CDISC 360 Use Cases - Industry Perspectives

Workstream 4 - DEFINE

Use Case 1: End to Start Standards Specification

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• The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.
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

Enhance Standards  
WS1

Publish Standards  
WS2

Define Study Library  
WS4

Build  
WS5

Execute  
WS6
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

UC1

Specify Study Definition
Specify Study Objectives
Select & Configure Endpoints
Select & Configure Analysis Concepts
Select & Configure Analysis Results
Select & Configure Biomedical Concepts
Select & Configure Schedule of Assessment

UC1 & UC2

CDISC Library

Specify Study Design
Select & Configure Data Collection
Select & Configure Schedule of Activities
Select & Configure SDTM mapping
Select & Configure ADaM mapping
Select & Configure ARM
Select & Configure TFL shells

CDISC Library

Load standard definitions
Search standard definitions
Study Metadata Library

UC2

Specify Study Design
Select & Configure Data Collection
Select & Configure Schedule of Activities
Select & Configure SDTM mapping
Select & Configure ADaM mapping
Select & Configure ARM
Select & Configure TFL shells

Study Meta data

Generate Study Specification
Guide Study Metadata Completion
Check Study Metadata
Export Metadata

List Stuy Metadata

Specify Study Evaluation

Study Design specification
ADaM define.xml specification
SDTM define.xml specification
Data Collect odm.xml specification
TFL specification
JSON
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
### List Study Metadata

#### Query

```
MATCH (s:Study)-->(ig:SDTMIGVersion)-->(r:REQUIRED_DOMAINS)-->(d:SDTMDataset)-->(v:SDTMVar...)
```

#### Table

<table>
<thead>
<tr>
<th>study_id</th>
<th>sdtm_dataset</th>
<th>order</th>
<th>variable_name</th>
<th>label</th>
<th>data_type</th>
<th>length</th>
<th>core</th>
<th>codelist</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDISC360-1</td>
<td>'DM'</td>
<td>1</td>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>'Char'</td>
<td>'40'</td>
<td>'Req'</td>
<td>null</td>
</tr>
<tr>
<td>CDISC360-1</td>
<td>'DM'</td>
<td>2</td>
<td>DOMAIN</td>
<td>Domain Abbreviation</td>
<td>'Char'</td>
<td>'8'</td>
<td>'Req'</td>
<td>null</td>
</tr>
<tr>
<td>CDISC360-1</td>
<td>'DM'</td>
<td>3</td>
<td>USUBJID</td>
<td>Unique Subject Identifier</td>
<td>'Char'</td>
<td>'40'</td>
<td>'Req'</td>
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</tr>
<tr>
<td>CDISC360-1</td>
<td>'DM'</td>
<td>4</td>
<td>SUBJID</td>
<td>Subject Identifier for the Study</td>
<td>'Char'</td>
<td>'40'</td>
<td>'Req'</td>
<td>null</td>
</tr>
<tr>
<td>CDISC360-1</td>
<td>'DM'</td>
<td>5</td>
<td>RFSTDTDC</td>
<td>Subject Reference Start Date/Time</td>
<td>'Char'</td>
<td>'64'</td>
<td>'Exp'</td>
<td>null</td>
</tr>
</tbody>
</table>
Search for Concepts in Standards Work Library

Search via light Apps

Search via generic graph GUI
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 with 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

1. Extract Template and BC
2. Transform Template and BC into JSON
3. Transform CDASH & BC into CRF
4. Transform SDTM & BC into Define-XML
5. Search and Select Concepts
7. Standard Specification

WS1

WS5
How do we load BC JSON files into Study Library

```json
{
    "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

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  "description": "A findings domain that contains...
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      "title": "Biomedical Concepts Version 1.0 (Final)",
      "type": "Biomedical Concept"
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    "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

• Visual of BC in Neo4j
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 CDIC 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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