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

EFSPI Newsletter September 2019

In this newsletter:

Regulatory

The **4th Regulatory Statistics Workshop** took place in Basel, Switzerland on the 23rd and 24th September 2019. Approximately 230 delegates attended the workshop with great discussion between regulators, academics, and industry on real-world data, analysis of safety in clinical trials, estimands, modern approaches for rare disease and contributed short topics. The slides will soon be available from the EFSPI website (www.efspi.org).

The ICH E17 working group have released training materials and videos for the **ICH E17 General principle on planning/designing Multi-Regional Clinical Trials.**

E17 Training Modules slides (zip)
E17 Training Introduction video (youtube)
E17 Training Module 1 video (youtube)

This material is also made available on the ICH website
https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

The FDA has released draft guidance on Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products. Comments are due by 23rd December 2019.

The Center for Drug Evaluation in the NMPA (National Medical Product Administration) in China have released two draft guidance on ***Guideline on Clinical Trial Data Monitoring Committees and Guideline on Non-inferiority Clinical Trials.*** Comments are due by the 24th October 2019.

The EMA have released draft guidance on ***Preparedness of Medicines' Clinical Trials in Paediatrics***. Comments are due by the 15th November 2019.

The **EFPIA/EFSPI estimand implementation working group** are having a kick-off meeting on **the 31st October 2019** at the Amgen Uxbridge office. Please contact Chrissie Fletcher (fletcher@amgen.com). If you would like to join this working group.

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Scientific

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

On **Thursday November 22**, this scientific meeting will take place at BMS in Brussels. The purpose of this meeting 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.

More information on the contents can be found on the flyer (https://www.efspi.org/Documents/Events/Events%202019/RCR-NOV19/efspi%20SM%20banner.PDF) and the registration is open (https://www.efspi.org/Core/Events/eventdetails.aspx?iKey=RCR-NOV19) Early bird up to October 18th.

Although we are only halfway 2019, the scientific committee is already brainstorming on topics for the scientific events in 2020. We are aiming to organise a joined meeting with the SBS/BVS (Belgium association) on Vaccines in the second half of 2020. If you have any suggestions for topics, please feel free to contact the scientific committee (chair: Egbert.biesheuvel@danone.com)

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Special Interest Group (SIG) News

Webinars: "Quantitative methods to support decision-making in clinical drug development" by the PSI/EFSPI SIG Quantitative Decision-Making

Webinar 1: December 3rd, 2 to 3:30 pm UK time

"Overview and awareness about quantitative decision-making in drug development"
Registration: https://www.psiweb.org/events/event-item/2019/12/03/default-calendar/overview-and-awareness-about-quantitative-decision-making-in-drug-development

Webinar 2: December 10th, 2 to 3:30 pm UK time

"Main statistical approaches for quantitative decision-making in drug development"
Registration: https://www.psiweb.org/events/event-item/2019/12/10/default-calendar/main-statistical-approaches-for-quantitative-decision-making-in-drug-development

Asbtract: Quantitative methods to support decision-making in clinical drug development already exist but may be unknown or unused by pharmaceutical companies. We performed a survey among pharmaceutical companies, targeting people with different profiles (statisticians, non-statisticians and decision-makers) working at different stages of the clinical development (study level, development level or portfolio level). This survey allowed us to analyse which quantitative methods are known, which quantitative methods are used (or not), what benefit is expected from this kind of methods, and what are the needs for a larger use of quantitative methods to support decision-making. It permitted to understand the gaps and some of the issues associated to the use of such methods in drug development. The webinars are intended to share the learnings from the survey and to promote different quantitative methods for decision-making.

REMINDER: 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).

REMINDER: 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).

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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 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.

DSBS (Denmark)

On 3-4 September 2019 the DSBS hosted a course on Adaptive designs with Christopher Jennison. The course was well attended, with all available seats used. The course described the set-up for groups sequential designs, but also covered other types of adaptive designs.

FMS (Sweden)

The Autumn Meeting will be held at Karolinska Institutet in Stockholm, October 18. Main topic will be: Observational studies/Real World Evidence.

Meeting headline: Observational studies - registers, ethical vetting, industry.
Speakers from academia, pharma industries and service providers.
See the program here: http://statistikframjandet.se/fms/wp-content/uploads/2019/09/Höstmöte-program-1.docx. Slides will be provided in the next newsletter.

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).

PSDM

Upcoming course: '***Applied Sample Size Calculations in Clinical Trials***'
on **November 12 and 13**, Utrecht, The Netherlands

The PSDM – the Dutch Association is excited to announce a two days course on ***Sample Size Calculations*** by **Prof. Steven A. Julious** from Sheffield University on the 12th and 13th of November in Utrecht.

More information can be found on the PSDM website: https://psdm.nl/2019nov12_13-psdm-course-sample-size/

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

Visual Analytics combines automated analysis techniques with interactive data visualizations for an effective understanding, reasoning and decision-making. Visual Analytics is more than graphics, it is a process that optimizes your work flow, discharging cognitive and memorization burden to the visual cortex so the expert can focus on the important task: interpreting the data. Click here to login and watch.

PSI Webinar: Statistical Challenges in Analytical Comparability and Biosimilarity Assessment. 15th October 2-3pm BST. This webinar will discuss statistical requirements for the assessment of analytical comparability and similarity assessments, for example between biosimilars and reference products or before and after manufacturing changes. This topic has been the subject of a recent EMA reflection paper and an EFSPI working group. New strategies are proposed as an alternative to mean comparisons and include the assessment of ranges, inferential approaches or the use of Bayesian methods. 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.

Non-parametric analyses – much more than just the Wilcoxon test!

Interview with Frank Konietschke. Learn about a whole universe of different approaches, which will help you overcome many limitations of the methods, which you're using daily.

New Episode: Don't be a victim

Statisticians tend to be more on the introvert side and there are discussions that introverts are more likely to have a victim mentality. According to Jon Gordon, the key is to differentiate between some venting, that we need from time to time, from systemically and constantly complaining.

Take this Power of Positive Leadership Self-Assessment and complete the questions to know your Positivity Quotient Score. By knowing your score you will be able to establish a baseline for growth. You'll also receive Jon Gordon's 6 Quick Tips to Help Stop Negativity in It's Tracks.

Listen to this episode and learn how to avoid victim mentality. Share it with others, who might learn from it!

SFdS (France)

The National Days GDR Santé, SFdS and SFB, will take place on the 10th and 11th October 2019 at the National Conservatory of Arts and Crafts (292 rue Saint-Martin, 75003 Paris), Amphitheater Jean-Baptiste Say. After the merger with the days of the French Society of Biometrics in 2016, the traditional days of the GDR Statistics and Health merged this year with the days of the group Biopharmacy & Health of the French Society of Statistics. The theme "Statistics and Health" is a topic that concerns a large number of research teams in France, as well as teams of mathematicians interested and motivated by the applications of statistics in the biomedical field, INSERM units of biostatistics, research units. clinical research, teams of doctors, biologists, pharmacists ... It is important that all these teams belong to the same community. These days are meant to be an opportunity for exchanges and collaborations. Click here for more information.

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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).

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Volunteers needed

EFSPI are seeking volunteers to join an EFSPI website and social media committee. If you have expertise in using a variety of communication channels and you have ideas and suggestions for how EFSPI could improve the website and its use of social media, please contact Chrissie Fletcher (fletcher@amgen.com).

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Job Opportunities

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.

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To view previous newsletters please see the EFSPI website in the “News” area.

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