

# 2<sup>nd</sup> EFSPi Workshop on Regulatory Statistics

**October 5-6, 2017 Basel (CH)**

After a very successful 1st workshop on regulatory statistics in September 2016, EFSPi will organise its 2<sup>nd</sup> regulatory workshop on October 5<sup>th</sup> and 6<sup>th</sup>, 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 15<sup>th</sup> of August**

Industry	€250
Academic	€175

### **After 15<sup>th</sup> of August**

Industry	€300
Academic	€225

## **Hotel Rooms**

Bildungszentrum 21

[www.bildungszentrum-21.ch/welcome/?L=2](http://www.bildungszentrum-21.ch/welcome/?L=2)

(mention EFSPi workshop)

**To Register Please Go To**  
[www.efspi.org](http://www.efspi.org)

### **Or contact:**

EFSPi Secretariat  
Tel: +44 (0)1625 664549  
[efspi@kingstonsmith.co.uk](mailto: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](mailto:koch.armin@mh-hannover.de)) or Hans Ulrich Burger ([hans\\_ulrich.burger@roche.com](mailto:hans_ulrich.burger@roche.com)) by August 31<sup>st</sup>

## 2<sup>nd</sup> EFSPi Workshop on Regulatory Statistics Agenda

Details on the program sessions

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"FDA's Draft Guidance on Multiple Endpoints: Overview, Reactions and Next Steps"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



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

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

