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Tufts Center for the Study of Drug Development
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Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

High turnover, protocol noncompliance plague the global site landscape

Half of all unique investigators in 2013 were first-time 1572 filers

- The number of active unique principal investigators (PIs) conducting FDA regulated clinical trials worldwide has reached a record of nearly 40,000, but growth is slowing.
- North America continues to lose its share of active global FDA-regulated PIs.
- The numbers of active PIs in India and China, countries once expected to see the most dramatic relative growth, have declined by 16% and 5%, respectively.
- Investigator turnover has increased dramatically: half of all unique PIs who filed a form 1572 in 2009 have yet to file again, up from 40% four years ago.
- The number of annual CDER inspections of sites outside the United States has tripled since 2001, while declining by 36% inside the U.S.
- Protocol noncompliance, the area of performance deficiency that has grown the most during the past decade, accounted for 46% of all investigative site deficiencies.