

The services provided by the CRO of the Hellenic Cardiovascular Research Society include, but are not limited to:

Clinical Operations

- Study Setup
- Feasibility & Investigator Selection
- Project Management
- Monitoring of Investigational Sites
- Assistance in Safety Reporting
- Study Close-out

Medical Affairs

- Clinical protocol design (also ICF/CRF/patient questionnaire/patient diary/patient leaflet/manual)
- Safety review
- Medical support & advice during study conduct
- Translation of medical documents
- Clinical study report preparation
- Article preparation for publication

Regulatory Matters in Clinical Research

- Regulatory Authorities submission
- National Ethics Committee submission
- Local EC submissions
- Ethics & Regulatory Authorities reporting
- Agreements negotiation (YPE, Universities, Private Hospitals)
- Investigator payment handling

Data Management & Statistics

- Database design
- Data entry
- Statistical analysis
- Statistical report

Training / Education

- Investigator Meeting & Congress organisation
- Scientific Presentations
- Study-specific & ICH/GCP training
- Lectures and interactive conferences
- Update on clinical practice and treatment guidelines

Secretarial Services

- Site coordination
- Telephone contacts and progress reporting

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In the **HEART** of Clinical Research



 **Hellenic Cardiovascular Research Society**
Ελληνική Εταιρεία Καρδιοαγγειακής Έρευνας

The Academic Clinical Research Organization of the Hellenic Cardiovascular Research Society (HCRS) is the first cardiovascular-focused full-service CRO in the Greek territory. The idea of the HCRS Board Members became reality in July 2008, with the establishment of the CRO, comprising a few dedicated Research Physicians and scientific personnel with expertise in clinical research.

Our Aim

- To provide a scientific background in the Project Planning procedure and continuous medical support to cardiovascular clinical trials
- To provide high quality CRO services in the cardiovascular field that comply with GCP guidelines and local regulatory standards
- To disseminate new knowledge in the cardiovascular field to the global medical community
- To educate future generations of clinical researchers in the cardiovascular field

Our Mission

To support & develop Cardiovascular Research & Clinical Trials in Greece by delivering highly specialized services in an accurate and cost-effective manner

Our Vision

To lead Cardiovascular Clinical Research in Greece and establish national Investigators as reliable partners in the international scientific community.

The HCRS is involved in clinical research studies, including:

- Pharmaceutical
- Post-Marketing Surveillance
- Epidemiological
- Devices
- Investigator Initiated
- Health Economics

A non-exhaustive list of cardiovascular indications in which the HCRS has been successfully involved is the following:

- Acute coronary syndromes
- Coronary artery disease
- Stroke
- Atherosclerosis
- Arrhythmias
- Hypertension
- Heart failure
- Metabolic disorders
- Pulmonary diseases

Why select us versus a conventional CRO as partners for your Cardiovascular trial:

The HCRS presents advantages at every stage of the trial process:

Setup phase

- **Expertise in Cardiovascular field:** Involvement of experienced Clinician Investigators in protocol design, combined with expert staff for project design. Real-world knowledge of current clinical practice, treatments and patient attitudes. Design based on current therapies and guidelines.
- **Scientific Value:** Your Project is reviewed and evaluated regarding its scientific status and value by the expert team of the HCRS Advisory Board, consisting of regional key opinion leaders and leading clinician/academics who are at the forefront of global research.
- **Investigators' Network:** The advantage of the Cardiology focus is the establishment in Greece of a network of more than 70 Investigators who are selected on the basis of their expertise in the field of cardiology & their academic qualifications, but also their extensive experience in clinical trials, covering geographically the entirety of the Greek territory. Being able to provide access to recognised key opinion leaders from around the globe, the HCRS helps to optimise a Client's recruitment strategies.
- **Selection of participating sites:** Sites are initially assessed according to their clinical focus (i.e. arrhythmias, ACS...), scientific orientation, staff expertise. Subsequently, feasibility studies are performed in order to guarantee that they have the desired patient population, time, personnel & laboratory availability, no competitive studies that could affect recruitment, and no restrictions in the regulatory domain.

Conduct phase

- **Patient Reliability:** Placing your Project under the auspices/coordination of the HCRS is an asset for study reliability and facilitates patient consenting procedure.
- **Investigators' Network:** Being part of a Network, the Investigators are in continuous collaboration, are motivated, feel part of a team and exchange project-related experiences & ideas.
- **Medical Coordination:** Every project is coordinated by an expert HCRS medical coordinator.
- **Rescue Plan:** The HCRS network provides full time and aspect support to the Project by offering alternatives: e.g. providing additional sites in the case of low recruitment rates.
- **Web Portal:** The HCRS offers password-protected, study specific web portals with multiple access layers regarding many procedures of the trial process (controlled documents, training material – Videos PowerPoint presentations, study updates, Newsletters)

Close-out phase

- **Interpretation of study results** by experts in the cardiovascular field ensures scientific reliability and integrity.
- **Publication:** Sponsors benefit from HCRS expertise, as authors know what crucial information editors require for publication.

The Academic Clinical Research Organization of the Hellenic Cardiovascular Research Society combines the clinical expertise and academic leadership of distinguished clinicians and KOLs with the full-service operational capabilities of a contract research organization. The HCRS can operate independently, or in conjunction with a sponsor's own in-house teams, or their designated CRO, depending upon the client's requirements.

