
# The Digital Health Library

2022

# DIGITAL HEALTH LIBRARY

## START YOUR JOURNEY HERE

The digital health landscape is complex, fascinating, and rapidly expanding.

Hundreds of relevant resources exist, but are often known only to a subset of individuals within the many different disciplinary silos that comprise the diverse field of digital health.

Newcomers to digital health and seasoned experts alike can find it challenging to find trustworthy information about best practices and regulations governing high-quality digital medicine.

The Digital Health Library is intended to be both a reference resource and a transparent library for the Medtech Founder community. Our goal is to make it easier to find trustworthy information all in one place.

**Additional resources? Send us a note at** hello@medtechfounder.com

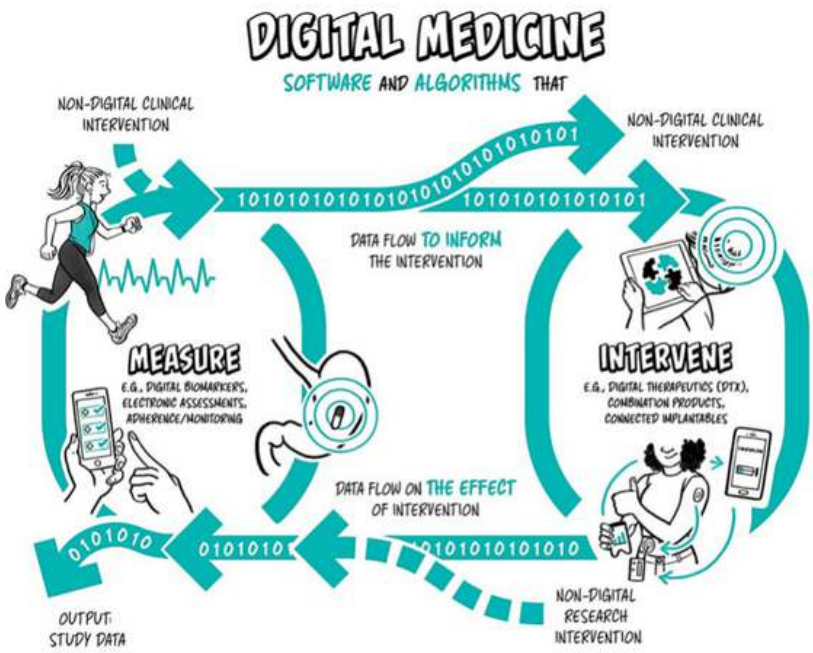
# DIGITAL BIOMARKERS

**2019**

## DIGITAL MEDICINE: A PRIMER ON MEASUREMENT (DIGITAL BIOMARKERS ARTICLE)

An introduction to core concepts and terms that define digital medicine. Specifically, the contrast between “clinical research” and routine “clinical care,” outlining the security, ethical, regulatory, and legal issues developers must consider as digital medicine products go to market.

Article Access




# DIGITAL HEALTH PRODUCT CATEGORIES

**2019**

## DIGITAL HEALTH, DIGITAL MEDICINE, DIGITAL THERAPEUTICS (DTX): WHAT'S THE DIFFERENCE?

A summary from the Digital Medicine Society that provides a high-level view of the different product categories in Digital Health and the most important issues for each. Article Access

# RPM IMPLEMENTATION PLAYBOOK (AMA)

**2018**

## AMERICAN MEDICAL ASSOCIATION® DIGITAL HEALTH IMPLEMENTATION PLAYBOOK

Digital tools that enable new methods and modalities to improve health care, enable lifestyle change, and create efficiencies are proliferating quickly. Clinical integration of these tools is lacking. We want to change that. Article Access

AMA
AMERICAN MEDICAL ASSOCIATION

# TELEHEALTH IMPLEMENTATION PLAYBOOK (AMA)

**2020**

## AMERICAN MEDICAL ASSOCIATION® TELEHEALTH IMPLEMENTATION PLAYBOOK

Before you embark on your telehealth implementation, it's important to understand what telehealth is and how it's impacting the world of health care. This playbook focuses on telehealth, a digital health solution that connects the patient and clinician through real-time audio and video technology. The challenges and best practices are defined and discussed as well overall Implementation recommendations as provided by the AMA. Article Access


AMA
AMERICAN MEDICAL ASSOCIATION

# REAL-WORLD EVIDENCE (FDA)

**2021**

## FDA SPECIAL TOPICS: REAL-WORLD EVIDENCE DEFINITION

The 21st Century Cures Act, passed in 2016, places additional focus on the use of these types of data to support regulatory decision-making, including approval of new indications for approved drugs. Congress defined RWE as data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials. FDA has expanded on this definition as discussed in this resource.
Article Access

# BIOMARKER GUIDANCE AND REFERENCE MATERIALS (FDA)

**2018**

## BIOMARKER GUIDANCES AND REFERENCE MATERIALS

Qualification Process for Drug Development Tools: Describes the process for qualifying drug development tools intended for potential use, over time, in multiple drug development programs. Article Access

# THE PLAYBOOK: DIGITAL CLINICAL MEASURES

**2021**

## THE ESSENTIAL INDUSTRY GUIDE FOR SUCCESSFULLY DEVELOPING & DEPLOYING DIGITAL CLINICAL MEASURES AND REMOTE MONITORING. (DIGITAL MEDICINE SOCIETY)

The Digital Medicine Society (DiMe) is the professional society for the digital medicine community. Their goal is to build a shared foundation for remote monitoring and digital clinical measures across research, care and public health. The playbook is an action-oriented guide for digital health practitioners building digital health programs.

Article Access

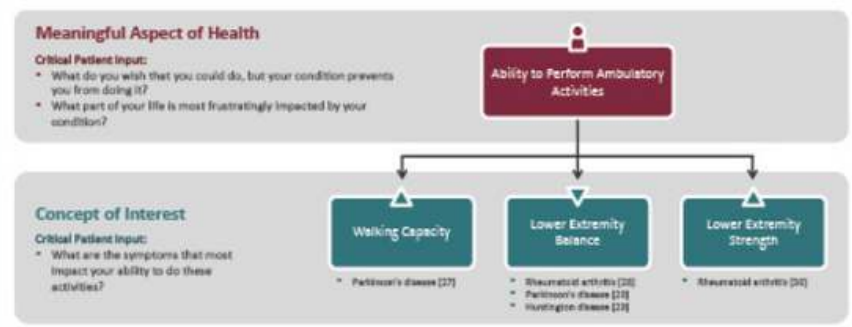
# DIGITAL MEASURES THAT MATTER TO PATIENTS

**2020**

## A FRAMEWORK TO GUIDE THE SELECTION AND DEVELOPMENT OF DIGITAL MEASURES OF HEALTH

This resource synthesizes and defines a sequential framework of core principles for selecting and developing measurements in research and clinical care that are meaningful for patients.

Article Access




# FDA GUIDANCES WITH DIGITAL HEALTH CONTENT

**2021**

## LIST OF FDA GUIDANCE DOCUMENTS WITH DIGITAL HEALTH CONTENT

The guidance documents listed here are FDA guidances with Digital Health content and are intended to provide clarity on the FDA's regulation of digital health products.

List Access

# FDA DIGITAL HEALTH CENTER OF EXCELLENCE

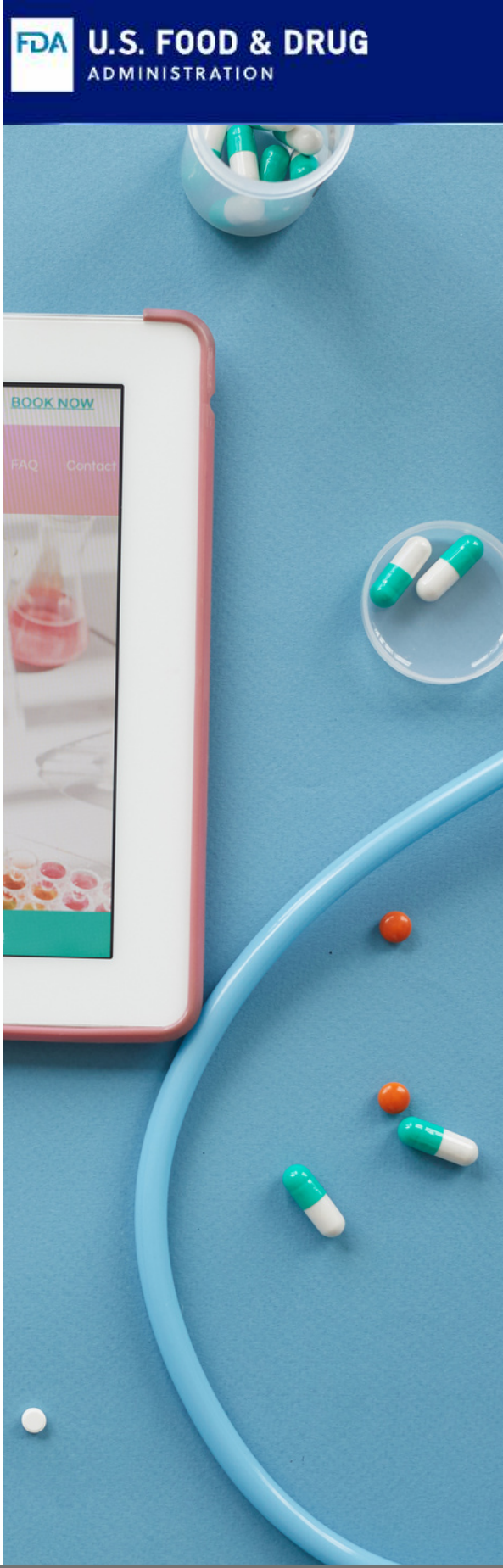
**2021**

## TO EMPOWER STAKEHOLDERS TO ADVANCE HEALTH CARE BY FOSTERING RESPONSIBLE AND HIGH-QUALITY DIGITAL HEALTH INNOVATION.

The Digital Health Center of Excellence aims to:

- Connect and build partnerships to accelerate digital health advancements.
- Share knowledge to increase awareness and understanding, drive synergy, and advance best practices.
- Innovate regulatory approaches to provide efficient and least burdensome oversight while meeting the FDA standards for safe and effective products.

Access the Center



# FDA AI/ML ACTION PLAN

**2021**

## ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ACTION PLAN

This AI/ML-Based Software as a Medical Device Action Plan was developed in direct response to the stakeholder feedback described herein, and it builds on the Agency's longstanding commitment to support innovative work in the regulation of medical device software and other digital health technologies.

Resource Access

# QUALIFICATION OF DIGITAL TECHNOLOGIES (EMA)

**2020**

## QUALIFICATION OF DIGITAL TECHNOLOGY-BASED METHODOLOGIES TO SUPPORT APPROVAL OF MEDICINAL PRODUCTS

The focus of the document is to support Qualification of methodologies based on digital technologies in the context of medicinal product development. It may also be of assistance to applicants in the preparation for other types of EMA procedures and interactions, such as Innovation Task Force (ITF) meetings, scientific advice briefing books drafting, and preparation of Marketing Authorisation Applications (MAAs).

Article Access