

Mitigating common challenges biotechs face in clinical trials

Top 5 questions biotech companies should ask to enable study success

Navigating the complexities of clinical trials can present significant challenges for biotech companies and startups. With the stakes so high, it's crucial to ask the right questions to enable the success of your clinical trials. From selecting the appropriate endpoints to optimizing for operational excellence, each decision can significantly impact the outcome of your study.

Explore the top 5 questions Clario's experts think biotechs should ask to enhance clinical trial success:

01 What clinical endpoints should we measure?

Selecting the right endpoints is crucial for the success of a clinical trial. Biotechs should consider:

Patient-centered endpoints: Don't lose focus on your drug's functional improvements and quality of life. Your endpoint strategy should go beyond regulatory minimums to demonstrate not only efficacy and safety, but also patient-relevant outcomes that may influence reimbursement decisions.

Trustworthy, high-quality data: Optimize data by considering your study design holistically, including considerations of sample size, endpoint modalities and technologies, and the schedule of clinical assessments.

Regulatory-accepted endpoints: Engage early with regulatory bodies to minimize submission delays and ensure endpoints are both clinically meaningful and regulatorily accepted.

02 How can we ensure operational excellence and meet critical milestones?

Operational pitfalls can delay clinical trials. Key considerations include:

Protocol design: Engage subject matter experts early on to ensure the protocol is scientifically sound and operationally feasible.

Study start hand-off: Avoid ambiguity by establishing clear roles and responsibilities, defined schedules, and collaboration among all stakeholders.

Flexibility: Be prepared to regroup and re-strategize if something isn't working as planned.

Role and responsibilities: Ensure that you and your CRO partner have a clear understanding of set up and monitoring responsibilities.



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03 What should we look for in a CRO or endpoint partner?

Choosing the right CRO or endpoint partner is critical. Biotechs should consider:

Proven expertise: Choose a partner with expertise in the therapeutic area and indication you're studying, and experience with delivery in countries where the study will be conducted.

Scientific depth: Make sure your partner has access to the right subject matter experts and key opinion leaders, with a proven track record in your area of focus.

Engagement model: Ensure your partner has demonstrated good collaboration, flexibility, and governance to manage study execution well.

04 How can we balance participant centricity with scientific value?

While scientific rigor is essential, it must simultaneously be balanced with patient centricity. Considerations include:

Participant burden: Minimize the burden on participants while ensuring data quality.

Data quality: Leverage technologies that allow for accurate and timely data capture, such as Patient-Reported Outcomes acquired remotely between clinic visits.

Engaging patient groups: Validate assumptions and gain insights from patient groups early on to optimize the study design and minimize burden.

05 How can we de-risk and ensure seamless study execution?

Unexpected issues can arise during study conduct. Strategies to de-risk include:

Study risk assessment kick-off meeting: Conduct a thorough upfront meeting involving all partners to walk through the protocol and identify potential risks.

Real-time study surveillance: Leverage innovative technologies for real-time monitoring and data cleansing to identify and address issues promptly.

The power of asking the right questions

By asking these important questions, biotechs can navigate the complexities of clinical trials more effectively, streamline processes, mitigate risks, and ultimately bring innovative treatments to market more efficiently.

Check out our recent webinar, [Keys to Success in Clinical Trials: A Strategic Guide for Biotechs and Startups](#).