

Study Definition Repository (SDR)

Reference Implementation User Interface User Guide Version 2.0

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Document History

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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

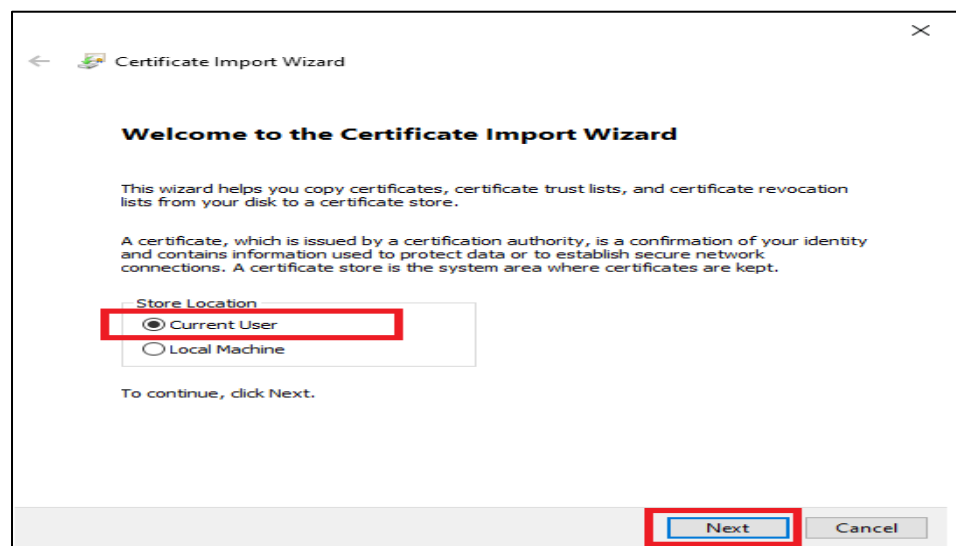
- User should be part of Azure Active Directory of SDR Azure subscription.
- Certificate Installation for accessing SDR User Interface

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

STEPS:

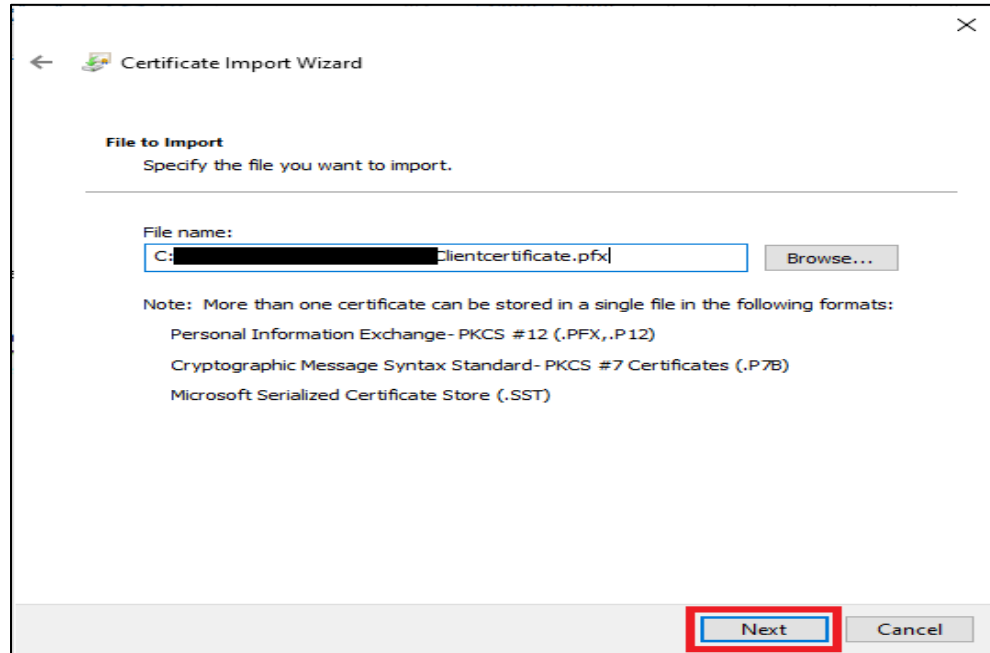
- i. Double click the .pfx certificate file.
- ii. Select “Current user” option and click next.

Figure 1 Certificate Import Wizard



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

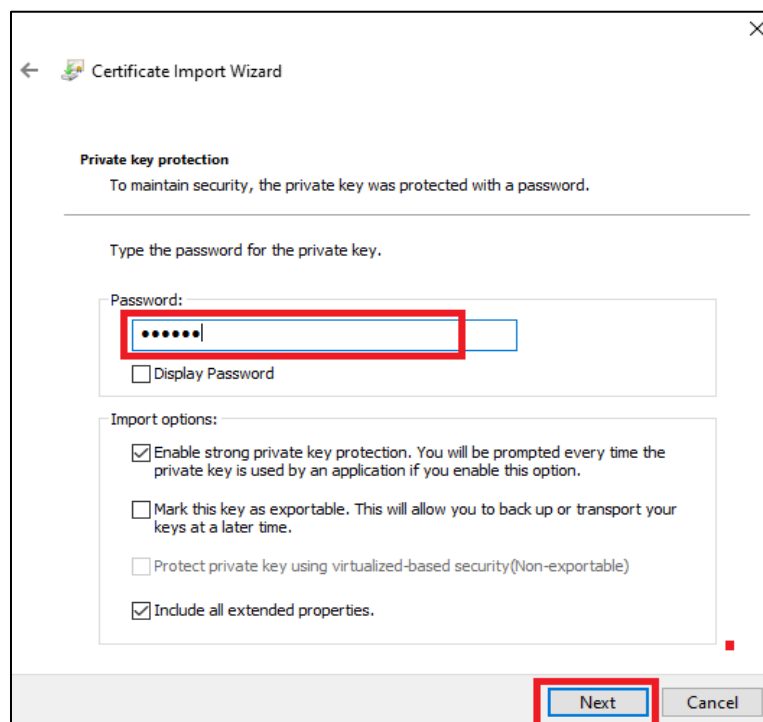
Figure 2 File to Import



The screenshot shows the 'File to Import' step of the Certificate Import Wizard. The title bar reads 'Certificate Import Wizard'. Below the title, there is a back arrow and a folder icon. The main heading is 'File to Import' with the instruction 'Specify the file you want to import.' Below this, there is a 'File name:' label and a text box containing 'C:\[redacted]clientcertificate.pfx'. To the right of the text box is a 'Browse...' button. Below the text box, there is a 'Note' section stating: 'Note: More than one certificate can be stored in a single file in the following formats: Personal Information Exchange- PKCS #12 (.PFX,.P12), Cryptographic Message Syntax Standard- PKCS #7 Certificates (.P7B), and Microsoft Serialized Certificate Store (.SST)'. At the bottom right, there are 'Next' and 'Cancel' buttons. The 'Next' button is highlighted with a red rectangle.

- iv. Provide the certificate password and click next

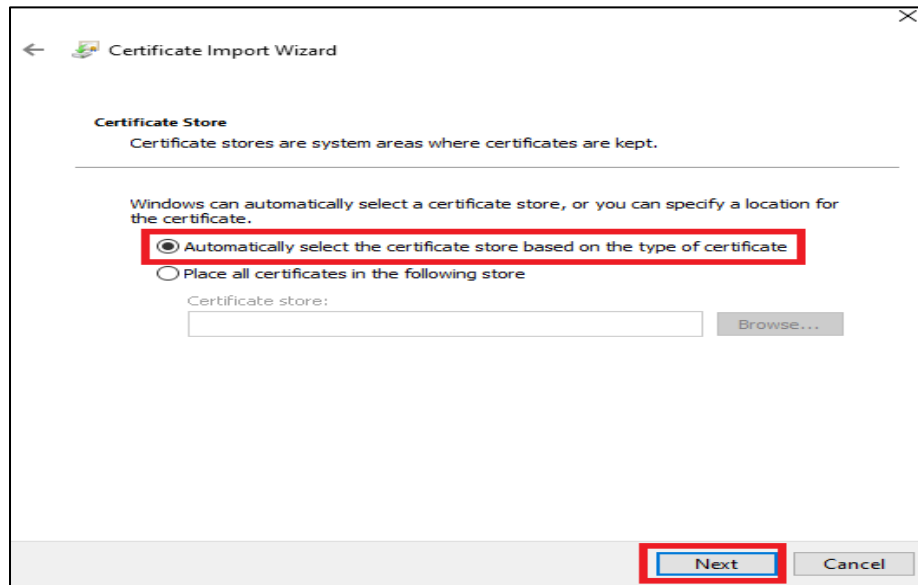
Figure 3 Certificate Password



The screenshot shows the 'Private key protection' step of the Certificate Import Wizard. The title bar reads 'Certificate Import Wizard'. Below the title, there is a back arrow and a folder icon. The main heading is 'Private key protection' with the instruction 'To maintain security, the private key was protected with a password.' Below this, there is a 'Type the password for the private key.' label and a 'Password:' label. The password text box contains several dots and is highlighted with a red rectangle. Below the password text box is a 'Display Password' checkbox. Below the password section, there is an 'Import options:' section with four checkboxes: 'Enable strong private key protection. You will be prompted every time the private key is used by an application if you enable this option.' (checked), 'Mark this key as exportable. This will allow you to back up or transport your keys at a later time.' (unchecked), 'Protect private key using virtualized-based security(Non-exportable)' (unchecked), and 'Include all extended properties.' (checked). At the bottom right, there are 'Next' and 'Cancel' buttons. The 'Next' button is highlighted with a red rectangle.

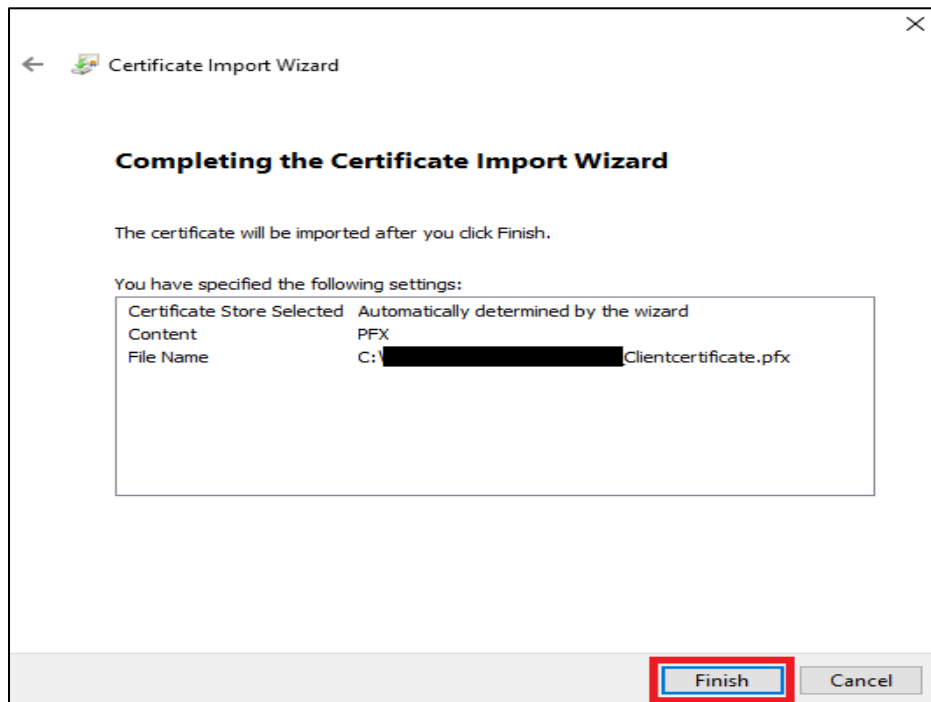
- v. Choose “Automatically select the certificate store” option and click next.

Figure 4 Certificate Store Selection



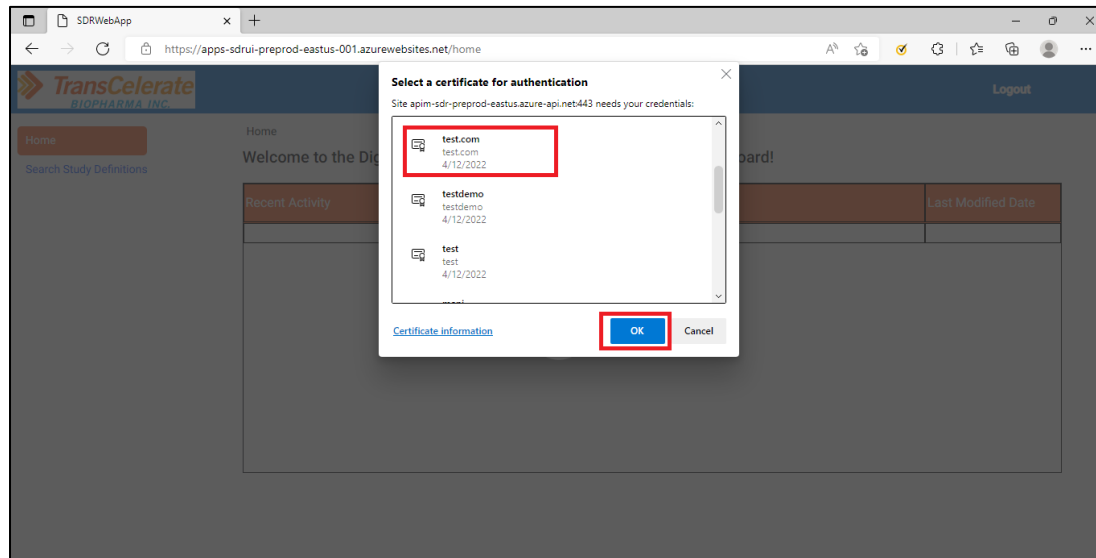
- vi. Click on finish

Figure 5 Certificate Finish Wizard



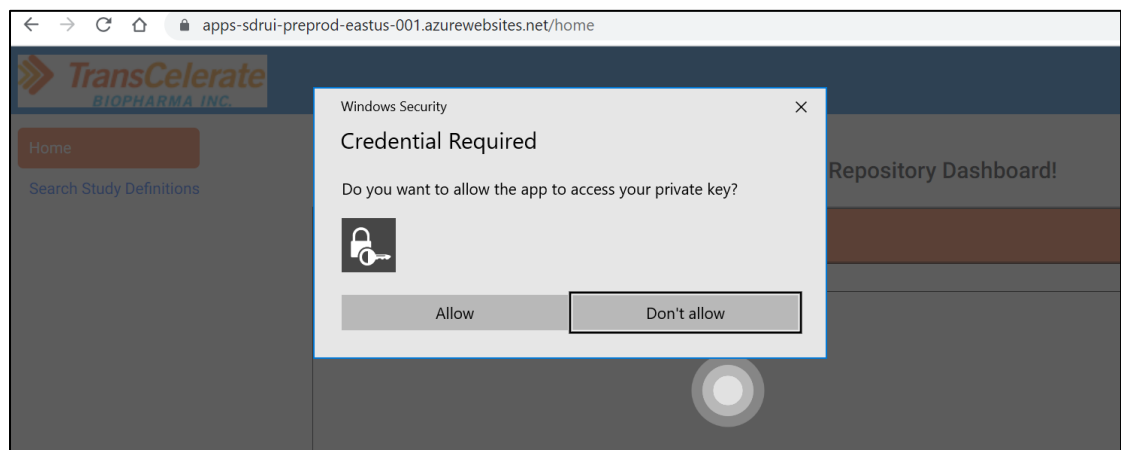
- vii. The browser will prompt for a certificate when accessing the SDR application after successful login. Select the installed certificate to access the application.

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 UI features

SDR UI Implementation has following features.

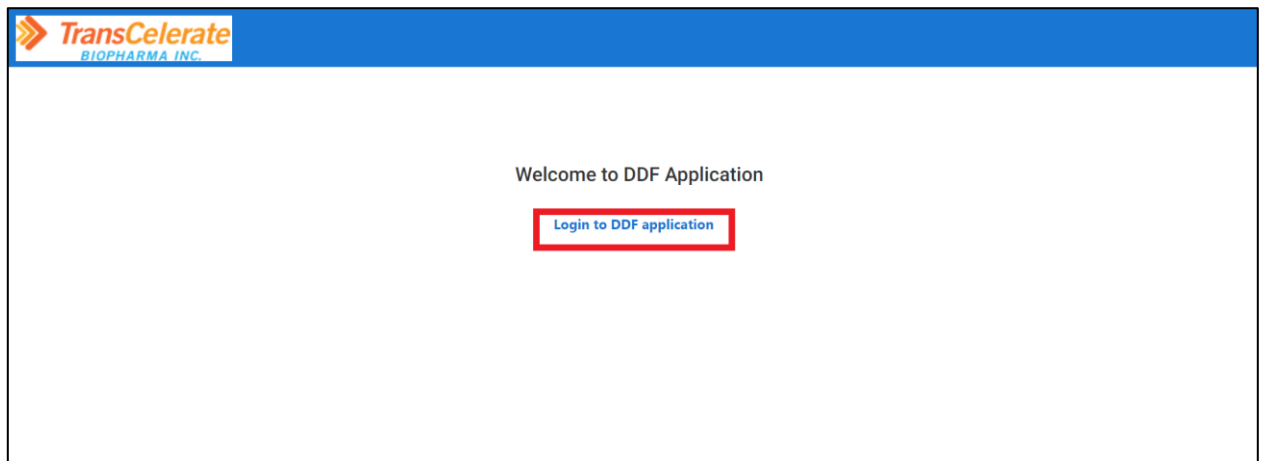
2.1. Login

This feature allows the user to login to the application.

STEPS:

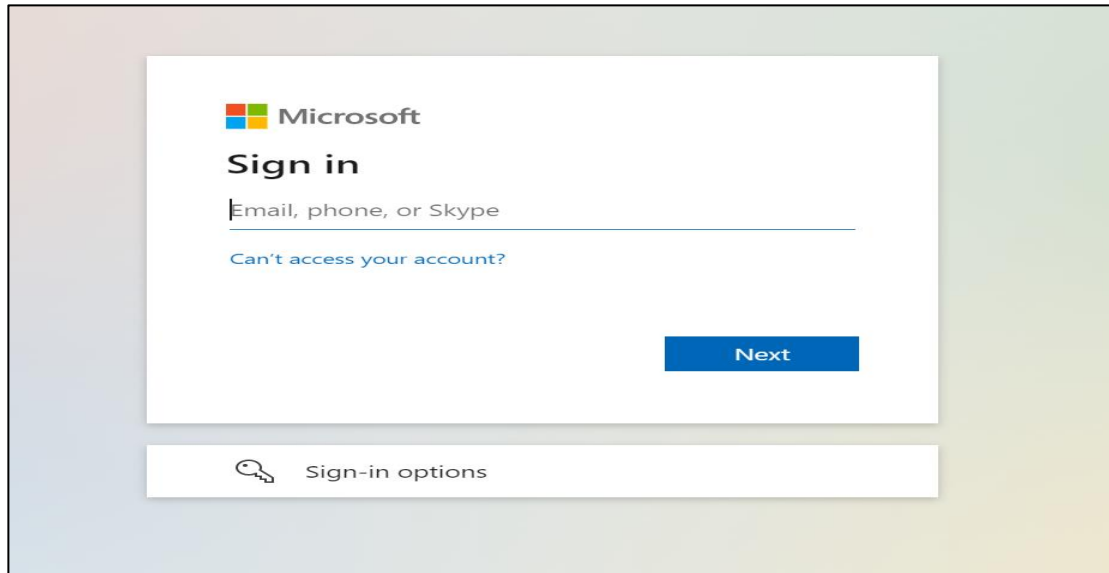
- i. Launch the SDR website.

Figure 8 Login Page



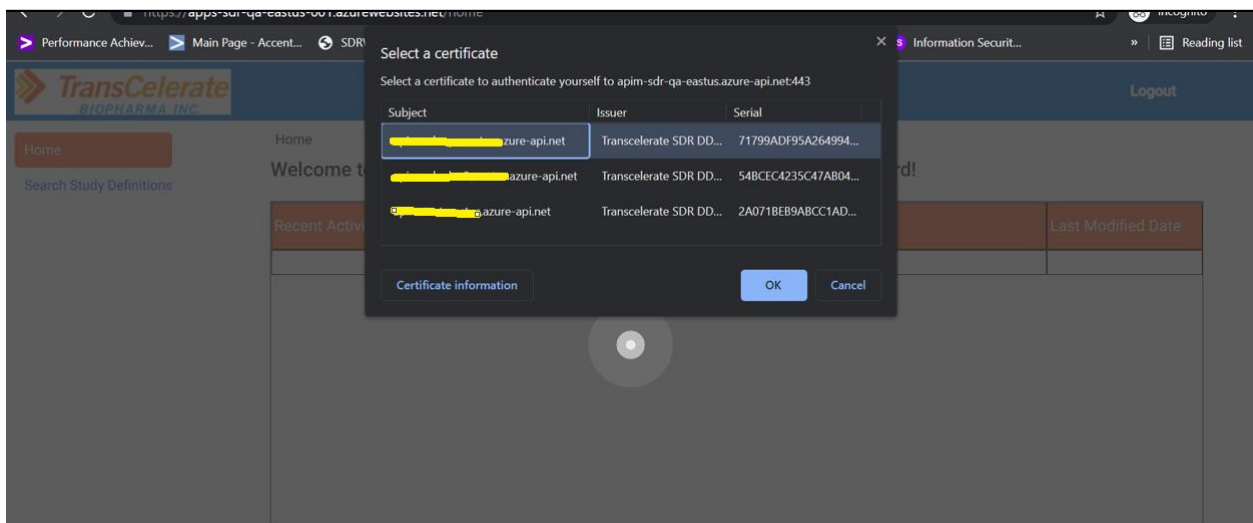
- ii. On click of login link, user is redirected to provide credentials as shown below.

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.

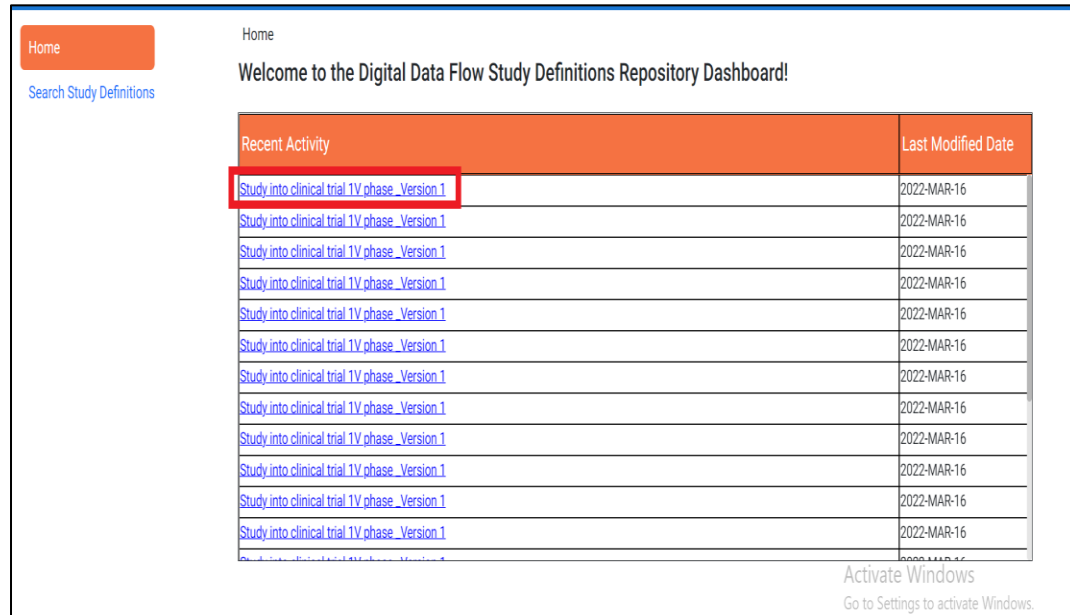
Figure 10 Selection of certificate



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

Search Study Definitions

Welcome to the Digital Data Flow Study Definitions Repository Dashboard!

Recent Activity	Last Modified Date
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16
Study into clinical trial TV phase_Version 1	2022-MAR-16

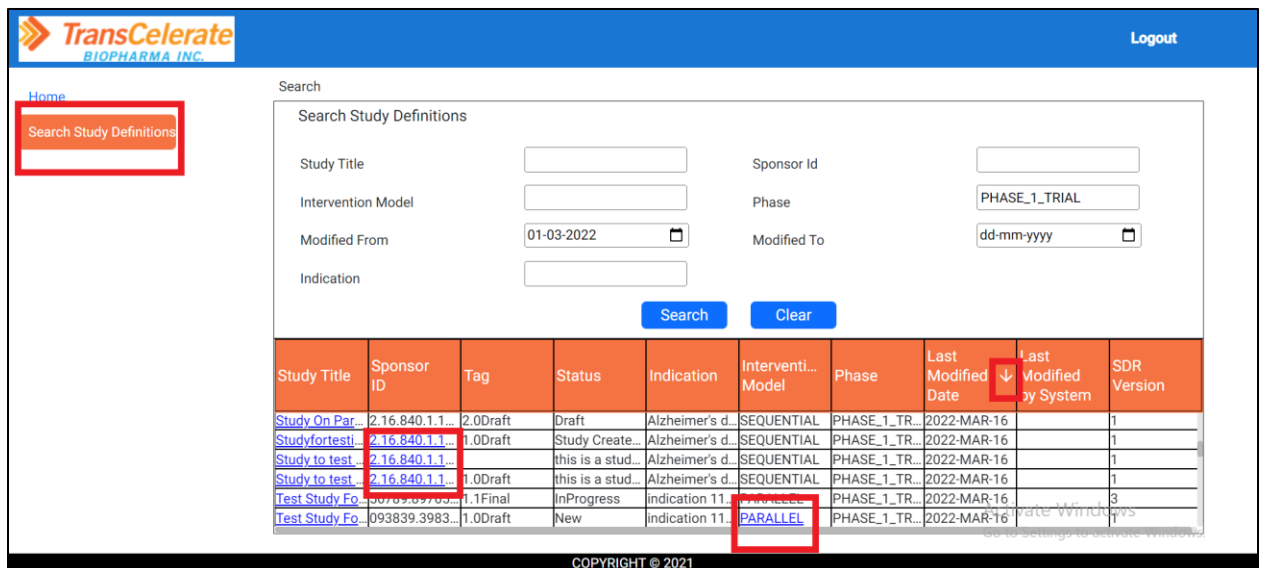
Activate Windows
Go to Settings to activate Windows.

2.3. Search Study Definitions

NAVIGATION STEPS:

- 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



TransCelerate BIOPHARMA INC. Logout

Home

Search Study Definitions

Search

Search Study Definitions

Study Title

Sponsor Id

Intervention Model

Phase

Modified From

Modified To

Indication

Search Clear

Study Title	Sponsor ID	Tag	Status	Indication	Interventi... Model	Phase	Last Modified Date	Last Modified by System	SDR Version
Study On Par...	2.16.840.1.1...	2.0Draft	Draft	Alzheimer's d...	SEQUENTIAL	PHASE_1_TR...	2022-MAR-16		1
Studyfortest...	2.16.840.1.1...	1.0Draft	Study Create...	Alzheimer's d...	SEQUENTIAL	PHASE_1_TR...	2022-MAR-16		1
Study to test...	2.16.840.1.1...	1.0Draft	this is a stud...	Alzheimer's d...	SEQUENTIAL	PHASE_1_TR...	2022-MAR-16		1
Study to test...	2.16.840.1.1...	1.0Draft	this is a stud...	Alzheimer's d...	SEQUENTIAL	PHASE_1_TR...	2022-MAR-16		1
Test Study Fo...	093839.3983...	1.1Final	InProgress	Indication 11...	PARALLEL	PHASE_1_TR...	2022-MAR-16		3
Test Study Fo...	093839.3983...	1.0Draft	New	Indication 11...	PARALLEL	PHASE_1_TR...	2022-MAR-16		1

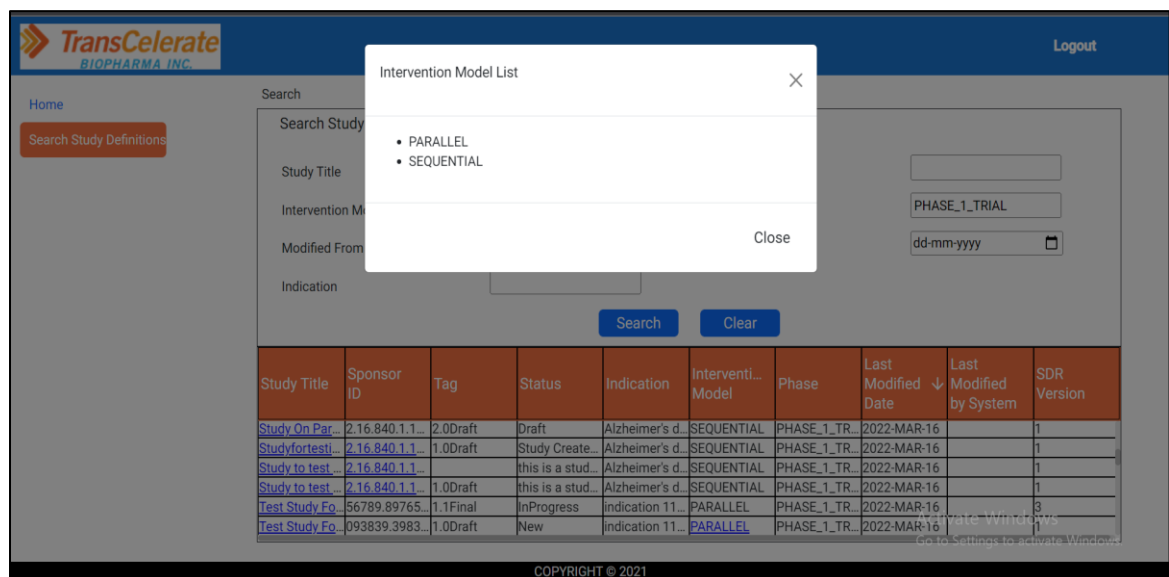
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- ii. On entering the search parameters, click on Search to get the matching study definitions. At least one search parameter is mandatory. Below is the list of search parameters:

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.

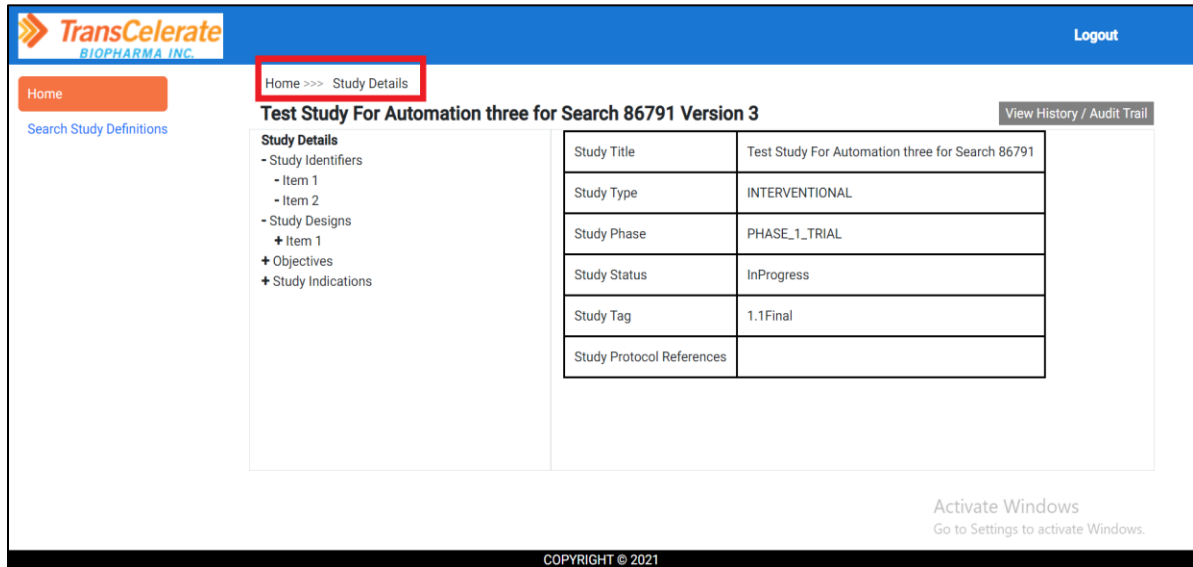
Figure 13 Multiple Value Popup



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



Home >>> Study Details

Test Study For Automation three for Search 86791 Version 3

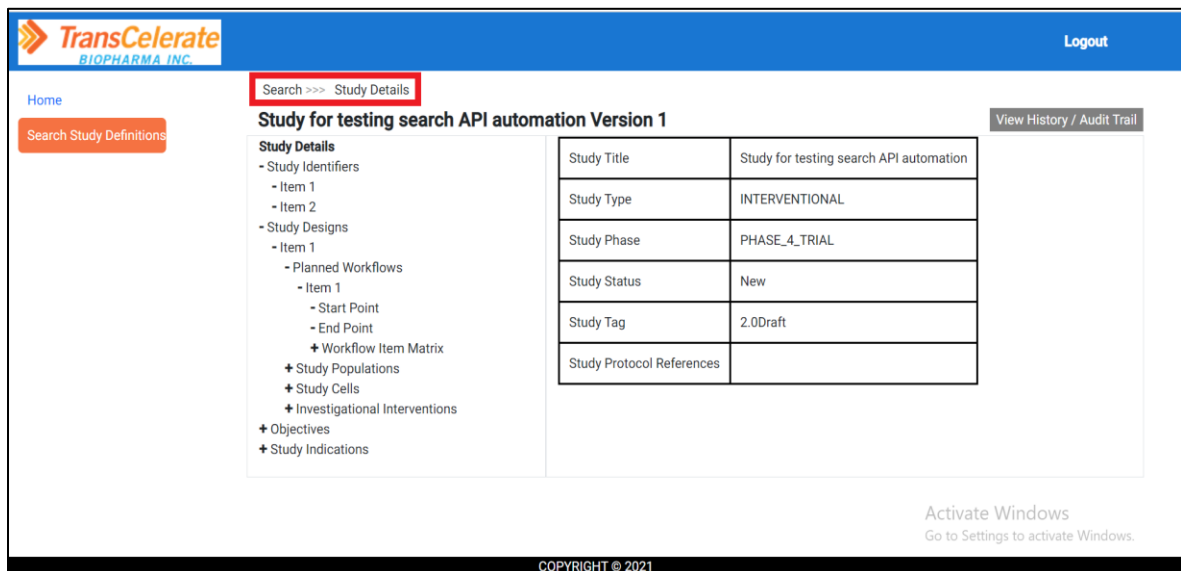
View History / Audit Trail

Study Title	Test Study For Automation three for Search 86791
Study Type	INTERVENTIONAL
Study Phase	PHASE_1_TRIAL
Study Status	InProgress
Study Tag	1.1Final
Study Protocol References	

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Figure 15 Study Details page from Search Grid



Search >>> Study Details

Study for testing search API automation Version 1

View History / Audit Trail

Study Title	Study for testing search API automation
Study Type	INTERVENTIONAL
Study Phase	PHASE_4_TRIAL
Study Status	New
Study Tag	2.0Draft
Study Protocol References	

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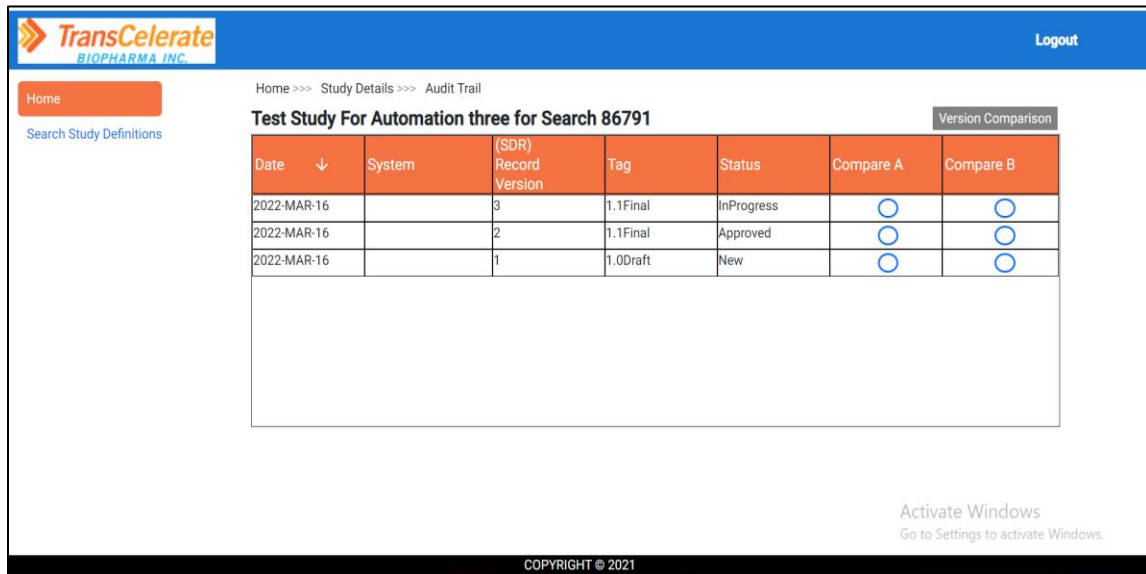
2.5. Audit Trail

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).

- iii. User can compare any two versions by selecting the corresponding radio buttons in columns "Compare A" and "Compare B".

Figure 16 Audit Trail Page



Home >>> Study Details >>> Audit Trail

Test Study For Automation three for Search 86791

Date	System	(SDR) Record Version	Tag	Status	Compare A	Compare B
2022-MAR-16		3	1.1Final	InProgress	<input type="radio"/>	<input type="radio"/>
2022-MAR-16		2	1.1Final	Approved	<input type="radio"/>	<input type="radio"/>
2022-MAR-16		1	1.0Draft	New	<input type="radio"/>	<input type="radio"/>

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2.6. Version Comparison

STEPS:

- i. On click of Version Comparison as shown in above screenshot, version comparison page will be loaded. This screen allows the user to compare two version of same study.
- ii. User can navigate between the pages using the breadcrumb as highlighted in the screenshot.

Figure 17 Version Comparison page



Home >>> Study Details >>> Audit Trail >>> Study Version Comparison

Version#5(Modified On:2022-MAR-16)

```

1 {
2   "studyId": "5d92ef19-621e-452e-9436-a46e100deef1",
3   "studyTitle": "Study Number Seven for POST API Aut",
4   "studyType": "INTERVENTIONAL",
5   "studyPhase": "PHASE_1_TRIAL",
6   "studyStatus": "New",
7   "studyTag": "1.0Draft",
8   "studyIdentifiers": [
9     {
10      "id": "10caedfd-415a-45b7-9fac-522d621c7d5f",
11      "orgCode": "2.16.840.1.113883.3.1077",
12      "name": "ClinicalTrials.gov",
13      "idType": "REGISTRY_STUDY"
14    },
15    {
16      "id": "07a6dba8-bee7-4ece-a31f-f4265c6088f1",
17      "orgCode": "2.16.840.1.113883.3.1077",
18      "name": "ClinicalTrials.gov",
19      "idType": "SPONSOR_ID"
20    }
21  ],
22 }
```

Version#6(Modified On:2022-MAR-16)

```

1 {
2   "studyId": "5d92ef19-621e-452e-9436-a46e100deef1",
3   "studyTitle": "Study Number Seven for POST API Aut",
4   "studyType": "INTERVENTIONAL",
5   "studyPhase": "PHASE_1_TRIAL",
6   "studyStatus": "New",
7   "studyTag": "1.0Draft",
8   "studyIdentifiers": [
9     {
10      "id": "ea933d39-1639-479f-a6f3-8db50489238e",
11      "orgCode": "2.16.840.1.113883.3.1077",
12      "name": "ClinicalTrials.gov",
13      "idType": "REGISTRY_STUDY"
14    },
15    {
16      "id": "a65c7307-4cdc-4259-9b03-0bc1feb674",
17      "orgCode": "2.16.840.1.113883.3.1077",
18      "name": "ClinicalTrials.gov",
19      "idType": "SPONSOR_ID"
20    }
21  ],
22 }
```

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2.7. Logout

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

Figure 18 Logout Screen

