Fixing the Problem of Representation in Clinical Research

Data-Driven Strategies for Recruitment

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The lack of demographic representation in clinical trials is long-felt and a well-known challenge for the research community. In the United States, for example, many communities of patients are under-represented. Whether these communities are defined by gender, race, ethnicity, or socioeconomic status, it is clear that their access to clinical trials is insufficient.

For some examples, Whites make up roughly two-thirds (67%) of the overall U.S. population, but account for 83% of research study participants. Compare that to African Americans who make up 13.4% of the U.S. population and 5% of study participants and Latinos who comprise 18.1% of U.S. residents yet make up less than 1% of clinical trial participants. Women are nearly twice as likely as men to experience adverse drug effects, a problem linked to the fact that not enough women are participating in clinical trials, leading to a lack of insights into how therapies will uniquely affect women.

Spurred on by the COVID-19 pandemic and the resulting need for a quickly produced, safe vaccine that would be effective for all people, the U.S. Food and Drug Administration (FDA) provided new guidance for industry around increasing the diversity of clinical trial populations and made clear that representation will an important factor in therapy approvals moving forward.

Challenges to Improving Representation in Clinical Trials

Location

Historically, clinical trials have relied upon study sites for the majority of patient data collection. These sites are, for the most part, large hospitals affiliated with major academic institutions. These sites tend to be used by trial sponsors repeatedly. Participation in studies, for patients, means regular and often frequent travel to study sites. This all leads to homogeneous patient groups tied to each site. With recent industry data revealing that 70% of study participants already live more than two hours from these sites, patients living even further away are inherently shut out from opportunities to enroll in studies.

Awareness

Many patients who could potentially benefit from study participation have no access to information about trials and no mechanism to draw their attention. Many patients rely on their physicians to refer them to new options for care. Physicians working in healthcare settings not affiliated with the typical academic study centers, such as those in rural or economically depressed areas, are not reliably informed about the existence and availability of clinical trials. These physicians are focused on patient care and usually see large volumes of patients – they simply do not have time to stay on top of open research studies.

Social determinants of health also impact awareness of clinical trials. While there are many disease-specific groups online where patients can engage with and learn from each other, patients who cannot afford online access or live in places where there is no reliable digital communications infrastructure miss out on the most common channel for learning about research opportunities.

Patient Burden

The trials themselves can be an obstacle for improving patient access and representation. Protocols that are overly complex and require a great deal of effort by participants (travel, self-data collection, frequent/intrusive in-home visits, etc.) can keep many patients away. Many under-represented communities are less affluent than those groups that make up the typical study cohort. For example, studies that would require these groups to make frequent site visits could be a non-starter for a number of reasons, including:

- Patients cannot afford to take the time off work necessary to make site appointments

- Patients cannot afford or do not have access to childcare during site appointments

- Patients do not have access to reliable transportation to and from site appointments

Even in the case of decentralized studies, protocols that rely too heavily on in-home appointments with home healthcare nurses can pose too much of an imposition on the busy lives of patients to make study participation reasonable. While any clinical study, either site-based or decentralized, will require some patient burden, overly complex

protocols make it very difficult for wide groups of patients to effectively enroll and perform.

Using Technology to Help Solve Representation Challenges

Advanced data-mining approaches can help break down these obstacles to truly representative enrollment. By employing data-science in some key ways, we can improve awareness and access for under-represented groups.

Knowing Your Target Patients – Personas

When seeking out different patient demographics to draw into a study, a combination of Real-world Data (RWD) - electronic health record (EHR), Claims and consumer-use data can help find those patients most likely to meet eligibility criteria. This is done by using validated platforms linked with major EHR/Claims databases, de-identified data, and a cross-check with mainstream data use, such as search information and social media use. For example, medical history information from the EHR – such as prior diagnoses or family histories – can be matched up with search and social media activity that is specific to the disease. All of this, again, is de-identified to maintain user privacy. However, it helps us to create a truly representative patient persona. While personal data remains unseen, demographic information and insights into patient interests are collected. With this information, effective strategies can be developed that are more likely to reach patients in the populations needed for the study.

Reaching Patients Where They Are

With patient personas created, the next step is delivering study information to those geographic locations where patients are most likely to live. The personas inform the development and deployment of key messages. This allows us to move beyond "wide-net" recruitment approaches as we deploy highly targeted and efficient communications strategies designed to meet patients where they are. Different strategies will be necessary to attract different patient groups. For example, the same messaging and method for outreach (online advertisement, TV advertisement, social media campaign, etc.) that works for a 45-year-old white man will not necessarily be effective if we're also looking to attract senior African American women. Thinking

about the demographic needs of a study earlier on (versus taking a chance that a general call for candidates will produce a representative group) and employing these bespoke strategies from the beginning of the recruitment push can help to hasten recruitment while maximizing representation and probable eligibility.

Think Early About Patient Experience

Meeting patients where they are can also apply to study design. As mentioned earlier, overly complicated study protocols can make participation difficult or impossible for many Individuals. What data needs to be collected and how that data can be collected should be considered through the lens of the patients' experience. Decentralized study approaches, approaches that allow for data to be collected remotely via technology (software applications, wearable sensors, mobile medical devices, etc.), can help to make participation more realistic and comfortable for many patients. It is also a good idea to avoid the temptation to use these tools – and their near limitless potential to collect all kinds of data – to collect more data than is necessary to meet study endpoint goals. Keeping things focused can help simplify the experience for patients which is an incentive for participation and a great way to maintain retention.

Creating a Mechanism for Physician Referral

To complement recruitment strategies aimed directly at patients, data-science can also be employed to reach patients through their trusted physicians. To improve study population representativeness, we must reach beyond physicians affiliated with traditional study centers. Validated, secure research software can work within major RWD platforms to identify patients likely to be eligible for a given study. The physicians caring for these patients can then be notified about the study opportunity and make an informed decision about whether to discuss it with them. This approach can bring any clinician into the loop about specific clinical trials that can help their patients, regardless of previous research experience.

Conclusion

The key to improving representation in clinical study participation is improving access to larger and more diverse groups of patients. Advanced data-science solutions and approaches, along with data-collection technologies, are now available to expand clinical trial recruitment far beyond the geographies and corresponding patient demographics of traditional academic study centers. Using these tools, we can help inform and attract a more diverse group of qualified candidates into research, resulting in better, more comprehensive safety and efficacy data.

For more information on how technology can help to optimize clinical trial recruitment and enrollment, visit www.trialbee.com.

Sources

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