

## **On Site: Tufts CSDD Survey Finds Study Startup Cycles Remain Inefficient for New Sites**

Companies reported 28% longer clinical trial cycle times and startup processes for new sites compared to repeat sites, according to a study conducted by the Tufts Center for the Study for Drug Development (Tufts CSDD) and goBalto.

Wide variation between companies showed that company practices have been highly inconsistent, according to the study, which focused on the end-to-end process from site identification to initiation. Start-up processes averaged five to six months, and only 10% of respondents said they were very satisfied with their study startup processes.

The report, based on the Start-up Time And Readiness Tracking (START) II study, found that contract research organizations described shorter total cycle times compared to sponsors, with CROs completing all site-related activities six to 11 weeks faster, on average.

Meanwhile, the percentage of sites never activated held at 11% and has not seen substantial changes in over a decade.

"Study startup through activation remains one of the most inefficient cycles facing clinical development operations," said Ken Getz, associate professor at Tufts CSDD and the principal investigator of the START II study.

"The impetus behind this follow-up study was to gather hard data quantifying cycle time durations and clinical team experience to identify new insights into this perennial challenge," said Getz. The study was published in *Therapeutic Innovation & Regulatory Science*, the official scientific journal of the DIA.

Investments in adequate clinical trials technology and data analytics largely led to time savings, with 30% of companies reporting shorter cycle times than companies with inadequate technologies, the report said.

"The results provided some very interesting insights about sponsor/CRO differences, centralized vs. decentralized site selection, and start-up groups, as well as the impact that technology has had on reducing cycle times," said study co-author Beth Harper, president of Clinical Performance Partners.

"There's more work to be done, but our findings should help point organizations in the right direction to areas that will have the biggest impact," Harper said.

The study surveyed biopharmaceutical companies and CROs, gathering data from 600 respondents and over 400 unique companies, approximately 65% from pharma and biotech, and 35% from CROs.

— *Conor Hale*

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