Webinar Summary: Promoting Diversity in Clinical Trials [May 1, 2024]

This document summarizes recommendations and action items brought forward by speakers at the Health Research Alliance DEI Learning Community Call on May 1, 2024.

Speakers:
Barbara Bierer, MD
Professor of Medicine, Harvard Medical School
Co-Founder, Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Alice Kuaban, MS
Deputy Director, Scientific Affairs, American Society of Hematology

Patricia Hurley, MSc
Senior Director, Strategic Research Initiatives, American Society of Clinical Oncology

Possible Roles and Actions:
Barbara Bierer's Slides:
Public Awareness and Communication

- Provide access to information to patients, potential participants, and communities
    - About their rights as research volunteers
    - About clinical trials in general
    - About disease-specific possible trials
- Provide and align patient and participant navigators
- Plan and support community health and health research activities

Workforce Diversity

- Intentionality: Funding students, trainees, and others from diverse backgrounds
- Supplemental awards for people who represent underserved communities
- Engage in and/or fund health fairs for the recruitment of future workforce
- Create (direct) or Fund (indirect) honorific awards, microgrants, training, internships

Equitable Access to Trial Participation

- Require diversity action plans
- Create (direct) or Fund (indirect) community advisory board review
- Require payment to patient partners as a condition of service
- Enable participant navigators
- Require plain language review of materials, user testing by patients/patient advocates
- Recommend or require translation and interpreter services
- Require accommodations
- Require reimbursement and compensation and allow incentive payments
- Provide advice on tax and means-tested eligibility implications
- Require (fund) or provide transportation

- Digital enablement
- Return of results (individual and aggregate data) to participants and the communities they represent

Comprehensive and Consistent Data

- Collect, aggregate, and provide data
    - Epidemiology of the disease or condition, by demographic variable
    - Common data elements and standards
    - Fund development of standards and data sharing
- As a condition of grant award:
    - Recommend data standards
    - Require data dictionary and data sharing

Accountability

- Self-assessment of current state within nonprofit funding organizations
- Diverse representation on board of directors, standing committees
- Review of, and metrics to inform, grant portfolio
- Bias training and cultural sensitivity training of defined populations

Alice Kuaban's Slides:

- Examine Inclusion/Exclusion Criteria: For rare disease, determinations about trial inclusion/exclusion criteria must be evaluated early to determine implications on diversity, accessibility, and alignment with real-world results
- Decentralized Clinical Trial options can enhance access
- Institutional Review Boards have a role to play in enhancing diversity in clinical trials
- Global standardization of definitions regarding diversity and inclusivity in clinical research are needed
- Action examples from ASH:
    - Developing DEI Toolkit for Clinical Trial Sponsors
    - Creating a learning ecosystem so clinical trialists can learn and share how to build inclusive clinical trials
    - Creating education resources and programs to support workforce development (e.g., ASH Clinical Research Training Institute includes DEI principles as part of study design curriculum)
    - Request for demographic information (sex, gender, race, ethnicity, age, disability, other relevant factors of enrolled subjects) to be submitted for individuals submitting/presenting on clinical studies (ASH Events, ASH publications). If demographics are NOT available, the investigator will be asked to describe the limitations that prevented these data from being collected.

Patricia Hurley's Slides:

- Graphic summarizing recommendations from the article "Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement"

- Prepare research sites and networks to improve EDI in clinical research
    - Research site self-assessment: Enable internal review of policies, programs, procedures to identify opportunities for improvement
    - Just ASK™ Increasing Diversity in Cancer Clinical Research: An ACCC-ASCO Training Program and companion Facilitation Guide - Implicit bias training program for clinicians and staff to assess and mitigate biases regarding who is screened for and offered clinical trials
    - Detailed list of resources for clinical trial sites (and other groups): https://society.asco.org/sites/new-www.asco.org/files/content-files/news-initiatives/documents/ASCO-ACCC-EDI-Clinical-Trial-Resources-May-2022.xlsx
- Broaden eligibility criteria and geographic access to trials
- Operationalize decentralized clinical trials
    - Clarify FDA Form 1572 requirements to ensure consistent interpretation
    - Advocate for routine acceptance of local laboratory and imaging facilities
    - Foster partnerships to increase patient and local clinician access to trials