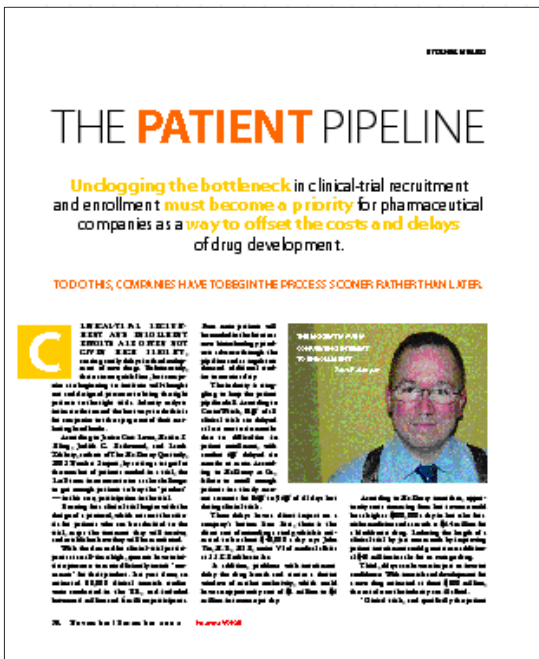


LETTERS



Two critical areas of success

The article on "The Patient Pipeline" highlighted many of the difficulties in patient accrual and retention. Unfortunately, the solutions missed two critical success factors.

— Dan Ulrey
MCSI

pliant investigators, as well as the amount and timeliness of reimbursement to be primary factors causing the shortage of patients across all clinical studies. Far too often investigators don't or can't perform complete due diligence and analysis of a study design or budget before being asked to accept study opportunities. Sponsors' internal organizations and their SOPs of study design, budget preparation, identification, evaluation, and selection of investigators and sites usually preclude full disclosure. Industry data clearly show recruitment of investigators begins well in advance of having a complete protocol or budget for thorough analysis. When the investigator does see a potential financial or ethical dilemma often their motivation to voice issues is not encouraged by the sponsor. As a consequence their focus and that of their supporting infrastructure for that study is gone. Yet they remain in the study. Organizational issues within the sponsor need to be changed to be able to provide complete study and budget information after the

initial investigator contact and in any event before execution of a study agreement.

Sites are businesses not commodities. Our metrics clearly show that when treated as businesses, investigative sites provide better focus and performance. In that light, sponsors need to reimburse more fairly and in a more timely manner despite their internal pressures to contain costs. The one-price-fits-all model based on sponsors' forecasted budgets does not consider the profit margins of a site. As sponsors attempt to contain costs even further, the per-patient enrolled cost, and retained cost, is increasing and the site margins are decreasing.

Physicians not participating in clinical research need to be financially motivated to participate. Those already in clinical research need to be financially motivated to improve their research skills and focus and hopefully remain in clinical research. Unless sponsors and investigators learn to "partner" more effectively to each others' mutual benefit no amount of advertising or Internet based recruiting models will stop the patient pipeline from shrinking.

Dan Ulrey
PRESIDENT, CEO, AND COFOUNDER
MCSI

Missed Opportunities

Your article on "The Patient Pipeline" highlighted many of the difficulties in patient accrual and retention. Unfortunately the solutions in my opinion missed two critical success factors.

As CEO and cofounder of MCSI, the largest U.S.-based network of independent investigators and sites, I consider the shortage of both informed, focused, and accountable GCP com-

What's Your Opinion?

PROACTIVE COMMUNICATIONS — IMPROVING THE INDUSTRY'S IMAGE

According to Alan Holmer, president of the Pharmaceutical Research and Manufacturers of America (PhRMA), with the rapid proliferation of television programming and commu- the industry must continue to find new, innovative ways to make policy leac and, most importantly, the American people aware of the tremendous l pharmaceutical companies make every day.

"It is imperative that we help people understand the serious risks pr islative initiatives that would jeopardize our continued ability to discove to save lives and improve the health of all Americans," Mr. Holmer says

To increase communication to all stakeholders, PhRMA has formed a n Strategic Communications and Public Affairs division. This division will co ceive and implement effective, innovative ways to get the message out.

In addition to the new PhRMA division, PharmaVOICE wants to what other ways can the industry positively increase its visibility to consumers and other stakeholders?

WHAT'S YOUR OPINION?

Please e-mail your comments to feedback@pharmalinx.com.



brand" article in the Novem- 2 issue was excellent. I thought the panel was more than well-qualified and represented a sufficient cross section of those most involved with the topic. I also found the discussion to go well beyond the typical article on nding, offering great ight with what everyone involved with branding is trying to achieve — particularly the scope of the emotional element.

Michael Reynolds
DIVERSION