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The EUROPEAN STATISTICAL FORUM is pleased to announce its 4th Annual Conference:

MISSING DATA IN CLINICAL TRIALS

Monday, 18th November 2013 NH Amsterdam Centre

Stadhouderskade 7, Amsterdam, The Netherlands 09:00 - 17:30 GMT+1

The handling of missing data in clinical trials has become a crucial topic for clinical drug development in particular with respect to the regulatory process, as they are one of the most important sources of bias when analyzing clinical trials.

New methodologies and techniques have emerged like mixed-model repeated measures, multiple imputations, pattern-mixture models for longitudinal data as well as specific censoring rules and models for time to event data. As a consequence, regulatory agencies have published several documents related to the handling of missing data (e.g., Guideline on Missing Data in Confirmatory Clinical Trials EMA 02 July 2010).

Therefore, in order to achieve a successful drug registration, biostatisticians and clinical teams have to cope with the - often informative and dependant - nature of the missing data (not) observed in the trial.

The fourth conference of the European Statistical Forum is dedicated to the **investigation**, **exploration** as well as **handling** and **analysis** of missing data in clinical trials by presenting:

- State-of-the art statistical methodology.
- Real-life case studies of clinical trials showing how missing data can be handled and how they can impact trial results.
- Regulatory viewpoints on this topic.

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

Insights will be provided on the newest trends and on how to apply techniques for pivotal clinical trials as well as regulatory aspects related to this topic.

> Sunday, 17th November, 7:00 pm Pre-Conference Dinner - Dinner Cruise

> > for more information visit: WWW.ESFORUM.EU

PROGRAMME EUROPEAN STATISTICAL FORUM



November 18th 2013 - NH Amsterdam Centre, Amsterdam, The Netherlands

SCIENTIFIC BOARD:

Jens-Otto Andreas

Director, Head Global Biostatistics EU Group, 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

08:30 - 09:10	Registration and Welcome
09:10 - 09:55	Handling Missing Data in Clinical Trials Mike Kenward, Professor of Biostatistics, Department of Medical Statistics, London School of Hygiene and Tropical Medicine
09:55 - 10:40	Analysis and Sensitivity Analysis for Incomplete Data from Clinical Studies Geert Molenberghs, Professor of Biostatistics, Center for Statistics, Limburgs Universitair Centru, Belgium
10:40 - 11:25	Impact of 2010 CHMP guideline on missing data in confirmatory trials David Wright, Expert Statistical Assessor and Deputy Manager of Statistics and Pharmacokinetics Unit, MHRA
11:25 - 11:50	Coffee Break
11:50 - 12:25	Implementing Current Regulatory Guidance: An Industry Perspective Mouna Akacha, Statistical Methodologist, Novartis Pharma AG
12:25 - 13:00	When could one use reference based imputation for missing data, and what kind should one use? Michael O'Kelly, Senior Strategic Biostatistics Director, Centre for Statistics in Drug Development, Innovation, Quintiles
13:00 - 14:00	Lunch
14:00 - 14:35	The Statistician's Role In The Prevention of Missing Data Robert Cuffe, Head of Statistics, Viivhealthcare
14:35 - 15:10	Accounting for missing values in sample size calculations Paolo Fina, Senior Statistician, CROS NT
15:10 - 15:45	Bayesian pattern mixture models for missing data in longitudinal studies Juan Abellan- Andres, Trial Biostatistician, Grünenthal
15:45 - 16:10	Coffee Break
16:10 - 16:45	The Performance of Mixed Model with Repeated Measures (MMRM) and Last Observation Carried Forward (LOCF) in an Observational Study – Results from Interim Data Thomas Kumke, Senior Biotatistcian, UCB BIOSCIENCES GmbH
16:45 - 17:20	A sensitivity analysis of missing data methods for planning a study: a statistician perspective Judith Anzures-Cabrera, Statistical Scientist, Roche Products Ltd UK
17:20 - 17:30	Discussion/Conclusion

HOW TO REGISTER

In order to attend the European Statistical Forum 2013 the registration form should be completed and faxed to (+39) 0354501262 or emailed to: info@esforum.eu

Please use one for each partecipant. Please state if you require information about accommodation in the conference hotel.

REGISTRATION FEE

€580,00* Early Bird registration before 4th November 2013
€670,00* Ordinary Fee after 4th November 2013
€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.

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.

Online:

WWW.ESFORUM.EU

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

EasyB S..r.I. Via Roma, 25 - 24022 Alzano Lombardo (BERGAMO) 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 before November 11th, 2013. 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. 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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Cheque No	Bank Transfer	Online					
I will participate to the Dinner Cruise (\in 75 - to b	e paid the day of the	e dinner)		Yes		No	
Name	Surname						
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City	Post Code						
Tel	Fax						
E-mail							
Special dietary requests							

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Date

Signature.....