

AMED 臨床研究・治験推進研究事業
「小児領域における新薬開発促進のための医薬品選定等に関する研究」
研究班主催
-小児医薬品評価・小児薬理国際シンポジウム-
International Symposium on Pediatric Drug Evaluation
and Clinical Pharmacology

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

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: Main Auditorium

National Center for Child Health and Development (NCCHD)

2-10-1 Okura, Setagaya-ku, Tokyo, JAPAN 157-8535

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)

<http://www.ncchd.go.jp/access/index.html>

共催: 「小児医薬品の実用化に資するレギュラト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

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|-------------------------|---------------------------------------------------|
| 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

14 :50-16:20

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 formulation
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

16:20-17:50

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