

RESEARCH AND TECHNICAL SUPPORT AT RTI INTERNATIONAL

HIV Drug Development and Therapeutics



Government and private-sector clients around the world rely on RTI for independent, objective, and scientifically rigorous research in support of the development of HIV drugs and therapeutics. We offer expertise in microbicides, immunization and vaccinology, and drug development.

Topical Microbicides

RTI applies a holistic, multidisciplinary approach to studying issues associated with the development and use of topical microbicides for prevention of HIV infection. Our unique combination of expertise in social, behavioral, and epidemiological sciences, as well as biomedical and laboratory services, allows RTI to conduct research directly and indirectly associated with microbicide development.

RTI experts serve in leadership roles on various multinational research networks with active microbicide studies in the field. Our experience and expertise include

- International and domestic research
- Technical support, collaboration, and consultation for microbicide studies
- Pharmaceutical development
- Ethics support.

Immunization and Vaccinology

RTI conducts programmatic and economic studies of immunization programs, vaccine safety concerns, and genetic influences on immune response. Our researchers

study the perception of risks associated with vaccines in order to promote informed decisions among diverse populations. RTI also provides guidance and technical assistance in research ethics and works to boost the comprehension of informed consent among participants in HIV vaccine trials.

Drug Development Expertise

- Lead compound identification
- Preclinical support, including manufacturing support, comprehensive reproductive and general toxicology studies, and candidate drug characterization
- Clinical trials coordination and sample analysis
- Medical monitoring
- Consumer preferences research
- Conjoint analysis
- Medical writing, including new drug applications (NDAs), investigational NDAs, phases I-III protocols, and post-marketing reports



Drug Development

Drug development specialists at RTI provide impartial scientific information on the efficacy, toxicity, chemical structure, and mechanisms of action of pharmaceuticals. We adhere to Good Laboratory Practices/Good Manufacturing Practices and have the capacity to fully support submissions for U.S. Federal Drug Administration review of investigational new drugs and new products.

RTI Health Solutions, a business unit of RTI International, provides scientifically rigorous consulting services in health economics, psychometrics, patient-reported outcomes, survey research, pricing and reimbursement drug safety, biostatistics, epidemiology, and risk management.

Key Project Highlights

RTI researchers and technical experts support the design, implementation, and evaluation of programs to slow the spread of HIV. With decades of experience in the field, we understand how to launch, scale up, and sustain successful programs.

Technical Support to IPM 011 Trial of Vaginal Ring

RTI is supporting efforts of the International Partnership for Microbicides (IPM) to accelerate the development and availability of microbicides. We are helping conduct a study of the safety and acceptability of a vaginal ring for delivery of microbicides, analyzing data, and helping prepare written reports and summaries of study findings.

Duet® Acceptability and Safety Study

With funding from the IPM, RTI is studying the safety and acceptability of using a novel diaphragm—known as Duet—for vaginal delivery of microbicide gels. As with all behaviorally dependent methods of preventing HIV infection, the timing of use is a key factor in the acceptability of

topical vaginal microbicides. This study, being conducted in Zimbabwe, focuses on women's and men's perspectives and their preferences for using the Duet routinely versus prior to having sex. If Duet is proven acceptable under different circumstances, it may be appropriate for delivery of a variety of microbicide gel products currently under development.

Development of Informed Consent for HIV Vaccine Trials

As the search for an effective HIV vaccine continues, clinical trials of candidate vaccines are being conducted in sub-Saharan Africa, where HIV incidence is high. In order to successfully and ethically conduct these trials, participants must understand the information provided during the informed consent process. Working with the International AIDS Vaccine Initiative, RTI has developed visual aids and training materials to be used by staff when they recruit and enroll trial participants. These materials can be adapted to the needs and study requirements of multiple clinical trials of HIV vaccine candidates.

For more information, please contact

Microbicides

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