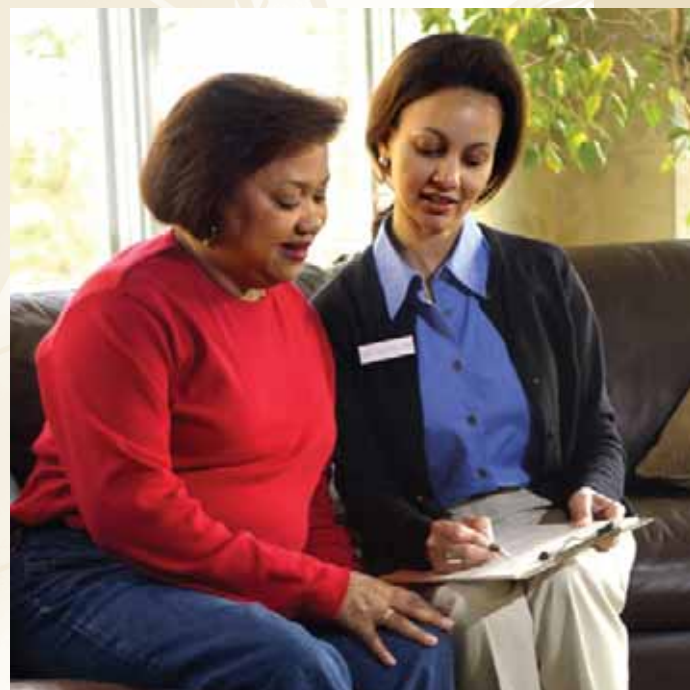


Coordinating Centers for Collaborative Research Networks

Data • Clinical • Statistical



RTI offers our clients comprehensive experience in the implementation and management of coordinating centers for collaborative research networks. With a multidisciplinary staff including statisticians, epidemiologists, site and protocol managers, and data managers, we provide effective study design, high-quality data systems and management, site training and coordination, statistical analysis and reporting, and study logistics support.

Study Design

RTI researchers design hundreds of studies in collaboration with clinical and behavioral investigators across the United States and throughout the world. Effective study design is crucial to study success.

Hypothesis Development. RTI researchers work with study investigators to translate initial hypotheses into statements that can be quantified and tested.

Selection of Study Outcome Measures. Outcome measures must be measured with little bias and low variability and must be collected using appropriate methods.

Statistical Design, Power Calculation, and Randomization. Our experience spans clinical, behavioral, and epidemiological studies using randomized trials, observational studies, and population surveys. Power calculations are used to select a sample allocation that yields adequate power but does not waste resources.

Protocol Development. Together with study investigators, RTI researchers prepare detailed protocols to guide uniform implementation across multiple sites.

Analysis Planning. Analysis plans developed by the study investigators and RTI statisticians account for the study hypotheses, types of measurement, study design, choice of randomization method, any stratifying or clustering, repeated measurements, and potential missing-data issues.

Data Capture and Management

RTI understands the importance of high-quality data systems and management for the integrity and security of research data.

Electronic Data Capture (EDC). RTI has adopted the InForm™ Integrated Trial Management (ITM) system as our standard for EDC. InForm ITM is 21 CFR Part 11 compliant for use with FDA-regulated clinical studies.

Patient-Reported Outcomes (PRO) Data. We have created several systems to facilitate the collection of PRO data: computer assisted personal interviewing (CAPI); computer-assisted telephone interviewing (CATI); audio computer-assisted self-interviewing (ACASI); IVR or telephone audio computer-assisted self-interviewing (T-ACASI); and computer-assisted recorded interviewing (CARI).

Ancillary Systems. We have developed many systems to support collaborative research networks, including web portals, biospecimen tracking systems, patient tracking systems, control systems that track events associated

with study participants and management activities, randomization tools to assign participants to a study, and medical device interfaces to import data from medical devices or laboratories.

Data Privacy and Health Insurance Portability and Accountability Act (HIPAA) regulations. RTI takes data privacy and security seriously. All data access is limited to authorized users whose access, views, and actions are controlled by a configurable set of rights based on their roles in the study.

Site Training and Coordination

RTI is a leader in the development of protocol manuals, site training, and oversight of study implementation. And we can help you with institutional review board (IRB) approvals as well as the tracking and banking of biological specimens.

Development of Manual of Operations (MOO). RTI researchers are well versed in MOO development, including network policies, standards for data management, and quality control. The MOO also provides detailed instructions on patient enrollment, data collection procedures, reporting requirements, instructions for coding, as well as the handling and labeling of biospecimens.

Site Training. RTI offers comprehensive training and certification programs that center on protocol-specific procedures.

Oversight of Study Implementation. RTI researchers' provide expert oversight of study implementation, site regulatory file(s) and standard operating procedures (SOPs), enrollment practices and patient retention, data collection, pharmacy and laboratory procedures, and adverse event management.



Enrollment Monitoring and Retention Support. RTI works with clients to research and better understand the target patient population and creates custom recruitment and retention programs that overcome enrollment challenges.

Statistical Analysis and Reporting

RTI statisticians offer extensive breadth and depth of statistical expertise, with over 150 statisticians on staff. Equally important is RTI's collaboration with study investigators on manuscripts, publications, and presentations.

Analytical Methods. RTI routinely employs analytical methods such as generalized linear mixed models, hierarchical linear models, multilevel models, and nonlinear mixed models. For time-to-event data, survival techniques are used, including the Kaplan-Meier method, life tables, parametric survival regression, and Cox proportional hazards regression. Structural equation modeling (SEM) is another powerful technique that accounts for nonlinearities, latent variables, correlation between independent variables or error terms, and the modeling of interactions.

Data Safety and Monitoring Board (DSMB) and Safety and Efficacy Reports. RTI statisticians are skilled in preparing summaries, by site and in aggregate form, of the progress of subject recruitment and retention, data integrity, safety issues including the reporting of adverse events and serious adverse events, and the results of various outcome measures and interim analyses.

Publications and Presentations. RTI statisticians, epidemiologists, and other staff have a strong record as primary authors and coauthors and are supported by in-house professional publications staff.

Regulatory Affairs

RTI's Office of Research Protection (ORP) ensures compliance with all regulations related to the protection of human research subjects and assists study investigators in developing appropriate study procedures.

Human Subjects Protection. All biomedical and behavioral research conducted by RTI involving human subjects must have the approval of the ORP, which consists of three Institutional Review Boards (IRBs). The Office for Human Research Protections of the Department of Health and Human Services has granted a Federalwide Assurance (FWA #3331) to RTI that allows RTI to independently review and approve studies.

IRB Coordination and Communications. RTI staff members assist clinical sites with IRB coordination and communications, including support with protocol and study forms review packages, interim reports, maintenance of regulatory files, and annual updates. We also assist with modifications required for site-specific IRB requirements.

Regulatory Filing and Submissions. RTI researchers serve as the regulatory liaison and resource for submissions to the U.S. Food and Drug Administration. Strategic regulatory plans, timelines, and milestones are discussed early in clinical program development with all appropriate parties.

Monitoring Adverse Events and Patient Safety. RTI staff members routinely coordinate and report safety data, such as adverse events and serious adverse events, to project data safety monitoring boards (DSMBs), IRBs, and scientific advisory committees during the conduct of clinical studies.

Study Logistics

RTI has extensive experience coordinating and managing study logistics for U.S.-based and international studies. RTI provides exceptional organizational skills and knowledge in logistics coordination. Our expertise includes meeting coordination, travel planning, communications, study reports, and site or investigator payments.

Selected Projects

National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (1998–2013). RTI provides statistical and data coordinating services to the NICHD Neonatal Research Network (<https://neonatal.rti.org/>), a cooperative group of 16 U.S. hospitals. These hospitals enroll premature babies into clinical trials and observational studies that test the efficacy and safety of various treatments, with



several protocols active at any given time. The network has been functioning for more than 20 years, with RTI as the data coordinating center (DCC) since 1998. As the DCC, RTI provides 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. Active studies in the network include ongoing registries for low-birthweight infants, clinical trials, observational studies, and a longitudinal study on long-term developmental outcomes.

Global Network for Women's and Children's Health Research (2001–2012). RTI serves as the data coordinating and analysis center for this international network initially funded by the Gates Foundation and the 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. Each of the 10 research units conducted its own protocol(s) during the first phase. The study 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. 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 data are major components of this study and are especially challenging given the diversity of the participating international communities.

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

RTI serves as the DCC for this National Heart, Lung and Blood Institute-sponsored registry, which includes five clinical centers. Clinical, laboratory, and family pedigree data, as well as biological specimens, are collected and analyzed on approximately 3,500 patients receiving treatment for aortic aneurysms, aortic dilatation, aortic insufficiency, heart failure, or aortic valve repair in which a genetic component is suspected. The information collected by the registry will facilitate research to determine the best medical practices for advancing the clinical management of genetic thoracic aortic aneurysms and other cardiovascular complications. RTI staff design all data collection materials and train the nurse coordinators in the collection and shipping of biospecimens and the completion of all clinical forms. The forms are keyed through the secure project Web site by clinical center staff. The Web-based data management system provides dynamic reports on the status of patient enrollment and follow-up evaluations, entry of data forms, and diagnosis of significant events. RTI is also responsible for all data analysis and dissemination of findings through preparation of manuscripts and presentations at scientific meetings in collaboration with the investigators from the clinical centers.

For more information contact

Rick Williams, Ph.D.
Principal Scientist
Phone: (919) 541-6075
Fax: (919) 541-6722
E-mail: rwilliams@rti.org

Sue Pedrazzani, MPH
Program Director, Public Health and
Clinical Research
Phone: (919) 541-6744
Fax: (919) 541-7250
E-mail: sdp@rti.org

RTI International
3040 Cornwallis Road, P.O. Box 12194
Research Triangle Park, NC 27709-2194

RTI 6497-2 10/09



RTI International is one of the world's leading research institutes, dedicated to improving the human condition by turning knowledge into practice. Our staff of more than 2,800 provides research and technical expertise to governments and businesses in more than 40 countries in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, international development, economic and social policy, energy and the environment, and laboratory and chemistry services. For more information, visit www.rti.org.

RTI International is a trade name of Research Triangle Institute.