

Managing Drug Development



RTI International has demonstrated the ability to move promising lead compounds quickly and effectively through the formulation-optimization, preclinical, and clinical studies required for regulatory approval of new therapeutics. To accomplish these high-quality and timely outcomes, we bring the necessary combination of effective planning, management, and technical and regulatory expertise to the drug development process. We have over 30 years of combined experience managing pharmaceutical research and development within multi-stakeholder environments.

RTI's expertise and our established systems for managing preclinical and clinical drug development programs facilitate the delivery of timely and high-quality management services to our clients. A key element of our approach is to consider, in consultation with the client, each drug development task in the context of the full development and regulatory strategy for a specific drug candidate. We are experienced in gap analysis, project management, management of formulation development and manufacturing supplies, pre-clinical and clinical phases of development, and regulatory operations and strategy.

When working with our clients, our goal is to articulate the overall program objective (i.e., indication, marketing, and labeling considerations) guiding formulation of a development program to

- Efficiently move products through the development pathway
- Identify gaps and other key issues to prioritize development activities
- Stage activities that best match timelines, information needs, budgets, and risk.

Partnership and Consortium Development

RTI has considerable experience conducting collaborative drug development. We successfully coordinate development partnerships between the public and private sectors, including government, academia, corporate, and philanthropic interests. Within these partnerships, RTI offers expertise in

- Investigational new drug (IND) development
- Collaboration with government, academic, and private corporate organizations
- Solicitation of research applications, funding decisions, and administration oversight
- Lobbying for support from federal and other levels of government
- Fundraising
- Fiscal management
- Addressing public policy issues



Select Project Experience

CLIENT	REPRESENTATIVE EXPERIENCE
Global Alliance for TB Drug Development (TB Alliance)	<ul style="list-style-type: none">• Helped to establish the TB Alliance by drafting key governance documents, facilitating licensing agreements, writing significant grant applications, and providing logistical support.• Currently serves as Food and Drug Administration contact for PA-824 IND for tuberculosis, including FDA meeting representation. Planned and oversaw rapid completion of IND-enabling program for PA-824; secured orphan designations (U.S. and EMEA) and fast-track status for PA-824; maintains PA-824's IND and orphan designations. Manages aspects of an integrated development program for PA-824 and other drug and device candidates.• Failed "fast and cheap" with a potential TB treatment, TBK-613
NIAID-Lilly Initiative	<ul style="list-style-type: none">• Assisted in the development of a new multi-stakeholder partnership, with support focused on early discovery and development through guidance in prioritizing compounds and compound families, planning development programs, and executing key development activities to facilitate candidate progression.• Currently provides preclinical and formulation development support for compounds, including CPZEN-45.• Developed and maintained a website, newTBx.org, to elicit potential candidates and status of compounds for the treatment of TB.
International Partnership for Microbicides (IPM)	<ul style="list-style-type: none">• Assisted with development of a broad strategy, and planned and conducted various discrete microbicide development projects.
Bill & Melinda Gates Foundation	<ul style="list-style-type: none">• Organized Pan African Clinical Evaluation of Antimicrobials (PanACEA), an industry-academia research consortium focused on TB clinical trials.• Developed the consortium's operational structure, and then led the consortium's development of a successful proposal to establish and build capacity and technical expertise in a network of developing-world clinical sites.
National Heart, Lung and Blood Institute	<ul style="list-style-type: none">• Serves as the coordinating center for translational medicines needing assistance on the path from discovery to human testing by coordinating and consulting on preclinical, chemistry manufacturing controls aspects, and through IND submission.

More Information

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RTI International is one of the world's leading research institutes, dedicated to improving the human condition by turning knowledge into practice. Our staff of more than 2,800 provides research and technical expertise to governments and businesses in more than 40 countries in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, international development, economic and social policy, energy and the environment, and laboratory and chemistry services. For more information, visit www.rti.org.

RTI International is a trade name of Research Triangle Institute.

