3rd EFSPI Workshop on Regulatory Statistics

24/25th September 2018 Basel (CH)

After two very successful workshops on regulatory statistics in 2016 and 2017, EFSPI is pleased to announce the 3rd regulatory statistics workshop taking place in Basel on 24th and 25th September 2018.

The workshop will be dedicated to the discussion of opportunities and challenges of statistical topics between regulators, academics and industry with dedicated time for interaction and discussion.

Members of the Scientific Committee are: Norbert Benda, Egbert Biesheuvel, Hans Ulrich Burger, Tim Friede, Christoph Gerlinger, Rob Hemmings, Khadija Rantell, Armin Koch, Frank Petavy, Kit Roes, Kaspar Rufibach, Anja Schiel, Nigel Stallard, and Emmanuel Zuber.

Monday 24th September

13:30	**Welcome**	
13:40	**Session 1:**	**Estimands: status of ICH E9 addendum and and case studies**
15:10	**Coffee break**	
15:40	**Session 2:**	**Complex data types and designs in confirmatory trials**
17:45	**Reception**	

Tuesday 25th September

8:45	**Session 3:**	**Basket / Umbrella trials**
10:15	**Coffee break**	
10:45	**Session 4:**	**Use of clinical practice data to support confirmatory trials**
12:30	**Lunch break**	
13:30	**Session 5:**	**Phase 1 dose escalation – extrapolation beyond the same population and/or the same dose regimen**
14:30	**Coffee break**	
15:00	**Session 6:**	**Contributed short topics – discussions**
16:15	**Official closure of the meeting**	
16:30	**Add-on session: Presentations from IDEAS Project & invite to Workshop on Wed 26th September (http://www.ideas-itn.eu/dissemination-workshop)**	
18:00	**Closure**	

Venue

Oekolampad Church
Allschwilerplatz 22
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

http://www.bildungszentrum-21.ch

(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 6, please contact either Armin Koch (koch.armin@mh-hannover.de) or Hans Ulrich Burger (hans_ulrich.burger@roche.com) by August 31st

3rd EFSPI Workshop on Regulatory Statistics

	24th September
13:30-13:40	**Welcome**
13:40-15:10	**Session 1: Estimands: status of ICH E9 addendum and and case studies** **Chairs:** Norbert Benda & Kaspar Rufibach
	Chrissie Fletcher (Amgen) Report from ICH E9 working group: Status of addendum and comments (30min) **Nicolas Rouyrre, Nikolaos Sfikas (Novartis) and Fabian Model (Roche)** Case study MS, incl. discussion of HA interactions (20min) **Kapildeb Sen (Novartis)** Case study oncology, incl. discussion of HA interactions (20min) **David Kardatzke and Hans Ulrich Burger (Roche)** Case study ophthalmology, incl. discussion of HA interactions (20min)
15:40-16:10	**Coffee break**
16:10-17:45	**Session 2: Complex data types and designs in confirmatory trials** **Chairs:** Armin Koch & Christoph Gerlinger
	James Roger (London School of Hygiene and Tropical Medicine) Estimands for recurrent event data & connection to time-to-first event analysis (20min) **Jiawei Wei (Novartis) and Franco Mendolia (Bayer)** Efficiency comparisons of recurrent event and time to first event analysis (15min) **Tobias Mütze (Novartis)** Group-sequential designs for recurrent events: new challenges and proposals (15min) **Andreas Brandt (BfArM)** Regulator's view on estimands for time-to-event data (15min) **Panel discussion with the chairs and all speakers (30min)**
17:45	**Closure of first day**
17:45-19:00	**Reception**

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	25th September
8:45-10:15	**Session 3: Master protocols: Platform, Matrix, Basket and Umbrella trials** **Chairs:** Benjamin Hofner & Emmanuel Zuber
	Khadija Rantell (MHRA) MHRA experience on these type of trials (20min) **Benjamin Hofner (Paul-Ehrlich Institute) and Frank Petavy (EMA)** European regulator's view on platform trials (20min) **Rajeshwari Sridhara (Division of Biometrics V, Office of Biostatistics, FDA)** Regulatory experience and perspective on master protocols (20min) **Panel discussion with the chairs and all speakers (30min)**
10:15-10:45	**Coffee break**
10:45-12:30	**Session 4: Use of clinical practice data to support confirmatory trials** **Chairs:** Khadija Rantell & Hans Ulrich Burger
	Carol Reid and Hans Ulrich Burger (Roche) When a threshold crossing approach may and may not be appropriate: SMA case studies (20min) **Christian Röver and Tim Friede (Department of Medical Statistics, University Medical Center Göttingen)** Complementing evidence from a small scale RCT by registry data in a rare disease setting (20min) **Rob Hemmings (MHRA)** Regulatory considerations when supplementing RCT with non-randomized data (15min) **Anja Schiel (Norwegian Medicines Agency & Chair of EMA BSWP)** HTA considerations when supplementing RCT with non-randomized data (15min) **Panel discussion with the chairs and all speakers (35min)**
12:30-13:30	**Lunch break**
13:30-14:30	**Session 5: Phase 1 dose escalation – extrapolation beyond the same population and/or the same dose regimen** **Chairs:** Flora Musuamba Tshinanu & Tim Friede
	Sarah Zohar (INSERM, Paris) Extrapolation and Bridging in dose-finding clinical trials (15min)

	Sebastian Weber (Novartis) Model-based extrapolation between dosing regimens (15min) **Flora Musuamba Tshinanu (Belgian Federal Agency for Medicines and Health Products)** Model informed dose finding/selection: regulatory perspective (15min) **Panel discussion with the chairs and all speakers (15min)**	
14:30-15:00	**Coffee break**	
15:00-16:15	**Session 6: Contributed short topics – discussions** **Chairs:** Armin Koch & 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	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)
16:15	**Official closure of the meeting**	
16:30 – 18:00	**Add-on session: Presentation from the IDEAS Project & invite to Dissemination Workshop on Wednesday 26th September (http://www.ideas-itn.eu/dissemination-workshop/)**	
18:00	**Closure of the meeting**