

# 1<sup>st</sup> EFSPi Workshop on Regulatory Statistics

**September 12-13, 2016 Basel (CH)**

Our first 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, Tim Friede, Christoph Gerlinger, Armin Koch, David Wright and Emmanuel Zuber

## ***Outline of the Agenda***

### **Monday Sept 12**

**13:30 Welcome**

**13:40 Session 1: Estimands, upcoming guidelines**

Speakers: *Thomas Permutt (tentative), Norbert Benda, Mouna Akacha*

**15:10 Coffee break**

**15:40 Session 2: Implications of Estimands Selection on Labeling**

Speakers: *Ann-Kristin Leuchs, Kaspar Rufibach, Chrissie Fletcher, Christoph Gerlinger/Michael Kunz*

**Panel Discussion**

**17:30 Reception**

### **Tuesday Sept 13**

**8:30 Session 3: Extrapolation (e.g. from adults to children)**

Speakers: *Efthymios Manolis, Armin Koch, Michael Looby*

**10:00 Coffee break**

**10:30 Session 4: Risk Benefit assessments**

Speakers: *David Wright, George Quartey*

**12:00 Lunch break**

**13:00 Session 5: Statistics in Quality and Quality Attributes**

Speakers: *Jens Lamerz, Bruno Boulanger*

**14:30 Coffee break**

**15:00 Session 6: Short topics discussions [debate]**

chairs: *Armin Koch and Hans Ulrich Burger*

**16:30 Closure of the meeting**



## **Venue**

Biozentrum  
University of Basel  
Klingelbergstrasse 50/70  
CH – 4056 Basel  
Switzerland

## **Registration Costs**

Fee includes lunch & refreshments

**Early bird before or on 1<sup>st</sup> of August**

Industry	€250
Academic	€175

**After 1<sup>st</sup> of August**

Industry	€300
Academic	€225

**TO REGISTER PLEASE GO TO  
(open from June 1):**

[www.efspi.org](http://www.efspi.org)

**Or contact:**

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

