



# Annual Report 2020



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# Welcome from the Chair

2020 was a challenging year for all of us and this was also true for PSI.

While we quickly adapted where we could to online events, not having events like our annual conference and training courses affected not only the impact we provide as an organisation to our members, but also to our finances. That being said we remained committed to ensuring we supported the PSI community and we kept our focus, delivering on many of our objectives in line with our Business plan developed in 2019. We also took the time in 2020 to reflect on how we as board need to be structured to enable us to maximise our impact in the years ahead and I'm excited to see how those changes will move us forward as an organisation. We also took the time to start to develop our digital strategy which is going to be increasingly important in 2021 to ensure we can maintain our high standards of content delivery and ensure the financial security of PSI.

I would like to highlight a few key areas for 2020, but please spend some time to read through the full report. **I would like to thank our many volunteers (board and committee members) who have made this possible.**

- Whilst we made a loss of £49k in 2020, our reserves are still very healthy (£327k) and I'd like to thank the diligence of the PSI boards past and present that enabled us to be in this financially secure place for a year which presented challenges none of us could have expected.
- After a large period of 2019/ early 2020 with sub-optimal support from MCI, I'm pleased to report we now have a great team in place again. The Board has dedicated a lot of time, hard work and negotiations to deliver a new contract with MCI for a further 3 years.
- We quickly pivoted from an in person conference in Spain to an online set of

webinars over the same days, free for PSI members to attend, with a total of 421 registered attendees. This was a massive effort from the conference team, who worked hard with MCI to manage the losses, which could have been significantly more

- We had 1171 members of PSI in 2020, while this is a reduction from 2019 (where we saw our highest membership numbers to date), this is still higher than historical numbers and is higher than I personally anticipated with events like the PSI conference where we gain a lot of members not taking place. What was great to see is we have membership now from 42 countries and about one third of our members are from outside the UK
- We awarded four students at the University of Leicester, MSc Scholarships for the academic year 2020/21 – this was a onetime award from PSI in recognition of the lack of funding to MSc whilst we work to get the Medical Statistics apprenticeship Level 7 (equivalent to an MSc) up and running
- We now have better metrics on traffic to our homepage through different communication paths, as well as on how people are using our video on demand content
- We now have 17 eSIGS! All putting out a large array of content. In 2020 we have seen a much closer collaboration with EFSPi in the overarching organisation and support of the eSIGs which we look forward to continuing.
- In addition to the annual conference, the Scientific Committee organised two one-day meetings (before we all went into lockdown) and seven webinars
- Two training courses were held face to face in 2020 before COVID-19 restrictions meant we had to postpone the remainder of the events. The ITIT course managed to successfully move some content online with some sessions postponed till 2021.
- Without the PSI Conference our commercial income came from sponsorship of events and the jobs board, through these efforts we raised £22,520 in revenue. I would like to thank Amgen, AstraZeneca, GSK, Roche and

Veramed for their continued support of PSI as we adapted the conference from in-person to online.

- The EFSP/PSI Regulatory SIG met with the MHRA statisticians as well as the EMA Biostats working party separately with statistical considerations from the impact of COVID-19 being on the agenda of both meetings.

#### Awards:

The **RSS/PSI Award for Statistical Excellence in the Pharmaceutical Industry** continues to establish itself as a prestigious award. This is awarded each year for the most influential example of the application of an existing statistical practice, or the implementation of an innovative statistical practice, in the pharmaceutical industry. **Sandeep Menon** (Pfizer) won in 2020 for “Influential Quantitative Leadership in several domains in Early Clinical Development – creating a culture of quantitative decision making within a major pharmaceutical company “

The **Mick Godley Award** to recognise the unsung heros of PSI went to **David Lawrence** (Novartis) who is a member of the Scientific Committee and always takes on a large amount of PSI Conference activities. Congratulations David!

While 2020 may not have been as anyone expected, I think we can be extremely proud as an organisation of what we still managed to deliver and the learnings and opportunities the pandemic has offered us to evaluate who we are and what we deliver as an organisation in pursuit of our purpose.

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

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

#### Lucy Rowell PSI Chair





# Treasurer's Report

During 2020, PSI made a loss of around £49k and our reserves now stand at £327k (63% of 2019 revenue). We aim to have reserves of at least £300k, which is expected to ensure the continued operating of the society even in case of substantial shortfalls on the income side. As such, PSI is still in a robust financial state for the continued uncertainty in 2021, but there is a need to look for new opportunities to generate income, as the operating costs are mostly fixed.

## Physical conference cancellation

2020 was a challenging year for PSI due to the cancellation of the physical conference, one of the main sources of revenue for the society. The organising team worked together with MCI and was able to recover most of the expenses using the "act of god" clause in the contracts, but a loss of approximately £40k remains. By organising a virtual conference event, the team was able to generate an income of approximately £18k through sponsorships and registrations. This was very valuable to help reduce the overall losses, but of course did not replace the loss completely.

## 2019 internal audit report

In their report for the 2019 accounts, the internal auditors noted "that PSI was run prudently in 2019 and did well to keep costs under control in 2020". However, they also recommended to reduce costs where possible and to aim to increase our reserves to deal with the growing uncertainty. As a first step, the MSc scholarship program had to be discontinued for 2021. The 2020 external audit is currently in progress and the internal audit will be conducted after the AGM.

## 2020 income overview

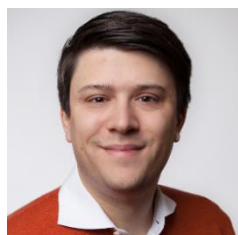
Profit (£k)*	2016	2017	2018	2019	2020
Membership	58	72	72	75	83
Conference	124	65	116	49	-22
Training & ITIT	18	22	19	24	22
CALC	3	11	-1	0	10
Scientific	9	11	3	16	-4
Publications	-18	-16	-5	-8	-8
Commercial	100	86	97	83	0*

Rounded to the nearest £1k. 2020 figures are subject to change. Overheads are not included in this table.

\* Sponsorship, exhibition, and advertising income would typically be shown in this row but were included in the Conference row for the 2020 accounts.

## Markus Elze

### Contracts and Finance Director



# Contracts Report

The remit of the Contracts Director is to establish and maintain key contracts with external suppliers on behalf of PSI.

## The current key contracts are for:

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

## CONTRACTS

### Business Administration Services

The contract with MCI to cover business administration services has been renegotiated in 2020 to meet PSI's future requirements and is expected to run for the next three years. It offers more flexibility for switching between physical and virtual meeting formats and gains some efficiency by removing outdated processes. The annual cost to PSI is £125k. Conference event management tasks are included in the overall business contract.

### Website

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

PSI's Digital Transformation was signed with MCI in December 2020 and includes one-off costs of £28,500. This will provide PSI with new infrastructure for membership management, a digital conference platform, and more efficient ways to set up and run seminars and other virtual events.

### 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

The contract with YUDU for the digital publishing of SPIN was renewed in November 2020 and will run for two years.

### Commercial

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

### Markus Elze

### Contracts and Finance Director

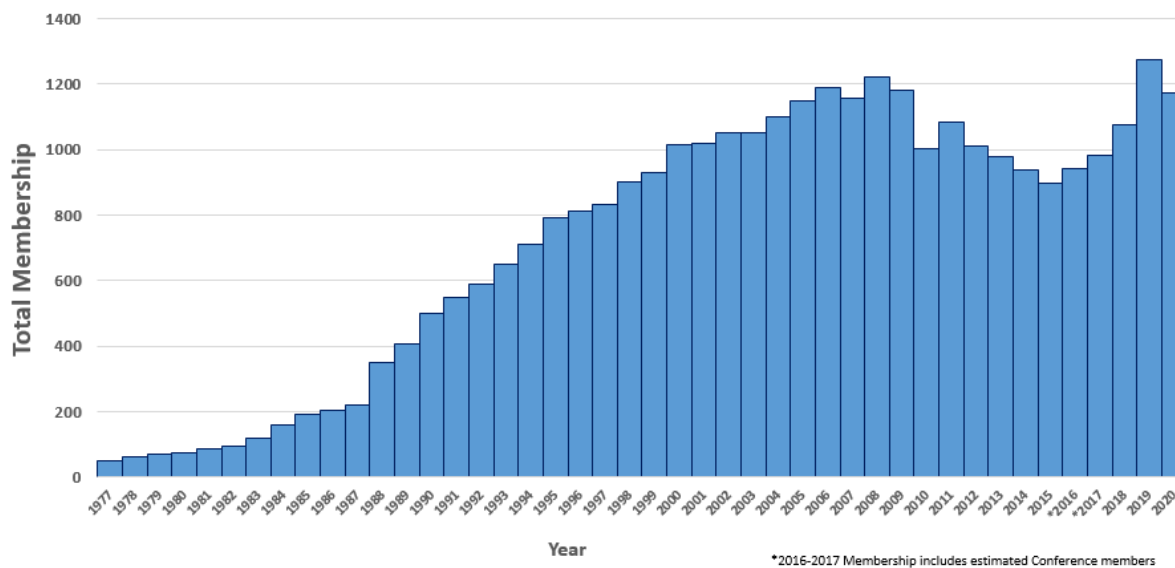


# Membership Report

2019 was a wonderful year for membership growth for PSI with membership up a massive 18% from 2018. Unfortunately, for various reasons, we did not manage to sustain this growth in 2020.

As detailed in the 2019 report, the level of support we received from MCI in 2019 was below expectations after several key employees supporting PSI left. This impact was noticeable in the early 2020 (Jan/Feb) renewals of Full Members which was down by approx. 25%. Additionally, the year 2020 could not be reviewed without mentioning the pandemic and its widespread impact on every single one of us. Despite this, we did grow membership throughout the summer months and thanks to the great work being done by CALC, we saw a continued growth in the student/teacher membership in 2020. We finished the year with 1171 members (just 8% down in total compared to 2020) but, more importantly, above the historical level of membership (approx. 950 members), something we should be very proud of during these challenging times.

## PSI Membership History



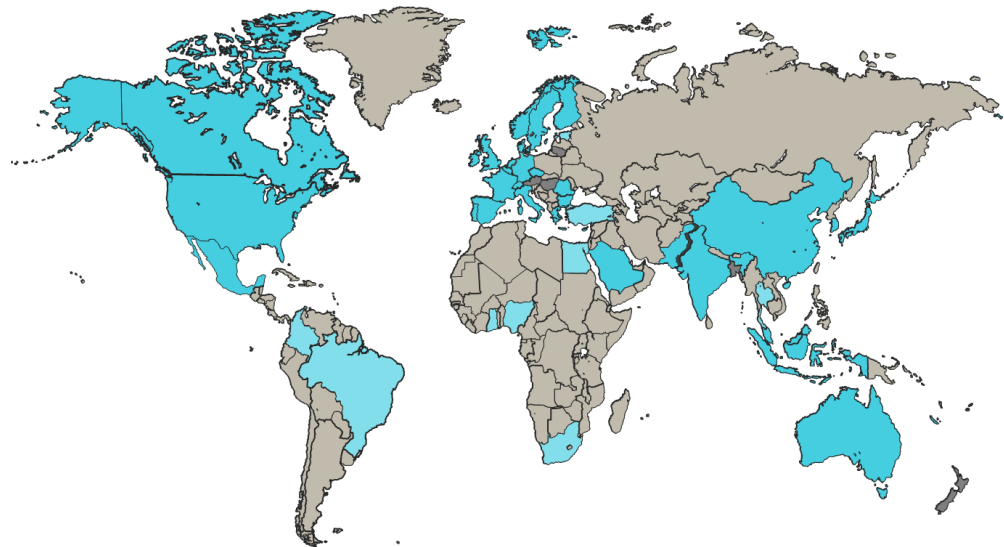
Membership Category	2016	2017	2018	2019	2020
Full	886	861	959	1070	867
Honorary	9	9	9	9	11
Reduced Rate	9	13	8	21	25
Student/Teacher			98	172	268
<b>Total</b>	<b>904</b>	<b>883</b>	<b>1074</b>	<b>1272</b>	<b>1171</b>

Whilst historically PSI was seen by some as a UK-centric organisation, for several years now we have had a strategic focus to strengthen our membership base across Europe and the Rest of the World. We have made considerable progress, and in 2020 it was wonderful to see that ~33% of our members were from outside the UK, with members in 42 countries. This speaks to the success of PSI ambition to support Statisticians in the Industry, by delivering high value scientific content & career development to our members, irrespective of location. We, the Membership & Community Committee, now aim to nurture a collaborative and engaged community across the globe.

### Membership by Region:



### Geographical Footprint:



**Kate Tsirtsonis**  
**PSI Membership Director**





# External Affairs Committee Report

The PSI External Affairs Committee in 2020 comprised Dawn Midwinter (GSK), Tammy McIver (Roche), Aris Perperoglou (AstraZeneca), Leanne Winzer (AstraZeneca), Genevieve Wills (University College London).

The focus of the EA Committee is outward-facing, ensuring that PSI remains included in the area of Pharmaceutical Statistics. In 2020, the business world changed, with organisations forced to cancel or make their meetings and conferences virtual. Many development initiatives were put on hold due to the financial constraints. All of this had an impact on the External Affairs Committee and many plans defined at the start of the year, including building on the relationship with the IASCT and with the “Before the Headlines” group at the Science Media Centre, were affected. There was continued communication with the RSS, including ongoing development of Professional Guidelines for the accreditation of Data Scientists, together with Universities and other organisations such as the BCS (the chartered institute for IT) and the Institute of Mathematics.

Since the Committee was first established, PSI and methods of global communication have changed and it was therefore decided to absorb the External Affairs Committee into the Communications Committee in December 2020.

**Stephen Jones**  
Communications Committee and External  
Affairs (and EFSPi) Chair



# Communications Committee Report

In 2020, the PSI communications committee focused on further driving forward the implementation of the communications strategy that the board of directors had endorsed.

The first focus was on further establishing the conference reporter team. This team aims to help the conference chair and the scientific committee with all the communication before, during, and after the event. Unfortunately, we could not have lots of live interviews with participants as planned, as we needed to change the conference into a series of webinars instead of a live event. Still, the conference reporter team tested new formats to help with the promotion of the conference in the virtual setting. The conference reporter team comprises Anastasiia Raievska (Roche) (Lead), Elena Mourouli (Veramed), Paolo Eusebi (UCB), Fiona Grimson (former IQVIA now UCB), Jessica Kirk (Sheffield University) and Nouran Hamza (MARS Research Hub).

The second focus of the committee was to better measure the performance of the PSI communication channels and test how to improve these. Jack Elkes (Imperial) and his team (Shikta Das (UCL), Karan Vadher (Lilly), Alex Zimmerman (Amgen), and Roz Baverst (Amgen)) made a huge step forward in enabling better tracking of the Video on Demand service by getting unique URLs for the videos. This sounds like a small step, but it is the key to better drive traffic to individual videos and also to track the performance of the promotions.

The communications committee also implemented tagging to track how individual links shared via different channels and different styles affected the traffic to the homepage, which we now track via google analytics. Jack and his team presented our new abilities to better understand how these capabilities help us inform the

PSI community about events and content to the Board of Directors.

The third focus of the committee was to automate and improve our social media footprint and to enhance the email communication. Priya Gokani (Amgen) and her team (Sophie Greenwood (IQVIA), Alex Zimmermann (Amgen), Eleni Mavropoulou (GSK) and Paolo Eusebi (UCB)) further improved leveraging our social media tool 'ZohoSocial' in collaboration with the delegates from the other committees. The combination of this automation together with the tagging mentioned previously, provided lessons on what works and what doesn't work. Also, you have already seen how the new formatting of the eNews helps to better get the content.

Finally, we continued to drive forward our content creation areas. For SPIN, you have seen a change in the editors with Matthew Gibb (Veramed) and Jamie Rees (GSK) swapping seats. Thanks so much to Matthew for the many years in charge of SPIN and growing this format, which many PSI members love. Sophie Greenwood helps with the social content in SPIN. We are currently looking for new members to help with SPIN. Please contact Jamie Rees at [jamie.c.rees@gsk.com](mailto:jamie.c.rees@gsk.com) to chat about this opportunity.

The journal club team, made up of Priya Gokani (Amgen) and Jens-Otto Andreas (UCB), organized several journal club webinars with growing numbers of attendees and interesting topics. This free content drives a lot of awareness of PSI beyond our current membership.

Steve Jones (Medable) took over from Alexander Schacht (UCB) as the chair of the communications committee at the end of 2020.

**Stephen Jones**  
**Communications Committee and External Affairs**  
**(and EFSPI) Chair**



# Regulatory Committee Report

The purpose of the Regulatory Committee is to co-ordinate regulatory activities across the European Pharmaceutical Statistical community and to engage with European Regulatory statisticians.

## This includes:

- Review of regulatory guidelines and policies to provide consolidated cross industry responses
- Identification of regulatory statistical issues that are of concern across industry for discussion with regulators
- Regular engagement on statistical issues with EMA's Biostatistics Working Party and MHRA statisticians
- Promotion of best practice and driving debate on future guidelines

During 2020 the regulatory committee held monthly committee meetings and met with both the MHRA and EMA statisticians. The committee coordinated the review of several regulatory guidance documents (more detail below). Committee members organized a webinar and helped organize the 5th EFSPi workshop on regulatory statistics held online.

In July, the Chair of the regulatory committee transferred from Christoph Gerlinger (now the co-chair of the committee) to Jürgen Hummel.

## Meetings with statisticians from regulatory agencies

On Wednesday 19 November 2020 the PSI/EFSPi Regulatory Committee met with the MHRA statisticians. For the first time the meeting was not held in person,

but instead virtually via MS Teams, which worked very well. The main topics of the discussion were MHRA's Future Drug Regulation Strategy, MHRA's experience with COVID-19 and complex innovative designs as well as estimands, Real World Evidence, biosimilars, bioequivalence and Patient Reported Outcomes (PROs).

On 2 October 2020 selected members of the PSI/EFSPi Regulatory Committee met with EMA's biostatistics working party. The meeting used a different format from previous years, as it was held jointly with other stakeholder organisations (which included EFPIA, AESGP, EGGVP, EUROPABIO, Animal Health Europe, Medicines for Europe and EUCOPE). The discussion focused on the impact of COVID-19 on methodological aspects of on-going clinical trials and statistical methods applied to the quality of medicines.

## Webinar

On 5 November 2020 the PSI/EFSPi Regulatory Committee jointly organised together with the American Statistical Association Biopharmaceutical Section (ASA BIOP) a webinar on Estimands, which covered the following aspects:

- Experience with proposals submitted to FDA and EMA on implementation of Estimands
- How the estimands framework facilitates interaction with clinicians in different therapeutic areas
- Common problems where the Estimands framework can help advance research
- Where further discussions and research is required, and particularly where industry and regulators can collaborate
- Issues related to alignment between different estimators to a given estimands
- Special considerations of estimand framework in COVID-19 vaccine trials.

The speakers were John Scott (FDA), Andreas Brandt (BfArM), Evgeny Degtyarev (Novartis) and Vladimir Dragalin (JNJ), which was followed by a panel discussion chaired by Anna Berglind (AstraZeneca).

## Guidelines

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

- EMA's draft Points to Consider on [implications of Coronavirus disease \(COVID-19\) on methodological aspects of ongoing clinical trials](#)
- EMA's draft guidance on [registry-based studies](#)

### Naming Convention

The status of the Regulatory Committee was changed in December 2020 to the Regulatory European Special Interest Group (ESIG).

### Jürgen Hummel

#### Regulatory Committee Chair



# Scientific Committee Report

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

At the start of 2020, we had two one-day meetings ready to happen in March and April – on Immunoncology and Missing Data. Due to the pandemic these were postponed but as I write this, these events are due to happen (online) in 2021 instead – so look out for them in the annual report in 2021!

This meant the scientific committees' efforts turned to making the change happen from an online conference to a series of 'conference' webinars.

We also increased our focus on delivering scientific webinars throughout 2020.

2020 webinars:

- Statistical Operations Research
- Chosen or Forced - How to manage working from home
- Using visualisation to help make decisions
- Master protocols - theory, application and regulatory considerations
- Patient preference studies
- Risk Based Monitoring & QTL's
- Innovative approaches in the development of paediatric medicines

A big thank you to all members of the scientific committee during the difficult year of 2020 and thanks to all the speakers who volunteered their time to prepare excellent talks for all the webinars.

**Rachael Lawrance**  
**Scientific Committee Chair**





# Careers and Liaison Committee Report

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 was fortunate to be able to hold the PSI Medical Statistics Careers Event in person on March 4<sup>th</sup> 2020. We were once again at De Montfort University, Leicester, with over 50 students attending on the day, which although was lower than previous years (most probably pandemic-related), still gave many students the opportunity to talk to exhibitors. We had a record number of exhibitors, with representatives from 33 pharmaceutical companies, CROs, clinical trial units and industry organisations, who were on hand to talk to students and to offer advice on what the industry has to offer statisticians and statistical programmers. The panel discussion session was again a great success, giving students the chance to hear first-hand from a range of people talking about their role and experience working in the industry.

Our BSc subteam have been busy this year researching and planning a new event that will be targeted at all undergraduates. It was felt that many students on more general Mathematics and Statistics undergraduate courses are not aware of the field of Medical Statistics, particularly as many degree courses have been combined and there are fewer specialist courses available. Therefore, this new event aims to provide a high-level introduction to the industry and career options, so that students can make informed decisions about further study in this area. In addition, four BSc prizes were awarded to undergraduate mathematics/statistics students at the Universities of St Andrews, Reading, Glasgow, and Sheffield.

The Schools subteam have developed new careers talk materials for PSI members to use in schools. They had the opportunity to try these out at the online Bucks Skills Show in October, where they helped Year 9 students learn about how we use maths and stats in medicine. The session involved a workshop, a careers talk covering our role and the skills required and finished with Q&A session (the video is available [here](#)). The Schools subteam and other CALC members have also been planning how to update the PSI Careers website to incorporate information and resources for schools.

CALC has also been involved in assessing applications for the new MSc Scholarship at the University of Leicester, awarding this to four students for the 2020/2021 academic year, and also providing input into the new Medical Statistics Level-7 apprenticeship proposal.

## Amanda Darekar CALC Chair



# Training Committee 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 2020, the training committee was able to run two face-to-face training courses at the start of the year, prior to travel restrictions due to the pandemic. The two courses were a Bayesian practical course and an adaptive design software course.

Unfortunately, the rest of our planned courses for 2020 were cancelled or postponed. The committee have been working hard to put in place virtual training solutions to ensure we can continue to offer high quality training to the PSI membership. We are excited to run virtual training in 2021 on Data Monitoring Committees, R for SAS users, Mixed Models and Repeated Measures, and Historical Data use in Clinical Trials.

## Introduction to Industry Training (ITIT) course

The ITIT Course provide an overview of the drug development process to statisticians and programmers who are new to the industry. The course takes delegates through 6 sessions at 6 companies covering topics from laboratory research work to marketing. It enables delegates to build a network of peers, all of whom are at the same stage of their careers.

In 2020 the course was cut short by the pandemic. The delegates attended 2 of the remaining 4 sessions of the 2019/20 course as virtual sessions. The final 2 sessions

were postponed and are due for completion in 2021. The places on the 2020/21 course were fully subscribed but the course has been delayed for a year with the hope of starting the course as a face-to-face course from September 2021.

## Mary Elliott-Davey Training Committee Chair



# Commercial Report

Due to the COVID-19 pandemic, the annual F2F conference was cancelled. Therefore, PSI organised a scaled down virtual conference instead. Five of the seven sessions were sponsored, and we raised £15,000 in revenue. Thank you to Amgen, AstraZeneca, GSK, Roche and Veramed for your continued support of PSI.

Advertising revenue in 2020 was £7,520. A revised pricing structure was rolled out including blocks of job adverts packaged at a discounted price. The new pricing structure has had some success, however, advertising slowed down following the pandemic outbreak.

A new revenue stream has been rolled out where one day events, webinars, and training courses can now be sponsored.

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

**Alexander Currie**  
Commercial Director



# Conference Report

PSI's 2020 Conference was held from 8<sup>th</sup> – 11<sup>th</sup> June. The conference was originally planned to be held in Barcelona, Spain, however due to the global coronavirus pandemic, the decision was taken in March to move the conference online. This gave the Scientific Committee just a matter of weeks to select the content to be presented and make all the necessary changes to adapting for an online presentation, as well as facilitating the cancellation of the face to face conference.

The conference theme was 'Shaping the Future of Statistics'. A total of 7 webinars were presented across the 4 days, one morning presentation and one afternoon one. The PSI AGM was also held online for the first time on Tuesday 9<sup>th</sup> June. Two of the planned plenary sessions for the face to face conference were presented. Deborah Ashby gave a talk on Florence Nightingale which celebrated 200 years since the famous nurse and statistician's birth and how her work is still relevant to a lot of the things that we do today. Stephen Ruberg also chaired a very interesting session on the idea of retiring statistical significance and the discussion also included the chairs of the 2 largest statistical organisations in the world, Ron Wasserstein from the ASA and Deborah Ashby for the RSS.

As well as the sessions noted above, we also had a Career Young Statisticians session, the Data Transparency SIG gave a session on how we can best re-use data, in memory of previous SIG chair, Sally Hollis. The Wednesday morning session gave us all an insight into the intersection of clinical trials and real-world data and Thursday was the PSI/RSS Prize Winner's session. The 2019 winners of the PSI/RSS awards were Mike Smith (Pfizer) and a joint submission from Graeme Archer and Jacque Christie (GSK). Later, the EFPIA/EFSPi Estimands Implementation Working Group gave a very topical presentation on the Impact of COVID-19 to Estimands. All sessions were also added

to the VoD platform for members to view at their leisure. Prior to moving the conference online, we also received 81 abstracts for oral presentation, the highest number to date.

Delegates had to register for all 7 conference webinars and registration was free for PSI members and £100 for non-members (which included PSI membership until the end of 2020). There were 421 registered attendees in total, 29 of which paid for their attendance. The individual sessions were attended by between 73 and 178 delegates which was a great response to the fantastic content that the presenters gave. There was also an opportunity for companies to sponsor individual sessions, with support from Veramed, AstraZeneca, GSK, Amgen and Roche.

Whilst it was a slightly different conference this year in terms of the social side, the Scientific Committee still put together a few virtual social activities. Delegates were encouraged to send pictures of themselves enjoying the conference from their working from home spaces, several people completed a run in their own local area and there was also an online quiz night.

The 2021 conference will be taking place from the 21<sup>st</sup> to the 23<sup>rd</sup> June and will, once again, be an online event. The preparations are well underway, with the abstract deadline upcoming. Information will continue to be shared regularly as we move closer to June. As we have done in previous years, 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 current plan is for the next face to face conference to be held in Gothenburg in 2022.

## Paul Terrill Conference Chair



# SIG Report

2020 was a busy year for the SIGs and we also saw further integration with EFSPI, with new pages at [www.psiweb.org](http://www.psiweb.org) for the Neuroscience Estimands and Oncology Estimands working groups, and connections established with the Small Populations EFSPI SIG. New SIGs were established for COVID-19 and Centralised Statistical Monitoring/Quality Tolerance Limits, and the PSI Regulatory Committee was realigned as a SIG.

2020 highlights are summarised below, and these speak to a broad range of achievements, including webinars, workshops, publications, and regulatory interactions. It is a truly impressive set of collective accomplishments, more remarkable in view of the challenges everyone faced in 2020. We thank everyone who has contributed to the PSI/EFSPi SIGs being so successful.

## Highlights:

SIG	Highlights
<b>AIMS</b>  Lyn Taylor (PHASTAR)	<p><b>Key objective 1:</b> Act as an intermediary between groups exploring the use of R in our industry and share this information with the wider PSI community. AIMS during 2020 is excited to support and collaborate with the following projects:</p> <ul style="list-style-type: none"> <li>• R Validation Hub. Produces general guidance on using R and ensures collaboration of various wider teams to ensure no duplication of effort. Created a package risk assessment framework in the form of a white paper <a href="https://www.pharmar.org/white-paper/">https://www.pharmar.org/white-paper/</a>. Created a riskmetric package (<a href="https://github.com/pharmaR/riskmetric">https://github.com/pharmaR/riskmetric</a>) and associated R Shiny App to interact with the package (<a href="https://www.pharmar.org/blog/2020/08/05/2020-08-05-risk-assessment-application/">https://www.pharmar.org/blog/2020/08/05/2020-08-05-risk-assessment-application/</a>). This allows users to create a report of risk metrics so that a risk assessment of packages can be undertaken and documented. The first CRAN version of riskmetric is expected any day now! See: <a href="https://www.pharmar.org/">https://www.pharmar.org/</a> for the Hub's activities.</li> <li>• R consortium RTRS. This working group is exploring the production of R Tables for regulatory submissions (RTRS): To join this group you can sign up at: <a href="https://lists.rconsortium.org/g/Rconsortium-wg-rtrs">https://lists.rconsortium.org/g/Rconsortium-wg-rtrs</a></li> <li>• PHUSE. Led by Mike Stackhouse (Atorus) and Michael Rimler (GSK), this project seeks to develop a framework for assessing</li> </ul>



	<p>differences in statistical modelling implementations across multiple programming languages. The project team will apply this framework for common use cases in clinical trial analyses and their implementations in R and SAS. The team also aims to deliver a repository of sample code which demonstrates each use case. The objective is to provide guidance on how to generate confidence in a particular implementation, independent of programming language and the differences which may naturally occur when comparing results across multiple languages. If you are interested please contact <a href="mailto:Mike.Stackhouse@atorusresearch.com">Mike.Stackhouse@atorusresearch.com</a> or <a href="mailto:michael.s.rimler@gsk.com">michael.s.rimler@gsk.com</a></p> <p><b>Key objective 2:</b> Provide a central storage site containing links to documentation and demonstration of R's capabilities and latest regulatory advice/industry key opinion leaders. See: <a href="https://psiweb.org/sigs-special-interest-groups/aims">https://psiweb.org/sigs-special-interest-groups/aims</a> for further information on our other objectives, on R training and to download any of our articles that have appeared in PSI SPIN over the last few years. Look out in a future PSI SPIN for our article on R licenses and what you need to know about re-use of code. If you want to join us, get in touch at <a href="mailto:lyn.taylor@phastar.com">lyn.taylor@phastar.com</a></p>
<p><b>Benefit Risk</b></p> <p>Shahrul Mt-Isa (MSD) Maria Costa (Novartis)</p>	<p>The BR SIG has been running for several years focussing on the methodologies and issues in benefit-risk assessment (BRA) with representatives from twenty individual contributors from thirteen organisations in the pharmaceutical industry, regulatory agency, and academia. In 2020, the SIG focussed on three topics: preferences, safety, and HTA in BRA. We work on manuscripts for these three topics for peer-reviewed publication. We also wrote a proposal for a book to be published by Wiley on preference-based BRA that has been accepted just before last Christmas. SIG members have also been engaging with and contributing to external BR activities, including the FDA, ASA and UK-MRC BRAINS project. We continue to monitor the evolving landscape on BRA for opportunities to exchange knowledge and expertise, as well as for any potential collaboration. We were saddened by the pandemic that had impacted our plans during 2020, including the cancellation of PSI Conference and the BR session. However, we are delighted to share our work at the virtual PSI meeting this year. We look forward to 2021, where we will ramp up our activities in preferences and safety in BRA, as well as organising educational series on BRA through webinars and external KoL engagement.</p>
<p><b>COVID-19</b></p> <p>Chrissie Fletcher (GSK) David Wright (AZ)</p>	<p>A new SIG for 2020. Partnered with the Vaccines SIG, since the spring there have been many webinars, meetings and publications. Also regulatory agencies have released a variety of guidelines. The SIG has discussed the statistical designs, study endpoints and planned methods of emerging vaccines and treatments. In 2021 there will be a focus on what we have learned in designing and conducting clinical trials.</p>

<b>CSM/QTL</b>  Tim Rolfe (GSK) Susan Talbot (Amgen)	<p>A new SIG, proposed late in 2020, focusing on Centralised Statistical Monitoring and Quality Tolerance Limits. Objective is to create a forum to collaborate and discuss strategies and methodology with other interested parties. The SIG will collate and summarise publications, presentations and training; develop best-practice recommendations and identify emerging news and trends. Watch out for a new SIG landing page on <a href="http://www.psiweb.org">www.psiweb.org</a> soon.</p> <p>A related <a href="#">webinar</a> was put on in December.</p>
<b>Data Science</b>  Julia Chernova (Bayer)	<p>Data Science SIG is a small group of data science enthusiasts from various backgrounds working in pharmaceutical and CRO environment. We have been busy this year trying to understand how we can help to connect statistical and data science communities and what activities would be helpful for our colleagues interested in learning more about data science or working as data scientists in our industry. We designed a survey to help us collect relevant information from our community and will be sharing the results with the audience. We are also planning to start a blog where we will be sharing our views and opinions related to data science filed and where we hope to engage in two-way conversation about a place of data science in our quantitative community.</p>
<b>Data Transparency</b>  Rebecca Sudlow (Roche) Mimmi Sundler (AZ)	<p>The SIG presented a session at the virtual PSI Conference in July, dedicated to founding Chair, Sally Hollis. Speakers from a mix of industry and academia shared the privacy issues and challenges of re-using clinical trial data and examples of where this work has resulted in new insights. A recording is available on the PSI website. Members have submitted a manuscript "Anonymizing Data for Secondary Use" to Pharmaceutical Statistics, hope to see published in 2021. SIG continues to encourage volunteers to join!</p>
<b>Decision Making</b>  Gaëlle Saint-Hilary (Servier)	<p>In 2020, the ESIG Quantitative Decision-Making (QDM) focused on writing two manuscripts on the awareness, the use and practical aspects of QDM methods in pharmaceutical development. These manuscripts extend the content of two webinars the SIG provided end 2019, and they will be submitted soon. We are also starting two new working groups: "Methods for QDM at the portfolio level" and "Awareness about QDM beyond statisticians". Few members left the SIG and new members joined, so we remain a motivated group of 19 members from industry and academia. We maintain our awareness on QDM methods by having presentations of internal members or external guests at each of our plenary meetings. We will organise a session at the PSI conference 2021, and we plan to give one webinar during the year.</p>
<b>Historical Data</b>  Nicky Best (GSK) Simon Wandel (Novartis)	<p>The Historical Data SIG has an active membership of 10-15 members from industry, academia and independent consultants. The SIG held regular monthly meetings with several presentations on methodological topics relevant to use of historical data in clinical</p>

	<p>trials, from both SIG members and external invited presenters. The latter included presenters from the DIA Bayesian Scientific Working Group and from Project DataSphere. SIG members have also been collaborating to develop methods and guidance on metrics for summarising type 1 error in clinical trial designs that utilize informative prior information from historical data. One paper (lead author Ros Walley) has just been published in Pharmaceutical Statistics (<a href="https://onlinelibrary.wiley.com/doi/epdf/10.1002/pst.2102">https://onlinelibrary.wiley.com/doi/epdf/10.1002/pst.2102</a>), and a second paper is currently in preparation. Due to COVID-19, the SIG's planned session on this topic at the 2020 PSI conference was cancelled; the SIG will consider running this as a virtual webinar at a future date. At the end of 2020, the SIG submitted a request to EMA for an Innovation Task Force (ITF) meeting to discuss statistical and regulatory issues in the evaluation and reporting of randomized clinical trial designs that formally use external data to augment the primary analysis. The EMA ITF expressed interest in this meeting, and the SIG are currently preparing a full briefing document.</p>
<p><b>HTA</b></p> <p>Lara Wolfson (Merck) Chrissie Fletcher (GSK)</p>	<p>The HTA ESIG celebrated its 10-year anniversary in early 2020. The HTA ESIG met every other month to share latest news and trends in HTA. The ESIG began with 11 members from 9 companies/consultants. In the statistics community few statisticians understood HTA so there was a great opportunity to show how statistics can influence and be involved in HTA strategy and HTA analytics. At the Statistical Leaders 2010 when quizzed about their views about HTA there was a sense of "...I don't understand what my Health Economics colleagues say, it is like they are speaking a different language...". The ESIG has presented at many scientific conferences on hot topics over the years. Each year an annual 1-day HTA meeting has been organised to share case studies. Publications have been written relating to HTA best practices, methods, subgroups, indirect comparisons, PROs, treatment switching. The ESIG has reviewed HTA guidelines from local HTA agencies and pan European HTA agencies. Over the years several round table Q&amp;A sessions have been held with invited guests to maximise the opportunity for statisticians to influence and make a difference in HTA activities. Significant progress has made to increase the awareness and understanding of HTA in the statistics community. Currently the ESIG has 40+ members from 25 companies/institutions. Thanks to everyone who has supported the HTA ESIG over the last 10 years. The collaborations and partnerships have been truly inspiring. We continue to be an active ESIG with much to do and lots of important discussions.</p>
<p><b>New Starters</b></p> <p>Jack Euesden (GSK)</p>	<p>On a crisp February morning, meandering through the bustle of central London, I headed to the New Starters' SIG annual face-to-face networking event. 40 statisticians from across biotech and</p>

	<p>pharma met in King's College London's Waterloo campus for an afternoon of networking activities and ice breaker events. The afternoon began with a keynote talk from Dr Kimberly Goldsmith on her work in Clinical Trials, psychological therapy and communication with the media. Delegates broke out into small teams to tackle a series of data analysis challenges – did Game of Thrones really get worse over time? Do the England football team win more often at home than away? Have UFO sightings got more common over time? Can Punxsutawney Phil – of Groundhog Day fame – really predict the start of spring? The day finished with presentations on each of these questions, with a staggering breadth of innovative data visualisation approaches and effective teamwork clearly on display.</p> <p>In 2021 we seek to capture the successful elements of the last event – the contacts made, the ice broken, the technical skills exchanged – and we are working with MCI to move this online.</p>
<b>Neuroscience Estimands</b>  Hans Ulrich Burger (Roche)	<p>Recent activities summarised <a href="#">here</a> . Highlights include a joint EFSPi/BBS workshop on estimands in Neuroscience.</p> <p>Neuroscience is a heterogeneous therapeutic area in which development pathways and study analyses can substantially differ between different indications. Efficacy is usually based on longitudinal assessments which makes the application of the estimand framework specifically interesting and rich with many specific aspects from which we all can learn a lot.</p>
<b>Oncology Estimands</b> (also an ASA Scientific Working Group)  Kaspar Rufibach (Roche)	<p>Despite the many challenges in 2020 the SIG was able to contribute to the implementation of the estimand addendum in drug development in oncology and beyond. Key achievements are:</p> <ul style="list-style-type: none"> <li>• The intercontinental team spirit that allowed to come up with a rapid response to COVID-19 pandemic: a <a href="#">slide deck</a> discussing the impact of the pandemic on a trial's estimand was published on the webpage less than five weeks after WHO declared the pandemic. A <a href="#">paper</a> followed only a few weeks later.</li> <li>• Several <a href="#">publications</a> of the SIG were published this year, and several more are in their last rounds of revision.</li> <li>• The SIG organized two webinars that brought together drug developers, academics, and regulators to discuss topics around estimands in oncology and beyond:</li> <li>• <a href="#">Estimands addendum is final: Anything new for oncology?</a> The highlight here was that several clinical colleagues contributed as presenters and panellists.</li> <li>• <a href="#">RCTs meeting causal inference: principal stratum strategy and beyond</a></li> </ul> <p>The SIG organized sessions and was invited to speak at virtual US conferences (JSM, ASA-FDA workshop, Deming conference on applied statistics). Further <a href="#">talks</a> were given at several occasions.</p> <ul style="list-style-type: none"> <li>• The SIG organized TCs with seven Health Authorities (FDA, HC, Swissmedic, China, Japan, Taiwan, MHRA) to share its work and get input on future directions.</li> </ul>

	<ul style="list-style-type: none"> <li>Set up a webpage (<a href="http://www.oncoestimand.org">www.oncoestimand.org</a>) to foster sharing of information and generated content such as presentations and publications. As of today, the SIG has 54 members (20 from Europe, 29 from US, and 5 from Asia) representing 28 companies.</li> </ul> <p>Currently the SIG is regrouping in task forces dedicated to eight topics that are considered relevant to develop implementation of the addendum further in oncology clinical trials. So, expect more output in 2021!</p>
<b>Small Populations</b>  Francois Aubin (Vennlife) Andreas Kaiser (Bayer)	<p>In 2020, Egbert Biesheuvels stepped down from the SIG chair, and Andreas Kaiser and François Aubin took over as co-chairs.</p> <p>The SIG held 10 meetings over the year; all were web meetings. The main activities were to continue the identification and review of publications of interest on three topics: historical controls, extrapolation and meta-analytical approach. The aim is to provide recommendations for articles of interest to newcomers to small populations. It is expected that this work will be completed in the first half of 2021 and will be made available on the SIG website.</p> <p>The SIG has been working with the EFSPi Scientific Committee to organize a scientific meeting originally scheduled for 2020. Due to the pandemic situation and the difficulty of identifying case studies to be presented, the meeting was postponed. It is expected that it could be organized in 2021.</p>
<b>Subgroups</b>  David Svensson (AZ)	<p>The Subgroup SIG had some joint work going that unfortunately had to take a backseat (including the 2020 PSI session), but we kept meeting on a regular basis and spent the meetings mostly informally discussing recent methodological papers &amp; ideas in the ITE/ITR area. There is no doubt that this has been useful for participants (sharing thinking on the rapid developments in this important area). We had a smaller IBIG SIG webinar in October where the scope of the SIG work was presented.</p>
<b>Toxicology</b>  Gareth Thomas (Covance)	<p>Continued to provide webinars on hot topics. Plans were in place for a face-to-face workshop but replaced by two additional webinars. Work towards a joint Toxicology SIG paper progressed and we are very close to submitting.</p>
<b>Vaccines</b>  Fabian Tibaldi (GSK)	<p>Very busy in 2020. Supported awareness of latest news and COVID-19 conferences, meetings and workshops. Supported and presented at a variety of events, highlighted important publications. <a href="#">Webinar</a> link on statistical topics on COVID-19 vaccine and therapeutic trials</p> <p>Webinar on Statistical Observations on SARS-CoV-2 &amp; Crisis Vaccine Clinical Testing also ran in December. Latest news <a href="#">here</a></p>
<b>Visualisation</b>  Bodo Kirsch (Bayer) Alexander Schacht (UCB)	<p>2-hour interactive training for design of visualization (tool agnostic) with about 50 participants</p> <p>10 webinars of the Wonderful Wednesday Webinar series (all recorded in VoD at <a href="https://www.psiweb.org/vod/Index/">https://www.psiweb.org/vod/Index/</a>)</p>



	<p>Corresponding blog articles for the WWW series (<a href="https://vis-sig.github.io/blog/">https://vis-sig.github.io/blog/</a>) with visualizations, code and data sets</p> <p>Guest posts on the r-views blog of R-studio</p> <p>Summary of great data vis resources (<a href="https://www.psiweb.org/sigs-special-interest-groups/visualisation/vis-sig-resources">https://www.psiweb.org/sigs-special-interest-groups/visualisation/vis-sig-resources</a>)</p> <p>The VIS SIG consists now of 16 highly active people with a trend for further growth</p>
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**Adam Crisp**  
**SIG Director**



**Gaëlle Saint-Hilary**  
**EFSPI**



# PSI Volunteers

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

## Board of Directors

Name	Company, Country	Role
Lucy Rowell	Roche, UK	Chair
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Mary Elliott-Davey	Amgen, UK	Training Committee Chair
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Paul Terrill	PT Stat Consulting, UK	Conference Chair
Stephen Jones	Medable, UK	Communications Committee and External Affairs (and EFSPi) chair

## Careers & Academic Liaison Committee (CALC)

Name	Company, Country	Role
Amanda Darekar	Pfizer, UK	Chair
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Jessica Kendall	CTRU, University of Leeds, UK	MSc Subteam
James Lay-Flurrie	Bayer, UK	BSc Subteam, German CALC Liaison
Rachael Loftus	GW Pharmaceuticals, UK	BSc Subteam
Shiv Makadia <sup>1</sup>	Amgen, UK	Schools Subteam (placement student)
Abeera Mohammad	Amgen, UK	Schools Subteam
Amy Phillips-Jones <sup>1</sup>	GSK, UK	BSc Subteam
Ian Ratcliffe	Veramed, UK	BSc Subteam
Tomas Rouse	AstraZeneca, Sweden	Website
Michael Seath <sup>2</sup>	Amgen, UK	Schools Subteam (placement student)
Katharine Thorn	GSK, UK	Schools Subteam
Xinyi Zhu	GSK, UK	MSc Subteam
Name	Company, Country	Role
Amanda Darekar	Pfizer, UK	Incoming Chair
Emma Crawford	MSD, UK	MSc Subteam

<sup>1</sup> Left committee during 2020

<sup>2</sup> Joined committee during 2020

## Commercial Committee

Name	Company, Country	Role
Alexander Currie	GSK, UK	Chair
Anna Passera	Novartis, Switzerland	Member

## Communications Committee

Name	Company, Country	Role
Alexander Schacht	UCB, Germany	Chair (stepped down December 2020)
Stephen Jones	Medable, UK	Chair (from January 2021)
Anastasiia Raievska	Roche	Conference Reporter Team Lead
Eleni Mourouli	Veramed	
Paolo Eusebi	UCB	
Fiona Grimson	UCB	
Jessica Kirk	Sheffield University	
Nouran Hamza	MARS research hub)	
Jack Elkes	Imperial, UK	Analytics Lead
Shikta Das	UCL	
Karan Vadher	Eli Lilly	
Alex Zimmerman	Amgen	
Roz Baverst	Amgen	
Sophie Greenwood	IQVIA, UK	
Matthew Gibb	Veramed, UK	
Jamie Rees	GSK, UK	
Priya Gokani	Amgen	Social Media Lead
Sophie Greenwood	IQVIA	
Eleni Mavropolou	GSK	
Jamie Rees	GSK	SPIN Editor
Matthew Gibb	Veramed	

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Dawn Midwinter	GSK, UK	
Tammy McIver	Roche, UK	
Aris Perperoglou	Astra Zeneca	
Leanne Wizner	Astra Zeneca	
Genevieve Wills	University College London	

## PSI/EFSPI Regulatory Committee

Name	Company, Country	Role
Jürgen Hummel	PPD, UK	Incoming Chair, Incoming PSI Regulatory Chair
Christoph Gerlinger	Bayer, Germany	Outgoing Chair / Incoming Co-chair, EFSPI Council Member, EFSPI Regulatory Chair
Anna Berglind	AstraZeneca, Sweden	Outgoing Co-chair, Outgoing PSI Regulatory Chair
Michael Cartwright <sup>2</sup>	Parexel, UK	
Olivier Collignon	GSK, UK	
Erika Daly	Cytel, Ireland	
Anne Danniau	UCB, Belgium	
Lars Endahl Laen	Novo Nordisk, Denmark	
Daniel Evans	Pfizer, UK	
Christine Fletcher	GSK, UK	EFSPI Council Member
Kerry Gordon <sup>1</sup>	Parexel, UK	
Mette Krog Josiassen	Lundbeck, Denmark	
Murray Lowe <sup>1</sup>	Phastar, UK	
Frances Lynn	Orchard Therapeutics, UK	
Roland Marion-Gallois	BMS, Switzerland	
James Matcham <sup>2</sup>	Cytel, UK	
Sireesha Pamulapati	Biogen, UK	
Carol Reid	Roche, UK	
Véronique Robert	Servier, France	
Kaspar Rufibach	Roche, Switzerland	
Antony Sabin <sup>1</sup>	AstraZeneca, UK	
Florian Voss	Boehringer-Ingelheim, Germany	
Heike Wöhling <sup>1</sup>	Novartis, Germany	

<sup>1</sup> Left committee during 2020

<sup>2</sup> Joined committee during 2020

## SIG Leads

SIG	name, company
AIMS	Lyn Taylor, Phastar
Benefit Risk	Shahrul Mt-Isa, MSD
Benefit Risk	Maria Costa, Novartis
Covid-19	Chrissie Fletcher, GSK
Covid-19	David Wright, AstraZeneca
CSM/QTL	Tim Rolfe, GSK
CSM/QTL	Susan Talbot, Amgen
Data Science	Julia Chernova, Bayer
Data Transparency	Rebecca Sudlow, Roche
Data Transparency	Mimmi Sundler, AstraZeneca
Decision Making	Gaelle Saint-Hilary, Servier
Historical Data	Nicky Best, GSK
Historical Data	Simon Wandel, Novartis
HTA	Lara Wolfson, Merck
HTA	Chrissie Fletcher, GSK

New Starters	Jack Eusden, GSK
Neuroscience Estimands	Hans-Ulrich Burger, Roche
Oncology Estimands	Kaspar Rufibach, Roche
Small Populations	Francois Aubin, Vennlife
Small Populations	Andreas Kaiser, Bayer
Subgroups	David Svensson, AstraZeneca
Toxicology	Gareth Thomas, Covance
Vaccines	Fabian Tibaldi, GSK
Visualisation	Bodo Kirsch, Bayer
Visualisation	Alexander Schacht, UCB

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Rimgaile Urbaityte	GSK, UK	
Charlotte Snape	Veramed, UK	
Ellie Grainger	AstraZeneca, UK	
Kerry Gordon <sup>1</sup>	Parexel, UK	
Fahmeeda Sheikh <sup>1</sup>	PPD, UK	

<sup>1</sup>Joined committee during 2020