

# Drug, Biologics, and Device Development Consulting



RTI International's highly experienced team provides project management and pharmaceutical development expertise to plan and coordinate preclinical and clinical projects. With more than 100 years of combined pharmaceutical industry experience in toxicology; pharmacology; clinical research; chemistry, manufacturing, and controls (CMC); and regulatory affairs, our team members understand drug development and the regulatory approval process. Our team offers the necessary combination of effective project management, technical, and regulatory expertise to seamlessly plan, budget, and execute drug development projects.

## Overview

RTI's drug development group is a dedicated team of scientists, project managers, and regulatory experts with a proven record of managing all phases of drug development. We work closely with our clients to develop a collaborative, responsive, and cost-efficient partnership to ensure the rapid progression of drug candidates through the drug development pathway.

We have a proven track record of developing and maintaining collaborative relationships with project teams, vendors, and other service providers. Our team will seamlessly apply an integrated approach to executing your preclinical or clinical drug development program. Whether you are a company, nonprofit institution, or an academic investigator, we will tailor our cost-efficient services to meet your needs using our scientific and tactical experience to help you navigate the drug development process.

RTI excels at managing programs that coordinate the numerous activities needed to advance products from preclinical through clinical development. Our team can provide the following services as needed:

- Project management and support
  - Proactive project planning, coordination, and oversight of activities
  - Managing cross-functional project team meetings
  - Defining project milestones and deliverables
  - Managing timelines, budgets, and scope
  - Portfolio management
  - Negotiation and comparison of bids
- Management of pharmacology/toxicology and ADME/PK studies
  - Preclinical study protocol writing, monitoring, and report writing
  - Evaluation of PK/Tox/ADME vendors
    - Auditing of vendor sites
    - Toxicology program planning
- Management of CMC activities
  - Formulation development
  - Evaluation of manufacturers
    - Drug substance and drug product manufacturing
    - Auditing of manufacturing sites

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- Regulatory writing and consulting
  - Project gap analysis
  - Regulatory due diligence
  - Food and Drug Administration (FDA) meetings support
  - Preparation of regulatory documents and FDA communications
    - Pre-Investigational New Drug Application (IND) briefing packages
    - INDs, IDEs, New Drug Applications, annual reports
    - Investigator brochures
    - Orphan drug applications
  - Essential document storage
- Clinical study support
  - Protocol review
  - Data management
  - Statistical consulting and analysis
- Scientific due diligence support

## Project Highlights

### Development of Drugs for Tuberculosis (TB)

RTI has successfully managed lead candidates for the Global Alliance for TB Drug Development (TB Alliance). Since 2000, RTI has worked with the TB Alliance to support five of its drug development programs. RTI assists the TB Alliance with integrated planning, implementation, project management, statistical analysis, medical writing, monitoring of nonclinical studies, manufacturing, and regulatory affairs to advance drug candidates through preclinical and clinical studies for regulatory approval.

We have been providing project management support to the Lilly TB Drug Discovery Initiative since 2008 to advance the development of preclinical compounds for the treatment of multidrug-resistant tuberculosis. RTI support of the Lilly Initiative projects includes preparation of development strategies, operational planning and implementation, and regulatory support.



### National Heart, Lung, and Blood Institute (NHLBI) SMARTT Translational Program

RTI provides program management, preclinical, and regulatory consulting services for NHLBI's Science Moving toward Research Translation and Therapy (SMARTT) program, which supports the translation of novel discoveries into successful new therapies for heart, lung, and blood diseases. Our drug development team provides preclinical and regulatory affairs consultation for the SMARTT program to academic and small company investigators, expediting the advancement of drug candidates to the clinic.

### Data Coordinating Centers

RTI provides data management, regulatory, and clinical assistance for clinical networks funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development. We provide regulatory assistance, training, and implementation of safety reporting processes; review clinical protocols; and maintain IND and regulatory documents.

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### More Information

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