Optimizing the Use of Real-World Evidence in Regulatory Decision Making for Drugs and Biological Products—Looking Forward

December 12, 2024
12:30 pm – 4:30 pm ET
North Bethesda Marriott and Conference Center

Workshop Objectives:
To provide an update, as well as to solicit input from interested parties, on current and future activities of the FDA Real-World Evidence (RWE) Program for drugs and biological products.

At the end of this convening, participants will better understand:

- FDA's approach to RWE for regulatory decision-making
- ongoing opportunities and challenges regarding RWE
- future initiatives for promoting the appropriate use of RWE

Workshop Agenda

12:30 pm **Welcome and Overview**
Duke-Margolis Institute for Health Policy

12:35 pm **Overview of FDA's RWE Program and Future Directions**
FDA

1:15 pm **Fireside Chat with FDA**

Session description: FDA staff will reflect on accomplishments and discuss current and future RWE-related activities such as guidance documents, research projects, and PDUFA VII commitments.

1:35 pm **Break**

1:50 pm **Session 1: Opportunities and Challenges When using Real-World Data**

Session description: In this session, panelists will discuss key considerations for utilizing real-world data (RWD) including promising opportunities, challenges and potential solutions within the current landscape. Panelists will discuss the role of artificial intelligence in this space, collaborative approaches to RWD data sourcing and curation, as well as whether there is an emerging consensus among regulators for key concepts such as data "reliability" and "relevance".

Opening Remarks
Moderated Panel Discussion and Q&A

3:00 pm **Break**

3:15 pm **Session 2: Methodological Considerations for RWE**

Session description: In this session, panelists will discuss pressing methodological considerations, challenges and potential solutions for generating RWE for regulatory decision-making. Panelists will highlight opportunities to incorporate RWD into randomized controlled trials, in addition to non-randomized methodological approaches.

Opening Remarks
Moderated Panel Discussion and Q&A

4:25 pm **Closing Remarks**
FDA

4:30 pm **Adjournment**

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