September 24, 2024

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

RE: Docket No. FDA-2021-D-07; Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies, Guidance for Industry—Draft Guidance

To Whom It May Concern:

On behalf of the LUNGevity Foundation, the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the more than 230,000 Americans diagnosed with lung cancer each year[i] and over 600,000 Americans living with the disease,[ii] we appreciate the opportunity to submit these comments to the U.S. Food and Drug Administration (FDA) regarding the draft guidance "**Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies**."

Clinical research is vital for improving our understanding of diseases and developing safe and efficacious treatments to address them. In diseases like lung cancer, with multiple defined subtypes and new molecular drivers still being discovered, patient participation in research is paramount for advancing the treatment landscape as well as providing access to potentially life-saving therapies when no alternative options exist. LUNGevity has long promoted the potential benefits of clinical trials, and is working on multiple fronts to ensure that **all** people diagnosed with lung cancer have access to relevant clinical trials that are easy to get on and stay on.

LUNGevity appreciates the FDA's commitment to improving representativeness in clinical trials. We have been heartened by the steady stream of guidance and information flowing from the Agency with recommendations and expectations for including marginalized and overlooked populations—those often perceived as "risky"—in industry-sponsored clinical trials. The Diversity Action Plan draft guidance is another offering in this same vein, and we believe it is much improved from the previous draft guidance on diversity plans.[iii] Herein we present our thoughts on the draft guidance from the perspective of those diagnosed and living with lung cancer, which despite significant progress is still the leading cause of cancer death in the U.S.[iv]

First and foremost, we applaud the broader scope of this draft guidance compared to the 2022 version.[iii] Although race and ethnicity are certainly important demographic factors to consider when setting a recruitment strategy, LUNGevity believes that a comprehensive approach to inclusivity and representativeness is needed in drug development. As such, we were pleased to see that FDA will be requiring industry to address representation across age groups, sexes, and races and ethnicities, and made mention of additional areas impacting health disparities like geographic location, socioeconomic status, sexual orientation, and more (lines 128-132.) We also welcome the acknowledgement that clinical development programs comprise multiple clinical

trials and that companies can take a programmatic approach, as opposed to trial-by-trial, to setting enrollment goals (lines 241-251). Our hope is that by thinking bigger but also more strategically, companies will be more likely to develop and implement feasible plans for recruiting and enrolling clinically relevant study populations, thereby more completely answering the questions that need answering and better serving both the immediate and long-term needs of patients.

We appreciate the clarification in the current draft guidance that enrollment goals should be tied to disease prevalence or incidence in the U.S. population (lines 267-269), as this was an open question based on the previous guidance. Additionally, seeing FDA's thoughts on how multi-regional clinical trials should be designed in service of enrollment goals is instructive (lines 295-311). However, it would be helpful to have more detail on the appropriateness and acceptability of (potentially) counting participants from countries outside the U.S. towards enrollment goals for specific races, as this is not explicitly spelled out either in this draft guidance or in the draft guidance on collecting race and ethnicity data.[v]

LUNGevity is pleased to see included among the measures for meeting enrollment goals mention of reducing participant burden and improving access to clinical trials (lines 411-420). Our research has shown that the number and location of clinical trials does not reflect the reality of disease prevalence by geographic location in the U.S.[vi] and that, relatedly, travel and logistical concerns rate highly among patients' considerations around trial participation.[vii] To increase participation among historically underrepresented groups, more must be done to make clinical trials available where patients live, both by building capacity and desire to open trials at community health centers and by increasing the use of decentralized elements such as shipping of trial medication and using local facilities for trial-related labs and imaging. When travel is necessary, compensation for participants' time and trial-related, out-of-pocket expenses should be a given. LUNGevity is part of a coalition that has outlined key considerations and recommendations for trial sponsors for designing financial support programs for participants.[viii]

Finally, the draft guidance makes no mention of enforcement by FDA for meeting enrollment goals, or consequences if they are not met. Perhaps counterintuitively, LUNGevity does not take issue with this and advocates flexibility on FDA's part when evaluating applications for which enrollment goals were not met. While we recognize the need to diversify clinical trial populations and support the intent of Diversity Action Plans, we understand that there are myriad reasons people may choose not to participate in trials—especially members of populations historically excluded from or underrepresented in clinical research. Provided there is evidence that companies are making good faith efforts toward meeting stated enrollment goals at the time they submit marketing applications, we recommend the continued approval of drugs that demonstrate safety and efficacy in order to speed access to beneficial therapies to the patients who need them. Collection of missing data should then continue as outlined in the draft guidance on postmarketing approaches to obtain data on populations underrepresented in clinical trials.[ix]

LUNGevity appreciates the opportunity to provide comments on this important step towards advancing health equity by increasing enrollment of historically underrepresented groups and making clinical trial populations more reflective of intended use populations. Please feel free to reach out to me at aeferris@lungevity.org with any questions.

Sincerely,

Andrea Stern Ferris
President and Chief Executive Officer
LUNGevity Foundation

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[i] Howlader N, Noone AM, Krapcho M, et al. (eds). SEER Cancer Statistics Review, 1975-2018, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2018/, based on November 2020 SEER data submission, posted to the SEER web site, April 2021.
[ii] Centers for Disease Control and Prevention. United States Cancer Statistics. Available at https://gis.cdc.gov/Cancer/USCS/#/Prevalence/.
[iii] Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials, Guidance for Industry; Draft Guidance (April 2022).
[iv] American Cancer Society. Key Statistics for Lung Cancer. https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html.
[v] Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products, Guidance for Industry; Draft Guidance (January 2024).
[vi] Geographic relationship between lung cancer clinical trial sites and patient prevalence and demographics in the Medicare Fee-for-service program. https://www.lungevity.org/sites/default/files/patient-force/Basu-Roy-et-al-geographic-relationship-lung-cancer-clinical-trial-sites.pdf.
[vii] Understanding Barriers to Participation in Clinical Trials—The Patient and The Caregiver Perspectives. https://www.lungevity.org/sites/default/files/patient-force/barriers-to-clinical-trial-participation.pdf.
[viii] Advancing Equitable Access to Clinical Trials: Eliminating the Financial Burden for Patients. https://www.eactproject.org/advancing-equitabl-access.
[ix] Postmarketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products, Guidance for Industry; Draft Guidance (August 2023).