Promoting Statistical Insight

2017 ANNUAL REPORT

www.psiweb.org

Contents

Welcome from the Chair

PSI had another successful year in 2017, due to the engagement and energy of our excellent volunteers:

- Our finances remain strong and we have a healthy reserve fund
- PSI celebrated its 40th anniversary at the 2017 PSI Conference in London with a record breaking UK attendance (336)
- Our membership numbers have stabilised (883)
- A Membership Director position has been introduced to the Board in order to expand membership
- We have changed our membership entrance criteria to make the society more open to new members
- A communications initiative has started to further improve our connectivity with our members
- The PSI Careers Day in February had a record attendance (100).
- Our Scientific Committee organized 10 events (including 4 Webinars)
- PSI is building a Video on Demand platform to share recordings and eLearning material. This will be launched in 2018 and will be freely available to members
- To make the PSI Introduction to Industry Course more accessible to members, sessions will be held in sites across mainland Europe in 2018 and 2019
- Members of our Regulatory Committee helped to organize the 2nd EFSPI Workshop on Regulatory Statistics
- Our SIGS also continue to be very active

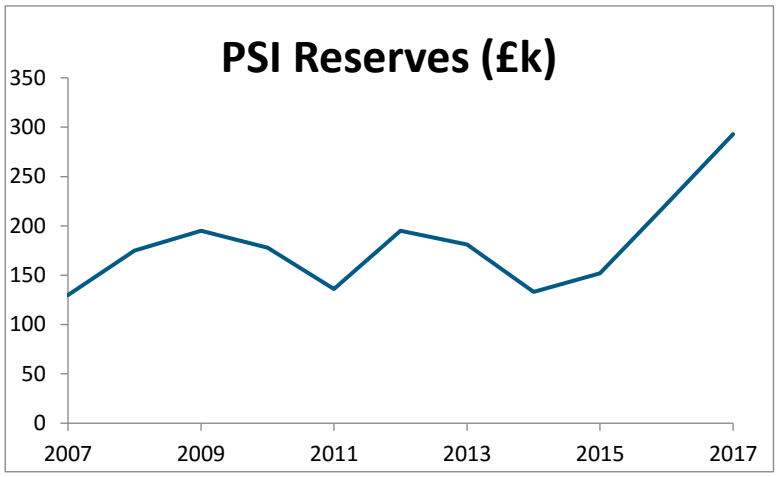
Updates from each of the committees are included in the following pages; I encourage you to read on.

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. The recipient in 2017 was Paul Terrill for his significant contribution to the Scientific Committee. The RSS/PSI Award for Statistical Excellence in the Pharmaceutical Industry continues to establish itself as a prestigious award. The worthy winner in 2017 was Michael O'Kelly for his work entitled 'Promoting analytical solutions and best practices for handling missing data in pharmaceutical industry'.

Nigel Howitt
PSI Chair

Treasurer's Report

During 2017, PSI made a modest profit of £71k. Over the past three years we have continued to grow our reserves, after we dipped into these in 2013/14 to invest in some of the infrastructure.



Although PSI is a not-for-profit organisation, we need to ensure that we are able to cover our overheads, have some reserves to cover a 'not-so-great' year and more importantly be in a financial position to invest in the infrastructure and other initiatives we may be working on or would like to work on.

Many years ago and during a previous treasurer's tenure, a target of £185k was set for the rainy-day reserves. With inflation and an increase in the turnover of PSI over the years, we recently sought advice from the Global VP of Association Management at MCI, who provided some guidance on this figure. Their recommendation was that reserves should be in the region of 75% of the annual turnover. Although our current reserves are around 60% of our turnover, they are confident that they are at an appropriate level.

Building the reserves means that we are now in a better position to be able to make more substantial investments in the infrastructure. For a number of years it has been PSI's mission to record a number of the courses and webinars and make them available to our membership. This is the major area of investment, in providing the video-on-demand content. In September 2017, the Scientific Committee piloted recording the one-day meeting on Estimands which we aim to launch as our first video-on-demand content in due course. These are exciting times as PSI are now able to invest in areas that will increase the value to membership.

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 three years:

Profit (£k)*	2015	2016	2017**
Membership	56	58	72
Conference	64	124	65
Training & ITIT	22	18	22
CALC	-3	3	11
Scientific	7	9	11
Publications	-23	-18	-16
Commercial	101	100	86

* Rounded to the nearest £1000(£k)
** Accounts still to be finalised.

As is evident, 2016 was a bumper year, mainly due to the success of the conference and some diligent transfers of euros to sterling around the time of the referendum vote. Although our membership increased marginally from 2015 to 2016, we saw a small dip in numbers in 2017. This was also the year where the increase in the membership fee came into effect, so although the income

has increased, the membership has decreased marginally. We have been able to reduce some of the costs within publications and CALC and across the board we are being savvier about where the funds are spent. This has all contributed to the £71k surplus for 2017 and an increase in the reserves.

We are looking to add more value for members: providing webinars at a reduced cost (or free) and making video-on-demand content available are just a couple of the areas we are investing in from 2018 onwards, and by having the increase in the reserves, all of this is now possible.

The finance team at MCI have done a great job 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 three years we have not had to write off any bad debts at all.

Fiona Brock
Treasurer

Membership Report

2017 saw the creation of a dedicated Membership Secretary role and changes to the classification of the PSI Membership categories.

Following the passionate feedback on the proposals to simplify the membership criteria and broaden the appeal of PSI that was received at PSI's Annual General Meeting in May, it has been agreed to implement the following changes which will come into effect in 2018:

- To simplify membership: 'Ordinary' and 'Affiliate' categories have combined into 'Full' membership, meaning that both former categories will now have equal voting rights.
- To make PSI more inclusive: membership will be broadened to anyone with an active interest in the analysis of data in pharmaceuticals, healthcare and/or medical research. Members will no longer be required to hold a degree in a statistical discipline (however, membership applications will continue to be screened to exclude Recruitment Consultants).
- Students and teachers will be entitled to a free, non-voting membership. We feel that this will make a significant difference and will attract new members who are in education and interested in the statistical field.
- The cost of Reduced Rate membership has been halved to £20 to make PSI membership more affordable to those from less privileged backgrounds, and lower income areas.

In 2017, membership numbers have continued to decrease from 904 to 883; but you will see a concerted effort to reverse this trend in 2018.

Membership Category	2012	2013	2014	2015	2016	2017
Full	989	954	916	881	886	861
Honorary	8	8	8	8	9	9
Reduced Rate	13	17	15	9	9	13
Total	**1010**	**979**	**939**	**898**	**904**	**883**

Tim Rolfe
Membership Secretary

Contracts/Partnership Report

The remit of the Contracts/Partnership Director is as follows;

To establish and maintain key contracts on behalf of PSI with external suppliers. 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
A new contract to cover business administration services from July 2017 to July 2020 was signed with MCI. A few minor changes were made to the previous contract to more accurately reflect the type and number of activities currently organised by PSI, for which MCI provides support. The cost of the contract increased by 2% on the previous year. The MCI/PSI relationship is working well with no issues noted.

Conference Event Management
A separate contract for conference event management was set up to cover preparation work for the 2018 PSI conference. Conference event management tasks have been moved back into the overall 2017-2020 business management contract with MCI.

Website
The website continues to be solely maintained by MCI UK Ltd.

Journal
The Pharmaceutical Statistics journal is owned by Wiley and the current contract is in place until the end of 2021. In 2017, an addendum to the current contract was put in place to reduce the annual fee for PSI from £19,828 to £14,500 to reflect the reduction in the number of PSI members since the initial contract with Wiley was signed.

Digital Publishing of SPIN
In 2017 a new two year contract with YUDU for the digital publishing of SPIN was signed.

Commercial
Two new contracts were agreed and signed between PSI and Watton Hall Ltd in 2017.
The first is a two year commission based contract to assist PSI with advertising activities and increasing potential commercial income through the securing of newly sourced advertising income, placing ads on social media and seeking sponsorship for meetings.
The second is a commission based contract for Watton Hall to promote the 2018 and 2019 PSI annual conferences alongside PSI. The contract covers items relating to sponsorship, exhibition space and overall delegate numbers.

Partnerships

Council of Biopharmaceutical Statistics
Naomi Givens, Tim Rolfe and Anna Berglind sit 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 2017 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

I assumed the role of Commercial Director in July 2017 after Nigel Howitt vacated the position to become Chair.

Exhibition and sponsorship at the 2017 Conference were excellent and we raised £91,595 in revenue. There were 19 exhibitors: Abbott, Adelphi Values, AZ, Cytel, Exploristics, GCE, GSK, Hays, Hobson Prior, Impellam, Pharma Direct, Phastar, PRA, Quanticate, SAS/JMP, Shafi Consultancy, SQN, and Veramed. We also had six sponsors: AZ, Covance, Cytel, Quintiles, Roche, and Wiley. We would like to thank all our exhibitors and sponsors for their kind support and making the conference a great success. Advertising revenue in 2017 was £17,140.

PSI Commercial was again supported by Watton Hall (a commercial company) and the contract was extended into 2019.

Alexander Currie
Commercial Director

Careers & Academic Liaison Committee (CALC) Report

Objectives
The role 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.

Activities in 2017
CALC held its annual PSI Careers Event on the 22nd February at the University of Reading. Approximately 100 BSc, MSc and PhD students participated in the interactive workshop, networking session and presentations. Representatives from 20 pharmaceutical companies, CROs, clinical trial units and regulatory agencies were on hand to answer the students' questions and to give advice on what the industry has to offer young statisticians. Feedback from students and companies alike was extremely positive and CALC would like to thank everyone who gave their time to support this great event. Work is now underway to organise the 2018 event which will take place on 28th February at the University of Leicester.

As well as reaching out to university-level students, CALC also ran two school events in 2017; one at Guildford College and one at the University of Bath. Approximately 90 students from local schools attended each event. CALC members introduced the students to medical statistics through three different workshops. An Alzheimer's workshop taught students about the debilitating disease and how clinical trials can be used to help find a cure. Similarly, an asthma workshop introduced students to the concepts of randomisation, blinding and t-tests, while a NICE workshop demonstrated the work involved in a cost-benefit analysis of new drugs. Both events were a great success with positive feedback from both teachers and students alike. CALC are now busy organising another school event in 2018 and hope that this will become an annual event. We will also be looking at other ways to increase awareness of medical statistics in schools.

To make sure we target all relevant age groups, CALC also set up a new BSc sub team in 2017. This team will look at ways to increase our reach across universities, and to make sure BSc students are aware of their options. In particular, we want to encourage students to study maths and statistics at MSc level, to enable them to enter the industry as a statistician.

CALC continue to work on improvements to the PSI careers and schools websites, and you will see this work continue in 2018. Other work included a webinar with a mix of university and industry representatives to assess MSc funding and syllabus requirements, supporting a PSI one-day event for career young statisticians, and attendance at several careers fairs across the country. CALC also spent time researching a possible apprenticeship standard which would offer students an alternative route into the industry.

Special thanks
While there are many more activities that could be mentioned, this short summary hopefully demonstrates the variety of work that CALC have been involved in during 2017. I want to say a huge thank you to the team for their hard work and enthusiasm throughout the year – and a special thank

you goes to Gail Lynn who is stepping down from CALC. Gail, thank you for everything you've done for CALC over the years. You (and your website wizardry!) will be sorely missed.

Vicky Marriott
CALC Chair

External Affairs Report

A continued focus for 2017 has been on the impact and value of statistical input and support for small and medium enterprises (SMEs). These organisations generally do not have in-house statistical resource and are often late to include qualified statisticians in their drug development thinking. In 2017 we expanded this scope to provide volunteer support to Cancer Research UK (CR UK) Centre for Drug Development (CDD) who do not employ any in-house statisticians but had the need for some expert support.

Achievements were:

1. Continuing to support the directory of consultant statistical services on the PSI website

2. Identifying and connecting PSI members who wished to volunteer their time and statistical knowledge with CR UK's CDD organisation in either of the following ways:

    - Being part of a team helping to create and run a workshop for CDD staff on key statistical considerations for early phase development oncology trials.

    - Individual volunteering of one or two days to:
        - contribute to the review of CDD's outline and full protocol templates to refine stats and analysis sections
        - advise and input into the development of outline & full protocols for up and coming trials
        - participate as a statistical reviewer in a session of the independent CDD protocol review committee

Three PSI members developed training materials and the training is scheduled to occur in 01Q18. Five PSI members volunteered their time to protocol input and review.

Rebecca Sudlow
External Affairs Chair

Publications Report

The Publications Committee is responsible for, or supports:

- SPIN, the quarterly electronic newsletter
- Pharmaceutical Statistics, the bi-monthly journal
- Fortnightly eNews alerts
- News page on PSI website
- Journal Club, quarterly
- LinkedIn, Twitter

Our thanks to all those on the Committee, and those who contribute to our range of publications, and MCI who support us. We welcomed Jamie who joined as SPIN sub-editor, supporting Matt, and Misti who joined to support the Journal Club.

The Journal Club meetings during 2017 were: Biomarkers; Adaptive Signature Design; Clinical Trial Safety Monitoring. These continue to be very popular with many lines accessing these talks during the calls. Following agreement from the Board of Directors to use Vimeo as the video content platform, the current and past Journal Club content will be put onto Vimeo. We are grateful to Wiley for their continued sponsorship throughout the year.

SPIN continues to be a key route of communication for the membership. It has included interesting video content.

There continues to be an increase in the use of LinkedIn and Twitter. LinkedIn is commonly used to promote PSI's wide range of activities and the Chair has used it for his welcoming statement and his quarterly SPIN update. Content is commonly 'liked' and some entries generate further discussion through the comments. ENews is a popular and much used route of communication with the membership.

Pharmaceutical Statistics continues to be a successful and well respected journal, effectively promoted by Wiley. We thank the Editors-in-Chief Thomas Permutt, David Morgan and Jorgen Seldrup for their work in ensuring the success of the journal. We had discussions with Wiley on the cost of the journal and came to an agreement to reduce these costs. We thank Wiley for the very successful working relationship we have and their continued strong support for Pharmaceutical Statistics.

As mentioned in the Chair's section, PSI's communication was looked at in 2017 and this will continue into 2018. Publications will be very engaged with the changing approaches to communication: 2018 will be an interesting year for Publications.

Ray Harris
Publications Chair

PSI/EFSPI Regulatory Report

Objectives
The role of the regulatory committee is to provide the EFSPI/PSI 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.

General
During 2017 the regulatory committee held six 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, first-in-human trials, and clinical trial transparency and anonymization. In addition; members of the committee helped organise the 2nd EFSPI workshop on regulatory statistics held in Basel as well as the regulatory hot topic session at the PSI conference in London.
In June the chair of the regulatory committee transferred to Christoph Gerlinger from Anna Berglind, who is now the Co-Chair of the committee.

Expert Groups
Two regulatory expert working groups have been active during 2017: the expert group on confidentiality of interim results was established following the 2016 meeting with the BSWP. This group has authored recommendations that were shared with the BSWP in 2017, and that will be shared further via a position paper. In addition, the expert group on subgroups continued the work on developing a best practice for subgroup analysis, and is currently finalising a paper on the topic to be submitted to Pharmaceutical Statistics.

Meetings with statisticians from regulatory agencies
The EFSPI/PSI regulatory committee met with the EMA's BSWP on 27 October 2017. Topics discussed included: confidentiality of interim results, non-proportional hazards as it relates to time to event endpoints, real world evidence in rare diseases, statistical assessment of quality attributes, and innovation in clinical trial design.
On 20 November 2017, the regulatory committee met with the MHRA statisticians in London. Topics discussed included: umbrella and basket trials, inconsistencies between hypothesis tests and estimates, statistical assessment of quality attributes, estimands, pragmatic clinical trials and the use of real world evidence/data generated in clinical practice in regulatory decision making, risk based monitoring, and Bayesian methods for incorporating historical data into paediatric trials.

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

- EMA's draft Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/07/WC500232186.pdf)
- FDA´s draft guidance on Multiple Endpoints in Clinical Trials Guidance for Industry (https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm536750.pdf)

- EMA's draft guideline on multiplicity issues in clinical trials (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500224998.pdf)
- EMA's draft reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development (EMA) (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500224995.pdf)
- The draft ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to guideline on statistical principles for clinical trials (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/08/WC500233916.pdf)
- EMA's draft reflection paper on the use of extrapolation in the development of medicines for paediatrics (Deadline in 2018) (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/10/WC500236640.pdf)

Special thanks to Bruno Boulanger, Maylis Coste, Erika Daly, Christoph Gerlinger and Alan Phillips for collating comments for the committee.

Anna Berglind
Regulatory Chair

Scientific Report

Objectives
To organise and facilitate one-day meetings and webinars of scientific statistical interest to our members in addition to organising the annual conference.

Activities in 2017
In addition to the Conference, the Scientific Committee organised six one-day face to face meetings and four webinars:

- Translational Statistics (30 March, hosted by Amgen, UK)
- Statistics for Companion Diagnostics (4 May, Webinar)
- Patient Engagement in Clinical Trials (13 June, Webinar)
- Cancer Immunotherapy (15 June, joint with the Basel Biometric Society (BBS), hosted by Roche, Switzerland)
- Career Young Statisticians (19 June, hosted by IQVIA, UK)
- Data Sharing and Data Privacy (21 June, Webinar, joint with EFSPI)
- Estimands (27 September, hosted by IQVIA, UK)
- Casual Inference (2 November, Webinar)
- Extrapolation (22 November, hosted by GSK, UK)
- Health Technology Assessments (28 November, joint with EFSPI, hosted by MSD, UK)

Feedback was positive for all the events. Slides from the one-day meetings and recordings from the webinars are available on the PSI website under the past PSI events web page. 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, and as such the number of attendees varied between events. The causal inference webinar and one day meeting on Estimands were particularly popular; not surprising given the release of ICH E9 (R1).

Of the six one-day meetings, one was free to attend (Translational Statistics) and one was at a discounted price (Career Young Statisticians). All four webinars were free to attend for both members and non-members. Moving forwards into 2018, PSI have reduced the registration cost of scientific meetings for PSI members from £120/£160 (early bird/full price) to £40 and will be charging a small registration cost for webinars to non-members.

The Scientific Committee is 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 would like to encourage members of PSI to contact us with their suggestions.

Special thanks to Mouna Akacha, Scientific Committee Chair up to the end of September 2017 and to all the Scientific Committee who worked so hard this year in order to put on some great and varied meetings and webinars. In addition, many thanks to the companies who kindly hosted our one day meetings: Amgen, GSK, IQVIA, MSD and Roche.

Paul Terrill
Scientific Committee Chair

2017 Conference

PSI's 2017 Conference was held from 14 – 17 May at The Grange Tower Bridge Hotel, London, and included two pre-conference half-day workshops: Early Phase Decision Making and Trial Design given by James Matcham and Alun Bedding and Sample Size, Power and Adaptive Trial Design for Late Stage Studies given by Pantellis Vlachos and Yannis Jemiai. This was our largest UK conference to date, with a record breaking 336 delegates. Approximately 35% of delegates came from outside the UK.

The conference theme was 'Celebrating 40 years of Promoting Statistical Insight'. The agenda included many hot topics and case studies. The three days were a mixture of four plenary sessions, 21 parallel sessions and a total of more than 60 speakers. We were delighted to welcome two keynote speakers; Richard Stephens, a patient advocate gave his thoughts on how patients are taking control of data and research and how the Pharmaceutical Industry can still do more to ensure our trials are patient focused. David Spiegelhalter talked about the importance of communicated statistics in a balanced way and the need for us all to take responsibility for ensuring messages are not misrepresented through the media.

As well as our two keynote speakers, we had a plenary session on Regulatory Hot Topics and a separate session specifically on Estimands. The parallel sessions covered topics ranging from decision making in drug development, biosimilar development, combination trials and a workshop dedicated to ways to improve influence and increase our impact. The poster session this year also saw success, with over 50 posters selected and a new 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 2018 conference will be taking place from the 3-6 June at Beurs van Berlage, Amsterdam. This will be the first time the conference will be held in a dedicated conference centre to allow us to grow the conference and content. The preparations are well underway, with all the sessions finalised and the majority of speakers identified. Information will continue to be shared regularly as we move closer to June. This 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.

Lucy Rowell
Conference Chair

Training Committee Report

Overview of the 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. Last year we ran a soft skills training course for the first time. We are aiming to run one soft skills course per year to enable statisticians to develop the consulting skills required in their roles. We limit most courses to 25 delegates or fewer so there is plenty of opportunity for discussion and workshops.

Courses
In 2017 the committee ran the following courses:

- Dose Finding in Drug Development using MCP-Mod (1 -2 March 2017*)*
- Early Phase Decision Making and Trial Design (pre-conference course) (14 May 2017*)*
- Estimating Sample Sizes in Clinical Trials (28 -29 June 2017)
- Improving Influence and Increasing Impact: Essential Skills for Industry Statisticians (21 September 2017*)*
- Statistics Fundamentals for Clinical Trials for Non-Statisticians (14 November 2017*)*

Courses planned for 2018 include Missing data on 6-7 March and Health Technology Assessment (HTA) on 24 - 25 April. The HTA course is going to be hosted by AstraZeneca Gothenburg. The committee are very excited to be running our first training course in mainland Europe.
The pre-conference course this year is going to be “Demystifying Causal Inference: Assessing efficacy when patients depart from randomised treatments”.

Introduction to Industry Training (ITIT) course
The ITIT course is a course ran each year for statisticians and statistical programmers who are new to the industry. The course takes delegates through six separate sessions covering the entire process of drug development, 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.

PSI wants to continue to engage with our colleagues in mainland Europe. As part of this initiative, the 2017/2018 ITIT course is holding one of the sessions at AstraZeneca in Gothenburg. The 2018/2019 course will include three sessions in mainland Europe.

Mary Elliott
Training Committee Chair

SIGs Report

Application and Implementation of Methodologies in Statistics (AIMS)

Objectives
Work with all other active SIGs and committees to plus industry leaders to:

- Understand the technology needs that exist for those group
- Identify new areas where PSI could push for technology enhancements
- Identify opportunities to work with leading technology vendors to support PSI and industry needs

Highlights
Following clear guidance at the EFSPI Statistical Leaders meeting in 2016, the SIG has focused on the understanding, education and validation of use of R in our industry.

The SIG has:

- Published four SPIN articles which have been distributed to PSI and EFSPI members
- Updated the website to reflect the work of the SIG
- Met and continue to meet with companies to understand their approaches to validation in R
- Prepared for a full session at the 2018 conference to cover:
    - The AIMS SIG's work to date and future plans
    - A summary of the SIGs SPIN articles including introductions to IDEs, R Studio and R validation concepts
    - An example of how R-Shiny can be used to interactively report adverse event data for safety signal detection.

Benefit-Risk

Objectives
The main aims of the Benefit-Risk Special Interest Group are split into five key areas:

1. To understand how best to apply Benefit-Risk Methodologies across the Pharmaceutical Industry.
2. To share examples of how Benefit-Risk has been used within pharmaceutical companies, any best practices arising from them and how they can best be used from an industry perspective.
3. To discuss and make recommendations on key methodological issues for example utility functions and weighting approaches.
4. To share external information including new developments around Benefit-Risk including those in the literature and outputs from Benefit-Risk initiatives and to produce guidance on how best they can be used within the EFSPI arena.
5. Outputs from the first 4 areas will be used to inform, educate and pass on learning for those within EFSPI and its affiliations.

Highlights
Key achievements in 2017 have been:

- Conducting three webinars on BR-related topics
    - "Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle: PREFER – an IMI Project" with Conny Berlin and Rachael L. DiSantostefano

    - "Measuring Patient and Physician Benefit–Risk Preferences in Antipsychotic Clinical Trials" with Eva Katz
    - "Do patient preference have a role in Health Technology Assessment? Current practice and future potential" with Kevin Marsh
- Growing a blog on benefit-risk at www.benefit-risk-assessment.com
    - Fairly regular blog post on new guidances
    - Articles from the "effects tables survey" conducted by the SIG earlier
    - Grown the traffic to about 5000 views by 2500 visitors

For 2018, the SIG is heavily involved in the preparation of the patient focus session as well as the workshop on preference elicitation at the PSI conference for 2018. Further webinars are also under discussion as well as further growth of the blog.

Biomarker SIG

Objectives
The PSI Biomarkers Special Interest Group has been formed with the aim of developing knowledge and opinions about biomarker usage and the related statistical and study design techniques that are involved. We hope to provide a forum for discussion and the sharing of experiences regarding the use of biomarker data across all stages of pharmaceutical development.

Highlights
There has been no physical activity within the Biomarker SIG in 2017, other than information sharing via the PSI Biomarkers SIG LinkedIn Group. The SIG is planning to reconvene in 2018 with two workshops and a re-run of the Biomarker hands-on training for Pharmaceutical Statisticians in 2019.

Data Sharing SIG

Objectives
The moves towards greater disclosure of data from clinical trials will have a significant impact on the pharmaceutical industry. Disclosure and analysis of these data involve many statistical issues. The Data Sharing SIG objectives are to identify, prioritise, co-ordinate and disseminate information important to data sharing.

Highlights
Presentation to the ScHARR group at the University of Sheffield on "New life for old data – an overview of the clinical trial data sharing environment".

Webinar "Data Sharing and Data Privacy - what every statistician needs to know" held. Registration was full (100) and 70 lines dialled in on the day. Recording and pdfs of slides published on the PSI website.

Participation and contribution to the MRCT/EMA Data Anonymization workshop.

Health Technology Assessment (HTA) SIG

Objectives

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 six times during 2017 via teleconferences, a huge thanks to all SIG members for their contributions in 2017. The HTA SIG organised and presented in the first PSI HTA Training course held in January 2017. The HTA SIG organised an HTA Session at the PSI Conference in May 2017 covering treatment switching, the IMI GetReal initiative and patient reported outcomes. The HTA SIG presented on estimands in HTA, value-based frameworks in oncology, and benefit-risk in HTA at the 1-day PSI/EFSPI HTA meeting in November 2017.

The HTA SIG continues to collaborate with the Integrated Data Analysis SIG on the topic of network meta-analysis, and with the benefit-risk SIG on how HTA stakeholders view benefit-risk in HTA decision making. The HTA SIG are actively researching benefit-risk in HTA, 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.

Integrated Data Analysis SIG

Objectives
Form working groups to review current methodology and practice, and where necessary develop new methods or practices for the integration of data, in the areas of: Efficacy Data in Phases II and III; Safety; and Network Meta-Analysis. To write position papers and engage in public debate by making presentations at public meetings and conferences.

Highlights
On 28 September 2017, PSI and EFSPI organised a webinar entitled “Spotlight on the Integrated Data Analysis SIG” which included the following presentations:

- Lessons learned from meta-analyses of randomized clinical trials for analysis of distributed networks of observational databases. Andrew Bate (Pfizer)
- A unified framework for safety data in the presence of varying exposure and risk. Sally Hollis (Phastar)
- Reporting adverse drug reactions in product labels: suggestions for improvement. Sally Lettis (GSK)

The activities of the SIG have stopped and it is not foreseen that they will resume in the near future.

Modelling & Simulation SIG

Objectives
The Modelling and Simulation Special Interest Group is a forum to share knowledge and understanding about statistical modelling and simulation related to pharmaceutical development.

Highlights
No 2017 highlights provided

Real World Data SIG

Objectives
The purpose of the Real World Data Special Interest Group (RWD SIG) is to provide statisticians working in the Pharmaceutical Industry engaged in Real World Data Analysis, and others in related fields of research, an opportunity to:

- Maintaining a strong alliance within the "statistics community" to respond to industry-wide issues regarding RWD and Drug safety
- 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 RWD research
- Keep abreast of new research and methodological developments
- Promote and highlight opportunities for statisticians to make a positive impact in RWD
- Interact with key opinion leaders in RWD research
- Organise and/or participate in workshops related to RWD

Highlights
No 2017 highlights provided

Subgroup Analysis Working Group

Objectives
To define statistical, methodological options for the analysis and interpretation of subgroups to inform Regulatory labelling decisions.

Highlights
The Subgroup Analysis Working Group (SAWG) have completed the investigation of the key methods and refined the simulation approaches to investigate these methods. A white paper has been submitted to Pharmaceutical Statistics and it is hoped this will be accepted in early 2018. Once this white paper is published the SAWG will make the R-code for the various methods available.
The outputs of this Working Group were presented at the ISCB meeting in Vienna in September 2017, and a PSI webinar is planned for the first half of 2018 summarising the Working Group findings, possible approaches to subgroup analysis and presenting a regulatory view of such approaches.
The future activities of the SAWG will be discussed during 1Q 2018.

Tim Rolfe
SIGs Chair

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
Nigel Howitt	Covance, UK	PSI Chair
Fiona Brock	Quanticate, UK	Treasurer
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Anna Berglind	AstraZeneca, Sweden	Regulatory Chair
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Training Committee

Name	Company, Country	Role
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Mark Dixon	Roche, UK	
Mary Elliott	Amgen, UK	Chair
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Ingrid Franklin	Veramed, UK	
Megan Chilton	PPDI, UK	
Margaret Jones	UCB, UK	
Rimgaile Urbaityte[2]	GSK, UK	

Commercial Committee

Name	Company, Country	Role
Alexander Currie	GSK, UK	Incoming Commercial Director
Nigel Howitt	Covance, UK	Outgoing Commercial Director
Anna Passera	Statistical Consultant, France	
Chris Watton	Watton Hall, UK	Sales (paid position)

Careers and Academic Liaison Committee (CALC)

Name	Company, Country	Role
Amanda Darekar	Pfizer, UK	MSc subteam, Apprenticeships
Jemma Greenin[1]	Eli Lilly, UK	Schools subteam
Kimberley Hacquoil	GSK, UK	MSc funding, Apprenticeships
Rhian Jacob	Roche, UK	BSc subteam
James Lay-Flurrie	GSK, UK	Website and social media, Millennium maths project
Gail Lynn[1]	PPD, UK	Website
Vicky Marriott	CROS NT, UK	Chair
Emma Mcentee	PAREXEL, UK	MSc subteam, Social media
Abeera Mohammad[2]	Amgen, UK	Schools subteam
Holly Moon[2]	Eli Lilly, UK	Schools subteam
Amy Phillips-Jones[2]	Plus Project, UK	BSc subteam
Rachael Poole	Quanticate, UK	BSc subteam
Tomas Rouse	AstraZeneca, Sweden	Website
Katharine Thorn	Eli Lilly, UK	Schools subteam
Cheryl Turkington	Amgen, UK	Schools subteam, University prizes
Xinyi Zhu	GSK, UK	MSc subteam

Publications Committee

Name	Company, Country	Role
Sarah Bray	Amgen, UK	Journal Club
Albert Chau	Datacision, UK	Technical Support for Journal Club
Jodie Crawford[1]	GSK, UK	SPIN sub-editor
Matthew Gibb	Veramed, UK	SPIN editor
Ray Harris	Eisai, UK	Chair and Pharmaceutical Statistics liaison
Noormaa Jaumdally	Merck, UK	ENews editor
Kevin Kane	Phastar, UK	Social Media
Rhiannon Maudsley	AstraZeneca, UK	SPIN social editor
Mairead North	IQVIA, UK	Journal Club
Misti Paul[2]	Advanced Analytics, UK	Journal Club
Jamie Rees[2]	GSK, UK	SPIN sub-editor
Anny Stari	Astellas, UK	News page and eNews
Laura Steven[1]	Numerus, UK	Journal Club

External Affairs Committee

Name	Company, Country	Role
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Dawn Midwinter	GSK, UK	
Sharon Richards	Amgen, UK	
Rebecca Sudlow	Roche, UK	Chair
Jenna Wills	MRC CTU, UK	

PSI/EFSPI Regulatory Committee

Name	Company, Country	Role
Julie Anderson	GSK, UK	
Anna Berglind	AstraZeneca, Sweden	Outgoing Chair / Incoming Co-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	Chair of CBS, EFSPI Vice President, EFSPI Council Member
Lesley France[1]	AstraZeneca, UK	
Christoph Gerlinger	Bayer, Germany	Outgoing Co-chair / Incoming Chair, EFSPI Council Member, EFSPI Regulatory Chair
Kerry Gordon	IQVIA, UK	
Jürgen Hummel	PPD, UK	
Teppo Huttunen[2]	4Pharma Ltd, FI	EFSPI Council Member
Melanie Jones[2]	Covance, UK	
Frances Lynn	Orchard Therapeutics, UK	
Robin Mukherjee[2]	DBV technologies, FR	
Carol Reid[2]	Roche, UK	
Kaspar Rufibach	Roche, Switzerland	
Antony Sabin	AstraZeneca, UK	
Ruthild Sautermeister[1]	Medicomp, Germany	
Florian Voss	Boehringer-Ingelheim, Germany	
Heike Wöhling[2]	Sandoz Biopharmaceuticals, Germany	

Scientific Committee

Name	Company, Country	Role
Mouna Akacha	Novartis, Switzerland	Outgoing Scientific Committee Chair
Jonathan Alsop[1]	Numerus, UK	
Tony Cornelius	CMed Research, Romania	
Adam Crisp	GSK, UK	
Maria Efstathiou	IQVIA, UK	
Jennifer Gilbride	Sum Of Squares Ltd, UK	
Andrew Holmes[1]	Veramed, UK	
Martin Jenkins[2]	AstraZeneca, UK	
Russell Jones	IQVIA, UK	
Vivian Lanius[2]	Bayer, Germany	
Rachael Lawrance	RL Biostatistics Ltd, UK	
David Lawrence	Novartis, Switzerland	
Nick Manamley[1]	Amgen, UK	
Rachel Moate	MedImmune, GSK	
Emanuela Pozzi	Roche, Switzerland	
Lucy Rowell	Roche, UK	Conference Chair
Julia Saperia	MHRA, UK	
Alexander Schacht[2]	Eli Lilly, Germany	
Kate Taylor	Amgen, UK	Conference Vice-Chair
Paul Terrill	Cytel, UK	Incoming Scientific Committee Chair
Sue Todd	University of Reading, UK	
Sarah Williams[2]	Roche, UK	
Lynsey Womersley	Phastar, UK	

Application and Implementation of Methodologies in Statistics (AIMS) SIG Committee

Name	Company, Country	Role
Sophie Canete	Bordeaux University Hospital, France	
Jules Hernandez-Sanchez[2]	Roche, UK	
Wilmar Igl[1]	AstraZeneca, UK	
David.Inman[1]	GSK, UK	
Craig McIlloney	PPD, UK	Chair
Andy Nicholls[2]	GSK, UK	
Yann Robert	Servier, France	
Helene Savel	Bordeaux University Hospital, France	
Lyn Taylor	PRA, UK	Vice Chair
Chris Toffis	Syne Qua Non, UK	

Benefit Risk SIG Committee

Name	Company, Country	Role
Marco Boeri	RTI1	
Michael Colopy	UCB	
Maria Costa	GSK / Novartis	Incoming Chair
Guillemette de La Borderie	Mitsubishi Tanabe Pharma2	
Dan Evans	Pfizer	
Alberto Garcia-Hernandez	Astellas	
Martin Gebel	Bayer	
Guenter Heimann	Novartis	
Ian Hirsch	AstraZeneca	Co-Chair
Yannis Jemiai	Cytel	
Del Jones	GSK	
David Morgan	Ipsen	
Shahrul Mt-Isa	Merck	
Mario Ouwens	Abbott	
Alan Phillips	ICON	
George Quartey	Genentech	
Veronique Robert	IRIS	
Alexander Schacht	Eli Lilly	Outgoing Chair
Hendrik Schmidt	Boehringer Ingelheim	
Susan Talbot	Amgen	
Kristina Unnebrink	AbbVie	

Biomarker SIG Committee

Name	Company, Country	Role
Nigel Dallow	GSK, UK	
Aiden Flynn	Exploristics, UK	
Athula Herath	Novartis (Global)	Chair
Jayantha Ratnayake	ClinStats, UK	
Tony Sabin	AstraZeneca, UK	

Data Sharing SIG Committee

Name	Company, Country	Role
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Christoph Gerlinger	Bayer, Germany	
Chris Harbron [2]	Roche, UK	
Ray Harris [2]	Eisai, UK	
Sally Hollis	Phastar, UK	
Rebecca Sudlow	Roche, UK	Chair
Katherine Tucker	Roche, UK	

Health Technology Assessment (HTA) SIG Committee

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

Subgroup Analysis Working Group

Name	Company, Country	Role
Aaron Dane	DaneStat Consulting Ltd, UK	Chair
Chrissie Fletcher	Amgen, UK	
Heiko Goette	Merck	
Necdet Gunsoy	GSK, UK	
Ilya Lipkovich	IQVIA, USA	
Henrik Loft	Lundbeck, Denmark	
Brian Millen	Eli Lilly, USA	

Tom Parke	Berry Consultants, UK	
Arne Ring	Martin Luther University, Germany	
Gerd Rosenkranz	Vienna University, Vienna	
Amy Spencer	Statistical Services Unit, UK	

Toxicology SIG Committee

Name	Company, Country	Role
Eloisa Brook	GSK	
Helena Geys	Janssen	
Philip Jarvis	Novartis	
Jim Saul	Covance	
Gareth Thomas	Envigo	Chair

[1] Left committee during 2017

[2] Joined committee during 2017

2017 PSI Events

SCIENTIFIC

28 November	European Statistical Meeting: Latest Trends in Health Technology Assessments
22 November	PSI One Day Meeting: Extrapolation
27 September	PSI One Day Meeting: Estimands – Examples for Statisticians!
19 June	PSI One Day Meeting: Career Young Statisticians
15 June	BBS/PSI One-day Event on Cancer Immunotherapy
14-17 May	PSI Annual Conference
30 March	Translational Statistics: Ideas-Evidence-Innovation-Communication

TRAINING

14 November	Statistics Fundamentals for Clinical Trials for Non-Statisticians
21 September	Improving Influence and Increasing Impact: Essential Skills for Industry Statisticians
28 June	Estimating Sample Sizes in Clinical Trials
01 March	Dose Finding in Drug Development using MCP-Mod
26 January	Health Technology Assessment (HTA) Training Course

WEBINARS

12 December	PSI Toxicology SIG Webinar
17 November	EFSPI/PSI Webinar: Anonymising Clinical Data
02 November	PSI Webinar: Causal Inference
30 October	New Draft ICH E9 Addendum on Estimands and Sensitivity Analysis
24 October	Patient Preferences – a Webinar with Kevin Marsh presented by the Benefit-Risk SIG
28 September	EFSPI/PSI Webinar: Spotlight on the Integrated Data Analysis SIG
26 September	Measuring Patient and Physician Benefit-Risk Preferences in Antipsychotic Clinical Trials
19 September	Statistics and the Ames Test
12 July	Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle: PREFER - an IMI Project
21 June	Data Sharing and Data Privacy - What Every Statistician Needs to Know
13 June	Patient Engagement in Clinical Trials Webinar
04 May	Personalised Medicine: Statistics for Companion Diagnostics
09 February	Structured Benefit-Risk Assessment Webinar

CALC

16 March	Schools Event 2017: Maths Meets Medicine, Bath
13 March	Schools Event 2017: Maths Meets Medicine, Guildford
22 February	PSI Careers Event 2017