

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**
- 17:30 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**
- 14:30 Coffee break
- 15:00 Session 6: **Contributed short topics – discussions**
- 16:15 Official closure of the meeting
- 16:30 Add-on session: **Presentation of PhD projects from IDEAS EU project**
- 18:00 Closure



Venue

Oekolampad Church
Schönenbuchstrasse 9
from Bildungszentrum 21
Missionsstrasse 21
CH – 4055 Basel
Switzerland

Registration Costs

Fee includes lunch & refreshments

Early bird before or on 15th of August

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| Industry | €250 |
| Academic | €175 |

After 15th of August

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| Industry | €300 |
| Academic | €225 |

Hotel Rooms

Bildungszentrum 21

<http://www.bildungszentrum-21.ch>

(mention EFSPi workshop)

To Register Please Go To
www.efspi.org
(expected to open end of April)

Or contact:

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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