



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:

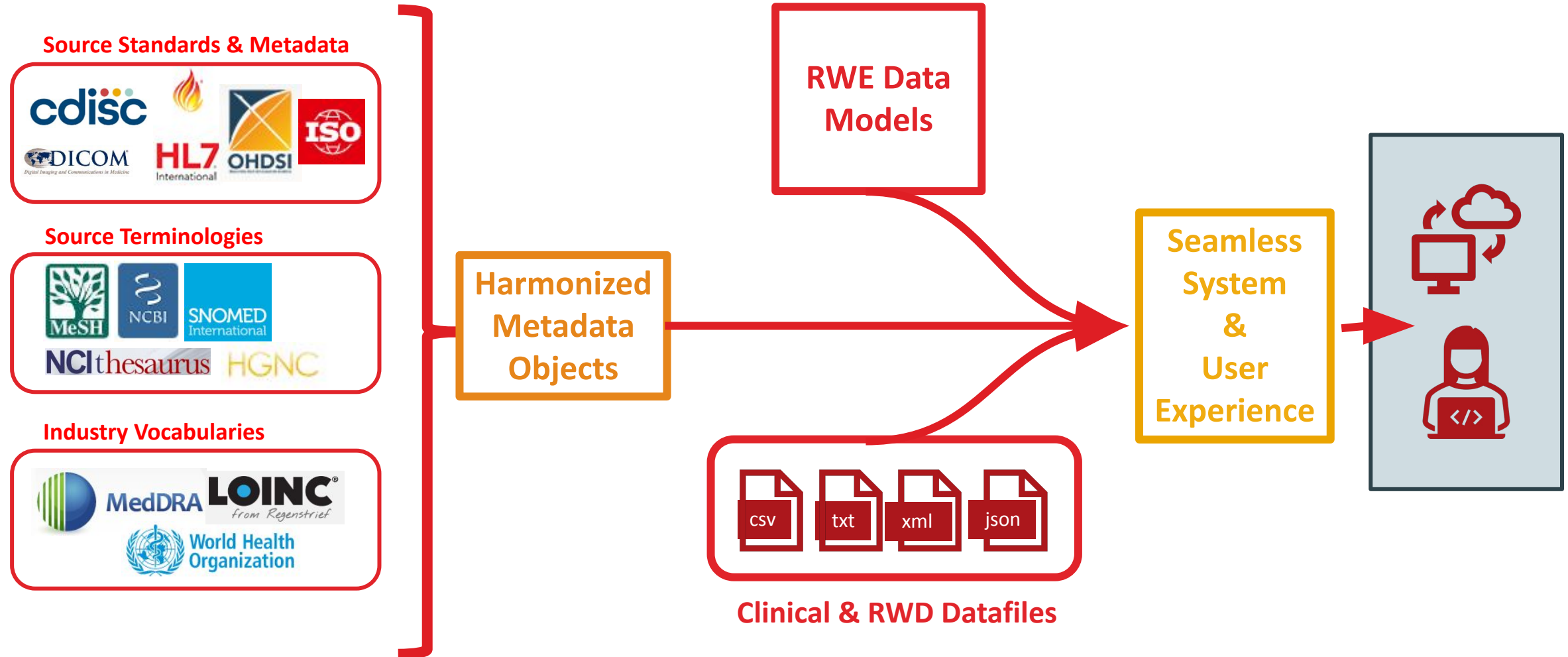
- Ensures data quality, integrity, and security

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

Focus Your Search
(all filters optional)

Hide <<

Condition or disease ⓘ

Other terms ⓘ

Intervention/Treatment ⓘ

Location

Search by address, city, state, or country and select from the dropdown list

Study Status ⓘ

Looking for participants

Clear Filters (3)
Apply Filters

Search Results

Viewing 1-10 out of 578 studies

[Synonyms of conditions or disease \(3\)](#)

Selected (0)
Download
Manage Columns

	Study Title	NCT Number	Status	Conditions	Interventions
<input type="checkbox"/>	Clinical Trial on Education Method of Flutero[®] Inhalation Inhaler for Asthma Control	NCT03110874	Completed	• Asthma	• Drug: one-way educator • Drug: two-way educator
1					
<input type="checkbox"/>	Local Phase 4 Pan-European SMART Study	NCT00463866	Completed WITH RESULTS	• Asthma	• Drug: Budesonide/formo
2					
<input type="checkbox"/>	Phase IV Study in Asthma Subjects for Dry Powder Inhaler (DPI) Versus (vs) Metered Dose Inhaler (MDI) Correct Use	NCT02794480	Completed WITH RESULTS	• Asthma	• Device: ELLIPTA DPI • Device: GSK MDI • Device: AZ MDI
3					
<input type="checkbox"/>	Budesonide for Emergency Treatment of Acute Wheezing in Children	NCT00733317	Completed	• Asthma • Acute Asthma	• Drug: 0.5 mg/ml budes • Drug: Saline
4					
<input type="checkbox"/>	A Study to Assess the Reduction of Daily Maintenance ICS/LAB A Treatment Towards Anti-Inflammatory Reliever Treatment in Patients With Severe Eosinophilic	NCT04159519	Completed	• Asthma • Severe Eosinophilic • Asthma	• Drug: Symbicort [®] • Drug: Fasenna [®] • Drug: Ventolin [®]
5					

Feedback

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



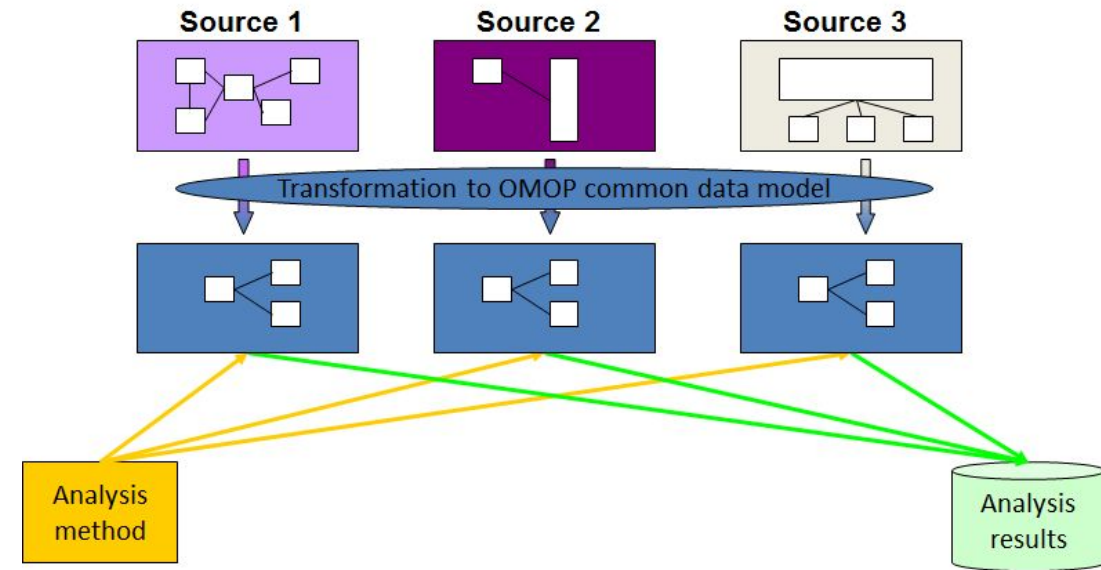
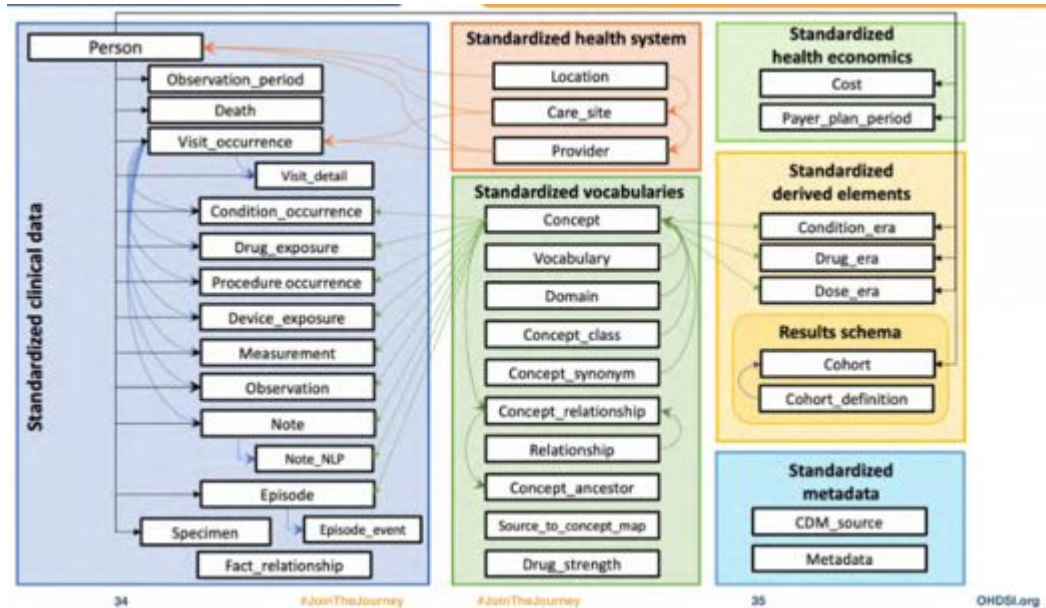
Semantic data models (OMOP & mappings)



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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Real-world data: a brief review of the methods, applications, challenges and opportunities

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Innovation at the Intersection of Clinical Trials and Real-World Data Science to Advance Patient Care

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