Non-Clinical Statistics Conference | 2008

Organized by *the Adolphe Quetelet Society* (Belgian Region, IBS) in collaboration with the *Non-Clinical Statistics working group* of the German Region (IBS) and the *Biostatistics Section* of the Belgian Statistical Society

Scientific Program

Pre-conference workshop

Tuesday, 23 September 2008			
13:45	14 :00	Welcome – Pre-Conference Workshop	Chair : G. Verbeke Katholieke Universiteit Leuven, Belgium
14:00	17 :30	An Introduction to Nonlinear Mixed-Effects Models	M. Davidian, North Carolina State University, Raleigh NC, USA
17:30		City tour of Leuven	
19:00		Drink at the Town Hall	

Wednesday, 24 September 2008			
08:15	08:30	Welcome – Main Conference	L Bijnens, Janssen Pharma, Beerse, Belgium
Session 1		Model Based Drug Development	Chair : F. De Ridder, Janssen Pharma, Beerse, Belgium
08:30	09:15	Some principles of modeling and simulation in preclinical research and development	Ph. Jacqmin, Exprimo NV, Mechelen, Belgium
09:15	10:15	Contributed papers	
09:15	09:35	Using desirability indices for decision making in drug development	Didier Renard, Novartis Pharma AG – Basel - Switzerland
09:35	09:55	Adaptive model-based dose selection methods	François Vandenhende, Clinbay, Genappe, Belgium
09:55	10:15	Clinical relevance of dissolution specifications	Tom Jacobs, Center for Statistics, Hasselt University, Diepenbeek, Belgium
10:15	10:45	Coffee Break & Poster Session	
Session 2		Methodology I	Chair : Bruno Boulanger, UCB Pharma SA, Braine-L'alleud, Belgium
10:45	12:05	Contributed papers	
10:45	11:05	Statistics in high-content biology	Rebecca Walls, AstraZeneca, Loughborough, UK
11:05	11:25	Combination of independent component analysis and statistical modelling for the identification of metabonomic biomarkers in H-NMR spectroscopy	Réjane Rousseau, Université Catholique de Louvain, Belgium
11:25	11:45	Expected and credible design space for analytical methods: a new perspective based on modeling and prediction	Pierre Lebrun, Université de Liège, Belgium
11:45	12:05	Symmetric and Asymmetric Sigmoid Curves: a close look at their statistical, numerical and mathematical properties	Charles Tan, Merck, West Point - USA
12:05	13:30	Lunch & Poster Session	

Session 3		Translational Medicine & Biomarkers	Chair : L. Bijnens, Janssen Pharma, Beerse, Belgium
13:30	14:15	Unified approaches for surrogate marker evaluation from multiple randomized trials	G. Molenberghs, Censtat, Hasselt University, Belgium
14:15	15:15	Contributed papers	
14:15	14:35	Fit for purpose limits and tolerance intervals: connecting the biomarker assay performance to the clinical trial	Astrid Jullion, UCB Pharma SA, Braine-L'alleud, Belgium
14:35	14:55	Investigating association between behavior, corticosterone, heart rate, and blood pressure in rats using surrogate marker evaluation methodology	Abel Tilahun, Center for Statistics, Hasselt University, Diepenbeek, Belgium
14:55	15:15	Genomic biomarkers for a binary response in early drug development microarray experiments	Suzy Van Sanden, Center for Statistics, Hasselt University, Diepenbeek, Belgium
15:15	15:45	Coffee Break & Poster Session	
Session 4		Methodology II	Chair : P. Lambert, Université de Liège, Belgium
15:45	16:30	Estimation of nonlinear mixed effects models in pharmacokinetics with the SAEM algorithm implemented in MONOLIX	France Mentré, Université Paris-7, France
16:30	17:50	Contributed papers	
16:30	16:50	A framework for estimation of area under the concentration versus time curves (AUC's) in complete and incomplete sampling designs	Thomas Jaki, Lancaster University, Lancaster, UK
16:50	17:10	Assessing repeatability and reproducibility of dose-response experiments	Marc Weimer, German Cancer Research Centre, Heidelberg, Germany
17:10	17:30	Mixed modeling using the SAS® PROC MIXED procedure: A simulation based approach to assess sample sizes and deal with a daily biostatistician dilemma for preclinical trials	Lisa Maiofiss, SFdS, Suresnes, France
17:30	17:50	Modeling Spatial Learning in rats based on morris water maze experiments	Christel Faes, Center for Statistics, Hasselt University, Diepenbeek, Belgium
20:00		Conference Dinner at Salon Georges	

Thursday, 25 September 2008			
Session 5		Chemical Manufacturing & Control	Chair : B.Govaerts Université Catholique de Louvain, Belgium
08:30	09:15	Application of the tolerance interval concept in quality assurance assessment of pharmaceutical products	Y. Tsong, Office of Biometrics, Center for Drug Evaluation, FDA, USA
09:15	10:15	Contributed papers	
09:15	09:35	Reconsidering shelf life: An update from the PQRI stability shelf life working group	James Schwenke, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, U.S.A.
09:35	09:55	Evaluation tolerance interval estimates: to capture or not to capture	Michelle Quinlan, University of Nebraska-Lincoln, Lincoln, U.S.A.
09:55	10:15	Development of statistical tools to test the equivalence between two measurement methods	Bernard Francq, Université Catholique de Louvain, Belgium
10:15	10:40	Coffee Break & Poster Session	
Session 6		Toxicology	Chair : L. A. Hothorn, Leibniz University Hannover
10:40	10:55	Semi- and non-parametric approaches to concentration-response modeling	C. Ritz, University of Copenhagen, Denmark
10:55	11:20	Evaluation of the in vitro mutagenicity assays	D. Gerhard, Leibniz University Hannover, Germany
11:20	11:45	Invitrostat: An open-source R-GUI for the statistical evaluation of in vitro assays in toxicology	F. Schaarschmidt, Leibniz University Hannover, Germany
11:45	12:30	Contributed papers	
11:45	12:00	The algae growth inhibition test – robust initial values for parameter estimation	Anke Schulz, Bayer Schering Pharma AG – Berlin, Germany
12:00	12:15	Assessing the similarity of bioanalytical methods	Jason Liao, Merck, USA
12:15	12:30	Dose-response evaluation using a combined parametric/non-parametric approach	John-Philip Lawo, Baxter BioScience, Vienna, Austria
12:30	14:00	Lunch & Poster Session	

Session 7		Omics	Chair : Z. Shkedy, Censtat, Hasselt University, Belgium
14:00	14:45	Tentacular analysis of high throughput omics data	D. Amaratunga, Johnson & Johnson Pharmaceutical Research & Development LLC, Raritan, NJ, USA
14:45	16:05	Contributed papers	
14:45	15:05	Estimation of power and analysis of qPCR data with normal mixed models	Auli Partanen, Orion Corporation ORION PHARMA, Turku - Finland
15:05	15:25	Order restricted clustering for dose-response microarray experiments	Adetayo Kasim, Center for Statistics, Hasselt University, Diepenbeek, Belgium
15:25	15:45	FARMS: a probabilistic latent variable model for summarizing Affymetrix array data at probe level	Djork-Arné Clevert, Institute of Bioinformatics, Johannes Kepler Universität Linz, Austria
15:45	16:05	A flexible probe level approach to improving the quality and relevance of affymetrix microarray Data	Chris Harbron, AstraZeneca, Macclesfield, UK
16:05	16:20	Closing and Concluding Remark	Bruno Boulanger, UCB Pharma SA, Braine-L'alleud, Belgium