First Announcement
Please take note of the agenda for the upcoming seminar:

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