FDA-Industry PDUFA VI Reauthorization Meeting – Regulatory Decision Tools Subgroup
December 2, 2015, 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1333

Purpose

To further discuss proposals on patient focused drug development, benefit-risk assessment, and analysis data standards

Participants

FDA		Industry	
Sara Eggers	CDER	Beatrice Biebuyck	BIO (Alexion)
Joe Franklin	OC	Cartier Esham	BIO
Laura Lee Johnson	CDER	Jeffrey Francer	PhRMA
Chris Joneckis	CBER	Sandra Milligan	PhRMA (Merck)
Lisa LaVange	CDER	Paula Rinaldi	PhRMA (Novartis)
Diane Maloney	CBER	Michelle Rohrer	BIO (Roche Genentech)
Theresa Mullin	CDER	Mark Taisey	PhRMA (Amgen)
Mike Pacanowski	CDER		

Discussion of patient focused drug development (PFDD) and benefit-risk assessment

On December 2, FDA and Industry discussed tentative draft language for the PDUFA VI commitment letter (contingent on agreement of the entire package) related to PFDD and benefit-risk assessment. FDA and Industry agreed that overall the tentative draft language in both areas reflected the previous meetings discussions on their respective proposal.

Discussion on FDA's proposal on analysis data standards

FDA and Industry continued discussion of proposed enhancements intended to advance analysis data standards as well as FDA's capacity to efficiently review and provide more timely feedback to sponsors on the readiness of submitted analysis data sets and programs for statistical review. Discussion topics included efforts (e.g., workshops) to advance the development of analysis data standards, as well as the development of Manuals of Policies and Procedures (MAPPs), Standard Operating Policies and Procedures (SOPPs) and internal training to support FDA biostatistical review staff. CDER and CBER further discussed the opportunity to enhance the role of data scientists (e.g., statisticians at the Master's degree level) in reviewing the readiness of submitted analysis datasets and programs, as well as to assist the review team in potentially resolving data-related issues. CDER also discussed the opportunity to enhance dedicated program management support within the biostatistical review team, which can facilitate data management and communication with sponsors on data-related issues. FDA commented that by increasing the above resources to focus on analysis data readiness and data management issues, FDA's more seasoned Ph.D.-level reviewers could better focus their

time on reviewing the application as well as on efforts to advance data standards (e.g., contributing more fully to therapeutic area user guides). FDA and Industry discussed the value in FDA's ability to provide early feedback that a sponsor's data is "fit-for-review," as well as the value in potentially reducing the likelihood of a major data-related information request or major amendment in the review cycle. Industry indicated its potential interest in this proposal but stated that a final assessment of the value of FDA's proposed resource requirements will need to be considered in light of the whole commitment package. FDA and Industry agreed to discuss further in a future meeting.

Plan for Future Meetings

Industry and FDA agreed to continue discussion at the next meeting on proposals related to innovative complex clinical trial designs, model-informed drug development, and analysis data standards.