cdisc®

2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

Building a library of instantiated biomedical concepts to ensure consistency and reusability in study designs.

Berber Snoeijer, ClinLine

Agenda

1. Introduction
2. Transitioning the MDR to USDM
3. Building the repository (demo)
4. Conclusion

Speaker

Berber Snoeijer
ClinLine

Berber has a degree in Biomedical Sciences and more than 25 years of experience in clinical research. During this time she:

- Founded and managed a data oriented CRO
- Acted as the R&D manager and department manager for a Real-World data institute
- Founded ClinLine dedicated to optimization of the data flow and real-world data utilization for clinical trials.

In these roles she designed process-aligned tools and solutions to optimize the efficiency of data flows. Drawing on stakeholder input and requirements, she now provides input and designs for data structures, solutions, and process optimization.
Berber has been involved in the TransCelerate DDF project since 2021 and is now acting as a Unified Study Definitions Model (USDM) technical expert, and CDISC USDM trainer. With the diverse open source tools she designs, she showcases how clinical research processes can be optimized using the USDM as a starting point.

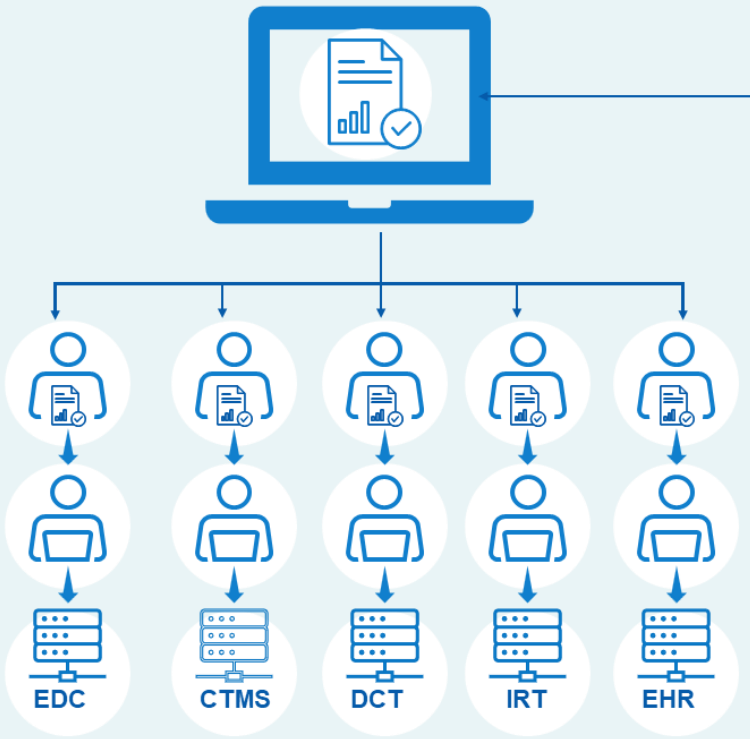
Introduction

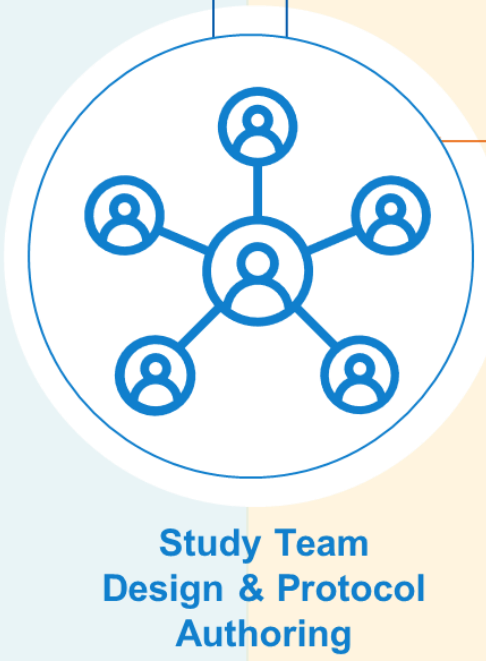
The digital data flow ambition

https://www.transceleratebiopharmainc.com/assets/digital-data-flow-solutions/

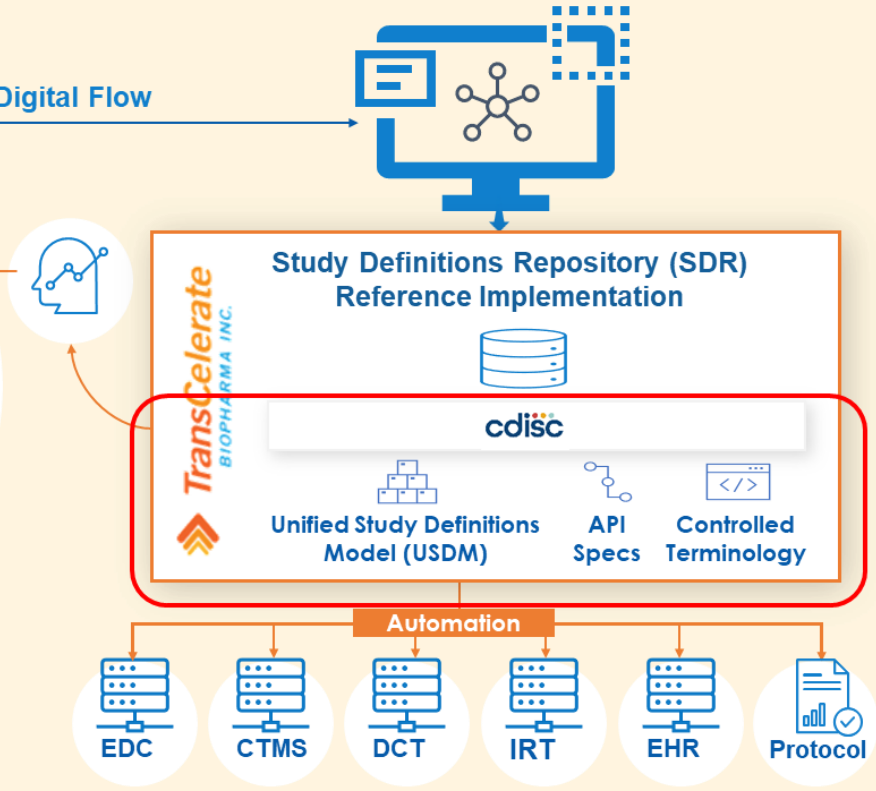
Write Once, Read Many

TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems





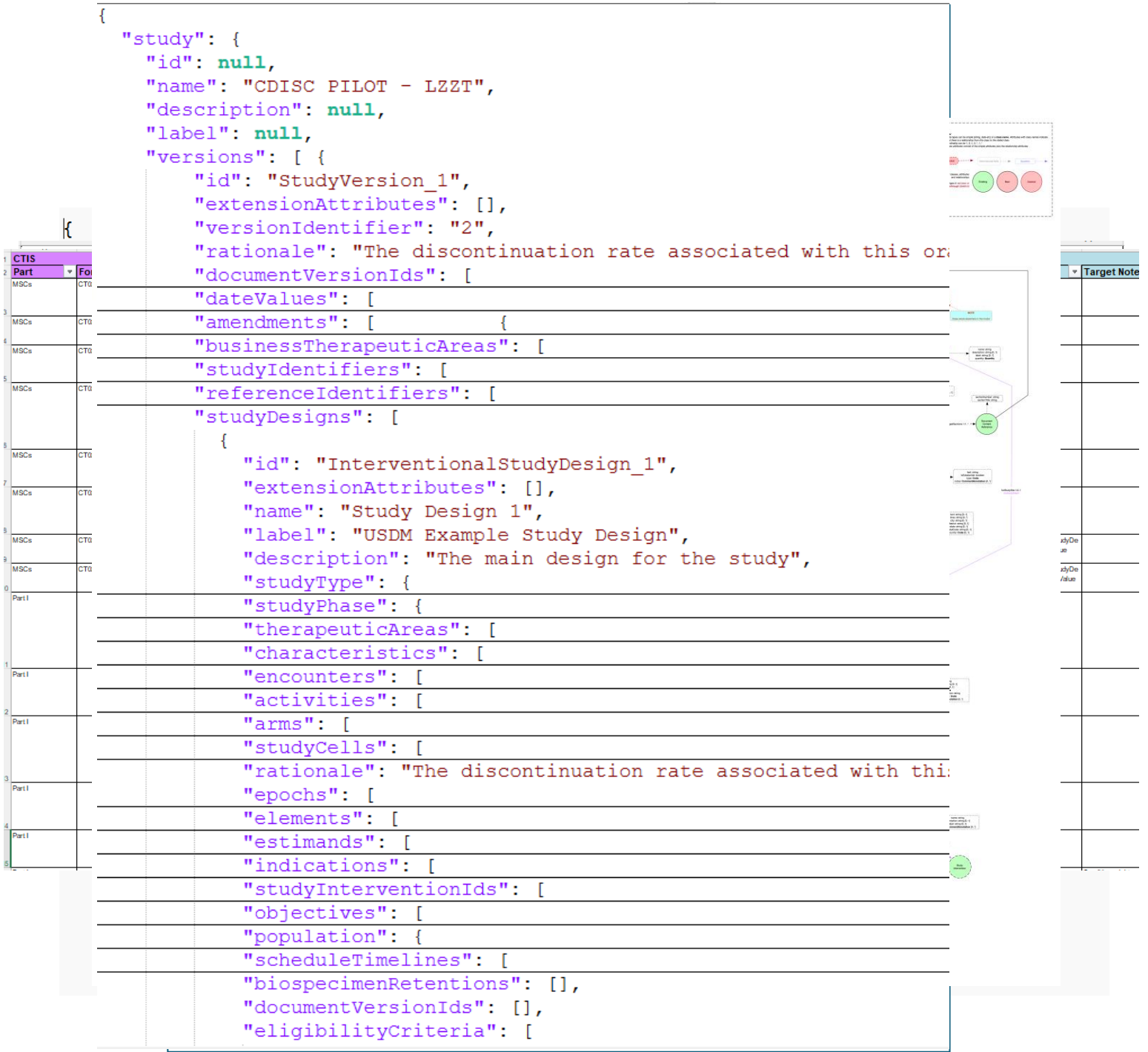
TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



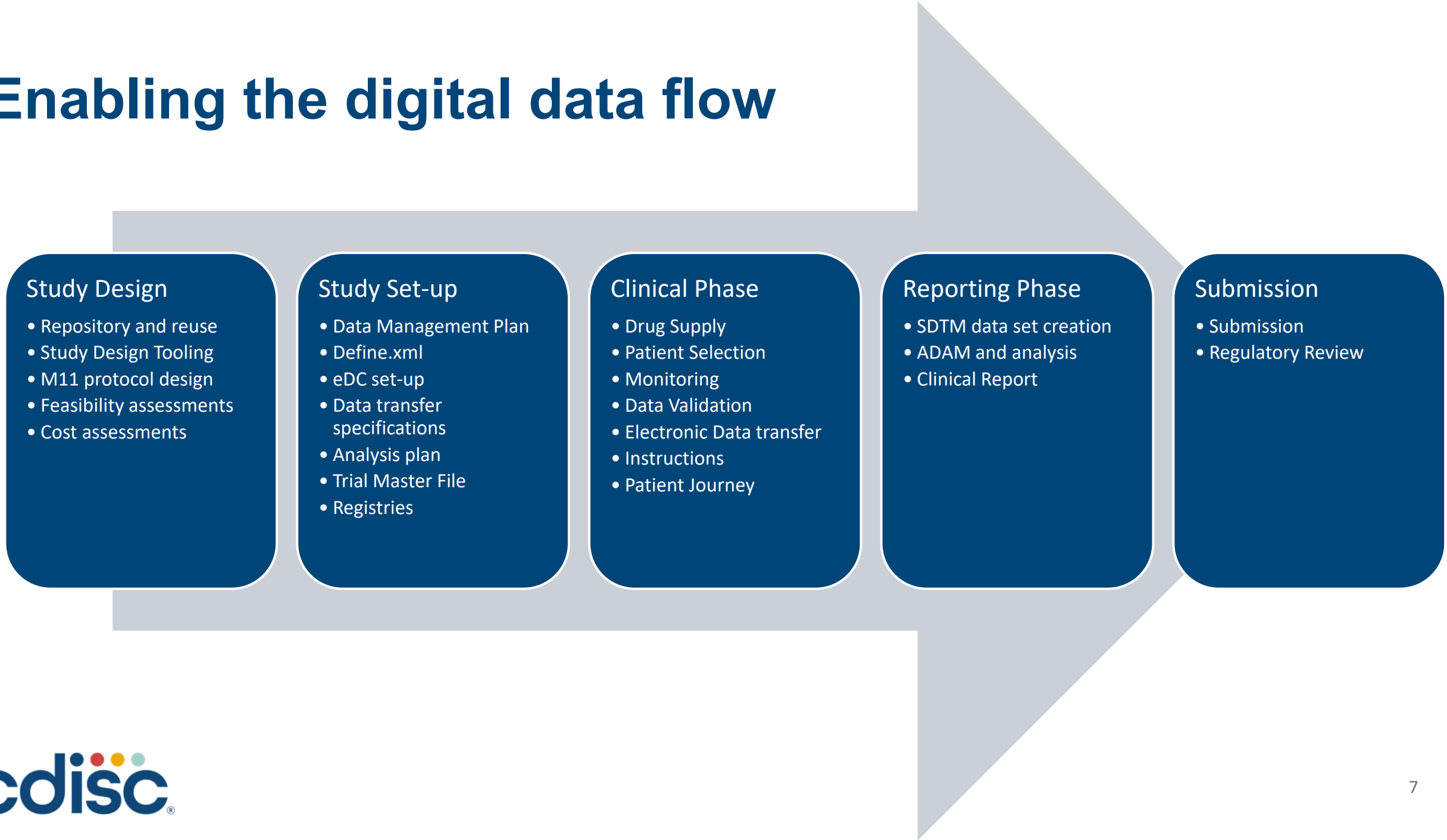
USDM v4.0

- **UML data model**
- **Controlled Terminology**
- **API definition**
- **Implementation Guide**
- **Conformance Rules**
- Mapping information
- Informative Diagram
- Examples

https://github.com/cdisc-org/DDF-RA

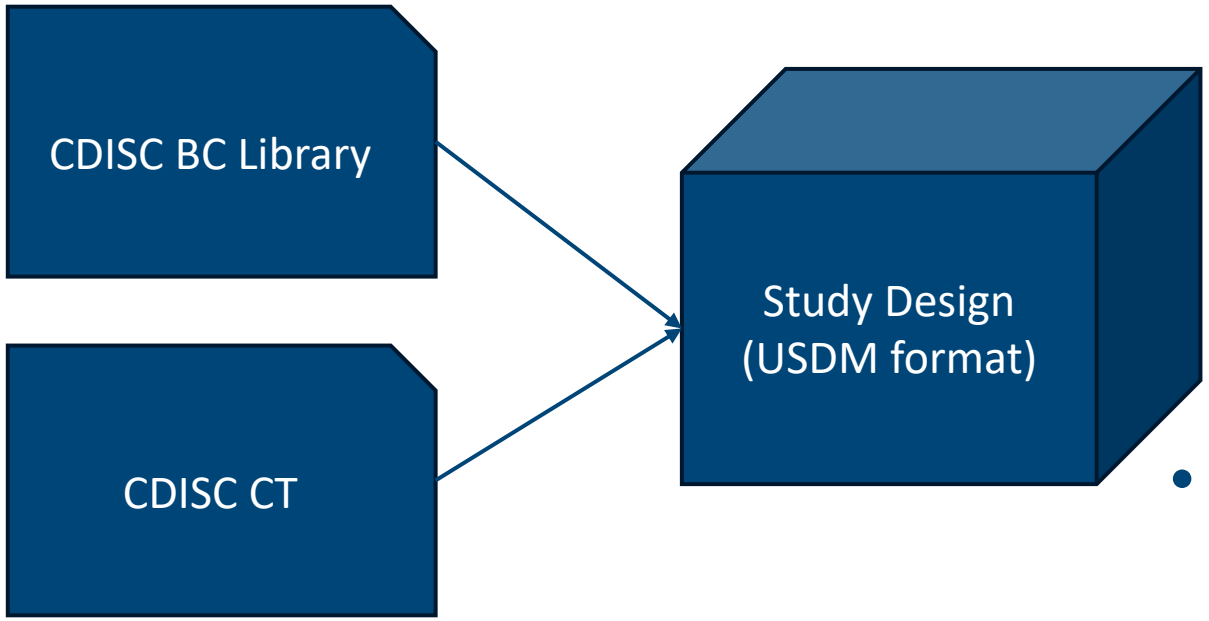


Enabling the digital data flow



Transitioning the MDR to USDM

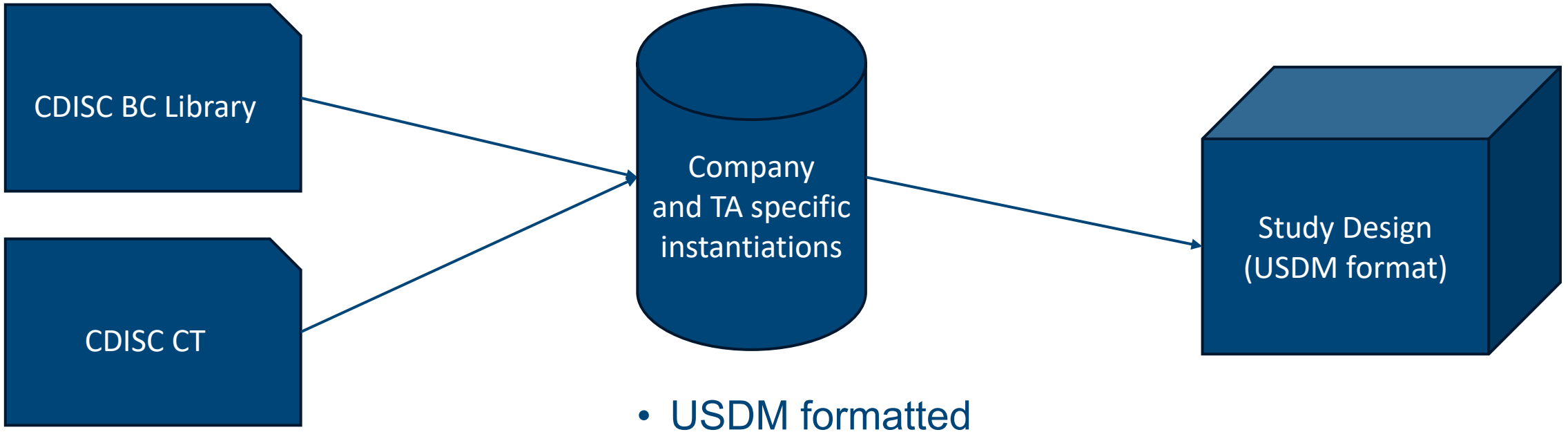
Utilizing CDISC CT and Biomedical Concepts



- Intended Process
  - Select applicable Controlled Terminology (CT) for a specific study design.
  - Select applicable Biomedical Concepts (BC) for a specific study design.
  - Indicate what properties are required for the study and enable them.
- However:
  - Labour intensive
  - Repetitive
  - Medical writers not used to it - resistance

Utilizing CDISC CT and Biomedical Concepts

- Flexible MDR approach:



- USDM formatted
- Labelled according to MW preferred terminology
- Option to adjust, if needed
- Ensures consistency within and between studies

Current Issues with a completely controlled MDR

- High maintenance/governance needs:
  - Versioning
  - New requirements
  - Outdated standards
- Too complex
  - Too many interdependencies
  - Review process
- Too standard
  - Trying to standardize the needs from different department and/or therapeutic area's
  - Not allowing exceptions
- Too siloed

The flexible MDR

- Include the interdependencies based on USDM structure
- Align to the target USDM structure
- AI
  - Suggest to reuse information when needed
  - Inform in case of inconsistent use
  - Suggest to add / adapt features and options when new
  - Warn when standard is not current any more / replaced
- Validate (if needed) on property / relationship level
  - After approval directly marked as such
  - Indicate when used what is approved or not
- Allow for changes and additions when instantiated

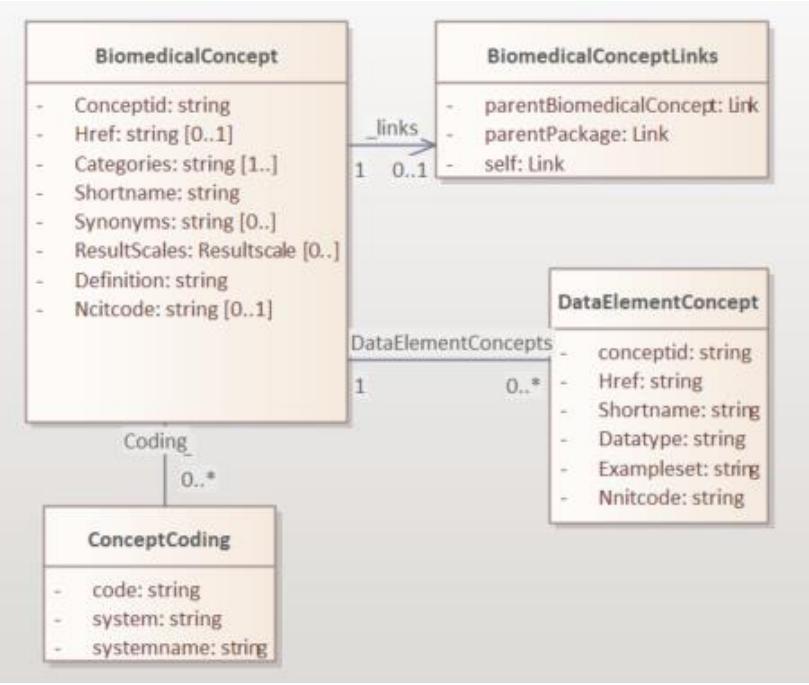
Building the Repository

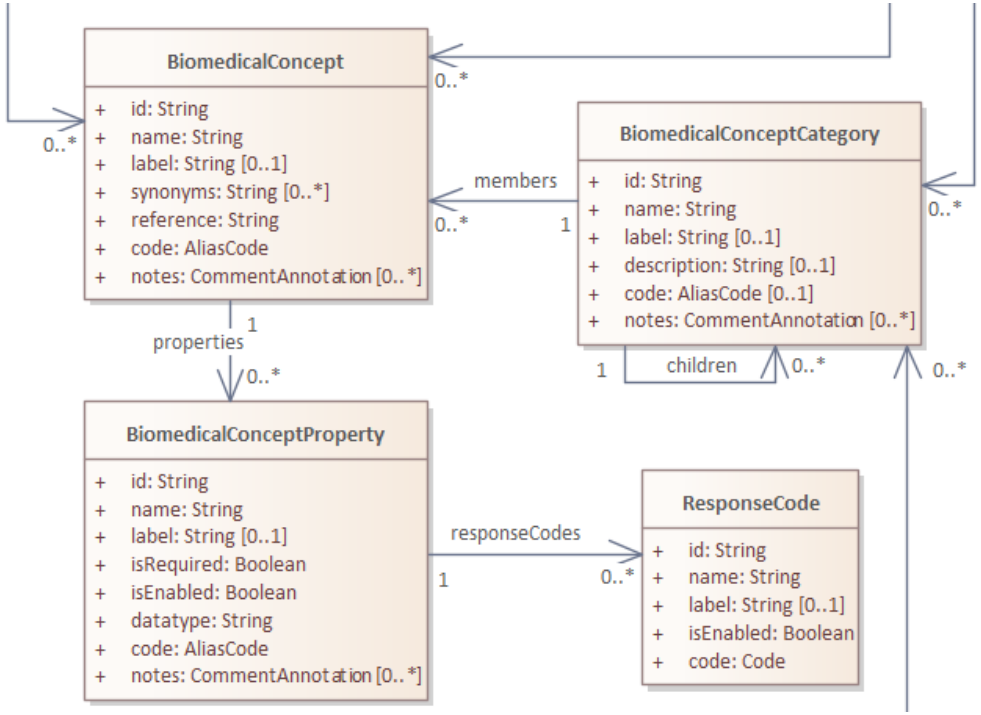
From CDISC BC library to flexible MDR

- Build your own specializations in USDM format
- BC2USDM Open Source tool
  - Pick up CDISC Biomedical Concepts from the library using the API
  - Select the Applicable BCs
  - Indicate what properties are enabled
    - => what methods, positions, specimens are allowed
    - => what information do you want to collect for trials
    - => what standard responses do you want to enable (if applicable)
  - Indicate the naming of the repository subset (BC grouping)
  - Export in USDM format to be utilized in multiple clinical studies.
  - Demo

Mapping

BC library vs USDM



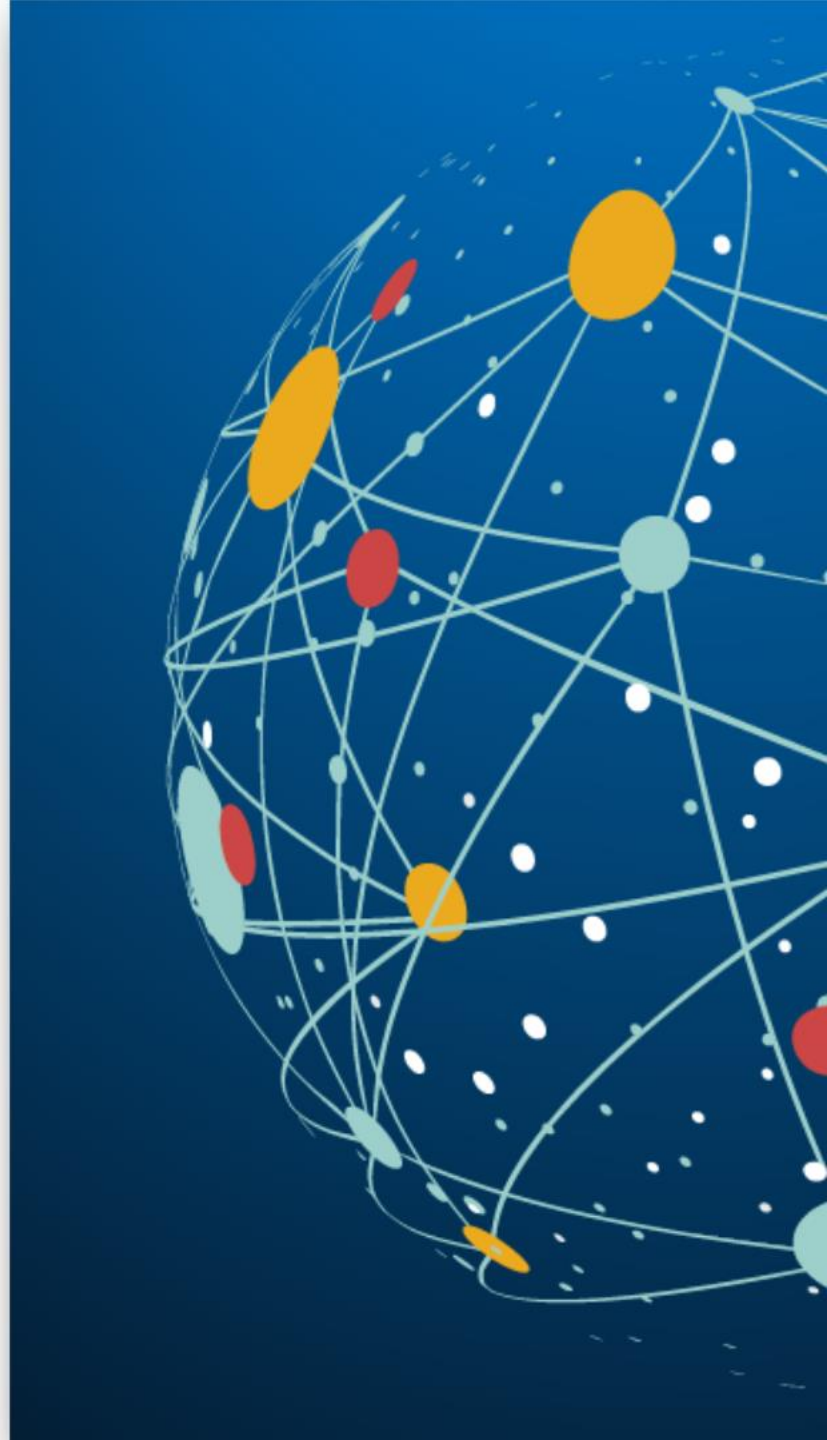


https://github.com/ClinLine/BC2USDM

Conclusions

Conclusions

- Company MDR (specializations) needed to:
  - Reduce burden in the design phase
  - Maintain the efficiency in the process
  - Ensure consistency within and between studies
- Storing in USDM format ensures:
  - Storing the relationships between items
  - Easy utilization for new trials stored in USDM format
  - Easily check new studies for alignment with the repository



Thank You!

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