March 22, 2022

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
Docket No. FDA-2021-D-1128
5360 Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA-2021-D-1128: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations
86 FR 72981 (December 23, 2021)

Dear Commissioner Califf:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Draft Guidance for Industry, Investigators, and Other Stakeholders. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influences evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

Clinical trials play an integral role in advancing potential new treatments that improve quality of life and survival for people with cancer. To successfully bring any new treatment from the research setting to the patient, clinical trials must enroll an adequate number of participants to assess a treatment's safety and efficacy. Although most cancer patients offered a clinical trial will participate, adequate enrollment is an ongoing challenge.[1] Only a minority of eligible patients have access to a trial available at their treatment location.[2] Our landscape report, *Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer*, details several provider, institutional, patient, and trial-design barriers that prevent cancer patients from enrolling in clinical trials.[2] Patient-specific barriers include factors such as travel time and distance to the trial site as well as non-medical costs like transportation and lodging.[2] The report includes specific recommendations, endorsed by a broad array of stakeholders, for addressing patient-specific barriers including a recommendation that trial sponsors and research programs explore the use of technology or other tools to reduce patient time and travel burdens associated with clinical trial participation.

We commend the Administration for recognizing the role digital health technologies (DHTs) can play in facilitating decentralized clinical trials and increasing opportunities for patients to participate in trials at

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locations remote from the investigator's site. During the COVID-19 pandemic the U.S. Food and Drug Administration (FDA) significantly expanded opportunities for decentralized trials and remote acquisition of patient data through the use of DHTs while allowing patients to remain in their homes or travel less. We believe that the use of DHTs hold promise outside of a pandemic setting and support the *Diversifying Investigations Via Equitable Research Studies for Everyone (DIVERSE) Trials Act* which allows trial sponsors to provide patients with the technology necessary to facilitate remote participation in clinical trials.

In addition to increasing opportunities for patients to participate in clinical trials, the use of DHTs may also increase the likelihood that patients, particularly those unable to overcome geographic, transportation, or cost barriers, will consent to participate. In 2021, ACS CAN surveyed 1,344 cancer patients and survivors about telehealth, remote care technologies, and willingness to participate in cancer clinical trials *(full results have been submitted for peer-review)*. More than 80% of respondents expressed a willingness to adopt DHTs (e.g., health applications, wearable technology) for care not specifically within the clinical trial context. When subsequently asked about DHTs in the context of trials, the opportunity to use DHTs increased likelihood to consent among respondents if the technology decreased the need to travel to a trial site. DHTs such as wearables and health applications used to track trial data, and DHTs used to facilitate trial check-ins or trial activities via video from home, resulted in increased reported likelihood of participation ranging from 73% to 82% depending on the DHT.

The quick adoption of DHTs in clinical trials during the COVID-19 pandemic demonstrated how DHTs can be leveraged to reduce the need for trial participants to travel to a centralized trial site, a significant barrier to patient participation. This draft guidance provides greater clarity for regulatory approval based on data collected using DHTs. We appreciate the opportunity to provide comments and look forward to working with you to ensure cancer clinical trials are more open and accessible to all patients. If you have any questions, please do not hesitate to contact Mark Fleury, PhD (mark.fleury@cancer.org), Principal, Policy Development - Emerging Science.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network

[1] Unger, J. M., Hershman, D. L., Till, C., Minasian, L. M., Osarogiagbon, R. U., Fleury, M. E., & Vaidya, R. (2021). "When Offered to Participate": A Systematic Review and Meta-Analysis of Patient Agreement to Participate in Cancer Clinical Trials. JNCI: Journal of the National Cancer Institute, 113(3), 244–257. https://doi.org/10.1093/jnci/djaa155

[2] Barriers to Patient Enrollment in Therapeutic Clinical Trials. American Cancer Society Cancer Action Network. (2019) Retrieved February 28, 2022, from https://www.fightcancer.org/sites/default/files/National%20Documents/Clinical-Trials-Landscape-Report.pdf