

CDISC 360

Session 4, Track C: CDISC 360, Part II



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1. Introduction, Future State, Process and Architecture of the PoC – *Bhavin and Mikkel* 10 mins
2. PoC for Study Design and Configuration using CDISC 360 Concept-based Standards – *Mikkel and Nicolas* 20 mins
3. Automation of SDTM & ADaM Generation and Artifacts using CDISC 360 Enriched Metadata – *Bhavin and Jimmy* 20 mins
4. **Automation of TFL Generation using CDISC 360 Enriched Metadata – *Bhavin, Prasanna & Stuart*** 20 mins
5. Concluding Remarks and Next Steps – *Bhavin and Mikkel* 5 mins
6. Q & A session 15 mins

Automation of TFL Generation using CDISC 360 Enriched Metadata

Bhavin Busa (Vita Data Sciences), Prasanna Murugesan (AstraZeneca) & Stuart Malcolm (Frontier Science)

CDISC US Interchange 2020

Oct 7th, 2020



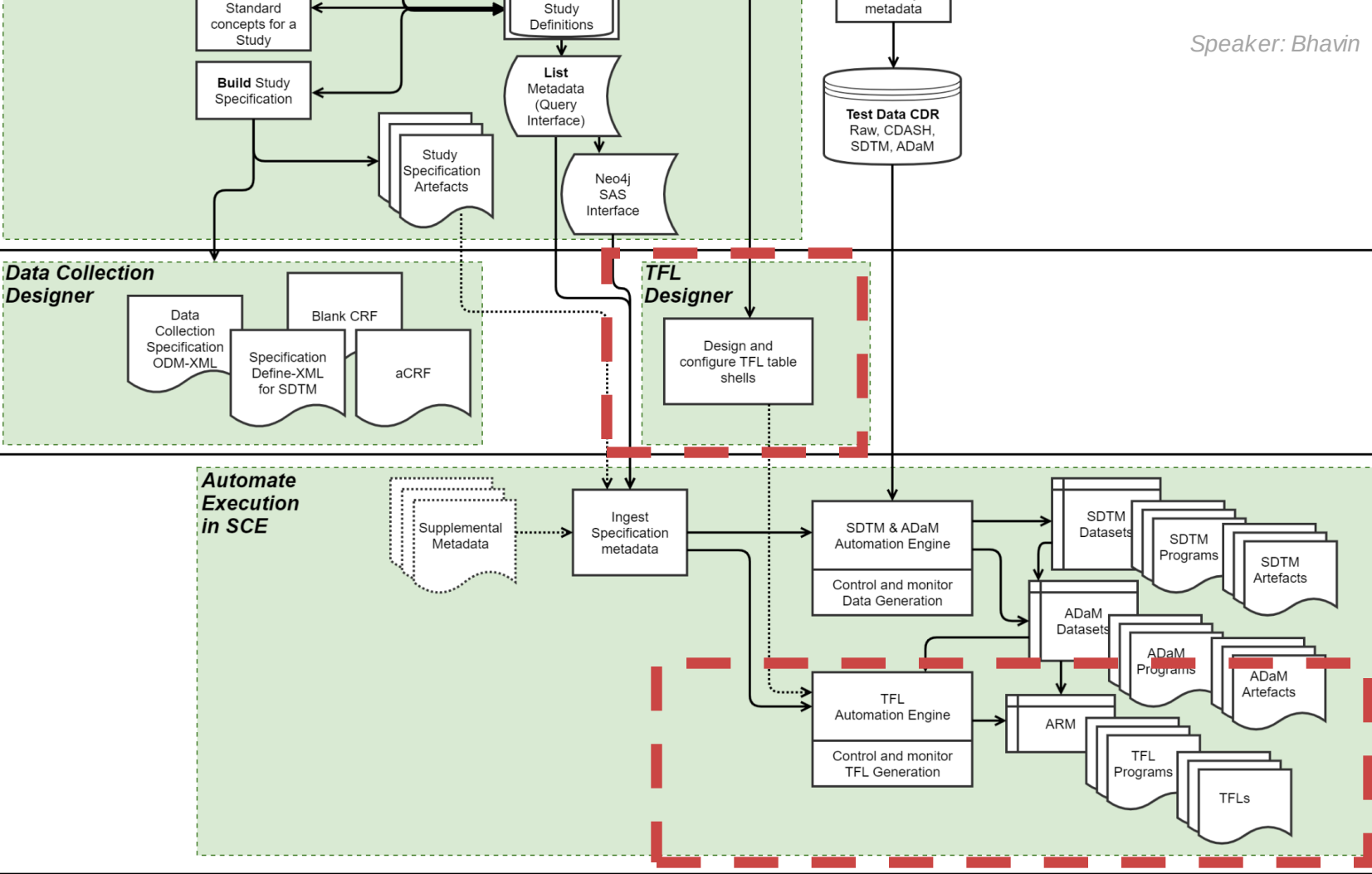
Agenda

1. Process Flow for CDISC 360 Proof of Concept (PoC)
2. CDISC 360 Enriched Metadata
 - ❑ CDISC 360 Enriched (Machine-readable) TFL Metadata
3. TFL Automation Engine – PoC Design
4. TFL Automation Engine – Live Demo
5. Learnings from CDISC 360 PoC

CDISC 360 PoC

WS4 & 6

WS6



CDISC 360: The Art of the Possible

The screenshot displays the CDISC 360 web application interface. The top navigation bar includes the CDISC 360 logo, "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and user profile and settings icons. The left sidebar contains a vertical list of six selection steps, each with a numbered circle and a checkmark indicating completion:

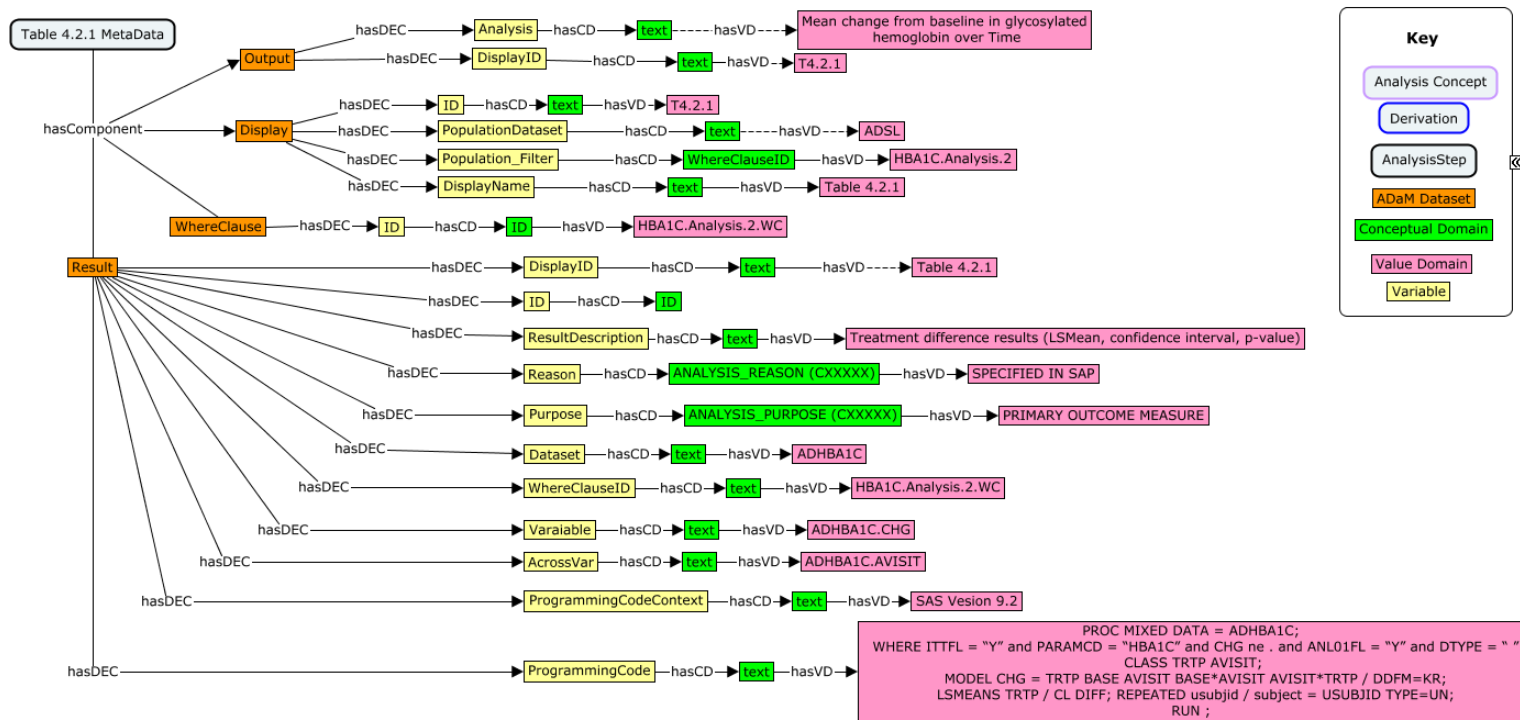
- 1 Disease Area (Endocrine)
- 2 Therapeutic Area (Diabetes - Type 2)
- 3 Standards Focus (Study Endpoint)
- 4 Study Endpoint (Analysis of Glycated Hemoglobin)
- 5 Standard Analyses (Mean Change from Baseline in HbA1c (%) Over Time)
- 6 Selection Summary (highlighted with a blue circle)

The main content area is titled "Selection Summary" and is divided into three columns:

- Study Endpoint:** Displays "Analysis of Glycated Hemoglobin" with a description: "Analysis of the continuous clinical endpoint of HbA1c. Example: a Phase III, parallel-group study designed to determine efficacy of Drug A for patients with Type II diabetes. The primary endpoint defined as the change in HbA1c from baseline." and a "View details" link.
- Analysis:** Displays "Mean Change from Baseline in HbA1c (%) Over Time" with a line graph showing mean change over time for two groups (Drug A and Drug B) and a "View details" link.
- Analysis Datasets:** Displays "ADSL" (Analysis Data Subject Level) and "ADHBA1C" (DBS - Structured Dataset), each with links to "View analysis dataset metadata", "View sample analysis data", and "View analysis dataset structure".

At the bottom of the main content area, there is a "Back" button and a "Save Selection" button.

Analysis Result Concept



CDISC 360 Enriched (Machine-readable) TFL Metadata

CDISC ARM v1 Metadata

Study - CDISC 360

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.

Datasets used - adsl

Executed by <Username> on DDMONYYYY:HH:MM

Result

ResultOID

Description

Reason

Purpose

Dataset

WhereClause

AnalysisVariable

Documentation

ProgrammingCode

Display

DisplayOID

Name

Title

Document

CDISC ARM v1 Metadata Extensions

Output

(Study, Analysis, Group, Filename/Type, Style)

Result

Version
DisplayPattern
Grouping
- AnalysisVar
- ByVar
CodeReference

Study - CDISC 360

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.

Datasets used - adsl

Executed by <Username> on DDMONYYYY:HH:MM

Display

Parent
Version
Grouping:
- Dataset
- WhereClause
- AnalysisVar
- ByVar
Template
Title 1..N
RowLabelHeader
Header 1..N
Footer 1..N

CDISC 360 Enriched TFL Metadata (ARM⁺⁺)

- Based on CDISC ARM v1
- Added OUTPUT & STYLE
- Extended DISPLAY and RESULT
 - Parent
 - Version
 - Grouping and ByVar
 - CodeReference
- Use-cases for production TFL automation

CDISC 360 Enriched TFL Metadata (ARM⁺⁺): Sample

Study - CDISC 360

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.
Datasets used - adsl
Executed by <Username> on DDMMYYYY:HH:MM

Study	Analysis	Group	Order	DisplayID	DisplayVersion	Filename	Type	StyleID
CDISC	CDISC 360	Safety	1	T14111_SAF_DEMOG	1	tdemog_saf	rtf	table_rtf
CDISC	CDISC 360	Safety	2	T14131_SAF_AE2TIER	1	tae_soc_pt_saf	rtf	table_rtf
CDISC	CDISC 360	Efficacy	3	T1421_EFF	1	tmace_edpt_fas	rtf	table_rtf

Output Display Result WhereClause Style TFL Metadata Tables TFL Metadata ...

DisplayID	DisplayName	DisplayTitle	Title1	Title2	Title3
T14111_SAF_DEMOG	Table 14.1.1.1	Demographic characteristics (SAF)	Study - CDISC 360	Table 14.1.1.1	Demographic characteristics (Safety Population)

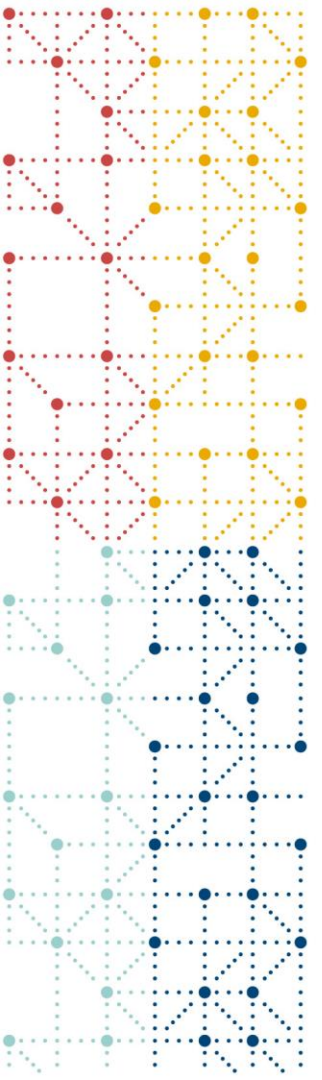
Output Display Result WhereClause Style TFL Metadata Tables TFL Metadata Variables ...

ResultDisplayOID	AnalysisResultOID	Version	ResultDescription	DisplayPattern
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	n	xxx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Mean	XX.X
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	SD	XX.XX
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Min	XX
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Q25	XX.X
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Median	XX.X
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Q75	XX.X

Output Display Result WhereClause Style TFL Metadata Tables TFL Metadata Variables ...

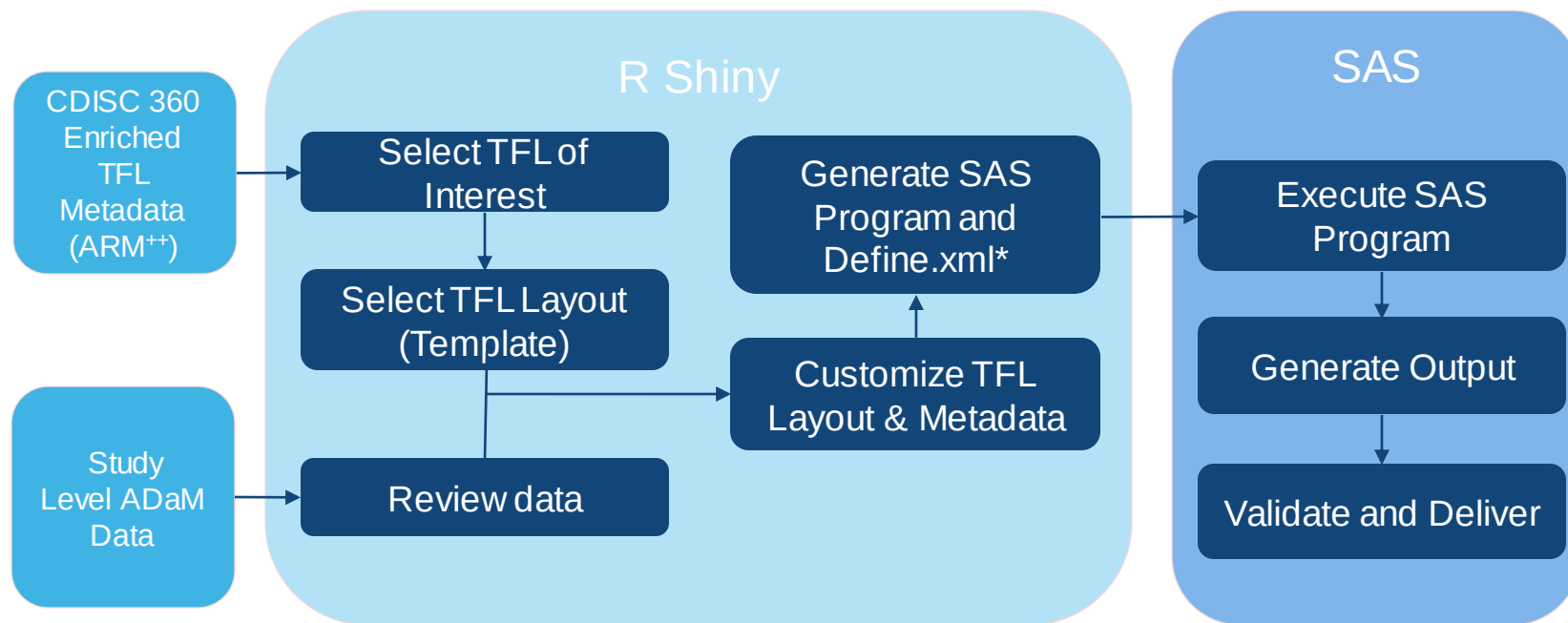
WhereClauseOID	Dataset	Variable	Comparator	Value
T14111_02_SAF_DEMOG_01	ADSL	AGEGR1	EQ	15 <= to <30 years
T14111_02_SAF_DEMOG_02	ADSL	AGEGR1	EQ	30 <= to <45 years
T14111_02_SAF_DEMOG_03	ADSL	AGEGR1	EQ	>=45 years
T14111_03_SAF_DEMOG_01	ADSL	SEX	EQ	M
T14111_03_SAF_DEMOG_02	ADSL	SEX	EQ	F

Output Display Result WhereClause Style TFL Metadata Tables TFL Metadata Variables ...



TFL Automation Engine – Proof of Concept Design

CDISC 360 – TFL Automation Engine PoC Design



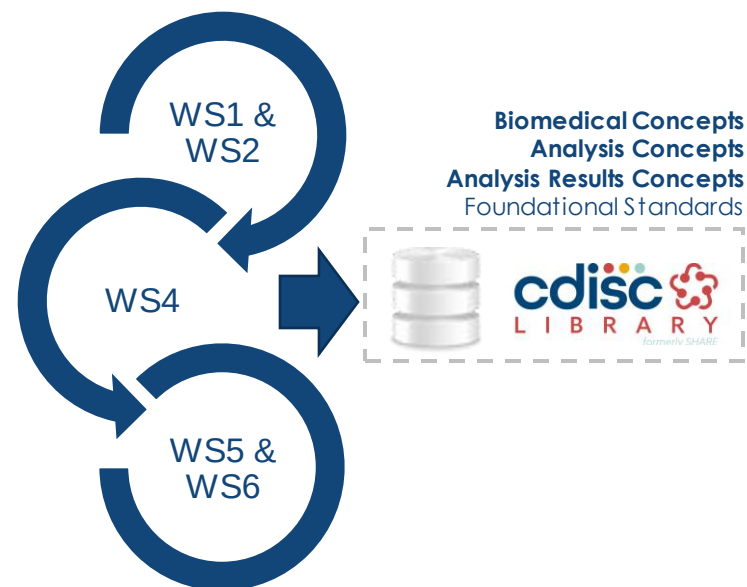
* ARM to be combined with ADaM Define

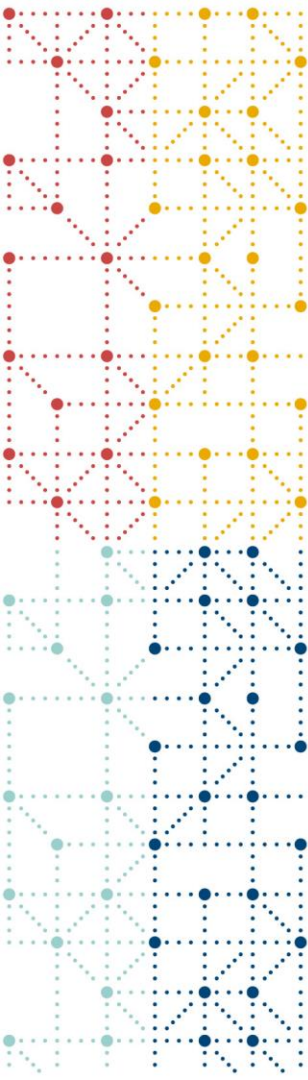
TFL Automation Engine – Live Demo!

Learnings from CDISC 360 PoC

Machine-readable TFL Metadata

- ARM + additional TFL Metadata (ARM⁺⁺)
 - Use case tested with enriched metadata
 - Can be consumed by any tool
 - Review performed by CDISC ARM team
- TFL Automation Engine PoC
 - Demonstrated execution of TFL & generation of Define.xml + ARM
 - Organization can build an automation engine their own way
- TFL Designer
 - Will help build TFL Shells and ADaM Specs



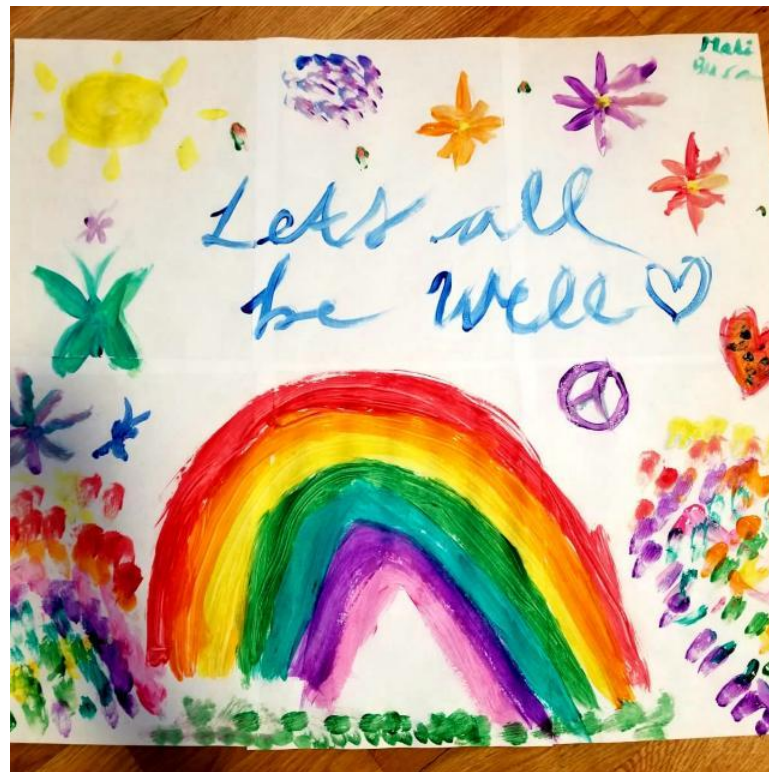


Thank You!

Bhavin Busa, *Vita Data Sciences*

Prasanna Murugesan, *AstraZeneca*

Stuart Malcolm, *Frontier Science*



Courtesy: Mahi Busa