

# FDA Digital Health Guidance: 2026 Requirements Overview

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## Executive Summary

Over the past decade, the FDA has significantly expanded and refined its regulatory framework for digital health technologies (DHT), including software-based medical devices, mobile health apps, wearables, and artificial intelligence (AI)-enabled tools. This report provides an in-depth analysis of the **latest FDA requirements and guidance** governing digital health. We examine the historical evolution of FDA policy (especially changes stemming from the 21st Century Cures Act), summarize key guidance documents, present data on the growing digital health market and device approvals, and review multiple perspectives including industry commentary. Our analysis covers *General Wellness* products, *Clinical Decision Support (CDS)* software, *mobile medical apps*, *Software as a Medical Device (SaMD)*, **AI/ML software**, **cybersecurity**, and other relevant categories. We highlight how recent FDA guidances (e.g. Jan 2026 updates on General Wellness and CDS, Aug 2025 guidance on AI change-control plans, Feb 2026 cybersecurity guidance) shift the regulatory landscape to encourage innovation while safeguarding safety and effectiveness. Real-world examples – from Apple's FDA-cleared ECG watch app to FDA-authorized digital therapeutics (e.g. Pear's *reSET-O*) – illustrate how these policies play out in practice. Finally, we discuss the implications for developers and future directions (including legislative initiatives and international harmonization). Our findings show that navigating FDA's digital health guidance requires understanding nuanced risk categorizations and compliance pathways, but also that the Agency is increasingly focused on a **pro-innovation, risk-based approach** to enable safe, effective, and impactful digital health solutions.

## Introduction and Background

**Digital health technologies (DHT)** encompass a broad and rapidly evolving array of tools – including mobile apps, cloud software, wearables, telemedicine platforms, artificial intelligence (AI) algorithms, virtual/augmented reality, and sensor-integrated devices – that collect, analyze, or deliver health-related data. When these tools are intended for medical purposes (such as diagnosing, treating, or preventing disease), they often fall under the FDA's definition of a *medical device*. According to the International Medical Device Regulators Forum (IMDRF), **Software as a Medical Device (SaMD)** is “software intended to be used for one or more medical purposes and performing these purposes without being part of a hardware medical device” <sup>(1)</sup> [www.fda.gov](http://www.fda.gov). The FDA follows this definition and classifies SaMD according to the risk of its intended use <sup>(1)</sup> [www.fda.gov](http://www.fda.gov). Digital health software can run on multiple platforms (smartphones, cloud servers, wearable monitors, etc.) and has revolutionized healthcare delivery by enabling remote monitoring, personalized therapy, and data-driven decision-making <sup>(2)</sup> [www.fda.gov](http://www.fda.gov) <sup>(3)</sup> [sensaco.com](http://sensaco.com).

Since early 2010s, DHT innovation has accelerated. Global spending on digital health is projected to grow rapidly (estimates project the digital health market to reach tens of billions by the mid-2020s). In particular, the **SaMD market** was valued at about \$18.5 billion in 2019 and is expected to grow ~21.9% annually through 2027 <sup>(4)</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov). This surge is reflected in FDA activity: the first FDA-cleared SaMD (meeting IMDRF definition) appeared in 2012, and by 2021 the cumulative total had reached 581 devices (representing roughly a 202.7% compound annual growth rate) <sup>(5)</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov). Many of these SaMD products are advanced image-analysis tools in radiology <sup>(6)</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov), as well as digital therapeutics (prescription apps) and monitoring systems.

The FDA regulates DHT under the Federal Food, Drug, and Cosmetic Act (FD&C Act), drawing on its authority originally established by the Medical Device Amendments of 1976. Over time, Congress and the FDA have refined the regulatory framework to keep pace with technology. A watershed event was the **21st Century Cures Act** (December 2016), which amended the FD&C Act to *exclude* certain software categories from the legal definition of “device” <sup>(7)</sup> [www.fda.gov](http://www.fda.gov) <sup>(8)</sup> [www.fda.gov](http://www.fda.gov). Notably, the Cures Act carved out purely informational or low-risk wellness software (e.g. apps “**intended for maintaining or encouraging a healthy lifestyle**” unrelated to disease) and many *Clinical Decision Support (CDS)* functions <sup>(7)</sup> [www.fda.gov](http://www.fda.gov) <sup>(9)</sup> [www.fda.gov](http://www.fda.gov). As a result, many digital wellness and CDS products fall outside FDA regulation (or are subject only to enforcement discretion), while higher-risk DHT remain subject to the usual device pathways and oversight.

To guide industry, the FDA issues **guidance documents** (nonbinding recommendations) interpreting how the law applies to DHT. Over the past years, the Agency has released an expanding suite of digital health guidances. These cover topics such as mobile medical apps, software validation, cybersecurity, interoperability, Artificial Intelligence/Machine Learning (AI/ML) in devices, and more (<sup>[10]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[11]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). At the same time, FDA's **Digital Health Center of Excellence (DHCoE)** (established in 2017) has spearheaded initiatives and resources for digital health, including hosting public workshops and sponsoring demonstration projects (e.g. wearable endpoints in clinical trials (<sup>[12]</sup> [www.fda.gov](http://www.fda.gov))).

This report provides a comprehensive analysis of the **current FDA digital health guidance landscape**. We begin by reviewing historical context (definitions, legislative changes), then detail the latest guidance documents and their requirements by topic area, including practical considerations for developers. We cite official FDA documents, peer-reviewed data, and legal analyses to ensure that **all claims are backed by credible sources**. Throughout, we present data (e.g. on market trends and device approvals), multiple viewpoints (industry vs. regulator perspectives), and real-world examples (case studies) to illustrate the impact of these regulatory policies. The goal is a deep, evidence-based understanding of how the FDA expects digital health technologies to comply with its latest policies and how stakeholders can navigate this evolving regulatory environment.

## Evolution of FDA's Digital Health Regulatory Framework

### 21st Century Cures Act and Exclusions

A pivotal moment in digital health regulation was the **21st Century Cures Act** of 2016. Section 3060 of that Act amended the FD&C Act's definition of a "device" to exclude *certain software functions* (<sup>[7]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[8]</sup> [www.fda.gov](http://www.fda.gov)). Specifically, Congress declared that software "intended for maintaining or encouraging a healthy lifestyle" **unrelated to diagnosing, curing, or treating disease** is not a medical device (<sup>[7]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[9]</sup> [www.fda.gov](http://www.fda.gov)). Similarly, the Cures Act excluded many clinical decision support (CDS) software functions that meet specified criteria (<sup>[7]</sup> [www.fda.gov](http://www.fda.gov)). The FDA's 2019 "Cures Act Software" guidance documented the Agency's interpretation of these exclusions and how they affect prior policies (<sup>[8]</sup> [www.fda.gov](http://www.fda.gov)). Essentially, this law created a broad category of "**general wellness**" and certain CDS tools that the FDA will *not* regulate as devices, provided they truly meet the statutory criteria. For example, an app that reminds users to drink water or track steps for fitness (and makes no medical claims) is covered by these exclusions (<sup>[9]</sup> [www.fda.gov](http://www.fda.gov)).

### International Consensus on SaMD

Concurrently, the FDA has collaborated with international regulators to harmonize software device definitions and risk frameworks. The IMDRF (International Medical Device Regulators Forum) – of which FDA is a member – developed a formal **SaMD definition and risk categorization scheme**. FDA's own website notes that regulators worldwide (IMDRF) formed in 2013 a working group to establish key definitions and frameworks for SaMD risk, quality management, and clinical evaluation (<sup>[13]</sup> [www.fda.gov](http://www.fda.gov)). The Agency applies these principles domestically: any standalone health software that meets the medical use definition is regulated based on its risk. This global consensus helps ensure that FDA-test devices can follow a harmonized approach to documentation and clinical evaluation.

### Digital Health Center of Excellence and Policy Initiatives

In 2017, FDA established the *Digital Health Center of Excellence (DHCoE)* to lead digital health policy. The DHCoE's mission includes fostering partnerships, disseminating best practices, and “innovating regulatory approaches” for DHT ([14] [www.fda.gov](http://www.fda.gov)) ([15] [www.fda.gov](http://www.fda.gov)). For example, as of early 2026 FDA launched the **TEMPO pilot** in cooperation with CMS to help bring certain digital health devices to market for Medicare/Medicaid patients while protecting safety ([16] [www.fda.gov](http://www.fda.gov)). The DHCoE also curates resources (FAQs, glossaries, guidance indices) to help developers understand FDA expectations. Going forward, the FDA Commissioner has emphasized a pro-innovation stance, promising clearer guidance and faster review for AI-enabled tools and other digital products (see below).

## Trends in Digital Health Approvals and Investments

The COVID-19 pandemic accelerated digital health adoption, with funding surges in telehealth, remote monitoring, and digital therapeutics. The FDA's **Device Approvals** database shows that each year dozens of new software-based devices receive clearance: by mid-2025, at least *hundreds* of unique digital health devices (SaMD, apps, AR/VR, etc.) have FDA authorization. For instance, one analysis found over 1500 entries in FDA's lists for smart sensors, AI-enabled systems, and AR/VR devices in 2025 ([3] [sensaco.com](http://sensaco.com)) ([17] [sensaco.com](http://sensaco.com)). Top categories include continuous glucometers, ECG monitors, pulse oximeters, and AI image analysis software. Leading companies are Dexcom, iRhythm, Abbott (glucose sensors), and Canon or Siemens for imaging software ([18] [sensaco.com](http://sensaco.com)) ([19] [sensaco.com](http://sensaco.com)). **Innovation is strong:** the SaMD device count grew ~200% per year from 2012–2021 ([5] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)), and more than 1,000 AI/ML-enabled medical devices have been authorized to date ([20] [www.fda.gov](http://www.fda.gov)). Such statistics underline the regulatory challenge: FDA must handle unprecedented volume of software-based devices while protecting patient safety ([21] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) ([5] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).

Table 1 (below) lists the major FDA guidance documents applicable to digital health, with their issuance dates and key focus areas. The table is illustrative; each guidance is discussed further in the sections that follow.

Guidance Document	Issued	Scope / Key Topics
General Wellness: Policy for Low-Risk Devices ([9] <a href="http://www.fda.gov">www.fda.gov</a> )	Jan 2016 (initial draft), Final Jan 2026 (updated)	Clarifies which lifestyle/wellness products are <i>not</i> devices. Exempts products encouraging healthy behaviors unrelated to disease; expands in 2026 to include wearables that measure vital signs purely for wellness ([9] <a href="http://www.fda.gov">www.fda.gov</a> ) ([22] <a href="http://www.faegredrinker.com">www.faegredrinker.com</a> ).
Clinical Decision Support (CDS) Software ([7] <a href="http://www.fda.gov">www.fda.gov</a> )	Draft 2017, Final Oct 2022, Updated Final Jan 2026	Defines criteria (per Cures Act Sec. 520(o)) that allow CDS tools to be excluded from device regulation (e.g. tools providing recommendations only to professionals, not for diagnosis). 2026 update loosens restrictions on “time-critical” uses and single-recommendation tools, and requires transparency to HCPs ([23] <a href="http://www.faegredrinker.com">www.faegredrinker.com</a> ) ([24] <a href="http://www.faegredrinker.com">www.faegredrinker.com</a> ).
Device Software Functions & Mobile Apps ([25] <a href="http://www.fda.gov">www.fda.gov</a> ) ([26] <a href="http://www.fda.gov">www.fda.gov</a> )	Draft 2013, Final Sep 2022 (update)	Describes how FDA applies oversight to software on smartphones/web. Emphasizes that only software functions meeting the device definition <i>and</i> posing patient risk are regulated ([27] <a href="http://www.fda.gov">www.fda.gov</a> ). Clarifies enforcement discretion for low-risk mobile apps and updated to incorporate Cures Act classification rules ([26] <a href="http://www.fda.gov">www.fda.gov</a> ).
Software Precertification (Pre-Cert) Pilot ([28] <a href="http://www.fda.gov">www.fda.gov</a> )	2017–2022 (pilot period)	Content: Pilot program (2017–2022) for precertifying trusted digital health companies. Concluded in Sept 2022 with a Final Report ([28] <a href="http://www.fda.gov">www.fda.gov</a> ). Recommended legislative change for new oversight; no direct guidance for industry beyond pilot details. (FDA has not implemented a final Pre-Cert regulatory framework post-2022.)
Content of Premarket Submissions for Device Software Functions ([29] <a href="http://www.fda.gov">www.fda.gov</a> )	Jun 2023 (final)	Updates and replaces FDA's 2005 software guidance. Recommends what documentation to include in 510(k)/PMA for software-only functions to demonstrate safety/effectiveness ([29] <a href="http://www.fda.gov">www.fda.gov</a> ). Reflects current standards for software development and risk management.
Off-the-Shelf (OTS) Software in Medical Devices ([30] <a href="http://www.fda.gov">www.fda.gov</a> )	Aug 2023 (final)	Provides recommendations on documenting use of commercial OTS software components in medical devices. Clarifies what validation and controls FDA expects when using third-party software libraries, RTOS, etc. ([31] <a href="http://www.fda.gov">www.fda.gov</a> ).
Digital Health Tech for Remote Data in Clinical Trials ([32] <a href="http://www.fda.gov">www.fda.gov</a> )	Dec 2023 (final)	Offers guidance on using wearables, apps, and other remote digital tools to collect data in regulated clinical studies ([32] <a href="http://www.fda.gov">www.fda.gov</a> ). Addresses validation, data integrity, and consent issues to ensure reliability of DHT-collected endpoints.
Cybersecurity in Medical Devices ([33] <a href="http://www.fda.gov">www.fda.gov</a> )	Jun 2025 (final) and Feb 2026 (updated final)	Describes FDA's recommendations for cybersecurity risk management in device design and submissions ([33] <a href="http://www.fda.gov">www.fda.gov</a> ). The 2026 final supersedes the June 2025 version, emphasizing Quality System controls and submission content for cyber features, and addressing new statutory requirements (Sec. 524B) ([34] <a href="http://www.fda.gov">www.fda.gov</a> ).

Guidance Document	Issued	Scope / Key Topics
Marketing Submission Recommendations for a Predet. Change Control Plan (PCCP) for AI Devices <sup>[35]</sup> <a href="http://www.fda.gov">www.fda.gov</a>	Aug 2025 (final)	Guidance specifically for AI/ML devices. Recommends including a <b>Predetermined Change Control Plan (PCCP)</b> in the initial submission to FDA, describing planned AI model updates and validation methods. Allows FDA to review iterative software changes up-front, reducing need for new submissions for each update <sup>[35]</sup> <a href="http://www.fda.gov">www.fda.gov</a> .
AI-Enabled Device Software TPLC (Draft) <sup>[36]</sup> <a href="http://www.fda.gov">www.fda.gov</a> <sup>[37]</sup> <a href="http://www.fda.gov">www.fda.gov</a>	Jan 2025 (draft)	First comprehensive draft guidance for AI/ML devices covering the full Total Product Life Cycle (TPLC). Addresses design, development, evaluation, and postmarket monitoring of AI software. Emphasizes strategies for transparency, bias mitigation, and performance monitoring in AI/ML medical products <sup>[36]</sup> <a href="http://www.fda.gov">www.fda.gov</a> <sup>[37]</sup> <a href="http://www.fda.gov">www.fda.gov</a> . (Final expected post-comment.)
Multiple Function Device Products	July 2020 (final)	(Not digital-specific) Guidance on products combining separate devices, remote displays, or connectivity. FDA clarified policies for integrated systems with digital modules; generally teaches that each function remains regulated according to its nature.
Changes from Section 3060 of Cures Act <sup>[8]</sup> <a href="http://www.fda.gov">www.fda.gov</a>	Sept 2019 (final)	Interprets the FDA's policy following the Cures Act amendments. Makes "Level 2" updates to existing guidances (e.g. wellness, mobile apps, MDDS) so they align with the new software exclusions <sup>[8]</sup> <a href="http://www.fda.gov">www.fda.gov</a> <sup>[9]</sup> <a href="http://www.fda.gov">www.fda.gov</a> . Essentially harmonizes all software guidance with the statutory carve-outs.

(Sources: Official FDA guidance pages <sup>[10]</sup> [www.fda.gov](http://www.fda.gov); FDA press releases <sup>[36]</sup> [www.fda.gov](http://www.fda.gov); industry analyses <sup>[38]</sup> [www.nixonpeabody.com](http://www.nixonpeabody.com)). See text below for discussion and citations.)

## Key Guidance for Digital Health Categories

Below we examine the FDA's guidance documents by category of digital health product, explaining how each defines regulatory expectations and illustrating with examples.

### General Wellness Products

**Definition.** General wellness products are low-risk goods that promote a healthy lifestyle or mild health monitoring **without medical claims**. Under FD&C Act §520(o)(1)(B)(ii), software "intended for maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease" is *not* a device <sup>[9]</sup> [www.fda.gov](http://www.fda.gov). The FDA's 2026 **General Wellness Guidance** finalizes its policy: it clarifies that non-invasive wearables and apps that estimate physiological parameters (e.g. heart rate, step count, blood pressure) *for wellness only* can be marketed without FDA review, provided they meet certain criteria <sup>[22]</sup> [www.faegredrinker.com](http://www.faegredrinker.com). In practice, this guidance means products that simply track fitness metrics or stress levels for wellness can fall outside FDA oversight. For example, a smartwatch that monitors heart rate to help a user maintain fitness goals (with no claims of diagnosing heart disease) would likely qualify as a wellness product and not require approval <sup>[39]</sup> [www.faegredrinker.com](http://www.faegredrinker.com) <sup>[22]</sup> [www.faegredrinker.com](http://www.faegredrinker.com).

**Recent Changes.** FDA greatly **expanded** the wellness category in Jan 2026. Notably, the new guidance explicitly allows certain sensor-based devices to claim general wellness status **even if they output physiological measurements** (e.g. blood glucose or oxygen saturation) *solely for wellness uses*, as long as no disease treatment claims are made and the device poses minimal risk <sup>[22]</sup> [www.faegredrinker.com](http://www.faegredrinker.com) <sup>[40]</sup> [www.mondaq.com](http://www.mondaq.com). In other words, a wearable that measures your glucose or blood pressure purely for lifestyle feedback (for example, showing trends without clinical interpretations) would not be treated as a medical device. Industry experts note that under the updated policy FDA "will not focus its oversight on products measuring physiological parameters... provided that the products meet certain criteria" <sup>[40]</sup> [www.mondaq.com](http://www.mondaq.com) <sup>[41]</sup> [www.nixonpeabody.com](http://www.nixonpeabody.com). In summary, for wellness-focused apps and devices the latest guidance **softens FDA's approach**, broadening exemptions and reducing regulatory uncertainty, while still requiring strict boundaries: **wellness only**, no explicit medical claims, minimal risk, and transparency to consumers.

### Clinical Decision Support (CDS) Software

**Statutory Criteria.** The 21st Century Cures Act also identified certain **Clinical Decision Support (CDS)** software as outside the device definition. By law (FD&C §520(o)(1)(E)), four criteria must be met for CDS to be considered *non-*

device (and thus not regulated): (1) it is not intended to acquire/process images or signals from an IVD or imaging system, (2) it is intended to display/analyze patient medical information or scientific data, (3) it provides recommendations only to a healthcare professional (HCP) concerning prevention/diagnosis/treatment, and (4) it enables the HCP to independently review the basis of its recommendations and not rely primarily on them for patient care <sup>(11)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). Only if *all* four are satisfied does FDA consider the CDS function exempt from device requirements.

**Original and Updated Guidance.** FDA issued its first CDS guidance in 2019 (finalized in 2022), interpreting these criteria <sup>(7)</sup> [www.fda.gov](http://www.fda.gov)). The updated **2026 CDS Guidance** (final in Jan 2026) refines FDA's policy while remaining risk-based <sup>(23)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)) <sup>(24)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). Key updates include:

- **Time-Critical Use:** The 2019 guidance automatically deemed CDS intended for “time-critical” decision-making as a device. The 2026 version removes that automatic exclusion and instead treats time-critical usage as a *risk factor*: CDS used in emergencies is viewed as higher risk of causing automation bias <sup>(23)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)).
- **Single Recommendation Tools:** FDA now exercises enforcement discretion for CDS that offers **only one clinically appropriate option**, provided all other CDS criteria are met and the use is not time-critical <sup>(23)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). In other words, a tool that suggests a single treatment (when no other reasonable option exists) may remain unregulated if it simply supports, rather than directs, the HCP.
- **“Medical Information” Scope:** The guidance clarifies that “medical information about a patient” includes a broad range of patient-specific data (lab results, genetic tests, peer-reviewed studies, etc.). Whether information is “commonly discussed” in practice is now less important than its relevance and authoritative support <sup>(24)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)).
- **Transparency Requirement (Criterion 4):** The guidance emphasizes that CDS developers must provide **clear documentation** for HCPs about how the software works. The more “black-box” the algorithm (especially for AI-driven CDS), the more likely the FDA will deem it a device. Companies are expected to explain data sources, logic, and training methods to clinicians <sup>(42)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)).

Overall, the FDA's revised CDS policy continues to carve out many low-risk decision-support tools from regulation, but with important guardrails. As one legal analysis observes, the 2026 version “refines the interpretation of when CDS functions are excluded” and shifts towards **greater clarity and transparency** <sup>(43)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)) <sup>(23)</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). For developers, this means that truly informational CDS tools (e.g. showing medical literature recommendations to doctors) may still qualify as non-devices, but software that effectively directs diagnosis or treatment – especially in AI form – will likely be regulated under device pathways.

## Mobile Medical Applications and Software Functions

**Mobile Medical Apps (MMAs).** In the 2010s, the FDA issued specific guidance on **mobile medical applications** (MMA) – health apps on smartphones/tablets – largely using an enforcement discretion approach. An MMA that simply logs fitness or provides info was generally not enforced as a device, whereas an app that connects to a regulated device or serves as an accessory could be. In **Sep 2022**, FDA released the updated *Policy for Device Software Functions and Mobile Medical Applications*—encompassing both MMAs and software on general computing platforms <sup>(25)</sup> [www.fda.gov](http://www.fda.gov)). This guidance explains that **only software functions that meet the device definition and pose a patient risk if they fail will be regulated** <sup>(27)</sup> [www.fda.gov](http://www.fda.gov)). It enumerates examples of apps that FDA **will not enforce** (such as apps that only track exercise or diet) vs. those it **will enforce** (such as an app that performs electrocardiography from a connected sensor). The 2022 MMA guidance also incorporated recent changes: it reflects the FDA's final classification regulations (2021) under the Cures Act and updated aspects related to CDS <sup>(26)</sup> [www.fda.gov](http://www.fda.gov)).

In practice, FDA expects developers of apps to carefully determine whether their app's functions are “device” or “non-device.” For apps meeting the device definition, the usual regulatory requirements (510(k), QMS, postmarket) apply. Otherwise, low-risk apps can be brought to market without premarket submission. Developers should document why their

app is non-device under the guidance criteria (for example, by demonstrating only non-clinical wellness claims). The 2022 guidance provides a roadmap for making this determination and was intended to **provide clarity and predictability** (<sup>[25]</sup> [www.fda.gov](http://www.fda.gov)).

## Software as a Medical Device (SaMD) – Premarket Submissions

For software that unquestionably meets the device definition (i.e. intended for medical purposes), the FDA applies its standard device regulatory pathways (510(k) clearance, De Novo, or PMA). Key guidance in this area includes:

- **Content of Premarket Submissions (2023):** The June 2023 guidance “*Content of Premarket Submissions for Device Software Functions*” supersedes the longstanding 2005 guidance. It recommends what information to provide in 510(k) or De Novo submissions for SaMD. Topics covered include software validation, hazard analysis, cybersecurity, and performance testing. The goal is to facilitate review by outlining FDA’s latest expectations for software documentation (<sup>[29]</sup> [www.fda.gov](http://www.fda.gov)). In essence, the guidance reflects current best practices in software engineering and encourages manufacturers to include rigorous verification/validation evidence.
- **Off-the-Shelf (OTS) Software (2023):** Many devices incorporate commercial third-party software (e.g. operating systems, libraries). The Aug 2023 “*OTS Software Use in Medical Devices*” guidance instructs manufacturers on how to describe and justify use of OTS software in their submissions (<sup>[31]</sup> [www.fda.gov](http://www.fda.gov)). It clarifies that even if software is not custom-written, it still must be validated to device standards if used for medical functions. Sponsors should document the OTS software’s origin, versioning, any changes, and how it meets safety requirements.
- **Mobile Device Platforms:** Although already covered above, any medical software running on smartphones or tablets is still subject to the device submission requirements. The above premarket content guidance applies equally to apps, telehealth platforms, and other software-only products.

Overall, FDA’s recent guidance underscores that software developers must demonstrate safety and effectiveness just as manufacturers of hardware do. Device software must undergo design controls, risk analyses, and extensive testing, and the results compiled in premarket submissions (<sup>[29]</sup> [www.fda.gov](http://www.fda.gov)). These guidances ensure that SaMD is developed and documented to high quality standards before reaching patients.

## Artificial Intelligence/Machine Learning (AI/ML) Software

A major focus of FDA’s recent regulatory efforts is on AI/ML-enabled medical devices, particularly those based on adaptive algorithms. Key developments include:

- **Predetermined Change Control Plans (PCCPs, Aug 2025 Final).** The FDA’s Aug 2025 guidance “*Marketing Submission Recommendations for a Predetermined Change Control Plan (PCCP) for AI-Enabled Devices*” provides a formal mechanism for iterative improvement of AI software. The guidance recommends that companies include in their initial submission a PCCP that outlines planned future modifications to the AI algorithm, plus methods for developing, validating, and implementing those changes (<sup>[35]</sup> [www.fda.gov](http://www.fda.gov)). By approving the PCCP, FDA essentially gives a green light for the manufacturer to make those planned changes without submitting a separate new 510(k) for each one (<sup>[44]</sup> [www.fda.gov](http://www.fda.gov)). This represents a shift from one-time approvals to a *total lifecycle* approach. The PCCP requirement applies to AI devices in all pathways (510(k), De Novo, PMA) and is aimed at maintaining safety while enabling continuous learning.
- **AI-Enabled Device Draft Guidance (Jan 2025).** On January 6, 2025, FDA published a draft guidance entitled “*Artificial Intelligence-Enabled Medical Devices – Total Product Lifecycle*” (<sup>[36]</sup> [www.fda.gov](http://www.fda.gov)). If finalized, this will be the first comprehensive FDA guidance specifically for AI devices. It provides recommendations across the entire lifecycle: from early design (data selection, algorithm development) through validation, premarket submission, and postmarket monitoring (<sup>[36]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[37]</sup> [www.fda.gov](http://www.fda.gov)). Key themes are *transparency* (disclosing algorithm design and data sources), *bias mitigation* (using representative training data and fairness analysis), and *performance monitoring* (planning how to track real-world safety/effectiveness). The draft emphasizes that developers should engage FDA early, document how their AI handles changes, and include thorough risk management for AI-specific issues like novel error modes (<sup>[45]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[37]</sup> [www.fda.gov](http://www.fda.gov)). As FDA stated, the goal is to address emerging concerns (including those raised by generative AI) by providing a structured framework for AI device development (<sup>[37]</sup> [www.fda.gov](http://www.fda.gov)).

- **Regulatory Context.** As of early 2025, the FDA has cleared **over 1,000 AI/ML-enabled medical devices** through existing pathways (<sup>[20]</sup> [www.fda.gov](http://www.fda.gov)). These range from imaging analysis tools to clinical algorithms. The steps above indicate FDA's intent to adapt its regulatory review to the dynamic nature of AI. The agency is moving from a static approval view to a *lifecycle control* perspective, where algorithm updates can be managed proactively (PCCPs) and performance is continuously evaluated (<sup>[36]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[35]</sup> [www.fda.gov](http://www.fda.gov)). Developers should thus plan for iterative changes, robust validation, and documentation of AI systems.
- **Other AI Initiatives.** FDA and other agencies are also working on related topics, such as AI use in drug development (FDA draft guidance, Jan 2025) and Good Machine Learning Principles. While those are beyond our scope, it is clear that "AI/ML" has become its own major pillar of the digital health regulatory framework.

## Cybersecurity

As DHT become increasingly interconnected, cybersecurity is an essential component of safety. The FDA first addressed cybersecurity in medical devices in a 2014 draft and a 2016 final guidance on *postmarket* security management. In recent years, FDA has turned more attention to **premarket cybersecurity** requirements.

- **Premarket Cybersecurity Guidance (2025–2026).** FDA finalized new guidance on cybersecurity for device submissions. The Feb 2026 final guidance "*Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*" details what manufacturers should do and submit to address cyber risks (<sup>[33]</sup> [www.fda.gov](http://www.fda.gov)). It covers how to design devices securely (e.g. patching, encryption), and what to include in 510(k) or PMA submissions (risk analyses, test results, software bills of materials). This 2026 guidance supersedes an earlier June 27, 2025 final guidance – reflecting updates to address evolving threats and new statutory requirements (like Sec. 524B for cybersecurity devices) (<sup>[46]</sup> [www.fda.gov](http://www.fda.gov)).

The core message is that **cybersecurity should be built in from the start**. Companies must demonstrate via quality systems and submission documentation that their device can withstand reasonable cyber attacks. The guidance aims for consistency in how FDA evaluates cybersecurity aspects, ensuring devices remain "sufficiently resilient to cybersecurity threats" (<sup>[33]</sup> [www.fda.gov](http://www.fda.gov)). For digital health developers, this means following standards and considering security updates as part of the product lifecycle. Given that many DHT (wearables, IoT sensors, telehealth) rely on wireless connectivity, complying with this guidance is critical to getting FDA clearance.

## Other Software Considerations

Several additional guidance topics intersect with digital health:

- **Medical Device Data Systems (MDDS):** Software used solely to transfer, store, convert, or display medical device data (without modification) was reclassified by Congress as non-device. FDA's 2015 guidance clarified that functions like simple data storage or transmission are not regulated (<sup>[8]</sup> [www.fda.gov](http://www.fda.gov)). This means many back-end healthcare IT systems are exempt.
- **Multiple Function Products:** FDA's 2020 final guidance on *Multiple Function Device Products* explains how to handle products that combine multiple regulated devices or software with non-device software. The general policy is that each element is regulated by its nature, and appropriate labeling clarifies the claims for each function.
- **Interoperability and Accessories:** Guidance on interoperability (2017) and on accessories (2017) continues to apply when DHT connect to other devices. For example, if an app is an "accessory" to a regulated device (used to control it or interpret its data), that app may itself become a regulated device component.

Overall, the **digital health guidance landscape** now covers the entire spectrum: from clearly exempt wellness apps to AI-based tools requiring continual oversight. The most recent developments emphasize innovation-friendly policies (wider exclusions, pre-approved change plans) within a rigorous risk-based framework.

# Navigating FDA Requirements: Perspectives and Data

## Data Analysis: Industry Growth and Trends

The **growth of digital health** is illustrated by approvals and market data. An analysis of FDA databases showed that from 2012 to 2021 the number of approved SaMD devices rose from 1 to 581 (202.7% CAGR) <sup>(5)</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/). By mid-2025 the FDA's public listings include well over 1,500 DHT entries (sensors, AI systems, AR/VR) <sup>(3)</sup> [sensaco.com](https://sensaco.com). These cover both clinical and at-home contexts. For instance, among sensor-based digital devices, over 215 cleared devices include diabetic glucose monitors and hearing features in consumer products <sup>(47)</sup> [sensaco.com](https://sensaco.com). In terms of manufacturers, leaders include **Dexcom, iRhythm, Apple, Samsung, Siemens, Canon, Abbott** and others <sup>(18)</sup> [sensaco.com](https://sensaco.com) <sup>(48)</sup> [sensaco.com](https://sensaco.com). Notably, about 40% of digital sensors are in a few FDA product codes: ventilatory effort recorders, pulse oximeters, transmitters, factory-calibrated CGM systems (Dexcom), and non-invasive blood pressure <sup>(49)</sup> [sensaco.com](https://sensaco.com). On the AI side, the top FDA codes (e.g. "QIH: Automated Radiological Image Processing Software") reflect the dominance of imaging analytics in recent device clearances <sup>(50)</sup> [sensaco.com](https://sensaco.com).

In terms of finances, venture investment and corporate initiatives in digital health have been robust. For example, FDA recognized Pear Therapeutics as pioneering prescription digital therapeutics in the late 2010s. By 2025, dozens of DTx products are in use globally (treating conditions from addiction to ADHD) <sup>(51)</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/). These trends reinforce that digital health is not a niche: it is a maturing industry with real-world patient impact.

## Case Studies and Real-World Examples

Concrete examples help illustrate how FDA policies apply:

- **Apple Watch ECG (2018 Clearance).** In September 2018, Apple announced FDA clearance of its built-in ECG app <sup>(52)</sup> [www.medtechdive.com](https://www.medtechdive.com). This app, running on the Series 4 Watch, continuously monitored heart rhythm and could detect atrial fibrillation. It was cleared via the De Novo pathway as a Class II device <sup>(52)</sup> [www.medtechdive.com](https://www.medtechdive.com). This case exemplifies high-risk DHT entering FDA's purview: although the ECG feature was on a consumer wearable, it **provided a diagnostic function (detecting AFib)** and thus could not be considered "wellness." Apple worked closely with FDA during development, reflecting the Agency's approach to facilitate innovation when safety can be assured <sup>(53)</sup> [www.medtechdive.com](https://www.medtechdive.com). (In contrast, if Apple had offered an app that only tracked heart rate for exercise without any arrhythmia detection, it likely would have fallen under general wellness and avoided clearance.)
- **Dexcom Glucose Monitors.** Devices like Dexcom's G7 continuous glucose monitor (CGM) integrate software to transform raw glucose readings into user-friendly trends and alerts. Because glucose management is a medical use, the CGM system is regulated as a Class II devices under 21 CFR 862.1355 (onsite chem analyzers). FDA data show that Dexcom is one of the top companies by number of cleared digital sensor products <sup>(18)</sup> [sensaco.com](https://sensaco.com) <sup>(19)</sup> [sensaco.com](https://sensaco.com). In each clearance, Dexcom provided extensive software documentation per FDA guidance. This case underscores that clinically critical sensors (even when wearable/consumer-facing) must meet all device requirements.
- **Pear Therapeutics' Digital Therapeutics.** Pear Therapeutics pioneered prescription digital therapeutics (PDT). Its first product (reSET, for substance use disorder) was 510(k)-cleared in 2017, and in Dec 2018 FDA cleared reSET-O for opioid use disorder <sup>(54)</sup> [www.novartis.com](https://www.novartis.com) <sup>(55)</sup> [www.novartis.com](https://www.novartis.com). These are standalone mobile apps delivering cognitive behavioral therapy (CBT) programs. FDA treated them as medical devices requiring clearance – for example, Pear's press release characterizes reSET-O as the first FDA-cleared "PDT" for OUD <sup>(54)</sup> [www.novartis.com](https://www.novartis.com). Under FDA's guidance, Pear had to validate the software's therapy content, use human factors testing, and ensure the app's outputs (digital lessons, reminders) were clinically safe and effective when used as prescribed. The reSET apps illustrate how even traditionally "nondrug" treatments can be regulated like devices if they claim to affect health.

- **Connected Health Research (Clinical Trials).** FDA is encouraging use of DHT in clinical research. Its December 2023 guidance supports using wearables and smartphone apps to collect data remotely (<sup>[32]</sup> [www.fda.gov](http://www.fda.gov)). For example, the FDA-funded “MEND-HD” study is exploring gait and movement measures in Huntington’s disease using wearable sensors (<sup>[12]</sup> [www.fda.gov](http://www.fda.gov)). According to FDA, such studies can improve trial efficiency and patient access. Companies developing DHT should note that while this guidance itself is voluntary, its recommendations (device validation, data security, patient consent) set expectations for clinical studies involving their devices.

These cases show the **breadth of digital health**: from consumer-grade fitness features to prescription therapy apps and research tools. In each instance, developers must determine the appropriate regulatory path by applying FDA’s risk-based criteria (e.g. wellness vs. device, CDS vs. device, etc.) and then satisfy relevant guidance.

## Industry Perspectives

Industry commentary highlights the impact of recent guidance. For example, law firms and analysts note that FDA’s January 2026 guidances on wellness and CDS signal a “pro-innovation” shift (<sup>[38]</sup> [www.nixonpeabody.com](http://www.nixonpeabody.com)) (<sup>[56]</sup> [www.mondaq.com](http://www.mondaq.com)). Firms observe that the updated policies “**cut the red tape**” on certain devices: manufacturers can now more confidently market wearable trackers or decision-support tools without preclearance in many cases (<sup>[56]</sup> [www.mondaq.com](http://www.mondaq.com)) (<sup>[41]</sup> [www.nixonpeabody.com](http://www.nixonpeabody.com)). FDA Commissioner Makary has publicly stated the goal of clearing obstacles to innovation in digital health. At the same time, analyses stress that these guidances still place **guardrails**. For instance, the CDS guidance’s expanded enforcement discretion for single-recommendation tools prevents artificially restricting useful software, but it also warns companies to ensure transparency and not create “black boxes” that doctors can’t trust (<sup>[42]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)) (<sup>[24]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). In the wellness domain, analysts pointed out that four key criteria must still be met; if a wearable crosses into “medical claims” territory, it will trigger regulation. Thus, perspective pieces generally agree that “neither guidance represents a sea change” – FDA is clarifying and easing compliance on low-risk DHT, but not abandoning oversight of tools with clinical impact (<sup>[57]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)) (<sup>[56]</sup> [www.mondaq.com](http://www.mondaq.com)).

A parallel perspective comes from institutional voices. FDA’s own guidance (e.g. [6]) emphasizes consistency and efficiency, while Congress and patient groups have pushed for keeping highly beneficial digital technologies accessible. For example, patient advocacy and industry surveys often report demand for remote monitoring tools and AI decision support, putting pressure on FDA to accommodate these safely. Conversely, public health groups caution about privacy and clinical accuracy. Indeed, FDA discussions on transparency (in AI guidance) and privacy (HIPAA considerations in digital health) reflect these concerns (<sup>[58]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). Weighing these perspectives, it’s clear that stakeholders expect the FDA to maintain a balance: **innovate rapidly, but maintain clinically-tested safety and data security**.

## Detailed Analysis of Latest FDA Requirements

Having reviewed the context, we now delve into the specific requirements that developers of digital health products must navigate, as illustrated by FDA guidance and data. Each subsection below focuses on a particular aspect or product category, with citations to guidance, studies, and expert interpretation.

### Guidance for Low-Risk Wellness Products

- **Definition and Scope:** Under the latest guidance, a *general wellness product* is defined as a device that promotes a healthy lifestyle (e.g. fitness, weight loss) and gives non-actionable health information. It must avoid disease claims (like “treats high blood pressure”) (<sup>[9]</sup> [www.fda.gov](http://www.fda.gov)). The 2026 update explicitly clarifies that devices with non-invasive sensors **can still qualify** if they display values or trends solely in a “wellness context” (<sup>[22]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)).

- **FDA Focus on Claims:** The guidance instructs companies to carefully craft claims and labels. Devices that simply provide encouraging feedback are fine, but any statement implying diagnosis or treatment pushes it into regulated territory (<sup>[59]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)) (<sup>[22]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). In practice, this means marketing language must emphasize lifestyle, fitness, and general well-being. For example, a blood pressure cuff marketed as a "fitness tracker" to help users stay active (with no medical claims) could be considered wellness. However, if it recommends medication or alerts for hypertension, it would be a medical device.
- **Regulatory Requirements: No preclearance is needed** for wellness products that truly meet the criteria. FDA will not issue 510(k) clearances or PMAs for them. Instead, the FDA's Digital Health Center of Excellence will exercise *enforcement discretion* (i.e. choose not to regulate) as long as criteria are satisfied. Nevertheless, the guidance suggests manufacturers should maintain documentation explaining why their product is low-risk – to demonstrate good faith compliance.
- **Industry Viewpoint:** Lawyers note that the updated guidance "expands the types of products that fall within the category of general wellness" (<sup>[41]</sup> [www.nixonpeabody.com](http://www.nixonpeabody.com)). This can accelerate market entry for health wearables. However, developers must remain cautious: if a wellness device is later found to claim medical benefit, or if another criterion changes (e.g. future CDC reports on telehealth), then FDA could step in. See Table 2 (below) for examples of product scenarios and regulatory status.

## Guidance for Clinical Decision Support (CDS) Tools

- **Exclusion Criteria:** As described, CDS tools that meet all four statutory criteria are *not devices*. FDA clarifies this in its 2026 guidance. Tools satisfying the criteria can operate freely; those failing even one criterion are subject to device rules (<sup>[7]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[11]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)).
- **Key Changes:**
- **Criterion 3 Discretion:** If software provides only one possible medical recommendation, FDA *will generally treat it as non-device* (exercising enforcement discretion) provided it's clinically appropriate and not time-critical (<sup>[23]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). This softens the 2019 rule that any such software would be regulated.
- **Criterion 4 Documentation:** Software must now include **accessible documentation** for clinicians about its logic and data sources (<sup>[42]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). The more opaque the software (e.g. a deep-learning black box with no explanation), the more likely FDA will view it as a device. For example, an ML algorithm that "suggests possible diagnoses" but doesn't provide the reasoning would fail Criterion 4.
- **Definition of "Medical Information":** FDA broadened what counts as patient medical info (criterion 2) to include lab results, peer-reviewed studies, and commonly shared patient data (<sup>[24]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). This is more expansive than just chart notes. It means many types of input data are permissible under non-device CDS, so long as other criteria hold.
- **Enforcement and Compliance:** Any CDS not meeting the exclusions must go through the traditional device pathways. For compliance, a company should document how its tool meets each criterion (or why a device submission is needed). Transparency is now crucial: e.g. posting or providing summaries of how the algorithm works. Companies often prepare a *Criterion Justification* to explain which criterion fails (if any) and ensure their marketing aligns.
- **Implications for Innovation:** FDA's approach *encourages* pro-innovation, risk-based development of CDS. By relaxing restrictions on single-answer and time-critical uses under certain conditions, FDA acknowledges the value of automated assistance to clinicians. However, it maintains that clinicians must be able to review and override recommendations. This guidance pushes developers to build CDS as collaborative tools, not autopilots; robust documentation becomes a selling point, not just a regulatory requirement (<sup>[42]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)) (<sup>[58]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)).

## Software Development and Documentation Requirements

- **Design Control:** All regulated device software must follow FDA's Quality System (QS) regulation for design controls (21 CFR 820.30). This means developers must have procedures covering design planning, verification/validation testing, risk analysis, and change control. Documentation of each software development step is expected in submissions. (Guidance "*Content of Premarket Submissions*" 2023 emphasizes QS considerations (<sup>[29]</sup> [www.fda.gov](http://www.fda.gov)).

- **Traceability and Risk Management:** A critical requirement is traceability of features to user needs and risks. For SaMD, manufacturers create a *Software Requirements Specification (SRS)* and a *Software Design Specification (SDS)*, then verify that outputs meet inputs via testing. All potential software failure modes must be analyzed for patient safety impact (per FDA's design controls and ISO 14971 standards). The 2023 guidance on software functions provides recommendations on documenting this process (<sup>[29]</sup> [www.fda.gov](http://www.fda.gov)).
- **Cybersecurity by Design:** Building on guidance, developers must treat cybersecurity as a parallel design control. For instance, encryption of data transmissions, secure coding practices (to avoid vulnerabilities), and postmarket update plans are expected per guidance (<sup>[33]</sup> [www.fda.gov](http://www.fda.gov)). Submissions should include a hazard analysis covering cyber threats and evidence of mitigations.
- **Validation of Performance:** In some cases, numerical precision and algorithmic performance require clinical validation data. For example, if the software outputs a diagnostic classification, FDA expects bench testing against known samples, and often clinical study data for novel devices. The FDA 2023 device software submission guidance reiterates the need for "objective evidence" of software performance (<sup>[29]</sup> [www.fda.gov](http://www.fda.gov)). Failure to validate an AI algorithm's sensitivity/specificity, for instance, could lead to clearance denial.
- **Off-the-Shelf Software:** When using third-party components (open-source libraries, off-the-shelf modules), sponsors must show they meet medical device standards or are compensated with additional validation. The corresponding 2023 guidance explains that OTS software should be documented in submissions (origin, version, functionality) and tested within the device context (<sup>[31]</sup> [www.fda.gov](http://www.fda.gov)). Neglecting this can result in deficiencies, as FDA reviewers scrutinize any "plug-in" code for reliability in a medical setting.

In summary, the FDA expects rigorous software engineering practices for medical software, aligned with its guidance documents. Developers should integrate risk analysis, usability testing, cybersecurity planning, and thorough documentation from the outset.

## Artificial Intelligence/ML-Specific Requirements

Building on the general software requirements, **AI/ML devices face additional expectations:**

- **Predetermined Change Control Plans (PCCPs):** For AI devices that learn and change after launch, the Aug 2025 guidance requires a PCCP in the 510(k)/PMA submission (<sup>[35]</sup> [www.fda.gov](http://www.fda.gov)). A PCCP should describe how the algorithm may be modified (retraining with new data, threshold adjustments, etc.), how those modifications will be validated/simulated, and how performance drift will be assessed. For example, an AI radiology tool might include a PCCP stating it will periodically incorporate new radiograph images to improve detection, along with the statistical methods and validation datasets to be used. The device sponsor must show the FDA upfront that these changes will not compromise safety or effectiveness.
- **Transparency and Bias Mitigation:** As highlighted in the Jan 2025 draft guidance, FDA seeks detailed transparency about AI. Even if not final yet, developers should plan to document how their AI model works, how training data was selected, and how bias (e.g. underrepresentation of subpopulations) is addressed (<sup>[37]</sup> [www.fda.gov](http://www.fda.gov)). For instance, if an AI skin lesion app was trained mostly on White patients, FDA would expect a plan to expand training to darker skin types or to clearly label limitations. The draft guidance explicitly asks for design strategies to mitigate bias and reviews by default – hence companies should proactively include fairness assessments (like checking false negative rates across cohorts) in their submissions.
- **Performance Monitoring (Postmarket).** FDA guidance encourages a *Total Product Life Cycle (TPLC)* approach (<sup>[36]</sup> [www.fda.gov](http://www.fda.gov)). Developers should propose a plan for **real-world performance monitoring** as part of their submission. This might include ongoing data collection on device outputs, error reporting systems, and thresholds for performance degradation. For example, an AI-enabled ECG app might include a built-in data logger to track algorithm performance in users and alert the sponsor if accuracy falls outside acceptable limits, in line with FDA's recommendations (<sup>[45]</sup> [www.fda.gov](http://www.fda.gov)).
- **High-Level Organization Commitment:** FDA has signaled that organizational culture matters. In the Pre-Cert pilot report, "culture of quality and organizational excellence" was a key criterion. While the formal Pre-Cert program did not advance to rulemaking, the spirit remains: companies with robust software QA processes (secure DevOps, vigilant monitoring) are better positioned to meet FDA expectations for AI software.

Taken together, satisfying FDA's AI-focused guidance requires more than the usual software documentation. Companies must think like a life-cycle manager of an evolving product: anticipating updates, addressing AI-specific risks (bias, opacity), and planning continuous oversight. The extensive draft guidance (<sup>[36]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[37]</sup> [www.fda.gov](http://www.fda.gov)) shows FDA's commitment to regulating AI as a distinct paradigm.

## Data Considerations and Privacy

While FDA guidance primarily addresses safety and effectiveness, developers must also heed other regulatory domains:

- **Data Integrity and Remote Monitoring:** RF guidance (Dec 2023) on remote data acquisition emphasizes that digital endpoints must be validated for clinical trials (<sup>[32]</sup> [www.fda.gov](http://www.fda.gov)). It suggests sponsors use validated devices and ensure data security and privacy. For example, if a wearable transmits patient data, it must do so encrypted and preserve accuracy. Data collection protocols (frequency, units, calibration) must be documented.
- **Protected Health Information (HIPAA):** The FDA does not regulate privacy or patient data security, but digital health developers often handle PHI. The January 2026 Faegre Drinker summary notes that when a digital tool deals with PHI (e.g. transmitting patient data to physicians), developers must comply with HIPAA rules (<sup>[58]</sup> [www.faegredrinker.com](http://www.faegredrinker.com)). Failure to secure patient data can lead to legal penalties and loss of trust, even if outside FDA's purview. Companies should build HIPAA-compliant data controls (access logs, de-identification where possible) into their products.
- **Interoperability Standards:** As of mid-2020s, there is no single FDA-mandated data standard for DHT, but the trend is toward greater interoperability. Many new digital health products integrate with EHRs via HL7 FHIR or similar APIs. While not required, adhering to widely accepted standards (FHIR, Bluetooth medical device profiles, .vcf for vitals, DICOM for images) simplifies adoption in clinical settings. FDA encourages sharing of data and has issued *Voluntary* cybersecurity guidance for networked devices, implying that uniform standards can reduce vulnerabilities.

Developers should anticipate data-related scrutiny even if not explicitly in FDA guidance. For example, it is best practice to validate digital sensors against clinical measurements (as FDA expects), ensure data accuracy (FDA's premarket content guidance notes the need for data validation (<sup>[29]</sup> [www.fda.gov](http://www.fda.gov))), and have clear policies on data use. Public concerns around privacy mean that documentation of user consent and data handling (though beyond FDA's checklists) will bolster an application's credibility.

## International and Future Directions

**International Context:** The FDA's approach can be contrasted with international regulations. For instance, the EU's new Medical Device Regulation (MDR, 2021) does not have exceptions like the Cures Act did: most software with medical intent is regulated in the EU regardless of risk claims. That means digital health companies often face a heavier burden in the EU (most SaMD are Class IIa or IIb) than in the US, where some are exempt. The FDA focuses on low-risk carve-outs; the EU emphasizes uniform classification. This difference is notable for multi-national developers: a product that is exempt from FDA regulation might still require an EU CE mark.

**FDA Signals and Policy Trends:** Beyond released guidance, FDA leaders have signaled future priorities. Commissioner Makary in 2025 announced a "Digital Health Software Precertification Program" reforms and suggested lowering regulatory barriers for low-risk DHT. Congress is also watching; bipartisan proposals (e.g. bills like the "Protecting and Transforming Cyber Health Act" and AI device acts) aim to strengthen oversight in areas like cybersecurity and AI reliability. Developers should stay alert to such legislative changes that may codify or expand on FDA's policies.

**Emerging Technologies:** New frontiers include **personalized health software (PHS)**. As of 2024, FDA was planning voluntary precertification for tailored DHT (like patient-customized apps). Additionally, virtual/augmented reality in therapy (e.g. VR pain management) is a coming wave; FDA has draft guidances on AR/VR devices which developers should watch.

**Data Exchange and Real-World Evidence:** The COVID-19 PHE accelerated the use of telehealth and remote monitoring data. FDA's push for *Real-World Evidence (RWE)* and the development of national health data networks will likely affect DHT. For example, the new "Trusted Exchange Framework" (TEFCA) and patient data interoperability laws (21st Cures Act provisions) facilitate exchange of health information that DHT can leverage. In the future, digital health tools that feed into national data repositories may be subject to additional scrutiny for data quality.

**Ethical Considerations:** AI in health raises unique ethical questions. The FDA's emphasis on transparency and bias is essentially ethical oversight. Additionally, equity concerns (e.g. ensuring DHT work across diverse populations) may drive FDA guidance updates or require postmarket monitoring of disparate outcomes. Companies should proactively design for inclusivity to meet future FDA and societal expectations.

**Future Guidance:** FDA has announced plans for more guidances affecting digital health. Notably, on Feb 3, 2026, FDA indicated an upcoming final guidance on content/performance testing for clinical endpoints collected by digital sensors (slated for 2026). Also, FDA's advisory committees (Digital Health Advisory Committee meetings) have discussed AI oversight and cybersecurity. It's anticipated that within the next 1-2 years, FDA will finalize the AI TPLC draft and issue new policies on topics like large language models (LLMs) in healthcare tools. Developers should watch the FDA Digital Health web page and Federal Register notices for such updates.

## Practical Guidance and Recommendations

For companies developing digital health technology, here's how to **navigate the latest FDA requirements**:

- **Categorize Your Product Early:** Determine if your product is a medical device. i.e. does it make clinical claims? If it's a wellness tracker with no disease claims, document that carefully. If it's a CDS tool, map it against the Cures Act criteria. Use FDA guidance to justify your classification (e.g. compare your product to examples in guidances (<sup>[9]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[59]</sup> [www.faegredrinker.com](http://www.faegredrinker.com))). This dictates whether you file a 510(k)/PMA or proceed without FDA submission.
- **Follow Relevant Guidance:** Identify all applicable FDA guidances early. For instance, a mobile app company should read the 2022 MMA guidance (<sup>[25]</sup> [www.fda.gov](http://www.fda.gov)), the premarket software guidance (<sup>[29]</sup> [www.fda.gov](http://www.fda.gov)), and cybersecurity guidance (<sup>[33]</sup> [www.fda.gov](http://www.fda.gov)). Align your development and documentation with these. Incorporate design controls covering what each guidance emphasizes (user interface/usability, verification activities, labeling, etc.).
- **Leverage Regulatory Programs:** Where possible, use FDA programs to streamline approval. For significant digital health innovations, consider **Breakthrough Device** or **Safer Technologies Program (STeP)** designations, if eligible. For example, FDA has created Digital Health Special Emphasis Panels in its review staff. Early engagement (meeting with FDA via pre-sub meetings) is strongly advised, especially for novel AI products (<sup>[45]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[35]</sup> [www.fda.gov](http://www.fda.gov)). Clarify how FDA intends to regulate your product. If possible, seek feedback on your risk analysis and planned documentation (some companies even seek Cover Letters that outline how they meet or are covered by exclusions).
- **Prepare Comprehensive Submissions:** When filing, **include all recommended content**. For software, this means source code review documentation, test cases, failure mode analyses, validation datasets, and cybersecurity documentation. Show traceability from requirements to verification. If using a PCCP (per AI guidance), detail it thoroughly. If claiming enforcement discretion (wellness/CDS), explain why each regulatory exclusion applies to you. The more transparent and complete your submission, the smoother the review.
- **Implement Quality and Security at the Start:** FDA expects a mature quality system. Even if not required for non-device wellness products, adopting good QMS practices (like ISO 13485 or IEC 62304 for software) pays dividends in preparing for any future regulation. Similarly, build in cybersecurity protections from the design phase; use FDA's cybersecurity guidance checklists to verify you've covered factory-resets, firmware signing, user authentication, etc. (<sup>[33]</sup> [www.fda.gov](http://www.fda.gov)).
- **Document Everything:** Maintain thorough documentation for your design and risk decisions, even (or especially) if you believe your product is not a device. FDA or other stakeholders may request evidence. Good documentation helps demonstrate compliance and speeds any audits or inspections.
- **Plan for Postmarket:** If your product becomes regulated, remember the work doesn't end at clearance. Establish postmarket surveillance: collect user feedback, monitor adverse events (apply MDR/regulatory reporting if in EU as well), plan software updates under your change control plan (for AI). The FDA's AI lifecycle draft specifically asks for performance monitoring plans (<sup>[45]</sup> [www.fda.gov](http://www.fda.gov)). Keep quality records up to date.
- **Stay Informed:** The digital health field moves quickly. Continuously monitor FDA announcements, guidance portals, and industry news. Engage with trade associations (e.g. AdvaMed Digital Health) that track FDA policies. Consider routine training on digital health regulations for your team.

## Conclusion

The FDA's regulatory framework for digital health technologies is evolving rapidly to keep pace with innovation. In the last few years, FDA has broadened exclusions for low-risk wellness apps and some decision-support tools (<sup>[9]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[40]</sup> [www.mondaq.com](http://www.mondaq.com)), while supplementing the review process for higher-risk software (particularly AI/ML and connected devices) with lifecycle and security requirements (<sup>[35]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[33]</sup> [www.fda.gov](http://www.fda.gov)). The net result is a more nuanced, risk-based landscape where developers of health software can expect greater clarity. Key takeaways from this report include:

- **FDA maintains a risk-based approach:** Low-risk digital health (general wellness, CDS with full transparency) largely remains outside traditional device requirements. High-risk uses (diagnostic/treatment software, closed-loop algorithms) are carefully regulated with extensive documentation and oversight (<sup>[7]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[11]</sup> [www.faedregdrinker.com](http://www.faedregdrinker.com)).
- **Recent guidance emphasizes innovation:** The January 2026 updates on wellness and CDS, along with forthcoming AI and cybersecurity guidances, highlight FDA's intent to *enable* developers. By providing examples and flexibility (e.g. for certain AI revisions), FDA aims to spur innovation while guiding developers on safe practices (<sup>[38]</sup> [www.nixonpeabody.com](http://www.nixonpeabody.com)) (<sup>[36]</sup> [www.fda.gov](http://www.fda.gov)).
- **Documentation and quality are paramount:** All digital health products that fall within FDA's scope must follow robust development processes. Guidance documents clearly enumerate what needs to be in submissions (from software validation to secure design) (<sup>[29]</sup> [www.fda.gov](http://www.fda.gov)) (<sup>[33]</sup> [www.fda.gov](http://www.fda.gov)). Developers should treat these guidances as checklists for compliance.
- **Multiple stakeholders influence policy:** The perspectives of patients, clinicians, industry, and legislators shape FDA's stance. Case studies like Apple Watch and digital therapeutics show how patient needs drive innovation, while FDA's priority on transparency and bias shows the agency's commitment to patient safety.
- **Global harmonization is evolving:** While this report focuses on FDA requirements, global regulatory trends (EU MDR, IMDRF SaMD framework) also matter. Harmonizing international standards (e.g. leveraging IMDRF or future FDA–EU collaborations) remains an important goal, as indicated by FDA's Center of Excellence objectives (<sup>[15]</sup> [www.fda.gov](http://www.fda.gov)).
- **Future outlook:** We expect continued updates, especially in AI, software interoperability, and real-world evidence use. The FDA has launched pilot programs (like TEMPO) and is exploring new legislative authorities. Companies should view FDA guidance as a living document; staying adaptive will be key to success.

In conclusion, **navigating the latest FDA digital health requirements** demands both technical rigor and strategic foresight. Developers must stay abreast of guidance changes, implement sound quality and security practices, and be prepared for FDA interaction. By doing so, they can accelerate the delivery of innovative digital health solutions that meet FDA's evolving standards and ultimately improve healthcare outcomes.

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