

Lauren K. Roth
Associate Commissioner for Policy
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Docket No. FDA-2016-D-3561

Associate Commissioner Roth:

Thank you for the opportunity to submit comments to the Food and Drug Administration's (FDA) draft guidance "Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products." As the leading organization of professionals working with healthcare data and protected health information (PHI), the American Medical Informatics Association (AMIA) supports the Administration's efforts to standardize collection and reporting race and ethnicity data in clinical studies and clinical trials for FDA-regulated medical products.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across care settings and patient populations.

Dignity and Respect for All People

First, we steadfastly support the following [Governing Principle](#) from the Federal Interagency Technical Working Group on Race and Ethnicity Standards:

Respect individuals. Respect for individual dignity should guide the processes and methods for collecting data on race and ethnicity; respondent self-identification should be facilitated to the greatest extent possible.

AMIA suggests that not only is self-identification (not by observer) the gold standard, but self-reporting also (not by proxy) should be facilitated to the greatest extent possible. Additionally, emphasis must be placed on confidentiality of data in all settings, especially among data providers who collect race and ethnicity data that is then sent to a federal agency.

FDA's Standardized Approach for Collecting Race and Ethnicity

AMIA commends FDA's expectations for, and recommendations on, use of a standardized approach for collecting and reporting race and ethnicity data, but perhaps the standards used do not capture the population holistically.

The Draft Guidance recommended approach is based on:

- Office of Management and Budget (OMB) Statistical Policy Directive No. 15 (Policy Directive 15) and was developed in accordance with section 4302 of the Affordable Care Act
- Health and Human Services (HHS) Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status
- Food and Drug Administration Safety and Innovation Act (FDASIA) Section 907 Action Plan

AMIA recommends to include the [CDC Race and Ethnicity Code Set Version 1.2 \(July 2021\)](#) as another standard to fully capture a participants' race and ethnicity. This CDC Code Set allows for further mapping of an individual's relationship to their ethnicity and race by allowing to select their ethnicity group with Hispanic or Latino and Race Category with more granularity.

MENA Population

I would like to bring the FDA's attention to the report from the [2020 Census](#). The reports highlight that 3.5 million people (1% of the US population) identify as Middle Eastern and North African (MENA). Based on current Federal standards, these people are categorized as "White". However, when offered the "Other" option in data collection, they often choose that option to specify their race as "MENA". Recent studies, such as [Middle Eastern and North African Americans may not be perceived, nor perceive themselves, to be White](#), have highlighted the importance of including the MENA category.

The FDA guidance states "FDA recommends offering an option of selecting one or more racial designations or additional subgroup designations. Recommended forms for the instruction accompanying the multiple response questions are "Mark one or more" and "Select one or more.""

However, it does not explicitly mention the "Other" or "MENA" category. As a result, individuals of MENA descent may be forced to choose "White," which could falsely represent them. Not only may they have different biological responses to drugs, but their life experiences, which can impact study results, may also differ from those identified as White.

By explicitly including the MENA category or providing an "Other" option with the ability to specify, the FDA can ensure more accurate representation and data collection for this population group. This suggestion would align with the guidance's recommendation to provide flexibility in characterizing race and ethnicity when appropriate.

Recommended Question Format

AMIA created an example recommended question format for the FDA to include in the finalized guidance document.

Question 1 (answer first): Are you Hispanic/Latino or not Hispanic/Latino?

- Yes
 - If yes, choose from the following:

- Spaniard
- Mexican
- Central American
- South American
- Latin American
- Puerto Rican
- Cuban
- Dominican
- Andalusian
- Asturian
- Castillian
- Catalanian
- Balearic Islander
- Gallego
- Valencian
- Canarian
- Spanish Basque
- Mexican American
- Mexicano
- Chicano
- La Raza
- Mexican American Indian
- Costa Rican
- Guatemalan
- Honduran
- Nicaraguan
- Panamanian
- Salvadoran
- Central American Indian
- Canal Zone
- Argentinean
- Bolivian
- Chilean
- Colombian
- Ecuadorian
- Paraguayan
- Peruvian
- Uruguayan
- Venezuelan
- South American Indian
- Criollo
- No

Question 2 (answer second): What is your race? More than one choice is acceptable.

Recommended choices:

- American Indian or Alaska Native
 - Please Provide Tribal Nation: (Text Box)
- Asian
 - Asian Indian
 - Bangladeshi
 - Bhutanese
 - Burmese
 - Cambodian
 - Chinese
 - Taiwanese
 - Filipino
 - Hmong
 - Indonesian
 - Japanese
 - Korean
 - Laotian
 - Malaysian
 - Okinawan
 - Pakistani
 - Sri Lankan
 - Thai
 - Vietnamese
 - Iwo Jiman
 - Maldivian
 - Nepalese
 - Singaporean
 - Madagascar
- Black or African American
 - Black
 - African American

- African
- Botswanan
- Ethiopian
- Liberian
- Namibian
- Nigerian
- Zairean
- Bahamian
- Barbadian
- Dominican
- Dominica Islander
- Haitian
- Jamaican
- Tobagoan
- Trinidadian
- West Indian
- Native Hawaiian or Other Pacific Islander
 - Polynesian
 - Native Hawaiian
 - Samoan
 - Tahitian
 - Tongan
 - Tokelauan
 - Micronesian
 - Guamanian or Chamorro
 - Guamanian
 - Chamorro
 - Mariana Islander
 - Marshallese
- Palauan
- Carolinian
- Kosraean
- Pohnpeian
- Saipanese
- Kiribati
- Chuukese
- Yapese
- Melanesian
- Fijian
- Papua New Guinean
- Solomon Islander
- New Hebrides
- Other Pacific Islander
- Middle Eastern or North African
 - Assyrian
 - Egyptian
 - Iranian
 - Iraqi
 - Lebanese
 - Palestinian
 - Syrian
 - Afghanistani
 - Israeli
 - Arab
- White

Future Outlook

There are clear unattended consequences with biases of data and by standardizing the collection of race and ethnicity could attempt to alleviate some of those concerns. This paradigm needs rethinking because it is becoming less significant when looking toward the future. There are other meaningful ways to capture relevant information about participants in clinical trials. The inclusivity of social determinants of health will depict a better understanding of individuals and their environment when analyzing clinical trials. Clinical trials are rooted in scientific methodology and must emphasize demographics beyond race and ethnicity to combat these scientific challenges. For example, phenotypes and genomic sequencing testing can gather information to be more scientific and better represent individuals. This is a step in the right

direction, but in the era of biomedical informatics, the evolution for collection demographic information of participants in clinical trials and studies must look at other factors further than race and ethnicity to assure data quality. Informaticists will allow for better advancement in identity for clinical trials and studies for FDA-regulated medical products.

If you have questions or require additional information, please contact AMIA's Vice President of Public Policy, Reva Singh, at rsingh@amia.org.