

Study Definition Repository (SDR)

Reference Implementation (RI)

User Interface User Guide

Version 7.0

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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.
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.
V6.0	29-Apr-2024	ACN	Added instructions to skip certificate selection after successful authentication.
V7.0	11-Sept-2025	Capgemini	Removed authentication, authorization management, and usage report.

Contents

1. Introduction	4
Overview	4
Scope of Document.....	4
Intended Audience.....	4
Definitions and Acronyms.....	5
2. SDR RI UI – General Features	5
Recent Activity Widget.....	5
Search Study Definitions	6
Study Details	7
SoA Matrix (Schedule of Activities).....	9
Revision History	11
Version Comparison.....	12
Study Comparison	13

1. Introduction

Overview

The UI application of the SDR Reference Implementation¹ allows the user to view and search Study Definitions. The RI UI features include -

- List Study Definitions and View Details including SoA Matrix
- Search Study Definitions
- View Revision History for a Study
- Compare Study Versions and Different Studies

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.

Intended Audience

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

Definitions and Acronyms

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

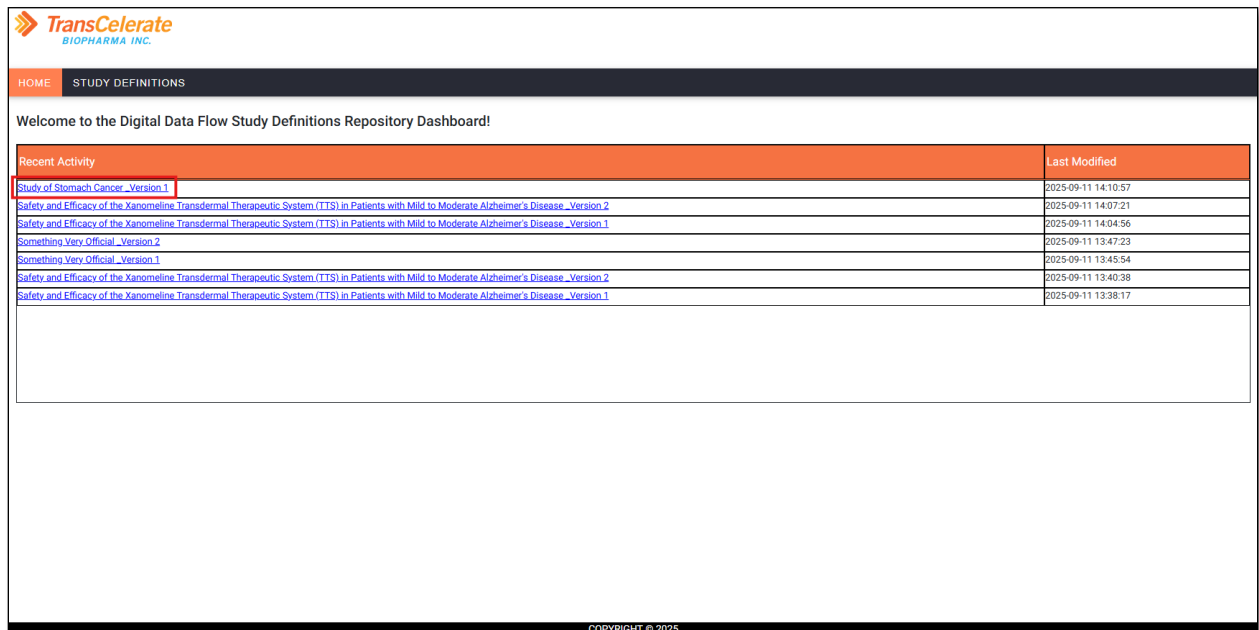
2. SDR RI UI – General Features

The SDR RI UI Implementation has the following features outlined below.

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 1 Recent Activity Widget



The screenshot shows the TransCelerate BIOPHARMA INC. logo at the top left. Below it is a navigation bar with 'HOME' and 'STUDY DEFINITIONS'. The main content area is titled 'Welcome to the Digital Data Flow Study Definitions Repository Dashboard!'. Below this is a table with two columns: 'Recent Activity' and 'Last Modified'. The table lists several study definitions, including 'Study of Stomach Cancer -Version 1' and 'Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease -Version 2'. The table is scrollable, and the bottom of the page shows a copyright notice: 'COPYRIGHT © 2025'.

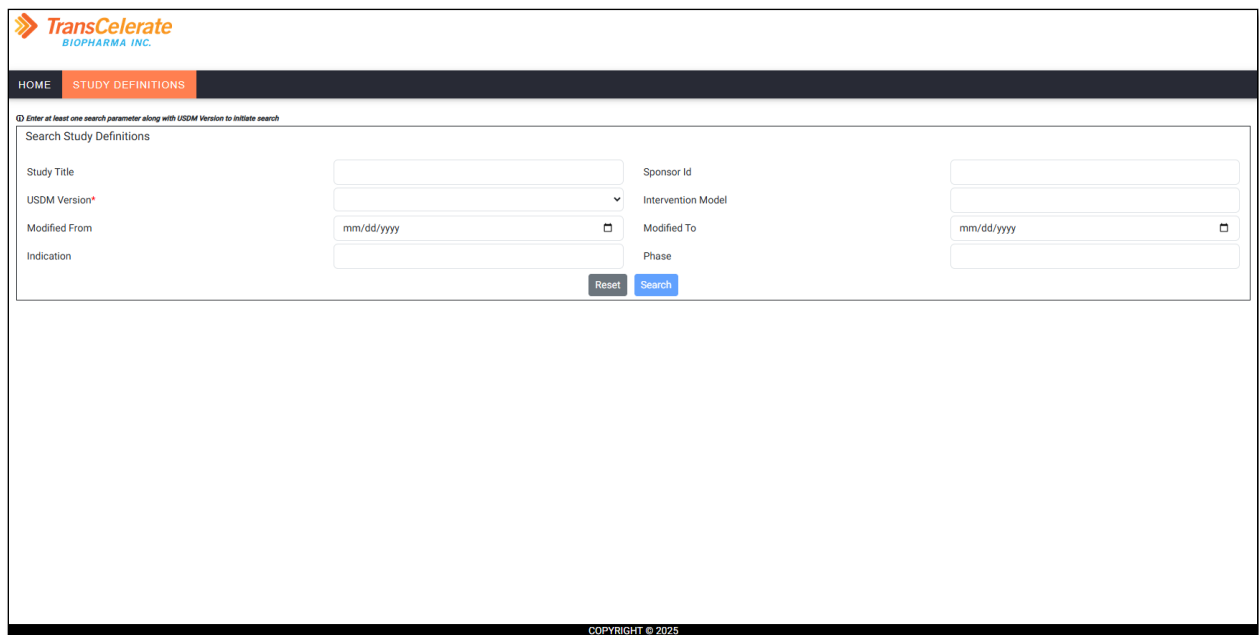
Recent Activity	Last Modified
Study of Stomach Cancer -Version 1	2025-09-11 14:10:57
Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease -Version 2	2025-09-11 14:07:21
Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease -Version 1	2025-09-11 14:04:56
Something Very Official -Version 2	2025-09-11 13:47:23
Something Very Official -Version 1	2025-09-11 13:45:54
Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease -Version 2	2025-09-11 13:40:38
Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease -Version 1	2025-09-11 13:38:17

Search Study Definitions

NAVIGATION STEPS:

- On clicking the Search Study Definitions in the menu, the user can navigate to the search page, where they can select any parameter along with the USDM Version parameter to search specific a study (the USDM Version parameter is a mandatory field):

Figure 2 Search Study page



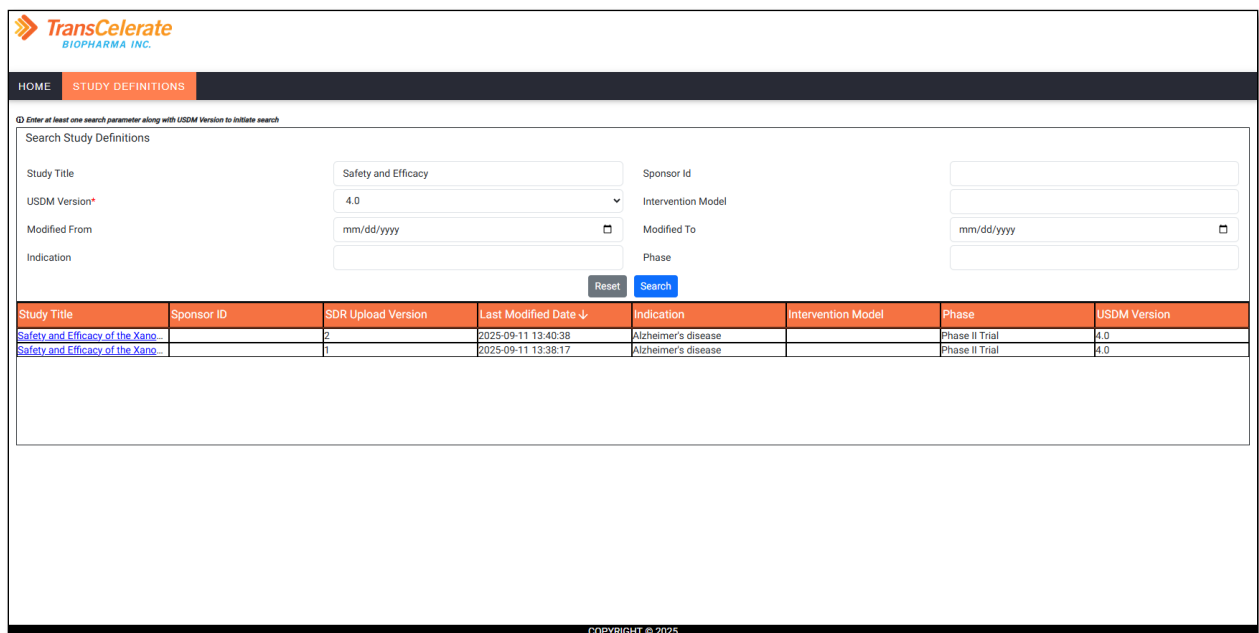
- Below is the list of search parameters and their types:

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 (Mandatory)	Dropdown containing list of different USDM versions.

- Once the user clicks on the Search button, the Search Results view is shown as below.

Figure 3 Search results



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HOME STUDY DEFINITIONS

Enter at least one search parameter along with USDM Version to initiate search

Search Study Definitions

Study Title: Safety and Efficacy

USDM Version: 4.0

Modified From: mm/dd/yyyy

Indication:

Sponsor ID:

Intervention Model:

Modified To: mm/dd/yyyy

Phase:

Reset Search

Study Title	Sponsor ID	SDR Upload Version	Last Modified Date ↓	Indication	Intervention Model	Phase	USDM Version
Safety and Efficacy of the Xano		2	2025-09-11 13:40:38	Alzheimer's disease		Phase II Trial	4.0
Safety and Efficacy of the Xano		1	2025-09-11 13:38:17	Alzheimer's disease		Phase II Trial	4.0

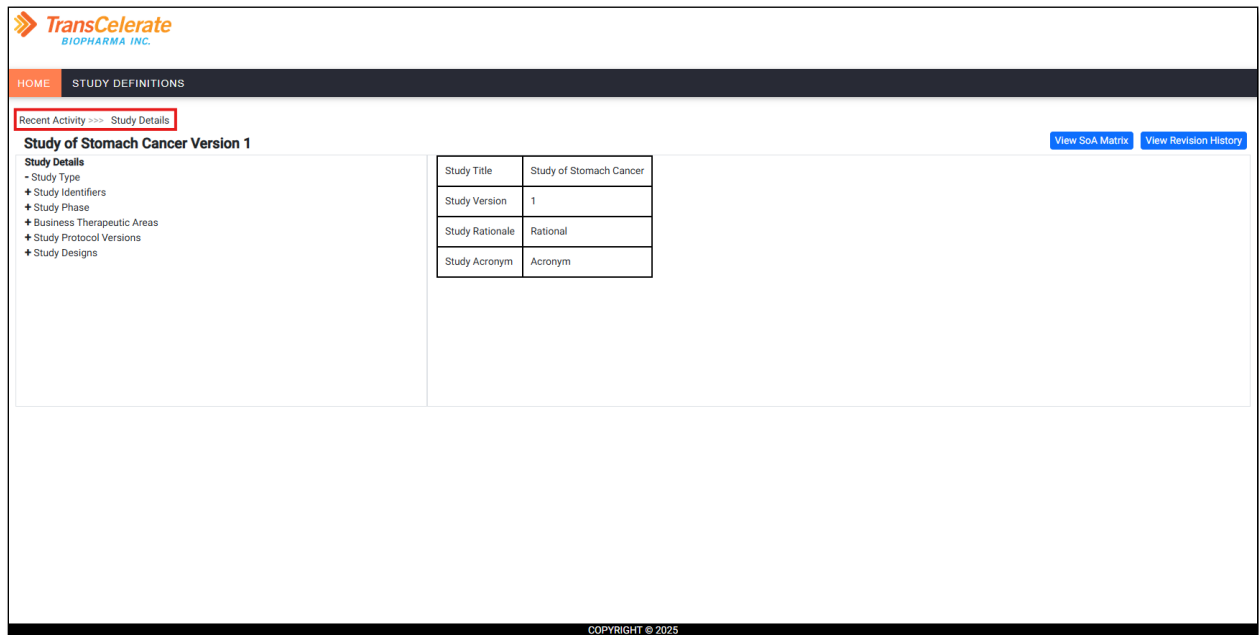
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- Columns in the search results are sortable (ascending/descending) except USDM Version.
- The top 20 documents are listed first, and the remaining results come into view as the user scrolls.

Study Details

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

Figure 4 Study Details Page from Home



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HOME STUDY DEFINITIONS

Recent Activity >>> Study Details

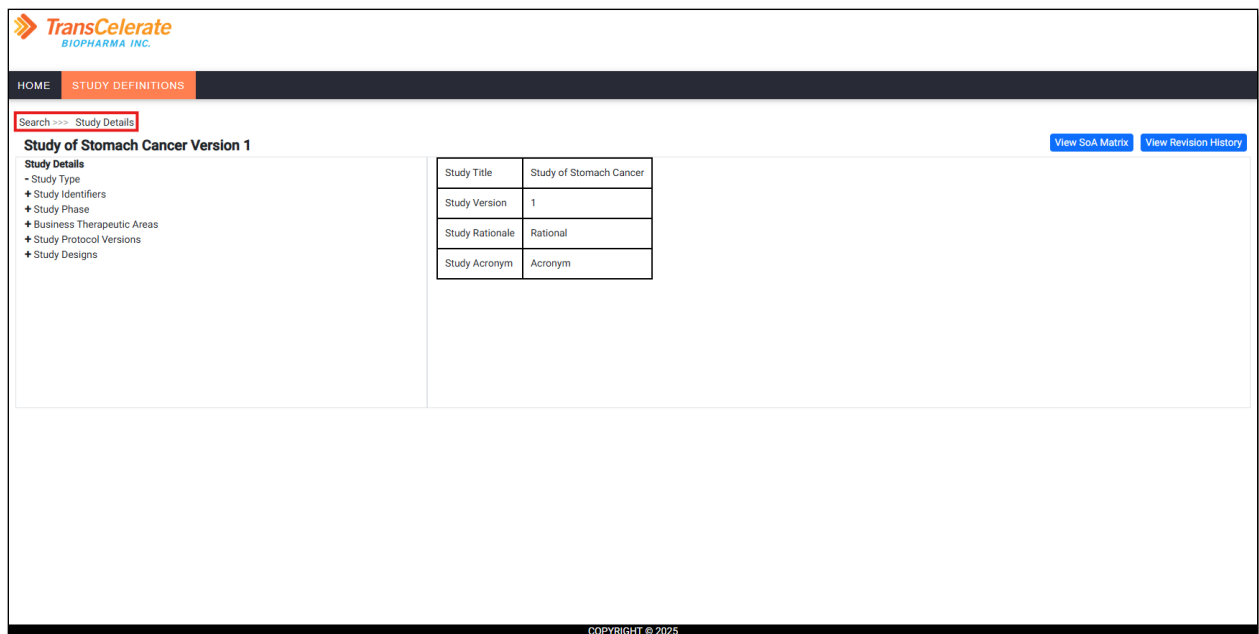
Study of Stomach Cancer Version 1

View SoA Matrix View Revision History

Study Title	Study of Stomach Cancer
Study Version	1
Study Rationale	Rational
Study Acronym	Acronym

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Figure 5 Study Details page from Search Grid



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HOME STUDY DEFINITIONS

Search >>> Study Details

Study of Stomach Cancer Version 1

View SoA Matrix View Revision History

Study Title	Study of Stomach Cancer
Study Version	1
Study Rationale	Rational
Study Acronym	Acronym

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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 (one table per schedule timeline per study design within tabs) as shown below.

Figure 6 SoA Matrix

TransCelerate

BIOPHARMA INC.

HOME

STUDY DEFINITIONS

Recent Activity >>> Study Details >>> SoA Matrix

Study of Stomach Cancer Version 1

Design for Lung C...

name

Name

name

Description

Timeline for Stage III

Condition

condition

Export to Excel

Encounter (Planned Time)	SCREENING VISIT		RUN-IN VISIT 1 (RUN-IN VISIT		RUN-IN VISIT		CYCLE 1, T...	CYCLE 1, T...	CYCLE 1, T...	CYCLE 2, T...	CYCLE 2, T...	CYCLE 3, T...	CYCLE 3, T...	FU 1 (WEEK	FU 2 (M
Timing	Day 1	Day 15	Day 1	Day 15	Day 10	Day 18	Day 20	Day 23	Day 25	Day 30	Day 35	WEEK 1	WEEK 3	WEEK 5	WEEK 6		
Window	window	window	window	window	window	window	window	window	window	window	window	window	window	window	window	window	
Activity																	
+ Informed consent	X	X															X
+ Eligibility criteria	X	X	X	X											X		
+ Demographics	X	X	X	X													X

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NAVIGATION STEPS:

- On clicking View SoA Matrix on the Study Details screen, the user will be redirected to viewing all SoA's for a given version of the study definition.
- Each study design tab will have child tabs that will display one SoA Matrix per Schedule Timeline.
- The schedule Timeline basic information (Name, Description and Condition) is above the SoA Matrix table. When there is no study design or timelines defined in the selected study version, a message is shown to the user indicating there is insufficient data to build the matrix.
- 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.

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

Figure 7 SoA Matrix with accordions

Study of Stomach Cancer Version 1

Design for Lung C...

name

Name	name
Description	Timeline for Stage III
Condition	condition

Export to Excel

Timing	Day 1	Day 15	Day 1	Day 15	Day 10	Day 18	Day 20	Day 23	Day 25	Day 30	Day 35	WEEK 1	WEEK 3	V
Window	window	window	window	window	window	window	window	window	window	window	window	window	window	v
Activity														
- Informed consent - Biomedical Concepts - Diastolic Blood Pressure - Procedures - Name : Desc - Name T1 : Desc Time Profile: name	X	X												
+ Eligibility criteria	X	X	X	X										
+ Demography	X	X	X	X										

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- 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.
- The user can also download the SOA Matrix by clicking on Export to Excel button which is available under each timeline.
- The 'Export to Excel' button is disabled if there is insufficient data inside any timeline.

Figure 8 Footnotes below SoA Matrix

Activity														
+ Informed consent	X													
+ Inclusion/exclusion criteria	X													
+ Patient number assigned	X													
+ Demographics	X													
+ Hachinski	X													
+ MMSE	X													
+ Physical examination	X													
+ Medical history	X													
+ Habits	X													
+ Chest X-ray	X													
+ Apo E genotyping				X										
+ Patient randomised			X											
+ Vital signs / Temperature	X	X	X	X	X	X	X		X		X		X	
+ Ambulatory ECG placed		X												
+ Ambulatory ECG														

^{A1} Performed if patient is an insulin-dependent diabetic
^{A2} Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.
^{A3} Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.
^{A4} Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.
^{A5} Practice only - It is recommended that a sampling of the CIBIC+, ADAS-Cog, DAD, and NPI-X be administered at Visit 1. Data from this sampling would not be considered as study data and would not be collected.

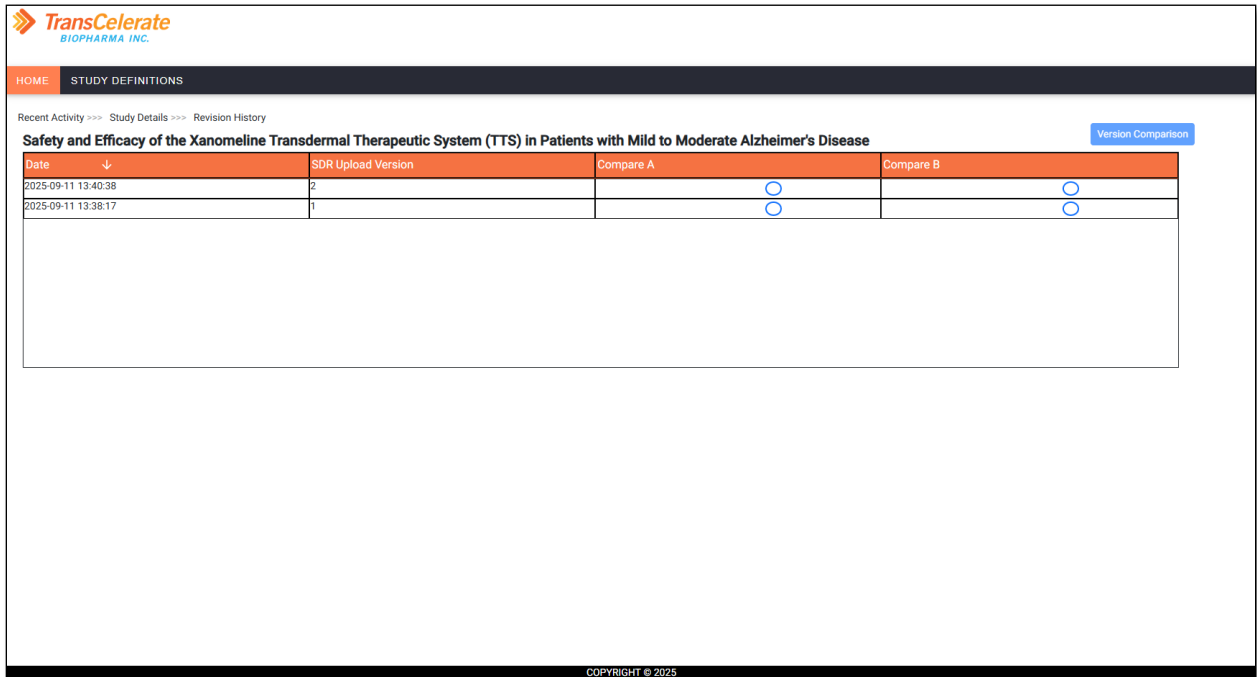
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Revision History

NAVIGATION STEPS:

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

Figure 9 Revision History Page



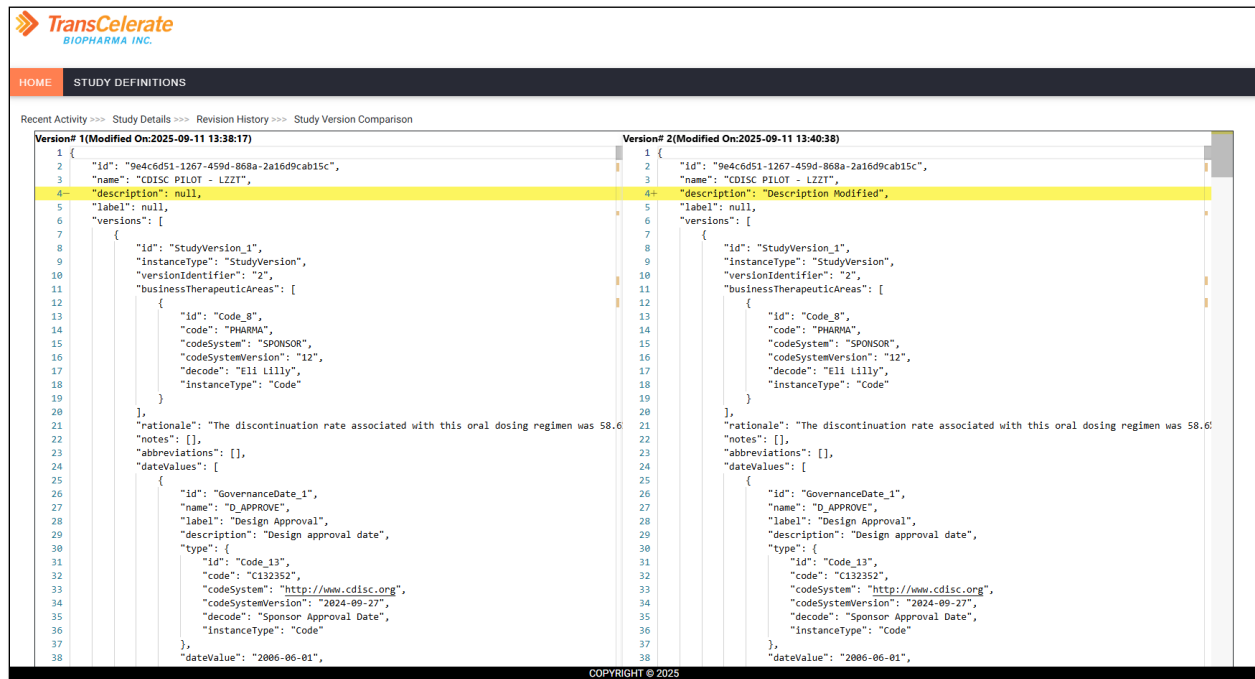
Date	SDR Upload Version	Compare A	Compare B
2025-09-11 13:40:38	2	<input type="radio"/>	<input type="radio"/>
2025-09-11 13:38:17	1	<input type="radio"/>	<input type="radio"/>

Version Comparison

NAVIGATION STEPS:

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

Figure 10 Version Comparison page

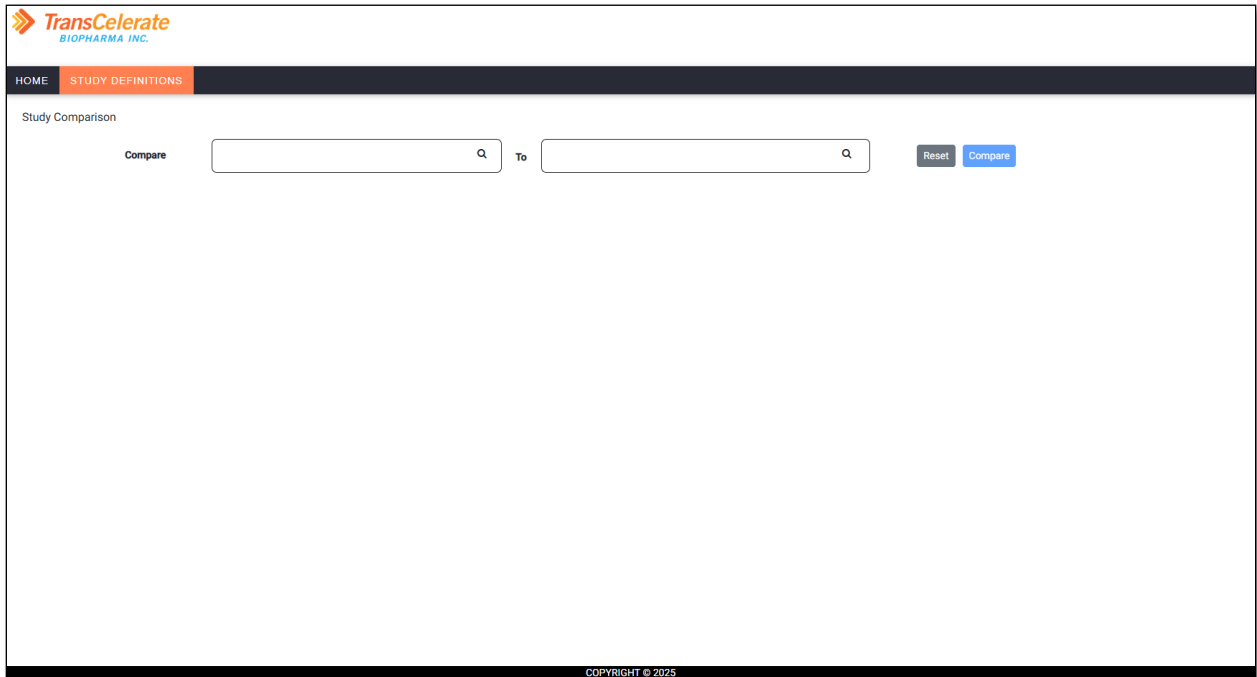


Version# 1 (Modified On: 2025-09-11 13:38:17)	Version# 2 (Modified On: 2025-09-11 13:40:38)
1 {	1 {
2 "id": "9e4cd51-1267-459d-868a-2a16d9cab15c",	2 "id": "9e4cd51-1267-459d-868a-2a16d9cab15c",
3 "name": "CDISC PILOT - LZT",	3 "name": "CDISC PILOT - LZT",
4 "description": null,	4+ "description": "Description Modified",
5 "label": null,	5 "label": null,
6 "versions": [6 "versions": [
7 {	7 {
8 "id": "StudyVersion_1",	8 "id": "StudyVersion_1",
9 "instanceType": "StudyVersion",	9 "instanceType": "StudyVersion",
10 "versionIdentifier": "2",	10 "versionIdentifier": "2",
11 "businessTherapeuticAreas": [11 "businessTherapeuticAreas": [
12 {	12 {
13 "id": "Code_8",	13 "id": "Code_8",
14 "code": "PHARMA",	14 "code": "PHARMA",
15 "codeSystem": "SPONSOR",	15 "codeSystem": "SPONSOR",
16 "codeSystemVersion": "12",	16 "codeSystemVersion": "12",
17 "decode": "Eli Lilly",	17 "decode": "Eli Lilly",
18 "instanceType": "Code"	18 "instanceType": "Code"
19 },	19 },
20],	20],
21 "rationale": "The discontinuation rate associated with this oral dosing regimen was 58.6",	21 "rationale": "The discontinuation rate associated with this oral dosing regimen was 58.6",
22 "notes": [],	22 "notes": [],
23 "abbreviations": [],	23 "abbreviations": [],
24 "dateValues": [24 "dateValues": [
25 {	25 {
26 "id": "GovernanceDate_1",	26 "id": "GovernanceDate_1",
27 "name": "D_APPROVE",	27 "name": "D_APPROVE",
28 "label": "Design Approval",	28 "label": "Design Approval",
29 "description": "Design approval date",	29 "description": "Design approval date",
30 "type": {	30 "type": {
31 "id": "Code_13",	31 "id": "Code_13",
32 "code": "C132352",	32 "code": "C132352",
33 "codeSystem": "http://www.cdisc.org",	33 "codeSystem": "http://www.cdisc.org",
34 "codeSystemVersion": "2024-09-27",	34 "codeSystemVersion": "2024-09-27",
35 "decode": "Sponsor Approval Date",	35 "decode": "Sponsor Approval Date",
36 "instanceType": "Code"	36 "instanceType": "Code"
37 },	37 },
38 "dateValue": "2006-06-01",	38 "dateValue": "2006-06-01",

Study Comparison

NAVIGATION STEPS:

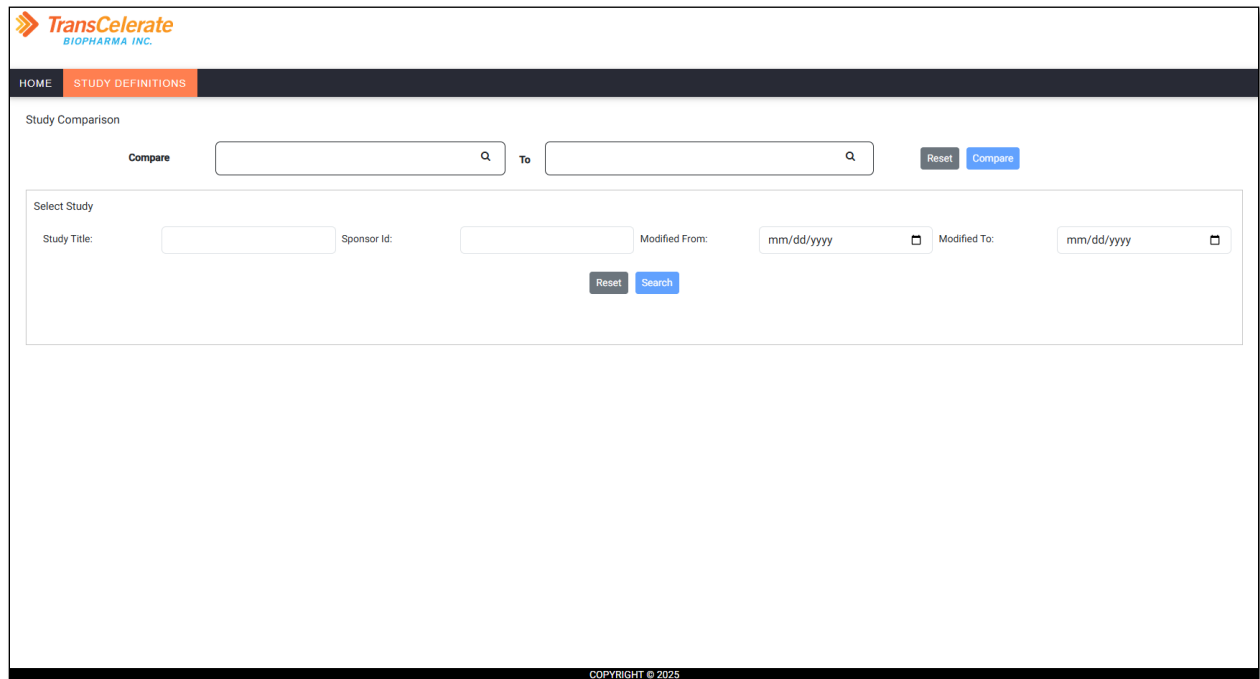
- On clicking the Compare button in the Study Definitions menu as shown in the below screenshot, the Study Comparison page will be loaded. This screen allows the user to do a side-by-side comparison of two different study definitions.

Figure 11 Study Compare Page

The screenshot shows the TransCelerate Biopharma Inc. web application interface. At the top, there is a navigation bar with 'HOME' and 'STUDY DEFINITIONS' tabs. Below this, the 'Study Comparison' section is visible. It features a 'Compare' label, two search input boxes with magnifying glass icons, and a 'To' label between them. To the right of the search boxes are 'Reset' and 'Compare' buttons. The footer of the page indicates 'COPYRIGHT © 2025'.

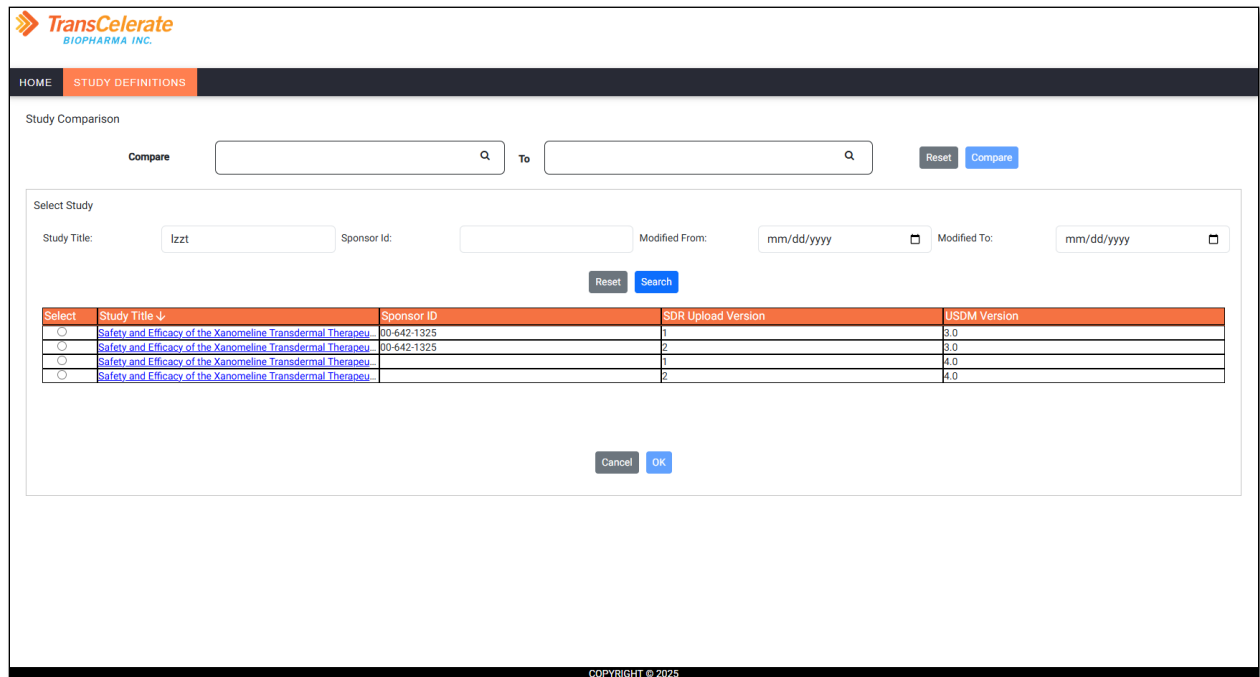
- The User can search any two studies to compare by using the search feature on the left and right sides of the compare. At any point, only two studies can be compared.
- The user searches separately for the two studies using the left and right search boxes
- In either case, once the user clicks on the search icon in the respective search box, search criteria will appear below the search boxes and the user can search a study by entering the criteria of interest and then pressing the “search” button. The user can search the study, by Study title, Sponsor ID and modified date range.

Figure 12 Search study compare page.



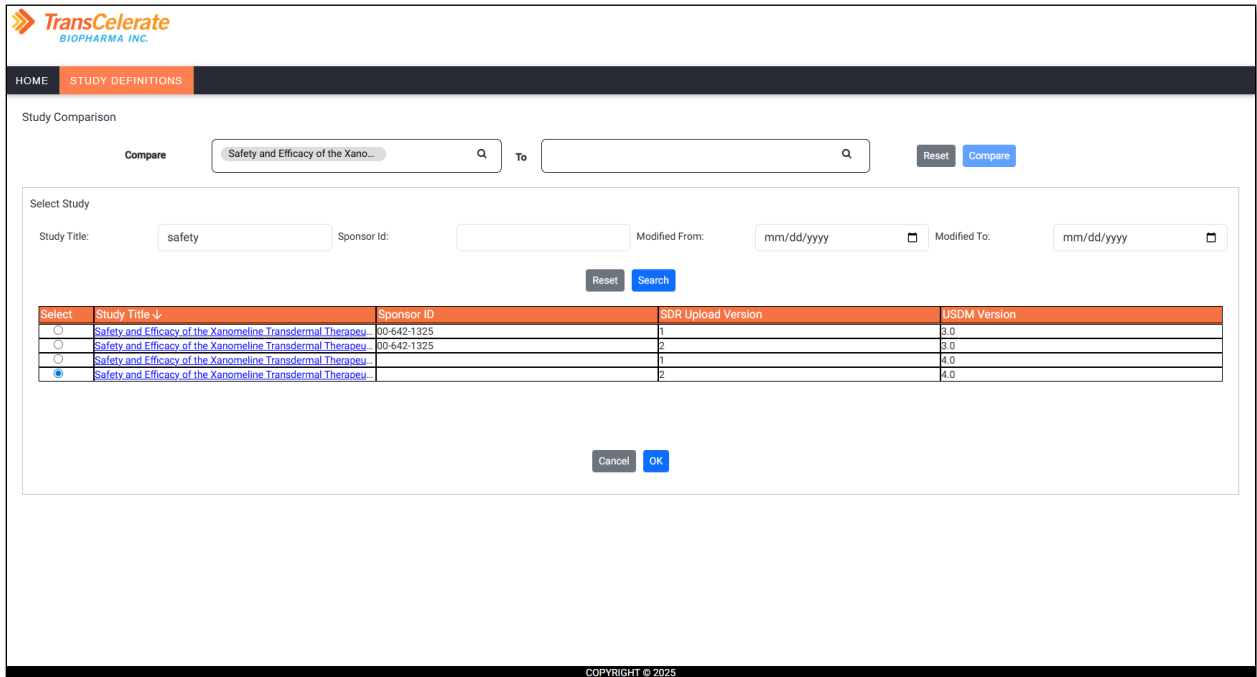
- Once the relevant study is found on search, user can click OK to add to compare.

Figure 13 Study Comparison - Search Results



Select	Study Title	Sponsor ID	SDR Upload Version	USDM Version
<input type="radio"/>	Safety and Efficacy of the Xanomeline Transdermal Therapeu	00-642-1325	1	3.0
<input type="radio"/>	Safety and Efficacy of the Xanomeline Transdermal Therapeu	00-642-1325	2	3.0
<input type="radio"/>	Safety and Efficacy of the Xanomeline Transdermal Therapeu		1	4.0
<input type="radio"/>	Safety and Efficacy of the Xanomeline Transdermal Therapeu		2	4.0

Figure 14 Search study on selection to compare



TransCelerate BIOPHARMA INC.

HOME STUDY DEFINITIONS

Study Comparison

Compare To

Select Study

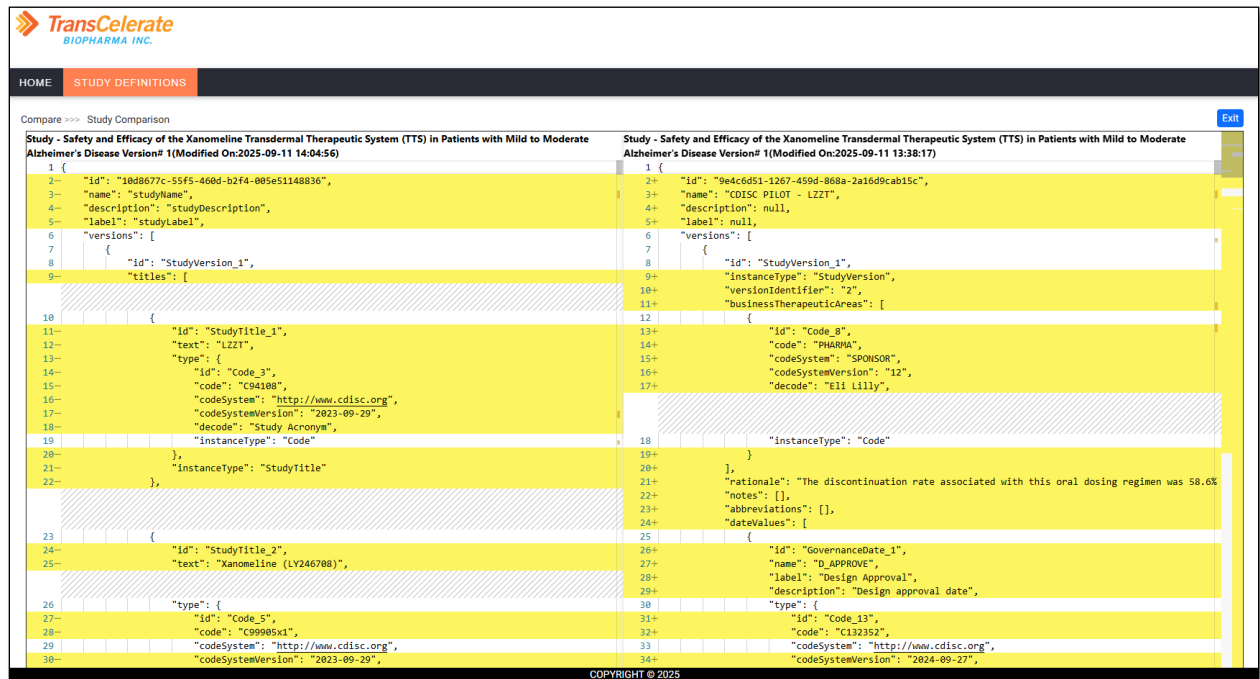
Study Title: Sponsor ID: Modified From: Modified To:

Select	Study Title ↓	Sponsor ID	SDR Upload Version	USDM Version
<input type="radio"/>	Safety and Efficacy of the Xanomeline Transdermal Therapeu...	00-642-1325	1	3.0
<input type="radio"/>	Safety and Efficacy of the Xanomeline Transdermal Therapeu...	00-642-1325	2	3.0
<input type="radio"/>	Safety and Efficacy of the Xanomeline Transdermal Therapeu...		1	4.0
<input checked="" type="radio"/>	Safety and Efficacy of the Xanomeline Transdermal Therapeu...		2	4.0

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- The above search process is repeated for each Search Box.

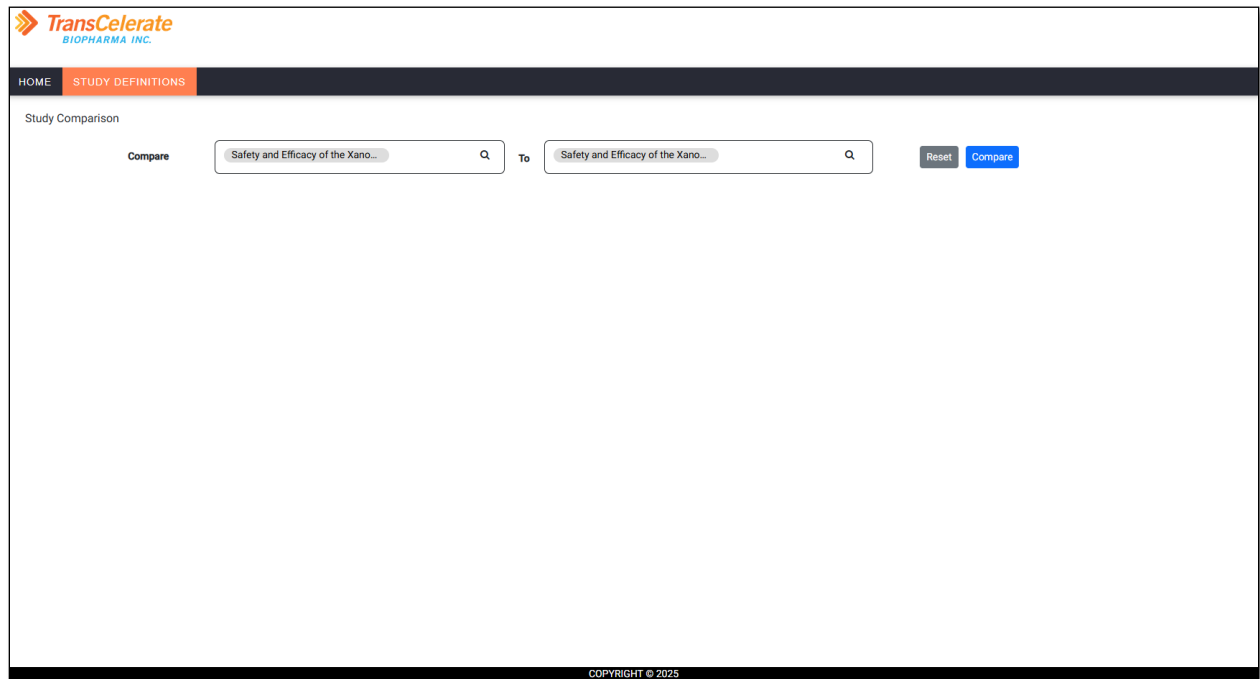
Figure 15 Study Comparison page



The screenshot displays the TransCelerate Study Comparison page. It features a navigation bar with 'HOME' and 'STUDY DEFINITIONS'. Below the navigation bar, there is a 'Compare' button and a 'Study Comparison' tab. The main content area shows two study definitions side-by-side, each with a scrollable JSON representation of the study definition. The left study is titled 'Study - Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease Version# 1 (Modified On:2025-09-11 14:04:56)'. The right study is titled 'Study - Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease Version# 1 (Modified On:2025-09-11 13:38:17)'. The JSON data is highlighted in yellow, and the comparison interface includes a scrollbar on the right side of the JSON content.

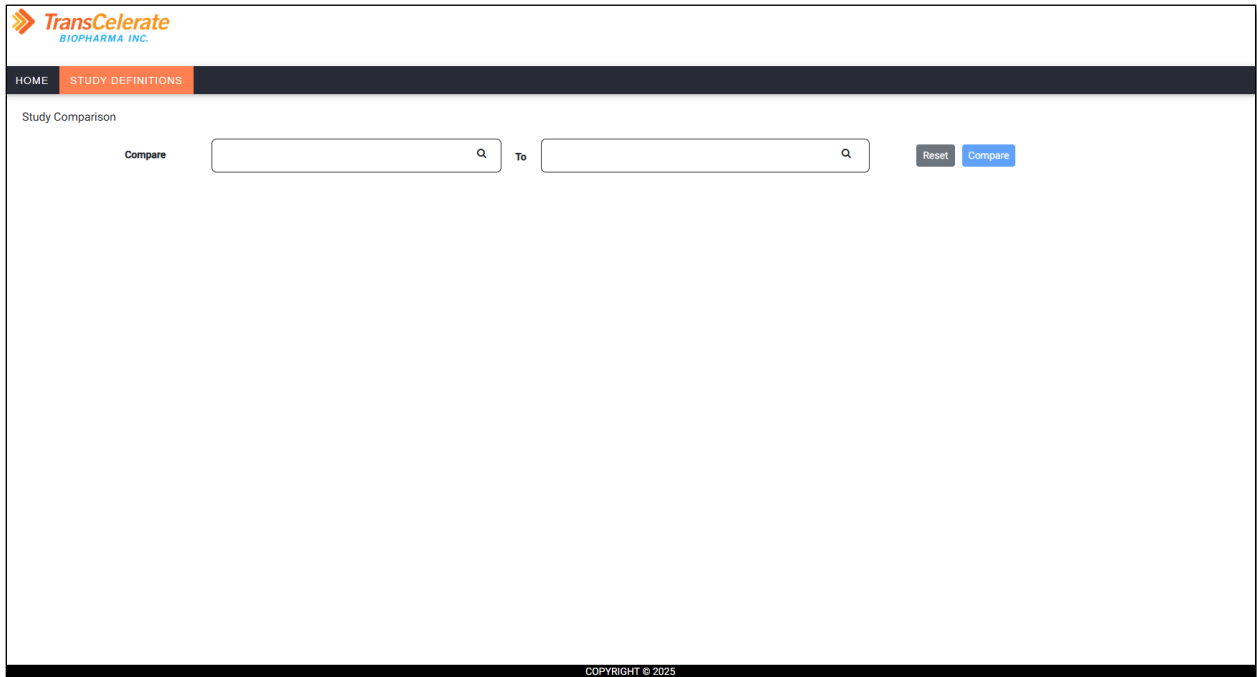
- Once two studies have been searched and selected on the left and right comparison boxes, user can click the “Compare” button.
- The application loads a side-by-side content comparison of the study definition JSONs. The comparison highlights the differences and the user can scroll through the comparison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

Figure 16 Compare page- navigation from breadcrumb.



- User can also click on “Exit” button on the Study Comparison screen to go back to the compare screen that is reset as shown below.

Figure 17 Compare page - Navigation using exit button.



The screenshot displays the TransCelerate BIOPHARMA INC. interface. At the top, there is a navigation bar with 'HOME' and 'STUDY DEFINITIONS'. Below this, the 'Study Comparison' section is visible. It features a 'Compare' label, two input fields with search icons, and a 'To' label. To the right of the input fields are 'Reset' and 'Compare' buttons. The footer of the page contains the text 'COPYRIGHT © 2025'.