Heart of the Matter

Late-Breaking Clinical Trials: It's All Theater

BY SIDNEY GOLDSTEIN, M.D.

Achieving selection at a national or international program for the late-breaking clinical trials session is the "brass ring" for both the clinical trialist and sponsor, whether they are the pharmaceutical industry or the National Institutes of Health. A double brass ring is achieved if you can get simultaneous publication of your results in JAMA or, even better, in the New England Journal of Medicine.

This year at the American College of Cardiology meeting there were three separate late-breaking clinical trial (LBCT) sessions with 13 presentations and three sessions devoted to "smaller" LBCTs with 18 presentations. The mini-LBCT is a new addition to the program, as if the 13 LBCTs were not enough. In addition, the Innovations in Intervention Summit (I2) held five LBCT sessions with a total of 24 presentations. This seems to be a high water mark and may be a manifestation of either the plethora of clinical trials coming to fruition at this time or a lowering of scientific standards.

These are high-visibility sessions presented in auditoriums with audiences of up to 5,000, made up of doctors, nurses, a smattering of members of the press and, most importantly, representatives of the investment community. Measured against the more than 30 simultaneous sessions held at the mammoth Morial Convention Center in New Orleans with audiences averaging 100 or less, the magnetism of the LBCTs is obvious. At least 20% of the attendees at the annual meeting are breathlessly awaiting the next LBCT presentation.

The selection process for the program and its presentation, and, if you are lucky, a simultaneous publication, is tied up in a litany of embargo agreements meant to prevent any release of information prior to that magic moment of presentation. The precise penalty for breaking the embargo and the prerelease of data is not spelled out. Unlike other scientific presentations, no abstracts are printed in the program, so the audience is in the dark about both the design and the outcome of the trial. The reason for all this secrecy is not entirely clear, but more than likely it can be ascribed to marketing on the part of both the College and the journals.

Why good science should be cloaked in such mystery is not obvious. This year, the veil of secrecy was lifted from two presentations—on ranolazine and the investigational antioxidant succinobucol—that were preceded by reports by the drug makers of their failure to achieve the primary end points because of a potential impact on the stock price of the drug. Of course, not all of the trials present have positive outcomes. In fact, a positive outcome is somewhat of a rarity even though the science may be very important.

All of this hocus-pocus has absolutely nothing to do with science or with the dissemination of information other than restricting it. If anything, it suppresses and delays the process. It does result in inflating the impact of the LBCTs, no matter what their scientific and clinical importance, and it diminishes the value of the science of other presentations.

One way to deflate the hype is to publish in advance the abstracts of the LBCT, either in the program or as a supplement handed out at registration. This would provide the audience with some background to evaluate and understand the importance of the data when the magic moment of presentation occurs. Of course, the best way to deal with it is to remove all the restrictions associated with the presentation and publication of LBCTs, but, as one cardiology wonk put it, "It's all theater." ■

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