FDA-Industry PDUFA VI IT Subgroup Meeting
November 4th, 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 publishing related eSubmission documentation, documenting procedures, publishing software versions, communicating submission status to Industry, and communicating strategies through quarterly and annual meetings.

Both parties agreed to revisit their proposals to suggest revised language.

Both parties also agreed to discuss with their respective leadership the level of detail and specificity of metrics that should be included in the commitment letter versus other outlets.

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.