Asthma and Allergy Foundation of America

September 26, 2024

The Honorable Robert M. Califf, MD
Commissioner, U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies [Docket No. FDA-2021-D-0789]

Dear Commissioner Califf:

Thank you for the opportunity to submit written comments on the Food and Drug Administration's (FDA) draft guidance for industry, "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies" (draft guidance).

I am writing on behalf of the Asthma and Allergy Foundation of America (AAFA), the leading patient organization for people with asthma and allergies and the oldest asthma and allergy patient group in the world. AAFA's mission is to save lives and reduce the burden of disease for people with asthma and allergies through support, advocacy, education and research.

Asthma is one of the most common and costly chronic diseases in the U.S. About 27 million adults and children are currently living with asthma.[1,2] The burden of asthma is disproportionately distributed, with an outside burden shouldered by communities of color. Decades of research and public health surveillance data identify disparities in asthma prevalence, mortality, and healthcare utilization along racial and ethnic lines. Racial and ethnic differences also persist in food allergies, with regard to prevalence, emergency room visits, and access to treatment and specialty care.

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[1] National Center for Health Statistics. (2023). 2022 NHIS Adult Summary Health Statistics. U.S. Department of Health and Human Services. https://data.cdc.gov/d/25m4-6qqq

[2] National Center for Health Statistics. (2023). 2022 NHIS Child Summary Health Statistics. U.S. Department of Health and Human Services. https://data.cdc.gov/d/wxz7-ekz9

AAFA applauds FDA's efforts to improve enrollment of participants from underrepresented populations in clinical studies by issuing draft guidance on Diversity Action Plans (DAPS). We strongly believe that having people from diverse backgrounds in clinical trials is critical to advancing health equity. Unfortunately, people from racial and ethnic minority and other diverse groups are often underrepresented or excluded in clinical research.[3,4,5] This exclusion has contributed to health disparities and has limited the medical community's understanding of how different populations respond to treatments. This is a significant concern because people of different ages, races, and ethnicities may react differently to certain drugs, devices and medical products being tested. This outcome can lead to drugs and treatments that are less effective or even harmful for certain groups of people.

AAFA has long advocated for broader diversity in clinical trials. For example, as noted in our report, *Asthma Disparities in America: A Roadmap to Reducing Burden on Racial and Ethnic Minorities*,[6] by excluding segments of the population that disproportionately shoulder the burden of asthma, clinical trials overlook potential differences in treatment response or resistance in various individuals. Our report documents the alarming lack of racial and ethnic diversity in clinical trials for asthma. Long and rigorous studies to ensure the safety and efficacy of potential new treatments for asthma are often conducted in populations that do not reflect the U.S. population.

Specific recommendations on increasing diversity in clinical trials from our report include:

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[3] Race/ethnicity reporting and representation in US clinical trials: A cohort study, Turner, Brandon E. et al. The Lancet Regional Health – Americas, Volume 11, 100252, July 2022.

[4] Agency for Healthcare Research and Quality. (2021). AHRQ policy on the inclusion of priority populations in research. Retrieved from https://www.ahrq.gov/topics/individuals-special-health-care-needs
.html#:~:text=The%20AHRQ%20Policy%20on%20the%20Inclusion%20of%20Priority,and%20justification%20is%20provided%20that%20inclusion%20is%

[5] Vitale, C., Fini, M., Spoletini, I., Lainscak, M., Seferovic, P., and Rosano, G. (2017). Under-representation of elderly and women in clinical trials. *International Journal of Cardiology, 232,* 216–221.

[6] Asthma and Allergy Foundation of America, (2020). [Asthma Disparities in America: A Roadmap to Reducing Burden on Racial and Ethnic Minorities]. Retrieved from aafa.org/asthmadisparities

- Significantly increase participation of Black, Hispanic, and Indigenous Americans in clinical trials;
- Address cultural stigmas and myths about research among minority populations and build trust in medical establishment and particularly in minority research;
- Expand research of patterns of asthma risk factors, morbidity, and mortality in underrepresented populations—particularly Black, Hispanic and Indigenous Americans— to inform public health interventions;
- Improve data collection standards to ensure uniformity in racial and ethnic data collection across agencies;
- Transform national, state and local surveillance systems to utilize uniform data collocation standards;
- Improve data collection to monitor disparities experienced by AI/AN populations and Hispanic subgroups; and
- Provide public access to disaggregated data to identify disparities within subgroups of each population.

Suggestions to Enhance FDA's Draft Guidance

The draft guidance is intended to assist sponsors conducting certain clinical studies involving drugs, biological products, and devices in meeting requirements for the submission of DAPS as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Food and Drug Omnibus Reform Act of 2022 (FDORA).

Overall, AAFA believes that the draft guidance provides helpful suggestions that will enhance sponsors' efforts to strategically recruit and retain participants from diverse backgrounds and will ultimately enhance the representativeness of clinical trials. We particularly appreciate that the draft guidance recognizes that diversity extends beyond race and ethnicity, encompassing factors such as age, disability, sex, gender

identity, sexual orientation, and socioeconomic status.[7] We applaud FDA's efforts to set clear expectations for including diverse populations in clinical trials and offer suggestions to further refine the draft guidance for sponsors.

- **Enrollment Goals:** AAFA appreciates that the draft guidance encourages sponsors to consider the unique challenges and barriers that different populations may face in accessing clinical trials. This effort will help sponsors develop more effective strategies for reaching underrepresented groups. In addition, AAFA supports the structured approach to setting enrollment goals, which are disaggregated by race, ethnicity, sex, and age group to promote inclusivity. Data-driven goal setting will help sponsors set realistic and actionable goals. We encourage the FDA to provide illustrative examples of how DAPs can disaggregate by category. Providing specific examples would further support these efforts.

- **Community Engagement and Cultural Competency:** We strongly support FDA's efforts to encourage sponsors to consult patients and healthcare providers as part of the process for developing a DAP, including considering enrollment and retention strategies such as implementing community engagement and providing cultural competency and proficiency training for clinical investigators and research staff. By encouraging sponsors to partner with community organizations, engage with local leaders, and tailor their outreach efforts to the needs of specific populations, the draft guidance provides a roadmap for building stronger relationships with the communities that clinical trials aim to serve. The draft guidance also emphasizes the importance of cultural competency training, ensuring that clinical trial staff are equipped with the knowledge and skills they need to effectively communicate with and support diverse participants.

  While we support these efforts, we encourage the FDA to more actively advance educational initiatives that provide clear, accurate information about

[7] Schoch, S. (2023). Patients, poverty, and participation in research: The hidden costs of disease and socioeconomic status. Retrieved from https://nationalhealthcouncil.org/blog/patients-poverty-and-participation-in-research-the-hidden-costs-of-disease-and-socioeconomic-status/

the importance of diversity in clinical research. These initiatives could include public awareness campaigns, community-based education programs, and partnerships with patient organizations. Developing educational materials that sponsors can use in their outreach efforts—such as brochures, videos, and online resources that explain the benefits of participating in clinical trials and address common concerns—can further increase participation and trust.

- **Integration of DAPs into ongoing Clinical Trials or Development Programs**: The draft guidance specifies that DAP requirements apply to clinical trials for which enrollment begins 180 days after the final guidance is published. The draft guidance is not clear about how DAPS should be integrated into ongoing clinical trials or development programs. AAFA encourages the FDA to provide clarification on how DAPs should be applied across different stages of development and to clarify how diversity data from earlier phases may inform later trial requirements.

- **Setting Enrollment Goals and FDA's Role**: The draft guidance lacks specific direction on calibrating enrollment goals to accurately reflect disease prevalence across different demographic groups. Detailed instructions on setting enrollment goals based on prevalence data is needed, along with clear criteria for how the FDA will evaluate and guide these goals.

- **Tracking Diversity Goals**: Monitoring and reporting on DAPs will be critical to the success of enrolling diverse populations into clinical trials. AAFA recommends that FDA require regular reporting from sponsors as a core component of the DAP framework. Sponsors should provide consistent updates to FDA on their progress toward meeting enrollment goals. The FDA should provide more clarity on the process for submitting DAPs, including guidance on when revisions or updates are required and the process for submitting modified DAPs. This reporting process will provide invaluable insight into how sponsors are meeting diversity targets and will help identify areas that need improvement.

- **Periodic Reviews and Feedback**: AAFA recommends that the FDA implement a periodic review and update mechanism to ensure that the draft guidance on

DAPs remains current with clinical research. An advisory committee consisting of patient advocacy organizations, FDA, industry and others could help inform this process and could recommend updates to the guidance as needed.

- **Cultural and Educational Adaptability:** While the draft guidance encourages inclusion of adaptable information and educational initiatives, specific recommendations for how sponsors can tailor their communication and outreach efforts to meet the diverse needs of communities is needed. This effort could include guidance on conducting community-based participatory research, developing culturally relevant messaging, and engaging with community leaders and organizations that have the trust of the target population. The draft guidance should also address health literacy. The FDA should provide guidance on how sponsors can assess the health literacy of their target populations and develop materials that are accessible and easy to understand.

Conclusion

We are encouraged by the FDA's draft guidance on Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies. For people living with asthma, allergies, as well as other health conditions, this is a good first step to greater representation in clinical trials and, ultimately, treatments that meaningfully benefit *all* communities impacted by illness. While we strongly support the overall direction of the guidance, we look forward to working with the FDA to further strengthen and clarify the guidance as detailed above. Please do not hesitate to contact me at kmendez@aafa.org if we can provide additional information or answer any questions.

Sincerely,

Kenneth Mendez

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America