THURSDAY I 1 OCTOBER 2015

08:00 REGISTRATION AND WELCOME COFFEE

08:45 WELCOME REMARKS

09:00 SESSION 1

Session Co-chairs:
Gesine Bejeuhr, Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany;
Paolo Tomasi, Head of Paediatric Medicines, European Medicines Agency, European Union

EMA Paediatric Committee (PDCO) Initiatives
Dirk Mentzer, Chairperson of PDCO at EMA, Head of Pharmacovigilance Unit, Paul-Ehrlich-Institut, Germany

Successful Navigation of the Paediatric Plan Life Cycle
Kate Beaujeux, Senior Director Regulatory Affairs, Member of EFPIA Paediatric Topic Group, Astra Zeneca, UK

Discussion

10:30 COFFEE BREAK

11:00 BREAKOUT GROUPS

Participants will choose a group according to their interest

Workshop A:
Age-Adapted Formulations – Challenges and Examples (EUPfi)
Chair: Catherine Tuleu, Reader in Pharmaceutics and Director of the Centre for Paediatric Pharmacy Research, University College London School of Pharmacy, UK

Brian Aylward, Chair of the PDCO Formulation Working Group at EMA, Clinical Assessor, Health Products Regularity Authority, Ireland

Workshop B:
Pre-Clinical Research for Medicines for Children
Chair: Jacqueline Carleer, Chair of the PDCO Non-clinical Working Group at EMA, Safety Assessor, Research and Development, Federal Agency for Medicines and Health Products, Belgium

Workshop C:
Post-Marketing Studies, Registries and Long-Term Safety
Chair: Dirk Mentzer, Chairperson of PDCO at EMA, Head of Pharmacovigilance Unit, Paul-Ehrlich-Institut, Germany

Workshop D:
Contraception in Paediatric Trials – How to Address it Best
Chair: Christina Bucci-Rechtweg, Global Head, Pediatric and Maternal Health Policy, Novartis, US

13:00 LUNCH

14:00 SESSION 2

Session Co-Chairs:
Emilie Desfontaine, Scientific Officer, Paediatric Medicines, European Medicines Agency, European Union;
Andrea Ecker, Scientific Officer, Paediatric Medicines, European Medicines Agency, European Union

Feedback from the Workshops
Rapporteurs

Report and Tentative Answers on Questions Collected Pre-Conference
Péter Károlyi, Scientific Officer, European Medicines Agency, European Union

Development of Paediatric Medicines in Japan
Pharmaceuticals and Medical Devices Agency speaker invited

15:30 COFFEE BREAK

16:00 PANEL DISCUSSION

LOOKING BACK AT THE 10 YEARS OF THE PAEDIATRIC LEGISLATION - THE WAYS FORWARD

Panellists:

Florian Schmidt, Principal Administrator, Directorate-General for Health and Food Safety, European Commission, European Union

Dirk Mentzer, Chairperson of PDCO at EMA, Head of Pharmacovigilance Unit, Paul-Ehrlich-Institut, Germany

Kerry Leeson-Beevers, Patient Representative on the PDCO at EMA representing EURORDIS, National Development Manager, Alstrom Syndrome, UK

Martine Dehlinger-Kremer, Global Vice President Medical and Regulatory Affairs, SynteractHCR, Germany

Mark Turner, Chair of the European Network for Paediatric Research at EMA, University of Liverpool, UK

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

17:30 NETWORKING RECEPTION AND SOCIAL EVENT

Key Note Speech
Nermeen Y. Varawalla, Executive Vice President, Global Clinical Trials, Lambda Therapeutic Research, UK

18:30 END OF DAY ONE

FRIDAY I 2 OCTOBER 2015

08:45 OPENING OF DAY 2

09:00 SESSION 3

COLLABORATION BETWEEN EMA AND FDA
Session Chair:
Mette Due Theilade Thomson, Principal Scientist, Novo Nordisk A/S, Denmark

Advancing Paediatric Product Development Through International Collaboration
Christina Bucci-Rechtweg, Global Head, Pediatric and Maternal Health Policy, Novartis, US

How is Convergence on Timing Between EU-US Possible?
Irmgard Eichler, Senior Scientific Officer, Paediatric Medicines, European Medicines Agency, European Union

Discussion Between EMA and FDA on PIP and Rare Diseases
Jean Temeck, Lead Medical Officer, Office of Pediatric Therapeutics, OC, FDA, USA

10:30 COFFEE BREAK

11:00 SESSION 4

FACILITATION OUTSIDE OF THE REGULATORY WORLD
Session Chair:
Detlef Niese, Chairman of the EFGCP Children's Medicines Working Party, European Forum for Good Clinical Practice, Belgium

CRO's Perspective on Feasibility and Challenges with Paediatric Clinical Trials
Martine Dehlinger-Kremer, Global Vice President Medical and Regulatory Affairs, SynteractHCR, Germany

HCP Voice on Practical Challenges/Suggestions
Mark Turner, Chair of the European Network for Paediatric Research at EMA, University of Liverpool, UK

The Case for a Global Pediatric Clinical Trials Network and Progress Towards That Goal
William R. Treem, Senior Director, Pediatric Drug Development, Child Health Innovation and Leadership Department (CHILD), Janssen Pharmaceutical Research and Development, US

12:30 LUNCH

14:00 SESSION 5

INNOVATIVE PAEDIATRIC PLAN DESIGN
Session Chair:
Efthymios Manolis, Scientific Officer, European Medicines Agency, European Union

What Can We Learn from Failed Paediatric Trials?
Gilbert Burckart, Associate Director for Pediatrics, Office for Clinical Pharmacology, FDA, USA

Extrapolation
Oscar Della Pasqua, Director, Clinical Pharmacology & Discovery Medicine, GlaxoSmithKline, UK

Clinical Trial Design/Modelling and Simulation – New Approaches in ICH E11
Solange Rohou, Director Regulatory Affairs, Member of EFPIA Paediatric Topic Group, Astra Zeneca, UK

15:00 DISCUSSION

15:50 CLOSING REMARKS

16:00 END OF CONFERENCE

EVALUATION

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference and can also be accessed through the following link:

https://www.surveymonkey.com/s/15109

PRESENTATION ACCESS

As a benefit of registration, presentations are available on the DIA website. Please sign in to DIA Website and choose "My Presentations" within "My account", where you will be able to download all presentations that have been submitted by speakers.

Note: You will need to enter your DIA User ID and password to verify your status. If you have forgotten your DIA User ID and password, use the Login Reminder.
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- The presenter has not supplied us with a presentation file
- There was no slide presentation planned by the speaker
- The speaker did not agree to share it with other participants
- You have not yet paid the registration fee

CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be e-mailed to all attendees after they have filled in the evaluation. Please note certification requires full attendance to the event.

For more information please contact DIA EMEA Contact Center on EMEA@DIAglobal.org or call +41 61 225 51 51.

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FORM | ID#15109

Better Medicines for Children Conference 2015
1-2 October 2015 | London, UK

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

€ 1'200.00 ❑

Registration fees	Fees
Non-Member Industry	€1560.00 ❑
DIA/EFGCP Member Industry	€1400.00 ❑
Non-Member Government/Charitable/Non-profit/Academia	€860.00 ❑
DIA/EFGCP Member Government/Charitable/Non-profit/Academia	€700.00 ❑
DIA Membership	€155.00 ❑

PAYMENT OF REGISTRATION FEES IS DUE 14 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE CONFERENCE.

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

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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, Middle East and Africa.**

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

Date	Signature

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All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
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If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

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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 office of any such substitutions as soon as possible.

Photography Policy

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The DIA Europe, Middle East & Africa Contact Centre 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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