Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

January 12th, 2021 | 10:00am-11:00am

Virtual Format

PURPOSE

To have a follow up discussion on previously discussed topics: Model-Informed Drug Development, Patient-Focused Drug Development, and Complex Innovative Designs.

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 Discussion on Model-Informed Drug Development (MIDD), Patient-Focused Drug Development (PFDD), and Complex Innovative Designs (CID)

In this meeting FDA and Industry focused on review and discussion of further proposed edits to draft commitment language from FDA and Industry, including the associated resource needs.

The discussion first considered proposed draft language for CID incorporating edits from FDA and Industry. FDA and Industry negotiators in the subgroup tentatively agreed to all proposed language discussed at the previous meeting with minor edits, including the paired meeting program and meeting timeframe. Additionally, Industry expressed a desire to be notified whenever a sponsor's program under CID would be discussed publicly. FDA also agreed to a discussion with the sponsor, before the initial CID meeting is granted, that would focus on what information FDA may share publicly in these case studies. FDA also agreed to notify sponsors in advance, when feasible, when their program would be the planned focus of a public meeting. Finally, for the timeframes associated with guidance-related commitments, FDA suggested using the standard language on timeframes from PDUFA VI, which Industry agreed to.

The discussion next addressed the proposed draft commitment language from FDA and Industry on MIDD. This language included all prior edits from FDA and Industry, with one minor edit to match the CID language on timeframes.

The final topic of discussion was the review of proposed draft commitment letter language from FDA and Industry on PFDD. FDA and Industry negotiators in the subgroup agreed to the previously discussed language, with one outstanding item. FDA and Industry agreed to further review and provide final considerations on a commitment for FDA to work to develop a virtual catalog of standard core sets of Clinical Outcome Assessments and Related Endpoints, for which FDA would pursue non-user fee funding. FDA and Industry indicated they would revisit this topic at the next meeting.

Plan for Future Meetings

FDA and Industry agreed to hold a short follow-up meeting on January 19th. It was also agreed that this meeting would aim to come to final agreement on proposed commitments to refer to the steering committee.

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