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.

The global clinical investigator landscape is changing rapidly. Perhaps most dramatically, the share of PIs worldwide, who are based in the U.S. has dropped nearly in half since 1990. More favorable economics elsewhere, fewer regulatory constraints, and well-positioned global contract research partners are prime factors behind this shift. In addition, active INDs now involve more PIs, with each PI enrolling smaller numbers of study volunteers; female and minority physicians represent a significant, untapped pool of PIs; and complaints filed with the FDA for non-compliance and fraud continue to rise.

These dynamics pose substantial management challenges for drug development sponsors that are aggressively seeking ways to improve site selection, volunteer enrollment, clinical study quality and efficiency, and regulatory compliance. This Tufts CSDD Impact Report builds on earlier studies that looked at the changing clinical investigator landscape. For more, see Tufts CSDD Impact Report 2007 Nov/Dec;9(6) and Tufts CSDD Impact Report 2005 May/June;7(3).