Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
http://www.regulations.gov

RE: Docket No. FDA-2021-D-1128
"Digital Health Technologies for Remote Data Acquisition in Clinical Investigations; Draft Guidance for Industry, Investigators, and Other Stakeholders; Availability"

Dear Sir or Madam:

We are writing on behalf of the ACDM

ACDM represents enthusiastic clinical research professionals with a passion to improve the drug development process by offering an environment for continuous learning and application of contemporary Clinical Data Management practices.

Serving the data management community for over 30 years, our commitment is to provide explicit settings for our fellow members to network, share experiences & keep up to date with the latest regulations & standards in the area of Data Management. We also take pride in helping our members in their professional development journey. Our mission is to provide opportunities to constructively engage, collaborate and learn from the industry experts in Data Management, to equip members with the necessary skills to excel in their careers, so they can become the data management experts of the future.

Kind regards

Ian Pinto. Chair of ACDM Board:
Contact details: admin@acdmglobal.org

Line #	Comment
25	Do you mean in case DHT is only collecting some records with the intention to transfer to a computerized system? If so, it would be convenient to remind the audience the already existing requirements on the regulation for this computerized system. (i.e. ICH standards on Computerized Systems Validation).
39	Should you recommend further through which regulation you do recommend to meet these validation? Should you also be recommending what should definitely not be used to capture data such as memory sticks or something?
24 & 80 & 345	Please consider duplication of text 'DHT can also be software applications that are run on general purpose computing platforms'
41/42	Should you recommend the same risk management as per the same pharmaceutical standards that we have in the industry?
126 -133	Please clarify process for DDT qualification at the CDRH in order to avoid overlaps with mandatory certification of devices as required by ANSI and ONC.
142 -144	This parallel "qualification" process infringes established Standardization, Certification and Intellectual Property Rules and Best Practices Why should any clinical research sponsor invest in a qualification effort for device or application which they do not manufacture?.
197-198	Ensure security of data transmission is risk-based
541	Please consider rewording, 'at rest and in transit' are necessary as the data should be secure in general.
653	There doesn't seem to be any mention of recommended back up plans should there be tool/system failure
692	We don't understand how data subjects/patients will have training records per GCP requirements. Patients are not responsible for data entry/acquisition. This can only be handled in the Consent process and protocol writing, we could not produce proof of clinical data subject training
870	This is contrary to prevalent statistical and engineering definitions, where precision is a measure of error and error significance (not "agreement").
883	Please clarify how this concept relates to ICH standards on Computerized System Validation (for application and software) and Quality Management System (audit/inspection CAPA)
887	This definition implies Source Document Verification and other similar visual comparison techniques. This goes against Risk Based Monitoring principles and the fact that DHT such as sensors and wearables do not have persistent memory