WHITE PAPER

Leveraging community-based clinical trial sites to expand oncology research access

A KEY QUESTION

How can leveraging community-based clinical trial sites improve patient access, diversity and operational efficiency in oncology research compared to traditional academic-centered models?

KEYWORDS Community Sites, Oncology Research, Clinical Trials, Patient Access, Diversity

Traditional oncology clinical trial models—largely centralized around academic medical centers and major hospitals—face challenges in activation, patient recruitment, diversity, accessibility and community engagement in clinical trial participation. These obstacles often delay study timelines, increase costs and limit the generalizability of trial results in terms of patient representation.

To address these issues, there is growing interest in community-based clinical trial sites, including local clinics, physicians and community health centers. These settings offer a promising avenue to expand trial access to cancer patients at the point of clinical care, improve enrollment diversity and foster greater trust between researchers and trial participants.

In this article, we aim to discuss the concept of a "community site," recognizing that its definition can vary significantly depending on regional healthcare structures and referral pathways. We will also explore the current barriers limiting the involvement of community sites in clinical trials. As a global CRO committed to site and patient centricity, we will outline how Fortrea is taking actions to overcome these challenges and contribute to expanding global access to, and diversity in, clinical research and emerging therapies.

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What are community sites?

Defining a "community site" can be complex, as the term varies across countries, healthcare systems and institutions. **In general, a community site is a clinical facility that operates outside of hospitals or academic medical centers.**

The National Center for Advancing Translational Sciences (NCATS) defines a community-based clinical trial as one run mainly through primary care physicians, community health centers or local outpatient clinics, rather than academic institutions. This aligns with the definition from the National Association of Community Health Centers.[1]

In the United States, more than half of all cancer patients receive care in community oncology settings. These clinics provide high-quality, affordable treatment close to patients' homes, allowing them to stay near family and support systems.[1] Many of these community sites consist of a single oncologist supported by a small team of nurses, pharmacists and other staff.[2] It is common for these sites to be privately owned, and an increasing number are forming alliances to improve coordination and access to trials.[1-3]

In Canada, the definition of a community site may vary slightly by province and therapeutic area. For oncology, it generally includes centers with trained professionals (nurses, doctors, pharmacists) who can safely handle cancer treatments, monitor patients through diagnostic services like hematology and manage complications 24/7.[4] This is like definitions used in many Latin American countries.

In most European countries, local hospitals are akin to U.S. community health centers. Depending on the country, these regional hospitals cover extensive areas with low population density. Typically, they address low-complexity care needs, although capacity and technological capabilities can vary.

Community-based solutions to clinical trial inequities

Access to clinical trials for cancer patients globally shows great disparity driven by a number of factors. As an example, in the U.S. this includes factors like race, ethnicity, geography and insurance coverage which can affect whether patients have the opportunity to participate in trials.[5-6]

In Europe, access to clinical trials is often less influenced by race, ethnicity or insurance status.[7] Instead, it largely depends on where patients are located and the distance they need to travel to an academic institution where trials are conducted. Academic and other larger hospitals often have access to the required technology, supportive care and staff to perform a trial which small or regional hospitals lack. However, with adequate support and training to reduce burden on patients and sites, regional/smaller hospitals could potentially conduct non-complex oncological clinical trials (for example, oral non-toxic treatments requiring fewer site visits). Additionally, home visits and at-home lab tests could be arranged to reduce the burden on patients.

Recognizing these disparities, organizations around the world are working to improve access to clinical trials:

- The **National Cancer Institute (NCI)** developed the Community Oncology Research Program (NCORP) to bring research opportunities into community settings and reach underserved populations (cancer.gov)
- The **Institute of Cancer Research (ICR)** advocates for expanding access to trials, emphasizing that they are essential for translating scientific discoveries into patient benefits; their reports highlight participation barriers and suggest solutions (icr.ac.uk)
- The **START Center for Cancer Research** examines how community-based trials can speed up access to targeted therapies, especially for patients with specific genetic profiles; they also discuss the important role of cancer centers in improving trial enrollment (startresearch.com)

Advantages of using community/ regional sites in clinical trials

Expanding clinical research into community and regional sites offers significant advantages that align with the evolving goals of modern clinical trials—namely, improving patient access at the point of clinical care, enhancing diversity in the patient population and accelerating innovation.

Improved patient access and convenience
Community and regional sites are embedded within local healthcare systems, making them more accessible to patients who may not be able to travel to academic centers. This proximity allows patients to receive trial-related care within familiar environments, often with their existing care providers and reduces logistical barriers such as transportation, time off work and child care.

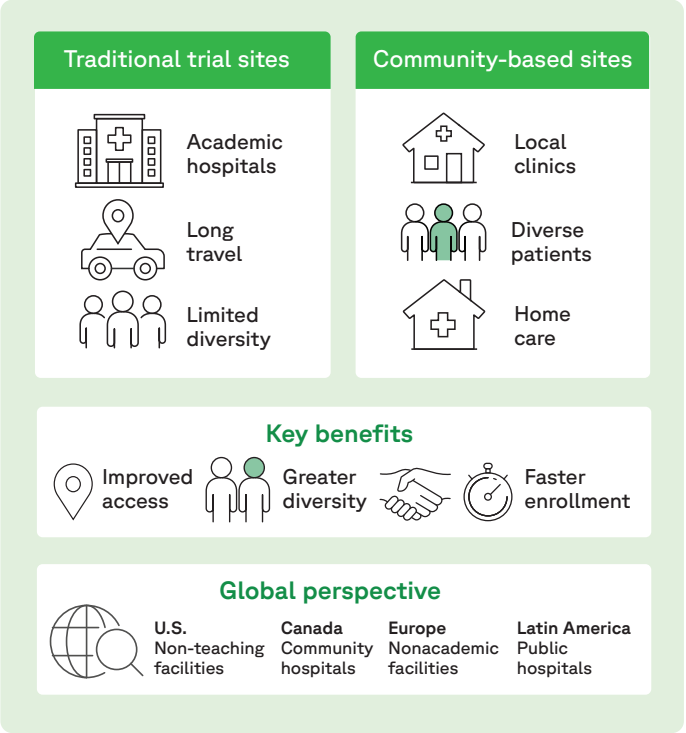
Enhanced diversity and broader geographic reach
Traditional clinical trials often fail to reflect the diversity of the real-world patient population.[5-6] Community sites typically serve a broader demographic, including racial and ethnic minorities, rural populations and individuals from underserved or lower-income communities. Involving these sites helps ensure that trial populations are more representative of those affected by the disease, leading to more generalizable and equitable findings.

Strengthened patient trust and engagement
Patients are more likely to participate in clinical trials when they are recommended and managed by trusted local providers.[8] Community clinicians often have long-standing relationships with their patients, which can increase enrollment rates, improve adherence to study protocols and reduce dropout rates.

Accelerated enrollment and retention
Due to their established patient bases and trusted reputations, community and regional sites can often recruit participants more quickly and retain them more effectively than larger academic institutions.[9] This can help sponsors meet recruitment goals faster and avoid costly delays in trial timelines.

Operational efficiency and scalability
Community-based trials can be more cost-effective due to lower overhead costs compared to major academic centers.[10] With the support of digital health tools and centralized monitoring, sponsors can manage multicenter studies efficiently while maintaining high standards for data quality and regulatory compliance.

Alignment with real-world care practices
Community sites often deliver care in settings that more closely reflect real-world clinical practice. This can enhance the external validity of trial results and support regulatory and payer decisions by demonstrating effectiveness in routine care environments.



Challenges in enrolling patients in community sites
Although there are many benefits to including community sites in clinical trials, sponsors must also consider several challenges to ensure an optimal experience for patients and site staff.

Limited infrastructure and resources
Many community sites can benefit from additional support for clinical research. They may have less experience running trials and do not often have dedicated personnel to handle trial documentation, regulatory requirements or data collection.

Regulatory and administrative burden
Complex protocols from sponsors and lengthy process from CROs can be overwhelming for sites unfamiliar with research, and lengthy contract negotiations and IRB approvals may delay trial activation. Additionally, strict Good Clinical Practice (GCP) requirements can be difficult for community sites to implement without proper training.

Challenges in patient recruitment and retention
There is often limited awareness of clinical trials among patients and providers in community settings.[11] Trust can be an additional barrier to recruitment, especially in underrepresented populations due to historical ethical concerns, like the complex history and cultural implications of HeLa cells. Providers can help build trust, but local physicians may not have time to promote trials alongside routine patient care.

Fortrea partners with several organizations to provide technology solutions that address recruitment and retention challenges. For example, Longboat supports study startup and collaboration, Datacubed offers engaging eCOA for pediatric cancer patients and Acclinate focuses on awareness and community building.

Financial and operational constraints
Training time and the burden of adapting to new processes may make research financially unsustainable for small community practices, and sites may struggle with cash flow, especially if sponsor payments are delayed. These funding limitations can lead to difficulty retaining research staff.

Patient-centric barriers
Travel and logistical challenges still exist in community settings. For U.S. sites with large populations of non-English speakers, language and cultural differences may require additional effort in communication and consent processes. When trials require eConsent, remote monitoring or digital diaries, digital literacy and access issues must also be considered.

Best practices for supporting community site engagement

To address common challenges for community sites, sponsors must implement solutions that consider the needs of sites and patients alike.

FOR SITES

- **Build site capacity and research infrastructure through partnerships.** Implementing a peer-mentorship model across sites can enable experienced partners to train emerging community sites; these trusted, research-ready sites can also help cocreate relevant and practical training materials
- **This approach is fostering the development of professionalized networks of community sites, increasingly focused on clinical trial engagement and strategic trial placement—aligned with the broader considerations outlined in this document**
- **Provide financial and operational support.** Startup funding and stipends can cover initial costs, while timely payments minimize financial strain
- **Adapt protocols to community sites.** Reduce the number of invasive tests and visits, design adaptable trials that allow flexible enrollment criteria and use real-world data to support traditional endpoints

- **Use centralized IRBs and standardized contracts.** This reduces approval delays and administrative burden, speeding up trial activation for community sites
- **Offer trial matching and patient screening tools.** AI-driven trial matching platforms help community physicians identify eligible patients while reducing recruitment workload supporting direct to site as well as patient referral activities
- **Leverage technology thoughtfully.** User-friendly electronic data capture (EDC), eConsent and remote monitoring tools can reduce cancer patient and staff burden; offer IT support and training to assist sites with these requirements

FOR CANCER PATIENTS

- **Engage local healthcare providers.** Training community care physicians and local clinics to refer eligible patients can improve recruitment, while patient navigators can guide individuals through the trial process
- **Utilize culturally tailored recruitment strategies.** Develop translated materials and support sites with bilingual staff where required; additionally, involving community leaders, churches and advocacy groups in recruitment can address historical mistrust, as can representative patient testimonials
- **Reduce patient burden.** Transportation assistance, decentralized trial methods and flexible scheduling can make it easier to accommodate patient work hours and family obligations
- **Build trust.** Addressing ethical concerns and being transparent about trial objectives, risks and benefits is essential; patient advisory boards and diverse staff are valuable for helping identify and address the most pressing concerns for the relevant population
- **Utilize hybrid and virtual trial models.** Digital technology can reduce patient burden by offering more flexible participation and integrating behavioral science; options include remote monitoring, mobile health units and sensors for remote data collection
- **Use technologies that balance data volume and quality with cancer patient needs.** Apply technology that is appropriate, not burdensome; to do this, you need to understand what matters to the patient population and how to create flexibility while maintaining compliance

Realizing the potential of community-based trials

Advancing a drug into initial Phase I trials requires stakeholders across the research ecosystem must take collaborative, strategic steps to enable better community-based clinical trials:

- **Sponsors:** Invest in long-term partnerships with community sites, not just short-term trial execution. Provide upfront funding, simplified protocols and flexible trial designs that reflect real-world care settings. Prioritize diversity and inclusion as core trial metrics, not just compliance checkboxes
- **CROs and academic institutions:** Rethink site selection strategies to include underrepresented community sites; support training, mentorship and quality oversight to enable community partners to participate confidently and competently
- **Regulatory bodies:** Provide clear guidance on centralized IRBs, decentralized models and adaptive trial designs that reduce barriers for community sites; help to navigate compliance requirements while supporting flexibility and innovation in underserved settings
- **Community leaders and advocacy groups:** Engage as trusted partners in outreach, design and feedback processes

Fortrea is committed to advancing community-based research as a strategic partner. We combine deep expertise in the needs of nontraditional research sites with a full range of tailored technological solutions that reduce staff and patient burden.

Reach out to discuss how we can support your next trial.

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