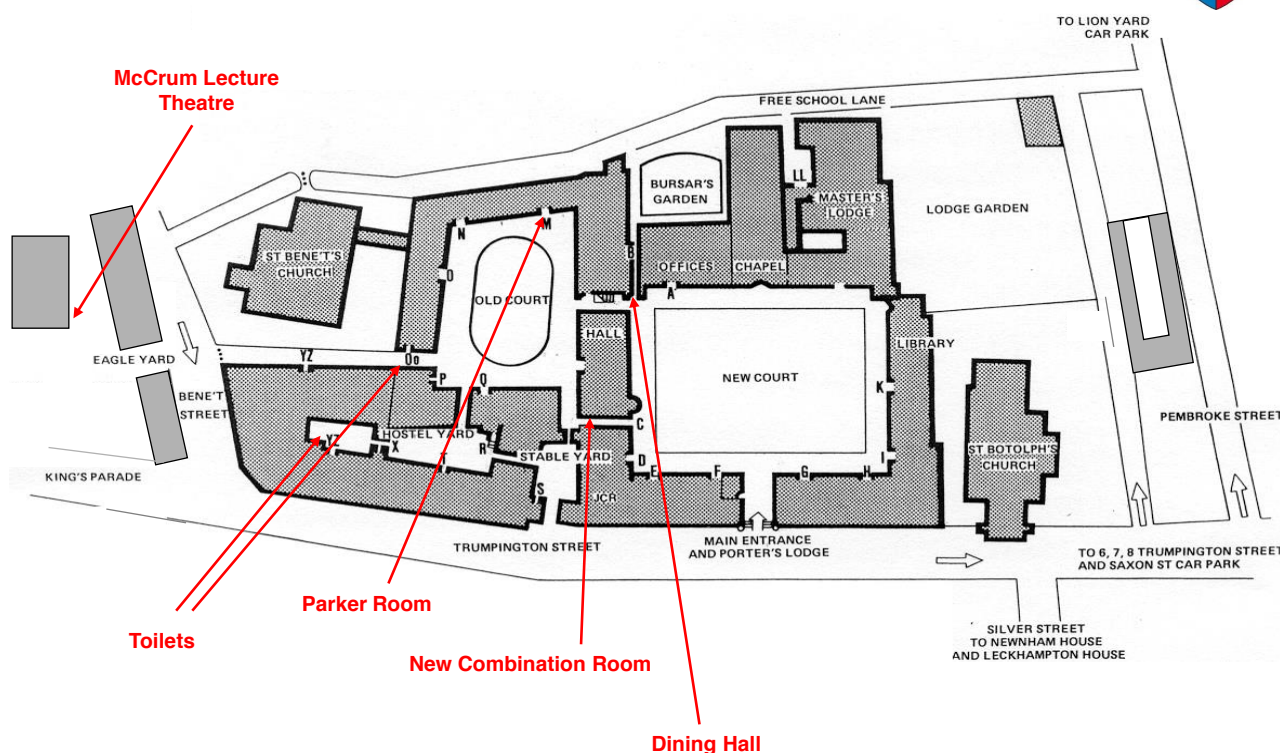




Non-Clinical Statistics Conference Programme

Corpus Christi College Cambridge
4-6 October 2016

Corpus Christi College



Key to programme notes:

- **MCT** – McCrum Lecture Theatre
- **NCR** – New Combination Room

Unless otherwise stated, all sessions will take place in the McCrum Lecture Theatre. This is also where registration will take place and the conference will begin and end. Parallel sessions taking place in the New Combination Room are indicated 'NCR' in the programme notes.

The lecture theatre foyer will also place where we will meet for coffee breaks and where posters will be displayed in the four poster sessions. Lunch will be held in the main Dining Hall on Wednesday and split between the lecture room foyer and Parker room suite on Thursday.

Details of the poster presentations and a presenter index are given at the end of this document.

Since the lecture theatre and other rooms are on a different site we will show you the most efficient way of moving between locations when you arrive. Otherwise, you can always enter the college by showing your conference badge at the main entrance and porter's lodge.

Day 1 – October 4 (Tuesday)

Welcome

13:00 – 13:45 *conference registration opens*

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

Half-day workshop on dose-response analysis

MCT: chair – Ludwig Hothorn

14:00 – 15:00 **Daniel Gerhard:** Mixed-effects dose-
-response analysis, *University of Can-
terbury, NZ*

break

15:00 – 15:30 coffee break (MCT foyer)

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 quantitative covariate, *University of
Hannover*

End of workshop

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

Reception

18:00 – 19:30 Drinks reception at Corpus Christi Col-
lege in the Old and New Combination
Rooms.

Day 2 – October 5 (Wednesday)

Welcome

08:45 – 09:10 *conference registration*

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

1 Pharmacology and Bayesian statistics 1 / CMC 1

MCT: chair – Helena Geys

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

10:00 – 10:10 short pause

MCT: Pharmacology – Kat Gore

NCR: CMC – Helena Geys

10:10 – 10:30 **Hannes-Friedrich Ulbrich:** How to make better use of advanced statistical methods in animal experiments in research, *Bayer Pharma Aktiengesellschaft*

Marion Chatfield: Assessment of priors to Estimate Uncertainty in Variance Estimates in small studies, *GSK / University of Southampton*

10:30 – 10:50 **Gonzalo Durán-Pacheco:** Characterization of vascular retinal diseases by causal modeling, *F. Hoffmann-La Roche AG*

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

break

10:50 – 11:20 coffee and poster session A (MCT foyer)

2 Pharmacology and Bayesian statistics 2 / CMC 2

MCT: 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

MCT: Pharmacology – Tom Jacobs

NCR: 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*

break

12:55 – 13:20 coffee and poster session B (MCT foyer)

3 High dimensional statistics 1 / CMC 3

MCT: HDS – David Willé

NCR: CMC – Pierre Lebrun

13:20 – 13:40 **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*

13:40 – 14:00 **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

14:00 – 15:00 lunch and poster session C (Dinning Hall)

4 Reproducibility

MCT: chair – Peter Ceuppens

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

15:45 – 16:05 **Ros Walley and Andy Grieve:** Reproducibility – the good, the bad and the ugly, *UCB*

16:05 – 16:25 **Brian J Eastwood:** Evaluation of touchscreen based visual discrimination in rats across multiple laboratories, *Lilly*

break

16:25 – 16:55 coffee and poster session D (MCT foyer)

5 High dimensional statistics 2 / Pharmacology and Bayesian statistics 3

MCT: HDS – Richardus Vonk

NCR: 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 organisational comments – David Willé

Evening social programme

18:15 – 19:15 Guided Walking tour of Cambridge (open to all, no charge, leaves from Corpus Christi).

19:30 – 22:00 Meal at **Browns Restaurant**, 23 Trumpington St, Cambridge CB2 1QA (pre-payment at registration necessary).

Day 3 – October 6 (Thursday)

Welcome

08:30 – 08:40 welcome to the final day – Kat Gore

6 Pharmacology and Bayesian statistics 4 / Microbiome

MCT: chair – Luc Bijnens

08:40 – 09:10 **Mike Cox:** Introduction to microbiome research, *National Heart & Lung Institute Imperial College London*

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

09:55 – 10:05 short pause

MCT: Pharmacology – David Willé

NCR: Microbiome – Luc Bijnens

10:05 – 10:25 **Zhenya Cherkas:** Analysis of Imaging of Hippocampal Epileptiform Calcium Motifs, *Janssen Pharmaceutica*

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

10:25 – 10:45 **Fabiola La Gamba:** A bayesian PK/PD model for synergy; a case study,, *University of Hasselt*

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

10:45 – 11:05 **Leacky Muchene:** Evaluation of Magnetic Resonance Imaging (MRI) parameters as Biomarkers in Alzheimer's Disease, *Hasselt University*

Stijn Hawinkel: Model-based visualization provides insightful biplots of microbiome datasets, *Ghent university*

break

11:05 – 11:35 coffee

7 Pharmacology and Bayesian statistics 5 / Synergy 1

MCT: Pharmacology – Richardus Vonk NCR: Synergy – Tom Jacobs

11:35 – 11:55 **Marjolein Crabbe:** Multivariate analysis strategies for the design of image-based compound profiling experiments, *Janssen Pharmaceutica* **Bie Verbist:** Introduction to drug synergy, *Janssen*

11:55 – 12:15 **Juliane Siebourg-Polster:** Causal modeling of histo-pathology image marker proteins in treated inflammation, *Roche Pharmaceutical Research and Early Development* **Mandy Bergquist:** 1+1 = 3 – A Search for In Vivo Synergy, *GSK*

12:15 – 12:35 **Robin Van Oirbeek:** Leading chemometrics into the lab: a case study, *Open Analytics* **Koen van der Borcht:** Generalised Loewe model, *Janssen*

Lunch

12:35 – 13:50 lunch at split locations (MCT foyer and Parker suite)

8 Synergy 2 / CMC 4

MCT: Synergy – Tom Jacobs NCR: CMC – Pierre Lebrun

13:50 – 14:10 **Olivier Thas:** Nonparametric synergy call: two F-tests, *University of Ghent* **Bianca Teodorescu:** Statistical considerations in setting product specifications, *UCB*

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

9 Toxicology and MVA / CMC 5

MCT: Toxicology and MVA – Luc Bij- NCR: CMC – Helena Geys
nens

15:10 – 15:30 **Mark Pilling:** High throughput screen- **Timothy Mutsvari:** Analytical biosimi-
ing of compounds for drug induced liver larity: an analysis of current practices
injury (DILI), *Astrazeneca* and a Bayesian proposal for a success-
ful strategy, *Arlenda*

15:30 – 15:50 **Tatsiana Khamiakova:** Multivariate **Martin Otava:** Continuous Manufac-
statistics for PAT data analysis: an turing of Pharmaceuticals: Statistical
application to IR synthesis monitoring, Challenges, *Janssen Pharmaceutica*
Janssen Research & Development

15:50 – 16:00 short pause

MCT: chair– Luc Bijmens

16:00 – 16:45 **David Lovell:** New Developments in
Statistics for Mutagenesis and Genetic
Toxicology, *St George's, University of
London*

End of meeting

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

Poster sessions

session A

Display time: day 2 between 10:50 and 11:20

1. **Alfred Barron:** A Dynamic Graphical Model of a Nonparametric MANOVA, *Janssen*
2. **Zhenya Cherkas:** Hippocampal Place Cells Analysis via Calcium Imaging, *Janssen Pharmaceutica*
3. **Ewoud De Troyer:** Connectivity Scores using Factor Analysis, *University of Hasselt*
4. **Davit Sargsyan:** Robust Estimation and Interpretation of Dose-Response Curves in Pre-clinical Experiments, *Janssen Pharmaceutica*
5. **Fetene Tekle:** Bias in AUC estimation using NCA for TK studies, *Janssen Research & Development*
6. **Jason Waddell:** Well-Plate Data Feature Selection using the MRMR Algorithm, *Open Analytics*
7. **Heidi Wouters:** A Bayesian approach for shelf-life prediction by accelerated stability tests, *Ablynx nv*

session B

Display time: day 2 between 12:55 and 13:20

1. **Balazs Banfai:** Evaluation of modeling approaches for longitudinal and hierarchical designs, *Roche*
2. **Eloisa Brook:** Simulating sampling scenarios from amplified clone populations, *GSK*
3. **Erika Cule:** Statistical consulting for next generation sequencing and 'omics technologies: design, analysis and interpretation., *GSK*
4. **N W Galwey:** Combining sources of evidence to identify gene-disease associations as targets for drug development, *GSK*
5. **Steve Novick:** A novel survival analysis for rodent oncology modeling, *MedImmune*
6. **Rudradev Sengupta:** Evaluation of Surrogate Endpoint in High Dimensional Data: A Longitudinal Analysis of Family-level Microbial Diversity and Immunoglobulin A, *University of Hasselt*
7. **David R Willé:** A new initiative for selecting and validating drug targets, *GSK*

session C

Display time: day 2 between 14:00 and 15:00

1. **Volker Harm:** Self-service statistical evaluation of the micronucleus test in vitro and in vivo according to the new OECD guidelines, *Bayer Pharma*
2. **Natasha Karp:** Embracing variation to address replicability challenge, *Mouse Informatics Group*
3. **Natasha Karp:** The Experimental Design Assistant, *Mouse Informatics Group*
4. **Jean-François Michiels:** Efficient algorithm to locate design space within a multidimensional experimental space, *Arlenda*

5. **Jean-François Michiels:** Multivariate logistic/probit regression using STAN: model and prediction., *Arlenda*
6. **Robin Van Oirbeek:** Statistical detection of outlying reaction conditions, *Open Analytics*
7. **Robin Van Oirbeek:** Calculating the area under the curve in toxicology studies using microsampling on non-standard sparse designs, *Open Analytics*

session D

Display time: day 2 between 16:25 and 16:55

1. **Stijn Hawinkel:** A broken promise: Microbiomics differential abundance methods do not control false discovery rate, *Ghent university*
2. **Graham F Healey:** Multiplex immunoassay for early detection of cancer: Aspects of control and calibration, *Oncimmune Ltd*
3. **Jens Lamerz:** 'Assessing practical significance of a process parameter in pharmaceutical technical development using the "Impact Ratio, *Roche*
4. **Kathy Mutambanengwe:** Longitudinal analysis of infant gut microbiome in relation to onset of Type 1 Diabetes, *Open Analytics NV*
5. **Laurent Natalis:** Internal Release Limits (IRL) computation for products with linear and non-linear degradations., *Arlenda*
6. **Herbert Thijs:** Sample Size for diagnostic agreement studies, *Biocartis*
7. **Ros Walley:** Using Bayesian statistical methods to model potential outliers in in-vivo studies, *UCB*

Presenter index

Stan Altan: day 2, *invited speaker*, 09:15 – 10:00, MCT

Balazs Banfai: poster session B, day 2, 12:55 to 13:20

Helen Barnett: day 2, *talk*, 17:15 – 17:35, NCR

Alfred Barron: poster session A, day 2, 10:50 to 11:20

Mandy Bergquist: day 3, *talk*, 11:55 – 12:15, NCR

Bjoern Bornkamp: day 1, *workshop*, 15:30 – 16:30, MCT

Eloisa Brook: poster session B, day 2, 12:55 to 13:20

Marion Chatfield: day 2, *talk*, 10:10 – 10:30, NCR

Zhenya Cherkas: day 3, *talk*, 10:05 – 10:25, MCT; poster session A, day 2, 10:50 to 11:20

Marjolein Crabbe: day 3, *talk*, 11:35 – 11:55, MCT

Erika Cule: poster session B, day 2, 12:55 to 13:20

Ewoud De Troyer: poster session A, day 2, 10:50 to 11:20

Luwis Diya : day 2, *talk*, 12:15 – 12:35, NCR

Gonzalo Durán-Pacheco: day 2, *talk*, 10:30 – 10:50, MCT

Brian J Eastwood: day 2, *talk*, 16:05 – 16:25, MCT

N W Galwey: poster session B, day 2, 12:55 to 13:20

Daniel Gerhard: day 1, *workshop*, 14:00 – 15:00, MCT

Nele Goeyvaerts: day 3, *talk*, 14:30 – 14:50, MCT

Coppenolle Hans: day 2, *talk*, 12:35 – 12:55, NCR

Volker Harm: poster session C, day 2, 14:00 to 15:00

Stijn Hawinkel: day 3, *talk*, 10:45 – 11:05, NCR; poster session D, day 2, 16:25 to 16:55

Graham F Healey: poster session D, day 2, 16:25 to 16:55
Maud Hennion : day 2, *talk*, 13:40 – 14:00, NCR
Susan Holmes: day 3, *invited speaker*, 09:10 – 09:55, MCT
Ludwig Hothorn: day 1, *workshop*, 16:30 – 17:30, MCT
Pieta IJzerman-Boon: day 3, *talk*, 14:10 – 14:30, NCR
Thomas Jaki: day 2, *talk*, 16:55 – 17:15, NCR
Natasha Karp: poster session C, day 2, 14:00 to 15:00
Tatsiana Khamiakova : day 3, *talk*, 15:30 – 15:50, MCT
Robert Kozarski: day 2, *talk*, 12:15 – 12:35, MCT
Max Kuhn: day 2, *invited speaker*, 11:20 – 12:05, MCT
Fabiola La Gamba: day 3, *talk*, 10:25 – 10:45, MCT
Jens Lamerz: poster session D, day 2, 16:25 to 16:55
Stanley E. Lazic: day 2, *talk*, 13:20 – 13:40, MCT
David Lovell: day 3, *invited speaker*, 16:00 – 16:45, MCT
Malcom Macleod: day 2, *invited speaker*, 15:00 – 15:45, MCT
Emma Martin: day 2, *talk*, 12:35 – 12:55, MCT
Jean-François Michiels: poster session C, day 2, 14:00 to 15:00
Leacky Muchene: day 3, *talk*, 10:45 – 11:05, MCT
Kathy Mutambanengwe: poster session D, day 2, 16:25 to 16:55
Timothy Mutsvari : day 3, *talk*, 15:10 – 15:30, NCR
Laurent Natalis: day 2, *talk*, 13:20 – 13:40, NCR; poster session D, day 2, 16:25 to 16:55
Maxim Nazarov: day 3, *talk*, 14:10 – 14:30, MCT
Steve Novick: day 2, *talk*, 10:30 – 10:50, NCR; poster session B, day 2, 12:55 to 13:20
Martin Otava: day 3, *talk*, 15:30 – 15:50, NCR
Nolen Joy Perualila: day 3, *talk*, 10:05 – 10:25, NCR
Mark Pilling: day 3, *talk*, 15:10 – 15:30, MCT
Marcus Rauch: day 3, *invited speaker*, 08:40 – 09:10, MCT
Davit Sargsyan: poster session A, day 2, 10:50 to 11:20
Rudradev Sengupta: poster session B, day 2, 12:55 to 13:20
Ziv Shkedy: day 2, *talk*, 16:55 – 17:15, MCT
Juliane Siebourg-Polster: day 3, *talk*, 11:55 – 12:15, MCT
Fetene Tekle: poster session A, day 2, 10:50 to 11:20
Bianca Teodorescu: day 3, *talk*, 13:50 – 14:10, NCR
Olivier Thas: day 3, *talk*, 13:50 – 14:10, MCT
Michel Thiel : day 2, *talk*, 13:40 – 14:00, MCT
Herbert Thijs: poster session D, day 2, 16:25 to 16:55
Hannes-Friedrich Ulbrich: day 2, *talk*, 10:10 – 10:30, MCT
Ariëlla Van de Sompel: day 3, *talk*, 14:30 – 14:50, NCR
Koen van der Borght: day 3, *talk*, 12:15 – 12:35, NCR
Wim Van der Elst: day 3, *talk*, 10:25 – 10:45, NCR
Marijke Van Moerbeke: day 2, *talk*, 17:15 – 17:35, MCT
Robin Van Oirbeek: day 3, *talk*, 12:15 – 12:35, MCT; poster session C, day 2, 14:00 to 15:00
Bie Verbist: day 3, *talk*, 11:35 – 11:55, NCR
Jason Waddell: poster session A, day 2, 10:50 to 11:20
Ros Walley: day 2, *talk*, 15:45 – 16:05, MCT; poster session D, day 2, 16:25 to 16:55
David R Willé: poster session B, day 2, 12:55 to 13:20
Heidi Wouters: poster session A, day 2, 10:50 to 11:20