FDA-Industry PDUFA VI IT Subgroup Meeting
November 18th, 2015, 9:30 – 11:30
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1419

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 set of proposals presented by each party to improve the efficiency of human drug review by utilizing consistent and predictable Electronic Submissions System and Processes. The proposals included the electronic system gateway business hours, the average compressed and uncompressed submission size, quarterly meetings, performance metrics, and the strategic plan. Both the FDA and Industry discussed the larger goals of the PDUFA program and how to ensure the best technology outcomes in the future. Both parties also discussed the level of specificity to be included in the commitment letter.

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.

Plan for Future Meetings
FDA and the 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.