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Planned and Unplanned Mid-Study Updates Pose Major Challenge to Clinical Trial Timelines, According to Tufts Center for the Study of Drug Development

Tufts Center for the Study of Drug Development Analysis Finds Larger Pharmaceutical Companies Experience Longer Delays due to Mid-Study Updates

BOSTON – March 2, 2021 – Planned and unplanned mid-study updates each add approximately 30 days to clinical trial durations according to a new study by the [Tufts Center for the Study of Drug Development](#).

The Tufts CSDD analysis, based on data from 194 drug developers worldwide, found that, on average, regardless of company size, each clinical trial has four planned and four unplanned mid-study updates.

Larger companies reported taking more time to resume their clinical trials after a planned or unplanned mid-study update, whereas smaller companies reported faster time resuming their studies after an update.

“Sponsor companies are seeing an increase in mid-study updates as they implement more amendments, conduct more interim analyses, and execute more flexible and ambitious clinical trial designs,” said Ken Getz, professor and director of Tufts CSDD, who oversaw the study. “This study demonstrates the challenge and impact of planned and unplanned updates and suggests an important opportunity to reduce clinical trial cycle times.”

While planned and unplanned mid-study updates were the most frequently reported challenge by survey respondents, other top challenges included issues related to flexibility and customization, database go-live delays, and lack of integrated patient engagement.

Study results were highlighted in the March/April [Tufts CSDD Impact Report](#), released today, and also included the following:

- Each planned and unplanned mid-study update typically takes approximately 30 days to complete before the study can resume.
- Planned mid-study updates on average take 1.5 days less time to go-live again, compared to unplanned mid-study updates.
- Data management cycle times for start-up and close-out activity have not changed since 2017.
- Respondents who were more satisfied with their electronic data capture system’s ability to manage mid-study updates reported a five-day, go-live again cycle time advantage.

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 School of Medicine is dedicated to optimizing drug development performance and efficiency through robust data-driven assessment, analysis, and insight. A multi-disciplinary center based in Boston, Tufts CSDD conducts scholarly research, hosts symposia, workshops, and public forums, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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