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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

Growing protocol design complexity stresses investigators, volunteers

Protocol design changes challenge study conduct cycle time and performance

- The annual growth rate of unique procedures per protocol grew 6.5% between 1999 and 2005. During that same period, the total number of times unique procedures were conducted per protocol grew at a faster rate.
- To participate in clinical studies today, volunteers on average must meet a total of 49 eligibility criteria, up 58% since 2002.
- The burden to administer clinical study protocols is rising faster than the rate of growth of unique procedures or their frequency.
- Clinical trials are taking longer: between 1999-02 and 2003-06, total time from protocol design readiness to data lock rose from 460 to 780 days, or 69.6%.
- Protocol design also impacts the ability of sites to recruit and retain volunteers: enrollment rates dropped from 75% in 1999-02 to 59% in 2003-06, while retention rates declined from 69% to 48%.