

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 Implementation v0.5 to migrate to version V 2.0 of the SDR Reference Implementation APIs.

As a part of the SDR Release V2.0, 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) 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.

1.1. Target Audience

This guide targets users who have established API connectivity with SDR Reference Implementation in the Release V0.5 (Connect-a-thon Environment) and want to migrate to the latest release of SDR (Release V2.0).

1.2. Out of scope

Data Migration of studies conformant with USDM Version V1.0 to V1.9 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
REST	Representational State Transfer
JSON	JavaScript Object Notation

2. List of API endpoints

The SDR RI API endpoints have been modified to support both USDM V1.0 and V1.9 study definitions. The version specific endpoints can now store and retrieve USDM V1.0 & V1.9 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 that correspond to the respective CDISC USDM Versions.

SDR RI API Versions	CDISC USDM Version
v1	1.0
v2	1.9

2.1. New Endpoints

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/v2/studydefinitions	To create new study documents conforming to USDM V1.9
Modify Study	PUT	/api/v2/studydefinitions/{studyId}	To submit revisions to existing studies conforming to USDM V1.9
Get Study	GET	/api/v2/studydefinitions/{studyId}	To get study definitions data conforming to USDM V1.9
Get Study Design	GET	/api/v2/studydesigns	To get study design data conforming to USDM V1.9
eCPT Export	GET	/api/studydefinitions/{studyId}/studydesigns/ecpt	To get transformed study design data that can be exported to CPT template

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
Get Schedule of Activities(SoA)	GET	/api/studydefinitions/{studyId}/studydesigns/soa	To get the schedule of activities (SoA) defined from a study conforming to USDM V1.9

2.2. Migrated V1 Endpoints

Endpoint	Method	Existing URL	New URL
Token	POST	/api/v1/auth/token	/api/auth/token
Study History	GET	/api/v1/studydefinitions/history	/api/studydefinitions/history
Audit Trail	GET	/api/v1/audittrail/{studyId}	/api/studydefinitions/{studyId}/audittrail/

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 Demo Environment 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.

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 v1.9, the study endpoints should refer to v2 version of SDR endpoints detailed in section 2.
- To upgrade the existing studies to USDM V1.9 user can submit a revision using the V2 PUT endpoint where the revision request must conform to USDM V1.9.
- 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
 - Ids of study elements except for StudyId. StudyId will be generated by SDR.
- Failure to send usdmVersion header attribute will result in Bad Request (400) response from the API.
- 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 by token endpoint, which will be valid for 120 minutes from the time of generation.
- To store / retrieve studies conformant to latest USDM version v1.9, 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.