

The 1st Asian Pharmacometrics Conference 2017 (APC 2017)

and

The 33rd Meeting of Population Approaches in Japan (PAGJa)

Sharing experiences on pharmacometrics, population approach,
and PK/PD modeling among Asian countries

26th and 27th, October 2017
Fujita Commemorative Lecture Hall
Kyoto University, Faculty of Pharmaceutical Sciences,
Kyoto, Japan
Hosted by: Population Approach Group in Japan (PAGJa)

Message from the President of PAGJa

On behalf of the organizing committee, I would like to cordially invite you to the “The 1st Asian Pharmacometrics Conference 2017 (APC 2017)”, which will be held in collaboration with the Professional Committee of Pharmacometrics in China (PCPC), Population Approach Group in Korea (PAGK), and Population Approach Group in Japan (PAGJa).

The PCPC, PAGK and PAGJa have organized A3 Pharmacometric Symposium until 2016, and agreed to expand to the Asian Pharmacometrics Conference where all Asian pharmacometricians can gather and exchange the science and application of pharmacometrics in Asia. The 1st APC is held at Fujita Commemorative Lecture Hall, Kyoto University, Faculty of Pharmaceutical Sciences, Kyoto, Japan on 26th and 27th October, 2017, hosted by PAGJa. The major theme is “Sharing experiences on pharmacometrics, population approach and PK/PD modeling among Asian countries”. This symposium should provide important opportunities to share professional experiences and create networks among pharmacometricians in Asian countries.

Thank you for joining the 1st APC 2017 in Kyoto, and I hope that all participants will have a memorable experience and a wonderful time in Kyoto.

Please also join with two satellite workshops held on 25th October:

1. Understanding Classical Estimation Methods of NONMEM
2. Translation of mAb PKPD: Theoretical basis and case studies

We look forward to seeing you at the 1st APC 2017 in Kyoto, Japan.



Yusuke Tanigawara, Ph.D.

Professor of Clinical Pharmacokinetics and Pharmacodynamics
Keio University School of Medicine, Tokyo, Japan

President of Population Approach Group in Japan (PAGJa)

The 1st Asian Pharmacometrics Conference 2017 (APC2017)

✓ Date: 26th(Thu) and 27th(Fri), October, 2017

✓ Location: Fujita Commemorative Lecture Hall, Kyoto University

Time	Contents	Speakers
Day 1 (26 Oct., Thu.)		
10:00 – 12:40	[APC Board Meeting] (Including Lunch, 11:45-12:40)	GROUP PHOTOS
12:00 – 13:00	Registration	
13:00 – 13:05	Opening Remarks by President of PAGJa	Yusuke Tanigawara (Keio University, JAPAN)
Opening Session		Coordinated by Yusuke Tanigawara
13:05 – 13:35	“Pharmacometrics in Asia”	Yusuke Tanigawara (Keio University, JAPAN) and Dong-Seok Yim (The Catholic University of Korea, KOREA)
Oral Session 1 (Methodology)		Chair: Qingshan Zheng, Atsunori Kaibara
13:35 – 13:55	“Modeling and simulation of bone mineral density in Japanese osteoporosis patients treated with zoledronic acid using tartrate-resistant acid phosphatase 5b, a bone resorption marker”	Hidefumi Kasai (CERTARA G.K., JAPAN)
13:55 – 14:15	“Evaluating ethnic differences using population pharmacokinetic modeling for bridging studies”	Pei Hu (Peking Union Medical College Hospital, CHINA)
14:15 – 14:35	“Beyond Michaelis-Menten: Accurate and efficient enzyme kinetics”	Jae Kyoung Kim (Korea Advanced Institute of Science and Technology, KOREA)
14:35 – 14:55	“External evaluation of population pharmacokinetic models for mycophenolate mofetil in adult renal transplant recipients”	Zheng Jiao (Huashan Hospital, Fudan University, CHINA)
14:55 – 15:15	“New diagnostics of NONMEM using R”	Kyun-Seop Bae (University of Ulsan, KOREA)
10min. Break (15:15 – 15:25)		
Oral Session 2 (Application 1)		Chair: Kyun-Seop Bae, Takahiko Tanigawa
15:25 – 15:45	“An analysis on distribution and inter-relationships of biomarkers under rivaroxaban in Japanese patients with non-valvular atrial fibrillation (CVI ARO 1)”	Shinya Suzuki (The Cardiovascular Institute, JAPAN)
15:45 – 16:05	“Semi-mechanistic PK modeling incorporating blood-lymphatic distribution for transdermal patch”	Hwi-yeol Yun (Chungnam National University, KOREA)
16:05 – 16:25	“Population pharmacokinetic model for the investigation of age-dependency of vancomycin clearance”	Muhammad Usman (University of Veterinary and Animal Sciences, PAKISTAN)

Poster Session		
16:30 – 17:25	Poster Session	
17:35 – 19:30	RECEPTION	
Day 2 (27 Oct., Fri.)		
** 9:30 – 9:40 Photo of All Speakers and Chairpersons		
Oral Session 3 (Application 2)		Chair: Dong-Seok Yim, Sang-Heon Cho
9:40 – 10:00	“Application of tissue penetration based population pharmacokinetics modelling and simulation technology to optimize treatment regimens of antimicrobial agents”	Jing Zhang (Huashan Hospital, Fudan University, CHINA)
10:00 – 10:20	“Debates on the allometric exponent for monoclonal antibody”	Soo Hyeon Bae (The Catholic University of Korea, KOREA)
10:20 – 10:40	“The impact of OATP1B1 polymorphisms on tamoxifen treatment in breast cancer patients: A population pharmacokinetics study”	Haitang Xie (Yijishan Hospital of Wannan Medical College, CHINA)
Oral Session 4 (Regulatory)		Chair: Jun Shi, Yoshitaka Yano
10:40 – 11:00	“A case of PMx-based regulatory decision in the approval of a biosimilar”	Seunghoon Han (The Catholic University of Korea, KOREA)
11:00 – 11:20	“Child clinical trials by regulatory requirement in China”	Qingshan Zheng (Shanghai University of Traditional Chinese Medicine, CHINA)
11:20 – 11:40	“Regulatory perspective on pharmacometrics in drug development and modeling & simulation related guidance development in Japan”	Shinichi Kijima (Pharmaceuticals and Medical Devices Agency, JAPAN)
10min. Break (11:40 – 11:50)		
Keynote Lecture		Chair: Yusuke Tanigawara (JAPAN)
11:50 – 12:35	“Benefit-risk assessment in chronic and rare diseases: The role of pharmacometrics in the development and approval of drugs”	Vikram Sinha (Merck &Co. Inc., USA)
12:35 – 12:40	Closing Remarks for APC by President of PCPC	Qingshan Zheng (Shanghai University of Traditional Chinese Medicine, CHINA)
12:50 – 13:50	Luncheon Seminar (by CERTARA, Japan) マルチコアを用いた並列計算による母集団薬物動態・薬力学解析の計算速度向上の検討 (Slides are in English, but presentation is in Japanese)	Takanori Ogawa (CERTARA, Japan)

The 33rd Meeting of Population Approaches in Japan (PAGJa)

✓ Date: 27th(Fri), October, 2017

✓ Location: Fujita Commemorative Lecture Hall, Kyoto University

Time	Contents	Speakers
27 Oct., Fri.		
8:20 – 9:20	[PAGJa Staff Meeting]	
9:30 - 13:50	APC Meeting, 2nd Day	
PAGJa Meeting		
14:00 – 14:05	Opening Remarks	Yusuke Tanigawara
Young Scientists Session		Chair: H. Kasai, T. Tanigawa
14:05 – 14:25	母集団解析のための試験デザイン検討ツールの開発	鈴木萌子、日本薬科大学 臨床薬学教育センター
14:25 – 14:45	骨肉腫患者におけるメトトレキサートの母集団薬物動態解析	スタッフ由紀子、金沢大学 医薬保健研究域薬学系
14:45 – 15:05	“Adapting a target-mediated drug disposition (TMDD) model to account for delayed Tmax following IV Infusion of a monoclonal antibody”	Hanaka Mimura (Eli Lilly Japan)
15:05 – 15:25	薬物相互作用によるレボドパ血中濃度低下に伴う薬効変動の予測 : Model-based meta-analysis に基づくシミュレーション	柏原祐志、 九州大学大学院薬学研究院
10min. Break (15:25 – 15:35)		
Technical Session		Chair: Akiyuki Suzuki
15:35 – 15:55	“Analysis results metadata implementation”	Chao Wang, Yuguang Zhao FMD K&L, Inc., USA
Educational Session		Chair: Yoshitaka Yano
15:55 – 16:20	ファーマコメトリクスの教育・研究に携わる人材の育成	Naomi Nagai, (Musashino University) 武蔵野大学薬学部 永井尚美
16:20 – 16:30	Closing Remarks	次回 PPK 研究会幹事

Satellite Workshops

Two Satellite Workshops for the 1st APC (Asian Pharmacometrics Conference) 2017

✧ Understanding Classical Estimation Methods of NONMEM (Wed. 25th Oct.)

It is hard to understand the background theory of NONMEM. Lectures and examples will be given to understand the internals of NONMEM. Participants are expected to have basic knowledge of R software (such as package installation) but not of NONMEM. They will produce essentially the same output as in NONMEM with R optimization functions only, without any help of NONMEM.

For more details and registration, please visit <http://pmx.amc.seoul.kr>

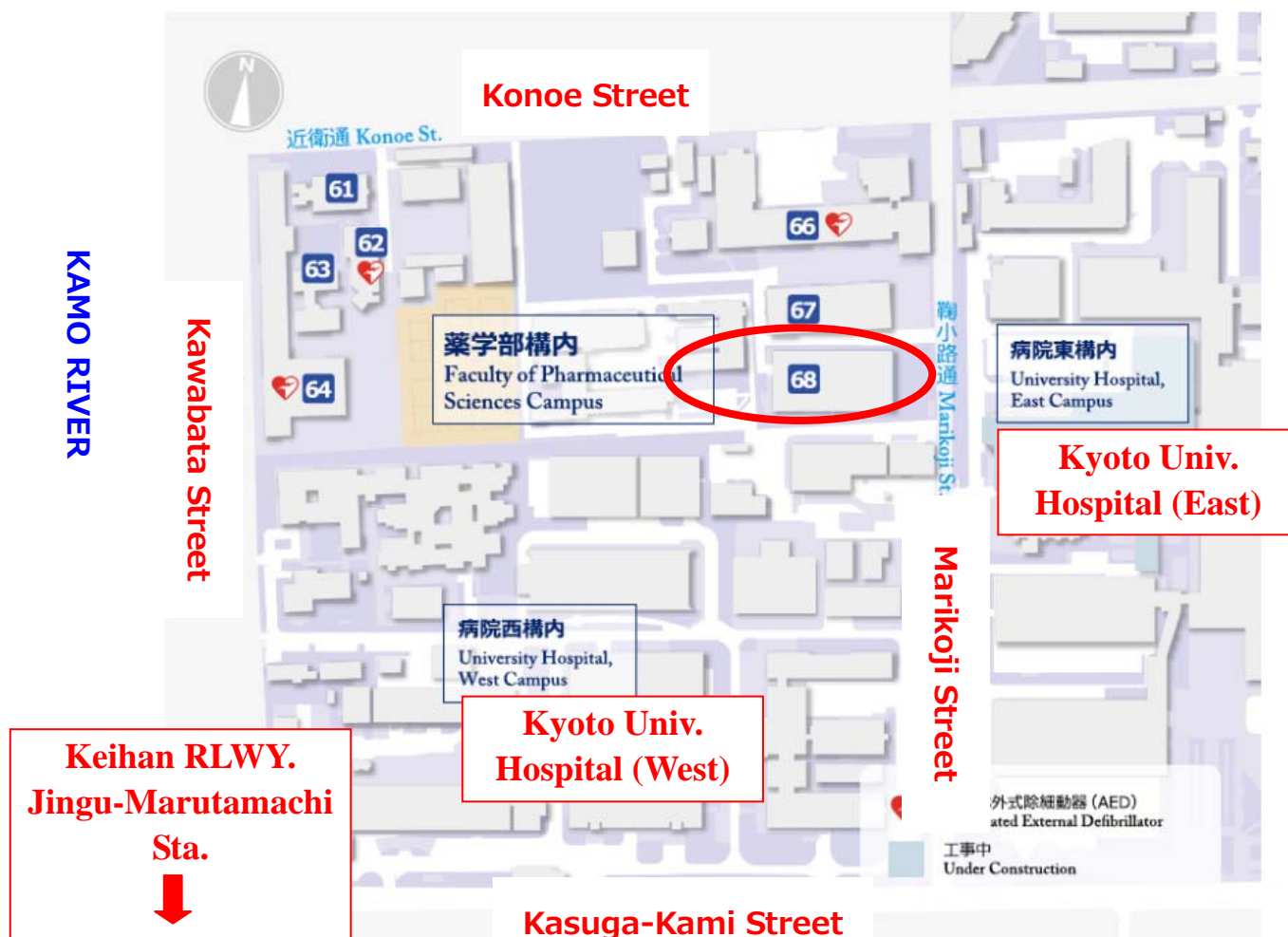
✧ Translation of mAb PKPD: Theoretical basis and Case Studies (Wed. 25th Oct.)

PIPET (Pharmacometrics Institute for Practical Education and Training) of the Catholic University of Korea will give a full day workshop in Kyoto. This is not a typical hands-on modeling workshop, but a course for comprehensive understanding of the PKPD of monoclonal antibodies and its practical application cases in clinical development. The course provides chances to look into theoretical background in physiology and resulting mathematical models as well as interesting cases of translation in human.

For detailed program and registration, please visit <http://pipetws.moou.com>

Location for Conference

- Fujita Commemorative Lecture Hall, Kyoto University
 - ✓ Graduate School and Faculty of Pharmaceutical Sciences, Kyoto University
46-29 Yoshida-Shimo-Adachi-cho, Sakyo-ku, Kyoto 606-8501, Japan
 - ✓ Building No.68 (see Map below)



How to get to Faculty of Pharmaceutical Sciences, Kyoto University

- ◇ From KANSAI (KIX) airport to Kyoto Station
 - By Train – Take JR Line “Haruka Express” to Kyoto Station
 - By Bus – Take a limousine bus (Kansai Airport Transportation) to Kyoto Station.
- ◇ From Kyoto Station to Venue (Faculty of Pharmaceutical Sciences, Kyoto University)
 - By Taxi – ca. 20min.
 - By Bus –
 - ◇ No. 206 (via Higashiyama, get off at Konoe-Dori) 40-50min.
 - ◇ No. 205 or (Via Kawaramachi, get off at Ko-Jin-guchi) 40min, and walk across the Kamo-River (10min)