



BioTechX 2026

Mastering the Jungle of Real-World Data

Clin
inLine

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- Solutions
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ClinLine



- Dedicated to optimizing efficiency in the clinical data flow
 - Reduce costs for drug and device development
 - Optimize opportunities for patients and health care professionals
- Combining technical skillsets with content knowledge and business process insights and experience
 - Driving innovative processes
 - Keeping the big picture
- Involved in industry-wide improvement processes like
 - TransCelerate / CDISC Digital Data Flow Initiative
 - Chair Real-World Evidence working group PHUSE

Introduction

■ Real-World Data Definition

- Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. (FDA Definition)
- The data that describe patient characteristics in routine clinical practice (EMA definition)

■ Real-World Data Opportunities

- More and more accepted for regulatory purposes
 - Real-World Data Control arms
 - Pragmatic trials
 - Decentralized trials
- Faster drug evaluation processes
- Less patient burden

Introduction – Variety of Data Sources

- Electronic Health Records

- General Practitioner (GP)
- Hospital/clinic data

- Claims

- Pharmacy
- GP, Hospital, Clinic
- Insurance companies

- Other

- Lab
- Physiotherapist
-



Real-World Data Challenges

- Guidelines and regulations
 - Data lineage
 - Source access
 - Reliability and Relevance assurance
- Source collection variation
 - Heterogeneity in information systems
 - Heterogeneity in treatment protocols and practice
 - Extensiveness, representativeness, and missingness
- Standards
 - Source standards
 - Transformations at the source
- AI validation



Solutions: Data Source & Patient Selection

- RWE workshop
 - Address all different aspects (from study design to analysis and reporting.)
- Study outline
 - Request for Information including all regulatory aspects
- Patient selection algorithms
- Data management & statistical support
- Reporting and submission
 - Data lineage overview



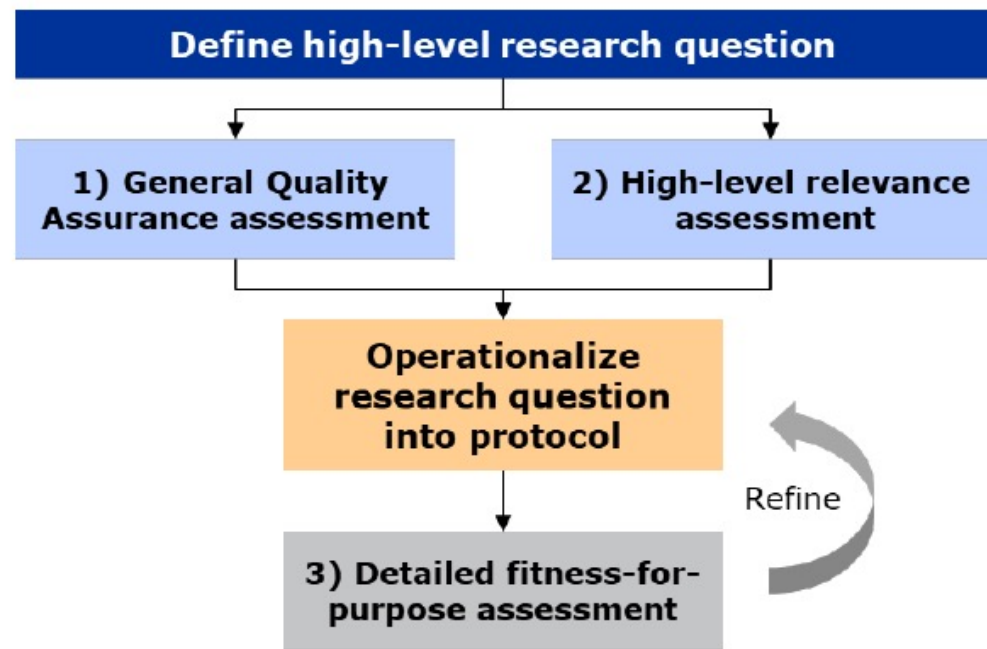
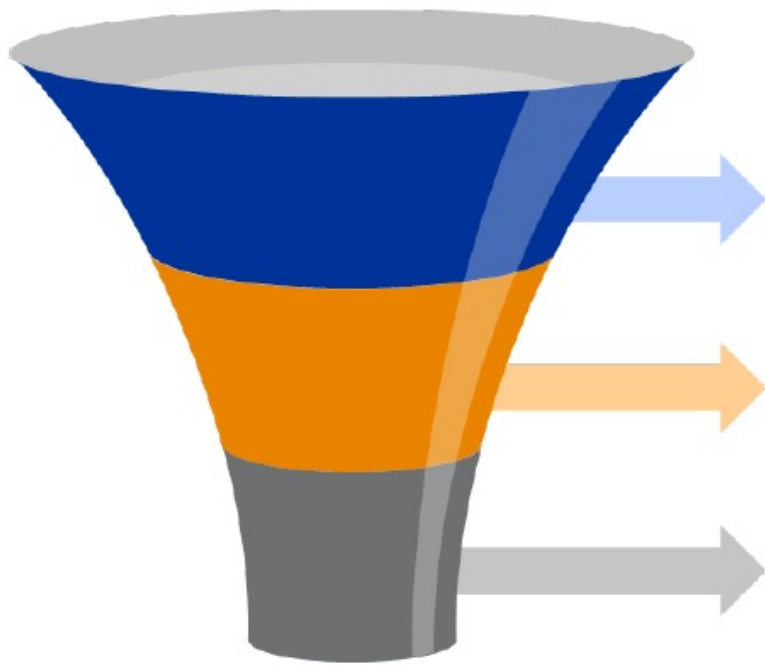
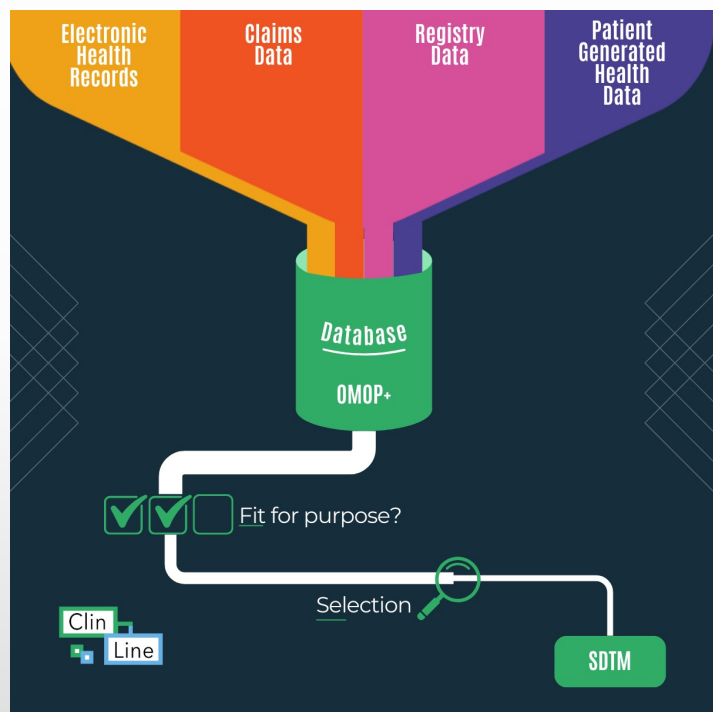


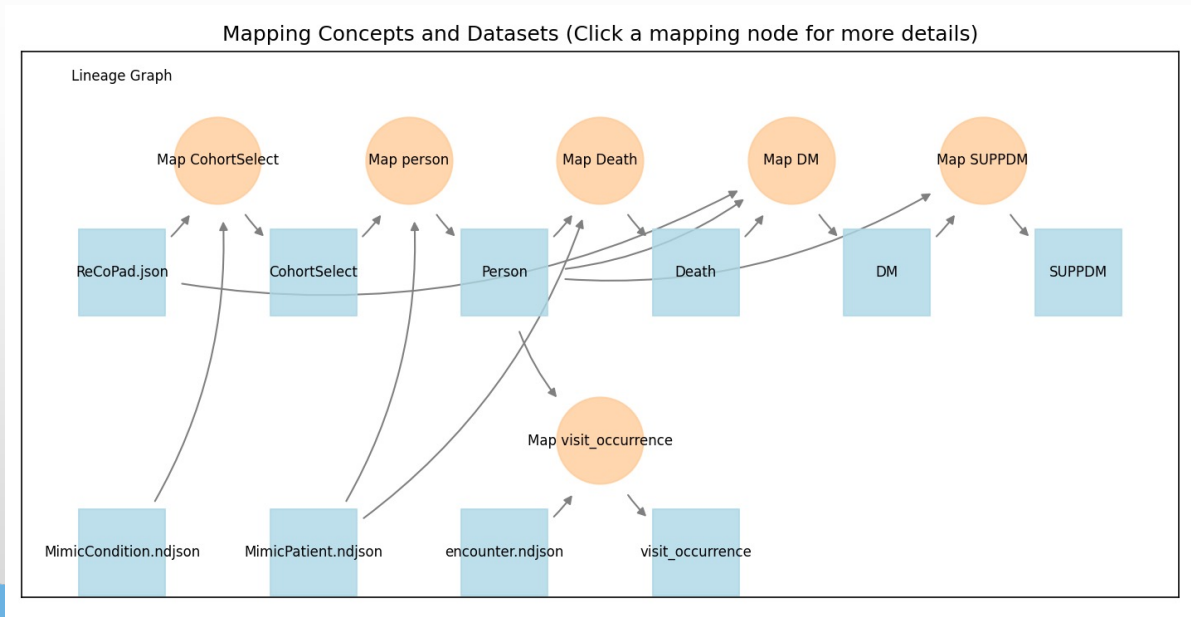
Figure 5 - General principles for assessment of DQ in relation to a research question

Data Quality Framework for EU medicines regulation: application to Real-World Data (draft Nov 2024)

Solutions: Data Lineage



- Automation
- Traceability
- Visualization



Solutions: Digital Data Flow

- CDISC Unified Study Definition Model (USDM)
 - Contains all study design elements in a digitized format
 - Enables full automated downstream processing
- Use cases
 - Study design repository
 - Study feasibility assessments
 - EDC and submission dataset automation
 - Trial Site alignment
 - Data transfer and government
- Technical expertise and implementation



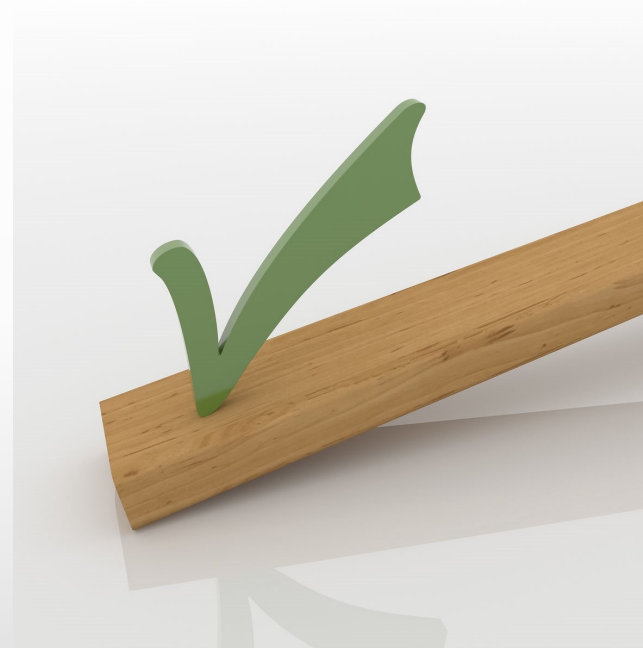
Solutions: Enable Semantic Interoperability

- Data transformations and mapping
- Mapping automation and human in the loop validation
- Automated summary, issue and inconsistency alerts

Codelist	Source 1		Source 2		OMOP				CDISC			
	Value	Code	Value	code	concept_id	Code	Name	Vocabulary	Codelist	Codelist code	CT	
Route	p.o.	0	PO		1	4132161	26643006	Oral route	SNOMED	C66729	C38288	ORAL
Route	p.r.	1	PR		2	4290759	37161004	Rectal route	SNOMED	C66729	C38295	RECTAL
Route	s.c.	2	SC		3	4142048	34206005	Subcutaneous route	SNOMED	C66729	C38299	SUBCUTANEOUS
Route	i.m.	3	IM		4	4302612	78421000	Intramuscular route	SNOMED	C66729	C28161	INTRAMUSCULAR
Route	i.v.	4	IV		5	4171047	47625008	Intravenous route	SNOMED	C66729	C38276	INTRAVENOUS
Route	nasal	5	NASAL		6	4262914	46713006	nasal route	SNOMED	C66729	C38284	NASAL
Route	td	6	TD		7	4262099	45890007	transdermal route	SNOMED	C66729	C38305	TRANSDERMAL
Route			SL		8	4292110	37839007	sublingual route	SNOMED	C66729	C38300	SUBLINGUAL
Route			INH		9	45956874	9011000001100	Inhalation	SNOMED	C66729	C38216	RESPIRATORY (INHALATION)
Route			OTHER		10	9177	74964007	Other	SNOMED			
Route			NOT AVAILABLE	NA		45884396	LA7338-2	Not Available	LOINC			

Solutions: Validation & Analysis

- Data Source Linkage
- Mapping & Standardization
- Bias assessments
- AI processes
- Missingness Imputations



Conclusions

- Real-World Data has a high potential. However, for regulatory purposes it must be carefully evaluated and used.
- We help solution providers, pharma and consultancy to enable their journey in the utilization of real-world data and/or enabling the digital data flow.
- We like to share our knowledge in the form of consultancy, solutions, webinars, and workshops.

Questions and contact

- Questions?
- Like to learn more?
 - Berber Snoeijer, ClinLine: b.snoeijer@clinline.eu

