



# PSI 2023 CONFERENCE

11-14 JUNE 2023

## Registration update

Dear Emily,

We're delighted to share that the response to the 2023 PSI conference has been amazing. At the time of writing we have over 500 registrations! If you're hoping to attend this year's Conference but are yet to register, we encourage you do so soon - due to venue capacity, we will have to close registration when we get to 600 people.

For more information on registration fees and to register click below.

[Register Now!](#)

If you have any questions about registration please use the enquiries email at the end of the newsletter.

## SPOTLIGHT ON: Pre-Conference Courses

The PSI training committee are running two pre-conference courses in 2023.

### [Pre-conference course 1: Increasing your agility](#)

Whether you are working on a project, company or personal objective, the ways in which we work will drive our impact and efficiency. Agile is an effective way of working to help balance and deliver on your priorities. This engaging and interactive session on agile ways of working will help you prioritise and deliver more effectively. You will leave the session with a clear understanding of what agile is, a range of tools to add to your professional toolkit and a personal action plan for how you can apply them. The session is highly interactive and includes a fully immersive workshop where you will be collaborating with other participants. This gives you the opportunity to practice and refine your new skills.

The course will be run by our partner JCURV and the course instructors are Payal Jain and Ben Beavers from JCURV.

*"The interactive workshop was great because you got to experience working in an agile way. Things change so fast in Pharma and project teams constantly move the goal posts – agile working would make me far more efficient!"* Kimberley Hacquoil, Chief Data Scientific Officer, Exploristics

## [Pre-conference course 2: Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables](#)

In May 2021, the U.S. Food and Drug Administration (FDA) released a revised draft guidance for the industry on “Adjustment for Covariates in Randomized Clinical Trials for Drugs and Biological Products”. Covariate adjustment is a statistical analysis method for improving precision and power in clinical trials by adjusting for pre-specified, prognostic baseline variables. Here, the term “covariates” refers to baseline variables, that is, variables that are measured before randomization such as age, gender, BMI, comorbidities. The resulting sample size reductions can lead to substantial cost savings, and also can lead to more ethical trials since they avoid exposing more participants than necessary to experimental treatments. Though covariate adjustment is recommended by the FDA and the European Medicines Agency (EMA), many trials do not exploit the available information in baseline variables or only make use of the baseline measurement of the outcome. The course is in 3 parts:

- In Part 1, we introduce the concept of covariate adjustment. In particular, we explain what covariate adjustment is, how it works, when it may be useful to apply, and how to implement it (in a preplanned way that is robust to model misspecification) for a variety of scenarios.
- In Part 2, we present a new statistical method that enables us to easily combine covariate adjustment with group sequential designs. The result will be faster, more efficient trials for many disease areas, without sacrificing validity or power. This approach can lead to faster trials even when the experimental treatment is ineffective; this may be more ethical in settings where it is desirable to stop as early as possible to avoid unnecessary exposure to side effects.
- In Part 3, we demonstrate the impact of covariate adjustment using completed trial data sets in multiple disease areas. We provide step-by-step, clear documentation of how to apply the software in each setting. Participants will have the time to apply the software tools on the different datasets in small groups.

The course instructors are: Kelly Van Lancker (Department of Applied Mathematics, Computer Science and Statistics, Ghent University, Ghent, Belgium), Josh Betz (Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, U.S.A.) and Michael Rosenblum (Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, U.S.A.)

[Course Registration](#)

We are still offering course attendance at the Early Bird rate:  
[250GBP +VAT for PSI Members](#)  
[300GBP +VAT for Non-Members](#)

## **PSI/RSS Prize-Winner**

A team of biostatisticians and statistical engineers from Roche in collaboration with the University of Bath won the 2022 Statistical Excellence in the Pharmaceutical Industry Award, which is presented jointly by the RSS and Statisticians in the Pharmaceutical Industry (PSI). The team comprised Marcel Wolbers, Alessandro Noci, Paul Delmar, Craig Gower-Page, Sean Yiu (of Roche) and Jonathan W. Bartlett (of the University of Bath).

Marcel Wolbers and Alessandro Noci will speak for the team at the PSI conference on ‘Standard and reference-based conditional mean imputation (methodology and open-

## SPOTLIGHT ON: PSI Special Interest Group Sessions

European Special Interest Groups (SIGs), sponsored by PSI and EFSPi, provide a forum for members to discuss topics of mutual interest, keep updated on developments in a particular area of industry, to organise events on their specialist field and/or to collaborate on developing the science of that field. The current SIGs cover a wide range of topics and a number of them are running sessions at the PSI conference.

SIG	Session Title
AIMS	Cross Industry R collaborations and challenges
Benefit-Risk	Small Steps Towards Patient Focused Benefit-Risk Assessment
Biomarkers	"PSI Biomarkers SIG: From basics to hot topics!"
CSM/QTL	Introduction to the Central Statistical Monitoring / Quality Tolerance Limits Special Interest Group
Data Science	
Decision Making	Advancing Quantitative Decision Making Methods
EIWG	ICH E9(R1) Impact beyond confirmatory superiority clinical trials
HTA and Launch & Life Cycle	Connecting the dots: how can statisticians drive end-to-end thinking in the development of new medicines?
Oncology <u>Eastimands</u>	Estimands – the journey continues or doing now what trial teams need next
RWD and Launch & Life Cycle	What is real - RWD or RCT? How to communicate evidence generation involving RWD"
Subgroup Analysis	The art of selecting a subgroup
Launch & Life Cycle	"Building a better bridge: Innovations in trial designs to address access and clinical practice questions
Vaccines	

View our Programme for details of the speakers and titles of talks in these sessions.

[View the Programme](#)

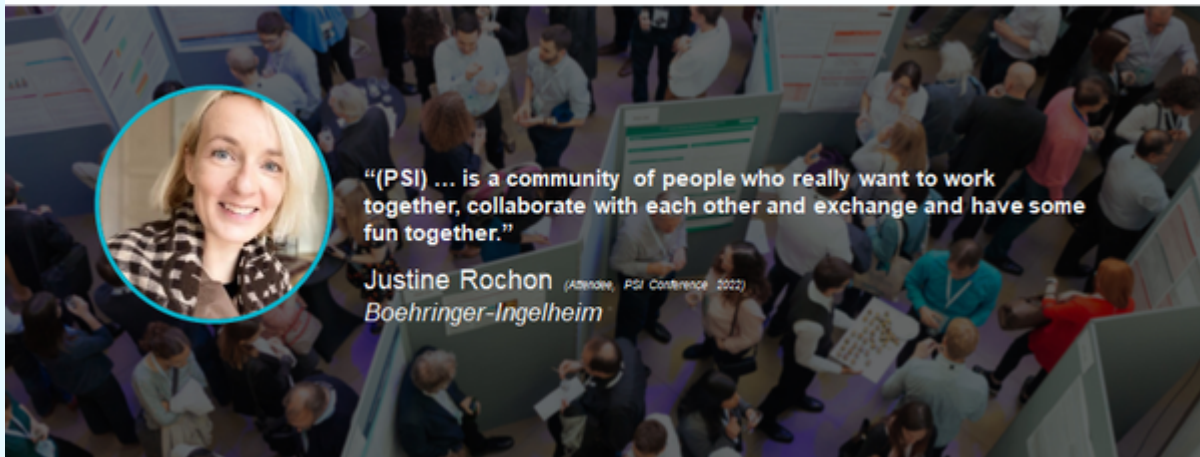
If you are interested in becoming an active member of PSI, the SIGs are a great place to start. For further information on any of the SIGs, [visit our website](#). To get involved in a specific SIG, please reach out to the identified SIG lead contacts, listed [here](#).

## Keynote Speaker: Timandra Harkness

Timandra Harkness will open the conference with a talk entitled "[From John Graunt to Next Slide Please: What a 17th Century haberdasher can teach us about data, risk and the public.](#)"

In plague-ridden London, self-taught haberdasher John Graunt used the weekly Bills of Mortality as his data, discovered patterns in the human tragedy, and invented analytical

tools we still use today. His work got him membership of the new Royal Society, but the 'Christopher Columbus' of statistics died in poverty after losing everything in the Great Fire of London. What can his work - and his eventful life story – teach us today about gathering and analysing data, and sharing that knowledge with the public?



“(PSI) ... is a community of people who really want to work together, collaborate with each other and exchange and have some fun together.”

**Justine Rochon** (Attendee, PSI Conference 2022)  
*Boehringer-Ingelheim*

### A Message from the Conference Chair

The records just keep tumbling! 2023 is set to be the biggest ever PSI conference with over 500 registrations so far. With only a few weeks to go we are fine-tuning the agenda and those all important social events. I am looking forward to the conference, and I hope you are too!



**David Lawrence**  
*Conference Chair*

### Let your colleagues know...

Please share this email with any colleagues and friends who you think will be interested in the PSI Annual Conference.

### Enquiries...

Should you require any assistance, please do not hesitate to contact the conference secretariat.

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