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US
INTERCHANGE
FALLS CHURCH, VA | 18-19 OCTOBER

From Proof-of-Concept to Reality:
The Transformative Evolution of CDISC 360
Charles Shadle, Head of Data Science Operations, CDISC

Meet the Speaker

Charles Shadle

Title: Head of Data Science Operations

Organization: CDISC

Charles Shadle is responsible for Data Science process and operations at CDISC. Working closely with the executive team, he plays a key role in strategic planning and risk management. In addition to Data Science, he also provides oversite of Web, IT and cloud operations. His experience (software engineer, architect, project, portfolio and strategy management) the last 19 years of which has been in regulated industry, enables him to effectively collaborate with a broad range of CDISC staff and stakeholders, including those associated with the CDISC Open Source Alliance (COSA) where he serves on the board.

His other interest include traveling abroad, biking, scuba diving, flying Cessna 172's, wineries, craft breweries, international foods and authoring children's books.

Agenda

1. COSA
2. CDISC 360
3. Study Builder
4. CDASH/eCRF to SDTM
5. SDTM to ADaM
6. ADaM to TFL
7. Conclusion

COSA

- *COSA supports, promotes, and sometimes sponsors open-source software projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community.*

- This is not about COSA…

- Nor about open-source software…

- But understand the importance of COSA to CDISC as an enabler for 360

- So, from the cockpit…

CDISC 360 - What

- Vision
  - Demonstrate the benefits of metadata-driven automation across the clinical research data lifecycle.

- Mission
  - Apply the 80/20 rule to ensure the Project automates 80% of the end-to-end metadata and data processing needed to generate study artifacts suitable for a regulatory submission.

- Goal
  - Proof-of-concept...

CDISC 360 – Why

- Industry Priorities:

  - Improved **Consistency**

  - Increased **Efficiency**

  - Enhanced **Reusability**

  - Greater **Compliance**

- CDISC Strategic Priorities:

  - Reduce implementation variability

  - Increase implementation automation

  - Reduce barriers to implementation

  - Increase interoperability with other standards

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WS 1 — Create concepts in knowledge graphs

WS2 — Transform concepts in machine readable form

Load into library

Biomedical Concepts
Analysis Concepts
Foundational Standards

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formerly SHARE

API — Extend API's

Use Case 1: Selecting standards concepts and linked metadata needed for a study
Use Case 2: Adding study design, concept configuration & generate artifacts
Use case 3: Automatic population of data into artifacts

WS3 — Add transformation semantics

WS 4 — Identify and select standards specification (Use Case 1)

WS 5 — Configure study specification and create artifacts (Use Case 2)

WS 6 — Automatically process and transform data (Use Case 3)
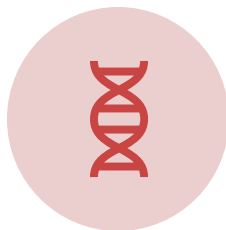
CDISC 360 - Outcome

- Q4 2020 - POCs
    - Biomedical Concept Maps
    - Study Builder
    - Analysis Results Metadata / Data
    - TFL Generator application

- Q1 2021 – CDISC 360 Whitepaper

What did we learn?
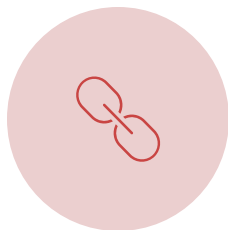
INCOMPLETE E2E FOUNDATIONAL STANDARDS

STANDARDS NEED ADDITIONAL METADATA (BC LAYER)

CDISC LIBRARY NEEDS IMPLEMENTATION LEVEL METADATA

INDUSTRY COLLABORATION NEEDED TO EXPEDITE BIOMEDICAL CONCEPTS

Obstacles

- Limited & Restricted CDISC Access
- Multiple Passwords
  - CDISC Learning System
  - CDISC Website
  - CDISC Library
  - API Portal
  - Wiki
  - Jira
- Data Quality / Ambiguous Rules
- 1980's Export Format
- Constant reinvention & lack of interoperability
- Resources
- Volunteer Availability
- Insufficient metadata to support process automation

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Converted to Catalysts

- Unlimited & Unrestricted CDISC Access
  - Members, Free
- One SSO Password
  - cdiscID
- Unambiguous Rules
  - Schema, Rule Editor, CORE
- ODM V2/ Dataset-JSON
  - CDISC/PHUSE/FDA Pilot
- TransCelerate DDF
  - Currently on Phase 3
- COSMoS
- COSA (https://cosa.cdisc.org/)

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Additional CDISC 360 Progress

Incomplete Standards
- eCRF Portal: 5 pages!
  - https://www.cdisc.org/kb/ecrf
- ARS: Public Review, Hackathon implementations
  - https://www.cdisc.org/standards/foundational/analysis-results-standards

Metadata enriched Standards
- Biomedical Concepts
- Dataset Specializations
- Collaborative curation
- Oak

CDISC Library API

v1 Biomedical Concept Endpoints

v1 SDTM Dataset Specialization …

v2 Biomedical Concept Endpoints

v2 SDTM Dataset Specialization …

CDISC Library w/Implementation Metadata
- Added QRS Content
- Modeled Concepts
- CLIB API
 - https://api.developer.library.cdisc.org/api-details

Industry Collaboration
- GSK
- Novo Nordisk
- Deloitte
- Boehringer-Ingelheim
- Roche
- Pfizer
- Formedix
- Bioforum

USDM/COSMoS Compliant Study Builder

- Next generation MDR solution for study design and configuration using concept-based standards that will drive
  - end-to-end consistency
  - more efficient processes
    - From protocol development / CRF design
    - To creation of datasets, analysis, reporting, submission to health authorities and public disclosures
- This overview will cover
  - its features
  - benefits
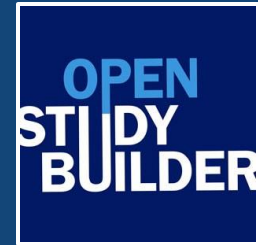 - how it fits into the end-to-end standards automation
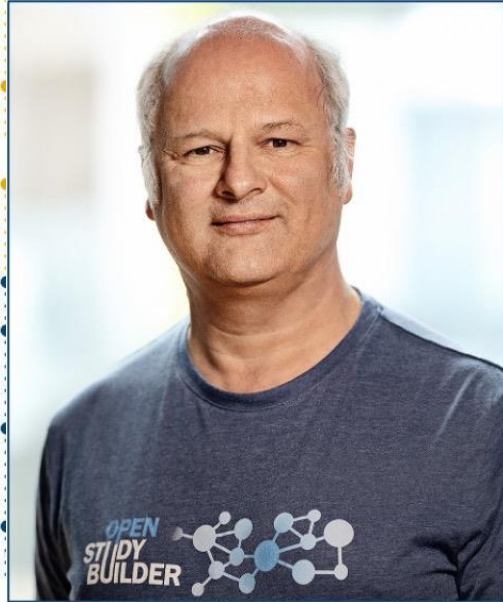
Meet the Speaker

Mikkel Traun

Title: Principal System Developer

Organization: Novo Nordisk A/S

Mikkel is one of the product owners for the next generation study builder and data standards repository solution at Novo Nordisk. Mikkel is also an active member of the TransCelerate and CDISC Digital Dataflow project, and previously the CDISC 360 project. He has worked as a principal system developer supporting the clinical data warehouse solution and the CDISC implementation at Novo Nordisk. Previously he has worked on several projects in pre-clinical, clinical and outcome research.

eCRF/CDASH to SDTM

- Roche, building on the ideas of CDISC 360
  - 22 mapping / transformation algorithms
  - EDC data to SDTM
  - Able to automate ~80%
- Pfizer used their own data and was able to verify the use case
- Roche has a strong commitment to open source
  - Scope
    - Oak
    - Mint
    - Synthetic Data Generator
  - 4 Teams
    - Leadership / Dev / Metadata Curation / Community

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Meet the Speakers

Yogesh Gupta

Title: Sr. Director, Statistical Data Sciences & Analytics

Organization: Pfizer

Strategic leader contributing to building large teams, plans, and roadmaps

Expertise in end-to-end standards , systems & processes

Rammprasad Ganapathy

Title: Principal Data Scientist, Data and Statistical Sciences

Organization: Genentech/Roche

Passionate about automation, with experience in statistical programming, EDC, and standards development. Enjoys R and SAS programming and leads software development projects.

SDTM to ADaM

- An open source, modularized toolbox that enables the pharmaceutical programming community to collaboratively develop ADaM datasets

- GSK is the project owner but there are >20 companies developing or testing

- It's in R, but they purposefully made the package simple enough for any users to use (with basic knowledge of ADaM standards and R)

- Tested this past year in hackathon

admiral

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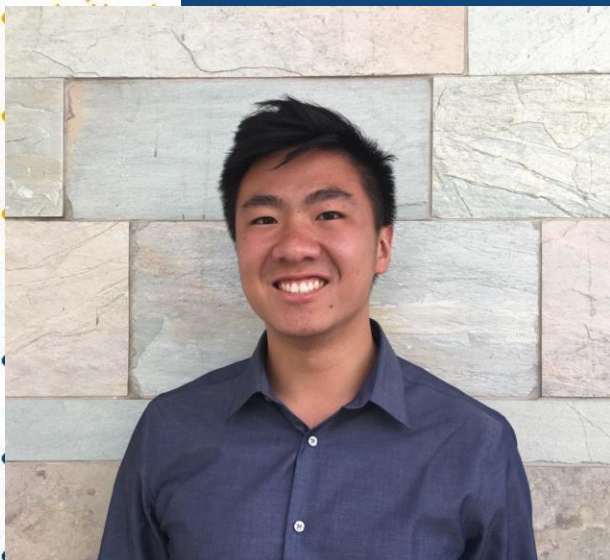
Meet the Speaker

Zelos Zhu

Title: Data Solutions Engineer

Organization: Atorus Research

I'm Zelos Zhu, a Data Solutions Engineer at Atorus Research, where I have the privilege of serving as a core developer for the R-Package, Admiral. My journey into clinical trials began as a Research Assistant at UCSF Breast Care Center and later as a Clinical Data Scientist at Boehringer Ingelheim, where I worked primarily on early phase oncology trials. When I'm not delving into the intricacies of data, you'll often find me pursuing my passions such as: cooking up delicious meals, embarking on breathtaking hikes, scaling V2s at the local bouldering gym, or working my way to 100 on a golf course.

Automated TFLs

- Some of the best attended CDISC 360 presentations had to do with automated TFL generation

- Using the findings of the CDISC360 project, work on a TFL Designer has progressed along side the CDISC Analysis Results Standard

- TFL Designer
  - Aligns with CDISC ARS
  - Provides a central repository for TFL standards and templates
  - Enables automated generation of TFL shells and machine-readable metadata.

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Conclusion

- The First Twenty Years - Laying the Foundation
  - Develop & promote standards that enable…

- We're now in the Transition
  - Linked metadata, enhanced interoperability, improved efficiency/quality/accuracy, security & privacy
  - Working towards that CDISC 360 Mission:
    - Apply the 80/20 rule to ensure the Project automates 80% of the end-to-end metadata and data processing needed to generate study artifacts suitable for a regulatory submission.

- The Emerging Future
  - Industry end-to-end automation
  - RWD
  - AI
  - …

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Thank You!

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