



# CDISC 2020 US Interchange

A Virtual Event | 7-8 October 2020

CDISC 360

## Session 4, Track C: CDISC 360, Part II



**Bhavin Busa**  
Vita Data Sciences  
VP, Clinical Data Services & Operations



**Nicolas De Saint Jorre**  
XClinical  
Product Owner - Data Manager



**Jianhui Zhao**  
AbbVie  
Associate Director



**Bess LeRoy**  
CDISC  
Head of Standards Development



**Mikkel Traun**  
Novo Nordisk  
Principal Developer



**Prasanna Murugesan**  
AstraZeneca  
Director



**Stuart Malcolm**  
Frontier Science (Scotland) Ltd  
Senior Programmer



🕒 4:00 PM - 5:30 PM EDT on Wednesday, 7 October

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### **PoC for Study Design and Configuration using CDISC 360 Concept-Based Standards**

*Mikkel Traun, Novo Nordisk; and Nicolas De Saint Jorre, XClinical*

### **Automation of SDTM Generation & Artifacts using CDISC 360 Enriched Standards**

*Bhavin Busa, Jianhui Zhao, Vita Data Sciences*

### **Automation of ADaM & TFL Generation using CDISC 360 Enriched Standards**

*Bhavin Busa, Prasanna Murugesan, Stuart Malcolm, Vita Data Sciences*



CDISC 360

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

# Workstream 4 & 6 - Task Team Leads

## Workstream 4 Lead



**Mikkel Traun,**  
Novo Nordisk



### App Development Lead



**Nicolas De Saint Jorre,**  
XClinical

### System Architect



**Tobias Krøgholt,**  
Novo Nordisk

## Workstream 6 Lead



**Bhavin Busa,**  
Vita Data Sciences

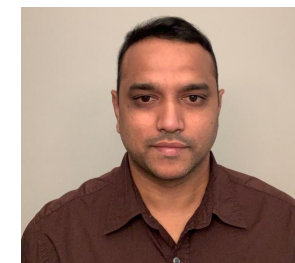


### SDTM/ADaM Automation



**Jianhui (Jimmy)  
Zhao,** AbbVie

### TFL Automation



**Prasanna  
Murugesan,**  
AstraZeneca



**Stuart Malcolm,**  
Frontier Science





# CDISC 360 Industry Perspective

# CDISC 360 Use Cases 1, 2 and 3

cdisc

***Enhance  
Standards***  
*Concept Based*

***Publish  
Standards***  
*CDISC Library*



Sponsor  
Study  
MDR



***Define***  
*Use Case 1*

***Build***  
*Use Case 2*

***Execute***  
*Use Case 3*

Industry





# CDISC 360 Enriched Metadata

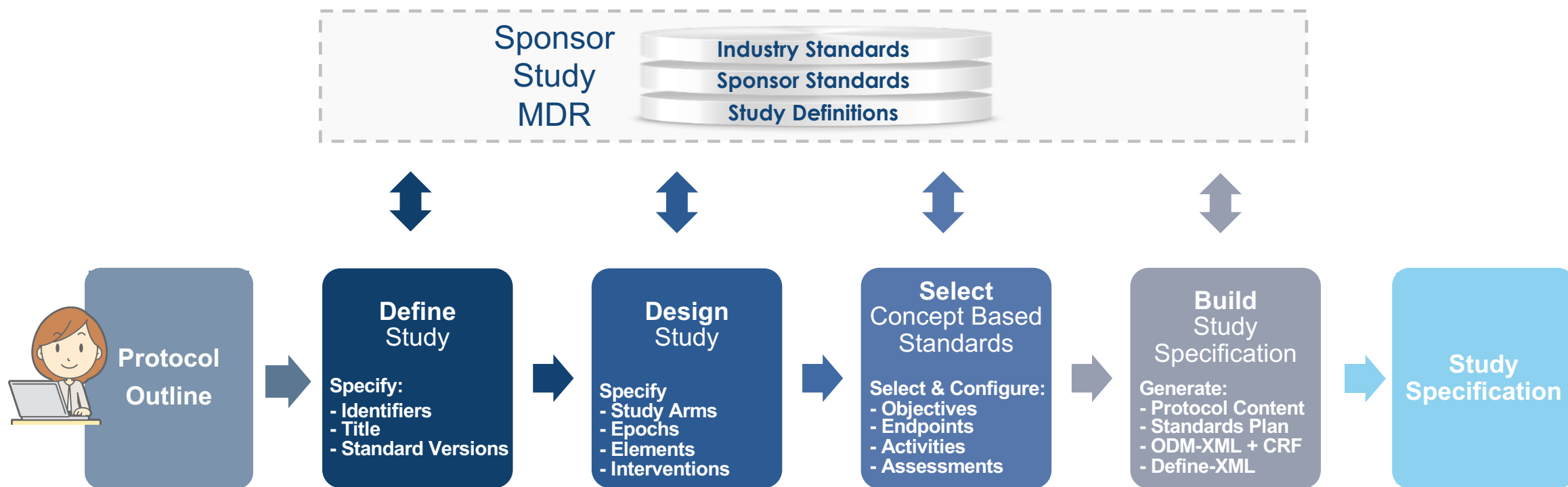
# Machine-readable CDISC 360 Enriched Metadata





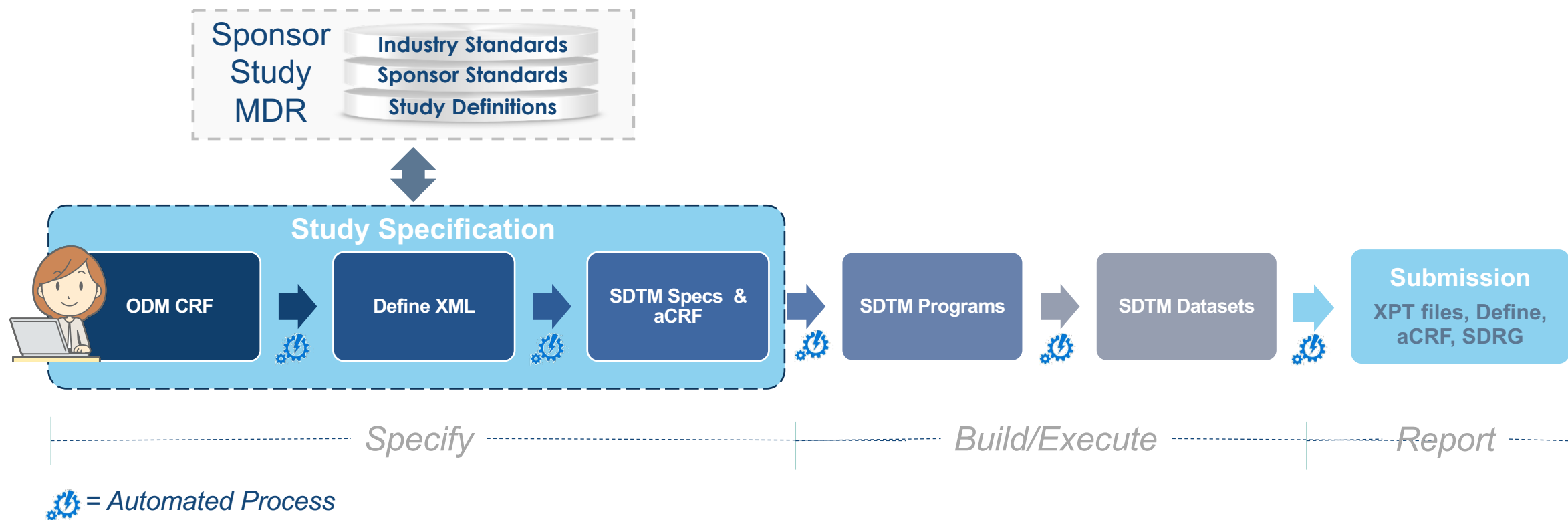
# Future State with Concept-based Standards

# Future State - with Concept-based Standards: Study Specification in a CDISC 360 Study Builder App

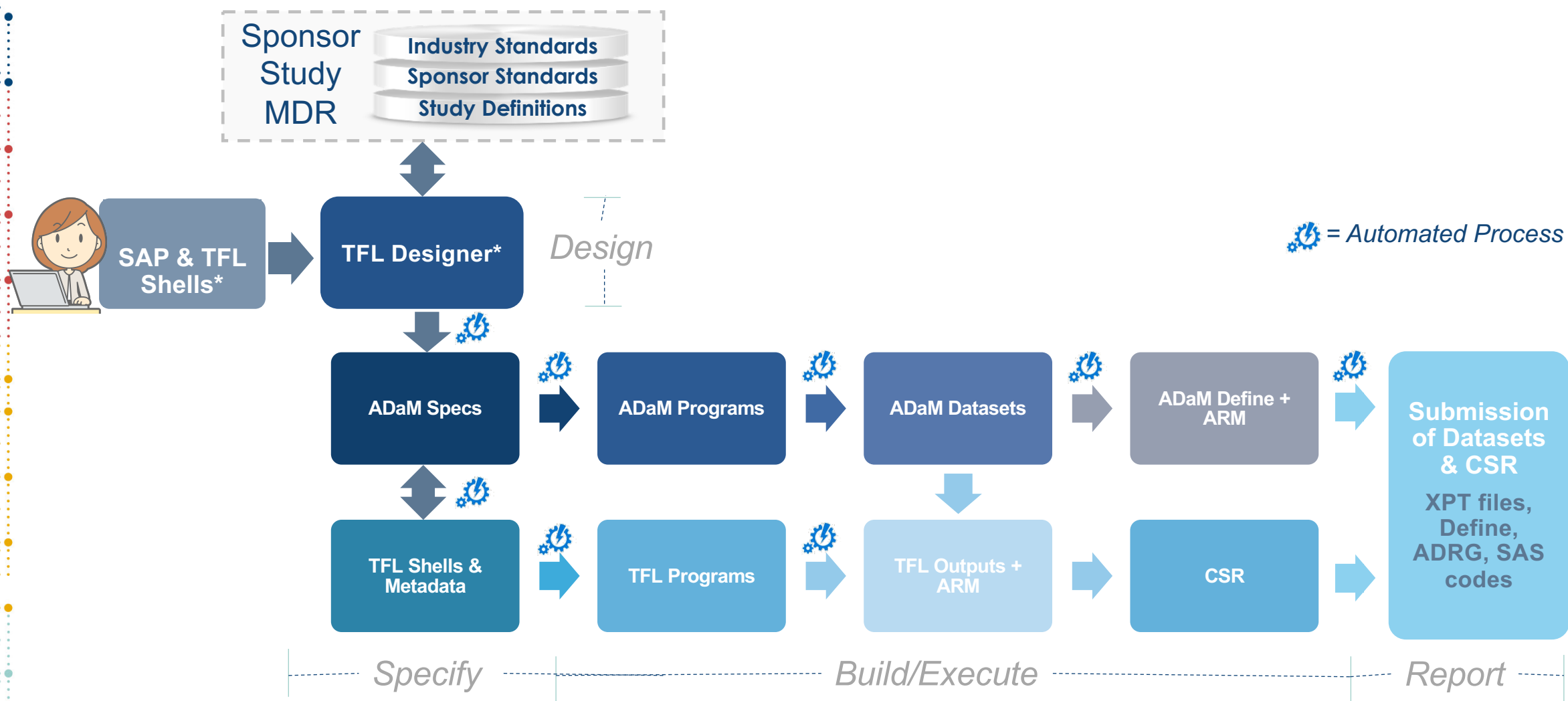




# Future State - with Concept-based Standards: CDASH to SDTM Execution



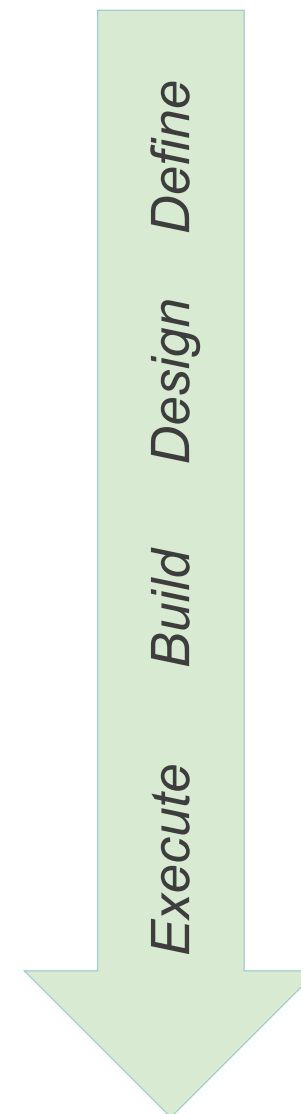
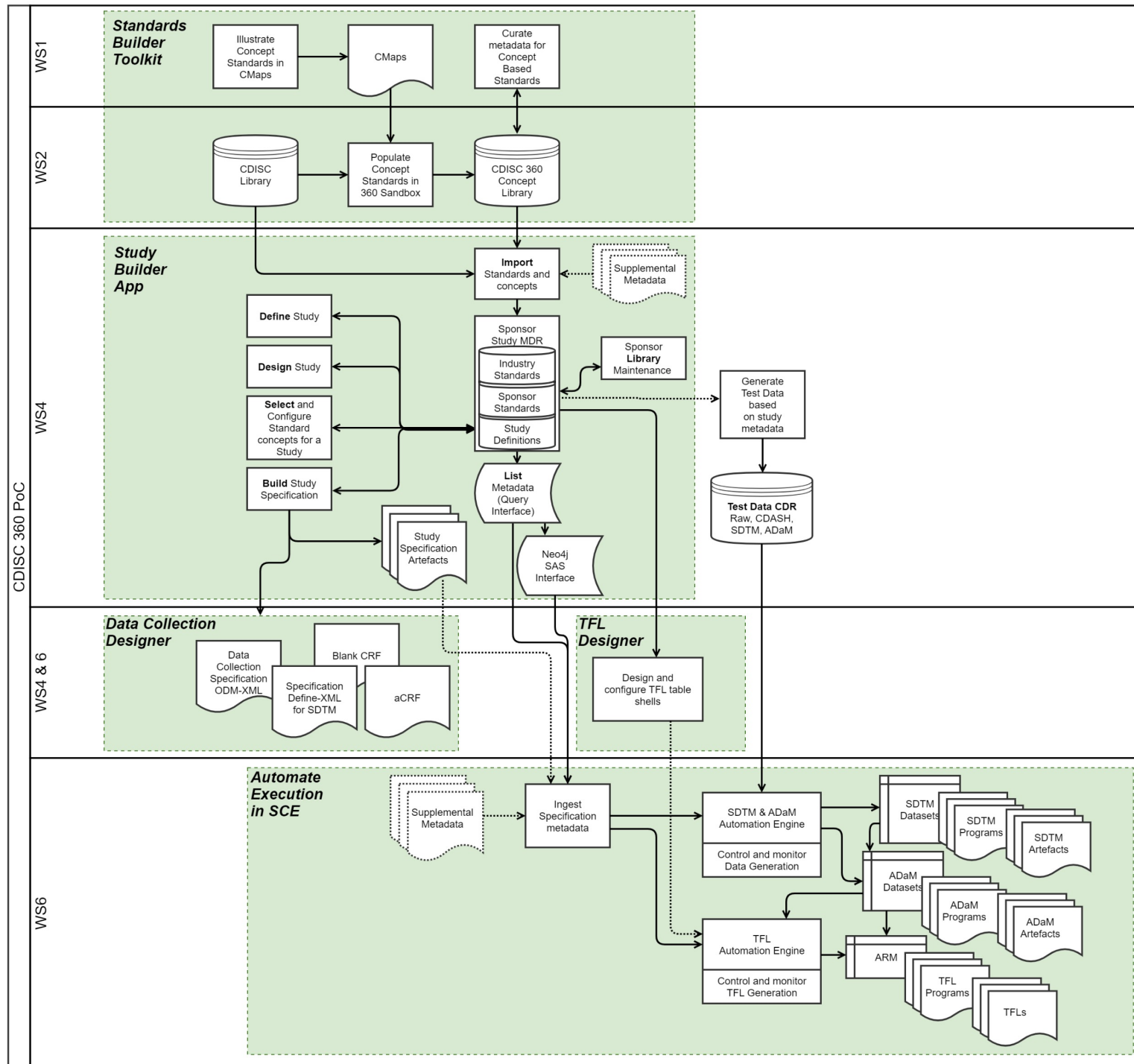
# Future State - with Concept-based Standards: Analysis Datasets and TFL Generation





# Flowchart and Architecture for PoC

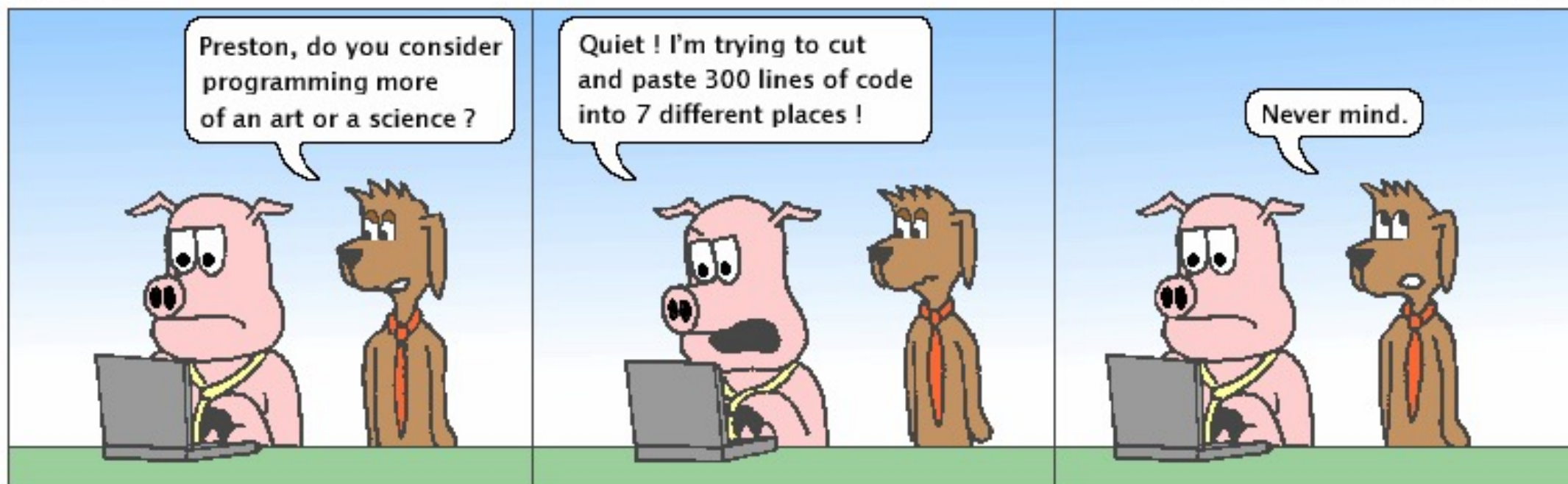
*How the Study Metadata fit in the overall CDISC 360 vision*



# Challenging the Status Quo

Hackles

By Drake Emko & Jen Brodzik



<http://hackles.org>

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