

Study Definition Repository (SDR)

Reference Implementation

User Interface User Guide

Version 3.0

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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
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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 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

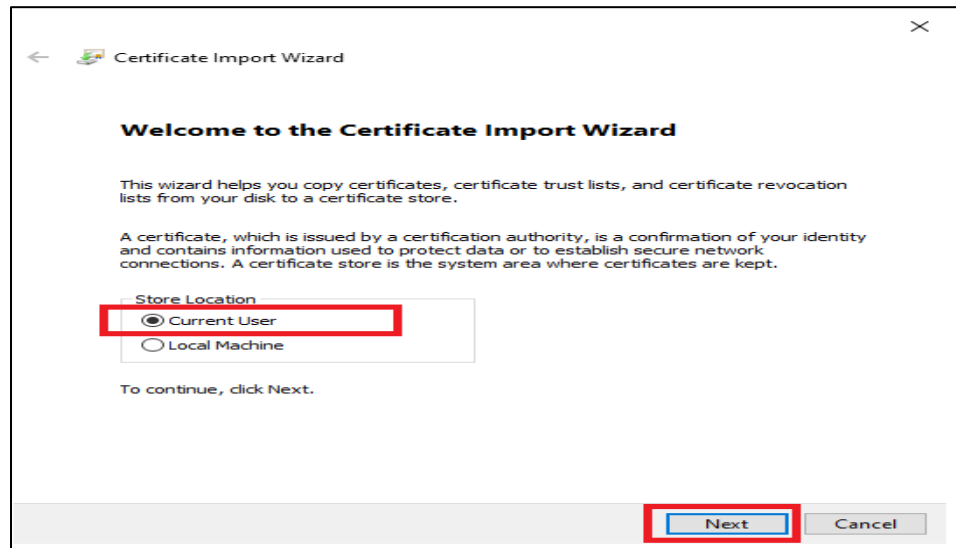
- User should be part of Azure Active Directory of SDR Azure subscription.
- Certificate Installation for accessing SDR User Interface

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

NAVIGATION STEPS:

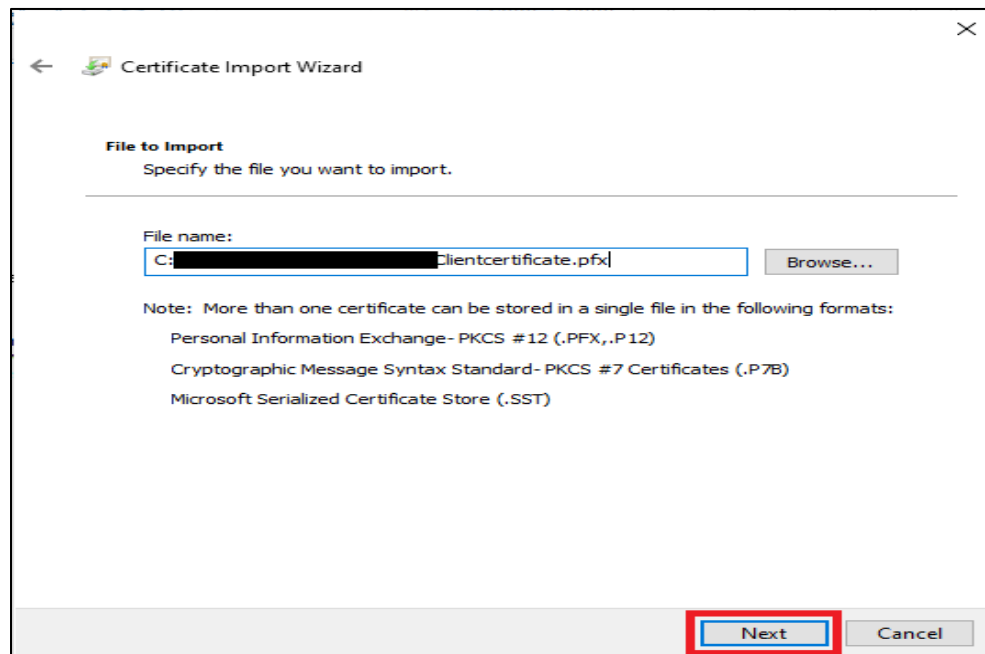
- i. Double click the .pfx certificate file.
- ii. Select "Current user" option and click next.

Figure 1 Certificate Import Wizard



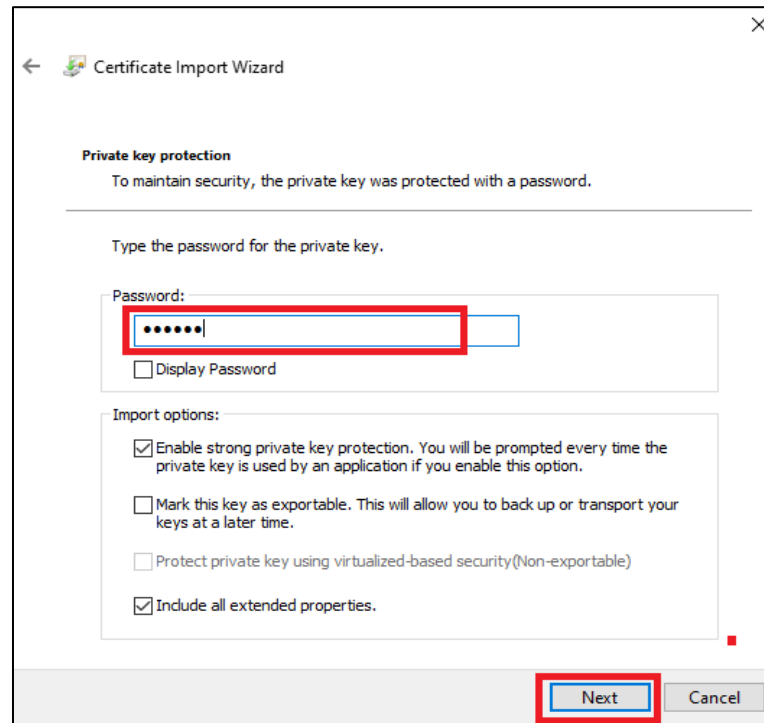
- iii. File to Import : Leave default values and click next

Figure 2 File to Import



- iv. Provide the certificate password and click next

Figure 3 Certificate Password



← Certificate Import Wizard

Private key protection
To maintain security, the private key was protected with a password.

Type the password for the private key.

Password:

☐ Display Password

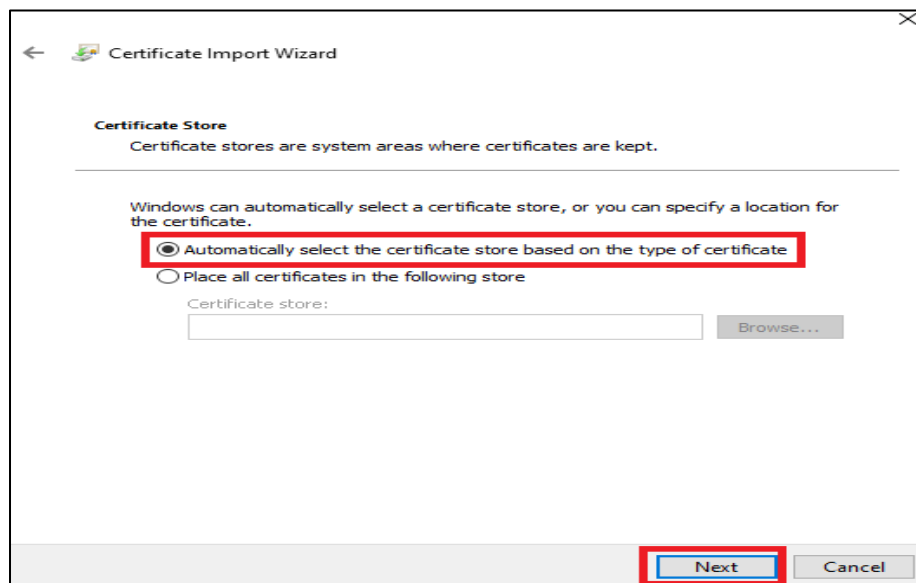
Import options:

- ☒ Enable strong private key protection. You will be prompted every time the private key is used by an application if you enable this option.
- ☐ Mark this key as exportable. This will allow you to back up or transport your keys at a later time.
- ☐ Protect private key using virtualized-based security(Non-exportable)
- ☒ Include all extended properties.

Next Cancel

- v. Choose “Automatically select the certificate store” option and click next.

Figure 4 Certificate Store Selection



← Certificate Import Wizard

Certificate Store
Certificate stores are system areas where certificates are kept.

Windows can automatically select a certificate store, or you can specify a location for the certificate.

☒ Automatically select the certificate store based on the type of certificate

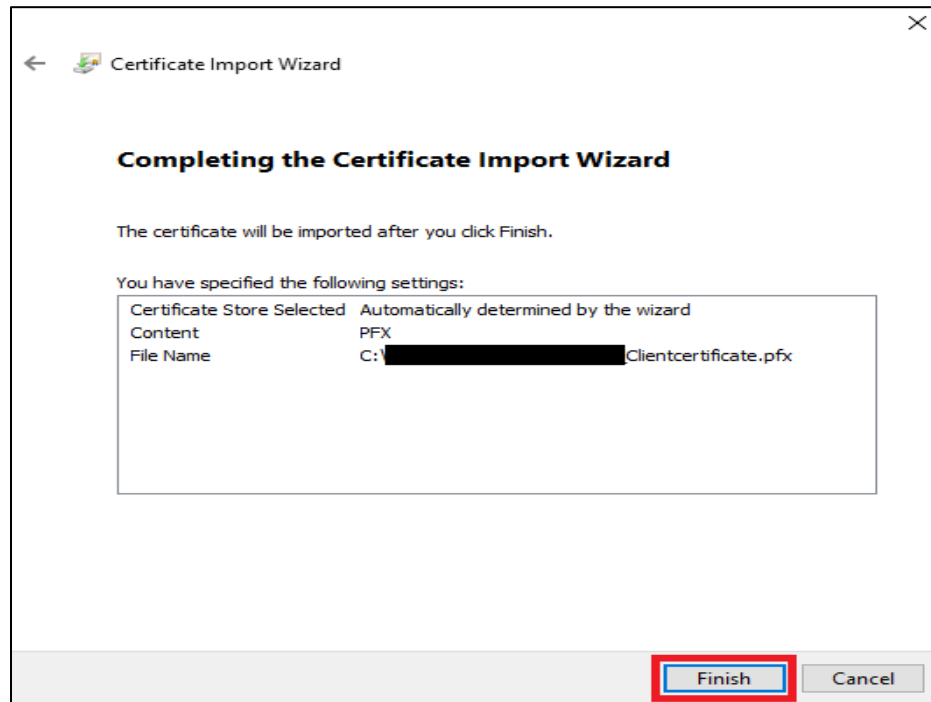
☐ Place all certificates in the following store

Certificate store: **Browse...**

Next Cancel

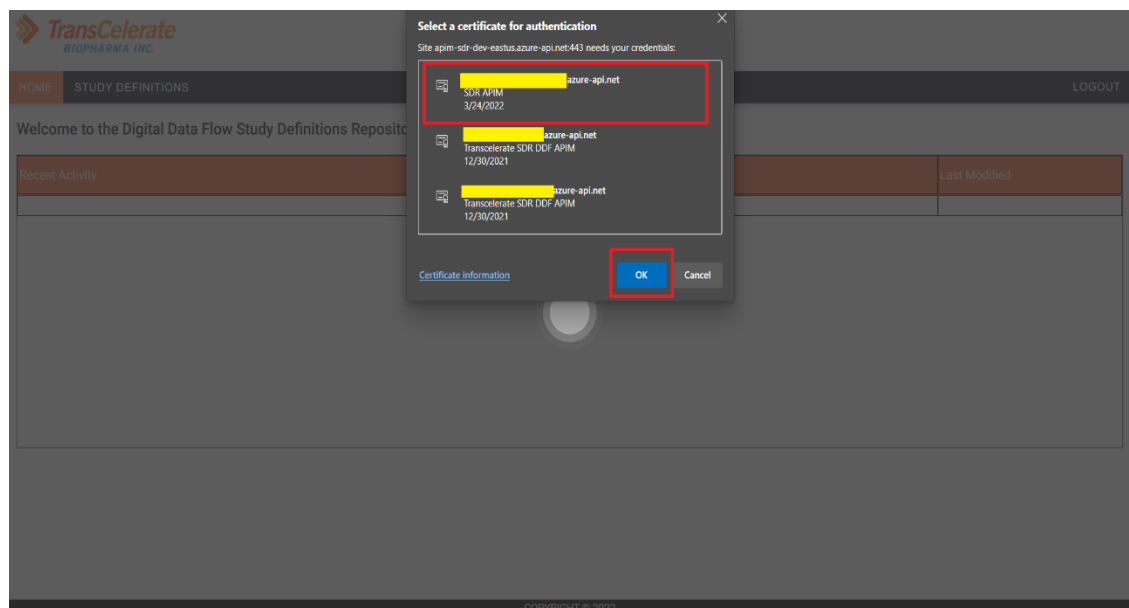
- vi. Click on finish

Figure 5 Certificate Finish Wizard



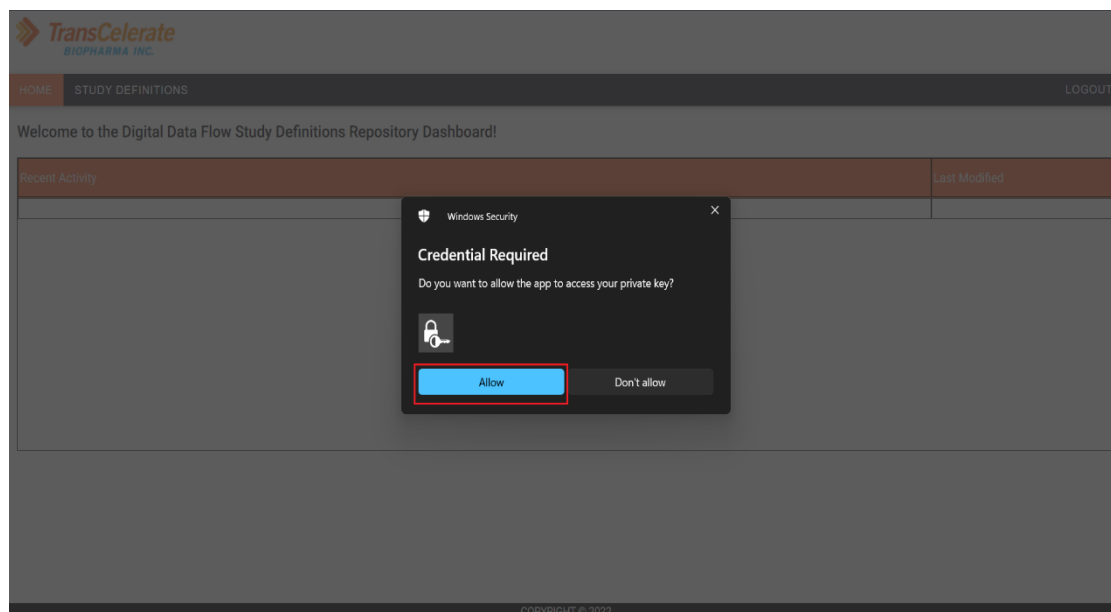
- vii. The browser will prompt for a certificate when accessing the SDR application after successful login. Select the installed certificate to access the application.

Figure 6 Certificate Prompt



- viii. Click on “Allow” if the below prompt appears in the taskbar/browser.

Figure 7 Credential 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.

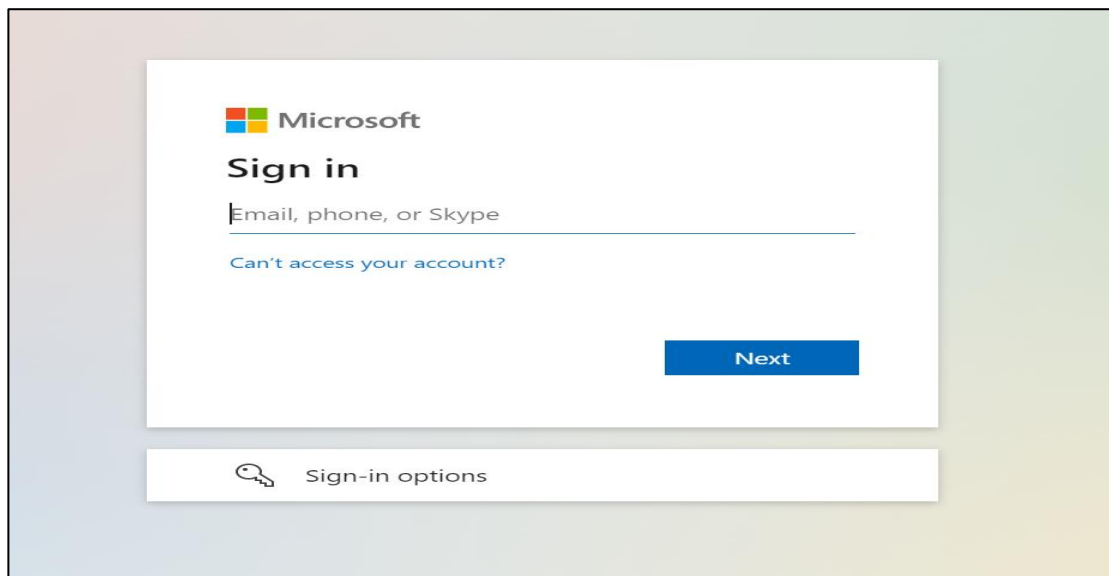
Figure 8 Login Page



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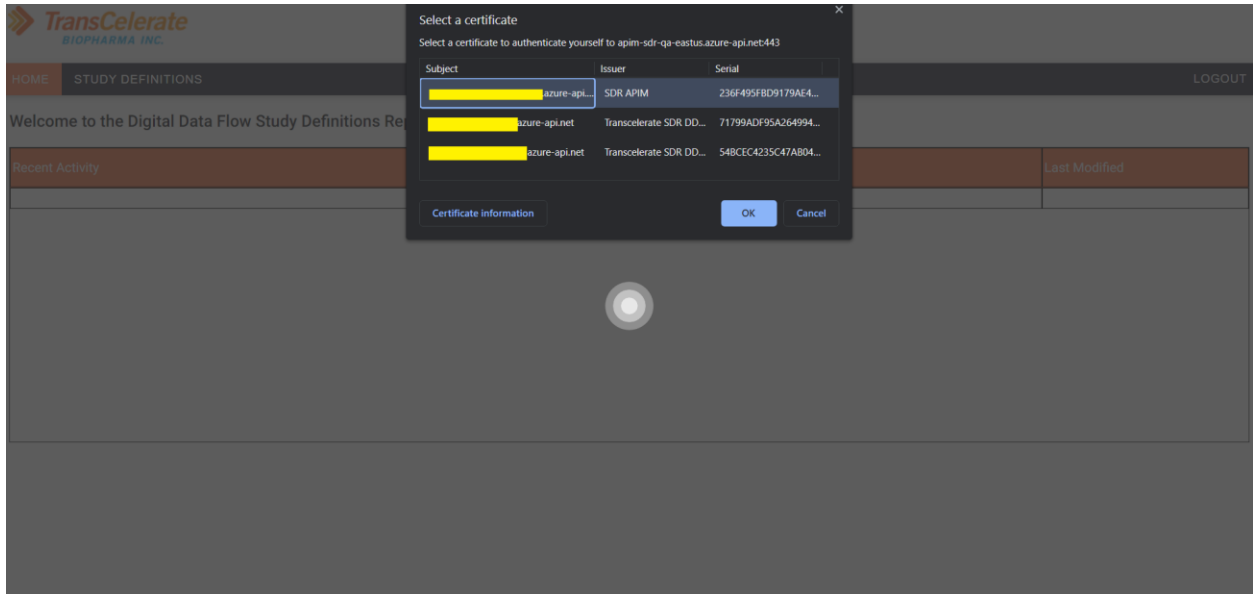
- ii. On click of login link, user is redirected to provide credentials as shown below.

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.


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



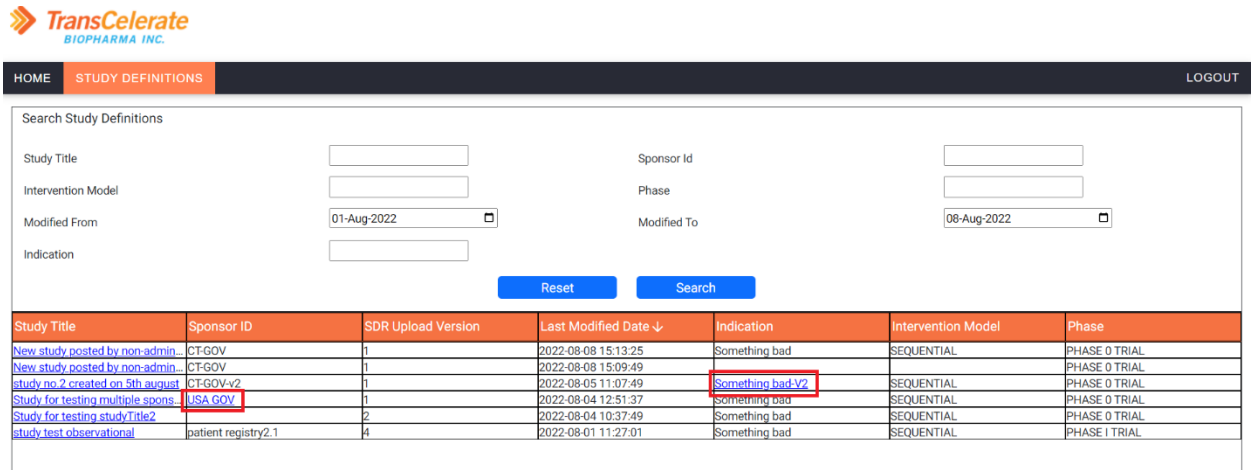
HOME STUDY DEFINITIONS LOGOUT	
Welcome to the Digital Data Flow Study Definitions Repository Dashboard!	
Recent Activity	Last Modified
New study posted by non-admin user _Version 1	2022-08-08 15:13:25
New study posted by non-admin user _Version 1	2022-08-08 15:09:49
study no 2 created on 5th august _Version 1	2022-08-05 11:07:49
Study for testing multiple sponsor ID _Version 1	2022-08-04 12:51:37
Study for testing studyTitle2 _Version 2	2022-08-04 10:37:49
study test observational _Version 4	2022-08-01 11:27:01
study test observational _Version 1	2022-07-31 19:15:11
study test at2 _Version 3	2022-07-31 18:52:09
study expanded access _Version 1	2022-07-28 15:21:18
study observational _Version 2	2022-07-28 15:19:41
Two study versions _Version 5	2022-07-22 14:51:00
Testing Search3.new _Version 4	2022-07-22 13:54:46

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 12 Search Study page



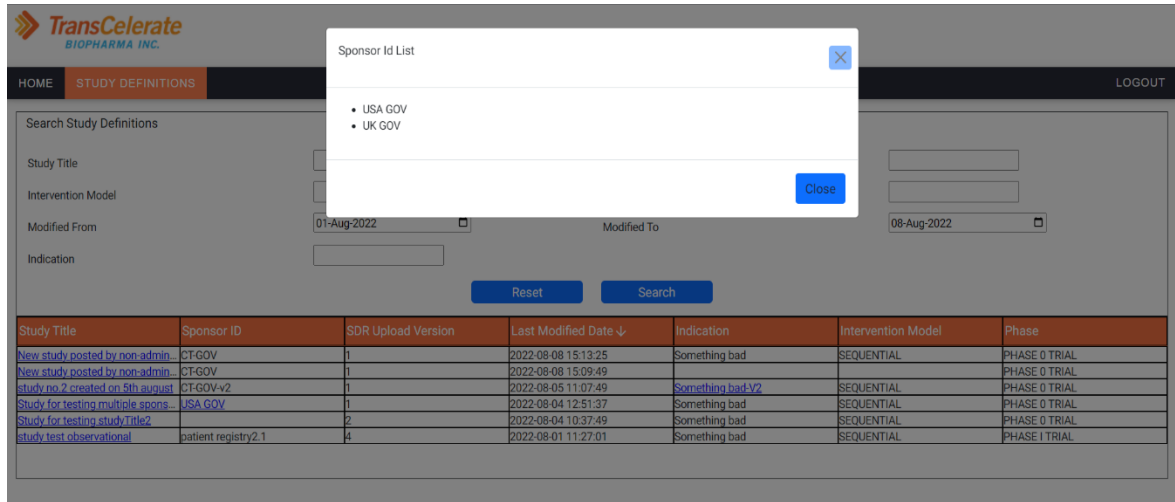
Study Title	Sponsor ID	SDR Upload Version	Last Modified Date	Indication	Intervention Model	Phase
New study posted by non-admin	CT-GOV	1	2022-08-08 15:13:25	Something bad	SEQUENTIAL	PHASE 0 TRIAL
New study posted by non-admin	CT-GOV	1	2022-08-08 15:09:49	Something bad	SEQUENTIAL	PHASE 0 TRIAL
study no 2 created on 5th august	CT-GOV-v2	1	2022-08-05 11:07:49	Something bad-V2	SEQUENTIAL	PHASE 0 TRIAL
Study for testing multiple spons	USA GOV	1	2022-08-04 12:51:37	Something bad	SEQUENTIAL	PHASE 0 TRIAL
Study for testing studyTitle2		2	2022-08-04 10:37:49	Something bad	SEQUENTIAL	PHASE 0 TRIAL
study test observational	patient registry2.1	4	2022-08-01 11:27:01	Something bad	SEQUENTIAL	PHASE I TRIAL

- 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.

Figure 13 Multiple Value Popup



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HOME STUDY DEFINITIONS LOGOUT

Search Study Definitions

Study Title

Intervention Model

Modified From 01-Aug-2022 Modified To 08-Aug-2022

Indication

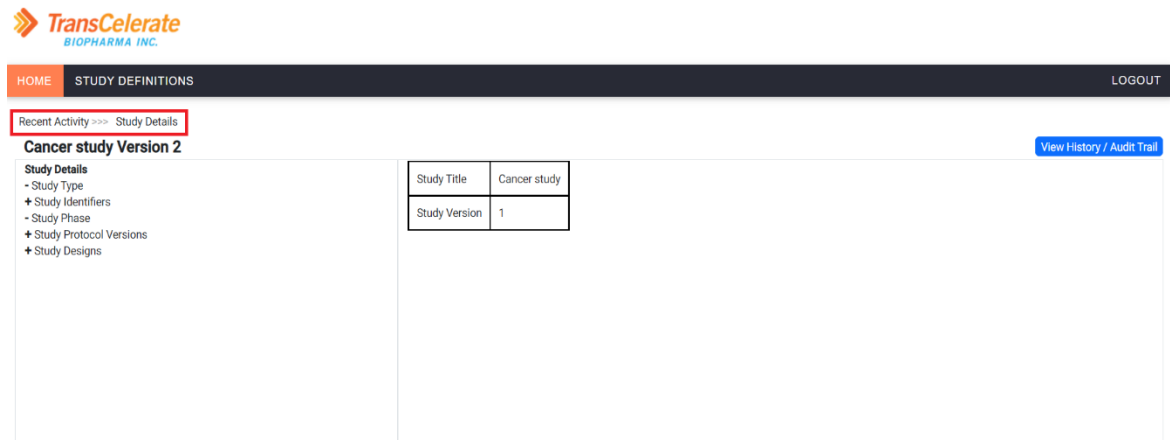
Reset Search

Study Title	Sponsor ID	SDR Upload Version	Last Modified Date ↓	Indication	Intervention Model	Phase
New study posted by non-admin...	CT-GOV	1	2022-08-08 15:13:25	Something bad	SEQUENTIAL	PHASE 0 TRIAL
New study posted by non-admin...	CT-GOV	1	2022-08-08 15:09:49	Something bad	SEQUENTIAL	PHASE 0 TRIAL
Study no 2 created on 5th august	CT-GOV-v2	1	2022-08-05 11:07:49	Something bad-V2	SEQUENTIAL	PHASE 0 TRIAL
Study for testing multiple spons...	USA GOV	1	2022-08-04 12:51:37	Something bad	SEQUENTIAL	PHASE 0 TRIAL
Study for testing studyTitle2		2	2022-08-04 10:37:49	Something bad	SEQUENTIAL	PHASE 0 TRIAL
Study test observational	patient registry2.1	4	2022-08-01 11:27:01	Something bad	SEQUENTIAL	PHASE 1 TRIAL

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



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HOME STUDY DEFINITIONS LOGOUT

Recent Activity >>> Study Details

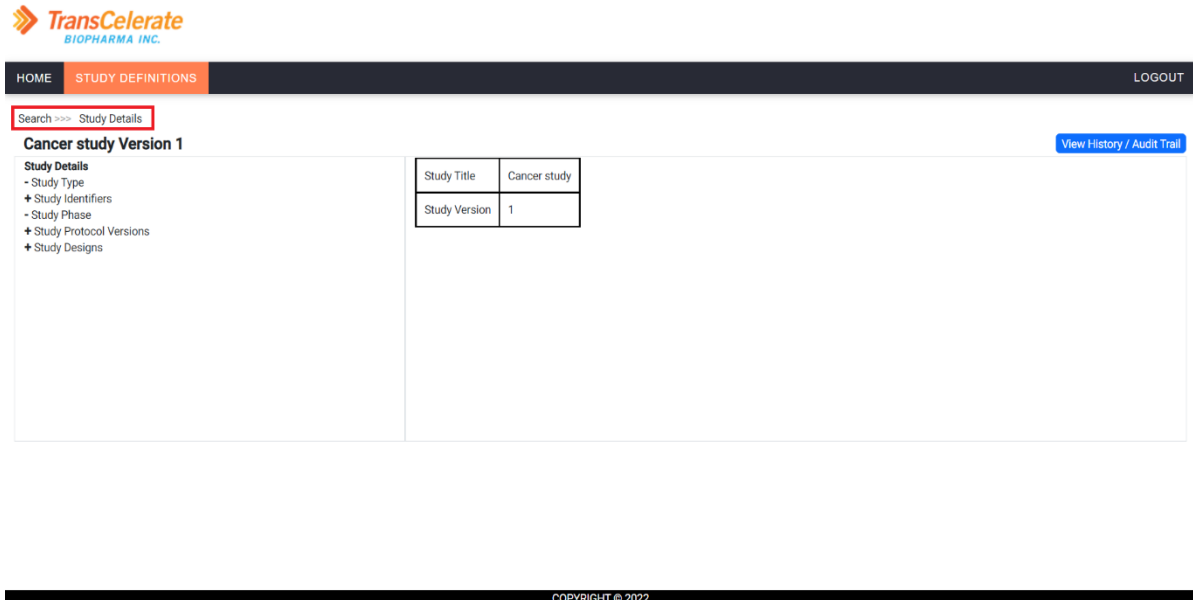
Cancer study Version 2 [View History / Audit Trail](#)

Study Details

- Study Type
- Study Identifiers
- Study Phase
- Study Protocol Versions
- Study Designs

Study Title	Cancer study
Study Version	1

Figure 15 Study Details page from Search Grid

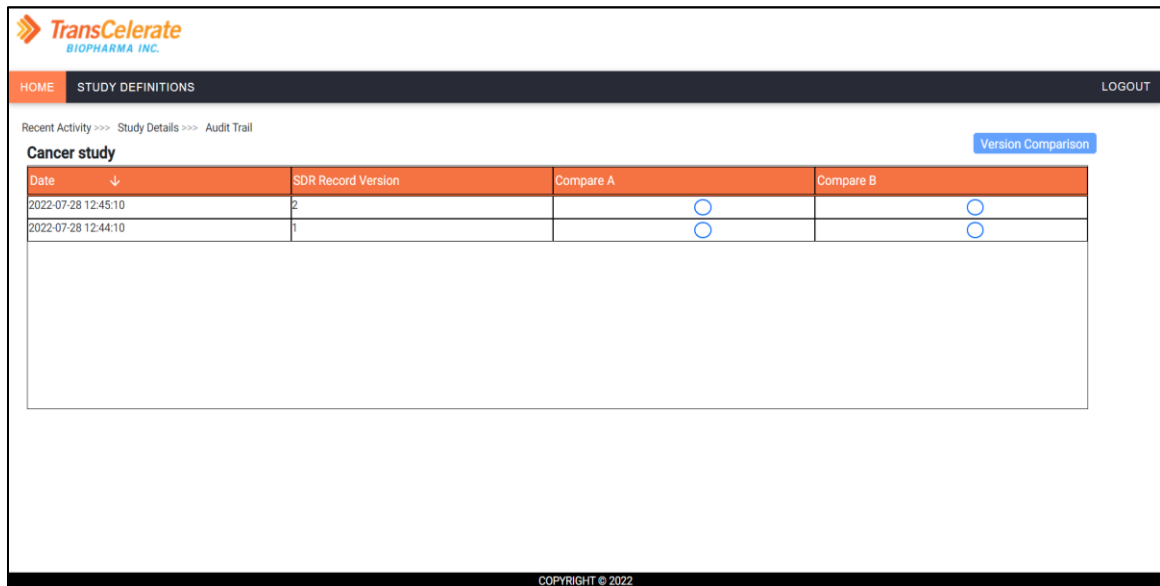


2.5. Audit Trail

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.
- Columns in the results are sortable (ascending/descending).
- User can compare any two versions by selecting the corresponding radio buttons in columns "Compare A" and "Compare B".

Figure 16 Audit Trail Page



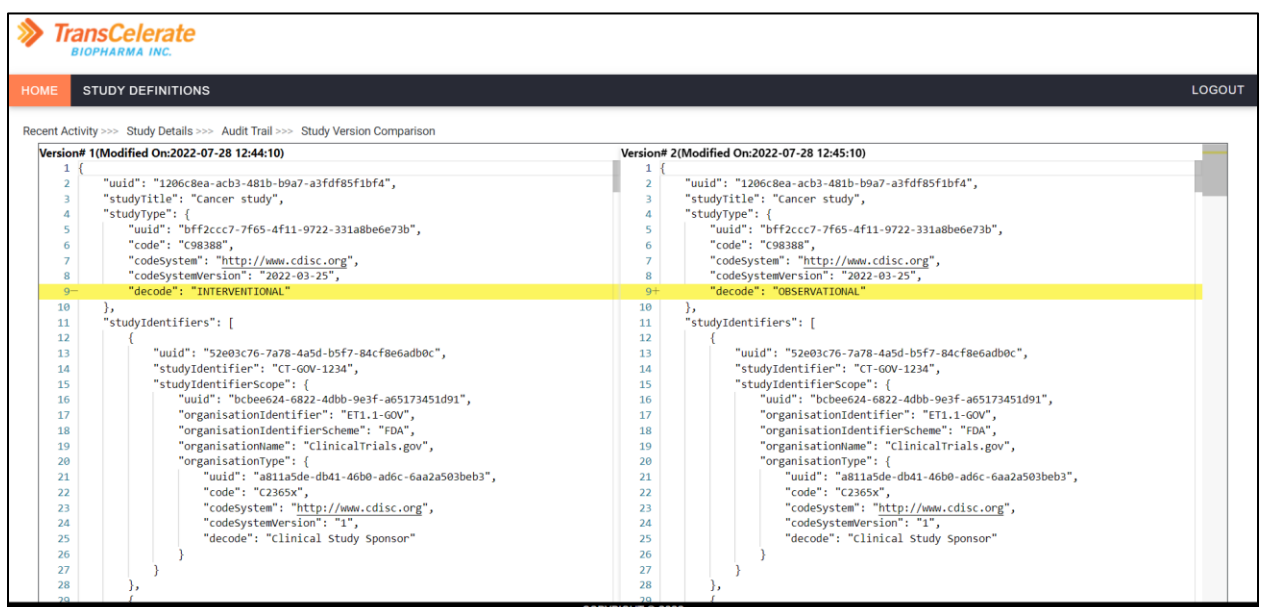
Date	SDR Record Version	Compare A	Compare B
2022-07-28 12:45:10	2	<input type="radio"/>	<input type="radio"/>
2022-07-28 12:44:10	1	<input type="radio"/>	<input type="radio"/>

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.
- User can navigate between the pages using the breadcrumb navigation.

Figure 17 Version Comparison page



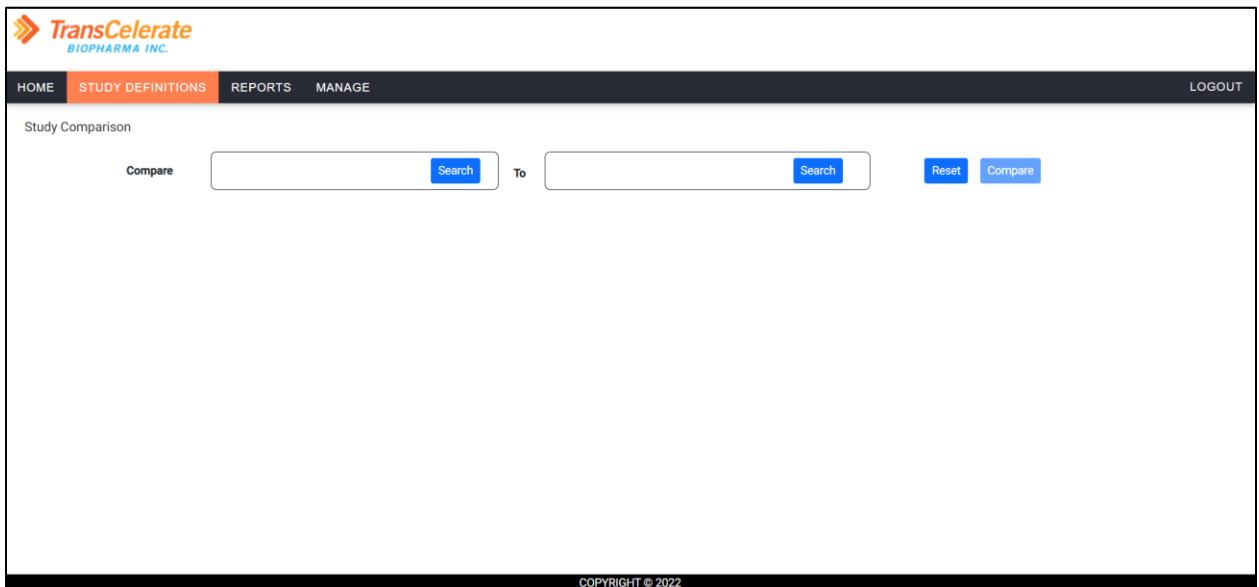
Version# 1 (Modified On: 2022-07-28 12:44:10)	Version# 2 (Modified On: 2022-07-28 12:45:10)
<pre> 1 { 2 "uuid": "1206c8ea-acb3-481b-b9a7-a3fdf85f1bf4", 3 "studyTitle": "Cancer study", 4 "studyType": { 5 "uuid": "bfff2ccc7-7f65-4f11-9722-331a8be6e73b", 6 "code": "C98388", 7 "codeSystem": "http://www.cdsc.org", 8 "codeSystemVersion": "2022-03-25", 9 "decode": "INTERVENTIONAL" 10 }, 11 "studyIdentifiers": [12 { 13 "uuid": "52e03c76-7a78-4a5d-b5f7-84cf8e6adb0c", 14 "studyIdentifier": "CT-GOV-1234", 15 "studyIdentifierScope": { 16 "uuid": "bcbee624-6822-4dbb-9e3f-a65173451d91", 17 "organisationIdentifier": "ET1.1-GOV", 18 "organisationIdentifierScheme": "FDA", 19 "organisationName": "ClinicalTrials.gov", 20 "organisationType": { 21 "uuid": "a811a5de-d41-46b0-ad6c-6aa2a503beb3", 22 "code": "C2365X", 23 "codeSystem": "http://www.cdsc.org", 24 "codeSystemVersion": "1", 25 "decode": "Clinical Study Sponsor" 26 } 27 } 28 } 29] 30 }</pre>	<pre> 1 { 2 "uuid": "1206c8ea-acb3-481b-b9a7-a3fdf85f1bf4", 3 "studyTitle": "Cancer study", 4 "studyType": { 5 "uuid": "bfff2ccc7-7f65-4f11-9722-331a8be6e73b", 6 "code": "C98388", 7 "codeSystem": "http://www.cdsc.org", 8 "codeSystemVersion": "2022-03-25", 9 "decode": "OBSERVATIONAL" 10 }, 11 "studyIdentifiers": [12 { 13 "uuid": "52e03c76-7a78-4a5d-b5f7-84cf8e6adb0c", 14 "studyIdentifier": "CT-GOV-1234", 15 "studyIdentifierScope": { 16 "uuid": "bcbee624-6822-4dbb-9e3f-a65173451d91", 17 "organisationIdentifier": "ET1.1-GOV", 18 "organisationIdentifierScheme": "FDA", 19 "organisationName": "ClinicalTrials.gov", 20 "organisationType": { 21 "uuid": "a811a5de-d41-46b0-ad6c-6aa2a503beb3", 22 "code": "C2365X", 23 "codeSystem": "http://www.cdsc.org", 24 "codeSystemVersion": "1", 25 "decode": "Clinical Study Sponsor" 26 } 27 } 28 } 29] 30 }</pre>

2.7. Study Comparison

NAVIGATION STEPS:

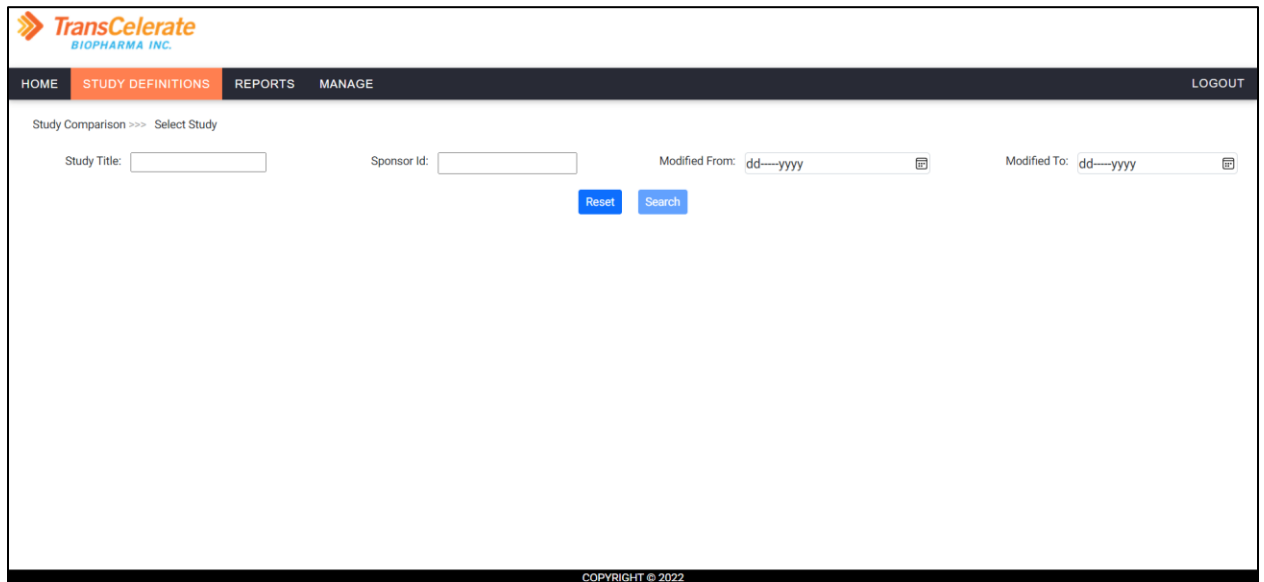
- i. On click of Compare option in the Study Definitions menu as shown in below screenshot, study comparison page will be loaded. This screen allows the user to do a side-by-side comparison of two different study definitions.

Figure 18 Study Compare Page

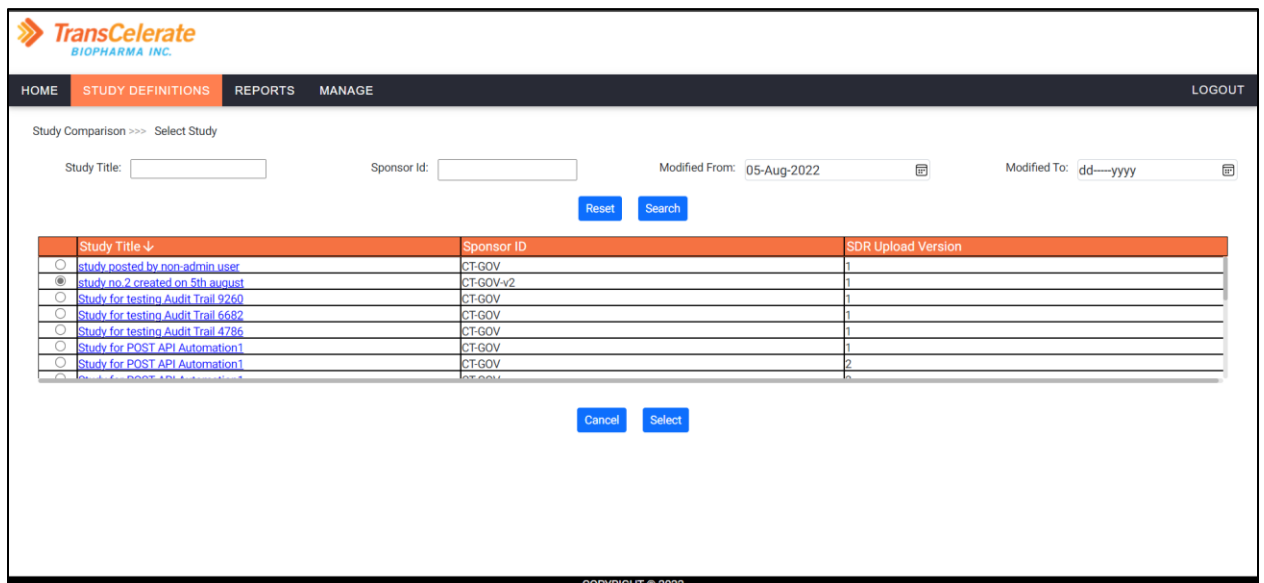


- ii. User can search any two studies to compare by using the search feature on the left and right sides of the compare. At any point, only two studies can be compared.
- iii. Once the user clicks on search, user is shown a screen to select a study by providing a criteria and finding the relevant study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

Figure 19 Search study compare page



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



Study Title ↓	Sponsor ID	SDR Upload Version
<input type="radio"/> study posted by non-admin user	CT-GOV	1
<input checked="" type="radio"/> study no.2 created on 5th august	CT-GOV-v2	1
<input type="radio"/> Study for testing Audit Trail 9260	CT-GOV	1
<input type="radio"/> Study for testing Audit Trail 6682	CT-GOV	1
<input type="radio"/> Study for testing Audit Trail 4786	CT-GOV	1
<input type="radio"/> Study for POST API Automation1	CT-GOV	1
<input type="radio"/> Study for POST API Automation1	CT-GOV	2
<input type="radio"/> Study for POST API Automation1	CT-GOV	1

Figure 20 Study Comparison page

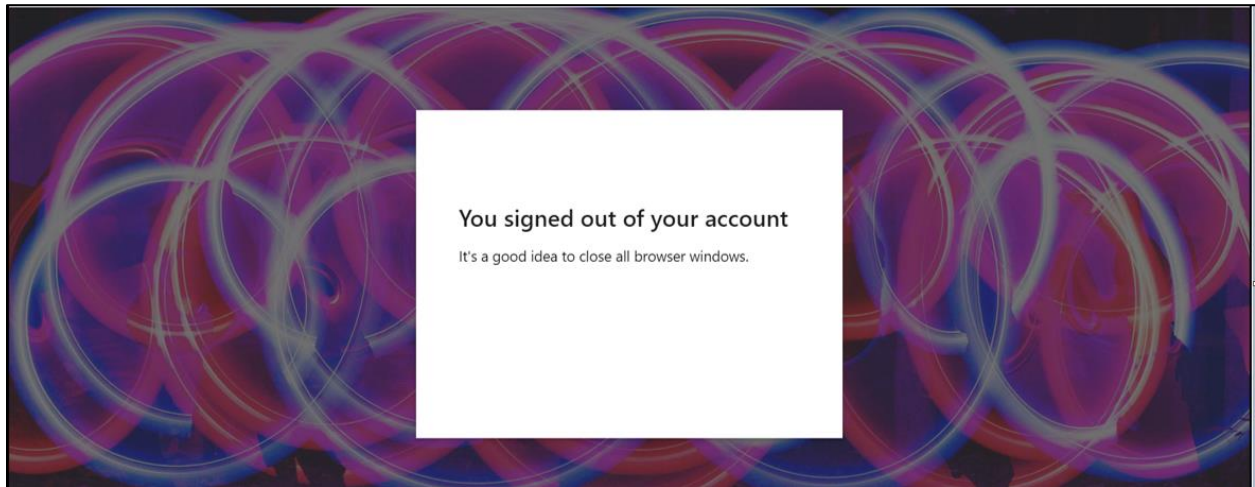


Study - Umbrella Study v2 Version# 1 (Modified On:2022-07-18 13:19:06)		Study - Umbrella Study Version# 3 (Modified On:2022-07-13 19:27:25)	
1	{	1	{
2	"uuid": "9085f2c7-1f7a-4f71-8b48-5d24592b6f17",	2+	"uuid": "f8c090ae-761a-4dca-9dd7-520556efcfaf",
3	"studyTitle": "Umbrella Study v2",	3+	"studyTitle": "Umbrella Study",
4	"studyType": {	4	"studyType": {
5	"uuid": "60924aa5-6642-4b5c-b8b1-79bef9e8cec3",	5+	"uuid": "4e46b876-e656-473f-971f-2768e5f677e6",
6	"code": "C98388",	6	"code": "C98388",
7	"codeSystem": "http://www.cdisc.org",	7	"codeSystem": "http://www.cdisc.org",
8	"codeSystemVersion": "2022-03-25",	8	"codeSystemVersion": "2022-03-25",
9	"decode": "EXPANDED ACCESS"	9+	"decode": "INTERVENTIONAL"
10	},	10	},
11	"studyIdentifiers": {	11	"studyIdentifiers": {
12	{	12	{
13	"uuid": "419ae723-72ec-4b89-89c5-142cb2cc496e",	13+	"uuid": "0f430f65-405c-47b4-ad70-ffb78f089df8",
14	"studyIdentifier": "CT-GOV-1234",	14+	"studyIdentifier": "CT-GOV-12346",
15	"studyIdentifierScope": {	15	"studyIdentifierScope": {
16	"uuid": "72cd78f1-0ba4-4c18-b4eb-5794ae2c4f16",	16+	"uuid": "4b7171a0-d305-4577-9abf-fc47977b9708",
17	"organisationIdentifier": "CT-GOV",	17	"organisationIdentifier": "CT-GOV",
18	"organisationIdentifierScheme": "FDA",	18	"organisationIdentifierScheme": "FDA",
19	"organisationName": "ClinicalTrials.gov",	19	"organisationName": "ClinicalTrials.gov",
20	"organisationType": {	20	"organisationType": {
21	"uuid": "0e6751a7-72c4-4f9f-9565-f55e8d2333a2",	21+	"uuid": "442f666b-20c7-4143-ac1d-ee0eabd35f2f",
22	"code": "C2365x",	22	"code": "C2365x",

- 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.

Figure 21 Logout Screen

3. SDR Administrative UI 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.

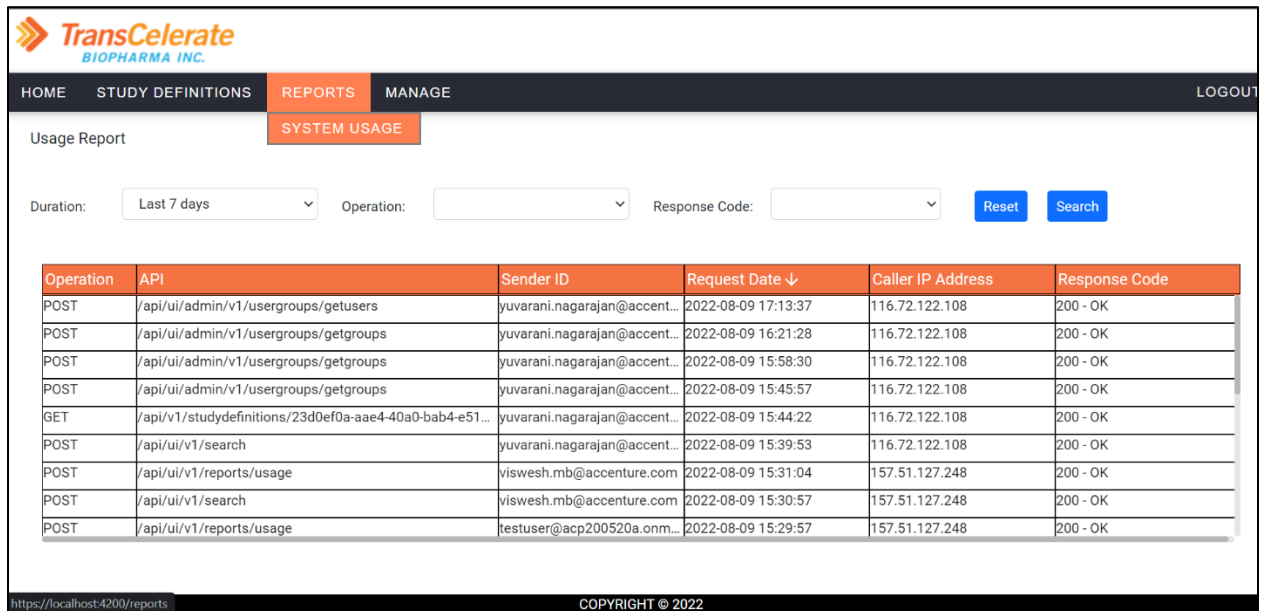
3.1. System Usage Report

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 last 7 days.

Figure 22 System usage page



Operation	API	Sender ID	Request Date ↓	Caller IP Address	Response Code
POST	/api/ui/admin/v1/usergroups/getusers	yuvarani.nagarajan@accent...	2022-08-09 17:13:37	116.72.122.108	200 - OK
POST	/api/ui/admin/v1/usergroups/getgroups	yuvarani.nagarajan@accent...	2022-08-09 16:21:28	116.72.122.108	200 - OK
POST	/api/ui/admin/v1/usergroups/getgroups	yuvarani.nagarajan@accent...	2022-08-09 15:58:30	116.72.122.108	200 - OK
POST	/api/ui/admin/v1/usergroups/getgroups	yuvarani.nagarajan@accent...	2022-08-09 15:45:57	116.72.122.108	200 - OK
GET	/api/v1/studydefinitions/23d0ef0a-aae4-40a0-bab4-e51...	yuvarani.nagarajan@accent...	2022-08-09 15:44:22	116.72.122.108	200 - OK
POST	/api/ui/v1/search	yuvarani.nagarajan@accent...	2022-08-09 15:39:53	116.72.122.108	200 - OK
POST	/api/ui/v1/reports/usage	viswesh.mb@accenture.com	2022-08-09 15:31:04	157.51.127.248	200 - OK
POST	/api/ui/v1/search	viswesh.mb@accenture.com	2022-08-09 15:30:57	157.51.127.248	200 - OK
POST	/api/ui/v1/reports/usage	testuser@acp200520a.onm...	2022-08-09 15:29:57	157.51.127.248	200 - OK

- ii.
- 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 ID 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.
- 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 are displayed on the home screen of Group Management.

Figure 23Figure 23 Group Management page




Group Name	Group Filter Field	Rule / Selected Value(s)	Permission	Action	
Observation 1	studyType	OBSERVATIONAL EXPANDED ACCESS	READONLY	 	
API regression 2	study	study test observat...	READ_WRITE	 	
New Group For Guide	studyType	EXPANDED ACCESS INTERVENTIONAL	READ_WRITE	 	
	study	study no 2 created ... Study for testing A...		 	
API regression	studyType	EXPANDED ACCESS OBSERVATIONAL	READONLY	 	

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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 24 Add Group page



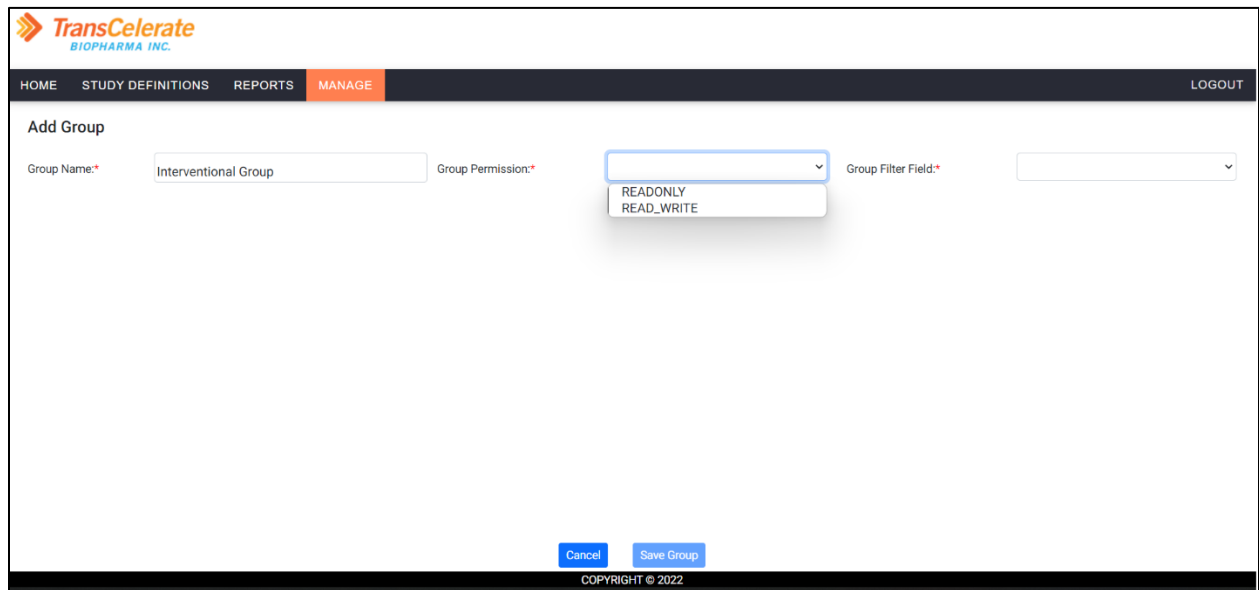
HOME STUDY DEFINITIONS REPORTS **MANAGE** LOGOUT

Add New Group

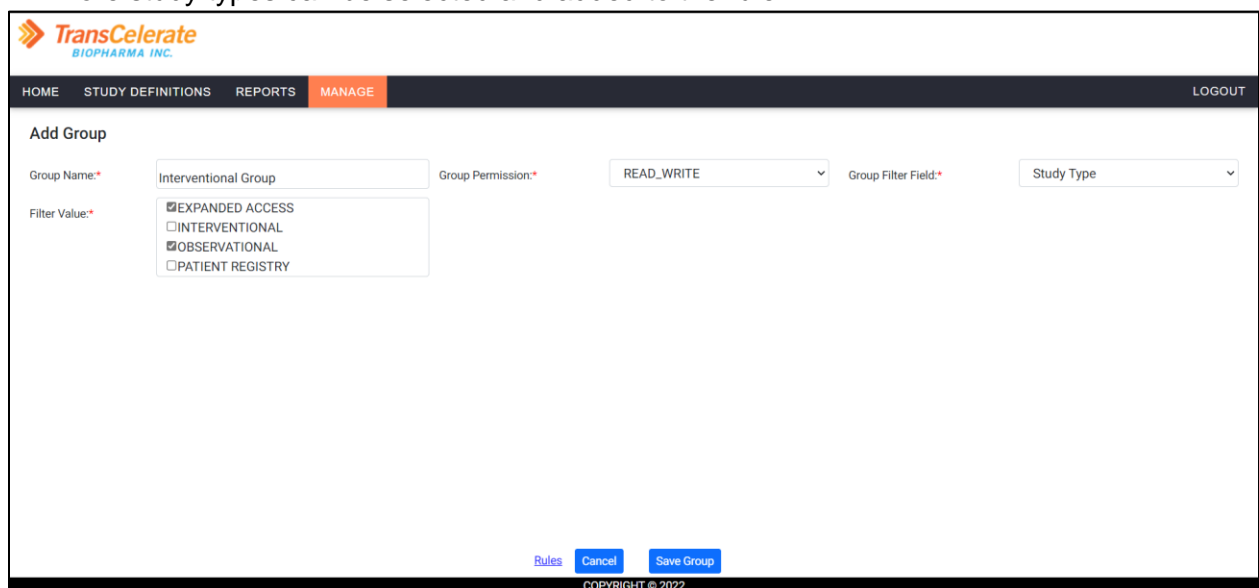
Group Name* Group Permission* Group Filter Field*

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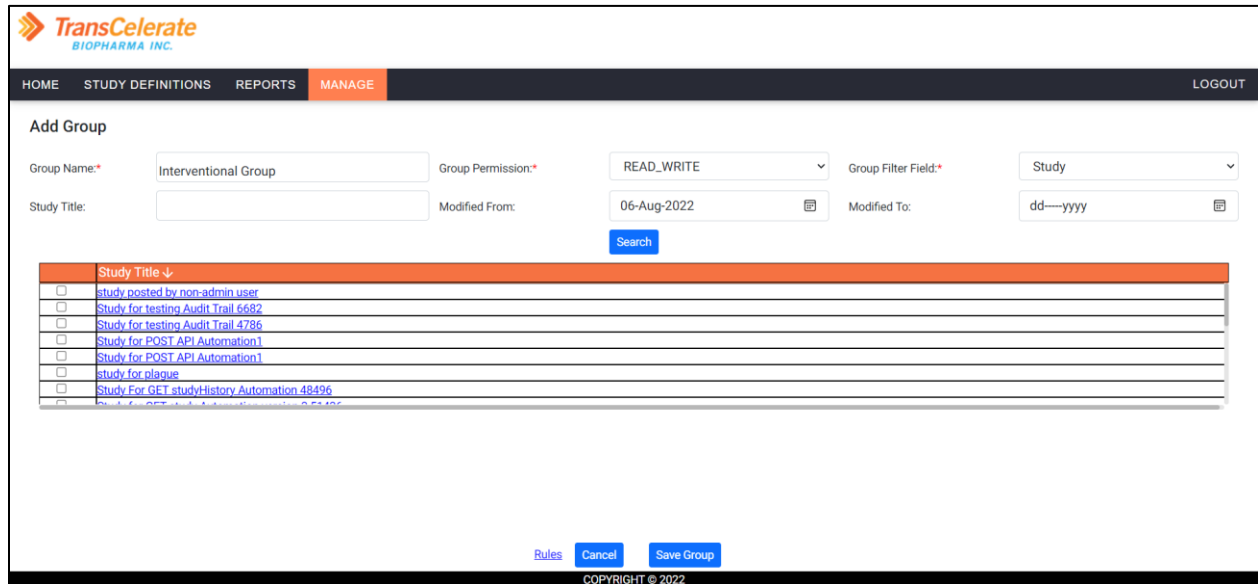
- v. Groups should have a distinct name throughout the system. Only AlphaNumeric characters are allowed in the name with a maximum length of 20 characters.
- vi. The Group Permissions allow the admin user to set the access privilege for users belonging to this group i.e. users can either READ or READ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



- 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.



Add Group

Group Name:* Interventional Group Group Permission:* READ_WRITE Group Filter Field:* Study

Study Title: Modified From: 06-Aug-2022 Modified To: dd-yyyy

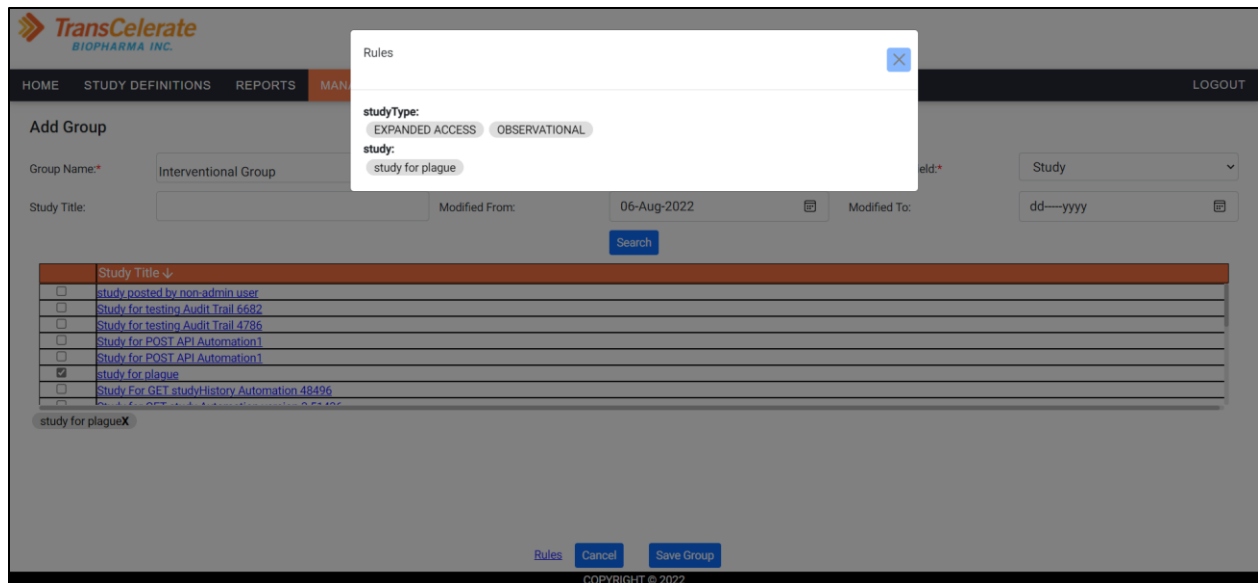
[Search](#)

Study Title ↓
<input type="checkbox"/> study posted by non-admin user
<input type="checkbox"/> Study for testing Audit Trail 6682
<input type="checkbox"/> Study for testing Audit Trail 4786
<input type="checkbox"/> Study for POST API Automation1
<input type="checkbox"/> Study for POST API Automation1
<input type="checkbox"/> study for plaque
<input type="checkbox"/> Study For GET studyHistory Automation 48496

[Rules](#) [Cancel](#) [Save Group](#)

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- 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.



Rules

studyType: EXPANDED ACCESS OBSERVATIONAL

study: study for plaque

[Rules](#) [Cancel](#) [Save Group](#)

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- 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.

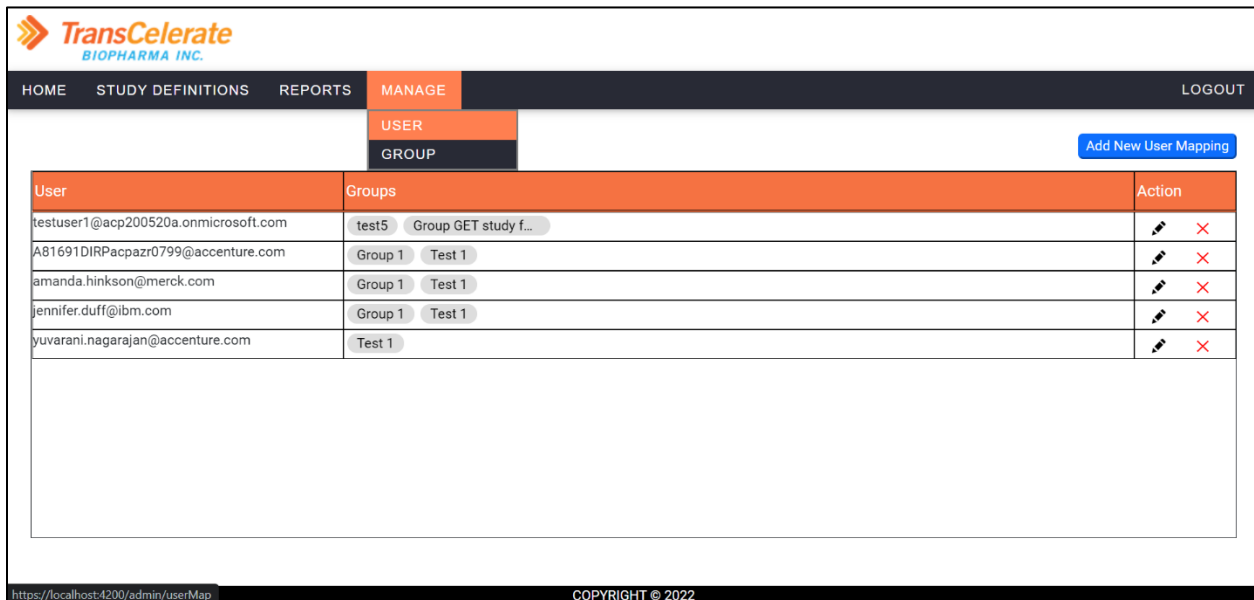
3.2.2. User Management

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.

Figure 25 Group management page

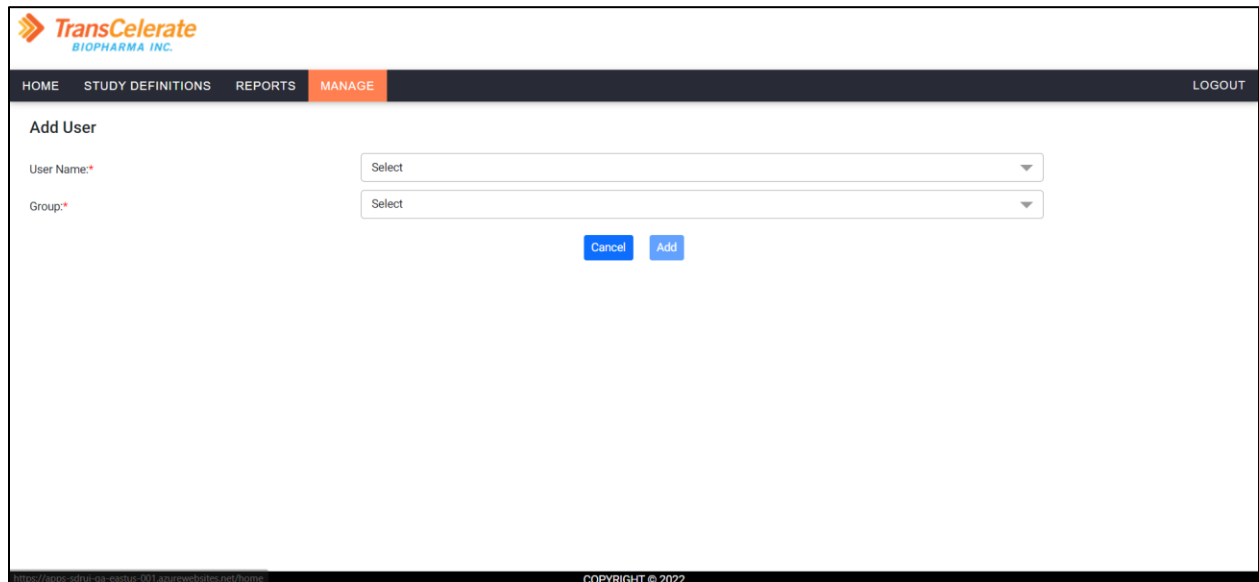


User	Groups	Action
testuser1@acp200520a.onmicrosoft.com	test5 Group GET study f...	
A81691DIRPacpazr0799@accenture.com	Group 1 Test 1	
amanda.hinkson@merck.com	Group 1 Test 1	
jennifer.duff@ibm.com	Group 1 Test 1	
yuvarani.nagarajan@accenture.com	Test 1	

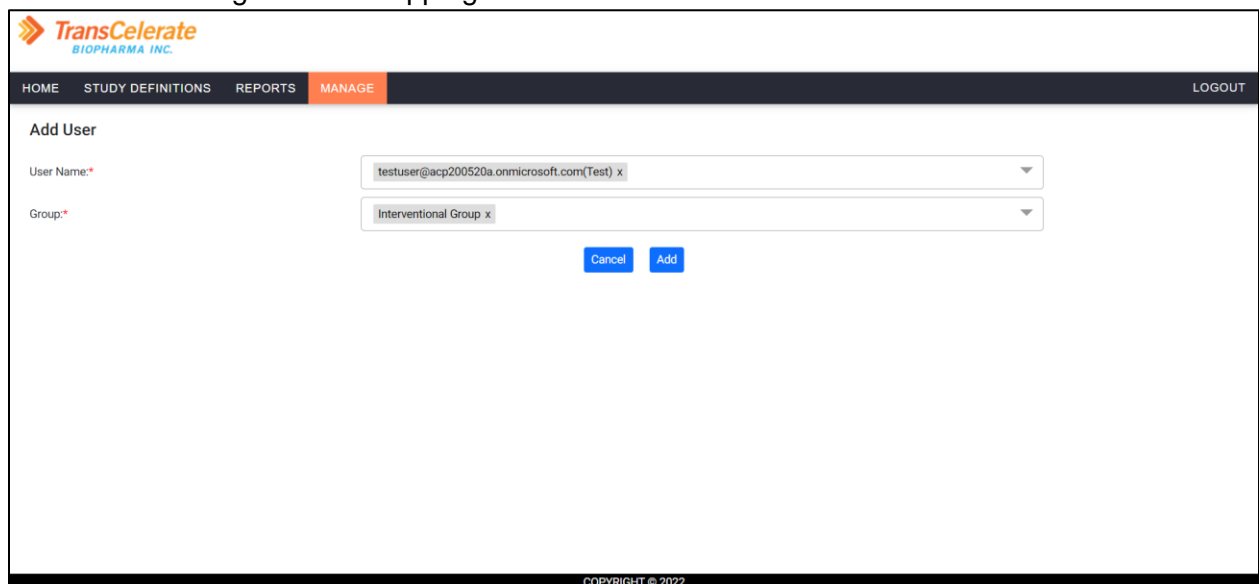
s feature allows the admin user to associate users to one or more groups. By default the existing list of user mappings are loaded on the home screen of this feature.

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

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.