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Cardialysis



*The annual listing of 10 companies that are at the forefront of
providing Contract Research Organization CRO
consulting / services and transforming businesses*

Cardialysis

At the Leading Edge of Cardiovascular Innovation

3 7 years ago, a group of visionary academicians at the Erasmus University Medical Center started Cardialysis as a local Electrocardiography Core Laboratory to create new breakthroughs in treatment of cardiovascular disease using science and innovation. Led by the university professor Paul Hugenholtz, this local lab grew exponentially to become a niche cardiovascular research organization, offering academic (ARO) and contract services (CRO). Today, the company conducts clinical trials to investigate pharmaceutical and device therapies used in coronary heart disease or structural heart disease, where interventional device therapies are offered in hospital catheterization laboratories. Besides expanding its footprint in heart failure trials, the company is striving to offer its services at a lower cost to counter the COVID-19 effect while exploring new ways to improve innovation outcomes in multi-CRO projects.

Cardialysis has emerged as the epicenter of cardiovascular innovation, connecting sponsors and investigational sites in sponsor-driven studies, and linking grant-givers, steering committees, and investigational sites in investigator-initiated studies. The company provides end-to-end services, including trial design, site selection, project management, Core Lab data analysis, and statistical reporting. Having completed 400 clinical investigations to date, the company has acquired deep expertise in every step of the research process. “Our research expertise is linked to the medical leadership at the Erasmus University Medical Center for Core Lab activities and trial design as well as to partnerships with leading investigators worldwide,” says Dr. Ernest Spitzer, Medical Director of the organization.



Dr. Ernest Spitzer

In addition, Cardialysis offers sponsor capabilities through the European Cardiovascular Research Institute (ECRI), founded in 2012, as a sister organization. ECRI provides a legal and compliant platform for principal investigators and manufacturers to run investigator-initiated studies. It also offers a unique European academic platform to bring together key opinion leaders in cardiovascular science to address hot topics in innovation. Moreover, the scientific board of ECRI keeps exploring new concepts around interventional cardiology, heart failure, cardiac imaging, and pharmacotherapy. This institute has conducted ten trials so far in more than 20,000 cardiovascular patients globally.

Over the years, Cardialysis has set several milestones for itself and the cardiovascular domain. The BENESTENT study completed in 1994 revolutionized the use of coronary stents in catheterization laboratories. To date, this study remains one of the most cited papers in cardiovascular research. In 2010, the company reported the sponsor-driven RESOLUTE All Comers trial (2010, Medtronic) which is still used as a methodological reference for pivotal or post-marketing coronary stent trials. This study compared two drug-eluting stent platforms in an unrestricted coronary artery disease population using a non-inferiority trial design. Recently, Cardialysis has contributed to the

sponsor-driven GALILEO trial (Bayer), randomizing the use of an anticoagulant versus an antiplatelet strategy after transcatheter aortic valve implantation in patients without other indication for anticoagulation. Contrary to the investigator’s hypothesis, GALILEO showed that anticoagulation was detrimental, highlighting the importance of randomized trials. These three studies were published in the New England Journal of Medicine.



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Apart from its stellar performance in compliance-driven innovation, Cardialysis separates itself in the market with its organizational culture. “Our team comprises highly committed individuals who maintain dynamic interaction with the company’s partners across open communication channels,” says Dr. Spitzer. In 2020, the company undertook two fundamental changes in itself to operate as a leaner firm with a flat organizational hierarchy driven by an enhanced focus on data integrity, security, and transparency. During the COVID-19 pandemic, Cardialysis had ‘zero’ downtime and remained fully operational through the critical moments. Currently, the company is running 40 clinical investigations with different groups of services, including several full-service projects.

In 2021, Cardialysis aims to expand its team and forge a stronger and long-lasting relationship with industry players, including professional, independent, and knowledgeable cardiovascular research organizations. 