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High Turnover and Protocol Noncompliance Continue to Plague the Global Investigative Site Landscape

BOSTON – Jan 15, 2015 – Global clinical trial performance and efficiency are hampered by high turnover and noncompliance among principal investigators and wide variation in investigative site experience, according to a recently completed assessment by the Tufts Center for the Study of Drug Development.

While the number of investigators globally now stands at nearly 40,000, a record, half of them were new to the job in 2013, the most recent year for which data are available, according to Tufts CSDD. In addition, although the highest turnover rates are observed among the least active investigators, turnover rates have been getting progressively worse among more active investigators.

At the same time, protocol noncompliance, the most common performance deficiency and one that has grown the fastest during the past decade, accounted for 46% of all investigative site deficiencies, Tufts CSDD said.

“Operating conditions for clinical trials have noticeably worsened in recent years,” said Ken Getz, associate professor and director of sponsored research at Tufts CSDD. “Most frustrating for drug sponsors and contract research organizations looking to achieve higher levels of predictable performance is the wide variation that exists in the infrastructure, stability, and experience levels of investigative sites conducting clinical trials globally.”

He also noted that the global investigative site landscape “remains highly fragmented” with no indication that it will consolidate and begin achieving scale efficiencies soon.

Other findings from the analysis, reported in the January/February Tufts CSDD Impact Report, released today, include the following:

- Growth in the number of unique principal investigators is beginning to decelerate: the most recent four-year annual growth rate was 3.3% compared with the prior four-year period of 4.1% and an average of 5.6% over the last 15 years.
- During the 2009 – 2013 period, the numbers of active investigators in India and China, areas once expected to see the most dramatic relative growth, have declined by 16% and 5%, respectively, due to limited infrastructure, lack of capacity, excessive bureaucracy, and difficult regulatory and health authority requirements.
- Differences in deficiencies between investigative sites inside and outside the U.S. were less pronounced in 2013, compared to earlier time periods, as the number of site inspections by the U.S. Food and Drug Administration approached parity.
ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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