



PSI 2022  
CONFERENCE

12-15 June 2022

GOTHENBURG

GOTHIA TOWERS | SWEDEN

**It's not too late to register!**

Dear Emily,

Registration for the 2022 PSI conference is still open! If you have not yet registered and would like more information on the conference, registration fees, etc. click below!

[Find Out More](#)

Places are also available for the [pre-conference courses](#) on “Estimand-aligned statistical analyses of clinical trials” and “A practical introduction to simulating complex trial designs”.

## PROGRAMME HIGHLIGHT: Regulatory Hot Topics

The conference will conclude with the **Regulatory Hot Topics** session, an exciting 75 minutes where you will be able to listen to a panel of top experts from regulatory agencies and industry. The session will include presentations from the panelists, as well as a discussion of regulatory hot topics in statistics.

*The panel will consist of:*

- **Anja Schiel**, Senior advisor at the Norwegian Medicines Agency
- **Chrissie Fletcher**, VP, Specialty & Primary Care Statistics at GSK
- **David Wright**, Head of Statistical Innovation, DS&AI, BioPharma R&D, AstraZeneca, Cambridge, UK
- **Florian Lasch**, Biostatistician Specialist at the European Medicines Agency

The panelists have chosen their hottest topics and will share their thoughts on those;

- Chrissie plans to discuss different aspects of innovation in clinical trials based on feedback from recent multi-stakeholder workshops. This includes the progress achieved to date, where key challenges remain, and how new initiatives will continue to advance innovation in clinical trials in the future.

- Anja will focus on how we can revert the unfortunate trend to incentivise ‘minimum evidence’ and instead return to ‘better evidence with smarter study designs’. She will discuss the misalignment between regulators and those Stakeholders that require relative effectiveness (which includes HTAs but also Physicians and Patients). She’ll also touch on study designs that can help to generate better evidence with still fewer patients as well as the role the Methodology Working Party (MWP).

- Florian will present on emerging data uses in the European regulatory system. This includes the increased use of real world healthcare, the use of Individual Patient Data from clinical trials as part of the assessment of Marketing Authorization Applications and structuring clinical trial protocols in the context of ICH M11.

- David will reflect on methodological issues with Decentralized Trials and the “validation” of Novel Endpoints. The COVID-19 pandemic forced ongoing trials to use alternative methods of data collection. What lessons were learnt and has this really accelerated the use of these alternative approaches in confirmatory clinical trials? Can drug development become more agile to changes in methods of data collection and to changes in measures of clinical benefit?

In addition, the regulatory SIG would like some challenging **Questions from the audience**, including real-life case studies suitable to be discussed by the panel. If you know of a suitable topic or have a question, then please contact the Regulatory SIG using this email address: [regsig@psiweb.org](mailto:regsig@psiweb.org)

## THANK YOU to our Sponsors!

As well as the attendees a major part of the success of the PSI conference is the support of our sponsors.

Thank you to the following sponsors who are all confirmed!



Other sponsors are in the pipeline. Please check the PSI conference website to see new names as they are added.

PSI 2022 Sponsors

Please contact [Chris Watton](#) or [Aiden Flynn](#) to discuss the sponsorship opportunities still available.

### A Message from the Conference Chair

As I write this there are 7 weeks to go until the start of the conference. The agenda is essentially final, and we have

over 320 participants registered. I cannot wait for our first face-to-face event since 2019!

**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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