TransCelerate BIOPHARMA INC.

Study Definition Repository (SDR)

Reference Implementation

User Interface User Guide
Version 5.0

Disclaimer

These materials and information, as well as the underlying code/application they relate to are provided by TransCelerate Biopharma Inc. AS IS. Any party using or relying on this information and, these materials and/or the underlying code/application 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, materials, or underlying code/application.

TransCelerate does not endorse any particular software, system, or service. And the use of specific brands of products or services by TransCelerate and its collaboration partners in developing the SDR Reference Implementation should not be viewed as any endorsement of such products or services. To the extent that the SDR Reference Implementation incorporates or relies on any specific branded products or services, this resulted out of the practical necessities associated with making a reference implementation available to demonstrate the SDR's capabilities.

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.
V4.1	27-Apr-2023	ACN	Added Token API link to generate auth token on login page in section 2.1
V5.0	26-Jun-2023	ACN	Added export to excel in SoA. Updated Study comparison screen. Updated all the figures with new images.

Contents

1. Introduction 6
1.1. Overview 6
1.2. Scope of Document 6
1.3. Intended Audience 6
1.4. Prerequisites 6
1.5. Definitions and Acronyms 7
2. SDR RI UI – General Features 7
2.1. Login 7
2.2. Recent Activity Widget 9
2.3. Search Study Definitions 9
2.4. Study Details 11
2.5. SoA Matrix (Schedule of Activities) 12
2.6. Revision History 14
2.7. Version Comparison 15
2.8. Study Comparison 15
2.9. Logout 19
3. SDR RI UI – Administrative features 20
3.1. System Usage Report 20
3.2. Group and User Management 21
3.2.1. Group Management 21
3.2.2. User Management 25

Table of Figures

Figure 1 Login Page 7
Figure 2 Sign In Page 8
Figure 3 Access token for SDR API 8
Figure 4 Copy to clipboard 9
Figure 5 Recent Activity Widget 9
Figure 6 Search Study page 10
Figure 7 Search results 10
Figure 8 Multiple Value Popup 11
Figure 9 Study Details Page from Home 12
Figure 10 Study Details page from Search Grid 12
Figure 11 SoA Matrix 13
Figure 12 SoA Matrix with accordions 13
Figure 13 Footnotes below SoA Matrix 14
Figure 14 Revision History Page 15
Figure 15 Version Comparison page 15
Figure 16 Study Compare Page 16
Figure 17 Search study compare page. 16
Figure 18 Study Comparison - Search Results 17
Figure 19 Search study on selection to compare 17
Figure 20 Study Comparison page 18
Figure 21 Compare page- navigation from breadcrumb. 18
Figure 22 Compare page - Navigation using exit button. 19
Figure 23 Logout Screen 19
Figure 24 System usage report page 20
Figure 25 Export Download Limit 21
Figure 26 Group Management page 22
Figure 27 Add Group page. 22
Figure 28 Group Management - Permissions 23

Figure 29 Create New Group 23
Figure 30 Group Management - Search Studies 24
Figure 31 Group Management - Rules 24
Figure 32 Group management page 25
Figure 33 Add user page 26
Figure 34 User Management - Group Mapping 26

1. Introduction

1.1. Overview

The UI application of the SDR Reference Implementation[1] 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
    - 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 itself 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] The SDR Reference Implementation is an attempt to demonstrate the vision of the DDF initiative, not a commercial product. To be clear, TransCelerate does not endorse any particular software, system, or service. And the use of specific brands of products or services by TransCelerate and its collaboration partners in developing the SDR Reference Implementation should not be viewed as any endorsement of such products or services. To the extent that the SDR Reference Implementation incorporates or relies on any specific branded products or services, such as Azure, this resulted out of the practical necessities associated with making a reference implementation available to demonstrate the SDR's capabilities. Users are free to download the source code for the SDR from GitHub and design their own implementations in whatever environments they choose.

1.5. Definitions and Acronyms

Term / Abbreviation	Definition
API	Application Programming Interface
DDF	Digital Data Flow
MSAL	Microsoft Authentication Library
SDR	Study Definition Repository
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 or get token for APIs.

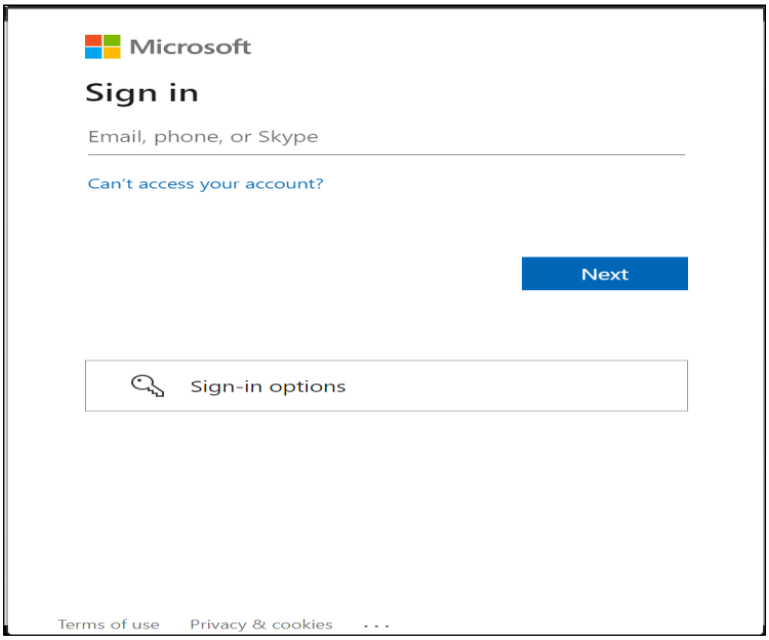
NAVIGATION STEPS:

- Launch the SDR website.

Figure 1 Login Page

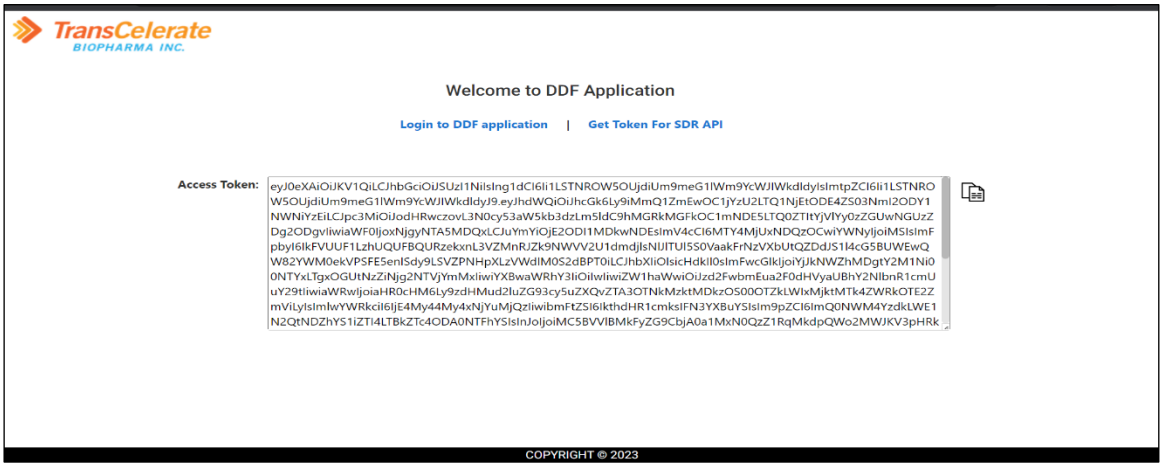
ii. On click of get token link, a popup is opened to allow user to provide credentials.

Figure 2 Sign In Page



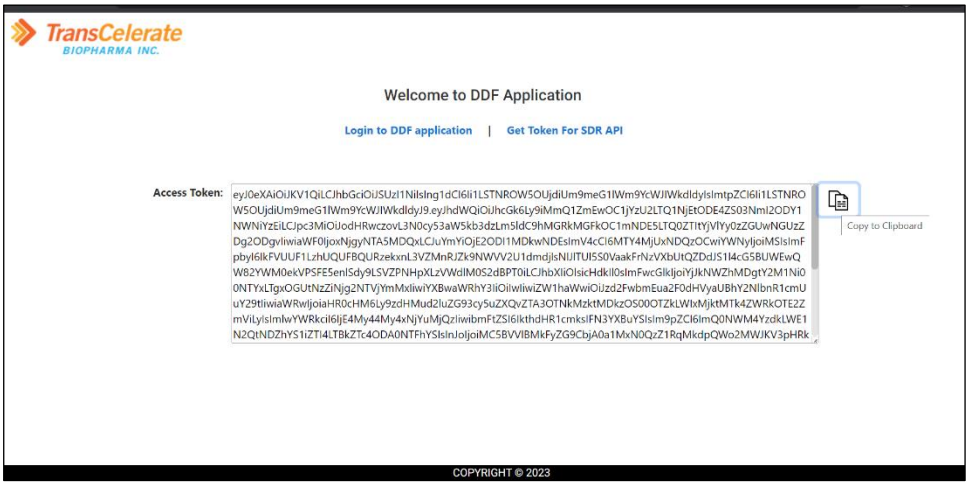
iii. On successful authentication, a text area with token is displayed.

Figure 3 Access token for SDR API



iv. User also has a privilege to copy the token using copy to clipboard icon.

Figure 4 Copy to clipboard

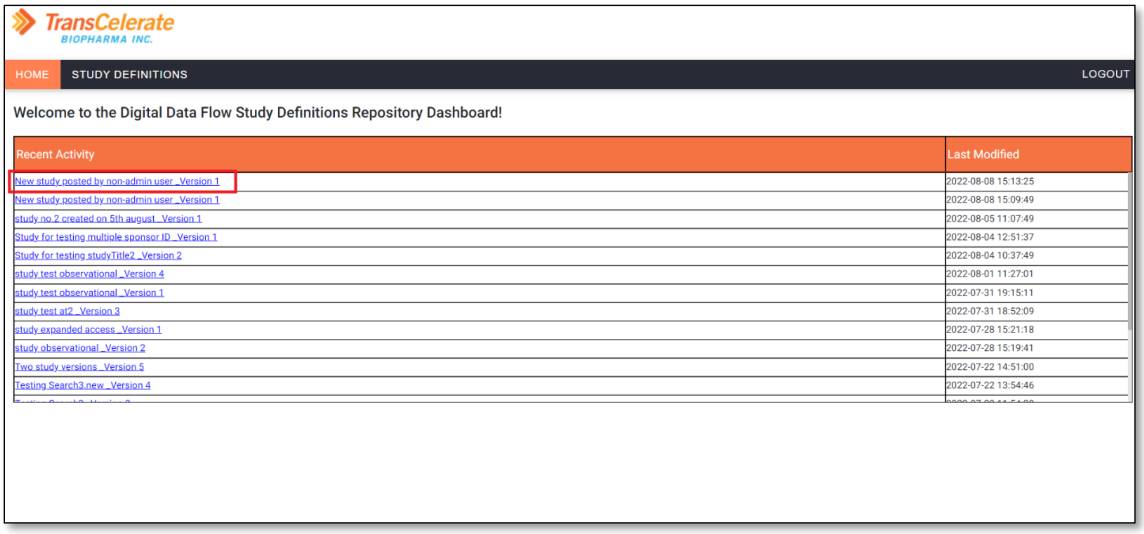


v. On clicking login link, user is redirected to Home Page if the user is already authenticated else user will be redirected to sign in page

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 5 Recent Activity Widget

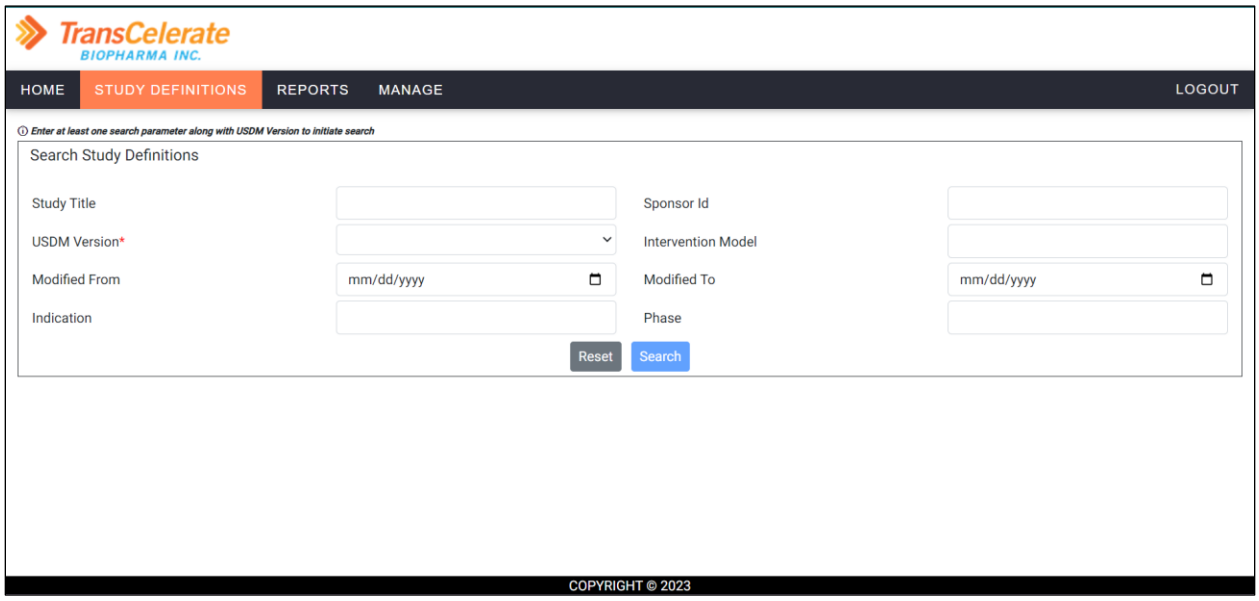


2.3. Search Study Definitions

NAVIGATION STEPS:

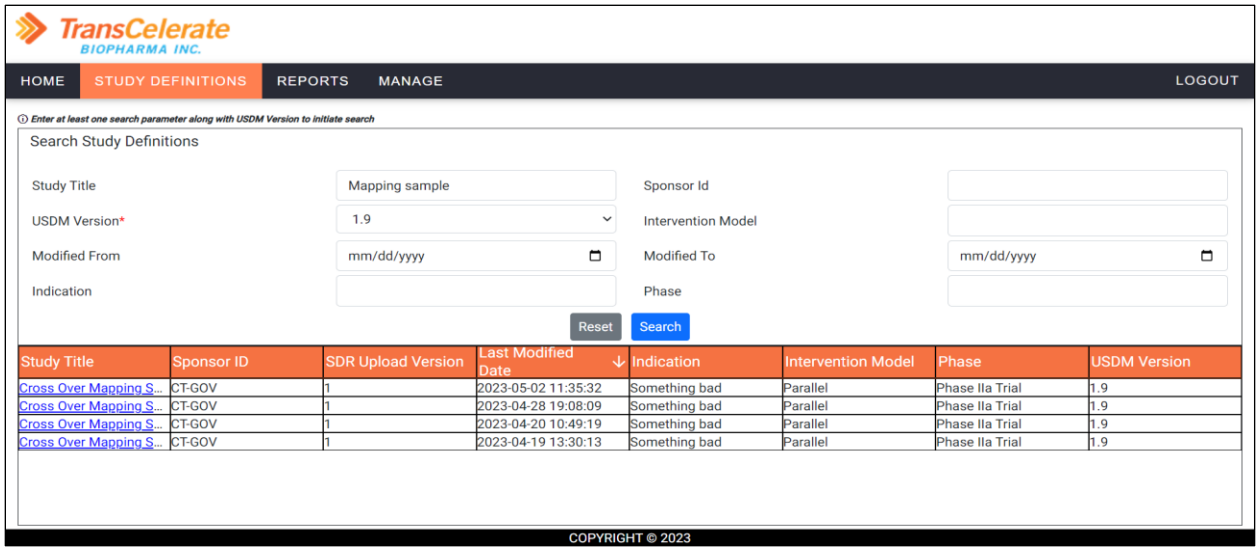
i. On click of Search Study Definitions in the left menu, user can navigate to search page, where the user needs to select any parameter along with USDM Version parameter to search specific study as USDM Version parameter is a mandatory field.

Figure 6 Search Study page



ii. Once the user clicks on search, the search results are shown as below.

Figure 7 Search results



iii. Below is the list of search parameters and their types:

Field Name	Field Type

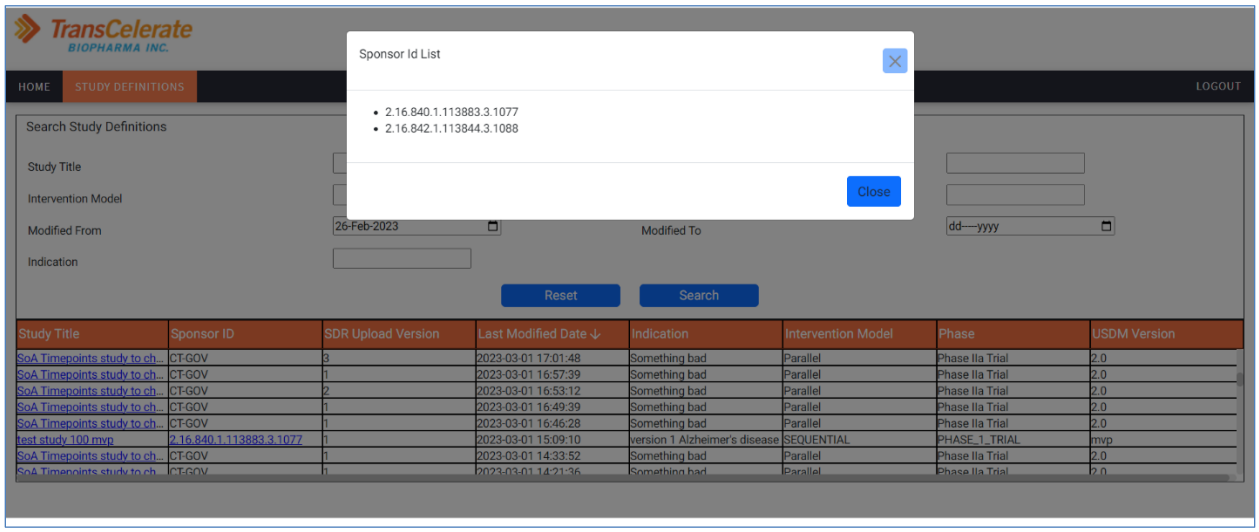
Study Title	Plain Text..
Sponsor Id	Plain Text.
Intervention Model	Plain Text with Suggestions
Phase	Plain Text with Suggestions
Modified From	Date Picker
Modified To	Date Picker
Indication	Plain Text.
USDM Version	Dropdown containing list of different USDM versions.

iv. Columns in the search results are sortable (ascending/descending) except USDM Version.

v. The top 20 documents are listed first, and the remaining results come into view as the user scrolls.

vi. 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 8 Multiple Value Popup

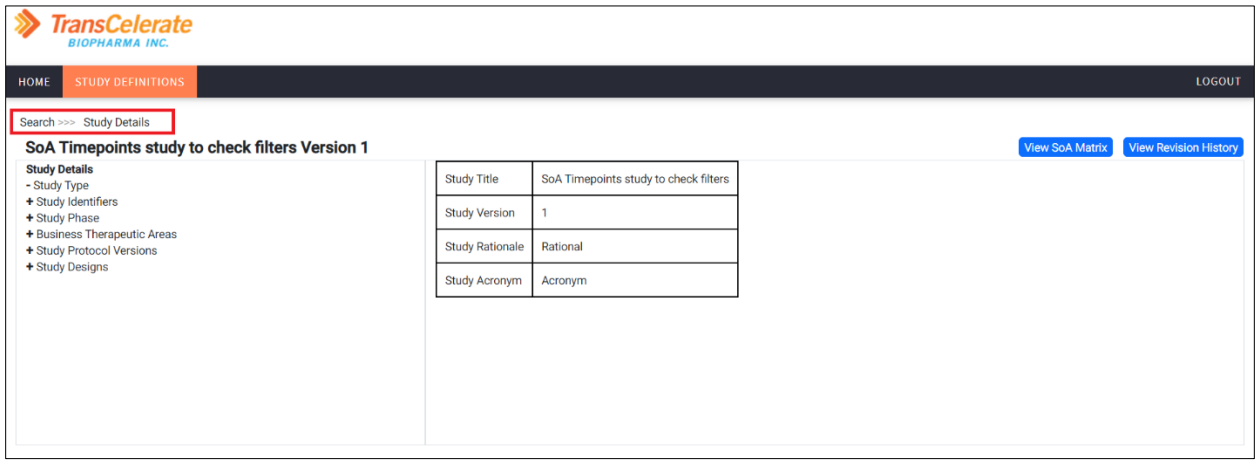


2.4. Study Details

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 9 Study Details Page from Home

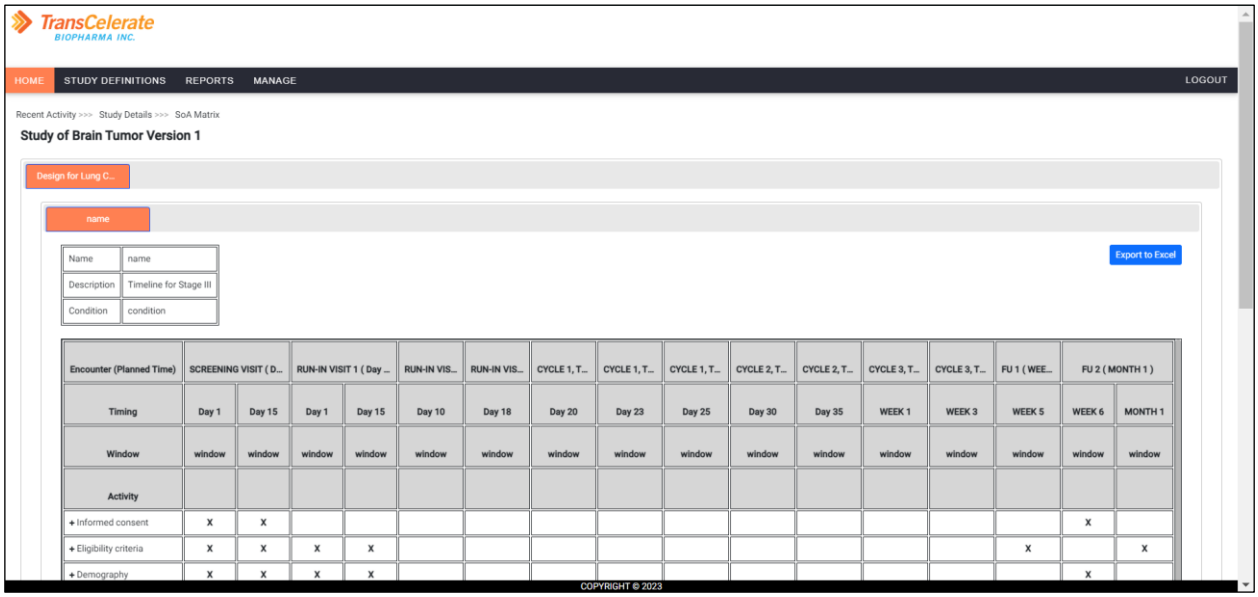
Figure 10 Study Details page from Search Grid



2.5. SoA Matrix (Schedule of Activities)

The SoA Matrix shows a 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.

Figure 11 SoA Matrix



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.

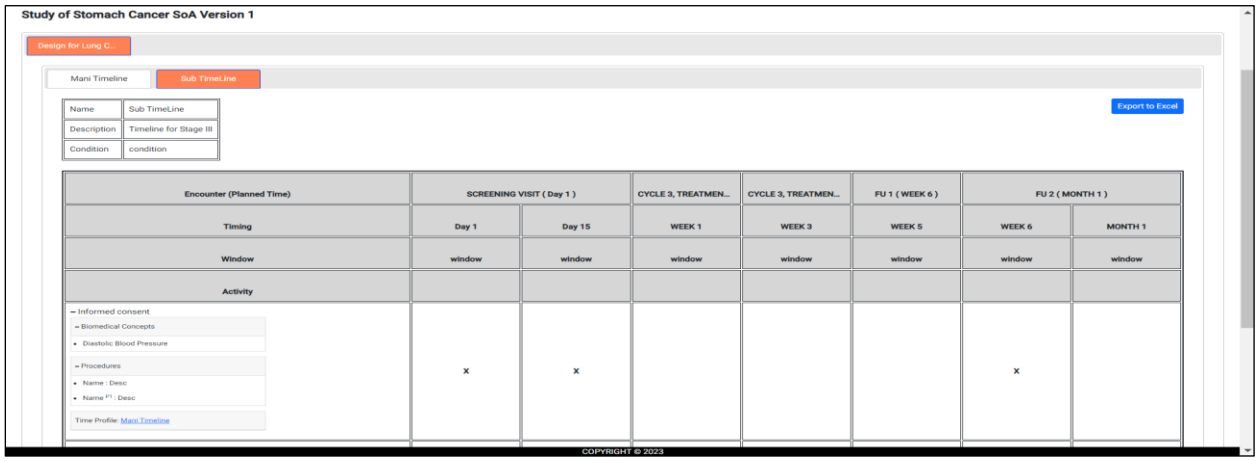
ii. Each study design tab will have child tabs that will display one SoA Matrix per Schedule Timeline.

iii. The schedule Timeline basic information (Name, Description and Condition) would be above the SoA Matrix table. When there is no study design or timelines defined in the selected study version, the appropriate message is shown to user indicating there is insufficient data to build the matrix.

iv. Each activity in the first column, will have an accordion component associated with it. On expanding the accordion control, Biomedical concepts, Procedures and Time Profile information will be displayed as sub items. Biomedical concepts and procedures will display names of the respective list of items associated with that activity.

v. If any Time profile is tagged to an activity, Time profile name along with a link to navigate to the specific matrix tab will be displayed.

Figure 12 SoA Matrix with accordions

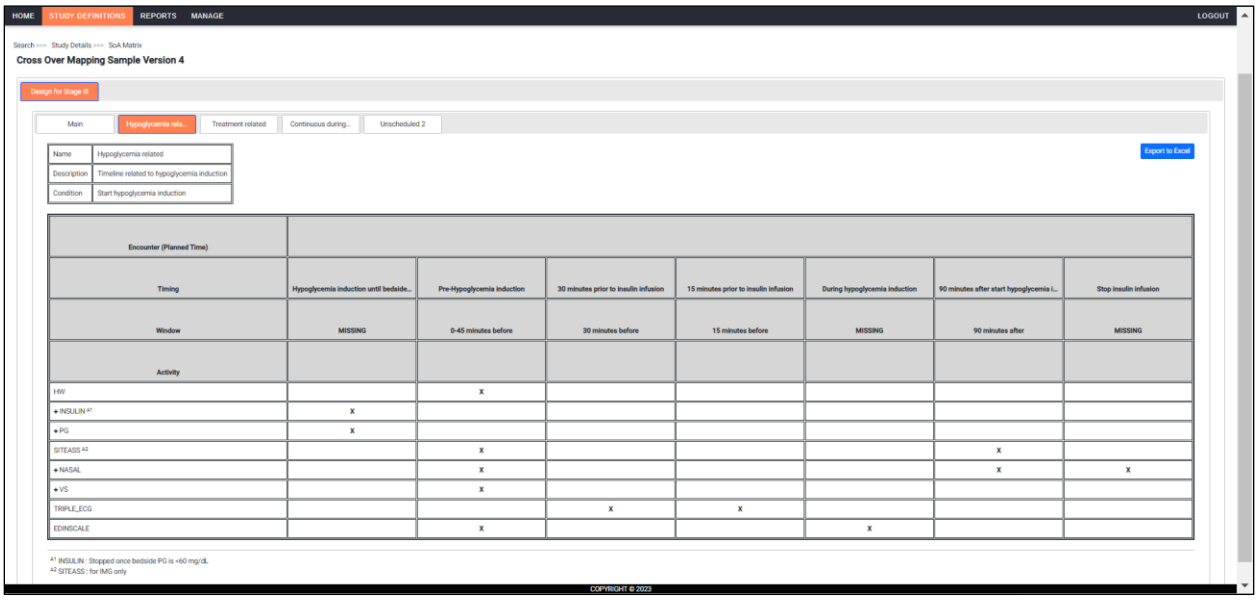


vi. Footnotes will be displayed below the SoA Matrix table to list additional information on activities and procedures when they are marked optional. Each footnote associated with an activity/procedure will display the reason for it being marked conditional.

vii. The user can also download SOA Matrix by clicking on Export to Excel button which is available under each timeline.

viii. 'Export to Excel' button is disabled if there is insufficient data inside any timeline.

Figure 13 Footnotes below SoA Matrix



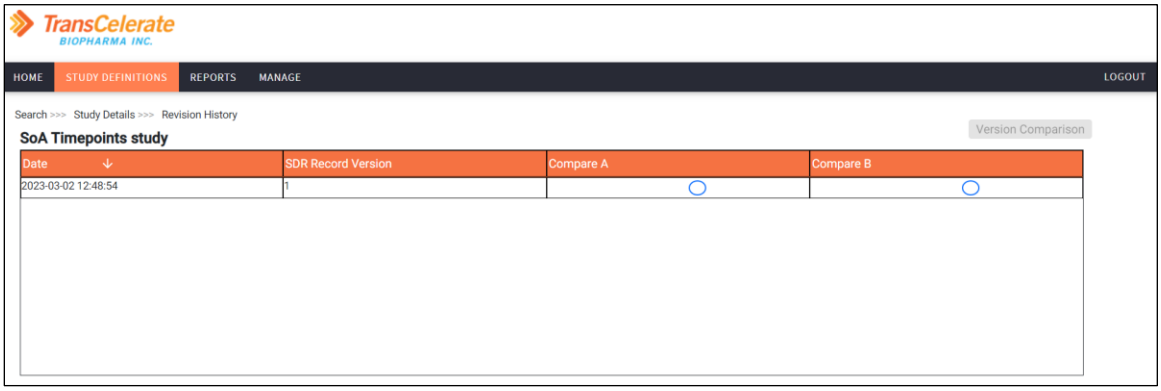
2.6. Revision History

NAVIGATION STEPS:

i. 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 14 Revision History Page

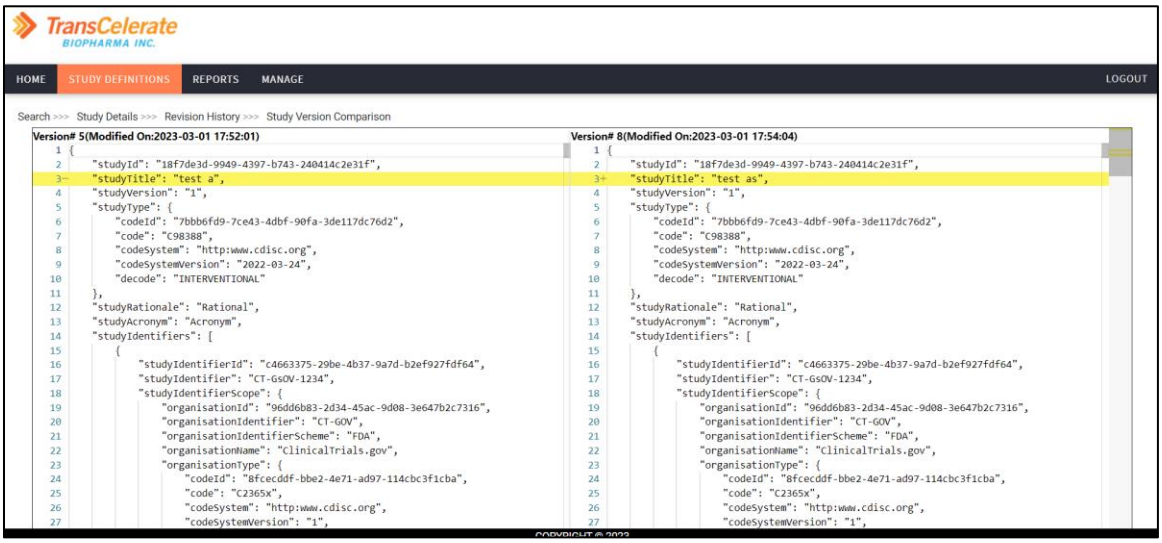


2.7. Version Comparison

NAVIGATION STEPS:

i. 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.

Figure 15 Version Comparison page

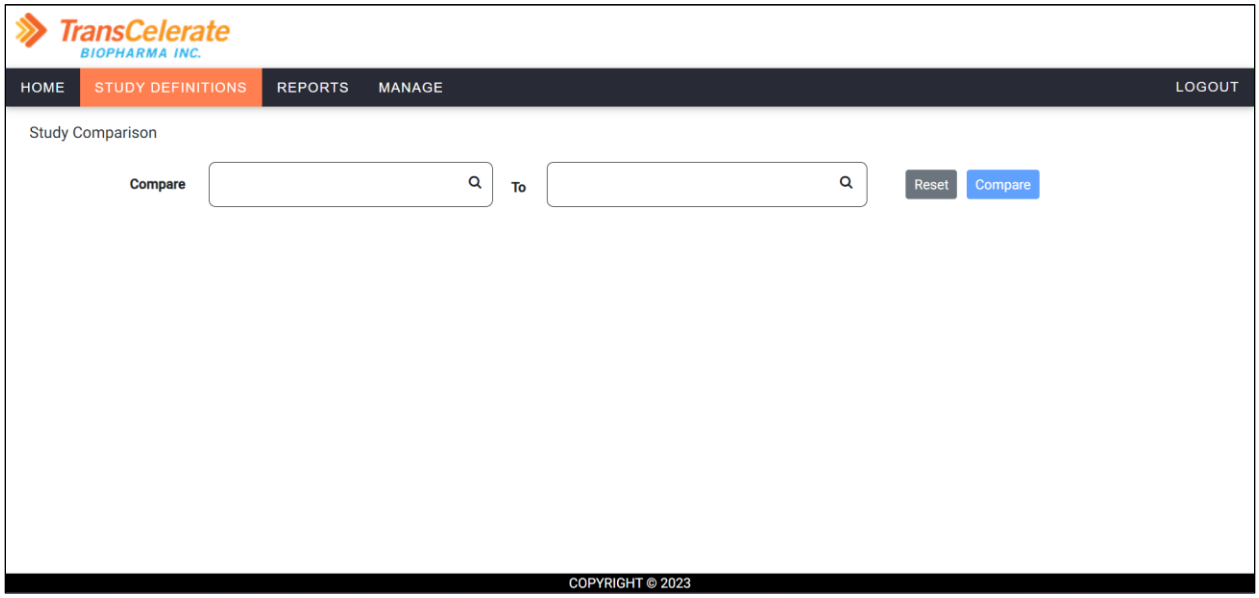


2.8. Study Comparison

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.

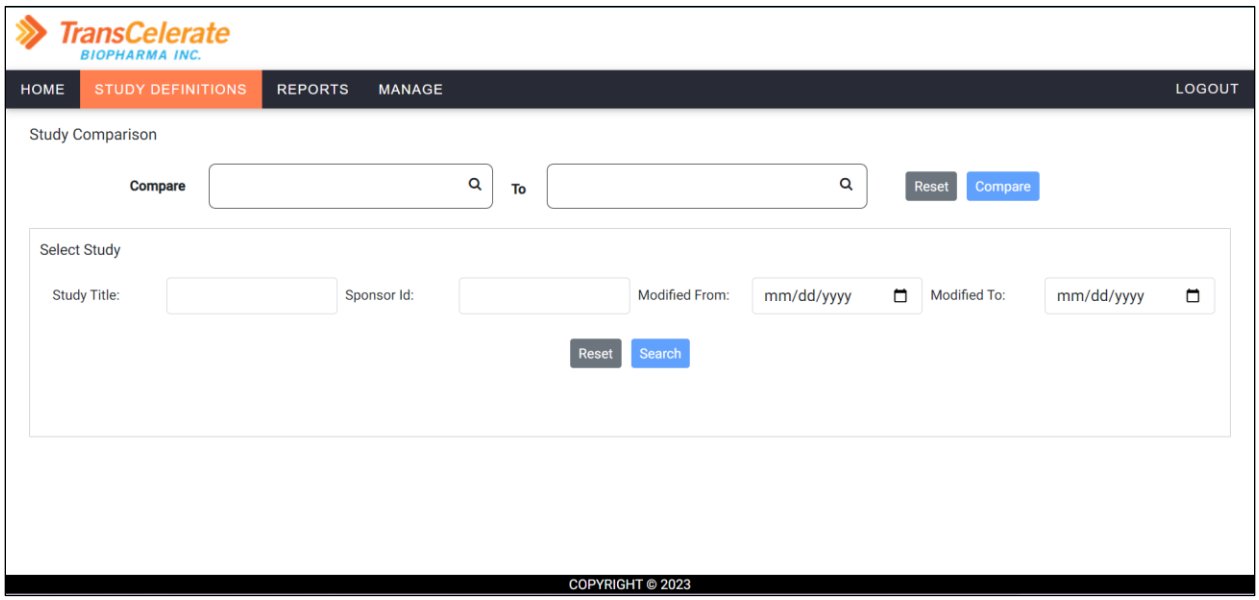
Figure 16 Study Compare Page



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 icon, user can search a study by providing a criterion and select it for comparison. The user can search the study, by Study title, Sponsor ID and modified date range.

Figure 17 Search study compare page.



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

Figure 18 Study Comparison - Search Results

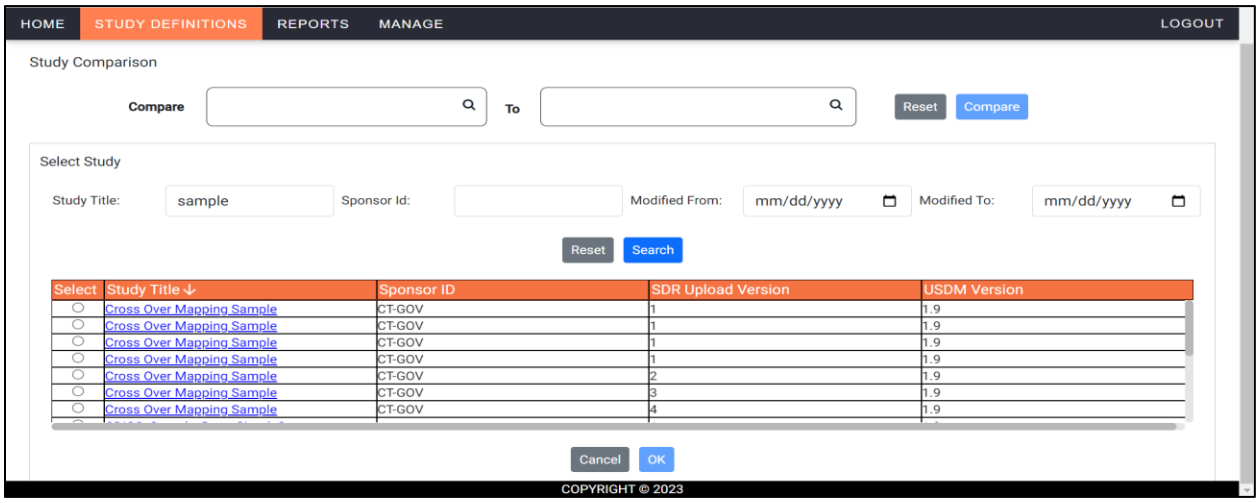


Figure 19 Search study on selection to compare

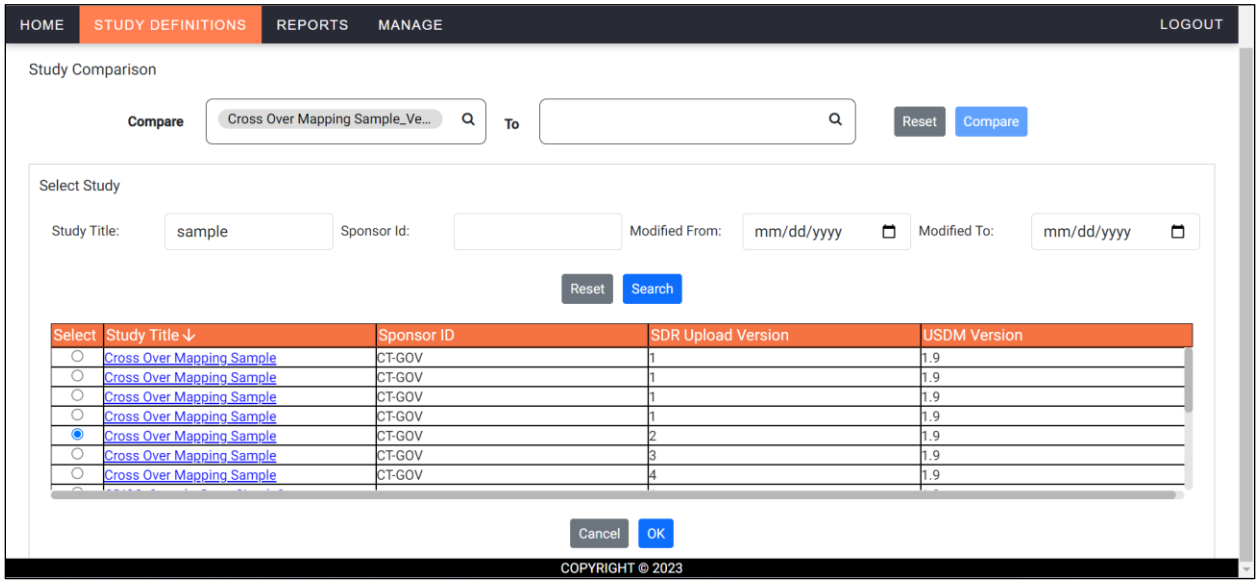
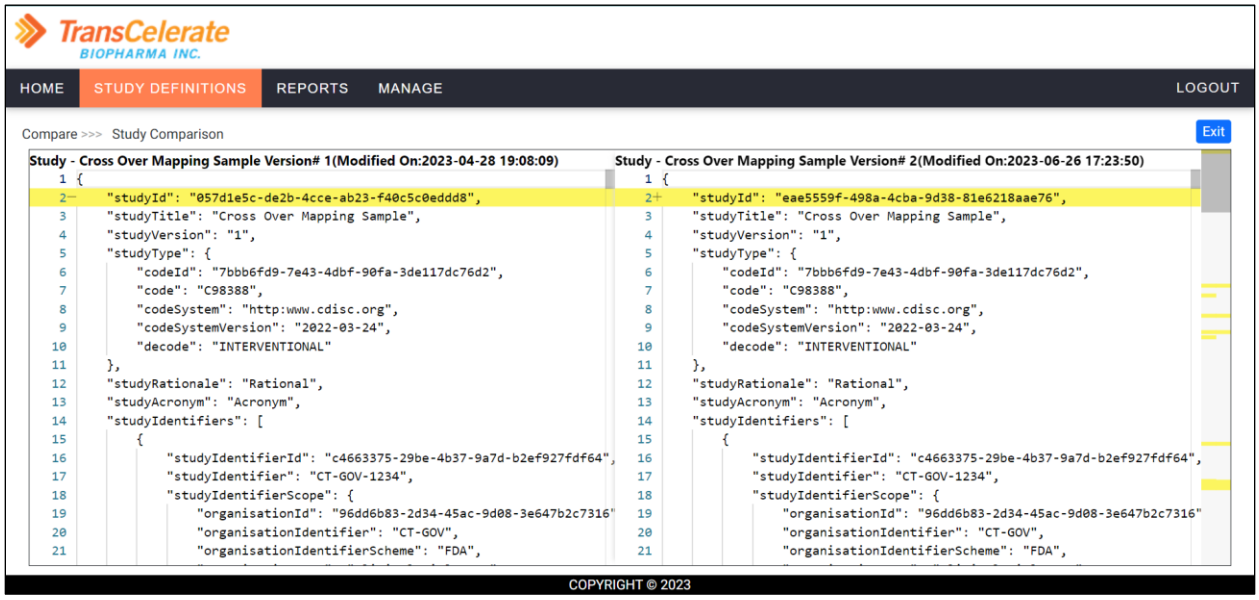


Figure 20 Study Comparison page

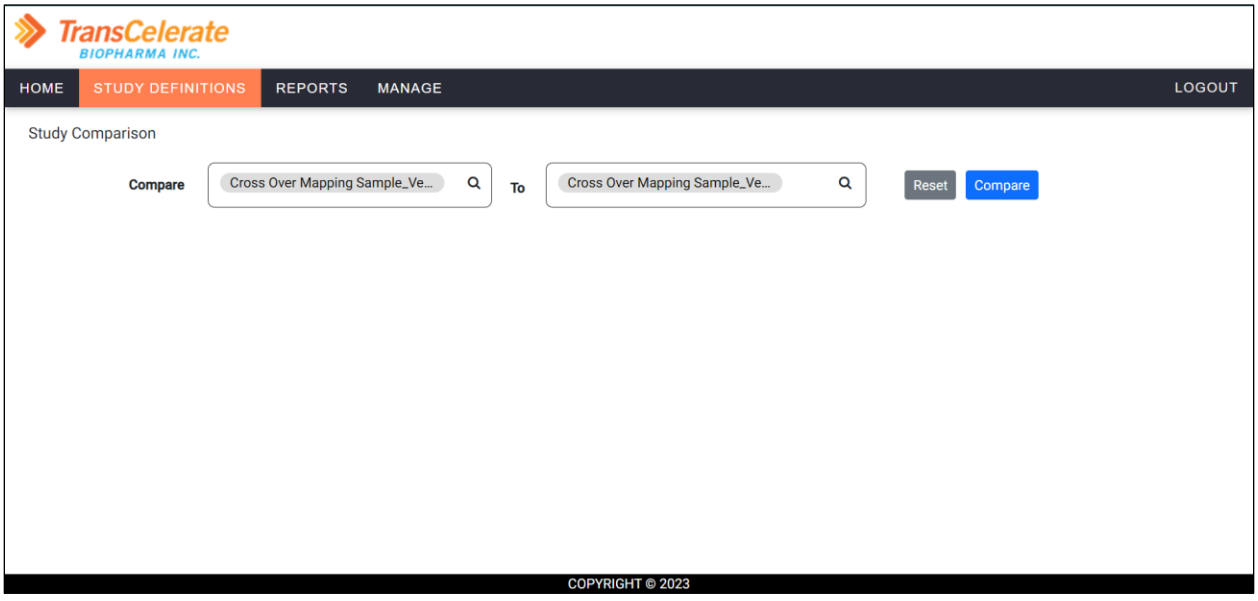


v. Once two studies have been searched and selected on the left and right comparison boxes, user can click Compare.

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.

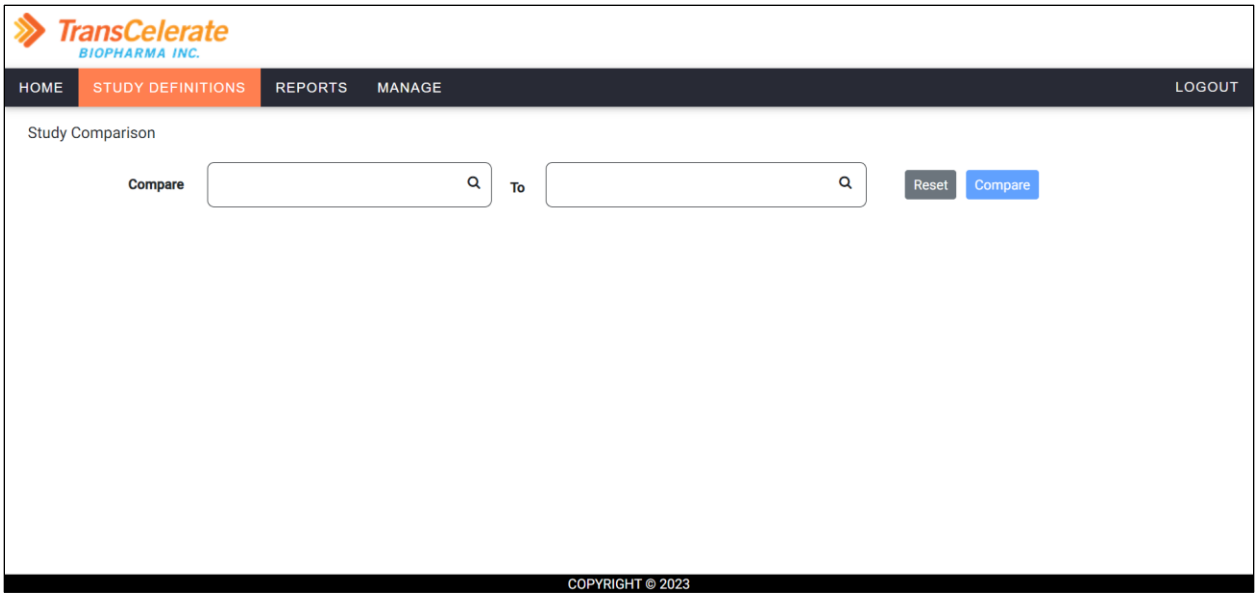
vii. User can go back to the study comparison screen by clicking on the breadcrumb navigation.

Figure 21 Compare page- navigation from breadcrumb.



viii. User can also click on exit button to go back to the compare screen that is resetas shown below.

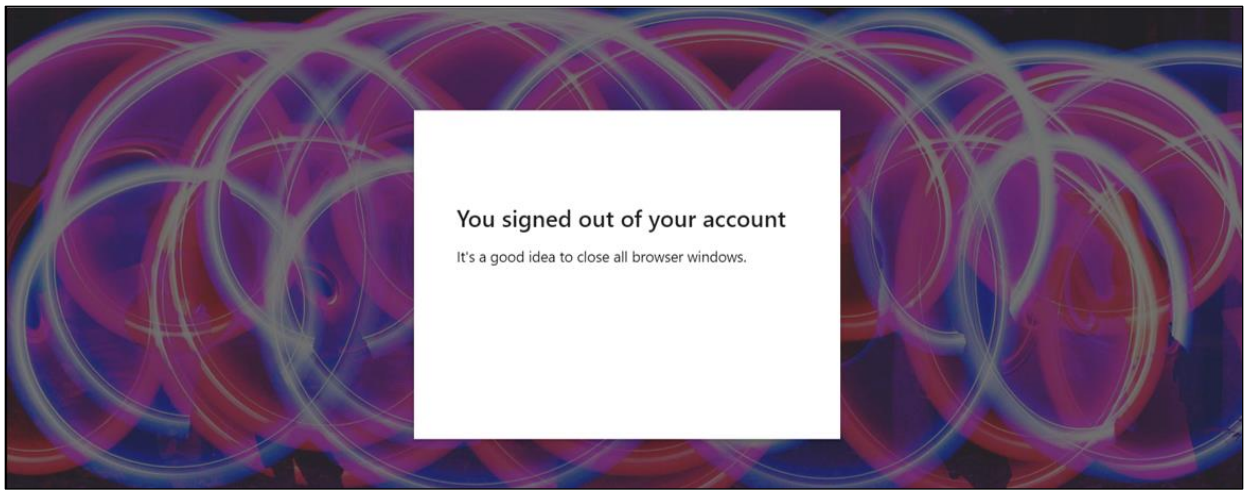
Figure 22 Compare page - Navigation using exit button.



2.9. Logout

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

Figure 23 Logout Screen



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.

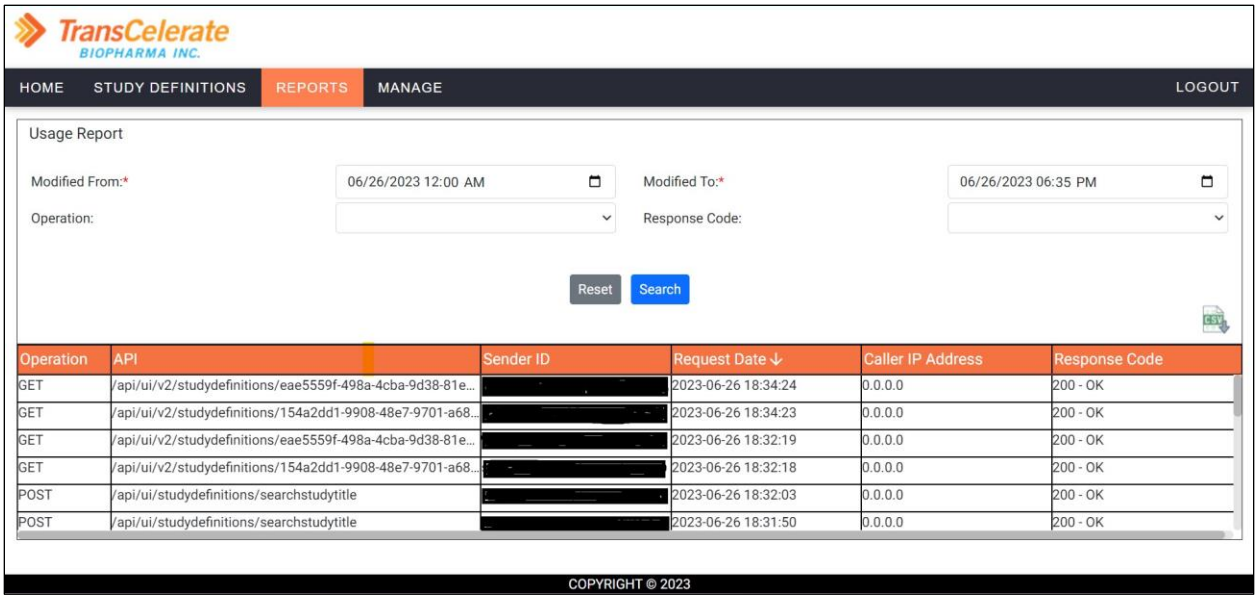
3.1. System Usage Report

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 24 System usage report page



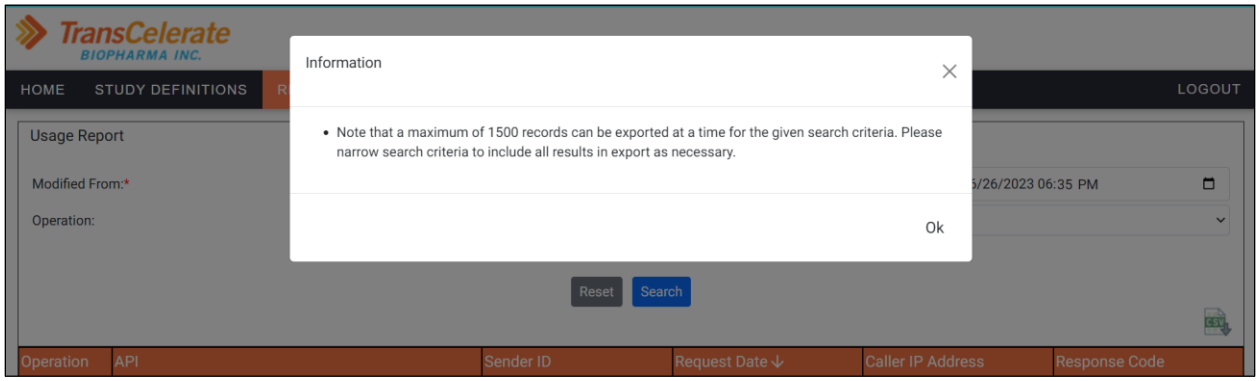
ii. User can change the duration of the report generated to see system usage for a maximum range of 30 days.

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.

Figure 25 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

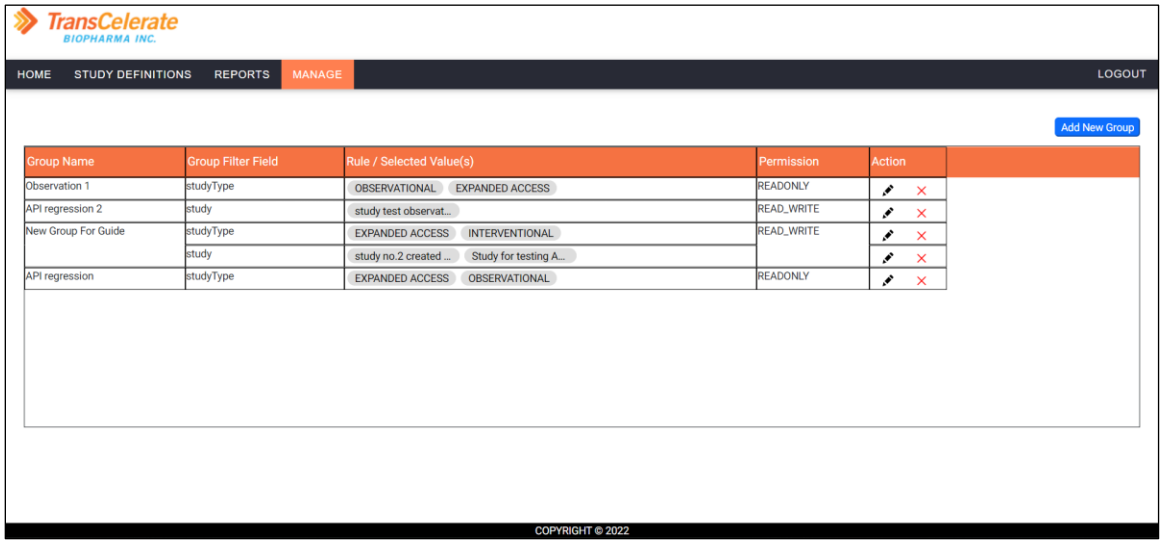
The group and user management features provide the ability to group users and associate them with specific study or group of studies to limit access for users only to those study definitions. The creation of groups and setting their criteria as well as associating users to these groups can be done only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

3.2.1. Group Management

NAVIGATION STEPS:

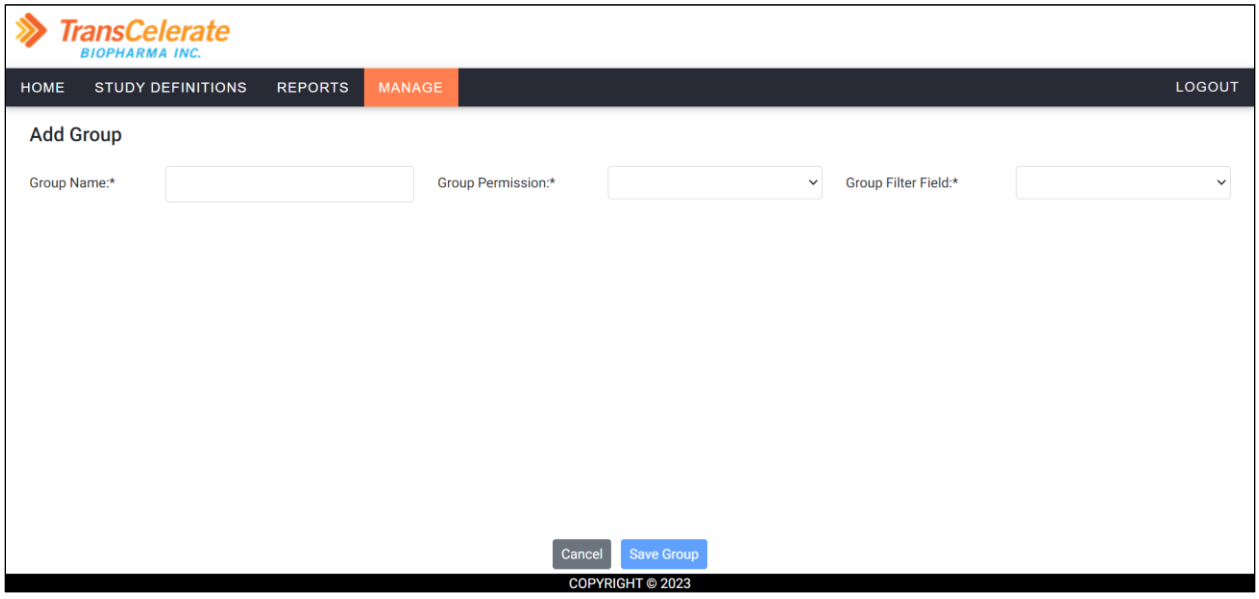
i. An admin user can navigate to the Group Management screen from the Manage main menu.
ii. On the Group Management screen, user can Add new groups as well as edit existing groups.
iii. By default, the list of existing groups is displayed on the home screen of Group Management.

Figure 26 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.

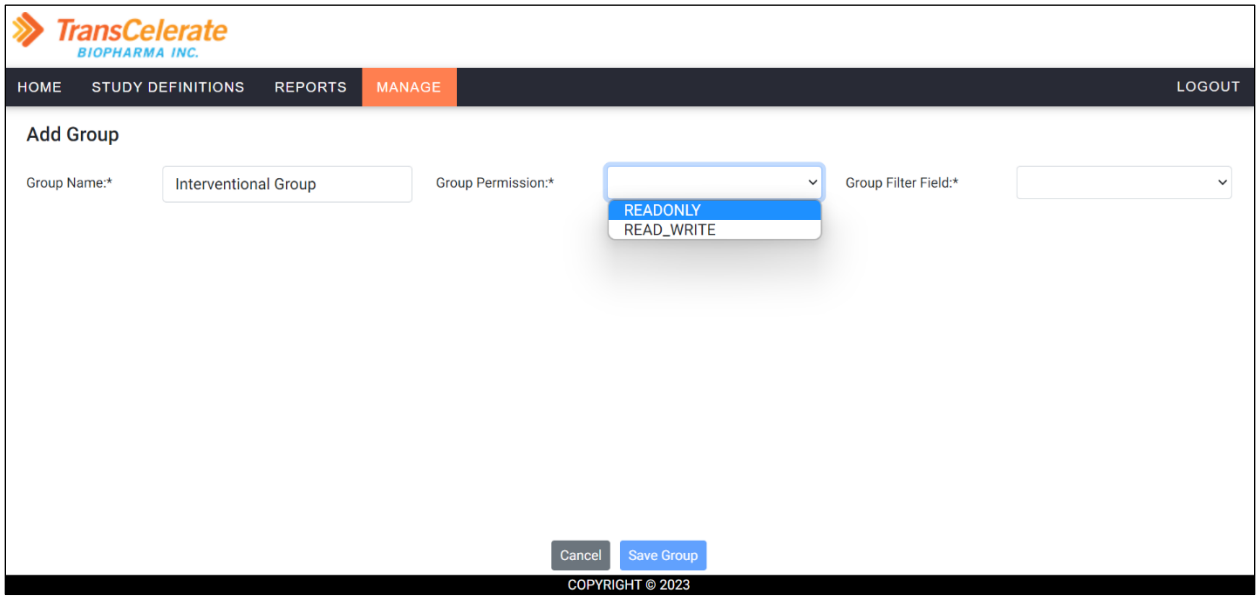
Figure 27 Add Group page.



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.

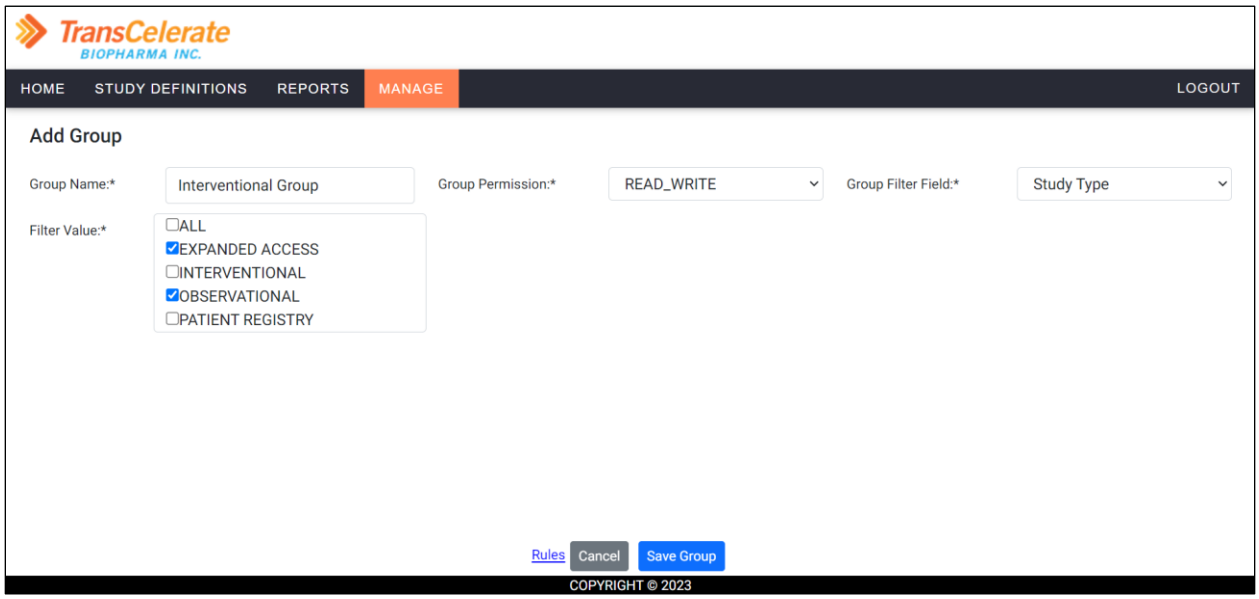
vi. The Group Permissions allow the admin user to set the access privilege for users belonging to this group i.e., users can either READ or READ & WRITE the studies associated with this group.

Figure 28 Group Management - Permissions



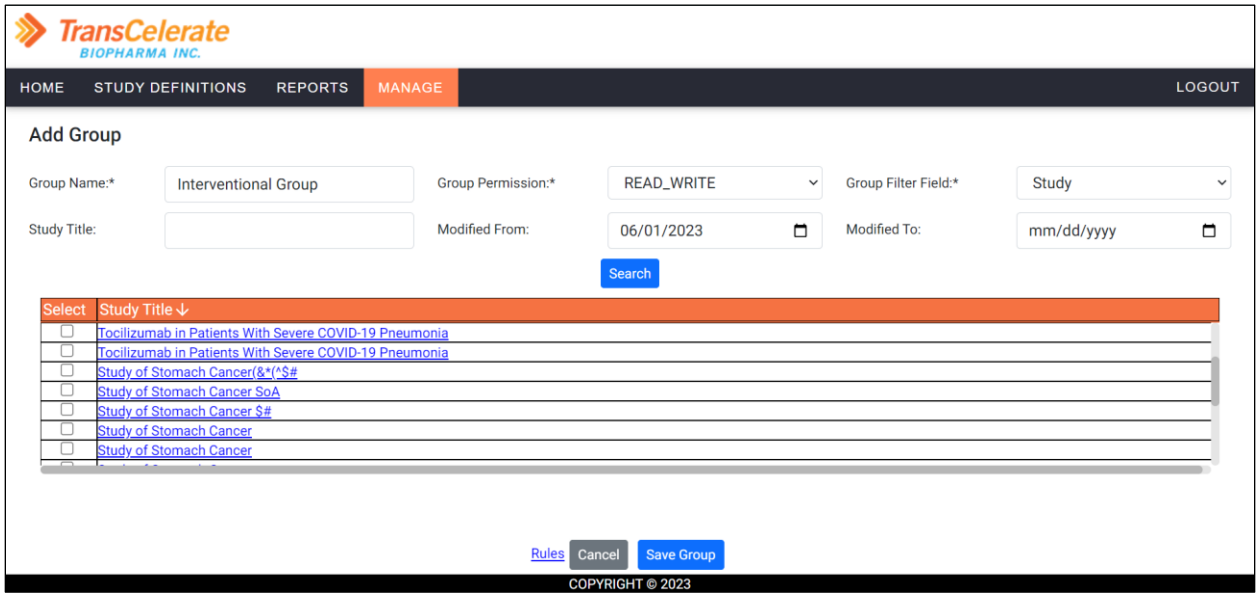
vii. The Group Filter Field allows the admin user to configure the rule that combines one or more studies to be associated with a group. When Study Type filter is selected, one or more study types can be selected and added to the rule.

Figure 29 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.

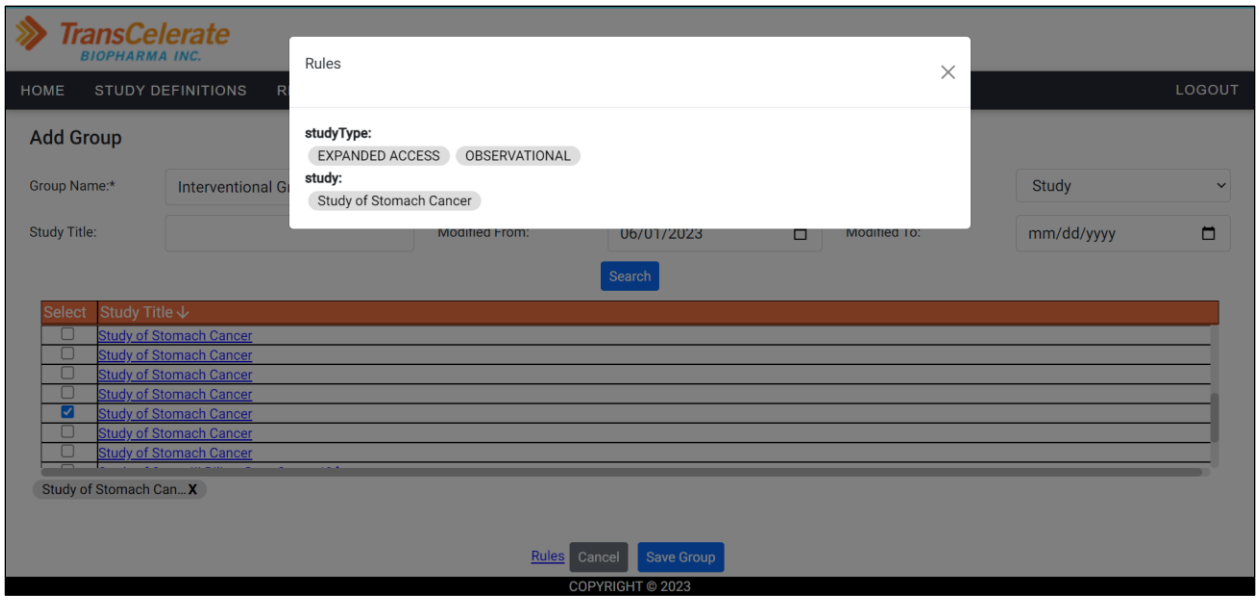
Figure 30 Group Management - Search Studies



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.

Figure 31 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.

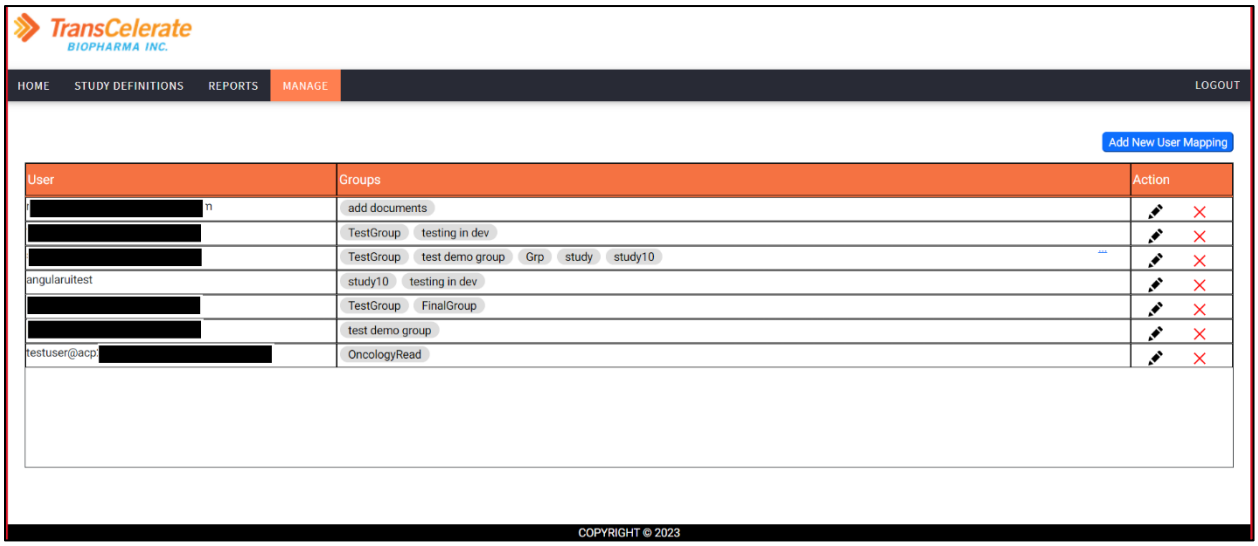
3.2.2. User Management

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.

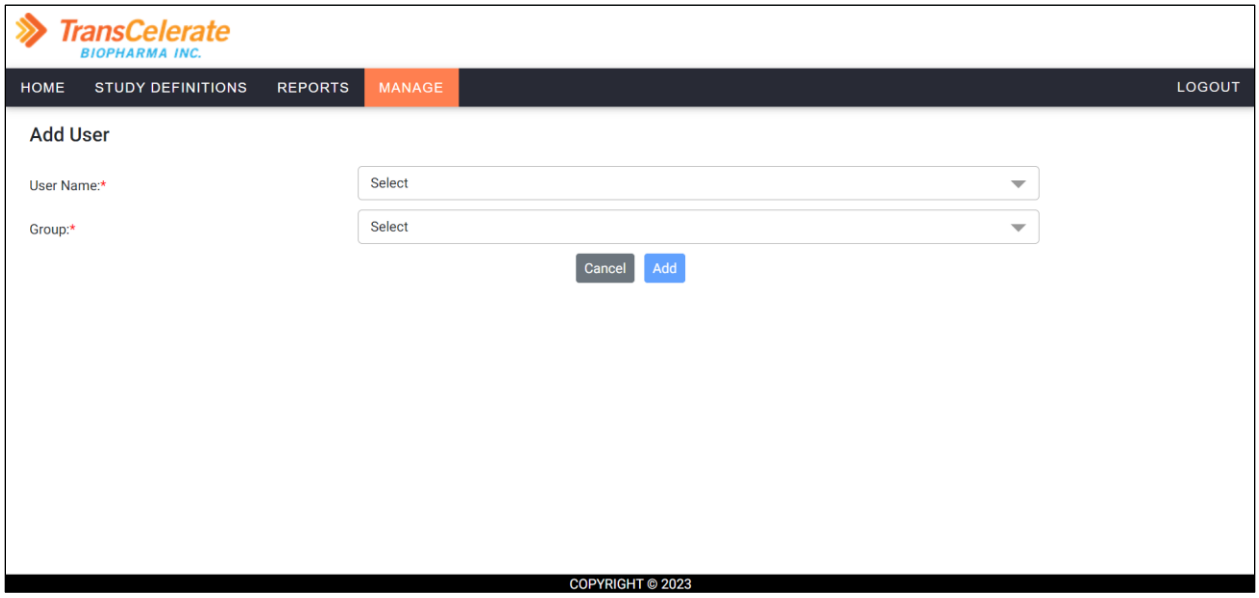
Figure 32 Group management page



ii. 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.

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

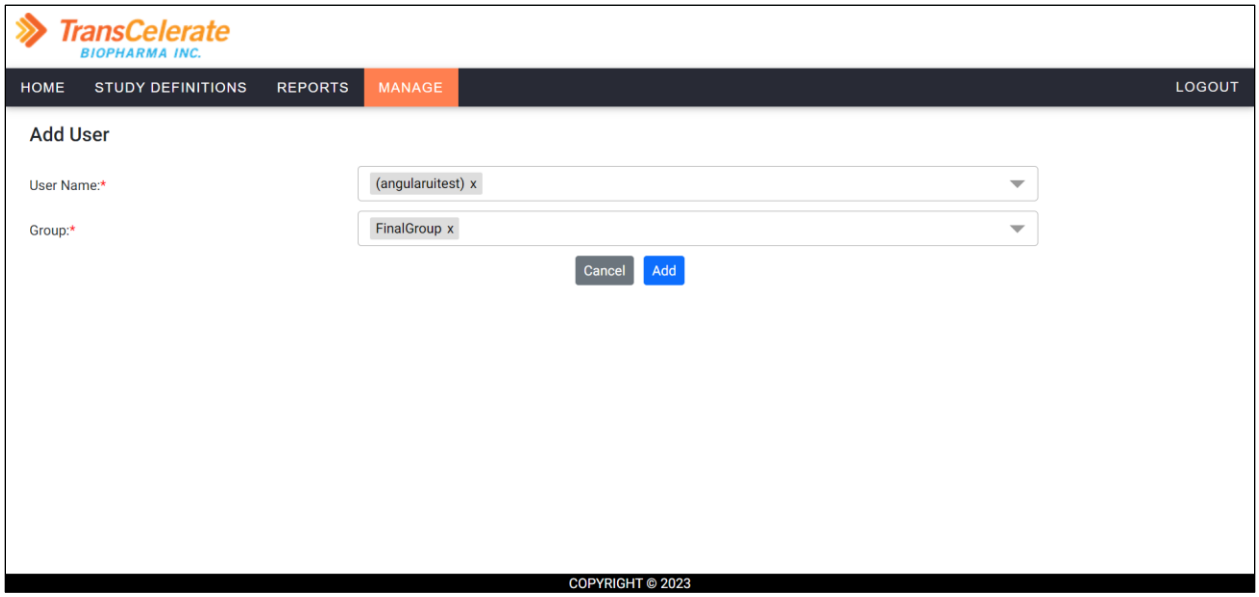
Figure 33 Add user page



iv. On Add User screen, admin can search and select a user to whom a group association needs to be added.

v. 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.

Figure 34 User Management - Group Mapping



vi. 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.

vii. 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.