Clinical site initiation process remains lengthy and highly inefficient

New study benchmarks each stage of the study initiation process

- Total duration from site identification to study start-up completion is 31.4 weeks, one month longer than the average duration observed 10 years ago.

- Sponsors and CROs report that 28% of engaged investigative sites are new relationships with no prior history or familiarity, a proportion that is expected to increase as more clinical trials focus on rare diseases and highly targeted patient sub-populations.

- The overall site initiation cycle time is 9.9 weeks shorter for repeat or familiar sites, compared to new sites.

- CROs, compared to sponsors, complete the site initiation process an average of 5.6 weeks faster for repeat sites and an average of 11 weeks faster for new sites.

- CROs are gaining specialization in the site initiation process through growing sponsor reliance on outsourcing investigative site management responsibilities and through higher relative investments in study start-up technology solutions.

- 30%-40% of sponsors and CROs report they are somewhat or completely unsatisfied with their site initiation processes.

During the past decade, site identification, site selection, and study start-up—collectively referred to as the study initiation process—have become priority improvement areas in the conduct of clinical trials. Despite implementation of new technology solutions and practices, the study initiation process remains highly inefficient with wide variation between companies.

This report summarizes key findings of a recent Tufts CSDD study, based on a global survey, the first to comprehensively benchmark site identification, site selection, and start-up cycle times for both repeat and new investigative sites for Phase II and III clinical studies. The findings indicate that the site initiation process has become increasingly challenging for sponsors and CROs looking to identify and engage more specialized investigators and patient sub-populations worldwide.