



Annual Report 2021

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Welcome from the Chair

In 2021 PSI continued to be impacted by the COVID-19 pandemic

We learned a great deal in 2020, the year the COVID-19 pandemic started, but the pandemic continued to have an impact on PSI through 2021. Despite this, we continued to offer members a broad range of activities to support career development and allow sharing and discussion of important statistical and scientific topics. All events were held online given the continued home and hybrid working and minimal/limited business travel, but events were well attended, highly valued and run to a high standard. Most events were recorded and available to members through the Video on Demand (VoD) platform.

A new board structure was rolled out in 2021 and this has led to the board being more efficient and effective. Consolidating all events under a single Director has led to increased transparency of all PSI activities with easier and quicker oversight and bringing more consistency to event planning. The communications and external affairs committee took on the role to oversee the digital strategy and this has been identified as a key area of focus in a new 2022-2023 business plan.

I would like to highlight a few key areas for 2021, but please spend some time to read through the full report. I would like to thank our many volunteers (board and committee members) who have made this possible;

- We made a loss of £23k in 2021 but our reserves are still healthy (£289k). We aim to have reserves of at least £300K so the board are looking for new opportunities to generate income whilst effectively managing operating costs.
- MCI have provided great support to the board in 2021 and the board continues to partner closely with MCI to seek ways of making processes supporting PSI business as efficient as possible.
- We had 1443 members in 2021, the highest in the last 5 years and this growth in membership has enabled PSI to be represented in 49 countries. A new membership platform, GlueUp, has led to significant improvements in the membership renewal process and more effective reporting of membership data.
- The new Careers Committee has expanded its remit to include a new Professional Development Committee (PDC) in addition to continuing the very successful Careers and Liaison Committee (CALC). The PDC successfully launched a new mentoring scheme, a book club and a careers lunch and learn series. CALC ran their first online Medical Statistics Careers Event, first MEDMaths event, and launched their first Student Newsletter. The new Medical Statistics Level-7 Apprenticeship was approved by the UK Government.
- The COVID-19 pandemic continued to impact sponsorship income led by the Commercial team. Thanks to all the sponsors who contributed to generating £20K profit from the conference and for providing feedback in how PSI could further evolve the sponsorship model allowing for more engagement between sponsors and delegates at future conferences. In addition, new sponsorship opportunities will be introduced in 2022.
- The communications committee have expanded their activities to develop statistics on both website and social media connections. Improved tracking is enabling committees to better use the google analytics platform and maximise engagement with members and non-members. A variety of discussions took place towards the end of 2021 to inform and evolve the Digital Strategy, ensuring PSI is maximising all the great content and which is accessible to all members, and to promote the value to entice new members to join.
- The new Events Committee, bringing together the conference, scientific and training committees, had a busy year with a total of 43 events in addition to running another very successful virtual annual conference. The



highest number of events related to communicating statistics, efficient trial design and operations, career development and advanced statistical methodology.

- The 2021 conference was the first fully online conference using a bespoke conference platform. A full conference program was able to be included, with a total of 433 registered attendees. Well done to the conference team for the high quality and diverse topics covered in the program, and for the extensive testing of the new platform with MCI.
- There were 20 eSIGs, European Special Interest Groups supported by PSI and EFSPi in 2021, including the Regulatory eSIG which was renamed from a committee to an eSIG. Each SIG was very active in 2021 arranging webinars, writing white papers, and presenting work at conference and scientific meetings. New eSIGs were launched covering Real World Data and Launch and Lifecycle. The Biomarkers eSIG plans to relaunch in 2022.

Awards:

- The RSS/PSI Award for Statistical Excellence in the Pharmaceutical Industry continues to establish itself as a prestigious award. This is awarded each year 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. Lisa Hampson (Novartis) won in 2021 for “Improving the assessment of the probability of success in drug development: A holistic framework encompassing statistical significance, regulatory approval, and market access”.
- The Mick Godley Award to recognise the unsung heroes of PSI went to Lyn Taylor who is the chair of the AIMS SIG to recognise her significant contributions to the new Medical Statistics Level-7 Apprenticeship. Congratulations Lyn!

2021 was another challenging year with the continuing COVID-19 pandemic. However, I think we should all be extremely proud of PSI as an organisation that continues to add tremendous value, share experiences and learnings, and offer opportunities for personal growth. Thanks again for all the support to PSI.

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

Chrissie Fletcher, PSI Chair





Treasurer's Report

The 2021 professional audit is ongoing and several items, such as VAT reimbursement, are pending, so the following numbers are subject to change. During 2021, PSI made a loss of around £23k. This result is in line with the loss of £15k projected in the annual budget in January 2021.

Our reserves now stand at £289k. We aim to have reserves of at least £300k, which is expected to ensure the continued operating of the society even in case of substantial shortfalls on the income side. As such, PSI is still in a robust financial state for the continued uncertainty in 2022, but there is a need to look for new opportunities to generate income, as the operating costs are fairly fixed.

Major drivers of the 2021 result

PSI has a number of fixed costs to operate the society, including our contract with MCI as well as IT systems, accounting, and legal fees. These are partly offset by membership fees, but not fully. The remaining income must come from activities, where events and especially the conference have historically made the biggest contributions. The continued need to rely on virtual events has limited the ability to generate income and driven up costs, due to the necessary investments into digital platforms. Despite these difficulties, the conference has generated a surplus of £21k and showed PSI's ability to adapt together with our volunteers and MCI as a strong partner. Similarly, events have provided additional income. Unusual expenses in 2021 include the inability to fully recover VAT due to insufficient UK income on which VAT was paid and relatively high costs for organising digital events.

2022 budget

Initial budget predictions for 2022 indicate a small net positive result. The increased membership fees and strong membership numbers are expected to make a bigger contribution to our fixed costs than in previous years. If a physical conference can be held in 2022, this is expected to be a major driver to bring PSI back to achieving our target reserves. However, if a cancellation is required very close to the event, many contracts cannot be cancelled and substantial losses would be expected. Moving the conference to virtual should help partly offset some of these losses, but is not expected to fully cover them if a cancellation were to happen very late.

2021 income overview

Profit (£k)*	2016	2017	2018	2019	2020	2021
Membership	58	72	72	75	83	89
Conference	124	65	116	49	-22	21
Training & ITIT	18	22	19	24	22	36
CALC	3	11	-1	0	10	4
Scientific	9	11	3	16	-4	16
Publications	-18	-16	-5	-8	-8	-3
Commercial	100	86	97	83	0*	0*

Rounded to the nearest £1k. 2021 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 and 2021 accounts.



Markus Elze
Contracts and Finance Director





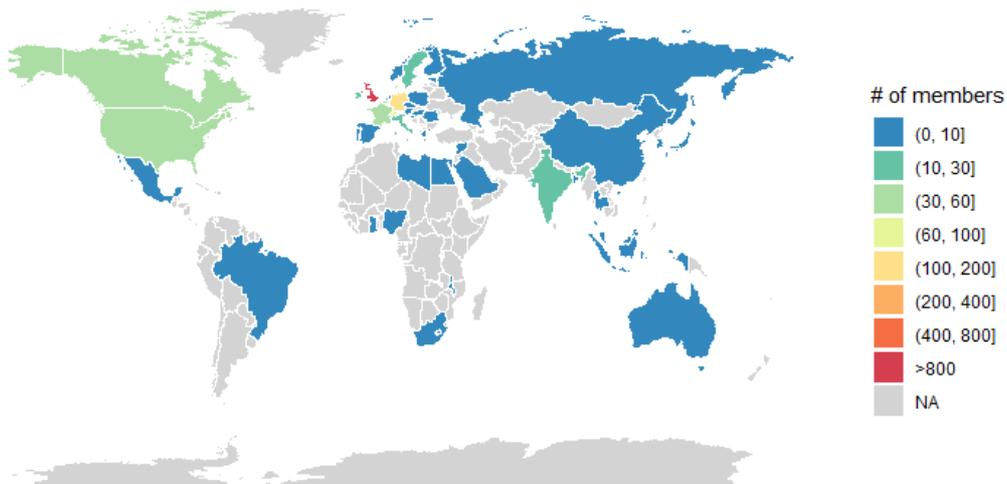
Membership Report



Thank you to our members for your continued support and for MCI's efforts rolling out GlueUp, our new membership platform, and corporate renewal processes. We have no doubt that the combination of these efforts has resulted in a much more efficient renewal process for all.

Membership Category	2017	2018	2019	2020	2021
Full	861	959	1070	867	1134
Honorary	9	9	9	11	11
Reduced Rate	13	8	21	25	22
Student/Teacher		98	172	268	276
Total	883	1074	1272	1171	1443

Despite the challenges on COVID-19, we made significant progress in our focus areas, particularly in terms of international growth. PSI is now represented in 49 countries across the globe.





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.

We, the Membership & Community Committee, now aim to continue to build and nurture a collaborative PSI community with more actively engaged members across the globe.

Kate Tsirtsonis
PSI Membership Director





Careers Report



2021 saw the creation of the Careers section to PSI which maintained the fantastic work from the well established **CALC** team and expanded to form a **Professional Development** team focusing on support for PSI members in the industry.

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



PSI Medical Statistics Careers Event 2022

CALC held the very first online PSI Medical Statistics Careers Event on March 3rd, 2021, utilising the virtual platform Career Fair Plus for the exhibitor session. Over 110 students attended from 40 universities, and they were able to talk to representatives from 24 pharmaceutical companies, CROs, clinical trial units and industry organisations. 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.



PSI CALC also hosted the first ever MEDMathS (Medicine Empowered by Data, Maths and Statistics) event on Wednesday 10th November. This brand-new webinar was targeted at undergraduate and postgraduate students, to introduce them 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. Over 100 highly engaged students attended from a wide range of backgrounds. 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. We plan to run this webinar biannually in the future.



PSI Student Newsletter



CALC were also pleased to launch their very first PSI Student Newsletter! 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, and the plan is to distribute this each term going forward. In addition, two PSI Undergraduate Awards were given to mathematics/statistics students at the Universities of Reading and Glasgow.



Institute for Apprenticeships & Technical Education

Members of PSI (specifically Lyn Taylor and Jim Saul) have been instrumental in the approval of the new [Medical Statistics Level-7 Apprenticeship](#) by the UK Government. This has been an extensive amount of work and the new apprenticeship will be an important new option available to educate and train the next generation of medical statisticians within the UK.

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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

In 2021, the committee was formed and set out its vision and objectives (short and long term). As part of this they launched two new initiatives: a mentoring scheme and a book club.



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.

A total of 14 mentees registered from pharmaceutical companies, CROs and other industry organisations for the first cohort. After 6 months we plan to match another cohort of mentors and mentees so there will be an opportunity for more PSI members to benefit from this scheme.



The book club is aimed at reading and discussing non-technical books relevant to the industry. The first book chosen by members was [“The Chimp Paradox” by Professor Steve Peters](#). 15 participants registered and were split into three 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. Overall, feedback of this approach was positive, especially as it allowed

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each group to become more familiar with each other and cover the concepts in depth. Planning is already underway to run this periodically through 2022.

Other Events/Courses and Activities

In September the Careers team ran a [Leading for Impact Workshop](#) in partnership with the Training Committee and delivered by our partner [JCURV](#). The interactive workshop was aimed to help people explore what might be holding them back and work to strengthen their leadership capability. Feedback was very positive and attendees valued taking the time to step back from their every day work to self-reflect on this topic.



After a very successful [lunchtime conversation event](#) with leaders in the industry (Chrissie Fletcher and Andy Grieve) at the beginning of 2021, and as part of the formation of the expanded Careers group within PSI, a new Careers Lunch and Learn event was piloted at the end of the year.

The session focused on [Imposter Syndrome](#) and had a panel of 4 people from within the industry talking about the topic. The session received great feedback and the plan is to run these quarterly in 2022 with a different topic each time.

Finally, the Careers team have also been busy updating the [PSI Careers website](#). The revamped website now encompasses careers information for schools and universities, as well as those working in industry, and provides a single source for news, information, resources relating to professional development and careers in medical statistics.

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 first contribution to the PSI annual report as Commercial Director. I would like to begin by thanking my predecessor, Alexander Currie (GSK), for supporting my transition in to the role and for his astute handling of commercial activities during a very difficult period for PSI.

From a commercial perspective, it is fair to say the past two years have been challenging. Aside from membership fees, PSI derives much of its earnings from registration and sponsorship of the annual conference. Due to the COVID-19 pandemic, the annual F2F conference has been replaced by an online/virtual conference for the past two years. This has had a dramatic impact on revenue from sponsorship related income alone, down by more than 80% in 2020 and 10% in 2021. Nevertheless, we were able to run a successful and profitable conference in 2021. Thanks to the support from all of the sponsors, we were able to generate £20K in profit from the conference.

When I took on the Commercial Director role, it was clear the sponsorship, as opposed to advertising, was an area that would have the greatest impact to PSI. PSI simply cannot continue to 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. From talking to previous sponsors, it was clear that the conference delivers value in terms of knowledge sharing, professional development and recruitment but perhaps was not so successful for developing new business opportunities. This year, we are implementing some changes to facilitate better engagement between sponsors and delegates at the conference. As a result of the changes, and the pent up demand for in-person meetings, I am pleased to report that we have secured sponsorship from companies who have never previously been involved in the conference. In addition, sales of sponsorship packages are currently exceeding those from any previous PSI conference. This bodes very well for the conference this year and for future sponsorship income.

Looking forward to 2022, I will continue to introduce new sponsorship opportunities for other PSI events and to offer new packages with more consideration of sustainability and the environment. 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 Watton Hall and by John McKellar (Resources for Business) and Salih Siam (Genpro Research).

Aiden Flynn
Commercial Director





Communications Committee Report

In 2021 the team grew, allowing the committee to focus on generating report summaries of both the website data and the social media outreach which we can start to share with other teams on the committee to understand our virtual audience. In the social media workflow, Oceana and Marta have now also integrated the use of UTM tracking links. This means we have better insight into which specific posts drive traffic to the website. We have also led several drop-in sessions to help other committees learn about the google analytics platform and promote better use of these metrics by other committee groups.

The pandemic and its impact on the format of the annual conference has had an impact on the activity of the Conference Reporter team (this team aims to help the conference chair and the scientific committee with all the communication before, during, and after the event). Further impact on attendance at the 2022 Conference is unknown, and in order to be confident in the attendance at conference of sufficient team members, this team is aiming to grow in 2022 - if you are interested in finding out more, then please contact Anastasiia, Elena or Leanne.

The communications committee also implemented tagging to track how individual links shared via different channels and different styles affected the traffic to the homepage, which we now track via google analytics. In 2022 it is aimed to further expand the use of tagging to SPIN and other member communications.

In 2021, the committee started an evaluation of the attractiveness to PSI Members of the quarterly SPIN magazine, both in terms of content and format. At the end of 2021 a brief survey was sent to members - unfortunately the response rate (fewer than 100 completed surveys) was poor. This will be an ongoing project for 2022.

Objectives for 2022;

- To develop our marketing strategy to ensure a consistent brand image for all our digital outreach, and to generate a more engaged community. This will include:
 - Researching what strategies are used by other similar organisations for their social media outreach.
- To increase the volume of articles being written for SPIN from ALL Committees and SIGs
 - Develop and test different creative posts to determine which strategies drive engagement
 - Review and update the social media guide
- Develop monthly reports for website and social media that can be shared with other teams and eventually other committees.

SPIN's Jamie Rees (GSK) is swapping seats. We are currently looking for new members to help with SPIN. Please contact Jamie Rees at jamie.c.rees@gsk.com to chat about this opportunity.

Stephen Jones

Communications Committee and External Affairs (and EFSPi) Chair





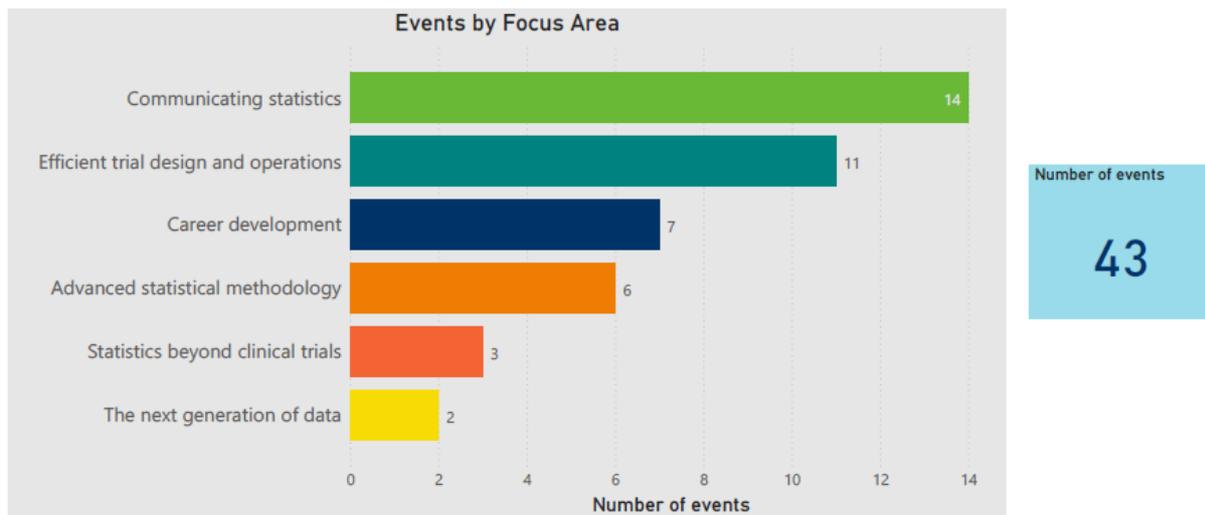
Events Report

At the June 2021 AGM, I was elected as board member for PSI events – incorporating activities of the conference committee, scientific committee and training committee. These committees continue to operate and have provided further information below of their achievements in 2021.

Overall, PSI offered a diverse programme of scientific events – a total of 43 different events – from conference, to SIG webinars, to scientific meetings (online) and training courses. Although events were online in 2021, various formats were used including some with interactive nature allowing participants to be really engaged. Numbers of attendees at the events ranged from 400 at conference, around 300 at EIWG webinars, 200 at journal clubs; 50-100 at scientific and SIG topic webinars and 20-40 at interactive training courses/webinar series. Introducing a coordinated programme of events for PSI has helped to ensure a high standard of PSI events as well as better communication of the events and topics to members and non-members alike. Most of the events were recorded and recordings are available to PSI members on the VoD platform – a valuable resource for members to be able to catch up on great scientific content.

And for 2022 – the programme of events – all high quality – continues to expand – thanks to all the event organisers across PSI/EFSPI and especially thank you to speakers/presenters at all these events.

PSI Events 2021



Conference Report

Paul Terrill , 2021 Conference Chair , David Lawrance & Kate Taylor, 2021 Conference vice - chairs

PSI's 2021 Conference was held from 21st-23rd June. This was PSI's very first fully online conference using a bespoke conference platform software, due to the ongoing coronavirus pandemic. Whilst the 2020 conference was very much an abbreviated version of a conference, in 2021 the PSI Scientific Committee strived to give the same amount of excellent content as you would find at a usual face to face event. This was in fact our largest ever event with a total of 433 registrations (533 if you include exhibiting staff).

The agenda included many hot topics and case studies. The three days were a mixture of three plenary sessions, 27 parallel sessions and around 70 speakers. We were delighted to welcome three keynote speakers; Alan Smith and Ian Bott spoke around their experience of visualising the pandemic with a very engaging talk on how they have used a huge variety of visualisations in their work with the Financial Times to engage and educate their readers on the COVID-19 pandemic. Janet Wittes spoke on the topic of designing trials for orphan and ultra-orphan indications and how trials in such areas should not be designed as miniature versions of a large randomised control trial and the different types of controls that are suitable in such small populations.

As well as our two keynote talks, we had a Regulatory session with 3 representatives from regulatory agencies and industry giving talks on a variety of regulatory based topics. The parallel sessions covered topics ranging from expanding our influence, Bayesian statistics, treatment effect heterogeneity, early phase decision making, innovative trial design, estimands case studies, the use of R in a regulatory setting and data science best practices. Due to the conference attracting an even more global audience than ever before we also had a session organised by the IASCT and another by statisticians in Canada on collaborative research. We also had 2 discussion sessions, where no presentations were given but the time allocated simply allowed a forum for attendees to discuss the topics of IDMC experiences and the importance of collaboration in outsourcing.

The platform used for the conference material also went down very well with most delegates. It required a lot of testing and hard work, so it was great to see it functioning well and the ease of finding whatever was needed. Delegates who registered for the conference could also go back platform to go back and watch any of the sessions they missed at the time. In 2022 the sessions will be moved on to the PSI VoD platform for all members to view.

As it was in 2020, the social element of the conference was very different to previous years, but the conference provided delegates with the access to yoga sessions on two mornings as well as a comedy performance for all the family by Steve Royale on the Tuesday evening. The conference platform also used a website called Wonder which allowed delegates to interact in groups socially via video and it was also used in the evenings to enjoy the social elements of a conference that are so important to so many.

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, which contributed to the high delegate numbers. There was also excellent support from companies in regard to sponsorship, with many high-quality interactions and meetings taking place and each company able to upload their details and videos etc to the platform. Delegates were encouraged to have as many interactions as possible through a competition based on a points leadership board.

The 2022 conference will be taking place from Sunday 12th – Wednesday 15th June at Gothia Towers in Gothenburg, Sweden. The scientific committee organises both conference and other scientific meetings throughout the year.

Scientific Committee Report

Tobias Mütze, Scientific Committee Chair

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 2021, we organized five online events and webinars spanning a range of topics:

- Generating Insights through Modern Applications of Data Visualisation
- Missing Data in Clinical Trials - Past, Present and Future
- Non-proportional hazards and applications in immuno-oncology
- Wearable Technologies - Challenges and Opportunities
- Oncology Ted Style Talks



The recordings and slides of these event are available to members through PSI's Video-on-Demand platform.

At the start of 2022, we have planned webinars on tipping point analyses, statistical challenges in gene therapy trials, and composite estimands. In 2022 we will resume organizing in-person events including an event on adaptive designs and multiplicity, but also continue offering online and hybrid meetings on theory and application of innovative methods in the pharmaceutical industry.

A big thank you to all members of the Scientific Committee for their effort and work during 2021. 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.

Training Committee Report

Mary Elliott-Davey, Training Committee Chair

The PSI training committee aims to meet the educational needs of the PSI membership. We run 4-5 courses per year, including the pre-conference course. Course topics range from core statistical topics to new and advanced methodology.

In 2021, the training committee successfully delivered 4 virtual training courses. Topics covered included R, Data Monitoring Committees, and Repeated Measures and Mixed Models. The R course in May was so popular that the course was repeated in November. Moving to a virtual platform was a big challenge, and it was unfortunate that delegates were not able to realise the networking opportunities which come with a face-to-face course. However, PSI is delighted to still be able to offer high quality training courses to support its members in their careers. The committee have a broad range of topics in the pipeline for 2022. Courses will continue to be virtual but the committee hopes that face-to-face events will be possible soon.

Rachael Lawrance

Events Director





SIG Report – March 2022

2021 was another busy year for our PSI/EFSPi European Special Interest Groups. In February, Gaëlle Saint-Hilary and I co-hosted a SIG Leader Meeting, bringing together many SIG leaders to connect with each other and discuss ways of working. Gaëlle has been my co-lead for SIG liaison on behalf of EFSPi for several years but has recently stepped down from the role. My thanks to Gaëlle for all her support. There was another notable change of leadership this year, with Gareth Thomas stepping down as long-term lead for the Pre-Clinical SIG (formerly known as the Toxicology SIG). Gareth has done a fantastic job, and the baton has now been passed on to Eloisa Brook. I would also like to acknowledge and thank Fabian Tibaldi and Jack Eusden who are stepping down as leads for the Vaccines and New Starters SIGs respectively, and Ray Harris, one of the longest-serving members of the Data Sharing SIG, who has left due to retirement.

It's always great to see the enthusiasm from the wider community to drive the SIGs forward. In 2021 the Real World Data SIG was launched under the leadership of Anny Stari and a new Launch-and-Lifecycle SIG was started under the leadership of Alexander Schacht and Jenny Devenport. Also the Centralised Statistical Monitoring/Quality Tolerance Limit SIG got fully up and running and is now an official collaboration with EFSPi and the ASA Biopharmaceutical Section. And although it strictly qualifies for the 2022 report, I'm delighted to note that Guillaume Desachy and Nicole Kraemer are re-launching the Biomarkers SIG. This is very timely, given the considerable growth in opportunity to apply advanced analytical methods in this area.

The detailed highlights from many of our SIGs are a great testament to how impactful the PSI/EFSPi SIGs are. A truly impressive collection of webinars, training courses, publications, workshops, regulatory interactions and so much more. Thank you to everyone involved! And if you'd like to find out more, please visit the SIG webpage at www.psiweb.org.

Adam Crisp SIG Director



AIMS – Lyn Taylor

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

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

The Medical Statistician Apprenticeship Scheme is now live. Employers can start the process to recruit an apprentice and register them onto the scheme to start in September 2022. The apprenticeship standard can be found here: <https://www.instituteforapprenticeships.org/apprenticeship-standards/medical-statistician>. For more information see: <https://www.psiweb.org/careers/educationandresources/medical-statistician-apprenticeship>

COVID-19 – Chrissie Fletcher (GSK), David Wright (AZ)

The COVID-19 ESIG was formed in the summer of 2020 to provide a forum for sharing experiences of statistical and methodological issues relating to clinical trials impacted by COVID-19, clinical trials investigating new treatments for COVID-19 and diagnostic/antibody tests for COVID-19. The members of the ESIG include statisticians from Industry, Academia and Regulatory Agencies. In addition, a collaboration was also formed with the Vaccines ESIG so information relating to the design of clinical trials investigating COVID-19 vaccinations and results from these trials could be shared and discussed.

In 2021 the COVID-19 ESIG continued to meet monthly to discuss latest news and trends relating to clinical research in the era of the COVID-19 pandemic. Building on the work achieved in 2020, the ESIG focussed on the impact of the availability of COVID-19 vaccines to ongoing and planned clinical trials, and the increased use of decentralised trials accelerated by the COVID-19 pandemic including key statistical and data considerations. Through various scientific forums, such as the PSI conference and other Industry webinars, ESIG members contributed to sharing experiences of designing trials to assess new treatments and vaccines for COVID-19 and sharing results of additional analyses to assess the impact of the COVID-19 pandemic following the best practices recommended in 2020.

At the end of 2021, the ESIG agreed the key objectives had been achieved, and instead of holding regular monthly meetings, ESIG members decided to remain connected via email. The final activity for the ESIG in 2022 will be to lead a COVID-19 session at the 2022 PSI Conference allowing further sharing of more case studies and key lessons learned in developing new treatments and vaccines for COVID-19 and analysing and reporting clinical trials during the COVID-19 pandemic.



Thanks to all the members of the COVID-19 ESIG for their support and contributions.

Christine Hicking	Merck
Lars Endahl	Novo Nordisk
Marcel Wolbers	Roche
Andrea Schulze	Bayer
Achim Guettner	Novartis
Khadija Rantell	MHRA
Marie-Laure Casadebaig	BMS
Rene Kubiak	Sanofi
Lucy Keeling	Exploristics
Chrissie Fletcher	GlaxoSmithKline (co-lead)
David Wright	AstraZeneca (co-lead)

CSM/QTL – Tim Rolfe (GSK), Susan Talbot (Amgen)

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

Data Sharing – Rebecca Sudlow (Roche)

The ESIG has focused on the potential uses of synthetic data and published a paper 'Synthetic Data Use: Exploring use cases to optimise data utility' in the globally peer reviewed journal: Discover Artificial Intelligence. Synthetic data is a rapidly evolving field, the pharmaceutical industry is starting to realise the value of synthetic data which is being utilised more prevalently as a method to optimise data utility and sharing. Following on from this the ESIG is organising a parallel session at the 2022 conference on this topic "Get Real with Synthetic Data".

The ESIG has diversified its membership via connections with the MRC-NIHR Trials Methodology Research Partnership (TMRP) to work together with their special interest group on data sharing. We also connected with the European Medical Writing Group (EMWA) Regulatory Public Disclosure Special Interest Group (RPD SIG) for discussions on document anonymization (a component of the EMA CTR requirements).

Ray Harris, one of the longest standing members of the ESIG, left due to retirement. Thank you Ray for all your contributions over the years!

Decision Making – Gaëlle Saint-Hilary (Saryga)

In 2021, the eSIG Quantitative Decision-Making (QDM):

- Submitted 2 manuscripts on the awareness, the use and practical aspects of QDM methods in pharmaceutical development.
- Organised a session on "Probability of success and beyond" at the PSI conference, with 3 speakers: Fredrik Öhrn (AstraZeneca), Damien Chimits (UCB) and Jane Temple (GSK).
- Created a new working group on Quantitative Decision-Making at the Portfolio level. The first objective of this working group is to perform and publish a literature review on the topic.

Few members left the eSIG and new members joined, so we remain a motivated group of 19 members from industry and academia. We maintain our awareness on QDM methods by having presentations of internal members or external guests at each of our plenary meetings, every two months.



Historical Data – Nicky Best (GSK), Simon Wandel (Novartis)

The main focus for the Historical Data SIG in 2021 has been to prepare a briefing book which was submitted to the EMA Innovation Task Force (ITF) on the topic of “**Bayesian Dynamic Borrowing : a framework to engage with Regulatory Authorities**”. On Nov 24th, the EMA ITF panel held a 90 min virtual F2F meeting with 6 members from the SIG (Nicky Best, Simon Wandell, Nelson Kinnersley, Gaelle Saint Hilary, Aaron Dane, Olivier Collignon) to discuss the topics raised in the briefing book. The panel was chaired by Ralf Herold (EMA Research & Innovation) and 30 ITF panel members joined the call (12 from EMA representing both methodology and clinical, and 18 representatives from several NCAs and EMA working parties – BSWP/SAWP/COMP/PDCO). The overall tone of the meeting was very positive, and the next steps proposed by EMA indicated strong desire to engage further on this topic. In particular, EMA ITF panel encouraged the SIG to consider submitting a Qualification Opinion (focused on the methods) based on content of the briefing book, which would permit more in-depth discussion and broader input from EMA. In addition, the panel recommended that a new ITF meeting should be requested to discuss the selection of historical data topic in more granularity. The SIG is currently exploring options to follow-up on both these proposals.

Two SIG members (Gaelle Saint Hilary and Sebastian Weber) were also asked to run a PSI training course on use of historical data for clinical trials (course delivered Jan 2022).

Launch & Lifecycle – Alexander Schacht (Veramed), Jenny Devenport (Roche)

New SIG founded by Alexander Schacht (Veramed) (Chair), Jenny Devenport (Roche) (Co-Chair), Daniel Saure (BI), and Pierre Mancini (Sanofi). The purpose of the SIG consists of 3 areas:

1. Provide a platform for statisticians from sponsors and CROs working in the launch and lifecycle management (including traditional medical affairs area, commercialization, HTA (in collaboration with the respective ESIG)) and new evolving areas) to help each other in areas of pre-competitive collaboration.
2. Shape the industry to increase the influence of statisticians in launch and lifecycle and show how good looks like for the work of statisticians e.g. through case studies.
3. Drive scientific projects and innovation forward related to the field of Launch and Lifecycle.

Our general objectives are to

- Create a homepage for external communication ([link](#)).
- Collect case studies of how good looks like
- Publish manuscripts in journals and communicate via other channels about:
 - The role statisticians do and can play in medical affairs and their impact.
 - Innovative designs in medical affairs.
 - Use of registries in medical affairs.
 - Use of historical data in medical affairs.
 - Implementation of pragmatic studies in medical affairs.
- Organise workshops and conference sessions around the topics mentioned above (a session for the 2022 PSI conference is planned).
- Public relation activities to show how statisticians and data can help make better decisions.
- Collaboration with non-statistical associations (e.g. medical) working in the field to improve the role of statistics.

Develop best practices for statisticians to be successful and efficient (evidence dissemination and resources, planning and strategic thinking).



Neuroscience Estimands – Hans Ulrich Burger (Roche)

The SIG is still quite active with three of currently four workstreams going on, one workstream finished with a submitted publication. The workstreams are:

Estimands in Pain and migraine type of diseases - a publication is in preparation (1. 'A Comparison of Estimand and Estimation Strategies for Clinical Trials in Early Parkinson's Disease' (together with Alessandro Noci, Marcel Wolbers, Markus Abt, Corine Baayen, Hans Ulrich Burger, Man Jin, Weining Zhao Robieson), 2021, submitted. 1. 'A Comparison of Estimand and Estimation Strategies for Clinical Trials in Early Parkinson's Disease' (together with Alessandro Noci, Marcel Wolbers, Markus Abt, Corine Baayen, Hans Ulrich Burger, Man Jin, Weining Zhao Robieson), 2021, submitted.)

Estimands in MS - a draft publication currently is in internal review

Estimands in Parkinson - a publication has been submitted.

DCT in Neuroscience: This workstream was created last year. It already contributed to the recent EFSEI seminar on decentralized trials with one presentation. A publication is in planning and more work is currently going on.

The SIG also had organized a joint BBS/EFPSI seminar on estimands in NSin 2020 and had put forward a 2020 a presentation with guidance on the impact of Covid in NS studies.

New Starters – Jack Euesden (GSK), Samuel Hadlington (Plus Project)

2021 was an exciting year for the New Starters' SIG, but it was also a transitional one. We began the year with a question that had been on many lips – how does a SIG whose primary focus is networking cope with a wholesale shift away from face-to-face meetings? We tackled this question by joining our expertise to that of the CALC SIG and co-organising a satellite event at the PSI 2021 conference. This event was very well-attended and leveraged a range of Zoom tools – from polls to breakout rooms – to facilitate networking sessions for students and early-career statisticians across the industry. The event was a success but in 2022 we are keen to resume face-to-face events when practicable. Jack Euesden is stepping down as SIG Chair – we are still in the process of finalising this handover.

Oncology Estimands (also an ASA Scientific Working Group) Kaspar Rufibach (Roche), Evgeny Degtyarev (Novartis)

The group has evolved into a global network of statisticians in industry and regulatory agencies that continues to contribute to the implementation of the ICH E9 addendum. Key achievements are:

- Several [publications](#) of the SIG appeared this year.
- The SIG has built a network of individuals with expertise and credibility in the broader biostatistical and drug development community. Testament to that is the fact that SIG members are regularly invited to review and comment on scientific publications in the field.
- Invited by the [EFSP/EFPIA estimands implementation working group](#) the SIG organized two webinars targeted at a broad audience of Clinicians, Investigators, Regulatory Experts, Medical Writers, Ethics Committees, Statisticians:
 - [PSI EIWG Webinars](#) (2 events, one for EU and one for US): Estimands in Oncology - How and Why.
- The WG also organized a [DIA Webinar](#) with the same target audience, including FDA discussants.
- Our SIG is also formally represented in the [EFSP/EFPIA estimands implementation working group](#).
- The SIG organized sessions and was invited to speak at conferences (Duke Industry Statistics Symposium, Society for clinical trials, JSM, ASA-FDA workshop, ISOQoL). Further [talks](#) were given at several occasions.

- Members of the SIG were also invited to FDA OCE Project Significant TCs to talk about application of estimands to decentralized trials and comment on non-proportional hazards.
- As a highlight of 2021 nine task forces were kicked off who have started their work on new topics relevant to the implementation of the addendum, and applying the addendum to extended areas such as, e.g., real-world data. Find them all, including rosters and objectives, [here](#).
- As of November 2021, the SIG has 77 members (30 from Europe, 38 from US, and 9 from Asia) representing 36 companies / institutions, see [status](#).

As an outlook in 2022 we plan to organize webinars reporting on the content that the task forces have generated so far. One goal is also to broaden our outreach and present not only at statistical but also at clinical conferences. We also plan to get involved with our Health Authority partners again.

Pre-Clinical – Eloisa Brook (GSK)

In 2021 we organised 2 webinars:

- Beyond the Looking Glass: Interpreting animal welfare and behaviour by monitoring and assessing mice activity data in March
- Carcinogenicity working group update in June

Both are available on the Video on demand section of the PSI website.

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

The Regulatory SIG is one of the oldest SIGs; it was established more than 15 years ago and was known as the Regulatory Committee until the end of 2020. We have a total of 19 members from 8 countries and 16 companies. Our main activities in 2021 were the following:

- On Wednesday 17 November 2021 we met with the MHRA statisticians. As was the case in 2020, the meeting took place virtually, with 5 statisticians from the MHRA and 19 members of the SIG attending. The main topics of the discussion were decentralized clinical trials, use of external controls, non-inferiority trials, estimands as well as the Post-Brexit regulatory world. Detailed minutes from the meeting are published in SPIN (Spring 2021).
- On 29 October 2021 several of our members met with EMA's biostatistics working party. The meeting was similar in its format as last year and therefore included several other statistical stakeholder organisations. This time the exchange focused on two topics only (raw data submissions and use of external control data) and therefore was better suited to an exchange of information than the previous year. Minutes from the meeting will be published once they are available.
- On 21 October 2021 we jointly organised a webinar on Complex Innovative Designs with the American Statistical Association Biopharmaceutical Section (ASA BIOP). Speakers were John Scott (FDA), Dieter Häring and Marius Thomas (Novartis) and Olivier Collignon (GSK), and it covered the following aspects:
 - Overview of the FDA Complex Innovative Trial Design pilot program and the applications received to date together with details on some of them
 - Overview of the FDA guidance on interacting on Complex Innovative Trial Designs
 - Detailed case study of a clinical trial in children which was evaluated within FDA's CID pilot program, applying borrowing of information from external trials in adults
 - Overview of statistical and regulatory considerations on master protocols, focusing on Phase III confirmatory trials
- We also collated and submitted comments on the following documents during 2021:
 - ICH' draft reflection paper on [patient focused drug development](#)

- FDA's draft guidance on [Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products](#)
-

Real World Data – Anny Stari (GSK), Josephine Wolfram (Astellas)

A new SIG, created in March 2021, focusing on strategies and methodologies applied in the utilization of Real World Data in the pharmaceutical industry. The objectives include facilitating the sharing of case studies and experiences in this area and identifying emerging news and trends. The SIG will collate and summarise publications, articles, presentations, and regulatory or professional body guidance; organise and participate in workshops related to RWD and aim to develop or highlight best practices and recommendations.

A poster was presented at EU ISPOR 2021 by the Methodology sub-team of the SIG: [ISPOR - Leveraging Real-World Data for Time-to-Event Endpoints in Clinical Trials](#)

Watch out for our coming Webinar on 22nd March: [PSI RWD SIG Webinar: Real-World Evidence Submission - a Case Study in Lung Transplantation \(psiweb.org\)](#)

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

Small Populations – Francois Aubin (Vennlife), Andreas Kaiser (Bayer)

Over the year 2021, the SIG held 11 meetings, all web meetings. The SIG closed its focus on its three main topics: historical controls, extrapolation and meta-analytical approach. A summary of the outcome has been published on the SIG's webpage. Mid-year the SIG decided to move to a new topic: "Utilizing RWD and observational clinical data in small populations". The SIG has been planning to organize a scientific meeting together with the EFSPi Scientific Committee. Unfortunately, because of the pandemic situation and lack of case studies to be presented it was decided to set organization of this meeting on hold.

Subgroups – David Svensson (AZ)

Recent years have seen an avalanche of novel methodologies for assessing treatment effect heterogeneity; there has been a shift from 'subgroups as we know it' towards agnostic data-driven causal inference approaches, modelling individual treatment effects sometimes based on advanced machine learning techniques. Some of this allows the application of off-the-shelf ML predictive techniques to enter as a component of the analysis while many other are specifically designed for assessing individual treatment effects (often developed for observational data too, and coming from other industries too where characterization of causal effects is important). This has prompted a lot of activity within the Subgroup SIG in the recent year, where we try to cover and discuss all these new trends.

Apart from having our regular group meetings (where we often cover novel methodology, e.g., dissecting a recent scientific paper) and generally frequently network with each other, we ran a subgroup session at the virtual PSI conference (22th June 2021, with several collaborative contributions) and we hosted a Webinar on 'Modern Approaches to Subgroup Identification' (Svensson, Lipkovich, Bornkamp, Sechidis, Eusebi, November 2021). The latter was quite popular with over 200 registered participants, and lead to seven new members to the SIG (including several well-known authors in this research area). The momentum has continued and in 2022 we will host another PSI session (the 13th June in Gothenburg) which includes an overview talk of recent approaches, and reports from a subgroup identification contest held at Novartis. The SIG keeps focusing on the new trends and it is e.g., worth stressing the ongoing collaborative efforts such as clusters of members working on upcoming scientific publications – watch this space.

A final comment to further clarify the scope of the Subgroup SIG: although there are often machine learning components in the current state of the art, the primary focus is not in itself on 'generic machine learning' (as in 'predictive supervised learning'); this makes it different from the broader Data Science. A lot of this research is on the relative merits of model-agnostic strategies (e.g., meta learning), approaches that e.g., by-passes the need to model the main effects (hence

not fitting models for the outcome), approaches for optimally allocate patients to a treatment (ITR), etc. Considerable specific difficulties also arise regarding e.g., honest estimation, estimation under constraints (e.g., prevalence, subgroup parsimony); this all gives this area its own flavour.

Vaccines – Fabian Tibaldi (GSK)

We organised a session in **JSM 2021 for the ASA** on “Stories from COVID-19 vaccine development: Statistical challenges and opportunities”, this was done in collaboration with colleagues from GSK Vx USA, Charlotte Baidoo, Wenji Pu; Chair: Fabian Tibaldi (GSK) . Agenda:

- Geert Molenberghs (Universiteit Hasselt & KU Leuven), “COVID-19: modeling, epidemiological, clinical and vaccine aspects”
- Scott Patterson (Sanofi-Pasteur) “Statistical Observations on SARS-CoV-2 Clinical Vaccine Development”
- Ye Yang (CBER, FDA) “Statistical Challenges in COVID-19 Vaccine Trials”
- Tsai-Lien Lin (CBER, FDA), discussant

Also a webinar by **Dr. Dan-Yu Lin** *Department of Biostatistics, University of North Carolina at Chapel Hill*: **Evaluating the Durability of Protection for COVID-19 Vaccines**. And a webinar co-organized with David Wright from AZ on COVID 19 related topics:

- **Ivan S. F. Chan, Ph.D.**
VP, Head of Hematology Biostatistics, Global Biometrics & Data and Sciences, Bristol Myers Squibb, USA.
Introduction to Statistical Methods and Challenges in Vaccine Development
- **Stephen Senn, PhD.**
Statistical Consultant, Edinburgh, Scotland, United Kingdom.
Vaccine quintet. Statistical issues in the design and analysis of five vaccine programmes

We also continue with our Newsletter and having our meetings to talk about general scientific topics on Stats in Vaccine development.

Visualisation – Bodo Kirsch (Bayer)

2021 marks a year in which the focus and awareness about data visualisations have reached a peak. A community of statisticians have worked on data visualisations for the last couple of years within PSI and have organised various sessions at the last conferences. In 2021 data visualisation became the main topic for the PSI conference. Keynote speakers highlighted the importance of data visualisation in communicating COVID data to the public and many of the concepts the data visualisation community has been talking about for years have been coming to the fore-front of people across the industry.

The VIS SIG (<https://www.psiweb.org/sigs-special-interest-groups/visualisation>) has been vividly active with the successful monthly Wonderful Wednesday Webinar series (<https://www.psiweb.org/sigs-special-interest-groups/visualisation/welcome-to-wonderful-wednesdays>) delivering 12 interactive challenges to improve data visualisations. Everybody has access to the recordings on the video-on-demand platform of PSI (<https://www.psiweb.org/vod>). Furthermore, the visualisations together with discussions and the corresponding code are available for everybody to use on the VIS SIG blog (<https://vis-sig.github.io/blog/>).

Beyond the 12 Wonderful Wednesday Webinars, the VIS SIG has also organised:

- a conference presentation
- a scientific event "Generating Insights through Modern Applications of Data Visualisation" spread over 2 half days (<https://www.psiweb.org/vod/item/psi-scientific-meeting-generating-insights-through-modern-applications-of-data-visualisation>)
- a webinar on the Grammar of Graphics (<https://www.psiweb.org/vod/item/psi-vissig-webinar-grammar-of-graphics---theory-to-implementation>)



- a webinar on Rapid Insights Into Data (<https://www.psiweb.org/vod/item/psi-vissig-webinar-rapid-insights-to-data>)

In 2022, the VIS SIG is going to continue to run the Wonderful Wednesday Webinar series.

Register here for these upcoming events:

https://zoom.us/webinar/register/WN_xeAHuUEXQzynthUXzUw23-Q

Also, the VIS SIG organises a session at the 2022 conference. The VIS SIG discusses other formats to increase the capabilities of statisticians around data visualisations and raise the awareness of data visualisations.

Bodo Kirsch, Alexander Schacht, Zachary Skrivanek, Lorenz Uhlmann, Steve Mallett on behalf of the VIS SIG.



PSI Volunteers

PSI relies on the contributions of our volunteers, without whom there would be no events and no opportunities to share our ideas with our colleagues or the external world. On behalf of the membership, the Board of Directors is deeply grateful to all those who give time to the society.

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Tomas Rouse	AZ, Sweden	Website
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Alexander Todd ²	AZ, UK	Careers Event
Heather White ²	Amgen, UK	Schools subteam (placement student)
Stella Zhan ²	University of Warwick, UK	MEDMathS, Student Newsletter

¹Left committee during 2021

²Joined committee during 2021

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¹Left committee during 2021

²Joined committee during 2021

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SIG Leads

Category	Name	Company
AIMS	Lyn Taylor	
Benefit-Risk	Shahrul Mt-Isa	Merck
Benefit-Risk	Maria Costa	Novartis
Biomarkers (new for 2022)	Guillaume Desachy	AZ
Biomarkers (new for 2022)	Nicole Kraemer	BI
COVID-19	Chrissie Fletcher	GSK
COVID-19	David Wright	AZ
CSM/QTL	Tim Rolfe	GSK
CSM/QTL	Susan Talbot	Amgen
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Data Science	Julia Chernova	Bayer
Data Sharing	Rebecca Sudlow	Roche
Decision Making	Gaëlle Saint-Hilary	Saryga
Historical Data	Nicky Best	GSK
Historical Data	Simon Wandel	Novartis
HTA	Lara Wolfson	MSD
Launch & Lifecycle	Alexander Schacht	Veramed
Launch & Lifecycle	Jenny Devenport	Roche
Neuroscience-Estimands	Hans Ulrich Burger	Roche
New Starters	Jack Eusden	GSK
New Starters	Sam Hadlington	Plus Project
Oncology Estimands	Kaspar Rufibach	Roche
Oncology Estimands	Evgeny Degtyarev	Novartis
Pre-Clinical	Eloisa Book	GSK
Regulatory	Jurgen Hummel	PPD
Regulatory	Christoph Gerlinger	Bayer
RWD	Anny Stari	GSK
RWD	Josephine Wolfram	Astellas
Small Populations	Francois Aubin	Vennlife
Small Populations	Andreas Kaiser	Bayer
Subgroup Analysis	David Svensson	AZ
Vaccines	Fabian Tibaldi	GSK
Visualisation	Bodo Kirsch	Bayer