NATIONAL MINORITY QUALITY FORUM

Best practices that help children and families to stay in clinical trials

ADEPT 9: Enhancing Diversity in Therapeutics Development for Pediatric Patients

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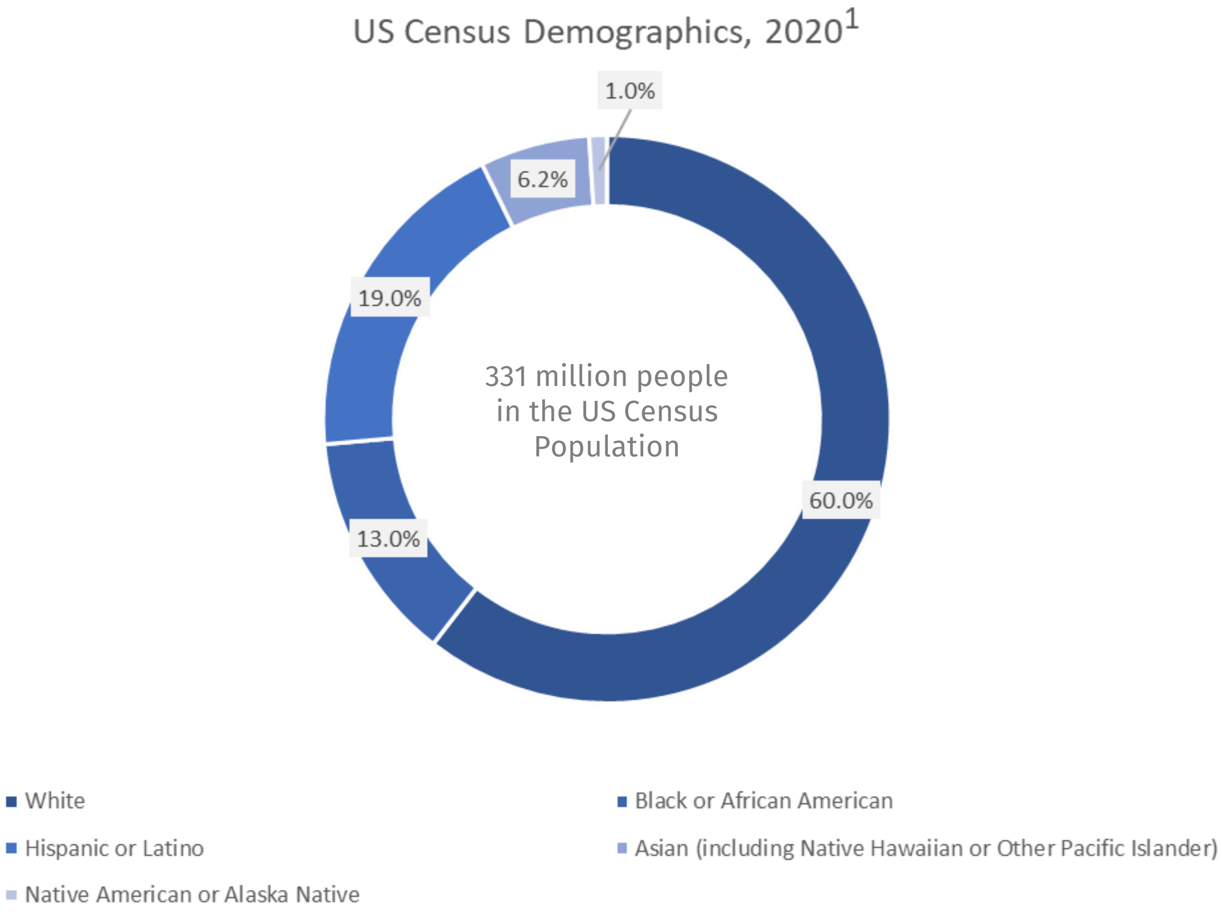
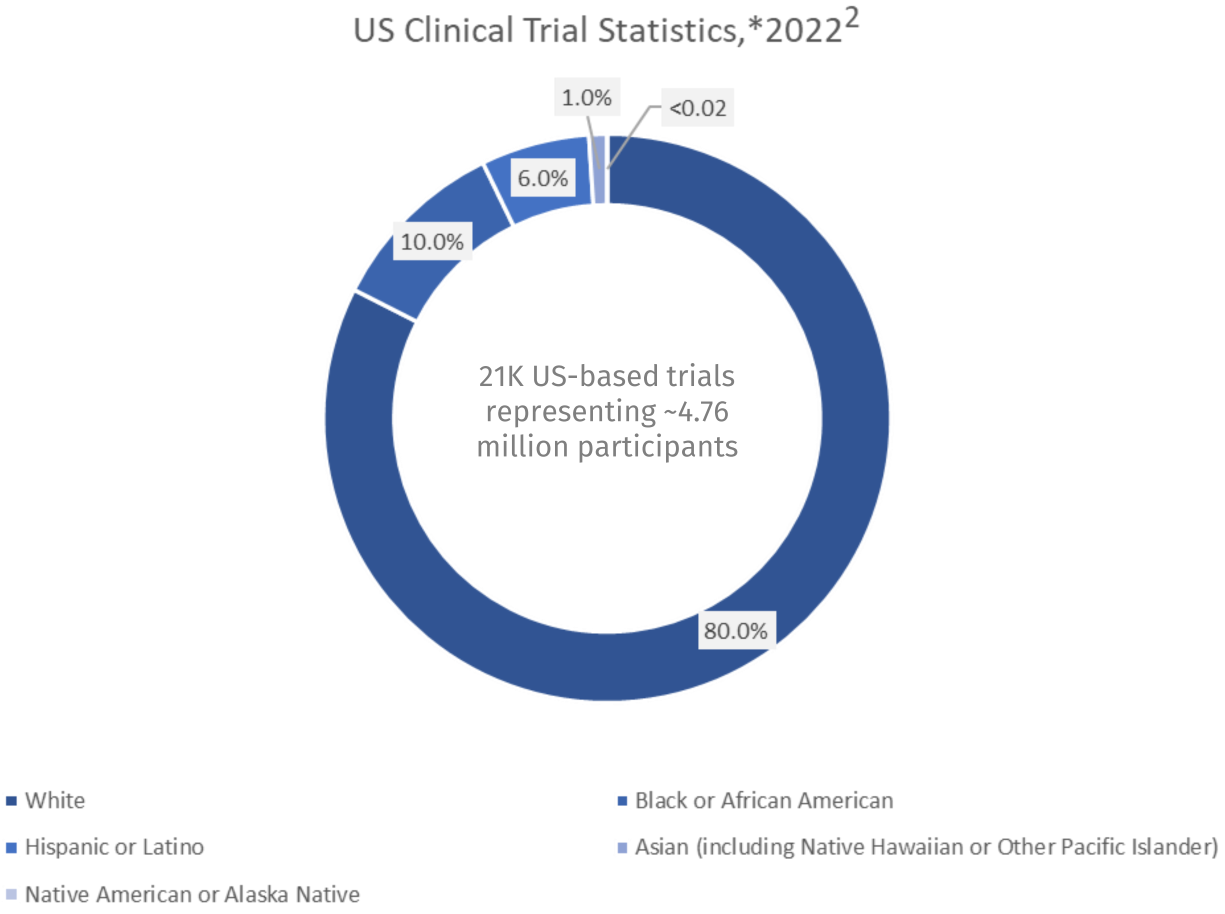
Disclaimer

- The views and opinions expressed in this presentation are those of the presenter and do not necessarily reflect the official policy or position of the U.S. Food and Drug Administration (FDA). Information presented is for educational purposes only and should not be interpreted as regulatory guidance or advice.

US Demographics vs. Clinical Trial Participation Statistics



US Census Demographics, 2020[1]



US Clinical Trial Statistics,*2022[2]

** Note: Of the 20,692 US-based trials represented, only 43% (8,898) reported any race/ethnicity data.*

1. *US Census, Quickfacts*
2. *E.B. Turner et al., "Race/Ethnicity Reporting and Representation in US Clinical Trials: A Cohort Study," The Lancet Regional Health: Americas 8.100252 (2022).*

Multi-Level Barriers to Clinical Research Participation

Individual

- Time
- Resource constraints
- Language and literacy
- Caregiver restraints

Interpersonal

- Attitudes and beliefs of patient, and provider
- Discrimination
- Bias
- Mistrust
- Lack of awareness and engagement

Institutional

- Lack of trust
- Racism
- Mistrust
- Competing goals
- Eligibility criteria
- Trial availability

Policy

- Funding mechanisms
- Accountability
- Supports for BIPOC investigators

BIPOC: Black, Indigenous, and People of Color. Sources: D.H. Bodicoat, A.C. Routen, A. Willis, et al., "Promoting Inclusion in Clinical Trials: A Rapid Review of the Literature and Recommendations for Action," Trials 22.880 (2021); N. Thakur, S. Lovinsky-Desir, et al., "Enhancing recruitment and retention of minority population for clinical research in pulmonary, critical care, and sleep medicine: An official American Thoracic Society research statement," Am J Respiratory and Critical Care Medicine 204.3 (2021); 204(3).

Community Engagement

- Conduct outreach and engage with community based organizations, advocacy groups, and community leaders to gain buy in and the trust of the community.
  - Evaluate the needs of the community
    - Conduct educational seminars, host events, etc. on the basis of those findings and to gain additional insight
      - Use events to address issues plaguing the community, applicable comorbidities and care options, including clinical trials
  - Liaise with trusted community members
    - Utilize their support/endorsement to bridge gap between sponsor and community
  - Partner with organizations already doing the work
    - Not always necessary to reinvent the wheel. Amend, tailor and adjust where applicable.
  - Have a dedicated team- familiar faces allow for relationship building

Promoting Health Equity Through the Education of Clinicians and Community Leaders

Clinician Engagement

Clinical teams and pharmacists partner with SHC to implement QI and community engagement projects in underserved communities

Community Engagement

Partnerships with Churches, barbershops, and hair salons around the country to engage, educate and connect people of color to health and social services

Community Partners

FAITH HEALTH ALLIANCE
A NMQF HEALTH CHAMPION NETWORK

The Faith Health Alliance raises health awareness in communities of color. Utilizing the influence of faith leaders, this initiative aims for sustainable health outcomes in communities of color, with churches playing a key role in promoting various health issues.

WELLNESS WARRIORS

HAIR Wellness Warriors unite nationally to combat health illiteracy and inequity in conditions like diabetes, cancer, and lupus. They offer education and outreach through barbershops and salons, where barbers and stylists address local beliefs and concerns, fostering conversations and promoting healthy outcomes.

Community
Pharmacist
Ambassadors

Community Pharmacist Ambassadors serve as health educators outside of the pharmacy, providing sound health information and increasing public recognition of the vital role pharmacists can play in health promotion. As part of the program, pharmacists can be connected to community partners.

Where Health Champions Are

- 83 clinics in 14 states
- 20,000 health champions in 892 cities
- 24 HAIR Wellness Warriors
- 22 Faith Health Alliance Churches
- Over 60 Community Pharmacists Ambassadors

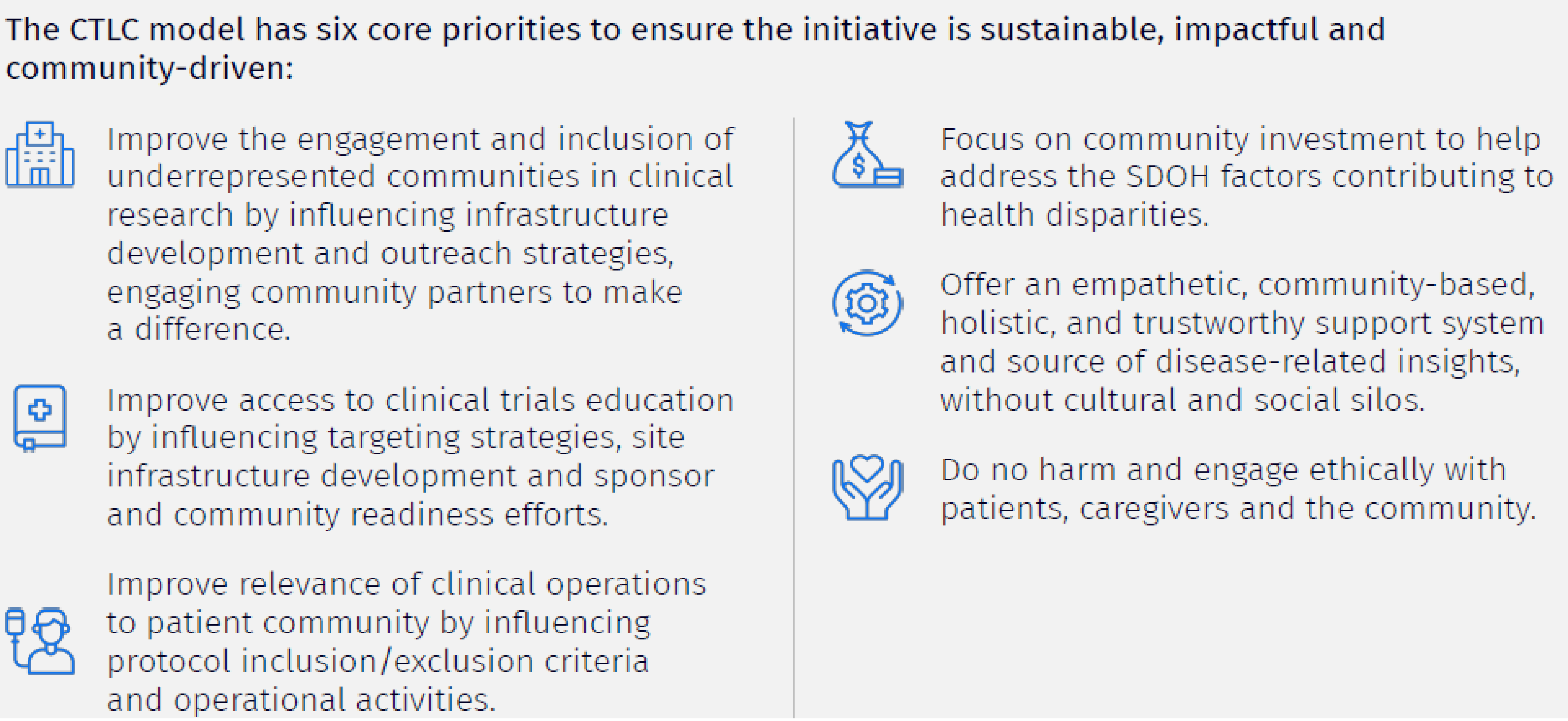
Community Engagement

- Ensure use of culturally tailored education
  - Communities are incredibly nuanced. Be sure to be culturally sensitive.
  - Tailor/customize materials
    - Advertising and recruitment materials, including social media marketing and outreach, should be tailored to targeted community

- Optimizing study teams
  - Principal Investigators, study staff should be representative of targeted population
    - Consider these dynamics during site selection

Clinical Trial Learning Community

Established in 2020, the National Minority Quality Forum (NMQF) and Biogen developed the Clinical Trial Learning Community (CTLC) model to identify and mitigate disparities in clinical research. Together with NMQF, Biogen, and its community partners, the CTLC serves as a space where local clinical researchers, physicians, patients, community leaders, and others work toward a common objective: reducing disparities in care and outcomes for underrepresented patient populations living with serious, chronic diseases by ensuring awareness of and access to available clinical trials close to home.



The CTLC model has six core priorities to ensure the initiative is sustainable, impactful and community-driven:

- Improve the engagement and inclusion of underrepresented communities in clinical research by influencing infrastructure development and outreach strategies, engaging community partners to make a difference.
- Improve access to clinical trials education by influencing targeting strategies, site infrastructure development and sponsor and community readiness efforts.
- Improve relevance of clinical operations to patient community by influencing protocol inclusion/exclusion criteria and operational activities.
- Focus on community investment to help address the SDOH factors contributing to health disparities.
- Offer an empathetic, community-based, holistic, and trustworthy support system and source of disease-related insights, without cultural and social silos.
- Do no harm and engage ethically with patients, caregivers and the community.

The CTLC model has been working directly with medical professionals to expand their knowledge on cultural competency and the importance of clinical research via virtual training modules and community town halls/educational sessions. Additionally, hearing patients and community concerns related to clinical research will lead to further minimizing barriers to trials.

Effective Communication Practices

- Communication style and preferences will vary by family.
  - Informed consent process- pivotal timepoint
    - Allocate additional time for participants during visits, especially during enrollment.
    - Ensure translation services are available.
      - Utilize interpreters and translated documents where applicable- Ideally all study materials should be in participant’s language
  - Clearly communicate trial details
    - Trial details should be effectively conveyed for total understanding.
      - Study purpose, benefits, requirements, and risks are key components.
    - Provide families with supplemental materials that will enhance their understanding of research, their role- expectations of them, and the trial.
  - During trial, be available, accessible
    - Reassure families you are available for questions, concerns
    - Helps to build trust and relationships
  - Share results and achievements with families.
    - Where allowed, inform families of study progress or any study changes
    - Continuous communication- conduct outreach between study visits

Roy A, Lieb W, Garrett B, Hodik M, Klipsch A, Young M, Barton B, Schwarz KB. Recruitment and retention strategies in a clinical trial for children with chronic hepatitis C infection. J Pediatr Nurs. 2013 May-Jun;28(3):243-8. doi: 10.1016/j.pedn.2012.08.006. Epub 2012 Sep 18. PMID: 22999994; PMCID: PMC3540171.

Comprehensive Care

- Accessibility: Barriers to entry
  - Transportation- if needed, be open to providing travel assistance. Consider supporting travel accommodations preemptively. Reimbursement not always feasible for families.
  - Childcare- Lack of childcare often an issue for parents. Be conscientious of this limitation and how it may negatively impact retention.
  - Scheduling-
    - Make best use of flexibility in visit windows to allow for variation in school and work schedules.
    - Be strategic and productive during study visits. Prepare in advance.
    - Decentralized trials- where applicable/feasible, ensure locations within close proximity and/or easily accessible for families.

Comprehensive Care

- Incentives
    - Monetary incentives should align with time and effort required of participant and family
    - Should be easily redeemable
    - Consider alternative incentives- within scope and institution policy

Comprehensive Care

Patient navigation

- Patient navigator, social worker and/ or caseworker-
  - Consider the participants health on the full spectrum.
  - Additional support services may further incentivize participants and families to enroll.
  - If unable to provide additional support at point of research care, refer/coordinate these health services.
- Continuum of Care-
  - Keeping families privy to a navigation plan may improve retention.
    - Communicate these efforts to the family.
      - Discuss post-trial plans/options.

Thank you

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