

Regulatory Engagement Pathways Map for Digital Health Products



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

Digital Health
Regulatory Pathways



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

No



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

Yes

What is your digital health product type?



For other drug development tools for developing digitally derived endpoints, refer to the [DiMe](#) and [CTTI](#) guides.

Standalone digital health product(s)

Combination product(s)

What type of advice are you seeking about your product?

What type of advice are you seeking about your product?

Informal

Formal

Informal

Formal

Digital health inquiry

513(g) request

Q-submission program

CDRH-payor connection

RFD/Pre-RFD process

General inquiry

Others

CPAM meetings

Application based mechanisms

Digital health inbox

DICE mailbox inquiry

CDRH List & Learn

Pre-Submission (Pre-Sub) program

Submission issue request (SIR)

Information meeting

Others

- Study risk determination
- Submission issue meeting

Early payor feedback program

Parallel review with CMS

OCP Outreach

Center product jurisdiction officers communication

CDER small business and industry assistance program