Study Definition Repository (SDR)

Reference Implementation (RI)

SDR API User Guide

Version 4.0

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1. Introduction

1.1. Overview

The SDR RI implements the CDISC DDF Reference Architecture which include USDM model and API Specifications defined using the OpenApi Specification. The API Layer of the SDR Reference Implementation complies with the Open API Specification (OAS) which allow 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 responds 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.

1.2. Scope of Document

This document details the list of API endpoints available in the Study Definition Repository Reference Implementation and provides 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.

1.3. Intended Audience

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

1.4. 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 Definitions Model

2. Pre-Requisites

To access APIs, a client certificate must be generated, and a postman rest client should be configured.

2.1. Self-signed Certificate Generation

Certificate can be created by using any one of the below Tools.

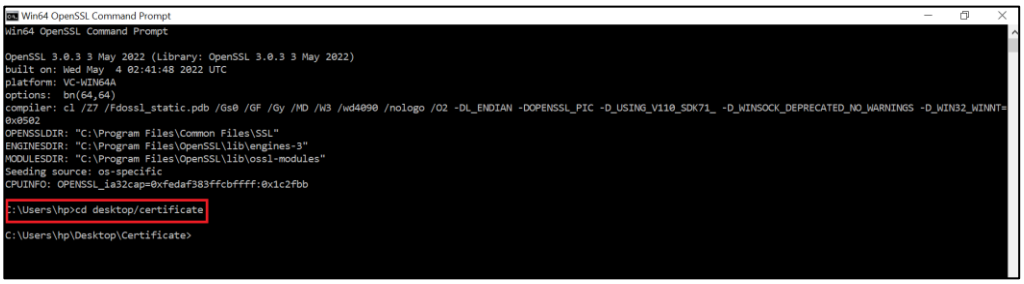
- Open SSL
- PowerShell

2.1.1. Certificate generation with OpenSSL

i. Install the OpenSSL.

ii. Run the OpenSSL Command Prompt and set the directory to the folder where certificate to be stored.

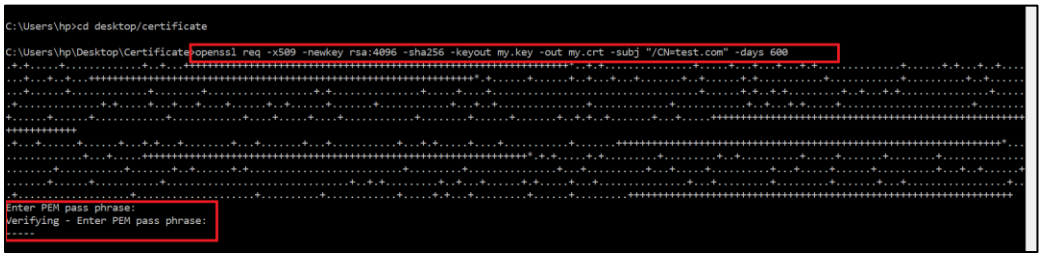
Figure 1 OpenSSL Command Prompt



iii. Run the below command → provide Enter PEM pass phrase and save the pass phrase to provide it on the command to generate .pfx certificate.

```
openssl req -x509 -newkey rsa:4096 -sha256 -keyout my.key -out my.crt -subj
"/CN=test.com" -days 600
```

Figure 2 OpenSSL Command



iv. Run the below command to generate the .pfx certificate.

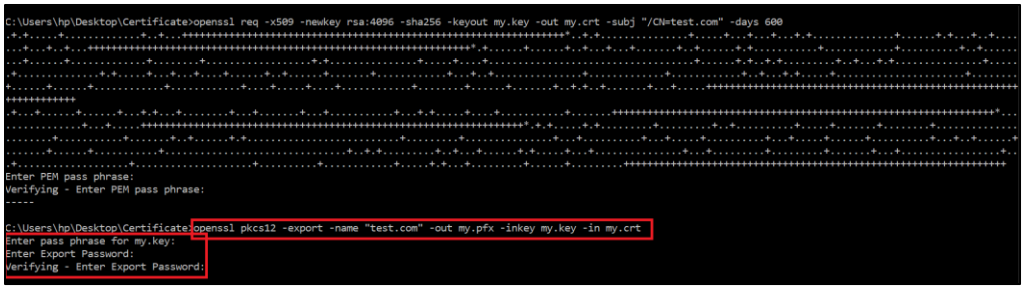
```
openssl pkcs12 -export -name “test.com” -out my.pfx -inkey my.key -in my.crt
```

Provide the below details.

Enter pass phrase for my.key: Provide the pass phrase passed on step 3

Enter Export Password: Provide the password for .pfx certificate and save it for later use.

Figure 3 Export Certificate



v. Exported .pfx certificate will be stored in the directory where OpenSSL was installed.

Note: Share the .pfx certificate and the password to SDR Support team to get access to SDR API’s on Demo Environment.

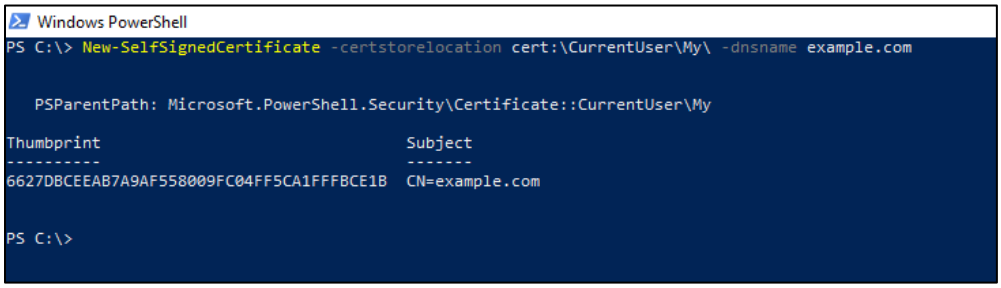
.

2.1.2. Certificate generation with PowerShell

i. Open PowerShell and run the following command to generate the self-signed certificate.

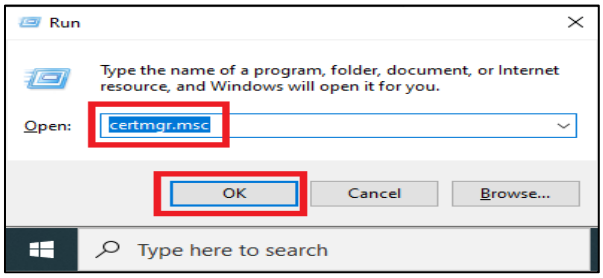
```
New-SelfSignedCertificate -certstorelocation cert:\CurrentUser\My\ -dnsname example.com
```

Figure 4 PowerShell Command



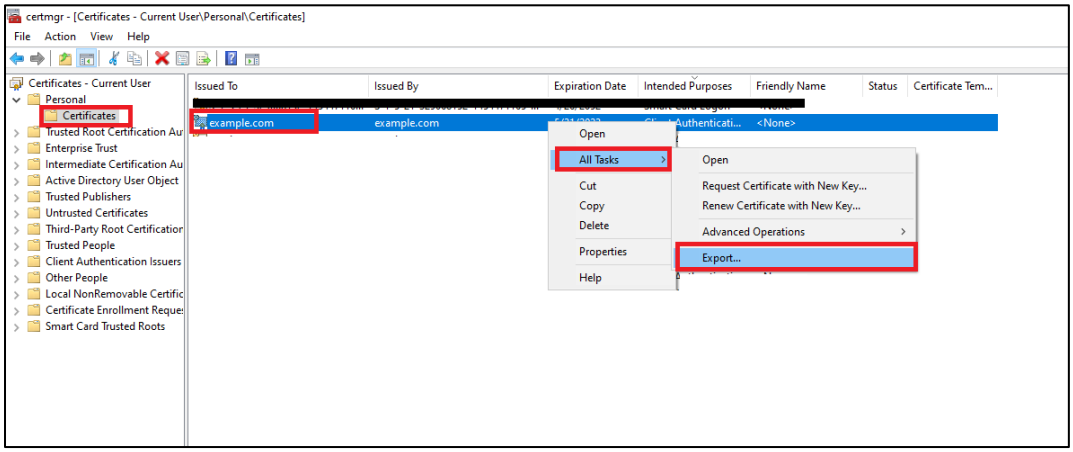
ii. To Export the certificate in .pfx format, go to run → type certmmgr.msc and click ok

Figure 5 Run Window



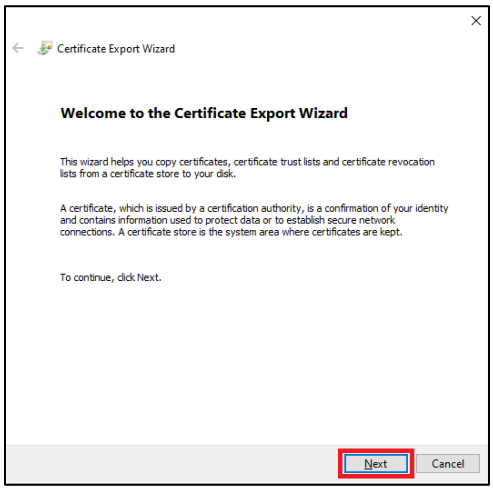
iii. In certificate manager go to personal → certificates → select the generated certificate and right click select All Tasks → Select Export.

Figure 6 Certificate Manager Console



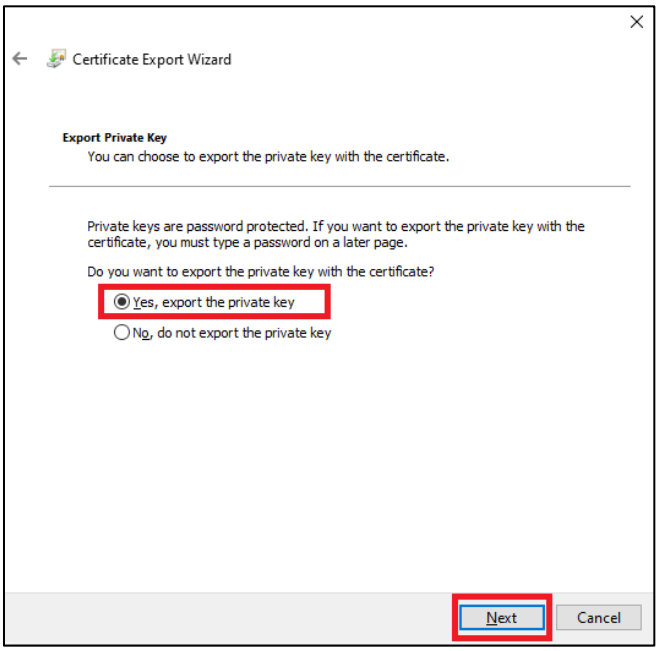
iv. In Certificate Export Wizard click Next to continue.

Figure 7 Certificate Export Wizard



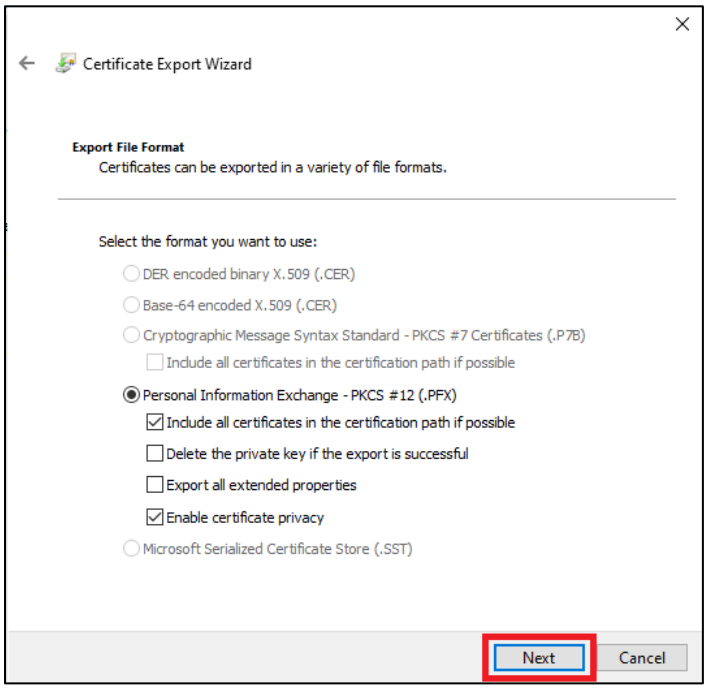
v. Select export the private key option and click next.

Figure 8 Export Private Key



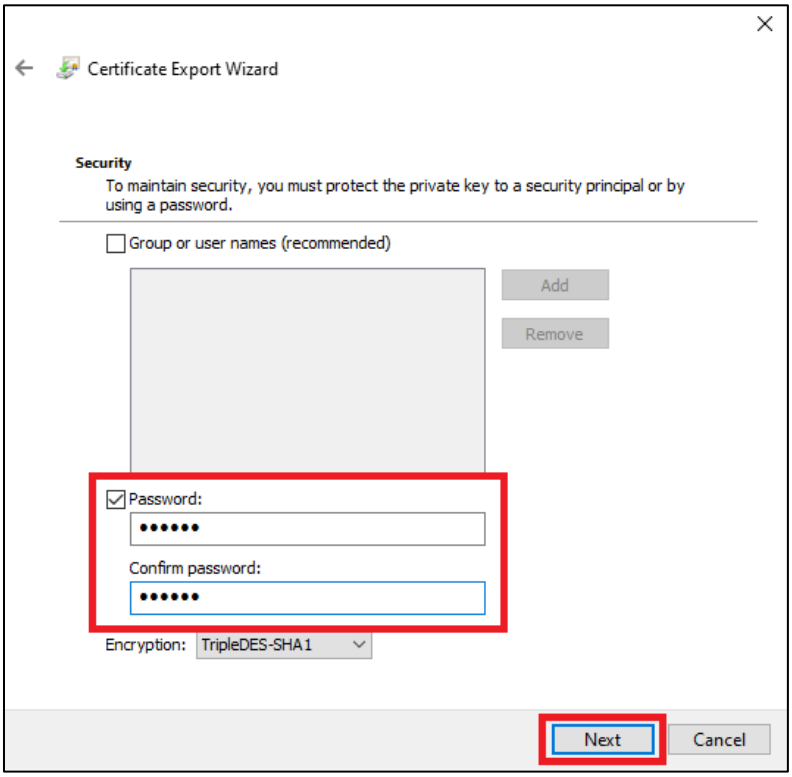
vi. Leave the defaults and click next.

Figure 9 Certificate Format .PFX



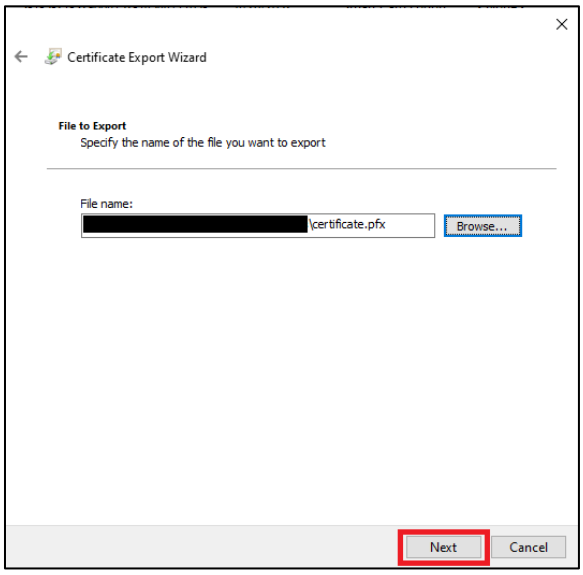
vii. Provide the password for certificate and click next.

Figure 10 Password for Certificate



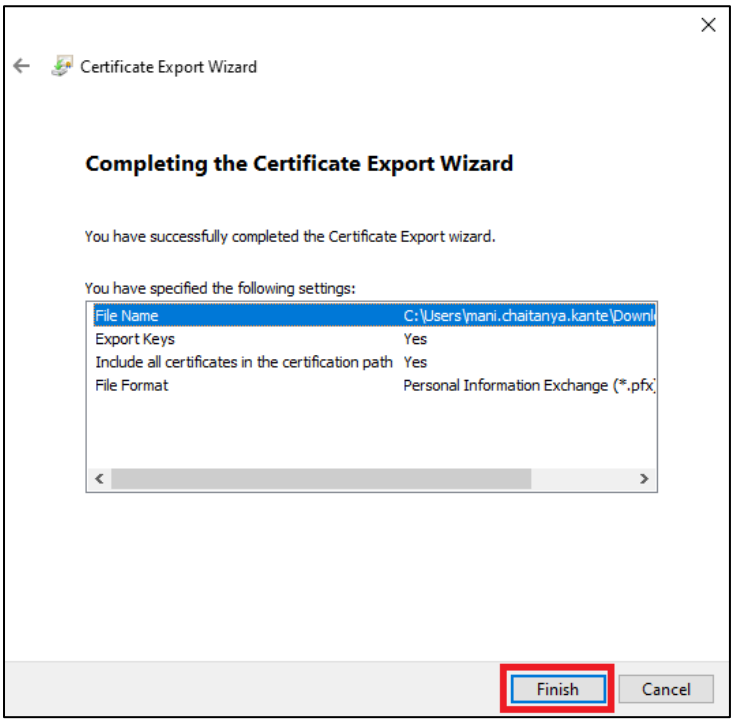
viii. Select the path to save the certificate.

Figure 11 Certificate File Name



ix. Click on Finish.

Figure 12 Certificate Export Wizard



x. Exported .pfx certificate will be stored on the folder path provided on step 8.

Note: Share the .pfx certificate and the password to SDR Support team to get access to SDR API's on Demo environment.

3. API End Points

SDR Reference Implementation exposes the following REST Endpoints to deliver application functionality including storing and retrieving study definitions. All the SDR RI API endpoints conform to the CDISC USDM format mentioned in **USDM Conformance for SDR RI_V1** for USDM Version 1.0 and in **USDM Conformance for SDR RI_V2** for USDM Version 1.9. For the Reference Implementation, only the required field validations mentioned in the CDISC USDM document have been included.

3.1. Token

This endpoint allows user to get an access token to access API's by providing a username and password in the request body. This access token must be passed as an authorization header for the other API endpoints.

Table 1 GET Token Endpoint

Method	URL
POST	**/api/auth/token**

REQUEST PARAMETERS

Table 2 GET Token - Request Parameters

Type	Mandatory	Sample Values
Body	Yes	{ "userName": "xxxx@email.com", "password": "xxxxx"

		}

RESPONSE

Table 3 GET Token Response

Status Code	Response	Comments
200	{ "token": "Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hMGRkMGFkOC1mNDE5LTQ0ZTItYjVlYy0zZGUwNGUzZDg2ODgvIiwiaWF0IjoxNjU5NzAxNDA3LCJuYmYiOjE2NTk3MDE0MDcsImV4cCI6MTY1OTcwNjgwNSwiYWNyIjoiMSIsImFpbyI6IkFTUUEyLzhUQUFBQWMrM2ZFQU5YRi9pM0ptMmpZV05RRGJCVDloMzFXZndhTU5FY2tzZncvZnM9IiwiYW1yIjpbInB3ZCJdLCJhcHBpZCI6ImJkOGJmMzZmLTJhNzMtNDEzNi04NDE5LTBjMjBjZTk0YzViYyIsImFwcGlkYWNyIjoiMSIsImVtYWlsIjoidGVzdHVzZXJAYWNwMjAwNTIwYS5vbm1pY3Jvc29mdC5jb20iLCJpcGFkZHIiOiI0MC43Ni4xNTIuMTAiLCJuYW1lIjoiVGVzdCIsIm9pZCI6IjhhOTFiZTQxLTU2NWUtNDZlOC1iMzA3LTUwMTQyNWQyNDg4ZiIsInJoIjoiMC5BVVlBMkFyZG9CbjA0a1MxN0QzZ1RqMkdpR196aTcxektqWkJoQmtNSU02VXhieEdBS1kuIiwicm9sZXMiOlsib3JnLmFkbWluIl0sInNjcCI6InVpLWFjY2VzcyIsInN1YiI6IlZ6WldkM1pMYUdVMnlNVVNMRHFjN0RYaU5pZE8" }	Successful
400	{ "statusCode": "400", "message": "An error occurred" }	Application Exception or Entered username or password is invalid.

	OR
	{
	"statusCode": "400",
	"message": "Invalid Credentials"
	}	

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

3.2. 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 user to get mapping between SDR API versions and CDISC USDM versions.

Table 4 GET API version ->USDM Version Mapping Endpoint

Method	URL
GET	**/api/versions**

RESPONSE

Table 5 API version ->USDM Version Mapping Response

Status	Response	Comments
200	{ "SDRVersions": [{ "apiVersion": "mvp",	

	"usdmVersions": [
	"mvp"
	]
	},
	{
	"apiVersion": "v1",
	"usdmVersions": [
	"1.0"
	]
	},
	{
	"apiVersion": "v2",
	"usdmVersions": [
	"1.9"
	]
	}
	]
	}	

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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an

		unauthorized response.
403	*Forbidden*	Invalid Client Certificate

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

3.3. V1 API (USDM Version - 1.0)

3.3.1. GET Study

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

Table 6 GET Study V1 Endpoint

Method	URL
GET	**/api/v1/studydefinitions/{studyId}**

REQUEST PARAMETERS

Table 7 GET Study 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
Header	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM	
Header	usdmVersion	String	Yes	1.0

RESPONSE

Table 8 GET Study V1 Response

Status	Response	Comments
200	Refer **Response for GET StudyV1** for the JSON Data	

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

401	{ "statusCode": "401",	When the API is invoked without access token or an expired access

	"message": "Access Denied" }	token, then the API will give an unauthorized response.
403	*Forbidden*	Invalid Client Certificate

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

3.3.2. GET Study Design

Retrieves the different study design elements for a particular study for SDR upload version.

Table 9 GET Study Design V1 Endpoint

Method	URL
GET	**/api/v1/ studydesigns**

REQUEST PARAMETERS

Table 10 GET Study Design V1 Request Parameters

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

Query Parameter	sdruploadversion	Integer	No	3
Header	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM	
Header	usdmVersion	String	Yes	1.0

RESPONSE

Table 11 GET Study Design V1 Response

Status	Response	Comments
200	Refer **Response for GET Study DesignV1** for the JSON Data	Successful
400	{ "statusCode": "400", "message": "An error occurred" }	Application Exception
401	{	When the API is invoked without access token or an expired access token, then

	"statusCode": "401", "message": "Access Denied" }	the API will give an unauthorized response.
403	*Forbidden*	Invalid Client Certificate

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

3.3.3. POST Study Definitions

This endpoint allows user to add and/or update a study definition in SDR that conforms to the USDM structure. The study GET endpoint allows the users to fetch data for individual section whereas the section specific adds/updates are not in scope of SDR Reference Implementation.

3.3.3.1. POST - Add Study Definition

For the first time, when a study is pushed into the SDR, the uuid fields in the JSON data must be empty. SDR will generate UUID for the uuid fields.

Table 12 POST Study V1 Endpoint

Method	URL
POST	**/api/v1/studydefinitions**

REQUEST PARAMETERS

Table 13 POST Study V1 Request Parameters

Type	Param Name	Sample Values
Body		Refer Request Body for POST – Add New Study DefinitionV1 for the JSON Data
Header	Authorization	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM
Header	usdmVersion	1.0

RESPONSE

Table 14 POST Study V1 Response

Status	Response	Comments
201	Refer Response Body for POST – Add Study Definition**V1** 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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

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

3.3.3.2. POST - Update Study Definition

i. For adding new elements to an existing study definition section

- **uuid** for the study should be passed in the request body

- **uuid** for the study and **uuid** for the studyDesign should be passed when updating study design data.
- New elements should be passed without **id** field data along with existing elements including SDR generated **id** values in the request body.
- SDR will generate UUID for only the new elements mentioned in the request and update the data for existing elements that had a valid UUID in the request.

ii. For example, there is an existing study definition in SDR as mentioned in Study Definition – **Existing DataV1**. 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 POST – **Update New Study DefinitionV1**.

Table 15 POST Study V1 Endpoint

Method	URL
POST	**/api/v1/studydefinitions**

REQUEST PARAMETERS

Table 16 POST Study V1 Request Parameters

Type	Param	Values
Body		Refer Request Body for POST – Update New Study Definition**V1** for the JSON Data
Header	Authorization	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM
Header	usdmVersion	1.0

RESPONSE

Table 17 POST Study V1 Response

Status	Response	Comments
201	Refer Response Body for POST – Update Study Definition**V1** 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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

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

3.4. V2 API (USDM Version - 1.9)

3.4.1. 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 18 GET Study V2 Endpoint

Method	URL
GET	**/api/v2/studydefinitions/{studyId}**

REQUEST PARAMETERS

Table 19 GET Study V2 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	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM
Header	usdmVersion	String	Yes	1.9

RESPONSE

Table 20 GET Study V2 Response

Status	Response	Comments
200	Refer Response for GET StudyV1.9 for the JSON Data	
400	{ "statusCode": "400", "message": "An error occurred" }	Application Exception
401	{ "statusCode": "401", "message": "Access Denied" }	When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

403	*Forbidden*	Invalid Client Certificate

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

3.4.2. 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
- trialIntentType
- trialType
- interventionModel
- studyCells
- studyIndications
- studyInvestigationalInterventions
- studyPopulations
- studyObjectives
- studyScheduleTimelines
- therapeuticAreas
- studyEstimands
- encounters
- activities
- studyDesignRationale
- studyDesignBlindingScheme
- biomedicalConcepts
- bcCategories
- bcSurrogates

Table 21 GET Study Design V2 Endpoint

Method	URL
GET	/api/v2/ studydesigns

REQUEST PARAMETERS

Table 22 GET Study Design Request V2 Parameters

Type	Param Name	Values	Mandatory	Sample Values
Query Parameter	study_uuid	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	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL

				3N0cy53aW5kb3dzLm5ldC9hM
Header	usdmVersion	String	Yes	1.9

RESPONSE

Table 23 GET Study Design V2 Response

Status	Response	Comments
200	Refer **Response for GET Study DesignV1.9** for the JSON Data	Successful
400	{ "statusCode": "400", "message": "An error occurred" }	Application Exception
401	{ "statusCode": "401", "message": "Access Denied" }	When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.
403	*Forbidden*	Invalid Client Certificate
404	{ "statusCode": "404", "message": "The requested study document not found" }	This can occur when requested Study Id is not found or Study Design is not found.

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

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

3.4.3. 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.

3.4.3.1. 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 24 POST Study V2 Endpoint

Method	URL
POST	**/api/v2/studydefinitions**

REQUEST PARAMETERS

Table 25 POST Study V2 Request Parameters

Type	Param	Values

Body		Refer Request Body for POST – Add New Study DefinitionV1.9 for the JSON Data
Header	Authorization	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM
Header	usdmVersion	1.9

RESPONSE

Table 26 POST Study V2 Response

Status	Response	Comments
201	Refer Response Body for POST – Add Study DefinitionV1.9 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
401	{ "statusCode": "401", "message": "Access Denied" }	When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.
403	*Forbidden*	Invalid Client Certificate
404	*Resource Not Found*	When the request URL is not valid.
500	*Internal Server Error*	Web server/Web API down

3.4.3.2. PUT - Update Study Definition

i. For adding new elements to an existing study definition section

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

ii. For example, there is an existing study definition in SDR as mentioned in Study Definition – **Existing DataV1.9**. 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 DefinitionV1.9**.

Table 27 PUT Study V2 Endpoint

Method	URL
PUT	**/api/v2/studydefinitions/{studyId}**

REQUEST PARAMETERS

Table 28 PUT Study V2 Request Parameters

Type	Param	Values
Body		Refer Request Body for PUT – Update New Study DefinitionV1.9 for the JSON Data
Header	Authorization	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM
Header	usdmVersion	1.9

RESPONSE

Table 29 PUT Study V2 Response

Status	Response	Comments
201	Refer Response Body for PUT – Update Study DefinitionV1.9 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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

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

3.4.4. 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 30 GET SoA V2 Endpoint

Method	URL
GET	/api/v2/ studydefinitions/{studyId}/studydesigns/soa

REQUEST PARAMETERS

Table 31 GET SoA Request V2 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	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM			
Header	usdmVersion	String	Yes	1.9

RESPONSE

Table 32 GET SoA V2 Response

Status	Response	Comments
200	Refer **Response for GET SoAV1.9** 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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

403	*Forbidden*	Invalid Client Certificate

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

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

3.5. Study History

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

Table 33 GET Study History Endpoint

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

REQUEST PARAMETERS

Table 34 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 35 GET Study History Response

Status Code	Response	Comments

200	[
	{
	"studyId": "9533aa2d-472a-4722-94eb-1a7b153b241a",
	"SDRUploadVersion": [
	{
	"uploadVersion": 1,
	"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",
	"organisationType": {
	"codeId": "8fcecddf-bbe2-4e71-ad97-114cbc3f1cba",
	"code": "C2365x",
	"codeSystem": "http:www.cdisc.org",
	"codeSystemVersion": "1",
	"decode": "Clinical Study Sponsor"
	},
		Successful

```
                    "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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

403	*Forbidden*	Invalid Client Certificate

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

3.6. 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 36 GET Audit Trail Endpoint

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

REQUEST PARAMETERS

Table 37 GET Audit Trail - 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 38 GET Audit Trail 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": {
	"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"
		Successful

```
            }
          ],
          "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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

403	*Forbidden*	Invalid Client Certificate

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

3.7. GET Change Audit

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

Table 39 GET Change Audit Endpoint

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

REQUEST PARAMETERS

Table 40 GET Change Audit Request Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	StudyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Header	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM	

RESPONSE

Table 41 GET Change Audit Response

Status	Response	Comments

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

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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

403	*Forbidden*	Invalid Client Certificate

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

3.8. 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 42 GET Raw JSON Endpoint

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

REQUEST PARAMETERS

Table 43 GET Raw JSON Request Parameters

Type	Param Name	Values	Mandatory	Sample Values

Path Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Header	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM	

RESPONSE

Table 44 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	{	Application Exception

Status	Response	Comments
	"statusCode": "400", "message": "An error occurred" }	

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

403	*Forbidden*	Invalid Client Certificate

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

3.9. GET eCPT Export

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

Table 45 GET eCPT Mapping Endpoint

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

REQUEST PARAMETERS

Table 46 GET eCPT Mapping Request Parameters

Type	Param Name	Values	Mandatory	Sample Values
Path Parameter	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Header	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM	

RESPONSE

Table 47 GET eCPT Mapping Response

Status	Response	Comments
200	Refer **Response Body for GET eCPT Mapping** for the JSON Data	

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

401	{
	"statusCode": "401",
	"message": "Access Denied"
	}
		When the API is invoked without access token or an expired access token, then the API will give an unauthorized response.

403	*Forbidden*	Invalid Client Certificate

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

4. Testing the API Endpoint

4.1. 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.

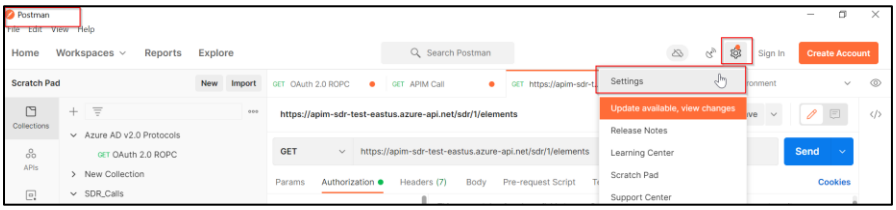
PRE-REQUISITES:

- Self-Signed .pfx certificate configured for SDR API Access.
- Install **Postman Tool**

STEPS:

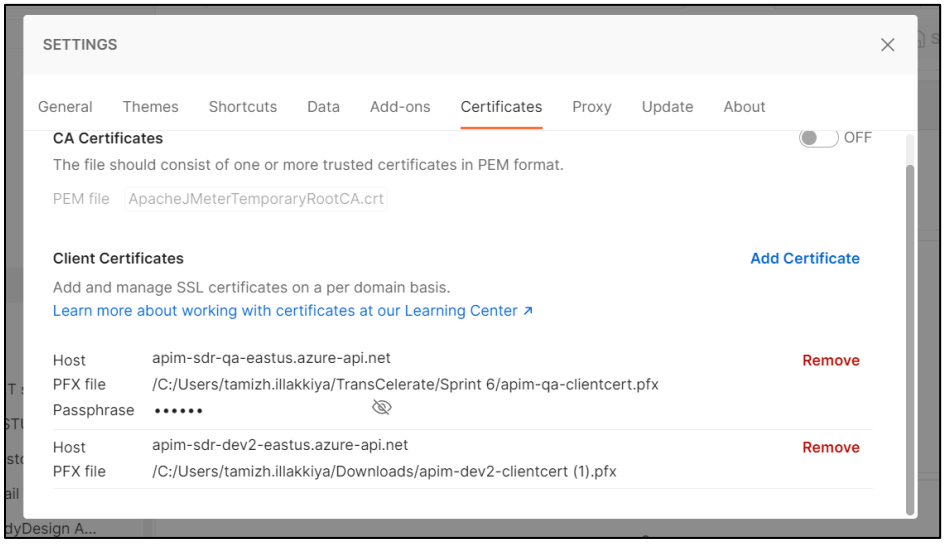
i. Open postman and go to “Settings” option.

Figure 13 Postman Upload Certificate



ii. Go to “Certificates” tab and upload the client certificate and provide the Host Name and Passphrase (certificate password) for the client certificate.

Figure 14 Postman Add Client Certificate



4.2. Accessing the GET API

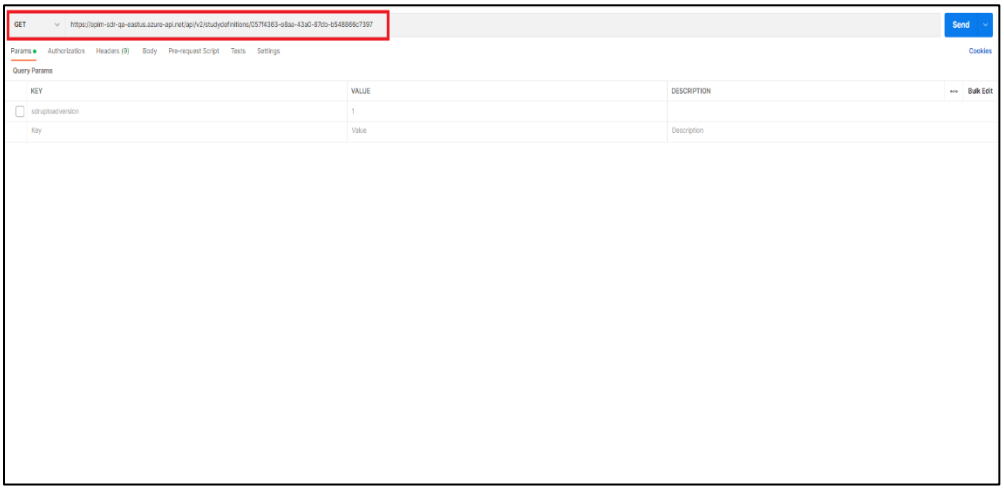
STEPS:

i. Enter the URL for the GET Request URL (APIM endpoint) as mentioned below.

https://apim-sdr-envname-eastus.azure-api.net/api/v2/studydefinitions/{studyId}

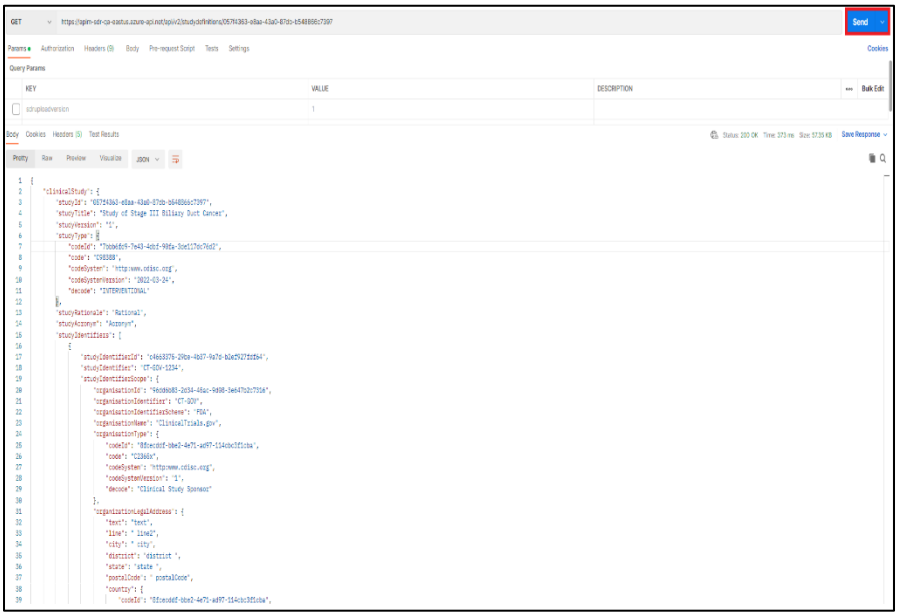
ii. Get the **StudyId** from **Response for GET StudyV1.9** and replace the Study ID path parameter value in the GET URL.

Figure 15 Postman set HTTP Request for GET



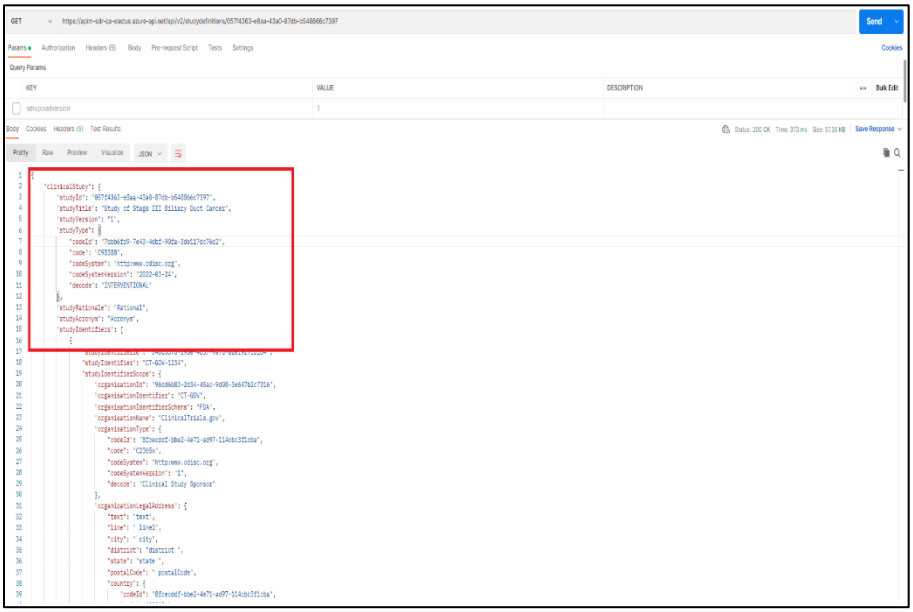
iii. Click on the “Send” button to get the study definition data for given studyId.

Figure 16 Postman Send Request



iv. For a valid certificate and correct SDR API URL, the API Response of HTTP Status code 200 along with the data will be returned.

Figure 17 Postman HTTP Response



Similarly, below response codes returned by SDR APIM 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
- 403 - indicates that the server understands the request but refuses to authorize it
- 404 - indicates that the server cannot find the requested resource
- Incorrect Domain/hostname
- Incorrect Protocol
- Incorrect Method