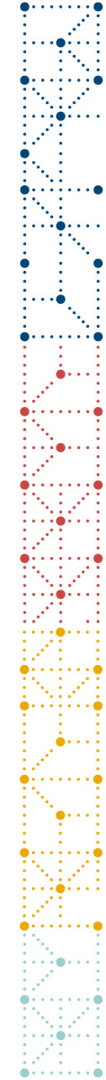


How Will You Use CDISC Library?

Sally Cassells

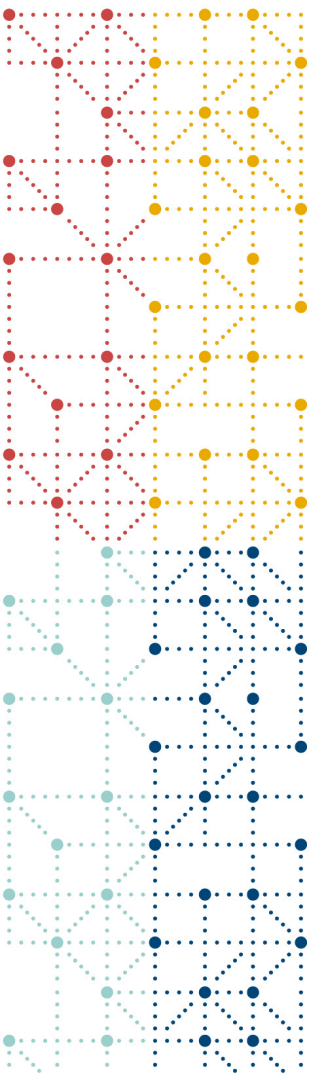
PhUSE EU Connect 13 November 2019





Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC.*
- *The author is a member of the Data Sciences staff at CDISC. She is the curator for the ADaM standards content.*



Agenda

Getting started

Using the API

What's next?

Data Collection

CDASH Model v...

CDASHIG v1.1

CDASHIG v2.0

Data Tabulation

SDTM v1.2

SDTM v1.3

SDTM v1.4

SDTM v1.5

SDTM v1.6

SDTM v1.7

SDTMIG v3.1.2

SDTMIG v3.1.3

SDTMIG v3.2

SDTMIG v3.3

SDTMIG-AP v1.0

SDTMIG-MD v1.0

SDTMIG-MD v1.1

SDTMIG-PGx v1...

SENDIG 3.0

SENDIG v3.1

SENDIG-DART v...

Data Analysis

ADaM ADAE v1.0

ADaM BDS for ...

ADaM OCCDS v...

ADaM v2.1

ADaMIG v1.0

ADaMIG v1.1

Controlled Terminology

CT 2014 Q3

CT 2014 Q4

CT 2015 Q1

CT 2015 Q2

CT 2015 Q3

CT 2015 Q4

CT 2016 Q1

CT 2016 Q2

CT 2016 Q3

CT 2016 Q4

CT 2017 Q1

CT 2017 Q2

CT 2017 Q3

CT 2017 Q4

CT 2018 Q1

CT 2018 Q2

CT 2018 Q3

CT 2018 Q4

CT 2019 Q1

CT 2019 Q2

SDTMIG v3.1.2

SDTMIG v3.1.3

SDTMIG v3.2

SDTMIG v3.3

SDTMIG-AP v1.0

SDTMIG-MD v1.0

SDTMIG-MD v1.1

SDTMIG-PGx v1...

Product: SDTMIG v3.3

Status: Final

Effective Date: 2018-11-20

Implements: **SDTM v1.7**

Classes:

General Observations

Special-Purpose

Interventions

Events

Findings

Findings About

Trial Design

Relationship

Study Reference

Data Sets:

DA

DD

EG

IE

IS

LB

MB

MS

MI

MO

CV

MK

NV

OE

RP

RE

UR

PC

PP

PE

QS

RS

SC

SS

TU

TR

VS

Findings **LB**

Name: Laboratory Test Results

Description: A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains. (Source: CDISC Controlled Terminology, DOMAIN, C49592, 2018-06-29)

Structure: One record per lab test per time point per visit per subject

Dataset Version: 3.3

Laboratory Test Results

Exp|

×

Exp|

✕ ≡

↑ Ordinal	Name	Label	Description	Data Type	Role	Core	Code List	Described Value Domain	Implements
7	LBSPID	Sponsor-Defined Identifier	Sponsor-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on the Lab page.	Char	Identifier	Perm			--SPID
10	LBCAT	Category for Lab Test	Used to define a category of related records across subjects. Examples: "HEMATOLOGY", "URINALYSIS", "CHEMISTRY".	Char	Grouping Qualifier	Exp			--CAT
12	LBORRES	Result or Finding in Original Units	Result of the measurement or finding as originally received or collected.	Char	Result Qualifier	Exp			--ORRES
13	LBORRESU	Original Units	Original units in which the data were collected. The unit for LBORRES. Example: "g/L".	Char	Variable Qualifier	Exp	C71620		--ORRESU
14	LBORNRO	Reference Range Lower Limit in Orig Unit	Lower end of reference range for continuous measurement in original units. Should be populated only for continuous results.	Char	Variable Qualifier	Exp			--ORNRO
15	LBORNRI	Reference Range Upper Limit in Orig Unit	Upper end of reference range for continuous measurement in original units. Should be populated only for continuous results.	Char	Variable Qualifier	Exp			--ORNRI
16	LBSTRESC	Character Result/Finding in Std Format	Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in LBSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in LBORRES and these results effectively have the same meaning, they could be represented in standard format in LBSTRESC as "NEGATIVE". For other examples, see general assumptions.	Char	Result Qualifier	Exp	C102580		--STRESC
17	LBSTRESN	Numeric Result/Finding in Standard Units	Used for continuous or numeric results or findings in standard format; copied in numeric format from LBSTRESC. LBSTRESN should store all numeric test results or findings.	Num	Result Qualifier	Exp			--STRESN
18	LBSTRESU	Standard Units	Standardized unit used for LBSTRESC or LBSTRESN.	Char	Variable Qualifier	Exp	C71620		--STRESU
19	LBSTNRLO	Reference Range Lower Limit-Std Units	Lower end of reference range for continuous measurements for LBSTRESC/LBSTRESN in standardized units. Should be populated only for continuous results.	Num	Variable Qualifier	Exp			--STNRLO

The content of this workbook represents the normative metadata found in the applicable SDTM or SEND Implementation Guide. A brief description of the columns in the workbook is given below; please see the Implementation Guide for in-depth information.

Please note that some column names have changed from previous versions released from CDISC Library.

Variables

Column Name	Previous Column Name	Description
Version (Column A)	Version (Column A)	SDTMIG or SENDIG version.
Variable Order (Column B)	Seq. For Order (Column B)	Sequence number indicating the order the variable appears in the implementation guide.
Class (Column C)	Observation Class (Column C)	Class in which the variable is defined in the implementation guide. The column includes the Events, Findings, and Interventions Observation Classes as well as classes for Relationship and Special-Purpose datasets.
Dataset Name (Column D)	Domain Prefix (Column D)	Name of the SDTMIG or SENDIG dataset.
Variable Name (Column E)	Variable Name (Column F)	Name of the SDTMIG or SENDIG variable.
Variable Label (Column F)	Variable Label (Column G)	Label for the SDTMIG or SENDIG variable.
Type (Column G)	Type (Column H)	Simple datatype (char or num) defined by the implementation guide.
Controlled Terms, Codelist or Format (Column H)	Controlled Terms, Codelist or Format (Column I)	The SDTMIG or SENDIG variable's controlled terminology, codelist, or format. Values in parentheses such as (LOC) refer to CDISC controlled terminology; values not in parentheses represent a format (in the case of ISO 8601) or the value list for the variable. Note: Values will be populated in a future release of CDISC Library.
Role (Column I)	Role (Column J)	Determines the type of information conveyed by the variable about each distinct observation and how it can be used. Values are controlled, and include "Topic", "Identifier", and "Variable Qualifier."
CDISC Notes (Column J)	CDISC Notes (for domains) Description (for General Classes) (Column K)	Explanatory text for the SDTMIG or SENDIG variable.
Core (Column K)	Core (Column L)	Provides guidance and compliance rules relevant to the inclusion of the variable in the SDTMIG or SENDIG dataset. Variables in SDTMIG or SENDIG are Required, Expected, or Permissible.

Datasets

Column	Previous Column Header	Description
Version (Column A)	Version (Column A)	SDTMIG or SENDIG version.
Class (Column B)	Observation Class (Column B)	Class in which the dataset is defined in the implementation guide. The column includes the Events, Findings, and Interventions Observation Classes as well as classes for Relationship and Special-Purpose datasets.
Dataset Name (Column C)	Domain Name (Column C)	Name of the SDTMIG or SENDIG dataset.
Dataset Label (Column D)	Domain Label (Column D)	Label for the SDTMIG or SENDIG dataset.
Structure (Column E)	Domain Structure (Column E)	Structure of the SDTMIG or SENDIG dataset.

Exports

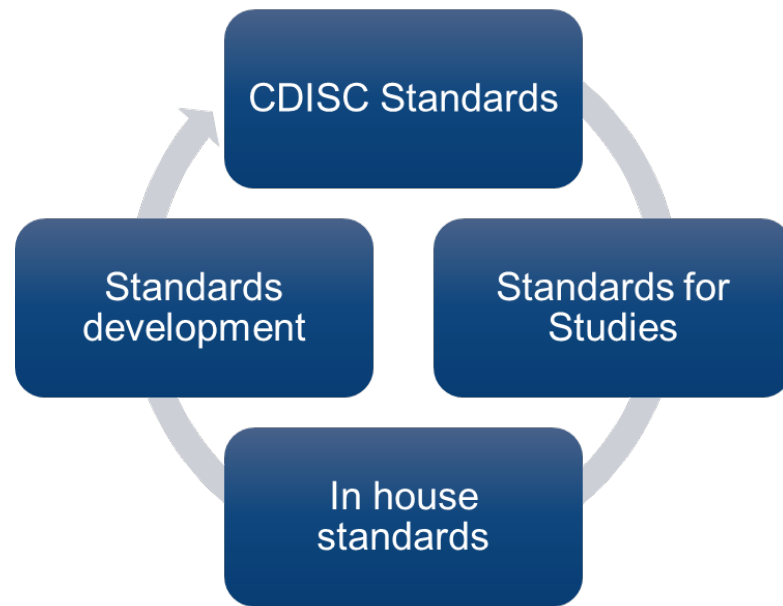
RP

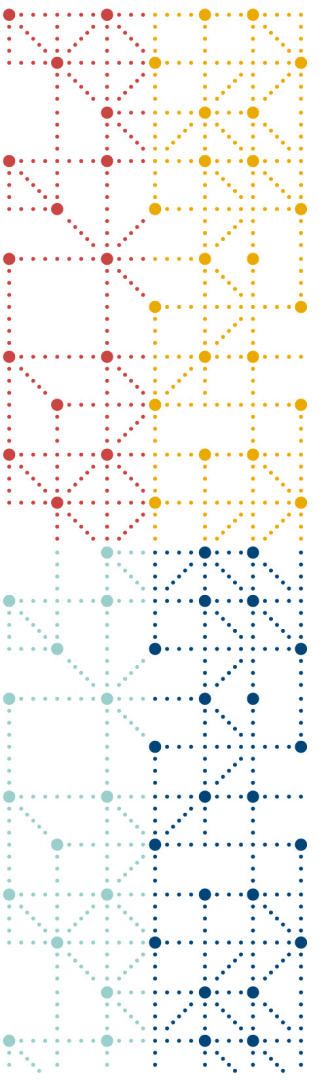
CDISC Controlled

X

Library Use Cases

- Source for study design and setup metadata
- Integration with sponsor or CRO inhouse metadata repositories
- Support continuing standards development within CDISC



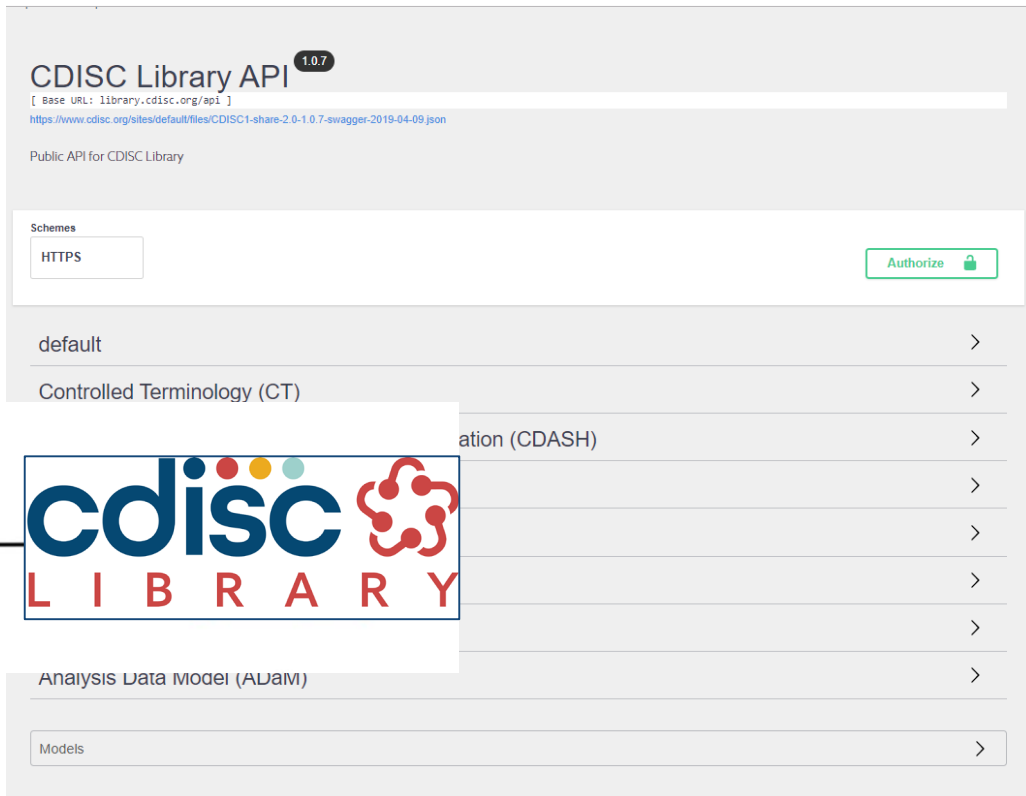
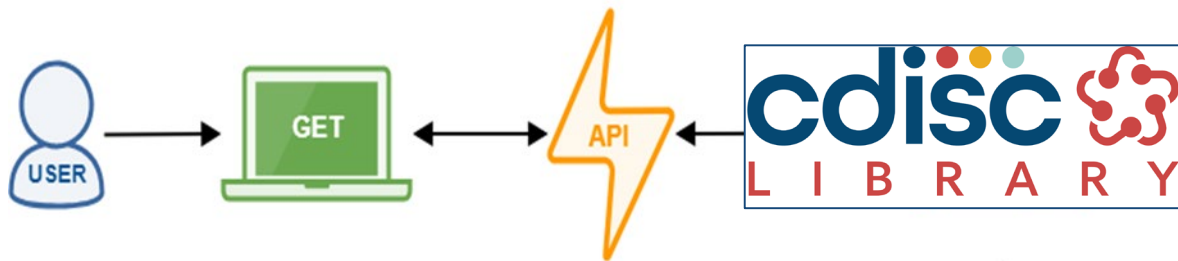


Getting Started with the API

Getting Started with the CDISC Library API

<https://www.cdisc.org/cdisc-library/api-documentation#/>

- Implemented using REST*ful web services.
 - Centered on the idea of information as a resource.
 - Represented as a set of resource Endpoints.
 - Each standard includes a set of standard endpoints.



Endpoint Examples

SDTM

<https://library.cdisc.org/api/mdr/sdtmig/3-3/datasets>

CDASH

<https://library.cdisc.org/api/mdr/cdashig/2-0/domains>

ADaM

<https://library.cdisc.org/api/mdr/adam/adamig-1-1/datastructures>

API Documentation

([CDISC Library API Documentation](#))

SDTM

SDTM Implementation Guide (SDTMIG)			▼
GET	/mdr/sdtmig/{version}	Get SDTMIG Product	🔒
GET	/mdr/sdtmig/{version}/classes	Get SDTMIG Class List	🔒
Classes			
GET	/mdr/sdtmig/{version}/classes/{class}	Get SDTMIG Class	🔒
GET	/mdr/sdtmig/{version}/classes/{class}/datasets	Get SDTMIG Class Dataset List	🔒
Datasets			
GET	/mdr/sdtmig/{version}/datasets	Get SDTMIG Dataset List	🔒
GET	/mdr/sdtmig/{version}/datasets/{dataset}	Get SDTMIG Dataset	🔒
GET	/mdr/sdtmig/{version}/datasets/{dataset}/variables	Get SDTMIG Dataset Variable List	🔒
Variables			
GET	/mdr/sdtmig/{version}/datasets/{dataset}/variables/{var}	Get SDTMIG Dataset Variable	🔒
GET	/mdr/root/sdtmig/datasets/{dataset}/variables/{var}	Get Root SDTMIG Dataset Variable	🔒

API Documentation

(CDISC Library API Documentation)

CDASH

CDASH Implementation Guide (CDASHIG) ✓		
GET	/mdr/cdashig/{version}	Get CDASHIG Product
GET	/mdr/cdashig/{version}/classes	Get CDASHIG Class List
Classes		
GET	/mdr/cdashig/{version}/classes/{class}	Get CDASHIG Class
GET	/mdr/cdashig/{version}/classes/{class}/domains	Get CDASHIG Class Domain List
Domains		
GET	/mdr/cdashig/{version}/domains	Get CDASHIG Domain List
GET	/mdr/cdashig/{version}/domains/{domain}	Get CDASHIG Domain
GET	/mdr/cdashig/{version}/domains/{domain}/fields	Get CDASHIG Domain Variable List
Fields		
GET	/mdr/cdashig/{version}/domains/{domain}/fields/{field}	Get CDASHIG Domain Field
GET	/mdr/root/cdashig/domains/{domain}/fields/{field}	Get Root CDASHIG Domain Field
GET	/mdr/cdashig/{version}/classes/{class}/scenarios	Get CDASHIG Class Scenario List
Scenarios		
GET	/mdr/cdashig/{version}/scenarios	Get CDASHIG Scenario List
GET	/mdr/cdashig/{version}/scenarios/{scenario}	Get CDASHIG Scenario
GET	/mdr/cdashig/{version}/scenarios/{scenario}/fields	Get CDASHIG Scenario Variable List
GET	/mdr/cdashig/{version}/scenarios/{scenario}/fields/{field}	Get CDASHIG Scenario Field
GET	/mdr/root/cdashig/scenarios/{scenario}/fields/{field}	Get Root CDASHIG Scenario Field

API Documentation

(CDISC Library API Documentation)

ADaM

Analysis Data Model (ADaM)			▼
GET	/mdr/adam/{product}	Get ADaM Product	🔒
GET	/mdr/adam/{product}/datastructures	Get Analysis Datastructures	🔒
Data Structures			
GET	/mdr/adam/{product}/datastructures/{datastructure}	Get ADaM Datastructure	🔒
GET	/mdr/adam/{product}/datastructures/{datastructure}/varsets	Get ADaM Variable Set List	🔒
Variable Sets			
GET	/mdr/adam/{product}/datastructures/{datastructure}/varsets/{varset}	Get ADaM Variable Set	🔒
GET	/mdr/adam/{product}/datastructures/{datastructure}/variables	Get ADaM Variable List	🔒
Variables			
GET	/mdr/adam/{product}/datastructures/{datastructure}/variables/{var}	Get ADaM Datastructure Variable	🔒

How to Access the API?

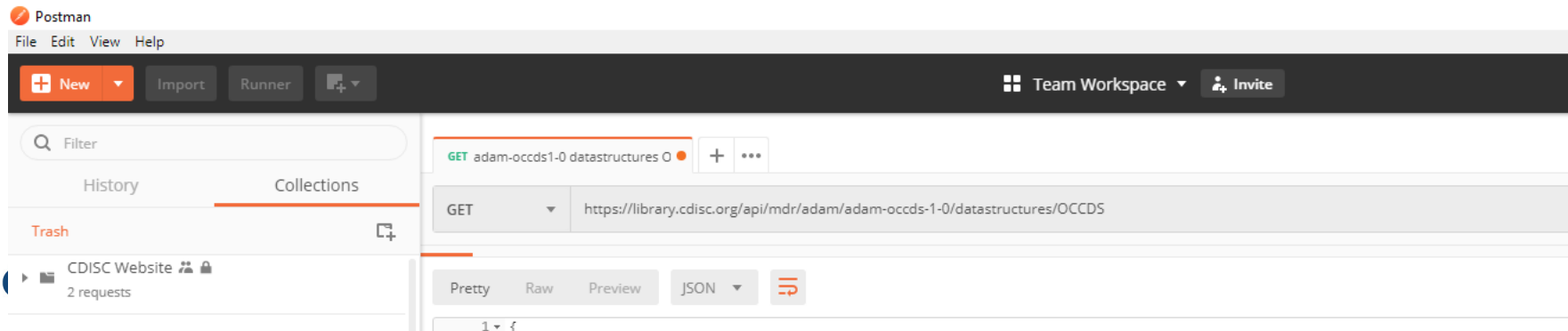
cURL

```
(base) C:\Users\scassells>curl --user myLibrary.username --url https://library.cdisc.org/api/mdr/products
```

- Command line tool
- Included in windows

Postman

- Desktop application. Supports request authoring, managing results, reuse,...
- Low cost -- free for individuals and small teams



GET Request example –XML response

GET

<https://library.cdisc.org/api/mdr/sdtmig/3-3/datasets/LB/variables/LBLOBXFL>

Body Cookies (1) Headers (5) Test Results

Pretty

Raw

Preview

XML



```
1 <?xml version="1.0" encoding="utf-8"?>
```

```
2 <datasetVariable>
```

```
3   <ordinal>31</ordinal>
```

```
4   <name>LBLOBXFL</name>
```

```
5   <label>Last Observation Before Exposure Flag</label>
```

```
6   <description>Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC. The value should be "Y"
```

```
7   <role>Record Qualifier</role>
```

```
8   <simpleDatatype>Char</simpleDatatype>
```

```
9   <core>Exp</core>
```

```
10  <_links>
```

```
11    <self>
```

```
12      <href>/mdr/sdtmig/3-3/datasets/LB/variables/LBLOBXFL</href>
```

```
13      <title>Last Observation Before Exposure Flag</title>
```

```
14      <type>SDTM Dataset Variable</type>
```

```
15    </self>
```

```
16    <codelist>
```

```
17      <href>/mdr/root/ct/sdtmct/codellists/C66742</href>
```

```
18      <title>Version-agnostic anchor resource for codelist C66742</title>
```

```
19      <type>Root Value Domain</type>
```

```
20    </codelist>
```

```
21  </datasetVariable>
```

GET Request example –json response

GET

<https://library.cdisc.org/api/mdr/sdtmig/3-3/datasets/LB/variables/LBLOBXFL>

Pretty

Raw

Preview

JSON



```
1 {
2   "ordinal": "31",
3   "name": "LBLOBXFL",
4   "label": "Last Observation Before Exposure Flag",
5   "description": "Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC. The value should be \"Y\" or null.",
6   "role": "Record Qualifier",
7   "simpleDatatype": "Char",
8   "core": "Exp",
9   "_links": {
10     "self": {
11       "href": "/mdr/sdtmig/3-3/datasets/LB/variables/LBLOBXFL",
12       "title": "Last Observation Before Exposure Flag",
13       "type": "SOTM Dataset Variable"
14     },
15     "codelist": [
16       {
17         "href": "/mdr/root/ct/sdtmct/codellists/C66742",
18         "title": "Version-agnostic anchor resource for codelist C66742",
19         "type": "Root Value Domain"
20       }
21     ],
22     "modelClassVariable": {
23       "href": "/mdr/sdtm/1-7/classes/Findings/variables/--LOBXFL",
24       "title": "Last Observation Before Exposure Flag",
25       "type": "Class Variable"
26     },
27     "parentProduct": {
28       "href": "/mdr/sdtmig/3-3",
29       "title": "Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.3 (Final)",
30       "type": "Implementation Guide"
31     }
32   }
33 }
```



Get Request – Excel Output

GET

{{library-api}}/mdr/cdashig/2-0



Accept

application/vnd.ms-excel

Key

Value

Body Cookies (1) Headers (5) Test Results

Pretty

Raw

Preview

Auto



```
1 PK-----N-----[Content_Types].xmlTMo00+U
2 paaaa-iC-----&Q1-9-----{v-hS1
3 -w]++6nQcFdHieB1-h8n`Z-Q-()-V-----"B-U.-d;-w-:
4 w
5 9Zi|>ds-PK-LNVr-----PK-----N-----_rels/.relsJ-1-_%m-i
6 雞y`#-Q--nkoO-h-DP_zq^kEàX
7 ![1-w--l9_-B?&-M=--_PK--6]g--PK-----N-----
8 B,(-#`B/ P0]
9 -M]J
```

CDASHIG2.xlsx - Excel					
File Home Insert Page Layout Formulas Data Review View Tell me what you want to do...					
Sally Cassells Share					
AS Version (Column A)					
A	B	C	D	E	F
The content of this spreadsheet represents the normative metadata found in the corresponding CDASH Implementation Guide. A brief description of the columns in the spreadsheet is given below; please see the Implementation Guide and associated CDASH model, if any, for in-depth information.					
Please note that some column names have changed from previous versions released from CDISC Library.					
1					
2					
3	Variables				
4	Column Name	Previous Column Name (CDASHIG v2.0)	Previous Column Name (CDASHIG v1.1.1)	Description	
5	Version (Column A)	N/A	N/A	CDASHIG version	
6	Class (Column B)	Observation Class (Column A)	N/A	SDTM Class for the domain.	
7	Domain (Column C)	Domain (Column B)	Domain (Column A)	Two-letter domain code.	
8	Data Collection Scenario (Column D)	Data Collection Scenario (Column C)	Domain (Column A) , as second part of the value.	This column identifies the different data collection options in CDASH for the same domain, combined with implementation options. Note Implementation Options are not defined for CDASHIG v.1.1. When this column contains "Horizontal-Generic", a sampling of the CDASHIG metadata is provided as a template for the metadata of the CRF in a denormalized structure. When this column contains "Horizontal-Example", it represents a specific execution of CRF metadata in a denormalized structure.	
9	Variable Order (Column E)	Order Number (Column E)	Order (Column C)	Suggested order of CDASHIG variables to be displayed on a CRF.	
10	CDASHIG Variable (Column F)	CDASHIG Variable (Column F)	SDTM or CDASH Variable Name (Column F)	CDASHIG variable name (e.g., CMONGO, AEDAT).	
11	CDASHIG Variable Label (Column G)	CDASHIG Variable Label (Column G)	N/A	CDASHIG variable label. Column will be empty for CDASHIG v.1.1.	
12	DRAFT CDASHIG Definition (Column H)	DRAFT CDASHIG Definition (Column H)	Definition (Column H)	Draft definition of the CDASHIG variable. This text may or may not mirror any text in the SDTMIG.	
13	Question Text (Column I)	Question Text (Column I)	Question Text (Column D)	Question text for the specific Domain, Data Collection Scenario and Implementation Options.	
14	Prompt (Column J)	Prompt (Column J)	Prompt (Column E)	Prompt text for the specific Domain, Data Collection Scenario and Implementation Options. The Prompt is a short version of the question.	
15	Type (Column K)	Data Type (Column K)	Data Type (Column M)	Simple data type of the CDASHIG variable (e.g., Char, Num, Date, or Time).	
16	CDASHIG Core (Column L)	CDASHIG Core (Column L)	Core (Column L)	This column contains the CDASHIG core designations for basic data collection fields (i.e., Highly Recommended (HR), Recommended/Conditional (R/C), Optional (O)).	
17	Case Report Form Completion Instructions (Column M)	Case Report Form Completion Instructions (Column M)	CRF Completion Instructions (Column J)	This column contains recommended example instructions for the clinical site on how to enter collected information on the CRF.	
18	SDTMIG Target (Column N)	SDTMIG Target (Column N)	SDTM Domain (Column C) and SDTM Variable (Column D) on separate cdash-2-sdtm-csv-map file	List of semicolon separated SDTMIG variable names as suggested mapping. A blank value indicates no SDTMIG Target available.	
19	Mapping Instructions (Column O)	Mapping Instructions (Column O)	Mapping Instructions (Column E) on separate cdash-2-sdtm-csv-map file	This column contains information on the suggested mapping of the CDASHIG variable to the SDTMIG variable.	
20	Controlled Terminology Codelist Name (Column P)	Controlled Terminology Codelist Name (Column P)	Codelist (Column I)	Controlled Terminology (CT) codelist name that is associated with the field, enclosed in parenthesis (e.g., (SEX)). It correspond to Controlled Terminology (CT) published as SDTM CT packages, followed by any applicable CDASH Subset Codelist name that may be used for that specific variable (e.g., (EXDOSFRM)) published as CDASH CT packages, separated with a semicolon. The values are as published in the source version of the standard. Note subsets are not defined for CDASHIG v.1.1	
21	Implementation Notes (Column Q)	Implementation Notes (Column R)	Information for Sponsors (Column K)	Further information, such as rationale and implementation instructions, on how to implement the CRF data collection fields and how to map CDASHIG variables to SDTMIG variables.	
22					
23					
24					
25					

Get Request example – CSV Format

GET

{{library-api}}/mdr/cdashig/2-0

☰

☑

Accept

text/csv

Key	Value
-----	-------

Body

Cookies (1)

Headers (5)

Test Results

Pretty

Raw

Preview

Auto

↕

```
1 "Version","Class","Domain","Data Collection Scenario","Variable Order","CDASHIG Variable","
2 "CDASHIG v2.0","Interventions","CM",,"1","STUDYID","Study Identifier","A unique identifier
3 "CDASHIG v2.0","Interventions","CM",,"2","SITEID","Study Site Identifier","A unique identif
4 "CDASHIG v2.0","Interventions","CM",,"3","SUBJID","Subject Identifier for the Study","A uni
5 "CDASHIG v2.0","Interventions","CM",,"4","CMCAT","Category for Concomitant Medication","A g
6 "CDASHIG v2.0","Interventions","CM",,"5","CMSCAT","Subcategory for Concomitant Medication",
7 "CDASHIG v2.0","Interventions","CM",,"6","CMYN","Any Concomitant Medications Taken","An ind
8 "CDASHIG v2.0","Interventions","CM",,"7","CMSPID","Concomitant Meds Sponsor-Defined Identif
9 "CDASHIG v2.0","Interventions","CM",,"8","CMTRT","Concomitant Medication Name","Verbatim me
```

Programming with the API



Define-XML

Getting Started: Consuming the Response

From the CDISC Library Service Desk Knowledge Base

```
1  /*
2      Example: A GET Request to the CDISC Library That Uses the HEADERS Statement
3      Adjusted by: Marcelina Hungria
4      Date: 2019-04-03
5      Notes: Requires SAS 9.4M3 or later
6  */
7
8  filename response TEMP;
9
10 proc http
11     url="https://library.cdisc.org/api/mdr/products/Terminology"
12     AUTH_BASIC WEBUSERNAME="user" WEBPASSWORD="pass"
13     out=response;
14     headers
15         /* Use "application/xml" instead of "application/json" to get the response in xml format */
16         "Accept"="application/json";
17 run;
18
19 data _null_;
20     infile response;
21     input;
22     put _infile_;
23 run;
```

You can obtain the full script using CDISC WIKI/JIRA account:

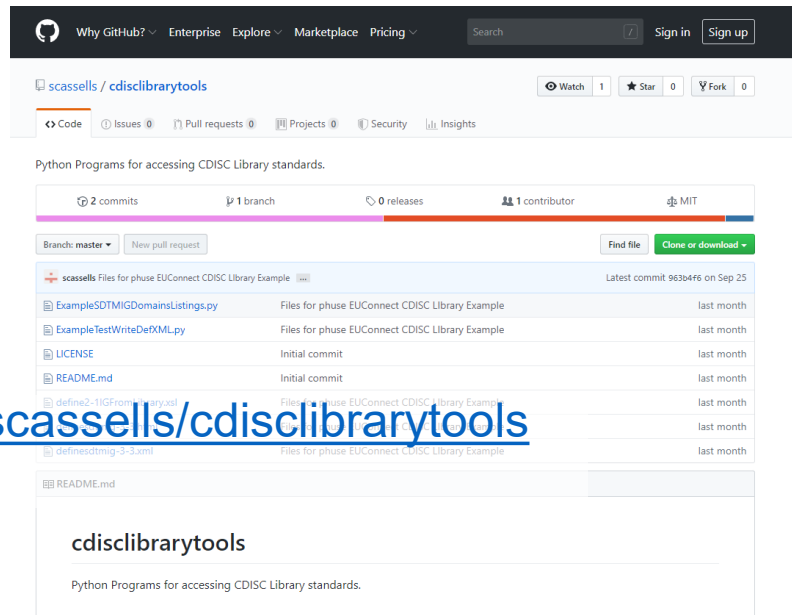
<https://bitbucket.cdisc.org/snippets/a84d469d6e86400f98af62547370b4dc/download>.

Link to sign up for CDISC WIKI/JIRA: <https://wiki.cdisc.org/signup.action>.

Examples

1. Metadata for a set of SDTM Datasets
2. Metadata for an ADaM Specification

- Available on GitHub <https://github.com/scassells/cdislibrarytools>



Standards for Study sdtmig-3-3

Standard	Type	Status	Documentation
sdtmig 3-3	IG	Final	

Variable Groups

Variable Group Label	Number o Variables			
DM [sdtmig 3-3]	Demographics	Special-Purpose Datasets	One record per subject	Tabulation
DS [sdtmig 3-3]	Disposition	Events Observation Class	One record per disposition status or protocol milestone per subject	Tabulation
EX [sdtmig 3-3]	Exposure	Interventions Observation Class	One record per protocol-specified study treatment, constant-dosing interval, per subject	Tabulation
AE [sdtmig 3-3]	Adverse Events	Events Observation Class	One record per adverse event per subject	Tabulation
CM [sdtmig 3-3]	Concomitant/Prior Medications	Interventions Observation Class	One record per recorded intervention occurrence or constant-dosing interval per subject	Tabulation
EG [sdtmig 3-3]	ECG Test Results	Findings Observation Class	One record per ECG observation per replicate per time point or one record per ECG observation per beat per visit per subject	Tabulation
LB [sdtmig 3-3]	Laboratory Test Results	Findings Observation Class	One record per lab test per time point per visit per subject	Tabulation
SU [sdtmig 3-3]	Substance Use	Interventions Observation Class	One record per substance type per reported occurrence per subject	Tabulation
VS [sdtmig 3-3]	Vital Signs	Findings Observation Class	One record per vital sign measurement per time point per visit per subject	Tabulation

ADamIG-1-1

Variable Groups

- ADSL Identifier Variables
- ADSL Subject Demographics Variables
- ADSL Population Indicator Variables
- ADSL Treatment Variables
- ADSL Dose Variables
- ADSL Treatment Timing Variables
- Subject-Level Period, Subperiod, and Phase
- ADSL Subject-Level Trial Experience Variable
- Identifier Variables for BDS Datasets
- Record-Level Treatment Variables for BDS D
- Record-Level Dose Variables for BDS Dase
- Timing Variables for BDS Datasets
- Period, Subperiod, and Phase Start and End
- Suffixes for User-Defined Timing Variables in
- Analysis Parameter Variables for BDS Dase
- Analysis Parameter Criteria Variables for BD
- Analysis Descriptor Variables for BDS Dase
- Analysis Visit Windowing Variables for BDS I
- Time-to-Event Variables for BDS Datasets
- Toxicity and Range Variables for BDS Dase
- Flag Variables for BDS Datasets
- BDS Population Indicators
- Datapoint Traceability Variables
- Controlled Terminology
- CodeLists
- AGEU
- SEX
- RACE
- CharacterNoYesResponse - values
- DATEFL
- TIMEFL
- PARAMTYP
- NumericNoYesResponse - values
- DTYPE
- CharacterYesResponse - values
- NumericIndicator - values

ADSL Population Indicator Variables (ADSL Population Indicator Variables) -

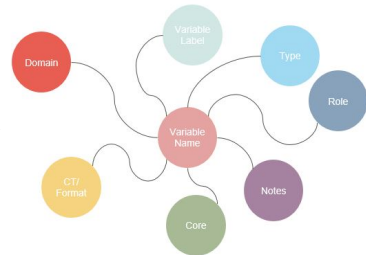
Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	CDISC Notes
FASFL	Full Analysis Set Population Flag	text	50	CharacterNoYesResponse - values • N • Y	These flags identify whether or not the subject is included in the specified population. A minimum of one subject-level population flag variable is required in ADSL. Not all of the indicators listed here need to be included in ADSL. As stated in Section 3.1.4, Item 2, only those indicators corresponding to populations defined in the statistical analysis plan or populations used as a basis for analysis need be included in ADSL. This list of flags is not meant to be all-inclusive. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included. Please also refer to Section 3.1.4.
SAFFL	Safety Population Flag	text	50	CharacterNoYesResponse - values • N • Y	These flags identify whether or not the subject is included in the specified population. A minimum of one subject-level population flag variable is required in ADSL. Not all of the indicators listed here need to be included in ADSL. As stated in Section 3.1.4, Item 2, only those indicators corresponding to populations defined in the statistical analysis plan or populations used as a basis for analysis need be included in ADSL. This list of flags is not meant to be all-inclusive. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included. Please also refer to Section 3.1.4.
ITTFL	Intent-To-Treat Population Flag	text	50	CharacterNoYesResponse - values • N • Y	These flags identify whether or not the subject is included in the specified population. A minimum of one subject-level population flag variable is required in ADSL. Not all of the indicators listed here need to be included in ADSL. As stated in Section 3.1.4, Item 2, only those indicators corresponding to populations defined in the statistical analysis plan or populations used as a basis for analysis need be included in ADSL. This list of flags is not meant to be all-inclusive. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN, where 0=no and 1=yes) of the population flag can also be included. Please also refer to Section 3.1.4.
PPROTFL	Per-Protocol Population Flag	text	50	CharacterNoYesResponse - values • N • Y	These flags identify whether or not the subject is included in the specified population. A minimum of one subject-level population flag variable is required in ADSL. Not all of the indicators listed here need to be included in ADSL. As stated in Section 3.1.4, Item 2, only those indicators corresponding to populations defined in the statistical analysis plan or populations used as a basis for analysis need be included in ADSL. This list of flags is not meant to be all-inclusive. Additional population flags may be added.

DM - Specification

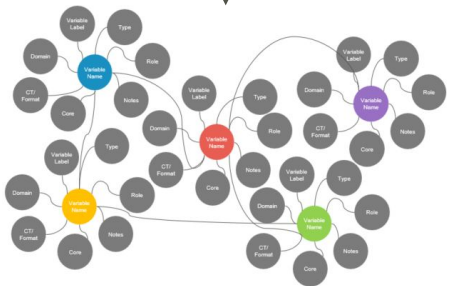
dm.xml_Demographics - Special Purpose, Version 1.3. One record per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Code list or Format ¹	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
USUBID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBID.	Req
SUBID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req

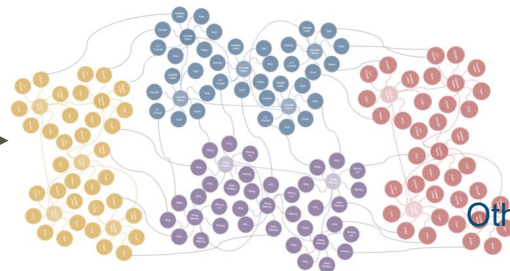
DM Variable as Linked Data



SDTMIG as Linked Data



CDISC as Linked Data

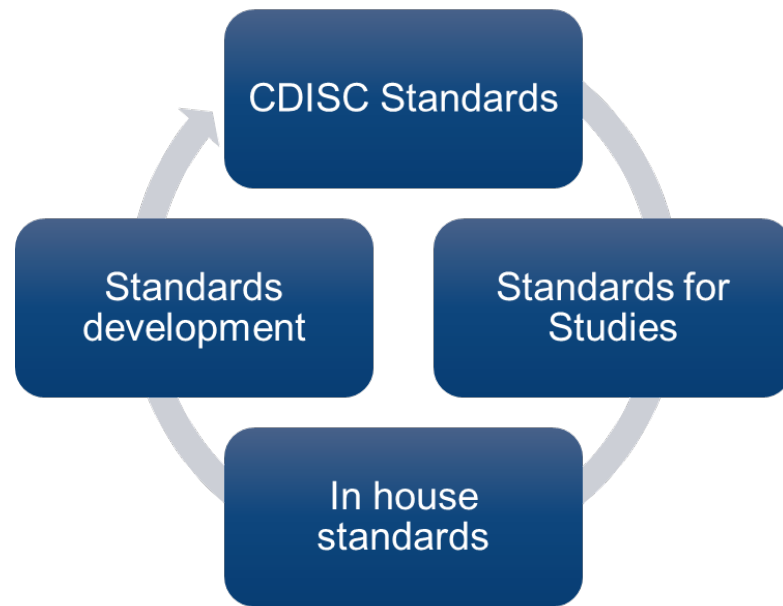


Other Standards as Linked Data



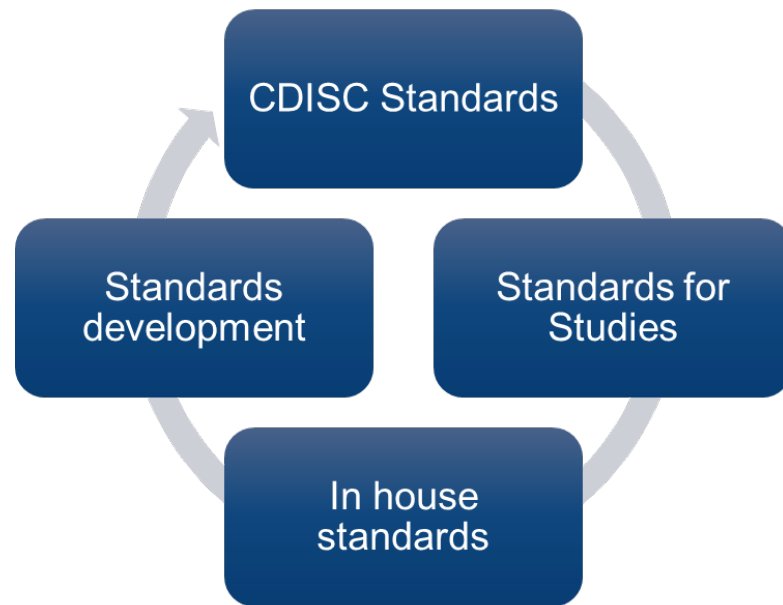
Library Use Cases

- Source for study design and setup metadata
- Integration with sponsor or CRO inhouse metadata repositories
- Support continuing standards development within CDISC



Benefits

- Links available through XML and JSON responses enable automation not possible with spreadsheets
- CDISC Library platform supports inclusion of new types of metadata
 - Examples
 - Conformance Rules
 - CDISC 360
- Access to open source developers
- Evolving set of open source tools



How Will You Use CDISC Library?

Sally Cassells

PhUSE EU Connect 11 November 2019



www.cdisc.org/cdisc-library



Thank You!

