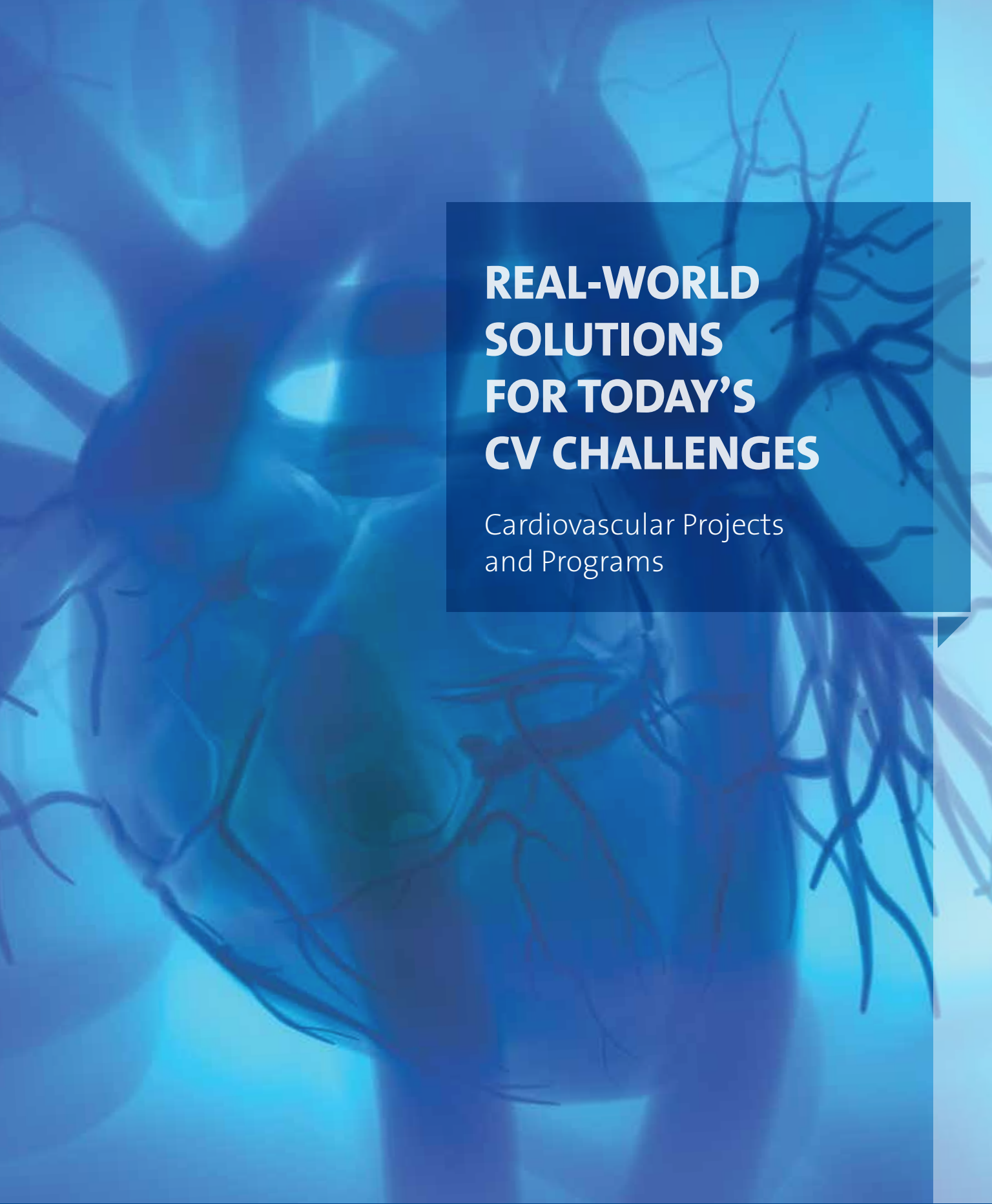


REAL-WORLD SOLUTIONS FOR TODAY'S CV CHALLENGES

Cardiovascular Projects and Programs

Duke Clinical Research Institute | FROM **THOUGHT LEADERSHIP** TO **CLINICAL PRACTICE**

OUR MISSION

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

Collaborating to Improve Patient Care

The Duke Clinical Research Institute is the world's leading academic research organization conducting cardiovascular clinical research and implementation science, and educating the next generation of clinical researchers. The DCRI is dedicated to streamlining and advancing the clinical research process through innovative study design, fit-for-purpose approaches, thoughtful analytics, and a commitment to rapid knowledge dissemination—all helping to improve patient care.

Our world-renowned faculty and operational expertise span the spectrum of cardiovascular disease. And our research experience covers all phases of evaluation, from proof-of-concept studies and multinational late-phase trials, to post-approval registries, outcomes, and real-world quality improvement initiatives. We have robust research and educational programs in acute coronary syndromes, chronic coronary artery disease, prevention, cardiac surgery, electrophysiology, heart failure care, interventional cardiology, peripheral vascular disease, cardiorenal, metabolic syndrome, and stroke.

This is an exciting time for investigators and participants in clinical research. Now more than ever, building rich and sustainable relationships with our partners and sponsors is essential to leverage new opportunities in randomized registry trials, electronic health record-based clinical trials, and direct-to-patient clinical research. By working side by side, our collective efforts will improve the care of patients with cardiovascular disease.

We welcome the opportunity to work with you and explore innovative treatment interventions and real-world observational research studies.

John H. Alexander, MD, MHS, FACC, FAHA
Director, CV Research, Duke Clinical Research Institute
Professor of Medicine, Cardiology
Vice Chief for Clinical Research, Cardiology

Eric D. Peterson, MD, MPH, FACC, FAHA
Executive Director, Duke Clinical Research Institute
Professor of Medicine, Cardiology
Fred Cobb, MD, Distinguished Professor of Medicine

Duke Cardiovascular and Clinical Pharmacology Faculty

Dennis Abraham, Assistant Professor
John Alexander, Professor
Karen Alexander, Professor
Sana Al-Khatib, Associate Professor
Monique Anderson, Assistant Professor
Brett Atwater, Assistant Professor
Tristram Bahnson, Professor
Thomas Bashore, Professor
Michael Blazing, Associate Professor
Gerald Bloomfield, Assistant Professor
J. (James) Matthew Brennan, Assistant Professor
Bruce Kendall Burnett, Assistant Professor
Patricia Cowper, Associate Professor
Lawrence Crawford, Assistant Professor
Anna Lisa Crowley, Assistant Professor
James Daubert, Professor
Melissa Daubert, Assistant Professor
Scott Denardo, Assistant Professor
Adam DeVore, Medical Instructor
Tracy DeWald, Assistant Consulting Professor
Mark Donahue, Assistant Professor
Timothy Donahue, Assistant Professor
Pamela Douglas, Distinguished Professor
Zubin Eapen, Associate Professor
Melvin Echols, Assistant Professor
Eric Eisenstein, Associate Professor
Robert Everhart, Assistant Professor
Camille Fazier-Mills, Assistant Professor
G. Michael Felker, Professor
Terry Fortin, Assistant Professor
Neil Freedman, Associate Professor
Thomas Gehrig, Assistant Professor
Geoffrey Ginsburg, Professor
Christopher Granger, Professor
Gus Grant, Professor
Joseph Greenfield, Distinguished Professor
Michael Dee Gunn, Associate Professor
Kevin Harrison, Professor
Robert Harrison, Assistant Professor
Alycia Hassett, Assistant Professor
Donald Hegland, Assistant Professor
Elizabeth Henke, Assistant Professor
Adrian Hernandez, Professor
Kevin Hill, Assistant Professor
Kevin Jackson, Assistant Professor
Larry Jackson, Medical Instructor
John Steward Jones, Assistant Professor
Schuyler Jones, Assistant Professor
Robert Judd, Professor
Radha Kachhy, Assistant Professor
Ravi Karra, Assistant Professor
Michel Khouri, Assistant Professor
Todd Kiefer, Assistant Professor
Han Kim, Assistant Professor
Ray Kim, Professor
Joseph Kisslo, Professor
Igor Klem, Assistant Professor
Michael Komada, Assistant Professor
David Kong, Associate Professor
Chris Kontos, Associate Professor
Jason Koontz, Assistant Professor
Judith Kramer, Professor Emeritus
William Kraus, Professor
Mitchell Krucoff, Professor
Nancy Allen LaPointe, Associate Professor
Robert Lefkowitz, Distinguished Professor
Mark Leithe, Assistant Professor
Lawrence Liao, Assistant Professor
Barbara Lipes, Assistant Professor
Renato Lopes, Professor
Lan Mao, Assistant Professor
Daniel (Dan) Mark, Professor
Robin Mathews, Assistant Professor
Rajendra Mehta, Consulting Professor
Robert McGarrah, Medical Instructor
Chiara Melloni, Assistant Professor
Robert Mentz, Assistant Professor
James Mills, Assistant Professor
Eric Moore, Assistant Professor
Ken Morris, Associate Professor
Martin Moseley, Associate Professor
Ann Marie Navar, Assistant Professor
L. Kristin Newby, Professor
Robert Noveck, Associate Professor
Emily O'Brien, Assistant Professor
E. Magnus Ohman, Professor
Chetan (Chet) Patel, Assistant Professor
Mahesh Patel, Assistant Professor
Manesh Patel, Associate Professor
Eric Peterson, Distinguished Professor
James Peterson, Assistant Professor
Harry Phillips, Professor
Jonathan Piccini, Associate Professor
Thomas Povsic, Associate Professor
Sudarshan Rajagopal, Assistant Professor
Sunil Rao, Associate Professor
Maria Rapoza, Assistant Professor
Stephen Robinson, Assistant Professor
Howard Rockman, Distinguished Professor
Matthew Roe, Professor
Joseph Rogers, Professor
Paul Rosenberg, Associate Professor
Zainab Samad, Associate Professor
Gillian Sanders-Schmidler, Professor
Douglas Schocken, Professor
Svati Shah, Associate Professor
Sudah Shenoy, Associate Professor
Sydney Short, Assistant Professor
Michael Sketch, Professor
Chris Slentz, Assistant Professor
Jonathan Stiber, Assistant Professor
Albert Sun, Assistant Professor
James Tcheng, Professor
Kevin Thomas, Associate Professor
Pierluigi Tricoci, Associate Professor
Eric Velazquez, Professor
Sreekanth Vemulapalli, Medical Instructor
Deepak Voora, Assistant Professor
Christopher Walters, Assistant Professor
Andrew Wang, Professor
Tracy (Yu-Ping) Wang, Associate Professor
Cary Ward, Associate Professor
David Whellan, Assistant Consulting Professor
Ying Xian, Assistant Professor
William Yancy Jr., Associate Professor

DUKE CARDIOVASCULAR: AT A GLANCE

Our Mission

To develop and share knowledge that improves the care of patients in all areas of cardiovascular clinical research by advancing innovation and excellence in thought leadership and operations, driving national and global policy, fostering a global community of collaborative clinical researchers, and training future investigators.

Our Vision

To be the most influential cardiovascular clinical research organization in the world.

What we offer

- Thought leadership in Phase I–IV clinical and outcomes research
- Breadth and depth of investigator network
- Rapid recruitment of the right patients into the right study
- Prompt and effective dissemination of evidence into practice
- Improved quality in care
- Management of multiple national registries
- Streamlined site start-up process

DCRI Cardiovascular Trials Attributes

Faculty Thought Leadership

- Practicing specialty physicians apply their clinical experience to design realistic protocols, and train and support investigator sites

Patient- and Site-Focused

- The patient and the site are at the center of what we do
- Collaborative relationships with the sites are essential to success

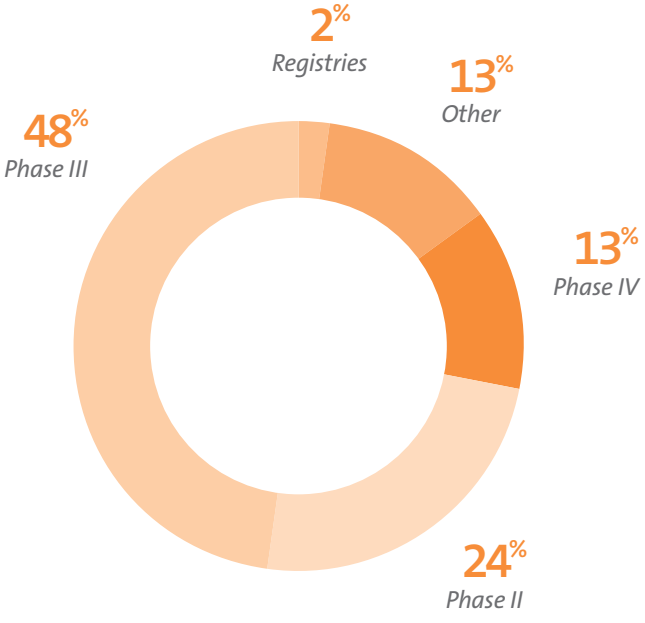
Emphasis on Quality and Integrity of Trial Conduct

- Adherence to Guiding Principles
- Data-driven operations

Streamlined and Efficient

- Trial integrated with standard-of-care clinical practice
- Efficient processes for trial conduct

Cardiovascular Trials Experience by Phase and Size



Trials and Outcomes Projects

Acute Coronary Syndromes

AEGIS_I
A Phase IIb Study of CSL112 in Subjects with Acute Myocardial Infarction
Phase IIb, multicenter, randomized, placebo-controlled, dose-ranging study to investigate the safety and tolerability of multiple-dose administration of CSL112 in subjects with acute myocardial infarction.
Sites: 50; Anticipated Enrollment: 1,200
PI: Pierluigi Tricoci, MD

ODYSSEY Outcomes
Evaluation of Cardiovascular Outcomes After an Acute Coronary Syndrome During Treatment with Alirocumab SAR236553 (REGN727)
Phase III, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effect of alirocumab (SAR236553/REGN727) on the occurrence of cardiovascular events in patients who have experienced an acute coronary syndrome event 4 to 52 weeks prior to randomization and are treated with evidence-based medical and dietary management of dyslipidemia.
Enrollment is completed.
PI: Matthew Roe, MD

RENEW
Efficacy and Safety of Targeted Intramyocardial Delivery of Auto CD34+ Stem Cells for Improving Exercise Capacity in Subjects with Refractory Angina
Prospective, randomized, double-blind study to assess the safety and efficacy of targeted intramyocardial delivery of autologous CD34+ cells for increasing exercise time and amelioration of anginal symptoms in subjects with refractory angina and chronic myocardial ischemia.
Sites: 41; Enrollment is completed.
PI: Thomas Povsic, MD

SOLSTICE
Study of Losmapimod Treatment on Inflammation and Infarct Size
Phase II, randomized, double-blind, placebo-controlled study to evaluate the safety of 12 weeks of dosing with GW856553 and the effects on troponin, CK-MB, inflammatory markers, and infarct size in subjects with myocardial infarction without ST-segment elevation.
Sites: 83; Enrollment is completed. Manuscripts are in process.
PIs: Christopher Granger, MD, and L. Kristen Newby, MD, MHS

Acute Stroke

SOCRATES
Acute Stroke or Transient Ischaemic Attack Treated With Aspirin or Ticagrelor and Patient Outcomes
Randomized double-blind multinational study to prevent major vascular events with ticagrelor compared to acetylsalicylic acid (aspirin) in patients with acute ischemic stroke or transient ischaemic attack.
Trial is completed and results have been presented.
PI: Daniel Laskowitz, MD

Chronic Coronary Artery Disease, Peripheral Vascular Disease, and Diabetes

ADAPTABLE
Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term
Pragmatic, randomized study to compare the effectiveness of two daily doses of aspirin (81 mg and 325 mg) in reducing a composite endpoint of all-cause death, hospitalization for nonfatal MI, or hospitalization for nonfatal stroke in high-risk patients with a history of MI or documented atherosclerotic cardiovascular disease (ASCVD).
CDRNs: 8; Sites: 35; Anticipated Enrollment: 20,000
PI: Matthew Roe, MD

ARTEMIS
Affordability and Real-World Antiplatelet Treatment Effectiveness after Myocardial Infarction Study
Prospective, cluster-randomized clinical trial that will evaluate whether patient copayment reduction significantly influences antiplatelet therapy selection and long-term adherence, as well as patient outcomes and overall cost of care after acute myocardial infarction. The purpose of this study is to learn more about how patients take antiplatelet medication after hospital discharge, and how this influences patients' long-term health and use of healthcare resources.
Enrollment is completed.
PI: Tracy Wang, MD, MHS, MSc

AUGUSTUS

Apixaban to Vitamin K Antagonist for the Prevention of Stroke or Systemic Embolism and Bleeding in Patients With Non-valvular Atrial Fibrillation and Acute Coronary Syndrome/Percutaneous Coronary Intervention

Open-label, 2 x 2 factorial, randomized, controlled clinical trial to evaluate the safety of apixaban vs. vitamin K antagonist and aspirin vs. aspirin placebo in patients with atrial fibrillation and acute coronary syndrome and/or percutaneous coronary intervention.
Sites: ~690 (North America, Latin America, Europe and Asia);
Anticipated Enrollment: 4,600
PI: Renato Lopes, MD, PhD

CARE-HEP C

Longitudinal Assessment of Cardiovascular and Renal Health in Patients With Hepatitis-C

Observational patient registry to monitor the cardiovascular and renal health of patients who previously took BMS-986094 (an investigational medication for hepatitis C) in comparison to patients with hepatitis C who have never taken BMS-986094.
Sites: 16; Anticipated Enrollment: 120
PI: Adrian Hernandez, MD

EUCLID

Examining Use of Ticagrelor in Peripheral Artery Disease

Randomized, double-blind, parallel-group, multicenter phase IIIb study to compare ticagrelor to clopidogrel treatment for the prevention of death and major cardiovascular events in patients with established peripheral artery disease.
Enrollment is completed. Results to be presented at AHA 2016.
PI: Manesh Patel, MD

EXSCEL

Exenatide Study of Cardiovascular Event Lowering Trial

Phase IIIb/IV, randomized, placebo-controlled trial to evaluate cardiovascular outcomes after treatment with exenatide once weekly in patients with type 2 diabetes mellitus.
Enrollment is completed.
PI: Adrian Hernandez, MD

HARMONY Outcomes

Evaluating the Effect of Albiglutide, When Added to Standard Blood Glucose Lowering Therapies, on Major Cardiovascular Events

A long-term, randomized, double-blind, placebo-controlled study to determine the effect of albiglutide, when added to standard blood glucose-lowering therapies, on major cardiovascular events in patients with type 2 diabetes mellitus.
Sites: 647, Anticipated Enrollment 9,400
PI: Adrian Hernandez, MD

ISCHEMIA

International Study of Comparative Health Effectiveness with Medical and Invasive Approaches

Phase IV, international, randomized controlled trial comparing the effectiveness of two initial management strategies—invasive versus conservative—for stable patients with moderate to severe ischemia on nuclear, echocardiographic, or cardiac MRI stress testing.
Sites: 350; Anticipated Enrollment: 5,000
PIs: Sean O'Brien, PhD; Karen Alexander, MD

Efficacy of LCQ908 on Cardiovascular Risk

Randomized, double-blind, placebo-controlled study designed to evaluate the potential for LCQ908 to impact cardiovascular risk.
Sites: 3; Anticipated Enrollment: 52
PI: Michael Blazing

LEVO-CTS

Levosimendan in Patients with Left Ventricular Systolic Dysfunction Undergoing Cardiac Surgery on Cardiopulmonary Bypass

Phase III, double-blind, randomized, placebo-controlled study to evaluate levosimendan compared with placebo in reducing the composite event rate of all-cause death, perioperative myocardial infarction, need for new dialysis, or use of mechanical assist (intra-aortic balloon pump or left ventricular assist device) in subjects with reduced ejection fraction undergoing cardiac surgery on cardiopulmonary bypass.
Sites: 127; Anticipated Enrollment: 760
PIs: Raj Mehta, MD, and John Alexander, MD, MHS

TACT-2

The Trial to Assess Chelation Therapy 2

Randomized, double-blind, placebo-controlled trial to test the effects of an EDTA-based chelation infusion plus high doses of oral multivitamin and minerals in post-MI diabetic patients.
Sites: 100 Anticipated Enrollment: 1,200
PIs: Kevin Anstrom, PhD; Daniel Mark, MD (DCRI);
Gervasio A. Lamas, MD (Columbia University)

Trials and Outcomes Projects (cont.)

Electrophysiology

ARTESIA
Apixaban for the Reduction of Thrombo-Embolism in Patients with Device-Detected Sub-Clinical Atrial Fibrillation
Sites: 20, Anticipated Enrollment: 800
PIs: Christopher Granger, MD, and Renato Lopes, MD, PhD

CABANA
Catheter Ablation Versus Antiarrhythmic Drug Therapy for Atrial Fibrillation
Multicenter, prospective, randomized, open-label study to determine whether the treatment strategy of percutaneous left atrial catheter ablation to eliminate atrial fibrillation is superior to current state-of-the-art drug therapy.
Sites: 160; Anticipated Enrollment: 2,200
PI: Kerry Lee, PhD

GENETIC-AF
Genetically Targeted Therapy for the Prevention of Symptomatic Atrial Fibrillation in Patients With Heart Failure
A genotype-directed comparative effectiveness trial of bucindolol and metoprolol succinate (Toprol-XL) for the prevention of symptomatic atrial fibrillation/atrial flutter in patients with heart failure.
Sites: 75; Anticipated Enrollment: 200
PI: Jonathan Piccini, MD

Heart Failure

CONNECT-HF
Care Optimization through Patient and Hospital Engagement Clinical Trial for Heart Failure
Large-scale, pragmatic, cluster-randomized clinical trial to evaluate the effect of two quality-improvement initiatives compared to usual care on heart failure outcomes and HF quality-of-care metrics at 1 year after discharge for patients hospitalized with acute HF and reduced ejection fraction.
Sites: 160; Anticipated Enrollment: 8,000
PI: Adam DeVore, MD, MHS

Heart Failure Network: ATHENA
Aldosterone Targeted Neurohormonal Combined with Natriuresis Therapy in Heart Failure
Randomized, double blind, placebo-controlled study of high-dose spironolactone vs. placebo (for patients not receiving MRA at home) or low-dose spironolactone (for patients already receiving low-dose spironolactone) in AHF.
Trial is completed. Results to be presented at AHA 2016.
PIs: Adrian Hernandez, MD, and Kevin Anstrom, PhD (DCRI); Javed Butler, MD (Stony Brook University Medical Center)

Heart Failure Network: FIGHT
Functional Impact of GLP-1 for Heart Failure Treatment
Phase II randomized, double-blind, placebo-controlled to test the hypothesis that therapy with a subcutaneous GLP-1 agonist in the post-acute heart failure syndrome discharge period will be associated with greater clinical stability at 6 months as assessed by a composite clinical endpoint.
Enrollment is completed.
PIs: Adrian Hernandez, MD, and Kevin Anstrom, PhD (DCRI); Kenneth Marguiles, MD, and Thomas Cappola, MD (University of Pennsylvania Health System)

Heart Failure Network: INDIE-HFpEF
Inorganic Nitrite Delivery to Improve Exercise Capacity in HFpEF
Randomized, double-blind, placebo-controlled crossover study to evaluate whether inhaled, nebulized inorganic sodium nitrite, as compared to placebo, improves maximal exercise capacity as assessed by cardiopulmonary exercise testing performed at peak drug levels.
Sites: 20; Anticipated Enrollment: 100
PIs: Adrian Hernandez, MD, and Kevin Anstrom, PhD (DCRI); Barry Borlaug, MD (Mayo Clinic)

Heart Failure Network: IRONOUT
Oral Iron Repletion Effects On Oxygen Uptake in Heart Failure
Multicenter, randomized, double-blind, placebo-controlled study to determine if oral iron polysaccharide is superior to oral placebo in improving functional capacity as measured by change in peak VO2 by cardiopulmonary exercise testing, of a broad population of patients with heart failure exercise testing and iron deficiency at 16 weeks.
Enrollment is completed. Results to be presented at AHA 2016.
PIs: Adrian Hernandez, MD, and Kevin Anstrom, PhD (DCRI); Greg Lewis, MD (Massachusetts General Hospital)

Heart Failure Network: HFN-LIFE
Entresto™ (LCZ696) in Advanced Heart Failure
Randomized, double-blind trial of advanced heart failure subjects with 1:1 randomization to either LCZ696 (sacubitril and valsartan) or valsartan.
Sites: 40; Anticipated Enrollment: 400
PIs: Kevin Anstrom, PhD (DCRI); Doug Mann, MD (Washington University)

Heart Failure Network: HFN-HIV
Characterizing HIV-related Diastolic Dysfunction
Multicenter, cross-sectional study to study the determinants, mechanisms, and consequences of diastolic dysfunction in HIV-infected individuals.
Sites: 12; Anticipated Enrollment: 200
PIs: Adrian Hernandez, MD and Kevin Anstrom, PhD (DCRI); Javed Butler, MD (Stony Brook University)

Heart Failure Network: HFN-SUBQ Pilot
Subcutaneous Furosemide in Acute Decompensated Heart Failure
Multicenter, open-label pilot study to evaluate the safety and feasibility of subcutaneous delivery of furosemide
Sites: 5; Anticipated Enrollment: 40
PIs: Adrian Hernandez, MD, Kevin Anstrom, PhD, and Michael Felker, MD

OCEAN
Omega-3 for Co-Morbid Depression and Heart Failure Treatment
Multisite phase II, proof-of-concept pilot trial to assess the impact and mechanisms of omega-3 supplementation on moderate to severe major depressive disorder (MDD), when added to the usual care of adult patients with chronic heart failure and MDD.
Sites: 3; Anticipated Enrollment: 108
PI: Wei Jiang, MD

PAL-HF
Palliative Care in Heart Failure
Prospective, controlled, unblinded, two-arm, single-center phase III trial for patients with advanced heart failure randomized to usual state of the art heart failure care or usual care combined with an interdisciplinary palliative care intervention.
Sites: 1; Enrollment is completed.
PIs: Joseph Rogers, MD, and James Tulsky, MD

PIONEER-HF
Comparison of Sacubitril/Valsartan versus Enalapril on Effect on ntpRo-bnp in Patients Stabilized from an Acute Heart Failure Episode
Multicenter, randomized, double-blind, double-dummy, parallel-group, active-controlled 8-week study to evaluate the effect of sacubitril and valsartan (LCZ696) versus enalapril on changes in NT-proBNP and safety and tolerability of in-hospital initiation of LCZ696 compared to enalapril in HFrEF patients who have been stabilized following hospitalization for acute decompensated heart failure (ADHF).
Sites: 120; Anticipated Enrollment: 730
PI: Eric Velazquez, MD

SPIHF 101
A Study Investigating the Safety, Tolerability, and Pharmacokinetics of MTP-131 in Subjects With Congestive Heart Failure
Phase 1, single-center, randomized, double-blind, single-ascending dose, placebo-controlled study in subjects aged 45-80 years with stable mild to moderate heart failure due to left ventricular systolic dysfunction, to evaluate the safety, tolerability, and pharmacokinetics of escalating single intravenous infusion doses of Bendavia™ (MTP-131).
Sites: 1 (Eastern Europe); Enrollment is completed.
PI: Melissa Daubert, MD

TACTICS-HF
Targeting Acute Congestion with Tolvaptan in Congestive Heart Failure
Phase III study to compare the effects of oral tolvaptan versus placebo as an adjunct to fixed dose intravenous furosemide on dyspnea relief, renal function, and changes in clinical status in patients hospitalized with acute decompensated heart failure. Enrollment is completed. Results to be presented at HFSA 2016.
PI: G. Michael Felker, MD

TARGET-HFDM
Technology to improve drug Adherence and Reinforce Guideline-based Exercise Targets in patients with Heart Failure and Diabetes Mellitus
Multicenter randomized controlled clinical trial in eligible subjects with heart failure and diabetes mellitus to measure activity levels and medication adherence via mHealth intervention.
Sites: 3–5; Anticipated Enrollment: 200
PI: G. Michael Felker, MD

VIVID
Educational Videos to Address Racial Disparities in Implantable Cardioverter Defibrillator Therapy via Innovative Designs
Sites: 12, Anticipated Enrollment: 480
PI: Kevin Thomas, MD

Trials and Outcomes Projects (cont.)

Imaging

PROMISE
Prospective Multicenter Imaging Study for Evaluation of Chest Pain
To determine whether an initial noninvasive anatomic imaging strategy with coronary computed tomographic angiography will improve clinical outcomes in subjects with symptoms suggestive of coronary artery disease relative to an initial functional testing strategy.
Sites: 213; Enrollment is completed.
PI: Pamela Douglas, MD

Interventional and Cardiovascular Devices

CAT-HF
Cardiovascular Improvements with Minute Ventilation-targeted ASV Therapy in Heart Failure
Randomized, unblinded, multicenter trial with parallel-group design, with subjects randomized 1:1 to control (optimized medical therapy for chronic heart failure) or active treatment (optimized medical therapy plus use of minute ventilation-targeted adaptive servo-ventilation).
Sites: 15; Anticipated Enrollment: 215. Enrollment is completed.
PI: Christopher O'Connor, MD, and Robert Mentz, MD

COAST
Coronary Orbital Atherectomy System Study
To utilize and gain approval in commercializing the micro crown (Diamondback 360®) as part of the Coronary Orbital Atherectomy system.
Sites: 20; Anticipated Enrollment: 100. Enrollment is completed.
PIs: David Kong, MD, and Mitchell Krucoff, MD

HARMONEE
Japan-USA Harmonized Assessment by Randomized, Multi-Center Study of OrbusNeich's Combo Stent
Assessment of a novel drug-eluting stent platform for percutaneous coronary revascularization in patients with ischemic coronary disease and non-ST-segment elevation myocardial infarction acute coronary syndrome. Site recruitment is closed. Enrollment is ongoing in Japan. Enrollment in the United States is expected to begin in late fall 2014.
Sites: 50; Enrollment is completed, but follow-up is ongoing.
PIs: David Kong, MD, and Mitchell Krucoff, MD

MITRAL
Mitral Implantation of Transcatheter Valves
Trial to establish the safety and feasibility of the Edwards SAPIEN XT™ and SAPIEN 3™ device and delivery systems in patients with severe symptomatic calcific mitral valve disease with severe mitral annular calcification who are not candidates for standard mitral valve surgery.
Sites: 8 (North America); Anticipated Enrollment: 90
PI: Pamela Douglas, MD

PARTNER
Placement of Aortic Transcatheter Valves Trial
Prospective, randomized-controlled, multicenter pivotal trial evaluating the safety and effectiveness of the Edwards SAPIEN™ Transcatheter Heart Valve and delivery systems, via transfemoral and transapical delivery, in a stratified population of high-risk patients with severe aortic stenosis.
Sites: 23 (North America); Enrollment is completed.
PI: Pamela Douglas, MD

PRESERVATION 1
IK-5001 for the Prevention of Remodeling of the Ventricle and Congestive Heart Failure After Acute Myocardial Infarction
Placebo-controlled, multicenter, randomized, double-blind trial to evaluate the safety and effectiveness of IK-5001 for the prevention of remodeling of the ventricle and congestive heart failure after acute myocardial infarction.
Sites: 85 (9 countries); Enrollment is completed.
PIs: Hussein al-Khalidi, PhD, Pamela Douglas, MD, Mitchell Krucoff, MD, and Sunil Rao, MD

SAFE STEMI for Seniors
Study of Access Site for Enhancing PCI in STEMI for Seniors
Multicenter, randomized, open-label, unblinded, active and historical-controlled trial in which approximately 1,100 seniors undergoing urgent PCI will be enrolled.
Sites: 70; Anticipated Enrollment: 1,100
PI: David F. Kong, MD

STICH(ES)
Surgical Treatment for Ischemic Heart Failure (STICH): The STICH Extension Study
A 5-year extension of the STICH comparative effectiveness trial designed to provide an average of 10 years of long-term follow-up for patients randomized 1:1 to CABG plus medication or medication alone.
Sites: 66; Enrollment completed with extended follow-up for 750 subjects.
PI: Eric Velazquez, MD

Clinical Event Adjudication Projects

ACHAOGEN, INC., ACHN-490-007
Phase III multicenter, randomized, open-label study to evaluate the efficacy and safety of plazomicin compared with colistin in patients with infection due to carbapenem-resistant enterobacteriaceae (CRE).
Patients to Enroll: 142; Events to Adjudicate: 142

AMG 20 - 337
Multicenter, international, randomized, double-blind, placebo-controlled, parallel-group study to assess the efficacy and safety of AMG 785 (alendronate) treatment in postmenopausal women with osteoporosis.
Patients Enrolled: 5,600; Events Adjudicated: 600

AMG 21 - 142
Phase III multicenter, international, randomized, double-blind, alendronate-controlled study to determine the efficacy and safety of AMG 785 (alendronate) in the treatment of postmenopausal women with osteoporosis.
Patients Enrolled: 4,000; Events Adjudicated: 540

AMG 20120102
Phase III study to evaluate the efficacy, safety, and effect of withdrawal and retreatment with brodalumab in subjects with moderate to severe plaque psoriasis: AMAGINE-1.
Patients Enrolled: 600; Events Adjudicated: 37

AMG 20120103 CEC
Phase III study to evaluate the efficacy and safety of induction and maintenance regimens of brodalumab compared with placebo and ustekinumab in subjects with moderate to severe plaque psoriasis: AMAGINE-2.
Patients Enrolled: 600; Events Adjudicated: 104

AMG 20120104 CEC
Phase III study to evaluate the efficacy and safety of induction and maintenance regimens of brodalumab compared with placebo and ustekinumab in subjects with moderate to severe plaque psoriasis: AMAGINE-3.
Patients Enrolled: 600; Events Adjudicated: 93

AMG 423 (Omecamtiv Mecarbil)
A double-blind, randomized, placebo-controlled, multicenter, dose escalation study to select and evaluate an oral modified release formulation of Omecamtiv mecarbil in subjects with heart failure and left ventricular systolic dysfunction.
Patients Enrolled: 450; Events Adjudicated: 495

AMG 423 (Omecamtiv Mecarbil) GALACTIC
Double-blind, randomized, placebo-controlled, multicenter study to assess the efficacy and safety of omecamtiv mecarbil on mortality and morbidity in subjects with chronic heart failure with reduced ejection fraction.
Planned Enrollment: 8,000; Events to be Adjudicated: 5,040

AUGUSTUS
Open-label, 2x2 factorial, randomized, controlled clinical trial to evaluate the safety of apixaban vs. vitamin K antagonist and aspirin vs. aspirin placebo in patients with atrial fibrillation and acute coronary syndrome and/or percutaneous coronary intervention.
Patients Enrolled: 573; Events Adjudicated: 45

BETRIXABAN HF MEDICALLY ILL
Multicenter, randomized, active-controlled efficacy and safety study comparing extended duration betrixaban with standard of care enoxaparin for the prevention of venous thromboembolism in acutely medically ill patients.
Patients Enrolled: 6,850; Events Adjudicated: 850

CEC CUBIST OIC-12-02
A multicenter, randomized, double-blind, placebo-controlled, phase III study to evaluate the efficacy and safety of cb-5945 for the treatment of opioid-induced constipation in adults taking opioid therapy for chronic non-cancer pain.
Patients Enrolled: 600; Events Adjudicated: 200

CEC CUBIST OIC-12-03
A multicenter, randomized, double-blind, placebo-controlled, phase III study to evaluate the efficacy and safety of cb-5945 for the treatment of opioid-induced constipation in adults taking opioid therapy for chronic non-cancer pain.
Patients Enrolled: 600; Events Adjudicated: 200

CEC CUBIST OIC-12-04
A multicenter, randomized, double-blind, placebo-controlled, phase III study to evaluate the efficacy and safety of cb-5945 for the treatment of opioid-induced constipation in adults taking opioid therapy for chronic non-cancer pain.
Patients Enrolled: 600; Events Adjudicated: 200

CEC CUBIST OIC-12-05
A multicenter, randomized, double-blind, placebo-controlled, phase III study to evaluate the long-term safety and tolerability of cb-5945 for the treatment of opioid-induced constipation in adults taking opioid therapy for chronic non-cancer pain.
Patients Enrolled: 1,800; Events Adjudicated: 450

Clinical Event Adjudication Projects (cont.)

DAIICHI-SANKYO - QUANTUM
Phase III, double-blind, placebo controlled study of quizartinib (ac220) administered in combination with induction and consolidation chemotherapy and administered as maintenance therapy in subjects 18 to 75 years old with newly diagnosed flt 3-itd (+) acute myeloid leukemia.
Patients to Enroll: 536; Events to Adjudicate: 900

ENDOMAX CEC
Endovascular Interventions with Angiomax study designed to demonstrate that anticoagulation with bivalirudin results in fewer major bleeding complications compared with unfractionated heparin in subjects undergoing peripheral endovascular interventions.
Patients Enrolled: 3,900; Events Adjudicated: 858

FERRING PHARMACEUTICALS
Multicenter, randomized, assessor-blind, controlled trial comparing the occurrence of major adverse cardiovascular events in patients with prostate cancer and cardiovascular disease receiving degarelix (GnRH receptor antagonist) or leuprolide (GnRH receptor agonist).
Patients Enrolled: 876: Events to Adjudicate: 225

GSK ASCEND-D
A phase III, randomized, open-label (sponsor-blind), active-controlled, parallel-group, multicenter, event-driven study in dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to recombinant human erythropoietin, following a switch from erythropoietin-stimulating agents.
Patients Enrolled: 3,151; Events Adjudicated: 1,040

GSK ASCEND-ND
A phase III, randomized, open-label (sponsor-blind), active-controlled, parallel-group, multicenter, event-driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa.
Patients Enrolled: 4,320; Events Adjudicated: 1,040

GSK Buproprion
Adjudication of cardiovascular related adverse events in controlled clinical trials of bupropion for the treatment of smoking cessation.
Patients Enrolled: N/A; Anticipated Events: 433

H9V-MC-GFRF CEC
Randomized, double-masked, placebo-controlled, multicenter, phase II study to evaluate the safety and renal efficacy of LY2382770 in patients with diabetic kidney disease due to type 1 or type 2 diabetes.
Planned Enrollment: 400; Anticipated Events: 150

HEARTFLOW - ADVANCE
The HeartFlow ADVANCE Registry: Assessing Diagnostic Value of Non-invasive FFRCT in Coronary Care
Planned Enrollment: 37,500; Events to be Adjudicated: 65

JACOB CEC
Pertuzumab or placebo in combo with trastuzumab and chemotherapy in subjects with HER2-positive metastatic gastroesophageal junction and gastric cancer.
Patients Enrolled: 2,250; Events Adjudicated: 25

JANSSEN - PIONEER
Open-label, randomized, controlled, multicenter study exploring two treatment strategies of rivaroxaban and a dose-adjusted oral vitamin K antagonist treatment strategy in subjects with atrial fibrillation who undergo percutaneous coronary intervention.
Patients Enrolled: 2,100; Events Adjudicated: 285

JANSSEN - GEMINI ACS I
Randomized, double-blind, double-dummy, active-controlled, parallel-group, multicenter study to compare the safety of rivaroxaban versus acetylsalicylic acid in addition to either clopidogrel or ticagrelor therapy in subjects with acute coronary syndrome.
Patients Enrolled: 3,000; Events Adjudicated: 740

KAI CLINICAL EVENTS ADJUDICATION
AMG 416 versus placebo for secondary hyperparathyroidism in subjects with chronic kidney disease on hemodialysis.
Planned Enrollment: 500; Anticipated Events: 100

LILLY LY2189265 CEC
Multiple protocols involving dulaglutide with insulin glargine on glycemic control in patients with type 2 diabetes and moderate or severe chronic kidney disease.
Patients Enrolled: 1,400; Events Adjudicated: 545

LILLY GBGE LY2189265
Randomized, parallel-arm, double-blind study of efficacy and safety of dulaglutide when added to SGLT2 inhibitors in patients with type 2 diabetes mellitus.
Patients Enrolled: 350; Events to Adjudicate: 125

LILLY GBGJ
Phase II, double-blind, placebo-controlled, 18-week trial of higher dulaglutide doses versus placebo in patients with type 2 diabetes on metformin monotherapy.
Patients Enrolled: 302; Events to Adjudicate: 30

LILLY GBGC LY2189265 in Diabetes-Pediatric Study)
Protocol H9X-MC-GBGC. Randomized, double-blind study with an open-label extension comparing the effect of once-weekly dulaglutide with placebo in pediatric patients with type 2 diabetes mellitus.
Patients Enrolled: 150; Events to Adjudicate: 10

MEPOLIZUMAB PROGRAM CEC DSMB
Multiple protocols for mepolizumab adjunctive therapy to reduce steroid use in subjects with severe refractory asthma.
Patients Enrolled: 1,060; Events Adjudicated: 545

MERCK - VICTORIA
Randomized parallel-group, placebo-controlled, double-blind, event-driven, multicenter pivotal phase III clinical outcome trial of efficacy and safety of the oral sgc stimulator vericiguat in subjects with heart failure with reduced ejection fraction (hfref)—vericiguat global study in subjects with heart failure with reduced ejection fraction.
Patients to Enroll: 4,872; Events to Adjudicate: 3,000

PARTNER
Prospective, randomized-controlled, multicenter pivotal trial evaluating the safety and effectiveness of the Edwards SAPIEN™ Transcatheter Heart Valve and delivery systems, via transfemoral and transapical delivery, in a stratified population of high-risk patients with severe aortic stenosis.
Patients Enrolled: 1,237; Events Adjudicated: 746

PORTICO CEC
Portico™ Re-sheathable Transcatheter Aortic Valve System U.S. investigational device exemption trial.
Planned Enrollment: 1,610; Anticipated Events: 600

PROSPECTIVE CEC STUDY 1
Multiple protocol study of the BRAF inhibitor dabrafenib in combination with the MEK inhibitor trametinib in the adjuvant treatment of high-risk BRAF V600 mutation-positive melanoma after surgical resection (COMBI-AD).
Patients Enrolled: 12,000; Events Adjudicated: 100

REGENERON - PCSK9 PROGRAM
Protocols: R727-CL1018, 1032, 1110, 1112, 1118, 1119, 1216, 1308

SANOFI - PCSK9 PROGRAM
Protocols: EFC11568, EFC11569, EFC11716, EFC12492, EFC12732, EFC13672, EFC13786, EFC14074, EFC14204, EFC14305, LTS11717, LTS13463

SUSPENSION CEC (BCB118)
Randomized, open-label, long-term, parallel-group, comparator-controlled, multicenter study to compare the glycemic effects, safety, and tolerability of exenatide once weekly suspension versus exenatide twice daily in subjects with type 2 diabetes mellitus.
Patients Enrolled: 375; Events Adjudicated: 15

SUSPENSION CEC (BCB120)
Randomized, long-term, open-label, three-arm, multicenter study to compare the glycemic effects, safety, and tolerability of exenatide once weekly suspension versus sitagliptin and placebo in subjects with type 2 diabetes mellitus.
Patients Enrolled: 360; Events Adjudicated: 15

TELESTO
Multicenter, randomized, double-blind, placebo-controlled trial of deferasirox in patients with myelodysplastic syndromes (low/intermediate-1 risk) and transfusional iron overload.
Patients Enrolled: 210; Events Adjudicated: 168

THERAVANCE BIOPHARMA TD-4208-0126
Phase III, 12-week, randomized, double-blind, placebo-controlled, parallel-group study of nebulized td-4208 in subjects with chronic obstructive pulmonary disease.
Patients Enrolled: 618; Events Adjudicated: 20

THERAVANCE BIOPHARMA TD-4208-0127
Phase III, 12-week, randomized, double-blind, placebo-controlled, parallel-group study of nebulized td-4208 in subjects with chronic obstructive pulmonary disease.
Patients Enrolled: 618; Events Adjudicated: 20

THERAVANCE BIOPHARMA TD-4208-0128
Phase III, 52-week, randomized, active-controlled parallel-group study to evaluate the safety and tolerability of nebulized td-4208 in subjects with chronic obstructive pulmonary disease.
Patients Enrolled: 1,050; Events Adjudicated: 35

Networks

Heart Failure Network (HF Network)

Established to promote research in the management of heart failure to ensure that the best use is being made of existing therapies and to develop new therapies, the ultimate goal of the HF Network is to improve patient care and quality of life. The HF Network comprises nine regional clinical centers, approximately 32 enrolling centers, and a coordinating center. The DCRI serves as the coordinating center for both clinical coordination and data coordination.

Sponsor: National Institutes of Health
More information: https://www.hfnetwork.org/about-us

International Collaboration on Endocarditis (ICE)

The ICE network aims to provide a mechanism to advance the understanding of infective endocarditis in areas that are difficult to study by traditional clinical research methods. The multinational nature of the collaboration provides a global view of infective endocarditis and opportunities for studies such as randomized trials of therapeutic treatment strategies.

Sponsor: DCRI
More information: http://www.endocarditis.org/ice

NIH Health Care Systems Research Collaboratory

Supported by the Common Fund at the National Institutes of Health, the Health Care Systems Research Collaboratory is intended to improve the way clinical trials are conducted by creating a new infrastructure for collaborative research. The ultimate goal is to ensure that health care providers and patients can make decisions based on the best available clinical evidence.

Sponsor: National Institutes of Health

More information: https://www.theresearchcollaboratory.org

Patient-Centered Outcomes Research Institute (PCORI) Projects

1. National Patient-Centered Clinical Research Network (PCORnet)
   PCORnet is intended to be a large, highly representative, national network for conducting clinical outcomes research. This network will improve the nation's capacity to conduct comparative effectiveness research efficiently and to learn from the health care experiences of millions of Americans. PCORnet aims to facilitate the shift in health research from researcher-driven to patient-centered research.

2. PCORnet project: Patients, Advocates and Rheumatology Teams Network for Research and Service (PARTNERS) Consortium
   The PARTNERS Consortium brings together the caregivers, advocates, and families of children with the most prevalent pediatric rheumatic diseases—juvenile idiopathic arthritis and childhood-onset systemic lupus erythematosus—to leverage knowledge being gained from the data of 9000 Childhood Arthritis & Rheumatology Research Alliance (CARRA) Registry and Pediatric Rheumatology Care & Outcomes Improvement Network (PR-COIN) patients housed at 62 pediatric centers.

   More information: http://pcornet.org

3. Optimizing Health Outcomes in Patients with Symptomatic Aortic Valve Disease
   Aortic valve disease is common and progressively disabling with no effective medical treatment. In November 2011, the U.S. Food and Drug Administration approved a transcatheter alternative to surgical aortic valve replacement (AVR). Given that transcatheter treatment is non-surgical and therefore much less invasive, many patients who were ineligible for surgical AVR became eligible for this new treatment. Using data from the Society of Thoracic Surgeons and American College of Cardiology registries linked to Medicare claims, the project will develop a new approach to the treatment of valve disease, by focusing on expected treatment outcomes for individuals using information collected from large groups of patients.

4. Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER)
   Stroke is the fourth leading cause of death and a leading cause of disability in the United States. Approximately 800,000 people in the United States have a stroke each year; of these, one-fourth will have another stroke. Using data from the Get With The Guidelines (GWTG)-Stroke and Adherence Evaluation After Ischemic Stroke Longitudinal (AVAIL) registries, PROSPER will conduct a series of comparative effectiveness studies.

5. Comparative Effectiveness of Rehabilitation Services for Survivors of an Acute Ischemic Stroke
   Most adult stroke survivors need help after the acute event. Rehabilitation care after stroke is the prime health care service for reducing disability and learning to manage the effects of a stroke, yet the risks and benefits of certain types of rehabilitation services, as well as the options that best support each individual's unique needs, are unknown. Using data from seven primary sources, this project will compare rehabilitation options in hopes of guiding individual decisions as well as improving future practice, policy, and patient-centered outcomes.

6. Improving Methods for Linking Secondary Data Sources for CER/PCOR
   Develop, test, and disseminate improved techniques for confidentially linking databases without the use of direct patient identifiers and to generate new knowledge to help researchers select and implement a record linkage procedure.

7. Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE)
   Pragmatic, randomized study to compare the effectiveness of two daily doses of aspirin (81 mg and 325 mg) in reducing a composite endpoint of all-cause death, hospitalization for nonfatal MI, or hospitalization for nonfatal stroke in high-risk patients with a history of MI or documented atherosclerotic cardiovascular disease.

Pediatric Trials Network (PTN)

The PTN is an alliance of clinical research sites located around the United States that are cooperating in the design and conduct of pediatric clinical trials to improve health care for the youngest patients. The PTN is studying the formulation, dosing, efficacy, and safety of drugs used in pediatric patients, as well as the development of medical devices used with this population.

Sponsors: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services

More information: https://pediatrictrials.org

Translational Research Centers in Thrombotic and Hemostatic Disorders (TRC-THD)

The TRC-THD is a network of research centers dedicated to developing novel approaches to treat thrombotic and hemostatic diseases. It supports investigators focused on the translation of fundamental discoveries to care delivery and then to global health.

Sponsor: National Heart, Lung, and Blood Institute

More information: https://www.trc-thd.org

Operational Improvement Programs

Cardiac Safety Research Consortium (CSRC)

The CSRC, established in 2006, has produced a broad and rapidly growing portfolio of programs, papers, and research projects. The CSRC's concentration on inclusive, collaborative approaches to precompetitive regulatory landscape barriers has created a frank and open forum for expert opinions that can flexibly focus on any key area of cardiac safety concerns. To date, such areas include QTc prolongation and pro-arrhythmia, new biomarker assays and cardiac imaging, blood pressure and vascular effects, arrhythmia ablation safety, women's health, obligatory drug/device safety interactions, novel anticoagulant drug development, and cardiac safety issues specific to diabetics and pediatric therapeutics. CSRC's signature think tank incubators devote more than 50% of program content to open discussion amongst experts, and from that discussion, new constructs, ideas, and research directions have emerged.

More information: https://cardiac-safety.org

International Multicenter Clustered Randomized Controlled Trial to Improve Treatment with Anticoagulants in Patients with Atrial Fibrillation (IMPACT AF)

IMPACT-AF will work to determine whether a comprehensive evaluation and customized multilevel educational interventions will increase the rate of use of oral anticoagulants and the adherence and persistence of use in patients with atrial fibrillation. The study has completed enrollment at 2,300 subjects, and the last patient last visit will occur January 31, 2017. The study team has targeted the 2017 ESC for presentation of results.

More information: http://continuingeducation.dcri.duke.edu/welcome-impact-af

Medical Device Epidemiology Network (MDEpiNet)

The MDEpiNet Public Private Partnership (PPP) is a shared public (government) and private partnership that facilitates the development of infrastructure, methods, and best practices for the evaluation of the performance of medical devices. As a PPP, MDEpiNet is funded and operated through a partnership of the U.S. Food and Drug Administration and organizations such as academia, various members of the health care sector, and industry. Each partner brings unique resources and strengths to the initiative. The resulting synergy will speed progress and improve processes to achieve common goals about the development and safe use of medical devices. The PPP focuses on identifying the effectiveness of devices in use, as well as emerging safety issues. This information and new knowledge also informs device innovation. MDEpiNet considers issues of data generation, quality, best practices in health informatics, and novel methodologies for the integration of data sources, including medical device registries, electronic health records, claims data, and other patient-centered data.

More information: http://www.mdepinet.org

Registries and Quality Improvement Programs

American College of Cardiology's National Cardiovascular Data Registry (NCDR®)

The NCDR provides leadership for several of the nation's largest cardiovascular clinical data registries, including the CathPCI Registry and the ACTION Registry–Get With The Guidelines. The DCRI has been an NCDR primary analysis center since 2005.

More information: http://cvquality.acc.org/ncdr-home.aspx

American Heart Association's Get With The Guidelines (GWTG) Program

GWTG is a national, acute, in-hospital quality improvement effort designed to improve guideline-based care for two cardiovascular disease states: stroke and heart failure. The DCRI has served as the analytic center for the GWTG program since 2005.

More information: http://www.heart.org/HEARTORG/Professional/Professional_UCM_001093_SubHomePage.jsp

American Heart Association's Mission: Lifeline

Mission: Lifeline is a national quality improvement program that focuses on processes of care for patients having an acute myocardial infarction, from symptom onset through hospital discharge. The program uses data from the ACTION Registry—Get With the Guidelines to produce quarterly feedback reports for participating hospitals, and to conduct scientific analyses. The DCRI serves as the analysis center for the program.

More information: http://www.heart.org/HEARTORG/Professional/Professional_UCM_001093_SubHomePage.jsp

Cascade Screening for Awareness and Detection of Familial Hypercholesterolemia (CASCADE-FH)

CASCADE-FH is a national registry for patients with familial hypercholesterolemia (FH) and is sponsored by the FH Foundation, which is a patient-led, nonprofit, charitable organization committed to raising awareness, promoting optimal disease management, and improving the quality of life and survival of FH patients. FH is a common genetic condition characterized by a dramatically high level of low-density lipoprotein cholesterol (>190 mg/dL) that is not related to diet or lifestyle.

More information: https://thefhfoundation.org/fh-research/registry/

Implementation of Demonstration Project for Health Systems: Atrial Fibrillation (INFORM AF)

INFORM AF is designed to improve stroke prevention at the health system level by optimizing the appropriate use of oral anticoagulants for stroke prevention in patients with atrial fibrillation within five U.S. health systems.

Outcomes Registry for Better Informed Treatment of Atrial Fibrillation II (ORBIT-AF II)

ORBIT-AF II is a multicenter, prospective, outpatient registry of patients with incident atrial fibrillation (AF) as well as those recently started on novel oral anticoagulants. Following on the work and success of ORBIT-AF I, this registry will provide postmarket surveillance data needed for assessing the safety of novel oral anticoagulants when used in broader patient populations and community practice settings. It will be the largest contemporary U.S. cohort of outpatients with AF, becoming the most in-depth study of novel anticoagulants and their management in general practice and subsequent outcomes in patients with AF. The registry started in December 2012 with a target enrollment of 15,000 patients from approximately 300 U.S. sites. Patients will be followed at 6-month intervals for at least 2 years across a broad range of clinic settings. Currently, more than 260 sites and 10,000 patients have been enrolled in the registry. The "Patient Survey of Disease Understanding, Treatment Preferences, and Decision Making" substudy has 54 sites participating and has enrolled 320 subjects..

More information: https://orbit-af.dcri.duke.edu

Patient and Provider Assessment of Lipid Management (PALM)

Sponsored by Regeneron Pharmaceuticals, the PALM registry is a prospective database of 175 U.S. sites and 7,500 patients, assessing current practice patterns in managing lipid levels based on the new American College of Cardiology/American Heart Association guidelines for managing 10-year atherosclerotic cardiovascular disease risk. The DCRI is providing thought leadership, site and project management, data management, and statistics analysis and support. This outpatient registry targets cardiology, general and internal medicine, and endocrinology practices for participation. Tablets preloaded with an informed-consent video and patient surveys are distributed to sites. These activities are completed in the clinic setting with the goal of accommodating existing workflows. This study has recently completed.

Registries and Quality Improvement Programs (cont.)

Regional Approach to Cardiovascular Emergencies Cardiac Arrest Resuscitation System (RACE CARS)

RACE CARS is a statewide system of emergency cardiovascular care, coordinating 119 hospitals and 540 EMS agencies in North Carolina to rapidly diagnose and provide emergency treatment for heart attacks and sudden cardiac arrest. The education outcomes strategy relies upon delivery of best practices at three critical levels: prompt action from bystanders, rapid response by quality care delivered by emergency medical services and first responders, and a coordinated approach to provision of specialized post-arrest care in the hospital.

More information: https://racecars.dcri.org

The Regional Systems Accelerator: Implementation of The American Heart Association's Mission: Lifeline - AMI Discharge and Follow-Up Demonstration Project (Accelerator 2)

The goal is to employ Duke University faculty and staff, national-level systems experts, and staff from the American Heart Association to build on the original learnings from the first Accelerator education program to increase the rate of timely coronary reperfusion by organizing coordinated STEMI care on a regional basis. Recent data from the Accelerator and Mission: Lifeline program demonstrate wide gaps in large U.S. cities being able to achieve guideline goals to timely reperfusion and clearly point to a need for more regional trauma-like approach to STEMI care. This expanded intervention will further facilitate the effective delivery of emergency cardiac care across 12 regional systems in a timely, coordinated, and uniform manner.

In addition to the need to improve emergent response and treatment of STEMI care in large U.S. cities, hospitals also need improved discharge planning and follow-up to discharge care. The work will also ensure a cost-effective approach to appropriate discharge planning and medications at the hospital level, and post-stent antithrombotic adherence in a Demonstration Project manner of education implementation methodology.

More information: http://accelerator.dcri.org

Society of Thoracic Surgeons (STS) National Adult Cardiac Surgery Database

The DCRI has served as the STS's data warehouse and analysis center since 1998 and is responsible for all STS site contact and electronic harvest management, as well as data management and data feedback. In addition, the DCRI develops the STS's clinical risk models and analyzes all research questions.

More information: http://www.sts.org/national-database

TVT Registry™

Created by the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), the TVT Registry is designed to monitor the safety and effectiveness of the transcatheter aortic valve replacement (TAVR) procedure for the treatment of aortic stenosis. The registry will serve as a platform for postmarket device surveillance and quality improvement initiatives. The DCRI will serve as the analytic center for the registry.

TVT Registry projects include:

- PARTNER Post Approval Study Part II Assessment of Safety, Effectiveness, Adherence to Indication and Learning Curve of the SAPIEN™ THV with Retroflex for Inoperable Patients Post Approval Period (US)
- Assessment of Alternative Access Approaches for TAVR in Inoperable Patients with Severe Aortic Stenosis

More information: https://www.ncdr.com/TVT

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Produced using paper from sustainable forests

DCRI Communications October 2016