Study Definition Repository (SDR)

Reference Implementation (RI)

API User Guide

Version 8.0

Document History

Version No.	Date	Author	Revision Description
V1.0	14-Mar-2022	ACN	Initial Version
V1.5	14-Mar-2022	ACN	Review comments addressed
V2.0	26-Apr-2022	ACN	Updated API response for POST
V3.0	05-Aug-2022	ACN	Updated with latest version of API Endpoints
V4.0	20-Mar-2023	ACN	Added new sections to list USDM version specific Study endpoints in section 3.2, 3.3 and 3.4. Added section 3.7, 3.8 and 3.9 for Change audit, Raw JSON and eCPT export endpoints.
V4.1	26-Apr-2023	ACN	Deprecated SDR RI Auth Token Endpoint in section 3 and added section 2.2 on steps to obtain user access token to access SDR RI API.
V5.0	23-Jun-2023	ACN	Added API specifications for V3 endpoints
V6.0	17-Oct-2023	ACN	Added API Key authorization specifications
V7.0	18-Mar-2024	ACN	Added V4 APIs for USDM 3.0
V8.0	11-Sept-2025	Capgemini	Removed API Key authorization specifications and added V5 APIs for USDM 4.0. Deprecated V2 APIs for USDM 1.9.

Table of Contents

1. Introduction

Overview

The SDR RI[1] implements the CDISC DDF Reference Architecture which includes the USDM model and API Specifications defined using the OpenAPI Specification (OAS). The API Layer of the SDR Reference Implementation complies with the OpenAPI Specification which allows systems to discover and understand the capabilities of the service without access to source code, documentation, or through network traffic inspection. When properly defined, a consumer can understand and interact with the remote service with a minimal amount of implementation logic.

It follows the REST architectural style that uses HTTP requests to GET and POST data. RESTful architecture is not linked with any technology or platform; it does not dictate exactly how to build an API. Instead, it introduces the best practices known as constraints. They describe how the server processes requests and respond to them. Operating within these constraints, the system gains desirable properties such as reliability, ease of use, improved scalability and security, low latency while enhancing the system performance and helping achieve technology independence in the process.

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[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. 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 Docker, 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.

Scope of Document

This document details the list of API endpoints available in the Study Definition Repository Reference Implementation and provides a sample Request and Response for each endpoint. These endpoints include implementation of the CDISC USDM API Specification and additional SDR Specific endpoints supporting the SDR RI features. It also explains the possible reasons behind the various error codes returned by the API. The technical design and implementation of these APIs is out of scope.

Intended Audience

The document is a guide for users/vendors who want to integrate and consume the SDR RI API to store and retrieve study definitions in USDM format.

Definitions and Acronyms

Term / Abbreviation	Definition
API	Application Programming Interface
DDF	Digital Data Flow
JSON	JavaScript Object Notation
REST	Representational State Transfer
SDR	Study Definition Repository
URL	Uniform Resource Locator
USDM	Unified Study Definition Model

2. API End Points

The SDR Reference Implementation exposes the following REST Endpoints to deliver application functionality including storing and retrieving study definitions.

API Version -> USDM Version Mapping

USDM version specific Study endpoints will allow users to create studies conforming to a specific USDM version (1 major and any related minor versions) and validate the study against conformance rules corresponding to that version. This endpoint allows users to get the mapping between SDR RI API versions and CDISC USDM versions.

Table 1 GET API version ->USDM Version Mapping Endpoint

Method	URL
GET	**/api/versions**

RESPONSE

Table 2 GET API version ->USDM Version Mapping Response

Status	Response	Comments
200	{ "SDRVersions": [{ "apiVersion": "v3", "usdmVersions": ["2.0"] }, {	

| | ```json
      "apiVersion": "v4",

      "usdmVersions": [

         "3.0"

      ]

   },

   {

      "apiVersion": "v5",

      "usdmVersions": [

         "4.0"

      ]

   }

  ]

}
``` | |
| **400** | ```json
{

   "statusCode": "400",

   "message": "An error occurred"

}
``` | Application Exception |
| **404** | ```json
{

   "statusCode": "404",

   "message": "The requested study document not found"

}
``` | Requested Study Id is not found, or the request URL path is not valid |
| **500** | *Internal Server Error* | Web server/Web API down |

V3 API (USDM Version – 2.0)

GET Study

This endpoint allows user to retrieve the different study elements for a particular study for a specific SDR upload version. This endpoint also allows user to retrieve specific sections.

LIST OF STUDY SECTIONS:

- studyTitle
- studyVersion
- studyType
- studyRationale
- studyAcronym
- studyIdentifiers
- studyPhase
- businessTherapeuticAreas
- studyProtocolVersions
- studyDesigns

Table 3 GET Study V3 Endpoint

Method	URL
GET	/api/v3/studydefinitions/{studyId}

REQUEST PARAMETERS

Table 4 GET Study V3 Request Parameters

Type	Param Name	Values	Mandatory	Sample Values

Path Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	sdruploadversion	Integer	No	2
Query Parameter	Listofelements	string	No	The parameter value should be comma separated values of the section names. For example, "studyDesigns,studyIdentifiers"
Header	usdmVersion	String	Yes	2.0

RESPONSE

Table 5 GET Study V3 Response

Status	Response	Comments
200	Refer **Response for GET StudyV2.0** for the JSON Data	

400	{
	
	   "statusCode": "400",
	
	   "message": "An error occurred"
	
	}
		Application Exception

404	{ "statusCode": "404",	Requested Study Id is not found, or the request URL path is not valid

	"message": "The requested study document not found" }	
500	*Internal Server Error*	Web server/Web API down

GET Study Design

Retrieves the different study design elements for a particular study for the SDR upload version. This endpoint also allows the user to retrieve specific study design sections.

LIST OF STUDY DESIGN SECTIONS:

- studyDesignName
- studyDesignDescription
- trialIntentTypes
- trialType
- interventionModel
- studyCells
- studyIndications
- studyInvestigationalInterventions
- studyPopulations
- studyObjectives
- studyScheduleTimelines
- therapeuticAreas
- studyEstimands
- encounters
- activities
- studyDesignRationale
- studyDesignBlindingScheme
- biomedicalConcepts
- bcCategories
- bcSurrogates
- studyepochs
- studyelements
- studyarms

Table 6 GET Study Design V3 Endpoint

Method	URL
GET	**/api/v3/ studydesigns**

REQUEST PARAMETERS

Table 7 GET Study Design Request V3 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Query Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	sdruploadversion	Integer	No	3
Query Parameter	listofelements	String	No	The parameter should be comma separated values of the section names. For example, "activities,encounters"
Header	usdmVersion	String	Yes	2.0

RESPONSE

Table 8 GET Study Design V3 Response

Status	Response	Comments
200	Refer **Response for GET Study DesignV2.0** for the JSON Data	Successful

400	{
	
	"statusCode": "400",
	
	"message": "An error occurred"
	
	}
		Application Exception

404	{
	
	"statusCode": "404",
	
	"message": "The requested study document not found"
	
	}
	
	OR
	
	{
	
	"statusCode": "404",
	
	"message": "The requested study design not found"
	
	}
		This can occur when requested Study Id is not found or Study Design is not found.

500	*Internal Server Error*	Web server/Web API down

POST/PUT Study Definitions

This endpoint allows user to add and/or update a study definition in SDR that conforms to the USDM structure. The PUT endpoint supports updates to specific study elements only when entire study data is sent in the request body. If partial

study elements (conforming to specific USDM version) are sent in request, the API will create study version with only the elements sent in request.

I.   POST - Add Study Definition

For the first time, when a study is pushed into the SDR, the studyId field in the JSON data must be empty. SDR will generate UUID for the studyId field. The Id for the other classes is mandatory, user defined, and expected to be sent in the request.

Table 9 POST Study V3 Endpoint

Method	URL
POST	**/api/v3/studydefinitions**

REQUEST PARAMETERS

Table 10 POST Study V3 Request Parameters

Type	Param	Values
Body		Refer **Request Body for POST – Add New Study DefinitionV2.0** for the JSON Data
Header	usdmVersion	2.0

RESPONSE

Table 11 POST Study V3 Response

Status	Response	Comments
201	Refer **Response Body for POST – Add Study DefinitionV2.0** for the JSON Data	Successful. For a new study document added into SDR, the unique IDs for Study and Study Design are generated by system and returned in response body along with SDR Upload Version is defaulted to "1". For updates to an existing study, the version is incremented by 1.

400	{
	   "statusCode": "400",
	   "message": "An error occurred"
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

II.　　　PUT - Update Study Definition

For adding new elements to an existing study definition section

- o New elements should be passed along with existing elements in the request body.

For example, there is an existing study definition in SDR as mentioned in Study Definition – **Existing DataV2.0**. If a new element is to be added to study objectives, the existing study data with the new element must be sent in the request body as mentioned in Request Body for PUT – **Update New Study DefinitionV2.0**.

Table 12 PUT Study V3 Endpoint

Method	URL
PUT	**/api/v3/studydefinitions/{studyId}**

REQUEST PARAMETERS

Table 13 PUT Study V3 Request Parameters

Type	Param	Values
Body		Refer **Request Body for PUT – Update New Study DefinitionV2.0** for the JSON Data
Header	usdmVersion	2.0

<u>**RESPONSE**</u>

Table 14 PUT Study V3 Response

Status	Response	Comments
201	Refer **Response Body for PUT – Update Study DefinitionV2.0** for the JSON Data	Successful. The new element in the section will be added on along with the existing element.

400	{
	
	   "statusCode": "400",
	
	   "message": "An error occurred"
	
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

GET Schedule of Activities (SoA)

This endpoint allows user to retrieve the Schedule of Activities (SoA) for a particular study. Also, the endpoint has optional parameter to retrieve the SoA for a particular study design and a particular schedule timeline.

Table 15 GET SoA V3 Endpoint

Method	URL
GET	**/api/v3/ studydefinitions/{studyId}/studydesigns/soa**

REQUEST PARAMETERS

Table 16 GET SoA Request V3 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversion	Integer	No	3
Query Parameter	Studydesignid	String	No	Value in studyDesignId
Query Parameter	studyWorkflowid	String	No	This is any one of the values in scheduleTimelineId under studyScheduleTimelines.
Header	usdmVersion	String	Yes	2.0

RESPONSE

Table 17 GET SoA V3 Response

Status	Response	Comments
200	Refer **Response for GET SoAV2.0** for the JSON Data	Successful. In the response, Workflow related fields will represent the data of scheduleTimeline (studyWorkflows → studyScheduleTimelines, workflowId → scheduleTimelineId and workflowDescription → scheduleTimelineDescription)

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Application Exception

404	{
	
	    "statusCode": "404",
	
	    "message": "The requested study document not found"
	
	}
	
	OR
	
	{
	
	    "statusCode": "404",
	
	    "message": "The requested study design not found"
	
	}
		This can occur when requested Study Id is not found or Study Design is not found.

500	*Internal Server Error*	Web server/Web API down

GET eCPT Export

This endpoint allows user to retrieve the eCPT Export for each study design in a given study that conforms to USDM Version 2.0 that is stored in SDR.

Table 18 GET eCPT V3 Endpoint

Method	URL
GET	**/api/v3/studydefinitions/{studyId}/studydesigns/ecpt**

REQUEST PARAMETERS

Table 19 GET eCPT Request V3 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversion	Integer	No	3
Query Parameter	Studydesignid	String	No	Value in studyDesignId
Header	usdmVersion	String	Yes	2.0

RESPONSE

Table 20 GET eCPT V3 Response

Status	Response	Comments
200	Refer **Response for GET eCPT V2.0** for the JSON Data	Successful. In the response, Workflow related fields will represent the data of scheduleTimeline (studyWorkflows → studyScheduleTimelines, workflowId → scheduleTimelineId and workflowDescription → scheduleTimelineDescription)

400	{
	
	   "statusCode": "400",
	
	   "message": "An error occurred"
	
	}
		Application Exception

| 404 | {

    "statusCode": "404",

    "message": "The requested study document not found"

}

OR

{

    "statusCode": "404",

    "message": "The requested study design not found"

} | This can occur when requested Study Id is not found or Study Design is not found. |
| 500 | *Internal Server Error* | Web server/Web API down |

POST Validate USDM Conformance

This endpoint allows user to validate whether the study definition conforms to USDM Version 2.0 without submitting the study definitions. If the study definition is conformant with USDM Version 2.0, success response code (200 - Ok) will be returned, otherwise the endpoint will return list of conformance errors with failure response code (400 – Bad Request).

Table 21 POST Validate USDM Conformance V3 Endpoint

Method	URL
POST	**/api/v3/studydefinitions/validate-usdm-conformance**

REQUEST PARAMETERS

Table 22 POST Validate USDM Conformance V3 Request Parameters

Type	Param	Values
Body		Refer **Request Body for POST – Add New Study DefinitionV2.0** for the JSON Data
Header	usdmVersion	2.0

RESPONSE

Table 23 POST Validate USDM Conformance V3 Response

Status	Response	Comments

200	{
	
	 "statusCode": "200",
	
	 "message": "The study definition is conformant with USDM Version : 2.0"
	
	 }
		Successful.
		
		 If the Study Definitions is conformant with the USDM conformance rules, API will give 200 Ok response

400	{
	
	 "statusCode": "400",
	
	 "message": "The study definition is not conformant with USDM Version : 2.0",
	 "error": {
	
	 "study.studyTitle": [
	
	 "Field is missing"
	
	]
	
	 }
	
	 }
		Validation Failed.
		
		 If the Study Definitions is not conformant with the USDM conformance rules, API will give 400 Bad Request response

400	{
	
	 "statusCode": "400",
	
	 "message": "An error occurred"
	
	 }
		Application Exception

| 404 | *Resource Not Found* | When the request URL is not valid. |
| 500 | *Internal Server Error* | Web server/Web API down |

GET Version Comparison

This endpoint allows user to compare two SDR Upload Versions of study definitions that conforms to USDM Version 2.0. The endpoint will list down the changes between the two SDR Upload Versions of a specific study definition that was sent in the request.

Table 24 GET Version Comparison V3 Endpoint

Method	URL
GET	**/api/v3/studydefinitions/version-comparison**

REQUEST PARAMETERS

Table 25 GET eCPT V3 Response

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversionone	Integer	Yes	3
Query Parameter	Sdruploadversiontwo	Integer	Yes	2
Header	usdmVersion	String	Yes	2.0

RESPONSE

Table 26 POST Study V3 Response

Status	Response	Comments

200	{
	
	    "studyId": "7dd4d676-8714-42d3-b2a9-c189b59fad67",
	
	    "LHS": {
	
	        "entryDateTime": "2023-06-21T12:52:48.216Z",
	
	        "SDRUploadVersion": 1
	
	    },
	
	    "RHS": {
	
	        "entryDateTime": "2023-06-21T12:53:16.601Z",
	
	        "SDRUploadVersion": 2
	
	    },
	
	    "elementsChanged": [
	
	        "study.studyTitle",
	
	        "study.studyAcronym",
	
	        "study.studyIdentifiers[1].studyIdentifier",
	
	    ]
	
	}
		Successful.
		
		The API will list down the differences between the two SDR Upload Versions sent in the request.

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

V4 API (USDM Version – 3.0)

GET Study

This endpoint allows user to retrieve the different study elements for a particular study for a specific SDR upload version. This endpoint also allows user to retrieve specific sections.

LIST OF STUDY SECTIONS:

- titles
- versionIdentifier
- studyType
- rationale
- documentVersionId
- dateValues
- amendments
- studyIdentifiers
- studyPhase
- businessTherapeuticAreas
- studyDesigns

Table 27 GET Study V4 Endpoint

Method	URL
GET	**/api/v4/studydefinitions/{studyId}**

REQUEST PARAMETERS

Table 28 GET Study V4 Request Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	sdruploadversion	Integer	No	2
Query Parameter	Listofelements	string	No	The parameter value should be comma separated values of the section names. For example, "studyDesigns,studyIdentifiers"
Header	usdmVersion	String	Yes	3.0

RESPONSE

Table 29 GET Study V4 Response

Status	Response	Comments
200	Refer **Response for GET StudyV3.0** for the JSON Data	
400	{ "statusCode": "400", "message": "An error occurred"	Application Exception

	}	

404	{
	
	    "statusCode": "404",
	
	    "message": "The requested study document not found"
	
	}
		Requested Study Id is not found, or the request URL path is not valid

500	*Internal Server Error*	Web server/Web API down

GET Study Design

Retrieves the different study design elements for a particular study for the SDR upload version. This endpoint also allows the user to retrieve specific study design sections.

LIST OF STUDY DESIGN SECTIONS:

- name
- label
- description
- trialIntentTypes
- trialTypes
- characteristics
- interventionModel
- studyCells
- indications
- studyInterventions
- population
- objectives
- scheduleTimelines
- therapeuticAreas
- estimands
- encounters
- activities
- rationale
- blindingSchema

- biomedicalConcepts
- bcCategories
- bcSurrogates
- epochs
- elements
- arms
- documentVersionId
- dictionaries
- maskingRoles
- conditions
- organizations
- instanceType

Table 30 GET Study Design V4 Endpoint

Method	URL
GET	**/api/v4/ studydesigns**

REQUEST PARAMETERS

Table 31 GET Study Design Request V4 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Query Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	sdruploadversion	Integer	No	3

Query Parameter	listofelements	String	No	The parameter should be comma separated values of the section names. For example, "activities,encounters"
Header	usdmVersion	String	Yes	3.0

RESPONSE

Table 32 GET Study Design V4 Response

Status	Response	Comments
200	Refer **Response for GET Study DesignV3.0** for the JSON Data	Successful

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Application Exception

404	{
	
	    "statusCode": "404",
	
	    "message": "The requested study document not found"
	
	}
	
	OR
		This can occur when requested Study Id is not found or Study Design is not found.

	{
	
	    "statusCode": "404",
	
	    "message": "The requested study design not found"
	
	}	

500	*Internal Server Error*	Web server/Web API down

POST/PUT Study Definitions

This endpoint allows user to add and/or update a study definition in SDR that conforms to the USDM structure. The PUT endpoint supports updates to specific study elements only when entire study data is sent in the request body. If partial study elements (conforming to specific USDM version) are sent in request, the API will create study version with only the elements sent in request.

    I.   POST - Add Study Definition

For the first time, when a study is pushed into the SDR, the studyId field in the JSON data must be empty. SDR will generate UUID for the studyId field. The Id for the other classes is mandatory, user defined, and expected to be sent in the request.

Table 33 POST Study V4 Endpoint

Method	URL
POST	**/api/v4/studydefinitions**

REQUEST PARAMETERS

Table 34 POST Study V4 Request Parameters

Type	Param	Values
Body		Refer **Request Body for POST – Add New Study DefinitionV3.0** for the JSON Data
Header	usdmVersion	3.0

Table 35 POST Study V4 Response

Status	Response	Comments
201	Refer **Response Body for POST – Add Study DefinitionV3.0** for the JSON Data	Successful. For a new study document added into SDR, the unique IDs for Study and Study Design are generated by system and returned in response body along with SDR Upload Version is defaulted to "1". For updates to an existing study, the version is incremented by 1.

400	{
	
	   "statusCode": "400",
	
	   "message": "An error occurred"
	
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

II. PUT - Update Study Definition

For adding new elements to an existing study definition section

- o New elements should be passed along with existing elements in the request body.

For example, there is an existing study definition in SDR as mentioned in Study Definition – **Existing DataV3.0**. If a new element is to be added to study objectives, the existing study data with the new element must be sent in the request body as mentioned in Request Body for PUT – **Update New Study DefinitionV3.0**.

Table 36 PUT Study V4 Endpoint

Method	URL
PUT	**/api/v4/studydefinitions/{studyId}**

REQUEST PARAMETERS

Table 37 PUT Study V4 Request Parameters

Type	Param	Values
Body		Refer **Request Body for PUT – Update New Study DefinitionV3.0** for the JSON Data
Header	usdmVersion	3.0

Table 38 PUT Study V4 Response

Status	Response	Comments
201	Refer **Response Body for PUT – Update Study DefinitionV3.0** for the JSON Data	Successful. The new element in the section will be added on along with the existing element.

400	{
	
	   "statusCode": "400",
	
	   "message": "An error occurred"
	
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

GET Schedule of Activities (SoA)

This endpoint allows user to retrieve the Schedule of Activities (SoA) for a particular study. Also, the endpoint has optional parameter to retrieve the SoA for a particular study design and a particular schedule timeline.

Table 39 GET SoA V4 Endpoint

Method	URL
GET	**/api/v4/ studydefinitions/{studyId}/studydesigns/soa**

REQUEST PARAMETERS

Table 40 GET SoA Request V4 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversion	Integer	No	3
Query Parameter	Studydesignid	String	No	Value in studyDesignId
Query Parameter	studyWorkflowid	String	No	This is any one of the values in scheduleTimelineId under studyScheduleTimelines.
Header	usdmVersion	String	Yes	3.0

RESPONSE

Table 41 GET SoA V4 Response

Status	Response	Comments
200	Refer **Response for GET SoAV3.0** for the JSON Data	Successful. In the response, Workflow related fields will represent the data of scheduleTimeline (studyWorkflows → studyScheduleTimelines, workflowId → scheduleTimelineId and workflowDescription → scheduleTimelineDescription)

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Application Exception

404	{
	
	    "statusCode": "404",
	
	    "message": "The requested study document not found"
	
	}
	
	OR
	
	{
	
	    "statusCode": "404",
	
	    "message": "The requested study design not found"
	
	}
		This can occur when requested Study Id is not found or Study Design is not found.

500	*Internal Server Error*	Web server/Web API down

GET eCPT Export

This endpoint allows user to retrieve the eCPT Export for each study design in a given study that conforms to USDM Version 3.0 that is stored in SDR.

Table 42 GET eCPT V4 Endpoint

Method	URL
GET	**/api/v4/studydefinitions/{studyId}/studydesigns/ecpt**

REQUEST PARAMETERS

Table 43 GET eCPT Request V4 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversion	Integer	No	3
Query Parameter	Studydesignid	String	No	Value in studyDesignId
Header	usdmVersion	String	Yes	3.0

RESPONSE

Table 44 GET eCPT V4 Response

Status	Response	Comments
200	Refer **Response for GET eCPT V3.0** for the JSON Data	Successful. In the response, Workflow related fields will represent the data of scheduleTimeline (studyWorkflows → studyScheduleTimelines, workflowId → scheduleTimelineId and workflowDescription → scheduleTimelineDescription)

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Application Exception

404	{
	
	   "statusCode": "404",
	
	   "message": "The requested study document not found"
	
	}
	
	OR
	
	{
	
	   "statusCode": "404",
	
	   "message": "The requested study design not found"
	
	}
		This can occur when requested Study Id is not found or Study Design is not found.

500	*Internal Server Error*	Web server/Web API down

POST Validate USDM Conformance

This endpoint allows user to validate whether the study definition conforms to USDM Version 3.0 without submitting the study definitions. If the study definition is conformant with USDM Version 3.0, success response code (200 - Ok) will be returned, otherwise the endpoint will return list of conformance errors with failure response code (400 – Bad Request).

Table 45 POST Validate USDM Conformance V4 Endpoint

Method	URL
POST	**/api/v4/studydefinitions/validate-usdm-conformance**

<u>**REQUEST PARAMETERS**</u>

Table 46 POST Validate USDM Conformance V4 Request Parameters

Type	Param	Values
Body		Refer **Request Body for POST – Add New Study DefinitionV3.0** for the JSON Data
Header	usdmVersion	3.0

<u>**RESPONSE**</u>

Table 47 POST Validate USDM Conformance V4 Response

Status	Response	Comments

200	{
	
	    "statusCode": "200",
	
	    "message": "The study definition is conformant with USDM Version : 2.0"
	
	}
		Successful.
		
		If the Study Definitions is conformant with the USDM conformance rules, API will give 200 Ok response

400	{
	
	    "statusCode": "400",
	
	    "message": "The study definition is not conformant with USDM Version : 2.0",
	
	    "error": {
	
	        "study.studyTitle": [
	
	            "Field is missing"
	
	        ]
	
	    }
	
	}
		Validation Failed.
		
		If the Study Definitions is not conformant with the USDM conformance rules, API will give 400 Bad Request response

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

GET Version Comparison

This endpoint allows user to compare two SDR Upload Versions of study definitions that conforms to USDM Version 2.0. The endpoint will list down the changes between the two SDR Upload Versions of a specific study definition that was sent in the request.

Table 48 GET Version Comparison V4 Endpoint

Method	URL
GET	**/api/v4/studydefinitions/version-comparison**

REQUEST PARAMETERS

Table 49 GET Version Comparison V4 Response

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversion one	Integer	Yes	3
Query Parameter	Sdruploadversiont wo	Integer	Yes	2
Header	usdmVersion	String	Yes	3.0

RESPONSE

Table 50 GET Version Comparison V4 Response

Status	Response	Comments

200	{
	
	    "studyId": "7dd4d676-8714-42d3-b2a9-c189b59fad67",
	    "LHS": {
	        "entryDateTime": "2023-06-21T12:52:48.216Z",
	        "SDRUploadVersion": 1
	    },
	    "RHS": {
	        "entryDateTime": "2023-06-21T12:53:16.601Z",
	        "SDRUploadVersion": 2
	    },
	    "elementsChanged": [
	        "study.studyTitle",
	        "study.studyAcronym",
	        "study.studyIdentifiers[1].studyIdentifier",
	    ]
	}
		Successful.
		
		The API will list down the differences between the two SDR Upload Versions sent in the request.

400	{
	    "statusCode": "400",
	    "message": "An error occurred"
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

V5 API (USDM Version – 4.0)

GET Study

This endpoint allows user to retrieve the different study elements for a particular study for a specific SDR upload version. This endpoint also allows user to retrieve specific sections.

LIST OF STUDY SECTIONS:

- titles
- versionIdentifier
- rationale
- documentVersionIds
- dateValues
- amendments
- studyIdentifiers
- businessTherapeuticAreas
- studyDesigns
- notes
- abbreviations
- referenceIdentifiers
- organizations
- studyInterventions
- narrativeContentItems
- roles
- administrableProducts
- productOrganizationRoles
- medicalDevices

- eligibilityCriterionItems
- conditions
- bcSurrogates
- bcCategories
- dictionaries
- biomedicalConcepts

Table 51 GET Study V5 Endpoint

Method	URL
GET	**/api/v5/studydefinitions/{studyId}**

REQUEST PARAMETERS

Table 52 GET Study V5 Request Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	sdruploadversion	Integer	No	2
Query Parameter	Listofelements	string	No	The parameter value should be comma separated values of the section names. For example, "studyDesigns,studyIdentifiers"
Header	usdmVersion	String	Yes	4.0

Table 53 GET Study V5 Response

Status	Response	Comments
200	Refer **Response for GET StudyV5.0** for the JSON Data	

400	{
	
	  "statusCode": "400",
	
	  "message": "An error occurred"
	
	}
		Application Exception

404	{
	
	  "statusCode": "404",
	
	  "message": "The requested study document not found"
	
	}
		Requested Study Id is not found, or the request URL path is not valid

500	*Internal Server Error*	Web server/Web API down

GET Study Design

Retrieves the different study design elements for a particular study for the SDR upload version. This endpoint also allows the user to retrieve specific study design sections.

LIST OF STUDY DESIGN SECTIONS:

- name
- label
- description
- characteristics
- studyCells
- indications

- studyInterventionIds
- population
- objectives
- scheduleTimelines
- therapeuticAreas
- estimands
- encounters
- activities
- eligibilityCriteria
- biospecimenRetentions
- rationale
- epochs
- elements
- arms
- documentVersionIds
- studyPhase
- studyType
- notes
- analysisPopulations
- subTypes
- intentTypes
- model
- blindingSchema
- timePerspective
- samplingMethod

Table 54 GET Study Design V5 Endpoint

Method	URL
GET	/api/v5/ studydesigns

REQUEST PARAMETERS

Table 55 GET Study Design Request V5 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Query Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	sdruploadversion	Integer	No	3
Query Parameter	listofelements	String	No	The parameter should be comma separated values of the section names. For example, "activities,encounters"
Header	usdmVersion	String	Yes	4.0

RESPONSE

Table 56 GET Study Design V5 Response

Status	Response	Comments
200	Refer **Response for GET Study DesignV5.0** for the JSON Data	Successful

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Application Exception

404	{
	
	    "statusCode": "404",
	
	    "message": "The requested study document not found"
	
	}
	
	OR
	
	{
	
	    "statusCode": "404",
	
	    "message": "The requested study design not found"
	
	}
		This can occur when requested Study Id is not found or Study Design is not found.

500	*Internal Server Error*	Web server/Web API down

POST/PUT Study Definitions

This endpoint allows user to add and/or update a study definition in SDR that conforms to the USDM structure. The PUT endpoint supports updates to specific study elements only when entire study data is sent in the request body. If partial study elements (conforming to specific USDM version) are sent in request, the API will create study version with only the elements sent in request.

      I.   POST - Add Study Definition

For the first time, when a study is pushed into the SDR, the studyId field in the JSON data must be empty. SDR will generate UUID for the studyId field. The Id for the other classes is mandatory, user defined, and expected to be sent in the request.

Table 57 POST Study V5 Endpoint

Method	URL
POST	**/api/v5/studydefinitions**

Table 58 POST Study V5 Request Parameters

Type	Param	Values
Body		Refer **Request Body for POST – Add New Study DefinitionV5.0** for the JSON Data
Header	usdmVersion	4.0

RESPONSE

Table 59 POST Study V5 Response

Status	Response	Comments
201	Refer **Response Body for POST – Add Study DefinitionV5.0** for the JSON Data	Successful. For a new study document added into SDR, the unique IDs for Study and Study Design are generated by system and returned in response body along with SDR Upload Version is defaulted to "1". For updates to an existing study, the version is incremented by 1.

400	{
	
	   "statusCode": "400",
	
	   "message": "An error occurred"
	
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

II.   PUT - Update Study Definition

For adding new elements to an existing study definition section

- o New elements should be passed along with existing elements in the request body.

For example, there is an existing study definition in SDR as mentioned in Study Definition – **Existing DataV5.0**. If a new element is to be added to study objectives, the existing study data with the new element must be sent in the request body as mentioned in Request Body for PUT – **Update New Study DefinitionV5.0**.

Table 60 PUT Study V5 Endpoint

Method	URL
PUT	**/api/v5/studydefinitions/{studyId}**

REQUEST PARAMETERS

Table 61 PUT Study V5 Request Parameters

Type	Param	Values
Body		Refer **Request Body for PUT – Update New Study DefinitionV5.0** for the JSON Data
Header	usdmVersion	4.0

Table 62 PUT Study V5 Response

Status	Response	Comments
201	Refer **Response Body for PUT – Update Study DefinitionV5.0** for the JSON Data	Successful. The new element in the section will be added on along with the existing element.

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

GET Schedule of Activities (SoA)

This endpoint allows user to retrieve the Schedule of Activities (SoA) for a particular study. Also, the endpoint has optional parameter to retrieve the SoA for a particular study design and a particular schedule timeline.

Table 63 GET SoA V5 Endpoint

Method	URL
GET	**/api/v5/ studydefinitions/{studyId}/studydesigns/soa**

REQUEST PARAMETERS

Table 64 GET SoA Request V5 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversion	Integer	No	3
Query Parameter	Studydesignid	String	No	Value in studyDesignId
Query Parameter	studyWorkflowid	String	No	This is any one of the values in scheduleTimelineId under studyScheduleTimelines.
Header	usdmVersion	String	Yes	4.0

RESPONSE

Table 65 GET SoA V5 Response

Status	Response	Comments
200	Refer **Response for GET SoAV5.0** for the JSON Data	Successful. In the response, Workflow related fields will represent the data of scheduleTimeline (studyWorkflows → studyScheduleTimelines, workflowId → scheduleTimelineId and workflowDescription → scheduleTimelineDescription)
400	{	Application Exception

	"statusCode": "400", "message": "An error occurred" }	

404	{
	
	"statusCode": "404",
	
	"message": "The requested study document not found"
	
	}
	
	OR
	
	{
	
	"statusCode": "404",
	
	"message": "The requested study design not found"
	
	}
		This can occur when requested Study Id is not found or Study Design is not found.

500	*Internal Server Error*	Web server/Web API down

GET eCPT Export

This endpoint allows user to retrieve the eCPT Export for each study design in a given study that conforms to USDM Version 4.0 that is stored in SDR.

Table 66 GET eCPT V5 Endpoint

Method	URL
GET	**/api/v5/studydefinitions/{studyId}/studydesigns/ecpt**

REQUEST PARAMETERS

Table 67 GET eCPT Request V5 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversion	Integer	No	3
Query Parameter	Studydesignid	String	No	Value in studyDesignId
Header	usdmVersion	String	Yes	4.0

RESPONSE

Table 68 GET eCPT V5 Response

Status	Response	Comments
200	Refer **Response for GET eCPT V5.0** for the JSON Data	Successful. In the response, Workflow related fields will represent the data of scheduleTimeline (studyWorkflows → studyScheduleTimelines, workflowId → scheduleTimelineId and workflowDescription → scheduleTimelineDescription)

400	{
	
	   "statusCode": "400",
	
	   "message": "An error occurred"
	
	}
		Application Exception

404	{
	
	 "statusCode": "404",
	
	 "message": "The requested study document not found"
	
	 }
	
	 OR
	
	 {
	
	 "statusCode": "404",
	
	 "message": "The requested study design not found"
	
	 }
		This can occur when requested Study Id is not found or Study Design is not found.

500	*Internal Server Error*	Web server/Web API down

POST Validate USDM Conformance

This endpoint allows user to validate whether the study definition conforms to USDM Version 4.0 without submitting the study definitions. If the study definition is conformant with USDM Version 4.0, success response code (200 - Ok) will be returned, otherwise the endpoint will return list of conformance errors produced by the CDISC Rules Engine with failure response code (400 – Bad Request).

Table 69 POST Validate USDM Conformance V5 Endpoint

Method	URL
POST	/api/v5/studydefinitions/validate-usdm-conformance

REQUEST PARAMETERS

Table 70 POST Validate USDM Conformance V4 Request Parameters

Type	Param	Values
Body		Refer **Request Body for POST – Add New Study DefinitionV5.0** for the JSON Data
Header	usdmVersion	4.0

RESPONSE

Table 71 POST Validate USDM Conformance V4 Response

Status	Response	Comments
200	Refer **Response for POST Valid USDM Conformance V5.0** for the JSON Data	Successful. If the Study Definitions is conformant with the USDM conformance rules, API will give 200 Ok response CDISC Rules Engine considers any "partially executable" issues to be warnings only
400	Refer **Response for POST Invalid USDM Conformance V5.0** for the JSON Data	Validation Failed. If the Study Definitions is not conformant with the USDM conformance rules, API will give 400 Bad Request response CDISC Rules Engine considers any "fully executable" issues to be errors

400	{
	    "statusCode": "400",
	    "message": "An error occurred"
	}
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

GET Version Comparison

This endpoint allows user to compare two SDR Upload Versions of study definitions that conforms to USDM Version 4.0. The endpoint will list down the changes between the two SDR Upload Versions of a specific study definition that was sent in the request.

Table 72 GET Version Comparison V5 Endpoint

Method	URL
GET	**/api/v5/studydefinitions/version-comparison**

REQUEST PARAMETERS

Table 73 GET Version Comparison V5 Response

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	Sdruploadversion one	Integer	Yes	3
Query Parameter	Sdruploadversiontwo	Integer	Yes	2
Header	usdmVersion	String	Yes	4.0

RESPONSE

Table 74 GET Version Comparison V5 Response

Status	Response	Comments

200	```{```
	 ```"studyId": "7dd4d676-8714-42d3-b2a9-c189b59fad67",```
	 ```"LHS": {```
	 ```"entryDateTime": "2023-06-21T12:52:48.216Z",```
	 ```"SDRUploadVersion": 1```
	 ```},```
	 ```"RHS": {```
	 ```"entryDateTime": "2023-06-21T12:53:16.601Z",```
	 ```"SDRUploadVersion": 2```
	 ```},```
	 ```"elementsChanged": [```
	 ```"study.studyTitle",```
	 ```"study.studyAcronym",```
	 ```"study.studyIdentifiers[1].studyIdentifier",```
	 ```]```
	 ```}```
		Successful.
		
		 The API will list down the differences between the two SDR Upload Versions sent in the request.

400	```{```
	 ```"statusCode": "400",```
	 ```"message": "An error occurred"```
	 ```}```
		Application Exception

404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

Study History

This endpoint allows user to retrieve the metadata information for Studies residing in the SDR.

Table 75 GET Study History Endpoint

Method	URL
GET	**/api/studydefinitions/history**

Table 76 GET Study History - Request Parameters

Type	Param Name	Values	Mandatory	Sample Values
Query Parameter	FromDate	Date	No	2022-Mar-10
Query Parameter	ToDate	Date	No	2022-Mar-15
Query Parameter	studyTitle	String	No	"Study On Oncology"

RESPONSE

Table 77 GET Study History Response

Status Code	Response	Comments

200	[
	
	  {
	
	     "studyId": "9533aa2d-472a-4722-94eb-1a7b153b241a",
	
	     "SDRUploadVersion": [
	
	      {
	
	       "uploadVersion": 1,
	
	       "entryDateTime": "2023-06-21T11:34:40.43798Z",
	
	       "studyTitle": "Study of Stage III Biliary Duct Cancer",
	
	       "studyVersion": "1",
	
	       "studyIdentifiers": [
	
	        {
	
	         "studyIdentifierId": "c4663375-29be-4b37-9a7d-b2ef927fdf64",
	
	         "studyIdentifier": "CT-GOV-1234",
	
	         "studyIdentifierScope": {
	
	          "organisationId": "96dd6b83-2d34-45ac-9d08-3e647b2c7316",
	
	          "organisationIdentifier": "CT-GOV",
	
	          "organisationIdentifierScheme": "FDA",
	
	          "organisationName": "ClinicalTrials.gov",
		Successful

```json
                        "organisationType": {
                                "codeId": "8fcecddf-bbe2-4e71-ad97-
114cbc3f1cba",

                                "code": "C2365x",

                                "codeSystem": "http:www.cdisc.org",

                                "codeSystemVersion": "1",

                                "decode": "Clinical Study Sponsor"
                        },
                        "organizationLegalAddress": {

                                "text": "text",

                                "line": " line2",

                                "city": " city",

                                "district": "district ",

                                "state": "state ",

                                "postalCode": " postalCode",

                                "country": {

                                        "codeId": "8fcecddf-bbe2-4e71-ad97-
114cbc3f1cba",

                                        "code": "C2365x",

                                        "codeSystem": "http:www.cdisc.org",

                                        "codeSystemVersion": "1",

                                        "decode": "Egypt"

                                }

                        }

                }

        }
```

	],
	
	"protocolVersions": [
	
	  "1"
	
	],
	
	"usdmVersion": "1.9",
	
	"links": {
	
	    "studyDefinitions": "/v2/studydefinitions/9533aa2d-472a-4722-94eb-1a7b153b241a?sdruploadversion=1",
	
	    "auditTrail": "/studydefinitions/9533aa2d-472a-4722-94eb-1a7b153b241a/audittrail",
	
	    "studyDesigns": [
	
	      {
	
	        "studyDesignId": "SD01",
	
	        "studyDesignLink": "/v2/studydesigns?study_uuid=9533aa2d-472a-4722-94eb-1a7b153b241a&sdruploadversion=1&studydesign_uuid=SD01"
	
	      }
	
	    ]
	
	  }
	
	 }
	
	]
	
	]	

400	{
	
	  "statusCode": "400",
	
	  "message": "An error occurred"
		Application Exception

	}	

404	{
	
	    "statusCode": "404",
	
	    "message": "The requested study document not found"
	
	}
		When Study Title is given in query param and there is no matching study definition in SDR, or the requested URI is not valid.

500	*Internal Server Error*	Web server/Web API down

GET Revision history

This endpoint allows the user to retrieve the revision history for a study residing in the SDR Repository. The SDR captures the history of all changes done on a study definition, including entry date time, entry system and sdr upload version.

Table 78 GET Revision History Endpoint

Method	URL
GET	**/api/studydefinitions/{studyId}/revisionhistory**

REQUEST PARAMETERS

Table 79 GET Revision History - Request Parameters

Type	Param Name	Values	Mandatory	Sample Values
Query Parameter	FromDate	Date	No	2022-Mar-10
Query Parameter	ToDate	Date	No	2022-Mar-15
Path Parameter	studyId	String	Yes	11adcf54-82cf-40d2-81a5-092d4e5b6819

RESPONSE

Table 80 GET Revision History Response

Status Code	Response	Comments

200	{
	
	    "studyId": "11adcf54-82cf-40d2-81a5-092d4e5b6819",
	
	    "auditTrail": [
	
	        {
	
	            "entryDateTime": "2023-03-16T05:31:04.927Z",
	
	            "usdmVersion": "1.9",
	
	            "SDRUploadVersion": 2,
	
	            "links": {
		Successful

```
            "studyDefinitions": "/v2/studydefinitions/11adcf54-
82cf-40d2-81a5-092d4e5b6819?sdruploadversion=2",

            "auditTrail": "/studydefinitions/11adcf54-82cf-40d2-
81a5-092d4e5b6819/audittrail",

            "studyDesigns": [

                {

                    "studyDesignId": "SD01",

                    "studyDesignLink":
"/v2/studydesigns?study_uuid=11adcf54-82cf-40d2-81a5-
092d4e5b6819&sdruploadversion=2&studydesign_uuid=SD01"

                }

            ],

            "SoA": "/v2/studydefinitions/11adcf54-82cf-40d2-
81a5-092d4e5b6819/studydesigns/soa?sdruploadversion=2"

        }

    },

    {

        "entryDateTime": "2023-03-16T05:30:26.628Z",

        "usdmVersion": "1.9",

        "SDRUploadVersion": 1,

        "links": {

            "studyDefinitions": "/v2/studydefinitions/11adcf54-
82cf-40d2-81a5-092d4e5b6819?sdruploadversion=1",

            "auditTrail": "/studydefinitions/11adcf54-82cf-40d2-
81a5-092d4e5b6819/audittrail",

            "studyDesigns": [

                {

                    "studyDesignId": "SD01",
```

	"studyDesignLink": "/v2/studydesigns?study_uuid=11adcf54-82cf-40d2-81a5-092d4e5b6819&sdruploadversion=1&studydesign_uuid=SD01"
	
	       }
	
	     ],
	
	     "SoA": "/v2/studydefinitions/11adcf54-82cf-40d2-81a5-092d4e5b6819/studydesigns/soa?sdruploadversion=1"
	
	   }
	
	  }
	
	]
	
	}		

400	{
	
	   "statusCode": "400",
	
	   "message": "An error occurred"
	
	}
		Application Exception

404	{
	
	   "statusCode": "404",
	
	   "message": "The requested study document not found"
	
	}
		When Study Title is given in query param and there is no matching study definition in SDR, or the requested URI is not valid.

500	*Internal Server Error*	Web server/Web API down

GET Change Audit

This endpoint allows user to retrieve the change audit for a particular study.

Table 81 GET Change Audit Endpoint

Method	URL
GET	**/api/studydefinitions/{studyId}/changeaudit**

REQUEST PARAMETERS

Table 82 GET Change Audit Request Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d

RESPONSE

Table 83 GET Change Audit Response

Status	Response	Comments

200	
	``json
	{
	    "changeAudit": {
	        "studyId": "8059cf15-57e9-45e3-a64b-5681896a0ffe",
	        "changes": [
	            {
	                "entryDateTime": "2022-10-19T10:32:17.673Z",
	                "SDRUploadVersion": 2,
	                "elements": [
	                    "clinicalStudy.studyType",
	                    "clinicalStudy.studyPhase"
	                ]
	            }
	        ]
	    }
	}
	``	

400	
	``json
	{
	    "statusCode": "400",
	    "message": "An error occurred"
	}
	``
		Application Exception

404	{
	
	    "statusCode": "404",
	
	    "message": "The requested study document not found"
	
	}
		Requested Study Id is not found, or the request URL path is not valid

500	*Internal Server Error*	Web server/Web API down

GET Raw JSON

This endpoint allows user to retrieve a particular study irrespective of the usdmVersion that is stored in SDR. This is useful for retrieving study data in plain text (stringified JSON), which is conformant to a USDM version that is not being supported in the current running instance of SDR. At a given point in time SDR will only support 3 USDM versions. When it is upgraded to a version that doesn't support any of the earlier versions of USDM, but the repository has studies conforming to those deprecated version, the data can be still retrieved via this endpoint. The version specific endpoints of that deprecated USDM version would have been decommissioned.

Table 84 GET Raw JSON Endpoint

Method	URL
GET	/api/studydefinitions/{studyId}/rawdata

REQUEST PARAMETERS

Table 85 GET Raw JSON Request Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d

RESPONSE

Table 86 GET Raw JSON Response

Status	Response	Comments

| 200 | {
"studyDefinitions": "{\"clinicalStudy\":{\"studyId\":\"7637afd1-d667-47c0-a842-780e129b73f8\",\"studyTitle\":\"Study of Biliary Duct Cancer\",\"studyVersion\":\"1\",\"studyType\":{\"codeId\":\"7bbb6fd9-7e43-4dbf-90fa-3de117dc76d2\",\"code\":\"C98388\",\"codeSystem\":\"http:www.cdisc.org\",\"codeSystemVersion\":\"2022-03-24\",\"decode\":\"INTERVENTIONAL\"},\"studyRationale\":\"Rational\",\"studyAcronym\":\"Acronym\",\"studyIdentifiers\":[{\"studyIdentifierId\":\"c4663375-29be-4b37-9a7d-b2ef927fdf64\",\"studyIdentifier\":\"CT-GOV-1234\",\"studyIdentifierScope\":{\"organisationId\":\"96dd6b83-2d34-45ac-9d08-3e647b2c7316\",\"organisationIdentifier\":\"CT-GOV\",\"organisationIdentifierScheme\":\"FDA\",\"organisationName\":\"ClinicalTrials.gov\",\"organisationType\":{\"codeId\":\"8fcecddf-bbe2-4e71-ad97-114cbc3f1cba\",\"code\":\"C2365x\",\"codeSystem\":\"http:www.cdisc.org\",\"codeSystemVersion\":\"1\",\"decode\":\"Clinical Study Sponsor\"},\"organizationLegalAddress\":{\"text\":\"text\",\"line\":\" line2\",\"city\":\" city\",\"district\":\"district \",\"state\":\"state \",\"postalCode\":\" postalCode\",\"country\":{\"codeId\":\"8fcecddf-bbe2-4e71-ad97-114cbc3f1cba\",\"code\":\"C2365x\",\"codeSystem\":\"http:www.cdisc.org\",\"codeSystemVersion\":\"1\",\"decode\":\"Egypt\"}}}}],\"studyPhase\":{\"aliasCodeId\":\"61ad4d8f-527c-4f1d-b227-4bbf6141f616\",\"standardCode\":{\"codeId\":\"61ad4d8f-527c-4f1d-b227-4bbf6141f613\",\"code\":\"C49686\",\"codeSystem\":\"http:www.cdisc.org\",\"codeSystemVersion\":\"2022-03-25\",\"decode\":\"Phase IIa Trial\"},\"standardCodeAliases\":[{\"codeId\":\"61ad4d8f-527c-4f1d-b227-4bbf6141f613\",\"code\":\"C49686\",\"codeSystem\":\"http:www.cdisc.org\",\"codeSystemVersion\":\"2022-03-25\",\"decode\":\"Phase IIa Trial\"}]},\"businessTherapeuticAreas\":null,\"studyProtocolVersions\":null,\"studyDesigns\":null},\"auditTrail\":{\"entryDateTime\":\"2023-03-17T06:07:39.546Z\",\"usdmVersion\":\"1.9\",\"SDRUploadVersion\":1}}"} | |

400	{
	
	    "statusCode": "400",
	
	    "message": "An error occurred"
	
	}
		Applicatio n Exception

404	{
	
	    "statusCode": "404",
	
	    "message": "The requested study document not found"
	
	}
		Requested Study Id is not found, or the request URL path is not valid

500	*Internal Server Error*	Web server/Web API down

3. Testing the API Endpoint

Postman REST client Setup

This section details steps to test the SDR RI API endpoints using a REST client. For the purpose of this document the tool used is Postman REST Client. Postman Collections for the SDR RI API endpoints are provided in the DDF SDR API GitHub repository under documents for each SDR release version.

STEPS:

- Install **Postman Tool**

Accessing the GET API

STEPS:

- Enter the URL for the GET Request URL (API endpoint) as mentioned below.

    https://{domain}/api/v5/studydefinitions/{**studyId}**

- Get the **StudyId** from **Response for GET StudyV5.0** and replace the Study ID path parameter value in the GET URL.

Figure 1 Postman set HTTP Request for GET
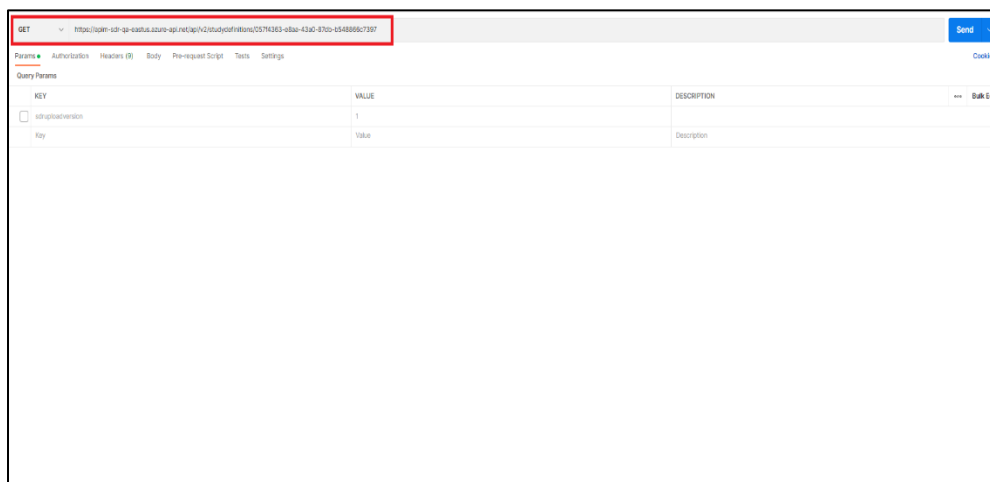
- Click on the "Send" button to get the study definition data for given studyId.

Figure 2 Postman Send Request
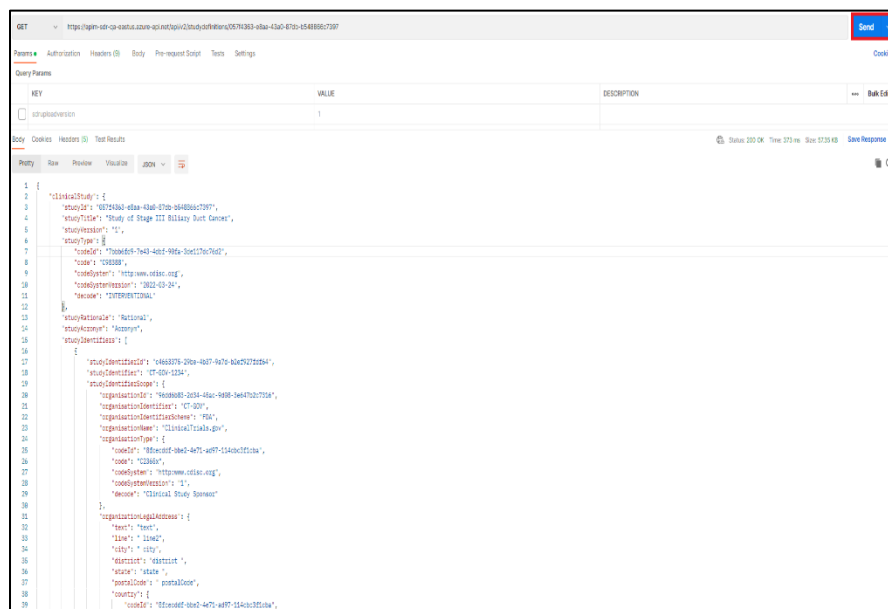
- For a correct SDR API URL, the API Response of HTTP Status code 200 along with the data will be returned.

Figure 3 Postman HTTP Response

Similarly, below response codes returned by SDR API endpoints can also be tested in Postman. These scenarios can be tested in any of the REST API tools other than Postman REST client.

- 400 – The server cannot or will not process the request due to something that is perceived to be a client error

- 404 - indicates that the server cannot find the requested resource

- Incorrect Domain/hostname
- Incorrect Protocol
- Incorrect Method