CARDIOVASCULAR

inVentivHealthclinical.com

DEDICATED CARDIOVASCULAR EXPERIENCE

inVentiv Health Clinical has successfully conducted more than seventy-five cardiovascular studies in the past five years. Our staff has the experience to develop innovative strategies and expertise to deliver high quality clinical services for your cardiovascular development programs in the America's, Europe, and Asia-Pacific regions

GENERAL AND CARDIOVASCULAR-SPECIFIC SERVICES

inVentiv Health Clinical offers a comprehensive range of general services for defining the development plan for your drug and achieving agreement with regulators and managing your clinical studies.

We will partner with you and provide solutions to your development challenges. We have longstanding relationships with global cardiovascular cooperative networks. We work collaboratively with cardiovascular opinion leaders, academic institutions (including ARO's), and ancillary service vendors such as ECG and imaging providers. These teams have know-how in working with clinical endpoint committees, which are often part of cardiovascular programs. The team continuously measures the quality of the endpoints and the efficiency of the process. inVentiv Health Clinical can support you in helping design a regulatory strategy, meet with health authorities, and gain regulatory agreement on pivotal study design.

At the onset of your program, inVentiv Health Clinical can identify cardiovascular investigators from our database and through our ongoing relationships. We have a longstanding history of collaborating with experienced, qualified, and motivated sites. Once selected, we establish regular communication with study centers. This ensures the timely start, effective recruitment, and continued retention of study subjects. We also work with you to identify program specific risks and develop proactive contingency plans.

Once the study has been launched, the program is monitored by experienced clinical research associates. Project managers and medical monitors also contribute to the oversight of the project and navigate the execution of the program. Most importantly, inVentiv Health Clinical has partnered with clients on studies that the results have been used for successful NDA and MAA submissions within the program timelines.

Let inVentiv Health Clinical's cardiovascular experts work for you.

OTHER SERVICES INCLUDE:

- Support for the obtaining of scientific advice from US and EU regulators
- Interdisciplinary strategic development planning, including chemistry, manufacturing, preclinical, and clinical development
- Protocol development
- Clinical development plan and compilation
- Endpoint management
- DSMB/DMC and Steering committee management
- Gap analysis for in-licensed drug candidates
- Quality control/assurance
- Biostatistical support for study design and analysis
- Case report form development
- Data entry/management/database design
- Study monitoring and site management plans
- Pharmacovigilance and risk management plans
- Regulatory strategy and submissions (IND, CTA, IMPD, MAA, NDA submissions)
- Medial writing for procols, patient materials, clinical study reports, regulatory submissions, manuscripts

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OUR EXPERTISE INCLUDES:

- Acute Coronary Syndrome
- Angina pectoris
- Arrhythmia
- Atherosclerosis
- Atrial fibrillation
- Cardiovascular disease
- Coronary artery disease
- Heart failure
- Hypercholesterolemia
- Hyperlipidemia
- Hypertension
- Hypovolemic shock
- Intermittent claudication
- Multiple Cardiovascular Events
  - Restenosis
  - Thrombosis
- Ventriculartachycardia/ventricular fibrillation

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inVentiv Health Clinical, formerly PharmaNet/i3, is a leading provider of global drug development services to pharmaceutical, biotechnology, generic drug, and medical device companies. With 7,000 employees in more than 36 countries, inVentiv Health Clinical offers therapeutically specialized capabilities for all phases of clinical development, bioanalytical services, and strategic resourcing from a single clinical professional to an entire functional team.