

EDITORIAL

Why a new CRO ?

Because the need for a completely different approach to clinical research became apparent.

How are we different?

The CERC was founded and conceived by physicians who have been involved in clinical research for many years and who are, as such, able to generate an optimal partnership between our industrial partners and medical research teams involved in the development of new techniques, new concepts and new treatments.

The CERC embodies the vital force of European clinical research.

Our industrial partners were also looking for a more cost-effective economic model which would not compromise quality. This was the aim that we strove to achieve by establishing a network with other clinical research organizations.

The CERC is not organized as a pyramid; it is in the shape of a star.

Marie Claude Morice
Chief Executive Officer

Bernard Chevalier
General Director

Philip Urban
Associate Director

CERC organization

Council Members :

Alaide Chieffo - Haim Danenberg - Eric Eeckhout - Andrejs Erglis - Eulogio Garcia - David Hildick-Smith - Adnan Kastrati - Thierry Lefevre - Chaim Lotan - Yves Louvard - Fina Mauri - John Ormiston - Horst Sievert - Martyn Thomas



Bernard Chevalier
General Director



Marie Claude Morice
Chief Executive Officer



Philip Urban
Associate Director



Nadia Benredjem
*Clinical & Regulatory
Affairs Manager*

CERC Team

- > Medical Writer
- > Information Technology (I.T)
- > Quality management
- > Project leaders
- > Data Management
- > Clinical Research Associates. CRA

Resource experts :



Nicolas Glatt
CLINIGRID E.D.C



Magali Bréhéret
Communication



Xavier Jouven
*INSERM
Associate Director
Biostatistic*

What's the purpose of the CERC Chronicle?

First of all, the originality of the CERC lies in its medical council which constitutes a natural network of Interventional Cardiology experts, all of whom are passionately involved in clinical research.

The CERC chronicle is primarily a means of communication between the council members, which was rendered necessary by the rapid growth of this 'start-up company' over the past 18 months.

With time we expect it to develop into the CERC network's communication channel for our industrial partners who have already placed their trust in our organization, or intend to do so in

the future, in order to accompany the clinical development of their innovative technologies. Finally, the CERC chronicle will serve as an interface with interventional cardiologists involved in clinical research programs.

Indeed, one of the CERC's ambitions is to promote the development of research projects initiated by physicians attempting to address unresolved clinical issues which are not directly related to any specific medical device.

We believe that such an approach is the key to broadening the clinical research spectrum. Projects of this nature require the financial support

of industry and one of the CERC's missions is to create the appropriate connections.

Two recent projects are concrete examples of the clinical studies that the CERC initiates and implements. Firstly, the strategy of bifurcation stenting following a request on the part of the European Bifurcation Club and the validation of the benefit of PCI in chronic total occlusions at the instigation of the European CTO club.

Long Live the CERC Chronicle !

Bernard Chevalier
General Director

Late Breaking News

► CERC IS PRESENT @

CERC is present in numerous congresses. In 2010 we participated in **EuroPCR**, **PCR London Valve** and **ICI Tel Aviv**. In early 2011 we will be present at **Asia PCR**.



CERC team at ICI Tel Aviv



CERC team at EuroPCR

- Alexandra Lanski has decided to leave the CERC management in order to carry out her new responsibilities in the United States. We were sorry to hear of her decision and would like to express our deepest gratitude to her for all her hard work and achievement over the past 2 years.

We are very honored and proud to welcome Philip Urban, as Associate Director within the CERC Management team, and we already know that he is going to bring a huge added value to the team.

► AUDIT

Cordis: We had a 4-day qualification audit by Cordis from June 25th to 28th June performed by Mrs. Alicia Rice, CBA, CSQE from AccuReg Inc.

Our Preferred partners Clinigrid and Inserm were also audited.

The audit was successful and we were selected by Cordis as a qualified CRO for Data management, statistical analyses and CEC organization.

Since its inception, the ambition of the CERC has always been to create a quality link between our industrial partners and the physicians involved in research.

New Contracts

► CTO Club and EBC

The CERC has been in charge of coordinating the funding and organization of two studies initiated by the two most efficient European clubs: the CTO club and the EBC club. Both studies are due to start soon.

► First in Man study

A first-in-man study investigating a new stent has been initiated in New Zealand. Riga's corelab (Andrej Erglis) will be carrying out the angiographic and IVUS analysis.



Dr Andrejs Erglis

► CYNERGY

Further to the favourable results of the audit conducted by Cordis, the CERC has been entrusted with major responsibilities in the CYNERGY registry (20,000 patients worldwide (excluding the USA), the coordination of CEC and DSMB meetings, and database management and biostatistics.

► EVIDENCE II

The protocol of the EVIDENCE II study (multicenter randomized French study evaluation the TITAN 2 stent) is currently being submitted to the Health Authorities. The CERC is in charge of setting up the CEC and will be performing data management and analysis, study monitoring and final reporting.

► QUALITE

Further to the audit conducted by Medtronic, the CERC has been given major responsibilities in the set-up and management of the QOL trial (A European prospective randomised (2:1) multicentre controlled trial evaluating quality of life improvement associated with PCI in stable angina) : Protocol drafting and submission, Data Management and randomization, coordination of the CEC, Statistics, Data analysis and final report.

► GIANT

Study evaluating the role of genetic profiling of Clopidogrel response in 15 000 AMI patients in 60 centers. CERC is in charge of the study with 40 centers opened and ¼ of the patients already enrolled.

► PLATINIUM PLUS

PLATINIUM PLUS is a randomised Post Market trial with 3000 patients in 60 European centers. It is a 2 / 1 study comparing Promus Element to Xcience.



Dr Jean Fajadet



Dr Eulogio Garcia

Acknowledgement

Two and a half very exciting and enriching years have passed since the CERC first came into existence. A very young, dynamic and enthusiastic team has been created and it has been a real pleasure and a highly rewarding experience to share the daily activities of the CERC with all its members who all come from very different backgrounds.

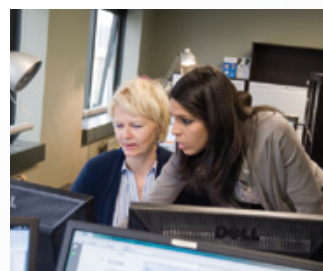
The participation of the council members in the CERC's projects has also proved a very valuable contribution to the achievements of our organization. We know that they are all very prominent physicians with many responsibilities and, despite their already substantial workload, we expect their increasing level of involvement in the CERC's activities to provide real added value to our common efforts.

We would like to express our gratitude to all of you for your unconditional loyalty and support which have helped us get through difficult times and will continue to guide us on the path to success

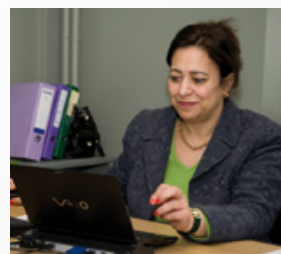
Marie Claude Morice
Chief Executive Officer



The spanish council members



CERC team at work



Nadia Benredjem



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CERC map & sites of council members



France - Germany - Israël - Italy - Latvia - New Zeland
Spain - Switzerland - United Kingdom