



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

January 27th, 2021 | 10:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To continue discussion of the Data/IT modernization 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 thirteenth PDUFA Negotiation meeting, FDA and Industry discussed draft commitment language and alignment on key priority areas for the Data/IT Modernization proposal.

In the context of Data/IT modernization commitment language, FDA and Industry discussed CBER's IT modernization plan and the degree to which CBER could leverage existing capabilities from other Centers. Industry asked questions about FDA's evolving roadmap and the associated milestones and costs. FDA described its enterprise-wide cloud-forward initiative. The parties have reaffirmed their alignment on digital transformation and agreed it was the right direction toward a more streamlined regulatory process.

The parties explored a range of IT Modernization topics including interoperability, ESG, and identity management, highlighting that such efforts would be examples of cross-Center enterprise-wide initiatives. The group agreed to include commitment language that captured a holistic view of PDUFA IT modernization activities in the context of Technology Modernization Action Plan (TMAP). FDA and Industry agreed to further consider commitments and to continue further discussion of the proposal at the next meeting.

There were no other substantive proposals or significant controversies.