WHITEPAPER:
Patient Engagement

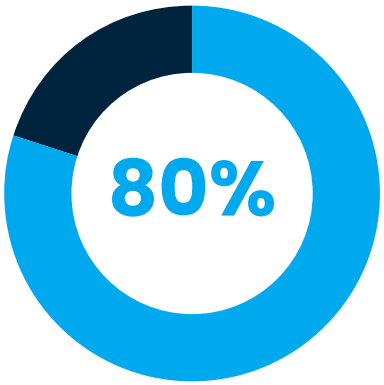
The Need to Recruit Better

Understanding the Barriers that Keep Patients from Participating in Clinical Trials

trialbee

Much has been written and discussed concerning the challenges around enrolling enough patients in clinical trials. Poor recruitment and insufficient enrollment stretch study timelines, add costs and can cause studies to fail outright before they can even begin, with 55% of terminated trials due to low enrollment and 80% of trials requiring timeline extensions or the addition of new study sites in order to enroll enough patients.[1] Concerns around timelines and cost certainly make sense, but to gain real insights into how to improve recruitment in clinical trials, the industry must think outside these business-specific concerns and begin looking at these problems through the eyes of the patients.

Some formidable barriers exist that work to keep eligible and interested patients out of clinical trials. By understanding these barriers, we can begin the necessary work to remove them.



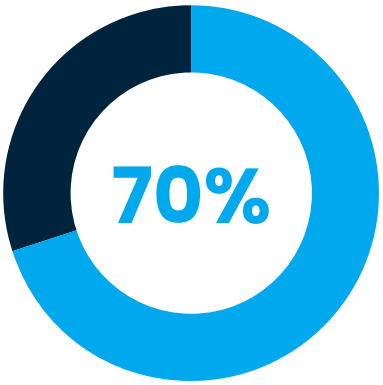
80% of studies fail to enroll enough patients on time.

Lack of Access

A recent study by the Center for Information and Study on Clinical Research Participation (CISCRP) revealed that 85% of patients interviewed said they would be willing to participate in clinical research.[2] Yet, poor enrollment continues to challenge the successful execution of studies. Lack of access to clinical research for participants is the largest and most obvious obstacle to recruitment, and it is a multi-faceted problem.

Geography

Clinical trials have long depended on centralized study centers, usually large hospitals and academic institutions located in major metropolitan areas. These studies have relied on recruitment efforts seeking out eligible participants living within reasonable distances to these sites. This makes trial participation difficult to impossible for large groups of interested and eligible patients. In fact, 70% of eligible participants for a clinical trial live more than two hours away from a study center.[3] By continuing to rely on study designs that require frequent clinical visits to these centralized study centers, the industry perpetuates two key problems – low enrollment numbers in general and homogenous patient groups. This leads us to the next issue around lack of access to research.



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Diversity

Homogenous patient cohorts are a significant problem for researchers. The clinical trial data resulting, for example, from a cohort that is largely male and Caucasian cannot be considered complete and comprehensive when related to a drug designed for use among the much broader human population. Additionally, populations living within short distances from traditional study centers tend to be more affluent and typically have more access to support systems. Again, data derived from these groups will likely not be representative of real-world usage and impact of a given therapy. This is a problem that regulators are keenly aware of, with the U.S. Food & Drug Administration recently releasing guidance highlighting the importance of inclusivity in clinical research.[4] The United States Congress has even begun to weigh in on the topic of diversity in clinical research with the 2021 ENACT bill, which aims to increase diversity in Alzheimer's clinical research, currently in front of the US House of Representatives.[5] Another forthcoming bill is planned and expected to have broader impact to our industry.[6]

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Overdependence on Certain Clinical Trial Sites

Clinical research has long depended on the model of site-based clinical trials – studies that require patients to make regular visits to specific clinic sites. This has led to a situation where the same sites are used over and over again for multiple studies. On one hand, this makes sense from the sponsor point of view, they want to work with the sites that have proven their ability to facilitate studies both through their patient access and experience with certain therapeutic areas. As we discussed in the previous point, however, this can lead to the enrollment of largely homogenous patient groups which can produce misleading or incomplete study data.

There is another important issue to consider here – by working with the same sites repeatedly, we are shutting out thousands of currently research-naïve sites that could lend access to new, talented teams of clinicians and a broader, more representative population of patients. By adopting modern approaches to study design, such as those that include remote data collection technologies, sponsors can open up access to their studies to sites that are not located near study centers. Otherwise, the clinicians at these centers may not otherwise know about studies that could benefit their patients.

Inability to Communicate Effectively with Target Populations

This leads us to another access-related barrier – communication. Historically, recruitment has been addressed through broad, geography-based approaches like advertising campaigns, or through person-to-person communication such as a patient hearing about a study from their doctor. Designing studies to include remote technologies is one part of broadening reach, but work must be done to understand who the patients are that are needed for the study, and how to talk with them.

Technology can help by mining data to find out where patients live online. Using this technology, insights can be derived regarding the kinds of messaging the audience typically engages with, so that recruitment messages can be accurate, transparent, and sensitive. Having this data gives sponsors the best chance at both educating the target population about the study and breaking down any misconceptions or trust issues that might cause otherwise ideal patients to stay away.

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Perceived Over-complexity of Research

Clinical research is complex, but work can be done to simplify how it is explained to potential participants. Transparency in terms of communicating eligibility criteria is important. Instead of burdening potential candidates with scientific jargon, it can be useful to simply be up front in all recruitment messages. Patients interested in clinical research are motivated because they themselves are seeking an improvement to their condition and because they want to help others in similar situations. Thus, it can be overwhelming and confusing for them to read through study descriptions (like those on Clinicaltrials.gov) when all they really want to know is if they are eligible to participate in any studies. Sponsors can help by leading the recruitment communication efforts with information such as:

- Demographic requirements (age, gender, race, etc.)
- Condition (diagnosis, stage, presence of co-morbidities, etc.)
- Number and frequency of required in-person clinical visits
- Location of clinical site
- Digital infrastructure needed for remote data collection and/or virtual visits (does the patient have reliable broadband internet access, does the patient have access to necessary devices, etc.)
- Approximate number of hours per day/per week that the patient will engage in data collection activities, either remotely or in-person

Getting this information out, up front, may reduce the volume of respondents to a recruitment campaign, but it will increase the percentage of truly qualified candidates. This, ultimately, saves everyone involved a great deal of time. It reduces the stress of outreach and false hope for patients looking to get involved in clinical trials and it saves study teams from spending countless hours disqualifying clearly ineligible patients.

Conclusion

Better understanding of the obstacles keeping many patients from participating in clinical trials is key to improving enrollment, both in terms of volume and inclusivity. Patients, by and large, are interested in clinical trial participation[2], yet the continued dependence on site-specific geographies shuts out the vast majority of potential study candidates and inhibits the ability to produce representative safety and efficacy data. Patient-first thinking can help to improve access to research for more patients and more study sites through data-driven approaches to recruitment and modern study designs that allow for at least some remote data collection.

For more information visit trialbee.com.

Citations

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trialbee.com | solutions@trialbee.com