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WHITE PAPER

Impacting Clinical Trial Diversity in 2023

Insights and Perspectives from Two Industry Thought Leaders

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Addressing diversity in research is critical to developing safe and effective therapies for all patients. It is equally important to improve access to clinical trials for more diverse patient populations who may benefit from these studies as a care option. Regulatory bodies, like the U.S. Food & Drug Administration are taking steps to help accelerate diversity and inclusion initiatives, with feedback related to diversity popping up in regulators' notes more than ever.

Q: How Important is Diversity in Your Clinical Trials?

56% - If we can't fix this, nothing else matters

34% - It's important, but the trial will go on either way

10% - We need to reach our enrollment goals regardless of demographics

In a survey of clinical research sponsors, more than half of respondents pointed to diversity as being their top recruitment priority

For the clinical research industry to make real progress toward achieving more diverse and representative trials, leaders must drive forward with the right tools, strategies and intentions. Following are some ideas and direction from two industry leaders who are deeply involved in transforming clinical trial recruitment to be more inclusive.

Meet the Experts

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Del Smith, PhD, is the CEO and Co-Founder of Acclinate, a company dedicated to improving clinical trial diversity through building trust and relationships with historically underrepresented patient populations. Their e-DICT solution uses predictive analytics and machine learning to accelerate the process of meeting recruitment goals of time, cost and diversity. Dr. Smith was drawn into the clinical trials space after his mother, a healthcare professional herself, contracted tuberculosis and, unfortunately, passed away due to the illness. A few months later, Dr. Smith learned of a clinical trial that may have been able to help. This led him to ask the question of how researchers can do better in terms of improving awareness and access to research for minorities and addressing issues of distrust. Today, he leads the team at Acclinate as they seek to break down barriers between researchers and underrepresented communities in order to make trials more diverse.

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Matt Walz is the CEO of Trialbee, a leading global technology provider that uses advanced data science and real-world data to help accelerate and optimize clinical trial recruitment. A software engineer by training, Walz was drawn into the clinical trials industry when his young (6-year-old) daughter was diagnosed with cancer and subsequently became involved in a clinical trial. This experience caused him to want to work to improve clinical trial awareness and access so that more people can benefit from research as a care option and so that research can, ultimately, produce better therapies. At Trialbee he leads a team dedicated to using technology to help researchers find and enroll patients more efficiently while simultaneously expanding access to research for all patients.

Early and Sustained Patient Engagement Need to be Part of the Business Strategy

"Traditionally, recruitment has been impersonal," Dr. Smith said. "Sponsors are saying, 'Hey, we don't know you and you don't know us, but do you want to be in our study?' There is no relationship, and with communities such as African-Americans who have a historical distrust of research, cold and impersonal approaches simply do not work."

These approaches, which include wide-net tactics like untargeted (or under-targeted) digital advertising, then, can be a dead end. The distrust that exists for many underrepresented patient populations has been earned through numerous historical examples of mistreatment but also generations of little to no meaningful outreach.

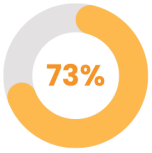
"If these patient groups do not trust the researchers or the projects it is unrealistic to expect any significant shift in clinical trial participation," Walz said. "Building trust takes time and intentionality."

According to Dr. Smith, engaging with underrepresented groups early is important, so important that it should be built into the business plan for each development initiative. Reaching out to these communities before recruitment helps to demonstrate the commitment of the researchers to the patients as people, not just participants.

Additionally, maintaining engagement with participants over the course of the study and in the years after study completion helps to foster longer term relationships.

"To gain trust, researchers need to be present, committed and sincere," said Dr. Smith.

Q: How Do You Connect with Communities of Color?



Leverage technology to identify best sites and digital marketing strategies

Engage community leaders, patient advocacy groups, etc.

Partner with community engagement experts

Rely on patient recruitment vendors and or CROs

Hope

Sponsors surveyed reported increasing investments in technology and partnerships to aid in improving clinical trial diversity, with more than two-thirds already involved in some level of community engagement. Still, nearly 20% reported that simply hoping for the best remains a strategy.

Implementing Trust-Enabling Technologies

Trust is relational. People are more likely to trust other people who they know and engage with regularly. So, it may seem counterintuitive to talk about using technology to build trust with underrepresented patient populations, but we must also acknowledge that true relationship building is made more difficult (if not impossible) when seeking to engage with globally dispersed patient groups. This is where trust-enabling technologies come in.

"Trust-enabling technologies are simply tools that allow trustworthy individuals a way to communicate and engage, remotely or in-person, with more patients," said Walz. "The trust-building here is less about the technologies themselves and more about the people behind the technologies that are using them as a demonstration of their commitment to remaining connected with patients."

Such solutions can include technologies that enable conversations via text or via video conference, allowing patients and members of the clinical trial team to stay connected. They also may include smart device apps that provide patients with easy-to-access information.

Technology also makes it possible for engagement to occur within trusted digital communities. There are many such communities where patients with similar health conditions and similar life experiences gather to share their stories and ask questions. Engaging with underrepresented groups as equal partners in these trusted online communities allows researchers to build trust through collaboration.

"By showing up in these digital spaces and providing expertise without demanding anything of the audience, researchers demonstrate a commitment to engage with and learn from patients on equal footing," said Dr. Smith.

Leveraging Real-world Data (RWD)

"Getting more out of the data available is crucial to identifying where patients are, both in the real world and online," said Walz. "Real-world data can tell us where to look and where to focus community-building initiatives so that we can build more diverse trials, all without jeopardizing individual patient privacy."

Real-world data (RWD) includes all data related to patient health and the delivery of healthcare services. This data comes from a variety of sources but is most commonly collected from electronic health records (EHR) along with claims and billing records. When it comes to how RWD is used in clinical trial recruitment, data is anonymized (tokenized) so that what researchers see does not identify specific patients, but rather represents types of patients.

"(RWD) has already proven incredibly useful to researchers, both in helping to measure study feasibility and in optimizing clinical trial site selection," Walz said. According to Walz, this has resulted in some interesting new outreach models designed to help improve clinical research diversity, including:

Outreach to Physicians – Increasing awareness of trial opportunities with trusted physicians in underrepresented communities to help them provide referrals for their patients.

Identifying racial and ethnic demographic information from provider records - Unfortunately, not all providers track this with any consistency.

Token-linking anonymized health and consumer data – Taking anonymized data from one source, such as EHR and linking to consumer data can, for example, provide insight into where these types of patients may be spending time online, allowing researchers to create targeted outreach strategies. While this has great potential for reaching target communities, it is still unproven.

Choosing the Right Technology to Track Recruitment in Near Real-Time

Using a robust software platform for recruitment tracking and results management can help study leaders stay on top of the recruitment process and intervene as necessary to keep things on the right track.

"Micro-management is usually discussed in a negative light, particularly when it comes to people management. However, with data management, it pays to stay on top of all the details," said Walz. "Passive approaches to overseeing recruitment data can mean that study managers are not catching potential problems until they are already causing significant problems. Technology that enables continuous monitoring is crucial."

For recruitment campaigns seeking out specific patient demographics, tracking activity via a platform that allows near real-time insight into various recruitment initiatives provides the ability to test both messaging and communication channels and make quick adjustments. Copy can be changed and/or messaging can be shifted from channels with low engagement to channels with higher engagement. Time and cost are not wasted with underperforming messaging or advertising buys. Platforms that deliver this level of flexibility can help sponsors to optimize how they communicate with underrepresented populations and speed recruitment of these groups.

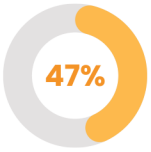
Q: What are Your Patient Recruitment Frustrations?

No quality checks; inappropriate referrals are not screened out early

Not enough precision; need targeted outreach based on RWD

No centralization; too many data sources and channels to manage effectively

No site efficiency; we are wasting sites' time with too much manual effort



No transparency; hard to know where referrals are coming from

Roughly half of sponsors surveyed outlined various data management challenges as being the most frustrating aspects of clinical trial recruitment. These challenges can all be addressed with robust recruitment tracking platforms.

The Need for Adequate and Equitable Patient Incentives

When making decisions about financial incentives for clinical trial participants, it is important to consider the full spectrum of patient experiences. The day-to-day realities and life experiences of various patients impact how they view a potential incentive.

"What one group of patients view as fair, another group may find insulting. If one patient population is known to be distrustful of clinical research, they may perceive an incentive offer as likely lower than another group would get," said Dr. Smith. "On the other hand, if they view an incentive as being too high, they may see it as an attempt to buy their trust. This solidifies the importance of early engagement and committed trust-building."

Dr. Smith reflected on an interesting test concerning research study incentives. In the test, two patient groups (one non-white and one white) were given choices between three different incentive options; no compensation, $100 in compensation, and $500 in compensation. Here is what they found:

"Zero Compensation – The white patient group was far more likely to participate than the non-white patient group

$100 in Compensation – The white patient group was even more likely than the non-white group to participate vs. the Zero Compensation option

$500 – The gap between the groups closed entirely, with both groups equally likely to participate

"One conclusion to draw from this example is that the low and no compensation models did not adequately address the needs of the non-white patient groups. This could mean that these patients viewed the disturbance to their lives caused by clinical trial participation, and their time commitment were far higher than this limited compensation acknowledged," Dr. Smith said. "When the higher dollar figure was introduced, it is likely that this demonstrated a more sufficient acknowledgement of the value of the non-white patients' time and involvement."

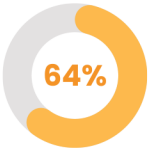
Revisiting the ideas from earlier in this paper, early engagement with patients can help study leaders develop a better understanding of their needs and potential study burdens. With this information, sponsors can determine incentive strategies that are fair and adequate and that will be more attractive to patients.

Q: Which trends discussed here do you feel will have a measurable impact in 2023?

Making early and sustained engagement a business imperative

Implementing trust-enabling technologies to help engage with more patients

Addressing the need for adequate and equitable patient incentives



Leveraging RWD to improve patient targeting

Employing robust technology platforms for better recruitment tracking and results management

Sponsors surveyed largely agreed that the key trends discussed by Dr. Smith and Mr. Walz are the most likely areas for progress in 2023, with the large majority echoing the importance of community engagement.

Conclusion

Improving diversity in clinical trials is a necessary step toward ensuring that new therapies are effective and safe for the broadest possible range of patients. The need to improve access to research for more patients, combined with heightened pressure from regulators to accelerate inclusivity efforts, makes 2023 a critical year for making progress. According to Dr. Smith and Walz, there are some key areas where researchers can focus efforts. Through early and sustained patient engagement, sponsors can begin to better understand traditionally underrepresented patient populations and work to build lasting trust and connections. Technology can be used to augment engagement and outreach initiatives while other technology platforms can help study teams track recruitment data in near real-time, allowing for faster, more impactful decision-making. Finally, enhanced patient engagement will allow sponsors to develop participant incentive strategies that are fair, adequate and effective.

To learn more about clinical trial diversity and recruitment, visit www.trialbee.com and www.acclinate.com.

In 2022, the FDA issued updated guidance, cementing the regulatory body's position that clinical researchers must do more to enroll patients from racial and ethnic minorities. The hope is that regulatory pressure will help to drive innovation and help make truly representative clinical trials a reality.

U.S. Regulatory Timeline for Diversity in Clinical Trials

- **1993:** The National Institutes of Health Revitalization Act is passed, established guidelines for the inclusion of women and persons from racial and ethnic minorities in clinical research
- **2016:** The FDA releases guidance to clinical trial sponsors around how to collect and present race and ethnicity data in FDA submissions, including recommendations that sponsors develop and submit plans around improving inclusion and diversity in enrolled patient populations
- **2022:** The FDA releases additional guidance regarding clinical research diversity, providing recommendations to sponsors for how to develop Race and Ethnicity Diversity Plans
- **2023:** U.S. President Joe Biden signs the Consolidated Appropriations Act into law. This bill includes language mandating that all clinical trial sponsors submit to the Secretary of the U.S. Dept. of Health and Human Services a Diversity Action Plan for certain late-state drug trials, including all Phase III studies and most medical device studies.

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