

GUF 2019-10



Cdisc Lib / Neo4j Demo



CDISC Lib

CDISC Library API ^{1.0.7}

[Base URL: library.cdisc.org/api/]

<https://www.cdisc.org/sites/default/files/CDISC1-share-2.0-1.0.7-swagger-2019-04-09.json>

Public API for CDISC Library

Schemes

HTTPS

Authorize



default >

Controlled Terminology (CT) >

Clinical Data Acquisition Standards Harmonization (CDASH) >

CDASH Implementation Guide (CDASHIG) >

Study Data Tabulation Model (SDTM) >

SDTM Implementation Guide (SDTMIG) >

SEND Implementation Guide (SENDIG) >

Analysis Data Model (ADaM) >

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

Only for CDISC Members... \$\$\$\$\$

The Cdisc Lib API — How to see the SDTMCT 2018-12-21

The screenshot shows a web browser window displaying the Cdisc API documentation for the endpoint `GET /mdr/ct/packages/{package}`. The interface includes a search bar, a list of endpoints, and a detailed view for the selected endpoint. The detailed view shows the endpoint description, parameters, a form to execute the request, and the resulting curl command and request URL.

GET `/mdr/ct/packages` Get CT Package List

GET `/mdr/ct/packages/{package}` Get CT Package

Parameters Cancel

Name	Description
package * required string (path)	CT Package Identifier

Execute Clear

Responses Response content type: application/json

Curl

```
curl -X GET "https://library.cdisc.org/api/mdr/ct/packages/sdtmct-2018-12-21" -H "accept: application/json"
```

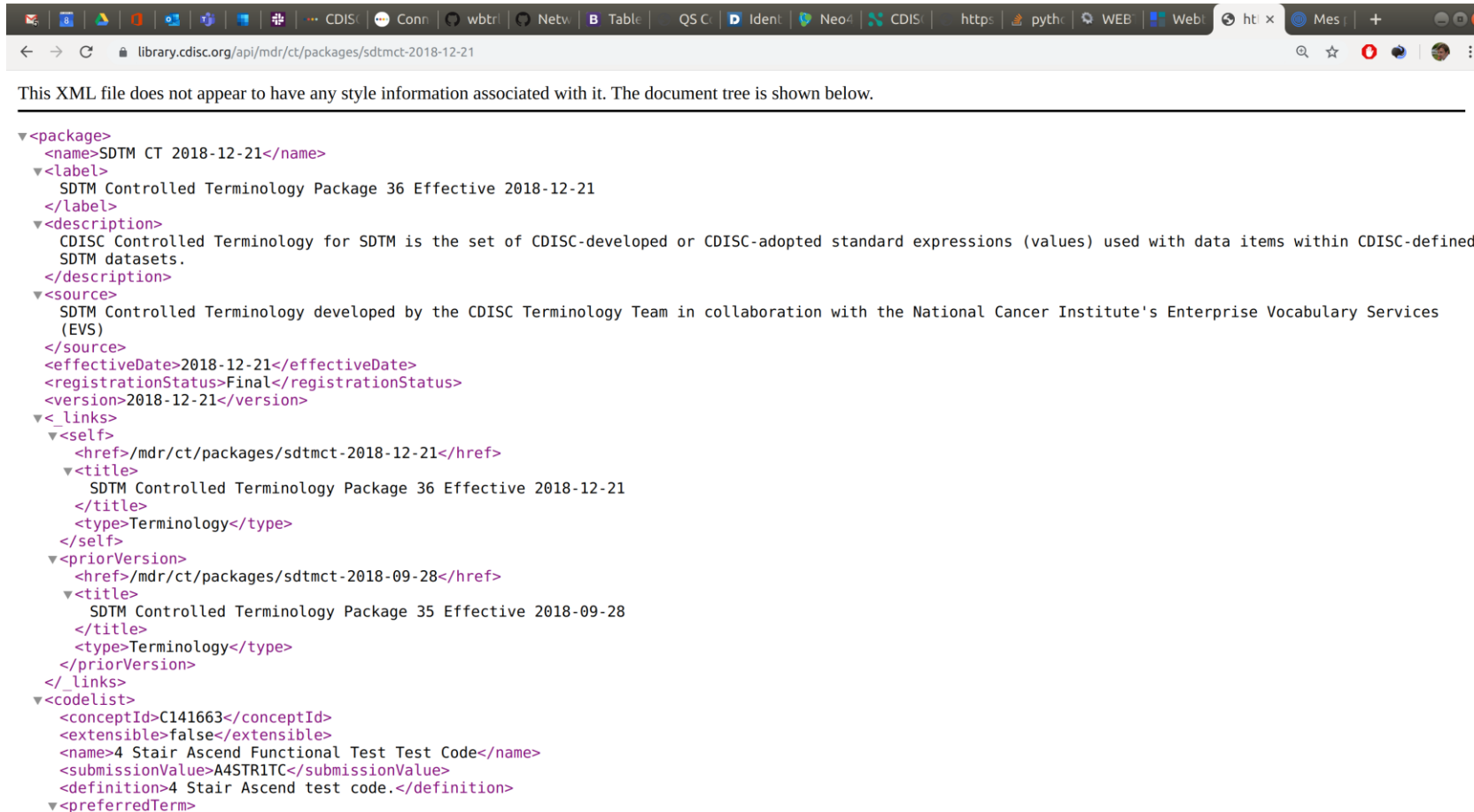
Request URL

```
https://Library.cdisc.org/api/mdr/ct/packages/sdtmct-2018-12-21
```

Server response

Code Details

And here is the result in a Web Browser!



This XML file does not appear to have any style information associated with it. The document tree is shown below.

```
<?xml version="1.0" encoding="UTF-8" ?>
<package name="SDTM CT 2018-12-21" label="SDTM Controlled Terminology Package 36 Effective 2018-12-21" description="CDISC Controlled Terminology for SDTM is the set of CDISC-developed or CDISC-adopted standard expressions (values) used with data items within CDISC-defined SDTM datasets." source="SDTM Controlled Terminology developed by the CDISC Terminology Team in collaboration with the National Cancer Institute's Enterprise Vocabulary Services (EVS)" effectiveDate="2018-12-21" registrationStatus="Final" version="2018-12-21" >
  <_links>
    <self href="/mdr/ct/packages/sdtmct-2018-12-21" title="SDTM Controlled Terminology Package 36 Effective 2018-12-21" type="Terminology" />
    <priorVersion href="/mdr/ct/packages/sdtmct-2018-09-28" title="SDTM Controlled Terminology Package 35 Effective 2018-09-28" type="Terminology" />
  </_links>
  <codelist conceptId="C141663" extensible="false" name="4 Stair Ascend Functional Test Test Code" submissionValue="A4STR1TC" definition="4 Stair Ascend test code." >
    <preferredTerm>

```


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

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 2017 Q1

CT 2017 Q2

CT 2017 Q3

CT 2017 Q4

CT 2018 Q1

CT 2018 Q2

<https://library.cdisc.org/browser/>

Better display in the Nurocor Browser...

The screenshot shows a web browser window displaying the CDISC Data Standards Browser. The URL is library.cdisc.org/browser/sdtmig/3-2?group=%2Fmdr%2Fui%2Fsdmig%2F3-2%2Fdatasets%2FAE. The page features a search bar and the Nurocor logo. A navigation bar contains buttons for various SDTMIG versions: 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, and SDTMIG-PGx v1.0. The main content area displays details for the selected product, SDTMIG v3.2, including its status (Final), effective date (2013-11-26), and implementation (SDTM v1.4). A 'Classes' section lists categories like General Observations, Special-Purpose, Interventions, Events, Findings, Findings About, Trial Design, and Relationship. Below this, 'Data Sets' includes AE, CE, DS, DV, HO, and MH. The 'Events' section is expanded, showing details for Adverse Events: Name: Adverse Events, Description: An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment. (Source: CDISC Controlled Terminology, DOMAIN, C49562, 2018-06-29), Structure: One record per adverse event per subject, and Dataset Version: 3.2. An 'Adverse Events' section is also visible at the bottom. An 'Exports' button is located in the top right of the main content area. The footer contains the copyright notice: © 2018-2019 Nurocor Inc. All Rights Reserved.

The browser provide links between metadata

The screenshot shows the CDISC Data Standards Browser interface. The browser's address bar displays the URL: library.cdisc.org/browser/sdtmig/3-2?group=%2Fmdr%2Fui%2Fsdmg%2F3-2%2Fdatasets%2FAE. The page title is "cdisc LIBRARY Data Standards Browser". A search bar is present, and the Nurocor logo is visible in the top right corner. The main content is a table with the following columns: Ordinal, Name, Label, Description, Data Type, Role, Core, Code List, Described Value Domain, and Implements. The table lists various metadata items, each with a green button in the "Implements" column that links to the metadata it implements. Some items also have blue buttons in the "Code List" column that link to specific code lists.

↑ Ordinal	Name	Label	Description	Data Type	Role	Core	Code List	Described Value Domain	Implements
21	AEBODSYS	Body System or Organ Class	Dictionary derived. Body system or organ class used by the sponsor from the coding dictionary (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables which may not necessarily be the primary SOC.	Char	Record Qualifier	Exp			--BODSYS
22	AEBDSYCD	Body System or Organ Class Code	Dictionary derived. Code for the body system or organ class used by the sponsor. When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables, which may not necessarily be the primary SOC.	Num	Variable Qualifier	Exp		MedDRA	--BDSYCD
23	AESOC	Primary System Organ Class	Dictionary-derived text description of the primary System Organ Class. Will be the same as AEBODSYS if the primary SOC was used for analysis.	Char	Variable Qualifier	Exp		MedDRA	--SOC
24	AESOCCD	Primary System Organ Class Code	Dictionary-derived code for the primary System Organ Class. Will be the same as AEBDSYCD if the primary SOC was used for analysis.	Num	Variable Qualifier	Exp		MedDRA	--SOCCD
25	AELOC	Location of Event	Describes anatomical location relevant for the event (e.g., ARM for skin rash).	Char	Record Qualifier	Perm	C74456		--LOC
26	AESEV	Severity/Intensity	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE.	Char	Record Qualifier	Perm	C66769		--SEV
27	AESER	Serious Event	Is this a serious event?	Char	Record Qualifier	Exp	C66742		--SER
28	AEACN	Action Taken with Study Treatment	Describes changes to the study treatment as a result of the event. AEACN is specifically for the relationship to study treatment. AEACNOTH is for actions unrelated to dose adjustments of study treatment. Examples of AEACN values include ICH E2B values: DRUG WITHDRAWN, DOSE REDUCED, DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE.	Char	Record Qualifier	Exp	C66767		--ACN
29	AEACNOTH	Other Action Taken	Describes other actions taken as a result of the event that are unrelated to dose adjustments of study treatment. Usually reported as free text. Example: "TREATMENT UNBLINDED.	Char	Record Qualifier	Perm			--ACNOTH

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SDTM CT example

The screenshot shows the CDISC Data Standards Browser interface. At the top, there are navigation buttons for different CDISC standards: CDASH CT 2019-06-28, PROTOCOL CT 2019-06-28, SDTM CT 2019-06-28 (which is highlighted), and SEND CT 2019-06-28. Below this, the 'Codelist: C74456' section provides details for the selected codelist:

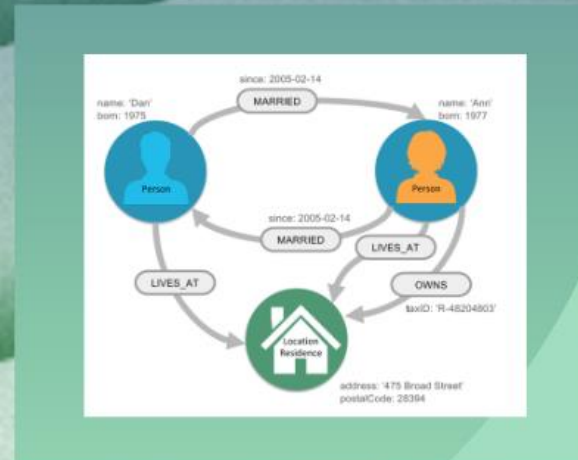
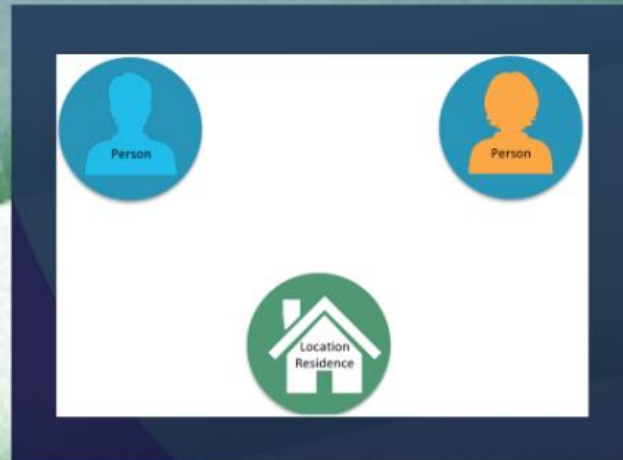
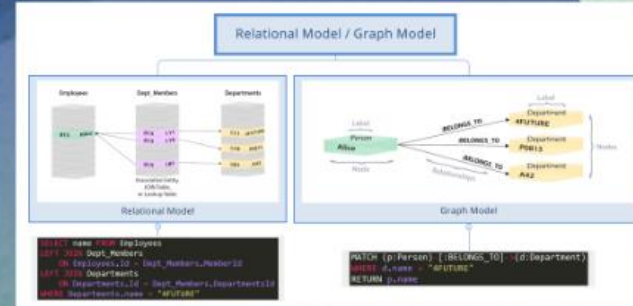
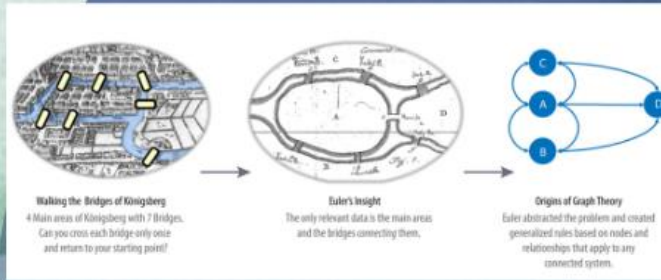
- Extensible:** Yes
- Submission Value:** LOC
- Definition:** Terminology codelist used for anatomical location within CDISC.
- Nci Preferred Term:** CDISC SDTM Anatomical Location Terminology
- Synonyms:** Anatomical Location

The main section is titled 'SDTM Controlled Terminology Package 38 Effective 2019-06-28'. It includes a 'Filter results' input field and an 'Exports' button. Below this is a table with the following columns: Term, Submission Value, Synonyms, Definition, and Preferred Term.

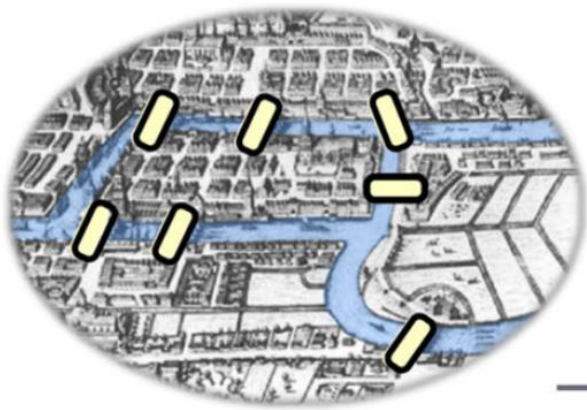
Term	Submission Value	Synonyms	Definition	Preferred Term
C102285	ACUTE MARGINAL ARTERY	ACUTE MARGINAL ARTERY SEGMENT(S) AMARG	The arteries that arise at the junction of the proximal and mid-right coronary artery conduit segments.	Acute Marginal Artery
C102286	CIRCUMFLEX, OBTUSE MARGINALS, LEFT POSTEROLETERAL AND		The left circumflex coronary artery and all of its branches.	Circumflex Artery and its

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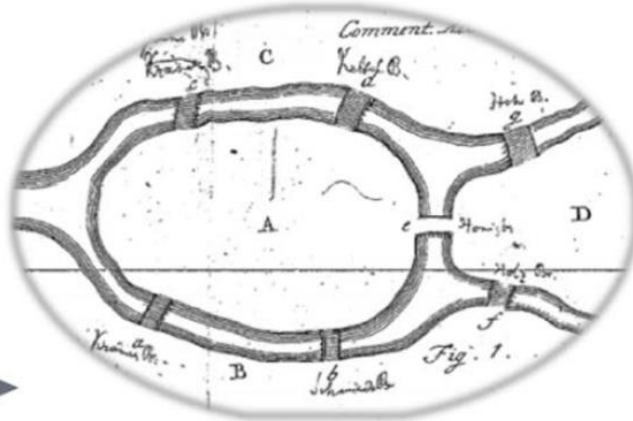
What are Graphs?



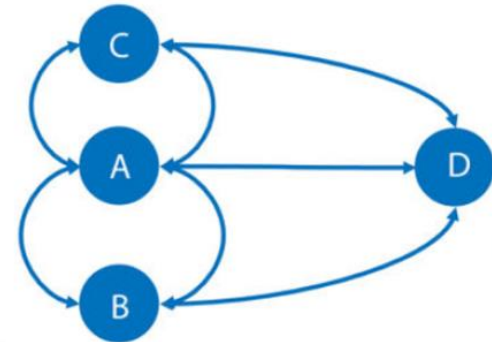
What is a Graph?



Walking the Bridges of Königsberg
4 Main areas of Königsberg with 7 Bridges.
Can you cross each bridge only once
and return to your starting point?

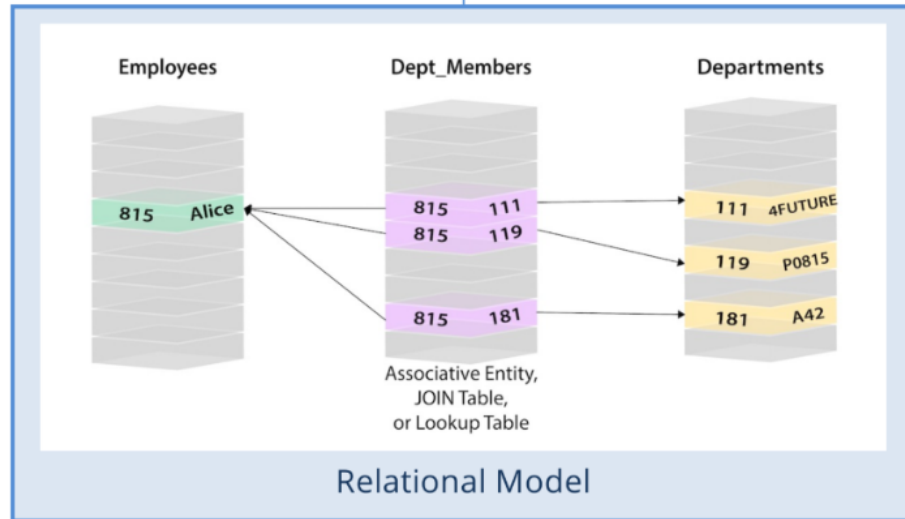


Euler's Insight
The only relevant data is the main areas
and the bridges *connecting* them.

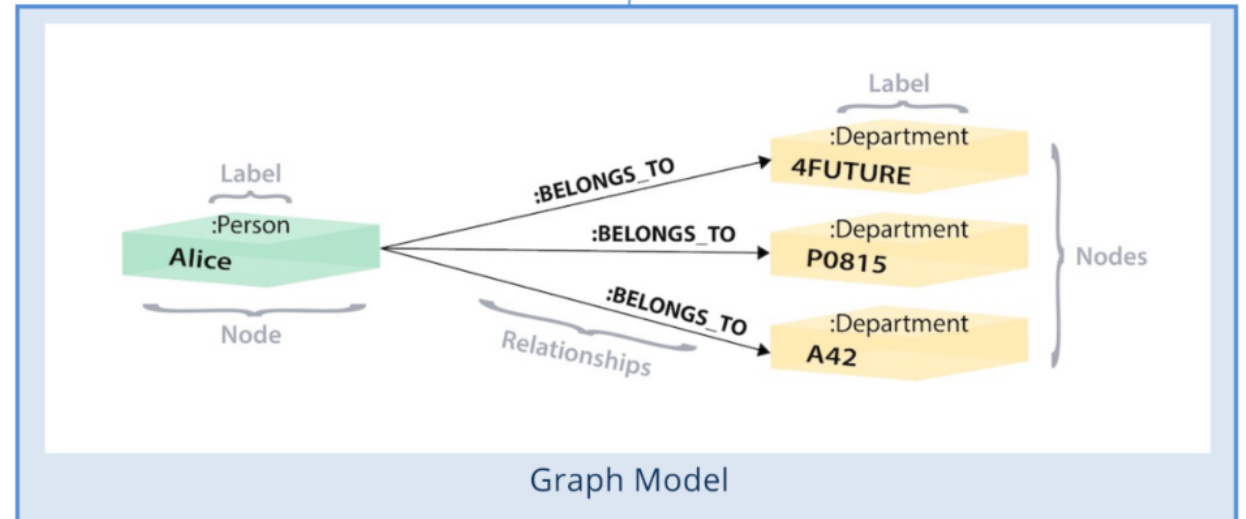


Origins of Graph Theory
Euler abstracted the problem and created
generalized rules based on nodes and
relationships that apply to any
connected system.

Relational Model / Graph Model

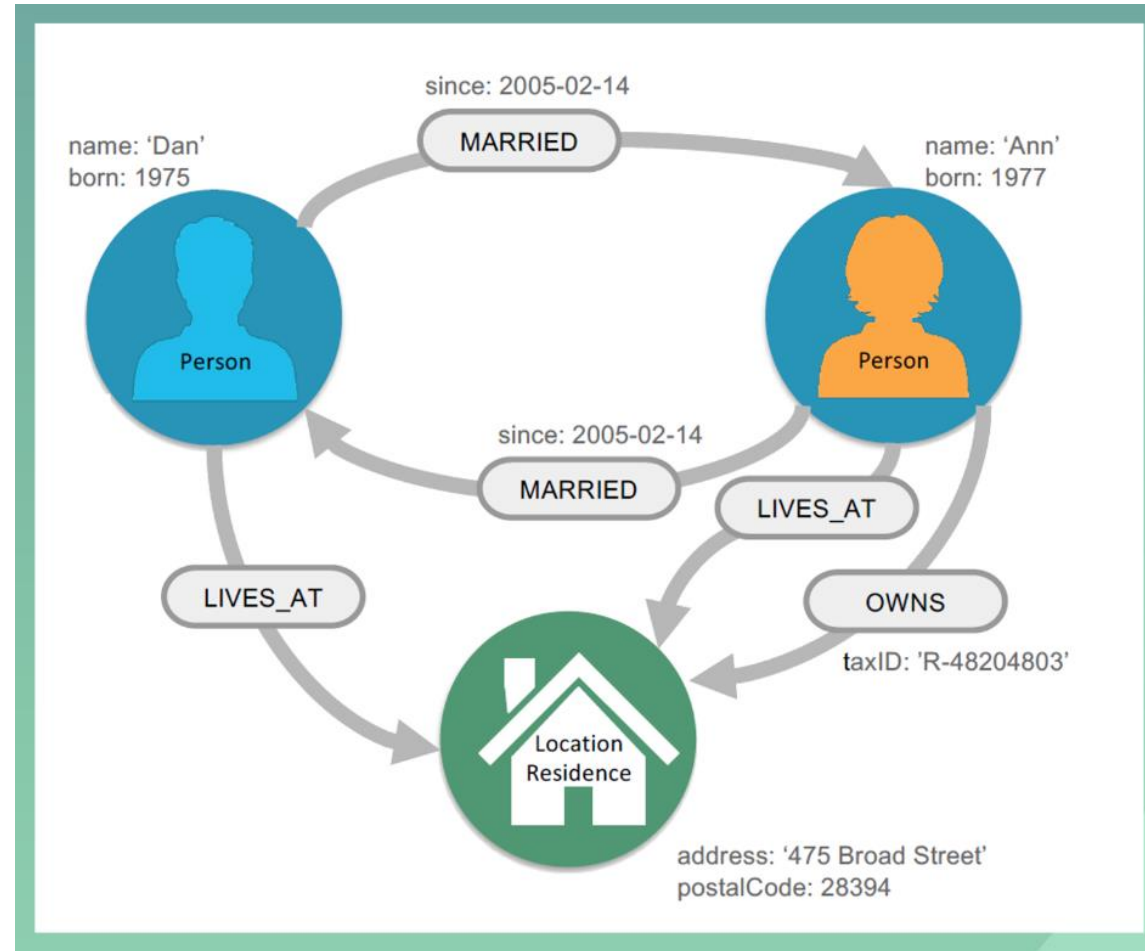


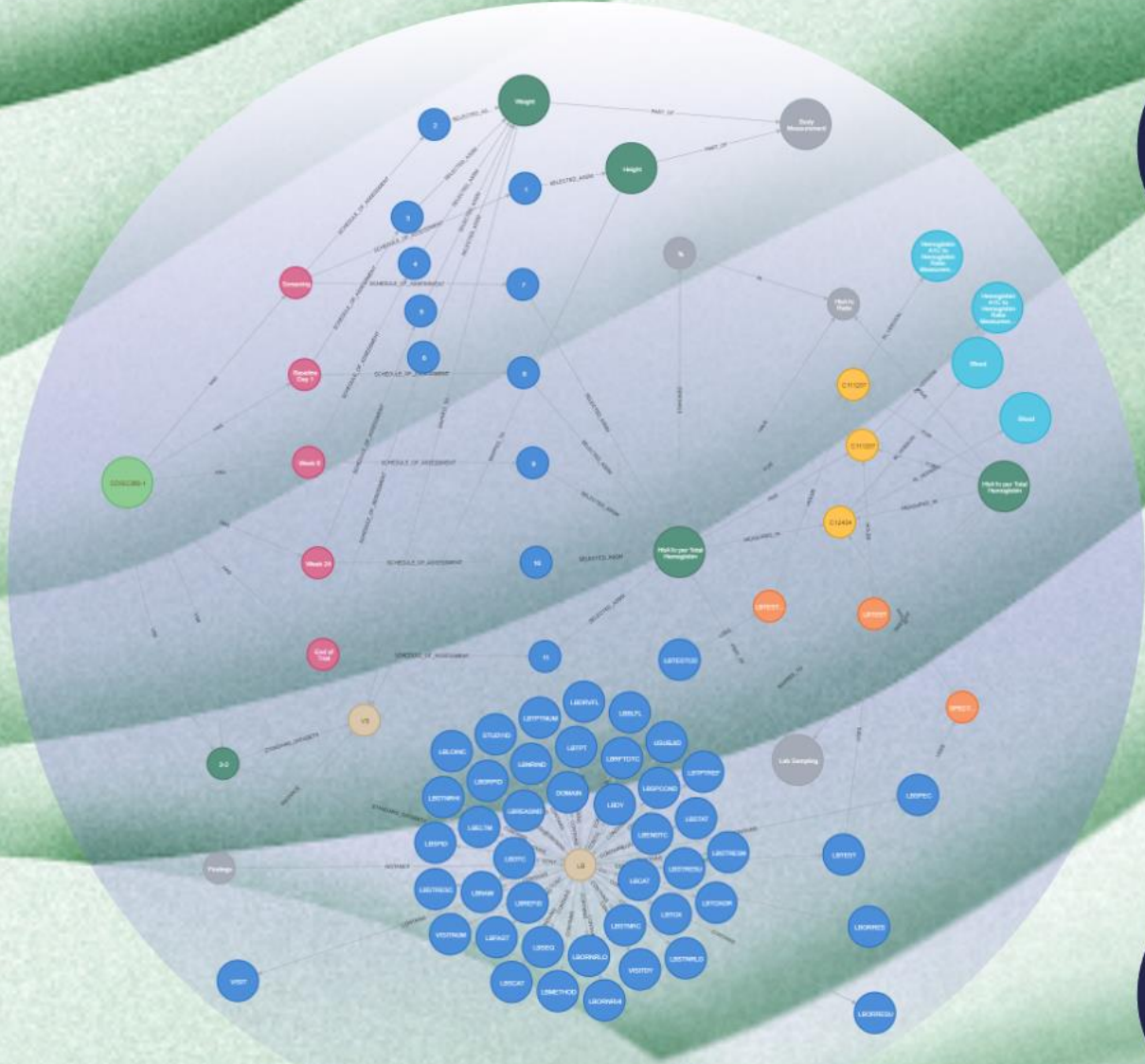
```
SELECT name FROM Employees
LEFT JOIN Dept_Members
  ON Employees.Id = Dept_Members.MemberId
LEFT JOIN Departments
  ON Departments.Id = Dept_Members.DepartmentsId
WHERE Departments.name = "4FUTURE"
```



```
MATCH (p:Person)-[:BELONGS_TO]->(d:Department)
WHERE d.name = "4FUTURE"
RETURN p.name
```


Graphs are Nodes and Relations!!





Cypher and
APOC

Our vision

Thank!!!

How is working Neo4j (<http://www.neo4j.com>)

The screenshot shows the Neo4j interface with a Cypher query and its results. The query is as follows:

```
1 // List CDISC CT definition
2 MATCH (l:CTList)--(rl:RootCTList {submission_value:'RACE'})-->
3   (rt:RootCTTerm)-->(t:CTTerm)-->(p:CTPackage {id:'sdmct-2018-12-21'})
4 RETURN p.id as CTVersion, rl.submission_value as CTList, rt.submission_value as CTTerm, rt.concept_id as CTCCode, t.definition as CTDefinition;
```

The results are displayed in a table format:

CTVersion	CTList	CTTerm	CTCCode	CTDefinition
"sdmct-2018-12-21"	"RACE"	"BLACK OR AFRICAN AMERICAN"	"C16352"	"A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." (FDA)"
"sdmct-2018-12-21"	"RACE"	"ASIAN"	"C41260"	"A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (FDA)"
"sdmct-2018-12-21"	"RACE"	"UNKNOWN"	"C17998"	"Not known, not observed, not recorded, or refused. (NCI)"
"sdmct-2018-12-21"	"RACE"	"NOT REPORTED"	"C43234"	"Not provided or available."
"sdmct-2018-12-21"	"RACE"	"AMERICAN INDIAN OR ALASKA NATIVE"	"C41259"	"A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. (FDA)"
"sdmct-2018-12-21"	"RACE"	"NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER"	"C41219"	"Denotes a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. The term covers particularly people who identify themselves as part-Hawaiian, Native Hawaiian, Guamanian or Chamorro, Carolinian, Samoan, Chuu. (FDA)"
"sdmct-2018-12-21"	"RACE"	"WHITE"	"C41261"	"Denotes a person with European, Middle Eastern, or North African ancestral origin who identifies, or is identified, as White. (FDA)"

Started streaming 7 records after 17 ms and completed after 54 ms.

In Neo4j

```
MATCH (mdl:Model)
WHERE mdl.name = 'ADaM'
WITH mdl
CALL apoc.load.jsonParams("https://library.cdisc.org/api/mdr/ct/packages", {Authorization: "Basic [REDACTED]", Accept:
"application/json"}, null) yield value as link
UNWIND link._links.packages AS package
WITH mdl, package
WHERE SPLIT(package.title, ' ')[0] = mdl.name
MERGE (ctpckg:CTPackage {title : package.title, id : substring(package.href, 17)})
WITH mdl, ctpckg, package
MERGE (mdl)-[r:HAS_PACKAGE {href : package.href}]->(ctpckg)
```

```
MATCH (study:Study)-[]->(plannedvisit:PlannedVisit)-[]->(plannedmeasurement:PlannedMeasurement)-[]->(assessment:Assessment)-[]->
(rootsdtdataset:RootSDTMDataset)
WHERE study.id = 'CDISC360-1' AND assessment.name = 'HbA1c per Total Hemoglobin'
WITH study, plannedvisit, plannedmeasurement, assessment, rootsdtdataset
MATCH (assessment)-[]->(activity:Activity)<-[]-(param:Param), (assessment)-[]->(rootctterm:RootCTTerm), (assessment)-[]->
(unitdefinition:UnitDefinition), (assessment)-[]->(unitdimention:UnitDimension)
RETURN study, plannedvisit, plannedmeasurement, assessment, rootsdtdataset, activity, rootctterm, unitdefinition, unitdimention, param
```

We can produce the TS domain from the available metadata loaded during the Cdisc 360 project!

```
9 RETURN s.id as studyid, 'TS' as domain, 'REGID' as tparmcd, 'Registry Identifier' as tparm, s.CTgov as tsval, 'CLINICALTRIALS.GOV' as tsvcdref, '' as tsvcdver
10 UNION
11 MATCH (s:Study)
12 RETURN s.id as studyid, 'TS' as domain, 'REGID' as tparmcd, 'Registry Identifier' as tparm, s.EUDRACT as tsval, 'EUDRACT' as tsvcdref, '' as tsvcdver
13 UNION
14 MATCH (s:Study)-->(ig:SDTMIGVersion)
15 RETURN s.id as studyid, 'TS' as domain, 'SDTIGVER' as tparmcd, 'SDTM IG Version' as tparm, ig.version as tsval, '' as tsvcdref, '' as tsvcdver
```

\$ MATCH (s:Study) RETURN s.id as studyid, 'TS' as domain, 'TITLE' as tparmcd, 'Trial Title' as tparm, s.title as tsval, '' as tsvcdref, '' as tsvcdver UNION OPTIONAL MATCH (s:Study)-->(p:RootT...

studyid	domain	tparamcd	tparam	tsval	tsvcdref	tsvcdver
"CDISC360-1"	"TS"	"TITLE"	"Trial Title"	"A Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Drug A in Patients with Type 2 Diabetes"	""	""
"CDISC360-1"	"TS"	"TPHASE"	"Trial Phase Classification"	"PHASE V TRIAL"	"CDISC"	"sdmct-2019-06-28"
"CDISC360-1"	"TS"	"REGID"	"Registry Identifier"	"NCT01234567"	"CLINICALTRIALS.GOV"	""
"CDISC360-1"	"TS"	"REGID"	"Registry Identifier"	"2019-012345-42"	"EUDRACT"	""
"CDISC360-1"	"TS"	"SDTIGVER"	"SDTM IG Version"	"SDTMIG v3.2"	""	""
"CDISC360-1"	"TS"	"SDTMVER"	"SDTM Version"	"SDTM v1.4"	""	""

Started streaming 6 records after 19 ms and completed after 19 ms.

Produce the Define.xml Domain listing in Neo4j

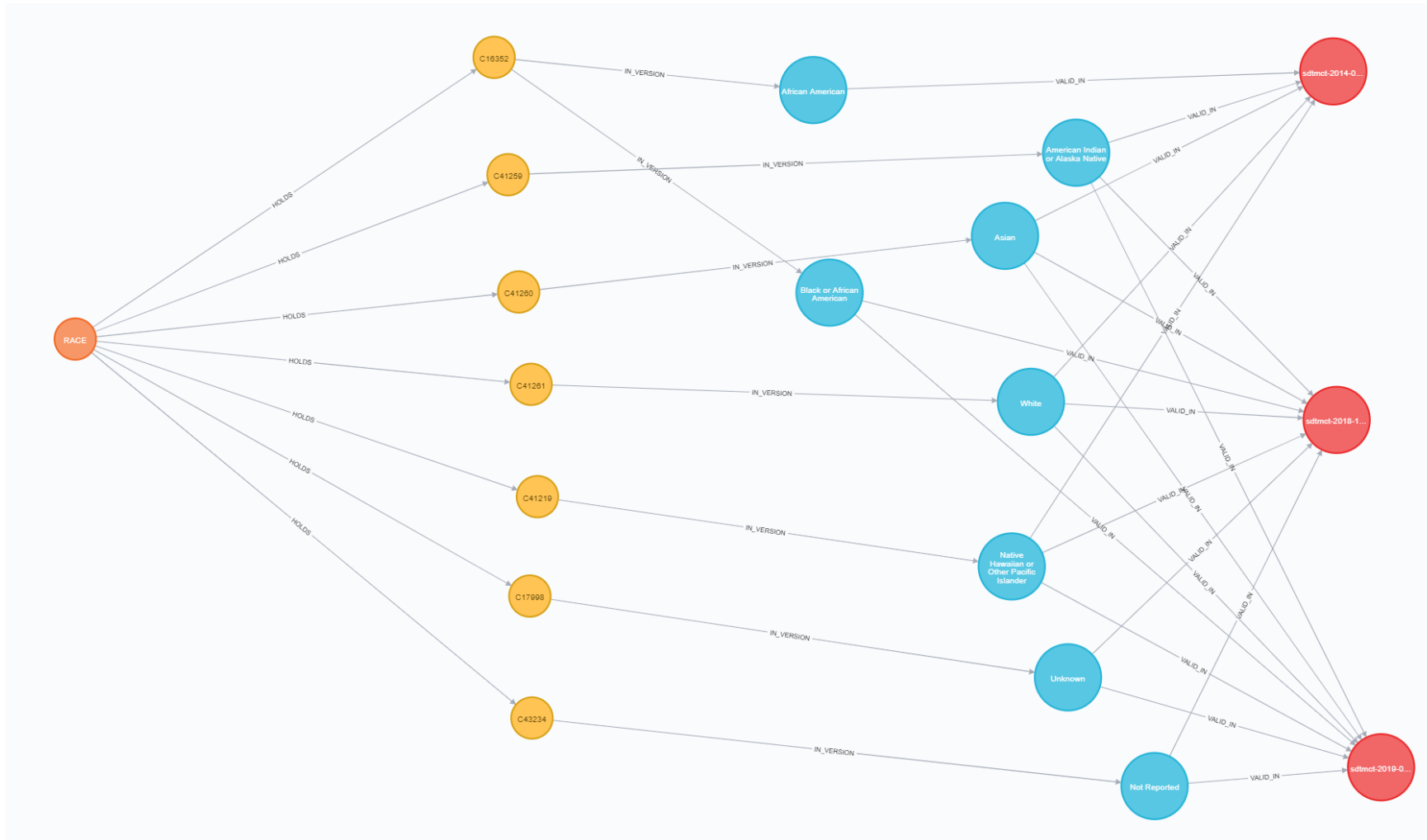
```
8 MATCH (s:Study)-[*3]->(a:Assessment)-[r:MAPPED_TO]->(d:SDTMDataset)
9 RETURN s.id as study_id, d.name as sdtm_dataset, d.label as label, d.description as description,
10      d.class_ds_title as class, d.structure as structure, 'Tabulation' as purpose,
11      d.key as key_variables, d.repeating as repeating, d.reference_data as reference_data,
12      '' as comment, d.ordinal as ordinal, 'Required' as include_type
13 ORDER BY study_id, sdtm_dataset;
```

```
$ MATCH (s:Study)-->(ig:SDTMIGVersion)-[r:REQUIRED_DOMAINS]->(d:SDTMDataset) RETURN s.id as study_id, d.name as sdtm_dataset, d.label as label, d.description as description, d.class_ds_title as class,
```

study_id	sdtm_dataset	label	description	class	structure	purpose	key_variables	repeating	reference_data	comment	ordinal	include_type
"CDISC360-1"	"TS"	"Trial Summary"	"A trial design domain that contains one record for each trial summary characteristic. This domain is not subject oriented. (Source: CDISC Controlled Terminology, DOMAIN, C53483, 2018-06-29)"	"Trial Design Model"	"One record per trial summary parameter value"	"Tabulation"	"TS"	"No"	"Yes"	""	44	"Required"
"CDISC360-1"	"TD"	"Trial Disease Assessments"	"A trial design domain that provides information on the protocol-specified disease assessment schedule, to be used for comparison with the actual occurrence of the efficacy assessments in order to determine whether there was good compliance with the schedule. (Source: CDISC Controlled Terminology, DOMAIN, C117699, 2018-06-29)"	"Trial Design Model"	"One record per planned constant assessment period"	"Tabulation"	"TD"	"No"	"Yes"	""	42	"Required"
"CDISC360-1"	"DM"	"Demographics"	"A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects. (Source: CDISC Controlled Terminology, DOMAIN, C49572, 2018-06-29)"	"Special-Purpose Datasets"	"One record per subject"	"Tabulation"	"DM"	"No"	"No"	""	2	"Required"

Started streaming 11 records after 22 ms and completed after 22 ms.

View evolution of the SDTM CT for RACE Codelist over time...



Produce the DM Domain metadata

```
1 // List SDTM domain definition
2 MATCH (d:RootSDTMDataset {name: 'DM'})-->(v:RootSDTMVariable)
3 OPTIONAL MATCH (v)-[r]->(l:RootCTList)
4 RETURN d.name as Domain, v.name as Variable, v.label as Label, v.role as Role, v.core as Core, l.submission_value as CodeList ORDER BY v.ordinal;
```

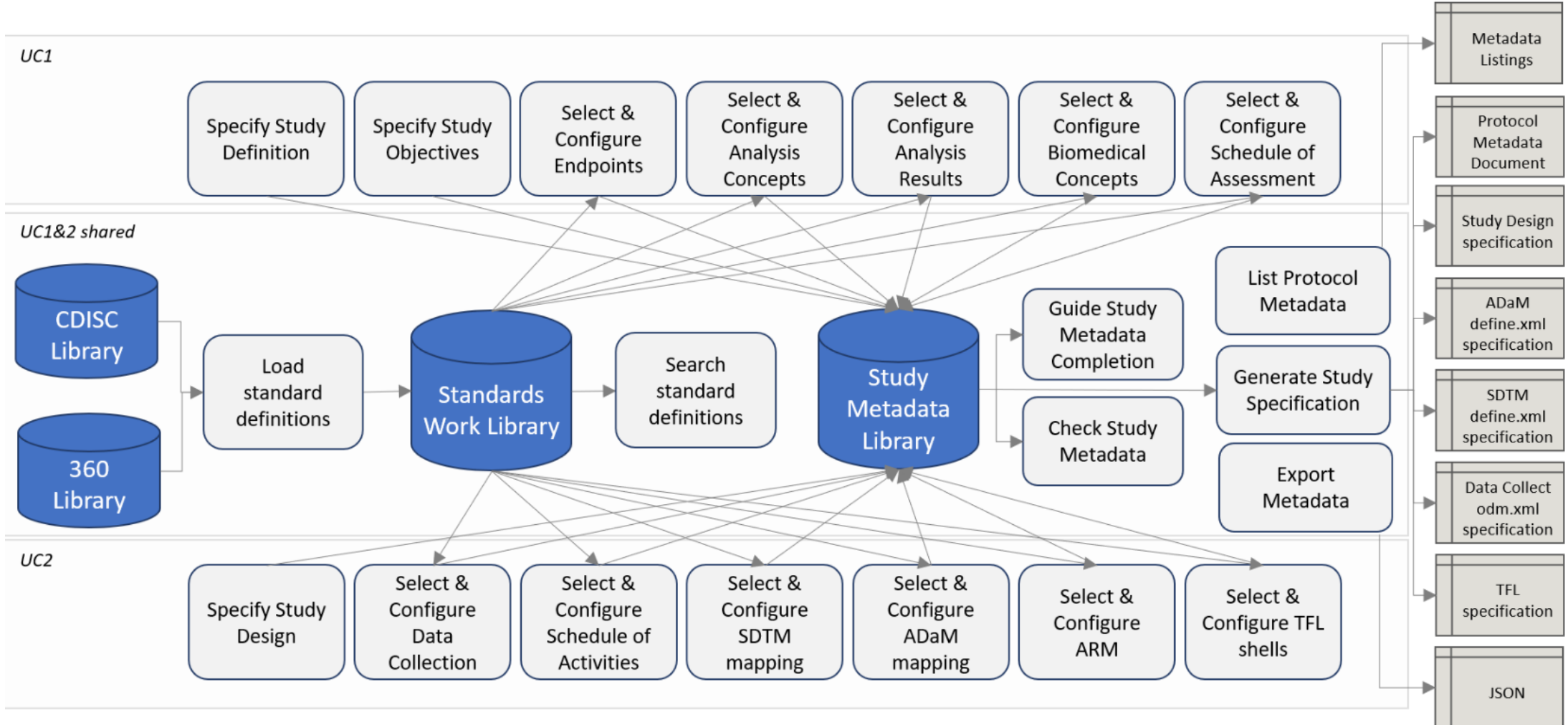
```
$ MATCH (d:RootSDTMDataset {name: 'DM'})-->(v:RootSDTMVariable) OPTIONAL MATCH (v)-[r]->(l:RootCTList) RETURN d.name as Domain, v.name as Variable, v.label as Label, v.role as Role, v.core as ...
```

Domain	Variable	Label	Role	Core	CodeList
"DM"	"STUDYID"	"Study Identifier"	null	"Req"	null
"DM"	"DOMAIN"	"Domain Abbreviation"	"Identifier"	"Req"	null
"DM"	"USUBJID"	"Unique Subject Identifier"	null	"Req"	null
"DM"	"SUBJID"	"Subject Identifier for the Study"	"Topic"	"Req"	null
"DM"	"RFSTDTC"	"Subject Reference Start Date/Time"	"Record Qualifier"	"Exp"	null
"DM"	"ARMCD"	"Planned Arm Code"	"Record Qualifier"	"Exp"	null
"DM"	"RFENDTC"	"Subject Reference End Date/Time"	"Record Qualifier"	"Exp"	null
"DM"	"ARM"	"Description of Planned Arm"	"Synonym Qualifier"	"Perm"	null
"DM"	"RFXSTDTC"	"Date/Time of First Study Treatment"	"Record Qualifier"	"Exp"	null
"DM"	"RFXENDTC"	"Date/Time of Last Study Treatment"	"Record Qualifier"	"Exp"	null
"DM"	"RFICDTC"	"Date/Time of Informed Consent"	"Record Qualifier"	"Exp"	null
"DM"	"RFPENDTC"	"Date/Time of End of Participation"	"Record Qualifier"	"Exp"	null
"DM"	"DTHDTC"	"Date/Time of Death"	"Record Qualifier"	"Exp"	null
"DM"	"DTHFL"	"Subject Death Flag"	"Record Qualifier"	"Exp"	"NY"
"DM"	"SITEID"	"Study Site Identifier"	"Record Qualifier"	"Req"	null
"DM"	"INVID"	"Investigator Identifier"	"Record Qualifier"	"Perm"	null

Started streaming 28 records after 8 ms and completed after 8 ms.

Workflow of the metadata from the Cdisc Lib

Draft user stories related to CDISC 360 WS4/5



Beta version of a Cdisc Lib application

CDISCLIB Home CDASH SDTM ADAM CT TOC

8.1.2 CM - Prior and Concomitant Medications

8.1.2.1 Description/Overview for the CDASH CM - Prior and Concomitant Medications Domain

The same basic data collection variables should be collected for all medications/treatments (Prior, General Concomitant Medications, and Medications of Interest), if additional fields are needed to collect other data about a medication of interest, those should be added as standard fields. Note: Sponsor may use terms like "concomitant medications", "treatments", or "therapies" as appropriate for the study. The text below may use one of these terms, but sponsors can always use the term most appropriate for their study.

The term "Prior" refers to medications/treatments that were started before study participation, since limited information may be available on prior medications taken by a subject; the core requirements were constrained to reflect this limitation. Sponsors should define the appropriate collection period for prior and concomitant medications/treatments in the study protocol.

8.1.2.2 Specification for the CDASH CM - Prior and Concomitant Medications Domain

Concomitant Medications (CM)

Metadata CM Table cdisc lib

Add to cart

CDASH Variable	Variable Label	Question Text	Controlled Terminology Code Set or Format	Data Type	Mapping Instructions	SDTM Variable	Core
<input checked="" type="checkbox"/>	STUDYID	Study Identifier	What is the study identifier?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	STUDYID	HR
<input checked="" type="checkbox"/>	SITEID	Study Site Identifier	What is the site identifier?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	SITEID	HR
<input checked="" type="checkbox"/>	SUBJID	Subject Identifier for the Study	What is the subject identifier?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	SUBJID	HR
<input type="checkbox"/>	CMCAT	Category for Concomitant Medication	What is the category for the (concomitant) [medication/treatment/therapy]?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	CMCAT	O
<input type="checkbox"/>	CMSCAT	Subcategory for Concomitant Medication	What is the subcategory for the (concomitant) [medication/treatment/therapy]?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	CMSCAT	O
<input type="checkbox"/>	CMYN	Any Concomitant Medications Taken	Were any (concomitant) [medication(s)/treatment(s)/therapy(ies)] taken?	Char	Does not map to an SDTM variable. The SDTM Annotated CRF is annotated to indicate that this field is NOT SUBMITTED.	NOT SUBMITTED	O
<input type="checkbox"/>	CMSPD	Concomitant Meds Sponsor-Defined Identifier	What is the (concomitant) [medication/treatment/therapy] identifier?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target". May be used to create RELREC to link this record with a record in another domain.	CMSPD	O
<input checked="" type="checkbox"/>	CMTRT	Concomitant Medication Name	What was the (concomitant) [medication/treatment/therapy] name?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	CMTRT	HR
<input type="checkbox"/>	CMOCCR	Concomitant Meds Occurrence	Did the subject take [pre-specified (concomitant) [medication/treatment/therapy/issue]?, Has the subject taken [pre-specified (concomitant) [medication/treatment/therapy/issue]?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target". If the response was not asked or answered, populate the SDTM variable CMSTAT with "NOT DONE".	CMOCCR	O
<input type="checkbox"/>	CMINGRD	Concomitant Meds Active Ingredients	What were the active ingredients?	Char	Does not map to an SDTM variable. The SDTM Annotated CRF is annotated to indicate that this field is NOT SUBMITTED.	NOT SUBMITTED	O
<input checked="" type="checkbox"/>	CMINDC	Concomitant Meds Indication	For what indication, was the (concomitant) [medication/treatment/therapy] taken?	Char	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	CMINDC	RIC
<input type="checkbox"/>	CMAREN	Related Adverse Event ID	What was the identifier for the adverse event(s) for which the (concomitant) [medication/treatment/therapy] was taken?	Char	This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the Adverse Events domain.	NOT SUBMITTED	O
<input type="checkbox"/>	CMRHNO	Related Medical History Event ID	What was the identifier for the medical history event(s) for which the (concomitant) [medication/treatment/therapy] was taken?	Char	This does not map directly to an SDTM variable. For the SDTM submission datasets, may be used to create RELREC to link this record with a record in the Medical History domain.	NOT SUBMITTED	O
<input type="checkbox"/>	CMDOSE	Concomitant Meds Dose	What was the individual dose (of the concomitant) [medication/treatment/therapy] per administration?	Num	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	CMDOSE	O

CDISCLIB Home CDASH SDTM ADAM CT TOC

CDISC Controlled Terminology for CDASH

Manage by the: National Cancer Institute

Name	Label	Description	Source	Effective Date	Registration Status	Version
CDASH CT	CDASH Controlled Terminology Package 36 Effective 2018-12-21	CDISC Controlled Terminology for CDASH is the set of CDISC-developed or CDISC-adopted standard expressions (values) used with data items within CDISC-defined CDASH datasets.	CDASH Controlled Terminology developed by the CDISC Terminology Team in collaboration with the National Cancer Institute's Enterprise Vocabulary Services (EVS)	2018-12-21	Final	2018-12-21

Concept Id	Extensible	Name	Submission Value	Definition	Preferred Term	Synonyms
C78418	true	Concomitant Medication Dose Form	CMDOSEFRM	A terminology subset of the CDISC SDTM Pharmaceutical Dosage Form codelist created for CDASH Concomitant Medication Dose Form codelist. (NCI)	CDISC CDASH Concomitant Medication Dose Form Terminology	[Concomitant Medication Dose Form]
C78417	true	Concomitant Medication Dose Units	CMDOSEU	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Concomitant Medication Dose Units codelist. (NCI)	CDISC CDASH Concomitant Medication Dose Units Terminology	[Concomitant Medication Dose Units]
C78419	true	Concomitant Medication Dosing Frequency per Interval	CMDOSEFRQ	A terminology subset of the CDISC SDTM Frequency codelist created for CDASH Concomitant Medication Dosing Frequency per Interval codelist. (NCI)	CDISC CDASH Concomitant Medication Dosing Frequency per Interval Terminology	[Concomitant Medication Dosing Frequency per Interval]
C78420	true	Concomitant Medication Route of Administration	CMROUTE	A terminology subset of the CDISC SDTM Route codelist created for CDASH Concomitant Medication Route of Administration codelist. (NCI)	CDISC CDASH Concomitant Medication Route of Administration Terminology	[Concomitant Medication Route of Administration]
C78422	true	ECG Original Units	EGORRESU	A terminology subset of the CDISC SDTM Unit codelist created for CDASH ECG Original Units codelist. (NCI)	CDISC CDASH ECG Original Units Terminology	[ECG Original Units]
C128690	true	Ethnicity As Collected	ETHNICC	A terminology codelist relevant to the ethnicity of an individual as collected on the case report form.	CDISC SDTM Collected Ethnicity Terminology	[Ethnicity As Collected]
C78426	true	Exposure Dose Form	EXDOSEFRM	A terminology subset of the CDISC SDTM Pharmaceutical Dosage Form codelist created for CDASH Exposure Dose Form codelist. (NCI)	CDISC CDASH Exposure Dose Form Terminology	[Exposure Dose Form]
C78745	true	Exposure Dosing Frequency per Interval	EXDOSEFRQ	A terminology subset of the CDISC SDTM Frequency codelist created for CDASH Exposure Dosing Frequency per Interval codelist. (NCI)	CDISC CDASH Exposure Dosing Frequency per Interval Terminology	[Exposure Dosing Frequency per Interval]
C78425	true	Exposure Route of Administration	EXROUTE	A terminology subset of the CDISC SDTM Route codelist created for CDASH Exposure Route of Administration codelist. (NCI)	CDISC CDASH Exposure Route of Administration Terminology	[Exposure Route of Administration]
C128689	true	Race As Collected	RACEC	A terminology codelist relevant to the race of an individual as collected on the case report form.	CDISC SDTM Collected Race Terminology	[Race As Collected]
C83004	true	Substance Use Never/Current/Former Classification	SUNCF	A terminology subset of the CDISC SDTM Never/Current/Former Classification codelist created for CDASH Substance Use Never/Current/Former Classification codelist. (NCI)	CDISC CDASH Substance Use Never/Current/Former Classification Terminology	[Substance Use Never/Current/Former Classification]
C78428	true	Total Volume Administration Unit	EXVOLTU	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Total Volume Administration Unit codelist. (NCI)	CDISC CDASH Total Volume Administration Unit Terminology	[Total Volume Administration Unit]
C78427	true	Unit for the Duration of Treatment Interruption	EXINTPU	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Unit for Duration of Treatment Interruption codelist. (NCI)	CDISC CDASH Unit for Duration of Treatment Interruption Terminology	[Unit for the Duration of Treatment Interruption]
C78421	true	Unit of Drug Dispensed or Returned	DAORRESU	A terminology subset of the CDISC SDTM Unit codelist created for CDASH Unit of Drug Dispensed or Returned codelist. (NCI)	CDISC CDASH Unit of Drug Dispensed or Returned Terminology	[Unit of Drug Dispensed or Returned]

Thank You...

Any Question ?

To contact us

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