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

EFSPI Newsletter August 2019

In this newsletter:

Regulatory

EFSPI is pleased to announce the 4th Regulatory Statistics Workshop taking place in Basel, Switzerland on the 23rd and 24th September 2019. 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. The agenda includes:

Session 1: Real-world data – beyond randomized clinical trials
Session 2: Real-world data – applications
Session 3: Analysis of safety in clinical trials – or how to bring a statistician out of his comfort zone
Session 4: Estimands – are we pushing any boundaries thanks to the ICH E9 addendum?
Session 5: Modern approaches for rare disease
Session 6: Contributed short topics – discussions

To register for the workshop, click here.

back to top

Scientific

Upcoming event: ***"Reproducibility in Clinical Research"***

On **Thursday November 22nd, 2019**, this scientific meeting will take place at BMS in Brussels. The purpose is to bring together speakers from industry, academia and regulatory agencies, who will address questions relating to the topic, and the role statistics (and statisticians) have in ensuring clinical research is conducted and reported in a reproducible manner.

First key speakers are announced, and a full agenda is expected end of summer. More information can be found on the flyer and the registration is open click here.

The scientific committee is brainstorming on topics for the scientific events in 2020. If you have any suggestions for topics, please feel free to contact the scientific committee (chair: Egbert.biesheuvel@danone.com)

back to top

Special Interest Group (SIG) News

A working group has been formed in the **Vaccines SIG** for the purpose of exploring implementation of the ICH E9 addendum on estimands to vaccine clinical trials. There will be joint leadership from regulatory, academia, and industry. Current participants are: Sang Ahnn (Co-lead, CBER, FDA), Holly Janes (Co-lead, Fred Hutch), Larry Moulton (Co-Lead, John Hopkins), Wenquan Wang (Co-chair, Sanofi Pasteur), An Vandebosch (Co-chair, J&J), Jianing Li (Merck), and Brigitte Cheuvart (GSK). If you are interested in contributing, please contact Wenquan Wang at wenquan.wang@sanofi.com for more information. For further information about the Vaccines SIG contact Fabian Tibaldi (FABIAN.S.TIBALDI@GSK.COM).

The **Health Technology Assessment (HTA) SIG** would like to announce the German HTA body, AMNOG, has recently released new submission templates effective in 2020 with a transition period from the current templates to the end of March 2020. A variety of additional analyses will be needed to support the new requirements, for example additional tables summarising adverse events, subgroup analyses of adverse events, and patient data listings will also be required. In 2018 the German Industry association, including members of the HTA SIG, consulted on the proposed new requirements which led to the final new requirements being reduced compared to the initial proposal.

Centralised Statistical Monitoring (CSM) has become an integral part of risk-based monitoring in clinical trials where signal detection methods allow potential issues to be identified and investigated during a clinical trial. In addition, as per ICH E6(R2) it is a requirement to establish Quality Tolerance Limits which introduce thresholds to monitor and measure key attributes of quality in the conduct of clinical trials. Both activities greatly benefit from statistical expertise. If you are engaged in CSM or QTL activities and would be interested to participate in a **proposed new CSM/QTL SIG,** then please email Chrissie Fletcher (fletcher@amgen.com).

back to top

Country News

AFP (Germany)

The annual workshop will take place Nov 29th at Ludwigshafen/Rhein hosted by Abbvie. The main topic will be Real World Evidence (see http://www.biometrische-

gesellschaft.de/fileadmin/AG_Daten/PharamzeutischeForschung/PDFs/Agenda_APF_73_Ludwigshafen_Nov_2019.pdf). The next German Statistics Leader Meeting will take place on Nov 28th, 2019.

BBS (Switzerland)

BBS held their Summer Seminar on the 21st August 2019 in Basel on the topic of ***Causal Inference in Drug Development***. The meeting was well attended with representatives from Academia, Industry and Regulatory. A variety of case studies were shared, including examples using principal stratification. The slides from the meeting will be available soon, click here to view the slides.

BBS are holding their Autumn Seminar on the 1st November 2019 in Basel with the topic of ***Predictive Modelling, Machine Learning and Causality***. The talks will present recent methodological advances and challenges as well as case studies from the pharmaceutical industry and academia. We welcome all quantitative scientists to this event which will be a great opportunity to meet with colleagues and exchange ideas on this emerging and vibrant field. Click here to view more details on how to register for the meeting.

IBIG (Italy)

The **IBIG Forum** will be held at the University of Milan-Bicocca on 10-11 October 2019. Main topics will be: randomization and blinding, study drug management, early phase clinical trials and Innovation in Statistics and next gen statistician role. Speakers from pharma industries, CROs, academia, public & private research institutes.

On 9 October, two pre-IBIG Forum courses are organized:

Simulation methods to estimate power and sample size in trial designs, with SAS
Instructors: Prof. Vincenzo Bagnardi, University of Milan-Bicocca
Valentino Conti, Expert Biostatistician, GSK Vaccine Institute for Global Health

Theory and practice for the creation of summary tables using ADaM domains
Instructors: *Valerio Romolini, Lead Statistical Analysts, GSK Vaccines*
Gabriele Di Domenico, Statistical Analyst, GSK Vaccines
Stefano Lombardi, Statistical Analyst, GSK Vaccines

The flyers for these events are available on the EFSPI website (www.efspi.org).

PSI (UK)

Register for future PSI events Register your interest now to receive updates, hear when registration opens and receive a 10% discount on the early bird rate (where applicable)!

- **Training Course:** PK Methods and Regulatory Considerations
- **Training Course:** Time to Event Methods
- **Training Course:** Bayesian analysis software
- **Training Course:** Adaptive design software
- **Training Course:** R for SAS users
- **PSI One day Scientific meeting**: Time-to-event and recurrent event endpoints in clinical trials

FEATURED VIDEO: PSI Webinar: Adaptive design: updated draft FDA guidance and its implications

Impact of AI on Clinical Development 11 September 2019, UCB, UK.

In association with PSI, UCB and Cytel are delighted to invite you to join a symposium, educating on Artificial Intelligence (AI) approaches and their impact on clinical development.

With so many recent advances in AI, it is important both for statisticians to keep up to date with the most recent methods and be involved in guiding their application to the most pressing statistical challenges. This one-day event will cover cutting edge examples of how data science and statistical sciences are intersecting, and where attendees can fit into that space. Come to learn and discuss why different approaches matter when looking at clinical development data. Click here to register.

Time-to-event and Recurrent Event Endpoints in Clinical Trials, 29th October 2019. This one-day workshop will cover a wide range of statistical aspects relating to event-driven trials. The first half of the day will be dedicated to time-to-event endpoints and adverse events with the afternoon focusing on recurrent event endpoints that are associated with a terminal event. Click here to register.

ICH for Statisticians, 19-20th November 2019. This training course will describe key guidelines from regulatory bodies such as EMA, FDA, PDMA and CDE. The focus of the course will be on the content of ICH E9 (Statistical Principles for Clinical Trials) and ICH E10 (Choice of Control Group in Clinical Trials), ICH E6 (Good Clinical Practice) and E17 (Multi-Regional Clinical Trials) but other key regulatory guidance documents will also be highlighted. The course will also include workshops, a Q&A session and guidance on how to seek advice from regulators. Click here to register.

back to top

Other events

5th International Clinical Trials Methodology Conference (ICTMC): 6th-9th October 2019 in Brighton

This event promises to be a unique opportunity for those working in clinical trials to meet and discuss the current issues within trials and trials methodology. The event will showcase the very latest in trials methodology research and offer plenty of valuable opportunities for networking. The Conference will also mark 10 years since the Network of Hubs for Trials Methodology Research began in 2009. Click here to see the program and register.

Group Sequential and Adaptive Clinical Trial Designs

The German Region of the International Biometric Society (IBS) is holding a summer school on Group sequential and adaptive clinical trial designs, 17-19 October 2019 in PfalzAkademie, Lambrecht, Germany. This summer school introduces group sequential and adaptive designs and covers advanced topics. The theory will be illustrated with case studies from the pharmaceutical industry. Each module of this course includes a computer practical. We will use the R software package rpact (R Package for Adaptive Clinical Trials, https://www.rpact.com/), a validated, comprehensive and freely available package for the design, simulation and analysis of group sequential and adaptive trials. More information can be found on the EFSPI website.

Women in Data

Women in Data UK is the largest women professional event and network, changing the data landscape. The aim of Women in Data UK is to ensure inclusion and diversity by encouraging females to shine in their careers. The 5th annual Women in Data UK conference is taking place at The Arora in the Intercontinental O2 in London on **Thursday 28th November 2019**. Attendees are welcome from the UK, Europe and other locations. A variety of keynote and prominent speakers will be sharing their expertise and experiences on the importance of women in data. A range of hands on workshops will be available, for example: upskilling and re-skilling in areas including coding, data, AI and machine learning; transforming business using data science; emotional fitness, mindfulness and wellbeing. The ***'2019 Twenty Women in Data and Technology'*** will also be announced. Click here to register to enter the ballot for ticket allocation (notified in late October).

back to top

Job Opportunities

There is an opportunity for Principal and Senior Biostatisticians. For information on how to submit recruitment adverts, please visit the EFSPI website: Job postings. If you are currently seeking to hire a statistician and wish to post a job advert, EFSPI are offering one free advert for every 3 adverts posted on the website.

back to top

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back to top

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back to top

Chrissie Fletcher
EFSPI Communications Officer