Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

October 28th, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

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

PARTICIPANTS

FDA		Industry	
Boris Brodsky	CDER	Rob Blanks	Ardelyx
Vid Desai	OIMT	Kristin Dolinski	PhRMA
Bushra Islam	CDER	Mathias Hukkelhoven	BMS
Chris Joneckis	CBER	Ryan Kaat	PhRMA
Khushboo Sharma	CDER	Robert Kowalski	Novartis
Mary Ann Slack	CDER	Heidi Marchand	Gilead
Ranjit Thomas	CDER	Camelia Thompson	BIO

At the fifth PDUFA Negotiation meeting on 10/28, FDA and Industry discussed draft commitment language regarding the use of Digital Health Technologies (DHT) in drug development as well as FDA Data/IT Modernization. FDA and Industry identified points of alignment, discussed areas for further adjustment, and agreed to continue discussion of components that required further clarification.

With respect to DHTs, FDA and Industry discussed the proposed workshops to understand issues and priorities around use of DHTs, the potential of cloud technology to support receipt and analysis of DHT-generated data, and areas that would benefit from additional clarity .

With respect to Data and IT modernization, FDA and Industry continued discussion on a Data/IT Modernization strategy, building upon FDA's Technology Modernization Action Plan (TMAP) and anticipated future expansions on its vision. Both parties recognized the success and value of current coordination efforts and discussed additional strengthening through IT Modernization strategy reviews.

The group will continue its detailed review and discussion of both areas of potential commitment.