Rising protocol complexity is hindering study performance, cost, and efficiency

New benchmarks highlight growth in protocol design complexity

- Phase I and II clinical trials are the most complex, based on numbers of distinct and total procedures, whereas Phase III trials have seen the highest increase in complexity during the past 10 years.

- The total number of endpoints rose 86%, and procedures supporting these endpoints contributed a much higher proportion of data informing secondary supplementary, tertiary, and exploratory endpoints.

- From 2001-05 to 2011-15, drug makers doubled the number of countries and increased the number of investigative sites by 63% to support Phase III protocols, as the mean number of patients declined 18%.

- As protocol complexity increased, investigative site initiation and data management cycle times has increased, with more observed variance.

- Companies expect electronic case report form data in the primary electronic data capture to decline as a share of all data collected to support protocol endpoints, highlighting the growing challenge of data coordination and integration.

Protocol design scope and complexity continue to rise steadily. And there is every indication that this trend will continue—and likely accelerate—as pharmaceutical and biotechnology companies target more difficult-to-treat and rare diseases, enroll more stratified patient populations, and collect higher volume and more diverse data. Research conducted by the Tufts Center for the Study of Drug Development (Tufts CSDD) has demonstrated that protocol design practices increase clinical costs and inefficiencies, place growing burden on internal and external staff performance, and impact study volunteer recruitment and retention rates.

This report, which summarizes recent studies conducted by Tufts CSDD, updates benchmarks on protocol design practices and offers insights into ways sponsor companies can optimize their study designs.