

TransCelerate

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

Vendor Enablement (SDR Release V2.0)

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Reference Implementation

The SDR Reference Implementation is an attempt to demonstrate the vision of the DDF initiative, not a commercial product.

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 and does not constitute an endorsement of those products and services.

Users are free to download the source code for the SDR from GitHub and design their own implementations.



Study Definition Repository (Release V2.0)

The Study Definition Repository Reference Implementation seeks to help transform the drug development process by enabling a digital workflow to move from a current state of manual asset creation to a future state of fully automated and dynamic readiness to support clinical study execution. SDR Reference Implementation is based upon the Unified Study Definitions Model (USDM) which is a standardized format for a study definition defined by CDISC. This model is an evolving data model and SDR is designed to support multiple versions of USDM that enables automated data exchange between the study builders and the EDC systems in clinical R&D.

- The SDR Reference Implementation Release V2.0 has implemented the USDM V1.9 model developed by CDISC as a part of DDF Phase 2. The model is currently in review.
- A running instance of the SDR Reference Implementation is currently hosted **for demonstration purposes only**. Interested participants on the DDF program can connect to this instance to store and retrieve study definitions, **scrubbed / non-production data only**, conforming to the USDM V1.9 and V1.0 for understanding the CDISC USDM.
- DDF Participants can also setup their instance of SDR using the infrastructure and application source code available on GitHub.
- The following slides provides information on how-to-connect to SDR Demo Environment. Additionally, it provides links to important documentation supporting the SDR RI.



Connecting to SDR Demo Environment

Pre-requisites

1. **User Access Requests for Demo environment** needs to be raised online. Request will undergo review and approval to enable user access.
2. **Certificate Creation Step** is required once per system per vendor connecting to the SDR APIs (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 any API call is attempted. If the certificate is not valid, the User will receive an error.
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 allowed at study level using studyId, and at study designs level within a study using studyDesignId.
6. **User and Group Management for restricting data access within SDR** is detailed in SDR UI User Guide for Admin users.



Creating & Identifying Studies in SDR

1. Study Unique Identifier:

- SDR generates UUID for each study and each component within the study that is stored in studyId attribute.
- The studyId 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. SDR Versioning:

- The SDR Upload 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 Upload Version is used to track updates made to the study data stored in the SDR.
- Changes to the same study in different transactions will appear in the SDR as separate Upload Versions.
- The Upload Version will be used for Study History and Study Version Comparison functionality by SDR Users and / or Downstream Systems
 - SDR will share the upload version number with the Study Builder as part of the API response required to submit studies within SDR) in **SDR Upload Version** attribute.

3. USDM Versioning

- The SDR Demo Environment allows users to create study definitions based on USDM versions V1.0 and V1.9 using the version specific SDR API endpoints. Refer to [API User Guide](#) for the list of endpoints.
- The USDM Version for a study is identified by the usdmVersion attribute on the study which is assigned on creation of a study that conforms to the corresponding USDM version structure.

4. Connectivity

- Study Builder or EDC Vendors to connect to the SDR through **USDM conforming APIs**



Connectivity Readiness Checklist for Study Builders

For Integrating with SDR Hosted in ACN Azure Subscription

1. User Registration on SDR

- Users can request access online.

2. Certificate Creation and Installation for Certificate-based Authentication

- Each Study Builder will need to create their own certificate and include it in the SDR API Requests. .

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 Demo Environment.

4. Data Model Mapping Layer

- Study Builder will need to create 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 the Study Unique Identifier (studyId) 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 in a USDM version 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.

6. Reference Integrity and Uniqueness Validation

- In the study definition there are attributes that refer to a unique identifier of another study element which is depicted as a cross-reference relationship in the USDM. The SDR validates these cross-references to be a valid and defined entry within the study definition. SDR also ensures distinct IDs for all elements within a given array.



Connectivity Readiness Checklist for EDC Vendors

For Integrating with SDR Hosted in ACN Azure Subscription

1. User Registration on SDR

- Users can request access online.

2. Certificate Creation and Installation for Certificate-based Authentication

- Each EDC vendor will need to create their own certificate and include it in the SDR API Requests.

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 Demo Environment

4. Data Model Mapping Layer

- EDC Vendor will need to create 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. Identify one or more studies using the SDR study history endpoint and note the unique studyId attributes to fetch the study details.
 4. Optionally, to generate CPT Export, vendors must use the [mapping sheet](#) to identify the CPT variables currently present in SDR and create mapping from SDR CPT API to their respective templates.



Important Documents

| Document | Description | GitHub Link |
|--|--|--|
| Certificate Creation | Steps to create client certificate to configure in SDR environment to enable vendor authentication | ddf-sdr-ri-certificate-creation-for-accessing-sdr-ri-api |
| UI User Guide | User guide that details the features available in SDR Web application and the navigation steps. | ddf-sdr-ri-ui-user-guide-v4.1 |
| API User Guide | User guide that details the list of API endpoints in SDR that enable data save and retrieval | ddf-sdr-ri-api-user-guide-v4.1 |
| Sample Study Data | Sample JSON Data based on USDM V1.0 and USDM V1.9 | ddf-sdr-api-study-sample-json-v1.9 |
| API Migration Guide | A guide that details changes required in order to move to the latest version of SDR API endpoints. | ddf-sdr-ri-api-migration-guide |
| SDR Code Repositories | UI and API code repositories | ddf-sdr-api ddf-sdr-ui |
| Conformance Rules | List of conformance rules that the study definitions must adhere to. | ddf-sdr-usdm-conformance-rules-v1.9 |
| SDR - CPT Mapping | Mapping sheet of SDR fields to CPT Variables available as CPT Export. | ddf-sdr-ri-usdm-cpt-mapping-sheet-v1.0 |
| SDR Process Flows | Process flows of data exchange presently available in SDR. | ddf-sdr-ri-process-flows-v4.0 |
| Postman Collection for SDR RI API | Postman tool collection of SDR RI API Endpoints | ddf-sdr-api-postman-collection |
| Infra Migration Guide | A guide that details changes required in order to move to the latest version of SDR RI Platform. | ddf-sdr-ri-infra-migration-guide-v1.1 |

