Digital Health Technologies (DHTs) & the Impact to Records & Retention

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Meet the Speaker

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Jamie is a Steering Committee member for the CDISC TMF Reference Model Working Group. She is the Chair of the Operations Committee and a Director for the Health Sciences Records and Archives Association (HSRAA). Jamie is a Board of Directors member for the Association for GxP Excellence (AGxPE).

In addition, she has led many industry workstreams for TMF/eTMF including the clinical trials email guidance and the TMF Plan Template s and currently kicked off the ISF Reference Model initiative and is a member of the Standards Committee as part of CDISC.

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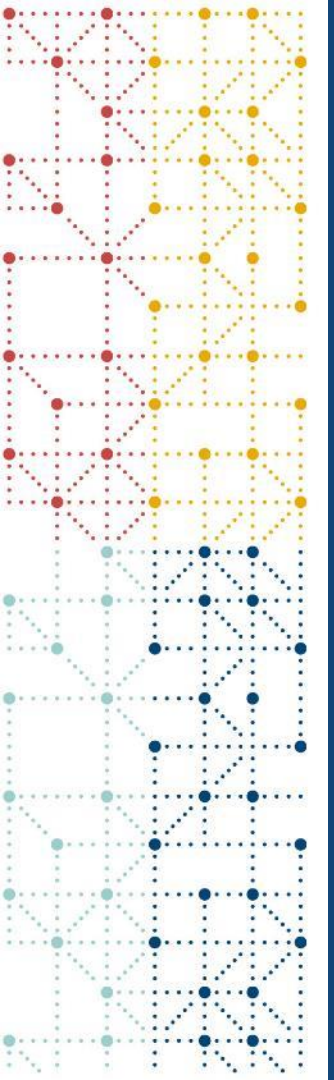
Topics

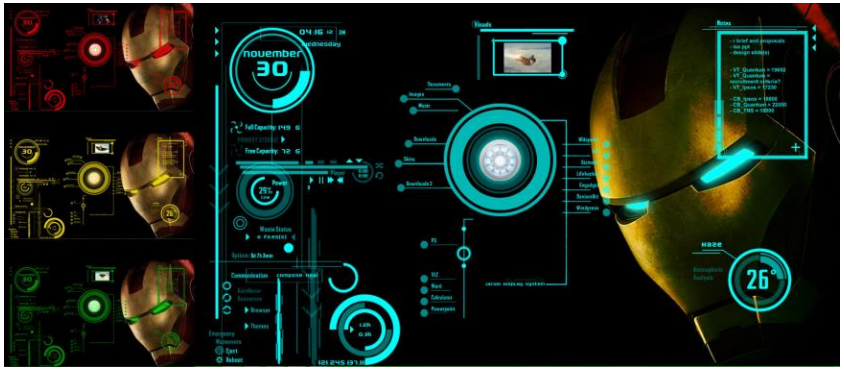
- Overview of DHTs
- FDA Guidance for DHTs and Electronic Systems, Electronic Records, and Electronic Signatures (Draft)
- DHTs in Real Life
- Summary



The idea of DHTs is not new...

- Iron Man, a character created for Marvel comics by the late Stan Lee in 1963!

- JARVIS was able to monitor all of Iron Man's thoughts, fluid levels, and other vitals...as a concept back in the 60s!



Overview of DHTs

Overview of Digital Health Technologies (DHTs)

Definition**: **Digital Health Technology

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

Includes:

- Health Information Technology (IT)
- Health Informatics
- Wearable medical devices
- Software as a medical device (SaMD)
- Personalized medicine
- Mobile Health (mHealth)
- Telemedicine
- Telehealth

Definition**: **DHT in Clinical Trials

Any instrument, tool or platform utilized at any point in the data lifecycle of electronic data captured and reported as part of a Clinical Trial.

Includes:

- any computer system
- software application and input sensors/devices used to collect, manage, transmit, store or report electronic data
- remote data acquisition tools

Sources: Digital Health Article (statpearls.com), Digital Health Explained: Why It Matters and What to Know | Coursera, FDA presentation: Technology in Clinical Trials Digital Health Technology – Elena Boley, February 13, 2024 – A Joint US-FDA, MHRA-UK, Health Canada GCP & PV Compliance Workshop

Categories of DHTs

1. Remote sensing and wearables
2. Telemedicine and health information
3. Data analytics and intelligence, predictive modeling
4. Health and wellness behavior modification tools
5. Bioinformatics tools
6. Medical social media
7. Digitized health record platforms
8. Patient-physician-patient portals
9. DIY diagnostics, compliance, and treatments
10. Decision support systems
11. Imaging

Examples: data sensors, mobile apps and data/computing platforms, ePRO devices and software, IRTs, eCRFs

Sources: Digital Health Article (statpearls.com), Digital Health Explained: Why It Matters and What to Know | Coursera

Advantages & Disadvantages

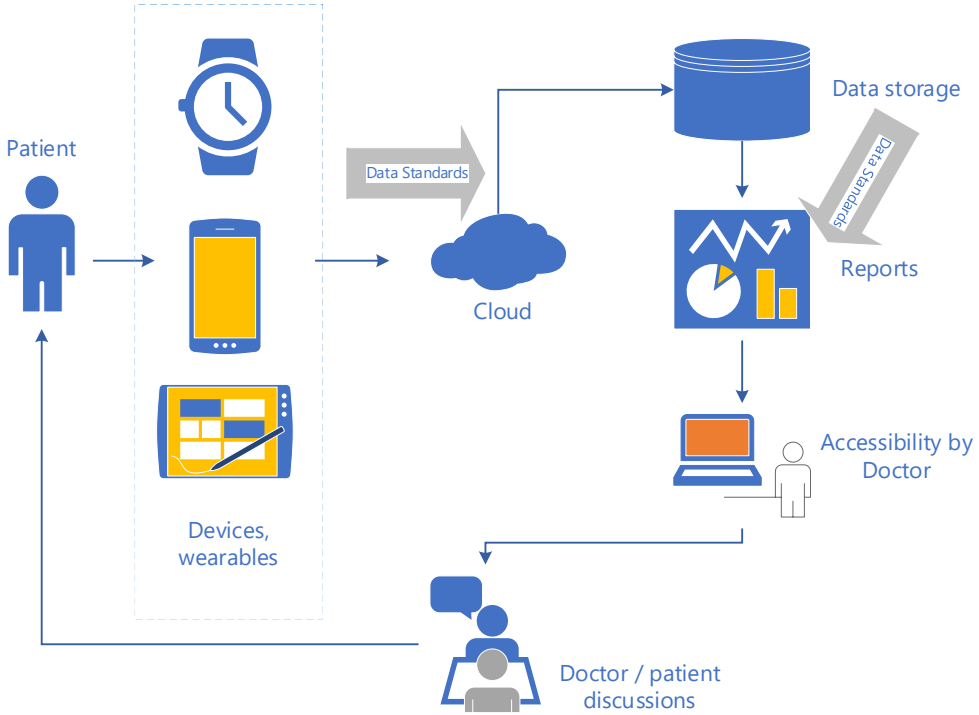
Advantages	Disadvantages
1. Reduce inefficiencies in the healthcare system	1 Cost of the devices
2. Improve access to healthcare	2. Limited government funding and low per capita income
3. Reduce costs of healthcare	3. Cultural differences
4. Increase quality of care	4. Lack of support for technical devices
5. Make medicine more personalized for patients	5. Internet and electric reliability
	6. Coverage issues
	7. Privacy and security concerns (in particular to wearables)
	8. Lack of sustainability
	9. Health system integration issues
	10. Lack of reliable high-quality evidence

Sources:
Digital Health Article (statpearls.com), Digital Health Explained: Why It Matters and What to Know | Coursera

FDA Guidance for DHTs

Data Flow 1

Each entry by a patient is a record and the same rules as apply for GxP records as well as applicable retention laws.



- 21 CFR Part 11, Subpart B Section 11.10 – Controls for closed systems: *"Persons who use closed systems to* ***create***, ***modify***, ***maintain***, *or* ***transmit electronic records*** *shall employ procedures & controls designed to ensure authenticity, integrity, and when appropriate, the confidentiality of* ***electronic records****…"*

FDA Guidance - 6 key areas

Topic	Brief Description
1. Selection of and description of DHTs in clinical investigations and in regulatory submissions	Fit for purpose!
2. Verification and validation	Able to be used as intended.
3. Usage to collect data for trial endpoints	Justifying endpoints, i.e. endpoint refers to how participant feels, functions, or survives.
4. Identification and management of risks	Risks to participant in using, risks to privacy, missing data and how to mitigate.
5. Retention and protection of data	Data transferred to a durable electronic repository and maintained/retained following applicable laws.
6. Roles of sponsors and investigators	Describes what the sponsor must do to ensure usability of the data, how to train investigator, and write ICF about the data, as well as the investigator ensuring that participants understand and are trained.

FDA considers electronic data that are located in the **first durable electronic data repository** to which data are transferred to be **the source data** and **must be available for inspection**.

Source:
FDA Guidance – December 2023 – Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

FDA Guidance – #5 Retention & Protection of Data – Draft Guidance e-Systems, e-Records…

Certified copy – maintain and retain a copy of an e-record, the copy maintained and retained must be a certified copy.

Retain e-records in durable electronic storage devices using cloud computing services.

Ensure authenticity, integrity, and confidentiality of the data from point of creation and ensure the meaning of the record is **preserved**.

Applies to **any e-system used** to collect clinical investigation data or to **create, modify, maintain, archive, retrieve or transmit e-records**.

Sponsors should **create a data flow diagram** from creation to final storage.

The **transmission** of the data captured using a DHT must be **secure**.

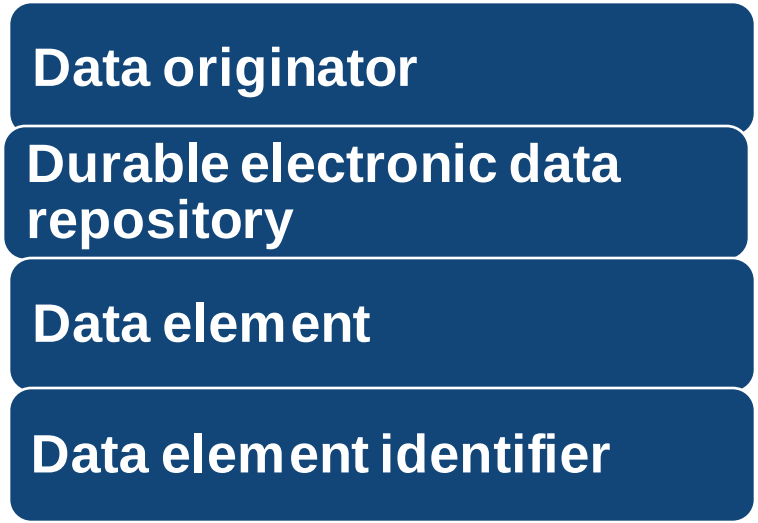
Cyber security and **privacy** considerations should be taken.

Multi-factor authentication and **biometrics** should be considered.

21 CFR Part 11 applies: ***Audit trails, system setup, validation, UAT, data backup, system account management, data collection and handling.***

Sources:
FDA Guidance – December 2023 – Digital Health Technologies for Remote Data Acquisition in Clinical Investigations
FDA Draft Guidance – March 2023 – Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions & Answers

FDA Guidance – #5 Retention & Protection of Data – Draft Guidance e-Systems, e-Record / Data Components

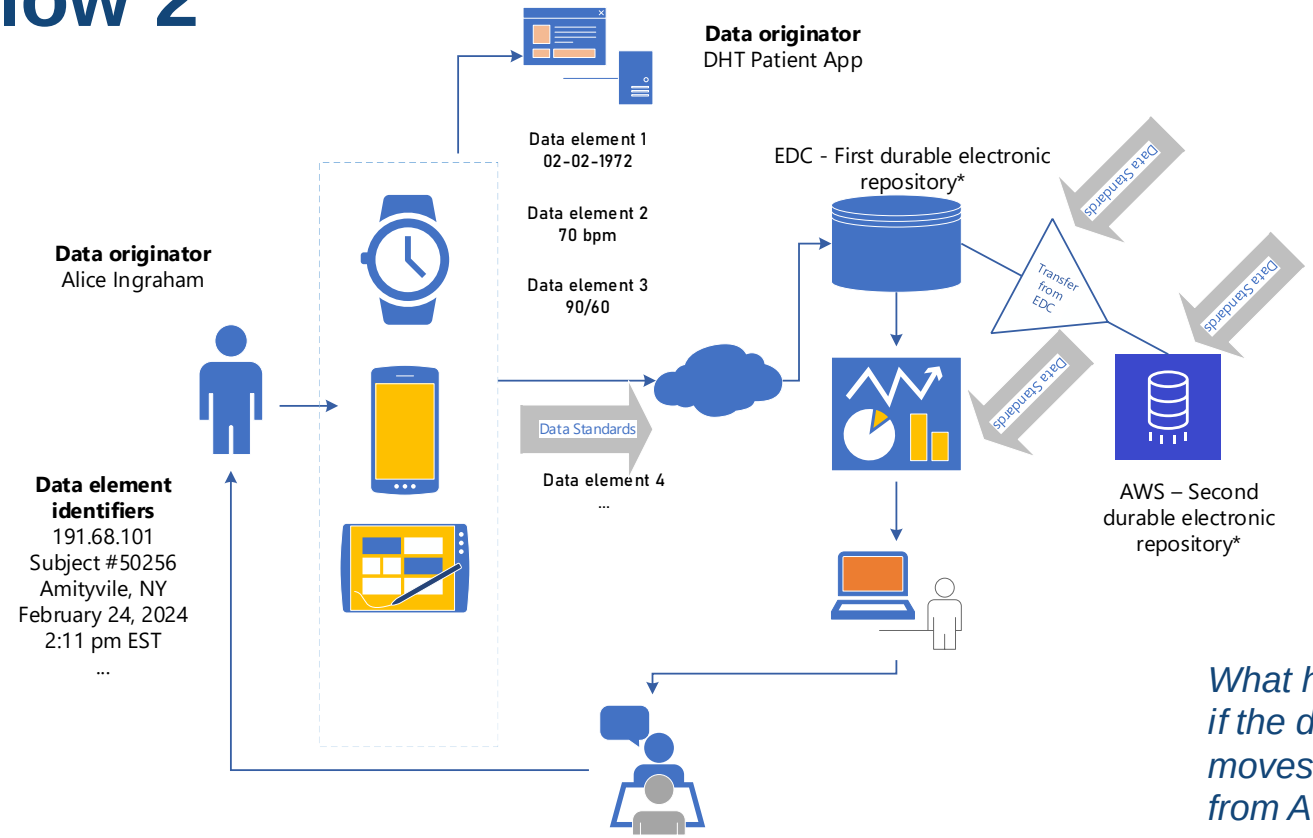


- *Sponsors should ensure that data obtained using DHTs are **correctly attributed to the data originator**.*
- ***Source data captured by a DHT can be subsequently moved from one durable electronic data repository to a different durable electronic data repository using a validated process.***

Sources:
FDA Guidance – December 2023 – Digital Health Technologies for Remote Data Acquisition in Clinical Investigations
FDA Draft Guidance – March 2023 – Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions & Answers

Data Flow 2

Records being generated and going to durable repository1 and 2



What happens if the data moves again from AWS?

*Source data, available for inspection

CDISC Standards

CDISC and the Digital Medicine Society (DiMe) have partnered to enhance interoperability and comparability of data across different DHTs and accelerate innovation in digital health through shared standards and common semantics. To this end, a volunteer team of diverse stakeholders is working to address opportunities for data standardization.

Standards development in 2024 is focused in the following areas:

- *Key DHT Concepts* in clinical research
- *Device Attributes* that contextualize collected data
- *Digital Endpoints* collected using DHTs
- *Best Practices* for using CDISC standards and DiMe resources with DHTs in clinical research.

Source: https://www.cdisc.org/standards/in-development/digital-health-technologies

- *"The sponsor is responsible for implementing the expectations for computerized systems to ensure that …**system data is reliable**. That includes **effective access controls**…**choose** [access controls] **wisely**….take **proactive steps to decrease and manage risk** by selecting DHT that is **fit for purpose**, employing **risk proportionate system controls**, **educating site staff, and monitoring data throughout your trial**."*

- Technology in Clinical Trials Digital Health Technology – Elena Boley, February 13, 2024 – A Joint US-FDA, MHRA-UK, Health Canada GCP & PV Compliance Workshop

DHTs in Real Life

One patient's story of using DHTs

Diagnosis: IDC – Invasive Ductal Carcinoma, Stage 2, Grade 3, Hormone triple negative (more aggressive)

Background: Usage of DHTs began from diagnosis.

DHTs: Symptom checker website, Physician-patient-physician portal, Vcee app

Usage:

- **Symptoms check in website** – This started once chemo began, 3 weeks after diagnosis. Receives a daily reminder and just clicks on a link and asked, "what are your symptoms today", completes and can also write in other feelings. Easy to check in. Don't have to call or have provider call. The physician team at cancer center reviews results.
- **Physician-patient-physician portal** – Used to get messages to nurses, for example for IV hydration, can get appointment for IV hydration, and reach out to providers and ask questions. Also receives patient education here, which they love!
- **Vcee app** - Used for virtual appointments, downloaded from app store, get link to a virtual room, VC Clinic, and have virtual appointment with provider. Able to do the visit from comfort of living room.

Results: Overall, very positive, and makes the patient feel very good. Providers are reachable and respond quickly. Patient loves the convenience, because they are reminded to inform the provider how they are feeling daily.

Source: *A real patient via interview – March 2024*

DHTs in real life – Sleep Disorders

Evaluating User Compliance in Mobile Health Apps: Insights from a 90-day study using a digital sleep diary -2023

Patient Population: Those with sleep disorders (sleep apnea, insomnia..)

Patients in study: 45

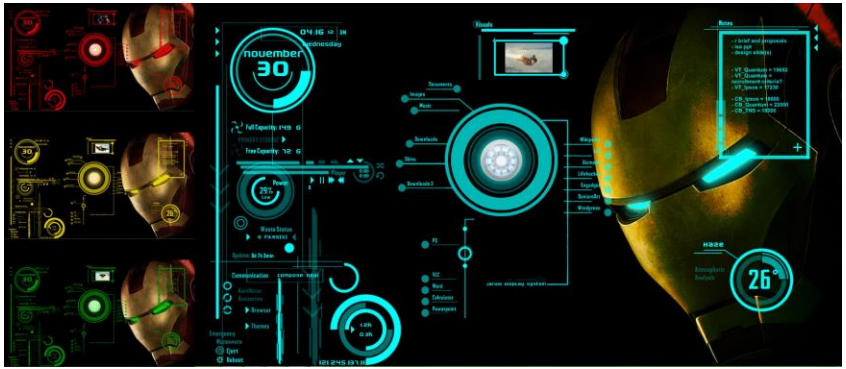
DHT: Mobile Sleep Diary, Sleep Revolution

- **Usage**: Patients had to complete an assessment twice a day (morning/evening) every day for 90 days on their sleep habits; in the past these patients used a paper-based method.
- **Results**: Overall compliance high in first 2 months, but decreased over time, participants had a frequency to respond more in the morning vs. the evening.
- **Conclusion**: Using a daily sleep diary was both feasible and compliance was satisfactory.

Source: Kristbersdottir, H.; Schmitz, L.; Arnardottir, E.S.; Islind, A.S. Evaluating User Compliance in Mobile Health Apps: Insights from a 90-Day Study Using a Digital Sleep Diary. Diagnostics 2023, 13, 2883. https://doi.org/10.3390/ diagnostics13182883

Summary

”Sometimes you gotta run before you can walk.” – Iron Man (2008)



Summary

- There are many considerations for DHTs which should be balanced with the benefits to patients.
- Like any technology, there are both advantages and disadvantages in long term usage that needs to be weighed, with all risk considered.
- A data flow diagram is required to identify how the data moves to ensure data integrity.
- Keeping DHT records safe and retained for the duration of the retention laws must be planned for.
- Privacy of patient's data must be addressed on an ongoing basis and as technology changes.
- Standards will help to achieve interoperability.
- *From one patient's perspective - DHTs are helping with their quality of life!*

Thank You!