The CERC Chronicle

European Cardiovascular Research Center

EDITORIAL

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CRO Session @ Euro PCR

As part of its long-standing didactic orientation, the EuroPCR board has decided to set up the first session of its kind entirely dedicated to Clinical Research Organizations.

The focus of this educational session will be on the specificities of CROs, and on their ability to coordinate clinical trials which may potentially generate substantial advancements in our specialty.

What are the latest achievements in coronary revascularization and what are the ongoing developments? Along the lines of the additional program on Innovation scheduled on Monday May 19th, the contents of this session will enable us to step into the future.

CERC is one of the 5 invited CROs and will present an outline of its organization: a CRO founded by interventional cardiologists with the objective of bringing to fruition progress-generating projects in our specialty.

Our mission is to provide expert guidance all the way from the design of trials to the presentation and publication of results in order to ensure optimal quality through the whole regulatory cycle of clinical research. We have obtained ISO-9001 certification and we have been successfully audited by all our prominent industry partners.

CERC has specific know-how in investigator-initiated trials which account for 50% of its activities.

The principal investigators of 'key' clinical trials managed by CERC will be presenting their trial designs and available results.

- GIANT (Sponsor BIOTRONIK France) : Genotyping acute MI patients treated by primary PCI to adjust thienopiridin treatment by Guillaume Cayla, 1,500 patients included in 57 French centers, one year primary endpoint was presented at the last TCT.

- LEADERS FREE (Grant BIOSENSORS Europe S.A) by P. Urban. First randomized, double blind trial conducted in patients at high risk of bleeding, treated with the BioFreedom eluting stent or a bare metal stent with dual antiplatelet therapy for one month only. The inclusion phase was completed on May 15th.

- The SENIOR trial (Grant Boston Scientific) was designed to address a similar issue. It is a randomized comparison between the Synergy Stent (BSCI) and a bare metal stent, with one-month antiplatelet treatment in stable elderly patients (over 75). The design of the study will be presented by O. Varenne, the study PI.

In a similar attempt to reduce the duration of DAPT, Terumo has proposed an extremely smart study design allowing OFDI assessment of the Ultimaster Stent endothelialization at 1, 2 and 3 months, the DISCOVERY 1 to 3 Trials. Dragica Paunovic will present the trial.

CERC goes Global

As Clinical Research is becoming increasingly global, CERC has developed robust relationships with Key Physicians from all continents. Prof. Saito is our special advisor for Japan. He kindly agreed to take part in a short interview with the CERC Chronicle.

Marie-Claude Morice

CERC Advisory Board

COME AND VISIT US@

CERC is present in numerous congresses: AsiaPCR, PCRLondon Valve, ICI Meeting at Tel Aviv and GulfPCR .

We will be present at the upcoming EuroPCR 2014. Do not hesitate to come and see us at booth M06, 2nd floor.

Interview with Dr Shigeru Saito, Shonan Kamakura General Hospital

Shigeru Saito

- What are the specificities of clinical research in Japan?

In Japan, PCI is performed in almost 2,000 hospitals. Thus, the case volume in most of the hospitals is relatively small (N < 200/year). This means that only a relatively small number of larger sites are appropriately equipped to take part in PCI clinical trials. Also, because of recent research controversies in Japan (the stem cell project was one of them), regulatory approval for clinical research is not getting any easier.

- How are European data perceived by Japanese regulatory authorities?

I think the CENTURY II Trial is a perfect test case for this question. Until recently, the PMDA (Japanese regulatory body) has often seemed to consider that the standards of European GCP were not quite up to Japanese standards.

NDR: CENTURY II is a Terumo sponsored randomised clinical trial comparing Ultimaster DES to Xience DES in simple and complex interventions with a large subgroup of patients enrolled in Japanese centres

- Is globalisation of clinical trials a challenge for Japanese physicians?

No, Japanese physicians have always welcomed the opportunity to participate in global international trials.

- You recently conducted a randomised clinical trial including a Japanese substudy, can you tell us about this experience?

My experience is summarized above (CENTURY II). The total number of cases enrolled in Japan is often small, compared to the US, for example. However, I know that we can provide very high quality data, with minimal delay, thus making it very advantageous to include Japanese centres in large international trials.

Bernard Chevalier

We have moved to another office

A new office is a great chance for new inspirations. Following a year of substantial achievements and consolidated growth, the CERC is happy to announce its recent move to bigger brand new premises.

When the adventure started in 2008 with 4 employees, it was of course difficult to imagine what would be the size of the company 6 years later. After a previous move from the center of Paris to Massy back in 2010, the CERC rapidly expanded its office to 2 different floors in 2011.

As the team is constantly growing, it was finally time to bring together all the CERC employees on a single level and this has been effective from the 12th May 2014.

We were all very excited by the project when the green light was given at the end of 2013 and we knew that good preparation was required in order to keep CERC's operations running. I think the whole team is ready to embark on a new chapter in the CERC history.

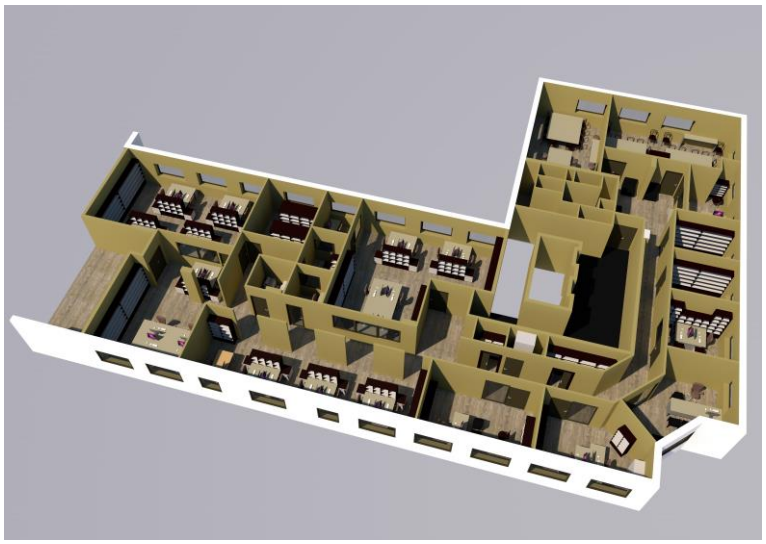
This further step in CERC's expansion is also the perfect moment to rethink our team organization and to take the opportunity to gather the workforces.

We know that the clinical teams as well as the way communication flows will be positively impacted.

Well-honed minds in a superb workplace. We remain focused on our objectives and we are committed to providing our clients with high quality services and to offering our teams a modern comfortable and pleasant environment.

We'll be hosting a happy hour soon, and if you're in the area, feel free to stop in and say hi! CERC address remains the same: 7 rue du Théâtre 91300 Massy France

Valérie Gombau Delavopierre



Cerc new premises

FERIC (Foundation for European Research Initiatives in Cardiovascular Medicine)

During the past few years, Investigator Sponsored Studies (ISS) have been the focus of growing attention in the field of cardiovascular medicine. This is because they have several distinct characteristics that make them well adapted to contemporary clinical research:

Since there is no direct industry sponsoring, the investigator and the trial data are rightly viewed as independent. Off-label applications are easier to explore, and some regulators accept ISS in support of product approval. Co-sponsoring of a projet can be implemented (for example a device and a pharma company can both contribute to funding the evaluation of a new combined drug & stent strategy).

ISS generally require an ad hoc structure to act as the legal sponsor of the project, since the investigators themselves are seldom in a position to do so, and any CRO that is contracted to run the trial cannot simultaneously be its sponsor.

After preliminary discussions with its industry partners, CERC therefore decided to set up a structure that would meet these needs, and FERIC and CERIC were recently created. FERIC is a non-profit Swiss Foundation that owns CERIC, an independent limited company organized to act as the direct sponsor of clinical trials and funded by grants from the industry. To date, two randomized trials have been signed, and several other projects are in discussion.

We are very happy that this new structure is now operational, and look forward to increasingly interacting with it in the future.

Marie-Claude Morice
Bernard Chevalier
Philip Urban

LEADERS FREE

Biosensors, CERC and all investigators are very happy to announce that the baseline clinical characteristics of the 2400+ patients enrolled in the

LEADERS FREE trial

will be presented for the first time at Euro-PCR 2014

(room 253, Wednesday, May 21 at 09:20 am).

First stent trial to specifically focus on patients at high risk of bleeding
First evaluation of a polymer-free DCS with clinical endpoints
First evaluation of an active stent with only one month DAPT

Data Management

Dhiwakar and Marion

Let me introduce our new Data Manager: Dhiwakar Anbarasu.

Dhiwa comes from India and has been living in France for 4 years. He used to play cricket, but unfortunately he had to stop since cricket is not a popular game here. However he still plays chess and seems to be a good strategist.

When I asked him about his hobbies he told me “I like to read Management books”, and to tell you the truth I was not surprised: “Dhiwakar” means “Sun” in Sanskrit and, indeed, since he started sharing my workload, I have had a clearer vision of the top of the Data Management Mountain!

Marion Martin, Data Manager CERC

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