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Yes, you can access the CDISC Library from SAS!

Angelo Tinazzi, Ctyel Inc.

ABSTRACT

With the availability of the CDISC Library, vendors can now develop software from which you can instantly access standards i.e., CDISC Controlled Terminology. This is also true for users working with traditional software such as SAS.

In SAS, the CDISC Library can be queried through the CDISC API using PROC HTTP; its code is simple, and you can easily “interpret answers” e.g., json or xml.

The main purpose of this presentation is to provide my first “impressions” on the use of CDISC Library especially from the SAS user perspective. I will first discuss requirements to access the CDISC Library and the two different methods to access it, “Data Standards Browser” vs “API queries”. I will then focus on the API use from SAS and the main “request” you can make. The Current limitations of the CDISC library will be also discussed.

INTRODUCTION

I started to think about this topic during last Christmas holiday and because we couldn't go anywhere I started to play with the CDISC Library from SAS to see how we could make use of it at Cytel, as although we are currently assessing alternative solutions or application and also developing internally some tools for more or less if not automatizing at least semi-automatize some of the process, the reality is that today especially for ADaM most if not all the programming is done in SAS and many metadata are handled using some sort of central SAS datasets repository we regularly update.

There have been several presentations already in the past events on how to access the library and how to make use of the CDISC Library API (Reference nr 1,2,3,4); also, some code snippets/examples, including SAS, are available on the CDISC Library webpage (<https://wiki.cdisc.org/display/LIBSUPRT/Getting+Started%3A+Programmatically+connect+to+CDISC+Library+API>). However, I thought that could be beneficial to provide more examples and to clarify a couple of technical concepts, a sort CDISC Library for dummies explained by a CDISC Library dummy.

HOW TO ACCESS THE CDISC LIBRARY

THE CDISC LIBRARY IN A NUTSHELL

The CDISC Library is a metadata repository, the official CDISC metadata repository.

From the library we can extract the metadata in various formats, including our loved excel:

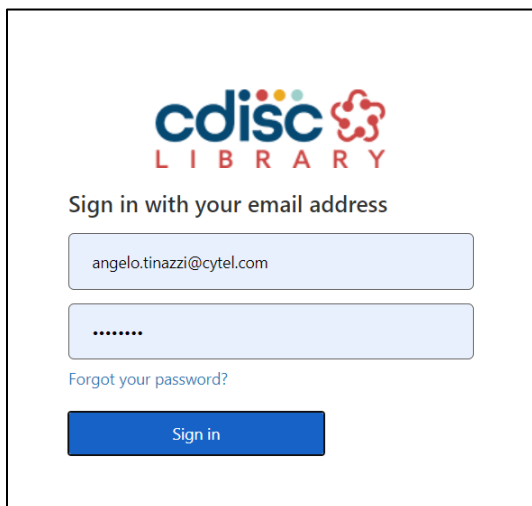
- .xlsx
- .csv
- .xml
- .json

The CDISC Library is structured, meaning that his format is predictable, whatever export format you chose.

Access to the library is available to CDISC Members and Open Source Dev only. Two accesses are possible:

- Data Standards Browser (<https://library.cdisc.org>)
- Querying through an API

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The image shows a sign-in page for the CDISC Library. At the top is the CDISC LIBRARY logo, with 'cdisc' in blue and 'LIBRARY' in red. Below the logo is the text 'Sign in with your email address'. There are two input fields: the first contains the email address 'angelo.tinazzi@cytel.com' and the second is a password field with dots. Below the password field is a link that says 'Forgot your password?'. At the bottom is a blue button labeled 'Sign in'.

Figure 1. Accessing the CDISC Data Standards Browser

DATA STANDARDS BROWSER VS API ACCESS

The following CDISC standards resources are currently available:

- CDASH
- SEND
- SDTM
- ADAM
- CDISC Controlled Terminology
- Draft Standards for testing purpose

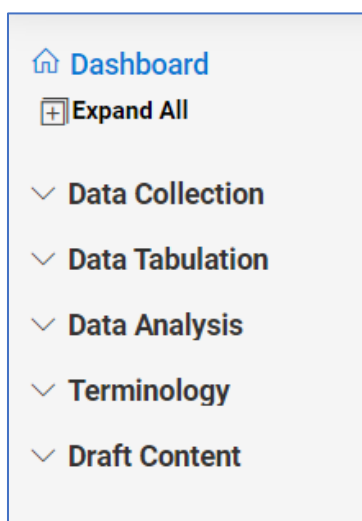


Figure 2. Browsing CDISC Standards Metadata

The Data Standards Browser

When you access the data standards library you have access to a dashboard where you can access several supportive resources (figure 3).

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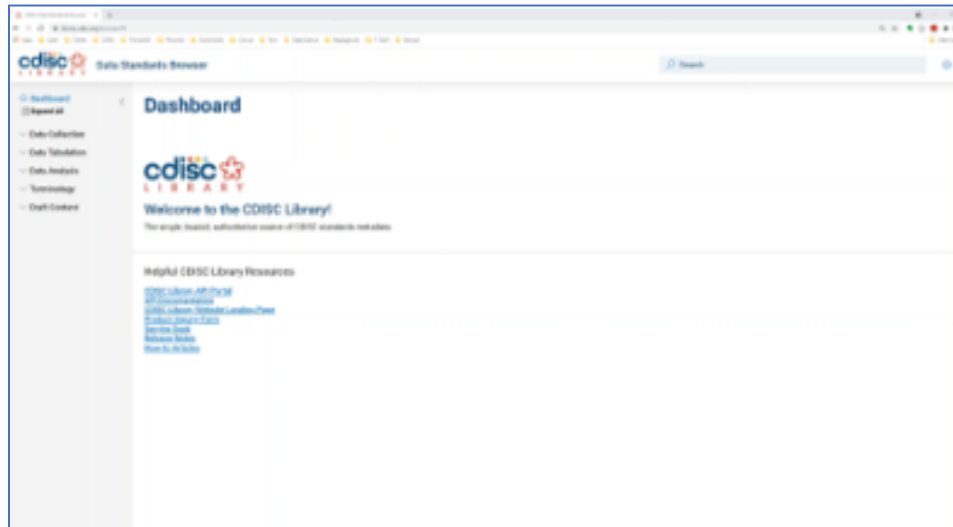


Figure 3. CDISC Library Dashboard

From there you can then interactively browse any version of any available standards. For example, for SDTM you can access all available standards and Implementation Guidance (IG), but also additional guidance such as the SDTM guidance for Medical Device.

Once you click the standard you want to browse, for example the latest SDTM IG, you will see the SDTM classes from which you can access the applicable standard SDTM domains. For example, if we select the Interventions class we can see all standard domains belonging to that class; we can for example browse the content of the EX/Exposure dataset then, still interactively, look at the details of each variable (figure 4), and if a variable has also associated a standard CDISC codelist, we can also look at the applicable codelist standard terms (figure 5), and from the same we can export the full content of the selected standard into either excel or csv format.

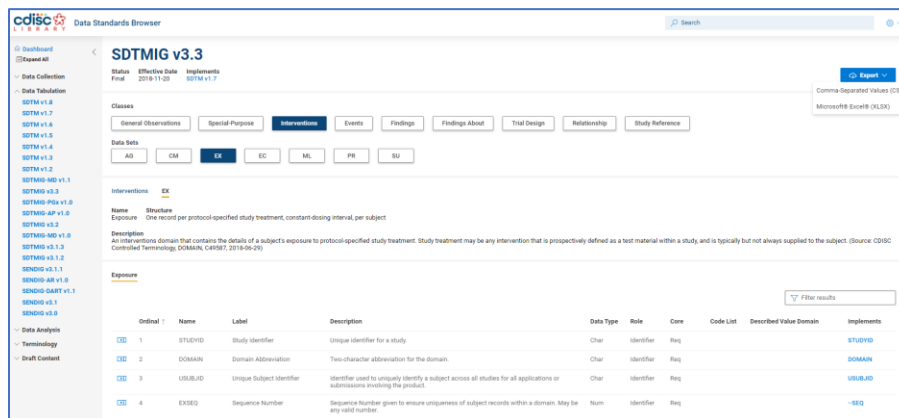


Figure 4. Browsing the SDTM IG 3.3

So with the CDISC Library Data Standards Browser it is not necessary anymore to look into the CDISC PDF documents except for the "assumptions" and the implementation examples for which you still need to look into the IG, as of now at least.

The other method for accessing the CDISC Library is through the API, but before entering onto this topic, I need to clarify a couple of technical aspects and terms.

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14	EXDOSTXT	Dose Description	Amount of EXTRT when non-numeric. Dosing amounts or a range of dosing information collected in text form. Example: 200-400. Not populated when EXDOSE is populated.	Char	Record Qualifier	Perm		-DOSTXT
15	EXDOSU	Dose Units	Units for EXDOSE, EXDOSTOT, or EXDOSTXT representing protocol-specified values. Examples: "mg", "mg", "mg/kg", "mg/m2".	Char	Variable Qualifier	Exp	C71620	-DOSU
16	EXDOSFRM	Dose Form	Dose form for EXTRT. Examples: "TABLET", "LOTION".	Char	Variable Qualifier	Exp	C66726	-DOSFRM
17	EXDOSFRQ	Dosing Frequency per interval	Usually expressed as the number of repeated administrations of EXDOSE within a specific time period. Examples: "Q2H", "QD", "BID".	Char	Variable Qualifier	Perm	C71113	-DOSFRQ

Controlled Terminology Package Effective 2021-03-26

Package: CDASH CT 2021-03-26 | Define XML CT 2021-03-26 | Protocol CT 2021-03-26 | **IGTM CT 2021-03-26** | SEND CT 2021-03-26

← C66726

Extensible: Yes
 Submission Value: FNU
 Definition: The form of the completed pharmaceutical product, e.g. tablet, capsule, injection, elixir, suppository. Dosage form can have a significant effect on the onset, duration and intensity of the pharmacological action of a drug. A pharmaceutical dosage form controls the rate at which the drug is released into the biological fluids.
 NCI Preferred Term: CDISC IGTM Pharmaceutical Dosage Form Terminology
 Synonyms: Pharmaceutical Dosage Form

Term	Submission Value	Synonyms	Definition	NCI Preferred Term
C4287	AEROSOL	aer	A product that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system. It is intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (oral aerosols), or lungs (inhalation aerosols).	Aerosol Dosage Form
C4288	AEROSOL_FOAM		A dosage form containing one or more active ingredients, surfactants, aqueous or non-aqueous liquids, and the propellant. If the propellant is in the internal (closed) phase (i.e., of the water-in-oil type), a stable foam is discharged, and if the propellant is in the external (continuous) phase (i.e., of the water-in-oil type), a spray or a quick-breaking foam is discharged.	Aerosol Foam Dosage Form
C4290	AEROSOL_METERED		A pressurized dosage form consisting of metered dose valves which allow for the delivery of a uniform quantity of spray upon each activation. (DC)	Metered Aerosol Dosage Form

Figure 5. Applicable CDISC terminologies

API, REST and JSON

Let me try to explain what those API, REST and JSON are about also giving the fact they are mentioned in the CDISC Library documentation (<https://www.cdisc.org/cdisc-library/api-documentation>).

CDISC Library API Documentation

The CDISC Library API is REST-based and by default returns JSON content. The CDISC Library API documentation below describes how to request each API endpoint and what to expect as a response.

INTRO TO API AND REST

API stands for “Application Programming Interfaces” and it allows your “product” (app) or “service” to talk to another product or service. API are often used to give people access to data that the owner of the data decides to make accessible, either freely or with a payment. For example, many financial web sites give access to their users through API from which the user can write their own programs to for example access historical stocks data.

The Library Browser makes use of API in background, the CDISC Library API. This is for the user hidden and, as we saw before, when we browse the library through the Data Standards Browser a request is made to the CDISC Library server, the server elaborate the request and it returns to your internet browser the result in a readable format, but the real format it is something else (figure 6).

The CDISC Data Standards Browser makes use of the CDISC Library API. So, with the CDISC Library API, CDISC allows your application to access the CDISC metadata.

REST is the most popular API standard for web application, and it is made of two main statuses or methods for accessing the application (the user request for example) and the response with some data returned to the requestor.

The request is composed of four main elements:

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- the Address, or the so called endpoint, where the address make uses of the URL format, so the way we already use to write web pages address when we want to access an internet resource through our internet browser
- an Header, where we supply additional instructions to the server, so to the API
- a Method, the type of action we want the server to do for us. For the time being only the GET method is available with the CDISC Library, meaning that we can only query the CDISC Library
- Data, this is only applicable for other methods I'm not covering here e.g. POST and PUT

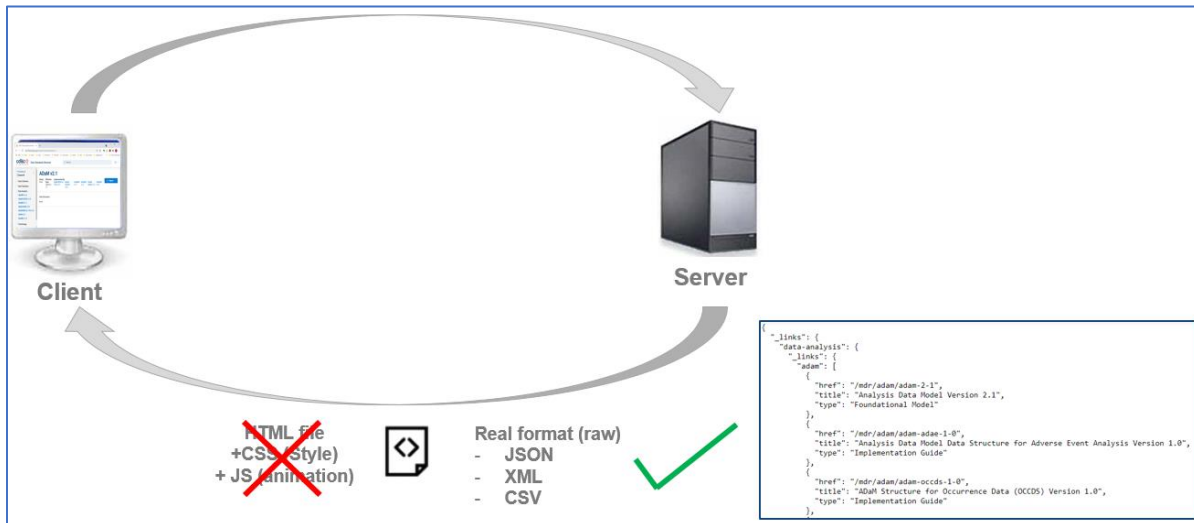


Figure 6. Interacting with the API

With the GET method you get a response, a file that can be based on different formats such as xml, json, but also csv and excel; the response has the following elements:

- a Header
- the Data we requested, so in the case of the CDISC Library it could be the content of a recent released CDISC CT
- the Status, whether the request was correct and the resource requested available on the server, or if the server was not available
- default Format for the CDISC API Library is JSON

JSON FORMAT

JSON stands for JavaScript Object Notation. If you are already familiar with the XML format, JSON is comparable to xml. Among its characteristics, the size of the JSON file is more compressed compared to xml. For example, if we query the CDIC Library to get the SDTM CT from last December the JSON file will be around 9 MB while the same in xml format is around 11MB (figure 7).

QUERYING THE CDISC LIBRARY FROM SAS

So, SAS is our client from which we want to access the CDISC Library, so being the CDISC library the server (figure 8). The SAS PROC HTTP it is the way to query an API from SAS, by sending a request to the API, in our case the CDISC Library API at the CDISC Library address (<https://library.cdisc.org/api>), and we want to get the answer in JSON format. The request is then interpreted by the server and a response is sent back to the SAS client in the format requested; of course we need to interpret the JSON

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format that is not native to SAS and we can do that in SAS by using for example the JSON libname engine.


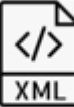
 9,664 KB	 11,489 KB
<pre>{ "_links": { "priorVersion": { "href": "/mdr/ct/packages/sdtmct-2020-11-06", "title": "SDTM Controlled Terminology Package 43 Effective 2020-11-06", "type": "Terminology" }, "self": { "href": "/mdr/ct/packages/sdtmct-2020-12-18", "title": "SDTM Controlled Terminology Package 44 Effective 2020-12-18", "type": "Terminology" } } }</pre>	<pre><?xml version="1.0" encoding="utf-8"?> <cdiscLibrary> <package> <name>SDTM CT 2020-12-18</name> <label>SDTM Controlled Terminology Package 44 Effective 2020-12-18</label> <description>CDISC Controlled Terminology for SDTM is the set... </description> ... <_links><self><href>/mdr/ct/packages/sdtmct-2020-12-18</href></pre>

Figure 7. JSON vs XML

The query in the example in figure 8, returns the full list of products, standards, available in the CDISC Library. We can see that one of the product is the ADaM Standard version 2.1 and by using its address with the SAS proc HTTP we can access and get the metadata from the standard (figure 9).

Thus, in this model we can say that through the proc http we make a request to the librarian, our CDISC Librarian, the librarian makes the search and it returns to us the requested resource and through the proper SAS libname engine, in this case JSON, we can try to interpret the answer and make use of it.

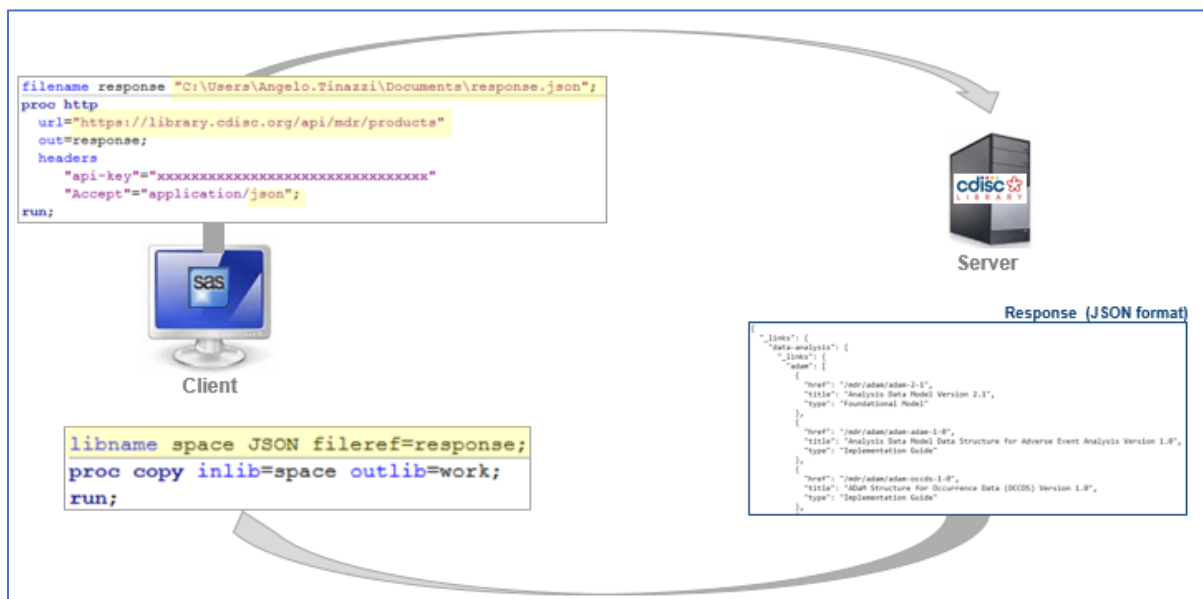


Figure 8. Querying the CDISC Library from SAS

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VIEWTABLE: Work.Allproducts								
	P	P1	P2	P3	P4	P5	V	Value
1		1_links						0
2		2_links	data-analysis					0
3		3_links	data-analysis	_links				0
4		4_links	data-analysis	_links	adam			0
5		5_links	data-analysis	_links	adam	href	1	/mdr/adam/adam-2-1
6		5_links	data-analysis	_links	adam	title	1	Analysis Data Model Version 2.1
7		5_links	data-analysis	_links	adam	type	1	Foundational Model
8		4_links	data-analysis	_links	adam			0
9		5_links	data-analysis	_links	adam	href	1	/mdr/adam/adam-adae-1-0
10		5_links	data-analysis	_links	adam	title	1	Analysis Data Model Data Structure for Adverse Event Analysis Version 1.0
11		5_links	data-analysis	_links	adam	type	1	Implementation Guide
12		4_links	data-analysis	_links	adam			0

Figure 9. Getting full list of CDISC standards available in the CDISC Library

ANATOMY OF A PROC HTTP CDISC LIBRARY QUERY

Let's decompose now the PROC HTTP syntax.

The main part is the full address of the resource we need to access, that is made of the CDISC Library URL

`https://library.cdisc.org/api/`

followed by the endpoint so the exact resource we need to get

`mdr/products`

The full set of endpoints, so requests we can make to the CDISC Library API, is available at the following address: <https://api.developer.library.cdisc.org/>, or it can be obtained with the `mdr/products` endpoint we saw in the earlier example (figure 10).

```
proc http
  url="https://library.cdisc.org/api/mdr/products"
```

<https://api.developer.library.cdisc.org/>

Full URL

CDISC Library Address
`https://library.cdisc.org/api/`

Endpoint
`mdr/products`

Ask for full list of CDISC "products" availability

Figure 10. CDISC Library Endpoints

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CHECKING THE RESPONSE FROM PROC HTTP QUERY

The response when returned will be saved in the file indicated in the OUT command so in our example in figure 11 the file will be simply named response.json and saved in my personal user area.

The header will have the authentication key I will have meanwhile obtained (generated) through my API developer CDISC library account (<https://api.developer.library.cdisc.org>); of note, in all the examples shown here the real key is masked.

The image shows a SAS PROC HTTP query and a screenshot of the CDISC Library API account page. The query is as follows:

```
proc http
  url="https://library.cdisc.org/api/mdr/products"
  out=response;
  headers
    "api-key"="XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX"
```

Labels in the image: "Full URL" points to the URL, "Response File" points to the out= command, and "Authentication" points to the api-key header.

The screenshot shows the "Account and API Key" page for Angelo Tinazzi. It includes account details (Email: angelo.tinazzi@cytel.com, Last name: Tinazzi, Registration date: 11/02/2020) and a table of subscriptions.

Subscription details	Product	State	Action
Name: Default subscription to CDISC Library API	CDISC Library API	Active	Cancel
Primary key: XX	Show Regenerate		
Secondary key: XX	Show Regenerate		

Figure 11. Anatomy of a PROC HTTP CDISC Library Query

After a while, hopefully a little while, we get the response back. The first thing we need to check is if our request was valid and therefore if the CDISC Library API was able to handle our request. This can be checked with the automatic macro variable `&SYS_PROCHTTP_STATUS_CODE`. For the CDISC Library API all the responses when correctly executed returns the code 200 so, because I did a little typo in my request, SAS returned an error code, or better the CDISC Library returned an error code (figure 12). The status code of each CDIC Library API can be consulted at the web site earlier mentioned.

The image shows SAS PROC HTTP code and its output. The code is as follows:

```
filename response "C:\Users\Angelo.Tinazzi\Documents\AllPROD.json";
proc http
  url="https://library.cdisc.org/api/mdr/product"
  out=response;
  headers
    "api-key"="XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX"
    "Accept"="application/json";
run;
%if &SYS_PROCHTTP_STATUS_CODE ne 200 %then %do;
  %put ERROR: Resource not found: &SYS_PROCHTTP_STATUS_PHRASE (&SYS_PROCHTTP_STATUS_CODE) ;
%end;
```

The output shows a "Response: 200 OK" message and a screenshot of the CDISC Library API product page. The product page shows a table with columns: Name, Required, Type, Description. The product name is "jms" and the type is "products".

Figure 12. Checking the response status

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INTERPRETING THE QUERY ANSWER –THE JSON ENGINE

Now, as I previously said, if we get a successful response, our returned file will have our request, in our case the info we need from the CDISC Standards, in our example a JSON file. We can then use some parsing techniques to interpret the JSON file or we can make use of the JSON SAS Libname engine. What the engine does for you is to try to “guess”, or interpret, the structure of your JSON file and organize the information into several datasets. The number and type of datasets depend on the type of request we made, as you can see with the list and number of datasets (figure 13) returned by this other request where we asked for the SDTM IG 3.3 metadata for DM domain.



Figure 13. Capturing JSON response

WHAT USE OF THE CDISC LIBRARY WE CAN MAKE OF IN SAS

So now that we know how to query the CDISC library from SAS, how much do you think it would be an added value for the SAS programmers to query and get use of the CDISC Library API from SAS? Well in my opinion accessing the library from SAS can be very useful to regularly check with some sort of automatic scheduled SAS programs if there is any update e.g. a new CDISC CT instead of regularly checking the CDISC website for any update or setting a quarterly reminder for example for the CDISC CT, and based on the fact that there is an update, we can automatically update our local tables, SAS datasets, where our organization stores CDISC metadata used for example by our SAS programmers when they do write code to either migrate legacy datasets to SDTM or when they create ADaM datasets. For this reason, because the way CDISC standards are handled nowadays by SAS programmers, there is not a big need of querying the library interactively from for example SDTM mapping programs. I do also think, when available, getting responses in excel format (**application/vnd.ms-excel**) rather than JSON or XML, would be easier as the structure of the excel file is already in a tabular format, so very closed to how SAS organize data, although the JSON and XML formats have the advantage of having other metadata not available in excel such as the link to earlier versions.

If we look for example at the full *Media Type Support Matrix* at <https://wiki.cdisc.org/display/LIBSUPRT/Media+Type+Support+Matrix>, for the main guidance / standards we can easily get the excel file of for example one of the latest CDISC-CT or the last SDTM IG version 3.3, while instead if we want to get only a partial set of metadata, such as only the DM domain metadata, these are only available in either XML or JSON format.

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CONCLUSIONS

From this first experience using the CDISC Library I can say that, while the Browser is a useful tool to interactively query the standards, as a SAS Statistical Programmer the API offers limited advantages. In general company doing the SDTM mapping directly in SAS, have metadata already organized somehow i.e., SAS datasets, so for this type of applications the library is only needed to regularly check for update and eventually automatically update sponsor / CRO metadata without going onto the CDISC website and check for any update and get the excel version of the metadata and import it.

There are number of aspects that I think can be improved, such as repeating mistakes in the IG, or the ability of more granular queries i.e. extracting all SDTM DM variables description, while the ability of comparing between versions i.e., diff file, as per last CDISC webinar, it seems this will be made soon available. Also, as per the recent CDISC webinar (*CDISC Webinar April 8th "CDISC Library: Ideas for using the CDISC Library and a Look at What's Coming Next"*, A. Chow and S. Hume), there is a plan to make available additional content such as TAUGs and conformance rules and many other:

- ODM Media Type
- Implementation Guidance
- Conformance Rules
- Initial CDISC 360 Content (Draft)
- Diff Functionalities
- More Content to come

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