7th DIA/EFGCP/EMA Medicines for Children Conference

Event #13115
24-25 September 2013
Hilton London Docklands Riverside Hotel
London, UK

Programme Committee

Gesine Bejeuhr
Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany and DIA Paediatric Community Chair

Christina Bucci-Rechtweg
Head, Pediatric & Maternal Health Policy, Global Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation, USA

Elin Haf Davies
Scientific Administrator, Paediatric Medicines, European Medicines Agency, EU

Thorsten Olski
Scientific Administrator, Paediatric Medicines, European Medicines Agency, EU

Klaus Rose
Klausrose Consulting, Pediatric Drug Development & More, Switzerland and Chairman Children's Medicines Working Party, European Forum for Good Clinical Practice (EFGCP)

Florian Schmidt
Legal Officer, Directorate-General Health and Consumers, European Commission, EU

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

Continuing Education

DIA meetings and training courses 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.

Overview

This year's DIA/EFGCP/EMA annual paediatric conference will take place in the 7th year of the EU Paediatric Regulation. Over 1'500 Paediatric Investigation Plans (PIPs) have been submitted so far and paediatric needs are now an integrated part of drug development, with the inclusion of children now accepted as standard procedure. However, the pharmaceutical industry continues to report a much higher impact than was originally expected. The discussion now therefore focuses more on the level of ‚how', ‚how much', and ‚how far'. 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. In addition you have the possibility to send your question already beforehand to be sure that the topic will be addressed during the conference.

Key Topics

- Achievements
- Break-out sessions
- Plenary session
- EMA update and debate
- Condition vs. indication / PIP scope
- eLearning from the real experts

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) and individuals involved in paediatric clinical trials
- Parent, patients and patient organisations
- Any stakeholder interested in the development of better medicines for children

Objectives

- Update participants on current paediatric regulatory requirements, scientific and operational success and challenges
- Exchange experiences with regulatory authorities, industry and academia
- Discuss long-term vision, challenges of implementation and potential ways to move forward and further improve processes for paediatric drug development

About DIA

DIA is a neutral, global, professional and member-driven, non-profit association of nearly 18,000 professionals involved in the discovery, development and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well-being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland; Tokyo, Japan; Mumbai, India; Beijing, China; Washington, D.C.; and Latin America.

For more information, visit www.diahome.org/Paediatrics2013 or call DIA Europe +41 61 225 51 51.

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TUESDAY I 24 SEPTEMBER 2013

08:00 **REGISTRATION AND WELCOME COFFEE**

08:45 **WELCOME ADDRESS BY PROGRAMME COMMITTEE**

09:00 **Session 1**

ACHIEVEMENTS

Session Co-Chairs:
Gesine Bejeuhr, Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany and DIA Paediatric Community Chair
Agnès Saint-Raymond, Head, Human Medicines Special Areas, European Medicines Agency, EU

The Paediatric Regulation initiated a further evolution of drug development with the PDCO in a driving seat. The outgoing PDCO Chair who had a huge task to form a recognised and efficient committee, the representative from the European Commission and an Industry representative will analyse the experience gained and give an outlook which improvements still lay ahead of us.

Chairing the PDCO – Highlights and challenges for the future
Daniel Brasseur, AFMPS, PDCO Chairman, Belgium

Commission Report on the Experience Acquired with the Paediatric Regulation
Florian Schmidt, European Commission, Legal Officer, EU

Industry perspective
Heidrun Hildebrand, Global Program Head, Bayer Pharma AG, Germany

Q&A and Introduction to Break-out Sessions
With session speakers

10:45 **COFFEE BREAK**

11:00 **Session 2**

PART 1: BREAK-OUT SESSIONS

Session Chair:
Christina Bucci-Rechtweg, Head, Pediatric & Maternal Health Policy, Global Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation, USA

During the break-out sessions, participants will have the opportunity to speak about their topic of interest and share successes and impediments to rational development of paediatric medicines in smaller groups. The goals of these sessions are to provide the participants with an opportunity to interact with members of the European Medicines Agency, industry and academia to share experiences on means of optimising paediatric drug development, including development of disease specific guidelines and development programme, validating paediatric biomarkers and other outcome measures in the era of personalised medicine, and applying the clinical trial legislation in paediatric medicine.

The workshops will also raise awareness of strategies that have been utilised to optimise clinical trial design in paediatric populations, to disseminate learned knowledge and information to the pharmaceutical industry, academia and regulatory agencies, and to stimulate more concerted efforts to advance paediatric drug development.

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

Break-out Session 1: Addressing PIP Challenges According to Therapeutic Areas: Examples from the diabetes experience
Presenter: Janina Karres, Paediatric Coordinator, Human Medicines Special Areas/Paediatric Medicines European Medicines Agency, EU
Rapporteur: Ron Portman, Pediatric Drug Development Lead, Bristol-Myers Squibb Company BMS, USA

Break-out Session 2: Validating Biomarkers and Outcome Measures
Presenter: Spiros Vamvakas, Head of Scientific Advice, Human Medicines Special Areas, European Medicines Agency, EU
Rapporteur: Sue Cammarata, Vice-President Clinical Research, Shire plc, USA

Break-out Session 3: Clinical Trial Legislation Implication
Presenter: Sabine Atzor, Head of EU Regulatory Policies, F. Hoffmann-La Roche Ltd, Switzerland
Rapporteur: Genevieve Michaux, Counsel, Hunton & Williams LLP, Belgium

13:00 **LUNCH**

14:00 **Session 2 continued**

PART 2: PLENARY SESSION

Session Chair:
Christina Bucci-Rechtweg, Head, Pediatric & Maternal Health Policy, Global Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation, USA

Feedback from break-out groups presented by rapporteurs

Follow-up on Workshops on Therapeutic Areas – Papers that emanated from them
Ron Portman, Pediatric Drug Development Lead, Bristol-Myers Squibb Company BMS, USA

16:00 **COFFEE BREAK**

16:15 **Paediatric Regulation: Five years of success**
Paolo Tomasi, Head of Paediatric Medicines, European Medicines Agency, EU

Report & Tentative Answers to Questions Collected Pre-Conference: send question to paediatrics@efgcp.eu until 17th September the latest
Paolo Tomasi, Head of Paediatric Medicines, European Medicines Agency, EU

Panel Discussion/Conclusions

17:15 **END OF DAY ONE**

18:30 **SOCIAL EVENT**
Keynote speaker
Dirk Mentzer, Head of Pharmacovigilance at Paul-Ehrlich-Institute, PDCO Chair at EMA, Langen, Germany
- Drinks
- Dinner

WEDNESDAY I 25 SEPTEMBER 2013

09:00 **Session 3**

CONDITION VS INDICATION / PIP SCOPE

Session Chair:
Klaus Rose, Klausrose Consulting, Pediatric Drug Development & More, Switzerland and Chairman Children's Medicines Working Party, EFGCP

The development of medicinal products is based on adult needs. Many indications in adults are not common in children. However, due to their mode of action these medicines might address paediatric needs in a similar indication. The details of this transition shall be discussed in this session.

Defining the Condition(s) in a Paediatric Investigation Plan/Waiver
Ralph Bax, Scientific Administrator, European Medicines Agency, EU

Defining the Condition(s) in a Paediatric Investigation Plan/Waiver – Industry perspective
Anne De Bock, Portfolio Leader Oncology - Infection, European Regulatory Affairs, AstraZeneca NV/SA, Belgium

Panel Discussion
With session speakers

10:20 **COFFEE BREAK**

10:45 **Session 4**

EMA UPDATE AND DEBATE

Session Chair:
Paolo Tomasi, Head of Paediatric Medicines, European Medicines

Agency, EU

EMA Reorganisation
European Medicines Agency representative invited

Transparency in Paediatrics
Agnès Saint-Raymond, Head, Human Medicines Special Areas, European Medicines Agency, EU

Debate and Q&A: Industry, regulator, academia & patient perspective
Solange Corriol-Rohou, Director, Global Regulatory Affairs, Astrazeneca R&D, France

Agnès Saint-Raymond, Head, Human Medicines Special Areas, European Medicines Agency, EU

Ron Portman, Pediatric Drug Development Lead, Bristol-Myers Squibb Company BMS, USA

Additional panellists are invited

12:15 LUNCH

13:30 **Session 5**

LEARNING FROM THE REAL EXPERTS
Session Chair:
Elin Haf Davies, Scientific Administrator, Paediatric Medicines, European Medicines Agency, EU

The views of those who will finally take the medicines will be explored in this session. Patients and parents will describe their experience in the direct drug development process, and debate whether medicines fulfil their needs – or not?

Information About Medicines for Children and Young People
Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK
Involvement of Children and Young People in the PDCO / Launching the approach
Elin Haf Davies, Scientific Administrator, Paediatric Medicines, European Medicines Agency, EU

From the Frontline: A mother's experience
Jo Bardoe, Parent representative, UK

From the frontline: A young lady's experience
Nadia Fattouki, Student, Patient representative, UK

15:00 COFFEE BREAK

15:15 **Session 5 continued**

Paediatric Electronic Patient Reported Outcomes (ePRO)
Valdo Arnera, General Manager Europe, PHT Corporation, Switzerland

Paediatric Patient Reported Outcomes and Measures
Jan Regnstroem, Scientific Administrator, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, EU

Conclusions
Gesine Bejeuhr, Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany and DIA Paediatric Community Chair

Thorsten Olski, Scientific Administrator, Paediatric Medicines, European Medicines Agency, EU

16:30 **END OF FORUM**

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe. Speakers and agenda are subject to change without notice.

Recording of any DIA Europe tutorial/workshop information in any type of media is prohibited without prior written consent from DIA Europe.

TRAVEL INFORMATION

London Gatwick Airport / Stansted Airport

Please use this link to get directions to the Hilton London Docklands Riverside Hotel: http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-Riverside/directions.do#localairports

London City Airport

Take the DLR train to Bank DLR Station, change platform at Poplar DLR Station towards Lewisham DLR Station or change to the Underground Jubilee Line towards Stanmore at Canning Town. Leave at Canary Wharf Station and walk to the Canary Wharf Pier. Take the complimentary ferry service (for hotel guests only) to cross the river Thames to arrive at the Hilton London Docklands Riverside Hotel.

The hotel is no longer allowed to operate the courtesy bus service to Canada Water. If you wish to use Canada Water Station, please use the C10 public bus service that stops outside the hotel. The stop is displayed and announced as the Hilton London Docklands Riverside.

For more details please visit: www.tfl.gov.uk

HOTEL INFORMATION

DIA has blocked a number of rooms at the:
Hilton London Docklands Riverside Hotel
265 Rotherhithe Street
London SE16 5HW, UK

http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-Riverside/index.do

at the special rate of:

£ 129.00 for room and breakfast, exclusive of VAT

Group Name: DIA Europe

To make your reservation please send your booking request to the following email address:

liane.lopes@hilton.com

Or call the reservation team:+44 (0) 207 2311001

Important: Please complete your reservation by 20 August 2013 at the latest. Reservations received after this date will be subject to hotel availability and room rate may vary.

In case of cancellation:

Cancellation of the hotel booking must be made in writing directly to the hotel 45 days prior to the arrival date due to the allocation booking. Cancellations made at least 45 days prior to arrival will not incur any cancellation charges. Any cancellation made less than 45 days 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

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24-25 September 2013 I Hilton London Docklands Riverside Hotel, London, UK

DIA www.diahome.org

ID #13115

Early-bird rates available for DIA/EFGCP members: Register by 12 August 2013

Join DIA now to qualify for the Early-bird member fee! The Early-bird registration form and accompanying payment must be received by the date above. Early-bird fee applies to industry members only. *(www.diahome.org/membership)*

€ 1'165.00 ❑

FEES (after 12 August 2013)

	Member (DIA or EFGCP)*	Non-Member*
Industry	€ 1'365.00 ❑	€ 1'480.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 683.00 ❑	€ 798.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

I am an EFGCP member ❑

I will participate in the Social Event on Tuesday, the 24th of September ❑

TOTAL AMOUNT DUE: _____

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

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and meeting material.

Payment is due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **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." Please include your name, company, Event ID #13115 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) € 200.00.
- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) € 100.00.
- Tutorial cancellation € 50.00.

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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 the DIA Europe office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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