

講演プログラム (Programs)

A会場 (Room A) October 9 (Wed.)

シンポジウム (Symposium) 1 9 : 30 ~ 12 : 00

PK-PD/TK-TD DIS, Quantitative Pharmacology and Toxicology: Its importance in drug development and regulation

Organizers • Chairs: 鈴木 洋史 東京大学医学部附属病院  
Hiroshi Suzuki The University of Tokyo Hospital  
中井 康博 大正製薬株式会社 開発推進部  
Yasuhiro Nakai Development management, Taisho Pharmaceutical Co., Ltd.

SY-01-01  
CURRENT PROGRESS OF MODELING AND SIMULATION FOR DRUG DEVELOPMENT  
中井 康博  
大正製薬株式会社 開発推進部  
Yasuhiro Nakai  
Development management, Taisho Pharmaceutical Co., Ltd.



1985 Graduate Faculty of Sciences, Kanazawa University  
2008 Received Ph.D. Biopharmaceutics  
1985-1998 Fuji central research, Mochida pharmaceutical Co., Ltd.  
1998-2007 Pfizer Global Research and Development Nagoya  
2007-current Taisho pharmaceutical Co., Ltd.

SY-01-02  
APPLICATION OF SYSTEMS PHARMACOLOGY IN DRUG DISCOVERY  
Neil Benson  
Xenologiq Ltd.



2011– Director Xenologiq Ltd. Denne Hill Business centre, Canterbury. CT4 6HD.  
Lead role in developing a spin out PKPD and systems pharmacology service business.  
2009–Aug2011 Head Systems Pharmacology, Department of Pharmacokinetics, Dynamics and Metabolism. Pfizer Research, Ramsgate road, Sandwich. CT13 9NJ.  
Responsible for 3 internal and 14 external modellers delivering M&S support to local and global research units including Pain and sensory pathways, Allergy and Respiratory and Epigenetics units. Exceeded expectations in the last 5 years out of 6.  
2005–2009 Leader translational PKPD Modelling & Simulation team, Department of Pharmacokinetics, Dynamics and Metabolism. Pfizer Research, Ramsgate road, Sandwich. CT13 9NJ.  
Responsibilities included PKPD modelling and simulation support to the Anti-infectives and Pain Translational Medicine Teams in pre-clinical area up to FIH. Promoted to Associate Research Fellow 2006.  
1999 – 2005 Enzymology team leader, Discovery Biology, Pfizer Research, Ramsgate road,Sandwich. CT13 9NJ.  
Leader of a team of up to 12 laboratory staff involved in the execution of the gene to screen process, involving kinetic characterisation of enzymes, High Throughput assay configuration, mechanistic evaluation of inhibitors and Hit to Lead SAR support. Promoted to Senior Principal Scientist October 2001.  
1993–1999 Mechanistic Enzymology team leader, Molecular Interactions Group at SmithKline Beecham Research Laboratories, New Frontiers Science Park, Harlow, Essex. CM19 5AW.  
Team leader of a Mechanistic enzymology team. Responsibilities included lead optimisation and defining steady state and pre-steady state kinetics of enzyme substrate and inhibitor interactions. Promoted SB05 1994.

SY-01-03  
SYSTEMS-BASED UNDERSTANDING OF TKI CARDIOTOXICITY  
本間 雅  
東京大学医学部附属病院 薬剤部  
Masashi Honma  
Department of Pharmacy, The University of Tokyo Hospital



Mar. 2005- Assistant Professor, Department of Pharmacy, The University of Tokyo Hospital  
Apr.1999 - Feb.2005 Sankyo (currently Daiichi Sankyo) Company, Limited  
-Mar.1999 Graduate School of Pharmaceutical Sciences, The University of Tokyo

SY-01-04

THE VIRTUAL LIVER: A MULTISCALE SYSTEMS BIOLOGY PLATFORM TO STUDY LIVER FUNCTION, DYSFUNCTION AND INJURY

Adriano M. Henney

The Virtual Liver Network University of Heidelberg Germany



Dr. Henney has a Ph. D. in Medicine and many years’ academic research experience, studying cardiovascular disease at the pathological, cellular, molecular and genetic level in laboratories in London, Cambridge and culminating in heading his own molecular genetics group in Oxford. He then moved into industry, spending 13 years with AstraZeneca. Ultimately leading global programmes exploring strategic improvements aimed at reducing drug failure in development, he created and headed a new department that focused on pathway mapping, modelling and simulation, which evolved to establish the practice of Systems Biology, supporting projects in discovery and development, such as Iressa. Since leaving AstraZeneca, Dr. Henney has continued his interest in Systems Biology and Systems Medicine through his company, Obsidian Biomedical Consulting Ltd. He now directs a major €50M German national flagship programme: the Virtual Liver Network, currently the largest Systems Biology programme in Europe.

特別講演 (Distinguished Lecture) 1

13 : 50 ~ 14 : 50

Chair: 杉山 雄一 独立行政法人理化学研究所 イノベーション推進センター  
杉山特別研究室

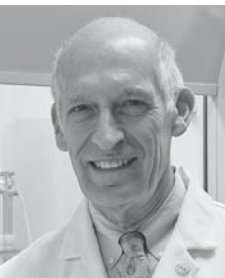
Yuichi Sugiyama Sugiyama Laboratory, RIKEN Innovation Center, Research Cluster for Innovation, RIKEN

DL1

NEW FRONTIERS IN DRUG METABOLISM, TRANSPORT AND PHARMACOKINETICS

Leslie Z. Benet

Department of Bioengineering and Therapeutic Sciences, School of Pharmacy and Medicine, University of California



Dr. Leslie Z. Benet, Professor and past Chairman (1978-98) of Bioengineering and Therapeutic Sciences, University of California San Francisco, received his AB, BS and MS from the University of Michigan, and Ph.D. from UCSF. He has received 8 honorary doctorates. His recent studies have led to the development of the Biopharmaceutics Drug Disposition Classification System. In 1986, Dr. Benet was a founder and first President of AAPS. In 1987 he was elected to the Institute of Medicine of the US National Academy of Sciences. From 1996-2000 he served as Chair of the International Pharmaceutical Federation (FIP) Board of Pharmaceutical Sciences. In 2007, he was made an International Honorary Member of JSSX, and has served as the Nagai Foundation Tokyo Distinguished Lecturer in 1998 & 2008. Dr. Benet has published >530 scientific papers, holds 11 patents and is listed among the most highly cited pharmacologists worldwide with his peer reviewed publications being referenced >20,000 times.

# シンポジウム (Symposium) 5

15 : 00 ~ 18 : 00

## 薬物相互作用ガイドンスの改訂 ～納得できるガイドンスにむけて～ Transporter & Regulatory DIS Joint Symposium Toward satisfying drug-drug interaction guidance —For reasonable guidance—

Organizers: 玉井 郁巳      金沢大学医薬保健研究域 薬学系  
Ikumi Tamai      Faculty of Pharmaceutial Sciences, Institute of Medical, Pharmaceutical  
and Health Science, Kanazawa University  
泉 高司      第一三共株式会社薬物動態研究所  
Takashi Izumi      Drug Metabolism & Pharacokinetics Reseach Laboratories, Daiichi  
Sankyo Co., Ltd.  
Chairs: 斎藤 嘉朗      国立医薬品食品衛生研究所 医薬安全科学部  
Yoshiro Saito      National Institute of Health Sciences  
奥平 典子      第一三共株式会社 研究開発本部 薬物動態研究所  
Noriko Okudaira      R & D Division, Drug Metabolism & Pharacokinetics Reseach  
Laboratories, Daiichi Sankyo Co., Ltd.

### SY-05-01

#### 薬物代謝が関与する薬物間相互作用 —科学のおよび規制的側面から— METABOLISM-BASED DRUG-DRUG INTERACTIONS -SCIENTIFIC AND REGULATORY ASPECTS-

久米 俊行  
田辺三菱製薬株式会社 薬物動態研究所  
Toshiyuki Kume  
DMPK Department I, DMPK Research Laboratories, Mitsubishi Tanabe Pharma Corporation



Dr. Kume is a General Manager, DMPK Research Laboratories at Mitsubishi Tanabe Pharma Corporation, Saitama, Japan. He graduated from Gifu Pharmaceutical University and thereafter received a Ph.D. from same university (Prof. Akira Hara). He joined Tanabe Seiyaku (former company) in 1986 and participated in the metabolism studies of Diltiazem, a cardiovascular agent. He had spent one year as a visiting scientist at Hokkaido University (Prof. Tetsuya Kamataki) with a view to study the genetic polymorphism of metabolic enzymes. Since 2001 and 2005, he has been a member of the Editorial Board of “Xenobiotica” and “Drug Metabolism and Pharmacokinetics”, respectively. He is a recipient of young scientist awards from the JSSX (2007) and is a JSSX Fellow (2009).

### SY-05-02

#### EXPECTATIONS FOR JAPANESE NEW GUIDELINE OF DRUG INTERACTION: ROLES OF MODELING AND INPACT ON LABELING

樋坂 章博  
東京大学医学部附属病院 薬理動態学  
Akihiro Hisaka  
Pharmacology and Pharmacokinetics, The University of Tokyo Hospital

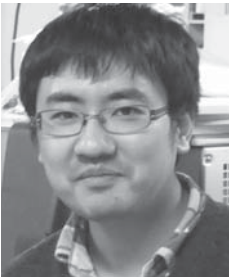


Akihiro Hisaka graduated, and received MS degree from Faculty of Pharmacy, Hokkaido University in 1982 and in 1984, respectively. He joined Banyu Pharmaceutical Co. Ltd in 1984 and charged in researches of pharmacokinetics and drug metabolism. In 1999, he received PhD degree from Faculty of Pharmaceutical Sciences, the University of Tokyo. In 2005, he joined the University of Tokyo Hospital as an assistant professor in Department of Pharmacy. From 2007, he served in the current position.

### SY-05-03

#### KEY POINTS FOR THE EVALUATION OF TRANSPORTER-MEDIATED DRUG-DRUG INTERACTIONS (TP-DDIS) IN A NOVEL JAPANESE DDI DRAFT GUIDANCE

前田 和哉  
東京大学大学院薬学系研究科 分子薬物動態学教室  
Kazuya Maeda  
Dept. of Molecular Pharmacokinetics, Graduate School of Pharmaceutical Sciences, The University of Tokyo



Dr. Maeda is an associate professor of the Department of Molecular Pharmacokinetics, Graduate School of Pharmaceutical Sciences, The University of Tokyo (Prof. Hiroyuki Kusuhabara) from Oct 2012. He is also working as a senior visiting scientist of Sugiyama Laboratory, RIKEN Research Cluster for Innovation from May 2012.  
He received his B.S. in the University of Tokyo in 1999, and graduated from the Master Course in the Graduate School of Pharm. Sci., the University of Tokyo in 2001. He was promoted to an assistant professor in 2002 in the middle of the Ph.D course in the University of Tokyo. He received Ph.D degree from the University of Tokyo in 2006. He received “The Japanese Society for the Study of Xenobiotics (JSSX) Award for Young Scientists” in 2009, “The Annual Clinical Pharmacology Research Award from the Japan Research Foundation for Clinical Pharmacology (JRFCP)” and “The DMPK Award for the Most Frequently Downloaded Article in 2008 (Review Article)” in 2010, “The Academy of Pharmaceutical Science and Technology, Japan (APSTJ) Award for Young Scientists” in 2011, “The DMPK Award for the Most Frequently Cited Article in 2008 (Review Article)” in 2012, “The Pharmaceutical Society of Japan (PSJ) Award for Young Scientists” in 2013.

SY-05-04

TRANSPORTER-MEDIATED DRUG-DRUG INTERACTIONS: POINTS TO CONSIDER IN THE REVISED DRAFT DOCUMENT OF “METHODS OF DRUG INTERACTION STUDIES”

佐藤 正延

独立行政法人 医薬品医療機器総合機構 新薬審査第二部

Masanobu Sato

Office of New Drug II, Pharmaceutical and Medical Devices Agency (PMDA)



2010 Ph.D. Kanazawa University

2010- Reviewer, Office of New Drug II, Pharmaceutical and Medical Devices Agency (PMDA)

SY-05-05

USEFULNESS AND PROBLEMS OF THE EVALUATION OF TRANSPORTER-MEDIATED DRUG-DRUG INTERACTION ACCORDING TO REGULATORY DRUG INTERACTION GUIDANCE

石黒 直樹

日本ベーリンガーインゲルハイム株式会社 神戸医薬研究所 薬物動態安全性研究部

Naoki Ishiguro

Pharmacokinetic and Non-clinical Safety, Nippon Boehringer Ingelheim Co., Ltd.



Empolyment

2008- Present Head of Drug Transporter, Nippon Boehringer Ingelheim Co., Ltd.

2010-2011 Principal Scientist of Drug Metabolism and Transporter, Boehringer Ingelheim Pharma GmbH and Co. KG, Germany

1998-2008 Drug Metabolism and Pharmacokinetic, Nippon Boehringer Ingelheim Co., Ltd.

Education

1992-1996 B.S. in school of Engineering, Osaka University

1996-1998 M.S. in Graduate school of Engineering, Osaka University

2004-2007 Ph.D. in Pharmaceutical Science, Tokyo University of Science

SY-05-06

PERSPECTIVES ON NONCLINICAL EVALUATION OF DRUG-DRUG INTERACTION THROUGH THE JPMA QUESTIONNAIRE SURVEY

谷 直子

大日本住友製薬株式会社 前臨床研究所

Naoko Tani

Preclinical Research Laboratories, Dainippon Sumitomo Pharma Co., Ltd. She has been working on DMPK research in drug



2005-present Dainippon Sumitomo Pharma Co., Ltd.

1995-2005 Sumitomo Chemical Co., Ltd.

1995 M.S. from Graduate School of Agriculture, Kyoto University

# C会場 (Room C) October 9 (Wed.)

## シンポジウム (Symposium) 2 9 : 30 ~ 12 : 00

バイオイメーシング (PET/MRI) の技術革新と新薬開発への活用～ヒトと動物を繋ぐ分析技術にもっと注目しよう 分析 DIS Part 1  
Analytical Methodologies DIS Part1, Innovation and the application of bioimaging technologies (PET/MRI) to new drug development. Why don't you have more attention to translational science technologies?

- Organizers・Chairs: 寺村 俊夫  
Toshio Teramura
- アステラス製薬株式会社 創薬推進研究所  
Analysis & Pharmacokinetics Reseach Laboratorys, Astellas Pharma Inc.
- 久米 俊行  
Toshiyuki Kume
- 田辺三菱製薬株式会社 薬物動態研究所  
DMPK Department I, DMPK Research Laboratories, Mitsubishi Tanabe Pharma corporation
- 西村 伸太郎  
Shintaro Nishimura
- アステラス製薬株式会社 バイオイメーシング研究所  
Bioimaging Research Laboratories Astellas Pharma Inc.

**SY-02-00**  
**MOLECULAR IMAGING IN CANCER PATIENTS (シンポジウム 1・シンポジウム 2 総合演者)**  
田村 研治  
独立行政法人国立がん研究センター中央病院 乳腺・腫瘍内科  
Kenji Tamura  
Dept of Breast and Medical Oncology, National Cancer Center Hospital.



- 1992-1993 2<sup>nd</sup> Dept. Internal Medicine, Hiroshima University.
- 1993-1995 2<sup>nd</sup> Dept. Internal Medicine, Osaka Prefectural Habikino Hospital.
- 1995-1998 Oncogene Division, National Cancer Center Research Institute.
- 1998-2000 Dept. of Pharmacology, Pittsburgh University, Pittsburgh, PA, US
- 2001-2005 Dept. of Medical Oncology, Kinki University School of Medicine
- 2005-2007 Dept. of Medical Oncology, Kinki University Nara Hospital
- 2007-Present
- Specificity: Medical oncology. Experimental therapeutics. Pharmacogenomics.

※シンポジウム6の最後発表者となります。  
シンポジウム2、6の総合的な発表を行っていただきます。

**SY-02-01**  
**INNOVATION AND APPLICATION OF BIOIMAGING TECHNOLOGY (PET/MRI/IMAGING-MS) TO THERAPEUTIC DRUG DISCOVERY AND DEVELOPMENT (PART I): PET AND MRI: INTRODUCTION**  
西村 伸太郎  
アステラス製薬株式会社 バイオイメーシング研究所  
Shintaro Nishimura  
Bioimaging Research Laboratories Astellas Pharma Inc.



- [Research and Professional Experience]
- 2009–Present Vice president, Bioimaging Research Labs, Astellas Pharma Inc.
- Visiting Professor, Institute of Basic Medical Science, University of Tsukuba
- 2005–2009 Senior Director, Astellas Pharma Inc.
- 2007–Present Visiting Professor, United Graduate School of Drug Discovery and Medical Information Science, Gifu University
- 2004–2010 Director, The Medical and Pharmacological Research Center Foundation
- 1999–2004 Director, Advanced Technology Platform, Fujisawa Pharmaceutical Co. Ltd
- [Education]
- 1997–1998 Research Fellow, The University of Michigan, Medical School
- 1990 Ph degree of engineering from Keio University by an investigation on medicinal chemistry of new  $\beta$ -lactam antibiotics
- 1983 Graduated from Master’s Program in Faculty of Applied Chemistry, Keio University
- 1981 Graduated from Faculty of Applied Chemistry, Keio University

**SY-02-02**  
**APPLICATION OF NON-HUMAN PRIMATE PET FOR BRAIN RESEARCH IN COMBINATION WITH BEHAVIORAL ASSESSMENT**  
塚田 秀夫  
浜松ホトニクス株式会社 中央研究所 PET センター  
Hideo Tsukada  
Central Research Laboratory Hamamatsu Photonics K.K.



- Education background :
- Department of Pharmacology, Shizuoka College of Pharmacy, April 1978 - March 1982 (Bachelor of Pharmacy, March 1982)
- Graduate School, Department of Pharmacology, Shizuoka College of Pharmacy, April 1982 - March 1987 (Ph. D. of Pharmacy, March 1987)
- Professional career :
- Manager of PET Center, Central Research Laboratory, Hamamatsu Photonics K.K., October 2001–September 2004.
- Senior Manager of PET Center, Central Research Laboratory, Hamamatsu Photonics K.K., October 2004–present.
- Visiting Professor of School of Pharmacology, University of Shizuoka, June 2006 –.present.
- Visiting Professor of School of Medicine, University of Hamamatsu, February 2007 – present.

SY-02-03

INNOVATION AND APPLICATION OF BIOIMAGING TECHNOLOGY (PET/MRI/IMAGING-MS) TO THERAPEUTIC DRUG DISCOVERY AND DEVELOPMENT (PART I): PET AND MRI: DRUG DEVELOPMENT IN NEUROPSYCHIATRIC DISORDERS

須原 哲也

独立行政法人放射線医学総合研究所 分子イメージング研究センター  
分子神経イメージング研究プログラム

Tetsuya Suhara

Molecular Neuroimaging Program, Molecular Imaging Center, National Institute of Radiological Sciences



Education:  
1991 Ph.D. (Doctor of Medical Sciences),  
1984 M.D. Jikei University School of medicine  
Research Appointment:  
2011- Program Director of Molecular Neuroimaging Program, Molecular Imaging center, National Institute of Radiological Sciences  
2005-2011 Group Director, Molecular Neuroimaging Group  
2001- 2005 Director of Special Research (Brain Imaging Project)  
1997-2002 Research director of CREST project (Japan Science and Technology Corporation)  
1996-2000 Senior Researcher, Division of Advanced Technology for Medical Imaging, National Institute of Radiological Sciences  
1992-1996 Senior Researcher, Division of Clinical Research and Radiation Health, National Institute of Radiological Sciences  
1992-1993 Visiting Scientist at Department of Clinical Neuroscience, Psychiatry and Psychology Section, Karolinska Hospital, Stockholm Sweden (PET group under Lars Farde)  
1989-1992 Researcher, Division of Clinical Research, National Institute of Radiological Sciences

SY-02-04

INTRODUCTION OF PHARMACEUTICAL APPLICATIONS OF MRI

余川 隆

バイオビュー株式会社

Takashi Yokawa

Bio View, Inc.



STUDIES  
[Veterinary medicine]  
March 1988 The University of Tokyo  
Licence : Practice veterinary medicine  
[Doctor in Sciences (section Vet Physiology)]  
March 1991 The University of Tokyo  
PhD Thesis: "The existance of a neuronal structure activating running activity as a enegy regulating center in the ventromedial nucleus of the hypothalamus"  
  
PROFESSIONAL CAREER  
09.2004- present CEO of BioView  
04.1998-12.2003 Head of Diagnostcs research department of Basic Reserch Institute of Schering  
04.96-03.98 Application chemist of Varian  
04.1991-09.1996 Head of the neurology deparment of ERATO of the Japan Science and Technology Agency (JST)

SY-02-05

APPLICATION OF MRI AND PET FOR BORON NEUTRON CAPTURE THERAPY (BNCT)

松村 明

筑波大学医学医療系 脳神経外科

Akira Matsumura

Tsukuba University Hospital



1974: Entered the Medical School at University of Tsukuba  
1980: ECFMG certification  
1980: Graduated from the School of Medicine, University of Tsukuba  
1980: Residency at University of Tsukuba Hospital (General Surgery)  
1982: Residency at University of Tsukuba Hospital (Neurological Surgery)  
1984: Scholarship of DAADD at Universitätsklinik Göttingen  
1986: "Postgraduate Intermediate Training Course in Neurology" National Hospital for Nervous Disease (University of London, GB).  
1988: Degree of "Doktor der Medizin" from University of Göttingen  
1988: Board Certification of Japan Neurosurgical Society  
1990: Chairman, Department of Neurosurgery , Moriya Daiichi General Hospital  
1991: Degree of "Doctor of Medical Science" from University of Tsukuba  
1992-2002: Assistant Professor, Department of Neurosurgery, University of Tsukuba  
1995: Scholarship of Alexander von Humboldt Stiftung, Biomedizinische NMR Forschungs GmbH, Max-Planck Institut für biophysikalische Chemie  
2002-2004: Associate Professor, Department of Neurosurgery, University of Tsukuba  
2004-present: Professor, Department of Neurosurgery, University of Tsukuba  
2004-2008: Board of Councilor, International Society for Neutron Capture Therapy  
2008.4-present: Deputy Director University of Tsukuba Hospital  
2008- 2010: President, International Society for Neutron Capture Therapy  
2012: PI for BNCT accelerator project in Tsukuba International Strategic Zone

※シンポジウム6と合わせて聴講ください。最後に総合討論がございます。

シンポジウム (Symposium) 6

15 : 00 ~ 17 : 30

バイオイメーシング (Imaging Mass Spectrometry) の技術革新と新薬開発への活用  
～突破口となるのか？その期待について語ろう！ 分析 DIS Part 2  
Analytical Methodologies DIS Part2, Innovation and application of IMAGING MASS  
SPECTROMETRY to new drug development –Breakthrough and Expectation of bio-  
imaging technologies–

- Organizers・Chairs: 寺村 俊夫 アステラス製薬株式会社 創薬推進研究所  
Toshio Teramura Analysis & Pharmacokinetics Reseach Laboratorys, Astellas  
Pharma Inc.  
濱田 哲暢 独立行政法人国立がん研究センター  
早期・探索臨床研究センター トランスレーショナルリサ  
ーチ分野研究所 TR 総合支援グループ 臨床薬理部門  
Akinobu Hamada Department of Clinical Pharmacology, Group for  
Translational Research support core, National Cancer Center  
Research Institute: Division of Translational Research,  
Exploratory Oncology Research & Clinical Trial center,  
National Cancer Center

SY-06-01

PHARMACO-IMAGING BY MALDI MASS SPECTROMETRY: BRIDGING PHARMACOLOGY AND  
CHEMISTRY IN DRUG DEVELOPMENT

- 濱田 哲暢  
独立行政法人国立がん研究センター 早期・探索臨床研究センタートランスレーショナルリサーチ分野  
研究所 TR 総合支援グループ 臨床薬理部門  
Akinobu Hamada  
Department of Clinical Pharmacology, Group for Translational Research support core, National Cancer  
Center Research Institute: Division of Translational Research, Exploratory Oncology Research & Clinical  
Trial center, National Cancer Center



- 2013-present Head, Department of Clinical Pharmacology, National Cancer Center Research  
Institute  
Visiting Professor, Graduate School of Medicine, Kumamoto University  
2012 Laboratory Head, National Cancer Center Research Institute, Tokyo  
2008- 2012 Associate Professor, Kumamoto University  
2005-2007 Visiting Fellow, National Cancer Institute / National Institutes of Health, USA.  
1999-2005 Assistant Professor, Kumamoto University  
1997 Ph.D., Kumamoto University  
1992 Graduated from Kumamoto University

SY-06-02

MASS SPECTROMETRY IMAGING –REVIEW OF RECENT DEVELOPMENT AND TECHNIQUES FOR  
PHARMACEUTICAL APPLICATIONS–

- 新聞 秀一  
独立行政法人国立がん研究センター 早期・探索臨床研究センタートランスレーショナルリサーチ分野  
Shuichi Shimma  
Exploratory Oncology Research & Clinical Trial Center, National Cancer Center



- Educations:  
2007 PhD degree (Physiology) from the graduate university for advanced studies  
Honors/Awards:  
2010 Research Award from mass spectrometry society of Japan  
2007 Research Award from the graduate university for advanced studies  
2006 BMS Travel Award from mass spectrometry society of Japan  
2005 5th International Symposium on Atomic Level Characterizations for New Materials  
and Devices '05 Student Award  
Professional Experiences:  
2007-2011 Post-doctoral fellow and assistant professor in Osaka University  
2012- Scientist in National Cancer Center Research Institute  
Research Interests:  
Imaging mass spectrometry development of miniaturized mass spectrometer

SY-06-03

QUANTITATIVE ANALYSIS OF PHARMACEUTICAL DRUG DISTRIBUTION IN MULTIPLE ORGANS BY  
IMAGING MASS SPECTROMETRY

- 田中 由香里  
塩野義製薬株式会社 創薬・開発研究所 薬物動態研究部門  
Yukari Tanaka  
Department of Drug Metabolism and Pharmacokinetics, Shionogi & Co., Ltd.



- 2003-Present Drug Metabolism and Pharmacokinetics,  
Drug Developmental Research Laboratories,  
Shionogi Pharmaceutical Research Center, Shionogi & Co., Ltd.  
2012 Ph. D., Kyoto Pharmaceutical University

SY-06-04

PROTEOMIC PROFILING AND IMAGING FOR THE STUDIES OF NEUROLOGICAL DISEASES

池川 雅哉  
同志社大学 生命医科学部 医生命システム学科  
独立行政法人放射線医学総合研究所 分子イメージング研究センター 分子神経イメージング研究  
プログラム  
Masaya Ikegawa  
Genomics, Proteomics and Biomedical Functions, Department of Life and Medical Systems, Faculty of  
Life and Medical Sciences, Doshisha University



Academic Career  
2013 Professor, Faculty of Life and Medical Sciences, Doshisha University  
2004 Associate Professor, Department of Genomic Medical Sciences, Graduate School of  
Medical Science, Kyoto Prefectural University of Medicine  
1998 Department of Molecular Biology, Graduate School of Medicine, Kyoto University  
1987 Department of Environmental Medicine, Graduate School of Medicine, Kyoto University,  
PhD  
1990 Kyoto University, Faculty of Medicine, MD

SY-06-05

VISUALIZATION AND QUANTIFICATION OF BRAIN METABOLIC "FLUXES" OF GLUCOSE IN THE AWAKE  
MICE BY MASS SPECTROMETRY

杉浦 悠毅  
慶應義塾大学医学部 医化学教室  
Yuki Sugiura  
Department of Biochemistry, Keio University School of Medicine



Position:  
2011-present Lecturer, Department of Biochemistry, Keio University School of Medicine  
Research and Professional experience:  
2007-2010 Research Fellow of the Japan Society for the Promotion of Science (DC1)  
2010-2011 Research Fellow of the Japan Society for the Promotion of Science (PD)  
2011-present Researcher, JST Precursory Research for Embryonic Science and Technology  
(PRESTO) Project, "Elucidation and Control the Mechanisms Underlying Chronic  
Inflammation" research area

D会場 (Room D) October 9 (wed.)

シンポジウム (Symposium) 3 9 : 30 ~ 12 : 00

薬物動態・毒性研究におけるバイオマーカーの選択と応用  
Toxicology DIS Part 1, Biomaker Discovery and Evaluation in DMPK and Toxicology Studies

Organizer・Chairs: 横井 毅 名古屋大学大学院医学系研究科 統合医薬学領域トキシコゲノミクス  
Tsuyoshi Yokoi Department of Drug Safety Sciences, Nagoya University Graduate School of Medicine  
Chairs: 堀井 郁夫 ファイザー株式会社  
Ikuo Horii Pfizer Japan Inc.

SY-03-01

BASIC CONCEPT FOR THE ESTIMATION OF TOXICOLOGICALLY RESPONSIBLE BIOMARKERS

堀井 郁夫  
ファイザー株式会社  
Ikuo Horii  
Pfizer Japan Inc.



1971: Hiroshima University / Agricultural Biochemistry (Master)  
1971: Kyoto University / Pharmacology, Faculty of Medicine  
1976: F. Hoffmann-La-Roche, Basel Research (Switzerland), Pathology  
1987: Nippon Roche Research Center (NRRC), Toxicology & Pathology, Dept. Head  
1997: Cambridge University (UK): Industrial Fellow  
2000: NRRC, Division of Preclinical Research and Development, Div. Head  
2002: Pfizer, Drug Safety Research & Development (Nagoya), Executive Director  
2007~ Showa University visit-Prof., Pfizer Global Consultant, Horii Science Associates,

SY-03-02

PHARMACOGENOMICS / BIOMARKER UTILIZATION IN DRUG DEVELOPMENT

八木 聡美  
独立行政法人医薬品医療機器総合機構 新薬審査第四部  
Satomi Yagi  
Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)



2010 Graduated from Faculty of Pharmacy, Keio University  
2010 Reviewer, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)

SY-03-03

CLINICAL AND NON-CLINICAL RESEARCH FOR ENDOGENOUS PROBES OF OCT2/MATEs AND OAT3

今村 勇一郎  
第一三共株式会社 薬物動態研究所  
Yuichiro Imamura  
Drug Metabolism & Pharmacokinetics Research Laboratories, Daiichi Sankyo Co., Ltd.,



Yuichiro Imamura has been a research scientist in the DMPRL Dept., Daiichi Sankyo Co., Ltd. He acquired his Ph.D. at The University of Tokyo in 2013 in Pharmaceutical Science. He joined the research laboratory of Daiichi Pharmaceutical Co. Ltd. in 1999. At present, his research focuses on discovering and evaluating DDI biomarkers.

SY-03-04

BIOMARKERS FOR DRUG-INDUCED LIVER INJURY

横井 毅  
名古屋大学大学院医学系研究科 統合医薬学領域トキシコゲノミクス  
Tsuyoshi Yokoi  
Department of Drug Safety Sciences, Nagoya University Graduate School of Medicine



1980 Graduate from Gifu Pharmaceutical University  
1980-1984 Research Associate, Gifu University  
1984-1989 Research Associate, Tohoku University  
1989-1990 Assistant Professor, Tohoku University  
1990-1997 Associate Professor, Hokkaido University  
1997-2013 Professor, Kanazawa University  
2013-Present Professor, Nagoya University

SY-03-05

CLINICAL EPIDEMIOLOGY OF ADVERSE DRUG EVENTS IN JAPAN

森本 剛  
兵庫医科大学 内科学総合診療科

Takeshi Morimoto  
Division of General Medicine, Department of Internal Medicine  
Hyogo College of Medicine



- Education:
- 2008      Keio University Business School, Kanagawa
  - 2000-2004    Kyoto University Graduate School of Medicine, Kyoto
  - 2001-2002    Harvard School of Public Health, Boston
  - 1989-1995    Kyoto University Faculty of Medicine, Kyoto
- Professional Training and Employment:
- 2013-present    Professor of Medicine, Hyogo College of Medicine
  - 2011-2013      Professor of Medicine, Kinki University School of Medicine
  - 2005-2011      Senior Assistant Professor of Medicine, Kyoto University Graduate School of Medicine
  - 2004-2005      Assistant Professor of Medicine, Kyoto University Graduate School of Medicine
  - 2001-2002      Research Fellow in General Internal Medicine, Brigham and Women’s Hospital, Boston
  - 1998-2000      Clinical Fellow in General Internal Medicine, Kyoto National Hospital
  - 1995-1998      Resident in Internal Medicine, Maizuru Municipal Hospital

シンポジウム (Symposium) 7

15 : 00 ~ 17 : 30

創薬における non-CYP 薬物代謝酵素研究の最前線

Drug Metabolism DIS Part 3, The cutting edge of the research on non-CYP drug-metabolizing enzymes in drug development

Organizers・Chairs: 中島 美紀 金沢大学医薬保健研究域 薬学系

Miki Nakajima Faculty of Pharmaceutical Sciences, Kanazawa University

石井 祐次 九州大学大学院薬学研究院 分子衛生薬学分野

Yuji Ishii Graduate School of Pharmaceutical Sciences, Kyushu University

SY-07-01

CHALLENGE TO IDENTIFY UNKNOWN DRUG-METABOLIZING ENZYMES IN DRUG DEVELOPMENT PROCESS

石塚 智子

第一三共株式会社 薬物動態研究所

Tomoko Ishizuka

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



1998 Graduated from Faculty of Pharmaceutical Sciences, Chiba University

1998-2007 Analytical and Metabolic Research Lab., Sankyo Co., Ltd.

2007-present Drug Metabolism & Pharmacokinetics Research Lab., Daiichi Sankyo Co., Ltd.

SY-07-02

RECENT PROGRESS IN CHARACTERIZATION OF ESTERASES IN HUMAN: IMPLICATIONS IN DRUG DEVELOPMENT

深見 達基

金沢大学医薬保健研究域 薬学系

Tatsuki Fukami

Faculty of Pharmaceutical Sciences, Kanazawa University



2008: Ph.D. Kanazawa University

2008-present: Assistant Professor, Kanazawa University

SY-07-03

IMPORTANCE OF PREDICTION OF ALDEHYDE OXIDASE-MEDIATED METABOLISM IN DRUG DISCOVERY

佐能 正剛

広島大学大学院医歯薬保健学研究院

Seigo Sanoh

Graduate School of Biomedical and Health Sciences, Hiroshima University



2002; MS., Graduate School of Biomedical Sciences, Hiroshima University

2002-2005; Researcher, Fujisawa Pharmaceutical Co., Ltd

2005-2009; Researcher, Astellas Pharma Inc

2009-2012; Research Associate, Graduate School of Biomedical Sciences, Hiroshima University

2012; Ph.D., Graduate School of Biomedical Sciences, Hiroshima University

2012-present; Assistant Professor, Graduate School of Biomedical and Health Sciences, Hiroshima University

Overseas study

2012; Laboratory of Molecular Biology, Institute di Ricerche Farmacologie "Mario Negri", Italy

SY-07-04

肝および小腸におけるグルクロン酸抱合の *in vitro-in vivo* extrapolation による予測

PREDICTION OF HEPATIC AND INTESTINAL GLUCURONIDATION USING *IN VITRO-IN VIVO* EXTRAPOLATION

成富 洋一

アステラス製薬株式会社 創薬推進研究所

Yoichi Naritomi

Analysis & Pharmacokinetics Research Labs., Astellas Pharma Inc.



1986 B.S. from Gifu Pharmaceutical University

1988 M.S. from Nagasaki University

1988 Joined Fujisawa Pharmaceutical Co., Ltd. (currently Astellas Pharma. Inc.)

2004 Ph.D. from the University of Tokyo

2005 Joined Astellas Pharma. Inc.

# E 会場 (Room E)    October 9 (wed.)

## シンポジウム (Symposium) 4 9 : 30 ~ 12 : 00

医薬品の創薬開発におけるデータマイニングの重要性 (1) —探索 DMPK データをいかに創薬に有効活用するか?—  
In silico DIS, Data mining: the importance of data mining in drug discovery and development (1)  
—How do we make the most of DMPK screening data to drug discovery?—

- Organizer • Chairs: 森脇 俊哉      武田薬品工業株式会社 薬物動態研究所  
リサーチマネージャー  
Toshiya Moriwaki      Drug Metabolism & Pharmacokinetics Research  
Laboratories, Takeda Pharmaceutical Company Limited
- Chairs: 山下 富義      京都大学大学院薬学研究科 薬品動態制御学分野  
Fumiyoshi Yamashita      Kyoto University  
加藤 晴敏      田辺三菱製薬株式会社 薬物動態研究所  
Harutoshi Kato      DMPK Research Laboratory, Mitsubishi Tanabe Pharma  
Corporation  
小林 好真      第一三共株式会社 薬物動態研究所  
Yoshimasa Kobayashi      Drug metabolism & Phamacokinetics Research  
Laboratory Daiichi Sankyo

### SY-04-01

#### IMPACT AND APPLICATION OF DATA MINING IN ADME RESEARCHES

山下 富義  
京都大学大学院薬学研究科  
Fumiyoshi Yamashita  
Graduate School of Pharmaceutical Sciences, Kyoto University



Dr. Yamashita is Associate Professor of Graduate School of Pharmaceutical Sciences, Kyoto University, Kyoto, Japan. He received his B.S., M.S., and Ph.D. in Pharmaceutical Sciences from Kyoto University, in 1987, 1990, and 1995, respectively. He was appointed Research Assistant Professor of Graduate School of Pharmaceutical Sciences, Kyoto University in 1992. From 1995 to 1996, he was a visiting scientist of School of Pharmacy, University of Southern California, Los Angeles, California. Since 1996, he has been Associate Professor of Graduate School of Pharmaceutical Sciences, Kyoto University. Research interests have included pharmacokinetics modeling of drug disposition behaviors, ADME-related chemoinformatics, and development of targeted drug delivery systems. Over 180 research papers have been published since 1989. He received Asahi-Kasei Young Investigator Award from Academy of Pharmaceutical Science and Technology Japan (APSTJ) in 2001, Young Investigator Award of Japanese Society for the Study of Xenobiotics (JSSX) in 2003.

### SY-04-02

#### 製薬企業における ADME データマイニング戦略 ADME DATA MINING STRATEGY IN PHARMACEUTICAL INDUSTRY

西岡 大貴  
エーザイ株式会社エーザイプロダクトクリエーション・システムズ バイオフーマシューティカル  
・アセスメント機能ユニット  
Tomoki Nishioka  
DMPK Japan, Eisai Co., Ltd.



Tomoki Nishioka is a principal researcher in DMPK Japan, Eisai Co., Ltd. He graduated from Tokushima University in 2008. His research interests include (Q)SAR, cheminformatics and computational ADME prediction.

### SY-04-03

#### DEVELOPMENT OF A NOVEL DATA-MINING TOOL FOR DRUG DISCOVERY, ADMETi AND ITS APPLICATION EXAMPLES

宮本 真紀  
武田薬品工業株式会社 医薬研究本部 薬物動態研究所  
Maki Miyamoto  
Drug Metabolism & Pharmacokinetics Research Laboratory, Takeda Pharmaceutical Company, Limited




1999      Graduated from Graduate School of Science, Osaka University  
1999-2005      Laboratory of medicinal chemistry., Takeda Pharmaceutical Company Limited  
2005-Present      Drug Metabolism & Pharmacokinetics Research Lab., Takeda Pharmaceutical Company Limited

SY-04-04

ADME DATA-MINING FOR DRUG DESIGN AND DECISION MAKING

小林 好真  
第一三共株式会社 薬物動態研究所  
Yoshimasa Kobayashi  
Drug metabolism & Pharmacokinetics Research Laboratory, Daiichi Sankyo



2000 Ph.D., Department of Chemistry, Graduate School of Science, The University of Tokyo.

2000- Daiichi Sankyo Co., Ltd.

2004-05 Visiting Researcher, Department of Pharmacology, University of Michigan.


2010 Best Presentation Award, 9th International ISSX Meeting.

Resent interest: Quantitative and model-based drug discovery (both chem & biol.).

SY-04-05

IN SILICO PREDICTION OF THE CLEARANCE OF LIVER MICROSOMES BASED ON THE LARGE DATA SET

大田 雅照  
中外製薬株式会社 研究本部創薬化学研究部  
Masateru Ohta  
Medicinal Chemistry Research Dept., Research Div., Chugai Pharmaceutical co. ltd.



Title  
Principal scientist and group manager of computer-aided drug design group (Chugai pharmaceutical)  
Executive board of Division of Structure-Activity Studies (The Pharmaceutical Society of Japan)

Education  
Ph.D., Kyoto University (Graduate school of agriculture), 2002  
B.S., Yokohama National University (School of engineering), 1980

Expertise  
Computer-Aided Drug Design, Structure-Based Drug Design, Quantitative Structure-Activity Relationships, and chemoinformatics

Teaching  
Kitasato University (School of pharmacy), 2011 - present  
Nihon University (School of pharmacy), 2012 - present

## シンポジウム (Symposium) 8

15 : 00 ~ 17 : 30

### Clinical Pharmacology and Pharmacometrics DIS Part 1, Model-based Drug Development (MBDD): current status and JSSX perspectives

Organizer: 川合 良成 第一三共株式会社 トランスレーショナルメディシン部  
 Ryosei Kawai R&D Division, Daiichi Sankyo Co., Ltd.

Chairs: 千葉 康司 横浜薬科大学臨床薬理学研究室  
 Koji Chiba Laboratory of Clinical Pharmacology Yokohama College of Pharmacy  
 大石 昌代 ファイザー株式会社 クリニカル・ファーマコロジー部  
 Masayo Oishi Clinical Pharmacology, Pfizer Japan Inc.

#### SY-08-01

#### THE ROLE OF MODEL-BASED DRUG DEVELOPMENT (MBDD): A LANDSCAPE ANALYSIS

Lawrence J. Lesko

University of Florida Center for Pharmacometrics and Systems Pharmacology



Dr. Lawrence J. Lesko is Professor of Pharmaceutics and Director of the Center for Pharmacometrics and Systems Pharmacology in the University of Florida College of Pharmacy at Lake Nona (Orlando). Dr. Lesko was Director of the Office of Clinical Pharmacology in the Center for Drug Evaluation and Research at the Food and Drug Administration for 16 years until his retirement in July 2011. At the FDA, Dr. Lesko led the advancement of personalized medicine through the update of labels of previously approved drugs with new genetic information. Dr. Lesko co-authored numerous Guidance for Industry including "Clinical Pharmacogenomics: Premarketing Evaluation in Early Clinical Trials" and "Pharmacogenomics Data Submissions". He also started a Division of Pharmacometrics that is responsible for quantitative analysis of dose-response and PK-PD relationships to support drug labels and NDA approvals, and the development of drug-disease models to support clinical trial simulations. Dr. Lesko led a program involved with mechanistic approaches to understanding drug safety including the prediction of off-target effects using bioinformatics approaches. Dr. Lesko has published more than 200 peer-reviewed manuscripts and is a frequent invited national and international speaker. In 2011, he received the Gary Neil Prize for Innovation in Drug Development from the American Society of Clinical Pharmacology and Therapeutics (ASCPT). Dr. Lesko also was honored with the Rawls-Palmer Progress in Medicine award from ASCPT, the Coriell Scientific Leadership Award for Personalized Medicine, the University of North Carolina Institute for Pharmacogenomics and Individualized Therapy Award for Clinical Service, and the Nathaniel B. Kwit Distinguished Service Award for Clinical Pharmacology from the American College of Clinical Pharmacology. His hobbies include riding motorcycles and underwater photography. He is a Divemaster certified by the Professional Association of Dive Instructors.

#### SY-08-02

#### MODELING AND SIMULATION IN CHINA

Kai Wu

Clinical Pharmacology, Modeling &amp; Simulation, Glaxo SmithKline R&amp;D China



Dr. Kai Wu is Associate Director of Clinical Pharmacology Modeling & Simulation Group at GlaxoSmithKline Research & Development Center in Shanghai, China. Before joining GSK, he was Associate Director in the Translational Medicine and Clinical Pharmacology Department, Daiichi-Sankyo, New Jersey, USA. He started his career in pharmaceutical industry in 2006 by joining Novartis Modeling and Simulation Department at Boston, USA. In 1999, Dr. Kai Wu obtained his Bachelor of Science degree at Nankai University, Tianjin, China majoring in Microbiology. In 2002 he went to the University of Florida, School of Pharmacy, and finished a joined degree program, M.S. in Statistics in 2005 and Ph.D. in Pharmacokinetics and Pharmacodynamics in 2006.

#### SY-08-03

#### THE USE OF MODELING AND SIMULATION TO FACILITATE INFORMED DECISION MAKING--FDA'S PERSPECTIVE

Bahru A. Habtemariam

U.S. Food and Drug Administration



Dr. Habtemariam is a clinical pharmacology reviewer in the Office of Clinical Pharmacology, the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Habtemariam received his Doctor of Pharmacy (Pharm.D) in 2004 from the University of Maryland School of Pharmacy. He completed a two year postdoctoral in pharmacometrics and drug development at Cognigen Corporation, Buffalo, New York. During his fellowship, Dr. Habtemariam gained experience in quantitative clinical pharmacology working on anti-infective, anti-diabetics, and anti-auto immune disease drugs. After completing his fellowship, Dr. Habtemariam worked at Novartis for 2 years. Dr. Habtemariam joined the FDA in 2008, where has reviewed numerous small molecule and biologic oncology and hematology drug products, looking at both general clinical pharmacology and pharmacometrics aspects of submissions.

#### SY-08-04

#### PBPK AND MODEL-BASED DRUG DEVELOPMENT (MBDD): CURRENT STATUS AND REGULATORY PERSPECTIVES IN JAPAN

永井 尚美

独立行政法人医薬品医療機器総合機構

Naomi Nagai

Center for Product Evaluation

Pharmaceuticals and Medical Devices Agency (PMDA)



Naomi Nagai works as a senior scientist for pharmacokinetics in the Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA). She had been working in the Department of Biopharmaceutics, Meiji Pharmaceutical University after completing B.S. and M.S. courses in the Kyoto University, School of Pharmacy. In 1997, she joined the Pharmaceuticals and Medical Devices Evaluation Center, National Institute of Health Sciences as a reviewer. Then she has been working as a review director in the Office of New Drug II and IV in the PMDA since 2004, and is currently the team leader of Nanomedicine Initiative Project as well as a member in several working groups such as drug interaction and bioequivalence in the PMDA and the Ministry of Health Labour and Welfare.

# A会場 (Room A)    October 10 (Thu.)

## シンポジウム (Symposium) 9 9 : 30 ~ 12 : 00

**薬物動態・安全性研究における細胞アッセイ系の進歩**  
**Toxicology DIS Part 2, Recent Progress Of Cell-based Assays in DMPK and Toxicology Studies**

Organizer・Chairs: 横井 毅      名古屋大学大学院医学系研究科 統合医薬学領域トキシコゲノミクス  
Tsuyoshi Yokoi    Department of Drug Safety Sciences, Nagoya University Graduate School of Medicine

Chairs: 小島 肇      国立医薬品食品衛生研究所 安全性生物試験研究センター 薬理部  
Hajime Kojima      新規試験法評価室  
Japanese Center for the Validation of Alternative Methods (JaCVAM), National Institute of health Sciences (NIHA)

SY-09-01

**In vitro 探索毒性試験の展望**  
**THE FUTURE OF IN VITRO SCREENING IN THE DEVELOPMENT OF NEW DRUGS**

小島 肇  
国立医薬品食品衛生研究所 安全性生物試験研究センター      薬理部 新規試験法評価室  
Hajime Kojima  
Japanese Center for the Validation of Alternative Methods (JaCVAM), National Institute of health Sciences (NIHA)



Dr. Hajime Kojima received his undergraduate degree in 1983 from Gifu University, Department of Agriculture, Faculty of Agricultural Chemistry. He received his PhD in 1996 in Information Science from the University of Nagasaki. He currently is the Secretary General of the Japanese Center for the Validation of Alternative Methods (JaCVAM) and a Visiting Lecturer at the Fujita Health University School of Medicine. Dr. Kojima is also a member of the International Cooperation on Alternative Test Methods (ICATM) and an observer on both the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) and the European Scientific Advisory Committee (ESAC).

Prior to joining JaCVAM in 2005, Dr. Kojima held several positions with increasing responsibility at the Nippon Menard Cosmetic Co., Ltd., including Researcher at the Biochemical Institute from 1986 to 1994, Chief of the Biochemical Institute from 1994 to 1995, Chief of the Research Laboratories from 1995 to 2001, and Assistant Manager of the Research Laboratories from 2001 to 2005.

Dr. Kojima has received several awards, including The Japanese Society for Alternative to Animal Experiments (JSAAE) Paper Prize in 1998, 2000, and 2003. Dr. Kojima is also a member of several professional societies, including the Japanese Society for Dermatoallergology and Contact Dermatitis, the Japanese Society of Toxicology, the Society of Toxicology, the Japanese Environmental Mutagen Society, the Japanese Society for Alternatives to Animal Experiments, the Safety Evaluation Forum, and the Japanese Association for Animal Cell Technology.

SY-09-02

**IN VITRO DRUG METABOLISM AND TOXICOLOGY STUDIES USING HUMAN HEPATOCYTE SPHEROID CULTURES**

太田 之弘  
中外製薬株式会社  
Kunihiro Ohta  
Safety Evaluation Forum, Spheroid WG  
Chugai Pharmaceutical Co., Ltd.



Kunihiro Ohta, Ph.D. is Clinical Scientist, Coordination group of Post-Marketing Clinical Trials, Chugai Pharmaceutical Co., Ltd. (2012-present). He acquired his Ph.D. at Pharmaceutical Sciences, Tokyo University of Pharmacy and Life Sciences (formerly Tokyo College of Pharmacy) in 1996 in Biopharmaceutical Science (Prof. S. Awazu); then joined Department of Drug Metabolism and Pharmacokinetics, Research/Development Division, Chugai Pharmaceutical Co., Ltd. (1996-2012).

SY-09-03

**GENERATION OF METABOLICALLY FUNCTIONING HEPATOCYTES FROM HUMAN PLURIPOTENT STEM CELLS FOR DRUG TOXICITY TESTING**

水口 裕之  
大阪大学大学院薬学研究科分子生物学分野  
大阪大学大学院薬学研究科附属創薬研究センター 創薬基盤技術開発 iPS 肝毒性・代謝ユニット  
大阪大学臨床医工学融合研究教育センター  
独立行政法人医薬基盤研究所 創薬基盤研究部肝細胞分化誘導プロジェクト  
Hiroyuki Mizuguchi  
Department of Biochemistry and Molecular Biology, Graduate School of Pharmaceutical Sciences, Osaka University  
iPS Cell-based Research Project on Hepatic Toxicity and Metabolism, Graduate School of Pharmaceutical Sciences, Osaka University  
The Center for Advanced Medical Engineering and Informatics, Osaka University  
Laboratory of Hepatocyte Regulation, National Institute of Biomedical Innovation



|              |  |
|--------------|--|
| -1996        | Ph.D. in Pharmaceutical Science, Osaka University, Osaka, Japan.   |
| 1996-1997    | Research Institute for Microbial Diseases, Osaka University, Osaka, Japan.   |
| 1997-1998    | Department of Medical Genetics, University of Washington, Seattle, WA, USA.  |
| 1998-2002    | Researcher, Division of Biological Chemistry and Biologicals, National Institute of Health Sciences, Tokyo, Japan.   |
| 2002-2004    | Senior Researcher, Division of Cellular and Gene Therapy Products, National Institute of Health Sciences, Tokyo, Japan.  |
| 2004-2005    | Sub-project Leader, Project III, Fundamental Research Laboratories for Development of Medicine, National Institute of Health Sciences, Osaka Branch, Osaka, Japan. |
| 2005-2010    | Project Leader, Division of Fundamental Technological Research, National Institute of Biomedical Innovation, Osaka, Japan.   |
| 2008-Present | Professor, Department of Biochemistry and Molecular Biology, Graduate School of Pharmaceutical Sciences, Osaka University, Osaka, Japan.                           |
| 2010-Present | Professor, The Center for Advanced Medical Engineering and Informatics, Osaka University, Osaka Japan  |
| 2010-2013    | Chief Project Leader, Division of Fundamental Technological Research, National Institute of Biomedical Innovation, Osaka, Japan.                                   |
| 2013-Present | Adjunct Project Leader, Division of Fundamental Technological Research, National Institute of Biomedical Innovation, Osaka, Japan.                                 |

SY-09-04

DIRECT REPROGRAMMING OF STEM CELL INTO FUNCTIONAL HEPATOCYTES: ITS STRATEGY AND APPLICATION TOWARD DRUG SAFETY EVALUATION

落谷 孝広  
独立行政法人国立がん研究センター 分子細胞治療研究分野  
Takahiro Ochiya  
Division of Molecular and Cellular Medicine, National Cancer Center Research Institute, Tokyo Japan



Dr. Takahiro Ochiya is a Chief of Division of Molecular and Cellular Medicine at the National Cancer Center Research Institute, Tokyo and he is also appointed as an invited professor of Waseda University (since 2004), Tokyo Institute of Technology (since 2008), Showa Univdersity (since 2012), and Hoshi University (since 2012). After he got Ph.D. in 1988 in Osaka University and then went to do a post-doc at La Jolla Cancer Research (Burnham Institute for Medical Research), CA, USA. Dr. Ochiya’s lab focuses the development of novel animal models, methods, and strategies to study cancer development and metastasis. Especially, current focuses are siRNA- and microRNA-based therapy against cancer stem cells and biology of extracellular vesicles.

特別講演 (Distinguished Lecture) 2

13 : 30 ~ 14 : 30

Chairs: 泉 高司 第一三共株式会社薬物動態研究所  
Takashi Izumi Drug Metabolism & Pharmacokinetics Research Laboratories, Daiichi Sankyo Co.,Ltd.

DL2

QUANTITATIVE CLINICAL PHARMACOLOGY: IMPACT ON DRUG DEVELOPMENT, REGULATORY DECISIONS AND CLINICAL PRACTICE

Lawrence J. Lesko  
University of Florida Center for Pharmacometrics and Systems Pharmacology



Dr. Lawrence J. Lesko is Professor of Pharmaceutics and Director of the Center for Pharmacometrics and Systems Pharmacology in the University of Florida College of Pharmacy at Lake Nona (Orlando). Dr. Lesko was Director of the Office of Clinical Pharmacology in the Center for Drug Evaluation and Research at the Food and Drug Administration for 16 years until his retirement in July 2011. At the FDA, Dr. Lesko led the advancement of personalized medicine through the update of labels of previously approved drugs with new genetic information. Dr. Lesko co-authored numerous Guidance for Industry including “Clinical Pharmacogenomics: Premarketing Evaluation in Early Clinical Trials” and “Pharmacogenomics Data Submissions”. He also started a Division of Pharmacometrics that is responsible for quantitative analysis of dose-response and PK-PD relationships to support drug labels and NDA approvals, and the development of drug-disease models to support clinical trial simulations. Dr. Lesko led a program involved with mechanistic approaches to understanding drug safety including the prediction of off-target effects using bioinformatics approaches. Dr. Lesko has published more than 200 peer-reviewed manuscripts and is a frequent invited national and international speaker. In 2011, he received the Gary Neil Prize for Innovation in Drug Development from the American Society of Clinical Pharmacology and Therapeutics (ASCPT). Dr. Lesko also was honored with the Rawls-Palmer Progress in Medicine award from ASCPT, the Coriell Scientific Leadership Award for Personalized Medicine, the University of North Carolina Institute for Pharmacogenomics and Individualized Therapy Award for Clinical Service, and the Nathaniel B. Kwit Distinguished Service Award for Clinical Pharmacology from the American College of Clinical Pharmacology. His hobbies include riding motorcycles and underwater photography. He is a Divemaster certified by the Professional Association of Dive Instructors.

会長講演 (President's Lecture)

16 : 05 ~ 16 : 30

Chairs: 泉 高司 第一三共株式会社薬物動態研究所  
Takashi Izumi Drug Metabolism & Pharmacokinetics Research Laboratories, Daiichi Sankyo Co., Ltd.

PL

Two years’ activity of the current JSSX directors

鈴木 洋史 東京大学医学部付属病院  
Hiroshi Suzuki The University of Tokyo  
President, The Japanese Society for the Study of Xenobiotics

受賞講演

16 : 30 ~ 17 : 40

座長：寺崎 哲也 東北大学大学院薬学研究科 薬物送達学分野

学会賞 Essential Roles of Transporters in Absorption and Disposition of Endo/Xenobiotics  
○ Ikumi Tamai  
Kanazawa University

座長：横井 毅 名古屋大学大学院医学系研究科 総合医薬学領域トキシコゲノミクス

北川賞 Quantitative and Qualitative LC-MS/MS Analysis for Drug Discovery, Research and Development  
○ Zenzaburo Tozuka  
Graduate School of Pharmaceutical Science Osaka University Professor

座長：鎌滝 哲也 北海道大学薬学部

奨励賞 Generation of humanized model mice of drug metabolizing enzymes using human artificial chromosomes  
○ Yasuhiro Kazuki  
Tottori University

座長：大戸 茂弘 九州大学薬学研究院 薬剤学

奨励賞 Chronopharmacokinetic study based on the molecular circadian clock  
○ Satoru Koyanagi  
Graduate School of Pharmaceutical Sciences  
Kyushu University

Tissue disposition of bioactive substances based on cellular expression and localization of transporters

○ Masanori Tachikawa  
Graduate School of Pharmaceutical Sciences, Tohoku University

C会場 (Room C) October 10 (Thu.)

シンポジウム (Symposium) 10 9 : 30 ~ 12 : 00

基礎から再構築するトランスポーターの新たな側面 (日本薬物動態学会・トランスポーター研究会合同シンポジウム)  
**Transporter DIS, New aspects of transporters: Reconstruction from basic research (Joint Symposium)**

Organizers・Chairs: 大槻 純男 熊本大学大学院生命科学研究部 薬学系  
Sumio Ohtsuki Faculty of Lifescience, Kumamoto University  
寺田 智祐 滋賀医科大学医学部附属病院 薬剤部  
Tomohiro Terada Department of Pharmacy, Shiga University of Medical Science Hospital

SY-10-01 THE ADVANCE OF MOLECULAR BASIS OF ZINC TRANSPORTERS IN HEALTH AND DISEASES

深田 俊幸  
理化学研究所 統合生命医科学研究センター  
Toshiyuki Fukada  
RIKEN Center for Integrative Medical Sciences



Academic and Professional Experiences  
1986-1990. BA, Applied Biological Science, Hiroshima University,  
1990-1992. MA, Applied Biological Science, Hiroshima University Graduate School  
1992-1994. Mochida Pharmaceutical Co. Ltd.  
1994-1998. Ph.D. Program, Osaka University Medical School, Supervisor: Prof. Toshio Hirano (1998-1999. JSPS Research Fellow)  
1999-2003. Post Doctoral Fellow, Cold Spring Harbor Laboratory, Supervisor: Prof. Nicholas K. Tonks (2000-2002. JSPS Research Fellow in abroad)  
2003-2015. Senior Research Scientist, RIKEN Research Center for Allergy and Immunology  
2015-. Senior Research Scientist, RIKEN Center for Integrative Medical Sciences

SY-10-02 EMERGING ROLES OF SODIUM-DEPENDENT PHOSPHATE TRANSPORTERS IN MINERAL METABOLISM, DISEASES AND BEYOND

竹谷 豊  
徳島大学大学院ヘルスバイオサイエンス研究部 臨床栄養学分野  
Yutaka Taketani  
Department of Clinical Nutrition, Institute of Health Biosciences, University of Tokushima Graduate School



Education/Previous Academic Appointments:  
1992 Course of Nutrition, School of Medicine, University of Tokushima  
1994 Graduate School of Nutrition, University of Tokushima  
1994-1999 Research Associate, University of Tokushima  
1998 Ph.D. degree (Nutrition), University of Tokushima  
1999-2001 Post-doctoral fellow, Department of Cell Biology, University of Texas Southwestern Medical Center at Dallas  
2001-2003 Research Associate, University of Tokushima  
2003-present Associate Professor, University of Tokushima

Research Interests:  
Calcium and phosphorus metabolism, nutrition in chronic kidney disease

SY-10-03 INTERACTION BETWEEN NUTRIENTS/FOOD COMPONENTS AND INTESTINAL EPITHELIAL TRANSPORTERS

薩 秀夫  
東京大学大学院農学生命科学研究科 応用生命化学専攻食糧化学研究室  
Hideo Satsu  
Department of Applied Biological Chemistry, Graduate School of Agricultural and Life Sciences, The University of Tokyo



1999 Ph.D., The University of Tokyo, Japan  
1999 Postdoctoral Research Fellow, National Food Research Institute, Japan  
2000 Domestic Research Fellowship of Japan Science and Technology (JST), Japan  
2000 Research Associate, The University of Tokyo, Japan  
2006-2007 Research Fellow, The Scripps Research Institute, USA  
2007- Assistant Professor, The University of Tokyo, Japan

SY-10-04 CHRONOPHARMACOLOGICAL ASPECTS OF TRANSPORTERS

大戸 茂弘  
九州大学大学院薬学研究院 薬剤学分野  
Shigehiro Ohdo  
Department of Pharmaceutics, Graduate School of Pharmaceutical Sciences, Kyushu University



Dr. Shigehiro Ohdo is a professor, Vice-Dean, Department of Pharmaceutics, Graduate School of Pharmaceutical Sciences, at Kyushu University. He graduated from the doctor course of Ehime University, School of Medicine in 1988. Then he has worked as research associate at University of Southern California since 1989, as assistant professor at Ehime University since 1990, as assistant professor at Kyushu University since 1993, as associate professor at Kyushu University since 2001, as professor at Kyushu University since 2005 and as Vice-Dean, Faculty of Pharmaceutical Sciences, at Kyushu University since 2010. His field of interest is the development of new chronopharmacotherapy from viewpoints of molecular clock mechanism.

SY-10-05

生薬・漢方研究のターゲットとしてのトランスポーター

**TRANSPORTER IS ONE OF THE RESEARCH TARGETS IN THE STUDY OF CRUDE DRUG AND KAMPO MEDICINE**

牧野 利明

名古屋市立大学大学院 薬学研究科 生薬学分野

Toshiaki Makino

Dept. of Pharmacognosy, Nagoya City University Graduate School of Pharmaceutical Sciences



- 1972 Born in Tokyo
- 2000 Department of Pharmacognosy, Graduate School of Pharmaceutical Sciences, Kyoto University. Awarded the degree of Ph.D. for a thesis entitled.
- 2000-2005 Assistant Professor, Department of Kampo Medicinal Sciences, Hokkaido College of Pharmacy, Otaru, Japan
- 2002-2003 Visiting Scientist, National Center for Natural Products Research, University of Mississippi, MS, USA
- 2005-2007 Lecturer and Assistant Professor, Department of Pharmacognosy, Graduate School of Pharmaceutical Science, Nagoya City University, Nagoya, Japan
- 2007- Associate Professor, Department of Pharmacognosy, Graduate School of Pharmaceutical Science, Nagoya City University, Nagoya, Japan

# D会場（Room D） October 10（Thu.）

## 共催シンポジウム（Joint Symposium） 9：30～12：00

医薬品適正使用における薬物動態・毒性インフォメーションの有効活用（学会活動活性化委員会企画・日本 TDM 学会・日本薬物動態学会共催シンポジウム）  
Best Use of Pharmacokinetic and to Toxicologic Information for Rational Use of Drugs (Joint Symposium with The Japanese Sositety of Therapeutic Drug Monitoring)

Organizers・Chairs: 谷川原祐介 慶応義塾大学医学部 臨床薬剤学  
Yusuke Tanigawara Deparment of Clinical Pharmacokinetics and Pharmacodynamics School of Medicine, Keio University  
齋藤 秀之 熊本大学医学部附属病院 薬剤部  
Hideyuki Saito Department of Pharmacy, Kumamoto University Hospital

### JSY-01

ENFORCEMENT OF CLINICAL PHARMACOLOGY AND TOXICOKINETIC EDUCATION IN MEDICAL AND PHARMACY STUDENTS WITH PROGRAMMABLE PHYSIOLOGICAL SIMULATOR MAY BE BENEFICIAL FOR GOOD PRESCRIBING AND MEDICATION SAFETY

越前 宏俊  
明治薬科大学薬物治療学  
Hirotoshi Echizen  
Department of Pharmacotherapy, Meiji Pharmaceutical University



1978 Graduation from Hokkaido University, School of Medicine  
1978-80 Resident of Internal Medicine, National Medical Center Hospital  
1980-1983 Research fellow, Division of Clinical Pharmacology, University of Colorado, USA  
1983-1984 Research fellow, Department of Internal Medicine, University of Bonn, Germany  
1984-1986 Senior resident, Department of Gastroenterology, National Medical Center Hospital  
1986-1994 Senior researcher, National Institute of Nutrition  
1994-1995 Assistant Professor, Department of Pharmacology, Kitasato University School of Medicine  
1995- Professor, Department of Pharmacotherapy, Meiji Pharmaceutical University  
2006- Vice President of Meiji Pharmaceutical University

### JSY-02

DISTINGUISHING THE PHARMACOKINETICS AND TOXIC INFORMATION OF NEW ORAL ANTICOAGULANTS FOR JAPANESE PHYSICIANS

志賀 剛  
東京女子医科大学 循環器内科  
Tsuyoshi Shiga  
Department of Cardiology, Tokyo Women's Medical University



2007-present Associate Professor, Department of Cardiology, Tokyo Women's Medical University  
2006-2007 Assistant Professor, Department of Cardiology, Tokyo Women's Medical University  
2003-2006 Lecturer, Department of Cardiology, Tokyo Women's Medical University  
2001-2003 Research Fellow, Section on Clinical Pharmacology, Hammersmith Hospital, Imperial College London, UK  
1999-2001 Instructor, Department of Cardiology, Tokyo Women's Medical University  
1993-1999 Clinical Fellow in Cardiology, Tokyo Women's Medical University  
1993 Ph.D. (Dr. of Medical Science) Jichi Medical School  
1988 M.D. Medical College of Oita

### JSY-03

“至適投与量”をどう決めるのか  
HOW TO DETERMINE "THE APPROPRIATE DOSE"

木村 利美  
東京女子医科大学病院 薬剤部  
Toshimi Kimura  
Department of Pharmacy, Tokyo Women's Medical University Hospital



1986.3 B.S. from Tokyo University of Pharmacy and Life Science  
1986.4 Department of Pharmacy, Kitasato University Hospital  
1993.3 University of Michigan Hospitals、University of California San Francisco（3 month）  
2000.12 Ph.D. from Kitasato University School of Medicine  
2001.1 The Japanese Society of Clinical Pharmacology (Clinical trainer)  
2001.11 An award of the Japan Antibiotics Research Association 2001  
2006.4 Vice Director, Tokyo Women's Medical University Hospital  
2007.6 An award of The Japanese Society of Chemotherapy 2007  
2009.7 Visiting Professor, Applied PK/PD Clinical Pharmacology and Therapeutics,Childrens Hospital of Philadelphia  
2010.11 Director, Tokyo Women's Medical University Hospital

JSY-04

CONTRIBUTION OF ADME RESEARCH TO THE PROPER USE OF DRUGS

奥平 典子  
第一三共株式会社 研究開発本部 薬物動態研究所  
Noriko Okudaira  
DAIICHI SANKYO CO., LTD. Drug Metabolism & Pharmacokinetics Research Laboratories, R&D Division



1983 B.S. from The University of Tokyo  
1985 M.S. from The University of Tokyo  
1985-1991 Nippon Roche  
1991-1992 Postgraduate resercher, UCSF  
1992-2004 Meiji Seika Kaisha, Ltd.  
2004-2007 Daiichi Pharmaceutical Co., Ltd.  
2007- Daiichi Sankyo Co., Ltd.

JSY-05

TOXICOGENOMICS AND SAFETY BIOMARKER

山田 弘  
独立行政法人医薬基盤研究所 創薬基盤研究部 トキシコゲノミクス・インフォマティクスプロジェ  
クト  
Hiroshi Yamada  
Toxicogenomics Informatics Project, National Institute of Biomedical Innovation



2012-Present Project Leader, Toxicogenomics Informatics Project , NIBIO  
2007-2012 Sub-Project Leader, Toxicogenomics Informatics Project , NIBIO  
2006-2007 Director, Safety Sciences-Research, Pfizer  
2003-2006 Manager, Investigative Toxicology and Pathology, Pfizer  
2002-2003 Manager, Investigative Toxicology, Pfizer  
1987-2002 Toxicology, Pfizer

# E 会場 (Room E)    October 10 (Thu.)

## シンポジウム (Symposium) 11 9 : 30 ~ 12 : 00

日本におけるバイオアナリシスの進展と薬物動態への関わり (日本薬物動態学会・Japan Bioanalysis Forum (JBF) 共催シンポジウム)

Regulatory DIS, Involvement of Evolved Bioanalysis In Pharmacokinetics and DRUG Metabolism

—Co-Organized with Japan Bioanalysts Forum (JBF)— (Joint Symposium)

- Organizer:

小林 信博

Nobuhiro Kobayshi

第一三共株式会社 薬物動態研究所

Daiichi Sankyo Co., Ltd. DMPK laboratories
- Chairs:

間瀬 雅成

Masanari Mabuchi

田辺三菱製薬株式会社 データサイエンスセンター

臨床薬理部
- 松丸 剛久

Takehisa Matsumaru

日本ベーリンガーインゲルハイム株式会社

薬物動態安全性研究部
- Pharmacokinetics and Non-Clinical Safety Dept.

Nippon Boehringer Ingelheim Co., Ltd.

### SY-11-01

#### INVOLVEMENT IN THE PHARMACOKINETICS AND THE HISTORY OF REGULATED BIOANALYSIS IN JAPAN

香取 典子  
国立医薬品食品衛生研究所 薬品部  
Noriko Katori  
National Institute of Health Sciences



Dr. Katori is Chief of Third Section at Division of Drugs of National Institute of Health Sciences, Tokyo, Japan. She received her B.S. (1978), and M.S (1980) in Pharmaceutical Science from the Tohoku University, and a Pharm.D. degree from the Meiji Pharmaceutical University in 1997. She is a member of the advisory committee of Japanese Pharmacopoeia and a member of the committee for bioequivalence guidelines. Research interests have included pharmacokinetics and pharmacogenomics and analytical chemistry in CMC area. She also has concerned with the regulation as a statistical advisor.

### SY-11-02

#### EXTENDED APPLICATION OF DRIED BLOOD SPOT (DBS) FOR DRUG DEVELOPMENT

—Why you should use DBS—

中井 恵子  
三菱化学メディエンス株式会社 治験センター バイオアナリシス研究部  
Keiko Nakai

Bioanalysis Department, Clinical Development Service Center, Drug Development Service Segment, Mitsubishi Chemical Medience Corporation



Bioanalysis Department, Clinical Development Service Center  
Drug Development Service Segment  
Mitsubishi Chemical Medience Corporation  
Work responsibility  
GLP Management  
Education  
Faculty of Pharmaceutical Sciences, Hokkaido University  
Research career  
Bioanalysis: 1984 - Present  
Drug Metabolism and Pharmacokinetics: 1985 - Present  
Concerned bodies  
Japan Bioanalysis Forum

SY-11-03

OUR APPROACH FOR QUANTITATIVE METABOLITE ASSESSMENTS ACCORDING TO MIST GUIDANCE

小林 信博  
第一三共株式会社 薬物動態研究所  
Nobuhiro Kobayashi  
DaiichiSankyo Co., Ltd. DMPK laboratories



Education:  
1983-1987                Kyoto University, Kyoto, Japan, B.S., Pharmaceutical Department  
1987-1989                Kyoto University, Kyoto, Japan, M.S., Analytical Chemistry  
2001                        Kyoto University, Kyoto, Japan, Ph. D., Analytical Chemistry  
2001-2002                University of Florida, Gainesville, Florida; Postdoctoral Associate  
Professional Experience:  
April 1989-Mar 2007    Sankyo Co., Ltd.  
April 2007-Present     DaiichiSankyo Co., Ltd.  
Responsible not only for oncology project management from the aspect of DMPK, but also for the global management of bioanalytical work.

SY-11-04

GCC RECOMMENDATIONS ON PD BIOMARKERS VALIDATION

○ Dominique Gouty<sup>1</sup>, Fabio Garofolo<sup>2</sup>  
<sup>1</sup>Intertek Pharmaceutical Services, <sup>2</sup>Algorithme Pharma



Dominique Gouty is the Senior Director for Intertek Pharmaceutical Services in San Diego, CA, where she directly interacts with Project Managers/Principal Investigators and Project Analysts during assay development and validation to provide guidance on the most effective route to robust and rigorous assays. As well as being a technical advisor, Dr. Gouty also ensures that all bioanalytical assays are performed according to strict GLP guidelines and validation requirements. Dr. Gouty received her PhD degree from Marseille School of Medicine in Endocrinology and has 20 years experience in various disciplines ranging from Research and Development to Clinical, spanning several countries.

# A会場（Room A） October 11（Fri.）

## フォーラム（Forum） 2013 13：00～16：00

### Special population の考え方 Trend and practice in responding to special population

|            |                             |  |
|------------|-----------------------------|--|
| Organizer: | フォーラム委員会<br>Forum committee |  |
| Chairs:    | 川合 良成                       | 第一三共株式会社   |
|            | Ryosei Kawai                | Daiichi Sankyo Co., Ltd.                                 |
|            | 吉村 義信                       | 株式会社武田分析研究所  |
|            | Yoshinobu Yoshimura         | Takeda Analytical Research Laboratories, LTD.            |
|            | 内藤 真策                       | 株式会社大塚製薬工場   |
|            | Shinsaku Naito              | Otsuka Pharmaceutical Co., Ltd.                          |
|            | 永田 清                        | 東北薬科大学   |
|            | Kiyoshi Nagata              | Tohoku Pharmaceutical University                         |
|            | 水間 俊                        | 松山大学薬学部  |
|            | Mizuma Takashi              | College of Pharmaceutical Sciences, Matsuyama University |

#### F-01

#### 高齢者および小児医療における薬物動態データの重要性とこれからの新しい挑戦

石川 智久  
理化学研究所ライフサイエンス技術基盤研究センター（CLST）  
Noriko Katori  
National Institute of Health Sciences



1977 年～ 1982 年 北海道大学 大学院理学研究科 博士課程（理学博士）  
1982 年～ 1987 年 ドイツ Düsseldorf 大学医学部 博士研究員  
1987 年～ 1989 年 大阪大学医学部 生化学教室 助手  
1989 年～ 1991 年 ドイツ癌研究所 腫瘍生化学部門 プロジェクトリーダー  
1991 年～ 1995 年 テキサス大学 M.D. アンダーソン癌センター 助教授  
1995 年～ 2000 年 ファイザー製薬 主任研究員、室長、部長  
2000 年～ 2009 年 東京工業大学 大学院生命理工学研究科 教授  
2009 年～現在 理化学研究所 横浜研究所 OSC および CLST 上級研究員  
2012 年～現在 理研 創薬・医療技術基盤プログラム・テーマリーダー  
2012 年～現在 横浜国立大学 大学院医学研究科 客員教授（兼任）  
2015 年 Gordon 会議 “Multi-Drug Efflux Systems” 大会長

#### F-02

#### マルチプルリスクファクターとしての加齢と薬物動態変化 平山 正史 武田薬品工業株式会社



武田薬品工業株式会社 医薬開発本部 日本開発センター クリニカルデータサイエンス部部長。  
入社後約 10 年間の非臨床薬物動態研究を経て、臨床開発業務に従事。2009 年 4 月より現職。  
2012 年 1 月から日米欧クリニカルファルマコロジーのグローバルリードを兼務。

#### F-03

#### 病態における肝機能および腎機能低下時の薬物動態情報の現状と問題点 今村 知世 慶應義塾大学医学部医学部



1989 年 熊本赤十字病院・薬剤部（1997 年より係長，2000 年に結婚に伴う転居のため退職）  
2002 年 慶應義塾大学病院・治験管理センター（2004 年より主任）  
2004 年 同・薬剤部（2006 年より課長代理，2007 年に米国留学のため退職）  
2007 年 米国 National Cancer Institute, Medical Oncology Branch, Clinical Pharmacology Program  
にて visiting scientist うち 3 カ月間 Cancer Therapy Evaluation Program(CTEP) にて研修  
2009 年 慶應義塾大学医学部臨床薬理学 講師

F-04

薬物動態モデルの Special Population への適用

川合 良成  
第一三共株式会社 トランスレーショナルメディシン部



【学歴】1986 年 千葉大学大学院薬学研究課博士後期過程終了 薬学博士  
【職歴】1986 年 野村総合研究所・生物科学研究所；1987 年 米国立衛生研究所 (NIH)、  
メディカルセンター核医学部 (Maryland 州)；1990 年 スイス・サント  
社 (Basel)；1993 年サント薬品(株)、つくば研究所；1996 年スイス・ノバルティ  
スファーマ社 (Basel)；2000 年ノバルティスファーマ(株)；2007 年 米国ノバ  
ルティス (Novartis Institute for Biomedical Research、ケンブリッジ、マサチュー  
セッツ州)；2011 年 9 月第一三共(株)

F-05

小児を対象とした医薬品の開発・承認審査について

坂口 宏志  
独立行政法人医薬品医療機器総合機構 新薬審査第二部



平成 19 年 3 月 東京大学薬学部薬学科卒業  
平成 21 年 3 月 東京大学大学院薬学系研究科薬科学専攻修士課程修了  
平成 21 年 4 月 独立行政法人医薬品医療機器総合機構入社

# D会場 (Room D) October 11 (Fri.)

## シンポジウム (Symposium) 12

9 : 30 ~ 11 : 40

### Clinical Pharmacology and Pharmacometrics DIS Part 2, Quantitative Systems Pharmacology (QSP) for translational drug research and development

Organizer・Chairs: 川合 良成 第一三共株式会社  
 Ryosei Kawai R&D Division, Daiichi Sankyo Co., Ltd.  
 Chairs: 樋坂 章博 東京大学医学部附属病院 薬理動態学  
 Akihiro Hisaka Pharmacology and Pharmacokinetics, The University of Tokyo Hospital

#### SY-12-01

#### TOP-DOWN, BOTTOM-UP OR MIDDLE-OUT: FUTURE REGULATORY SCENE IN THE USE OF PBPK

Amin Rostami  
 Manchester Pharmacy School, University of Manchester



Amin Rostami became a Professor of "Systems Pharmacology" at the University of Sheffield in 2007. He joined the University of Manchester in 2009 (Centre for Applied Pharmacokinetic Research). He has published over 135 highly cited peer reviewed papers (over 5000 citations) and has contributed to a number of book chapters. Amin has been an invited speaker at over 130 international meetings (several of them in Japan). As a co-founder of Simcyp Consortium (1999) he has directed R&D activities of Simcyp Limited since its inception in 2001. This currently involves overseeing the activities of a team of 40 scientists working on extrapolation of *in vitro* data on drug metabolism, transport and pharmacological activity to predict *in vivo* pharmacokinetics and PKPD in "virtual patients". Simcyp Simulator, a sophisticated commonly-used modelling and simulation platform for ADME by global pharmaceutical industry, is used by several Japanese companies such as Takeda, Daiichi-Sankyo, Otsuka, Eisai and Daiippon-Sumitomo. Amin has served as a member of the Editorial Board for many journals including advisory board of DMPK, the official journal of The Japanese Society for the Study of Xenobiotics (JSSX) and has recently received the JSSX Fellowship Award.

#### SY-12-02

#### QUANTITATIVE PHARMACOLOGY: SEEING DRUG DISCOVERY AND DEVELOPMENT THROUGH NEW EYES

Carolyn Cho  
 Modeling and Simulation, Global Clinical and Regulatory Development, Merck & Co.



Dr. Carolyn Cho has applied computer-based modeling and systems biology approaches to a range of decisions in the drug development pipeline in the therapeutic areas of diabetes, osteoporosis, Alzheimer's and cardiac disease. She has previously held positions as Director, Systems Biology Targets, at Pfizer and Global Head of Computational Systems Biology at Novartis Institutes for Biomedical Research (NIBR), as well as at Physiome Sciences (Princeton, NJ), SmithKline Beecham Pharmaceuticals (King of Prussia, PA), and Princeton University. Dr. Cho received her Ph.D. in biological physics from the University of Toronto and studied at the Institute of Space and Astronautical Science in Tokyo, Japan.

#### SY-12-03

#### APPLICATION OF MECHANISTIC PHYSIOLOGICAL MODELING IN THE DRUG DEVELOPMENT PROCESS—OVERVIEW AND CASE STUDIES

Michael Reed  
 Rosa & Co. LLC



Dr. Reed is the Chief Scientist at Rosa & Co. LLC and is responsible for managing strategic client collaborations. His experience in applying mathematical models to product development has given him unique insight into the difficult issues faced by biotechnology, pharmaceutical, and consumer product companies. In model development, he established rapport with clients to facilitate mutual knowledge exchanges in metabolic disease areas. Mike's previous work in preclinical pharmacology and drug development (Tularik, Shaman Pharmaceuticals) moved him into lead positions for evaluating the safety and efficacy of candidates in animal models of various diseases. Apart from metabolic diseases, his background also includes rheumatoid arthritis, antibacterials, nutrition, exercise physiology, and pediatric and animal health.

Dr. Reed completed his B.S. degree in Biology and his M.A. degree in Exercise Physiology at The University of Texas at Austin and attained a Ph.D. in Exercise Physiology at The Ohio State University, where his research focused on the effect of muscle contraction on skeletal muscle insulin resistance. Following his Ph.D., Dr. Reed completed a post-doctoral fellowship at Stanford University with Dr. Gerald Reaven, focusing on the mechanistic evaluation of insulin resistance in animal models of type 2 diabetes.

#### SY-12-04

#### SIMULTANEOUS ANALYSIS OF LONG TERM CHANGES OF MULTIPLE BIOMARKERS IN ALZHEIMER'S DISEASE BY STOCHASTIC REVERSE FRAGMENTATION

樋坂 章博  
 東京大学医学部附属病院 薬理動態学  
 Akihiro Hisaka  
 Pharmacology and Pharmacokinetics, The University of Tokyo Hospital



Akihiro Hisaka graduated, and received MS degree from Faculty of Pharmacy, Hokkaido University in 1982 and in 1984, respectively. He joined Banyu Pharmaceutical Co. Ltd in 1984 and charged in researches of pharmacokinetics and drug metabolism. In 1999, he received PhD degree from Faculty of Pharmaceutical Sciences, the University of Tokyo. In 2005, he joined the University of Tokyo Hospital as an assistant professor in Department of Pharmacy. From 2007, he served in the current position.

E会場 (Room E) October 11 (Fri.)

シンポジウム (Symposium) 13 9 : 30 ~ 11 : 40

薬物代謝研究の新規基盤技術  
Drug Metabolism DIS Part 2, Newly Based Technology in Drug Metabolism Research

Organizers・Chairs: 小林 カオル 千葉大学大学院薬学研究院 薬物学研究室  
Kaoru Kobayashi Laboratory of Pharmacology and Toxicology, Graduate School of Pharmaceutical Sciences, Chiba University  
野崎 和吉 アステラス製薬株式会社 創薬推進研究所 創薬代謝研究室  
Kazuyoshi Nozaki Analysis and Pharmacokinetics Research Labs. Discovery Drug Metabolism & Pharmacokinetics Astellas Pharma Inc.

SY-13-01

薬物動態研究の新規材料として期待されるヒト iPS 細胞  
EXPECTATION TOWARD HUMAN iPS CELLS AS A GOOD TOOL TO USE FOR EXAMINATION OF PHARMACOKINETICS

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1988-2001 Research Assistant and Assistant Professor, Hokuriku University  
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SY-13-02

INTERPLAY OF METABOLISM AND TRANSPORT IN SANDWICH-CULTURED HEPATOCYTES

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SY-13-03

A NOVEL APPROACH TO IDENTIFICATION OF THE METABOLIC SITES OF DRUG CANDIDATES USING ION MOBILITY SPECTROMETRY

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SY-13-04

一細胞質量分析の薬物代謝研究への応用  
LIVE SINGLE-CELL MASS SPECTROMETRY FOR DIRECT SINGLE CELL DRUG METABOLISM ANALYSIS

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シンポジウム (Symposium) 14

13 : 10 ~ 15 : 30

薬物代謝の変動要因とその分子基盤：基礎から臨床へ  
Drug metabolism DIS Part 1, Factors involved in drug metabolism and its molecular basis: From bench to bedside

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SY-14-01

miRNA による薬物代謝関連遺伝子の発現調節  
NEW KNOWLEDGE OF THE MICRORNA-MEDIATED REGULATION OF DRUG METABOLISM

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SY-14-02

薬物動態関連遺伝子のエピジェネティックな発現調節：プロモーターメチル化を中心に  
DNA METHYLATION PROFILE OF ADME-RELATED GENES AND ITS IMPLICATIONS IN PHARMACEUTICS

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SY-14-03

薬物代謝と脂質代謝の遺伝子発現レベルでのクロストーク：個人差、酵素誘導への寄与  
ROLE OF STEROL-RESPONSIVE TRANSCRIPTION FACTORS IN CYP3A GENE EXPRESSION

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Received JSSX Award for Young Scientists (2009) and ISSX Asia-Pacific New Investigator Award (2011).

SY-14-04

病態時の薬物代謝・薬物動態変動  
DRUG METABOLISM UNDER DISEASE STATE  
-EFFECT OF OBESITY ON DISPOSITION OF TACROLIMUS AND CUTAENOUS FENTANYL-

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SY-14-05

薬物代謝酵素の時間薬理学：制御機構の理解とその臨床応用へ向けて

**MOLECULAR MECHANISM REGULATING CIRCADIAN EXPRESSION OF DRUG METABOLISM ENZYMES IN HUMAN CELLS**

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