1st 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 (FDA), Norbert Benda (BfArM)/Frank Pétavy (EMA), Mouna Akacha (Novartis)*

15:10 **Coffee break**

15:40 **Session 2: Implications of Estimands Selection on Labeling**
Speakers: *Ann-Kristin Leuchs (BfArM), Kaspar Rufibach/Hans Ulrich Burger (Roche), Chrissie Fletcher (Amgen), Christoph Gerlinger/Michael Kunz (Bayer)*

Panel Discussion

17:30 **Reception**

Tuesday Sept 13

8:30 **Session 3: Extrapolation (e.g. from adults to children)**
Speakers: *Jacob Brogren (MPA), Kristin Weber/Armin Koch (MH Hannover), Thomas Dumortier/Steffen Ballerstedt (Novartis)*

10:00 **Coffee break**

10:30 **Session 4: Benefit Risk assessments**
Speakers: *David Wright (MHRA), George Quartey (Roche), Alexander Schacht (Lilly)*

12:00 **Lunch break**

13:00 **Session 5: Statistics in Quality and Quality Attributes**
Speakers: *Jens Lamerz (Roche), Bruno Boulanger (Arlenda), Thomas Lang (AGES)*

14:30 **Coffee break**

15:00 **Session 6: Contributed short topics – discussions**
chairs: *Armin Koch (MH Hannover) and Hans Ulrich Burger (Roche)*

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 1st of August

Industry	€250
Academic	€175

After 1st of August

Industry	€300
Academic	€225

TO REGISTER PLEASE GO TO:
www.efspi.org

Or contact:

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

Proposals for short topics for Session 6, please contact either Armin Koch (koch.armin@mh-hannover.de) or Hans Ulrich Burger (hans_ulrich.burger@roche.com) by August 15

1st EFSPI Workshop on Regulatory Statistics **Agenda**

	Monday September 12	
13:30-13:40	**Welcome**	
13:40-15:10	**Session 1: Estimands: Upcoming guidelines** **Chair:** David Wright, Tim Friede	
	The Per Protocol principle	Thomas Permutt (FDA)
	Estimands in drug approval: the way forward	Norbert Benda, (BfArM) Frank Pétavy (EMA)
	Estimands: are we estimating what we intend to estimate?	Mouna Akacha (Novartis)
15:10-15:40	**Coffee break**	
15:40-17:10	**Session 2: Implications of Estimands Selection on Labelling** **Chair:** Norbert Benda, Egbert Biesheuvel	
	Regulatory considerations on estimands in specific indications	Ann-Kristin Leuchs (BfArM)
	Estimands for time-to-event endpoints in oncology and beyond	Kaspar Rufibach and Hans Ulrich Burger (Roche)
	Incorporating estimands in the clinical trial protocol	Chrissie Fletcher (Amgen)
	Defining estimands in a pain study – (short case study)	Christoph Gerlinger and Michael Kunz (Bayer)
	Panel discussion	
17:10	**Closure of first day**	
17:30-19:00	**Reception**	

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	Tuesday September 13	
8:30-10:00	**Session 3: Extrapolation (e.g. from adults to children)** **Chair:** Tim Friede and Christoph Gerlinger	
	Confirmation of extrapolation based on PK/PD data and modelling	Jacob Brogren (MPA)
	On the road to clinical extrapolation	Kristina Weber and Armin Koch (MH Hannover)
	Supporting a paediatric investigation plan in liver transplantation – a pharmacometric approach	Thomas Dumortier and Steffen Ballerstedt (Novartis)
10:00-10:30	**Coffee break**	
10:30-12:00	**Session 4: Benefit Risk assessments** **Chair:** Thomas Lang (to be confirmed) and Emmanuel Zuber	
	Practical Benefit Risk assessment	David Wright (MHRA)
	What's going on in benefit-risk and what is our role as a statistician?	Alexander Schacht (Lilly)
	Benefit-Risk assessment via case studies: key considerations and lessons learned	George Quartey (Roche)
	Panel Discussion	
12:00-13:00	**Lunch break**	
13:00-14:30	**Session 5: Statistics in quality and quality attributes** **Chair:** Norbert Benda and Hans Ulrich Burger	
	The role of statistics in ensuring Quality in pharmaceutical manufacturing	Jens Lamerz (Roche)
	Assessment of analytical biosimilarity: the objective, the challenges and the opportunities	Bruno Boulanger (Arlenda)
	To be confirmed	Thomas Lang (AGES)
14:30-15:00	**Coffee break**	
15:00-16:30	**Session 6: Contributed short topic – discussions** **Chair:** 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: Norbert Benda, David Wright, Tim Friede, Armin Koch*	Proposals of topics can be addressed until August 15 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**	