European Federation of Statisticians in the Pharmaceutical Industry

Representing Statistical Associations in Europe

EFSPI Newsletter February 2022

In this newsletter

EFSPI acknowledges the very challenging and disruptive times with the fact that Russia has taken military action in Ukraine. EFSPI hopes all its members are keeping well and staying safe.

EFSPI Council News

Please join me in congratulating ***Chrissie Fletcher*** as the new chair of the EFSPI Statistics Leaders Forum.

A big thanks to Novartis and Roche who are the co-hosts for the 2022 EFSPI Statistics Leaders Forum which will be a face to face meeting taking place on the **6th and 7th July 2022 in Basel, Switzerland**. The invitations to attend this year's meeting will be sent by mid-March. Further details on the agenda and topics for discussion will be shared in future newsletters. All the materials from previous EFSPI Statistics Leaders meetings are available on the EFSPI website.

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ESIG of the month – AIMS Application and Implementation of Methodologies in Statistics (AKA: The R SIG!)

The AIMS ESIG key objective is to act as an intermediary between groups working with R in the Biopharmaceutical industry and to share this information with the wider PSI community. We also help with other PSI initiatives like the medical statistician apprenticeship scheme. Our ESIG members represent PSI on the wide variety of groups described below. Each member then feeds back to the central team, sharing ideas, brainstorming solutions together and promoting collaborations. If you

would like to join this SIG or if you have questions about any of the below initiatives, please contact: psi.aims.r.validation@gmail.com.

Our ESIG members are currently involved with following initiatives, so we've listed some of the key achievements of 2021:

- R Validation Hub including riskmetric and the r shiny app. https://www.pharmar.org/
    - cran release of 'riskmetric' which aids users to assess R packages against a number of metrics to help quantify their robustness. https://cran.r-project.org/web/packages/riskmetric/index.html
    - Further development of the shiny app (the front interface for riskmetric) https://www.r-consortium.org/blog/2022/02/03/risk-assessment-shiny-app-update-from-r-validation-hub
- Following the successful delivery of the "R for SAS Users" PSI training courses, you are now invited to participate in a "R for clinical trial simulations" training course on 14th March 2022. https://www.psiweb.org/events/event-item/2022/03/14/default-calendar/psi-training-course-simulation-of-clinical-trials-using-tidyverse
- R Consortium working groups are really bringing people together to build on the use of R in the regulatory setting:
    - R Tables for regulatory submissions https://github.com/RConsortium/rtrs-wg
    - Submissions https://www.r-consortium.org/blog/2021/12/08/successful-r-based-test-package-submitted-to-fda
    - R adoption series https://www.r-consortium.org/webinars
- phuse initiative: The clinical statistical reporting in a multi-lingual world team are exploring key differences between SAS and R results using examples from survival analysis, CMH, linear and mixed models. The team are now working towards release of a white paper https://github.com/phuse-org/CSRMLW
- The Medical Statistician Apprenticeship Scheme is now live. Employers can start the process to recruit an apprentice and register them onto the scheme to start in September 2022. The apprenticeship standard can be found here: https://www.instituteforapprenticeships.org/apprenticeship-standards/medical-statistician. For more information see: https://www.psiweb.org/careers/educationandresources/medical-statistician-apprenticeship

Finally, news for 2022! The PSI AIMS ESIG Conference session will be 4pm on 14th June entitled "A showcase of using R for regulatory work." Please join us at the PSI conference and come meet the PSI AIMS ESIG team. In this conference session, PSI AIMS ESIG will demonstrate case studies using R for regulatory work in pharmaceutical research. The session will include some of the challenges and possible solutions, ranging from implementation of a full R platform to using R for a single piece of work. Particular focus will be on the methods used for implementation of an R platform at PHASTAR, followed by details of the process used at GSK for creating a platform for a full submission in R. In addition, several discrepancies have been discovered in statistical analysis results between different programming languages, even in fully qualified statistical computing environments. The Clinical Statistical Reporting in a Multilingual World (CSRMW) project seeks to clearly define this problem and

provide a framework for assessing the fundamental differences for a particular statistical analysis across languages. This presentation will provide an update on the CSRMW project and will demonstrate one of the used cases the team has investigated - Implementation of Survival Analyses in R vs. SAS.

I would like this opportunity to give special thanks to the all the lovely AIMS ESIG members for their contribution and dedication over many years: Andy Nicholls (GSK), Chris Toffis (SQN Clinical), Christina Fillmore (GSK), Jules Hernadez-Sanchez (Roche), Mark Bynens (JnJ), Martin Brown (PPD), Matt Neilson (PHASTAR), Michael Cartwright (PAREXEL), Michael Grayer (Floating point statistics), Min-Hua Jen (Eli Lilly) and Yann Robert (Sevier).

Lyn Taylor (AIMS ESIG Chair)

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Other ESIG News

Regulatory ESIG

EMA recently announced their EU clinical trials transformation initiative: Accelerating Clinical Trials in the EU (ACT EU). See here to read their white paper on their regulatory network objectives, governance, organisation, priority actions for 2022-2023, and resourcing. The implementation of ACT EU will contribute to delivering the Network strategy to 2025 and the Commission Pharmaceutical Strategy. The proposed initiative objectives are:

1. Optimise the EU environment for clinical research in Europe, whilst maintaining high-level participant protection, data robustness and transparency, by:
   a. Strengthening leadership and coordination on clinical trial authorisation and execution.
   b. Optimising ethical oversight and further integrate ethics committees into the clinical trial and medicines regulatory lifecycle.
   c. Supporting the conduct of large-scale multinational clinical trials with broader geographical scope.
   d. Reducing administrative burden and increasing efficiency.

2. Strengthening clinical trials that deliver decisional evidence for unmet medical needs, rare diseases, and on vaccines and therapeutics for public health crises and pandemics, ensuring support for HTA bodies as well as for academic and SME sponsors.

3. Heighten the impact of European clinical trials through excellent and coordinated scientific advice as a complement to trial authorisation and to support marketing authorisation and access throughout the medicine lifecycle.

4. Engage all stakeholders to proactively deliver inclusive patient-oriented medicines development and delivery across populations.

5. Ensure a clear and unified European position on clinical trials in strategic matters at the international level.

6. Build capacity in all aspects of drug development and regulatory science through, amongst others, research collaboration and training with academia.

Many of the recommendations from the EFPIA led workshop held in October 2021 on Accelerating Adoption of Complex Trials in Europe and Beyond have been referenced in ACT-EU.

The ICH E9 Working Group have released **final training materials** supporting the implementation of the final ICH E9(R1) *Estimands and Sensitivity Analyses in Clinical Trials*. Following the release of the final training materials, the ICH E9 Working Group has officially closed. The Estimand Implementation Working Group (EIWG) continues to be the hub for sharing implementation experiences. A new EWIG webpage is under development and will be shared in a future newsletter. Anyone wishing to learn more about the EIWG or join can contact Chrissie Fletcher (chrissie.a.fletcher@gsk.com).

Launch and Lifecycle ESIG

The Launch & Lifecycle SIG kicked off in January of 2022 with enthusiastic membership from most of the big pharmaceutical companies in Europe. The purpose of this SIG is to provide a platform for statisticians working in the launch and lifecycle management space (i.e., traditional medical affairs, commercialization, etc) to collaborate in the pre-competitive space, shape the industry and increase the influence of statisticians in the launch and lifecycle space, and to drive scientific projects and innovation forward. A baseline membership survey and discussed results at a recent meeting. Highlights are summarized below.

Survey Highlights

- Membership **experience** in the launch and lifecycle space = 133 years (mean = 12.09, range 5 to 20)
- 54.5% have dedicated MA statistics support, and the remainder sit within the larger biostatistics organization (most) or within molecule teams. Most (> 80%) rely on a sourcing model characterized by minimal in-house staff supplemented with contractors or CRO staff.
- Most respondents reported being involved in the planning and conduct of clinical trials, noninterventional studies, exploratory data analyses, real-world evidence generation, advisory boards, external proposal review and scientific publications. Roughly half of respondents reported being involved in integrated evidence planning / strategic medical plans and HTA. A few statisticians reported being involved in PASS/PAEs and COA / PRO.
- Three common themes stood out of key characteristics and mindsets that make statisticians successful in MA roles: **(i)** Great communication & listening skills: Successful statisticians can explain complex concepts in simple terms; they are curious, engaged, collaborative, and diplomatic; (ii) Business acumen / Understanding the big picture: the most successful statisticians understand the treatment landscape and appreciate the needs of multiple stakeholders. They are interested in the strategic discussions, have thorough understanding of the development program, and can help identify remaining evidence gaps and opportunities for other stakeholders; (iii) Leadership: As in any area, statistician leaders are able to prioritize and ask questions to ensure understanding of the key problems to solve. They are influential and bring a strong voice to the table. They understand that a pragmatic approach will be more successful than an overly dogmatic approach

Priorities for the SIG to accomplish in 2022 include sharing best practices in medical affairs (e.g. strategic evidence generation, scientific dialog, innovative designs, resourcing), learning from others (e.g. coaching, networking), and raising awareness of the importance of evidence generation beyond the filing in the launch and lifecycle space. The SIG will be hosting a session at the annual PSI meeting to give an overview of the SIG.

If you want to be part of this group, please connect with Jenny Devenport or Alexander Schacht on LinkedIn. Click here to see more information on the launch and lifecycle SIG.

Jenny Devenport & Alexander Schacht (SIG co-leads)

VIS ESIG

The Visualisation (VIS) SIG celebrates the 25th Wonderful Wednesday Webinar in March. A group of statisticians passionate about data visualisation founded the VIS SIG about 2.5 years ago. The aim of the SIG is to elevate the capabilities of statisticians in terms of data visualisation skills, as many data visualisation being used in healthcare are far from being optimal. Many efforts focus only on providing templates for visualisations to reduce the burden of data visualisations, yet this misses on the point, that great data visualisations – especially explanatory data visualisation using story telling – need to be highly customized to be effective. As every data visualisation expert knows, the sum of the details makes a great data visualisation. We cannot achieve quality graphs by just using only plug-and-play templates. One of the major efforts of the SIG was to set up a platform, which would help statistician learn about data visualisation practically, provide relevant examples of data visualisation coming from our day-to-day work, set up a collection of code examples, which we all can use as a starting point to program customized data visualisations, and share inspiring data visualisations to show the opportunities for our work.

The Wonderful Wednesday Webinars (WWW) support all these four points. In addition, they created a community of statisticians meeting on a monthly basis to share their work and receive feedback about it. The passion and collaboration within this community is outstanding and the expertise regarding data visualisation is world class. As this flagship event of the SIG turns 25 (months) or 2 years, we will celebrate the SIG with a special webinar. Instead of talking about data visualisations of a specific data set, we will review the favourite data visualisations of the last 2 years. Everybody in the community can submit their favourite data visualisation from the WWW together with a brief description of why it is especially useful, inspiring, or outstanding in other ways. Please email alexander.schacht@veramed.co.uk or use the usual form on the WWW homepage. As usual, the WWW will take place on the 2nd Wednesday of the month at 4pm UK time. Attendance is free for everyone. Just register here:

https://www.psiweb.org/sigs-special-interest-groups/visualisation/welcome-to-wonderful-wednesdays

Alexander Schacht, ESIG Chair

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Local Association of the month – PSI (UK)

PSI is a community dedicated to leading and promoting the use of statistics and data sciences within the biomedical and healthcare industry for the benefit of patients. PSI has 4 strategic objectives:

Empower members in their profession by strengthening and broadening their technical

and influencing skills

Nurture and expand a collaborative and engaged community

Promote the value of statistics and data sciences in healthcare and career opportunities for statisticians and data scientists

Advance healthcare by being a leading partner in the application of statistics

Further details of the activities supporting these objectives and the current Board of Directors and their responsibilities can be found in the 2022-2023 business plan.

PSI is excited for the upcoming annual conference being face to face in Gothenburg on the 12th – 15th June 2022. Further details are provided below, don't forget the early bird deadline is Friday 25th March. As noted above in the AIMS ESIG update, PSI is thrilled that the new Medical Statistician Apprenticeship is live, a huge thanks to those involved to make this happen. PSI continues to promote careers within the Pharmaceutical Industry with schools and universities and given the shortage of data skills including maths, statistics and data science, it is even more important to ensure we have the next generation of statisticians coming into the profession. The video on demand platform continues to thrive allowing members to access materials from online events at a time that suits them. Professional development and supporting members throughout their career remain a core focus for PSI and details of upcoming events are provided below. The Pharmaceutical Statistics official journal of PSI and published by Wiley continues to excel in bringing latest thinking and methodological advances including promoting discussion of statistical applications in drug development. A key focus for PSI in 2022 is developing a digital strategy and more will be shared on this in future newsletters.

Thanks to all the members for their tremendous support and continued engagement. Priya Gokani as the new PSI Engagement Lead will be working within the Membership and Community Committee to further develop and build the PSI community.

PSI Conference 2022 update

While we appreciate there are still uncertainties around COVID in many countries, the PSI Scientific Committee and Board of Directors confirm **it is our intention that the 2022 PSI conference in Gothenburg will go ahead as a face to face event on the 12th – 15th June.**

The draft programme is now available online and the registration portal for the conference is open with the early bird deadline of March 25th. Look out for more details on the sessions and additional information on Gothenburg soon. **We look forward to seeing you at the conference!**

MEETINGS, WEBINARS AND COURSES

02 Ma — **PSI Medical Statistics Careers Event**

14 Ma — **PSI Training Course: Simulation of Clinical Trials using Tidyverse (TRNG270)**

23 Ma — **PSI Webinar: Statistical Challenges in Gene Therapy Trials (WEB271)**

ON-DEMAND WEBINARS AND PODCASTS

PSI VisSIG Wonderful Wednesday 23: Gestalt principles and pre-attentive attributes

Alexander Schacht presents the Wonderful Wednesday special edition on designing a plot to focus attention. Examples for visualisations are available on the Wonderful Wednesday blog.

Watch here

Watch here

PSI Webinar: Tipping Point Analyses - Introduction & Case Studies

What is a tipping point analysis, and how is one performed? What are the different approaches for continuous, binary and time to event data? Kevin Ding (AstraZeneca) and Juan Abellan (GlaxoSmithKline) present some practical examples.

Beyond SOPs – What is quality?

During my early years, I was overwhelmed by so many training, SOPs, and processes. Gary fundamentally helped me and many others have a very different and more insightful/helpful/easy perspective about this topic.

Challenges and opportunities of combining RWE and RCT data

I've been working on RWE most of my career and the clinical trial data for a while now. And 20 years ago, we would have never thought about merging them together but there's a lot of opportunities if we do this. Join us while we talk about the challenges and opportunities of it.

10 reasons to submit a poster for the PSI conference!

If you are working in healthcare industry, there is no other conference like this. And submitting a poster for the conference would be best! In this episode, I am sharing with you the 10 reasons to submit a poster for the PSI conference.

Listen to these episodes and share them with your friends and colleagues who might learn from it.

Ciao and be an effective statistician!

Alexander Schacht

Listen here

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Other Country News

APF (Germany)

On Tuesday, March 29, 14:00 -16:00 (CEST), we will host a special German Stats Leaders online meeting: "Open-source R-packages for innovative, GCP-compliant reporting – available building blocks & initiatives."

BBS (Switzerland)

The Basel Biometric Society (BBS) has a new website. Thanks to Kaspar Rufibach for his leadership to develop it at a fast pace with increased functionality.

All materials from previous BBS events are available for free. Recent topics include machine learning in clinical drug development, COVID-19 and how we deal with data, precision and Innovative medicine and health technology assessment, statistical challenges in the clinical development of CAR T-cell therapies, graphics for decision-making in biomedical research and drug development and a gentle introduction to Causal thinking.

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Job Opportunities

See here for more details on the Biostatistics Project Manager Oncology/Neurology position available. 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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And finally…..

To add your e-mail address to the EFSPI mailing list, click on "Sign up to our newsletter" on the homepage of the EFSPI website.

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

This will be my final newsletter, thanks to **Justine Rochon** who is taking over as the editor for the EFSPI newsletters.

Chrissie Fletcher, EFSPI Newsletters 

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