

# Class Labeling: Implications for Treatment and Challenges to Differentiation in Development

Co-Chairs:

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## Why a Class Labeling Session?

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- Safety is of primary importance when choosing a pharmacological intervention
- A “Class Label” raises an important concern about a group of drugs, but may not sufficiently inform patient-level decision making
- Generating relevant data for an individual medicine, alone or comparatively, would be of use to clinicians—how best to do this?

- This session will
  - Raise key concerns from an Industry and Academic perspective (Romano/Potkin)
  - Discuss context for effective risk communication which may better inform health decision for patients (Fischhoff: Chair, FDA's *Risk Communication Advisory Committee*)
  - Provide regulatory viewpoints (FDA/BfArM), including review evidentiary standards for class labeling (Laughren/Broich)
  - Discuss implications for drug development and post-marketing data generation (All)

# Industry Perspective on Class Labeling: Opportunities and Challenges

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# Key Questions

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- What makes a “class” a “class”?
- What is the evidence base for class labeling?
- Can a class label be altered/modified?
- Is there an opportunity to include comparative data in a product label?
- How can we contribute to more effective prescriber decision making?

# What Constitutes a Class?

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- Physicochemical similarities
  - Ergot derivatives (certain dopamine agonists)
  - Benzodiazapines
- Pharmacology
  - SSRIs
- Therapeutic indication
  - Anti-epileptic drugs
  - Antidepressants
  - Antipsychotics

# Could The Following Activities Modify a Current Class Label?

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- Demonstrating differential safety profile in appropriately designed and powered trials
- Conducting preclinical experiments to elucidate any differential effects
- Demonstrating a neutral or beneficial effect on the outcome of interest
  - Effects on dimensions of metabolic syndrome, as with certain atypical antipsychotics.

# Could the Following Activities Prevent a Class Label?

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- Relevant preclinical investigations
  - Characterize mechanism early
- Development programs
  - Incorporate robust prospective evaluations
  - Ensure adequate monitoring plans and thorough clinician evaluations of key events
- Post-Approval Commitments
  - Observational, LST, RCT
- Post-marketing pharmacovigilance

- Provide context for patient-level decisions
  - Help manage vulnerable/at-risk patients
- Express meaningful differential effects
- Contribute data which may refine treatment guidance/guidelines
- Help inform value assessments by stakeholders
  - Payers, formularies, HTA

- Key safety considerations impact development/investment decisions
- Undifferentiated medicines less likely to advance
  - Product specific data on key safety parameters may contribute to appropriate therapeutic positioning
- Known class concerns may place greater focus on developing therapies for relevant subpopulations

**THANK YOU**



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