MedTechColor

COLLABORATIVE COMMUNITY CHARTER

Name of Community	MedTech Color Collaborative Community on Diversity and Inclusion in Medical Device Product Development and Clinical Research
Convener	MedTech Color is a 501(c)(3) organization dedicated to advancing thought-leadership on issues that affect the medtech industry as well as professionals and communities of color.
Mission and Purpose of Collaborative Community	MedTech Color is committed to advancing research, thought-leadership and engagement on public health issues that affect racial and ethnic minorities. The medical device industry has long recognized the need to develop thoughtful, proactive and evidence-based strategies to address and mitigate the impacts of unconscious bias, social determinants of health and lack of inclusion or consideration of racial and ethnic minorities in critical aspects of the medical device lifecycle. These issues influence critical processes from early product development to clinical research to characterization of disease pathways and disease progression, and product safety and effectiveness in racial and ethnic minority populations. 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 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 on the following issues: 1. Disease state awareness, prevalence and symptomology presentation in 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; and 4. Evidence development, analysis and identification of unmet needs and minority health issues. This Charter describes the overarching framework in which the members will work to develop, define, evolve and execute the mission and activities of the collaborative community.

Date of last revision	12/14/2020
Problem	The lack of diversity and inclusion in overall medical device product development, is not merely a social or cultural concern, it is a public health issue. This issue directly affects the safety and effectiveness of medical devices and clinical outcomes for patients. The absence of diversity and lack of inclusion and consideration of racial and ethnic minority issues and leadership in the lifecycle of medical devices create critical gaps in various processes ranging from design and engineering to clinical research (including human factors testing) to characterization of disease and clinical outcomes. The opportunities on the horizon resulting from the speed of innovation and increased convergence of novel technologies such as artificial intelligence and machine learning with traditional diagnostics and drug treatments further underscores the importance of considering diverse populations and minimizing bias. Inadequate participation and consideration of racial and ethnic minorities in product development, including clinical research reduce the generalizability of research findings, create disparities in the safety, quality and effectiveness of treatments and therapies, exacerbate health inequality and inequity, and decrease opportunities to deliver high-quality care, tailored treatments and therapies to underserved minority populations.
Areas of Focus	The Collaborative Community will develop (1) events (webinars, meetings, or training sessions) and (2) proposed guidelines, white papers, and other publications focused on the following work streams: **1. Disease State Information and Awareness** a. Identify current initiatives, guidelines, activities, best practices and opportunities for collaborations related to minority health and disease awareness for racial and ethnic minorities; b. Assess gaps in knowledge and opportunities for improvement in developing best practices for understanding and communicating disease assessments and progression for minority populations; c. Develop best practices for engaging minority patients and healthcare providers to promote more effective recognition of disease symptoms and patterns of disease progression in minority communities; and d. Develop best practices to promote greater engagement and visibility for or with minority clinicians, researchers and subject matter experts to identify new product development and research opportunities, encourage greater disease education and awareness among minority patients and create more robust pipelines of minority clinical study participants. **2. Recruitment and Retention of Minority Participants and Investigators (Pipeline)** a. Identify current initiatives, guidelines, activities, best practices and opportunities for collaborations related to recruitment and retention of racial and ethnic minorities for clinical research or other product development activities; b. Develop strategies and opportunities to recruit minority investigators, professionals and patient advocates (e.g.,

	outreach to consortium of historically black medical colleges, blackdoctor.org, etc.); and c. Create a searchable database or membership roster in which minority clinicians, researchers, etc. could opt-in to have profiles, biographical and other related information available to stakeholders who are seeking to hire or engage with this community for professional opportunities. **3. Product Development and Clinical Research** a. Identify current initiatives, guidelines, activities, best practices and opportunities for collaborations related to the absence of inclusion and consideration of ethnic minority- issues in medical device development, including clinical research, design or other product activities; b. Strategies to address cultural implications, bias and other issues in optimizing processes such as the identification of product development targets and disease states, engineering, design, and development risk management and other activities; c. Strategies for minimizing unconscious bias or other forms of bias in recruitment, informed consent and retention of investigators and participants; d. Identifying and characterizing clinical outcomes and needs of minority populations in defining research priorities; and e. Targeting specific trial design enhancements to foster greater inclusion of minority researchers and patients, and raise awareness of issues that may affect this population. **4. Evidence Development and Analysis of Minority Clinical and Health Issues and Outcomes related to the use of Medical Devices** a. Curate and develop a repository or centralized registry of medical device clinical research focused on or of significant impact to minority populations; b. Establish a special repository or section on clinicaltrials.gov for medical device clinical research targeting minority participants (e.g., layperson summaries); and c. Engage with leading medical journals and societies or organizations to encourage publication of research studies or papers on minority health issues, and reporting of study results by race, ethnicity and sex to improve the data quality and increase transparency.
Governance	**<u>Executive Planning Committee</u>** – The Executive Planning Committee will be responsible for the initial and ongoing planning and coordination activities of the Collaborative Community. This committee will consist of at least three, and up to five, individuals who will serve two-year terms. The Executive Planning Committee will consist of at least one member of the MedTech Color Board of Directors and two other individuals. This committee will assist the Convener and the Steering Committee with planning, project management, coordination of activities and identification and allocation of resources of the Collaborative Community's activities. The

representatives of this committee will be non-voting members of the Steering Committee. Steering Committee members will be selected by the Executive Planning Committee.

Steering Committee

- *Responsibilities and Functions* – The Steering Committee will be responsible for determining, planning, overseeing and executing the strategic initiatives of the Collaborative Community. This committee will be responsible for defining and implementing the objectives of the Collaborative Community in a manner that fosters collaboration, effective communication, distributed leadership, clear roles and responsibilities, accountability, transparency and trust. The Steering Committee may amend or revise this charter as appropriate to achieve the objectives of the collaboration.

- *Composition* – The Collaborative Community will be governed by a Steering Committee of at least seven individuals ("voting members") and up to fifteen individuals who will serve two year-terms. The Steering Committee must include at least one representative from each of the following stakeholder communities:
  1. Clinicians/Healthcare Providers
  2. Medical Device/Technology Company
  3. Other MedTech or BioTech Companies
  4. Patient Representative
  5. Legal Professional
  6. Industry Organization (professional society)
  7. Academic Organization
  8. Member at Large (e.g., IRB member, Research Coordinator, etc.)
  9. Nonprofit/Patient Organization
  10. Other Government Agencies
  11. MedTech Color representative(s)

- *Voting* – Each voting member of the committee will have an equal vote on all matters or decisions of the Steering Committee. Decisions of the Steering Committee can only be implemented with the affirmative agreement of a three-fourths majority of the voting members of the Steering Committee present for any votes. At least five members of the Steering Committee must be present for any meeting in which voting will occur. If a participant, the FDA or other governmental agency representatives will have a non-voting role on the Steering Committee.

- *Governance* - There will be a chair and/or two co-chairs of the Steering Committee. This committee will meet at least four times per year and at least once per quarter in a given calendar year. Agendas and items for vote and discussion will be developed by the Chair(s) and distributed to the Steering Committee members at least one week prior to each meeting.

Subcommittees – The Collaborative Community will have a Budget and Finance Subcommittee and four Standing Subcommittees.

	• Budget and Finance – This committee will be responsible for reviewing and maintaining the budgets and finances of the Collaborative Community, to include ensuring appropriate auditing and review of subcommittee budget requests, conflicts of interest, sponsor company contributions and related activities. This committee will have a Chair and up to four members. • Four Standing Subcommittees – These committees will be responsible for developing and executing one of four objectives of the collaborative: (1) disease state information and awareness; (2) recruitment and retention of minority participants and investigators; (3) product development and clinical research study design; and (4) evidence development and analysis of minority health issues and outcomes. Each of the four standing subcommittees will have a chair and/or two co-chairs and up to twenty individuals. Each of these subcommittees must include at least one member of the Steering Committee among its members. **Governance of Subcommittees** - The subcommittee chairs report to the Chair(s) of the Steering Committee. Budgets and expenditures for the Standing Subcommittees' activities and initiatives must be submitted to, and conditionally approved by, the Budget and Finance Committee and approved by the Steering Committee. Subcommittees will meet monthly or on a schedule to be determined by the subcommittee chair(s), but not less than once per quarter in a single calendar year. The Steering Committee may create additional temporary or standing subcommittees as and where necessary. Decisions regarding the creation of such committees must be approved by the Steering Committee.
Funding, Budget and Fundraising	**Funding and Sponsorships** - The Collaborative Community will be funded through financial and in-kind contributions from industry members of the Collaborative Community or other supporters. Funding can include financial contributions in the form of sponsorships for specific Collaborative Community events or activities or donations of money or in-kind services. **Funds and Operations** – Funds collected from sponsorships or other resources to support the Collaborative Community will be maintained in a dedicated bank or trust account by MedTech Color. The Chair(s) of the Steering Committee and the Chair(s) of the Budget and Finance Committee will have access to the account and responsibility for oversight, auditing and review of the deposits and expenditures from this account. The Budget and Finance Committee Chair and the Chair of the Steering Committee will coordinate with the Treasurer of MedTech Color and the Executive Planning Committee to conduct quarterly reviews of all deposits and expenditures from this account. The Steering Committee can establish and collect registration fees to fund or support public events or curated content developed, sponsored or organized by the Collaborative Community. Public events include webinars, in-person

	meetings or other activities that are open to the general public and intended to contribute to generalized knowledge, learning, information or advancement of the Community's mission.
Communication, Transparency and Documentation	The Collaborative Community will produce an Annual Report describing the activities of the prior year, planned initiatives for the current calendar year and future initiatives. Each of the four Standing Subcommittees must provide a summary of the prior year's subcommittee activities to the Steering Committee and Executive Planning Committee by December 31 of each Calendar year.
Membership and Composition of Collaborative Community	The membership of the Collaborative Community will consist of representatives from the following stakeholder communities. 1. MedTech Color – as the convener 2. FDA – CDRH and Office of Minority Health and Health Equity 3. Industry Organizations 4. Academic Organizations 5. Other Government entities (e.g. NIH, CDC, etc.) 6. Investors and VCs 7. MedTech Color Sponsor Companies 8. Collaborative Community Sponsor Companies 9. Patient Groups 10. Payors and Healthcare Organizations 11. Professional organizations 12. Journals, Newspapers, Periodicals Membership will be free and open to representatives of the identified stakeholder groups who wish to participate or contribute to the Collaborative Community. The Steering Committee may establish additional criteria and requirements for membership. Any changes to the membership criteria must be implemented through the affirmative agreement of a three-fourths majority of the voting members of the Steering Committee present for any votes on membership criteria.

Executive Planning Committee:	**Executive Planning Committee:**
	• MedTech Color:
	  ○ Nada Hanafi, Chief Strategy Officer, Experien Group LLC
	  ○ Vernessa Pollard, Partner and FDA Practice Leader, McDermott Will & Emery
	• Jaime Wheeler, VP Global Clinical Affairs at Edwards Lifesciences LLC
	• Kenita Barrow, Deputy General Counsel, Otsuka America Pharmaceutical, Inc.