Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

November 4th, 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 sixth PDUFA Negotiation meeting on 11/04, FDA and Industry discussed remaining areas for alignment as well as the resources needed to implement to support and enhance use of Digital Health Technology (DHT) in drug development and review. FDA and industry noted the mutual desire to apply consistency of practice across the human drugs and biologics program and where practicable, across the Agency.

FDA and Industry also continued their discussion on Data/IT Modernization, identifying points of alignment on a commitment and areas requiring further clarity and alignment. A particular area of interest is the advancement in the use of cloud and cloud-enabled technologies in support of the human drugs and biologics program and beyond. FDA and industry discussed the mutual objective and approaches to progress the development of innovative cloud-based submission and collaboration tools and capabilities. FDA and Industry agreed to continue their discussion on Data/IT Modernization at the next meeting.

There were no other substantive proposals or significant controversies.