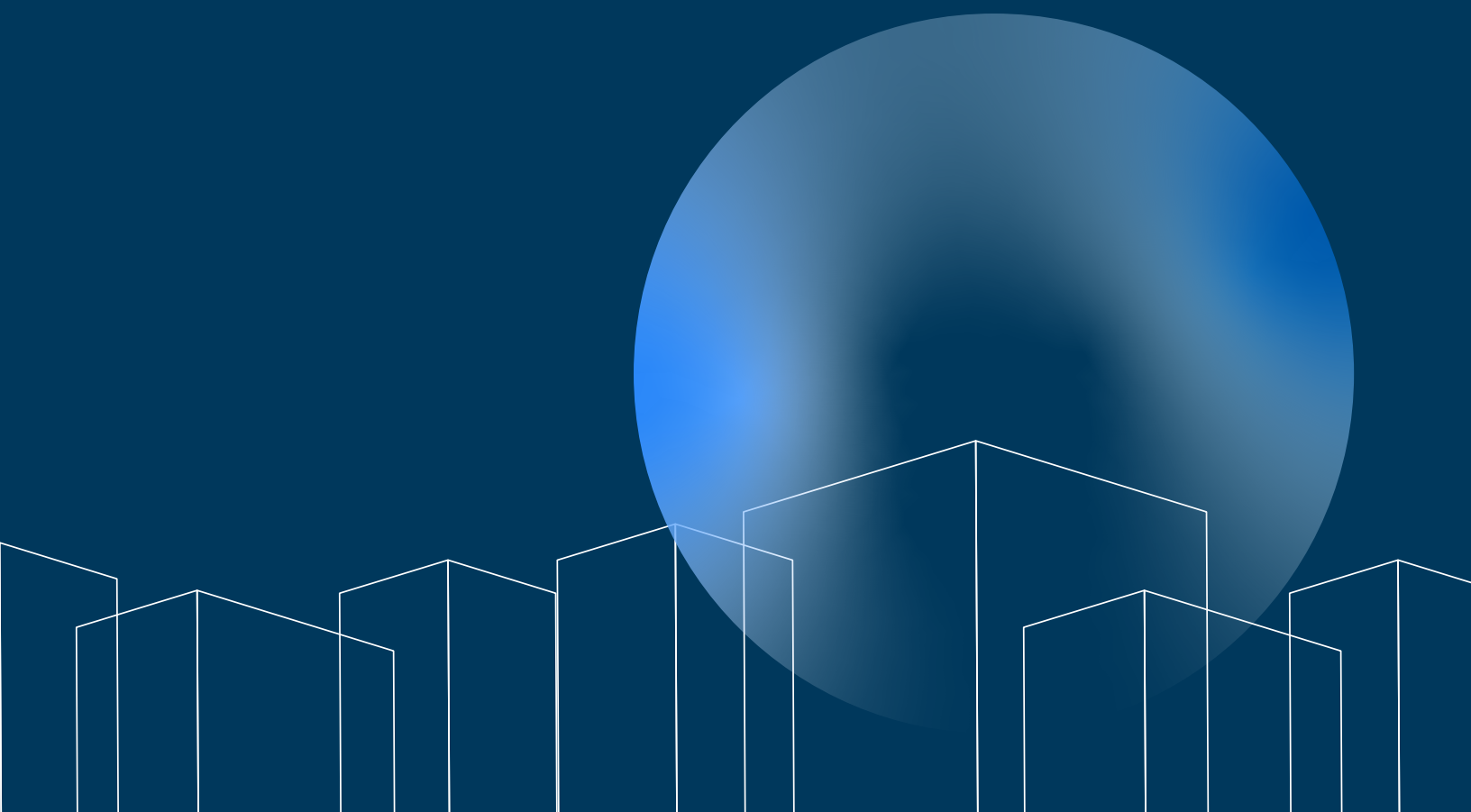


BEYOND THE FAMILIAR

Perspectives on Modernizing
the U.S. Clinical Research Site
Network and Reaching New
Patient Communities

An ACRP Special Report

This work was supported by Genentech, a member of the Roche Group;
Duke University; and National Medical Fellowships (NMF).



Expanding and modernizing the site network is critical to building and sustaining U.S. clinical research capability and serving the evolving healthcare needs of the nation.

This report is informed by critical insights from life sciences sponsors and clinical research sites. Their first-hand experience provides a window into the realities of site selection today—highlighting the forces that perpetuate familiar approaches and the opportunities for change.

Executive Summary

1. Project scope

- 1.1 Project rationale and methodology
- 1.2 Key contributors
- 1.3 Sponsor and site interviewees
- 1.4 Terminology and definitions

2. Setting the scene

- 2.1 The U.S. clinical research site network: a vision for the future
- 2.2 Site selection: the inflection point in clinical trial delivery
- 2.3 The current U.S. site landscape
- 2.4 How different site models may contribute to key goals
- 2.5 The “revolving door” of familiar sites
- 2.6 The supply/demand imbalance

3. Insights from interviews: sponsors’ perspectives

- 3.1 Moving beyond familiar sites: the risk/benefit equation
- 3.2 Individual sponsor positions

4. Insights from interviews: sites’ perspectives

- 4.1 Building and maintaining a research site: key considerations and challenges
- 4.2 Critical success factors for securing studies
- 4.3 The feasibility process

5. Discussion

- 5.1 Beyond the “revolving door”: a strategic shift in site selection
- 5.2 Uniting the “house divided”
- 5.3 From intent to action: practical pathways for sponsors
- 5.4 Starting the journey

6. Conclusion and call to action

Appendix

- Key publications and cited references
- Related reading

EXECUTIVE SUMMARY

The U.S. clinical research site network is at a critical inflection point. Persistent recruitment delays, growing pressure to improve participant representation, and increasing demand for study capacity are exposing structural weaknesses in the current site selection paradigm. Although sponsors widely acknowledge the need for change, operational behaviors continue to favor a relatively small pool of familiar research-centric sites, creating a “revolving door” effect that constrains capacity, limits access to research, and leaves large segments of the U.S. population under-represented.

This report explores the realities of site selection through qualitative interviews with sponsors and a diverse range of sites, including dedicated research centers, specialist practices, community hospitals, federally qualified health centers, and primary care medical groups. The findings reveal that the challenge is not a lack of awareness, but a lack of actionable pathways for sponsors to broaden and diversify their site networks without assuming unmanageable operational risk. A central finding is that the term “emerging site” is often used ambiguously. It may refer to sites with limited research experience, sites operating within non-traditional care-centric models, or both. These distinctions matter because the barriers, capabilities, and support needs differ substantially between site types.

We spotlight the divide between the conduct of clinical research and the settings where patients receive routine healthcare. Research-centric sites remain essential for complex and highly specialized studies, particularly in oncology and rare diseases. However, for common chronic conditions, care-centric and community-embedded environments may offer major advantages: direct access to large and naturally heterogeneous patient populations with trusting, longitudinal relationships. Sponsors interviewed consistently recognized the strategic value of expanding beyond familiar sites. Yet at the level of individual study execution, operational teams often remain focused on minimizing short-term delivery risk by defaulting to familiar sites and investigators. Prior experience continues to function as the dominant proxy for capability, creating a structural Catch-22 for aspiring sites and investigators.

At the same time, we demonstrate that establishing and maintaining a research site requires substantial operational commitment. Research-readiness is not primarily about large capital investment, but about assembling the right combination of people, processes, infrastructure, regulatory understanding, and organizational support.

Many sites describe research-readiness as a gradual operational build requiring continual calibration between investment, study flow, staffing, and overheads. Our findings suggest that expanding and modernizing the U.S. site network will require a more strategic and differentiated approach to site selection. Sponsors will need to:

- Move beyond experience alone (and in particular the principal investigator’s [PI’s] research experience) as the primary screening criterion
- Assess site competency and potential with a broader lens
- Match site models more deliberately to therapy areas and protocol demands
- Develop clearer pathways to cultivate and de-risk emerging sites
- Align budgets and operational models with how different sites access patients
- Create incentives that support broader site engagement in practice, not only in principle

Ultimately, site selection should no longer be viewed as a routine operational exercise, but as a strategic determinant of whether clinical trials can achieve their scientific, commercial, and societal goals.

1. PROJECT SCOPE

1.1 Project rationale and methodology

The current U.S. clinical research site network is profoundly overstretched and increasingly unable to meet its goals. Patient recruitment remains a chronic bottleneck and trial populations continue to poorly reflect the real-world populations they are meant to represent. In general, sponsors recognize these problems and acknowledge that the status quo is not sustainable. Yet site selection habits remain largely entrenched, with the same familiar sites repeatedly favored by default. This project set out to explore the realities of U.S. site selection from the perspective of both sponsors and sites, and to spotlight the drivers and barriers that shape progress. In this first phase, the goal was to generate deep insights to sharpen the framing of the problem, better articulate its underlying dynamics, and begin to consider what an actionable way forward might look like. We conducted a range of in-depth qualitative interviews with sponsors and with sites of various types, spanning a range of operational models and clinical research experience. This report synthesizes and analyses these insights within a “big picture” framework.

1.2 Key contributors

- Association of Clinical Research Professionals (ACRP): project concept and delivery
- Altura: subject matter expertise
- Spectrum Science: sponsor and site interviews

Financial support and high-level contributions were provided by:

- Roche | Genentech
- Duke Clinical Research Institute
- National Medical Fellowships

1.3 Sponsor and site participants

Sponsor participants

- Stacey Bledsoe, Gilead
- Patrick Ezech, Biogen

- Ken Harper, Novartis
- Brian Mitchell, Amgen
- Ruma Bhagat, Roche | Genentech

SITE PARTICIPANTS	LOCATION	MODEL
Sam Stein ALSA Research	Connecticut/New York	Dedicated research center
Pete Gonzalez Futuro Clinical Trials	Texas	Dedicated research center
Vincent Giacalone, DPM Curalta Clinical Trials	New Jersey	Research add-on to specialist medical practice
Kara Colucci Mayflower Clinical	Massachusetts	Research add-on to specialist medical practice
Rakesh Patel, MD Neighborhood Healthcare	California	Primary care community health center (Federally Qualified Health Center [FQHC])
Marc Hoffing, MD Desert Oasis Healthcare	California	Primary care medical group
Stephen Wilson, MD Mercy Health	Ohio	Community hospital group
Jyoti Angal, PhD Avera Research Institute	South Dakota	Community hospital group
Abiodun Adefurin, MD Cedar Health Research	Texas	Dedicated research center
Vida Henderson, PhD and Judes Fleurimont UI Health Mile Square Health Center	Illinois	Academic-based primary care community health center (FQHC)

1.4 Terminology and definitions

For stakeholder alignment and the avoidance of ambiguity, we found it necessary to clarify our interpretation/definition of several terms during the course of the research:

“Emerging” sites

- For some stakeholders, “emerging” as a site descriptor simply denotes a lack of research experience. It can be taken to mean sites with no prior experience of conducting clinical trials—often described as research-naïve, de novo, novice, virgin, or greenfield.
- However, “emerging” can also be used more relatively. A site may have some research experience but still be in the process of developing a scalable and sustainable clinical research capability.
- Importantly, the concept of “emerging” can also refer to the type of site (i.e., one with a less standard operational model, often community-based and care-centric).

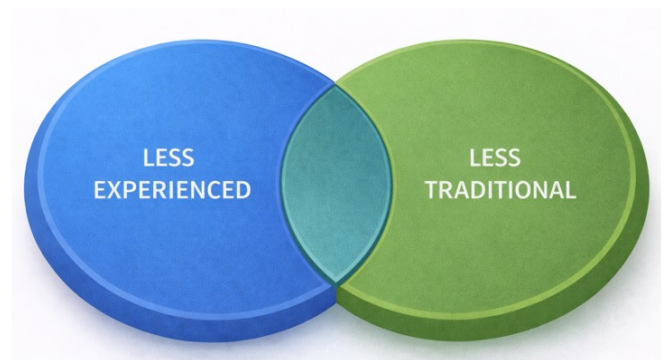
“Research-centric” vs “care-centric” sites

- These terms were coined by us to differentiate between the two ends of a spectrum of site types. A “research-centric” site denotes one that has been purposefully set up to run clinical trials as its sole or predominant activity. In contrast, a “care-centric” site is a research entity embedded in a much larger organization primarily focused on delivering healthcare. Between these are a range of hybrid archetypes leaning either toward research-centricity or toward care-centricity.

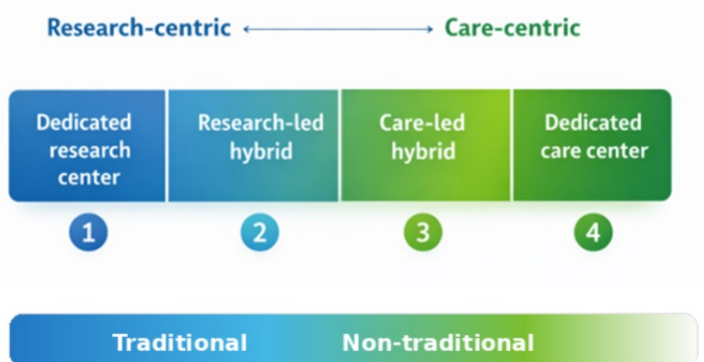
“Non-traditional” sites

- Like “emerging,” the term “non-traditional” has no official definition. It may be interpreted simply as “any site that is not an academic medical center,” but the more common interpretation refers to care-centric health centers in local communities as opposed to research-centric institutional hubs.

We have used the term “emerging” in an umbrella sense, to mean sites with a relative lack of experience and/or a less traditional operating model:



We use the term “non-traditional” to mean a site that is care-centric (i.e., a healthcare center not purposely set up for research).



2. SETTING THE SCENE

2.1 The U.S. clinical research site network: a vision for the future

Despite the rise of decentralized trial models, clinical research delivery still depends fundamentally on sites. Yet the current U.S. site network is overburdened, under resourced, and structurally ill-equipped to meet escalating demand. To address urgent unmet health needs and keep pace with advances in discovery science, the U.S. must invest in a strategically expanded and modernized site network that:

1. Increases site capacity, enabling greater study throughput
2. Accelerates patient recruitment (still the primary bottleneck in trial delivery)
3. Improves patient representation, in line with U.S. Food and Drug Administration (FDA) Food and Drug Omnibus Reform Act requirements, to better reflect corresponding real-world U.S. populations



The commercial and societal gains of expanding site capacity and accelerating patient recruitment are evident. But greater patient representativeness is no less critical. When trial populations reflect the demographic and socioeconomic characteristics of the real-world patients for whom investigational interventions are intended, the resulting evidence is more scientifically robust, more generalizable, and more reliable. This matters not only to regulators such as the FDA, but also to clinicians who must ultimately trust and apply that evidence in practice.

Thought leaders have consistently argued for broadening the site network to include “non-traditional” sites, rooted in community healthcare provision, that may anchor evidence generation in a wider geographic and demographic cross-section of the U.S. population. In an editorial in the *New England Journal of Medicine*, Woodcock et al. argue that one of the most promising but underdeveloped strategies for improving minority representation is greater involvement of community clinicians who can leverage their existing relationships with a broad spectrum of patients. This imperative is part of a broader recognition that clinical trials and routine healthcare currently function as “a house divided,” as described in a pivotal paper in *JAMA* [Angus et al. 2024].

The Integration of Clinical Trials with the Practice of Medicine: Repairing a House Divided

Angus DC et al. *JAMA* 2024; 332(2):153–62.

“Modern society expects not only the best possible care today but better care tomorrow. These goals assume integration of the practice and science of medicine. However, in most resource-rich countries, the clinical trials and healthcare delivery enterprises are supported by separate people, policies, institutions, and funding, leading to siloed incentives and goals. Keeping clinical research so separate from clinical care exacerbates the problems for both domains: [randomized controlled trials (RCTs)] cannot provide better answers on how to care for patients without better integration into clinical care, and clinical care cannot improve without better RCT evidence on what care to provide and how best to provide it. Many adverse consequences of this fractured system of science and practice are borne disproportionately by vulnerable, poor, and minoritized populations. A healthcare delivery system equitable and accessible to all must be built upon knowledge that is based on the experiences of, and relevance to, all.”

When it comes to site selection, many sponsors recognize the need to expand their site footprint and understand the desirability of bringing trials closer to routine care. Yet a persistent chasm separates that high-level vision from the practical realities of operationalizing it.

“Do sponsors really believe they have a problem? Because if they do, it’s not that hard to fix.”

– **Rakesh Patel, MD, CEO of Neighborhood Healthcare**

2.2 Site selection: the inflection point in clinical trial delivery

At study conception and protocol development, life sciences sponsors follow a largely linear path within a regulatory framework firmly grounded in the research domain. Site selection marks a decisive shift. The focus moves from defining a scientific ambition to identifying real physicians and real patients capable of delivering it. At least in part, site selection is driven by FDA requirements which stipulate that sponsors must choose investigators with appropriate qualifications, training, and experience (21 CFR 312.50-53 in the *Code of Federal Regulations*), ensure that all individuals with trial-related responsibilities are appropriately qualified (ICH E6(R3) Sec. 3.1-3.6 from the International Council for Harmonization), and aim for representative patient enrollment.

From site selection onwards, the process can no longer be contained within the structured logic of research design, but must be embedded in the variable, incentive-driven realities of clinical practice.

This isn’t a simple proposition, not least because the demands of clinical research are an imposition on routine healthcare delivery. As stated in the 2024 JAMA paper “A House Divided,” healthcare providers are already swamped with commitments and spending time on research can be perceived as detracting from their primary duty to care.

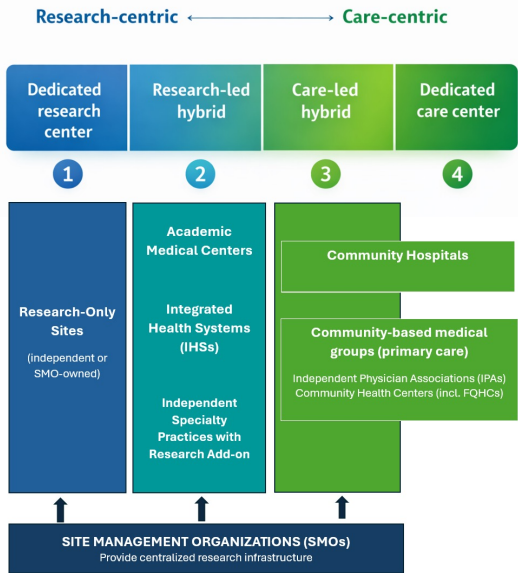
“The U.S. healthcare system’s move toward disease prevention and financial accountability, coupled with the ongoing shortage of providers, will make it increasingly difficult to allocate human and monetary resources to research within primary care. Partnerships are needed to ensure initial investment and ongoing supply of studies.”

– **Marc Hoffing, MD, Medical Director for Desert Oasis Healthcare**

The fact that the U.S. healthcare system is not built for RCTs has driven sponsors to rely heavily on academic medical centers—the traditional “safe haven” where research expertise, infrastructure, and regulatory fluency are concentrated. Yet these centers have become increasingly saturated and, in many therapeutic areas, are unable to meet enrollment and representativeness goals at the scale required.

2.3 The current U.S. site landscape

Over the past two decades, a diverse range of site models has emerged, spanning a continuum from specialist, research-centric institutions to healthcare-centric community-based providers:



Category 4 centers are not yet research sites and most have no research ambition.

Within and across these categories, individual sites vary considerably in size, governance structures, and ownership—factors that materially influence how they operate. While all site archetypes have a role to play within the broader ecosystem, their differing characteristics shape how effectively they advance the three enterprise-level objectives of increasing site capacity, accelerating patient recruitment, and improving patient representation.

2.4 How different site models may contribute to key goals



INCREASE SITE CAPACITY

Bringing additional sites into the network—of any type—increases overall delivery capacity. The question then focuses on which site types are best aligned to the demands of a given trial. Therapy area, protocol complexity, and need for specialist oversight or advanced equipment shape that decision. Research-centric environments may be particularly suited to rare, severe, and life-limiting conditions, and to technically demanding studies, while more care-centric settings may be well positioned for high-prevalence conditions embedded in routine care.



ACCELERATE PATIENT RECRUITMENT

Recruitment speed is influenced by where eligible patients naturally concentrate and how they move through the healthcare system. In specialist or low-incidence conditions, recruitment may depend on referral pathways and concentrated expertise. In common chronic or preventive indications, eligible patients are more likely to be dispersed across routine care settings. Sites that already maintain longitudinal relationships with patients through care provision are well placed to identify and approach known prospective participants directly—particularly if supported by appropriate research infrastructure and the time and resources needed to carry out Health Insurance Portability and Accountability Act (HIPAA)-compliant electronic health record (EHR) database searches. As with capacity, recruitment performance reflects the alignment between patient flow and trial requirements.



IMPROVE PATIENT REPRESENTATION

When representativeness becomes a primary objective, the frame shifts. The question no longer focuses mainly on efficient protocol delivery, but on which sites are best positioned to penetrate the deepest and most representative layers of the

affected population. Research-centric sites tend to draw those able and willing to travel to specialized centers and rely on advertising to attract them. In contrast, non-traditional care-centric sites are typically embedded within communities and already care for large, heterogeneous patient populations. The trust inherent in longitudinal care can lower participation barriers and broaden demographic reach. Frequently, the staff at such sites reflect the demographic make-up of the patients they serve. Community-based primary care settings, in particular, represent substantial and largely untapped potential when meaningful gains in representativeness are sought.

Taken together, this landscape suggests that matching site types to research studies fundamentally depends on the therapy area and protocol. In the case of common, chronic conditions (in realms such as cardiovascular, metabolic, respiratory, and musculoskeletal), meaningful shifts in the demographic representativeness of trial participants may depend on greater penetration of non-traditional care-centric and community-embedded environments.

“Primary care and community-based healthcare organizations have an abundant supply of what research needs most: patients. Established, trusting relationships are an integral part of this setting. Whether such organizations act as sites themselves or as referral partners for research-centric sites, more integration is needed.”

– Pete Fronte, MBA, Founder and CEO of Altura

2.5 The “revolving door” of familiar sites

Many sponsors are aligned with the enterprise-level imperatives of increasing site capacity, accelerating patient recruitment, and improving patient representation—and recognize the need for genuine behavior change, including bringing non-traditional care-centric sites into the mix. But, at the level of the individual study, the immediate pressures of timelines, delivery risk, and operational convenience continue to exert a powerful gravitational pull toward familiar sites.

This preference for familiarity is understandable: clinical trials are high-stakes endeavors. Contract research organizations (CROs) responsible for site monitoring may also tend to favor known entities, where established working relationships and operational routines reduce uncertainty. However, this concern about unfamiliar sites de-emphasizes the fact that risk exists in the system anyway: established sites often fall short of their enrollment targets, precipitating the need for rescue strategies, and prevailing site staff turnover means past performance doesn't necessarily reflect future performance. Risk is also inherent through clinical research associate (CRA) churn, which may lead to suboptimal site training and lapses in monitoring vigilance. Yet these existing risks are seemingly accepted as a fact of life.



The result is a revolving door: the same saturated sites tend to be selected again and again, while large patient populations remain unreachable.

What should be a strategic transition is repeatedly deferred as a problem for tomorrow—even though tomorrow has already arrived.

Site selection should be viewed not as a routine operational decision but as a strategic determinant of whether trials can fulfil their scientific, commercial, and societal promise.

2.6 The supply/demand imbalance

Viewed through an economic lens, the clinical trials ecosystem is exhibiting signs of a growing supply/demand imbalance. On the demand side, sponsors face mounting pressure to accelerate timelines, improve efficiency, and enhance data quality—all of which require access to a broader and more resilient site network. On the supply side, aspiring sites of all types are investing heavily to meet that demand.

They are building infrastructure, training staff, implementing digital tools, and preparing for regulatory compliance in order to reduce perceived sponsor risk and increase their competitiveness. These would-be sites are operating in a high-risk, low predictability market.

Sponsors, seeking to mitigate their own risk, tend to default to known sites, effectively overweighting performance on past studies as a proxy for capability and patient recruitment potential on future studies, which may well pose different challenges. On the other hand, many care-centric community-based health centers are reluctant to pursue clinical research at all, deterred by the operational burden, financial uncertainty, and opportunity costs involved. Those that make an attempt must demonstrate early returns to governing boards and leadership teams, and many abandon their efforts when those returns fail to materialize quickly. As a result, the divide between clinical research and routine care remains entrenched, to the detriment of both innovation and equity.

3. INSIGHTS FROM INTERVIEWS: SPONSOR PERSPECTIVES

3.1 Moving beyond familiar sites: the risk/benefit equation

Our interviews with sponsors brought into focus a central tension in site selection: the value of expanding the site base, set against the perceived need for security and confidence when entrusting a study—especially a pivotal one—to an unfamiliar site. When considering sites outside their existing networks, two factors weigh heavily in sponsors' risk/comfort calculations: the prior experience of the site and PI (both overall research pedigree and specific therapeutic area experience) and the site model. Lack of experience is often a non-negotiable barrier. In terms of model, research-centric settings generally feel less risky than care-centric settings (non-traditional sites) where research is not the dominant activity. At the same time, many sponsors recognize that, for common chronic conditions, care-centric environments may offer the richest returns: access to large reserves of previously untapped, research-naïve, and naturally heterogeneous patients, many of whom already have trusting relationships with staff.

When it comes to translating vision into action, sponsors vary in both their appetite for change and their tolerance for risk. Three main themes emerge:

- **No clear blueprint for implementation:** The case for change is stronger on the “why” than on the “how.” For most sponsors, there is still no clear blueprint for how to de-risk the use of unfamiliar sites in practice, or how to operationalize that shift at scale.
- **Execution defaults to the familiar:** Even where the vision at the top is clear, it may not survive the journey to the point of execution. The people articulating enterprise-level ambition are not the same people making study-by-study site selection decisions on the ground. Faced with tight timelines, delivery pressures, and accountability for near-term performance, it is understandable that operational teams tend to lock onto familiar sites where the perceived odds of success feel highest.
- **Reluctance to move first:** Even sponsors that are open to broadening the site base may be reluctant to shoulder the perceived risk of inexperienced or non-traditional sites alone. Many are willing to follow, but fewer are willing to lead unless that risk can be shared, absorbed, or reduced by other sponsors or government entities. In the absence of such mechanisms, the path of least resistance usually wins.

3.2 Individual sponsor positions

Within individual sponsor interviews, some conceded that past performance with their own studies remains the primary driver of site selection, eclipsing local patient demographics and all other factors. They reflected that, conceivably, their study teams might be open to hearing about sites who are working with their primary competitors, but would otherwise be resistant to the idea of new and unfamiliar sites. Others observed that every sponsor is eager in theory to bring in new sites, but that senior decision-makers will always question the potential return on investment. They noted that, whatever the site type, there needs to be a convincing business case for bringing an unknown new site on board. Some expressed the view that it may take a third-party consortium—with some commercial and/or federal government funding—to establish a program that identifies, cultivates, and de-risks new sites and new PIs for the benefit of the industry as a whole.

In contrast, other interviewees stated that “if we do things the way we always have, how can we expect progress?”

Some told us that new internal policies were being developed to ensure that every clinical trial program has a clear strategy to meet patient representation goals, underpinned by a robust, data-driven approach to site selection which does not automatically value prior experience above other criteria. One interviewee also commented that, for many patients, big academic medical centers feel anonymous and “cold” compared to the “coziness,” proximity, and approachability of a local community site. This all underlines the importance of “bringing the trial to the patient.” If a new community-based site has clear potential, and some resources and infrastructure in place, at least two sponsors told us they would be willing to take a chance and provide the necessary hand-holding. Some are even beginning to think beyond individual studies, exploring how aspiring sites might be cultivated as part of a long-term strategy, rather than assessed solely through the lens of immediate study feasibility.

In summary, although sponsors vary considerably in their tolerance for risk, many are genuinely committed to evolving their approach. What remains uncertain is not the direction of travel, but how that ambition can be translated into operational reality.

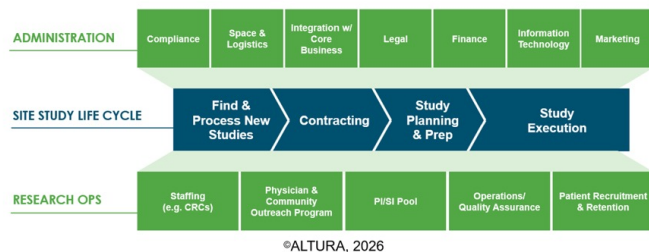
4. INSIGHTS FROM INTERVIEWS: SITE PERSPECTIVES

4.1 Building and maintaining a research site: key considerations and challenges

Getting started: a high bar to entry

Setting up a clinical research site is not for the faint-hearted. It demands substantial organizational commitment, operational readiness, and commercial agility. The governing boards of prospective research sites must be confident that a fertile pipeline of studies exists and that the organization has the capability to compete for them. They must be able to move quickly through Confidential Disclosure Agreements and contracting, negotiate appropriate budgets and indemnification, and secure suitable insurance coverage. At the same time, they need to put in place robust infrastructure—including standard operating procedures, financial and payment systems, and quality assurance processes—while recruiting and training staff to support research activity. Ultimately, however, success depends on execution: delivering competitive patient

enrollment, conducting visits within protocol windows, generating high-quality data, and minimizing sponsor queries. This, in turn, requires well-trained clinical research coordinators (CRCs), effective mentoring, and reliable access to PIs and sub-investigators for key protocol activities—something that can be difficult to sustain when clinicians are already carrying heavy clinical workloads.



Site Building Blocks for Care-Centric Healthcare Centers

The Catch-22 of gaining experience

When trying to secure studies, new sites face a familiar paradox: despite all their investment in training and infrastructure, experience remains the overriding sponsor requirement—yet experience cannot be gained without first being awarded a study. The challenge is not only securing that first study, but building the operational foundation needed for long-term viability and growth. From a business development perspective, the overriding priority of a research site is to secure a steady flow of study opportunities and enroll them effectively. As Pete Fronte explains, study visits are the oxygen of sites. Yet even when a site performs well, sponsor personnel and monitoring teams change frequently, and new decision-makers often revert to familiar sites or well-known investigators. Securing the first study is therefore only the beginning; sustaining a pipeline of work can be equally difficult.

Making the business case: opportunity vs. risk

The decision to invest in research capability is fundamentally a business decision, requiring organizations to balance the upfront costs against the likelihood of future returns. For Sam Stein at ALSA Research—a multisite research organization with locations in Connecticut and New York City—clinical research had been the family business for a generation, but expansion required a clear strategy. ALSA's sites are located in more affluent areas than is typical for clinical research, meaning that therapy areas and participation drivers needed to be carefully considered. Sam noted:

"We noticed there were not many independent sites in New York City apart from academic medical centers, which can be bureaucratic, so we spotted a gap in the market."

For care-centric sites not originally set up for research, the business case is significantly more complex. Insurance may not cover research activities, appropriate space may be lacking, and the required financial and information technology infrastructure may not yet exist. Developing a viable strategy can take three to 12 months and requires board-level alignment on risk and time horizon, with break-even often two years or more away. Even where frontline staff are strongly mission-driven, they must continually justify the investment to boards focused on financial performance; if study flow and enrollment are inconsistent, research may be deprioritized in favor of core clinical services.

"In primary care in particular, where margins are already tight and tolerance for variability is low, sustaining a research function can resemble titrating a medication with a narrow therapeutic window. Too many staff members without enough work hurts financials, while insufficient investment ahead of uncertain study and visit volume compromises growth."

– Pete Fronte, Altura

Mission meets reality

These tensions are reflected in the experiences of sites working at the interface of care and research. Clinical research remains a relatively rare activity in community health centers, most of which are deterred by the learning curve, operational burden, and commercial pressures, even if they recognize the strong rationale for involvement. They are also highly protective of their patients, with whom longitudinal relationships may have been built over many years.

Dr. Rakesh Patel, CEO at Neighborhood Healthcare, a primary care community health center in San Diego, described both the challenge and the motivation: “Health centers like ours have so much to contend with anyway that it’s really hard to contemplate getting into something like this. Even referring patients to other sites can take a lot of trust; we need to be sure they will not be treated like guinea pigs. Having been a family doctor for many years, I was personally motivated to get uninsured and under-insured people from ethnic minority subpopulations into research—potentially as a care option for some of them, but also to improve their representation when new medicines are assessed. When starting out, we already had the key asset—a PI with experience.”

Dr. Stephen Wilson, an aspiring PI at Mercy Health, a community hospital network in Ohio serving a predominantly African American population, reflected: “A few years ago, I was involved in community-based research on lifestyle interventions to improve blood pressure, cholesterol, and other cardiovascular risk factors. I realized that the local population could benefit from involvement in research—and research could benefit from the involvement of the local population. But convincing sponsors to consider a new PI at an emerging site is not a simple prospect.”

Dr. Marc Hoffing, Medical Director at Desert Oasis Healthcare—one of the country’s longest-running non-traditional sites—offered a pragmatic perspective: “Our location is nowhere near the sort of tertiary care center that normally runs trials, so our patients aren’t reachable via typical trial outreach. We felt that clinical research was a good thing to be offering our patients within a familiar, local setting. Naturally, we need to be profitable, but it’s not a real money-spinner for us. I would advise any prospective site to consider carefully why they are interested in research. It’s unlikely to turn a big profit, so you need other reasons. You also need to be committed—at least for a while—and you need a couple of people doing it full-time, not squeezing it into their other roles. Patient recruitment is everything and our CRCs can’t do it all, so we rely on a HIPAA-compliant partner to handle our EHR-driven patient outreach and scheduling. This way, CRCs can focus on screening and study visits, which drive our success.”

No clear roadmap to research-readiness

Whether research-centric or care-centric, all the sites we spoke to emphasized the value of experienced guidance. Consultancy partners can help sites navigate decisions around premises, finance, equipment, insurance, staffing, and infrastructure, while also shaping business strategy and connecting them with potential opportunities. As Dr. Vincent Giacalone at Curalta Clinical Trials observed: “There is no ‘Clinical Trials for Dummies’ manual, so when you’re new to this game, you need a lot of guidance.” Dr. Rakesh Patel concurred: “Apart from the PI with experience, having a strong consultant relationship was key to our foundational success. In this business, relationships are everything.” Dr. Marc Hoffing added: “In retrospect, it would have been extremely helpful to have an established roadmap to site competence or research-readiness, culminating in some sort of third-party certification. If this ‘stamp’ were recognizable and meaningful to sponsors, it might enhance their confidence.”

4.2 Critical success factors for securing studies

Our interviews with both sites and sponsors suggest that the critical success factors for securing studies fall into four main categories:



The need for the first three may keep sponsors conservative and risk-averse, defaulting to the sites (and PIs) they know; it’s the fourth one that’s most likely to make them look further afield.

Principal investigators: rethinking experience and risk

Across interviews, sponsors’ emphasis on PI experience emerged as both a key driver of confidence and a potential constraint on expanding the site base. For new or

lesser-known sites in particular, the PI's track record is often the primary signal of credibility. As Dr. Rakesh Patel at Neighborhood Healthcare noted, "For a new site, the only credibility in the eyes of the sponsor is the experience/expertise of the PI." Dr. Jyoti Angal at Avera echoed this, observing that even well-resourced sites with strong patient access can be overlooked if the PI lacks highly specific sub-specialty experience.

This reliance on narrowly defined PI experience can exclude otherwise capable sites. In practice, experience in related or adjacent fields may be transferable, and site performance depends not only on the PI, but on the broader clinical and operational team. Less experienced PIs can be effectively supported by strong sub-investigators, nurse practitioners, and study coordinators, while experienced PIs can help anchor newer sites. A more holistic assessment of site capability—rather than a binary view of PI experience—may enable sponsors to expand their site networks without materially increasing risk.

There is also a broader structural constraint: the PI pool itself is limited and under pressure. Only a small proportion of U.S. healthcare providers act as PIs, and many do not remain in research long-term, citing lack of time, financial incentives, and institutional support. The Tufts Center for the Study of Drug Development has documented substantial attrition among U.S. PIs, reporting that 35% to 40% do not go on to lead another FDA-regulated clinical trial after initially serving as a study investigator [Getz 2021, Fordyce et al. 2019]. As Sam Stein at ALSA Research observed, "Many doctors will say they are interested in research, but the challenge is finding those who are truly committed." Taken together, these dynamics suggest that expanding the site base requires a more flexible and forward-looking approach to PI assessment.

Therapy area expertise: widening the lens

Therapy area capability is often closely linked to the PI's credentials but also reflects whether a site has the diagnostic and monitoring capabilities required by the protocol, including specialist equipment and oversight. Sites typically take a deliberate approach to building capability in selected therapeutic areas, balancing depth with responsiveness to shifts in sponsor demand. As Sam Stein noted, activity tends to follow what is "hot" in research and development: "you have to skate where the puck is going." For some sites, this means maintaining breadth across multiple therapy areas; for others, it means focusing on a smaller number of indications and building depth. In

both cases, expanding into new areas is challenging and often requires partnerships, new hires, or other forms of capability-building.

A consistent theme across interviews was that sponsor expectations around indication-specific experience are a frequent barrier. Dr. Abiodun Adefurin at Cedar Health Research commented "Sponsors frequently require a certain number of years of experience in their particular therapy area, which may close doors to all but the top specialists in that field." Even well-established sites can struggle to enter new therapeutic areas, despite having the infrastructure, patient access, and operational capability to deliver. A less literal view of "relevant experience"—recognizing transferable skills, care models, and patient populations—could help unlock additional capacity, particularly in community-based settings with access to a wide range of patients. There is also an opportunity for earlier collaboration. As Dr. Jyoti Angal observed, eligibility criteria or protocol requirements can sometimes conflict with the realities of care delivery, particularly in non-academic settings. Engaging a broader range of sites earlier in protocol development could help ensure studies are both feasible and inclusive.

Research proficiency: proving capability without a track record

Sponsors assess research proficiency through evidence that a site can deliver trials reliably and compliantly—typically prioritizing prior study experience, trained staff, established processes, and a demonstrated ability to generate high-quality data. For sites without a track record, however, this creates a structural barrier. While some may point to Good Clinical Practice (GCP) training or investments in infrastructure, sponsors need confidence that these can be translated into consistent execution in practice. In the absence of prior performance, sponsors often fall back on proxies—such as the experience of the PI and team or the presence of governance and quality systems—but these may not be sufficient to offset a preference for proven sites. As Sam Stein observed, even where a new site appears promising and has access to a desirable patient population, sponsors still need assurance that it can handle the operational complexities of research. In practice, this risk aversion can limit the inclusion of sites that are capable but unproven. Expanding the site base will therefore require new ways of assessing and demonstrating research-readiness—beyond reliance on prior study experience alone.

The extent of sponsor risk aversion was illustrated in a story told by Dr. Abiodun Adefurin about an established site that moved premises. Even though it kept its original name, management, and staff, the site was forced to prove itself to several sponsors all over again as it was perceived as “new.”

Prior to becoming CEO of the Association of Clinical Research Professionals (ACRP), David Vulcano’s work focused on integrating clinical research into large health systems. Reflecting on that experience, he recalls: “Countless times, sponsors would ask us to identify potential sites. We would provide a heat map showing locations with high volumes of potentially eligible patients. Overlaying research experience created an A-list of high-volume, highly experienced sites. But the B-list presented a choice: lower-volume sites with experienced PIs, or high-volume sites led by new PIs. Regardless of all the trusted support and infrastructure we would put around new PIs, sponsors nearly always picked sites with lower patient volumes, simply because the PI’s resume listed more studies.” Vulcano adds “not surprisingly, we would often get calls back from those same sponsors months later asking if we had any more sites because study-wide recruitment was behind target... and they still would not take on the newer, high-volume sites.”

Access to relevant patient populations: an untapped resource

A consistent theme across interviews was that sponsors’ continued reliance on familiar sites—perpetuating the “revolving door” dynamic—leaves large numbers of local communities without access to research, regardless of the potential eligibility, interest, and demographic variety of the people who live there. As Dr. Vincent Giacalone observed: “By defaulting to the same sites each time, sponsors are missing out on many thousands of research-naïve patients. And patients up and down the

country are missing out on their chance to be involved in research. If no one has run a trial in a particular condition within our vicinity, the area will be ‘ripe’ for it, unlike established sites where the local population may have been on ‘rinse and repeat’ for years.”

When a site does establish itself within a previously under-served area, the impact can be significant, as Pete Gonzalez of Futuro Clinical Trials explained: “Our site is located in McAllen, Texas, close to the Mexican border. The population is largely Hispanic and predominantly low income, with significant unmet healthcare needs, including the highest obesity rate in the U.S. Many people cannot afford to travel outside the area, even for care. Our staff, who are bilingual in English and Spanish, spend a lot of time educating the community about clinical research and participating in local events. Many of our previous participants now advocate for us.”

This illustrates what can be achieved when research is brought closer to where people live and embedded within the cultural context of a local community.

Dr. Jyoti Angal at Avera—a community hospital network in South Dakota—expanded on this theme: “As a rural site, we have a geographically large catchment area, with some people travelling long distances. This is an unfamiliar model for sponsors, but it extends our reach into under-represented subgroups like the Native American population in the Mount Rushmore area. For remote communities like this, we try to involve employees who themselves come from those communities in the interests of building connections.”

While geographic proximity and racial/ethnic concordance are both important, they are not always enough to bring people into trials. As Dr. Rakesh Patel explained: “The biggest driver of trial participation is trust. Our patients trust us not only because we are embedded in their community but because we are already caring for them across multiple disease areas. We look after their arthritis, their diabetes, their COPD... we know them and they know us. But most sponsors don’t really understand the community health idea in research. They are used to trial participants being the PI’s patients—rather than patients who routinely use the health center.”

Research-centric sites generally rely on centralized advertising initiatives, digital marketing, and social media campaigns for patient recruitment—approaches that can work well in rare, progressive, or life-limiting diseases where patients are often actively searching for trials. However, for common chronic conditions, which may not

be central to people's lives, this sort of outreach from an unknown source often fails to resonate. More targeted efforts to reach minority communities may include local radio, barbershops, and places of worship, but when it comes to health decisions, people tend to place greatest trust in their own healthcare providers. For a common, chronic condition—and with the right organizational mindset—community-based care-centric sites can identify and enroll two to five times the average enrollment of research-centric sites by searching their own electronic medical record (EMR) databases. If appropriate partnership and compensation mechanisms are put in place, these care-centric facilities could also serve as referral hubs for studies that must be conducted at specialized centers.

Dr. Marc Hoffing at Desert Oasis agrees that most sponsors don't understand the concept of medical groups and the power of a large patient database that can be accessed through an EMR. "We have still not been able to get a dementia trial, for example, even though we have neurologists/psychiatrists, a database of 60,000 patients of our own, and over two decades of research experience."

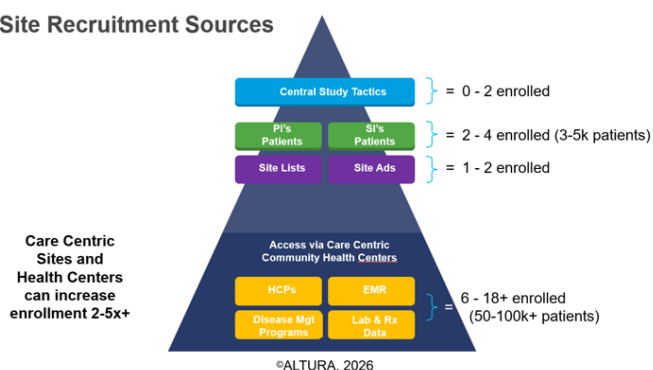
Pete Fronte of Altura makes a broader point: "Closer integration of research opportunities with routine care—the union of the 'house divided,'—highlights the fact that clinical research has traditionally been conducted in an overly short-termist and transactional manner. The conventional recruitment process wastes the interest and goodwill of the many individuals who fail screening, or for whom a suitable trial is not available. Instead of simply sending them away, such individuals can be encouraged to take part in observational research, like the American Cancer Society's Voices of Black Women study or the Michael J. Fox Foundation's Brain Health Study. This helps build a general research 'culture' within the community, creating receptivity to future trial opportunities the site may offer."

Judes Fleurimont at Mile Square observed: "I believe that trials should be better integrated into a patient's own personal healthcare journey, where existing trust with their own healthcare provider elongates through the referral and trial process. With community-based research, our mantra is 'leave the community better off than when you found it.' This doesn't just mean providing stipends for enrolled participants, it also means ensuring that all who engage with the process, even screen failures, gain something from it, in terms of insights or learnings." He added: "It's also important to close the communication loop by keeping patients informed about the findings of research within their communities and about future plans. This moves us from transactional to collaborative." Dr. Vida Henderson reflected that "sponsors need to accommodate this sort of local community engagement process within their budgets; not just the immediate resourcing needs of their trial."

4.3 The feasibility process

Securing inclusion in feasibility shortlists remains the main barrier for emerging sites. But the feasibility process itself reflects a narrow and somewhat outdated view of what a research site should look like. The sites we interviewed—spanning both research-centric and care-centric models—were united in their view that feasibility assessments remain geared primarily toward academic medical centers. Dedicated research centers, which now

Site Recruitment Sources



Dr. Rakesh Patel at Neighborhood Healthcare observed: "We don't need to advertise as we have 110,000 patients under our care. We're able to leverage our EMR data to run eligibility queries on our own patients—most of whom are racial/ethnic minorities, exactly the sort of demographic profile that clinical research most needs. This equips us to regularly exceed enrollment targets. But every time we try to make our case with a new sponsor, it feels like climbing a mountain."

If a site like Neighborhood Healthcare is selected for a study, leveraging their potential to reach patients depends on funds to enable HIPAA-compliant database searches. As an example, it takes an EMR search of 10,000 people with diabetes and pre-screening of hundreds of patients to identify 10 to 20 eligible participants for a Phase III study. Yet sponsor and CRO budgeting processes usually allocate funds specifically for advertising—even though advertising is unnecessary in this setting—and do not permit re-deployment of these funds, underscoring their lack of understanding of the model.

make up a significant proportion of U.S. sites, are faced with whole sections of questions about routine care provision that are not relevant to their model. Conversely, sites with limited research experience are expected to provide detailed data on prior trials. As Dr. Vincent Giacalone observed: “They want to know how many previous trials, what exactly they were, your target and actual enrollment for each one, the percentage of screen failures, the dropout rate—and if you haven’t previously done a study in that area, that whole section will be blank.”

The process is also widely perceived as opaque. When not selected, sites receive little or no feedback as to why they didn’t succeed. As Sam Stein noted, “It often feels like a black box... it gives us nothing to learn from.” Some interviewees expressed concern that the feasibility forms are being filtered by artificial intelligence (AI), so a lack of checks in the right places and too much reliance on explanatory free text can mean automatic rejection. Unless AI tools are trained to recognize indicators of capability beyond previous study experience, they will continue to favor established sites and make it even harder for emerging sites to gain a foothold. Kara Colucci at Mayflower, Dr. Jyoti Angal at Avera, and the team at Curalta all voiced the opinion that if sponsors could find the time to visit their premises and meet their staff—or at least arrange a phone conversation—this could make a real difference to their perception of the site’s strengths and capabilities.

Early in a site’s development, the pressure to accept studies—even those for which they are not well suited—can be considerable. This creates a tension between short-term selection and long-term performance. As Dr. Rakesh Patel explained, “Right now, it’s difficult to express doubts about any capability—you risk simply being passed over.” Dr. Jyoti Angal added that greater transparency from sponsors about future study plans would enable sites to invest proactively in readiness, rather than responding reactively to each individual opportunity.

5. DISCUSSION

Taken together, these findings point to a clear conclusion: the current model of site selection is not failing for lack of awareness of its limitations, but for lack of a structured and actionable pathway to change.

5.1 Beyond the “revolving door”: a strategic shift in site selection

Expanding and modernizing the site base The “revolving door” of familiar sites is fundamentally constraining the U.S. clinical research enterprise from meeting capacity, recruitment, and representation needs. Unless meaningful steps are taken to expand and diversify the site base, the situation will only get worse. Being open-minded to aspiring and emerging sites of all types brings much needed capacity expansion; engaging with non-traditional care-centric sites brings access to untapped “natural resources”: prospective participants in the numbers and demographic variety that research really needs.

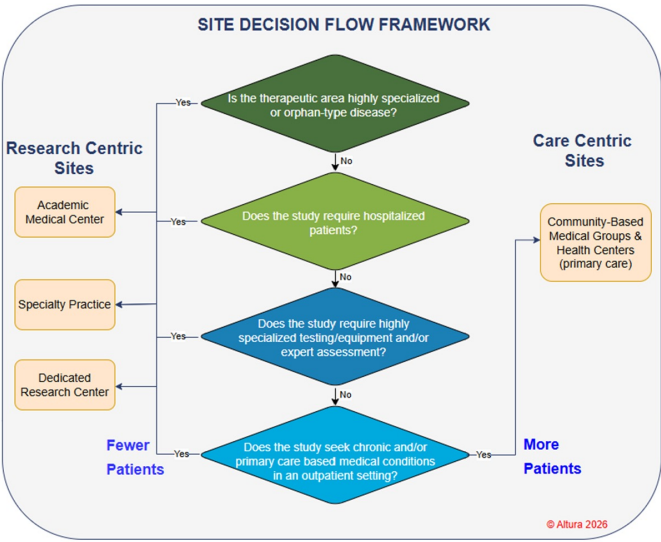
Assessing competency and potential instead of just experience

It is time to move beyond experience as the only dominant filter at site selection. The site base cannot expand if prospective new sites continue to be rejected due to limited experience. Much as employers considering aspiring clinical research professionals should adopt hiring principles based on skills and competencies, instead of continuing to require “two years of experience” [Freel et al. 2023], sponsors need more structured and sophisticated ways to assess a candidate site’s competence and potential, beyond prior performance. In particular, too much focus on the research experience of the PI will overlook sites where a relatively inexperienced PI is ably supported by a highly proficient study team.

Matching site models to therapy areas and protocols

In addition, site selection needs a strategic framework that aligns therapy area and protocol requirements with best-fit site model(s). Research-centric sites remain essential for complex, specialist studies—particularly in areas such as oncology and rare disease—where concentrated expertise, infrastructure, and experience are critical. On the other hand, care-centric, community-embedded sites—generally regarded as “non-traditional”—offer distinct advantages for common chronic conditions, namely direct access to large, heterogeneous, and often research-naïve patient populations, as well as the trust inherent in longitudinal care relationships.

A prototype decision framework is shown below:



5.2 Uniting the “house divided”

Making research more relevant to the real world

As stated in the 2024 JAMA paper on “The Integration of Clinical Trials with the Practice of Medicine: Repairing a House Divided,” significant benefits stand to be gained by bringing clinical research closer to routine care. The purposeful cultivation and utilization of community-based, care-centric sites as an integral part of the site mix will help to make research outputs more relevant and generalizable to the U.S. population as a whole, including historically under-served sub-groups.

Building connections with future prescribers

From a commercial point of view, engaging with clinicians embedded in communities enables sponsors to start building longitudinal connections with their future prescribers. Historically, key opinion leaders at academic centers were viewed as the predominant drivers of prescribing after licensing. However, Pharmacy and Therapeutics Committees, which decide what goes on formulary, are now also strongly influenced by Physician Care Organizations and community-based clinicians seeking to deliver value-based care.

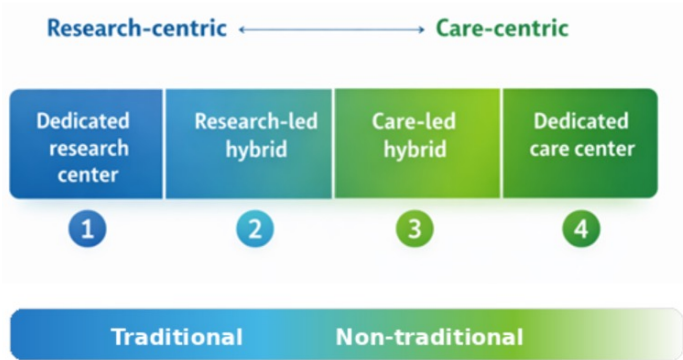
Creating a new pathway into research for aspiring PIs—including physicians of color

There is yet another key benefit of bringing research into care-centric environments: it creates a new, integrated pathway into research for community physicians who may have an interest in becoming PIs. As mentioned, PIs are

an endangered species and a rate-limiting step in many research initiatives. Physicians of color—and from other minority groups—are especially poorly represented in the current PI pool. Finding pathways into research for physicians of color—and attracting people of color into other professional research roles—is important not only from a career equity perspective but also because ethnic/racial congruence between staff and prospective trial participants can be a factor in trust-building, with a positive impact on patient recruitment and retention (Alsan et al. 2023, Bains et al. 2023, Getz et al. 2022, Kuri et al. 2023). Career progression is hard enough for physicians of color; striving for parallel success within the competitive, conservative field of clinical research usually requires a degree of resilience and self-advocacy that may not seem worth the effort. However, if research were to be introduced into community-based healthcare settings, where many physicians of color are already working, a natural and supported pathway into a PI career would be set up, potentially boosting declining PI numbers and improving the demographic match of the nation’s PIs to the patient populations they serve. As Dr. Vida Henderson at Mile Square notes: “In our model, we can attract physicians from ethnic minority groups who care about their communities but also have an interest in becoming a PI.”

5.3 From intent to action: practical pathways for sponsors

While many sponsors recognize the need to broaden their site base, translating this vision into action requires an intentionally strategic and proactive approach based on the model and maturity of prospective sites:



For aspiring research-centric sites, the site model is familiar but the barrier is lack of experience.

- Sponsors need a plan for how to assess according to competency and potential instead of just experience.
- These new research-centric sites may also benefit from relationships with care-centric health centers for access to patient populations from trusted sources.

Some care-centric entities are already experienced, research-ready sites but the unfamiliarity of the model continues to be a barrier.

- Sponsors should recognize the untapped opportunity at established care-centric sites and strongly consider them at study feasibility for common, chronic conditions.

Care-centric entities without prior experience face both major barriers. The great majority of centers in this category have no research ambition.

- For care-centric sites not yet established in research, sponsors should consider a mid-to-long term strategy to cultivate them as new sites and/or patient referral sources (with the right partnership arrangement). As part of cultivation, they could be considered for less critical studies (e.g., Phase IV programs or non-pharmacological assets).

Successful expansion and diversification of the site network will require sponsors to shift from consumers to long-term partners

Without a long-term partnership to build their infrastructure and capability, many potentially valuable sites will remain unable—or unwilling—to participate in research. A collaborative effort (e.g., grant scheme) led by third party—with commercial funding from a range of sponsors—may be one way to de-risk new sites for the benefit of the enterprise as a whole.

5.4 Starting the journey

Realizing this ambition is not a simple undertaking for sponsors. It will take substantial commitment, resources, and disruptive thinking. There is no single blueprint—and no short-term fix. However, this should not prevent sponsors from beginning to act. The following are not intended to be comprehensive interventions. Rather, they represent a set of practical workstreams that could be initiated now, helping to build momentum while more fundamental changes in strategy, operating models, and collaboration begin to take shape.

- **Evolve the feasibility process to better reflect the spectrum of site models and foster a more transparent, collaborative culture:** Introduce greater flexibility and a broader strategic perspective to site selection by moving beyond prior experience as the dominant screening criterion (including in AI-enabled feasibility tools); creating opportunities for direct engagement with prospective sites (virtually where appropriate); validating access to large, diverse patient populations and the capability to identify and screen them efficiently; and providing constructive feedback to unsuccessful applicants to support their future development.
- **Set explicit targets for engaging non-traditional sites:** For studies in common, chronic conditions, sponsors can consider setting explicit numeric objectives for including community-based, care-centric sites within the site portfolio. For example, a study requiring 20 U.S. sites might aim to include two care-centric sites that have undergone appropriate due diligence. To manage risk, sponsors can provide additional CRA support during study start-up, set modest initial enrollment targets (e.g., initially capped at two to three patients but later increased if the site proves capable and coachable), and monitor protocol compliance and data quality closely.
- **Support flexible outreach approaches:** In care-centric settings, where large numbers of known patients can be identified through EHR searches, site budgets should support this approach, rather than being automatically allocated to advertising.
- **Strengthen internal continuity and institutional memory:** High levels of staff turnover within sponsors and CROs can mean that original default sites keep re-surfacing at the top of feasibility lists;

non-traditional, care-centric sites may slip off the radar even if they have been previously engaged successfully. Robust, consistently utilized tracking systems are needed to preserve institutional memory.

- **Consider incentivization:** Ultimately, meaningful change will depend on incentives. Operational teams working under tight timelines and expectations will continue to default to familiar sites unless incentives and accountability mechanisms explicitly support broader site engagement. As Dr. Rakesh Patel observed: “Any sponsor who really wants change has to incentivize the local site selection teams to follow through. ‘Kumbaya’ type stuff alone does not move the needle.”

6. CONCLUSION

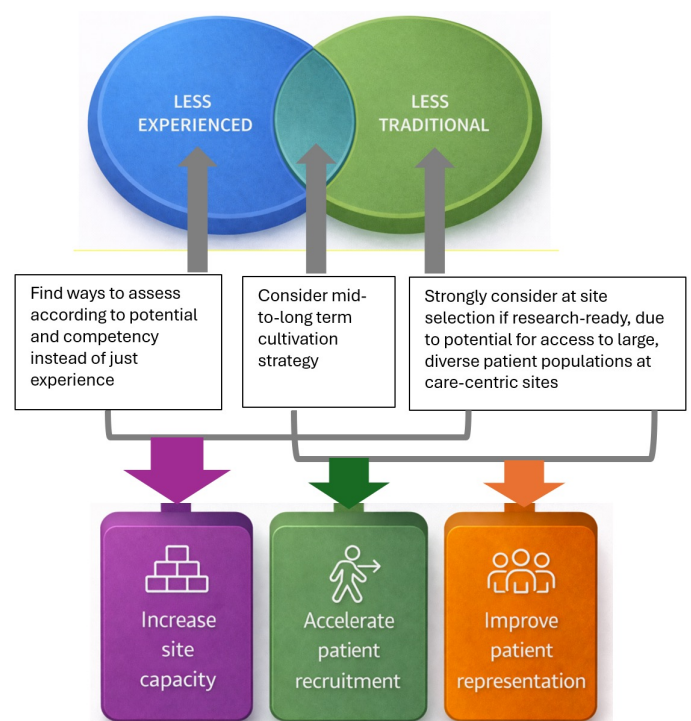
The U.S. clinical research enterprise is at an inflection point. Persistent recruitment challenges, limited representativeness, and growing demand for trial capacity are not new problems—but they are becoming increasingly difficult to ignore. This report shows that the constraints are not primarily scientific or even operational. They are structural. They reflect deeply embedded patterns in how sites are identified, assessed, and selected—patterns that have evolved to manage risk at the level of individual studies, but which now limit the performance of the system as a whole. The opportunity is clear. A broader, more deliberate site ecosystem—one that integrates research-centric and care-centric models—can unlock additional capacity, accelerate recruitment, and improve the relevance of clinical evidence.

This will not happen through intention alone. It will require sponsors to act differently. To look beyond experience as the default proxy for capability. To align site models with study needs more strategically. To invest in the development of new sites and investigators. And, critically, to create the incentives and structures that allow operational teams to make different decisions in practice. No single sponsor can drive this change alone. But collective inaction will only reinforce the current trajectory. The path forward is not without risk—but greater risk lies in continuing as we are.

Key takeaways

- Sponsors still cling to experience and familiarity, perpetuating the “revolving door”
- “Emerging” sites differ widely—one-size-fits-all solutions will fail
- Research-readiness is built operationally, fueled by study opportunities
- Community-based care-centric sites offer access to untapped patient populations for common, chronic conditions
- Existing trusting relationships are often fundamental for participation
- Expanding the site network requires vision and partnership, not just procurement
- Site selection is a strategic decision—not just an operational one

Call to Action for Sponsors



Beyond the Revolving Door: Rethinking Site Selection

Appendix

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About ACRP

With more than 22,000 members, the Association of Clinical Research Professionals (ACRP) is the only non-profit solely dedicated to representing, supporting, and advocating for clinical research professionals. ACRP supports individuals and life science organizations globally by providing community, education, and credentialing programs. Founded in 1976, ACRP is a registered 501(c)(3) charitable organization whose mission is to promote excellence in clinical research and whose vision is that clinical research is performed ethically, responsibly, and professionally everywhere in the world. Advancing People Advancing Health™. **Learn more at acrpn.net.org.**

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