Is the regulatory engagement with FDA related to design, development, or deployment of a digital health product?

Yes

What is your digital health product type?

Standalone digital health product(s)

What type of advice are you seeking about your product?

Informal

Digital health inquiry

DICE mailbox inquiry

CDRH List & Learn

Pre-Submission (Pre-Sub) program

Submission Issue request (SIR)

Information meeting

513(g) request

CDRH-payer connection

RFD/Pre-RFD process

Early payer feedback program

Parallel review with CMS

OCP Outreach

For other drug development tools for developing digitally derived endpoints, refer to the DiMe and CTTI guides.

No

Sorry! This chart focuses on FDA engagement pathways for digital health products.

What type of advice are you seeking about your product?

Informal

Formal

Digital health inquiry

CDRH-payer connection

RFD/Pre-RFD process

Early payer feedback program

DICE mailbox inquiry

CDRH List & Learn

Pre-Submission (Pre-Sub) program

Submission Issue request (SIR)

Information meeting

CDRH-payor connection

General inquiry

Others

Application based mechanisms

Others

CPAM meetings

CDER small business and industry assistance program

Key
CDRH - Center for Devices and Radiological Health
CMS - Centers for Medicare & Medicaid Services
DICE - Division of Industry and Consumer Education
OCP - Office of Combination Products
RFD - Request for Designation
CPAM - Combination Product Agreement Meetings