May 28, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Advancing the Use of Digital Health Technologies in Clinical Investigations for Drugs and Biological Products; Request for Information and Comments (FDA-2026-N-2476).

To whom it may concern:

On behalf of 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 in response to the Request for Information and Comments on Advancing the Use of Digital Health Technologies in Clinical Investigations for Drugs and Biological Products (FDA-2026-N-2476).

LUNGevity Foundation supports the use of digital health technologies (DHTs) in clinical trials as a powerful means to facilitate access to clinical trials, minimize burdens on trial participants, and advance patient-focused drug development (PFDD). We commend the US Food and Drug Administration (FDA) for its past issuance of guidance on this topic and offer these comments as the Agency considers additional opportunities to support DHT implementation in clinical research.

Facilitating Clinical Trial Decentralization

Trial decentralization mitigates common hurdles patients face to enrolling and participating in clinical studies, including far distances from central trial sites with limited time and resources necessary for travel. LUNGevity has long supported efforts to promote the decentralization of clinical trials to reduce burdens on trial participants and broaden clinical trial accessibility. By enabling remote data acquisition, DHTs are an invaluable tool to facilitate the conduct of decentralized and hybrid trials. Digital devices can be used to remotely assess vital signs in trial participants at timepoints set forth in the trial protocol as part of the schedule of assessments. These devices may also be used to track medication adherence enabling additional confidence to allow remote drug administration which may lessen burdens for patients. DHTs can also be used for continuous safety monitoring, enabling earlier capture of adverse events and subsequent interventions. Wearable devices continuously measuring core body temperature, for example, can flag the onset of fever, a key feature of cytokine release syndrome linked to CAR-T therapies, and facilitate early intervention.

By enabling remote and secure data transmission from trial participants regardless of their location, DHTs serve as a powerful tool to facilitate trial decentralization and patient participation in clinical research. However, while some patients may have personal access to common DHTs (e.g., wearable activity trackers), others do not. Furthermore, not all patients will have adequate technological literacy to be able to use DHTs as intended. We supported the FDA's past recommendations aimed at ensuring patient access to DHTs in clinical trials through sponsors' provision of DHTs to all participants, as well as sponsor-provided training on use of DHTs, in the Agency's draft guidance on conducting decentralized trials (ultimately finalized September 2024).[iii] DHTs must also be suitable for use, meaning patients should be able to use them efficiently without errors and that measurements made in a remote setting are reliably accurate and precise. Thus, we also appreciate the Agency's issuance of final guidance on the use of DHTs in clinical trials which included recommendations for the conduct of DHT usability studies in the intended trial population.[iv]

LUNGevity supports the issuance of further guidance on the appropriate use of DHTs in clinical trials to facilitate participation and minimize patient burdens while meeting appropriate standards to maintain patient safety. For example, guidance for industry on how to ensure data collected from DHTs for the purposes of continuous safety monitoring is fit for purpose and consistent with that which would otherwise be collected by a clinician would be valuable.

Advancing Patient-Focused Drug Development

DHTs are also useful to the advancement of PFDD, in which the preferences, priorities, and experiences of patients, collected as patient experience data (PED), are incorporated into drug development and evaluation. PED can be captured through clinical outcome assessments (COAs) like patient-reported outcomes (PROs), which are particularly prevalent in oncology clinical research.[v] DHTs are increasingly used for COA data collection, such as the use of software applications to capture PRO questionnaire data.

In September 2025, FDA published a draft COA evidence dossier template, through which COA data is to be submitted for review by the Agency.[vi] In feedback on the draft COA dossier, industry has highlighted a need for clarity on how DHT-derived data should be documented into regulatory submissions under the new COA template. Specifically, information on where DHT-derived data should be added to the template, what the Agency expects regarding description of the DHTs used, and how DHT verification and validation data should be presented have been requested. **We ask that the FDA address the appropriate submission of DHT-derived COA data for regulatory review.** This will help ensure the continued incorporation of valuable PRO and other COA data into regulatory submissions to advance PFDD.

It is also critical that PED-related endpoints accurately reflect what is being measured by DHTs, which can be particularly nuanced. In an example from our experience, the number of steps a patient takes in a day as measured by a pedometer could be perceived as a proxy for the amount of

energy a patient generally has. According to feedback from the lung cancer community, however, step count alone does not accurately capture overall energy levels. Despite similar steps being taken from day to day, for instance, patients may still experience considerable differences in whether their energy levels are sustained throughout the day or taper off towards the end of each day, affecting their quality of life. **LUNGevity advocates for the development of guidance on defining appropriate DHT-supported PED endpoints, in which we stress the importance of consulting patients and patient advocates.**

LUNGevity appreciates the FDA's consideration of these comments on challenges and areas of needed guidance regarding the use of DHTs in clinical investigations of drugs and biological products. We are hopeful that addressing these issues will further the ability of DHTs to facilitate clinical trial participation for more patients and to capture data on outcomes that are key priorities for patients.

Please feel free to contact me at bmckelvey@lungevity.org with any questions or for further discussion.

Sincerely,

Brittany McKelvey

Brittany McKelvey

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LUNGevity Foundation

[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] U.S. Food and Drug Administration. Conducting Clinical Trials with Decentralized Elements. 2024 Sep; Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements

[iv] U.S. Food and Drug Administration. Digital Health Technologies for Remote Data Acquisition in Clinical Investigations. 2023 Dec; Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations

[v] Kim Y, Gilbert MR, Armstrong TS, Celiku O. Clinical outcome assessment trends in clinical trials-Contrasting oncology and non-oncology trials. Cancer Med. 2023 Aug;12(16):16945-16957. doi: 10.1002/cam4.6325.

[vi] U.S. Food and Drug Administration. Draft COA Evidence Dossier Template. 2025 Sep; Available at https://www.fda.gov/media/188624/download.