



The EUROPEAN STATISTICAL FORUM is pleased to announce its 6th Annual Conference:

## Applications of statistical methodology in early drug development

Monday, 16th November 2015

Vienna Marriott Hotel

Parkring 12a - Vienna, Austria

08:50 - 17:25 CET

The field of early drug development provides various challenges with respect to the application of statistical methodology. Main focus is to know the compound characteristics in terms of **doses and regimen, efficacy and safety, subpopulations and predictive biomarkers, pharmacokinetics and pharmacodynamics**. Drug development teams may need to identify Maximum Tolerated Doses, design trials for Dose Finding, Proof of Principle and Proof Of Concept, ensure efficient definition of Go/No Go criteria up to PK/PD modeling.

Recently there have been many new developments and applications in this field, for example extensions to the continual reassessment method (CRM) like time-to-event continual reassessment method (TITE-CRM) or inclusion of biomarkers, Bayesian group sequential designs and methods for efficient dose finding like Multiple Comparisons & Modeling (MCP-Mod). The use of such techniques has recently been embraced by EMA in the face of dose response testing and estimation models uncertainties. Statistics has thereby helped to **improve the process of efficient drug development** and is continuing to do so.

The sixth edition of the *European Statistical Forum* is therefore dedicated to the application of statistical methodology in early drug development, in particular by presenting:

- Current state-of-the art dose finding **trial designs** like MCPMod
- Statistical techniques on the **integration of biomarker** as well as pharmacogenetic data into the early drug development process
- Implementation of efficient **Proof of Principle** and **Proof of Concept trials**
- Transfer of the **preclinical knowledge** into first in human trials
- **New developments** in and designs for PK and PK/PD trials
- Recent **enhancements in statistical methodology** by leaders in academia

Both case studies and methodological background will be covered. The conference aims at promoting the exchange of expertise, bringing together statisticians, pharmacometricians, physicians, regulators, academia and other experts interested in the field of early drug development.

The Scientific Board:

**Jens-Otto Andreas** - Head EU Biostatistics, UCB Biosciences GmbH

**Lisa Comarella** - Director Biostatistics, CROS NT Group

**Frank Fleischer** - Global BCA, Boehringer Ingelheim Pharma GmbH & Co. KG

**Giacomo Mordenti** - Head of Biostatistics, Grünenthal

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

### Who should attend?

The conference is addressed to statisticians, pharmacometricians, physicians, regulators, academia and other experts interested in the field of early drug development, belonging to: Pharmaceutical, and Biotechnology companies; CROs; Universities/Hospitals; Academic Research.

### Pre-Conference Dinner - Vienna

Sunday, 15th November, 7:30 PM (the meeting is set for 7:15 PM at the restaurant)

*Restaurant Der Kuckuck* (Himmelfortgasse 15, 1010 Vienna)

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

### Event sponsored by



### Patronage



## AGENDA

- 08:20 - 08:50 **Registration and welcome coffee**
- 08:50 - 09:00 **Welcome from the Scientific Board**  
Frank Fleischer - Global BCA, Boehringer Ingelheim Pharma GmbH & Co. KG  
Giacomo Mordenti - Head of Biostatistics, Grünenthal  
Jens-Otto Andreas - Head EU Biostatistics, UCB Biosciences GmbH  
Lisa Comarella - Director Biostatistics, CROS NT
- 09:00 - 09:40 **Statistics in Early Clinical Development – The Way Ahead of Us**  
Richardus Vonk - Senior Director, Head of Research and Clinical Sciences Statistics, Bayer Pharma AG  
Harry Mager - Senior Director / Expert Statistician Pharmacometrics – Early Drug Development, Bayer Pharma AG
- 09:40 - 10:20 **A Statistical Framework for Decision Making in Early Clinical Development**  
James Matcham - Head, Early Clinical Development Biometrics, AstraZeneca
- 10:20 - 11:00 **Maximize your ability to make predictions using Bayesian optimal designs**  
Bruno Boulanger - CSO, Arlanda
- 11:00 - 11:25 **Coffee break**
- 11:25 - 12:25 **MCP-Mod in longitudinal phase II trials – practical experiences in the pharmaceutical industry**  
Lieven Kennes - Department of Biometrics, Grünenthal GmbH
- 12:25 - 13:05 **MCPMod for the Adaptive Design and Analysis of Dose-Finding studies under Model-uncertainty**  
Tobias Mielke - Statistical Consultant, ICON PLC
- 13:05 - 14:00 **Networking Lunch**
- 14:00 - 14:40 **Bioequivalence testing in Pharmacokinetics/Pharmacodynamics-How to avoid unsuccessful studies by using Two stage designs**  
Thomas Zwingers - Head of Statistical Consultancy, CROS NT
- 14:40 - 15:20 **SPCD/Trimentum: improved signal detection when placebo response is high**  
Jürgen Hummel - Statistical Science Director, Biostatistics, PPD
- 15:20 - 15:45 **Coffee break**
- 15:45 - 16:25 **Incorporating a search for predictive biomarkers into clinical trials**  
Foteini Strimenopoulou - Principal Exploratory Statistician, UCB  
Ros Walley - Director Exploratory Statistics, UCB
- 16:25 - 17:05 **Learning from years of failure in a difficult indication**  
Laurence Colin - Associate Director Statistical Scientist, Novartis
- 17:05 - 17:20 **Q&A**
- 17:20 - 17:25 **Conclusion**

# HOW TO REGISTER



In order to attend the *European Statistical Forum 2015*, you can send the filled registration form, for each attendee, via mail: [info@esforum.eu](mailto:info@esforum.eu) or via fax **+39.035.4501262** and pay by bank transfer

OR

you can directly register online and pay by credit card, clicking on <http://events.lsacademy.it/conferences>

## REGISTRATION FEE (for the conference)

€ 580,00 Early Bird fee by 28th October 2015  
€ 670,00 ordinary fee after 28th October 2015  
€ 530,00 Patronage members fee  
€ 350,00 for Academy, Public Administration, Freelance

**The fee includes:** *seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.*

## REGISTRATION FEE (for the conference + the dinner on Sunday, 15th November 2015)

### **Free pre-Conference Dinner for registrations received before June 26th**

*For registrations received after June 26th, 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 fee by 28th October 2015  
€ 705,00 ordinary fee after 28th October 2015  
€ 565,00 Patronage members fee  
€ 385,00 for Academy, Public Administration, Freelance

**The fee includes:** *seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, networking lunch, coffee breaks, organisational office assistance, certificate of attendance, dinner on Sunday, 15th November 2015.*

## METHODS OF PAYMENT

If you pay by bank transfer, please attach proof of payment to the registration form. Bank transfer payable to:

EasyB S.r.l.  
Via Roma, 20 - 24022 Alzano Lombardo (BERGAMO)  
VAT number: IT03633040161  
Banco Popolare Società Cooperativa- Filiale di Carobbio degli Angeli  
IBAN: IT81 F 05034 53960 000000003450  
SWIFT Code: BAPPIT21AY5

If you pay online (by credit card), you need to register clicking on:  
<http://events.lsacademy.it/conferences>

*Invoice will be sent as proof of received payment*

### How to reach Vienna Marriott Hotel

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

or

<http://www.marriott.com/hotels/travel/vie-at-vienna-marriott-hotel/>

**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.



IN ORDER TO ATTEND THE EVENT, PLEASE COMPLETE THE REGISTRATION FORM FOR EACH ATTENDEE AND SEND IT VIA FAX: (+39) 035.4501262 OR VIA EMAIL: [info@esforum.eu](mailto:info@esforum.eu)

- € 580,00\* **Early Bird fee by 16th October 2015**
- € 670,00\* Ordinary Fee (after 16th October 2015)
- € 530,00\* Patronage Members fee (name: .....)
- € 350,00\* for Academy, Public Administration, Freelance (please specify.....)

\*For Italian companies: +22% VAT

**The fee includes:** seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.

**Method of payment**

The full amount must be paid on registration to EasyB s.r.l by bank transfer. If paying by bank transfer please attach proof of payment to the registration form. Bank transfer payable to:

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SWIFT Code: BAPPIT21AY5

Free Pre-Conference Dinner (Sunday, 15th November) for registrations received before June, 26th  
I would like to attend the Pre-Conference Dinner  yes  no

**For any additional information, please contact:**

Stefania Sarga      [info@esforum.eu](mailto:info@esforum.eu)      Tel.: +39.035.515684      Fax: +39.035.4501262

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