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Digital Medicine: Clinical Opportunities, Regulatory Changes, and Implementation Barriers

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Abstract. Literature analysis shows that digital medicine can improve clinical decision-making, develop remote medical services, and manage medical data. At the same time, data security, digital inequality, expert training and regulatory issues are preventing its widespread introduction.
Keywords: Digital Medicine; telemedicine; artificial intelligence; clinical decision support (CDS); electronic medical records; wearable devices; FDA; cybersecurity; data privacy; digital disparity; low and middle income countries; health care.

Introduction

Over the past decade, the healthcare system has undergone a profound digital transformation. Telemedicine, electronic medical records, wearable devices, mobile health apps, and artificial intelligence (AI)-based clinical decision support systems (CDS) are no longer theoretical possibilities, but are being implemented in practice. This process is summarized by the concept of "digital medicine" and requires not only technological, but also regulatory, organizational, and social changes. This article analyzes the main possibilities of digital medicine in clinical practice, regulatory changes adopted by the U.S. Food and Drug Administration (FDA) in 2026, and the main obstacles to the practical implementation of these technologies, especially in middle and low-income countries.

1. Clinical opportunities

Digital medicine is significantly enriching clinical practice in a number of areas. First, telemedicine allows patients to access specialist doctors regardless of geographic distance, which alleviates the problem of unequal access to medical services, especially in rural and remote areas. Second, clinical decision support (CDS) software tools provide physicians with additional information and recommendations when making diagnoses, selecting medications, and formulating treatment plans. Third, generative AI-based tools are being used as an aid to physicians in analyzing medical images, such as colonoscopies or evaluating radiological images. Fourth, wearable devices and remote monitoring systems enable continuous monitoring of chronic diseases (diabetes, cardiovascular diseases), creating conditions for timely intervention. Finally, electronic medical records and cross-adaptive (interoperable) data systems allow for rapid exchange of clinical data and population-level analysis, which is instrumental in disease monitoring and health policy formulation.

At the same time, all these possibilities must be carefully evaluated: SI tools can make erroneous conclusions, data bias (bias) can negatively affect clinical outcomes. For this reason, experts emphasize the need to view generative AI tools as an assistant to the doctor, not an "autonomous decision-maker."

2. Regulatory changes

In January 2026, the U.S. Food and Drug Administration (FDA) released updated guidance for clinical decision support software and general health products. These guidelines clarify the scope of FDA regulation of certain low-risk digital health products and software features. However, not all digital medical devices are exempt from pre-approval; regulatory requirements depend on the product's intended use, risk level, and status as a medical device.

In contrast, the FDA's digital health center of Excellence has released a discussion document on the regulation of generative SI — based medical devices and is gathering feedback from stakeholders — device manufacturers, physicians, researchers -. This document discusses post-market monitoring approaches proportional to risk levels for baseline models (foundation models) and agent SI Systems, among others. The FDA issued its final guidance on cybersecurity in medical devices on June 27, 2025. This guideline focuses on assessing and managing cybersecurity risks in the development and marketing of medical devices.

These developments are also resonating globally: many countries, including emerging economies, are aligning their digital health strategies with their goals of strengthening national health systems and expanding universal health coverage (UHC). However, it is emphasized that, along with regulatory easing, there is a need to maintain a clear regulatory framework on data privacy, cybersecurity, and clinical liability issues.

3. Barriers to implementation

The real-world implementation of digital health technologies into clinical practice faces a number of significant barriers. Studies categorize these barriers into organizational, ethical, and human-related groups in low- and middle-income countries (LMICs). Organizational barriers include a lack of infrastructure — reliable internet connectivity, uninterrupted power supply, and modern technical equipment — and limited financial resources. According to the data, the lack of reliable high-speed internet access in rural and remote areas is one of the most important factors hindering the widespread introduction of telemedicine services.

Among the barriers associated with the human factor, problems such as digital discrepancy (digital divide), cultural and linguistic inconsistency, poor user experience and increased workload of medical personnel are distinguished. The lack of adequate training of healthcare workers in using new systems, as well as low patient trust in digital tools, also slows down the pace of implementation. Additionally, concerns about data privacy and security—especially when commercial applications are used to store medical data—further erode trust between patients and physicians.

Another significant obstacle is the lack of interoperability (interoperability) between different systems. Electronic medical records and clinical databases are often designed as separate systems that cannot communicate with each other, which complicates data exchange and leads to fragmentation. Global analyses show that while high-income countries focus on optimizing workflows, low-income countries need to invest in basic infrastructure first — otherwise, digital health inequalities could deepen.

Thus, the successful introduction requires not only a technological solution, but also a suitable regulatory framework, stable financing, a comprehensive approach aimed at training medical personnel and the formation of patient confidence.

Conclusion

Digital medicine is an area with the potential to fundamentally transform the modern healthcare system. Telemedicine, CDS systems, generative artificial intelligence, and wearable devices are

significantly enriching clinical practice and improving the quality of patient care. At the same time, updates to the regulation of digital medical products require a special focus on patient safety and clinical responsibility, while supporting innovation. In the process of implementation, overcoming infrastructure, skills, trust, and interoperability barriers — particularly in developing economies — is crucial to realizing the full potential of digital medicine.

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