Assessment of Pharmacologic-induced Increases in BP During Clinical Development: Is there a need for more intensive systematic BP evaluation and how should this be considered?

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Why Hold a Think-Tank

- Blood pressure is an area of increased scientific and regulatory focus
- Torcetrapib, sibutramine
- Mirabegron FDA AC discussion

TOPICS

Session I: Drug-induced BP Increases: Clinical Implications

Session II: How to Establish Risk Boundaries

Session III: Preclinical Models

Session IV: The Role of Phase I Data and Technical Aspects of BP Measurement During Development

Session V: Key Issues

Program Committee

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Think-Tank

- Short, provocative talks focused on a key issue
- Main focus is on discussion
- Chairs keep discussion focused
- Lead discussant gets the talk started with a one minute identification of key points
- Recognized to speak- cards and microphones