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FDA Digital Health Guidance: 2026 Requirements Overview

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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. The **QMSR** took effect on February 2, 2026, incorporating ISO 13485:2016 into 21 CFR Part 820. Real-world examples include Apple's ECG app, classified through **FDA's De Novo order** with informational outputs requiring clinician consultation, and **reSET-O**, a prescription adjunct intended to increase retention in clinician-supervised adult outpatient treatment alongside transmucosal buprenorphine and contingency management. 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” (www.fda.gov). The FDA follows this definition and classifies SaMD according to the risk of its intended use (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 (www.fda.gov) (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 (pmc.ncbi.nlm.nih.gov). This surge is reflected in FDA activity: a 2023 study identified 581 SaMD products through database filtering (pmc.ncbi.nlm.nih.gov). Many of these SaMD products are advanced image-analysis tools in radiology (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” (www.fda.gov) (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 (www.fda.gov) (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 (www.fda.gov) (www.faegredrinker.com). At the same time, FDA’s **Digital Health Center of Excellence (DHCoE)** (established on **September 22, 2020**) has spearheaded initiatives and resources for digital health, including hosting public workshops and sponsoring demonstration projects (e.g. wearable endpoints in clinical trials (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 support the discussion. 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* (www.fda.gov) (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 (www.fda.gov) (www.fda.gov). Similarly, the Cures Act excluded many clinical decision support (CDS) software functions that meet specified criteria (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 (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 (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 (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 devices reviewed by FDA can follow a harmonized approach to documentation and clinical evaluation.

Digital Health Center of Excellence and Policy Initiatives

FDA established the *Digital Health Center of Excellence (DHCoE)* on **September 22, 2020**. The separate **Pre-Cert pilot** launched in 2017 and concluded in September 2022. FDA's **TEMPO pilot** is connected to CMS's **ACCESS model**, which tests outcome-aligned payment in Original Medicare. FDA began accepting statements of interest on January 2, 2026 and announced the **first selected manufacturer on July 22, 2026**. Participation in this pilot is distinct from product marketing authorization.

Trends in Digital Health Approvals and Investments

FDA maintains public lists of **AI-enabled devices** and **sensor-based digital health devices**; both are explicitly non-comprehensive. Listing counts should not be interpreted as a census of unique digital health devices or a market-share ranking. In its January 2025 announcement, FDA reported **more than 1,000 authorized AI-enabled devices** through established premarket pathways. Authorization encompasses different regulatory decisions; it is not synonymous with 510(k) clearance.

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 (www.fda.gov)	Updated final January 6, 2026	Distinguishes software excluded under section 520(o)(1)(B) from enforcement discretion for qualifying low-risk general wellness products. Physiological sensing must be non-invasive, non-implanted and low risk, solely for wellness, without disease purposes, substitution for an FDA-authorized device or outputs guiding clinical action or medical management; values mimicking clinical measurements require validation (www.fda.gov) (www.faegredrinker.com).
Clinical Decision Support (CDS) Software (www.fda.gov)	Updated final January 29, 2026	The section 520(o)(1)(E) exclusion requires all four criteria: no acquisition, processing or analysis of medical images, IVD signals or signal-acquisition patterns or signals; display, analysis or printing of medical information; recommendations to HCPs about prevention, diagnosis or treatment; and independent HCP review of the basis without primary reliance on the recommendations for an individual patient's diagnosis or treatment. The FDA guidance distinguishes Non-Device CDS from device functions; applicable enforcement-discretion policies must be considered separately.
Device Software Functions & Mobile Apps (www.fda.gov) (www.fda.gov)	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 (www.fda.gov). Clarifies enforcement discretion for low-risk mobile apps and updated to incorporate Cures Act classification rules (www.fda.gov).
Software Precertification (Pre-Cert) Pilot (www.fda.gov)	2017–2022 (pilot period)	Content: Pilot program (2017–2022) for precertifying trusted digital health companies. Concluded in Sept 2022 with a Final Report (www.fda.gov). 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 (www.fda.gov)	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 (www.fda.gov). Reflects current standards for software development and risk management.
Off-the-Shelf (OTS) Software in Medical Devices (www.fda.gov)	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. (www.fda.gov).
Digital Health Tech for Remote Data in Clinical Trials (www.fda.gov)	Dec 2023 (final)	Offers guidance on using wearables, apps, and other remote digital tools to collect data in regulated clinical studies (www.fda.gov). Addresses validation, data integrity, and consent issues to ensure reliability of DHT-collected endpoints.
Cybersecurity in Medical Devices (www.fda.gov)	Jun 2025 (final) and Feb 2026 (updated final)	Describes FDA's recommendations for cybersecurity risk management in device design and submissions (www.fda.gov). 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) (www.fda.gov).
Marketing Submission Recommendations for a Predet. Change Control Plan (PCCP) for AI Devices (www.fda.gov)	Aug 2025 (final)	Guidance specifically for AI/ML devices. Recommends including a Predetermined Change Control Plan (PCCP) 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 (www.fda.gov).

Guidance Document	Issued	Scope / Key Topics
<i>AI-Enabled Device Software TPLC (Draft)</i> (www.fda.gov) (www.fda.gov)	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 (www.fda.gov) (www.fda.gov). (Final expected post-comment.)
<i>Multiple Function Device Products</i>	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.
<i>Changes from Section 3060 of Cures Act</i> (www.fda.gov)	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 (www.fda.gov) (www.fda.gov). Essentially harmonizes all software guidance with the statutory carve-outs.

(Sources: Official FDA guidance pages (www.fda.gov); FDA press releases (www.fda.gov); industry analyses (www.nixonpeabody.com). See text below for discussion and citations.)

Key Guidance for Digital Health Categories

Below we examine FDA guidance by product category, distinguishing statutory exclusions, enforcement discretion and applicable device requirements.

General Wellness Products

Under FD&C Act section 520(o)(1)(B), qualifying software intended to maintain or encourage a healthy lifestyle, unrelated to disease diagnosis, cure, mitigation, prevention or treatment, is excluded from the device definition. Separately, FDA's **January 6, 2026 general wellness guidance** describes enforcement discretion for low-risk general wellness products. A physical product does not become a statutory non-device simply because it is marketed for wellness.

The policy includes healthy-lifestyle claims unrelated to disease and a separate category of accepted claims that healthy lifestyle choices may reduce the risk or impact of certain chronic diseases, or help people live well with them. The latter require a well-understood, generally accepted association supported by scientific publications or professional organizations.

For physiological outputs such as blood pressure, oxygen saturation or glucose, FDA's **policy conditions** require solely wellness use, non-invasive and non-implanted sensing, low risk without specific regulatory controls, no disease-purpose functionality, no substitution for an FDA-authorized device, and no outputs guiding clinical action or medical management. Values resembling clinical measurements must be validated to reflect those values. Labels, advertising, interfaces and functionality matter; calling a blood-pressure cuff a fitness tracker does not establish eligibility.

Clinical Decision Support (CDS) Software

FDA's **January 29, 2026 CDS guidance** describes four criteria under section 520(o)(1)(E). Qualifying functions must:

1. Not acquire, process or analyze a medical image, an IVD signal, or a pattern or signal from a signal-acquisition system.
2. Display, analyze or print patient medical information or other medical information, such as studies or clinical practice guidelines.
3. Support or provide HCP recommendations about prevention, diagnosis or treatment, rather than replace or direct clinical judgment.
4. Enable the HCP to independently review the recommendation's basis without relying primarily on it for an individual patient's diagnosis or treatment decision.

If only one option is clinically appropriate and the other criteria are met, FDA intends to exercise enforcement discretion for that device function; it remains a device rather than becoming statutory non-device CDS. Independent review requires understandable information about inputs, underlying sources and recommendation logic. FDA considers automation and time-critical decision-making when assessing whether review is feasible. Failure to satisfy the statutory exclusion does not invariably require a premarket submission: applicable requirements and enforcement-discretion policies must be evaluated.

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 (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** (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 (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** (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 (see below), and performance testing. The goal is to facilitate review by outlining FDA’s latest expectations for software documentation (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 (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 (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, August 2025 final).** A PCCP is an **optional mechanism** for planned modifications. FDA’s **final guidance** describes seeking authorization through an appropriate 510(k), De Novo or PMA submission. An authorized plan allows specified changes implemented consistently with that plan without an additional submission for each change. Significant changes outside the plan or its implementation protocol must be evaluated under usual modification rules and may require a new submission.
- **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*” (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 (www.fda.gov) (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 (www.fda.gov) (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 (www.fda.gov).

- **Regulatory Context.** As of early 2025, the FDA had authorized **more than 1,000 AI-enabled medical devices** through existing pathways (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 (www.fda.gov) (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 (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 existing statutory requirements (section 524B for qualifying cyber devices) (www.fda.gov).

Binding duties and nonbinding recommendations. **Section 524B** was enacted on December 29, 2022 and applies to qualifying submissions from March 29, 2023. A cyber device includes sponsor-validated, installed or authorized software, can connect to the internet, and has technological characteristics that could be vulnerable to cybersecurity threats. Relevant pathways include 510(k), PMA, PDP, De Novo and HDE, including applicable supplements.

Sponsors must submit a postmarket vulnerability-management plan, including coordinated disclosure; establish security processes and procedures and provide updates and patches; and provide an SBOM covering commercial, open-source and off-the-shelf components. The **guidance** recommends documentation and design practices to help meet these obligations; its recommendations are distinct from the statutory duties.

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 (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

A [2023 research study](#) identified 581 SaMD products using keyword filtering and review of device descriptions from records spanning January 2012 through February 2022. This is a defined research cohort, not an exhaustive FDA census.

FDA's [AI-enabled device list](#) and [sensor-based digital health device list](#) are explicitly non-comprehensive. Their entries do not establish unique-device totals or manufacturer market share. Counts from different lists should not be combined into a market estimate without checking coverage and overlap.

Case Studies and Real-World Examples

Concrete examples help illustrate how FDA policies apply:

- **Apple ECG App (De Novo classification).** FDA's [DEN180044 order](#) classified the original ECG app into Class II in September 2018. The [De Novo summary](#) describes a user-initiated 30-second single-channel ECG recording with AFib/sinus-rhythm classification. Its output is informational, does not replace diagnosis or treatment, and must not prompt clinical action without a qualified healthcare professional. It is not intended for people under 22 and is not recommended for users with other known arrhythmias. This ECG recording function should not be described as continuous monitoring.
- **Dexcom G7 Glucose Monitoring.** FDA's [K213919 decision summary](#) describes the G7 as a continuous glucose monitoring system indicated for diabetes management in people aged two and older.

- **reSET and reSET-O Digital Therapeutics.** FDA's [2017 De Novo order for reSET](#) classified it into Class II as a prescription adjunct for adults enrolled in clinician-supervised outpatient treatment, alongside contingency management. Its substance-use indications exclude patients on opioid replacement therapy, those abusing alcohol solely and those abusing opioids as their primary substance. The separate [reSET-O 510\(k\) record, K173681](#) concerns increasing retention in adult clinician-supervised outpatient OUD treatment as an adjunct to transmucosal buprenorphine and contingency management. These authorizations do not establish company-level FDA endorsement or substitution for the associated treatment programs.
- **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 (www.fda.gov). For example, the FDA-funded “MEND-HD” study is exploring gait and movement measures in Huntington’s disease using wearable sensors (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 (www.nixonpeabody.com) (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 (www.mondaq.com) (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 (www.faegredrinker.com) (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 (www.faegredrinker.com) (www.mondaq.com).

A parallel perspective comes from institutional voices. FDA’s own guidance 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 (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

The wellness and CDS criteria are consolidated above. The following subsections address development, AI changes and data governance. FDA guidance recommendations are nonbinding unless they cite specific statutory or regulatory requirements ([FDA CDS guidance](#)).

Software Development and Documentation Requirements

- **Quality Management and Design/Development:** Since February 2, 2026, FDA's [QMSR](#) under 21 CFR Part 820 incorporates ISO 13485:2016. Section 820.10 requires an applicable quality management system. Under [section 820.10\(c\)](#), ISO 13485 clause 7.3 and its subclauses apply to Class II and III devices and specified Class I devices, including those automated with computer software. Former QSR section 820.30 is a legacy citation; sections 820.20–820.30 are now reserved. QMSR applies to finished-device manufacturers intending commercial distribution, subject to applicable exemptions. CGMP-exempt devices still require complaint files and applicable records under section 820.35; IDE devices remain subject to applicable design-and-development requirements. Review the product's classification and exemption provisions before determining its obligations.
- **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 (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 (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 (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 (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 implementation of the **optional mechanism** described above, consult the guidance (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. When seeking authorization, the sponsor should provide evidence supporting continued safety and effectiveness. See the earlier discussion of **specified changes implemented consistently with the authorized plan** and changes outside its scope or protocol.
- **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 (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 (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 (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. The **Pre-Cert pilot concluded in September 2022**; FDA said a new regulatory paradigm would require legislative change. The pilot should not be presented as an available authorization route.

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 (www.fda.gov)

(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:** FDA guidance (Dec 2023) on remote data acquisition emphasizes that digital endpoints must be validated for clinical trials (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.
- **Privacy and Device Security:** The [HIPAA Rules](#) apply to covered entities and business associates. A developer's obligations depend on that status and its relationship to a covered entity; handling or transmitting health information alone does not establish HIPAA applicability. Separately, FDA addresses cybersecurity affecting device safety and effectiveness, including [section 524B obligations for qualifying cyber devices](#). HHS privacy oversight and FDA device-security oversight are distinct.
- **Interoperability Standards:** Evaluate the data representations needed by the intended clinical workflow, including applicable FHIR and DICOM implementations. Nonbinding cybersecurity guidance recommendations must be distinguished from the existing cyber-device statutory duties described above.

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 (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.

Established Programs and Policy Research: The [Pre-Cert pilot](#) completed in September 2022. FDA concluded that a new software regulatory paradigm would require legislative change; it should not be described as a revived or available precertification pathway. Existing [section 524B cybersecurity duties](#) were enacted through the Consolidated Appropriations Act, 2023, signed December 29, 2022. They are current law, rather than a prospective "Protecting and Transforming Cyber Health Act."

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: Monitor FDA's [digital-health guidance index](#) for issued documents and their final or draft status. Predictions about future AI, interoperability or sensor-endpoint policies should not be treated as announced dates or current compliance requirements.

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 (www.fda.gov) (www.faegredrinker.com)). Assess applicable pathways, exemptions and enforcement-discretion policies before determining whether a submission is required ([FDA CDS guidance](#)).
- **Follow Relevant Guidance:** Identify all applicable FDA guidances early. For instance, a mobile app company should read the 2022 MMA guidance (www.fda.gov), the premarket software guidance (www.fda.gov), and cybersecurity guidance (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. Early engagement (meeting with FDA via pre-sub meetings) is strongly advised, especially for novel AI products (www.fda.gov) (www.fda.gov). Clarify how FDA intends to regulate your product. If possible, seek feedback on your risk analysis and planned documentation.
- **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 relying on enforcement discretion (wellness/CDS), document why that policy applies; distinguish this from a statutory exclusion. 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. (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 marketing authorization. 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 (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 (www.fda.gov) (www.mondaq.com), while addressing lifecycle planning for higher-risk software (particularly AI/ML) and existing security obligations for qualifying cyber devices (www.fda.gov) (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 (www.fda.gov) (www.faegredrinker.com).
- **Recent guidance emphasizes innovation:** The January 2026 updates on wellness and CDS, along with the AI lifecycle draft and final cybersecurity guidance, 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 (www.nixonpeabody.com) (www.fda.gov).
- **Documentation and quality are paramount:** Determine applicable quality-management obligations and exemptions under the QMSR, as described above. Guidance documents clearly enumerate what needs to be in submissions (from software validation to secure design) (www.fda.gov) (www.fda.gov). Use guidance to plan documentation while distinguishing recommendations from binding law ([FDA's explanation](#)).

- **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 (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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Source links

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