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First Comprehensive Clinical Site Initiation Benchmark, Developed by Tufts CSDD, Finds Study Startup Is Lengthy and Inefficient

FOR IMMEDIATE RELEASE

BOSTON – March 7, 2018 – The clinical site initiation process—time needed to identify and select sites and begin studies—takes an average of nearly eight months, longer than it did a decade ago, and remains inefficient, according to a study recently completed by the Tufts Center for the Study of Drug Development.

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.

The finding, based on a global survey of drug sponsors and contract research organizations, is the first study to comprehensively benchmark site identification, site selection, and start-up cycle times for repeat and new investigative sites for Phase II and III clinical studies.

"Although the biopharma industry has implemented new technology solutions and practices to shorten the study initiation process, it remains highly inefficient with wide variation between companies," said Mary Jo Lamberti, senior research fellow at Tufts CSDD, who led the analysis. "Overall, a high percentage of sites under-enroll, and one in 10 sites are never activated, which reflects that process improvements have not been made."

The analysis, summarized in the March/April Tufts CSDD Impact Report, released today, also found that:

- 28% of engaged investigative sites are new relationships with no prior history or familiarity of working with a CRO or sponsor, 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.
- 30% – 40% of sponsors and CROs report they are somewhat or completely unsatisfied with their site initiation processes.
ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

Established in 1976, the Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) is a multidisciplinary academic research group that provides data-driven analyses and strategic insight to help developers, regulators, and policy makers improve the efficiency and productivity of pharmaceutical R&D. Tufts CSDD also offers CME-accredited professional development courses, hosts workshops and public forums, and publishes the Tufts CSDD Impact Report, a bimonthly newsletter focusing on critical drug development issues.

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