



IWRS Slot Reservations and Cohort Management User Guide

Version 2.1, 03-APR-2024

This User Guide provides instructions on how to process a Slot Reservation and perform Cohort Management in IWRS.

Technical support: support.iwrs@theradex.com



Table of Contents

OVERVIEW[3](#)

Accessing IWRS[4](#)

Slot Reservations - Requesting.....[5](#)

Slot Reservations - Approving[8](#)

Cohort Management[11](#)

OVERVIEW

The intent of this document is to provide instructions on how to request a Slot Reservation and perform Cohort Management in IWRS.

For multi-site studies, Slot Reservations is a feature used to ensure a slot is available for a potential study participant. IWRS can be configured to require Lead Institution approval on slot reservations.

Cohort Management provides the Primary Investigator, and/or designee, a facility for opening and closing cohorts and changing accrual limits. As a study progresses, management of active cohorts is essential. Email notifications to sites of cohort changes are sent automatically.

At any time, all Cohorts can be set to Not Active, preventing further registrations. For the studies that are defined as Single-Active cohorts, setting a Cohort to Active will deactivate all other cohorts.

Changes to Cohorts fields that are not editable by the sites are managed by Theradex.

Accessing IWRS – The following steps describe how to access IWRS.

Step 1

Login to **Open** by entering <https://open.ctsu.org> into your URL. At the **Open** login screen, enter your **CTEP-IAM Username and Password** and **Sign In** or use the **ID.me** login option if applicable.

Welcome to the Oncology Patient Enrollment Network (OPEN) Portal system

OPEN is the web-based registration system for patient enrollments onto NCI-sponsored Network Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Network Groups' registration/randomization systems for patient registration/randomization. OPEN provides the ability to enroll patients on a 24/7 basis.

Training and Demonstration Materials:

- [User Guide\(PDF\)](#) » This users guide has a linkable Table of Contents that will bring you to any topic you choose, or you can scroll through and/or print the entire guide.
- [Frequently Asked Questions \(FAQ\)](#) » Frequently asked questions about OPEN Portal.
- [Access & Crediting Guidelines\(PDF\)](#) » Guidelines for OPEN Portal Access and Crediting.
- [Slot Reservation Quick User Guide\(PDF\)](#) » This user guide is a quick reference intended to assist you with the process of reserving a slot for a patient on protocols that use the slot reservation system.
- [OPEN T&UM Quick Reference Site User Guide\(PDF\)](#) » This document provides instructions for using OPEN's Transfer and Update Module to update completed patient enrollments that are maintained in OPEN.

CTEP-IAM **ID.me** **NIH**

Username
Password

Sign In **Reset**

[Forgot Password?](#) | [Reset Password?](#) | [Annual Registration](#) | [Request New Account](#) | [Help Center](#)

Warning Notice:
For public facing web pages to which the public has privileged access, e.g., clinical trial or adverse effects systems where users/patients are logging in to enter PII(PH). [Read More...](#)
[NIH Web Policies and Notices](#)

Step 2

At the **Welcome (Home)** screen, click on the **Theradex IWRS Cohort Management/Slot Reservations** link listed under **Enrollment**.

Welcome back
Last login: 04-Jan-2023 12:50:15 PM EST

Site: [CITN: Cancer Immunotherapy Trials Network](#)

Role: **Group Registrar Admin**

» This system is best viewed at 1024 x 768 resolution and above
» Please do NOT use the browser's back button for navigation
» Please enable popups from OPEN Portal

Message of the day:
In order to enroll patients via OPEN, you must be affiliated with at least one institution and carry the role of "registrar" at the institution(s).
If you have any questions please contact the [CTSU Help Desk](#) at 1-888-823-5923.

Start Practice to practice test enrollments!

My five recent "In Progress" enrollments

Track #	Protocol	Site	Step	Status	Status Date
No recent activities!					
Create New Enrollment					

Enrollment

- Create New Enrollment
- In Progress Enrollments
- Enrollment History
- Override Management
- Theradex IWRS Cohort Management/Slot Reservations**
- COG Patient Registry

Form Setup

- Forms List
- caDSR Form Definitions

RSS

- Person Search
- Site Registration Search

Other

- CTEP IAM
- Reports
- Charts
- Funding Report

The next screen will be the IWRS Registrar Dashboard providing a Welcome message. The Registrar Dashboard provides information on Institution Enrollments.

Welcome to the Interactive Web Response System

 Protocol Generic

Institution Enrollments

Institution	Patients Enrolled	Patient Screen Failures	Patients Pending
Test Hospital	0	0	0
Total	0	0	0

Export Patient Status to Excel

Slot Reservations – The following steps describe the process of requesting a Slot Reservation.

Please note: Slot Reservations are reserved at the site level and can be used for any patient.

Step 1

To Reserve a Slot, hover your mouse over **Patients** on the menu bar and select **Reserve a Slot**.

Reserve a Slot

Patient List

Register New Patient

Screen Failure List

Welcome to the Interactive Web Response System

 Protocol Generic

Institution Enrollments

Institution	Patients Enrolled	Patient Screen Failures	Patients Pending
Test Hospital	0	0	0
Total	0	0	0

Export Patient Status to Excel

Step 2

At the **Reserve a Slot** screen, click on the **Reserve** link to reserve a slot for the selected cohort. Only active cohorts that have open slots available will be eligible for new reservations. A limit is placed on how many slots a site can reserve at a time.

View	Cohort	Accrual Limit	Slots Available	Active	Action
	Test Cohort 1	100	100	☒	Reserve

Step 3

Select the Registering Institution (site) from the dropdown and click on the Reserve link.

Please select a Registering Institution
001 - Test Hospital

Request Date
2/16/2023

[Reserve](#)

For studies that require reservations to be approved, this confirmation is displayed, and will show in the **Slot Reservation** list as **Pending Approval**. A **Slot Reservation** email is automatically sent to the person who reserved the slot and the approver.

001 - Test Hospital has requested a slot in the Test Cohort 1 cohort.
The approver has been emailed and when a decision is made, you will receive approval notification by email.

For Studies that do not require approvals, the slot is now reserved.

Registrar Dashboard	My Assignments	Patients	Study Docs
---------------------	----------------	----------	------------

Slot Reservation Request Confirmation

001 - Test Hospital has reserved a slot in the Test Cohort 1 cohort.
It is expected that registration will be completed in 10 days.

Slot Reservation Status

At the **Reserve a Slot** screen, to view slot reservations, click on the magnifying glass icon in the View column for the selected Cohort.

Registrar Dashboard	My Assignments	Patients	Study Docs
---------------------	----------------	----------	------------

Reserve a Slot

Protocol Filter: Generic

Show: 10 entries

Search:

View	Cohort	Accrual Limit	Slots Available	Active	Action
	Test Cohort 1	100	99	☒	<button>Reserve</button>

Showing 1 to 1 of 1 entries

First Previous 1 Next Last

Slot Reservation for the Selected Cohort

Institution	Requested By	Status	Patient ID	Screening ID	Request Date	Reservation Date	Action
001 - Test Hospital	Kathryn Maguire	Reserved			02/16/2023	02/16/2023	

Slot Reservation Cancellation

A **Slot Reservation** can be cancelled if the reservation status is **Reserved** or **Pending Approval**. The slot will have a red **X** on the associated line listed under **Actions**.

To cancel a slot reservation, click on the red **X** listed under **Actions** on the same line as the corresponding reservation. If the Status reads **Registered**, the slot cannot be removed.

Registrar Dashboard
My Assignments
Patients
Study Docs

Reserve a Slot

Protocol Filter
Generic

Show 10 entries
Search:

View	Cohort	Accrual Limit	Slots Available	Active	Action
	Test Cohort 1	100	99	☒	Reserve

Showing 1 to 1 of 1 entries

First Previous 1 Next Last

Slot Reservation for the Selected Cohort

Institution	Requested By	Status	Patient ID	Screening ID	Request Date	Reservation Date	Action
001 - Test Hospital	Kathryn Maguire	Reserved			02/16/2023	02/16/2023	X

A **Cancel Slot Reservation** popup will appear asking you to confirm if you are sure you want to cancel the reservation. Select **Yes** or **No**.

Registrar Dashboard
My Assignments
Patients
Study Docs

Reserve a Slot

Protocol Filter
Generic

Show 10 entries
Search:

View	Cohort	Accrual Limit	Slots Available	Active	Action
	Test Cohort 1	100	99	☒	Reserve

Showing 1 to 1 of 1 entries

First Previous 1 Next Last

Slot Reservation for the Selected Cohort

Institution	Requested By	Status	Patient ID	Screening ID	Request Date	Reservation Date	Action
001 - Test Hospital	Kathryn Maguire	Reserved			02/16/2023	02/16/2023	X

Cancel Slot Reservation

Are you sure you want to cancel this reservation?

Yes
No

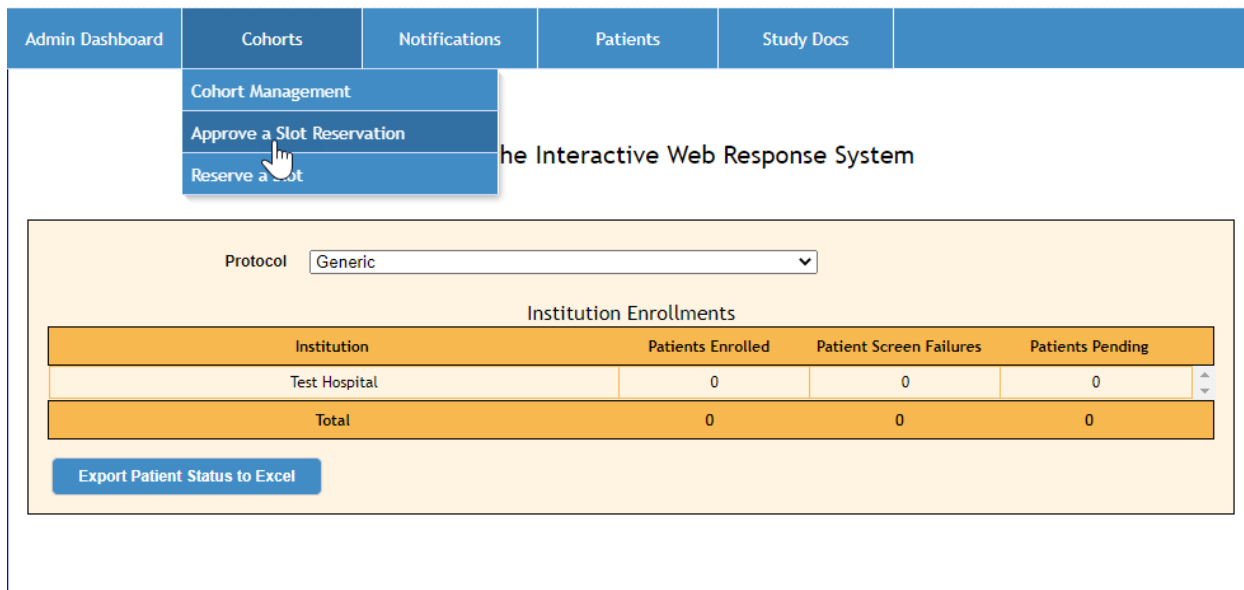
Slot Reservations – The following steps describe the process of approving (or denying) a Slot Reservation.

Approving a Slot Reservation

Depending on their role, a user may have the responsibility of approving slot reservation requests. The user is notified via email that a slot reservation request has been made.

Step 1

Log into IWRS, hover the mouse over the **Cohorts** tab and select **Approve a Slot Reservation**.



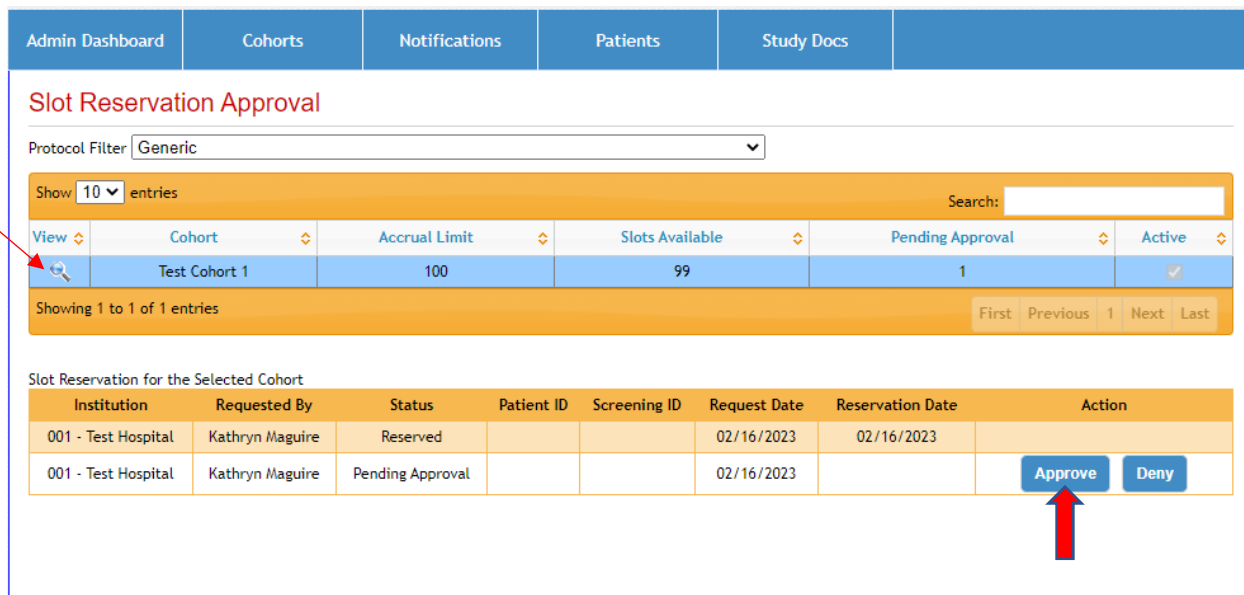
The screenshot shows the Admin Dashboard with the following tabs: Admin Dashboard, Cohorts, Notifications, Patients, Study Docs, and a partially visible tab. The Cohorts tab is selected, and a dropdown menu is open showing three options: Cohort Management, Approve a Slot Reservation (highlighted with a mouse cursor), and Reserve a Slot. Below the tabs, the text 'The Interactive Web Response System' is visible. The main content area shows a 'Protocol' dropdown set to 'Generic' and a table titled 'Institution Enrollments'.

Institution	Patients Enrolled	Patient Screen Failures	Patients Pending
Test Hospital	0	0	0
Total	0	0	0

Below the table is a button labeled 'Export Patient Status to Excel'.

Step 2

To approve the reservation request, click the magnifying glass in the **View** column to view the slot reservations for that cohort which will be listed at the bottom of the screen. Click on the **Approve** link.



The screenshot shows the 'Slot Reservation Approval' page. At the top, there's a 'Protocol Filter' dropdown set to 'Generic'. Below it, a 'Show 10 entries' dropdown and a 'Search:' input field are visible. A table lists cohorts with columns: View (magnifying glass icon), Cohort, Accrual Limit, Slots Available, Pending Approval, and Active. The first row is 'Test Cohort 1' with values 100, 99, 1, and an active status. A red arrow points to the magnifying glass icon in the 'View' column. Below the table, it says 'Showing 1 to 1 of 1 entries' with pagination links: First, Previous, 1, Next, Last. Below this is a section titled 'Slot Reservation for the Selected Cohort' with a table showing reservation details.

Institution	Requested By	Status	Patient ID	Screening ID	Request Date	Reservation Date	Action
001 - Test Hospital	Kathryn Maguire	Reserved			02/16/2023	02/16/2023	
001 - Test Hospital	Kathryn Maguire	Pending Approval			02/16/2023		Approve Deny

A red arrow points to the 'Approve' button in the 'Action' column of the second row.

Step 3

At the **Approve Slot Reservation** pop-up, click on **Yes** to approve. Click on **No** to cancel the approval process without affecting the pending request.

The screenshot shows the 'Slot Reservation Approval' interface. At the top, there is a navigation bar with 'Admin Dashboard', 'Cohorts', 'Notifications', 'Patients', and 'Study Docs'. Below this, the 'Slot Reservation Approval' section is visible. It includes a 'Protocol Filter' set to 'Generic', a 'Show 10 entries' dropdown, and a 'View' dropdown set to 'Cohort'. A table lists 'Test Cohort 1' with a magnifying glass icon. Below the table, it says 'Showing 1 to 1 of 1 entries'. A table titled 'Slot Reservation for the Selected Cohort' has columns: Institution, Requested By, Status, Patient ID, Screening ID, Request Date, Reservation Date, and Action. The table shows two entries: one 'Reserved' and one 'Pending Approval'. The 'Pending Approval' entry has 'Approve' and 'Deny' buttons. A pop-up titled 'Approve Slot Reservation' is displayed in the center, asking 'Are you sure you want to approve this slot reservation?' with 'Yes' and 'No' buttons.

Institution	Requested By	Status	Patient ID	Screening ID	Request Date	Reservation Date	Action
001 - Test Hospital	Kathryn Maguire	Reserved			02/16/2023	02/16/2023	
001 - Test Hospital	Kathryn Maguire	Pending Approval			02/16/2023		<button>Approve</button> <button>Deny</button>

Reservation Denial

To deny the reservation request, click the magnifying glass in the **View** column to view the slot reservations for that cohort which will be listed at the bottom of the screen. Click on the **Deny** link.

The screenshot shows the 'Slot Reservation Approval' interface. At the top, there is a navigation bar with 'Admin Dashboard', 'Cohorts', 'Notifications', 'Patients', and 'Study Docs'. Below this, the 'Slot Reservation Approval' section is visible. It includes a 'Protocol Filter' set to 'Generic', a 'Show 10 entries' dropdown, and a 'View' dropdown set to 'Cohort'. A table lists 'Test Cohort 1' with a magnifying glass icon. Below the table, it says 'Showing 1 to 1 of 1 entries'. A table titled 'Slot Reservation for the Selected Cohort' has columns: Institution, Requested By, Status, Patient ID, Screening ID, Request Date, Reservation Date, and Action. The table shows two entries: one 'Reserved' and one 'Pending Approval'. The 'Pending Approval' entry has 'Approve' and 'Deny' buttons. A pop-up titled 'Reservation Denied' is displayed in the center, asking 'Please enter the reason for denial. This information will be included in the Denial Notification that will be sent to the site that requested the reservation.' There is a text input field for the reason. Below the field, it says 'If Deny was selected in error, click Cancel.' with 'Save' and 'Cancel' buttons.

Institution	Requested By	Status	Patient ID	Screening ID	Request Date	Reservation Date	Action
001 - Test Hospital	Kathryn Maguire	Reserved			02/16/2023	02/16/2023	
001 - Test Hospital	Kathryn Maguire	Pending Approval			02/16/2023		<button>Approve</button> <button>Deny</button>

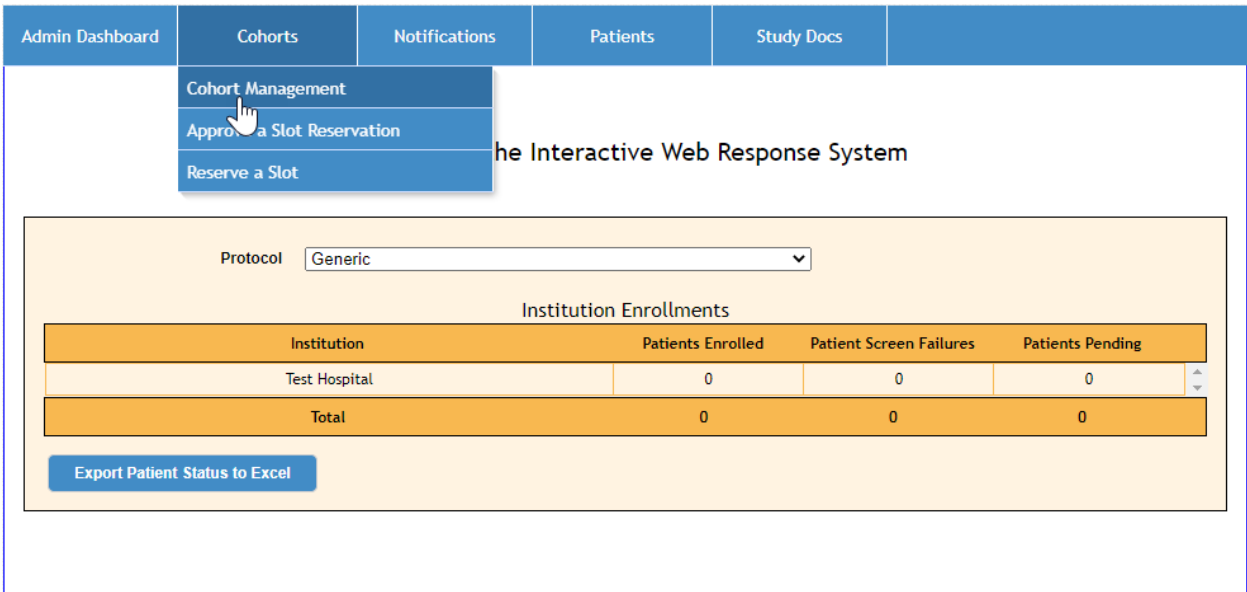
Enter the reason for denial in the provided field and click on **Save** to continue, otherwise, click **Cancel**.

Cohort Management – The following steps describe the process of managing Cohorts.

The Primary Investigator, and/or designee, has the responsibility of managing cohorts for a study.

Step 1

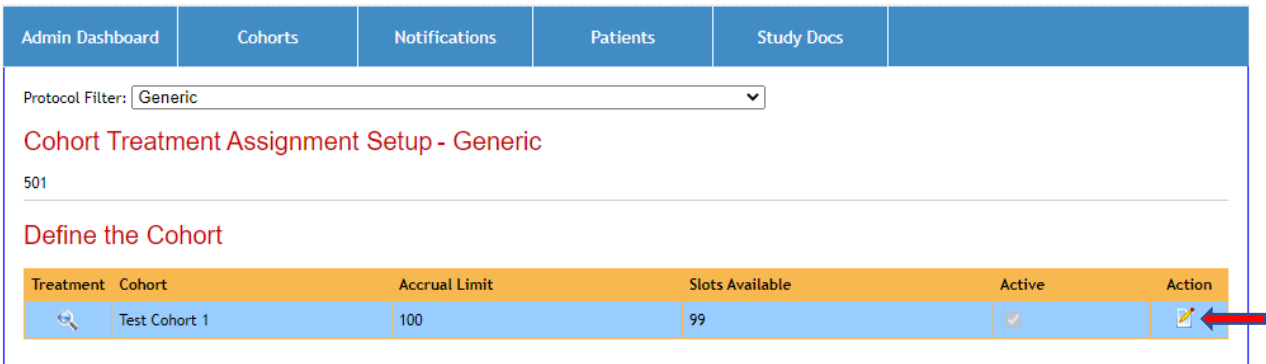
Log into IWRS, hover the mouse over the **Cohorts** tab and select **Cohort Management**.



Step 2

Opening or Closing a Cohort

To open or close a cohort, navigate to the selected cohort, and click the edit icon in the **Action** column.



At the **Define the Cohort** screen, click the box for the selected cohort in the **Active** column to open or close a cohort. A checked box indicates “Open”, and an unchecked box indicates “Closed”. When done, click on the green check mark to save changes and exit edit mode. To cancel changes, click on the **X** under **Action**.

Admin Dashboard	Cohorts	Notifications	Patients	Study Docs	
Protocol Filter: Generic					
Cohort Treatment Assignment Setup - Generic					
501					
Define the Cohort					
Treatment	Cohort	Accrual Limit	Slots Available	Active	Action
	Test Cohort 1	100	99	☒	☒ ☐

Once you are out of the edit mode, click **Save** to save your changes.

Admin Dashboard	Cohorts	Notifications	Patients	Study Docs	
Protocol Filter: Generic					
Cohort Treatment Assignment Setup - Generic					
501					
Define the Cohort					
Treatment	Cohort	Accrual Limit	Slots Available	Active	Action
	Test Cohort 1	100	99	☒	
Define Treatment(s) for Selected Cohort					
Arm	Treatment	Accrual Limit	Active	Action	
1	Test Cohort 1	100	☒		
2	Test Cohort 2	3	☐		
3	Test Cohort 3	3	☐		
Save Cancel					

Changing Accrual Limits

To change accrual limits, navigate to the selected cohort, and click the edit icon in the **Action** column. At the **Define the Cohort** screen, change the **Accrual Limit** by entering a value in the accrual limit field for the selected cohort, and click **Save**.

When done, click on the green check mark to save changes and exit edit mode. To cancel changes, click on the **X** under **Action**.

Admin Dashboard	Cohorts	Notifications	Patients	Study Docs
-----------------	---------	---------------	----------	------------

Protocol Filter: Generic

Cohort Treatment Assignment Setup - Generic

501

Define the Cohort

Treatment	Cohort	Accrual Limit	Slots Available	Active	Action
	Test Cohort 1	100	99	☒	✓ ✗

Once you are out of the edit mode, click **Save** to save your changes.

Admin Dashboard	Cohorts	Notifications	Patients	Study Docs
-----------------	---------	---------------	----------	------------

Protocol Filter: Generic

Cohort Treatment Assignment Setup - Generic

501

Define the Cohort

Treatment	Cohort	Accrual Limit	Slots Available	Active	Action
	Test Cohort 1	100	99	☒	

Define Treatment(s) for Selected Cohort

Arm	Treatment	Accrual Limit	Active	Action
1	Test Cohort 1	100	☒	
2	Test Cohort 2	3	☐	
3	Test Cohort 3	3	☐	

Save Cancel

Please note: The numbers entered in the Accrual Limit for the 'Active' cohort in both the Define the Cohort and Define Treatment(s) for Selected Cohort sections need to match.