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

Dates and times (CET):
Wednesday, 14th September 2022, 9-17 (+ 2h wine tasting)
Thursday, 15th September 2022, 9-18
Date of this program version: 8th September 2022

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 venue is the Biozentrum, find address and directions here.

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 with panel discussions, a poster session of the EFSPI / PSI SIGs, 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, Lorenzo Hess, Armin Koch, Helle Lynggaard, Eftychia-Eirini Psarelli, Khadija Rantell, Kit Roes, Anja Schiel, Viktoriya Stalbovskaya, David Wright.

Registration: Please register here: https://forms.gle/HVvyGRBzoHkiGGDc6. The registration fee for the entire event for in-person attendance is €250 (comprises all sessions, lunches, coffee breaks, wine tasting), irrespective of how many days you attend and how many meals you enjoy. If you only plan to attend virtually the fee is €50. As part of the registration process we would like to ask you to make a payment of €50 or €250 (depending on your mode of attendance) to EFSPI as contribution to the 7th EFSPI Regulatory Statistics Workshop. Please use the reference “Regulatory 22”. Due to this informal registration process we can keep the price low. Therefore we cannot accept credit card transfers and we cannot provide you with a formal invoice after the payment. In case you have any question on your payment, please contact Egbert Biesheuvel (egbert.biesheuvel@viatris.com).

Bank details: European Fed Stat Pharm Ind, **Bank**: HSBC, **IBAN**: GB53HBUK40127677385084, **BIC**: HBUKGB4B, **Reference**: Regulatory 22.

Participation of scientific committee members, speakers & panel discussants, colleagues at regulatory agencies, and students is free, see here for details. In addition, some companies have block bookings (for F2F + virtual or virtual participation only, see here for details and please still register using the above link!). If your company is interested in getting a collective registration for virtual please reach out to egbert.biesheuvel@viatris.com.

We answer a few questions regarding registration (block bookings, change from face-to-face to virtual attendance, etc.) here. Please read this FAQ page first before you reach out to the organizers with questions.

For those who have registered and paid the registration fee a link to a Zoom TC will be shared a few days prior to the event.

In the program below it is indicated who will only attend virtually.

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7th EFSPI regulatory statistics workshop, Day 1

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

Time	Duration	Presentation
0900-0920	20	**Arrival**
0920-0930	10	**Opening remarks** Justine Rochon (EFSPI president)
0930-1100	90	**Introductory Keynotes: Regulator on "What happened in the last two years in regulatory and HTA landscape"** Chairs: Randi Gron (Novo Nordisk) & Eftychia-Eirini Psarelli (EMA) Talk 1 (25min): Kit Roes, EMA & Radboud UMC : Guidances / restructuring / new ways to interact with stakeholders Talk 2 (25min): Frank Bretz, Novartis: What happened in the last two years in industry? Talk 3 (20min): Anja Schiel, EMA & Norwegian Medicines Agency: Selection of "HTA hot topics" that need discussion in coming months Talk 4 (20min): Jasvinder Singh, MHRA: Which parts of the regulatory flexibility introduced in the pandemic are here to stay (potential examples: raw data submission / rapid review)?
1100-1130	**30**	**Coffee Break**
1130-1230	60	**Q&A and discussion of morning session.** Chairs: Randi Gron (Novo Nordisk) & Eftychia-Eirini Psarelli (EMA)
1230-1500	150	EFSPI SIGs poster sessions & lunch. Details see below.
1500-1700	120	**Postbaseline subpopulation analyses: Known to be improper, but frequently done. Can we fix them?** Chairs: Mouna Akacha (Novartis) and Khadija Rantell (MHRA) Talk 1 (25min): Björn Bornkamp, Novartis: relevant scientific questions for drug development Talk 2 (25min): Anja Schiel: relevant scientific questions for HTA Q&A and panel discussion (70min): Speakers + Mats Stensrud (EPFL Lausanne), Fabrizia Mealli (Uni Florence), Kaspar Rufibach (Roche), Steve Ruberg (Analytix thinking), Wanje Sun (FDA, virtual), Florian Klinglmüller (AGES)
1700-1900	**120**	**Wine tasting, organized by Uli Burger and Emmanuel Zuber**

7th EFSPI regulatory statistics workshop, Day 2

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15th September, 0900-1800.

Time	Duration	Presentation
0900-1100	120	**Regulators and HTA bodies for new designs in Europe - how to deal with different priorities, especially for new design types?** Chairs: Christoph Gerlinger (Bayer) and Andreas Brandt (BfARM) Talk 1 (15min): Dieter Haering & Marius Thomas, Novartis: Neos pediatric trial of Kesimpta and Mayzent in multiple sclerosis. Talk 2 (20min): Theodor Framke (EMA & Med Hochschule Hannover): Regulatory view on complex innovative designs Talk 3 (20min): Anders Viberg (Dental and Pharmaceutical Benefits Agency, Sweden): HTA's view on complex innovative designs Q&A and panel discussion (65min): Speakers + Anja Schiel + Kit Roes + Katharina Hees + Franz Koenig.
1100-1130	**30**	**Coffee Break**
1130-1315	105	**Generalizability and external validity: How to generate evidence about a treatment effect?** Chairs: Kaspar Rufibach (Roche) and Kit Roes (Radboud University Medical Center & EMA) Talk 1 (20min): Stephen Senn, Statistical Consultant: Clinical trials are about comparability, not generalizability. Talk 2 (20min): Florian Klinglmüller, AGES: Regulatory view on generalizability. Talk 3 (20min): Joshua Ray, Roche: Let them in or build a wall? Transporting inferences across borders Q&A and panel discussion (50min): Speakers + Rob Hemmings.
1315-1415	**60**	**Lunch**
1415-1600	105	**Role of statistics / quantitative science in regulatory decision-making.** Chairs: Emmanuel Zuber (Novartis) and Benjamin Hofner (PEI) Talk 1 (15min): Aloka Chakravarty (FDA, virtual): Generating Actionable Insights Using RWD during COVID-19 pandemic. Talk 2 (15min): John Johnston (MHRA): What role should statistics play in regulatory decision-making? Talk 3 (15min): Yuki Ando (PMDA, virtual): Role of biostatisticians in regulatory decision making: the current discussion in Japan. Talk 4 (15min): Rajeshwari Sridhara (FDA, virtual): Experience with the project SignifiCanT. Q&A and panel discussion (30min): Speakers + Kit Roes + Anja Schiel + Rob Hemmings
1600-1630	**30**	**Coffee Break**

1630-1750	110	**Short topic session: three short topics, presentation on 2 slides, get input from panel (= all regulators).** Chairs: Uli Burger (Roche) & Armin Koch (U Hannover & EMA) Topic 1: A. Schulze (Bayer): methodological aspects of the war in Ukraine for clinical trials. Topic 2: O. Sailer, S. Wojciekowski, D. Neubacher (Boehringer-Ingelheim): Bayesian borrowing from simulated paediatric patients with type 2 diabetes mellitus Send further proposals until 16th August to kaspar.rufibach@roche.com
1750-1800	10	**Closure** Kaspar Rufibach (Roche, local organizing and scientific committee)

PSI / EFSPI SIGs that will present a poster in the lunch session on 14 September:

eSIG	**Poster presenter**
Regulatory eSIG	Juergen Hummel (PPD)
Data Sharing eSIG	Janice Branson (Novartis)
Onco Estimands eSIG	Stefan Englert (J&J)
Vaccines	An Vandebosch (J&J)
HTA (2 posters)	Anders Gorst-Rasmussen (Novo Nordisk) Lara J. Wolfson (MSD)
Launch & Lifecycle	Jenny Devenport (Roche)
Visualization	Alexander Schacht (Veramed)