

**EFSPI Scientific Meeting:
Reproducibility in Clinical Research
Friday, 22nd November 2019**

This meeting will bring together speakers from industry, academia and regulatory agencies, who will address questions relating to reproducibility in clinical research, and the role statistics (and statisticians) have in ensuring clinical research is conducted and reported in a reproducible manner. Some questions of interest in this context are:

- The regulatory requirement for two independent pivotal studies in marketing applications is intended to ensure reproducibility of results. How good is this criterion, and in what circumstances can we deviate from it? What would be the 'optimal' type-1 error rate?
- What alternative statistical methods are there to hypothesis tests, and how much better are these methods in ensuring reproducibility? Are Bayesian methods the answer?
- What statistical methods are there to ensure reproducibility when extrapolating results from a (planned or unplanned) sub-group analysis?
- How can we ensure reproducibility of phase II results when going into phase III?
- How can real world evidence increase the reproducibility of clinical studies?
- How can we increase 'translational reproducibility', that is, the chance of predicting the outcome of a trial in humans based on animal data? What more can statisticians contribute to the validation of biomarkers?
- What requirements should journal editors make to ensure reproducibility of published data analyses?
- In general, what can statisticians contribute to resolving the reproducibility crisis?

The final agenda will be made available in due course.

Confirmed Speakers:

- Norbert Benda (BfArM, Germany)
- Bruno Boulanger (Pharmalex, Belgium)
- Heiko Götte (Merck, Germany)
- Lisa Hampson (Novartis, Switzerland)
- Leonhard Held (University of Zurich, Switzerland)



Venue:

NV Bristol-Myers Squibb Belgium SA
Parc de l'Alliance
Avenue de Finlande 4
B – 1420 Braine-l'Alleud
Belgium

Note that there is only limited parking space. Public transport is recommended

Registration:

Fee includes lunch & refreshments

On or before 18th October 2019

Industry Rate: €150
Academic Rate: €75

After 18th October 2019

Industry Rate: €200
Academic Rate: €100

Students: a limited number of places is available free of charge, please contact: axel.krebs-brown@merckgroup.com

REGISTRATION WILL OPEN
SHORTLY.

TO REGISTER, PLEASE GO TO:

www.efspi.org

For any queries, please contact:

EFSPi Secretariat
Tel: +44 (0)1625 664549
efspi@kingstonsmith.co.uk