



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Current investigator landscape poses a growing challenge for sponsors

Number of subjects per new drug application declined steadily over 10 years

- The proportion of principal investigators (PIs) based in the United States has steadily declined, from 96% of the total global pool of FDA-regulated investigators in 1990 to 54% in 2007.
- The number of active PIs in the U.S. declined 3.5% annually since 2001, while active PIs outside the U.S. increased 13.5% each year during that same period.
- Gender and racial disparities among PIs suggest that there is an untapped pool of investigators who could potentially provide increased enrollment of women and minority patients in clinical trials.
- The number of PIs per active IND has nearly doubled during the past decade, while the proportion of clinical trials in Phase I has increased substantially.
- Complaints of PI non-compliance and fraud as a proportion of active clinical trial activity have been increasing since 2003.