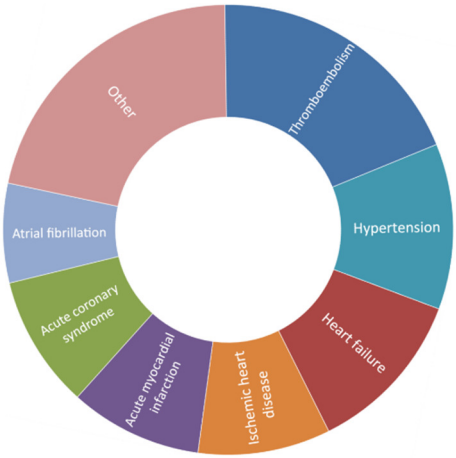
Cardiovascular Diseases
Clinical Trial Solutions in Europe

Pharmnet expertise

Pharmnet has significant expertise in the field of cardiovascular diseases and cardiac surgery having conducted more than 40 trials (with four projects involving paediatric population).

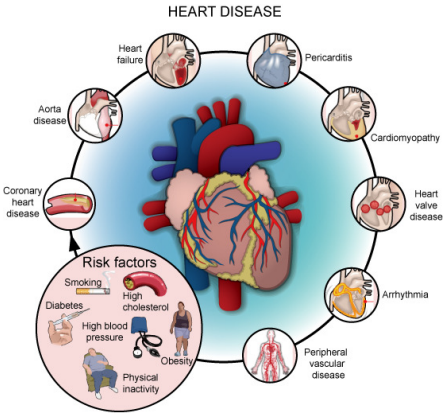
We have extensive experience with the following indications:



Other: Atherosclerosis, Heart valve replacement, Anticoagulation, Venous insufficiency

A summary of key clinical trials:

- interventional cardiology trials on new generation, novel stent technology, and strategies to guide revascularization in stable and unstable coronary artery disease
- acute coronary syndrome trials on out-of-hospital cardiac arrests, anti-platelet treatment
- intervention trials on aortic valve replacement
- heart failure trials with sodium-glucose cotransporter 2 (SGLT2) inhibitors, sacubitril/valsartan, and novel drugs for hypertrophic cardiomyopathy
- prevention trials on proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors
- electrophysiology trials on atrial fibrillation screening, new evidence for rhythm vs. rate control strategies
- pulse field ablation



Why conduct a clinical trial with us?

We can offer knowledge of healthcare facilities, treatment strategies in European countries, and site allocation based on our years of experience working in the cardiology field. We offer the benefit of long-term cooperation with clinical centers, local authorities, and experience in effective patient recruitment for clinical trials. We can also accelerate the process of drug development, reduce costs, and ensure regulatory compliance.

We take the diagnosis-oriented approach when doing top-line feasibility for selected countries of interest. The executive summary results for a specific pathology/protocol and proposed scenarios assists our clients in selecting the best study solution in terms of study speed and cost.

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Key figures in cardiology in Europe

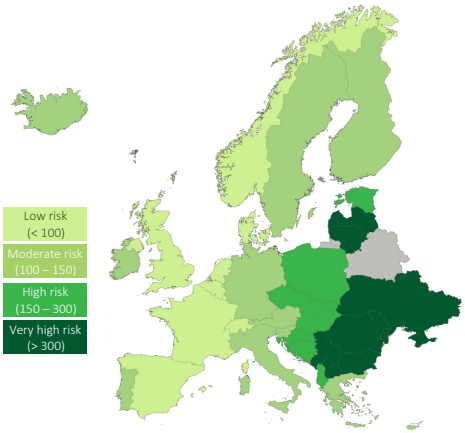
Cardiovascular diseases (CVD) continue to be the leading cause of death in Europe, accounting for 45% of all deaths. Sadly, over 4 million Europeans die each year from CVD, primarily from coronary heart disease (CHD) and stroke. Many more are hospitalized, and many develop long-term disabilities that necessitate life-long treatment.

Besides the human suffering, CVD has major economic implications for Europe. The economic cost CVD imposes to the EU economy is estimated at €210 billion a year. Of the total cost of CVD in the EU, around 53% (111€ billion) is due to health care costs, 26% (€54 billion) due to productivity losses and 21% (€45 billion) due to informal care of people with CVD.

Central and Eastern Europe have the highest cardiovascular disease mortality rate in the world, with deaths occurring at younger ages. Ischemic heart disease (IHD) and stroke death rates are generally higher in Central and Eastern Europe than in Northern, Southern, and Western Europe. However, reduced occurrence of risk factors, improved concentration of care in specialized centers, and new available treatments all contribute to a slight decrease in mortality.

The European Society of Cardiology (ESC) is the leader in the discovery and dissemination of best practices in cardiovascular medicine. This unique network of national cardiac societies from around the world enables researchers and clinicians to better understand the impact of CVD and how to reduce its burden.

Risk regions based on standardised CVD mortality rates per 100,000 people reported to WHO:



Case study

Pharmnet participated in a paediatric phase III study for a major pharmaceutical company to compare IMP to standard of care for the treatment of venous thromboembolism. Pharmnet took over the regulatory and monitoring responsibilities in the Czech Republic at a time when the study was already underway in 26 countries, but recruitment was slow.

Because of Pharmnet's understanding of the local milieu, we were able to identify additional sites to boost recruitment. In addition, we proposed collaborating on the study with several haematologists in the country who had referred potentially suitable patients. CRAs actively listened to investigators' concerns about recruitment issues and communicated them to the sponsor, who reflected these in protocol. Despite having a country with a smaller population, we ranked among the top recruiters accounting for approximately 17% of global recruitment. The client's needs were met successfully, as global recruitment recovered as a result of the Czech Republic's significant contribution.

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