The Duke Clinical Research Institute (DCRI) is a world-class, one-of-a-kind academic research organization. Since its inception in 1986, the DCRI has coordinated more than 400 multicenter clinical trials involving more than 1 million patients in 63 countries. Possessing both operational knowledge and extensive networks spanning the world of industry-sponsored clinical research, the DCRI is a living laboratory for clinical research informatics, where novel informatics advances are developed and applied to help answer critical clinical questions. These activities range from improving clinical study projects to spearheading national data standards initiatives.

The unique combination of clinical trial operations expertise and academic thought leadership at the DCRI creates an environment where innovations in research informatics can be evaluated and developed for larger-scale adoption in the field of clinical trials. The DCRI was the first to combine research data with patient care using the Duke Databank for Cardiovascular Disease, the first to implement CDISC standards in a clinical data management system, and the first to implement the HL7 ECG Waveform standard.

A living laboratory for research informatics innovations

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DCRI innovations

Clinical decision support

Physician decision-making about drug dosing and treatment is increasingly becoming dependent on biomarkers; however, studying these measurements within the context of patient care can pose challenges for accepted research designs.

To address this issue, the DCRI’s Informatics group developed and implemented a centralized clinical review methodology for double-blind clinical trials that allows investigators to design research protocols that mimic the patient care process.

These methodological advances allow physicians to receive and evaluate patient data, as well as make protocol-specific treatment decisions alongside local clinicians without revealing to the clinicians what treatment is being used. Based on the rapidly increasing use of electronic health records (EHR) and computerized physician order entry to support clinical decision-making, this methodology is part of the foundation being built to support the growing pipeline of translational biomarker research taking place at Duke and elsewhere.

ClinicalTrials.gov data for analysis

The Clinical Trials Transformation Initiative (CTTI) approached the DCRI in the summer of 2010 to create a dataset for analysis using data from ClinicalTrials.gov. The DCRI partnered with a team from CTTI, which included representatives from the National Library of Medicine and the U.S. Food and Drug Administration, to review the data, analyze its quality, and transform it so that it can more easily support secondary...
analyses, such as finding out what research is being done in certain clinical areas and what percentages of trials meet enrollment targets. The DCRI also profiled the data, characterizing data quality for several types of questions, and produced a dataset for analysis. The team will continue to process the data and will extract more information using natural language processing techniques.

DCRI informatics at a glance

- Initiates 18 study databases per year.
- Uses electronic data capture (EDC) for more than 90 percent of studies. Captures data directly from electronic sources for more than 75 percent of studies.
- Has a data management and informatics support team comprised of more than 130 people, including 16 Certified Data Managers, two PhD-level informaticians, and dozens of programmers and clinical data associates.
- Has completed more than 400 clinical trials and outcomes research projects at approximately 4,000 sites in 63 countries.
- Processes more than 6,000,000 data items per year via EDC alone.