

CDISC 360

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



**Bhavin Busa**

Vita Data Sciences  
VP, Clinical Data Services & Operations



**Nicolas De Saint Jorre**

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Novo Nordisk  
Principal Developer



**Prasanna Murugesan**

AstraZeneca  
Director



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Frontier Science (Scotland) Ltd  
Senior Programmer



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

# Reflections from CDISC 360 PoC – Industry Perspective

- Smart People, Infrastructure and Processes
- Applied Linked graph data model (Neo4j)
  - CDASH → SDTM & SDTM → ADaM bindings
- Developed & tested additional metadata elements required for automation
  - CDASH to SDTM & SDTM to ADaM Mapping Specifications Templates
  - TFL Metadata (ARM++)

...continued

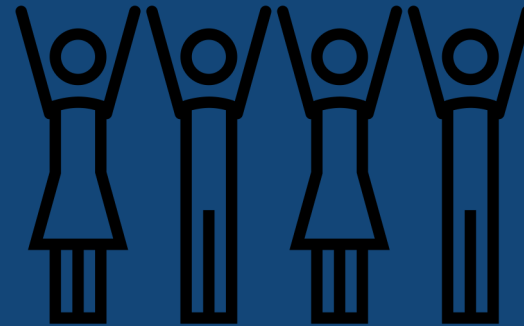
# Reflections from CDISC 360 PoC – Industry Perspective

- Developed automation engines to automatically process and transform data and analyses results
  - Demonstrated automatic execution of: CDASH → SDTM, SDTM → ADaM, ADaM → TFL
- Tool agnostic solutions
  - Incorporated open-source tools without disrupting current workflows

# What's Next

- **Yellow-paper** on CDISC 360 PoC will be published soon
- CDISC should continue to implement standards as **linked metadata** with a conceptual foundation
- Evolve CDISC standards to support **metadata driven** automation across end-to-end clinical data lifecycle
- Industry wide **collaboration** required to develop **open-source** solutions
- **API** standards for exchange of metadata between tools and Sponsor Study Metadata Repositories (MDR's) are needed
- Continue collaboration with **TransCelerate** Digital Data Flow initiative

**Thank you to all the CDISC 360 participants**





# Q&A Session

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**Bess LeRoy**

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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*