WHITE PAPER

Beyond awareness: Insights to increase willingness to participate in clinical research

Why and when patient awareness efforts fall short

By April Lewis, Emily Goldsher-Diamond, Victoria Zlotnikova, Katie Orlando and Kelsi King

Impact where it matters.

Despite significant investments in patient education and awareness campaigns, enrollment in clinical trials is stagnant and has been at a standstill for years. The percentage of trials that have struggled with patient recruitment and retention has remained the same since 2012, with 80% of trials reporting enrollment-related delays.

While many sponsors have long assumed patient education and awareness is the key to increasing willingness, our team at ZS wanted to explore if knowledge is the panacea it's often made out to be. To seek answers, we leveraged ZS's expertise in clinical research and analyzed two groups—one of patients from across the globe with varied backgrounds, and one of people who work in the life sciences industry. While it seems easy to assume those who work in life sciences would be more willing to participate, we found their willingness to participate in an interventional study was lower than the broadly representative group, despite their understanding of the importance of clinical research. We also found that education can drive a significant boost in willingness among patients with a clear medical need, but it's not as effective in reaching those who don't have a clear need.

While we saw expected apprehension regarding safety and efficacy, we also observed reservations around the level of commitment needed to participate in clinical research. Members of both groups share concerns about fitting clinical trial participation into their busy lives, and some people—especially in the group with varied backgrounds—face other barriers to participation, like the travel and financial burdens associated with commuting to a trial site.

3 ways to increase trial participation

If general education isn't a cure-all to low clinical trial participation, what could be? We believe our analysis uncovered three insights that may point the way forward as the industry moves beyond focusing on broad awareness.

Insight 1: Collaborate with healthcare providers

More than 75% of the life sciences employees said they would consider participating in a clinical trial if their physician recommended it, and 90% of respondents from the broadly representative group said the same. Large majorities of both groups said they trust their physicians' decisions, making trust a critical component to driving willingness, regardless of how knowledgeable the patient is. That's why we believe building and leveraging trust is a more effective long-term solution than general education and awareness efforts.

The importance of familiarity in the physician-patient relationship cannot be overstated. We found patients are two-and-a-half times more likely to look into a trial recommendation from "your doctor" rather than "a doctor you have just met." A pre-existing physician-patient relationship is key to establishing a strong foundation of trust, but many clinical trial investigators—especially those at large academic research institutions—may not have existing relationships with potential participants. In conversations about trials, these investigators should explore ways to leverage the trusted relationships patients have with their referring physicians. At the study level, we encourage ensuring your site mix includes a sufficient volume of investigators who have existing relationships with potential patients. Additionally, novel operating models that enable a physician to maintain primary oversight of a patient's care—while leveraging an investigator as needed for trial activities—may be another way to engage physicians and patients more effectively in research.

We also found increased willingness to participate among patients who shared a racial or ethnic background with their physician, and this was especially true among life sciences employees who identified as Hispanic or Latino. This is welcome news and shows emerging efforts to develop new investigators within underrepresented communities are likely to make a positive difference.

Insight 2: Focus on the intersection of need and awareness

Broad awareness campaigns come from a general hypothesis that an individual at the intersection of awareness and access is the right target to drive participation in a trial. By looking at the group of life sciences employees where awareness and access are already in place, we saw aiming efforts at this intersection is unlikely to drive willingness alone. Instead, we found those living with a health condition were more likely to be willing to participate than people without health conditions. Life sciences employees living with a health condition were the most willing among their group to participate, especially if a trial was their only available care option. This indicates that the intersection of unmet need and awareness is a stronger place for sponsors to focus their recruitment efforts. Specifically, we found:

- Life sciences employees living with a health condition were one-and-a-half times more willing to participate in clinical trials than life sciences employees not living with a health condition.
- Respondents who are actively treating a disease are twice as willing to participate in clinical trials.
- Willingness to participate jumps to 77% among those living with a health condition when the trial is their only available care option.

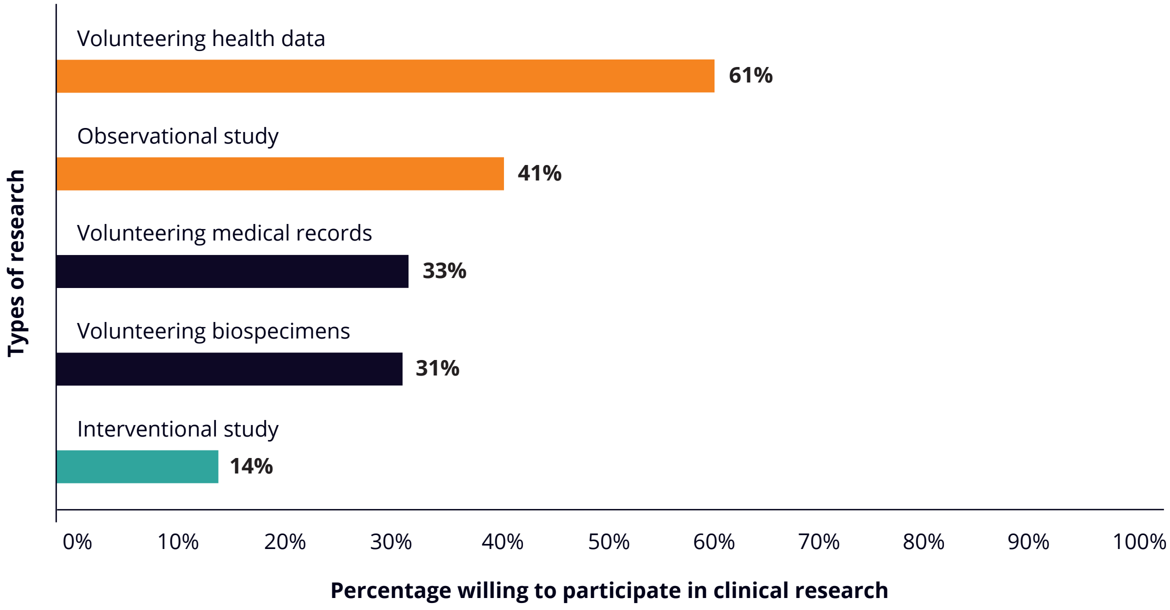
Digging deeper into the data, we see the group of life sciences employees we examined features many younger people with busy careers who don't have chronic medical conditions. They may feel they don't stand to directly benefit from a clinical trial and therefore find it's not worth the considerable effort to participate—even though they were more likely than the broadly representative group to say they believe their participation in research would have value. Perhaps the benefits of trial participation are simply more tangible to those who stand to experience gains in the immediate term. It's important for sponsors to plan to be present when patients need a trial opportunity. They should aim to meet these patients at the intersection of awareness and need and reach them through the channel that drives activation and trust—their physician.

Insight 3: Reframe clinical research

We found breaking down clinical research into distinct types creates opportunities to shift patients' perspectives on clinical trial participation. When framing clinical trials as health innovation opportunities to the group of life sciences employees, we found 61% respondents were willing to volunteer their health data, 41% were willing to participate in an observational study and 33% were willing to volunteer medical records.

FIGURE 1:

Willingness to contribute to the clinical research process among life sciences employees



Rather than trying to convince 86% of this group to participate in an interventional study, it seems the shortest leap is to engage the 61% who are willing to volunteer health data. Sponsors can leverage widescale willingness to share or donate health data to reach patients who may be open to healthcare innovation but are not yet ready to say yes to an investigational drug trial opportunity. For patients who are open to sharing data and information, we recommend looking for ways to bridge them into other trial opportunities after trust has been established and it's possible to provide a relevant research option based on the data they shared.

Focus more on trust than awareness

It may seem surprising that a group of life sciences employees are less likely to participate in a clinical trial compared to a broadly representative group, but we believe that only highlights how critical it is for trial sponsors to explore strategies and tactics outside of broad awareness campaigns. Perhaps the top takeaway from our analysis is the importance of building trust with patients where there is a clear need. Only then do we believe that education can produce a boost in willingness. Sharing a relevant trial opportunity's value proposition relative to an unmet need early and clearly is a demonstration of good faith and can help increase the patient's sense of ownership and understanding around why their participation is so vital.

Another way to grow trust with patients is to engage with them across the development life cycle, as this can highlight a sponsor's commitment to advancing treatments. Can teams challenge themselves to extend that commitment even after product approval, which will require continuity and collaboration with colleagues in the commercial organization? Overtures like this reiterate that trust is a core value for the sponsor, which should help increase long-term willingness to participate in clinical research.

About this analysis

In addition to leveraging ZS's expertise in the clinical research space, we examined a commercially available ZS data set (the ZS Patient Experience Bank) that features insights and analysis from more than 7,000 patients surveyed across 39 countries. In this white paper, these respondents were often referred to as the broadly representative group. Separately, we also surveyed a group of more than 1,000 life sciences employees across six global regions. This group includes a mix of demographics and health statuses.

About the authors

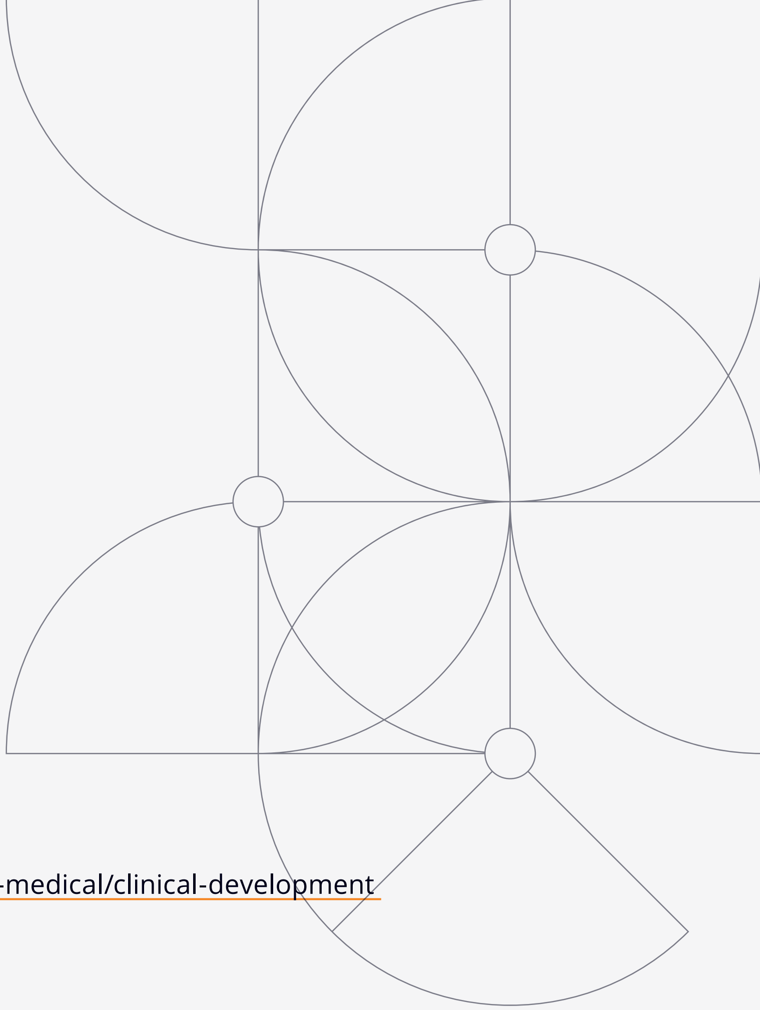
April Lewis has 25 years of experience leading global teams focused on innovating and disrupting clinical operations. As a change agent, she has worked directly within sponsors and clinical research organizations, and as a service and technology provider to more than 100 large, midsize and emerging clinical operations organizations. She has served on multiple large transformational initiatives. April is known as a thought leader in the areas of trial planning and operations, as well as patient and site engagement.

Emily Goldsher-Diamond has spent nearly a decade applying human-centered design to healthcare's thorniest problems. She is a founding leader of the ZS human-centric trials team, where she helps sponsors bring patients and sites to the center of trials. As an anthropologist, Emily is interested in how systems, cultures and structures produce behaviors that impact both trial design and planning. Emily has moderated hundreds of interviews and conducted rapid field research, co-design and observation with providers, patients, payers, healthcare customers and entrepreneurs, employees, athletes and technologists.

Victoria Zlotnikova has extensive experience working directly with patients to create unique solutions. As a pharmacist, Victoria is interested in the intersections between patients, providers and pharma, and their respective impact on patient decision-making. A key part of ZS's clinical development excellence team, Victoria works closely with clinical trial sponsors, bringing a patient-centered lens to uncover and analyze hidden pain points. Her novel insights help shape digital tools to increase clinical trial success through recruitment and retention strategies.

Katie Orlando is a member of the ZS cognitive team and she focuses on health decision science. Katie is motivated by working with various clients to eliminate barriers that prevent diversity in clinical trials and healthcare engagement. Using a variety of experimental modalities of research that are rooted in psychology, she helps educate manufacturers and doctors on how to elucidate patients' underlying values when facing important health decisions. She aims to maximize clarified and informed decisions about healthcare engagement across traditionally marginalized patients.

Kelsi King is passionate about elevating and understanding patient perspectives. She has spent countless hours speaking to patients to uncover the factors that motivate and deter them from participating in clinical trials. Whether she is moderating patient interviews, analyzing transcripts or fielding surveys, she is always eager to unpack the underlying "Why?" Kelsi is a firm believer that developing a holistic understanding of the elements that shape a patient's perspective is critical to ensuring patient engagement and recruitment efforts continue to evolve as the clinical trial landscape changes.



About ZS

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