WORLDWIDE CLINICAL TRIALS

7 TRENDS IN EARLY PHASE CLINICAL TRIALS

AND HOW TO MAKE THEM WORK FOR YOU

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THE RISKY BUSINESS OF EARLY PHASE TRIALS

Without a doubt, early phase trials are a risky business. An MIT study published in 2018 indicates the probability of success for a compound from Phase I through approval to be about 7-14%. The high variability in cost drivers – staff, clinical site and equipment, patient recruitment, digital data management – necessitate a high level of trial design and management expertise to ensure a cost-effective use of time and budgetary resources so that targets are met without compromising data integrity and regulatory compliance.

EARLY PHASE SUCCESS IS NO GUARANTEE OF FINAL APPROVAL

The most frequently identified reasons for trial failure are study design, site selection, inadequate recruitment, patient burden or safety issues, and poor trial execution. Success in an early phase trial is just the first step along the path to market approval. Therefore, strategic design, proactive business decisions, and meticulous execution are crucial to laying a firm groundwork for subsequent phases. Protocol execution starts with recruitment. Enrolling the right amount of patients or healthy volunteers to make your dataset viable enables advancement in later phase trials.

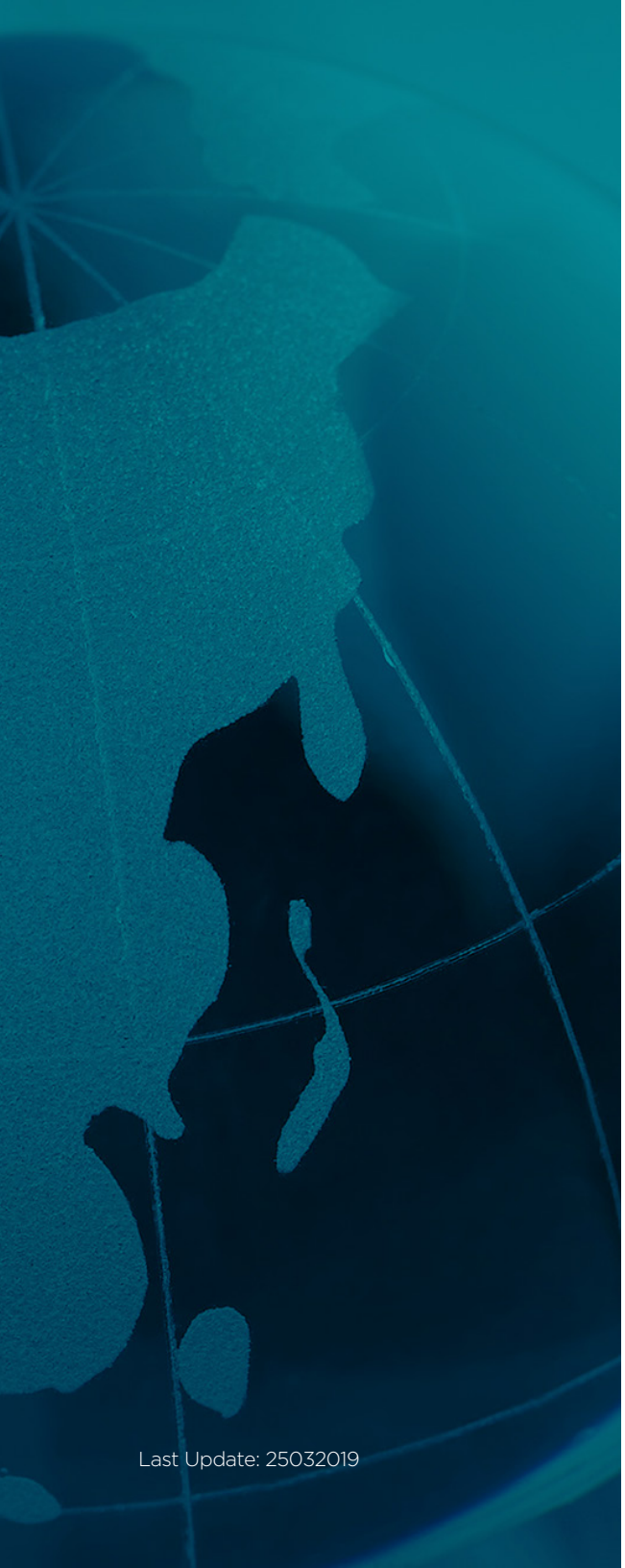
THE SHIFTING LANDSCAPE OF EARLY PHASE TRIALS

The field of pharmaceutical research is in a perpetual state of flux, with the continuous emergence of new scientific knowledge and the constant refinement of regulatory policy. Sponsors need to be alert to new regulatory developments, while at the same time remaining poised for new opportunities as they arise.

You have a lot at stake in your early phase trial, and the perpetual movement of science and regulation adds extra levels of risk. But, by applying a strategic approach to innovation, you can discern and leverage the necessary and beneficial shifts in early phase trial practice to drive your success. As we discuss these emerging trends, we hope to identify new opportunities for sponsors to extend their successes beyond Phase I and optimize potential for success all the way through to market approval.

TRIAL EXECUTION:
LAB SERVICES AND EVALUABLE STUDY PARTICIPANTS

Trial execution can make or break your early phase program. If lab services and study participants are ignored, the outcome of your study is questionable at best. Finding the right partner who offers only the highest standards and levels of expertise is your best bet for a successful program.



TREND 1: DO YOU HAVE ACCESS TO BEST-IN-CLASS LAB SERVICES?

Dedicated clinical and laboratory facilities must be able to support projects requiring personal focus and attention. This includes the essentials for storing and dispensing study drugs as well as maintaining investigator site files and study data.

Of course, the facilities must also maintain the latest and greatest compliance, such as GCP and ICH. The best facilities can seamlessly transfer specimens for analysis to a top bioanalytical lab.

Lastly and most importantly, the CRO you choose must accommodate your study participants.

TREND 2: A COMMITMENT TO YOUR HEALTHY VOLUNTEERS AND PATIENTS

When you're in need of healthy volunteers, it's important to work with a CRO that understands your goals. What screening questions will you ask volunteers? What health assessments must the volunteers pass? What requirements must the healthy volunteers understand and comply with in order to participate successfully? A great CRO will ensure compliance with established procedures and oversight. This trend is a must-have for any drug developer looking to take their asset to the next step.

When you're ready to move your asset into patients, there are several questions you should use to assess your CRO partner. Does your CRO know the therapeutic area? Does it have the expertise necessary to recruit the right patients to provide you with the valuable data necessary to make decisions about your asset? Can it help you create a proactive action plan for any and all outcomes and be flexible during implementation?

Whether you're analyzing your drug in healthy volunteers or patients, this is one trend that will never go away.

PROTOCOL DESIGN: TAKING THE LONG VIEW

Emerging trends in the clinical trial industry indicate that sponsors and researchers are increasingly taking a long-view approach to early phase clinical trials. Thought leaders in pharmaceutical research are advising that early phase trials gather as much knowledge as possible. Because the ultimate goal is getting your compound approved for release into market, your investment in earlier phases of study needs to pack a proactive punch.

TREND 3: OLD COMPOUNDS, NEW IDEAS

Researchers in both industry and academia continue to advance knowledge of diseases, identifying biomarkers and other potential targets. These new learnings are leading drug developers to re-examine compounds that have failed in the past, attempting to refine applications based on new research. Evaluation of previous studies, combined with innovative approaches, may create new opportunities for sponsors and new hope for patients needing treatment. A good CRO partner will be able to step into your previous processes or analyze historical data from previous regulatory submissions and adapt them to new applications. Its scientific and medical experts will be aware of the state of the industry, current regulatory guidances, and already be up to speed on what is working.

TREND 4: FAILING UP

Although failure is not your desired outcome, it's best to identify ineligibility of a compound early to mitigate expense and timeline risks. Meticulous procedures combined with aggressive timelines and proactive protocols will ensure that you get the best results within reasonable resource constraints. As a sponsor, you need absolute trust in your CRO, not only for its research expertise but also for its loyal commitment to your long-term success. A CRO that knows the history of your product and understands your ultimate goals will give you precision in both service and guidance. The ideal CRO is committed not only to completion of this early phase of your project but also to your ongoing success, recognizing and adapting to unexpected study outcomes as they arise.

TREND 5: PROACTIVE TRIAL DESIGN

Another trend in early phase clinical trials is an increase in multiple-cohort trials, incorporating both target patients and healthy volunteers. This design feature enables an accelerated progression from early to later phases. While creating opportunity for faster advancement of therapies to market, the added complexity calls for meticulous trial design and execution, with a view to bringing early phase data forward for application in later phases. Your CRO partner will be able to design a study to accommodate multiple treatment arms and access the necessary subject populations. It should also maintain the flexibility to adapt as new data emerges. Lastly, it will have the expertise to evaluate your needs and implement strategies to optimize data quality and minimize risk while accelerating your process from early phase all the way through to approval.

RESEARCH COLLABORATION: BUILDING BRIDGES

As sponsors seek to improve their success rates in drug approvals, they are looking to external resources that can enable them to fine-tune their research strategies. The challenge for sponsors is to create pathways for exchange of ideas and opportunities between researchers and patients.

TREND 6: BRIDGING THE GAP BETWEEN INDUSTRY AND ACADEMIA

In the last decade, professionals in the pharmaceutical industry were beginning to recognize the fact that while academic researchers continue to make medically important discoveries, they do not always have the access or resources to translate these discoveries into therapeutic solutions beneficial to real-world patients. Thus, recent years have seen a move toward increased collaboration and communication between academia and the pharma industry. A CRO that has strong relationships with academic advisory groups is the sponsor's best resource for ensuring its study benefits from front-of-the-line access to emerging research.

TREND 7: THE POWER OF PATIENT ADVOCACY

As patients are becoming more self-advocating, they are educating themselves about their disease or medical condition and connecting with other patients to share experiences and information. For the sponsor, increasing trial complexity makes recruitment and retention strategies even more critical, particularly in earlier phase trials where subjects have less incentive to participate than patients in later-phase studies. Low recruitment often leads to protocol amendments, which can affect study timelines and costs. Increased patient interactivity presents new opportunities for industry to engage with its target population, opening new avenues for improvement of recruitment and retention. Although sponsors often have their hands full managing the practical concerns related to compound development and approval, a good CRO partner can bring to the process a pre-existing network of relationships with patient advocacy groups and key opinion leaders as well as an arsenal of proven strategies and tools for optimizing recruitment compliance and retention of study participants.

WORLDWIDE CLINICAL TRIALS: YOUR EARLY PHASE PARTNER

With three decades of proven reliability in clinical trial design and execution, the team at Worldwide Clinical Trials has uncommon expertise that combines grounded dependability with adaptive flexibility. We have what it takes to move your project forward in the face of changing dynamics in the pharma research space, to spot trends as they emerge, and leverage change to your advantage.

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DEDICATED FACILITIES. Our dedicated early phase clinical and laboratory facilities in Texas are available for those projects requiring up-close focus. In addition to our dedicated GCP/ICH compliant 300-bed clinical site with on-site cGMP Phase 1 compounding pharmacy service, CLIA safety testing, and local PK bioanalytical validation and GLP testing in San Antonio, we have a bioanalytical lab in Austin, Texas.

PATIENT FOCUS. Through our relationships with patient advocacy groups, we are learning more about the patient's experience with their medical condition, which enables us to devise patient-focused solutions to meet the challenges of recruitment and retention. Through strategic protocol design and digital technologies, we minimize the burden associated with clinical trial participation, while still preserving data quality.

HEALTHY VOLUNTEER RECRUITMENT. Our subject recruitment team makes clinical trial opportunities inviting and accessible for healthy volunteers. Through a careful process of evaluation, we can ensure those subjects enrolled in your study not only meet appropriate inclusion/exclusion criteria but also are most likely to be compliant and stay the course of the trial.

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GLOBAL PRESENCE. With clinical trial sites in more than 60 countries worldwide, we have access to large patient populations and clinical professionals, as well as a close-up understanding of regional variations in patient care and regulatory considerations. Yet, despite our global footprint, we maintain our commitment to each unique trial and its individual participants and stakeholders.

COLLABORATIVE PARTNERSHIPS. We continue to forge relationships with academic research organizations. Among our current academic partners are Duke Clinical Research Institute, TIMI Study Group, and Atlas in the US, as well as PHRI in Canada.

INNOVATION. With a history in clinical trial design and execution that dates back to the 1970s, we have been instrumental in numerous cutting-edge therapies across a number of therapeutic areas, many of which are commonly used today.

TRUSTWORTHINESS. Our award-winning service has made us the CRO of choice for service, accessibility, budget, and delivery factors. But, equally important, we have proven, award-winning loyalty to our customers. We make your success our priority.

STRATEGIC PROTOCOL DESIGN. Because we give each project an individual focus, we are able to evaluate your project's goals and potential pain points to customize a protocol. Drawing on partnerships with vendors across a range of state-of-the-art data collection and trial management technologies, we can identify the tools best suited to your project's needs.

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