



# Prescription Drug User Fee Act (PDUFA) Reauthorization

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

February 1<sup>st</sup>, 2021 | 11:00am-1:00pm

Virtual Format (Zoom)

### PURPOSE

To finalize discussion on the Data/IT modernization and 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
Robert Kowalski	Novartis
Heidi Marchand	Gilead
Camelia Thompson	BIO

At the fourteenth PDUFA Negotiation meeting, FDA and Industry reached agreement on the remaining issues and on commitment language relating to Digital Health Technology (DHT) and Data/IT Modernization.

The parties agreed that FDA would report milestones and metrics over the course of modernization as it develops its strategy, with inputs from Industry at the annual joint meeting outlined in the commitment. FDA and Industry discussed the means through which advancement of information exchange and review process would occur through interaction with key stakeholders. Industry expressed its support for technology convergence across FDA Centers. FDA and Industry agreed to draft commitment language.

There were no other substantive proposals or significant controversies.