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American Society of Hematology Response to the National Institutes of Health's (NIH) Request for Information (RFI):
Strategies for Maximizing Public Engagement in NIH Supported Clinical Research

The NIH is soliciting feedback to their RFI on Strategies for Maximizing Public Engagement in NIH Supported Clinical Research. The feedback will inform a new initiative the NIH is leading titled "Engaging the Public as Partners in Clinical Research (ENGAGE)." By way of background, ENGAGE is an initiative aimed at developing a vision and framework for incorporating public voices in all phases and types of clinical research.

Below are ASH's comments in response to NIH's request (also submitted electronically to the NIH submission site on August 14, 2024).

1. **Strategies for researchers to best partner and work with people and communities. For example, developing resources respectful of different cultures, facilitating open dialogues for decision-making, sharing results in a way that is valuable, etc.**

   The American Society of Hematology (ASH) has long been committed to combating inequities in hematology, supporting physicians and researchers from backgrounds underrepresented in medicine, and embracing diverse voices in the community. As part of this mission, ASH has created several key resources and initiatives to foster the design of hematology clinical trials that reflect the epidemiology of the disease and are inclusive of the population that will benefit from the therapeutic under investigation. The importance of designing clinical trials that reflect individuals in the real-world cannot be overstated, since trial results need to be generalizable. However, several groups (e.g., women, Blacks, Hispanics, the elderly, etc.) have been historically underrepresented in clinical trials, meaning the outcomes generated from those studies can't be applied to all patients.[i] [ii]

   ASH, and its members have employed many strategies to effectively partner with people and communities. Including:

   - Establishing strong connections with patient-facing groups and local healthcare providers as these collaborations help the hematology researchers understand the unique needs and concerns of the patient population. For example, as part of ASH's multifaceted sickle cell disease (SCD) initiative, the Society founded the Sickle Cell Disease Coalition (SCDC), a group of over 100 national and global organizations to help amplify the voice of the SCD stakeholder community, promote awareness, and improve outcomes for individuals with SCD through cross organizational collaboration. ASH's ongoing engagement with the SCD community and provider groups through the Coalition has enhanced ASH and our members' understanding of the unique needs of patients with SCD. ASH members have indicated that outreach to community leaders specifically to highlight the value of clinical trial participation, helps with the dissemination of trial information and ultimately improves participation in research initiatives from that community.
   - Meeting patients where they are, an approach that involves going beyond the traditional clinical settings to engage with patients in their own communities. ASH members have found success giving talks and presentations to communities, in language they can easily understand and in areas they are familiar with and can easily access.
   - Training the next generation of investigators on the importance of community engagement and strategies for connecting with diverse populations is essential. This is a core component of ASH's curriculum for its Clinical Research Training Institute – a year-long education and mentoring program that is geared towards

training the next generation of clinical trialists. This will help equip future investigators to conduct meaningful research.

For additional resources, ASH refers the NIH to its DEI Toolkit for Clinical Trial Sponsors: https://www.hematology.org/-/media/hematology/files/dei/ash-dei-toolkit-for-clinical-trial-sponsors.pdf. Designed to help sponsors incorporate DEI principles throughout the trial life cycle, the toolkit includes actionable recommendations, reference articles, and additional resources from both national and international regulatory bodies and research organizations.

2. **Ways for institutions performing research (e.g., academic medical centers, universities, health systems, primary care providers) to support and incentivize active, bi-directional partnerships between researchers and people/communities. Examples may include encouraging people/community members to establish shared decision-making on project milestones, prioritizing local community review of research questions and research proposals, specific research design factors, leveraging existing patient-clinician relationships, etc.**

Institutions performing research can support and incentivize active, bi-directional partnerships between researchers and people/communities through several key strategies:

- Ensuring that sponsors establish a local presence at trial sites can improve trust and engagement with patients. It is important to create a relationship with the research team and the community.
- Creating effective ways for patients and practitioners to identify clinical trials that they can participate in, through accessible platforms and clear, culturally and linguistically appropriate resources. Moreover, streamlining trial consent forms and ensuring that they are written in clear language that patients can understand is vital to ensure that patients are fully informed. Additionally, translating consent forms and resources into other languages is crucial to accommodate non-English speaking participants and enhance inclusivity.
- Providing funding support for all stakeholders participating in a clinical trial, especially lived experience experts (LEEs). It is critical for investigators to include as part of their research budget appropriate funding to compensate individuals who are participating in trials not only for their time, but also for some of the financial challenges that could impede them from participating e.g., travel and housing costs, childcare assistance, etc.). In addition, researchers should consider adding LEEs as key personnel in their research grants and compensate them for their time.

3. **Approaches for research funders (e.g., government agencies, non-profits, companies) to incorporate partnerships between people, communities, and researchers into their programs and priorities.**

Research funders should forge partnerships between people, communities, and researchers in the following ways:

- Developing a framework for adequate funding support for LEEs participating in clinical trials. This might take the form of clear allowances for LEE support in the terms and conditions of the grant. One step further would be to require LEE engagement as a part of the funding mechanism.
- Engaging communities and incorporating their input in all clinical research supported by the NIH, particularly hematology focused research. This will foster trust within the community and help achieve research outcomes that would be relevant to the communities. An example of this critical engagement has been implemented by the ASH Research Collaborative SCD Research Network, which is fostering collaborative partnerships to accelerate progress in clinical research and improve outcomes for individuals living with SCD by expediting the development of therapeutics and generating high-quality evidence to support clinical decision-making. The Network provides support for SCD Community Advisory Boards have been established at each consortium to promote Network efforts that are informed by the needs and desires of those living with and caring for those with SCD; a national advisory board, elected from the local boards advises at the national level.
- Encouraging investigators to integrate health systems in their study designs since such systems highlight real world data that could inform hypothesis generation and protocol design.

4. **Specific examples of things that may make people and communities more likely to want to engage with researchers and research institutions. Examples may include specific technologies to reduce the burden of research participation, opportunities, fair compensation, cultural competence training and/or culturally competent research models, etc.**

   Specific examples of factors that may increase the likelihood of people and communities engaging with researchers and research institutions include:

   - Leveraging telemedicine and other decentralized approaches for data collection to meet patients where they are.
   - Taking advantage of patient-facing groups that offer trial navigation resources.
   - Seeking the expertise of and providing funding support for LEEs participating in trials.
   - Improving the navigation of *ClinicalTrials.gov* to ensure easier end user searches.

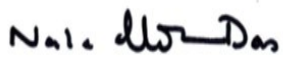
5. **Specific examples of things that may make people and communities less likely to want to engage with researchers and research institutions. Examples may include no/unfair compensation, participation opportunities only happening during typical work hours, lack of awareness of opportunities, etc.**

   In hematology, the following factors may make hematology patients and their caregivers less likely to want to engage with researchers and research institutions:

   - Lack of awareness of existing trial participation resources for patients
   - Mistrust in clinical research
   - Insurance barriers
   - Restrictive inclusion and exclusion criteria (e.g., requiring that all trial participants speak English)
   - Limited funding provided to defray the cost of a patient's participation in a trial
   - Lack of diverse personnel and opinions in clinical trial teams
   - Limited time available to participate in trials – *It is important to consider ways to reduce the amount of time needed to participate. For example, using telemedicine and constructing trials that keep the number and duration of visits that require time away from work or home to a minimum.*

ASH appreciates the opportunity to provide these comments. Please consider ASH a resource; we would be pleased to provide additional information, support and/or schedule a meeting to discuss these issues further. If you have any questions or would like to arrange a meeting with the Society, please use ASH Director of Government Relations and Public Health, Stephanie Kaplan (*skaplan@hematology.org* or 202-776-0544), as your point of contact.

Sincerely,



Mohandas Narla, DSc
President

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[i] *Sex, racial, and ethnic diversity in clinical trials*

[ii] *FDA's Draft Guidance for Industry: Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies*