

April 29, 2024

Robert M. Califf  
Commissioner  
Food and Drug Administration,  
Department of Health and Human Services,  
Attention: FDA-2016-D-3561  
10001 New Hampshire Ave.,  
Hillandale Building, 4th Floor,  
Silver Spring, MD 20993-0002

**SUBMITTED ELECTRONICALLY VIA**

<https://www.regulations.gov>

**Re: Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for Food and Drug Administration-Regulated Medical Products; Draft Guidance for Industry; Availability (FDA-2016-D-3561)**

Dear Commissioner Califf:

The American Geriatrics Society (AGS) appreciates the opportunity to comment to the Food and Drug Administration (FDA) on the draft guidance for the Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products. AGS is a nationwide not-for-profit organization dedicated to improving the health, independence, and quality of life of all older adults. Our 6000+ members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician assistants, pharmacists, internists, and others who are pioneers in advanced-illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons. We provide leadership to healthcare professionals, policymakers, and the public by implementing and advocating for programs in clinical care, research, professional and public education, and public policy.

AGS' vision is a nation where we can all have a fair and equitable opportunity to contribute to our communities and maintain our health, safety, and independence as we age. AGS believes in a just society – one where we all are supported by and able to contribute to communities and where ageism, ableism, classism, homophobia, racism, sexism, xenophobia, and other forms of bias and discrimination no longer impact healthcare access, quality, and outcomes for older adults and their caregivers. We believe discriminatory policies—especially when they are perpetuated across the healthspan and lifespan—can have a negative impact on public health for us all as we age. We strongly support the steps FDA is taking to ensure a standardized approach in collecting race and ethnicity data in submissions for clinical studies and trials for FDA-regulated medical products with the goal of ensuring the safety and efficacy of all products in all populations.

**GENERAL COMMENTS**

AGS commends FDA for maintaining the self-report recommendation as a standard for collection of data on race and ethnicity. In addition to prioritizing self-report, we appreciate the explicit callout that using

race or ethnicity from health records is not recommended and that accuracy of the information should be confirmed with the study participant.

Studies have shown that all too often clinical trials lack racial, ethnic, and gender diversity.<sup>1,2</sup> We believe that part of the key goal of collecting disaggregated data is to provide personalized care with cultural humility. By capturing richer data, we may also weave a richer tapestry honoring individual subgroup cultures and traditions without eliminating cultural expressions. Furthermore, the compositions of the U.S. populations, and thus study populations, will inevitably change over time. AGS appreciates FDA's focus on ensuring study populations adequately reflect the larger population for which treatments are being developed and we see the draft guidance as an important tool for ensuring we can detect key differences in clinical effectiveness or safety. We encourage FDA to consider steps to address the lack of inclusion of older adults in clinical trials as a part of its ongoing efforts to improve the data it has available when assessing the safety and efficacy of new drugs and devices. An analysis of research found that 33 percent of federally funded clinical trials had an upper age limit, with one-quarter of the studies not allowing people 65 and older to participate.<sup>3</sup>

AGS also agrees with the recently updated standard from the Office of Management and Budget (OMB)<sup>4</sup> requiring collection of detailed race and ethnicity data where possible unless it is determined that the potential benefit of the detailed data would not justify the additional burden or risk to confidentiality. *Line 99* implies that another purpose for this level of data collection is to look for population-specific signals, however, there is minimal additional guidance on how to use the data for this purpose. In addition to citing that detailed data may only apply to specific situations like clinical trials enrolling participants outside the U.S., AGS encourages FDA to make a stronger justification for collecting more granular race and ethnicity data and expand on how to use this detailed data in analysis in appropriate ways. For example, there are health-related risk factors such as smoking and disability that vary among racial/ethnic groups and influenced by social drivers of health.<sup>5</sup> We also recommend considering the Data Analysis and Study Interpretation section included in the National Institutes of Health (NIH) "Inclusion Across the Lifespan: September 2, 2020 Workshop" as well as the "Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals"<sup>6</sup> to support informing an expanded rationale for collecting detailed data.

Given the increasing diversity among older people and rapid growth of the older population,<sup>7</sup> it is pivotal to ensure representative study populations that are inclusive of older adults from diverse backgrounds. When medical evidence is generated from study populations that do not resemble most of the people who ultimately will be the ones treated, we miss opportunities to learn how to optimize health and

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<sup>1</sup> Flores LE, et al. Assessment of the inclusion of racial/ethnic minority, female, and older individuals in vaccine clinical trials. *JAMA Netw Open*. 2021;4(2):e2037640. doi:[10.1001/jamanetworkopen.2020.37640](https://doi.org/10.1001/jamanetworkopen.2020.37640)

<sup>2</sup> Loree JM, et al. Disparity of race reporting and representation in clinical trials leading to cancer drug approvals from 2008 to 2018. *JAMA Oncol*. 2019;5(10):e191870. doi:[10.1001/jamaoncol.2019.1870](https://doi.org/10.1001/jamaoncol.2019.1870)

<sup>3</sup> Lockett J, Sauma S, Radziszewska B, Bernard MA. Adequacy of inclusion of older adults in NIH-funded phase III clinical trials. *J Am Geriatr Soc*. 2019;67(2):218-222. doi:[10.1111/jgs.15786](https://doi.org/10.1111/jgs.15786)

<sup>4</sup> 89 Fed. Reg. 22182 (March 29, 2024)

<sup>5</sup> Allore H, Shakhnovich V. National Institutes of Health. Inclusion Across the Lifespan-II Workshop Report (Topic 4: Data Analysis and Study Interpretation). Published December 10, 2020. Accessed April 22, 2024. <https://grants.nih.gov/sites/default/files/IAL-II-Workshop-Report.pdf>

<sup>6</sup> Flanagan A, Frey T, Christiansen SL. Updated guidance on the reporting of race and ethnicity in medical and science journals. *JAMA*. 2021;326(7):621-627. doi:[10.1001/jama.2021.13304](https://doi.org/10.1001/jama.2021.13304)

<sup>7</sup> Administration for Community Living. 2021 Profile of Older Americans. Published November 2022. Accessed April 22, 2024. [https://acl.gov/sites/default/files/Profile%20of%20OA/2021%20Profile%20of%20OA/2021ProfileOlderAmericans\\_508.pdf](https://acl.gov/sites/default/files/Profile%20of%20OA/2021%20Profile%20of%20OA/2021ProfileOlderAmericans_508.pdf)

resilience and avoid suffering. It is critically important to eliminate avoidable differences in health outcomes, as well as consider and mitigate unintended consequences of changes in guidance.

## **SPECIFIC COMMENTS**

AGS applauds FDA for explicitly recognizing that differences in response by race or ethnicity to medical products may be due to both extrinsic factors (e.g., diet, environmental exposure, socioeconomic status, culture) and intrinsic factors (e.g., genetics, metabolism, elimination, skin pigmentation) as well as the potential interactions of these factors.

We appreciate the inclusion of multiple subgroup designators for Asian as well as Native Hawaiian or Other Pacific Islanders categories (Lines 216-226). We are concerned, however, that the Black or African American choice is limited in scope without suggested subgroup designators. A fundamental challenge with race and ethnicity designation is the likelihood of leaving individuals out. There may be additional environmental and genetic factors that could be further elucidated if the guidance specified collection of more granular data on Black, African American, African, Afro-Caribbean, and Caribbean populations. We also encourage adding the new Middle Eastern or North African (MENA) category which is part of the updated OMB standards per Statistical Policy Directive No. 15 (SPD 15)<sup>4</sup> for maintaining, collecting and presenting race/ethnicity data across federal agencies. This will be important for adequate representation of individuals in these groups as there is currently none. We also recommend additional categories for optimal disambiguation for Central American (Costa Rican, Guatemalan, Honduran, Salvadorian, etc.) and South American (Argentinean, Bolivian, Chilean, etc.). AGS believes this is an opportunity to include subcategories beyond the minimum standard for all racial designators as well as options to indicate “other” or mixed race/ethnicity.

While the increased granularity for Hispanic or Latino ethnicity is also appreciated, there is no option for Spanish origin nor a sufficient rationale for separating Hispanic or Latino/Not Hispanic or Latino as the only ethnic designator. Further, Hispanic ethnicity is not recognized outside the U.S. and will be absent for data from many countries that are sites for new drug or therapeutic evaluations which raises the question of its importance with regard to the FDA’s mission. We recommend FDA to elaborate on the Ethnicity Data Standard (Lines 201-208).

In addition, the ordering of categories for detailed racial groups does not follow the new OMB reporting guidelines, listing White as the first category, and could be alphabetized as in the updated SPD 15. Ideally, there would be more uniformity as this will require different types of disambiguation/data collection potentially across activities with one exception – maintaining separate categories for race/ethnicity that promotes identification of Black and Indigenous races among Hispanic individuals, which has been an area of concern among many in these groups.

AGS is pleased that the FDA has proposed to set standards for collecting race and ethnicity data in clinical trials, which we believe are an important incremental step to ensure efficacy and safe of all FDA-regulated products. AGS strongly supports more representative inclusion in clinical trials and studies to support generalizability to the target populations for which products are being developed and recommends that FDA require greater granularity in sociodemographic factors for subpopulations particularly in race and ethnicity as well as age. FDA reporting of adults 65 and older ignores the major changes in drug metabolism and responses that occur across the older age span—from 65 to very old

ages (80 and older)—leading to underrepresentation of older adults who are very old in clinical trials.<sup>8</sup> Given the increasing prevalence of many diseases among the growing population of those older than 65, we believe that age, in addition to race and ethnicity, should be reported meticulously to detect clinically important differences across and between older age subgroups, as well as the inclusion of very old adults in clinical trials who would likely receive a large portion of medications, once approved.

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Thank you for taking the time to review our feedback and recommendations. For additional information or if you have any questions, please do not hesitate to contact, Anna Kim at [akim@americangeriatrics.org](mailto:akim@americangeriatrics.org).

Sincerely,

A handwritten signature in black ink that reads "Nancy E. Lundebjerg". The signature is written in a cursive style with a large, stylized initial "N".

Nancy E. Lundebjerg, MPA  
Chief Executive Officer

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<sup>8</sup> Lau SWJ. History of FDA Guidance on Drug Evaluation in Older Adult Patients. Virtual Presentation at Roadmap to 2030 for New Drug Evaluation in Older Adults Public Workshop: March 23, 2021. Accessed April 26, 2024. <https://www.fda.gov/media/147956/download>