

EDITORIAL

► Looking back over the 5 years

that have elapsed since we embarked on the CERC adventure, we can legitimately be proud of what our organization has accomplished in a relatively short period of time.

How time flies! We have now gathered enough momentum to pursue our goals with robust enthusiasm and unabated energy. We are continuing our expansion and are actively involved in the recruitment of new staff. We will soon be renting additional facilities to accommodate the CERC's ever growing team.

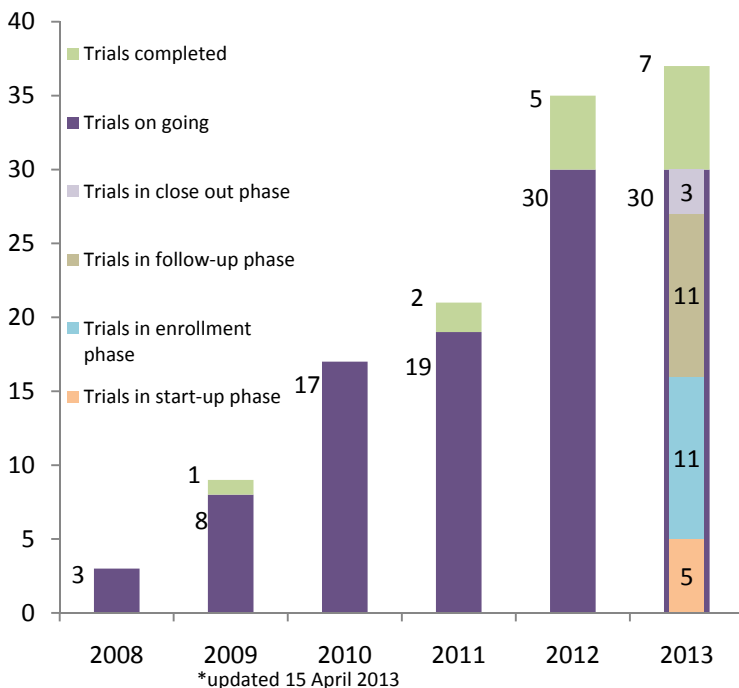
Our clients' satisfaction remains our prime objective. Our relentless efforts to reach and maintain high standards of quality have been rewarded by the achievement of ISO 9001 certification which we obtained earlier this year.

Our management team has also undergone a number of changes over the past few months and management responsibilities were redistributed. A General Manager and a Clinical Operation Manager were appointed in order to optimize our quality processes, task assignments and communication strategies.

We will continue to try to fulfill our major objective which is to increase the quality and visibility of clinical research in Europe. We already have a large number of interventional cardiology centers all over Europe providing rapid and high quality recruitment. CERC is a link between our industry partners and researchers.

Marie Claude Morice
President / Chief Executive Officer

Number of projects and their status



Staff and Clients progression at CERC



► **Bernard Chevalier :**

Interview with Thierry Herbreteau, President of St Jude Medical for Europe, Middle-East, Africa and Canada

Who are you ?

I'm Thierry Herbreteau, President of St Jude Medical for the Europe, Middle-East, Africa and Canada region. St Jude Medical is a global medical device company that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide.

SJM has been invited to the 2nd CERC advisory board, how different is this meeting with CERC medical council ?

It's a unique forum where as a company we can come to share and debate innovations, strategies, environmental aspects with European KOLs.

Did this interaction meet your objectives ?

Yes it did. We actually enjoyed it very much, finding the interaction with KOLs and experts as much challenging as constructive. It was open, thought provoking, pragmatic and intense. We brought it back home with good ideas and questions.

What do you expect from the CERC as a clinical research organization ?

Our expectations go beyond the classical CRO as it should also cover the clinical strategy itself with its implications from the regulatory to the funding/reimbursement aspects. We would like then to see it more like a true clinical partner and less like a clinical support/network.

► **Marie-Claude Morice:**

Interview with Dr Alaide Chieffo, MD Invasive Cardiology Unit, San Raffaele Hospital, Milan

Dr Chieffo, you are the PI of the WIN TAVI registry, can you describe the trial for us?

WIN TAVI registry is a prospective, multicenter, European study evaluating the safety and performance of transcatheter aortic valve implantation (TAVI) with all commercially available devices according to Valve Academic Research Consortium 2 (VARC 2) and Bleeding Academic Research Consortium (BARC) definitions specifically in the female population. Specific gender related issues will be investigated. A total of 1,000 patients will be enrolled in the study from 30 European centers and MSCT and echo substudies have been planned.

Why a dedicated trial for women, instead of analysing the gender data of the big post market registries performed by the companies?

WIN designed an ad hoc e-CRF with specific gender related questions that in our opinion could impact on the clinical outcomes of TAVI procedures in women population. These questions are not present in current big post market registries performed by the companies.

Why looking specifically at women data for TAVI is of particular interest?

Because women represent half of the population undergoing TAVI procedures as opposed to CAD studies where women usually represent a minority of the population treated.

► **Valérie Gombau Delavoipierre :**
ISO 9001: what does it mean?

In December 2012 CERC obtained the ISO 9001-2008 certification.

This certification is the result of a strong commitment from CERC's top management to bring the organization to a new dimension. The process is completely voluntary and aims to demonstrate that CERC is focusing on maintaining a high quality level and strives to guarantee constant commitment to clients. In the context of medical device clinical research, it gives a clear message as to CERC's ability to be a key player and to act as a credible partner between industrials and regulatory authorities.

ISO 9001 uniqueness:

ISO 9001 accreditation is granted for a period of 3 years but an audit is performed yearly by the certification body to ensure the organization still complies with the ISO standards.

The benefits:

A Competitive advantage

We consider ISO 9001 certification to be a major competitive advantage, as it ensures that our business objectives are matched by our processes and working practice. We thus raise CERC's performance beyond those of our competitors that are not using management systems.

To simplify and to streamline working methods

Our mission is to provide consistent and high quality services to our customers. The ISO 9001 certification demonstrates CERC's ability to meet worldwide recognized standards and, therefore, to meet client and applicable regulation requirements. In a very dynamic context CERC is working with a standard replicable methodology.

To intensify team spirit

ISO 9001 certification also ensures employees and management are working jointly to implement a company policy. We all target the same objective by increasing customer satisfaction.

To increase customer satisfaction

Our clients mean everything to us. ISO 9001 certification helps to demonstrate our ability to understand their needs and to answer them with appropriate solutions. It confirms to our customers that CERC is a trustworthy organization, working with tangible processes. The best reward we can hope for is to see our clients come back to CERC with new projects!



Chiara Bernelli from Milan, Cardiologist with the first WIN TAVI patient

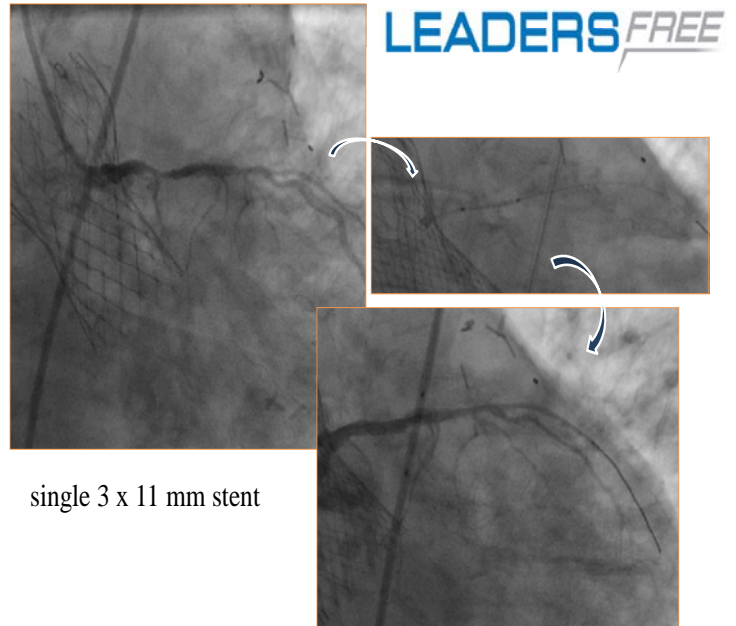
► Philip Urban : LEADERS-FREE

On the 12th of December, 2012 (12/12/12) the first patient was included in LEADERS FREE at La Tour Hospital, Geneva. He was a highly emblematic « non-comer » with a high bleeding risk, but is now doing well, 4 months after presenting with ACS and receiving a study stent to his protected LMS (see figures below). He is currently taking aspirin only, and has developed neither stent thrombosis nor further significant bleeding.

The trial aims to recruit ca. 2600 PCI patients considered at high risk of bleeding, randomize them to receive either a BMS (Gazelle TM) or a DCS (Drug Coated Stent - BioFreedom TM) in a double-blind fashion, and then prescribe DAPT for 1 month only, followed by long term aspirin alone. Both an efficacy (TLR) and a safety (cardiac death, MI or stent thrombosis) are the primary one year endpoints.

We estimate that patients who are candidates for enrolment represent ca. 10-15% of the overall volume of each participating centre. However, given the novel design of the trial, getting over the hurdles of the numerous Ethical Review Boards and National Competent Authorities is an ongoing effort, and has required a LOT of explaining.

In mid-April 2013, 15 centres have enrolled their first patient, and 13 more are expected to do so before EuroPCR this year. An investigator meeting is planned for May 23 in Paris. It will allow all concerned to share their initial experience: New, largely uncharted ground is being explored, and all investigators are in a position to contribute greatly to move this exciting project forwards!



single 3 x 11 mm stent

- **First LEADERS-FREE patient enrolled**
- **89 year old**
 - Prior CABG x 3 1994
 - Prior left carotid endarterectomy 2003
 - Prior BMS to RCA 2003
 - Prior TAVI (Corevalve) in 2010
 - **Creatinine clearance 19 ml/min**
 - Epistaxis 2 weeks ago
- Admitted for ACS with + troponin, Dec 8
- Stabilized on Med Rx



CERC is proud to announce

that the primary endpoint of the PLATINUM PLUS trial will be presented by Prof. Sigmund Silber during the LBT session at EuroPCR on Tuesday 21st May 2013 – Main arena 15:00-16:45



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 2013. Do not hesitate to come and see us at booth M06, 2nd floor.





visit our app



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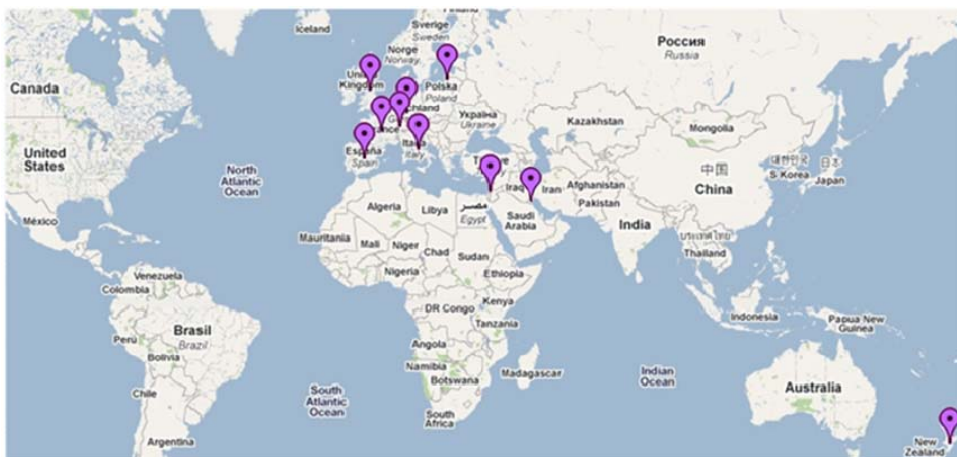
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CERC map & sites of council members

France - Germany - Israel - Italy - Kuwait - Latvia - New Zealand

Spain - Switzerland - United Kingdom