The CERC Chronicle

European Cardiovascular Research Center

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EDITORIAL

The CERC comes of age

CERC now offers medical companies the opportunity to obtain a well structured, confidential and objective feed-back from a group of International experts in the field of cardiovascular medicine, in order to help them to make unbiased decisions for their future strategies. This is why we are holding our 1st Advisory board at EuroPCR this year. CERC was founded and conceived by physicians who have been involved in clinical research for many years and who, therefore, can develop and maintain a true partnership between industrial stakeholders and medical research teams, involved in the development of new concepts and solutions.

Today, we are convinced that CERC is in a position to contribute very significantly to the field of interventional cardiology, and its broad base of 17 Council members allows it to draw on a deep store of accumulated knowledge and expertise worldwide. The group is involved both with several important investigator-initiated projects, and also with some major industry-sponsored trials.

We know that device or drug companies that are active in cardiology have welcomed the availability of a new and dynamic CRO in Europe, and several of them have carried out a fully satisfactory audit of our activities. Because CERC is comparatively small and young, the staff is enthusiastic and committed, the overhead costs are limited, and our price policy is intended to remain competitive. We prefer quality to quantity, and intend to continue functioning with a group of manageable size. This approach should enable us to deliver the kind of service that our partners expect, while making it possible for us to continue enjoying our work at CERC as much as we have ever since day one!

Marie Claude Morice
Chief Executive Officer

Bernard Chevalier
General Director

Philip Urban
Associate Director

CERC Team at work

Late Breaking News

May 2010

FIRST ADVISORY BOARD at EUROPCR 2011

Central to the features that make CERC unique, is the diversity of expertise, experience, and geographic location of its council members. This certainly constitutes one of the mains strengths of CERC, and is one of the reasons why the companies, start-ups and others stakeholders in interventional cardiology find a particular interest to partner with CERC. It is therefore very important that council members take an active part in defining CERC strategy.
For 2011, our main objective is to make sure CERC council members will increasingly work as a team and will thus demonstrate their common added value to the cardio-vascular community.
In order to achieve this goal we are organizing our 1st advisory board just before Euro-PCR.
We will welcome 4 companies with a specific focus and key questions on which they require advice in order to make strategic decisions.
The Objective of the meeting is to offer to selected companies the opportunity to obtain a well structured, confidential and objective feed-back from a group of International experts in the field of cardiovascular medicine, in order to help them to make unbiased decisions for their future strategies.

May 2010

THEMIS

Developed by CERC European Cardiovascular Research Center | CliniGrid Healthcare community Orchestration

Themis, a CEC application developed by CLINIGRID and CERC was launched on the occasion of EUROPCR 2011.

CERC IS PRESENT @

PCR london valves | euro PCR | asia PCR

The CERC takes part in a number of International Congresses. In 2011 we participated in **Asia PCR**, **PCR London Valve** and **ICI Tel Aviv**.
Should you wish to meet with us, we would be delighted to welcome you to our **booth MO6, level 2** at the **EuroPCR 2011**.

New Contracts and selected projects

Nadia Benredjem - Clinical & Regulatory Affairs Manager

PLATINUM-PLUS

The European Platinum-Plus study is an Investigator-initiated trial (prospective, randomized multicenter) to compare the Promus Element stent to the Xience prime one, in an all comer format. The PI's are Jean Fajadet and Eulogio Garcia, steering committee consisting of Franz-Josef Neumann, David Hildick Smith and Sonia Petronio.
The protocol obtained the regulatory approvals for all participating countries and the study is currently in its recruitment phase; 757 patients have been enrolled to date. The CERC is in charge of the regulatory submission, study monitoring and setting up of the CEC and will be performing the data management and final reporting. The statistical analysis will be performed by Pr. Xavier Jouven from INSERM.

e-BioMatrix (France)

The e-BioMatrix protocol is a French postmarket registry. The leading PI for this study is Dr Eric Maupas from Nîmes. The purpose of this registry is to capture clinical data of the BioMatrix™ stent system in current practice in France. The study is being conducted in 30 French interventional cardiology centers. The majority of the participating sites were initiated over a one-month period.

To date, 504 patients have been included, and the recruitment rate is in line with the enrollment plan. The CERC is in charge of the regulatory submission, study monitoring, setting up of the CEC and will be performing the data management, statistical analysis and final reporting.

Partner EU and Prevail TA trials

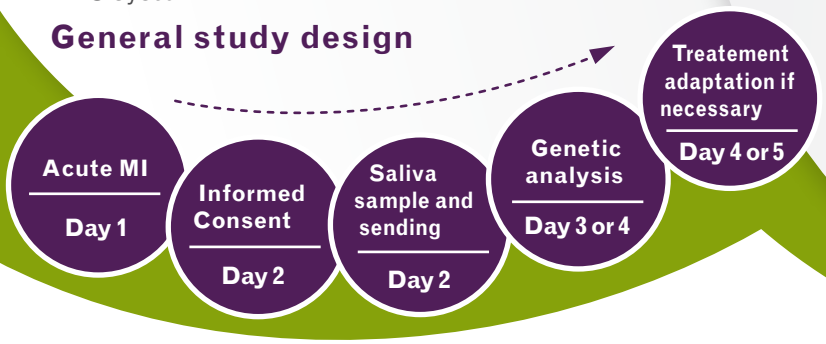
For the Partner EU trial (placement of aortic transcatheter Heart Valve) and for the Prevail TA trial (placement of the SAPIEN XT™ Transcatheter Heart Valve) the CERC is in charge of coordinating the CEC and DSMB.

For the CEC activities, CERC organizes and manages the meetings on a monthly basis. The CEC Members are Prof. Kristian Thygesen as Chairman, Dr. Philip Urban, and Pr. Philippe Menasché.

Focus

GIANT is a study sponsored by Biotronik, evaluating the role of genetic profiling of Clopidogrel response in 1 500 AMI patients, in 60 centers.
The Steering committee is composed of 4 leading physicians: Dr Bernard Chevalier, Pr Gilles Montalescot, Dr Loïc Belle and Dr Guillaume Cayla
The CERC is in charge of the study with 58 centers opened and 963 patients already enrolled. Inclusions started on June 2010 and should be completed by the end of October.
Primary Endpoint is to compare Deaths, MI and stent thrombosis at 12 Months between normal / rapid Clopidogrel metabolizer patients and slow / very slow Clopidogrel metabolizer patients.
The results of this study rely on the genetic response, which is delivered extremely efficiently by **Dr Jean-Sébastien Hulot's team** through the Clinigrid EDC system.

General study design



Dr Bernard Chevalier

Dr Loïc Belle

Dr Gilles Montalescot

Article

Why we need registries in interventional cardiology

Dr Philip Urban

Randomized controlled trials (RCT's) are the irreplaceable building blocks of evidence-based medicine. They are, however, complex and costly. They also usually aim at decreasing heterogeneity by targeting selected patients in selected centres, and by defining several trial-specific rules (procedure technique, duration and type of antithrombotic medication, tests to be obtained during the follow-up period, etc).

More recently, large multicenter international registries have gained acceptance as valid complements to the information derived from RCT's. To generate reliable results, they should, however, satisfy a number of conditions: have a detailed protocol with predefined endpoints and definitions, use a signed informed consent for every patient included, rely on a user-friendly electronic CRF with inbuilt help menus and plausibility checks, and ensure both full adjudication of all major adverse events by an independent CEC, and final data analysis by an organism independent from the sponsor.
Registries are less expensive to run than RCT's, have high patient acceptance, often allow for faster recruitment, and are well suited to the evaluation of several specific issues:

- Capture a better picture of "real life" since the inclusion/exclusion criteria are usually few or none, and the generally broad selection of participating centres may be more representative
- Assess and quantify safety issues (for example stent thrombosis or major bleeding) that may often be rare but clinically very important
- Analyse sub-groups (saphenous vein graft lesions, elderly patients, severe comorbidity, etc) that may not have been included in the original pivotal RCT's
- Monitor compliance with guidelines in routine practice (duration of anti-platelet therapy after stent implantation, for example)
- Compare practice patterns between centres or between geographical areas

CERC is now participating in the currently enrolling CYNERGY registry: it is planned to include 14,000 high-risk patients from 36 countries WW in two sequential arms (Cypher-Select+ stent now, NEVO stent later). Three high risk groups are included based on clinical or procedural parameters (diabetes, STEMI and multi-vessel procedures). Enrolment in the Cypher Select+ arm, for which currently 1,860 out of 5,400 patients are included, will be followed by inclusion of 8,600 patients in the NEVO arm. This new dataset will give us a great opportunity to see how practice will have developed over time and to analyse 2 year outcomes. It will also allow a comparison (with a non-inferior statistical design) between the two devices. This will be rendered all the more meaningful by the comprehensive assessment of chronic co-morbid conditions, so that any differences in baseline parameters can be accounted for as fully as possible.

We, at CERC, are proud (and thrilled!) to be involved in this new generation of large and powerful registries. We strongly believe they can significantly impact our daily practice and help us better care for our patients.

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CERC map & sites of council members

France - Germany - Israël - Italy - Latvia - New Zeland

Spain - Switzerland - United Kingdom