ACCC COMMUNITY ONCOLOGY RESEARCH INSTITUTE

June 13, 2022

The Honorable Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: File Code FDA-2021-D-0789-0001; Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry

Dear Commissioner Califf:

The Association of Community Cancer Centers (ACCC) Community Oncology Research Institute is pleased to submit the following comments in response to the Food and Drug Administration (FDA) draft guidance on *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials*, published in the Federal Register on April 14, 2022 (FR Doc. 2022-07978).

ACCC is the leading education and advocacy organization for our nation's cancer care community, representing a network of 28,000 multidisciplinary practitioners from 2,100 private practices, hospital-based cancer programs, large healthcare systems, and major academic centers from across the country. ACCC has established the ACCC Community Oncology Research Institute (ACORI) to build on its existing mission to close the gap in cancer research through optimal community oncology partnerships. ACORI works to establish clinical trials as a standard of care in treatment plans and to help achieve equitable cancer care delivery for all patients.

ACORI would like to thank the FDA for enhancing its commitment to address the lack of diversity in biomedical research and appreciates the opportunity to offer some overarching recommendations. In summary, we encourage the agency to:

- **Incorporate guidance for sponsors to collect social determinants of health (SDOH) data in their Diversity Plans**. While the document alludes to some elements of SDOH, it does not explicitly recommend that sponsors collect SDOH data in addition to data on race and ethnicity. Given the significant impact of SDOH on outcomes and efficacy and the barriers that these social factors may create in underrepresented racial and ethnic populations, we feel strongly that sponsors should address SDOH in their Plans and make efforts to document social needs data throughout the development life cycle of the medical product.

- **Improve framing around equity and the use of race, race categories, and ancestry.** At its core, the lack of diversity in clinical trials is an equity issue, so the FDA should use an equity lens to address equitable access to clinical trials. Additionally, the FDA should consider defining and noting the difference between race as a social construct and ancestry (or otherwise direct readers to a clarifying document). Specifically, it is important to emphasize that race is a social construct with recognition based on phenotypic characteristics. If we are talking about differences in biological processes, the more appropriate term to use is "ancestry". It is important to aim for clarity in this framing, given heightened concerns about biological attributes to race.
- **Address rural vs. urban populations within the context of racial and ethnic diversity.** While the focus of this document is on the enrollment of underrepresented racial and ethnic populations, it is important to note that some parts of the country lack racial and ethnic diversity in their patient populations to begin with, particularly in rural areas. For these clinical trial sites, it may be more impactful to address disparities related to socio-economic status, access to care, level of education, etc. Moreover, it may be necessary to customize racial and ethnic enrollment targets for component geographic locations participating in a trial.

Recommended Elements of the Diversity Plan

Category 2: Scope of medical product development program

Regarding eligibility criteria for the study population, ACORI recommends the FDA highlight that eligibility criteria can either address or negatively impact diversity in biomedical research participation due to "ghost criteria." Such criteria are not properly vetted to determine whether certain pre-existing conditions, or the use of medications for specific health conditions, will have an impact on the study outcome. Some of these "ghost criteria" often disproportionately impact historically underrepresented racial and ethnic groups.

Category 3: Goals for enrollment of underrepresented racial and ethnic participants

ACORI supports the recommendation that sponsors provide specific goals for the enrollment of underrepresented racial and ethnic participants as a percentage of all study participants. The publication of these targets and the sponsor's actual enrollment figures following the study would allow others to assess the generalizability of the study's results.

Additionally, the point referring to "increased enrollment of certain populations… to elucidate potential important differences" could benefit from having an example, such as prostate cancer, where men of African Ancestry carry a disproportionate burden of the disease and are underrepresented in prostate cancer biomedical research. Several studies have highlighted better outcomes for men of African Ancestry when the enrollment target is appropriate or even purposefully oversampled.

Category 4: Specific plan of action to enroll and retain diverse participants

ACORI supports the recommendation that Plans include a description of specific strategies for enrollment and retention, including through the sustained engagement of community advisory boards, navigators, and community health workers. However, this work may be more effectively done with local resources that the clinical trial site can provide or engage with, rather than through industry engagement. To the extent that it is possible, sponsors should provide support directly to clinical trial sites, which in many cases already have the necessary relationships and cultural competencies in place to enroll diverse populations.

ACORI emphasizes the criticality of considering cultural practices in offering clinical trials. For example, among the American Indian and Alaska Native populations, having a trusted member of the community serve as a community health representative is crucial to their participation. Therefore, it is essential to have a strategy to engage and educate these key individuals about clinical trial opportunities.

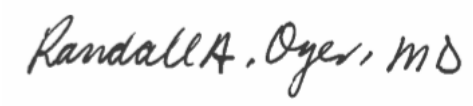
Category 5: Status of meeting enrollment goals

ACORI recommends that for sponsors that fail to achieve enrollment goals despite their best efforts, the FDA should strongly encourage such sponsors to either keep the study open to enroll additional participants from underrepresented populations *or* establish a written plan to collect the necessary data to meet enrollment targets in the post-market setting.

Conclusion

We appreciate the opportunity to share our comments on the FDA's draft guidance to increase diversity in clinical trials through the creation of Diversity Plans. If you have any questions, please contact Matt Devino at mdevino@accc-cancer.org or (301) 263-3510.

Respectfully,



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