# Navigating *The Playbook:* Digital Healthcare Edition

Your user guide to *The Playbook:* **Digital Healthcare Edition**

The **opportunities** digital health solutions bring to deliver high-value healthcare.

**Industry definitions, classification** and **regulation** of digital health solutions.

## Your micro-playbooks to digital health solutions

- **AI/ML**
- **AR/VR/MR**
- **Connected Sensor Technology**
- **Digital Therapeutics**
- **Electronic health records**
- **Mobile health applications**
- **Engagement and Social Media**
- **Virtual care**

## PRO TIP

Throughout the slides you will see ***'TL;DR'***. This is a common acronym for '***Too Long; Didn't Read.***'

We are acknowledging how busy you are and that a **small chunk of text is easier to digest** than a large portion of text on a slide.

Source: FDA, DiMe-VHA The Playbook: Healthcare team analysis

# Connected sensor technology

## TL;DR

**Connected Sensor Technology** products process data captured by mobile sensors using algorithms to generate measures of behavioral and/or physiological function

## What is **connected sensor technology?**

- **Connected sensor technologies** includes **wearables**, **activity trackers,** heart rate monitors, smart scales, sensors embedded in smartphones (e.g. microphone), **Ingestibles** such as smart pills (e.g., MyCite), **Implantables** (e.g., pacemaker, subdermal wearable), **Implantables** (e.g., pacemaker, subdermal wearable)

- Defined characteristics that are measured as indicators of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions
  Connected sensor products:
  - Also known as **biometric monitoring technologies (BioMeTs)**
  - Sometimes these technologies are worn and thus called **"wearables"**
  - And/or **internet of medical things (IoMT)** (e.g., smart speakers, internet connected scale)

**Applications**

- Lifestyle intervention
- Diagnostic and prevention
- Remote tracking and monitoring
- Disease management and treatment
- R&D and production optimization
- Clinical decision support
- Communication and engagement

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://playbook.dimesociety.org/tools/glossary/#digital-clinical-measure%20&%20%20https://www.karger.com/Article/FullText/500413

# Sensor tech bringing value with passively collected information

*Opportunities to create value for patients, providers and healthcare systems*

**Monitoring and tracking** for any ongoing health condition or clinical intervention.

**Maximize** the biometric physiology **information collected** for the end users

Facilitate analysis and **application of real world evidence** and/or product performance data

Facilitate **collection of richer data** and insights to enhance understanding of the effects of treatment

**Connectedness creates efficiencies** for the information collection and exchange

Provide **invasive and non-invasive** capabilities to understand patients health better

**Reusable product** that offer process data accurately, reliably, and continuously

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.nature.com/articles/s41746-020-0237-3

# With the rising tide of connected sensor technology comes questions around variability, security & utilization

The connected sensor industry continues to grow, reaching more people with the healthcare they need while reducing the associated burdens for both patients and healthcare professionals. However, the evolving field also poses risks from the technology variability from data to security to its right utilization.

*Risk*

**Reliability, validity, and accuracy** of data may vary greatly based on various factors

*Challenge*

**Tech barriers** can be an impediment to effective and appropriate **utilization and usage** of the technology

*Risk*

**Cybersecurity vulnerabilities** can emerge when connected to another electronic device or network

*Challenge*

**Disparities of reach and impact** with barrier of technical literacy and digital knowledge

*Risk*

**Concerns** about **privacy and security** of users

*Challenge*

Existing systems of care **not utilizing the advantage** of home sensor data.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://pubmed.ncbi.nlm.nih.gov/32393301/, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732146/

# What does the FDA say about connected sensor technology?

- Regulatory environment is **far from established for governing "digital specimens"** (e.g., data generated from connected sensor technologies).
- FDA **only oversees** digital specimen-collecting tech like wearables, **if classified as medical devices**.
- Today, narrow definition of device and revisions with the 21st Century Cures Act, leaves **connected sensor. technologies outside the purview of FDA**.
- So its oversight of functionality and health claims are under Federal Trade Commission, which policies unfair and deceptive trade practices, including enforcing rules against false or misleading advertising.
- In US, **NIST, FCC and ONC may each have oversight of components** of connected sensor technologies, but **no regulator has full responsibility for digital specimens.**

## 3 key de-facto agreements for the data rights disclosure that has become a common practice

**Privacy policies (PP)** disclose the terms for collection and use of the app/website user's personal information.

**Terms of service (ToS)** disclose the rules and requirements of website and/or app use, for example, copyright, allowed uses, and the definition of abusive use.

**End-user license agreements (EULAs)** are a form of intellectual property licensing that tell people who have purchased software if/how many times they can copy the software and how they can or cannot use those copies.

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://www.karger.com/Article/FullText/500413, https://www.wsj.com/articles/the-internet-of-bodies-is-here-are-courts-and-regulators-ready-1542039566

# **Case study:** Using connected technology to understand variations in constipation symptoms and med management

## The Challenge:

Understanding day-to-day variations in symptoms and **medication management** can be important in describing patient-centered **outcomes** for people with constipation. **Patient Generated Health Data (PGHD)** from digital sensing products is a potential solution.

## The Approach:

- Opportunity to enrich and **characterize treatment response** in subset of participants.
- Faster recruitment and shorter trial duration
- Trial risk reduction for disruption (drop out, non-adherence, inconclusive study).
- **Better inform regulatory approval, reimbursement strategies and adoption.**

## The Result:

- **Evidation Health** and **Sanofi-Aventis** designed a virtual, 16-week prospective study of 1540 individuals with frequent constipation from an online wellness platform that connects mobile consumer digital devices that described the association between passively collected PGHD and constipation symptoms and severity at a day-to-day granularity level. 38 predetermined day-level behavioral activity metrics were computed from minute-level data streams for **steps**, **sleep**, and **heart rate.**
- At a daily-level, **22 of 38 activity metrics were significantly associated with bowel movement or medication treatment patterns** for constipation.
- Constipation status, irregular or constipated, was associated with a number of activity metrics in steps and sleep, and likelihood to treat with medication increased with increasing severity for a number of constipation symptoms.
- These findings provide evidence that:
  - **Better characterization of real-world experiences** could lead to better understanding of the **meaningfulness to patients.**
  - Objective insights can **aid monitoring** and **management.**

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://ieeexplore.ieee.org/document/8964569; Learn more about gait differences in healthy adults using wearables https://youtu.be/duhrERQx4_E

# **Case study:** Gait as a digital clinical measure to identify early signs of Parkinson's disease

## The Challenge:

The fastest growing brain disease in the world, **Parkinson's disease** (PD), currently, has **no objective biomarker** to measure onset, progression, and severity. Despite millions of dollars invested into genetics, molecular, and imaging modalities, diagnostic accuracy to differentiate PD from other neurological disorders by movement disorder specialists ranges between 74% and 80%.

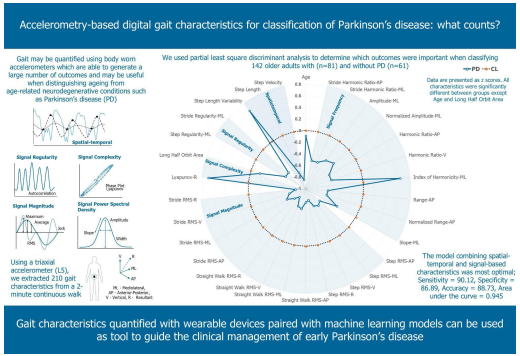
## The Approach:

With **low cost, objective** and **scalable** digital clinical measures, walking patterns (gait) have been shown to be useful tools in measuring health and brain function in PD. Using **wearables** (e.g. accelerometry) and machine learning models this study:

- Quantifies a digital battery of commonly utilized **gait characteristics** (spatiotemporal and signal-based),
- Identifies the most informative **digital clinical measures** of gait for classification of PD.

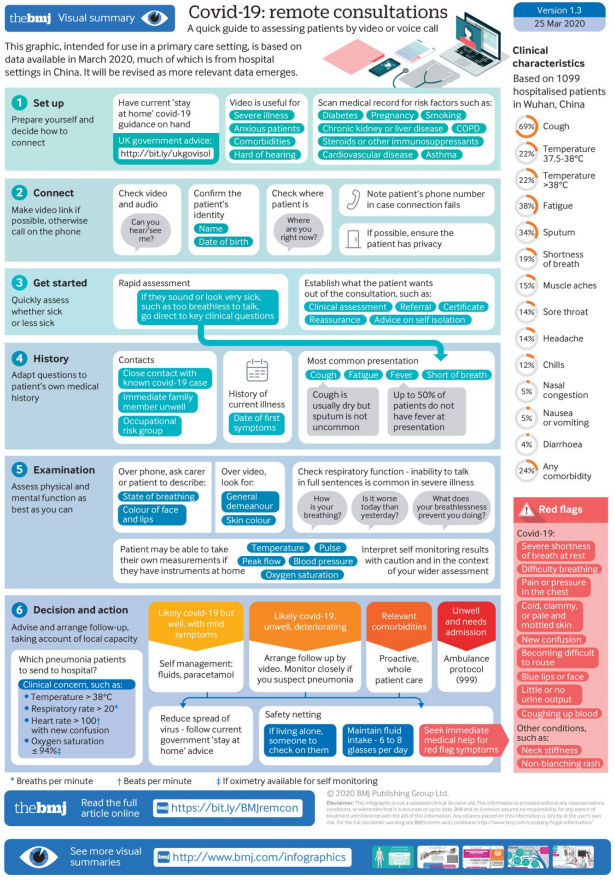
## The Result:

The study highlights the importance of using **connected sensor technology** to measure the **gait characteristics** in the development of tools to help **classify early PD**.




**Gait characteristics quantified with wearable devices paired with machine learning models can be used as tool in early clinical management of Parkinson's disease.**

Source: DiMe-VHA The Playbook: Healthcare team analysis, https://ieeexplore.ieee.org/document/8964569; Learn more about gait differences in healthy adults using wearables https://youtu.be/duhrERQx4_E



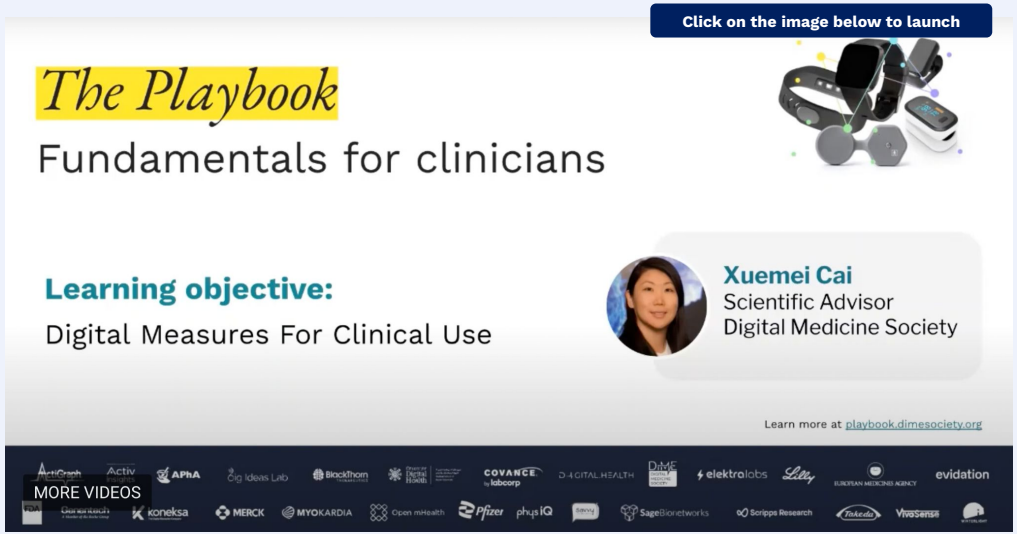

SPOTLIGHT

# A remote assessment in the primary care setting

This manuscript in BMJ presents some guiding principles on how to choose between telephone and video appointments and **also considerations for when and how** to collect **digital clinical measures** using connected sensors a virtual visit.

Source: DiMe-VHA The Playbook: Healthcare team analysis

## LEARN FROM THE EXPERTS




Source: DiMe-VHA The Playbook: Healthcare team analysis, https://playbook.dimesociety.org/dossiers/clinicians/#learnlet-4-evaluate-the-utility-of-digital-clinical-measures-in-different-clinical-settings-and-in-different-patient-populations