FDA-Industry PDUFA VI IT Subgroup Meeting
October 21st, 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		

Meeting Schedule
The group discussed potential options for upcoming meetings in October and November. Meeting dates may be changed to accommodate the availability of meeting participants.

Industry Presentation
Industry reviewed a set of proposals that would improve the transparency and accountability of IT activities. Specifically the proposals were aimed at improving communication, ensuring effective meetings, collaborating on strategic priorities, and measuring and assessing progress towards mutual goals.

FDA and Industry agreed that further discussion is warranted on each proposal.

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 quarterly meetings, IT roadmaps, the FDA IT Strategic Plan, data standards, and metrics.

Review of 2014 PDUFA IT Report
In response to an earlier inquiry by the Industry, FDA presented Table 7: FY 2014 Total Number of Standards-Based Electronic Submission Failures (Rejection). The group discussed the scope of the problem and the preventable causes for failed submissions.

Plan for Future Meetings
A proposal related to PDUFA eSubmission and processes was presented by industry for FDA to review in advance of the next meeting scheduled for October 28th.

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