

Clinical trial patient recruitment challenges and solutions

Patient recruitment is a critical aspect of clinical research, yet it poses significant challenges. Finding suitable participants and enrolling them efficiently is essential for the success and timely completion of trials. Globally, around 80% of trials fail to enroll participants on time. This often results in a study extension, incurring additional operational costs and potentially delaying time to market. In addition to this, around 55% of global trials report termination due to low accrual rate.¹ How can patient recruitment be optimized to avoid delays and terminations? In this article, we will discuss some of the major challenges associated with patient recruitment and explore solutions for overcoming these challenges.

Patient recruitment challenges

LIMITED AWARENESS

Despite the potential benefits of participating in clinical trials, such as access to cutting-edge treatments and closer medical monitoring, many potential participants are unaware of these opportunities which can make finding and recruiting participants difficult. The lack of awareness can stem from insufficient dissemination efforts and healthcare provider knowledge gaps, among other factors.

STRINGENT ELIGIBILITY CRITERIA

While eligibility criteria are necessary to ensure participant safety, maintain study integrity, demonstrate efficacy on the target population, and generate reliable results, overly strict criteria can present challenges. Too stringent eligibility criteria can disproportionately exclude certain demographic groups and make the pool of eligible participants too narrow, contributing to slower and more difficult recruitment processes.

On the other hand, when criteria are too relaxed, the trial may include participants with varying characteristics and medical histories, resulting in a heterogeneous population that makes it difficult to draw meaningful conclusions. The generalizability of results becomes limited, as the study population may not represent the intended target population.

GEOGRAPHICAL BARRIERS

Trials conducted in specific locations face difficulties in recruiting participants due to geographical constraints. Limited access to trial sites in more rural or remote areas impedes enrollment.

PATIENT EXPERIENCE

Even for patients who live in close proximity to a trial site, there are still barriers that keep them from participating in a trial. Clinical trials typically require regular visits to the trial site, which can be time-consuming. In some cases, patients may also need to adhere to specific treatment schedules, including medication administration or follow-up appointments. Balancing these trial-related activities with work, family responsibilities, and other commitments can be demanding and may create additional stress for patients which may deter them from enrolling.

RECRUITMENT TIME AND COST

The efficiency and effectiveness of the recruitment process can greatly influence the overall success of a study. The process of advertising, screening, and enrolling participants is time-consuming and expensive. Streamlining these processes is essential to meet recruitment targets efficiently from both a time and resources perspective.

Solutions for tackling patient recruitment challenges

INCREASED PUBLIC AWARENESS

Educating the general public about the importance and benefits of clinical trials is crucial. Launching awareness campaigns and pursuing partnerships with advocacy and patient groups can help disseminate trial information more effectively.

STREAMLINED ELIGIBILITY CRITERIA

Streamlining and simplifying eligibility criteria is an important avenue to consider as it can greatly improve the overall efficiency of a study. However, it should always be done with caution to maintain scientific rigor, participant safety, and the study's objectives.

For example, engaging with healthcare professionals and patient advocacy groups or organizations representing the target population can help a researcher gain insight into the challenges and concerns participants may face when considering trial enrollment. This collaboration can help refine eligibility criteria to be more patient-centered and increase accessibility.

INFORMED SITE SELECTION

Choosing the right site for a clinical trial is crucial as it directly impacts participant recruitment and retention, data quality, adherence to protocol, regulatory compliance, and overall study efficiency. Collaborating with research institutions, healthcare providers, and patient advocacy groups can enhance patient recruitment efforts. Leveraging their expertise and networks can help identify suitable trial sites and attract relevant participants.

OVERCOMING GEOGRAPHICAL BARRIERS

Virtual clinical trials, also known as remote or decentralized clinical trials, have become a patient-favored approach. Unlike traditional clinical trials that require participants to visit physical research sites, virtual trials leverage technology to remotely collect data and engage with participants from the comfort of their homes. This eliminates the need for frequent visits to research sites, reducing the burden on participants and potentially increasing recruitment and retention rates.

LEVERAGING DATA

Trial designers and researchers can turn to historical data to assist them in the clinical trial design process. Utilizing historical data may reveal crucial insights that can help overcome or mitigate recruitment roadblocks. By having a look at data points from similar studies in the past, such as recruitment start dates, enrollment duration, enrollment per country or site, endpoints and outcomes, among other data points, trial designers can make informed, data-driven decisions regarding site selection, endpoint selection, and more when in the trial design process. Armed with this data, trial design can be optimized for patient recruitment and retention.

Did you know? DISCOVER, ONTOFORCE's powerful data and knowledge platform, is utilized by researchers and trial designers in pharmaceutical organizations across the globe to discover such data to optimize patient recruitment and retention. By enabling users to access and analyze a vast amount of data from diverse sources, DISCOVER drives more efficient and effective patient recruitment strategies.

Optimizing patient recruitment

Insufficient or delayed patient recruitment for clinical trials can cause a trial to be extended leading to increased resource use and costs. In addition, longer trials postpone the availability of potentially valuable treatments to the public. For trials that don't reach the appropriate sample size, it could be likely that it ends up abandoned with no publishable results.

Despite all this, it's still quite [common for investigators to largely overestimate](#) the pool of available patients who meet the set inclusion criteria. Having a better understanding how eligibility criteria and site selection, along with the barriers that deter patients from enrolling in a trial, impact recruitment rates and processes is essential in addressing these challenges. Having a firm understanding of these factors enables trial designers, researchers, and investigators to tailor their recruitment approaches properly to hopefully drive optimized and efficient patient recruitment.

Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7342339/>