April 29, 2024

Lauren K. Roth
Associate Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments on Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products, Federal Register Docket FDA-2016-D-3561

Dear Ms. Roth,

FasterCures is pleased to respond to the Request for Comments on the FDA Draft Guidance for the Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products. FasterCures firmly believes in the importance of collecting accurate and comprehensive data on the racial and ethnic composition of the American population. These data are crucial for improving the quality and relevance of clinical and biomedical research.

As a nonprofit, nonpartisan think tank, the Milken Institute believes in the power of capital markets to solve urgent social and economic challenges to improve lives. At the heart of the Institute's work is the idea that societies prosper if they have an educated, healthy workforce, open and efficient capital markets, and effective social institutions. The Milken Institute's FasterCures is driven by a singular goal: to save lives by speeding scientific advancements to all patients. With an independent voice, FasterCures is working to build a system that is effective, efficient, and driven by a clear vision: working with our partners to build a patient-centric system where science is accelerated, unnecessary barriers are overcome, and lifesaving and life-enhancing treatments get to those who need them as rapidly and as safely as possible.

Since 2020, FasterCures has focused on health equity across the biomedical research ecosystem. This includes addressing gaps in standard data collection processes, particularly regarding the collection of accurate race and ethnicity data.

In light of recent policy developments and changes introduced by the Census Bureau regarding the collection of demographic information,[1] the urgency of our response is underscored. These changes reflect a growing recognition of the critical role that accurate data collection plays in informing equitable biomedical research practices and addressing disparities in health outcomes.

The following recommendations focus on the main priority areas for collecting race and ethnicity data in clinical trials. They aim to enhance inclusivity, accuracy, and effectiveness in clinical research practices, which can ultimately advance health equity and improve patient outcomes.

- Expand existing question formats to accommodate more open-ended responses encompassing diverse racial and ethnic groups.
- Provide clearer guidance on when detailed racial and ethnic categorizations are appropriate in clinical trial data collection to improve accuracy in reporting.
- Address barriers inhibiting accurate data collection on race and ethnicity, ensure equitable data collection practices, and increase the integration of real-world data to inform regulatory decisions and promote diversity in drug development.

I. Expansion of Existing Question Formats

FasterCures supports the Biden-Harris Administration's newly approved proposals guiding data collection for the next US census and future government forms. Additionally, we recommend a revision of the questions regarding race and/or ethnicity. Specifically, we recommend:

1. Align more closely with the administration's new approval for clinical trials in FDA-regulated medical products to replace the two-question format in the current draft guidance with a singular, more open-ended question that encompasses both race and ethnicity (see 2, below).
2. Combine the race and ethnicity questions to allow respondents to select more than one category or multiple categories.
    - For example, the question in the current draft guidance asks, "*Are you Hispanic or Latino*?" This question in Section 3C would thus be absorbed into this question.
3. Replace the existing "Other" categories, when possible, and replace them with a field in which respondents can self-identify through write-in fields or an open comment box.
4. In reference to Section D, include, at minimum, choices for race and/or ethnicity, such as "Middle Eastern or North African" following the shift in the US government's definition of "White" for ethnicity.

II. Increased Granularity in Race and Ethnicity Categorization

The draft guidance states that "*where appropriate, FDA recommends using more-detailed categories by geographic region to provide sponsors flexibility in characterizing race and ethnicity.*" We recommend that the agency provide more clarity and guidance on determining which geographic regions would require more granularity in data collection. Additional guidance will help sponsors determine when more detailed characterizations may be appropriate to enhance the collection of demographic data on clinical trial participants.

The collection of accurate data on race and ethnicity is crucial for robust reporting requirements to support an equitable clinical trial ecosystem. Currently, many clinical trials collect data on race and ethnicity using broad categories that may not accurately capture the diversity within these populations. For example, grouping all Asian Americans together without distinguishing among different ethnicities, such as Chinese, Indian, or Filipino, overlooks the unique health needs, experiences, and challenges of each subgroup. Alignment with recent updates from the Office of Management and Budget to Statistical Policy Directive No. 15 would promote data standardization.[2]

To ensure that clinical trials are truly representative and equitable, it is imperative to collect and analyze data at a more granular level. This includes disaggregating data by specific racial and ethnic subgroups, as well as considering other relevant factors such as socioeconomic status, language proficiency, and geographic location. In alignment with current data standards for drug and biological product submissions containing real-world data, sponsors should select an appropriate mapping approach for race and ethnicity that best fits the characteristics of the data and the nature of the study.

III. Addressing Barriers to Promote Accuracy in Data Collection

While the current draft guidance lays a foundation underscoring the need for representative data and reporting, further action is necessary to ensure data disaggregation based on racial and ethnic subgroups at clinical trial sites. For example, the state government of New York passed Assembly Bill A6896A into law in December 2021.[3] The law requires state agencies to include disaggregated response options for Asian Americans, Native Hawaiian, and Pacific Islander groups in demographic questionnaires, which serves as an effort to systematically document the inherent diversity of the state's fastest-growing racial group. Disaggregating data allows researchers to better understand the unique health needs and challenges different communities face, leading to more targeted interventions and improved outcomes.

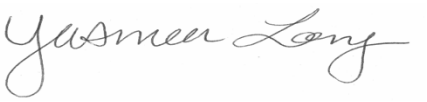
Existing data collection models used during clinical trials are not sufficiently powered to detect nuances in enrollment by ethnicity.[4] Leveraging real-world data and real-world evidence where appropriate may help overcome this barrier. Real-

world data (RWD) and real-world evidence (RWE) offer valuable opportunities to enhance the accuracy and inclusivity of data collection in clinical trials. By increasing the use of these data sources, researchers can improve the representativeness of clinical trial populations, identify and address disparities in treatment outcomes, and enhance the generalizability of study findings to diverse patient populations.

1. FDA could address barriers inhibiting accurate data collection on race and ethnicity in their reporting requirements across all therapeutics, devices, and biologics.

In conclusion, FasterCures emphasizes the importance of accurate data collection on race and ethnicity to support equitable clinical trial practices, including its design and execution. Our recommendations serve an instrumental purpose in advancing health equity and ensuring that all patient populations are adequately represented in biomedical research. We urge careful consideration and implementation of these recommendations to enhance the inclusivity and effectiveness of clinical research.

Sincerely,



Yasmeen Long, MA
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Milken Institute

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[1] https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and

[2] https://www.census.gov/newsroom/blogs/random-samplings/2024/04/updates-race-ethnicity-standards.html

[3] https://www.nysenate.gov/legislation/bills/2021/A6896

[4] https://milkeninstitute.org/report/diversity-clinical-trials-call-action