



Cardiovascular.

Premier Research has a long tradition in cardiovascular research for drugs and devices. The company was involved in the evolution of collection and monitoring of cardiotoxicity data for new molecular entities. More recently, we have supported the approval of many new devices including drug eluting stents, catheters, ablation systems, and cardiac assist devices, as well as critical pharmaceutical studies in the treatment of conditions.

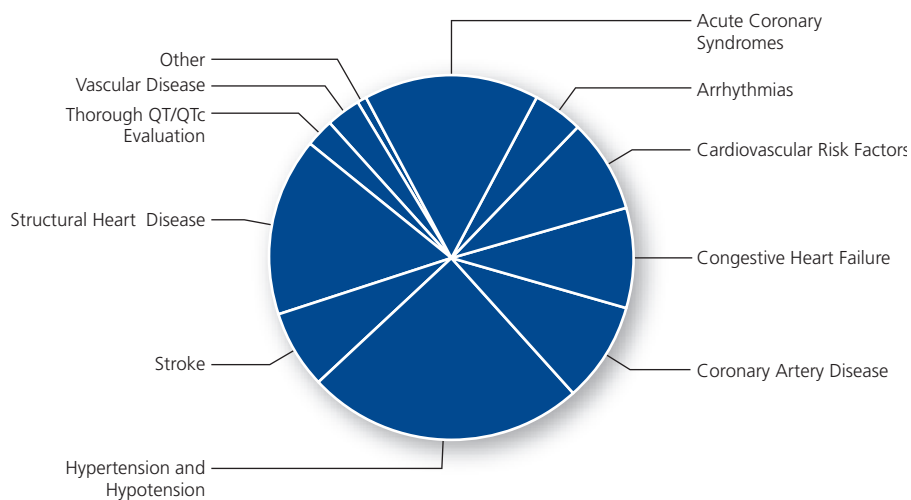
Proven Experience

- More than 105 clinical trials and 35 consulting projects in cardiovascular indications conducted in the past five years
- More than 66,000 patients treated for cardiovascular disorders in the past five years
- Experience includes cardiovascular registries involving more than 80,000 subjects
- Global team with local knowledge and expertise allows us to recruit large cardiovascular trials
- Broad experience spanning all major cardiovascular disorders

Expertise: The People

- More than 78% of project managers/directors and 72% of CRAs experienced in cardiovascular clinical research
- In-house physician with specialty in Lipidology and Preventative Cardiology with experience in designing and implementing successful proof of concept clinical trials for novel cardiovascular compounds
- Long-term relationships with leading scientists, experts, and investigators in cardiovascular research including interventional cardiologists
- In-house regulatory consultants provide guidance on development and regulatory strategy

Experience Within the Past 5 Years



Case Study: Providing Support from Concept to Market

Premier Research supported a device manufacturer from concept to market clearance in Europe for their novel device. This program began with our strategic consulting team, in collaboration with the client, developing the regulatory strategy during the early stages of product development and supporting the Notified Body selection process including presenting technical data and the proposed clinical plan to demonstrate early compliance with the appropriate EU essential requirements.

We assisted in developing the appropriate design dossier, including the essential requirements matrix, risk analysis, critical literature review, investigators' brochure, and clinical trial protocols. Our expert clinical team then managed site selection, study start-up, project management, and monitoring as well as provided technical site support with the operation of the unique system being tested.

Premier Research's dedicated medical device safety officer continuously monitored patients' safety and reported any reportable events to the regulatory authorities. Our biometrics department managed the data utilizing Oracle Clinical Remote Data Capture, performed the statistical analysis of the data, and wrote the study reports.

All members of our team worked together to exceed the client's expectations and ultimately helped gain the market clearance of this novel device on time. Premier Research continues to support the client during their IDE study.

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Premier Research is well positioned to quickly execute cardiovascular studies for investigational products seeking regulatory approval as well as marketed drugs and devices with an intent to expand labeling, meet post marketing surveillance requirements for regulators, and to assess safety.

Evidence-based Research

Cardiovascular disease is one of the leading causes of premature morbidity worldwide. The need for evidence-based research for cardiovascular disease is paramount, especially given the current emphasis on the 'Comparative Effectiveness'.

Getting the right answers requires an understanding of how to ask the right questions. Applying the right study design and the data collection techniques combined with the correct data analysis will yield the evidence needed in today's cardiovascular research development programs. Our biostatisticians with their clear understanding of cardiovascular disease provide sponsors with robust analytical design and analysis to ensure that trials provide clear measurement of treatment efficacy and safety. This is precisely what the marketplace requires and what the regulatory agencies mandate.

Successful execution of a well-designed study requires an experienced team. Our clinical experts with the local knowledge and expertise draw upon years of experience managing cardiovascular trials and relationships with networks of investigators with proven track records for subject recruitment and quality data. Our experts select the investigators (e.g. cardiologists, endocrinologists, general practitioners) and study site locations (e.g., academic institutions, specialty clinics, community-based sites) from our databases that are best-suited to meet the goals of each study and the objectives of the sponsor. Our teams are committed to efficient, effective study execution.

Interventional Cardiology

There is perhaps no other therapeutic area where interventional approaches have so dramatically changed the outcomes of not just acute cardiac care needs but long-term cardiac morbidity and mortality. Premier Research is among the most experienced CROs in interventional cardiology and more broadly, in medical devices.

The conduct of clinical research in interventional medicine requires knowledge of both device and pharmaceutical clinical development and the appropriate regulatory path. Premier Research can provide this significant knowledge and apply its expertise to study design, statistical planning, and the operational aspects of your clinical program.

Further, patient recruitment for interventional cardiology studies require knowing the appropriate interventional cardiology sites for each study. Premier Research is a leader in investigator selection and recruitment in this arena.

Our experience includes the following types of cardiovascular devices:

- Ablation Systems (RF and Ultrasound)
- Atrial Fibrillation Devices
- Baroreflex Stimulators
- Cardiac Assist Devices
- Cardiac Bioprostheses
- Cardiac Imaging Diagnostics
- Cardiac Pressure Monitoring Devices
- Catheters (Laser and Drug Eluting)
- Drug Eluting Balloons
- Mechanical Reperfusion Devices
- Optical Coherence Tomography Devices
- PFO Closure Devices
- PFO Sizer Devices
- Pulmonary Artery Pressure Sensors
- Stents (Bare Metal and Drug Eluting)
- Thoracic Endoprostheses
- Valve Replacements
- Vascular Access Devices

Case Study: Managing a Global Registry for Acute Coronary Syndrome

For over seven years, Premier Research managed an Acute Coronary Syndrome (ACS) registry developed under the guidance of an 18-member scientific advisory committee comprised of cardiologists and epidemiologists experienced in ACS research and clinical practice. The registry was an international, multicenter, observational study that gathered and analyzed data on ACS patients and treatment practices used in the hospital management of these patients. The data captured and reported in this registry reflected a 'real world' approach to the diagnosis and treatment of ACS patients.

The goal of this registry was to improve the medical care of ACS patients through a better understanding of patient demographics, management, in-hospital and post-discharge outcomes. 100 centers in 14 countries across four continents participated in the registry recruiting more than 40,000 patients.

The success of this program prompted several other registries. The largest included 169 centers and enrolled over 10,000 patients with ACS. It was more broadly dispersed across 24 countries and five continents.

Through Premier Research's efforts, data from the registry was published in 26 scientific manuscripts, and more than 175 abstracts were presented at international meetings. The findings from the registry have been published in such renowned journals as The Lancet, European Heart Journal, and Circulation.

Premier Research's international presence, cost effective data collection, and investigator management enabled this study to expand and continue.



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