

A wide banner featuring a panoramic view of the Berlin skyline at sunrise. The sky is a mix of orange and blue. The cityscape includes various buildings, a prominent white tower with a sphere at the top (Fernsehturm), and a church with a tall spire. The text is overlaid on this image.

2024 CDISC + TMF  
EUROPE INTERCHANGE

**BERLIN**

24-25 APRIL: CONFERENCE & EXPO | 22, 23, 26 APRIL: TRAININGS

## **Adopt and Adapt CDISC CORE: A Sponsor's Reflections**

Addie Nina Olsen, Standards Specialist, Novo Nordisk A/S  
Vicky Poulsen, Principal Standards Specialist, Novo Nordisk A/S



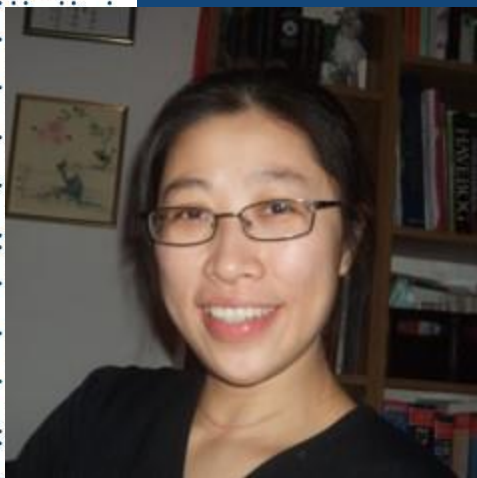
# Meet the Speakers

Addie Nina Olsen

**Title:** Standards Specialist

**Organization:** Novo Nordisk A/S

Addie has a PhD in molecular biology and protein chemistry. She has worked as a forensic geneticist and as a programmer of laboratory information management systems before becoming Senior Statistical Programmer in Novo Nordisk A/S in 2018. In her present position as Standards Specialist in Clinical Data Operations & Insights, she is developing programs for the SDTM Generation Framework and focusing on process improvement.



Vicky Poulsen

**Title:** Principal Standards Specialist

**Organization:** Novo Nordisk A/S

Joined Novo Nordisk A/S in 2015 after being a SAS consultant for a decade in the public health sector specialising in End-to-End BI solutions. She participated in the CDISC Implementation Project shortly after. In her present position, Vicky leads the standard programming strategy and development efforts that drive the SDTM Generation Framework for SDTM, define.xml and SDRG automation.



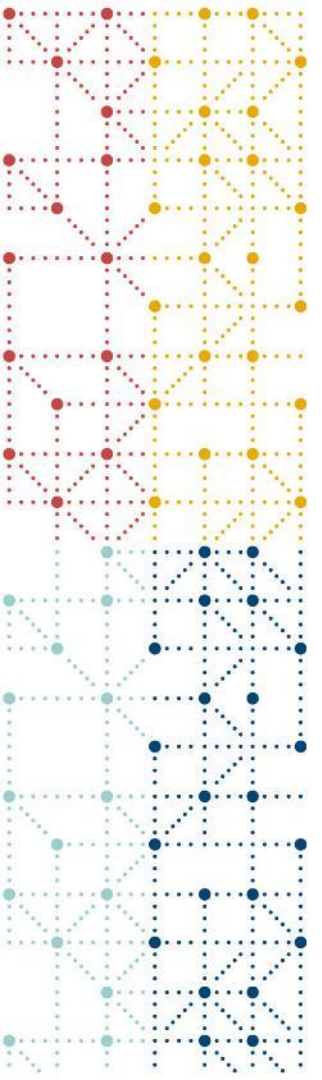
# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the authors and do not necessarily reflect the official policy or position of CDISC/Novo Nordisk A/S.*
- *The authors have no real or apparent conflicts of interest to report.*



## Agenda

1. Past, Present and Future
2. Adopting CDISC CORE
3. Adapting and Extending CDISC CORE
4. Reflections



# Past, Present and Future

# SDTM Validation



2017

**OCV Community Implementation in SCE**  
SDTM Validation executed as an integral part of SDTM Generation flow

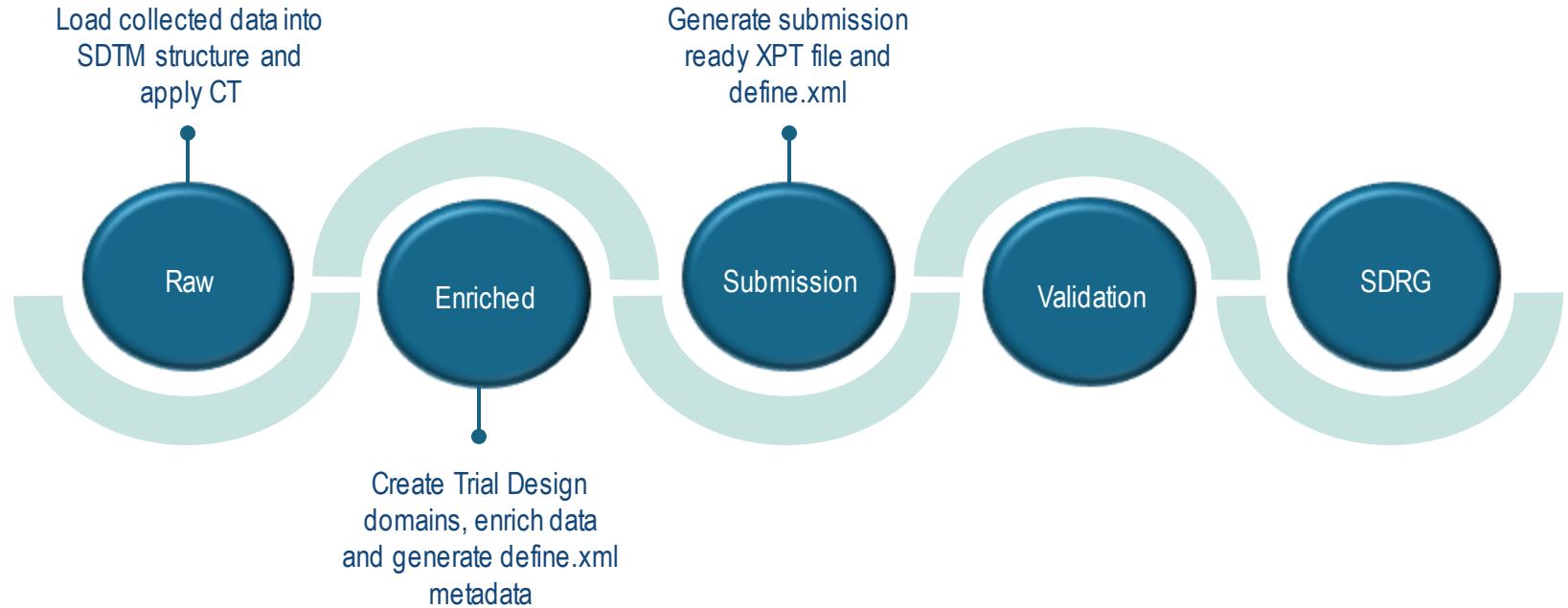
2021

**Adoption of P21E**  
SDTM Validation process separated from SDTM Generation flow due to limitation of CLI

2024

**CDISC Core Implementation + P21E**  
Reinstate SDTM Validation using CDISC Core Engine as an integral part of SDTM Generation flow for internal use

# The Complete Automation Flow



# The Optimal Validation Engine



Human friendly +  
machine readable



Notifications

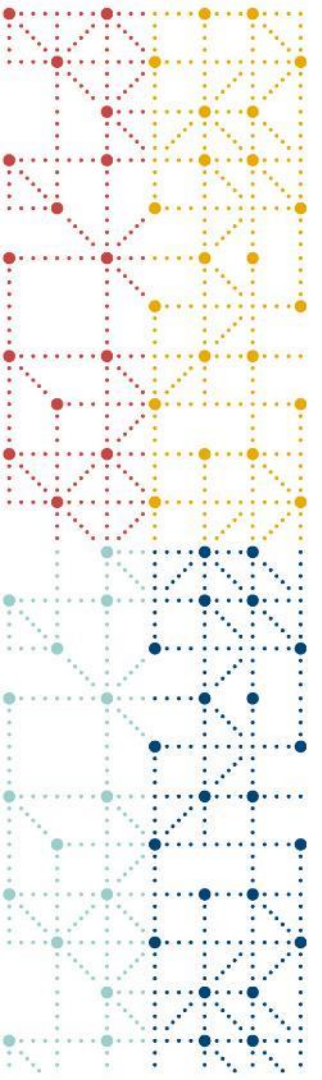


Explanations and fix tips



Cross-study summaries





# Adopting CDISC CORE

# Plans for Using CORE

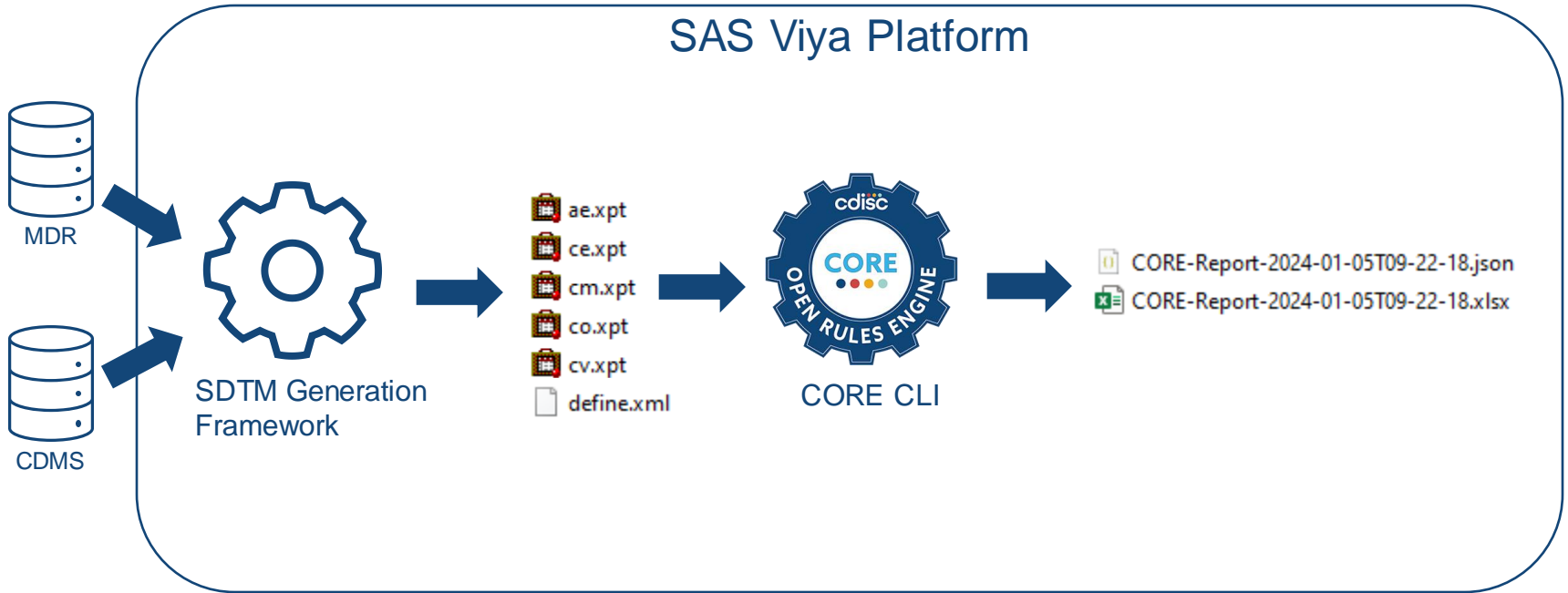


- Automated validation
  - Use during conduct of clinical studies
  - Use to detect issues in studies faster



- Manually initiated validation
  - Use to check submission data
  - Use for ad hoc checks

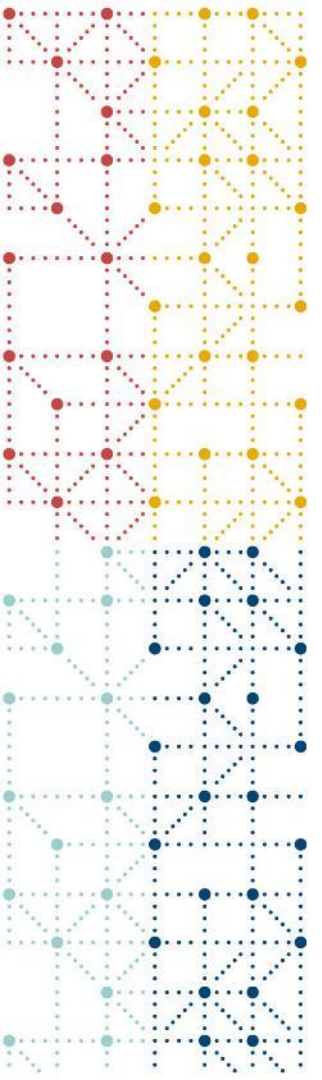
# Automated Validation



# Manually Initiated Validation

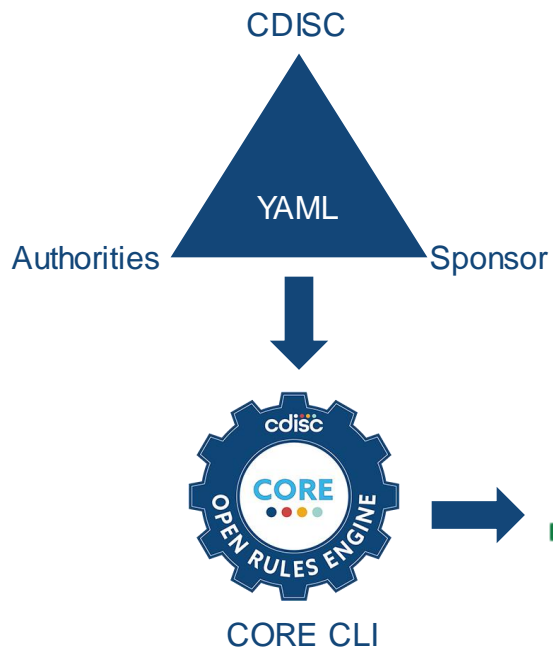
- Non-programmers should be able to execute CORE using a simple interface:
  - Selection of study and execution settings
  - Independent of commercial software





# Adapting CDISC CORE

# Applying a Trifecta of Validation Rules



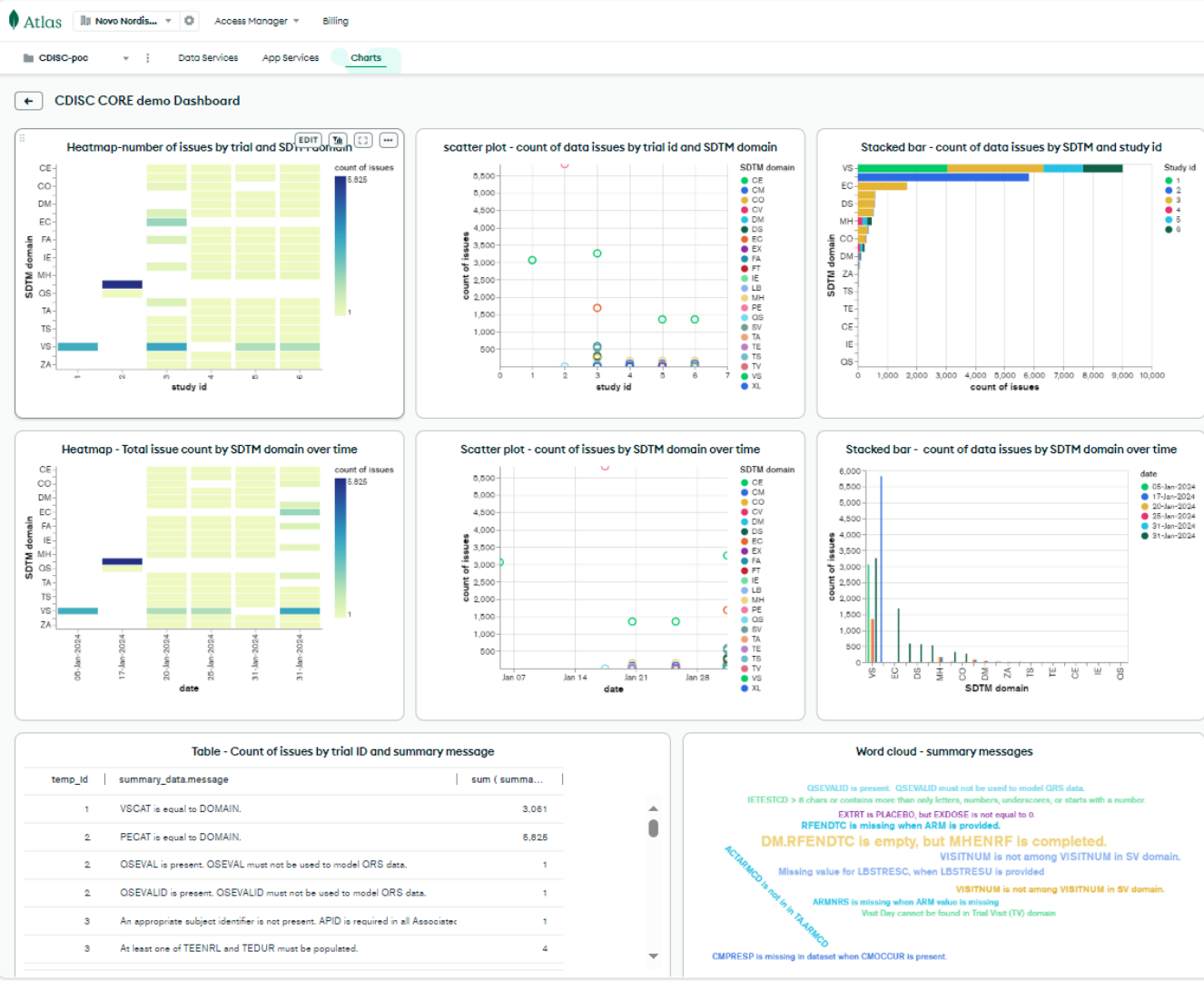
Summarise and visualise issues detected by SDTM Generation Framework and CORE



# Collecting CORE Output Across Studies

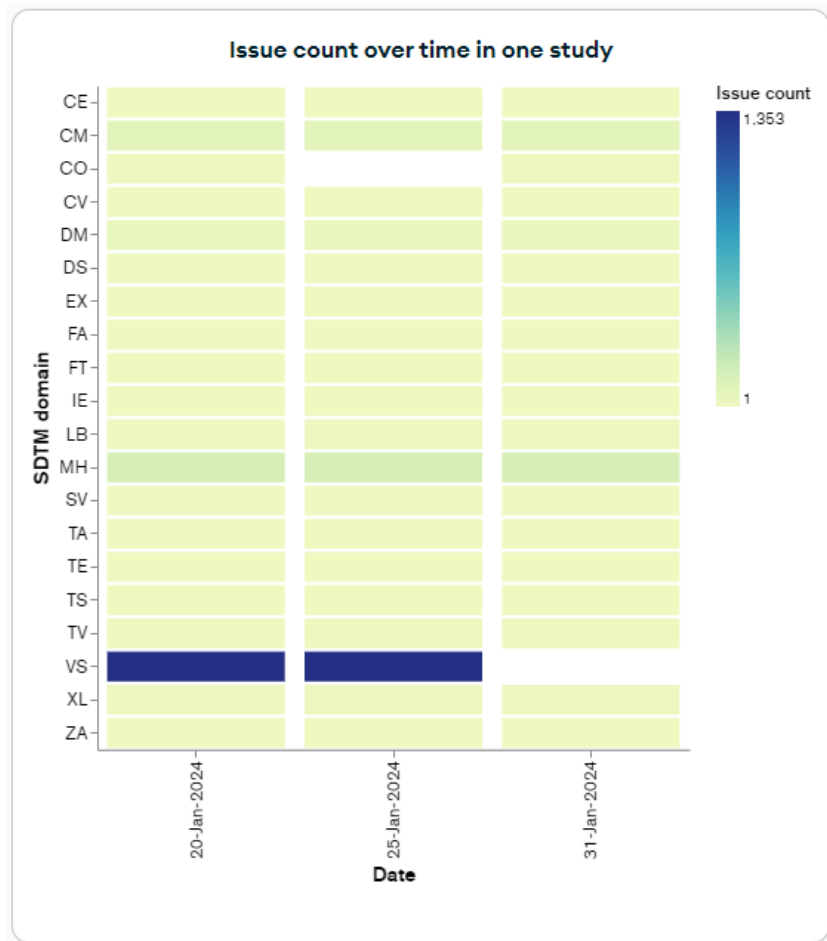
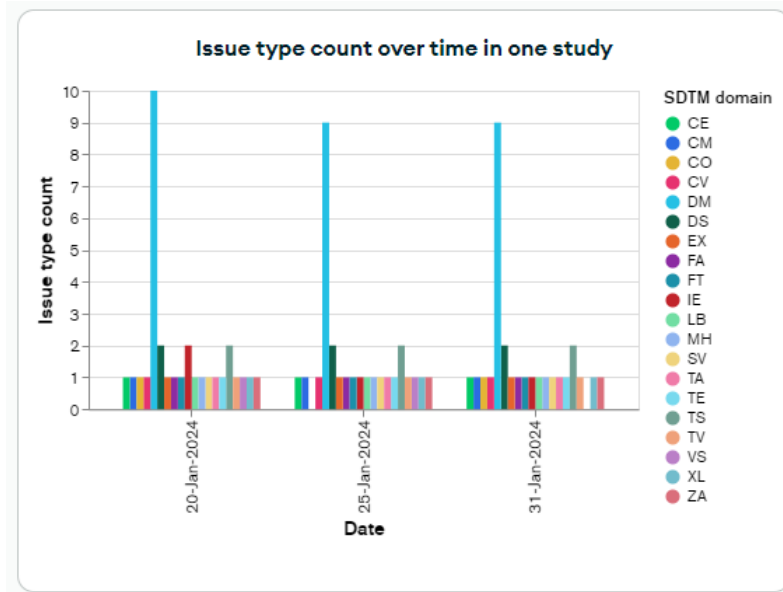
- Import CORE JSON files to a document database:
  - Stores data in JSON-like format
  - Designed with built-in flexibility
  - With tools for querying and aggregating data
- Vision:
  - See issue occurrence in a study over time
  - Detect trends across studies
  - Detect trends across datasets
  - Optimise standard programs in SDTM Generation Framework

# Visualisation of Issues

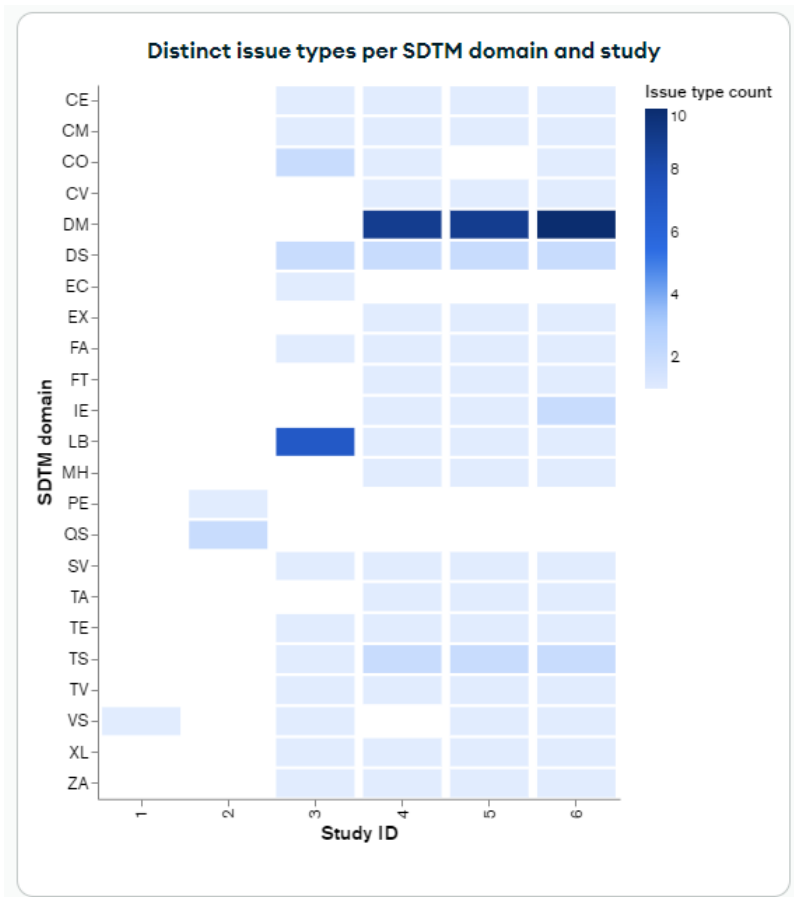
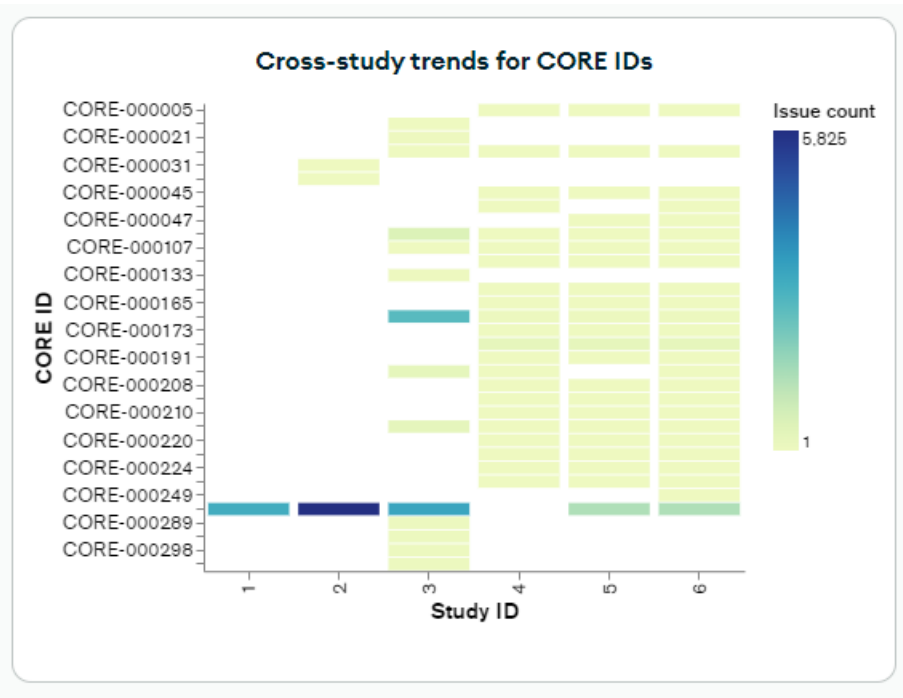


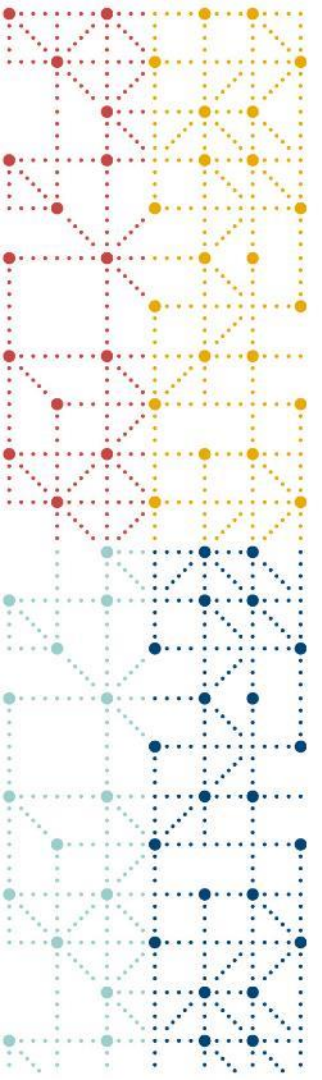


# Issue Trends Within a Study



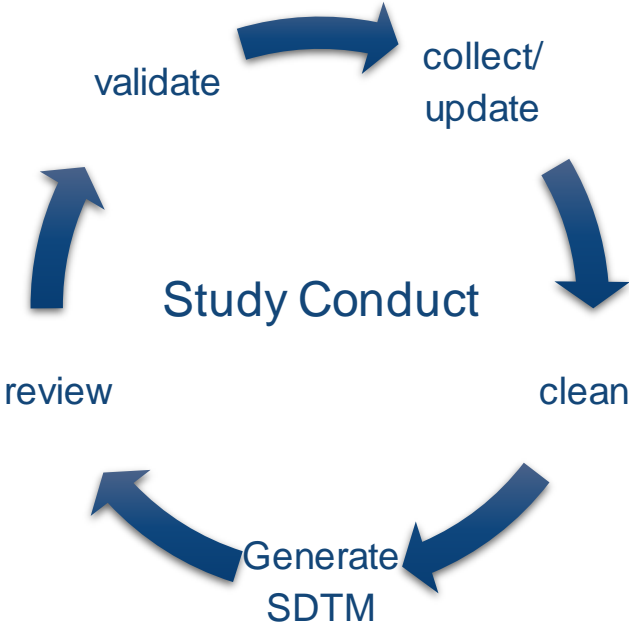
# Issue Trends Across Studies





# Reflections

# Data Validation as an Integral Part of Study Conduct



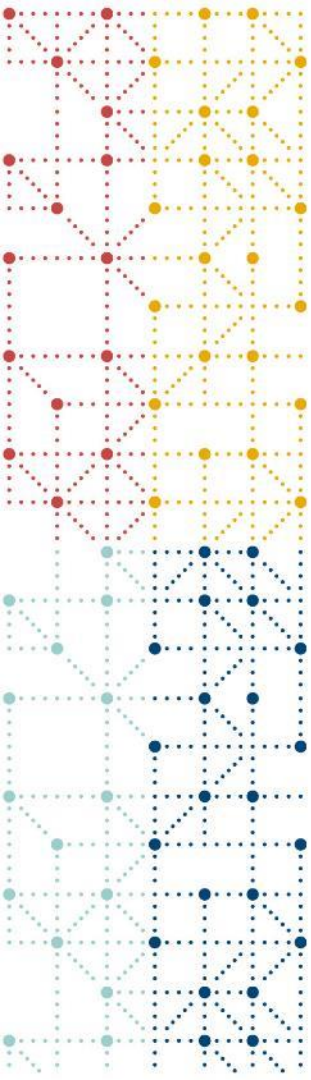
# Increase CORE Adoption Among Sponsors

- Expand guidance for CLI:
  - More execution examples
  - Overview of implemented features and features pending implementation
  - Make guidance friendly to non-programmers
- Focus on user-friendliness of CLI:
  - Meaningful error messages in commonly occurring scenarios, e.g. missing input parameter
  - Add option of tailoring output
- Make it clear that CLI can be used "as is" - no need for sponsors to develop their own validation software
- Uptake and alignment across authorities

# Concerns and Considerations

- CORE maintenance
  - Various IG versions
  - Keep up with rules from various authorities
  - Manage releases
  - Rely on volunteers
- Technical concerns
  - IT security
  - Open source and GxP compliance
- Risk of evolving into another vendor-dependent solution
- Conflicts with P21 findings





# Thank You!

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