Real-world evidence

Real-world evidence studies — Diverse Data Designs

Our novel Diverse Data Design (DDD) approach for real-world evidence studies provides a tailored data selection strategy for the design of custom study solutions that combine multiple data sources, including proprietary data sets, secondary data and primary data collection. This unique, integrated approach to answer your scientific questions optimizes use of available data to reduce research burden and costs and drive innovation to improve study efficiencies.

In close collaboration with sponsors, we identify and understand multi-stakeholder evidence needs across the product lifecycle. The right combination of data sources is then identified to optimize evidence generation for the sponsor's research question by applying an integrated scientific approach driven by:

A multidisciplinary team of experts
in clinical, regulatory, epidemiology, statistics, strategy and advanced artificial intelligence (AI) methods

A custom data selection & integration strategy
driven by a deep understanding of primary data collection, existing primary and secondary data sources and access to linkable, proprietary data sets

What makes us different?

We provide integrated insights and innovative solutions to reduce research burden while ensuring scientific excellence and optimizing use of available data.

Integrated scientific approach

- Strategic insight across a dedicated team of multidisciplinary experts including epidemiologists, biostatisticians, programmers, data scientists and clinicians
- Consultative approach to ensure comprehensive understanding of the research question to optimize study design and data selection
- Extensive experience with both retrospective and prospective non-interventional research designs and primary data collection
- Deep expertise across a wide variety of data sets and linking multiple data sources via tokenization
- Scalable, efficient and nimble operational solutions tailored to novel study designs

Data strategy

- Insights from 20+ years of experience conducting secondary database studies with 100+ data sources across the globe
- Proven experience linking disparate data (EMR, claims, registries, etc.), both proprietary and third-party assets
- Data selection strategy that considers existing primary and multiple secondary data approaches and expands to include primary data collection as needed

Delivery innovations

- Custom staffing and right-fit delivery models tailored to specific research needs, including:
  - Decentralized study solutions, mobile applications and in-house call center
  - Flexible data collection with less site and investigator burden
- Technology solutions to streamline workflows and align to sponsor preferences; expertise drawing upon a variety of approaches for tailored delivery, including:
  - Automated data extraction from electronic health records (EHRs)
  - Patient-mediated data collection
  - Patient insights and lived experience
  - Decentralized electronic data collection
  - Data lake approaches
  - Tokenization

Benefits of our DDD study solution

Optimizes use of data – proprietary and external – and data expertise to tailor the data strategy to the scientific question

Right-fit delivery models and reduced research cost

Leverages multidisciplinary, best-in-class scientific bench

Reduces site and patient burden

Case study

Flexible protocol design enables optimal data approach

Background / Challenge

- First gene therapy in a rare pediatric disease coming to market
- Committee for Medicinal Products for Human Use (CHMP)-mandated post-authorization efficacy study (PAES): a long-term, prospective study
- **Study objectives**
  - Assess disease progression and compare the data collected with natural history data collected from untreated patients
  - Provide further data on long-term effectiveness in treated patients
- **Challenges**
  - Recruitment and retention
  - Limiting burden on physicians

Solution

- Designed and developed the protocol for a multi-country, non-interventional, longitudinal cohort study to accommodate use of secondary data supplemented or augmented by primary data collection
- Conducted database feasibility of existing registries in parallel with protocol development
- Partnered with four core patient registries in Europe
- Worked with data providers to validate and improve registry data quality to meet sponsor needs
- Used innovative privacy-protecting analytic methods to enable study data from KOLs in countries with data sharing challenges (i.e., Italy)

Results / Impact

- CHMP approved the protocol as submitted without comment, saving valuable time
- Strategically including different data options in the protocol avoided potential need for lengthy protocol amendment procedures
- Based on feasibility assessment, a full secondary data approach was deemed possible, further optimizing the approach to data collection

Learn more at **thermofisher.com/ppd**