Developing Community-Based & Trial-Naïve Sites: The Real ROI

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In the current clinical trial landscape, access to the right patients in the right settings is more crucial and more challenging to achieve than ever before — an estimated 8 of 10 international trials struggle to recruit enough patients.[1] The pandemic, which disrupted drug discovery, development, and delivery at every level, also revealed the advantages of remote and decentralized clinical trials, setting the stage for more accessible, configurable study conduct.

In parallel, the FDA and other regulatory bodies have begun to push for greater access for underserved populations in clinical trials.[2] For many of these patients, the traditional venues for clinical trial participation — large academic medical centers, often in major cities — represent a logistical and financial hurdle that can be challenging to overcome. This, in turn, can serve to curtail access and discourage continued participation for patients who find traveling to a central site difficult. Moreover, as more sponsors and clinical research organizations (CROs) struggle to recruit patients at new or smaller sites, or even to launch new trials at highly competitive, bandwidth-limited research centers, the drive to diversify sites — and by extension, patients — is galvanizing a movement: onboarding more trial-naïve sites into clinical study networks.

The argument for trial-naive sites, which have little to no prior experience conducting clinical research, is a compelling one: their relative access to untapped patient populations, coupled with faster enrollment, comparatively low operating costs, and the potential for forward-looking footprint expansion for multi-trial programs, are all strategic assets in an increasingly competitive clinical landscape.

When sponsors invest not only in using these sites for a single study but also in building their long-term infrastructure, the potential ROI compounds over time. This leads to greater administrative efficiency, faster recruitment, higher retention, and sustained access to diverse patient populations without having to repeat the costly process of site setup. This sort of flexibility is crucial in a landscape where access to community care and clinical trials is often out of reach for many. This is demonstrated in a recent study that found that while cancer care is usually delivered in the community, most clinical trials exist in academic centers – this is a good example of a broad therapeutic area that has an untapped opportunity for community-based recruitment that trial-naive sites are uniquely positioned to address.[3]

Yet the hurdles that have previously limited this expansion are likewise considerable, making many sponsors and CROs wary of venturing too far from well-worn sites with incumbent expertise and existing relationships. Ultimately, expanding clinical trial networks to be inclusive of trial-naïve sites requires expanding perspectives, embracing new models of site support and infrastructure development, and rethinking long-held assumptions about where and how to conduct research.

Trial-Naïve Sites As Untapped Assets

Trial-naïve sites are an underutilized resource within the larger clinical trial landscape. Geographic and institutional biases have long favored large academic medical centers or high-volume research hubs, reinforcing a centralized model that overlooks community hospitals, clinics, and smaller healthcare providers. These community sites are often seen as resource-intensive when compared to experienced sites with proven track records, and the effort needed to mobilize these sites is significant: from training research personnel on both trial conduct and technologies to establishing foundational practices around data collection, patient oversight, and regulatory adherence, the up-frontinvestment can cause sponsors and CROs to balk.

This is where community-focused site networks can make a significant impact: by managing the complexity of trial-naïve sites directly, combining their specialized expertise with sponsor and CRO investment, these networks provide the infrastructure, processes, and oversight needed to bring trial-naïve sites online quickly and effectively. This is precisely where Medical Research Network (MRN) excels, acting as the critical enabler that transforms financial investment into operational readiness and long-term site success.

However, avoiding these sites often means leaving large, diverse patient populations untapped — hindering enrollment, narrowing demographic representation, and ultimately delaying market entry. Common misconceptions surrounding trial-naïve sites include:

- **A perceived lack of trust among patients:** In reality, community-based providers often have deeper, longer-standing relationships with patients than large academic centers, which can boost recruitment and retention when leveraged effectively.[4]
- **Slower enrollment driven by insufficient experience:** Experience is built quickly when infrastructure, technology, and mentorship are in place; many trial-naïve sites demonstrate competitive enrollment rates within their first one or two trials.
    - A strong example comes from an MRN-supported site in South Carolina that had no prior research experience: MRN sourced a dedicated research professional, trained the team, and helped them become research-ready in just five months. Within the first month of screening, the site identified 17 patients for further evaluation—despite only being expected to enroll two or three participants overall. In less than a year, the site randomized two patients and plans to enroll five more, underscoring the tangible ROI possible when trial-naïve sites are supported effectively.
- **A higher cost to incorporate trial-naïve sites:** Direct comparisons overlook the long-term efficiencies, including high retention, repeated use without re-onboarding, and reduced reliance on overburdened high-volume sites.

The push to mobilize trial-naïve sites sits at the intersection of two industry lessons: the reach and agility enabled by decentralized methods during COVID-19 and the enduring value of patient–physician relationships in traditional site models.

The pandemic proved that geography should not be a barrier to research participation, yet it also revealed the financial, operational, and relational limits of a fully remote approach. For trial-naïve sites, the challenge is compounded, as they often require intensive onboarding, infrastructure investment, and sustained support to achieve compliance and patient enrollment targets.

Running an initial study entirely with these sites is rarely practical, but strategically integrating them into a hybrid network can expand access to underserved populations without sacrificing speed or quality. The opportunity lies in designing solutions versus defaults, blending experienced and novice sites, matching visit formats to protocol and patient needs, and selectively decentralizing where it adds value. This "solution-by-design" mindset allows sponsors to address recruitment bottlenecks, broaden demographic reach, and maintain operational efficiency – transforming the onboarding of trial-naïve sites from a resource drain into a strategic growth lever.

From Potential To Performance: Standing Up Successful Sites

Mobilizing trial-naive sites for clinical research begins with identifying healthcare facilities that not only have access to the right patient populations but also possess a baseline level of resources and skills that can be built upon. Ideal candidates often include community hospitals, regional clinics, specialist practices, and integrated health networks in suburban or rural areas where patients may otherwise have no opportunity to participate in clinical trials.

For many individuals in these regions, particularly those facing complex or late-stage conditions, research is sometimes the only viable care option rather than just an alternative. By working with community-based site networks that are activating these sites, sponsors can unlock access to untapped and often underserved populations, improve enrollment diversity, and extend the reach of innovative therapies beyond major metropolitan research hubs.[5]

The foundation for onboarding such sites requires two essential components: patients and resources. A site that serves a relevant patient pool and has core infrastructure such as clinical space, basic equipment, and qualified healthcare professionals can be developed into a research-ready facility with targeted support. Often, these organizations simply need guidance on trial operations, staffing models, and compliance. This may mean supplementing existing teams with trained personnel like principal investigators (PIs), sub-investigators, and study coordinators, ensuring access to secure drug storage and providing appropriate workspace for trial conduct. Support in these areas yields a high return by enabling sites to manage more complex or multiple trials over time, reducing the need for repeated setup costs and accelerating start-up for each subsequent study.

While research is inherently resource-intensive, gaps can be bridged through sponsor investment, or CRO partnerships, through shared-service models, such as community-focused site networks, that bring the necessary capabilities on-site. Community-focused site networks play a central role in driving this investment, providing experienced trialists, site specialists, tools, solutions, processes, and technology that strengthen local infrastructure. With the right training and operational reinforcement, trial-naïve sites can transition quickly from potential partners to high-performing contributors in the clinical research ecosystem.

Building Long-Term Value Through Broader Site Networks

Successfully integrating trial-naïve sites into a clinical trial network requires more than simply contracting them for participation — it demands deliberate infrastructure, tailored training, and ongoing operational support. When the site is part of a satellite model under an experienced PI, there is a built-in pathway for mentorship and resource sharing. In contrast, a truly independent trial-naïve site must be prepared to operate autonomously, with the PI fully accountable for all study activities. In these cases, proactive sponsor or CRO investment is critical in order to identify site network solutions that can support their programs across indications, populations, and evolving regulatory demands.

Effective support often includes placing dedicated clinical research coordinators, recruitment specialists, or even healthcare providers within the site to offset staffing

limitations. Participation in an established site network, such as those maintained by specialist organizations, can further reduce isolation by providing access to shared knowledge, troubleshooting support, and standardized procedures.

Likewise, training strategies should blend protocol-specific instruction with broader, protocol-agnostic competencies such as Good Clinical Practice (GCP), data management workflows, and patient engagement principles. This dual approach equips sites not only for the immediate study but also for future research opportunities, reducing the "one-and-done" effect that can occur when training is narrowly scoped. Early conversations with sites to assess patient demographics, facility capabilities, and therapeutic strengths allow sponsors to match trials to the populations most accessible at each location.

The long-term value of these efforts extends far beyond a single protocol: expanding into trial-naïve settings builds a more resilient investigator pipeline, addresses health equity by reaching underrepresented populations, and mitigates the risk of recruitment bottlenecks that can delay market entry.

From a purely operational standpoint, site networks that cultivate a mixed portfolio of experienced and novice sites within a network benefit from standardized contracting, pre-collected essential documents, and accelerated study start-up timelines. Equally important is the technology layer. All sites benefit when digital platforms are streamlined, interoperable, and consistent across studies, which reduces the administrative lift and allows staff to focus on patient care. The combination of immediate recruitment gains and long-term sustainability makes investment in trial-naïve site development a strategic imperative rather than an optional outreach exercise.

Conclusion

Expanding access to clinical research requires more than identifying new sites. It calls for thoughtfully designed support models that make participation feasible for both patients and trial teams. For trial-naïve sites, this can mean targeted resource planning, integration into established networks, and access to both in-person and remote visit options. Flexibility in visit formats, such as telehealth check-ins or home-based procedures, can reduce patient burden, provide ongoing behavioral and lifestyle support, and help maintain engagement over long study durations.

Sponsors that balance standardization with tailored operational design — matching tools and services to the needs of a specific protocol and patient population — are better positioned to build strong, lasting relationships with sites.

Through its site network, MRN facilitates these connections by aligning sponsors and CROs with community-based sites, ensuring both sides have the support and infrastructure needed for successful, sustainable partnerships. In turn, this strengthens recruitment, retention, and the overall quality of data, creating a foundation for sustainable research growth.

References

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About MRN

MRN accelerates patient recruitment and improves patient engagement and retention through site-centric and patient-centric solutions.

As an innovative market-leader, MRN provides customized solutions to optimize each individual protocol and create more flexible, efficient and accessible clinical trials that deliver accelerated timelines.

Through integrated in-home visit delivery and a vast global network of trained, research ready sites, all empowered by MRN's digital solutions, MRN engages with and empowers diverse communities around the world to participate in and advance medical research.

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