FDA Publishes Final Guidance on Using DHTs for Remote Data Acquisition in Clinical Trials

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In December 2023, FDA finalized its draft guidance on using digital health technologies (DHTs) in clinical research, Digital Health Technologies (DHTs) for Remote Data Acquisition in Clinical Investigations (December 2023). This post builds on our prior analysis of the draft DHT guidance, and discusses some key new points and clarifications made in the final guidance. Here, we focus on updates to the guidance that study sites, sponsors and CROs should consider when procuring, implementing and managing DHTs in clinical trials. The key updates we walk through will impact your contracts with the DHT vendors, study operations, informed consent and the clinical trial agreement. Topics range from study participants and caregivers to security and source data, and more.

I. Background.

The guidance defines DHT as "a system that uses computing platforms, connectivity, software, and/or sensors, for health care and related uses." The final guidance contains recommendations for sponsors, investigators and other stakeholders on using DHTs for remote data acquisition in clinical investigations.

II. Key Updates.

Simplified Treatment of DHTs and Other Technologies; AI. The final guidance streamlines the draft guidance's somewhat confusing discussion of DHT hardware and software, and general-purpose computing platforms. The final guidance still notes that DHTs "can include hardware and/or software," including software enabled by artificial intelligence. However, instead of elaborating on the differences between DHT software and hardware, FDA focuses on DHTs themselves, removing the distinction from the examples provided at the end of the guidance as well. Additionally, the term "general-purpose computing platform," which appeared quite frequently in the draft guidance, is now lumped into the category of "other technology"; FDA explains that DHTs "may rely on or work with other technologies that support their operation, such as general-purpose computing platforms (e.g. smartphones) and communication networks." FDA recommends that sponsors ensure these other technologies are adequate to support the DHT functions.

Fit-For-Purpose. While continuing to stress that the level of validation of the DHT should be appropriate to ensure the DHT is fit-for-purpose, the final guidance adds that the sponsor must ensure the DHT remains fit-for-purpose

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throughout its use in the clinical trial.

Feedback to Users and Blinding. The final guidance explains that some DHTs have a feature that provides users with direct feedback on the data collected. FDA cautions that this feedback may affect the way participants behave in the study, and notes that studies can instead be designed to maintain blinding or masking of data when appropriate by having the data transferred directly to investigators without transmission to users.

Data Flow. FDA emphasizes in the final guidance that sponsor submissions should include descriptions of the data flow from the DHT to the first durable electronic data repository. FDA considers the data in the first durable electronic data repository to be the source data (see Section ix below for more information on source data).

Leveraging Verification and Validation Data. In the final guidance, FDA expands on sponsor options for leveraging verification and validation data from third parties. Instead of just stating that sponsors can leverage this data from "manufacturers or other third parties," as is written in the draft guidance, FDA specifies that sponsors can leverage data "(1) by DHT manufacturers or other third parties publicly, (2) in device labeling, or (3) by right of reference to other FDA submissions, when appropriate."

Run-in Period. As part of verification and validation, FDA notes that it may be appropriate to compare measurements obtained from the DHT from participants remotely vs. from participants in a clinic setting using the same DHT. FDA observes that a run-period may be appropriate to ensure reliable data quality and collection.

Statistical Analysis Plan and Trial Design. FDA notes that sponsors should have a plan in place to reduce the potential for missing data. This could include sponsor and/or investigator automated data monitoring and alerts, participant reminders, a "run-in" period for participants, or investigator outreach to participants. The sponsor's plan should also address how to handle missing and erroneous data.

Electronic Informed Consent. Addressing a topic not included in the draft guidance, the final guidance states that DHTs can be used to obtain electronic informed consent and includes a link to the FDA guidance on electronic informed consent.

Record Retention and Source Data.

- DHT data must be maintained in accordance with the record retention requirements of 21 CFR 312.62(c) and 812.140(d), and per Part 11, the data "should be in human readable form." The guidance goes on to explain that "Generally, FDA does not intend to request machine or raw data that require electronic processing to be understood (e.g., voltages) during an inspection."

- FDA makes clear that it considers the source data to be the "electronic data that are located in the first durable electronic data repository to which the data are transferred." FDA notes that it does not intend to inspect specific DHTs "for source data when the data…including all associated metadata, are securely transferred to and retained in the durable electronic data repository according to the sponsor's prespecified plan."

Sponsor's Role: Safety Monitoring and Closeout. The final guidance adds some new considerations for the sponsor's safety monitoring plan, such as how often investigators will review continuous data and reporting of abnormal findings to trial participants. FDA also advises sponsors to develop closeout procedures for the end of the study, such as when and how data collection and/or transmission ends, and revocation of system access.

Investigator's Role: Trial Participant Understanding. In the final guidance, FDA advises investigators to ensure that trial participants understand how the information collected by the DHT in the study will be used, monitored, and

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acted upon, as well as who will have access to the information. This recommendation is in addition to data and privacy disclosures that should be addressed in the informed consent and reflects greater focus on data privacy from the trial participant's perspective.

DHT Updates and Other Technology Changes. The final guidance delves deeper into the impact of software and hardware updates on DHTs and associated technologies. It may be necessary, for example, to validate measurements after the update and, if changes have occurred, to compare before and after DHT data. Importantly, "Significant changes in the measurement after updates may invalidate the results form a clinical investigation."

Examples in Appendix A. The examples of uses of DHTs in clinical trials have been streamlined. The final guidance removes the sections that identify the hardware versus software aspects of the DHT, and instead describes the DHT in one "descriptions" section. FDA also removes the section identifying the relationship of the DHT to general-purpose computing platforms.

Training of Caregivers. In the final guidance, FDA clarifies that training may be appropriate not just for trial participants and personnel, but also for participants' caregivers. FDA also recommends that training include a confirmation that use of the DHT will be restricted to participants and/or caregivers.

III. Final Thoughts.

Although this is the final guidance, it is important to keep in mind that the use of DHTs for remote data acquisition in clinical trials is an exciting and evolving field. Just two months prior to the issuance of this final guidance, FDA announced the creation of a Digital Health Advisory Committee to help explore the rapidly-evolving and complex digital health space, a space that spans a wide range of technologies like artificial intelligence, machine learning, virtual reality or wearables. This Committee may advise on DHT use in clinical trials or post-market studies, including in decentralized clinical trials. The formation of this advisory committee highlights the growing role that FDA envisions DHTs continuing to play in the clinical trials space. We invite you to stay tuned as the committee undertakes its mandate and as the recommendations in this final guidance play out in industry.

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If you have any questions or would like more information about these developing issues, please contact the following:

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