

News and Perspectives

The US Food and Drug Administration's TEMPO Pilot Signals a New Regulatory Approach for AI-Enabled Medical Devices

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Abstract

As the pace of evolution and nature of AI-based technologies outgrow traditional frameworks for evaluation, regulatory bodies are developing new models to keep up. In this *News and Perspectives* article, JMIR Correspondent Tejas Athni reports on the US Food and Drug Administration's (FDA's) new Technology-Enabled Meaningful Patient Outcomes (TEMPO) pilot for AI-enabled medical devices.

Key Takeaways:

- The US Food and Drug Administration's (FDA's) Technology-Enabled Meaningful Patient Outcomes (TEMPO) pilot creates a new model for regulating AI-enabled medical devices through provisional access and real-world evidence generation.
- TEMPO's first four participants—Dexcom, Cadence, Limbic AI, and SonderMind—span cardiometabolic and behavioral health applications.
- The pilot could inform the FDA's broader approach to regulating increasingly adaptive generative AI in medicine.

The US Food and Drug Administration (FDA) is in the process of piloting a new approach to regulating AI-enabled medical devices. In July 2026, the agency [announced](#) the first participant in its new Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot program—Dexcom—followed by three additional companies in the subsequent month: Cadence, Limbic AI, and SonderMind.

[AI-enabled medical devices](#) use AI to perform or support functions such as diagnosis, monitoring, prediction, or treatment. The FDA has already authorized some 1600 such devices for marketing in the United States, which typically requires stringent premarket review, with evaluations of safety and effectiveness through, for example, clinical trials. As AI evolves, the FDA is also developing methods to identify devices incorporating foundation models, including large language models and multimodal architectures.

TEMPO: Implementation and Testing at Pace

[TEMPO](#)—a voluntary, pilot regulatory framework—provisionally enables certain manufacturers to launch digital health devices for clinical use before obtaining traditional FDA marketing authorization, while the agency evaluates their performance in real-world settings. The program is a key new element of the agency's [Home as a Health Care Hub](#) initiative, which launched in 2024.

TEMPO is designed around an important premise: some digital health technologies may be difficult to evaluate entirely through traditional premarket pathways because their

performance depends on how they are used in real-world clinical environments.

For these technologies, a manufacturer may request that the FDA exercises discretion on the enforcement of certain regulatory [requirements](#) when its device is intended to provide care covered by the Advancing Chronic Care With Effective, Scalable Solutions (ACCESS) model—a Centers for Medicare and Medicaid Services (CMS) payment model that expands technology-enabled care for patients with chronic conditions. Rather than broadly exempting devices from FDA oversight, TEMPO utilizes a risk-based enforcement approach where, depending on potential patient impact, certain requirements might be waived or deferred.

TEMPO is currently limited to four clinical areas—early cardio-kidney-metabolic, cardio-kidney-metabolic, musculoskeletal, and behavioral health—and is not intended for speculative technologies without a functional prototype. Participating manufacturers are expected to eventually seek appropriate authorization, potentially using data generated during the TEMPO pilot alongside additional evidence.

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TEMPO's Impact

Regulatory frameworks have generally struggled to keep up with the rapid pace of generative AI innovation. The traditional evaluation of medical devices assumes that the product's performance and characteristics are sufficiently characterized before widespread clinical deployment. However, this is often not the case with AI-enabled devices, whose performance may vary dynamically across patients and clinical contexts in ways that are difficult to characterize before deployment.

This makes TEMPO a regulatory learning laboratory as much as a pathway for manufacturers. The FDA can observe how AI systems perform outside of controlled environments. For manufacturers, the attraction is also substantial. TEMPO may derisk the deployment pipeline of new AI technologies by enabling companies to generate real-world evidence while working toward eventual FDA marketing authorization.

In an August 2026 discussion paper, the FDA described a potential “[competency-based approach](#)” to evaluating AI products, which would assess a device's capabilities through benchmarking and clinical confirmation, rather than attempting to evaluate every possible use case before deployment. TEMPO could serve as an early sandbox for the FDA's evolving approach to AI regulation, with early real-world deployment and competency-based evaluation informing one another.

The First Four TEMPO Participants

Dexcom: Continuous Glucose Monitoring

[Dexcom](#), which was founded in 1999 in the United States, is a publicly traded medical device company and global leader in glucose biosensing, generating approximately US \$4.7 billion in [revenue](#) in 2025 and building its business around continuous glucose monitoring technology. Its Glucose Health Program combines real-time glucose data with AI-driven insights to support clinical decision-making and behavioral modification. The company aims to support screening for prediabetes and type 2 diabetes while helping patients improve their glycemic control. Under TEMPO, Dexcom will collect, monitor, and analyze real-world data related to these uses.

Cadence: Hypertension Management

[Cadence](#), which was founded in 2020, is a privately held US-based company focused on technology-enabled chronic disease management. Its HypertensionOS platform is designed to help clinicians manage and adjust medications for adults with stage 2 hypertension. The platform uses AI to continuously monitor blood pressure readings and recommend medication titrations. The Cadence platform is designed to automate routine and protocol-driven care while escalating complex cases to physicians.

Limbic AI: Cognitive Behavioral Therapy

[Limbic AI](#), which was founded in 2020, is a London-based and privately held digital health company developing AI-enabled tools for mental health care. Supporting more than 650,000 patients, its proprietary “Limbic Layer” is a clinical reasoning architecture that is designed to constrain large language models to ensure safety, with the company reporting 92% diagnostic accuracy. Its TEMPO product—the Unpacked platform—uses an AI voice agent to deliver cognitive behavioral therapy to Medicare patients with significant depression or anxiety. The system is designed to operate under the supervision of licensed clinicians, including psychiatrists, psychologists, and therapists.

SonderMind: Digital Mental Health

[SonderMind](#), which was founded in 2014, is a US-based and privately held mental health company that connects patients with therapists and psychiatrists for both in-person and virtual care. Its TEMPO product is a smartphone app intended for adults (aged 22 years and older) with moderate depression or anxiety, and it is intended to be used alongside therapy or medication. The app is designed to provide a digital support bridge between clinical encounters and at-home symptom management.

Expanding the Pilot

TEMPO participants are entering a period of real-world deployment and evidence generation. The FDA plans to expand the pilot to include up to approximately 10 manufacturers in each of the four clinical areas—roughly 40 participants in total. The agency has indicated that it hopes this cohort will include a broad representation of manufacturers across different sizes, types, and stages of maturity.

As the pilot expands, manufacturers will collect, monitor, analyze, and report real-world performance data, including data relevant to predefined patient outcomes. The FDA may use these data to better understand the benefit-risk profiles of participating devices and to support manufacturers' eventual marketing submissions. The agency plans to engage participants through time-limited “[sprint discussions](#)” focused on specific regulatory or submission-related questions, potentially creating more iterative interactions between manufacturers and regulators.

TEMPO is not a permanent alternative to FDA authorization; rather, the pilot creates a temporary bridge between

development and authorization. The more consequential question is what the FDA learns along the way during this pilot. If real-world evidence can reliably identify safety risks while establishing clinical benefit, then TEMPO could provide a streamlined model for evaluating certain AI-enabled technologies. Conversely, if important problems and perils emerge only after widespread clinical use, this suggests the limits of relying on postmarket evidence.

TEMPO represents an important experiment on how the FDA may regulate AI-enabled medical devices, providing regulators an opportunity to learn from technologies in real time. The lessons from TEMPO may shape not only the future of digital health innovation but also broader FDA frameworks in the age of generative AI.

Keywords: artificial intelligence; AI; digital health; medical devices; US Food and Drug Administration; FDA; Technology-Enabled Meaningful Patient Outcomes; TEMPO; health care innovation

Please cite as:

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J Med Internet Res 2026;28:e112391

URL: <https://www.jmir.org/2026/1/e112391>

doi: [10.2196/112391](https://doi.org/10.2196/112391)

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