**International Symposium on Pediatric Drug Evaluation and Clinical Pharmacology**

**Date and time:** June 30, 2018, 08:15 to 18:15

**Venue:** Main Auditorium
National Center for Child Health and Development (NCCHD)
2-10-1 Okura, Setagaya-ku, Tokyo, JAPAN 157-8535

**Date and time:** 2018年6月30日土曜日7時45分受け付け開始、8時15分-18時15分

**Venue:** 東京都世田谷区大蔵2-10-1国立成育医療研究センター講堂
（入退館は、病院西側の防災センター・救急外来入り口より）

**共催:** 「小児医薬品の実用化に資するレギュラリーサイエンス研究」研究班
日本小児臨床薬理学会（JSDPT）

**参加費:** 無料
※: 当日は日本語・英語両方向の同時通訳が入ります。

**Program**

07:45-

**Open for registration 受付開始**

08:15-08:30

**Opening remarks 開会挨拶**

Takao Takahashi President, Japan Pediatric Society

**Congratulatory speech by a guest of honor 来賓挨拶（依頼中）**

Makoto Suematsu (TBC) President, Japan Agency for Medical Research and Development

08:30-10:00

1. **Networks for pediatric drug development and possible collaboration 小児医薬品開発ネットワークと国際連携**

   **Chairs:** Mark Turner, University of Liverpool
   Hidefumi Nakamura, NCCHD

   1) Japanese situation Masao Nakagawa, Kyoto Kizugawa Hospital
   2) EU, Connect4Children Mark Turner, University of Liverpool, UK
   3) US Ed Conner from iACT and/or from other network, US
   4) Discussion
10:00-10:20  Coffee Break

10:20-11:50

2. **International Neonatal Consortium and better medicines for neonates** 新生児医薬品開発国際シンポジウムの活動
   Chairs: Karel Allegaert  University of Leuven, NL  
           Kusuda Satoshi  Kyorin University
   1) Introduction and overview  Mark Turner, University of Liverpool, UK
   2) AE grading  Karel Allegaert, University of Leuven, NL
   3) Data WG  Shinya Hirano, Osaka Women’s and Children’s Hospital
   4) PMDA: collaboration with FDA/EMA  Junko Sato, PMDA

11:50-12:50  Lunch Break (Lunch will not be served to general audience)

12:50 -14:30

3. **Pediatric Clinical Pharmacology Research toward Precision Dosing: Now and Future** 小児薬理評価と個別化治療
   Chairs: Tsuyoshi Fukuda  Cincinnati Children’s Hospital Medical Center, US  
           Sara Van Driest  Vanderbilt University, US
   1) Pediatric Pharmacogenomics: Getting To and Beyond Genotype-Guided Prescribing  
      Sara Van Driest,  Vanderbilt University, US
   2) Clinical evidence essential to PGx informed Precision Medicine in Pediatrics  
      Keiko Hikino,  RIKEN Center for Integrative Medical Science
   3) Antibiotic pharmacometrics in pediatric patients: What is needed at the frontline of clinical practice?  
      Kensuke Shoji,  NCCHD
   4) Population Model-Based Approach in Neonates and Infants: Tips, Tricks and Traps  
      Wei Zhao,  Shandong University, China
   5) PBPK modeling as a knowledge-integrating methodology: Tips in Pediatrics  
      Chie Emoto,  Cincinnati Children’s Hospital Medical Center, US
   6) Sample size and other design considerations for PK/PD studies in children  
      Hanneke van der Lee,  Emma Children’s Hospital, NL

14:30-14:50 Coffee break
4. Toward the international collaboration for better pediatric formulation 小児剤形検討の国際連携にむけて

Chairs: Takahiro Matsumoto, Daiichi Sankyo
       Junpei Saito, NCCHD

1) Paediatric formulations: Challenges or opportunities
   Catherine Tuleu UCL School of Pharmacy, UK

2) The current status and issues of pediatric formulation in Japan
   Junpei Saito NCCHD

3) Introduction of drug products with some pharmaceutical technologies
   a Coating of granules and pills for taste masking
      Masanori Kobayashi Astellas Pharma Inc.
   b Design of functional granules
      Shin Sugimoto Kowa Co., Ltd.

4) Pharmaceutical technology to support pediatric formulation development
   c Fine particles coating technology for targeting pediatric drug ormulation
      Shigemi Isobe Freund Corp.
   d Continuous fluidized bed apparatus CTS-SGR capable of continuous production of fine particle
      API Granule for mini and/or OD tablet manufacturing
      Naotoshi Doi Powrex Corp.

5) Prospects for Collaboration of Pediatric Formulation Research
   Tsutomu Harada Showa University

6) Discussion

5. Training and Education 小児薬開発と臨床薬理評価の教育・トレーニング

Chairs: Shinya Ito The Hospital for Sick Children, CA
        John van den Anker University of Basel, CH, and Children’s National Medical Center, US

1) Introduction Shinya Ito, The Hospital for Sick Children, CA

2) Training/Education at C4C Francesca Rocchi (TBC), Ospedale Pediatrico Bambin Gesù, Italy

3) Chinese situation Wei Zhao, Shandong University, China

4) African situation Natella Rakhmanina, George Washington University, US

5) Japanese pharmacists Toshiya Fuke, Ozawa Hospital

6) Japanese pediatricians Masanobu Takeuchi, Yokohama City University

7) Perspective from the Japan Society for Developmental Pharmacology and Therapeutics
   Kou Kawada, Setsunan University

8) Discussion
17:50-18:10

6. **Discussion/Scope for the future**  総合討論

18:10

**Closing remarks**  閉会挨拶:

Kazuyuki Saito,  Director, Center for Clinical Research, NCCHD