



Research Centers in Minority Institutions
Translational Research Network
Data Technology Coordinating Center

RTRN Data Technology Coordinating Center (DTCC)

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The **Research Centers in Minority Institutions (RCMI) Translational Research Network (RTRN) Data Technology Coordinating Center (DTCC)** is a highly-complex and computerized network of clinical and collaboratory technologies designed to facilitate multi-site translational research. The mission of DTCC is to provide the technology infrastructure and data management resources to facilitate inter-institutional collaborations including community engagement, information and data sharing and dissemination of information across the diverse RCMI communities to improve health outcomes, especially for the underserved populations. The DTCC is grounded in research design, biostatistics, clinical ethics, regulatory knowledge and data management and provides coordinated data collection, management, and analytic support for each of the major Network Platforms—clinical, biomedical and educational.

This unique environment provides a secure, centralized web portal with functionalities that include data capture and integration of many different forms of clinical data. It also provides a user-friendly system for data mining and data sharing and a public portal to facilitate information dissemination to clinicians, researchers, the lay public, and health policy officials. The center facilitates the design of study protocols, data management and statistical analysis including statistical reports for the Data Safety Monitoring Board (DSMB). The DTCC provides the backbone to truly support a unique enterprise-wide infrastructure to improve collaboration and coordination of clinical and translational research programs among partnering RCTR participants.

RTRN DTCC Specific Aims

- To serve as the hub of the RTRN to facilitate sharing of innovative research tools and information technology resources across inter-institutional and intra-institutional basic and clinical research teams dedicated to improving the health of disadvantaged communities;
- To integrate new technologies and create research synergies that will support interdisciplinary interaction and multi-site translational research;
- To implement a highly-functional network of cyber workspaces to facilitate inter-institutional collaborations including supporting community engagement and information sharing and dissemination among the research clusters; and
- To provide the infrastructure for an integrated training environment to support the development of a new generation of scientists grounded in the principles of multidisciplinary and translational research.

RTRN DTCC Services and Functions

RTRN DTCC provides an array of services in clinical data and project management, data collection and technology integration, statistical design and analysis, and in communications to support translational research. The following is a consolidated list of services:



Clinical Data Management

(Services provided by the Clinical Data Services and Informatics Division)

- Protocol Development, Review and Submission
- Facilitation of Case Report Forms Creation
- Database Design, Validation, and Testing
- Electronic Data Entry (EDC)
- Data Management Plan Documentation
- eCRF Completion Instructions
- Query Rules (edit checks) Development (data cleaning), Validation, and Testing
- Management of Standard Global Libraries of Case Report Forms
- Laboratory Management
- Ensuring Regulatory (ICH, FDA, IRB) Compliance
- Coding of Adverse Events (MedDRA)
- Coding of Concomitant Medications (WHO Drug)
- Query Resolution Support and Rules Maintenance
- Database Freeze, Locks and Transfers
- Database Quality Control
- Study-specific eCRF Training and Support
- Study-specific Protocol Training and Support
- Provide Standard Project Reports on Project Status and Compliance
- Laboratory Data Management

Clinical Monitoring

(Services provided by the Clinical Data Services and Informatics Division)

- Facilitate Development of Method of Procedures Manuals
- Source Data Monitoring
- Clinical Guidance on Study Conduct
- Provide Guidance on Grants and Responses to RFAs
- Regulatory Compliance Tracking
- Clinical Input on Study Protocols
- Project Management of Studies

Systems Administration and Security, Technology Integration

(Services and functions provided by the Information Security and Technology Integration Division)

- Case Report Form Design and Development
- Database Development and Validated Edit Checks
- Database Testing and Quality Control
- Data Integration
- Training on RDC Data Entry
- Help Desk Support

Statistical Design and Analysis

(Services and functions provided by the Biostatistical Division)

- Protocol Development
- Statistical Needs Assessment
- Randomization Schema
- Power Analysis and Sample Size Calculations
- Validation and Data Transfer
- Analyses for Publication of Final Study Results
- Secondary Analyses
- Development and Review of Tables and Listings
- eCRF Review
- Statistical Analysis Plan
- Query Review
- DSMB Coordination, Interim Analysis and Safety Monitoring
- Data and Analysis Specifications
- Final Statistical Analyses and Report Development
- CDISC modeling



Communications

- Information Development and Dissemination
- Website Management
- Material Production: Print, Audio and Video
- Meeting Support Services
- LISTSERVs
- Public Relations and Marketing
- Multi-Media Presentation Development

Training and Help Desk Support

(Services and functions provided by the Information Security and Technology Integration Division)

- Portal Training: Access to cyber workspace and Collaboratory Tools
- Multi-media Support: Web, Video and Teleconferencing
- Portal Account Management and Support
- Help Desk Support

For more information about the DTCC services, visit <http://www.rtrn.net/DTCC/services/servmain.htm>.



DTCC Tools and Technologies

The DTCC has many collaboration tools and technologies that provide the following capabilities and services:

- Secure portal system that provides users access to many of the systems and information needed during the lifecycle of a clinical study such as: 1) overseeing protocols; 2) managing data; 3) monitoring adverse effects; 4) developing electronic case report forms (eCRFs) and manuals of operation (MOPs); 5) implementing training; 6) conducting reviews and evaluations; 7) maintaining databases and analyzing data; 8) posting study findings; and, 9) assuring quality control.
- Collaborative tools are used to support a continuum of services from synchronous to asynchronous interactions.
 - Synchronous interactions such as meetings are supported by:
 - Audio or video conferencing capabilities (H.323, Virtual, Webex, Access Grid,, teleconference)
 - Real-time shared presentations and desktops
 - Seminar capture and broadcast
 - Some key asynchronous collaboration tools include workspaces, document sharing systems, content management and shared file spaces.

Security

The DTCC provides investigators with a secure environment to store their data. Attention is paid to both physical security and electronic security of data. Electronic security includes the following: a firewall, real-time intrusion detection systems, and network-based virus and vandal scanning and prevention systems. There are multiple levels of physical access controls including biometric identification and a 7x24x365 color video monitoring and recording. High-capacity tape libraries provide rapid as well as reliable backup for several terabytes of data storage. The automated data center and network management tools help to ensure continuous operations.

The DTCC uses VPN/Secure Socket Layer (SSL) connections to provide researchers role-based access to data over the web. Security procedures are continuously monitored and upgraded as necessary. The DTCC strives to comply with all [HIPAA](#) regulations as they pertain to implementing protocols.

RTRN DTCC Clinical Management System

The DTCC clinical management system allows the clinical researchers the opportunity to collaborate in a secure and regulated environment. It also provides a streamlined standardized system for managing study participant data collected during clinical trials.

The DTCC clinical management system includes:

- *Remote Data Capture:* Single application architecture provides for both clinical data management and electronic data capture of Case Report Forms (CRFs). Additional functionality is provided in key areas such as study setup, discrepancy management,



lab data management and reporting. The Remote Data Capture interface is designed with the clinical site user in mind to facilitate an ease of use during data entry and provide the ability to significantly reduce errors normally incurred during the paper CRF data entry process.

- *Thesaurus Management System (TMS)*: TMS is specifically designed to handle the complexities of dictionary management. These complexities include the multi-axial hierarchy of the MedDRA dictionary and its updates which require version control. TMS can handle any type of dictionary or thesaurus and integrates with Oracle Clinical which ensures that proper coding occurs in a consistent manner across all systems.

The DTCC clinical data analysis system includes:

- Server-based SAS: It is the main statistical software used to conduct efficacy and safety assessment, sample size determination, randomization code creation, advanced data analyses, and analyses for bioinformatics.
- Supporting statistical software includes:
 - RandomAllocation v.1.10: Generating random code
 - ConQuest: Generalized Random Coefficient Rasch model
 - Winstep: Modern item response theory
 - PASS: Calculating sample size
 - Latent gold: latent growth model, growth mixture model, latent class analysis, multi level model, etc.

The DTCC statistical data analysis system provides quality of analysis outcomes. The ultimate goal of the statistical analysis system is to maximize customer satisfaction by providing timely, prompt, appropriate, reliable, valid, and innovative analytical outcomes.

DTCC Hardware Environment

The DTCC hardware mainly consists of a cluster of servers and other network and computer equipment to support the various DTCC services.

In addition, the DTCC leverages the capabilities of several state-of-the-art University research laboratories (Remote Sensing Laboratory, Geographic Information Systems Laboratory and Science-Visualization Laboratory.) The capabilities of these laboratories enable the investigator to conduct research without regard to a geographical location and allow them to perform the following tasks: interaction with colleagues, access to instrumentation and digital libraries, computational resources, collaborative scientific visualization, distance training/education, complex information presentation and delivery, as well as development of hierarchical storage management and shared filing.

For additional information about the RTRN Data Technology Coordinating Center, visit www.rtrn.net or contact the DTCC offices at 601.979.0332.

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