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Background
Clinical trials lack full representational and proportional diversity across race, ethnicity, socioeconomic status, sexual orientation, gender identity, persons with disabilities, region, and age. Since people from diverse backgrounds experience physical conditions differently, accurate, representative research requires inclusivity. Barriers to clinical trial diversity include historic medical mistrust, exclusionary eligibility criteria, and limited access to trials. Due to these barriers, among others, there are numerous gaps in knowledge for marginalized populations, and not all communities are able to benefit from scientific advances.
Relevance Today

Drawing recent insights from Capitol Hill and executive agencies, we found significant interest in exploring ways to improve diversity in clinical trials; and noted this topic as a bipartisan issue - particularly given inequitable health outcomes observed during the COVID-19 pandemic.

Stakeholders also noted that there was a desire to continue to build on the work undertaken in the FDA Reauthorization Act of 2017. For example, the Clinical Treatment Act (S.4742 and H.R. 913), introduced in the 116th Congress, was one of several policy ideas that stakeholders may look to explore further. Congressional staff also highlighted the need to better understand how technology could impact clinical trial diversity and how to best utilize public-private partnerships. Specifically, they urged highlighting underrepresented populations such as people of color and people who live in rural areas.

More recently, H.R. 2617, the Consolidations Appropriations Act of 2023 became law and includes a codification of the FDA’s current proposal for diversity action plans. This was followed by a January 6, 2023, White House Roundtable centered on how to better support the clinical trials ecosystem. Then on April 3, 2023, the White House released a National Cancer Plan to spur activity on ways to increase diversity in clinical trials.
Overview of Alliance for Health Policy Clinical Trial Diversity Program

Because of the significant policymaker and stakeholder interest in this topic, the Alliance for Health Policy developed a program that consisted of two listening tours, a Thought Leader Roundtable, and a fall 2023 public webinar.

The range of participants on the listening tour and the Thought Leader Roundtable covered the patient voice, health care providers, advocacy groups, biopharma, academia, and legislative sectors among others.

Garnering insights from Capitol Hill and our diverse stakeholder community, the following themes emerged:

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Following our listening tours, we convened a diverse group of stakeholders ranging from industry to patient advocates for a Thought Leader Roundtable discussion. Using five of the themes that emerged from our listening tours, we developed five framing questions for the Thought Leader Discussion.

The key takeaways from our Thought Leader Roundtable will shape the public webinar scheduled for the Fall.
Centering a community-based approach to clinical trial diversity design and improving health care provider training

How do we sustainably partner with and invest in members of historically underrepresented communities to help build out clinical trial study designs?

- Streamline and decentralize community participation in clinical trials by meeting the community where they are (i.e., remote, multiple trial sites).
- Incorporate elements of community-based participatory research (CBPR); and include patient, caregiver, and community representatives as early and often as possible in the clinical trial design process.
- Recruit and retain diverse investigators and staff across all aspects of the clinical trials infrastructure; and encourage community-based physicians to explore and offer clinical trials as a health care option for their patients.
Workforce diversity and non-traditional caregivers (e.g., community health workers (CHWs)/navigators, pharmacists, etc.)

How do we better train, incorporate, and logistically support health care providers in the clinical trials research enterprise?

- Sustainably fund training workforce pipeline beginning as early as possible (e.g., medical school, nursing school, etc.) and throughout the career; and provide opportunities and resources to participate in trials at the community level.
- Sustainably fund community health care workers (CHWs, navigators, etc) as part of the clinical care team to provide patients with education and support in decision-making regarding clinical trials.
- Incorporate principles related to diversity, equity, inclusion, anti-racism, and belonging into all discussions and decision-making.

Patient-centered engagement

How do we center the patient voice and reexamine the standard of care, screening guidelines, and study protocols to make sure they match the burden of disease in the population or subpopulations?

- The patient voice should be included in designing the study questions and metrics.
- Ensure that protocol design teams are educated and aware of historically racially-driven factors and diagnostics (e.g., kidney function tests, pulmonary function tests, etc.) that may make inclusion and exclusion criteria unnecessarily exclusionary.
- Work closely with focus groups of historically underrepresented community members before the study protocol design is finalized.

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Leveraging digital health and remote patient monitoring

How do we leverage digital health and remote patient monitoring to ensure that patients are engaged in more holistic, meaningful, and nuanced ways?

- Include patients, caregivers, and community members in the evaluation of socio-culturally appropriate digital health tools that will be patient-facing and how data will be used in plain language.
- Ensure regulatory validation of digital health technologies and remote patient monitoring tools; while making the burden of participation (e.g., remote visits, at-home testing) as light as possible.
- Support historically underserved communities regarding internet broadband access to help facilitate digital health access.

Administrative, legislative, or regulatory levers

What administrative, legislative, or regulatory challenges may need to be overcome in order to achieve meaningful progress in achieving better diversity in clinical trials?

- Encourage study teams to use data analytics tools to carefully assess the impact each eligibility criterion will have on the inclusion and exclusion of underserved populations into the trial and appropriate accommodations should be made as needed.
- Provide needs-based financial assistance for ancillary clinical trial expenses (e.g., transportation, child care, caregiver support, interpretation services, etc.) incurred as a result of participation in a clinical trial.
- Facilitate reimbursement incentives for physicians to evaluate and refer patients for clinical trials via Medicare and Medicaid programs.
Successful Models

- Partnering with federally qualified health centers (FQHCs) and other community entities (e.g., faith-based organizations, civic organizations, advocacy groups, medical homes, etc.)

- **Patient Navigation Programs**

- **Research Centers in Minority Institutions (RCMI), Clinical Research Network for Health Equity (CRNHME)**

- **NIH Community Engagement Alliance (CEAL), Against COVID-19 Disparities Initiative**

- **Network for Community-Engaged Primary Care Research (NCPCR)**

- **NIH Community Partnerships to Advance Science for Society (ComPASS)** seeks to advance the science of health disparities and advance health equity research.

- Two of the **NIH Minority Health and Health Disparities Strategic Plan’s** major goals focus on issues of diversity and inclusion in NIH-funded research and clinical trials.
Additional Resources from Interviewees

- Milken Institute, Faster Cures reports
  - Diversity in Clinical Trials Call to Action report
  - An Action Plan to Address Diversity across Clinical Trials and Biomedical Research

- National Minority Quality Forum
  - Integrating Research into Community Practice – Toward Increased Diversity in Clinical Trial
  - Expanding Pediatric Exclusivity Provision
  - Priority review: provide accelerated FDA decisions for diversity in a particular therapeutic area; this would be a great incentive for companies without the issue of extending patents

- Patient-Centered Outcomes Research Institute
  - Community Health Workers Study
  - PCORI Landscape Review on Value in Health Will Inform Continuing Conversation
  - Equity and Inclusion Guiding Engagement Principles
  - PCORI’s pragmatic studies are large-scale patient-focused Comparative Effectiveness Research (CER) projects.
  - The PCORI Strategic Plan
  - Advisory Panel on Healthcare Delivery and Disparities Research
  - Patient Engagement Advisory Panel

- TOUCH, The Black Breast Cancer Alliance
  - The Black Breast Cancer Alliance
  - When We Trial
  - Love of My Gurls

- Lazarex Cancer Foundation
  - Lazarex Cancer Wellness Hub
• National Institute on Minority Health and Disparities (NIMHD)
  o March 30-31, 2023, Inclusive Participation in Clinical Research Workshop
  o NIH established the Diversity, Equity, and Inclusion Workgroup of the NIH Clinical Trial Stewardship Task Force to review the progress of implementing prior NIH policies on diversity and inclusion in clinical research and effectiveness in fulfilling policy goals, as well as identify areas of opportunity for improvement.
  o The North Carolina Central University (NCCU) Research Centers at Minority Institutions (RCMI) Practice-Based Equity Research Network

• (PBERN) is a NIMHD-funded project that focuses on healthcare sites that are not traditionally involved in clinical research networks.
  o NIH UNITE acts as a think tank to promote equity, generate bold ideas, and catalyze new actions. Collectively, it identifies and addresses any structural racism that may exist within the NIH and throughout the biomedical and behavioral workforce.
  o RADx® Underserved Populations (RADx-UP) created by NIH to ensure that all Americans have access to COVID-19 testing, with a focus on communities most affected by the pandemic.
  o NIMHD and NIH resources on diversity and inclusion of clinical trials can be found here and here.
  o Initial Proposals For Updating OMB’s Race and Ethnicity Statistical Standards Federal Register notice.

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