

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

January 13th, 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 twelfth PDUFA Negotiation meeting, FDA and Industry discussed the Data/IT Modernization proposal. FDA and Industry discussed commitment language, resources, and alignment regarding key priority areas.

FDA and Industry reviewed draft Data/IT commitment language and discussed FDA's plans related to enterprise-wide IT modernization efforts. Industry shared its interest in reporting modernization progress, and its impact on enhancing review process. FDA described its continued efforts in developing a roadmap toward modernization including milestones and phasing and clarified its expected scope. FDA outlined its plans to engage with external stakeholders in the area of cloud technologies, offering to provide quarterly reports on the progress of demonstration projects. FDA and Industry agreed to continue further discussion of the proposal at the next meeting.

There were no other substantive proposals or significant controversies.