Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

October 13th, 2020 | 9:00am-11:00am

Virtual Format

PURPOSE

To provide FDA and Industry perspectives on Regulatory Decision Tools enhancements for PDUFA VII (Complex Innovative Trial Designs), and to have a follow up discussion on previously discussed topics (Model-Informed Drug Development).

PARTICIPANTS

FDA		Industry	
Robyn Bent	CDER	Rob Blanks	BIO (Ardelyx)
Richard Forshee	CBER	Kristin Dolinski	PhRMA
Rajanikanth Madabushi	CDER	Danielle Friend	BIO
Theresa Mullin	CDER	Carl Garner	PhRMA (Eli Lilly)
Dionne Price	CDER	Kelly Goldberg	PhRMA
Graham Thompson	CDER	Ann Kurowski	BIO (Alkermes)
Julia Tierney	CBER	Mark Taisey	PhRMA (Amgen)

The meeting discussion was focused on the issues of interest to industry and FDA.

FDA & Industry Perspectives on Complex Innovative Designs and Model-Informed Drug Development (MIDD).

In this meeting FDA discussed the current Complex Innovative Trial Design (CID) program. FDA provided an overview of the original goals of the CID pilot program under PDUFA VI, the progress in meeting PDFUA VI commitments, and the lessons learned. FDA then discussed its proposals related to CID. FDA identified a need to build upon the current pilot in order to provide time, expertise, and resources to progress toward full implementation of the appropriate use of CIDs. To address this, FDA proposed enhancements related to moving beyond the pilot program.

Industry asked questions related to the current CID pilot, including the current resource and staffing allocations and workload. Industry also asked questions regarding pain points of the CID program.

Industry then presented their proposal related to CID. Industry proposed building upon PDUFA VI to provide further clarification and promote acceptance of CIDs.

FDA asked questions regarding intent and content of the proposed guidances and suggested some topics were related and could potentially be combined. FDA and Industry agreed to have a follow up conversation regarding the proposed guidances and guidance writing timeframes.

FDA and Industry then had a follow-up discussion on Model-Informed Drug Development.

Plan for Future Meetings

The goals for the next meeting on October 20th will be to have a follow up discussion on potential enhancements related to, Complex Innovative Trial Designs, Model-Informed Drug Development, and Patient-Focused Drug Development, as well as to introduce and discuss in more detail potential enhancements related to Advancing Translations Models and Tools.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.