Taking a Long-Term Approach to Improving Vaccine Trial Recruitment

The groundbreaking mRNA technology used in the COVID-19 vaccine has potential applications in preventing a number of other infectious diseases and is ushering in a wave of new vaccine development. At the time of writing, there are over 1,700 active vaccine trials found on clinicaltrials.gov. In our own practice at Accellacare, we've experienced a sharp increase in the number of vaccine trials we're supporting; we estimate that we're recruiting for 30 percent more trials today than in the pre-COVID era. Covid-19 also highlighted the need to increase diversity in clinical trials for equity and also to ensure that the vaccines have been tested in appropriate subgroups. This has heightened the need for finely tuned recruitment strategies.

At the same time, the public's experience with COVID-19 vaccines has led to a degree of "vaccine fatigue and hesitancy" that makes recruitment for vaccine trials challenging, over and above the growing competition for participants. There are, however, a number of strategies and tactics that have proven successful in reaching potential participants, educating them on the value of vaccine research, and motivating them to take part.

Numerous Factors at Play

Enrolling participants into clinical trials for vaccines is challenging for several reasons.

First, there's simply a greater demand for the eligible pool of participants, and enrolment periods are typically short. Not only are there more studies, but studies are also larger; it is not uncommon to seek 20,000 to 25,000 participants per trial. Plus, participants should represent the target population in all of its diversity. The US Food and Drug Administration (FDA) encourages drug sponsors to ensure that "people of different ages, races, ethnic groups, and genders are included in clinical trials."[1]

Second, factions of the public have questions about the new technology used in the COVID-19 vaccines and the apparent speed with which they were developed. The political climate – coupled with misinformation and disinformation about the virus, treatments, and the vaccines – has fuelled vaccine hesitancy and polarised people. And a pre-existing mistrust of the medical community in some demographic groups has made matters worse.

Third, the public has been exposed to a glut of vaccine-related news for nearly three years. A Google search for "vaccines" netted 3.5 trillion results. Yet, ironically, it seems that the public is largely unaware of the risks posed by the many other non-COVID diseases (such as respiratory syncytial virus (RSV)) on which vaccine research is being conducted.

Multi-level Solutions

The traditional methods of recruiting participants – connecting with investigators and employing digital media to reach potentially interested/eligible people – are no longer sufficient. These pre-pandemic tactics must be augmented with initiatives at the community, site and individual participant level.

Build Relationships within the Community

If we are to overcome vaccine hesitancy, the public must come to trust the research community and to understand the research process. Long before the start of any study, sites and site networks need to be engaged within their communities to develop relationships and demonstrate being trusted partners who will be around for the long haul. Sites can, for example, offer value to the community by holding general health screenings, mental state exams, blood pressure or diabetes screenings, and increasing access to healthcare. Sponsoring community organisations and events at the senior centre, children's sporting events, and church activities are all ways of connecting to potential participants.

Accellacare has pursued this approach with success. To mark the grand opening of a treatment centre on a busy urban street, we sponsored a food truck over the lunch hour and gave tours of the clinic. Over 200 people attended, with 140 opting into a database of interest in clinical trials. The cost of acquisition per name was calculated at just $40 – far less than the cost associated with digital advertising campaigns and enabling us to have a more targeted approach to recruitment.

Educate the Public

Sustained information campaigns at various levels can help to counter disinformation and misinformation by providing factual material on diseases, and the risks/benefits of trial participation as part of this.

Public service announcements (PSAs) explaining the value of vaccines and the indications they prevent would be valuable in raising the public's awareness of, and appreciation for, vaccine research. Year-round advertising and community outreach sponsored by the pharmaceutical industry and clinical sites could supplement these PSAs. The messaging and imagery, however, needs thoughtful consideration with regards to each community's specific concerns and be sensitive to cultural differences.

To address questions about clinical research and to dispel their fears of the investigational process, sites, sponsors and CROs could commit to sponsoring educational programs about the role of clinical research, accomplishments, and what participation entails. Again, this is a tactic that Accellacare has used successfully. We've held seminars for members of the public who meet basic study inclusion criteria to convey general information about clinical trials as well as trial-specific details. Attendees were encouraged to bring a friend, to extend the outreach and were given an opportunity to tour sites and meet clinical teams, removing fear of the unknown.

Communicate with Participants/Potential Participants

To build relationships, site staff should engage in open, interactive communication with participants, answering questions and validating their concerns. Conducting surveys with participants to better understand concerns with the goal of constantly improving relations can reveal important patient insights. Also, it's advantageous for the site to maintain connections with prospective participants. While they may not initially be interested in participating in vaccine studies, they could change their minds. What's more, they may have an interest in studies in other therapeutic areas or may be open to referring a friend.

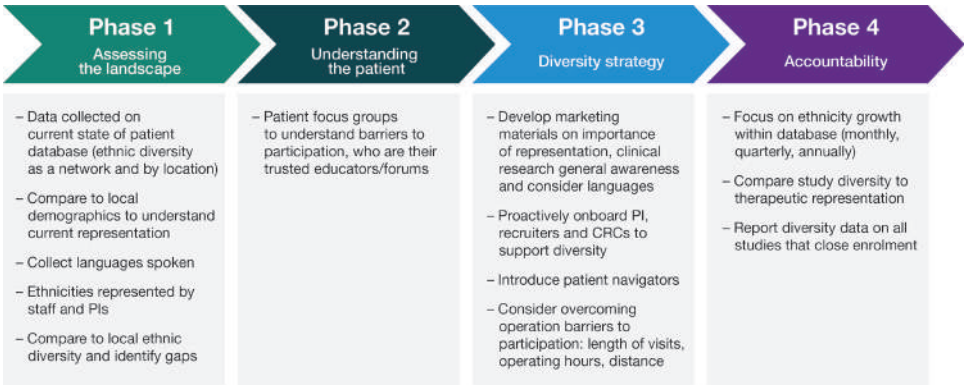
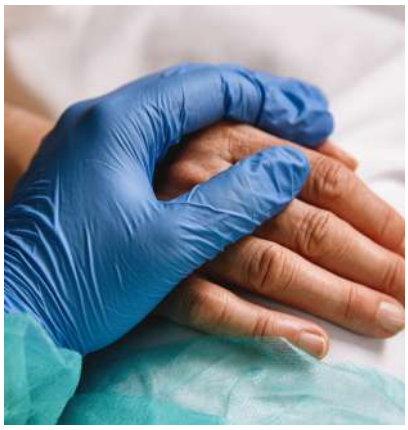


Figure 1: Sample Diversity Strategy



Striving for Diversity

Increasing the diversity of study participants cannot not be tackled one study at a time, but rather should stem from a broad commitment that will improve diversity within all studies. Figure 1 displays the four phases of a well-developed strategy for expanding trial diversity: assessing the baseline state, gathering insights from participants/patients, taking active steps to support diversity and measuring and reporting on progress against the baseline.

In following this strategic approach, Accellacare conducted focus groups among Black and Latino communities to gain insight into their current understanding of clinical research, motivation and hesitation around participating, as well as into their sources of information. Based on the findings, we developed a patient partnership program featuring patient navigators who help build collaborative and sustainable relationships in the community. Specifically, they identify outreach opportunities for us, preview our marketing materials and represent us at community events.

Developing and Measuring the Recruitment Plan

A good participant recruitment plan is foundational to enrolment success and should encompass both resourcing needs and accountabilities.

The first step is to analyse historical data from analogous trials, examining no-show rates, not-eligible rates and not-interested rates. These should be calculated by month, weekday, and around holidays to identify patterns in the data. (See Figure 2.) Next, the logic derived from the historical data should be used to model enrolment rates for the upcoming trial. This exercise will reveal when peak enrolment and enrolment delays could be expected – insight that can be used in resource planning.

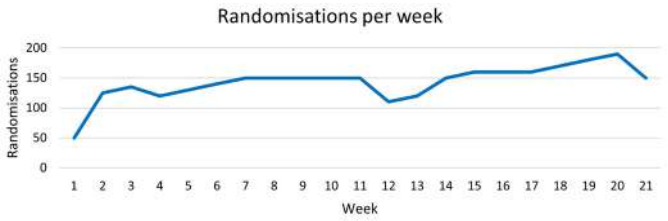


Figure 2: Historical Randomisation Trend

Once the plan is enacted, the team will be able to measure success against established key performance indicators (KPIs) such as the number of leads obtained, enrolments per site, and enrolments against diversity targets.

Conclusion

The current challenges in recruiting participants for vaccine studies can't be overcome simply by relying on traditional means of outreach and advertising. Helping people overcome their vaccine fatigue and/or hesitancy will take a concerted effort on the part of sponsors, CROs and sites. By striving to become trusted partners in the community, building and maintaining relationships and keeping the lines of communication open, researchers can expect to access a wider pool of potential participants.

REFERENCES

1. US Food and Drug Administration Website. Updated August 14, 2018. Accessed September 30, 2022. https://www.fda.gov/patients/clinical-trials-what-patients-need-know/diversity-clinical-trial-participation.

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Dinah has been working in the clinical research industry for more than 25 years and in her current role is leading the Accellacare Site Network for North America. She started her career working at University Park Research Centre as a study coordinator and then moved to the CRO side as a CRA and progressed in various study leadership roles. She moved to Sarah Cannon Research Institute as Director of Clinical Operations, working closely with the site network on both sponsor and investigator initiated trials. Dinah has been at ICON for more than 11 years and has held many leadership roles across multiple therapeutic areas including oncology, cardiovascular, rare disease, vaccines, dermatology, CNS and gastrointestinal. She has over 5 years' experience leading and overseeing the operational delivery of large Tier 1 partnerships with the largest having over 75 active studies and achieving over $300 million in new awards. Dinah led the operational delivery of the first Pfizer COVID vaccine study with over 48,000 subjects enrolled, receiving Emergency Use Authorisation in an unprecedented 247 days and full FDA approval in record time. Dinah holds a BA in Mathematics from Purdue University and Post Graduate Diploma in International Business Management, University College of Dublin, Michael Smurfit Graduate Business School.

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Nazneen Qureshi is the Director of Patient Recruitment at Accellacare, where she oversees all patient engagement and recruitment activities for the US. She is committed to developing a patient centric framework as she builds the centralised marketing and recruitment function - with focus on driving engaged, motivated participants and advocates for clinical research. Qureshi has over 10 years of experience in patient recruitment and was the recipient of the SCRS 2017 Site Patient Recruitment Innovation Achievement Award.