



9th Statistics Leaders Meeting

Thursday, July 12, 2018

Louvain-la-Neuve, Belgium



2018 Organizing Committee

Bruno Boulanger
Hans Ulrich Burger
Maylis Coste
Anne Danniau
Stefan Driessen
Justine Rochon

Elisabeth Dupont



EFSPi Statistics Leaders Meetings

- EFSPi leadership meetings are a tradition and important piece of EFSPi as they help shaping the strategy for EFSPi
- Basic objectives
 - Keep statistics leaders informed about important EFSPi initiatives
 - Get input on EFSPi priorities
 - Discuss areas of emerging interest
 - Strengthen network among statistics leaders and companies



Today's meeting

30 confirmed participants from
Abbott, Abbvie, Actelion, Amgen, Arlenda, Astellas,
BMS, Biogen, Boehringer Ingelheim, Celgene, Chiesi, Danone,
GSK, IQVIA, Janssen, Merck, Novo Nordisk, Orion Pharma,
Roche, Sanofi, Servier, UCB

We would kindly request you to officially register if you haven't done it yet. For **official registration and transfer of the registration fee**, please use the link:

<https://www.efspi.org/Core/Events/eventdetails.aspx?iKey=SLM-JUL18>

Welcome to Louvain-la-Neuve!



Today's agenda

Morning	Opening & Updates	Justine Rochon Hans Ulrich Burger
	Impulse presentation with discussion on “The raise of Bayesian statistics in pharmaceutical development: How to organize the transition?”	Bruno Boulanger
	Management of SIGs with experience sharing session from “Quantitative Decision Making SIG”	Maylis Coste, Anne Danniau, Stefan Driessen <u>Invited speaker:</u> Gaëlle Saint Hillary
Afternoon	Story Mapping workshop on “Pragmatic trials and external controls”	Justine Rochon, Hans Ulrich Burger <u>Invited speakers:</u> Josephine Wolfram, Hendrik Schmidt <u>Moderator:</u> Marc Weimer
	Wrap-up & Outlook 2019: <ul style="list-style-type: none">• What are the topics of interest for 2019?• Announcement of 2018 EFSPi Workshop on Regulatory Statistics and call for emerging topics	Justine Rochon Hans Ulrich Burger



Today's agenda

Break 1	11:00
Lunch	12:15
Break 2	Coffee/tea during the afternoon session between 13:00 and 15:30



What is EFSPi?

- EFSPi = European Federation of Statisticians in the Pharmaceutical Industry
- Founded in 1992
- EFSPi is an “umbrella”, non-profit making organisation
- A federation of National European Groups
- Now we have 10 national groups
- No individual members
- Our national organisations collectively represent 2800 members
- Each organisation has 2 members on the EFSPi Council
- Website: www.efspi.org

EFSPI members



*Denmark
DSBS*



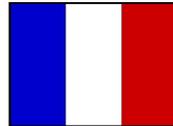
*Belgium
SBS/BVS*



*United Kingdom
PSI*



*Finland
SSL*



*France
SFdS*



*Switzerland
BBS*



*Germany
APF*



*Sweden
FMS*



*Italy
BIAS*



*Netherlands
PSDM*



EFSPI Objectives

- To promote professional standards of statistics and the standing of the statistical profession in the pharmaceutical industry
- To offer a collective expert input on statistical matters to national and international authorities and organisations
- To exchange information on and harmonise attitudes to the practise of statistics in the European Pharma Industry and within member groups



EFSPi Regulatory Statistics Workshop

- We have this year the third regulatory statistics workshop in Basel
- Program made together with HA statisticians
- High participation from Health authorities
- 1.5 day workshop in September. Last year we had more than 200 participants
- Pendant to FDA-industry workshop in the US, very important to keep up the dialogue between industry and HA statisticians in Europe



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.

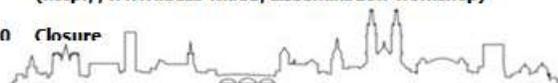
Members of the Scientific Committee are: Norbert Benda, Egbert Biesheuvel, Hans Ulrich Burger, Tim Friede, Christoph Gerlinger, Rob Hemmings, Khadija Rantell, Armin Koch, Frank Petavy, Kit Roes, Kaspar Rufibach, Anja Schiel, Nigel Stallard, and Emmanuel Zuber.

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



EFSPI regulatory statistics workshop Program

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EFSPi Regulatory Statistics Workshop

One important session

15:00 Session 6: Contributed short topics – discussions

- This is a great opportunity!
 - Everyone can apply
 - Provide a 2-3 slide summary of a topic/issue you want to discuss with regulators (and everyone else)
 - Send proposal to me or Armin Koch who both lead through the session
- My ask for you:
 - Think about a topic now and come up with a proposal
 - Use this chance, it is not only a great session at the end, a testimony for an open dialogue we want but also a great opportunity to get quickly feedback



Wrap-Up

Emerging topic of EFSPi Stats Leaders Meeting 2018:

“Pragmatic trials and external controls”

with a new workshop format

What could be next year's topics?

EFSPI Stats Leaders Meeting 2019

- Welcome to Boehringer Ingelheim (Germany)!



Ingelheim
am Rhein





Thank you...

...for your participation today! Have a safe trip back home and see you again soon!

