Study Start-up Pulse Report & Assessing Post-COVID Readiness

The Veeva 2020 Study Start-up Pulse Report examines the life sciences industry's progress toward streamlining study start-up by gathering the experiences and opinions of over 500 clinical operations professionals from around the globe. The goal of the research is to understand the drivers, barriers, and benefits of modernizing clinical systems and processes to accelerate trials and gives an industry-wide view of study start-up technology adoption.

Executive Summary

Findings show an urgent need to streamline study start-up processes to increase operational efficiency, quality, and speed in clinical trials.

All respondents say they need to improve study start-up processes. The top drivers are faster study start-up times (75%) and reduced manual processes (53%).

Nearly all respondents (98%) report significant challenges with study start-up, likely due to the heavy reliance on manual processes since most (81%) use spreadsheets to manage this area.

More than one-third say faster collection of site essential documents (44%) and easier collaboration (42%) are critical to improving study start-up.

Majorities say automating key study start-up processes like contracts and budgets (63%) and site essential document collection (61%) would have a significant, positive impact on trial quality and speed.

Industrywide Focus on Improving Study Start-up

Study start-up is one the most time-intensive areas within clinical drug development, accounting for 61% of total trial lifecycle times.[1] Cycle times can be significantly delayed due to paper-based processes, multiple document handoffs between study partners,[2] and manual methods of information exchange.[3]

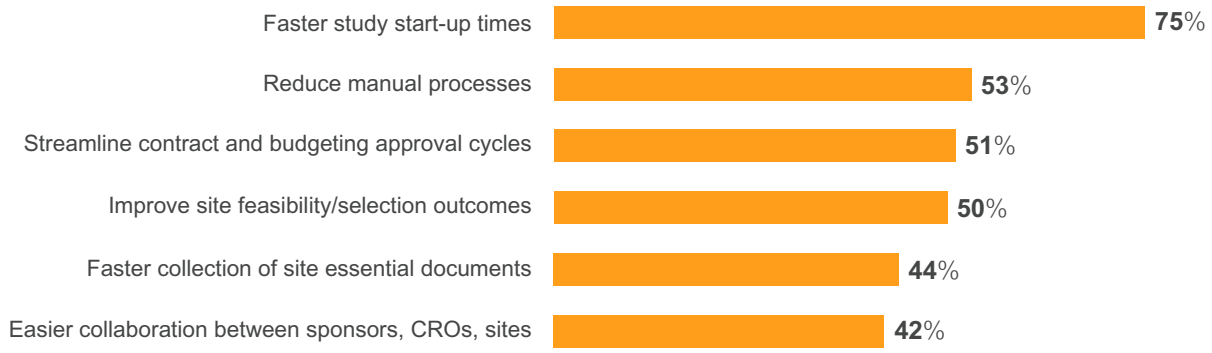
Findings show that study start-up is an area of significant potential to positively impact clinical trials, especially as organizations ramp up for post COVID-19 trial starts.[4]

All respondents say they need to improve study start-up processes. The top drivers are faster start-up times (75%), reduce manual processes (53%), streamline contracting and budgeting (51%), and improve site feasibility and selection outcomes (50%).

More than one-third say faster collection of site essential documents (44%) and easier collaboration (42%) will improve study start-up, highlighting the importance of streamlined information sharing and collaboration to trial performance.

Drivers to Improve Study Start-up Processes

Base: Total Respondents, N=524



To the extent your organization needs to improve study start-up processes, what are the primary drivers? Select all that apply. (Q.12)

Biggest Challenges in Early Stages of Study Start-up

Tufts Center for the Study of Drug Development (CSDD) research shows that the early stages of study start-up, like site contracting and budgeting, account for most of the cycle time in the start-up phase and take twice as long today than five years ago.[5]

As companies increasingly seek global approvals to improve study diversification during the COVID-19 pandemic,[6] challenges with country selection, initiation, and regulatory compliance add to these cycle times.[7]

More than two-thirds (68%) say site contracting and budgeting is their most challenging study start-up process, followed by site identification, feasibility, selection (55%), and IRB/ethics committee approval and planning (46%).

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1 Lamberti, Mary Jo. Tufts Center for the Study of Drug Development Impact Report. March 2018.
2 Applied Clinical Trials. The Need and Opportunity for a New Paradigm in Clinical Trial Execution. June 2018.
3 Veeva 2019 Unified Clinical Operations Survey Report. Methods of Information Exchange.
4 Informa PharmaIntelligence. COVID-19 and the impact on the clinical trial space. May 2020.
5 BioSpace. Site Contracts from Weeks to Months: Results from KMR Groups Site Contracts Study. August 2016.
6 Informa PharmaIntelligence. COVID-19 and the impact on the clinical trial space. May 2020.
7 Lamberti MJ, Wilkinson M, Harper B, Morgan C, Getz KA. Assessing Study Start-up Practices, Performance, and Perceptions Among Sponsors and Contract Research Organizations, Therapeutic Innovation & Regulatory Science, DOI: 10.1177/2168479017751403 tirs. sagepub.com

Site essential document collection is an issue for more than one-third of respondents (44%). This may be due, in part, to the prevalence of email and paper shipments to exchange trial documents with sites.[8]

Biggest Challenges with Study Start-up Processes

Base: Total Respondents, N=524

What are the most challenging study start-up processes, if any, that limit your organizations ability to speed clinical trials? Select all that apply. (Q.11)

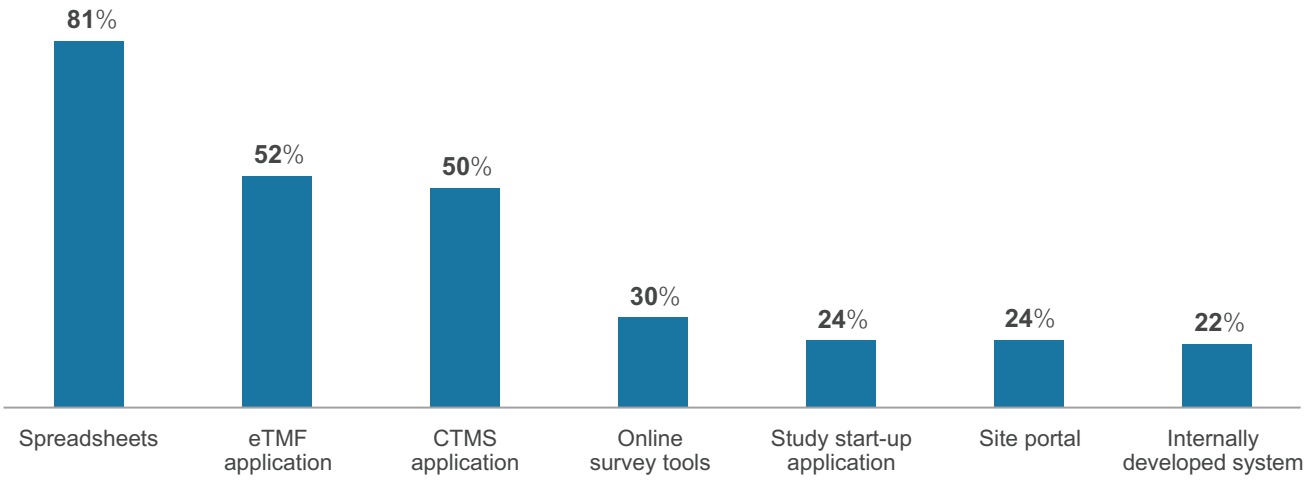
Heavy Reliance on Spreadsheets and Manual Processes

Majorities (81%) use spreadsheets to manage study start-up processes. Roughly half use eTMF (52%) and CTMS (50%) applications, followed by online survey tools (30%).

One-fourth or less use site portals (24%), purpose-built study start-up applications (24%), or internally developed systems (22%).

Tools Used to Manage Study Start-up

Base: Total Respondents, N=524



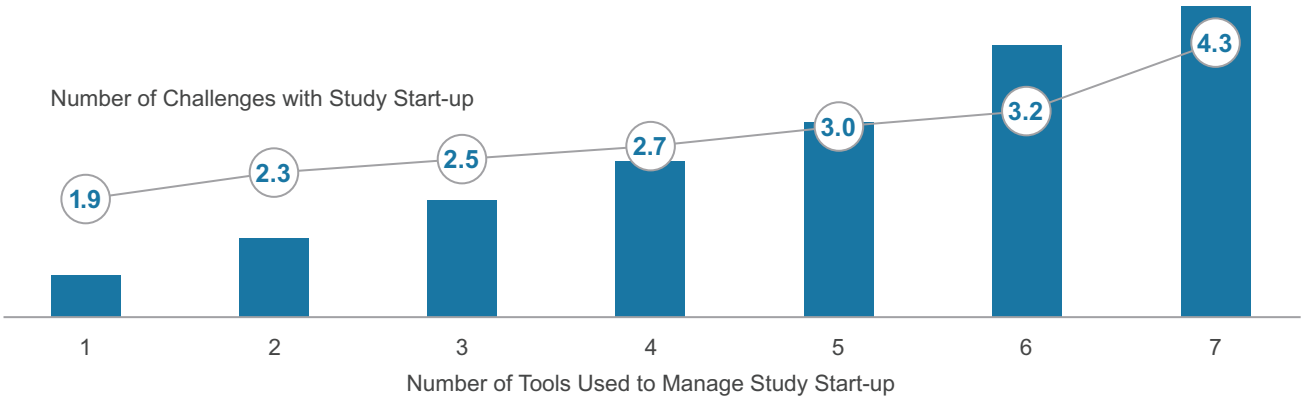
What tools do you use to manage study start-up processes? Select all that apply. (Q.10)

[8] Veeva 2019 Unified Clinical Operations Survey Report. Methods of Information Exchange.

The more tools used to manage study start-up, the more challenges respondents say they have with this process (r=.32, p<.001). On average, respondents use three tools to manage start-up activities and have two challenges.

Number of Challenges with Study Start-up Processes by Number of Tools Used

Base: Total Respondents, N=524



What tools do you use to manage study start-up processes? Select all that apply. (Q.10)
What are the most challenging, if any, study start-up processes for your organization? Select all that apply. (Q.11)

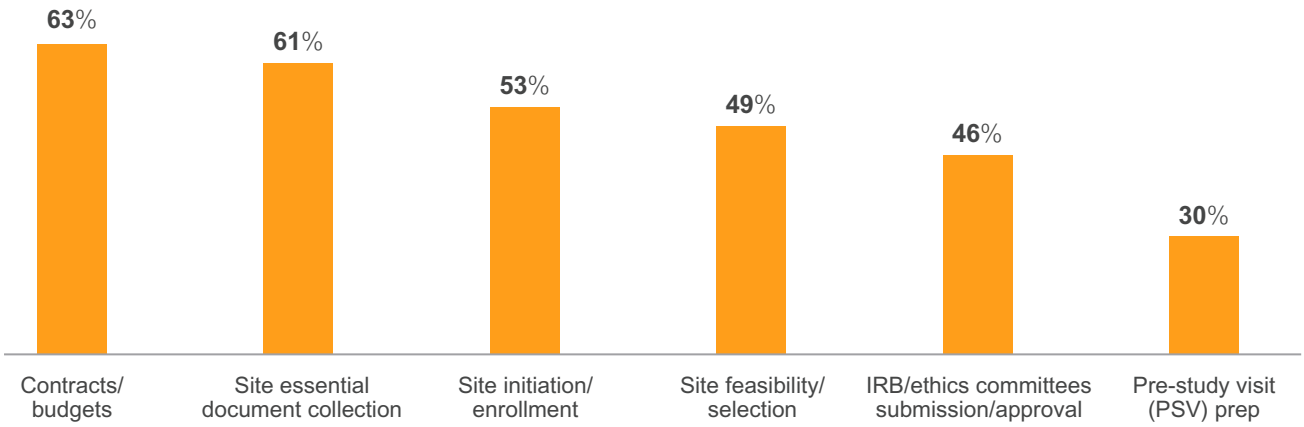
Improving Study Start-up Processes

The predominant use of spreadsheets and other general-purpose methods increases manual effort, as these tools are not purpose-built to manage study start-up processes.

More than half of survey respondents say automating key study start-up processes, like contracts and budgets (63%), site essential document collection (61%), and site initiation and enrollment (53%), will improve trial quality and speed study start-up.

Automating Study Start-up

Base: Total Respondents, N=524



Which of the following processes, if better automated, would improve trial quality and speed? Select all that apply. (Q.13)

Conclusion

There is industrywide recognition that streamlining study start-up is essential for improving the quality and speed of clinical trials.

While companies have made progress toward that goal, the COVID-19 pandemic has created urgency to keep existing trials on track and get new studies up and running faster.

As the industry takes action to address the critical need to accelerate study start-up, this research underscores the impact of:

- **Optimizing study start-up processes:** Study start-up is one of the clinical areas with the most potential to improve trial efficiency and execution. Encouragingly, adoption of study start-up applications is on the rise and is reducing cycle times by automating and streamlining start-up activities – bringing a higher level of predictability, quality, and speed to clinical trials.
- **Rapid, collaborative input and information sharing:** There is tremendous opportunity to streamline information sharing during study start-up. Modern, purpose-built study start-up systems on a unified platform streamline (and where possible, automate) the exchange of trial information for improved efficiency and collaboration.
- **Real-time, end-to-end visibility:** Positive change is underway as the industry adopts newer, advanced study start-up systems and processes. Manual trackers and spreadsheets are eliminated, and study progress is made visible to all parties in real-time – leading to significant gains in visibility and oversight to effectively manage and optimize trials.

The clinical trial operating model is changing as the industry reimagines its study start-up processes, driving new levels of efficiency, quality, and stakeholder engagement. The resulting gains will speed study activation and allow patients to be enrolled faster – and ultimately, bring safe and effective therapies to market more quickly.

The Veeva 2020 Study Start-up Survey consisted of four questions designed for individuals with knowledge of clinical operations processes and with full or partial responsibilities for clinical operations within their organization. Of the 524 validated responses, sponsors (76%) and CROs (24%) represented geographic locations from the U.S. (76%), EU and UK (14%), and ROW (10%).