Overcoming Barriers To Clinical Trial Participation In Oncology

By Medical Research Network

Recruiting and retaining patients for clinical trials is often difficult, regardless of indication or modality; however, oncology research presents even more complexity, as these studies render enrollment and participation distinctly challenging. There is a wealth of variables that can serve to influence the number of patients who start or complete a cancer trial, with many of them linked to the burden and risks associated with these complex investigations.

As with many clinical trials, one of the first barriers to entry is awareness — many oncology patients and providers often do not know about ongoing or emerging trials, particularly smaller sites not associated with major medical centers. This lack of awareness often extends to misconceptions surrounding clinical research, as many patients may be reluctant to participate in studies, believing that they involve only experimental treatments or are only geared toward end-stage cancer patients. The uncertainty that often accompanies the prospect of participating in a clinical study is far-reaching, as are the implications for sponsors, researchers, and the industry at large.

The many factors that influence oncology trial participation — travel, compensation, severity of illness, eligibility criteria, etc. often converge to create a complex landscape for sponsors to navigate effectively. Many of these hurdles can be overcome with the right technology and support, with solutions that can enable more decentralized and remote trial design. Specifically, studies that incorporate Home Trial Support and / or community-focused Site Networks serve to enhance the patient experience by reducing participant burden and improving both convenience and, ultimately, quality of life.

Factors Impacting Enrollment For Oncology Trials

Although many patients, when asked, express their willingness to participate in oncological trials, only a small fraction ever enroll. Moreover, even more generous estimates of cancer trial participation have a notable caveat — a study from researchers at Fred Hutchinson Cancer Center and some of its peer institutions found that enrollment in treatment trials was over five-fold higher at National Cancer Institute-designated cancer centers than at community sites (21.6% versus 4.1%).[1]

While these findings highlight the importance of funding support on sites' ability to offer trials and recruit patients, they also underscore the challenges facing smaller sites and, by extension, the patients they serve.

According to the American Cancer Society's Cancer Action Network,[2] approximately 20% of cancer trials fail as a result of inadequate enrollment. A qualitative study of cancer clinical trial enrollment in 2022 found that there are four levels of barriers to clinical trial enrollment.[3] These include:

- **The patient level** – includes issues ranging from personal beliefs and degree of trust, and extends to factors like health insurance coverage, immigration status, travel constraints, language barriers, as well as other considerations.
- **The provider level** – encompasses awareness of trials, time and resource constraints, and non-cooperation from colleagues, among other variables.
- **The clinical level** – involves considerations linked to study design and eligibility criteria, among other factors.
- **The institutional level** – includes a number of issues related to policy, regulation, logistical support, and other considerations.

Another qualitative study from the perspective of physicians in the community identified several key barriers to study participation for patients. These included restrictive eligibility criteria, insufficient infrastructure support, a lack of appropriate trials for community-based settings, and financial limitations.[4]

Community-based settings, a crucial resource for certain segments of the patient population, are often limited by staffing and infrastructure constraints, rendering their utility for complex clinical trial conduct limited.

Furthermore, many community-based physicians may be less well-versed in clinical trial protocols and eligibility criteria when compared to academic physicians and, as a consequence, may fail to recognize when a patient is well-suited to clinical trial participation.

The longstanding barriers to clinical trial participation were likewise exacerbated by the COVID-19 pandemic, which, in addition to disrupting healthcare systems and reducing access to care in the short term, created both backlogs and delays that the industry is still working to recover from.[5]

Yet the pandemic also galvanized a substantial shift in clinical trial conduct that may ultimately prove transformative in improving overall access. By incorporating more decentralized clinical trial designs and leveraging resources that enable more clinical trial activities to be conducted in patients' homes, sponsors and trial teams can open up access to novel treatments for more patients, improving the state of cancer research and potentially saving more lives.

Many community sites have untapped potential for conducting high-quality oncology research, often possessing the necessary infrastructure, patient pools, and motivated staff but lacking the support typically available to academic research sites.

By expanding site networks to include these community facilities, clinical trial sponsors can improve patient recruitment, especially among underserved populations who may have limited access to major academic centers.

Moreover, supporting and empowering these sites with training, resources, and access to centralized research platforms can help address logistical and operational barriers, thereby enabling a more patient-centered approach in oncology trials. This also ensures that trials can capture a broader demographic and geographic patient base, ultimately contributing to a more comprehensive understanding of therapeutic efficacy across diverse populations.

Breaking Down Barriers: Decentralized Trials And Home-Based Care

In the post-pandemic research landscape, Decentralized Clinial Trials (DCTs) have emerged as a valuable option for improving patient access and inclusion, a shift championed by patient advocacy groups, regulatory bodies, and sponsors alike.

By allowing patients to participate from their homes or local community sites, Home Trial Support and Site Networks remove barriers to trial involvement, which is particularly impactful for rural patients and those far from major medical centers. For oncology patients, whose health conditions and daily routines can vary widely, having the option of in-home trial visits enhances comfort, conserves resources, and reduces the time away from their loved ones.

Home Trial Support solutions, such as MRN's in-home clinical trial services, have demonstrated substantial potential in improving access to oncology trials.

Since 2006, MRN has completed thousands of at-home clinical visits for oncology patients, addressing the unique challenges that these patients often face. By conducting trials in a patient's community — whether at home, work, school, or a nearby clinical site — these services remove the typical travel and logistical barriers, making trial participation significantly less burdensome.

Additionally, accessing trials has traditionally posed challenges for oncology patients in rural or underserved areas who may struggle with extensive travel to central sites, especially when limited mobility or financial constraints are factors.

Collaborating with local healthcare providers in these communities allows sponsors to conduct trials at "trial-naïve" sites, effectively democratizing clinical trial participation and reaching a wider patient pool.

In-home support reduces the physical and emotional burden of trial participation, offering convenient visit times and personalized care from home healthcare professionals (HCPs). This model not only improves recruitment but also boosts retention rates by providing a more comfortable and accessible experience.

Improving Access And Diversity Through Community-focused Site Networks

By partnering with a comprehensive and community-focused site network, sponsors can broaden access, expedite trial timelines, and enhance trial diversity, all essential elements in advancing oncology research and improving patient outcomes.

Research by the Tufts Center for the Study of Drug Development has shown a strong link between the diversity of investigative site staff and the diversity of enrolled patients,[6] underscoring the importance of representative staffing. Private sector sites were found to have more diverse teams, with almost half of their staff from minority backgrounds, compared to only one-third at academic centers and hospitals.

A dual-site approach—utilizing both private sector and academic sites—can optimize patient recruitment by broadening the scope and appeal of trials to diverse populations. Strategically selecting private sites within or near communities with high racial and ethnic diversity, and that employ staff reflective of those communities, can help overcome barriers to participation, such as mistrust or logistical challenges.

Solutions like Medical Research Network's (MRN) rapidly expanding Site Network, which will soon include over 100 sites across North America, the UK, and Europe, reflect its commitment to bringing clinical research to diverse communities worldwide.

By leveraging both teams of professionals and long-term partnerships, MRN serves as a single, centrally managed provider capable of delivering trials with localized support on a global scale. In addition, its International Development Office and Vendor Management team continuously seek innovative approaches to expand MRN's services, ensuring trials are accessible to more patients and are delivered with consistent quality across diverse locales.

Ultimately, these community-based models also offer flexible scheduling options that can be adapted to the patient's lifestyle, work obligations, family responsibilities, and physical condition – including any mobility limitations resulting from their illness.

Sponsors and trial teams can likewise benefit significantly from Home Trial Support, where data collection is streamlined, safety is enhanced, and real-time patient monitoring ensures prompt interventions. The result is a cost-effective model that accelerates recruitment, facilitates data quality, and promotes greater patient satisfaction.

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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