FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
October 7, 2015: 9:30am-11:30am
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1333

Purpose

To introduce FDA and Industry post-market proposals.

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	Robert Metcalf	PhRMA (Eli Lilly)

Introduction and Review of Ground Rules

This was the first meeting of the post-market sub-group, and began with introductions and a brief review of the agreed-upon ground rules. Both sides then introduced their proposals, on the topic of real world evidence (RWE).

Industry Real World Evidence Proposal:

Industry noted that both sponsors and FDA use RWE for various purposes (e.g., safety surveillance) and proposed a plan that they believed would build the evidence base through a public process to explore the use of RWE in regulatory decision making for both safety and effectiveness issues. The plan calls for a regulatory science initiative to determine the benefits of and methodologies available for use of RWE in this context, as well as the gaps that need to be overcome to achieve the goal of broader use of RWE in the post-market setting. FDA and Industry agreed to discuss the proposal further.

FDA Real World Evidence Proposal:

FDA's proposal attempts to increase available pharmacovigilance data sources by expanding the capacities of the Sentinel System and exploring new sources of RWE for safety. FDA noted that significant resources have already been dedicated to developing the Sentinel Initiative, and it is important to continue to support the ongoing development of the System so that all stakeholders can benefit from its expanding capabilities. The proposal seeks to enhance the Sentinel System by expanding the types of available data, and building new analytic methods. It also aims to fully integrate Sentinel into the existing FDA post-market safety regulatory review apparatus. FDA clarified that it is not its intention for the Sentinel System to replace existing data sources (e.g., the Adverse Event Reporting System), but instead, augment them.

In addition, new sources of RWE would be examined by exploring work being conducted by other stakeholders and conducting a public meeting which would inform the need for other projects to refine and understand the value of these new data sources for safety surveillance. One possible new data source of interest mentioned was social media. FDA stated their belief that expanding use of RWE for safety

would represent a large new source of proactive safety surveillance data. FDA and Industry agreed to discuss the proposal in future meetings.

Agenda for Next Meeting:

This meeting was concluded by discussing the agenda for the following week, and identifying new information needed to inform ongoing discussion. FDA agreed to provide a more comprehensive understanding of historical Sentinel funding sources, and what new resources might be needed. Industry agreed to share a landscape analysis on RWE data sources. There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.