# Joint DIA/EFGCP/EMA Paediatric Forum

## The paediatric regulation in its 5th year: Transition from toddler to school age

Event #11115
26-27 September 2011
De Vere Venues Canary Wharf, London, UK

## Programme Committee

**Gesine Bejeuhr**
Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany

**Agnes Gyurasics**
Head, Division of European Affairs, National Institute of Pharmacy, Hungary

**Klaus Rose**
klausrose Consulting, Pediatric Drug Development & More, Switzerland

**Paolo Tomasi**
Head of Paediatric Medicines, European Medicines Agency, EU

## Overview

This year's DIA/EFGCP/EMA paediatric annual conference will take place in the 5th year of the EU paediatric regulation. Over 1000 Paediatric Investigation Plans (PIPs) have been submitted so far, and the impact on pharmaceutical industry has been much higher than originally expected. Consideration of paediatric aspects is becoming an integrated part of drug development. As with most introductions of new regulatory requirements, challenges and difficulties have been experienced by stakeholders. Inclusion of children into the drug development process is now accepted as standard. The discussion is more on the ‚how', ‚how much', and ‚how far'-level. The requirements may be stringent, and the workload for applying companies is not negligible. This year's conference has the European Medicines Agency (EMA) as official co-organiser of the conference, after DIA and European Forum for Good Clinical Practice (EFGCP) have decided to merge their annual conferences in 2009. This is THE conference to meet EMA paediatric coordinators and Paediatric Committee (PDCO) members face-to-face, offering an ideal opportunity to approach them with direct questions for which you can expect direct answers.

## Who Will Attend

- Regulatory, clinical and drug development professionals from health authorities and industry
- Paediatricians, representatives from academia, paediatric societies and networks
- Employees from Clinical Research Organisations (CROs) involved in paediatric clinical trials
- Any stakeholder interested in the development of better medicines for children

## Objectives

- Deal with paediatric regulatory requirements, scientific and operational challenges
- Exchange experiences with regulatory authorities, academia and industry
- Discuss visions, daily challenges and potential ways to move forward and further improve processes for paediatric drug development

## Continuing Education

DIA meetings are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available on request from the registration desk.

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## MONDAY | 26 SEPTEMBER 2011

11:00 REGISTRATION AND WELCOME COFFEE

12:00 Session 1

**WELCOME NOTE**

Session Chair:
**Gesine Bejeuhr**, Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany
**Klaus Rose**, klausrose Consulting, Pediatric Drug Development & More, Switzerland

Paediatric Regulation stimulated the consideration of paediatric needs at an early stage of drug development in many ways. With the operational implementation of the European network of Paediatric Research at the European Medicines Agency (Enpr-EMA), another organisation dedicated to cooperation towards better medicines for children started its work. Industry collected their experience in a broad and in-depth survey. The results were first presented at the EFPIA/EMA Information Day in May 2011. Consideration how the results might shape future conversation between applicants and agency will be presented.

**Keynote 1: Enpr-EMA**
Paolo Rossi, Policlinico di Tor Vergata, Cattedra di Pediatria, Rome, Italy and PDCO representative within Enpr-EMA coordinating group

**Keynote 2: Industry**
Judith Creba, Head EU Liaison and Policy, Drug Regulatory Affairs, Novartis Pharma AG, Switzerland

**Introduction to Breakout Sessions**
Gesine Bejeuhr, Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany
Klaus Rose, klausrose Consulting, Pediatric Drug Development & More, Switzerland

13:30 LUNCH BREAK

14:30 Session 2

**BREAKOUT SESSIONS**

During the breakout sessions, participants will have the opportunity to speak about their topic of interest in smaller groups. These highly interactive sessions offer an ideal platform for lively discussions with experts, peers and regulators.

*Registrants have the opportunity to choose between one of the following three topics when registering for the conference.*

**Collaboration between Industry and Networks**
- Mark Turner, NIHR Medicines for Children Research Network, UK
- Ramesh Padavala, Head Paediatrics, Novartis Pharma AG, Switzerland
- Irmgard Eichler, Scientific Administrator Paediatric Medicines, European Medicines Agency, EU

**Paediatric Ethics Committees – Practical aspects of consents and assents**
- Ralf Herold, Scientific Administrator Paediatric Medicines, European Medicines Agency, EU

**Standard Assent by German Ethics Committees**
- Thorsten Ruppert, Senior Manager, Research/Development/ Innovation, vfa Research-based Pharmaceutical Companies, Germany

**Informed Consents from Infants and Children**
- Martine Dehlinger-Kremer, Vice President, Global Regulatory Affairs,ReSearch Pharmaceutical Services, Germany and Head of the Paediatric Working Group of EUCROF

**Recruitment Issues and Answers to Operational Challenges**
- Matthew Kibby, Director, Global Operations, BBK Worldwide, UK
- Alexander Cvetkovich Muntañola, Director Paediatrics, INC Research LLC., Spain
- John Illingworth, Illingworth Research Ltd, UK

16:00 COFFEE BREAK

16:30 Session 3

**PAEDIATRIC ISSUES IN PRODUCT DEVELOPMENT**

Session Chair:
**Agnes Gyurasics**, Head, Division of European Affairs, National Institute of Pharmacy, Hungary

EMA issues guidance on development for drugs in various ways in individual indication areas. The first indication-specific conference on paediatric drug development took place in 2004 in London, organised then by the EMEA, and industry participants were still welcome. In the meantime, a multitude of new guidelines have been published, a growing number of specific conferences on drug development are hosted by the EMA (in general without industry participation in the last years). This session will give an overview of the available tools from the points of view of regulatory authorities, pharmaceutical industry, and academia.

**Guidelines, Standard PIPs, Output on Expert Meetings at EMA/PDCO – Support offered by authorities**
Paolo Tomasi, Head of Paediatric Medicines, European Medicines Agency, EU

**Industry Experience – Case studies in answer to the EMA presentation**
Ronald Portman, Group Director, Bristol-Myers Squibb Company, USA
Susanna Del Signore, Head of Global Regulatory Policy, Sanofi-aventis, France
Solange Corriol-Rohou, Director, Regulatory Affairs, Astrazeneca R&D, France
Mette Due Theilade Thomsen, Principal Scientist, Regulatory Affairs, Novo Nordisk A/S, Denmark

18:00 **Get connected!** Meet & Greet Reception with Patrick Le Courtois, EMA

19:00 END OF DAY ONE

## TUESDAY | 27 SEPTEMBER 2011

08:30 **Report from the breakout sessions**
Session Chair:
**Gesine Bejeuhr,** Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany

09:30 **Report from the Legislative Renewal in the US**
Thomas H. Hassall, Senior Director Regulatory Policy & Intelligence, Abbott, USA

10:15 COFFEE BREAK

10:45 Session 4

## COOPERATIVE STUDIES

Session Chair:
**Ralf Herold**, Scientific Administrator Paediatric Medicines, European Medicines Agency, EU

The growing number of PIPs requires resources in many ways. In particular, conditions with a small number of patients could not be investigation by many different companies. Collaborative approaches need to be considered. So far, the experience is limited and in most cases classical co-development is preferred. This session shall explore the advantages of collaborative approaches.

**Paediatric Haematology**
Andrea Biondi, Professor of Pediatrics, University of Milano-Bicocca, Italy

**Industry Experience**
Klaus Rose, Klausrose Consulting, Pediatric Drug Development & More, Switzerland

11:30 LUNCH BREAK

12:30 Session 5

## OXFORD DEBATE

- Does the EU paediatric legislation translate into better medicines for children?
- Will the effort used for PIPs be worth the later potential clinical outcome?

**Moderator:**
Andrea Biondi, Professor of Paediatrics, University of Milano-Bicocca, Italy

**Debaters:**
- Dirk Matthys, Professor, Head of Paediatrics and Medical Genetics, University of Ghent, Belgium
- Dirk Mentzer, Vice-Chair of PDCO, Head of Pharmacovigilance Unit, Paul-Ehrlich-Institut, Germany
- Agnes Saint Raymond, Head of Human Medicines Special Areas, European Medicines Agency, EU
- Ronald Portman, Group Director, Bristol-Myers Squibb Company, USA

14:00 COFFEE BREAK

14:15 **Comment from the Clinical Development Side on Standard PIPs in Allergology**
Ralph Moesges, Professor, Institute of Medical Statistics, Informatics and Epidemiology, University of Cologne, Germany

14:45 Session 6

## PAEDIATRIC INVESTIGATION PLAN (PIP): OPERATIONAL ASPECTS

Session Chair:
**Klaus Rose**, Klausrose Consulting, Pediatric Drug Development & More, Switzerland

When the Paediatric regulation was implemented the post-EMA decision workload was underestimated. Companies, EMA and PDCO must stay in close contact during the development process. This requires resources and needs to be planned as carefully as the initial submission process in order to achieve a positive compliance statement in time and to continue to be compliant also after the marketing authorisation for adults. Practical experience and best practice shall be shared in this session.

**Lifecycle of a PIP (Industry)**
Marcello Milano, Executive, Corporate Regulatory Affairs, Chiesi Farmaceutici S.p.A., Italy

**EMA Experience with Annual Reports on Deferred Measures**
Elin Haf Davies, Scientific Administrator Paediatric Medicines, European Medicines Agency, EU

**Interaction of PDCO and Scientific Advice**
Karl-Heinz Huemer Scientific & Information, International Affairs, AGES Pharmmed, Austria

16:15 Session 7

## WRAP UP

**Closing Remarks**
Gesine Bejeuhr, Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany (DIA)
Klaus Rose, klausrose Consulting, Pediatric Drug Development & More, Switzerland (EFGCP)
Paolo Tomasi, Head of Paediatric Medicines, European Medicines Agency, EU

16:45 END OF CONFERENCE

*For more information please contact michael.hediger@diaeurope.org or call +41 61 225 51 78*

## TRAVEL INFORMATION

**De Vere Venue Canary Wharf**
The De Vere venue in Canary Wharf is located in one of London's premier business areas. With fast links to central London by Westferry DLR station and the Jubilee Underground line is just a five-minute walk away.

For more details on the DLR go to:
http://www.tfl.gov.uk/assets/downloads/dlr-route-map.pdf

## HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:
**Hotel Hilton London Docklands**
265 Rotherhithe Street, London SE16 5HW, United Kingdom
http://www.hilton.co.uk/docklands

at the special rate of: £ 133.00 single room, inclusive of breakfast, exclusive of taxes

To make your reservation please use this link:
http://www.hilton.com/en/hi/groups/personalized/L/LONNDHI-GDIAD-20110925/index.jhtml

To make your reservation please:
Tel: +44 (0) 20 7231 1001 - Fax: +44 (0) 20 7231 0599

Please quote the booking reference (group name and code)
**Group name: GDIAD**
**Group code: GDIAD**

**Important**: Please complete your reservations by **19 August 2011** at the latest. Reservations received after this date will be subject to hotel availability and room rate may vary.

The hotel is situated opposite Canary Wharf conveniently connected by a shuttle boat. The landing stage is in walking distance of the European Medicines Agency (2 min). A three day ferry ticket is included in the room rate. Please make sure you receive it when checking in. For further information, please go to: http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-hotel/index.do

For other hotels in the Canary Wharf area please go to:
http://canary-wharf.hotels-london.co.uk/hotels.php?arriving=26%20Sep%202011&currency=GBP&mode=list&search=canary%20wharf

**In case of cancellation:**
Cancellation of the hotel bedroom booking must be made in writing directly to the hotel 48 hours prior to the arrival date. Cancellations made at least 48 hours prior to arrival will not incur any cancellation charges. Any cancellation made less than 48 hours prior to arrival will be subject to the first night being charged at the full agreed rate. All no shows will be billed for the entire stay.

# REGISTRATION FORM

Joint DIA/EFGCP/EMA Paediatric Forum 2011 - The paediatric regulation in its 5th year:
Transition from toddler to school age | 26-27 September 2011 I London, UK

**ID# 11115**

DIA www.diahome.org

**If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.**

## Early-Bird rates available for DIA and EFGCP Members: Deadline on or before 15 August 2011

Join DIA now to qualify for the early-bird member fee! To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. **Does not apply to government/academia/non-profit members**

| Early-Bird Fee (on or before 15 August 2011) | FEE |
|---|---|
| **Join DIA now to qualify for the Early-Bird Rate** | € **115.00** ❑ |
| **Early-Bird Industry** | € **1'165.00** ❑ |

| CATEGORY | DIA or EFGCP MEMBER FEE (after 15 August 2011) FEE | CATEGORY | NON-MEMBER FEE FEE |
|---|---|---|---|
| **Industry** | € **1'365.00** ❑ | **Industry** | € **1'480.00** ❑ |
| **Government/Non-profit/Academia** (Full-Time) | € **683.00** ❑ | **Government/Non-profit/Academia** (Full-Time) | € **798.00** ❑ |

❑ **I am an EFGCP member**

**For this meeting, DIA will offer a reduced registration fee for small to medium-sized enterprises (SMEs). Please contact DIA Europe at diaeurope@diaeurope.org for more information.**

*A one-year membership to DIA is available to those paying a non-member registration. If paying a non-member fee, please indicate if you do, or do not wish to become a member:* ***YES___ NO___***

**TOTAL AMOUNT DUE:** € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the event

## PLEASE SELECT ONE OF THE FOLLOWING BREAK-OUT GROUP TOPICS:

❑ **Collaboration between Industry and Networks**
❑ **Paediatric Ethics Committees – Practical aspects of consents and assents**
❑ **Recruitment Issues and Answers to Operational Challenges**

**STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT DIA FOR MORE INFORMATION.** 11115DIAWEB

## PARTICIPANT

**PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE**

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## PAYMENT METHODS

❑ **Please charge my credit card** - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

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Card Number

Exp. Date

Cardholder's Name

Date Cardholder's Signature

❑ **Cheques** should be made payable to: DIA and mailed together with a copy of the registration form to facilitate identification to:
**DIA, Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland**

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 11115 as well as the invoice number to ensure correct allocation of your payment.
**Payments must be net of all charges and bank charges must be borne by the payer.**

## CANCELLATION POLICY

**All cancellations must be in writing and received at the DIA office by 17:00 CET on 19 September 2011**

Cancellations received by the date above are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/non-member) = 200.00. Government/Academia/Non-profit (Member/non-member) = 100.00. Tutorial cancellation: 50.00. Regretfully, if you do not cancel by the date above and do not attend, you will be responsible for the full registration fee. You are responsible for cancelling your own hotel reservations. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA Europe is not responsible for airfare, hotel or other costs incurred by yourself.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify DIA Europe office of any such substitutions as soon as possible.

**IMPORTANT:** **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.**

## HOW TO REGISTER

**The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.**

| **Online** www.diahome.org | **Fax** +41 61 225 51 52 | **Email** diaeurope@diaeurope.org | **Mail** DIA European Office Postfach, 4002 Basel, Switzerland |
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