

American Society of Hematology Helping hematologists conquer blood diseases worldwide



ASH's Strategy to Address DEI in Hematology Clinical Trials

Alice Kuaban, MS American Society of Hematology

The Challenge

- Ensuring hematology clinical trials reflect the epidemiology of the disease and are inclusive of the population to benefit from the therapeutic under investigation.
- Initial focus on classical hematologic diseases
 - Small numbers of patients (<100)
 - Recruitment can be difficult
 - Novel trial designs are needed to generate meaningful results

Why is this important?

Having diverse clinical trials:

- Builds trust in medical research and institutions
- Promotes fairness for potential participants and their communities
- Ensures that study findings can be generalizable*
- Advances biomedical knowledge and drives scientific innovation

ASH's Strong Commitment to DEI





"The American Society of Hematology is committed to addressing and reversing historic inequities in hematology, supporting scientists and clinicans from backgrounds underrepresented in medicine, and elevating diverse voices across our patient and healthcare communities. ASH's efforts in diversity, equity and inclusion apply to everyone, regardless of race, ethnicity, religion, age, sexual orientation, gender identity or expression, ability, national origin or other attributes."



https://www.hematology.org/advocacy/policy-news-statements-testimony-and-correspondence/policy-statements/2021/ash-statement-addressing-diversity-equity-and-inclusion-in-hematology-research-practice-and-training

How is ASH Addressing this Challenge?

The ASH Roadmap to Integrate DEI in Clinical Trials





Representation in the Roadmap Initiative





Headlines from the Initiative



Lived Experience Experts (LEEs)

Lived Experience Experts involved throughout the clinical trial life cycle (design, implementation, dissemination).



Community Physicians

Community physicians need to be engaged in the clinical trial ecosystem and their contributions need to be acknowledged.



DEI at each step

Sponsors need guidance on how to incorporate DEI principles throughout the trial life cycle.



Headlines from the Initiative



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 Trials

Decentralized Clinical Trial options can enhance access.



Headlines from the Initiative



Institutional Review Boards

IRBs have a role to play in enhancing diversity in clinical trials.



Global Standardization

Global definitions regarding diversity and inclusivity in clinical research are needed.



ASH is Now Taking Steps To Address All The Key Headlines from the Roadmap Initiative



Developing DEI Focused Resources for the Hematology Trialist - Toolkit



(NEW!) ASH DEI TOOLKIT FOR CLINICAL TRIAL SPONSORS

This guide is designed to help trial sponsors incorporate DEI principles throughout the trial life cycle.

FORMULATING THE RESEARCH QUESTION TRIAL DESIGN TRIAL BUDGET STUDY CONDUCT & DATA COLLECTION

ACTIONABLE STEPS TO INCORPORATE DEI IN THE CLINICAL TRIAL PROCESS





American Society of Hematology

Exploring the Creation of a Learning Ecosystem Focused on Building Inclusive Trials

Access to DEI in Clinical Trial Resources

EDUCATIONAL EXPERIENCE

Peer-to-Peer knowledge sharing

Consultative Services for Effective Community Engagement Strategies

CALLING ALL

Are you interested in making a lasting impact on the future of medical reserach?

TAKE OUR SURVEY >>>

Xour expertise matters in shaping the future of clinical trials. Take a brief survey to share your journey and insights on promoting diversity and inclusivity in research. Together,

let's make a difference! Take the survey>>



Creating Educational Resources on DEI & Clinical Trials



Submission of Manuscripts to Blood



Annual Meeting Content



Integrating DEI into Study Design at the ASH Clinical Research Training Institute

- 1. CRTI is a unique year-long education and mentoring program
- 2. Focused on the foundation, methodologies, and application of patient-oriented clinical research
- 3. Geared towards hematology fellows and junior faculty at academic medical centers
- 4. Incorporating DEI principles as new addition to the curriculum
- 5. Goal: To produce leaders armed with ideas for clinical hematology research and the tools and resources to make their ideas a reality





Request for Demographic Information in Clinical Trial Studies Submitted to ASH

- Demographic Information (sex, gender, race, ethnicity, age, disability, or other relevant factors of enrolled subjects) will be requested of individuals submitting and/or presenting on clinical studies:
 - ASH Events (including relevant Annual Meeting invited program sessions, submitted abstracts, and oral and poster presentations; small scientific and educational meetings).
 - ASH Publications
- If demographics are not available, the investigator will be asked to describe the limitations that prevented these data from being collected.



Questions

