Protocol design optimization starting to improve study performance

The incidence of non-core data remains high

- One-fifth of Phase II and one-third of Phase III protocol procedures, on average, collect non-core data that are not associated with a primary or key secondary endpoint, regulatory compliance, or standard baseline assessments.
- 80% of all Phase II non-core data and 87% of all Phase III non-core data collected were source data verified by study monitors.
- The majority of surveyed large and mid-size pharmaceutical and biotech companies reported implementing facilitated review processes and mechanisms within the past five years to challenge protocol design feasibility.
- 21% of surveyed companies use simple adaptive trial designs to improve data quality and success rates and cut costs.
- Drug companies are reluctant to use social media to solicit feedback from sites and patients on protocol feasibility, although they recognize the value it can provide.

Drug developers and their partners have long recognized that complex protocol designs negatively impact clinical trial performance. Still, during the past decade it has been difficult for sponsor companies to streamline protocol design given the need to provide robust and comprehensive data in light of increasing scientific complexity, anticipate and address regulatory, health authority, and payer requests, and identify new areas of inquiry and development direction.

Pressure to achieve higher levels of operating efficiency and performance is prompting some drug companies to place greater emphasis on upfront planning and governance to assess and challenge protocol feasibility. Sponsor companies have been implementing a variety of approaches, including establishing facilitated review mechanisms and making greater use of adaptive trial designs. Studies conducted by Tufts CSDD and summarized in this report suggest that these efforts are bearing positive results.