

# pharma

**TECH OUTLOOK** EUROPE SPECIAL



**CLINICAL TRIAL  
MANAGEMENT  
EDITION**



Mr. Frits Kesselring,  
Chief Executive Officer

Dr. Goran Rudez,  
Director of Innovation  
and Quality

Dr. Ernest Spitzer,  
Chief Medical Officer

# CARDIALYSIS

WHERE INNOVATION  
MEETS MULTI-DISCIPLINARY  
CARDIOVASCULAR EXPERTISE



# COVER STORY



With a multi-disciplinary management that combines all areas of expertise, Cardialysis easily connects all the dots of a CV clinical study, and runs precise procedures day-to-day in a seamless manner



Mr. Frits Kesselring,  
Chief Executive Officer

Dr. Goran Rudez,  
Director of Innovation  
and Quality

Dr. Ernest Spitzer,  
Chief Medical Officer

# CARDIALYSIS

## WHERE INNOVATION MEETS MULTI-DISCIPLINARY CARDIOVASCULAR EXPERTISE

**C**ardiovascular clinical research (CV) is either driven by medical experts with a passion for scientific research (investigator-initiated research) or by the medical industry (industry-driven research). Both groups require intermediary organisations that can tactfully facilitate the design, management, monitoring, and reporting of CV study results. But, when embarking on a CV study, the looming question for the research group always remains if the CRO is the right fit for the CV arena.

Several imperative factors are driven by which a CRO's expertise in CV clinical research can be tested.

For starters, clinical research conducted in the CV arena is challenging due to the various underlying disease conditions affecting most potential research participants. So, clinical researchers need to be mindful while approaching research participants with multiple co-morbidities. In addition to that, the entire design of CV studies themselves can also be quite complex. Anyone from the medical academia would agree to the complexities

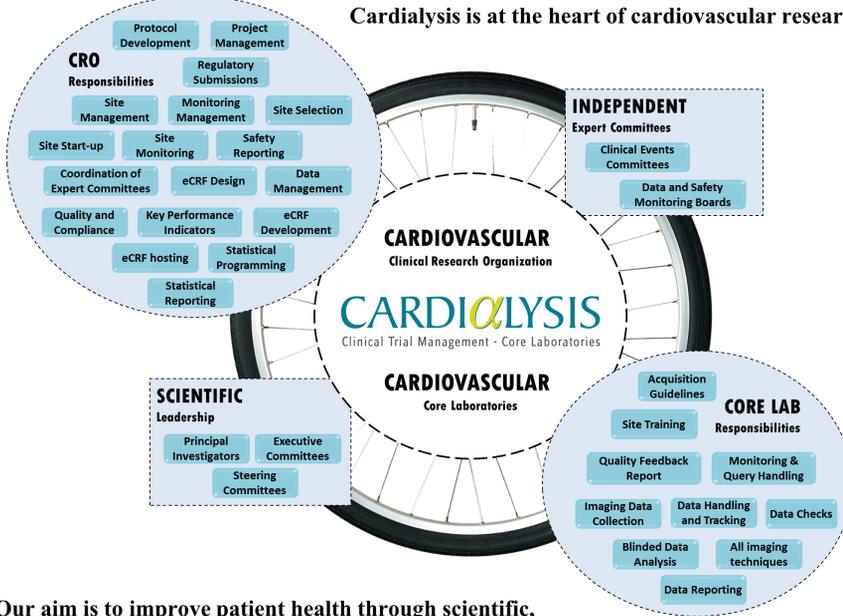
encountered in, for example, selection of meaningful endpoints and measurement techniques, or complex randomisation schemes.

If these initial complexities are further layered with protocol designs that may incorporate a control group, retrospective and prospective elements, long-term follow-up, or imaging requirements to support the safety and efficacy of new technology, the scope of the study becomes even more challenging to manage. These difficulties can result in inconsistency, inferior quality, and non-compliance by sites struggling with a very complex protocol.

At this juncture, Cardialysis, the CV clinical research specialist based in the Netherlands, brings forth their unique route of staying successful in the domain since 1983. Dr. Ernest Spitzer, the Chief Medical Officer of the company, says, "Our secret sauce is our multi-disciplinary CV clinical research team owing to which Cardialysis has developed a niche expertise in the cardiovascular CRO landscape over the years." The company believes that the execution of clinical trials following good clinical practices,

Based in Rotterdam, the Netherlands

Cardialysis is at the heart of cardiovascular research



Our aim is to improve patient health through scientific, innovative and value-based cardiovascular research

ethical codes, and regulatory science efficiently requires maturity and proven expertise. At the same time, to ensure clear agreements among players in a clinical trial, establishing a proper legal and financial disposition is critical. This is precisely where Cardialysis' forte lies. With multi-disciplinary management that combines all areas of expertise, Cardialysis efficiently connects all the dots of a CV clinical study and runs precise procedures day-to-day in a seamless manner. "Above all, we work together to always pay careful attention to quality assurance by keeping one foot on innovation," adds Dr. Goran Rudez, Director of Innovation and Quality at Cardialysis, further highlighting the critical pieces that constitute the success formula of Cardialysis.

### For the Cardiologists, By the Cardiologists

A group of cardiologists formed Cardialysis from the Thoraxcenter of the Erasmus Medical Centre in Rotterdam, the Netherlands. Back in the '80s, Cardialysis only consisted of a small Holter data analysis unit, but the company always aimed to scale new heights from the start. "We were one of the firsts in numerous segments; for instance, when offering the first on-line clinical endpoint adjudication platform or

designing the first core lab for conducting quantitative analysis of the coronary artery stenosis," points out Dr. Spitzer. Riding on this innovation bandwagon over the years, Cardialysis kept growing to become an internationally recognised independent cardiovascular research organisation today, collaborating with primary scientific, medical device, and pharmaceutical partners from around the world. However, Cardialysis likes to stay grounded to its roots and still maintains its liaison with the Erasmus Medical Center, which continues to play a prominent role in expanding the international faculty surrounding Cardialysis currently.

### A Problem-Solving Mind-Set that Breeds Success

While collaborating with fellow cardiologists for CV clinical studies, Cardialysis mostly evidences two significant types of challenges. On the one hand, for large volume trials requiring consistency and powerful logistical capabilities over years of execution, the challenge circles around trust; such clients look for established methodologies and professional research networks, for which ideal CROs should pass the test of time. On the other hand, the goal of small yet complex clinical trial activities is to find better expertise. Their work often

gets delayed due to a lack of standardized core laboratory imaging techniques, insufficient guidance on endpoint adjudication, regulatory submissions and monitoring strategies. So, those sections of clients seek the best experts in the field for their trial design and scientific and execution input.

Being a versatile and agile CRO specialising in the CV arena, Cardialysis can serve all the unmet needs of both worlds. Executing over 400 cardiovascular trials in almost four decades of its existence, trust and assurance come naturally and synonymously with the company's name today. Moreover, considered a one-stop, full-service CRO for cardiovascular research, all trial activities performed by Cardialysis are well integrated, allowing for increased efficiency, timely execution, and reduced burden to the investigators or companies, which also comes in handy for small-scale clinical trial activities. "To sum it up, we act as true partners of our clients from the beginning until the completion of the study," mentions Mr. Frits Kesselring, Chief Executive Officer at Cardialysis. "We not only assist our current and future partners to address the scientific question but also help them with the study set-up, planning, costs, and timelines." With such a comprehensive and collaborative outlook, CV researchers can rest assured that their setbacks are always being taken care of by Cardialysis' experts.

### Under the Hood of Excellence

Cardialysis' core strengths in the execution of clinical trials are displayed through two key facets: its established research networks and its imaging core laboratory capabilities.

In this regard, Dr. Spitzer also draws attention to the importance of selecting suitable investigational sites for the success of a clinical study and Cardialysis' broad network of investigational sites to make that possible. He says, "Choosing wrong sites can often lead to delays, increase unplanned costs, and utilise less reliable data." However, Cardialysis, with an established network of over 1,400 cardiology sites worldwide (of which 1,200 are in Europe), effectively evades any mishaps, thereby reducing the

time for site selection and the overall budget of the study to a minimum, but without compromising on the quality and patient volume of participating sites.

Adjacently, continuous innovations and imaging modalities in different settings make Cardialysis' core lab services a very successful and all-around trial specialist in the domain. Data from numerous clinical trials conducted using Cardialysis' core lab capabilities have been used for competent authority submissions (including FDA, EMA, and PMDA new drug marketing approval applications and CE marking).

### **Tangible Proofs of Success**

A testament to the company's expertise in cardiovascular clinical research is its role in studying MOre REsponse (MORE) on Cardiac Resynchronisation Therapy (CRT). Cardialysis was the global echocardiographic core laboratory for the MORE CRT trial. This was a sponsor-driven trial (NCT02006069), which aimed to assess the impact of the multi-point pacing in the treatment of patients not responding to standard CRT. This trial enrolled almost 7000 subjects in over 200 investigational sites worldwide and required the analysis of over 10,000 echocardiograms. This study, which lasted eight years, required a team of 10 imaging analysts and three supervisors from Cardialysis, who ensured consistency through time to bring the trial to its successful finalisation.

This is but one of the many success stories Cardialysis has scripted over the years, thanks to their multi-disciplinary team of specialists. Leaning on its proficiency, right now, Cardialysis is the MRI core lab for a phase III pharma trial in China (NCT04468529), intracoronary imaging techniques for an approval trial in Japan (NCT02972671), and echocardiographic analysis for an IDE trial in the U.S., Canada, Europe, and Australia (NCT03735667). Coupled with that, Cardialysis is also the CRO for a phase II clinical trial testing the emergent use of inhaled flecainide to treat paroxysmal atrial fibrillation (NCT03539302).

These projects only stand to substantiate further that Cardialysis is among the inventive players currently changing the game in CV clinical research by driving a fresh wave of modernisation globally with their knowledge and leading-edge lab capacities.

### **Powering Successful Studies amidst the Pandemic**

One of the biggest obstacles that Cardialysis, as a company, have been able to weather in the last year and a half successfully is the COVID-19 pandemic. Like any other company in the world gripped by the pandemic, Cardialysis was also forced to work remotely. Describing the situation, Dr. Spitzer says, "As a close-knit company, we were used to working face to face a lot; it was one of our key strengths to act quickly. But, with the sudden onslaught of the pandemic, everything changed."



## **Cardialysis' core strengths in the execution of clinical trials are displayed through two key facets: its established research networks and its imaging core laboratory capabilities**



Nevertheless, it could not dampen the spirit of Cardialysis to deliver results to its clients. "Although challenging, we adapted to the new normal, steered our high level of cooperation and communication with the help of remote tools, and continued offering our clients the quality they expect from us," adds Mr. Rudez, justifying Dr. Spitzer's statement.

Besides careful attention to growing areas of research, right now, Cardialysis is also prioritising its corporate culture—to strengthen and motivate its people in times where remote work is becoming an essential component of daily life. Notably, the company has already implemented a workshop on 'happiness at work' for the same, which has shown success, kicking off a series of allied activities, including the

corporate use of an app that keeps track of employee's physical activities and rewards those who remain active. These efforts ensure a constant 'feel good' factor among employees, steering a workforce with a happy and healthy mind.

### **Paving a New Tech-Driven Path for the CV Researches**

Cardialysis is presently focused on expanding its expertise—through collaborations—in specific areas where its work can complement other top global providers. "Some of the areas where we are investing are hypertension, where we recently partnered with dabl®, an Irish global provider of ambulatory blood pressure measurements, launching the first dedicated Hypertension Core Lab in Europe" shares Dr. Spitzer.

Likewise, the company is also designing strategies to expand on

therapeutic areas for aortic disease, where technologies are constantly evolving. And when it comes to bolstering tech capacities, the next step for Cardialysis would be prioritising the use of artificial intelligence, which, according to the company's leadership team, is progressively becoming more critical in CV clinical research and medical practice.

"As we move forward on these tracks of transformation, with our multi-disciplinary team, we aim to remain the bridge between clinical trial investigators, regulatory authorities, and the medical industry, and in that process, help the entire CV clinical research landscape emerge more victoriously," summarises Dr. Spitzer, Mr. Kesselring, and Dr. Rudez, with a mutual nod and agreement.

SEPTEMBER · 2021

ISSN 2644-2787

# pharma

**TECH OUTLOOK**

[WWW.PHARMATECHOUTLOOK.COM](http://WWW.PHARMATECHOUTLOOK.COM)



## CARDIALYSIS



*The annual listing of 10 companies that are at the forefront of providing  
Clinical Trial Management services and transforming businesses*