LETTERS

The Future of eClinical

Recently, I had the opportunity to participate in an eClinical conference sponsored by etrials Inc. Clearly, among the participants at the event — both sponsors and trial partners — there was an underlying consensus that we understand the benefits of real-time data, know the importance of adaptive trials, and recognize that cleaner data faster enables us to make better decisions sooner. All of these factors result in cost savings and quicker time to market, and most importantly, benefit patients who need these important medicines. The question remains: why is there still a seemingly widespread reluctance to embrace eClinical/EDC systems?

Interestingly, it seems that the barrier for adoption of eClinical is not cost. Instead, the prevailing sense is that the roadblock is an unwillingness to embrace, adopt, and change processes.

Going forward, sponsors will need to embrace process change to realize the many benefits that EDC and eClinical technologies can bring to the table. The time has come to think differently — and embrace change.

JeanMarie Markham
President
CLINLOGIX LLC

Process Change is the Barrier to eClinical Adoption

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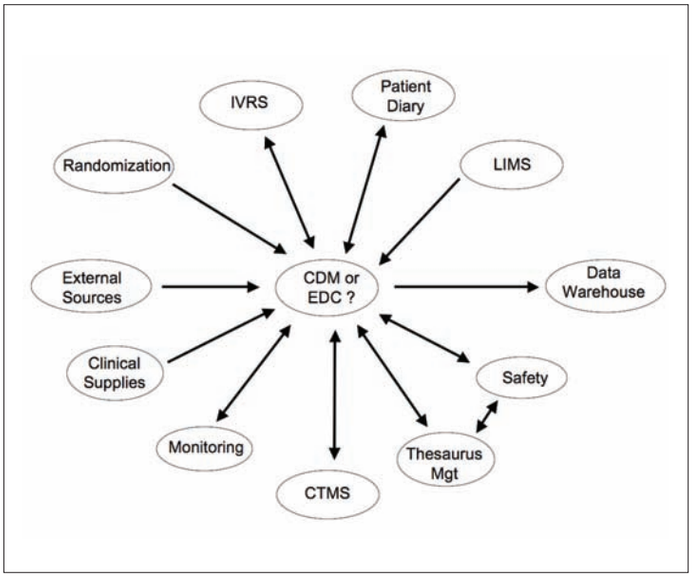
— JeanMarie Markham, Clinlogix LLC



Pardon us ...

In the November/December 2006 edition of PharmaVOICE, Keith Howells, VP of Engineering of Medidata Solutions, contributed an article entitled "EDC vs. CDM – Choosing a Data Collection Model." The article proposed that a "hub and spoke" integration model produces far fewer interfaces than a "point-to-point" integration model, and is therefore preferable. The article then discussed the pros and cons of whether the hub should be a clinical data management system (CDM) or an electronic data capture system (EDC). Unfortunately the accompanying diagram showed the proposed solution as CDM, which is actually the opposite of what the article concluded. The corrected diagram — showing the choice as between CDM and EDC — is shown above.

In the January issue of PharmaVOICE we inadvertently listed Darren Jones of Protiviti as Darren M. Jones in the Sound Bites section of the Forum: Sales & Marketing Compliance: Keeping Up with Global and Local Challenges.

PharmaVOICE apologizes for the errors.

What's Your Opinion?

THE NEW FDA

In the last year, the FDA has achieved momentum in speeding drug development and addressing product safety. PharmaVOICE wants to know what you think is in store for the coming year and what do you anticipate will be on the top of the list in terms of regulatory priorities? Finally, what impact will the "new" Congress have on the regulatory environment? (For a related article on this topic, please turn to page 34 of the January 2007 issue.)

WHAT'S YOUR OPINION?

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