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Rising Protocol Complexity Is Hindering Performance while Driving Up Cost of Clinical Trials, According to the Tufts Center for the Study of Drug Development

BOSTON – July 17, 2018 – Rising protocol complexity is hindering clinical trial performance and efficiency, and helping to drive up the cost of developing new drugs, according to a recently completed analysis by the Tufts Center for the Study of Drug Development.

"Protocol design scope and complexity have steadily increased, and this trend will continue—and likely accelerate—as pharmaceutical and biotechnology companies target more difficult-to-treat and rare diseases, enroll more stratified patient populations, and collect higher volume and more diverse data," said Ken Getz, associate professor and director of sponsored research at Tufts CSDD, who led the analysis.

He said that in addition to increasing clinical costs and inefficiencies, current protocol design practices increase the burden on internal and external staff to execute trials and hinder study volunteer recruitment and retention rates.

The analysis was based on an assessment of 9,737 protocols from 178 global pharmaceutical and biotechnology companies.

Key findings stemming from the study, summarized in the July/August Tufts CSDD Impact Report, released today, included the following:

- Phase I and II clinical trials are the most complex, based on numbers of distinct and total procedures, whereas Phase III trials have seen the highest increase in complexity during the past 10 years.
- The total number of endpoints rose 86%, between 2001-05 and 2011-15, and procedures supporting these endpoints contributed a much higher proportion of data informing secondary supplementary, tertiary, and exploratory endpoints.
- From 2001-05 to 2011-15, drug makers doubled the number of countries and increased the number of investigative sites by 63% to support Phase III protocols, as the mean number of patients declined 18%.
- Over the next three years, companies expect electronic case report form data in the primary electronic data capture to decline as a share of all data collected to support protocol endpoints, highlighting the growing challenge of data coordination and integration.

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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