Welcome to EFSPI's

8th Statistics Leaders Meeting

July 4, 2017
AbbVie Deutschland facilities
Ludwigshafen, Germany

Welcome to Ludwigshafen!

Outline

- Welcome — Stefan
- Logistics — Daniele
- EFSPI — Marisa
- Statistics Leaders Meeting — Stefan

Organization

- Organizing Committee
  - Stefan Driessen
  - Uli Burger
  - Chrissie Fletcher
  - Marisa Bacchi
  - Daniele Compagnone
  - Maylis Coste
- Local Organization
  - Daniele Compagnone (AbbVie)
  - **Thank You AbbVie** for Hosting the Meeting & the great dinner last night

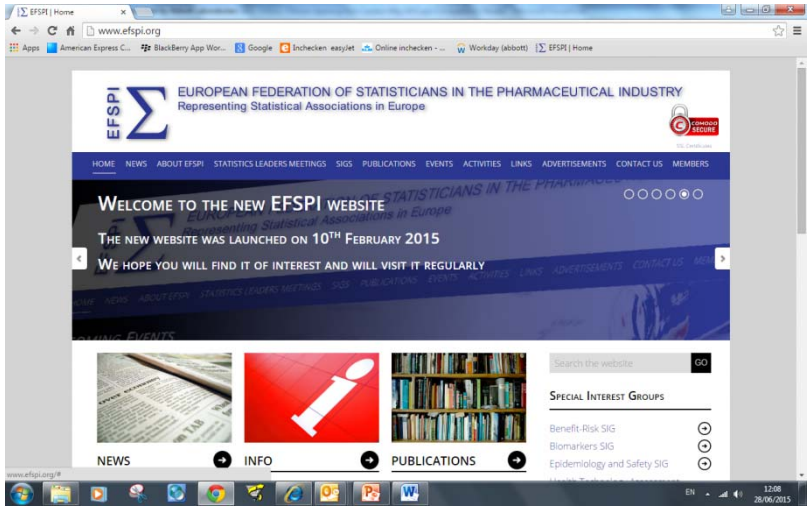
Logistics

- WiFi ➔ KRYPTON (no password needed)
- Extra room (breakout sessions) ➔ 304
- Before lunch ➔ group picture!
- Lunch ➔ beside the meeting room
- Smoking ➔ only at the designated areas
- Taxi ➔ please sign in on the list
- Rear exit ➔ Ludwigshafen main station
- Before leaving ➔ please return name badge
- Questions? ➔ Martina Berroth or me

This is an EFSPI Meeting

- Please visit our website:

www.efspi.org



EFSPI

- EFSPI = European Federation of Statisticians in the Pharmaceutical Industry
- Founded in 1992
- EFSPI is an “umbrella”, non-profit making organisation
- A federation of 10 National European Groups
- No individual members
- Our national organisations collectively represent ~ 2200 members

EFSPI
Strategic Objectives 2016-2018

1. Represent the association members of EFSPI and provide a united and respected voice on key scientific, regulatory and statistical issues in drug development

- Develop program of scientific meetings and partner with association members to provide opportunities to discuss and align on key scientific, regulatory and statistical issues (responsible: Scientific Chair)
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8th Statistical Leaders Meeting

Year	Venue	Host	# attendees
2017	**Ludwigshafen**	***AbbVie***	**39**
2016	Paris	*Sanofi*	34
2015	Brussels	*MSD*	32
2014	Basel	*Roche*	31
2013	Copenhagen	*Novo Nordisk*	23
2012	Amsterdam	*Abbott*	26
2011	London	*Amgen*	22
2010	Berlin	*Bayer*	26

You have been selected for the Statistical Leaders forum

- 55 Active members
  - All 10 EFSPI countries
  - Pharma: 40
  - CROs: 10
  - BioTech: 2
  - Med. Devices 2
  - Nutrition: 1
- Agenda's, presentations, and minutes of the EU Statistical Leaders Meetings 2010 – 2016 available on the EFSPI website:

http://www.efspi.org/EFSPI/Statistics_Leaders_Meetings/Previous_Meetings/EFSPI/Statistics_Leaders_Meetings/Previous_Meetings.aspx?hkey=29eeb7f4-a023-47f2-96e8-046a1a2dd254

Aim Meeting

- Set up by EFSPI
- Network and share ideas
- Shape and influence our environment
  - Education & Continuing Professional Development
  - Methodology Development & Identification of Best Practice
  - Regulatory and Industry policies
  - Effective working with differing resourcing models
- Help to shape the strategy for EFSPI

Professional Accreditation

- Systems for accreditation of statisticians are available in some countries
- A combination of education and experience is vital

- Proposal by FenStatS
  - FenStatS to set the criteria and standard
- National Associations
  - receive and evaluate applications

- Feedback possible during afternoon session

EFPIA Clinical Development Expert Group

- Clinical Trial Design Taskforce
- Lead: Chrissie Fletcher
- Aim: white paper on innovation in CT design and advances in this area to support future clinical development strategies
  - Goal: EFPIA endorsement of paper in Q1 2018 and going into public domain as position paper
- Link with ICH E8 ”General Considerations for CTs” revision; kick-off mid November

- Request for people interested
  - Contact: fletcher@amgen.com

Past Regulatory Interaction

- FDA and EMA guidances on multiplicity commented
  Thanks to Erika Daly
- EMA the First In Humans Guideline commented
  Thanks to Bruno Boulanger
- PSI/EFSPI expert working group on Confidentiality of Interim Results to be established following a suggestion from BSWP
  Lead: Jürgen Hummel

Future Regulatory Interaction

EFSPI/PSI regulatory committee will meet with

- EMA's BSWP on October 26th or 27th
- MHRA statisticians on November 20th

- More or less informal exchange
- Your chance to have your question asked

Update - Data Transparency

Study protocols and SAPs need to be posted in redacted form in US since 2017-04-18

- Already required by EMA under Policy 070

International Committee of Medical Journal Editors (ICMJE) published Requirement for Data Sharing Statements

- Submissions from 2018-07-01 must state if (and if yes, how) data shall be shared
- Trials from 2019-01-01 must include a data sharing plan in trial registration
- Data sharing is not required, „but investigators should be aware that editors may take into consideration data sharing statements when making editorial decisions.“
- 4 out of 5 papers by EFSPI data sharing working group were cited

Update - Estimands

ICH E9 R1 reached step 1 of ICH procedure

- Release for comments July/August 2017
- Training material will be released shortly thereafter
- 6 months consultation period

Planned EFSPI activities

- Comments on draft
- Webinars on concept
- Meeting to discuss draft
- Webinar/Training on principal stratification

Update – 2nd EFSPI Workshop on Regulatory Statistics

October 5-6, 2017 Basel

Speakers from EMA, FDA, academia, and industry

€300,- (250,- until July 31st) for 1½ days

- Session 1: Multiplicity: FDA guideline
- Session 2: Estimands: ICH E9 addendum
- Session 3: Estimands: First real life experience
- Panel Discussion Estimands
- Session 4: Predictive biomarkers for therapeutic decision making
- Session 5: Role of early development in regulatory approval
- Session 6: Open disease specific drug development issues
- Session 7: Contributed short topics – discussions

SIG Update

SIG AIMS

Purpose of AIMS:

- “To support PSI Committees and PSI/EFSPI Special Interest Groups (SIGs) with the technological application and implementation of statistics. To develop understanding of new analytical tools and approaches to share with PSI & EFSPI members via appropriate forums. To ensure PSI & EFSPI members are supported with understanding the requirements for the implementation of industry data standards.”

SIG AIMS

- Membership changes with the SIG now having
  - 2 CRO staff (PPD, PRA)
  - 4 Pharma staff (Amgen, Astrazeneca, GSK, Servier)
  - 2 Academia staff (Bordeaux University)
  - One potential further member but need more!!!

- Got clear remit that R should be the initial focus of the group so moved forward
  - Met with vendors who validate in R
  - Sought feedback from various sources on potential solutions to validation of R (this has been the main activity)
  - Had the PSI Regulatory committee raise the topic in their F2F meeting with the MHRA who stated
    - "There are no regulations that restrict the use of software. Validation principles to show the results are accurate need to be applied, including which functions used and how they are accessed. All validation processes need to be traceable."

SIG AIMS

- What have the group actually produced?
  - One "R" article published in PSI SPIN magazine and EFSPI newsletter
  - One "R Shinny" article in final draft to publish in autumn PSI SPIN magazine (and EFSPI newsletter at a similar time)
  - One further "R Shinny" article conceptually agreed for later in the year

SIG AIMS

- We have agreed objectives for the next 12 months
  - Update PSI website to include SIG details and articles
  - Target one article per quarter for publication current topics in the list with agreed authors are:
    - R notebook
    - Literate programming
    - Reproducible research Cloud computing
    - Bayesian: Linking R with other software (ie. Bugs) MCMC now available in SAS comparison
    - High performance in R vs SAS
    - Intro to Validation (Tips)
    - SAS Viya
  - Run a parallel session at the 2018 PSI conference
    - Already agreed in principal at the PSI Board meeting on 7th June
    - Idea would be for 2 presentations then a working demonstration of a tool (we already have the material for most of this)
  - Increase membership

SIG Toxicology

- In March 2017 we held a 2 day workshop, covering current hot topics in industry. Topics included:
  - Repeated Measures analyses in Toxicology,
  - Historical control data,
  - CRO and Pharma statistician interactions,
  - Carcinogenicity studies and
  - How do we empower our scientists to perform some routine analyses, whilst also ensuring quality of results.

- During 2017 we plan to hold regular webinars for a wide audience to join, all based around toxicology and non-clinical topics. We are also always interested to hear from anyone who works in this area, so that we can share our work wider. Please contact Gareth Thomas gareth.thomas@envigo.com

- We are also starting to plan our next workshop, which will likely take place in 2018.

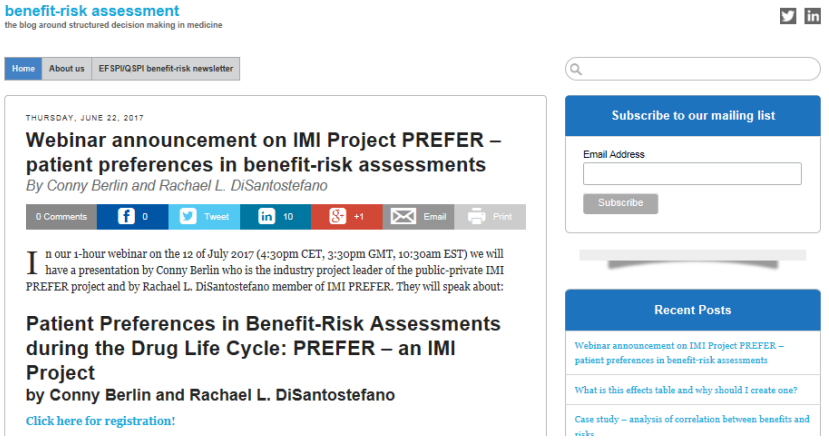
SIG Small Populations

- Chair: Egbert Biesheuvel
- 12 members
- Link with 3 FP7 projects:
  - IDEAL,
  - INSPIRE,
  - ASTERIX
- Provided feedback on INSPIRE congress and PSI presentation on Small Populations
- SIG focus now on role of historic controls

- Request to EFSPI: keep promoting SIG

SIG Benefit - Risk

- Chair: Alexander Schacht
- Several webinars planned for this year
- Active blog:
  www.benefit-risk-assessment.com



- Question to EFSPI: availability
  of company independent virtual meeting facility
  - skype is often problematic

Agenda

Time	Topic	Presenter / Facilitator
8:30-9:00	*Registration + Coffee*	
9:00 - 9:15	• **Welcome address + Intro** o Org. Ctee o EFSPI President o Recap Stats Leaders meeting 2016 ▪ SIGs (AIMS, …) o Qualification Biostatisticians	**Stefan Driessen, Daniele Compagnone** **Marisa Bacchi** **Stefan Driessen**
9:15 – 9:45	• **Future of Statistical groups – F-up of workshop 2016** o Statistics and Decision making support	**Maylis Coste, Sylvain Nicolas**
9:45 – 10:45	• **Close collaboration with Academia?** o What can they do for us? o What can we (EFSPI) do for them? o What can we (Statistical Leaders) do for them? o How can we support EU supported academic initiatives (ASTERIX, IDEAL, ASPIRE) and how already ongoing collaborations (IMI)	**Uli Burger**
10:45 - 11.15	*Coffee Break*	

Agenda cont.

Time	Topic	Presenter / Facilitator
11:15 – 12:30	• **Invited session by host AbbVie** o Company intro o Discussion topics as determined by Host: • Patented clinical trial designs	**Daniele Compagnone**
12:30 – 12:45	• **Data Science - intro** o Background RSS section on Data Science o Example of Data Science in action (AZ)	**Andy Garrett, Jim Weatherall**
12:45-14:00	*Lunch break*	
14:00 – 15:45	• **Data Science - workshop** o Presentation Survey results o Outline topics for discussion o Break-out groups, present back to main group o Wrap up	**Andy Garrett, Jim Weatherall**
15:00 – 15:15	*Refreshments Break*	
15:45 – 16.15	• **What should be the priorities for EFSPI ?** o Statistics Leaders identify the priorities for EFPSI based on outcome Stats Leaders workshop 2016 (“the bubbles”)	**Marisa Bacchi, Maylis Coste**
16:15 – 16:30	• **Program Statistical Leaders Meeting 2018**	**Stefan Driessen**
16:30	*2017 Meeting Closure*	

Back Up slides

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2. Set and promote professional standards in Europe for the development, application, understanding and communication of statistics in drug development and related fields

- Write 1-2 professional position papers / best practice papers per year in collaboration with representatives from association members and SIGs (responsible: Council representatives, SIG Chairs)
- Hold Annual EFSPI meeting, produce monthly newsletters, and disseminate relevant information (responsible: Communication Office, Scientific Chair)
- Foster collaboration between local organizations to promote relationships and share best practices (responsible: EFSPI president)

3. Enhance the profile of EFSPI and strengthen alliances and collaborations with other bodies within Europe and other regions

Seeking opportunities to collaborate with:

- the EMA Biostatistics Working Group and regulatory statisticians (responsible: Regulatory Chair)
- the EUneHTA Network (responsible: HTA SIG)
- International statistical community and associations important to the Special Interest Groups (SIGs)(responsible: SIG Chair)
- the European Federation of Pharmaceutical Industry Associations (EFPIA) (responsible: President, Scientific Chair)

On the following key activities:

- ❖ Methodology/research and good research practice papers/reports
- ❖ Training opportunities, scientific meetings and discussing mutual areas of interest
- ❖ Development and review of regulatory and payer guidelines
- ❖ Professional development and successfully adapting to changes in the environment

Current SIGs*

- Biomarker (leader = Athula Herath, heratha@MedImmune.com)
- Benefit-risk (leader = Alexander Schacht, schacht_alexander@lilly.com)
- Health Technology Assessment, HTA (leader = Chrissie Fletcher, fletcher@amgen.com)
- Integrated Data Analysis (leader = Byron Jones, byron.jones@novartis.com)
- Medical Devices (leader = Martin Wadepuhl, wadepuhl.m.vsa@t-online.de)
- Modelling & Simulation (leader = Chris Campbell, ccampbell@mango-solutions.com)
- Real World data (leader = Maurille, maurille@amgen.com)
- Toxicology (leader = Gareth Thomas, ThomasG@UKOrg.Huntingdon.com)
- Small Populations (leader = Egbert Biesheuvel, egbert.biesheuvel@danone.com)
- AIMS (leader = Craig McIlloney, craig.mcilloney@ppdi.com)

* Majority of SIGs formed under leadership of PSI and subsequently expanded to include EFSPI members

Professional accreditation

June 2017

Background

- Systems for accreditation of statisticians are available in some countries
  - United States, Netherlands, United Kingdom, Canada, Hong Kong
- A combination of education and experience is vital

Criteria

The criteria are based on the systems applied by ASA and RSS

A. MSc degree in statistics or education deemed equivalent
B. Five years of documented working experience as statistician
C. Continual Professional development after graduation
D. Communication and pedagogical skills
E. Comply to FenStats ethical standards and other relevalnt standards
F. Member of national statistical association

SM2

Slide 35

SM2 At the date of certification or to be renewed every year?

Sebastien MARQUE, 6/5/2017

FenStat and National Associations roles

- FenStatS
  - set the criteria and standard for accreditation
  - keep a register of accrediations
  - evaluate the accreditation process
- National Associations
  - Receive applications
  - Evaluate the applications
  - Issue credentials to successful applicants

Questions for the National Associations

- Are the roles separated in a good way?
- Continous application terms or fixed dates
- Application fees
- Recruitment of auditors
- Are extensions (eg biostatistics) useful?

What assistance is needed from FenStatS?

FenStatS project group for accreditation

- Arne Bathke, Austria
- Dominik Rozkrut, Poland
- Feridun Turkman, Portugal
- Gerardo Sanz Sáiz, Spain
- Luigi Pieri, Italy
- Magnus Pettersson, Sweden
- Paul Koopman, the Netherlands
- Sebastien Marque, France

ACCREDITATION AS PROFESSIONAL STATISTICIAN

John Doe, MSc

From Brussels, Belgium
DOB 1 december 1968

DRAFT

Has, the 19th April 2017 fulfilled the requirements of accrediation as statistician as set out by FenStatS (criteria dated 1 April 2017). Further information on the criteria and the accreditated professional can be aquired from FenStatS (www.fenstats.eu).

Jane Doe,
President of Fenstats

M Kilroy
President of Sweden Statistical Association