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%.

It is widely known that protocol design plays a crucial role in the success of clinical research studies. Yet, how protocols have changed over time, and the impact of these changes on clinical trial performance, have never been quantified. A new study from Tufts CSDD comprehensively measured the impact of protocol design on trial performance, the results of which are summarized in this report.

During the past decade, protocol designs have become far more demanding and complex due in large part to the changing nature of diseases under investigation. Most investigational treatments today target chronic diseases for which clinical endpoints are more difficult and time-consuming to measure, patient populations may be more targeted, and subjective patient feedback is a more common protocol procedure. Competition has also intensified, driving drug developers to collect larger amounts of clinical research data. At the same time, developers are carefully controlling their spending on grants to investigative sites. The impact of these operating challenges is manifest in today’s protocol designs and the challenge they pose for study conduct success.