

7th EFSPi Regulatory Statistics Workshop
14th – 15th September 2022
Face-to-face meeting in Basel, Switzerland



Dates and times (CET):

Tuesday, 14th September 2022, 9-17 (+ 2h wine tasting)

Wednesday, 15th September 2022, 9-18

EFSPi is pleased to announce the 7th regulatory statistics workshop that will take place on 14th-15th September 2022. We are planning the event in Basel with a focus on in-person attendance. However, sessions will also be broadcasted and recorded (all pending speaker approval).

The workshop will discuss opportunities and challenges of statistical topics in drug development between regulators, academics, and industry. The two days will be filled with various formats such as presentations, roundtable discussions, the well-established short topic session, lots of coffee breaks, and the legendary wine tasting.

Members of the Scientific Committee are: Egbert Biesheuvel, Hans Ulrich Burger, Christoph Gerlinger, Kaspar Rufibach, Emmanuel Zuber, Elina Asikanius, Andreas Brandt, Randi Gron, Cecilia Hedlund, Lorenzo Hess, Armin Koch, Helle Lynggaard, Eftychia-Eirini Psarelli, Khadija Rantell, Kit Roes, Anja Schiel, Viktoriya Stalbovskaya, David Wright.

Registration: Will open later. We will offer an option for in-person or virtual attendance.

On 13 September the Basel Biometric Society offers a full day training course “Advanced adaptive confirmatory clinical trial designs, with R practicals using rpart”, find the announcement here. We invite all participants who intend to travel to Basel to consider registration for that training as well!

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BBS training course

13th September 0900-1730.

“Advanced adaptive confirmatory clinical trial designs, with R practicals using rpact”. Announcement and registration available on www.bbsbasel.ch.

7th EFSPI regulatory statistics workshop, Day 1

14th September, 0900-1700 (+ wine tasting).

Time	Duration	Presentation
0900-0920	20	Arrival
0920-0930	10	Justine Rochon (EFSPI president) Opening remarks
0930-1100	90	Introductory Keynotes: Regulator on "What happened in the last two years in regulatory and HTA landscape"
1100-1130	30	Coffee Break
1130-1230	60	Q&A and discussion: 2-3 smaller groups in separate rooms, moderated by 1 industry + 1 regulatory member.
1230-1500	150	EFSPI SIGs poster sessions & lunch
1500-1700	120	Subgroups generated by post-baseline variables: can we expect causal conclusions?
1700-1900	120	Wine tasting, organized by Uli Burger and Emmanuel Zuber

7th EFSPI regulatory statistics workshop, Day 2

15th September, 0900-1800.

Time	Duration	Presentation
0900-1100	120	Regulatory and HTA landscape for complex innovative designs in Europe - how can we move towards harmonization? Q&A and panel discussion (65min): Speakers + Anja Schiel + Kit Roes.
1100-1130	30	Coffee Break
1130-1315	105	Generalizability and external validity: How to generate evidence about a treatment effect? Q&A and panel discussion (50min).
1315-1430	75	Lunch
1430-1600	90	Role of statistics / quantitative science in regulatory decision-making. Q&A and panel discussion (50min): Speakers.
1600-1630	30	Coffee Break
1630-1750	110	Uli Burger & Armin Koch + panel with all regulators Short topic session: three short topics, presentation on 2 slides, get input from panel please send proposals until 16th August to kaspar.rufibach@roche.com
1750-1800	10	Kaspar Rufibach (Roche, local organizing and scientific committee) Closure