

# DCRI TIMELINE/MILESTONES

1967

- Awarded 5-year Myocardial Infarction Research Unit (MIRU) grant from the National Institutes of Health (NIH); goal is to create a computerized record to help care for patients. Alliance formed between physicians, statisticians, and programmers. Group located in the “Tin Hut,” originally the first hyperbaric chamber at Duke.

1968

- Under the direction of Eugene A. Stead, Jr., MD, C. Frank Starmer, MD, and Paul Elliott, first use of computers to capture cardiac patient data
- Five 3-MB hard drives hold the MIDAS and CIRCE systems
- Awarded Specialized Center Of Research (SCOR) grant from NIH

1969

- Bypass surgery info added to patient database. First predictor of mortality in cardiac patients identified (low temperature)

1971

- Cardiac-catheterization data added to patient database, retroactive to 1969

1975

- Under the direction of Edward Hammond, The Medical Record (TMR) created in collaboration with the University of North Carolina at Chapel Hill and IBM

1976

- Duke Databank for Cardiovascular Disease (DDCD) officially created and converted to TMR; Robert A. Rosati, MD named director
- Radionuclide angiogram, treadmill data added to DDCD
- Awarded second SCOR contract from the Agency for Health Care Policy and Research (AHCPR), now the Agency for Healthcare Research and Quality (AHRQ)
- Awarded National Library of Medicine, Robert Wood Johnson grants to train “clinical scholars”

1980

- DDCD group moves to Duke Hospital



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1981

- Treadmill risk score developed; Duke Activity Specific Index (DASI) score developed

1982

- Duke University Digestive and Epidemiological Studies (DUDES) group formed

1983

- Robert M. Califf, MD and David Pryor, MD named clinical research codirectors of the DDCD
- Echocardiographic, angioplasty data added to DDCD
- First calculator for coronary disease risk developed

1984

- Electronic electrocardiogram (eECG) core laboratory created

1985

- First multicenter trial begun (TAMI-1)

1986

- First multicenter trial completed (TAMI-1)

1987

- Duke University Cooperative Cardiology Studies (DUCCS) group formed

1989

- Economics and Quality of Life (EQOL) group formed; Daniel B. Mark, MD, MPH named director

1990

- Virtual coordinating center for Global Collaborative Cardiovascular Research (VIGOUR) created to aid in conduct of multinational trials
- Awarded an Ischemic Heart Disease Patient Outcomes Research Team (IHD-PORT) grant from the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality, AHRQ), team evolves into the Outcomes group



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1992

- Move to Erwin Square

1993

- First international trial completed (GUSTO-I), largest comparative thrombolytic trial in history
- Donald F. Fortin, MD, leads development of the Duke Information System for Clinical Cardiology (DISCC)

1994

- DISCC goes “live”; TMR data converted to DISCC
- EQOL and Outcomes groups merge under leadership of Daniel B. Mark, MD, MPH

1995

- Robert M. Califf, MD named Associate Vice Chancellor for Clinical Research
- First psychiatric trial completed (SADHAT)

1996

- Duke Clinical Research Institute (DCRI) created from the DDCD, Robert M. Califf, MD named Director
- Califf named Editor-in-Chief of the American Heart Journal
- Joint venture with Summit Medical Systems to produce DISCC for practitioners

1997

- DCRI Intranet launched
- Primary Care Research Consortium (PCRC) formed
- Clintrial data-management system implemented
- First genetics trial completed (GeneQuest)
- First neurology trial completed (HALT)



# DCRI TIMELINE/MILESTONES

## 1998

- Move to the North Pavilion, our current headquarters
- Pharmacy spun off to focus on study materials packaging and distribution
- Duke Affiliated Rheumatology Trials (DART) group formed
- First infectious disease trial completed (TFPI-2)

## 1999

- DCRI external website (DCRI.org) launched
- Center for Clinical and Genetic Economics (CCGE) moves to DCRI from Georgetown
- DCRI named data coordinating center for the Society of Thoracic Surgeons (STS) database
- DCRI named coordinating center and site for the Centers for Education Research on Therapeutics (CERTs), funded by AHRQ

## 2000

- American College of Surgeons Oncology Group (ACOSOG) moves headquarters to DCRI from Chicago
- Pharmacy sold and integrated into Clinical Trial Services, Inc. (CTS) and Interactive Clinical Technologies, Inc. (ICTI), which become preferred providers for DCRI
- Become founding member of the Clinical Data Interchange Standards Consortium (CDISC)
- In collaboration with Conceptis, Inc., CyberSessions debut through theheart.org
- First ear/nose/throat study completed (CAFFS)
- First endocrinology trial completed (Frailty)
- First anesthesiology trial completed (Lexipafant)
- First pediatric trial completed (PATH-1)
- First peripheral vascular disease trial completed (TRAFFIC)
- First rheumatology trial completed (IL-10 Methotrexate)



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## 2001

- Named data coordinating center for the Child Traumatic Stress Network, funded by the Substance Abuse and Mental Health Services Administration (SAMHSA)
- Named coordinating center for the North Carolina Node of the drug-abuse Clinical Trials Network (CTN), funded by the National Institute on Drug Abuse (NIDA)
- Perioperative Organ Protection (POP) group formed
- First alternative medicine trial completed (MANTRA-1)
- First reproductive medicine trial completed (OP-SCCP)

## 2002

- *Lessons from a Horse Named Jim*, DCRI's manual on clinical trials, published
- General Perioperative Research Organization (GPRO) formed in collaboration with the International Anesthesia Research Society (IARS)
- International Collaboration on Endocarditis (ICE) group formed
- Duke Image Analysis Laboratory (DIAL) created
- Named coordinating center for the Reproductive Medicine Network (RMN), funded by the National Institute of Child Health and Human Development (NICHD)

## 2003

- Duke Cardiomics Network (DCN) (link) founded
- Alliance formed with Phase Forward, Inc. for enhanced electronic data capture (EDC)
- Named coordinating center of the Child and Adolescent Psychiatry Network (CAPTN) by the National Institute of Mental Health (NIMH)
- Named editorial office for the Journal of Alternative and Complementary Medicine



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2004

- Robert M. Califf, MD receives American College of Cardiology's Distinguished Scientist Award for clinical research
- "Keys to Building a Successful Research Site" training kit developed
- The Duke Clinical Medicine Series launched the Cardiac Cath Lab Conference, followed the next year with 5 new conferences: Acute Coronary Syndromes, Endocrinology, Heart Failure, Gastroenterology, Nephrology

2005

- Clinical Trials Network Best Practices (CTNBP) website launched

2006

- Duke won NIH Clinical and Translational Science Award grant and launched the Duke Translational Medicine Institute (DTMI) led by Robert Califf, MD
- Robert Harrington, MD, appointed director of the DCRI
- The DCRI awarded the Heart Failure Network Data Coordinating Center grant

2008

- The DCRI selected as 1 of 3 American Heart Association Outcomes Research Centers in the United States

2009

- Celebrated the 40th anniversary of the founding of the Duke Databank for Cardiovascular Diseases, the precursor to the DCRI

2010

- PLATO makes AHA's Top 10 list of most important research for 2009
- The DCRI's Danny Benjamin, MD, PhD, receives \$95m NIH grant over 7 years for the Pediatric Trials Network



# DCRI TIMELINE/MILESTONES

## 2011

- NICHD approves \$1m grant to develop UNC-Duke clinical pharmacology post-doc training program
- The Pediatric Trials Network enrolls its first patient in its first trial, a study of the drug metronidazole.
- ARISTOTLE results: Apixaban safer and more effective than warfarin August 31, 2011
- Using social media to provide an interactive approach to covering the ACC March 25, 2011
- New study finds high rate of patients receiving a defibrillator against evidence-based guidelines

## 2012

- Eric Peterson, MD, MPH, becomes the DCRI's third director since its inception
- The DCRI and Duke Translational Research Institute awarded \$6.4 million grant to develop and support the Lung Repair and Regeneration Consortium
- The DCRI awarded a \$9 million grant to serve as the coordinating center for the NIH's Health Care Systems Research Collaboratory
- The DCRI begins a clinical immunization safety assessment that has a potential contract value of up to \$50 million over 10 years.
- Duke and NHLBI launch trial of strategies for assessment of stable patients with symptoms of coronary artery disease
- The DCRI awarded a \$9 million grant to serve as the coordinating center for the NIH's Health Care Systems Research Collaboratory.



# DCRI TIMELINE/MILESTONES

## 2013

- DCRI launches new education program that allows high school students and undergraduates to explore careers in clinical research
- DCRI wins another 5 years as coordinating center for DILIN
- The Patient-Centered Outcomes Research Institute (PCORI) Board of Governors has selected a consortium with Robert Califf as co-principal investigator to serve as the Coordinating Center for a major new national clinical research network
- SAFE-PCI, a trial of many “firsts,” announces database lock, paving the way for the future of clinical trials.
- The NIH awards a \$6 million grant to the DCRI’s Vance Fowler, MD, MHS, to form a national leadership group focused on antibacterial resistance. ARLG research network will target the problem of antibacterial resistance
- PCORI awards funds to Laura Schanberg, MD, for new research network
- Robert Califf named co-principal investigator of Coordinating Center for new national clinical research network

## 2014

- New statistical framework devised by DCRI investigators and colleagues allows researchers to better analyze rare genetic variation.
- The DCRI, with Boehringer Ingelheim Pharmaceuticals, Inc., launched a patient registry to help researchers and clinicians identify, manage and study people who have a progressive lung disease called idiopathic pulmonary fibrosis. The registry is the first multi-center registry in the United States focused specifically on idiopathic pulmonary fibrosis.
- The National Heart, Lung, and Blood Institute announces that the DCRI, in conjunction with RTI International, will serve as data coordinating center for the Molecular Atlas of Lung Development Program (LungMAP).
- DCRI research findings lead to new guidelines for statin use.
- DCRI research points to new recommendations to relax blood pressure medication guidelines for millions of patients.





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## 2015

- The National Institute of Allergy and Infectious Diseases (NIAID) announces that the DCRI will become one of three national sites to run early clinical trials of new anti-infection therapies. The DCRI could launch and manage up to four early-phase clinical trials a year, and potentially receive \$90 million over the life of the 10-year contract.
- Robert Califf named as deputy FDA commissioner.
- A DCRI study finds that almost one quarter of thyroid cancer patients receive unnecessary treatment.
- Kristin Newby, MD, MHS, named principal investigator for MURDOCK Study.
- DCRI researchers find that results from most clinical trials of medical products are not reported to ClinicalTrials.gov, despite legal requirements to do so. The Duke University School of Medicine, which includes the DCRI, has achieved 100 percent compliance with the reporting requirements for the last three quarters.
- The DCRI announces the launch of the Center for Community and Population Health Improvement under the direction of Ebony Boulware, MD, MPH.
- A 2011 study conducted by Daniel Benjamin, Jr., MD, MPH, PhD, and other DCRI researchers results in the FDA relabeling the antibiotic meropenem.
- The DCRI is awarded the first PCORnet demonstration study to determine the best aspirin dose to protect patients with heart disease (ADAPTABLE).
- CTTI receives 2015 DIA Regional Inspire Award for the Americas.
- DCRI faculty members, including Michael Pencina, PhD, and Adrian Hernandez, MD, MHS, are named as editors of a new journal, JAMA Cardiology.
- The DCRI's Laura Schanberg, MD, Kevin Thomas, MD, and Ebony Boulware, MD, MPH, are approved for a funding award by the Patient-Centered Outcomes Research Institute (PCORI).
- The DCRI's Evan Myers, MD, MPH, contributes to the development of the American Cancer Society's new breast cancer screening guidelines.
- Robert Califf nominated to be FDA commissioner.



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## 2016

- DCRI was named the coordinating center as part of a \$157-million federal initiative involved in studying how environmental factors affect childhood health.
- Researchers at DCRI received a seven-year, \$26.5 million grant to create a Trial Innovation Center with Vanderbilt University Medical Center to study how multisite clinical trials of new drugs and therapies in children and adults can be conducted more rapidly and efficiently.
- The National Institute of Neurological Disorders and Stroke, part of the National Institutes of Health, awarded a 10-year contract to Duke to design, manage, and conduct Phase I clinical trials to treat neurological conditions such as Alzheimer's disease and neuropathy. The trials will be conducted at the DCRI's Early Phase unit.
- The Idiopathic Pulmonary Fibrosis – PROspective Outcomes (IPF-PRO) Registry, developed to uncover insights into a rare and serious lung disease, announced an increase in study enrollment from 300 patients at 18 study sites to 1,500 patients at approximately 45 sites, creating the largest registry of newly diagnosed IPF patients.
- A new collaboration gave more researchers access to the largest and oldest cardiovascular database in the world. The DCRI and analytics leader SAS will provide researchers worldwide with data management and analytics tools to explore 45 years of cardiovascular patient data collected by the Duke University Health System. The data set is part of the Duke Databank for Cardiovascular Disease (DDCD).

## 2017

- Former FDA commissioner Robert Califf returns to Duke as Vice Chancellor for Health Data Science for Duke Health and senior advisor to the DCRI.
- The DCRI breaks ground on its new office buildings on Morris Street, in the heart of the Downtown Durham Innovation District.
- The DCRI expands the IPF-PRO Registry to more than 1,500 patients at approximately 45 sites, making it the largest IPF registry in the world.
- The DCRI-led IMPROVE Stroke Care program begins utilizing novel data-capture technology and a network of stroke centers and hospitals to collect clinic performance metrics.
- The Project Baseline study, a partnership between DCRI, Stanford Medicine and Verily Life Sciences, launches to expand the understanding of the journey from health to disease in 10,000 participants.
- The DCRI study Care Optimization through participant and Hospital Engagement Clinical Trial for Heart Failure (CONNECT-HR) becomes the largest quality improvement trial in heart-failure research.

