Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

October 7th, 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		Industry	
Boris Brodsky	CDER	Rob Blanks	Ardelyx
Vid Desai	OIMT	Kristin Dolinski	PhRMA
Martin Ho*	CBER	Mathias Hukkelhoven	BMS
Bushra Islam	CDER	Ryan Kaat	PhRMA
Chris Joneckis	CBER	Robert Kowalski	Novartis
Leonard Sacks*	CDER	Heidi Marchand	Gilead
Khushboo Sharma	CDER	Camelia Thompson	BIO
Mary Ann Slack	CDER		
Ranjit Thomas	CDER		

* Digital Health Technology (DHT) SMEs

At the second PDUFA Negotiation meeting on 10/07, FDA provided Industry with an overview of its IT governance structure and Information Management (IM) program and roadmap. FDA and Industry then engaged in a fruitful discussion of Digital Health Technologies (DHT), identifying points of alignment and areas for particular focus.

1. **FDA Governance Structure.** FDA described its IT governance structure, discussing with Industry how IT strategic decision-making occurs across Agency and Centers to meet both Program and enterprise needs effectively. FDA confirmed that while Programs have unique needs, the governance model is geared towards taking an enterprise approach.

2. **Information Management Roadmap.** FDA described its IM program and roadmap, informing Industry that the primary objective is to create a user-centric advanced analytics ecosystem to answer regulatory questions. While sponsored by CDER, the initiative is being developed in close collaboration with CBER and the Agency for broader use.

3. **Digital Health Technologies**. FDA and Industry agreed that a program focused on continually improving the ability to utilize DHTs in drug development and oversight would be mutually beneficial. FDA and Industry identified two key themes, including additional guidance to industry on the use of DHTs in drug development and oversight, and consistency within and across Centers where appropriate. FDA and Industry will continue discussion on this topic at subsequent negotiation sessions.