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