

5th EFSPi Regulatory Statistics Workshop 12th/13th October 2020



Dates: Monday, 12th October 2020, 14:00-16:35 (CEST)
Tuesday, 13th October 2020, 14:00-16:35 (CEST)

Webinar: dial-in details will be communicated to registered participants

EFSPi is pleased to announce the 5th regulatory statistics workshop on 12th/13th October 2020. Given the COVID-19 situation the scientific committee has decided to make this a virtual workshop this year, consisting of two webinars.

The workshop will discuss opportunities and challenges of statistical topics between regulators, academics, and industry. We plan for two webinar sessions devoted to topics that are key in handling the impact of COVID-19 on drug development. We also allocate time for questions and discussion.

Members of the Scientific Committee are: Egbert Biesheuvel, Hans Ulrich Burger, Christoph Gerlinger, Kaspar Rufibach, Emmanuel Zuber, Andreas Brandt, Randi Gron, Maria Grünwald, Cecilia Hedlund, Lorenzo Hess, Benjamin Hofner, Armin Koch, Khadija Rantell, Kit Roes, Ina-Christine Rondak, Aldana Rosso, Anja Schiel, Steven Teerenstra.

Both webinars are free of charge, but we ask to you register. A link for dial-in will be shared upon registration.

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12th October 2020 - Webinar 1: Data monitoring committees – evolving their role in a changing drug development landscape

Registration link: https://docs.google.com/forms/d/e/1FAIpQLSch2TNYpB6Z0IgxZ_386oT-igMtUNZ1Qgfta3mBLa6MspZDg/viewform

14:00 – 14:10 **Stefan Driessen (EFSPI president)**

Welcome and scene setting

14:10 – 14:30 **Steven Teerenstra (Radboudumc & EMA Biostatistics Working Party)**

The new EMA Q&A document on data monitoring committees

14:30 – 14:45 **Paul Gallo (Novartis)**

An example of a difficult interim decision – what should be the role of the iDMC in ensuring trial integrity?

14:45 – 15:00 **Lisa Squassante (Roche)**

Use of futility interim boundaries to inform production or portfolio decisions

15:00 – 15:15 **Break**

15:15 – 15:30 **Thomas Jaki (MRC Cambridge Biostatistics Unit)**

Role of iDMC for complex clinical trials, incorporating portfolio decisions

15:30 – 15:45 **Janet Wittes (Statistics Collaborative Inc.)**

Navigating between sponsor, iDMC, and regulators

15:45 – 16:00 **Hans Ulrich Burger (Roche)**

iDMC in the context of adaptive designs

16:00 – 16:30 **Panel discussion (all speakers + Tom Fleming, University of Washington)**

All speakers

16:30 – 16:35 **Hans Ulrich Burger (EFSPI council member and “local” organizing committee)**

Closure

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13th October 2020 - Webinar 2: Estimands – emerging questions now that we are using the framework

Registration link:

https://docs.google.com/forms/d/e/1FAIpQLSdlqa1_T9lqMboJwOO3vAhrhp9TbNKKLX4AO2beFgwVfBtdGA/vi/ewform

- 14:00 – 14:10 **Egbert Biesheuvel (EFSPI council member and “local” organizing committee)**
Welcome and scene setting
- 14:10 – 14:30 **Finbarr Leacy (Health Products Regulatory Authority, Ireland)**
Regulatory update: learnings, planned guideline updates, and recommendations & asks for industry
- 14:30 – 14:50 **Vivian Lanius (Bayer), Armin Schüler (Merck KGaA), David Wright (AstraZeneca)**
Feedback from EFSPI / EFPIA estimand implementation working group
- 14:50 – 15:00 **Break**
- 15:00 – 15:45 **Impact of COVID-19 on clinical trials and estimands: examples and general considerations**
Yongming Gu (Eli Lilly): Using a mix of strategies in handling intercurrent events and missing values for studies impacted by the COVID-19 pandemic

Guenther Mueller-Velten, Yi Wang, Melanie Wright (Novartis): Impact of COVID-19 and risk mitigation in a global cardiovascular outcomes trial
- 15:45 – 16:30 **Panel discussion**
All speakers
- 16:30 – 16:35 **Kaspar Rufibach (“local” organizing committee)**
Closure

We look forward to your participation!