



June 10, 2022

The Honorable Robert Califf
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: FDA-2021-D-0789; Draft Clinical Trials Guidance for Industry

Dear Commissioner Califf:

On behalf of the American Academy of Family Physicians (AAFP) and the 127,600 family physicians and medical students across the country we represent, I am pleased to submit these comments regarding the Food and Drug Administration's (FDA) [Federal Register](#) notice seeking comments on [draft guidance](#) for industry entitled "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry."

The AAFP truly appreciates the Agency's commitment to clinical trial diversity and to improving underrepresented communities' access and opportunity to participate in clinical trials. The AAFP [supports](#) the inclusion of diverse populations in clinical trials, surveys, and other research as an [essential tool](#) to understand better the drivers of health disparities and their impact on health, whether it be increased risk for disease or differences in treatment efficacy.

The draft guidance recommends that sponsors of medical products develop and submit a Race and Ethnicity Diversity Plan to the agency early in clinical development, based on a framework outlined in the guidance. The AAFP strongly supports the majority of provisions in the draft guidance. This guidance provides valuable information for the biopharmaceutical industry and will encourage them increase diversity in clinical trials and develop medical products and devices that family physicians and their patients rely on for high-quality healthcare services. Encouraging the adoption of practices to increase diversity in clinical trials is essential to developing the most effective medical products and devices, as well as advancing health equity. The AAFP is pleased to submit the following feedback and additional recommendations on the draft guidance for the FDA's consideration.

1. Recommend that sponsors include demographic information on clinical trial investigators and site staff.

The current draft guidance details the recommended categories for a race and ethnicity diversity plan. The categories include an overview of the disease or medical device, goals and plans to enroll diverse trial participants, and status of diverse enrollment plan outcomes where applicable. This recommended information is an important step towards ensuring clinical trials are representative of the populations impacted by the research.

STRONG MEDICINE FOR AMERICA

President
Sterling Ransone, MD
Deltaville, VA

President-elect
Tochi Iroku-Malizi, MD
Islip, NY

Board Chair
Ada Stewart, MD
Columbia, SC

Directors
Andrew Carroll, MD, Chandler, AZ
Steven Furr, MD, Jackson, AL
Teresa Lovins, MD, Columbus, IN
Jennifer Brull, MD, Plainville, KS
Mary Campagnolo, MD, Bordertown, NJ
Todd Shaffer, MD, Lee's Summit, MO

Gail Guerrero-Tucker, MD, Thatcher, AZ
Sarah Nosal, MD, New York, NY
Karen Smith, MD, Raeford, NC
Samuel Mathis, MD (New Physician Member), Galveston, TX
Amanda Stisher, MD (Resident Member), Owens Cross Roads, AL
Amy Hoffman (Student Member), State College, PA

Speaker
Russell Kohl, MD
Stilwell, KS

Vice Speaker
Daron Gersch, MD
Avon, MN

Executive Vice President
R. Shawn Martin
Leawood, KS

However, research suggests that patients experience a higher quality of care when they have physicians of their race or ethnicity.ⁱ Additional research suggests similar of clinical trial participants.ⁱⁱ The AAFP recognizes the importance of and is dedicated to ensuring diversity among healthcare providers and [strongly believes](#) this should be prioritized in clinical research as well. **For this reason, we ask that the FDA recommend sponsors include, to the extent that it is available, information on clinical trial investigators and site staff.** Such information could include but is not limited to how sponsors plan to identify and select diverse investigators and site staff and goals for selecting diverse staff.

2. Continue expanding and leveraging decentralized trials, reducing trial participant burden and creating opportunities for physicians.

Decentralized and hybrid clinical trials can support patient needs in ways that traditional clinical trials have not been able to meet, such as reducing the burden of travel to appointments, and the need to take time off from work or pay for childcare, all of which can be barriers to participating in a trial, specifically for those in lower-income or rural areas.ⁱⁱⁱ

Decentralized and hybrid clinical trials can also create more opportunities for physicians, specifically diverse physicians or those serving underserved and underrepresented communities, to be involved in the clinical trial process, making trials more accessible to trial participants (i.e., making touchpoints local to patients).^{iv} Only a small percentage of physicians partake in the trial process for reasons such as workload and time.^{v,vi} However, because decentralized and hybrid clinical trials heavily utilize remote technologies and often make touchpoints virtual or local to patients, they create opportunities for more physicians, especially diverse physicians, to be involved in the trial process in ways that account for their workload balance and time.

In section 4B of the draft guidance, the FDA asks sponsors to “describe specific trial enrollment and retention strategies, including but not limited to reducing burdens due to trial/study design/conduct.” The AAFP recommends that the Agency expand this portion of the guidance to reference specific aspects of decentralized trials that may alleviate trial participant burden and create opportunities for the involvement of physicians, such as mobile clinics, use of alternative sites, wearable technology, and virtual or local touchpoints.

3. Recommend that sponsors utilize culturally appropriate, inclusive materials that accommodate various languages and reading levels.

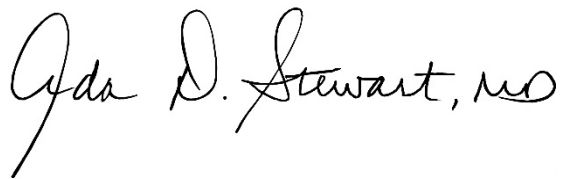
As clinical trial sponsors are enrolling ethnically or racially diverse trial participants, it is important that they tailor their outreach and educational materials so that they are culturally appropriate, inclusive, and accommodate various languages, as participants with limited English proficiency may face challenges in reading or understanding materials. Further, since physicians often partake in discussions with patients about clinical trials, they too should be equipped with informational materials and strategies relevant to patients’ ethnicity, culture, language, and cognitive functioning.

For this reason, the AAFP encourages the FDA to expand section 4B of the guidance and recommend that sponsors, during recruitment and throughout the trial process, provide prospective and enrolled trial participants and physicians with educational tools and information that are not only informative and make it easier for patients to enroll (or physicians to enroll their patients) in relevant trials, but that are also inclusive, culturally appropriate, and address all health literacy backgrounds.

The AAFP recognizes and supports the FDA's efforts to improve clinical trial diversity, and we thank the FDA for its consideration of our comments. The AAFP believes this guidance will provide the biopharmaceutical industry with a clear framework as they develop their diversity plans.

As valuable to the FDA, we welcome the opportunity for further discussion on the draft guidance and related topics. Should you have any questions please contact Meredith Yinger, Manager of Regulatory Affairs, at myinger@aafp.org.

Sincerely,

A handwritten signature in black ink that reads "Ada D. Stewart, MD". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Ada D. Stewart, MD, FAAFP
Board Chair, American Academy of Family Physicians

ⁱ Junko Takeshita, MD. "Racial/Ethnic and Gender Concordance between Patients and Physicians and Patient Experience Ratings." *JAMA Network Open*, JAMA Network, 9 Nov. 2020, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2772682?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=110920.

ⁱⁱ *Enhancing Clinical Trial Diversity*. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/DEI/US114100_CHS-Clinical-Trial-Diversity-PhRMA.pdf.

ⁱⁱⁱ "No Place like Home? Stepping up the Decentralization of Clinical Trials." *McKinsey & Company*, McKinsey & Company, 28 July 2021, <https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials>.

^{iv} *Enhancing Clinical Trial Diversity*. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/DEI/US114100_CHS-Clinical-Trial-Diversity-PhRMA.pdf.

^v Tanya Albert Henry Contributing News Writer. "'Trial-in-A-Box' to Help More Practices Take Part in Clinical Trials." *American Medical Association*, 27 May 2021, <https://www.ama-assn.org/practice-management/digital/trial-box-help-more-practices-take-part-clinical-trials>.

^{vi} Corneli, Amy, et al. "One and Done: Reasons Principal Investigators Conduct Only One FDA-Regulated Drug Trial." *Contemporary Clinical Trials Communications*, Elsevier, 8 Mar. 2017, <https://www.sciencedirect.com/science/article/pii/S245186541630093X>.