

Tuberculosis



Tuberculosis threatens public health worldwide, infecting one-third of the world's population, with nearly 2 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 the treatment of TB have been introduced to the market in 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 the development of new tools and solutions in the fight against TB.

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.

Industry Involvement and Partnerships for New

Treatments. Through support from the National Institute of Allergy and Infectious Diseases, RTI facilitates partnerships and develops business agreements between sources of promising compounds for TB treatment and public- and private-sector organizations with resources and expertise for development of these candidates. Effective action against TB requires the resources, skills, and involvement of governments, international health organizations, philanthropic organizations, and industry. RTI partners 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 Global Alliance for TB Drug Development, 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.



Epidemiology. RTI works 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
- Determine the local epidemiologic patterns to plan programs of targeted tuberculin skin testing and treatment of latent infection
- Evaluate and define the role of promising diagnostic tests and new drugs in TB elimination

Examples of RTI's Work in Tuberculosis

Tuberculosis Technology Transfer Support

This program facilitates 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. Between 2002 and 2005, NIH supported RTI's role as project manager for the TB Alliance's lead compound, PA-824. To build industry interest, RTI compiles global epidemiology and market data for new TB drugs to present a business case for investment in drug development. For example, RTI coordinated and authored major sections of the 2001 TB Alliance report *Economics of Tuberculosis Drug Development*, providing a basis for the public and private sectors to make informed decisions regarding investments in new TB therapeutics.

Funded by the National Institute of Allergy and Infectious Diseases, 1999 to date

TB Drug Development Support

RTI currently works with the TB Alliance to provide support for its drug development programs. As TB Alliance project manager for the development of PA-824, RTI is assisting the TB Alliance in the integrated planning, implementation,

contract monitoring of studies, and manufacturing to advance the compound through preclinical and clinical studies for regulatory approval. RTI serves as a resource to the TB Alliance for regulatory affairs, and for drafting FDA submissions, including the successful investigational new drug application for PA-824. RTI also provides project management support for the development of several preclinical compounds for the Lilly TB Drug Discovery Initiative. RTI's support of the Lilly Initiative includes preparation of development strategies, operational planning and implementation, and regulatory support.

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

Tuberculosis Epidemiology

RTI is a member of the Tuberculosis Epidemiologic Studies Consortium, consisting of U.S. and Canadian scientists and public health practitioners. The consortium sites work 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 will implement the Institute of Medicine's recommendations for TB elimination. RTI studies address topics that include 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.

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More Information

Doris Rouse, PhD
Vice President, Global Health Technologies
RTI International
3040 East Cornwallis Road
Research Triangle Park, NC 27709-2194 USA
+1.919.541.6980
rouse@rti.org
www.rti.org

RTI 7511 0211