U.S. FOOD & DRUG ADMINISTRATION

Guidance Snapshot

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

Guidance for Industry, Investigators, and Other Stakeholders

What is recommended in this guidance?

This final guidance provides recommendations for sponsors, investigators, and other interested parties on the use of digital health technologies (DHTs) for remote data acquisition from participants in clinical investigations that evaluate medical products. The guidance focuses on recommendations for ensuring that a DHT is fit-for-purpose and that the level of validation associated with the DHT is sufficient to support the use, including the interpretability of its data, in the clinical investigation. This involves considerations of the DHT's form (i.e., design) and function(s) (i.e., distinct purpose within an investigation).

What is a DHT?

A DHT is a system that uses computing platforms, connectivity, software and/or sensors for health care and related uses. DHTs for remote data acquisition in clinical investigations can include hardware and/or software to perform one or more functions. They may rely on or work with other technologies that support their operation, such as general-purpose computing platforms (e.g., smartphones) and communication networks. Depending on the intended use of a DHT, the DHT may meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Why is this guidance important?

This guidance outlines recommendations intended to facilitate the use of DHTs in clinical investigations as appropriate for the evaluation of medical products. This guidance may improve the efficiency of clinical trials for sponsors, investigators, and other interested parties and may improve convenience and opportunities for individuals to participate in research. Increasing access to and use of DHTs in clinical trials can potentially enable the inclusion of diverse and underrepresented populations by facilitating decentralized clinical trials. Reducing the burden on trial participants can also improve trial recruitment, participant engagement, and retention throughout the study.

Examples of DHTs

Guidance Snapshots are a communication tool and are not a substitute for the guidance document. To learn more about DHTs, read the final Guidance. To see additional Guidance Snapshots, check out the pilot program.

Regulatory Considerations

- Some DHTs used in clinical investigations may be medical devices, so certain medical device regulatory requirements may apply.
- As long as the investigation complies with the investigational device exemption (IDE) regulations, FDA generally does not intend to request that sponsors submit a separate IDE application, depending on a number of factors such as the risk of the DHT.
- The Digital Health Center of Excellence (DHCoE) in the Center for Devices and Radiological Health serves as a resource on DHTs, including their regulatory status and medical device regulatory requirements.

DHT Selection and Rationale for Use in a Clinical Investigation

- When selecting DHTs and/or other technologies for use in clinical investigations, consider, among other factors, the clinical trial population, technical and performance specifications of the DHT, design and operation of the DHT, and potential for use of a participant's own DHT and/or use of other technologies.

DHT Description in a Submission

- Submissions should describe how a DHT is fit-for-purpose. The description should include information on the design and technological characteristics of the DHT, data provided to the sponsor and investigator, and how the DHT measures the clinical event or characteristic of interest (e.g., the use of accelerometry to measure steps or the use of photoplethysmography to count heartbeats).

Verification, Validation, and Usability Evaluation of DHTs

- Verification and validation help ensure that the DHT is fit-for-purpose for remote data collection in a clinical investigation.
- Verification is confirmation by examination and provision of objective evidence that the parameter that the DHT measures (e.g., acceleration, temperature, pressure) is measured accurately and precisely.
- Validation is confirmation by examination and provision of objective evidence that the selected DHT appropriately assesses the clinical event or characteristic in the proposed participant population (e.g., step count or heart rate).
- Usability evaluations should identify and address any potential use errors or difficulties that trial participants or other intended users may experience when using the DHT.

Evaluations of Endpoints Involving Data Collected Using DHTs

- DHTs may serve as new ways to measure clinical characteristics or events that were previously measured in a clinical setting (e.g., blood pressure monitoring at home versus in a clinic).
- When DHT measurements replicate existing measurements (e.g., weight measurements at home versus in the clinic) for the same endpoint, a new justification for the choice of the endpoint may not be needed. However, the DHT should still be verified and validated for use in the clinical investigation.
- Novel endpoints based on data captured by DHTs may provide opportunities for additional insight into participant function or health that was previously not easily measured.

Statistical Analysis and Trial Design Considerations

- FDA evaluates data collected via DHTs based on factors including, but not limited to, the endpoint under consideration, the medical product under investigation, and the patient population in which the product will be used.
- Analyses of data collected from DHTs should be discussed in a statistical analysis plan.

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Risk Considerations When Using DHTs

- Sponsors, investigators, and institutional review boards (IRBs) should consider any risks to trial participants associated with use of the DHTs for data collection and should include them in the informed consent.
- The risks of using a DHT in a clinical investigation can generally be categorized as clinical risks and privacy-related risks.

Record Protection and Retention

- When using DHTs to record and transmit data during a clinical investigation, the relevant data captured from the DHT, including all relevant associated metadata, should be securely transferred to and retained in a durable electronic data repository as part of the record of the clinical investigation.
- The draft guidance for industry *Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers* addresses electronic records collected by DHTs during a clinical investigation.

Other Considerations When Using a DHT in a Clinical Investigation

- To help ensure the quality and integrity of data, adequate protection of participants, and satisfaction of regulatory requirements applicable to clinical investigations, sponsors and investigators should consider the sponsor's role, investigator's role, training, and impact of DHT updates and other changes.

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Insights About the Guidance

This guidance is being issued, in part, to satisfy the mandate under section 3607(a) of the Food and Drug Omnibus Reform Act of 2022 (FDORA) to issue guidance regarding the appropriate use of DHTs in clinical trials and meets a Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goal to finalize guidance on DHTs (section IV.C.5.b of the PDUFA VII commitment letter). Additional information on FDA's DHT PDUFA commitments is available on the webpage DHTs for Drug Development.

This guidance finalizes the draft guidance of the same title issued on December 23, 2021 (86 FR 72981). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarification on the definition of DHTs and their function(s); further explanation on regulatory considerations for DHTs that meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act; inclusion of references to Form FDA 1571 and Form FDA 356h for tracking submissions that include DHT data; and revisions to the Verification, Validation, and Usability Evaluations section.

Sponsors should engage early with the appropriate center responsible for the medical product under investigation to discuss the use of DHTs in a specific clinical investigation. The responsible center will consult other centers as needed. Sponsors should follow each FDA center's procedures for engaging with the Agency in the context of a development program.

Guidance Recap Podcast – Hear highlights straight from FDA staff

Speaker(s): Elizabeth Kunkoski, Consumer Safety Officer, Center for Drug Evaluation and Research and Anindita Saha, Associate Director for Strategic Initiatives, Digital Health Center of Excellence, Center for Devices and Radiological Health

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