August 6, 2019

Norman E. Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
[Submitted Electronically]

Re: Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs; Draft Guidance for Industry; Availability [Docket No. FDA-2019-D-1264]

Dear Dr. Sharpless:

On behalf of LUNGevity Foundation, the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the approximately 230,000 Americans diagnosed with lung cancer each year and the 538,243 Americans living with the disease,[1] we appreciate the opportunity to submit our comments in response to the Food and Drug Administration's (FDA) Draft Guidance on Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs, posted in the Federal Register on June 7, 2019.

As a leading patient advocacy group that represents the voice and interest of the national lung cancer survivor community by accelerating research to patients that is meaningful to them, empowering patients to be active participants in their care and care decisions, and helping remove barriers to access to high quality care, LUNGevity applauds the FDA for producing this draft guidance and raising awareness to the need to increase and enhance diversity of clinical trial populations. The draft guidance accurately highlights many of the current barriers to enhancing diversity of clinical trial populations, and LUNGevity strongly encourages the FDA to retain each of the recommendations outlined in this draft guidance in the final guidance. In addition to supporting this draft guidance, LUNGevity would also like to share some suggestions to strengthen the draft guidance, as well as offer recommendations as to how the FDA can strengthen and build off this draft guidance with future work streams and collaborations. The below comments reflect these suggestions.

Use of terminology such as "older adults" and/or "older patients"

While we understand that it has been common practice to use the term "elderly" for individuals 65 and older, we recommend that the FDA use terms consistent with those used by the National Comprehensive Cancer Network (NCCN) and replace "elderly people" with "older adults" and "older patients." These terms are both neutral and patient-friendly. The first time one of the terms appears in a document, it can be followed by the definition, e.g., "older adults (individuals at least 65 years old)," as defined in the NCCN guidelines.[2]

Guidance on older patient population

Cancer is a disease of older adults. By 2030, 70% of all new cancer diagnosis will occur in adults above the age of 65.[3] Ironically, age of patients included in adult cancer clinical trials often do not reflect the population of patients in the real-world. A study by Ludmir and colleagues in JAMA Oncology reported that the age of trial participants was a mean of 6.49 years younger than the disease population median age.[4] These disparities were heightened in trials sponsored by the pharmaceutical industry. Specifically, the age of lung cancer clinical trials patients was a mean of 8.98 years younger than the population median age.[4] Given that the median age of diagnosis of a lung cancer patient is 70 years,[1] we encourage the FDA to provide specific language around the inclusion criteria of older adults in clinical trials. For example, inclusion criteria that juxtapose age with performance status and presence of co-morbid conditions would be helpful for sponsors of clinical trials.

Additional guidance on data-sharing

LUNGevity is thankful that the FDA is encouraging trial sponsors to broaden and increase the use of data-sharing as a means to reduce trial participation burden for patients (as mentioned on Page 8, Lines 260-265). To create more of an incentive for trial sponsors to change how they conduct trials in this manner, we believe it would be beneficial for the FDA to strengthen this section of the draft guidance by providing additional details as to what this might look like. In addition, LUNGevity welcomes the opportunity to work with the FDA and other stakeholders to develop a roadmap for data sharing across trials sites, such as types of data to be shared and frequency of data sharing.

Future guidance on improving access to clinical trials

LUNGevity would like to continue to partner with the FDA to continue to improve the clinical trials system so that all individuals, especially those in underserved areas, have access to cutting-edge research. It is well documented that multiple non-clinical factors such as financial barriers, logistical concerns, and the lack of resources for patients and clinicians to support clinical trial enrollment and retention, contribute to sub-optimal access to clinical trials.[5-7] Lung cancer has a high symptom burden and travel for patients, especially those participating in Phase 1 trials, may be both physically challenging and logistically difficult.

This issue is compounded for patients living in rural areas and those belonging to a lower socio-economic status, as demonstrated in a study by Borno and colleagues.[5] The FDA may want to consider issuing a draft guidance that goes beyond the clinical nature of this draft guidance to address barriers for accessing clinical trials in a more practical way – such as clear guidelines for providing financial support to cover non-clinical expenses. LUNGevity welcomes the opportunity to collaborate with the FDA to identify opportunities and solutions to remove or circumvent these types of barriers to increase diversity in clinical trials.

As always, the recommendations outlined above can be discussed with me, my staff, and LUNGevity's Scientific Advisory Board, which is made up of some of the world's leading experts in lung cancer biology, practice management, access to innovative medicines, and overall patient care. I can be reached at 240-454-3100 or aeferris@lungevity.org if you have any questions or would like to engage in further dialogue.

Thank you for your attention to this very important matter.

Sincerely,

Andrea Stern Ferris
President and Chief Executive Officer
LUNGevity Foundation

ABOUT LUNGEVITY:

LUNGevity's mission is to improve outcomes for people diagnosed with lung cancer. Our goals are three-fold: (1) to accelerate research to patients that is meaningful to them; (2) to empower patients to be active participants in their care and care decisions; and (3) to help remove barriers to access to high quality care. We have the largest lung cancer survivor network in the country and actively engage with them to identify, understand, and address unmet patient needs. We also have a world class Scientific Advisory Board that guides the programs and initiatives of the organization. Additionally, we collaborate with other lung cancer patient advocacy groups and organizations, such as the American Lung Association and CHEST, who serve the lung cancer community.

REFERENCES:

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4. Ludmir EB, Mainwaring W, Lin TA, et al. Factors Associated With Age Disparities Among Cancer Clinical Trial Participants. *JAMA oncology.* Jun 3 2019.
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6. Manne S, Kashy D, Albrecht T, et al. Attitudinal barriers to participation in oncology clinical trials: factor analysis and correlates of barriers. *European journal of cancer care.* 2015;24(1):28-38.
7. Nipp RD, Hong K, Paskett ED. Overcoming Barriers to Clinical Trial Enrollment. *American Society of Clinical Oncology educational book. American Society of Clinical Oncology. Annual Meeting.* Jan 2019;39:105-114.