

Development and appropriate use of drugs for new-born infants to children

Organizer :	Ichiro Ieiri	Department of Clinical Pharmacokinetics, Graduate School of Pharmaceutical Sciences, Kyushu University
Chair :	Masayuki Suzuki	Mitsubishi Tanabe Pharma Corporation
	Yoshimichi Sai	University Hospital, Kanazawa University

SY-08-01

Current status of pediatric drug development in the US, EU and Japan

Hidefumi Nakamura

Center for Clinical Research and Development, National Center for Child Health and Development

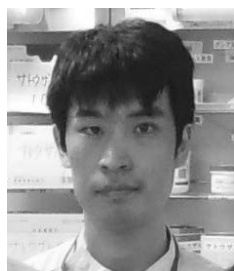


Hidefumi Nakamura, MD, PhD is the Director for Clinical R&D, Clinical Research Center, NCCHD, Tokyo. He is a pediatrician, a pediatric pharmacologist and a clinical trialist trained at the National Medical Center, Tokyo, Hospital for Sick Children, Canada and the Rainbow Babies and Children's Hospital, USA. He also has experience as a senior reviewer at the Japanese regulatory agency, PMDEC. He has been involved in 70+ industry-sponsored and 25+ investigator-initiated multi-center clinical trials in Japanese children. He is currently involved in several national and international activities including the following: the advisory board for the PMDA, the Pediatric WG for the Expert Panel for Off-label and Unlicensed Drugs, the Committee on Pharmaceutical Affairs of Japan Pediatric Society, the Steering Committee for the Japan Society of Developmental Pharmacology and Therapeutics, the Coordinating Committee of the International Neonatal Consortium, and the executive committee of the Pediatric Clinical Pharmacology Section of IUPHAR.

SY-08-02**The current states and issues regarding pediatric formulation in Japan: How can we facilitate the age-appropriate drug development?**

Jumpei Saito

Department of Pharmacy, National Center for Child Health and Development



2007. 4 - 2009. 3

Kyushu University, Graduate School of Pharmaceutical Sciences, Department of Clinical Pharmacokinetics, Master of Pharmaceutical Sciences

2009. 4 - 2012. 3

Kyushu University, Graduate School of Pharmaceutical Sciences, Department of Clinical Pharmacokinetics, Doctor of Philosophy in Pharmaceutical Sciences

2012. 4 -

Pharmacist, Department of Pharmacy, National Center for Child Health and Development

2018. 4 -

Researcher, Division of Clinical Pharmacology and Oral Formulation Development, Department of Clinical Research, National Center for Child Health and Development

SY-08-03**Clinical trials of oral propranolol (hemangioma syrup for pediatric) in infantile hemangioma**

Tomoki Takechi

Drug Development Laboratories, Kyoto R&D Center, Maruho Co., Ltd.



2004

MSc, Kyoto Prefectural University

2004-2007

Kyorin Pharmaceutical Co., Ltd.

2007-present

Maruho Co., Ltd

2018

Ph.D., Graduate School of Pharmaceutical Sciences, Kyushu University

SY-08-04

Clinical trials and researches in drug development companies -(2) Clinical trials of direct oral anticoagulants in the pediatric population-

Takahiko Tanigawa

Clinical Sciences Japan, Bayer Yakuhin, Ltd



He is currently head of Clinical Sciences Japan at Bayer Yakuhin, Ltd. Prior to that, he was head of clinical pharmacokinetics for oncology at Bayer Pharma AG in Germany from 2012 to 2015. He has a lot of experiences for clinical drug development in global base as a clinical pharmacologist, such as strategy and study design making, bioanalytical works, population PKPD analysis and so on. He is a member of the clinical evaluation department, drug evaluation committee of Japan Pharmaceutical Manufacture Association (JPMA) since 2013.

SY-08-05

Clinical trials and researches in drug development companies -(3) Lessons and learnt from clinical trials conducted by pharma industries-

Kimio Terao

Clinicalpharmacology Dept, Chugai Pharmaceutical co ltd.



1990: Graduated from Department of Chemistry, Faculty of Science, Chiba University.
1992: Graduated from Faculty of Science and Graduate School of Science
1992: Chugai Pharmaceutical co., Ltd. (Central Research lab)
2000: Chugai Pharmaceutical (Clinical pharmacology)
2015~ Heading of Clinical pharmacology in Chugai Pharmaceutical co ltd