The CERC Chronicle

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CERC at London Valves 2025

CERC proudly takes part in London Valves 2025 as a trusted European CRO leading major valve and coronary clinical studies. With a proven track record across both industry-sponsored and investigator-initiated trials, we turn smart design into strong results.

Discover three of our ongoing flagship studies in this issue, showcasing our commitment to scientific excellence and innovation.

New Clinical Trials at CERC

START YOUNG	Ceric Meril	CYCLOPES	RCSI University of Medicine and Health Sciences, 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	Ceric Meril
BASKET BALL	B|Braun	CLARIT	Ceric Philips
Validation of blood pressure monitors	B.Well		

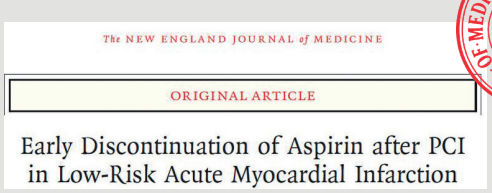
Come & Meet us at our booth A27

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.

Late-Breaking News

TARGET FIRST *results available in*
The New England Journal of Medicine



ABILITY DIABETES -GLOBAL

accepted in

THE LANCET

Concept Medical · Mount Sinai · CERC

START YOUNG – Redefining the Future of Aortic Valve Treatment

By Clemence Barnjak & Van Tuan Nguyen,
Clinical Projects Leaders

At the heart of START YOUNG is a shared ambition to demonstrate that the Myval balloon-expandable transcatheter heart valve (THV) can achieve outcomes comparable to surgical bioprosthetic valve replacement (SAVR) in patients aged 65–75 years with severe aortic stenosis. This investigator-initiated-trial unites interventional cardiology and cardiac surgery to confirm that a less-invasive TAVI approach can match surgical standards in safety and efficacy. The study is led by four outstanding coordinating investigators, representing the synergy between both disciplines: Dr. Tchetche and Dr. Garot, interventional cardiologists, and Dr. Doguet and Dr. Bapat, cardiac surgeons. Their leadership embodies the multidisciplinary excellence at the core of START YOUNG, bridging surgical precision and interventional innovation. As Clinical Project Leaders at CERC, we are privileged to oversee this ambitious, multinational project, ensuring its scientific vision is delivered through rigorous operational excellence.

A Study with a Forward-Looking Vision

START YOUNG study seeks to determine whether earlier, less invasive intervention using the Myval transcatheter heart valve could offer durable outcomes and improved recovery compared to conventional surgery. By extending TAVI evaluation to a younger cohort, START YOUNG could reshape future guidelines and patient management strategies. Driven by strong collaboration between interventional cardiology and cardiac surgery, the study brings together expert centres united by a shared goal: advancing science through teamwork and innovation.

Operational Excellence and Multinational Coordination

From the outset, START YOUNG required meticulous coordination across countries and languages. Our role as Clinical Projects Leader at CERC covers every operational layer: from protocol finalisation and regulatory submissions to site activation and study oversight.

The first challenge was ensuring compliance with diverse ethics and regulatory requirements across the participating countries. In collaboration with ethics committees, national authorities and hospital research departments, we successfully submitted and received approval in 6 countries and are currently preparing next submissions in close collaboration with our hospital partners. The first patient was enrolled in May 2025 at the University Hospital of Valladolid by Prof. Ignacio Amat-Santos and Prof. Stepanenko, marking an important milestone for the study.

Since then, active screening has been ongoing at participating sites.

Patient Safety and Data Quality

Since enrolment began, patient safety has remained central to the START YOUNG study. Sites are strongly engaged in screening and accurate data entry in the EDC system ahead of the first monitoring visit, ensuring high data quality from the outset and timely event reporting throughout the study. The CERC operational team acts as a safeguard, ensuring protocol compliance, patient safety, and data integrity, all of which are essential to the study's excellence and to achieving strong and reliable results for the primary endpoint analysis.

Building the Foundation for the Future

Beyond the operational aspects, START YOUNG carries a sense of responsibility. Managing a study that questions current clinical paradigms requires both rigour and vision. Our role extends beyond timelines and deliverables: it is about ensuring that the study remains faithful to its scientific and ethical foundations.

We are proud to see START YOUNG evolve from a concept into an active, multicentre reality. Each approval, site initiation, and investigator meeting reflects the dedication of a wide international network committed to improving patient care. We are delighted with the approvals already obtained in Spain, France, Switzerland, the Czech Republic, Serbia and Estonia and we look forward to securing the next authorisations and accelerating recruitment, driven by motivated investigators and a shared commitment to excellence and innovation in aortic valve therapy.

Looking Ahead

The coming months will focus on continued enrolment, new site activations, and regulatory submissions in additional countries. Our goal is to maintain the study's momentum while preserving the quality standards that define CERC's work.

START YOUNG will not only generate valuable data, it will also contribute to shaping the next generation of clinical guidelines in aortic valves therapy.

3rd START YOUNG investigator meeting, September 1st, 2025

Selution DeNovo Trial

By Estelle Darrau
& Nozomi Watanabe
Clinical Projects
Leaders

We are proud to share progress on one of our most ambitious and impactful clinical projects to date — the SELUTION DeNovo Trial — a pivotal international, study evaluating Drug eluting balloon (DEB) approaches to treating coronary artery disease. This project represents a significant milestone in our ongoing commitment to supporting innovative, data-driven advances in cardiovascular medicine.

SELUTION DeNovo is a prospective, randomized, multi-centre, open-label trial designed to demonstrate non-inferiority of the **Selution SRL Drug-Eluting Balloon (DEB)** strategy with that of traditional **Drug-Eluting Stents (DES)**. With an enrollment of over **3300 patients** across **Europe and Asia**, this study aims to generate critical clinical data that could influence future treatment pathways in interventional cardiology.
The study falls within the cardiovascular therapeutic area and has been designed to provide robust, real-world insights. As a randomized interventional trial, Selution DeNovo is positioned to address key clinical questions around long-term outcomes of 5 years and treatment durability for patients with coronary artery disease.

As the selected **full-service CRO** for this high-profile trial, our organization is responsible for comprehensive project delivery — regulatory submissions, site monitoring, data management, medical review, safety, corelab and statistical analyses, and last but not least, project management- with two Clinical Project Leaders.
This end-to-end involvement has allowed us to work closely with both the sponsor and investigative sites to ensure the study's scientific rigor, patient safety, and operational efficiency. Our integrated approach has been crucial in aligning trial objectives across multiple geographies and regulatory environments.

Like many global clinical studies, the Selution DeNovo trial has also presented unique operational challenges. The initial **enrollment timeline** experienced delays, requiring strategic adjustments and intensified engagement to sites to maintain momentum.
Furthermore, the large geographic footprint and diversity of participating sites brought variability in pathways and barricades reaching the same goal; demanding flexible, close oversight and proactive site training interventions.

Another significant aspect has been the **volume of reported adverse events**, consistent with the complexity of the patient population. A robust tracking and signal detection processes are made to manage this effectively, ensuring timely reporting and high data integrity, followed by Clinical Event Committee meetings consisting of 3 to 5 members, for close review of the source documents to ensure the event adjudication is precise and according to the definitions.

Despite the early challenges, the study has achieved several major milestones:

- Enrollment was completed on 31st July 2024, a significant achievement given the scale of the study
- The **data up to 1-year follow-up** has been successfully collected and the corresponding **database was timely locked**
- Notably, the **1-year follow-up was completed ahead of deadline**, reflecting strong collaboration across sites, effective patient retention strategies, and close project coordination.
- Finally, the primary endpoint results of the study, Target Vessel Failure -TVF (a campsite of cardiac death, target vessel myocardial infarction and clinically indicated target vessel revascularization) were presented at **Late Breaking Clinical Trials Session at TCT congress in October 2025**.

These accomplishments are a testament to the dedication of our project team and our partnerships with the sponsor and investigators across regions.
The study is now entering its **long-term follow-up** phase, with **4 additional years** of patient follow-up and planned monitoring. The focus will be on gathering data to assess the main co-primary endpoint TVF at 5-years and all **secondary endpoints**, including long-term safety.
Our team is preparing for this next phase with renewed focus and strategic planning. A **«lessons learned» session** was and will be conducted on ongoing basis to capture insights from the initial phase of the study — with an emphasis on enhancing site communication, refining data collection workflows, and optimizing monitoring approaches for long-term engagement.

Commitment to Quality and Impact
The SELUTION DeNovo trial exemplifies the type of work we strive to deliver: scientifically significant, operationally complex, and ultimately meaningful to patients and the broader medical community. We remain committed to ensuring the highest standards of quality, compliance, and collaboration throughout the remainder of the study.
As we look ahead to the continued execution of long-term follow-up, we thank our sponsor, investigators, and study partners for their ongoing trust and partnership. Together, we are helping to shape the future of cardiovascular care — one milestone at a time.

SELUTION DENOVO 1-year results at TCT 2025 by Prof C. Spaulding

Target First study– A Landmark for Antiplatelet Therapy

By Léa Dupré,
Clinical Projects Leader

The TARGET FIRST study is a multicenter, randomized controlled trial, sponsored by MicroPort and coordinated by CERC, investigated the following question:
Is early discontinuation of aspirin, specifically 1-month post-percutaneous coronary intervention (PCI), safe in low-risk patients with acute myocardial infarction (AMI) who have undergone complete revascularization?

The primary outcome was a composite of death from any cause, myocardial infarction, stent thrombosis, stroke, or major bleeding (defined by the Bleeding Academic Research Consortium [BARC] as a bleeding event of type 3 or 5) at 11 months after randomization (tested for non-inferiority). The main secondary outcome was BARC type 2, 3, or 5 bleeding (clinically relevant bleeding) at 11 months after randomization (tested for superiority).
A total of **1,942 patients were randomized across multiple European centers**. The study demonstrated the non-inferiority of P2Y12-inhibitor monotherapy compared to continued dual antiplatelet therapy (DAPT) with respect to Net Adverse Clinical and Cerebral Events (NACCE) at 12 months post-PCI. Importantly, the trial also revealed a **superiority in bleeding events**, thereby providing compelling evidence to support the strategy of early aspirin discontinuation in this well-defined, low-risk population.
The study was presented by the coordinating investigator Prof. Giuseppe Tarantini at **ESC Congress in Madrid**, end of August, and was simultaneously published in the New England Journal of Medicine, further validating its clinical impact.

TARGET FIRST trial results at ESC 2025, by Prof. G Tarantini

This achievement was a great experience for CERC team who successfully managed a complex, multicenter trial through the implementation of risk-based monitoring strategies, meticulous site management, and close collaboration with participating investigators.

All these tasks have required an excellent communication among Clinical Research Associates and Clinical Project Management team.

The collaboration with the sponsor was also exemplary, thanks to the precise oversight and clear messages. Dedicated tools were also used to improve interactions between CERC's crew and the sponsor, allowing the good connection between data management, statistics work, safety reporting, and monitoring adjustment. This cooperation ensured the high quality and timely delivery of the study results.

This study was a rewarding experience for everyone involved in the clinical research process and marked a meaningful step forward in improving post-PCI care.

Did You Know? CERC Was Founded by Some of the World's Leading Cardiovascular Experts

By Dragica Paunovic
& Peter Smits,
MDs

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
- PharmacologicalManagement
- 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!

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