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DIGITAL HEALTH MONTHLY

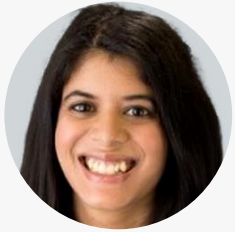
SCIENTIFIC WEBINAR SERIES

Navigating the FDA DHT Guidance: Perspectives from Across the Industry

September 25, 2024

October's Digital Health Monthly topic:
Stay Tuned...

Speakers



Annie Saha

Associate Director for Strategic Initiatives

Digital Health Center of Excellence at FDA

Carrie Northcott

Head of Digital Sciences; Biomeasures, Endpoints and Study Technologies

Pfizer

Nicholas Fountoulakis, RAC

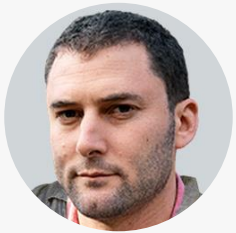
Manager, North America Regulatory Scientist Global Regulatory Affairs, Immunology

Janssen Research & Development, LLC

Bert Hartog

Chief Impact & Innovation Officer

Digital Medicine Society



Sylvan Zorman, PhD

Director of Digital Health Sciences, Moderator

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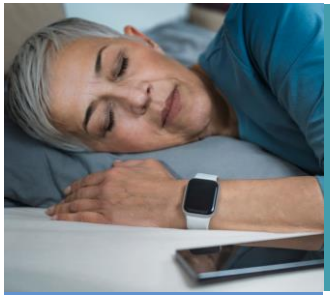
Agenda

- **Overview of the DHT guidance by Annie Saha (10min)**
- **Panel discussion (30min)**
- **Q&A** (Zoom Q&A button)

Overview of the DHT Guidance

Anindita Saha
Associate Director for Strategic Initiatives
Digital Health Center of Excellence
September 25, 2024

We work to advance health care by fostering responsible and high-quality digital health innovation



Digital therapy device to reduce sleep disturbance for psychiatric conditions

AI-enabled device for skin cancer evaluation

Digital therapy device for ADHD

Self-fitting over-the-counter hearing aids

Virtual reality behavioral therapy device for pain relief

Electrocardiograph software for over-the-counter use

Digital health technologies can transform how we study medical products

Enable Remote Data Collection in Decentralized Clinical Investigation

- More frequent or continuous monitoring compared to traditional methods
- Longitudinal view of participant's health status
- Improved recruitment and retention of participants leading to less missing data

Improve Access to Clinical Investigations

- Meet a participant where they are at for a clinical investigation
- Fewer visits to a study site places less burden on participants
- Reach a more diverse population, advancing health equity

Facilitate Innovative Clinical Investigation Endpoints

- New types of data to inform novel endpoints
- Complementary to other forms of data used to support a regulatory submission

Capture Real-World Data (RWD) and Patient-Generated Health Data (PGHD)

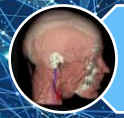
- Data reflects a participant's daily life
- Remote and longitudinal follow-up with participants beyond the clinical investigation
- More detailed picture of the impact of a medical product on a participant
- Potential to capture infrequent clinical events (e.g., arrhythmia, apnea)

Digital Health Technology (DHT)

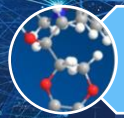
"A system that uses computing platforms, connectivity, software, and sensors for healthcare and related uses"*

Used as a medical product

Incorporated into a medical product



Used to develop a medical product



Used to study a medical product

Used as a companion or adjunct to a medical product, including diagnostics and therapeutics

*Definition from FDA-NIH BEST Glossary. Available at https://www.ncbi.nlm.nih.gov/books/NBK338448/

Guidance on Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

- This guidance provides recommendations to facilitate the use of DHTs in clinical investigations
- Designed to help accelerate efficient medical product development to help bring new innovations and advances to patients
- Supports decentralized trials and health equity
- Developed collaboratively across the Agency
- Impacts CDRH both as reviewers of devices and clinical investigations

Some DHTs meet the definition of a medical device* while others do not

*A device is defined by the Federal Food, Drug, & Cosmetic Act, Section 201(h) as:

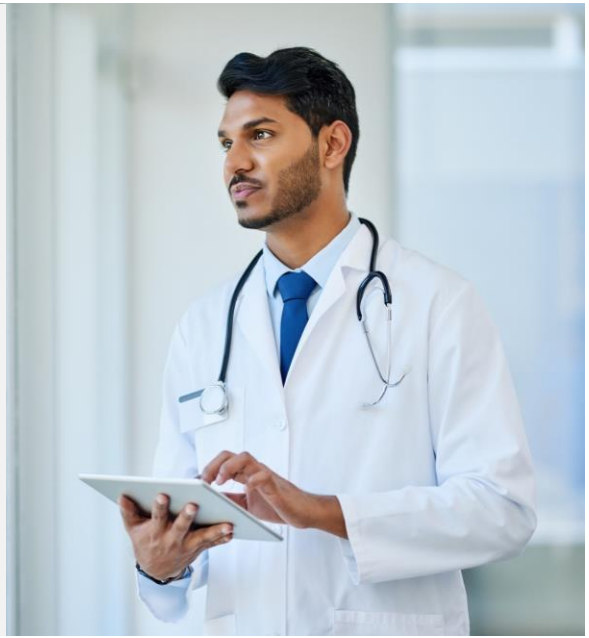
an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals…

When is an Investigational Device Exemption (IDE) application to FDA required?

For DHTs that are Devices,

- ***For a Non-Significant Risk Device,*** an IDE application to FDA is not required if the investigation complies with abbreviated requirements in 21 CFR 812.2(b).
- ***For a Significant Risk Device,*** when all information required in an IDE application under 21 CFR 812.20 is also contained in an IND, FDA generally does not intend to request sponsors to submit a separate IDE application.
- ***For a Device used in accordance with its approved or cleared indications for use,*** an IDE application to FDA is not required.



Other Good Clinical Practice (GCP) Regulations also apply, including those related to Institutional Review Boards and Protection of Human Subjects.

If a DHT has marketing authorization (premarket clearance or approval), does that mean it is appropriate for use in a clinical investigation?

FDA

Generally, yes if the following are true

DHT used in the clinical investigation is ***fit-for-purpose****

Fit-for-purpose: A conclusion that *the level of validation associated with a biomarker or COA is sufficient to support its proposed use.*

DHT measures can inform clinical investigation ***endpoints**** that reflect the outcome(s) of interest

Endpoint: *A precisely defined variable intended to reflect an outcome of interest* that is statistically analyzed to address a particular research question…

*Definitions from FDA-NIH BEST Glossary. Available at https://www.ncbi.nlm.nih.gov/books/NBK338448/

Are design controls required?

What are design control requirements?

*Basic controls needed to ensure that the device being designed will perform as intended**

DHTs that are devices are also subject to design control requirements

- ***For devices that do not have FDA marketing authorization AND are used only in a clinical investigation for remote data collection,*** FDA's assessment as to whether the device is fit-for-purpose in the investigation is primarily based on the information submitted to the Agency
  - This guidance describes the types of information that can provide assurance that these devices, when used only for remote data collection in clinical investigations, will perform as intended
  - Therefore, where sponsors conduct the types of verification and validation activities recommended in this guidance to ensure that a DHT used only in clinical investigations for remote data collection is fit-for-purpose, FDA does not intend to otherwise assess sponsors' compliance with design control requirements, when applicable
  - This policy does not apply when a DHT that is a device is intended for use outside of a clinical investigation

*See 21 CFR 820.30 for further information on design control requirements

DHTs should be *fit-for-purpose* when used in a clinical investigation

***Fit-for-purpose**: a conclusion that the level of validation associated with a DHT is sufficient to support its proposed use, including the interpretability of its data, in the clinical investigation*

- What clinical event or characteristic is of interest?
- Can the DHT measure the clinical event or characteristic of interest?
- What is the population of interest, including age, technical aptitude, and education level, etc.?
- How does the DHT form (i.e., design) and function(s) (i.e., distinct purpose(s) within an investigation) impact participant use?

Applies regardless of if the participant is bringing their own DHT or other technology for use in the clinical investigation

Sponsors should explain in their submission how the DHT is fit-for-purpose for use in the clinical investigation

Design, technical characteristics

Data provided to sponsor, investigator

How DHT measures clinical event, characteristic of interest

Features impacting usability (e.g., user interface, wear, maintenance)

Data privacy, security

Access control methods

Potential for user reported information

Data management (e.g., collection, storage, transmission)

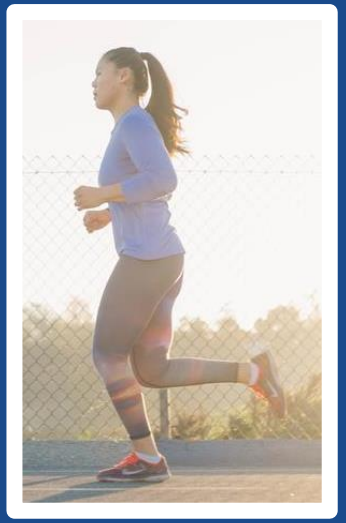
Verification and validation are important steps to help ensure a DHT is fit-for-purpose

Verification: 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.* Verification is often viewed as part of the validation process

Validation: confirmation by examination and provision of objective evidence that the selected DHT appropriately assesses the clinical event or characteristic (e.g., step count or heart rate) *in the proposed participant population*

Verification and validation data made available by other sources may be leveraged, when appropriate

Benchtop studies



Studies with healthy volunteers

Studies with individuals representing the population to be studied in the clinical investigation

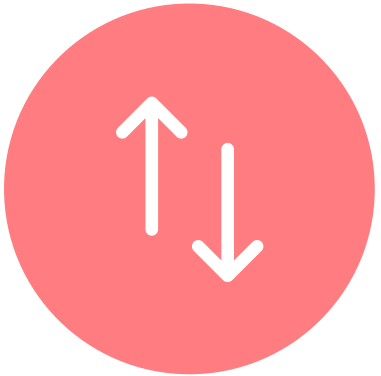
Data may be made available 1) by DHT manufacturers or 3rd parties publicly, 2) in device labeling, or 3) by right of reference to other FDA submissions

When using data from a DHT to inform an endpoint, treat the endpoint like you would any other endpoint

Definition

Justification

Type
(Safety, Effectiveness)



Positioning
(Primary, Secondary, etc.)

MDDT Program Qualifies DHT to support Regulatory Decision Making

- Apple Atrial Fibrillation History Feature Qualified 5/1/2024
- **The first digital health technology** qualified under the MDDT program, providing a non-invasive way to check estimates of atrial fibrillation (AFib) burden within clinical studies.
- **Designed to be used as a biomarker test** to help evaluate estimates of AFib burden as a secondary effectiveness endpoint within clinical studies intended to evaluate the safety and effectiveness of cardiac ablation devices to treat.
- **Designed to be used throughout the clinical study**, both before and after cardiac ablation devices, to monitor a study participant's weekly estimate of AFib burden.

Questions: MDDT@fda.hhs.gov
To Submit to the MDDT Program: Medical Device Development Tools (MDDT) | FDA

Interactive Tool to Help Developers Navigate Digital Health Policy

- Guides users through a series of questions about their software function.
- Users receive one of four different outcomes that reflects digital health policy.

DHTs can revolutionize the ability to remotely obtain clinically relevant information from diverse individuals

Potential for continuous or more frequent data collection

Opportunities to record data directly from trial participants wherever the participants may be

Can facilitate the direct collection of information from participants who are unable to report their experiences

Engage with Us!

For informal questions about digital health policy please reach out to:

Digital Health Center of Excellence (DHCoE)

DigitalHealth@fda.hhs.gov

For general questions about CDRH, please reach out to:

CDRH's Division of Industry and Consumer Education (DICE)

DICE@fda.hhs.gov

Sign up for the DHCoE Newsletter (at the bottom of the page).	Check out the Digital Health Policy Navigator.

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Scan for Survey

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