FDA-Industry PDUFA VI Reauthorization Meeting – Regulatory Decision Tools Subgroup
January 12, 2016, 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1333

Purpose

To discuss proposal on drug development tool (DDT) qualification for biomarkers and tentative draft commitment language on patient focused drug development, complex innovative designs, model-informed drug development, and analysis data standards.

Participants

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

Discussion of DDT qualification for biomarkers

On January 12, 2016, FDA and Industry discussed proposed enhancements in PDUFA VI related to DDT qualification for biomarkers. FDA noted that the goal is to improve predictability of the biomarker qualification process by clarifying evidentiary standards for biomarkers and refining processes related to review of qualification submissions and communication among FDA and other stakeholders about proposals.

FDA and Industry discussed the approaches proposed by both parties, including a public meeting, development of guidance for internal staff and industry on DDT qualification for biomarkers, and maintaining a public website to communicate a list of biomarker qualification submissions in the qualification process. FDA also discussed the need to strengthen its staff capacity to enhance biomarker qualification review by increasing base capacity.

Discussion of draft tentative PDIFA VI commitment language

FDA and Industry discussed tentative draft language for the PDUFA VI commitment letter related to patient-focused drug development, model-informed drug development and analysis data standards. FDA and Industry also discussed draft language for complex innovative designs. Industry noted that further revisions to the draft language may be necessary to provide details about the pilot program and clarify the need for 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.