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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

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.