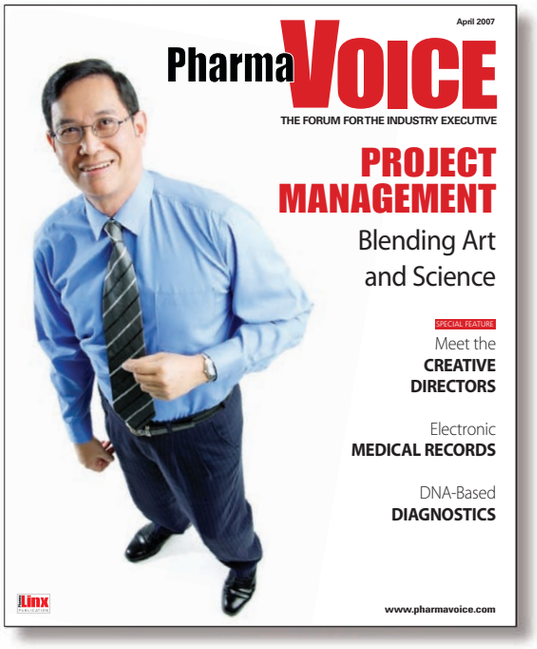
LETTERS



Project Teams Can Benefit from Better Data

The one thing we see more than anything else, regardless of company size, is a lack of trustworthy data.

— Karen Briegs, Director, 3C Company

Embracing Business Intelligence

It was so interesting to read the thoughts of the various project managers on the evolving role that project managers hold in the process of clinical R&D. My firm works with several companies to help them improve the infrastructure they use to support effective planning and management and the one thing we hear about more than anything else, regardless of company size, is a lack of trustworthy data. The tools that are used in R&D — CTMS, EDC, CDM, IVRS, EPS — are all still so siloed. There is precious little interaction or ability to join together the information from these sources to make a meaningful assessment of a project's status. Teams get tangled in comparing reports and spreadsheet analysis, and they stop talking about the problems that these reports are unveiling.

Shifts in market share in the CTMS space, new ideas for using nontraditional sources of data for trial tracking, and the whole business intelligence explosion that is ongoing in clinical research and development overall are extremely interesting.

Gartner Research released a paper recently that echoes the PharmaVOICE article that predicts that by 2008 (just around the corner) life-sciences companies will recognize the benefits from implementing formal performance measurement and that there must be a connection between these metrics and actual operational tasks goals. This is a hot topic growing hotter as companies start to see the firms that have embraced business intelligence become streamlined and efficient. I would like to read a follow-up PharmaVOICE article that discusses some of the excellent solutions that exist to support these initiatives.

Karen Briegs
DIRECTOR
3C COMPANY

What's Your Opinion?

WHAT IS THE NEXT EVOLUTION OF LATE-STAGE CLINICAL STUDIES?

In May, the Senate approved by a 93-1 vote legislation that would require the Food and Drug Administration to actively monitor the safety of drugs on the market and require pharmaceutical companies to develop plans to manage any serious risks associated with new medications.

A companion bill has yet to be considered in the House.

Drug companies would be required to do follow-up studies on certain medicines or risk fines. The FDA could require label changes for drugs. An active surveillance program would replace the largely passive way the FDA now learns of potential problems with drugs on the market. It calls for the mining of federal and private databases that log side effects in tens of thousands of patients.

FDA officials were criticized for not reacting sooner when serious problems were linked to Vioxx, which was withdrawn voluntarily in 2004 after research showed it doubled the risk of heart attacks and strokes.

Stripped from the legislation was a provision that would have prohibited consumer advertising of newly approved drugs. The final bill does allow for fines for ads that are false or misleading. The Senate also voided an effort to allow consumers to buy prescription drugs from abroad at a significant savings over domestic prices. The bill also would reauthorize a related user-fee program for medical device manufacturers and legislation meant to ensure that drugs and devices for children are safe and effective.

The FDA's proposal to Congress calls for the industry to pay $393 million in annual fees; the Senate bill proposes increasing that by $50 million to defray added drug safety costs.

In your opinion, what impact will this legislation have on the late-stage clinical study market?

Send us your opinions to accompany a larger article on this topic scheduled for the September issue of PharmaVOICE.

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