1. Introduction, Future State, Process and Architecture of the PoC – Bhavin and Mikkel

2. PoC for Study Design and Configuration using CDISC 360 Concept-based Standards – Mikkel and Nicolas

3. Automation of SDTM & ADaM Generation and Artifacts using CDISC 360 Enriched Metadata – Bhavin and Jimmy

4. Automation of TFL Generation using CDISC 360 Enriched Metadata – Bhavin, Prasanna & Stuart

5. Concluding Remarks and Next Steps – Bhavin and Mikkel

6. Q & A session
Automation of SDTM & ADaM Generation and Artifacts using CDISC 360 Enriched Metadata

Bhavin Busa (Vita Data Sciences), Jianhui [Jimmy] Zhao (AbbVie)
CDISC 2020 US Interchange
October 07, 2020
Agenda

1. Process Flow for CDISC 360 Proof of Concept
3. SDTM/ADaM Automation Engine – PoC Design
4. SDTM/ADaM Automation Engine – Live Demo
5. Learnings from CDISC 360 PoC
Study Specifications from WS4

Speaker: Bhavin

Formats:
- XML
- CSV
- SAS
Machine-readable Mapping Specifications
Essential Elements for Machine-readable Mapping Specifications

We break down the essential elements in 2 dimensions to meet the 4 key aspects of the machine readability

Dimension 1

- **Source**: location (library name), datasets, processing sequence
- **Mapping**: fields needed to describe how source transits to target
- **Target**: location (library name), datasets, processing sequence, attributes (label, class, structure, purpose, etc.)

Dimension 2

- **Dataset Level**: Transit datasets from source to target
- **Variable Level**: Map variables from source to target
- **Value Level**: Map variables from source to target under different conditions
# Mapping Specifications: Dimension 1

**Mapping Details:**

**Source:** CDASH VS

**Target:** Study Identifier

**Mapping:**

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<th>Source Library</th>
<th>Source Dataset</th>
<th>Source Variable</th>
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**Target Details:**

**Target Library:** CDISC VS

**Target Dataset:** Study Identifier

**Target Variable:**

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Dataset Level

Variable Level

Value Level
Mapping Specifications: Dataset Level

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```plaintext
data VS1;
  set CDASH.VS;
  /********
  variable level: Source Sequence = 1
  ********/
run;

proc sort data=VS1; by SUBJID;
proc sort data=CDAHS.DM OUT=DM2; by USUBJID;

data VS2;
  merge DM2(in=a) VS1(in=b);
  by USUBJID;
  if b;
  /********
  variable level: Source Sequence = 2
  ********/
run;

... Sequence 3, 4, 5, 6

proc sort data=VS6;
  by USUBJID VSTESTCD VISITNUM VSDTC;
run;

data SDTM.VS;
  set VS6;
  by USUBJID VSTESTCD VISITNUM VSDTC;
  /********
  variable level: Source Sequence = 5
  ********/
run;
```
Mapping Specifications: Variable Level

---

**Variable Level Processing**

```sas
data VS1;
  set CDASH.VS;

  ***** Variable level processing ;
  1. DOMAIN = 'VS';
  2. USUBJID = catx('.', STUDYID, SUBJID);
  3. VISITNUM = input(put(VISIT, $VISITNUM.), BEST.);
  4. [origin = Predecessor, do nothing];
  5. if not missing(VISDAT) then
     VSDTC = put(VISDAT, E8601DA.);
  else if not missing(VSDAT) then
    VSDTC = put(VSDAT, E8601DA.);
  6. if VISIT = "VISIT 2 (WEEK 0)" then VSBLFL = 'Y';
run;
```

---

**Source Variable Mapping**

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<th>Source Dataset</th>
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**SAS Code**

```sas
USUBJID = catx('', STUDYID, SUBJID);
if not missing(VISDAT) then
  VSDTC = put(VISDAT, E8601DA.);
else if not missing(VSDAT) then
  VSDTC = put(VSDAT, E8601DA.);
if VISIT = "VISIT 2 (WEEK 0)" then VSBLFL = 'Y';
run;
```
Mapping Specifications: Value Level

```plaintext
data VS3;
  set CDASH.VS;

  if DIABP_VSPREF = 'Y' then do;
    VSTESTCD = 'DIABP';
    VSORRES = DIABP_VSORRES;
    VSORRESU = DIABP_VSORRESU;
    VSSTRESN = 'mmHg';
    VSSTRESN = INPUT(VSORRES, BEST.);
    VSSTRESC = PUT(VSSTRESN, 4.0);
    VSPOS = DIABP_VSPOS;
    OUTPUT;
  end;

  *** CONTINUTE ***;

  if HEIGHT_VSPREF = 'Y' then do;
    VSTESTCD = 'HEIGHT';
    VSORRES = HEIGHT_VSORRES;
    VSORRESU = HEIGHT_VSORRESU;
    VSSTRESN = 'm';
    VSSTRESN = INPUT(VSORRES, BEST.);
    VSSTRESC = PUT(VSSTRESN, 4.0);
    OUTPUT;
  end;
run;
```

Speaker: Jimmy
SDTM/ADaM Automation Engine – Proof of Concept Design
CDISC 360 – SDTM/ADaM Automation Engine PoC Design

CDISC 360 Enriched Mapping Specifications

- Import Metadata
- Edit Metadata
- Review Data

R Shiny (front-end) & SAS

- Generate SAS Program
- Run SDTM/ADaM Automation Engine

Study Level CDASH or SDTM

- Review & Execute SAS Program
- Generate Target Dataset
- Generate Define.xml

Speaker: Bhavin
### R-Shiny Front-end Interface: Automate Execution

#### Data Browser

**Folder Name**: CDASH

**File Name**: dm.sas7bdat

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Showing 1 to 10 of 100 entries
### Metadata Import/Editor

**Folder Name**
- Metadata

**File Name**
- cdash2sdtm_v1.1.xlsx

**Metadata Sheet**
- Variables

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R-Shiny Front-end Interface: Automate Execution

Metadata Import/Editor

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- Metadata

File Name
- cdash2sdmt_v1.1.xlisp

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- Variables

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Showing 1 to 10 of 75 entities

Speaker: Bhavin
SDTM/ADaM Automation Engine – Live Demo!
Learnings from CDISC 360 PoC

Machine-readable Metadata
Machine-readable Metadata

- CDISC 360 Enriched Metadata = Structural + Conceptual + Semantic + Process [Key to Automation]
  - Content is part of the standards (CDISC library)
  - ETL Metadata (mapping inference & derivation)
- System agnostic standards, concepts and elements
  - Can be consumed by any tool
  - Organization can build an automation engine their own way
Thank You!

Bhavin Busa, *Vita Data Sciences*
Jianhui [Jimmy] Zhao, *AbbVie*