

## Latest News from CERC

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**THE CERC** council members are delighted to welcome a new member. We are pleased to announce that Dr Ibrahim al-Rashdan has joined us. We feel honored and fortunate that Dr Ibrahim al-Rashdan has decided to share his invaluable expertise with us and support our exciting new projects in the Gulf and the Middle East area.



Dr Ibrahim al-Rashdan

### Council members updated list :

Marie-Claude Morice (France)  
Bernard Chevalier (France)  
Philip Urban (Switzerland)

Alaide Chieffo (Italy)  
Haim Danenberg (Israel)  
Eric Eekhout (Switzerland)  
Anders Erglis (Latvia)  
Eulogio Garcia (Spain)  
David Hildick-Smith (UK)  
Adnan Kastrati (Germany)  
Thierry Lefèvre (France)  
Chaim Lotan (Israel)  
Yves Louvard (France)  
Fina Mauri (Spain)  
John Ormiston (New Zealand)  
Ibrahim Al Rashdan (Kuwait)  
Horst Sievert (Germany)  
Martyn Thomas (UK)

**The CERC** is currently on a steep expansion path as a result of the numerous new contracts which have been signed with start-up organizations as well as large medical device companies.

The sharp increase in our activity has resulted in the recruitment of 7 employees, including a CRA trainee, an administrative assistant and 5 CRA/project leaders.

The CERC has also recently doubled its office space and equipped new facilities in the same building.

### CERC's ongoing projects:

Thirty-eight studies are currently being conducted, representing a potential number of 385 investigating centers. A total of 8,542 patients have already been included in the trials managed by the CERC.

## CERC IS PRESENT @

**The CERC** takes part in a number of International Congresses. In October 2011 we were at **PCR London Valve**, in December 2011 at **ICI Tel Aviv** and in January 2012 at **Asia PCR**. We will be present at **EuroPCR 2012**.



CERC team at ICI-meeting 2011



CERC booth at London Valve 2011

# CERC and the start-up companies

## FOCUS : SPIDER STUDY

The Spider study is a First-In-Man study (51 patients included) initiated by Lifetech Scientific, a Chinese company established since 1999 in Shenzhen. The objective is to obtain CE mark for their PFO closure device. The Chinese cardiac devices market is expanding and we are proud to be involved in their studies for the first time at CERC. The CERC is in charge of the study and has opened two centers (one in Germany and one in France).

The Spider™ device is a PFO (Patent Foramen Ovale) Closure System consisting of a PFO occluder (self-expandable double disc device) and an introducer. Prof. Horst Sievert (CardioVasculär Centre, Frankfurt) included 50 patients in this study over a period of three months.

His site was very efficient, and was successfully audited by the German authorities. The advantage of working with small companies is that we are able to build close relationships and that one single individual is responsible for the whole study (1 person from Lifetech, 1 person from CERC).

Indeed, this study ran its course smoothly all along, despite the fact that during the study period three babies were born to the CRA at CERC (Lucie) and to the manager at Lifetech (Lily).

The study has now reached the site closure stage. We should be able to start the study report and write a scientific article soon.



Lucie's twins



Lily's baby

## New Trials & 2<sup>nd</sup> Advisory Board

- ▶ **EuroCTO** is now enrolling patients in a randomised comparison between PCI and Optimal Medical Treatment in centers with high level of expertise in CTO (CTO club members).
- ▶ **ITALIC PLUS** is an extension of the French 'ITALIC', an already completed trial. It is now enrolling patients in Europe and the Gulf area comparing 6 to 24 months of Dual Anti Platelet Therapy in patients non-resistant to aspirin.
- ▶ **ACTIVATION**, initiated by the UK TAVI group with most centers in the UK, but also in France and Germany, is a randomized comparison between PCI and a conservative approach before TAVI in patients with Coronary Artery Disease.
- ▶ **CENTURY II** is evaluating a new Limus based DES in a head to head comparison vs. Xience in Europe, Japan and Korea.
- ▶ **DANUBIO** is a registry which is evaluating the efficacy of a Drug Eluting Balloon for the treatment of in-stent restenosis and bifurcation lesions.



CERC

CERC team

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### ▶ 2<sup>nd</sup> ADVISORY BOARD

The aim of this advisory board is to provide selected companies with 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 make unbiased decisions for their future strategies.

After the very successful 1st ADVISORY BOARD which was held during EuroPCR last year, the decision was made to organise a 2nd ADVISORY BOARD.

We will welcome several companies with a specific focus and key questions on which they require advice in order to make strategic decisions.

The 2nd Advisory Board will take place on May 14th 2012.



1st CERC Advisory Board 2011