cognizant®

Streamlined site study startup: Key components, perspectives and research-based insights

Introduction

Study startup (SSU) is integral to launching a clinical trial. Successful SSU requires close collaboration between sponsors and research sites. When well-orchestrated, SSU can reduce overall trial timelines, mitigate financial risks and help bring novel therapies to patients sooner. This article reviews key SSU steps from both sponsor and site perspectives, using recent research and industry benchmarks to validate the strategies and tools that can accelerate trial activation.

Feasibility assessment and site selection

Sponsor perspective

Sponsors begin by identifying sites capable of meeting trial requirements. Feasibility assessment (FA) typically involves sending questionnaires and feasibility surveys to potential sites to evaluate patient pools, staff expertise, facility capabilities and prior performance. Data from multiple sponsors suggest the full FA process can take approximately **30 days**, with actual site responses averaging around one week and sponsor deliberations making up the remainder.

Site perspective

Sites must respond to repeated, often duplicative queries from different sponsors. A 2021 ASCO analysis found that sites spend **a median of 264 hours per year** completing feasibility surveys, leading to an estimated **$1.6 billion** in labor costs across the industry.

Shared Investigator Platform (SIP)

Cognizant SIP reduces redundancy by storing site profiles (e.g., investigator CVs, facility data) that can autopopulate sponsor surveys and provide up-to-date information, significantly reducing the number of survey questions. For example, Roche reported a **36%** reduction in FA completion time after adopting SIP, decreasing from 11 to 7 days on average, translating into a 13%–19% overall site selection time savings compared to industry reported data[1,2].
By eliminating repetitive data entry, SIP speeds up sponsor decisions and site onboarding.

Budget and contract negotiation

Why it matters

Negotiating the budget and contract is frequently identified as the longest single component of SSU. National surveys indicate that contract negotiations exceed **100 days** for many multisite trials, while IRB approvals can be finalized in 30–45 days[3]. The lengthy negotiation phase can push back every other aspect of trial activation.

Sponsor perspective

Sponsors aim to standardize agreements and ensure fair market value payments. Adopting **master agreement templates** or standard contract language can trim several weeks off negotiations. For instance, using the Accelerated Clinical Trial Agreement (ACTA) has been shown to save **48–57** days on average compared to fully customized contracts[4].

Site perspective

Sites must adequately budget for all protocol-required procedures and overhead costs to avoid unbudgeted work. Transparent, detailed budgets, complete with justifications, tend to reduce sponsor pushback and keep negotiations on track.

TrialPro for budget creation

What it is: TrialPro is an AI-driven budgeting software that processes the study protocol, suggesting a granular budget outline and highlighting potential unbudgeted tasks. It also references fair market rates.

Key benefits:

- Autogeneration of itemized budgets, reducing 80–90% of manual work
- Real-time fair market value benchmarks, making requests easier to justify
- Fewer negotiation cycles due to well-supported initial budget proposals, often reducing cycle times by 4–6 weeks

By using a tool like TrialPro, sites can minimize guesswork, present stronger cost rationales and complete budgeting steps faster, all of which help expedite contract finalization, including coverage analysis.

Regulatory package completion

A comprehensive **regulatory package** is required before a site can enroll participants. It typically includes the Form FDA 1572, financial disclosure forms, investigator CVs, staff training records, delegation of authority (DOA) logs and other study-specific documents.

SIP integration

The Cognizant Shared Investigator Platform (SIP) simplifies regulatory document management by centralizing staff credentials, investigator CVs, and key facility data for one-time entry and reuse across multiple trials. Instead of manually completing new forms each time, sites can rely on SIP's autopopulation functionality to fill repeated fields in Form FDA 1572s, financial disclosures and delegation of authority (DOA) logs, dramatically reducing paperwork.

During Pfizer's Hyperspeed Program, for example, entire regulatory packages could be finalized in "a single sitting" because the system already housed the site's essential data, allowing for rapid site activation even under urgent conditions. By cutting out redundant data entry and enabling swift regulatory submissions, Cognizant SIP helps both sponsors and sites compress study startup timelines and accelerate the journey to first patient in.

IRB submission and approval

Local vs. central IRB

Although IRB review is sometimes viewed as a bottleneck, studies show **central IRBs** typically act faster than local IRBs. A JAMA Network Open analysis found central IRBs approved protocols in a median of **78 days**, whereas local IRBs averaged **165 days**, a roughly twofold difference[5]. As a result, many sponsors strongly encourage central IRB use to save potentially months of approval time.

Parallel submissions

IRB submission can often run in parallel with contract negotiations and regulatory documentation. Sites that tackle these tasks concurrently generally reduce their total activation time.

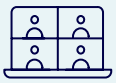
Other key site setup steps

Site systems (eSource, CTMS, eISF/eREG, lab and pharmacy management systems, various sponsor portals and patient facing systems)

Configuring the new study in internal systems before first patient visit avoids data entry delays. Some sponsor platforms automate tasks (e.g., screening logs) to expedite startup.

Pharmacy and lab setup

Proper storage conditions, lab kits and shipping processes must be ready. Delays in these areas can impact dosing start dates.



Staff training and investigator meetings

Sponsor-led investigator meetings and site initiation visits allow staff to master protocol procedures. Documenting training ensures compliance and reduces protocol deviations.

Financial systems

Aligning internal accounting or CTMS budgets with the finalized contract allows sites to track reimbursements and avoid payment delays.

Receipt of investigational product and supplies

Upon full activation (all approvals in place), the site receives IP shipments. Early inventory and organization ensure no “day one” supply issues.

Centralization, site networks and technology

Industry trends show **large site networks** are increasingly chosen for complex or high-volume trials, often because they use centralized business processes and standardized operations. A CRIO analysis of COVID-19 vaccine trials revealed that **49%** of selected sites were part of significant site networks. Centralized models (including single IRB use and integrated budget/contract teams) consistently demonstrate shorter activation times compared to standalone or academic sites[6].

SIP and centralization

The Shared Investigator Platform (SIP)'s organization structure supports centralization and large site networks by providing a unified, cloud-based ecosystem that connects sponsors, sites and technology providers. This centralized approach streamlines clinical trial management by eliminating redundant workflows and enabling a single point of access for all studies across different sponsors. SIP's ability to define centralized contacts (e.g., email inboxes) for large networks and site management organizations ensures efficient communication and task management. Additionally, its scalability and integration capabilities make it ideal for managing extensive site networks, ultimately improving operational efficiency and accelerating study startups.

Agentic AI in SSU—Beyond SIP and TrialPro:

SSU-focused technologies aim to coordinate tasks, track milestones and reduce administrative handoffs. Adoption of these systems, along with process improvements (e.g., Lean Six Sigma), has helped some sponsors cut months off standard startup timelines.

In addition, AI-driven orchestration and oversight, including agentic AI[7,8], is transforming SSU efficiency. By leveraging multi-agent frameworks, AI can automate site-specific startup processes, dynamically adjust workflows based on site capabilities, preemptively flag potential bottlenecks in regulatory approvals and provide near-real-time risk mitigation insights.

Conclusion

By aligning sponsor-driven feasibility assessment, budget/contract workflows and site-based regulatory activities in a parallel, tech-enabled process, organizations can significantly compress SSU timelines. **SIP** reduces redundant data entry, accelerates feasibility and regulatory submissions, and promotes centralized oversight. **TrialPro** helps sites present fair, fully justified budgets, enabling a smoother negotiation path. Meanwhile, leveraging central IRBs, consolidated site networks and integrated startup platforms can further streamline operations.

Through validated metrics and case studies, it is clear that technology, process harmonization and standardization are transforming traditional site startups. While achieving universal "90-day activation" remains challenging, especially for academic institutions, there is a clear path toward more efficient SSU, as also suggested by recent study[9]. With collaborative planning, data sharing and robust tools, sponsors and sites can ultimately bring new therapies to patients faster.

Note: Timelines and metrics can vary by region, trial complexity and individual site processes. The data and examples above represent industry-wide averages and observed case studies.

1. "Roche Genentech Cuts Trial Feasibility Process by 36%" Cognizant, https://www.cognizant.com/en_us/case-studies/documents/roche-cuts-feasibility-process-by-36-percent-codex6804.pdf
2. Abbott, Diana, et al. "Cycle Time Metrics for Multisite Clinical Trials in the United States" Therapeutic Innovation & Regulatory Science, January, 2013, http://journals.sagepub.com/doi/abs/10.1177/2168479012464371
3. Lawrence, CE, et al. "Quantitative assessment of the impact of standard agreement templates on multisite clinical trial start up time" Journal of Clinical and Translational Science, September, 2023, https://www.cambridge.org/core/journals/journal-of-clinical-and-translational-science/article/quantitative-assessment-of-the-impact-of-standard-agreement-templates-on-multisite-clinical-trial-start-up-time/5D7F4408016C708396E40C1346025D35
4. Lawrence, CE, et al. "Quantitative assessment of the impact of standard agreement templates on multisite clinical trial start up time" PMC, September, 2023, https://pmc.ncbi.nlm.nih.gov/articles/PMC10565190/Assessment of North American Clinical Research Site Performance During the Start-up of Large Cardiovascular Clinical Trials - PMC
5. Goyal, Akash, et al. "Assessment of North American Clinical Research Site Performance During the Start-up of Large Cardiovascular Clinical Trials" JAMA Netw Open, July, 2021, https://pmc.ncbi.nlm.nih.gov/articles/PMC9435961/
6. "CRIO sites were nearly 30% of U.S. COV19 Vaccine Sites. What this means for eSource adoption" CRIO, January, 2023, https://clinicalresearch.io/blog/running-a-study/crio-sites-were-nearly-30-of-u-s-cov19-vaccine-sites-what-this-means-for-esource-adoption/ACT0225_digital_watermark.pdf
7. Agentic AI – Multi-Agent Accelerator | Cognizant https://www.cognizant.com/us/en/services/neuro-intelligent-automation/neuro-generative-ai-adoption/enterprise-agentic-ai
8. "Agentic Artificial Intelligence (AI): A Game Changer in Clinical Trials" Everest Group, February, 2025, https://www.everestgrp.com/blog/agentic-artificial-intelligence-ai-a-game-changer-in-clinical-trials.html
9. "Clinical Operations and Strategy" Applied Clinical Trials, Vol. 1, February, 2025, https://cdn.sanity.io/files/0vv8moc6/act/9acaf5b8f0bae1315cc8575b3db13a298d4e7d28.pdf/ACT0225_digital_watermark.pdf

cognizant

Cognizant helps engineer modern businesses by helping to modernize technology, reimagine processes and transform experiences so they can stay ahead in our fast-changing world. To see how Cognizant is improving everyday life, visit them at www.cognizant.com or across their socials @cognizant.

World Headquarters
300 Frank W. Burr Blvd.
Suite 36, 6th Floor
Teaneck, NJ 07666 USA
Phone: +1 201 801 0233
Fax: +1 201 801 0243
Toll Free: +1 888 937 3277

European Headquarters
280 Bishopsgate
London
EC2M 4RB
England
Tel: +44 (01) 020 7297 7600

India Operations Headquarters
5/535, Okkiam Thoraipakkam,
Old Mahabalipuram Road,
Chennai 600 096
Tel: 1-800-208-6999
Fax: +91 (01) 44 4209 6060

APAC Headquarters
1 Fusionopolis Link, Level 5
NEXUS@One-North, North Tower
Singapore 138542
Tel: +65 6812 4000

WF3395242