



Basel Epidemiology Seminar

BBS
Basler Biometric Section

Causal Inference in Drug Development: Why, When, How?

BBS/BES Seminar

August 21, 2019 from 9:00-16:00

Location: Roche, Grenzacherstrasse 124 | Bldg 1 | Floor 2

This Seminar is free of charge. However, please register via the BES homepage: <http://bes.ceb-institute.org> Registration closes on August 9, 2019

Agenda

- 08:30 – 9:00** **Registration**
- 09:00 – 9:10** **Welcome from the organizing committee**
(Thibaut Sanglier, Simon Wandel)
- 9:10-10:40** **Causal Inference in Drug Development – Why or why not**
(Session chair: Simon Wandel, Novartis)
Beyond intention-to-treat. Causal inference guidelines for causal inference.
(Miguel Hernan, Harvard University)
The Final ICH E9(R1) E9 addendum (Christine Fletcher, Amgen)
A regulator's perspective (Frank Pétavy, EMA)
- 10:40 – 11:10** **Coffee break**
- 11:10 – 12:30** **Case studies 1** (Session chair: Giusi Moffa, University of Basel)
Adverse reactions confounded by prior medication: (how) can causal inference solve the problem? (Valentine Jehl, Novartis)
Treatment sequencing and effectiveness: challenges and considerations (Thibaut Sanglier, Roche)
- 12:30 – 13:20** **Lunch**
- 13:20 – 14:40** **Case studies 2** (Session chair: Heinz Schmidli, Novartis)
Principal stratification techniques in the context of regulatory decision making
(Nikolaos Sfikas, Novartis)
Implementing the Principal Stratum estimand strategy using Instrumental Variable methods: An emulation of the CANTOS trial (Jack Bowden, University of Bristol)
- 14:40 – 15:00** **Coffee break**
- 15:00 – 16:00** **Panel discussion: Where do we go from here?**
Session chairs: Sigrid Behr (Novartis) and Marisa Bacchi (J&J)
Including all Speakers
- 16:00** **Closure of the meeting**

