DUCCS and SWANS: When U.S. Site-Based Research Was Highly Successful

In this issue of *JACC: Heart Failure*, we received another delivery to the Dead Letter Office with the PRAISE-2 study by Packer et al. (1,2).

One of the many important themes from this paper was the outstanding recruitment of a very difficult patient population. The PRAISE-2 study set out to enroll nonischemic cardiomyopathy patients with an EF of <30%, NYHA class IIIB to IV on no background beta-blocker therapy. One might imagine that this would be an enormous challenge. By today's standards, it would likely have a recruitment rate of less than 0.25 patients per site per month. However, in this trial, two sets of competing consortia were set up for enrollment. The “DUCCS” group (the “Duke University Cooperative Cardiovascular Society”) — a group of former Duke University trainees, predominantly at large private practices; and a competing network of independent investigative sites, entitled “SWANS” for “Sites Without A Name Study group.” Throughout the trial, the DUCCS and the SWANS competed as teams against each other and challenged each other to have the highest recruitment and the best quality data for the study. In this capacity, the trial successfully enrolled over 1,600 patients in a 4-year period, with 50 sites representing approximately 0.75 patients per site per month, an unprecedented enrollment rate for this subset of the general heart failure population. While the trial did not confirm the hypothesis that there would be improved survival in this patient population with amlodipine, it did achieve the study goals by accruing the requisite number of clinical events.

Today in the United States we see a much different environment for site-based research. Many studies recruit at far lower rates, require a much greater number of investigative sites, and often require extensions of timelines and expansions of sites beyond North America into Eastern Europe, Russia, South America, and Southeast Asia. There are many reasons for the challenged environment for conducting site-based research in the United States. The increased regulatory environment, the reduced reimbursement rate, the increased overhead for conducting research, the migration of patients out of academic and tertiary care centers to other centers who may have less infrastructure for conducting research, and the reduced payments by sponsors to support cardiovascular trials are among the issues that have significantly challenged the site-based research infrastructure for cardiovascular trials in the United States. We are now seeing that many trials are conducted solely outside the United States. It is important to remember, however, that as these trials are conducted outside the United States, the demographics of the patient populations, cultural and genetic differences, and the treatment goals and interactions all may play a role. Results obtained may be quite different than if a significant number of patients were recruited in the United States, which challenges the applicability of therapies in the United States. Furthermore, regulatory bodies are often forced to make incomplete decisions because of the lack of U.S. citizens participating in these trials. One of the goals of the *Journal* is to bring greater attention to the importance of site based research. Heart failure continues to remain a cardiovascular condition with an unacceptably high morbidity and mortality despite evidence-based therapies. Given this high event rate, it seems imperative that as
a community of healthcare providers, we should continue to foster the advancement of knowledge, so that we can bring more therapies to the bedside to improve the quality of life for patients. The only way to do this is to have a 100% commitment from the community to participate in these trials, to provide the highest level of quality data, and to be committed to the conduct and completion of the questions evaluating new approaches, diagnostics and therapeutics for our heart failure patients. The PRAISE-2 trial reminds us of an era when there was a great enthusiasm by the heart failure community to participate in clinical trials and achieve results quickly to answer questions. While PRAISE-2 was a neutral trial, it helped redirect our efforts into different directions and was highly informative in completing the body of knowledge regarding calcium channel antagonists in congestive heart failure. I hope by bringing this trial into the public arena, we are not only focusing on the results but also on the method of conduct of an important trial. The consortia approach of the DUCCS and SWANS should challenge us to bring back this era to the United States, where we are committed to advancing knowledge through site-based research.

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REFERENCES