



# Annual Report 2024

[www.psiweb.org](http://www.psiweb.org)

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# Welcome from the Chair

2024 was another very successful year for PSI where we consolidated the large growth in membership numbers and finished the year with over 2000 members for the first time. The 2024 Annual Conference was very successful and had a record amount of sponsorship. Personally, it was fantastic to be part of such a successful conference and I am very much looking forward to the next conference at Wembley in June 2025.

The PSI Board is working very hard to improve how we serve our members and support Special Interest Groups (SIGs) where we are rolling out access to MS Teams channels to enable them to work more efficiently. Improvements to the website and how we communicate digitally with members will follow soon.

PSI offered a mix of in-person, hybrid and virtual events, with a total of 46 events run in 2024. The type 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.

Below are a few key highlights for 2024, but please spend some time reading through the full report:

- We made a profit of £54k in 2024. Our reserves are £673,000, with a target of maintaining at least £400,000. This reserve level is crucial for ensuring the continued operation of the society, even in the event of significant shortfalls. PSI is in a strong financial position, allowing us to invest in future initiatives, including the next phase of our digital strategy, ongoing work on the website, and various training and outreach activities.
- The transition from MCI to Moore Engage has gone smoothly. Thank you to MCI for the operational support for PSI over many years. PSI are working closely with Moore Engage to implement an improved offering to members via the digital strategy which will also provide benefits to SIGs and PSI Committees.
- We had 2177 members in 2024, the highest ever in the history of PSI (and a notable 9% increase in full members from 2023). PSI is represented in over 50 countries. The Glue Up platform continues to make it easier to manage and oversee PSI membership.
- The Careers team had a very busy 2024. The Universities Committee was re-structured to focus on delivering flagship events as well as providing outreach and now there is a specific sub-group that focuses on Apprenticeships. The Schools Committee has completed its first full academic year and continues to build partnerships with external STEM groups and materials for PSI members to utilise in their own outreach. The Professional Development Committee continues to support people within industry with plans to extend some offerings in 2025. The Introduction to Industry Training (ITIT) Committee has delivered its well-established and very popular course again this year and has overcome some challenges to make it a huge success.
- The 2024/2025 PSI Medical Statistics Career Event took place in Bloomsbury where there were 20 exhibitors and 90 students in attendance. Around 60 students attended the MEDMathS (Medicine Empowered by Data, Maths and Statistics) webinar in November. There are currently over 30 students enrolled in the Medical Statistics Level-7 Apprenticeship hosted by 14 companies. PSI is working to ensure that more universities can become training providers and interested companies are able to take on apprentices, as well as providing support for apprentices.
- 2023/2024 saw the first year of the new PSI incentive scheme for schools outreach, the PSI Careers Outreach Champions Challenge Cup. This year we had 12 participants who completed a total of 20 school outreach activities. For our winning spot, we actually had a tie. Both winners delivered an impressive 3 schools outreach activities each this year and each received a £50 voucher of their choice and a £125 STEM grant for a school of their choosing. We are pleased to announce that our first ever winners of the Outreach Champions Challenge Cup were Katie Gwinnell from Bayer and Katie Law from Veramed.

- The Professional Development Committee continues with the popular mentoring scheme, book club, Lunch and Learn events and developing career young statisticians with the help of the Career Young Committee.
- We thank the Commercial team for attracting 26 Sponsors to the Annual Conference resulting in record levels of sponsorship.
- Alun Bedding stepped down from his role as Director for Communication and External Affairs and was replaced by Jennifer Visser-Rogers. As part of this role, Jennifer will join me to represent PSI on EFSPi Council. Sophie Greenwood has also stepped down from her role as Communications co-lead to focus on her PhD studies, thanks also to Sophie for her contribution. Sophie's role has been split into 2 roles, a Committee Secretary, thanks to Leanne Winzer for taking on this role, and we are currently advertising for a Newsletter Editor.
- The digital strategy is continuing its evolution thanks to Jamie Chai-Rees. The strategy will be guided by the recent membership survey and the upcoming Strategy Day which has one of its key topics the membership value proposition. To better communicate with members, Moore Engage are now delivering more administrative tasks to free up time for the committee to concentrate on the communications strategy.
- For External Affairs, contacts are regularly made with EFSPi, the International Biometrics Society British and Irish Region and the Royal Statistical Society. In collaboration with EFSPi we are engaging with academic institutions on how PSI can help them with their work. One key area is how to evolve the skillset of a graduate statistician to prepare them for a career in the pharmaceutical industry.
- The Events Committee had another busy year with a total of 46 events in addition to running a very successful in-person annual conference. Numbers of attendees at the events ranged from 540 at conference, 50-330 at scientific/SIG topic/careers webinars and journal clubs and 20-40 at interactive training courses/workshops.
- Popular events (with over 100 attendees) included "*Estimands framework in action, the Alzheimer's disease case*", "*HTA and Indirect comparisons*", "*Open Source Software*", "*Hierarchical Compositity Endpoints*", a joint webinar from the PSI/EFSPi Small Populations & RWD SIGs on "*Harnessing Real-World Data (RWD) in clinical trials for small populations and rare diseases*", a Causal Inference SIG webinar on "*Virtual Control Groups in Toxicity Studies*" and a journal club webinar on "*Limitations and Challenges with Mixed Model Repeated Measures (MMRM) Analysis*".
- The 2024 conference had 548 delegates from 26 countries and 215 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 proposals received to present at conference.
- The European Special Interest Groups supported by PSI and EFSPi were very active in 2024. There are now 24 SIGs sponsored by PSI and EFSPi and 24 ESIG events took place in 2024 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. Thank you to the Board of Directors who have worked tirelessly in their roles and to Moore Engage for their recent partnership and administrative support to run PSI. Thank you to the individuals leading or involved in a PSI committee or group; you have enabled PSI to further advance and become a stronger association. And finally thank you to all the individuals who have attended PSI events or sponsored PSI, your support is very much valued and appreciated.

## Awards

The 2024 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 2024 award went to Nicky Best, Andrea Callegaro, Brigitte Cheuvart, Cui Xiong, Dawn Edwards and Jodie Crawford for their work on Bayesian Borrowing methods in regulatory settings. The judging panel were impressed by the culmination of years of work invested in this project – starting with the development & publication of innovative methodology, followed by diligent efforts to communicate this methodology to regulators and stakeholders. The acceptance of Bayesian approaches by regulators is a big step forward, widely acknowledged within the industry and beyond.

The 2024 Mick Godley Award to recognise the unsung heroes of PSI went to Priya Gokani who has been working within the pharmaceutical industry for over 6 years as a statistician across early and late-stage oncology. She has been an active member of PSI since 2017, holding roles across different communities. They previously led social media efforts as part of the communications team. They are currently the PSI Engagement Lead within the membership and community committee, and co-lead of the PSI Journal Club.

The Rising Star award recognises the impact of PSI volunteers who are in the early stages of their career. Given the fantastic work of so many volunteers it is not surprising that the Board decided to give 2 Rising Star awards in 2024.

The first went to Sophie Greenwood who has been the driving force behind the improvement to comms with PSI. She leads all of the work relating to comms, putting in place processes for it to run smoothly. She also took part in the RFP from a Comms perspective to ensure what was required was to be provided. She does all of this whilst studying for a PhD. Sophie will often carry out interviews at conferences and do the photography. Without Sophie the PSI Comms would be much poorer. So many congratulations and thanks to Sophie.

The second winner of the Rising Star Award was Ellie Grainger who has been part of the training committee since 2019 and took over as lead of the committee in early 2023. Since then, she has expertly managed a very new post-COVID outlook on training. Prior to the pandemic most training took place face to face, which obviously moved to virtual in 2020 and 2021. She became lead of the committee around the time that the conference came back to face to face, and we tried to work out how events would look after the pandemic. She has helped PSI to reintroduce face to face training, not just through the pre-conference courses (which this year are looking very to be a big success), but also in non-conference training courses too. She is looking to introduce a Statistics for Non-Statisticians course in the future which will be a huge undertaking alongside the other events the training committee do so well. She is an active part of the Events Committee as well.

If you are motivated to get involved in PSI, we would love to hear from you. Please contact us at: [admin@psiweb.org](mailto:admin@psiweb.org)

## David Wright PSI Chair



# Treasurer's Report

The professional audit for 2024 is currently underway, and several items, including VAT reimbursement, are still pending. Therefore, the figures presented below are subject to change. In 2024, PSI achieved a profit of approximately £54,000. The total income amounted to £856,000, with purchases totalling £593,000 and overheads at £209,000. This profit is lower than that of 2023, primarily due to the cost of the transition from MCI to Moore Engage and increased conference costs of Amsterdam. Nevertheless, there was still a profit in 2024. There are ongoing efforts within the Board and Committees to enhance efficiency, advance our digital strategy, and engage in candid discussions with vendors.

Our reserves now total £673,000, with a target of maintaining at least £400,000. This reserve level is crucial for ensuring the continued operation of the society, even in the event of significant income shortfalls. PSI is in a strong financial position, allowing us to invest in future initiatives, including the next phase of our digital strategy, ongoing work on the website, and various training and outreach activities.

## Key Factors Influencing the 2024 Results

The positive results for 2024 can be attributed to several factors, including sustained membership growth, strong conference attendance, and robust support from sponsors. Additionally, our comprehensive events program, which includes the ITIT course, has contributed significantly. PSI continues to hold a combination of in-person and virtual events; while virtual events are more cost-effective, in-person gatherings are often viewed as more beneficial due to increased networking opportunities.

The Board has remained vigilant in managing PSI's finances, particularly in light of the rising costs associated with conference operations. Unfortunately, venues, catering, equipment, and personnel expenses have increased since the pandemic, resulting in higher costs for the conference and the PSI strives to moderate and limit the increase in registration fees.

PSI incurs considerable overhead costs to maintain operations. At the start of 2024 we were working with MCI then there was a transition period to Moore Engage, and then at the end of the year we were with Moore Engage. In addition, there are expenses for IT systems, accounting, and legal services. Almost all PSI activities generate revenue and are financially positive. Historically, PSI has relied on highly profitable conferences and events to offset annual overheads. While this dependence has diminished in recent years, we still rely on these revenue streams to sustain operations. Given the general inflationary trends, we anticipate that professional service costs will rise in the future, necessitating ongoing prudence and a strong focus on efficiency.

## 2024 income overview

Surplus (£k)	2020	2021	2022	2023	2024
Membership	83	93	132	146	154
Conference	-6	22	147	174	71
Scientific	-0.5	16	8	0.5	4
SIGs	2	4	11	3	7
Training	22	40	34	19	24
Communications (publications and website) *	-17	-43	-26	-17	-8
Careers	10	10	45	3	10

Rounded to the nearest £1k. 2024 figures are subject to change. Overheads are not included in this table.

\* Includes £20k on initiatives in the 2021 accounts.

# Contracts Report

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

## Current Key Contracts Held by PSI:

- Business Administration Services – Moore Engage (transitioned from MCI in 2024)
- Conference Event Management – Moore Engage (transitioned from MCI in 2024)
- Journal Publishing – Wiley
- Professional Indemnity Insurance – Tokyo Marine HCC
- Auditor – TC Group
- Membership and Event Booking – GlueUp
- Netherlands VAT Compliance – SOVOS

## Contracts Overview

### Business Administration Services

In 2024, the administrative and event management services transitioned from MCI to Moore Engage. As PSI's virtual activities continue to expand, the effective scheduling and execution of webinars, virtual training sessions, and Special Interest Group (SIG) events remain a critical area for development. The annual fixed cost for these services is £152,034, which is subject to annual inflation adjustments. Conference management tasks are incorporated within the overall business contract.

### Website and Digital Infrastructure

The website is maintained by Moore Engage as part of the existing contract. A planned migration from Google Drive to Teams and SharePoint is scheduled for 2025. Additionally, PSI email accounts will be established for Board of Directors members and other key PSI contacts. Efforts to enhance efficiency and automation in digital tasks are ongoing.

### Journal Publishing

The Pharmaceutical Statistics journal is published by Wiley. The contract was renewed in 2021 and is currently in effect until the end of 2026.

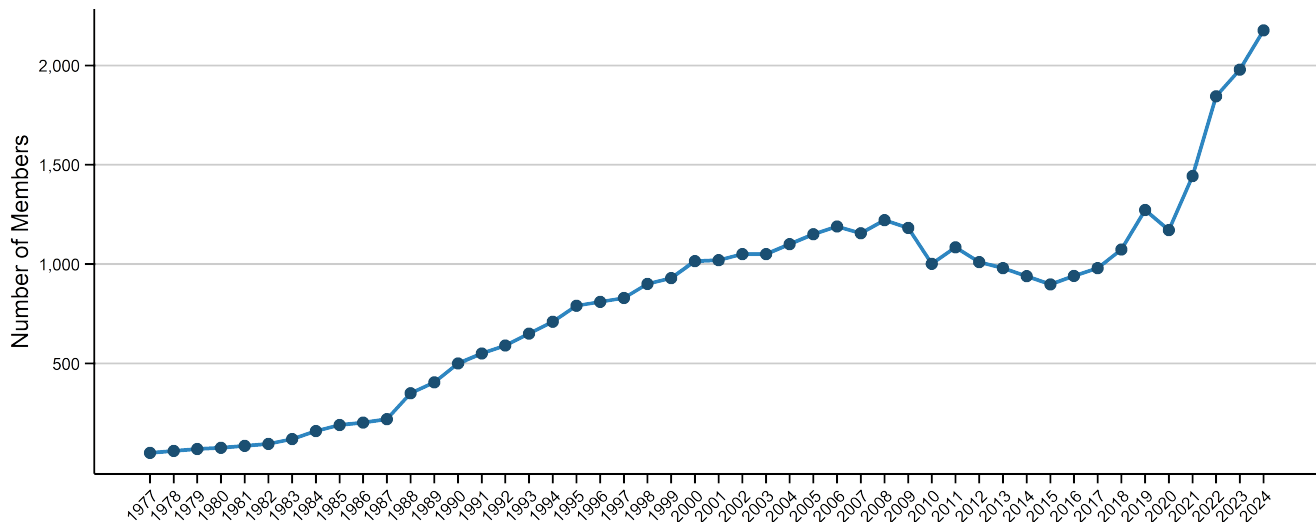
## Jennifer Gilbride and Markus Elze

### Incoming and outgoing Contracts and Finance Directors

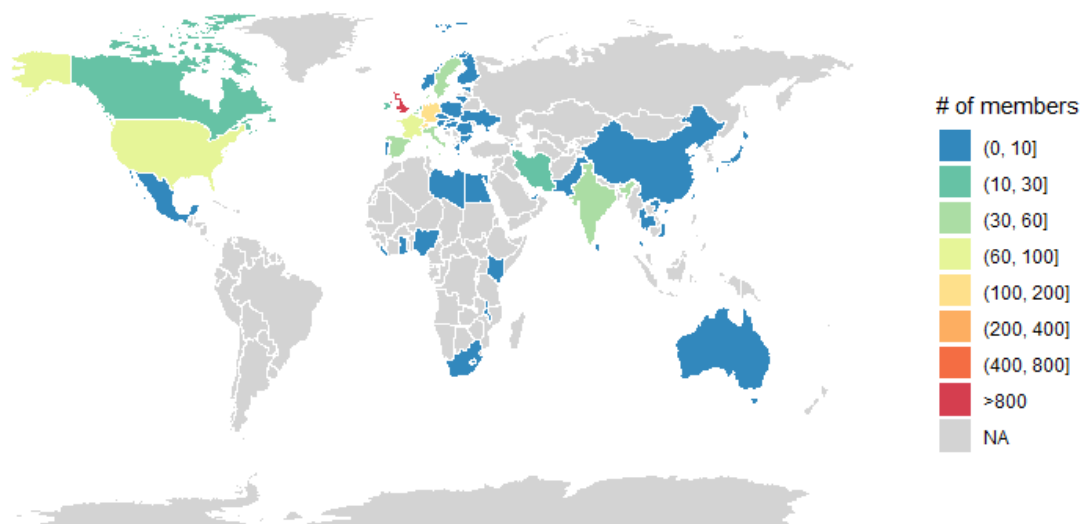


# Membership Report

PSI Membership Over Time



We are delighted that 2024 saw PSI's membership reaching an all-time high, surpassing the 2,000-member milestone for the first time. By the end of 2024, our community grew to 2,177 members across more than 50 countries—an overall increase of 10% compared to the end of 2023. This includes a notable 9% rise in Full Members, reflecting the continued strength and expansion of our global network. We continue to use GlueUp for our membership renewals process, and corporate renewals are still proving successful.



Membership Category	2018	2019	2020	2021	2022	2023	2024
Full	959	1070	867	1134	1442	1562	1709
Honorary	9	9	11	11	11	12	12
Reduced Rate	8	21	25	22	25	21	21
Student/Teacher	98	172	268	276	366	384	435
<b>Total</b>	<b>1074</b>	<b>1272</b>	<b>1171</b>	<b>1443</b>	<b>1844</b>	<b>1979</b>	<b>2177</b>

In 2024, the Membership & Community Committee has tried to strengthen engagement with PSI members. This has included connecting with company representatives to gather feedback on how well PSI is meeting members' needs and exploring ways to enhance engagement. These discussions also provided an opportunity to share information on upcoming PSI events, ensuring members stay informed about professional development and networking opportunities. We also successfully filled several positions on PSI Committees, including one temporary board position. Finally, at the end of 2024 PSI created a DE&I working group, to be led by Emma Crawford, which aims to ensure the PSI community is diverse, equitable, and inclusive.

We are hugely 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.

Feel free to reach out if you have any suggestions on how we can further enhance engagement among our global members in 2025. Your input is invaluable in shaping our initiatives and ensuring they resonate with our diverse community worldwide.

## Alicia Aylott PSI Membership Director



# Careers Report



The Careers team has been very busy in 2024. The **Universities Committee** has been re-structured a little to be able to focus on delivering flagship events as well as providing outreach and with the increased uptake of Apprenticeships it made sense to create a specific subgroup to concentrate on this. The **Schools Committee** has completed its first full academic year and continues to build partnerships with external STEM groups and material for our members to utilise in their own outreach. The **Professional Development Committee** continues to support people within the industry with plans to extend some offerings in 2025. The **Introduction to Industry Training (ITIT) Committee** has delivered its well-established and very popular course again this year and has overcome some challenges on the way to make it a huge success.

## Universities Committee



**Lizzi Pitt, Universities Chair**

*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.*



**PSI Medical Statistics  
Careers Event**

The Universities team is now organised into several subgroups: Outreach, Events and Apprenticeships. Lizzi stepped into the role of chair in June 2024 as Amanda stepped down after many years. We thank her for all the time and energy she has put into inspiring people to join our industry. The Outreach group produce a student newsletter twice a year, coordinate university prizes and placement student testimonials amongst other activities to engage with students. Events are responsible for the annual PSI Medical Statistics Careers Event and MEDMathS, an annual webinar which was developed by the Outreach team. The apprenticeships arm expanded towards the end of 2024 with the addition of an Apprentice Network.

The 2024/2025 Medical Statistics Careers Event was held in Bloomsbury, London. 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 20 exhibitors and approximately 90 students attended. The day began with a welcome introduction outlining PSI's role in supporting students and early-career statisticians. Angus Jennings from the MRC Clinical Trials Unit at UCL gave the



New Starter presentation. Angus was then joined by four others for the panel discussion which discussed different types of roles, pathways and experiences within Medical Statistics:

- Fiona Grimson (UCB)
- Violeta Balinskaite (Medpace)
- Elliot Thomas (Apprentice at AstraZeneca)
- Paul Terrill (Independent consultant)

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 9 pharmaceutical companies, 3 Contract Research Organisations (CROs), 2 Clinical Trials Units (CTUs), 1 professional society and 5 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, as well as PSI volunteers, 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 6th November 2024. 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.

Around 60 students attended from a wide range of backgrounds and were highly engaged with 20+ questions being submitted during the presentation. This year Katie Dixon, Sophie Edmonds and Lizzi Pitt were the presenters. 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.

## PSI Student Newsletter



We were also pleased to continue to grow the content of the PSI Student Newsletter, with two editions distributed, in Spring and Autumn 2024. The newsletter 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, the Medical Statistics Apprenticeship, SIG Spotlights, and insights into the impact of statisticians. In addition, following nominations received from their universities, seven PSI Undergraduate Awards were awarded to mathematics/statistics students at the following universities from across the UK: Bath, Cardiff, Glasgow, Queen's (Belfast), Reading, Sheffield and Warwick. Several prize winners featured in the Autumn 2024 newsletter.

Further, we interviewed several placement students to produce content that informs students about what doing a placement entails and the benefit from the point of view of both the students and the host company.

There are currently over 30 students enrolled on the Medical Statistics Level-7 Apprenticeship, hosted by 14 companies. PSI is working to ensure that more universities can become training providers and interested companies are able to take on apprentices, as well as providing support for apprentices.

- The University of Leicester hoped to be able to offer the apprenticeship but unfortunately are not able to go ahead with it. However, LSHTM is approved for a 2025 intake for Face-to-Face learning.
- The University of Strathclyde and UCL are providing virtual options. The majority of apprentices are enrolled on the course at Strathclyde with 4 enrolled at UCL.
- Valerie has worked closely with the Institute for Apprenticeships & Technical Education and the universities to ensure that the masters dissertation project can be used for the endpoint assessment.
- In 2024, apprentices Jasmine, Anna and Isabelle joined the committee to set up an Apprentice Network. The aim is to bring together apprentices across different companies for networking, peer support and knowledge sharing, particularly on aspects of the apprenticeship such as how to collect evidence for their portfolios and endpoint assessments.

## 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**

2024 was the first full calendar year for the Schools team and it was a busy one!



2023/2024 saw the first year of the new PSI incentive scheme for schools outreach, the PSI Careers Outreach Champions Challenge Cup. Participants submitted to us any time they completed an outreach activity with a school and now at the end of the academic year we have tallied them up and pleased to announce our winner. This year we had 12 participants who completed in total 20 schools outreach activities, and they all received a certification of completion.

For our winning spot, we actually had a tie. Both winners delivered an impressive 3 schools outreach activities each this year and each received a £50 voucher of their choice and a £125 STEM grant for a school of their choosing. We are pleased to announce that our first ever winners of the Outreach Champions Challenge Cup were Katie Gwinnell from Bayer and Katie Law from Veramed. We hope to continue the scheme this year, so keep an eye out in the coming months for announcement for the 2024/25 entries.

We continue to maintain connections with relevant external STEM organisations to help support our members in accessing schools outreach opportunities and maintain a range of volunteering and sponsorship opportunities available for our PSI members. This year we also advertised several adhoc volunteering opportunities on the website and via our new Outreach Champions email distribution list.

We maintained our partnership with I'm a Scientist and sponsored 3 spots in their engagement competition for PSI members. We were proud to have Ria Kalaitzaki (GSK), Fiona Grimson (UCB) and Laura Barker (AZ) represent PSI in I'm a Scientist for 2024. Between them, they attended



59 chats with 45 different schools reaching ~ 950 students in 2024. Due to the popularity of this opportunity, we are pleased to sponsor 5 spots in the competition for 2025. Our scientists for 2025 will be Paul Terrill (PT stat), Kerry Gordon (Phastar), Kathryn Howells (AZ), Eloisa Brook (GSK) and Jan McKendrick (Avalere Health), we look forward to updating you next year on how they get on in the competition.

We created some new marketing materials, an e-poster for Year 6+ students and an e-leaflet for Year 11+ students. These are available for download on the PSI website via [this link](#). Here, you will also find the poster we presented at the 2024 PSI Conference in Amsterdam. We also hosted a drop-in lunchtime session at the conference, as well as covering a slot on the PSI stand in the exhibition session. Across all these opportunities at the conference we had some great conversations about members who were either interested or already engaging in schools outreach activities. We even came home with some new volunteers to join our team 😊

We also were represented for the first time in the National Careers Week Virtual Fair 2024 which took place 4-9<sup>th</sup> March 2024. We had a virtual exhibition stand which could be viewed by students and teachers during National Careers Week, as well as for several months afterwards. You can view our virtual stand at [this link](#). We are pleased to confirm we will be supporting this event again in 2025.

We formed a collaboration with the Data Visualisation SIG (led by Steve Mallett) to work on new school workshops that will utilise RShiny Apps to demonstrate data visualizations. We look forward to piloting them in 2025. We also shared several communications in eNews and via social media to promote participation in schools outreach activities. For more details on how to get involved with Schools Outreach [please visit our website](#).

## 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 now in its fourth year with continued interest from all levels of experience, different organisations and different time zones. In 2024 26 mentoring pairs were matched, of which there were two mentors matched to two mentees. While there was an option to register as both mentor and mentee, we continued to find more members registering as mentees. Due to the increase in registrations, matching took longer than anticipated and the team are exploring whether automation can be incorporated to match participants in the 2025 scheme. However, there was a greater variety of mentors and mentees which we expect to be reflected in the 2025 registrations. A mailing list was also set up in 2024, helping the team to reach more potential participants.



In 2024, the Book Club continued to host sessions to discuss “The 7 Habits of Highly Effective People” by Stephen R. Covey, eventually taking over a Lunch and Learn webinar for an interactive discussion. Book club facilitators Alun Bedding and Steve Mallett led the discussion along with members of the organising committee. In total there were 86 registrations, 75 of which were PSI members. With its success, we are planning to incorporate more one-off webinars on shorter form content such as podcasts, to supplement the usual Book Club sessions.



Lunch and Learn events were paused this year as the team focused on organising the Neurodiversity plenary session at the 2024 PSI Conference in Amsterdam. The plenary session was a hit, with a follow up workshop on Diversity, Equity and Inclusion (DE&I) planned for the 2025 conference and the formation of a DE&I working group. The PSI website contains recordings of past sessions which members can access. We aim to restart Lunch and Learn events in 2025 so please look out for further information soon.



The Career Young Committee had a successful year continuing to lead virtual events quarterly, and hosting networking events at the PSI conference as well as representing PSI at external meetings. The virtual events continue to have over 20 diverse attendees per event. Participants ranged from students to those with roughly four years of experience in industry. This year there were guest speakers presenting on their experience presenting at the PSI conference and their apprenticeship. The conference networking sessions were also well attended with over 30 participants joining the lunch time session. We attended the Young Statistician Meet again at the University of Birmingham Medical School, presenting on PSI and promoting the industry to approximately 80 attendees ranging from students to post-docs. We are exploring a face-to-face event in 2025.

Finally, PSI Careers and the Professional Development Committee organised two workshops at the 2024 PSI Conference. Xinyi led the “Level up your career: How coaching and mentoring can help you take the Next Step” workshop with Alun Bedding and Lucy Rowell while Kim Hacquoil, PSI Careers Director, Naomi Givens and Vicky Marriott, led a workshop on project leadership. More workshops are expected for the 2025 conference so please look out for them!

## 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.*

**Zelig Bailes, ITIT Chair**



Again this year the ITIT course has been in high demand and oversubscribed, receiving 36 applications, the highest number we have received in a long time. It was great to see a number of applicants from new or returning companies who have not sent delegates in recent years, and we have achieved a good mix of applicants from across the industry, with 26 delegates from 16 different

companies. It's fantastic to see the course remains as popular as ever! The high number of applicants of course means there were some applicants who will have been disappointed not to get a place this year, and we hope they will reapply next year.

Whilst the interest in the course remains high with companies wanting to send delegates, we continue to face challenges with securing companies to host sessions. The start of the 2024-2025 course was delayed until January due to struggles with finding hosts for the first 2 sessions, and for the first time in a long time we will unfortunately only be able to put on 5 of the 6 sessions, due to not having a company willing to host the Toxicology session. We will therefore be providing a partial refund to delegates on the course this year, and the committee are still working to see if we can provide a virtual offering to cover some of the toxicology topics to avoid this year's attendees missing out on this topic entirely.

I would like to thank the companies that are confirmed for hosting a session this year, including AstraZeneca, ICON, Bayer, and Roche.

I would also like to thank the passionate ITIT committee members who volunteer their time to help organise the course, on top of their day-to-day work, and ensure its continued success.

Applications for the 2025-2026 course are now open and will remain open until 27<sup>th</sup> June 2025. We look forward to welcoming our next set of delegates!

Thank you to everyone who has been involved with making the Careers team a success this year. I am always impressed with the volume and quality of work the volunteers do and without their enthusiasm and dedication we wouldn't be able to provide such varied, diverse and successful events. Well done!

## 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 final year as Commercial Director and we have continued to generate substantial additional revenue for PSI, allowing the organization to develop further benefits for members. PSI derives a substantial proportion of its earnings from sponsorship of the annual conference. We have continued to engage with a broader group of sponsors as well as increasing the levels of sponsorship. The conference in 2024 attracted 26 different Sponsors and saw the largest ever levels of sponsorship, beating the previous year. Since the pandemic, we have experienced multiple record-breaking years in terms of revenue and number of Sponsors which has put the future of PSI on very solid ground.

During my tenure, it is clear that persistent 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. When I took on the role, I wanted to increase revenues from sponsorship by attracting a broader group of Sponsors and offering more sponsorship opportunities. The changes have attracted sponsorship from companies who have never previously been involved in the conference and have become regular Sponsors.

Looking forward to the conference in 2025, my last year as Commercial Director, sponsorship is running in line with the previous record. This is very encouraging given the uncertainty that the Pharmaceutical Industry continues to face. It is clear that many companies are experiencing budget constraints which may well impact on PSI as an organisation. Nevertheless, the support we receive is really appreciated as it provides much needed funding, allowing PSI to invest in better services to members.

The Commercial Director role is perhaps not the one that many statisticians would be drawn to when considering a place on the PSI Board. It can be uncomfortable trying to sell conference packages or chasing Sponsors for money. However, the role is arguably one of the most important within the organisation. It is a role that is able to transform the fortunes of PSI. The Board now spends a considerable amount of time discussing where we should spend the funds we have accrued over the past few years. The nature of these discussions is very different to those that took place previously. For anyone interested in making a real difference to existing and new statisticians in the Pharmaceutical Industry, I encourage you to consider the Commercial Director role. The impact you will have will serve you well in the future and I will be around to support you.

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 have been supported by Ian Ratcliffe (Veramed), Mary Elliott-Davey (Amgen) and Frances Denny (Exploristics).

**Aiden Flynn**  
**Commercial Director**





# Communications Committee & External Affairs Report

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

Alun Bedding stepped down from his role as Director for Communication and External Affairs and was replaced by Jennifer Visser-Rogers. As part of this role, Jennifer will also represent PSI on EFSPi Council. I'd like to thank Alun for his time as Director for Communications and External Affairs and I am looking forward to having the opportunity to build upon the great work that he and the Committee have been doing.

Sophie Greenwood has also made the decision to step down from her role as Communications co-lead to focus on her PhD studies. Sophie has been a pivotal member of the Committee for a very long time, and will be sorely missed, but we all wish her the very best of luck as she completes her PhD. We have decided to replace Sophie with two roles: Committee Secretary, and Newsletter Editor. Leanne Winzer has taken on the role of Committee Secretary, and at the time of writing, we are advertising for the Newsletter Editor role.

Jamie Chai-Rees continues to work on the Digital Strategy, and we are considering the evolution of the Communications general strategy. The recent membership survey and upcoming strategy day are going to be key activities that feed into our Communications plans. Thinking about the membership value proposition, we will be thinking about the activities that PSI does and how best we communicate these with our members. With this in mind, Moore Engage have taken on a lot of the administrative tasks of putting out social media posts, freeing up time for Oceana to think more strategically about what content we should be posting beyond standard announcements. This, alongside the appointment of a Newsletter Editor, will really allow us to think about how we communicate with PSI members and what information we put out.

For External Affairs, I will be continuing to reach out to other statistical organisations such as EFSPi (where I sit on the Council), International Biometrics Society British and Irish Region (where I am President), and the Royal Statistical Society to forge links and explore potential partnership/collaboration opportunities. I will also be picking up the brilliant work that Alun had been doing to start engaging with academic institutions to look at where PSI could help them in their work. This is being done in collaboration with EFSPi, and I will look to also pull in other relevant parties to enrich the discussion. One of the key topics being discussed is the evolving skillset that graduate statisticians are leaving University with and a desire to ensure that fundamentals of applied statistics (such as design of experiments) is not excluded from university curriculums. I think that this is going to be a really worthwhile activity, and one where my background in both academia and industry will hopefully be useful.

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!!

**Jennifer Visser-Rogers**

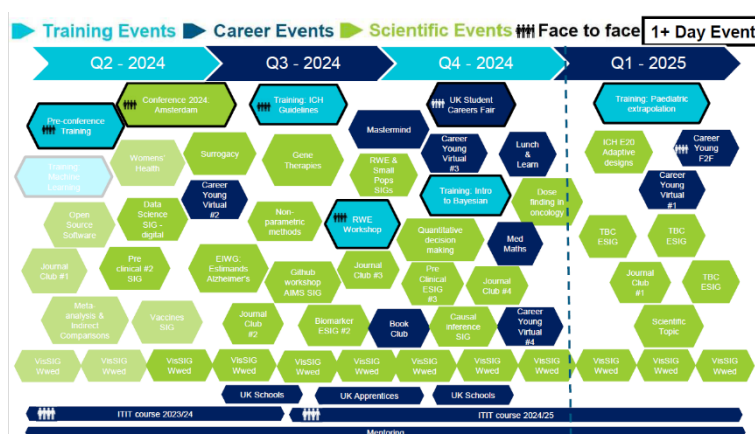
**Communications Committee & External Affairs (and EFSPi) Director**



# Events Report

In 2024 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 2024 PSI offered both members and non-members a widely varied programme of scientific events – a total of 46 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 in this report. In 2024 again our events were almost all online – the exceptions were our fantastic conference in Amsterdam, the Pre-Clinical SIG workshop in Paris, a training course on ICH Guidelines for Statisticians in London, the annual Medical Statistics Careers Event and the ever-popular ITIT course for those new to the industry (2024/2025 cohort). Our online meetings included ability to ask questions for discussion by presenters and we also held multiple successful online training courses.



Numbers of attendees at the events ranged from 540 at conference, 50-330 at scientific/SIG topic/careers webinars and journal clubs and 20-40 at interactive training courses/workshops.

Popular events included “*Estimands framework in action, the Alzheimer’s disease case*”, “*HTA and Indirect comparisons*”, “*Open Source Software*”, “*Hierarchical Compositivity Endpoints*”, a joint webinar from the PSI/EFSPi Small Populations & RWD SIGs on “*Harnessing Real-World Data (RWD) in clinical trials for small populations and rare diseases*”, a Causal Inference SIG webinar on “*Virtual Control Groups in Toxicity Studies*” and a journal club webinar on “*Limitations and Challenges with Mixed Model Repeated Measures (MMRM) Analysis*”.

All the events just mentioned had over 100 attendees and the huge benefit of delivering so many of our invites online now is the wide audience we can reach. Don’t worry if you missed out on any of the PSI 2024 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 2025 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 2025 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 2024. 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 2025 or beyond then please reach out!

## Conference Report

The PSI 2024 Conference took place 16th – 19th June at The Beurs Van Berlage, Amsterdam. The conference was well attended, with 548 delegates registered. These 548 delegates represented ~26 countries and ~215 unique companies and organisations. We were generously supported by 25 sponsors. Of the 123 attendees who completed the post conference questionnaire approximately one third were new PSI members and just over 40% were attending for the first time.

On the Sunday before the start of the main conference two half-day courses were held:

- Bayesian methods for borrowing of information (with applications in clinical trials), which was presented by Dr Haiyan Zheng (Senior lecturer in statistics, University of Bath), Dr Lisa Hampson (Senior Director, Novartis Statistical Methodology group) and Dr Sebastian Weber (Director, Novartis Advanced Exploratory Analytics Group)
- Applying causal inference for effective implementation of the estimand framework in drug development, which was presented by Dr Tobias Mütze (Novartis Pharma AG) an Associate Director in Novartis' Statistical Methodology group in Basel. Dr Simon Newsome (Novartis Pharma AG) an Associate Director in Novartis' Statistical Methodology group in Basel and Prof Karla Diaz Ordaz (University College London) a Principal Research Fellow in Biostatistics.

Both courses proved very popular and were well attended.

We were delighted to welcome two keynote speakers, Geert Molenberghs (Universiteit Hasselt & KU Leuven) spoke on Biostatistics in a post-pandemic era: lessons learned for research, public health, drug and vaccine development, policy advice, and communication. He was an active advisor, researcher and communicator in the SARS-CoV-2 pandemic response.

Our second keynote speaker was Theo Smith who spoke on neurodiversity at work and how we can unleash the power in every mind, followed by a panel discussion that comprised of PSI members. Theo Smith is the founder of Neurodiversity World & Neuromine.ai, a LinkedIn Top Voice, author of the award-winning book 'Neurodiversity at Work' and podcast host of 'Neurodiversity with Theo Smith'. Theo has been in HR and Talent leadership for 15+ years and together with Dynamis Group we've consulted on a wide variety of industry leaders, their organisations and governments on the topic of Talent and Neurodiversity at Work.

In total the conference consisted of 38 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 nine sessions showcasing their work. Parallel sessions based on contributed abstracts covered many diverse topics including estimands, data visualization, Bayesian borrowing, digital health, adaptive designs, patient reported outcomes and master protocols. Based on feedback of the value of workshops, three

interactive workshops were included in the programme: Vicky Marriott, Kimberly Haquoil and Naomi Givens ran a workshop on Project Leadership. David Lawrence, Tobias Mütze, Tim Friede, Kit Roes, Emma May and Michael Cartwright ran an interactive session on data monitoring committees. Xinyi Zhu, Alun Bedding and Lucy Rowell ran a workshop titled “Level up your career: How coaching and mentoring can help you take the next step”.

As usual we included two 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. We included two TED-style talks sessions and these proved to be hugely popular and will return in 2025. Following its introduction at the 2023 conference, we continue to hold a plenary session focusing on Health Technology Assessment (HTA) entitled “EU HTA in 2025: Finish line or starting gate?” 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 and discussing key topics in this space, alongside 2 industry representatives. 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 conference newsletters, eNews and LinkedIn 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, updates during the conference itself, an opportunity for attendees to connect and message each other as well as post their thoughts on sessions “live” during the conference.

The 2025 conference will be taking place from the 8th – 11th June at Wembley Stadium, London UK. The preparations are well underway, with the majority of sessions finalised and all speakers identified. Information will continue to be shared regularly as we move closer to June. A conference newsletter will be issued regularly and the scientific committee sub-team who have agreed a communication plan with the PSI communications team to release more information on sessions before the event through LinkedIn. The conference app is due to be launched in May.

**Sarah Williams**  
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 19 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 2024, the scientific committee organized 7 events and webinars spanning a range of topics:

- 2024 PSI Conference (see conference report)
- PSI Webinar: HTA and Indirect Comparisons
- PSI Webinar: Open-Source Software
- PSI Webinar: Drug Development in Women’s Health
- PSI Webinar: Surrogacy
- PSI Webinar: Development of Gene Therapies
- PSI Webinar: Hierarchical Composite Endpoints

## Training Committee

In 2024, the training committee successfully delivered 3 online training courses and one face to face training course in London:

- PSI Training Course: R (held virtually over 5 sessions)
- PSI Training Course: Machine Learning (held virtually over 4 days)
- PSI Training Course: ICH Guidelines for Statisticians (held face to face over 2 days)
- PSI Training Course: Introduction to Bayesian Methods (held virtually over 3 days)

The online courses in 2024 worked well for delegates, and in 2025 the training committee are looking to continue offering online 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 2024, the Journal club delivered 3 webinars. In 2025, we look forward to providing more journal club webinars to members and non-members.

### 3 Journal Clubs:

- PSI Journal Club: Limitations and Challenges with Mixed Model Repeated Measures (MMRM) Analysis
- PSI Journal Club: Subgroup and Covariate Analysis
- PSI Journal Club: Group Sequential Designs

## PSI SIGS

We now have a total of 23 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.

### 23 ESIG events:

- PSI/EFSPi **Data Vis SIG** Wonderful Wednesday (series of 12)
- PSI/EFSPi **Pre-Clinical SIG** Workshop (face to face in Paris, France)
- PSI/EFSPi **HTA SIG** Webinar: Navigating HTA and Patient Access with Insights from Indirect Treatment Comparisons
- PSI/EFSPi **Pre-Clinical SIG** Webinar: Mixed-Level OMARS Designs for Quantitative and Categorical Factors: Theory and Application
- PSI/EFSPi **Vaccine SIG** Webinar: Statistical and Mechanistic Models for Correlates of Protection
- PSI/EFSPi **Data Science SIG** Webinar: Developing Digital Measures (Digital Biomarkers) in Drug Development – insights from Mobilise D consortium
- PSI/EFSPi **EIWG** Webinar: Estimands framework in action, the Alzheimer's disease case
- PSI/EFSPi **Pre-Clinical SIG** Webinar: Efficient R&D: SVEM and Advanced DOE in Preclinical Toxicity Testing
- Joint PSI/EFSPi **Small Populations & RWD SIG** Webinar: Harnessing Real-World Data (RWD) in clinical trials for small populations and rare diseases
- PSI/EFSPi **Causal Inference SIG** Webinar: Opportunities in applying a causal inference framework during the analysis of an RCT
- PSI/EFSPi **Vaccine SIG** Webinar: Statistical designs for assessment of vaccine safety in pregnancy
- PSI/EFSPi **Pre-Clinical SIG** Webinar: Virtual Control Groups in Toxicity Studies



## PSI Careers

The PSI Careers team, split into the sub teams 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.

### 9 Career events:

- PSI Mentoring 2024
- PSI Career Young Virtual Meet (4 separate meetings or webinars throughout the year)
- PSI Careers - MEDMathS: Medicine Empowered by Data, Maths and Statistics
- PSI Medical Statistics Student Careers Event 2024: Face to face event in London
- PSI Book Club Webinar: 7 Habits You Wish You Had (But Probably Don't)
- Introduction to Industry Course (started in 2024 and continued into 2025)

## Kate Taylor Events Director





## SIG Report – March 2024

The year 2024 proved to be another successful period for the PSI/EFSPI Special Interest Groups, with a multitude of impactful achievements. While it's challenging to fully capture the breadth of outstanding contributions in a brief summary, notable highlights include significant input to the 2024 PSI Conference through numerous sessions and posters, engaging webinars and workshops, multiple published papers, collaborations with groups like PHUSE and ASA, and valuable feedback on regulatory guidance documents. The ESIG community's exceptional efforts are truly commendable, and the PSI Board extends gratitude to all contributors.

Collaborating with my EFSPI counterpart, Emmanuel Pham, has been a rewarding experience, and his support is greatly appreciated. The expansion of SIGs continues, with recent additions such as Patient Focused Drug Development, Causal Inference, CMC, AI & ML, bringing the total to 24 SIGs.

The year 2025 has commenced on a positive note, with new SIGs launching and numerous submissions for the upcoming 2025 PSI Conference. In addition, with the support of Moore Engage, we are in the process of setting up collaboration and document storage sites for the SIGs in MS Teams. This was a much needed request from the SIGs, so we are delighted to be in the implementation phase.

For those interested in learning more or joining or creating an ESIG, please reach out or visit the [SIG webpage](#) for further information.

**Angela McPartlane, ESIG Director, PSI**

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### AI & ML: Sam Hadlington (Plus-Project)

The artificial intelligence and machine learning (AI&ML) SIG was created in 2024 in order to address the growing influence of AI systems and how they might be incorporated in our day-to-day work. We currently have 11 members and have had 3 meetings since our formation, mainly refining the goals of this SIG.

In our last meeting Paola and Danila presented on “AI Generated Synthetic Control Arms to optimize Clinical Trials”. They will also present this at the 2025 conference as part of our SIG session alongside others in our team.

We are currently in the process of compiling comments from across PSI and EFSPI on the latest FDA guidance on the use of AI in clinical trials(<https://www.fda.gov/media/184830/download>). We have also been engaging with other machine learning teams from across the PSI SIGs to learn from their experience and share this learning with our members. We hope in the future to be able to offer some assistance to these ML teams based on our learnings across this space.

#### Goals

- Aligning machine learning groups across all SIGs.
- In context of clinical research how and where are AI and ML useful – specifically related to statisticians.
- Consulting with regulatory authorities on guidance for the future.
- *Longer term:* Regular webinars to deliver knowledge back to industry colleagues

- *Longer term:* Develop common framework for explainable AI in statistics
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### **AIMS: Martin Brown (PPD)**

The AIMS SIG continues to support and contribute to researching the use of R / Open-source within the industry. We are currently a group of 13 from across different companies that have been meeting monthly. We have links and strong connections with a number of other groups (e.g. CAMIS, Openstatsware, Phuse) - this grew through 2024 and resulted in guests attending meetings and supercharging a number of great discussions throughout the year. There was another successful run of the PSI Training Course: R for Clinical Trial Statisticians (Andy Nicholls) and presentations at posit:conf (Mark Bynens - Mastering the Art of Adopting R and Python: Innovative Strategies for Effective Change Management) and R in Pharma (Christina Fillmore - Accelerating GSK's Open-Source Journey with Gen AI).

Thank you to all of our members who contributed in 2024, and we look forward to more R discussions and progress in 2025. If you would like to join us, please get in touch ([PSI AIMS Special Interest Group – PSI AIMS SIG Website](#)).

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

In 2024, the Benefit-Risk ESIG focused on several key activities that contributed to the field of benefit-risk assessment.

One of the major tasks was the review of the Blueprint, which will also be a focus for 2025. This review aims to guide future activities and ensure that the group's efforts are aligned with the latest developments and best practices in the field. Additionally, significant work was done on the communication strategy, creating new opportunities for members to be more involved, such as through communications roles, which led to the successful recruitment of additional members.

Another key achievement was the presentation of a poster at the PSI conference. This poster discussed the use of discrete choice experiments (DCEs) in benefit-risk decision-making, highlighting the limitations of traditional ratio-based benefit-risk (BR) assessments. It proposed compensating variation (CV) as an alternative approach, which better captures patient preferences, especially when considering opt-out options. The presentation used simulated data to demonstrate the advantages of CV over traditional methods.

The SIG also collaborated with the Safety Working Group within the BR SIG, including a meetup at PSI 2024 organized by members of this SIG. This collaboration aimed to enhance the understanding and application of safety considerations within benefit-risk assessments.

Although the group reviewed the CDE MRCT guidance on BR in China, we did not provide feedback during the public consultation period. We continue to monitor BR guidance development, and plan to review them holistically in the near future. However, efforts were made to engage with other groups, such as the ASA Safety Working Group and the Regulatory ESIG, fostering collaboration and knowledge sharing across different areas of expertise.

The Benefit-Risk ESIG actively collaborated with other conferences such as ISPOR and SMDM, working across industry, academia, and public bodies, and across geographies to provide recommendations on key methodological issues across product life cycles. These collaborations helped to broaden the impact and reach of the SIG's work.

Overall, the Benefit-Risk ESIG's activities in 2024, while less extensive than the previous year, continued to contribute valuable insights and foster collaboration within the field of benefit-risk assessment. The group's dedication to

improving the ethical and scientific aspects of BRA remains evident through their ongoing efforts and achievements. The work on the Blueprint and the communication strategy will be instrumental for the success of the SIG in future years.

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## **Biomarkers: Guillaume Desachy (Pierre Fabre), Nicole Kraemer (Boehringer-Ingelheim)**

Once again, the Biomarkers ESIG had an exciting year in 2024! They have written an excellent overview posted [here](#) on LinkedIn.

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## **Causal Inference: Sanne Roels (J&J), Kelly Van Lancker (Ghent University)**

The Causal Inference Special Interest Group (SIG) was initiated and eventually launched in 2024. The SIG started with a core group of five members and has been growing to approximately 20 active participants who have joined since mid-2024.

Our SIG quickly gained momentum by organizing a well-attended webinar last November, featuring Kaspar Rufibach, Susan Gruber, and Florian Lasch, who discussed the motivations for applying causal perspectives in answering the scientific question of interest and analyzing data collected in randomized controlled trials (RCTs).

Our monthly regular meetings have focused on causal inference methodologies and concepts essential for analyzing clinical trial data to appropriately answer questions, i.e. visualization using DAGs, analysis methodology in the presence of post-baseline events. We explore how such methods can enable more direct answers to scientific questions of interest and how they enable us to estimate the desired summary metric from the available data (and under which assumptions).

We have formed a sub-team dedicated to mediation analysis and are in the process of establishing a separate sub-team focused on covariate adjustment in the analysis of RCT data.

Looking ahead to 2025, we are preparing a proposal for a symposium at the ISCB (in August in Basel) and will be chairing a session on Causal Inference at the upcoming PSI conference. We are also in the planning of a second webinar to continue our efforts. Lastly, we have been also working towards a collaboration with the RWD SIG for the organization of a joint webinar.

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## **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 team have had another successful year in 2024 with sub-committees working in parallel on the topics of CSM and QTL.

Summary of annual accomplishments:

- Highlight new techniques and best practices:
- QTL evaluation paper:
  - “Evaluation of current statistical methods for implementing Quality Tolerance Limits”. Submitted to *Statistics in Biopharmaceutical Research* November 2024.
    - Pending acceptance/review comments.
- CSM methods review paper:
  - “Fronc M, Jakubczyk M, Love SB, Talbot S, Rolfe T. Central statistical monitoring in clinical trial management: A scoping review. *Clinical Trials*. 2025;0(0). doi:10.1177/17407745241304059”
    - Published 02Jan2025 in Clinical Trials
- Discussion topics presentation slide deck for EMA Methodological Considerations submitted to EFSPi Statistical Methodology Leaders Group, including questions on adoption and acceptability of risk-based approaches, over intervention, monitoring deviations in treatment adherence and open label study considerations.

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

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## CMC: Kevin Lief (GSK)

- Having joined EFPSi/PSI as a SIG, initiated a successful membership drive.
  - Launched our SIG, at the Non-Clinical Statistics Conference, Wiesbaden, Germany in September 2024, with a very well received short presentation.
  - SIG presented on data re-use as a platform for product development, at the EMA Quality Innovation Group, 4<sup>th</sup> Focussed Listen and Learn session, November 2024. In preparation for the presentation, networked with EFPSi – Manufacturing Quality Expert Group/VE subgroups.
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## Data Science: Carsten Henneges (Sanofi)

We are a group of statisticians, computer and data scientists - professionals with a range of backgrounds, experiences and skills, working in various functions across the Pharmaceutical Industry on tasks related to this huge field of knowledge called Data Science (DS).

We see our mission as bridging DS knowledge and expertise across various groups and functions within the pharmaceutical industry to increase collaboration, awareness, knowledge sharing and enhance drug development. We'll encourage the development of new statistical and machine learning methods and approaches as well as in novel applications of the well-established methods.

For more information on the Data Science SIG please see [here](#)

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## **Data Sharing: Rebeca Sudlow (Roche) and Catrin Tudor Smith (Uni of Liverpool)**

Clinical data has greater use beyond the original trial. These data can be used to further increase our scientific understanding of diseases and their treatment for the benefit of future patients. This re-use is a challenge, as both the data privacy and the regulatory framework continue to evolve. The members of this ESIG intend to lead the industry discussion in this area.

For more information on the Data Sharing SIG please see [here](#)

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## **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.

For more information on the Decision Making SIG please see [here](#)

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

In 2024, the Historical data SIG published a paper “Beyond the classical type I error: Bayesian metrics for Bayesian designs using informative priors” in SBR ([Full article: Beyond the Classical Type I Error: Bayesian Metrics for Bayesian Designs Using Informative Priors](#)) and successfully submitted a Qualification Opinion request to EMA on “Bayesian dynamic borrowing using the robust meta-analytic prior (RMP) methodology as an appropriate statistical approach for confirmatory randomised clinical trials, including a general framework to evaluate its value and acceptability”. The start of the procedure was delayed by the EMA who have now confirmed that the procedure will start in March 2025.

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. A number of new members also joined during 2024, showing the ongoing interest in the topics of the SIG.

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## **HTA: Anders Gorst-Rasmussen (Novo Nordisk)**

The HTA SIG remained highly engaged in various activities, particularly related to EU HTA throughout 2024, seeing a notable increase in membership, reaching a milestone of 100 members.

Some key achievements include:

- PSI 2024 in Amsterdam: The SIG actively participated in various sessions at the PSI 2024 conference, including a poster session driving a SIG session addressing evolving indirect treatment comparisons

methodologies and their implications for health technology assessment. Additionally, the SIG organized a social catch-up and a Town Hall session “EU HTA in 2025: Finish line or starting gate?”

- EFSPi Regulatory Statistics Workshop in Basel: SIG members were heavily involved in the HTA Scientific Subcommittee of the EFSPi Regulatory Statistics Workshop 2024, driving the agenda for the last morning of the 2024 workshop. This pilot aimed to provide a specialized platform for statistical dialogue tailored to the HTA community's specific needs. The SIG also presented a poster on how to account for HTA and access needs during pivotal trial design.
- European Commission EU HTA Stakeholder Network: SIG member represented EFSPi in the European Commission EU HTA Stakeholder Network, including a presentation in November on open-source solutions in EU HTA to the EU HTA Coordination Group, contributing to fostering dialogue and collaboration within the EU HTA landscape.
- Other Achievements: played an important role in fostering dialogue across companies, enhancing readiness for EU HTA through regular monthly meetings; made progress in updating the HTA handbook and advancing its work on whitepapers and various technical sub-teams.

We provided regular updates via PSI/ EFSPi communication channels as well as updating and maintaining our [webpage](#).

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## Launch & Lifecycle: Jenny Devenport (Roche) & Yulia Dyachkova (Merck)

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 ([link](#)) or reach out to co-leads [yulia.dyachkova@merck.com](mailto:yulia.dyachkova@merck.com) or [jenny.devenport@roche.com](mailto:jenny.devenport@roche.com).

Wishing everyone an impactful 2025!

### Publications

Do You Want to Stay Single? Considerations on Single-Arm Trials in Drug Development and the Post regulatory Space

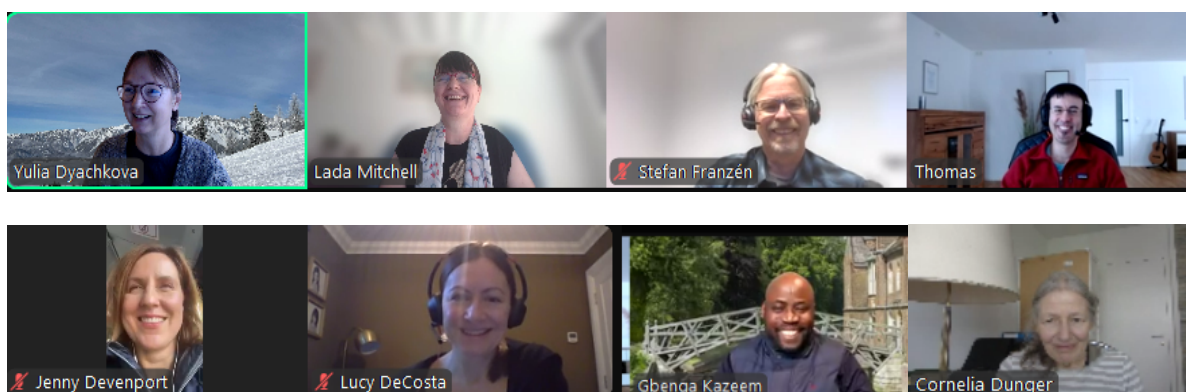
- Published manuscript: [link](#)
- The Effective Statistician Conference Session

### Ongoing work

1. (in collaboration with other SIGs) - Implementation of estimands in RWD studies to evaluate questions of interest in the post-marketing space.
  - a. Translating concepts like treatment patterns in practice to the estimand framework
  - b. Different types of intercurrent and / or competing events that occur in the real-world
  - c. Challenges with estimands inherent to RWD



2. Various presentations on integrated evidence plans: The Evidence Odyssey: From Clinical Trial Data to Clinical Practice Success



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## Neuroscience-Estimands: Paul Delmar (Roche)

This SIG has the objectives of supporting/strengthening the role of biostatistics in the development of new medicine for Neuroscience and to identify areas where collaboration between companies makes sense.

There are two connected topics:

1. General Biostatistics Neuroscience community
2. Working groups on estimands in neuroscience and other topics in neuroscience

For more information on the Data Science SIG please see [here](#)

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## Oncology Estimands: Kaspar Rufibach (Roche)

As of December 2024, the SIG had 102 members (36 from Europe, 56 from US, and 10 from Asia) representing 51 companies / institutions.

The working group officially ended its activities at the end of 2024.

Some of the [taskforces](#) will continue their work under other EFSPi / PSI / ASA working groups and may take new members. Please directly reach out to them as indicated [here](#).

Our webpage ([www.oncoestimand.org](http://www.oncoestimand.org)) continues to remain a resource to foster sharing of information and generated content such as presentations, event recordings (if available), and publications.

Summary of annual accomplishments (see also [here](#))

- One scientific paper was published and one more submitted, see [publications page](#).

- The SWG has organized a session at this year's PSI conference, see [here](#).
- A summary of the SIG's 2024 achievements is available on its webpage [here](#).

#### Projection of upcoming activities next year

- The SWG plans to record at least two more LinkedIn videos, one on estimands and RWD and the other on current thinking around principal stratification.
- No other activities planned anymore.

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### **openstatsware: Alessandro Gasparini (Red Door Analytics), Ya Wang (Gilead), Daniel Sabanés Bové (RCONIS)**

The openstatsware SIG was originally formed in August 2022 and was associated as an official EFSPi/PSI SIG in 2024. We are very happy to have joined the EFSPi/PSI SIG family!

The primary goal of the openstatsware SIG is to engineer R packages that implement important statistical methods to fill in gaps in the open-source statistical software landscape. Our first product, the R package `{mmrm}`, was first published on CRAN in October 2022 and several updates have been published since. We aim to establish this package as a new standard for fitting mixed models for repeated measures (MMRM), and the package has been presented several times at scientific conferences (e.g., useR! 2024, China R Conference 2023, R/Pharma Conference 2023, JSM 2023, PSI 2023).

In 2023 the SIG developed a Bayesian implementation of the `{mmrm}` package, named `{brms.mmrm}`, which was published on CRAN in August 2023. As with `{mmrm}`, several updates have been released since the initial publication, and the package has been presented at the Bayesian Biostatistics Conference in 2024.

In 2024 the SIG finalised work on `{maicplus}`, an R package providing tools to perform matching-adjusted indirect comparison (MAIC) analyses. `{maicplus}` was published on CRAN in November 2024, and further developments are ongoing.

The SIG developed its first Julia product as well, the `{SafetySignalDetection.jl}` package to implement Bayesian safety signal detection. The package was published on the central Julia registry in April 2024.

The SIG took over maintenance of the CRAN Clinical Trials task view, which is planned to relaunch in 2025, and developed a Hexwall visualization for the task view which is published on the openstatsware website: <https://www.openstatsware.org/hexwall>

The secondary goal of the working group is to develop and disseminate best practices for engineering high-quality open-source statistical software. To this end, the “Good Software Engineering Practice for R Packages” workshop run seven times between 2023 and 2024, around the world: Basel, Shanghai, San José, Rockville, Montreal, Zurich, Salzburg. For 2025, additional workshops including in Tokyo and Paris are being organized.

The WG published the first draft of openstatsguide, openly available on our website at <https://www.openstatsware.org/guide>, which provides an opinionated, short, and concise set of minimum viable good practices. Development and refinement of openstatsguide is ongoing.

Finally, the WG has contributed to scientific conferences in 2024 (useR! 2024, PSI 2024, R/Pharma, Effective Statistician Conference) and plans to contribute to more in 2025: a session proposal for PSI 2025 was already accepted, and several others have been submitted by members of the SIG.

In 2025, the openstatsware SIG is expected to have presentations at various conferences and webinars to introduce the SIG, to promote the SIG's packages, and to disseminate best practices for software engineering.

- The SIG will keep developing public training materials and to disseminate best coding software engineering practices.
- The SIG also plans to increase the collaboration with other SIGs to develop new software packages with the aim of filling important gaps in the open-source statistical software community

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## **Patient Focused Drug Development (PFDD) *Rachael Lawrance (Adelphi Values), Konstantina Skaltsa (IQVIA)***

The patient focused drug development (PFDD) SIG was created in early 2024 with the purpose to connect statisticians in pharmaceutical industry roles who work on progressing the inclusion of patient-reported outcomes (PROs) and clinical outcome assessments (COAs) across all phases of drug development process to share their knowledge and also lead statistical thinking and methods to solve common statistical challenges of use of COAs in drug development.

Knowledge sharing of good practice is a key objective and we were pleased to have an interactive session at the PSI Conference 2024 as a PFDD SIG. We presented a summary of useful regulatory guidance about PROs in clinical trials, and team members talked about setting clear PRO objectives, patient-centric tolerability endpoints and patient centered digital health technology. During the session we conducted an interactive poll with the attendees to help guide our future SIG work stream.

- 40% of attendees were aware of FDA guidance about PROs but were not sure what applies to them.
- 30% of attendees found the current FDA/EMA PRO guidance about PROs in oncology was complicated and that were not sure what standards or changes to their current ways of working was needed.

And key topics of interest for the future were:

- Use of PROs in early phase studies and their role in dose optimization
- Working with diary data endpoints
- Estimands and estimators for PROs assessing tolerability and safety.
- Missing data – what is practical

In the SIG we have used this information to focus our workstreams during 2024/2025. Knowledge sharing remains key for us, including having links to key PRO-related guidance documents on our SIG webpage: [Patient-Focused Drug Development](#).

We are still small but have been growing in numbers during 2024 – we welcome new contributing members to join us. Our current active workstreams involve:

- Daily diary data and endpoints
- Use of structural equation modelling methodology in PRO endpoints
- PROs assessing tolerability

- PROs in dose optimization

We are looking forward to presenting work from sub-team members at the PSI conference 2025.



*Photo from PSI 2024 Conference in Amsterdam. PFDD SIG members after their session (from left to right): Konstantina Skaltsa, Devin Peipert, Alexandra Lauer and Rachael Lawrance.*

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### Pre-Clinical: Eloisa Brook (GSK)

The Pre-Clinical SIG had the following webinars in 2024:

Date	Title	Presenter	
26 March 2024	Mixed-Level OMARS Designs for Quantitative and Categorical Factors: Theory and Application	Professor Peter Goos, KU Leuven	To access video on demand, click <a href="#">here</a>
8 October 2024	Efficient R&D: SVEM and Advanced DOE in Preclinical Toxicity Testing	Phil Kay and Chandra Ramnarayanan, JMP	To access video on demand, click <a href="#">here</a>
26 November 2024	Virtual Control Groups in Toxicity Studies	Lea Vaas, Bayer	To access video on demand, click <a href="#">here</a>

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**Randomisation: Annika Scheffold (Boehringer Ingelheim), Johannes Krisam (Boehringer Ingelheim)**

In 2024, the Randomisation SIG made significant efforts in advancing the field of randomisation in clinical trials. The group's efforts were highlighted through contributions to statistical and clinical trial conferences, publications in peer-reviewed journals, development of open-source software, and an active social media presence.

Our SIG held two contributed sessions on randomisation at major conferences. The first session took place at the Society for Clinical Trials 45th Annual Meeting in Boston in May, where we presented a progress report on recent development of advanced randomisation designs. The second session was the PSI conference in Amsterdam in June, where we also shared the recent work efforts of our group with the audience.

Throughout the year, the members of the SIG published and submitted a total of 19 papers on various important topics related to randomisation, along with a book chapter. Highlights include the completion of a [special issue of Statistics in Biopharmaceutical Research](#), which featured seven papers by SIG members. The group also published papers on different methodology and implementation aspects of randomisation, such as [predictability of central randomisation](#), [forced randomisation](#), [maximum tolerated imbalance randomisation](#), and [randomisation in multi-center trials with stochastic recruitment considerations](#). Additionally, four more papers were submitted and are currently under consideration, covering topics like platform trials, response-adaptive randomisation, and allocation predictability of restricted randomisation procedures.

On the software development front, the SIG finalized Incertus.jl, a statistical software package developed in Julia for implementing state-of-the-art randomisation methods for multi-arm clinical trials. This package, along with statistical software to assess and compare various methods for forced randomisation, has been made [publicly available](#).

The SIG also established a [LinkedIn Public group](#), which has attracted 73 members, to enhance its social media presence and engage with the broader community.

Looking ahead to 2025, the SIG has ongoing and planned publications, has submitted proposals for several conferences, and is in the process of launching a new website. The group also plans to host educational and learning sessions, which will be available to both members and non-members.

Additionally, our SIG welcomed 14 new members over the past year and is looking forward to making the learning sessions accessible to a wider audience through recordings posted on our upcoming website. We also plan to add a link to our new website on the PSI page, further expanding their reach and impact in the field of randomisation in clinical trials.

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## Regulatory: Jürgen Hummel (Novo Nordisk) and Christoph Gerlinger (Bayer)

Several members of the Regulatory SIG changed company in 2024, which was the main reason for some changes to the membership (as we have a rule of only one representative per company). At the end of 2024 we had a total of 21 members from 8 countries. Our main activities in 2024 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 2024 this included the following documents:
  - FDA draft guidance on [Master Protocols for Drug and Biological Product Development](#)
  - FDA draft guidance on [Use of Data Monitoring Committees in Clinical Trials](#)



- FDA draft guidance on [Generating Evidence from Oncology Multiregional Clinical Development Programs](#)
- Supporting the organization of the EFSPi Regulatory Statistics Workshop (held 11-13 September 2024 in Basel, Switzerland). We also contributed to the poster session with a poster on the activities of the Regulatory SIG.
- On 13 November 2024 we had an informal exchange meeting with the MHRA statisticians. The meeting took place virtually and was organised jointly with the EFSPi Statistical Methods Leaders. The main topics of the discussion were Bayesian statistics and inference in confirmatory trials (including for non-rare diseases and beyond paediatric trials) and Covariate adjustment in randomised clinical trials (including approaches based on ML). Detailed minutes from the meeting are published on the PSI website ([2024-minutes-of-meeting-with-mhra-biostatisticians-\(final\).docx](#))

### 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. We hold meetings monthly during which members share case studies as well as information on initiatives, methods, guidelines, data sources. Topics discussed in 2024 included immortal time bias, the use of RWD to estimate prevalence, distributed RWD & use of OHDSI tools, hybrid designs and an MIDD case study incorporating RWD. Furthermore, we debriefed on relevant conference/workshop content plus reviewed and discussed new drafts, or final versions, of several regulatory guidelines/papers from FDA, EMA and ICH.

A couple of our conversations led to blogs on the “Let’s T@lk Real Corner” on our webpage:

- [Immortal Time Bias - Zeroing in on time-zero](#)
- [Federated real-world data and common data models](#)

At the 2024 PSI Conference we held a session on [How to Generate Evidence from Real World Data](#), and also had the chance to present the ‘Industry Perspective of the EMA Reflection Paper on Non-interventional Studies’ at the Regulatory Townhall.

We collaborated with the Small Populations SIG on a webinar held in October on "[Harnessing Real-World Data \(RWD\) in clinical trials for small populations and rare diseases](#)" (which is well worth catching up on via video-on-demand!).

We also made connections with other SIGs, planning future shared sessions (e.g. via webinars) with the Historical Data SIG and the Causal Inference SIG; plus connecting with the L&L SIG on implementation (or not) of estimands in RWE studies.

From an operational perspective, our webmaster Rachel Tham adopted a Mailchimp managed list where interested members can sign themselves up indicated if they are “active members” or “informed members” (even if all are welcome to join meetings and contribute, the membership designation only sets expectations and mindset!). Our SIG page is here [RWD SIG \(psiweb.org\)](#), and you may subscribe via this [link](#).

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

The Small Populations SIG had two objectives going into 2024:

- Increase the membership to at least 15 people to create a sustainable working group
- Arrange one webinar

I am glad to say that we achieved both objectives successfully. At the end of the 2024, the SIG included 17 active and fully engaged members from industry and academia. We established a rota of presentations and regular updates so that attendance at our monthly calls remained above 85% across the entire year.

In Q1 of 2024 we started a collaboration with the RWD SIG with the aim to co-arrange a webinar by end of the year. As a result, in October we held a webinar titled “Harnessing Real-World Data (RWD) in clinical trials for small populations and rare diseases”, which included two presentations by experts in the field followed by a short panel discussion. The webinar was well attended and attracted additional members to the SIG.

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### **Treatment Effect Heterogeneity SIG: David Svensson (AstraZeneca)**

During 2024 the SIG changed name from ‘Subgroups’ to this new more precise name, in order to better reflect what the group is looking at. E.g., methodology for identifying patients at higher risk is outside scope since this constitutes prognostic effects and notoriously leads to suggestions to consider machine learning for predicting such. However, this is ‘orthogonal’ to what the problem this group is focusing on: how to target individual treatment effects and the aspects related to it (predictive biomarkers, who should have the active treatment first (scoring systems), deriving dynamic Individual Treatment Regimes, how to evaluate performance of CATE models (with inherent uncertainty quantified) despite the targets being fundamentally unobservable.

The SIG has expanded considerably the last year, with some academic researchers regularly participating. We had eight SIG meetings in 2024, all focusing on research questions - with some external experts presenting (e.g., Imai Kosuke from Department of Statistics at Harvard University). Several scientific papers were co-written and published in cross-industry collaborations between members of the SIG: e.g., recent methodological trends from the last five years were overviewed in a rather vast Statistics-In-Medicine Tutorial Paper [1] (with 230 references). The paper also conducted CATE estimation benchmarking with head-to-head comparisons of many popular methods under different assumptions. Another SIG collaboration [2] gave rise to a structured framework for how to best approach the problem of heterogeneity, which also contains valuable advice on communication of results to stakeholders.

Yet another SIG effort [3] resulted in a benchmarking of many popular algorithms such as model based recursive partitioning and penalized regression techniques. All the above papers were discussed/presented at the SIG regular meetings. Furthermore, the SIG arranged and held a session at the PSI conference in Amsterdam, dominated by presenting the aforementioned papers (presenters where David Svensson (AstraZeneca) and Kostas Sechidis (Novartis)); also Tobias Mielke from Janssen gave a great talk on Considerations on when and how to perform subgroup selection in Phase 2/3 programs.



The SIG was furthermore represented with a collaborative poster at the EFSPi Regulatory Statistics Workshop, Basel, 2024. The SIG took part in the all-SIG meeting (February 2024). Ongoing SIG work includes another cross-industry collaborative initiative on a research paper, to be submitted in the near future.

[1] I. Lipkovich, D. Svensson, B. Ratitch, and A. Dmitrienko. "Modern approaches for evaluating treatment effect heterogeneity from clinical trials and observational data". In: *Statistics in Medicine* n/a.n/a (2024).

[2] K. Sechidis, S. Sun, Y. Chen, J. Lu, C. Zang, M. Baillie, D. Ohlssen, M. Vandemeulebroecke, R. Hemmings, S. Ruberg, and B. Bornkamp. "WATCH: A Workflow to Assess Treatment Effect Heterogeneity in Drug Development for Clinical Trial Sponsors". In: *Pharmaceutical Statistics* <https://doi.org/10.1002/pst.2463> (2024). DOI: <https://arxiv.org/abs/2405.00859>.

[3] S. Sun, K. Sechidis, Y. Chen, J. Lu, C. Ma, A. Mirshani, D. Ohlssen, M. Vandemeulebroecke, and B. Bornkamp. "Comparing algorithms for characterizing treatment effect heterogeneity in randomized trials". In: *Biometrical Journal* 66.1 (2024), p. 2100337.

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

The SIG Vaccines grew significantly during 2024, and we welcomed three new members to our committee: Ian Hirsch from AstraZeneca, Claire Brittain from BioNTech, and Honghong Zhou from Moderna. The group had plenary meetings every two months, which included discussions around scientific and clinical aspects of statistical

methodology in the world of vaccines. We also planned and organized webinars to increase our impact on the broader statistical community.

The committee is now comprised of:

- Andrea Callegaro – GSK, Belgium
- Dean Follmann - National Institute of Allergy and Infectious Diseases (NIAID), USA
- David Radley – Pfizer, USA
- Fabian Tibaldi, GSK Vaccines, Belgium. (Chair)
- Larry Moulton - Pfizer, USA
- Claire Brittain – BioNTech, UK
- Tsai-Lien Lin - U.S. Food and Drug Administration (FDA), USA
- Tulin Shekar – Merck, USA
- Niel Hens - Hasselt University (UHasselt), Belgium
- Danyu Lin - University of North Carolina at Chapel Hill (UNC), USA
- Sue McKendrick - PPD, UK
- Ruoyu Xing – Seqirus, Italy
- Min Yao – Sanofi, USA
- Ian Hirsch – AstraZeneca, UK
- Honghong Zhou – Moderna, USA

The PSI/EFSPi **Vaccine SIG Webinar**, held on April 25, 2024, focused on **Statistical and Mechanistic Models for Correlates of Protection**. The webinar aimed to provide insights into statistical models used to identify and validate Correlates of Protection (CoPs), offering quantitative tools for assessing vaccine efficacy. Additionally, it covered mechanistic models that elucidate the underlying biological mechanisms driving immune responses, enhancing the understanding of vaccine-induced protection. The webinar featured talks from Dr. Melanie Prague, a permanent researcher at Inria (University of Bordeaux, France) in the SISTM team (Statistics in Immunology and Translational Medicine), and Dr. Erin Gabriel, an Associate Professor in Biostatistics at the University of Copenhagen.

Additionally, we organized a SIG Webinar on November 20, 2024, which focused on **Statistical designs for assessing vaccine safety in pregnancy**. The webinar was introduced by Fabian Tibaldi from GSK and chaired by David Radley from Pfizer. The featured speaker was Professor Nick Andrews, Head of Vaccines Analysis at the Immunisation Department of the UK Health Security Agency (UKHSA).

The PSI Annual Conference 2024 in Amsterdam included a session organized by the Vaccines SIG titled **"Advanced Statistical Methods in Vaccine Clinical Trials."** This session, chaired by Fabian Tibaldi, covered advanced methods used in vaccine clinical trials to assess efficacy and safety. Three talks addressed critical statistical aspects of vaccine clinical development, namely correlates of protection and safety in these clinical trials. The first talk, "Joint modelling of sparse immune response data and time-to-disease for prediction of vaccine efficacy," was presented by Greg Papageorgiou, Toufik Zahaf, and Andrea Callegaro from GSK. The second talk, "Application of causal inference methodology in evaluation correlates of risk," by Sanne Roels and Joris Menten, J&J and a the third talk, "Harmonizing the collection of solicited adverse events in prophylactic vaccine clinical trials," by Brigitte Cheuvart, Bart Spiessens, Roy van Heesbeen, Derchieh Hung, Coralie Andrade, Joanna Korejwo-Peyramond, and Fernanda Tavares-Da-Silva, proposed recommendations to improve and harmonize the collection of actively solicited adverse events in prophylactic vaccine clinical trials.

Our group has also built a list of recent publications in the field of vaccine statistics research, highlighting works on Bayesian sequential probability ratio tests, replicate testing of clinical endpoints, prioritizing candidate peptides for cancer vaccines, and harmonizing the collection of solicited adverse events in clinical trials. These publications contribute to the advancement of statistical methods and their application in vaccine research. In 2024, two newsletters including our publication lists were published by the SIG and shared through our distribution list.



The PSI Vaccines SIG will continue to contribute to addressing statistical challenges in vaccine development and foster knowledge exchange among professionals in the field. The team is organizing a face-to-face workshop to be held in the city of Wavre in Belgium in October 2025.

If you would like to contact us regarding the activities of these SIG, email any of the committee members or visit our 'contact us' page at <https://psiweb.org/sigs-special-interest-groups/vaccines>. To add a name to the mailing list, update your address or remove your name please send an email to [David.Radley@pfizer.com](mailto:David.Radley@pfizer.com)

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### Visualisation: Bodo Kirsch (Bayer)

Highlights of the Visualisation SIG's activities in 2024 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!

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**Angela McPartlane**  
SIG Director





# PSI Volunteers

## Membership and Community Committee

Name	Company, country	Role
Alicia Aylott <sup>1</sup>	GSK, UK	Chair
Emma Crawford <sup>1</sup>	ICON, UK	DE&I Lead
Sophie Edmonds	Amgen, UK	Metric Analyst
Priya Gokani	Amgen, UK	Community Lead
Nigel Howitt	Fortrea, UK	Volunteering Manager
Tim Rolfe	GSK, UK	Committee Member
Kate Tsirtsonis	Amgen, UK	Committee Member

<sup>1</sup> Joined the committee in 2024

## Careers - Universities Committee 2024

Name	Company, country	Role
Amanda Darekar <sup>1</sup>	Pfizer, UK	Chair until June/Events
Lizzi Pitt	UCB, UK	Events/Chair from June
Deanna Galloway	Roche, UK	Outreach
Stella Zhan	Duke-NUS Medical School, Singapore	Outreach
Diana Voiniciuc <sup>2</sup>	Veramed, UK	Outreach
Katie Dixon <sup>2</sup>	Phastar, UK	Outreach
James Lay-Flurrie <sup>1</sup>	Bayer, UK	Outreach
Alicia Aylott <sup>1</sup>	GSK, UK	Outreach
Rachel Phillip	CTRU, University of Leeds, UK	Events
Alexander Todd	AZ, UK	Events
Amy Ashworth <sup>2</sup>	Pfizer, UK	Events
Sophie Edmonds <sup>2</sup>	Amgen, UK	Events
Valerie Millar	GSK, UK/ MoonLake, UK	Apprenticeships
Jasmine Paul <sup>2</sup>	Parexel, UK	Apprentice Network
Anna Kirkley <sup>2</sup>	Veramed, UK	Apprentice Network
Isabelle Santhiapillai <sup>2</sup>	GSK, UK	Apprentice Network

<sup>1</sup> Left the committee in 2024

<sup>2</sup> Joined the committee in 2024

## Careers - Website Committee 2024

Name	Company, country	Role
Tomas Rouse	AZ, Sweden	Website
Heather White	Phastar, UK	Website
Sam Adams <sup>1</sup>	University of Bath, UK	Website

<sup>1</sup> Left the committee in 2024

<sup>2</sup> Joined the committee in 2024

## Careers - Schools Committee 2024

Name	Company, country	Role
Emma Crawford	MSD, UK	Chair
Rejina Verghis	GSK, NI	Sub-team Lead
Katie Law <sup>2</sup>	Veramed, UK	Member
Sarah Crossley <sup>2</sup>	Phastar, UK	Member
Alex Spiers	GSK, UK	Sub-team Lead
Dea Hazewinkel <sup>2</sup>	LSHTM, UK	Member
Stephen Corson <sup>2</sup>	Phastar, UK	Member
Katie Gwinnell	University of Bath, UK	Sub-team Lead
Hayley Perry	JnJ, UK	Member
Sophie Hodge <sup>2</sup>	Bayer, UK	Member
Fiona Grimson <sup>2</sup>	UCB, UK	Member
Jennifer Gilbride <sup>1</sup>	Bayer, UK	Member
Jackie Wall <sup>1</sup>	Plus-Project, UK	Member

<sup>1</sup>Left committee during 2024

<sup>2</sup>Joined committee during 2024

## Careers - Professional Development Committee 2024

Name	Company, country	Role
Xinyi Zhu	GSK, UK	Chair
Isabelle Smith <sup>2</sup>	Veramed, UK	Events
Marius Sieverding	Veramed, Germany	Book Club Lead
Holly Prescott	Plus Project, UK	Book Club
Emma May <sup>2</sup>	Biontech, UK	Book Club
Agne Zarankaite	GSK, UK	Lunch & Learn
Zainab Walsh	Veramed, UK	Mentoring Lead
Robert (Bobby) Day	Phastar, UK	Mentoring
Ursula Garczarek	Sepul Bio, Germany	Mentoring
Claire Brittain <sup>1</sup>	UCB, UK	Lunch & Learn Co-lead
Chetan Mistry <sup>1</sup>	Veramed, UK	Lunch & Learn Co-lead
Jemma Greenin	Veramed, UK	Career Young Lead
Oswald Dallimore	Pre-Doctoral Fellow at Imperial College London studying at UCL, UK	Career Young
Holly Moon <sup>1</sup>	Parexel, UK	Career Young

<sup>1</sup>Left committee during 2024

<sup>2</sup>Joined committee during 2024

## Careers - ITIT Committee 2024

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

## Communications Committee

Name	Company
Jennifer Visser-Rogers	Char
Oceana Faria	Fortrea
Jamie Chai-Rees	Compass Pathways
Leanne Winzer <sup>2</sup>	AstraZeneca
Elena Mourouli	GSK
Steve Jones	Medable
Emi Widdeson	Amgen
Lara Collingwood	Amgen
Leo Gortzak	Amgen
Sophie Greenwood <sup>1</sup>	Aberdeen University

<sup>1</sup> Left the committee in 2025

<sup>2</sup> Joined committee in 2025

## 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	

## Conference & Scientific Committee

Name	Company, country	Role
Julia Niewczas	Janssen	Scientific Chair
Sarah Williams	Roche	Conference Chair
David Lawrence <sup>a</sup>	Novartis	Conference Vice-Chair
Vicky Marriott	Phastar	Conference Vice-Chair
Kate Taylor	Amgen	PSI Events Director
Amitava Mukhopadhyay	MorphSys	
Ayon Mukherjee*	Merck	
Clelia Cahuzac*	Roche	
Ian Wadsworth	Phastar	
Jennifer Gilbride <sup>a</sup>	Bayer	
Julia Saperia	MHRA	
Jyoti Soni*	GSK	
Kristina Weber <sup>a</sup>	Roche	
Lara Wolfson*	MSD	
Maria Efstathiou	IQVIA	
Martin Jenkins	AstraZeneca	
Nicola Scott*	GSK	
Paul Terrill <sup>a</sup>	PT Stat Consulting Ltd	
Russell Jones <sup>a</sup>	Calliditas Therapeutics	
Sarah Williams	Roche	
Sue Todd	Reading University	
Tobias Mütze	Novartis	
Tom Burnett	Bath University	

<sup>a</sup> Left the committee in 2024

\*Joined the committee in 2024

## Training Committee

Name	Company, country	Role
Ellie Grainger	AstraZeneca	Chair
Anna Patten	Eisai	
Margaret Jones*	N/A	
Kerry Gordon*	Phastar	
Caroline Kennedy	AstraZeneca	
Alison Mcleod	Phastar	
Jess Piatek	Veramed	
Emily Hammarstrom-Wickens	GSK	

Lydia Buckley	Fortrea
Sam Ruddell	Chiesi
Andisheh Bakhshi	Paraxel
Preenan Sarkar	IQVIA
Adetayo Kasin	GSK

\*Left the committee in 2024