Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

October 27th, 2020 | 9:00am-11:00am

Virtual Format

PURPOSE

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

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
David Strauss	CDER	Ann Kurowski	BIO (Alkermes)
Graham Thompson	CDER	Mark Taisey	PhRMA (Amgen)
Julia Tierney	CBER		

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), Complex Innovative Designs (CID), and Advancing Translational Models and Tools (ATMT).

In this meeting FDA and Industry both focused on follow-up questions regarding perspectives on the proposals discussed to date. FDA began by providing a brief overview of the impetus behind each of its proposals for regulatory decision tools program enhancements, including a discussion on how regulatory experience leads to guidances and the impact guidances have on FDA and sponsors. FDA and Industry then focused on FDA's responses to Industry's follow up questions and requests for clarification.

FDA first discussed how additional resources could help sustain the MIDD program at the current PDUFA VI level. FDA then provided further detail on the Patient-Focused Drug Development

proposal, including a discussion on deliverables that could be provided with current resources and how work done under PDUFA VI would impact the proposals under PDUFA VII.

FDA discussed how the standard core clinical outcome assessments (COA) portion of the PFDD proposal could be incorporated into PDUFA VII, including potential resources that would be needed to support the program and how priority areas for future core set development could be identified. FDA also provided further clarity on its proposal related to Patient Preference Information and discussed Industry's proposals related to Patient Preference Information, and stated that the topic would need further discussion.

Industry posed additional questions on the CID proposal. Citing the substantial variation and novelty of each trial design currently considered under the CID pilot, FDA indicated that more experience would be needed in order to issue guidance on some topics related to CID. After additional discussion of this topic, FDA and Industry discussed questions related to ATMT, including further clarification on what resources would be needed.

FDA and Industry both agreed to take the full set of questions back for further discussion internally, and to discuss them in more detail at the next scheduled meeting.

Plan for Future Meetings

As per the original agreed-upon schedule, no meeting is scheduled for November 3rd. At the next scheduled meeting on November 10th, the goal will be to have another follow-up conversation in more detail about all four proposal areas discussed to date: Model-Informed Drug Development, Patient-Focused Drug Development, Complex Innovative Designs, and Advancing Translational Models and Tools.

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