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.

RTI began serving as a DCC in 1975 for a multicenter study sponsored by the National Heart, Lung, and Blood Institute (NHLBI). Since then, we have continuously served as the DCC for complex multicenter research projects, including many conducted through large, multistudy clinical research networks.

As a DCC, RTI staff members collaborate with other investigators to

- Partner with clinicians to select and design rigorous studies
- Provide statistical leadership from initial study design throughout implementation, analysis, and manuscript production
- Design, develop, and maintain innovative informatics tools for collecting, analyzing, and sharing data
- Coordinate and monitor data acquisition from multiple sources (e.g., study participants, electronic health records, laboratories, devices)
- Perform data integration and data harmonization
- Plan and conduct site training and monitoring visits
- Manage regulatory aspects of studies, including reports to oversight bodies, sponsors, and regulatory agencies
- Facilitate and participate in communication among all researchers, core facilities, and funding agencies
- Manage study logistics, including capitation awards
- Maintain standardization and quality control across sites.

Study-Related Capabilities

At RTI, we understand that data quality determines analytic value. For each study, we provide systems and applications to collect, manage, and analyze data. Our expertise includes data capture, data harmonization, data warehousing, online analysis tools, web hosting, high-performance computing, and other computer technologies that can streamline and automate operations. We develop web-based forms, operation and procedures manuals, and comprehensive training to assist sites in establishing standards for data quality and efficient data acquisition.

Our staff members are experienced in manipulating; de-identifying; and merging large, disparate data sets—some with millions of records—to generate analytical data files.

Our study designs and analyses are tailored for each study. We use innovative designs (e.g., Bayesian, adaptive, cluster randomized) and statistical analysis techniques (e.g., modeling, simulations, missing data imputation) when appropriate. Our staff members have expertise in bioinformatics, biostatistics, genetics and microbiomics, study coordination, and logistics.

Highlights of RTI's DCC Work

NICHD Neonatal Research Network (1998–2023)

The Neonatal Research Network, funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), is a cooperative group of 15 U.S. neonatal intensive care units enrolling mostly premature babies into clinical studies that test the efficacy and safety of treatments to improve survival rates and

the health of neonates. We collaborate with network investigators to identify high-priority research topics, design and implement studies to rigorously evaluate treatment strategies (some under an Investigational New Drug application), provide study and data management systems that ensure data quality, lead statistical analyses, and publish study results. We prepare periodic reports for the Data Safety and Monitoring Committee. Studies include in-hospital trials and long-term follow-up registries.

Environmental Influences on Child Health Outcomes (ECHO) Data Analysis Center (DAC) (2016–2023)

ECHO is an ambitious initiative of the National Institutes of Health to investigate how exposure to a wide range of environmental factors in early development influences the health of children and adolescents. Combining resources from Johns Hopkins University and RTI, the ECHO DAC is responsible for managing extant and new data on more than 50,000 children from 84 preexisting study cohorts and providing statistical and epidemiological expertise in the design, analysis, and interpretation of ECHO-wide cohort studies. RTI's responsibilities include establishing and maintaining a secure cloud-based IT infrastructure; a robust portfolio of tools for data capture, management, and analysis; a scalable, central database built upon defined data standards to maximize the utility of both extant and prospectively collected data; a well-managed information dissemination process that includes a tiered approach to data access and web-based interactive visualization tools; and central tracking of all DAC processes to ensure high-quality data and reproducible findings. An important feature of the central data platform, developed by RTI, is a metadata catalog that allows researchers to explore characteristics of ECHO cohorts and their data.

Global Network for Women's and Children's Health Research (2001–2022)

The research commitment of the Global Network emphasizes the assessment of cost-effective, integrated biomedical, behavioral, social, and public health interventions to reduce morbidity and mortality among pregnant women, infants, and young children in low- and middle-income countries. The network conducts collaborative research protocols related

to common problems that affect women's and children's health across low-resource regions of Asia, Africa, and Latin America. Collaborative efforts have included a cluster-randomized trial to assess neonatal resuscitation training for community health workers, a study of preconception maternal nutrition to improve infant growth, and a trial of antenatal corticosteroids to reduce risk of mortality associated with preterm birth in rural settings. Major study components include data sustainability, enhancement of local research capacity, and quality assurance. Several studies have been cofunded by NICHD and a research foundation.

Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) (2011–2018)

The REDS-III DCC, sponsored by NHLBI, is responsible for overall coordination, communications, data management, and analytical and statistical support for participating domestic blood centers and hospitals, as well as programs in China, South Africa, and Brazil. We have supported the design and successful implementation of more than 20 studies in blood banking; donor safety; transfusion practices; and clinical outcomes of transfusion, including collection of core data from linked blood donors and recipients to study the effect of donor characteristics on transfusion outcomes.

More Information

Susan Mitchell
Senior Director, Center for Clinical Research Network Coordination
202.974.7827
smitchell@rti.org

RTI International
3040 E. Cornwallis Road, PO Box 12194
Research Triangle Park, NC 27709-2194 USA

RTI 7590 R6 0918