The CERC Chronicle

Cardiovascular European Research Center

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EDITORIAL

2014 is a very successful year for CERC with many very interesting studies about to start including a substantial number of investigator-initiated trials. These are precisely the type of studies which initially prompted the creation of CERC with the mission of acting as a link between industry and physicians in order to enable optimal research progress in our field. The foundation (FERIC) that we set up this year is perfectly adapted to these objectives and is now in full swing.

Pr Martine Gilard presented the results of the ITALIC study during the hotline sessions of the AHA with simultaneous publication of the corresponding paper in JACC. ITALIC was the very first study entrusted to CERC (many thanks to Abbott team for their support).

Finally, all these studies have allowed us to reinforce our teams which have in turn provided us with an incredible wealth of resources. For instance, the 17 different languages which are now spoken at CERC testify to the international status of our company, in addition to being invaluable tools for translating submission documents or communicating with study nurses from across the world.

Marie-Claude Morice

Special Advisors

With the purpose of becoming increasingly efficient in the organization of international research through a more global network, CERC has set up a partnership with four thought-leaders as special advisors: Alexandre Abizaid for South America, Junbo Ge for China, Mitchell Krucoff for USA and Shigeru Saito for Japan.

The first global meeting took place during the last TCT in order to establish the main objectives of these new relationships. Key points were easily selected: reinforcing cooperation with different CROs particularly for Latin America and China, and improving harmonization of clinical programs to ensure compatibility with specific regulations in Europe, USA and Japan.

The target is to provide our customers not only with a European response to their clinical needs but also to place European clinical activities in a worldwide perspective and to generate data which can be used for regulatory submissions and market access beyond Europe.

Bernard Chevalier

CERC is proud to announce that our CEO, Marie-Claude Morice, received the Geoffrey O. Hartzler Master Clinical Operator Award on September 14, 2014, at TCT.

The award is given to a physician who has advanced the field of interventional cardiovascular medicine through technical excellence and innovation. This was the 6th time the award was given, but the very first time it went to a woman.

In the packed ballroom, Martin Leon MD reminded the audience of Marie-Claude's numerous achievements as a pioneering clinician, academician and educator, and stressed her central role in pivotal trials such as MUST, RAVEL, REALITY, SYNTAX or EXCEL.

In her own address, Marie-Claude thanked Martin Leon and Gregg Stone, talked of her commitment to patient care and clinical research, expressed her gratitude to her main mentors, Jacques Crepeau and Jean Marco, and to her colleagues and fellows in Paris. She strongly encouraged women to take the leading roles they deserve in the field of interventional cardiology.

Concluding on a highly inspiring and emotional note, Marie-Claude ended by singing some lyrics of a famous French song by Barbara ("Ma plus belle histoire d'amour c'est vous") and dedicated it to her patients.

Philip Urban and Bernard Chevalier

Corelab MRI

CERC is now initiating an MRI corelab activity under the supervision of Pr Jerôme Garot who is heading one of the largest cardiac MRI programs in Europe, at Institut Cardiovasculaire Paris-Sud, evaluating more than 5,000 cardiac patients per year. MRI is the best standard to assess microvascular obstruction, oedema and infarct size, providing with very accurate and powerful endpoints in STEMI trials.

Dedicated software is able to precisely measure these specific criteria and, of course also, LV function and flow analyses.

Bernard Chevalier

FDA Meeting

In October, I had the opportunity to attend a meeting of the FDA entitled 'Data, Infrastructure and methods: Crossroads and Bridges'.

The topic of the meeting was to discuss different national registries and their scientific contribution. A number of very eminent participants were present: M. Krucoff, M. Mach, R. Waksman, to name but a few, as well as members of the industry and FDA officials.

The state of advancement of MDEpiNet was presented. The Medical Device Epidemiology Network Initiative (MDEpiNet) is part of the Epidemiology Research Program (ERP) at the FDA's Center for Devices and Radiological Health (CDRH). The initiative is a collaborative program through which CDRH and external partners share information and resources to enhance our understanding of the safety and effectiveness of medical devices after they are marketed.

By bridging gaps in evidence, developing datasets and creating new methods of conducting robust analytic studies, MDEpiNet aims to develop new ways to study medical devices that improve our understanding of their safety and effectiveness throughout their life cycle.

A list of registries called 'Passion' were reviewed. Thus, on the basis of studies such as the International Registry of vascular treatment and the International TAVI registry, innovative methodologies were debated such as the nesting of a randomized trial within national and international registries as illustrated by the TASTE trial (aspiration vs. no aspiration in primary PCI) inside the SCAAR registry, and the comparative safety of the radial vs. femoral approach in women within the US angioplasty registry. The issues of data validity, patient consent, absence of monitoring were addressed and the Mitral rhythm and heart failure registries were also discussed.

We were joined by our Japanese colleagues to take part in a discussion about international cooperation conducted in this new manner of approaching clinical research, i.e. nesting a randomized trial in a global registry, thus potentially allowing rapid enrollment and results.

Marie-Claude Morice

The ITALIC trial and DAPT duration: a major focus point at AHA 2014

During a hotline dedicated to DAPT duration after stenting, Martine Gilard presented the results of the ITALIC trial at AHA on November 16, on behalf of her co-investigators, and a publication was simultaneously available online in JACC. Over 2,000 patients were enrolled after PCI with one or several Xience EES (Abbott Vascular) and randomized at 6 months to either stop DAPT and continue aspirin alone or continue DAPT for a further 6 months. The non-inferiority primary endpoint was reached, with nearly identical and very low MACE rates in both groups, suggesting that when there have been no early complications, maintaining DAPT beyond 6 months is safe but quite unnecessary after PCI with EES.

CERC is particularly pleased to report on these results, since not only do they confirm the safety and efficacy of the EES, but after enrollment was completed, the data were collected, analyzed and published in a record time thanks to the commitment of investigators, CEC members and our own team.

During the same LBT session, the ISAR-SAFE results were presented by Stephanie Schulz-Schüpke: these largely confirmed the safety of 6 vs.12 months DAPT in a cohort of 4,000 patients treated with ca. 90% new generation DES.

Quite a different message was conveyed during the same session by Laura Mauri when she presented the long-awaited results of the DAPT trial. This uniquely large NIH funded study compared 12 with 30 months DAPT in nearly 10,000 patients treated with a 50/50 mix of 1st and 2nd generation DES. Prolonged DAPT was associated with significantly less ST and less MI, but with more bleeding and a higher all-cause mortality.

Emilie Piquet,
CERC - ITALIC Clinical Project Leader

It is not easy to reconcile these apparently conflicting results. Most commentators stressed that the "one size fits all" approach was now outdated. When considering the relative risks of thrombosis and bleeding, both the intensity and the duration of DAPT will increasingly need to be adapted to patient and procedure characteristics and also to the type of implanted stent.

Philip Urban

Inauguration of CERC New premises

On November 13, the CERC inaugurated the new premises of its Head Office located in Massy in the Greater Paris Area.

Ever since the CERC was founded in 2008, its teams have been constantly growing. It is important to underline that over a period of less than 2 years the staff has practically doubled from 23 to 42 employees. This rapid evolution has generated new requirements in terms of work space and office equipment.

The CERC teams are still at the same address and all of the staff members are now grouped on the 2nd floor in offices which are more functional and twice as spacious as before.

Operational teams have been provided with smaller scale open space offices in order to ensure optimal working conditions and well-being in a comfortable atmosphere, as well as smooth staff interaction.

The other members of the staff have either individual or shared offices.

The premises have been fitted with state-of-the-art equipment so that each employee may perform to the best of his/her capabilities.

The offices were specifically designed to integrate the most modern and reliable installations in terms of safety, such as secure access via a biometric control system and use of flame-retardant materials.

This move to a larger work space is intended to enable us to accommodate all the activities associated with the CERC's growth and to develop new departments.

We express our thanks to all our customers, partners, collaborators and friends who joined us for our inauguration party!

Valérie Gombau Delavoipierre

CERC Clinical Project Leader

Ute Windhövel:

Respect, patience, rigor, involvement, sense of humor, partnership, knowledge, calm, kindness.

These are the words that come to my mind when I think of how to introduce Ute Windhövel our senior Clinical Project Leader.

I have now been her assistant for two years, since I joined the company. Ute is one of the pioneers of CERC as she started in May 2010 when only 10 people were working in Massy.

Last but not least she is German, from Solingen. Her surname means "Wind of hill". The funny part of it is that my surname means "Mount of pearls" in an Indian dialect. Hill and Mount...! It was written in the stars that we should work together!

Lydie Moutoumalaya, Clinical Trial Assistant CERC

Lydie and Ute

VIVA Study

The CERC team has been working hard in order to prepare the VIVA study for the first site activation in early December.

This important international trial, sponsored by Medtronic, will evaluate the role of the Corevalve in the treatment of failed aortic bioprosthesis implantation, an important expanding field for TAVI procedures and the first prospective multicenter study dedicated to this specific indication. Twenty five centres in four countries will enroll two hundred patients using Corevalve including the new Evolut R generation.

Bernard Chevalier

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