



The EUROPEAN STATISTICAL FORUM is pleased to announce its 5th Annual Conference:

**The current status of the application of Bayesian Methods in Drug Development**

**Monday, 17th November 2014**  
**Sheraton Brussels Hotel**  
3 Place Charles Rogier - Brussels, Belgium  
09:00 - 17:10 GMT+1

In the last years there is an increasing interest in the application of **Bayesian methodology** in drug development as it provides a framework for determining probabilities relevant to inferences from current trials and previous knowledge.

Bayesian statistics has the potential to play an important role throughout the drug/device development process lifecycle and in particular in the decision-making process. Its range of applications contains early phase studies, dose-finding, safety analyses, meta-analyses, decision theory as well as the quantification of the benefits and risks essential to health economic evaluation. In particular in exploratory phases the use of Bayesian methodologies has significantly increased in the recent years whilst in later phases Bayesian techniques get increasing attention with respect to interim decision making.

The fifth edition of the *European Statistical Forum* is dedicated to **Bayesian Statistics**, in particular by presenting:

- Current state-of-art implementation in clinical trials by companies like Roche, Novartis, GSK and UCB
- Recent enhancements in the methodology by scientific leaders in academia
- Regulatory perspectives on its application in clinical trials

The conference aims at promoting the exchange of expertise in the field coming from academia and industry as well as regulators.

The Scientific Board:

- **Jens-Otto Andreas**, Head EU Biostatistics, **UCB BIOSCIENCES GmbH**
- **Lisa Comarella**, Director, Biostatistics, Senior Project Manager, **Cros NT Group**
- **Frank Fleischer**, Global BCA, **Boehringer Ingelheim Pharma GmbH & Co. KG**
- **Giacomo Mordenti**, Senior Director Compound Development & Branding-Head Biostatistics, **Grünenthal**

will share best practices, results and experiences in this field.

**Who should attend?**

The conference is addressed to professionals working in biostatistics, pharmacometrics / M&S, regulatory affairs and medicine as well as others interested in the application of Bayesian methodology in clinical trials belonging to: Pharmaceutical, Biotechnology and related Industries, CROs, Academy, Hospital Centres, University.

**Pre-Conference Dinner at Aux Armes de Bruxelles, Brussels**

**Sunday, 16th November, 7:30 pm**

**For further information, please visit: [www.esforum.eu](http://www.esforum.eu)**

**Sponsor**



**Patronage**



## PROGRAMME

- 08:30 - 09:00 **Registration**
- 09:00 - 09:10 **Welcome from the Chair**
- 09:10 - 09:50 **From hypothesis testing to prediction-based decision making: Quality by Design thinking applied to clinical development**  
**Bruno Boulanger - CSO, Company co-founder - Arlenda**
- 09:50 - 10:30 **Comparative Bayesian escalation designs**  
**Emmanuel Lesaffre - Professor in Biostatistics, Chair Department of Biostatistics, Erasmus MC, The Netherlands and L-Biostat, School of Public Health, KULeuven University of Leuven, Belgium**
- 10:30 - 11:10 **Dose-escalation using safety and biomarker data: A Bayesian adaptive approach**  
**Giuseppe Palermo - Statistician, F. Hoffman-La Roche**
- 11:10 - 11:35 **Coffee Break**
- 11:35 - 12:15 **Implementing Bayesian Methods in Early Clinical Development at UCB**  
**Foteini Strimenopoulou - Senior Exploratory Statistician, UCB**
- 12:15 - 12:55 **Using Simulated Biomarkers to Speed Phase 1– 2 Development – a Case Study**  
**Pantelis Vlachos - Principal Biostatistician, Cytel Inc**
- 12:55 - 13:55 **Networking Lunch and Exhibitor Area**
- 13:55 - 14:35 **Bayesian group sequential designs in clinical practice**  
**Heinz Schmidli - Statistical Methodology, Novartis Pharma AG**
- 14:35 - 15:15 **Model-Based Meta Analysis (MBMA) of integrated prior- and emerging clinical trial data to support informed decision making in drug development**  
**Eugène Cox - Vice President & Managing Director, Quantitative Solutions BV**
- 15:15 - 15:40 **Coffee Break**
- 15:40 - 16:20 **Prior elicitation in practice: GSK's experiences with eliciting expert opinion to enhance decision making in drug development**  
**Nicky Best - Senior Director Statistical Innovation Group, GSK**
- 16:20 - 17:00 **Augmenting pediatric trials with adult data: how complicated should it be?**  
**Dominic Magirr - Postdoc, Medical University of Vienna, Center for Medical Statistics, Informatics and Intelligent Systems**
- 17:00 - 17:10 **Discussion/Conclusion**

# HOW TO REGISTER



In order to attend the European Statistical Forum 2014 the registration form should be completed and faxed to **(+39) 035.4501262** or emailed to: [info@esforum.eu](mailto:info@esforum.eu)

Or register and pay online <http://events.lsacademy.it/conferences>

Please use one for each participant.

Please state if you require information about accommodation in the conference hotel.

## REGISTRATION FEE (for the conference)

€ 580,00\* Early Bird registration by 3rd November 2014

€ 670,00\* Ordinary Fee after 3rd November 2014

€ 530,00\* for Patronage Members

€ 350,00\* for Academy, Public Administration, Freelance

\* Only for Italian companies: +22% VAT

**The fee includes:** *seat at the conference, copy of presentations will be made available by the Speakers, informative literature for the day, networking lunch, coffee breaks, organisational assistance from registration to event day, certificate of attendance.*

## REGISTRATION FEE (for the conference + the dinner on Sunday, 16th November 2014)

\*The dinner costs € 35,00 beverage included. Please note that the dinner's cost will not be reimbursed for any cancellation.

€ 615,00\*\* Early Bird registration by 3rd November 2014

€ 705,00\*\* Ordinary Fee after 3rd November 2014

€ 565,00\*\* for Patronage Members

€ 385,00\*\* for Academy, Public Administration, Freelance

\*\* Only for Italian companies: +22% VAT

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## PAYMENT

Payment should be made online, or by bank transfer (please see details below), or by mailing a cheque, along with the registration form. Upon receipt of payment, the registration will be confirmed. Invoice will be sent following receipt of payment. We couldn't accept late registrations or due to limited conference place available or registrations of roles that are not included in the target of the event.

**Online:** <http://events.lsacademy.it/conferences>

### Bank transfer:

(Please send proof of bank transfer via fax or email)

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BERGAMO) - Italy

VAT: IT03633040161

Banca Popolare di Vicenza - Filiale di Nese

**SWIFT Code:** BPVIIT21820

**IBAN:** IT27H0572852521820570697999

### CANCELLATION

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. Please note that the dinner's cost will not be reimbursed for any cancellation. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

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(+39)035.4501262 OR VIA EMAIL: [info@esforum.eu](mailto:info@esforum.eu)  
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Cheque No. .... Bank Transfer  Online   
Name..... Surname.....  
Company Name..... Job title .....  
Address .....  
City ..... Post Code .....  
Tel. .... Fax. ....  
E-mail .....  
Special dietary requests .....

### INVOICING DETAILS:

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**Terms of payment:** The registration fee must be paid at the time of registration. Confirmation of event admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants or registrations of roles that are not included in the target of the event. **Cancellation:** Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. Please note that the dinner's cost will not be reimbursed for any cancellation. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities. **Information collection and use:** Participants information is collected and utilised by EasyB S.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.

Date .....

Signature.....