Poster
RWD173

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Framework for RWD Transformations from Native Data Models to CDISC Data Standards

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Background and Rationale

- Regulatory agencies including the FDA, EMA, DKMA, PMDA, and NMPA increasingly require or recommend that real-world data (RWD) submitted in regulatory packages be transformed into compliant standards such as CDISC, particularly for studies supporting effectiveness claims.
- Guidance on implementing RWD transformations remains limited, creating potential variability in how source data are mapped, derived, and operationalized across studies.
- Transformation decisions may directly influence traceability, interpretability, and analytic validity, making transparent and fit-for-purpose implementation increasingly important for regulatory review.

Objective: To evaluate performance of data transformations and present a framework on key considerations for implementation.

Methods

Study Design

- Using our framework for best practices in transforming HL7, OMOP, and PCORnet data to CDISC SDTM and ADaM datasets, synthetic real-world datasets were mapped into CDISC-compliant formats.
- Multiple native architectures, including HL7, OMOP, and PCORnet, were evaluated to assess implementation considerations across heterogenous source models.

Study Types & Therapeutic Areas

- Study types evaluated included retrospective cohort and test-negative control design studies.
- Therapeutic area considerations, such as transformation of domains specific for immunology, oncology/hematology, imaging, and genomics were evaluated.
- Design-dependent implementation challenges related to data structure, outcome derivation, and domain-specific harmonization were evaluated.

Synthesis

- Strengths, gaps, and operational challenges of mapping and transformation processes were assessed.
- Findings were synthesized into a practical decision framework for implementation across source models, study design, and other design choices including:
  - Observational study design,
  - Presence of a trial component,
  - Index date assignment,
  - Treatment arm assignment, and
  - maintaining investigator blinding.

Key Findings

Transformation Principles

- RWD-to-CDISC conversion is a reconstruction process requiring clinical and analytic interpretation, not simple one-to-one mapping.
- Key transformation decisions may influence downstream interpretability, reproducibility, and lineage preservation.
- Effective transformation workflows require multidisciplinary collaboration across clinical, epidemiologic, statistical, and data standards expertise.

Context-Specific Implementation Challenges

- Transformation complexity varies across both study designs and therapeutic areas.
- Special issues like temporal alignment, atypical treatment patterns, evolving coding practices, and heterogeneous follow-up require tailored transformation approaches.
- Trial-aligned designs (e.g., ECAs and hybrid trials) may be the easiest to convert, though important harmonization challenges remain.

Regulatory & Operational Considerations

- Raw and source data should be retained and available for regulatory audits, to the extent possible.
- Data should comply with standardized formats, including SDTM and ADaM, and documentation of transformation decisions should be integrated into Reviewers' Guides.
- Regulatory requirements apply to data submitted for Investigational New Drugs, New Drug Applications, and Biologics License Application, including supplementals.

Limitations

- Transformation workflows may require substantial manual clinical review and domain expertise, limiting scalability across studies and therapeutic areas.
- This framework offers recommendations and should not be interpreted as mandatory or prescriptive.
- This framework is intended for RWD used in regulatory submissions, although this may also be used as good practice for RWD/RWE used for other non-interventional observational studies.

Why is this Research Important

- Decisions made during RWD transformation can alter how exposures, outcomes, and longitudinal patient journeys are represented.
- Context-specific implementation challenges vary substantially across study designs and therapeutic areas, highlighting the importance of a tailored transformation approach.
- Practical frameworks that link harmonization decisions to downstream analytic and regulatory implications may improve transparency, reproducibility, and confidence in RWE submissions.
- Transparent transformation workflows may improve confidence in RWD used to support regulatory decision-making.

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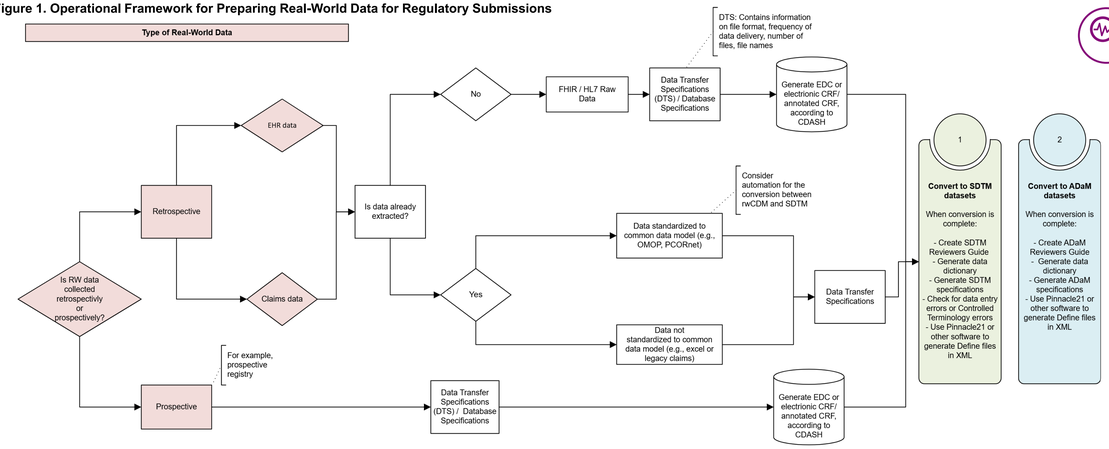
Results

Figure 1. Operational Framework for Preparing Real-World Data for Regulatory Submissions



Reviewer's Guide: A Brief Primer

- A *single summary document* that serves as a reference guide for the FDA reviewer, the RG should describe:
  - Available datasets (e.g., tabulation or analytic),
  - Special considerations or directions,
  - Conformance issues identified,
  - Hardcodes, and
  - Any other items that may facilitate the reviewer's use of the submitted data.
- The Reviewer's Guide also assists the reviewer in understanding the relationships between the study report and the data.
- Sponsors may use templates to complete the Reviewer's Guides.

Ensure documentation of transformation decisions is integrated into the Reviewer's Guides

Figure 2. Comparison of Workflow from General Purpose RWE to RWE for Regulatory Submission

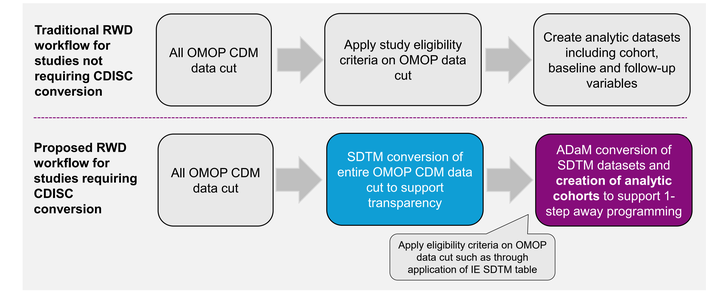


Figure 3. Multidisciplinary Team

Transformation requires a multidisciplinary team with expertise in clinical medicine, data standards, informatics, and statistics.

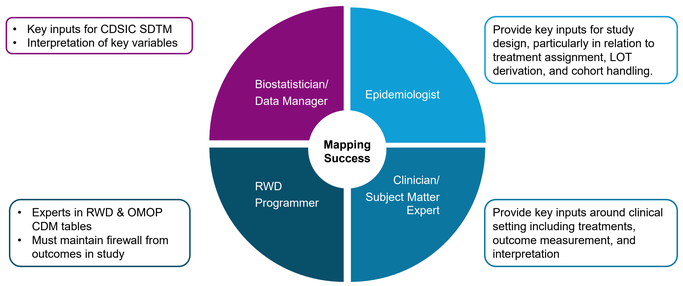


Figure 4. Types of RW Study Design for Conversion

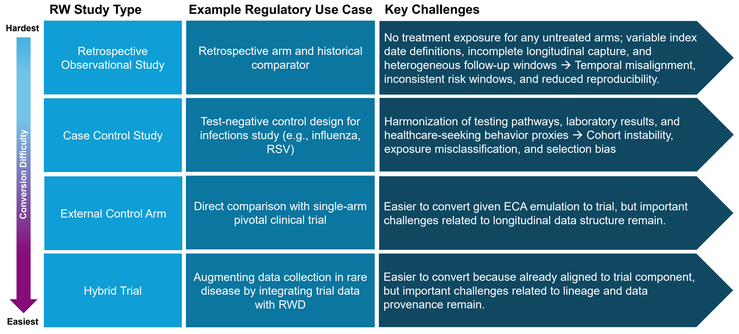
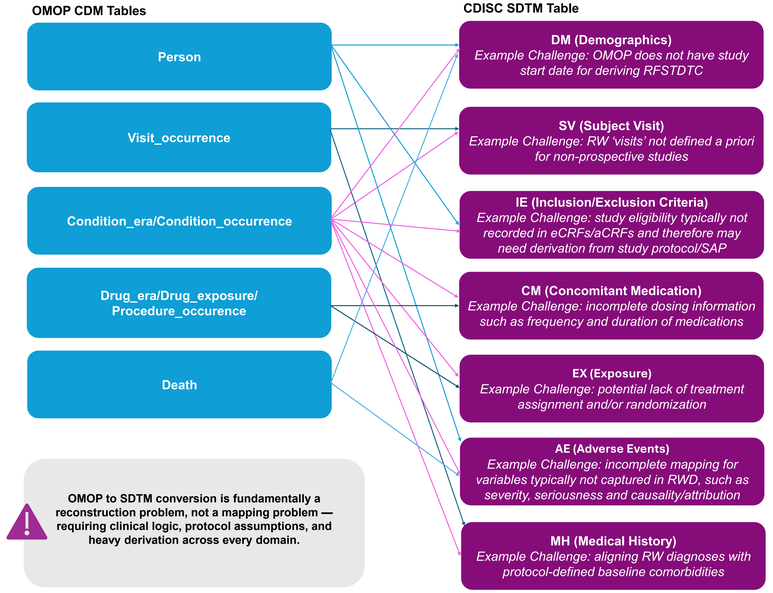


Figure 5. Mapping OMOP Tables to Key SDTM Tables



List of tables is not exhaustive. A core set was evaluated for the purposes of this exercise.

Table 1. Therapeutic Area Specific Considerations for Mapping & Transformation

Therapeutic Area	Key Challenges	Downstream Implications
Oncology/Hematology	Line-of-therapy definitions and heterogeneous response assessment frameworks	Exposure episode construction, response endpoint derivation, and temporal alignment
Emerging Disease	Dynamic disease definitions and coding practices, evolving diagnostic and treatment patterns	Cohort instability, longitudinal harmonization challenges, and reproducibility concerns
Reproductive Health	Indication ambiguity for similar drugs, non-standard exposure or concomitant medication patterns, and care fragmentation	Complex exposure derivation, longitudinal harmonization challenges, and lineage preservation
Imaging	Heterogeneous imaging metadata, modality-specific outputs, and cross-platform integration	SDTM domain alignment challenges, incomplete traceability, and inconsistent endpoint derivation
Genomics	Variability in variant nomenclature and biomarker standardization, and evolving assay standards	Lineage preservation complexity and reproducibility concerns

References: References are available upon request to the corresponding author at Shivani@landmarkscience.com;
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