WHITEPAPER

Disrupting the Clinical Trial Enrollment Process

Disrupting Enrollment

trialbee

Clinical trial recruitment and enrollment is an area ripe for disruption. Clinical trials are responsible for approximately 40% of the overall pharmaceutical research budget in the United States – around $7 billion, and 40% of that is made up of costs associated with patient recruitment, totaling nearly $2 billion. Despite this huge expenditure, the recruitment process has been and, in many cases, continues to be inefficient. For example:

- 80% of all clinical trials fail to meet enrollment timelines [2]
- 55% of all clinical trials that terminate do so due to insufficient patient enrollment [2]
- 20% of clinical trial participants drop out of the study at some point [3]
- Only 10% of all clinical trial participants represent minority populations [4]

Viewing these challenges alongside the sheer cost of clinical trial recruitment, it is clear that traditional recruitment and enrollment strategies are neither efficient nor sufficient. Despite advances in technology that have driven innovations in other facets of clinical research (e.g. eCOA, telehealth, the use of mobile medical devices, etc.), recruitment initiatives have clung to broad approaches aimed at funneling large groups of candidates into the enrollment process. This type of approach relies almost exclusively on patient databases held by large clinical study centers. The scattershot approach brings in high numbers of ineligible candidates, thus wasting time and budget on patient vetting.

Old methods that rely heavily on experienced study sites also tend to lock themselves into the same patient demographics study after study. This leads to homogenous patient populations that do not reflect the real-world population.

Why Older Methods are Inefficient

Traditional recruitment models give sponsors little to no control over enrollment outcomes. With nearly half the budgets of clinical research already going toward recruitment, spending alone is not an answer. These models utilize mostly human-driven processes and are, as a result, widely inconsistent. It is common for sponsors to turn to multiple

different recruitment strategies for a single trial in the hope that through attracting high volumes of interested candidates, they can reach their enrollment goals and timelines.

However, these broad strategies fall short in a few key ways:

Over-reliance on sites

As mentioned earlier, traditional recruitment approaches depend on bringing in patient candidates that live within reasonable proximities to clinical trial sites. These geographic constraints inherently limit the number of potential candidates. Because sponsors tend to reuse the same study sites repeatedly, site teams are over-burdened having to comb through their databases over and over again to find patients that may meet eligibility criteria. They then must spend more time vetting candidates, most of whom will end up being excluded.

Poor Patient Inclusion

Repeated use of the same clinical trial sites also means that enrolled populations tend to look the same, demographically. Only those patients living within an hour or two – typically – are realistically capable of participating in research. Because major clinical trial sites tend to be located in more affluent population centers, these patient groups tend to be affluent and, largely, white. This means that large swaths of people do not have adequate access to clinical studies that they, otherwise, would be eligible for and motivated to take part in.

For example, currently whites make up approximately two-thirds (67%) of the overall U.S. population, but account for 83% of research study participants[5]. Compare that to African Americans who make up 13.4% of the U.S. population and only 5% of study participants and Latinos who comprise 18.1% of U.S. residents yet make up less than 1% of clinical trial participants.[6]

New Ideas to Transform Patient Recruitment

Patient centered approaches to recruitment, made possible through technology, can help to transform clinical trial enrollment. The first step to a more patient-centric recruitment program is utilizing all of the

information available to better understand patients.

Targeted recruitment

For any given clinical trial, there are ideal patients. Knowing what makes an ideal patient is important, but does not, by itself, help to overcome the research access challenges that keep large numbers of likely-qualified candidates from participating. Using advanced data-science, de-identified patient data from major electronic health record databases can be combined with consumer-use data to create very accurate patient profiles. Through health records it is possible to identify those patients that are likely to meet study eligibility criteria along with information on where those patients are and which clinical sites (that may or may not be involved with research) they visit for care. Consumer-use data then reveals details like patient demographics and, importantly, where patients are going online to learn about their disease or engage with others regarding health issues.

With these highly-specific patient profiles as a guide, study leaders can develop focused messaging likely to resonate with potential candidates and deliver that messaging through the digital channels those candidates prefer. This approach allows for precise targeting – not simply those patients that likely meet eligibility criteria, but also patients that help to meet goals for inclusivity and diversity. A technological approach is also more efficient than the broader, "wide-net" strategies that have been utilized over the years, as it minimizes advertising effort and spend to only those channels likely to produce strong candidates. By significantly reducing the number of poorly-qualified candidates that enter the recruitment funnel, the data-driven approach also helps to reduce the amount of time and labor required by study teams to vet and eliminate ineligible patients.

Data-science also aids recruitment at the point-of-care. While historically, direct from physician referrals have depended on clinicians that are closely tied to traditional study centers, technology is now available that can notify any clinician – regardless of location and network – when they have patients who may be eligible for clinical trials. Using data pulled from health record databases, clinicians can now be pinged whenever one or more of their patients match recruitment criteria. This is helpful for recruiting less tech-savvy patients who may be less reachable through digital communications like advertising and social media.

An Easy Path Into Research for Patients

Using technology, study leaders can also improve chances for recruitment success by simplifying the patients' journey throughout the enrollment process. Many likely-qualified candidates fall out of the recruitment funnel simply because it takes too long to follow up with a real person. Dedicated recruitment technology platforms work to guide patients quickly and easily along the path to enrollment. Here is a look at how it can work:

- High-quality candidates are pulled in through the data-driven messaging and advertising campaign
- They click on a URL to visit a dedicated landing page
- Patients then complete a simple self-screening questionnaire
- Those that pass this gate are immediately put in touch with a member of the clinical study team
- The team member, typically a study nurse, surveys the patient to confirm likely eligibility
- The patient is then scheduled for an in-person clinic visit to finalize enrollment

This approach minimizes the loss of quality candidates while accelerating the patient vetting process. Patients experience a less stressful path to enrollment while sites and sponsors endure less burden associated with determining which patients are included versus excluded, allowing them to focus more time and effort on engaging with those candidates best suited for participation.

Improved Visibility and Transparency

Older recruitment models have generally relied upon multiple, concurrent methods for bringing in large numbers of candidates, the thought being that enrollment requirements can be reached through sheer volume. This makes management and oversight of the recruitment process more time and labor intensive as study teams work to try and keep track of patients and where they are coming from. Using modern recruitment technology, study leaders can now consolidate participants recruited from multiple sources and more easily view progress of all recruitment activities across an entire study. Real-time study analytics provide study teams with the necessary transparency

to see what recruitment initiatives are working and which are not, allowing them to make changes quickly to optimize the process.

Conclusion

New technologies, grounded in the advanced use of data, have the opportunity to facilitate significant improvements to how patients are recruited for clinical trials. With the need to quickly and safely bring new therapies to market only increasing, outdated and inefficient recruitment strategies must be replaced. Approaches that help to better-target quality candidates and deliver potential enrollees that meet both eligibility and demographic criteria are available. By shifting to these technology-driven solutions, study leaders are better equipped to manage the recruitment process, to discover new efficiencies, and to improve the patient experience.

For more information, visit trialbee.com.

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