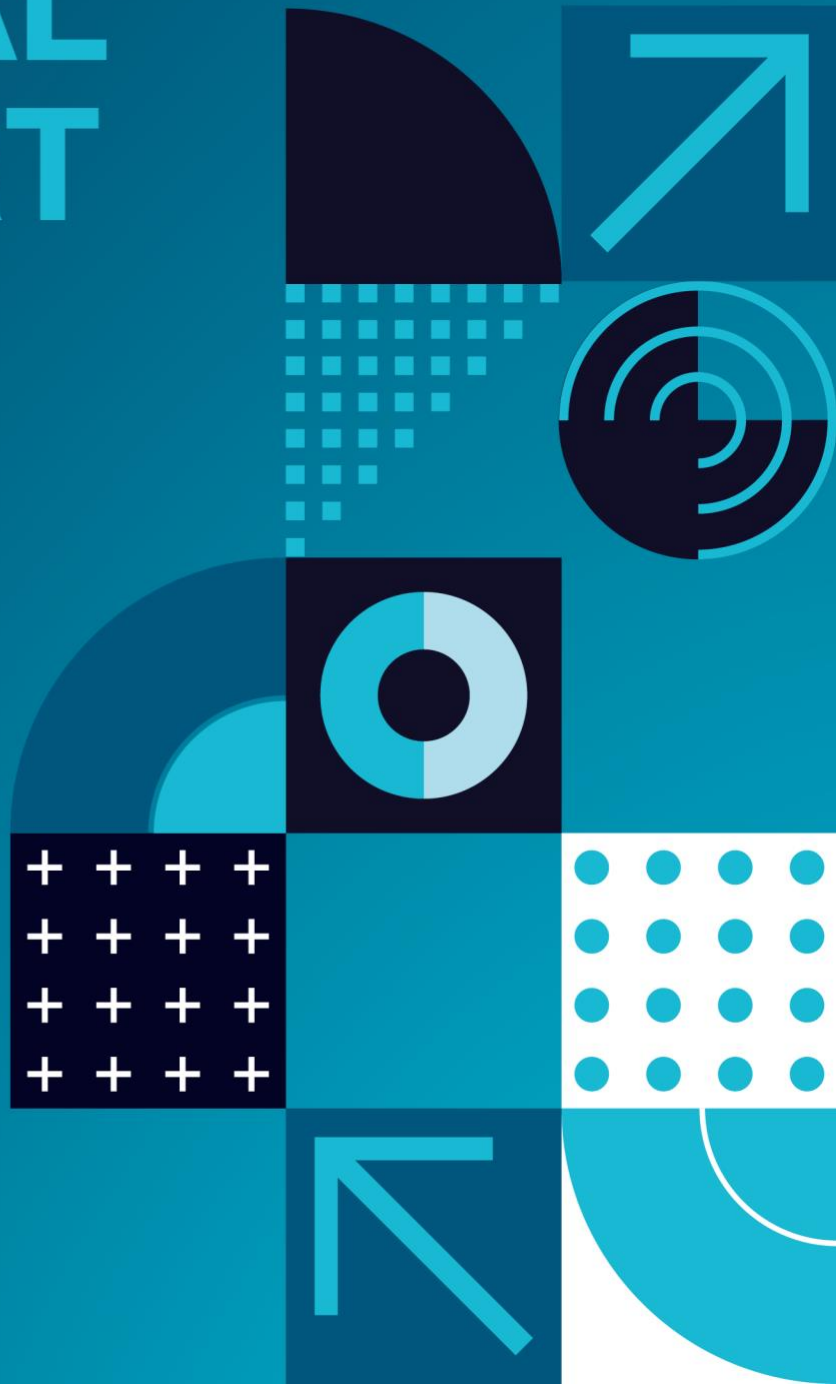




ANNUAL REPORT 2025



psiweb.org



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Welcome from the Chair

2025 has been a year of strong delivery, thoughtful investment, and sustained volunteer commitment across PSI. At a time when professional organisations are under increasing pressure to demonstrate value, relevance and transparency, PSI has continued to deliver high-quality scientific, career development and community activity, while taking deliberate steps to invest in the future of our profession.

Our core offer remains clear. PSI brings statisticians together across industry and academia through a vibrant programme of events, training and Special Interest Group (SIG) activity; supports statisticians at every career stage through targeted careers, mentoring and development initiatives; and provides an active professional community driven almost entirely by volunteers. In 2025, we continued to deliver this at scale.

Throughout the year, PSI ran a comprehensive programme of scientific and professional events, alongside a well-attended annual conference in London. Our events portfolio continues to balance accessibility and reach through online delivery, with the added value of in-person interaction where it matters most. Recordings through our Video on Demand platform ensure that learning is shared well beyond the live event, extending benefit across our global membership.

Career development and the future talent pipeline have been a major focus in 2025. Against a challenging external backdrop — including the withdrawal of funding for Level 7 apprenticeships — PSI has demonstrated a strong commitment to sustaining entry routes into the profession. This includes careers events, mentoring, outreach and the Apprentice Network, and importantly direct investment of members' funds to sponsor Medical Statistics MSc students. This reflects PSI's long-term view: supporting skills, access and capability is fundamental to the sustainability of our profession.

We have also continued to invest in our digital and operational foundations. During 2025, the Board supported strategic work to strengthen PSI's communications and digital direction, improve ways of working, and ensure that systems and processes support volunteers effectively. These investments are about enabling PSI to operate efficiently, communicate clearly, and maximise the impact of volunteer effort.

Financially, PSI remains in a strong and stable position. While the Board has made deliberate decisions to deploy reserves for the benefit of members — particularly in digital capability and future talent — we continue to maintain prudent reserve levels to safeguard the organisation and support sustainable delivery. Members can be confident that their subscriptions are reinvested directly into activities that deliver professional value.



Awards and Recognition

A highlight of the 2025 PSI Annual Conference at Wembley was the opportunity to recognise excellence, innovation and service across our community through a number of Society awards. Together, these awards reflect the breadth of contribution that sustains PSI — from methodological leadership and scientific impact to exceptional volunteer commitment and emerging leaders.

The PSI / Royal Statistical Society Award for Statistical Excellence in the Pharmaceutical Industry was awarded to Vlad Anisimov and the Data Science Team at the Center for Design & Analysis at Amgen, recognising their innovative work on forecasting and cost-efficient design of restricted enrolment in clinical trials. The judging panel highlighted the creativity, technical excellence and practical applicability of their statistical framework in addressing a critical operational challenge in clinical development.

The Mick Godley Award, which recognises outstanding volunteer contribution to PSI, was presented to Sue McKendrick. Sue's leadership in education and capability-building, including the development and delivery of a highly successful PSI Training Course on Estimands, exemplifies the dedication and generosity of service on which PSI depends.

Honorary Membership was awarded to Paul Terrill in recognition of his exceptional and long-standing contribution to PSI. Since first becoming involved in 2012, Paul has held key leadership roles across the society, including Chair of the Scientific Committee and Conference Chair, and has played a pivotal role in scientific delivery, strategic discussion and community building. His continued commitment and collaborative ethos have left a lasting impact on PSI.

The Rising Star Award, introduced to recognise early-career volunteers making a significant impact, was awarded to two recipients in 2025, reflecting the strength of talent within PSI. Samuel Hadlington was recognised for his leadership in establishing the AI Special Interest Group and his contributions to Careers Committee activities, while Oceana Faria was recognised for her outstanding behind-the-scenes contribution to PSI communications and strategic engagement.

Finally, 2025 saw the introduction of a new award — SIG of the Year — recognising outstanding contribution by a Special Interest Group. The inaugural award was presented to the Randomisation SIG, in recognition of its impactful programme of high-quality scientific activity, publications, regulatory engagement and open-source outputs. The award includes a guaranteed session at the 2026 PSI Conference.

Collectively, these awards highlight the scale, quality and diversity of contribution across PSI and underline the vital role that volunteers, SIGs and scientific leadership play in advancing our profession.

None of this would be possible without our volunteers. Across committees, SIGs, advisory groups and working parties, statisticians continue to give their time, expertise and energy to PSI. Their commitment underpins everything we do, and I would like to offer my sincere thanks to everyone who contributed during 2025.

As is typical for PSI, 2025 included mid-year Board transitions, and I am grateful to all Directors — outgoing and incoming — for maintaining strong governance and continuity across the year.



PSI exists to serve its members and the wider statistical community. In 2025, we have continued to demonstrate what a volunteer-led professional organisation can achieve when it combines strong governance, careful investment and a clear sense of purpose. I am proud of what we have delivered together and look forward to building on this momentum in the year ahead.

Naomi Givens
PSI Chair



Governance

Board of Directors – 2025

Name	Role	Served during 2025
David Wright	Chair	Jan–Jun 2025
Naomi Givens	Vice Chair & Secretary	Jan–Jun 2025
Naomi Givens	Chair	Jun–Dec 2025
David Wright	Vice Chair & Secretary	Jun–Dec 2025
Jennifer Gilbride	Contracts & Finance Director	Jan–Dec 2025
Alicia Aylott	Membership and Community Director	Jan–Dec 2025
Kim Hacquoil	Careers Director	Jan–Jun 2025
Claire Brittain	Careers Director	Jun–Dec 2025
Jennifer Visser-Rogers	Communications & External Affairs (and EFSPI) Director	Jan–Dec 2025
Kate Taylor	Events Director	Jan–Dec 2025
Angela McPartlane	ESIG Director	Jan–Dec 2025
Aiden Flynn	Commercial Director	Jan–Jun 2025
Emma Jones	Commercial Director	Sep–Dec 2025

Service periods reflect formal Board roles held during the 2025 reporting year.



Treasurer's Report

The professional audit for 2025 is currently in progress, with several items, including VAT reimbursement, still pending resolution. As such, the figures presented below may be subject to adjustments. In 2025, PSI reported a profit of approximately £26,000. Total income reached £740,000, with purchases amounting to £508,000 and overheads totalling £205,000. This profit reflects a strategic decision to utilize reserves for the benefit of our members. Notably, during 2025, the Board of Directors invested in advancing our digital strategy and provided sponsorship for two MSc students.

Our reserves now total £686,000, 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, including work on the website and activities to support the future talent pipeline.

Key Factors Influencing the 2025 Results

The results for 2025 can be attributed to several factors, including sustained membership numbers, conference attendance, and robust support from sponsors. Additionally, our training courses contributed. PSI continues to hold a combination of in-person and on-line events; while on-line 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, resulting in higher costs for the conference, and PSI strives to moderate and limit the increase in registration fees.

PSI incurs considerable overhead costs to maintain operations. We are supported by Moore for our general administration and management including for events. In addition, there are expenses for IT systems, accounting, and legal services. Almost all of PSI activities generate revenue and are financially positive or neutral. Historically, PSI has relied on the profitable conference and events to offset annual overheads. While this dependence has diminished in recent years as the levels of membership have increased, 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.



2025 income overview

Surplus (£k)	2021	2022	2023	2024	2025
Membership	93	132	146	154	159
Conference	22	147	174	71	75
Scientific	16	8	0.5	4	0
SIGs	4	11	3	7	5
Training	40	34	19	24	30
Communications (publications and website) *	-43	-26	-17	-8	-8
Careers	10	45	3	10	-10

Rounded to the nearest £1k. 2025 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
- Conference Event Management – Moore Engage
- Journal Publishing – Wiley
- Professional Indemnity Insurance – Hiscox
- Auditor – TC Group
- Membership and Event Booking – GlueUp

Contracts Overview

Business Administration Services

In 2025, the administrative and event management services continue with Moore Engage. As PSI's online activities expand, the effective scheduling and execution of webinars, online training sessions, and Special Interest Group (SIG) events remain critical. The annual cost for these services is £183,000, 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 and we are in the process of reviewing and updating the content and structure. The migration from Google Drive to Teams and SharePoint has been completed. Additionally, there are PSI email accounts 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

Contracts and Finance Directors

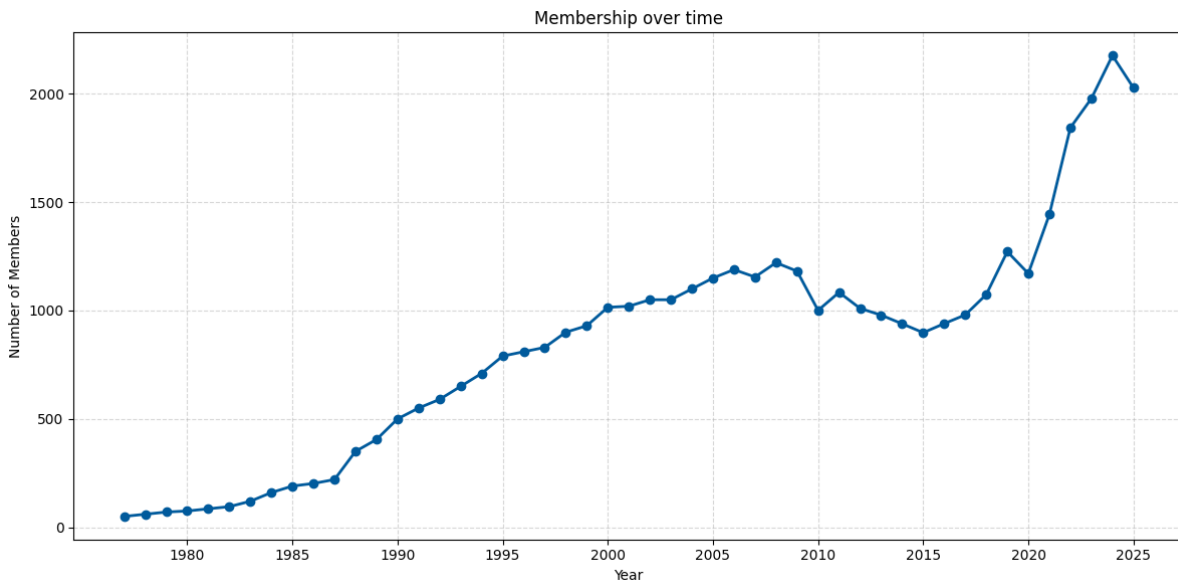




Membership Report

MEMBERSHIP

Our PSI membership remains in a strong position, although we have seen a slight decrease compared to 2024. As of 31st December 2025, our database recorded **2,027 members**.



For many years, our reported membership figures were based on data extracted in October each year, due to legacy nuances in how renewals are processed. Thanks to the excellent work of our admin team at Moore Engage, the database is now being managed with greater accuracy. This means that, going forward, we will be able to publish full-year membership numbers that reflect the complete calendar year.

This change is particularly important for PSI, as we can often run events in October and November, which attract new members. Ensuring these are captured gives us a more accurate picture of our overall membership trends.

If we compare to the same point in 2024, our 2025 membership shows an approximate 12% decrease. The PSI Board is actively reviewing the possible reasons behind this and is committed to strengthening our membership offering. A key focus for the coming year is to ensure that membership remains attractive and relevant to our community.

Membership Category	2021	2022	2023	2024	2025 to Q3	2025 Year-end
Full	1134	1442	1562	1709	1459	1541
Honorary	11	11	12	12	12	12
Reduced Rate	22	25	21	21	16	16
Student/Teacher	276	366	384	435	420	458
Total	1443	1844	1979	2177	1907	2027



ENGAGEMENT

In 2025, the Membership & Community Committee continued to implement established engagement strategies, connecting with company contacts on an as-needed basis to support PSI activities. Toward the end of the year, we began preparations for a refresh of our company contact list, with the full rollout planned for 2026.

In April 2025, PSI held a Strategy Day, during which “Membership Proposition” was the focus of one of the three breakout sessions. Feedback was generally positive, with networking highlighted as a key benefit of PSI membership. Additional suggestions included improving communication around the purpose of the membership fee and how it contributes to PSI’s activities, as well as better showcasing volunteering opportunities as a valuable benefit of being part of our community.

VOLUNTEERING

We wouldn't be the community we are without our amazing volunteers! A few years ago, PSI decided to employ a volunteers' manager to recruit and place volunteers within the PSI, for the purpose of resourcing our many committees and Special Interest Groups (SIGs). This is a voluntary position also, and is currently held by Nigel Howitt, a previous PSI Chair. In order to make the selection process as open as possible, new positions are advertised on our website in eNews, via social media and sometimes via direct email. We had a very successful year in 2025 and placed over 20 volunteers on our various committees, including one temporary board position. If you would like to get involved, please check our current open positions on: <https://www.psiweb.org/about-us/volunteer-with-us>, or simply contact our volunteering team directly at volunteering@psiweb.org, and specify your areas of interest.

DIVERSITY, EQUITY, INCLUSION AND BELONGING

In February 2025, the DEIB Advisory Group (AG) was formally established, led by Emma Crawford, with the aim of fostering a diverse, equitable, and inclusive community within PSI where everyone feels a sense of belonging. The group began with nine volunteers and grew to fifteen by the end of the year, supporting a sub-team structure that aligns each DEIB AG sub-team with one of the core PSI committees.

Since its inception, the group has focused on addressing member feedback and developing its core operating documentation, including its mission statement, COG, and 2026 deliverables. This documentation is available on the dedicated DEIB webpage on the PSI website: <https://www.psiweb.org/DEIB>.

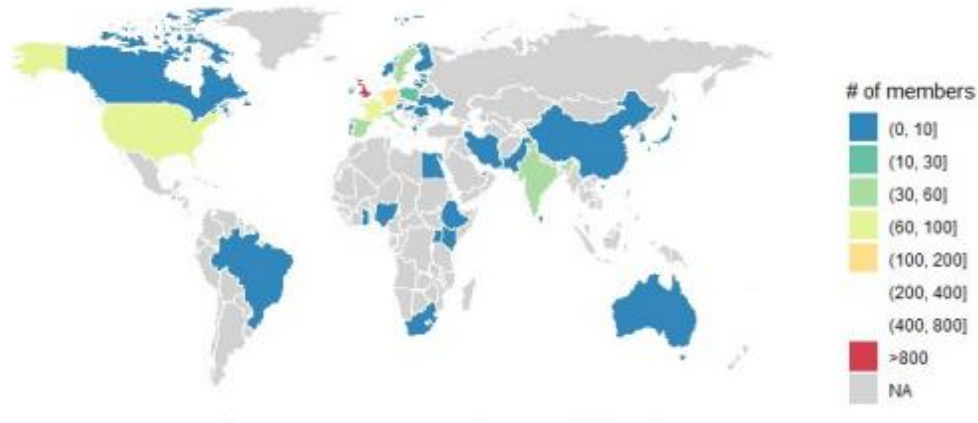
The group also presented a poster at the 2025 PSI Conference and engaged with members during a dedicated DEIB day at the PSI exhibitor stand. This activity was supported by Inclusive Employers, who sponsored an interactive workshop on inclusive work cultures—an event organised by a subset of DEIB AG volunteers prior to the group being formally established.



IN SUMMARY

We are hugely grateful for the continued support you all provide to PSI. A special mention and heartfelt thanks go to our volunteers, whose tireless contributions ensure that PSI's offerings remain relevant, valued, and well-received.

We encourage you to reach out with any suggestions on how we can further strengthen engagement across our global membership in 2026. Your insights are 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 extremely busy in 2025. Amid the significant volume and breadth of work covered by the PSI Careers team, an unexpected challenge arose in June when the UK government announced it would no longer fund Level 7 apprenticeships. This decision effectively removes the pathway for MSc apprenticeships in medical statistics.

While committees, members, and the Board of Directors have all rallied to provide input and support, a special mention must go to **Valerie Millar** for her tireless and inspiring campaign to raise awareness of the issue and advocate for meaningful change.

Universities Committee

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.



Lizzi Pitt, Universities Chair



The Universities team continues to be organised into several subgroups: Outreach, Events and Apprenticeships. The Outreach group produces 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 which aimed to bring together MSc apprentices at different organisations for knowledge sharing and peer support.

The 2025/2026 Medical Statistics Careers Event was held in Cambridge, hosted by AstraZeneca with additional sponsorship from Medpace. As with previous events, it aimed to showcase the range of careers available to students in the field of Medical Statistics. This year, we welcomed 18 exhibitors, slightly fewer than previous years reflecting the fact companies have smaller budgets for recruitment and outreach activities. Just over 90 students attended, a record in recent years. The afternoon began with a welcome introduction outlining PSI's role in supporting students and early-career statisticians. Jamarl Webley from Veramed gave the New Starter presentation. The panel discussion explored the different types of roles, pathways and experiences within Medical Statistics with representatives from academia, CTUs, CROs and pharmaceutical companies. Further, the panel members had experience working in several different parts of the drug development process:

- Lucy Abell (University of Birmingham Cancer Research UK Clinical Trials Unit)
- Violeta Balinskaite (Medpace)
- Emma May (Independent consultant)
- James Schmidt (AstraZeneca)
- Sasha Tatum (Apprentice at AstraZeneca)
- James Willard (MRC Biostatistics Unit).

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 4 pharmaceutical companies, 5 Contract Research Organisations (CROs), 3 Clinical Trials Units (CTUs), 1 professional society and 5 universities advertising postgraduate study opportunities. Students appreciated the opportunity 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 5th November 2025. 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.



80 students attended from a wide range of backgrounds and were highly engaged with 20+ questions being submitted during the presentation. This year Amy Ashworth (Universities Events), Diana Voiniciuc (Universities Outreach), Emma May (Professional Development) and Oswald Dallimore (Professional Development) 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 2025. 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, MSc funding, and SIG Spotlights. In addition, following nominations received from their universities, ten PSI Undergraduate Awards were awarded to mathematics/statistics students at the following universities from across the UK: Aberystwyth, Bath, Cardiff, Glasgow, Greenwich, Lancaster, Queen's (Belfast), Reading, Sheffield and Warwick. Additionally, the Outreach team maintained the placement opportunities listed on the PSI website and updated the University Contact list which is our main method of communication with students via their universities.

The focus of the apprenticeship group unfortunately had to pivot from growing the scheme to trying to over-turn the government's decision to remove Level 7 funding for apprentices over the age of 21. This has included:

- RSS and PSI Joint Open Letter
- Industry Open Letter
- MP Letters
- Formal Government Petition.

We received a formal response from Baroness Smith (Minister of State for Skills) which did not address our concerns or our proposals to work collaboratively to ensure funding remains available for career entry roles. As a result of the government changes, both Strathclyde and UCL have withdrawn their apprenticeship course.

The Apprentice Network successfully launched with a half day virtual conference on 14th February 2025 with 17 apprentices attending, representing more than half of the apprentice cohort at the time. The event included networking, a Q&A, and an inspiring presentation from a statistician who had recently completed a Statistics MSc while working as a programmer. The event also marked the first time apprentices from both Strathclyde and UCL were brought together. The team successfully held three further virtual events throughout the year with 12-13 current apprentices attending each one. Each event featured a core presentation from either a current or past apprentice, followed by time to network. The Network has created a space for apprentices to be able to come together during these events, creating a sense of community that is often missing as the MSc learning relies on pre-recorded lectures. Within this community, they can discuss shared experiences and share knowledge.



In 2025 PSI sponsored two students to conduct an MSc in Medical Statistics. This scheme was launched due to the limited funding opportunities available to UK students looking to undertake an MSc, combined with the high course fees and limited government support available. Since the master's degree is an entry requirement for statisticians in the pharmaceutical industry, this is a vital step in PSI supporting the next generation of statisticians in the UK.

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.



Rebecca Randhawa, Schools Chair



2025 was a fantastic year for the Schools committee. 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 5 volunteer places for PSI members, sponsoring 5 spots in the competition for 2025. Our scientists for 2025 were Paul Terrill (PT stat), Kerry Gordon (Phastar), Kathryn Howells (AZ), Eloisa Brook (GSK) and Jan McKendrick (Avalere Health). We look forward to continuing this partnership into 2026.

2025 was all about investing in school resources. The team has been refreshing workshops to keep them aligned with current curriculum and make them more engaging for the next generation.

While so much of the world now happens online, students still get a lot from hands-on learning. So we've also invested in banners, PSI t-shirts, and freebies for volunteers attending school events. It turns out that, for younger students especially, a well-timed sticker can work wonders.

We're also developing new workshops featuring RShiny apps and hands-on escape room activities, which are set to roll out in 2026.

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](#).



We know many of our members support their local schools by giving careers talks, running workshops, and mentoring students. Thank you for helping to inspire the next generation. If you'd like any support, resources, or even a few stickers, please do get in touch.

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 success of the Mentoring Scheme continues with 43 participants registered in 2025 resulting in 31 mentor-mentee pairs due to the option to register as both mentor and mentee. We still find more members registering as

mentees. The organising committee piloted an automated approach to matching using a distance algorithm with great success and will continue to use the approach in 2026.



During 2025, the Book Club continued to grow, offering an even wider range of professional development activities for both members and non-members. In

spring, the Book Club hosted a special Lunch and Learn session featuring a discussion of Atomic Habits. At the conference, we introduced several new initiatives, including a lunchtime networking session, a competition to win The Art of Explanation, the launch of our newsletter, and new promotional seed bookmarks. In September, we ran our most successful Book Club to date, with 37 participants joining discussion groups on The Art of Explanation. In autumn, we launched our newsletter, reaching almost 100 recipients.

We're looking forward to even more exciting plans in 2026.



Career Young Statisticians

The Career Young Statisticians Committee had a strong and busy year in 2025, continuing to deliver quarterly virtual events and building further momentum through in-person engagement. Our virtual sessions consistently attracted 20+ attendees, with participants ranging from students to those with 4+ years of industry experience. Topics were shaped by the community and included guest speakers sharing their experiences of presenting at the PSI conference and completing an apprenticeship, alongside informal discussion and Q&A.

At the PSI Conference, we hosted and led Career Young networking activities, including a registration meet-up (15+ attendees) and a well-attended lunchtime session (30+ attendees) featuring an ice-breaker activity to encourage connections. We also represented PSI at the Young Statistician Meet at the University of Liverpool, with around 80 attendees across pre-doc and post-doc levels; this included a PSI presence/stand and a careers panel contribution, with a focus on medical statistics.

In 2025 we also expanded our face-to-face offering with a dedicated Career Young event at Imperial College London. This included a careers panel, an Estimands workshop, debate tables, and networking, attracting around 30 attendees spanning pre-doc and post-doc stages.



Peer Support Initiative

Planning is underway for a new Peer Support Initiative, designed as a 12-month programme for members with around 5+ years' experience who are looking for structured development and peer connection as they progress in their careers. Throughout 2025, we have been shaping the format and content, gathering feedback to inform recruitment and selection, and scheduling initial meetings with prospective coaches. Wider promotion is planned across multiple platforms in 2026.

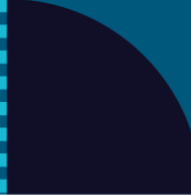
Finally, PSI Careers and the Professional Development Committee organised networking sessions as well as two workshops at the 2025 PSI Conference. Isabelle Smith and Lucy Rowell led the "Grow your own way" workshop and Emma May, Sam Ruddell and Katie Thorn led the "Navigating Difficult Conversations" workshop, both highly interesting and impactful sessions. More workshops and activities are expected for the 2026 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.

Zelie Bailes, ITIT Chair



Again, this year the ITIT course has been in high demand and oversubscribed, receiving 34 applications. It was great to see a number of applicants from new companies, as well as returning companies who had not sent delegates in recent years, and we have achieved a good mix of applicants from across the industry, with 26 delegates from 14 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 2025-2026 course was delayed until February due to host availability. Whilst we are grateful to Janssen for stepping in to allow us to put on the Toxicology session this year, after having to cancel this session last year, we are still struggling to secure a host for the DM & CRO session. We are considering some alternative options, including running this session out of order, running a single day session or having a central session with presenters from multiple companies, to ensure delegates do not miss out. With securing hosts still our biggest challenge, this year we will explore how we can collaborate with the wider PSI organisation to make hosting more appealing and ensure companies are appropriately recognised for their support. I would like to thank the companies that are confirmed for hosting a session this year, including some new hosts for this year: AstraZeneca, Janssen, Bayer, Novo Nordisk and Chiesi.

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 2026-2027 course are now open and will remain open until 26th June 2026. We look forward to welcoming our next set of delegates!

Claire Brittain **Careers Director**

I have been honoured to take on the role of PSI Careers Director since June 2025, and it has been a privilege to see first-hand the impact the Careers team has across the full early-career pipeline and professional development.

This year has included strong delivery across all four committees: a record student turnout at the Medical Statistics Careers Event in Cambridge, a highly engaged MEDMathS webinar, continued growth in the Student Newsletter and undergraduate awards, and the launch and consolidation of the Apprentice Network at a time when Level 7 funding changes have created real challenges for the pathway. The School's Committee has built further momentum through partnerships such as I'm a Scientist, new outreach materials, and new collaborations (including work towards RShiny-based workshops). The Professional Development Committee has continued to expand member support through the Mentoring Scheme, Book Club activity and conference workshops, while ITIT has again demonstrated its value to the industry with an oversubscribed and widely supported programme, despite ongoing host availability pressures.



At a time when alternative entry routes are under pressure, PSI has demonstrated real commitment to sustaining the talent pipeline through MSc sponsorship funded from PSI reserves. This was reflected in the endorsement to sponsor two Medical Statistics MSc students, with our first two sponsored students commencing their studies in September 2025, and plans in place to sponsor a further two students in 2026.

None of this happens without volunteers. Thank you to every committee member, chair, speaker, host organisation, sponsor and supporter who has given their time, expertise and enthusiasm. Your efforts make PSI Careers what it is, and I'm proud to support and represent this work.

Claire Brittain
Careers Director





Commercial Report

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

Having taken on the role in September 2025, I have focused on understanding the landscape, listening to our Sponsors, and ensuring that the work we do is steady, thoughtful and anchored in value for both PSI and our partners.

Volunteering for this role felt like the right thing to do. PSI played an important part in supporting me early in my career, and I felt compelled to give something back to an organisation that has helped shape my professional path. With my experience in growing a company and navigating commercial relationships, I felt I could bring some of the necessary attributes and skills to add value and help ensure the long-term success of PSI. This role is central to PSI's ability to thrive, and I wanted to contribute in a way that makes a tangible difference.

The transition into the role has been smooth, and I am grateful to Aiden Flynn for the clarity and organisation he brought to PSI's commercial activities over recent years. This has allowed me to pick things up without disruption and concentrate on maintaining the strong foundations already in place.

The 2025 conference took place in London and was a record-breaking year in many ways. We welcomed 31 Sponsors, up from 26 in 2024, and total sponsorship reached £152k, surpassing both the budget and the previous record of £143k set in 2024. Half of our sponsorship came from CROs, with the remainder spread across pharma, recruitment agencies and other supporters, including one technology partner. Seeing new types of organisations join the PSI community has been encouraging and adds variety to our partnerships.

During my first months in role, I have taken time to reflect, listen and understand where we can add value for Sponsors in the long term. Two key initiatives have shaped this work. Firstly, a full review of the 2025 prospectus to consider where we can enhance value and improve clarity for Sponsors in 2026. Secondly, a broad review of past, current and potential Sponsors across pharma, CROs, agencies and technology, ensuring we have a clear view of the landscape and future opportunities.

Engagement for the 2026 conference has already been extremely positive, with three new Sponsors signed up and sponsorship levels are tracking well against the budget. This early momentum gives us confidence during a period when many organisations continue to face financial pressures, and we thank everyone for their continued support of our organisation. PSI simply cannot deliver its activities without this much-needed partnership.

As with any PSI Board role, this work relies on collaboration and connection. If anyone is interested in supporting commercial activities over the coming year, I would be delighted to hear from you. Being involved offers the chance to make a real difference to PSI's future and to strengthen the network that supports statisticians across our industry.

Emma Jones
Commercial Director





Communications Committee & External Affairs Report

This year has been a period of progress for Communications and External Affairs, with major strategic developments that will support PSI's long-term ambitions. After spending my first year settling into the role and understanding the breadth of PSI's communications, this year has been about laying down the structures, plans, and partnerships that will shape how PSI presents itself and engages with its community over the coming years.

One of the most substantial pieces of work has been the creation of a new PSI Communications and Digital Strategy. This strategy is aligned tightly with PSI's broader aims and provides clarity on how communications can better serve our members, our volunteers, and the wider statistical community. It sets out a vision for a more connected, more visible, and more engaging PSI, and it has already begun to influence how the committee operates.

Alongside this, we have also recognised the need for PSI's digital presence to evolve, and so we have begun the process of a brand refresh and full website redevelopment. The Request for Proposals for the new website will be going out in Q1 2026, we are in the process of reimagining what the PSI online experience should be. The website is often the first point of contact for prospective members and an essential resource to current ones, so ensuring that it is modern, intuitive, and representative of who we are as a community is vital to strengthening our identity as a Society. To support this, we will be forming a working group drawn from across PSI to help guide the branding and website development, making sure the final result reflects the whole Society. I look forward to sharing more on this as the work progresses.

As part of implementing the new strategy, we are spending time strengthening our internal ways of working within the Communications Committee. We are still in the process of discussing updates to our governance documents, committee structure, and the development of a more structured content calendar that reflects the breadth of PSI's activities. While these discussions are at an early stage, they are laying the groundwork for more consistent, timely, and better-coordinated communications across newsletters, social media, the website, and committee and SIG updates. I want to thank the committee for their constructive engagement as we continue this work.

In addition to the internal communications developments, External Affairs has also been an important focus for me this year. I continue to represent PSI on the EFSPi Council, and this continues to be an invaluable forum for relationship building and collaborative opportunities with other European statistical societies. A major new initiative has emerged from this work: I am leading an EFSPi Academic–Industry Collaboration Project, which aims to map the landscape of academic–industry interaction in pharmaceutical statistics across Europe. This includes understanding existing partnerships, identifying variation in training and curriculum, and assessing skills gaps and career awareness among students. We will be running a series of surveys and follow-up interviews, and later this year we expect to begin producing outputs such as a best-practice guide for collaboration and a “graduate preparedness framework.” This project reflects one of the areas I feel most passionate about: ensuring that new statisticians entering the profession have the right grounding and visibility of careers in industry and strengthening the relationships between universities and employers. My background across both academia and industry has been invaluable here, and I am excited to see where this work leads.



As always, none of this work would be possible without the tireless enthusiasm and dedication of the Communications Committee. They consistently give their time, creativity, and energy to ensure that PSI's communications run smoothly and effectively, and I am extremely grateful for their efforts. It remains a huge privilege to work alongside such an engaged and committed group of volunteers.

I look forward to the year ahead as we begin to deliver on the initiatives we have set in motion, and I am excited for the positive impact these developments will have on PSI's visibility, influence, and sense of community.

Jennifer Visser-Rogers

Communications Committee & External Affairs (and EFSPI) Director

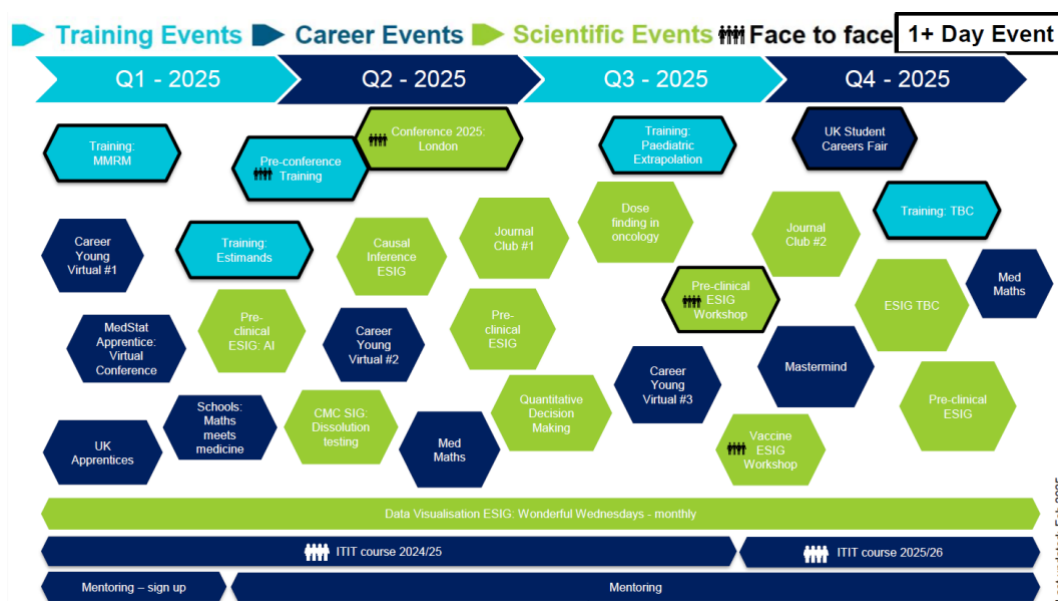




Events Report

In 2025 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 2025 PSI offered both members and non-members a widely varied programme of scientific events – a total of 43 different events, although simply counting events is probably not the fairest method at all to reflect the depth and diversity of content. More detail of some of the events is included elsewhere this report. In 2025 again our events were almost all online – the exceptions were our fantastic conference in London, a PSI Career Young Event in London, the Pre-Clinical SIG workshop in Verona, a vaccine SIG workshop in Brussels, the annual Medical Statistics Careers Event (this year held in Cambridge) and the ever-popular ITIT course for those new to the industry (2025/2026 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 541 at conference, 20-190 at scientific/SIG topic/careers webinars and journal clubs and 20-40 at interactive training courses/workshops.

Popular events included “*Maths Meets Medicine: Exploring Careers in the Pharmaceutical Industry*”, “*Dose-Finding in Oncology webinar*”, a joint webinar between the PSI/EFSPI RWD and Historical Data SIGs titled “*Methods and tools integrating clinical trial evidence with historical or real-world data, Bayesian borrowing, and causal inference*”, a webinar from the EIWG on “*Applying the Estimand Framework to Clinical Pharmacology Trials with a Case Study in Bioequivalence*”, a Vaccine SIG webinar on “*Challenges in Estimating Vaccine Effectiveness Against Progression to Severe Disease*” and a Causal Inference SIG webinar on “*Instrumental Variable Methods*”.

All the events just mentioned had over 90 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 2025 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.



Looking ahead to 2026, 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 2026 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 2025. 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 2026 or beyond then please reach out!

Conference Report

The PSI 2025 Conference took place 8th – 11th June at Wembley Stadium, London. The conference was well attended, with 541 delegates registered. These 541 delegates represented ~19 countries and ~181 unique companies and organisations. We were generously supported by 31 sponsors.

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

- Unlocking Insights: Advanced Pooled Analysis Techniques for Clinical Trial Statisticians, which was presented by Dr. Thomas Debray (Smart Data Analytics and Statistics B.V., The Netherlands) and Prof. Tim Friede (University Medical Center Göttingen, Germany)
- Adaptive and Complex Innovative Designs across trial phases for accelerated approval, which was presented by Dr. Thomas Burnett (Lecturer, Department of Mathematical Sciences and Institute for Mathematical Innovation (IMI) University of Bath), Dr. Ayon Mukherjee, C. Stat, (Director Biostatistics, Eli Lilly), Dr. David Robertson (Senior Research Associate at the MRC Biostatistics Unit, University of Cambridge) and Dr Sofia Villar (MRC Investigator (Programme Leader) at the MRC Biostatistics Unit, University of Cambridge)

Both courses proved very popular and were well attended.

We were delighted to welcome two keynote speakers.

Alex Bellos one of the UK's most celebrated maths communicators. He has sold more than a million books, writes a popular puzzle column in the Guardian and appears regularly on Radio 4, spoke on “Communicating the magic of maths”. He spoke of what he has learned about communicating maths to different audiences. He told stories, showed beautiful images and gave the audience some puzzles to solve!

Our second keynote speaker was Jennifer Visser Rogers who gave a keynote titled “Bridging the Divide: How Academia/Industry collaborations have the power to transform clinical development”. In her talk, Jen spoke of her journey from academia to industry, and what she has learnt along the way. She discussed the differences between academic-run and industry-led clinical trials and what they can learn from each other. As we see a shift towards more innovative and complex clinical trials, it will become increasingly important to foster collaboration between the two groups. And as we see academics wanting to make the move into industry, how can we present ourselves as a viable alternative that is rich in research. The talk was followed by a panel discussion with other industry speakers.

In total the conference consisted of 38 sessions held across 3 days, including traditional plenary lectures and presentation sessions, informal networking sessions and workshops. 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: Isabelle Smith and Lucy Rowell ran a workshop on career paths called Grow your own way. Addison Barnett, Emma Crawford, Ursula Becker, Nicola Hewson and Karen Smith ran an



interactive workshop on Inclusive work Cultures. Emma May, Sam Ruddell and Katie Thorn ran a workshop on navigating difficult conversations in the workplace.

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, which are still proving popular. 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: readying ourselves for the road to 2025 and beyond” reflecting the importance of the changes in HTA application in the EU. In addition, the usual Regulatory Hot Topics session took place on Tuesday afternoon with 3 representatives from regulatory agencies presenting on and discussing key topics in this space, alongside 4 industry representatives. The poster session was also a great success including the 45 second poster presentations.

Regular updates were provided in advance of the event through a variety of methods including conference newsletters, eNews and LinkedIn posts 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 2026 conference will be taking place from the 14th – 17th June at the ICC, Belfast. The preparations are well underway and information will continue to be shared regularly as we move closer to the conference. 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 June 2026.

Sarah Williams
Conference Chair

Committee Events

Scientific Committee

The PSI Scientific Committee organises webinars of scientific statistical interest to our members and beyond, as well as the annual PSI conference. The scope of the committee has been updated recently to allow the SIGs more opportunity to become the experts in their fields and allow them to organise more events on the topics they focus on. Therefore, fewer scientific webinars are being run by the Scientific Committee now than in recent years. There are currently 18 members of the committee 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 2025, the scientific committee organized 2 events:

- 2025 PSI Conference (see conference report)
- PSI Webinar: Dose-Finding in Oncology

Training Committee

In 2025, the training committee successfully delivered 4 online training courses.

- PSI Training Course: MMRM (held virtually over 4 days)
- PSI Training Course: Estimand Training Workshop (held virtually over 4 days)
- PSI Training Course: Paediatric Extrapolation (held virtually over 3 sessions)
- PSI Training Course: Introduction to Machine Learning (held virtually over 4 days)

The online courses in 2025 worked well for delegates, and in 2026 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 2025, the Journal club delivered 2 webinars. In 2026, we look forward to providing more journal club webinars to members and non-members.

2 Journal Clubs:

- PSI Journal Club: Randomisation
- PSI Journal Club: Missing Data

PSI SIGS:

We now have a total of 27 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.

26 ESIG events:

- PSI/EFSPi **Data Vis SIG** Wonderful Wednesday (series of 12)
- PSI/EFSPi **Pre-Clinical SIG** Webinar: AI in Medicinal Products
- PSI/EFSPi **Pre-Clinical SIG** Webinar: Methodology and first results of the iRISE (improving Reproducibility In Science) consortium
- PSI/EFSPi **Pre-Clinical SIG** Webinar: AI agents for drug discovery and development
- PSI/EFSPi **Causal Inference SIG** Webinar: Instrumental Variable Methods
- Joint PSI/EFSPi **RWD & Historical Data SIG** Webinar: Methods and tools integrating clinical trial evidence with historical or real-world data, Bayesian borrowing, and causal inference
- PSI/EFSPi **AIMS SIG** Scientific Meeting face to face: Change Management for Moving to R/Open-Source
- PSI/EFSPi **Vaccines SIG** Webinar: Challenges in Estimating Vaccine Effectiveness Against Progression to Severe Disease
- PSI/EFSPi **AIMS SIG** Open-Source Lunch Bites (series of 5)
- Joint PSI/EFSPi **RWD and Causal Inference SIG** webinar: Data Fusion, Use of Causal Inference Methods for Integrated Information from Multiple Sources
- PSI/EFSPi **Pre-Clinical SIG** Workshop: Face to face event in Italy

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.

17 Career events:

- PSI Mentoring 2025
- PSI Career Young Virtual Meet (4 separate meetings or webinars throughout the year)
- PSI Careers - MEDMathS
- PSI Book Club Webinar: Atomic Habits - The Science of Getting Your Act Together
- PSI Book Club Webinar: The Art of Explanation: How to Communicate with Clarity and Confidence
- Introduction to Industry Course (started in 2025 and continued into 2026)
- PSI Medical Statistics Student Careers Event 2025: Face to face event in Cambridge



- PSI Career Young Face to Face Event in London
- MedStat Apprentice Quarterly Networking Sessions (4 separate meetings or webinars throughout the year)
- Medical Statistician Apprenticeship Scheme: Final Project Presentation session
- PSI MedStat Apprentice Virtual Conference

Kate Taylor
Events Director





SIG Report

The year 2025 has been another highly successful and productive period for the PSI/EFSPi Special Interest Groups, with an impressive breadth of activity and impact across the community. While it is impossible to capture the full extent of the work undertaken in a short overview, highlights once again include strong contributions to the PSI Conference through numerous sessions, posters and town halls, a wide range of well-attended webinars and workshops, multiple high-quality publications, and continued engagement with regulatory and methodological guidance. Collaboration remains a defining strength of the ESIG community, both across SIGs and with external organisations such as EFSPi, PHUSE, ASA and regulatory bodies, and the collective commitment and enthusiasm of our volunteers continues to be exceptional.

2025 has also seen important progress in how our SIGs work together. We have received excellent feedback on the newly established MS Teams collaboration and document-sharing area, which has already improved connectivity, visibility and cross-SIG working. Our ESIGs continue to grow and evolve, reflecting emerging scientific priorities and member interests, with the launch of new SIGs in Medical Devices (led by Michael Mader), Early Phase (led by Sam Hinsley), and Multi-Component Endpoints (led by Mickaël De Backer). With these additions, we now have 27 active SIGs, alongside continued momentum across our established groups. I would also like to warmly congratulate the Randomisation SIG, winners of the first SIG of the Year Award, in recognition of their outstanding contributions, innovation and engagement with the wider statistical community. On behalf of the PSI Board, I would like to thank all SIG leads and members for their continued dedication and impact throughout 2025.

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



AI & ML: Sam Hadlington (Plus-Project)

The artificial intelligence and machine learning (AI&ML) SIG was created in 2024 to address the growing influence of AI systems and how they might be incorporated in our day-to-day work. We continue to grow, increasing our membership from 11 to 21 members, and have held quarterly meetings in 2025.

This year we have created several sub-teams within the SIG to work on specific areas. So far, we have the SAP Generator team, the R tools for machine learning team and the using AI for HTA team. We have plans for other sub-teams that have not yet been taken on for things like ethics, AI&ML regulation and looking into what AI can't do.

We had 4 well attended meetings this year which we have used as an opportunity for people to present as well as to discuss the fast-paced areas of AI and machine learning. Moving forward we are hoping to continue these presentations and to hear more from the sub-teams and what they are working on, as well as engaging AI experts from outside the SIG to share knowledge.

At the conference this year we ran a session entitled "AI & ML SIG: Artificial Intelligence updates, applications and regulatory insights" which was well attended (approx 60 people) and received good feedback. We have been accepted to present again at the Belfast conference in 2026. We are also looking at possibly presenting a webinar later in the year.

At the start of the year, we finished compiling comments on the latest FDA guidance on the use of AI in clinical trials and sent these over. We have also continued to engage other machine learning teams across the SIGs to learn from their experience and share these learnings with our members.

Goals

- Engaging 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

AIMS: Martin Brown (PPD, part of Thermo Fisher Scientific)

The PSI AIMS Special Interest Group had a productive and impactful year in 2025, with a particular focus on R and open-source adoption, change management, and further understanding of statistical method implementation across software within the industry. The SIG remained an active, collaborative group, supporting the use of R and broader open-source tools while recognising that successful adoption is as much about people and processes as it is about technology.

A major highlight of the year was running a session at the PSI Conference – "*Navigating the Move to Open Source – Effective Strategies for Adoption and Working with Different Software*". The session featured talks on R adoption and change management from a large CRO perspective, innovative strategies for adopting R and Python, and the replication of statistical results across software (CAMIS). The session was very well attended and generated excellent discussion and engagement. The presentation on *R Adoption & Change Management* was also repeated at a Japanese conference and at PHUSE EU Connect.

[Video-on-Demand](#)

Building on this success and feedback, the SIG organised a one-day, in-person UK event on Change Management for Moving to R/Open-Source in July. The event attracted strong attendance from all



sides of the industry (pharma, biotech, CRO, academia) and focused on practical change management challenges associated with open-source adoption. Topics included training, organisational change, managing during periods of significant transition, effective communication with colleagues and managers, and the timing and resourcing of change initiatives. Engagement was high and feedback was very positive, with participants expressing a clear desire for a similar event to be run regularly in the future. This looked to extend the SIG's impact beyond the conference into more practical, community-focused learning.

[One Day meeting on Change Management in the Transition to Open-Source / R – PSI AIMS SIG Website](#)

In response to growing interest in open-source skills, the SIG launched a new blog series on Open-Source Skills, publishing four posts throughout 2025 covering topics such as why open-source skills matter, understanding the open-source landscape, choosing R packages for statistical work, and navigating open-source statistical resources and working groups. The blogs aim to support readers and introduce them to key foundational concepts.

[Blog – PSI AIMS SIG Website](#)

The SIG also introduced a new “Open-Source Lunch Bites” webinar series (first Friday of the month, 30 minutes), delivering four short, practical sessions covering IDEs, debugging, and R package fundamentals. These webinars provided accessible, practical content and helped lower the barrier to entry for those newer to open-source tools.

[AIMS SIG - Open-Source Lunch Bites](#)

Thank you to all AIMS SIG members and contributors for their enthusiasm and support throughout 2025. The group looks forward to continuing discussions on R, open-source software, and effective adoption strategies in 2026. If you would like to get involved, please get in touch via the PSI AIMS SIG website.

[PSI AIMS Special Interest Group – PSI AIMS SIG Website](#)



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

The **Benefit-Risk ESIG** was formed in 2012 with the vision to ensure industry professionals understood and effectively utilize Benefit-Risk methods throughout the entire medicinal product lifecycle process. The group is open to professionals from industry, academia, and public bodies (including regulatory and HTA agencies).

In 2025, the EFSP/PSI Benefit-Risk Assessment ESIG focused on strengthening engagement and setting a clear strategic direction for the future. A central activity was the revision and development of a new BRESIG Blueprint, updating the original 2013 document to articulate a shared vision for the coming years. The emphasis was on clarifying scope, priorities, and intended outputs to guide medium-term activities.

The revised blueprint identified key focus areas including patient preferences in benefit-risk assessment, safety and tolerability methodology implementation, review of benefit-risk guidance's, and partnerships with external working groups. The ESIG adopted a pragmatic, implementation-oriented approach, prioritising practical experiences, case studies, and knowledge-sharing formats such as seminars and webinars alongside methodological work.

A major development in 2025 was the establishment of focused working groups aligned with this vision. In particular, the Safety Implementation working group, led by Naomi Givens, was created to address the practical adoption of novel safety and tolerability methodologies. The group began defining priority topics and committed to presenting its work at the PSI Conference Belfast in June 2026.

The ESIG held a session titled "Future-proofing healthcare beyond today for tomorrow's medicines with advancement in benefit-risk assessments" at the 2025 Annual conference in Wembley. The session covered the new CIOMS working group guidance on benefit risk assessments, appropriate de-biasing methods in innovative trial designs, a case study highlighting the methodological and practical application of quantitative benefit-risk assessment and an introduction to the new Safety Implementation working group.

Overall, 2025 was a formative year, laying strong foundations for coordinated delivery and impact in the years ahead.

We continually welcome new members and collaborators! Please reach out to [Shahrul Mt-Isa](#) or [Marco Boeri](#) if you have an interest in being involved in this ESIG, or have an interesting case study or experience of carrying out a structured Benefit-Risk assessment to share.

For more information: <https://psiweb.org/bresig>



Biomarkers: Laura Schlieker (Staburo GmbH) & Mathias Cardner (AstraZeneca)

As 2025 draws to a close, the Biomarkers ESIG has continued to push boundaries in innovation, collaboration, and knowledge sharing. This year, we welcomed new co-leads and energised a number of sub-streams dedicated to driving progress at the interface of statistics, machine learning, and biomarker science. The highlights are covered in an overview article posted [here](#) on LinkedIn.



Causal Inference

Sanne Roels (J&J) – Alex Ocampo (Roche)

The Causal Inference Special Interest Group (SIG) was initiated in 2023 and eventually launched in 2024. The SIG started with a core group of five members and in 2025 continued to grow to approximately 30 active participants who have joined since the foundation.

Our SIG organised one webinar in 2025 on the use of Instrumental Variables in Randomized Clinical Trials. We also contributed to the organization of a Joint webinar with the RWD SIG, focusing on Data Fusion, Use of Causal Inference Methods for Integrated Information from Multiple Sources.

Our monthly regular meetings continue to focus on causal inference methodologies and concepts essential for analyzing clinical trial data to appropriately answer questions, i.e. visualization using DAGs and analysis methodology in the presence of post-baseline events. We explore how such methods can enable more direct answers to the 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.

In 2025, we co-organized a mini-symposium at the ISCB (in August '25 in Basel), organized a session on Causal Inference at the PSI conference, and contributed to several other sessions at the conference. Looking ahead to 2026, we are planning a webinar to continue our efforts and are also preparing an event focused on covariate adjustment.



Centralised Statistical Monitoring and Quality Tolerance Limits:

Tim Rolfe (GSK), Susan Talbot (Amgen)

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

The team have had another successful year in 2025 with sub-committees working in parallel on the topics of CSM and QTL.

Summary of annual accomplishments:

Highlight new techniques and best practices:

- **QTL methodology paper**

Kilaru R, Amodio S, Li Y, Zeng Y, Khaplonov A, Wang Z, Wells CL, Love SB, Rolfe T, Talbot S, Fronc M, Jelizarow M, Ye J, Balakumar A, et al.

Evaluation of current statistical methods for implementing quality tolerance limits.

Statistics in Biopharmaceutical Research. 2025;1–14.

doi:10.1080/19466315.2025.2579549

- **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;22(3):342–351.

doi:10.1177/17407745241304059

Presentations and engagement:

- PHUSE Single Day Event (Utrecht, April 2025)
- Regulatory-Industry Statistical Workshop (RISW): poster presentation and parallel session submissions

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

CMC: Kevin Lief (GSK)

- Having joined EFPSI/PSI as a SIG in 2024, continued to grow our membership through 2025. Driven by running webinars (open to non-members), and round-table discussion groups on hot topics (members only).
- Through 2025 we have focussed on initial steps to progress towards our long-term aim of recognition by regulatory authorities as a group representative of CMC statisticians in industry within Europe.
 - Taken the themes for our two webinars from ICH Quality documents that are being re-developed. Hence, we believe this approach of focussing on hot topics drove fantastic attendance and engagement from the CMC statistical-side of pharma industry.
 - The two round-table discussion groups tailed the webinars, including launching our first position paper, on the ICH Q6 update to guidelines for specification setting. Recruited a small cross-industry group, which will kick off in February 2026.
- Began the planning and initial steps for two further webinars, to continue our momentum into 2026



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](#)



Data Sharing: Rebecca Sudlow (Roche) and Catrin Tudor Smith (Uni of Liverpool)

- Presented a webinar to PhD Data Science students (UK and EU) outlining pharma clinical trial transparency commitments and how external researchers can request access to participant level data. The presentation was done in collaboration with [Vivli.org](https://vivli.org) and provided an end to end overview of the data request, review and access process. Access to scale and variety of data available via the Vivli platform is a key enabler of their planned PhD research. Insights from the audience regarding their data request experiences was insightful and educational to the data contributors too.
- Ongoing: The ESIG conducted a survey in 3Q25 regarding the challenges and increasing complexity of responsible/compliant data reuse driven by the rise of AI and increasing fragmentation globally regarding data privacy requirements and ethics committee expectations. The intent of this survey was to provide an assessment of how pharma companies are addressing these challenges and whether there are opportunities at an industry level to work on solutions that benefit our patients and society. The responses we received highlighted a wide variety of approaches and will form the basis of a reflection piece this year.

At end of Feb **Rebecca Sudlow will retire** from Roche and the ESIG will be temporarily co-chaired by Professor Catrin Tudor Smith (Univ of Liverpool) and Mimmi Sundler (Novo Nordisk).

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



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

The decision-making SIG is currently a group of 29 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.

A highlight for the group was a QDM session at the PSI conference 2025 titled “Quantitative Decision Making – How Frameworks Could Help You” with 4 speakers: Trevor Smart (UCB), Gustaf Rydevik (UCB), Julian Tanniou (Saryga) and Nima Shariati (Hoffmann-La Roche).

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

Early Phase: Sam Hinsley (Phastar)

The Early Phase ESIG was created in December 2025 with the aim of improving the use of early phase clinical trial methodologies in order to improve standards within the early phase clinical trials community and ultimately reduce substandard treatments being taken into later phase trials.

Our key objectives are:

- **Improving understanding and implementation** of statistical methodologies within early phase trials via training, meetings or publications
- **Sharing knowledge and real-life experiences** between key stakeholders in both academia and industry
- **Allowing space for collaboration**, fostering a community of support rather than competition

The group is actively growing, with interest from 20 statisticians to date. Members of the group will be presenting a session at PSI 2026 entitled “Developments in early phase dose-finding trials”.



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

In 2025, the Historical data SIG was mainly engaged in the 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 outcome of the procedure was a Qualification Advice issued by EMA in late December 2025. The SIG members are currently reviewing the EMA Advice and planning how the work done so far can be shared and built upon.

In addition, the SIG continued with regular presentations from group members and external guests on topics of high interest (including review of 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.



HTA: Arthur Allignol (Daiichi Sankyo), Katrin Kupas (Merck KGaA), Lara Wolfson (MSD)

The HTA SIG remained highly engaged in various activities, particularly related to EU HTA and methodological advances throughout 2025.

Some key achievements include:

- **PSI 2025 in London:** Members of the SIG were involved in various sessions at the PSI 2025 conference, including a session on Structured Expert Elicitation and on evidence synthesis in HTA. Additionally, the SIG organized a Town Hall session “EU HTA: readying ourselves for the road to 2025 and beyond”
- **EFSPI Regulatory Statistics Workshop in Basel:** The SIG presented 4 posters giving an HTA viewpoint on win-ratio, adaptive designs, target trial emulation, and on extending and extrapolating evidence from trials to target populations
- **European Commission EU HTA Stakeholder Network:** SIG member represented EFSPI in the European Commission EU HTA Stakeholder Network
- **Other Achievements:** played an important role in fostering dialogue across companies, enhancing readiness for EU HTA through regular monthly meetings; finalized the HTA handbook; provided trainings via webinars on HTA “hot-topics”, and advancing its work on whitepapers and various technical subteams (2 papers published).

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



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

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

Wishing everyone an impactful 2026!

Ongoing activities

Implementation of estimands in RWD studies to evaluate questions of interest in the post-marketing space (with collaborators from the RWD SIG)

- Treatment patterns are very important in the post-approval space. Furthermore, there is interest in investigating outcomes as a result of different treatment patterns and pathways. We have been exploring how the estimand framework can enhance these activities.

Invited to present for Rare Disease RealisedD webinar (4 Feb 2026)

Do You Want to Stay Single? Considerations on Single-Arm Trials in Drug Development

Single-arm trials (SATs), while not preferred, remain in use, especially in the Rare disease space. They may be accepted by regulators in specific contexts e.g. when the potential effects of new treatments are very large, and placebo treatment is unethical.

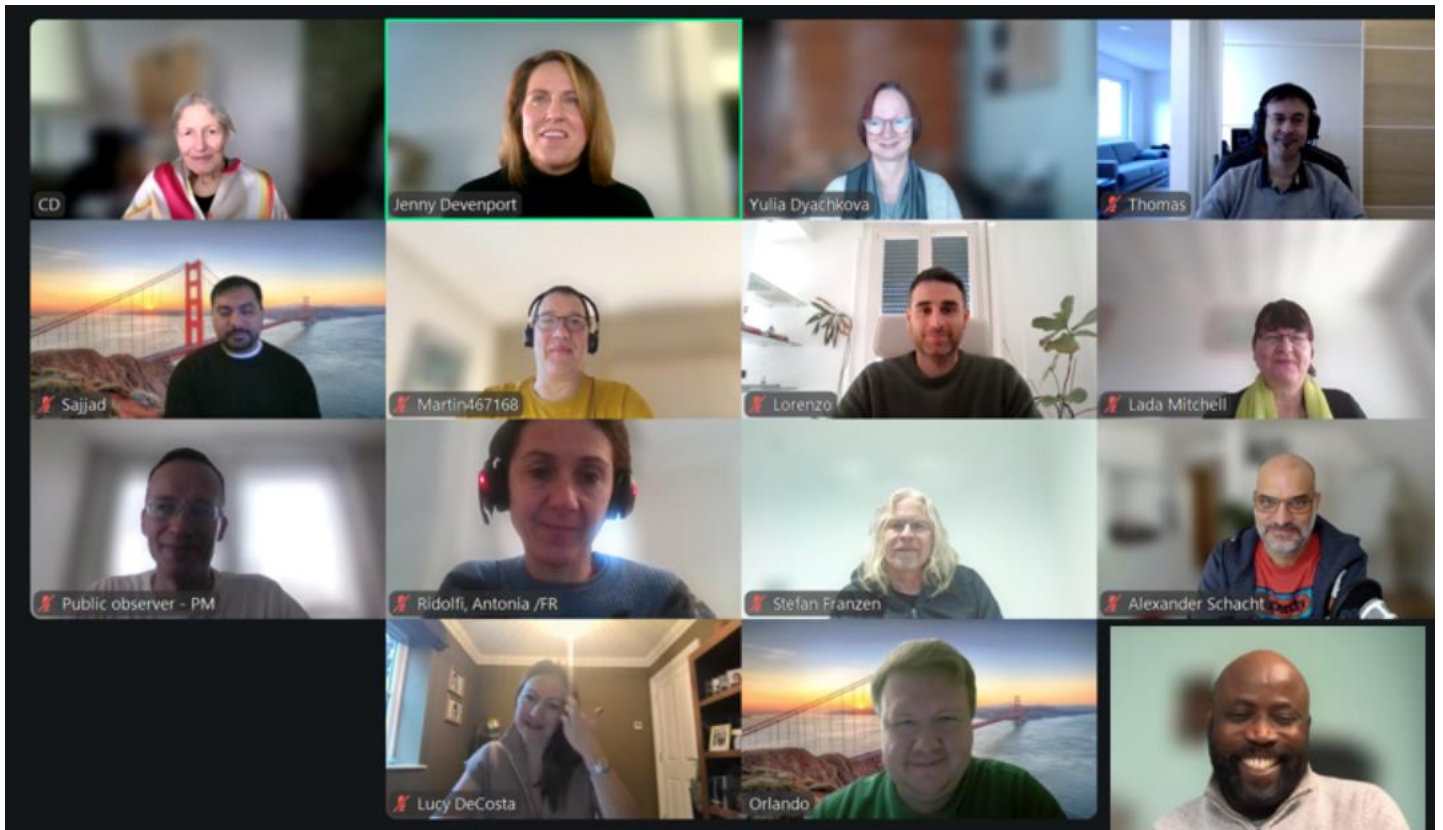
In this presentation, we review regulatory and HTA positions on SATs; case studies in rare diseases where SATs could and could not address research questions, illustrating challenges posed when using SATs, evolving statistical methods and strategies to optimize study design to address evidence needs.

Conference presence

PSI Annual Conference - poster

EFSPi Regulatory Statistics Conference

- [LnL SIG poster](#)



MedDev: Michael Mader (Nobel Biocare)

The MedDev SIG was newly formed in 2025. Initial focus is on three main pain points in the Medical Device Biostatistics environment.

1. Adapting the estimand framework to medical device trials with focus on the challenges defining intercurrent events
2. Evidence requirements by different audiences
3. Analysis of the medical device-specific regulatory landscape. Differences between U.S., Europe, and Asia is still prevailing. For example, different comparator groups and predicate devices are requested. The sequence of various evidences varies as well.

In addition, we continue to focus on developing and improving algorithms to reflect the multiplicity of devices, procedural influence on endpoints, high timing variability, diversity of endpoints, and Bayesian futility analysis strategies.

Multi-Component Endpoints:

Mickaël De Backer (UCB) & Vivian Lanius (UCB) & Patrick Schlömer (Bayer)

The Multi-Component Endpoints SIG is a newly formed SIG (EFSPi & PSI endorsement in Dec 2025).

What this is about

Randomized clinical trials are typically built around a single primary endpoint that should capture disease impact, enable clear interpretation, and support efficient analysis. In many settings, however, no single outcome adequately reflects patients' experiences, leading to the use of multi-component endpoints.

Not all such endpoints are alike. Traditional composite endpoints combine outcomes without reflecting their relative clinical importance, whereas newer structured approaches aim to better represent patient



experiences and potentially improve both statistical sensitivity and clinical relevance. These methods also create opportunities to revisit how intercurrent events are handled within the composite strategy of the estimand framework.

This SIG was formed to advance thinking in this area. It will focus on best practices for defining, applying, and interpreting multi-component endpoints. This SIG aims to foster collaboration across industry, academia, and regulatory bodies, engage experts to refine methodologies, and share insights through reviews, case studies, and training.



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](#)



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.

The primary goal of the 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 {mrmr}, was first published on CRAN in October 2022 and several updates have been published since, with the last one in December 2025. In 2023 the working group developed a Bayesian implementation of the {mrmr} package, named {brms.mrmr}, which was published on CRAN in August 2023. As with {mrmr}, several updates have been released since the initial publication. In 2024 the SIG published {maicplus}, an R package providing tools to perform matching-adjusted indirect comparison (MAIC) analyses. 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 also wants to enable more open collaboration by adopting company-initiated packages under the openstatsware umbrella for further development. To this end, there is a new “ideas” page on openstatsware.org providing points of contact, discussion board, etc.

The SIG took over maintenance of the CRAN Clinical Trials task view as a one stop shop for R packages, and in 2025 successfully launched a completely revamped page at <https://cran.r-project.org/web/views/ClinicalTrials.html>, which is supported further by the Hexwall visualization for the task view which is published on the SIG website: <https://www.openstatsware.org/hexwall>

The secondary goal of the SIG 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 has been offered multiple times since 2023. In 2025, it was run 4 times around the world: Tokyo, JP, 8 April @ GSK; Philadelphia, US, 12 August @ MCP25; Basel, CH, 24 August @ ISCB25; Paris, FR, 10 October @ SnB25.

Short overview of the 2025 accomplishments:

- In 2025, the SIG expanded the cross-company collaboration to include more than 70 members from over 35 organizations.
- Several packages are actively developed and supported by the WG: {mrmr}, {brms.mrmr}, {maicplus}, {SafetySignalDetection.jl}.
- Collaboration with Pediatric Drug Development SIG on power/sample size tool for safety
- Relaunched the CRAN Task View on Clinical Trials
- Contributed to scientific conferences (Session at PSI conference, posters at EFSPi workshop and BBSW)
- 4 workshops on “Good Software Engineering Practice for R Packages”
- Podcast recording on R package and Shiny development
- Blog post on Posit blog ([link](#))
- Submitted a paper on the open-source revolution in Pharma to “Drug Discovery Today”

In 2026, 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.



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.

Our key activity in 2025 was focused on presentation of PFDD “Hot Topics” at PSI Conference 2025. This included a talk about using PROs to capture tolerability in early phase clinical trials, project Optimus in action and a case study in sickle cell disease about use of patient-reported pain as an endpoint. We were also pleased to introduce ourselves to other PSI members at the SIG at the bar lunchtime sessions – and thank you to Piper’s company for sponsoring and supplying some PFDD beakers we gave away.

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 we welcome new contributing members to join us. Our current active workstreams involve:

- PROs assessing tolerability
- PROs in dose optimization
- Daily diary data and endpoints

We are looking forward to presenting work from the tolerability sub-team members at PSI conference 2026.

Pre-Clinical: Eloisa Brook (GSK)

We are a group of statisticians working at CROs and pharmaceutical industry supporting preclinical drug discovery on animal and cell based experiments. As a group, our focus is on diverse range of preclinical topics such as;

- Discovery
- Robust study design/good statistical practices in in-vitro, ex-vivo and in-vivo assay development
- Reproducibility and Translation from pre-clinical to clinical
- Toxicogenomics
- General Toxicology
- Eco-Toxicology
- Toxicokinetics
- DMPK / Pharmacokinetics
- ECG
- Immuno Toxicology
- Histopathology
- Pharmacology
- Developmental and Reproductive Toxicology
- Carcinogenicity



We organise webinars and workshops on topics and methodological developments in preclinical research and now have a list of over 50 affiliates on our e-mail distribution list.

**For more information look at our page on PSI:
<https://psiweb.org/sigs-special-interest-groups/pre-clinical>**



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

In 2025, the Randomisation SIG continued to make substantial contributions to advancing randomisation methodology and practice in clinical trials. Our activities spanned conference presentations, publications, software development, and community engagement, reflecting the group's commitment to innovation and collaboration. Currently, as of January 2026, our SIG consists of 45 active members.

Conference Contributions

The SIG was honored with the *PSI SIG of the Year Award* for “outstanding contributions by a Special Interest Group that have demonstrated exceptional impact through innovative initiatives, active member engagement and meaningful contributions to the wider statistical community.”

Additionally, throughout the year, we organized and contributed to multiple sessions at major conferences:

- **ISCB 2025 (Basel, Switzerland):** “Forced Randomisation – a powerful, sometimes controversial, tool for multi-centre RCTs”
- **ROeS 2025 (Graz, Austria):** “Allocation Ratios Achieving Maximal Power in Controlled Experiments” and “Using Randomization Tests to address disruptions in clinical trials”
- **JSM 2025 (Nashville, USA):** A dedicated Randomisation WG session with four presentations on topics ranging from response-adaptive designs to regulatory perspectives, followed by an open discussion with ~20 attendees.

Publications and Methodological Advances

Our members published 8 peer-reviewed publications in leading journals, covering topics such as [covariate-adaptive/response-adaptive designs](#), [randomization-based inference](#), [allocation predictability](#), and [randomisation challenges in platform trials](#).

Additionally, the group coordinated responses to key regulatory and reporting guidelines, including the [CONSORT 2025 update](#) and [ICH E20 draft guidance on adaptive designs](#), ensuring that randomisation considerations are well represented in global standards.

Software Development

One of our SIG members launched [RandomForge](#), an open-source R package providing a transparent and extensible framework for implementing randomisation procedures. The package, along with its comprehensive online manual, is publicly available on GitHub and designed to evolve into a broad ecosystem supporting diverse trial designs.

Community Engagement and Learning

Our [LinkedIn group](#) grew to 164 members, fostering active discussions and knowledge sharing. We introduced a new meeting structure featuring bi-monthly **Learning Sessions**, open to both members and non-members, covering topics such as minimizing selection bias, and enabling optimal response-adaptive designs. Recordings and materials are accessible [via our newly launched website](#), which also serves as a hub for publications, events, and membership requests.

Looking Ahead to 2026

We plan to expand our leadership structure with dedicated sub-workstreams for education, methodology, and software. The leaders of this sub workstreams will be responsible for driving collaboration and advances in the respective areas.

Accepted session proposals for 2026 include:

- **JSM (Boston, MA, USA):** “Rethinking Randomization: Bias, Ethics and the Future of Clinical Trial Design”



- **SCT (Phoenix, AZ, USA):** “Beyond Blocks: A New Era of Randomization”
- **PSI (Belfast, UK):** “Beyond Chance: Randomisation Designs for Innovative Clinical Trials”

Further initiatives include additional learning sessions and strengthening collaborations across academia and industry. Our goal remains to advance the science and practice of randomisation, ensuring robust and innovative trial designs for the future.

Regulatory: Yolanda Barbachano (BioNTech) and Fredrik Öhrn (Johnson and Johnson)

Several members of the Regulatory SIG changed company in 2025, 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 2025 we had a total of 22 members from 8 countries. Our main activities in 2025 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 2025 this included the following documents:
 - o [MHRA draft guideline on on the use of external control arms based on real world data to support regulatory decisions](#)
 - o [ICH E20 Guideline on adaptive designs for clinical trials Step 2b](#)
 - o FDA draft guidance on [Approaches to Assessment of Overall Survival in Oncology Clinical Trials](#)
- The Regulatory SIG and the PSI Scientific Committee jointly organised the Regulatory Hot Topic session at the PSI Annual Conference. The two topics covered at the session held on 10 June 2025 were Perspectives on Bayesian Statistics in Regulatory Decision Making and Development of the ICH E20 Guideline on Adaptive Design in Clinical Trials. In addition, we also took part at the SIG at the bar session to introduce the activities of the Regulatory SIG.
- Supporting the organization of the EFSPi Regulatory Statistics Workshop (held 9-11 September 2025 in Basel, Switzerland), by participation on the scientific committee as well as moderating and presenting in the different sessions. We also contributed to the poster session with a poster on the activities of the Regulatory SIG.
- On 26 November 2025 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:
 - The definition of the estimand in studies with repeated measures
 - Non-inferiority studies.
 - Causal inference.

The minutes of the meeting will be uploaded to our eSIG webpage after approval from MHRA.



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 2025 included: relevance of estimands in descriptive RWD studies (together with the L&L SIG), target trial emulation, and borrowing external data in external control or hybrid designs. Furthermore, we debriefed on relevant conference/workshop content and regulatory guidelines/papers.

The RWD SIG co-organized two webinars in 2025 discussing augmenting clinical trials with external data (potentially RWD):

- Joint webinar with the Historical Data SIG on May 22nd 2025: [Methods and tools integrating clinical trial evidence with historical or real-world data, Bayesian borrowing, and causal inference](#) with four industry speakers (with one, Antonio Remiro Azocar, a SIG member)
- Joint webinar with the Causal Inference SIG on October 23rd 2025: [Data Fusion, Use of Causal Inference Methods for Integrated Information from Multiple Sources](#) with two industry speakers, an FDA discussants & an industry discussant (again Antonio)

We provided comments on the [MHRA draft guidance document on the use of external control arms based on real-world data](#), as well as the [EMA Draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making](#). Also, the RWD provided feedback on two presentations by Rima Izem, respectively for the regulatory workshop [EFSPi regulatory statistics workshop](#) (topic: target trial emulation), and the EMA [Workshop on the use of external controls for evidence generation in regulatory decision-making](#) on November 3rd (topic: sources of bias).

Looking forward to 2026, Rima Izem will step down from SIG leadership though remain an active member (thanks Rima for all the wonderful leadership you have provided the SIG!). Eleanor Ralphs will take over the leadership role.

Our SIG page is here [RWD SIG \(psiweb.org\)](https://www.psiweb.org), and interested new members may subscribe via this [link](#).



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

The Small Populations SIG had the following objectives going into 2025:

- Increase the membership to create a sustainable working group
- Arrange a panel session in Bayes Conference in Leiden
- Prepare a poster for EFPSI Regulatory workshop to increase visibility of the subgroup
- Work on the sub-streams to contribute to the field related to small populations clinical trials (subgroups: Bayesian dynamic borrowing; clarify terminology on external control, hybrid control, etc; review of the guidelines focusing on small populations and create a repository of those)
- Monthly CHMP updates related to orphan drug approvals

We are glad to say that we achieved most of our objectives successfully. At the end of the 2025, the SIG included 22 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 Q3 of 2025 we have presented a poster at EFPSI regulatory workshop to help us increasing the visibility of our SIG. In the Q4 we had a presentation ("[Quantifying Uncertainty in the Face of Rarity: Bayesian Methods in Regulatory Contexts](#)") and an accompanying panel session in Bayes Conference in Leiden.

Treatment Effect Heterogeneity SIG: David Svensson (AstraZeneca)

There was substantial activity in 2025 within the SIG. We once again ran a PSI SIG session in London, focusing on new investigations aimed at improving the assessment of treatment effect heterogeneity in clinical trials, including Bayesian shrinkage and enrichment strategies. The session was very well received and generated extensive audience engagement. Regulators were present and contributed valuable perspectives on the findings presented by the speakers—Björn Bornkamp, Marie Riviere, and Wilmar Igl—under the moderation of the SIG lead.

A key theme throughout the session was the practical value of Bayesian approaches for assessing consistency of treatment effects. Discussions highlighted both the theoretical and empirical merits of shrinkage estimators, noting that these methods generally outperform naïve estimates across most published benchmark studies. Several recently developed shrinkage techniques were also presented, adding further depth to the scientific dialogue.

Beyond the conference, the SIG held 11 regular meetings, all dedicated to statistical methodology. Topics ranged from the evaluation of pre-specified subgroups to data-driven approaches for more holistic assessment of evidence for heterogeneity. Several member groups presented ideas rooted in Interpretable Machine Learning, including the use of SHAP and LIME frameworks as complementary tools for investigating treatment effect variation. Some meetings were devoted to preparation for the PSI session, while others focused on ongoing SIG collaborations that resulted in multiple submitted papers, including <https://arxiv.org/abs/2502.00713> and <https://arxiv.org/abs/2505.01145> (the latter published in *Statistics In Medicine*, January 2026: <https://onlinelibrary.wiley.com/doi/10.1002/sim.70375>).

The SIG was also represented with a poster at the Regulatory Workshop, co-authored by a large number of members. Further research continues within the SIG, with several collaborations carrying over from 2025 into 2026. We remain strongly committed to a cross-industry mode of collaboration aimed at producing peer-reviewed publications, as this remains one of the most effective ways to achieve broader scientific and regulatory impact.

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

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



Visualisation: Bodo Kirsch

In 2025 the Visualisation SIG continued to promote the use of effective visualisations in the pharmaceutical industry and healthcare related data presentation.

The highlight of the Visualisation SIG's activities is the monthly instalment of the [Wonderful Wednesday](#) Webinar. Each episode is addressing a specific challenge of data visualisation. The proposed solutions can be found at the [VIS-SIG Blog](#). The site developed to a rich resource for visualisations and coding of graphical displays and tools. In 2025 examples have been added to showcase the use of AI in data simulation and visualisation.

Angela McPartlane
SIG Director





PSI Volunteers

Membership and Community Committee

Name	Company, country	Role
Alicia Aylott	GSK, UK	Chair
Emma Crawford	UK	DEIB Advisory Group Lead
Priya Gokani	Amgen, UK	Community Lead
Nigel Howitt	ICON, UK	Volunteering Manager
Tim Rolfe	GSK, UK	Committee Member
Kate Tsirtsonis	Amgen, UK	Committee Member

DEIB Advisory Group Sub-Team Structure

PSI Committee	DEIB AG Sub-Team Lead	DEIB AG Sub-Team Members
Comms & External Affairs	Achille Dunne	Ursula Becker, Ana Luisas Costa, Nicola Hewson
Events	Karen Smith	Justyna Mlynarczyk, Agnieszka Tomczyk
Careers	Lily Perrin	Konstantina Skaltsa, Lillian Ahumuza
SIGs	Sharon Richards	Paolo Pio Vitiello, Irina Garanina
Membership & Community	Sharon Richards	Paolo Pio Vitiello, Irina Garanina
Operations	Christine Fletcher	Karen Smith

During 2025, the following individuals also supported the DEIB AG: Kate Tsirtsonis, Alun Bedding and Lydia Dickinson.

Careers - Universities Committee 2025

Name	Company, country	Role
Lizzi Pitt	GSK, UK	Chair
Deanna Galloway ¹	Roche, UK	Outreach
Stella Zhan	Duke-NUS Medical School, Singapore	Outreach
Diana Voiniciuc	Anthony Nolan, UK	Outreach
Katie Dixon	Phastar, UK	Outreach
Im Chiew Ng ¹²	LSHTM, UK	Outreach
Elsbeth Horgan ²	LSHTM, UK	Outreach
Pankaj Mistry ²	Johnson & Johnson, UK	Outreach
Rachel Phillip	CTRU, University of Leeds, UK	Events
Alexander Todd	AZ, UK	Events
Amy Ashworth	Pfizer, UK	Events
Sophie Edmonds	Amgen, UK	Events
Valerie Millar	MoonLake, UK	Apprenticeships
Jasmine Paul	Parexel, UK	Apprentice Network
Anna Kirkley	Veramed, UK	Apprentice Network
Isabelle Santhiapillai	GSK, UK	Apprentice Network

¹ Left the committee in 2025

² Joined the committee in 2025



Careers - Website Committee 2025

Name	Company, country	Role
Tomas Rouse ¹	AZ, Sweden	Website
Heather White	Amgen, UK	Chair
Felicity Knighton ²	Phastar, UK	Website
Benjamin Jones ²	AZ (student), UK	Website
Sam Adams ¹	University of Bath, UK	Website

¹ Left the committee in 2025

² Joined the committee in 2025

Careers - Schools Committee 2025

Name	Company, country	Role
Rebecca Randhawa	Amgen, UK	Chair until March
Steve Mallet	Veramed, UK	Chair from April
Rejina Verghis	GSK, NI	Sub-team Lead
Katie Law	Veramed, UK	Member
Sarah Crossley	Phastar, UK	Member
Alex Spiers	GSK, UK	Sub-team Lead
Dea Hazewinkel	LSHTM, UK	Member
Stephen Corson	Phastar, UK	Member
Katie Gwinnell	University of Bath, UK	Sub-team Lead
Hayley Perry	JnJ, UK	Member
Sophie Hodge	Bayer, UK	Member
Fiona Grimson	UCB, UK	Member
Jennifer Gilbride ¹	Bayer, UK	Member
Jackie Wall ¹	Plus-Project, UK	Member

¹Left committee during 2025



Careers - Professional Development Committee 2025

Name	Company, country	Role
Xinyi Zhu	GSK, UK	Chair
Isabelle Smith	Veramed, UK	Events/Peer Support Initiative Lead
Ellie Grainger ²	AstraZeneca, UK	Peer Support Initiative Lead
Marius Sieverding	Veramed, Germany	Book Club Lead
Holly Prescott	Plus Project, UK	Book Club
Emma May	Biontech, UK	Book Club
Agne Zarankaite ¹	GSK, UK	Lunch & Learn
Zainab Walsh	Veramed, UK	Mentoring Lead
Robert (Bobby) Day	Phastar, UK	Mentoring
Ursula Garczarek	Sepul Bio, Germany	Mentoring
Claire Brittain ¹	UCB, UK	Lunch & Learn Co-lead
Chetan Mistry ¹	Veramed, UK	Lunch & Learn Co-lead
Jemma Greenin	Veramed, UK	Career Young Lead
Oswald Dallimore	Imperial CTU, UK	Career Young Co-Lead
Charlotte Chrispin ²	AstraZeneca, UK	Career Young Co-Lead
Ailsa Neil ²	AstraZeneca, UK	Career Young
Lucia Poyatos Baena ²	GSK, UK	Career Young
Holly Moon ²	Parexel, UK	Career Young

¹Left committee during 2025

²Joined committee during 2025

Careers - ITIT Committee 2025

Name	Company, country	Role
Zelie Bailes	GSK, UK	Chair
Laura White	Plus Project, UK	Treasurer
Ruth Lowe	IQVIA, UK	Member
Sophie Hodge ¹	Bayer, UK	Member
Hoi-Shen Radcliffe	Bayer, UK	Member
Sam Ruddell	Chiesi, UK	Member
Mahesh Shivhare	Roche, UK	Member
Marianne Uguen	Roche, Switzerland	Member
Zoe Macintyre	Phastar, UK	Member
Claudio Marchese	AZ, Spain	Member

¹Left committee during 2025



Communications Committee

Name	Company
Jennifer Visser-Rogers (Chair)	Coronado Research
Oceana Faria	Fortrea
Jamie Chai-Rees	Compass Pathways
Leanne Winzer	AstraZeneca
Elena Mourouli	GSK
Steve Jones	Medable
Sophie Edmonds	Amgen
Thomas Henderson	Amgen Intern (12 months)
Ciara Lucas-Garner	Amgen Intern (12 months)
Toby Smith	Amgen Intern (12 months)

Events Committee

Name	Company, country	Role
Kate Taylor	Amgen, UK	Chair
Julia Niewczas	AstraZeneca, Sweden	Scientific Committee
Ellie Grainger	AstraZeneca, UK	Training Committee
Steve Jones	Medable, UK	Communications Committee
Sam Hadlington	Plus-Project, UK	Careers Committee
Rachael Lawrance	Adelphi Values, UK	

Conference & Scientific Committee

Name	Company, country	Role
Julia Niewczas	Janssen	Scientific Chair
Sarah Williams	Roche	Conference Chair
Vicky Marriott	Phastar	Conference Vice-Chair
Kate Taylor	Amgen	PSI Events Director
Amitava Mukhopadhyay	MorphSys	
Ayon Mukherjee	Lilly	
Clelia Cahuzac	Roche	
Ian Wadsworth	Phastar	
Julia Saperia ¹	MHRA	
Jyoti Soni	GSK	
Lara Wolfson	MSD	
Maria Efstathiou	IQVIA	
Martin Jenkins	AstraZeneca	
Nicola Scott	GSK	
Simon Newsome ²	Novartis	
Sue Todd	Reading University	
Tobias Mütze ¹	Novartis	
Tom Burnett	Bath University	

¹ Left the committee in 2025
² Joined the committee in 2025



Training Committee

Name	Company, country	Role
Ellie Grainger	AstraZeneca	Chair
Anna Patten	Eisai	
Caroline Kennedy	AstraZeneca	
Alison Mcleod	Phastar	
Jess Piatek	Veramed	
Emily Hammarstrom-Wickens	GSK	
Lydia Buckley	Fortrea	
Sam Ruddell	Chiesi	
Andisheh Bakhshi	Parexel	
Preenan Sarkar	IQVIA	
Adetayo Kasin	GSK	

*Left the committee in 2025