

2nd EFPSI Workshop on Regulatory Statistics



October 5-6, 2017 Basel (CH)

After a very successful 1st workshop on regulatory statistics in September 2016, EFPSI will organise its 2nd regulatory workshop on October 5th and 6th, 2017

Our Statistical Workshop will be dedicated to opportunities and challenges of statistical topics between regulators, academics and industry with dedicated time for interaction and discussion.

The Scientific Committee consists of: Norbert Benda, Egbert Biesheuvel, Hans Ulrich Burger, Christoph Gerlinger, Rantell Khadija, Armin Koch, Franz König, Frank Petavy, Kaspar Rufibach, Ferran Torres, Thomas Yaki and Emmanuel Zuber.

Outline of the Agenda

Thursday October 5

- 13:30 Welcome**
- 13:40 Session 1: Multiplicity: FDA guideline**
- Session 2: Estimands: ICH 9 addendum**
- 15:10 Coffee break**
- 15:40 Session 3: Estimands: First real life experience**
- Panel Discussion**
- 17:30 Reception**

Friday October 6

- 8:45 Session 4: Predictive biomarkers/companion diagnostics for therapeutic decision making**
- 10:15 Coffee break**
- 10:45 Session 5: Role of early development in regulatory approval**
- 12:15 Lunch break**
- 13:00 Session 6: Open disease specific drug development issues**
- 14:30 Coffee break**
- 15:00 Session 7: Contributed short topics – discussions**
- 16:30 Closure of the meeting**



Venue

Bildungszentrum 21
Missionsstrasse 21
CH – 4055 Basel
Switzerland

Registration Costs

Fee includes lunch & refreshments

Early bird before or on 1st of August

Industry	€250
Academic	€175

After 1st of August

Industry	€300
Academic	€225

TO REGISTER PLEASE GO TO:

www.efspi.org

(expected to be open soon)

Or contact:

EFPSI Secretariat
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efspi@kingstonsmith.co.uk

For information regarding the scientific content, contact one of the members of the Scientific Committee

Proposals for short topics for Session 7, please contact either Armin Koch (koch.armin@mh-hannover.de) or Hans Ulrich Burger (hans_ulrich.burger@roche.com) by August 3

