

# CSRC and MDEpiNet Thinktank Meeting:

## “The Role of Endpoint Adjudication in Medical Device Clinical Trials”



Cardiac Safety Research Consortium



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Scientific Programs Committee,  
Cardiac Safety Research Consortium  
President, ACI Clinical



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# Program Committee

- FDA
  - Andrew Farb
  - Ken Skodacek
  - Bram Zuckerman
- Academia
  - Britt Barham, Duke
  - Don Cutlip, Harvard
  - Sharon Lise-Norman, Harvard
  - Mitch Krucoff, Duke
  - Peter Kowey, Lankenau
- Industry, Service Provider
  - Bev Lorell, King and Spalding
  - Philip Sager, Sager Consulting
  - Roseann White, Abbot
  - Jonathan Seltzer, ACI Clinical
- Special Recognition
  - Kadie Maness, Duke
  - Valarie Morrow, Duke



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# Agenda

Session I: Tailoring best practices for the evaluation of endpoints in clinical device trials.

Session II- Practical Issues in the adjudication of events in device trials: Case studies which highlight the issues involved with adjudicating event occurrence, causality, blinding, operator variability, committee composition, endpoint definitions, gathering endpoint data, and clinical study operational issues.

Session III: The Role of Adjudication in Efforts to Streamline the Process of Making Beneficial Devices Available to the Public: Regulatory and Reimbursement Issues



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# Meeting Overview

- **Short provocative presentations**
  - Presenters have promised to stay within their allotted time limit 😊
  - End of Session Discussant will summarize major points
  - Moderated Discussion to follow
- **Robust discussion time**
  - Discussion is key– AUDIENCE PARTICIPATION IS CRUCIAL
  - Multiple viewpoints
  - Taken in the order self-identified
    - Speakers: Please flip name cards
    - Audience: Please approach microphone
- **Goal**
  - Discussion to air various and conflicting viewpoints
  - Areas of Consensus will be summarized
  - Publication committee will author document for AHJ



# Housekeeping

- Breaks: mid-morning, lunch, mid-afternoon
  - Breaks are in the lobby
- Wi-Fi is available
- Please silence phones



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