FDA-Industry PDUFA VI IT Subgroup Meeting
January 12, 2016, 12:30 pm – 2:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1417

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 draft commitment letter language 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 documenting submission process details, notifications to Industry on system changes, the purpose of annual meetings, and data standards.

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 the discussions. Specifically, both parties agreed to review the data on submission size and consider the implications on preliminary metrics and targets associated with submission size, system availability, and upload throughput.

Plan for Future Meetings
FDA and the Industry agreed to continue discussing preliminary metrics and targets.

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