Promoting Statistical Insight

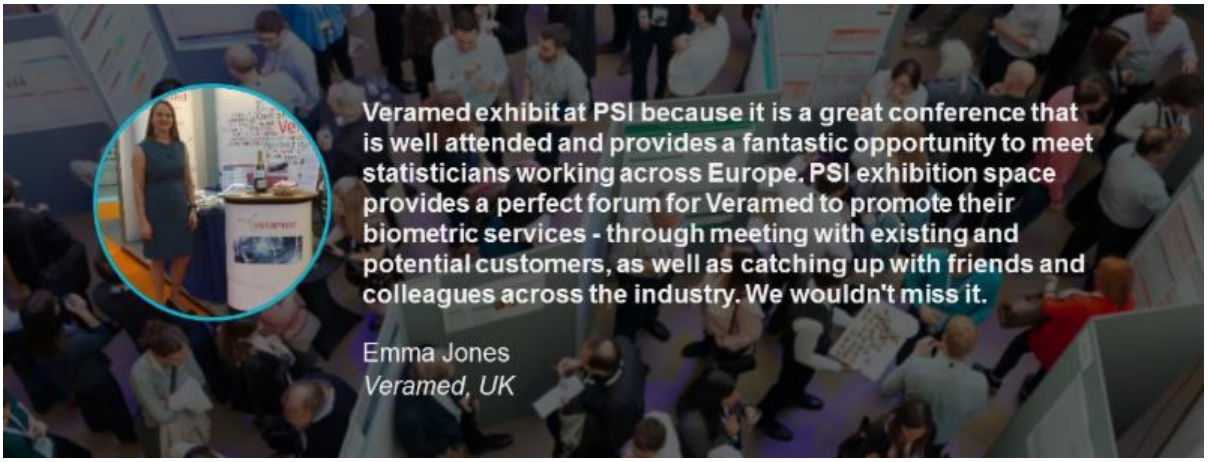
IT'S NOT TOO LATE TO REGISTER!

Registration for the 2019 PSI Conference is still open.

Group registration discounts are also available to companies sending a group of 10 or more full conference delegates. Click here to find out more about the group registration discount rates available.

Click here to register. **More information on registration fees.**

Register Now



PROGRAMME HIGHLIGHT: **Regulatory & HTA Townhall**

Do you have a question you would like to ask an EU HTA specialist or regulatory statistician?

If so then please take advantage of the Regulatory & HTA Town Hall session taking place on Wednesday 5th June at the PSI Conference in London. This session will provide you with the opportunity to ask our panel of EU regulators, HTA experts and industry representatives any of your questions.

The session will be chaired by Anja Schiel and the panellists will be:

- Ralf Bender (IQWiG)
- Rose Lovett (NICE)
- Kit Roes (UMC Utrecht)
- James Matcham (Astrazeneca)

To submit a question please click on the link below. Questions can be submitted anonymously.

Submit a Question

SPOTLIGHT ON: **Pre-Conference Courses**

The PSI training committee are organising two exciting pre-conference courses on Sunday 2nd June, 1pm-5pm.

Pre-Conference Course 1
Stated Preference Methods: Eliciting patient preferences in the age of personalized medicine
Presented by the Benefit-Risk SIG. Location: QEII, London

Many crucial questions need to be answered throughout drug development: “which efficacy measures best represent clinically meaningful outcomes?”, “which adverse events should be monitored closely?”, “what drives the decision: maximizing efficacy or reducing the risk of adverse events?”

Pharmaceutical companies can conduct preference elicitation studies as part of clinical development programs to assess how the benefit-risk trade-off of a new drug will impact various stakeholders. Typically, there is a focus on patient preferences, but other stakeholders, such as physicians, can also be included in the assessment.

The course will include a hands-on workshop where participants will have the opportunity to learn about preference elicitation approaches, and the advantages and challenges with patient preference elicitation from the design of the study to the analysis of the data and its interpretation.

Pre-Conference Course 2
Evidence Synthesis for Clinical Trials: Use of Historical Data and Extrapolation - Methods, applications and implementation with the R package RBesT
Presented by Sebastian Weber and Satrajit Roychoudhury. Location: Park Plaza, Waterloo

There is an intrinsic interest of leveraging all available information for an efficient design and analysis of clinical trials. The use of external data in trials are nowadays used in earlier phases of drug development (Trippa, Rosnerand Muller, 2012; French, Thomas and Wang, 2012; Hueber et al., 2012), occasionally in phase III trials (French et al., 2012), and also in special areas such as medical devices (FDA, 2010a), orphan indications (Dupont and Van Wilder, 2011) and extrapolation in pediatric studies (Berry, 1989). This allows trials with smaller sample size or with unequal randomization (more subjects on treatment than control). In this short course, we'll provide a statistical framework to use trial external evidence to better plan and/or incorporate external information into a trial.

During the first part of the course we will introduce the meta-analytic predictive (MAP) model (Neuenschwander, 2010). The MAP model is a Bayesian hierarchical model, which combines the evidence from different potentially heterogeneous sources (usually studies).

In the second part of the course we will focus on key applications of the MAP approach in biostatistics, which are (i) the derivation of informative priors from historical controls and (ii) probability of success. These applications will be demonstrated using the R package RBesT, the R Bayesian evidence synthesis tools, which are freely available from CRAN. During the second part hands-on exercises will be part of the course to enable participants to apply the presented approach themselves.

If you would like to register for either of these courses, you can log in to your existing conference registration or contact psi2019conference@mci-group.com

More information is available on the PSI website

Let Your Colleagues | **Enquiries** | **A Message from the**

Know!

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

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

Email:
psi2019conference@mci-group.com

Tel:
+ 44 (0) 1730 715 235

Website:
www.psiweb.org/psi-conference-2019

Conference Chair

With less than 50 days to go, we are in the final stages of planning. I am so excited to see the content, socials, venues and of course the attendees, all come together for what we hope will be a fantastic 2019 PSI conference.

Kate Taylor
Conference Chair
