



CDISC 360 Use Cases - Industry Perspectives

Workstream 4 - DEFINE

Use Case 1: End to Start Standards Specification

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CDISC US Interchange, October 2019





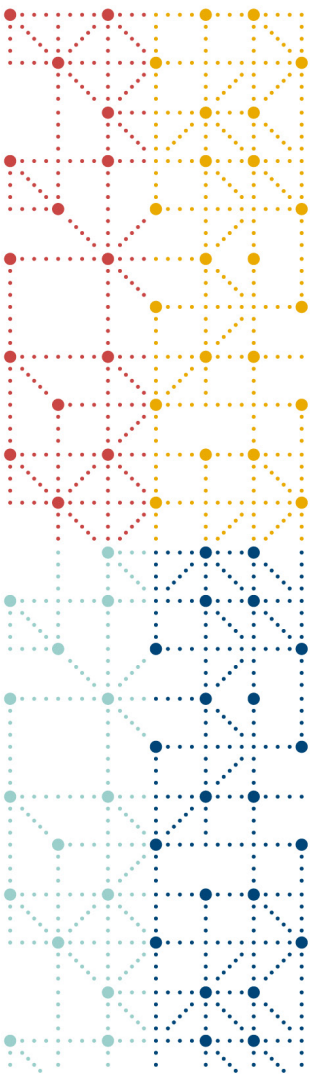
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Agenda

1. Workstream 4 (Use Case 1) Intro
2. Approach for our Proof of Concept
3. Demo
4. Learnings so far



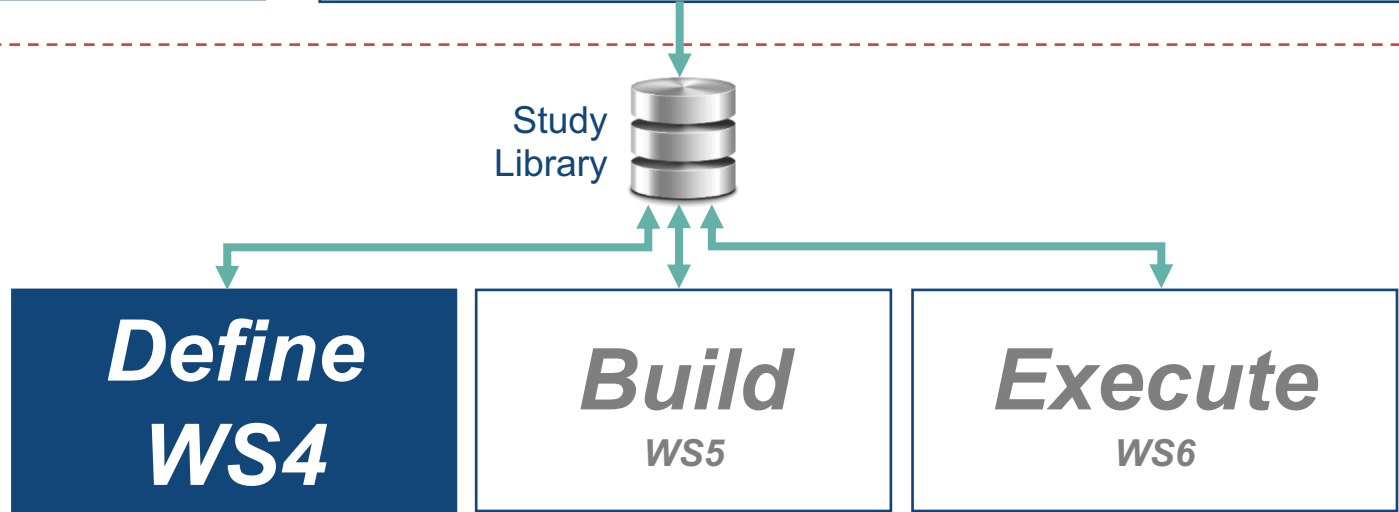
Workstream 4 (Use Case 1) - DEFINE

End to Start Standards Specification

Selecting standards concepts and linked metadata needed for a study

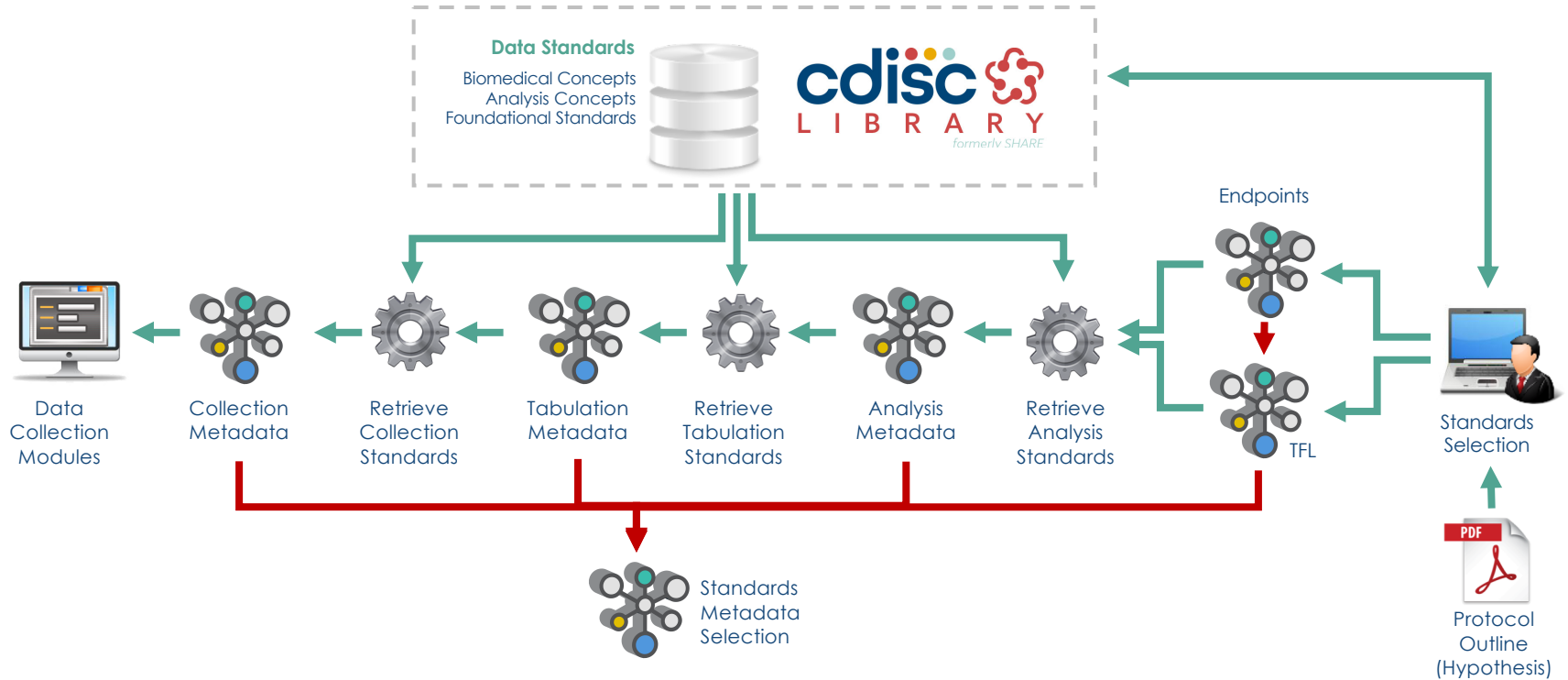
Identify and select standards specification

CDISC 360 Workstreams



Use Case 1 : Define

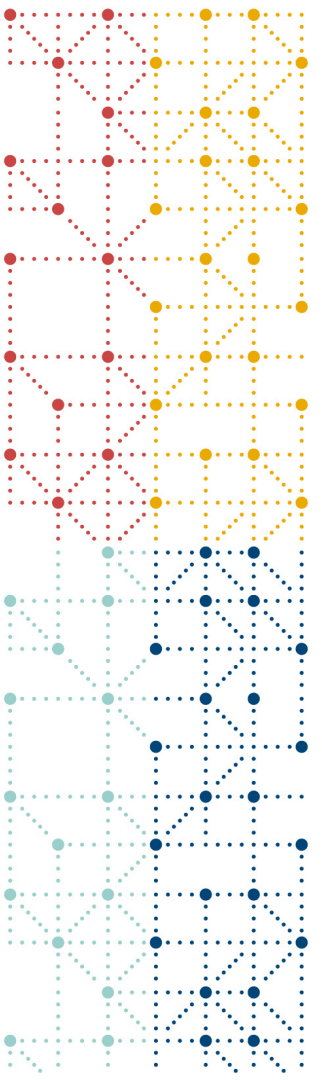
Selecting standards concepts and linked metadata needed for a study





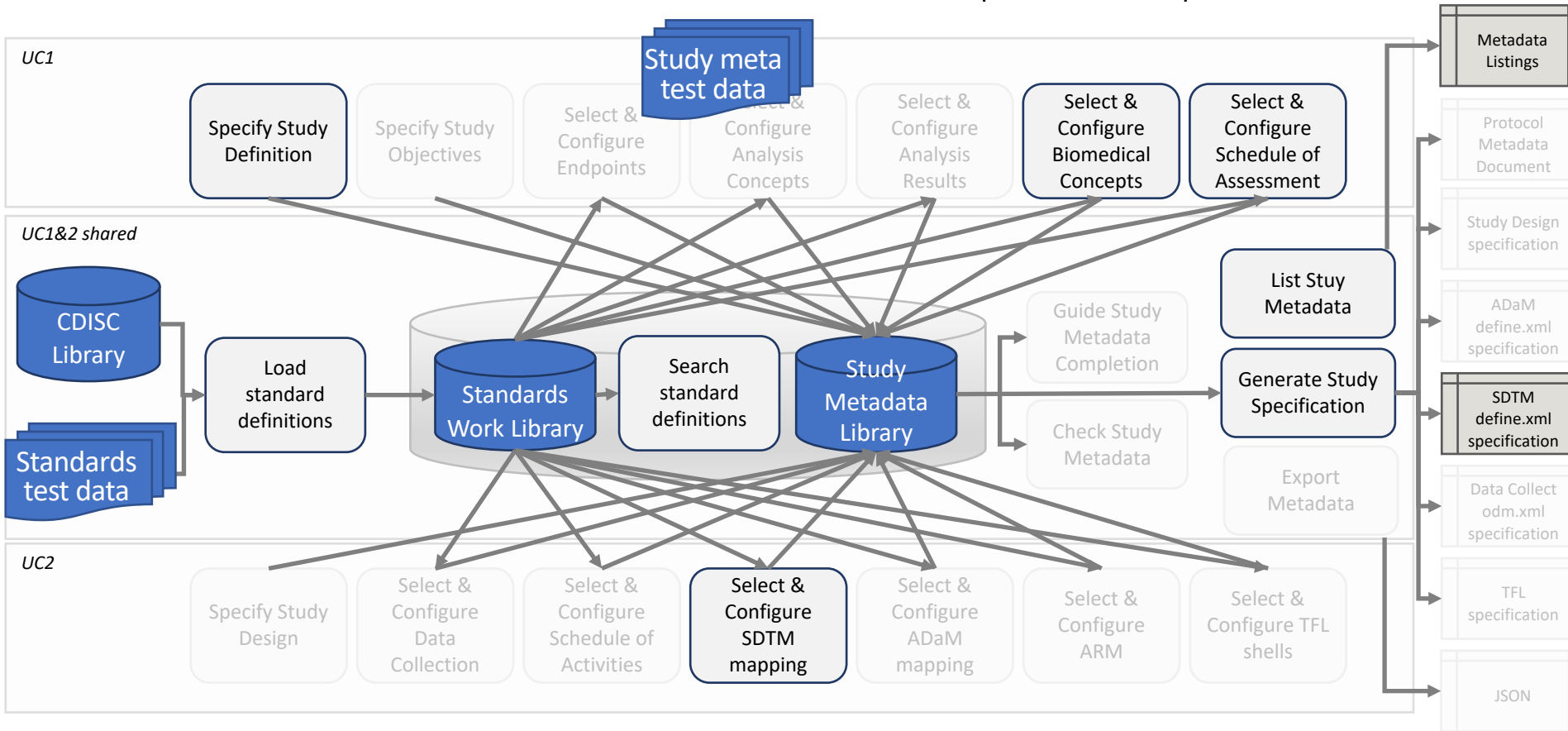
Goal for WS4 Proof of Concept (POC)

- Import Concept Based standards
 - Including end-to-end definitions
- Select Concept Based standards to be used in a study
 - Search and select concept standards for a study
- Deliver selection of Concept standards to support study configuration
 - Concepts will drive CDASH-SDTM-ADaM-Output automation
- To limit scope
 - we start in the middle with SDTM,
 - we now add CDASHIG,
 - and later ADaM, Endpoints, TFLs



Approach for our Proof of Concept

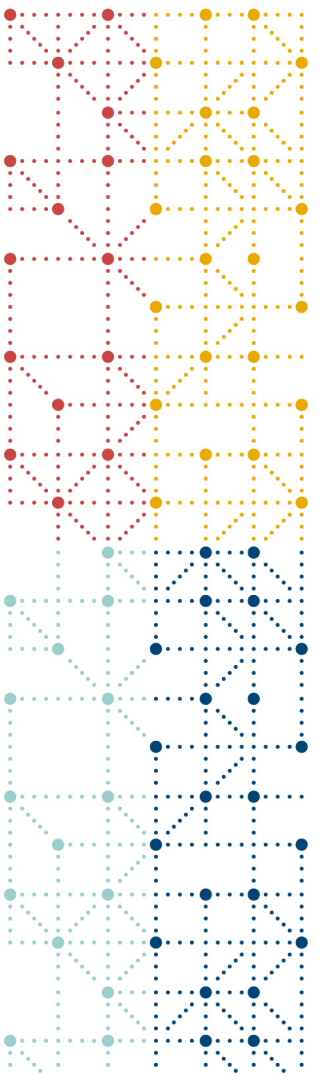
Draft user stories related to CDISC 360 WS4/5 – Scope in next sprints





Study Library POC in Label Property Graph Model (Neo4j)

- What is a Label Property Graph
 - A linked graph model where nodes can have properties and unique relationships
- Why
 - Representing study metadata close to our logical model
 - Enable dynamic linking between study definition and standards metadata
 - Cypher Query language very efficient for POC development
- How
 - In program scripts
 - Simple listing exports in CSV files
 - Simple Browser Guide Apps
 - Generic GUI (Bloom)
 - Interface with Python and SAS
 - Rapid application developments



Demo

List Study Metadata

\$:play https://360filestore.blob.core.windows.net/neo4j-browser-guides/cdisc360-neo4j-landing.html



Jump to other guides

- List study metadata
- List objectives and endpoints
- List selected activities and assessments

\$ MATCH (s:Study)-->(ig:SDTMIGVersion)-[r:REQUIRED_DOMAINS]->(d:SDTMDataset)-->(v:SDTMVar...

	study_id	sdtm_dataset	order	variable_name	label	data_type	length	core	codelist
Table	"CDISC360-1"	"DM"	1	"STUDYID"	"Study Identifier"	"Char"	"40"	"Req"	null
Text	"CDISC360-1"	"DM"	2	"DOMAIN"	"Domain Abbreviation"	"Char"	"8"	"Req"	null
Code	"CDISC360-1"	"DM"	3	"USUBJID"	"Unique Subject Identifier"	"Char"	"40"	"Req"	null
	"CDISC360-1"	"DM"	4	"SUBJID"	"Subject Identifier for the Study"	"Char"	"40"	"Req"	null
	"CDISC360-1"	"DM"	5	"RFSTDTC"	"Subject Reference Start Date/Time"	"Char"	"64"	"Exp"	null

Search for Concepts in Standards Work Library

Search via light Apps



CDISC 360

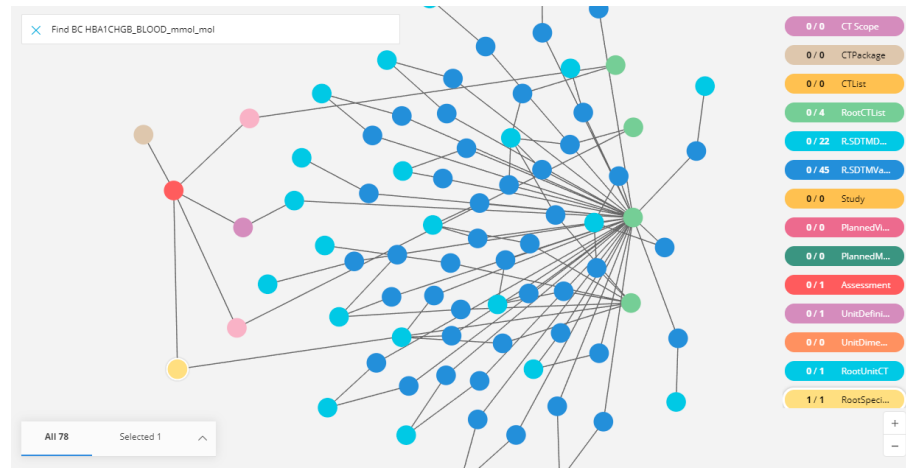
jump to other guides

- List study metadata
- List objectives and endpoints
- List selected activities and assessments
- List CDASHIG
- List SDTMIG
- List ADaMIG

```
$ MATCH (s:Study)-[*3]->(a:Assessment) RETURN DISTINCT s.id as study_id, a.name as bc_name
```

study_id	bc_name	param	paramcd
"CDISC360-1"	"Weight"	"Body Weight (kg)"	"WEIGHT"
"CDISC360-1"	"HbA1c per Total Hemoglobin"	"HbA1c (%)"	"HPA1CP"
"CDISC360-1"	"Height"	"Height (m)"	"HEIGHT"

Search via generic graph GUI



Find BC HBA1CHGB_BLOOD_mml_mol

- 0/0 CT Scope
- 0/0 CTPackage
- 0/0 CTList
- 0/4 RootCTList
- 0/22 RSDTM...
- 0/45 RSDTMVa...
- 0/0 Study
- 0/0 PlannedW...
- 0/0 Planned...
- 0/1 Assessmen...
- 0/1 UnitDefini...
- 0/0 UnitDeme...
- 0/1 RootUnicCT
- 1/1 RootSpeci...

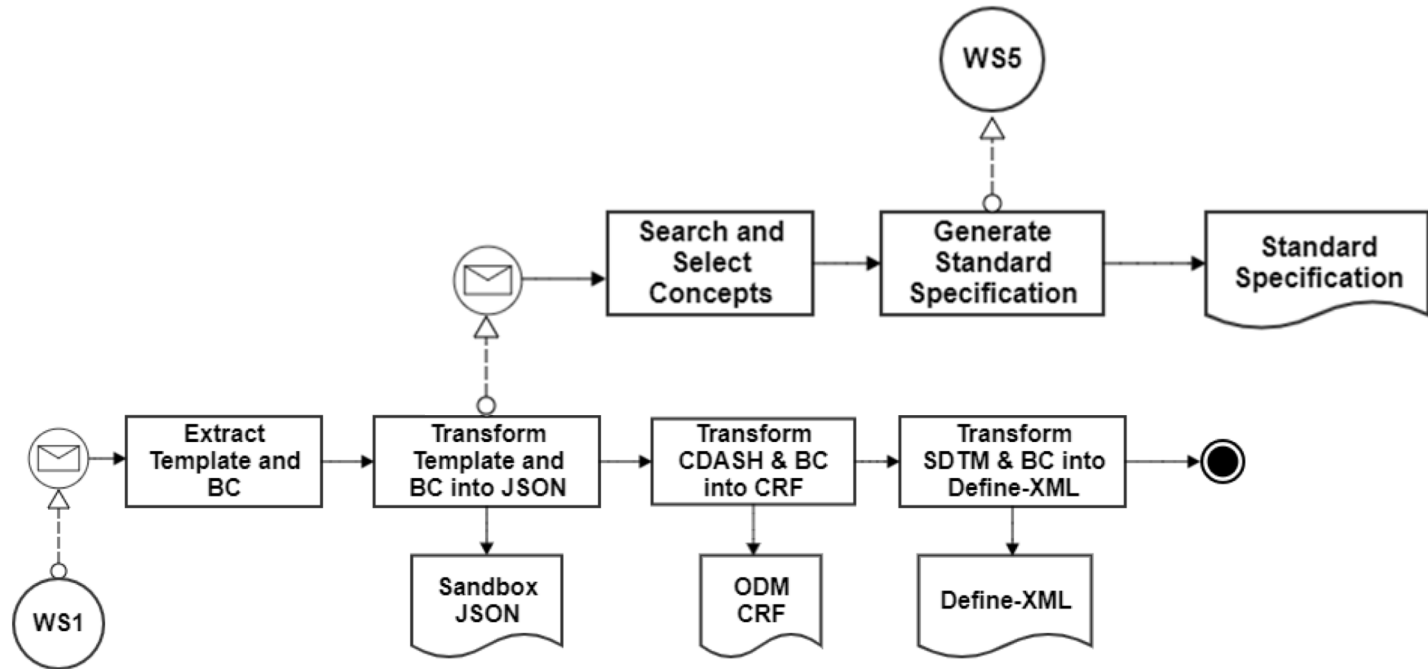
All 78 Selected 1

Select Standards for a Study - via Cypher Script program

```
// Create Study node
CREATE (s:Study {id: 'CDISC360-2',
                title: 'A Double-Blind, Placebo-
Controlled Study of the Safety and Efficacy of Drug A in Patients w
ith Type 2 Diabetes',
                CTgov: 'NCT01234567',
                EUDRACT: '2019-012345-42'}));

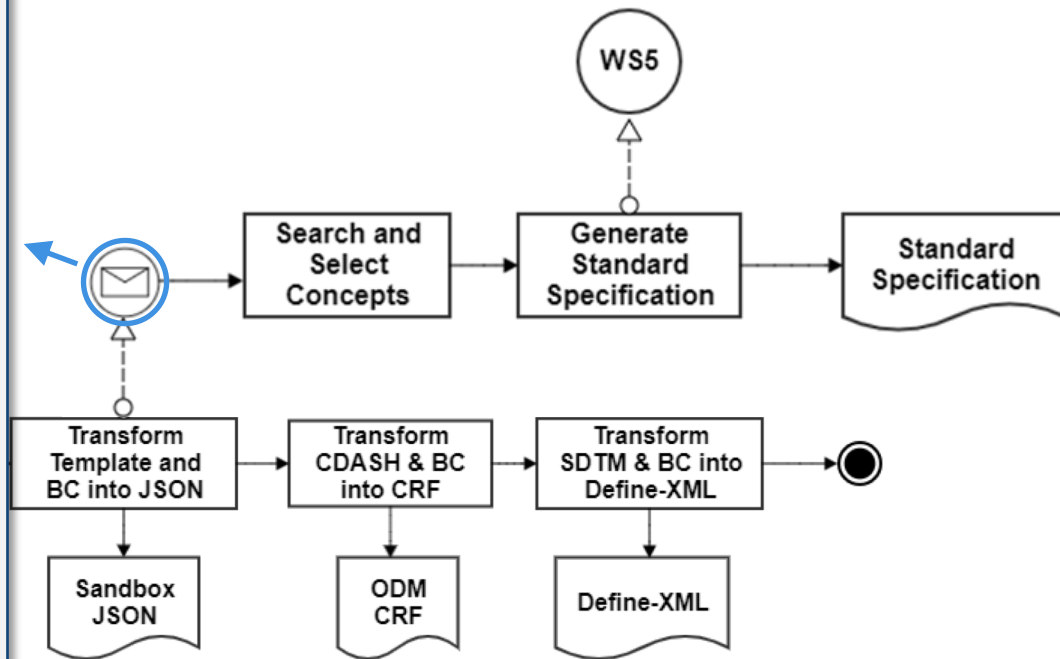
// Select Trial Phase
MATCH (s:Study), (p:RootTPhase {submission_value:'PHASE III TRIAL'})
CREATE (s)-[:IS_A]->(p);
```

How do we load BC JSON files into Study Library



How do we load BC JSON files into Study Library

```
{
  "designation": "VS_BC",
  "label": "Vital Signs Activity Concept",
  "description": "A findings domain that contains...",
  "_links": {
    "self": {
      "href": "/mdr/bc/1-0/VS",
      "title": "Vital Signs Activities",
      "type": "VS Biomedical Concept"
    },
    "parentProduct": {
      "href": "/mdr/bc/1-0",
      "title": "Biomedical Concepts Version 1.0 (Final)",
      "type": "Biomedical Concept"
    }
  },
  "biomedicalConcepts": [
    {
      "designation": "Temperature",
      "conceptId": "X25206",
      "label": "Body Temperature",
      "definition": "The property of a .... (NCI)",
      "testCode": "TEMP",
      "testConceptId": "C25206",
      "testName": "Temperature",
      "loincCode": "8310-5",
      "resultType": "Numeric",
      "unitList": [
        "C (C42559)", "F (C44277)"
      ],
      "standardUnit": "C (C42559)",
      "_links": {
```



How do we load BC JSON files into Study Library

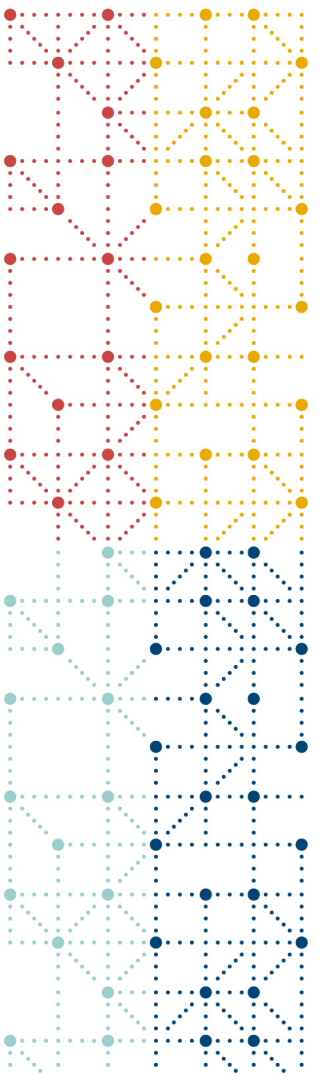
```
{
  "designation": "VS_BC",
  "label": "Vital Signs Activity Concept",
  "description": "A findings domain that contains...",
  "_links": {
    "self": {
      "href": "/mdr/bc/1-0/Vs",
      "title": "Vital Signs Activities",
      "type": "VS Biomedical Concept"
    },
    "parentProduct": {
      "href": "/mdr/bc/1-0",
      "title": "Biomedical Concepts Version 1.0 (Final)",
      "type": "Biomedical Concept"
    }
  },
  "biomedicalConcepts": [
    {
      "designation": "Temperature",
      "conceptId": "X25206",
      "label": "Body Temperature",
      "definition": "The property of a .... (NCI)",
      "testCode": "TEMP",
      "testConceptId": "C25206",
      "testName": "Temperature",
      "loincCode": "8310-5",
      "resultType": "Numeric",
      "unitList": [
        "C (C42559)", "F (C44277)"
      ],
      "standardUnit": "C (C42559)",
      "_links": {
```

```
// Load directly from JSON file pused into /import folder via Git
CALL apoc.load.jsonParams("file:/vs_bc.json", null, null) yield value as link1
WITH link1
MERGE (act:ActivityBC {designation: link1.designation})
SET act.label      = link1.label,
    act.description = link1.description,
    act.href       = link1._links.self.href
WITH link1, act
UNWIND link1.biomedicalConcepts as link2
MERGE (assm:AssessmentBC {designation: link2.designation})
SET assm.concept_id      = link2.conceptId,
    assm.label           = link2.label,
    assm.definition      = link2.definition,
    assm.test_code      = link2.testCode,
    assm.test_name      = link2.testName,
    assm.concept_id     = link2.conceptId,
    assm.loinc_code     = link2.loincCode,
    assm.result_type    = link2.resultType,
    assm.standard_unit  = link2.standardUnit
WITH link2, act, assm
UNWIND link2._links as link3
SET assm.cdashig_variable_binding = link3.cdashigVariableBinding.href,
    assm.sdtmig_variable_binding = link3.sdtmigVariableBinding.href
WITH link2, act, assm
MERGE (act)-[r:HOLDS]->(assm)
RETURN act, assm;
```

How do we load BC JSON files into Study Library

- Visual of BC in Neo4j

Work in Progress

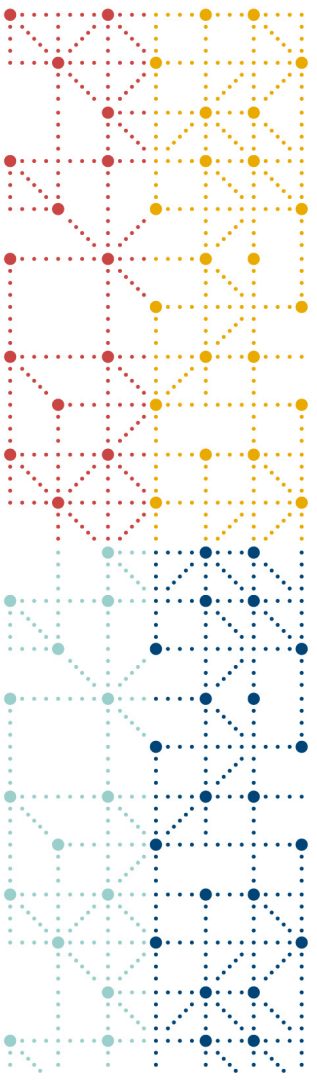


Learnings so far



Learnings from initial implementation of Study Library in a Property Label Graph database (Neo4j)

- Very efficient to load JSON data from API's into Neo4j with no duplication of metadata
- Intuitive to represent BCs in a Property Label Graph Model linked with metadata from the CDISC Library
- Intuitive to define and query standards selections for a study in Property Label Graph Model
- Difficult to articulate and agree on what a BC is
 - Iterations are needed to learn and evolve definitions of a BC
- Learning new tools takes time
- Working and setting things up in Azure require support
 - Big thanks to Microsoft, Neo4j and CDISC IT



Thank You!

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cdisc