FDA-Industry PDUFA VI IT Subgroup Meeting
December 15th, 2015, 12:30 – 2:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 3100

Participants

FDA		Industry	
Brad Wintermute	OIMT	Sandy Milligan	PhRMA (Merck)
Ron Fitzmartin	CDER	Mike Levy	PhRMA
Virginia Hussong	CDER	David Donohue	PhRMA (GlaxoSmithKline)
Mark Gray	CBER	Michelle Rohrer	BIO (Genentech Roche)
Hilmar Hamann	CDER		
Urvi Shah	CDER		

FDA / Industry Commitment Letter Discussions
FDA and Industry reviewed a draft commitment letter that contained previously discussed proposals to improve the efficiency of human drug review by utilizing consistent and predictable Electronic Submissions System and Processes. FDA and Industry also clarified specific language related to sharing and publishing documentation, data standards, implementation timing, and strategic planning.

Both parties agreed to revisit their proposals to suggest revised language. In some instances language will be edited, augmented, or summarized to better reflect the intent and tone of the discussions. Specifically, both parties agreed to review the data on submission size and consider the implications for the commitment letter. FDA also agreed to consider ways to consolidate similar proposals in the commitment letter.

Plan for Future Meetings
FDA and Industry agreed to continue commitment letter discussions and negotiations.

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