PP07 Mastering the Jungle of Real-World Data

Introduction

Real-World Data (RWD) is increasingly used in regulatory submissions within the healthcare and pharmaceutical industries. The large variety in disparate data sources makes it complex to efficiently leverage the data, assess relevance, and show reliability and traceability. This poster shows how we enable data lineage from real-world data source to submission ready datasets.

Disparate Data sources

Electronic Health Records:
-Sources from GP, Hospital, Specialists
-Geographic differences
-Information system variation
-Treatment protocol variation

Claims:
-More structured
-Less depth

Registries:
-More depth
-Focus on 1 topic
-Trial elements

Patient Generated Health Data:
-Social Media
-Commercial Devices
-Unstructured and without protocol

Source Information Systems

- Large variation in information systems.
- No Standard Common Data Model used.
  - Data needs to be standardized either at source (FHIR mapping) or at the data Vendor site (OMOP-like mapping)
- Entry options and ease of use have an effect on:
  - what data is collected, and
  - the level of structure in the source data
- AI and Analysis Options may be used:
  - to define level of consistency between systems, and
  - for leveraging unstructured information.

Alignment to CDISC 360i

- A multi-year initiative with the aim to transform the way we develop and use standards within clinical research connected and interoperable information
  - enabling automation,
  - enhancing data integrity,
  - accelerating innovation.
- Use Cases
  - LZZT
  - Breast Cancer
  - Parkinson (aligning to LZZT)
  - CDISC Digital Data Flow
  - RWD Lineage Project
  - 360i Project

See CDISC 360i webpage for resources and recordings: https://www.cdisc.org/cdisc-360i

Automation and traceability

Source 1
Source 2
Source xxx

Computable mapping sheet:
-Location
-Selection
-Transformation
-Target
-Documentation

MAPPING ENGINE
CDISC DATA CONVERSION DONE FASTER

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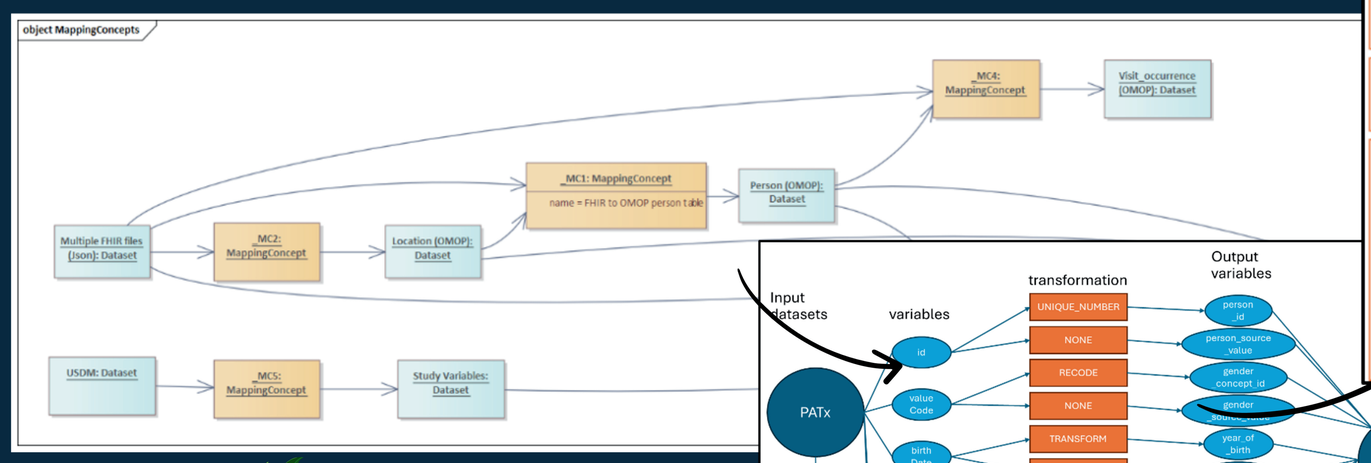
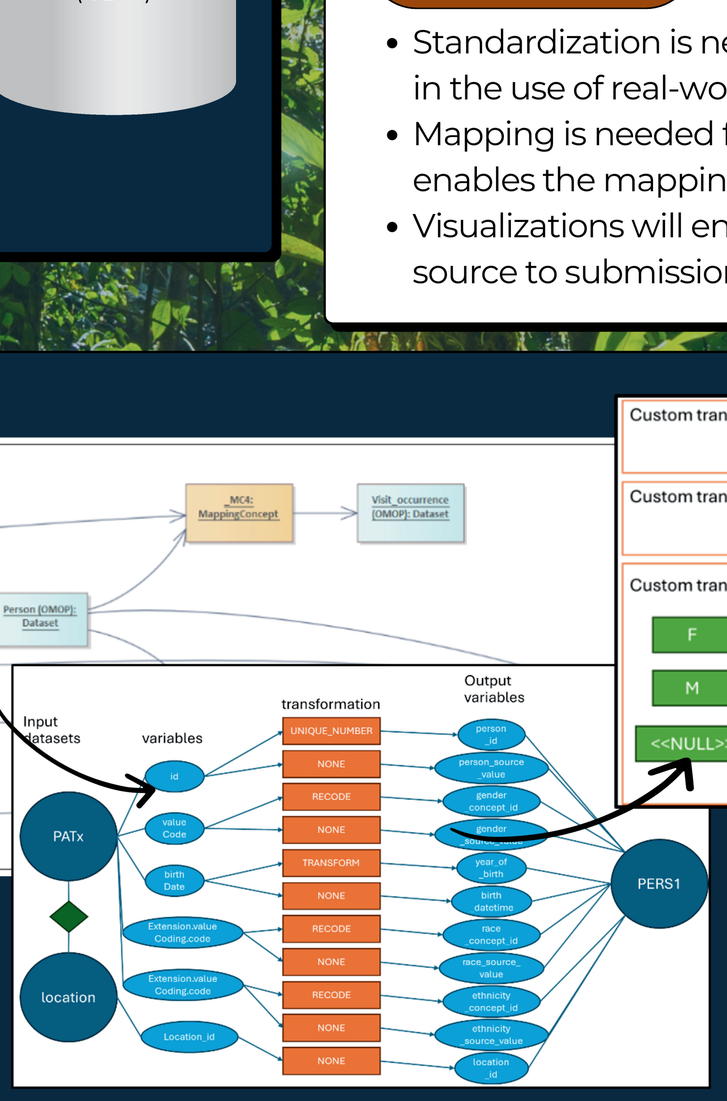
Target Common Data Model (CDM)

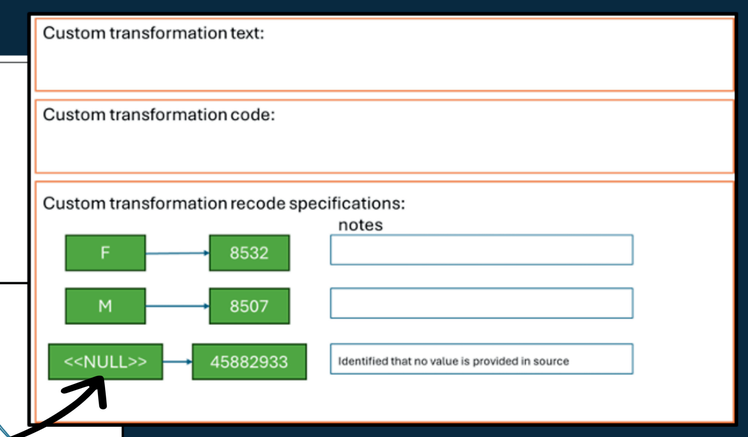
Key Take Aways

- Standardization is needed for interoperability and efficiency in the use of real-world data sources.
- Mapping is needed for standardization where automation enables the mapping efficiency.
- Visualizations will enable easy overview of the lineage from source to submission ready datasets.

Data Lineage







ClinLine Open Source Lineage Tool

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ClinLine

View our dedicated Break&Learn presentations on data lineage and the jungle of Real-World Data.