

EDITORIAL

CERC moves to the next level

ISO 9001 : Certification

The CERC has now been audited successfully by four major interventional cardiology companies and we have just been ISO 9001 certified: we are thus living up to our ambitions, and have spread our wings to embark on several clinical trials which are conducted far beyond European borders:

ITALIC +, an investigator initiated trial sponsored by Abbott Vascular with three centers in the Far East, is designed to compare two distinct durations of antiplatelet treatments in recipients of Xience stents.

CENTURY 2, sponsored by Terumo, will investigate a new SES in centers implanted all over Europe and also in Japan, under Japanese regulation, where legal requirements are known to be among the most stringent in the world.

LEADERS free, a clinical trial investigating the last-generation stent by Biosensors in patients at high bleeding risk, in 70 centers in Europe, Asia and South America. All our other studies are progressing well.

Our level of responsibility has naturally grown in parallel with the increasing number of studies in which we have become involved. Consequently, we have carried out a thorough internal restructuring plan. The CERC has hired a General Manager, Valérie Gombau Delavoipierre, whose professional background is ideally suited for this position.

Needless to say, the growing number of trials which we have been contracted to coordinate requires impeccable quality control on our part. Two staff members are in charge of Quality at CERC: a quality control coordinator (Lucie Vandromme) and a quality assistant (Maritta Farault). All our quality control operations are supervised by our partner, Sunnikan.

While we are very proud of our achievements so far, we still have a long road ahead of us. We are confident that our enthusiasm and energy will guide us along the way and keep us on the right path!

The CERC is a unique CRO thanks to the expert support of its council members. We like to think that all of them take pride in belonging to an organization whose ambition it is to impact the practice of Interventional Cardiology in a significant and durable fashion.

Marie Claude Morice
Chief Executive Officer



visit our app



The CERC released its iPad application last September. It was not intended to be just an app presenting the CERC's activities. Indeed, its graphic design and ergonomics were conceived to reflect the CERC's website atmosphere and our network approach.

The app is available on App Store for any iPad version. Download it:

<https://itunes.apple.com/fr/app/cerc/id547372707?mt=8&ign-mpt=uo%3D2>

Article

► Marie-Claude Morice

The CERC is a youthful and dynamic organization which places its trust in the younger generation.

Indeed, we received considerable praise for our offices which were very elegantly decorated and furnished by a team of interior designers in their early thirties. Subsequently, we contracted another team of dynamic thirty-year olds in order to re-design and enhance our website and create our apps. The results of their creative work can be seen at www.cerc-europe.org and app CERC.(download on your Ipad)

We are extremely grateful to our partner companies which have accompanied us since the inception of CERC. They have stood by us and have helped us to overcome our initial weaknesses and vulnerability. They have renewed their trust in our organization by requesting our services in the management of other trials. I would like to express my particular gratitude to Abbott, Biosensors, and Terumo teams.

We would also like to congratulate our council members from the UK for bringing two major studies to CERC, namely a TAVI trial, ACTIVATION (Martyn Thomas) and an Occlutec PFO closure trial, OPPOSE. (David Hildick Smith)

One of the CERC's missions is to impart its energy to the two most active and inventive interventional cardiology groups in Europe, the CTO club and the European bifurcation Club. We are currently coordinating their two studies but patient enrollment has been a little slow lately. The message that we would like to convey to them is that while technical virtuosity is highly praiseworthy, demonstrating the usefulness of these techniques to the scientific community is an even greater achievement.

Finally, we would like to welcome our new council member, Christoph Naber from Germany, who has recently joined the CERC. He is another young, bright and energetic addition from a major country where we intend to develop our activities.



Christoph Naber

► Valerie Gombau Delavoipierre, CERC General Manager



"In a lifetime, you do not have several opportunities like this one": this is exactly what I thought when I was given the possibility of joining the CERC this summer. After more than 12 years in clinical research, I felt very excited by the CERC story and

rapidly understood how I could fit into the organization. What I found when I arrived was impressive in many ways: a new and unique business model with already some very significant achievements. The presence of a board of experienced interventional cardiologists is a key factor enabling CERC to play a pivotal role when scientific and medical consultancy is requested by our partners in the medical device industry. The beauty of our approach is that we not only help the medical device companies to build their clinical research, but we do so always keeping in mind how this contributes to the well-being of patients and to the improvement of available treatment

for heart disease. As I adjust to my new position and interact with the CERC team, I feel that my role is now to help demonstrate that CERC can both continue to grow as a reference for benchmarking medical issues, and also provide the best level of service a client can expect from a CRO. Our goal is that along the entire process, from the first contact to the final clinical report, we conduct a project in an optimal fashion, always keeping in mind the high quality of the deliverables, the respect of the regulations and the client's satisfaction.

► Philip Urban LEADERS

On September 10, the first LEADERS-FREE investigator meeting took place in Frankfurt. 53 physicians from 23 countries in Europe, Asia and the Americas took part in an in-depth review of the project. Patient enrolment is due to start before the end of the year.



Leaders Free Investigators' meeting in Frankfurt

Interviews

► Marie-Claude Morice Interviews

Chaim Lotan: *President at Israel Heart Society*

For how long have you been organizing the ICI congress and what is its concept?

We had a meeting for interventional cardiology for more than 15 years but about 8 years ago we decided to change the format and concentrate mainly on innovation and change the name to ICI – Innovation and Cardiovascular intervention

Why did you decide to organize a cardiology congress dedicated to innovation ?

Il decided to move to innovation because I felt that this is the "new" hot thing and I was very much interested in innovation and also realized that this is our strength in Israel

You are one of the founders of CERC. How can such a structure help start-up companies and innovative projects?

CERC can provide startups with the know how and connections to do FIM and file for agencies (as CE)

Could ICI identify which innovative projects could be discussed during the next CERC Advisory board? And what benefits do you think they could derive from this board?

I think that we can (as a team) asses what are the good innovations and also help and open the door to the big companies...)



Chaim Lotan



Sanjeev Bhatt

► Bernard Chevalier

Interview with Mr Bhatt, General Manager of Meril Life

Could you introduce Meril Life?

Meril is the global medical device & technology arm of an Indian MNC group owned by Bilakhia group.

The company is dedicated to design, development, manufacturing and marketing of clinically essential, best-in-the-class and state-of-the-art medical devices

Head quartered in Vapi, the company is based 150 kms north of Mumbai.

The company was established in 2006, initially with an objective to enter the CardioVascular (Coronary Stents) and Orthopedic (Joints) markets and has since engaged enthusiastically and passionately in broader operational canvas such as diagnostics, endosurgery, ophthalmology, dental and imaging.

Today Meril's key focus beyond operational interests is R&D and Training/Education of Physicians and support staff.

Why did you decide to enter into the European market?

India always has more affection towards Europe. Not only due to its geographic proximity, but also since most Indians (doctors, engineers etc) are trained professionally in Europe. Secondly, Europe accounts for the second largest developed markets in the world. Third, Europeans understand technology well and appreciate it when they see it.

What are the challenges for an Indian company to become a player in Europe?

Today the world markets are getting homogenized in their behavior. So the market forces are pretty much the same across geographies. Still being an Indian company is not easy. It is easy to get slotted into the undifferentiated generic segment. In order to make the right impression in EU, Meril had to convince and demonstrate to EU customers, its high commitment to quality and technology and finally the clinical science. Interestingly, EU is quick to understand and appreciate high standards in quality towards manufacturing, quality assurance and scientific service. Finally, what convinced and continues to convince our customers is clinical science and our commitment to training and education.

How can a European CRO help you in this process?

A well rounded CRO can help a group like Meril in helping connect the dots. A group with experience in conducting high quality clinical studies and ensuring right investigators who hold highest quality of data generation and management will be a good asset to an aspiring group like Meril.

COME AND VISIT US @...

CERC is present in numerous congresses.
In 2012 we participated in EuroPCR, PCR London Valve .

In December we will be present at ICI Tel Aviv.



In early 2013 we will be at Asia PCR.



New at CERC

THEMIS

A new Web Based Electronic CEC



Themis is an innovative web based electronic CEC system designed to improve CEC processes and reduce both shipping and travel costs. It is also a major time and money saver.

Themis streamlines adverse event management throughout the study, managing all adjudication phases, from event preparation all the way up to event reconciliation.

When connected to a compatible EDC system, the entire adverse event management process is further simplified, by automatically importing adverse events for CEC preparation and providing users with direct access to the EDC event related content.

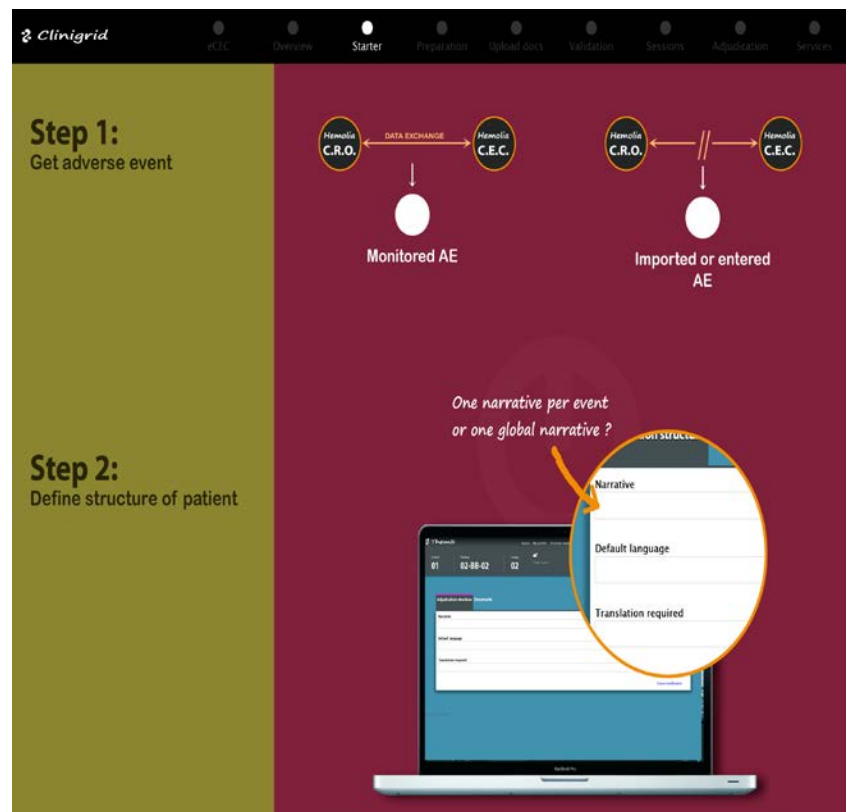
Themis provides both study centers and CERC with tools for sharing documentation and managing adverse events preparation.

Themis automatically resolves the adjudication status of the session events based on the study criteria, determining whether they are considered adjudicated or should be re-examined during a reconciliation session.

From a CERC user:

Ute Windhovel Ph.D - Clinical project leader

My first experience with the Themis adjudication system was the adjudication of end-point-related events for the PLATINUM PLUS study. I highly appreciate the easy to use system for both, the preparation and the actual adjudication process. The CEC members are able to access all information necessary for adjudication, the narrative, the source documents and the CRF. Moreover, they can review the angiography films thoroughly to decide if an event is Target Lesion, Target Vessel or Non-Target Vessel related. Each CEC member carries out the adjudication independently from the other members. As it is not necessary to find a common date, convenient for all members as in the case of physical meetings, adjudication of events can be performed much faster and deadlines for congresses can be met much more easily. The adjudication results are directly recorded in exportable tables, thus avoiding the need for entering them in a database after the adjudication session, as well as saving time.



CERC

7, rue du Théâtre

F 91300 Massy France

Tél : +33 (0)1 76 73 92 10

Fax : +33 (0)1 60 11 17 91

www.cerc-europe.org