Duke Clinical Research Institute

3120 sites in 49 countries

the largest thromb

DCRI—the choice is academic.

over 155,000 patients enrolled

over 280 tons of data forms collected

over 800 publications

over 75 trials conducted

over 30 drugs approved by the FDA

over 4146 investigators worldwide

olytic trial in history

240,000 case report form pages collected each year

the oldest and largest
cardiovascular database in the
world (115,000 patients and counting)

Alan Kay

“The best way to predict the future is to *invent* it.”

The **Duke Clinical Research Institute (DCRI)** has always been ahead of its time. We are an academic research organization that for more than 15 years has combined the best of the academic environment with a customer-driven focus, to perform world-class clinical research and outcomes analysis for our clients. Our 750+ employees are dedicated to providing the best services, with the ultimate goal of improving the care and outcomes of patients around the world. Whether assisting with a small, focused study or coordinating a large, multinational clinical trial, we bring the same enthusiasm and professionalism to all of our projects.

DCRI GOALS

- To work as a partner with our clients in conducting research that benefits the practice of medicine
- To provide the best mix of expertise and services that will achieve our clients' research goals
- To continuously improve our methods and knowledge, to provide innovative solutions to our clients' needs
- To be cost-effective and flexible in bringing new treatments to patients as quickly as possible

DCRI MISSION

To develop and share knowledge that improves the care of patients around the world through innovative clinical research.

Anonymous

“Do not follow where the path may lead. Go instead where there is no path and leave a trail.”

The DCRI has a long history of innovation and trail-blazing. As a result, we can offer many advantages to our clients.

INNOVATIONS

- Computerized medical records (ca. 1966)
- "Large, simple trials"
- Economics and quality-of-life analyses
- Standardized Core Laboratories: Enzymatic, Ischemia Monitoring, ST-segment Monitoring
- Evidence-based medicine
- Global investigative collaborations
- Trial coordination via the World Wide Web
- Strategic alliances with other academic research organizations
- Steering Committee leadership
- Data and Safety Monitoring Board participation

ADVANTAGES

- Commitment to client satisfaction
- Practice-friendly protocol designs
- leadership and consultation
- Scientific and biostatistical expertise
- Sophisticated statistical modeling and data-analysis techniques
- Diverse patient populations around the world (49 countries and counting)
- Access to multiple historical databases
- Computerized clinical event adjudication systems
- Interactive Voice Response System, for 24-hour randomization and consultation services
- "Just-in-time" drug shipments
- Expertise in "getting the word out" through peer-reviewed journals, international scientific sessions, symposia

THE FUTURE

- Maintain our tradition of excellence in cardiovascular research, while expanding even more into other therapeutic and geographic areas
- A "virtual" Coordinating Center for trials
- Training future clinical researchers

Margaret Fuller

“If you have knowledge, let others light their candles at it.”

We believe in sharing our knowledge about research with our clients. We can then tailor our services to match their needs, from project planning to data analysis to presentation. We design and conduct both large, multinational and small clinical trials, and provide outcomes analyses of internal and external databases.

PROJECT MANAGEMENT

- With physician and project leadership, design protocols for main study and any substudies
- Confer with regulatory authorities
- Arrange and conduct investigator and Steering Committee meetings
- Provide 24-hour clinical consultation Hotline

SITE MANAGEMENT

- Identify, recruit, and train sites
- Develop in-service materials
- Prepare site contracts and payments
- Manage and monitor sites
- Close-out sites
- Regulatory audits

CLINICAL SUPPLY PACKAGING AND DISTRIBUTION

- Design, label, and package clinical supplies
- Randomize patients—24-hour manned or IVRS system
- "Just-in-time" drug shipments
- Distribute clinical materials worldwide

DATA MANAGEMENT

- Develop data-collection forms and databases
- Enter, query, and clean data
- Verification of data against source documents
- Process adverse event reports
- Adjudicate clinical events

DATA ANALYSIS

- Prepare interim data and safety reports
- Clean and lock final database
- Analyze and interpret data
- Prepare data and summary tables for regulatory submissions

FOLLOW-UP

- Short-term (3 months, 6 months, 1 year)
- Long-term (up to 29 years)
- Patient locator services
- Patient surveys

COMMUNICATIONS

- Present results at scientific meetings, symposia
- Develop and submit manuscripts for peer-reviewed journals, including our own *American Heart Journal*
- Accompany sponsor to regulatory meetings

John Donne

“No man is an island, entire of itself…”

CLINICAL RESEARCH AREAS

- Cardiology: acute coronary syndromes, arrhythmias, congestive heart failure, devices, primary and secondary prevention
- Endocrinology
- Neurology
- Otolaryngology
- Primary care
- Psychiatry
- Rheumatology

OTHER RESEARCH AREAS

- Cost-effectiveness studies
- Economics analyses
- Quality-of-life analyses
- Outcomes studies
- Decision modeling
- Provider profiling

The DCRI believes that the best research results from building bridges. Over time, we have expanded our research capabilities to 49 countries by developing strategic collaborations with other coordinating centers, academic research organizations, and investigator consortia.

INTERNATIONAL CONSORTIUM

VIGOUR (VIrtual coordinating center for Global collaborative cardiovascUlar Research): the DCRI is proud to be a member of this group, formed in 1995 to perform global clinical trials. Its eight coordinating centers each have decades of experience in the conduct of clinical trials, can provide diverse patient populations worldwide, and offer a most efficient way to address important medical questions. <http://vigour.dcri.duke.edu/>

OTHER AFFILIATED ACADEMIC RESEARCH ORGANIZATIONS

Mayo Clinic Foundation
Rochester, MN

INVESTIGATOR CONSORTIA

DAPPER Duke Alliance for Perioperative Projects, Education, and Research

DART Duke Affiliated Rheumatology Trials

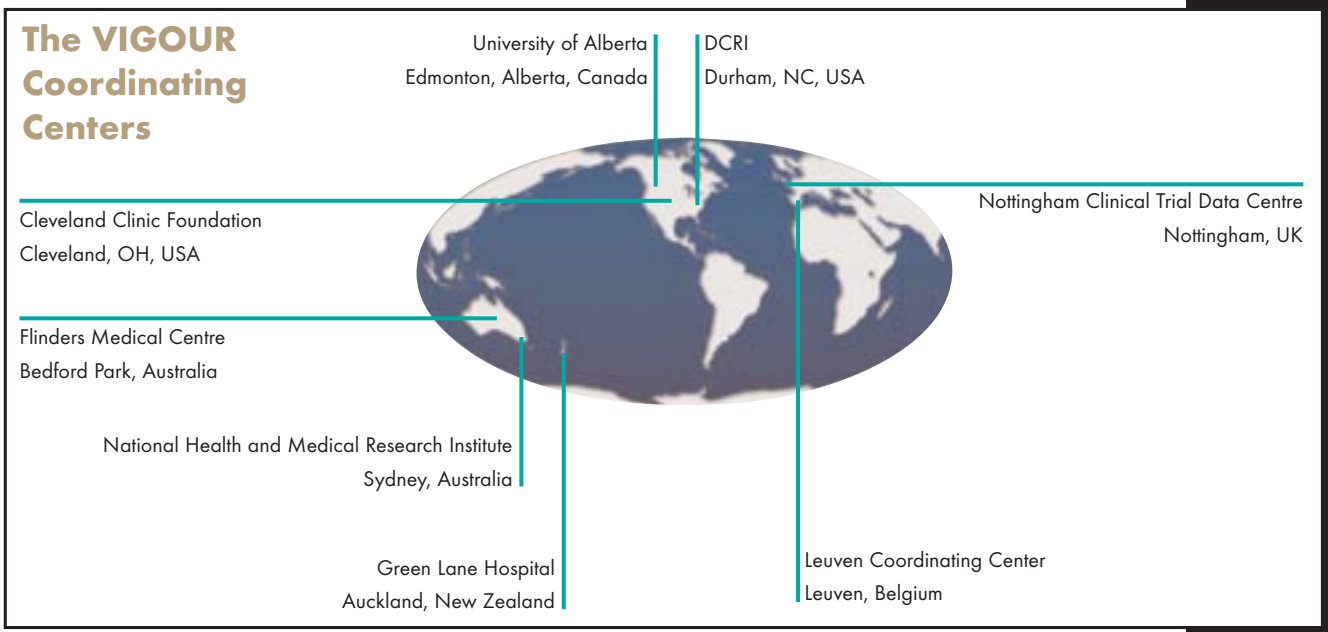
DUCCS Duke University Cooperative Cardiovascular Society
<http://dcl.duke.edu/duccs/>

DUDES Duke University Digestive and Epidemiological Studies

IDRC Infectious Disease Research Consortium

PCRC Primary Care Research Consortium

SOURCE Surgeons' OUtcomes Research CooperativE in Otolaryngology
<http://www.sourcesite.org>



Publius Syrus

"It takes a long time to bring excellence to maturity."

Our largest clinical trial:
41,021 patients enrolled in 15 countries

Our smallest clinical trial:
53 patients enrolled in one hospital

Our longest follow-up:
29 years (Duke Databank for Cardiovascular Disease)

Trials conducted by the DCRI:
28 phase II; **30 phase III**; **8 phase IV**
9 economics and quality-of-life studies
11 device trials and registries

Outcomes grants awarded to the DCRI:
 # private; **# government**

Almost 30 years ago, the **DCRI** began as a research group within Duke University Medical Center. Then, data were collected from the in-hospital care of patients undergoing coronary angiography and entered into a database. These data were then used to improve the care of succeeding patients. Follow-up of patients in this database continues today and is over 99% complete since 1969.

In the mid-1980s, the group began to coordinate clinical trials, using the expertise of its clinicians to help design realistic, well-crafted protocols and the expertise of its biostatisticians to ensure that the data collected could answer the questions posed by the protocols. After coordinating a series of 10 relatively small trials within the U.S., the group took on its first megatrial in 1990. Many multinational trials have followed.

The **DCRI** has expanded steadily over the last 10 years, such that experienced personnel can now perform multiple small and large trials simultaneously, in disciplines beyond cardiology.

Our past accomplishments set a very high standard for our future work, but because of our unique, collaborative organization, we will maintain our history of excellence.

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