One in five procedures generates extraneous clinical trials data

Tufts CSDD study sets benchmark for quantity and cost of less essential data

- The typical protocol has an average of 7 objectives and 13 endpoints.
- 22.3% of all procedures are considered to be non-core: 17.7% of Phase II procedures and 24.7% of Phase III procedures.
- Half of all procedures—54.3% of Phase II procedures and 47.9% of Phase III—support primary and key secondary endpoints.
- $1.1 million (18%) of a typical study budget is spent on procedures for supplementary secondary, tertiary, and exploratory endpoints, and another $1.3 million (22%) is spent on procedures supporting regulatory compliance.
- Based on the total number of active FDA-regulated Phase II and III trials conducted annually, the pharmaceutical industry spends $4 billion to $6 billion each year on procedures that generate extraneous clinical trial data.

During the past decade, Tufts CSDD studies have consistently demonstrated the inverse relationship between protocol complexity and clinical trial performance; more complex protocols are associated with longer study cycle times, poorer patient recruitment and retention rates, and a higher number of protocol amendments.

It is widely believed that clinical trial protocols contain a growing number of procedures that support supplementary, tertiary, and exploratory endpoints, generating extraneous data and imposing substantial additional costs. The impetus to collect these data is strong: sponsors collect more data to interpret findings, guide development decisions, support adherence to protocol authoring templates and design practices, and anticipate requests from regulatory agencies, purchasers, and payors. Until now, there has been no systematic study of the issue. The findings summarized here offer pharmaceutical and biotechnology companies insight into, and a framework to use in, streamlining protocol designs, improving clinical research performance, and reducing cost.