



AMERICAN SOCIETY OF HEMATOLOGY

2021 L Street, NW, Suite 900, Washington, DC 20036-4929 **ph** 202.776.0544 **fax** 202.776.0545 **e-mail** ASH@hematology.org

April 26, 2024

2024

President

Mohandas Narla, DSc
New York Blood Center Enterprises
310 E 67th Street
New York, NY 10065
Phone 212-570-3056

President-Elect

Belinda Avalos, MD
Atrium Health Levine Cancer Institute
1021 Morehead Medical Drive
Building I, Suite 3000
Charlotte, NC 28204
Phone 980-442-2000

Vice President

Robert Negrin, MD
Stanford University
CCSR Building, Room 2205
269 W. Campus Drive
Stanford, CA 94305
Phone 650-723-0822

Secretary

Cynthia Dunbar, MD
NHLBI/NIH
Translational Stem Cell Biology Branch
Building 10-CRC, Room 5E-3332
10 Center Drive
Bethesda, MD 20892
Phone 301-402-1363

Treasurer

Joseph Mikhael, MD, FRCPC, MEd
Translational Genomics Research Institute
City of Hope Cancer Center
445 N. Fifth Street
Phoenix, AZ 85004
Phone 602-343-8445

Councillors

Christopher Flowers, MD, MS
H. Leighton Grimes, PhD
Mary Horowitz, MD
Charlotte Niemeyer, MD
Sarah O'Brien, MD, MSc
Betty Pace, MD
Jamile Shammo, MD
Wendy Stock, MD, MA

Executive Director

Martha Liggett, Esq.

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: FDA Draft Guidance: *Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products* ([FDA-2016-D-3561](#))

Dear Dr. Califf:

The American Society of Hematology (ASH) appreciates the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) in response to the Agency's draft guidance on the *Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products* ([FDA-2016-D-3561](#)).

ASH represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematology (non-malignant) conditions like sickle cell disease (SCD). In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the fields of stem cell biology, transfusion medicine, and gene and cell therapies. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients. ASH has a longstanding commitment to combating inequities in healthcare and research; and in 2021, the Society released a [Statement on Addressing Diversity, Equity, and Inclusion in Hematology Research, Practice, and Training](#); it is with this lens that we provide the following comments.

ASH commends the FDA for releasing this draft guidance. ASH members work on diseases that effect people of all races and ethnicities, and some, like SCD and multiple myeloma, primarily impact Black or African Americans. Ensuring clinical trials are reflective of the epidemiology of the disease and inclusive of populations to benefit from the therapeutic under investigation is critical to ensuring that trial results are generalizable, interpreted accordingly, and overall helps build trust in the trial results especially for historically underserved populations. This is also important especially as we enter a new era of precision medicine and gene and cell therapy products.

Overall, the Society is grateful for the work done to update the previous 2016 guidance. While we recognize that much of the underpinning regulatory framework for the guidance is generated by the Office of Management and Budget (OMB), our comments here are directed only at the FDA. We also appreciate the recent revisions to the OMB Statistical Policy Directive 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), and encourage the FDA to quickly update this guidance to reflect the new categories and concepts contained in the final rule.

SECTION SPECIFIC COMMENTS:

Section III. Collecting Race and Ethnicity Data in Clinical Trials and Clinical Studies

- The Society appreciates FDA's clarification in the guidance that race is a socio-political construct and not a biological one, and that self-reporting of race and/or ethnicity could be unreliable as such. Given recent cultural trends, the Society asks the Agency to state the purpose of collecting this information more clearly in the guidance so that sponsors have a broader understanding of its usefulness. In addition, while representation of different races and ethnicities is important to ensuring fair access to trials and making sure study results can be generalizable, we believe that this type of demographic data is most reliable when combined with genomic data. Furthermore, the U.S. population is continuing to evolve and becoming more heterogenous in its make-up with more individuals being multiracial. Because of these challenges, we recommend that the FDA, (a) leverage the expertise of geneticists (especially those focused on ancestry genetics) to inform revisions to this draft guidance; and (b) add language to the guidance on how to incorporate genomic data when race and ethnicity data are also being collected. In addition, we hope the Agency considers the Society as a resource both in incorporating genomics as well as articulating the importance of collecting this information. ASH's Subcommittee on Precision Medicine, a group with expertise and interest in genetics and diversity, has been working on these issues, and they would be pleased to serve as a resource to the Agency.

Section III B. Self-Reporting

- While the Society believes that the inclusion of genomic data will capture patterns of genetic variation more effectively than labels of race and ethnicity, we recognize that this data is not typically collected as a part of patient records. In lieu of that data, the next best mechanism to ensure diverse representation of patients in trials is to collect demographic data from the patient themselves. Thus, the Society agrees with the recommendation that investigators and/or other clinical staff verify the accuracy of electronic health record (EHR) information with study participants. Our members recognize that EHRs can contain incorrect information, and this proposed verification step is important to ensure the highest possible accuracy within this framework. One recommendation the Society has is that the OMB definitions of race categories be provided in the guidance, so that individuals having these conversations can provide the necessary context to subjects. This is also necessary to ensure that sponsors are meeting FDA's expectations of enrolling participants who reflect the demographics of the disease under investigation.

Section III E. Use of More-Detailed Racial and Ethnic Categories

- Additionally, relating to the FDA's guidance on the use of more detailed racial and/or ethnic categories, particularly for international studies, the Society recommends that the Agency again consider the consequences of this guidance for creating accurate data. Similar to what is occurring in the United States, the global population is becoming more heterogenous, and cultural understanding of race and/or ethnicity is evolving. With genomic information becoming more available and scientifically rigorous, there are likely areas of opportunity for sponsors to identify more specific racial and/or ethnic categories beyond self-identification, which can further the understanding of products being developed. As OMB SPD 15 is an ever-evolving directive, the FDA can take the directive a step further by creating guidance that asks sponsors to leverage existing resources to provide more information about race and/or ethnicity.

Section IV. Presentation of Race and Ethnicity Data in Clinical Trials and Clinical Studies

- While we believe it is important to capture race and/or ethnicity data on product labels for reasons of transparency (i.e., clarity on the trial study population) and education of patients and their clinicians, we understand that it can also be complicated since listing this information could have unintended consequences such as limiting access to these therapies for certain patient groups. Thus, the Society asks that the Agency carefully consider ways to include this information. Our membership would like to make itself available to the Agency as it thinks of ways to achieve this goal while maintaining patient access to products.

ASH appreciates the opportunity to provide these comments and looks forward to any response you might have. 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 Deputy 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