RARE MEETS REAL

UNIQUE RARE DISEASE EXPERIENCE PARTNERED WITH REAL-WORLD EVIDENCE CAPABILITIES FOR YOUR SUCCESS

Worldwide Clinical Trials is uniquely experienced in the design and execution of rare disease research initiatives that embrace the evolving need for real-world evidence at all points along the drug development and commercialization continuum.

Our Worldwide Evidence team is dedicated to the development and implementation of health economics and outcomes research, observational studies and patient registries, and patient communities in key orphan diseases.

Often combining prospective research with innovative data sources, we balance the needs of clinical development with marketplace realities demanding the generation and communication of real-world evidence with clinical, economic, and humanistic value.

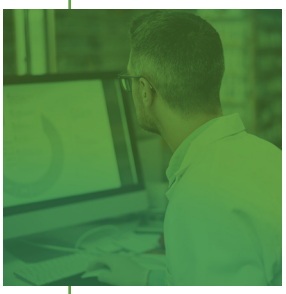
At Worldwide, we combine our focused experience in rare diseases with our Worldwide Evidence expertise to design solutions for both regulatory approval and commercial success.

For early-stage clients in particular, we develop strategic evidence plans to guide the inclusion of measures critical to marketplace success, while serving as an important business asset to optimize enterprise value.

At Worldwide Clinical Trials, we believe the ultimate success of an orphan drug requires insightful real-world thinking early on in clinical development to address the needs of all regulatory and marketplace stakeholders.

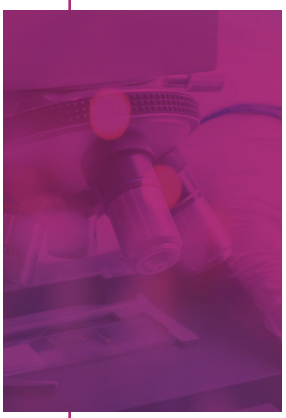
Let us help you ensure your development processes embrace both rare disease experience and real-world evidence expertise.

WORLDWIDE CLINICAL TRIALS



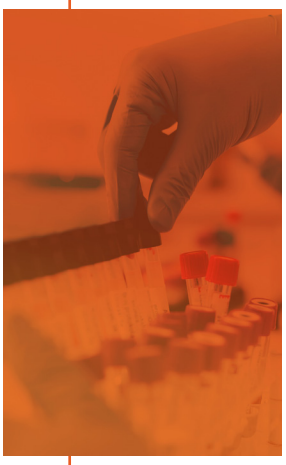
PATIENT REGISTRY ESTABLISHING BURDEN OF ILLNESS

The Worldwide Evidence team designed and implemented a global, prospective, 400-site, 5,000-patient, 39-country patient registry to document treatments and outcomes of four rare lysosomal storage disorders. The registry was critical in understanding the burden of the rare diseases and as a baseline against which to assess the impact of a specific drug in development.



RWE PLAN FOR COST-EFFECTIVENESS AND IMPROVED PATIENT QOL

For a biotech company developing a drug for orphan complications of liver disease, we developed a comprehensive real-world evidence plan to ensure the clinical development program could also serve as a foundation for assertions of cost-effectiveness and improved patient quality of life. Implementation of the plan included the inclusion of economic and patient-centric measures in pivotal clinical trials, a distinct economic model, and structured interaction with a disease community to begin compiling patient experience data.



COMPREHENSIVE STUDY PROGRAM ESTABLISHING CLINICAL, ECONOMIC, AND HUMANISTIC VALUE FOR NEW DRUG

A biotech company developing a drug for a rare hematologic disease engaged the Worldwide Evidence team in the development of a 1,200-patient, 450-site, international, web-based registry as part of a comprehensive development program. Working with a global Scientific Advisory Panel, Worldwide Evidence implemented the registry alongside pivotal clinical trials as a mechanism for establishing evidence of the drug's clinical, economic, and humanistic value in actual practice.