

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 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 – PRESENTATION TITLES PRELIMINARY, NOT FINAL YET

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



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

	Model-based extrapolation between dosing regimens (15min) N.N. (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

