CARDIALYSIS

Clinical Trial Management - Core Laboratories

Company profile

The allround trial specialist in cardiology Leading since 1983

cardialysis.com

About Cardialysis

Cardialysis is a leading specialist clinical research organization (CRO) with an exclusive focus on cardiovascular clinical trials. Cardialysis provides the full range of clinical research and cardiovascular core laboratory facilities necessary for the fast-track, high-quality development of medical devices, pharmaceutical products and combinations in phase II and phase III clinical studies, registries, post-marketing studies and investigator sponsored studies. All processes are in compliance with Good Clinical Practice (GCP), guidelines of the European Medicines Agency (EMA), Food and Drug Administration (FDA) and according to International Conference on Harmonization (ICH) and ISO standards.

Cardialysis is headquartered in Rotterdam, the Netherlands and operates in virtually all Western and Eastern European countries and the United States. Through its network of over 1,200 clinical sites monitored by specialized local CRAs, Cardialysis has access to a large part of the cardiological clinical trial population in the world.

The company has a track record of over 250 clinical development studies including several landmark trials that have contributed to the major advances in the Cardiology field over the last 30 years and to the approval of drugs and devices currently used in every day practice across the globe.

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Mission and vision

To serve the interests of our clients, our global network of collaborating cardiology professionals and most importantly to pursue improvements in the care of patients, by offering and continuously improving our unique state-of-the-art full service infrastructure for the design and conduct of the smartest studies with the world's most promising innovations.

History

Cardialysis was incepted in 1983 by cardiologists from the Thorax centre of Erasmus Medical Centre, the Netherlands, the centre that still plays a prominent role in the increasingly international faculty that surrounds Cardialysis today. From a small Holter data analysis unit in the early eighties Cardialysis has developed into an internationally recognized independent clinical research organization, having collaborative activities with major scientific, medical device and pharmaceutical partners from around the globe. Nowadays, Cardialysis has a long diversified track record and is one of the leading specialized global organizations in the field of cardiology drug and medical device development.

"over 1,200 cardiology sites world-wide"

With a strong academic background and long track record within cardiology Cardialysis has an established network of over 1,200 cardiology sites worldwide of which 800 are in Europe. Site selection and site activation are two crucial elements in staying within budget and closing the study within expected time lines. Cardialysis is fully aware what the consequences could be by selecting unqualified and improper sites.

By using our experience and relationships in the field we reduce time for site selection to a minimum without compromising on the quality and patient volume of participating sites. Furthermore, the involvement of Thought Leaders in the field of cardiology and experienced Project Managers provide insight in the unique aspects per site for therapeutic area expertise and quality of provided clinical data and images.

Our network of sites has been built on relationships, past experience and understanding of the site's capabilities. Consequently, we take care of additional assessments based on specific trial requirements if required by the sponsor.

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Scientific advisors

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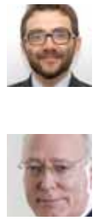

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Academic and clinical background

Cardialysis is recognized for its opinion-leader expertise, strong academic network and in-depth cardiology expertise. Due to its close relationship with thought leaders from leading research institutions, Cardialysis has a keen awareness of the demands of clinical research in relation to daily clinical practice. Cardialysis can respond rapidly to requests for the design, organisation and co-ordination of trials. We publish in the major scientific journals and present the results of our trials at the international scientific congresses. Testimony to the success of this approach is our extensive list of publications.

Web based clinical event adjudication

Cardialysis has extensive experience in Clinical Event Committee (CEC) adjudication services. As such, Cardialysis is actively involved in the Academic Research Consortium (ARC) to create a dynamic, transparent, collaborative forum across stakeholders with the objective to harmonize clinical endpoints for specific key therapeutic areas.

The adjudication of clinical events by an independent CEC is critical in the establishment of unbiased and reliable trial results based on the endpoint definitions in the study protocol. CEC members are physicians currently practising in the field of interest who are fully trained to the CEC procedures. Several years ago, Cardialysis developed a web-based adjudication system that allows the CEC members to adjudicate events individually at their own locations or together as a group in the form of meetings. This provides flexibility in the set-up of the CEC process and the direct availability of adjudication results.

Core laboratory facilities

Cardialysis has over 30 years of experience acting as an independent core laboratory for cardiovascular clinical trials. Continuous innovations and application of imaging modalities in different settings such as animal research have made Cardialysis into the successful provider of core laboratory services that it is today.

Leading experts in the field of cardiovascular imaging are supervising Cardialysis' core laboratory activities. We guarantee an independent and accurate central analysis according to the latest standards of definitions.

Cardialysis activities extend to the following areas

Trial Design
- Protocol development
- CRF development

Project Management
- Budget control
- Timeline control
- Resource control
- Communication
- Site selection

Clinical Monitoring
- Site management
- Pre-study visit
- Initiation visit
- Monitoring visit
- Close-out visit

Data Management & Logistics
- eCRF development
- eCRF review
- eCRF database development
- User Acceptance Testing
- Central Tracking System
- Query resolution set-up and Data cleaning

Safety Monitoring & Reporting
- Data Safety Monitoring Board
- SAE Reporting
- Safety Reports
- Hotline service

Web-based Event Adjudication
- WebCEC application
- CEC configuration
- CEC member contracting
- CEC Charter

Imaging Techniques
- Angiography
- Intra coronary imaging
- MRI
- Electrocardiography
- Echocardiography
- MSCT

Statistical Analysis and Reporting
- Statistical analysis
- Report writing
- Scientific presentations-support
- Pooled analyses

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Track Records Landmark Trials

ABSORB (Abbott, Bioresorbable scaffold)
Serruys et al. Lancet 2009;373:897-910
30 patients, 5 sites, Europe and New Zealand

ABSORB Cohort B (Abbott, Bioresorbable scaffold)
Ormiston et al. Lancet 2008;371:899-907
Serruys et al. Lancet 2009;373:897-910
101 patients, 10 sites in Europe and New Zealand

APPROACH (GSK, rosiglitazone)
Gerstein et al. Circulation 2010;121:1176-87
672 patients, 92 sites, 19 countries in Europe, US, Asia and South-Amercia

BENESTENT (J&J, coronary stent)
Serruys et al. NEJM 1994;331:489-95
520 patients, 28 sites, 9 countries in Europe and South-Amercia

COMPARE I and II (WESPH, drug eluting stent)
Kedhi et al. Lancet 2010;375(9710):201-9
Smits et al. Lancet 2013;381(9867):651-60
Total: 4,500 patients in Europe

EUROPA (Servier, perindopril)
Fox et al. Lancet 2003;362:1-7
13,200 patients, 450 sites, 25 EU countries

EXAMINATION (Abbott, bare metal stent & drug eluting stent)
Sabate et al. JACC 2014;7(1):55-63
2,665 pts, 5 sites, 2 countries in Europe

HELVETICA (Ciba Geigy, hirudin)
Serruys et al. NEJM 1995;333:757-63
1,141 patients, 28 sites, 7 countries in Europe

IBIS-2 (GSK, darapladib)
Serruys et al. Circulation 2008;118:1172-82
330 patients, 25 sites, 10 countries in Europe

LEADERS (Biosensors, drug eluting stent)
Windecker et al. Lancet 2008;372:1163-73
1,707 patients, 10 sites in Europe

LIPS (Novartis, fluvastatine)
Serruys et al. JAMA 2002;287:3215-22
1,677 patients, 77 sites, 10 countries

PROSPECT - MSCT sub study
(Abbott, stent)
Papadopoulou et al. JACC 2012;5(3 suppl):s28-37
350 patients, 40 sites in US and Europe

PURSUIT (Schering-Plough, eptifibatide)
Harrington et al. NEJM 1998;339:436-43
12,500 patients, 351 sites, 18 countries US, Europe and South-America

RAVEL (Cordis, drug eluting stent)
Morice et al. NEJM 2002;346:1173-80
238 patients, 19 sites, 7 countries in Europeand South-Amercia

RESOLUTE (Medtronic, drug eluting stent)
Serruys et al. NEJM 2010;363:136-462
1,300 patients, 79 sites in Europe

SOFA (WCSF, fish oil)
Brouwer et al. JAMA 2006;295:2613-19
500 patients, 25 sites in Europe

SYNTAX (Boston Scientific, stent & CABG)
Serruys et al. NEJM 2009;360:961-72
3,075 patients, 86 sites US and Europe

TWENTE I and II (Dutch Peers, drug eluting stent)
Von Birgelen et al. Lancet 2014;383(9915):413-23
Von Birgelen et al. JACC 2012;59(15):1350-61
3,200 patients, 1,000 sites global

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