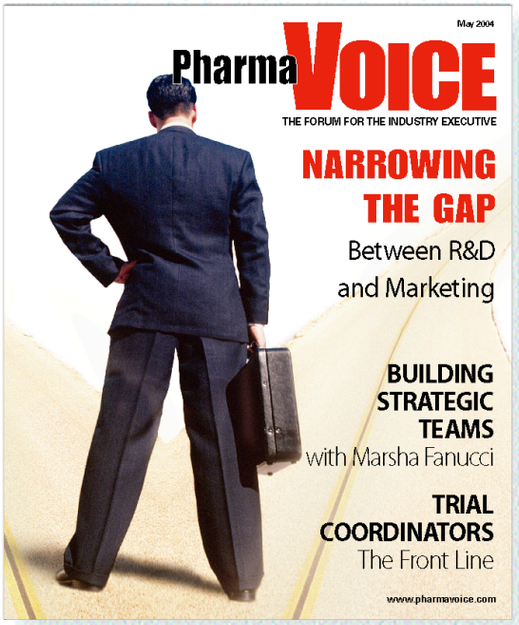
LETTERS



Information for Real-World Value Messages

The combination of hands-on resources of a CRO supplemented with information from health-insurance claims allows for faster patient recruitment and more bang for the research buck.

— Nancy A. Dreyer, MPH, Ph.D.

Building bridges

There are other valuable resources for helping R&D bring the commercial perspective earlier into the drug-development process, beyond those discussed in the May issue.

There are HIPAA-compliant methods that permit use of administrative health-insurance claims data to target doctors with patients of interest to expedite and enrich clinical research. Health-insurance claims data provide comprehensive information about illnesses, hospitalizations, prescription drugs, and the costs of these products and services.

When claims data are coupled with information obtained directly from physicians and patients participating in trials and registries, a tremendous amount of information about diseases and users of particular drugs, including those of the competition, can be assembled.

The combination of hands-on resources of a CRO supplemented with information from health-insurance claims allows for faster patient recruitment and more bang for the research buck.

Understanding disease diagnosis and treatment patterns, prescribing practices, and healthcare behavior helps guide development of products to meet real needs, and can support marketing by providing information for real-world value messages.

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The trial must be the priority

I read the May 2004 article — The Coordinator: The Heart of the Study — with interest having reviewed the statistics from the BBK survey several days earlier. I recalled reading an article several years ago entitled The Invisible Hand in Clinical Research: The Study Coordinator's Critical Role in Human Subjects Protection [The Journal of Law, Medicine & Ethics, 30 (2002):411-419 ©2002 by the American Society of Law, Medicine & Ethics] that quoted a figure of 128 different activities performed by study coordinators across 19 skill sets.

These skill sets included everything from teaching skills to clinical skills to people skills. The study coordinator, according to the authors, has the challenge of serving three masters: the patient, the patient-turned-subject, and the study.

Adding the difficulties of learning sponsor SOPs, new EDC systems, and HIPAA compliance has only increased their responsibilities exponentially. This leads to the question: Do study coordinators have the time to fulfill the most important function they have in the clinical-research arena — the protection of, and ethical treatment toward, human subjects?

According to the results from the BBK survey, if a coordinator is responsible for more than two to

What's Your Opinion?

REGISTERING RESULTS: A PUBLIC DATABASE OF CLINICAL-TRIALS INFORMATION

GlaxoSmithKline has announced that it will publish clinical-trial results for marketed medicines on the Internet. GlaxoSmithKline is defending itself in a lawsuit that claims the company suppressed negative data on one of its drugs. The company has stated that, independent of the pending litigation, it will create an electronic database to be called the GSK Clinical Trial Register, which has been in development for some time and which it plans to make accessible to doctors and the public.

"The GSK Clinical Trial Register will be a major advance in providing online access to information to support patient care, facilitating access to study summaries by putting them on a single Internet site," Tadataka Yamada, GSK chairman of research and development, said in a published statement.

A group of editors from leading medical journals said they were considering a proposal that would require drug manufacturers to register their clinical trials in a public database once the trials begin. In a published article, The International Committee of Medical Journal Editors said such a database would allow the public to see if results are submitted on schedule or look for a pattern of companies quietly dropping trials that do not have the hoped-for outcomes. The American Medical Association also is calling for disclosure of all medical studies to the public.

PharmaVOICE wants to know: Should companies have to register their clinical trials as they are initiated in a public database?

WHAT'S YOUR OPINION?
Please e-mail your comments to feedback@pharmavoice.com.