

Programme (Stand November 26th 2018)

Tuesday May 28, 2019

MONTREAL ROOM – 8:00-17:45

08:00-08:45: Registration

08:45-09:00: Welcome. John van den Anker, President ESDP and Jean-Pierre Guignard, founder ESDP

09:00-10:30: Precision medicine in children

09:00-09:30: William Evans: Pharmacogenomics: a cornerstone of precision medicine for childhood cancer

09:30-10:00: Matthias Schwab: Personalized medicine in children: more than just development?

10:00-10:30: Gregory Kearns: Personalized medicine in young infants: more than just genetics?

Information about speakers:

William Evans is the Endowed Chair in Pharmacogenomics and former President and CEO of St. Jude's Children's Research Hospital in Memphis, TN, USA

Matthias Schwab is Professor and Chair of Clinical Pharmacology at the Dr. Margarete Fischer-Bosch Institute of Clinical Pharmacology in Stuttgart and the Department of Clinical Pharmacology in Tuebingen, Germany

Gregory Kearns is President of the Arkansas Children's Research Institute and Chief Research Officer at Arkansas Children's Hospital

10:30-11:00: Coffee, posters and networking

11:00-13:05: Use of modeling in all stages of life

11:00-11:25: Andre Dallmann: Building the PK-Sim pregnancy model

11:25-11:50: Xiaomei (Mae) Liu: Physiology-based maternal-fetal models: application and regulatory implications

11:50-12:15: Wei Zhao: Model-based extrapolation: optimal trial design and personalized dosing in children

12:15-12:40: Catherijne Knibbe: Use of bodyweight as dosing scalar in children in the era of obesity

12:40-13:05: Catherine Sherwin: How to select datasets for external evaluation

Information about speakers:

Andre Dallmann is a postdoctoral fellow at the University Children's Hospital Basel, Switzerland

Xiaomei (Mae) Liu is a postdoctoral fellow at the Children's National Medical Center in Washington, DC, USA

Wei Zhao is Professor and Director of the Institute of Clinical Pharmacy and Pharmacology, Shandong University in Jinan, China

Catherijne Knibbe is Professor of Individualized Drug Treatment, Leiden Academic Centre for Drug Research, the Netherlands

Catherine Sherwin is Director of the Division of Clinical Pharmacology, University of Utah, Salt Lake City, USA

13:05-14:15 Lunch, posters and networking

14:15-17:15: Research infrastructures to conduct neonatal and paediatric clinical trials

14:15-14:40: Edward Connor: I-ACT

14:40-15:05: Mark Turner: IMI-2

15:05-15:30: Sam Maldonado: Industry's view

15:30-16:05: Susan McCune: FDA's view

16:05-16:20: Ralph Bax (tbc): EMA's view

16:20-17:15: Q&A moderated by Gregory Kearns and John van den Anker

Information about speakers:

Edward Connor is Chairman and President of Institute for Advanced Clinical Trials for Children (I-ACT)

Mark Turner is Chair of the European network of pediatric research at EMA (EnprEMA)

Samuel Maldonado is the Vice President and Head of the Pediatric Development Center of Excellence at Johnson & Johnson Pharmaceutical Research and Development

Susan McCune is Director of the Office of Pediatric Therapeutics at the FDA

Ralph Bax is Head of Pediatric Medicines (ad interim) at the EMA

Gregory Kearns is President of the Arkansas Children's Research Institute and Chief Research Officer at Arkansas Children's Hospital

John van den Anker is the Eckenstein-Geigy Distinguished Professor of Paediatric Pharmacology at the University of Basel Children's Hospital in Switzerland and President of the European Society for Developmental Perinatal and Pediatric Pharmacology (ESDP)

17:15-17:45: 3 free oral presentations (speakers TBC)

OSAKA ROOM – 14:00-17:30

14:15-16:15: Novel methods to support paediatric pharmacotherapy

14:15-14:45: Pablo Sinues: TDM using breath analysis

14:45-15:15: Wouter Vaes: How to optimize the use of microtracers in neonatal and pediatric pharmacology

15:15-15:45: Hubert Caron: MOA-matching to develop adult pipelines for children with cancer

15:45-16:15: Julia Vogt: Machine learning for clinical data analysis and precision medicine

Information about speakers:

Pablo Sinues is Botnar Research Professor at the University Children's Hospital Basel, Switzerland

Wouter Vaes is Senior Director Human Biology, the Netherlands Organisation for Applied Scientific Research (TNO), the Netherlands

Hubert Caron is Senior Medical Director Pediatric Oncology at Roche, Global Development Team Leader Pediatrics (iPODD) at Genentech and Research Professor at the University of Amsterdam

Julia Vogt is Assistant Professor, Department of Mathematics and Computer Science, University of Basel, Switzerland

16:15-16:45: Coffee, posters and networking

16:45-17:45: 6 free oral presentations (speakers TBC)

FOYER – 08:45-17:30

08:45-17:30: Industry exhibition, Poster exhibition Day 1

SOCIAL PROGRAMME

17:45-19:15: Reception (all participants)

19:30: Faculty and Council dinner (by invitation only)

Wednesday May 29, 2019

MONTREAL ROOM – 8:30-18:00

08:30 – 10:00: Drug development study design for rare diseases

08:30-09:00: Florian Lagler: Orphan drug trials in inborn errors of metabolism - Lessons learned and future challenges

09:00-09:30: Eric Hoffman: The experience with Duchenne muscular dystrophy

09:30-10:00: Gilbert Burckart: The FDA's experience

Information about speakers:

Florian Lagler is Head of the Institute for Inherited Metabolic Diseases of Paracelsus Medical University Salzburg, CEO of the Clinical Research Centre Salzburg GmbH, and advisor for the Austrian Agency for Health and Food Safety.

Eric Hoffman is Professor of Pharmaceutical Sciences, Bingham University –SUNY, USA and CEO of ReveraGen BioPharma, Rockville, USA

Gilbert Burckart is Associate Director for Pediatrics at the Center of Drug Evaluation and Research, Office of Translational Sciences, Office of Clinical Pharmacology at the FDA

10:00-10:30: 3 free oral presentations (speakers TBC)

10:30-11:00: Coffee, posters and networking

11:00-12:30: Hot topics in perinatal pharmacology

11:00-11:30: Jan Bonhoeffer: Vaccinations in pregnant women

11:30-12:00: Dirk Bassler: Inhaled steroids and bronchopulmonary dysplasia

12:00-12:30: Dick Tibboel: Evidence based pharmacotherapy for neonatal pulmonary hypertension

Information about speakers:

Jan Bonhoeffer is President of the Brighton Collaboration Foundation and Vice-Chair, Pediatric Infectious Diseases and Vaccines at the University Children's Hospital Basel, Switzerland

Dirk Bassler is Professor and Chair of the Department of Neonatology in Zürich, Switzerland

Dick Tibboel is Professor and Director of Research Intensive Care at Erasmus MC-Sophia Children's Hospital in Rotterdam, the Netherlands

12:30-13:00: 3 free oral presentations (speakers TBC)

13:00-14:30: Lunch, posters and networking

14:30-16:00: PK/PD modeling and simulations: quo vadis?

14:30-15:00: Wei Zhao: The perspective of the academician

15:00-15:30: Richard Peck: The perspective of the industry

15:30-16:00: Gil Burckart: The perspective of the regulatory agency

Information about speakers:

Wei Zhao is Professor and Director of the Institute of Clinical Pharmacy and Pharmacology, Shandong University in Jinan, China

Richard Peck is Global Head Clinical Pharmacology, Pharmaceutical Sciences, Roche Pharma Research and Early Development, Roche Innovation Center, Basel, Switzerland

Gilbert Burckart is Associate Director for Pediatrics at the Center of Drug Evaluation and Research, Office of Translational Sciences, Office of Clinical Pharmacology at the FDA

16:00-16:30: Coffee, posters and networking

16:30-17:00: 3 free oral presentations (speakers TBC)

17:00-18:00: Selected poster presentations

OSAKA ROOM – 08:30-18:00

08:30-10:00: Tools to improve clinical trials in children and adolescents?

08:30-09:00: Olivier Blanson Henkemans: Robotic Buddy “PAL Charly” to improve diabetic selfmanagement in children

09:00-09:30: To be selected

09:30-10:00: Urs Frey: Use of pulmonary function to facilitate clinical trials

Information about speakers:

Olivier Blanson Henkemans is Senior Scientist Child Health, the Netherlands Organisation for Applied Scientific Research (TNO), the Netherlands

Urs Frey is the Chairman of Pediatrics, University of Basel Children’s Hospital, Basel, Switzerland

10:00-10:30: 3 free oral presentations (speakers TBC)

10:30-11:00: Coffee, posters and networking

11:00-12:30: Treatment of serious infections in low and middle-income countries

11:00-11:30: Catia Marzolini: Treatment of children living with HIV

11:30-12:00: Irene Kuepfer: Treatment of children with malaria

12:00-12:30: Julia Bielicki: Treatment of children with bacterial infections

Information about speakers:

Catia Marzolini is a PharmD, PhD in the Division of Infectious Diseases and Hospital Epidemiology, University of Basel, Switzerland

Irene Kuepfer is Assistant Professor at the London School of Hygiene and Tropical Medicine, UK and Senior Scientific collaborator at the Swiss Tropical and Public Health Institute, University of Basel, Switzerland

Julia Bielicki is Senior Lecturer, St George’s University of London, UK and Consultant in General Pediatrics, Pediatric Infectious Diseases and Pediatric Pharmacology at the University of Basel Children’s Hospital, Switzerland.

12:30-13:00: 3 free oral presentations (speakers TBC)

13:00-14:30: Lunch, posters and networking

14:30-16:00: Special topics in paediatric pharmacology

14:30-15:00: Gideon Koren: Pharmacology of cannabis in adolescents

15:00-15:30: Helle Holst: Child friendly, age-appropriate formulations: how important are excipients?

15:30-16:00: Karel Allegaert: Perinatal use of acetaminophen; a shotgun approach

Information about speakers:

Gideon Koren is Professor at the Maccabi Institute of Research and Innovation at the Tel Aviv University in Israel

Helle Holst is an Associate Professor in the Department of Clinical Pharmacology, Copenhagen, Denmark

Karel Allegaert is Professor of Neonatology at the University of Leuven, Belgium and Faculty at the Erasmus Medical Center-Sophia Children’s Hospital, Rotterdam, the Netherlands

16:00-16:30: Coffee, posters and networking

16:30-17:00: 3 free oral presentations (speakers TBC)

17:00-18:00: 6 free oral presentations (speakers TBC)

FOYER – 08:30-18:00

08:30-18:00: Industry exhibition, Poster exhibition Day 2

17:00-18:00: Poster walks – then SOCIAL PROGRAMME

Thursday May 30, 2019

POST-CONGRESS EDUCATIONAL SYMPOSIUM

OSAKA ROOM – 09:00-17:00

9:00 – 09:30

Welcome and introduction to the educational symposium

Kalle Hoppu

09:30 – 10:00

General introduction to the theme of the symposium

- The concept of children as “Therapeutic Orphans”
- Off-label and unlicensed use of medicines in children
- The paediatric initiatives (US, EU, WHO)

Kalle Hoppu

10:00 - 11:00

Basics of developmental/paediatric pharmacology

- Birth to adulthood, pharmacodynamics and pharmacokinetics
- Considerations of dose calculation
- Routes of administration in children

Greg Kearns

11:00 - 11:30 Break

11:30 - 12:00

Drug safety in children

- Are adverse effects more common or rare in children?
- Adverse effects related to or affecting growth and development
- Dosing errors

John van den Anker

12:00 -12:30

Pharmacological aspects in case of severe disease in children in relation to the pharmacodynamics and pharmacokinetics?

John van den Anker (**confirmed**)

12:30 – 13:30 Light lunch

13:30 - 14:00

When evidence is absent can we extrapolate data from adults to children or should we do clinical trials?

- Off-label or off-knowledge use of medicines?
- Experimental therapy vs. clinical trials

John van den Anker

14:00 - 15:00

Paediatric formulations

- Formulations most suitable for use in children
- Considerations of excipients used in paediatric formulations
- Extemporaneous formulations

Greg Kearns

15:00 – 15:30

Ethical aspects of drug research in children

Greg Kearns

15:30 – 16:00 Break

16:00 – 16:30

Understanding the basics of drug development in children

- Finding the right dose
- Demonstrating efficacy
- Demonstrating safety
- Regulatory assessment and why it is important

Kalle Hoppu (**confirmed**)

16:30 - 17:00

What you need to know as an investigator of a paediatric clinical trial

- What is a good study and what is not
- Good Clinical Practice (GCP)
- Recruiting children for a study
- Protocol deviations
- Adverse Events

Greg Kearns

17:30 - 18:00

Questions and General Discussion

Kalle Hoppu

18:00 - 18:30

Summary & Closing of the meeting (including evaluation)

Kalle Hoppu

Information about speakers:

Kalle Hoppu is an Associate Professor of Pediatric Clinical Pharmacology at the University of Helsinki, Finland

Gregory Kearns is President of the Arkansas Children's Research Institute and Chief Research Officer at Arkansas Children's Hospital

John van den Anker is the Eckenstein-Geigy Distinguished Professor of Paediatric Pharmacology at the University of Basel Children's Hospital in Switzerland and President of the European Society for Developmental Perinatal and Pediatric Pharmacology (ESDP)

ESDPPP2019

c/o Congrex Switzerland Ltd.
Peter Merian-Strasse 80
4002 Basel / Switzerland

+41 61 686 77 77

+41 61 686 77 88

[esdppp\[at\]congrex.com](mailto:esdppp[at]congrex.com)