

Clinical Trial Access Manager (CTAM) Guide August 2024



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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.

۹, Search	All 👻		Active	All Sort by: Created date 💌	Order by: 🔘 Ascending 🔘 Desce
Trial 11111	Trial 1111	Trial 110	Trial 109	Trial 1081	FirstLetter Caps
왕 Members 1 🗰 Apps 5	Apps 5	Apps 5 Members 3	😤 Members 0 🗰 Apps 0	🕰 Members 0 🗰 Apps 0	Apps Members 0
Pending requests: 0	 Pending requests: 0 				
Days since last request:	Days since last request:				

CREATE NEW TRIAL

To create a new clinical trial:



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

2, Search	All 👻		Active	All Sort by: Created date 💌	Order by: O Ascending O Desce
Trial 11111	Trial 1111	Trial 110	Trial 109	Trial 1081	FirstLetter Caps
Apps 5	Members 4 III Apps 5	Apps 5	路 Members 0 🗰 Apps 0	온 Members 0 III Apps 0	은 Members 0 III Apps
Pending requests: 0	 Pending requests: 0 				
Days since last request:	 Days since last request: 0 				

2. Input a **Trial Name**, **Start Date**, and **Projected End Date**. Click **Create Trial**. **NOTE**: The Trial Name must be unique.

EXOSTAR			20 🛛 🕲 Help Customer :	Service Welcome@123
Clinical Trials Reports	Role Management Site Management		View All Trials	+ Create New Trial
Trial Name * Clinical Trial Test	Start Date*	Projected End Date*	Members Applications 0 0	Create Trial
Applications Stu	dy Members Investigators	Sites	No applications have been added, please click on + Add Applicati	ons.

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

EXOSTAR	20 O Help Customer Service Velcome@123
Clinical Trials Reports Role Management Site Management	View All Trials + Create New Trial
Clinical Trial Test	
Application: Study Members Investigators Sites Q. Search + Add Applications	No applications have been added, please click on + Add Applications.



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

XOSTAR						20 3 Help	Customer Service Welco	ome@1
Clinical Trials Reports	Role Management Si	te Management					View All Triats + Create New Tr	rial
	⊗ (^{statt}	oate* Aug 02, 2024	Projected Er				V Done End In	
				Available Applic	cations		Cancel	ave
+ Add Applications				Test Service SANJAY_AZI	Access Manager dev Provider			

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.

EXOSTAR			20 🖉 Help Customer Service 🦲 Welcome@123
Clinical Trials Reports			View All Trials + Create New Trial
Clinical Trial Test	Start Date*	Projected End Date*	Members Applications C Done End Trial
	tudy Members Investigators	Sites	
Add Study Members			
TJ Tom <mark>Joh</mark> nson	tom <mark>joh</mark> nson@exostar.com	+ Add	
JW John Wick	rpraveen.kumar+_test_user1@exostar.com		
JW John Wesly	rpraveen.kumar+_00200@exostar.com		
IW John Wesly	rpraveen.kumar+_00202@exostar.com		

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.

EXOSTAR				20	Help Customer Service Welcome@123
Clinical Trials Reports					View All Trials
	Start Date" Tate" Aug 02, 2024	Projected End			
			TJ Tom Jol	hnson tomjohnson(Dexostar.com
+ Add Study Members				Applications	Sites
			Subscription Status	App Name	Assigned Role
			-	Test Service Provider 2	-Assign Role-
			•	Clinical Trial Access Manager dev	New Name +
			•	Test Service Provider	Role for test +
				CAN JAY AZUDE TECTO	

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

NOTE: A confirmation message displays.

JS	hn Smith john	.smith@feelgoodpharma.com	Cancel Save
	Applications	Sites	
Subscription Status	App Name	Assigned Role	
-	Test Service Provider 2	-Assign Role-	•
	Clinical Trial Access Manager d	ev	
	Test Service Provider	-Assign Role-	•

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.

EXOSTAR®				(20 🕅 Help Customer Service	Welcome@12
Clinical Trials Reports					View All Trials + Crea	
Clinical Trial Test	Start Date*	Projected End	Date*7, 2028		Applications 5 Done	End Trial
Applications Stud	y Members Investigators	Sites	TJ Tom J	ohnson tomjo	hnson@exostar.com	
TJ Tom Johnson	tom.johnson@exostar.com			Applications	Sites	
+ Add Principle Investigator			Subscription Status	App Name	Assigned Role	
Sub Investigator				Test Service Provider 2	Role for test	•
JW John Wick	ohn Wick rpraveen.kumar+_test_user1@exostar.com		•	Clinical Trial Access Manager dev	,	
+ Add Sub Investigator			•	Test Service Provider	-Assign Role-	•

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

EXOSTAR					20 1 Help Customer Service	Welcome@123
Clinical Trials Report					View All Trials + Create	
Clinical Trial Test	Start Date*	Projected En	d Date*		Applications 5 Done	End Trial
Applications Principle Investigator	Study Members Investigators	Sites	TJ Tom Jo	ohnson tomjol	hnson@exostar.com	
TJ Tom Johnson	tom.johnson@exostar.com			Applications	Sites	
+ Add Principle Investigator			Subscription Status	App Name	Assigned Role	
Sub Investigator				Test Service Provider 2	Role for test	•
JW John Wick	rpraveen.kumar+_test_user1@exostar.com		•	Clinical Trial Access Manager dev	,	
+ Add Sub Investigator				Test Service Provider	-Assign Role-	•

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 righthand panel. Click the **Create & Add** button.



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

XOSTAR			20 🛛 🕲 Help Customer Service 🔍 Welcomed
Clinical Trial Test	Start Date" Aug 02, 2024	Projected End Date*	Members Applications 0 5 End Trial
Applications	Study Members Investigators	Sites	
Add Site			No sites have been added to the trial at this time.
Q. Search			
+ Create New Site		8	
Sakha Hospitals 3 Bangalore			
Apollo 1 Bangaloredsfs			
Site 7 efws Bangalore			

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.

EXOSTAR			20	Help Customer Service	Welcome@
Clinical Trials Reports Role Manag	ement Site Management				
Audit Report by Trial This is an audit report for a trial. It will show User , Site and applications details.	Audit Report by Site This is an audit report for a site per trial. It vill show User and applications details.				
Q Search				1 – 15 of 43 🛛 🔀	< > >
Trial Name	Site Name	Date Range	Requested on 🔸	(Actions
Trial 110		Jul 01, 2024 - Jul 25, 2024	Jul 25 2024, 05:45 PM		🛃 Download
Trial 110	Apollo hospitals bangalore Ind	Jul 01, 2024 - Jul 25, 2024	Jul 25 2024, 02:46 PM		🛃 Download
Trial 11111		Jul 09, 2024 - Jul 25, 2024	Jul 25 2024, 02:45 PM		🛃 Download

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.

Clinical Trials Reports	Role Management Site Management	t
Audit Report by Trial This is an audit report for a trial. I	t will show User , Site and applications details.	Audit Report by Site This is an audit report for a site per trial. It will show User and applications details.
Clinical Trial 28		
Report Date Range		
Start Date	End Date	

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.

EXOSTAR	
Clinical Trials Reports Role Management Site Manageme	ent
Q Search	
App Name	Actions
Test Service Provider 2	Add/Edit
Clinical Trial Access Manager dev	Add/Edit
Test Service Provider	Add/Edit
SANJAY_AZURE_TEST2	Add/Edit
Test Service Provider - Application Wizard	Add/Edit



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

XOSTAR	
Clinical Trials Reports Role Management Site Management	
Test Service Provider 2	
Role for test tesing	Role Details
New Name New Role	Role Name Role for test
	Role Info tesing

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

EXOSTAR		20	Help Customer Service Welcome@123
Clinical Trials Reports Role Management Site Management			View All Applications
Test Service Provider 2			
Select All	+ Add Role	Role Details	
Role for test tesing		Role Name*	
New Name New Role		Role for test	â

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.

XOSTAR	
Clinical Trials Reports Role Management	Site Management
Q Search	
App Name	Actions
Test Service Provider 2	Add/Edit
Clinical Trial Access Manager dev	Add/Edit
Test Service Provider	Add/Edit
SANJAY_AZURE_TEST2	Add/Edit
Test Service Provider - Application Wizard	Add/Edit



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

EXOSTAR	
Clinical Trials Reports Role Management Site Management	
Test Service Provider 2	
Role for test tesing	Role Details
New Name New Role	Role Name Role for test
	Role Info tesing

- 4. Input role details. Click Add Role.
- 5. When you complete editing or adding roles, click **Done**.

EXOSTAR	20 🕅 Help Customer Service 🤐 Welcome@123
Clinical Trials Reports Role Management Site Management	View All Applications
Test Service Provider 2	
	Role Details
	Role Name*
	Role Info* 4
	Cancel Add Role

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.

EXOSTAR	20 🛛 🕲 Help Customer Service 🤷 Welcome@123
Clinical Trials Reports Role Management Site Management	
Q Search	Apollo 1
Sort by: Site Name Order by: Ascending Descending Create News	
Apollo 1	Site Details Associated Trials
Bangaloredsfs	
Apollo 12 new	Address
Bangalore	Bangalore , line 2224
Apollo 1 Hospitals	Karnataka, Great Britain
city	
Apollo 3	Principal Investigator
Bangalore	HAdminOrg1 KhanAdminOrg1 hidayath.khan+_KhanAdminOrg19
Apollo 96	Software Engg
Bangalore	MO Miller Oooo bindu.mahadev+_mo02@exostar.c
Apollo Canada	

Create New Site

To create a new site:

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

EXOSTAR [®]					
Clinical Trials	Reports	Role Management	Site Management		
Q Search					
Sort by: Site Name 💌	Order by: 🧿	Ascending O Descending		+ Create New Site	J —
Apollo 1 Bangaloredsfs					
Apollo 12 new Bangalore					

2. Complete all required Site Details.

	2 Telp Customer Service Welcome@123
Site Management	
+ Create New Ste	Site Details
	Site Name*
	Country
	Select Country* 👻
	Address
	Address line 1*
	Address line 2



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.

	20	Help Customer Service	Welcome@123
City/Town* Austin Principal Investigator	Texas	Postal/Zip Code* 73301	
Q Search	rpra	veen.kumar+_00200@exostar.com	
Contacts			
Q. Search			
TJ Tom Johnson	tom	johnson@exostar.com	
Cancel			