eClinical Data Volume and Diversity Pose Increasing Challenges and Delays

FOR IMMEDIATE RELEASE

BOSTON - Jan. 9, 2019 - The growing volume of data collected in clinical trials is contributing to longer development times and posing technical and integration challenges to clinical data management staff, according to a recently completed analysis by the Tufts Center for the Study of Drug Development.

Despite improvements and enhancements in data management technologies supporting clinical trials, during the past decade data management cycle times have gotten longer according to Tufts CSDD. The time from last patient, last visit to database lock, for example, has increased from an average of 33.4 days in 2007 to an average of 36.1 days in 2017.

"The volume of clinical data being collected from numerous and disparate data sources has grown dramatically in response to the rising scope and complexity of clinical trial protocols," noted Ken Getz, associate professor and director of sponsored research at Tufts CSDD, who led the analysis, “Drug development performance is heavily dependent on pharmaceutical and biotechnology companies, and contract research organizations (CROs), effectively and efficiently managing and integrating all of this data.”

While all 257 drug developers surveyed by Tufts CSDD reported using electronic data applications in clinical trials, nearly one-third still use paper case report forms to support those investigations.

Getz added that research sponsors and CROs report using their primary electronic data capture systems to collect and manage traditional data from case report forms and central and local labs, but not to collect and manage data from newer sources, including electronic health/medical records, mobile devices, and social media communities.

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

- 77% of sponsors and contract research organizations (CROs) have difficulty loading data into their primary EDC system due to compatibility, technical demands, and integration challenges.
- Sponsors and CROs use an average of six applications to support clinical trial activities.
- Protocol changes are the most common reason for delays in building study databases, accounting for 45.1% of database build delays reported by sponsors and CROs.
- Frequency of releasing the final study database after the first patient visit is associated with longer downstream delays and inefficiencies.
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 quality and efficiency of pharmaceutical development, review, and utilization. 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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