

SEVEN

COMMON

SIGNALS

THAT YOUR

STUDY

MAY BE

AT RISK



In clinical research, it's more common than not to run into obstacles.

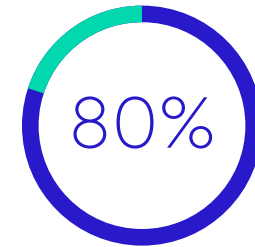
Clinical trial delays rarely stem from a single issue. More often, studies fall behind because several challenges converge: difficulty identifying and converting protocol-matched patients, limited site capacity, competing operational priorities, and participant burden that can lead to attrition. While teams often recognize when a study is stalling, determining the root cause can be far more difficult.

The impact can be significant. [Studies show](#) that nearly 80% of trials fail to meet enrollment goals and timelines, while [more than half](#) of terminated trials cite enrollment-related challenges as a contributing factor.

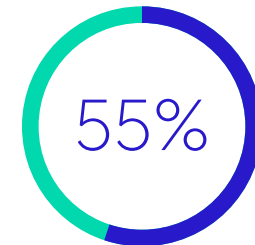
In some cases, the consequences aren't apparent until much later. [On average](#), 1 in 9 sites never enrolls a single participant, creating avoidable cost and operational burden while contributing little to study progress. Sponsors supported by WCG can experience 3x lower non-enroller rates, demonstrating the value of identifying performance barriers and intervening before they become larger study execution challenges.

"Most studies aren't on the targeted timeline," says Kari Lotsberg, vice president of operations at WCG. "Often, failure can be averted."

The organizations most successful at restoring study momentum don't simply react to missed milestones. They look for signals that performance is beginning to decline, understand what those signals reveal about study burden on sites, participant enrollment or engagement, and apply targeted support before delays compound.



of trials fail to meet their initial enrollment goals and schedules.



of all trials in the Clinical Trials Database terminated because of enrollment issues.

Source links:

[PMC](#); [Pharmaceutical Technology Analysis](#)

Avoiding Delays and Identifying Common Warning Signals in Clinical Trials

Clinical trials play a key role in advancing medicine. These studies have the potential to deliver medicines, medical devices, and hope to the patients who need them. By nature, clinical trials test scientific innovations and novel treatment options. As such, a variety of obstacles could arise that jeopardize the successful completion of the study and potentially threaten the future availability of that therapeutic.

[According to Pharmaceutical Research and Manufacturers of America](#) (PhRMA), it can take 10 to 15 years, on average, to develop a new medicine, costing around \$2.6 billion. And then there's the risk involved: only about 12% of drugs entering clinical trials receive approval by the U.S. Food and Drug Administration.

Following are seven common signals that your study may be at risk, along with solutions for rescuing the research.

SIGNAL 1

Activated sites are not reaching their enrollment potential.

Lagging recruitment is a key signal of underlying issues—not the main roadblock, but an important symptom to look at more closely. Proper participant identification, ineffective screening, overly burdensome protocols, and complicated site workflows are often the root causes of a site not meeting its enrollment goals. [One study](#) found that **85%** of study sites failed to meet their enrollment goals and [another study](#) noted that **11%** of trials failed to enroll a single participant. While increasing recruitment may seem like the obvious fix, it doesn't address the underlying barriers and can lead to increased dropout rates and retention challenges later.

By diagnosing where enrollment efforts are breaking down, targeted interventions can be deployed so sponsors can recover study momentum and sites can reach their full enrollment potential.

“Identifying the available sources of potential individuals for a study is just one step,” says Lotsberg. “Efficient participant identification across available tactics and optimizing site workflows, sometimes through local interventions, can support effective recruitment efforts for sustainable retention throughout the clinical trial lifecycle.”

Source links: [PhRMA](#); [PubMed](#); [PMC](#).

SIGNAL 2

Participants are dropping off before the study is complete.

Clinical trials depend on participants who volunteer their time and trust in pursuit of potentially life-saving therapies. Proper communication, consistent follow-up, and thoughtful protocol design accumulate to create a positive experience that helps participants feel informed, engaged, and respected throughout the experience. [Research shows](#) approximately **30%** of trial participants fail to complete the study. “That first impression is really critical,” says Lotsberg. Inconsistent or lacking communication, coupled with burdens like frequent site visits or confusion about next steps, can deter them from study participation, and could negatively impact their willingness to consider participating in trials in the future. “There’s a finite number of people in the world and only a small portion are open to participating in clinical trials,” she says. “How each person is treated can impact the advancement of science.”

SIGNAL 3

Teams lack visibility into the source of delays.

If a study encounters a roadblock, site managers should be honest and transparent with the sponsor about the issues they’re facing.

These issues can vary based on factors like site capacity, location, and capabilities, underscoring the importance of operational benchmarking to better understand the nuances unique to each site. A clearer understanding of each site’s specific challenges allows teams to implement targeted interventions that address current barriers and prevent similar issues from recurring.

Maintaining study momentum depends on understanding what’s happening at the site level. Because each site faces different challenges, it’s critical to have an open dialogue with stakeholders at each site and implement tailored solutions. All of this must be done with an eye toward success and not blame. “Our goal isn’t to unpack where they might have gone wrong to assess blame,” says Lotsberg. “Our goal is to support the study and advance science. To do that we need a detailed understanding of where the process went off track, so we know what it takes to course correct.”

Our goal is to support the study and advance science. To do that, we need a detailed understanding of where the process went off track.

—KARI LOTSBERG, VICE PRESIDENT OF OPERATIONS, WCG



Source links: [PMC](#).

SIGNAL 4

Participant interest is high, but conversion remains low.

Identifying prospective participants is a single step in a larger recruitment strategy. Enabling sites with the proper materials to inform and connect with participants and their caregivers is a key differentiator between interest and retention. Optimizing processes and reducing potential burden on those participants is another strong indicator of whether they will remain enrolled. “We’ve seen instances where studies have made no materials available and are having a hard time engaging individuals who are considering participating,” says Lotsberg. “Simply offering them a brochure or referring them to a website can make a big difference. Individuals want to feel empowered and informed when considering participation in clinical research. Further, they expect a level of legitimacy. All these factors drive the importance of having study-specific collateral available.”

SIGNAL 5

Protocol criteria are misaligned with real-world patient populations.

As science advances and protocols become more complex, the ideal participant can become increasingly difficult to identify. This complexity requires sponsors and sites to optimize their recruitment

strategy to ensure precision and effectiveness in targeting and engaging the right participants. Leveraging study feasibility and protocol intelligence tools backed by real-world data can bridge the gap between assumptions and realistic expectations. Leaning only on internal historical knowledge can unnecessarily increase complexity and burden, leading to attrition and reduced chance of future participation. Collaborating with a centralized partner who can identify true qualification trends and patterns in identification and enrollment can help determine whether a protocol is likely to enroll within the desired timeframe, or whether adjustments may be needed. The partner can also serve as the communication pathway between the sponsor and the sites to address any bottlenecks and safeguard study momentum.

Understanding where the opportunity for improvement lies in each study is key to effective acceleration. However, identifying the roadblocks to recruitment will be necessary for success at any speed. “The sponsors focused on moving their study forward have been thrilled with knowing that the initially targeted population was not enrollable. That type of information saves time and money,” says Lotsberg.

In fact, it’s not unusual for the scope of the protocol to change. The Tufts Center for the Study of Drug Development found that **57%** of protocols had at least one substantial amendment - although nearly half (**45%**) of those were deemed avoidable, had they been designed and planned differently.

SIGNAL 6

New sites are added to fix an existing problem.

When a study encounters delays, the challenges may revolve around one or more sites. Because of that, a default response is to open new sites in hopes they will solve the problem. In fact, seeking out new sites may take more work, demand more time, and result in new challenges, further compounding existing constraints and complexity. By identifying underlying indicators of enrollment issues, site performance can be improved, and sites with strong enrollment can become super-enrollers. “Let’s figure out what’s causing the problems before we add to them,” says Lotsberg. Talking to teams at the site level, unearthing barriers to success, and deploying targeted interventions are key to solving the problems at hand and rescuing the study.

SIGNAL 7

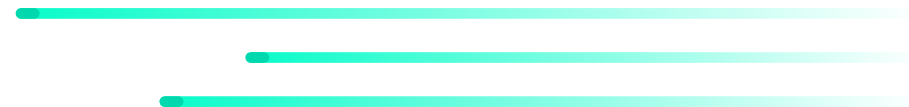
Study teams operate reactively to downstream issues.

Careful planning and consistent communication with research sites can help a trial steer clear of problems that will impact timelines down the road. Site selection might be conducted weeks, months, or even a year in advance, so early and honest collaboration

between sponsors and sites can mitigate issues before they arise. Continuous visibility, ongoing performance monitoring, and proactive intervention can save time and budgets from unnecessary derailments. “You might think a site is going to be a super-enroller, and for whatever reason, that didn’t happen. But you might also have a site that you didn’t think was going to deliver, and they exceeded their target,” says Lotsberg. “That’s why it’s important to have oversight of the centralized strategy of the study, including site-level feedback, so we can consistently adjust the dial to reach the overarching goals of the research.”

It’s important to have oversight of the centralized strategy of the study... so we can consistently adjust the dial to reach the overarching goals of the research.

—KARI LOTSBERG, VICE PRESIDENT OF OPERATIONS, WCG



The Power of Partnership

Clinical trials are complex. But accelerating your study start-up doesn't have to be. WCG's relationship-first approach and data-driven insights enable sponsors and sites to identify problems, design site-specific solutions, and when needed, rescue studies that are at risk.

Early dialogue and education about warning signals, what they mean, and where to deploy targeted intervention can make the difference between a study that is reactive and in need of rescue and one that is proactively planned and ready for first patient in. Either way, the intention is the same:

“WCG's mission, put simply, is to improve lives by accelerating research, together.”

—Kari Lotsberg, vice president of operations, WCG





We are the decision infrastructure of clinical research, combining trusted oversight with intelligence that scales judgment and reduces risk across the trial lifecycle.

With decades of experience and the industry's deepest dataset powering responsible AI, we help teams make confident decisions that keep trials moving forward for therapies at every stage of development.

For more information, please visit wcgclinical.com or follow us on [LinkedIn](#).

