FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
December 9, 2015: 10:00am-11:00am
Conference Call

Purpose

To discuss proposed revisions to Real World Evidence (RWE) Proposal.

Participants

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

Background:

At this sub-group's previous meeting (December 2, 2015), FDA and Industry discussed the RWE proposal and FDA agreed to provide edits to a proposed process for continued discussion at a future meeting. This was the topic of discussion for this conference call.

Summary:

Industry requested that specific timeframes be included as a part of the goals letter consistent with other PDUFA regulatory science programs. FDA and Industry discussed potential timeframes that could be considered. FDA and Industry also agreed that a public process, including a public meeting, was an essential component of the proposal. Industry inquired about the resource estimate provided by FDA at the previous meeting. FDA agreed to provide a more detailed justification to support the estimate at a future meeting. Finally, there was discussion of what type of activity should constitute the culmination of the proposal. FDA and Industry agreed to continued discussion of the proposal at a future meeting.

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