

When to Sound an Alarm: Tough Benefit/Risk Assessments that Lead to Decisions of Omission or Commission

11:15am-12:45pm

Moderators: Flavio Vincenti, MD, UCSF, San Francisco, CA, USA. Shirish Huprikar, MD, The Mount Sinai Hospital, New York, NY, USA.

11:15am-11:35am

The Role of the Journal in Keeping the Public Informed

Lindsey Baden, MD, Brigham and Women's Hospital, Boston, MA.

11:35am-11:45am

Audience Discussion

11:45am-12:05pm

Decision Making in Drug Development

Spyros Chalkias, MD, Medical Director, Biogen, Boston, MA, USA.

12:05pm-12:15pm

Audience Discussion

12:15pm-12:35pm

How the FDA Assess Risk and Benefits

Edward Cox, MD, MPH, U.S. Food and Drug Administration, Silver Spring, MD, USA.

12:35pm-12:45pm

Audience Discussion