



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Digital Health and Informatics | Meeting Summary

October 14<sup>th</sup>, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

### PURPOSE

To begin discussion of 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
Khushboo Sharma	CDER
Mary Ann Slack	CDER
Ranjit Thomas	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

At the third PDUFA Negotiation meeting on 10/14, FDA and Industry discussed FDA's digital health technologies (DHT) proposal. FDA and Industry identified and agreed upon points of alignment regarding primary objectives.

FDA discussed the DHT proposal with Industry to determine Industry's perspective. FDA proposed convening public forums focusing on DHTs in clinical trials; Industry concurred that this would enable community discussion as different groups currently are shaping the digital health ecosystem. Industry expressed interest in learning more about how CDER/CBER would interact with the Digital Health Center of Excellence (DHCoE). FDA presented its proposal to enhance consistency. FDA also proposed ensuring IT support to enable review of DHT-generated data. FDA noted that this could not be performed without a cloud capability, viewing cloud as an enterprise-wide solution to fix the issue of scalability. Industry agreed that the DHT proposal as a whole was moving in the correct direction but wanted further clarity around FDA's proposals.

FDA and Industry began their conversation of the FDA's cloud proposal at a high-level and potential pilot to enhance the review process and agreed to continue the conversation at the next negotiation meeting.