



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Digital Health and Informatics | Meeting Summary

December 16<sup>th</sup>, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

### PURPOSE

To discuss digital health and Data/IT modernization commitments in the context of the PDUFA reauthorization.

### 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 tenth PDUFA Negotiation meeting on 12/16, FDA and Industry discussed draft commitment language for the DHT (Digital Health Technology) proposal in addition to the Data/IT Modernization proposal. FDA and Industry discussed commitment language, and alignment regarding key priority areas.

FDA and Industry discussed draft DHT commitment language. The parties continued exploring alignment on an appropriate scope and level of planning, review and reporting in the identified priority areas. FDA expressed its intent to build a steering committee of experts across centers to enhance consistency across the human drugs and biologics program and more broadly. FDA and Industry discussed the means to identify initiatives that would inform policy and address key priority areas relevant to DHT evaluation.

FDA and Industry also reviewed Data/IT modernization commitment language. The parties discussed the scope and objectives of the annual and quarterly meetings described in the draft commitment, including level of participation in meetings for best efficiency. FDA CBER described its developing IT roadmap that will outline performance objectives and milestones for tracking progress. The group also discussed drawing a line of sight between the proposed enterprise data and IT strategy and PDUFA-only commitments and goals. FDA and Industry agreed to further consider commitments and to continue discussion at the next meeting.

There were no other substantive proposals or significant controversies.