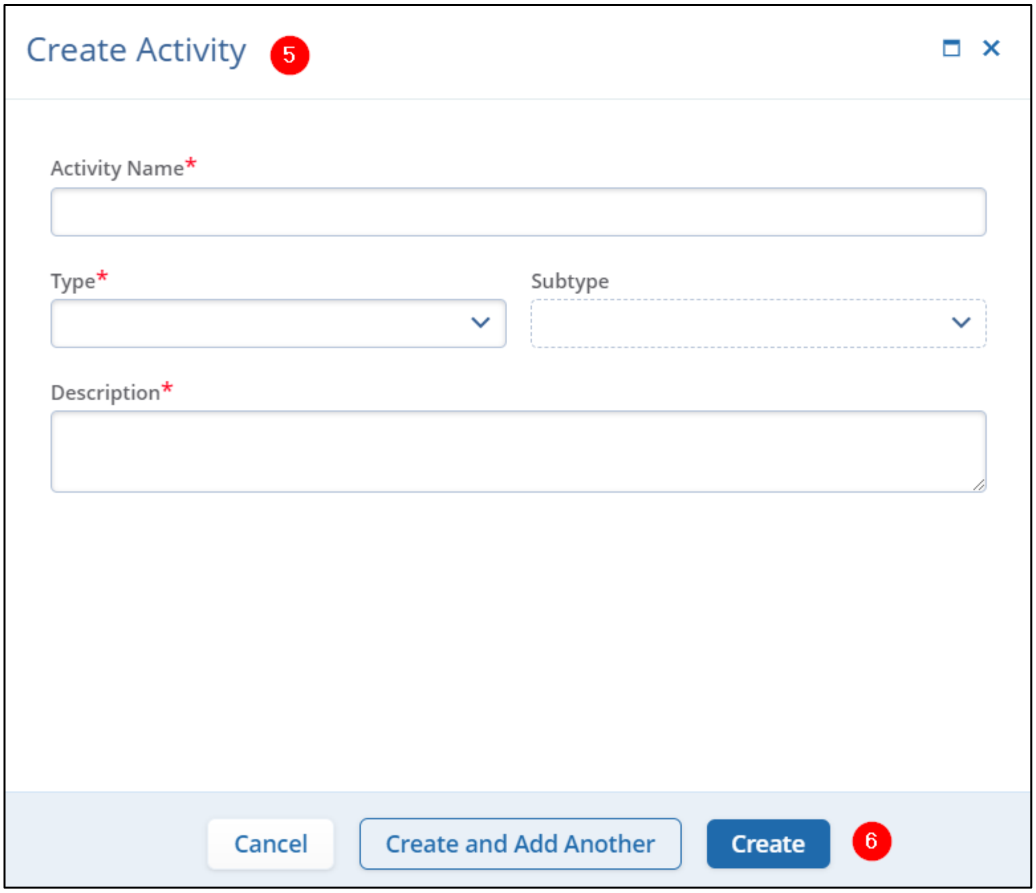


Figure: Tracking Activities

To edit any activity, follow the steps below

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

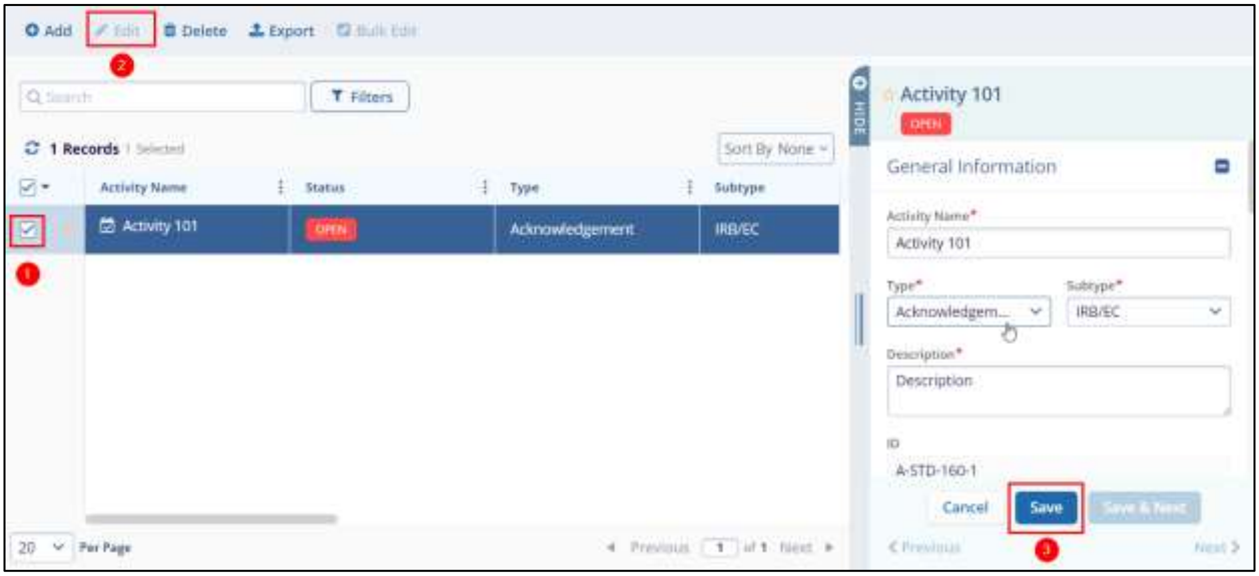


Figure: Editing Activities outside of the Activity Plan

Tracking Actions Towards Activity Completion

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

To track activity completion actions, follow the steps below.

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

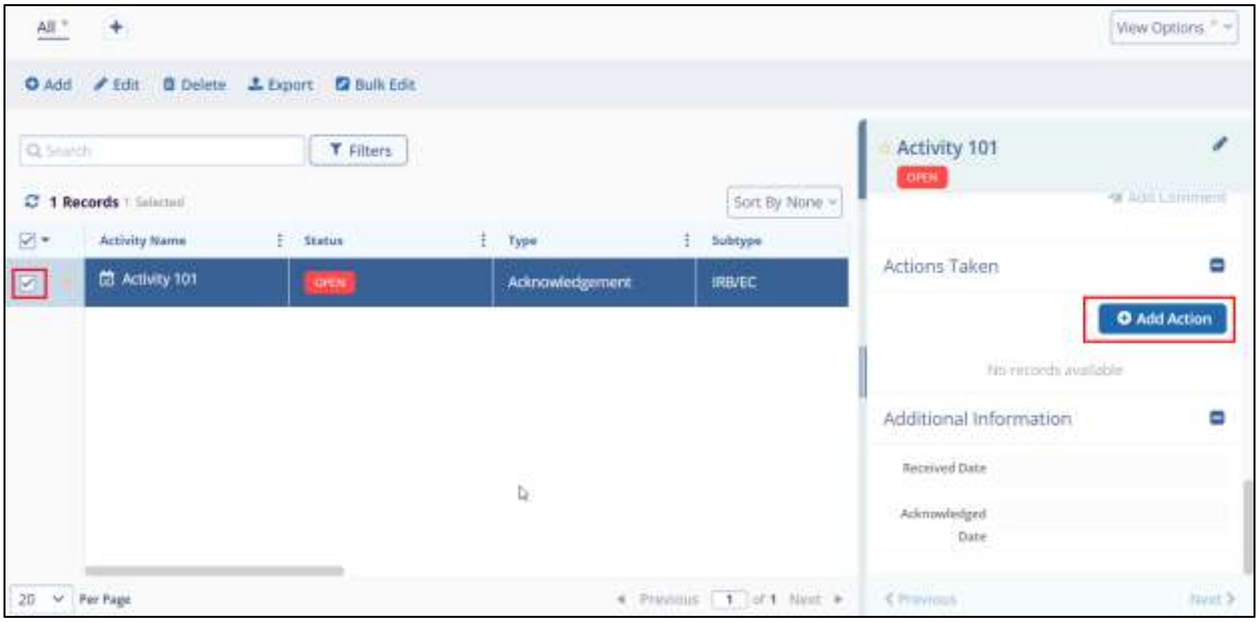


Figure: Actions Taken on quick view panel

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

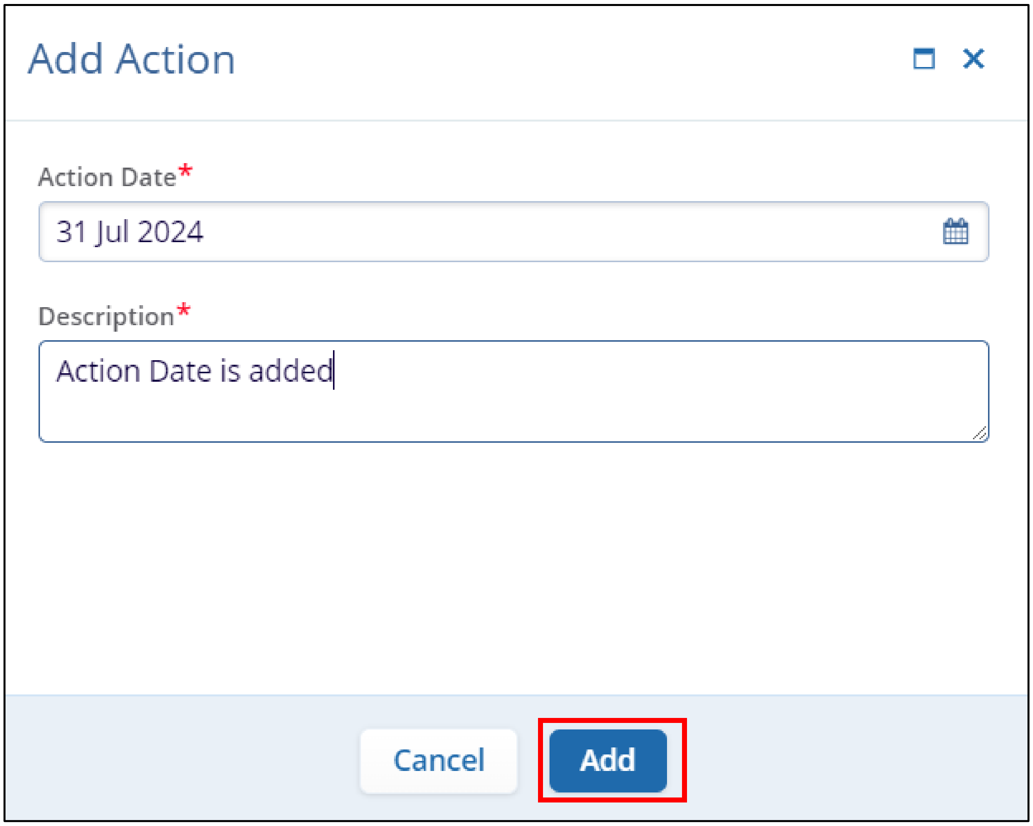


Figure: Add Action screen

Customizing Activity Plan Templates screen

Filters

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

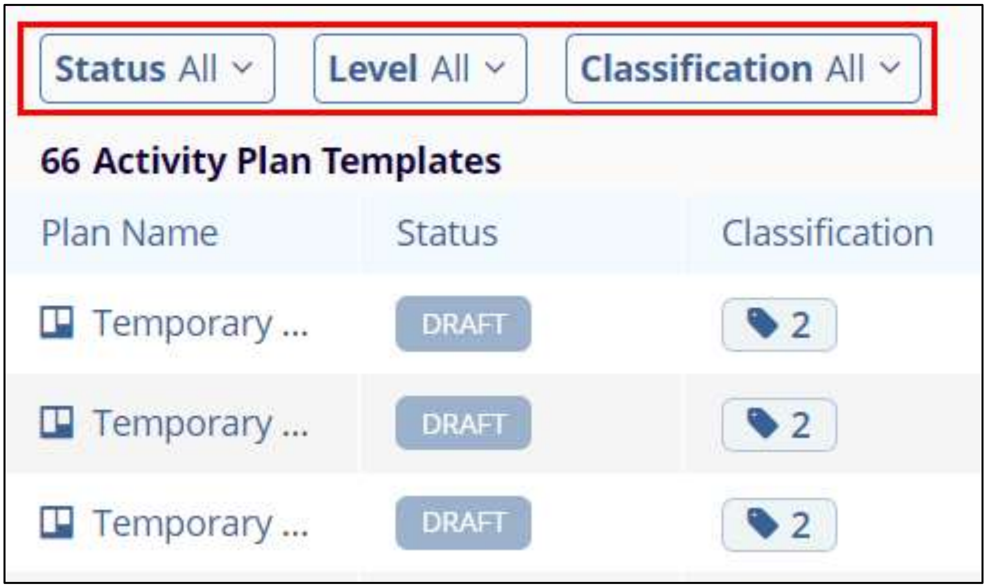


Figure: Activity Plan Templates screen filters

CHAPTER 13. MILESTONES

This section describes the Milestones module in the application.

Important

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

Pre-Requisites

Any 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.

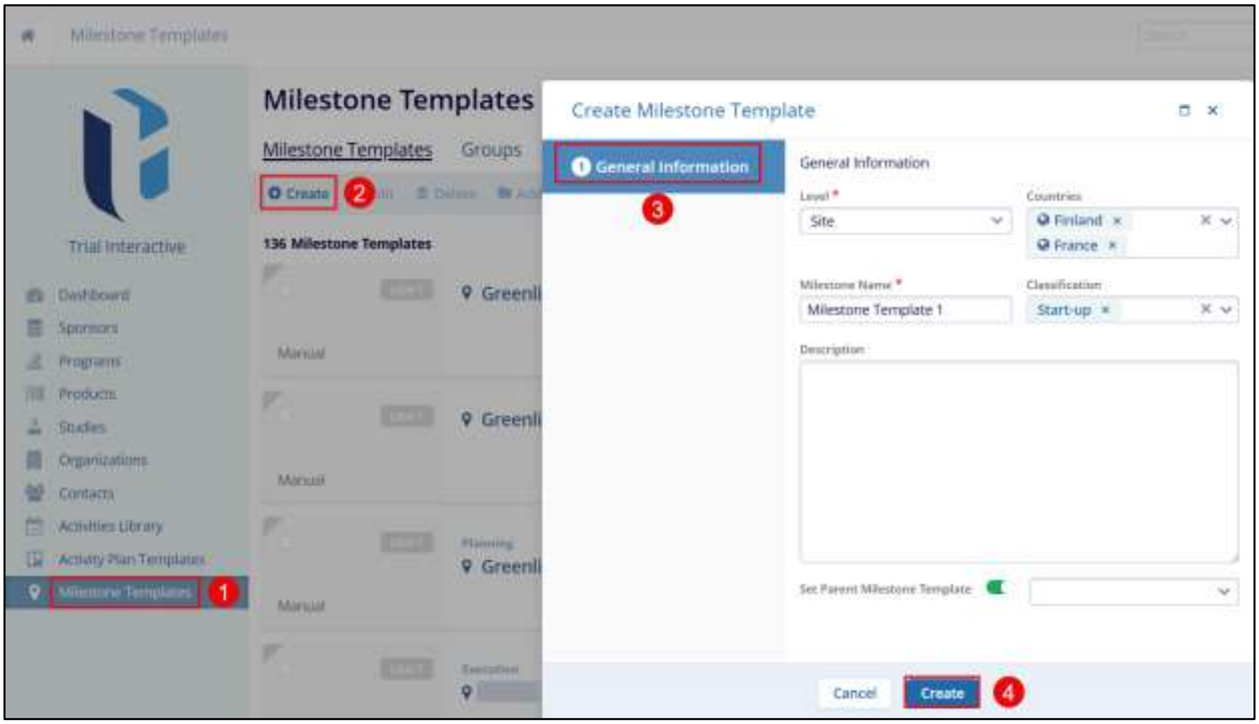


Figure: Creating Domain Library Milestone Template

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

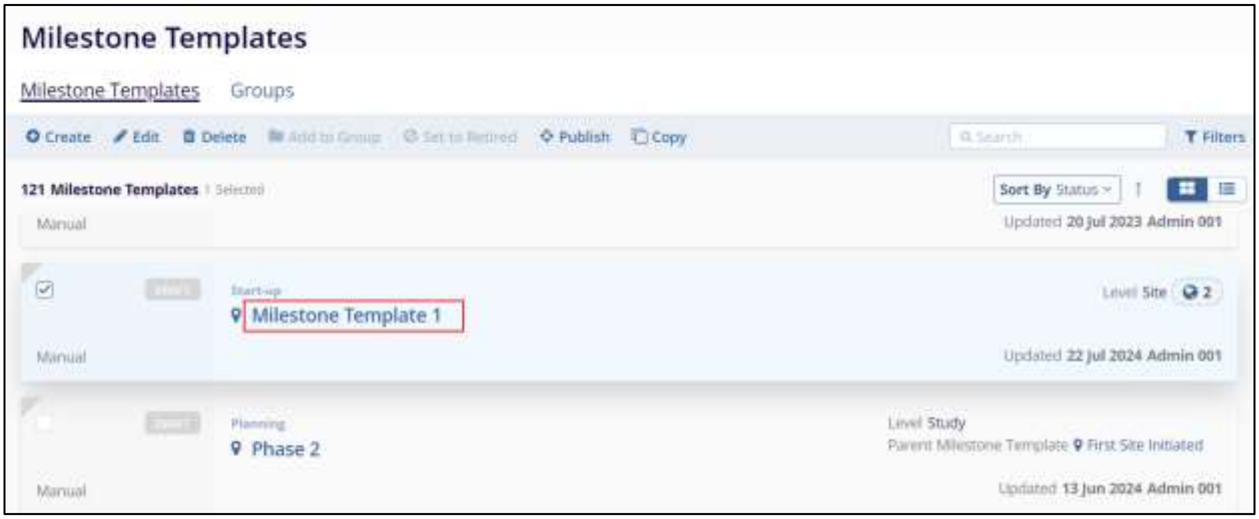


Figure: Newly created milestone template

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.

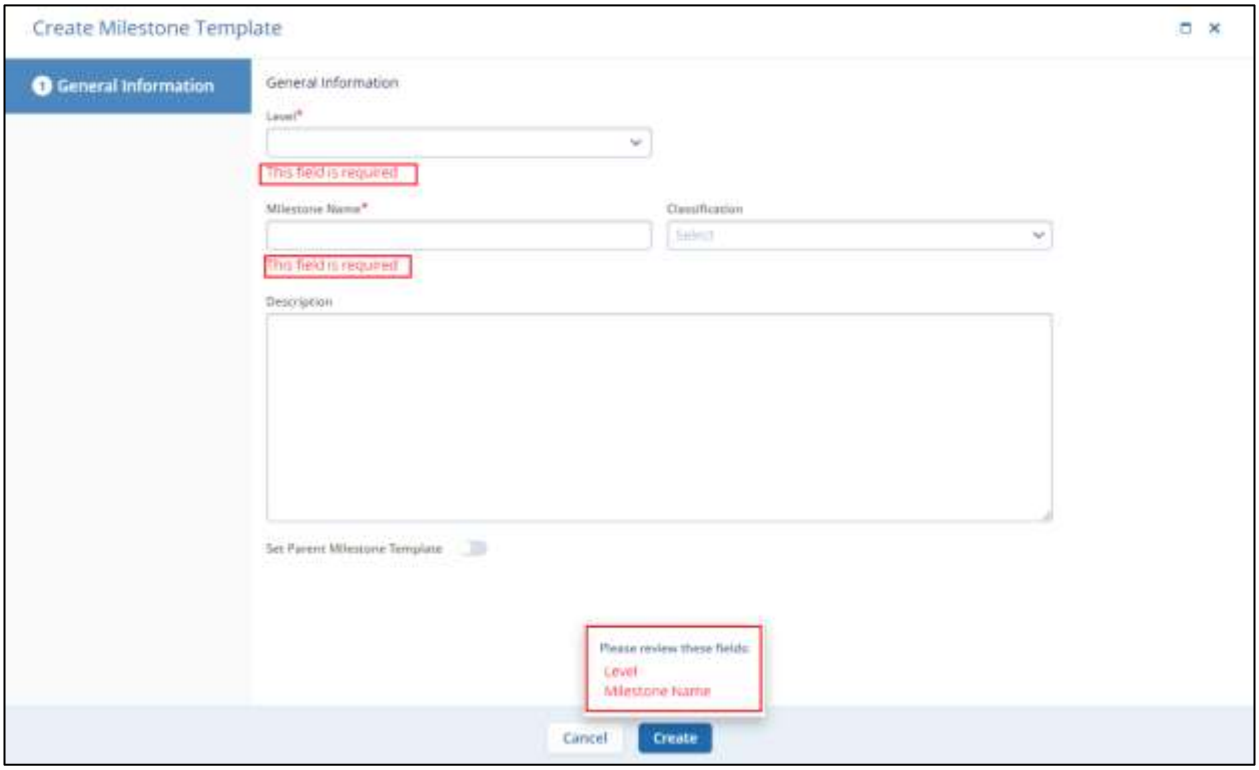


Figure: Mandatory fields error

Creating a Study Milestone from a Template

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

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

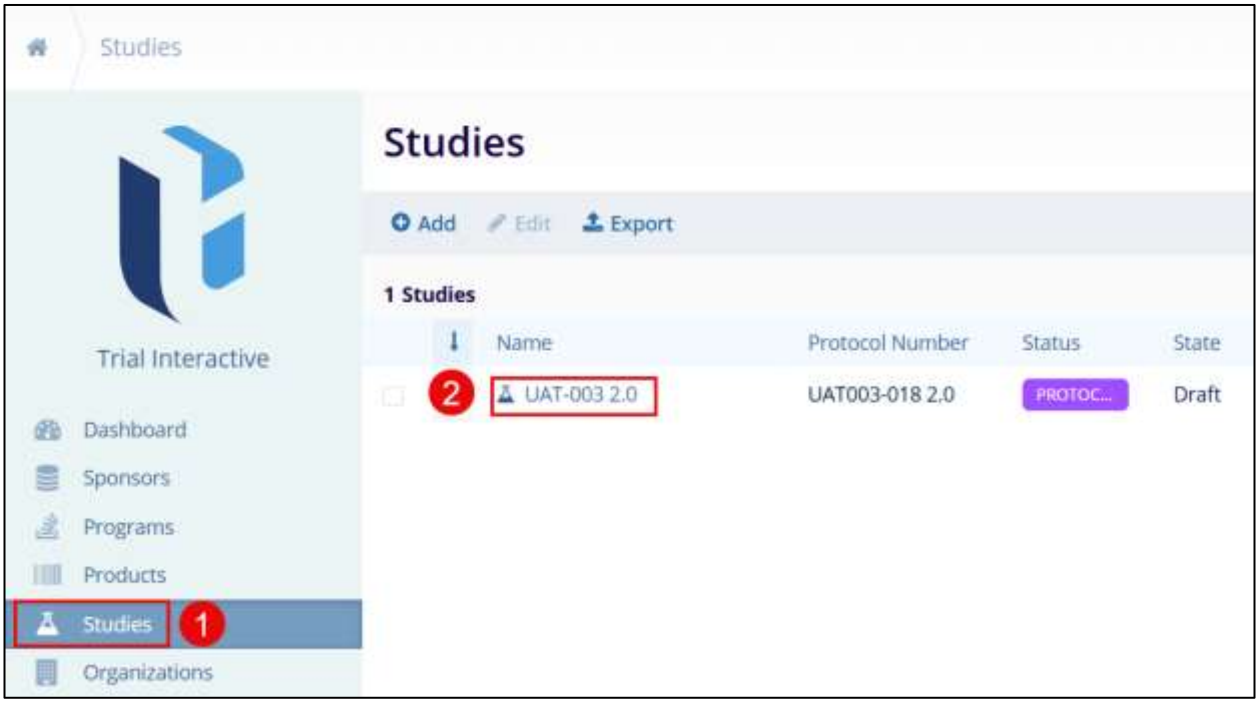


Figure: Selecting a study

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

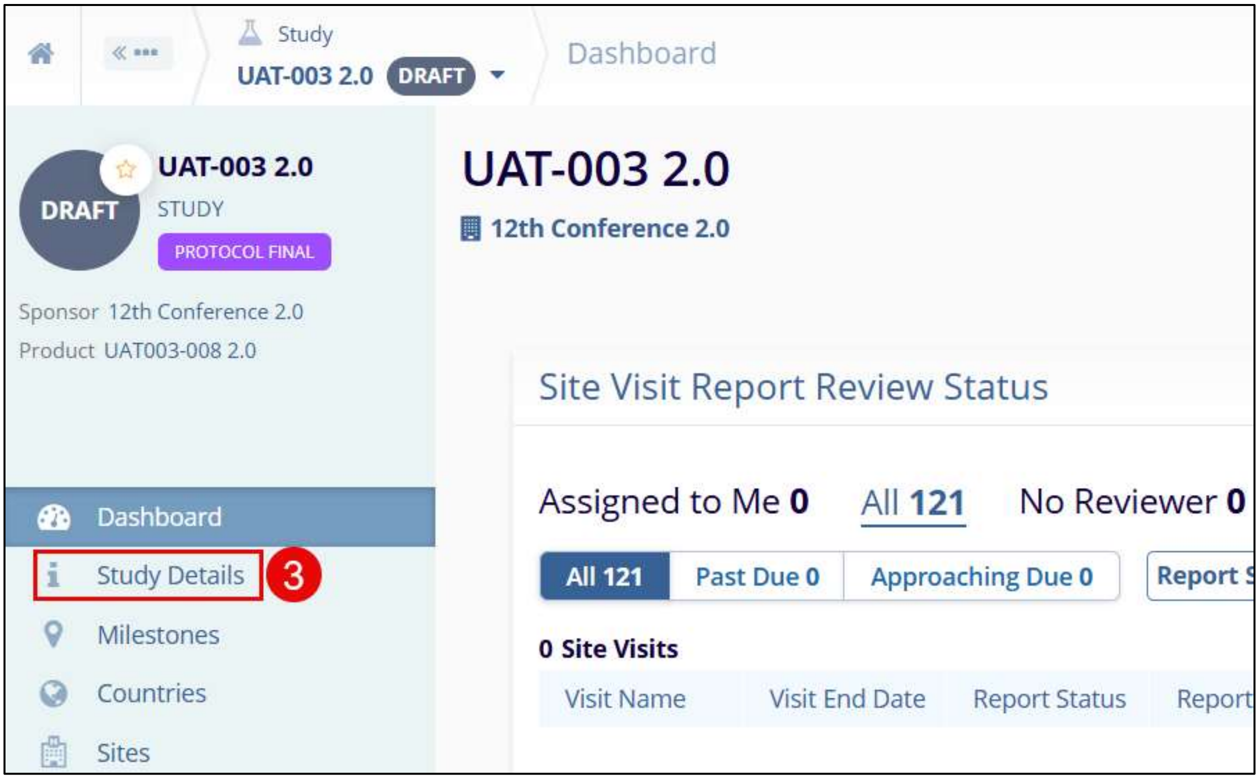


Figure: Select Study Details

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

Figure: Select Settings on the Study Details screen

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

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

7. Click on Add From Sponsor option.

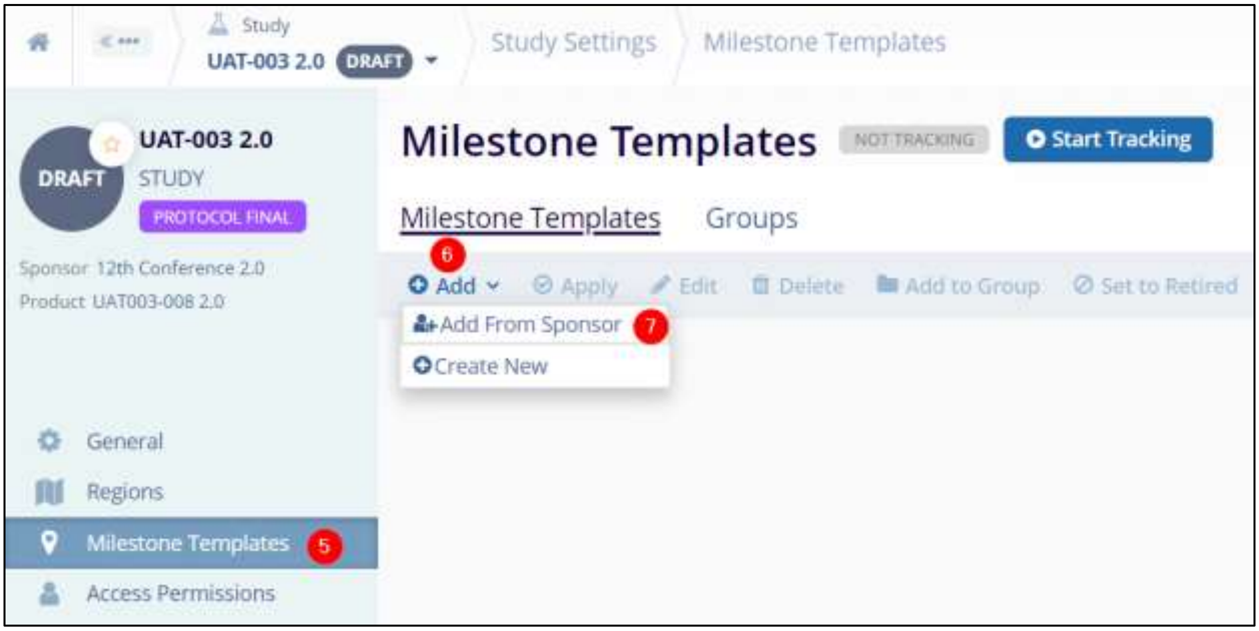


Figure: Select Add From Sponsor

8. On the Add Milestone Template From Sponsor screen, select the milestone template.
9. Click on the Add button.

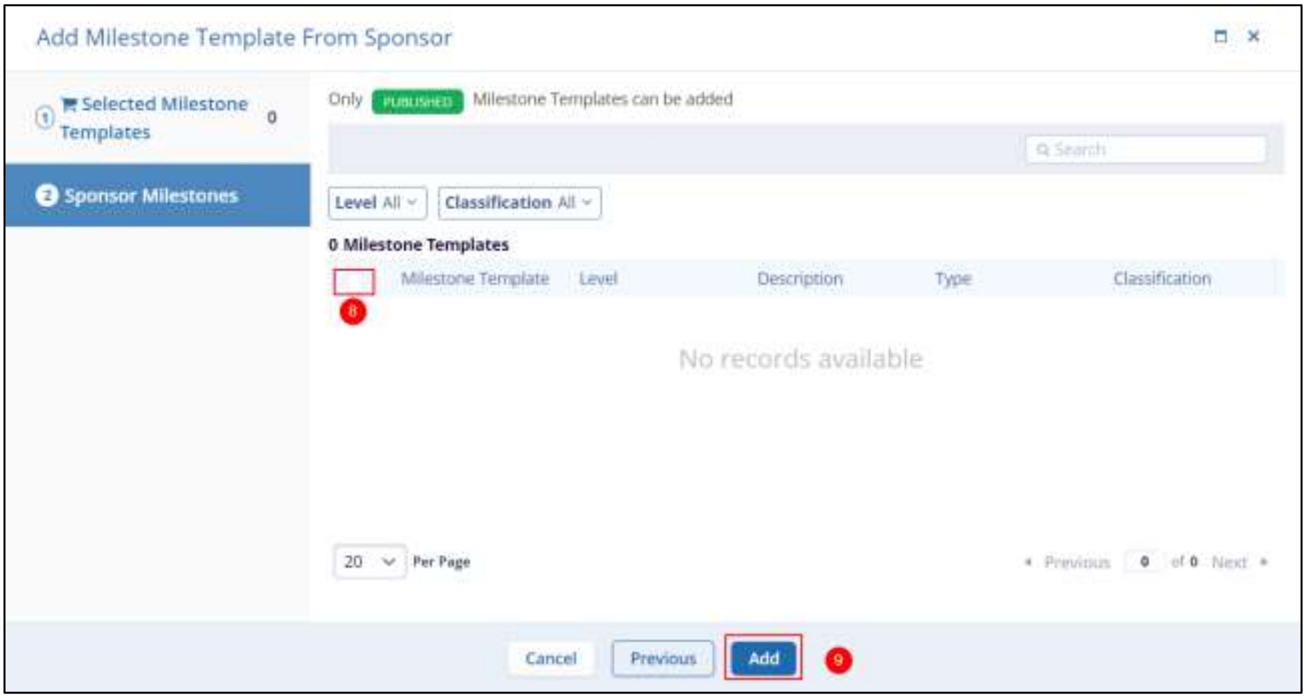


Figure: Add Milestone Template From Sponsor

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.

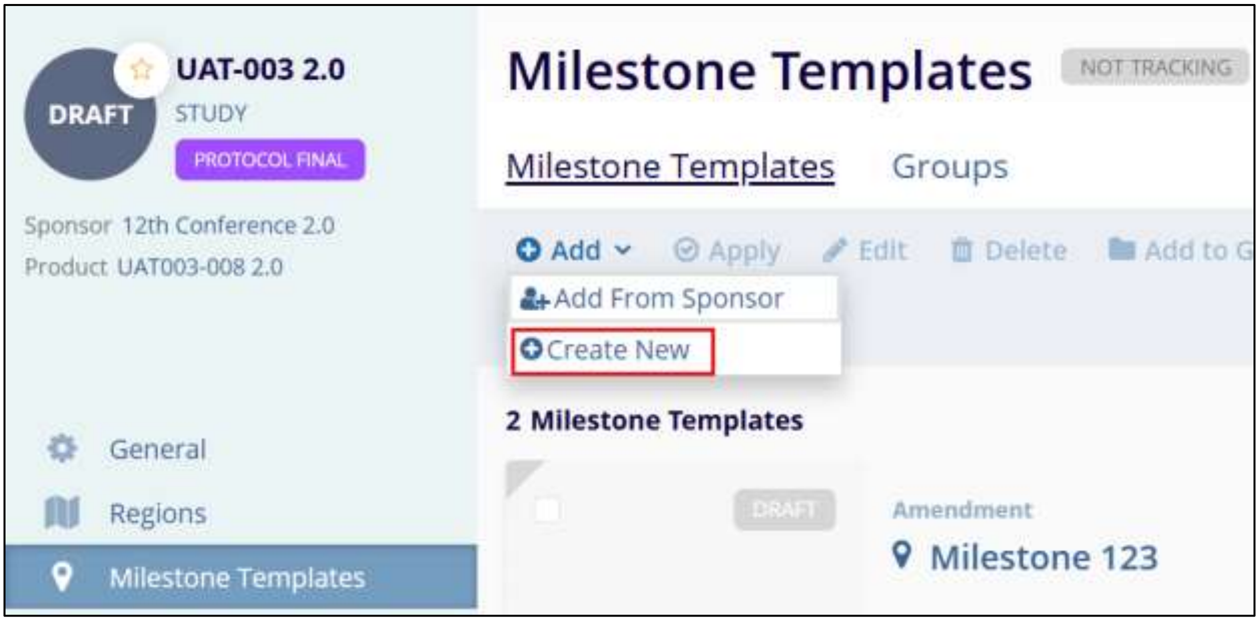


Figure: Create a New Template

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.

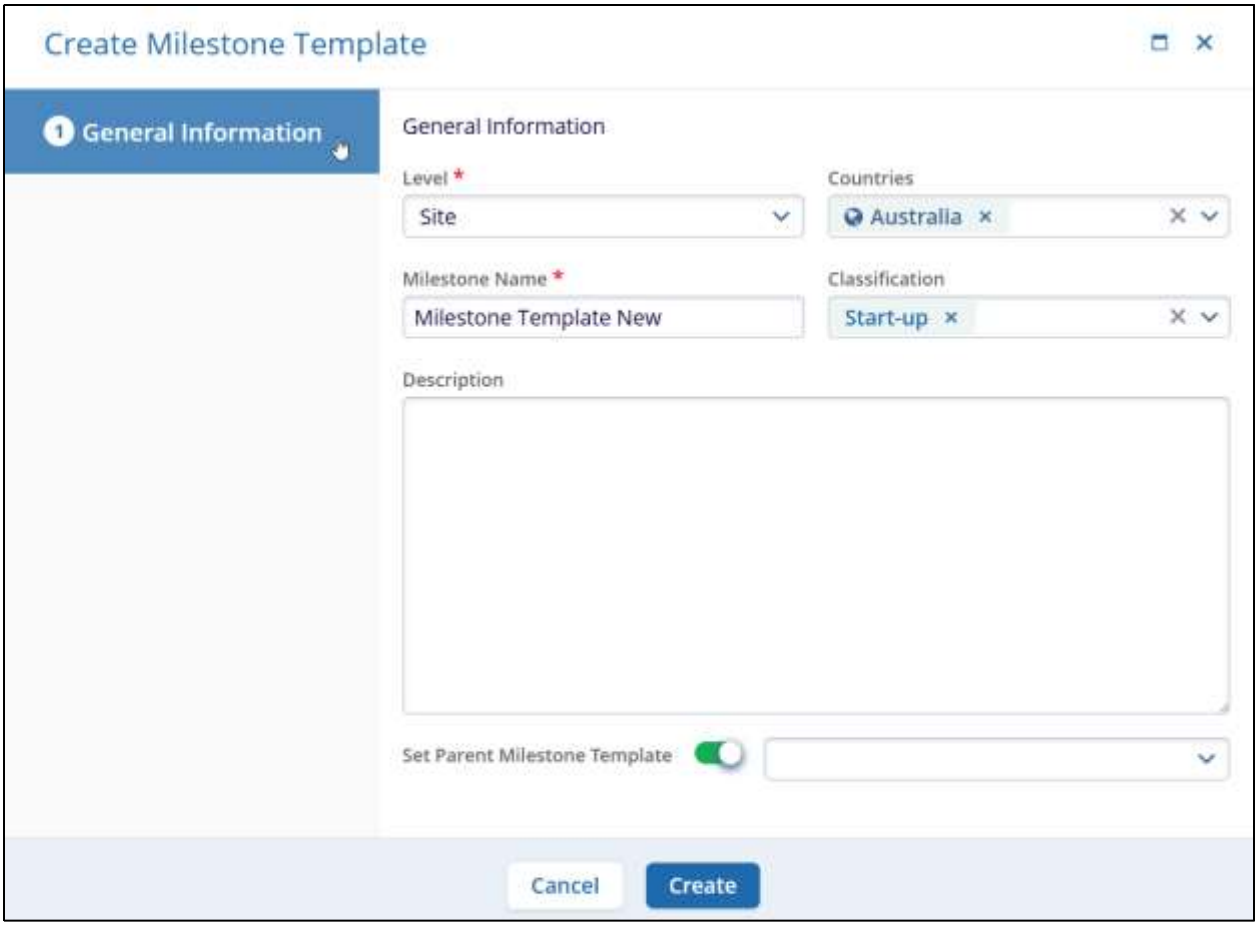


Figure: Save the new template

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 need to be mandatorily 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.

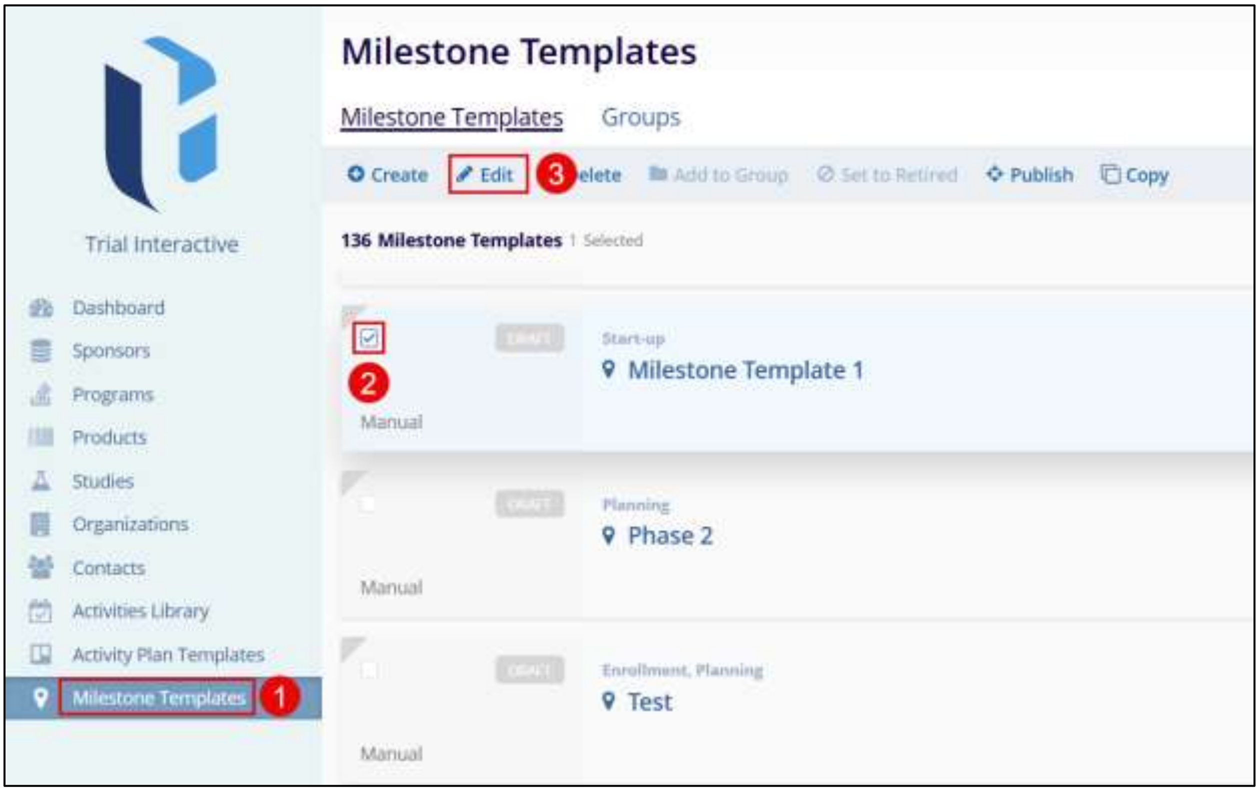


Figure: Select a template to edit

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

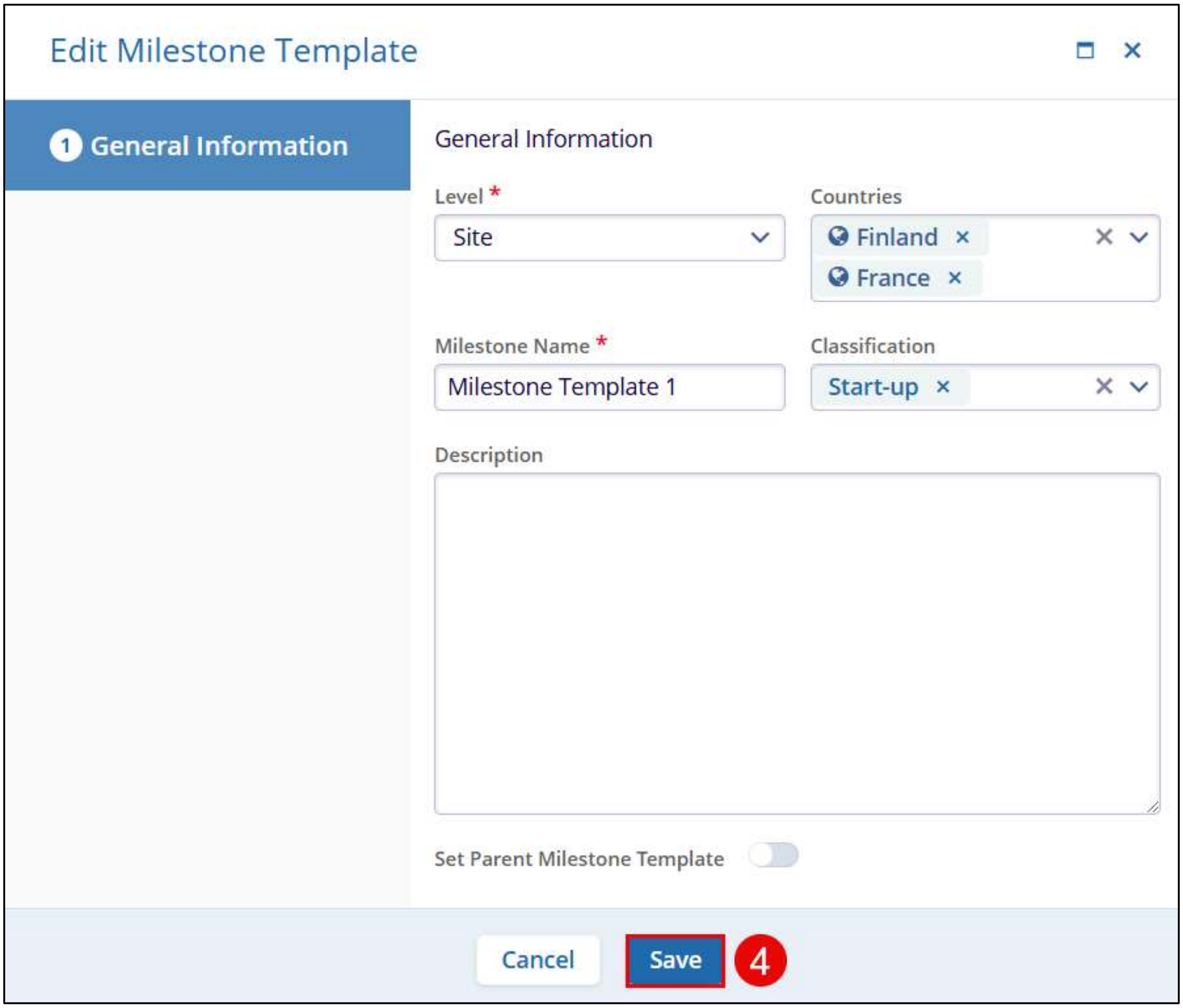


Figure: Edit Milestone Template

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.

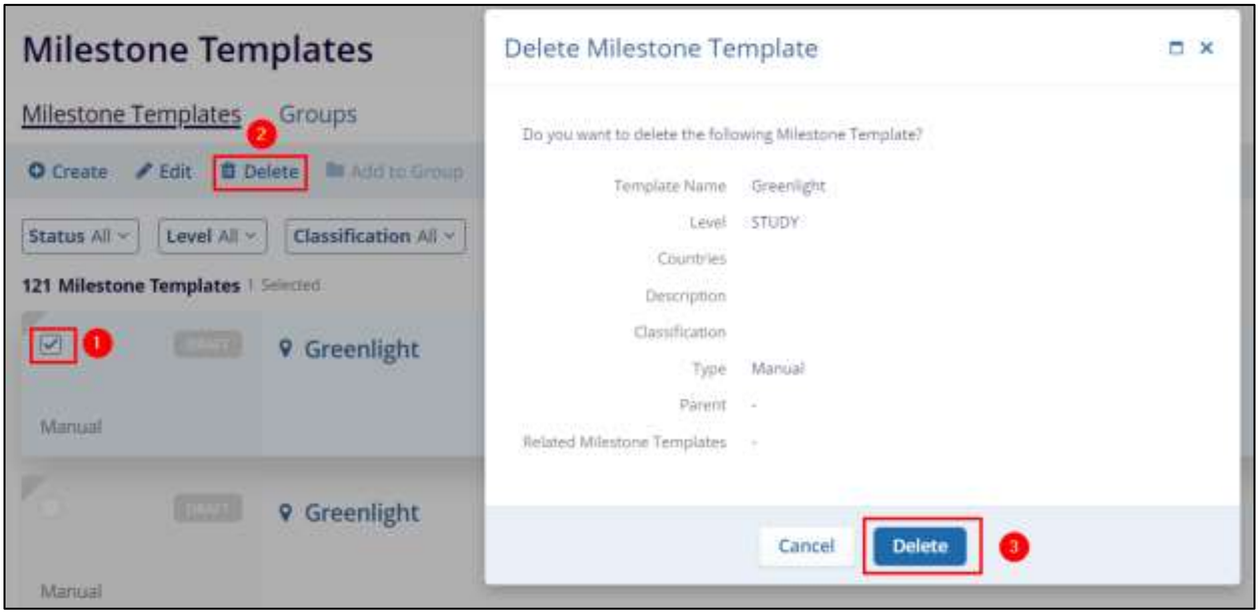


Figure: Deleting Milestone Template

Note: Users can edit templates only with the Draft status.

Publishing Milestone Templates

To publish Milestone Templates, follow the steps below.

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

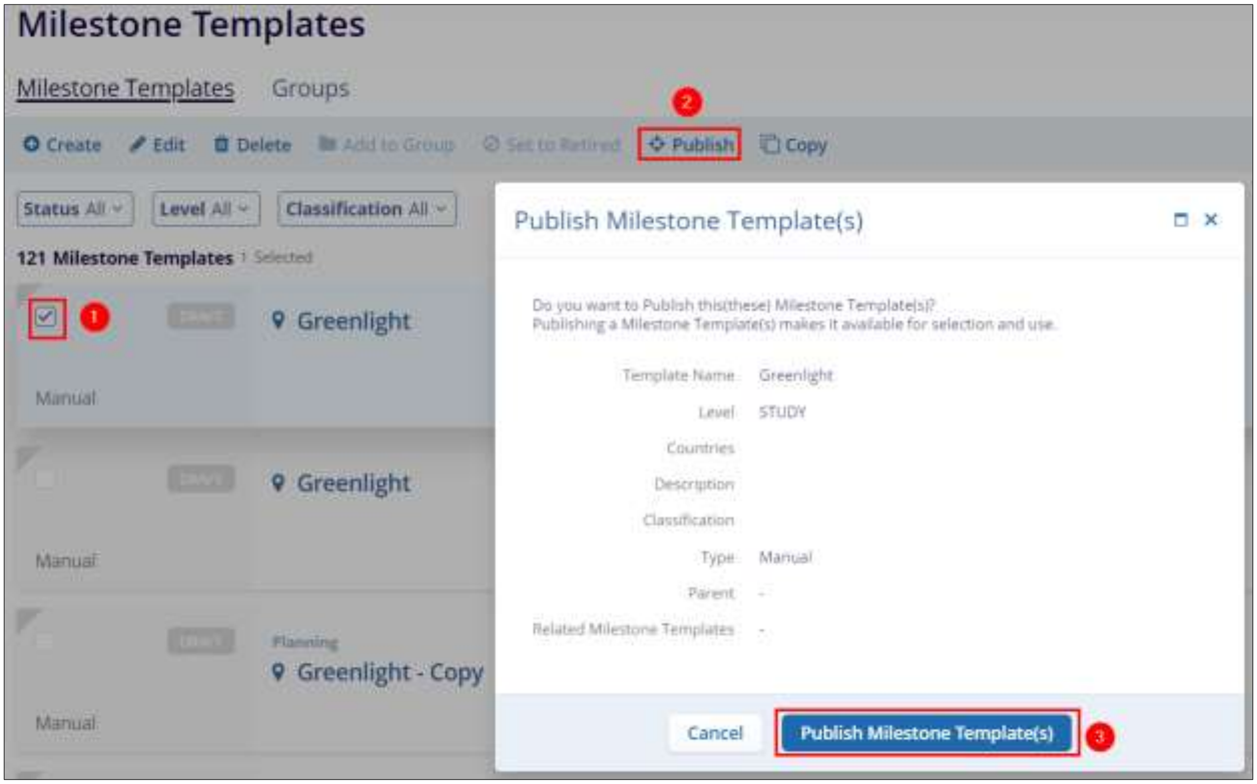


Figure: Publishing Milestone templates

Note: Milestone Templates with Draft status can be published.

Retiring Milestone Templates

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

To retire a Milestone Template, follow the steps below.

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

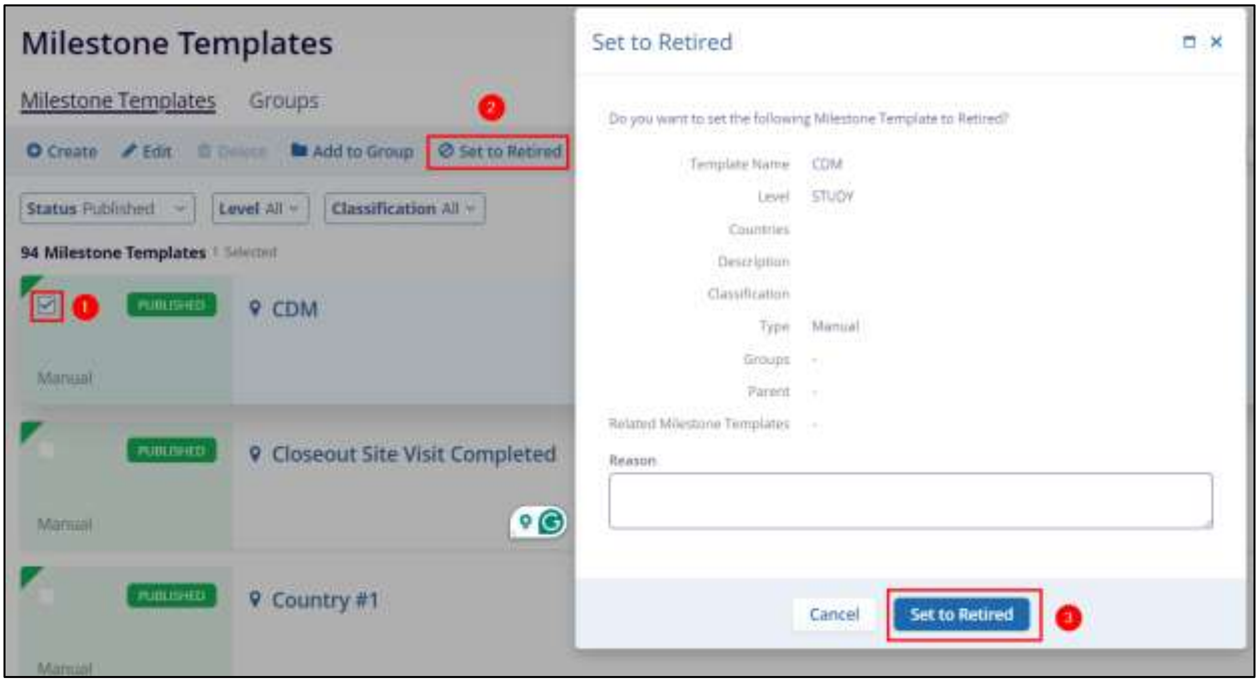


Figure: Retiring Milestone Template

Copying Milestone Templates

To copy Milestone Templates, follow the steps below.

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

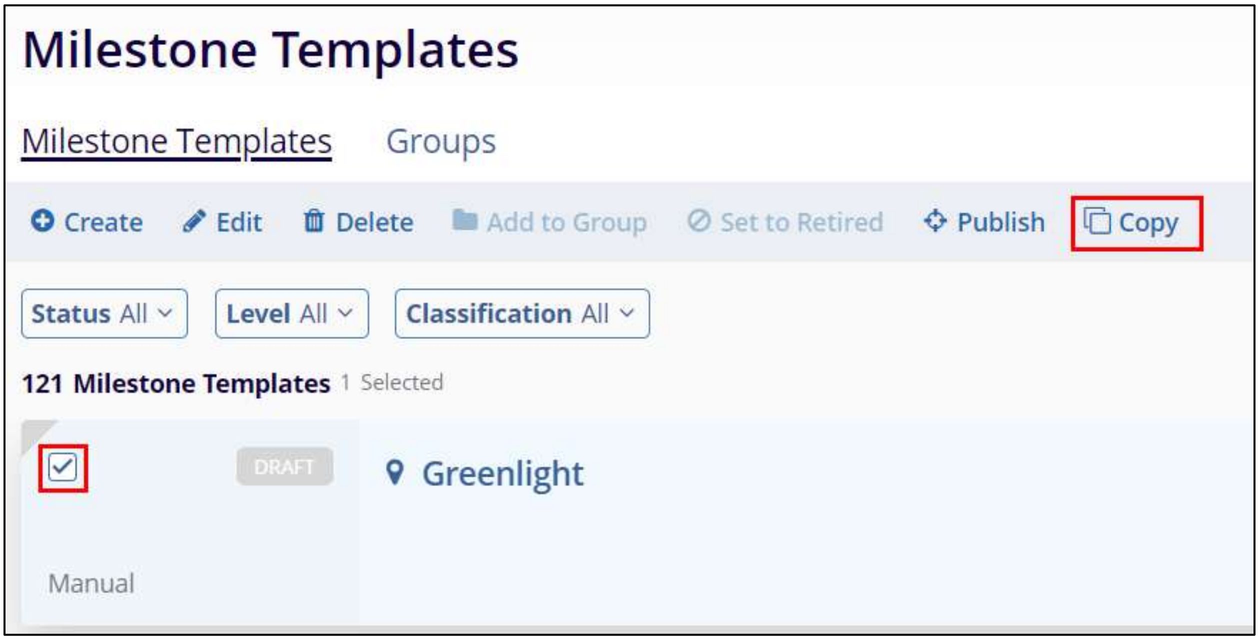


Figure: Copying a milestone template

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

Associating Milestone Templates to a Sponsor

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

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

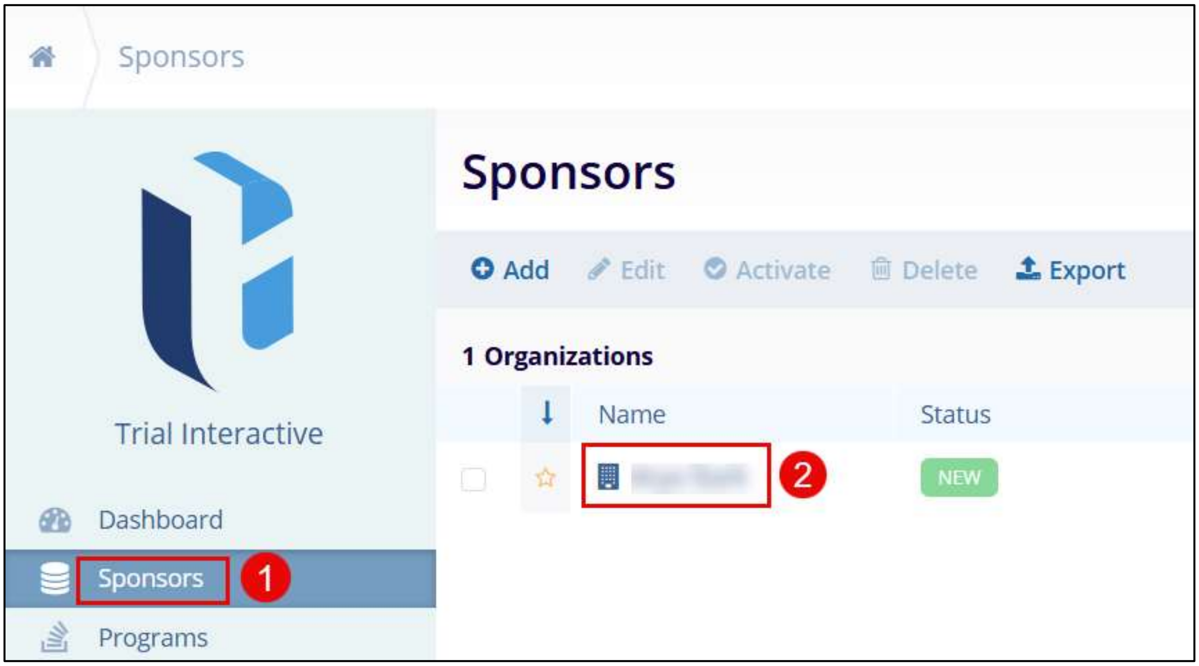


Figure: Select Sponsors

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

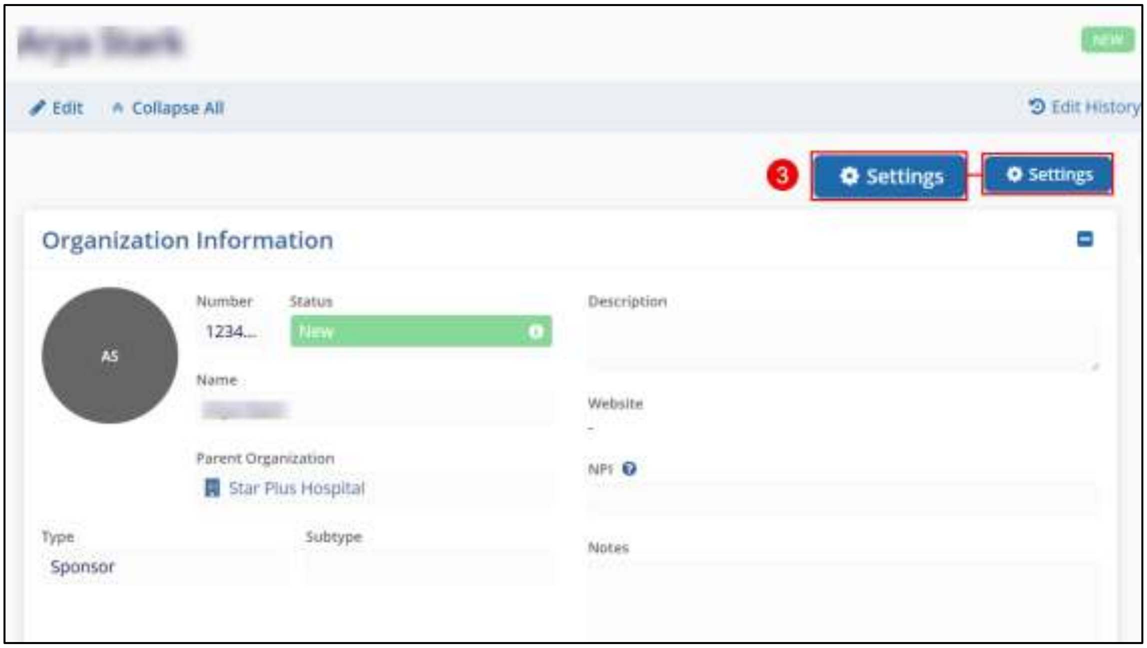


Figure: Access Setting on the Sponsor Details screen

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

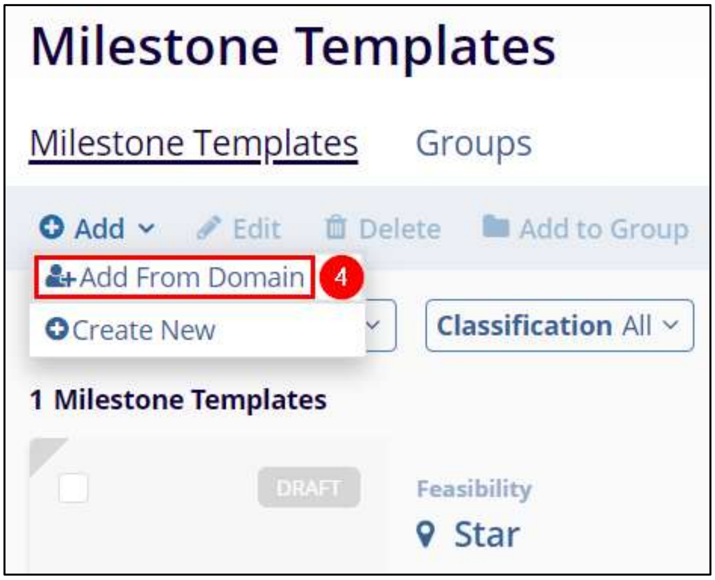


Figure: Add Template From Domain

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.

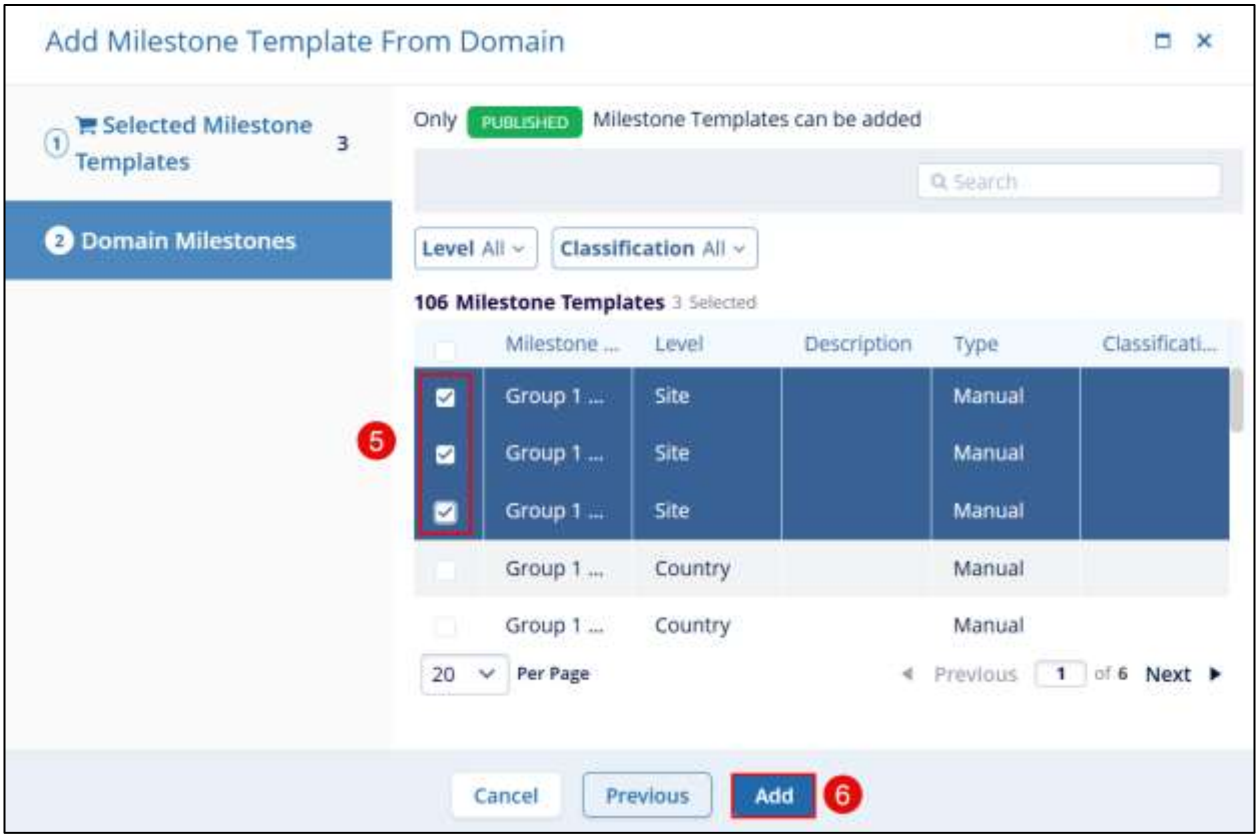


Figure: Add Milestone From Domain screen

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.

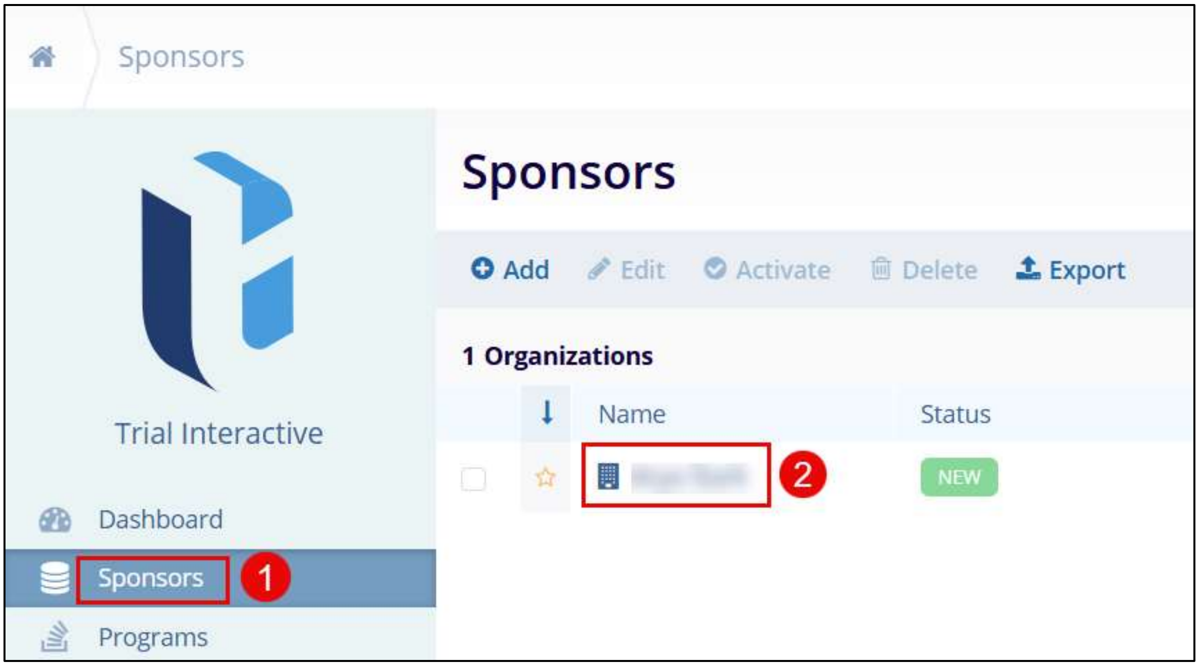


Figure: Select Sponsors

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

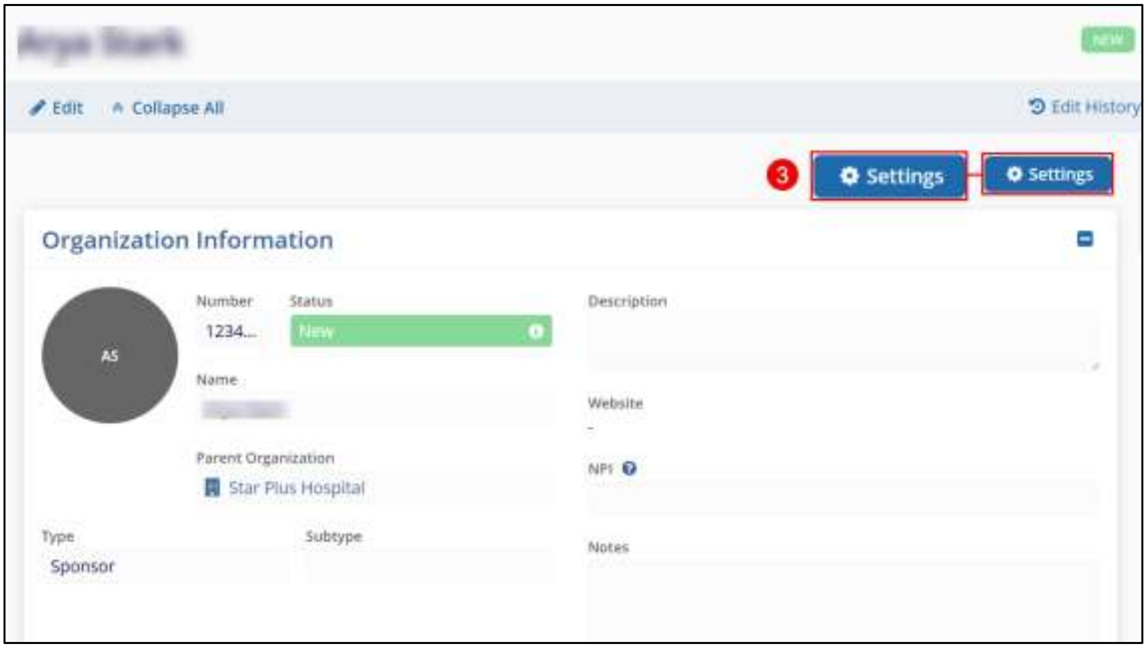


Figure: Access Setting on the Sponsor Details screen

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

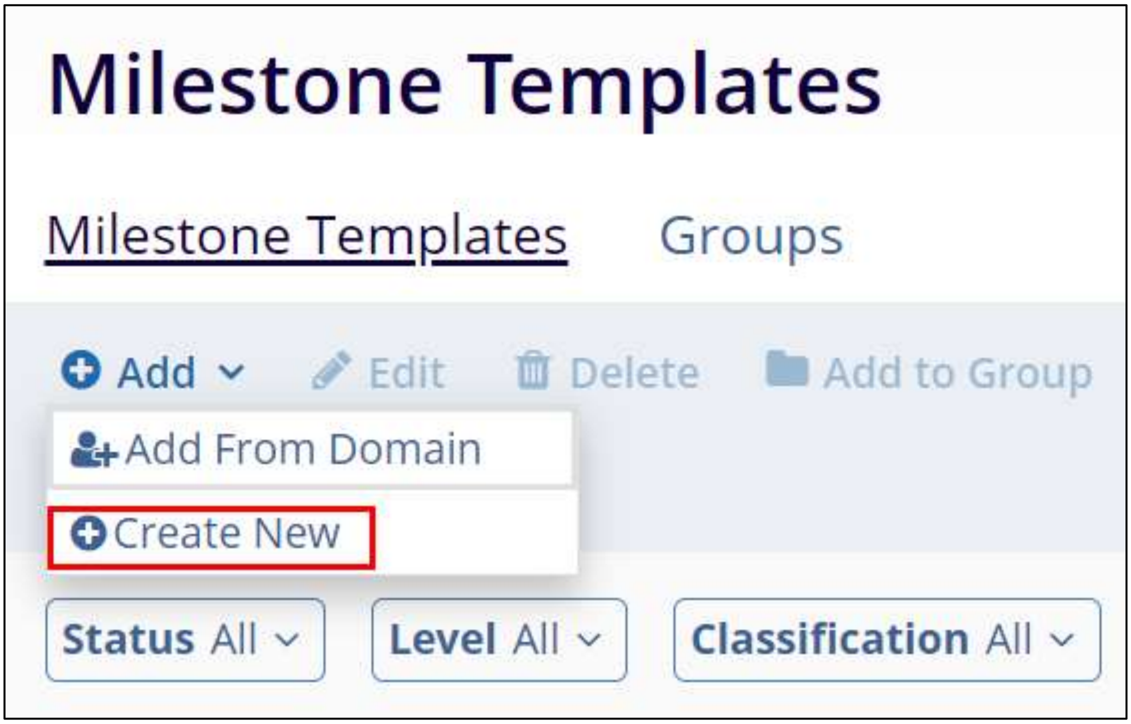


Figure: Create a new milestone template for the sponsor

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.

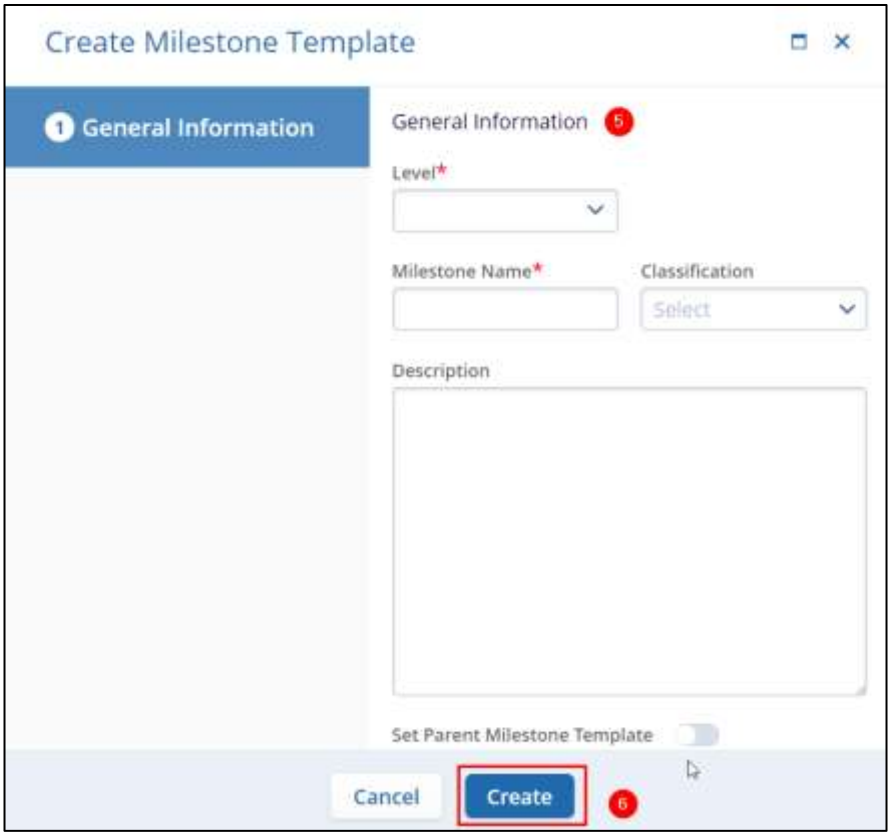


Figure: Creating new milestone template for sponsor

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.

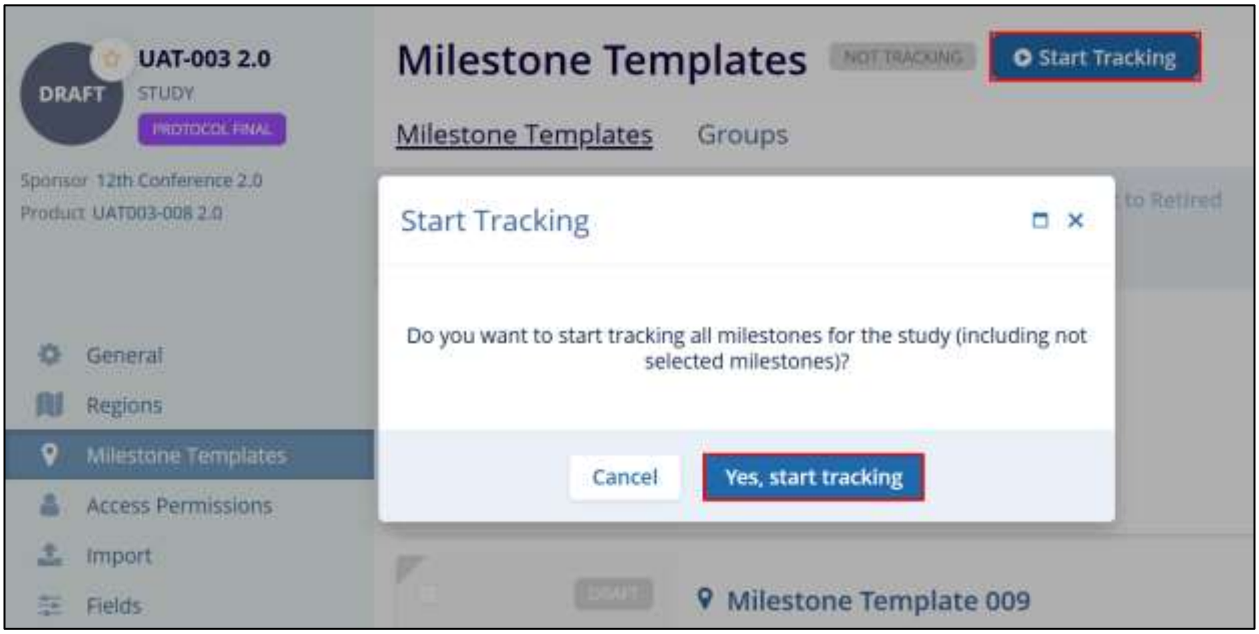


Figure: Tracking Milestones

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.

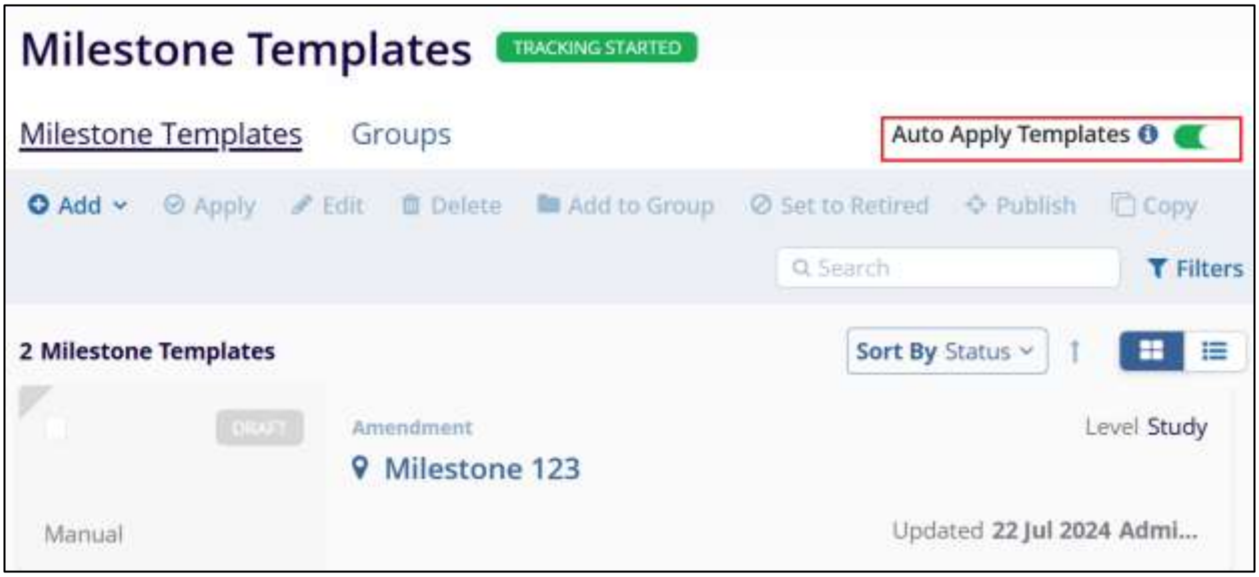


Figure: Auto Apply Templates

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.

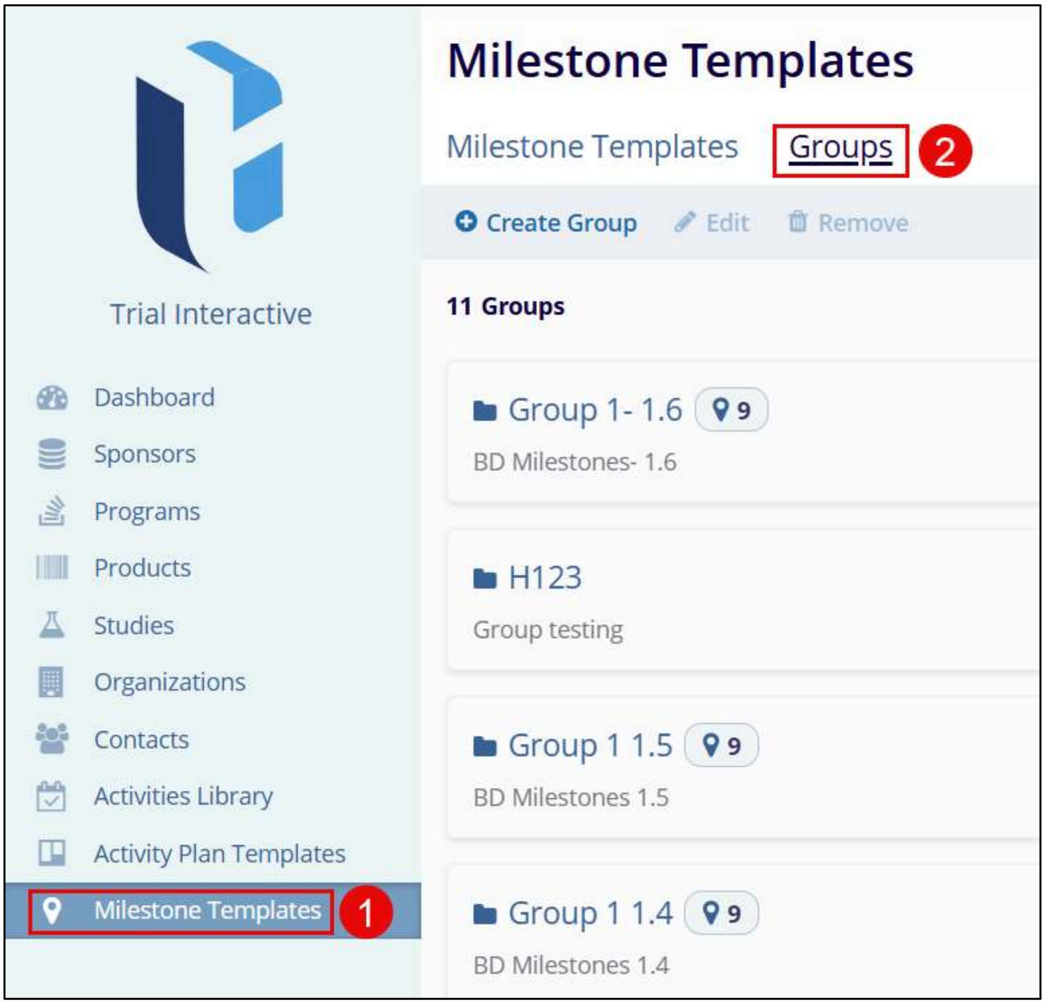


Figure: Milestone Groups

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.

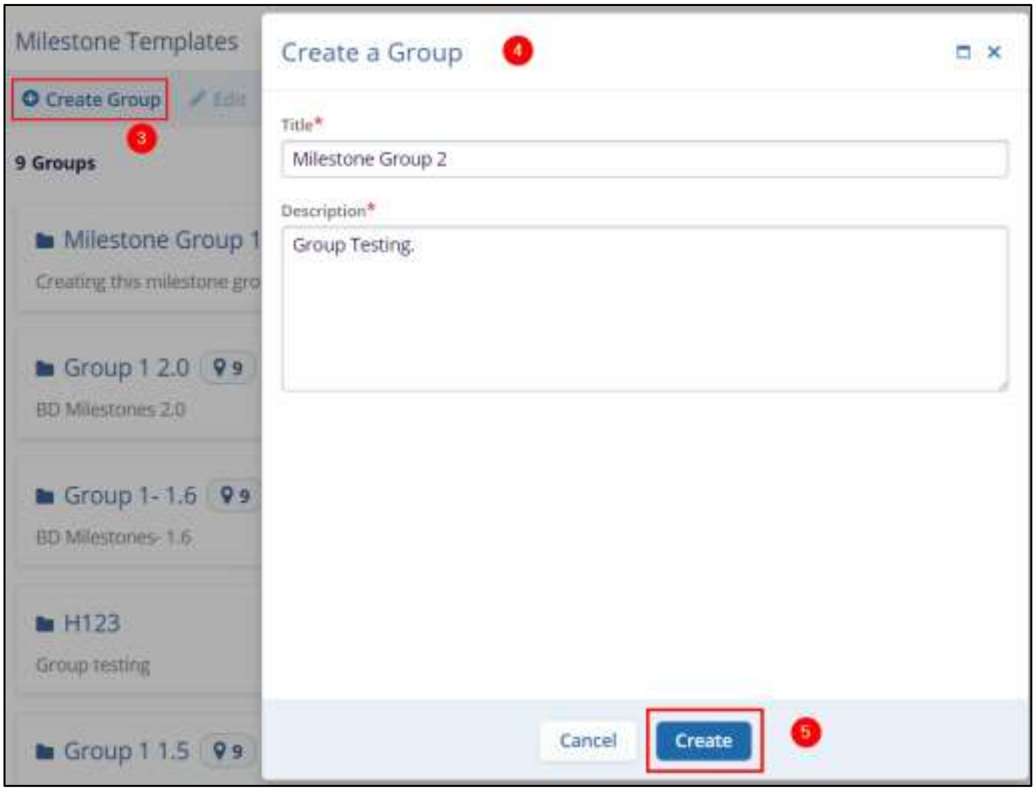


Figure: Create a Group

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.

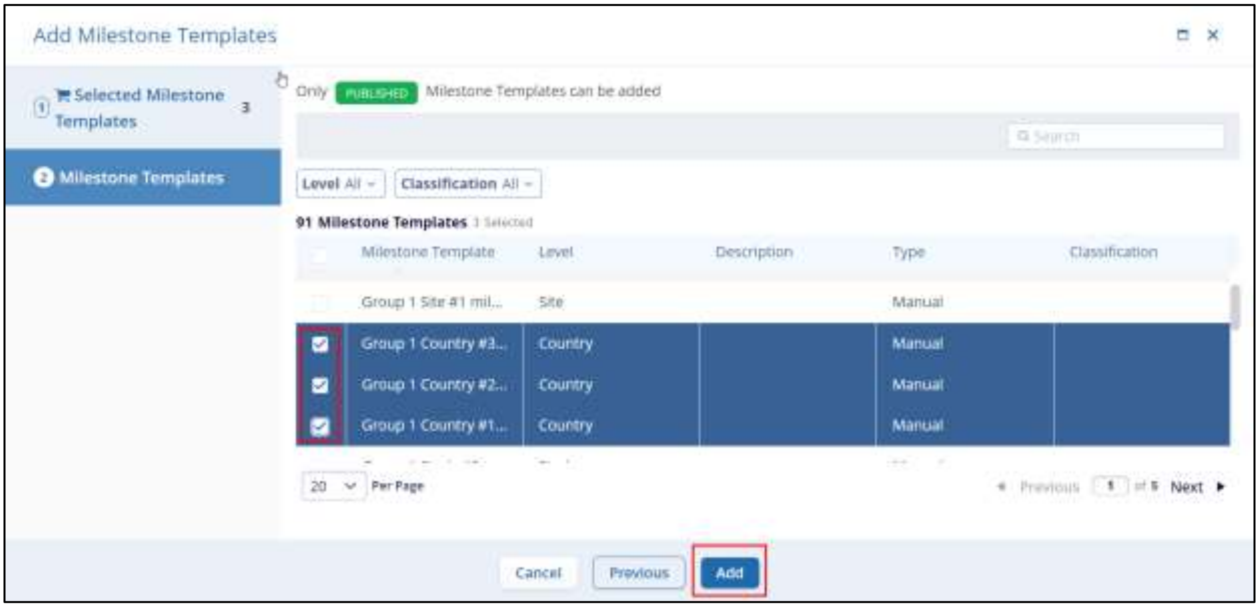


Figure: Select and Add milestone templates to groups

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.

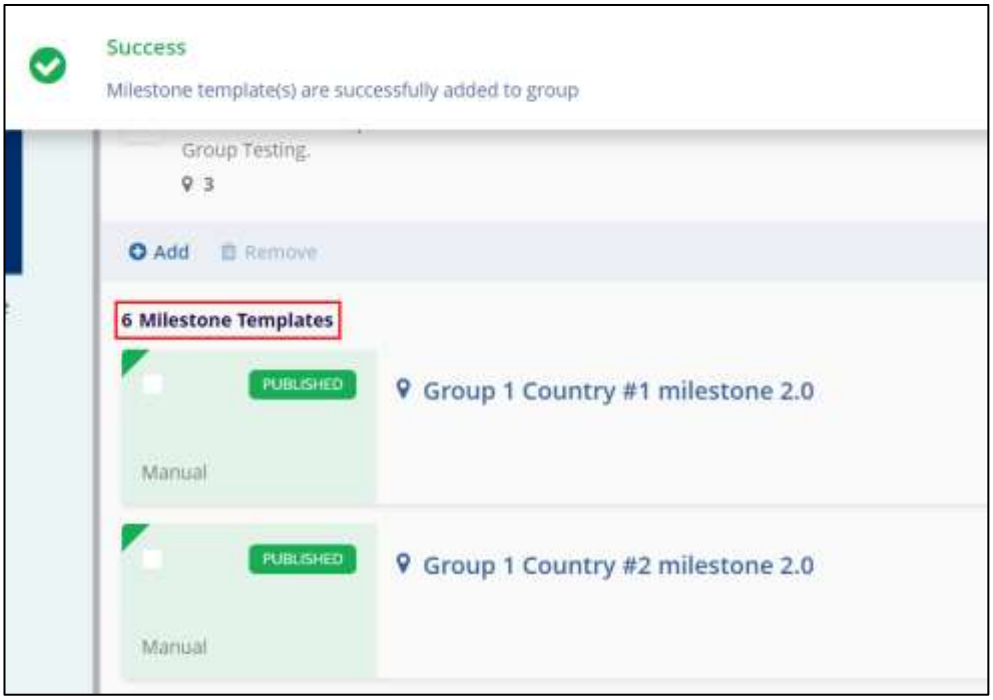


Figure: Milestone template success notification

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.

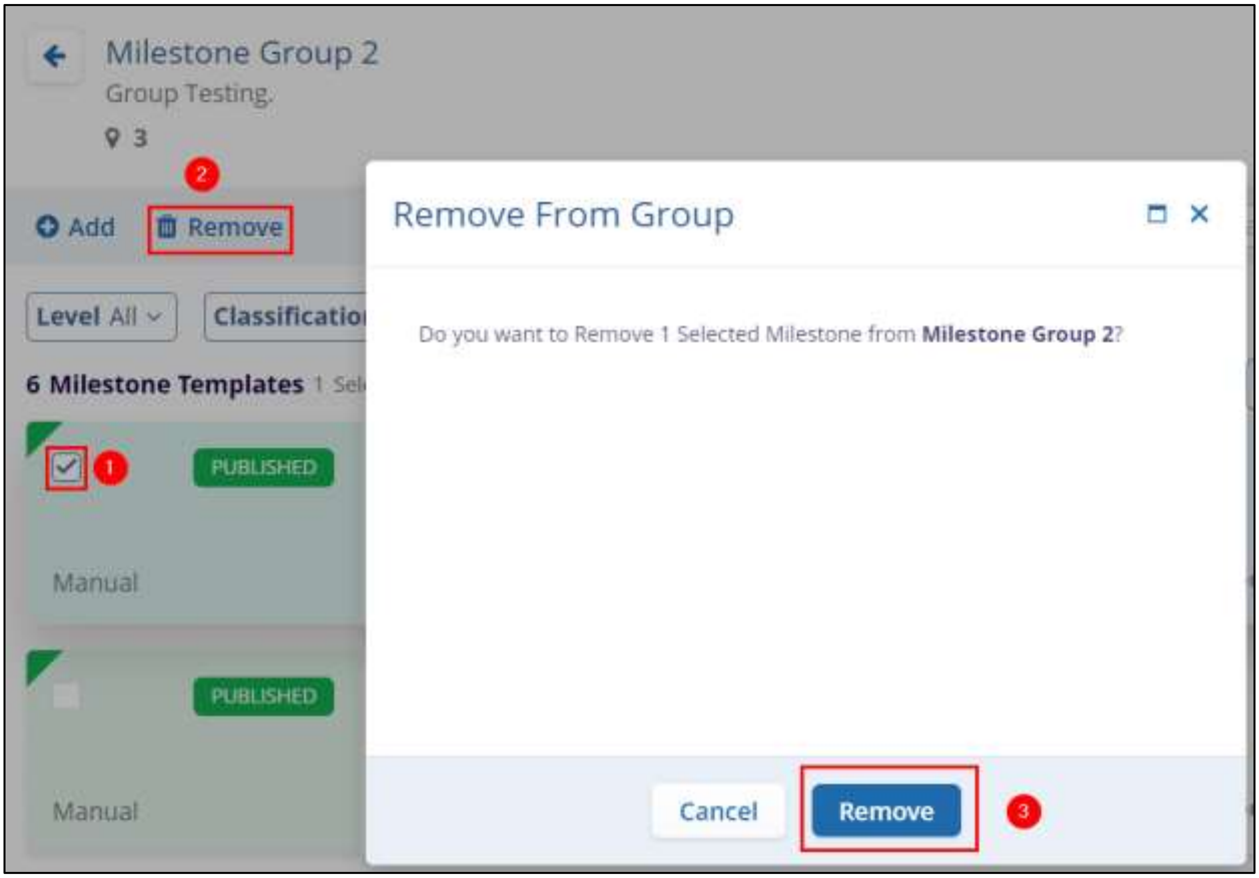


Figure: Removing templates from group

Customizing Milestone Groups screen

Users can apply filters and sorting criteria, as well as customize the screen view of the selected milestone group.

3. 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

4. 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.

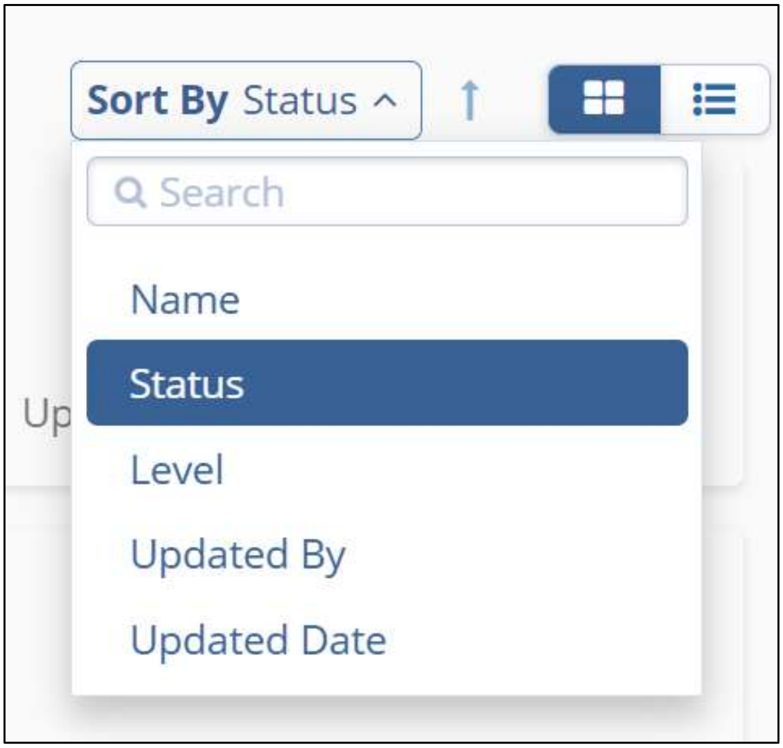


Figure: Sorting criteria

5. 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

6. 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.

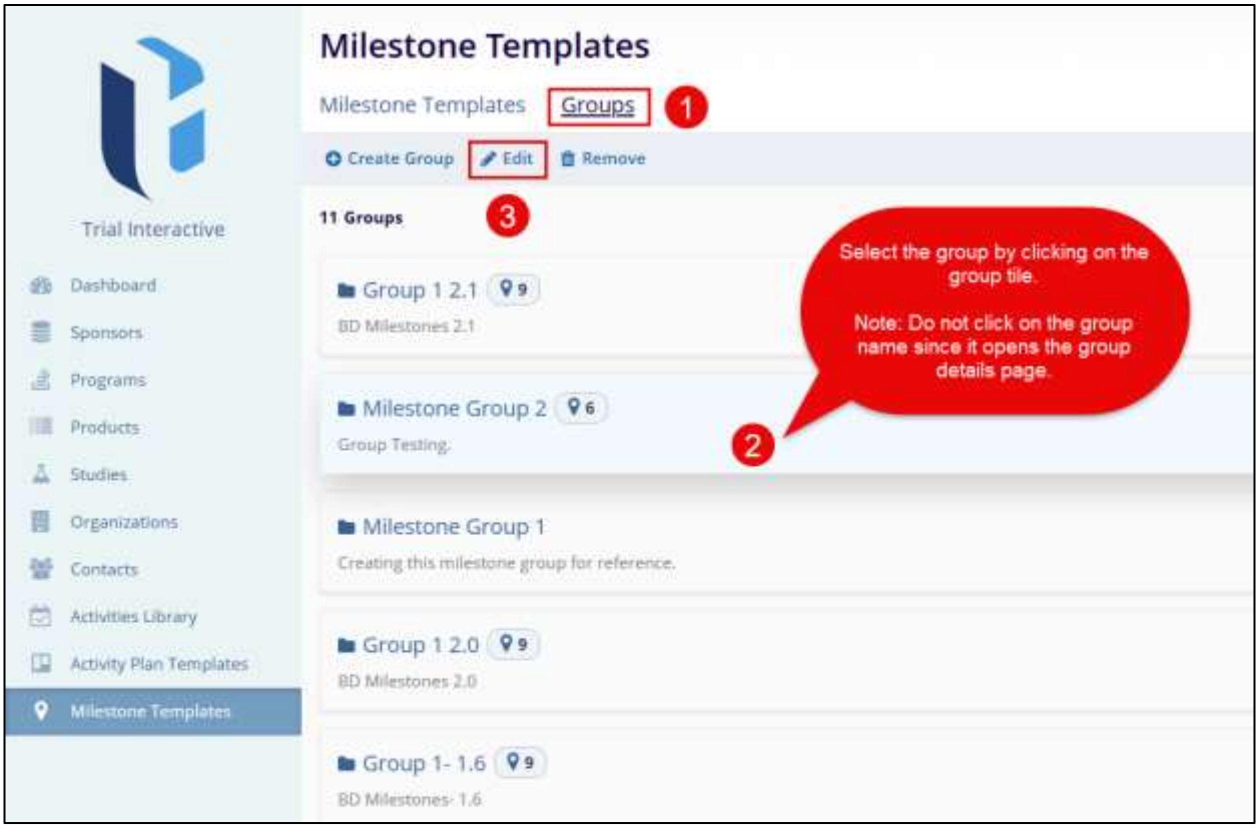


Figure: Editing Group

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.

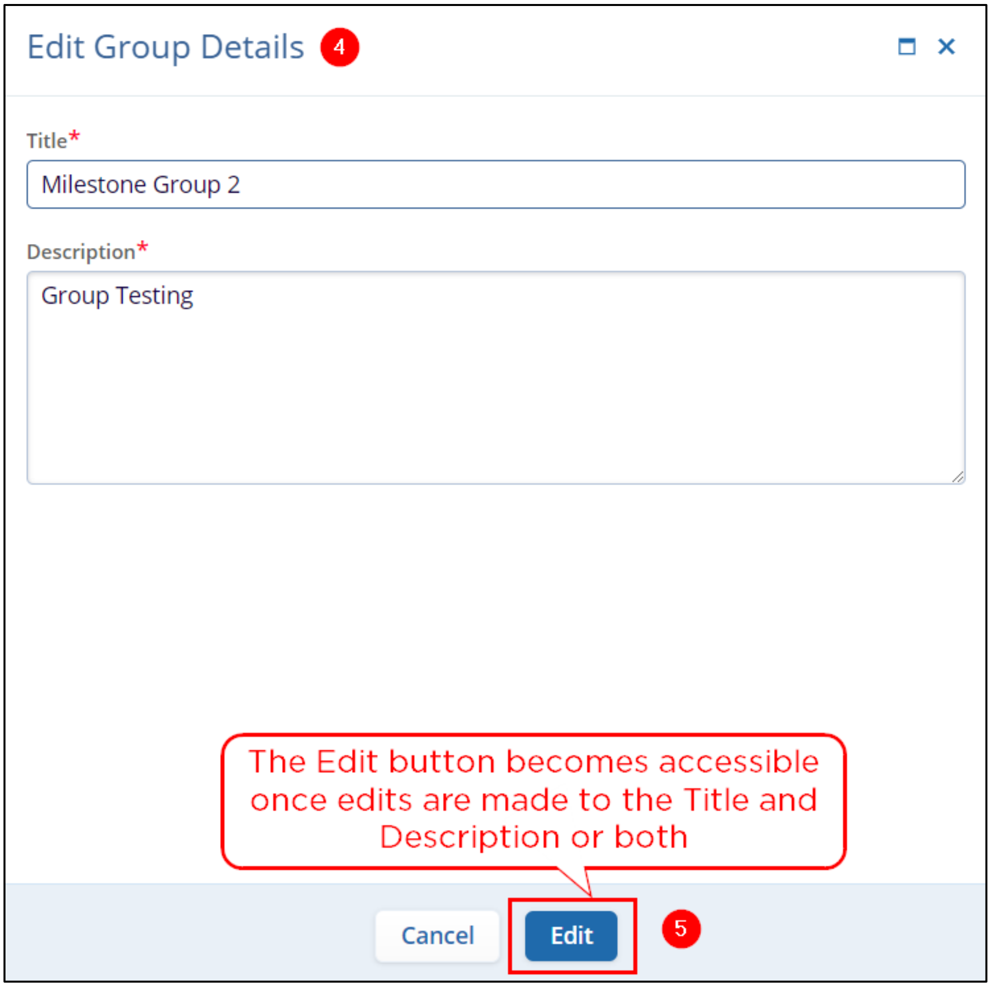


Figure: Edit Group Details screen

7. 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.

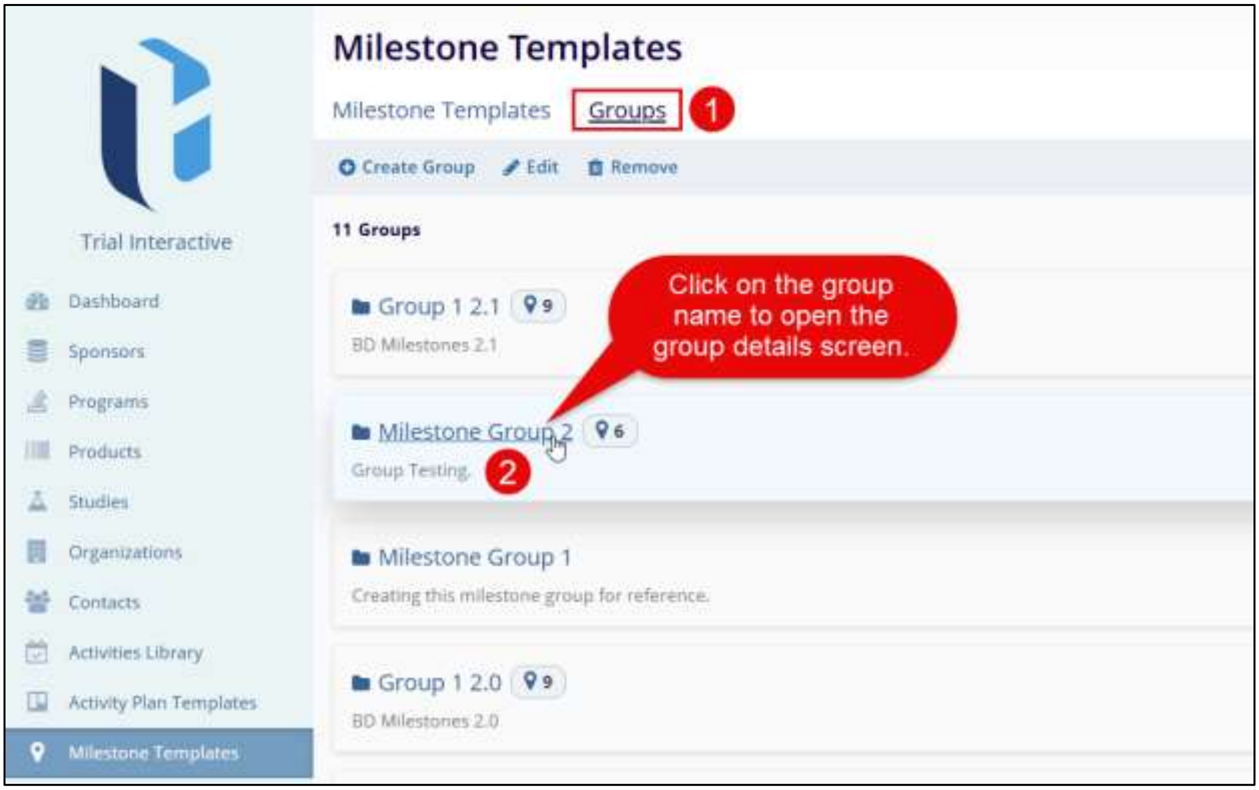


Figure: Select the group name

3. Click on Edit Details,
4. Make the required changes on the Edit Group Details screen, and select Edit.

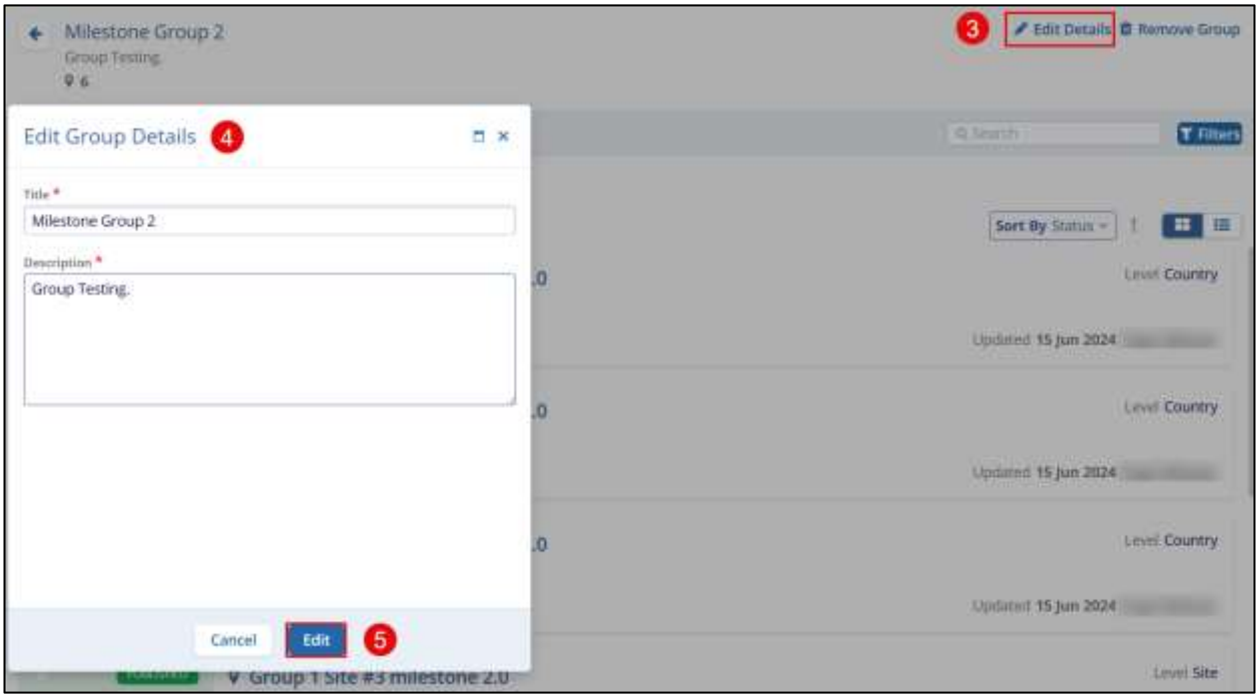


Figure: Edit Group Details-method 2

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.

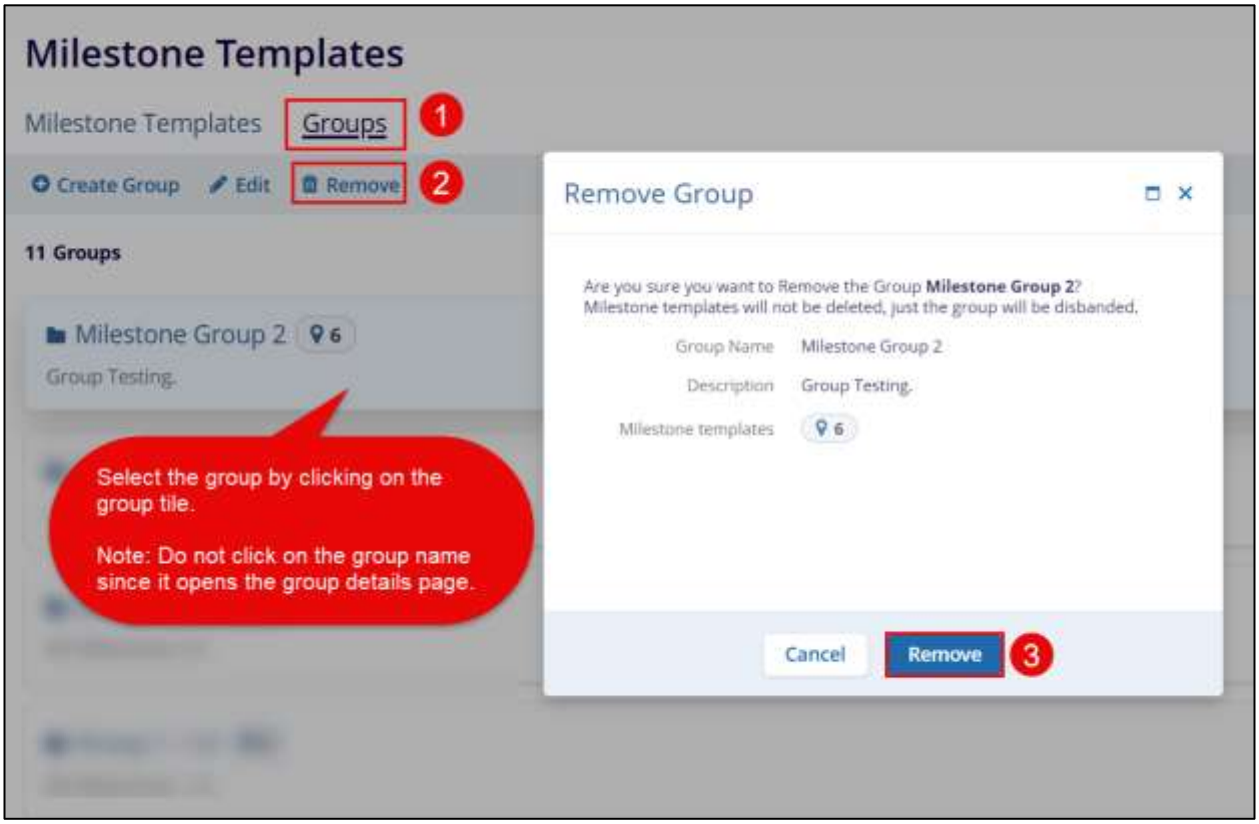


Figure: Removing Group-method 1

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.

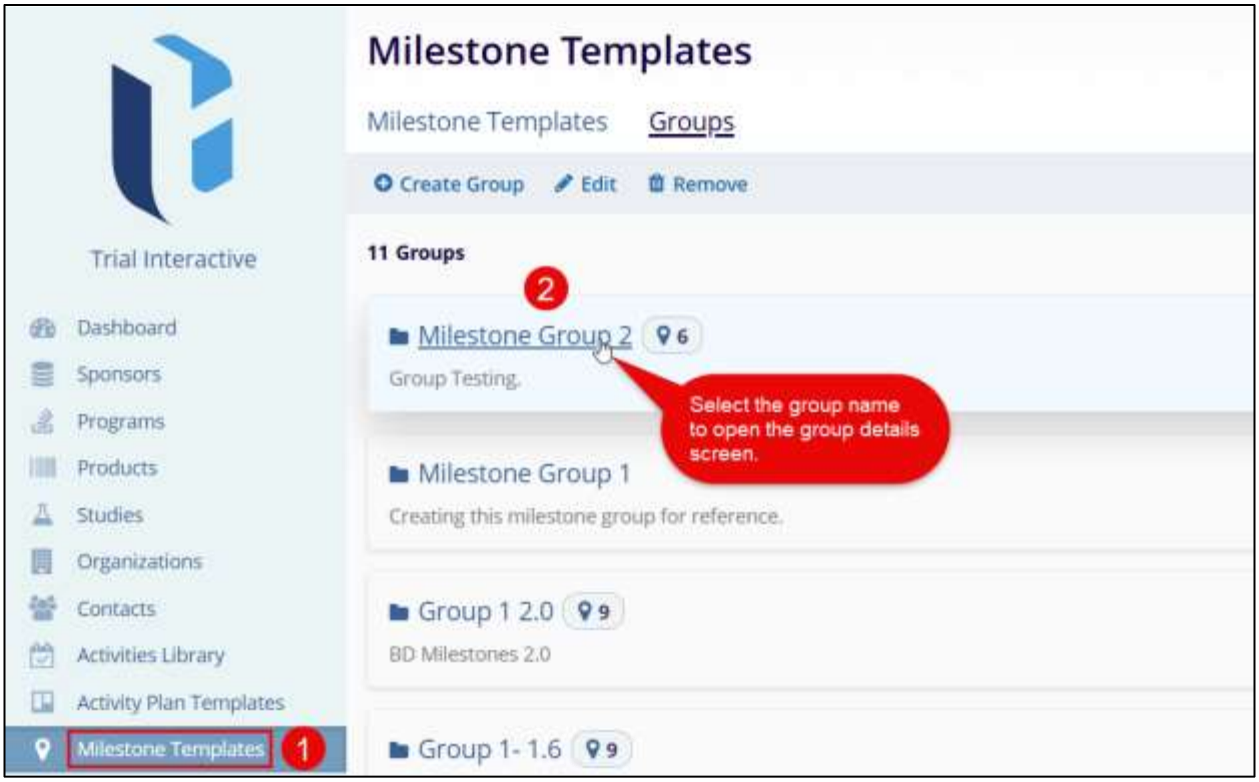


Figure: Select the group name

3. Click on the Remove Group button.
4. Click on the Remove button on the Remove Group screen.

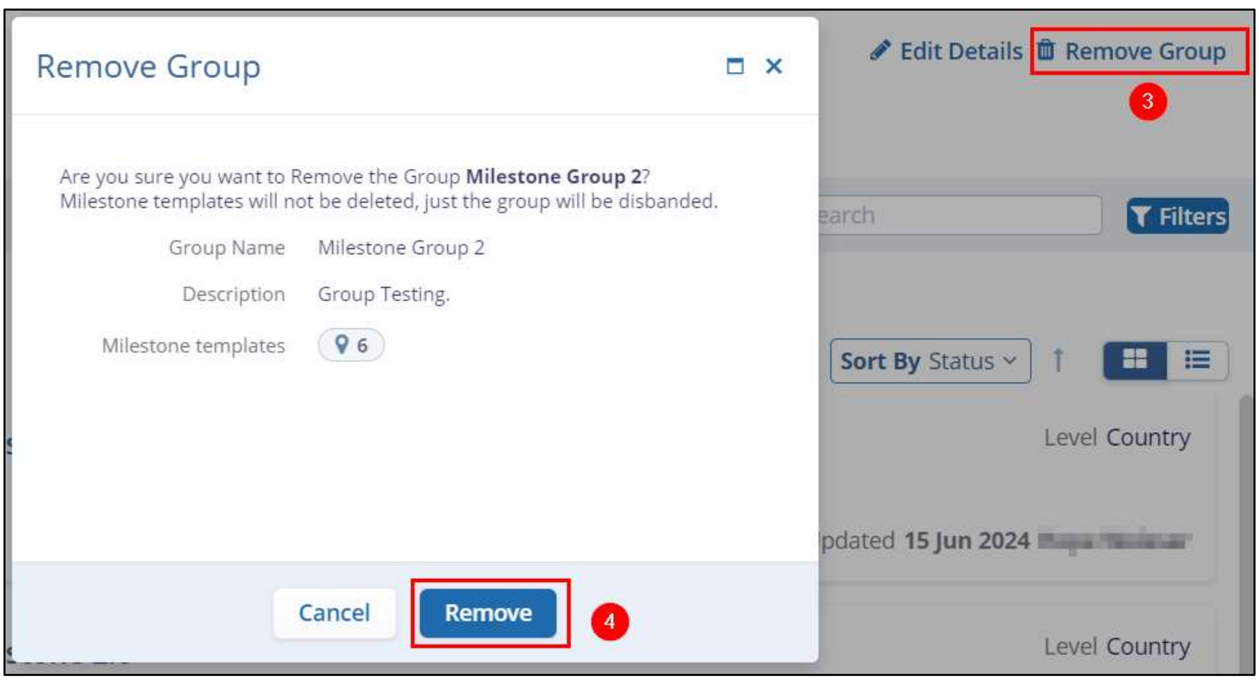


Figure: Remove Group-method 2

CHAPTER 14. 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.

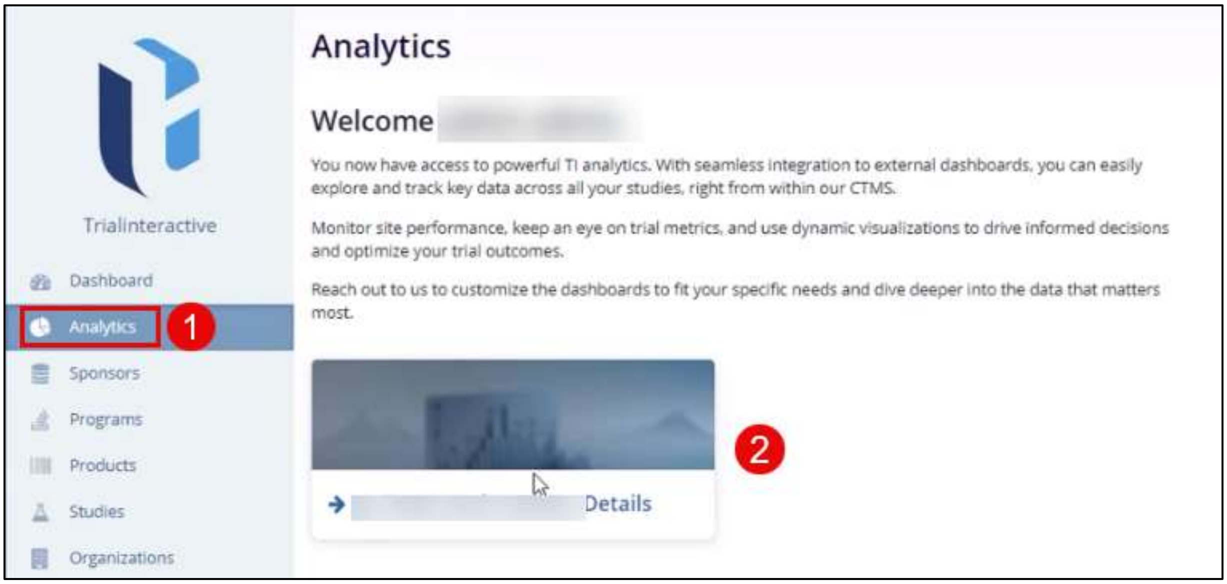


Figure: Access Analytics module

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.

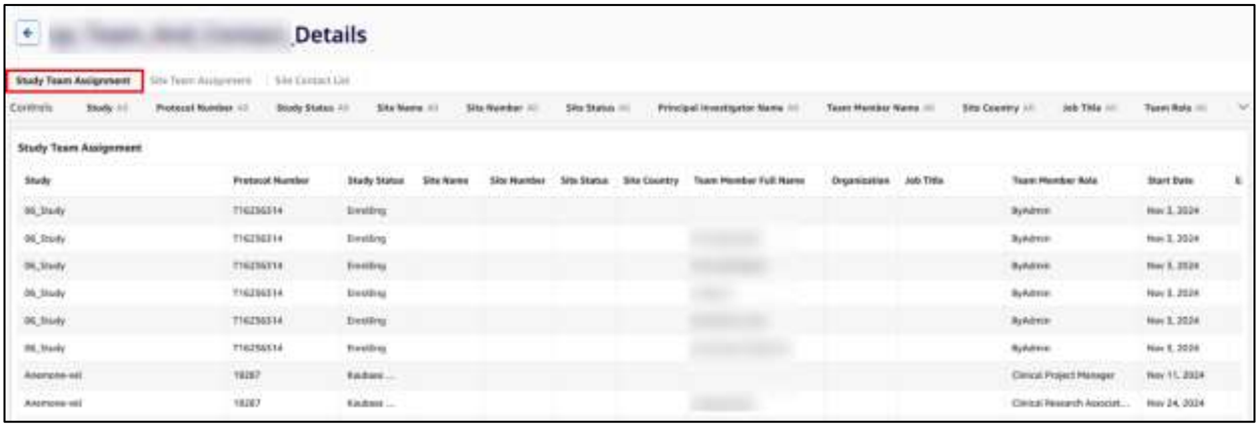


Figure: Study Team Assignment

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

Refer to the description detailed in the New Dashlet: TI Analytics – Sites by Status Dashlet

Deviation Activities

Refer to the description detailed in the New Dashlet: TI Analytics - Protocol Deviation Dashlets

Issue Action Activities

Refer to the description detailed in the New Dashlet: TI Analytics - Issue/Actions Activities Dashlet

CHAPTER 15. WAFFLE MENU

The waffle 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 waffle menu.

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 over the course of 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.

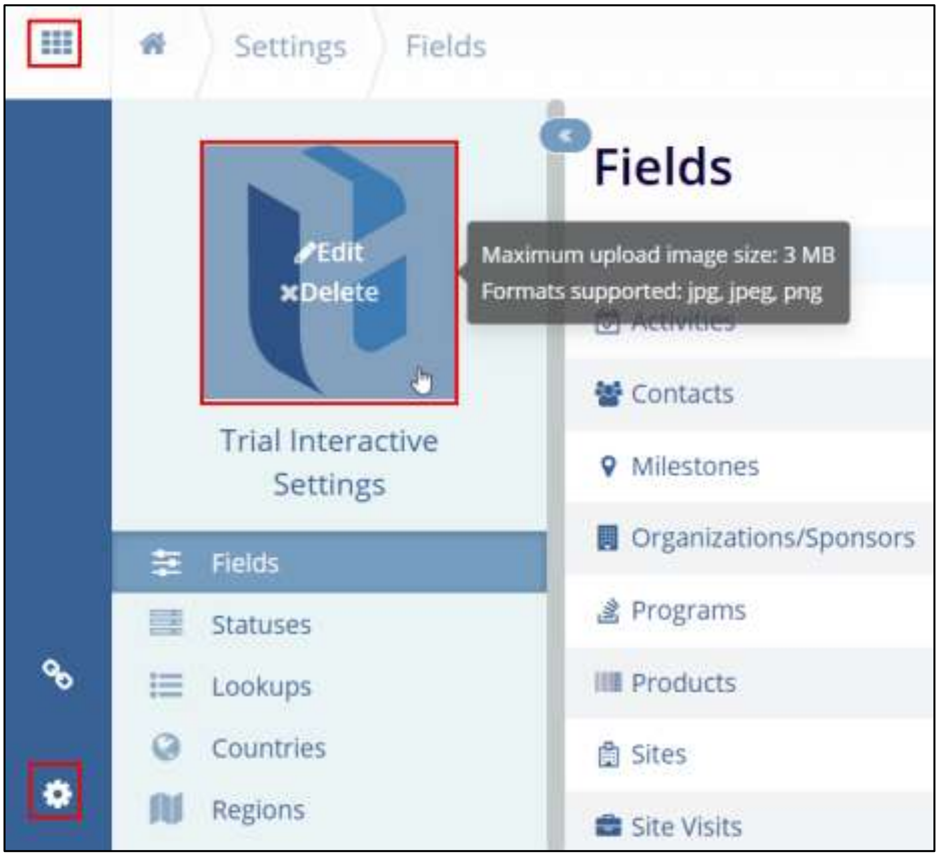


Figure: Edit Company Logo

Note: The maximum size of the image and the formats supported are displayed after hovering the image. Refer to the screenshot below.

Fields

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.

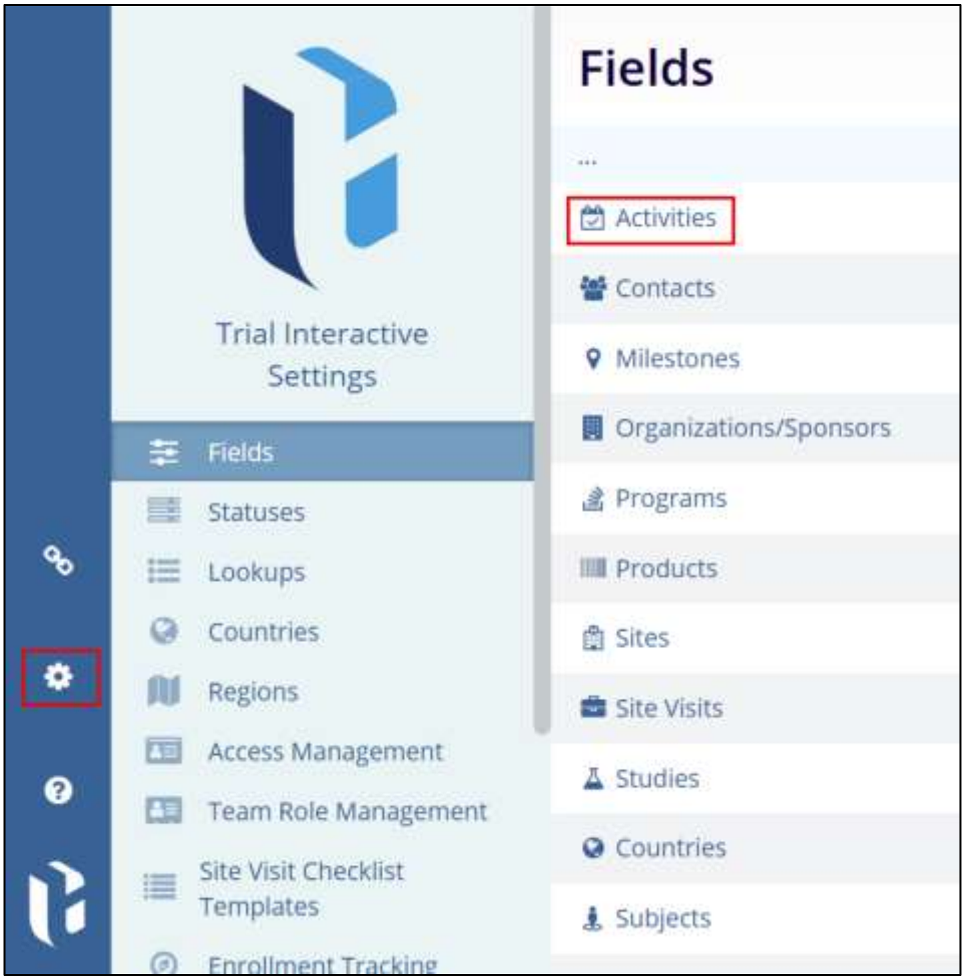


Figure: Fields

3. In step 1, mandatorily add the field and optionally the other details and click on the Next button.

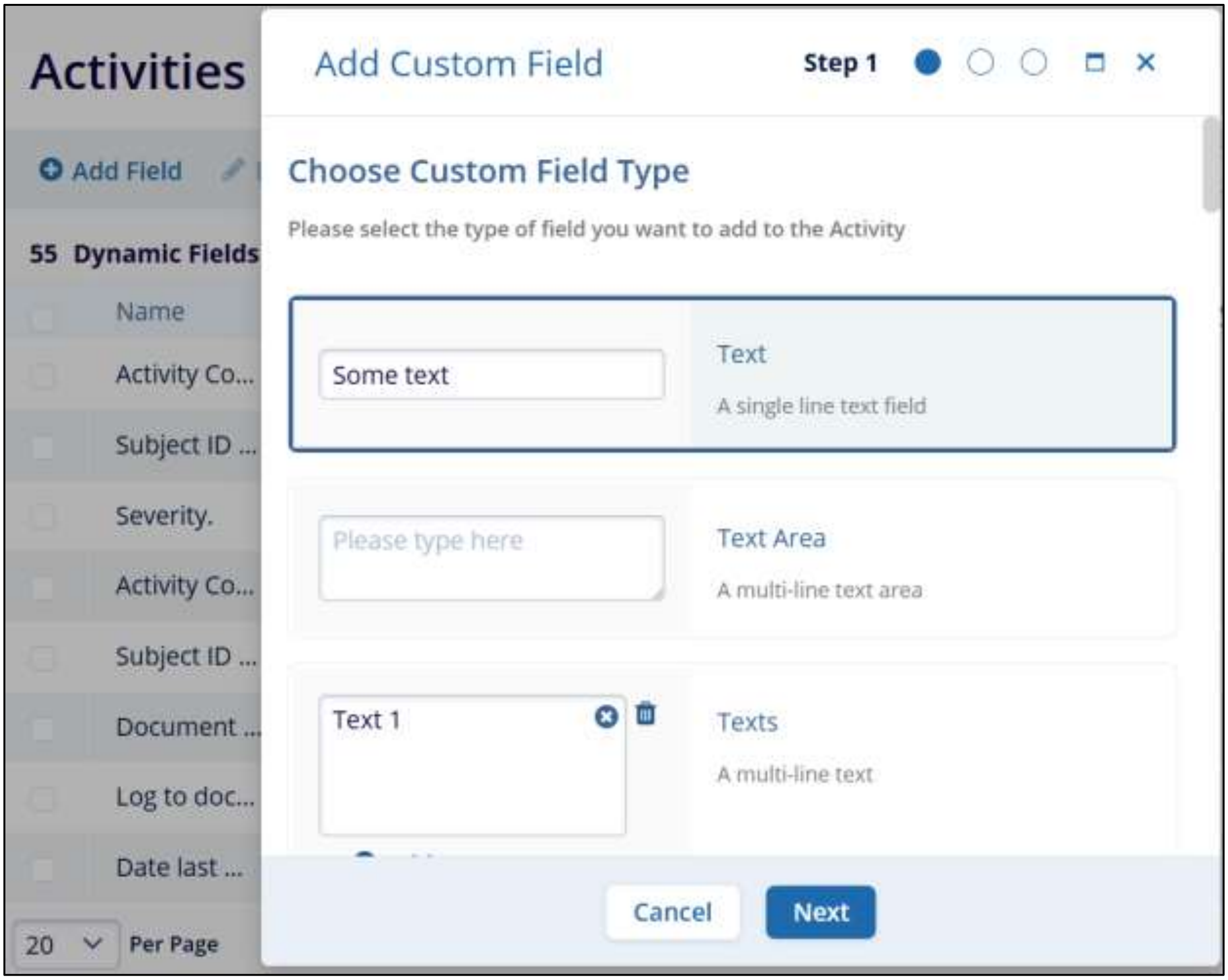


Figure: Add Custom Field

4. In Step 2, add a name for the field and description. Click on the Next button.

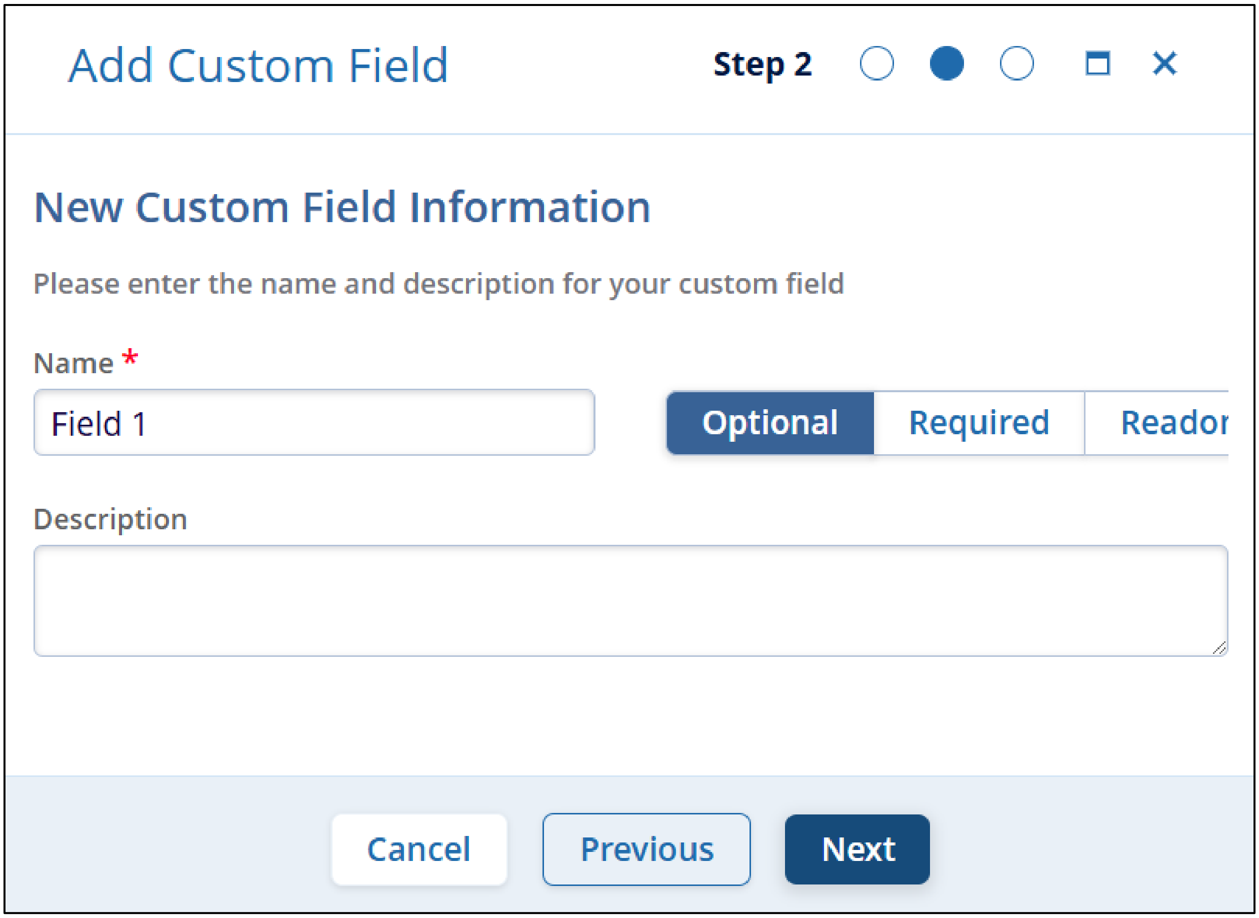


Figure: New Custom Field Information

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

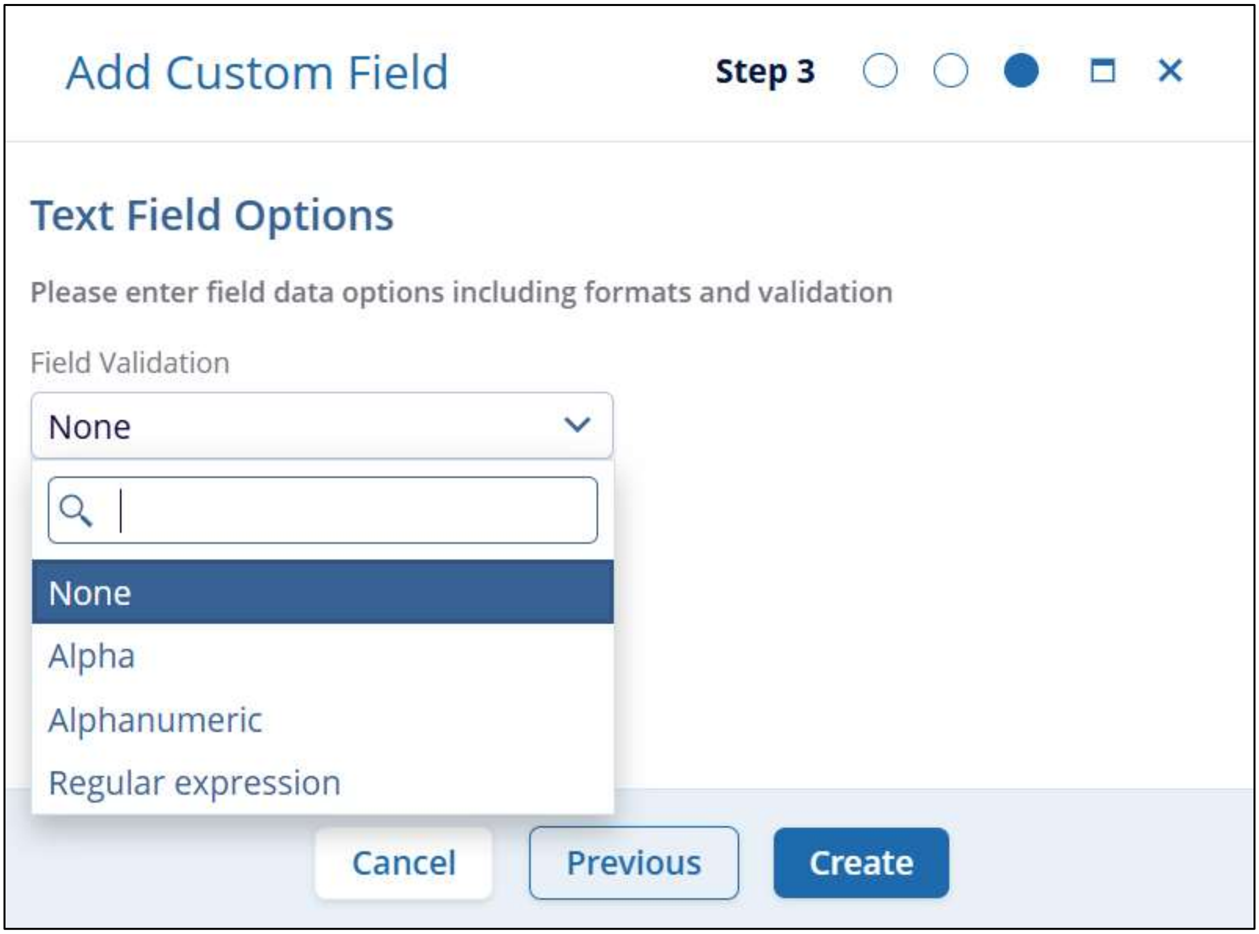


Figure: Add Custom Field

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.

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.

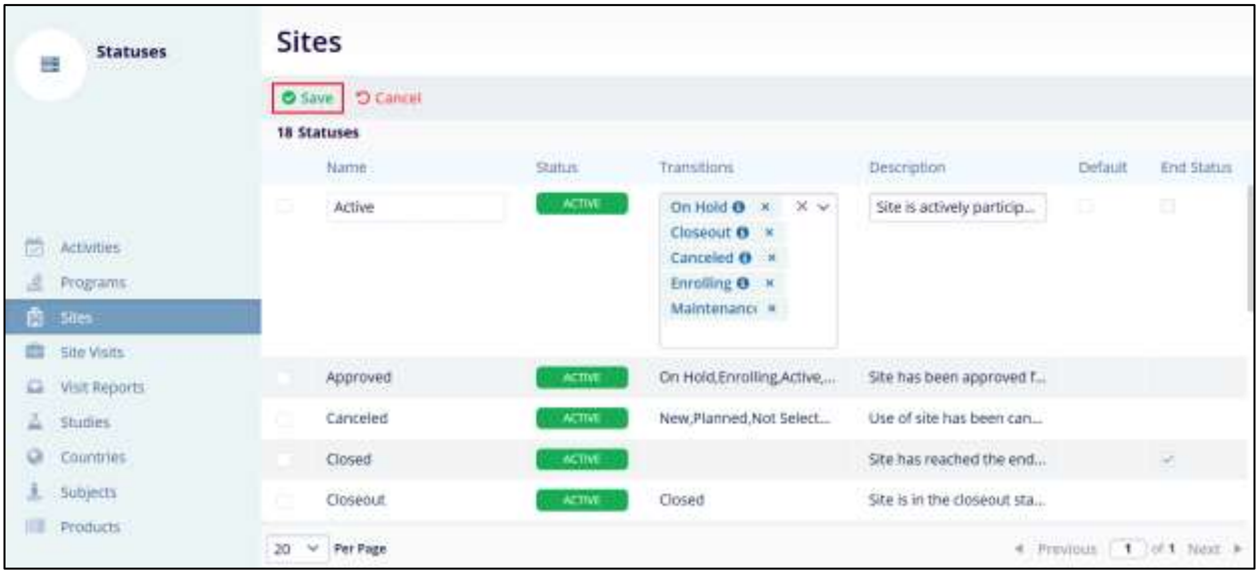


Figure: Settings - Statuses

Note:

- The end status is not available for all areas.

Lookups

The term ‘Lookups’ refers 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’.

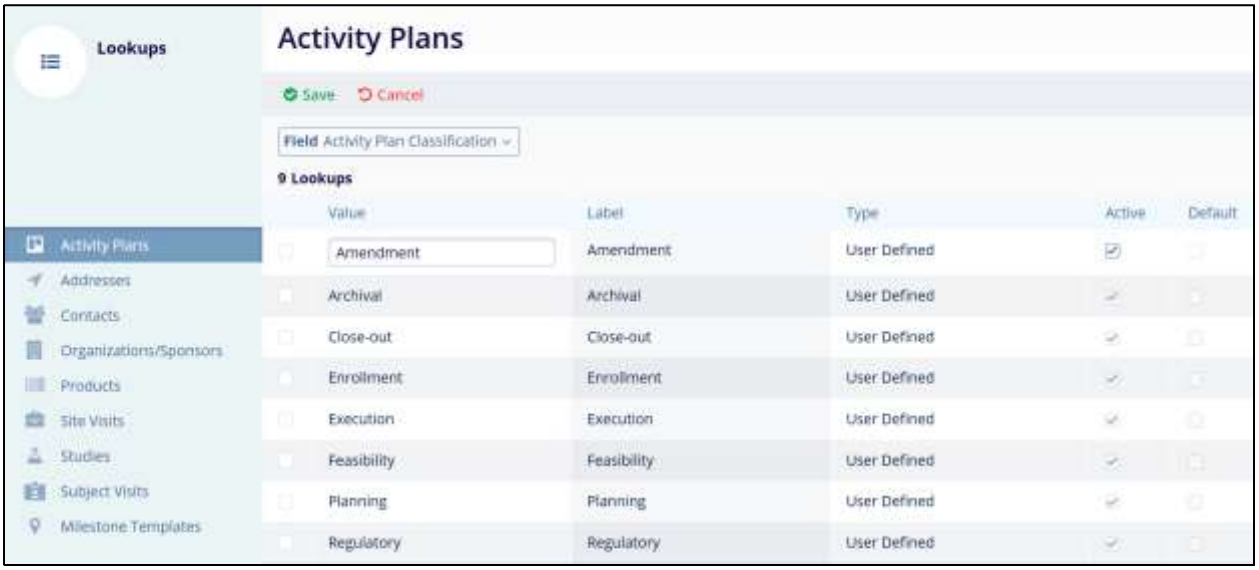


Figure: Settings - Lookups

Countries

To activate or deactivate countries, 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

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

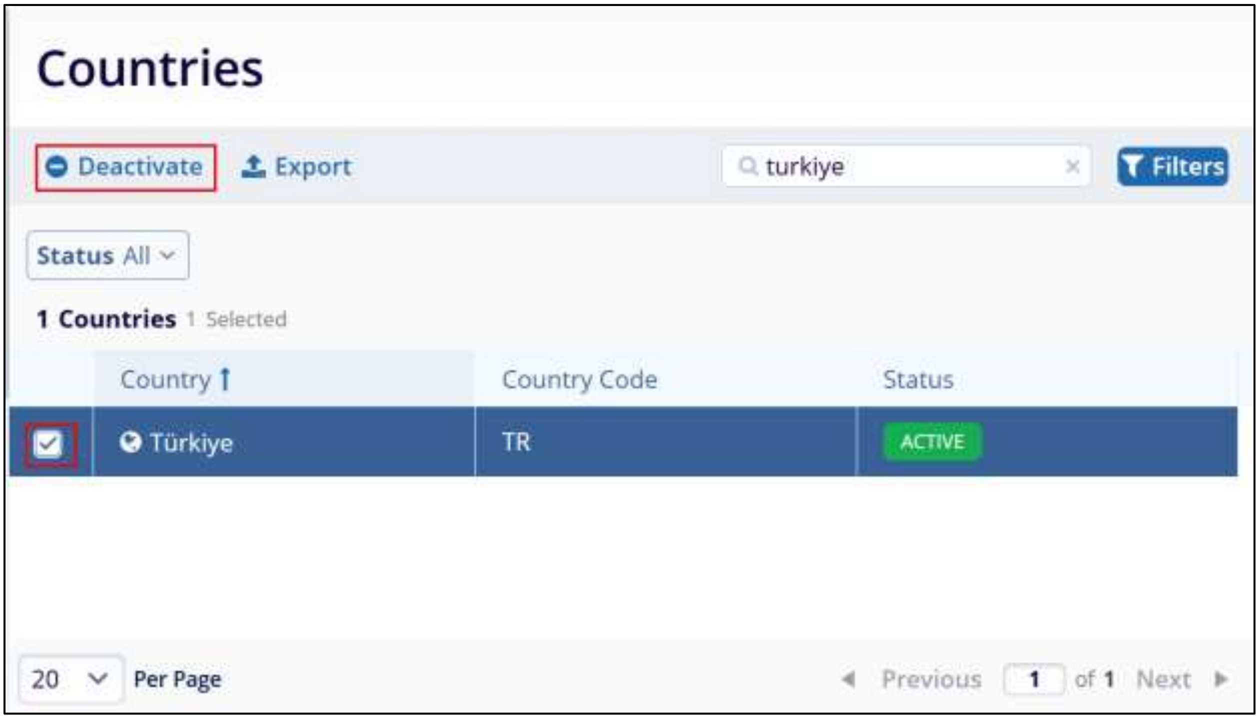


Figure: Settings – Deactivate country

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

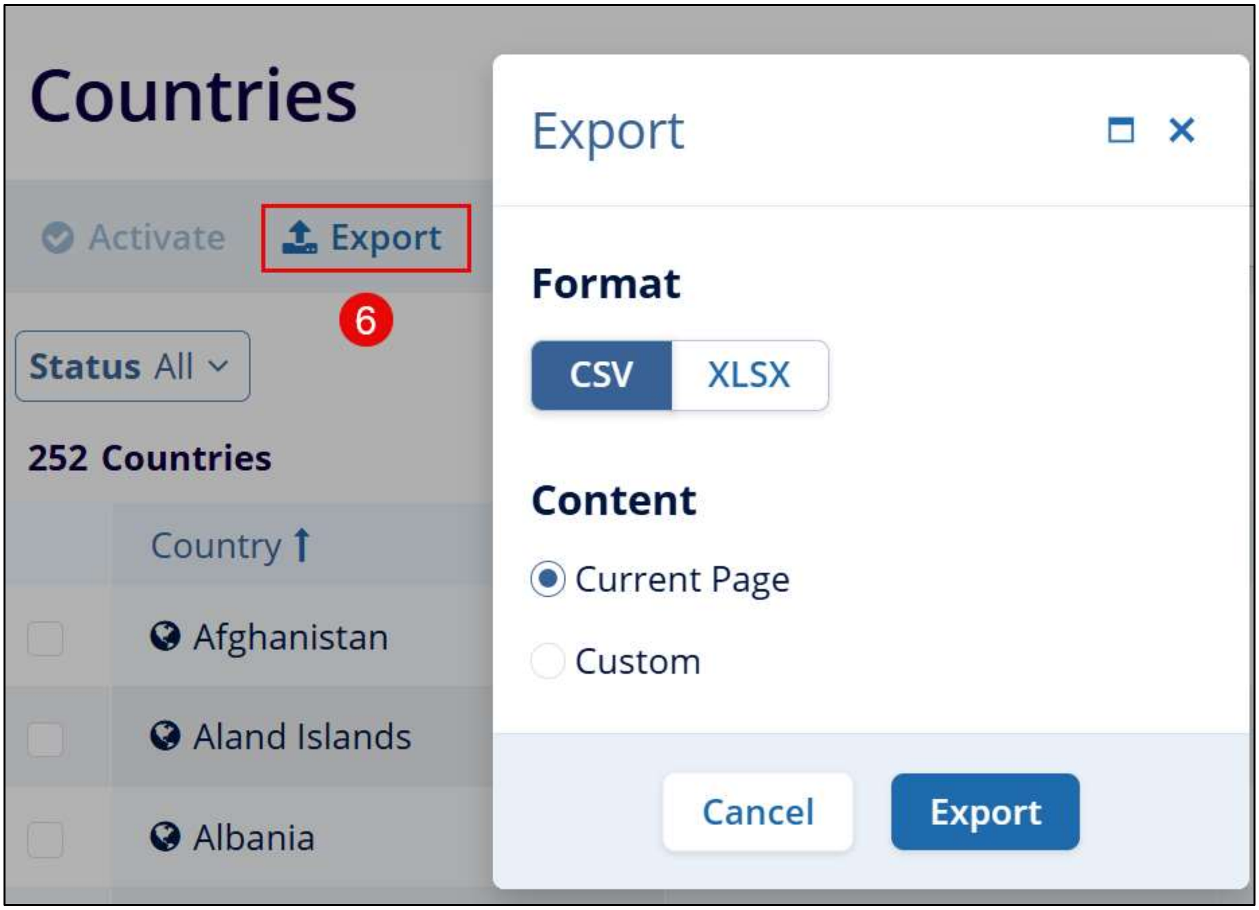


Figure: Settings – Export Countries Data

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 Create button.
3. On the Create Region screen, mandatorily enter the Region Name and Countries
4. Click on the Create button.

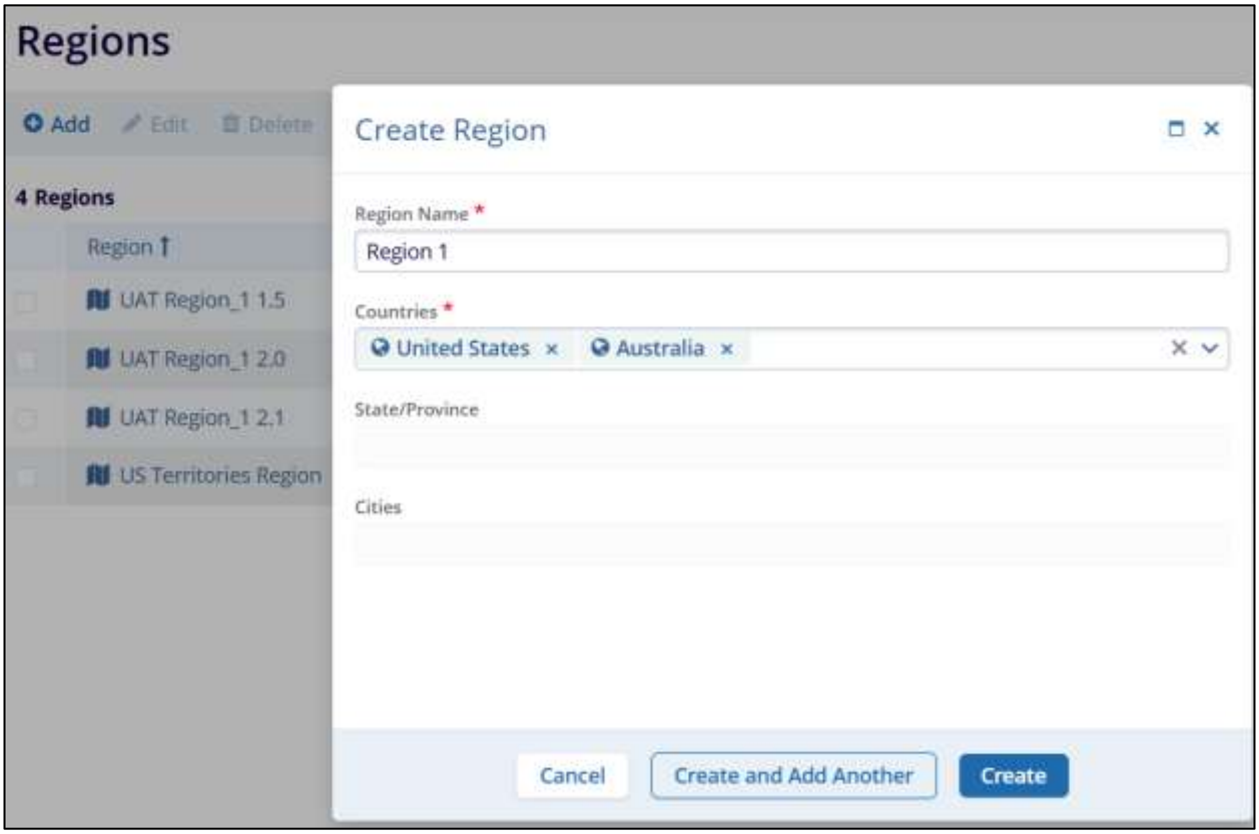


Figure: Settings – Add Region

5. To edit a region, select the region and click on the Edit button from the top menu bar.
6. On the Region Details screen, make the required edits and click on the Save button.

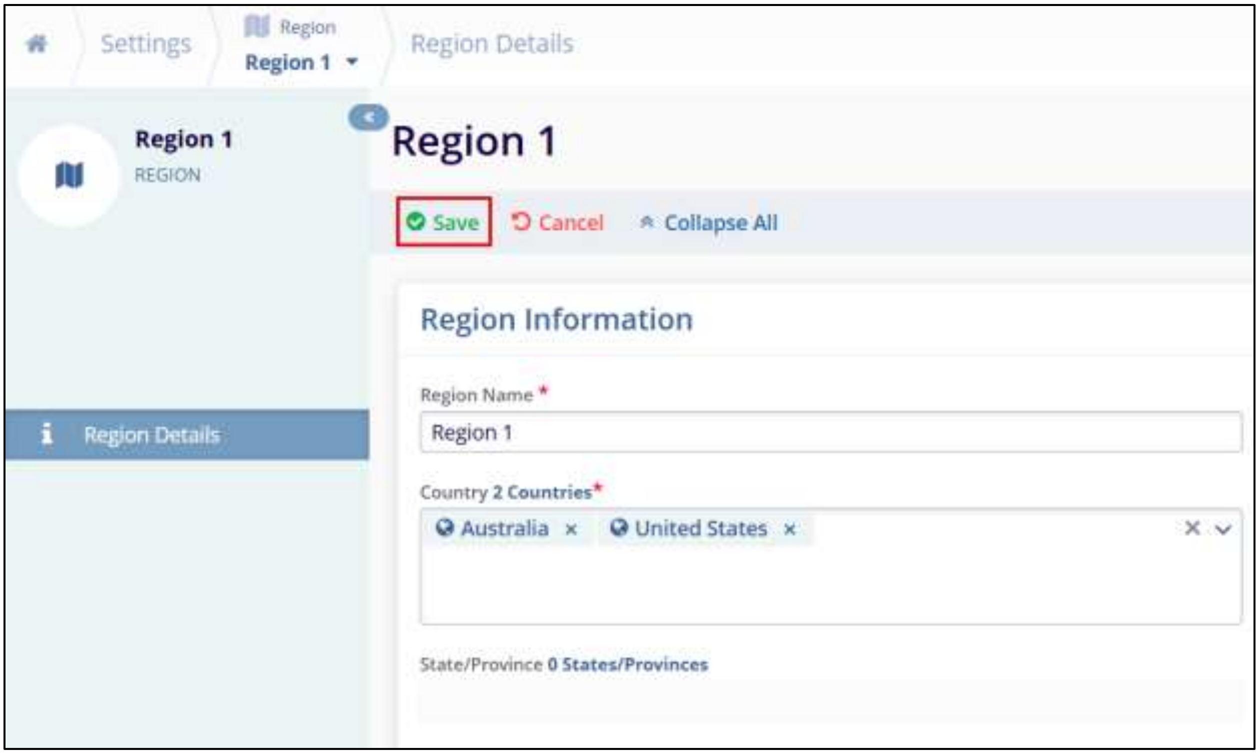


Figure: Settings – Edit Region

7. Select the region and click the Delete button from the top menu bar.
8. Click on the Delete button on the Confirmation popup.

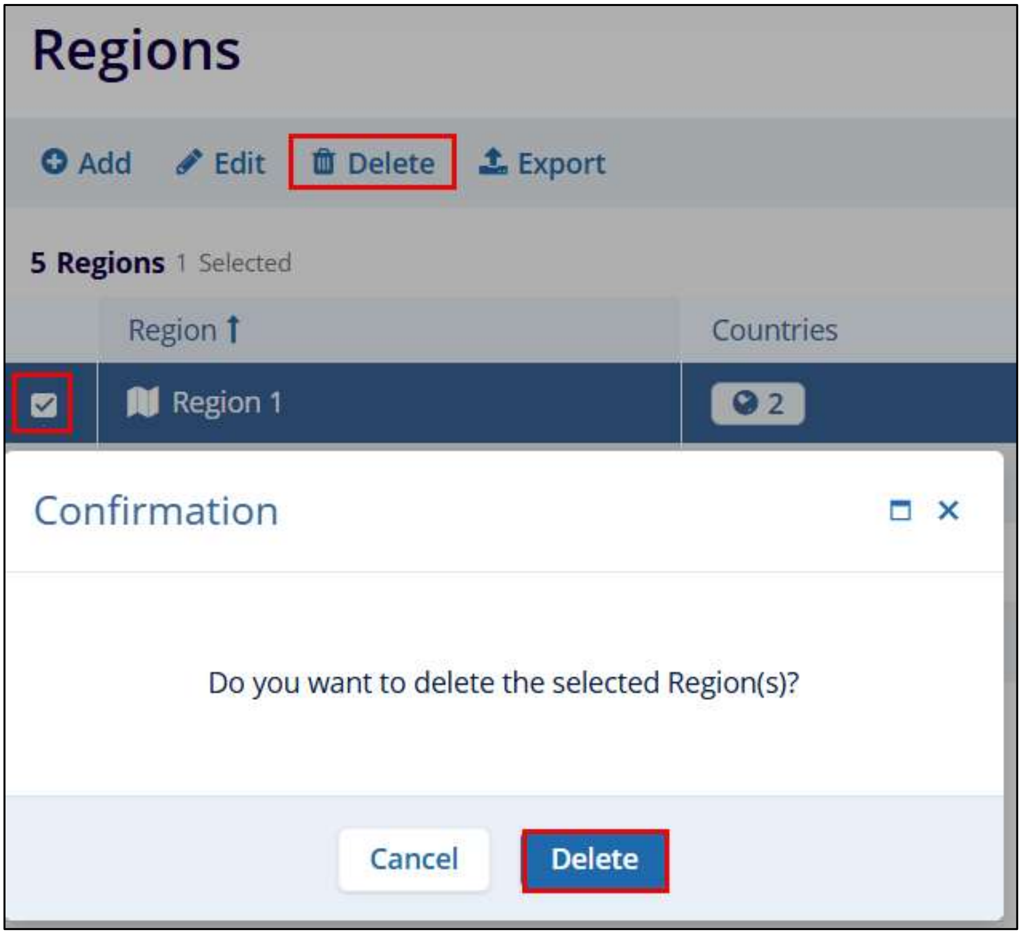


Figure: Delete Region

9. 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.

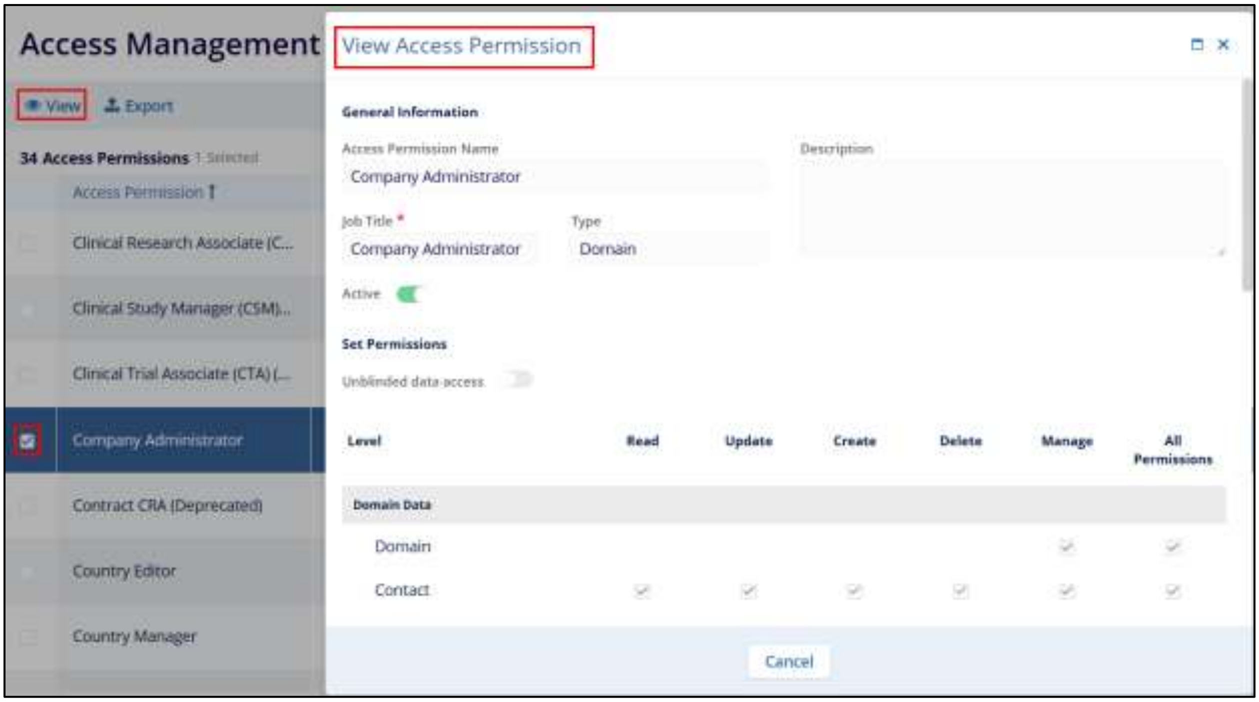


Figure: Access Management

Team Role Management

To access the Team Role Management settings, 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 enter the name and level
4. Click on the Save button.

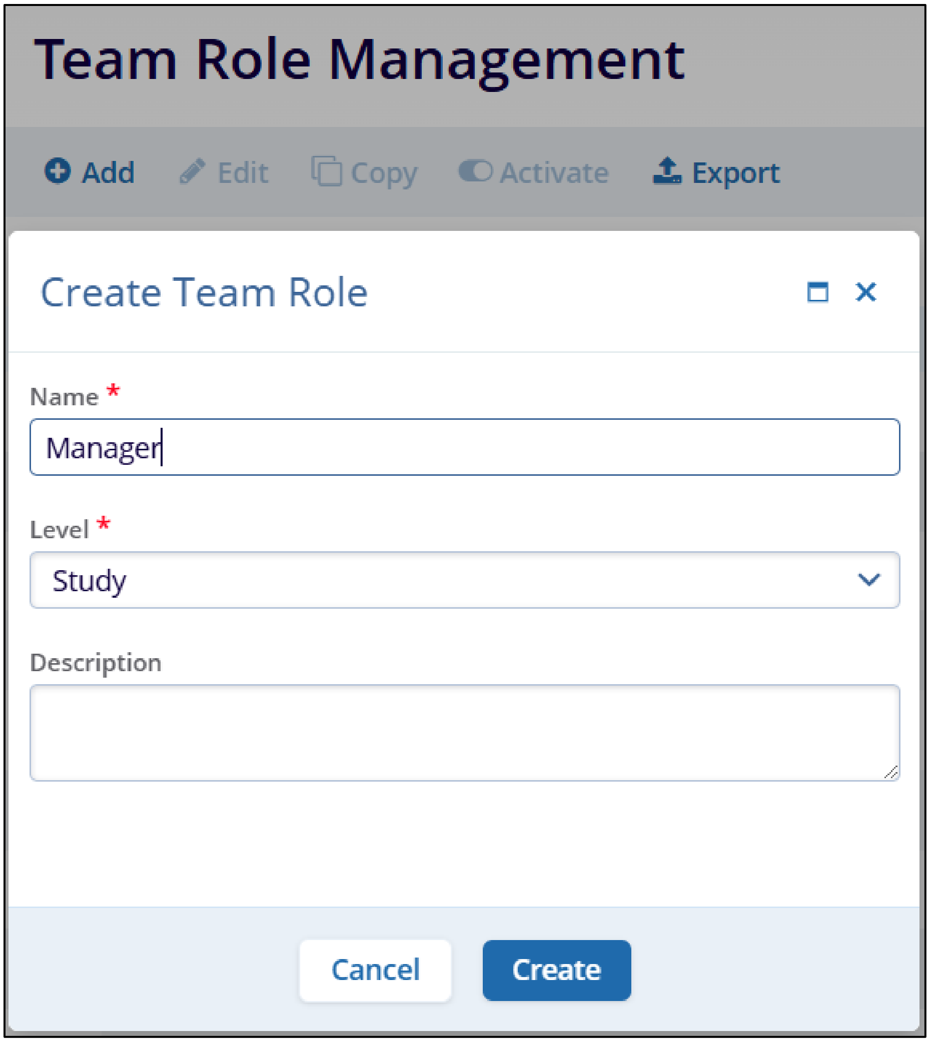


Figure: Create Team Role

5. Select a role to edit and click on the Edit button from the top menu bar.
6. Make the required edits and click on the Save button.

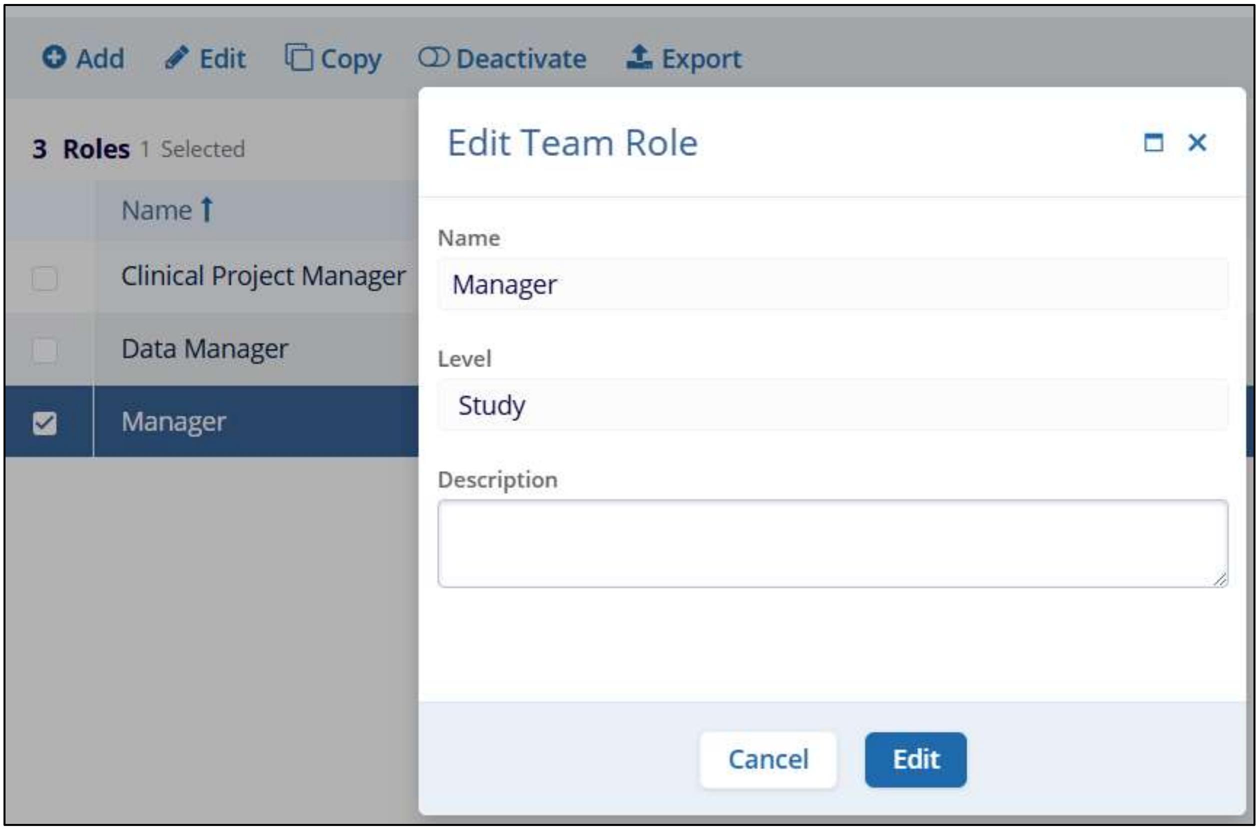


Figure: Edit Team Role

7. Select a role and click on the Copy button.
8. On the Copy Team Role screen, make the required changes and click on the Create button.

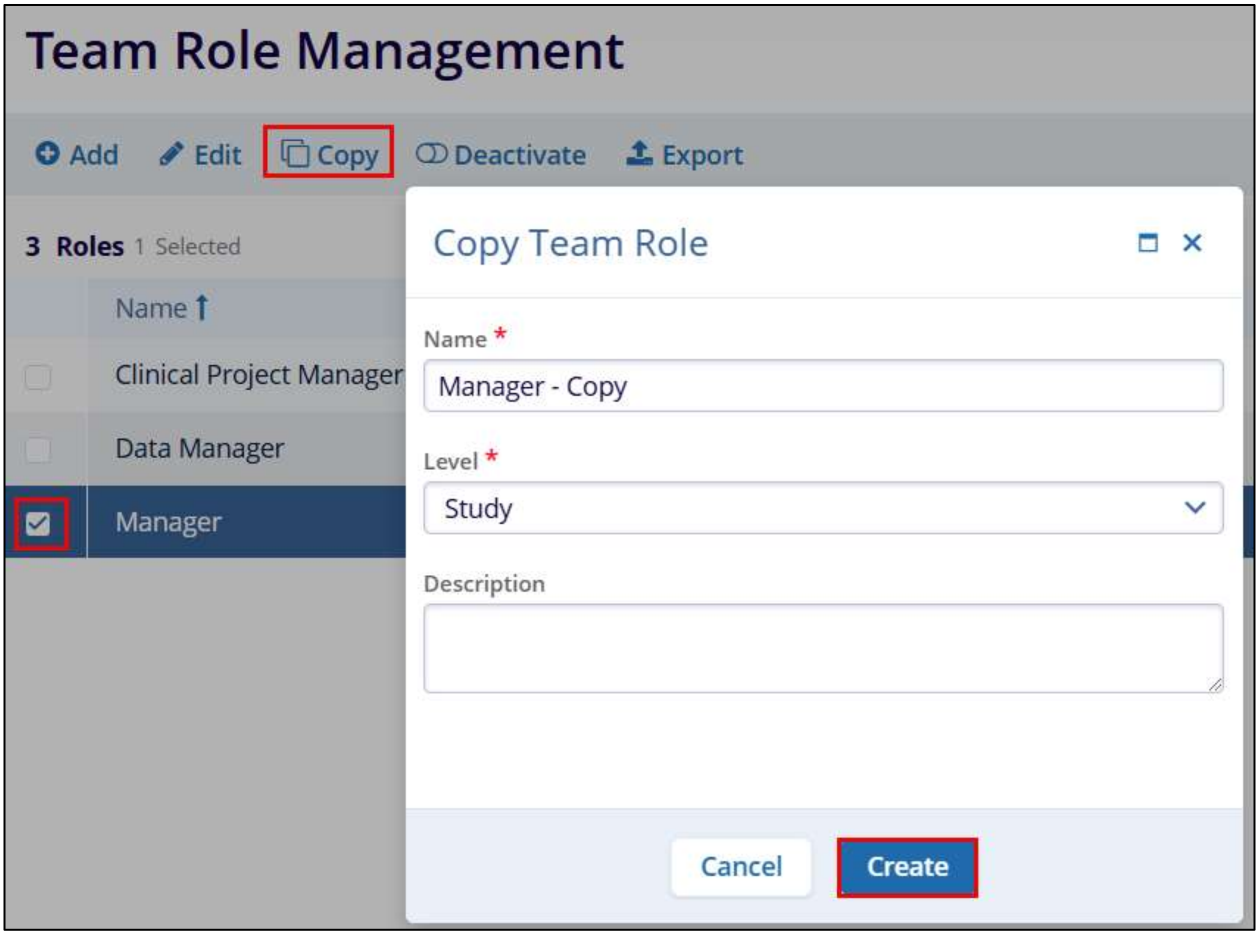


Figure: Copy Team Role

9. Select an active user and click on the Deactivate button.
10. Click on the Deactivate button on the Confirmation popup.

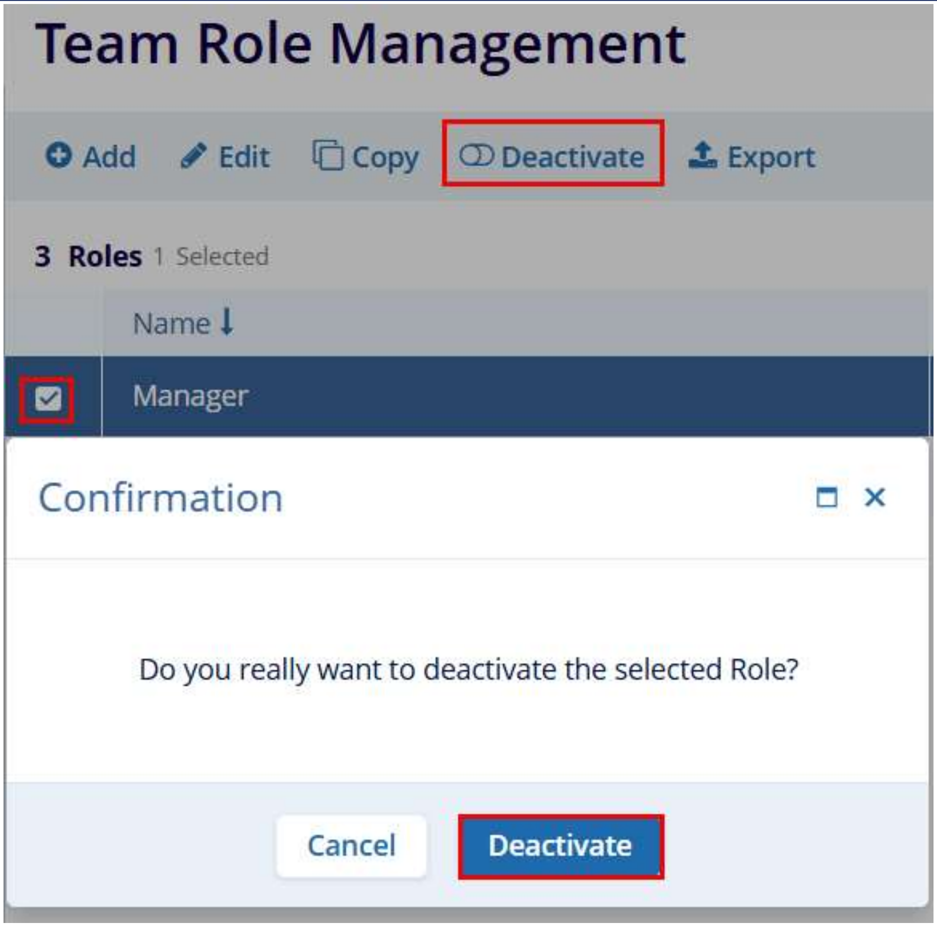


Figure: Deactivate role

11. Select an inactive role and click on the Activate button.
12. Click on the Activate button on the Confirmation popup.

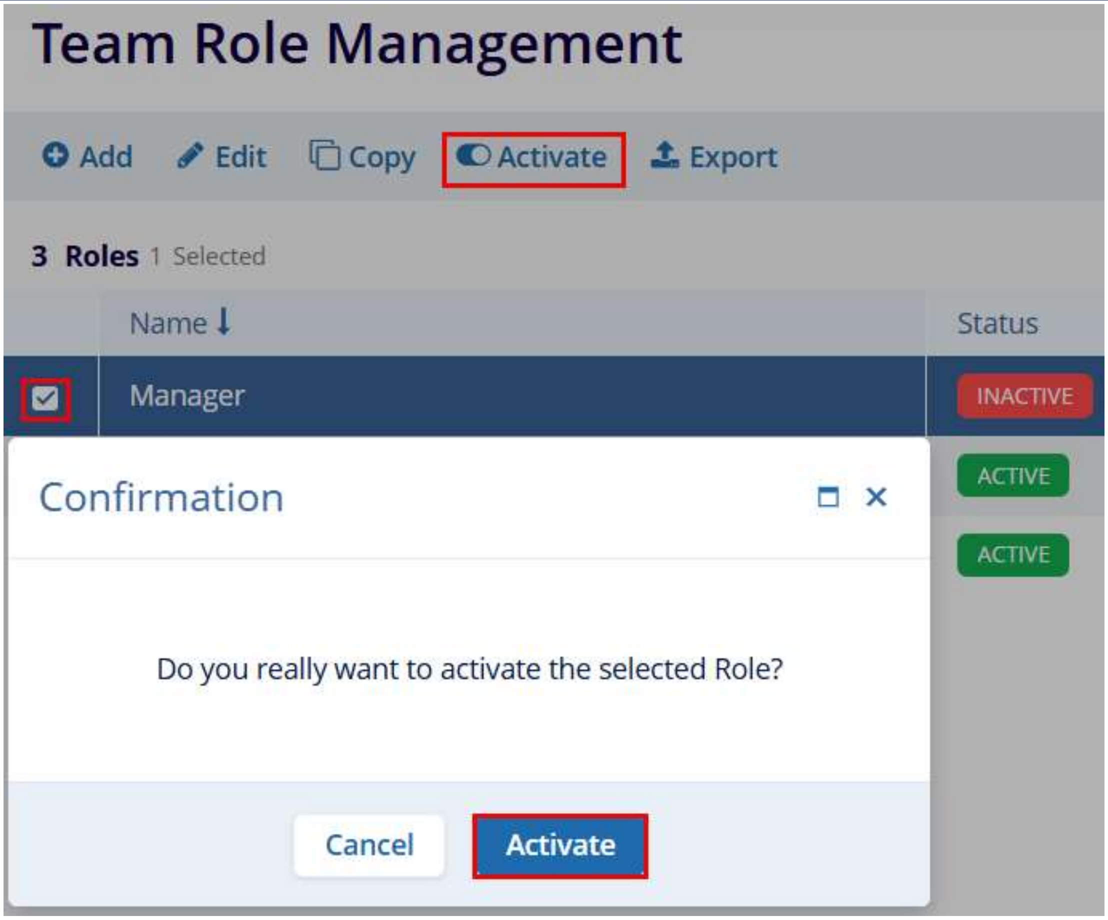


Figure: Activate role

Site Visit Checklist Templates

Refer to the User-Defined Site Visit Checklists section.

Enrollment Tracking

To add, edit, delete, and export enrollment tracking details, follow the steps below.

1. Navigate to the Settings area and select the Enrollment Tracking option.
2. Click on the +Add button and select a status that has not be added yet
3. Click on the Add button

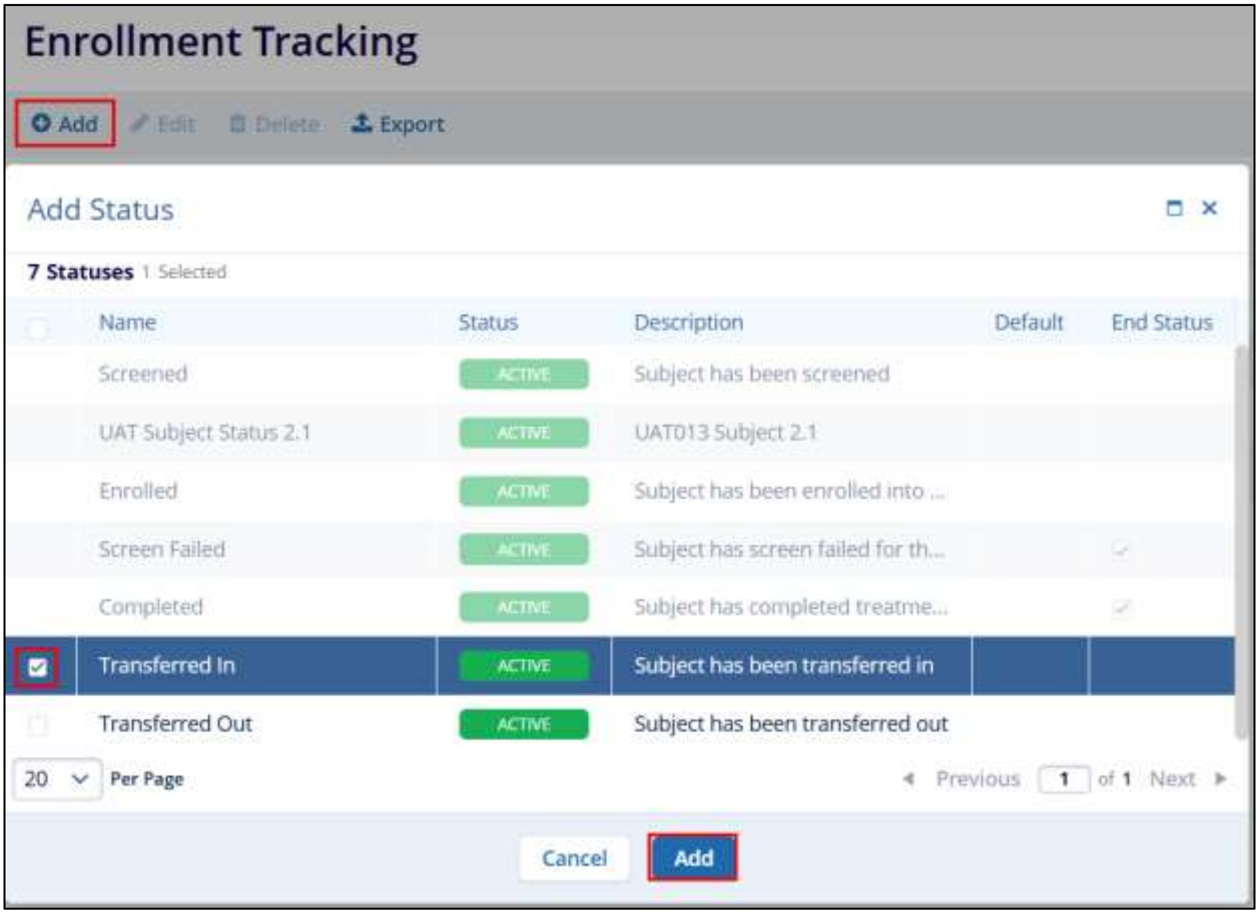


Figure: Add Enrollment Tracking

4. Select a status and click on the Edit button.
5. Make the required button and click on the Save button.

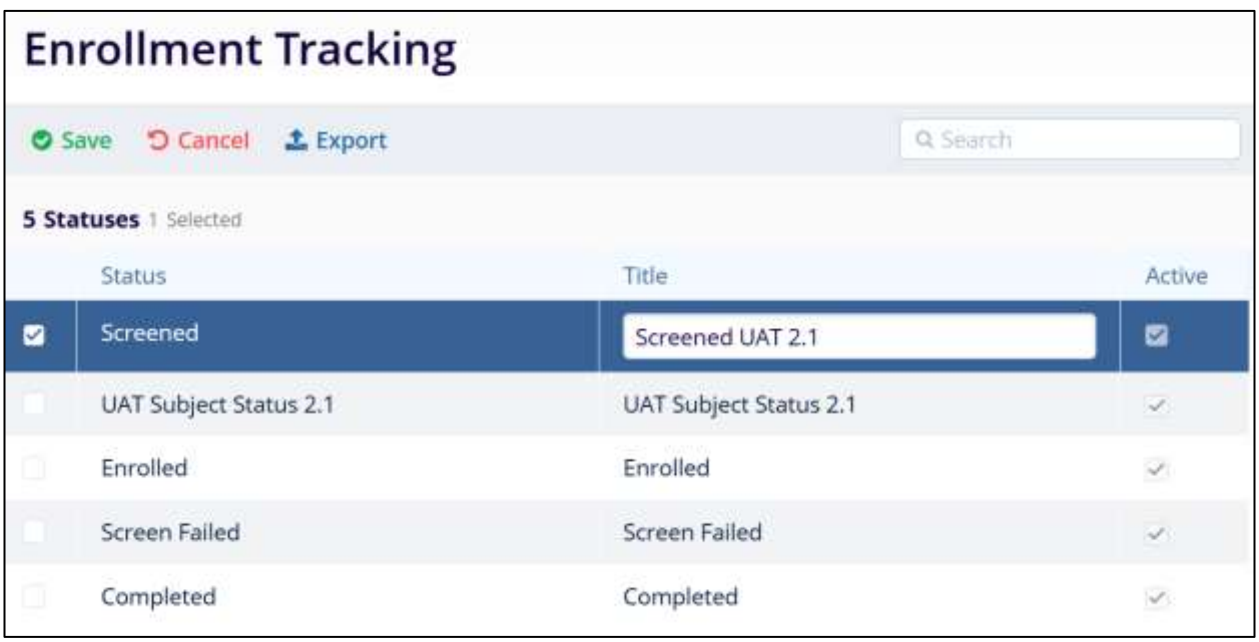


Figure: Edit Enrollment Tracking Status

6. Select a status to delete and click on the Delete button from the top menu bar.
7. Click on the Yes button on the Confirmation popup.

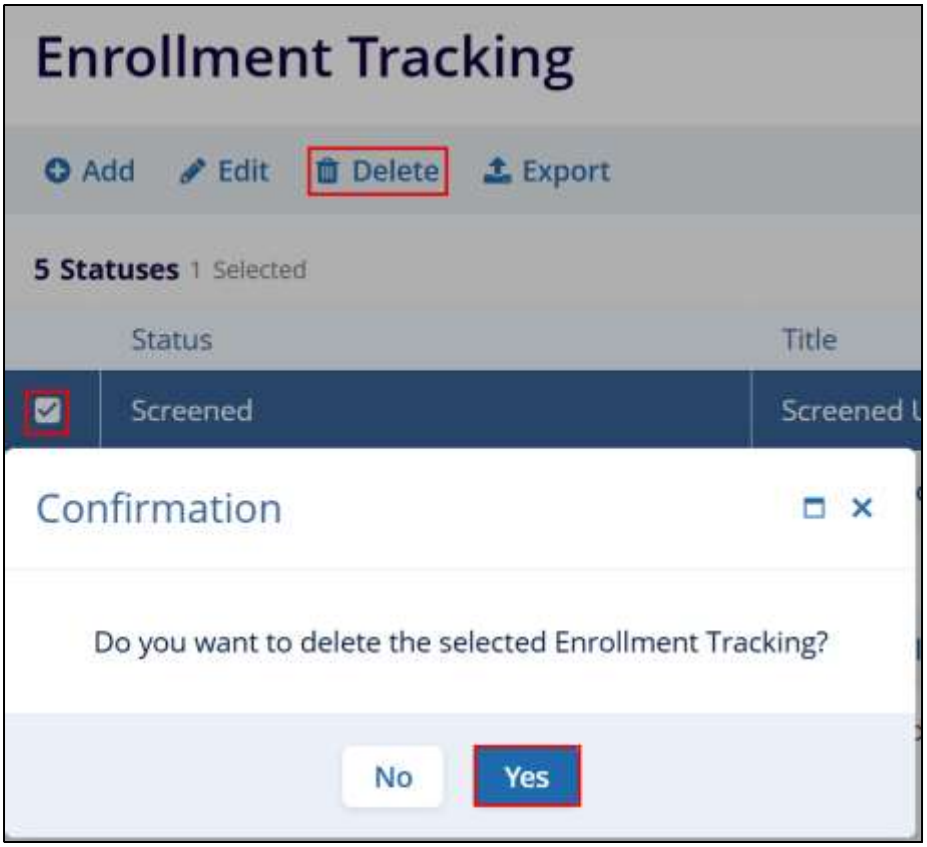


Figure: Delete enrollment tracking status

8. Click on the Export button to retrieve the enrollment tracking data in an XLSX or CSV file format.

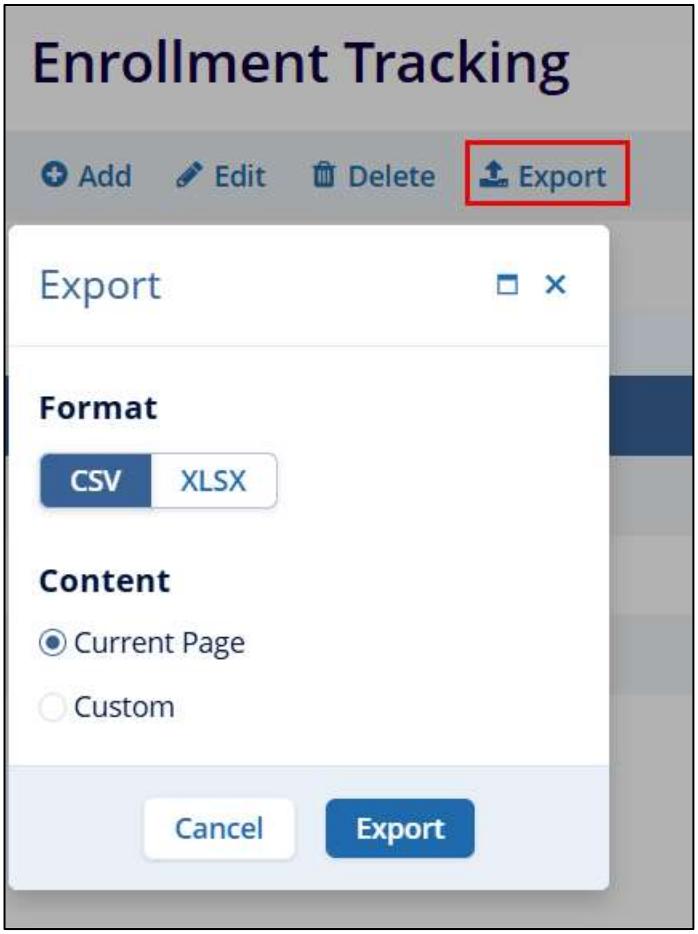


Figure: Export Enrollment Tracking Data

Activity Type/Subtype

To add, edit, delete, deactivate, and export 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. Enter the required details and click on the Save button.

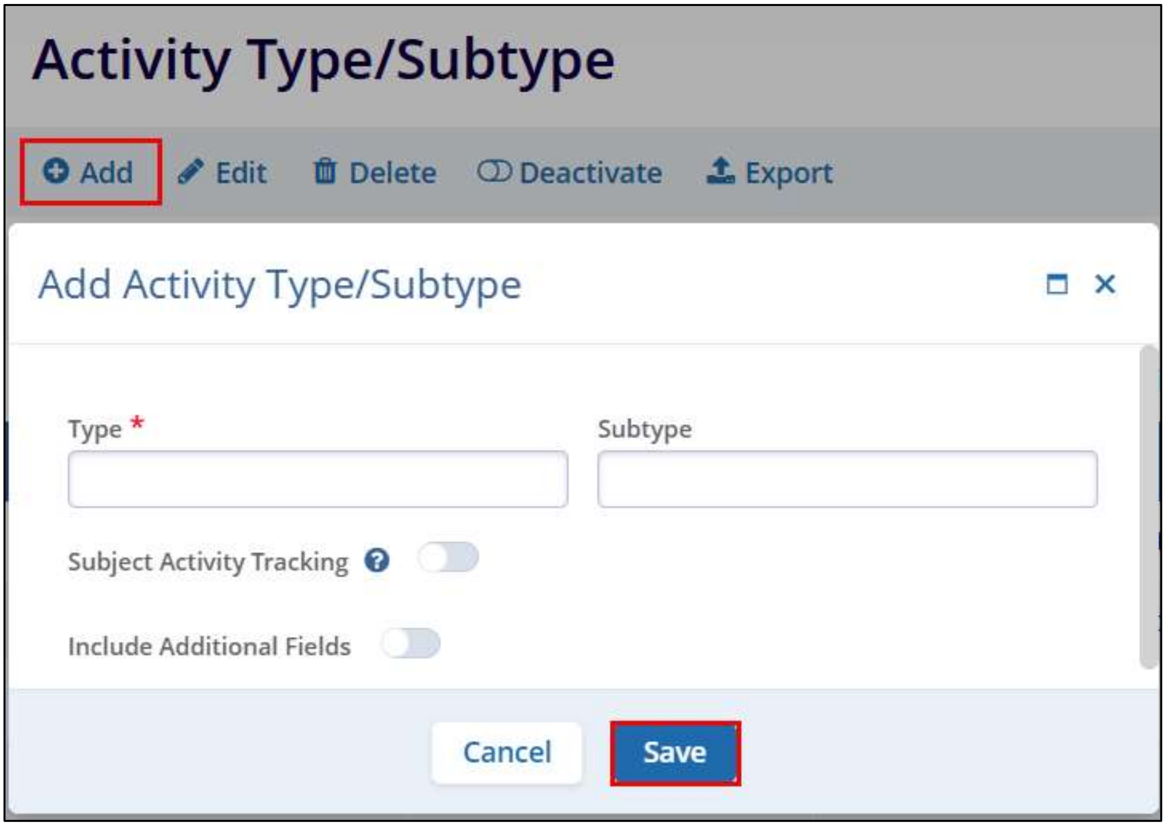


Figure: Add Activity Type/Subtype

4. To edit, select an activity type/subtype and click on the Edit button.
5. Make the required edits and click on the Save button.

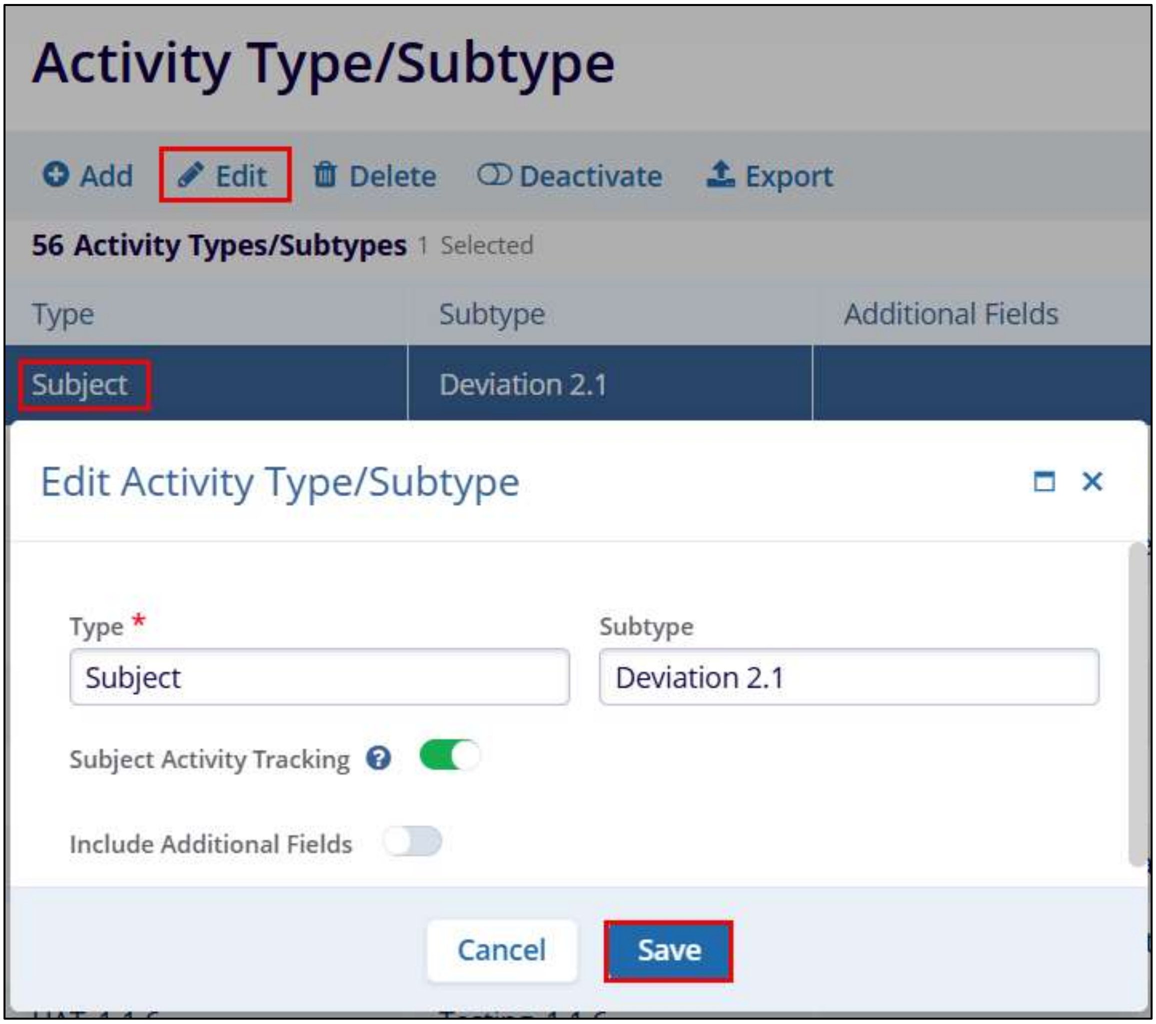


Figure: Edit Activity Type/Subtype

6. To delete a subject, select the subject and click on the Delete button from the top menu bar.
7. Click on the Delete button on the Confirmation popup.

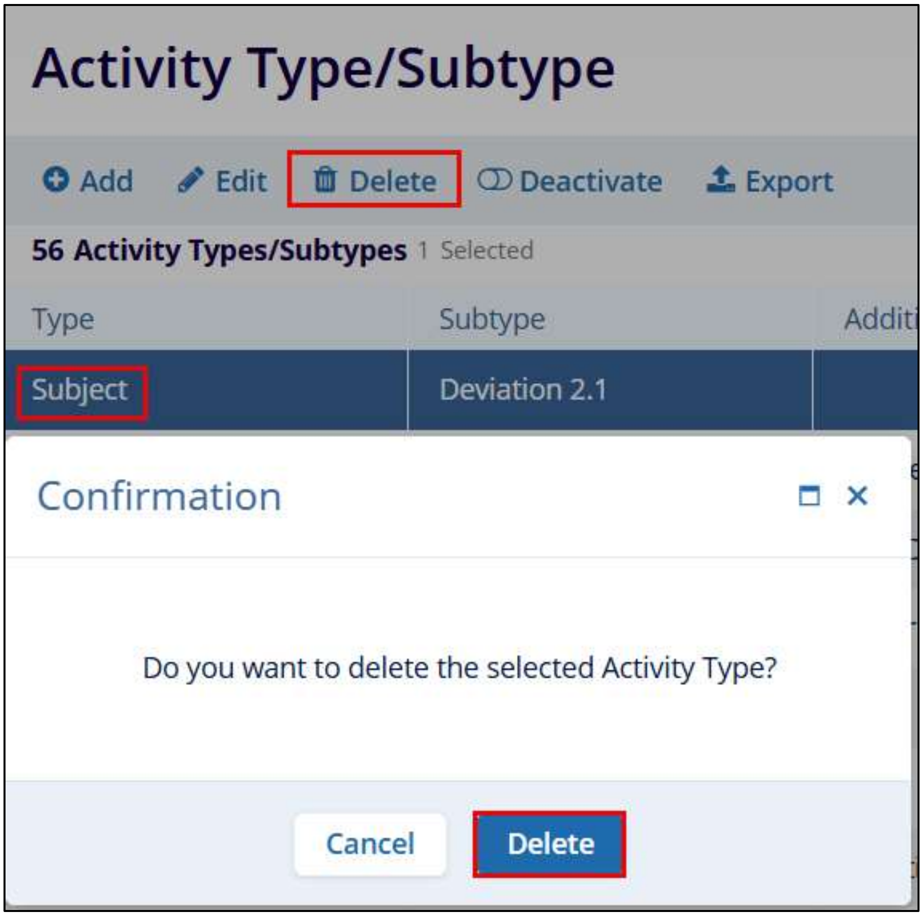


Figure: Delete activity type/subtype

8. Select an active record and click on the Deactivate button from the top menu bar.

Figure: Deactivate activity type/subtype

9. Select an inactive record and 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, make the required edits to the General Settings, Study Auto-naming Rules, and Site Auto-naming Rules.
3. Click on the Save button once all the changes are made.

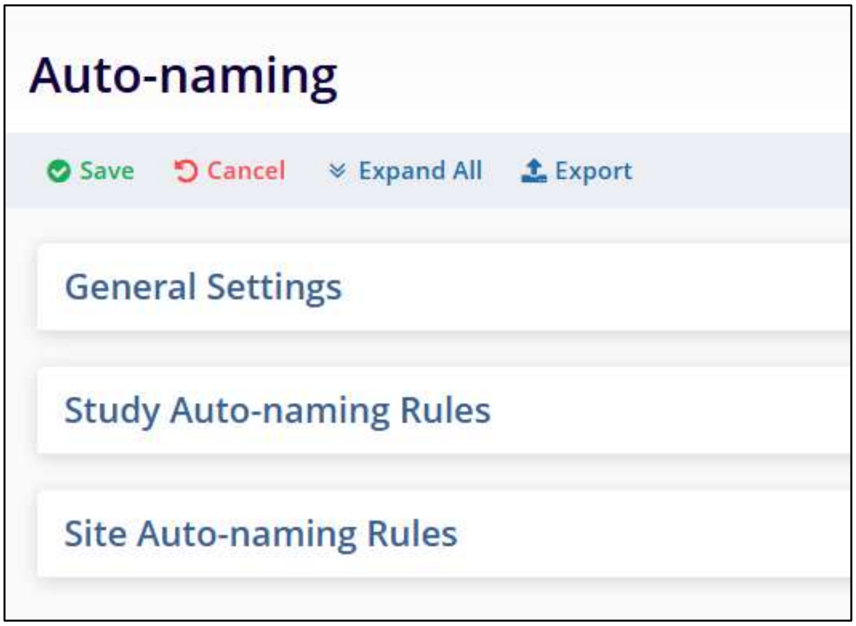


Figure: Auto-naming

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.

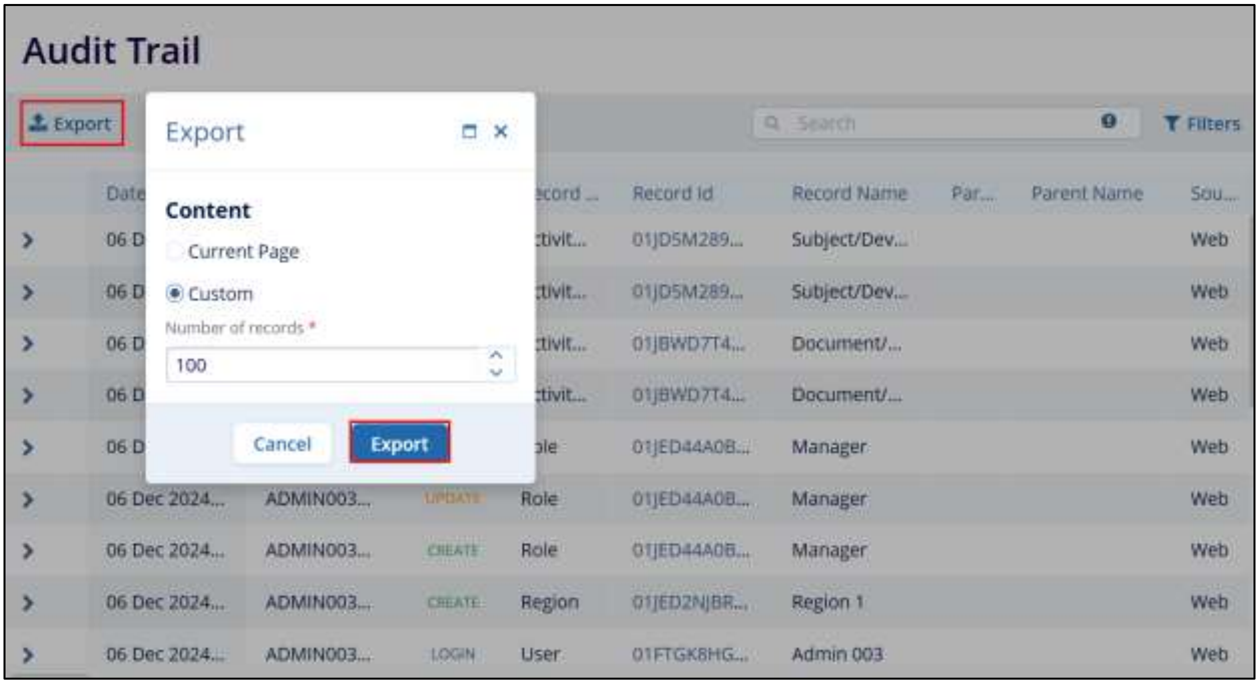


Figure: Audit Trail

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.

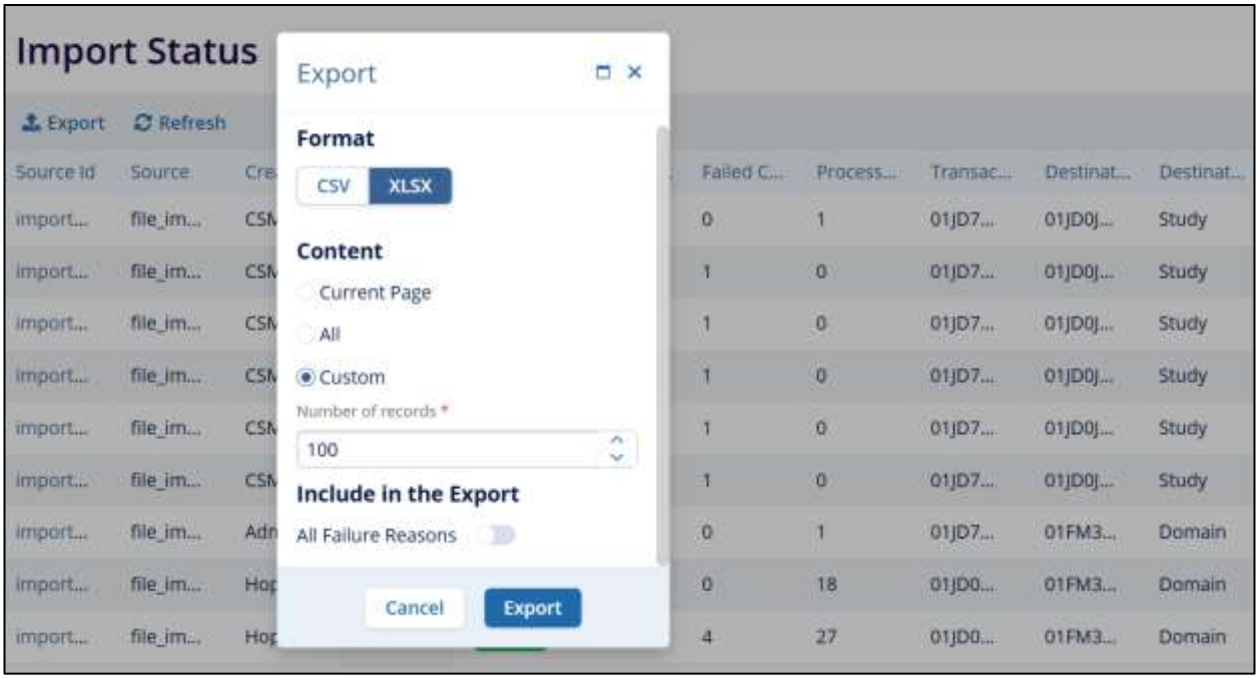


Figure: Export Import Status Records

8. Click on the Get Job Results button.

Figure: Get Job Results

Site Visit Types

Creating a field will not automatically make it available across all visit types. Likely, any one field will not apply to all visit types across the board so, to allow for a customized list based on the visit type, once a custom site visit field has been created, the user must navigate to the Site Visit Types in Settings and manually choose to add the new field to the associated visit type before it will be applied.

To apply a custom field, follow the steps below.

1. Create a custom field by following the steps outlined in the previous section.
2. Navigate to the Settings area and go to the Site Visit Types option.
3. Select the site visit type and click on the +Add button from the top menu bar.

4. On the Add Site Visit Type screen, enter the details and 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.

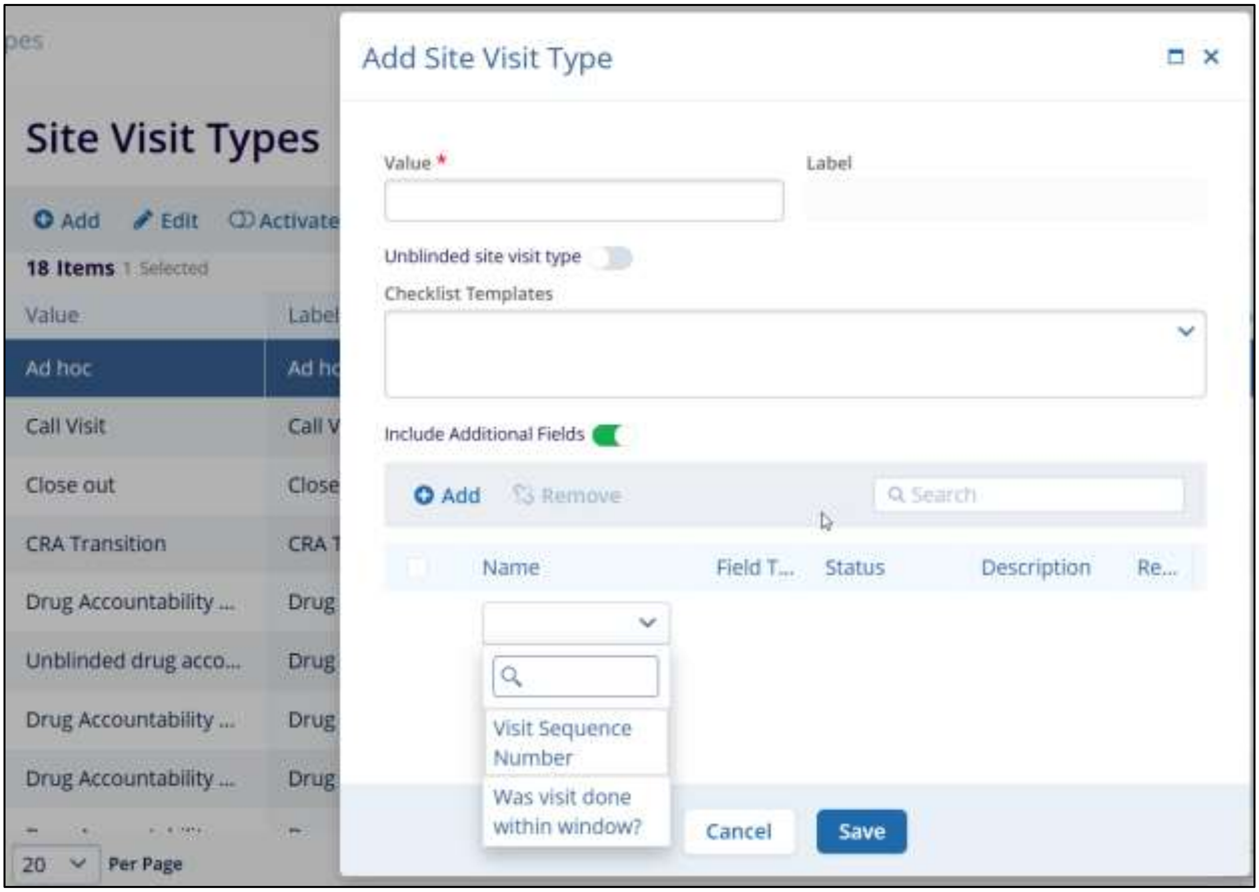


Figure: Site Visit Types

7. To edit, activate, deactivate, and export the data, refer to the previous sections for the standard steps.

Accessing Online Help

To access online help, follow the steps below.

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

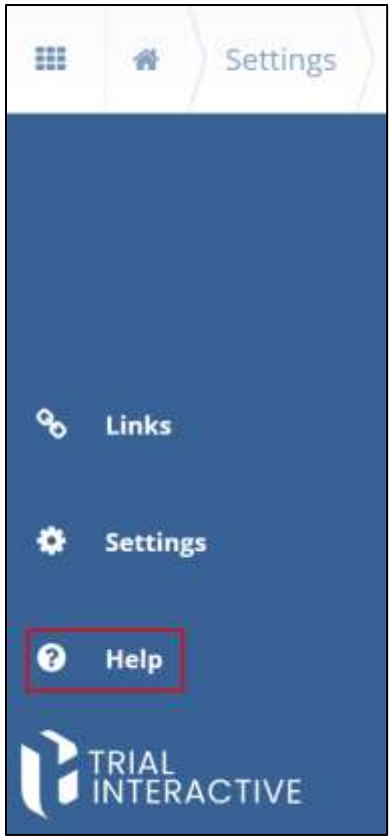


Figure: Accessing Online Help

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

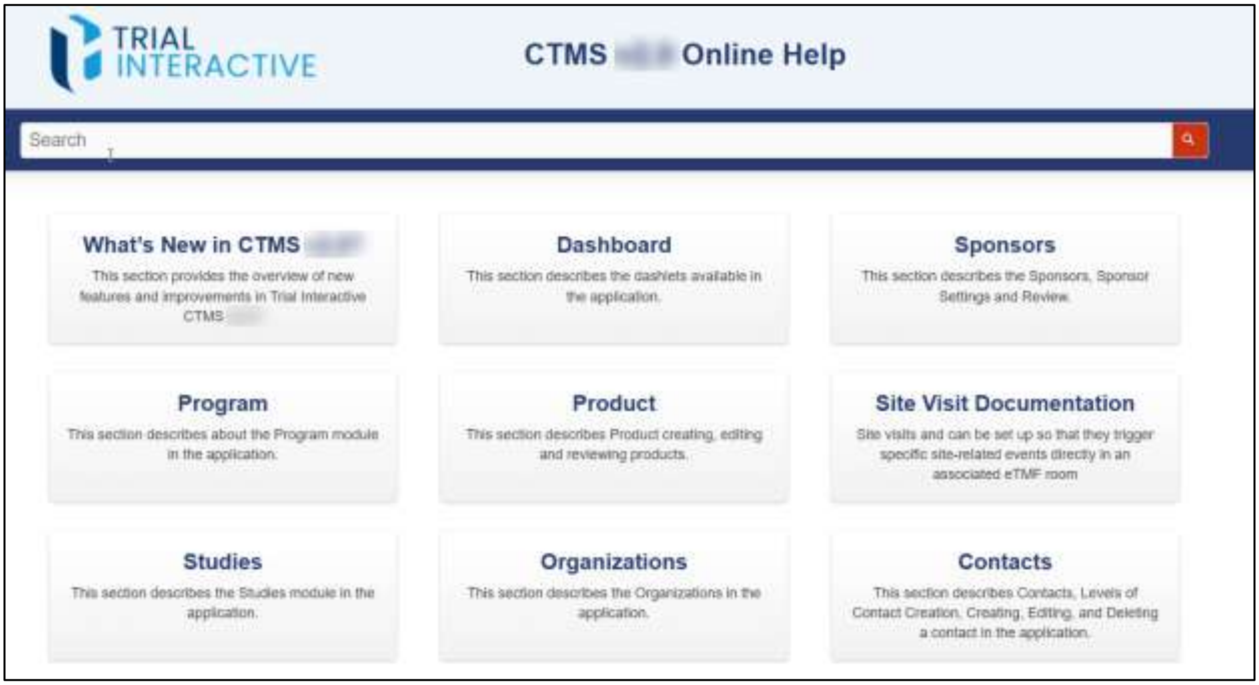


Figure: Online Help Webpage