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|  | 1st EFSPI Workshop on Regulatory Statistics |
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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 Scientfic Committee consists of: Norbert Benda, Egbert Biesheuvel, Hans Ulrich Burger, Tim Friede, Christoph Gerlinger, Armin Koch, David Wright and Emmanuel Zuber

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| **Outline of the Agenda** |
| **Monday Sept 12** |
| **13:30** | **Welcome** |
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| **13:40** | **Session 1: Estimands, upcoming guidelines**Speakers: *Thomas Permutt (FDA), Norbert Benda (BfArM), Mouna Akacha (Novartis)* |
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| **15:10** | **Coffee break** |
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| **15:40** | **Session 2: Implications of Estimands Selection on Labeling** Speakers: *Ann-Kristin Leuchs (BfArM), Kaspar Rufibach (Roche), Chrissie Fletcher (Amgen), Christoph Gerlinger/Micheal Kunz (Bayer)* |
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|  | **Panel Discussion** |
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| **17:30** | **Reception** |
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| **Tuesday Sept 13** |
| **8:30** | **Session 3: Extrapolation (e.g. from adults to children)**Speakers: *Efthymios Manolis (EMA), Armin Koch (U Hannover), Michael Looby (Novartis)* |
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| **10:00** | **Coffee break** |
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| **10:30** | **Session 4: Risk Benefit assessments**Speakers: *David Wright (MHRA), George Quartey (Roche)* |
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| **12:00** | **Lunch break** |
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| **13:00** | **Session 5: Statistics in Quality and Quality Attributes**Speakers: *Jens Lamerz (Roche), Bruno Boulanger (Arlenda), EU regulatory statistician (tbd)* |
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| **14:30** | **Coffee break** |
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| **15:00** | **Session 6: Short topics discussions [debate]**chairs: *Armin Koch (U Hannover) and Hans Ulrich Burger (Roche)* |
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| **16:30** | **Closure of the meeting** |











**Venue**

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Biozentrum

University of Basel

Klingelbergstrasse 50/70

CH – 4056 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
(open from June 1):
www.efspi.org**

**Or contact:**

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