

4/28/2022



Collaborative Community Annual Report



MedTech Color Collaborative Community Annual Report

Collaborative Community Overview

MedTech Color has convened this [Collaborative Community](#) to create a forum in which a diverse cross-section of MedTech industry stakeholders can work together to identify issues and opportunities for improvement of current practices, share and curate existing knowledge, and develop evidence-based solutions to address racial and ethnic minority health issues in medical device product development and clinical research. The Collaborative Community will work to develop targeted strategies, including education and awareness activities, guidelines, best practices, and thought leadership to increase the awareness, understanding, access, engagement, and participation of racial and ethnic minorities.

Our community is comprised of volunteers united by our common drive, passion, and dedication for creating more diverse and representative populations in clinical research. The potential to support better patient outcomes by promoting greater diversity in medical device development fuels our mission.

Key Accomplishment and Takeaways

We have achieved several milestones in our first year. We created a framework for collaboration that leverages the diverse experiences, insights, and dynamic leadership of our 55 members, from over 25 different organizations. Our Steering Committee and Executive Planning Committee provided guidance and support to each of the four subcommittees: Recruitment and Retention, Disease State Awareness, Evidence Development, and Product Development and Clinical Research. Our subcommittees collaborated to advance our core objectives.

Our Steering Committee leads efforts to refine our work streams and areas of focus to develop problem statements for each of our four subcommittees. We also contributed to a growing body of thought-leadership on diversity and inclusion in medtech with two successful webinars: "Demystifying Clinical Trials: Engaging Patients and Communities of Color in Clinical Research" and "Product Development and Clinical Research – Learning to Design with Diversity and Inclusion in Mind: A Fireside Chat with Leading Experts Transforming Healthcare Across MedTech." We received great feedback from these webinars. Participants were particularly impressed with the candor, transparency, and diverse perspectives of our panelists. We shared perspectives from patients, clinicians, industry executives and regulators on the challenges and opportunities to create more diverse and inclusive clinical trials and product development strategies. We incorporated learnings from these webinars in our plans for future Collaborative Community events. We published "A Call to Action" that builds upon themes in our first webinar by describing steps to promote more diverse and inclusive clinical trial recruitment and retention strategies.

We held the first in a series of focus-groups with patients from historically under-represented groups to hear their perspectives and experiences. In addition, and in collaboration with the American Medical Association, we held a virtual panel discussion on the Physician Innovation Network exploring how women have historically been underrepresented in clinical research. We plan to use these learnings to develop targeted programs and outreach to address both health equity concerns and ways to



reduce barriers to clinical trial participation for Black women and other historically underrepresented groups.

With direction from the Steering Committee, we developed workstreams and objectives to drive our mission for 2022 and beyond. This report includes our dashboard, which highlights proposed activities and work streams for the future. Each workstream harnesses insights from our members to address diversity, equity, and inclusion within clinical research and product development.

Below we summarize our learnings and best practices, subcommittees, and problem statements as well as proposed activities for 2022 and beyond.

Learnings and Best Practices

We leveraged the input and collective feedback from our members to learn and implement practices to support our future activities. In our first year, we:

- Held monthly new member orientation meetings
- Established a regular meeting cadence with agendas defined objectives
- Recorded and archived meeting minutes
- Initiated regular touch points with subcommittee chairs to:
 - Ensure that individual subcommittee needs are considered, and concerns addressed
 - Support refinement of each subcommittee's mission, focus, goals, and objectives
 - Encourage cross-committee collaboration on common goals
- Engaged all members and aligned on overall objectives of the Steering Committee
- Defined the deliverables of the Steering Committee to support the Subcommittees
- Ensured the Steering Committee maintained effective follow-up timelines for decision-making on subcommittee requests
- Developed a Collaborative Community Member Portal for direct communication and document management
- Established a formal Budget Committee and approval process for funding requests



Collaborative Community Subcommittees

1. Disease state awareness, prevalence, and symptomatology presentation in racial and ethnic minority populations.
2. Recruitment and retention of minority patients, investigators, and other stakeholders in product development throughout the lifecycle and clinical research.
3. Product development and clinical research.
4. Evidence development, analysis and identification of unmet needs and minority health issues.

Subcommittee Problem Statements

1. Disease State Awareness

The Disease State Awareness Subcommittee will focus its efforts on creating a customizable, best practice model that includes community members representing ethnic minority and racial groups, alongside healthcare providers, to accelerate the identification of solutions that advance access to cost effective care. The goal is to develop practices to address both access to care and awareness of care.

2. Recruitment and Retention

The Recruitment and Retention Subcommittee will focus its efforts on racial and ethnic minority populations that are historically underrepresented in clinical trials due to a lack of access to trials and/or to clinical trial investigators, which impacts health outcomes and proposed care guidelines for communities of color.

3. Product Development and Clinical Research

The Product Development and Clinical Research Subcommittee will focus its efforts on the multi-factorial underrepresentation of diverse patients in medical device development which results in a lack of high-quality scientific knowledge resulting from well-designed clinical trials, applicable to drive continuous improvement in clinical care decisions.

4. Evidence Development and Pipeline

The Evidence Development Subcommittee will focus its efforts on transforming the way medtech generates, uses, and communicates scientific evidence by including diverse populations, researchers, and innovators to improve patient outcomes, and continuity of experience that builds trust in clinical research and adoption of technology.



Subcommittee Activity Dashboard

COMPLETED ACTIVITIES/DELIVERABLES

Date of Completion	Activity	Description
Disease State Awareness		
Q3 2021	Mission Statement	The purpose of the Disease State Awareness subcommittee is to develop a customizable, best practice model that creates lasting partnerships with ethnic minority and racial groups that can serve as community advisors to identify regional health/clinical disparities including symptom presentation, prevalence, and disease pathways. The subcommittee values the meaningful engagement of community members and healthcare providers to collaborate and identify solutions that advance access to cost effective care.
Q3 2021	Defining the "Why"	<p>The immediate priority of this committee is commitment to advancing research, thought leadership, and engagement in marginalized communities. The DSA Subcommittee will address the following items</p> <ul style="list-style-type: none"> ▪ Building community trust and transparency within the patient/consumer community ▪ Identifying the population at-risk and ensuring health literacy and better engagement opportunities ▪ Providing a more equitable approach through diversity - be the voice and face for marginalized community representation in medical device innovation
Q3 2021	Gap Analysis	Identify current public health initiatives addressing treatment disparities in marginalized populations to identify gaps for team focus.
Q4 2021	Identified scope for pilot project, cardiovascular disease	The group agreed to select cardiovascular disease as the condition for the focus groups largely given its linkages to co-morbidities. They chose to potentially focus on women's hearts to narrow the disease site and address existing disparities.



Recruitment and Retention		
Q3 2021 – Q4 2021	Identified First Subcommittee Deliverable	<ul style="list-style-type: none"> ▪ Discuss and develop webinar on engaging patients of color in clinical research ▪ Defined content details ▪ Speakers identified/invited ▪ Develop marketing strategy
Q4 2021	Problem statement identified	Minoritized populations are historically underrepresented in clinical trials due to a lack of access to trials and/or to clinical trial investigators, which impacts health outcomes and proposed care guidelines for communities of color.
Q4 2021	<u>Webinar: Demystifying Clinical Trials- Engaging Patients and Communities of Color in Clinical Trial Research</u>	One-hour moderated discussion designed to educate diverse patient groups about the benefits of participating in clinical research by “demystifying” a process that many communities of color may view with suspicion based on historical events, lack of information, and current misconceptions.
Product Development and Clinical Research		
Q4 2021	Identified Problem Statement and First Subcommittee Deliverable	<p>Defined structural and operationalized approach that reliably addresses (a) the cultural implications, bias, and related issues, (b) quality of patient-provider communication, (c) characterization of categories of the needs of minority populations in research, (d) “patient-friendly” trial design enhancements, and (e) the existing and emerging research priorities in digital health innovation (e.g. potentially including digital biomarkers), then the barriers to understanding and the active pursuit of diverse clinical trial participation will likely continue.</p> <ul style="list-style-type: none"> ▪ Discuss and develop webinar on learning to design with diversity in mind ▪ Defined content details ▪ Speakers identified/invited ▪ Develop marketing strategy
Q1 2022	<u>Webinar: Product Development and Clinical Research- Learning to Design with Diversity and Inclusion in Mind</u>	The first of a webinar series to foster a dialogue on best practices to ground product design considerations around the unique needs of the end users, while elevating awareness and understanding regarding the importance of including diverse, and often underrepresented, participants in clinical studies.
Evidence Development and Pipeline		
Q4 2021	Problem Statement created and refined	Clinical data, including real world data (RWD), on communities of color is neither complete nor robust.



		<p>We need broader and more granular insights to gain understanding of the root cause of health disparities.</p> <p>The landscape is unclear on RWD data collection. Access and availability for researchers and patients remains a challenge.</p>
Q2 2022	AMA Physician Innovation Network Panel	<p>AMA Virtual Panel Discussion on AMA Physician Innovation Network Topic: Improving and Diversifying Evidence- Engaging Women of Color as Participants in Clinical Research and Evidence Development</p> <p>Unique healthcare needs and perspectives of women of color are neither considered nor valued which is demonstrated/evidenced in the disparities of health outcomes. There is a need for broader and more granular insights to elucidate the root causes of healthcare disparities. Our goal is to understand what barriers and practices exist that are influencing clinical study participation in the medtech sector with the intent of using this information to propose actionable and measurable change.</p>

FUTURE ACTIVITIES PLANNED 2022

Date of Completion	Activity	Description
Disease State Awareness		
Q1-Q2 2022	Patient / Community Input Board	<p>Organize Community Advisory Boards (Community Advisors, Care Providers and Community Participants) and set up focus group discussions.</p> <p>Heart to Heart Program:</p> <p>The DSA subcommittee will arrange small focus groups with defined targeted questions to elicit the greatest need for disease state awareness regarding cardiovascular disease in Richmond, Nashville, and Atlanta Communities.</p> <p>What are the barriers?</p> <p>Evaluate understanding of treatment options – which may identify a clear care plan.</p> <p>It is imperative that we have the ‘voice’ at the center of our focus. Access to patients in all communities - rural and metro.</p>



Q3 2022	Care Model	<p>Develop customizable care models for cardiovascular disease; and collaborate with Community Participants, Medical device manufacturers, Hospitals/Community Care providers, and Patient Advocacy groups</p> <p>An early set of fundamental principles that:</p> <ul style="list-style-type: none"> ▪ Are patient centric ▪ Address trust variable ▪ Has localized flexibility and considers equity of access ▪ Supports integrated care and efficient utilization of resources ▪ Has a robust and standardized set of outcome measures and evaluation processes ▪ Innovative and considers new ways of organizing and delivering care ▪ Sets the vision for services in the future to raise awareness
Recruitment and Retention		
Q1 2022 – Q4 2022	Repository of best practices	<p>Develop repository of resources, guidelines, other sources of best practices on the recruitment and retention of ethnic and racial minority subjects and investigators in medical device clinical investigations</p> <p>Target audiences-</p> <ol style="list-style-type: none"> 1. Healthcare providers who serve historically marginalized communities—with 1 pager on how to talk to community on clinical trials 2. Patients- how to talk to patients about their disease, and hopeful participation in clinical trials 3. General public can use the additional repository of tools
Q1 2022 – Q4 2022	Survey/database on diversity benchmark	<p>Develop and conduct a survey of medical device manufacturers to gather information on the participation of minority populations in medical device clinical investigations. Current sources of statistical data on minority populations in device trials are fragmented. Goal is to develop a comprehensive and reliable report on minority subject participation in clinical investigations.</p>
Q1 2022 – Q4 2022	Researcher/talent pipeline/repository	<p>Develop searchable online database of clinical investigators of color and/or individuals interested in such positions. Database will feature short biographical information, photos, areas of specialty, level of expertise, etc.; accessible via MedTech Color CC website; decisions to be made regarding access rights, opt-in requirements, and outreach and PR strategy to solicit interest participants.</p>



Product Development and Clinical Research		
Q2-Q4 2022	Webinar Series: Product Development and Clinical Research- Learning to Design with Diversity and Inclusion in Mind	The continuation of a webinar series to foster a dialogue on best practices to ground product design considerations around the unique needs of the end users, while elevating awareness and understanding regarding the importance of including diverse, and often underrepresented, participants in clinical studies. The goal is to bring together trialists, medical officers, strategists, and more from major medical device companies to have a “fire-side” chat.
Q4 2022	Database of Sites/Investigators Part 1: Glossary of Product Development and Clinical Research Terms	<p>The database would provide access to sites/investigators with strong desire and/or reliable experience enrolling diverse patient and investigator populations and is actively engaging diverse participation in med device clinical trials (includes prospects that may not yet participate in trials but are interested).</p> <p>An addendum will provide a glossary of terms intended for patients to understand terminology used in clinical trials.</p>
Evidence Development and Pipeline		
Q3 2022	Create Guide for Repositories of RWD	Many different organizations are housing RWD that is untapped for research. There are also many other organizations working with and focused on RWD. We would like to develop a tool for researchers to locate and access needed RWD.
Q4 2022	MedTech Office Hours	Host office hours with FDA and other Federal Agencies to discuss the importance of ensuring diverse patient populations are included in clinical trials, validated PRO development tools and QoL studies. Patient voices on the issue of benefit/risk must be heard.

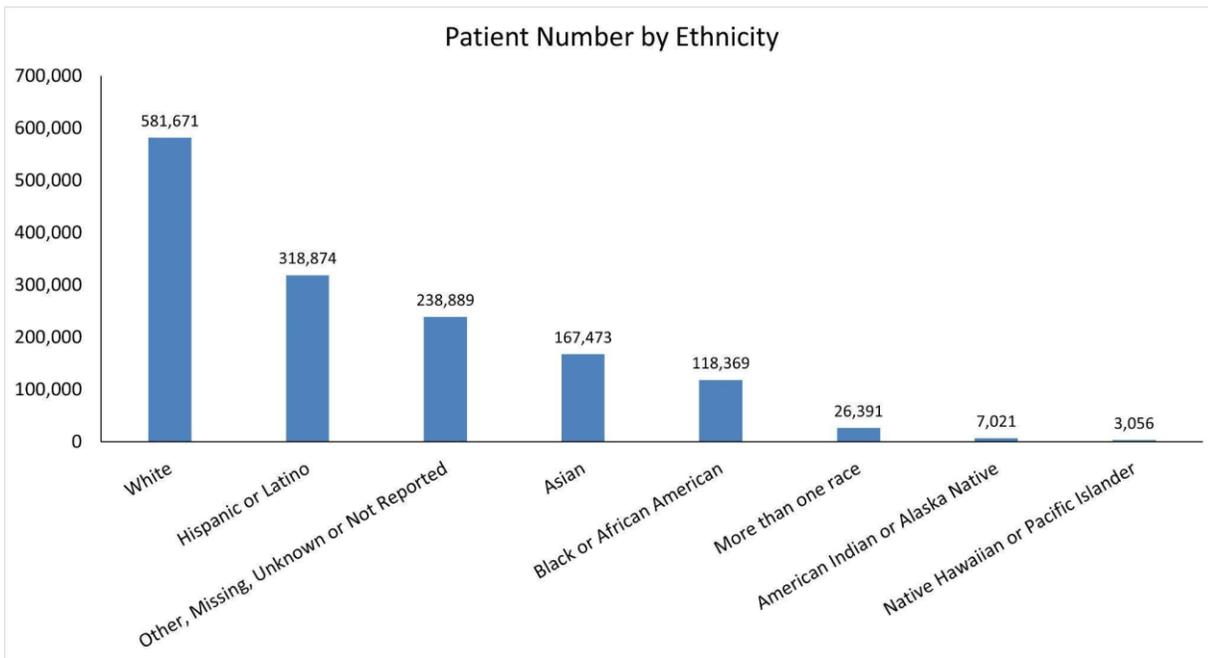


Ethnic Participation in US Medical Device Trials

According to <https://clinicaltrials.gov>, there were 2,514 US Medical Device Trials, sponsored by Industry with results posted. Of those trials, 1,222 (45%) posted demographic data that included ethnicity:

- 39% White (n=581,671 patients)
- 26% Hispanic (n=318,874 patients)
- 10% Asian (n=238,889 patients)
- 8% Black or African American (n=118,369 patients)
- <1% American Indian, Native Alaskan, Native Hawaiian, Pacific Islander

US Medical Device Clinical Trials Industry Participant Number by Ethnicity



Source: Publicly posted trial results from Clinicaltrials.gov for Medical Device trials in the USA. Data generated on 20APR2022.

Conclusion

This Collaborative Community is dedicated to driving change that positively impacts patients. We are harnessing diverse perspectives to begin to close the gap in health care disparities through innovative and informative messaging, action, and engagement. We are grateful for the significant and transformative contributions of our support staff, who have been instrumental to our successes to date and critical in helping us to envision and achieve our short and long-term goals. We are also grateful for the continued support of our sponsors, FDA Liaisons, Steering Committee, Subcommittees, Executive Planning Committee and our convenor MedTech Color.



Thank you to the MedTech Color Collaborative Community Sponsors

