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Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

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.