

FDA Drug Development Regulatory Consulting

STRATEGY, GUIDANCE, COORDINATION, OVERSIGHT, AND SUBMISSION

RTI International's Global Health Technologies (GHT) team provides drug development consulting services including regulatory strategy, guidance, coordination, submission, and ongoing support as your drug progresses from proof-of-concept, through nonclinical studies, clinical studies, and approval. We offer our clients interdisciplinary expertise, seamless collaboration, and expansive knowledge to advance research results through an efficient product development program. Our regulatory experts and scientists excel at **facilitating** the development of drugs, biologics, and combination products into streamlined, scientifically sound solutions that meet the **regulatory requirements** needed to bring products to market efficiently.

Regulatory Services

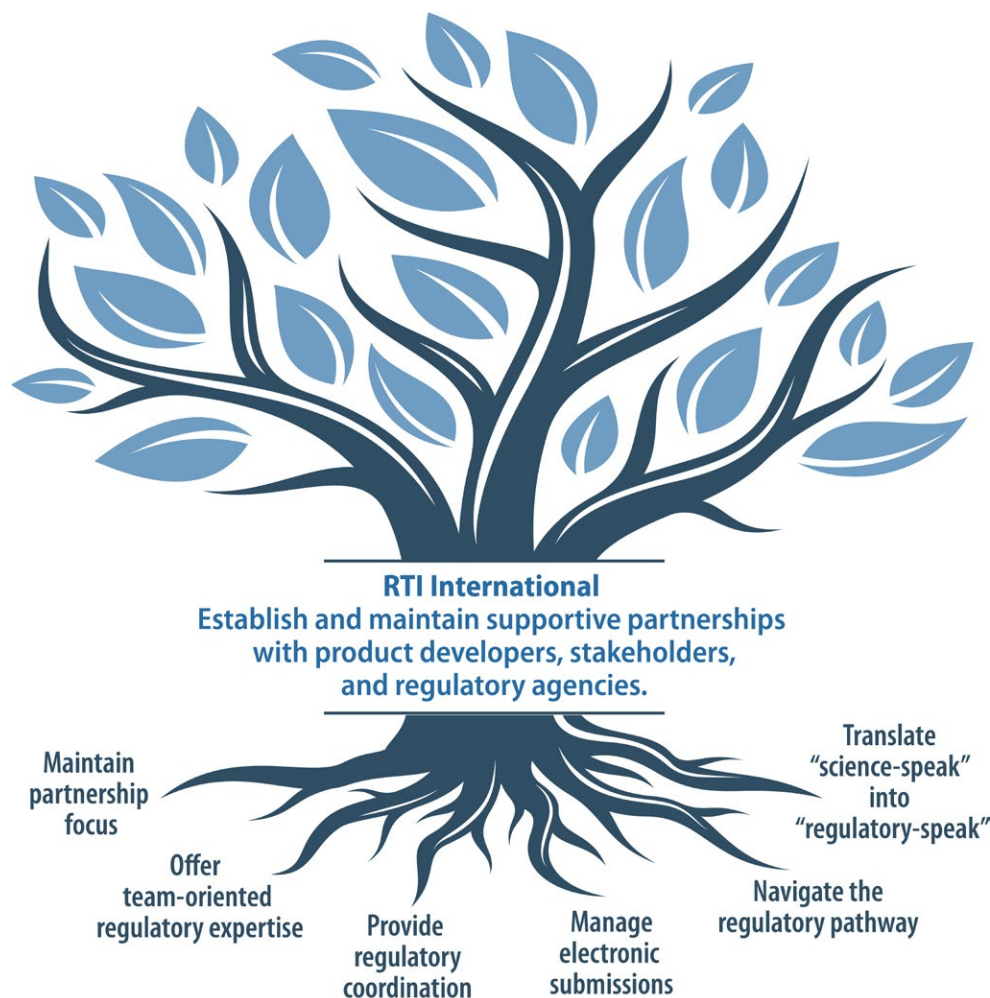
Our clients seek a customized, collaborative, responsive, and cost-efficient partnership—one that yields first-time clearance of U.S. Food and Drug Administration (FDA) Investigational New Drug applications (INDs), New Drug Applications (NDAs), and Biologics License Applications (BLAs). RTI's skilled 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. As a non-profit organization focused on improving global public health, RTI can serve as a virtual regulatory support arm for smaller companies that require comprehensive and cost-effective regulatory support.

Demonstrated Drug Development Expertise

- Develop efficient drug development regulatory and scientific strategies
- Strategic planning to address short- and long-term challenges with scalable solutions
- Scientific expertise and guidance with the development, coordination, and oversight of nonclinical/toxicology and Chemistry, Manufacturing, and Controls (CMC) programs
- Strong Project Management support to ensure efficient project coordination and progress
- 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 gap analysis and due diligence
- Develop efficient drug development regulatory and scientific strategies
- Optimize development plans through leveraging accelerated regulatory pathways (e.g., Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review)
- Function as authorized representative to regulatory agencies
- Manage and prepare for FDA meetings, including the following:
 - » Pre-IND
 - » INTERACT
 - » End of Phase 1
 - » End of Phase 2
 - » Pre-NDA/BLA
- Manage and prepare strategic documents, such as:
 - » Request For Designation
 - » Orphan Drug application
 - » Qualified Infectious Disease Product (QIDP) designation request
 - » Special Protocol Assessment
- Manage, prepare, review, and submit regulatory submissions (e.g., meeting requests and packages, IND, NDA, BLA, amendments, reporting)



- Prepare electronic submissions to comply with FDA standards
- Publish and submit electronic Common Technical Documents (eCTDs) and related resources through the FDA Electronic Submissions Gateway (ESG)
- Guidance and review of clinical synopsis and protocol development
- Prepare and maintain information for inclusion on ClinicalTrials.gov
- Store and manage essential documents in electronic archive 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.

RTI International is a trade name of Research Triangle Institute.
RTI and the RTI logo are U.S. registered trademarks of Research Triangle Institute.

More Information

Rebecca Barry, PhD
Director, Global Health Technologies
814.441.9942
rbarry@rti.org

RTI International
3040 E. Cornwallis Road, PO Box 12194
Research Triangle Park, NC 27709-2194
USA