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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability, Docket No. FDA-2016-D-0734

The Association of American Medical Colleges (AAMC) is pleased to have this opportunity to offer comments related to evaluating and reporting on age, race and ethnicity sub-group data in medical device clinical studies. The AAMC is a not-for-profit association representing all 145 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences.

The AAMC recognizes that health and health care disparities arise from conditions in which people are born, live, work and age. These disparities are persistent in certain populations such as racial/ethnic subgroups, the elderly, veterans, individuals from lower socioeconomic status backgrounds, and LGBT and rural populations. Research has shown that these disparities in health can, in part, be created or exacerbated when the diffusion of medical knowledge and innovation is not equitable. Easy, equitable access to current, useful information related to risks, benefits and proper use of medical products and devices is essential to address this mechanism.

AAMC therefore applauds and supports the FDA's efforts to gather, report and evaluate age, race and ethnicity data in medical device clinical studies. Without such information, it is impossible to detect group differences in treatment outcomes and subsequently report appropriate information regarding risks and benefits of medical device use to specific populations.

While the FDA is correct in noting the importance of valid, robust age, race and ethnicity data collection in service of producing an "unbiased estimate of treatment effect in the general population", the importance of such data collection is even greater for subgroups in the United States who disproportionately suffer from morbidity and mortality. Presenting analyses specific

to racial and ethnic minorities and varying age groups can help ensure generalizability of findings, increased uptake of medical treatments and devices by underserved communities, and, when purposefully and appropriately disseminated to patients, providers and communities, can decrease health and health care inequities.

The AAMC offers the following recommendations for this important effort:

1. Although FDA guidance documents do not establish legally enforceable responsibilities, **we urge FDA to strengthen their encouragement of race, ethnicity and age data collection** in the following ways:

    a. **Suggest *all* studies consider collection of race, ethnicity and age data, not solely those for which subgroup differences are anticipated**. Given the relative lack of research investigating subgroup differences in medical device use and related outcomes, it is very likely that unanticipated differences will arise. To build the evidence base needed to anticipate group differences, FDA should encourage all researchers ensure adequate diversity in their study sample.

    b. Suggest scientists ensure methodological rigor in recruitment of racial and ethnic minorities and participants from diverse age groups by requesting that **sponsors present sample size calculations when clinically meaningful differences in safety, effectiveness, (probable benefit, for HDEs), or benefit-risk profile are expected or possible across these groups. Sponsors should demonstrate that their studies are sufficiently powered to detect subgroup differences.** Without adequate statistical power, researchers are likely to miss important subgroup differences even when they exist.

    c. Rather than requesting sponsors collect race and ethnicity data according to FDA's 2005 guidance document *Collection of Race and Ethnicity Data in Clinical Trial*s, **urge sponsors to collect data with the granularity required by Section 4302 of the Affordable Care Act (ACA)**. While the ACA's categories can be aggregated to reflect FDA's 2005 guidance, they allow for more specific group differences to be examined provided adequate sample sizes. Race/ethnicity categories such as "Asian American" are composites of many smaller subgroups (e.g. Chinese Americans, Korean Americans, etc.) between which there might also be differences in utilization of and outcomes related to medical devices. Such differences will be missed if sponsors categorize according to the 2005 guidance.

2. In previous letters to FDA,[1,2,3] the AAMC has encouraged **community and patient engagement** as a means to enhance recruitment efforts as well as to maximize communication of important health information, and dissemination of study results - particularly those related to subgroup differences. While we appreciate the discussion in the current draft guidance of various barriers to enrollment and how sponsors can plan for diverse study recruitment, AAMC suggests FDA offer more specific guidance on the activities, tactics and strategies – developed in partnership with patients and communities – that will yield success. For example:

    a. **Identify communication pathways that will be effective to reach patient populations** who may not benefit from the infrastructure and technologies that facilitate communication through electronic means and social media.

    b. **Work with minority health professional organizations and advocacy groups to support effective communication and outreach to racial/ethnic subpopulations**, and couple the efforts described in FDA's outreach strategy on medical information with the efforts to engage patients in the regulatory process.

    c. While issues of low literacy or limited English proficiency may make engagement with certain populations more difficult, to exclude those patients from research and dissemination efforts risks cutting out critical perspectives. **The FDA should develop specific outreach to engage non-English speakers and those with low literacy.**

    d. As the FDA moves forward with these strategies for increasing patient and community participation, the **AAMC fully supports the evaluation and assessment of any new efforts to determine their effectiveness**. It is important to keep in mind the goals of patient engagement for the FDA, and to establish a definition for successful patient involvement. An ideal outcome should not only include an end result of medical products which meet the needs of a diverse patient population, but also the development of a broad community of patients who are active participants in medical product development. This will in turn facilitate dissemination efforts and outreach to populations that would benefit from information about those medical products.

AAMC applauds FDA's efforts to enhance collection of age group and race/ethnicity data in medical device studies, however, there are other populations such as veterans, persons with disabilities, and LGBT and rural communities who are equally burdened by health disparities and are often underrepresented in clinical trials. We encourage the FDA to broaden its current efforts to include all populations who experience disproportionate morbidity and mortality.

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[1] AAMC Comment Letter, September 5, 2013,(available at https://www.aamc.org/download/353860/data/aamccommentsonfdasreportonensuringaccesstoadequateinformationon.pdf)
[2] AAMC Comment Letter, November 20, 2013,(available at https://www.aamc.org/download/362116/data/aamclettertofdaondemographicsubgroupdata.pdf)
[3] AAMC Comment Letter, April 16, 2015 (available at https://www.aamc.org/download/430468/data/aamcsubmitslettertofdaonpublichealthconcernsofdemographicsubgro.pdf)

The AAMC appreciates the opportunity to comment to the FDA on this issue and would be happy to provide any further information which would be of use to the FDA and HHS as they prepare the final guidance. Please contact me or my colleague Philip M. Alberti, Ph.D. (palberti@aamc.org) with any questions about these comments.

Sincerely,

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