



INTERNATIONAL DEVELOPMENT

# Global Health Technologies



## Expertise

- Managing drug/medical device development
- Regulatory strategy (domestic and international)
- Technology assessment and commercialization
- Market/demand assessment
- Research ethics and informed consent
- Strategic and operational planning
- Gender issues and HIV/AIDS



## Contact information

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Creating new health interventions that address unmet needs in the developing world is critical for improving global health. RTI International's Global Health Technologies provides an enabling infrastructure to help our clients design and implement product development programs for drugs and medical devices. RTI works closely with multidisciplinary teams drawn from both the public and private sectors to help clients achieve their development goals. The RTI team has broad experience in product assessment and commercialization; drug/device development; clinical and regulatory strategy; and social, economic, and behavioral research.

## Managing drug/device development

The RTI team provides demonstrated expertise and achievement in the rapid development of new products for global health. Key elements of our approach to product development include

- **Capacity:** Staff and facilities with extensive capacity to deliver comprehensive development services
- **Regulatory Support:** Effective solutions for working with both domestic and international regulatory agencies
- **Scientific Excellence and Quality:** Unwavering commitment to the scientific and regulatory integrity of the work performed, including quality assurance of work conducted by third-party vendors
- **Comprehensive View:** Thorough analysis of each study's data and consideration of the implications with respect to the larger project and regulatory requirements
- **Flexibility:** Experience to guide effective product strategy in response to unexpected study results

## Clients

- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Child Health and Human Development (NICHD)
- Centers for Disease Control and Prevention (CDC)
- Global Alliance for TB Drug Development (TB Alliance)
- International Partnership for Microbicides (IPM)
- International AIDS Vaccine Initiative (IAVI)
- DuBiotech Research Park

RTI's work includes support to TB Alliance for development of PA-824 a tuberculosis treatment drug. We are assisting the TB Alliance in the integrated planning, implementation, and contract monitoring of studies to advance the compound through preclinical and clinical studies required for regulatory approval. RTI supported the TB Alliance in the preparation of a successful Investigational New Drug application for PA-824 and serves as the TB Alliance's regulatory contact with FDA for the drug.

We are also working with the IPM to investigate the safety and acceptability of innovative vaginal delivery systems that provide HIV prevention drugs to women

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for weeks or even months. We are investigating the acceptability of other topical microbicides for HIV prevention at clinical trial sites in Malawi and Zimbabwe. The findings will be used for problem solving of emergent adherence, retention, acceptability, and ethics issues in larger clinical trials. RTI staff are also providing broader support for clinical trials, including

- Ethnographic studies
- Protocol development
- Ethics review and training
- Clinical trial management
- Data collection and analysis

### Technology assessment and commercialization

Technology transfer is the process of developing practical applications from the results of scientific research. For more than 30 years, RTI staff have conducted technology and market assessments for government and industry. RTI coordinated and authored major sections of the 2001 TB Alliance report, *Economics of Tuberculosis Drug Development*, providing a basis for public and private sectors to make informed decisions regarding investments in new TB therapeutics. As part of the NIAID TB Drug Development Program, RTI is actively facilitating partnerships between biotechnology companies, research labs, foundations, and international organizations to cooperatively develop, test, and introduce new TB therapies. RTI provides

- Market and pharmacoeconomic data on drugs and medical devices

- Resources and opportunities to find partners to establish public and private collaborations for the development of promising global health products
- Technology evaluation and transfer support
- Regulatory strategy for domestic and international approvals

### Research ethics and informed consent

Clinical research in low- and middle-income populations requires additional efforts to ensure trial subjects' ability to freely and effectively decide on participation in research. RTI staff are actively involved in ethics consultation and generation of informed consent approaches for clinical studies in the developing world. RTI staff have

- Led the development of an array of materials supporting a comprehensive informed consent process for multiple international studies
- Consulted on development of video materials for international clinical trials
- Contributed to ethics training curricula and conducted ethics training for staff at multiple levels, including researchers, community leaders, and peer recruiters

RTI has also collaboratively authored six Codes of Practice for DuBiotech, a biotech research park effort in Dubai. We helped establish a set of foundational regulations to facilitate and regulate biotechnology research at DuBiotech. The Codes of Practice focus on Good Clinical



A doctor in Binjai local clinic examines a patient.  
[Photo: Project staff]

Practices (GCP) and bioethics, including informed consent for human research, formation and function of independent ethics committees, and responsibilities of investigators and sponsors engaged in clinical research. RTI is now assisting DuBiotech's implementation of these Codes.

### Gender issues and HIV/AIDS

By providing program and planning guidance through the Office of the Global AIDS Coordinator to all U.S. government agency HIV/AIDS programs, RTI staff have played an instrumental role in the development of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). We are making major contributions to PEPFAR efforts to strengthen gendered approaches to HIV/AIDS including

- Preventing and mitigating gender-based violence
- Addressing male norms and behavior
- Increasing gender equity in access to programs and services, to income, and to legal rights

RTI International is one of the world's leading research institutes, dedicated to improving the human condition by turning knowledge into practice. With projects in more than 40 countries and a staff of more than 2,600, RTI offers innovative research and technical solutions to governments and businesses worldwide in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, democratic governance, economic and social development, energy, and the environment. For more information, visit [www.rti.org](http://www.rti.org).

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