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GERMAN ePHARMA DAY 2010



Adaptive Trial Designs: The latest approaches to empower clinical development process and success rates



ARITHMOS
INFORMATION TECHNOLOGY

Thursday, 22th April 2010

Max Planck Institute of Biochemistry - MPI

Am Klopferspitz 18
D-82152 Martinsried
München

10:00 - 17:30



Adaptive Trials are an innovative approach to clinical trials that plays on the latest in clinical technologies and science to make pre-determinate adaptations to a clinical trial without compromising the statistical validity of the trial. Adaptation is a design feature, not a remedy for poor planning.

This event will cover the latest techniques and software for accurate planning and successful execution of adaptive trials. After a review of the current international regulatory attitudes, a description of the methods and software specifically used for planning and successfully running adaptive trials will be presented.

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WHO SHOULD ATTEND

Pharmaceutical Companies: Medical Director, Medical Affairs Director, Medical Informatics, R&D Manager, Pharmacovigilance Operation Manager, Clinical Manager, Clinical Research Associate, Clinical Project Manager/Clinical Project Leader, Statisticians and Data Managers.

Biotech: Managing Director, Chief Medical Officer.

Hospital Research Centre/University/Private: Managing Director, Principal Investigator.

CRO: Managing Director, Business Development, Medical Director, Project Manager, Clinical Research Associate.

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GERMAN ePHARMA DAY 22nd APRIL 2010

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Adaptive Trial Designs: The latest approaches to empower clinical development process and success rates

Programme

- 10:00 - 10:30 **Registration & Coffee**
- 10:30 - 11:00 **Welcome and Adaptive Trial Designs Overview & Discussion**
Dr. Paolo Morelli - General Manager and Scientific Director - CROSnt
- 11:00 - 11:30 **The Future of Clinical Development in Pharma and Biotech**
Dr. Samson Fung - M.D. - Fung Consulting HealthCare and Life Sciences
- 11:30 - 12:00 **Adaptive Trial Design: Challenges for the Project Manager**
Alexander Gissler - Director - ProjectPharm Ltd.
- 12:00 - 12:30 **Adaptive Trial Designs in Clinical Drug Development**
Dr. Heinz Schmidli - Statistical Methodology - Novartis Pharma AG
- 12:30 - 13:00 **Adaptive Bayesian Randomization as a tool for Proof of Concept studies**
Giacomo Mordenti - Senior Expert Biostatistician, Group Leader Global Biostatistics - Merck Serono S.A. Genève
- 13:00 - 14:00 **Networking Lunch and Demo Area**
- 14:00 - 14:30 **Optimal Dose de-escalation Trial Designs for novel contraceptives in women**
Dr. Christoph Gerlinger - Senior Director, Therapeutic Area Expert Statistician Women's Health - Bayer Schering Pharma AG
- 14:30 - 15:00 **Pitfalls of Adaptive Designs - A practical view**
Thomas Zwingers - Managing Director - Estimate GmbH
- 15:00 - 15:30 **Operating a genuine flexible trial design in Oracle solutions for Life Sciences. Methodology and steps**
Hervé Fouché - Sales Consultant - Oracle HealthSciences Business Unit
- 15:30 - 16:00 **Coffee Break**
- 16:00 - 16:30 **New Features in Oracle Remote Data Capture (RDC) 4.6 to Execute Adaptive Trial Designs**
Dr. Hauke Kindler - Partner - Reliable Lifesciences Consulting (RELICO)
- 16:30 - 17:00 **How to track your e-CRF to provide the data needed at pre-defined timepoints**
Franziska Falk - Associate Clinical Research Director - Astellas Pharma Global Development Europe
- 17:00 - 17:30 **Panel of discussion and Closure**

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HOW TO PARTICIPATE

In order to attend the Meeting the registration form should be completed and faxed to **(+39) 035 4501262** or emailed to: german@epharmaday.org
Please use one form for each participant.

REGISTRATION FEE

€ 320,00 before 31th March 2010
€ 360,00 on or after 1st April 2010
€ 280,00 for ACRP Members

***The fee includes:** seat at the conference, copy of speakers' presentations, 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:

EasyB S.r.l.
Via Adobati, 1 - 24022 Alzano Lombardo (BERGAMO) P.IVA 03633040161
Banca Popolare di Vicenza - Filiale di Nese

IBAN: IT27H0572852521820570697999

(Invoice will be sent following receipt of payment).

Upon receipt of payment, the registration will be confirmed. Please send proof of bank transfer via fax or email.

HOW TO REACH MAX PLANCK INSTITUTE OF BIOCHEMISTRY - MPI

For detailed information on how to reach the location, please visit our website: www.epharmaday.org or visit the official site of MPI: www.biochem.mpg.de

CANCELLATION

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received before March 22nd, 2010. 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.

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REGISTRATION FORM

PLEASE FILL IN AND SEND VIA FAX: (+39) 035 4501262
OR EMAIL german@epharmaday.org

For any additional information, please contact at any time the Event Manager:
Enrico Pedroni - enrico.pedroni@epharmaday.org
Mobile: (+39) 33 88 42 25 61

Early Bird Registration fee is applicable until 31st March, 2010

ACRP Member

Cheque No

Bank transfer

Online

Name

Surname

Company name

Job Title

Address

City

CAP

Tel.

Fax

E-mail

special dietary requests:

INVOICING DETAILS:

Company name

Address

Mail Address (if different)

City

Post code

VAT Number

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.

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