Joint EFGCP / DIA / EMA
Better Medicines for Children Conference 2014 on

Explore Ways to Enhance Collaboration Between Key Players

30th September & 1st October 2014
EMA, London, United Kingdom

Organised by

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where science and ethics meet

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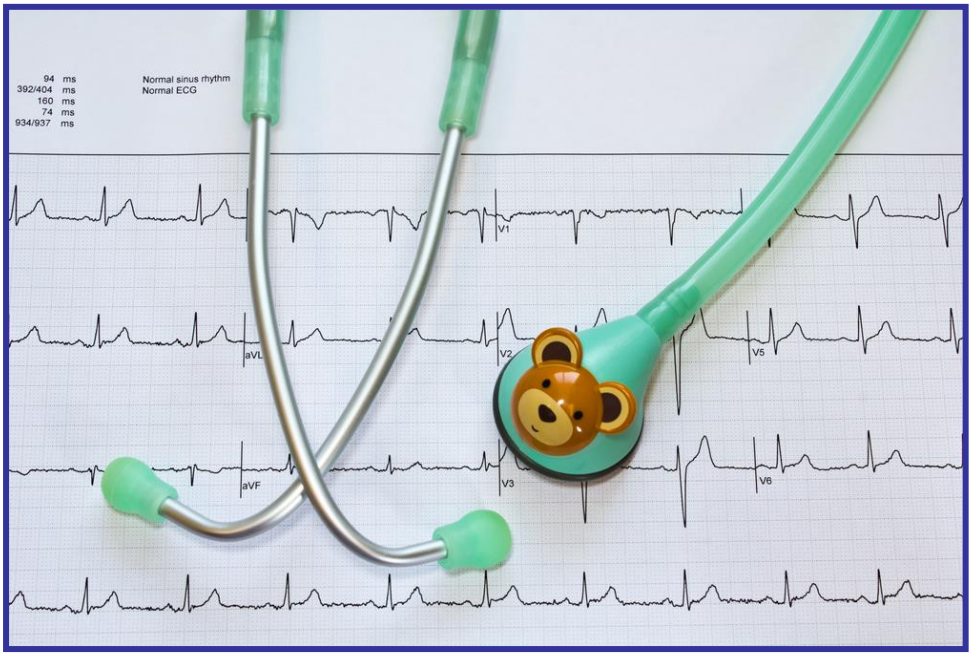

conferences@efgcp.eu – www.efgcp.eu

Conference Rationale

The EU paediatric regulation is now in force since 2007. Drug development is no longer possible without considering children. Furthermore, companies developing medicines need to consider the paediatric requirements early in the development. This legislation has transformed paediatric drug development from a topic discussed by a few interested paediatricians, clinical pharmacologists and regulators to an issue that is broadly known within pharmaceutical industry and regulatory authorities, and to a lesser degree in the clinical world. More than 1000 PIP decisions are now published on the EMA website, and virtually everybody within pharmaceutical industry has heard of paediatric investigation plans and waivers. The EU Commission has published a 5-year report, and a 10-year report will be submitted by the Commission to the European Parliament and Council in 2017.

The aim of this conference is to discuss on a high level how the EU paediatric regulation is working and how it contributes to children's health. This will include a discussion on the preparedness for the 10-year report; strategic thoughts within the EMA on how to streamline paediatric development and a session dedicated to paediatric oncology.

As always, experts from all involved parties will be present, and on day 1 participants will discuss more specialized and hot topic issues in four breakout sessions. This will allow participants to discuss face-to-face with all stakeholders, which otherwise usually occurs by email or phone. Questions on any topic relating to the Agency's activities can be submitted before the conference to paediatrics@efgcp.eu, and will be answered by Peter Karolyi from the Paediatric Medicines office at the EMA.

Programme Committee

Gesine Bejeuhr	vfa Research-based Pharmaceutical Companies, DIA Paediatric Group, Germany
Emilie Desfontaine	European Medicines Agency (EMA)
Thorsten Olski	European Medicines Agency (EMA)
Jytte Lyngvig	Drug Information Association (DIA), Switzerland
Klaus Rose	klausrose Consulting & EFGCP Children's Medicines Working Party, Switzerland
Paolo Tomasi	European Medicines Agency (EMA)
Mette Due Theilade Thomsen	Novo Nordisk, Denmark

Faculty

Peter Adamson	The Children's Hospital of Philadelphia, USA
Kate Beaujeux	MedImmune, United Kingdom
Gesine Bejeuhr	vfa Research-based Pharmaceutical Companies, DIA Paediatric Group, Germany
Gerlind Bode	International Confederation of Childhood Cancer Parent Organizations (ICCCPO), Germany
Christina Bucci-Rechtweg	Novartis Pharmaceuticals, USA
Alexander Cvetkovich-Muntañola	INC Research, Spain
Irmgard Eichler	European Medicines Agency (EMA)
Zaide Frias	European Medicines Agency (EMA)
Sabine Fürst- Recktenwald	F. Hoffmann-La Roche, Switzerland
Oliver Gross	University Medicine Göttingen, Germany
Ralf Herold	European Medicines Agency (EMA)
Peter Karolyi	European Medicines Agency (EMA)
Janina Karres	European Medicines Agency (EMA)
Dirk Mentzer	Paediatric Committee (PDCO), European Medicines Agency (EMA) & Paul Ehrlich Institut, Germany
Marcello Milano	Chiesi Farmaceutici, Italy

Koenraad Norga	Paediatric Committee (PDCO), European Medicines Agency (EMA) & Antwerp University Hospital (UZA), Belgium
Thorsten Olski	European Medicines Agency (EMA)
Andy Pearson	Institute of Cancer Research, United Kingdom (represented)
Solange Rohou	AstraZeneca, United Kingdom
Klaus Rose	klausrose Consulting & EFGCP Children's Medicines Working Party, Switzerland
Agnes Saint-Raymond	European Medicines Agency (EMA)
Michiyo Sakiyama	Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Mette Due Theilade Thomsen	Novo Nordisk, Denmark
Paolo Tomasi	European Medicines Agency (EMA)
Charles A. Thompson	Pfizer, USA
Gilles Vassal	Gustave Roussy, France
Philip Walson	Georg-August-University Medical School, Göttingen, Germany

Conference Language

The language of the conference will be English.

Conference Venue

European Medicines Agency (NEW ADDRESS!)
Churchill Place 30, Canary Wharf
London E14 5EU, United Kingdom
Website: www.ema.europa.eu

Registration & Information

E-mail conferences@efgcp.eu or visit www.efgcp.eu

Programme

Tuesday 30th September

08:00 Registration & Welcome Coffee

08:45 **Welcome**

Zaide Frias, *European Medicines Agency (EMA) &* ***Klaus Rose,*** *klausrose Consulting & EFGCP Children's Medicines Working Party, Switzerland*

SESSION 1
SETTING THE SCENE

Chairperson: ***Zaide Frias,*** *European Medicines Agency (EMA) &* ***Klaus Rose,*** *klausrose Consulting & EFGCP Children's Medicines Working Party, Switzerland*

09:00 **Preparedness for the 10-year report and perspectives of the PDCO chairman**
Dirk Mentzer, *Chairman of the Paediatric Committee (PDCO), European Medicines Agency (EMA) & Paul Ehrlich Institut, Germany*

09:30 **The Drug Developers' Perspective**
Christina Bucci-Rechtweg, *Novartis Pharmaceuticals, USA*

10:00 **Discussion**

10:30 Coffee Break

11:00 **Parallel break-out groups**

Group 1 **Pre-competitive paediatric collaboration between pharma companies and the role of EnprEMA?**
Chair: ***Gesine Bejeuhr,*** *vfa Research-based Pharmaceutical Companies, DIA Paediatric Group, Germany*
Introduction: ***Irmgard Eichler,*** *European Medicines Agency (EMA) &* ***Charles A. Thompson****, Pfizer, USA*
Rapporteur: ***to be determined***

Group 2 **Practical challenges of paediatrics clinical trials and possible solutions**
Chair: ***Janina Karres,*** *European Medicines Agency (EMA)*
Introduction: ***Alexander Cvetkovich-Muntañola,*** *INC Research, Spain*
Rapporteur: ***Sabine Fürst- Recktenwald****, F. Hoffmann-La Roche, Switzerland*

Group 3 **Practical challenges with PIPs**
Chair: ***Klaus Rose,*** *klausrose Consulting & EFGCP Children's Medicines Working Party, Switzerland*
Introduction: ***Kate Beaujeux,*** *MedImmune, United Kingdom*
Rapporteur: ***Marcello Milano****, Chiesi Farmaceutici, Italy*

Group 4 **International framework for paediatric drug development**
Chair: ***Thorsten Olski,*** *European Medicines Agency (EMA)*
Introduction: ***Agnes Saint-Raymond,*** *European Medicines Agency (EMA) &* ***Michiyo Sakiyama****, Pharmaceuticals and Medical Devices Agency (PMDA), Japan*
Rapporteur: ***Mette Due Theilade Thomsen,*** *Novo Nordisk, Denmark*

13:00 Lunch

SESSION 2
GROUP REPORTS AND FEEDBACK FROM EMA

Chairpersons: ***Mette Due Theilade Thomsen,*** *Novo Nordisk, Denmark &* ***Klaus Rose,*** *klausrose Consulting & EFGCP Children's Medicines Working Party, Switzerland*

14:00 **Feedback from the 4 parallel breakout groups**
Rapporteurs of the Groups

15:00 **One stop-shop: a new EMA approach**
Paolo Tomasi, *European Medicines Agency (EMA)*

15:30 Coffee break

15:50 **Report & Tentative answers on questions collected prior to the conference (send questions to paediatrics@efgcp.eu) / Update on paediatric procedures / PIP Format and content guideline revision**
Peter Karolyi, *European Medicines Agency (EMA)*

16:20 **Panel & General Discussion**

17:00 **Conclusions**

17:15 **End of Day 1**

18:30 **Social Event**

- Key note speech: ***Professor Philip Walson,*** *Board Certified in Paediatrics, Clinical Pharmacology and Medical Toxicology; Visiting Professor, Department of Laboratory Medicine at Georg-August-University Medical School, Goettingen, Germany*

Wednesday 1st October

08:30 Welcome coffee

SESSION 3
ENHANCED COLLABORATION BETWEEN KEY PLAYERS

Chairpersons: ***Ralf Herold,*** *European Medicines Agency (EMA) &* ***Gesine Bejeuhr,*** *vfa Research-based Pharmaceutical Companies, DIA Paediatric Group, Germany*

09:00 **Paediatric Oncology: The EU Perspective**
Gilles Vassal, *Gustave Roussy, France*

09:15 **Paediatric Oncology: The UK ICR Perspective**
Gilles Vassal, *Gustave Roussy, France on behalf of* ***Andy Pearson,*** *Institute of Cancer Research (ICR), United Kingdom*

09:30 **Paediatric Oncology: The US Perspective**
Peter Adamson, *The Children's Hospital of Philadelphia, USA*

09:50 **Panel Discussion**
Speakers of the session

10:30 Coffee Break

11:00 **Paediatric Oncology: The patient and parent perspective**
Gerlind Bode, *International Confederation of Childhood Cancer Parent Organizations (ICCCPO), Germany*

11:20 **Paediatric Oncology: EMA/PDCO Perspective**
Koenraad Norga, *Vice-Chairman of the Paediatric Committee (PDCO), European Medicines Agency (EMA) & Antwerp University Hospital (UZA), Belgium*

11:40 **Alport Syndrom: Challenges of clinical research and its translation into clinical practice**
Oliver Gross, *University Medicine Göttingen, Germany*

12:00 **Panel Discussion**
Speakers of the session

13:00 Lunch

SESSION 4
INTERNATIONAL DEVELOPMENT IN PAEDIATRICS

Chairpersons: ***Mette Due Theilade Thomsen,*** *Novo Nordisk, Denmark &* ***Thorsten Olski,*** *European Medicines Agency (EMA)*

14:00 **ICH E 11/ ICH E 6**
Dirk Mentzer, *Paediatric Committee (PDCO), European Medicines Agency (EMA) & Paul Ehrlich Institut, Germany*

14:20 **ICH E 11/ ICH E 6**
Solange Rohou, *AstraZeneca, United Kingdom*

14:40 **TTIP (Transatlantic Trade and Investment Partnership)**
Gesine Bejeuhr, *vfa Research-based Pharmaceutical Companies, DIA Paediatric Group, Germany*

15:00 **Panel & General Discussion**

15:50 **Conference Wrap Up**
Mette Due Theilade Thomsen, *Novo Nordisk, Denmark &* ***Thorsten Olski,*** *European Medicines Agency (EMA)*

16:00 **End of Day 2**