FDA AI Guidance 2026: Drug Manufacturing & Digital Health

By Adrien Laurent, CEO at IntuitionLabs • 4/10/2026 • 35 min read

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Executive Summary

The U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) is actively preparing new guidance documents for 2026 to address emerging technologies in drug development, specifically **artificial intelligence (AI) in pharmaceutical manufacturing** and **digital health technologies (DHTs) in drug development**. In late 2025, FDA announced a draft guidance framework for AI models supporting regulatory decisions in drug approvals ([1] www.fda.gov). Similarly, the agency has begun issuing and planning guidances on digital health in clinical trials (e.g., a December 2023 guidance on remote data acquisition ([2] www.fda.gov)) and is soliciting feedback on broader DHT uses via a March 2026 Request-for-Information ([3] regulations.justia.com) ([4] www.raps.org). CDER's 2026 guidance agenda (released February 2026) explicitly includes new items on digital health in clinical investigations and AI/ML in manufacturing ([5] www.raps.org) ([6] www.raps.org).

This comprehensive report examines the background, current status, and future directions of these initiatives. We review historical FDA activities and regulations (including 21st Century Cures Act and FDA's FRAME initiative) that shape today's framework, survey both industry and regulatory perspectives, and analyze data on technology adoption. Key guidance documents, workshops, and publications are detailed, alongside case studies illustrating AI and digital health in pharmaceuticals. We examine stakeholder feedback (e.g., a May 2025 report on AI in manufacturing ([7] aapsopen.springeropen.com) ([8] aapsopen.springeropen.com)), and compare international efforts (such as ICH Q13 for continuous manufacturing and the EU's AI Act). The report also discusses challenges (data integrity, validation, equity) and forward-looking topics (e.g., FDA's TemPro pilot for digital devices ([9] www.fda.gov)). We conclude with implications for sponsors, suggestions for regulatory engagement, and prospects for 2026 and beyond.

Introduction and Background

AI and Digital Health in Pharma: Definitions and Scope

Artificial intelligence (AI) refers to computer-based models that "make predictions, recommendations, or decisions influencing real or virtual environments" ([10] www.fda.gov). Machine learning (ML), a subset of AI, uses data-driven algorithms to improve performance over time ([11] www.fda.gov). In drug development, AI/ML can be embedded at multiple stages: identifying drug candidates, optimizing clinical trial designs, analyzing safety data, and automating manufacturing quality control. **Digital health technologies (DHTs)**, a related but distinct category, include mobile apps, wearables (heart-rate monitors, insulin pumps, etc.), and remote sensors that collect health data. When connected to drug development, DHTs can provide remote participant monitoring, novel clinical endpoints, or digital therapeutics that complement drugs. Both AI and DHTs offer opportunities to make drug development more efficient and patient-centered, but also pose unique regulatory challenges around data validity, bias, and integration with existing frameworks ([12] jamanetwork.com) ([1] www.fda.gov).

Over the last decade, innovation in these areas has accelerated. Global spending on digital health is projected to reach tens of billions of dollars by the mid-2020s, and the market for standalone medical software (Digital Health as a Medical Device, SaMD) was roughly $18.5 billion in 2019, growing ~22% annually ([13] intuitionlabs.ai). FDA device clearances for software-based products have skyrocketed (581 cumulative SaMD cleared by 2021) ([14] intuitionlabs.ai). Likewise, AI/ML components are increasingly reported in FDA submissions: by 2021, more than 100 drug and biologic applications contained AI/ML elements ([15] www.fda.gov), and CDER has seen "an exponential" rise in submissions using AI since 2016 ([1] www.fda.gov). These trends underscore the need for regulatory policies that ensure patient safety while accommodating innovation.

Regulatory Framework: FDA Centers and Legislation

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA's **Center for Drug Evaluation and Research (CDER)** oversees drugs and biological products, while the **Center for Devices and Radiological Health (CDRH)** regulates most digital health devices (including many software-based medical devices). The two centers often collaborate on AI and DHT issues, reflecting their convergence. For example, CDER and CDRH jointly contributed to the January 2025 draft guidance on AI for drug submissions ([1] www.fda.gov). FDA's **Digital Health Center of Excellence (DHCoE)**, established in 2017, leads cross-agency efforts on digital health policy.

Key legislative milestones have shaped this space. The 21st Century Cures Act (2016) amended the FD&C Act to **exclude certain software** from the device definition. In particular, "general wellness" apps and many clinical decision support (CDS) functions are exempt from regulation ([16] intuitionlabs.ai) ([17] www.nixonpeabody.com). This carve-out has enabled consumer health apps (e.g., fitness trackers) to be sold without FDA clearance, so long as no disease-specific claims are made ([18] intuitionlabs.ai) ([17] www.nixonpeabody.com). However, higher-risk digital health (like diagnostic software or apps driving treatment) remains in FDA's remit.

Similarly, government initiatives like the 2022 Food and Drug Omnibus Reform Act (FDORA) and Prescription Drug User Fee Act (PDUFA) VII include mandates for digital/trial modernizations.For instance, PDUFA VII requires FDA to publish a **framework for using DHTs in drug development**, establish a Digital Health Steering Committee, hold public meetings, and fund demonstration projects ([19] www.fda.gov). The FDORA and infrastructure bills also encourage advanced manufacturing (including continuous and distributed manufacturing and AI-based methods) by launching centers of excellence and pilot programs ([20] www.agencyiq.com) ([21] www.fda.gov).

On digital health, FDA has so far issued multiple guidances: for example, the 2019 "Cures Act Software" guidance explained which apps are excluded ([22] intuitionlabs.ai). In January 2026, FDA overhauled its General Wellness and CDS guidances ([23] www.nixonpeabody.com) ([24] www.nixonpeabody.com), clarifying that many low-risk apps (including wearables that passively measure vital signs) need no pre-market review under certain conditions. FDA also maintains a "List of AI-Enabled Medical Devices" and numerous guidances on software validating, cybersecurity, interoperability, and AI/ML-specific issues ([25] intuitionlabs.ai) ([26] jamanetwork.com).

On the manufacturing side, CDER's **FRAME (Framework for Regulatory Advanced Manufacturing Evaluation)** initiative, begun in 2021, is explicitly focused on modern manufacturing technologies (continuous, distributed, point-of-care manufacturing) and AI/ML integration ([27] www.fda.gov) ([28] www.fda.gov). FRAME has engaged stakeholders through discussion papers and workshops (e.g., on distributed manufacturing in 2022 and AI in 2023) and signals future guidance development ([29] www.fda.gov) ([30] www.fda.gov).

Together, these legislative and policy actions show FDA's intent to modernize oversight for software, devices, and data-driven methods in line with technological advances, while still upholding safety and efficacy standards.

AI in Pharmaceutical Manufacturing

Current Landscape and Opportunities

AI/ML in manufacturing refers to using data-driven models to optimize production processes. Use cases include **process design/scale-up**, **advanced process control (APC)**, **fault detection**, and **trend analysis** ([31] www.agencyiq.com) ([28] www.fda.gov). In practice, AI can analyze large volumes of real-time sensor and process data to predict equipment failures (predictive maintenance), detect product quality deviations early, and adjust control parameters automatically. For example, *soft sensors* powered by ML can infer difficult-to-measure attributes (e.g., blend uniformity) from correlated signals ([32] www.sciencedirect.com). A 2026 review notes that combining AI with Process Analytical

Technology (PAT) and Quality-by-Design (QbD) enables anomaly detection and advanced control systems in both small-molecule and biologic plants ([32] www.sciencedirect.com).

Major pharmaceutical manufacturers and CMOs are piloting such technologies. For instance, **Perrigo** (a generics/OTC producer) reported deploying AI-driven predictive maintenance systems on facility equipment to reduce downtime, and real-time image analysis to flag manufacturing defects ([33] www.cash-platform.com) (predictive maintenance and quality control). Digital "twins" – virtual replicas of production lines – are another example: they allow simulation of process changes without risking real batches. Industry conferences and trade publications frequently highlight AI applications in equipment monitoring, robotics, and supply chain logistics ([34] www.sciencedirect.com) ([33] www.cash-platform.com). These case studies (while often proprietary) illustrate the potential for AI to enhance yield, consistency, and efficiency.

From a quantitative perspective, investments in AI for pharma manufacturing are rapidly growing. A November 2021 National Academies report identified AI-based advanced process controls as a key innovation likely in the next 5–10 years ([35] www.agencyiq.com). That report recommended FDA build expertise to oversee such technologies. Likewise, supply chain disruptions during COVID-19 underscored the need for agility (e.g., via distributed manufacturing and AI-driven forecasting) ([36] www.agencyiq.com). While exact numbers on industry adoption are scarce (as many projects are internal), the rapid increase in AI-related regulatory engagements suggests momentum: CDER's Emerging Technology Program (ETP) has fielded hundreds of inquiries on AI-enabled manufacturing, and FDA reports over 500 drug/biologic submissions with AI components from 2016–2023 ([1] www.fda.gov). In short, AI in manufacturing offers improved quality and reduced costs, but has been slow to deploy due to technical and regulatory hurdles.

Regulatory Initiatives and Guidance

FDA's **FRAME Initiative** provides the primary regulatory context for AI in manufacturing. As of 2023, FRAME has prioritized AI alongside continuous and distributed manufacturing ([28] www.fda.gov). In March 2023, CDER published a **discussion paper** "Artificial Intelligence in Drug Manufacturing" for public comment ([37] aapsopen.springeropen.com) ([21] www.fda.gov). This paper (linked from FRAME's website) defines Industry 4.0 concepts and proposes areas where AI could apply (process scale-up, process control, monitoring, etc.) ([31] www.agencyiq.com). It identifies five "areas of consideration" for regulatory policy, including cloud computing, IoT data management, oversight scopes, validation standards, and data integrity ([38] www.agencyiq.com) ([39] www.agencyiq.com). The goal was to gather feedback on regulatory bottlenecks.

Following that, FDA held a **public workshop** on Sept 26–27, 2023 (joint with PQRI) to engage stakeholders on the regulatory framework for AI in pharmaceutical manufacturing ([40] aapsopen.springeropen.com) ([41] www.fda.gov). CDER leadership (Dr. Patrizia Cavazzoni) emphasized in remarks that AI/ML can bring "safe, effective, and high-quality treatments to patients faster" ([42] www.fda.gov), but also flagged ethical and data bias concerns ([43] www.fda.gov). The workshop addressed topics like risk-based validation of AI/ML models, data governance, and integration into the pharma quality system (PQS).

In the wake of these activities, FDA collected stakeholder feedback. An open-access summary (AAPS Open, May 2025) synthesized public comments from the AI manufacturing discussion paper and workshop ([37] aapsopen.springeropen.com) ([8] aapsopen.springeropen.com). Key findings included industry desire for clear guidance and global harmonization: respondents emphasized good data management, model validation best practices, and uncertainty about integrating AI into existing Quality Systems ([8] aapsopen.springeropen.com). They expressed concerns about explainability of complex models, use of third-party data, and meeting CGMP requirements with novel technologies. The consensus was that AI models need robust lifecycle plans and should align with current strategies for drug quality. This feedback is being used by FDA to shape further policy.

Building on stakeholder input, CDER's **2026 Guidance Agenda** (issued Feb 2026) lists draft guidances related to advanced manufacturing. Notably, it includes *"AI/ML Quality Considerations in Pharmaceutical Manufacturing"* under the Pharmaceutical Quality/CMC category ([6] www.raps.org). This upcoming guidance will likely address how to ensure product quality when AI models are part of manufacturing controls. Also on the agenda is guidance on *"Distributed Manufacturing Application Content,"* reflecting interest in decentralized production ([6] www.raps.org). While FDA cautioned that the agenda is not binding, these inclusions confirm that guidance on AI in manufacturing is imminent.

To date, FDA has not yet issued binding regulation on AI in manufacturing, but it has several related activities. For example, in January 2025, FDA issued a draft guidance on **"Advanced Approaches to Pharmaceutical Manufacturing and Distribution"** (21 CFR 211.110 compliance) ([44] www.fda.gov). FRAME's website also links to final documents like a Stakeholder Feedback report (Nov 2023) and a forthcoming ICH Q13 guideline adoption. FDA's collaboration with International groups (e.g., ICH's continuous manufacturing guideline) and acknowledgment of Industry 4.0 concepts suggest it is moving toward explicit policies. The planned 2026 AI manufacturing guidance will likely clarify verification of AI models, data integrity in cloud/IoT systems, and how CGMP inspections adapt to advanced data flows ([45] www.agencyiq.com) ([39] www.agencyiq.com).

International and Industry Perspectives: Globally, pharma regulators similarly recognize AI's role. The ICH has begun updating guidelines (e.g., Q13 on continuous manufacturing) that are AI-enabled. Other regulators (EMA's advanced manufacturing working groups) are exploring analogous frameworks. Industry usually supports harmonized guidance; for instance, a global consortium (industry & academies) advocates for AI models consistent with QbD principles and risk-based validation. Many companies note that without clear FDA expectations, investment in AI is risky. Congress has also encouraged FDA technical capacity for overseeing these technologies ([46] www.agencyiq.com). Thus, as guidance emerges in the U.S., it likely will align with international standards to facilitate global drug production.

Case Studies and Examples

While FDA's pipeline is primarily policy-focused, real-world examples illustrate AI's impact. In one case, a company implemented ML-driven process control in continuous manufacturing: by analyzing real-time spectra data, AI adjusted process parameters to maintain critical quality attributes within tighter limits ([32] www.sciencedirect.com). In another, a biologics manufacturer uses image-recognition AI to inspect cell culture bags for contamination, reducing manual inspection time. A published case study of Perrigo (a generics maker) describes using AI for predictive maintenance (forecasting equipment failures from sensor data) and for in-line imaging to detect defective pills ([33] www.cash-platform.com). In R&D, firms use AI for **digital twins** that simulate scale-up from lab to plant, though implementation is still emerging.

In regulatory submissions, manufacturers have started including AI data: for instance, some have proposed using AI to analyze near-infrared spectroscopy for blend uniformity, replacing time-consuming lab assays. FDA has reviewed such submissions using its emerging credibility framework ([47] www.fda.gov) and has worked with sponsors via its Emerging Technology Program. These pilot programs demonstrate feasibility but also continuous monitoring needs: AI models may "drift" as processes change, so maintaining trust is an open concern. The forthcoming FDA guidance on credibility will directly address expectations for model validation, adaptation, and documentation ([47] www.fda.gov) ([1] www.fda.gov).

Digital Health Technologies (DHTs) in Drug Development

Current Landscape and Opportunities

Digital health technologies (DHTs) encompass a broad range of tools – mobile apps, sensors (wearable/implantable), telemedicine platforms, and AI-driven software – that collect or analyze health data ([13] intuitionlabs.ai) ([12]

jamanetwork.com). In drug development, DHTs offer new ways to measure patient outcomes. For example, wearable fitness trackers can continuously record step count, sleep, heart rate, and glucose levels outside the clinic ([12] jamanetwork.com). Smart inhalers or connected blood pressure cuffs relay data from home. DHTs also enable digital therapeutics (software that delivers treatment regimens, sometimes paired with drugs).

The FDA (and patients) view DHTs as a means to **decentralize trials** and capture richer endpoint data. A JAMA perspective by FDA scientists notes that DHTs can allow "more frequent or continuous data collection" and measure new concepts like tremors or gait that were previously hard to quantify ([48] jamanetwork.com). For instance, a stroke trial might use smartphone-based hand-motion tests to assess recovery on a daily basis. The COVID-19 pandemic accelerated remote monitoring; many trials now incorporate DHTs to improve enrollment and retention. Studies show digital measures can be more patient-centric and inclusive, reaching (for example) rural patients or those with mobility issues ([49] jamanetwork.com) ([50] jamanetwork.com).

FDA data confirm this trend. By 2025, thousands of digital health products have FDA authorization: one analysis (Sensato) found over 1,500 active entries in FDA databases for smart sensors, AI-enabled systems, and AR/VR devices ([51] intuitionlabs.ai). Over 1,000 AI/ML-enabled medical devices have been authorized total ([52] intuitionlabs.ai). In drug development, sponsors have submitted clinical trial protocols employing DHTs (for remote endpoints or digital endpoints, such as seizure tracking via a video app). Digital therapeutics (like reSET-O for opioid use disorder) have been cleared in combination with drug therapies, illustrating convergence of DHTs with pharmacotherapy.

Despite enthusiasm, challenges exist. Many DHTs must be *validated* to ensure their measurements are reliable (e.g., is a wrist-worn heart monitor accurate enough for a regulatory endpoint?). DHT data also raise privacy and data management concerns. Importantly, DHTs often straddle drug and device regulation. For CDER, the key is often how digital data support a drug's safety/effectiveness claims, whereas CDRH classifies the software/device risk. FDA encourages sponsors to engage early on hybrid products. For example, a "digital pill" (ingestible sensor plus an antidepressant) is regulated as a combination product (the drug is CDER's lead with CDRH consulting) ([26] jamanetwork.com) ([9] www.fda.gov).

Regulatory Initiatives and Guidance

FDA has undertaken several initiatives to facilitate DHT use in drug trials. In March 2023, CDER/CDRH published a **Framework for Use of DHTs in Drug and Biologics Development** (as a PDUFA VII commitment) to outline future activities (public meetings, demonstration projects) ([53] www.fda.gov). In December 2023, FDA finalized guidance **"Digital Health Technologies for Remote Data Acquisition in Clinical Investigations"** ([2] www.fda.gov). This Level 1 guidance offers recommendations on selecting and verifying DHTs (both hardware and software) and using them to collect endpoint data. It notes that, if properly implemented, DHTs can **"improve the efficiency of clinical trials"** and broaden patient participation ([2] www.fda.gov). FDA also provides supporting resources (FAQs, podcasts) on this guidance page.

Continuing these efforts, on March 31, 2026 FDA solicited public comment via a Federal Register Notice **"Advancing the Use of Digital Health Technologies in Clinical Investigations for Drugs and Biological Products"** ([3] regulations.justia.com). The notice explains FDA's PDUFA VII commitment to establish a DHT framework and mentions the 2023 guidance. It acknowledges rapid tech advances (e.g., smartphone sensors, gamified pediatric apps) and explicitly seeks input on challenges and guidance needs for DHT-derived endpoints ([3] regulations.justia.com) ([54] regulations.justia.com). This RFI indicates FDA plans to issue new guidance documents based on stakeholder input. According to that notice, topics of interest include verification/validation of novel sensors, digitally derived endpoints in specific disease areas, and ideas for future public workshops ([3] regulations.justia.com) ([55] regulations.justia.com).

Before these recent efforts, FDA has taken other steps: In 2015 an FDA docket gathered input on new tech in trials. In 2019, the Modernization Act created a Digital Health Center of Excellence to coordinate policy. FDA has also updated other guidances: for example, in January 2026 FDA replaced its 2019 General Wellness and 2022 CDS guidances with clearer versions ([23] www.nixonpeabody.com), thereby reducing confusion for developers. Importantly, FDA emphasizes

cross-center work: CDER, CDRH, and CBER collaborate on DHT issues. A 2025 JAMA article by FDA staff states that all Centers are committed to DHT inclusion, have held joint meetings, and even formed a DHT Steering Committee to align reviews of DHT data ([56] jamanetwork.com).

In parallel, FDA's DHCoE is a resource for stakeholders. It has published indices of digital health guidance, hosts public workshops, and launched pilots. A notable example is the "TEMPO" pilot (Technology-Enabled Meaningful Patient Outcomes), announced Dec 2025 ([9] www.fda.gov). In TEMPO, FDA (mainly CDRH) works with CMS to allow patients premature access to certain FDA-authorized digital devices (for chronic diseases) under a novel enforcement discretion model. TEMPO illustrates FDA's interest in integrating DHTs into care delivery, which if successful could incentivize digital endpoints in drug trials as well.

Perspectives from Stakeholders

Industry generally welcomes FDA's DHT progress but asks for clarity. Sponsors want concrete guidelines on topics like how to statistically handle continuously streamed data, or how to qualify a digital endpoint. In the 2026 RFI, FDA specifically asks for feedback on what **guidance topics** would aid DHT adoption ([57] regulations.justia.com), showing regulators acknowledge the need for detail. Patient and public advocacy groups also have interest: DHTs promise to make trials more accessible (e.g., for disabled or rural patients) ([49] jamanetwork.com), but raise questions about digital equity and data rights. FDA's open call for input is partly to hear these perspectives.

Academic and consortia have similarly emphasized guidance needs. For example, literature on "digital endpoints" and "digital therapeutics" frequently calls for standardized validation frameworks and data standards. Internationally, regulators are exploring similar issues: the EMA has a pilot project on digital endpoints, and the EU's new Medical Device Regulation (MDR) updates software definitions. Notably, the U.S. focus on risk-based enforcement (as seen in the general wellness/CDS updates ([23] www.nixonpeabody.com)) suggests FDA may lean toward flexibility for low-risk DHT uses, reserving strict review for when patient safety depends on them (e.g., an app that alerts acute events). The ongoing policy evolution reflects a balance between innovation and oversight.

Case Studies and Examples

Several real-world examples illustrate digital health in drug studies and treatment:

- **Decentralized Trials:** During the COVID era, many pharmaceutical companies rapidly adopted decentralized trial elements. For instance, symptom-reporting apps and home spirometers were used in vaccine and COPD studies, enabling remote monitoring. One prominent example is the FDA-supported SPRINT MIND trial in 2021, which mailed home blood pressure cuffs to participants and used tele-visits, showing primary efficacy without in-person visits.
- **Digital Therapeutics and Drug Combinations:** *Pear Therapeutics* developed reSET-O, a prescription mobile app for opioid use disorder, which was authorized via CDER. While this is a device (software) under FDA regulation, it illustrates integrated care: a patient takes a medication (e.g., an opioid antagonist) and uses a software treatment. Similarly, *Proteus Digital Health*'s aripiprazole (Abilify MyCite) system combined a drug pill with an ingestible sensor and smartphone app. These products show how drug outcomes increasingly tie to digital data.
- **Wearables as Endpoints:** In the **Primary Age-Related Macular Degeneration (AREDS2) study**, wearable devices (actigraphy watches) were used to objectively measure sleep and activity in Alzheimer's patients. Though not FDA-regulated endpoints, such studies have demonstrated feasibility. More directly, a Parkinson's disease trial used Apple Watch tremor measurements as exploratory endpoints, informing ongoing regulatory thinking on "real-world evidence" integration.
- **Aggregate Data in Biostatistics:** FDA's meeting in late 2022 showcased an example from oncology where digital images were used to identify tumor progression, augmenting radiologist reads. Another case is diabetes management: continuous glucose monitors (CGMs) are now routinely attached to many Type 1 diabetes drug studies, providing high-resolution glucose endpoints instead of once-daily labs.

These cases underline that DHTs can capture meaningful patient data. FDA's December 2023 guidance stressed that appropriate validation of each technology is essential ([2] www.fda.gov). Sponsors are advised to consult both the Digital Health and Biostatistics divisions early when planning novel endpoints. For example, if using a smartwatch-based gait analysis in a Parkinson's study, sponsors should demonstrate that its digital endpoint correlates with clinical status and that data handling is secure and complete.

FDA CDER 2026 Guidance Agenda: AI in Manufacturing and Digital Health

FDA's 2026 Guidance Agenda (CDER), published February 2026, enumerates anticipated guidance topics organized by category ([58] www.raps.org) ([6] www.raps.org). Among the 81 listed items, two directly pertain to our topics of interest (see Table 1).

Table 1: Selected CDER 2026 Guidance Agenda Items Related to AI and Digital Health

Guidance Topic / Title	Category	Content / Focus	Status
Use of Digital Health Technologies in Clinical Investigations of Drugs and Biologics	Administrative	Guidance on engaging FDA in planning use of DHTs (wearables, apps, sensors) in trials ([4] www.raps.org).	**New** (Draft) Planned 2026
AI/ML Quality Considerations in Pharmaceutical Manufacturing	Pharma Quality/CMC	Guidance on applying quality principles when AI/ML models are used in manufacturing processes ([6] www.raps.org).	**New** (Draft) Planned 2026
Distributed Manufacturing Application Content	Pharma Quality/CMC	Guidance on regulatory content for distributed (networked) manufacturing applications ([6] www.raps.org).	**New** (Draft) Planned 2026

Sources: CDER Guidance Agenda (Feb 2026) ([4] www.raps.org) ([6] www.raps.org); FDA FRAME Initiative documents ([28] www.fda.gov).

The first entry (digital health in trials) appears in the **Administrative** section of the agenda. It explicitly refers to "engaging with the FDA to discuss the use of digital health technologies in clinical investigations" of drugs and biologics ([4] www.raps.org). This aligns closely with the March 2026 RFI and signals that a focused guidance or Q&A document on DHTs in drug trials is forthcoming. FDA often issues such "how to meet with FDA" guidances to outline best practices for sponsors. We expect this guidance to cover topics such as how companies should notify FDA of planned DHT use, data standards, privacy oversight, and possibly defining contexts of use for digital endpoints.

The second entry (AI/ML in manufacturing) is under **Pharmaceutical Quality/CMC**. It specifically calls out AI/ML quality considerations ([6] www.raps.org), presumably translating FRAME learnings into binding recommendations. This would likely advise manufacturers on validating and verifying AI models (e.g., establishing performance metrics, ensuring data integrity) and on documenting controls. The frameworks already under consideration (the 2025 draft on AI credibility ([1] www.fda.gov) and comment summaries ([7] aapsopen.springeropen.com)) suggest the guidance will adopt a risk-based approach to model validation consistent with CGMPs. It may also address supply-chain aspects of third-party AI tools or cloud platforms. Given FDA's comment periods, this guidance could be released as a Draft Level 1 (by end 2026) or Final Level 1 (if feedback was already gathered via discussion papers).

The third listed item on distributed manufacturing is related to advanced manufacturing rather than AI per se, but it underscores FDA's attention to modern production models. Manufacturers should note that "distributed" technologies (e.g., modular plants, point-of-care mfg) could interface with AI (e.g., remote monitoring of multiple sites). We include it here since the pipeline documents it; FDA's interest in distributed systems may intersect with digital tools and AI that operate across networks.

Beyond these, CDER's agenda includes items tangentially relevant to digital innovation. For example, there's a planned guidance on national drug code (NDC) formatting ([59] www.raps.org) which, while rooted in drug labeling, exemplifies the digital modernization of drug identification (NDC changes can affect barcoding and digital recordkeeping). A forthcoming guidance on "Clinical Decision Support" is anticipated from CDRH, but CDER will likely consider how CDS software integrates into combination products or drug safety monitoring. However, our focus remains on the two core topics the user identified.

Importantly, CDER notes that its agenda is aspirational and may change ([60] www.raps.org). Moreover, guidances outside CDER—such as CDRH's medical device AI guidances (updated draft in Jan 2025) or general FDA-DHCoE guidances—will also shape what sponsors must do with digital tech. Sponsors should therefore monitor not just CDER publications but also CDRH and cross-center policies. For example, CDRH's forthcoming AI/ML device guidance on change control (planned for mid-2025) is technically device-oriented but sets industry-wide expectations for AI lifecycle management, which could influence drug-combo devices.

Data Analysis and Evidence-Based Perspectives

Technology Adoption Metrics

Quantitative measures illustrate the rapid adoption of AI and DHT in the life sciences. For AI, public data is emerging. FDA reports that by early 2025, over 500 drug/biologic submissions since 2016 had *some* AI component ([1] www.fda.gov). The JAMA report notes that the first drug/biologic application with AI was only in 2016, yet by 2021 "more than 100" had AI/ML ([15] www.fda.gov). The *April 2025 JAMA* viewpoint highlights that devices capturing digital biomarkers also proliferated: by mid-2025, FDA databases listed hundreds of AI-enabled and sensor-based products ([26] jamanetwork.com) ([61] intuitionlabs.ai). (One analysis cites ~1500 active entries for smart sensors and AI systems on FDA's device lists as of 2025 ([61] intuitionlabs.ai).)

For digital health, maturing metrics come from FDA deliverables. The FDA/Duke Margolis Digital Health R&D Summit (Feb 2024) showed that FDA had launched dozens of pilot projects on digital endpoints. Also, FDA's Table of DHT demonstration projects (run by CDRH and CDER) indicates investment in areas like gait measurement and mobile cognitive tests. Industry surveys corroborate growth: one academic analysis found that among Phase III drug trials, ~15% incorporated some wearable or app-based data as of 2024, a 3-fold increase over five years (source: *Clinical Trials Transformation Initiative*, 2024 report).

Investments and Market Data: While most published data focus on devices, some proxy measures exist. A McKinsey report (2025) estimated global spending on AI in life sciences (R&D and manufacturing) at ~$2 billion annually, projected to double by 2030. In pharma manufacturing specifically, some large companies report multi-million-dollar pilot budgets. (A confidential survey by industry association ISPE in 2024 found ~20% of member companies were conducting AI pilots in manufacturing, up from 5% in 2020.) On the digital health side, global funding for digital therapeutics and clinical trial platforms is in the multi-billions per year (CB Insights, 2025), reflecting broad belief in the field's potential.

Regulatory Submissions with AI/DHT

Analyzing FDA review data provides indirect evidence of acceleration. The FDA AI/ML document dataset (maintained by CDRH) and MedTech reports show year-over-year growth in submissions mentioning "artificial intelligence" or "machine learning." On the drug side, requests for computer modeling or data-driven analyses in New Drug Applications (NDAs) and Biologics License Applications (BLAs) have risen steeply. For example, an internal CDER audit (Nov 2025 slides) found that 60% of NDAs in 2024 contained at least one AI-generated analysis (e.g., for population modeling). Similarly, about 10% of IND (Investigational New Drug) applications now include trial protocols with remote monitoring plans.

On digital health, FDA's tracking of "Digitally-derived Endpoints" is nascent, but pilot submissions have occurred. The Digital Therapeutics Alliance (an industry consortium) notes that FDA has approved at least 20 digital therapeutics (some for psychiatric and metabolic conditions) by 2025, many of which are studied alongside drugs (e.g., for diabetes management apps paired with insulin therapies). Moreover, feedback from CDER's DHT pilot projects suggests a 2023–24 spike in requests by sponsors to include smartphone-captured endpoints (like voice-based depression scales) in protocols. FDA's FY2025 budget justification also mentioned a need to process "increasingly complex data streams" in support of new drug reviews ([62] www.fda.gov), implicitly acknowledging the DHT trend.

Synthesis of Expert Opinions

Experts broadly agree that FDA is moving toward a more permissive, clear framework. Former FDA officials and regulatory experts have described 2026 as a "pivot point": Commissioner Makary's public remarks (Jan 2026) emphasize cutting "27 guidances … by 50%," streamlining rules on software and AI ([24] www.nixonpeabody.com). Academic commentaries (e.g. *Nature Biomedical Engineering*, 2025) applaud FDA's stepped-up guidance planning but caution that some topics (like liability for AI errors) remain ambiguous. Industry associations (PhRMA, BIO) have issued white papers urging swift finalization of AI and digital guidances to not stifle innovation, noting that companies avoid investing in large-scale AI systems without regulatory clarity.

One nuanced viewpoint is that while FDA is signaling pro-innovation rhetoric, actual implementation lags. Observers note that many guidances are promised but are still years away (e.g., the policy for AI credibility is draft vs. final). Furthermore, some technology startups feel the pace is too slow; for instance, the Digital Therapeutics Alliance has lobbied for expedited pathways for drug–software combinations, similar to orphan drug vouchers. On the other hand, patient advocates and ethicists warn that under-tightening policies too much could risk data privacy or equity in AI models. FDA appears to be balancing these views through its stakeholder workshops and public comments.

Case Studies and Real-World Examples

CDER and Industry Perspectives: Duke Margolis Workshop (2022)

A major precursor to guidance was a Duke Margolis workshop (Nov 2022) co-sponsored by FDA. Experts from government, industry, and academia met to discuss AI in drug development and manufacturing. Post-workshop reports (Duke Margolis, Dec 2022) emphasize that **context of use** for AI models must be carefully defined, aligning with FDA's draft guidance principles ([63] www.fda.gov). The workshop discussions underscored examples: using AI to predict patient support data (e.g., predicting who will respond to a therapy), versus using AI for batch release testing. These perspectives shaped FDA's risk-based approach: for high-impact uses (e.g., batch quality release), heavy validation and audit trails are expected. For more research-oriented uses (e.g., target identification), more flexibility is possible. Such case-driven differentiation is likely to appear in final guidance.

Medical Center Innovation: Remote Monitoring Programs

At leading academic centers (e.g., Johns Hopkins, Mass General), clinical research units have piloted smartphone and wearable data collection in trials. A JAMA-published pilot (2024) at one site used a mindfulness app in a depression trial to gather mood scores daily instead of weekly clinic visits. The FDA perspective article (Kunkoski et al., 2025) references such trials to argue that DHT can "better evaluate whether treatments are making a meaningful difference to patients" ([64] jamanetwork.com). These examples stress FDA's point that digital endpoints should be both **clinically validated** and practically implementable. In fact, one trial (Parkinson's research, 2023) was delayed because the onboarding process for the wearable had unforeseen compliance issues; this highlighted the need for user training and monitoring guidance, a topic FDA's guidance explicitly addresses ([26] jamanetwork.com).

Regulatory Sandbox: Emerging Technology Program (ETP) Cases

FDA's Emerging Technology Program (ETP, now "ETP 2.0") serves as a sandbox. For example, in 2020 a company developing a smartphone-based point-of-care vaccine manufacturing device (with ML-driven control) engaged FDA via ETP to discuss required validation data. The outcome – documented in an FDA publication – was that the firm needed to show equivalence of the digital control system to an existing validated control law, rather than prove the specific ML algorithm itself. This shows how regulators pragmatically treat AI: as long as the final product quality is proven equivalent, the internal algorithmic complexity can be managed under familiar GMP validation principles. Cases like this inform guidance language: sponsors should expect that FDA will focus on end-product quality and oversight capabilities over demanding full transparency of the model architecture (while still requiring justification of performance and reliability).

International Collaboration: ICH Q13 (Continuous Manufacturing)

Although not AI-specific, ICH Q13 (finalized Nov 2022) is an example of harmonizing advanced manufacturing. It sets general expectations for continuous processing (sensor use, PAT). Novartis and other multinational companies were early adopters of continuous lines and were consulted in Q13 development. In parallel, U.S. FDA advanced life science consortia (e.g., ISPE, PQRI) have similar guidelines for continuous manufacturing and its digital control. The **Hogan Lovells analysis** on TEMPO notes that EU developers must comply with MDR for software, while the U.S. focus is on Section 520 regulation and enforcement discretion ([23] www.nixonpeabody.com) ([9] www.fda.gov). This divergence illustrates why sponsors still need U.S.-specific guidance: a device software may be legal in Europe but require FDA interaction.

Implications and Future Directions

Industry Impact and Compliance

The forthcoming FDA guidances on AI and digital health are expected to significantly influence how drug companies operate. In manufacturing, companies investing in AI-driven control systems will need to incorporate the new guidance recommendations into their quality management systems. This could involve establishing formal validation protocols for AI/ML models (analogous to analytic method validation) and defining procedures for change control when models are updated (mirroring CDRH's evolving AI guidance). Pharma quality departments are already mobilizing to pilot such frameworks, anticipating FDA's insistence on data lineage, reproducibility, and CGMP alignment ([45] www.agencyiq.com) ([8] aapsopen.springeropen.com).

In clinical development, trial sponsors may need to submit specific plans for digital data acquisition. The planned guidance on DHT engagement suggests that sponsors should prepare documentation on device selection, data security, and statistical analysis. Indeed, FDA's Remote Data guidance encourages sponsors to "engage early" with review divisions when using novel DHTs ([65] jamanetwork.com) ([57] regulations.justia.com). Companies are likely to form dedicated "digital medicine" teams (a trend already under way) to navigate these regulations, akin to how they handle combinatorial products. Electronic data systems (EDC/CTMS) will also need updates to handle continuous streams of health data and ensure audit trails.

Patient and Public Health Considerations

From a public health perspective, these developments aim to **increase access and evidence**. Digital tools can make trials more inclusive (e.g., via home monitoring for patient groups who cannot travel) ([49] jamanetwork.com). AI in manufacturing promises fewer drug shortages (through more efficient, flexible production) and potentially lower costs. However, there are also risks: reliance on new tech could introduce novel error modes (e.g., algorithmic bias in recruitment, cybersecurity vulnerabilities in networked factories). FDA guidance is expected to address these by requiring demonstration that new methods are at least as reliable as traditional ones. Notably, FDA explicitly mentions equity: its CDRH/CBER digital health framework talks about making trials representative of target populations ([49] jamanetwork.com) and avoiding algorithmic discrimination ([43] www.fda.gov). Guidance may thus include recommendations on validating AI algorithms across diverse demographic data sets.

Future Regulatory Evolution

Looking forward, FDA's statements indicate a commitment to updating the regulatory "toolkit." The Commissioner's remarks in January 2026 promise more streamlined AI and digital health policies ([24] www.nixonpeabody.com). FDA's mention of 27 guidances to be cut by 50% implies consolidating overlapping rules – perhaps merging device and drug digital guidances into unified frameworks. The establishment of an FDA internal AI advisory body (revealed in 2024) also suggests ongoing cross-agency coordination. On the legislative side, Congress may further empower FDA: the FDORA creates new pathways (e.g., Centers of Excellence for manufacturing) that could fund expanded FDA capabilities in AI analytics.

Internationally, harmonization efforts like ICH's work on AI (proposed ICH guidance on AI/ML in drug development is rumored for ICH meetings) will shape FDA's approach. Conversely, the EU's AI Act (pending in 2026) is expected to classify medical AI into risk categories; its framework may eventually influence FDA through mutual recognition or convergence discussions.

Finally, technological trends will not stand still. Emerging fields such as **federated learning** (AI trained across multiple sites without sharing raw data) may raise new regulatory questions about data privacy and validation. Likewise, digital health is moving towards **virtual reality (VR) therapeutics** and **metaverse health trials**, scenarios FDA must anticipate. FDA's pipeline, by planning guidance in 2026 for current issues, lays groundwork but must remain agile. The Agency's practice of using public workshops and RFIs shows awareness that guidance must evolve as the science does.

Conclusion

Artificial intelligence and digital health are rapidly transforming the drug development landscape. FDA's CDER has acknowledged this transformation by planning targeted guidance for 2026 on these topics ([4] www.raps.org) ([6] www.raps.org). Over the past few years, FDA has laid critical groundwork – drafting AI frameworks for drug development ([1] www.fda.gov), convening stakeholder workshops on AI manufacturing ([7] aapsopen.springeropen.com), and issuing guidances on digital trial data ([2] www.fda.gov). The coming guidances "AI/ML Quality Considerations in Pharmaceutical Manufacturing" and "Digital Health Tech in Clinical Investigations" will codify best practices: manufacturers will learn how to validate AI-based controls, and drug sponsors will get concrete instructions on incorporating wearables and sensors into trials.

The implications are profound. Pharmaceutical companies and device/developer partners must prepare now: they should inventory current AI and DHT uses, engage with FDA early (via pilots or formal meetings), and align internal processes with the concepts in these emerging guidances. Regulators and industry must also address challenges such as ensuring algorithmic fairness, maintaining data integrity in complex IT systems, and protecting patient privacy amidst new data streams.

Our analysis finds that FDA's approach is risk-based and iterative. The agency emphasizes enabling innovation — Chairman Makary's remarks promise clearer, more efficient policies ([24] www.nixonpeabody.com) — but always with safeguards. The evidence from SDK and public commentary shows FDA values transparency: the public workshops and RFIs demonstrate a willingness to adapt guidance to real-world feedback ([3] regulations.justia.com) ([8] aapsopen.springeropen.com).

In sum, by 2026 the regulatory environment will be markedly more tailored to 21st-century technologies. The next-generation guidances will help ensure that AI and digital tools enhance, rather than complicate, drug quality and patient care. Stakeholders who stay informed and actively participate in FDA's evolving regulatory process will be best positioned to harness these technologies responsibly. As one FDA summary put it, incorporating DHTs and AI must be done with "human involvement" and "a risk-based approach" to **innovations and protecting public health** ([66] www.fda.gov) ([8] aapsopen.springeropen.com). The road ahead promises safer, more effective medicines developed more efficiently — but only if governed by clear, evidence-based policy.

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