Study Definition Repository (SDR)

Reference Implementation

SDR API User Guide

Version 3.0

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1. Introduction

1.1. Overview

The API Layer of the SDR Reference Implementation complies with the Open API Specification (OAS) standards 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. REST standards are 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 Study Definition Repository and provides sample Request and Response for each endpoint. 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.

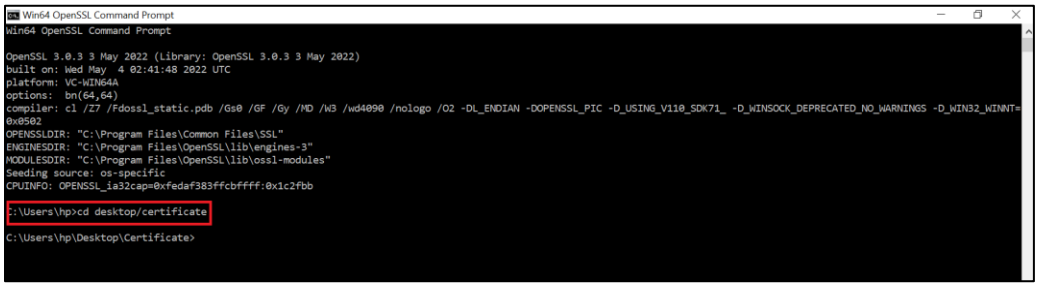
- Open SSL
- PowerShell

2.1.1. Certificate generation with Open SSL

i. Install the Open SSL.

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

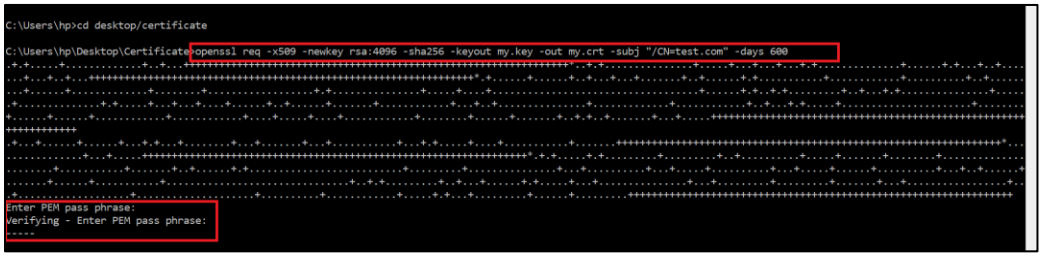
Figure 1 OpenSSL Command Prompt



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

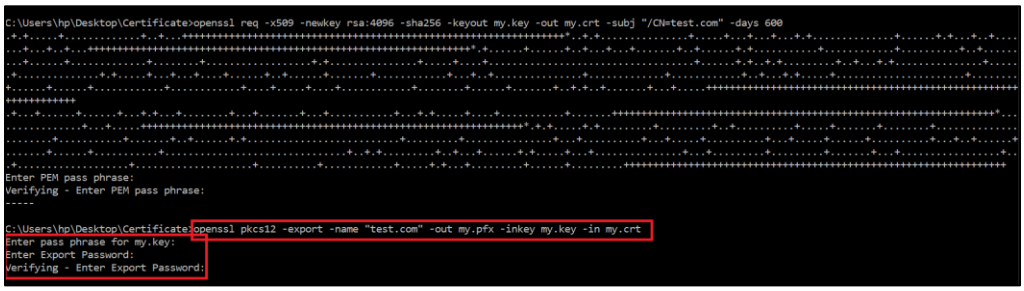
```
openssl pkcs12 -export -name “test.com” -out my.pfx -inkey my.key -in my.crt
```

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 on the folder path provided on step 1

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

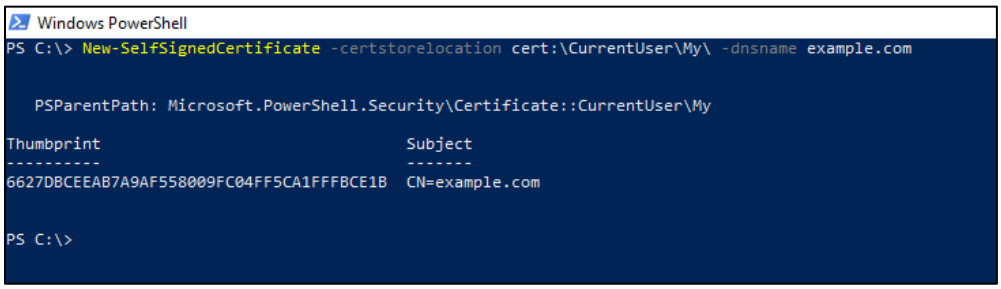
.

2.1.2. Certificate generation with PowerShell

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

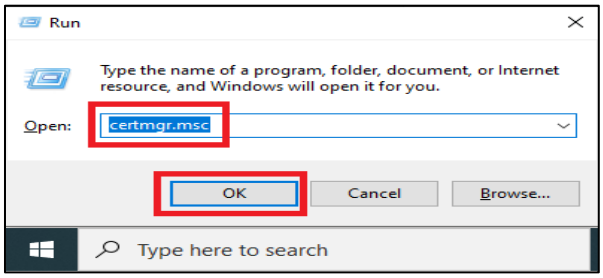
```
New-SelfSignedCertificate -certstorelocation cert:\CurrentUser\My\ -dnsname example.com
```

Figure 4 PowerShell Command



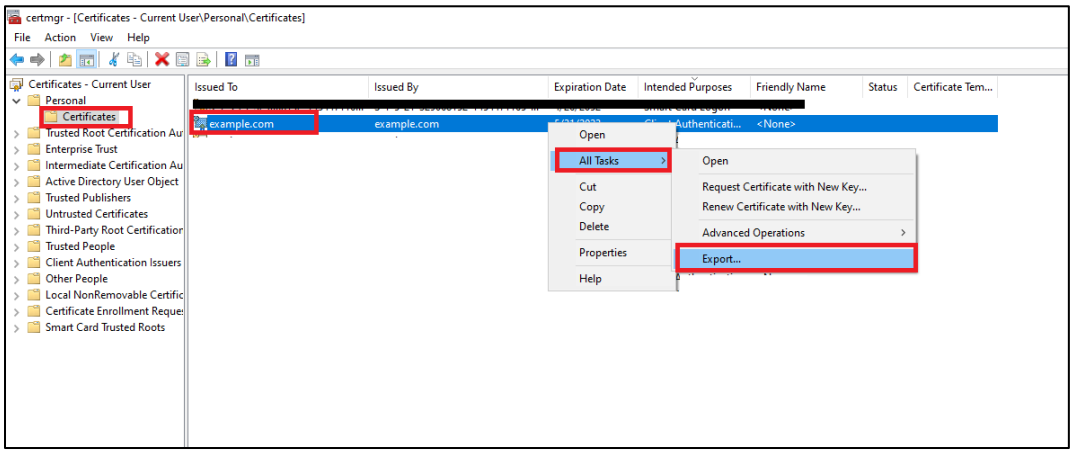
ii. To Export the certificate in .pfx format, go to run → type certmmgr.msc and click ok

Figure 5 Run Window



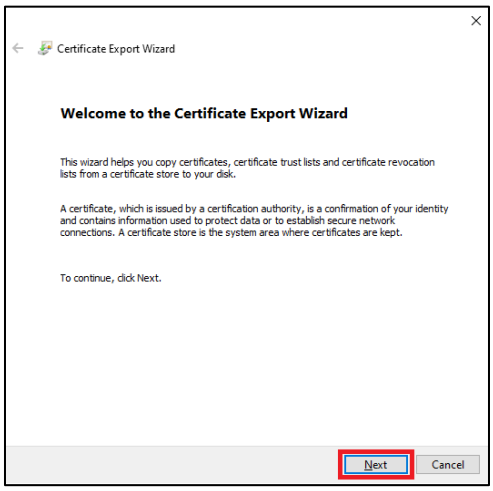
iii. In certificate manager go to personal → certificates → select the generated certificate and right click select All Tasks → Select Export.

Figure 6 Certificate Manager Console



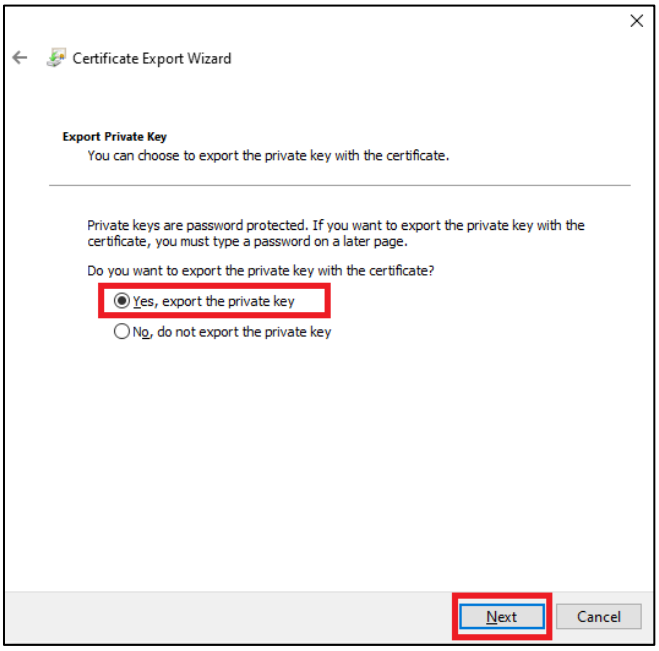
iv. In Certificate Export Wizard click Next to continue.

Figure 7 Certificate Export Wizard



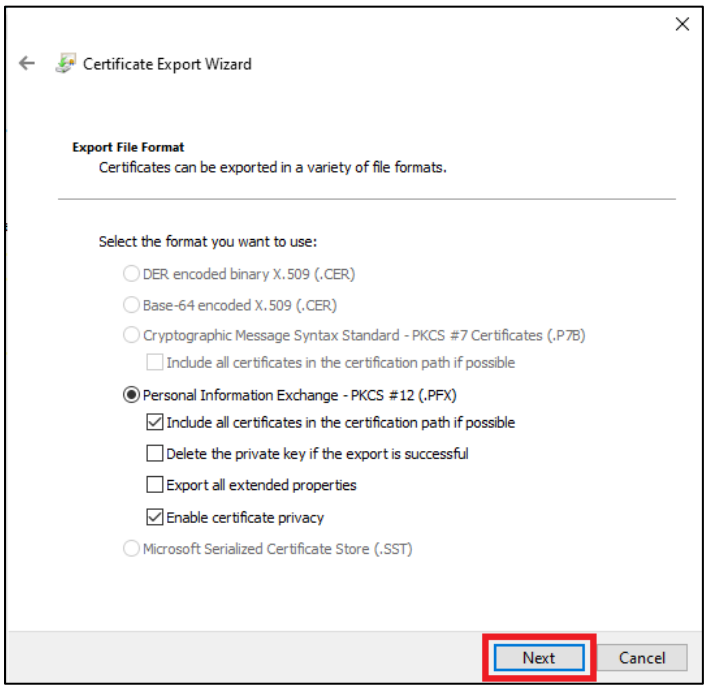
v. Select export the private key option and click next.

Figure 8 Export Private Key



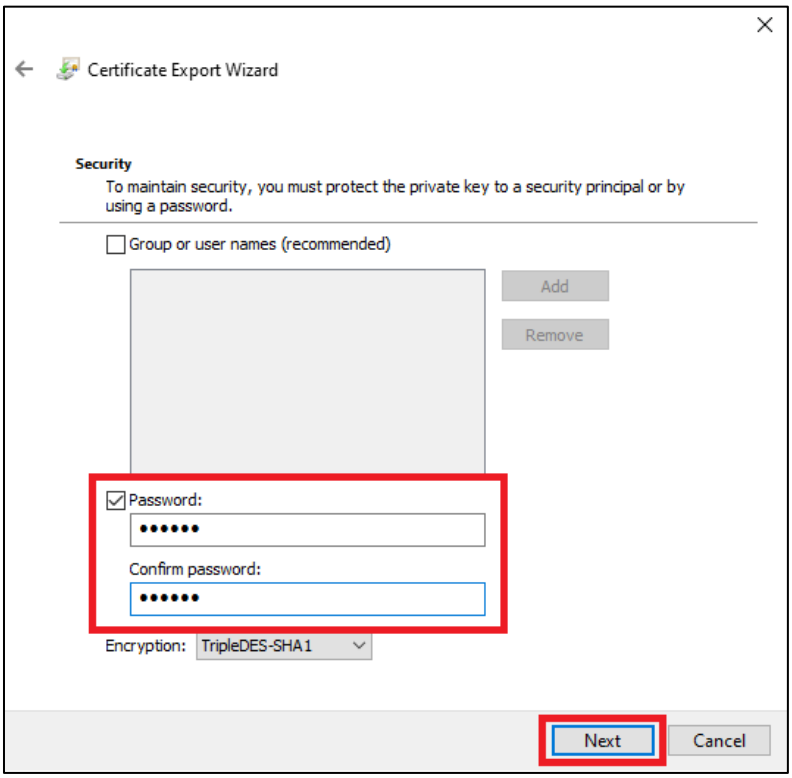
vi. Leave the defaults and click next.

Figure 9 Certificate Format .PFX



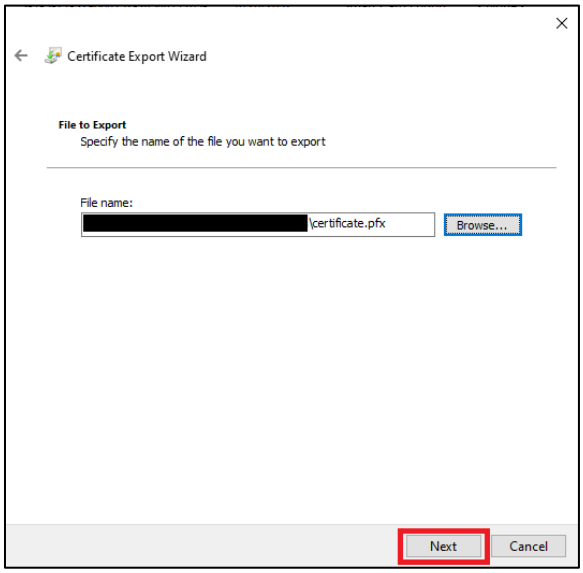
vii. Provide the password for certificate and click next.

Figure 10 Password for Certificate



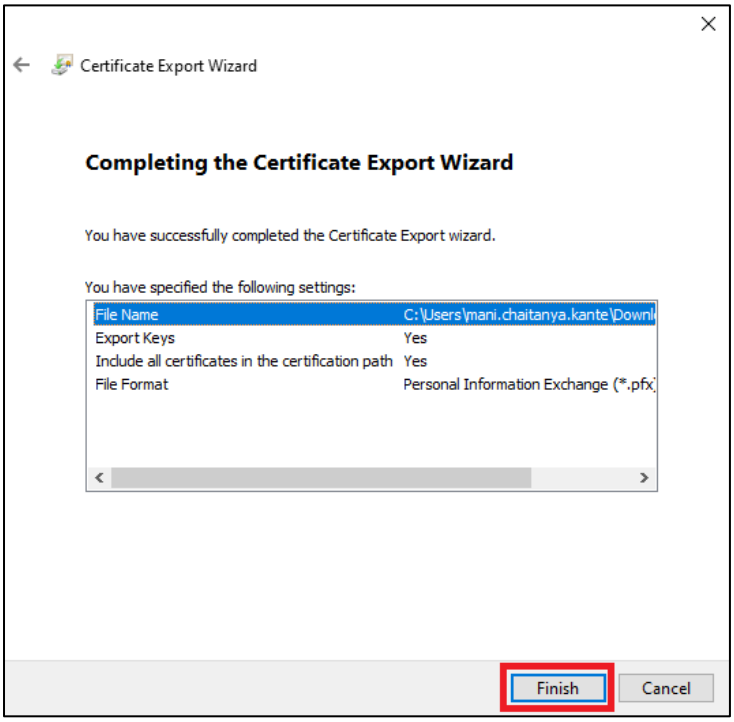
viii. Select the path to save the certificate.

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 7.

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

3. API End Points

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

3.1. Token

This endpoint allows user to get access token to access API's by providing 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/v1/auth/token**

REQUEST PARAMETERS

Table 2 GET Token - Request Parameters

Type	Mandatory	Sample

Body	Yes	{
		"userName": "xxxx@email.com",
		"password": "xxxxx"
		}

RESPONSE

Table 3 GET Token Response

Status Code	Response	Comments

200	{
	"token": "Bearer
	eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBK
	M1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJa
	UXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhd
	WQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0w
	YzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW
	5kb3dzLm5ldC9hMGRkMGFkOC1mNDE5LTQ0ZTItYjVlYy0z
	ZGUwNGUzZDg2ODgvIiwiaWF0IjoxNjU5NzAxNDA3LCJuYm
	YiOjE2NTk3MDE0MDcsImV4cCI6MTY1OTcwNjgwNSwiYWN
	yIjoiMSIsImFpbyI6IkFTUUEyLzhUQUFBQWMrM2ZFQU5YRi
	9pM0ptMmpZV05RRGJCVDloMzFXZndhTU5FY2tzZncvZnM
	9IiwiYW1yIjpbInB3ZCJdLCJhcHBpZCI6ImJkOGJmMzZmLTJ
	hNzMtNDEzNi04NDE5LTBjMjBjZTk0YzViYyIsImFwcGlkYWN
	yIjoiMSIsImVtYWlsIjoidGVzdHVzZXJAYWNwMjAwNTIwYS5v
	bm1pY3Jvc29mdC5jb20iLCJpcGFkZHIiOiI0MC43Ni4xNTIuM
	TAiLCJuYW1lIjoiVGVzdCIsIm9pZCI6IjhhOTFiZTQxLTU2NW
	UtNDZlOC1iMzA3LTUwMTQyNWQyNDg4ZiIsInJoIjoiMC5BV
	VlBMkFyZG9CbjA0a1MxN0QzZ1RqMkdpR196aTcxektqWkJo
	QmtNSU02VXhieEdBS1kuIiwicm9sZXMiOlsib3JnLmFkbWluIl
	0sInNjcCI6InVpLWFjY2VzcyIsInN1YiI6IlZ6WldkM1pMYUdVM
	nlNVVNMRHFjN0RYaU5pZE8"
	}
		Successful

400	{
	"statusCode": "400",
	"message": "An error occurred"
	}
	OR
	{
	"statusCode": "400",
	"message": "Invalid Credentials"
	}
		Application Exception or entered username or password is invalid.

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

3.2. Study History

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

Table 4 GET Study History Endpoint

Method	URL
GET	**/api /v1/ studydefinitions/history**

REQUEST PARAMETERS

Table 5 GET Study History - Request Parameters

Type	Params	Values	Mandatory	Sample
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 6 GET Study History Response Parameters

Status Code	Response	Comments

200	[
	{
	"studyId": "e03a98e1-a267-4f01-b226-fb037f693905",
	"SDRUploadVersion": [
	{
	"uploadVersion": 1,
	"studyTitle": "Study on Oncology",
	"studyVersion": "1",
	"studyIdentifiers": [
	{
	"uuid": "4fac73e1-eb68-48ba-9bc6-b303593bec07",
	"studyIdentifier": "CT-GOV-1234",
	"studyIdentifierScope": {
	"uuid": "35512f0a-ac5f-4404-b6e5-83adc67b6d75",
	"organisationIdentifier": "CT-GOV",
	"organisationIdentifierScheme": "FDA",
	"organisationName": "ClinicalTrials.gov",
	"organisationType": {
	"uuid": "a690f504-eb42-4f30-b4ef-33964ae2c90b",
	"code": "C2365x",
	"codeSystem": "http://www.cdisc.org",
	"codeSystemVersion": "1",
	"decode": "Clinical Study Sponsor"
	}
	}
	}
	],
	"protocolVersions": [
	"1"
	]
	}
	]
	}
	]
		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"
	}
		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

3.3. Get Study

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

Table 7 GET Study Endpoint

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

REQUEST PARAMETERS

Table 8 GET Study Request Parameters

Type	Params	Values	Mandatory	Sample
Path	studyId	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	sdruploadversion	Integer	No	2
Header	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJh

				cGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM

RESPONSE

Table 9 GET Study 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",
	"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. Get Study Design

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

Table 10 GET Study Design Endpoint

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

REQUEST PARAMETERS

Table 11 GET Study Design Request Parameters

Type	Params	Values	Mandatory	Sample
query	study_uuid	String	Yes	25f58eb5-bda8-4c85-8a27-685af9f6743d
Query Parameter	sdruploadversion	Integer	No	3
Header	Authorization	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM	

RESPONSE

Table 12 GET Study Design Response

Status	Response	Comments
200	Refer **Response for GET Study DesignV1** for the JSON Data	Successful
400	{ "statusCode": "400",	Application Exception

	"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"
	}
	
	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

3.5. Audit Trail

This endpoint allows user to retrieve the audit trail information for a study residing in SDR Repository. Audit trail captures the history of all changes done on a study definition including entry date time and SDR upload version.

Table 13 GET Audit Trail Endpoint

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

REQUEST PARAMETERS

Table 14 GET Audit Trail Request Parameters

Type	Params	Values	Mandatory	Sample
Path	studyId	String	Yes	af999877-1c32-4aa8-beb6-c43779a5d759

Query Parameter	FromDate	Date	No	2022-Mar-05
Query Parameter	ToDate	Date	No	2022-Mar-15
Header	Authorizatio	String	Yes	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM	

RESPONSE

Table 15 GET Audit Trail Response

Status	Response	Comments

200	{
	"uuid": "25f58eb5-bda8-4c85-8a27-685af9f6743d",
	"auditTrail": [
	{
	"entryDateTime": "2022-03-12T11:07:11.871Z",
	"SDRUploadVersion": 3
	},
	{
	"entryDateTime": "2022-03-10T12:04:12.421Z ",
	"SDRUploadVersion": 2
	},
	{
	"entryDateTime": "2022-03-09T07:06:34.171Z ",
	"SDRUploadVersion": 1
	}
	]
	}
		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"
	}
		Requested Study Id is not found, or the request URL path is not valid

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

3.6. Post Study

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.

3.6.1. 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 16 POST Study Endpoint

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

REQUEST PARAMETERS

Table 17 POST Study Request Parameters

Type	Param	Values
Body		Refer **Request Body for POST – Add New Study DefinitionV1** for the JSON Data

Header	Authorization	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM

RESPONSE

Table 18 POST Study Response

Status	Response	Comments
201	Refer **Response Body for POST – Add Study DefinitionV1** 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

3.6.2. 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 19 POST Study Endpoint

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

REQUEST PARAMETERS

Table 20 POST Study Request Parameters

Type	Param	Values
Body		Refer **Request Body for POST – Update New Study DefinitionV1** for the JSON Data
Header	Authorization	Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSIsImtpZCI6IjJaUXBKM1VwYmpBWVhZR2FYRUpsOGxWMFRPSSJ9.eyJhdWQiOiJhcGk6Ly9iZDhiZjM2Zi0yYTczLTQxMzYtODQxOS0wYzIwY2U5NGM1YmMiLCJpc3MiOiJodHRwczovL3N0cy53aW5kb3dzLm5ldC9hM

RESPONSE

Table 21 POST Study Response

Status	Response	Comments
201	Refer **Response Body for POST – Update Study DefinitionV1** 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

4. Testing the API Endpoint

4.1. Postman REST client Setup

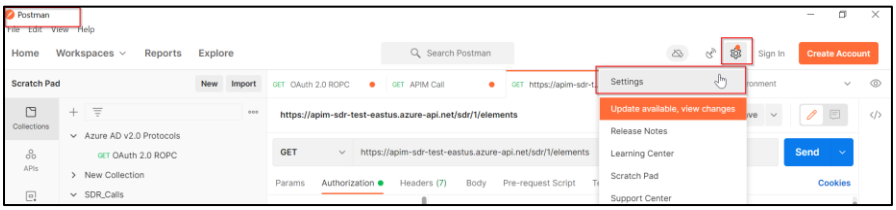
Pre-Requisites:

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

STEPS:

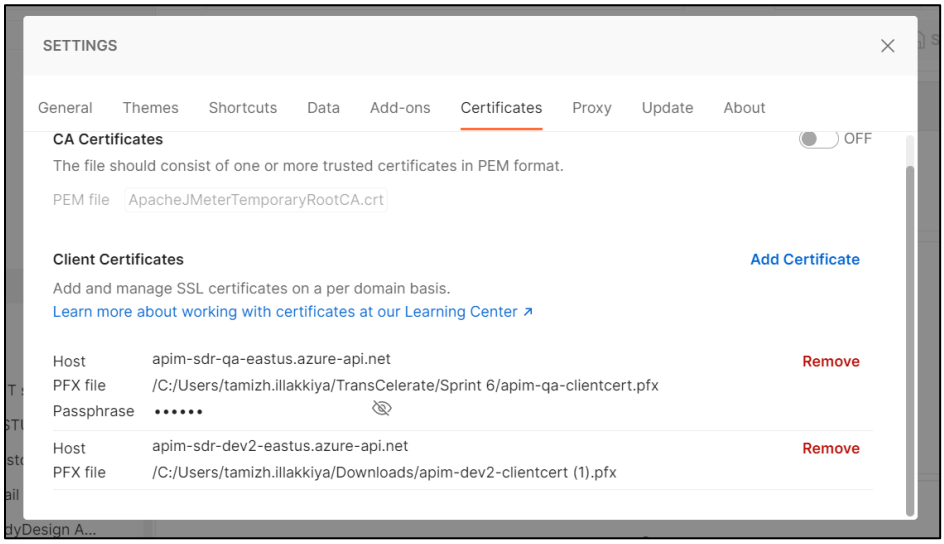
i. Open postman and go to “Settings” option

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

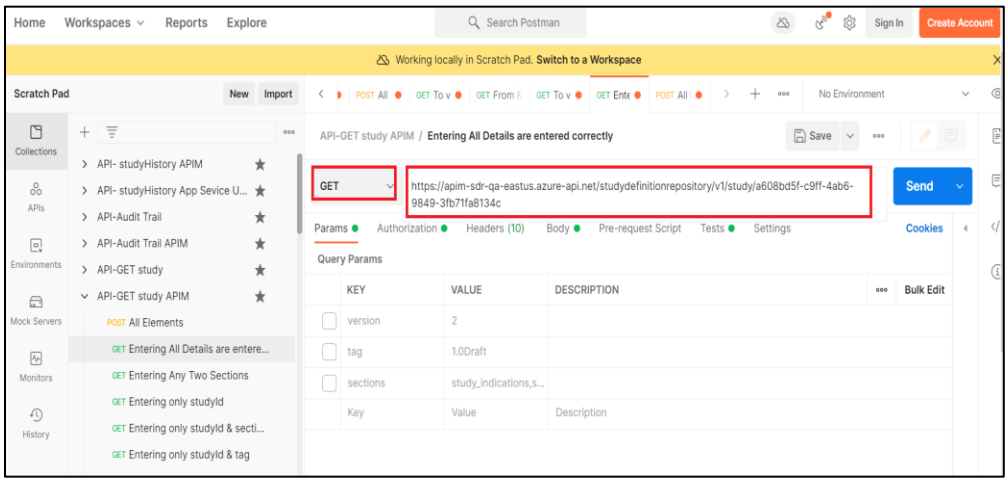
STEPS:

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

https://apim-sdr-*envname*-eastus.azure-api.net/studydefinitionrepository/v1/study/

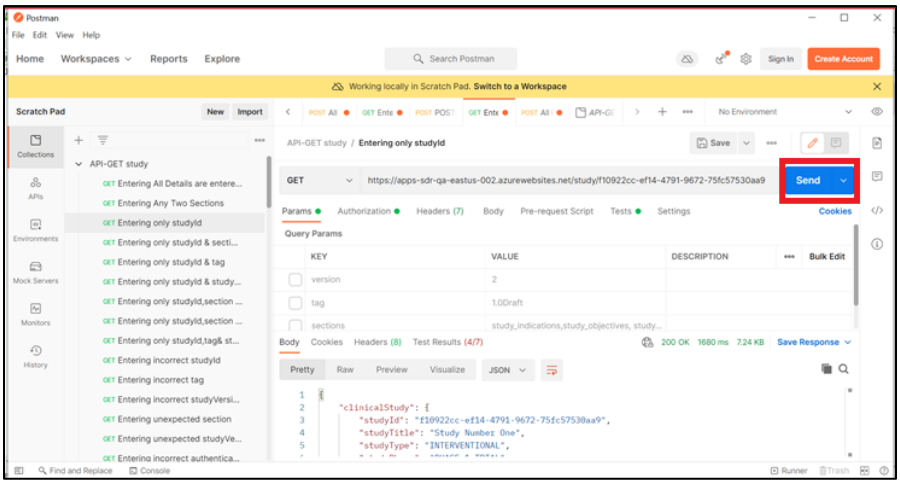
ii. Get the clinical study **StudyId** from **Response for GET Study** and append the Study ID to the GET URL.

Figure 15 Postman set HTTP Request for GET



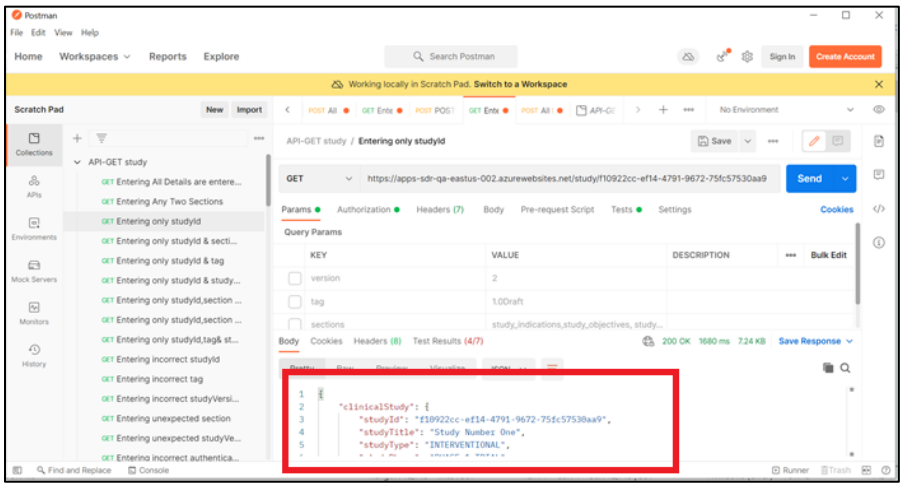
iii. Click on the “Send” button to get the study definition data for given studyId.

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 tested in postman. These scenarios can be tested in any of the REST API tools other than Postman.

- 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