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Investigative Site Landscape Remains Highly Fragmented as the Number of Active Investigators Worldwide Reaches an All-time High, According to the Tufts Center for the Study of Drug Development

BOSTON – March 12, 2013 – More than half of all clinical trials worldwide that are regulated by the U.S. Food and Drug Administration (FDA) were conducted by independent, community-based principal investigators, as opposed to universities, hospitals, and government clinics, with the number of active principal investigations reaching a record high, according to a newly completed analysis from the Tufts Center for the Study of Drug Development.

Whereas the proportion of community-based investigators worldwide has grown, site performance has been exceedingly variable due, in part, to the limited experience and scale established by sites outside North America, according to Tufts CSDD.

"The investigative site landscape remains highly fragmented, with declining numbers of experienced professionals and limited infrastructure," said Ken Getz, associate professor and director of sponsored research at Tufts CSDD. "The landscape is also less stable, as turnover rates remain high, particularly in regions outside North America."

He said that high turnover rates—partly a function of onerous regulatory requirements, a challenging operating environment, and companies scaling back their global development programs—contribute to high site selection and management costs.

Reported in the March/April *Tufts CSDD Impact Report* released today, the study is the latest in a series of analyses of the global principal investigator landscape. Among the key findings:

- Nearly 28,000 principal investigators around the world participated in clinical studies in 2012, with 61% of them based in North America, down from 84% conducted there in 1996.
- Principal investigators work at more than 15,000 unique locations, with a high proportion being novice investigators.
- China, India, and Eastern Europe, have seen relatively high growth among FDA-regulated investigators since the late 1990s, largely for confirmatory, later-stage clinical trials.
- Turnover rates are particularly high in Asia Pacific, Europe, and Latin America, where more than half of all investigators choose not to conduct trials in the subsequent year.

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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