

FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
January 19, 2016: 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1325

Purpose

To continue discussions on the RWE-Efficacy and Safety Communication Proposals.

Participants

<u>FDA</u>		<u>Industry</u>	
Bob Ball	CDER	Beatrice Biebuyck	BIO (Alexion)
Aloka Chakravarty	CDER	Jennifer Boyer	BIO (Alkermes)
Mwango Kashoki	CDER	Jeffrey Francer	PhRMA
Melissa Robb	CDER	Kay Holcombe	BIO
Aaron Sherman	CDER	Paula Rinaldi	PhRMA (Novartis)
Terry Toigo	CDER		
Craig Zinderman	CBER		

RWE-Efficacy Proposal:

FDA noted that an important element of the proposal is a commitment to developing expertise within FDA related to potential uses of Real World Evidence (RWE). Towards this end, FDA described how resources associated with this proposal would be utilized in the various program offices. Discussion then shifted to possible commitments for this proposal.

FDA and Industry reviewed the details of possible commitments, including timeframes for completion and opportunities for stakeholder feedback to be built into the process. In addition, potential activities to serve as the culmination of the proposal were discussed.

Safety Communications Proposal:

FDA and Industry continued discussing the possibility of commitments related to notification of Sponsors regarding FDA's quarterly posting of safety issues ("921 postings" as mandated by the Food and Drug Administration Amendments Act of 2007, section 921) and improving the consistency of FDA's communications with Sponsors upon opening a tracked safety issue. FDA and Industry also discussed potential notification of Sponsors about analyses of their products using Sentinel.

Agenda for Next Meeting:

FDA agreed to provide updated Sentinel and Safety Communications commitment language, and Industry agreed to provide updated RWE-Efficacy commitment language, for discussion at the next meeting. There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.