Promoting
Statistical
Insight

2018

ANNUAL REPORT

www.psiweb.org

Contents

Welcome from the Chair

I am delighted with the progress that PSI made in 2018. We delivered on many of our objectives and the society is in excellent health. I have summarized our achievements below and 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 883 to 1074 in 2018, covering 29 countries worldwide.
- Video-on-demand was launched as promised at the PSI Conference. A total of 150 videos have been loaded so far and are free to watch for members.
- A total of 391 delegates registered for the 2018 PSI Annual Conference in Amsterdam. This is a record for PSI.
- Exhibition and sponsorship raised €113,386, the second highest amount ever raised at a conference.
- Our reserves are at the highest ever levels (£341k) since the formation of PSI, and we made a profit of £59k in 2018.
- Despite the snow, 80 students and 25 pharma companies, CROs and CTUs attended the PSI Careers event in Leicester, UK in February 2018.
- As part of our re-investment PSI signed a contract to refresh the PSI Website. The new website will be rolled out in 2019.
- The Effective Statistician (podcast) was launched to make our communications more personal and show people behind the news.
- The Regulatory Expert Working Group published a paper on 'Best Practice for Subgroup Analyses' in Pharmaceutical Statistics.
- PSI reduced the Scientific Meeting registration fee from £160 to £40 to make meetings more accessible. A total of two meetings and six webinars were organised in 2018.
- The AIMS SIG launched a R Validation Hub Website in January (https://www.pharmar.org/
- The New Starters SIG was reformed in the second half of 2018.
- Meetings were held with the RSS to discuss a range of topics of mutual interest. These meetings will continue to occur in the coming years.
- Regulatory Committee Members helped to organize the 3rd EFSPI Workshop on Regulatory Statistics

Updates from each of the committees are included in the following pages; I encourage you to read on.

Awards

The Mick Godley Award is given every year to an unsung hero in one of the PSI committees in memory of Mick Godley, one of the early stalwarts of PSI, with the recipient receiving free attendance at a PSI conference of their choice. We had two recipients this year:

Amanda Darekar (Pfizer) for her significant contribution to the CALC Committee. During her 10 years on the committee, she has supported a huge number of school workshops, career fairs, university talks, and Big Bang events. I am very pleased that Amanda has now joined the PSI Board.

Ingrid Franklin (Veramed) who played a significant role in the delivery of the Video-on-Demand plaform, which was a primary object for PSI. Ingrid helped to research and test potential platforms and to investigate methods of organising the videos. Furthermore, along with another member of the training committee, Ingrid will be helping to maintain the site going forward to ensure PSI members have access to a valuable and professional platform.

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:

Dr Mouna Akacha (Novartis), “Enhancing drug development using clinically interpretable treatment effect measures (‘estimands‘) that allow for efficient statistical analyses” was recognised for the quality of intellectual framing of an approach to an important question of how to analyze RCTs with incomplete follow-up in line with new ICH guidance on estimands.

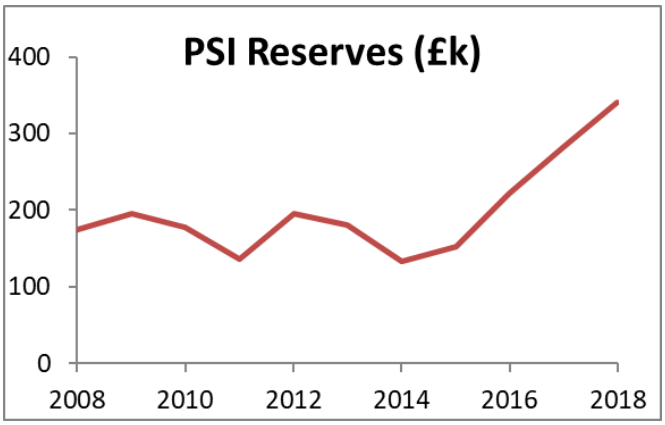
Dr Simon Bate (GSK), “Improving the quality and reliability of animal research through the use of InVivoStat: a statistical software package for animal researchers” was recognized for the significant body of work created and the obvious beneficial impact it has had within the intended user community over many years.

Nigel Howitt
PSI Chair

Treasurer's Report

During 2018, PSI made a modest profit of £59k, and our reserves now stand at £341k.

I have proposed that we keep the reserves at a nominal level (£300k) and any profits over and above this are then reinvested in the organisation's infrastructure and initiatives. This level will ensure that we would still be able to meet our financial commitments in a lean year. Although PSI is a not-for-profit organisation, we do still need to ensure that our financial commitments can be met.



In 2017, we sought advice from the Global VP of Association Management at MCI who provided some guidance on the level of reserves. Their recommendation was that reserves should be in the region of 75% of the annual turnover. Since I took on the role of treasurer in 2014, our reserves have more than doubled; the organisation has grown; membership has started to grow again; conference, training courses and scientific meetings offered have all seen organic growth. Our turnover has grown in line with this and our current reserves are just over 61% of our turnover, which is still at an appropriate level and an increase on 2017's figure.

We are now in a better position to make more substantial investments in the infrastructure. The board have planned initiatives over the next few years to provide enhancements to the membership, ensuring it is value for money. There is also an initiative planned to support industry in terms of the number of statisticians starting out their careers within pharmaceuticals. In the past year, we launched Video-on-Demand, bringing recordings of webinars, conference sessions and the like to the members, all free of charge.

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 3 years:

Profit (£k)*	2016	2017	2018**
Membership	58	72	72
Conference	124	65	116
Training & ITIT	18	22	19
CALC	3	11	-1
Scientific	9	11	3
Publications	-18	-16	-5
Commercial	100	86	97

* Rounded to the nearest £1000(£k)

** Accounts still to be finalised.

The finance team at MCI have done a great job at staying on top of 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.

Fiona Brock

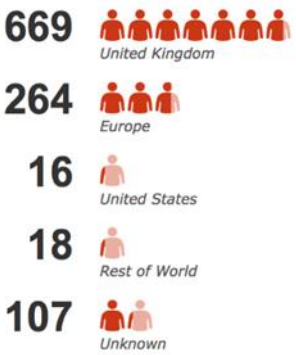
Treasurer

Membership Report

2018 saw the return to growth for PSI membership helped in part by another wonderfully successful conference and the reintroduction of the student/teacher membership category. With a membership total of 1074, the membership is back over 1000 members, a level the organisation hasn't seen since 2011.

Membership Category	2014	2015	2016	2017	2018
Full	916	881	886	861	959
Honorary	8	8	9	9	9
Reduced Rate	15	9	9	13	8
Student/Teacher					98
Total	**939**	**898**	**904**	**883**	**1074**

2018 also saw updates to the PSI membership database, making it simpler to profile the geographical distribution of the membership.



The Board has had a strategic focus on strengthening our membership base across Europe and beyond for several years and this is coming to fruition with members residing in 29 countries worldwide.

Whilst PSI is still seen by some as a UK-centric organisation, it's great to see that ~30% of our members are from outside the UK. Much of the credit for this is the success of the decision to seek mainland European venues for the annual conference, the introduction of the PSI video-on-demand and, of course, the enthusiasm of the European members sitting on the Board, in the SIGs and committees.

Tim Rolfe
Membership Secretary

Partnership Report

The remit of the Contracts/Partnership 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.

CONTRACTS

Business Administration Services

The current contract to cover business administration services runs until July 2020. The MCI/PSI relationship is working well with no issues noted. Conference event management tasks are included in the overall business contract.

Website

The website continues to be solely maintained by MCI UK Ltd. A contract for a Website Refresh was signed with MCI UK Ltd October 2018; scope of works included an audit of the current website, design of new website templates and application of the new templates and restructure. The cost of the contract is £10,125.

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 2019.

Commercial

Two contracts ongoing between PSI and Watton Hall Ltd which expire in 2019. Both are commission based and in place to assist PSI with advertising and promotion.

PARTNERSHIPS

Council of Biopharmaceutical Statistics

Naomi Givens, Tim Rolfe, Anna Berglind and Mouna Akacha sat on the CBS (Council for Biopharmaceutical Statistics) along with representatives from the DIA (EU, North America and China), EFSPI, QSPI, ASA, FDA & ISBS. The goal of the CBS is to create and foster a forum for sharing information among organisations that have a statistical community. During 2018 there was sharing across organisations of information regarding events, courses, publications and scientific working groups with advertising across groups where applicable.

Naomi Givens

Contracts and Partnerships Director

Commercial Report

Exhibiting and Sponsorship at the 2018 Conference was excellent and we raised £100,511.30 in revenue, the second highest amount ever raised at the Conference.

There were 17 exhibitors which included: Aerotek, AZ, Biotrials, Clinbay Limited, CROS NT, Cytel, GCE Solutions, GSK, Hays, IDDI, Phastar, PRAHS, Quanticate, Shafi Consultancy Ltd, Tools 4 Patients, Veramed, and Warman O'Brien. We also had 7 sponsors: AZ, Covance, Cytel, GSK, IQVIA, Phastar, Roche.

We would like to thank all our exhibitors and sponsors for their kind support and making the conference an enormous success. Advertising revenue in 2018 was £9,880 which was lower compared to previous years. A refresh of the PSI Jobs Board is therefore an objective for 2019.

PSI Commercial was again supported by Watton Hall (a commercial company).

Alexander Currie
Commercial Director

Careers & Academic 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.

CALC held its annual PSI Careers Event on the 28th February at the University of Leicester, with approximately 80 students attending on the day (despite the snow!). Representatives from 25 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 new panel discussion session was a particular success, giving students the chance to hear first-hand from a range of people talking about their role and experience working in the industry.

Our BSc subteam have also been busy this year. The team focussed on updating and improving promotional materials and information available on the website; a promotional video and digital poster were created, aimed at inspiring undergraduate students to consider the industry. The team also compiled information on companies who offer placement schemes for the newly relaunched careers website. In addition, the team were set the goal of establishing new links and strengthening existing links with universities across the UK. This included awarding 5 BSc prizes to the highest performing undergraduate mathematics/statistics students at the Universities of Glasgow, Birmingham, St Andrews, Reading and Cardiff. The BSc subteam are also working on a series of podcasts aimed at university students, covering topics from a general overview of the drug development process from a statistician's perspective, to advice on how to prepare for a job application. Watch this space for further details coming soon!

The schools subteam continue to work hard and have run two successful school events this year. They attended the Bucks Skills Show in October, meeting with hundreds of school-aged students, teachers and parents. They also ran a PSI schools event at the University of Reading on the 5th November, where they ran 3 statistics-based workshops for 45 students based in and around Reading. The event received great feedback from students and teachers alike.

Another big activity for the group this year was the re-launch of the PSI careers section of the website. Thanks to Tom Rouse and the whole of CALC, the pages were successfully reviewed, redesigned and relaunched. The schools and education area of the website has also been completely revamped. In addition to this, CALC have been involved in the Millennium Maths Project, attended careers events at various universities, and have been heavily promoting the benefits of free PSI student membership. At the end of 2018 we had approximately 98 students registered as PSI members which is great news!

Going forward, PSI CALC have plans to further investigate the current MSc funding situation and plan to lobby the NIHR to continue funding MSc places. We'll also be looking into other options to encourage students into the industry, including promoting the benefits of an MMath in Statistics (as an alternative to the more costly MSc option), part-time funding while students work in the industry, and a possible apprenticeship standard for statisticians in medical

research. We're also looking to support a new subteam based in Germany who hope to network with local universities and students and run similar career sessions using our existing material.

Vicky Marriott
CALC Chair

Special thanks

Once again, 2018 has been a busy year for CALC and I want to say a huge thank you to the whole committee who always go above and beyond expectations. After 11 years on CALC and nearly 4 years on the board of directors, I'll be stepping down at the end of February as I go on maternity leave. Amanda Darekar will be picking up the reins, and I know she'll do a fantastic job (as she has already done for the past 8 years as part of her role on CALC). All the best to Amanda and the rest of CALC going forward. I'll miss you all but I know you'll continue to do amazing work!

External Affairs

During 2018, Rebecca Sudlow stood down as Chair and I was seconded to take on the role. My thanks to Rebecca for her clear guidance of the Committee and for progressing its aims.

Also, thanks to Sharon for her contributions and we were pleased to welcome Leanne and Tammy.

During the year we worked on a range of initiatives and organisation interactions. Those of note are:

RSS: We met representatives of the RSS and discussed a range of topics of mutual interest and we will continue to work together and exchange information. EA acts as the liaison but hands on any specific actions to the relevant person or committee. There is now a PSI member in the RSS Medical Section.

Volunteers: There are currently several volunteers from PSI. Individuals have provided a variety of support including training and protocol review for Cancer Research UK. This has been well received. We would be pleased to welcome more volunteers or any requests for volunteer support.

Statistical Advice page on website: This is currently in review to consider how to better help link organisations that are looking for statistical support and those that are able to provide such support.

Datasets for academia: There is a need for data for MSc and PhD students to work on. EA has been looking at how PSI may help with this.

Questionnaires were sent out to company and academic contacts to get feedback. We are currently working to progress this.

Ray Harris
Chair of External Affairs Committee

Communication & Publications Report

The Communications Committee is responsible for SPIN, the quarterly electronic newsletter, Pharmaceutical Statistics, the bi-monthly journal, fortnightly eNews alerts, the news page on PSI website, Journal Club, LinkedIn and Twitter.

We thank all those on the Committee and those who contribute to our range of publications, and MCI who support us very well.

We welcomed Anni back, as well as Doug, Katie, and Sandra who joined the Committee.

We have formed a new team to specifically focus more on social media in alignment with the overall new communication strategy, which was developed together with Nick Manamley in 2018.

Also in accordance with this strategy, we are making communications more personal showing the people behind the news. This includes using more pictures in the news as well as introducing PSI members via the podcast “The Effective Statistician”, which runs in association with PSI.

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. A first corresponding webinar is planned for 2019. The other meetings were successful and can be found in the video-on-demand platform. The video-on-demand platform is now continuously promoted in the enews via the video of the month, which is usually tied to a relevant upcoming event such as a one-day meeting or a webinar.

We are grateful to Wiley for their continued sponsorship throughout the year. The editorial board looks into opportunities to better connect the conference to the journal, e.g. via a dedicated edition based on the conference.

SPIN continues to be a key route of communication for the membership and we are grateful for the content provided by different members.

As an outlook into the future, we are working on ways to improve the communication around the job postings together with the commercial team to improve the overall value of the job postings. We are also working on implementing other parts of the new communication strategy such as segmenting emails by different recipient groups to make them more relevant.

Alexander Schacht
Communications Chair

PSI/EFSPI Regulatory Report

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 2018 the committee held five regular committee meetings, as well as meetings with the EMA's Biostatistics Working Party (BSWP) and the MHRA statisticians. The committee coordinated the review of several regulatory guidance documents (more detail below). Committee members have contributed to EMA and industry workshops as well as webinars on topics such as estimands, clinical trial transparency and PROs. In addition, members of the committee helped organize the 3rd EFSPI workshop on regulatory statistics held in Basel as well as two plenary sessions at the PSI conference in Amsterdam (the regulatory town hall and an estimand role play).

In July, the Chair of the Regulatory Committee transferred to Anna Berglind from Christoph Gerlinger, who is now the Co-Chair of the committee.

Expert Groups

Two regulatory expert working groups were active at the beginning of 2018: the expert group on subgroups continued the work on developing a best practice for subgroup analyses and published a paper on the topic in Pharmaceutical Statistics[1]. This expert group is still active. In addition, the expert group on confidentiality of interim results established following the 2016 meeting with the BSWP was still active at the beginning of the year. The committee agreed at the September 2018 meeting to pause the work in this expert group following finalizing the slides and minutes from the BSWP-meeting 2017 in which the recommendations from the group are documented.

Meetings with statisticians from regulatory agencies

On 19th September 2018, the PSI/EFSPI Regulatory Committee met with the MHRA statisticians in London. Topics discussed included the use of historical / dynamic borrowing / synthetic control arms for regulatory decision making, innovative study designs, quality tolerance limits and risk based monitoring, estimands, protocols for device (non-drug) studies, statistical assessment of quality attributes, treatment switching in oncology, parametric modelling for estimation of treatment benefit in survival analyses, the increase in innovative adaptive designs to evaluate biomarkers, how to analyse multiple occurrences of hospitalisation in CV trials, the use of trimmed means to handle missing data and CRF standards for reason for withdrawals.

In addition, the Regulatory Committee met with the EMA's BSWP on 8th October 2018. Topics discussed included implications of EMA's Brexit preparedness business continuity plan on statistics, use of external ("real world") evidence in confirmatory studies and sharing blinded data of an ongoing study.

Guidelines

The Regulatory Committee collated comments on the following documents during the year:

- FDA's draft guidance on Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics; draft Guidance for Industry
- FDA's draft guidance on Adaptive Designs for Clinical Trials of Drugs and Biologics; draft guidance for industry
- FDA's draft guidance on Meta-Analyses of Randomized Controlled Clinical Trials to Evaluate the Safety of Human Drugs or Biological Products Guidance for Industry
- FDA's draft guidance on Presenting Quantitative Efficacy and Risk Information in

- Direct-to-Consumer Promotional Labeling and Advertisements Guidance for Industry
- EMA's draft Questions and Answers on Data Monitoring Committees issues

Special thanks to Anne Danniau, Jürgen Hummel, Tony Sabin and Kaspar Rufibach for collating comments for the committee.

Anna Berglind

Regulatory Chair

[1] Dane A, Spencer A, Rosenkranz G, Lipkovich I, Parke T, on behalf of the PSI/EFSPI Working Group on Subgroup Analysis. Subgroup analysis and interpretation for phase 3 confirmatory trials: White paper of the EFSPI/PSI working group on subgroup analysis. Pharmaceutical Statistics. 2018;1–14. https://doi.org/10.1002/pst.1919

Scientific Report

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

In addition to the annual Conference in Amsterdam, the Scientific Committee organised two one-day face-to-face meetings and eight webinars. For 2018, PSI reduced the registration cost of scientific meetings for PSI members from £120/£160 (early bird/full price) to £40; non-members pay £135 which includes the annual PSI membership fee. Webinars are free for PSI members and £20 for non-members.

One Day Meetings

- Bayesian Methods for Dose Finding and Biomarkers (RSS, UK)
- Real World Evidence: Generalisability of Treatment Comparisons for Decision Making (Lilly, Germany)

The Bayesian meeting was held at the RSS in London. Unfortunately, heavy snow on the day meant that some attendees and one speaker were unable to get there. For those who did manage to attend, the talks were of high quality and there was a lot of engagement from the audience. Lilly (Bad Homburg, Germany) kindly hosted the Real World Evidence meeting. Attendance was good, including many non-PSI members, as was the feedback. The presentations from both one-day meetings were recorded and are available to PSI members at the PSI Video-on-Demand Library.

Webinars

- A series of three webinars on HTA submissions in Germany
- Big Data and it's Impact
- Basket, Umbrella and Platform Trials – Experiences and Practical Considerations
- Patient Reported Outcomes – Clinically Meaningful Interpretation
- Avoiding Pitfalls in Supervised/Unsupervised Learning
- Use of Prior Knowledge/Data

The webinars covered a wide variety of areas and there were many interesting talks. The Scientific Committee look to arrange meetings that include topics that are of interest to a large number of people as well as more specialist topics that still deserve time and attention. All the webinars were recorded and are available to PSI members in the Video-on-Demand Library.

The Scientific Committee would like to thank all the speakers at our events who gave up their time to present and share their knowledge and experience. My thanks also to all of the Scientific Committee who worked so hard this year in order to put on some great and varied meetings and webinars.

We are constantly looking for suggestions for speakers, topics and talks and would also like to hear from companies interested in hosting our one-day meetings. We encourage members of PSI to contact us with their suggestions.

Paul Terrill
Scientific Committee Chair

2018 Conference

PSI's 2018 Conference was held from 3rd - 6th June at The Beurs Van Berlage, Amsterdam and included a pre-conference half-day workshop titled "Demystifying Causal Inference: Assessing efficacy when patients depart from randomised treatments" given by Sabine Landau and Ian White. This was our largest ever conference to date, with a record breaking 391 delegates registered. Over 55% of the delegates for 2018 came from outside the UK.

The conference theme was 'Breaking Boundaries in Drug Development' and the agenda included many hot topics and case studies. The three days were a mixture of five plenary sessions, 26 parallel sessions and a total of almost 90 speakers. We were delighted to welcome two keynote speakers; Napu Kohli, a doctor and award winning public speaker, gave her thoughts on the future of healthcare, the pressures it faces and questioned whether healthcare could keep up with the fast-past changes of technology. Steven Ruburg spoke about the differences between Data Scientists and Statisticians and challenged us to make sure that we think about the value statisticians can bring to all areas of drug development.

As well as our two keynote speakers, we had a Regulatory Town Hall session with 5 representatives from regulatory agencies making up the panel and answering audience questions. There was also a Scientific Advice Role Play where we had speakers play out a few different roles (from industry, regulators, HTA and patients) in a discussion around a respiratory drug to work out what matters most in drug development. The parallel sessions covered topics ranging from causal inference, machine learning, estimands, data science, data sharing and multiple workshops on improving communication, owning your own development and preference elicitation. The poster session this year also saw success, with over 60 posters selected 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 third year, the ceremony for the PSI/RSS Award for Statistical Excellence in the Pharmaceutical Industry.

The 2019 conference will be taking place from the 2nd - 5th June at the QEII Centre in London. The preparations are well underway, with all the sessions finalised and many speakers identified. Information will continue to be shared regularly as we move closer to June. As we did last year, we have also put together a monthly conference newsletter and have agreed a communication plan to release more information on sessions before the event through LinkedIn and in the newsletter. The conference app is due to be launched towards the end of April.

Kate Taylor
Conference Chair

Training Report

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.

In the past year, we have also increased our offerings for soft skill training via the Impact & Influence program: Increasing essential skills for statisticians. Members of the Training Committee organised two soft skill workshops at the 2018 conference. We are planning follow-on sessions for the 2019 conference and a one-day training course later in the year.

One of the main achievements for the Training Committee this year was the launch of the video-on-demand platform. There are already over 150 videos, which are all free to watch for PSI members, and the platform is proving to be very popular. In 2019, we want to continue to develop the platform to improve usability and upload as many of our webinars and meetings as possible.

In 2018 the committee ran the following courses:

- Health Technology Assessment
- Missing Data
- Multiple Testing in Confirmatory Trials
- Statistics Fundamentals of Clinical Trials for Non-Statisticians
- Regulatory Interactions for Statisticians
- Demystifying Causal Inference (pre-conference course)

Courses in the pipeline for 2019 include Network Meta-Analysis, Estimands and Sensitivity Analysis in Clinical Trials, (pre conf), ICH Guidelines for Statisticians, Time to Event Methods, Introduction to Bayesian Analysis, PK Methods and Regulatory Considerations, and a further course as part of the Impact & Influence program

The 2019 conference will have two pre-conference courses: Stated Preference Methods: Eliciting patient preferences in the age of personalized medicine, organised in collaboration with the Benefit-Risk SIG, and Evidence Synthesis for Clinical Trials: Use of Historical Data and Extrapolation - Methods, applications and implementation with the R package RBesT.

The ITIT Course provides 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 2018/19 course the delegates have travelled to 3 sessions in mainland Europe and 3 sessions in the UK. PSI wants to continue to engage with our colleagues in mainland Europe and intends to continue with having 3 mainland European ITIT sessions and encourage a greater number of delegates from mainland Europe.

Mary Elliott-Davey
Training Committee Chair

Application and Implementation of Methodologies in Statistics SIG (AIMS)

The SIG aims to support PSI Committees and PSI/EFSPI Special Interest Groups (SIGs) with the technological application and implementation of statistics.

It also aims to develop understanding of new analytical tools and approaches to share with PSI & EFSPI members via appropriate forums and ensure that PSI & EFSPI members are supported with understanding the requirements for the implementation of industry data standards.

We are pleased to announce the launch of our R Validation Hub Website which went live on 7th January 2018: https://www.pharmar.org/

In June 2018, the R consortium granted funding for PSI AIMS SIG initiative to create an online 'R package validation repository'. Following the R Pharma Conference in August 2018 (Attended by Andy Nicholls- GSK/AIMS SIG), we created a subgroup of the AIMS SIG, the 'R Validation Hub' team and membership was expanded to include participants from Abbvie, Amgen, Biogen, Eli Lilly, FDA, GSK, J&J, Merck, Merck KGaA, Novartis, PPD, PRA, Pfizer, Roche / Genentech and Syne qua non.

This subgroup team now meets regularly to discuss the R Validation project also ensuring collaboration with the Transcelerate project. We will be looking to expand on the website content and encourage contribution of R metrics and tests for packages from all R-users. These Metrics and test will be free to access and download and will help users assess the risk associated with user of each R package. The R validation Hub now have their own email contact address: psi.aims.r.validation@gmail.com and github site pharmaR.gitub.io to accompany the website. Given the success of the above project which was assigned to AIMS by the PSI board as the most important aspect to focus on, the AIMS SIG is now in a position to move onto some of the other objectives which it was originally set up to do. Our original areas of interest were to include supporting other SIGs in the application of Methodologies in Statistics to include many areas of applied statistics such as Estimands, Multiple imputation, high performance computing and machine learning.

We were recently made aware of the proposal for creation of a new SIG for Data Science. Given the potential for overlap of objectives between the two SIGs, we met on 8th January with Michele Jones and Stephen Jones to discuss how best to proceed and to assess similarities and differences between a Data Science SIG and the AIMS SIG. It was proposed that perhaps there is much overlap and instead we should look to re-structure to bring both SIGs together with Subgroups. The proposal was that the main SIG would be Data Science however the subsections could focus on 1) Application and implementation of Methodologies in Statistics (AIMS – focused on stats methods), 2) R (including R validation/ Validation Hub work, 3) Data Science such as High performance computing, various software, machine learning and appealing to non statisticians. This proposal will be discussed at the first Data Science SIG meeting next week. Then the two groups will meet again to discuss how to proceed.

Benefit-Risk SIG

The main aims of the SIG are to understand how best to apply Benefit-Risk methodologies across the Pharmaceutical Industry, to discuss and make recommendations on key methodological issues, to share examples of how Benefit-Risk has been used within pharmaceutical companies and to share external information including new developments around Benefit-Risk

Objectives for 2019

- Half-day course on preference elicitation at PSI 2019 conference – June 2019
- Session on benefit-risk at PSI 2019 conference – June 2019
- Potential webinar on challenges in preference studies, or podcast to follow from last year's webinar "Do you understand the patient point of view on benefit-risk tradeoffs? Introduction and case studies of stated preference elicitation methods" – TBD
- Manuscript on BR in HTA – submission this year
- Develop and grow a subteam focused on Safety assessment during 2019

Highlights

- The BR-SIG organised two webinars on BR-related topics:
    - "Quantitative benefit-risk assessment using MultiCriteria Decision Analysis (MCDA) and its extensions: practical application" (13th March 2018) - Gaelle Saint-Hilary (Servier) and Stephanie Cadour (Servier)
    - "Do you understand the patient point of view on benefit-risk tradeoffs? Introduction and case studies of stated preference elicitation methods" (20th November 2019) - Alexander Schacht (Lilly), Marco Boeri (RTI-HS), Shahrul Mt-Isa (MSD), Brett Hauber (RTI-HS) and Daniel Saure (Lilly)
- Four presentations at international conferences:
    - Recent development in benefit risk assessment within health - Shahrul Mt-Isa (PSI 2018)
    - Personalized benefit-risk assessment - Maria Costa (PSI 2018)
    - Preference elicitation strategies in drug development - Necdet Gunsoy (PSI 2018)
    - The emerging and merging fields of benefit-risk and health technology assessments - Susan Talbot & Sharul Mt-isa (JSM 2018)
- The SIG also organised a workshop on preference elicitation at PSI 2018

Data Science SIG

The new SIG will be led by Steve and Michelle Jones (Covance). In addition to supporting statisticians with their Data Science needs, the group will look to reach out to those who identify as 'Data Scientists' (and would therefore not typically look to an organisation such as PSI for support).

We are yet to formally define objectives but the following areas have been discussed as likely sub-streams:

- Analytics
- Software
- Technology
- Data
- Ethics

One of the key discussions points thus far has been the overlap in interests with the existing PSI/EFSPI AIMS SIG, particularly around software/technology.

Data Transparency SIG

The objectives of the SIG are to share experiences and challenges of external patient level data sharing with particular focus on data privacy and anonymization processes.

Highlights

- PSI Conference presentation (for info Novartis are in the process of publishing their work)
- EMA Policy 70 TAG involvement via Chrissie (providing input/reflections from across pharma)
- SPIN article published Spring 2018, based on the EMA workshop and DIA meetings held in Dec 2017
- Provided comments on the Health Canada White Paper on publishing clinical trial documents

Decision Making SIG

The objectives of the SIG are to share cases studies, to perform literature reviews, discuss and make recommendations on existing methodologies, to develop new methodologies or practices where needed, to promote the role of the statistician in supporting decision-making in pharmaceutical companies and/or other stakeholders and to propose trainings, public meetings or publications to share methods and experience.

Highlights

- Presentations within the group to share case-studies and examples of applications of quantitative decision-making methods and processes.
- Collection of articles on the sharepoint.
- Preparation of a survey to collect decision-makers' needs and preferences, regarding decisions at the study level, the development level and the portfolio level (launched beginning of 2019, results to be presented soon).
- Joint organisation with the EFSPI Scientific Group of a 1-day meeting on "Decision-making in drug development" on December 12th 2018 at Servier, Suresnes (near Paris), France.

Historical Data SIG

Many approaches for designing and analyzing clinical trials using historical (or other external study) data have been proposed in the recent past.

For example, proposals have been made for bridging studies, the combination of randomised and non-randomised evidence, and also for more general problems such as across-phases probability of success calculations. In addition, the ever-increasing number of patient registries and databases for routinely collected data, and recent data sharing initiatives (e.g. TransCelerate), further underline the importance of these approaches. However, there are still many open questions concerning the role which clinical trials that use such data can have in drug development. In our opinion, the three most important questions are:

- What is the state of the art regarding approaches to incorporate historical data into the formal design and analysis of clinical trials?
- Which statistical methods should we use to make historical and current data comparable?
- What are the regulatory requirements necessary for the acceptance of historical data in drug approval?

The scope of this SIG is to provide some answers to the above questions through a variety of activities. These will include:

- Publishing reviews of the available methods, sources of historical data and case studies.
- Collaborating with experts to refine and possibly extend the available methods.
- Interacting with regulators to obtain a better understanding of their requirements.
- Providing trainings, workshops and talks.
- Promoting good practice through templates for study protocols and statistical analysis plans.

Highlights

- A successful webinar and discussion on paper by Weber, Hemmings & Koch on "How to use prior knowledge and still give new data a chance" was held on 19th December 2018. Slides and a recording of the webinar will be made available on the PSI website. The Historical Data SIG are now considering the best way to follow-up on this, e.g. manuscript submitted to PSI capturing key points from the discussion; points to consider document etc.
- Short course on use of historical data using the RBesT R package will be given by one of the SIG members (Sebastian Weber) at the PSI 2019 conference
- Development of guidelines for writing protocols for studies using Bayesian historical borrowing design.

HTA SIG

The purpose of the HTA SIG is to provide statisticians working in the Pharmaceutical Industry engaged in Health Technology Assessments across Europe, and others in related fields of research, an opportunity to:

- Collaborate and discuss strategies and methodology being applied in this area of research;
- Exchange information and share case studies and statistical/analytical challenges faced in HTA research;
- Keep abreast of new research and methodological developments;
- Promote and highlight opportunities for statisticians to make a positive impact in HTAs
- Interact with key opinion leaders in HTA research;
- Organise and/or participate in workshops related to HTAs.

Highlights

The HTA SIG met five times during 2018 via teleconferences. A huge thanks to all SIG members for their contributions in 2018. The HTA SIG help to organise and presented in the second PSI HTA Training course held in April 2018. The HTA SIG submitted a poster at the PSI Conference in June 2018 and at the Joint Statistical Meeting (JSM) in August 2018 covering benefit-risk in HTA. A virtual round table was held with Anja Schiel, Senior Advisor and HTA Assessor at the Norway Medicines Agency and current chair of the EMA Biostatistics Working Party (BSWG) in September 2018. Key themes discussed included: differences in the scientific advice processes, differences between regulatory and HTA perspectives, gaps in evidence presented in HTA, estimands in HTA, benefit-risk and relative effectiveness.

The HTA SIG continues to collaborate with the Benefit-risk SIG and the subgroup analyses working group. The HTA SIG are actively researching trends in network meta-analyses, extrapolation of clinical trials for economic modelling, methods for treatment switching, and HTA processes and methodologies used in Germany.

For more information about the HTA SIG, please contact Chrissie Fletcher (fletcher@amgen.com) (Chair) or see the HTA SIG area on the PSI website.

New Starters SIG

A special interest group to facilitate networking amongst 'new starters' (statisticians and programmers) working in medical research - the pharmaceutical industry, Contract Research Organisations and Clinical Trial Units.

The group will organise between one and three events per year to achieve this. Networking will be facilitated through three types of event – symposia, development and social.

Highlights

- Re-established in the 2nd half of 2018 following a hiatus, established operating guidelines, social media and a group sub-committee
- In the final stages of organising our inaugural New Starters' event at IQVIA Reading at the end of Q1 2019, organised with the invaluable help of Samuel Hadlington
- Establishing a mailing list to update interested PSI members about future opportunities.

Toxicology SIG

The Toxicology SIG has now been running for a number of years, having formed in 2006, and continues to provide a forum to communicate amongst statisticians working in this area. Our objective is to form a consensus on the best statistical practice in various areas of Toxicology.

During April 2018 we held a 2 day workshop, but have continued to have limited time to progress publications. The workshop was attended by 15 delegates and covered the following topics:

- Self-admin/abuse potential
- Statistical methods for analysing the Ames-test
- Discussions about the role of a non-clinical statistician
- Bioassay validations
- Statistics in safety testing

Our next 2-day workshop is booked for April 2019. We also continued a series of webinars, covering different topics related to the Toxicology area. These continue to run every quarter.

Most companies have very few statisticians supporting the toxicology area and the Toxicology SIG provides an excellent forum for sharing problems and proposing solutions. Under the Toxicology SIG umbrella seven papers have been published. Our aim is to now progress work on the following topics, have further discussions (via web meetings and/or teleconferences) and publish our proposals/recommendations on each of the following:

- Approaches to combining sexes in analyses
- Anti-Drug Antibody Assay analyses
- Carcinogenicity data and the use of transgenic study data

If you are interested in contributing to one of these areas/publications and/or are interested in joining the Toxicology SIG, please contact Gareth Thomas (gareth.thomas@envigo.com).

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.

Application and Implementation of Methodologies in Statistics (AIMS) SIG

Name	Company, Country	Role
Mark Bynens	JnJ	
Markus Elze	Roche	
Jules Hernandez-Sanchez	Roche, UK	
Craig McIlloney	PPD, UK	Vice-Chair
Andy Nicholls	GSK, UK	R validation Hub Chair
Yann Roberts	Servier, France	
Karma Tarap	JnJ	
Lyn Taylor	Phastar, UK	Chair
Chris Toffis	SQN Clinical	

Benefit-Risk SIG

Name	Company, Country	Role
Mounir Aout	Novartis	
Thomas Bartmus	MSD	
Marco Boeri	RTI	
Michael Colopy	Cytel	
Maria Costa	Novartis	Chair
Daniel Evans	Pfizer	
Sabine Fiala-Buskies	Bayer	
Ursula Garczarek	Roche, Switzerland	
Martin Gebel	Bayer	
Necdet Gunsoy	GSK	
Sebastian Heidenreich	Evidera	
Yannis Jemiai	Cytel	
Shahrul Mt-Isa	MSD	
Natasa Rajicic	Cytel	
Veronique Robert	Servier	
Cornelia Schepers	Boehringer-Ingelheim	
Pritibha Singh	Novartis	
Susan Talbot	Amgen	

Board of Directors

Name	Company, Country	Role
Anna Berglind	AstraZeneca, Sweden	Regulatory Chair
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Tim Rolfe	GSK, UK	Membership Secretary
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Alexander Schacht	Eli Lilly, Germany	Communications Chair
Kate Taylor	Amgen, UK	Conference Chair
Paul Terrill	Cytel, UK	Scientific Chair

Careers & Academic Liaison Committee (CALC)

Name	Company, Country	Role
Amanda Darekar	Pfizer, UK	Incoming Chair
Rhian Jacob	Roche, UK	BSc Subteam
Jessica Kendall[2]	Leeds Institute of Clinical Trials Research, UK	MSc Subteam, Social Media
James Lay-Flurrie	GSK, UK	Millennium Maths Project, German CALC Liaison
Rachael Loftus	GW Pharmaceuticals, UK	BSc Subteam
Harriet Longley[2]	Eli Lilly, UK	Schools Subteam
Vicky Marriott	IQVIA, UK	Outgoing Chair
Emma Mcentee	PAREXEL, UK	MSc Subteam, Social Media
Abeera Mohammad	Amgen, UK	Schools Subteam
Holly Moon[1]	Eli Lilly, UK	Schools Subteam
Amy Phillips-Jones	Plus Project, UK	BSc Subteam
Tomas Rouse	AstraZeneca, Sweden	Website
Katharine Thorn	GSK, UK	Schools Subteam
Cheryl Turkington	Amgen, UK	Schools Subteam, University Prizes
Xinyi Zhu	GSK, UK	MSc Subteam

Commercial Committee

Name	Company, Country	Role
Alexander Currie	GSK, UK	Chair
Abigail Doe[2]	Decision Resources Group, UK	
Anna Passera	Consultancy, France	

Communications Committee

Name	Company, Country	Role
Jack Elkes	IQVIA, UK	
Matthew Gibb	Veramed, UK	
Priya Gokani	Amgen, UK	
Noormaa Jaumdally	MSD, UK	
Sandra Joksaite	GSK, UK	
Katie Murphy	Katie Murphy	
Jamie Rees	GSK, UK	
Alexander Schacht	UCB – former Lilly, Germany	Chair
Anny Stari	Astellas, UK	
Douglas Thompson	GSK, UK	

Data Transparency SIG

Name	Company, Country	Role
Janice Branson	Novartis, Switzerland	
Irene Ferreira	PPD, UK	
Chrissie Fletcher	Amgen, UK	
Christoph Gerlinger	Bayer, Germany	
Chris Harbron	Roche, UK	
Ray Harris	Eisai, UK	
Sally Hollis	Phastar, UK	
Rebecca Sudlow	Roche, UK	Chair
Katherine Tucker	Roche, UK	

Decision Making SIG

Name	Company, Country	Role
Juan Abellan	GSK, UK	
Gianluca Baio	UCL, UK	
Nicolas Bonnet	Sanofi, France	
Sarah Bray	Amgen, UK	
Alex Carlton	GSK, UK	
Pierre Colin	Sanofi, France	Co-chair
Cecile Dubois	Grunenthal, Germany	
Beki Finch	Roche, UK	
Paul Frewer	AstraZeneca, UK	
Heiko Goette	Merck, Germany	
Martin Johnson	UCB Pharma, USA	
John-Philip Lawo	CSL Behring, Germany	
Emmanuel Pham	Ipsen, France	
Laurent Quinquis	Danone, France	
Veronique Robert	Servier, France	

Oliver Sailer	Boehringer Ingelheim, Germany	
Gaëlle Saint-Hilary	Servier, Polytechnic Univ Turin, Italy	Co-chair
Guido Thömmes	Grunenthal, Germany	

External Affairs Committee

Name	Company, Country	Role
Leanne Hall[2]	IQVIA, UK	
Ray Harris[2]	Eisai, UK	Incoming Chair
Stephen Jones	Covance, UK	
Tammy McIver[2]	Roche, UK	
Dawn Midwinter	GSK, UK	
Sharon Richards[1]	Amgen, UK	
Rebecca Sudlow[1]	Roche, UK	Outgoing Chair
Jenna Wills	MRC CTU, UK	

Historical Data SIG

Name	Company, Country	Role
Maxine Bennett	MRC, UK	
Nicky Best	GSK, UK	Joint Technical Lead
David Dejardin	Roche, CH	
Frank Fleischer	Boehringer Ingelheim, DE	
Tim Friede	University of Goettingen, DE	
Toshi Hamasaki	NCVC, JP	
Lisa Hampson	Novartis, CH	
George Hawkins	AstraZeneca, UK	
Byron Jones	Novartis, CH	Chair
Nelson Kinnersley	Roche, UK	
Martin Posch	Medical University of Vienna, AT	
Christian Roever	University of Goettingen, DE	
Gaelle Saint-Hilary	Servier, IT	
Ros Walley	UCB, UK	
Simon Wandel	Novartis, CH	Joint Technical Lead
Sebastian Weber	Novartis, CH	

HTA SIG

Name	Company, Country	Role
Abdallah Abouihia	Medtronic, Switzerland	
Thomas Bartmus	MSD, Germany	
Simone Borley	MAP BioPharma, UK	
Monika Bruederl	AMS, EU	
Chrissie Fletcher	Amgen, UK	Chair
Lili Fokas	Numerus, Germany	
Christoph Gerlinger	Bayer, Germany	
Jes Birger Hansen	Leo, Denmark	
Kirsten Hermann[2]	Amgen, Germany	
Cristina Ivanescu	Quintiles, EU	
Friedhelm Leverkus	Pfizer, Germany	
Yannis Jemiai	Cytel, US	
Paul Mahoney[1]	Roche, Switzerland	
Helen Mann	AstraZeneca, UK	
Jade Marshall	MAP BioPharma, UK	
Jan McKendrick	PRMA Consulting, UK	
Shahrul Mt-Isa	MSD, UK	
Danielle Norman[1]	MAP BioPharma, UK	
Marie-Ange Paget	Eli Lilly, France	
De Phung[1]	Astellas, The Netherlands	
Carol Reid	Roche, UK	
Juan Sanchez	Mundipharma, EU	
Michael Schlichting	MSD, EU	
Fred Sorenson	Xcenda. Switzerland	
Achim Steup[2]	Astellas, US	
Helen Tate[1]	Consultant, UK	
Alexandra Thiele	AMS, EU	
Jason Wang	Celgene, Switzerland	
Claire Watkins	Consultant, UK	
Caroline Whately-Smith	Consultant, UK	

New Starters SIG

Name	Company, Country	Role
Jack Euesden[2]	GSK, UK	Incoming Chair
Samuel Hadlington	IQVIA, UK	

PSI/EFSPI Regulatory Committee

Name	Company, Country	Role
Julie Anderson	GSK, UK	
Anna Berglind	AstraZeneca, Sweden	Outgoing Co-chair / Incoming Chair, PSI Regulatory Chair
Maylis Coste	Servier, France	EFSPI Council Member
Erika Daly	ICON, UK	
Anne Danniau	Grünenthal, Belgium	
Daniel Evans	Pfizer, UK	
Chrissie Fletcher	Amgen, UK	EFSPI Council Member
Christoph Gerlinger	Bayer, Germany	Outgoing Chair / Incoming Co-chair, EFSPI Council Member, EFSPI Regulatory Chair
Kerry Gordon	IQVIA, UK	
Jürgen Hummel	PPD, UK	
Teppo Huttunen	4Pharma Ltd, FI	EFSPI Council Member
Melanie Jones	Covance, UK	
Frances Lynn	Orchard Therapeutics, UK	
Robin Mukherjee[1]	DBV technologies, FR	
Sireesha Pamulapati[2]	Eli Lilly, UK	
Carol Reid	Roche, UK	
Kaspar Rufibach	Roche, Switzerland	
Antony Sabin	AstraZeneca, UK	
Florian Voss	Boehringer-Ingelheim, Germany	
Heike Wöhling	Novartis, Germany	

Scientific Committee

Name	Company, Country	Role
Mouna Akacha	Novartis, Switzerland	
Tom Burnett[2]	Lancaster University	
Tony Cornelius[1]	CMed Research, Romania	
Adam Crisp	GSK, UK	SIG Liaison
Maria Efstathiou	IQVIA, UK	
Jennifer Gilbride	GSK, UK	
Martin Jenkins	AstraZeneca, UK	
Russell Jones	Orchard Therapeutics, UK	
Vivian Lanius[1]	Bayer, Germany	
Rachael Lawrance	Adelphi Values, UK	
David Lawrence	Novartis, Switzerland	
Rosie Leach[2]	Numerus, UK	
Rachel Moate[1]	MedImmune, GSK	
Amitava Mukhopadhyay[2]	Cytel, India	
Ioulietta Mulligan[2]	Worldwide Clinical Trials	

Emanuela Pozzi	Roche, Switzerland	
Khadija Rantell[2]	MHRA, UK	
Lucy Rowell	Roche, UK	Conference Chair
Julia Saperia	MHRA, UK	
Alexander Schacht[1]	Lilly, Germany	
Kate Taylor	Amgen, UK	Conference Vice-Chair
Paul Terrill	Cytel, UK	Scientific Committee Chair
Sue Todd	University of Reading, UK	
Sarah Williams	Roche, UK	
Lynsey Womersley	Phastar, UK	

Toxicology SIG

Name	Company, Country	Role
Eloisa Brook	GSK	
Helena Geys	J&J	
Philip Jarvis	Novartis	
Jim Saul	Covance	
Fetene Tekle	J&J	
Gareth Thomas	Envigo	Chair
Bernd-Wolfgang Igl	Bayer	

Training Committee

Name	Company, Country	Role
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 MacLeod	Phastar, UK	
Anna Patten	Eisai, UK	
Maria Taboada[1]	AstraZeneca, UK	
Ingrid Franklin	Veramed, UK	
Megan Chilton	PPDI, UK	
Margaret Jones	UCB, UK	
Rimgaile Urbaityte	GSK, UK	
Sarah Vowler[2]	AstraZeneca, UK	

[1] Left committee during 2018
[2] Joined committee during 2018

2018 PSI Events

CALC

5 November	Maths Meets Medicine 2018
12 October	Bucks Skills Show 2018
28 February	Medical Statistics Taster Day 2018

Journal Club

11 December	PSI and DIA Journal Club: Statistical Considerations for Innovative Designs in Clinical Trials
24 September	PSI/RSS Journal Club: Meta-Analysis
12 July	PSI Journal Club: Bayesian Methods
26 April	PSI Journal Club: Modelling and Simulation

Scientific

18 September	Real World Evidence: Generalisability of Treatment Comparisons for Decision Making
3-6 June	2018 PSI Annual Conference
24 April	PSI Toxicology SIG Workshop 2018
28 February	Bayesian Methods for Dose Finding and Biomarkers

Training

26 September	Regulatory Interactions for Statisticians
20 September	Statistics Fundamentals of Clinical Trials for Non-Statisticians
9 May	Multiple Testing in Confirmatory Clinical Trials
24 April	Health Technology Assessment (HTA)
6 March	Missing Data

Webinars

19 December	PSI Webinar: How to use prior knowledge and still give new data a chance?
11 December	How Well do Toxicology Studies Predict Clinical Safety Outcome? A Translational Safety Big Data Analysis
29 November	PSI Webinar: Avoiding Pitfalls in Supervised/Unsupervised Learning
20 November	EFSPI/PSI Webinar: Do you understand the patient point of view on benefit-risk tradeoffs?
18 September	Toxicology SIG Webinar: Strengths, Weaknesses, Opportunities and Threats to the Pre-Clinical Statistician
19 June	Toxicology SIG Webinar
8 May	PSI Webinar: Patient Reported Outcomes (PROs) - Clinically Meaningful Interpretation
18 April	PSI Webinar: Basket, Umbrella and Platform trials - Experiences and practical considerations
17 April	Toxicology SIG Webinar
22 March	PSI Webinar: What's the big deal with big data and will it have a big impact on me?

13 March	PSI/EFSPI Webinar: Quantitative benefit-risk assessment using MultiCriteria Decision Analysis (MCDA) and its extensions: practical application
6 March	PSI Webinar: HTA submissions in Germany, what do statisticians need to know to be successful with their GBA dossiers – Part Three
20 February	PSI Webinar: Integrating transcriptomics into early safety screening
31 January	PSI Webinar: HTA submissions in Germany, what do statisticians need to know to be successful with their GBA dossiers – Part Two
23 January	PSI Webinar: HTA submissions in Germany, what do statisticians need to know to be successful with their GBA dossiers – Part One