

Generate evidence to understand the real-world use, value, and safety of your products.

Generating Real-World Evidence

Understanding the real-world use, value, and safety of your products can help you build a successful strategy and bring the right products to the right patients.

Grounded in science and supported by state-of-the-art technology, we can help you develop the evidence you need to inform your approach and better meet the needs of payers, providers, patients, and regulators. We provide:

- Multinational capabilities
- Methodological expertise
- Regulatory consultation and ethics support
- Integrated data management

Expert Scientists

Your RTI-HS project team is experienced, client-focused, and drawn from an expert pool of survey developers, health economists, outcomes researchers, epidemiologists, biostatisticians, psychometricians, and drug safety leaders who will become true research partners with you. As applied scientists with deep experience across most therapeutic areas, we will consult and collaborate with you to design and implement the right study to meet your needs.

Systematic Approach

Once we understand your specific study objectives, we'll take a systematic approach and collaborate with you on feasibility assessment, operations, and

Project Management:

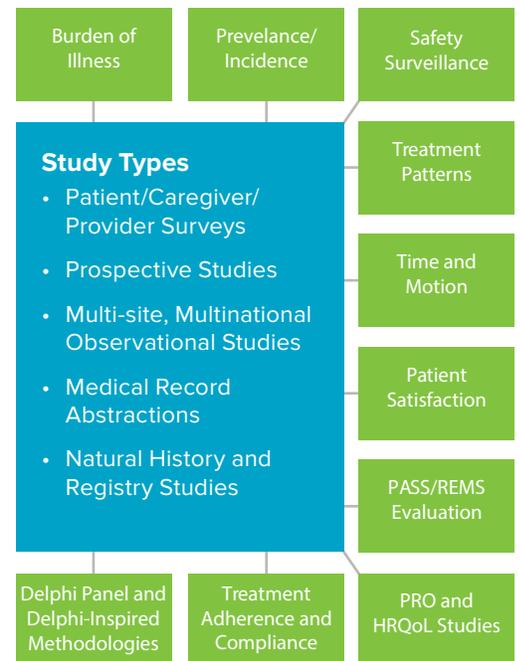


oversight. Our seasoned project managers actively work to understand your priorities while managing projects according to industry standard guidelines and best practices.

Leveraging Observational Study Data

Observational studies capture data that will help you better characterize the natural history of a disease, develop value stories for your products, gain market access, and meet post-marketing safety commitments. These studies can inform your strategic planning process and meet multiple research objectives. Our experience includes a wide variety of cross-sectional and longitudinal study designs.

Our Experience:



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Key Technical Staff

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See How We've Helped Others

The Burden of Illness of Chronic Spontaneous Urticaria/Chronic Idiopathic Urticaria: A Multicountry Study

We are conducting an observational study for a client to understand real-world treatment patterns, health care resource use, health-related quality of life, and indirect burden associated with chronic spontaneous urticaria/chronic idiopathic urticaria (CSU/CIU). Data collection is via medical record abstractions, surveys, and diaries from approximately 700 patients in Canada, France, Germany, Italy, the Netherlands, Spain, and the UK. In collaboration with the client and KOLs, we are conducting all aspects of the study including ethics submissions, data collection, and analysis. The study is ongoing, but preliminary results have been presented at multiple conferences.

Risk Evaluation Mitigation Strategy (REMS) and Post-Authorization Safety Studies (PASS)

To evaluate stakeholder (patient and provider) understanding of risks associated with medication use, we have worked with over 40 US and EU clients on REMS and PASS studies for over 50 products covering numerous therapeutic areas such as osteoporosis, HIV, irritable bowel syndrome, infectious disease, multiple sclerosis, cardiovascular disease, and Crohn's disease.

- **Davis K, Su J, Gonzalez JM, Trudeau JJ, Nelson L, Hauber B, Hollis K.** Assessment of satisfaction and importance of inhaler attributes in patients using Combivent Respimat. Presented at AMCP's Nexus 2014 meeting; October 7-10, 2014. Boston, MA.
- **DiBenedetti DB, Price MA, Andrews EB.** Cognitive interviewing in risk minimization survey development: patient and healthcare professional surveys. *Expert Rev Clin Pharmacol.* 2013;6(4):369-73.

Meet the High Threshold of Expectations for Real-World Evidence

Real-world evidence and patient centricity have become increasingly important in drug development, commercialization, and safety decisions, and as a result so have evidence standards.

Beyond rigorous scientific methods and operational processes, we can help you synthesize data and communicate results in a meaningful way.

Whatever your patient population demographics, disease areas, data types, geography, timeline, and budget, we provide best-of-breed solutions and select the most appropriate data collection tools, technology, and methods.

Innovative Recruitment Strategies

Site networks	Advocacy groups
Pharmacy networks	Social media
Web panels	

State-of-the-Art Data Collection

Laptop & tablet computers	IVRS
Web applications	Call center
Cell phones	Paper forms
Handheld patient diaries	

Data Management

CATI	ePRO data
Web survey	Laboratory data
Electronic data capture	Integrated systems

Our internal processes are aligned with data management best practices as guided by ICH Good Clinical Practices, the FDA, the EMA, and other agreed-upon industry standards.