WHITEPAPER

Building Empathetic Clinical Trial Recruitment Programs

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Effective and efficient clinical trial recruitment remains a fundamental challenge for ultimate study success. Sponsors and sites have turned to numerous strategies to improve recruitment and keep patients engaged, with varying results. While the goal remains the same – to get adequate numbers of eligible candidates enrolled as quickly as possible – many fail to consider that the solution may be as simple as considering the human factors faced by patients as they explore possibilities of research participation.

What Does Empathy Mean in the Context of Clinical Research?

In an industry driven by numbers and data, empathy can get lost. Empathy, the ability to understand and share the feelings of others, can be a powerful tool for improving both clinical trial recruitment and retention. By working to build a better, more complete understanding of our patients, we can begin to break down the barriers to recruitment in a number of ways.

Improving Study Access

There are two sides to the issue of access; sponsor access to patients and patients' access to the clinical trial process. For sponsors, access to patients remains a key pain point. This refers both to access to patients in general – i.e. getting enough patients enrolled to conduct a viable study – and access to a broader, more demographically representative population of patients.

Access for the patients themselves boils down to a few important factors, including:

- Having successful methods for educating potential study candidates about the existence of clinical trials they may be eligible for
- The ability to quickly inform candidates of eligibility criteria
- Time and travel requirements for participation
- A realistic and non-intimidating path through the recruitment process

Empathy for patients and their experiences helps to solve the access problem from both perspectives – patient and sponsor. By utilizing approaches and technologies that are built from the ground up with the patient experience in mind, barriers to access can be removed. For example, using advanced data-mining, we can build accurate patient profiles that include such details as age, location, gender, race, and ethnicity. Data can also tell us if the patients we're seeking are likely to have comorbidities and, if so, which ones. Learning all of this, we can anticipate things like average patient distance from a study site, socioeconomic status of patients, and other similar factors. If we know that many of the patients we are looking for are poorer and likely to have physical or financial limitations that would make travel difficult for them, we can develop study protocols that allow these patients to participate remotely.

In this example, the work done to better understand patients leads to a solution that allows a broader group of patients to participate. This not only improves access to studies for the patients, it expands the scope of recruitment beyond clinical site geographies, allow sponsors to reach larger, and potentially more representative, groups of patients.

Recruit Leakage

Leakage, in terms of clinical trial recruitment, refers to when interested candidates drop out of the recruitment process before they can be successfully enrolled. To understand why leakage occurs, we can take a look at a typical clinical trial recruitment process:

- The patient discovers a clinical trial they may be eligible for
- This often happens when a motivated patient is actively seeking information about their condition. Patients may also be referred to a study by their healthcare provider.
- The patient is faced with a description of the study that is either vague with few details or densely written with complex scientific jargon
- Frustrated, the patient eventually locates instructions for taking a pre-screening survey. However, the survey questions are difficult to understand.
- Upon completing the survey, the patient waits several weeks with no word from the study team. Exhausted by the process they move on to other treatment options.

- Two more weeks later a study team member finally contacts the patient. The patient, understandably irritated, tells them they are no longer interested in participating in the trial.

Applying empathy to this situation can result in adopting methods that make the path to enrollment easier to follow. For example, a pre-screening questionnaire can be developed that is written at an appropriate education level for the population and is brief enough to not frustrate patients. An effective process would then get those patients as quickly as possible to the next step in the process, typically a short interview with a study nurse. If a patient isn't likely to meet eligibility requirements, then the nurse can convey that to the patient so as not to waste their time. For those that can move on, the nurse can schedule their first appointment. Simply by making the effort to employ a less frustrating patient journey, we can prevent the leakage of highly qualified candidates and reach enrollment goals more efficiently.

Applying Empathy to the Site Experience

Pausing to consider the experiences of all study stakeholders can lead to smoother trials. In addition to patients, the day-to-day of site team members is another smart target as we seek to build more empathetic study methodologies. So while we may have taken steps to adopt new approaches and technologies that make study recruitment and participation easier for patients, we need to also consider how those changes impact trial sites and study team members.

Site team members may view the adoption of a new technology to manage recruitment as yet another tool they have to manage. Nearly all clinical trial enablement technologies come with their own software and platforms, some of which are more intuitive than others. Thus, as we identify solutions based on our empathy for patients, we must ensure that they do not add undue burden for sites. Effective solutions account for this, designing their technology with interoperability in mind. The best ideas can be wasted if they cannot work within a site's existing IT ecosystem.

Tech headaches aside, solutions should also attempt to make the jobs of site teams easier. In terms of clinical trial recruitment, site teams can be beleaguered with large volumes of candidate data coming from multiple recruitment strategies and vendors. Keeping track of all of this across entire studies is a difficult task for the best-equipped and most experienced sites. To help simplify things, technology can be employed

that takes in all recruitment activity data and provides easy-to-digest visibility. By consolidating recruitment activity data, we can help site teams to quickly see what is working – messaging, channel, technique, etc. – and what is not working. This kind of approach addresses the site experience and offers functionality to make it easy for them to effectively manage, regardless of scale, study recruitment across all referral sources.

Conclusion

Clinical trial recruitment is certainly not easy. That said, neither is clinical trial participation for patients, nor the work done to manage the process by study sites. Possible solutions with the most potential to finally crack the code on improving study recruitment lie in the simple need to consider and care about the experiences of those involved. By thoroughly investigating how we can make the study recruitment experience easier and more positive for all involved, we can build processes that deliver more qualified, more representative, and more motivated study enrollees. Doing so can help studies get moving more quickly and deliver better data overall.

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