Addressing Diversity Through Patient Centered Trials

The third and final workshop in our series focused on the benefits and best approaches for structuring clinical trials in a manner that stimulates interest, enrollment, and retention of diverse patients. The program began with a presentation from Dr. Georges Benjamin, the Executive Director of the American Public Health Association. Dr. Benjamin shared his best practices for engaging minority patients in clinical trials, including modifying consent terminology to be more easily understood, emphasizing the benefits of clinical trial research to the individual and others in that individual's community, and relocating trial sites to academic institutions closer to minority patient communities. Following Dr. Benjamin was Representative Robin Kelly (D-IL), with a presentation centered around her efforts in Congress to introduce legislation on diversifying and improving clinical trials. The presentations were followed by stakeholder breakout discussions which covered the following issues and questions:

Removing Enrollment Barriers

Taking into consideration what we have heard from patients, what barriers impact patient participation in trials?

How might barriers to trial participation be addressed/alleviated?

Leveraging Technology

What role does technology play in improving trial participation?

What types of support is needed to make these technologies accessible for trial use and improvement?

How can stakeholders and the government support these efforts?

Inclusive Trial Design

Flexibility in the structure, sponsorship, and design of trials is important for recruitment and retention, how can trials be designed to be more appealing to diverse patient populations?

What role do diverse investigators play in improved enrollment?

What role do diverse trial sites play in improved enrollment?

Policy Considerations

What policy considerations should be evaluated and/or modified to improve diversity in trials (e.g., waivers, site locations, etc.)?

The breakout discussions resulted in the identification of tools and strategies that attendees believe will improve the recruitment, enrollment, and retention of diverse patient groups. The following approaches, associated with the thematic areas guiding the various discussions, were identified:

Removing Enrollment Barriers

Simplify consent discussions so patients are not deterred by confusing legal terms

Utilize community partnerships to increase awareness and to ensure that information is accessible and understandable (e.g., language considerations)

Publicize and promote trials where patients get care

Set up patient advisory panels to inform trial design

Design trials that fit patient lives—not the other way around

Make trials simpler and accommodate barriers to participation and enrollment

Provide opportunities for patient feedback and make patients aware of participation benefits

Inclusive Trial Design

Decentralize trials to ensure they are more patient focused (i.e., go to the patients)

Utilize/develop partnerships with groups that represent the patients you are trying to reach

Train care providers to better communicate with prospective trial patients, emphasizing empathy, respect for the patient population, and awareness of patient needs

Account for the impact of SDOH and how trial infrastructure can account for and address these factors

Develop materials to help prospective patients find trials and that promote increased health awareness/literacy

Engage the community and use a data driven approach to select trial sites

Recruit with clear intention and goals

Leveraging Technology

View technology as an enabler and not a solution

Understand the barriers created by technology reliance (e.g., access to broadband, aversion to use of technology)

Use technology to:

- recruit unique patients from areas outside of academic medical institutions
- identify researchers
- bridge the gap between researchers and patients

Engage government agencies (e.g., FDA) to create a pool of interested parties

- make data accessible to researchers and companies

Policy Considerations

Introduce compensation for transportation travel time, childcare, and other responsibilities that might otherwise deter patients

Create a systematic approach for tackling diversity issues to include bringing together interested stakeholders to discuss streamlining the approach

Create programs for long-term relationship and network building in communities of color

Modernize and simplify informed consent

Revisit where research can be conducted (e.g., short-term and community-based practices)Engage government agencies (e.g., FDA) to create a pool of interested parties

- Provide more research opportunities in areas with a higher condition prevalence