C5Research

C5Research is a team of experienced and dedicated clinical trial specialists within the Heart, Vascular & Thoracic Institute of Cleveland Clinic. We bring scientific and clinical leadership in cardiovascular disease in combination with operational excellence to conduct Phase II-IV multicenter clinical trials. We understand industry timelines and commit to delivering on time. We bring world class academic leadership to clinical trials and a viewpoint and independence that satisfies the demanding peer-reviewed scrutiny of the academic and scientific community.

**Mission**
Design and conduct innovative clinical research that enhances scientific knowledge and positively impacts the care of patients.

**Research Priorities**
- Patients: Integrity
- Investigators: Compliance

**Functional Teams**
- Project & Site Management
- Quality Assurance & Regulatory
- Contracts & Finance
- Information Systems
- Clinical Events Committee
- Imaging Core Laboratory
- Graphics & Design
- Statistics & Data Management

**Physician Leadership**
- **Steven E. Nissen, MD**
  Chief Academic Officer, Heart, Vascular & Thoracic Institute
- **Venu Menon, MD**
  Associate Director of C5R & Director of Clinical Events Committee
- **Wael A. Jaber, MD**
  Director, Cardiovascular Imaging Core Laboratory
- **Rishi Puri, MBBS, PhD**
  Director, Atherosclerosis Imaging Core Laboratory
- **Vidyasagar Kalahasti, MD**
  Associate Director, Clinical Events Committee
- **Luke Laffin, MD**
  Co-Director, Center for Blood Pressure Disorders
- **Milind Desai, MD, MBA**
  Director of Clinical Operations of Cardiovascular Medicine
- **Erik Van Iterson, PhD, MS**
  Director, Cardiac Rehabilitation & Quality Director, Metabolic

**Clinical Trial Results**
- Publication of trial results in top tier medical journals having a major impact on the practice of medicine: 24 Tier 1 Medical Journal Publications

**Overview Clinical Trials**
- Clinical Events Committee:
  - Highly reliable and timely in adjudication of clinical events
  - Completed Reviews: 12,194
  - Total Events Reviewed: 6,795
  - QA Accuracy: 98%

**Imaging Core Laboratory**
- Performing high quality and expedient image analysis
  - CT and MRI Reviews: 116
  - Echo Reviews: 4,567
  - Songraphers and Coordinators Trained: 1,682
  - Total Clinical Trial Sites: 807

**Regulatory Guidance**
- We are an academic group dedicated to achieving the highest quality work following ICH/GCP guidelines
  - Quality Assurance Audits: 11
  - Employees Trained in Compliance: 81
  - Information Systems Requests Fulfilled: 584
  - 21 CFR Part 11 Validation Projects Completed: 30

**Care for the Patient**
- C5Research capabilities, extensive research experience, and renowned expertise allows for the dissemination of new knowledge to the clinical community and patient population being studied
  - Clinical Study Participants 2023: 70,000