

The Case for Working with Emerging Sites:

A BRIEF FOR SPONSOR 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 research sponsors. Please refer to the complete roadmap for further context.

Setting the Stage: Enrollment Challenges

Your organization already knows the headline: 80 percent of clinical trials fail to meet enrollment targets on time and 37 percent of participating sites under-enroll. The standard response has been to invest more in recruitment—better outreach, faster screening, and more patient-facing technology. These efforts matter, but they address the symptoms rather than the cause.

The enrollment problem is largely structural. Trial sites cluster around major academic medical centers, systematically excluding the communities where large portions of the patient population actually live. Sponsors' selection processes are built to favor sites with a prior track record. As a result, established sites continue to receive studies while emerging community and regional hospitals are passed over—leaving enrollment targets difficult to achieve.

Working with emerging sites should be a core element of enrollment strategy, not a separate initiative.

Process Design Shapes Site Participation

Emerging sites struggle in sponsor partnerships not from a lack of clinical capability but from the failure of sponsors to design their processes with them in mind.

Standard site qualification criteria, feasibility assessments, and standard operating procedure (SOP) language evolved to evaluate established sites with prior research infrastructure. When applied to a community hospital or regional medical center new to sponsored research, these processes frequently flag disqualifying issues—documentation gaps, unfamiliarity with sponsor-specific systems, limited investigator past experience, and inexperience with budget negotiation—that are often easy to fix and rarely reflect capability or patient safety concerns.

The needed changes center on reforming internal processes, not adding new resources. Sponsor leadership must evaluate which qualification criteria are truly necessary and which are simply artifacts of working exclusively with experienced sites. Current processes often cannot make that crucial distinction; they treat a documentation gap and a fundamental readiness failure as equivalent and disqualify sites accordingly.

Some emerging sites are not ready to conduct complex sponsored research. The goal is not to lower standards but to build selection processes that can distinguish fixable from disqualifying gaps and that create pathways for emerging sites to address the former before being screened out.

Rethinking Site Selection and Practices That Create Barriers

Several common sponsor practices create unintended barriers for emerging sites, each with practical fixes.

PRACTICE	HOW IT CREATES BARRIERS	POTENTIAL SOLUTIONS
Site readiness and selection criteria	Sponsors often default to familiar site relationships and may lack confidence in emerging sites' capabilities, thereby filtering them out before formal evaluation even begins.	Revisit internal readiness criteria to confirm that they are calibrated to emerging sites rather than assuming that established-site benchmarks apply.
Site qualification questionnaires	Questions about prior enrollment volume and sponsor relationships filter out capable emerging sites at the first evaluation stage.	Revise internal qualification questionnaires to weight current capability and patient population fit alongside track record.
Feasibility and selection models	Data-driven selection models, now widely used by sponsors, weigh historical performance data in ways that automatically disadvantage emerging sites, regardless of their clinical strengths or patient population.	Add an emerging site readiness indicator alongside traditional criteria.
Budget and fair-market value tools	Rates often do not cover actual costs at smaller sites still building infrastructure, making early trials financially unsustainable.	Budget community outreach and recruitment infrastructure as an explicit line item.
Site initiation visits	Single-session protocol overviews create information overload; static presentations do not build practical readiness.	Replace with on-demand, simulation-based training modules via learning management systems.
Enrollment and retention	Overly restrictive eligibility criteria and demanding visit schedules push the consequences of upstream design decisions onto sites and participants, making enrollment targets more challenging to reach.	Commit to reviewing and amending protocols when data show that eligibility criteria or visit burden create systematic barriers to enrollment. Fund point-of-care recruitment tactics such as electronic health record (EHR) queries, rather than traditional advertising. Emerging sites often need more funding directed to these health-care-based capabilities.
Feedback mechanisms	Most sponsor processes lack structured mechanisms for sites to report what worked well and what created unnecessary burden.	Build bidirectional feedback loops into standard processes.

The Strategic Opportunity Ahead

By addressing these barriers, sponsors can rethink how they identify, prepare, and support site partnerships. Creating a stronger site network does not mean lowering standards; it means designing processes that better recognize readiness, address fixable gaps, and expand access to capable research partners.

KEY TAKEAWAYS

- **The current model does not meet enrollment targets.** Persistently missed enrollment targets point to structural limitations in site strategy, not just execution gaps.
- **Process design is the primary barrier.** Many emerging sites are excluded by processes that reward prior experience over current capability.
- **Solutions are actionable today.** Adjustments to sponsors' feasibility criteria, SOP language, training models, and start-up processes can be piloted without major system overhaul. Identifying emerging sites with large populations is not enough on its own; sponsors must also fund point-of-care and EHR-based recruitment to effectively reach relevant patients.
- **Investment is strategic, not just operational.** Building relationships with emerging sites creates a broader, more diverse network that compounds in value over time.
- **Early movers have an advantage.** Sponsors that establish these partnerships now will be better positioned as regulatory expectations around trial diversity continue to evolve.

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