

Day 1 – October 4 (Tuesday)

workshop **Welcome**

13:45 – 14:00 Welcome to pre-conference workshop –
David Willé

Half-day workshop on dose-response analysis

chair – Ludwig Hothorn

14:00 – 15:00 **Daniel Gerhard and Christian Ritz:**
Mixed-effects dose-response analysis,
*Universities of Canterbury and Copen-
hagen*

break

15:00 – 15:30 Coffee break

15:30 – 16:30 **Bjoern Bornkamp:** Model selection
versus model averaging in dose finding
studies, *Novartis*

16:30 – 17:30 **Ludwig Hothorn:** Trend tests assum-
ing dose as a qualitative factor and/or
as a quatitative covariate, *University of
Hannover*

End of workshop

17:30 – 17:40 wrap up and orientation – David Willé

Reception

19:30 – 21:00 Drinks reception at the college.

Day 2 – October 5 (Wednesday)

Welcome

09:10 – 09:15 main conference welcome – David Willé

2 CMC 1 / Pharmacology and Bayesian statistics 1

chair – Helena Geys

09:15 – 10:00 **Stan Altan:** Controversies, questions and recent advances in stability modelling, *Janssen*

10:00 – 10:10 short pause

2a: CMC – Helen Geys

2b: Pharmacology – Kat Gore

10:10 – 10:30 **Marion Chatfield:** Assessment of priors to Estimate Uncertainty in Variance Estimates in small studies, *GSK*

Hannes-Friedrich Ulbrich: How to make better use of advanced statistical methods in animal experiments in research, *Bayer Pharma Aktiengesellschaft*

10:30 – 10:50 **Steve Novick:** Setting control limits using Bayesian methods when most observations are below the limit of quantification, *MedImmune*

Gonzalo Durán-Pacheco: Characterization of vascular retinal diseases by causal modeling, *F. Hoffmann-La Roche AG*

break

10:50 – 11:20 Coffee and posters

3 Pharmacology and Bayesian statistics 2 / CMC 2

chair – Tom Jacobs

11:20 – 12:05 **Max Kuhn:** Statistical methodology in pre-clinical in vivo modelling: advances and improvements with Bayesian methodology, *Pfizer*

12:05 – 12:15 short pause

3a: Pharmacology – Tom Jacobs

3b: CMC – Pierre Lebrun

12:15 – 12:35 **Robert Kozarski:** Growth-Inhibition Model in Pre-Clinical In-Vivo Modelling: Advances and Improvements with Bayesian Methodology, *MedImmune*

Luwis Diya: Modeling dissolution profiles using a Bayesian beta mixed regression model, *Janssen Pharmaceutica NV*

12:35 – 12:55 **Emma Martin:** Accounting for dropout in xenografted tumour efficacy studies: Integrated endpoint analysis, reduced bias and better use of animals, *University of Manchester*

Coppenolle Hans: Design considerations for process qualification activities applied to dissolution testing, *Janssen Pharmaceutica*

12:55 – 13:05 short pause

4 CMC 3 / High dimensional statistics 1

4a: HDS – David Willé

4b: CMC – Bruno Boulanger

13:05 – 13:25 **Stanley E. Lazic:** Using general linear models to adjust for total cell number and technical artefacts in high-throughput screens, *Novartis*

Laurent Natalis: Promotion of the Quality by Design principles in the pharmaceutical industry via the Robustness Index initiative, *Arlenda*

13:25 – 13:45 **Michel Thiel:** Analyzing unbalanced multifactorial experiments with ASCA and APCA: Application in metabolomics, *Janssen Pharmaceutica*

Maud Hennion: From the laboratory to the clinic: A Bayesian perspective to accelerate the validation of a diagnostic test, *Arlenda*

Lunch

13:45 – 15:00 Lunch and posters

1 Reproducibility

chair – Peter Ceuppens

15:00 – 15:45 **Malcom Macleod:** Risks of bias in animal research - and how to mitigate them, *University of Edinburgh*

15:45 – 16:05 **Brian J Eastwood:** Evaluation of touchscreen based visual discrimination in rats across multiple laboratories, *Lilly*

16:05 – 16:25 **Ros Walley and Andy Grieve:** Reproducibility – the good, the bad and the ugly, *UCB*

break

16:25 – 16:55 Coffee and posters

5 High dimensional statistics 2 / Pharmacology and Bayesian statistics 3

5a: HDS – Richardus Vonk

5b: Pharmacology – Kat Gore

16:55 – 17:15 **Ziv Shkedy:** Integrated analysis of gene expression, chemical structure and bioassay data in drug discovery experiments, *University of Hasselt*

Thomas Jaki: Comparing sampling methods for pharmacokinetic studies using the derived parameters, *Lancaster University*

17:15 – 17:35 **Marijke Van Moerbeke:** Integrated Cluster Analysis in Drug Discovery Experiments using Multi-Source Data, *University of Hasselt*

Helen Barnett: Optimal designs for pharmacokinetic studies analysed using non-compartmental methods, *Lancaster University*

End of conference sessions

17:35 – 17:45 wrap up and organisation – David Willé

Conference social event

19:30 – 22:00 Meal at **Browns Restaurant**, 23 Trumpington St, Cambridge CB2 1QA. Additional activities may also be planned.

Day 3 – October 6 (Thursday)

Welcome

08:30 – 08:40 welcome to the final day – TBD

6 Microbiome / Pharmacology and Bayesian statistics 4

chair – Luc Bijnens

08:40 – 09:10 **Marcus Rauch:** Introduction to microbiome research, *Janssen Prevention Center*

09:10 – 09:55 **Susan Holmes:** Statistical aspects of microbiome experiments, *Stanford University*

09:55 – 10:05 short pause

6a: Microbiome – Luc Bijnens

6b: Pharmacology – David Willé

10:05 – 10:25 **Nolen Joy Perualila:** Development of microbiome biomarkers for Immunoglobulin A: a joint modeling approach, *University of Hasselt*

Fabiola La Gamba: A bayesian PK/PD model for synergy; a case study, *University of Hasselt*

10:25 – 10:45 **Wim Van der Elst:** Evaluating surrogate endpoints based on causal-inference and information theory, with illustrations in a microbiome setting, *Janssen Research & Development*

Yauheniya Cherkas: Analysis of Imaging of Hippocampal Epileptiform Calcium Motifs, *Janssen Pharmaceutica*

10:45 – 11:05 **Stijn Hawinkel:** Model-based visualization provides insightful biplots of microbiome datasets, *Ghent university*

Leacky Muchene: Evaluation of Magnetic Resonance Imaging (MRI) parameters as Biomarkers in Alzheimer's Disease, *Hasselt University*

break

11:05 – 11:35 Coffee and posters

7 Synergy 1 / Pharmacology and Bayesian statistics 5

7a: Synergy – Tom Jacobs

7b: Pharmacology – Richardus Vonk

11:35 – 11:55 **Bie Verbist:** Introduction to drug synergy, *Janssen*

Marjolein Crabbe: Multivariate analysis strategies for the design of image-based compound profiling experiments, *Janssen Pharmaceutica*

11:55 – 12:15 **Mandy Bergquist:** 1+1 = 3 – A Search for In Vivo Synergy, *GSK*

Juliane Siebourg-Polster: Causal modeling of histo-pathology image marker proteins in treated inflammation, *Roche Pharmaceutical Research and Early Development*

12:15 – 12:35 **Koen van der Borght:** Generalised Loewe model, *Janssen*

Robin Van Oirbeek: Leading chemometrics into the lab: a case study, *Open Analytics*

Lunch

12:35 – 13:50 Lunch and posters

8 Synergy 2 / CMC 4

8a: Synergy – Tom Jacobs

8b: CMC – Pierre Lebrun

13:50 – 14:10 **Olivier Thas:** Nonparametric synergy call: two F-tests, *University of Ghent*

Timothy Mutsvari: Analytical biosimilarity: an analysis of current practices and a Bayesian proposal for a successful strategy, *Arlenda*

14:10 – 14:30 **Maxim Nazarov:** One and two-stage modelling approaches for assessing synergy in Harbron's framework, *Open Analytics*

Pieta IJzerman-Boon: A Comparison of Experiments to Estimate Qualitative Microbiological Test Parameters, *MSD*

14:30 – 14:50 **Nele Goeyvaerts:** open discussion, *Janssen*

Ariëlla Van de Sompel: A Bayesian approach to tobit regression for longitudinal and censored data, *Ablynx nv*

break

14:50 – 15:10 Coffee and posters (20m)

9 Toxicology and MVA / CMC 5

chair– Luc Bijmens

15:10 – 15:55 **David Lovell:** New Developments in Statistics for Mutagenesis and Genetic Toxicology, *St George's, University of London*

15:55 – 16:05 short pause

9a: Toxicology and MVA – Luc Bijmens

9b: CMC – Kat Gore

16:05 – 16:25 **Mark Pilling:** High throughput screening of compounds for drug induced liver injury (DILI), *Astrazeneca*

Martin Otava: Continuous Manufacturing of Pharmaceuticals: Statistical Challenges, *Janssen Pharmaceutica*

16:25 – 16:45 **Tatsiana Khamiakova:** Multivariate statistics for PAT data analysis: an application to IR synthesis monitoring, *Janssen Research & Development*

Bianca Teodorescu: Statistical considerations in setting product specifications, *UCB*

End of meeting

16:45 – 16:55 Closing remarks – David Willé