FDA-Industry PDUFA VI IT Subgroup Meeting
October 14th, 2015, 9:30 – 11:30
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1311

Purpose
To review detailed industry proposals
To review updated subgroup schedule

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		

Industry Presentation
Industry reviewed a set of proposals that would improve the efficiency of PDUFA eSubmission systems and processes, including the Electronic Submissions Gateway (ESG). The proposals were aimed at improving the stability, predictability and transparency of the eSubmission systems and processes, which are critical to enabling more effective submissions to FDA.

FDA agreed, questioned, and disagreed with some of the industry proposals, and it was agreed that further discussion is warranted on each proposal. FDA also agreed to research the causes of ESG submission rejections and quantify the magnitude of the problem.

During the meeting, both FDA and Industry discussed a number of topics that would inform the negotiations and the specifics for each proposal. These topics included the causes for submission rejections, submission acknowledgements, ESG availability, validation and visualization tools, and the annual meeting.

Plan for Future Meetings
The team discussed adjusting the meeting schedule to accommodate other meetings and the holiday schedule.

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