

# The Growing Regulatory Burden and Revolution in Global Clinical Trials

Over the last few years, there have been major challenges facing the pharmaceutical industry. Drug development and drug costs have risen, fewer blockbuster drugs are in the pipeline and time to market is taking too long and costing too much. Patient safety and ethical concerns are being voiced by regulatory agencies and public groups as the safety of drug development has been called into question. At the same time that drug companies are being forced to look at how to streamline their manufacturing practices, they must also make changes to the way drugs are developed and marketed. Never before has the pharmaceutical industry faced such costly and complex issues. In this section of Advanstar's *Pharmaceutical Regulatory Guidance Book*, we look at the challenges facing clinical trial sponsors and their outsourcers as regulatory policies and guidances change in the United States and abroad.

Jill Wechsler discusses the "proliferation" of rules, principles and practices that guide the processes involved in running a clinical trial and its effect on the industry as well as patient groups. As a result of the transformation taking place in the industry, the FDA has expanded its outlook and it is also focusing attention on safety and human rights protection. In addition, the FDA has been working with its counterparts abroad to establish GCP standards for clinical trials.

Phil Ward continues the discussion of regulations abroad and the challenges member states continue to face in the implementation of the EU Directive. As Ward notes, implementation has not been straightforward and delays are still being caused by uncertainties and definitions. Several European thought leaders add their concerns to the report and note that the cost of compliance to the Clinical Trials Directive is continuing to have a great impact on trials.

Douglas Mackintosh and Vernetta Molloy add their expertise to this discussion by answering some common questions about regulatory compliance and clinical trials.

Rob Davidson discusses the development of software solutions to the compliance and regulatory issues that continue to surface in the clinical trial industry. Several technology leaders working within the clinical trial universe offer some useful information and commentary.



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