January 24, 2022

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

Dear Sir or Madam:

On behalf of the 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 year[i] and the more than 600,000 Americans living with the disease,[ii] we appreciate the opportunity to submit comments on the draft guidance "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products" (Docket No. FDA-2020-D-2307). 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.

LUNGevity thanks the U.S. Food and Drug Administration (FDA) for drafting the entire set of real-world data (RWD)-related guidance documents as part of its Real-World Evidence (RWE) Program. We applaud data-driven efforts like FDA's RWE Program that aim to increase and speed access to safe, effective treatments for a broader range of patients.

We are especially interested in the potential that RWD sources such as electronic health records (EHRs) hold for creating or supplementing external control arms for evaluating expanded indications of approved therapies. Reducing randomization to control arms of clinical trials is of great interest to people diagnosed with lung cancer as many rely on clinical trials for access to their next treatments options. Utilization of EHR data to generate external controls could increase the number of patients randomized to experimental arms, speeding access to potentially life-saving therapies.

As the generators of RWD and the targeted beneficiaries of the applications of RWE, patients must be central to efforts to advance and optimize the utility of RWD. There is currently a paucity of literature examining patients' understanding of and attitudes toward the use of RWD and RWE, particularly in a regulatory context. However, as they become better understood, patients' concerns (e.g., around privacy, data access, and data commercialization) must be considered when developing and evaluating the use of RWD in future studies.

It is also essential to understand the potential introduction of bias into RWD studies through the use of incomplete data sources such as EHRs. Although FDA addresses data missingness in EHRs in the guidance, it is possible that selecting only those patients whose data can be "completed" through linkages to other data sources and/or by the use of proxies for RWD studies

may not provide the full picture of how drugs are performing in the intended patient population. Sponsors should consider what biases might be introduced into a study by using incomplete data like those in EHRs and explain how they will account for them.

LUNGevity thanks the FDA for the thoughtfulness that went into drafting "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products." By outlining considerations around common challenges with the use of EHR data as a source of RWD and providing clear guidance on the standards and transparency expected of RWD studies, FDA has taken an important step toward improving access to safe and effective treatments for a broader range of patients.

LUNGevity looks forward to RWD and RWE reaching their optimal utility in supporting regulatory decision-making to advance the understanding of medical product safety and effectiveness in more real-world patient populations. We support the draft guidance in addition to the FDA's other ongoing efforts to optimize the quality and advance the application of RWD/RWE in ways that will ultimately benefit 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,

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.

[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/.