

Clarity First: A Better Way to Study Start-up

How CNS Healthcare Uses Structure to Ensure Success

Study start-up is one of the most demanding phases of clinical research. For sites managing large and diverse portfolios, success depends on getting the right information early and keeping communication clear as complexity increases.

In a recent Collaborate Forward InterVIEW, leaders from CNS Healthcare focused on how structure, consistency, and follow-through help CNS sites take control of study start-up and reduce avoidable delays. And, what can be done more broadly across the industry. At its core, study start-up breaks down when sites are asked to operationalize studies without timely, complete, and consistent information across sponsors, CROs, and vendors.

Starting with Structure

At CNS Healthcare, study start-up begins with a disciplined approach to information gathering. Once a site is selected, the team uses a site selection checklist, followed by a study launch checklist once the study is formally assigned. This

structured approach, which is featured in the recently released **Collaborate Forward Playbook**, helps CNS surface critical information early and create alignment across internal teams before start-up activities accelerate.

These tools are designed to surface critical details early so that internal teams can plan effectively. Budget and contract teams need the protocol to accurately negotiate compensation and understand study-specific requirements. Regulatory and operational teams rely on early clarity to prepare documentation, training, and resources.

As soon as CNS receives a site selection letter, contract, or budget, the team sends a structured questionnaire to the sponsor or CRO. This checklist focuses on key areas such as training expectations, patient recruitment, study visits, and vendor involvement. In parallel, the regulatory team sends a separate checklist outlining regulatory requirements.

This approach allows internal teams to move forward together rather than waiting for information to arrive in fragments. For sponsors and CROs, this early clarity reduces rework, prevents downstream delays, and sets more realistic expectations for timelines and study execution.

Getting the Information Back

While the value of these checklists was clear from a site perspective, sponsors and CROs were at first hesitant or uncertain how best to respond.

Early in 2025, response rates to CNS's questionnaires were low and often incomplete. By the end of the year, nearly 90% of sponsors and CROs were responding fully. What changed? CNS focused on consistent follow-up and clear communication about why the information mattered.

Once the CNS team emphasized that the checklist is not intended to create obstacles, but to ensure the study can move forward efficiently and without surprises, completion of the checklist was dramatically improved. When possible, the CNS team had these conversations on the phone as that was the preferred method as it allows for faster clarification than email alone. Still, reaching the right contacts proved to be a challenge at times, particularly when sponsors defer communications to CROs.

Managing Growing Communication Complexity

As trials grow more complex, the cost of incomplete or delayed information increases, making early structure less optional and more essential. It's no secret that the study start-up today looks very different than it did a decade ago. Trials now involve more vendors, platforms, and specialized services. This added complexity increases the administrative burden on sites and pulls staff away from patient-facing work.

CNS manages start-up for approximately 100 studies per year. In 2025 alone, the team worked with more than 20 new vendors. Many studies involve 10 or more vendors, each with its own systems and processes.

At the same time that sites are managing this increased administrative burden, they are inundated with study communications, including monthly or quarterly newsletters from sponsors and CROs that may contain critical operational updates or protocol deviations without corresponding protocol amendments.

For sites managing large portfolios, this can result in hundreds or even thousands of must-read communications each year. Without clear information governance and ongoing feedback loops between sites, sponsors, and CROs, the risk of missed or misunderstood information increases, and opportunities to learn from completed studies are often lost.

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Early Signals Set Expectations

In this environment, responsiveness during start-up becomes an important signal. The CNS team has observed that sponsors and CROs who take weeks to complete start-up questionnaires often demonstrate similar response patterns once the trial is underway.

In some cases, the questionnaire itself helps sites evaluate the study team. Clear answers, timely responses, and a willingness to engage early can indicate a more collaborative partnership throughout the trial lifecycle.

From Site Practice to Industry Learning

The CNS approach highlights a broader opportunity for the industry. Practical, site-driven tools such as structured start-up checklists are already improving efficiency and reducing risk. By capturing and sharing these practices in the **Collaborate Forward Playbook**, CNS and other contributors are helping translate proven site solutions into scalable approaches that can be applied more broadly across studies.



From Site Practice to Industry Learning

When discussing what makes a strong sponsor partner, CNS leaders pointed to clear communication and accessible relationships. Direct lines of contact matter, particularly for site staff balancing patient care with administrative responsibilities. Clear expectations and shared understanding help reduce friction throughout the study.

CNS declines significantly more trials than it accepts, often due to overly complex protocols or unrealistic recruitment requirements. These decisions are driven by direct conversations between investigators and sponsors, reinforcing the importance of transparency from the outset.

Ultimately, collaboration comes down to people and culture. Teams that invite learning, mentorship, and honest dialogue tend to build more productive partnerships. While smaller sponsors are often perceived as more flexible, collaboration is possible at any scale when the right behaviors are in place.

Collaborate Forward Takeaways

- **Clarity enables speed:** Early, structured information gathering helps sites avoid delays later in the study.
- **Follow-up is not optional:** Persistent engagement is essential as trials grow more complex.
- **Start-up sets the tone:** Early responsiveness often reflects how a study will operate long term.
- **Information governance matters:** Growing vendor ecosystems and communication volume increase risk without clear processes.
- **People drive success:** Strong relationships and open communication remain the foundation of collaboration.
- **Shared tools accelerate progress:** Site-tested practices like CNS's start-up checklist, featured in the *Collaborate Forward Playbook*, help turn proven approaches into industry-wide improvement.

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