Real-World Evidence

A Growing Need for Real-World Evidence

Real-world evidence of safety, effectiveness, and value is necessary to achieve successful market access and product uptake. In addition to robust early development clinical trial programs, payers and other key stakeholders, such as patients, physicians, and caregivers, demand evidence of benefits and risks in a real-world setting.

Evidera's team of researchers offers leadership in the design and execution of studies to meet payer and regulator evidence requirements. We offer diverse scientific methods and high quality project and data management expertise. Methods include analytics of secondary data sources, bespoke multinational data collection, hybrid studies, and pragmatic/adaptive studies.

We Can Help You

- Delineate the natural history and course of disease. (e.g., incidence, prevalence, standard(s) of care)
- Determine unmet clinical and humanistic needs by characterizing the burden of illness.
- Collect robust data from rare disease populations.
- Quantify real-world, product-specific, and/or comparative safety, effectiveness, adherence, and other outcomes.
- Evaluate country-specific treatment patterns, quantify associated costs of care, and populate health economic models.

Excellence in Study Design and Execution

- **Extensive experience** – Dedicated real-world, non-interventional study operations, regulatory, and global clinical supply teams with over 25 years of experience across ~116,000 patients and ~15,000 sites globally in the past 5 years.
- **20+ year track record** – Have designed and implemented health-related quality of life, treatment satisfaction, adherence, resource use, epidemiological, burden of illness, and safety outcomes studies.
- **Specialist medical affairs team** – Rapid study start-up and patient recruitment when working under an early engagement partnership model.
- **Therapeutic area experts** – Capabilities across a wide range of indications, and ability to leverage our network of clinicians and global operations professionals.
- **Integrated partnership model** – Flexible and proactive operating and governance model customized to unique needs.
- **Innovative methodologies** – Application of innovative methods (e.g., pragmatic studies) resulting in optimal study design, endpoint selection, and statistical analyses.
- **Expertise in study design and protocol development** – All studies governed by a scientifically robust protocol that is reviewed and quality controlled by an in-house, industry-recognized research team.

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Real-World Evidence Offerings

Database Analytics

Identify, analyze, and understand treatment patterns, natural history of disease, risk of clinical outcomes, and risk factors.

Social Media Analyses

Directly monitor drug safety and provide evidence of the opinions and unmet needs of large numbers of real patients.

Real-World Data Identification

Identify the best data sources to address research questions and develop a real-world data strategy.

Advanced Statistical Modeling, Predictive Analytics, and Machine Learning Approaches

Go beyond the surface of data to see important patterns and associations.

Post Hoc and Exploratory Analytics of Trial and Observational Data

Closely examine the product's trial or observational data to unlock hidden value.

Coding Algorithm Development

Determine and optimize definitions of key clinical variables and outcomes for database studies to ensure quality definitions for those events.

Patient or Physician Surveys

Evaluate outcomes of interest with direct-to-participant surveys, typically conducted via electronic data collection with no need for study sites.

Hybrid Database and Direct-to-Patient Studies

Build upon the available data with a cross-sectional or longitudinal database analysis of prescription and/or medical claims plus patient and/or site reported data.

Time and Motion Studies

Understand efficiency/time saving with a prospective time and motion study.

Medical Chart Review Studies

Evaluate unmet need, burden-of-illness, patterns and/or costs of care, or patterns of drug utilization and (in)appropriate use via data abstraction from medical charts.

Prospective Disease Registries and HEOR Studies

Evaluate unmet need, burden-of-illness, and patterns and/or costs of care using bespoke data collection methods.

Product and Pregnancy Registries

Evaluate patterns of use and product uptake and safety.

Post-Authorization Safety and Efficacy Studies (PASS and PAES)

Gather real-world clinical, health economic, outcomes research, or safety related endpoints to supplement or complement data from other studies.

Risk Management Plans (RMPs) and Risk Evaluation and Mitigation Strategy (REMS) Programs

Ensure that the benefits of your product outweigh the risks utilizing our dedicated risk management team of regulatory, safety, and epidemiology experts.