**Prescription Drug User Fee Act (PDUFA) Reauthorization**

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

**January 27th, 2021 | 10:00am-12:00pm**

**Virtual Format (Zoom)**

**PURPOSE**
To continue discussion of the Data/IT modernization related topics 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 thirteenth PDUFA Negotiation meeting, FDA and Industry discussed draft commitment language and alignment on key priority areas for the Data/IT Modernization proposal.

In the context of Data/IT modernization commitment language, FDA and Industry discussed CBER’s IT modernization plan and the degree to which CBER could leverage existing capabilities from other Centers. Industry asked questions about FDA’s evolving roadmap and the associated milestones and costs. FDA described its enterprise-wide cloud-forward initiative. The parties have reaffirmed their alignment on digital transformation and agreed it was the right direction toward a more streamlined regulatory process.

The parties explored a range of IT Modernization topics including interoperability, ESG, and identity management, highlighting that such efforts would be examples of cross-Center enterprise-wide initiatives. The group agreed to include commitment language that captured a holistic view of PDUFA IT modernization activities in the context of Technology Modernization Action Plan (TMAP). FDA and Industry agreed to further consider commitments and to continue further discussion of the proposal at the next meeting.
There were no other substantive proposals or significant controversies.