

**DAY 1 - Thursday 14 September, 2017**

08:15 - 09:00 REGISTRATIONS .....Hall (Main floor)  
09:00 - 09:10 WELCOME by Pr Bruno FALISSARD, Ph. D. .Auditorium (Ground floor)

**Session 1: REGULATORY STATISTICS AND BEYOND**

*Chairperson:* Marisa BACCHI (Actelion, Switzerland)

Invited Speakers

09:15 - 10:00 **Bruno FALISSARD, Université Paris Sud (FR)**  
30min + Q&A 15min POST-APPROVAL APPRAISAL: WHAT ARE THE MAIN METHODOLOGICAL ISSUES?

10:00 - 10:45 **Stephen J. RUBERG, Eli Lilly and Company (US)**  
30min + Q&A 15min DISRUPTIVE APPROACHES FOR CLINICAL TRIALS PRE-AND POST-APPROVAL.

10:45 - 11:30 **COFFEE BREAK, EXHIBITORS & POSTERS SESSION**  
Contributed Speakers

11:30 - 11:50 **Marie-Ange PAGET, Eli Lilly and Company (FR)**  
15min + Q&A 5min WHAT'S JUST BEYOND REGULATORY FOR THE PHARMA STATISTICIAN? A EUROPEAN PERSPECTIVE

11:50 - 12:10 **Mohamed Amine BAYAR, Institut Gustave Roussy (FR)**  
15min + Q&A 5min INTERIM ANALYSIS AND TREATMENT SELECTION IN TIME-TO-EVENT RANDOMIZED TRIALS IN RARE DISEASES ON A LONG-TERM HORIZON

12:10 - 12:30 **Achim GÜTTNER, Novartis (SZ)**  
15min + Q&A 5min COMPARISON OF FRAMEWORKS FOR TIPPING POINT ANALYSES

12:30 - 14:00 **LUNCH BUFFET, EXHIBITORS & POSTERS SESSION**

**Session 2: STATISTICAL INFERENCE IN BIOSTATISTICS OF THE 21<sup>st</sup> CENTURY**

*Chairperson:* Martin POSCH (Medical University of Vienna, Austria)

Invited Speakers

14:00 - 14:45 **Hans C. VAN HOUWELINGEN, Leiden University Medical Center (NL)**  
30min + Q&A 15min THE FUTURE OF BIOSTATISTICS: ROBUST PREDICTION!

14:45 - 15:30 **Antoine CHAMBAZ, Université Paris Nanterre (FR)**  
30min + Q&A 15min THE FUTURE OF BIOSTATISTICS: TARGETED LEARNING IN ACTION

15:30 - 16:00 **COFFEE BREAK, EXHIBITORS & POSTERS SESSION**  
Contributed Speakers

16:00 - 16:20 **Gaëlle SAINT-HILARY, Politecnico di Torino (IT)**  
15min + Q&A 5min COMPARING DRUG DEVELOPMENT STRATEGIES WITH PROBABILITIES OF SUCCESS INCLUDING BENEFIT-RISK ASSESSMENT TO INFORM DECISION-MAKING

16:20 - 16:40 **Marco MUNDA & Anaïs DEBARD, Arlenda (BE) & Servier (FR)**  
15min + Q&A 5min BAYESIAN MODELLING AND PREDICTION OF ACCRUAL IN AN ONGOING CLINICAL TRIAL

16:40 - 17:00 **Stéphanie CLERC, Sanofi (FR)**  
15min + Q&A 5min SAFETY SIGNAL DETECTION: A BALANCE BETWEEN FALSE DISCOVERY RATE AND NON DISCOVERY RATE

**DAY 2 - Friday 15 September, 2017**

**Session 3: SUCCESSFUL MARRIAGE BETWEEN BIOINFORMATICS & BIOSTATISTICS**

Chairperson: Stefan MICHIELS (*INSERM, France*)

Invited Speakers

**09:00 – 09:45**  
30min + Q&A 15min

**Jean-Philippe VERT**, *Institut Curie, Mines ParisTech & ENS Paris (FR)*  
IDENTIFYING PREDICTIVE BIOMARKERS IN HIGH-DIMENSIONAL GENOMIC DATA FROM RANDOMIZED CLINICAL TRIALS.

**09:45 – 10:30**  
30min + Q&A 15min

**Jelle GOEMAN**, *Leiden University Medical Center (NL)*  
NEW DIRECTIONS IN MULTIPLE TESTING OF BIOMARKERS: FLEXIBLE APPROACHES WITH RIGOROUS CONTROL.

**10:30 – 11:00**

**COFFEE BREAK, EXHIBITORS & POSTERS SESSION**

Contributed Speakers

**11:00 – 11:20**  
15min + Q&A 5min

**Derek DINART**, *Inserm CIC1401 Institut Bergonié (FR)*  
GUIP1: A GRAPHICAL USER INTERFACE TO DESIGN PHASE 1 CANCER CLINICAL TRIALS

**11:20 – 11:40**  
15min + Q&A 5min

**Florent GUINOT**, *GENOPOLE Université D'Evry Val d'Essonne (FR)*  
ARE SINGLE NUCLEOTIDES THE RIGHT SCALE FOR GENOME-WIDE ASSOCIATION STUDIES ?

**11:40 – 12:00**  
15min + Q&A 5min

**Milada CVANCAROVA SMÅSTUEN**, *Oslo and Akershus University College of Applied Sciences (NO)*  
IMPAIRED KIDNEY FUNCTION IN CISPLATIN TREATED TESTICULAR CANCER SURVIVORS. A LARGE REGISTRY BASED STUDY.

**12:00 – 13:30**

**LUNCH BUFFET, EXHIBITORS & POSTERS SESSION**

**Session 4: RECURRENT EVENT ANALYSES**

Chairperson: Frank BRETZ (*Novartis, Switzerland*)

Invited Speakers

**13:30 – 14:15**  
30min + Q&A 15min

**Mouna AKACHA**, *Novartis (SZ)*  
ARE WE MAKING GOOD USE OF OUR DATA: MOVING BEYOND TIME-TO-EVENT DATA.

**14:15 – 15:00**  
30min + Q&A 15min

**Richard COOK**, *University of Waterloo (CA)*  
**Yujie ZHONG**, *MRC Biostatistics Unit, University of Cambridge (UK)*  
MARGINAL AND PARTIALLY CONDITIONAL ANALYSIS OF RECURRENT EVENTS IN CLINICAL TRIALS

**15:00 – 15:30**

**COFFEE BREAK, EXHIBITORS & POSTERS SESSION**

Contributed Speakers

**15:30 – 15:50**  
15min + Q&A 5min

**Virginie RONDEAU**, *INSERM U1219 (FR)*  
THE USE OF TUMOR DYNAMICS AND NEW LESIONS TO PREDICT SURVIVAL WITH MULTIVARIATE JOINT FRAILTY MODELS

**15:50 – 16:10**  
15min + Q&A 5min

**Tiba DELESPIERRE**, *Korian/Paris-Saclay (FR)*  
VACCINATIONS, A RECURRENT EVENT TO FOLLOW THE RESIDENTS' HEALTH STATUS IN NURSING HOMES

**16:10 – 16:30**  
15min + Q&A 5min

**Fredrik ÖHRN**, *AstraZeneca (SE)*  
GROUP SEQUENTIAL DESIGNS FOR RECURRENT EVENTS: OPTIMAL TESTS AND APPLICATIONS TO RESPIRATORY DATA