



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Amendments reduce number of patients, but at high cost, longer study times

Nearly half of all substantial amendments are deemed avoidable

- 57% of all protocols, across all phases, have at least one substantial global amendment (defined on page 4 in “About this study”).
- Phase II protocols have the highest incidence of substantial amendments (77%), averaging 2.2 amendments per protocol.
- The most frequent changes stemming from amendments are associated with modifications and revisions to study volunteer demographics and eligibility criteria.
- Protocols with even one amendment experience a substantially lower actual number of patients screened and enrolled relative to plan, compared to protocols without any amendments.
- Study conduct durations for protocols with at least one substantial amendment take, on average, three months longer.
- The total median direct cost to implement a substantial amendment for Phase II and Phase III protocols is \$141,000 and \$535,000, respectively.