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FDA sets up CoE for digital health

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The US Food and Drug Administration (FDA) has announced that it is launching the Digital Health Center of Excellence within the Center for Devices and Radiological Health (CDRH).

The launch of the Digital Health Center of Excellence (CoE) is an important step in furthering the agency's overarching dedication to the advancement of digital health technology, including mobile health devices, Software as a Medical Device (SaMD), wearables when used as a medical device, and technologies used to study medical products.

The FDA will continue to build and formalize the coordinating structure and operation of the Digital Health Center of Excellence as part of an effort to modernize digital health policies and regulatory approaches, and provide efficient access to highly specialized expertise, knowledge, and tools to accelerate access to safe and effective digital health technology.

The agency is appointing Bakul Patel as the first director. Bakul Patel has been leading regulatory and scientific efforts related to digital health devices at the FDA since 2010.

The Digital Health Center of Excellence is primarily focused on helping both internal and external stakeholders achieve their goals of getting high quality digital health technologies to patients by providing technological advice, coordinating and supporting work being done across the FDA, advancing best practices, and reimagining digital health device oversight.

Along those lines, the Digital Health Center of Excellence is creating a network of digital health experts and engaging in Collaborative Communities to share knowledge and experience concerning digital health issues and priorities with FDA staff.