

Study Definition Repository (SDR)

Reference Implementation
User Interface User Guide
Version 4.0

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Document History

Version No.	Date	Author	Revision Description
V1.0	17-Mar-2022	ACN	Initial Version
V2.0	30-Jun-2022	ACN	Added Pre-requisites for certificate installation
V3.0	09-Aug-2022	ACN	Added Study Comparison in General features and added a new section for administrative features.
V4.0	01-Mar-2023	ACN	Added SoA Matrix (section 2.5) and Report Export (section 3.1) feature details. Removed certificate access pre-requisite (section 1.4) for accessing SDR RI UI.

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1. Introduction

1.1. Overview

The UI application of the SDR Reference Implementation allows the user to view and search Study Definitions. The RI UI features include -

- Authentication (implemented using MSAL)
- List Study Definitions and View Details including SoA Matrix
- Search Study Definitions
- View Revision History for a Study
- Compare Study Versions and Different Studies
- Administrative Features
 - o Manage study access with users and groups management
 - System Usage Report

1.2. Scope of Document

This document details the list of UI features available in Study Definition Repository Reference Implementation and provides steps for navigation. The technical design and implementation of these features is out of scope.

1.3. Intended Audience

The document is a guide for users/vendors who want to view and search the study definitions using SDR RI UI.

1.4. Prerequisites

While the SDR is vendor-agnostic, the Reference Implementation uses Azure and MSAL to establish authentication on SDR RI UI. User should be part of Azure Active Directory of SDR Azure subscription to login to SDR RI UI.

1.5. Definitions and Acronyms

Term / Abbreviation	Definition
API	Application Programming Interface
DDF	Digital Data Flow
MSAL	Microsoft Authentication Library
SDR	Study Definition Repository

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URL	Uniform Resource Locator

2. SDR RI UI - General Features

SDR RI UI Implementation has following features.

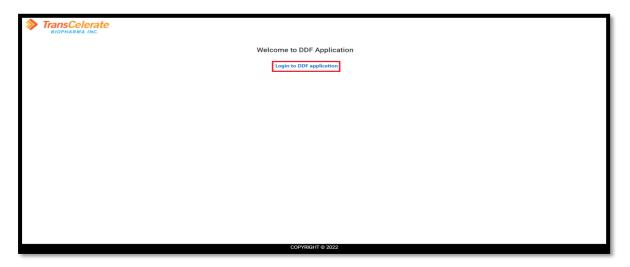
2.1. Login

This feature allows the user to login to the application.

NAVIGATION STEPS:

i. Launch the SDR website.

Figure 1 Login Page

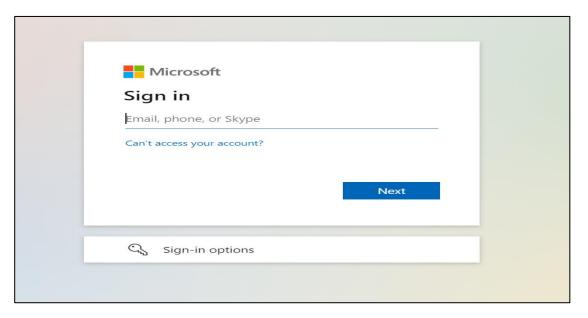


ii. On click of login link, user is redirected to provide credentials as shown below.

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Figure 2 Sign in Page



On successful authentication, user is redirected to the Home Page.

2.2. Recent Activity Widget

On the Home Page, the Recent Activity Widget screen shows the list of Study Definitions modified over the last 30 days, with most recently modified definitions on the top. The top 20 documents are listed first, and the remaining come into view as the user scrolls.

Figure 3 Recent Activity Widget



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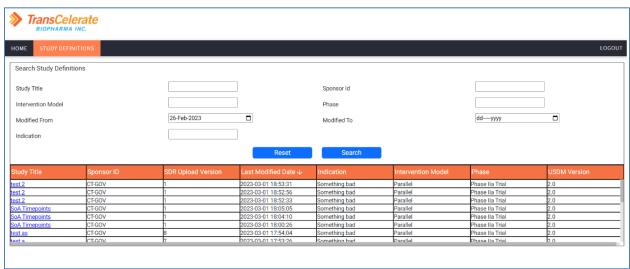


2.3. Search Study Definitions

NAVIGATION STEPS:

i. On click of Search Study Definitions in the left menu, user can navigate to search page, where it allows user to search specific study with certain search parameters.

Figure 4 Search Study page



ii. On entering the search parameters, click on Search to get the matching study definitions. At least one search parameter is mandatory. Below is the list of search parameters:

Field Name	Field Type
Study Title	Plain Text. Allows alphanumeric characters only.
Sponsor Id	Plain Text. Allows alphanumeric characters and "." Character only.
Intervention Model	Plain Text with Suggestions
Phase	Plain Text with Suggestions
Modified From	Date Picker
Modified To	Date Picker
Indication	Plain Text. Allows alphanumeric characters only.

iii. Columns in the search results are sortable (ascending/descending).

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- iv. The top 20 documents are listed first, and the remaining results come into view as the user scrolls.
- v. For multi-value fields like Sponsor Id and Interventional Model, the first value from the list will be displayed as a link. On clicking the link all the values are displayed in the modal. If there is only one value, it will be displayed as text.

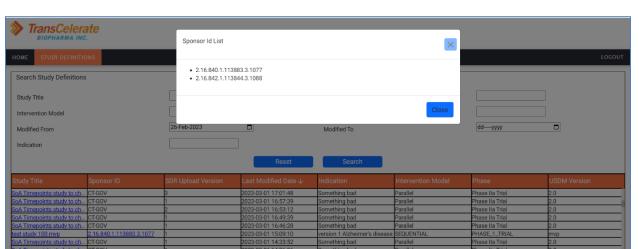


Figure 5 Multiple Value Popup

2.4. Study Details

On click of any study title link from either Recent Activity widget or from Search results, study details page will be displayed, grouped by sections. User can expand each section to view detailed information as shown below.

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Figure 6 Study Details Page from Home

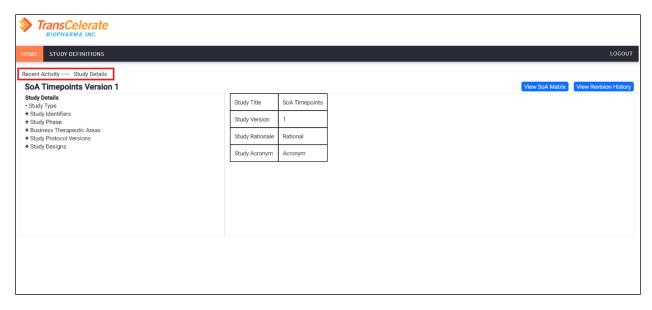


Figure 7 Study Details page from Search Grid



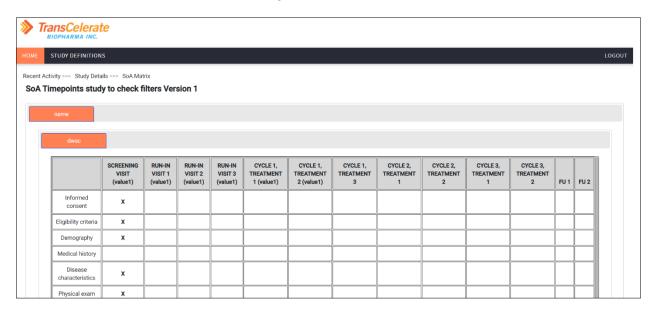
2.5. SoA Matrix (Schedule of Activities)

The SoA Matrix shows the tabular representation of the schedule of activities for a given Schedule timeline under a Study Design. The SoA displays the mapping of encounters and activities in a matrix along with basic timing related information. This screen displays the SoA matrix for all study designs and schedule timelines under the (one table per schedule timeline per study design within tabs) as shown below.

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Figure 8 SoA Matrix



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NAVIGATION STEPS:

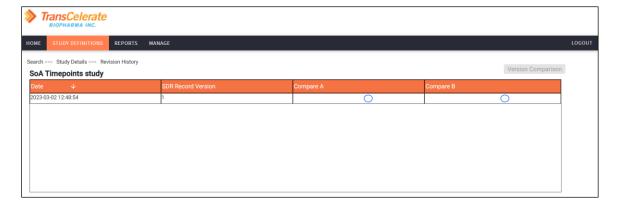
- i. On clicking View SoA Matrix on the Study Details screen, user will be redirected to viewing all SoA for a given version of the study definition.
- ii. Each study design tab will have child tabs that will display one SoA Matrix per Schedule Timeline.
- iii. When there is no study design or no timelines defined in the selected study version, the appropriate message is shown to user indicating there is insufficient data to build the matrix.
- iv. When there is duplicate entries, repeated mappings will be shown to notify user of the discrepancy.

2.6. Revision History

NAVIGATION STEPS:

- On click of View Revision History on the Study details page, revision history page for the study will be loaded. This screen allows the user to view the version history for the study definition selected.
- ii. Columns in the results are sortable (ascending/descending).
- iii. User can compare any two versions by selecting the corresponding radio buttons in columns "Compare A" and "Compare B".

Figure 9 Revision History Page



2.7. Version Comparison

NAVIGATION STEPS:

- On click of Version Comparison in the revision history screen (as shown in Figure 9), version comparison page will be loaded. This screen allows the user to compare two versions of the same study.
- ii. User can navigate between the pages using the breadcrumb navigation.

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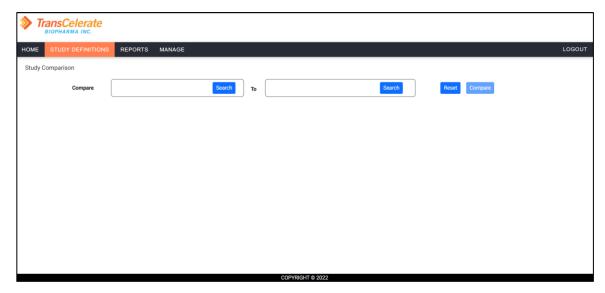
Figure 10 Version Comparison page

2.8. Study Comparison

NAVIGATION STEPS:

i. On click of Compare option in the Study Definitions menu as shown in below screenshot, study comparison page will be loaded. This screen allows the user to do a side-by-side comparison of two different study definitions.

Figure 11 Study Compare Page



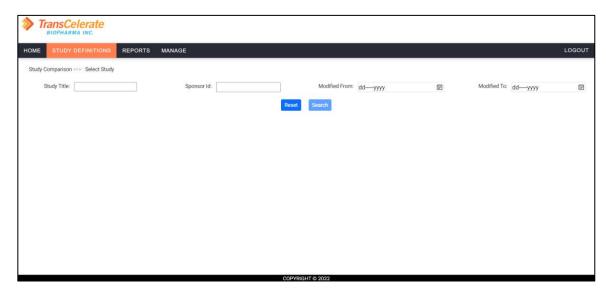
ii. User can search any two studies to compare by using the search feature on the left and right sides of the compare. At any point, only two studies can be compared.

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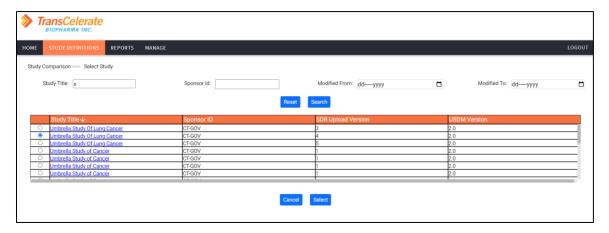
iii. Once the user clicks on search, user is shown a screen to select a study by providing a criterion and finding the relevant study for comparison. The user can search the study by Study title, Sponsor ID and modified date range.

Figure 12 Search study compare page



iv. Once the relevant study is found on search, user can click Select to add to compare.

Figure 13 Study Comparison - Search Results



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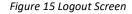
Figure 14 Study Comparison page

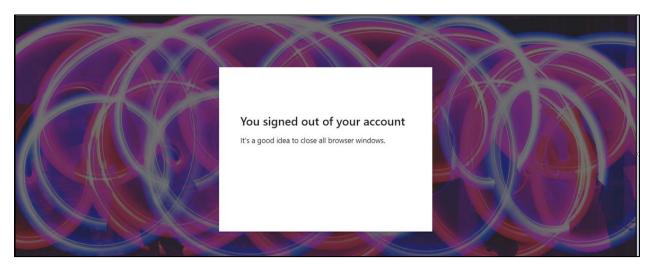


- v. Once two studies have been searched and selected on the left and right comparison boxes, user can click Compare.
- vi. The application loads a side-by-side content comparison of the study definition JSONs. The comparison highlights the differences and user can scroll through comparison or directly jump to a difference by clicking the comparison highlights on the scrollbar.
- vii. User can go back to the study comparison screen by clicking on the breadcrumb navigation.

2.9. Logout

On click of Logout, user will be logged out from the application, and gets redirected to the Login Page.





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3. SDR RI UI - Administrative features

This section explains the features available to a SDR Administrative user only. The menu options for these features are not visible to a non-admin user in the main menu.

3.1. System Usage Report

The System Usage Report lists all the API calls made to the SDR application for a given duration. Information is limited to the endpoint called, the HTTP Operation, Sender ID, the calling IP address, HTTP response code and request date.

NAVIGATION STEPS:

i. On click of System Usage option in the Reports menu as shown in below screenshot, system usage report screen will be loaded. By default, the report is loaded for the current day.

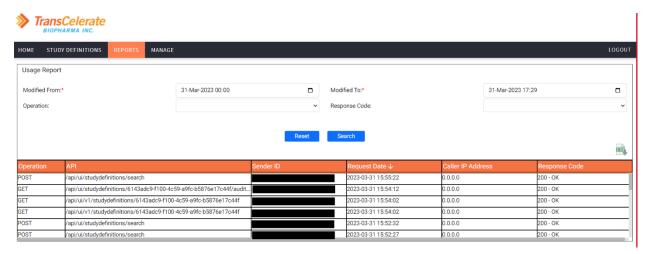


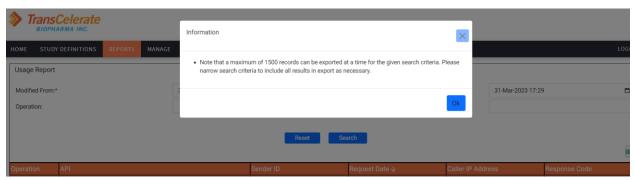
Figure 16 System usage report page

- ii. User can change the duration of the report generated to see system usage for a maximum range of 30 days.
- iii. The results can be further filtered by Response code to see only success or failures or a specific HTTP response status code.
- iv. The report columns in the grid are sorted in descending order of Request date by default. All except Sender ID columns in the result grid are sortable.
- v. User can export the full results of the search request using the Export to CSV icon on the top right of the results grid. A generic message that a maximum of 1500 records can be exported in a single download is shown to the user on click.

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Figure 17 Export Download Limit



vi. When the user changes the search criteria, the export to CSV is disabled and user must execute a search request to be able to export results.

3.2. Group and User Management

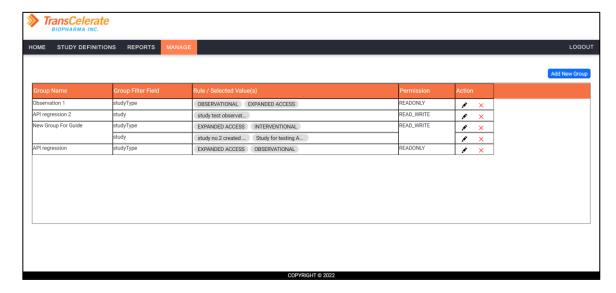
The group and user management features provide the ability to group users and associate them with specific study or group of studies to limit access for users only to those study definitions. The creation of groups and setting their criteria as well as associating users to these groups can be done only by an Admin user in the SDR application.

3.2.1. Group Management

NAVIGATION STEPS:

- i. An admin user can navigate to the Group Management screen from the Manage main menu.
- ii. On the Group Management screen, user can Add new groups as well as edit existing groups.
- iii. By default, the list of existing groups is displayed on the home screen of Group Management.

Figure 18 Group Management page

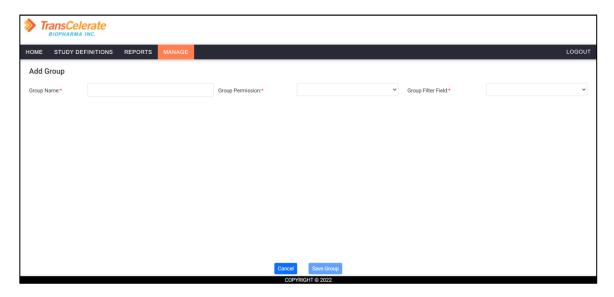


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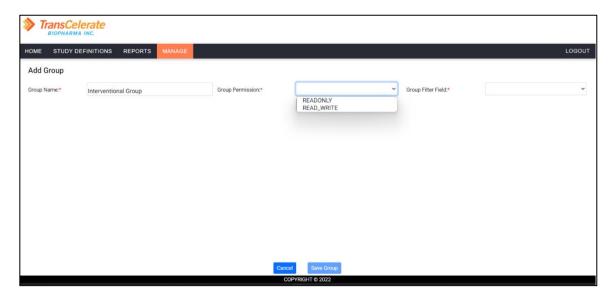
iv. For adding a new group user can click on Add New Group button. User is then redirected to create a new Group.

Figure 19 Add Group page



- v. Groups should have a distinct name throughout the system. Only Alphanumeric characters are allowed in the name with a maximum length of 20 characters.
- vi. The Group Permissions allow the admin user to set the access privilege for users belonging to this group i.e., users can either READ or READ & WRITE the studies associated with this group.

Figure 20 Group Management - Permissions

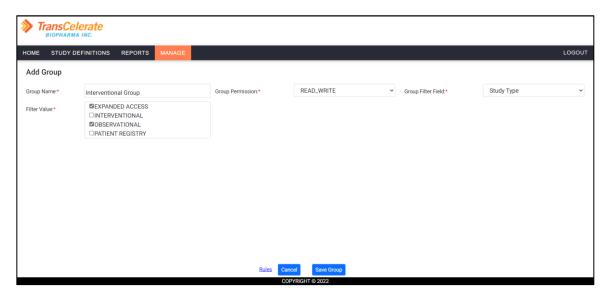


vii. The Group Filter Field allows the admin user to configure the rule that combines one or more studies to be associated with a group. When Study Type filter is selected, one or more study types can be selected and added to the rule.

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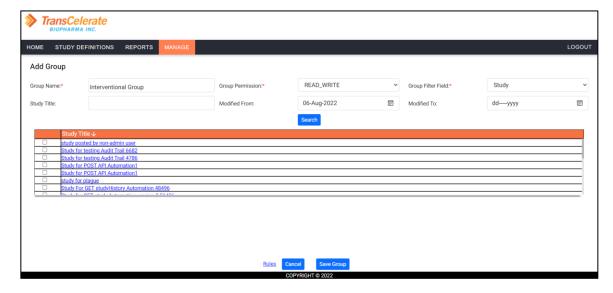


Figure 21 Create New Group



viii. In addition to Study Type, even specific studies can be searched by selecting the Group Filter Field as Study, which will then allow user to search studies and select them to add to the Group rule.

Figure 22 Group Management - Search Studies



- ix. Group Rules can have filters with just one filter field or a combination of available filter fields.
- x. At any point in time, the current rule configuration on the Group can be seen by clicking on the Rules link at the bottom.

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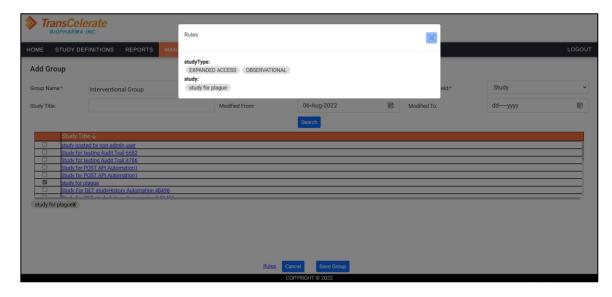


Figure 23 Group Management - Rules

- xi. Once the rule has been configured, user can click Save Group to create the Group.
- xii. All studies that satisfy the rule on a group will be accessible to users belonging to that group. The permission selected on the group will govern the access level (READ or READ & WRITE)
- xiii. Existing Groups can be edited from the home screen of the Group Management feature.
- xiv. Groups can be deleted using the delete action on the list of groups table. Each Group filter field in a group can be individually deleted and when the last group filter is deleted, the Group is also deleted.
- xv. Note that, when a user creates a new study the group mapping is required to be done by an Admin user if the study does not qualify for any rules on any existing groups in the system.
- xvi. Also note that, any user having association with at least one group where they have READ & WRITE permissions can create a new study in SDR. If user belongs to groups which are configured to have only READ permissions, user cannot add/edit study definitions.

3.2.2. User Management

This screen allows admin users to map existing users in the system to Groups. Note that this screen is not to onboard or provision access to new users to SDR system.

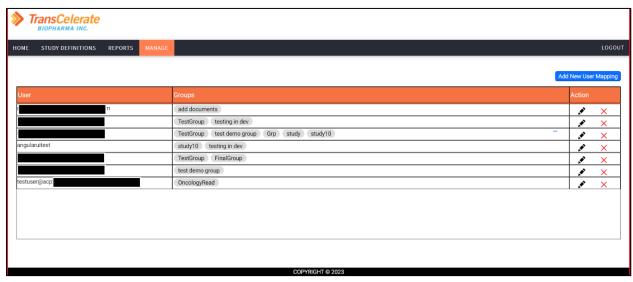
NAVIGATION STEPS:

i. An admin user can navigate to the User Management screen from the Manage main menu by selecting User option.

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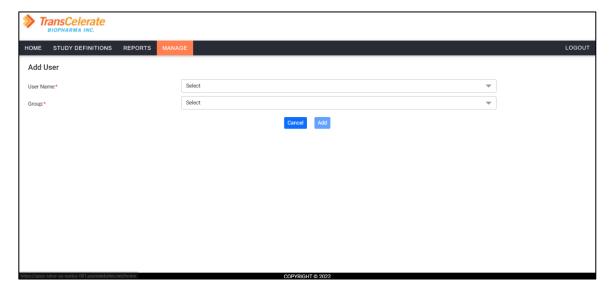
Figure 24 Group management page



This feature allows the admin user to associate users to one or more groups. By default, the existing list of user mappings are loaded on the home screen of this feature.

ii. To create a new user mapping, admin can click on Add New User Mapping.

Figure 25 Add user page

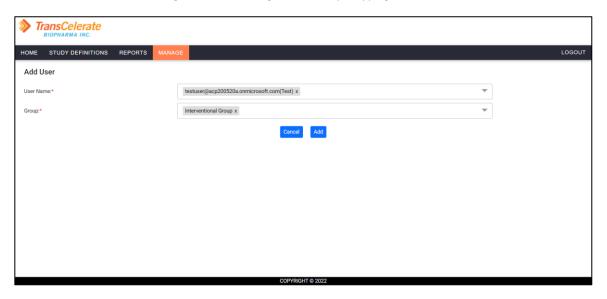


- iii. On Add User screen, admin can search and select a user to whom a group association needs to be added.
- iv. Once the user is selected, in the Group dropdown one or more groups can be selected and on clicking Add the mapping can be saved.

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Figure 26 User Management - Group Mapping



- v. To edit the group association for a specific user, admin can click edit on that user in the mappings table and add/remove group associations.
- vi. Group associations can be deleted from the mappings table which will remove all group associations & revoke access for user to all data in the system.

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