

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

October 21st, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To discuss the digital health and informatics related topics in the context of the PDUFA reauthorization.

PARTICIPANTS

FDA

Boris Brodsky	CDER
Vid Desai	OIMT
Bushra Islam	CDER
Chris Joneckis	CBER
Bakul Patel*	CDRH
Khushboo Sharma	CDER
Mary Ann Slack	CDER
Ranjit Thomas	CDER

Industry

Rob Blanks	Ardelyx
Kristin Dolinski	PhRMA
Mathias Hukkelhoven	BMS
Ryan Kaat	PhRMA
Robert Kowalski	Novartis
Heidi Marchand	Gilead
Camelia Thompson	BIO

*Director, Digital Health Center of Excellence

At the fourth PDUFA Negotiation meeting, FDA and Industry focused on the Industry's Data and Technology Modernization Proposal. FDA and Industry identified points of alignment and explored areas for further clarification and adjustment. FDA reaffirmed its ongoing commitment to transparency, highlighted the alignment with FDA's Technology Modernization Action Plan (TMAP).

The Director of the recently announced Digital Health Center of Excellence (DHCoE) joined the meeting to provide an overview of the DHCoE and its focus on providing technological advice across FDA in the area of digital health devices and creating a network of digital health experts to share digital health technology expertise across FDA medical product Centers. Industry also provided clarifications of their proposed Digital Health Framework to FDA.

Discussions will continue at the next meeting.