**FDA-Industry PDUFA VI IT Subgroup Meeting**
**October 7th, 2015, 9:30 – 11:30**
**FDA White Oak Campus, Silver Spring, MD**
**Building 22, Room 1311**

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**Participants**

| FDA | | Industry | |
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| Brad Wintermute | OIMT | Sandy Milligan | Merck (PhRMA) |
| Ron Fitzmartin | CDER | Mike Levy | PhRMA |
| Virginia Hussong | CDER | David Donohue | GlaxoSmithKline (PhRMA) |
| Mark Gray | CBER | Michelle Rohrer | Genentech Roche (BIO) |
| Hilmar Hamann | CDER | | |
| Urvi Shah | CDER | | |

**Introductions**
Members from industry and the FDA introduced each other.

**FDA Presentation**
The meeting began with an open discussion to review the accomplishments of PDUFA V. The accomplishments included specific references to regulatory electronic submissions, data standards, and communications and technical interactions. Some of the notable accomplishments included:

- Establishing an Program Governance Board (PGB);
- Designing a new architecture that will feature enhancements to support higher submission volumes and increase system availability for the user community;
- Implementing the eCTD Module 1 update to include promotional advertising and labeling submission capabilities;
- Publishing multiple guidance, technical specifications and standards documents; and
- Publishing the annual PDUFA V IT/ Informatics Assessment to the FDA Web site.

**Ground Rules**
The FDA team reviewed the high level ground rules. The meetings are preferably to be conducted in person. Meeting materials will be distributed prior to the meeting and meetings will be conducted as efficiently as possible.

**FDA Presentation - Themes for PDUFA VI**
FDA presented three themes to focus future discussions: Electronic Transmission Capabilities, Electronic Submission Standards, and Transparency & Communications. FDA wants to ensure ESG future planning incorporates feedback from industry to address challenges with the existing system as well as the evolving needs of industry users. FDA proposed to continue standardization initiatives. Finally, FDA wanted to support increased collaboration by holding quarterly meetings to ensure open channels of communication and by developing an interactive dashboard on the FDA website that provides access to important information, data and metrics.

**Industry Perspectives on Reauthorization**
Industry noted the positive momentum from PDUFA V and acknowledged that communication and transparency is important, as is recognition of outages on ESG. From an industry perspective, issues of high importance are:

- Decisions that FDA takes regarding technology impacts industry and patients
- Predictability, stability, transparency, communication and collaboration are important
- Ongoing commitment to support improved Industry/FDA communication

ESG is one of the primary concerns for Industry. It is important that the gateway is stable, reliable, and that industry understands the processes undergone by submissions to preempt avoidable submission and validation issues.

**Plan for Future Meetings**

The team agreed that the objectives for the next meeting would be to:

- Discuss roadmap and timeline
- Agree and identify the difficult and relatively easy themes of the negotiation.
- Industry noted that we should discuss both the difficult and easy topic in parallel.

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