



July 31, 2023

Dockets Management Staff
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir or Madam:

On behalf of LUNGeVity Foundation, the nation's preeminent lung cancer nonprofit organization that funds research, provides education and support, and builds communities for the more than 230,000 Americans diagnosed with lung cancer each yearⁱ and the more than 600,000 Americans living with the disease,ⁱⁱ we appreciate the opportunity to submit comments on the draft guidance "Decentralized Clinical Trials for Drugs, Biological Products, and Devices" (Docket No. FDA-2022-D-2870). Our mission is to improve lung cancer survivorship and quality of life for patients living with the disease, and it is with those patients in mind that we submit the following comments.

One of the overarching goals of LUNGeVity Foundation is to improve outcomes for people diagnosed with lung cancer, which entails efforts to address hurdles patients face accessing, enrolling onto, and adhering to clinical trials. Barriers to participation in traditional clinical trials include patient distance from the central trial site and limited time and resources necessary for travel. Decentralized and hybrid clinical trials can improve patient enrollment and reduce trial participant attrition by abrogating such hurdles. Increasing the adoption of these trials has the potential to improve the number and racial/ethnic, geographic, and socioeconomic diversity of clinical trial participants, thus aiding in reducing lung cancer disparities.

LUNGeVity appreciates the FDA's leadership and many efforts to encourage the uptake of decentralized and hybrid clinical trials, including by participating in our discussions and those of other stakeholders. In general, we agree with the considerations for the appropriate design and conduct of these trials outlined in the draft guidance, which will be a critical tool to enhance their capacity to improve access to clinical trials for all patients.

One area of potential confusion is the draft guidance's framing of which clinical trial personnel belong on Form FDA 1572 as a subinvestigator. A significant barrier to the uptake of decentralized and hybrid clinical trials is hesitancy among investigators and their institutions who are averse to accepting responsibility for remote subinvestigators over whom they do not have direct oversight. The guidance states that subinvestigators to be listed on the form include trial personnel who "contribute directly and significantly to the trial data." This phrase could easily be interpreted to include procedures such as radiological imaging, laboratory work, and physical assessments. However, the draft guidance also asserts that local healthcare providers providing trial-related services as part of routine clinical practice, including performing physical examinations and reading radiological images, should not be listed on the form. To better clarify this point, **the Agency is encouraged to update guidance to specify that only clinical trial personnel making trial-related treatment decisions warrant inclusion as subinvestigators on the 1572 form.**

We support the inclusion of considerations for the use of remote informed consent in the draft guidance. Allowing patients to enroll onto clinical trials without having to travel for the sole purpose of signing a form is an important tool for improving patient participation. Interestingly, LUNGeVity, together with the National Brain Tumor Society, found that as of 2021 ten of fourteen major academic medical centers surveyed allowed for the use of remote informed consent for investigational clinical trial enrollment.ⁱⁱⁱ Although greater than fifty percent, uptake was lower than expected given that the FDA and the National Cancer Institute recommended the use of remote



informed consent for clinical trial enrollment during the COVID-19 public health emergency. Affirming through guidance that FDA allows and encourages the use of remote informed consent could increase its adoption.

Furthermore, we appreciate that the guidance highlights the need to notify trial participants of relevant contacts, which patients themselves have indicated is an important component of informed consent forms. It is important to remember, though, that informed consent is not just a form, but a process. Regardless of whether the process takes place in person or virtually, there must be clear and transparent communication with the patient, including opportunities to ask questions, to facilitate patients' decision-making around trial participation.

LUNGEvity supports the use of digital health technologies (DHTs) to facilitate participation in decentralized and hybrid clinical trials, so long as their use does not exacerbate existing disparities. We appreciate the inclusion of considerations for the use of DHTs related to ensuring patient access, such as the provision of DHTs by the sponsor as an option even when participants may use their own, to avoid excluding otherwise eligible patients. We also agree with the importance of sponsor-provided training of participants and trial personnel on using DHTs as well as the conduct of DHT usability studies for the intended trial population, as recommended in previous draft guidance.^{iv}

Finally, to better understand what is desirable and feasible for any given decentralized or hybrid clinical trial, it is important that sponsors design the trial in consultation with patients, caregivers, investigators, and trial sites. Sponsors may want to consider exploring the possibility of variable decentralization, when appropriate. Having more visits conducted at a central site before progressively adding decentralized elements, for example, would not only allow for closer monitoring early in the trial in cases where uncertainty around anticipated patient response is high, but also facilitate relationship development between patients and investigators. **We recommend the inclusion of these considerations to ensure decentralized and hybrid clinical trials are designed appropriately on a case-by-case basis.**

LUNGEvity thanks the FDA for the thoughtfulness that went into drafting “Decentralized Clinical Trials for Drugs, Biological Products, and Devices.” Detailing important considerations around the design and conduct of decentralized clinical trials represents an important step toward improving access to clinical trials for all patients.

Please feel free to reach out to me at 240-454-3100 or aeferris@lungevity.org if you have any questions or would like to engage me or my staff in further dialogue.

Sincerely,

A handwritten signature in blue ink that reads "Andrea Stern Ferris".

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 and Health Equity Council that guide the programs and initiatives of the organization.



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/#/NationalPrevalence/>.

ⁱⁱⁱ Barksdale E, Lee EQ, Meehan C, Rudin C, Selig W. [White Paper] Assessing Uptake of Remote Consent for Clinical Trials: Opportunities to Reduce Patient Burden. 2023. National Brain Tumor Society, LUNGevity Foundation. Available at .

^{iv} U.S. Food and Drug Administration. Digital Health Technologies for Remote Data Acquisition in Clinical Investigations. 2021 Dec; Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations>.