

DIA 2013 49th Annual Meeting "Advancing Therapeutic Innovation and Regulatory Science" June 23 – 27, 2013 Boston Convention and Exhibition Center Boston, MA

Session 262 - First-in-Human Studies: How Much Complexity Is Too Much?

A study by the Tufts Center for the Study of Drug Development showed the complexity of clinical trials: a typical protocol in 2012 included 167 procedures, half of which did not support any trial endpoint. A session chaired by Dr. Royce Morrison, Executive Vice-Chair, Quorum Review, focused on phase I: the institutional review board perspective was presented by Dr. Morrison, the study site and patient perspective by Dr. William Smith, President and Principal Investigator, New Orleans Center for Clinical Research, the clinical contract research organization perspective by Dr. Mary Westrick, Vice President, US Phase I, Quintiles, and the sponsor perspective by Dr. Stacie Bell, Director, Clinical and Translational Research, Questcor Pharmaceuticals.

The sponsor perspective emphasized pressures: more information, including confirmation of mechanism of action in the target patient population and preliminary evidence of efficacy, not only permits early go/no-go decisions that may reduce late-phase failures but also facilitates regulatory submission and, in the case of start-up companies, is vital to secure funding.

The study site and CRO perspectives emphasized the negative impact of complexity: enrollments decrease, drop-out rates increase, procedures are too time-consuming for the time-conscious phase I environment, study durations lengthen and costs swell. In addition, phase I studies are often conducted in patients when healthy volunteers may be more useful: patient cohorts are more heterogeneous, older and take more concomitant medications, thereby complicating pharmacokinetic and study results. Ultimately, all stakeholders recommend a more balanced approach and the inclusion of healthy volunteers to trial design.

Unable to attend the DIA's 2013 49th Annual Meeting?

Now is your opportunity to listen to global thought leaders involved in the discovery, development, and life cycle management of medical products. Purchase the live recordings from the 2013 program **NOW** for **\$699** and access the recordings until July 9, 2014.



View details related to the DIA 2014 50th Annual Meeting "Celebrate the Past – Invent the Future"