

Study Definition Repository (SDR) Reference Implementation

API Migration Guide

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1. Introduction

This document details the steps to be performed by existing users/vendors of the SDR Reference Implementation¹ v0.5 to migrate to version V 2.0.2 of the SDR Reference Implementation APIs.

As a part of the SDR Release V2.0.2, the SDR APIs have undergone the changes listed below:

- **UUID Management** - SDR will only generate and maintain a unique identifier for a study at the parent element level. All other study element identifiers can be passed and maintained by study builders creating & updating studies in SDR. Reference Integrity and elementID uniqueness checks will be performed by SDR for user managed identifiers.
- **USDM Versioning** – Study definitions based on USDM (Version 1.0,1.9 & 2.0) developed by CDISC as part of Digital Data Flow are now supported in the SDR.
- **Version specific API Endpoints** - Study USDM version specific endpoints will allow users to create studies conforming to a specific version (1 major and any related minor versions) of USDM and validate the study against conformance rules corresponding to that version.
- **Change Audit Log** - Each change submitted to SDR is tracked by the Change Audit feature built into SDR. The http trigger will capture details of elements changed in the POST and PUT requests into a separate collection.
- **Common Protocol Template (CPT) Export API** - A new endpoint has been created to export study details mapped to a limited set of CPT Variables grouped by sections within the Common Protocol Template. Mapping Sheet from SDR fields to CPT variables is available [here](#).
- **Retrieval of unsupported USDM versions** of study definitions will be available from a new GET endpoint that will fetch raw JSON of the unsupported versions.
- **SoA Matrix** – A new endpoint has been created to fetch data from study definitions that help build the Schedule of Activities matrix for a given Schedule Timeline in a Study Design.
- **Validate USDM Conformance** – A new endpoint has been created to validate the conformance rules of the study definitions against a specific USDM Version.
- **Version Comparison** – A new endpoint has been created to list down changes between two SDR Upload Versions of a specific study definition.

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.

1.1. Target Audience

This guide targets users who have established API connectivity with SDR Reference Implementation in the Release V0.5 and want to migrate to the latest release of SDR (Release V2.0.2).

1.2. Out of scope

Data Migration of studies from prior USDM versions to latest version is out of scope.

1.3. Definitions and Acronyms

Term / Abbreviation	Definition
SDR	Study Definitions Repository
API	Application Programming Interface
POC	Point of Contact
USDM	Unified Study Definition Model (developed by CDISC)
REST	Representational State Transfer
JSON	JavaScript Object Notation

2. List of API endpoints

The SDR RI API endpoints have been modified to support USDM Versions V1.0, V1.9 and V2.0 study definitions. The version specific endpoints can now store and retrieve USDM V1.0, V1.9 & V2.0 conformant studies. Existing study definitions (USDM V1.0) submitted using the previous versions of APIs are retained and can be accessed via the same set of endpoints. Below is the list of API versions in SDR RI Release V2.0.2 that correspond to the respective CDISC USDM Versions.

SDR RI API Versions	CDISC USDM Version
v1	1.0
v2	1.9
v3	2.0

2.1. New Endpoints

The below mentioned common and version specific endpoints have been added.

Endpoint	Method	URL	Description
Version	GET	/api/versions	To get details of all supported SDR API and USDM versions along with mapping information.

Create Study	POST	/api/v3/studydefinitions	To create new study documents conforming to USDM V2.0
Modify Study	PUT	/api/v3/studydefinitions/{studyId}	To submit revisions to existing studies conforming to USDM V2.0
Get Study	GET	/api/v3/studydefinitions/{studyId}	To get study definitions data conforming to USDM V2.0
Get Study Design	GET	/api/v3/studydesigns	To get study design data conforming to USDM V2.0
eCPT Export	GET	/api/v3/studydefinitions/{studyId}/studydesigns/ecpt	To get transformed study design data conforming to USDM V2.0 that can be exported to CPT template
Validate USDM Conformance	POST	/api/v3/studydefinitions/validate-usdm-conformance	To get validate conformance rules of study data conforming to USDM V2.0
Get Version Comparison	GET	/api/v3/studydefintions/version-comparison	To get differences between two study SDR Upload Versions conforming to USDM V2.0
Get Schedule of Activities(SoA)	GET	/api/v3/studydefinitions/{studyId}/studydesigns/soa	To get the schedule of activities (SoA) defined from a study conforming to USDM V2.0
Raw JSON	GET	/api/studydefinitions/{studyId}/rawdata	To get entire study definitions data in string format. This

			endpoint will be useful to fetch study definitions data for unsupported versions
Change Audit	GET	/api/studydefinitions/{studyId}/changeaudit	To get details of study attributes modified across all revisions of a study definition

2.2. Migrated V1 Endpoints

Endpoint	Method	Existing URL	New URL
Study History	GET	/api/v1/studydefinitions/history	/api/studydefinitions/history
Revision History	GET	/api/v1/audittrail/{studyId}	/api/studydefinitions/{studyId}/revisionhistory

Note: The URLs listed in the above table will be decommissioned once all users have migrated to new version of SDR APIs.

3. Pre-requisites before migration

To access SDR RI APIs, a user account (or) service account with SDR application access is needed along with a valid client certificate configured on the hosted platform.

3.1. Access to SDR environment

3.1.1. Service Account / System Account for System Integration

- Existing SDR RI Environment users having automated processes/interfaces developed to communicate with SDR RI APIs, need to create a Service account (with valid email address) and share with SDR support team.
- Email invite will be sent to service account email address for SDR application access.
- Vendor POC who is managing this service account, should accept the invite and complete the account set-up.

3.1.2. User Account

- Users with no automated processes/interfaces can continue to use their own credentials to generate a token and communicate with SDR RI APIs using any REST client tools.

- Users who have not accepted the invites that were earlier triggered by [SDR support team](#), will have to complete the user set-up process if they wish to access the SDR RI APIs using their own accounts. They can request SDR support team to trigger the email invite again, if they fail to find one in their inbox (or) if the old invite is expired.

3.1.3. Client Certificate

- Users who had already generated the client certificate and got it configured in SDR can continue to use the same certificate when accessing the new list of SDR RI APIs.

3.2. Group Association

- Refer [UI User guide](#) for Group and User set-up for data access.

3.3. API User Guide

- Refer latest version of [API User Guide](#) to get complete details about the new version of API Endpoints.

3.4. API-Key Authorization

SDR RI APIs can be authorized using bearer token from SDR UI Application or API-Key generated from Developer Portal. To establish a system-to-system integration, the API-Key authorization is enabled in SDR RI APIs.

- Refer latest version of [API User Guide](#) to get the details of API-Key authorization.
- Refer [SDR RI API Key Generation](#) for API-Key generation.

4. Migration Steps

- To continue using the USDM v1 version of study definition, the existing study endpoints must be replaced with version specific endpoints. Also, refer to section 2 for other common endpoint updates.
- To create and maintain studies conformant to USDM v2.0, the study endpoints should refer to v3 version of SDR endpoints detailed in section 2. To upgrade the existing studies to USDM V2.0 user can submit a revision using the V3 PUT endpoint where the revision request must conform to USDM V2.0. Irrespective of the version of SDR APIs being invoked, all API Request now should mandatorily include,
 - usdmVersion header. The expected values are as below –

SDR API Versions	USDM Version Header Value
v1	1.0
v2	1.9
v3	2.0

- Failure to send usdmVersion header attribute will result in Bad Request (400) response from the API.
- Users need to pass Ids for all study elements except for StudyId. StudyId will be generated by SDR.
- Failure to send IDs for study elements will result in conformance error.
- Continue to send access token and client certificate in the request as before with the token generated, which will be valid for 24 hours from the time of generation.
- To store / retrieve studies conformant to latest USDM version v2.0, modify the data mapping referring to the JSON sample available [API User Guide](#).
- Add a fallback/retry step for all API activities/tasks to generate a new token if the existing token is expired.
- The SDR RI APIs now support API keys as an additional authentication method alongside client certificates. Once generated in the developer portal, API keys can be used indefinitely for authorizing requests to the APIs.
- The generated API keys are non-expiring, and it is the responsibility of user/organization to make sure API keys are re-generated at regular intervals in alignment with security best practices. User can click on Regenerate link available in Profile page of developer portal to generate new keys.