

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

January 22nd, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To discuss digital health and Data/IT modernization commitments 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
Robert Kowalski	Novartis
Heidi Marchand	Gilead
Camelia Thompson	BIO

At the twelfth PDUFA Negotiation meeting, FDA and Industry discussed draft DHT commitment language and alignment of key priority areas for Data/IT Modernization language.

The parties continued exploring alignment on appropriate usage and reporting of data from DHT's trials, including proper measurement and detection. FDA and Industry discussed FDA progress reporting options on the IT modernization strategy, as well as the feasibility of specific deadlines proposed by Industry. The group discussed FDA's progress on implementing cloud-based technology in the Agency. FDA and Industry agreed to further consider commitments and to continue discussion at the next meeting.

There were no other substantive proposals or significant controversies.