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Rising Protocol Design Complexity Is Driving Rapid Growth in Clinical Trial Data Volume, According to Tufts Center for the Study of Drug Development

New Tufts CSDD Study Updates and Expands Earlier Benchmarks

BOSTON – Jan. 12, 2021 – Ever more complex clinical trial designs are collecting much higher volumes of data from a variety of sources, intensifying pressure on drug sponsors to meet speed and efficiency goals, according to the [Tufts Center for the Study of Drug Development](#).

Phase III clinical trials currently generate an average of 3.6 million data points, three times the data collected by late stage trials 10 years ago, according to a newly completed study from Tufts CSDD.

“What we’re seeing is the consequence of biopharmaceutical companies engaging in more ambitious and customized drug development activity that targets a growing number of rare diseases, stratifies participant subgroups using biomarker and genetic data, and relies on more structured and unstructured patient data from a larger number of sources,” said Ken Getz, professor and director of Tufts CSDD.

He added that clinical trial designs are expected to become more complex in the future, generating even greater data volume and diversity.

“Drug developers will be compelled to further leverage data management strategies and tactics—including real-time interim assessment, risk-based approaches, automation, and augmented analytics—to support scientific and operating decisions,” Getz said.

The new study updates earlier benchmarks and establishes a number of new baseline measures. The research was based on 220 recently completed protocols targeting multiple therapeutic areas worldwide.

Other key findings from the study, summarized in the January/February [Tufts CSDD Impact Report](#), released today, include the following:

- Phase II and III protocols currently involve 263 procedures per patients, supporting approximately 20 endpoints.
- The mean number of distinct Phase II and III protocol procedures increased 44% since 2009.
- The average number of investigative sites conducting Phase II and III protocols increased 33% from 2009-12 to 2017-20.
- Master protocol designs entail more patients and take an average of 1.9 years longer than traditional trials.

Noting that the coronavirus pandemic has spurred drug companies to evolve approaches to new product development, Getz said, “The industry is showing resourcefulness, agility, and an unprecedented level of collaboration that will be critical to future development success.”

ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the efficiency and productivity of pharmaceutical R&D. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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