

CDISC 360

Session 4, Track C: CDISC 360, Part II



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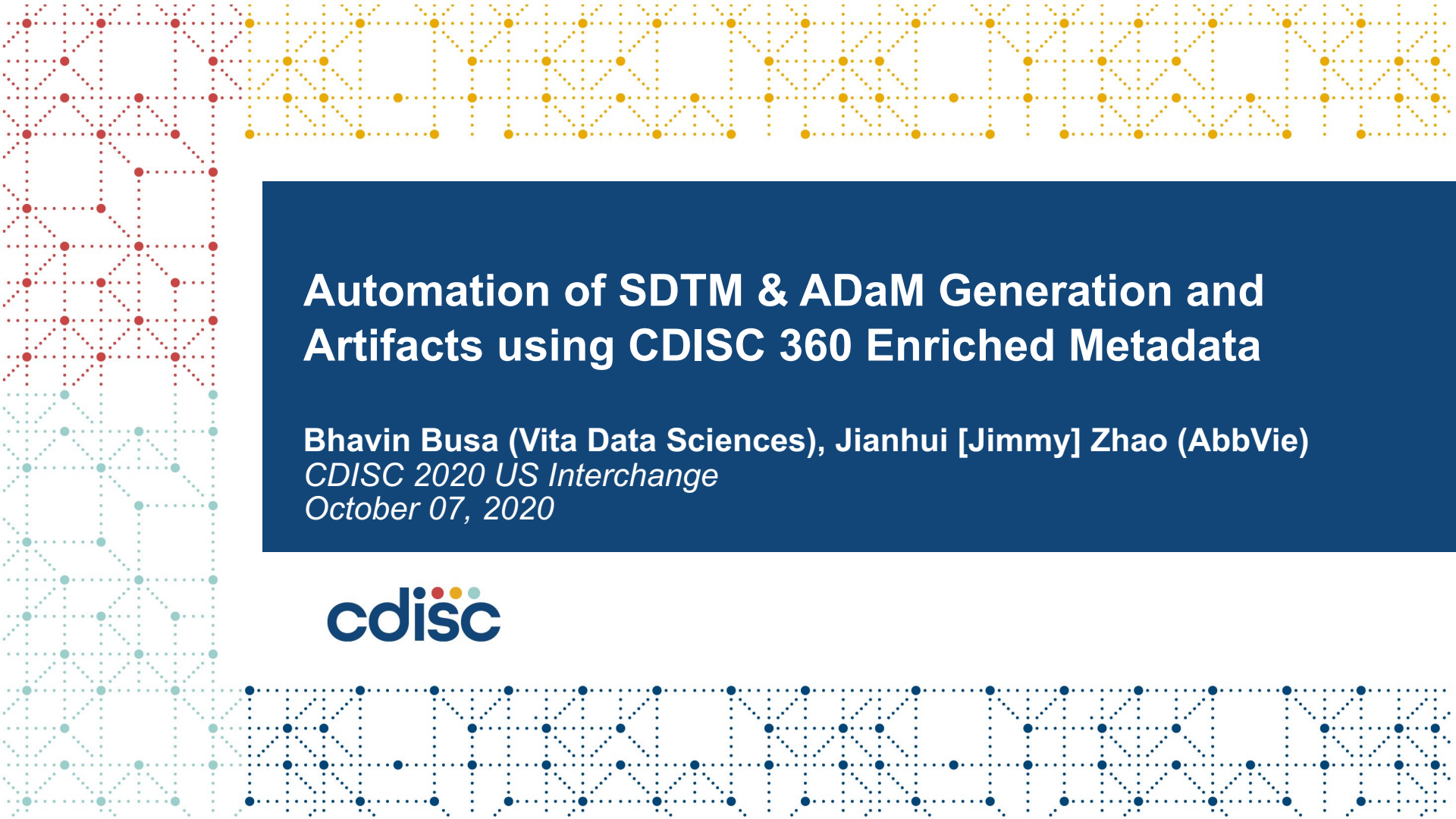
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1. Introduction, Future State, Process and Architecture of the PoC – *Bhavin and Mikkel* 10 mins
2. PoC for Study Design and Configuration using CDISC 360 Concept-based Standards – *Mikkel and Nicolas* 20 mins
3. **Automation of SDTM & ADaM Generation 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



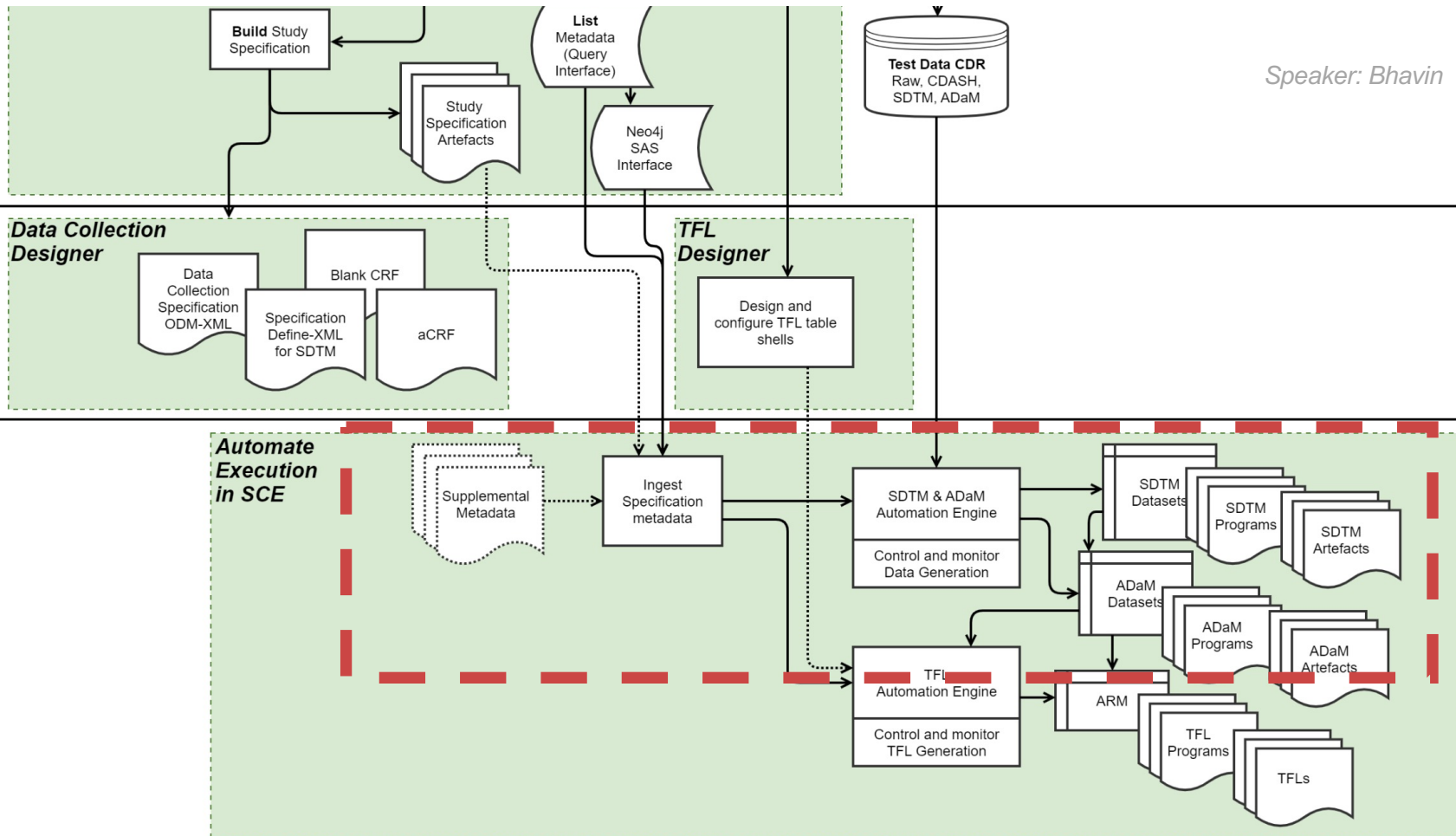
Automation of SDTM & ADaM Generation and Artifacts using CDISC 360 Enriched Metadata

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

1. Process Flow for CDISC 360 Proof of Concept
2. Machine-readable Mapping Specifications
3. SDTM/ADaM Automation Engine – PoC Design
4. SDTM/ADaM Automation Engine – Live Demo
5. Learnings from CDISC 360 PoC



Study Specifications from WS4

cdisc360 Study Builder Library Studies Define Design Select Build List Help CDISC360-2 nicolas

CDASH to SDTM

SDTM Trial Design ODM SDTM Listing SDTM Define P21 SDTM Define CST ADaM Define ▲ CTR TOC ▲ DTE

Study Datasets Variables ValueLevel

Variables

Search

STUDYID	ASSESSMENT	SRCSEQ	SRCLIB	SRCDSN	SRCVAR	SRCTYPE	MAPSEQ	ORIGIN	METHOD	COMMENT	CODELIST	TGTLIB
CDISC360-2	[PULSE, 'BODY_WEIGHT', 'HEIGHT', 'BP_DIASTOLIC', 'BODY_TEMPERATURE']	1	CDASH	VS			0	Assigned		CDISC360-2	None	SDTM
CDISC360-2	[PULSE, 'BODY_WEIGHT', 'HEIGHT', 'BP_DIASTOLIC', 'BODY_TEMPERATURE']	1	CDASH	VS			0	Assigned		VS	None	SDTM
CDISC360-2	[PULSE, 'BODY_WEIGHT', 'HEIGHT', 'BP_DIASTOLIC', 'BODY_TEMPERATURE']	1	CDASH	VS	SUBJID	text	0	Assigned	ALL.USUBJID		None	SDTM
CDISC360-2	[PULSE, 'BODY_WEIGHT', 'HEIGHT', 'BP_DIASTOLIC', 'BODY_TEMPERATURE']	1	CDASH	VS			0	Assigned	VS.VSSPID		None	SDTM
CDISC360-2	[PULSE, 'BODY_WEIGHT', 'HEIGHT', 'BP_DIASTOLIC', 'BODY_TEMPERATURE']	1	CDASH	VS	VISIT	text	0	Predecessor			None	SDTM
CDISC360-2	[PULSE, 'BODY_WEIGHT', 'HEIGHT', 'BP_DIASTOLIC', 'BODY_TEMPERATURE']	1	CDASH	VS	VSDAT	text	0	Assigned	VS.VSDTC		None	SDTM
CDISC360-2	[PULSE, 'BODY_WEIGHT', 'HEIGHT', 'BP_DIASTOLIC', 'BODY_TEMPERATURE']	1	CDASH	VS	VISDAT	text	0	Assigned	VS.VSDTC		None	SDTM
CDISC360-2	[FIRST_TRIAL_PROD_DATE, 'FIRST_TRIAL_PROD_DATE']	3	CDASH	DS_FDRUGDT	DSSTDAT	date	0	Assigned	DM.RFSTDTC		None	SDTM

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

Source				Mapping					Target						
Source Sequence	Source Library	Source Dataset	Source Variable	Map Sequence	Origin	Method	Comment	Code List	Target Library	Target Dataset	Target Variable	Target Description	Target Data Type	Target Length	Target Sorting Order
1		VS			Assigned		CDISC360-2		SDTM	VS	STUDYID	Study Identifier	text	10	1
1	CDASH	VS			Assigned		VS	DOMAIN	SDTM	VS	DOMAIN	Domain Abbreviation	text	2	2
1	CDASH	VS	SUBJID		Assigned	ALL.SUBJID			SDTM	VS	USUBJID	Unique Subject Identifier	text	14	3
1	CDASH	VS			Assigned	VS.VSSPID			SDTM	VS	VSSPID	Sponsor-Defined Identifier	text	4	5
1	CDASH	VS	VISIT		Convert			VISITNUM	SDTM	VS	VISITNUM	Visit Number	integer	8	16
1	CDASH	VS	VISIT		Predecessor			VISIT	SDTM	VS	VISIT	Visit Name	text	18	17
1	CDASH	VS	VSDAT		Assigned	VS.VSDTC			SDTM	VS	VSDTC	Date/Time of Measurements	date	10	19
1	CDASH	VS	VISDAT		Assigned	VS.VSDTC			SDTM	VS	VSDTC	Date/Time of Measurements	date	10	19
1	CDASH	VS			Derived	VS.VSBLFL			SDTM	VS	VSBLFL	Baseline Flag	text	1	14
2	SDTM	DM	RFSTDTC		Derived	VS.VSDY			SDTM	VS	VSDY	Study Day of Vital Signs	integer	8	20
2			VSDTC		Derived	VS.VSDY			SDTM	VS	VSDY	Study Day of Vital Signs	integer	8	20
3	SDTM	SV	VISITDY	1	Predecessor				SDTM	VS	VISITDY	Planned Study Day of Visit	integer	8	18
3	SDTM	SV	EPOCH	2	Predecessor			EPOCH	SDTM	VS	EPOCH	Epoch	text	9	15
4				3	Assigned	VS.VSTESTCD		VSTESTCD	SDTM	VS	VSTESTCD	Vital Signs Test Short Name	text	6	6
4				4	Derived	VS.VSORRES			SDTM	VS	VSORRES	Result or Finding in Original Units	text	4	9
4				5	Derived	VS.VSORRESU		VSUNIT	SDTM	VS	VSORRESU	Original Units	text	9	10
4				6	Assigned	VS.VSSTRESU		VSUNIT	SDTM	VS	VSSTRESU	Standard Units	text	9	13
4				7	Derived	VS.VSSTRESN			SDTM	VS	VSSTRESN	Numeric Result/Finding in Standard Units	float	8	12
4				8	Derived	VS.VSSTRESC			SDTM	VS	VSSTRESC	Character Result/Finding in Std Format	text	4	11
4				9	Assigned	VS.VSPOS		VSPOS	SDTM	VS	VSPOS	Position	text	7	13
5			VSTESTCD		Convert			VSTEST	SDTM	VS	VSTEST	Vital Signs Test Name	text	24	7
5			VSTESTCD		Convert			VSCAT	SDTM	VS	VSCAT	Category for Vital Signs	text	16	8
5					Derived	VS.VSSEQ			SDTM	VS	VSSEQ	Sequence Number	integer	8	4

Mapping Specifications: Dimension 2

Source			Mapping					Target		
Source Sequence	Source Library	Source Dataset	Subset Condition	Pre Processing	Join Timing	Join Type	Merge Key	Target Sequence	Target Library	Target Dataset
1	CDASH	VS						5	SDTM	VS
2	SDTM	TV			PRE	TARGET	VISIT	5	SDTM	VS
3	SDTM	DM			PRE	TARGET	USUBJID	5	SDTM	VS
4	SDTM	SE		VS.SE.SE_EPOCH	PRE	TARGET	USUBJID, VSDTC	5	SDTM	VS
5	WORK	VS4				SORT	USUBJID, VISITNUM, VSDTC	5	SDTM	VS
6	WORK	VS5		VS.VS5.VSBASEFL	PRE	TARGET	USUBJID, VSPOS, VSTESTCD, VSDTC	5	SDTM	VS
7	WORK	VS6				SORT	USUBJID, VSTESTCD, VISITNUM, VSDTC	5	SDTM	VS

Dataset Level

Source Sequence	Source Library	Source Dataset	Source Variable	Mapping Sequence	Origin	Method	Comment	Code List	Target Library	Target Dataset	Target Variable	Target Description	Target Type	Target Length	Target Sorting Order
5	WORK	VS4		3	Assigned	VS.VSTESTCD		VSTESTCD	SDTM	VS	VSTESTCD	Vital Signs Test Short Name	text	6	6
5	WORK	VS4		4	Derived	VS.VSORRES			SDTM	VS	VSORRES	Result or Finding in Original Units	text	4	9
5	WORK	VS4		5	Derived	VS.VSORRESU		VSUNIT	SDTM	VS	VSORRESU	Original Units	text	9	10
5	WORK	VS4		6	Assigned	VS.VSSTRESU		VSUNIT	SDTM	VS	VSSTRESU	Standard Units	text	9	13
5	WORK	VS4		7	Derived	VS.VSSTRESN			SDTM	VS	VSSTRESN	Numeric Result/Finding in Standard Units	float	8	12
5	WORK	VS4		8	Derived	VS.VSSTRESC			SDTM	VS	VSSTRESC	Character Result/Finding in Std Format	text	4	11
5	WORK	VS4		9	Assigned	VS.VSPOS		VSPOS	SDTM	VS	VSPOS	Position	text	7	13

Variable Level

Source Sequence	Source Library	Source Dataset	Source Variable	Where Clause	Condition	Output	Mapping Sequence	Origin	Method	Comment	Code List	Target Library	Target Dataset	Target Variable	Target Data Type	Target Length
5	WORK	VS4	DIABP_VSORRES	VS.PARAMCD.EQ.DIABP	DIABP_VSPERF = "Y"	Y	7	Copy				SDTM	VS	VSTESTCD	integer	8
5	WORK	VS4	SYSBP_VSORRES	VS.PARAMCD.EQ.SYSBP	SYSBP_VSPERF = "Y"	Y	7	Copy				SDTM	VS	VSTESTCD	integer	8
5	WORK	VS4	HR_VSORRES	VS.PARAMCD.EQ.PULSE	HR_VSPERF = "Y"	Y	7	Copy				SDTM	VS	VSTESTCD	integer	8
5	WORK	VS4	TEMP_VSORRES	VS.PARAMCD.EQ.TEMP	TEMP_VSPERF = "Y"	Y	7	Copy			10.1	SDTM	VS	VSTESTCD	float	8
5	WORK	VS4	HEIGHT_VSORRES	VS.PARAMCD.EQ.HEIGHT	HEIGHT_VSPERF = "Y"	Y	7	Derived	VS.VSSTRESN.item1		10.2	SDTM	VS	VSTESTCD	float	8
5	WORK	VS4	WEIGHT_VSORRES	VS.PARAMCD.EQ.WEIGHT	WEIGHT_VSPERF = "Y"	Y	7	Copy				SDTM	VS	VSTESTCD	integer	8

Value Level

Mapping Specifications: Dataset Level

	Source Sequence	Source Library	Source Dataset	Subset Condition	Pre Processing	Join Timing	Join Type	Merge Key	Target Sequence	Target Library	Target Dataset
1	1	CDASH	VS						5	SDTM	VS
2	2	SDTM	TV			PRE	TARGET	VISIT	5	SDTM	VS
3	3	SDTM	DM			PRE	TARGET	USUBJID	5	SDTM	VS
4	4	SDTM	SE		VS.SE.SE_EPOCH	PRE	TARGET	USUBJID, VSDTC	5	SDTM	VS
5	5	WORK	VS4				SORT	USUBJID, VISITNUM, VSDTC	5	SDTM	VS
6	6	WORK	VS5		VS.VS5.VSBASEFL	PRE	TARGET	USUBJID, VSPC, VSTESTCD, VSDTC	5	SDTM	VS
7	7	WORK	VS6				SORT	USUBJID, VSTESTCD, VISITNUM, VSDTC	5	SDTM	VS

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

1

```
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;
```

2

... Sequence 3, 4, 5, 6

3 4 5 6

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

7

```
data SDTM.VS;
  set VS6;
  by USUBJID VSTESTCD VISITNUM VSDTC;

  /*****
    variable level: Source Sequence = 5
    *****/
run;
```

Mapping Specifications: Variable Level

Source Sequence	Source Library	Source Dataset	Source Variable	Map Sequence	Origin	Method	Comment	Code List	Target Library	Target Dataset	Target Variable	Target Description	Target Data Type	Target Length	Target Sorting Order	
1	CDASH	VS			Assigned		VS	DOMAIN	SDTM	VS	1	DOMAIN	Domain Abbreviation	text	2	2
1	CDASH	VS	SUBJID		Assigned	ALL.USUBJID			SDTM	VS	2	USUBJID	Unique Subject Identifier	text	14	3
1	CDASH	VS	VISIT		Convert			VISITNUM	SDTM	VS	3	VISITNUM	Visit Number	integer	8	16
1	CDASH	VS	VISIT		Predecessor			VISIT	SDTM	VS	4	VISIT	Visit Name	text	18	17
1	CDASH	VS	VSDAT		Assigned	VS.VSDTC			SDTM	VS	5	VSDTC	Date/Time of Measurements	date	10	19
1	CDASH	VS			Derived	VS.VSBLFL			SDTM	VS	6	VSBLFL	Baseline Flag	text	1	14

ID	Description	Function	Parameter
2	Concatenation of STUDYID and SUBJID	Concatenate	dot/STUDYID/SUBJID
5	Convert assessment date (VISDAT/VSDAT) to ISO8601 date format.	ISODTC	VISDAT/VSDAT
6	Baseline flag set to Y when the assessment is collected at the visit marked as baseline in the trial flowchart.	Baseline	"VISIT/VISIT 2 (WEEK 0)"

SAS Code
2
USUBJID = catx('.', STUDYID, SUBJID);
if not missing(VISDAT) then
5 VSDTC = put(VISDAT, e8601da.);
else if not missing(VSDAT) then
VSDTC = put(VSDAT, e8601da.);
6
if VISIT = "VISIT 2 (WEEK 0)" then VSBLFL = 'Y';

```

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;

```

Mapping Specifications: Value Level

Source Sequence	Source Library	Source Dataset	Source Variable	Where Clause	Y Condition	Output	Map Sequence	Origin	Method	Comment	Code List	Target Library	Target Dataset	Target Variable	Target Data Type	Target Length	Significant Digits
3	CDASH	VS		VS.VSTESTCD.EQ.DIABP	DIABP_VSPERF = 'Y'	Y	3	Assigned		DIABP		SDTM	VS	VSTESTCD	text	6	
3	CDASH	VS	DIABP_VSORRES	VS.VSTESTCD.EQ.DIABP	DIABP_VSPERF = 'Y'	Y	4	Predecessor				SDTM	VS	VSORRES	text	4	
3	CDASH	VS	DIABP_VSORRESU	VS.VSTESTCD.EQ.DIABP	DIABP_VSPERF = 'Y'	Y	5	Predecessor				SDTM	VS	VSORRESU	text	9	
3	CDASH	VS		VS.VSTESTCD.EQ.DIABP	DIABP_VSPERF = 'Y'	Y	6	Assigned		mmHg		SDTM	VS	VSSTRESU	text	9	
3	WORK		VSORRES	VS.VSTESTCD.EQ.DIABP	DIABP_VSPERF = 'Y'	Y	7	Convert			best.	SDTM	VS	VSSTRESN	float	8	0
3	WORK		VSSTRESN	VS.VSTESTCD.EQ.DIABP	DIABP_VSPERF = 'Y'	Y	8	Convert			4.0	SDTM	VS	VSSTRESC	text	6	
3	CDASH	VS	DIABP_VSPOS	VS.VSTESTCD.EQ.DIABP	DIABP_VSPERF = 'Y'	Y	9	Predecessor				SDTM	VS	VSPOS	text	7	
3	CDASH	VS		VS.VSTESTCD.EQ.HEIGHT	HEIGHT_VSPERF = 'Y'	Y	3	Assigned		HEIGHT		SDTM	VS	VSTESTCD	text	6	
3	CDASH	VS	HEIGHT_VSORRES	VS.VSTESTCD.EQ.HEIGHT	HEIGHT_VSPERF = 'Y'	Y	4	Predecessor				SDTM	VS	VSORRES	text	4	
3	CDASH	VS	HEIGHT_VSORRESU	VS.VSTESTCD.EQ.HEIGHT	HEIGHT_VSPERF = 'Y'	Y	5	Predecessor				SDTM	VS	VSORRESU	text	9	
3	CDASH	VS		VS.VSTESTCD.EQ.HEIGHT	HEIGHT_VSPERF = 'Y'	Y	6	Assigned		m		SDTM	VS	VSSTRESU	text	9	
3	CDASH	VS	HEIGHT_VSORRES	VS.VSTESTCD.EQ.HEIGHT	HEIGHT_VSPERF = 'Y'	Y	7	Derived	VS.VSSTRESN.item1			SDTM	VS	VSSTRESN	float	8	2
3	CDASH	VS	VSSTRESN	VS.VSTESTCD.EQ.HEIGHT	HEIGHT_VSPERF = 'Y'	Y	8	Convert			4.2	SDTM	VS	VSSTRESC	text	6	
3	CDASH	VS		VS.VSTESTCD.EQ.HEIGHT	HEIGHT_VSPERF = 'Y'	Y	9	Assigned		NULL		SDTM	VS	VSPOS	text	7	

```

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;

```

```

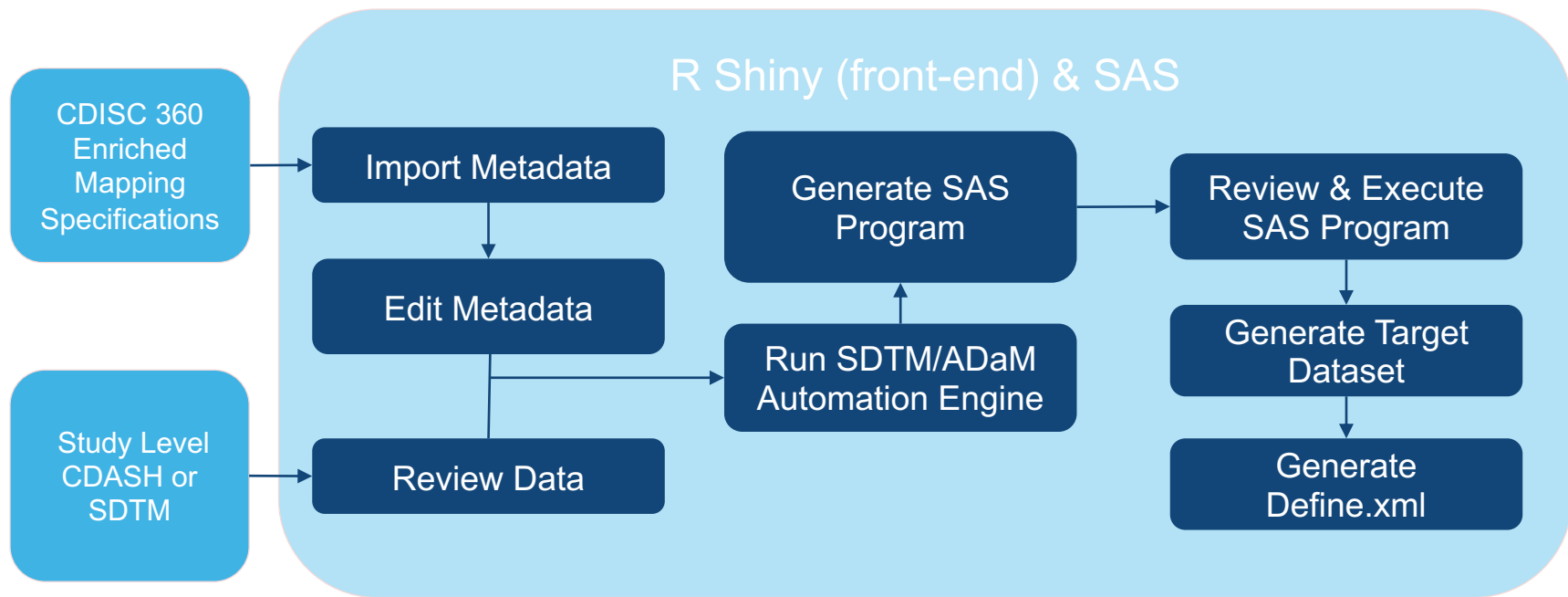
*** CONTINUE ***;

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;

```

SDTM/ADaM Automation Engine – Proof of Concept Design

CDISC 360 – SDTM/ADaM Automation Engine PoC Design



R-Shiny Front-end Interface: Automate Execution


SDTM/ADaM Automation

Data Browser

Metadata Import/Editor

Automation Engine

Review Mapping Code

Generate Target Datasets

Generate Define.xml

Generate SDTM aCRF

Data Browser

Folder Name

CDASH

File Name

dm.sas7bdat

Search:

race	ethnic	studyid	domain	subjid	age	ageu	sex	siteid	dmdat
All	All	All	All	All	All	All	All	All	All
1 NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	CDISC360-2	DM	001	51	YEARS	F	101	20-FEB-2019
2 AMERICAN INDIAN OR ALASKA NATIVE	UNKNOWN	CDISC360-2	DM	002	37	YEARS	M	101	22-JAN-2019
3 ASIAN	UNKNOWN	CDISC360-2	DM	003	40	YEARS	F	102	06-FEB-2019
4 WHITE	NOT HISPANIC OR LATINO	CDISC360-2	DM	004	50	YEARS	F	101	10-JAN-2019
5 BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CDISC360-2	DM	005	33	YEARS	M	103	01-FEB-2019
6 AMERICAN INDIAN OR ALASKA NATIVE	HISPANIC OR LATINO	CDISC360-2	DM	006	20	YEARS	M	101	03-FEB-2019
7 BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	CDISC360-2	DM	007	35	YEARS	M	103	29-JAN-2019
8 ASIAN	NOT HISPANIC OR LATINO	CDISC360-2	DM	008	62	YEARS	F	101	22-JAN-2019
9 BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	CDISC360-2	DM	009	61	YEARS	F	102	23-JAN-2019
10 ASIAN	NOT HISPANIC OR LATINO	CDISC360-2	DM	010	61	YEARS	F	103	27-JAN-2019

Showing 1 to 10 of 100 entries

Previous 1 2 3 4 5 ... 10 Next

R-Shiny Front-end Interface: Automate Execution

cdisc 360 SDTM/ADaM Automation

Data Browser

Metadata Import/Editor

Automation Engine

Review Mapping Code

Generate Target Datasets

Generate Define.xml

Generate SDTM aCRF

Metadata Import/Editor

Folder Name: Metadata

File Name: cdash2sdm_v1.1.xlsx

Metadata Sheet: Variables

CSV Excel

Search:

	SRCSEQ	SRCLIB	SRCDSN	SRCVAR	SRCTYPE	MAPSEQ	ORIGIN	METHOD	COMMENT	CODELIST	TGTLIB	TGTDSN	TGTVAR	TGTLBL
1	CDASH	VS			All		Assigned		CDISC360-2		SDTM	VS	STUDYID	Study Identifier
1	CDASH	VS					Assigned		VS	DOMAIN	SDTM	VS	DOMAIN	Domain Abbreviation
1	CDASH	VS		SUBJID	text		Assigned	ALL.USUBJID			SDTM	VS	USUBJID	Unique Subject Identifier
1	CDASH	VS					Assigned	VS.VSSPID			SDTM	VS	VSSPID	Sponsor-Defined Identifier
1	CDASH	VS		VISIT	text		Predecessor			VISIT	SDTM	VS	VISIT	Visit Name
1	CDASH	VS		VSDAT	text		Assigned	VS.VSDTC			SDTM	VS	VSDTC	Date/Time of Measurement
1	CDASH	VS		VISDAT	text		Assigned	VS.VSDTC			SDTM	VS	VSDTC	Date/Time of Measurement
2	SDTM	TV		VISITNUM	integer		Predecessor				SDTM	VS	VISITNUM	Visit Number
2	SDTM	TV		VISITDY	integer	1	Predecessor				SDTM	VS	VISITDY	Planned Study Day
3	SDTM	DM		RFSTDTC	date		Derived	VS.VSDY			SDTM	VS	VSDY	Study Day of Vital Status

Showing 1 to 10 of 75 entries

Previous 1 2 3 4 5 ...

R-Shiny Front-end Interface: Automate Execution

cdisc 360 SDTM/ADaM Automation

Data Browser

Metadata Import/Editor

Automation Engine

Review Mapping Code

Generate Target Datasets

Generate Define.xml

Generate SDTM aCRF

Metadata Import/Editor

Folder Name: Metadata

File Name: cdash2sdm_v1.1.xlsx

Metadata Sheet: Variables

CSV Excel

Search:

	SRCSEQ	SRCLIB	SRCDSN	SRCVAR	SRCTYPE	MAPSEQ	ORIGIN	METHOD	COMMENT	CODELIST	TGTLIB	TGTDSN	TGTVAR	TGTLBL
1	CDASH	VS			All		Assigned		CDISC360-2		SDTM	VS	STUDYID	Study Identifier
1	CDASH	VS					Assigned		VS	DOMAIN	SDTM	VS	DOMAIN	Domain Abbreviation
1	CDASH	VS		SUBJID	text		Assigned	ALL.USUBJID			SDTM	VS	USUBJID	Unique Subject Identifier
1	CDASH	VS					Assigned	VS.VSSPID			SDTM	VS	VSSPID	Sponsor-Defined Identifier
1	CDASH	VS		VISIT	text		Predecessor			VISIT	SDTM	VS	VISIT	Visit Name
1	CDASH	VS		VSDAT	text		Assigned	VS.VSDTC			SDTM	VS	VSDTC	Date/Time of Measurement
1	CDASH	VS		VISDAT	text		Assigned	VS.VSDTC			SDTM	VS	VSDTC	Date/Time of Measurement
2	SDTM	TV		VISITNUM	integer		Predecessor				SDTM	VS	VISITNUM	Visit Number
2	SDTM	TV		VISITDY	integer	1	Predecessor				SDTM	VS	VISITDY	Planned Study Day
3	SDTM	DM		RFSTDTC	date		Derived	VS.VSDY			SDTM	VS	VSDY	Study Day of Vital Status

Showing 1 to 10 of 75 entries

Previous 1 2 3 4 5 ...

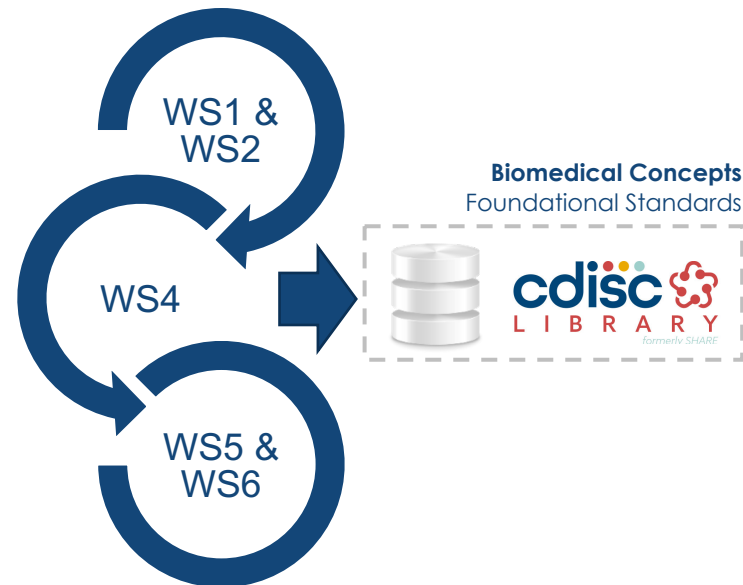
SDTM/ADaM Automation Engine – Live Demo!

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*



Courtesy: Mahi Busa