

U.S. Environmental Protection Agency  
Advancing Systematic Review for Chemical Risk Assessment  
Arlington, VA  
December 16–17, 2015

---

## Agenda

**Wednesday, December 16, 2015**

**9:00 – 10:00    REGISTRATION**

10:00 – 10:15    **Opening Remarks and Introduction to Day 1**

**Session I – From theory to practice: Lessons learned from the evaluation of studies of chemical exposures**

10:15 – 10:45    **A tool for evaluating risk of bias in non-randomized studies of interventions (ROBINS-I): development and applications**

Jonathan Sterne | *University of Bristol (via webinar)*

10:45 – 11:15    **Applicability of GRADE to studies of environmental exposures**

Rebecca Morgan | *McMaster University*

11:15 – 11:45    **Risk of bias and causality assessments**

Douglas L. Weed | *DLW Consulting Service LLC*

**11:45 – 12:45    LUNCH BREAK**

12:45 – 1:30    **Adaptation of Risk of Bias Assessment for Environmental Exposures: The IRIS Experience**

Glinda Cooper and Audrey Galizia | *U.S. EPA*

Jane Burns | *Harvard School of Public Health (via webinar)*

Ana Navas-Ascien | *Johns Hopkins University (via webinar)*

Anna Pollack | *George Mason University*

Sharon Sagiv | *University of California, Berkeley (via webinar)*

1:30 – 2:20    **Lessons from the Navigation Guide experience: Developing and evaluating risk of bias tools for exposure metrics in epidemiology studies**

Juleen Lam | *University of California, San Francisco*

**Lessons from the Navigation Guide experience: Issues in evaluating multiple study outcome measures for the same type of effect in systematic reviews**

Tracey Woodruff | *University of California, San Francisco*

2:20 – 3:05    **Q&A/Discussion** [speakers from session + additional discussants]:

Miguel Hernán | *Harvard School of Public Health (via webinar)*

Melissa Perry | *George Washington University*

**3:05 – 3:15    BREAK**

3:15 – 3:55     **Lessons learned in protocol development and implementation of multi-endpoint systematic reviews**  
Daniele Wikoff | *ToxStrategies*

3:55 – 4:15     **Wrap-up**

**4:15             ADJOURN**

## Thursday, December 17, 2015

**9:00 – 10:00     REGISTRATION**

**Session II – Systematic review relating to mechanistic data: What is really needed and how can it be efficiently applied?**

10:00 – 10:15     **Introduction to Day 2**  
Catherine Gibbons | *U.S. EPA*

**Current applications in the field**

10:15 – 10:35     **Approaches for considering mechanistic information in systematic reviews**  
John Bucher | *National Toxicology Program*

10:35 – 10:55     **Analysis of *in vitro* studies**  
Andy Rooney | *National Toxicology Program (via webinar)*

10:55 – 11:15     **Improving systematic review and usability of NexGen/high throughput data in studies of chemical toxicity using AOPs**  
Ed Perkins | *U.S. Army*

11:15 – 11:45     **Q&A/Discussion**

**11:45 – 12:45     LUNCH BREAK**

**Systematic review focused on carcinogenic mechanisms**

12:45 – 1:05     **Key characteristics of carcinogens as a basis for organizing data on mechanisms of carcinogenesis**  
Martyn Smith | *UC Berkeley*

1:05 – 1:25     **Systematic identification of the mechanistic evidence for cancer hazard assessment: Experience of the IARC Monographs programme**  
Kate Guyton | *IARC (via webinar)*

1:25 – 1:45     **Epigenetic alterations induced by genotoxic occupational and environmental known human carcinogenic chemicals: A systematic literature review**  
Ivan Rusyn | *Texas A&M University*

1:45 – 2:15     **Q&A/Discussion**

**2:15 – 2:30      BREAK**

**Application of systematic review principles for linking noncancer mechanistic data to hazard characterization decisions**

2:30 – 2:55      **The adverse outcome pathway as integrating framework for systematic reviews**  
Katherine von Stackelberg | *Harvard Center for Risk Analysis*

2:55 – 3:10      **Examination of human relevance of anti-androgenic effects observed following exposure to dibutyl phthalate**  
Xabier Arzuaga | *U.S. EPA*

3:10 – 3:35      **Noncancer MOA decision points: Examples from the draft formaldehyde inhalation assessment of respiratory tract effects**  
Andrew Kraft | *U.S. EPA*

3:35 – 4:10      **Evidence-based methodologies in toxicology: Application to test methods comparison**  
Katya Tsaioun | *Johns Hopkins University*

4:10 – 4:55      **Q&A/Discussion** [speakers from session + additional discussants]:  
Lyle Burgoon | *U.S. Army Corps of Engineers*  
Deborah Cory-Slechta | *University of Rochester Medical School Center*  
Elaine Faustman | *University of Washington (via webinar)*  
Natalia Garcia-Reyero | *Mississippi State University (via webinar)*  
Daniele Wikoff | *ToxStrategies*

4:55 – 5:15      **Wrap-up**

**5:15              ADJOURN**