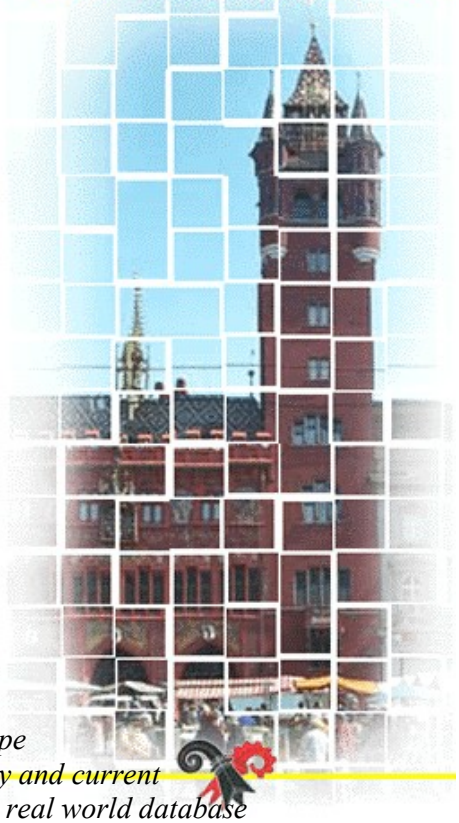
First Announcement

Please take note of the agenda for the upcoming seminar:

BBS
Basler Biometric Section



Synthetic controls – what do we need and how far can we go?

BBS Spring Seminar

➔ May 10, 2019 from 9:00-16:30
Roche Auditorium, Viaduktstrasse, Basel

The Seminar is this year free of charge. For organizational reasons please register by sending an email in advance to fred.sorenson@xcenda.com
Registration will close by Friday, April 26, 2019

Agenda

08:30 – 9:00 **Registration**

09:00 – 9:10 **Welcome,** Uli Burger, BBS President

9:10-10:40 **First Session: What is needed?**
This session should provide an overview on the landscape of synthetic controls. It will summarize regulatory policy and current methodology and provide an example for a high quality real world database
Confirmed speakers are Thomas Brookland, Roche, ,Kaspar Rufibach, Uli Burger, Roche, Somnath Sarkar, Flatiron, and Thibaut Sanglier, Roche.

10:40 – 11:10 ***Coffee break***

11:10 – 12:40 **Second Session: Examples of synthetic controls**
This session should provide examples of using synthetic controls in clinical development today and highlight the quality of such controls
Confirmed speakers are Laurence Colin, Cornelia Dunger-Baldauf, Charis Papavassilis, Novartis, Gonzalo Duran-Pacheco and Chris Harbron, Roche

12:40 – 13:30 ***Lunch***

13:30 – 15:00 **Third Session: Rejoinders from academia and regulatory**
This session will consist of rejoinders on the talks of the morning sessions from regulatory, HTA and academia
Confirmed speakers are Norbert Benda, BfArM, Jan Müller-Berghaus, PEI, Anja Schiel, Norwegians Medicine Agency, Chair BSWP, Kit Roes, UMC Utrecht, MEB and EMA BSWP and Meinhard Kieser, University of Heidelberg

15:00 – 15:30 ***Coffee break***

15:30 – 16:30 **Fourth Session: Panel discussion**
This session will open up a panel discussion with all speakers and the audience.

16:30 **Closure of the meeting**

Program

08:30 – 9:00 **Registration**

09:00 – 9:10 **Welcome**
Uli Burger, BBS President

9:10-10:40 **First Session: What is needed?**
Session Chair: Simon Wandel, Novartis
Thomas Brookland (Roche): *Global regulatory policy overview on RWD*
Kaspar Rufibach, Uli Burger (Roche): *Overview talk on the synthetic controls*
Somnath Sarkar, (Flatiron): *Introduction to the concepts of Flatiron*
Thibaut Sanglier (Roche): *Clinical measures with real-world data*

10:40 – 11:10 ***Coffee break***

11:10 – 12:40 **Second Session: Examples**
Session chair: Dominik Heinzmann, Roche
Laurence Colin (Novartis): *Synthetic controls for safety assessments in early development*
Cornelia Dunger-Baldauf, Charis Papavassilis (Novartis): *For the sake of the patient – reducing placebo exposure by using historical controls*
Gonzalo Duran-Pacheco (Roche): *Electronic Health Records used to Derive Control Arms for Single-Arm Oncology Trials: Proof-of-Concept using Randomized Controlled Trials in lung cancer*
Chris Harbron (Roche): *Decision framework for regulatory approval*

12:40 – 13:30 ***Lunch***

13:30 – 15:00 **Third Session: Rejoinders from academia and regulatory**
Session chair: Kaspar Rufibach, Roche
Rejoinder from academia – Meinhard Kieser, University of Heidelberg (tbc)
Rejoinder from regulatory statistics – Norbert Benda, BfArM & Benjamin Hofner, PEI
Rejoinder from regulatory statistics – Kit Roes, UMC Utrecht, MEB and EMA BSWP
Rejoinder from regulators clinical – Jan Müller-Berghaus, PEI
Rejoinder from HTA – Anja Schiel, Norwegians Medicine Agency, Chair BSWP

15:00 – 15:30 ***Coffee break***

15:00 – 16:30 **Fourth Session: Panel discussion**
Session chair: Marisa Bacchi, J&J
Including all Speakers

16:30 **Closure of the meeting**