The CERC Chronicle

Cardiovascular European Research Center

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EDITORIAL

Presentation of CERC Germany

CERC is pleased to announce the opening of CERC Germany in Essen under the aegis of CERC's directors and the dedicated supervision of its German founders, Drs. Christophe Naber, Horst Sievert and Felix Mahfoud.

Christophe Naber

Felix Mahfoud

Horst Sievert

The role of CERC Germany, which has been specifically assigned to Pavel Dublin, is to oversee the study sites involved in German trials coordinated by CERC.
CERC Germany's mission is also to manage any registry or clinical study initiated and/or conducted in Germany.

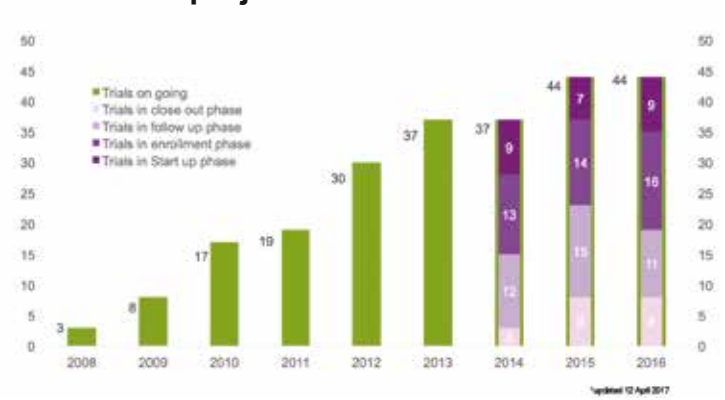
Marie-Claude Morice
CEO

CERC Areas of Activity

By Alaide Chieffo

CERC New Members

Number of projects and their status



CERC @ Euro PCR

The EUROPCR congress is of special importance to us this year since a large number of studies in which CERC participated will be presented during the hotline and other sessions. In particular, the primary endpoint at one year of the EuroCTO trial (randomized study of PCI versus optimal medical treatment) will be presented by its PI, **Gerald Werner.**

The VIVA (valve in valve) trial involving 202 patients will be presented by **Ran Kornowski.**

Various outcomes of the MAVERIC trial (ARTO device for reduction of functional mitral regurgitation) will be outlined by **Andrejs Erglis** and **Inga Narbute.**

Also scheduled for presentation are the latest results of WIN TAVI, a large registry dedicated to women undergoing TAVI, the BIVAL study (MRI-measured reduction of infarct size after bivaluridin treatment), FANTOM 2 and CENTURY II (Ultimaster vs. Xience randomized trial).

"New results will be presented from the LEADERS FREE trial: the 2-year results of the ACS subgroup, outcomes of the diabetic subgroup and results of cost-effectiveness evaluation."

Marie-Claude Morice
CEO

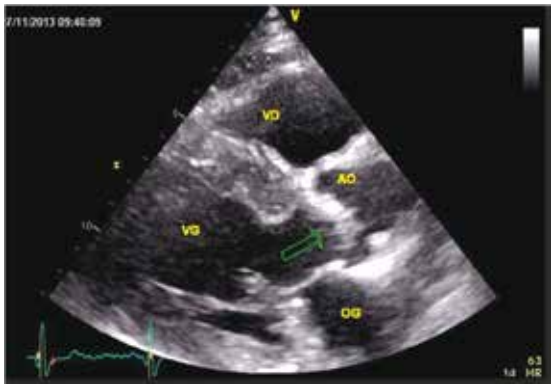
COME AND VISIT US
BOOTH M6
LEVEL 2

SELECTED CURRENT TRIALS AT CERC

VIVA

The VIVA study will be presented at EuroPCR 2017. It is the first prospective multicenter trial dedicated to the evaluation of CoreValve/Evolut R safety and efficacy in degenerated bioprostheses;

201 patients have been enrolled and the 30-day results will be shown on May 17th 8:56 in Room Maillot by Ran Kornowski on behalf of the VIVA investigators.
Importantly, since hemodynamic results are the most important challenge in this complex population, the presentation will include the results of echocardiography Corelab evaluation performed by CERC.



RAC

SCOPE II

SCOPE II, a European multicenter trial is now starting its enrollment phase: it is the first head-to-head randomised comparison between the Accurate Neo Symetis Valve and the Evolut R Medtronic in a large cohort of 764 patients, in 20 centers and 7 countries.

This study will provide important information for this device, recently acquired by Boston Scientific, which is expected to combine the advantages of supra-annular leaflets and self-expanding valves with a low rate of conduction disturbances.

Bernard Chevalier
Director

Ceric
Center for European Research Initiatives in Cardiovascular Medicine

CELTIC BIFURCATION STUDY

The **CELTIC BIFUCATION STUDY** has now completed recruitment of its 170 patients. The study examines outcomes for patients with Medina 1,1,1 bifurcation disease (excluding left main), where a 2-stent strategy is planned for PCI in 6 UK and 3 Ireland centers.

The experience of the operators prior to trial enrolment commencing was that the outcomes for bifurcation stenting with a culotte strategy was better with contemporary 2nd and 3rd generation DES than had been reported previously in the literature.

We are now into the clinical and angiographic follow-up phase and hope that this study will provide valuable information about treatment options for these complex patients in the future.

Boston Scientific

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Center for European Research Initiatives in Cardiovascular Medicine

CONSISTENT CTO STUDY

There have been major technological advances in CTO PCI over recent years, such that technical success rates of >90% are achievable irrespective of anatomical complexity.

This study has also completed recruitment and specifically examines longer term outcomes for patients who have successful CTO PCI who are treated with a 3rd generation DES (bioabsorbable polymer, Everolimus eluting Synergy stent).

There will be a close look at healing within the vessel after wire based ('within intimal plaque') and dissection based strategies. We are now in the clinical and angiographic follow-up phase of the study.

Simon Walsh
is the Chief Coordinating Investigator for CELTIC BIFURCATION and CONSISTENT CTO trials.

High Bleeding Risk patients (HBR)

As a group, High Bleeding Risk patients (HBR) were analysed for the first time in the LEADERS FREE trial, and results were reported in October 2015. These patients represent ca. 20% of PCI candidates, suffer very high event rates, and until recently, had been under-represented or excluded from nearly all randomised trials of coronary devices and antithrombotic regimens.

It is now apparent that tailored solutions are required, adapted to the specific needs of these “forgotten patients”. Intensity and duration of antiplatelet treatment need to be reduced as much as possible, and such strategies require solid clinical validation with each and every stent design that is deemed a suitable candidate.

Patients at High Bleeding Risk (HBR)

CERC is therefore proud to be associated with several new major clinical trials that focus on HBR patients:

- **LEADERS FREE II**, a single arm IDE trial in the US and Europe (BioFreedom DCS, Biosensors), currently enrolling (PI Mich Krucoff);
- **LEADERS FREE 3,** in the final planning stage, to evaluate a new cobalt chrome DCS platform (Biosensors) (PI Franz Eberli);
- **SENIOR,** a randomised trial of the Synergy DES (Boston Scientific) vs. a BMS, both arms with short DAPT, in elderly patients. Results expected later in 2017 (PI Olivier Varenne);
- **MASTER DAPT**, a randomised trial of short vs standard DAPT with the Ultimaster DES (Terumo) due to start enrolling in mid-2017 (PI’s Marco Valgimigli and Pieter Smits).

Philip Urban
Associate Director

How to turn the patient into a clinical research partner ?

UP SMART FOLLOW UP was created by CERC and BEPATIENT (expert in digital health) and designed as a new approach to patient follow-up. By connecting to a smartphone application, patients can perform their own follow-up directly from their home.

Why rethink patient follow up?

We have been involved in clinical research for the past 9 years, and on more than one occasion we experienced some frustration at the sub-optimal accuracy of the collected data, especially in trials where follow-up is scheduled only once a year. Indeed, most patients have difficulties remembering all their medication changes as well as the adverse events that may have occurred over a one-year period.

In order to improve the quality of the follow-up data, study patients can now be requested to connect to our user-friendly app on a regular basis in order to complete QOL questionnaires and update their health status and medical treatment (with special emphasis on DAPT for PCI trials).
They can also communicate with the investigator site via an open dialog box available in the app. This feature facilitates collection of source documents and decreases the loss to follow-up rate. Very often, a costly and time-consuming hospital visit can be replaced by forwarding ECG tracings and lab values (or any additional examination results requested by the protocol) to the site via the dialog box.

UP SMART FOLLOW-UP

UP smart FU also makes it possible to collect additional information thanks to connected devices. For instance, an activity tracker connected to the application allows us to assess the degree of mobility recovery after TAVI by measuring a patient’s ability to perform physical activities.

The application is customizable and includes optional connected devices or eLearning programs that can be implemented according to follow-up requirements. The content of each questionnaire as well as the frequency of required connections are thus tailored to the needs of each individual trial.

We believe that UP smart FU will fast become an essential component of all cutting-edge clinical trials at CERC.

Laure Morsiani
Clinical Operations Manager

Cardiovascular European Research Center

CERC
7, rue du Théâtre
91300 Massy France
Tél : +33 (0)1 76 73 92 10
Fax : +33 (0)1 60 11 17 91

www.cerc-europe.org

Marie Claude Morice
Chief Executive Officer
mcmorice@cerc-europe.org

Bernard Chevalier
General Director
bchevalier@cerc-europe.org

Philip Urban
Associate Director
purban@cerc-europe.org

Laure Morsiani
Clinical Operations Manager
lmorsiani@cerc-europe.org

Ute Windhovel
Clinical Operations Manager
uwindhovel@cerc-europe.org

Asmah Amrani
Contracts & Proposals Manager
aamrani@cerc-europe.org

Isabelle Simoes
Executive Assistant
isimoes@cerc-europe.org

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