

Is Clinical Research Right for You?

A BRIEF FOR EMERGING SITE LEADERSHIP

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Introduction

This brief offers key insights from *A Roadmap for Engaging Emerging Sites and Investigators in Clinical Research*, tailored to an executive-level audience of emerging research sites. Please refer to the complete roadmap for further context.

The Opportunity

Clinical trials are struggling to enroll enough patients. Across the United States, 80 percent of trials fail to meet their enrollment targets on time, and 37 percent of participating sites under-enroll study volunteers. Geography is a significant part of the problem: Trial sites cluster around major academic medical centers, leaving large portions of the patient population, and their communities, without access to clinical research.

This situation creates an opening for organizations that have not historically been research sites. Sponsors—the pharmaceutical, biotech, and device companies that fund clinical trials—need new sites and new patient populations. By bridging this gap, sites can diversify funding streams, offer additional services and capabilities to their patients, and provide career development opportunities for their staff. The relevant question for leadership teams at emerging sites is whether participation makes sense for their organization, and if so, where and how to start.

Entry Points to Clinical Research

Clinical research covers a wide spectrum of activities with very different operational demands. A clear understanding of this spectrum is essential for a realistic assessment.

At one end of the spectrum are complex, interventional trials that are typically Phase 2 or 3 studies of investigational drugs or devices. These trials require dedicated research infrastructure, significant staff training, and rigorous regulatory oversight. Therefore, they are an unlikely first step for most organizations entering research.

At the other end of the spectrum are more accessible trials, for example, pragmatic Phase 4 studies conducted after a treatment is already approved, registry studies that collect data on outcomes in real-world patient populations, and biomarker studies that require biological samples but minimal procedural change. These study types can often be conducted within existing workflows, with modest additional staffing and training, and represent a proportionate entry point for a site at an early stage of research engagement.

Between these poles sits a broad range of options. The entry point depends on your patient population, your existing strengths, and your staff's appetite for change. Choosing a study type that aligns with your capabilities—rather than being the most prestigious or lucrative option—is an important early decision.

Early Considerations for Your Organization

The research life cycle often reflects a consistent pattern: problems that originate in the early phases can become more difficult and costly to address later. Decisions made before patient enrollment begins can shape much of what follows.

Here are a few actions worth exploring at this contemplative stage:

- **Honestly assess your initial position.** A realistic self-assessment of your capabilities, patient population, and staff readiness that is conducted before selecting a study type or engaging a sponsor can prevent common and costly mistakes. [Frameworks](#) to support this assessment exist.
- **Build your workforce capacity intentionally.** Adequately trained staff are essential to any research operation, yet training is expensive and time-consuming. [Core competency frameworks](#) offer a practical starting point for assessing your team's current capabilities and identifying gaps before they become operational problems.
- **Intentionally select your initial [study type](#).** The study's complexity should match your team's capabilities. A registry study or pragmatic trial that your staff can perform effectively is far more valuable—to your institution, your patients, and your future sponsors—than an overly ambitious trial that overburdens your operations and fails to enroll enough participants.
- **Allocate a [budget for community engagement](#) from the start.** Most trials that fail do so at recruitment, which depends on community trust. Sites that invest intentionally and consistently in community outreach tend to experience stronger engagement than those that treat it as an afterthought. This approach is especially relevant for institutions that serve populations who have historically been underrepresented in research.
- **Standardize your legal and contractual processes early.** Inconsistent approaches to legal negotiations create delays and unpredictable workloads across studies. [START clauses](#) provide standardized language for key elements of clinical trial agreements, reducing back-and-forth and accelerating study start-up.
- **Establish sponsor visibility.** Sponsors tend to choose sites with which they are already familiar. An emerging site that clearly demonstrates its capabilities—through shared investigator platforms, intermediary relationships, and participation in research networks—can significantly shorten the time to its first study opportunity.

Key Takeaways for Entering Clinical Research

The decision to enter clinical research is ultimately a strategic one, and leadership teams reviewing the same evidence will reach different conclusions. Not every organization will decide that clinical research is the right strategic fit. However, for those that do, approaching entry with a clear, disciplined plan can reduce risk and help facilitate the process.

- The opportunity for organizations beyond traditional academic medical centers to participate in research is real and growing.
- Entry does not require starting at the highest level of complexity; many sites build early success with lower-burden study types.
- Early decisions around study selection, staffing, and community engagement have a significant impact on long-term success.
- The broader ecosystem is changing to support emerging entrants, but success will always depend on a site's performance and delivery over time.

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