



Creating Reliable Global Regulatory and Promotional Plans: Outcomes Research and Regulatory Strategy

Develop a reliable outcomes research roadmap for supporting your commercialization plans

Full-Service Outcomes Services

Our colleagues from across RTI Health Solutions collaborate to provide you with robust outcomes research and regulatory strategy services, including:

- Situational and gap analysis
- Regulatory and commercial strategies
- Clinical trial and patient-reported outcome (PRO) endpoint design
- Labeling and promotional claims strategies
- PRO evidence dossiers
- Competitive analyses
- Consulting services and educational workshops

Additionally, because we employ over 70 researchers with expertise in outcomes research, PRO, health economics, psychometrics, and pricing and reimbursement, we are able to offer a suite of comprehensive services to inform your commercialization plans. (Please visit our website at www.rtihs.org for a full explanation of our capabilities.) Drawing on their extensive industry and regulatory experience, our staff are able to provide expert guidance on your early-, mid- and late-stage product development programs.

Establish a Clear Roadmap

The strategies that we develop together will provide your clinical and marketing teams with a roadmap to follow to ensure the value of your product is maximized in the marketplace.

Determine Appropriate Endpoints

By helping you determine appropriate endpoints for your clinical trials, we can strengthen your global product commercialization plans. Appropriate endpoint selection is critical in achieving desired product labeling claims and in developing value messages for your physicians, patients, payers and other stakeholders. Our outcomes researchers and regulatory strategists have deep experience providing expert guidance on endpoint selection that will provide the best commercialization opportunities.

Assess Product Value

Upon the launch of your product, your commercial success will depend, in part, on your ability to achieve preferred positioning on payer formularies. We will conduct competitive product assessments to develop an outcomes research plan that will position your product to get the best potential placement on formularies. To ensure a solid foundation is established for positioning your product, we advocate starting this process early in the development cycle, ideally in Phase II.

Stay Informed

Navigating complex and changing regulatory environments can be challenging. Our experts provide consultation services and conduct workshops to help you and your staff understand the regulatory environment as it relates to achieving the health outcomes labeling claims that are critical to successfully commercializing your product.

Contact

RTI Health Solutions
Research Triangle Park, NC, USA
+1.800.262.3011

Ann Arbor, MI, USA
+1.734.213.5372

Barcelona, Spain
+34.93.241.7766

Lund, Sweden
+46.706.58.3442

Manchester, UK
+44(0)161.232.3400

Sheffield, UK
+44(0)114.213.3390

Waltham, MA, USA
+1.781.434.1700

rtihealthsolutions@rti.org
www.rtihs.org

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RTI Health Solutions Key Thought Leaders

*Kati Copley-Merriman, MS,
MBA*

*Global Head, Regulatory and
Health Outcomes Strategy*

Amy Barrett, MSPH, MA

*Director, Regulatory and
Health Outcomes Strategy*

Melissa Juniper, MS

*Director, Regulatory and
Health Outcomes Strategy*

Shahnaz Khan, MPH

*Director, Reimbursement
Dossier Services*

Margaret Mordin, MS

*Senior Director, Regulatory
and Health Outcomes
Strategy*

See How We've Helped Others

PRO Evidence Dossier to Support Label Claims in Cancer

The FDA questioned a client's pain relief claim for a new cancer drug. To help our client address FDA concerns, we prepared a PRO evidence dossier based on FDA's "Draft Guidance for Industry: Patient-Reported Outcome Measures." We were able to support the labeling claim by using the Brief Pain Inventory. To complete the dossier, we reviewed the Phase III protocol, selected published literature, and other information provided by the company. In addition to developing the dossier, we advised the company on the PRO sections of the Phase III protocol so that they matched the strategy outlined in the dossier. To prepare the dossier, we developed the claim structure, endpoint model, conceptual framework, and responder analysis; designed the PRO statistical plan; and conducted sample size calculations to determine if the trial was powered to achieve the claim. The dossier was submitted to the FDA as part of our client's end-of-Phase-II meeting.

Clinical Trial Endpoint and Payer Feedback Assessment to Inform Product Development Strategy

We were commissioned to review a client's Phase II and III clinical protocols for a novel topical dermatological treatment to determine the optimal clinical trial endpoints that would meet the value requirements of patients, providers, and payers. To complete this task, we reviewed the product profile, existing clinical trial results, planned Phase II and III draft protocols, selected published literature, and other information provided by the company, including existing payer research. We developed a list of potential endpoints; revised the product profile, analysis plan, and measurement strategy; and conducted a payer assessment. Our efforts enabled the client to identify the studies best suited to support product pricing and reimbursement, to avoid unnecessary costly studies being considered by the client, and to develop a clinical trial and product value communication strategy geared toward optimizing product adoption, formulary placement and pricing, and competitive positioning.

Let RTI-HS Help You

To learn more about our capabilities, please visit us online at www.rtihs.org, email us at rtihealthsolutions@rti.org, or call one of our international offices listed on the front.