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Transition to Decentralized Clinical Trials during the Coronavirus Pandemic is Far More Nuanced than Expected, According to Tufts Center for the Study of Drug Development

Select virtual and remote approaches—including telemedicine and e-consent—have seen more rapid adoption, Tufts CSDD found

BOSTON – Nov. 12, 2020 – The coronavirus pandemic has facilitated rapid adoption of decentralized clinical trial execution, with more than half of all global clinical trials now using remote and virtual support—a sharp contrast to the vast majority of clinical trials that historically relied on in-person patient visits at research facilities—a recently completed analysis by the Tufts Center for the Study of Drug Development has found.

Noting that 55% of active ongoing clinical trials have transitioned to remote and virtual execution models since early spring, Ken Getz, professor and deputy director of Tufts CSDD, said the appeal of these decentralized approaches "is compelling."

"Among other benefits, decentralized trials have provided increased convenience and minimized coronavirus transmission risk for study volunteers, while offering drug developers potentially lower costs and faster access to scientific and operating data," he said.

Getz cautioned, however, that decentralized clinical trials introduce a number of challenges, including those associated with remote communication and remediation, and data coordination and integration.

The analysis, based on global surveys of investigative sites and interviews with representatives of the largest pharmaceutical companies, was summarized in the November/December *Tufts CSDD Impact Report*, released today.

Other key findings from the analysis include the following:

- Telemedicine is the most frequently used approach to conducting decentralized clinical trials.
- Investigative sites conducting remote trials rate patient safety as their greatest concern.
- 60% of investigative sites report having had no prior experience with remote processes and solutions before the pandemic.
- For many developers, particularly smaller companies, contract service organizations have been the primary provider of remote monitoring personnel and capabilities.

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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