FDA-Industry PDUFA VI Reauthorization Meeting – Regulatory Decision Tools Subgroup
December 15, 2015, 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1211

Purpose

To further discuss proposals on patient focused drug development, benefit-risk assessment, and complex innovative designs

Participants

FDA		Industry	
Sara Eggers	CDER	Cartier Esham	BIO
Joe Franklin	OC	Jeffrey Francer	PhRMA
Laura Lee Johnson	CDER	Sandra Milligan	PhRMA (Merck)
Chris Joneckis	CBER	Paula Rinaldi	PhRMA (Novartis)
Lisa LaVange	CDER	Michelle Rohrer	BIO (Roche Genentech)
Diane Maloney	CBER	Mark Taisey	PhRMA (Amgen)
Theresa Mullin	CDER		
Mike Pacanowski	CDER		
Pujita Vaidya	CDER		

Discussion of patient focused drug development (PFDD) and benefit-risk assessment

On December 15, FDA and Industry discussed revisions to tentative draft language for the PDUFA VI commitment letter (contingent on agreement of the entire package) related to PFDD and benefit-risk assessment.

FDA and Industry also discussed the resource estimates for the PFDD proposed enhancements. FDA stated that it seeks to strengthen staff capacity to effectively address the increasing volume of submissions and requests for consultation on the use of patient input to support drug development and review work and facilitate development and use of patient-focused methods to inform regulatory decisions.

Discussion on FDA's proposal on Complex Innovative Design

FDA and Industry continued discussion of proposed enhancements intended to facilitate the advancement and use of complex adaptive, Bayesian and other novel clinical trial designs. FDA and Industry discussed tentative draft language for the PDUFA VI commitment letter related to complex innovative designs and model-informed drug development. Potential commitments in both areas included developing staff capacity, conducting a limited pilot program to facilitate interaction with sponsors, conducting workshops, and developing or revising guidances and Manuals of Policies and Procedures/Standard Operations Policies and Procedures as appropriate. FDA and Industry further discussed the design and implementation of the

proposed pilot program for complex innovative trial designs for which simulations are necessary to determine trial operating characteristics. FDA and Industry noted that it would be helpful to provide further clarity regarding the pilot program, program proposal selection, and potential discussion of the use of designs as case studies to advance the science and promote innovation in this area. FDA and Industry noted that it will be necessary to implement the program in a way that ensures agreement between a sponsor and FDA regarding information about a trial design that FDA may use in publicly available case studies.

Plan for Future Meetings

Industry and FDA agreed to continue discussion of tentative draft language for the PDUFA VI commitment letter at the next meeting, further discuss overall resource requirements and address any additional pending issues.