



OIG NEWS

For Immediate Release
Phone: 202/619-1343
September 28, 2007

Office of Inspector General
Department of Health & Human Services
330 Independence Avenue SW.
Washington, DC 20201

OIG Releases Report of FDA's Oversight of Clinical Trials, Concludes Improvement of Information Systems and Processes is Needed

Washington, DC —Weaknesses in the Food and Drug Administration's (FDA) information systems and management processes hinder the agency's ability to oversee clinical trial inspections. So concludes Inspector General Daniel R. Levinson of the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) in a report released today: "FDA's Oversight of Clinical Trials."

To protect human subjects, federal law requires that all new drugs and medical devices undergo clinical trials to demonstrate their safety and efficacy prior to receiving FDA approval. FDA inspects clinical trials to determine whether sponsors, clinical investigators, and institutional review boards responsible for conducting or overseeing clinical trials for investigational products are complying with relevant regulations. FDA oversees clinical trials through a variety of mechanisms that include protocol reviews and onsite inspections through its Bioresearch Monitoring Program (BiMo). The OIG report focused exclusively on BiMo inspections, an important mechanism for protecting human subjects once a clinical trial is underway.

OIG concluded that the FDA does not have a mechanism to identify all clinical trials and Institutional Review Boards (IRBs), which approve, monitor, and review research involving human subjects. Moreover, it lacks a comprehensive database for tracking its inspections of clinical trials. Previous OIG reports found similar weaknesses.

"Data limitations hinder the FDA's ability to ensure that participants are protected from unreasonable risks," said Daniel R. Levinson, HHS Inspector General. "Accurate record-keeping is critical to maintaining the safety of clinical trial patients."

-- More --

FDA inspected about 1 percent of clinical trial sites from fiscal year (FY) 2000 to FY 2005, OIG concluded after reviewing multiple data sources. Of these inspections, 75 percent were surveillance inspections, which generally target completed trials and often focus on verifying the quality of data from clinical trials. FDA also inspected few IRBs.

In 1998, a series of OIG reports concluded that IRBs lacked the time and expertise to sufficiently monitor the research. And a 2000 report found that data integrity concerns, rather than human subject protection, drove FDA's oversight of clinical investigators.

OIG identified steps that FDA could take to improve its system for overseeing clinical trials, which are:

- Develop a comprehensive internal database of all clinical trials,
- Create a registry of IRBs,
- Create a cross-center database that allows complete tracking of FDA inspections,
- Seek legal authority to provide oversight that reflects current clinical trial practices; and
- Establish a mechanism to provide feedback to FDA district office staff on their inspection reports and findings.

FDA concurred with four of the OIG's recommendations but did not address the provision of feedback regarding inspection reports and findings. FDA's full response to OIG's recommendations is included as an appendix to the report.

To read the OIG Report in full: www.oig.hhs.gov/oei/reports/oei-01-06-00160.pdf