



# Public Meeting on Benefit-Risk Framework Implementation



September 18, 2017

8:00 – 9:00 am

## Registration

9:00 – 9:05 am

## Welcome

Graham Thompson  
Office of Program and Strategic Analysis (OPSA), Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

9:05 – 9:15 am

## Opening Remarks

Richard Moscicki, M.D.  
CDER, FDA

## Session 1: Regulatory and Industry Experiences with Benefit-Risk Assessment Approaches

9:15 – 10:00 am

## FDA

This session reflects upon FDA's Benefit-Risk Framework and its implementation into the drug review process

### Overview of FDA's Benefit-Risk Framework and its Implementation

Sara Eggers, Ph.D.  
OPSA, OSP, CDER, FDA

### Regulatory Case Study

Mary Thanh Hai, M.D.,  
Office of New Drugs (OND), CDER, FDA

### Assessing the Implementation of FDA's Benefit-Risk Framework

Valerie Overton  
Eastern Research Group, Inc.

10:00 – 10:15 am

## International Council for Harmonization

This session provides an overview of the ICH efforts to revise ICH guidance "M4E: The CTD- Efficacy" and standardize the presentation of benefit-risk information in regulatory submissions, providing greater specificity on the format and structure of the benefit-risk information.

Patrick Frey, M.P.P.  
OND, CDER, FDA

10:15 – 10:30 am

## Break

10:30: – 11:00 am

## International Regulatory Agencies

This session elicits experiences and perspectives from other regulatory agencies on implementing benefit-risk assessment approaches to support drug development and evaluation.

Francesco Pignatti, M.D.  
European Medicines Agency (EMA)

Clause Bolte, M.D.  
Swissmedic

11:00 – 11:30 am **Pharmaceutical Industry**

This session asks pharmaceutical developers to share their experiences with FDA's Benefit-Risk Framework, as well as efforts they have undertaken to implement benefit-risk assessment approaches into drug development.

Tarek Hammad, M.D., Ph.D.  
EMD Serono, Inc.

Rebecca Noel, Dr.PH, MSPH  
Eli Lilly and Company

11:30 am – 12:00 pm **Panel Discussion and Q&A**

Panel includes Session 1 presenters plus:

Jeff Roberts, M.D.  
Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER), FDA

12:00 – 1:00 pm **Lunch**

**Session 2 – Approaches to Incorporating Patient Perspectives into Benefit-Risk Assessment**

1:00 – 1:45 pm **FDA Experiences and Perspectives**

This session provide an overview of FDA's on-going efforts to incorporate patient experiences and perspectives to support regulatory decision making.

Theresa Mullin, Ph.D.  
Office of Strategic Programs (OSP), CDER, FDA

Telba Irony, Ph.D.  
Office of Biostatistics and Epidemiology (OBE), CBER, FDA

Martin Ho, M.S.  
Office of Office of Surveillance and Biometrics, Center for Devices and Radiological Health (CDRH), FDA

1:45 – 2:30 pm **Stakeholders' Perspectives**

This session discusses other stakeholders' on-going efforts to incorporate patient experiences and perspectives into drug development.

Brett Hauber, Ph.D.  
Research Triangle Institute

Leah McCormick Howard, J.D.  
National Psoriasis Foundation

Alicyn Campbell, M.P.H.  
Genentech

2:30 – 3:00 pm **Panel Discussion and Q&A**

3:00 – 3:15 pm **Break**

### **Session 3 – Special Topics in Benefit-Risk Assessment**

3:15 – 3:30 pm **Advancing Decision Science Methods for Regulatory Use**  
Baruch Fischhoff, Ph.D.,  
Carnegie Mellon University

3:30 – 3:45 pm **Potential Areas for Quantitative Benefit-Risk Approaches**  
Richard Forshee, Ph.D.  
OBE, CBER, FDA

3:45 – 4:00 pm **Communicating Benefit-Risk to the Public**  
Lisa Schwartz, M.S., M.D., & Steve Woloshin, M.S., M.D.  
Dartmouth Institute for Health Policy and Clinical Practice and Dartmouth Medical School

4:00 – 4:30 pm **Panel Discussion and Q&A**

Panel includes Session 3 Presenters plus

Peter Stein, MD,  
OND, CDER, FDA

Bennett Levitan, M.D. Ph.D.  
Janssen R&D Pharmaceutical Companies of Johnson & Johnson

Clause Bolte, M.D.  
Swissmedic

4:30 – 4:50 pm **Open Public Comment**  
Graham Thompson,  
OPSA, OSP, CDER, FDA

4:50 – 5:00 pm **Closing Remarks**  
Theresa Mullin, Ph.D.  
OSP, CDER, FDA