Pistoia Alliance Annual Conference

Breakout session Two: Accelerate Use of RWD/RWE

The Challenges in RWD/RWE integration for R&D

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Better Health, Brighter Future

Gaps in Public Health Sector Data and Metadata Alignment & Management

Public Health relies on RWD and RWE to innovate and advance treatments

The public health sector generates vast amounts of data from hospitals, clinics, research, surveys, and campaigns

- Challenges in Public Health Data Management:
  - **Data Fragmentation**: Dispersed data across different databases and systems encumbers comprehensive access and limits insights and informed decision-making
  - **Data Quality/integrity**: Inconsistent metadata compromises public health data reliability and data provenance
  - **Interoperability**: Lack of standardized metadata limits collaboration among different public health sectors (e.g., Government Agencies, Researchers, Hospitals etc.) and obstruct trend identification to address health disparities
  - **Data Privacy**: Inadequate or inefficient management risks privacy breaches

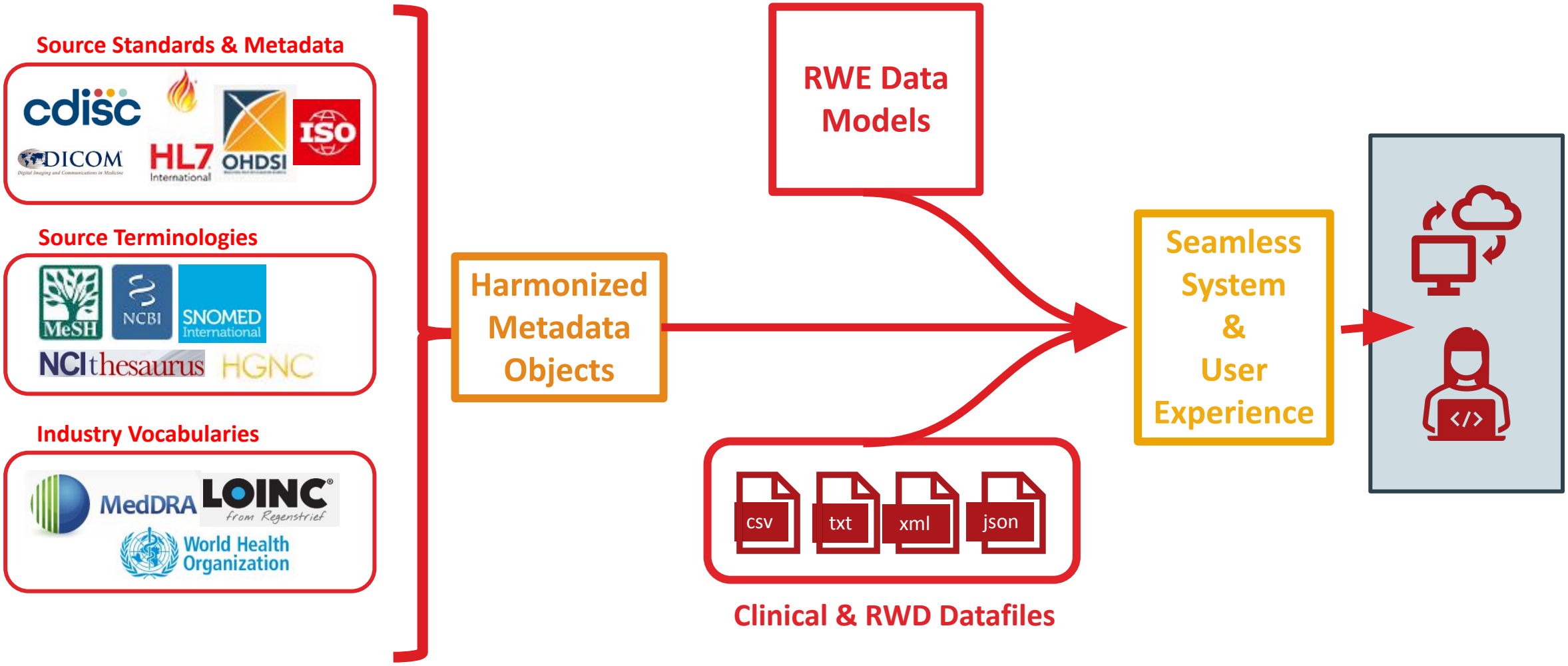
How can Metadata Management address these gaps to achieve efficient utilization of health-related data?

- **Standardization**:
  - Enables data integration and interoperability across various public health entities
  - Facilitates comprehensive analysis, aiding researchers and policymakers in making data-driven decisions
- **Data Governance**:
  - Ensures data quality, integrity, and security

Transformative metadata management empowers public health and enables RWE/RWD usability & impact

The Vision - Standards and Metadata alignment within Datasets and Systems:

Shared meaning along the discovery & development pipeline, seamless data accessibility and efficient analysis



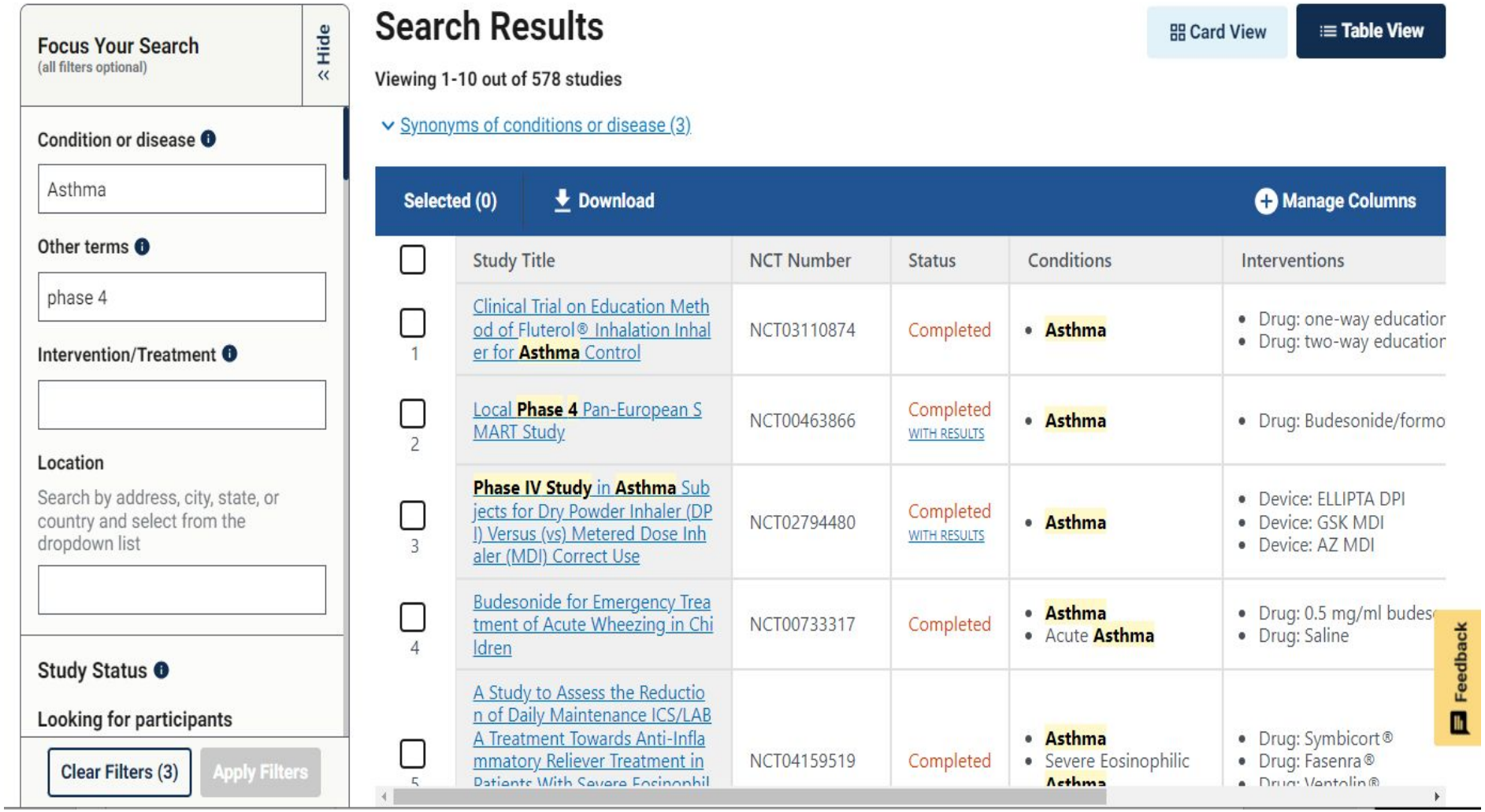
Accelerating the impact of RWD and RWE from Phase 4 Trials and beyond

Key Considerations:

- Data Sources & availability
- Use Cases: Vaccines, Medicines, Medical Devices
- Reporting requirements: Safety and Adverse Events
- Common Data Models and Mappings
- Data Consolidation and Harmonization
- Methods – Curation
- Methods – Analysis

Hot Topics:

- ML/AI
- NLP & LLMs
- Big Data
- Real-time Analytics
- Public and Curated Data Sets



Leveraging OMOP:

Observational Medical Outcomes Partnership Common Data Model

Technical enablement of systems and data to carry out OMOP standardization of internal and external data sets depends upon:

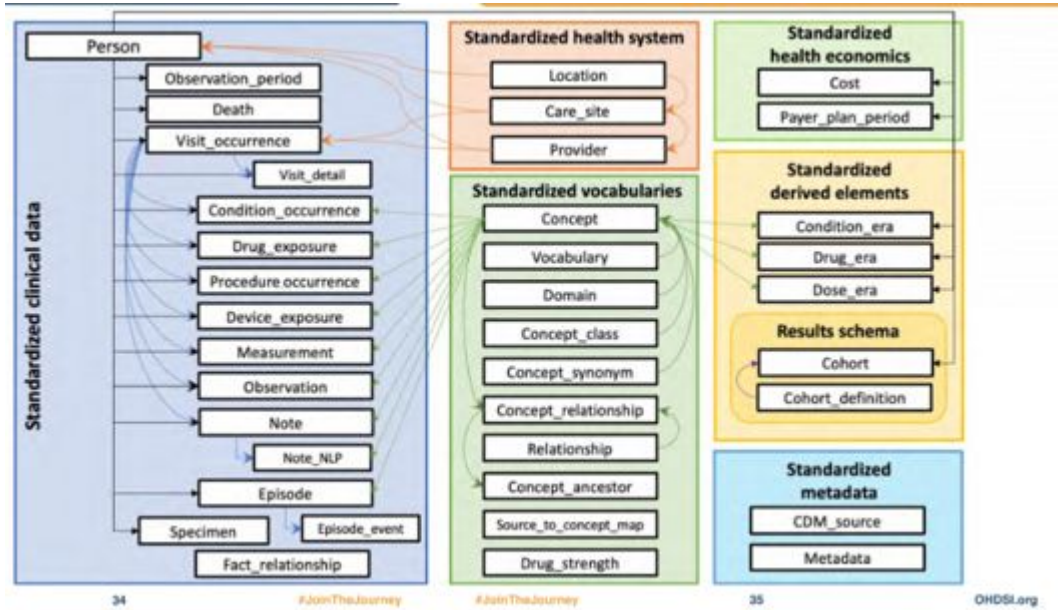
Data availability and accessibility

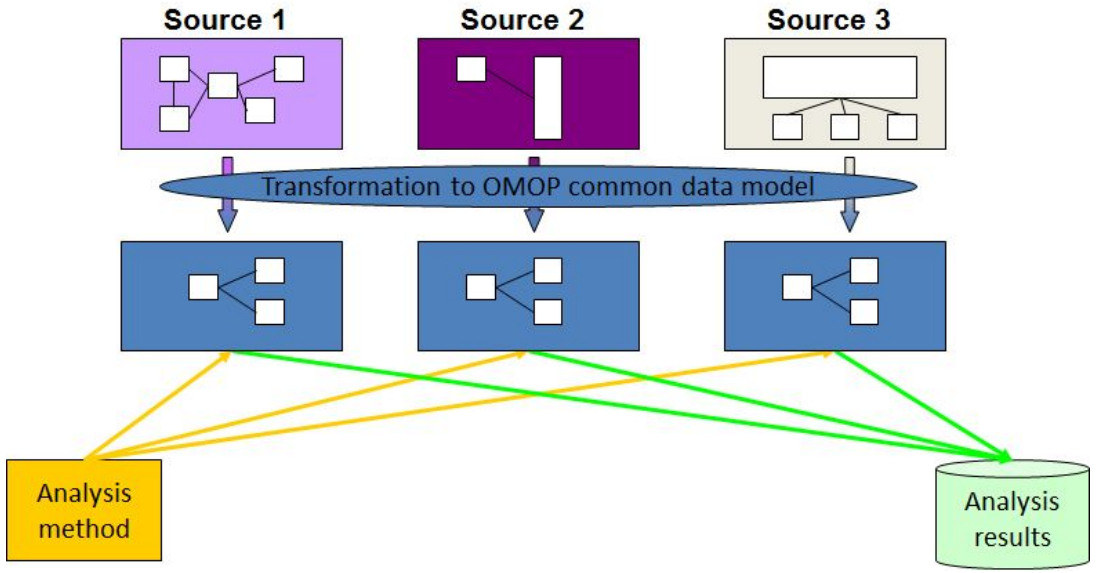
Semantic tools

Semantic data models (OMOP & mappings)

Named entity and Natural language processing

Metadata and data harmonization pipelines





https://www.ohdsi.org/data-standardization/

https://athena.ohdsi.org/search-terms/start

Leveraging OMOP to produce analytics ready RWD

Enabling the industry & organization with the methods and tools needed to accelerate the usability and impact of RWE

Data availability and accessibility

- Data Sources
- Data Annotations
- Data Access

Semantic tools

- Ontologies
- Curation tools
- Data Science Capabilities

Semantic data models (OMOP & mappings)

- Application Schema (EHR)
- Terminologies
- Industry Standards

Named entity and Natural language processing

- Internal and External Entities
- Relationships
- Context

Metadata and data harmonization pipelines

- Computational & user driven curation
- Metadata alignment
- Structured output

Transformative metadata management empowers public health and enables RWE/RWD usability & impact

Useful references

Generate Analysis-Ready Data for Real-world Evidence: Tutorial for Harnessing Electronic Health Records With Advanced Informatic Technologies

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