

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

December 9th, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To continue 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

Industry

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

At the ninth PDUFA Negotiation meeting, FDA and Industry discussed draft commitment language for the Data/IT Modernization proposal in addition to the required cost of funding for projects and resources. FDA and Industry expressed their alignment on the IT Modernization draft commitment language and priority and agreed to integrate CBER IT Modernization into it. FDA noted that IT modernization efforts were enterprise-wide and with the objective to promote consistent application of capabilities across the agency. FDA and Industry discussed PDUFA funding for modernization-related efforts, cloud initiatives, and resources, with FDA highlighting the fact that majority of its present IT investments are allocated toward operation and maintenance costs. FDA and Industry agreed to continue their discussion of the IT Modernization commitments at the next meeting.

There were no other substantive proposals or significant controversies.