Annual Report

2023

Contents

Welcome from the Chair

2023 was a very successful year for PSI where we consolidated the large growth in membership numbers and finished the year with nearly 2000 members. The 2023 Annual Conference was a record breaking success, both in terms of number of delegates and the amount of sponsorship. It was fantastic to be part of such a large meeting. The PSI Board is working hard to improve how we serve our membership in terms of the website and better communication. Training and development opportunities and a successful conference also provide the necessary means for us to undertake these improvements.

PSI offered a mix of in-person, hybrid and virtual events, with a total of 48 events run in 2023. The type of events and range of events held has continued to expand providing something for everyone, and for both members and non-members. Most events were recorded and available to members through the Video on Demand (VoD) platform. This level of engagement is a huge testament to the PSI committees and special interest groups that together delivered a comprehensive package of highly valuable events and also enabled PSI to reach out to new members across the world. PSI membership has significantly grown in recent years both inside and outside of the UK.

The PSI Board of Directors has progressed a number of important initiatives in 2023. Most importantly the digital strategy which although taking longer than originally planned is now in good shape to be implemented in 2024.

Highlights

Below I note a few key highlights for 2023, but please spend some time reading through the full report:

• We made a large profit of £163k in 2023, matching the profit made in 2022. We aim to keep reserves of at least £360k and currently have reserves of £655k which will enable PSI to advance the digital strategy, improve communication, for example by redesigning our webpage, and enhance training and outreach activities.
• MCI have provided strong support to the board in 2023 and the board continues to partner closely with MCI to share feedback and identify ways of making processes supporting PSI business as efficient as possible.
• We had 1,979 members in 2023, the highest ever in the history of PSI (and an 8% rise in full members since 2022). PSI is represented in over 50 countries. The Glue Up platform continues to make it easier to manage and oversee PSI membership.
• The Careers Committee was restructured; the Careers and Liaison Committee (CALC) now focuses solely on promotion of the industry to Universities and a new Schools Committee was created to lead outreach focussed on school age students.
• The Professional Development Committee continue to support people within the industry and the Introduction to Industry Training (ITIT) Committee developed its popular course (the 2023/24 course was oversubscribed).
• The PSI Medical Statistics Career Event took place in Sheffield where there were 25 exhibitors and 90 students in attendance.
• Over 80 students attended the MEDMathS (Medicine Empowered by Data, Maths and Statistics) webinar in November.
• The Medical Statistics Level-7 Apprenticeship is continuing to be a success and PSI is working closely with a number of universities and so by 2025 there should be 4 options (2 F2F, 2 Virtual) for students to undertake Apprenticeships.
•The Schools Committee has made a great impact since forming in July 2023. I look forward to seeing who are the top 10 PSI members who completed the highest number of outreach activities in the 2023/24 academic year.
• The Professional Development Committee continues with the popular mentoring scheme, book club and lunch and learn events. Whilst the New Starters Special Interest Group has been rebranded as the Career Young Committee.
• We thank the Commercial team for attracting 27 Sponsors to the Annual Conference resulting in record levels of sponsorship. For 2024 Sponsorship for the Conference is running in line with the previous record.
• The communications and external affairs committee now has a separate lead for Communications (co-led by Sophie Greenwood and Oceana Faria) due to the role communications play for reporting events and monitoring social media. The development of the digital strategy was a huge undertaking; thank you to Jack Elkes for all he did to support this work and thanks to the new Digital Strategy Lead Jamie Rees, who is now working on implementing priority changes

to our website and collaboration tools. For external Affairs, contact is regularly made with EFSPI and relevant academic institutions.

• The Events Committee had another busy year with a total of 48 events in addition to running a very successful in-person annual conference. Over 100 people attended events on Estimands, ChatGPT and Bayesian Methods as well as Journal Club sessions on Propensity Scores and Bayesian Approaches to Efficacy and Safety.

• More records were broken at the 2023 conference where we had 620 delegates from 28 countries and 171 different companies and organisations. Well done to the conference team for the high quality and diverse topics covered in the program and how they coped with the extra workload due to the additional number of delegates.

• The European Special Interest Groups supported by PSI and EFSPI were very active in 2023. There are now 21 SIGs sponsored by PSI and EFPSI and 20 ESIG events took place in 2023 as well as a huge contribution from SIGs at the conference.

Thank you to every person who has joined PSI; I hope you enjoy being part of the PSI family. Thanks to the board who have worked tirelessly in their roles and to MCI for their partnership and administrative support to run PSI. Thanks also to the individuals leading or involved in a PSI committee or group; you have enabled PSI to further advance and become a stronger association. Thanks to all the individuals who attended PSI events or sponsored PSI, your support is very much valued and appreciated.

Awards

The 2023 RSS/PSI Award for Statistical Excellence in the Pharmaceutical Industry is a prestigious annual award for the most influential example of the application of an existing statistical practice, or the implementation of an innovative statistical practice, in the pharmaceutical industry. The 2023 award went to Dr Satrajit Roychoudhury who made a significant impact in developing, implementing, and disseminating efficient statistical methodology in four distant areas; Bayesian design for COVID-19 vaccine trial, Use of external control data, Implementation of model-based approach in Phase I oncology studies and Statistical approaches for non-proportional hazard.

The 2023 Mick Godley Award to recognise the unsung heroes of PSI went to Claire Brittain to recognise her significant contributions to inspire the next generation of statisticians and programmers in the industry. She has been the driving force for a huge number of careers activities, working within the CALC team.

In 2023 the PSI board introduced the new Rising Star award to recognise the impact of PSI volunteers who are in the early stages of their career. This award went to Tom Burnett for his advocacy work between the pharmaceutical industry and academia. Tom has played a huge role in the young statisticians session and social every year at the conference. We are a community dedicated to leading and promoting the use of statistics within the healthcare industry for the benefit of patients.

If you are motivated to get involved in PSI, we would love to hear from you. Please contact us at: psi@mci-group.com

David Wright
PSI Chair

Treasurer's Report

The 2023 professional audit is ongoing and several items, such as VAT reimbursement, are pending, so the following numbers are subject to change. During 2023, PSI repeated the previous year's record profit of around £163k. The total income was £738k, purchases were £405k, and overheads were £170k. This result is the outcome of continued steps by the Board and Committees to gain efficiency, push forward with the digital strategy and having tough discussions with vendors.

Our reserves now stand at £655k. We aim to have reserves of at least £360k, which is expected to ensure the continued operating of the society even in case of substantial shortfalls on the income side. PSI is in an excellent financial state and can invest in its future, which includes new digital strategy activities after the completion of the first wave, communications activities such as a website redesign, and training and outreach activities.

Major drivers of the 2023 result
The very positive 2023 result is mainly due to a continued growth in membership, excellent conference attendance and support from sponsors, as well as a comprehensive events programme, including the ITIT course. PSI continues with a mix of in person and virtual events, where virtual events are more cost-efficient to run, and in-person events are generally perceived as better value due to networking opportunities. The Board has continued to be careful about managing PSI's money, especially in light of continually rising costs of running the conference. Venue hiring costs as well as catering, equipment, and personnel costs have massively risen since before the pandemic, leading to fairly high registration fees for the conference.

PSI has very substantial overheads to operate the society, including our contract with MCI as well as IT systems, accounting, and legal fees. Almost all PSI activities are revenue-generating and financially net positive. Historically PSI always needed to ensure highly profitable conferences and events to compensate for the annual overheads. While this dependence has been reduced in recent years, PSI still depends on these revenue sources to continue operating. The Request for Proposal process has revealed that professional service cost are likely to be much higher in the future, so continued prudence and focus on efficiency is needed.

2023 income overview

Profit (£k)	2016	2017	2018	2019	2020	2021	2022	2023
Membership	58	72	72	75	83	89	130	145
Conference	124	65	116	49	-22	20	7	29
Training & ITIT	18	22	19	24	22	36	22	27
CALC/SIGs	3	11	-1	0	10	4	17	3
Scientific	9	11	3	16	-4	15	8	1
Publications	-18	-16	-5	-8	-8	-4	-7	-6
Commercial	100	86	97	83	0*	16	140	151

Rounded to the nearest £1k. 2023 figures are subject to change. Overheads are not included in this table.
* Sponsorship, exhibition, and advertising income would typically be shown in this row, but were included in the Conference row for the 2020 accounts.

Contracts Report

The remit of the Contracts Director is to establish and maintain key contracts with external suppliers on behalf of PSI.

The current key contracts PSI holds are for:
- Business Administration Services – MCI UK Ltd
- Conference Event Management – MCI UK Ltd
- Journal Publishing – Wiley
- Professional indemnity insurance - Tokyo Marine HCC
- Auditor - TC Group

CONTRACTS

Business Administration Services
An in-depth Request for Proposal process was completed in 2023 to assess the current market for professional services. MCI were asked to quote, along with several other providers, with all quotes currently being considered. The current contract continues until it is terminated by either side, allowing for protracted negotiations.

As PSI's virtual activities grow, the cost-effective scheduling and running of webinars, virtual trainings and SIG events continues to be a key area for development. The annual fixed cost to PSI is £139,352 with services beyond the contract producing additional costs (~£12k in 2023 outside of the conference). This cost is adjusted for inflation annually. Some conference management tasks are included in the overall business contract.

Website and digital infrastructure
The website continues to be solely maintained by MCI and is included in the main MCI contract. In 2023 PSI investigated topics such as a blog, community forum, individual email addresses for committees, and a new file hosting and conferencing service. Not all of these were seen as good value for money for the members, but feedback on what would really benefit each member personally is welcome! A switch to Microsoft Teams and a website redesign are planned for 2024. More efficiency and automation with digital tasks are also still in progress.

Journal
The Pharmaceutical Statistics journal is owned by Wiley. The contract was renewed in 2021 and the current contract is in place until the end of 2026.
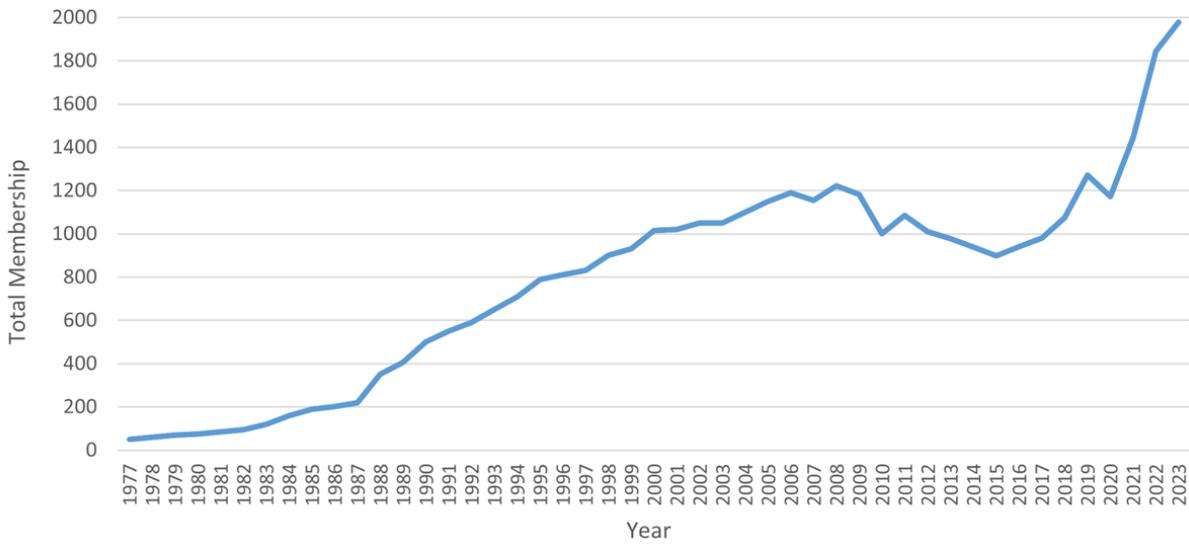
Markus Elze
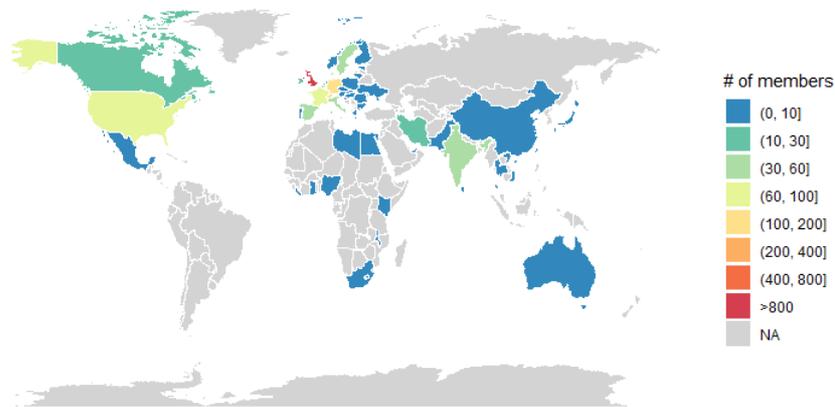**Contracts and Finance Director**

Membership Report

PSI Membership History

Our membership numbers have reached record highs, with an impressive 8% rise in Full members (totalling a 7% increase overall) spanning across more than 50 countries.

We finished 2023 with a staggering 1979 members.

Membership Category	2018	2019	2020	2021	2022	2023
Full	959	1070	867	1134	1442	1562
Honorary	9	9	11	11	11	12
Reduced Rate	8	21	25	22	25	21
Student/Teacher	98	172	268	276	366	384
Total	**1074**	**1272**	**1171**	**1443**	**1844**	**1979**

Thanks to GlueUp, our renewals process is now streamlined, and the success of our corporate renewals has gathered excellent feedback. We are immensely grateful for the continued support for PSI from all of you. A special mention and thanks go out to all the company representatives who tirelessly contribute to ensuring that PSI offerings receive maximum visibility within our organizations.

To uphold our commitment to openness and diversity within PSI, we encourage you to visit our volunteers page on our website. This is where we showcase any available voluntary positions.

Should you have any suggestions on how we can foster greater engagement among our global members in 2024, please don't hesitate to reach out. Your input is highly valued in shaping our initiatives and ensuring they effectively resonate with our diverse community worldwide.

Kate Tsirtsonis
PSI Membership Director

Careers Report

The Careers team has been very busy in 2023. The Careers and Liaison Committee (CALC) has been re-branded to one that solely focusses on promotion of the industry to Universities and we have created a new Schools Committee to lead outreach focussed on school age students. The Professional Development Committee has continued to support people within the industry and the well-established Introduction to Industry Training (ITIT) committee has delivered its popular course.

Universities Committee (formerly known as CALC)

The objective of Universities Committee is to promote the role of statisticians and statistical programmers within the medical research industry to university students. We aim to engage with universities to inspire and educate students about future opportunities for study and possible career opportunities within the industry.

Amanda Darekar, Universities Chair

We were delighted to travel to Sheffield for our 2023/2024 Medical Statistics Careers Event for students, held this year in the beautiful Cutler's Hall. As with previous events, it aims to showcase the range of careers available to students in the field of Medical Statistics. This year, we welcomed 25 exhibitors, and approximately 90 students attended. The event kicked off with lunch followed by an introduction from the PSI vice-chair Chrissie Fletcher and the PSI Careers Universities committee chair Amanda Darekar. We heard from New Starter to the industry Max Howard who is a biostatistician at Fortrea in Leeds. Following Max's excellent talk, was the panel discussion with representatives from six organisations, each of whom had a wealth of experience in different types of roles within Medical Statistics:

- Stewart Ravenhall (Roche)
- Violeta Balinskaite (Medpace)
- Bethan Thomas (ICON)
- Patrik Atkinson (Veramed)
- Esther Herbert (Sheffield Clinical Trials Unit)
- Laura Marsden (GSK)

The panel shared thoughts and opinions about their work such as, what motivates them, what they find challenging about their job, their proudest achievements, what they wished they'd have known as a student and also answered questions from the audience.

As ever, the main highlight of the event was the chance for students to speak face-to-face with representatives from many different organisations including potential employers in the exhibitor session. The event featured 6 pharmaceutical companies, 8 Contract Research Organisations (CROs), 6 Clinical Trials Units (CTUs), 3 professional societies and 7 universities advertising postgraduate study opportunities, including the Medical Statistics apprenticeship. It was a real bonus for students to be able to speak directly with the company and university representatives, all of whom could share information about their own career paths and the different types of roles available within medical statistics, providing students with a wide range of perspectives about possible next steps.

We hosted the latest edition of our MEDMathS (Medicine Empowered by Data, Maths and Statistics) event on Wednesday 1st November 2023. This webinar is targeted at undergraduate and postgraduate students, aiming to:

- Introduce the world of medical statistics
- Provide an awareness of career opportunities that exist within medical statistics
- Demonstrate how PSI can help in pursuing such a career

Over 80 students attended from a wide range of backgrounds and were highly engaged with 20+ questions being submitted during the presentation. The PSI Careers Universities committee hopes this webinar will demonstrate the appeal of a career in medical statistics, as well as helping to drive free student membership and student attendance of PSI events.

We were also pleased to continue to grow the content of the PSI Student Newsletter, with two editions distributed, in March and October 2023. This aims to provide institutions and students with useful information and links to resources while studying a maths-related degree at university and when thinking about future career options. The newsletter includes a huge variety of content, including information about PSI Events (both Careers and non-Careers related), the PSI Conference, Medical Statistics Apprenticeship, SIG Spotlights, and insights into the impact of Statisticians. In addition, following nominations received from their universities, eight PSI Undergraduate Awards were awarded to mathematics/statistics students at the following universities from across the UK: Aberystwyth, Bath, Cardiff, Glasgow, Lancaster, Queen's (Belfast), Reading, and Warwick.

There are currently several students undertaking the Medical Statistics Level-7 Apprenticeship. As reported last year, this has been an extensive amount of work to get this approved (and re-approval, with some planned updates, is underway), and it has been rewarding to see that students have been able to take advantage of this new route into the industry. PSI is working closely to ensure that more universities can become training providers and interested companies are able to publicise the apprenticeship:

- The University of Leicester is approved for a 2024 intake for Face-to-Face learning
- UCL are planning to be a virtual learning provider
- LSHTM are hoping to be available for a 2025 start date for Face-to-Face learning
- The University of Strathclyde (virtual) are still on board as well

Schools Committee

The objective of the Schools Committee is to encourage and support PSI members to engage in Schools Outreach activities. By empowering our PSI members with materials to take into schools, as well as fostering collaborations with relevant STEM engagement organisations, we aim to promote the opportunities of working in numerate careers in the pharmaceutical and healthcare industry and hopefully inspire the future workforce to continue with their studies in STEM subjects.

Emma Crawford, Schools Chair

The Schools committee formed in July 2023, and we launched formally with a webinar in September 2023 to promote engaging in Schools Outreach to the PSI membership as well as sharing the content we had available to support them, such as our classroom workshops. We were pleased to be joined by Steve Mallett, Claire Brittain, Doug Thompson and Nicola Voyle as panellists to share their own experiences of engaging in Schools Outreach.

The webinar also saw us launch a new incentive scheme for PSI, the PSI Careers Outreach Champions Challenge Cup. This scheme will aim to recognise PSI members who have made exceptional outreach contributions throughout the year. PSI members are encouraged to submit an activity completion form each time they complete an outreach activity within a School. At the end of each month, we will total the number of activities submitted by each member to see who makes it into our top champions leaderboard. There is still time to join the competition as the scheme will close on **31st May 2024**. At the PSI conference in June 2024, we will announce the top 10 members who completed the highest number of outreach activities during the 2023/24 academic year whom will receive a certificate. The winner will also receive a £50 voucher of their choice and a £250 STEM grant for a participating school. For more details on the scheme and how to get involved with Schools Outreach please visit our website.

Following feedback received at the webinar, we have been proactively seeking out connections with relevant external STEM organisations to help support our members in accessing schools outreach opportunities and were pleased to collate a range of volunteering and sponsorship opportunities available for our PSI members. We also formed a partnership with I'm a Scientist and sponsored 3 spots in their engagement competition for PSI members. We are proud to have Ria Kalaitzaki (GSK), Fiona Grimson (UCB) and Laura Barker (AZ) represent PSI in I'm a Scientist for 2024 and look forward to hearing how they get on in the competition.

Professional Development Committee

The objective of the Professional Development Committee is to empower the PSI community to be more proactive in their personal and professional development journeys. The committee aims to provide resources and career support through interactive webinars and events helping members to take the next step in their careers.

Xinyi Zhu, Professional Development Chair

The Mentoring Scheme is aimed at members interested in networking with other colleagues from the industry, learning from more experienced industry colleagues and having a sounding board for their current challenges and future aspirations. Members can sign up as either a mentee, mentor, or as both. People are matched based on years of experience, goals and interests/areas of expertise. 2023 was very successful with 16 mentor/mentee pairs participating and feedback was generally very positive. Registration for the 2024 cohort has just ended with an even better response than the previous two years, showing that the demand for mentoring within the industry continues to grow.

The Book Club is aimed at reading and discussing non-technical books for personal development. In 2023, the books were "Dare to Lead" by Brené Brown, and "The 7 Habits of Highly Effective People" by Stephen R. Covey, with 17 and 23 participants registering, respectively. Participants were split into groups to review the content and main messages of the books over multiple hour-long facilitator led sessions. They were also encouraged to devise a plan to implement the learnings of each book. The Book Club have a mailing list keeping members updated on recent developments such as the start of registration for each new book.

The Lunch and Learn events of 2021/2022 set the stage for a series of engaging webinars in 2023. These webinars covered cutting-edge topics, such as "Modern Leaders: Remote not Distant," "ChatGPT and Beyond," and "Is it AI? Can you spot the fake," drawing registrations from 75-150 participants each. The feedback was overwhelmingly positive, with attendees appreciating the fresh insights and discussions on emerging subjects that are often overlooked in technical circles. The interactive format was a hit, notably the "Unconscious Bias" workshop at the PSI Conference in London, which was fully booked and highly praised. Looking ahead, the 2024 PSI Conference in Amsterdam will feature a plenary session led by our team on the topic of Neurodiversity. Additionally, the PSI website has been updated for better accessibility, allowing users to easily find and view recordings of past sessions.

The New Starters SIG rebranded as the Career Young Committee and had a successful year leading virtual events, hosting networking events at the PSI conference and representing PSI at external meetings. The quarterly virtual events facilitated networking and fostered engagement with 20-30 diverse attendees per event. Participants ranged from students seeking guidance on career progression to those on apprenticeship schemes and placement programs. At the conference, they organized a networking event during registration and lunchtime on the first day to welcome

those new to conference or the industry. They also represented PSI at the Young Statistician's Meet hosted by the YSS, in a panel discussion on careers. Looking forward, the committee remain committed to organizing both the conference and virtual events while actively expanding our network to forge connections across the industry.

Introduction to Industry Training (ITIT) Committee

The objective of the ITIT Committee is to organise the introduction to industry training course which runs yearly from October to July. The ITIT course is an introductory course for statisticians and statistical programmers new to the pharmaceutical industry, giving an overview of the industry and the complete drug development process. It comprises of six 2-day face-to-face sessions covering a range of topics including Research, Toxicology, Data Management and the Role of a CRO, Clinical Trials, Reimbursement, and Marketing.

Zelie Bailes, ITIT Chair

Following our return last year after COVID disruption, it was great to receive a high number of applications for the 2023-2024 course, resulting in us being oversubscribed. We have welcomed the maximum number of 25 delegates, from 11 different companies, onto the course this year, and we hope to welcome any applicants that we were unable to accommodate this year onto next year's course! The 1st session of the course was hosted by Roche in Basel and the 2nd session by Janssen in Beerse, Belgium. The remaining 4 sessions of the course will be held in the next few months in 2024, with hosts including ICON, Amgen and AZ. We are still searching for a host for our marketing session, to be held in July 2024. The success of the course relies heavily on the companies volunteering to host a session, and therefore I would like to take this opportunity to thank all those who have been, or are planning to be, involved with hosting a session. Applications for the 2024/2025 course will open on 1st April, with the deadline for applications set for 21st June.

"Thank you to everyone who has been involved with making the Careers team a success, without the enthusiasm and dedication from our volunteers, we wouldn't be able to provide such varied and diverse events."

Kimberley Hacquoil
Careers Director

Commercial Report

The remit of the Commercial Director is to generate additional revenue for PSI, primarily via sponsorship and advertising

This is my third year as Commercial Director and we have continued to build on the successes of previous years. PSI derives much of its earnings from registration and sponsorship of the annual conference. From a commercial perspective, we have continued to engage with a broader group of sponsors as well as increase the levels of sponsorship. The conference in 2023 attracted 27 different Sponsors and saw the largest ever levels of sponsorship, beating the previous year which also had record levels of sponsorship. Since the pandemic, we have had a few solid years of revenue which has put the future of PSI on very solid ground.

For me, it is clear that increasing focus on sponsorship will have the greatest impact to PSI. PSI simply cannot deliver all the activities described in this report without the much needed support of our Sponsors. One of the key objectives I had was to increase revenues from sponsorship by attracting a broader group of Sponsors and offering more sponsorship opportunities. In 2023, we added more sponsorship opportunities, such as the Protect the Environment package. Many thanks to Veramed and to Sanofi for helping us make the conference the first PSI carbon positive event. The changes have attracted sponsorship from companies who have never previously been involved in the conference. Feedback from Sponsors was extremely positive, which also resulted in advanced bookings for the coming year.

Looking forward to 2024 and my last year as Commercial Director, sponsorship for this year's conference is running in line with the previous record. This is very encouraging given the uncertainty that the Pharmaceutical Industry at the moment. It is clear that many companies are facing budget constraints which may well impact on PSI as an organization. Nevertheless, the support we receive is very much appreciated as it provides much needed funding, allowing PSI to invest in providing better services to members in the future.

In developing and executing PSI's commercial activities, I am ably supported by others who give up their valuable time for an organisation that plays such an important role in our industry. The PSI Commercial activities are supported by Ian Ratcliffe (Veramed), Mary Elliott-Davey (Amgen) and Frances Denny (Exploristics).

Aiden Flynn
Commercial Director

Communications Committee Report

This year has been one of change for Communications and External Affairs.

With the increased workload of Communications Committee it was decided that there needs to be a specific lead for this, and separate it from External Affairs. This is in recognition of the importance communications plays in PSI in reporting from events and the monitoring of social media. The work done in 2022 and 2023 in putting together an improved process has helped but to be truly effective, a Communications Lead was needed.

With this in mind, Communications will have co-leads, Sophie Greenwood and Oceana Faria. Together they will work with all of the PSI committees to ensure that the communications is good. They will also attend BoD meetings when there is a need to.

The new process established last year is already showing its value, with reporting now being seen at all events. This process is also helping other committees, knowing they have reporting in place. We shall continue to monitor the process and make any adjustments accordingly.

Owing to the increase workload of his PhD, Jack Elkes decided to step down from the committee and thus, the lead of the digital strategy. I would like to take this opportunity to thank Jack for all his hard work on the Digital Strategy. Without his diligent efforts, we would not have the strategy in the first place. Moving forward, the Digital Strategy lead will be Jamie Rees, who is already looking into the priorities of the website and collaboration tools. We aim to have completed these parts of the strategy this year.

One of the main activities last year was to develop a general strategy for all the communication activities for PSI. We achieved this, but know that this document is a living one and will continue to be updated.

As I mentioned, there was a realisation that Communications and External Affairs needed to be treated separately within the committee. To this end, I will now be dedicating my time to External Affairs, and leaving Sophie and Oceana to lead Communications, and Jamie to lead the Digital.

For External Affairs, I will be continuing to reach out to other statistical organisations such as EFSPI (where I sit on the Council as the Academic Liaison). I will also be engaging with academic institutions to look at where PSI could help them in their work. This will also be a two-way interaction. I plan to pull senior academics and industry statisticians together to discuss better ways to work together.

I want to end this report by thanking the fantastic effort of every one of the Communications team, who tirelessly put in so much effort to make things work. It is entirely them who make this happen. Thank you!!

Alun Bedding
Communications Committee and External Affairs (and EFSPI) Director

Events Report

In 2023 the PSI Events Committee, led by the Events Director continued to ensure the coordination of delivering a full programme of PSI events – in person and virtually and covering scientific topics, technical training topics as well as more career development focused events. Many different committees now organise different types of events; the events committee's role is to coordinate and support this so that our members and non-members are provided with excellent professional PSI events.

In 2023 PSI offered both members and non-members a widely varied programme of scientific events – a total of 48 different events, although simply counting events is probably not the fairest method at all to reflect the depth and diversity of content. More detail of some of the events is included elsewhere this report. In 2023 again our events were almost all online – the exceptions were our fantastic conference in Hammersmith, London, the Scientific meeting on Master Protocols in High Wycombe (UK), a training course on Sample Size in central London, the annual Medical Statistics Careers Event and the ever-popular ITIT course for those new to the industry (2023/2024 cohort). Our online meetings included ability to ask questions for discussion by presenters and we also held several successful online training courses

Numbers of attendees at the events ranged from 620 at conference, 50-300 at scientific/SIG topic/careers webinars and journal clubs and 20-40 at interactive training courses/workshops. Popular events included "Proposing Estimands from Different Perspectives", "ChatGPT and Beyond", "Application of Bayesian Methods in Confirmatory Trials" and also both Journal club sessions on "Propensity Scores" and "Bayesian Approaches in Efficacy and Safety" as well as the HTA SIG webinar on "Estimands, PICOs and Cp. – Are we losing or gaining in translation". All the events just mentioned had over 100 attend[...]ine now is the wide audience we can reach. Don't worry if you missed out on any of the PSI 2023 programme of events though – PSI members can access recordings of webinars (and conference recordings) on the Video on Demand platform which is a fantastic resource.

And for 2024 a full programme of events is planned and can be found on the website – keeping the great diversity of topics and types of events going as all benefit different members in different ways. We are continuing to keep all PSI events run professionally – organisers and speakers are all volunteers for which we are very grateful. Our PSI admin team provide us with consistent support in the background to ensure that events run smoothly. In 2024 all PSI online webinar/meetings will continue to be free to PSI members and also to PSI non-members as a way to promote great science and reach broader audiences. Training courses and interactive workshops (online or in person) will still have a fee as we have other costs associated with these activities. We are also still proud to be supporting students to attend PSI events for free as we promote our industry to them.

A big thank you to all members of the all the organising committees involved in events for their effort and work during 2023. A big 'Thank you' also to all the speakers who volunteered their time to prepare excellent talks and to you, our members and audience, for your active participation in the events and webinars. If you have an idea for an event for 2024 or beyond then please reach out!

Conference Report

The PSI 2023 Conference took place 11th – 14th June at The Novotel London West in the UK. This was our largest ever conference, with a record breaking 620 delegates registered (compared with the previous record of 433 who attended the conference in Sweden in 2022). These 620 delegates represented 28 countries and 171 unique companies and organisations. We were generously supported by 24 sponsors. Of the 124 attendees who completed the post conference questionnaire approximately one third were new PSI members and just under 40% were attending for the first time.

On the Sunday before the start of the main conference a half-day course on Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables took place. This course was presented by Kelly Van Lancker (Department of Applied Mathematics, Computer Science and Statistics, Ghent University, Ghent, Belgium), Josh Betz (Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, U.S.A.) and Michael Rosenblum (Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, U.S.A.) and covered covariate adjustment concepts and how to use them in practice.

We were delighted to welcome two keynote speakers. The writer, broadcaster and presenter Timandra Harkness spoke on "From John Graunt to Next Slide Please: What a 17th Century haberdasher can teach us about data, risk and the public" describing what the work and eventful life story of self-taught haberdasher John Graunt can teach us today about gathering and analysing data and sharing that knowledge with the public. Our second keynote speaker was Andy Grieve who spoke on "If you Can't Teach an Old Dog New Tricks, Can Old Dogs Teach Young Ones Old Tricks?" using examples from his archives to show the value of having learnt the practice of statistics in an era not dominated by ever quicker computers.

In total the conference consisted of 40 sessions held across 3 days, including traditional plenary lectures and presentation sessions, informal networking sessions, roundtable discussions and workshops. The PSI Special Interest Groups (SIGs) ran fourteen sessions showcasing their work. The RSS/PSI prizewinners Marcel Wolbers and Alessandro Noci presented on "Standard and reference-based imputation methods based on conditional mean imputation". Parallel sessions based on contributed abstracts covered many diverse topics including estimands, data visualization, Bayesian borrowing, adaptive designs, data monitoring committees, patient reported outcomes and master protocols. Two interactive workshops were included in the programme: Clarie Brittain and Kim Harquoil ran a Professional Development Workshop on "Building A Fantasy Stats Team - Unconscious Bias". Colleagues from GSK and Chartwell ran a session on "Positive Power and Influence" outlining how positive influence skills can be used to drive decision making. As usual we included specific sessions for career young statisticians (those with less than 5 years working in industry) to allow newcomers to industry to present in a lower pressure environment. For the first time we introduced TED-style talks and these proved to be hugely popular and will return in 2024. In 2023 we included a plenary session focusing on Health Technology Assessment (HTA) entitled "EU HTA: readying ourselves for the road to 2025 and beyond" reflecting the increasing importance of this topic. In addition the usual Regulatory Hot Topics session took place on Tuesday afternoon with 4 representatives from regulatory agencies presenting on key topics in this space. The poster session was also a great success including the one minute poster presentations.

Regular updates were provided in advance of the event through a variety of methods including eNews, LinkedIn and Twitter to increase overall awareness and enthusiasm. The conference app returned and this will continue to be the main way the conference content will be shared with attendees immediately before the conference and during the conference itself. The app included speaker and scientific committee member biographies and photos as well as the scientific programme, abstracts and updates during the conference itself.

The 2024 conference will be taking place from the 16th – 19th June at the Buers van Berlage in Amsterdam. The preparations are well underway, with all the sessions finalised and the majority of speakers identified. Information will continue to be shared regularly as we move closer to June. As we did last year, we have also put together a monthly conference newsletter and have agreed a communication plan to release more information on sessions before the event through LinkedIn and in the newsletter. The conference app is due to be launched in May.

David Lawrence
Conference Chair

Committee Events

Scientific Committee

The PSI Scientific Committee organises one-day meetings and webinars of scientific statistical interest to our members and beyond, as well as the annual PSI conference. There are currently 18 of us working for a wide range of employers from large pharmaceutical companies, CROs, academics, and regulatory agencies and we really enjoy getting together to bring interesting events to the community.

In 2023, the scientific committee organized 7 events and webinars spanning a range of topics:

- 2023 PSI Conference (see conference report)
- PSI Webinar: Decentralized Clinical Trials
- PSI Webinar: Discover Data Science
- PSI Webinar: Application of Bayesian Methods in Confirmatory Trials
- PSI Scientific Meeting: Patient Focused Drug Development
- PSI Scientific Meeting: Master Protocols – Industry, Academic and Regulatory Perspectives
- PSI Webinar: Causal Inference in Randomised Clinical Trials

Training Committee

In 2023, the training committee successfully delivered 2 online training courses, one face to face training course in London and one pre-conference course.

- PSI Training Course: Propensity Scores
- PSI Training Course: Missing Data (held virtually over 4 days)
- PSI Training Course: Sample Sizing for Clinical Trials (in person)
- Pre-conference course: Improving Precision and Power in Randomised Trials by Leveraging Baseline Variables (in person at Conference)

The online courses in 2023 worked well for delegates, and in 2024 the training committee are looking to continue offering some online and some in-person courses.

Journal Club Committee

The PSI journal club committee organises meetings featuring papers from PSI's official journal Pharmaceutical Statistics which is published by John Wiley & Sons, Ltd. The authors of two papers are invited to present their work and each presentation is followed by a discussion. In 2023, the Journal club delivered 2 webinars. In 2024, we look forward to providing more journal club webinars to members and non-members.

2 Journal Clubs:

- PSI Journal Club: Propensity Scores
- PSI Journal Club: Bayesian Approaches in Efficacy and Safety

PSI SIGS:

We now have a total of 21 SIGs sponsored by PSI and EFSPI who between them put on a huge amount of very popular events. As well as the ones listed below, they also made a huge contribution to sessions presented at the conference.

20 ESIG events:

- **Data Vis SIG** Wonderful Wednesday (series of 11)
- PSI **Biomarker SIG** Webinar
- PSI **Pre-Clinical SIG** Webinar: End-user Tool for Immunogenicity Cut-points Calculation
- PSI **EIWG** Webinar: Proposing Estimands from Different Perspectives
- PSI **Pre-Clinical SIG** Webinar: An Investigation to Improve Non-Linear Mixed-Effects Approach for EC50 Estimation based on Multi-Donor Dose-Response Data
- PSI **Launch & Lifestyle SIG** Webinar: Do you want to stay single? Considerations on single arm trials in the post-regulatory space
- PSI **Pre-Clinical SIG** Webinar: Adjusting Experimental & Statistical Approaches throughout Preclinical development pathways
- PSI **Vaccine SIG** Webinar: A Vaccine Statistician's Journey in Designing and Analyzing Monoclonal Antibody Studies
- PSI **Biomarker SIG** Webinar: A promising adaptive biomarker-based design strategy for early phase and machine learning as an enabler of precision medicine!
- PSI **HTA SIG** Webinar: Estimands, PICOs and Cp. – Are we losing or gaining in translation?

PSI Careers

The PSI Careers team, split into the subteams of schools, universities and industry continue to put on a large number of successful events which have increased year on year, helping support members at every stage of their career.

15 Career events:

- PSI Career Young Virtual Meet (4 separate meetings or webinars throughout the year)
- PSI Careers Lunch and Learn: Modern Leaders – Remote Not Distant
- PSI Careers Book club Webinar
- PSI Careers Apprenticeship Webinar
- PSI Careers Mentoring Scheme Webinar
- PSI Careers Schools Webinar
- PSI Careers Book club Webinar #2
- PSI Careers Lunch and Learn: ChatGPT & Beyond
- PSI Careers – MEDMaths
- PSI Medical Statistics Careers Event (November 2023)

- Introduction to Industry Course (started in 2023 and continued into 2024)
- PSI Careers Lunch and Learn: Is it AI? Can you spot the fake?

Kate Taylor
Events Director

ESIG Report – March 2024

2023 was another great year for the PSI/EFSPI Special Interest Groups. The highlights summarised below represent a huge amount of impactful work from a large group of people. It's not possible to do justice to all the outstanding contributions in a short summary, but highlights include substantial contributions to the 2023 PSI Conference (many sessions and posters), webinars, workshops, many papers published, chapters contributed to books, collaborations with other groups such as PHUSE and ASA, and providing feedback on regulatory guidance documents. The ESIG community continue to do truly outstanding work and on behalf of the PSI Board I thank every single person who has contributed to that.

As ever, it has been a pleasure to collaborate with my EFSPI counterpart Emmanuel Pham and I much appreciate his support.

The number of SIGs continues to grow, with recent launches of new SIGs for Causal Inference, Patient-Focused Drug Development and Software Engineering.

2024 is already off to a strong start with new SIGs getting underway and many submissions offered for the 2024 PSI Conference.

This will be the last annual report for SIG activities that I'll have the privilege of compiling as I am stepping down from my PSI Director role in June. Applications for taking on the role are welcome, and requested by 9th April, for more details see this link Volunteer with Us (psiweb.org).

If you would like to find out more or are interested in joining or creating an ESIG then please do get in touch or check out the SIG webpage at www.psiweb.org .

Adam Crisp, ESIG Director, PSI

AIMS: Martin Brown (PPD)

In 2023 the PSI AIMS SIG had a change of leadership, as Lyn Taylor (PAREXEL) stood down as chair, handing over to Martin Brown (PPD). The SIG's renewed momentum led to a launch of a new logo, new objectives and collective agreement that we are now thought of as "The R SIG" but that our future shouldn't just be limited to R! In June, the SIG enjoyed numerous conference contributions, including a contributed session and 2 posters, sharing topics such as: The current R collaborations in medical research (including a hexagon diagram containing links to R working groups and information), CAMIS (introducing the SIGs involvement with the PHUSE working group Comparing Analysis Method Implementations in Software), ASA Biopharm MMRM package project (development of an R package which can reproduce the same analysis performed by proc mmrm), and a general discussion on R open source community project challenges and benefits. In October, the SIG ran a workshop at R/Pharma on Version Control with Git and R studio, which is available on YouTube (Version Control with Git & RStudio (youtube.com)). November saw the completion of Phase I of our new website PSI AIMS SIG Website - PSI AIMS Special Interest Group. Driven by R, it allows all of our SIG to upload information online, so it can be shared with the wider community. We hope it will become a go to source for information about R in Pharma. As we look forward to 2024, the SIG are looking to hold more git training, improve and promote the website further with more resources and links and keep apace with fast-moving open-source developments.

Thank you to all our members who contributed in 2023 and we look forward to more R discussions and progress in 2024. If you would like to join us, please get in touch.

Benefit-Risk: Marco Boeri (Open Healthgroup), Shahrul Mt-Isa (MSD)

1. Reorganization of the ESIG and revision of membership
2. Providing feedback on draft CIOMS Working Group XII report
3. Running a session at the PSI Conference 2023 in London
4. Advertising the ESIG and recruiting additional members
5. Updating ESIG homepage on PSIWEB
6. Presentations at scientific conferences
7. Continuing work on manuscript series on preference-based BRAs
8. Bringing in new expertise related to BRA

One of the key achievements in 2023 was the successful restructuring of the BRESIG (benefit-risk ESIG) and revision of its membership. This was done by defining contributing roles that facilitated engagement and collaboration within the group. The reorganization aimed to enhance the effectiveness and efficiency of the group's work in benefit-risk assessment (BRA). As part of the restructuring, we created a Communications Team to increase the BRESIG communication and community engagement via its homepage https://psiweb.org/bresig. The new homepage is aimed to provide up-to-date and relevant information about the BRESIG's activities, initiatives, and resources. The enhanced homepage also aimed to raise awareness about the importance of BRA and its ethical and scientific considerations.

Led by Marco Boeri, the BRESIG provided feedback on the draft CIOMS (Council for International Organizations of Medical Sciences) Working Group XII report on benefit-risk balance for medicinal products. The feedback focused on areas such as patient preference, risk communications, and addressing uncertainty in BRAs. This contribution would help to improve the draft report and ensure that important considerations were taken into account in the final version.

The BRESIG organized and ran a session titled "Small Steps Towards Patient Focused Benefit-Risk Assessment" at the PSI Conference 2023 held in London. The session covered preference-based BRA, BRA in clinical trials with composite endpoints, and sample size calculations for discrete choice experiments in pharmaceutical and healthcare applications. This session provided an opportunity for knowledge sharing and discussion on important aspects of BRA.

Through the session and through networking during the conference, an achievement in 2023 was the successful advertisement of the BRESIG and subsequent recruitment of additional members into the working group. This expansion of the group's membership helped to broaden the expertise and perspectives within the ESIG, fostering a more diverse and collaborative environment.

The ESIG members presented their work at scientific conferences, including at the Society for Medical Decision Making (SMDM) conference held in Philadelphia. These presentations provided opportunities for us to share our research and insights with the wider scientific community. Such contributions help to advance the field of BRA and promote best practices.

The BRESIG continued its work on a manuscript series that focused on preference-based BRAs. The aim of this initiative was to establish a formal link between patient preferences and BRA methods throughout the drug lifecycle. By developing manuscripts on this topic, the BRESIG continues to actively contribute to the scientific literature and promote evidence-based approaches in BRA.

Another accomplishment in 2023 was the integration of new expertise within the ESIG. This included adding and developing subject-matter experts in the area of BRA to the group. By expanding and diversifying the expertise within the ESIG, the group aimed to explore and pursue future research topics, further enhancing the group's contributions to the field, and reach wider audience.

Overall, the BRESIG made significant achievements in 2023, ranging from restructuring the group and revising its membership to actively participating in conferences, providing feedback on important reports, and advancing the field of preference-based BRAs. These accomplishments demonstrate the dedication and commitment of the BRESIG members towards improving the ethical and scientific aspects of BRA.

Biomarkers: Guillaume Desachy (AZ), Nicole Kraemer (BI)
The Biomarkers ESIG had a very busy 2023, they've written a great overview posted here at LinkedIn.

Centralised Statistical Monitoring and Quality Tolerance Limits:
Tim Rolfe (GSK), Susan Talbot (Amgen)

The CSM/QTL team is jointly sponsored by PSI, EFSPI and ASA-Biopharm providing a forum to collaborate and discuss strategies and methodology with other interested parties.

The goals are to collate and summarise regulatory guidance and industry publications, presentations and training; develop best practice recommendations; and identify emerging methodologies and trends.

The team have been very busy in 2023 with sub-committees working in parallel on the topics of CSM and QTL.

Summary of annual accomplishments:

- PSI conference: Introduction to the Central Statistical Monitoring (CSM/QTL SIG): 90min session 12-14 June 2023 conference
- Duke-Industry Statistics Symposium (DISS2023) March 29-31, 2023. Session number S3C, "Centralized Statistical Monitoring Tools in Trial Conduct" March 30th.
- QTL methodology paper published in TIRS:
- Kilaru, R., Amodio, S., Li, Y. et al. An Overview of Current Statistical Methods for Implementing Quality Tolerance Limits. Ther Innov Regul Sci 58, 273–284 (2024). https://doi.org/10.1007/s43441-023-00598-y (published 26Dec2023 with open access)

- CSM methods review paper "Central statistical monitoring in clinical trials: a scoping review" (submitted Jan 2024 to Clinical Trials)
- Sub-team formed focused on CSM/QTL elements in decentralized clinical trials.

Goals for 2024:

Highlight new techniques and best practices:

- QTL methodology assessment paper
- CSM methods review paper (re-submitted '24)
- CSM/QTL in decentralized clinical trials: article or paper
- Collaboration on open-source GSM package

Thanks to all the members of the CSM/QTL team for their support and contributions:

Susan Talbot (Co&CSM-chair), Amgen	Tim Rolfe (Co-chair), GSK	Rakhi Kilaru (QTL chair), PPD
Jingjing Ye, BeiGene	Chris Wells, Roche	Sonia Amodio, Danone
Sharon Love, UCL	Maciej Fronc, GSK	Yuling Zeng, BeiGene
Arseny Khaplanov, Parexel	Abhinav Balakumar, Novartis	Monika Jelizarow, UCB
Christopher Weir, Edin Uni ECTU	Anne Sofie Osterdal, ALK	Jonathan Rowe, ZS
Sheetal Chandarana, Roche	JianChang Lin, Takeda	Matilde Kam, FDA
Paul Schuette, FDA	Tina Wang, FDA	Lu Zhang, Lilly
Rob Davis, Roche	Gordon Thomson, Fortrea	Alicia Worrall, Abbvie
Magali Traskine, GSK	Wiktor Majewsk, GSK	Kate Tomlinson
Charles Liu, Gilead	Yasha Li, BeiGene	Melissa Span, Lilly
Annett Keller, Boehringer Ingelheim	Zhongkai Wang, Gilead	

Data Science: Carsten Henneges (Sanofi)

- Presented at the PSI Scientific Meeting on Data Science in the Pharmaceutical Industry
- Hosted one session at the 2023 PSI conference in London giving 3 presentations.
- Had +5 presentations and discussions within the PSI Data Science SIG biweekly meetings covering a broad range of methods and techniques applicable to pharmaceutical data scientists.
- Members of the Data Science SIG had been active beyond the SIG as reviewers and authors of methodological publications:
  - Vlad Anisimov – Wrote two book chapters, two accepted publications, and gave 8 conference presentations. Also, he served as reviewer to three peer reviewed journals (Statistics in Medicine, Pharmaceutical Statistics, Trials, Therapeutic Innovation & Regulatory Science).
  - Domingo Salazar – Served as reviewer for peer reviewed journals (Bioinformatics)
  - Julia Chernova - Very active on social media (LinkedIn) on digital patient outcomes
- Worked on obtaining a digital presence as a PSI SIG.

Data Sharing: Janice Branson (Novartis), Mimmi Sundler (AstraZeneca)

EFSPI Stats Leaders Forum

The SIG was invited to present at the EFSPI Stats Leaders meeting. The presentation "Maximizing the value of clinical trial data: A decade of data sharing, what have we learnt?" covered the following themes:

- Reflections on the last 10 years of data sharing
- What might the Data Sharing Future hold?
- What opportunities are there for collaboration? What are the opportunities for statisticians?

This was followed by a breakout session where participants discussed how much data sharing knowledge statisticians need to have and how we need to consider these other sources of data in our drug development thinking.

Cochrane Colloquium – Workshop

This was a joint effort between the ESIG and the Vivli organisation. The intent of the session was "How to access patient-level data from the Vivli data sharing platform for evidence synthesis". Presenters included ESIG representatives from pharma (as data contributors) and academia (as data requesters) alongside the patient advocate from the Independent Review Panel and a senior representative from Vivli.

The session was interactive and provided an opportunity for the audience to learn more about requests for access to participant level data as well as feedback on their experiences using the site.

Decision Making: Alex Carlton (GSK), Tadhg Guerin (Theravance)

The decision-making SIG is currently a group of 28 from industry and academia. The group have plenary meetings every two months which include discussions around practical aspects of implementing QDM as well as presentations from internal and external guests. In addition, there are two working groups, one focusing on decision making for non-statisticians who are planning to develop a best practice for communicating probability of success to non-statisticians, the other focusing on QDM at the portfolio level who developed a viewpoint paper during the year. Highlights for the group in 2023 include:

- Publication of a viewpoint paper in Pharmaceutical statistics discussing decision making at the portfolio level. *Going beyond probability of success: Opportunities for statisticians to influence quantitative decision-making at the portfolio level* link
- A QDM session at the PSI conference 2023 titled "Advancing Quantitative Decision Making Methods" with 3 speakers: Kevin Kunzmann (Boehringer Ingelheim), Daniel Bratton (GSK), Marie-Karelle Riviere (Saryga).
- Guest-speakers included:
    - Lisa Hampson on "A New Comprehensive Approach to Assess the Probability of Success of Development Programs Before Pivotal Trials
    - Professor Thomas Jaki on "Updating the probability of study success for combination therapies using related combination study data"
    - Charles Liu on "Epistemic uncertainty in Bayesian predictive probabilities"

Historical Data: Nicky Best (GSK) and Simon Wandel (Novartis)

The focus of the Historical data SIG in 2023 was on getting ready for an EMA qualification request for "Bayesian Dynamic Borrowing" in 2024. A lot of the work thus was dedicated to putting material together, aligning on key messages and also mapping out a realistic timetable. In this context, SIG members also submitted a paper (currently under revision) on Beyond the classical type I error: Bayesian metrics for Bayesian designs using informative priors.

In addition, the SIG continued with to have regular presentations from group members and external guests on topics of high interest (including review latest publications in the field), to keep up with recent developments.

HTA: Emma Crawford (MSD)

During 2023 the HTA eSIG continued to be particularly active in regards to external engagement activities related to EU HTA. Across the year we gained 25 new members, ending the year with 79 members in total. Please see below a summary of our achievements:

In May 2023, EFSPI was appointed a member of the European Commission Stakeholder Network. You can view the full list of members here. Our two representatives are Christoph Gerlinger (Member of EFSPI council) and Anders Gorst-Rasmussen (Co-Chair of EFSPI HTA ESIG). You can view more news on HTAR from the European Commission on their HTA webpage.

We held a parallel session on Multiplicity, an informal lunch-time catch-up and the first ever HTA Townhall at the PSI 2023 conference in June. We also had SIG members chairing and presenting during the HTA contributed parallel session as well as presenting 3 posters.

We submitted comments on behalf of EFSPI on 2 of the methodological EUnetHTA21 guidelines during their periods of public consultation (July).

On 13th September 2023, we presented 2 posters related to EU HTA at the 8th EFSPI workshop on Regulatory Statistics 2023. You can view the posters presented here.

On 15th November 2023, we presented a poster at ISPOR Europe 2023. You can view the poster presented here.

On 7th December 2023, we hosted a webinar "Estimands, PICOs and Co. - Are we losing or gaining in translation?". If you missed it, watch the recording on Video on Demand!

We submitted a proposal for an additional HTA session as part of the annual EFSPI regulatory statistics workshop 2024, with a long term aspiration to shape an opportunity for eye-level dialogue between industry, HTA bodies and HTA statisticians. We have successfully confirmed an additional half day session focussed on HTA as part of the event, with a corresponding HTA scientific committee.

We submitted plans for 3 sessions at PSI 2024 conference (HTA parallel session, HTA Townhall, and joint session with Launch & Lifecycle eSIG) and had the HTA parallel session and HTA Townhall accepted.

We provided regular updates via PSI/ EFSPI communication channels as well as updating and maintaining our webpage.

Launch & Lifecycle: Jenny Devenport (Roche) & Alexander Schacht (Sanevidence)

It was another great year for the Launch and Lifecycle SIG–a group of statisticians interested in increasing the influence of statisticians to optimize evidence generation and inform clinical practice. The SIG meets monthly to discuss how to shape the field, common challenges and opportunities in the post-approval space, and solutions. If you would like to learn more or join our SIG, please find us on the web (https://psiweb.org/sigs-special-interest-groups/launch-lifecycle-esig) or reach out to co-leads jenny.devenport@roche.com or alexander@sanevidence.com

Wishing everyone an impactful 2024!

Publications
Published manuscript: https://onlinelibrary.wiley.com/doi/10.1002/pst.2325
Recently submitted manuscript: https://doi.org/10.31219/osf.io/sy5zk
Webinar: https://www.psiweb.org/vod/item/psi-launch-lifecycle-sig-webinar-%27do-you-want-to-stay-single-considerations-on-single-arm-trials-in-the-post-regulatory-space

The PSI Annual Meeting (London)
LnL SIG session "Building a better bridge: Innovations in trial designs to address access and clinical practice questions." We are grateful to the PSI meeting organizers for giving us the plenary room, and thus had a very large and engaged audience. https://www.psiweb.org/vod/item/psi-conference-2023-building-a-better-bridge-innovations-in-trial-designs-to-address-access-and-clinical-practice-questions

Joint HTA and LnL SIG session: "Connecting the dots: how can statisticians drive end-to-end thinking in the development of new medicines?" (this was an interactive session so no video is available)

Joint RWD and LnL SIG session: "What is real - RWD or RCT? How to communicate evidence generation involving RWD" https://www.psiweb.org/vod/item/psi-conference-2023-what-is-real---rwd-or-rct-how-to-communicate-evidence-generation-involving-rwd

EFSPI Regulatory Conference (Basel)
LnL SIG poster

Neuroscience-Estimands: Paul Delmar (Roche)

We had a manuscript about decentralized trials in Neuroscience accepted for publication. There was major progress on two other manuscripts related to estimands in different neuroscience indications. We also started working on a book chapter. Overall the group has been really active with concrete deliverables and also progress in terms of aligning key players in industry and regulatory bodies on their interpretation and understanding of the ich e9 R1 addendum.

Oncology Estimands: Kaspar Rufibach (Roche)

The group continues to be an influential player in the global discussion on estimands between industry, regulators, and academia. Key achievements in 2023 are:

- Seven publications of the SIG appeared or have been submitted this year (numbers 9-15 in publication list). In total, (at least) 15 published papers and numerous talks meanwhile come out of this group.
- The SIG gave many talks and organized sessions at conferences and webinars, see events.

  Some highlights:

    o Jonathan gave an invited talk at the Duke industry statistics symposium 2023.
    o Co-organized and contributed to a BBS seminar on Quantification of risk: ask the right questions or time to apply the estimand framework to safety!
    o Organized two sessions at the LIDS 2023 conference in Raleigh.
    o An entire session organized by the SIG at the PSI 2023 conference in London. Hong Tian, Konstantina Skaltsa, Stefan Englert, Lynda Grinsted, Elizabeth Pilling, and Yufei Wang presented outcomes from various taskforces to a completely full room.
    o Invited talk and pre-conference course on "Causal Inference in Randomized Controlled Trials" at JSM in Toronto.
    o Panel discussion at ASA Biopharmaceutical Section Regulatory Industry Statistics Workshop.
    o Stefan and Francois contributed talks to a BBS seminar on *Estimands in Early Development (ED) across Therapeutic Areas*.
    o Kaspar was invited to present in an FDA / Lungevity TC within Project significant on *Impact of Cross-over in the Evaluation of Overall Survival in cancer RCTs*, find slides here.
    o Evgeny was invited for a plenary talk at the Nordic lymphoma meeting. It is great to see the rising interest in estimands also in the clinical community! Find slides here.
    o Stefan contributed a talk to the yearly APF workshop.

- As a spin-off of our WG, a few colleagues from the PRO task force submitted a proposal to EFSPI for a special interest group. We except to start this very soon under the formal EFSPI umbrella.
- As of December 2023, the SIG has 99 members (36 from Europe, 53 from US, and 10 from Asia) representing 47 companies / institutions, see status.

Pre-Clinical: Eloisa Brook (GSK)

The Pre-Clinical SIG had the following webinars in 2023:

Date	Title	Presenter

14 March 2023	End-user Tool for Immunogenicity Cut-points Calculation	Dr. Els Pattyn, Ablynx	To access the video on demand, please click here
27 June 2023	EC50 Estimation based on Multi-Donor Dose-Response Data	Dr. Weiliang Qiu and Dr. Cheng Wenren, Sanofi	To access the video on demand, please click here
24 October 2023	Adjusting Experimental and Statistical Approaches throughout Preclinical Development Pathways	PD Dr. Ulf Tölch, Berlin Institute of Health at Charité	No recording available.

Randomisation: Annika Scheffold (Boehringer Ingelheim)

We published 7 papers (jointly or in co-authorship) for a special issue on randomisation in Statistics in Biopharmaceutical Research (the issue will be published early 2024).

Sverdlov et al.	Which Randomization Methods Are Used Most Frequently in Clinical Trials? Results of a Survey by the Randomization Working Group
Carter et al.	Regulatory Guidance on Randomization and the Use of Randomization Tests in Clinical Trials: A Systematic Review
Uschner et al.	Randomization Tests to Address Disruptions in Clinical Trials: A Report from the NISS Ingram Olkin Forum Series on Unplanned Clinical Trial Disruptions
Sverdlov and Ryeznik	Balancing the Objectives of Statistical Efficiency and Allocation Randomness in Randomized Controlled Trials
Kuznetsova	Minimizing Selection Bias Under the Blackwell and Hodges Model with an Equal Allocation Procedure in a Symmetric Allocation Space
Heussen et al.	Randomization-Based Inference for Clinical Trials with Missing Outcome Data

Johnson, Gekhtman, Kuznetsova	Validity of tests for time-to-event endpoints in studies with the Pocock and Simon covariate-adaptive randomization

We submitted proposals for conference sessions that will take place in 2024, two of which were accepted so far.

We appointed a new member to the leadership team who will work on increasing our presence on social media (mostly LinkedIn at the moment) as well as at conferences.

We worked on additional papers that have been submitted earlier this year or will be submitted soon.

**Regulatory: Jürgen Hummel (PPD, part of Thermo Fisher Scientific) and
Christoph Gerlinger (Bayer)**

The Regulatory SIG continued to receive request from people interested in joining. During 2023 we reviewed and updated our membership, so that each company had no more than one representative and that all members were practising statisticians. At the end of 2023 we had a total of 20 members from 7 countries. Our main activities in 2023 were the following:

- Review and collation of comments on key statistical documents released for comments by regulatory authorities, which was done in collaboration with other Special Interest Groups or cross-industry organizations (where appropriate). During 2023 this included the following documents:

  - ICH draft guidance M11 on Clinical Electronic Structured Harmonized Protocol
  - FDA draft guidance on Statistical Approaches to Establishing Bioequivalence
  - FDA draft guidance on Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases
  - FDA draft guidance on Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products
  - FDA draft guidance on Decentralized Clinical Trials for Drugs, Biological Products, and Devices
  - FDA draft guidance on Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints For Regulatory Decision-Making
  - EMA draft reflection paper on Establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation
  - EMA draft Revised consolidated 3-year work plan for the Methodology Working Party (MWP)

- Supporting the organization of the EFSPI Regulatory Statistics Workshop (held 13-14 September 2023 in Basel, Switzerland). We also contributed to the poster session with a poster on the activities of the Regulatory SIG.
- On 8 November 2022 we had an informal exchange meeting with the MHRA statisticians, using a previously used virtual format with 4 statisticians from the MHRA and 18 members of the SIG attending. The main topics of the discussion were intercurrent events of treatment switching and its handling for long-term outcomes, subgroup analyses and considerations about acceptability of novel endpoints for regulatory decision making. Detailed minutes from the meeting are published on the PSI website (2023-minutes-of-meeting-with-mhra-biostatisticians-(final).docx (live.com)).

RWD: Josephine Wolfram (Astellas), Rima Izem (Novartis)

The RWD SIG focuses on strategies and methodologies applied in the utilization of Real World Data in the pharmaceutical industry. The SIG welcomed several new members through 2023 – and notably a new co-lead in Rima Izem from Novartis.

We held meetings monthly during which members shared case studies as well as presentations on initiatives, methods, guidelines, data sources. Specific topics discussed included Quantitative Bias Analysis, Cluster and pragmatic trials, hybrid designs, DAGs. Furthermore, we discussed and commented the FDA External Control Arm draft guidance, and the EMA Single Arm one as well as shared our learnings from various other publications and meetings.

A joint with L&L SIG was presented at the PSI Conference, London, June 2023: "What is real - RWD or RCT? How to communicate evidence generation involving RWD"

We continued our blog series on RWD topics, "Let's T@lk Real Corner", posting on the following topics:

- What Are Real World Data?
- Let's talk external controls!
- Directed Acyclic Graphs

These blogs and other information for the SIG are on our PSI site SIG page that is looked after by our wonderful webmaster Rachel Tham.

Finally, we continued to establish connections with other groups of similar interest: connected with STRATOS, with the Small Populations SIG, joined RWE4Decisions roundtables.

Small Populations: Tal Otiker (GSK), Aysun Cetinyurek Yavuz (Medicine Evaluation Board and Radboud University Medical Center)

The main objective of the Small Populations SIG in 2023 was to jointly author a Points to Consider-type document on "Utilizing External Data for Clinical Development in Small Populations". The document covers the following topics:

- The benefit and challenges of using external data in small populations
- External data sources and their characteristics
- Data quality of external data
- Statistical methods for external data in small populations
- Regulatory perspective

A final draft was completed towards the end of the year and the group is looking to share the final document in the coming months. In addition, the SIG held monthly meetings throughout the year, where various members presented and discussed their work in the field of rare diseases. We also initiated a collaboration with the Real World Data SIG which we hope will result in a joint webinar in 2024. Sadly a few key members had to leave the SIG during 2023 with no new members joining. With the appointment of new co-chairs in the beginning of 2024, our first objective of the year is to build up the membership to approximately 15 people and increase the visibility of the group.

Subgroups: David Svensson (AstraZeneca)

There has been a range of activities within the SIG during 2023 and early 2024.

One highlight is the **PSI Subgroup session arranged by SIG held in London** (June 2023). Each talk was based on collaborative efforts within the group, with main speakers being Paolo Eusebi, Nicole Krämer, and Yuejia Xu (attaching a photo from the occasion, with the moderator Fredrik Öhrn included too; photo was shared at the PSI/LinkedIn). It is worth mentioning that other SIG members were co-authors on the talks, including Xin Huang, Ilya Lipkovich, Björn Bornkamp, Bohdana Ratitch, David Svensson.

The presentations covered notorious difficulties in the assessment of subgroups (such as inherent biases due to selection). We were very proud to see a large audience and lively discussions in the session.

During 2023 we ran our usual regular SIG meetings where we often discuss **research questions related to recent papers in the area**. Worth mentioning here is several meetings spent on the material from a highly relevant paper by Björn Bornkamp / Kostas Sechidis / Sophie Sun (and others). the paper described a simulation benchmarking of many modern approaches for discovering predictive biomarkers (and associated cutpoints) and the first meeting was a deep dive into how the simulations were set up (to be realistic) and the methodology options; a second meeting was then held by Sophie were the focus now was on the results.

Furthermore, the SIG is proud to share that it **expanded with several new members**. Many of these new members are authors of interesting recent papers and/or software packages (relating e.g., 'Personalized', 'grf', 'rlearner', 'evalITR').

Within the SIG, there has been intensive **methodological research collaborations**, including writing two papers (Ilya Lipkovich, David Svensson, Bohdana Ratitch jointly with Alex Dmitrienko) which also were presented externally on

meetings & conferences. The second paper aims to overview recent trends in the area and will be the basis for a presentation at PSI 2024 (see below).

The ambition of the SIG is to promote knowledge sharing between experts in the academia and industry and to promote collaborations; the networking is deemed highly important, and in the recent time we opt for inviting more external speakers. One soon upcoming event is the **Joint 'Biomarker SIG / Subgroup SIG Meeting'** taking place in February with Björn Bornkamp as the main speaker (special thanks to Nicole Krämer for arranging it). Finally, another **Subgroup SIG session will take place in Amsterdam June 2024** and involves two speakers from the SIG: Kostas Sechidis, David Svensson (plus an external one) and with Yuejia Xu as Moderator.

Vaccines: David Radley (Pfizer), Fabian Tibaldi (GSK)

At the 2023 PSI conference in Hammersmith London, the PSI Esig on Vaccines organized a session titled '**Statistical Innovations and Novel Applications in Vaccine Development'**. Experts addressed key statistical challenges in vaccine development, sparking lively discussions with the audience. Hege Michiels from Ghent University proposed an alternative estimand to measure vaccine efficacy in situations with delayed immune response, focusing on the causal interpretation of per-protocol analyses in vaccine trials. Andrea Callegaro from GSK showcased the use of Bayesian dynamic borrowing to evaluate vaccine effectiveness in the Boostrix Maternal Immunization study. Daniel Backenroth from J&J discussed the application of negative control methods to assess the success of confounding adjustments and the robustness of open-label analysis in COVID-19 vaccine trials. Chaired by Sanne Roels from J&J, the session fostered knowledge exchange among attendees, including those less familiar with vaccine settings.

In October Dr Yunda Huang gave an entertaining and informative presentation on her experiences working in the field of HIV interventions at a webinar "A Vaccine Statistician's Journey in Designing and Analyzing Monoclonal Antibody Studies" (see link). After several HIV vaccine candidates had been tested and produced only modest efficacy, attention turned to monoclonal antibody (mAb) therapies. For Dr Huang this meant wearing the different 'hats' of a vaccine statistician and a monoclonal antibody statistician. Concepts familiar from vaccine trials have analogues in monoclonal antibody trials, such as use of serum mAb concentration as a response instead of vaccine-induced antibodies in vaccine trials. A critical new tool she had to learn and apply was the 2-compartment pharmacokinetic model, which was described in detail. A key challenge in this field is the variability of the HIV-1 virus and identifying the best measure of mAb response. Dr. Huang described several key publications of mAb trials in which good efficacy was demonstrated and efficacy was modeled as a function of mAb response.

Visualisation: Bodo Kirsch (Bayer)

Highlights of the Visualisation SIG's activities in 2023 can be found at this great blog resource: VIS-SIG Blog. The site showcases the series of "Wonderful Wednesdays" events and there are some great resources, do check it out!

Adam Crisp
SIG Director

PSI Volunteers

Membership and Community Committee

Name	Company, country	Role
Kate Tsirtsonis	Amgen. UK	Chair
Nigel Howitt	Fortrea, UK	Recruitment Manager
Priya Gokani	Amgen, UK	Community Lead
Sophie Edmonds	Amgen, UK	Metric Analyst
Tim Rolfe	GSK, UK	Committee Member

Universities Committee 2023

Name	Company, country	Role
Amanda Darekar	Pfizer, UK	Chair
Heather White	Brunel University, UK (placement student)	Website
Deanna Galloway	Roche, UK	MEDMathS
Stella Zhan	University of Warwick, UK	MEDMathS, Student Newsletter
James Lay-Flurrie	Bayer, UK	MEDMathS
Emma Crawford[1]	MSD, UK	Careers Event
Rachel Phillip	CTRU, University of Leeds, UK	Careers Event
Alexander Todd	AZ, UK	Careers Event
Lizzi Pitt	UCB, UK	Careers Event
Tomas Rouse	AZ, Sweden	Website
Alicia Aylott	GSK, UK	Student Newsletter, University prizes
Sam Adams	Bayer, UK (placement student)	Website
Valerie Millar[2]	GSK, UK	Apprenticeships

[1] Left the committee in 2023

[2] Joined the committee in 2023

Schools Committee 2023

Name	Company, country	Role
Emma Crawford[2]	MSD, UK	Chair
Alex Spiers[2]	GSK, UK	Outreach Sub-team lead
Jackie Wall[2]	Plus-Project, UK	Outreach Sub-team
Rejina Verghis[2]	GSK, NI	Outreach Sub-team
Katie Gwinnell[2]	Bayer, UK	Events Sub-team lead
Jennifer Gilbride[2]	Bayer, UK	Events Sub-team
Hayley Perry[2]	JnJ, UK	Events Sub-team
Sophie Hodge[2][1]	Bayer, UK	Member

| Liz Cole[2][1] | eClinical Solutions, UK | Member |

[1]Left committee during 2023
[2]Joined committee during 2023

Professional Development Committee 2023

Name	Company, country	Role
Xinyi Zhu	GSK, UK	Chair
Marius Sieverding	Veramed, Germany	Book Club Lead
Holly Prescot[2]	Plus Project, UK	Book Club
Agne Zarankaite	GSK, UK	Book Club, Lunch & Learn
Zainab Walsh	Veramed, UK	Mentoring Lead
Robert (Bobby) Day[2]	Phastar, UK	Mentoring
Ursula Garczarek[2]	Cytel, Germany	Mentoring
Claire Brittain	UCB, UK	Lunch & Learn Co-lead
Chetan Mistry	Veramed, UK	Lunch & Learn Co-lead
Jemma Greenin	Veramed, UK	Career Young Lead
Rebecca Randhawa[1]	Amgen, UK	Career Young
Oswald Dallimore	University Student, UK	Career Young
Holly Moon[2]	Parexel, UK	Career Young
Katie Thorn[1]	GSK, UK	Events

[1]Left committee during 2023
[2]Joined committee during 2023

ITIT Committee 2023

Name	Company, country	Role
Zelie Bailes	GSK, UK	Chair
Gareth Thomas [1]	IQVIA, UK	Treasurer
Laura White [2]	Plus Project, UK	Treasurer
Ruth Lowe	IQVIA, UK	Member
Sophie Hodge	Bayer, UK	Member
Hoi-Shen Radcliffe	Bayer, UK	Member
Sam Ruddell	ClinChoice, UK	Member
Mahesh Shivhare	Roche, UK	Member
Marianne Uguen	Roche, Switzerland	Member

[1]Left committee during 2023
[2]Joined committee during 2023

Communications Committee

Name	Company
Steve Jones	Medable

Jake Holton	
Josh Williams	Amgen
Oceana Faria	Fortrea
Priya Gokani	Amgen
Sophie Greenwood	Aberdeen University
Marta Kwiatkowska	Evidera
Elena Mourouli	GSK
James Oyee	GSK
Jamie Rees	Compass Pathways
Rosemary Sayle	Amgen
Ryan Smith	Amgen
Leanne Winzer	AstraZeneca

Events Committee

Name	Company, country	Role
Kate Taylor	Amgen, UK	Chair
Julia Niewczas	AstraZeneca, Sweden	Scientific Committee
Ellie Granger	AstraZeneca, UK	Training Committee
Steve Jones	Medable, UK	Communications Committee
Sam Hadlington	Plus-Project, UK	Careers Committee
Rachael Lawrance	Aldelphi Values, UK	
Ian Ratcliffe*	Veramed, UK	
Stefanie Ernst*	Parexel, UK	

*Left the committee in 2023

Conference & Scientific Committee

Name	Company, country	Role
Julia Niewczas	Janssen	Scientific Chair
Tobias Mütze	Novartis	Outgoing Scientific Chair
David Lawrence	Novartis	Conference Chair
Sarah Williams	Roche	Conference Vice-Chair
Kate Taylor	Amgen	Conference Vice-Chair and incoming PSI Events Director
Amitava Mukhopadhyay	MorphSys	
Jennifer Gilbride	GlaxoSmithKline	
Julia Saperia	MHRA	
Kate Taylor	Amgen	
Kristina Weber	Roche	

Maria Efstathiou	IQVIA
Martin Jenkins	AstraZeneca
Paul Terrill	PT Stat Consulting Ltd
Russell Jones	Calliditas Therapeutics
Sarah Williams	Roche
Sue Todd	Reading University
Teodora Trasieva[a]	AstraZeneca
Tom Burnett	Bath University
Vicky Marriott*	Phastar

[a] Left the committee in 2023, *Joined the committee in 2023

Training Committee

Name	Company, country	Role
Ellie Grainger	AstraZeneca	Chair
Anna Patten	Eisai	
Gemma Hodgson*	QI Statistics	
Margaret Jones	N/A	
Rimgaile Urbaityte*	GSK	
Charlotte Snape*	Veramed	
Fahmeeda Sheikh*	PPD	
Kerry Gordon	Phastar	
Caroline Kennedy	AstraZeneca	
Mary Elliott-Davey*	Amgen	
Alison Mcleod	Phastar	
Jess Piatek	Veramed	
Emily Hammarstrom-Wickens	GSK	
Lydia Buckley	Fortrea	
Andisheh Bakhshi	Paraxel	
Preenan Sarkar	IQVIA	
Adetayo Kasin	GSK	

*Left the committee in 2023