



# Annual Report 2019



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# Welcome from the Chair

I am very excited with the progress that PSI made in 2019. We delivered on many of our objectives and the society is in excellent health. We also developed our [Business plan](#) for the next couple of years, where we re-defined what our purpose as an organisation is and the strategic objectives we need to focus on.

## PSI Purpose:

We are a community dedicated to leading and promoting the use of statistics within the healthcare industry for the benefit of patients

PSI's four key strategic objectives for 2020-2021:

- **Empower** members in their profession by strengthening and broadening their technical and influencing skills
- **Nurture** and expand a collaborative and engaged community
- **Promote** the value of career opportunities related to the use of statistics in healthcare
- **Advance** healthcare by being a leading partner in the application of statistics

We had many achievements as an organisation to be proud of in 2019, I have highlighted a couple of them below, 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.

- Our membership strategy is working, and our membership has increased from 1074 in 2018 to 1272 in 2019, with ~40% of members from outside the UK. We have now surpassed the previous membership high of 1221 from 2008

- Video-on-demand content is nicely growing with 200 videos uploaded at the end of 2019, all of them free to watch for members
- A record-breaking 409 delegates registered for the PSI Conference. Around 43% of the delegates for 2019 came from outside the UK and it was the first year we offered a reduced student fee for attendance on the first day of conference
- In addition to the annual conference, the Scientific Committee organised five one-day meetings (4 in UK and 1 in Europe) and 6 webinars
- 6 courses were held throughout the year, plus the ITIT course
- Exhibition and sponsorship raised £97,951 in revenue
- Our reserves are at the highest ever levels (£377k) since the formation of PSI, and we made a profit of £42k in 2019
- 90 students and 27 pharma companies, CROs and CTUs attended the PSI Careers event in Leicester, UK in February 2019
- The new PSI website was launched
- We successfully linked with IASCT (Indian Association of Statistics in Clinical Trials) in 2019 and attended their conference to talk to the IASCT members about the collaboration between the two organisations
- The EFSPi/PSI Regulatory SIG met with the MHRA and discussed topics such as estimands, quality tolerance limits and RWD
- It was agreed to bring together all SIGs across PSI/EFSPi under a common governance framework, known collectively as "European SIGs sponsored by PSI and EFSPi – we also brought the SIG director back as a board position
- The level of support we received from MCI in 2019 was below expectations after a number of key employees supporting PSI left. We will maintain monitoring the support in 2020, when the MCI contract is up for renewal

**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. Again, we had two winners:

**Mike Smith (Pfizer)** for “Improving the quality and reliability of animal research through the use of InVivoStat: a statistical software package for animal researchers”

**Dr Graeme Archer & Jacquie Christie (GSK)** for “Enhancing drug development using clinically interpretable treatment effect measures (‘estimands’) that allow for efficient statistical analyses”

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

**Lucy Rowell**  
PSI Chair



# Treasurer's Report

During 2019, PSI made a modest profit of around £42k, and our reserves now stand at £377k (72% of revenue). We aim to have reserves at a nominal level of (£300k), with a target of approximately 75% of revenue. These targets were set to ensure that we would still be able to meet our financial commitments in a lean year. We are therefore well set to manage the effects of COVID-19 in 2020.

In terms of initiatives, there are plans also to provide 4 MSc scholarships in the UK to make-up for the

significant decrease in NHR awards. In addition, the board are planning to provide enhancements to the membership experience, whilst ensuring it is value for money.

The table below gives a full breakdown of the main areas for PSI's income and expenditure and how this has fluctuated over the last 4 years.

The finance team at MCI have done a great job of staying on top of this, ensuring that issued invoices are paid in a timely manner. Our debtors list has decreased in size – both in terms of the number of debtors and the amount owed. Over the past 4 years we have not had to write off any bad debts.

| Profit (£k)*               | 2016 | 2017 | 2018 | 2019 |
|----------------------------|------|------|------|------|
| <b>Membership</b>          | 58   | 72   | 72   | 75   |
| <b>Conference</b>          | 124  | 65   | 116  | 49   |
| <b>Training &amp; ITIT</b> | 18   | 22   | 19   | 24   |
| <b>CALC</b>                | 3    | 11   | -1   | 0    |
| <b>Scientific</b>          | 9    | 11   | 3    | 16   |
| <b>Publications</b>        | -18  | -16  | -5   | -8   |
| <b>Commercial</b>          | 100  | 86   | 97   | 83   |

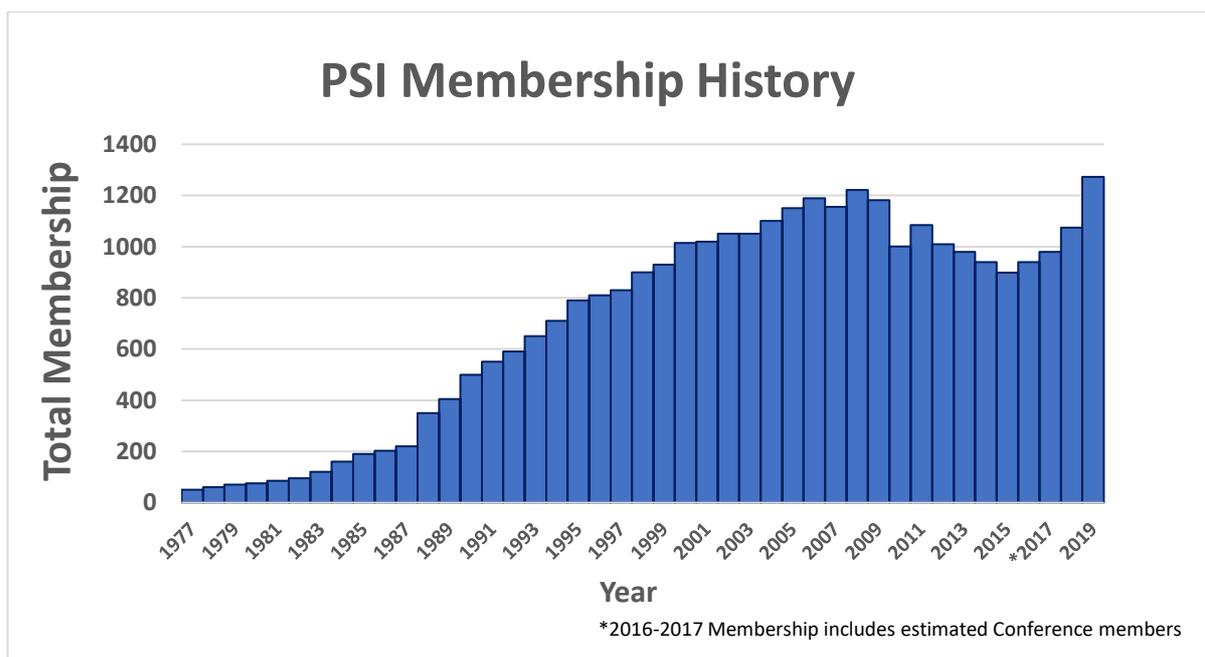
\* Rounded to the nearest £1000(£k)

Veronique Cadic  
PSI Treasurer



# Membership Report

2019 saw continued growth for PSI membership as the Membership Strategy. With a record membership total of 1272 (up 18%), we have now surpassed the previous membership high of 1221 from 2008 (prior to the financial crisis).



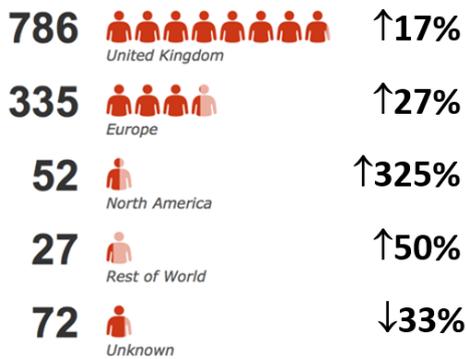
We have also seen a continued growth in our Student/Teacher membership, thanks to the great work being done by CALC.

| Membership Category | 2015       | 2016       | 2017       | 2018        | 2019        |
|---------------------|------------|------------|------------|-------------|-------------|
| Full                | 881        | 886        | 861        | 959         | 1070        |
| Honorary            | 8          | 9          | 9          | 9           | 9           |
| Reduced Rate        | 9          | 9          | 13         | 8           | 21          |
| Student/Teacher     |            |            |            | 98          | 172         |
| <b>Total</b>        | <b>898</b> | <b>904</b> | <b>883</b> | <b>1074</b> | <b>1272</b> |

The strategic focus on strengthening our membership base across Europe and in countries which aren't well served is continuing to be embedded.

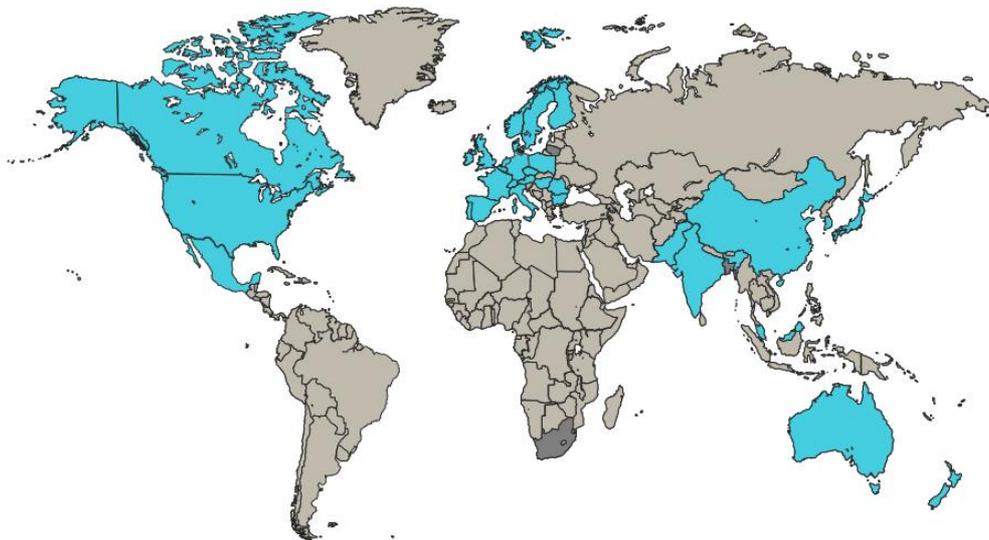
Whilst historically PSI has been seen by some as a UK-centric organisation, it is great to see that ~40% of our members are from outside the UK. The growth outside of the UK, speaks to the success of PSI ambition to support Statisticians in the Industry, by delivering high value scientific content & career development to our members, irrespective of location.

Membership by Region:



We are looking to grow our footprint in areas such as Canada, which up until now do not have a dedicated pharmaceutical focussed statistical support organisation. Our strategic aim is also to continue partnering with existing organisations, including our long-standing membership of EFSPi & our new partnership with the Indian Association for Statistics in Clinical Trials (IASCT). PSI have also agreed to continue its partnership with The Effective Statistician to help support the statistical community via its regular podcast series, which has helped to broaden awareness of PSI activities to a global audience.

Geographical Footprint:



As an output of the PSI Strategy Day earlier in the year, the membership committee is also broadening its remit, so in addition to our focus on membership growth, we are now also looking at other areas where PSI can support existing membership community. As such we have changed our name to be Membership & Community Committee

Tim Rolfe  
PSI Membership Director



# Careers and Liaison Committee

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.

CALC held its annual PSI Medical Statistics Careers Event on the 20th February at the De Montfort University, Leicester, with over 90 students attending on the day. Representatives from 27 pharmaceutical companies, CROs, clinical trial units and industry organisations were on hand to talk to students and to offer advice on what the industry has to offer statisticians and statistical programmers. The panel discussion session 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. The new venue also worked well, with plenty of space for all the exhibition stands and time for students to network with the exhibitors.

Our BSc subteam have been busy this year recording a series of five podcasts, with invaluable help and guidance from Alexander Schacht, as part of his Effective Statistician podcasts. A huge amount of work went into planning, recording and editing the podcasts

(which wouldn't have been possible without the help of two Roche undergraduate placement students – Cameron Wilson and Angus Jennings). The series covered topics such as the role of a medical statistician, career paths and opportunities, how to become a medical statistician and an overview of the drug development process. The download figures have been particularly impressive, with 300 downloads in the first week for episode 1. The BSc team have continued to strengthening links with universities across the UK, and this year 6 BSc prizes were awarded to the highest performing undergraduate mathematics/statistics students at the Universities of Bath, Glasgow, Lancaster, Reading, Sheffield and Southampton.

The schools subteam have also been hard at work, revamping the schools/education section of the PSI website, developing new material for the fourth Maths Meets Medicine schools' event and attending the Bucks Skills Show in October, meeting with hundreds of school-aged students, teachers and parents. Maths Meets Medicine was held at the University of Reading on the 5th November and school students from the local area took part in a day of workshops, which followed the development of a new medicine. The new structure of the day and the content was very well received by students and teachers alike.

CALC has also been involved in assessing the funding situation for MSc courses, providing input into the new Medical Statistics MSc level apprenticeship proposal and also organising the Career Young Statisticians networking session at the PSI Conference in June.

Amanda Darekar  
CALC Chair



# External Affairs Committee

External Affairs has expanded its engagement with outside organisations this year.

The External Affairs Chair sits on the EFSPi Council. The organisations work together in many ways, and some of these are noted elsewhere in this report.

RSS: We meet representatives of the RSS every six months to discuss topics of mutual interest and we continue to work together and exchange information. Ray Harris completed his term on the RSS Medical Section and Aris Perperoglou joined it at the end of the year, and joined External Affairs, and we welcome him to the group.

Indian Association for Statistics in Clinical Trials (IASCT): We have successfully linked with IASCT this year. Jenna was able to attend the ConSPIC conference (Conference for statistics and programming in clinical research) on behalf of PSI to talk to the IASCT members about the collaboration between the organisations. Jenna continues to maintain our links with IASCT and we look forward to a beneficial relationship.

Medical Research Council National Institute for Health Research Trials Methodology Research Partnership (MRC-NIHR TMRP): We have discussed how to work together. The immediate actions are to look how their Working Groups and our SIGs may interact to share knowledge and areas of common interest.

American Statistical Association Biopharmaceutical Section: We have had useful discussions and will keep communications open for areas where we may work together, such as webinars.

Association of Clinical Data Managers: We have discussed areas of common interest and there are likely to be useful interactions in some of our SIGs.

Council of Biopharmaceutical Statistics: Dawn has joined the Council as one of the three PSI representatives.

Volunteers: Our PSI volunteers provided further support this year, for example, advice on study design for CRUK. There is a new page on the web site that is the first place to go to for members who want to volunteer and for organisations seeking help (<https://www.psiweb.org/need-statistical-advice/need-help-from-psi>). We would be pleased to welcome more volunteers or any requests for volunteer support.

Datasets for academia: There is a need for data for MSc and PhD students to work on however it was agreed that PSI should have no direct role in this. An information page providing guidance was prepared for the web site.

Ray Harris  
Chair of External Affairs Committee



# Communication Report

## The Communications Committee expanded into new areas in 2019.

Traditionally the Committee has focused on the PSI quarterly magazine SPIN, the scientific journal Pharmaceutical Statistics in collaboration with the Editorial Team and Wiley, the fortnightly eNews alerts, the news page on PSI website, the about quarterly Journal Club as well as social media (LinkedIn and Twitter). We established 2 new groups in 2019. First, we have now a dedicated conference reporter team, which will support the Conference Chair in terms of all the communication before, during and after the conference. Second, we have created a new team around the homepage, video (including the video on demand platform) and metrics. One of the goals of this team is to create a dashboard showing key performance indicators of how PSI is tracking against its goals and how impactful the different activities are

With the new responsibilities we have tripled the size of the Committee in terms of participant becoming one of the biggest Committees in PSI. This expansion occurred without much chaos. The committee benefits now from being able to many more communication channels and formats. In addition the diversity of the team creates more ideas and innovations in the committee.

It's especially notable that we have a great team spirit in the committee with the attitude remaining positive around the changes. With so much changing over the last 12 months it wouldn't be a surprise if a lot of people stopped volunteering or we became stuck because of barriers, but it's amazing that this isn't the case. On the opposite, as we've developed we are seeing more positivity towards each changing step we take. All these changes are rooted in the overall communication strategy, which was developed together with Nick Manamley in 2018.

The Journal Club started a new initiative to include statisticians early in their career to foster their presentation skills and provide a platform for them to present their research and run a such a webinar in 2019 in addition to the usual webinars. All recordings can be found on the video-on-demand platform.

We're currently working on the video-on-demand platform to increase its user friendliness and visibility on social media, where we have introduced a new tool to improve the experience of members on social media. In line with our overall vision, this will help us to become a truly global community. In combination with changes on the email format and structure, members and "not-yet"-members will experience a more consistent and constant flow of relevant information. The vast amount of content, which our members have created and are continuously being created will therefore become more visible and have a bigger impact.

We are grateful to Wiley for their continued sponsorship throughout the year. Currently, some ideas are discussed to connect the conference to the journal.

SPIN continues to be a key route of communication for the membership and we are grateful for the content provided by different members. Especially as we have increased the number of "regular" articles, which implies that even in quarters where contribution is traditionally more scarce, we always produced a good value edition. In addition, SPIN includes now an increased number of video and multimedia articles.

The chair update is now a vlog (thanks to Lucy) and we also have a getting to know you section for board members that is video too. These are working well and are incorporated into the online version of SPIN. We're also happy that Sophie Greenwood has taken on the social side of SPIN in addition to her email related activities. This post has been vacant for over a year since Rhiannon Maudsley went on maternity leave and the social side of SPIN had been a little in decline. Now we can plan to get this back on the up!

In addition to the upcoming activities mentioned above, we will be working together with the training committee on creating an online self-paced training program about estimands as well as other initiatives supporting the strategic objectives of PSI created last autumn.

The Board of Directors and especially myself thank all those on the Committee and those who contribute to our range of publications, and MCI who support us.

If you're interested in joining the amazing journey of the communications committee e.g. by helping with the data science like activities on the metrics team or working together with the editorial team for the journal, please contact me at:

[alexander.schacht@ucb.com](mailto:alexander.schacht@ucb.com)

Alexander Schacht  
Communications Chair



# Regulatory Committee

The role of the regulatory committee is to provide the PSI/EFSPI viewpoint on regulatory issues. This includes promoting best practice, reviewing regulatory policy and guidelines, driving debate on future guidance, and engaging with statisticians in European regulatory agencies.

During 2019 the regulatory committee held five regular committee meetings and met with the MHRA statisticians. The committee coordinated the review of several regulatory guidance documents (more detail below). Committee members contributed to EMA and industry workshops, as well as webinars; helped organize the 4th EFSPI workshop on regulatory statistics held in Basel as well as a plenary session on Regulatory and HTA hot topics at the PSI conference in London.

In July the chair of the regulatory committee transferred to Christoph Gerlinger from Anna Berglind, who is now the co-chair of the committee.

## Expert Groups

The regulatory expert working group on subgroup analyses was still active during 2019 and continued the work on developing best practice for subgroup analyses.

## Meetings with statisticians from regulatory agencies

On Wednesday 13 November 2019 the PSI/EFSPI Regulatory Committee met with the MHRA statisticians in London for an informal exchange of statistical topics important for both regulators and industry. There was great discussion on topics such as estimands,

subgroup analyses and predefined Quality Tolerance Limits as well as quality attributes, model-based dose escalation studies, real world evidence, use of historical controls and the lack of statisticians in many ethics committees in England.

The planned meeting with EMA's biostatistics working party was postponed to 2020 due to EMA's business continuation plan for Brexit.

## Webinar

On July 4th, 2019, the PSI/EFSPI Regulatory Committee organized the Webinar: 'Adaptive design: updated draft FDA guidance and its implications'. In the webinar Jürgen Hummel (PPD) shared an overview of the FDA's updated guidance on adaptive design for clinical trials of drugs and biologics, and discussed implications for industry. This was followed by the introduction to an open-source statistical software for adaptive designs, RPACT (an R package available on CRAN that enables the design and analysis of confirmatory adaptive clinical trials) led by Kaspar Rufibach (Roche). Kit Roes (Working Group Methodology of the Dutch Medicines Evaluation Board and member of the EMA Biostatistics Working Party) closed the webinar by commenting on the guidance from a European Regulatory perspective.

In addition, Anna Berglind chaired a joint PSI/DIA Journal Club Webinar on Subgroup Analyses on October 24, where Cynthia Huber from the University of Göttingen discussed her paper "A comparison of subgroup identification methods in clinical drug development: Simulation study and regulatory considerations", and Christoph Muysers and Bodo Kirsch (both Bayer) shared a systematic approach for post hoc subgroup analyses with applications in clinical case studies.

## Training course

Two members of the committee (Chrissie Fletcher and Kerry Gordon) joined James Matcham (AZ) and Caroline Pothet (GSK) in delivering the two-day training course "ICH for Statisticians" on 19/20 November. Of note, 100% of attendees said they would recommend the course to others.

## Guidelines

The regulatory committee collated comments on the following documents during the year:

- EMA's draft Questions and Answers on [Data Monitoring Committees issues](#)
- EMA's draft guidance on [Qualification Opinion of Clinically Interpretable Treatment Effect Measures based on Recurrent Event Endpoints that Allow for Efficient Statistical Analyses](#)
- FDA's draft guidance in [Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products](#).
- FDA's draft guidance on [Patient-Focused Drug Development: Methods to Identify What Is Important to Patients](#).
- EMA's draft guidance on [Preparedness of Medicines' Clinical Trials in Pediatrics](#).
- FDA's draft guidance on [Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes](#)
- The Center for Drug Evaluation in the NMPA (National Medical Product Administration) in China's "" two draft guidelines on Clinical Trial Data Monitoring Committees and on Non-inferiority Clinical Trials.

Anna Berglind  
PSI Regulatory Chair



# Scientific Committee

The PSI Scientific Committee organise one-day meetings and webinars of scientific statistical interest to our members, as well as the annual PSI conference.

We are a pretty big committee – currently 18 of us working for a wide range of employers from large Pharma companies, CROs, academics and regulatory and we really enjoy getting together to bring interesting meetings to the community of PSI members (and non-members!).

During 2019, in addition to the annual conference, we organised five one-day meetings (4 in UK and 1 in Europe) and 6 webinars. If you missed out, these meetings & webinars are now available to PSI members on the Video-on-Demand platform which is a fantastic resource for PSI members.

## One-day meetings:

- **New Emerging Topics around estimands & ICH Addendum**  
Jan 2019, IQVIA, Reading, UK
  - ❖ [Key themes](#)
  - ❖ [The exciting new world of the estimand](#)
  - ❖ [A case study in Lymphoma](#)
  - ❖ [Causal inference and clinical trials](#)
  - ❖ [Causal graphs to understand estimands and estimation](#)
  - ❖ [Mendelian randomization investigations](#)
  - ❖ [Non-inferiority trials](#)
  - ❖ [Panel Discussion](#)
- **Designing and Analysing Adaptive Trial Design Studies**  
June 2019, University of Bath, Bath, UK

- **The analysis and reporting of PROs in Clinical Trials**  
July 2019, Roche, Welwyn-Garden City, UK
  - ❖ [Introduction to pro-measurement](#)
  - ❖ [Improving the design and reporting of pro trial data](#)
  - ❖ [Analysing pros in oncology](#)
  - ❖ [Analysis of pro data sisaqol recommendations](#)
  - ❖ [Analysis and interpretation of pros](#)
  - ❖ [Iqwig perspective when assessing treatment effects with pros](#)
  - ❖ [Q&A](#)
- **Impact of AI on Clinical Development**  
Sept 2019, UCB, Slough, UK (Joint meeting with Cytel)
  - ❖ [Understanding activity patterns through wearable devices](#)
  - ❖ [The need for data science in the new clinical development paradigm](#)
  - ❖ [Predicting crohn's disease risk in asymptomatic relatives](#)
  - ❖ [Roche's experience developing advanced analytics communities](#)
- **Time-to-event and Recurrent Event Endpoints in Clinical Trials**  
Oct 2019, Novartis, Basel, Switzerland

2019 was also a bumper year for scientific webinars:

- [HTA submissions in the UK](#)
- [Statistical engagement with Commercial Activities](#)
- [MCP-Mod - Theory Implementation and Extensions](#)
- [Effective Insight Communication: Data Visualisation \(joint with APGB\)](#)
- [Statistical Challenges in Analytical Comparability and Biosimilarity Assessment](#)
- [Longitudinal Modelling: Time to take the next step?](#)

A big thank you to all members of the scientific committee, support from companies hosting meetings and also a really big thanks to all the speakers who volunteered their time to prepare excellent talks for all of these meetings.

Rachael Lawrance  
Scientific Committee Chair



# Conference Committee

The PSI 2019 Conference was held from 2nd – 5th June at The QEII Centre, London

The Conference included 2 pre-conference half-day workshops. The first was titled “Stated Preference Methods: Eliciting patient preferences in the age of personalised medicine” given by member of the Benefit-Risk SIG. The second was on “Evidence Synthesis for Clinical Trials: Use of Historical Data and Extrapolation – Methods, applications and implementation with the R package RBesT” given by Sebastian Weber and Satrajit Roychoudhury. This was our largest ever conference to date, with a record breaking 409 delegates registered. Around 43% of the delegates for 2019 came from outside the UK.

The conference theme was ‘Data driven decision making in medical research’. The agenda included many hot topics and case studies. The three days were a mixture of four plenary sessions, 26 parallel sessions and a total of over 80 speakers. We were delighted to welcome two keynote speakers; John Pullinger, the UK National Statistician, spoke about us living in the time of data and what a great time it was to be a statistician. He also spoke a bit about the history of statistics, the UK census and his role and its independence from the government. Robert Cuffe, from the BBC spoke about statistics in the news, the challenges of his incredibly fast paced role and included a short role play session where we were allocated different roles within the newsroom and asked to write a news headline.

As well as our two keynote speakers, we had a Regulatory & HTA Town Hall session with 5 representatives from regulatory agencies and industry making up the panel and answering audience questions. The parallel sessions covered topics ranging from innovative design, portfolio decision making, estimands, data science, PROs, analysing non-

continuous data and a workshop on impact and influencing. The poster session this year also saw success, with our highest ever number of submitted poster abstracts (67) and the return of the very popular session dedicated to allowing our poster presenters to have one minute to share their work prior to the poster session itself.

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. We also used the popular conference app again and this will continue to be the main way the conference content will be shared with attendees in the future. The app included speaker and scientific committee member biographies and photos as well as the scientific programme, abstracts and updates during the conference itself. We were delighted to hold for the fourth year, the ceremony for the PSI/RSS Award for Statistical Excellence in the Pharmaceutical Industry.

The 2020 conference was due to take place from the 7th – 10th June at the Crowne Plaza Fira Centre in Barcelona. Unfortunately, due to the ongoing situation in 2020 with COVID-19 the difficult decision was taken by the PSI Board of Directors to cancel the conference. Anyone who had registered for the conference is entitled to a full refund of their delegate fees and any hotel stay at the Crowne Plaza booked through the PSI registration system. In lieu of a face to face conference this year the Scientific Committee are looking to host a series of online webinars, during the week that the conference should have been held, as a way to showcase some of the excellent material that would have been presented during conference. We are also contacting speakers about presenting their content at the 2021 conference if appropriate.

Kate Taylor  
Conference Chair



# Training Committee

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 standard core statistical topics to new and advanced methodology. One of the most successful courses in 2019 was the Estimands Training course, delivered by members of the ICH E9 R1 working group.

In 2019 the committee ran the following courses:

- ICH for Statisticians
- Introduction to Bayesian Analysis
- Estimands
- Network Meta Analysis
- Benefit-risk and patient preference elicitation (pre-conference course)
- Evidence Synthesis for Clinical Trials: Use of Historical Data and Extrapolation (pre-conference course)

Courses in the pipeline for 2020 include Practical Approaches to Adaptive Clinical Trial Design, Bayesian Analysis in R and SAS, Sample Size, and a course on R software. The committee is also planning to run two courses at the 2020 PSI conference:

- Biomarker Informed Clinical Designs - Where Innovation Meets Precision: Concepts, Rationale, and Case Studies
- Understanding Complex Trial Designs by Simulation

Introduction to Industry Training (ITIT) course:

The ITIT Course provide an overview of the drug development process to statisticians and programmers who are new to the industry. The course takes

delegates through 6 sessions at 6 companies covering topics from laboratory research work to marketing. It enables delegates to build a network of peers, all of whom are at the same stage of their careers.

For the 2019/20 course the delegates will attend 6 sessions across mainland Europe and the UK. PSI wants to continue to engage with our colleagues in mainland Europe and intends to continue with having a combination of mainland European and UK ITIT sessions and encourage a greater number of delegates from mainland Europe

Mary Elliott-Davey  
Training Committee Chair



# Special Interest Groups

The Special Interest Groups (SIGs) play a key role in our statistical communities, supporting scientific debate and collaboration across disciplines, industry societies and countries/regions.

In 2019 the PSI Board and EFSPi Council discussed opportunities to align and improve their joint support and sponsorship for SIGs, in order to provide greater clarity in relation to PSI/EFSPi sponsorship. It was agreed to bring together all SIGs across PSI/EFSPi under a common governance framework, known collectively as “European SIGs sponsored by PSI and EFSPi”, and in that regard I’m pleased now to be partnering with Gaëlle Saint-Hilary to provide joint oversight of all SIGs. The PSI website has been chosen as the common platform for SIGs to develop, disseminate and promote their activities, and we have been working with EFSPi to update its website to align with PSI’s. A benefit of this approach is that we can provide greater visibility to SIGs that previously were operating outside of the PSI framework, and as such we will be seeing some new entries on the SIG landing page of the PSI site link (e.g. the Oncology-Estimands SIG is new to our site in 2019).

The SIGs were very active in 2019, here are a few highlights to call out:

- Application and Implementation of Methodologies in Statistics SIG provided ongoing support to the R Validation Hub which now has over 100 members in over 60 companies link
- Toxicology SIG held its 9th 2-day workshop!
- The New Starters SIG held a successful and well-attended networking event with a series of talks for a new-to-industry group
- The Subgroup Analysis SIG contributed several presentations to an EFSPi workshop

- PSI Conference: a great contribution from SIGs to support several sessions, including a parallel session organised by the Decision-Making SIG in support of the overall conference theme.
- New SIGs: A new Visualisation SIG led by Alexander Schacht is up and running with events already taking place. We’re also hoping to bring the EFSPi Neurosciences SIG to the PSI site very soon, as well as the Small Populations SIG. And a Data Science SIG should also be added soon.
- Webinars: a lot of activity here from across the SIGs, do look out for content in the Past Events section of the PSI site, link where lots of great content is available.
- Website updates: we’re seeing more updates being posted across the SIGs, e.g. newsletters from Vaccines, upcoming events etc, giving the SIG webpage a more relevant and up-to-date feel.

During 2019 it was decided to transition the role of SIG oversight from the Scientific Committee to the Board. As such I have been co-opted to the Board and will stand for formal election in 2020. Transitioning SIG oversight to the Board will allow a stronger connection with the wider PSI strategy and committee framework. This is a clear sign of the importance and value that the Board associates with SIG activities.

I must close with a sincere Thank You to all the SIG leads and team members. The SIGs are a great success story, and already it’s clear that 2020 will be another great year for the SIGs.

Adam Crisp  
SIG Director (co-opted)



# 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 are for:

- Business Administration Services – MCI UK Ltd
- Conference Event Management – MCI UK Ltd
- Website – MCI UK Ltd
- Journal Publishing – Wiley
- Digital Publishing of SPIN – YUDU
- Commercial Contracts – Watton Hall Ltd.

## Business Administration Services

The current contract with MCI to cover business administration services runs until July 2020 and negotiations on a future contract are currently in progress. MCI has offered several proposals on process improvements and a deeper relationship with PSI. A deterioration in the level of service has been noted in mid-2019 because of staff changes, but marked improvements were seen towards the end of 2019 and in 2020. The annual cost to PSI is £120k. Conference event management tasks are included in the overall business contract.

## Website

The website continues to be solely maintained by MCI and is included in the main MCI contract.

## Journal

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

## Digital Publishing of SPIN

Ongoing contract with YUDU for the digital publishing of SPIN which expires in November 2020.

## Commercial

Two contracts are ongoing between PSI and Watton Hall, which expire in 2021. Both are commission based and in place to assist PSI with advertising and promotion.

## Markus Elze

Contracts Director (co-opted)



# 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.

## Board of Directors

| Name               | Company, Country   | Role                                       |
|--------------------|--------------------|--|
| Lucy Rowell        | Roche, UK          | Chair                                      |
| Nigel Howitt       | Covance, UK        | Vice Chair                                 |
| Veronique Cadic    | Covance, France    | Treasurer                                  |
| Alexander Currie   | GSK, UK            | Commercial Director                        |
| Mary Elliott-Davey | Amgen, UK          | Training Chair                             |
| Markus Elze        | GSK, UK            | Contracts Director                         |
| Ray Harris         | Eisai, UK          | External Affairs Chair                     |
| Amanda Darekar     | Pfizer, UK         | Careers & Academic Liaison Committee Chair |
| Tim Rolfe          | GSK, UK            | Membership Director                        |
| Kate Taylor        | Amgen, UK          | Conference Chair                           |
| Rachael Lawrance   | Adelphi Values, UK | Scientific Chair                           |
| Adam Crisp         | GSK, UK            | SIG Chair                                  |
| Alexander Schacht  | UCB, Germany       | Communications Chair                       |

## Careers & Academic Liaison Committee (CALC)

| Name                           | Company, Country                   | Role                          |
|--------------------------------|------------------------------------|-------------------------------|
| Amanda Darekar                 | Pfizer, UK                         | Incoming Chair                |
| Emma Crawford                  | MSD, UK                            | MSc Subteam                   |
| Rhian Jacob                    | Roche, UK                          | BSc Subteam                   |
| Jessica Kendall                | Leeds Institute of Clinical Trials | MSc Subteam, Social media     |
| James Lay-Flurrie              | Bayer, UK                          | German CALC Liaison           |
| Rachael Loftus                 | GW Pharmaceuticals, UK             | BSc Subteam                   |
| Harriet Longley <sup>1</sup>   | Eli Lilly, UK                      | Schools Subteam               |
| Shiv Makadia <sup>2</sup>      | Amgen, UK                          | Schools Subteam, Social media |
| Vicky Marriott <sup>2</sup>    | IQVIA, UK                          | Outgoing Chair                |
| Abeera Mohammad                | Amgen, UK                          | Schools Subteam               |
| Amy Phillips-Jones             | GSK, UK                            | BSc Subteam                   |
| Ian Ratcliffe <sup>2</sup>     | IQVIA, UK                          | MSc subteam, Social media     |
| Tomas Rouse <sup>1</sup>       | AstraZeneca, Sweden                | Website                       |
| Katharine Thorn                | GSK, UK                            | Schools Subteam               |
| Cheryl Turkington <sup>1</sup> | Amgen, UK                          | Schools Subteam               |
| Xinyi Zhu                      | GSK, UK                            | MSc Subteam                   |

<sup>1</sup> Left committee during 2019

<sup>2</sup> Joined committee during 2019

## Commercial Committee

| Name             | Company, Country    | Role  |
|------------------|---------------------|-------|
| Alexander Currie | GSK, UK             | Chair |
| Anna Passera     | Consultancy, France |       |
| Abigail Doe      | Vitaccess           |       |

## Communications Committee

| Name                | Company, Country        | Role  |
|---------------------|-------------------------|-------|
| Alexander Schacht   | UCB, Germany            | Chair |
| Priya Gokani        | Amgen, UK               |       |
| Douglas Thompson    | GSK, UK                 |       |
| Sophie Greenwood    | IQVIA, UK               |       |
| Matthew Gibb        | Veramed, UK             |       |
| Jamie Rees          | GSK, UK                 |       |
| Eleni Mavropoulou   | GSK                     |       |
| Eusebi Paolo        | UCB                     |       |
| Jens-Otto Andreas   | UCB                     |       |
| Anastasiia Raievska | Roche                   |       |
| Fiona Grimson       | IQVIA                   |       |
| Jack Elkes          | Imperial College London |       |
| Necdet Gunsoy       | GSK                     |       |
| Tom Naylor          | Amgen, UK               |       |
| Shikta Das          | UCL, UK                 |       |
| Karan Vadher        | Eli Lilly               |       |

## External Affairs Committee

| Name                          | Company, Country | Role  |
|-------------------------------|------------------|-------|
| Ray Harris                    | Eisai, UK        | Chair |
| Aris Perperoglou <sup>1</sup> | AstraZeneca, UK  |       |
| Dawn Midwinter                | GSK, UK          |       |
| Jenna Wills                   | MRC CTU, UK      |       |
| Leanne Hall                   | IQVIA, UK        |       |
| Stephen Jones                 | Covance, UK      |       |
| Tammy McIver                  | Roche, UK        |       |

<sup>1</sup> Joined committee during 2019

## PSI/EFSPi Regulatory Committee

| Name                           | Company, Country    | Role  |
|--------------------------------|---------------------|---|
| Anna Berglind                  | AstraZeneca, Sweden | Incoming Co-chair/Outgoing Chair, PSI Regulatory Chair                          |
| Christoph Gerlinger            | Bayer, Germany      | Ingoing Chair / Outgoing Co-chair, EFSPi Council Member, EFSPi Regulatory Chair |
| Julie Anderson <sup>1</sup>    | GSK, UK             |   |
| Olivier Collignon <sup>2</sup> | GSK, UK             |   |

|                                    |                               |                      |
|------------------------------------|-------------------------------|----------------------|
| Maylis Coste <sup>1</sup>          | Servier, France               | EFSPI Council Member |
| Erika Daly                         | ICON, UK                      |                      |
| Anne Danniau                       | UCB, Belgium                  |                      |
| Lars Endahl Laen <sup>2</sup>      | Novo Nordisk, Denmark         |                      |
| Daniel Evans                       | Pfizer, UK                    |                      |
| Christine Fletcher                 | GSK, UK                       | EFSPI Council Member |
| Kerry Gordon                       | IQVIA, UK                     |                      |
| Jürgen Hummel                      | PPD, UK                       |                      |
| Teppo Huttunen <sup>1</sup>        | 4Pharma Ltd,FI                | EFSPI Council Member |
| Melanie Jones <sup>1</sup>         | Covance, UK                   |                      |
| Mette Krog Josiassen <sup>2</sup>  | Lundbeck, Denmark             |                      |
| Murray Lowe <sup>2</sup>           | Phastar, UK                   |                      |
| Frances Lynn                       | Orchard Therapeutics, UK      |                      |
| Roland Marion-Gallois <sup>2</sup> | Cellgene, Switzerland         |                      |
| Sireesha Pamulapati                | Biogen, UK                    |                      |
| Carol Reid                         | Roche, UK                     |                      |
| Véronique Robert <sup>2</sup>      | Servier, France               |                      |
| Kaspar Rufibach                    | Roche, Switzerland            |                      |
| Antony Sabin                       | AstraZeneca, UK               |                      |
| Florian Voss                       | Boehringer-Ingelheim, Germany |                      |
| Heike Wöhling                      | Novartis, Germany             |                      |

<sup>1</sup> Left committee during 2019

<sup>2</sup> Joined committee during 2019'

## SIG Leads

### SIG

AIMS  
Benefit Risk  
Data Science  
Data Transparency  
Decision Making  
Historical Data  
HTA  
New Starters  
Oncology Estimands  
Subgroups  
Toxicology  
Vaccines  
Visualisation

### Company, Country

Lyn Taylor, Phastar  
Maria Costa, Novartis  
Julia Chernova, Bayer  
Rebecca Sudlow, Roche  
Gaelle Saint-Hilary, Servier  
Byron Jones, Novartis  
Chrissie Fletcher, GSK  
Jack Eusden, GSK  
Kaspar Rufibach, Roche  
David Svensson, AstraZeneca  
Gareth Thomas, Covance  
Fabian Tibaldi, GSK  
Alexander Schacht, UCB

## Training Committee

| <b>Name</b>                  | <b>Company, country</b> | <b>Role</b> |
|------------------------------|-------------------------|-------------|
| Mark Dixon                   | Roche, UK               |             |
| Mary Elliott-Davey           | Amgen, UK               | Chair       |
| KarolAnne Fitzpatrick        | Parexel, UK             |             |
| Alex Godwood                 | Heptares, UK            | ITIT Chair  |
| Gemma Hodgson                | Qi Statistics Ltd, UK   |             |
| Caroline Kennedy             | AstraZeneca, UK         |             |
| Alison McLeod                | Phastar, UK             |             |
| Anna Patten                  | Eisai, UK               |             |
| Ingrid Franklin <sup>1</sup> | Veramed, UK             |             |
| Megan Chilton <sup>1</sup>   | PPDI, UK                |             |
| Margaret Jones               | UCB, UK                 |             |
| Rimgaile Urbaityte           | GSK, UK                 |             |
| Sarah Vowler <sup>1</sup>    | AstraZeneca, UK         |             |
| Charlotte Snape <sup>2</sup> | Veramed, UK             |             |
| Matthew Radford <sup>2</sup> | Amgen, UK               |             |
| Collette Letham <sup>2</sup> | PPD                     |             |
| Ellie Grainger <sup>2</sup>  | AstraZeneca, UK         |             |

<sup>1</sup> Left committee during 2019

<sup>2</sup> Joined committee during 2019

# 2019 PSI Events

## CALC

- 20 February Medical Statistics Taster Day
- 5 November Maths Meets Medicine

## Journal Club

- 24 January Journal Club Webinar: Missing Data
- 19 May Journal Club Webinar: PhD Webinar
- 10 July Journal Club Webinar: The RSS & PSI's Journal Club presents: Survival Analysis
- 5 November Journal Club Webinar: The PSI & DIA's Journal Club presents: Subgroup Analyses

## Scientific

- 29 January Estimands and Casual Inference
- 28 March PSI One Day Meeting: New Starters SIG 28 March 2019
- 02 April PSI Toxicology SIG Workshop
- 03 – 05 June 2019 PSI Annual Conference
- 24 June Designing and Analysing Adaptive Trial Design Studies
- 17 July One day meeting: Analysis and reporting of PROs in Clinical Trials
- 11 September Impact of AI on Clinical Development

## Training

- 07 March Network Meta-Analysis (NMA) for Statisticians
- 22 May Estimands Training Course
- 25 June Introduction to Bayesian Statistics
- 16 September Training Course: Improving Influence and Increasing Impact
- 02 October Effective Insight Communication
- 29 October Time to Event and Recurrent Event Endpoints
- 19 November A PSI Training Course on ICH for Statisticians

## Webinars

- 21 January PSI Webinar: HTA Submissions in the UK
- 19 February PSI Toxicology SIG Webinar
- 12 March Webinar: Statistical Engagement with Commercial Activities
- 08 May Webinar: MCP-Mod – Theory, Implementation and Extensions
- 18 June Toxicology SIG Webinar: Pig-A Assay
- 04 July Adaptive design: updated draft FDA guidance and its implications
- 01 October PSI Webinar: Subgroup Analysis
- 11 October PSI Webinar: Effective Insight Communication
- 15 October PSI Scientific Webinar: Statistical Challenges
- 03 December PSI Webinar: Overview and awareness about quantitative decision-making in drug development
- 10 December PSI Webinar: Main statistical approaches for quantitative decision-making in drug development
- 18 November PSI Webinar: Longitudinal modelling: Time to take the next step?