Avoca Quality Consortium® Leading Change Collaborative Forum

Meeting Highlights

Topic: Diversity in Clinical Trial Research

Meeting Date: November 17, 2020

Background Information

The meeting discussion started with a preview of the 2020 Avoca Industry Survey data on diversity in clinical trial participation. Among other topics, this survey addressed: how industry respondents rate the importance of diversity in clinical trial participation; how they each feel their own organization and the industry at large are performing in these respects; and how familiar they are with FDA Guidance on Diversity in comparison to their familiarity with other guidance documents and regulations. The interim data shows that most people in the industry feel that diversity is important and that their organization could be doing more; but that their organization is performing better than the industry.

Discussion Summary

Below, please find a summary covering the key points to emerge from the discussion:

- Diversity in Clinical Trials is critical – the scientific and ethical imperatives have been around for some time.
- This is not a competitive space – collaboration is crucial to overcome the challenges in reaching certain patient groups.
- Recognizing clinical trials as a care option will lead to greater participation.
- Enhancing diversity is particularly important as we have fallen victim to one-size-fits-all in past recruitment efforts.
- We need to work together to build trust, provide better education about clinical trials, and facilitate participation among all interested parties. There is a need for community outreach, understanding to address lack of trust, and active information campaigns.
- Improving diversity within the clinical trial workforce is important for driving diversity among the patient population and will improve the quality of trials by attracting more diverse patient volunteers. Raising awareness of clinical research as a career option; targeting minorities in high school and college for careers as clinical monitors, study coordinators, auditors, and various other roles that interface directly with patients and/or are reviewing study data and working directly with sites.
- With societal issues that are taking place and clinical research organizations addressing COVID-19, Diversity in Clinical Research is coming to the forefront in terms of people's awareness and that this is an important initiative.
- A training component is needed, with a focus on incorporating new and creative ways to attract diverse populations.

Based on interim 2020 Avoca Industry Survey data, there does not appear to be significant awareness on patient diversity guidance in the industry. Although the guidance for the industry from National Institutes of Health (NIH) and Food and Drug Administration (FDA) goes back to the late 1980s, it really has no statutory power, as there is no penalty for lack of adoption. A new light on patient diversity issues due to a confluence of societal upheaval with the COVID-19 pandemic has gained much attention over the past year. With final FDA guidance recently put in place, the industry is anticipating next steps from the agency. There is a need to look for ways to continue to build presence within diverse communities, diverse sites, and for ways to ensure that needs are being met in terms of bringing our clinical trials to different populations.

The responsibility to have ethical research and address who is disproportionally burdened by the disease is paramount. Understanding the disease burden and knowing which patients to target for enrollment with your drug is primary. Once understood; education, site engagement, patient outreach, and setting metrics is critical. There may be a need to partner with other research group and Institutions to educate people and provide support.

There needs to be a long-term commitment in building trust with the patient community. Meeting patients where they live and partnering with community advocacy groups to better understand challenges. Social determinants need to be addressed in patient-centric models in recruitment and retention that focus on supporting patients through educational materials, compensation for caregiver, transportation, clinics' hours, etc.

The discussion also focused on operational issues such as protocol design and metrics. Consensus on the need to consider up-front protocol design and the impact of inclusion/exclusion criteria and other protocol design elements which could negatively impact recruitment and retention of ethnically diverse populations. There are a series of workstreams that fall under overarching diversity initiative that can help programs to establish KPIs and milestones on communication activities, data, design, site selection. When reviewing data and metrics, being deliberate in looking across the process is a must for improvement in reaching patient populations. Make sure to communicate with investigators, explain what information to collect in terms of data in patients, and why and how it's linked to disease and science. Expectations should be set with sites and study teams, i.e., "This is what we know about prevalence of incidence data and prevalence by race, gender, age, and comorbidities that may factor in." Information sharing and education ensures everyone is aligned with what the representative population looks like.

In order to overcome the challenges in patient diversity, participants discussed various aspects in change management. As an industry, we need to think differently about how we engage with sites and collect data to drive us to the logical solutions for trials that we are trying to do. We need to understand the diversity of the physicians and their staff within those institutions, their community outreach, and how are they building trust with minority groups. There is a need for sites to have strategies that are effective enough to reach large numbers of minority individuals. It takes a methodical approach to ensure that we are addressing the underlying concerns that are the foundation of that mistrust, such as informed consent issues and historically unethical clinical trial behavior and how new regulations or processes are in place that put safeguards there to protect individuals that volunteer for clinical trials. Change management can take form in intentional site placement, more patient-centric initiatives, especially in community outreach.

The meeting moved to discuss perspectives on how the COVID pandemic put the spotlight on the awareness of diversity in clinical trials. In both vaccines and treatments, and on the disparity that COVID has impacted African Americans, Hispanics, the elderly and the difficulty that industry has had in reaching out to these populations and gaining their trust and desire to participate in clinical trials. Individuals and groups on social media represent a challenge as they are actively looking to create more distrust about pharma, data collection and how it is used. Pfizer and Moderna both released diversity data, setting the stage for future approvals. New technologies and decentralization of clinical research represents an opportunity for more rural and harder to reach places. The challenge remains for formulations administered intravenously and getting drugs to patients. It all comes back to understanding the uniqueness of patients you are trying to access.

Concluding Remarks – Putting Together Parts of the Jigsaw Puzzle:

- We must break the myth that this is a time and cost burden.
- Encourage organizations to retrieve and share success stories.
- It's the right thing to do from a science and societal perspective.
- It is not a competition and there is a lot to learn from each other – this should be a cooperative and collaborative effort.
- Build your network of SMEs in this area and make sure it includes all stakeholders from various parts of the industry and reach out to brainstorm and share practices.
- Drugs work differently on some groups of people – understand differences through a representative group of patients.
- Long-term commitment – collaborate and support not-for-profit organizations. Think about protocol specific solutions. To market a product, you must have a unique strategy and grassroots effort at a regional or local level.

Links Referenced during the Session:

- ACRP: Association of Clinical Research Professionals
- ACRP: Find Your Element Campaign
- Black Health Matters
- Center for Information and Study on Clinical Research Participation (CISCRP)
- MRCT Diversity Initiative through Harvard University: Diversity, Inclusion, and Equity in Clinical Trials
- NCI Community Oncology Research Program (NCORP)

If you are interested in learning more about the Avoca Quality Consortium (AQC) or its Leading Change series, please contact Dawn.Auerbach@theavocagroup.com.