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### The Power of Community Collaborations and Partnerships for Achieving Diversity in Clinical Research

By: Luther T. Clark, MD - Deputy Chief Patient Officer, Merck

Barriers to participation of racially and ethnically underrepresented patients in clinical trials include: (1) mistrust, (2) fear, (3) lack of comfort with the clinical trial process, (4) lack of information about clinical trials, (5) logistical constraints such as time and out-of-pocket expenses. In addition, social and economic factors (the social determinants of health) may negatively impact patients' willingness to participate in clinical research.

Meaningful patient and community engagement can help achieve diversity as well as advance both science and patient care. In addition to helping empower patients to be more active participants in their medical care, appropriate and meaningful engagement between trusted community stakeholders (participants, patients, caregivers, patient advocacy organizations and leaders) and researchers (clinical trial sponsors, investigators, clinical research sites) can help effectively address the perspectives and priorities that are important for patients — those who will be impacted by the research.

In order to gain insights about what matters to patients and their communities, we engage with patients and their advocates through activities such as patient advisory panels and expert input consultations. These engagements have been especially helpful for: (1) increasing awareness and education to build trust and increase understanding of the importance and benefits of clinical trials; (2) increasing opportunities for underrepresented groups to participate in clinical trials by removing barriers (i.e., logistics, out-of-pocket costs); and (3) increasing partnerships with minority investigators and others who serve communities of color to help improve the diversity of participants -- as well as to better demonstrate the safety and efficacy of new drugs, vaccines, and other therapeutic and diagnostic products

in all population groups.

Mistrust of research and the fear of being a "guinea pig" are among the most significant barriers to clinical trial participation for underrepresented groups. While the ultimate decision regarding clinical trial participation rests with the patient, that decision may be influenced by family, close friends, and other trusted individuals and groups in their own communities. Therefore, building trust between researchers and trusted community stakeholders (faith-based organizations, non-profit and civic groups, community leaders, patient advocacy groups, community healthcare providers, etc.) is also critical for overcoming barriers. Furthermore, while altruism and other factors are important considerations, patients and their families are usually most concerned with obtaining the best treatment. Therefore, reassuring patients about the importance of their health and safety, reinforcing that their health will be closely monitored, and including family members in decision-making can increase comfort with the clinical trial process and help build trust. Effective and meaningful community engagement should be long-term rather than based solely on specific trial or project needs.

In summary, increasing research participant diversity continues to be a challenge for industry, academia and other sponsors. However, during this deeply troubling moment for our nation, the confluence of two major catastrophes — the COVID-19 pandemic and community unrest due to racial injustice and inequities — that have amplified disparities and the impact of health inequities, provides perhaps an opportunity to make real and sustainable progress toward achieving diversity and inclusion in clinical research as well as improving healthcare access and outcomes for all communities.

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