

# Prescription Drug User Fee Act (PDUFA) Reauthorization

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

January 6<sup>th</sup>, 2021 | 10:00am-12:00pm

Virtual Format (Zoom)

### PURPOSE

To negotiate Data/IT modernization PDUFA commitments.

### 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 eleventh PDUFA Negotiation meeting, FDA and Industry discussed commitment language, resources, and alignment in key priority areas.

FDA and Industry reviewed draft Data/IT commitment language and discussed the FDA commitment to key focus areas of the modernization effort. FDA went over the OIMT plans to develop enterprise-wide cloud infrastructure as part of the agency's digital transformation.

FDA and Industry also discussed the goals and key components of the proposed CBER IT Modernization. FDA described business requirements reflected in the evolving roadmap and outlined the steps necessary to ensure success accomplishment of the modernization objectives. FDA and Industry agreed to continue discussing the proposal at the next meeting.

There were no other substantive proposals or significant controversies.