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# FDA Publishes Framework for Digital Health Technologies in Clinical Trials

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On March 23, the U.S. Food and Drug Administration (FDA) published a framework to guide regulatory decision-making on the use of digital health technologies (DHT) in clinical drug trials.

DHTs include a wide array of technologies, including software applications that run on a phone, wearables, and environmental sensors, among others. As DHT becomes more sophisticated, the technologies have the potential to play an even larger role in health care, including clinical research.

The framework builds upon FDA's draft guidance, DHT remote acquisition of clinical trial data (December 2022), and is a step toward fulfilling FDA's commitment under the Prescription Drug User Fee Act VII (PDUFA VII) to clarify its stance on DHTs' use in drug, device, and biologics product development. While the framework is not an official guidance document and does not establish policies, it provides important insight into the FDA plans to regulate this area.

## FDA Regulatory Framework

FDA's framework proposes internal and external programs that will address the development and use of DHTs. Internal programs include a DHT steering committee with senior staff from the Center for Biological Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH) (collectively called the "Centers") to help evaluate DHT-based data in drug and device approval applications and device clearances.

- The DHT steering committee will help coordinate different working groups across the Centers and make policy recommendations impacting the use of DHT-based measurements in clinical drug trials.

- If implemented effectively, the DHT steering committee could help harmonize inconsistent policies across the Centers that, in the most egregious of examples, require DHTs to meet burdensome regulatory requirements even when the DHTs will never be commercialized. The framework is ambiguous regarding implementation, however.

- FDA also plans to upgrade its technical expertise and training, leverage its statistical expertise to analyze endpoints derived from DHT data, and upgrade its IT capabilities to allow for large-scale analysis of DHT-generated data.

The framework also proposes external programs aimed at engaging stakeholders to help FDA understand the most pressing challenges facing DHTs.

- FDA will hold meetings with sponsors during different stages of product development to discuss a variety of matters, including the regulatory status of DHTs, the development of trial endpoints, and the selection of appropriate DHTs for clinical investigations.

- FDA pledges to release and finalize more guidance to reflect FDA's current thinking on various other DHT topics. Of note, FDA plans to publish draft guidance in 2023 regarding Decentralized Clinical Trials for Drugs, Biological Products, and Devices and the Regulatory Considerations for Prescription Drug Use-Related Software.

- FDA also plans to convene public meetings and workshops to enable key stakeholders to provide input on DHT-related challenges and opportunities.

The newly released framework lays out FDA's plans and provides a roadmap for regulating the new and emerging area of DHTs in clinical trials.



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