FDA-Industry PDUFA VI Reauthorization Meeting – Regulatory Decision Tools Subgroup
October 21, 2015, 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1211

Purpose

To discuss in detail FDA and Industry proposals on Patient-Focused Drug Development

Participants

FDA		Industry	
Sara Eggers	CDER	Beatrice Biebuyck	BIO (Alexion)
Laura Lee Johnson	CDER	Cartier Esham	BIO
Chris Joneckis	CBER	Jeffrey Francer	PhRMA
Lisa LaVange	CDER	Michelle Rohrer	BIO (Roche Genentech)
Theresa Mullin	CDER	Mark Taisey	PhRMA (Amgen)
Mary Parks	CDER		
Mike Pacanowski	CDER		
Pujita Vaidya	CDER		

Discussion on Patient-Focused Drug Development (PFDD)

Guidance development and public workshops on recommended approaches to critical aspects of PFDD

FDA and Industry continued their discussion on PFDD, particularly the approaches proposed by both parties that included guidance development and public workshops intended to advance the science of integrating patient input in drug development and integrating into regulatory evaluation of medicines. FDA and Industry discussed areas of common interest and alignment in their respective proposals and discussed what might be desirable to be addressed in a proposed series of related guidances, including collection of comprehensive patient-community input, impacts that are important to patients, and the measurement of those impacts.

FDA also stated that the agency would also need to resource the hiring of additional staff with experience in PRO development and methodologies to effectively address the already increasing volume of work. FDA indicated that the currently very-limited staffing in these areas would create a bottleneck for development programs seeking consultation with FDA on patient engagement and use of PROs. It was agreed that FDA's resource estimate for the PFDD work plan would be revisited in future discussions.

Creation of a publicly available information repository

FDA and Industry discussed FDA's proposal for the agency to create and maintain a repository of information on available tools and ongoing efforts. This could be made publicly available on

FDA's website as a resource for stakeholders. FDA noted that this may be a valuable resource for patient organizations, sponsors, and FDA staff, on developments and activities that FDA is aware of, in the area of patient-focused drug development.

Enhancement of patient engagement in clinical trials

FDA proposed to conduct a workshop inviting patient stakeholders to discuss the ideas and experiences of the patient community on engaging patients in the planning and conduct of clinical trials. This meeting, which was proposed to be conducted by a qualified third-party, could result in a published report on the proceedings. Industry and FDA noted that issues to address at the meeting could include topics including patient engagement, recruitment and retention, and testing requirements (e.g., lab tests). FDA and industry agreed to continue discussing both the PhRMA-BIO and FDA proposals for public engagement.

Plan for Future Meetings

Industry and FDA agreed to detailed discussion on benefit-risk at the next meeting.