

## ▶ The **CRYSTAL BALL**

We asked our readers to act as prognosticators and identify the top trends that they expect to shape the industry in the coming year and beyond. **SOME OF THEIR RESPONSES MAY ALREADY BE PART OF YOUR STRATEGIC VISION, WHILE OTHERS MAY ADD A WRINKLE TO YOUR PLANS.** Whether you agree or not with the following predictions, 2009 is sure to shape up to be a tumultuous 12 months punctuated by cost reductions, belt-tightening, and an overall mandate to do more with less.

*(Below is an excerpt from the larger article published in PharmaVOICE magazine.)*

### **BACK TO BASICS**

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The incorporation of Operational Excellence and concepts such as Lean and Six Sigma will become even more prevalent as drug companies refocus attention on speeding the trial cycle time and getting important drugs to patients sooner. CRAs will be empowered to make decisions on the front line that increase efficiency and remove wasted time, resources, etc.

With a renewed focus on getting back to the basics of drug development, more pharmaceutical companies will turn to functional outsourcing models. In clinical research, the outsourcing provider manages specific functions within the study, while the sponsor maintains overall management and control of the study.

Patient recruitment in the United States will continue to plague trials as unfavorable media portrayal of the industry, more studies competing for a limited number of patients, and patient concerns about side effects persist. Thus, globalization will increase with Eastern Europe emerging as a hotbed for new studies. This area will become increasingly desirable because of the similarities between the European Union standards and those of the FDA.

*Kforce Clinical Research, Tampa, Fla., provides customized and flexible functional outsourcing solutions to the biopharmaceutical industry, including clinical monitoring, site management, study management, drug safety, clinical data management, data entry, clinical programming, and*