TransCelerate

Digital Data Flow (DDF) Study Definition Repository (SDR)

Vendor Enablement

TransCelerate
BIOPHARMA INC.

Table of Contents

1   Connecting to SDR

2   Study Identification (Version, UUID, etc.)

3   Study Builder and EDC Systems Connectivity and Readiness Checklists

4   References and Links

Connecting to SDR
Pre-requisites

1. **User Access Requests** will be shared by TCB in bulk to SDR Support team.

2. **Certificate Creation Step** is required once per system per vendor connecting to the SDR (until the expiry date of the certificate which is defined by the vendor creating the certificate). The process of certificate creation will be specific to each vendor. The validation check of certificate occurs when a GET or POST call is attempted. If the certificate is not valid, the User with receive an error. (***Note:** For vendors who have already been onboarded to SDR Shared environment, this step can be skipped as the same certificates will be configured for Demo environment access as well*)

3. **The API User Guide** details the steps to access SDR APIs.

4. **User Access Token is required** to retrieve and save any data via SDR API. The SDR exposes token generation endpoint to obtain a user access token which authenticates the user. This token is further used in other endpoints which then authorizes access to different study definitions within the system.

5. **Retrieving Components from the SDR** is possible only for the complete study or study designs of a given study using UUID (unique study identifier).

6. **User and Group Management for restricting data access within SDR** is detailed in SDR UI User Guide for Admin users.

Identifying Studies From Study Builder to SDR

Connectivity and Dataflow to the SDR

1. **UIUD:**
   - SDR generates **UUID** for each study and each component within the study
   - UUID cannot be changed after creation by either the SDR or Study Builder
   - After generation, the SDR will provide it to the Study Builder as part of the API response required to submit studies within SDR)

2. **Versioning:**
   - The (SDR) Record Version is a new **_internal_** record that gets created and saved within the SDR when information (study components etc.) is received from a Study Builder and is conformant to the USDM
   - The (SDR) Record Version is used to track updates made to the study data stored in the SDR.
   - Multiple changes to the same study will appear in the SDR as separate Record Versions
   - The Record Versions will be used for Audit Trail and Study Version Comparison functionality by SDR Users and / or Downstream Systems
     - SDR will share the version number with the Study Builder as part of the API response required to submit studies within SDR) in **_SDR Upload Version_** attribute.

3. **Connectivity**
   - Study Builder to connect to the SDR through **USDM conforming APIs**

Readiness and Connectivity Checklist for Study Builders

For Integrating with SDR Hosted in ACN Subscription

1. **User Registration on SDR**
   - TCB shall provide list of study builders who need access to the Demo environment.
2. **Certificate Creation and Installation for Certificate-based Authentication**
   - Each Study Builder will need to create their own certificate and install it within their system.
3. **Sharing Certificate Public Key with SDR**
   - Study Builder will then share the certificate with passphrase with the SDR Support Team, so the same can be configured in the SDR Environment.
4. **Data Model Mapping Layer**
   - Study Builder will need to provide a mapping layer to adapt study elements to the USDM-conformant JSON response sent by the SDR
     1. Map the existing Study elements with JSON key
     2. Add any additional Study elements as needed by the JSON structure
     3. Add ability to persist UniqueIdentifier returned by SDR APIs, so subsequent changes to the same study can be submitted
5. **Conformance Check per CDISC Standards**
   - As designed, entities which have been identified as required per CDISC's defined standard must have a populated value, otherwise it will be flagged as a conformance error when submission to the SDR is attempted and the request is rejected.

Readiness and Connectivity Checklist for EDC Vendors

For Integrating with SDR Hosted in ACN Subscription

1. **User Registration on SDR**
   - TCB shall provide list of EDC Vendors who need access to the Demo environment.

2. **Certificate Creation and Installation for Certificate-based Authentication**
   - Each EDC vendor will need to create their own certificate and install it within their system.

3. **Sharing Certificate Public Key with SDR**
   - EDC Vendor will then share the certificate and passphrase with the SDR Support Team, so the same can be configured in the SDR Environment

4. **Data Model Mapping Layer**
   - EDC Vendor will need to provide a mapping layer to adapt study elements to the USDM-conformant JSON response sent by the SDR
     1. Map the existing Study elements with JSON key
     2. Add any additional Study elements as needed by the JSON structure
     3. Map eCRF Link information from USDM-conformant JSON response to the appropriate ODM forms

Important Documents

Document	Description	Link
Certificate Creation	Steps to create client certificate to configure in SDR environment to enable vendor authentication	DDF_SDR_Certificate-Creation-for-accessing-SDR-UI-and-API
Certification Installation	Steps to install client certificate in local system to enable accessing SDR UI or API	DDF_SDR_Certificate-Installation-for-accessing-SDR-UI.pdf
Access and Incident Management	Steps to raise access requests and log incidents for SDR Environment	DDF_SDR_Access-and-Incident-Management.pdf
UI User Guide	User guide that details the features available in SDR Web application and the navigation steps.	ddf-sdr-user-guide-ui-v3.0.pdf
API User Guide	User guide that details the list of API endpoints in SDR that enable data save and retrieval	ddf-sdr-user-guide-api-v3.0.pdf
Sample Study Data	Sample JSON Data based on USDM V1	Sample Study Definition JSON
API Migration Guide	A guide that details changes required in order to move to the latest version of SDR API endpoints.	DDF_SDR_API-Migration-Guide.pdf
SDR Code Repositories	UI and API code repositories	API Repo UI Repo
Conformance Rules	List of conformance rules that the study definitions must adhere to.	USDM Conformance Rules