Clinical Trial Access Manager (CTAM) Guide

August 2024

Contents

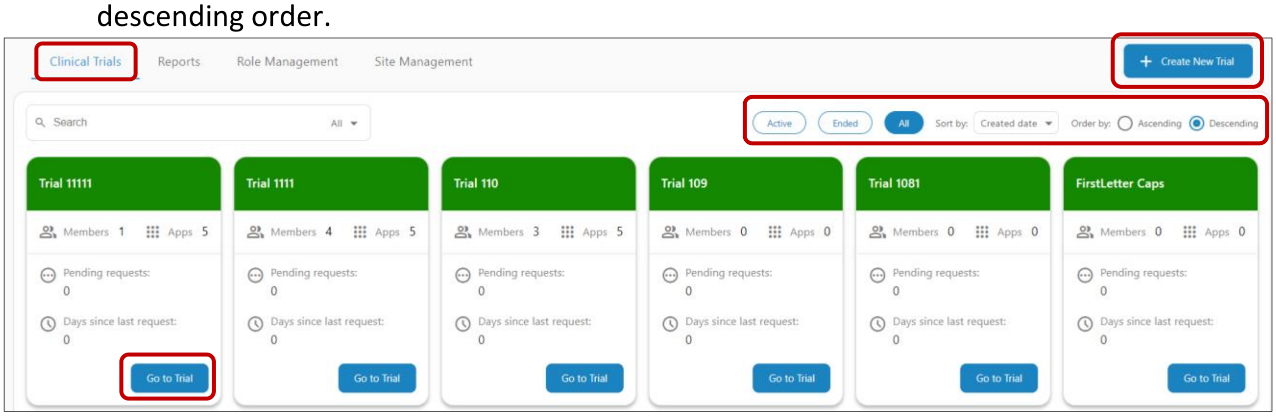
Clinical Trial Access Manager (CTAM) Overview

Exostar's Clinical Trial Access Manager (CTAM) is a transformative solution targeting inefficiencies in site personnel access management within clinical studies. CTAM aims at unifying and streamlining access control. It responds to the industry's call for a more integrated, secure, and user-friendly system. CTAM aids in simplifying the processes, emphasizing compliance and operational efficiency thereby achieving the goal for a hassle-free clinical study.

Clinical Trials Tab

The Clinical Trials tab works as a dashboard for the application and provides a snapshot view of existing clinical trials with key metrics (Members, Apps, Pending requests, Days since last request) in a widget format. The following options are available from this tab:

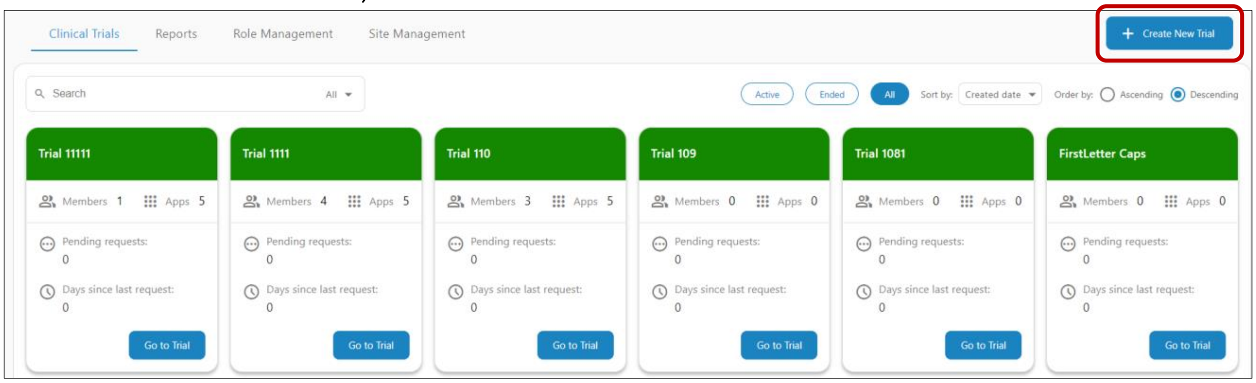
- **Create New Trial**: This button is located on the right-hand side of the screen, in line with the other tab options. Select this to build a new clinical trial. Please see the Create New Trial section for detailed instructions on building a new clinical trial.
- **Go To Trial**: This option is located in each separate clinical trial widget. This blue button allows you to view and edit active or ongoing trials, as well as view ended trials.
- **Filter Ribbon**: The filter ribbon enables administrators to filter trials by site, investigator, trial name, and status (**Active**, **Ended**, **All**). The user can search for clinical trials from the search bar based on trial names, associated investigators, or sites.
- **Sorting**: Sorting helps the user sort the retrieved results alphabetically or according to the date. The user can select **Trial Name**, **Created Date**, **Ended Date**, or **Last Updated** from the **Sort by** dropdown menu. These results can also be arranged in the ascending or descending order.



Create New Trial

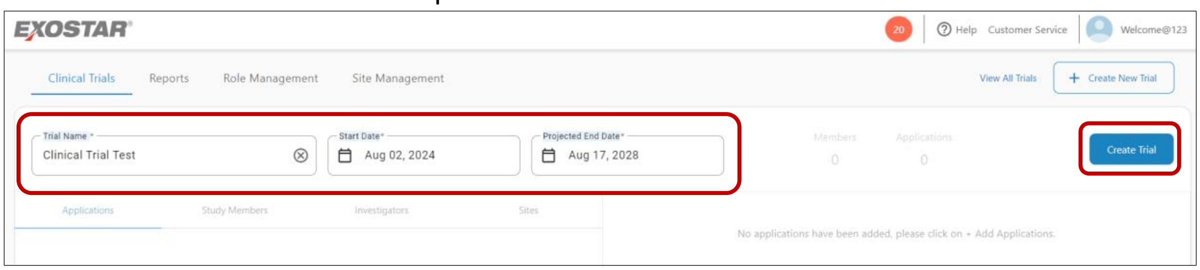
To create a new clinical trial:

1. From the dashboard, click the **Create New Trial** button.

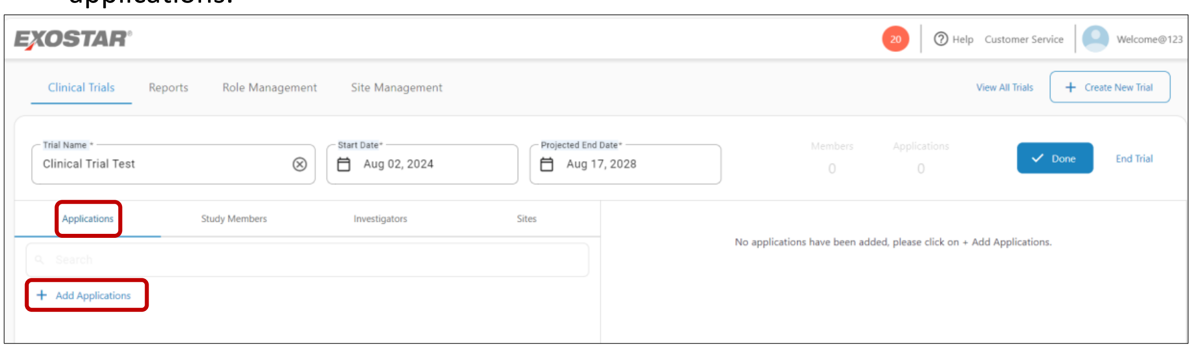


2. Input a **Trial Name**, **Start Date**, and **Projected End Date**. Click **Create Trial**.

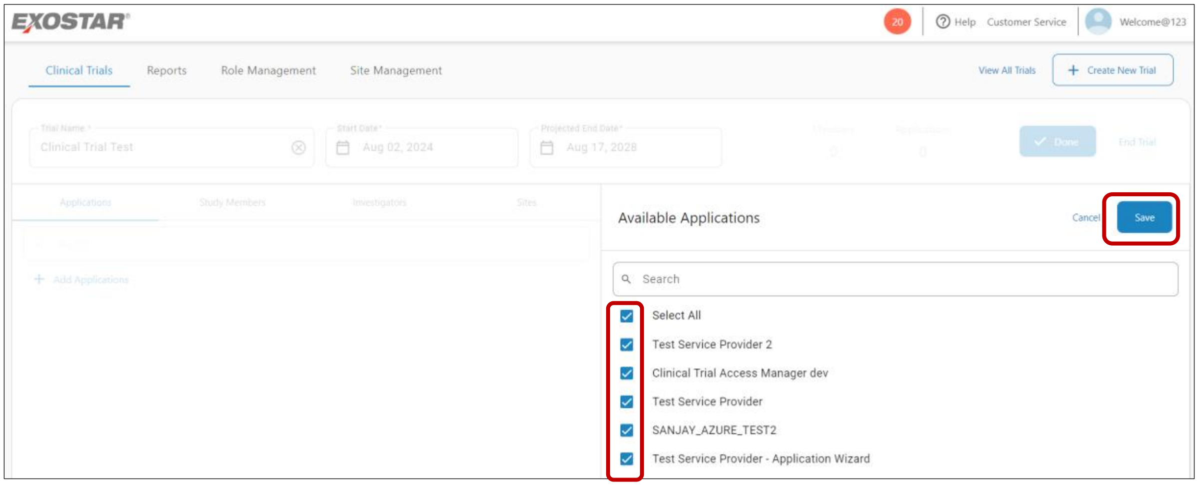
NOTE: The Trial Name must be unique.



3. Select **Add Applications** under the **Applications** tab to display a list of available applications.



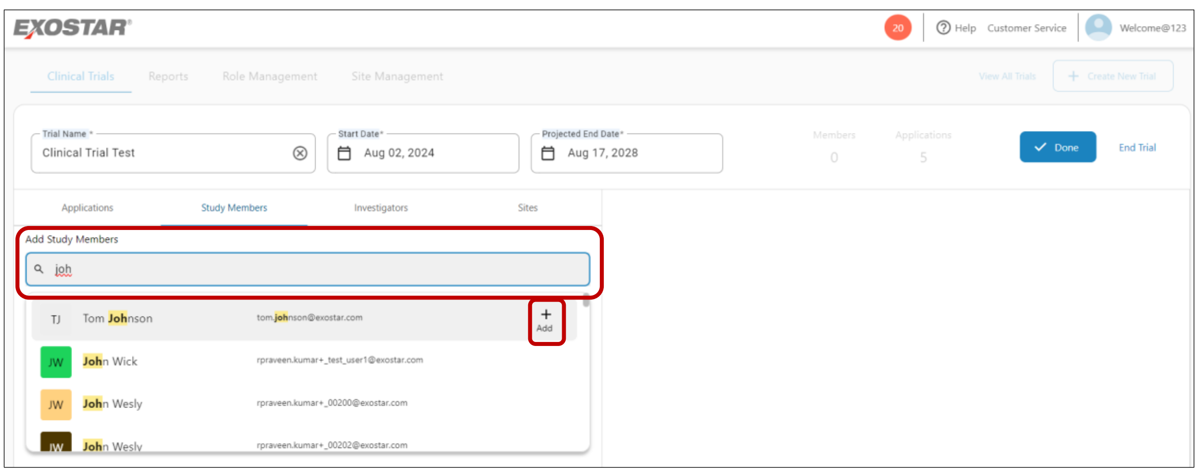
4. Place checkmarks next to the desired applications. Click the **Save** button.



NOTES:

- The list of available applications are the applications the CTAM Admin has associations within Secure Access Manager (SAM).
- Once the applications are saved, the role name and role info for each of the application (if) specified will show on the right-side panel.

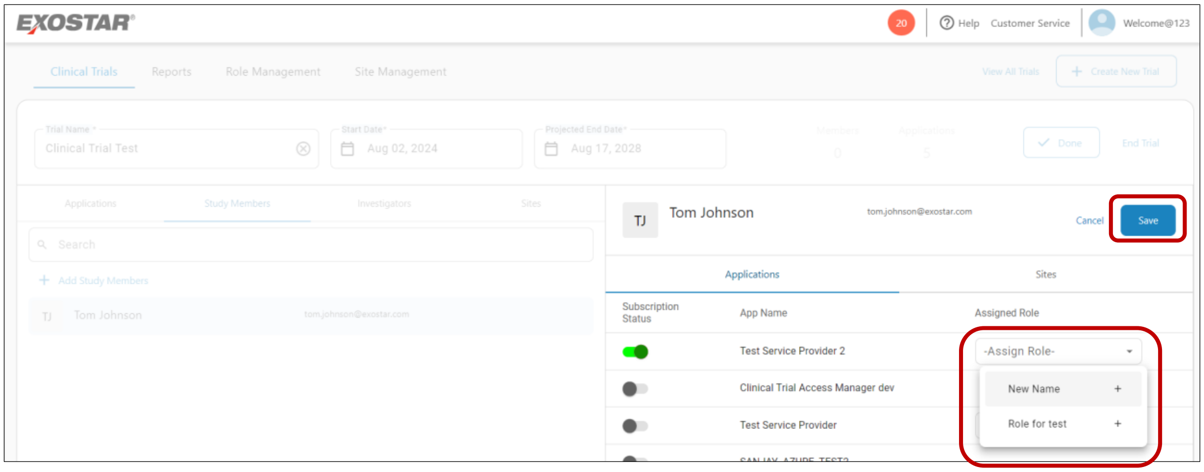
5. Navigate to the **Study Members** tab. Search for the desired study members. Once located, click the **Add** button.



NOTE: Once study members are added, the **Subscription Status**, **Application Name**, and **Role** for that study member display on the right-side panel under the **Applications** tab.

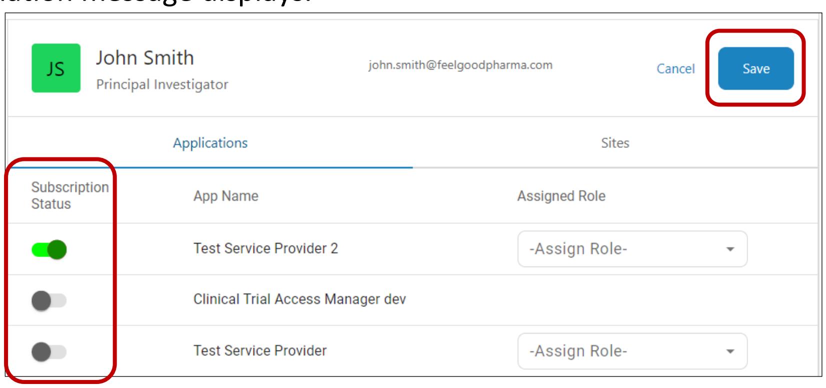
6. Select the desired role from the **Assign Role** dropdown. The status changes with a yellow indicator and a – symbol from where the user can cancel the role request. Click the **Save** button to send the role request.

NOTE: A confirmation message displays.



7. Use the toggle provided per application to request subscriptions. Click the **Save** button to send the subscription request.

NOTE: A confirmation message displays.

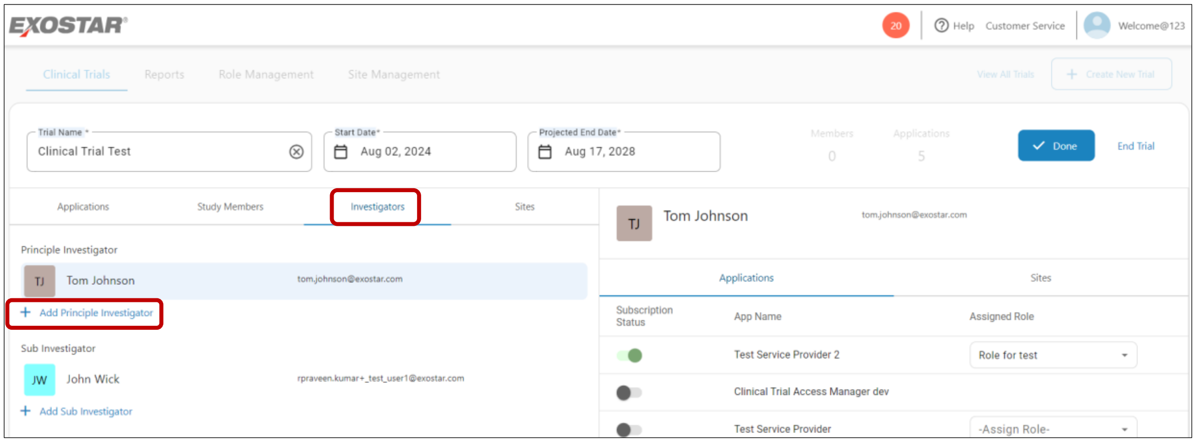


Subscription Status Icons

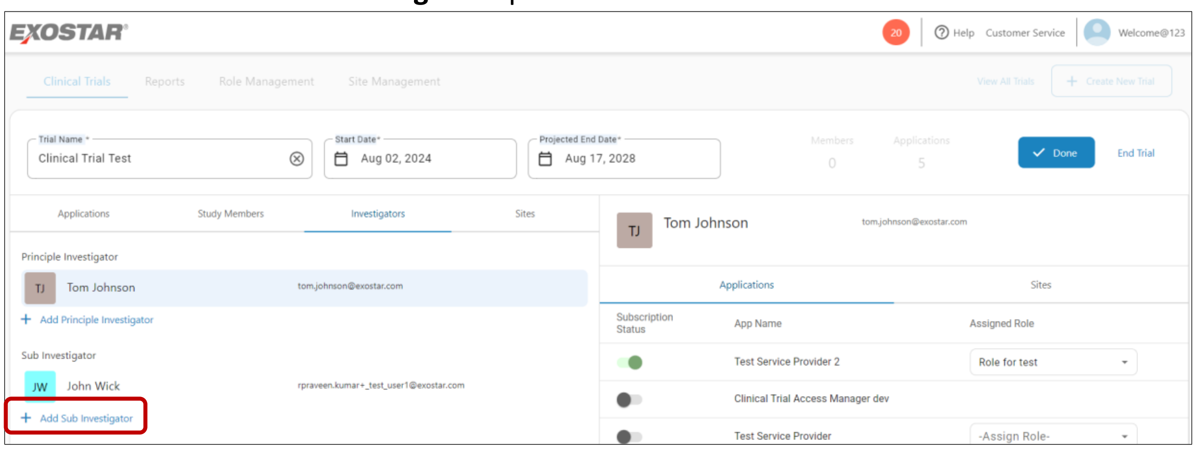
- **Green shield w/tick mark**: The member is subscribed to the application.
- **Grey Toggle button**: Not subscribed or Subscription request not sent.
- **Green toggle button**: Subscription request sent.
- **Yellow shield w/tick mark**: Subscription suspended.
- **Disabled grey toggle button**: Subscription request denied.

8. Navigate to the **Investigators** tab. Select the **Add Principal Investigator** option and search for the required person.

NOTE: Users can add multiple Principal Investigators.



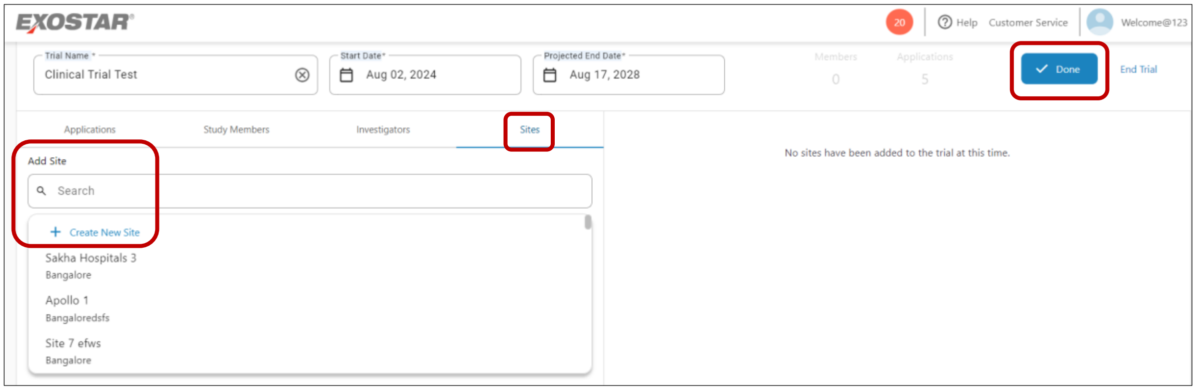
9. Select the **Add Sub Investigator** option. Search the desired members.



NOTE: Once investigators have been added, the **Subscription Status**, **Application Name**, and **Assigned Role** pertaining to the selected Principal or Sub Investigator(s) display on the left. The admin can now assign and request a role, as well as request an application subscription for the Principal Investigator and Sub Investigator using the same steps above.

10. Navigate to the **Sites** tab.
    a. To add an existing site, complete a search. Click **Add Site**. The **Site Details** display in the right-hand column.
    b. To add a new site, select **Create New Site**. Complete the **Site Details** in the right-hand panel. Click the **Create & Add** button.

11. Once you complete all trial details, click **Done**.



NOTE: The trial details can be saved at any time during the workflow by clicking the **Done** button.

Reporting

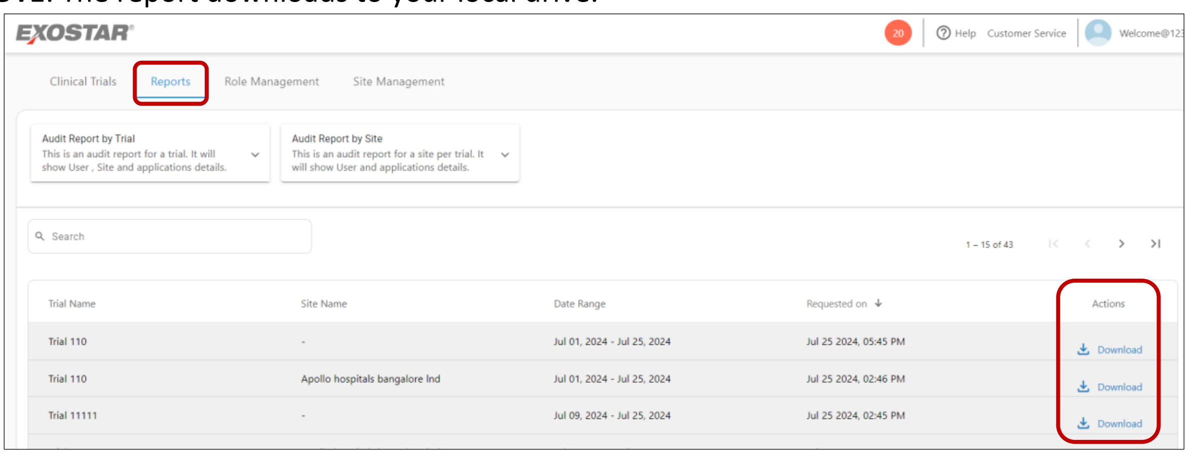
The Reports tab provides the ability to create and customize audit reports for trials to ensure compliance. This article provides instructions on downloading existing reports, as well as generating new reports.

Download Existing Report

To download an existing report:

1. Navigate to the **Reports** tab. Use the search bar provided to locate desired report.
2. Select the **Download** icon via the **Actions** column in the desired report row.

NOTE: The report downloads to your local drive.



Generate New Report

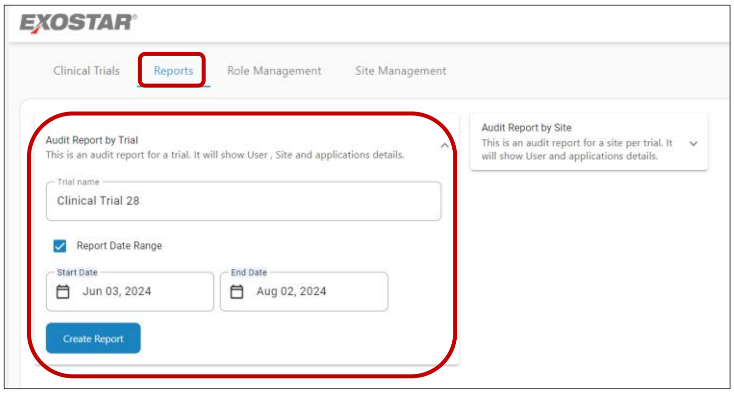
To generate a new report by audit or site:

1. Navigate to the **Reports** tab. Select either **Audit Report by Trial** or **Audit Report by Site**.

2. Enter the **Trial** or **Site Name** (depending on your previous selection), as well as the **Report Date Range** (if required).

3. Click the **Create Report** button.

NOTE: The new report now displays at the top of the table via the **Reports** tab.



Role Management

You can add or edit the role name and information for each application via the Role Management tab.

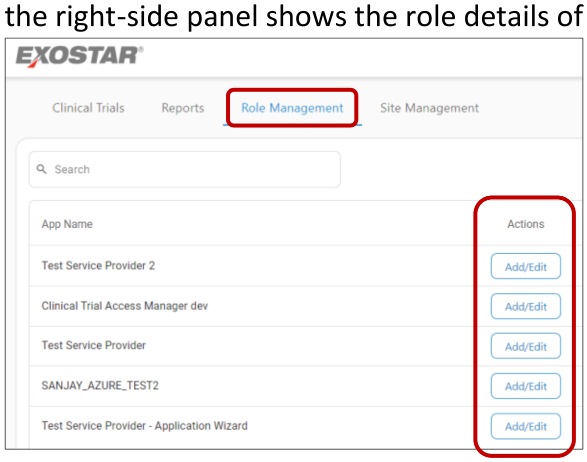
IMPORTANT! Roles that are not in use for an application can be selected and deleted. The roles that are in use for an application are disabled and cannot be deleted.

Add Existing Role

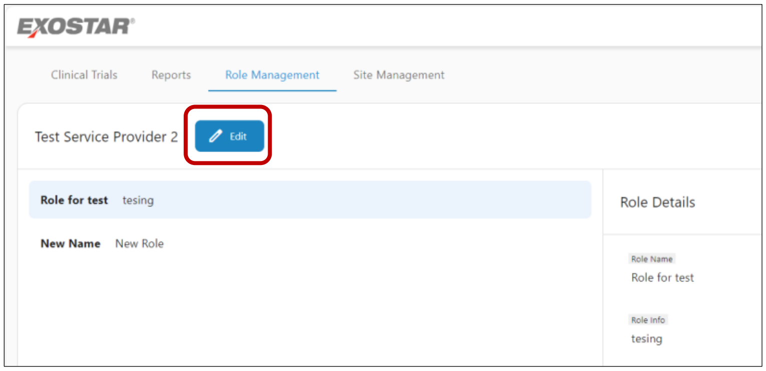
To edit an existing role:

1. Navigate to the **Role Management** tab.
2. Click the **Add/Edit** button for the desired application.

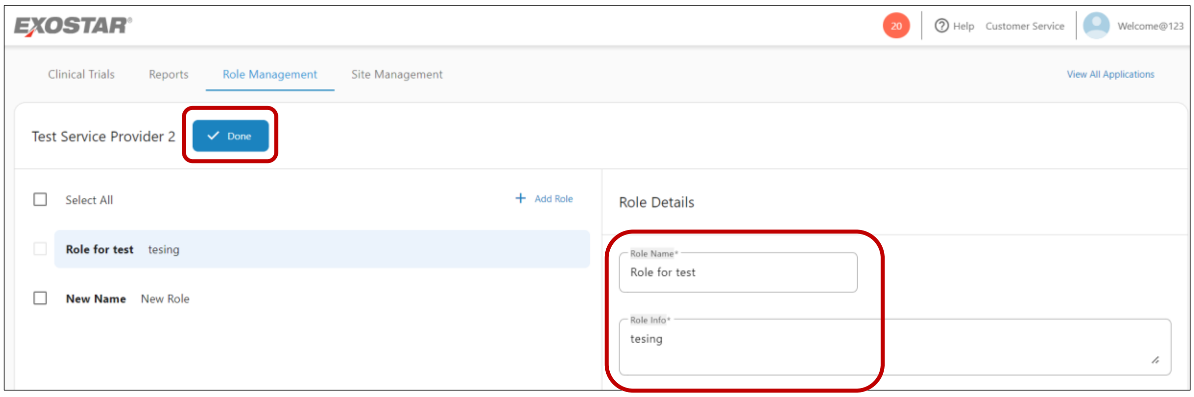
NOTE: Once you select to **Add/Edit**, the left-side panel shows the list of role names, along with the role information, and the right-side panel shows the role details of the selected role.



3. Click the **Edit** button to edit an existing role's **Name** and **Info**. Click **Save**.



4. When you complete editing or adding roles, click **Done**.

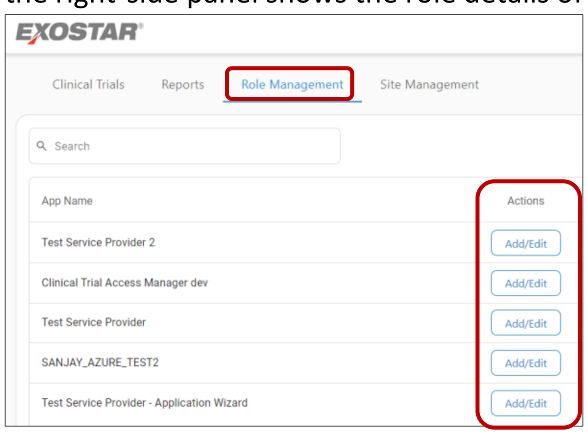


Add New Role

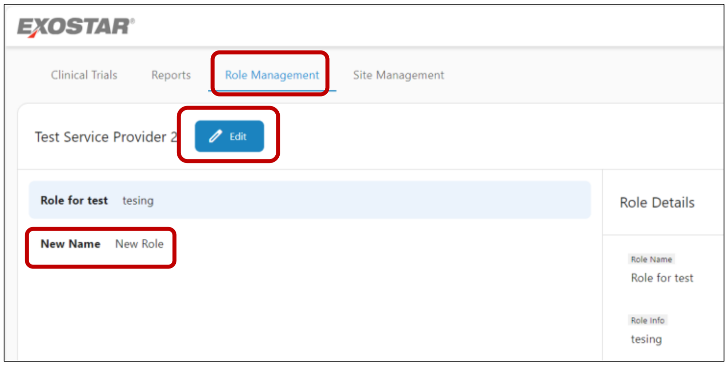
To add a new role:

1. Navigate to the **Role Management** tab.
2. Click the **Add/Edit** button for the desired application.

NOTE: Once you select to **Add/Edit**, the left-side panel shows the list of role names, along with the role information, and the right-side panel shows the role details of the selected role.

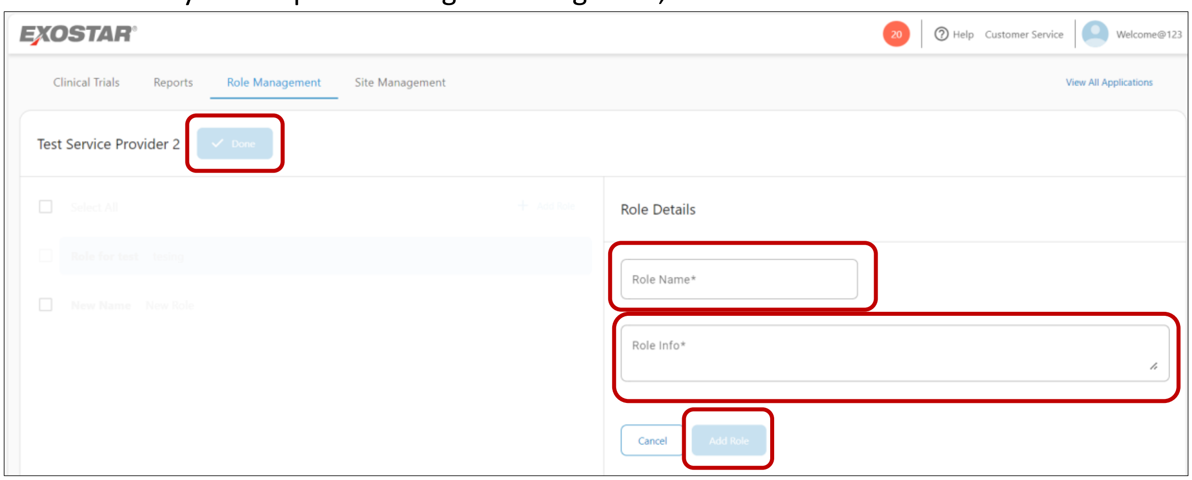


3. Select the **New Name / New Role** option. Click **Edit**.



4. Input role details. Click **Add Role**.

5. When you complete editing or adding roles, click **Done**.



Site Management

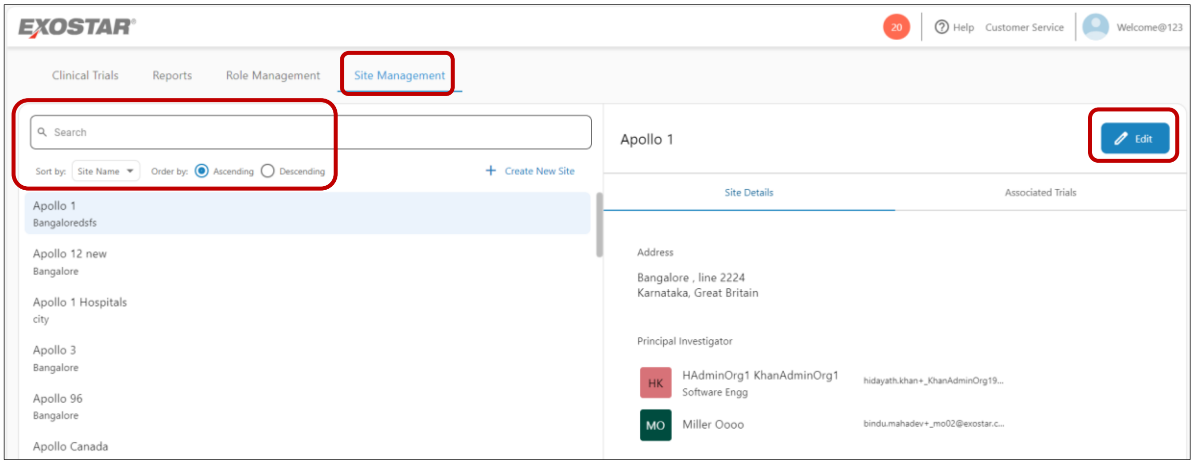
The Site Management tab allows users to create and manage sites to maintain appropriate site data. These sites can then be associated to trials.

Site Management Navigation

The following options are available to navigate the **Site Management** tab:

- Use the search bar to locate existing site.
- The search results can be further refined using **Site Name**, **Created Date**, or **Updated Date**.
- Search results can be reordered in ascending or descending order.

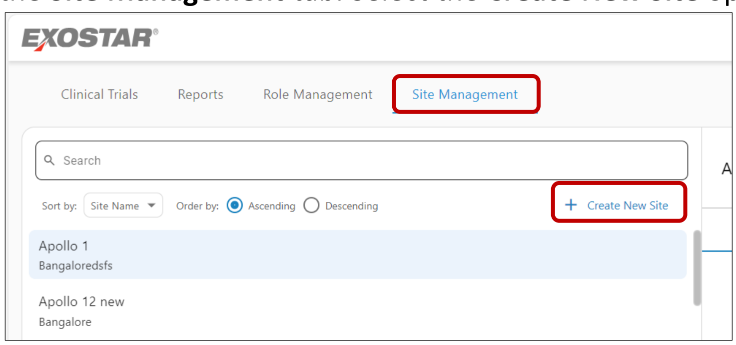
- The right-side panel displays a view-only mode of site details and associated trials for the currently selected site.



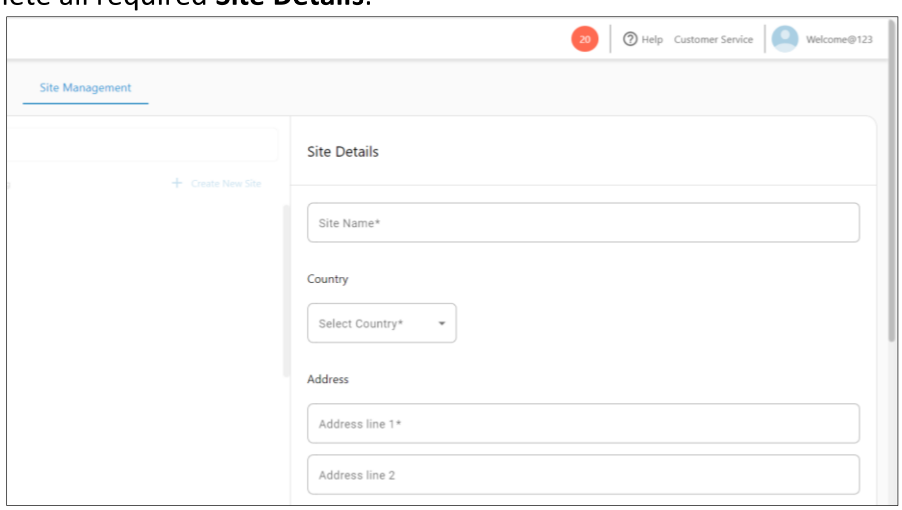
Create New Site

To create a new site:

1. Navigate to the **Site Management** tab. Select the **Create New Site** option.



2. Complete all required **Site Details**.



3. Click the **Create** button.

NOTE: The selected site can be associated to trials by selecting the **Edit** button and searching and/or (multi)selecting from the list of clinical trials. The changes can then be saved and display under the associated Trials tab on the right-side panel.