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The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Diversity Plans To Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry

Dear Commissioner Califf:

The American Kidney Fund appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) draft guidance for industry entitled, "Diversity Plans To Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials."

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF commends the FDA for issuing this draft guidance and providing recommendations to sponsors developing medical products on the approach for developing a race and ethnicity diversity plan. Advancing health equity is an important priority in AKF's work, as kidney disease disproportionately affects people from communities of color. Though Black Americans make up 13 percent of the U.S. population, they account for 35 percent of Americans with kidney failure (end-stage renal disease or ESRD) and are 3.4 times more likely than white Americans to develop kidney failure. Native Americans are 1.9 times, and Asian Americans are 1.3 times, more likely than white Americans to develop kidney failure. People of Hispanic ethnicity are 1.5 times more likely to develop kidney failure than non-Hispanics.

A key pillar of our health equity efforts is developing recommendations and advocating for policies to increase clinical trial diversity. We also educate the public on the [facts of the clinical trial process](#) and the importance of [clinical trial diversity](#) through resources on our website. While people from communities of color have a disproportionate disease burden for leading chronic conditions in addition to kidney disease such as diabetes and cardiovascular disease, they are underrepresented in clinical trials, overall. For example, Black Americans represent only 5 percent of clinical trial participants, and people of Hispanic ethnicity represent a mere 1 percent of clinical trial participants.¹

We focus our comments on expanding the recommended scope in the draft guidance for sponsors to include in their plans more information on participant and community engagement, clinical trials education for providers, reducing financial and logistical barriers to participation, and clinical trial workforce diversity. We also recommend FDA consider publicly reporting the race and ethnicity diversity plans they receive to foster accountability for sponsors in their commitment to improving clinical trial diversity.

Participant and Community Engagement

Under Category 4, “Specific plan of action to enroll and retain diverse participants,” AKF recommends the FDA encourage sponsors to include specific strategies for how they intend to work with patient organizations and community-based organizations by applying culturally competent communication and enrollment efforts to increase clinical trial participation among underrepresented racial and ethnic populations.

Sponsors should also outline evidence-based strategies to improve retention among clinical trial participants from underrepresented populations.

Clinical Trials Education for Providers

In the “Recommended Scope” section under Category 4, AKF recommends FDA include strategies for equipping providers with information on clinical trial participation and patient-centered communication skills in its guidance. Specifically, sponsors should include strategies to develop and disseminate resources and tools to health care providers that will help them discuss clinical trial options with patients, particularly those from underrepresented populations. Research shows that patients who receive information about clinical trials from their health care provider are more likely to participate.²

¹ Luther T. Clark, Laurence Watkins, Ileana L. Piña, Mary Elmer, Ola Akinboboye, Millicent Gorham, Brenda Jamerson, Cassandra McCullough, Christine Pierre, Adam B. Polis, Gary Puckrein, Jeanne M. Regnante, “Increasing Diversity in Clinical Trials: Overcoming Critical Barriers,” *Current Problems in Cardiology*, Volume 44, Issue 5, 2019, Pages 148-172, ISSN 0146-2806, <https://doi.org/10.1016/j.cpcardiol.2018.11.002>.

² Albrecht TL, Eggly SS, Gleason ME, Harper FW, Foster TS, Peterson AM, Orom H, Penner LA, Ruckdeschel JC. Influence of clinical communication on patients' decision making on participation in clinical trials. *J Clin Oncol*. 2008 Jun 1;26(16):2666-73. doi: 10.1200/JCO.2007.14.8114. PMID: 18509178; PMCID: PMC3807688.

Reducing Financial and Logistical Barriers to Participation

AKF recommends that sponsors should include in their plans—and should be reflected in the guidance—tactics that eliminate or reduce financial and logistical barriers to increasing enrollment and retention of clinical trial participants, such as reimbursement for trial-related expenses, such as travel and lodging. Additionally, AKF recommends sponsors should include strategies that eliminate or reduce logistical barriers to clinical trial participation, such as incorporating telehealth, offering various, non-standard days/times to participate, or conducting research off-site at community-based establishments, such as community centers, pharmacies, or churches.

Clinical Trial Workforce Diversity

AKF recommends that FDA include in the guidance a section on clinical trial workforce diversity. Specifically, sponsors should include in their race and ethnicity diversity plans strategies to ensure a diverse team of researchers and staff in clinical trials. Recent research shows that a key factor for patients from underrepresented racial and ethnic populations enrolling in clinical trials is also having a diverse staff working at the investigative site.³

Public Reporting of Plans to Promote Accountability

In addition to our recommendations on the draft guidance, we recommend FDA consider implementing a plan to publicly report the race and ethnicity diversity plans they receive from sponsors. This could be done through a publicly available dashboard that includes the applications that were accepted and rejected, and the dashboard could be updated to show the progress of enrollment targets. Additionally, FDA could publicly release an annual report that summarizes the diversity plans it receives. Making sponsors' plans and enrollment progress publicly available will help promote accountability and encourage them to follow through on their commitment to clinical trial diversity.

Thank you for the opportunity to provide comments on this draft guidance.

Sincerely,



LaVarne A. Burton
President and CEO

³ Tufts University School of Medicine, "To Increase Diversity in Clinical Trials, First Increase Staff Diversity," <https://medicine.tufts.edu/news-events/news/increase-diversity-clinical-trials-first-increase-staff-diversity>