Duke | MARGOLIS CENTER for Health Policy

Duke Margolis-FDA Workshop: Advancing Pre-Market Safety Analytics

Virtual Public Workshop

September 14, 2022, 12:00 – 5:00 p.m. ET

Agenda

Background:
Due to a lack of standardization of safety data analysis and visualization, inconsistencies in adverse event definition, categorization, analysis, and presentation have been noted in marketing applications. The U.S. Food and Drug Administration (FDA) Office of New Drugs Biomedical Informatics Team led the development of two documents in collaboration with the FDA Medical Queries working group as well as the Standard Safety Tables and Figures working group to facilitate review of safety data. The first document, the FDA Medical Queries, are a standardized approach to group preferred terms. The second document, the Standard Safety Tables and Figures Integrated Guide, are standardized methods for visualization of clinical trial safety data into tables and figures. The agency values transparency and collaboration with external stakeholders—therefore both documents will be made available for public comment through an FDA-created docket.

Meeting Objective:
FDA will present their enhanced work and perspective on pre-market review of safety data. The FDA documents will serve as a launch point for broader conversations on best practices and innovative approaches for advancing pre-market safety signal analytics.

12:00 pm **Welcome and Introduction**

12:10 pm **FDA Opening Remarks**
FDA leadership will review efforts made by the agency's Pre-Market Safety Assessment Working Group and set expectations for the meeting—highlighting the FDA-created docket as a place for feedback on presented materials.

12:25 pm **Overview of FDA Medical Queries**
FDA will present its ongoing efforts on a standardized approach of adverse event term groupings to ensure optimal safety signal detection. An overview of the FDA Medical Queries (FMQs) will cover rationale for development, identification and categorization of Preferred Terms. Algorithmic FMQs will be highlighted as an approach to detect complex conditions. In addition, the impact of FMQs future uses on product safety labeling will also be explored.

01:35 pm **Stakeholder Perspectives Exploring Pre-Market Adverse Event Grouping**
Panelists will review clinical safety signal evaluation from a broad range of clinical areas and therapeutics. Discussion will focus on best practices and emerging technologies to identify and categorize Preferred Terms. In addition, the panel will address how approaches to grouping safety events, including FMQs, may affect labeling for approved products.

02:35 pm **BREAK**

02:50 pm **Overview of the Standard Safety Tables and Figures Integrated Guide**
This presentation will provide an overview of the Standard Safety Tables and Figures Integrated Guide (IG)—including the rationale for development and the goals of the IG. Standard safety topics such as treatment emergent adverse events, drug-induced liver injury screening, missing data analysis, and standard laboratory analyses will be presented. Expanded safety topics such as last value on-treatment analyses also will be spotlighted.

03:50 pm **Examining Strategies for Adverse Event Analysis**
Panelists will present their perspectives on adverse event and laboratory data analyses—including innovative approaches. Discussion will build on key standard and expanded safety topics introduced in the IG presentation. Furthermore, the panel will consider how the IG may affect pre-market submission of safety data.

04:50 pm **Meeting Recap and Closing Remarks**

5:00 pm **Meeting Adjournment**

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