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Editorial Note

For the past 10 years we have presented our readers with an editorial note generated from information given in the issue's table of contents. Because the information sometimes seemed redundant, I felt the need to change our format to one that more closely resembles an op-ed piece (of course related to an interesting cardiology topic). I will continue writing the editorial note, however, our readers are invited to contribute as well. Allow me to present to you the first, newly fashioned editorial note, which discusses a novel approach to conducting clinical trials.

A novel approach for a clinical trial based on a cardiology meeting

Imagine that in one week 250 patients are enrolled in a clinical trial that includes participation of 100 sites from 26 countries (five continents). While this may sound unreal, this novel concept was executed successfully in the Valentines Trial, held in conjunction with the 2010 Cardiovascular Research Technology (CRT) meeting in Washington, DC.

In June 2009 when I was solicited to conduct a clinical trial related to an interventional cardiology meeting, I immediately thought about our CRT meeting held annually very close to Valentine's Day. The concept was intriguing: we called for investigators via the Web, and interested parties could review the study synopsis presented on the designated Valentines study site, www.valentines-trial.com. Those who committed to participate were asked to enroll patients in the days surrounding the meeting. With the enthusiasm of an international steering committee representing Europe, Asia, and the United States, a clinical protocol was assembled to test the safety and efficacy of the Dior (Eurocor GmbH) drug-eluting balloon for the treatment of bare metal and drug-eluting in-stent restenosis.

We called for participants on two Web sites: www.pcronline.com and www.crtonline.org. Within a month, more than 100 individual investigators volunteered to participate in the study and to enroll patients from Valentine's Day through the last day of the 2010 CRT meeting, comprising 7 days of enrollment. In total, we selected 104 investigators from 27 countries who qualified for participation. The study, sponsored by Eurocor GmbH, was initiated as a collaboration among the sponsor, CRT 2010, the international steering committee, and the local investigators. Eurocor arranged the appropriate approval with each site in accordance with the International Conference on Harmonisation (ICH) guidelines, local laws, and regulation. An electronic data capture system was designed and deployed, and a data monitoring structure was organized to ensure that approximately 50% of the data were verified. Throughout the 7-day enrollment period, 252 patients considered eligible according to the inclusion/exclusion criteria were enrolled. Baseline clinical and angiographic characteristics and in-hospital outcome were entered into the electronic database within 28 days. Nine months' clinical follow-up is complete and will be presented at CRT 2011 and soon in print.

For those of us involved in the Valentines Study, it was an interesting exercise to test the feasibility of running a quality, midsized clinical study via the Web, which, rather than defining a total enrollment number, instead defined an enrollment/treatment period of 7 days. Overall, this experimental endeavor was successful and showed that the interventional cardiology community is well connected via the Web and is certainly capable of executing a Web-based clinical study that met the total goals. Advantages of this novel approach include quick enrollment as well as the capability to enroll a diverse study population that represents the international, real-world performance of a device or drug. This approach enabled us to build a Web-based network of hundreds of sites that each contributed a small number of study subjects and to expedite the enrollment period, which may normally take months and sometimes years. Having a large number of sites eliminated the potential bias of high enrollment per site.

What is the importance of linking a study like this to a major cardiology meeting? We found in the Valentines Trial that the linkage to CRT 2010 and CRT 2011 not only generated great enthusiasm from investigators but also set forth transparent data collection deadlines, thereby allowing the investigators to feel more in touch with this study's data and to know that their participation is a part of a scientific

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meeting. Through this meeting, the participating investigators can identify with other investigators and share their experiences while learning the results.

Throughout the trial, we detected three novel components that differentiated it from traditional trials. First, we called for interested participants, rather than soliciting from a selected list of potential investigators. Second, the number of subjects enrolled was not determined upfront; rather, the enrollment period determined the number of enrolled subjects. Finally, linking the study to a scientific meeting enhanced the enthusiasm, the hype, and the participants' commitment to conduct a high-quality study.

This novel trial concept did come with challenges as well. For those investigators not actively taking part in other clinical studies, it was difficult finding a common denominator in terms of language and cultural barriers in order to conduct a high-quality study, to follow meticulously the inclusion/exclusion criteria, and to submit accurately the data points into the electronic data capture system. It was also challenging to control the significant number of investigational sites spread over five continents and to ensure that, because a small subjects were enrolled in each center, the results were not influenced by a learning curve with the device. Despite these challenges, the Valentines Trial was well executed and met the industry standards expected from such postmarketing studies.

The concept of a meeting-based, global study is intriguing and should be used for postmarketing evaluation of drugs and devices; and perhaps for selected pivotal and randomized clinical trials once a solid network of investigators has been established. We hope that the success of the Valentines Trial may lead to the initiation of similar studies at future meetings and help the interventional cardiology community transition from the traditional management of clinical trials to this novel approach of meeting-based clinical trials. Time will tell if the Valentines Trial is among the first in changing the landscape of global clinical trials.

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