Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

October 20th, 2020 | 9:00am-11:00am

Virtual Format

PURPOSE

To provide FDA and Industry perspectives on Regulatory Decision Tools enhancements for PDUFA VII (Advancing Translational Models and Tools), and to have a follow up discussion on previously discussed topics (Patient-Focused Drug Development, 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
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 Perspectives on Advancing Translational Models and Tools, Patient-Focused Drug Development (PFDD), and Model-Informed Drug Development (MIDD).

In this meeting FDA discussed its proposals related to Advancing Translational Models and Tools (ATMT). FDA provided an overview of the goals of the proposal, which relate to leveraging translational science, including models and tools, into the drug review process in order to overcome challenges and hurdles in clinical development. ~~In order to address this, FDA proposed enhancements related to four areas: in vitro efficacy data to support FDA approval, expanding the impact of cardiac safety models & biomarkers, microphysiological systems to streamline drug development, and further exploring translational safety biomarkers. FDA also stated that the overall proposal would provide training and expert consultation for FDA review staff as well as annual meetings and workshops to review progress and discuss emergent areas.~~ Industry ~~stated that they~~

~~generally support advancing regulatory science, and~~ asked questions relating to current resourcing and workload in this area and asked for more details about proposal and resourcing.

Industry asked questions related to the current MIDD program~~.~~, ~~Industry's question focused on the resource needs to maintain the current levels of activity~~ including the pilot program, guidance development, ~~and~~ workshops, and resource needs.

Industry then asked questions related to PFDD, including~~. Industry's questions focused on what enhancements would be possible with current resources,~~ current resources and hiring under PDUFA VI, and exploring the scope of current work and potential proposals.

Plan for Future Meetings

The goals for the next meeting on October 27th will be to have a follow up discussion on potential enhancements related to all four proposal areas discussed to date: Complex Innovative Trial Designs, Model-Informed Drug Development, Patient-Focused Drug Development, and Advancing Translations Models and Tools.

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