Tuberculosis threatens public health worldwide, with nearly 1.5 million dying of tuberculosis each year. To address the scope and complexity of the global tuberculosis problem, RTI International uses its multidisciplinary experience and skills in drug development, epidemiology, policy, and health economics.

Improved prevention and treatment of tuberculosis (TB) requires new drugs, enhanced case detection, and strengthened health care systems. Despite the rising incidence of TB worldwide, no new drugs for treating drug-sensitive TB and only one new drug for treating multidrug-resistant TB have been introduced to the market during the past 40 years. Improved surveillance and case detection are required to identify critical risk factors, treat active cases, and limit transmission to others.

RTI scientists bring significant experience and expertise to developing new tools and solutions in the fight against TB.

**Industry Involvement and Partnerships for New Treatments**

Through support from the National Institute of Allergy and Infectious Diseases, RTI facilitated partnerships and developed business agreements between sources of promising compounds for TB treatment and public- and private-sector organizations with resources and expertise for developing these candidates. Effective action against TB requires the resources, skills, and involvement of governments, international health organizations, philanthropic organizations, and industry. RTI partnered with all of these stakeholders to address important needs in TB prevention and treatment. For example, RTI played an important role in the planning and formation of the TB Alliance, an international nonprofit organization formed to develop and provide new TB medicines at an affordable price. RTI is a stakeholder in the TB Alliance and provides assistance in many of the Alliance activities with its global partners.

**Drug Development**

RTI has demonstrated the ability to move promising lead compounds quickly and effectively through the formulation development, preclinical, and clinical studies required for regulatory approval of new therapeutics. To accomplish these high-quality and timely outcomes, RTI brings the necessary combination of effective planning, management, technical, and regulatory expertise, as well as extensive laboratory facilities, to the drug development process. RTI has demonstrated success managing lead compounds for the Global Alliance for TB Drug Development (TB Alliance) and the Lilly TB Drug Discovery Initiative.

**Epidemiology**

RTI has worked with public health organizations and research institutions to develop and evaluate more effective methodologies to identify persons with new infections and treatment of latent infection. This work has helped determine the local epidemiologic patterns to plan programs of targeted tuberculin skin testing and treatment of latent infection, and has evaluated and defined the role of promising diagnostic tests and new drugs.
**Project Highlights**

**Tuberculosis Technology Transfer Support, 1999–2011**  
*Funded by the National Institute of Allergy and Infectious Diseases*

This program facilitated the development and commercialization of new anti-TB compounds. RTI assisted staff from the National Institutes of Health and global health organizations in planning activities that resulted in the TB Alliance, a public-private partnership formed in 2000 for development of new drugs to treat TB. To build industry interest, RTI compiled global epidemiology and market data for new TB drugs to present a business case for investment in drug development. RTI also provided project management support for developing several preclinical compounds for the Lilly TB Drug Discovery Initiative. RTI's support of the Lilly Initiative included preparation of development strategies, operational planning and implementation, formulation, and regulatory support.

**TB Drug Development Support, 2005 to date**  
*Funded by the Global Alliance for TB Drug Development*

Since 2000, RTI has worked with the TB Alliance to support five of its drug development programs. RTI assists the TB Alliance in integrated planning, implementation, project management, statistical analysis, medical writing, contract monitoring of studies, manufacturing, and regulatory affairs to advance compounds through preclinical and clinical studies for regulatory approval. For example, RTI serves as a resource to the TB Alliance for drafting Food and Drug Administration submissions, including the successful investigational new drug application for the compound PA-824.

**Tuberculosis Epidemiology, 2001–2011**  
*Funded by the Centers for Disease Control and Prevention*

RTI served as a member of the Tuberculosis Epidemiologic Studies Consortium, consisting of U.S. and Canadian scientists and public health practitioners. The consortium sites worked with the Centers for Disease Control and Prevention to plan, design, and execute a series of epidemiologic, behavioral, economic, laboratory, and operational research studies that implemented the Institute of Medicine's recommendations for TB elimination. RTI studies addressed topics that included diagnosing latent infection in high-risk patients, identifying and overcoming barriers to treatment, establishing systems for enhanced surveillance, identifying risk factors associated with adherence to treatment of latent TB infection, and testing new tools for self-evaluation of TB programs.

**Pan African Consortium for Evaluation of Antituberculosis Antibiotics (PanACEA), 2008**  
*Funded by the Bill & Melinda Gates Foundation*

RTI managed the process of creating the PanACEA concept and document that brought together the consortium and was used to raise a total of €27 million in funding from the European & Developing Countries Clinical Trials Program and participant countries in Europe. PanACEA advanced the development of therapeutics for shortening and simplifying TB treatment by supporting regulatory-quality Phase II–III clinical trials and developed enhanced clinical trial capacity in sub-Saharan Africa. PanACEA established a network of 6 European research organizations, 12 sub-Saharan clinical trial sites, and 3 pharmaceutical companies. Synergies created by PanACEA across the trial sites led to the development of processes, tools, and capacity for more efficient and effective future clinical trials for TB drug candidates.

**More Information**

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