# Duke Margolis-FDA Workshop: Advancing Premarket 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) Center for Drug Evaluation and Research's Office of New Drugs led the development of two documents to facilitate review of safety data and improve safety signal detection. 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 have been made available for public comment through an FDA-created docket.

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

**12:00 pm** **Welcome and Introduction**

**Speaker:**
- **Marianne Hamilton Lopez,** Duke-Margolis Center for Health Policy

**12:10 pm** **FDA Opening Remarks**
FDA leadership will review efforts made by the Center for Drug Evaluation and Research's Office of New Drugs and set expectations for the meeting—highlighting the FDA-created docket as a place for feedback on presented materials.

**Speaker:**
- **Peter Stein**, U.S. Food and Drug Administration
- **Vaishali Popat,** U.S. Food and Drug Administration

**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.

**Speaker:**

- **Vaishali Popat,** U.S. Food and Drug Administration
- **Scott Proestel,** U.S. Food and Drug Administration
- **Eric Brodsky,** U.S. Food and Drug Administration

**01:25 pm** **Stakeholder Perspectives Exploring Premarket 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 discuss how approaches to grouping safety events, including FMQs, may be included in prescription drug labeling.

Moderator: **Scott Proestel,** U.S. Food and Drug Administration

**Panelists:**

- **Ellis Unger,** Hyman, Phelps & McNamara
- **Greg Ball,** Novavax (PHUSE)
- **Barbara Hendrickson,** Abbvie (DIA-ASA Interdisciplinary Safety Evaluation Working Group)

**02:25 pm** **BREAK**

**02:40 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. In addition, 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 and optional safety topics including exposure adjusted analyses also will be spotlighted.

**Speaker:**

- **Vaishali Popat,** U.S. Food and Drug Administration
- **Nhi Beasley,** U.S. Food and Drug Administration
- **Veronica Pei,** U.S. Food and Drug Administration
- **Mat Soukup,** U.S. Food and Drug Administration

**03:50 pm** **Examining Strategies for Premarket Adverse Event Analysis**

Panelists will present their perspectives on adverse event analysis—including innovative approaches for presentation of clinical safety data into tables and figures. Discussion will build on key standard safety topics introduced in the IG presentation. Furthermore, the panel will consider how the IG may affect premarket submission of safety data.

Moderator: **Vaishali Popat,** U.S. Food and Drug Administration

**Panelists:**

- **Mary Nilsson,** Eli Lilly (PHUSE)

- **Bess LeRoy,** Clinical Data Interchange Standards Consortium
- **Jeremy Wildfire,** Gilead (DIA-ASA Interdisciplinary Safety Evaluation Working Group)

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

**Speaker:**

- **Marianne Hamilton Lopez,** Duke-Margolis Center for Health Policy

**5:00 pm** **Meeting Adjournment**

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