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US FDA under pressure to step up inspections of trials in developing countries

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<http://www.pharmabiz.com/article/detnews.asp?articleid=56223§ionid=>

Under increased pressure from the Department of Health and Human Services, the US Food and Drug Administration (FDA) which has already set up representative offices in many countries including India, may soon step up the site inspections of clinical trials in the developing countries.

Based on a recent report on the oversight of foreign clinical trial data, the health department has already called upon the FDA to improve the inspections. Though India was not specifically mentioned as a key destination, being one of the most favourite sites for trials for the vast number of subjects and other factors, the drive may cover India largely also, according to the information reaching here.

The report had found flaws in FDA oversight of foreign clinical trials as the sponsors were found to be relying heavily on the data generated from abroad to support their marketing applications back home. While 80 per cent of drugs and biologics applications approved by the FDA in fiscal year 2008 contained clinical trial data from foreign sites, the agency inspected clinical trial investigators at only 0.7 per cent of foreign sites compared to 1.9 per cent of domestic of domestic clinical trial sites, revealed a report by the HHS's Office of Inspector General.

Over the years, India has been emerging as a key destination for trials by the companies from the developed world. Though the exact number of trials by the US companies in India is not known, a search in the official Clinical Trial Registry of India (CTRI) has found that there are hundreds of trials going on in the country with the sponsors from the US. The FDA is likely to make use of its manpower at the two representative offices in Delhi and Mumbai for the purpose of on-site inspections of trials as it was one of the key agenda while setting up the offices here.

According to the HHS report based on the figures of 2008, Western Europe account for 58 per cent of subjects enrolled at foreign sites and 60 per cent of foreign sites. Central and South America also enrolled a significant number of subjects – around 26 per cent of all subjects at foreign sites – but the region accounted for only 7 per cent of total foreign sites. Peru, the report notes, had the fourth-largest subject enrolment, yet the FDA inspected no trials there. The report also lists several other countries with a large number of subject enrolments that were not inspected by the FDA for marketing applications approved in FY 2008. These include: Colombia, Chile, Panama, Venezuela, Nicaragua, the Dominican Republic, Denmark, Norway and Poland.

The domestic industry sources said India in fact gained more attention as a favourite destination in the recent years. Large number of trials by the US companies started here only after 2008 and hence India was

not specifically mentioned in the report. The situation has changed a lot now and there could be added pressure on the investigators for the better, if the FDA steps up the inspections.