

The use of external data for decision making

BBS Spring Seminar

Friday, May 5, 2017 from 9:00-17:00

Actelion Auditorium

Hegenheimermattweg 95, 4123 Allschwil

The Seminar fee is 100 CHF for industry and free for all others

Please register by sending an email in advance to fred.sorenson@xcenda.com

Registration will close on April 27, 2017



Program

- 08:30 – 9:00** **Registration**
- 09:00 – 9:10** **Welcome**
Uli Burger, BBS President
- 9:10-10:40** **First Session: Introduction and overview on future data**
Session chair: Marcel Wolbers, Roche
- Real world data and clinical trials: Promises, Confusions, Limitations, Solutions*
Lars Hemkens, University of Basel
- The reality of real world data?*
David Evans, Roche
- Data, Data Everywhere: But where is the data that will create key insights?*
Mikael Eliasson, Roche
- 10:40 – 11:10** **Coffee break**
- 11:10 – 12:40** **Second Session: Positions on the use of such data**
Session chair: Achim Guettner, Novartis
- Issues with the use of external data in drug approval*
Norbert Benda, BfArM
- Use of registries and observational data in the benefit assessment of medical interventions* Ralf Bender, IQWiG
- Threshold-crossing: A Useful Way to Establish the Counterfactual in Clinical Trials*
Frank Bretz, Novartis
- 12:40 – 13:30** **Lunch**
- 13:30 – 15:00** **Third Session: Practical examples**
Session chair: Amanda Ross, Swiss Tropical and Public Health Institute, Basel
- Dynamic borrowing of historical data: Performance and comparison of existing methods based on a case study* David Dejardin, Roche
- Strategies for synthesizing real world evidence effectively in pharmaceutical industry*
Athula Herath and Michael Seewald, Novartis
- Lessons learned from interactions with the Pharmacovigilance Risk Assessment Committee of EMA* Lilla Di Scala, Actelion

15:00 – 15:30 **Coffee break**

15:30 – 17:00 **Fourth Session: Presentation of Final Recommendations from IMI GetReal Initiative, RWD and RCTs, and Panel discussion with all Speakers** Session chair: Marisa Bacchi, Actelion

Eva Didden, University of Bern, Institute of Social- and Preventive Medicine (ISPM);
IMI GetReal - Real-Life Data in Drug Development

“IMI GetReal: Three years on!”

Sebastian Schneeweiss, Harvard Medical School (via live video link-up to the US)

“RWD studies and RCTs – lessons learned and what do they have in common”

**Panel discussion with all speakers and Tim Friede, Dept. of Medical Statistics,
University Medical Center Göttingen, Germany**

17:00 **End of the meeting**
Uli Burger, BBS President