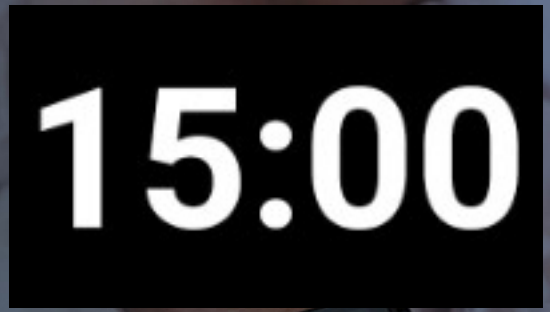
Operationalizing Digital Health Technologies: Successes and Failures in Clinical Research



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Operationalizing Digital Health Technologies: Successes and Failures in Clinical Research

September 21, 2022

Overview

- A recorded version will be available after the webinar
- Interaction
  - Poll questions throughout
  - Use the Q/A option to direct questions to the panelists
- Goal: To provide attendees with some best practices related to the deployment and management and of Digital Health Technologies (DHTs) in clinical trials.
  - **Increase your knowledge** of typical operational challenges encountered by top sponsors and CROs
  - **Equip you** with the right questions to ask when preparing for a clinical trial with DHTs
  - **Inspire you** – DHTs are changing clinical trials – the challenges you think are daunting have mostly been encountered and addressed
- Minutes will be taken during today's session and shared with attendees (pdf)

Featured Speakers

Jeremy Wyatt

Chief Executive Officer

ActiGraph

Robin Harris

Sr. Director, Digital Health Operations

ActiGraph

Marie McCarthy

Develop. Unit Digital Endpoint Lead

Novartis

Elan Josielewski

Sr. Principal, Patient Centered Endpoint Solutions

IQVIA

Poll Question:

Which role in industry do you represent?

DHT Operational Success & Failures

Scope

In Scope

Operational challenges related to the deployment of DHTs

Not in Scope

- Selection and validation of DHT and corresponding algorithms
- Statistical analysis
- Precision/accuracy considerations of the DHT
- Interpretation and statistical plan related to the measurement derived from the DHT
- Safety monitoring

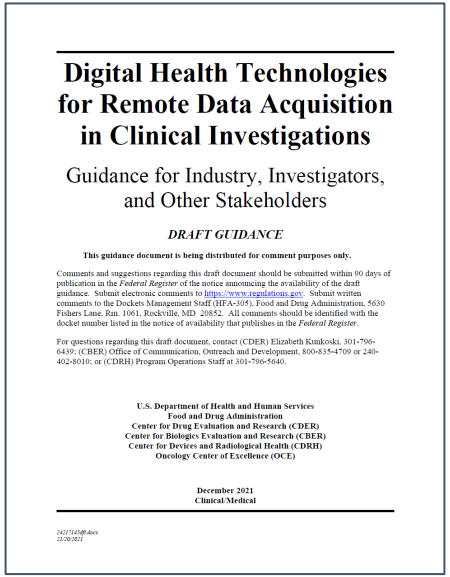
Poll Question:

Why are you attending this webinar?

DHTs are here to stay!

DHTs Defined - *A digital health technology (DHT) is a system that uses computing platforms, connectivity, software, and/or sensors, for healthcare and related uses.*

FDA Draft Guidance on DHTs references the importance of operational considerations as they relate to clinical investigations



Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

Guidance for Industry, Investigators, and Other Stakeholders

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Elizabeth Kunkoski, 301-796-6439; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Program Operations Staff at 301-796-5640.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)

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Clinical/Medical

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12/20/2021

Operational Factors for Consideration*

Data Loss
- Having backup/replacements DHTs

Design
- Material/size/weight/portability

Power needs
- Battery/charging

Technical assistance
- Regional support
- Costs

Participant/site training
- Timing
- Translations
- Simplicity

Data storage capacity
- On the DHT
- In the platform

Data transmission
- From DHT->
- To the platform->
- To the sponsor or CRO->

Environmental factors
- Performance impacting
  - Temperature
  - Humidity

Privacy & Security

*__Digital Health Technologies for Remote Data Acquisition in Clinical Investigations__ – *Guidance for Industry, Investigators, and Other Stakeholders*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations; Accessed 9/19/2022

DHT Benefits in Clinical Research

- The use of DHTs to remotely collect data from trial participants may allow for continuous or more frequent data collection [which can be used to] provide a **broader picture of how participants feel or function** in their daily lives. [1]

- Data aggregation from wearables also provides a multitude of opportunities for more observational studies that have not been possible before. This can lead to new hypotheses for **future interventional studies that can be used to improve patient care** by providing new treatments and protocols. [2]

- Collecting dense data from trial participants using wearables in natural settings — often not collectible otherwise —**may fundamentally change how clinical trials are designed and conducted**. [3]

- Leveraging such data – typically called real -world data (RWD) - to **improve regulatory decisions is a key strategic priority for the FDA**. [4]

VALENCELL

Clinical Pharmacology & Therapeutics ASCPT

Takeda

FDA

1 - FDA DHT Draft Guidance - Jan 2022, Accessed 9/20/2022
2 - Valencell: Wearables in Clinical Trials: Opportunities and Challenges, Accessed 9/20/2022
3 - Wearable Devices in Clinical Trials: Hype and Hypothesis - Izmailova, E.S., Wagner, J.A., Perakslis, E.D., Accessed 9/20/2022
4 - Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's new strategic framework to advance use of real-world evidence to support development of drugs and biologics, Accessed 9/20/2022

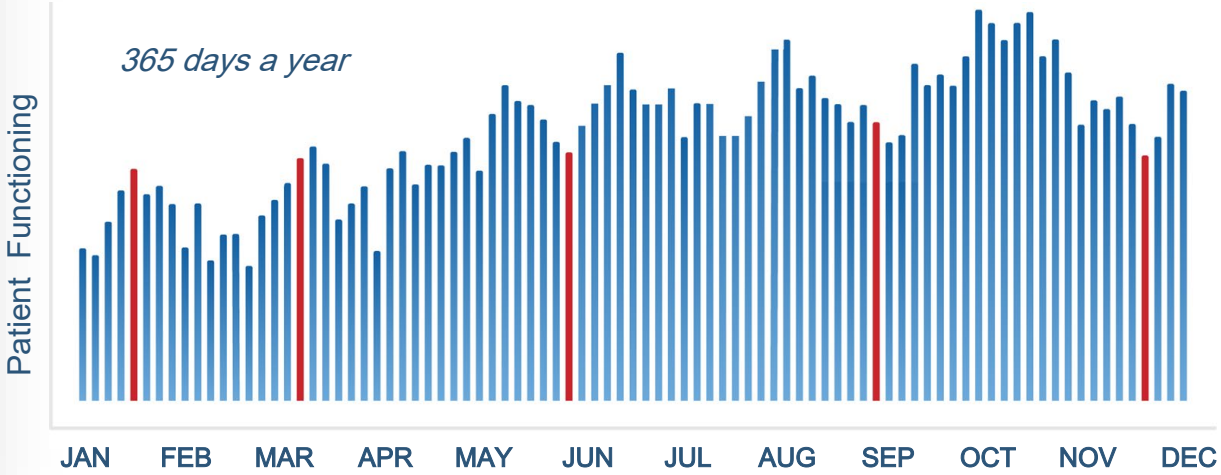
> If you cannot measure it, you cannot improve it.
>
> ~ Lord Kelvin

- Inadequate measures of the course of disease trajectory
- Long and big clinical trials, and low confidence in detecting clinical benefits.

Measurement Challenges in Drug Development

Visible: Conventional outcomes: Episodic data points in a clinic

Invisible: Patients' conditions in real life: Chronic and progressive with fluctuations



Four stages of operational considerations when deploying remote monitoring

1

Procure digital measurement products

Acquire access to the needed technologies

2

Prepare product-level ecosystem

- Authenticate, configure, and provision the tech
- Integrate tech into broader platform
- Prepare User Acceptance testing (UAT)
- Train the staff

Go Live

Patients start using digital measurement products

3

Post Go-Live

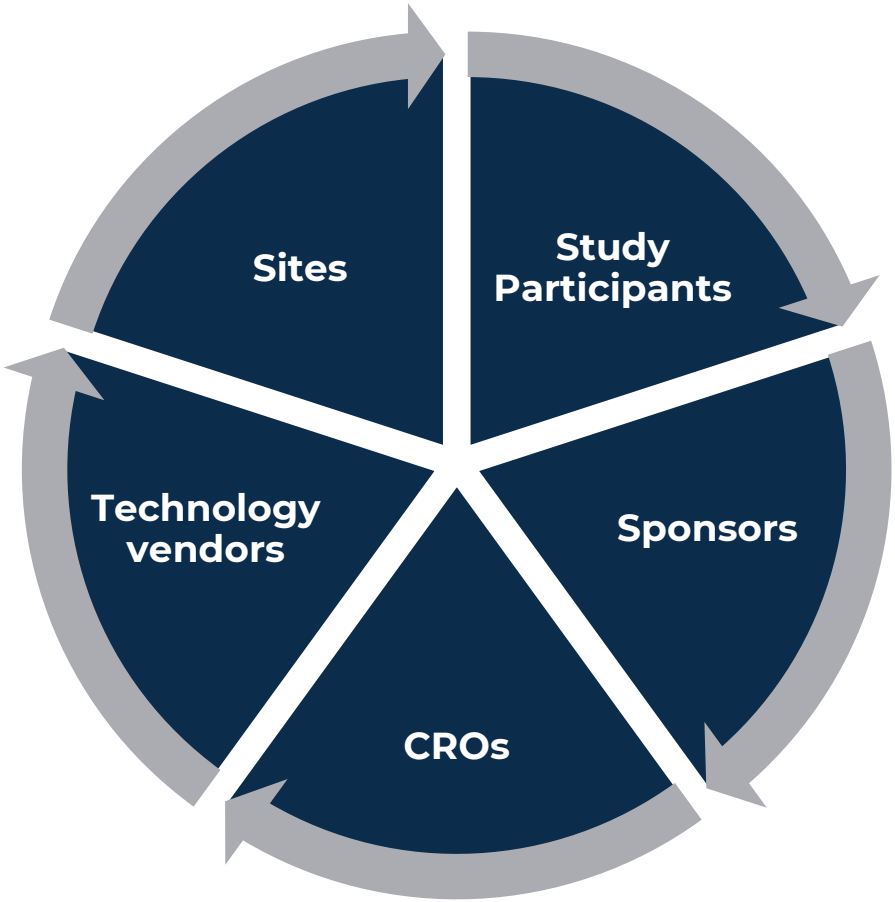
- Monitor and serve the population
- Provide alerts, software updates, maintenance
- Tech support as needed

4

Close Out

'Close out' processes look different across research, care and public health, though exist across all contexts

Stakeholders Involved in Operational Success



Study Participants

Operational Considerations: Clinical Trial Participants

- Ease of Use
- Ease of Wear
- Impact of Disease on Usage
- Protocol Alignment
- Stigma/Image
- Lifestyle & Preference

Pre-Go-Live
Procuring the digital measurement product

- Lease/Buy
- Country regulatory requirements
- Regional-specific information (cellular, time zones)
- Contracting contingencies
- Data flow expectations : Understanding cost and useability
- Wearable configuration options
- Ethics submission timing requirements

Procuring the Digital Health Technology

Wearable Configuration
Watch configuration (sample rate, sensors selection) must be consistent across all participants

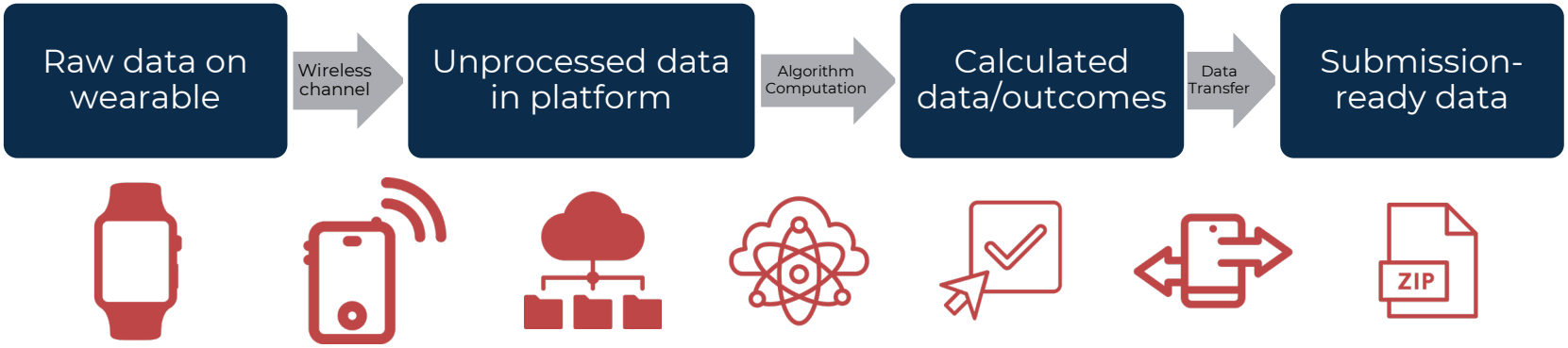
Wearable Configuration
Watch band must align to participant preference, be comfortable for night wear, and fit properly on different body types, etc)

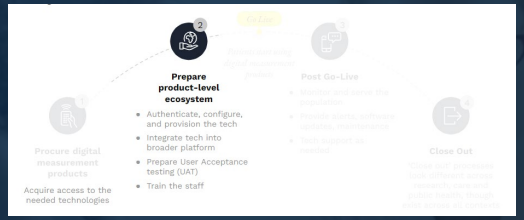
Regional Considerations
Time/date display must align to site/study participant
(no GPS)

Lease/Buy
On-shelf battery management is crucial to ensure longevity

Regulatory
Records of biocompatibility, CE marking, UK safety mark, data privacy, country approval

DHT Data Flow (Ecosystem) Considerations





Pre-Go-Live

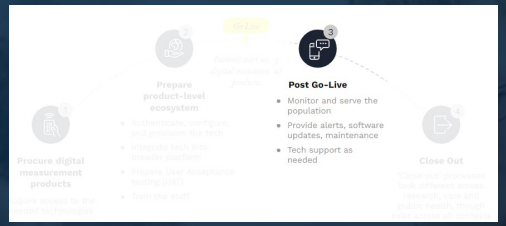
Prepare Product Level Ecosystem

Technology integration (API)

Study setup (tech vendor)

UAT

Training and equipping sites and study participants



Post-Go-Live

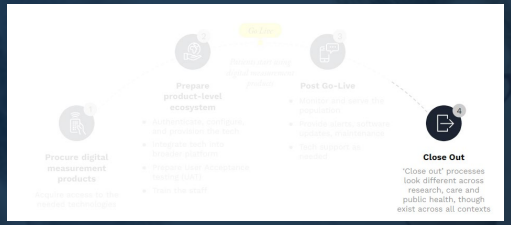
Technical support

Site support expectations

Compliance monitoring

Data transfers & read outs

- Considerations around real-time data calculations



Close Out

Returning the technology

Database Lock (do tech vendors understand?)

- Residual data coming in

Archiving the data

Giving feedback to study participants

Data science open access

Poll Question:

What do you consider the most important part of successful deployment of DHTs?

Reference Initiatives

eCOA
ELECTRONIC CLINICAL OUTCOME ASSESSMENT CONSORTIUM

TOUR OF DUTY: Driving adoption

The Playbook: Digital Clinical Measures

Introducing the essential industry guide for successful remote monitoring across *clinical research*, *clinical care*, and *public health*.

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

DiME
DIGITAL MEDICINE SOCIETY

Thank you!

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ActiGraph Digital Data Summit 2022

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