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Fact Sheet

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations:

Understanding the FDA draft guidance

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Digital Health Technologies for Remote Data Acquisition in Clinical Investigations: Understanding the FDA draft guidance

What will you find in this fact sheet?

Last month (December 2021) the FDA published draft guidance regarding Digital Health Technologies for Remote Data Acquisition in Clinical Investigations.

The guidance document outlines recommendations intended to facilitate the use of Digital Health Technologies (DHTs) in clinical investigations as appropriate for the evaluation of medical products.

Our easy-to-read fact sheet outlines:

- **What the guidance covers**
- **What you need to consider**
- **What you need to include in your submission**
- **Where to find examples regarding potential DHT use in Clinical Evaluations, and selecting a DHT for a Clinical Investigation**

A Digital Health Technology (DHT) is a system that uses computing platforms, connectivity, software, and/or sensors, for healthcare and related uses.

The guidance provides recommendations on the use of DHTs for remote data acquisition from participants in clinical investigations evaluating medical products.

What does the guidance cover?

The guidance provides comprehensive background on the composition of DHTs, covering sensor technology, general purpose computing platforms and data transmission and storage. Information on the following is also covered:

- Selection of DHTs that are suitable for use in clinical investigations
- Verification and validation activities of DHTs for use in clinical investigations
- Use of DHTs to collect data for trial endpoints
- Identification and management of risks associated with the use of DHTs during clinical investigations
- Regulatory considerations and how to engage with the FDA

The guidance does not cover whether a DHT meets the definition of a medical device under section 201(h) of the FD&C Act.

Important considerations

Devices intended for use in clinical investigations are exempt from most requirements applicable to medical devices, including premarket clearance or approval, if the investigation complies with applicable requirements under 21 CFR part 812.

Selecting your DHT

In choosing an appropriate DHT, you should consider:

- The clinical event/characteristic of the disease/condition of interest that is to be measured
- The design of the clinical investigation
- The clinical investigation population
- The design and operation of the DHTs
- The characteristics of the DHT that may influence trial participant use
- Whether the use of a participant's own DHT or general-purpose computing platform and telecommunications (e.g., mobile phone, tablet, or smart watch) may be appropriate to reliably collect or facilitate the collection of data during the clinical investigation

You should ensure that a DHT is fit-for-purpose, i.e. that the level of validation associated with the DHT is sufficient to support its use and interpret-ability in the clinical investigation.

Other considerations

Assessing risk

You should consider any clinical and privacy-related risks to trial participants associated with the use of the DHTs for data collection as well as the requirements for informed consent.

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 meta data, should be securely transferred and retained in a durable electronic data repository as part of the record of the clinical investigation.

Data, participant protection, regulatory requirements

The guidance provides training and planning information to help ensure the quality and integrity of data, adequate protection of participants, and satisfaction of regulatory requirements applicable to clinical investigations.

What to include in your submission

Digital Health Technology Description | This should contain basic information about the DHT, and explain why the DHT is fit-for-purpose for use in the clinical investigation. For many commercially available DHTs, the technical specifications and descriptions provided by the DHT manufacturer may be sufficient.

Verification, Validation, and Usability of Digital Health Technologies | You should include relevant verification and validation data on the DHT and, if applicable, the general-purpose computing platform, as well as a discussion of any DHT modifications made because of testing.

Here, the guidance covers:

- Sensor-Based DHTs
- DHT Software
- General-Purpose Computing Platforms
- Inter-operability
- Usability Studies

Evaluation of Clinical Endpoints from Data Collected Using Digital Health Technologies | You should include a description of the clinical endpoint or endpoints measured from data collected through a DHT. If the endpoint is novel, you should justify use of the endpoint in the clinical investigation.

Statistical Analysis | Analyses of data collected from DHTs should be discussed in a statistical analysis plan.

Where to find helpful examples

Examples of potential DHT use in Clinical Investigations

Appendix A of the guidance gives several examples of potential DHT use in Clinical Investigations.

An example of selecting a DHT for a Clinical Investigation

Appendix B of the guidance gives an example of selecting a DHT for a Clinical Investigation. The example chosen is for a portable wearable device to assess sleep parameters in the home setting in trial participants with insomnia disorder.

The example covers:

- DHT Selection, Verification and Validation
- Usability Testing
- Endpoint Justification

Should you require assistance with an eHealth, regulatory or clinical challenge, please don't hesitate to get in touch – we'd be happy to help.

Congenius AG
Riedstrasse 1
CH- 8953 Dietikon
E: info@congenius.ch
T: +41 44 741 04 04