FDA-Industry PDUFA VI Reauthorization Meeting – Regulatory Decision Tools Subgroup
January 19, 2016, 12:30pm-2:00pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1333

Purpose

To further discuss tentative draft commitment language on model-informed drug development, complex innovative designs, and biomarker qualification

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)
Theresa Mullin	CDER	Michelle Rohrer	BIO (Roche Genentech)
Mike Pacanowski	CDER	Mark Taisey	PhRMA (Amgen)
Pujita Vaidya	CDER		

Discussion on draft tentative PDUFA VI commitment language

On January 19, 2016, FDA and Industry discussed revisions to tentative draft language for the PDUFA VI commitment letter (contingent on agreement of an entire package) including proposed enhancements related to model-informed drug development, complex innovative designs, and biomarker qualification. FDA and Industry identified a small number of minor clarifying edits. Contingent on these further edits, FDA and Industry agreed that the overall tentative draft language for these proposals reflected previous discussions of their respective proposed enhancements and were ready for review by the larger Steering Committee.