

Pre-Meeting Workshop: Methods

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PRE-
MEETING
WORKSHOP
October 21

Objectives:

- To discuss study of medical devices in the observational setting, including methods framework and causal inference
- To review data sources for studies for medical devices and the role of UDI, external comparator studies, and diagnostic efficacy

| TIME | TOPIC | PRESENTER |
|----------------------|---|---|
| Registration | | |
| 12:00pm-12:30pm | Attendee Introductions | |
| 12:30pm-1:00pm | The Basics of Studying Medical Devices in an Observational Setting – Epi 102 | Mary Beth Ritchey (RTI Health Solutions) |
| 1:00pm-1:30pm | Methods Framework and Causal Inference | Sharon-Lise Normand (Harvard) |
| 1:30pm- 2:00pm | Data Sources for Studies of Medical Devices and the Role of UDI– positives, particularities, and pitfalls | Eric Barrette (Medtronic) |
| 2:00pm-2:15pm | | |
| Break | | |
| 2:15pm-2:45pm | Spotlight on Attendees - your case examples and challenges | All; Facilitated by Chairs |
| 2:45pm-3:30pm | External Comparator Studies: Methodological Considerations and Working Case Example | Christina Mack (IQVIA) Kim Kelly (Bioventus) |
| 3:30pm-4:15pm | Active Surveillance: Methods, Lessons Learned and Case Examples | Michael Matheny (Vanderbilt) |
| 4:15pm-4:45pm | Diagnostic Efficacy: How to Consider Real World Factors in Assessing the Efficacy of Devices and Diagnostic Tools | Hannah Mamuszka (Alva10) |
| 4:45pm-5:00pm | Close | |