

## FDA Revises Compliance Program Manual for Sponsors, CROs, Monitors

The FDA revised its Compliance Program Guidance Manual for inspections of sponsors, contract research organizations and monitors (CP 7348.810) to include information on foreign inspections. The manual was last revised in 2001. The revised manual specifies that domestic inspection assignments are issued to the FDA district offices and international inspection assignments are issued to the Division of Foreign Field Investigations (DFFI). The revised manual also specifies the items that should be identified in the inspection assignment, such as the type and purpose of the inspection, the background materials, specific issues or concerns to be addressed and the due date of the completed establishment inspection report. *Page 2*

## IOM Workshop Examines Problems Of Multiple IRB Reviews for Trials

Multiple institutional review board review of multi-center clinical trials continues to be a bottleneck for getting trials started quickly, participants at a recent Institute of Medicine (IOM) workshop on the national cancer clinical trial system said. "A lot of institutions seem very wedded to having their own IRBs" review multi-center trials that will take place in their institution, Jerry Menikoff, director of the HHS Office for Human Research Protections (OHRP) told the workshop March 21. "OHRP has actually officially endorsed the notion that we think there are benefits to moving from so many IRBs to fewer IRBs and perhaps ideally to one IRB per study." *Page 3*

## European Union Opens Its Clinical Trial Registry to the Public

The European Union opened its Clinical Trials Register to the public March 23 after months of delay. "Originally the website was scheduled to be released at the end of 2009, but the challenges of converting the database to its current structure to support this and future developments, and additional difficulties encountered in data migration and testing of the software" delayed the release, the European Medicines Agency (EMA), which is responsible for management of the registry, said in a statement. Trial sponsors are responsible to provide and update registry information through the national competent authorities where the trial is being conducted. The information will become public after the trial is authorized. The announcement of the registry noted that "EMA has limited control over the completeness or accuracy of the information entered in the EurdraCT database." *Page 6*

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