

The 27th Workshop of the Japanese Society for the Study of Xenobiotics

From Human PK Prediction to Efficacy/Safety Prediction - A roadmap of the revolutionary period for drug metabolism and pharmacokinetic research-

Hitotsubashi Hall (Gakujutsu Sogo Center), Tokyo

May 9 - 10, 2013

May 9th (Thu)

14:50~15:00

Opening Remarks

Toshiyuki Kume, DMPK Research Laboratories, Mitsubishi Tanabe Pharma Corporation

15:00~15:50

Prediction of pharmacokinetics taking disease states and interindividual differences into account

Yuichi Sugiyama, RIKEN Innovation Center, RIKEN

15:50~16:40

MicroRNAs as potential biomarkers for drug safety and efficacy

Tsuyoshi Yokoi, Drug Metabolism and Toxicology Faculty of Pharmaceutical Sciences, Kanazawa University

16:40~17:10 (Break)

17:10~18:00

A value of biomarker/M&S data in regulatory review for drug approval

Yoshiaki Uyama, Pharmaceuticals and Medical Devices Agency

18:40~20:30 (Banquet at Gakushi Kaikan)

May 10th (Fri)

Theme 1: Pharmacokinetics in Disease States and Prediction of Drug Efficacy and Safety

9:40~10:25

Clinical Pharmacology of Drug Transporters: Influence of Disease on Functional Change

Satohiro Masuda, Department of Pharmacy, Kyoto University Hospital

10:25~11:00

Pharmacokinetics and Pharmacodynamics of Tolvaptan in the heart failure patients

Seong Ryul Kim, Division of Clinical Research & Development, Clinical Pharmacology, Otsuka Pharmaceutical Co., Ltd.

11:00~11:35

Population pharmacokinetic (PPK) analysis of S-1 in Western patients with solid cancer
Ken-ichiro Yoshida, Pharmacokinetics Research Laboratory, Taiho Pharmaceutical Co., Ltd.

11:35~13:00 (Lunch break)

(11:55~12:40 : Luncheon seminar)

Theme 2: Prediction of Drug Efficacy using M&S and Biomarkers

13:00~13:45

Issues in Disease Modeling: A Case for Alzheimer's Disease

Akihiro Hisaka, Pharmacology and Pharmacokinetics, The University of Tokyo Hospital

13:45~14:20

Pre-clinical M&S that is useful for clinical development: clinical M&S perspective

Kazutaka Yoshihara, Translational Medicine & Clinical Pharmacology Dept., Daiichi Sankyo Co., Ltd.

14:20~14:40 (Break)

14:40~15:15

Recent Advance in Translational Modeling and Simulation

Peter Bonate, Global Head Clinical PK and M&S, Astellas Pharma Inc.

15:15~15:50

A Novel Pharmacodynamic Modeling Approach to Determine Long Term Disease Progression

Rates in Japanese Type 2 Diabetes Patients: Pioglitazone vs. Conventional Therapy

Fran Stringer, Clinical Data Science Dept. Takeda Development Center Japan, Pharmaceutical Develop. Div. Takeda Pharmaceutical Co. Ltd

15:50~16:10 (Break)

Theme 3: Prediction of Drug Safety using M&S and Biomarkers

16:10~16:45

Assessment of safety and DDI in human using PBPK models

Hidenori Matsushita, Pharmacokinetics Research Laboratories, Dainippon Sumitomo Pharma Co., Ltd.

16:45~17:20

Pros & Cons for biomarkers: Focusing on renal transporters related to TK and DDI estimation

Yuichiro Imamura, Drug Metabolism & Pharmacokinetics Research Laboratories, Daiichi Sankyo Co., Ltd.

17:20~17:55

Current activity and challenges of JPDS, an approach to personalized medicine

Shyh-Yuh Liou, Clinical Pharmacology, Clinical Data Science Dept. Takeda Development Center Japan, Pharmaceutical Develop. Div. Takeda Pharmaceutical Co. Ltd

17:55~18:00

Closing Remarks

Toshiyuki Kume, DMPK Research Laboratories, Mitsubishi Tanabe Pharma Corporation