Annual Report
2022

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Contents

Welcome from the Chair

2022 saw the beginning of a new normal for PSI

In January 2022, the PSI Board of Directors had to decide whether to return to holding a face-to-face annual conference at a time where business travel was still prohibited. It was a nervous time as a wrong decision could lead to a significant and detrimental impact on PSI finances. But, the decision to go ahead with the in-person conference turned out to be a great decision! Not only was it fantastic to see over 400 colleagues in Gothenburg, Sweden, the high level of sponsorship and the success of other events over the year enabled PSI to make its biggest ever profit. Whilst a proportion of the profit will be used to increase reserves to levels recommended by the PSI auditors, the majority of the profit will be re-invested to improve services for members and to further advance PSI activities.

PSI offered a mix of in-person, hybrid and virtual events, with a total of 44 events run in 2022. The type of events and range of events held has continued to expand providing something for everyone, and for both members and non-members. Most events were recorded and available to members through the Video on Demand (VoD) platform. This level of engagement is a huge testament to the PSI committees and special interest groups that together delivered a comprehensive package of highly valuable events and also enabled PSI to reach out to new members across the world. PSI membership has significantly grown in recent years both inside and outside of the UK.

The PSI Board of Directors has continued to thrive with the new board structure. Events have been planned with increased co-ordination across the various groups that organise them. There were significant efforts made in 2022 to better understand the ways of working in each of the committees as part of developing a digital strategy for PSI. Opportunities have been identified to increase efficiencies, and improvements in ways of working will be implemented in 2023.

Below I note a few key highlights for 2022, but please spend some time reading through the full report:

- We made a large profit of £163k in 2022. We aim to keep reserves of at least £330k which will enable PSI to re-invest approximately £125k. Advancing the digital strategy in PSI is one of the priority areas for investment.
- MCI have provided strong support to the board in 2022 and the board continues to partner closely with MCI to share feedback and identify ways of making processes supporting PSI business as efficient as possible.
- We had 1844 members in 2022, the highest ever in the history of PSI with significant growth in 2022. PSI is now represented in 59 countries. The Glue Up platform continues to make it easier to manage and oversee PSI membership.
- The Careers Committee has continued to increase activities supporting Professional Development with mentorships, book club sessions and lunch and learns, and connecting with schools and universities to promote careers in the Pharmaceutical Industry with multiple successful and popular career events. The new Medical Statistics Level-7 Apprenticeship was implemented in 2022 and this continues to be an area of focus, for example encouraging companies to create apprenticeship roles and use the tax levy, creating a win-win outcome.
- We thank the Commercial team who increased sponsorship income to £140K in 2022. The new sponsorship options were popular at the 2022 conference and contributed to advanced bookings for 2023.

- The communications and external affairs committee have advanced the digital strategy which will be implemented in 2023. A new communications strategy is under development and will be shared in 2023.
- The Events Committee had another busy year with a total of 44 events in addition to running a very successful in-person annual conference. The highest number of attendees related to events held on tipping point analyses, covariate adjustments and use of real-world evidence.
- The 2022 conference was back to an in-person conference with a record breaking 427 attendees registered. Well done to the conference team for the high quality and diverse topics covered in the program.
- The European Special Interest Groups supported by PSI and EFSPI were very active in 2022. The COVID-19 eSIG was closed and the biomarker eSIG was re-launched. The Randomisation Working Group, part of a DIA Innovative Design Scientific Working Group, will be adopted as an ESIG in 2023.

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

Awards

The 2022 RSS/PSI Award for Statistical Excellence in the Pharmaceutical Industry is a prestigious annual award for the most influential example of the application of an existing statistical practice, or the implementation of an innovative statistical practice, in the pharmaceutical industry. A team of biostatisticians and statistical engineers from the healthcare company Roche in collaboration with the University of Bath won this year's award for their entry 'Standard and reference-based conditional mean imputation (methodology and open-source software)'. Well done to Marcel Wolbers, Alessandro Noci, Paul Delmar, Craig Gower-Page, Sean Yiu (of Roche) and Jonathan W. Bartlett (of the University of Bath).

The 2022 Mick Godley Award to recognise the unsung heroes of PSI went to Emma Crawford to recognise her significant contributions to CALC, including her leadership of the online career events held in 2021 and 2022, and her valued contributions to many other CALC events and initiatives over many years. Emma, you bring tremendous energy and passion, so thank you and congratulations!

We are a community dedicated to leading and promoting the use of statistics within the healthcare industry for the benefit of patients. If you are motivated to get involved in PSI, we would love to hear from you.
Please contact us at: psi@mcigroup.com

Chrissie Fletcher, PSI Chair

Treasurer's Report

The 2022 professional audit is ongoing and several items, such as VAT reimbursement, are pending, so the following numbers are subject to change. During 2022, PSI made a record profit of around £163k from a total income of £625k, purchases of £267k, and overheads of £196k. This result has exceeded the Board's expectations and is the best financial result for PSI in recent history.

Our reserves now stand at £456k. We aim to have reserves of at least £330k, which is expected to ensure the continued operating of the society even in case of substantial shortfalls on the income side. PSI is in an excellent financial state and has the ability to invest in its future, including additional digital strategy activities, a new communication strategy, and training and outreach activities such as the apprenticeship scheme.

Major drivers of the 2022 result
The very positive 2022 result is mainly due to a strong growth in membership, excellent conference attendance and support from sponsors, as well as a comprehensive events programme, including the ITIT course. Many of these activities were in-person again for the first time since the start of the pandemic. Steps taken during COVID to limit expenses and identify more cost-effective ways of operating are now also paying off. The result required all Board and committee members to very prudently manage our money over the last few years. While many of the improvements on the cost side should continue benefitting the society, it is unclear if the demand for PSI's offering will remain strong and sponsors will remain as generous in the coming years or if 2022 was an exceptional year due to high post-COVID demand for in-person events.

PSI has very substantial overheads to operate the society, including our contract with MCI as well as IT systems, accounting, and legal fees. Almost all PSI activities are revenue-generating and financially net positive. Historically PSI always needed to ensure highly profitable conferences and events to compensate for the annual overheads. The growing membership numbers as well as an increased membership fee reduce this dependence and put PSI on a more sustainable footing. Especially on the IT side substantial additional investments are likely needed for the coming years to gain additional efficiency and keep pace with PSI's growth.

2022 income overview

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

Rounded to the nearest £1k. 2022 figures are subject to change. Overheads are not included in this table.
* Sponsorship, exhibition, and advertising income would typically be shown in this row, but were included in the Conference row for the 2020 accounts.

Contracts Report

THE REMIT OF THE CONTRACTS DIRECTOR IS TO ESTABLISH AND MAINTAIN KEY CONTRACTS WITH EXTERNAL SUPPLIERS ON BEHALF OF PSI.

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

CONTRACTS

Business Administration Services

The contract with MCI to cover business administration services needs to be renewed at the end of 2023. The Board is satisfied with the service MCI provide as a reliable partner. However, to ensure the best value for money, PSI will use a competitive request for proposal process to select our new provider. As PSI's virtual activities grow, the cost-effective scheduling and running of webinars, virtual trainings and SIG events continues to be a key area for development. The annual fixed cost to PSI is £132,200 with services beyond the contract producing additional costs (~£11k in 2022 outside of the conference). This cost was adjusted for inflation for 2022. Some conference management tasks are included in the overall business contract.

Website and digital infrastructure

The website continues to be solely maintained by MCI and is included in the main MCI contract. In 2022 the first version of the digital strategy was completed with substantial improvements to processes especially around membership management (Glue Up platform) as well as video on demand and conference registrations. The next step in our digital journey is planned for 2023.

Journal

The Pharmaceutical Statistics journal is owned by Wiley. The contract was renewed in 2021 and the current contract is in place until the end of 2026.

Digital Publishing of SPIN

Due to the changes in our SPIN offerings, the contract with YUDU was not renewed.

Commercial

The contracts between PSI and Watton Hall for advertising and promotion have not been extended and instead PSI has chosen to bring these activities in-house. PSI continues to engage in collaborations where there are benefits for the members, such as The Effective Statistician podcast and EFSPI membership.
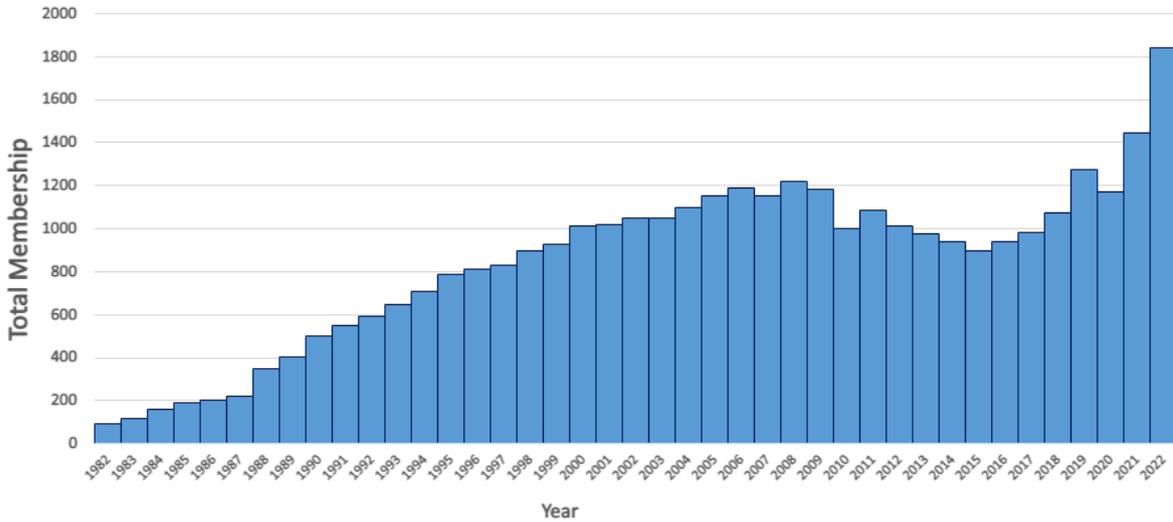
Markus Elze
Contracts and Finance Director
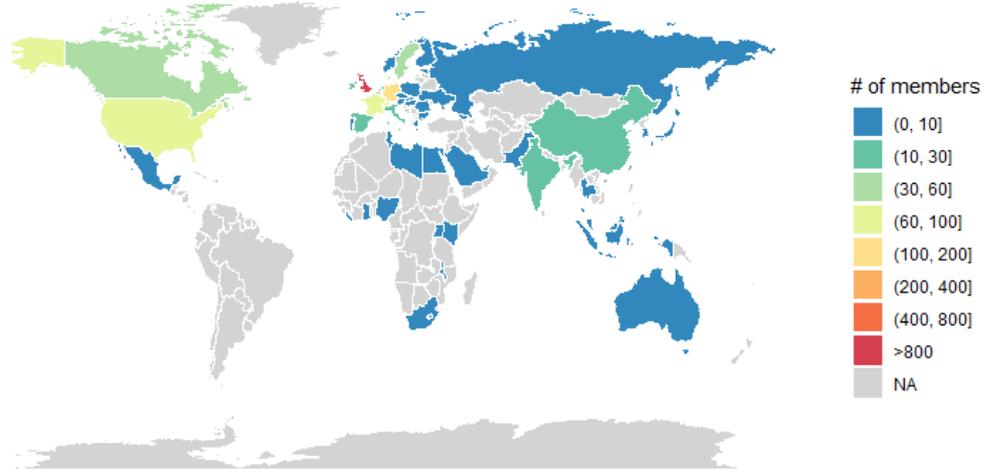
Membership Report

PSI Membership History

Over the last year we have seen the reward for our investments in new technology (our GlueUp membership platform) and the immense efforts from MCI to refresh our individual membership and corporate renewal process. We finished 2022 with a phenomenal number of members; a staggering 1844. We cannot thank you all enough for your continued support for PSI.

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

In addition to a significant increase in our total number of members we also continued to progress our international growth. PSI is now represented in 59 countries across the globe. Just 4 years ago we only had members in 28 countries. This speaks to the success of PSI's ambition to support Statisticians, Programmers & Data scientists in the Industry, by delivering high value scientific content & career development to our members, irrespective of location.

During the PSI strategy day earlier this year there was lots of discussion around ensuring our current members are engaged and feel supported by PSI. We, the Membership & Community Committee, promise to continue to build and nurture a collaborative PSI community. We have a number of plans in the pipeline to ensure our members across the globe are more actively engaged in 2023. Watch this space.....

Kate Tsirtsonis
PSI Membership Director

Careers Report

The Careers team has gone from strength to strength during 2022. The Careers and Liaison Committee (CALC) has continued to successfully promote the industry to school and university students, and the Professional Development Committee has increased its support to people within the industry. We have also expanded the team to bring in the well-established Introduction to Industry Training (ITIT) committee and the New Starters SIG to align all similar career focused groups together.

Careers and Liaison Committee (CALC)

The objective of CALC is to promote the role of statisticians and statistical programmers within the medical research industry and to establish links with relevant professional groups. We aim to engage with schools and universities to inspire and educate students about the practical applications of maths and statistics, and the possible career opportunities within the industry.

Amanda Darekar, CALC Chair

For the first time ever, CALC held two careers events within one calendar year in 2022!

We held our second online PSI Medical Statistics Careers Event on 2nd March 2022, again utilising the virtual platform Career Fair Plus for the exhibitor session. A mixture of 234 BSc, MSc and PhD students registered from 42 universities. Although the event was global, 88% of registered students were from UK universities, and they had the opportunity to speak to 28 exhibitors. A cross-industry panel discussion was held as a webinar in the morning of the event, which was again a great success, giving students the chance to hear first-hand from a range of people talking about their role and experience working in the industry. A number of videos from the event can be found on the VoD section of the website.

In response to feedback received after the March 2022 event, we decided to bring forward the date of the next event to 7th December 2022, so that it was held earlier in the academic year. We also switched back to a face-to-face event for the first time since March 2020. We were fortunate to be able to hold the event at GSK House in Brentford and welcomed 25 exhibitors, and 60 students attended from 35 different universities. The students were grateful for the opportunity to speak to company representatives in person, and also listen to some in-person presentations, as well the popular interactive panel discussion, all of which is available via VoD.

PSI CALC also hosted two more MEDMathS (Medicine Empowered by Data, Maths and Statistics) events – one on Wednesday 9th February 2022, and an event for the next academic year on Wednesday 9th November where around 90 students attended and at which there were plenty of questions (a recording is available here). This new webinar has grown from strength to strength and has helped to introduce undergraduate and postgraduate students to the world of medical statistics, provide an awareness of career opportunities that exist within medical statistics and demonstrate how PSI can help in pursuing such a career. CALC 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.

CALC were also pleased to continue to grow the content of the PSI Student Newsletter, with two editions distributed, in March and October 2022. This aims to provide institutions and students with useful information and links to resources while studying a maths-related degree at university and when thinking about future career options. In addition, following nominations received from their universities, seven PSI Undergraduate Awards were awarded to mathematics/statistics students at universities across the UK.

Finally, the first cohort of Medical Statistics Level-7 Apprentices have started on their apprenticeships. As reported last year, this has been an extensive amount of work to get this approved, and it has been rewarding to see that students have been able to take advantage of this new route into the industry. PSI is working closely with university training providers and interested companies to publicise the apprenticeship and hopes to help more universities to become training providers and encourage more companies to create apprentice medical statistician roles.

Professional Development Committee

The objective of the Professional Development Committee is to support the continued professional development of the PSI community with experience in the healthcare industry. The committee aims to provide resources and career support through interactive webinars and events helping members to take the next step in their careers.

Xinyi Zhu, Professional Development Chair

The mentoring scheme is for members interested in networking with other colleagues from the industry, learning from senior leaders and having a sounding board for their current issues and future aspirations. Mentors and mentees are matched based on years of experience, goals and interests. The first cohort completed in 2022 with positive feedback and 5 mentors volunteering to continue to support the next cohort. Registration for the second cohort opened at the end of 2022 with both mentors and mentees able to sign up as participants.

The book club is aimed at reading and discussing non-technical books relevant to the industry. In 2022, the book chosen by members was "Never Split the Difference" by Chis Voss. 22 participants registered and were split into groups. The book was then reviewed over three hour-long facilitator led sessions reviewing the content and main messages as well as devising a plan to implement the learnings of the book. A mailing list was also set up for alerts on recent developments including registrations for each new book.

Following the success of the Lunch and Learn events last year, 3 webinars were held in 2022 with topics including: "The Floating Ladder", "Relaunchers" and "Pharma-ly Fortunes". On average 50 participants registered for each session and feedback was very positive. In particular, participants found that they offered interesting perspectives from experienced statisticians in the industry with information presented interactively. In addition, a workshop on "Unconscious Bias" was run at the PSI Conference in Gothenburg which received great feedback and will be run again in 2023.

The New Starters SIG transitioned to the Professional Development Committee in the second half of 2022 with the continued aim to connect career young members within the industry (with new starters now termed "Career Young"). Three virtual networking sessions were held with an average of 50 participants registered for each session. Feedback was positive and some participants were even keen to have more regular networking events! A face-to-face networking session was also held at the conference for career young statisticians. This has been ongoing for the past 6 years with continued success.

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 pharmaceutical 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

In 2022, we were thrilled to get the course back up and running again following several years of disruption and cancellations due to COVID. We successfully ran the first session of the 2022/2023 course, hosted by Roche in Basel, with 23 delegates attending from 5 different companies. The remaining 5 sessions of the course will be held in 2023, and planning for the 2023/2024 course is well underway. The success of the course relies heavily on the companies volunteering to host a session, and therefore I would like to take this opportunity to thank all those who have been, or are planning to be, involved with hosting a session. Additionally, we have worked to update the website and move our application process online. Applications for the 2023/2024 course will be open until 30th June 2023.

Kimberley Hacquoil, Careers Director

Commercial Report

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

This is my second year as Commercial Director of PSI. From a commercial perspective, it is fair to say that 2022 was a year where we were able to recover from some of the challenges we faced during the pandemic. PSI derives much of its earnings from registration and sponsorship of the annual conference. The conference in 2022 attracted 25 different Sponsors and saw the largest ever levels of sponsorship, being more than 30% higher than any other previous PSI conference.

For me, it is clear that increasing focus on sponsorship will have the greatest impact to PSI. PSI simply cannot deliver all the activities described in this report without the much needed support of our Sponsors. One of the key objectives I had was to increase revenues from sponsorship by attracting a broader group of sponsors and offering more sponsorship opportunities. In 2022, we implemented some changes, such as the round table discussions, to facilitate better engagement between sponsors and delegates at the conference. These changes attracted sponsorship from companies who have never previously been involved in the conference. Feedback from Sponsors was extremely positive which also resulted in advanced bookings for 2023.

Looking forward to 2023, I have introduced new sponsorship opportunities with more consideration of sustainability and the environment. As the time of writing, Sponsorship for 2023 has already exceeded the level obtained at the same time last year. This is very encouraging as will provide much needed funding, allowing PSI to invest in the future.

In developing PSI's commercial activities, I am supported by others who give up their valuable time for an organisation that plays such an important role in our industry. The PSI Commercial activities were supported by John McKellar (Resources for Business), Salih Siam (Genpro Research) and Brent Burger (Jazz Pharmaceuticals).

Aiden Flynn
Commercial Director

Communications Committee Report

Firstly, I would like to thank Steve (Jones) for his excellent leadership of the Communications Committee over the years. Thanks to Steve's leadership, we are now in a good place. I am glad that Steve has decided to continue on the Communications Committee, and his experience will be invaluable.

During 2022 one of the major activities has been the work of Jack Elkes on the digital strategy. The digital strategy has been an extended exercise in discovering workflows and where digital tools fit into these. Digital goes beyond communications and impacts all of PSI. By getting a handle on the digital strategy, we are best able to advise on what tools can be maximised. The Communications Committee will roll out the digital strategy during 2023.

One of the main activities for this year for the Communications Committee will be to develop a general strategy for all the communication activities for PSI. Within our companies, the Communications team are the voice, and the PSI Communications team is no different.

In January 2023, the team met face-to-face for the first time to discuss the strategy and ask why we exist within PSI. The two themes we came up with are in line with the objectives of PSI:

1. Promote statistics (external): changes in the industry and the latest research, as well as provide content to guide people in learning new areas in statistics

2. Support professional development (internal): activities and resources for people that want to become a biostatistician or develop their professional skills

Some things we are already working on to achieve these two objectives. These include looking critically at the website to produce this ourselves. We are currently demoing WIX, to see if we can use it for SPIN content. First, we are simplifying our social media presence by having simplified accounts and not duplicates, for example, on LinkedIn. We also want to create more engaging content to show the vibrant organisation PSI is. We will still share details of events, but these are not the only content.

We will look to centralise the emails going out so that these will come from the Communications team and not from separate parts of PSI. With this, the Communications team will propose to anyone representing PSI to have PSI email signatures. We are investigating how a dedicated PSI address can send an email and consider other branding. To do this and other things, we are trialling Microsoft Office 365.

Regarding events, a team is developing an improved process to align the Events team with the Communications team. The process includes a planning schedule of what needs to be in place from six months before the event. We will continue to report on events, including photos, videos, testimonials, tweets etc.

We will seek to reach out to other organisations such as EFSPI and other statistics associations to promote more activities further.

From this, members can see that we are planning many activities. Currently, the committee is not significant; therefore, we will be looking for more support. This could be through more PSI members volunteering, and we will engage with an external communications professional(s). This will bring a more professional appearance to PSI.

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

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

Events Report

In 2022 we formed a PSI Events Committee, led by the Events Director to improve 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 2022 I totalled up the number of PSI events – although "counting" by event is probably not the fairest method at all to reflect the depth and diversity of content – but it is one metric! Overall, PSI offered a diverse programme of scientific events – a total of 44 different events – more detail of some of the events is included elsewhere this report. In 2022 again our events were almost all online – the exceptions were our fantastic conference in Gothenburg (Sweden), a successful one-day scientific meeting held as a hybrid meeting both online and at University of Cambridge (UK) on Adaptive Designs and their Application and a return to in-person UK Student Careers Fair (GSK, UK) and ITIT course cohort 2022/2023. Our online meetings included ability to ask questions for discussion by presenters and we also held successful online training courses and a workshop (organised by the Pre-Clinical ESIG).

Numbers of attendees at the events ranged from 427 at conference, 50-200 at scientific/SIG topic/careers webinars and journal clubs and 20-40 at interactive training courses/workshops. Popular events included "Tipping Point Analysis – Introduction and case studies", "Covariate adjustment – considerations and examples", "RWD SIG: Real World Evidence submission – a case study in lung transplantation" and Journal club on "Treatment switching in clinical trials" as well as the series of three webinars on "R use in Pharma". Don't worry if you missed out on any of the PSI 2022 programme of events though – PSI members can access recordings of webinars (and conference recordings) on the Video on Demand platform which is a fantastic resource.

And for 2023 a full programme of events is planned and was communicated early in the year – 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 (MCI) provide us with consistent support in the background to ensure that events run smoothly. In 2023 all PSI online webinar/meetings will be free to PSI members and also to PSI non-members as a way to promote great science and reach broader audiences. For training course and interactive workshops (online or in person) will still have a fee as we have other costs associated with these activities. Also, in 2023 we are piloting supporting students to attend PSI events for free as we promote our industry to them. Students can already join PSI as a student member for free, and PSI are piloting supporting travel expenses for students attending in person events*(*some limitations apply).

A big thank you to all members of the all the organising committees involved in events for their effort and work during 2022. 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.

Conference Report

PSI's 2022 Conference was held from 12th – 15th June at The Gothia Towers, Gothenburg, Sweden. This was our largest ever conference to date, with a record breaking 427 delegates registered (compared with the previous record of 409 who attended London in 2019). These 427 delegates represented 17 countries and just under 100 unique companies and organisations. Of the 140 attendees who completed the post conference questionnaire approximately 30% were new PSI members and 40% were attending for the first time.

As well as 3 days of presentations and interactive sessions there were also 2 pre-conference half-day courses. One course focused on Estimand-aligned statistical analyses of clinical trials and was presented by Dominic Magirr and Björn Bornkamp. The second course was A practical introduction to simulating complex trial designs. During this course Thomas Burnett and Thomas Jaki taught participants how to use R to construct simulation studies to evaluate the potential of complex designs.

We were delighted to welcome two keynote speakers; Jonas Haggstrom speaking on "Evaluating Therapeutics to reduce the effects of COVID -19 - a coordinated Global Research approach"; and Thomas Jaki "Mastering master protocols: some solutions and open questions".

In 2022 the SIGs were invited to run sessions at the conference. Thirteen SIGs took this opportunity. As the conference was taking place in a new location we also invited local statistical groups to run session based on their interests. The Swedish Society for Medical Statistics (FMS) ran a session and the Danish Society for Biopharmaceutical Statistics (DSBS) ran a session on Focused machine learning in the Pharmaceutical Industry. The parallel sessions based on contributed abstracts covered many diverse topics including decision making, estimands, adaptive designs, and analysing non-proportional hazards. Two interactive workshops were included in the programme and proved to be very popular. Clarie Brittain and Kim Harquoil ran a Professional Development Workshop on "Building A Fantasy Stats Team - Unconscious Bias". Sue McKendrick, Oliver Keene and David Wright from the EFPIA/EFSPI Estimand Implementation Working Group led an interactive and fun role play workshop on estimands. On the final day we had a Regulatory Hot Topics session with 4 representatives from regulatory agencies presenting on key topics in this space. The poster session was also a great success including the one minute poster presentations.

Regular updates were provided in advance of the event through a variety of methods including eNews, SPIN, LinkedIn and Twitter to increase overall awareness and enthusiasm. These combined with this being the first face-to-face conference for 3 years contributed to the very high delegate numbers. The conference app returned and this will continue to be the main way the conference content will be shared with attendees immediately before the conference and during the conference itself. The app included speaker and scientific committee member biographies and photos as well as the scientific programme, abstracts and updates during the conference itself.

The 2023 conference will be taking place from the 11th – 14th June at the Novotel London West in Hammersmith, London. The preparations are well underway, with all the sessions finalised and the majority of speakers identified. Information will continue to be shared regularly as we move closer to June. As we did last year, we have also put together a monthly conference newsletter and have agreed a communication plan to release more information on sessions before the event through LinkedIn and in the newsletter. The conference app is due to be launched in May.

David Lawrence
Conference Chair

Scientific Committee

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

In 2022, the scientific committee organized 10 events and webinars spanning a range of topics:
- Conference and pre-conference course on complex trial design (see conference report)
- PSI Webinar: Tipping Point Analyses - Introduction & Case Studies
- PSI Webinar: Statistical Challenges in Gene Therapy Trials
- PSI Webinar: Novel composite estimands and their analysis
- PSI Scientific Meeting: Adaptive Designs and their Application (hybrid – online and in person, University of Cambridge, UK)
- PSI Scientific Meeting: Use of R in Pharma (series of 3 webinars)
- PSI Webinar: Covariate Adjustment - Considerations and Examples

Training Committee

In 2022, the training committee successfully delivered 3 online training courses and one preconference course.

- PSI Training Course: Use of Historical Data in Clinical Trials: An Evidence Synthesis Approach
- PSI Training Course: Simulation of Clinical Trials using Tidyverse
- PSI Training Course: Hybrid Frequentist / Bayesian Power and Bayesian Power in Planning Clinical Trials
- Pre-conference course: Estimands (in person at Conference)

The online courses in 2022 worked well for delegates, and in 2023 the training committee are looking to continue offering some online and some in-person courses.

Journal Club Committee

The PSI journal club committee organises meetings feature 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 2022, the Journal club delivered 2 webinars. In 2023, we look forward to providing more journal club webinars to members and non-members.

2 Journal Clubs:
- PSI Journal Club: Treatment Switching in Clinical Trials
- PSI Journal Club: Estimating Treatment Effects

PSI Events Committee

So if you have been counting…..what were the other 30 events? So there are plenty of other organisers of PSI events which will be generally discussed elsewhere in the report – but if you were counting by event here are all our other events in 2022:

18 ESIG events:
- **Data Vis SIG** Wonderful Wednesday (series of 10)
- PSI **RWD** SIG Webinar: Real-World Evidence Submission - a Case Study in Lung Transplantation
- PSI **Pre-Clinical SIG** Webinar: Optimal experimental design in preclinical dose-response studies
- PSI **VIS SIG** Webinar: Collaborative & Exploratory Data Analysis
- PSI **Pre-Clinical SIG** Webinar: Assay Qualification by Linear Mixed Model: Confidence, Prediction & Tolerance Intervals
- PSI **Pre-Clinical SIG Workshop** 2022
- PSI **Pre-Clinical SIG** Webinar: Therioepistemology - Rethinking how we conduct animal-based experimentation
- PSI **Vaccine SIG** Webinar: Assessing Population Level Vaccine Effectiveness Under Different Study Designs
- Joint PSI & EFSPI **HTA SIG** Webinar: Statistics in EU HTA - PICOs, Estimands & More

10 Career events:
- PSI Careers - MEDMathS: Medicine Empowered by Data, Maths and Statistics
- PSI Medical Statistics Careers Event (March 2022)
- PSI Medical Statistics Careers Event – webinar
- PSI Careers - Lunch & Learn: The Floating Ladder
- PSI Career Young Virtual Meet
- PSI Career Young Virtual Meet #2
- PSI Careers - Lunch & Learn: Relaunchers
- PSI Careers - MEDMathS: Medicine Empowered by Data, Maths and Statistics #2
- PSI Medical Statistics Careers Event (December 2022 – in person)
- PSI Careers Lunch & Learn: Pharma-ly Fortunes

Rachael Lawrance
Events Director

SIG Report – March 2023

2022 was another busy year for our PSI/EFSPI European Special Interest Groups. Detailed reports are provided below from many of the ESIGs, it's always hard to pick out highlights for the annual report as there are so many to choose from! Our ESIGs were especially active at the 2022 Conference, leading sessions and contributing posters. The re-launched Biomarkers ESIG has got off to a flying start and it's great to see examples of collaborations between ESIGs, and I expect to see more in 2023. The ESIGs were also very active with webinars, workshops and publications and the detailed reports below highlight just how much they contribute.

Among the changes in 2022 we saw the closure of the COVID-19 ESIG, a change of leadership for the Benefit-Risk and Decision-Making ESIGs, and I was very pleased to welcome Emmanuel Pham as my EFSPI Council counterpart. It's been great to have Emmanuel's input and I'm looking forward to our ongoing collaboration.

As we head in to 2023 I'm pleased to say that a Randomisation Working Group, part of a DIA Innovative Design Scientific Working Group, is to be adopted as an ESIG, and I'm expecting another strong contribution at the Conference.

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

Adam Crisp, ESIG Director, PSI

AIMS – Martin Brown (PPD)

The **Application and Implementation of Medical Statistics (AIMS)** Special Interest Group's (SIG's) objective is to promote and contribute to researching the use of R in pharmaceutical, biotechnology and healthcare research. https://www.psiweb.org/sigs-special-interest-groups/aims

We have representatives from PPD, PAREXEL, GSK, PHASTAR, Eli-Lilly, Veristat, J&J, Roche, Incyte and Boehringer Ingelheim.

Our team members collaborate with various working groups, such as the R validation hub (White paper documenting the framework to assess package risk, riskmetric package and R shiny app https://www.pharmar.org), pharmaverse (Suite of R packages aiding SDTM, ADaM and TFL creation https://pharmaverse.org/), and other R Consortium working groups such as RTRS (looking at table creation), R Submissions Pilot (test submission in R to the FDA), and Comparing Analysis Method Implementations in Software (CAMIS) PSI/PHUSE initiative (looking at differences in statistical analysis results between different programming languages).

Our efforts help to ensure groups don't work in isolation, spreading knowledge of each groups work with the wider PSI and EFSPI community, with the hope this avoids duplication of effort and makes teams more efficient with the resources they have available.

Key Successes

- Ran a training course on R for Simulation of Clinical Trials using the Tidyverse
- Ran a PSI conference session entitled "A showcase of using R for regulatory work" covering:
  - Collaborations who are developing resources for using R for regulatory work
  - Implementing an R platform (CRO perspective)

- Implementation of an R platform for full submissions
- Clinical Statistical Reporting in a Multilingual World: Implementation of Survival Analysis in R vs. SAS
- Produced SPIN articles on "Best approaches to move between SAS and R" and for SIG of the Month

- Comparing Analysis Method Implementations in Software (CAMIS): AIMS have taken over leadership of the CSRMLW PHUSE working group renaming it as CAMIS and making advancements in the creation of an open source repository for storage of information which documents comparisons between how SAS and R implement analysis methods: CAMIS (psiaims.github.io). During 2023, the working group will be expanded with the main focus to advertise the repository and invite contributions from the wider community.

- Continued support of various R working groups including:
- R Validation Hub - Cran release of the package riskmetric and the associated R shiny app
R adoption series - number of webinars held on what R adoption has looked like in different companies.

Benefit Risk – Shahrul Mt-Isa (MSD), Marco Boeri (RTI)

The 2022 highlights for the BR SIG are the presentations at the PSI where we initially discussed the latest *Trends in Benefit-Risk Analyses* and how companies and other initiatives are tackling them. We also presented more specifically on *Pharmaceutical Statisticians' Views on FDA BRA Guidance* in its draft form that was published in September 2021, where we took the audience through the guidance content and also presented our public feedback on the draft guidance (Docket Number: FDA-2020-D-2316) that was submitted the previous year. We also collaborated with the HTA ESIG, who spoke about *BRA Implications of the new EU HTA (Health Technology Assessment) Regulation* that is expected to change the way BR assessments are viewed across regulatory and HTA submissions.

In 2022, we also refocused the SIG's objective to transition from writing a book to writing a series of manuscripts on preference-based benefit-risk assessment (pBRA). Specifically, the team reviewed the literature and started an outline for the first (introductory) manuscript. Other 3 manuscripts have been planned, topics were selected and external experts were sought for collaboration. The topic of pBRA from the first manuscript will be presented at the PSI Conference this year in London.

The team also worked on revisiting and restarting the paper on discrete choice experiments and sample size. Writing this paper will be beneficial for researchers who are planning a DCE study and need to justify their sample size decisions. Furthermore, the paper will be crucial when deciding which research questions can be answered with the available instrument and the sample size that is reasonably possible to achieve in the target population.

Maria Costa, who had been chairing the SIG for over 5 years, decided to leave the SIG due to conflicting priorities, and we thank her for her energetic leadership, contribution, and camaraderie. Shahrul Mt-Isa (MSD) and Marco Boeri (RTI) succeed Maria as the current co-lead of the BR SIG. Looking ahead into 2023, and under the new leadership, Shahrul and Marco plan to "re-launch" the SIG to recruit new members at this year's PSI Conference, refocus and align its work to current BR

trends, and increase collaboration. The team will focus on coordinating with external groups focused on benefit risk (examples are the ISPOR, ISPE and ASA SIGs on benefit risk). The team has already started this coordination and will meet with the ISPE SIG in March 2023. Coordination with other

external groups is also part of the plan. We continue to work on the manuscripts this year with a plan to submit them as a series to a journal by the end of the year. We are also discussing about alternative arrangements to replace our BR blog that we started a few years ago to provide more timely updates and information about our work to the public.

Biomarkers - Guillaume Desachy (AstraZeneca), Nicole Krämer (Boehringer Ingelheim)

In 2022, the Biomarkers Special Interest was brought back to life after a few years in hibernation mode. The SIG now counts 30+ members coming from industry and academia. Looking back, 2022 was quite an exciting year!

Here are some of the highlights:

- In April 2022, we had our kick-off meeting. Since then, the Special Interest Group has had monthly meetings, with 10+ participants joining the discussions.
- When the group first got together in 2022, things were kicked off with a brainstorming session, and three topics of interest for 2022 were identified.
  - Biomarker-based designs
  - Machine Learning for Biomarker Analysis
  - Identification of publicly-available datasets to create a data repository
- In May 2022, Nicole and Guillaume, the two co-leads, were invited by Alexander Schacht for an episode of The Effective Statistician podcast. The topic of this podcast was biomarkers and their importance in drug development: https://bit.ly/bm_esig_podcast.
- We represented the Biomarkers Special Interest Group at the 2022 PSI conference in Gothenburg, Sweden.
- Nicole and Guillaume had a Meet & Greet with the Subgroup SIG to discuss ideas for collaboration.
- We got ready for our first PSI webinar on Biomarkers in Clinical Development, which took place on January 19th 2023.

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

The CSM/QTL team kicked off its activities in 2021 bringing together members of PSI, EFSPI and ASA-Biopharm in a forum to collaborate and discuss strategies and methodology with other interested parties. The goals are to collate and summarise regulatory guidance and industry publications, presentations and training; develop best practice recommendations; and identify emerging methodologies and trends. The team have been very busy in 2022 setting up sub-committees working in parallel on the topics of CSM and QTL.

Summary of annual accomplishments:

- Review regulatory guidance and associated publications
- Awareness articles published in BIOP Report/PSI SPIN newsletters
- CSM/QTL discussion at ASA BIOP regulatory industry workshop. Roundtable held Sep'22.
- Methodology review papers for both CSM & QTL under development

- Sessions submitted for 2023: PSI 12-14 June 2023 conference and Duke Industry Stats symposium submitted DISS 2023 (virtual submitted session 'Empower Clinical Development by Harnessing Data from Diverse Sources', March 29-31)

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

Susan Talbot (Co&CSM-chair), Amgen	Tim Rolfe (Co-chair), GSK	Rakhi Kilaru (QTL chair), PPD
Magali Traskine, GSK	Chris Wells, Roche	Sonia Amodio, Danone
Sharon Love, UCL	Sheetal Chandarana, Roche	Kate Tomlinson
Wiktor Majewsk, GSK	Maciej Fronc, GSK	Gordon Thomson, Labcorp
Christopher Weir, Edin Uni ECTU	Monika Jelizaro UCB, UCB	Jonathan Rowe, ZS
Jingjing Ye, Beigene	Abhinav Balakumar, Novartis	Matilde Kam, FDA
Paul Schuette, FDA	Tina Wang, FDA	Lu Zhang, Lilly
Rob Davis, Roche	JianChang Lin, Takeda	Alicia Worrall, Abbvie

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

The decision-making SIG is currently a group of 25 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 is an ongoing working group focusing on QDM at the portfolio level with the objective to write a position paper on the topic. Gaëlle, who has chaired the SIG since its initiation in 2017, decided to step down as chair during the year and continue as a member of the group, we thank her for her leadership over the past 5 years and look forward to her continued support.

Highlights for the group include:
- Publication of two manuscripts on arXiv which cover awareness, use and practical aspects of QDM methods in the pharmaceutical industry.
- Awareness and use of quantitative decision-making methods in pharmaceutical development ([2203.00684] Awareness and use of quantitative decision-making methods in pharmaceutical development (arxiv.org))
- Implementation and practical aspects of quantitative decision-making in clinical drug development ([2207.07977] Implementation and practical aspects of quantitative decision-making in clinical drug development (arxiv.org))
- A QDM session at the PSI conference 2022 with 3 speakers: Daniel Bratton (GSK), James Salsbury (University of Sheffield / Novartis) and Amelia Thompson (University of Warwick / AstraZeneca).

HTA – Emma Crawford (MSD), Lara Wolfson (MSD), Anders Gorst-Rasmussen (Novonordisk)

During 2022 the HTA ESIG has been particularly active in regards to external engagement activities related to EU HTA. Please see below a summary of our achievements:

We submitted comments on behalf of EFSPI on 6 of the methodological EUnetHTA21 guidelines during their periods of public consultation (Mar - Oct).

We held an informal lunch-time catch-up at the PSI 2022 conference and also participated in Benefit-risk Session.

Met with Niklas Hedberg & Marcus Guardian (EUnetHTA21) in August.

On 14th September 2022, we presented 2 posters related to EU HTA at the 7th EFSPI workshop on Regulatory Statistics 2022. You can view the posters presented here --> EFSPI Regulatory HTA Workshop September 2022 - HTA SIG EU HTA Posters.

Participated in the ISPOR EU Endpoints Panel in November.

On 14th November 2022, we hosted a webinar "Statistics in EU HTA - PICOs, Estimands & More!". If you missed it, watch the recording on Video on Demand!

We have recorded a series of 4 podcast episodes with The Effective Statistician:

- Episode 1: What is EU HTA and why should statisticians care?
- Episode 2: What is the role of estimands in the EU HTA?
- Episode 3: Future implications of EU HTA and how Next Gen get involved
- Episode 4: What will be the role of health economics in the future EU HTA?

We submitted plans for 3 sessions at PSI 2023 conference (HTA parallel session, HTA Townhall, and joint session with Launch & Lifecycle eSIG) and had them accepted.

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

We participated in RWE4Decisions Sessions.

Launch and Lifecycle – Jenny Devenport

It was a great year for the Launch and LIfecycle SIG. Through engaging discussions and a survey of our members we were able to identify that there are a lot of shared opportunities. We meet on a monthly basis and speak about our challenges and approaches to solve them. Despite different cultures, company set-ups, indications, portfolios etc, our professional obstacles look very similar. And sharing how one person approaches them helps all of the others.

The SIG also contributed to several conferences this year including:

- The PSI Annual meeting - a lively 90 minute interactive session "Launch & Lifecycle SIG - are medical affairs the wild west of statistics" (https://psiweb.org/events/past-psi-events/2022/06/12/default-calendar/2022-psi-annual-conference)
- A poster at the EFSPI Regulatory Workshop (https://psiweb.org/docs/default-source/sigs/efspi_launch_liifecycle-poster-basel-2022.pdf?sfvrsn=337fa2db_0).
- We were also able to have our first face-to-face meeting in Basel after the EFSPI meeting. Capitalizing on the dynamic barcamp format, we were able to identify and thoroughly discuss topics of highest interest to the attendees and share a summary on the SIG website

  (https://psiweb.org/docs/default-source/sigs/efspi_launch_liifecycle-poster-basel-2022.pdf?sfvrsn=337fa2db_0)

Medical Affairs topics and SIG were also featured in several episodes of The Effective Statistician Podcast.

Some highlights include:
- 5 use cases for Network Meta-Analyses (https://theeffectivestatistician.com/5-use-cases-for-network-meta-analyses-you-should-know-about/)
- Publications in Launch & Lifecycle (https://theeffectivestatistician.com/publications-in-launch-and-lifecycle/)
- Training in Launch & Commercialisation (https://theeffectivestatistician.com/training-in-launch-and-commercialisation/)
- What is the current state of Launch & Lifecycle (https://theeffectivestatistician.com/what-is-the-current-state-of-launch-and-lifecycle-work-and-how-did-it-evolve/)

Finally, we kept our commitment to promoting collaboration with the other SIGs and have two joint sessions accepted for PSI 2023–one with RWD and one with HtA. In both sessions, we hope to highlight the value that statisticians can bring to the table. Our own LnL SIG session was approved for this meeting as well, and we will focus on the FACTIVE design and alternative approaches to evidence generation for stakeholders beyond health authorities.

Wishing everyone an impactful 2023!

Oncology Estimands – Kaspar Rufibach

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

Key achievements in 2022 are:

- General activities listed as achievements in last years below are continued by the group.
- Several publications of the SIG appeared or have been submitted this year.
- Two SIG papers published in 2021 were among the five most downloaded in Pharmaceutical statistics in 2021, see publications.

- The SIG gave many talks and organized sessions at conferences and webinars, see events. Some highlights:
  - An entire session organized by the SIG at the PSI conference.
  - The SIG organized two sessions at the ASA FDA workshop ("Adjusted and Unadjusted Estimate in Clinical Trials: Reward, Risk and Myth" and "Estimands in Oncology: A Topical Panel Discussion"), see events page.
  - DIA held a webinar in China, with a talk by Jiajun Xu from the conditional and marginal effect force. With a peak attendance of 4460 colleagues this likely sets a new record for a talk by this WG!
  - Together with ASA NJ chapter the WG is co-organizing a webinar ASA New Jersey Chapter Webinar Series: Getting the question right: Applying the Estimand and Target Trial Frameworks with External Controls.

- On June 28th & 29th we had two full group TCs with regulators attending where we presented our work. Slidedecks are available here.
- eunethta is currently seeking comments for their set of guidelines for a joint clinical assessment of European HTA bodies. Several of the WG's papers were cited in EFPIA's response to deliverable 4.5.
- As of November 2022, the SIG has 98 members (37 from Europe, 51 from US, and 10 from Asia) representing 48 companies / institutions, see status.

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

The Regulatory SIG has a total of 22 members from 8 countries and 19 companies. Our main activities in 2022 were the following:

- The Regulatory SIG hosted the Regulatory Hot Topic session at the PSI Conference, which was held 13-15 June in Gothenburg, Sweden.
- Several of our members served on the organizing and scientific committee for the EFSPI Regulatory Statistics Workshop (held 14-15 September 2022 in Basel, Switzerland). We also contributed to the poster session with a poster on the activities of the Regulatory SIG.
- On Wednesday 23 November 2022 we met with the MHRA statisticians. Continuing with the format used during the previous 2 years the meeting took place virtually, with 4 statisticians from the MHRA and 15 members of the SIG attending. The main topics of the discussion were planning for safety assessments, dose optimization in oncology and statistical methods for small populations. Detailed minutes from the meeting are published in the PSI eNews and the EFSPI Newsletter.

RWD – Josephine Wolfram (Astellas), Anny Stari (GSK)

The RWD SIG focuses on strategies and methodologies applied in the utilization of Real World Data in the pharmaceutical industry. The SIG welcomed several new members through 2022 and held meetings at least bi-monthly during which members shared case studies as well as presentations on initiatives, methods, guidelines and data sources.

A session was presented at the PSI Conference, Göteborg, June 2022: "Real World Data: Opportunities & Methodological Challenges".

A webinar was delivered on 22nd March:
PSI RWD SIG Webinar: Real-World Evidence Submission - a Case Study in Lung Transplantation (psiweb.org)

A presentation was given at the 2022 International Clinical Trials Methodology Conference (ICTMC), in Harrogate in October: "Leveraging Real-World Data for Time-toEvent Endpoints in Clinical Trials"

A blog with discussions on RWD topics and event highlights, "Let's T@lk Real Corner", was initiated with a first edition: Let's T@lk Real 19th December 2022

Represented (along with HTA SIG) EFSPI at RWE4Decisions roundtables.

If you are interested in joining please contact:
anny.x.stari@gsk.com
Josephine.Wolfram@astellas.com

Small Populations – Andreas Kaiser and Francois Aubin

In 2022 the SIG consists of 9 members.
The SIG held regular meetings on a monthly basis. Purpose of the meetings were to establish exchange of information and experience related to small populations including a forum to raise open questions if advice is needed. In addition, the meetings offered the opportunity to present on a specific statistical topic like dynamic borrowing of external data by shrinkage estimation (Tim Friede).

In 2022 the main activity of the SIG was on writing an introductory document on what is specific to the design and analysis of clinical trials in small populations and what challenges are encountered. The document addressing statisticians who become new to the area of small populations. Basic points to consider in clinical development for small populations were addressed and potential useful statistical

approaches were proposed in this document. The document was finalised in December 2022 and made available on the SIGs Webpages: Small Populations Points To Consider

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Subgroup Analysis – David Svensson

The year saw a lot of activity within the SIG. First of all, we had eight regular meetings where participants presented material on recent methodology; these included novel aspects regarding Bayesian shrinkage, resampling for consistency assessment, optimal assignment of patient to treatment (ITR approaches), Bayesian Causal Forests, Modified covariate approaches for estimating individual treatment effects. It is worth mentioning that these meetings often are very lively, resulting in with many interesting discussions and email loops afterwards; the SIG is for promoting knowledge sharing and collaborations across the industry, and - indeed - this is also what happens in the reality.

Furthermore, the SIG also had a meeting where the Biomarker SIG co-leads visited us, telling us about the scope and work of this new SIG. We discussed how our SIGs are likely to have both some similarity and some differences regarding scope; we agreed we will run a joint meeting during 2023 and make sure there are some informal channels between the SIGs. Another 2022 activity worth mentioning within the Subgroup SIG – perhaps the most important aspect – is the research work (writing joint papers) that has developed among certain configurations of members. Some papers were submitted/appeared during the year, and several papers are in the making. It is worth

mentioning that there has been a tremendous general research activity in the causal inference area in the last years; many novel approaches have been proposed for estimating individual treatment effects (and related aspects such as dynamical treatment rules), and some of this come from researchers in other industries. Their applications are different, but still the techniques and inherent problems are much relevant to our industry, and the SIG is following the developments with a great interest. E.g., Bayesian Causal Forest is such an approach. Another is the class of meta learning approaches where the key aspect is not so much about what type of machine learning to use (Random forest? Xgboost? Penalized regression?) but rather more how to apply these schematically speaking (e.g. using separate models? Cross fitting?) and how to derive useful information from such models (parsimoniously defined subgroups, versus more 'black box' subgroups).

Apart from keeping a focus on novel data driven subgroup identification, there still are lots of unresolved considerations regarding the more classical assessment of pre-specified subgroups (and we take the chance here to remind that the SIG is covering all aspects regarding such apart from formal confirmatory testing under strong control). Another major 2022 event was the Subgroup session at the PSI conference in Gothenburg, where Björn Bornkamp and David Svensson were SIG speakers (together with 'special guest' Stefan Franzen); many other SIG members were also present at the conference, giving plenty of opportunities to catch up.

We are pleased to insert here that there will be another such SIG session in London 2023; we were able to fully plan that session already in October thanks to the volunteering and very active SIG members. These talks are all co-work within the SIG, and although the presentations themselves take place in 2023 the work behind it started already last year. The talks will cover Honest estimation, Good and Bad approaches for detecting a subgroup, and simulation benchmarking.

Adam Crisp
SIG Director

PSI Volunteers

CALC 2022

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

[1] Left CALC in 2022
[2] Joined CALC in 2022

Professional Development Committee

Name	Company, country	Role
Xinyi Zhu	GSK, UK	Chair
Marius Sieverding	Veramed, Germany	Book Club lead
Agne Zarankaite	GSK, UK	Book Club
Alun Bedding[1]	Roche, UK	Mentoring lead
Zainab Walsh	Veramed, UK	Mentoring lead
Sophie Barthel[1]	PRA, Germany	Events/Mentoring
Claire Brittain	UCB, UK	Lunch & Learn co-lead
Chetan Mistry	Veramed, UK	Lunch & Learn co-lead
Jemma Greenin[2]	Veramed, UK	Career Young Statisticians lead
Rebecca Randhawa[2]	Amgen, UK	Career Young Statisticians
Oswald Dallimore[2]	UCB, UK (placement student)	Career Young Statisticians
Katie Thorn[2]	GSK, UK	Events

[1]Left committee during 2022
[2]Joined committee during 2022

ITIT Committee 2022

Name	Company, Country	Role
Zelie Bailes	GSK, UK	Chair
Gareth Thomas	IQVIA, UK	Treasurer
Ruth Lowe	PPD part of Thermo Fisher Scientific, UK	Member
Sophie Hodge	Bayer, UK	Member
Hoi-Shen Radcliffe	Bayer, UK	Member
Sam Ruddell	Cromsource, UK	Member
Mahesh Shivhare	Roche, UK	Member

Membership and Community Committee

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

Communications Committee

Name	Company
Steve Jones	Medable
Jakob Holton	Amgen
Jack Elkes	Imperial College
Josh Williams	Amgen
Oceana Faria	LabCorp
Sophie Greenwood	Aberdeen University
Kieran Breathnach	Amgen
Priya Gokani	Amgen
Marta Kwiatkowska	Evidera
Elena Mourouli	Veremed
James Oyee	GSK
Jamie Rees	Compass Pathways
Karan Vadher	Lilly
Leanne Winzer	AstraZeneca

Events Committee

Name	Company, Country	Role
Rachael Lawrance	Aldelphi Values, UK	Chair
Tobias Mütze	Novartis,	Scientific
Mary Elliot	Amgen, UK	Training
Steve Jones	Medable, UK	Communications Committee
Sam Hadlington	Plus-Project, UK	Careers
Ian Ratcliffe	Veramed,	
Stefanie Ernst	Paraexcel,	

Conference & Scientific Committee

Name	Company, Country	Role
Tobias Mütze	Novartis	Scientific Chair
David Lawrence	Novartis	Conference Chair
Paul Terrill	PT Stat Consulting Ltd	Conference Vice-Chair
Kate Taylor	Amgen	Conference Vice-Chair
Rachael Lawrance	Aldelphi Values	PSI Events Director
Amitava Mukhopadhyay	MorphSys	
Jennifer Gilbride	GlaxoSmithKline	
Julia Niewczas	Janssen	
Julia Saperia	MHRA	
Kate Taylor	Amgen	
Kristina Weber	Roche	
Maria Efstathiou	IQVIA	
Martin Jenkins	AstraZeneca	
Rosie Leach	Parexel	
Russell Jones	Calliditas Therapeutics	
Sarah Williams	Roche	
Sue Todd	Reading University	
Teodora Trasieva	AstraZeneca	
Tom Burnett	Bath University	

Training Committee

Name	Company, Country	Role
Mary Elliott-Davey	Amgen	Chair
Alison Patten	Eisai	
Gemma Hodgson	QI Statistics	
Margaret Jones	UCB	
Rimgaile Urbaityte	GSK	
Charlotte Snape	Veramed	
Ellie Grainger	AstraZeneca	
Fahmeeda Sheikh	PPD	
Kerry Gordon	Parexel	
Caroline Kennedy	AstraZeneca	

Journal Club

Name	Company, Country	Role
Priya Gokani	Amgen	Chair
Jens-Otto Andreas	UCS+B	Co-Chair