Global site landscape remains highly fragmented with variable performance

Number of investigators worldwide reached an all-time high in 2012

- Nearly 28,000 principal investigators (PIs) in 2012 participated in studies regulated by the U.S. Food and Drug Administration (FDA) worldwide.
- The proportion of PIs based in North America has steadily declined, from 84% of the total pool of FDA-regulated investigators in 1996 to 61% in 2012.
- 53% of all global FDA-regulated clinical trials are now conducted by independent, community-based principal investigators.
- North American investigators have the fastest study start-up times and higher than average enrollment performance.
- After peaking in 2003, the rate of complaints for PI non-compliance and fraud has dropped.
- Turnover rates among PIs is high, with about 40% of participating PIs annually choosing not to conduct another FDA-regulated clinical trial.

Change continues to be the watchword for the FDA-regulated principal investigator landscape since Tufts CSDD began examining the field in detail seven years ago. In 2012, for the first time, more than half of all FDA-regulated clinical trials worldwide were conducted by independent, community-based principal investigators, as opposed to universities, hospitals, and government clinics. But the investigative site landscape remains highly fragmented, with growing numbers of less experienced professionals and limited infrastructure. The landscape is also less stable as turnover rates remain high – particularly in regions outside North America.

This Tufts CSDD Impact Report presents recent analyses on the changing site landscape and offers new insights, as well as updates to results of analyses presented in earlier reports. See Tufts CSDD Impact Report 2005 May/June:7 [3] and Tufts CSDD Impact Report 2009 January/February:11 [1].