European Federation of Statisticians in the Pharmaceutical Industry
Representing Statistical Associations in Europe

EFSPI COUNCIL MEETING UPDATES

Tuesday 4th December 2012

Monza, Italy

Belgium – SBS/BVS	No report
Denmark - DSBS	2
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France – SFdS	2
Germany – APF	3
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Sweden – FMS	No report
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Scientific Report	No report
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DENMARK
DSBS

Membership: DSBS

Forthcoming events:

January 10 2013 there will be a half day meeting regarding interaction with regulatory agencies. Topics: Multiplicity, submissions and potentially also missing data and subgroup analyses.

FINLAND
SSL

Membership: 55

Forthcoming events: Joined event with FMS on Bayesian Statistics in 2013 under preparation

Notes of interest Activity related to Year of Statistics:
Material to promote biostatistics in high schools under preparation
Issues/Concerns

FRANCE
Société Française de Statistique (SFdS) – Groupe Biopharmacie et Santé

Membership: 550+

Forthcoming events

- 16-17 September 2013: International Meeting, "Statistical Methods in Biopharmacy – *Current Emergent Topics in Statistical Methods for Clinical Trials"*
  Scientific Committee
  - Chair : *Frank Bretz* (Novartis Pharma & Medizinische Hochschule Hanover)
  - - *Loic Darchy* (Sanofi)
  - - *Jean-Marie Grouin* (Université de Rouen – INSERM U657)
  - - *Frank Harel* (Vanderbildt University School of Medicine)
  - - *Martin Posch* (European Medicine Agency)
  - - *Stephen Ruberg* (Eli Lilly & Company)
  - - *Martin Schumacher* (Université de Freiburg)
  - - *Stephen Senn* (CRP Santé)
  - - *Pascale Tubert-Bitter* (Inserm - Université Paris Sud UMRS 1018)

  Organising Committee chair: Karine Le Malicot (Abbott – Lab. Fournier)
  Topics: 4 among the 5 topics below: final decision to be made by Scientific Committee:
  1. Graphical methods
  2. Model based drug development / Dose finding
  3. Subgroup analysis
  4. Multiple endpoint analyses
  5. Statistical learning and biomarkers

Recent successes/issues

- 11-12 October 2012, Paris: Training session on *Statistical Approaches for Adaptive Designs* Frank Bretz and Bjoern Bornkamp (Novartis, CH)

- 15 November 2012: Yearly General Meeting of the Biopharmacie et Santé group: administrative meeting + scientific communications (end of internship dissertation by trainees by Trainees finishing their Masters) – Very successful, well attended (60+ people) and appreciated
  During the administrative meeting, a brief update on EFSPI has been presented.

Notes of interest
New President of the board of Biopharmacie et Santé elected on June 26th: Gérard Derzko (2 VPs: Emmanuel Pham and François Aubin)

Issues/Concerns
None

Issues to escalate to Council/Possible agenda items
The Non-Clinical Statistics Working group of Biopharmacie et Santé would be interested by expanding to a European SIG if other EFSPI countries statisticians show interest. To be discussed during the SIG topic at the Council meeting.

GERMANY
Arbeitsgemeischaft pharmazeutische Forschung (APF)

Membership: ~300 on mailing list

Forthcoming events

APF will contribute to the 3rd joint Statistical Meeting DAGStat 2013 in Freiburg which includes the 59th 'Biometrische Kolloquium' and the 'Pfingstagung der Deutschen Statistischen Gesellschaft. (www.dagstat2013.uni-freiburg.de)

Recent successes/issues

Our 66. workshop was held on 16. November 2012 in Hofheim am Taunus with speakers from industry, BfArM and IQWiG. The topic was "benefit, additional benefit and Risk/Benefit". Some 120 members attended.

Notes of interest

Joachim Röhmel stepped down as speaker of the APF. Frank Langer was elected as the new speaker. Vice-speakers are Christoph Gerlinger and Hans-Jürgen Lomp.

ITALY
BIAS

Membership: 100

Forthcoming events
February/March 2013 – Seminar on SAS programming

September 2013 - V BIAS national congress

Recent successes/issues
September 2012, Padua, IV BIAS national congress “Advanced Methods in Clinical Trials: surrogate endpoints and adaptive designs” and “Data Quality in Clinical Trials” in collaboration with SSFA.

THE NETHERLANDS
(PSDM working group of the VVS)

Membership: approx. 100

Forthcoming events

PSDM has the intention to organize at least two events in 2013. The first event will probably be an event dedicated to risk-based monitoring. The second event, in the autumn, will be most likely centered on 'The International Year of Statistics'.

Recent successes/issues

On June19th 2012 the event "Open Source Software in Clinical Research: cost-saving opportunities or high-risk solution?" was hosted by Julius Clinical Research in Zeist. Four speakers were planned to participate, but unfortunately on speaker declined his participation at the day of the event, so no replacement could be arranged. After the presentations there was a lively plenary discussion. With more than 40 people participants it was considered a successful meeting.

The second activity was a workshop on adaptive design by Prof. Andy Grieve (Aptiv Solutions) held on November 8th hosted by MSD in Oss. An excellent and informative workshop attended by more than 60 delegates. Highlights of this event (including photos) and the complete slide deck can be found on the website (http://www.psdm.eu/php/psdm-events/2012-november-8.php)

Notes of interest

Most reorganizations of R&D sites of major pharmaceutical companies in the Netherlands are done, however, some are still in progress, like Genzyme (ending Dec 2012).

Due to these changes one of the board members has been decided to stop his activities. We have been able to replace him with a new board member (Yasemin Atil) who will represent the SAS programmers.

Egbert Biesheuvel, November 22nd 2012

SWITZERLAND
BBS Update

Membership: ca. 100

Forthcoming events in Fall 2012 / Spring 2013:

Winter Seminars

3 events every 2 months beginning in November / December. Format is usually 2 speakers.

November 28, 2012 - Optimal Design for Non-linear Models (Chair: Byron Jones)

Professor Anthony Atkinson (London School of Economics)
Experiments for Building Enzyme Kinetic Models

Dr Tobias Mielke (Aptiv Solutions, Cologne)
Optimal Population Designs for Non-linear Mixed Effects Models

Dr Barbara Bogacka (Queen Mary College, University of London)
Population Optimum Design for Non-linear Mixed Effects Models in the Presence of Covariates

Spring Conference: Early Spring 2012

3rd Annual Comparative Quantitative Assessments: Effectiveness and Benefit-Risk: Health Technology Assessment (HTA) – planned for a joint meeting together with EFSPI and possible participation of the PSI HTA SIG

Recent successes

BBS Website is still running smooth and with the presentations from the meetings freely available: http://www.ceb-institute.org/bbs

Summer / Fall Seminars 2012

Summer Seminar: 9 July 2012 (half-day event)

BBS Seminar "Emerging topics in pharmaceutical statistics"

Stephen Julious (University of Sheffield):
Sample sizes for multiple must-win trials

Eric Derobert (Sanofi-Aventis):
A parameterized strategy of gatekeeping, keeping untouched the probability of having at least one significant result

Mouna Akacha, Günther Müller-Velten (Novartis Pharma):
Recurrent event approaches in cardiovascular outcome trials

Lisa Hampson (University of Lancaster):
Group sequential tests for delayed responses

Modelling and Simulation (Joint one-day BBS and EFSPI meeting)

13 September 2012

Fall Seminar: 25 September 2012 (full day event)
Benefit Risk & Comparative Effectiveness

Benefit-Risk (Session chair: Conny Berlin)

Filip Mussen (Janssen)
The use of frameworks and quantitative methods for regulatory benefit-risk decision making: a status update.

Andrea Beyer (University Groningen, NL)

Understanding the risk tolerance of regulatory assessors in Europe: The role of quantitative models in risk communication.

Christoph Dierig (Bayer)
A Case Study using the BRAT framework for Benefit Risk Assessment: A Generalization of the NNT/NNH concept.

Richard Nixon (Novartis)
A Case Study using the BRAT framework for Benefit Risk Assessment: Application and visualization of Multi-Criteria Decision Analysis (MCDA).

Christian Hove Rasmussen (Novo Nordisk)
Benefit-Risk Assessment from a Clinical Point of View: a structured approach with focus on transparency, clinical significance and visualization.

Comparative Effectiveness (Session chair: Fred Sorenson)

Ralf Bender (Head of Medical Biometry, IQWiG, Germany)
Biometrical requirements in (early) benefit assessments

Neil Hawkins (University of Glasgow, United Kingdom)
Key elements contained in the upcoming 'Guide to Methods of Technology Appraisal' recently released from NICE for review

Fred Sorenson (BBS)
Benefit-risk assessment and Comparative Effectiveness Research: Are they really converging?

Issues/Concerns

No issues / concerns
Conny Berlin, head of drug safety statistics at Novartis, joined as a new board member of the BBS.

Fred Sorenson
27 November 2012

PSI (UK)

Membership: approx 1000

Forthcoming events

- PSI's Pharmaceutical Statistics Journal Club TC sponsored by Wiley presents Modelling in Drug Development Thursday 6 December 1400-1530
- PSI 1-Day Scientific Meeting: The Design and Analysis of Observational Studies, London - Wednesday 27 February 2013 - Registration will open shortly
- PSI 1 Day Scientific Meeting: Predictive Inference: Can this Reduce Late Phase Failures?, Stevenage - Thursday 18 April 2013 - Registration will open shortly
- PSI 36th Annual Conference, Glasgow -12 to 15 May 2013

Publications

- PSI Journal “Pharmaceutical Statistics” and SPIN

Recent successes/issues

- 1-day HTA Scientific meeting held in London, additional interest of ~5 individuals to join the HTA SIG
- Journal Club hosted by the Toxicology and Biomarker SIGs
- Modelling and simulation drug development training course
- Biomarker validation case study meeting
- Therapeutic Area meeting: Oncology

Notes of interest

- Board of Directors held a 1-day strategy meeting. Topics covered include: what will PSI look like in 10 years?, who will be members?, profile of PSI (e.g. increase scope to beyond Pharma), website requirements (new website planned for 2013), increasing membership, rewording strategic objectives.
- PSI wishes to make their scientific meetings, training opportunities and the Pharmaceutical Statistics journal more accessible to the EFSPI community. We have had to cancel a number of scientific meetings recently due to low numbers

Chrissie Fletcher
26th November 2012

REGULATORY REPORT

Guidelines commented upon

No statistical guidelines were published since last meeting. Pending drafts are

- Guideline on the Use of Subgroup Analyses in Confirmatory Clinical Trials (EMA)
- Update on Concept Paper on guideline on Adjustment for Baseline Covariates (EMA)
- Update of Points to Consider on Multiplicity Issues in Clinical Trials (EMA)
- Multiple Endpoints (FDA)

EMA workshop on multiplicity issues in clinical trials on 16 Nov. 2012

EFSPI has been invited by EMA to participate (E. Biesheuvel).
(Report to follow.)

EMA workshop on disclosure of clinical trial data on 22 Nov. 2012

EFSPI has been invited by EMA to participate (C. Gerlinger).

EMA plans to make individual patient data from submissions available to the public starting January 1st, 2014. The only question is how this will happen. Views expressed from stakeholders at the meeting ranged from “put all data freely on the internet” to access tightly controlled to ensure patient data privacy and to protect commercial interests.

EMA will call for five advisory groups from stakeholders, namely:
* protecting patient confidentiality;
* clinical trial data formats;
* rules of engagement;
* good analysis practice;
* legal aspects.

Results should be finalized by end of April 2013. Then EMA will draft a guidance document on the topic by June 30th with a consultation period until September 30th 2013.

COMMUNICATIONS REPORT

- EFSPI newsletter distributed in early November
- Final newsletter for 2012 will be issued before Xmas break
- Website updates continue
- Challenge with website – lack of ability to make any changes to home page, can be a limiting factor to making urgent/quick minor changes (as discovered with recent EFSPI webinar on doses in phase 2

Chrissie Fletcher
Communications Officer