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](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)

(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