euroPCR

The CERC Chronicle

Issue No. 26 – May 2025

CERC at EuroPCR 2025

Proud to stand alongside EuroPCR, CERC brings outcomes from eight clinical trials to the 2025 program, including five highlights in the Late Breaking Clinical Trials sessions.

CERC Clinical Trials Presentation Program

Wednesday 21 May

9:45-10:45
Room 242AB
Hotline / LBT session

ACURATE IDE	Early ACURATE prime: Multicenter study to evaluate safety and effectiveness	A. Rück

11:15-12:15
Théâtre Havane
Hotline / LBT session

COMPARE ABSORB	Final seven-year outcome	P. Smits
BIOADAPTOR RCT	Percutaneous coronary treatment with bioadaptor versus stent: three-year outcomes	S. Saito

12:30-14:00
Théâtre Bordeaux

LANDMARK	One-year pacemaker dependency in PPI patients	P. Smits

Thursday 22 May

8:30-9:30
Room 341

REVERSE	DCB vs. DES in large coronary artery disease—patient selection and lesion prep matter	E. S. Shin

9:45-10:45
Room Arlequin

RNS DWP	Safety and efficacy of renal stimulation with direct wire pacing technique during renal denervation	F. Mahfoud

11:15-12:15
Théâtre Havane
Hotline / LBT session

Room 341

MASTER DAPT	Multiple events after PCI in patients at high bleeding risk	M. Valgimigli
	Antiplatelet therapy after PCI in high bleeding risk patients with chronic kidney disease	A. Landi

16:15-17:15
Théâtre Havane
Hotline / LBT session

DESyne BDS Plus	Site-specific antithrombotic therapy: DESyne BDS Plus Trial 24-month outcomes	S. Verheye

A full service CRO

We would be delighted to connect with you and dive into the latest developments in cardiovascular research. Let's explore cutting-edge ideas for innovative trials together and share our thoughts on unmet needs to improve patient care.

CERC new Trials

NETROD	BRATTEA	CYCLOPES	RCSI Boston Scientific
Eucalimus	OrbusNeich	Support C	OrbusNeich
Support Vitus	OrbusNeich	VitaFlow LIBERTY Europe	MicroPort CardioFlow
THE THRIVE	SoniVie	CONFORM	conformal
Lithotripsy-DCB	Evangelisches Krankenhaus Paul Gerhardt Stift / SHOCKWAVE MEDICAL	EBC DCB	Ceric Medtronic
TACTIC	Ceric Penumbra	SYNC	VDI technologies
rEpic PMCF	Epic B|BRAUN	iPerf Femoral Arterial Canula	iPerf
SAITO 1	CARANX MEDICAL	LEAVE NOTHING BEHIND	Meril

Come and meet us at Booth M11 Level 2

7-years follow-up COMPARE-ABSORB trial;

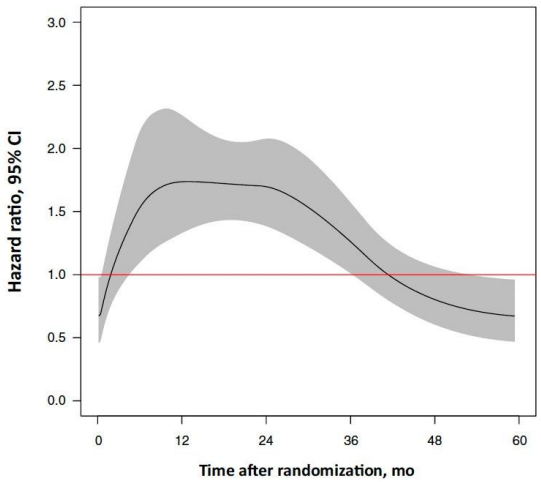
will the promise of BVS finally becomes true?

By Peter Smits

Second-generation drug-eluting stents (DES) show a linear target lesion failure (TLF) rate increase of ~2.0% annually up to 5-10 years post-implantation. To improve long-term percutaneous coronary intervention (PCI) outcomes, bioresorbable vascular scaffolds (BVS) and drug-coated balloons (DCB) aim to flatten this TLF curve. These 'leave nothing behind' strategies restore vessel physiology, pulsatility, vasomotion, and remodeling, avoiding neoatherosclerosis triggered by permanent metallic implants.

Previous trials comparing BVS to metallic DES reported higher TLF and device thrombosis rates, especially early on, due to suboptimal implantation techniques, small vessel selection, or thick strut limitations yielding less acute gain. A second wave of scaffold thrombosis around 3 years was linked to intraluminal dismantling of malapposed scaffold remnants. This raised questions about whether a BVS-specific implantation technique could prevent very late adverse events and if fully resorbed scaffolds eliminate late complications in 'uncaged' vessels.

Prior ABSORB trials (II, III, IV, China, Japan, AIDA) lacked a fully developed BVS-specific implantation protocol, excluded complex lesions (except AIDA), and had follow-ups limited to 5 years, despite BVS resorption completing between 3-4 years. The COMPARE-ABSORB trial hypothesized that BVS, using a tailored implantation protocol in high-restenosis-risk patients, could outperform everolimus-eluting stents (EES) after full resorption, with a 7-year follow-up. Spline analysis from 5-year ABSORB results supports this potential.



Spline Analysis Demonstrating the Hazard With Bioresorbable Vascular Scaffold vs Everolimus-Eluting Stent for Target Lesion Failure During 5-Year Follow-Up (Power et al. JACC Cardiovascular Interventions 2025;18:1–11)

At EuroPCR 2025, COMPARE-ABSORB's 7-year results, with a 96% follow-up rate, will reveal outcomes years after full scaffold resorption. This is the only trial assessing clinical results in fully 'uncaged' vessels. Will BVS and the 'leave nothing behind' approach finally fulfill their promise?

CERC at EuroPCR 2025:

Leading the LAARC Initiative to Shape the Future of Stroke Prevention in AF

By Philippe Garot

At EuroPCR 2025, the Cardiovascular European Research Center (CERC) took center stage as a driving force behind the Left Atrial Appendage Academic Research Consortium (LAARC)—a groundbreaking international collaboration designed to standardize clinical endpoint definitions in trials evaluating left atrial appendage closure (LAAC) for stroke prevention in atrial fibrillation (AF).

Co-chaired by four globally recognized leaders—Philippe Garot (ICPS Massy), Mohamad Alkhouli (Cleveland Clinic), Roxana Mehran (Mount Sinai), and Marie-Claude Morice (ICPS Massy)—the LAARC initiative builds on the legacy of ARC and VARC to provide a unified framework for LAAC research.

Initiated through two high-level meetings in Washington, DC (October 2024) and Paris (March 2025), LAARC brought together a diverse panel of experts from cardiology, neurology, imaging, and regulatory bodies including the FDA, European Notified Bodies, and Japan's PMDA. CERC played a pivotal role in the coordination, methodology, and drafting of the consensus manuscript, reinforcing its commitment to advancing academic-led innovation in cardiovascular science.

The proposed definitions cover critical domains such as mortality, stroke, bleeding, and device performance, forming the basis of standardized composite endpoints for future LAAC trials. With this initiative, CERC reinforces its leadership in ensuring scientific rigor, transparency, and patient-centered outcomes in interventional research.

As LAAC expands to broader patient populations, LAARC represents a vital step forward—ensuring trial consistency, facilitating regulatory dialogue, and ultimately enhancing the quality of stroke prevention strategies in AF.

EuroPCR 2025 marked the formal unveiling of this collaborative achievement—a testament to CERC's enduring dedication to excellence in cardiovascular research.

Presentation:

- *Session Academic Research Consortium on LAA Closure*
- *Room 252b*
- *Wednesday May 21st 9:45-10-45*

Did You Know?

CERC Was Founded by Some of the World's Leading Cardiovascular Experts

By Dragica Paunovic and Peter Smits

At CERC, innovation starts at the top. Founded by internationally recognized key opinion leaders (KOLs) in cardiovascular medicine, we are redefining clinical research with one clear mission: to address critical unmet patient needs through smart, intelligent study designs that demonstrate the true value of groundbreaking therapies.

Our founders don't just inspire — they lead. Each one actively drives our five specialized Innovation Groups:

- Coronary Interventions
- Structural Heart Disease
- Renal Denervation
- Pharmacological Management
- Clinical Trials of the Future

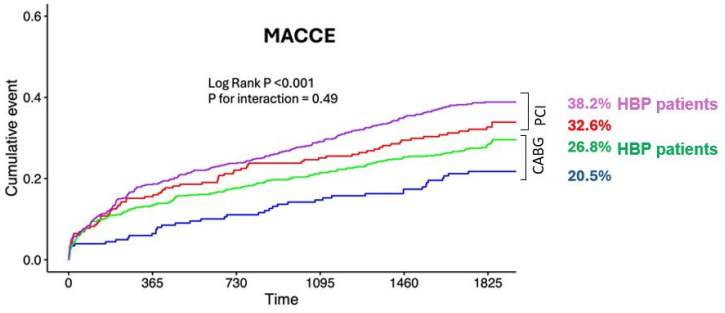
Our unparalleled expertise ensures that every trial is strategically crafted to turn your product's promise into powerful clinical evidence, driving guideline, upgrading recommendations.

When you partner with CERC, you are not just running a study, you are shaping the future of cardiovascular care. Let's work together to create smarter trials, improve patient outcomes, and bring the next generation of therapies to life. Talk to us today - lead tomorrow!

The Driving Force Behind Renal Denervation: Interventional Cardiologists in Action!

By Marie-Claude Morice and Estelle Darrau

Hypertension, a leading modifiable risk factor for cardiovascular disease, remains inadequately controlled in many patients, particularly those with resistant hypertension. The SYNTAX trial highlighted the consequences of suboptimal blood pressure control, showing that hypertensive patients, despite medical treatment, faced significantly higher rates of major adverse cardiovascular and cerebrovascular events (MACCE) at five years, whether treated with PCI or CABG. (figure 1)



Incidence of HBP on MACCE at 5 years after treatment with PCI or CABG (Data from SYNTAX trial)

Renal denervation (RDN) has emerged as a transformative catheter-based therapy to reduce blood pressure in patients unresponsive to medications alone. Interventional cardiologists are uniquely positioned to lead RDN's adoption due to their extensive expertise in catheter-based interventions and their daily management of ~80% of hypertensive patients with conditions like coronary artery disease, heart failure, cardiac valve issues, or chronic kidney disease. Their proficiency in vascular access, catheter manipulation, and intravascular imaging ensures seamless integration of RDN into clinical practice, optimizing patient outcomes.

The success of RDN relies on meticulous patient selection, procedural precision, and structured follow-up. Interventional cardiologists, who routinely manage hypertension-related complications such as multivessel coronary disease or heart failure, are well-equipped to identify ideal RDN candidates. By incorporating RDN into treatment algorithms, such as alongside percutaneous coronary interventions (PCI) in high-risk patients, they can streamline care, enhance efficiency, and minimize procedural burden.

Widespread RDN adoption demands guideline-directed practices, multidisciplinary collaboration, and robust education. Establishing dedicated hypertension programs that embed RDN within existing cardiovascular treatment pathways will improve accessibility and drive better outcomes.

In conclusion, interventional cardiologists are the driving force behind RDN's integration into routine care. As primary physicians managing hypertensive patients requiring catheter-based therapies, they lead the charge in leveraging RDN to reduce long-term cardiovascular risks, transforming patient care through innovation and expertise.

Dr. Roxana Mehran and Dr. Felix Mahfoud, CERC Board Members

The Future of Coronary Intervention:
The Leave Nothing Behind Study

By Davide Capodanno

The "Leave Nothing Behind" study is a step forward in redefining percutaneous coronary intervention (PCI). While drug-eluting stents (DES) have set the benchmark for treating coronary artery disease, they leave a permanent implant. This study explores whether alternative strategies—drug-coated balloon (DCB) treatment with selective bioresorbable scaffold (BRS) implantation or a primary BRS approach—can achieve comparable or superior outcomes while avoiding long-term foreign material in the vessel.

The trial includes patients with chronic coronary syndromes (CCS) and acute coronary syndromes (ACS), enrolled across 50 sites in Europe, Asia, and South America. It focuses on relatively young patients undergoing PCI for de novo native coronary lesions. By limiting the number of target lesions and the total treated length, the study aims to assess the feasibility of an approach that minimizes permanent implants.

The primary hypothesis is that a DCB-first strategy, with BRS implantation only when necessary, provides clinical outcomes at 12 months equivalent to those of a primary BRS approach. A key secondary objective is to determine whether these strategies improve long-term outcomes compared to current-generation DES.

Despite technological advances, DES still carry the drawback of leaving metallic struts in the vessel, which may affect long-term vascular function. Bioresorbable technologies offer an alternative, with the potential for natural vessel restoration and reduced need for prolonged dual antiplatelet therapy. However, their mechanical properties and risk of scaffold thrombosis remain subjects of ongoing investigation.

CERC plays a central role in coordinating the study, ensuring rigorous methodology and consistency across sites. The trial includes an angiographic substudy to assess net lumen gain and vascular function at 13 months, providing critical data on long-term vessel healing. Additionally, optical coherence tomography (OCT) is incorporated to evaluate scaffold behavior and vascular response.

The "Leave Nothing Behind" study represents an effort to shift PCI toward a future without permanent implants. The results will help determine whether these evolving strategies can redefine best practices in interventional cardiology.

CERC Announces Strategic Partnership with Europa Group to Advance Cardiovascular Research

By Dragica Paunovic

As 2025 opens new avenues for progress, we at the Cardiovascular European Research Center (CERC) are thrilled to announce a transformative strategic partnership with Europa Group, France's leading health information, publishing, education and events organization. This collaboration marks a pivotal moment in our mission to lead innovation in cardiovascular clinical research.

We have welcomed Europa Group as a minority shareholder, making it our largest investor. This investment is more than financial—it is a resounding affirmation of our shared vision to enhance cardiovascular healthcare through cutting-edge research, scientific excellence, and global collaboration.

Since our founding in 2008, CERC has earned a distinguished reputation for conducting high-quality clinical trials that address unmet needs, shape best practices and improve patient outcomes. Our work has been instrumental in advancing cardiovascular intervention and informing global standards of care.

Through this partnership, we unite with Europa Group, a leader in orchestrating global medical congresses and advancing medical education. Together, we are committed to forging a vibrant ecosystem that seamlessly connects clinical research with real-world implementation, expediting the development of groundbreaking treatments. By harnessing Europa Group's extensive network, we aim to amplify our global impact, while fostering innovation through collaborative platforms that bring together clinicians, researchers, and industry pioneers.

This strategic alliance empowers us to redefine cardiovascular research and drive transformative improvements in patient care. To our dedicated partners, clinicians, investigators, and supporters, thank you for being part of our journey. With Europa Group as our partner, we, together, are poised to shape a future of unparalleled promise in cardiovascular medicine.

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