



Regulatory Consulting and Translational Medical Product Services Planning

As a **translational research organization**, RTI International's Global Health Technologies offers our clients interdisciplinary expertise, seamless collaboration, and expansive knowledge to advance research results through an efficient product development program. Our scientists excel at **facilitating** the development of drugs, biologics, and devices into streamlined, scientifically sound solutions that meet the **regulatory requirements** needed to bring products to market efficiently.

Regulatory Services

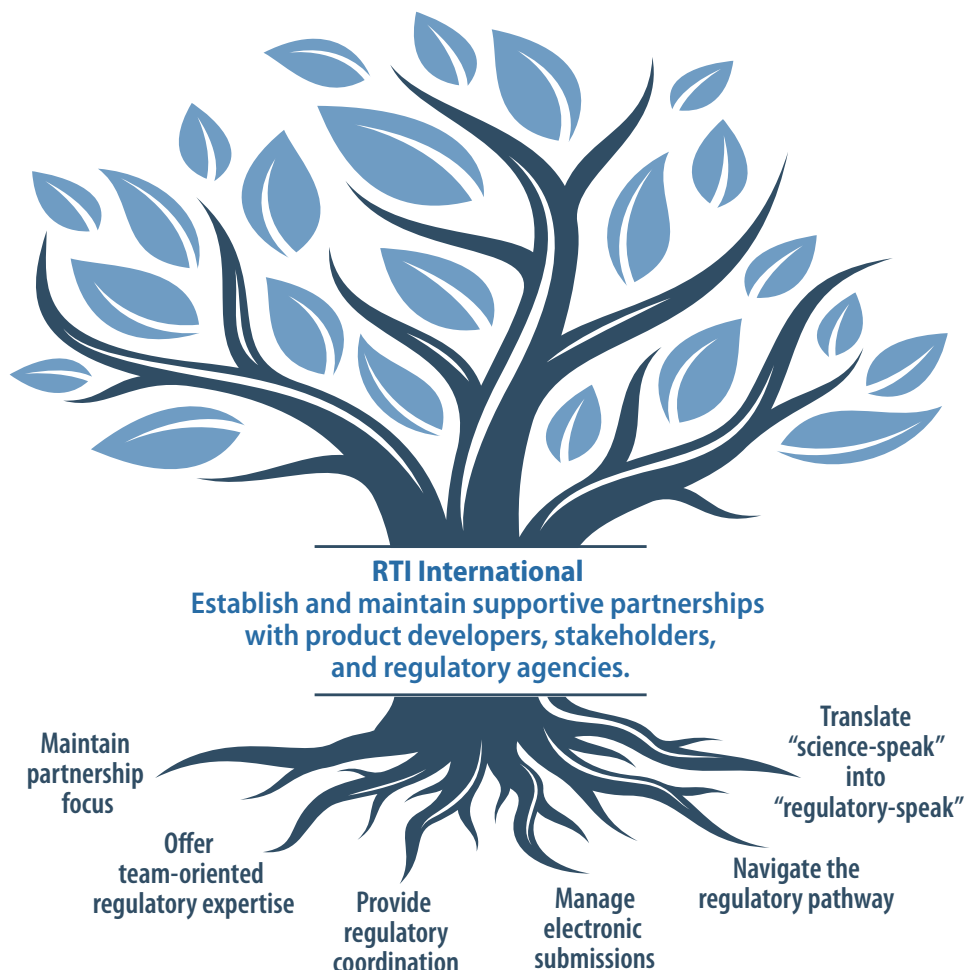
Our clients seek a customized, collaborative, responsive, and cost-efficient partnership—one that yields first-time clearance of Investigational New Drugs (INDs), investigational device exemptions, and 510(K)s, as well as first-time approval of New Drug Applications (NDAs), Biologics License Applications, and premarket approval and optimized development programs. RTI's skilled regulatory scientists tailor services to complement our clients' expertise and develop a regulatory strategy in partnership to progress the product, ensure milestones are met, and utilize budgetary resources efficiently.

Demonstrated Expertise

- Scientific expertise in toxicology; chemistry, manufacturing, and controls; and preclinical studies
- Successful management of full-cycle drug development programs
- Strategic planning skills to address short- and long-term challenges with scalable solutions
- Effective strategic planning for commercial product development
- Strong leadership skills
- Proven ability to work effectively at all levels of an organization to facilitate positive outcomes for goals and objectives related to product development and commercialization
- Consultant sourcing to complement development team with specialized expertise where needed

To support our clients' regulatory strategy and product development, RTI offers the following services:

- Conduct regulatory due diligence/gap analysis performance
- Optimize development plans through leveraging accelerated regulatory pathways
- Function as authorized representatives to regulatory agencies
- Manage and prepare for U.S. Food and Drug Administration (FDA) meetings, including the following:
 - » Initial Targeted Engagement for Regulatory Advice on CBER products (INTERACT)
 - » Pre-IND
 - » End of Phase 1
 - » End of Phase 2
 - » Pre-NDA/BLA
- Manage and prepare strategic documents, such as
 - » Request for designations
 - » Orphan drug applications
 - » Qualified infectious disease product designation requests
 - » Special protocol assessments
- Manage, prepare, and review regulatory submissions
- Prepare electronic submissions to comply with FDA standards



- Publish and submit electronic common technical documents and related resources through the FDA Electronic Submissions Gateway
- Prepare and maintain information for inclusion on ClinicalTrials.gov
- Store and manage essential documents on our validated electronic trial master file system

RTI International is an independent, nonprofit research institute dedicated to improving the human condition. Clients rely on us to answer questions that demand an objective and multidisciplinary approach—one that integrates expertise across the social and laboratory sciences, engineering, and international development. We believe in the promise of science, and we are inspired every day to deliver on that promise for the good of people, communities, and businesses around the world. For more information, visit www.rti.org.

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More Information

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