

2014
Population Approach Group in Korea (PAGK) –
Population Approach Group in Japan (PAGJA)
Joint Meeting
and the 30th PAGJA Annual Meeting

Date: November 7-8, 2014

Place: Translational Research Informatics Center, Kobe, Japan

2014 年度 PAGK-PAGJA 合同研究会
2014 年度 第 30 回 Population Pharmacokinetics 研究会
講演要旨集

2014 年 11 月 7、8 日
臨床研究情報センター（神戸）

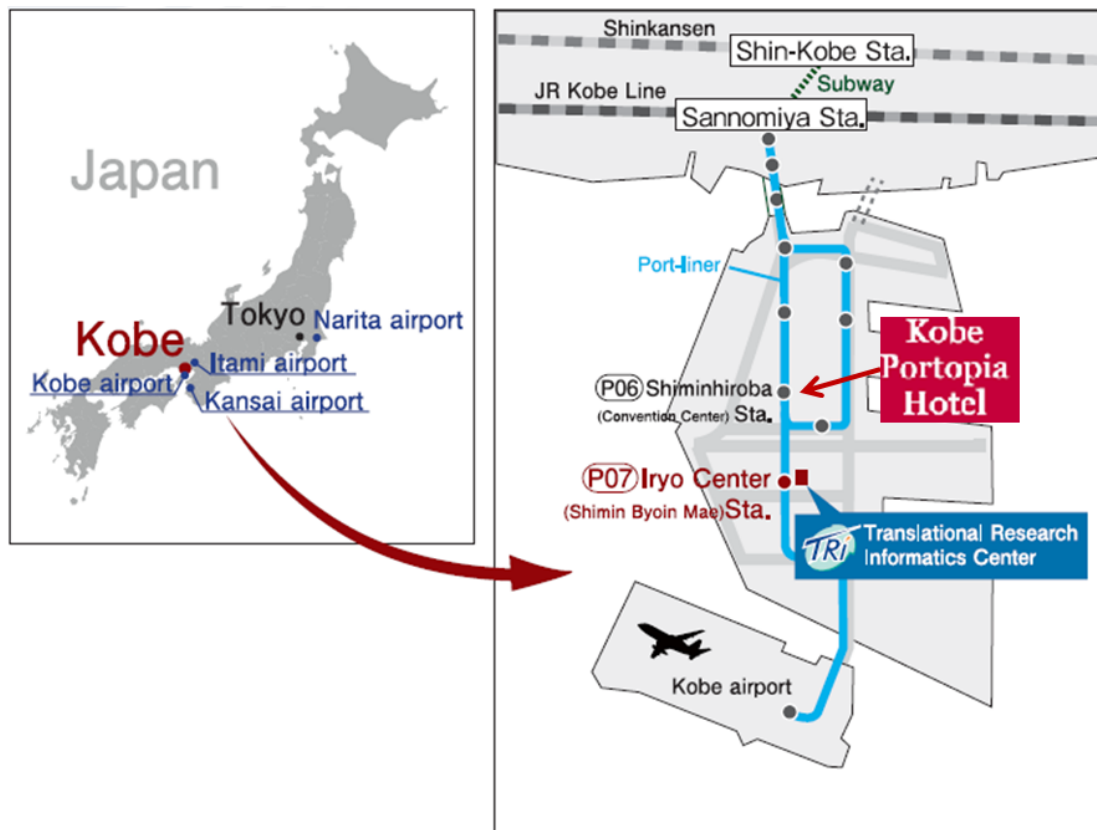
Location Map

Translational Research Informatics Center

1-5-4 Minatojima-Minamimachi, Chuo-ku, Kobe, Hyogo, Japan, 650-0047

Kobe Portopia Hotel

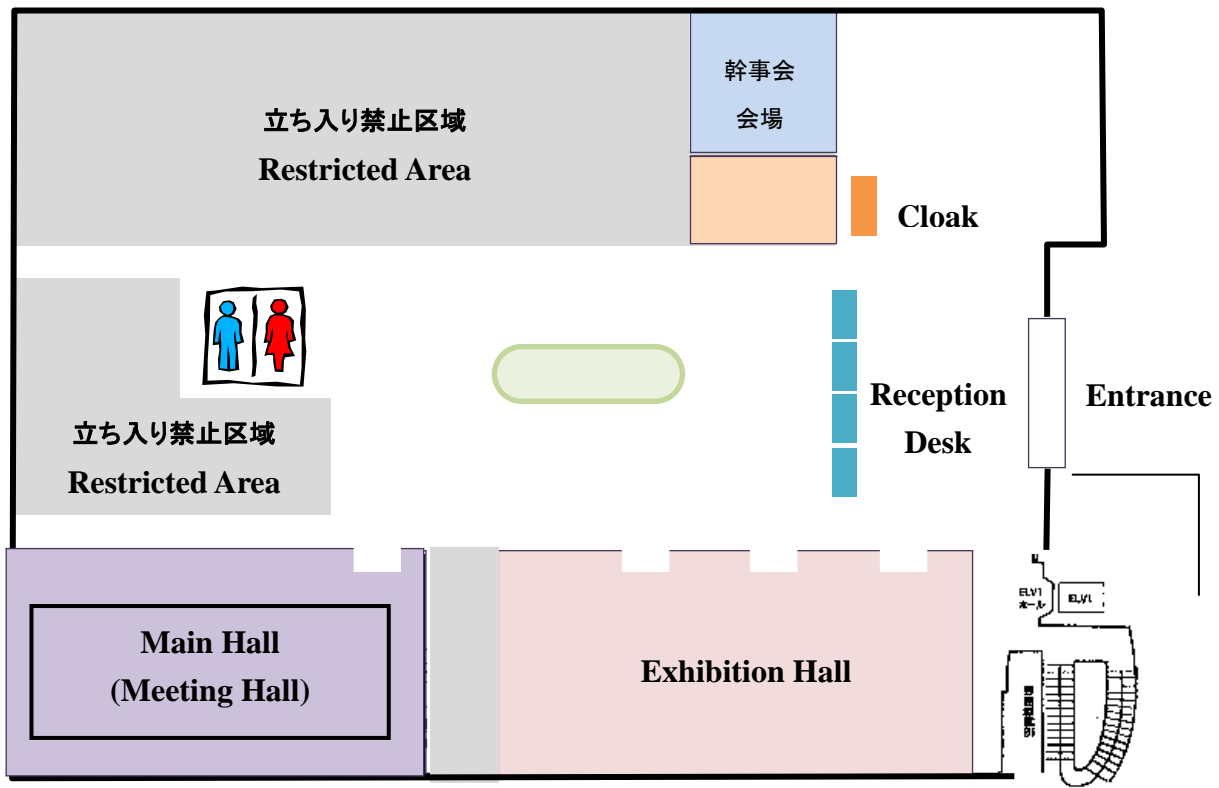
6-10-1 Minatojima Nakamachi, Chuo-ku, Kobe, Hyogo, Japan, 650-0046



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Translational Research Informatics Center (TRI)



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**2014 Population Approach Group in Korea (PAGK)-
Population Approach Group in Japan (PAGJA) Joint Meeting**

Place: Translational Research Informatics Center, Kobe

Nov. 7 (Fri.) [**2014 PAGK-PAGJA Joint Meeting**]

13:00 – 13:05	Opening Remark	<i>Yusuke Tanigawara - President of PAGJA (Keio University, Japan)</i>
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13:05 – 14:45	Session 1. Methodology	Chairs: Kyungsoo Park (Yonsei University, Korea) Atsunori Kaibara (Astellas Pharma, Inc, Japan)
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13:05 – 13:30	An Example of Adaptive Phase I Clinical Trial Design Using PK-PD Modeling and Simulation	Seunghoon Han (Catholic University, Korea)
13:30 – 13:55	Investigation of the Relationship between Biomarker and Endpoint – a Simulation Study –	Chihiro Hasegawa (Ono Pharmaceutical Co. Ltd., Japan)
13:55 – 14:20	Full Covariate Model Using Fixed Effect and Random Effect	Jung-Woo Chae (Chungnam National University, Korea)
14:20 – 14:45	Theory of Quasi-Random Parametric Expectation Maximization algorithm and its application to Population Modeling Analysis	Takanori Ogawa, Hidefumi Kasai (CERTARA G.K., Japan)
14:45 – 15:00	<i>Coffee Break</i>	

15:00 – 15:50	Session 2. Application	Chairs: Kyun-Seop Bae (University of Ulsan, Korea) Yusuke Tanigawara (Keio University, Japan)
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15:00 – 15:25	ADAS-Cog Model Identifies Ethnic Differences in Placebo Response in Patients with Alzheimer's Disease	Jae Yong Chung (Seoul National University, Korea)
15:25 – 15:50	Application of Population Pharmacokinetics / Pharmacodynamics for the Clinical Development of Rivaroxaban	Masato Kaneko (Bayer Yakuhin Ltd., Japan)
15:50 – 16:00	<i>Break</i>	

16:00 – 16:50	Session 3. Regulatory	Chairs: In-Jin Jang (Seoul National University, Korea) Naomi Nagai (PMDA, Japan)
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16:00 – 16:25	The Regulatory Status for Drug Review Focusing on Pharmacometrics at MFDS	Kyungshin Lee (MFDS, Korea)
16:25 – 16:50	Advanced Review / Consultation with Electronic Data in PMDA – Regulatory Perspectives on Pharmacometrics in Drug Development –	Shinichi Kijima (PMDA, Japan)

16:50 – 17:00	Closing Remark	<i>Kyungsoo Park - President of PAGK (Yonsei University, Korea)</i>
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17:30 – 19:30 *Reception Party at KOBE PORTPIA HOTEL*

第 30 回 Population Pharmacokinetics 研究会プログラム

Nov. 8 (Sat.) [2014 PAGJA Annual Meeting]

10:00 – 10:05	開会の辞 (Opening Remark)	谷川原祐介 (慶應義塾大学医学部臨床薬剤学) <i>Yusuke Tanigawara (Keio University)</i>
10:05 – 11:05	一般口頭演題 (Oral Session)	座長：矢野義孝 (京都薬科大学) <i>Yoshitaka Yano (Kyoto Pharmaceutical University)</i> 貝原徳紀 (アステラス製薬) <i>Atsunori Kaibara (Astellas Pharma, Inc.)</i>
10:05 – 10:20	親薬物・代謝物同時解析時の母集団アプローチの有用性 Significance of Pharmacometric Modeling of Metabolite Data ○深江真登、加唐誠剛東、五反田圭介、廣田 豪、家入一郎 (九州大学大学院 薬学府 薬物動態学分野)	
10:20 – 10:35	サルにおける行動評価を指標とした PKPD 解析による化合物の選択 Candidates Selection Using PKPD Analysis for Behavioral Scoring in Monkey ○仲丸善喜 (田辺三菱製薬)	
10:35 – 10:50	NONMEM を用いた非線形動態データモデリングの有用性 Significance of Nonlinear Pharmacokinetic Data using NONMEM ○小松完爾 (アステラス製薬)	
10:50 – 11:05	がん化学療法における薬学的副作用対策を考慮した費用対効果に関する モデリング&シミュレーション Modeling and Simulation for Comparative Evaluation of Cost-Effectiveness for Cancer Chemotherapy including Pharmaceutical Care Related to Adverse Events ○矢野義孝、地寄悠吾 (京都薬科大学)	
11:10 – 12:10	ランチョンセミナー (Luncheon Seminar)	座長：矢野義孝 (京都薬科大学) <i>Yoshitaka Yano (Kyoto Pharmaceutical University)</i>
11:10 – 12:10	Population PK 解析のフローの標準化 1) イントロダクション 笠井英史 (サターラ合同会社) 2) Quality Control のための一企業の取組み 豊島純子 (アステラス製薬) 3) "Best Practices and Guidance in Population Modeling" について 鈴木昭之 (ファイザー)	
12:10 – 12:20	Break	
12:20 – 13:10	昼食、ソフトウェアデモンストレーション (サターラ合同会社)	

13:10 – 15:30	Debate Session with PMDA	座長：谷川原祐介（慶應義塾大学医学部臨床薬剤学） <i>Chair: Yusuke Tanigawara (Keio University, Japan)</i>
	PMDA 講師：本間尚子、川名純一、木島慎一、高德敬之、永井尚美、夏井和子	
	論点 1：小児集団を対象とした母集団解析について Topic 1: Population Analysis in Pediatric Patients	
	論点 2：母集団解析に用いるデータの品質管理・品質保証（QC/QA）について Topic 2: Quality Control and Quality Assurance (QC/QA) for Population Analysis Data Set	
15:30 – 15:35	閉会の辞 (Closing Remark)	矢野義孝（京都薬科大学） <i>Yoshitaka Yano (Kyoto Pharmaceutical University)</i>