



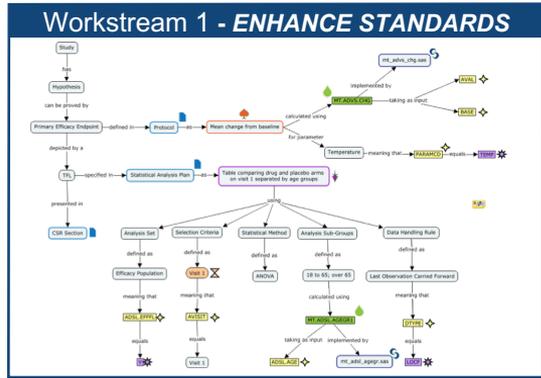
CDISC 360 Use Cases - Industry Perspectives

Use Case 3 (Workstream 6): Automated Data Processing

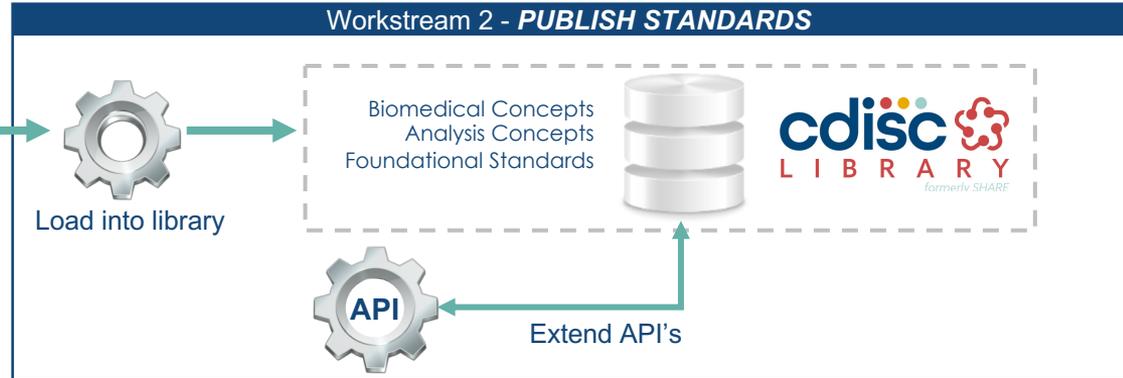
Bhavin Busa, WS6 Lead
2019 CDISC U.S. Interchange
October 16, 2019



CDISC 360 Workstreams

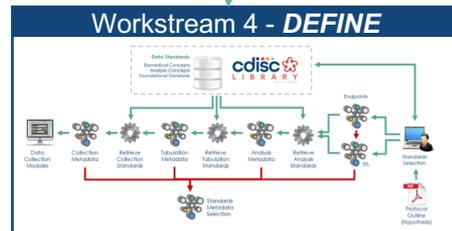


Create concepts in knowledge graphs

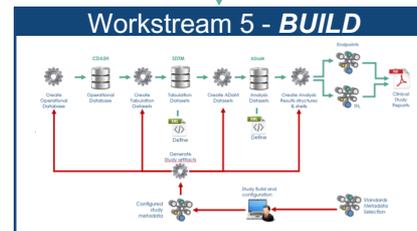


Transform concepts in machine readable form

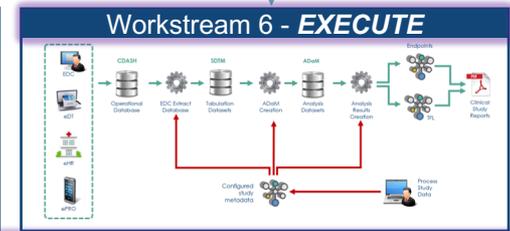
Study Library



Identify and select standards specification (Use Case 1)



Configure study specification and create artifacts (Use Case 2)



Automatically process and transform data (Use Case 3)

CDISC 360 Workstreams



*Enhance
Standards*



*Publish
Standards*

Study
Library



Define
WS4

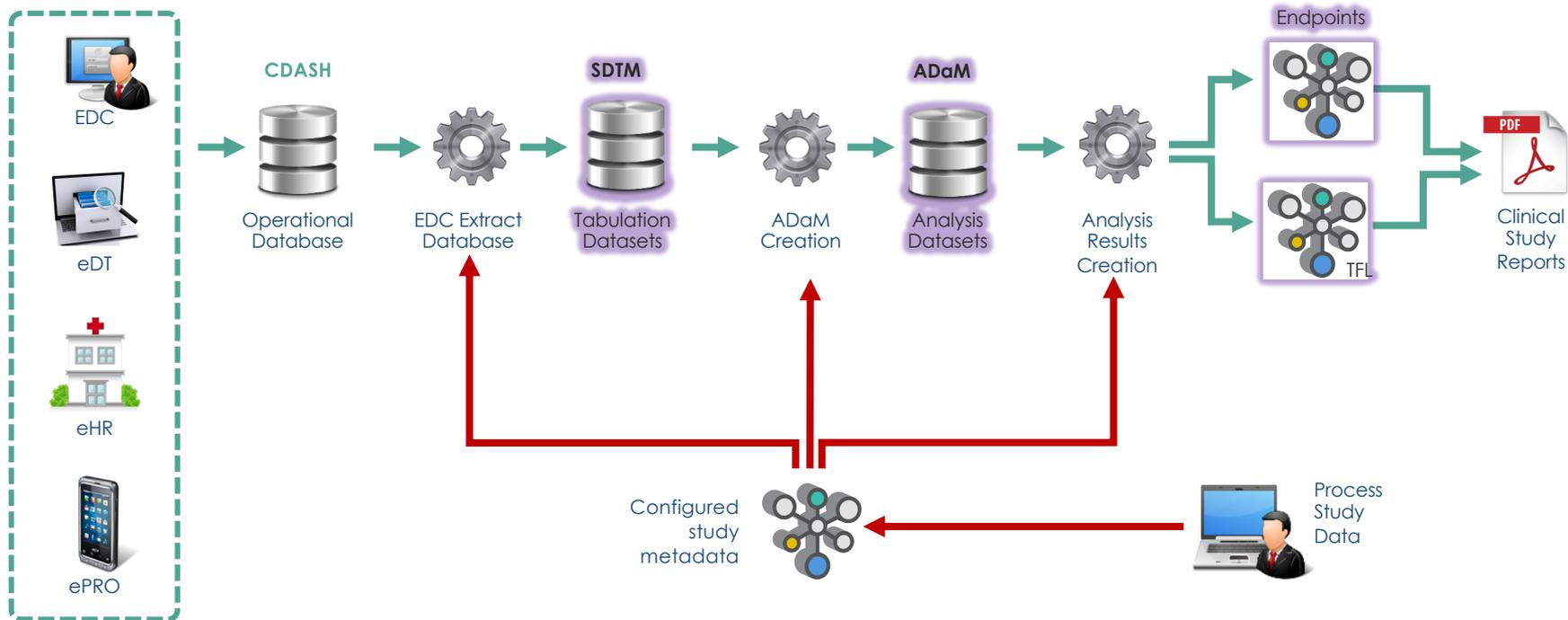
Build
WS5

Execute
WS6

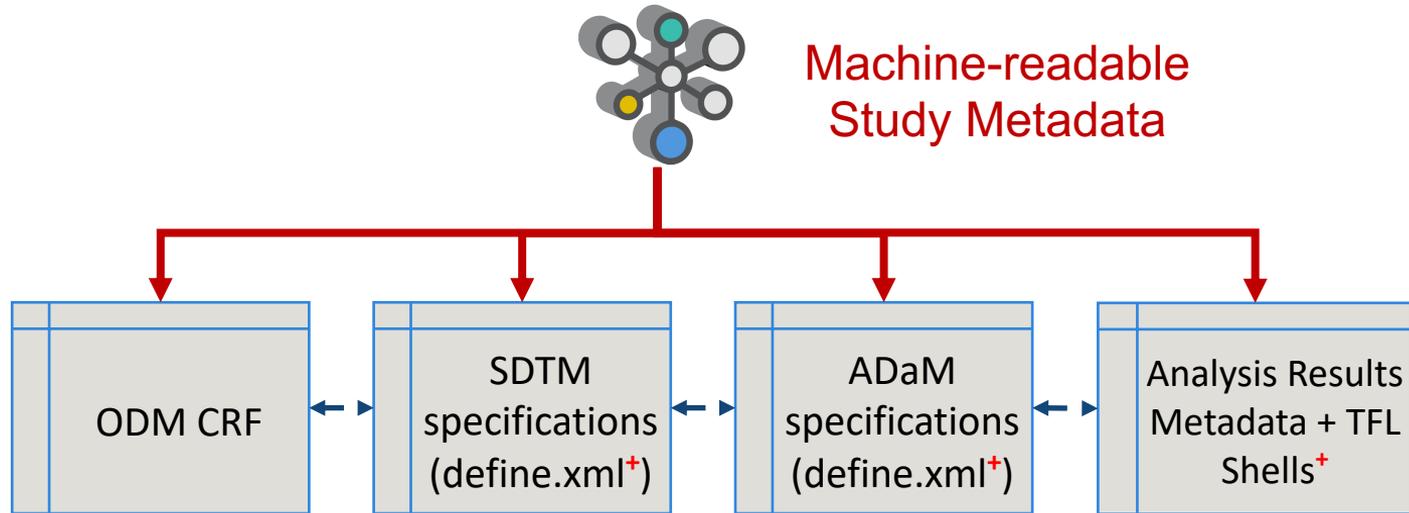


Use Case 3 (Workstream 6): Execute

Automatic population of data into artifacts



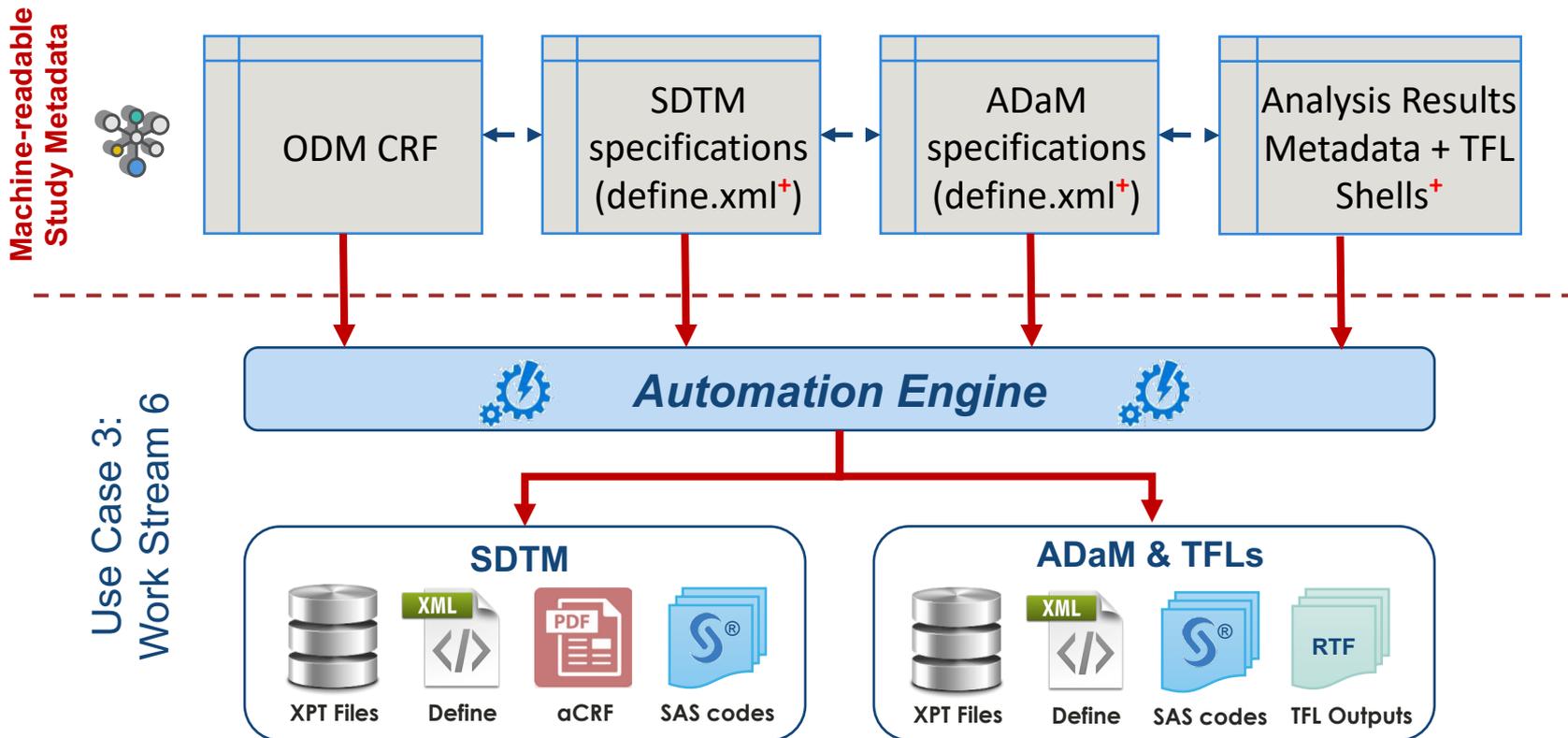
Build (Workstream 5): Generate Study Metadata Artifacts



Machine-readable
Study Metadata

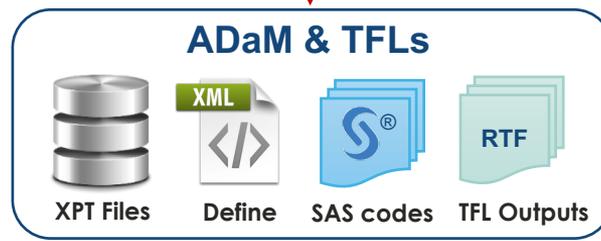
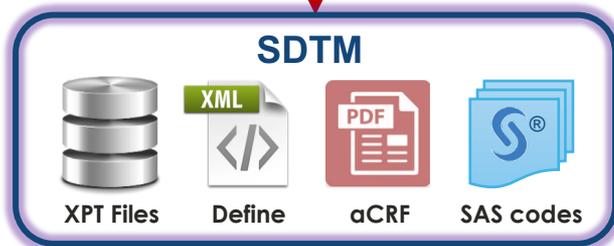
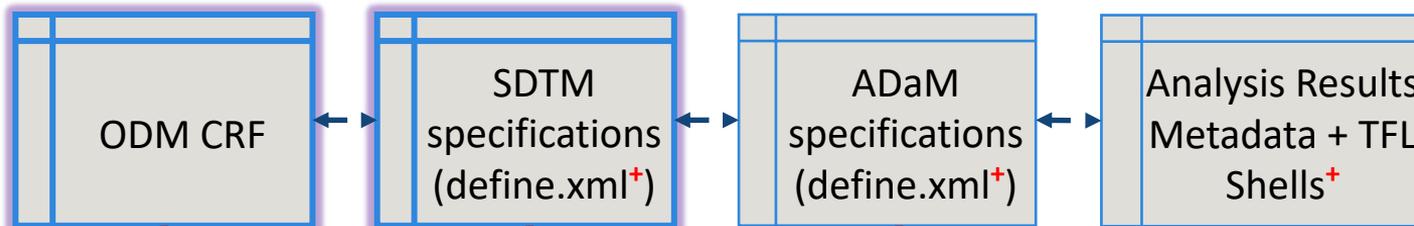
⁺ *Additional elements needed for automation*

High-level Artifacts (Build to Execute)



High-level Artifacts (Build to Execute)

Machine-readable
Study Metadata



ODM CRF Generated using Biomedical Concepts, Bindings, & Standards

ODM-based Vital Signs (VS) CRF

```
<MetaDataVersion Description="CDASH BC CRF Example" Name="CDASH CRF Example" OID="MDV.CDISC360.DEMO1">
  <FormDef Name="VS Form" OID="F.VS" Repeating="Yes">
    <ItemGroupRef ItemGroupOID="IG.BC.VS.COMMON" Mandatory="No"/>
    <ItemGroupRef ItemGroupOID="IG.BC.VS.TEMPERATURE" Mandatory="No"/>
    <ItemGroupRef ItemGroupOID="IG.BC.VS.HEIGHT" Mandatory="No"/>
    <ItemGroupRef ItemGroupOID="IG.BC.VS.DIASTOLICBP" Mandatory="No"/>
    <ItemGroupRef ItemGroupOID="IG.BC.VS.SYSTOLICBP" Mandatory="No"/>
    <ItemGroupRef ItemGroupOID="IG.BC.VS.WEIGHT" Mandatory="No"/>
    <ItemGroupRef ItemGroupOID="IG.BC.VS.HEARTRATE" Mandatory="No"/>
  </FormDef>
  <ItemGroupDef Name="VS Common" OID="IG.BC.VS.COMMON" Repeating="No">
    <ItemRef ItemOID="IT.BC.VS.STUDYID" Mandatory="Yes" OrderNumber="1"/>
    <ItemRef ItemOID="IT.BC.VS.SITEID" Mandatory="Yes" OrderNumber="2"/>
    <ItemRef ItemOID="IT.BC.VS.SUBJID" Mandatory="Yes" OrderNumber="3"/>
    <ItemRef ItemOID="IT.BC.VS.VISIT" Mandatory="No" OrderNumber="4"/>
    <ItemRef ItemOID="IT.BC.VS.VSPERF" Mandatory="No" OrderNumber="6"/>
    <ItemRef ItemOID="IT.BC.VS.VSDAT" Mandatory="No" OrderNumber="7"/>
    <ItemRef ItemOID="IT.BC.VS.VSTIM" Mandatory="No" OrderNumber="8"/>
  </ItemGroupDef>
  <ItemGroupDef Name="VS Temperature" OID="IG.BC.VS.TEMPERATURE" Repeating="No">
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    <ItemRef ItemOID="IT.BC.VS.TEMPERATURE.VSORRES" Mandatory="Yes" OrderNumber="2"/>
    <ItemRef ItemOID="IT.BC.VS.TEMPERATURE.VSORRESU" Mandatory="No" OrderNumber="3"/>
  </ItemGroupDef>
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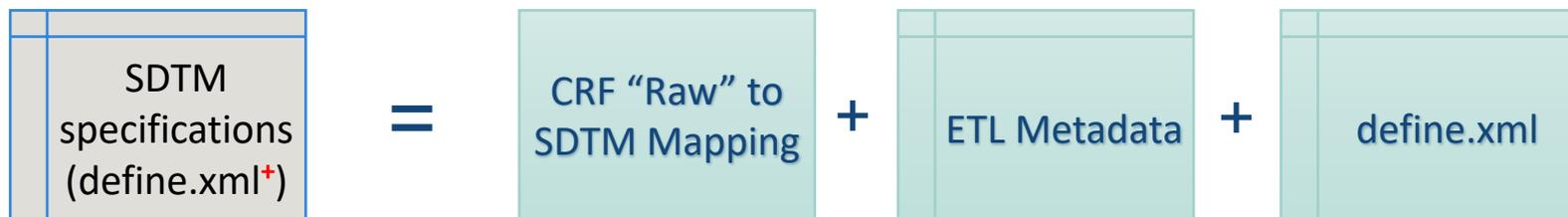
Stylesheet rendering of ODM VS CRF

Group: VS Temperature	
OID=IG.BC.VS.TEMPERATURE, Repeating=No	
What is the vital sign test name?	<input type="radio"/> Temperature
What was the result of the measurement?	<input type="text"/> . <input type="text"/>
What was the unit of the measurement?	<input type="radio"/> C <input type="radio"/> F

Group: VS Height	
OID=IG.BC.VS.HEIGHT, Repeating=No	
What is the vital sign test name?	<input type="radio"/> Height
What was the result of the measurement?	<input type="text"/> . <input type="text"/>
What was the unit of the measurement?	<input type="radio"/> cm <input type="radio"/> in <input type="radio"/> mm

Group: VS DiastolicBP	
OID=IG.BC.VS.DIASTOLICBP, Repeating=No	
What is the vital sign test name?	<input type="radio"/> Diastolic Blood Pressure
What was the result of the measurement?	<input type="text"/>
What was the unit of the measurement?	<input type="radio"/> mmHg <input type="radio"/> cmHg
What was the position of the subject during the measurement?	<input type="radio"/> SITTING <input type="radio"/> STANDING <input type="radio"/> SUPINE

SDTM Specifications Define.xml⁺



This is **NOT** Machine-readable Specifications

SDTM Domain	SDTM Variable	SDTM Label	Controlled Terminology	Derivation/ Comment
DM	SEX	Sex	SEX 1 = 'F' 2 = 'M'	Map per Controlled Terminology
DM	RFPENDTC	Date/Time of End of Participation	ISO8601	Date/time when subject ended participation in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact
DM	RFSTDTC	Subject Reference Start Date/Time	ISO8601	First non-missing date/time of study drug. Null for screen failures or not assigned subjects.
DM	RFENDTC	Subject Reference End Date/Time	ISO8601	Last date/time of study drug. Null for screen failures or not assigned subjects

This is **Machine-readable** Specifications

SDTM Domain	SDTM Variable	SDTM Label	Controlled Terminology	Relationship	Processor/Derivation
DM	SEX	Sex	SEX 1 = 'F' 2 = 'M'	Transformation	CDASH
DM	RFPENDTC	Date/Time of End of Participation	ISO8601	Derived	Last Visit
DM	RFSTDTC	Subject Reference Start Date/Time	ISO8601	Derived	First Exposure Date
DM	RFENDTC	Subject Reference End Date/Time	ISO8601	Derived	Last Exposure Date

Relationship: Assigned, Direct move, Decode, Transformation, and Derived

Machine-readable Instructions for Transformation & Derivation

Transformation Details:

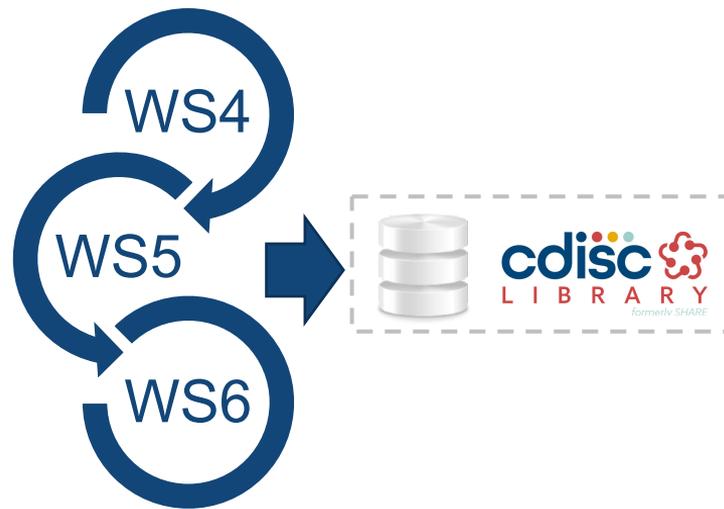
SDTM Variable	Processor/Derivation	Type	From	To
SEX	CDASH	C2C	C16576	F
SEX	CDASH	C2C	C20197	M

Derivation Details:

SDTM Variable	Processor/Derivation	Method	Join/Merge	Key
RFPENDTC	Last Visit	max(SDTM.SV.SVENDTC)	Merge	USUBJID
RFSTDTC	First Exposure Date	min(SDTM.EX.EXSTDTC)	Merge	USUBJID
RFENDTC	Last Exposure Date	max(SDTM.EX.EXENDTC)	Merge	USUBJID

Machine-readable Metadata

- ETL Metadata (mapping inference & derivation)
- Can be consumed by any tool
- System agnostic standards, concepts and elements
- Organization can build an automation engine their own way
- Content is part of the standards (CDISC library)
 - Machine-readable elements will be part of the library





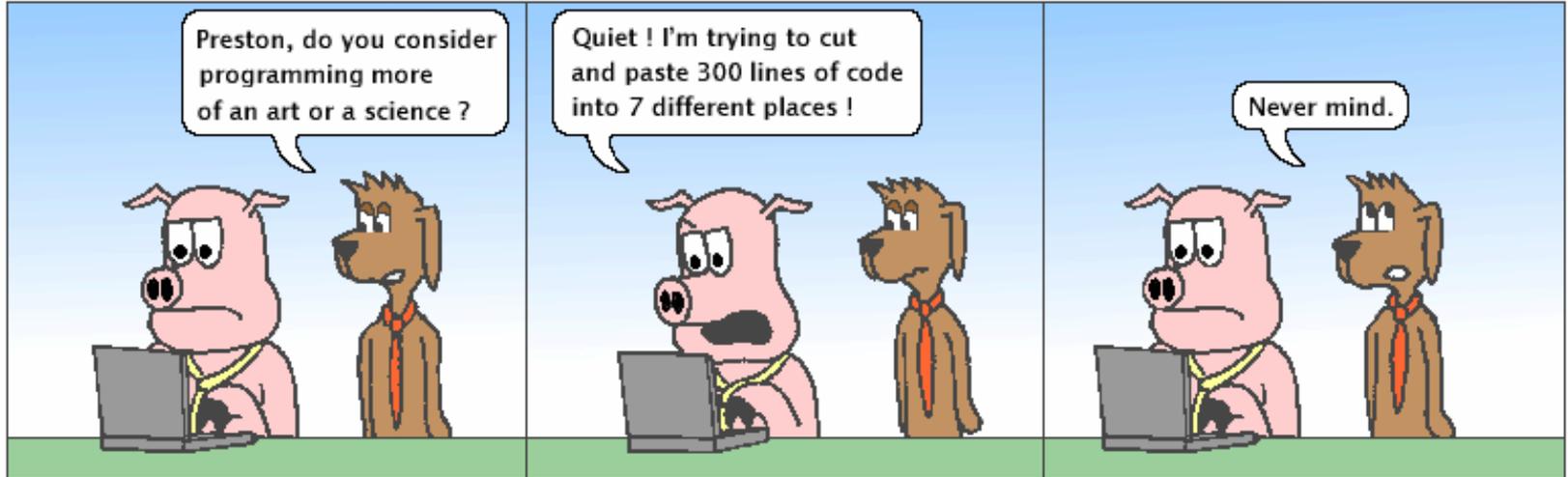
Work in Progress

- Python to ingest metadata
 - Read in the metadata and generate specifications in XML format (define.xml⁺)
 - Parse define.xml⁺ to the automation engine
- Build machine-readable rules & instructions
 - Transformation & Derivation
 - Function (copy, statement, recode, etc.)
 - Merge key
 - Supplemental
 - Rule version
- Advance work using “360 Test Study” data
 - 1-2 statistical & MACE endpoints, ~3-4 ADaM, ~7-8 SDTM and ~15 CDASH CRF

Challenging the Status Quo

Hackles

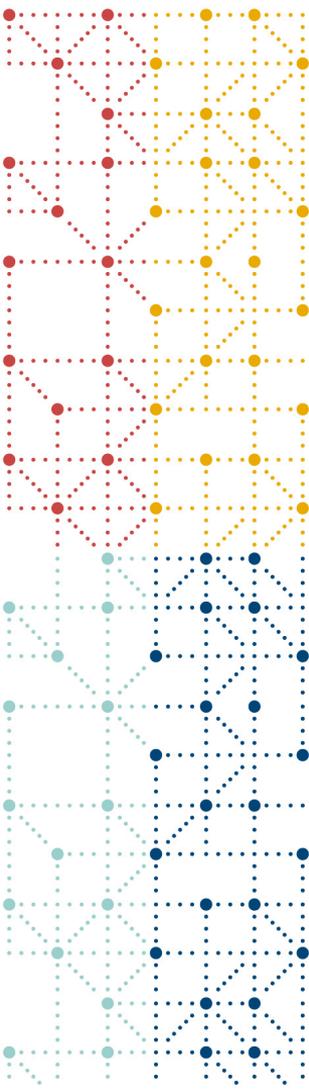
By Drake Emko & Jen Brodzik



<http://hackles.org>

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"copy-paste programming" to "meta-programming"



Thank You!

Bhavin Busa

VP, Clinical Data Services & Operations

Vita Data Sciences

