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

Registration Costs

Fee includes lunch & refreshments

Early bird before or on 15th of August

Industry	€250
Academic	€175

After 15th of August

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

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	John Scott (FDA) *"FDA's Draft Guidance on Multiple Endpoints: Overview, Reactions and Next Steps"* **Norbert Benda (BfArM)** *"Regulatory Issues with Multiplicity in Drug Approval and Current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

EFSPI

	Friday October 6
8:45-10:15	**Session 4: Role of early development in regulatory approval** **Chairs:** Thomas Jaki & Armin Koch
	Khadija Rantell (MHRA) *"Facilitating the use of biomarkers in early development: the role of regulators"* **Richardus Vonk (Bayer)** *"How to Gamble if You Must: Early Clinical Statistics in Decision Processes."* **Oliver Sander and Achim Guettner (Novartis)** *"Case study: Cosentyx in psoriasis - we need both, exploratory and confirmatory"* 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) *"Predictive Biomarkers in Drug Development"* **Allison Florance (Novartis)** *"Drug-device co-development in the era of precision medicine: approval of Tafinlar and Mekinist combination therapy and next generation sequencing companion diagnostic in non-small cell lung cancer"* **Dominik Heinzmann (Roche)** *"Opportunities and risk related to companion diagnostics: The MET biomarker story"* **H Ulrich Burger (Roche)** *"Short intro into biomarker and big data"* 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) *"Basket and platform protocols in full development in Oncology"* **Lorenzo Guizzaro (EMA)** *"Delayed start design in neurodegenerative diseases"*
14:30-15:00	**Coffee break**

15:00-16:30	**Session 7: Contributed short topics – discussions** **Chairs:** Armin Koch and Hans Ulrich Burger	
	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 *Panel members: ….<mainly regulators>*	Proposals of topics can be addressed until August 31 to either Armin Koch (koch.armin@mh-hannover.de) or Hans Ulrich Burger (hans_ulrich.burger@roche.com)
16:30-16:35	**Closure of the meeting**