



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

November 18th, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To begin discussion of the digital health and informatics related topics in the context of the PDUFA reauthorization.

PARTICIPANTS

FDA

Boris Brodsky	CDER
Vid Desai	OIMT
Bushra Islam	CDER
Chris Joneckis	CDER
Khushboo Sharma	CDER
Mary Ann Slack	CDER
Ranjit Thomas	CDER

Industry

Rob Blanks	Ardelyx
Kristin Dolinski	PhRMA
Mathias Hukkelhoven	BMS
Ryan Kaat	PhRMA
Robert Kowalski	Novartis
Heidi Marchand	Gilead
Camelia Thompson	BIO

At the seventh PDUFA Negotiation meeting on 11/18, FDA and Industry continued discussing draft commitment language for the Digital Health Technology (DHT), Data/IT Modernization, and CDER IT Modernization proposals, including resources and funding for both IT modernization proposals.

FDA and Industry discussed the expected impacts of IT modernization, in particular cloud technology, on the experience of interdisciplinary review teams. The parties affirmed their shared interest in ensuring that technical solutions under PDUFA remain meaningful and impactful in light of the future technology developments. FDA and Industry identified further points of alignment regarding the draft commitment language for both proposals and continued the discussion of specific regulatory activities and scenarios to be explored through cloud collaboration pilots. Industry has recognized the value of transitioning to new IT technology and systems under CDER IT modernization, aligned with the FDA-wide enterprise solution, and considered the IT modernization approaches a way of helping to ensure long-term sustainability.

FDA and Industry agreed to continue the discussion of proposals and resources at the next meeting. In light of the extensive agenda, the parties agreed to extend December 2nd session from 2 to 3 hours.

There were no other substantive proposals or significant controversies.