

INTRODUCTION TO PEDIATRIC CLINICAL TRIALS

Clinical, Methodological and Regulatory Aspects to perform clinical research in pediatrics



July 8th 2011

HOTEL MELIÀ – MILAN

Room “La Palma”

Via Masaccio 19-20149 Milan

9:30 am - 5:30 pm

EARLY BIRD
discount rate €85
deadline is
June 28th 2011

For more information, please contact:

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Who should attend?

The course is addressed to staff of pharmaceutical companies, Biotech companies and CROs interested in increasing their knowledge in the context of clinical research in pediatrics, in particular: Clinical Operations, R & D, Quality Assurance Department, Pharmacovigilance Department, Data Management & Statistical Department
In addition to investigational Sites: testing centers: Investigators, Project Manager, Pharmacist

Why to participate?

Drug testing on humans always requires a great sense of responsibility, care and respect for the principles of precaution. Clinical trials in children, in particular, is burdened with ethical concerns that merit the additional safeguards to protect the child and his physical or mental integrity. The child must have drugs that are effective and safe, coming from "ad hoc" clinical trials to verify the numerous differences (including the use of drugs) between the infant and the adult.

This course aims to be a useful tool to provide guidance for conducting clinical trials in children by encouraging appropriate training of all the personnel involved in trials.

Lecturer

Nicola Principi - University of Milan

Nicola Principi was born in Rome, Italy. In 1979, having won a National Competition to qualify for a Chair of Pediatrics, he was appointed Professor of Pediatrics of the University of Milan, a position he still holds today. Since 1 November 2000, he has been responsible for the Pediatric Department of the University of Milan included in the biggest teaching hospital of Milan, the one at the moment named Fondazione IRCCS Ospedale Maggiore Policlinico, Mangiagalli and Regina Elena. His research activities have been mainly dedicated to the study of developmental pharmacology, nutrition, nephrology and pediatric infectious diseases, particularly respiratory tract infections, vaccines, and HIV infection. He has been a member of several Committees of the Italian Ministry of Health, including the National AIDS Commission (1989-1996). In 1998, he founded the Italian Society of Paediatric Infectious Diseases, of which he was the first President (1998-2002) and the Vice-President in the period 2005-2008. He has been the Director of the Italian Journal of Paediatrics (1991-1996), and in 1997 he founded the Italian Journal of Pediatric Infectious Diseases (Giornale Italiano di Infettivologia Pediatrica), for which he is currently the Director. He is the author and/or co-author of more than 1,500 publications in national and international journals, Congress Proceedings and books and his publications have an impact factor higher than 1,500.

Beate Beime - Head of Clinical & Medical Affairs, Diapharm

Beate Beime is Managing Director of Diapharm Clinical Management GmbH, Oldenburg which was founded in 2005 (as "Beate Beime & Team"). She started her career in regulatory affairs in 1997 in the Diapharm group. Her company coordinates, on behalf of the pharmaceutical industry, preclinical tests and clinical trials including project management. Beate Beime herself puts her focus on regulatory support for drug development. Another activity of the company is conducting readability user-testing of patient information leaflets. In addition to taking action in their own companies she is involved in the Federation of Pharmaceutical Manufacturers (BAH), the German Society of Pharmaceutical Medicine (DGPharMed) and the German Society for Regulatory Affairs Association (DGRA). Beate Beime has a degree in biology.

Carlo Alessandro Rizzi - Medical Director, Medineos

Born in Genoa in 1957, he achieved a degree in Medicine and a Specialization degree in Clinical Pharmacology at the University of Pavia. The majority of his career (1988-2010) was built in International Pharmaceutical Companies, both in Pre-clinical Research and development (lab coordination of pharmacological models for serotonergic drugs), and in Clinical Research (Medical Advisor for National and International studies, International Team Leader, Head of Clinical Research Unit in Italy). In his activities in Clinical Research, Carlo A. Rizzi has developed knowledge on Paediatric studies and their critical aspects. Since May 2011, he is Medical Director of Medineos (part of the MediData Group), a CRO fully devoted to clinical studies in Paediatrics. The initial activity of Medineos has consisted of conduction of Randomised Clinical Trials in Neonatology, and networking with Groups of Paediatricians aimed at developing an increase of high quality research in Paediatrics.

Maria Grazia Valsecchi - University "La Bicocca", Milan

Maria Grazia is a Professor in Medical Statistics at the Department of Clinical Medicine and Prevention, University of Milano-Bicocca (since November 1st 2001). She is involved in various national and international research projects, mainly in pediatric oncology and hematology, and she is currently coordinating a statistical unit at the University of Milano-Bicocca aimed at planning, conducting and analyzing clinical studies, with specific interest in the methodology for: controlled clinical trials, survival analysis and clinical epidemiology. She is responsible for the Center for Biostatistics and Clinical Epidemiology of the University of Milano-Bicocca, Medical School

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Programme

Composed by:

Prof. Nicola Principi, University Of Milan
 Beate Beime, Head of Clinical & Medical Affairs, Diapharm
 Dr. Carlo Alessandro Rizzi, Medineos
 Prof. Maria Grazia Valsecchi, University "La Bicocca", Milan



Anatomic, medical and therapeutic aspects

- Differences between children and adults
- Different stages of childhood
- Pharmacokinetics and dynamics in children
- Pharmacosensitivity and dose adjustments

Research and development in paediatrics:

- Regulatory framework
- Market authorization for paediatrics
- Paediatric Investigational Plans (PIP)

Clinical trials in children:

- Ethical considerations
- Authority notifications
- Clinical trial protocols
- Patient information and informed consent
- Patient-related outcomes in children
- Target parameters of special attention

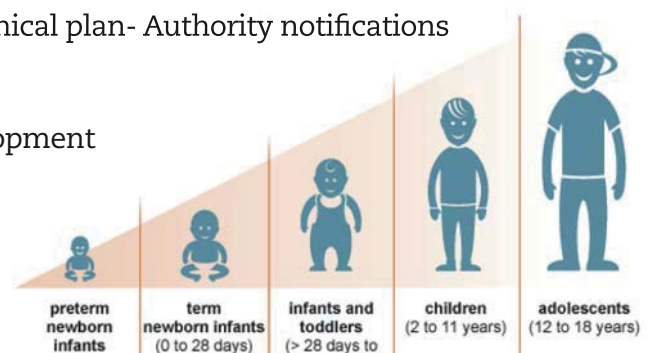
Methodological aspect in pediatric clinical trials:

- Clinical Trials Design (superiority and non inferiority, endpoint definition; sample size)
- Specific aspect in rare disease
- Principles of statistical analysis: statistical test and confidence interval, interim analysis, subgroup analysis

Issues in clinical trials in children:

- Ethical considerations in developing the Pediatric clinical plan- Authority notifications
- Informed consent and assent
- Authority notifications and obligations
- Success Factors and Barriers to Pediatric Drug Development
- Clinical pharmacology considerations
- Optimizing pediatric clinical trial protocols

AGENDA	
9.00 am	Welcome and participants registration
9.30 am	Course begins
11.15 am - 11.30 am	Coffee Break
1.15 pm - 2.00 pm	Lunch
3.45 pm - 4.00 pm	Coffee Break
5.45 pm	End of course



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Euro 735 before 28th June 2011 (early bird)

Euro 820 on or after 29th June 2011

Euro 575 for Academy and Public Administration personnel*

The fee includes: seat at the course, educational material, copy of lecturers' presentations, networking lunch, coffee breaks, organisational assistance leading up to the event, certificate of attendance.

*The early bird discount of € 85 does not apply to the Academy and P.A. fee.

Packaged rates for multiple enrolment

2 pax: Euro 1312 (Euro 1176 before 28th June 2011)

3 pax (2 + 1 free) : Euro 1640 (Euro 1470 before 28th June 2011)

How to reach Meliã Hotel

Via Masaccio 19 Milan ITALY 20149

Tel: (39) 02 44406 - Fax: (39) 02 44406600

melia.milano@solmelia.com

The Meliã Milano hotel has a convenient position at a walking distance from Fiera Milano City, just 8 minutes from the new Exhibition Centre in Rho-Pero and 10 minutes from the city centre. Located 5 minutes from the access to the main highways, 45 km from Malpensa Airport and 25 km from Linate Airport. The underground is 200 mt away from the hotel entrance (red line, "Lotto" stop).

In order to attend the course the registration form should be completed and faxed to (+39) 035 4501262 or emailed to: segreteria@lsacademy.it

Please use one form for each participant.

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

Payment

Payment should be made online (<http://www.easy-b.it/events.html>), or by bank transfer (please see details below), 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 course place available.

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

EasyB S.r.l.

Via Roma, 25 - 24022

Alzano Lombardo (BG)

P. IVA 03633040161

Banca Popolare di Vicenza -

Filiale di Nese

IBAN:

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REGISTRATION FORM - PLEASE FILL IN AND SEND VIA FAX: (+39) 035.4501262

OR E-MAIL: segreteria@lsacademy.it

On line (<http://www.easy-b.it/events.html>)

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Special dietary requests

INVOICING DETAILS

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Address

Mail address (if different) Post Code

City VAT number

I would like to receive information on accomodation:

Cancellation

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received before June 28th, 2011. 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.

THE COURSE WILL PROCEED WITH A MINIMUM OF 8 PARTICIPANTS.

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

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

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