CDISC 2020 US Interchange
A Virtual Event  |  7-8 October 2020
Session 4, Track C: CDISC 360, Part II

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AbbVie
Associate Director

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Frontier Science (Scotland) Ltd
Senior Programmer

Bess LeRoy
CDISC
Head of Standards Development

4:00 PM - 5:30 PM EDT on Wednesday, 7 October
Add to Calendar

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
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 and Stuart
5. Concluding Remarks and Next Steps – Bhavin and Mikkel
6. Q & A session
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

Speaker: Mikkel & Bhavin
CDISC 360 Industry Perspective
CDISC 360 Use Cases 1, 2 and 3

Enhance Standards
    Concept Based

Publish Standards
    CDISC Library

Define
    Use Case 1

Build
    Use Case 2

Execute
    Use Case 3

Sponsor
Study
MDR

Speaker: Mikkel & Bhavin
CDISC 360 Enriched Metadata
Machine-readable CDISC 360 Enriched Metadata

- Structural
- Conceptual
- Process
- Semantic

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

**Protocol Outline**
- Define Study
  - Specify:
    - Identifiers
    - Title
    - Standard Versions
- Design Study
  - Specify
    - Study Arms
    - Epochs
    - Elements
    - Interventions
- Select Concept Based Standards
  - Select & Configure:
    - Objectives
    - Endpoints
    - Activities
    - Assessments
- Build Study Specification
  - Generate:
    - Protocol Content
    - Standards Plan
    - ODM-XML + CRF
    - Define-XML

**Sponsor Study MDR**
- Industry Standards
  - Sponsor Standards
  - Study Definitions

**Study Specification**
Future State - with Concept-based Standards: CDASH to SDTM Execution

Sponsor Study MDR

Industry Standards
Sponsor Standards
Study Definitions

Study Specification

ODM CRF
Define XML
SDTM Specs & aCRF

SDTM Programs
SDTM Datasets

Submission
XPT files, Define, aCRF, SDRG

Specify
Build/Execute
Report

= Automated Process

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

Sponsor Study MDR

TFL Designer*

ADaM Specs

ADaM Programs

ADaM Datasets

ADaM Define + ARM

Submission of Datasets & CSR XPT files, Define, ADRG, SAS codes

TFL Shells & Metadata

TFL Programs

TFL Outputs + ARM

CSR

= Automated Process

Specify Build/Execute Report

Speaker: Bhavin
Flowchart and Architecture for PoC

How the Study Metadata fit in the overall CDISC 360 vision
Challenging the Status Quo

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