

SMG 1251.26a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Devices and Radiological Health

Office of Strategic Partnerships and Technology Innovation

Digital Health Center of Excellence

Effective: August 8, 2023

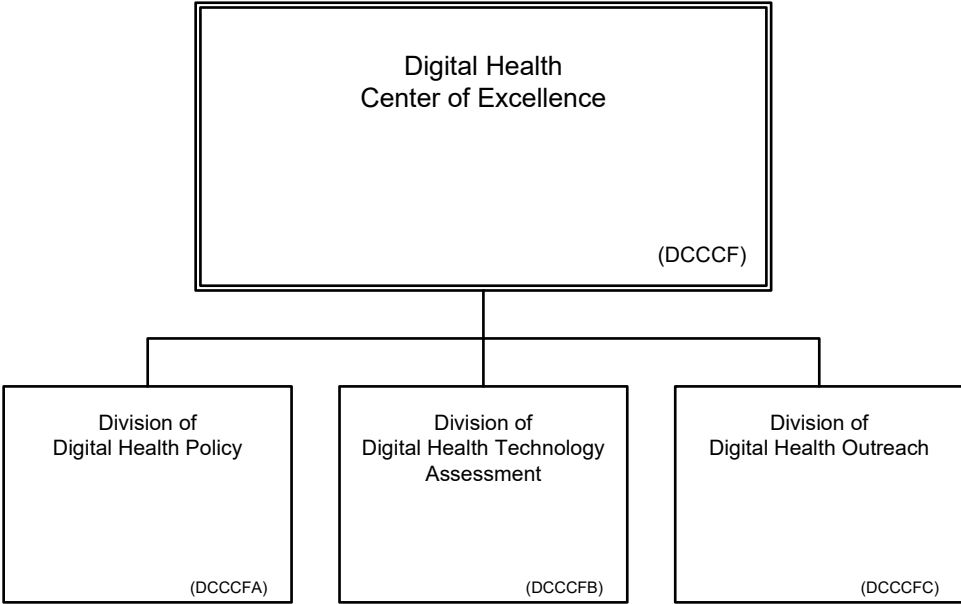
1. Digital Health Center of Excellence (DCCCF).

- A. Provides leadership and strategic direction on software and digital health technologies and associated emerging topics for the Food and Drug Administration (FDA).
- B. Represents the Center for Devices and Radiological Health (CDRH) and the FDA in collaborations with a broad and diverse array of national and international entities including other government agencies, Congress, industry, academia, consumer and patient organizations, and healthcare professional organizations, with mutual interests in digital health technologies.
- C. Provides leadership and subject matter expertise to foster the development of regulatory science and policies in support of digital health technologies including those addressing unmet public health needs.

2. Authority and Effective Date.

The functional statements for the Digital Health Center of Excellence were approved by the Secretary of Health and Human Services on June 27, 2023, and effective on August 8, 2023.

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Strategic Partnerships and Technology Innovation, Digital Health Center of Excellence organization structure depicting all the organizational structures reporting to the Director:

Digital Health Center of Excellence (DCCCF)
Division of Digital Health Policy (DCCCFA)
Division of Digital Health Technology Assessment (DCCCFB)
Division of Digital Health Outreach (DCCCFC)