UBC

Having Access to Data
Doesn't Mean it's *Fit-for-Purpose*

Feasibility assessments can occur long before companies consider buying data.
Rigorous, study-specific scientific evaluation of the fitness of a real-word data source is essential.

UBC Performs Comprehensive RWD Feasibility Assessments According to Regulatory Guidelines

Two-Phase approach

Initial scan assesses potential to meet study needs and narrow down options; subsequently, more comprehensive assessment of the candidate data sources is done.

Regulatory Readiness Considerations

Evaluation includes data traceability, governance, auditability, and timeliness to meet regulatory standards.

Methodology

Systematic feasibility assessments that align with regulatory guidelines produce well- documented assessments regulators can verify..

$1M–$5M+
at risk per program

Registry-based studies represent $1M–$5M+ investments. Selecting an unfit data source means restarting not just the feasibility investigations — but the protocol, site relationships, and regulatory timeline built around the original data source.

Cost range: Moore et al., Pharmacology & Therapeutics; IQVIA CostPro benchmarks.

What Systematic Assessment Reveals

BEFORE ASSESSMENT
9 registries for the same disease. All appear viable.

AFTER SYSTEMATIC FEASIBILITY
Only 4 of 9 are fit-for-purpose.

REGISTRY	FIT-FOR-PURPOSE	REASON (IF NOT FIT)
R2	✓	*Fit-for-purpose*
R3	✓	*Fit-for-purpose*
R7	✓	*Fit-for-purpose*
R9	✓	*Fit-for-purpose*
R1	✗	Not representative of disease population
R4	✗	Length of follow-up too short for study needs
R5	✗	Lack of required details on exposure status (duration, dosing)
R6	✗	No or limited data access
R8	✗	Lack of key healthcare outcome variables

Fit-for-purpose ✓ Not fit-for-purpose ✗

UBC

ubc.com

Systematic Feasibility at UBC

Assessment Framework

Every candidate data source evaluated across five dimensions of fitness

- **Population Representativeness & Size** — Demographic alignment, inclusion criteria, **sufficient sample size**
- **Data Availability & Timeliness** — Contemporaneous data capture, **sufficient follow-up duration**
- **Data Quality & Integrity** — Capture methods, completeness, **AI/NLP for unstructured data**
- **Access & Governance** — Ownership, sharing policies, **consent & ethics compliance**
- **Linkage & Harmonization** — Secondary source linkage, **multi-registry interoperability**

PHASE 1: PRELIMINARY SCAN
High-level assessment of data sources against study needs. Narrows candidates before detailed evaluation.

PHASE 2: IN-DEPTH ASSESSMENT
Detailed fit-for-purpose evaluation including variable gap analysis, quality scoring, and compliance verification.

66 Registries assessed across different indications

Covering multiple, diverse therapeutic areas, including autoinflammatory diseases, hepatology and autoimmune liver diseases, neuromuscular diseases, and systemic connective tissue disorders

21 CFR Part 11 compliance check included

Sample Publications

PUBLISHED | MEREO BIOPHARMA

Osteogenesis Imperfecta

REQueST + gap analysis + 21 CFR Part 11 compliance check. UBC co-author. Peer-reviewed publication.

Peer-reviewed

PUBLISHED | ADVANZ PHARMA

Primary Biliary Cholangitis

6 global registries, REQueST across 23 criteria. 4 satisfactory; 2 flagged before investment.

6 registries

3 ADDITIONAL SPONSOR ENGAGEMENTS

SMA • DMD • Ultra-Rare

Spinal muscular atrophy, Duchenne, and type 1 interferonopathies. Multi-country PASS designs with endpoint-specific registry evaluation.

18+ registries

UBC References for Registry Feasibility

- Grozinger K, Cosmatos I, Tao S. Improving evidence generation from rare disease registries: need for harmonization of data. ISPOR Europe. 12-15 November 2023, Copenhagen, Denmark.
- Sangiorgi L, Boarini M, Mordenti M, et al. SATURN: assessing the feasibility of utilising existing registries for real-world evidence data collection to meet patients, regulatory, health technology assessment and payer requirements. Orphanet J Rare Dis. 2004 Sep 12; 19(1):336. doi: 10.1186/s13023-024-03341-4.
- Tao S. Registry feasibility assessments for post-authorization safety studies (PASS): learnings and challenges. UBC Insights. November 19, 2025.
- Cosmatos I, Lowry J. Is your real-world data 'fit-for-purpose'? The critical role of feasibility assessments. UBC Insights. September 15, 2025.

UBC

ubc.com