

patientIQ

Top 5 Roadblocks of **Clinical Research Studies**

A comprehensive guide for clinical research directors, managers, and their teams

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INTRODUCTION

Why efficient study execution matters: A proactive approach to overcoming challenges

As clinical research studies grow increasingly complex, clinical research teams face multiple study execution hurdles. Each one can impede progress, inflate costs, and jeopardize study integrity.

Many of these challenges begin during study design and protocol development. If not promptly addressed, they can lead to downstream issues with site training, patient recruitment and enrollment, study launch, participant engagement, and, ultimately, data capture. When left unaddressed, these challenges lead to delays, with each day of postponement creating substantial financial burdens. Research suggests an estimated 85% of studies will experience delays, which can lead to costs of between $600,000 and $8 million per day. Furthermore, clinical research studies often involve multiple sites, a wide variety of endpoints, and a dizzying amount of data that must be collected, categorized, and analyzed.

Clinical teams must proactively plan for how to manage these details to avoid cascading issues, such as:

- Elongated timelines
- Unnecessary burdens for patients and providers
- Increased patient dropout rates
- Delays getting treatments or devices to market

A number of complexities can hinder study launch, management, and successful completion. However, strategic solutions can address these challenges before they impact outcomes, enabling clinical teams to secure data quickly and efficiently. With the right tools, clinical teams can streamline execution, heighten efficiency, and enable transformative outcomes in clinical research.

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Exploring 5 Common Study Execution Pitfalls

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5 Common Study Execution Pitfalls

1 Failure to capture all endpoints accurately

The challenge:

When it comes to accurately capturing the necessary endpoints in a clinical trial, researchers face a triple challenge:

- The sheer number of endpoints is growing, with a 58% increase in the average number of tasks per participant.
- Simultaneously, those endpoints are becoming increasingly complex.
- Researchers today are often managing large cohorts and sample sizes.

Without a careful plan to mitigate these challenges, clinical teams may find themselves with either inadequate or redundant data points—both of which create critical risks. Vital endpoint data may be incomplete or completely missing, compromising the study's validity and efficacy. On the other hand, redundant data collection increases the burden on patients, leading to retention problems over the course of long-term studies.

The solution:

Clinical research teams must adopt new approaches to gather endpoints as efficiently and effectively as possible. The solution lies in automating as many processes as possible. By implementing multiple touchpoints tailored to the patient population they’re studying, researchers can increase participant engagement and ensure more comprehensive data collection.

Custom timelines that align with established standards of care can further streamline the process, reducing the burden on patients and enhancing retention rates. Through automation and strategic planning, studies can achieve their research objectives more effectively, ensuring robust and reliable data that supports the validation of new treatments and interventions.

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2 Recruitment and enrollment issues delay launch

The challenge:

Difficulties in identifying, enrolling, and retaining patients can impact study launch significantly. For example, research suggests that recruitment problems cause delays—or even termination—for 80% of studies. As a result, actual enrollment timelines can grow to be twice as long as initially planned.

Why is enrollment so difficult? First, it takes considerable time to identify and enroll quality patients. Once researchers overcome this hurdle, they may struggle to engage those qualified patients. For example, data from Centerwatch shows that 69% of patients fail pre-screening, 58% decline consent, and 8% drop out after enrollment.



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2 Recruitment and enrollment issues delay launch

The solution:

Tackling recruitment and enrollment hurdles can lead to big payoffs when it comes to study timelines. However, to overcome these challenges, researchers need a more strategic approach to streamline study launch:

- Determining the optimal number of study sites from the outset can ensure a sufficient sample size and prevent recruitment bottlenecks.
- Leveraging auto-enrollment systems that are integrated with electronic health records (EHR) can significantly speed up the identification of qualified patients. This process can include customized inclusion and exclusion criteria, such as specific procedure or demographic factors.
- Automating site training through enrollment protocols can reduce staff workload. This method can also minimize the recruitment of patients who may not meet the enrollment criteria, thereby reducing drop-out rates.

By implementing these measures, clinical research directors and their teams can achieve more timely launches, maintain robust patient participation, and ensure smoother execution.

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3 Unengaged site staff

The challenge:

Provider and staff engagement can wane over time, especially if clinical teams don't take the right precautions. Additionally, site engagement can decline for a number of reasons, so a one-size-fits-all approach may be ineffective.

Two major causes can lead to a drop-off in site engagement. First, while providers may be initially motivated by the prospect of publication, this incentive alone may not be enough to sustain their participation throughout a lengthy study. Additionally, studies that require providers to learn external systems can further hinder engagement, as they add to the substantial administrative burdens healthcare professionals face today.

The solution:

Overcoming these hurdles requires a two-pronged approach. First, it's important to minimize the burden of study participation. One effective strategy is to leverage existing workflows, such as integrating study processes with EHR systems already in use. This minimizes the need for additional tools while also simplifying enrollment and data collection.

Second, researchers can encourage site engagement by adding value for providers beyond publication. In particular, many clinicians are motivated by the prospect of enhanced data access. When critical data — like adverse events or patient-reported outcomes — is collected and stored in a centralized system that's already part of a clinician's workflow, it provides the clinician insights into patient progress they may have otherwise been unaware of. By adding these layers of value, researchers can enhance the likelihood of smooth implementation and foster sustained engagement from site staff and providers.

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4 Patient fatigue limits data collection and increases dropout rates

The challenge:

Even after studies move through enrollment and launch, patient retention problems can stymie study execution. In fact, as many as 23% of participants who enroll in a research study don't see it through to completion.

Unnecessary or repetitive data collection can frustrate patients. Complicated data tracking systems can cause patients to incorrectly report outcomes or opt out of reporting altogether. These barriers affect patient retention and compromise the ability to collect comprehensive, complete data.

The solution:

To combat patient fatigue, researchers must adopt methodologies that maximize engagement and reduce burdens. Advanced digital platforms can tailor outreach to engage patients effectively without overwhelming them.

An automated platform with a user-friendly interface and flagged tasks can simplify participation, making it straightforward for patients to complete required actions. Additionally, recency logic can eliminate unnecessary or repetitive steps or questions to ensure that patient interactions are efficient and relevant, and alleviate burden associated with study participation. By implementing these strategies, researchers can enhance patient retention and improve the quality of the dataset.

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5 Costly on-site monitoring

The challenge:

The manual workload associated with on-site monitoring can escalate study expenses, accounting for a significant portion of overall costs. Additionally, scheduling visits and gaining access to sites has become increasingly challenging in the post-COVID world, further complicating the monitoring process.

The solution:

Enhanced remote monitoring offers a viable solution that reduces both costs and logistical burdens. By leveraging electronic tools for source data verification and audit logs, researchers can streamline data management and ensure accuracy without the need for frequent physical visits. Timely and efficient data queries done from a central location can identify and correct errors early in the process, preventing them from compounding over time. Furthermore, real-time review of PHI-restricted databases allows monitors to verify that data is complete, accurate, and collected expeditiously.



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Next Step: Elevate your Clinical Research Studies

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Elevate your Clinical Research Studies

In addition to addressing the five most common study pitfalls, you can improve execution even further with a tech-enabled research infrastructure. With advanced tools like PatientIQ's ResearchPRO, you can streamline processes, enhance data capture, and modernize the overall patient experience. By adopting such solutions, clinical research directors and their teams can ensure more efficient study execution, ultimately benefiting patients, researchers, and institutions alike.

What can ResearchPRO do for your clinical study?

PatientIQ's EDC Solution, ResearchPRO, includes a comprehensive suite of research modules designed to help teams collect high-quality data more efficiently and with less hassle. Its capabilities allow teams to rapidly deploy clinical studies and registries, seamlessly integrate study enrollment and patient data with existing EHR systems, and increase patient and provider compliance.

By elevating site engagement and easing provider burden and administrative tasks, ResearchPRO automates enrollment and streamlines site training. Additionally, it simplifies on-site monitoring, improves data integrity and compliance, and provides real-time, actionable insights, making it an indispensable asset for successful study execution.



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Elevate your Clinical Research Studies

How ResearchPRO streamlines study execution

ResearchPRO is a comprehensive, tech-enabled research infrastructure designed to streamline study execution and reduce costs, particularly for multi-center research studies. It effectively manages various types of studies, including clinical data registries, post-market surveillance, prospective studies, multi-center studies, and retrospective studies.

ResearchPRO enhances study execution, ensures compliance with FDA CFR Part 11, and supports multi-format data export and multi-center study collaboration. Its streamlined workflows include automated EHR-integrated enrollment with more than 10,000 providers as well as customized project design, defined user roles and permissions, and electronic consent. Advanced monitoring features such as query functionality, audit logs, patient data completion tracking, and real-time visibility allow for efficient remote monitoring and real-time reporting.

The platform also offers tools for data viewing and cohort building. Plus, it provides a biostatistics engine that supports near real-time feedback for benchmarking. This feedback can also increase provider and site engagement through enhanced clinical decision-making based on timely data.

ResearchPRO modernizes the patient experience with digital consent and customized automated touch points. Real-time data capture ensures timely and accurate collection of electronic patient-reported outcomes . Through these features, ResearchPRO significantly reduces the burden on researchers and enhances the efficiency and effectiveness of study execution.

From recruitment to implementation and monitoring, ResearchPRO offers a comprehensive solution that can help researchers design, launch, and manage their projects. When studies are conducted on time and on budget—with meaningful data in hand—it helps move research one step closer to product success and improved outcomes for patients. That's a win-win for everyone.

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CONCLUSION

The five most common study execution pitfalls don't just disrupt timelines. They also strain resources, hinder patient and provider participation, and delay the delivery of potentially life-changing treatments to those in need.

However, with proper planning—and the right tools—you can avoid these major challenges by:

- Enabling reliable and robust endpoint capture
- Strategizing recruitment and enrollment efforts for maximum efficiency
- Engaging site providers by adding value to clinical practice and relieving staff demands
- Minimizing patient burden
- Reducing costly on-site monitoring

Adopting a tech-enabled research infrastructure like ResearchPRO can bring you further efficiencies and help you capture the data you need quickly and conveniently.

About PatientIQ

PatientIQ is the healthcare technology partner for deriving actionable insights from patient data. Its proprietary, cloud-based platform has demonstrated years of experience and an unparalleled ability to help organizations leverage data to improve clinical and operational performance. The cloud-based, EHR-integrated platform enables health systems, specialty practices, and medical device companies to systematically collect and analyze patient data. The platform facilitates collaboration, from research to registries, and pushes medicine forward.



For more, visit **www.patientiq.io** or request a demo at **www.patientiqi.io/request-a-demo.**

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