

Study Definition Repository (SDR)

Reference Implementation
User Interface User Guide
Version 3.0

Disclaimer

These materials and information are provided by TransCelerate Biopharma Inc. AS IS. Any party using or relying on this information and these materials do so entirely at their own risk. Neither TransCelerate nor its members will bear any responsibility or liability for any harm, including indirect or consequential harm, that a user may incur from use or misuse of this information.



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.

V3.0 2 of 25



Contents

1.	Intr	roduction	5
	1.1.	Overview	5
	1.2.	Scope of Document	5
	1.3.	Intended Audience	5
	1.4. P	rerequisites	5
	and A	Acronyms	9
2.	SD	R General UI features	9
	2.1.	Login	9
	2.2.	Recent Activity Widget	11
	2.3.	Search Study Definitions	11
	2.4.	Study Details	13
	2.5.	Audit Trail	14
	2.6.	Version Comparison	15
	2.7.	Study Comparison	16
	2.8.	Logout	18
3.	SD	R Administrative UI features	19
	3.1.	System Usage Report	19
	3.2.	Group and User Management	20
	3.2	2.1. Group Management	20
	3.2	2.2. User Management	24



Table of Figures

Figure 1 Certificate Import Wizard	6
Figure 2 File to Import	6
Figure 3 Certificate Password	7
Figure 4 Certifcate Store Selection	7
Figure 5 Certifcate Finish Wizard	8
Figure 6 Certificate Prompt	8
Figure 7 Credintial Required Prompt	9
Figure 8 Login Page	10
Figure 9 Sign in Page	10
Figure 10 Selection of certificate	11
Figure 11 Recent Activity Widget	11
Figure 12 Search Study page	12
Figure 13 Multiple Value Popup	13
Figure 14 Study Details Page from Home	13
Figure 15 Study Details page from Search Grid	14
Figure 16 Audit Trail Page	15
Figure 17 Version Comparison page	15
Figure 18 Study Compare Page	16
Figure 19 Search study compare page	17
Figure 20 Study Comparison page	18
Figure 19 Logout Screen	19
Figure 22 System usage page	20
Figure 23Figure 23 Group Management page	21
Figure 24 Add Group page	21
Figure 25 Group management page	24
Figure 26 Add user page	25



1. Introduction

1.1. Overview

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

- List Study Definitions and Details
- Search Study Definitions
- View Audit Trail for a Study
- Compare Study Versions

1.2. Scope of Document

This document details the list of UI features available in Study Definition Repository 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 UI.

1.4. Prerequisites

- User should be part of Azure Active Directory of SDR Azure subscription.
- Certificate Installation for accessing SDR User Interface

Below are the steps for certificate installation on the local PC for accessing the SDR User Interface.

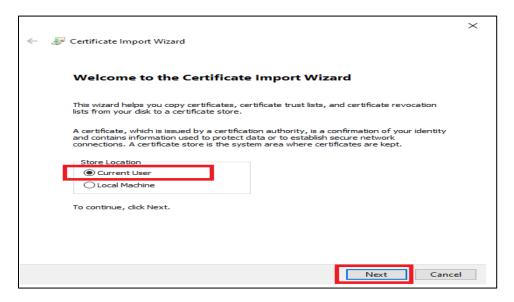
NAVIGATION STEPS:

- i. Double click the .pfx certificate file.
- ii. Select "Current user" option and click next.

V3.0 5 of 25

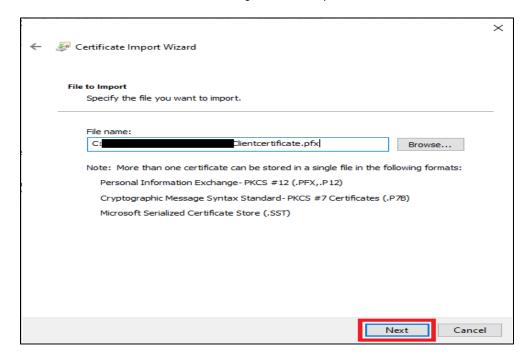


Figure 1 Certificate Import Wizard



iii. File to Import: Leave default values and click next

Figure 2 File to Import

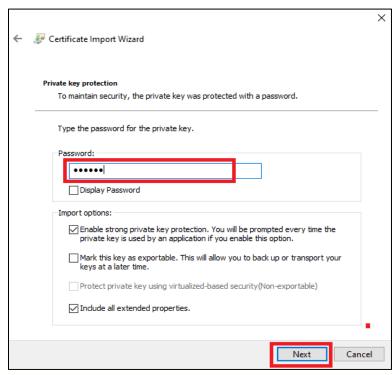


iv. Provide the certificate password and click next

V3.0 6 of 25

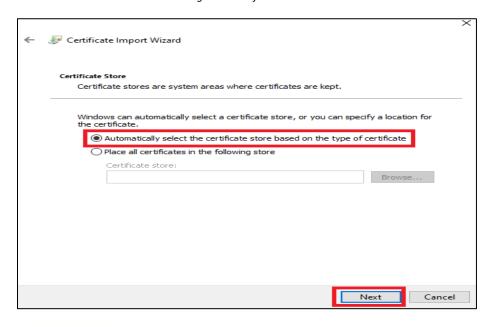


Figure 3 Certificate Password



v. Choose "Automatically select the certificate store" option and click next.

Figure 4 Certifcate Store Selection

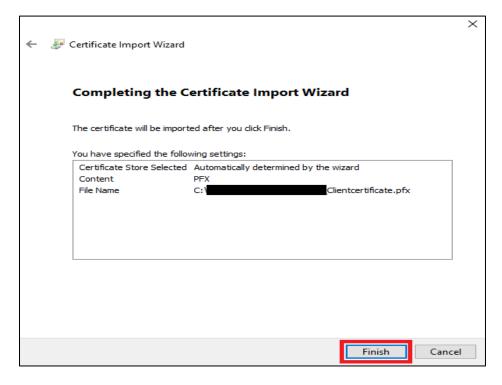


vi. Click on finish

V3.0 7 of 25

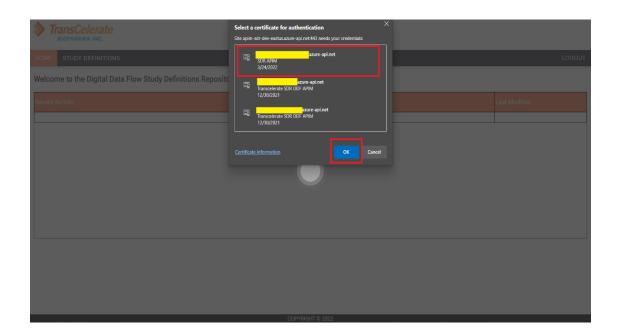


Figure 5 Certifcate Finish Wizard



vii. The browser will prompt for a certificate when accessing the SDR application after successful login. Select the installed certificate to access the application.

Figure 6 Certificate Prompt

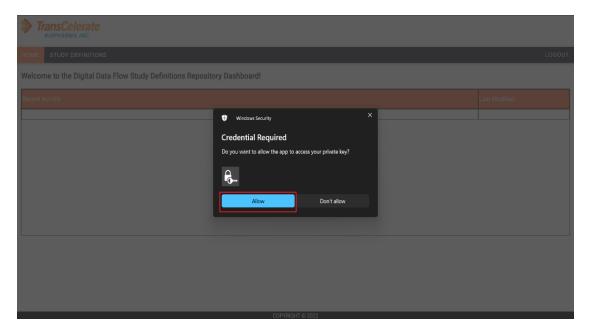


V3.0 8 of 25



viii. Click on "Allow" if the below prompt appears in the taskbar/browser.

Figure 7 Credintial Required Prompt



1.5. Definitions and Acronyms

Term / Abbreviation	Definition
API	Application Programming Interface
DDF	Digital Data Flow
SDR	Study Definition Repository
URL	Uniform Resource Locator

2. SDR General UI features

SDR 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.

V3.0 9 of 25



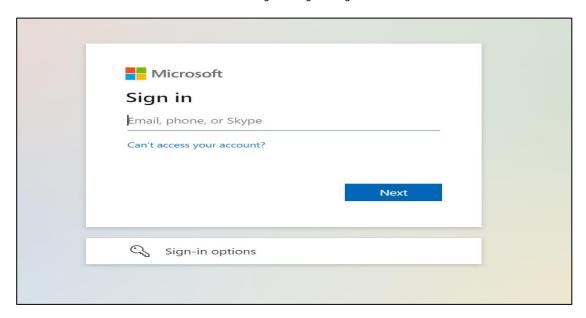
Figure 8 Login Page





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

Figure 9 Sign in Page



iii. On successful authentication, user is redirected to the Home Page. When prompted user must select the environment specific client certificate.

V3.0 10 of 25



Select a certificate suffericate yourself to apim-sdr-qa-eastus.acure-apinet443

Solyect source spinet Insure spinet443

Solyect source Serial source spinet443

Solyect source Serial source spinet443

Solyect source Serial source spinet443

Solyect source spinet Insure spinet443

Solyect source Serial source spinet443

Solyect source Serial source spinet443

Solyect source spinet Insure spinet443

Solyect source spinet444

Solyect source spinet444

Certificate information Series source spinet443

Solyect source spinet444

Solyect source spinet444

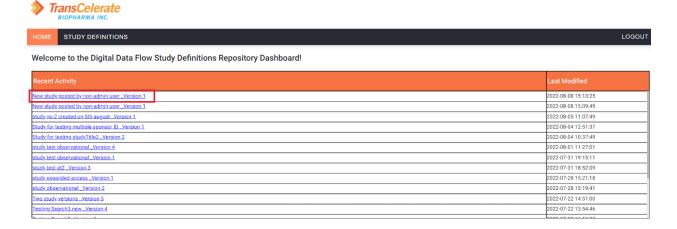
Certificate information Series sour

Figure 10 Selection of certificate

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 11 Recent Activity Widget



2.3. Search Study Definitions

NAVIGATION STEPS:

V3.0 11 of 25



New study posted by non-admin... 0 study no.2 created on 5th august

patient registry2.1

Study for testing multiple spons.

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.

TransCelerate
BIOPHARMA INC.

HOME STUDY DEFINITIONS

Search Study Definitions

Study Title Sponsor Id
Intervention Model Phase

Modified From 01-Aug-2022 Modified To
Indication

Reset Search

2022-08-08 15:13:25

2022-08-05 11:07:49

022-08-04 12:51:37

Something bad

mething bad

SEQUENTIAL

EQUENTIAL

PHASE 0 TRIAL

PHASE 0 TRIAL

PHASE 0 TRIAL

Figure 12 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).
- iv. The top 20 documents are listed first, and the remaining results come into view as the user scrolls.
- v. For multi values field 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.

V3.0 12 of 25

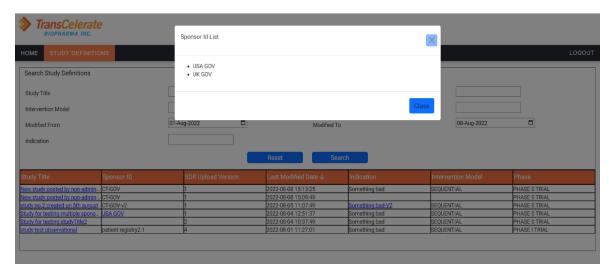


Figure 13 Multiple Value Popup

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.

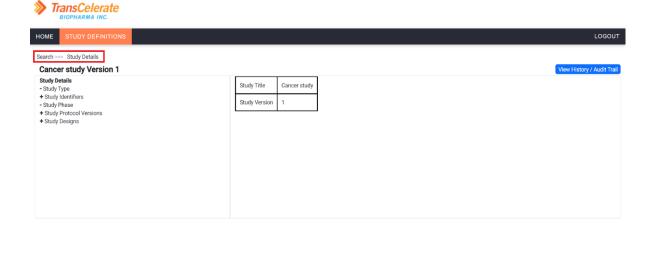
Figure 14 Study Details Page from Home



V3.0 13 of 25



Figure 15 Study Details page from Search Grid



COPYRIGHT © 2022

2.5. Audit Trail

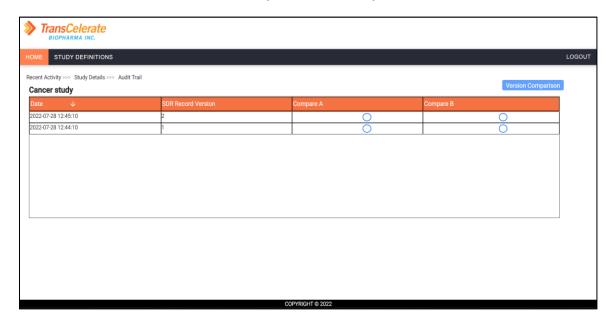
NAVIGATION STEPS:

- On click of View History / Audit Trail on the Study details page, audit trail page for the study will be loaded. This screen allows the user to view the audit 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".

V3.0 14 of 25



Figure 16 Audit Trail Page



2.6. Version Comparison

NAVIGATION STEPS:

- On click of Version Comparison in the audit trail screen (as shown in Figure 16), 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.

Figure 17 Version Comparison page



V3.0 15 of 25

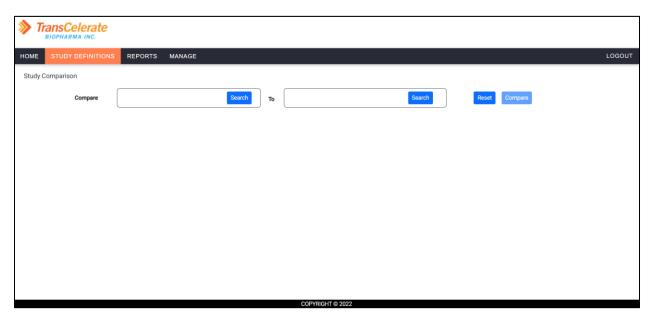


2.7. Study Comparison

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 18 Study Compare Page

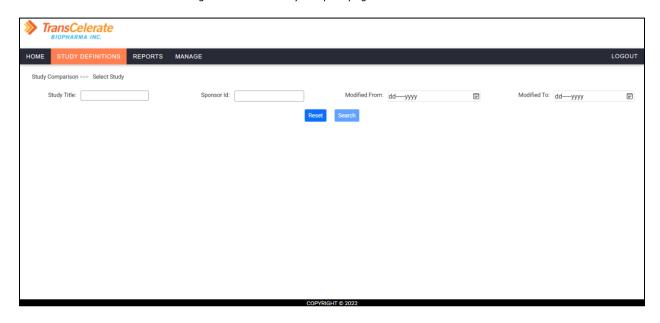


- ii. User can search any two studies to compare by using the search feature on the left and right sides of the compare. At any point, only two studies can be compared.
- iii. Once the user clicks on search, user is shown a screen to select a study by providing a criteria and finding the relevant study for comparison. The user can search the study by Study title, Sponsor ID and modified date range.

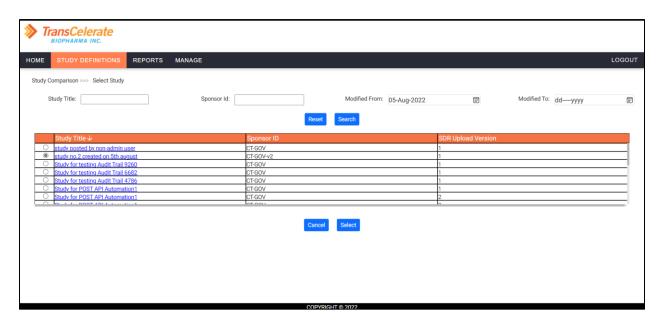
V3.0 16 of 25



Figure 19 Search study compare page



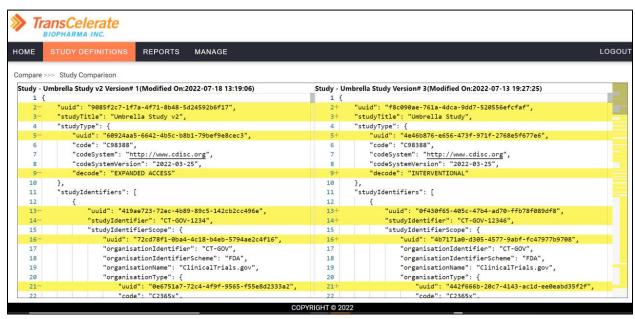
iv. Once the relevant study is found on search, user can click Select to add to compare.



V3.0 17 of 25



Figure 20 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.

SS4

vii. User can go back to the study comparison screen by clicking on the breadcrumb navigation.

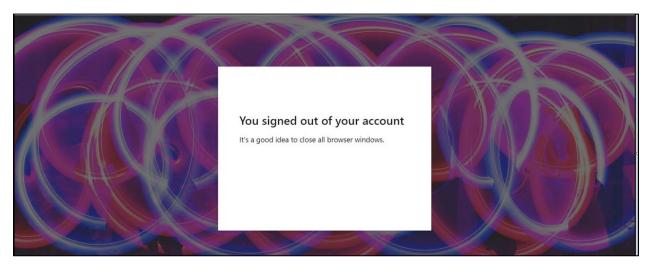
2.8. Logout

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

V3.0 18 of 25



Figure 21 Logout Screen



3. SDR Administrative UI features

This section explains the features available to a SDR Administative 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:

 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 last 7 days.

V3.0 19 of 25



ii.

TransCelerate STUDY DEFINITIONS MANAGE LOGOU HOME Usage Report Last 7 days Duration Operation Response Code POST /api/ui/admin/v1/usergroups/getusers yuvarani.nagarajan@accent... 2022-08-09 17:13:37 116.72.122.108 200 - OK /api/ui/admin/v1/usergroups/getgroups yuvarani.nagarajan@accent... 2022-08-09 16:21:28 116.72.122.108 200 - OK 116.72.122.108 POST /api/ui/admin/v1/usergroups/getgroups yuvarani.nagarajan@accent... 2022-08-09 15:58:30 200 - OK 116.72.122.108 /api/ui/admin/v1/usergroups/getgroups yuvarani.nagarajan@accent... 2022-08-09 15:45:57 200 - OK GET 116.72.122.108 200 - OK /api/v1/studydefinitions/23d0ef0a-aae4-40a0-bab4-e51... yuvarani.nagarajan@accent... 2022-08-09 15:44:22 yuvarani.nagarajan@accent... 2022-08-09 15:39:53 116.72.122.108 200 - OK /api/ui/v1/search 157.51.127.248 viswesh.mb@accenture.com 2022-08-09 15:31:04 200 - OK /api/ui/v1/reports/usage POST 157.51.127.248 200 - OK viswesh.mb@accenture.com 2022-08-09 15:30:57 /api/ui/v1/search POST 157.51.127.248 200 - OK testuser@acp200520a.onm... 2022-08-09 15:29:57 /api/ui/v1/reports/usage

COPYRIGHT © 2022

Figure 22 System usage page

- iii. User can change the duration of the report generated to see system usage for last 30 days or last 60 days as well.
- iv. The results can be further filtered by Response code to see only success or failures or a specific HTTP response status code.
- v. The report columns in the grid are sorted in descending order of Request date. All except Sender ID columns in the result grid are sortable.

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 in order 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.
- On the Group Management screen, user can Add new groups as well as edit existing groups.
- iii. By default the list of existing groups are displayed on the home screen of Group Management.

V3.0 20 of 25

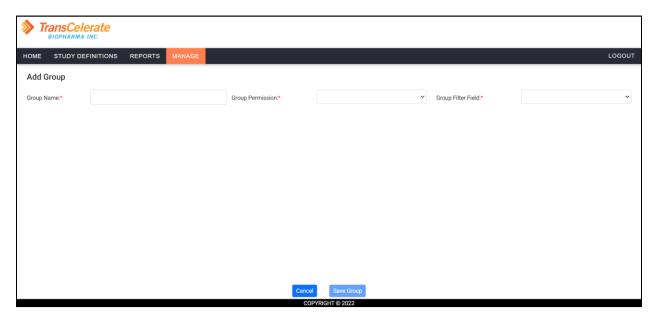


Figure 23 Figure 23 Group Management page



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

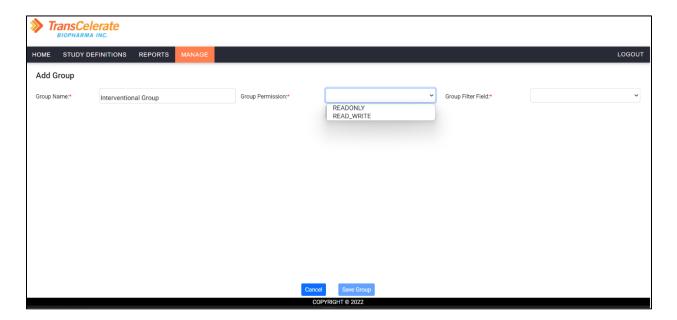
Figure 24 Add Group page



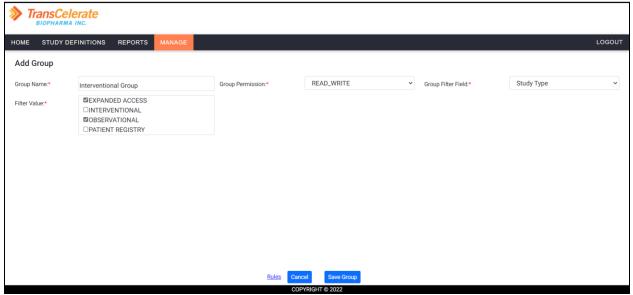
- v. Groups should have a distinct name throughout the system. Only AlphaNumeric characters are allowed in the name with a maximum length of 20 characters.
- vi. The Group Permissions allow the admin user to set the access privilege for users belonging to this group i.e. users can either READ or READ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

V3.0 21 of 25





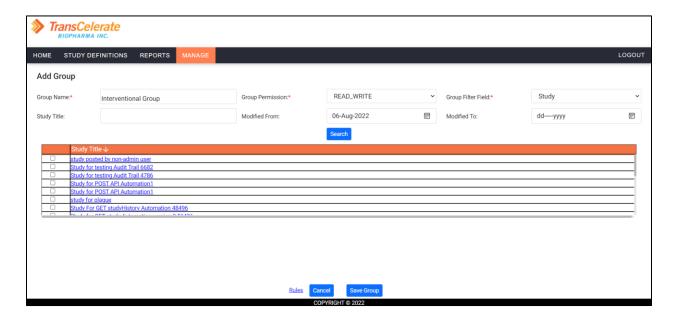
vii. The Group Filter Field allows the admin user to configure the rule that combines one or more studies to be associated with a group. When Study Type filter is selected, one or more study types can be selected and added to the rule.



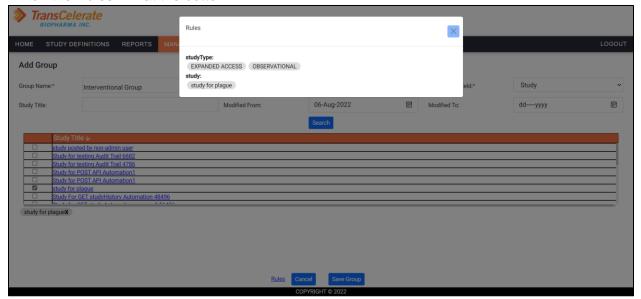
viii. In addition to Study Type even specific studies can be searched by selecting the Group Filter Field as Study, which will then allow user to search studies and select them to add to the Group rule.

V3.0 22 of 25





- 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.



- 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.

V3.0 23 of 25



- 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.
- Also note that, any user having association with at least one group where they have READ
 WRITE persmissions 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.



Figure 25 Group management page

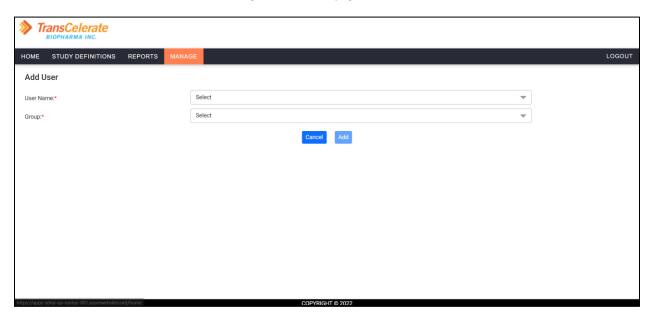
s feature allows the admin user to associate users to one or more groups. By default the existing list of user mappings are loaded on the home screen of this feature.

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

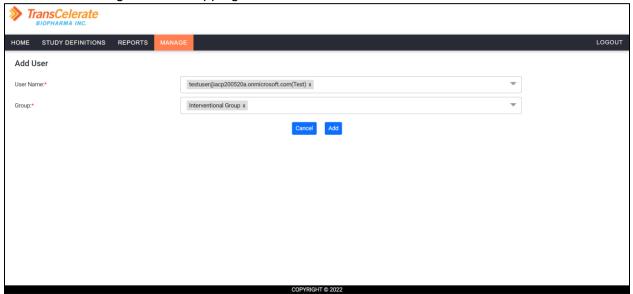
V3.0 24 of 25



Figure 26 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.



- 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.

V3.0 25 of 25