The CERC Chronicle

Issue No. 28 - May 2026

EuroPCR 2026

Meet us at Booth **M11**

Editorial

Smart Trials, Strong Results: From Vision to Impact

CERC is entering a new phase with renewed governance, building on its established strengths: a model led by distinguished key opinion leaders, supported by a high-level CRO infrastructure, and driven by highly active Innovation Groups delivering trials to set new standards, such as START YOUNG, LEAVE NOTHING BEHIND, and EMBRACE, with more in advanced development. This model has demonstrated strong impact, with major publications in leading journals including The Lancet, NEJM, and Circulation, reflecting clinical insight, methodological rigor, and operational excellence.

Innovation remains central. Artificial intelligence, already integrated into our core lab, will be expanded across the research pathway from trial design to data analysis, enabling AI-structured trials.

CERC continues to broaden its scope with new devices and strategic studies, while strengthening its position in cardiovascular research. The partnership with Europa will support larger studies and expanded networks. In parallel, CERC aims to federate European cardiovascular CROs and core labs into a structured network, leveraging processes and a quality system recognized by regulatory authorities including the FDA and PMDA. Built on collaboration and scientific excellence, CERC is well positioned to move forward with renewed governance, expanded partnerships, and a clear commitment to innovation.

Dr Philippe Garot, CEO

New CERC Trials

BASKETBALL	B|BRAUN	EVOQUE	Cerific / Edwards
CLARIT	Cerific PHILIPS	PASCAL	
Valid-B.Well BP25 Study	B.Well	DEFINE DM	CVRF Abbott
EMBRACE	Cerific Medtronic	PHOSLINE	DOTTER

Program

Tuesday 19 May

12:00 - 13:00 Room 341 Hotline / LBT sessions	INFINITY-SWEDEHEART RCT - *D. Erlinge* DESyne BDS Plus 36-month outcomes - *A. Abizaid* BIOADAPTOR-RCT 4-year outcomes - *S. Saito*
15:00 - 16:00 Room 341	TARGET FIRST substudy - *G. Tarantini*
Room Maillot	TARGET study interim results - *G. Nickenig*

Wednesday 20 May

08:30 - 09:30 Abstract & Case Corner 2A	E-ULTRA 10K (4,000 patients outcomes) - *P. O'Kane*
11:15 - 12:15 Room Maillot Hotline / LBT sessions	ALL WOMEN Primary endpoint - *I. Cruz-Gonzalez*
15:00 - 16:00 Room Maillot Hotline / LBT sessions	SELUTION DE NOVO - *S. Eccleshall*
16:35 - 17:35 Room 153	LEAVE NOTHING BEHIND : Focus on DCB - *P. Smits*

Thursday 21 May

09:45 - 10:45 Room 341	LANDMARK trial : Pacemaker predictors - *P. Smits*
11:15 - 12:15 Abstract & Case Corner 1A	TARGET FIRST substudy on side effects of P2Y12 inhibitors - *P. Smits*
e-poster	MENA TAVI

Future Challenges in Interventional Cardiology

If one were to distill this year's American College of Cardiology Annual Scientific Session into a single sentence, it might be this: we have become highly proficient at performing interventions yet remain less certain about when they truly confer benefit.

Consider intravascular imaging. Intravascular ultrasound (IVUS) has increasingly been viewed as essential in complex PCI. However, the OPTIMAL trial showed longer procedural time without benefit in left main disease, a finding echoed by the IVUS-CHIP trial in high-risk PCI. This consistency suggests a pattern rather than coincidence. Whether this challenges prior evidence will be clarified by future meta-analyses, but it raises important questions: are we extrapolating beyond the data, or missing key nuances? IVUS may be effective, but not universally or consistently, and its benefit may depend less on the tool itself than on how it is applied and the expertise behind its use.

The ORBITA-CTO trial offers methodological clarity by addressing not whether a vessel can be opened, but whether doing so improves patients' lives. CTO PCI reduces angina beyond placebo. While there is no survival benefit, it increases symptom-free days. Importantly, the comparison is against placebo rather than optimal medical therapy, so incremental benefit in well-treated patients remains unproven. Nonetheless, it reinforces a critical principle: improving quality of life is not a secondary objective: it is the endpoint.

Equally complex is the role of devices for myocardial protection during PCI. Micro-axial flow pumps are effective in cardiogenic shock but show no benefit—and possibly harm—in high-risk PCI. Yet the concept of "protected PCI" continues to expand, raising a critical question: are we protecting patients, or ourselves?

This tension is even clearer in ST-elevation myocardial infarction. Pre-emptive mechanical support in patients without shock may appear proactive, but it delays prompt reperfusion, the only intervention proven to preserve myocardium, and increases bleeding risk. We are, once again, reminded of a fundamental principle: within STEMI care, time is not merely important; it is decisive.

The CHAMPION-AF trial further illustrates ongoing uncertainty. Left atrial appendage closure appears non-inferior to NOACs with less bleeding, while CLOSURE-AF suggests otherwise, highlighting how trial design and endpoints shape clinical conclusions.

Despite these complexities, there is reason for cautious optimism. These findings are not setbacks but necessary course corrections. The field is evolving, less driven by procedural complexity and more focused on outcomes that matter to patients. The challenge is not to do more, but to do better, with greater selectivity, rigor, and intellectual humility.

At CERC, our effort is directed toward designing trials that are both impactful and efficient, making judicious use of available resources within a methodological framework that is continuously evolving, adapting, and learning.

Dr Davide Capodanno

CERC Innovation Groups

Within CERC, we capitalize on the extensive experience and expertise of our shareholder network in cardiovascular research. Four years ago, we established five Innovation Groups, each dedicated to a specific field: coronary artery disease, structural heart disease, pharmacology, renal denervation, and artificial intelligence - digital technology.

Each Innovation Group consists of 4–8 expert members, led by a chair and supported by a Clinical Operational Manager or Clinical Project Leader. The groups meet regularly throughout the year—primarily online—to design clinical trials that address unmet clinical needs and advance cardiovascular treatment toward improved patient outcomes.

To date, the Innovation Groups have been highly successful in designing large, multicenter randomized controlled trials (RCTs), supported by industry partners. Examples include START YOUNG, LEAVE NOTHING BEHIND, and EMBRACE.

START YOUNG aims to expand the indication for transcatheter aortic valve implantation (TAVI) to younger patients. In this study, 1,180 patients aged 65–75 years are randomized between TAVI and surgical aortic valve replacement (SAVR). TAVI is performed using the balloon-expandable Octocor Pro valve (Meril), while SAVR utilizes surgical bio prostheses. The study includes a 10-year follow-up and is being conducted across 60 sites in 20 countries.

LEAVE NOTHING BEHIND evaluates the equivalence of two "leave nothing behind" strategies in relatively young patients with coronary artery disease. Drug-coated balloon (DCB) treatment with bailout bioresorbable scaffold (BRS) is compared to a primary

BRS strategy in 2,256 patients, using the MOZEC DCB and MeRes100 scaffold (Meril). A secondary objective is to compare both strategies with drug-eluting stents (DES) based on predefined performance goals. The trial will be conducted at approximately 100 sites worldwide.

EMBRACE is designed to integrate renal denervation into the PCI workflow for hypertensive patients. Patients undergoing PCI for multivessel disease and hypertension are randomized after the index procedure to staged PCI with radio-frequency renal denervation versus staged PCI with standard care. This is the first study to expand access to renal denervation within the PCI setting for patients with complex disease. The trial employs an innovative win-ratio design, is supported by Medtronic and will enrol 1,000 patients across 55 sites globally, including the US.

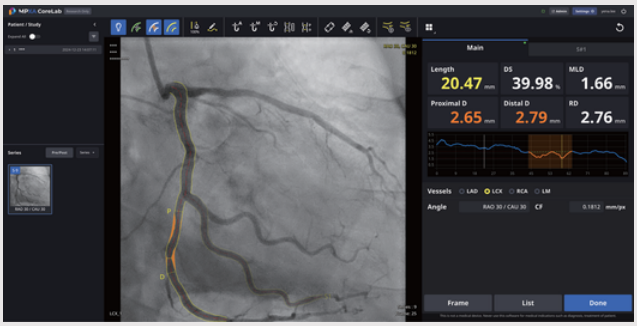
Dr Pieter Smits

AI assisted CoreLab

At CERC we strive to be the first full artificial (AI) assisted core lab. We believe that with AI we can analyse images quicker, more uniform and with less manual corrections. This will enhance the productivity and quality of our core lab analyses.

Coronary angiography

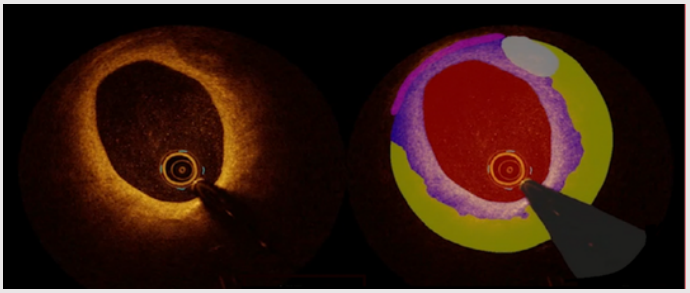
For quantitative coronary angiography (QCA) we have partnered with Medipixel (Seoul, South Korea) in the development of MPXA core-lab. MPXA core lab software automatically calibrates, automatically assesses the relevant coronary artery, automatically detects and draws the contours, including the side branches, and provides the relevant QCA data for the main branch and – if needed- for side branch. We believe that this QCA software is one of the best, as it takes the influence of the side branch on the reference vessel diameter into account and can-do main branch and bifurcation analyses all in one.



Optical Coherence Tomography

Artificial intelligence (AI) is rapidly transforming the analysis of coronary optical coherence tomography (OCT), addressing one of the main limitations of the technique: the need for time-consuming and expert-dependent interpretation. Traditional OCT-analysis requires manual frame-by-frame assessment of large datasets, which introduces interobserver variability and limits its routine use. Recent developments in AI —particularly deep learning—are enabling automated, fast, and highly reproducible analysis of OCT images, making the technology more accessible and scalable in clinical practice and research.

A major area of progress is automated image interpretation, including classification, segmentation, and quantification of coronary structures. Modern deep learning algorithms can accurately delineate the lumen, lamina media, detect stent struts, and characterize plaque components such as lipid-rich or calcified lesions. These models often achieve near–expert-level performance, especially for lumen and stent assessment, while plaque characterization continues to improve with larger datasets and better architectures. The ability to automatically quantify plaque burden and identify high-risk features (e.g., thin-cap fibroatheroma) is particularly important, as plaque vulnerability—rather than stenosis severity—drives clinical events. For this we have partnered with CARA lab, an academic spin-off of the Radboud University in Nijmegen, the Netherlands.



AI segmentation of the coronary vessel wall, identifying calcification, lipidic and fibrotic plaque

Echocardiography

In the echo core lab variability arises from image acquisition, measurements and interpretation. All of these directly impact trial endpoints.At CERC we understand the key role AI has in addressing some of these issues.

Reducing inter and intra observer variability, faster analysis and reliable longitudinal comparisons can be effectively addressed through implementing AI driven solutions. We are working with US2.AI who provide FDA cleared analysis solutions to pilot and implement AI in the core lab thus strengthening the reliability of imaging endpoints.

Dr Antoinette Neylon
& Dr Pieter Smits

CERC's Expanding Worldwide Footprint

CERC continues to expand its operational footprint worldwide, strengthening its ability to deliver complex international clinical trials.

In recent months, key studies, including Start Young and Leave Nothing Behind, have been successfully submitted in several countries, notably Estonia, Slovenia, Slovakia, the Czech Republic, Lithuania, North Macedonia, Hungary, Greece, Cyprus, and Croatia. This momentum continues, with upcoming countries such as Australia, New Zealand, Canada, and Japan. This expansion reflects CERC's growing international reach through the continuous addition of new investigator sites worldwide and its ability to navigate diverse regulatory environments. By continuously extending its network, CERC not only accelerates patient recruitment but also ensures broader representation of patient populations, ultimately strengthening the robustness of clinical data. This ongoing expansion illustrates CERC's ambition to position itself as a leading international CRO, capable of supporting large-scale trials across an ever-expanding network of countries and sites.

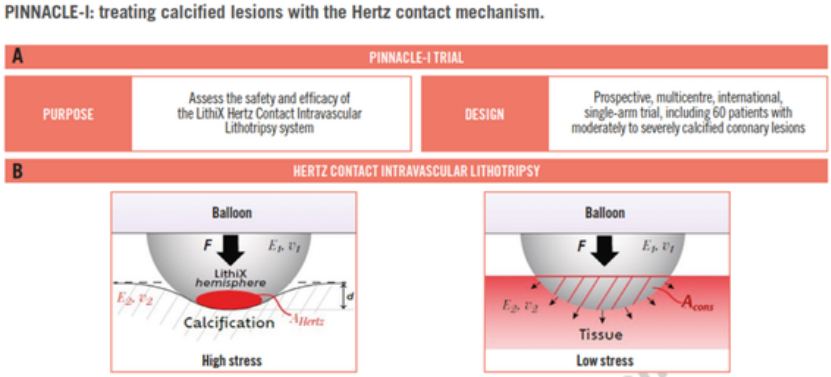
Solenne Paiva
Regulatory Affairs Specialist

From Innovation to Impact: Key Developments at CERC

Within CERC's clinical operations, we focus on ensuring robust and timely execution of projects through structured project management and strong cross-functional coordination. A key priority has been the management of multiple regulatory submissions across countries, requiring careful planning, alignment with local requirements, and continuous follow-up to meet expected timelines.

In parallel, we closely monitor budgets and project timelines, ensuring adherence to financial constraints while maintaining operational efficiency and quality standards. We collaborate with sponsors to align on expectations and deliverables, supported by proactive communication, risk identification, and mitigation strategies.

A recent example is the Pinnacle I study, managed by CERC (especially corelab), which reached publication in EuroIntervention, representing both strong collaboration and a true "pinnacle" of operational success.



Resource allocation remains central, with dedicated teams assigned at each stage to ensure continuity and performance.

Carine Bikai
Clinical Project Leader

Driving Quality, Compliance, and Efficiency Through eQMS

CERC has officially launched the implementation of its electronic Quality Management System (eQMS), marking a key milestone in strengthening its quality framework and operational efficiency.

Designed to replace fragmented tools and manual processes, the eQMS will centralize document management, automate workflows, and enhance audit readiness. The platform will integrate CAPA management, training tracking, and real-time quality metrics, ensuring robust compliance with GxP and ISO 9001 requirements.

Beyond compliance, the system is expected to deliver substantial efficiency gains while leveraging AI-driven insights to support faster, data-informed decision-making.

This initiative reflects CERC's continued commitment to innovation, scalability, and excellence in clinical research.

Phuong Hai Nguyen
Quality Manager

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Smart trials. Strong results.