

2nd EFSPI 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, Khadija Rantell, Armin Koch, Franz König, Frank Petavy, Kaspar Rufibach, Ferran Torres, Thomas Jaki and Emmanuel Zuber.

Outline of the Agenda

Thursday October 5

- 13:30 Welcome**
- 13:40 Session 1: Multiplicity: FDA guideline**
- Session 2: Estimands: ICH E9 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: Role of early development in regulatory approval**
- 10:15 Coffee break**
- 10:45 Session 5: Predictive biomarkers for therapeutic decision making**
- 12:30 Lunch break**
- 13:30 Session 6: Open disease specific drug development issues**
- 14:45 Coffee break**
- 15:00 Session 7: Contributed short topics – discussions**
- 16:30 Closure of the meeting**



Venue

Oekolampad Church
Schönenbuchstrasse 9
from Bildungszentrum 21
Missionsstrasse 21
CH – 4055 Basel
Switzerland

How to reach? – see last page

Registration Costs

Fee includes lunch & refreshments

Industry	€300
Academic	€225

Hotel Rooms

Bildungszentrum 21

www.bildungszentrum-21.ch/welcome/?L=2

(mention EFSPI workshop)

To Register Please Go To
www.efspi.org

Or contact:

EFSPI Secretariat
Tel: +44 (0)1625 664549
efspi@kingstonsmith.co.uk

For information on the scientific content, contact 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 31st

2nd EFSPi Workshop on Regulatory Statistics Agenda

Details on the program sessions

	<u>Thursday October 5</u>
13:30-13:40	Welcome
13:40-15:40	Session 1: Multiplicity: FDA guideline Chairs: Ferran Torres & Christoph Gerlinger
	John Scott (FDA) <i>"FDA's Draft Guidance on Multiple Endpoints: Overview, Reactions and Next Steps"</i> Norbert Benda (BfArM) <i>"Regulatory Issues with Multiplicity in Drug Approval and Current Controversies"</i>
	Session 2: Estimands: ICH E9 addendum Chairs: Norbert Benda & Christoph Gerlinger
	Frank Petavy (EMA) <i>"Translation of the estimand framework into regulatory guidance: what's next?"</i> Frank Bretz (Novartis) <i>"How the ICH E9 addendum around estimands may impact our clinical trials"</i>
15:40-16:10	Coffee break
16:10-17:10	Session 3: Estimands: First real life experience Chairs: Ann-Kristin Leuchs & Emmanuel Zuber
	Francesca Callegari (Novartis) <i>"A journey towards estimand specification in pain: motivation and challenges"</i> Kaspar Rufibach (Roche) <i>"Construction of an Estimand in a Clinical Trial on Progressive Multiple Sclerosis"</i>
17:10-17:30	Panel discussion All speakers and Chrissie Fletcher
17:30	Closure of first day
17:30-19:00	Reception



	<u>Friday October 6</u>
8:45-10:15	Session 4: Role of early development in regulatory approval Chairs: Thomas Jaki & Armin Koch
	Khadija Rantell (MHRA) <i>"Facilitating the use of biomarkers in early development: the role of regulators"</i> Richardus Vonk (Bayer) <i>"How to Gamble if You Must: Early Clinical Statistics in Decision Processes."</i> Oliver Sander and Achim Guettner (Novartis) <i>"Case study: Cosentyx in psoriasis - we need both, exploratory and confirmatory"</i> Panel discussion
10:15-10:45	Coffee break
10:45-12:30	Session 5: Predictive biomarkers for therapeutic decision making From predictive biomarkers to prediction modeling Chairs: Khadija Rantell & Kaspar Rufibach
	Andy Stone (Stone biostatistics) <i>"Predictive Biomarkers in Drug Development"</i> Allison Florance (Novartis) <i>"Drug-device co-development in the era of precision medicine: approval of Tafenlar and Mekinist combination therapy and next generation sequencing companion diagnostic in non-small cell lung cancer"</i> Dominik Heinzmann (Roche) <i>"Opportunities and risk related to companion diagnostics: The MET biomarker story"</i> H Ulrich Burger (Roche) <i>"Short intro into biomarker and big data"</i> Panel discussion
12:30-13:15	Lunch break
13:15-14:30	Session 6: Open disease specific drug development issues Chairs: Ferran Torres & Egbert Biesheuvel
	Viktoriya Stalbovskaya and Amy Racine (Novartis) <i>"Basket and platform protocols in full development in Oncology"</i> Lorenzo Guizzaro (EMA) <i>"Delayed start design in neurodegenerative diseases"</i>
14:30-15:00	Coffee break

15:00-16:30	Session 7: Contributed short topics – discussions Chairs: Armin Koch and Hans Ulrich Burger
	<i>Up to 6 topics from practice will briefly be presented (5 min) followed by a 10-15 min discussion of the panel and with audience</i> <i>Panel members:<mainly regulators></i>
16:30-16:35	Closure of the meeting

The Oecolampad is only a 10-minute walk from the Hotel Bildungszentrum 21 and is centrally located at Basel's Allschwilerplatz. From Basel's main railway station (Bahnhof SBB) it can be reached in 10 minutes, using either Tram 1 (get off at "Birmannsgasse") or Tram 6 (get off at "Brausebad")

