

Data Coordinating Centers



As the data coordinating center (DCC) for a multisite research study, RTI International collaborates with the sponsor and with clinical investigators to design and implement clinical and behavioral epidemiological studies and clinical trials.

Over the past three decades, RTI has served as the DCC for more than 25 multisite studies that include a strong portfolio in HIV/AIDS, maternal and child health, and other emerging public health challenges.

As a DCC, RTI staff collaborate with other investigators to

- Provide statistical guidance during the initial study design and throughout implementation
- Design and provide the data capture and data management systems
- Coordinate and monitor data collection and data management activities
- Provide reports to the governing and oversight bodies of the study and the funding agency
- Facilitate communication among all researchers, core laboratories, and funding agencies
- Manage study logistics
- Maintain standardization and quality control across sites.

We also help our clients obtain federal-wide assurance and institutional review board approvals and track the collection and banking of biological specimens.

In all of our efforts, we collaborate with local researchers, communities, and local organizations to improve global health and ensure scalability, replicability, and sustainability of programs.

Capabilities Across All Study Phases

At RTI we understand that the quality of data determines its analytic value. For each study or trial, we provide systems and applications to collect, manage, edit, and analyze the data. Our expertise includes relational databases, data warehousing, online analysis tools, Web hosting and site development, data extraction and transformation, and other computer technologies that can streamline and automate operations. We can customize Web-based forms and provide operation manuals, standard operating procedures, and comprehensive training to assist sites in establishing standards for data and reducing the burden of its collection.

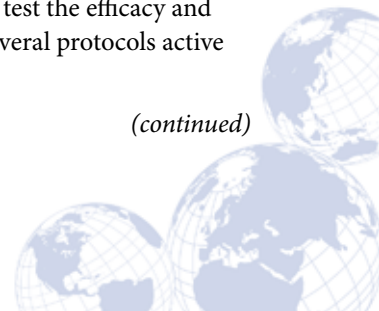
Our staff are experienced in managing, manipulating, and merging large, disparate data sets—some with millions of individual records—to provide analytical data files in various formats.

Highlights of RTI's Work as a DCC

NICHD Neonatal Research Network (1998–2013)

RTI provides data coordinating services to the Neonatal Research Network, funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). This cooperative group of 16 U.S. hospitals enrolls mostly premature babies into clinical trials and observational studies that test the efficacy and safety of various treatments, with several protocols active

(continued)



at any given time. This Network has been functioning for more than 20 years, with RTI as the DCC since 1998. As the DCC, RTI provides the following support: study design; development and distribution of study materials; development of randomization systems; development and implementation of data entry and management systems; production of enrollment, quality assurance, safety, and efficacy reports; and data analysis and manuscript preparation. An important role we play is to prepare periodic reports for the Data Safety and Monitoring Committee, an external review group that monitors the recruitment and results from randomized clinical trials and advises NICHD on whether such trials should be continued as planned, continued with changes, or halted. Active studies in the network include registries for low-birthweight infants, a longitudinal study on long-term developmental outcomes, clinical trials, and observational studies.

National Registry of Genetically Triggered Thoracic Aortic Aneurysms and Cardiovascular Conditions (GenTAC) (2006–2010)

RTI serves as the DCC for the GenTAC Registry, which is funded by the National Heart, Lung, and Blood Institute. The broad purpose of this registry is to facilitate research to determine best medical practices to advance the clinical management of genetic thoracic aortic aneurysms and complications. The registry is establishing a repository of data and biological specimens that can be used by investigators to examine the cause, treatment, and outcomes of aortic disease in several genetic conditions, including Marfan syndrome and bicuspid aortic valve. As the DCC, RTI is collaborating with five regional clinical centers (RCCs) that will enroll over 2,500 patients. Data collected by the RCCs include blood, tissue, medical history, physical exam, surgical interventions, genetic testing, imaging studies, family history of disease, and personal health behaviors. RTI's responsibilities include development of the protocol, data collection forms, study Web site and data management systems; training and monitoring of RCC coordinators; quality control; statistical analyses and manuscript preparation; and data sharing to qualified investigators.

Global Network for Women's and Children's Health Research (2001–2012)

RTI serves as the DCC for this international network initially funded by the Gates Foundation and NICHD. The research commitment of the Global Network emphasizes the development, testing, and adaptation of cost-effective, integrated biomedical, behavioral, social, and public health interventions to reduce morbidity and mortality among reproductive-age women and young children in developing countries. The ten research units conducted their own protocols during the first phase of the study. The focus is shifting to collaborative research protocols related to common problems affecting women's and children's health across the six research units funded for the second phase of the study. Collaborative efforts have included a protocol with the National Cancer Institute to assess tobacco use among pregnant women and a cluster-randomized neonatal resuscitation protocol. Sustainability and quality assurance of the data are major components of this study and are especially challenging, given the diversity of the participating international communities.

NIH-DC Initiative to Reduce Infant Mortality in Minority Populations (1993–2010)

The purpose of the NIH-DC Initiative is to develop coordinated projects designed to better understand the reasons for the high rate of infant mortality in the District of Columbia and to design and evaluate intervention projects aimed at reducing the number of infants in the District who are at increased risk of dying in their first year of life. Based on the initial epidemiological studies, integrated intervention programs are designed to address risk factors such as smoking and exposure to second-hand smoke, depression, and intimate partner violence. The program is sponsored by the NIH Office of Research on Minority Health and NICHD.

More Information

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