

ESDPPP

The European Society for Developmental, Perinatal
and Paediatric Pharmacology



*Use of clinical pharmacology to improve
safe and effective use of drugs in neonates,
infants, children and adolescents worldwide*

**European Society
for Developmental,
Perinatal
and Paediatric
Pharmacology**

Congress

JUNE 28–30, 2023

PRAGUE, CZECH REPUBLIC

PROGRAMME AT A GLANCE

Day 1 – Wednesday June 28th

9:00 – 9:05	Welcome
09:05 – 10:15	Clinical Pharmacology Update
10:15 – 10:45	<i>coffee break</i>
10:45 – 12:00	Renal Pharmacology Update
12:00 – 13:00	<i>lunch break</i>
13:00 – 14:00	Poster Walk I Satellite Symposia
14:00 – 15:15	Clinical Trials in Pharmacology
15:15 – 15:45	<i>coffee break</i>
15:45 – 17:00	New Activities within ESDPPP
17:00 – 18:00	General Assembly
18:00	Closing the day

Day 2 – Thursday June 29th

9:00 – 10:15	Drugs in Special Populations and Settings I
10:15 – 10:45	<i>coffee break</i>
10:45 – 12:00	Drugs in Special Populations and Settings II
12:00 – 13:00	<i>lunch break</i>
13:00 – 14:00	Poster Walk II
14:00 – 15:15	Pharmacology of Rare Diseases
15:15 – 15:45	<i>coffee break</i>
15:45 – 17:00	Pharmacology in Neonatal and Paediatric Critical Care
17:00 – 18:00	Round table
18:00	Closing the day

Day 3 – Friday June 30th

9:00 – 10:15	Innovative Tools in Clinical Pharmacology I
10:30 – 10:45	<i>coffee break</i>
10:45 – 12:00	Innovative Tools in Clinical Pharmacology II
12:00 – 13:00	Closing the meeting

Principles of Neonatal and Paediatric Clinical Pharmacology

Chairs: Gregory Kearns and John van den Anker

Presenters: Karel Allegaert, Sinno Simons, Robert Flint and Pavla Pokorná

- 10:00 – 10:30** **Welcome and pre-workshop quiz**
Gregory Kearns and John van den Anker
- 10:30 – 11:30** **Developmental pharmacology**
Karel Allegaert
- 11:30 – 12:30** **How to use data from continuous monitoring of neonates to guide treatment**
Sinno Simons
- 12:30 – 13:00* *lunch (sandwiches, coffee, tea)*
- 13:00 – 14:00** **How to understand the role of non-developmental factors superimposed on developmental factors**
Pavla Pokorná
- 14:00 – 15:00** **How to use therapeutic drug monitoring in the NICU/PICU**
Robert Flint
- 15:00 – 16:00** **Postworkshop quiz**
Gregory Kearns and John van den Anker
- 16:00** **Closing remarks**
Gregory Kearns and John van den Anker
- 17:30 – 19:00** **Opening Ceremony**
The Senate of the Parliament of the Czech Republic

WEDNESDAY JUNE 28TH

- 9:00 – 9:05** **Welcome**
- 9:05 – 10:15** **Session 1:**
Clinical Pharmacology Update in Neonatology and Paediatrics
chairs: Pavla Pokorná and Florian Lagler
- 9:05 – 9:35 **Paediatric and neonatal clinical pharmacology: Quo vadis?**
 (John van den Anker)
- 9:35 – 10:05 **How to implement paediatric and neonatal clinical pharmacology globally?**
 (Gregory Kearns)
- 10:05 – 10:15 discussion
- 10:15 – 10:45 *coffee break*
- 10:45 – 12:00** **Session 2:**
Renal Pharmacology: A Session Dedicated to Prof. Dr Jean-Pierre Guignard, ESDPPP Founder
chairs: Evelyne Jacqz-Aigrain and John van den Anker
- 10:45 – 11:15 **Hot topics in neonatal renal pharmacology**
 (Karel Allegaert)
- 11:15 – 11:45 **Hemodialysis and drug dosing in children and adolescents on chronic hemodialysis treatment**
 (Verena Gotta)
- 11:45 – 12:00 discussion
- 12:00 – 13:00 *lunch break*
- 12:30 – 13:00** **Satellite Symposium**
Bi-VirTest® - MxA Lateral flow test
New differential diagnostics of viral vs. bacterial infections for effective antibiotic treatment
(Upon CM approval)
- 13:00 – 14:00** **Poster walk I**
Saskia de Wildt and Sinno Simons
- 14:00 – 15:15** **Session 3:**
Clinical Trials in Neonatal and Paediatric Clinical Pharmacology
chairs: Christiane Garnemark and Pieter de Cock
- 14:00 – 14:25 **How to conduct an investigator-initiated trial successfully: randomized controlled trials forever ever?**
 (Dick Tibboel)20'+5'
- 14:25 – 14:50 **How to optimize model-based trial design in neonatology and paediatrics**
 (Catherijne Knibbe)20'+5'

14:50 – 15:15	<p>3 oral presentations from selected abstracts</p> <p>Towards more Robust Evaluation of the Predictive Performance of Physiologically Based Pharmacokinetic Models 7' (<u>Marjolein D. van Borselen</u>, Laurens Sluijterman, Saskia N. de Wildt, Rick Greupink)</p> <p>Pediatric clinical trials need pediatric clinical trial budgets 7' (<u>Stavros Koulizakos</u>, Tina Kjellén, Karin Mellgren, Jenny M Kindblom)</p> <p>Paediatric investigation plans in Systemic Lupus Erythematosus: review of the PDCO's experience 7' (<u>Roberto De Lisa</u>, Fernando de Andres Trelles, Sara Galluzzo, Brian Aylward, Ralph Bax, Gunter Egger)</p> <p>discussion..... 3'</p>
15:15 – 15:45	<i>coffee break</i>
15:45 – 17:00	<p>Session 4:</p> <p>New Activities Within ESDPPP: What We Have Reached after Liverpool 2022</p> <p>chairs: Mark Turner and Anna Maria Wiesinger</p>
15:45 – 16:10	<p>Training the next generation of researchers: An update on the Young Researcher Section of ESDPPP (Eva Degraeuwe and Anna Maria Wiesinger) 20'+5'</p>
16:10 – 16:35	<p>TDM Network Group update (Pieter de Cock) 20'+5'</p>
16:35 – 17:00	<p>3 oral presentations from selected abstracts</p> <p>CzechPharmPed: starting the optimization of pharmacotherapy in children in daily clinical practice in the Czech Republic and Slovakia (initiative of a networking group of young researchers) 7' (<u>Sabina Pavlíková</u>, Petra Rozsivalová, Michaela Slezáková, Petr Ježdík, Petr Kulíšek, Pavla Pokorná)</p> <p>Reduction of risks in the medication process after adapting the EMR-system to children and introduction of the national Swedish medication database for children 7' (<u>Christiane Garnemark</u>, AL Eriksson, JM Kindblom)</p> <p>Harmonisation, optimisation and individualisation of dosing recommendations for children in Switzerland: a three-step approach 7' (<u>Romy Tilen</u>, Verena Gotta, Paolo Paioni, Henriette E. Meyer zu Schwabedissen, Christoph Berger)</p> <p>discussion..... 3'</p>
17:00 – 18:00	meeting of members of the ESDPPP General Assembly
...	
19:00	<i>congress dinner</i>

9:00– 10:15	Session 5: Drugs in Special Populations and Settings I: Pharmacology of Therapeutic Hypothermia and Other Settings chairs: Karel Allegaert and Robert Flint
9:00 – 9:25	Thermopharmacology in neonates and children (Pavla Pokorná)20'+5'
9:25 – 9:50	Antimicrobial drugs under hypothermia in neonates (Anne Smits)20'+5'
9:50 – 10:15	3 oral presentations from selected abstracts
	Caffeine therapy for apnea of prematurity: real world data on effectivity7' (<u>Kelly Storm</u> , Robert Flint, Wes Onland, Anton van Kaam, Irwin Reiss, Jeroen Hutten, Sinno Simons)
	Tissue penetration of piperacillin-tazobactam in critically ill children – a microdialysis study7' (<u>Eline Hermans</u> , Evelyn Dhont, Mathias Devreese, Johan Vande Walle, Peter De Paepe, Pieter A. De Cock)
	The QTc interval in former very preterm infants is not different from term-born controls7' (Jill Vanthienen, Marine Vassilev Petrov, Thuy Mai Luu, Anik Cloutier, Anke Raaijmakers, Jan A Staessen, Zhenyu Zhang, Thomas Salaets, Annouschka Laenen, Anne Smits, Anne-Monique Nuyt, Adrien Flahault, <u>Karel Allegaert</u>) discussion.....3'
10:15 – 10:45	<i>coffee break</i>
10:45 – 12:00	Session 6: Drugs in Special Populations and Settings II: Pharmacology of ECMO and other Extracorporeal Devices chairs: Christiane Garnemark and Dick Tibboel
10:45 – 11:10	Pharmacology during ECMO: How to dose drugs in neonates during extracorporeal membrane oxygenation (ECMO) (Genny Raffaeli)20'+5'
11:10 – 11:35	Pharmacology during cardiopulmonary bypass (CPB) (Dick Tibboel)20'+5'
11:35 – 12:00	3 oral presentations from selected abstracts
	Microdosed Yohimbine as CYP2D6 Probe Drug in Pediatric Heart Patients aged 6 Months to 6 Years7' (<u>Victoria C. Ziesenitz</u> , Simon A. Hermann, Kathrin Förster, Patrick Saur, Kristine Chobanyan-Jürgens, Jürgen Burhenne, Gerd Mikus, Matthias Gorenflo)

Medical Cannabis for Children with Autistic Spectrum Disorder: Is there a difference between those treated with cannabis as monotherapy vs those treated with cannabis and concomitant conventional medications? 7'
(Adi Dagan, Orit Stolar, Elkana Kohn, Ariela Hazan, Ibrahim Abu-Kishk, Dana Barchel, Nir Treves, Eli Heyman, Mirit Lazinger, Matitiahu Berkovitch)

Individualized Use of 6-mercaptopurine in the Maintenance Treatment of Chinese Children with Acute Lymphoblastic Leukemia: A Multicenter Randomized Controlled Trial 7'
(Yue Zhou, Li Wang, Li-Rong Sun, Li Zhang, Hong-Mei Wang, Xi-Ting Liu, Fan Yang, Ke-Liang Wu, Yu-Li Liang, Bei-Bei Zhao, Yong Zhuang, Jin-Qiu Fu, Ling-Zhen Wang, Hui-Juan Xu, Yan Gu, John van den Anker, Xiu-Li Ju, Xiao-Fan Zhu, Wei Zhao)

discussion..... 3'

12:00 – 13:00 *lunch break*

13:00 – 14:00 Poster walk II
Anne Smits and Pieter de Cock

14:00 – 15:15 Session 7:
Pharmacology and Pharmacotherapy of Rare Diseases in Neonates and Children
chairs: Jenny Kindblom and Florian Lagler

14:00 – 14:25 **Pharmacotherapy in children with inherited metabolic disorders**
(Jiří Zeman) 20'+5'

14:25 – 14:45 **Assessing the expected clinical benefit of gene therapy in rare diseases – a pharmacological perspective**
(Florian Lagler) 15'+5'

14:45 – 15:05 **Pharmacoeconomics of rare diseases**
(Aleš Klímek) 15'+5'

15:05 – 15:15 1 oral presentation from selected abstracts
A Precision Medicine Tool for High Utilization and Quality of Individual Treatment Trials with Immunomodulatory Drugs in Mucopolysaccharidosis
(Anna-Maria Wiesinger, Brian Bigger, Roberto Giugliani, Christina Lampe, Maurizio Scarpa, Tobias Moser, Christoph Kampmann, Georg Zimmermann, Florian B Lagler)..... 7'+3'

15:15 – 15:45 *coffee break*

15:45 – 17:00 Session 8:
Pharmacology in Neonatal and Paediatric Critical Care and Legal, Operational and Regulatory Aspects
chairs: Evelyne Jacqz-Aigrain and Wei Zhao

15:45 – 16:10 **Enpr-EMA update 2023**
(Pirkko Lepola) 20'+5'

16:10 – 16:30 **Pharmacology of antimicrobial agents in critically ill neonates and children**
(Wei Zhao) 15'+5'

CONGRESS PROGRAMME

16:30 – 16:50	Off-label and off evidence? Towards all children effective and safe therapy (Saskia de Wildt) 15'+5'
16:50 – 17:00	1 oral presentation from selected abstracts Availability of Neonatal Specific Data in Labelling of Commonly Used Anti-infective Drugs: Comparison Among Three Regulatory Agencies (<u>Ajilan Sivaloganathan</u> , Kate Sushko, John van den Anker, Samira Samiee-Zafarghandy)7'+3'
17:00 – 18:00	“Round table” Perspectives of Clinical Pharmacology at Different Levels of Education
...	
19:00	<i>congress dinner</i>

FRIDAY

JUNE 30TH

09:00 – 10:15 **Session 9:**

Innovative Tools in Clinical Pharmacology I: Artificial Intelligence in Clinical Pharmacology chairs: **Synnove Lindemalm and Ilan Matok**

- 9:00 – 9:25 **Genotranslation: Interpretation of genome data in diagnostic and treatment**
(Milan Macek) 20'+5'
- 9:25 – 9:45 **Assessing medication safety in pregnancy and paediatrics using big data
and the potential of using artificial intelligence**
(Ilan Matok) 15'+5'
- 9:45 – 10:05 **Children's drug safety programme – sharing Swedish experiences**
(Synnove Lindemalm) 15'+5'
- 10:05 – 10:15 1 oral presentations from selected abstracts
Drug-drug interactions and adverse drug reactions in neonates
(Nadir Yalcin) 7'+3'
- 10:15 – 10:45 *coffee break*

10:45 – 12:00 **Session 10:**

Innovative Tools in Clinical Pharmacology II: The FAIR Principle in Clinical Pharmacology Chairs: **Jenny Kindblom and Jeff Barrett**

- 10:45 – 11:10 **Scientific collaboration both in terms of data sharing and the development
of opensource computing tools**
(Jeff Barrett) 20'+5'
- 11:10 – 11:35 **Conec4children, the pan-European paediatric clinical research network:
advice, education, sites, and data**
(Mark Turner) 20'+5'
- 11:35 – 12:00 3 oral presentations from selected abstracts
Artificial intelligence for the safe use of medications during breastfeeding
..... 7'
(Elkana Kohn, Guy Shtar, Maya Berlin, Bracha Shapira, Lior Rokach, Matitiahu Berkovitch)
- Use of Machine Learning for Dosage Individualization of Vancomycin in
Neonates** 7'
(Bo-Hao Tang, Jin-Yuan Zhang, Karel Allegaert, Guo-Xiang Hao, Bu-Fan Yao, Stephanie Leroux, Alison H. Thomson, Ze Yu, Fei Gao, Yi Zheng, Yue Zhou, Edmund V. Capparelli, Valerie Biran, Nicolas Simon, Bernd Meibohm, Yoke-Lin Lo, Remedios Marques, Jose-Esteban Peris, Irja Lutsar, Jumpei Saito, Evelyne Jacqz-Aigrain, John van den Anker, Yue-E Wu, Wei Zhao)
- Open-science solutions enabled within a digital research environment to
support pediatric drug development and precision dosing** 7'
(Jeff Barrett, Scott Russell)

discussion..... 3'

12:00 – 13:00 Current and Future Directions of ESDPPP
Summary by President ESDPPP (Pavla Pokorná),
President Elect (Saskia de Wildt)
and General Secretary (Florian Lagler)

13:00 Closing the meeting

WEDNESDAY JUNE 28TH

13:00 – 14:00 Poster walk I – Paediatrics

Moderators: Saskia de Wildt and Sinno Simons

- 1) **m-Health Clinic Partnership Project between HHU Düsseldorf and Bosnia-Herzegovina: Creation of a digital network of Diabetes Type 1 children and adolescents in rural and remote areas in Bosnia and Herzegovina**
Obarcanin, Emina, Hasanbegovic, Snijezana, Rustempasic, Elma, Ali-Sherazi, Bushra, Kinny; Florian, Laeer, Stephanie
- 2) **A First-In-Human Phase 1 Study of SIM0417, a 3CL-like Protease Inhibitor for Treatment of COVID-19, in Healthy Adult Subjects**
Xin-Mei Yang, Yang Yang, Bu-Fan Yao, Pan-Pan Ye, Yan Xu, Shao-Ping Peng, Yu-Mei Yang, Pan Shu, Pei-Jin Li, Shan Li, Hong-Lin Hu, Qian Li, Lin-Lin Song, Ke-Guang Chen, Hai-Yan Zhou, Ye-Hui Zhang, Fu-Rong Zhao, Bo-Hao Tang, Wei Zhang, Xin-Fang Zhang, Shu-Meng Fu, Guo-Xiang Hao, Yi Zheng, Jing-Shan Shen, Ye-Chun Xu, Xiang-Rui Jiang, Lei-Ke Zhang, Ren-Hong Tang, Wei Zhao
- 3) **Melatonin dosing in children and adolescents in relation to age and overweight status**
Elin Kimland, Elin Dahlén, Jari Martikainen, Jimmy Céline, Jenny M Kindblom
- 4) **Up to one third of rapid thiopurine-S-methyltransferase metabolizers manifest clinical and/or laboratory Azathioprine side effects: A single centre experience**
Nabil El-Lababidi
- 5) **Therapeutic Drug Monitoring of Lacosamide among Children with Refractory Epilepsy: Is it Helpful?**
Rinat Komargodski, Mirit Lezinger, Daniel Sharon, Majdi Masarwi, Nurit Brandriss, Adina Bar-Chaim, Elkana Kohn, Eli Heyman, Matitahu Berkovitch
- 6) **Development of a Suspicion Index Tool to Aid Diagnosis of ASMD Disease**
Anna-Maria Wiesinger, Georg Zimmermann, Nicole Muschol, Charlotte Aries, Daniela Karall, Sabine Scholl-Bürgi, Dorothea Möslinger, Vasiliki Konstantopoulou, Eugen Mengel, Roberto Giugliani, Florian B Lagler
- 7) **Antiepileptic Drug Use in Children Beyond Epilepsy: a Population-based Longitudinal Study**
Hans Jürgen Gober, Kathy H Li, Bruce C Carleton
- 8) **Saliva Sampling to Facilitate Pharmacokinetic Studies in Children: A Case Study with Metamizole**
Marion Anliker-Ort, Frédérique Rodieux, Victoria Ziesenitz, Thomas O. Erb, Stefan Holland-Cunz, Urs Duthaler, Deborah Rudin, John van den Anker, Marc Pfister, Verena Gotta
- 9) **Can Pupillometry Be Used For CYP2D6 Phenotyping In Children Treated With Tramadol?**
Rodieux Frédérique, Flavia Storelli, Francois Curtin, Sergio Manzano, Alain Gervaix, Klara Posfay Barbe, Jules Desmeules, Youssef Daali, Caroline Flora Samer
- 10) **Utilization of pharmacogenetic medications at a German pediatric University Hospital**
Igor Bachmat, Sonja Eberl, Wolfgang Rödle, Filippa Schreeck, Matthias Schwab, Antje Neubert

- 11) Five-Year Report on the Activities of the Connect4Children (c4c) European Paediatric Clinical Trials Network in Belgium**
Eva Degraeuwe, Laura Persyn, Mark Turner, Lieve Nuytinck, Annelies De Maré, Daphné Christiaens, Ann Raes, Karel Allegaert, Johan Vande Walle
- 12) Czech National Centre: Potential for improving pharmacotherapy in the paediatric population in the Czech Republic and Slovakia**
Lucie Špatenková, Sabina Pavlíková, Natálie Sladká-Švestková, Martina Bašková, Ondřej Slanař, Mark Turner, Pavla Pokorná
- 13) An Update on the Challenges of Conducting Pediatric Clinical Trials: 15 Years of Progress since EMA Regulation Implementation**
Eva Degraeuwe, Pirkko Lepola, Mark Turner, Kim Jennings, Lieve Nuytinck, Ann Raes, Karel Allegaert, Johan Vande Walle, Fenna Mahler
- 14) Empowering the Next Generation: How the young ESDPPP Community is Nurturing Young Paediatricians and Pharmacology Experts**
Eva Degraeuwe, Anna-Maria Wiesinger, Florian B. Lagler, Ann Raes, Johan Vande Walle, Mark Turner, Paula Pokorna, Young ESDPPP community
- 15) When the child vomits after oral drug intake - development and introduction of a decision support**
Christiane Garnemark, G Lernfelt, AL Eriksson, JM Kindblom

THURSDAY JUNE 29TH**13:00 – 14:00 Poster walk II – Neonatology****Moderators: Anne Smits and Pieter de Cock**

- 16) **Pharmacotherapy-related practices and skills as reported by attendees of the Neonatal Online Training and Education (NOTE) course on neonatal clinical pharmacology**
Karel Allegaert, Dotan Shaniv, Sinno Simons, Robert Flint, Anne Smits, Susan Smith, Mike Hall
- 17) **Prescribing Behavior of Analgosedatives for Extremely Premature Neonates: A Retrospective Analysis**
Samir El Abdouni, GE van den Bosch, F van Rosse, SHP Simons, RB Flint
- 18) **Implementation processes in pain assessment in the NICU: an interactive Meet the pain “tutorial”**
Hana Jancova, Radek Janca, Magdalena Zadakova, Pavla Neradova, Radka Samonilova, Zuzana Tomaskova, Martina Baskova, Pavla Pokorna
- 19) **Pharmacokinetics of Intravenous Fentanyl in Neonates, a Systematic Review**
Kristian Ashali, Kate Sushko, John van den Anker, Samira Samiee-Zafarghandy
- 20) **Accuracy of antibiotic concentrations in drug dispensing: a risk for low doses in neonates**
Li-Yuan Zheng, Wei-Ping Gu, Na Liang, Li-Li Gao, Wen-Wen Guo, Xin Wang, Rui-Rui Li, John van den Anker, Yue-E Wu, Wei Zhao
- 21) **Population pharmacokinetics of meropenem in neonatal and pediatric extracorporeal membrane oxygenation: a retrospective pilot study (preliminary analysis)**
Danica Michaličková, Jonas Berner, Dick Tibboel, Pavla Pokorná
- 22) **No difference in the incidence of hearing loss after introducing a vancomycin loading dose in neonates: A single center analysis of a tertiary NICU**
Shannon L. van der Zeeuw, Anne Smits, Karel Allegaert, Catherijne A.J. Knibbe, Swantje Völler
- 23) **Drug treatment of neonatal seizures by neonatologists and paediatric neurologists: A survey of practice in Australia and New Zealand**
Angela Williams, Kathryn Browning Carmo, John Lawson, Christine Staatz, Helen Liley
- 24) **Clinical endpoints for phenobarbital in neonatal trials**
Natalie Sladká Švestková, Pokorná Pavla, Ondřej Slanář
- 25) **Correlation between maternal, fetal and neonatal digoxin and flecainide concentrations and (side) effects in mother and child, treated for fetal supraventricular tachycardia – a case series to improve dosing**
Rosa M.A. Smeets, Jérôme M.J. Cornette, Johanna A. van der Zande, Ingrid M. van Beynum, Jolien W. Roos-Hesslink, Robert B. Flint
- 26) **Prenatal Cannabis Exposure and the Risk for Neuropsychiatric Anomalies in the Offspring: A Systematic Review and Meta-Analysis**
Ilan Matok, Hely Basalov, Noa Yakirevich Amir, Inbal Reuveni, Omer Bonne

- 27) Don't cry over spilt milk: Women treated with medications CAN (in many cases) donate milk to a Human Milk Bank**
Tal De-Haan, Maya Berlin, Elkana Kohn, Sharon Bransburg- Tzabari, Matitiahu Berkovitch
- 28) I am a law student treated with amphetamines for Attention Deficit Hyperactive Disorder (ADHD): Can I breastfeed my child? A pilot study**
Nofar Benassayag Kaduri, Ariela Hazan, Tal De- Haan, Elkana Kohn, Maya Berlin, Matitiahu Berkovitch
- 29) Determining the concentration of maternal medicines in human milk: the UmbrellACT study protocol**
Martje Van Neste, Nina Nauwelaerts, Michael Ceulemans, Kristel Van Calsteren, An Eerdeken, Pieter Annaert, Karel Allegaert, Anne Smits