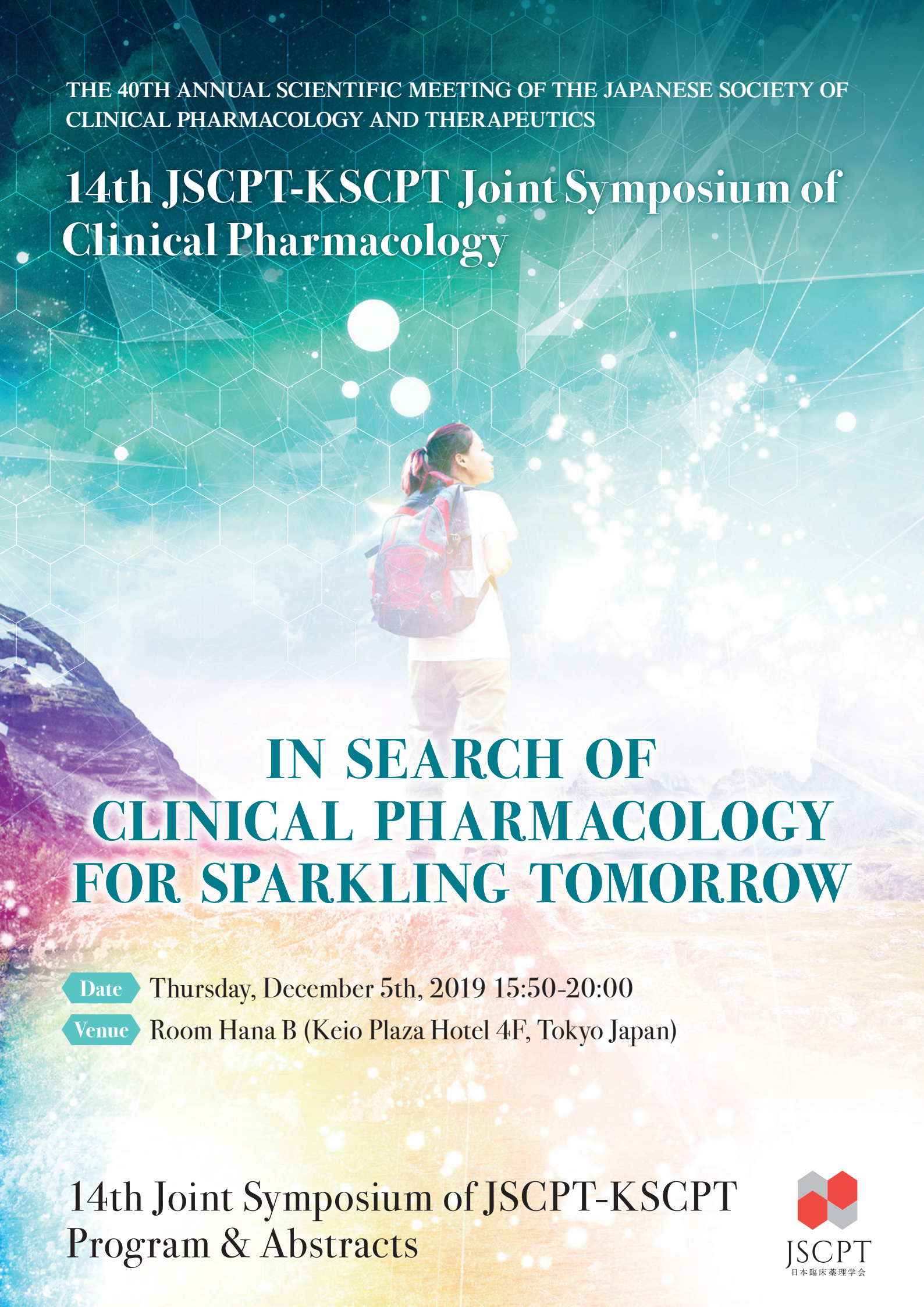
THE 40TH ANNUAL SCIENTIFIC MEETING OF THE JAPANESE SOCIETY OF CLINICAL PHARMACOLOGY AND THERAPEUTICS

14th JSCPT-KSCPT Joint Symposium of Clinical Pharmacology



IN SEARCH OF CLINICAL PHARMACOLOGY FOR SPARKLING TOMORROW

Date Thursday, December 5th, 2019 15:50-20:00

Venue Room Hana B (Keio Plaza Hotel 4F, Tokyo Japan)

14th Joint Symposium of JSCPT-KSCPT Program & Abstracts

JSCPT
日本臨床薬理学会

Program

14th Joint Symposium of JSCPT-KSCPT

Session Title : 14th Joint Symposium of JSCPT-KSCPT
Date : Thursday, December 5th, 2019 15:50-20:00
Venue : Room Hana B (Keio Plaza Hotel 4F, Tokyo Japan)

15:50-17:50 First Session: Precision medicine
Chairman : In Jin Jang
Takahisa Furuta

15:50-15:55 Opening by chairman

15:55-16:23 Pharmacogenomic implementation for precision medicine
Eun-Young Kim

16:23-16:51 Cancer Genome Medicine: promise and problem
Hironobu Minami

16:51-17:19 Precision Medicine in the Clinic: The real world experience
Young Suk Park

17:19-17:47 Pharmacogenetics in Psychiatry
Norio Furukori

Commenter : Kazuhiko Yanai

17:47-17:50 The summary by chairman

17:50-18:00 Break Time

18:00-20:00 Second Session: AI
Chairman : Min Soo Park
Naoki Matsumoto

18:00-18:05 Opening by chairman

18:05-18:33 The role of Artificial intelligence in endoscopic field
Tomohiro Tada

18:33-19:01 AI, bridge between reality and ideal in drug development
Dukyong Yoon

19:01-19:29 Artificial intelligence (AI) for medical imaging
Takuya Ueda

19:29-19:57 JARVIS: Using RWD to Support Clinical Drug Development
Jae Yong Shim

Commenter : Masako “Mako” Nakano

19:57-20:00 The summary by chairman

First Session : Precision medicine

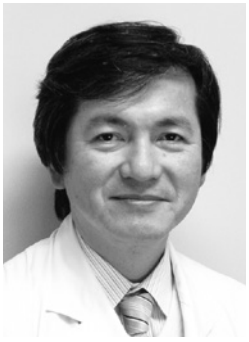
Chairman: **In Jin Jang**
(Seoul National University)
Takahisa Furuta
(Hamamtsu University School of Medicine)

Chairman

In Jin Jang

In-Jin Jang is Professor of Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Director of Department of Clinical Pharmacology and Therapeutics, and Clinical Trials Center of Seoul National University Hospital.

He obtained degrees of M.D. and PhD in 1987 and 1992 at Seoul National University, College of Medicine. He is a clinical pharmacologist who majors in pharmacogenomics, population PK/PD modeling/simulation and early clinical drug development methodologies. He worked as a visiting research fellow at Center for Drug Development Science, Georgetown University Medical Center from 1998 to 2000, where he worked in population PK/PD modeling and simulation of clinical trial. At Seoul National University and Hospital, he is responsible for research and education in the field of pharmacology and clinical pharmacology, especially pharmacogenomics and PK/PD. He is in charge of therapeutic drug monitoring consultation, execution of phase 1 clinical trials and general management of Clinical Trials Center at Seoul National University Hospital.



Takahisa Furuta

Education

1996	Ph.D. (Dr. of Medical Science), Hamamatsu University School of Medicine
1987	University of Occupational and Environmental Health
1979	Graduated from High School

Professional Training and employment

2012 -	Professor, Center for Clinical Research, Hamamatsu University School of Medicine
2005 – 2012	Associate Professor, Center for Clinical Research, Hamamatsu University School of Medicine a Instructor (Gastroenterology), First Department of Medicine, Hamamatsu University School of Medicine
2001- 2003:	Visiting fellow, Laboratory of Molecular Pharmacology, NCI, NIH
1998-2001:	Instructor (Gastroenterology), First Department of Medicine, Hamamatsu University School of Medicine
1996-1998:	Medical Staff in First Department of Medicine, Hamamatsu University School of Medicine, Hamamatsu.
1992-1996:	Graduate School of Hamamatsu University School of Medicine
1991-1992:	Medical Staff in First Department of Medicine, Hamamatsu University School of Medicine, Hamamatsu
1988-1991:	Medical Staff of Hamamatsu Rosai Hospital, Hamamatsu
1987-1988:	Resident in Internal Medicine, Hamamatsu University School of Medicine, Hamamatsu.
1987	Passed the Examination of National Board

Societies:
Japanese Society of Internal Medicine
Japanese Society for Gastroenterology
Japanese Society for Clinical Pharmacology
Japanese Society for Gastrointestinal Endoscopy
Japanese Society for Helicobacter
The Japanese Gastroenterological Association
Japanese Society of Clinical Oncology
Japanese Society of Medical Oncology
Japanese Society of Gastroenterological Mass Survey
American Society for Cancer Research (AACR)
American Gastroenterological Association (AGA)
American Society for Clinical Pharmacology & Therapeutics (ASCPT)

S13-1-1

Pharmacogenomic implementation for precision medicine

Eun-Young Kim

Department of Clinical Pharmacology, Inje University Busanpaik Hospital, Busan, Korea

The principle of optimal pharmacotherapy is to select the most appropriate drug and determine its dose. Pharmacogenetics and pharmacogenomics are considered as a part of precision medicine and have been contributed to this field of personalized medicine implicating the individual variation in drug response due to genetic polymorphisms. It was based on genetic variations in drug-metabolizing enzymes, drug transporters, drug targets, and human-leukocyte antigen (HLA) affecting the drug efficacy or/and toxicity in individuals. Pharmacogenomics has been moving from bench to bedside due to the advantage of improving a patient's care. The pharmacogenetic/pharmacogenomic evaluation in a patient may help clinicians for clinical decision in drug selection and dosing. The pre-emptive assessment of a patient's genetic profile can be available for future use in the patient's care. Recently, pharmacogenetic guidelines/labeling have been developed and updated to support the use of pharmacogenetic information in clinical setting. These include Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline, Dutch Pharmacogenetics Working Group (DPWG) guideline, and US Food and Drug Administration (FDA) labeling on a variety of drugs. In Korea, these efforts have been also made for clinical implementation by professionals in Ministry of Food and Drug Safety, academia, and hospitals. It will be introduced the status of clinical implementation for pharmacogenomics-guided pharmacotherapy in Korea and experience in our hospital will be also introduced.

Education

PhD (Clinical pharmacology): Seoul National University School of Medicine, Seoul, Korea
MS (Medical informatics): Massachusetts Institute of Technology (MIT), USA
MD: Korea University College of Medicine, Seoul, Korea

Professional Experiences

2005 – present : Professor and Head, Department of Clinical Pharmacology, Inje University Busanpaik Hospital
2018 – present : Representative chair person, IRB of Inje University Busanpaik Hospital
2014 : Visiting professor, Program in Personalized and Genomic Medicine, Division of Endocrinology, Diabetes and Nutrition, University of Maryland, Baltimore, USA
2000 – 2004 : Research fellow, Decision Systems Group, Brigham & Women's Hospital, Harvard Medical School, USA (Biomedical informatics)
1994 – 1998 : Residency training, Laboratory Medicine, Inha University Hospital, Korea

S13-1-2

Cancer Genome Medicine: promise and problem

Hironobu Minami

Medical Oncology/Hematology Kobe University Graduate School of Medicine and Hospital

Cancer is a disease of genes, and most cancers develop by the accumulation of somatic mutations. Survival of many tumors depends on activation of specific proteins via gene aberration, providing the opportunity to use targeted therapy. For example, tyrosine kinase inhibitors are used to treat non-small cell lung cancers harboring aberrations of *EGFR*, *ALK*, *ROS1* and *NTRK*. Therefore, patients should be screened sequentially for these gene aberrations using companion diagnostics.

Screening for hundreds of genes simultaneously has recently been introduced to oncology practice and the cost can be reimbursed by health insurance. However, these tests should be used for cancer patients with good performance status and those eligible for cancer drug therapy after standard therapies fail (i.e., candidates for phase I studies). The identification of targetable gene aberrations offers great hope for patients with no other treatment options, and who would be eligible to participate in phase I studies of investigational new drugs.

Cancer genome medicine is a rapidly evolving field that holds great promise; however, several issues remain. Among cancer patients who underwent multi-gene tests, only 20% had an aberration that could be treated with molecularly targeted drugs, and tumor shrinkage response was only observed in 2-3%. More clinical trials of drugs targeting specific gene aberrations should therefore be carried out. In Japan, currently, most clinical trials of this type are conducted in several hospitals in Tokyo. Access to clinical trials in areas outside Tokyo should therefore be improved. The cost of multi-gene testing is another issue, as is the challenge of off-label use of molecularly targeted drugs, which is unrealistic in Japan. Most matched treatments are performed in the context of clinical studies conducted by pharmaceutical companies; therefore, the cost of panel tests should be at least partly covered by these organizations.

Dr Minami is Professor of Medicine at Kobe University Graduate School of Medicine and the head of Medical Oncology and Hematology, Kobe University Hospital. He is also director of the Cancer Center and Center for Genome Medicine of the University Hospital. He graduated from Nagoya University Graduate School of Medicine and trained in internal medicine. He was a postdoctoral fellow at Hematology/Oncology, the Department of Medicine and Committee on Clinical Pharmacology of the University of Chicago in the US. From 1995 to 2007, he worked for the National Cancer Center Hospital East in Japan where he served as the head of the Section of Oncology/Hematology and the Office of Clinical Trials. His principal area of clinical practice and research is developmental therapeutics and clinical pharmacology/pharmacogenetics in oncology. He conducted more than 100 early clinical trials of anticancer agents and served on IDMC of more than 30 studies.

S13-1-3

Precision Medicine in the Clinic: The real world experience

Young Suk Park

Division of Hematology-Oncology Department of Medicine Samsung Medical Center, Sungkyunkwan University Medical School, Seoul, Korea

With the advent of molecular sequencing era, upfront high-throughput genomic profiling of patient's tumor specimen is now becoming part of clinical trials. Furthermore, systematic efforts to characterize the cancer genome constantly add genome alterations to the compilation of potentially actionable genomic alterations. There may be several reasons for hindering from rapid application of clinical sequencing in oncology patients: 1) There is a discrepancy between genomic sequencing results and available matched drugs to the sequence in the clinic; 2) the clinical implication of genomic sequencing in each cancer type is not fully understood; 3) currently, unless a master protocol is present for "umbrella" genomic sequencing project which is simultaneously aligned with several matched drugs, the time from target identification through NGS and the actual application of the drug takes relatively long period of time.

Recently, the interim results of the Molecular Screening for Cancer Treatment Optimization (MOSCATO01) trial were reported in 2013. Heavily pretreated 129 patients consented to participation, and 111 (86%) had dedicated tumor biopsy samples. An actionable target was identified in 52 patients (40%), of whom 25 were treated with a matched targeted therapy. In their report, the PFS ratio was greater than 1.3 among 9 out of 19 evaluable patients (47%), which led to the conclusion that high-throughput molecular analysis was feasible in daily practice. Notably, the percentage of patients undergoing treatment with a matched molecularly targeted agent based on genomic profiling was similar in our study (24.1%) and the MOSCATO01 trial (25%). The SHIVA trial also used an NGS platform similar to the one used in our study (AmpliSeq for cancer panel). In this trial, the success rate for acquiring mutations was 66%, with a tumor content cut-off of greater than 50%.

Despite the high success rate in genomic profiling and the reasonable rate of patients being treated with matched targeted agents, we need to increase the efficiency of the match rate between genomic data and actual treatment.

Professor Young Suk Park is a board certified medical oncologist. Dr. Park received his medical degree (1986) at Seoul National University College of Medicine, Seoul, Korea. Presently, Dr. Park is Professor of Hematology-Oncology division, Department of Medicine at the Sungkyunkwan University School of Medicine and the director of Clinical Trial Center in Samsung Medical Center. Many national projects for developing clinical trial support and training programs in Korea has been involved with Dr. Park.

Dr. Park's primary clinical interest is in the treatment of gastrointestinal cancers with an emphasis in conducting clinical trials as an active investigator. In this way, Dr. Park has conducted several clinical trials as a Principal Investigator since 2002. In addition, Dr. Park has several book chapters and authored about 190 published articles in international journals.

S13-1-4

Pharmacogenetics in Psychiatry

Norio Furukori

Department of Psychiatry, Dokkyo Medical University School of Medicine

It has been suggested that the reduced function allele with reduced cytochrome P450 (CYP) 2D6 activity, CYP2D6*10, is associated with the interindividual differences in the plasma paroxetine concentrations. In this study, we attempted to evaluate the degree of the impact of different CYP2D6 genotypes on the pharmacokinetic (PK) variability of paroxetine in a Japanese population using a population PK approach. This retrospective study included 179 Japanese patients with major depressive disorder who were being treated with paroxetine. The allele frequencies of CYP2D6*1, *2, *5, *10, and *41 were 39.4, 14.5, 4.5, 41.1, and 0.6%, respectively. A one-compartment model showed that the apparent Km value was decreased by 20.6% in patients with the CYP2D6*10/*10 genotype in comparison with the other CYP2D6 genotypes. Plasma concentrations of the S-enantiomer of citalopram were different between extensive and poor CYP2C19 metabolizers in healthy subjects and depressed patients. We studied the effects of polymorphisms of the CYP2C19 gene on raw plasma drug concentrations in Japanese patients with depression. Subjects in this study consisted of 412 depressed patients receiving 5, 10, 15, or 20 mg of escitalopram once a day. ANOVA showed significant effects of CYP2C19 genotypes on the dose-adjusted plasma concentration of escitalopram but not in the dose-adjusted plasma concentration of desmethylescitalopram.

2019-	Associate professor, Department of Psychiatry, Dokkyo Medical University School of Medicine
2009-19	Associate professor, Department of Neuropsychiatry, Hirosaki University School of Medicine
2005-09	Assistant professor, Department of Neuropsychiatry, Hirosaki University School of Medicine
2001-05	Assistant professor, Department of Clinical Pharmacology, Hirosaki University School of Medicine
1998-99	Kalorinska Institutet, Huddinge University Hospital, Department of Clinical Pharmacology, under the instruction of Professor Bertilsson
1997	PhD, Hirosaki University, Graduate School of Medicine
1993	MD, Hirosaki University, School of Medicine

Norio Yasui-Furukori, MD, PhD is the Associate professor, Department of Psychiatry, Dokkyo Medical University School of Medicine, JAPAN. He is a qualified Psychiatrist and Clinical Pharmacologist trained in Japan and Sweden. His main research interest is currently focused on Clinical Psychopharmacology and Biological Psychiatry. He has authored more than 30 case reports as well as 280 original research papers in peer-reviewed journals.

Research Interest:
Clinical Psychopharmacology
Biological Psychiatry

Second Session : AI

Chairman: **Min Soo Park**
(Yonsei University Collage of Medicine)
Naoki Matsumoto
(St. Marianna University School of Medicine)

Chairman

Min Soo Park

Min Soo Park graduated from Yonsei University College of Medicine (YUCM) in Seoul, Korea, and was trained in Pediatrics and Neonatology at Severance Hospital, Yonsei University. He received his MSc in Clinical Pharmacology at University of Aberdeen, UK, and PhD in Medicine at Ajou University, Korea. He served as Vice President of Korea National Enterprise for Clinical Trials (KoNECT) between 2008-2014. And he established the Clinical Trials Center of Severance Hospital and served as Director from 2004 to 2016. He served as Director of Medical Science Research Affairs & President of University-Industry Foundation, Yonsei University Health System between 2016 and 2018, and as the Chair of Korea Clinical Trials Global Initiative (KCGI), funded by Korea Ministry of Health and Welfare between 2014 and 2019.
Currently he is Professor in Pediatrics at YUCM, Head of Clinical Pharmacology at Severance Hospital, and a member of the Board of Trustees of KoNECT.

Naoki Matsumoto

Education:
-1991 St. Marianna University Graduate School of Medicine, Kawasaki, Japan
-1985 St. Marianna University School of Medicine, Kawasaki, Japan

Work experience:
2012- Professor of Pharmacology, St. Marianna University School of Medicine, Kawasaki, Japan
Director, Center for International Exchange, St. Marianna University
Director, Clinical Trial Unit, St. Marianna University Hospital
-2011 Associate Professor of Pharmacology, St. Marianna University School of Medicine
1998 Clinical Fellow, Mirowski Fellowship Program, Department of Cardiology, Good Samaritan Hospital, L.A., CA, USA
1991-1992 Postdoctoral Fellow, Department of Cardiology, Johns Hopkins University School of Medicine, Baltimore, MD, USA
-2000 Faculty of Medicine, Division of Cardiology, Department of Internal Medicine, St. Marianna University School of Medicine
1985-1987 Resident, Department of Internal Medicine, Central Hospital of Japanese National Railway, Tokyo, Japan

Speciality:
Arrhythmiology, Cardiology
Internal Medicine,
Clinical Pharmacology

S13-2-1

The role of Artificial intelligence in endoscopic field

Tomohiro Tada

AI MEDICAL SERVICE INC. CEO, University of Tokyo

In recent years, it has been found that AI's image diagnostic capability surpasses human beings in the image recognition field by having three functions of deep learning (in other words CNN: convolutional neural network) , high-performance computer (GPU), and a large amount of digitized image data. The introduction of AI in the medical field has begun in the field of diagnostic imaging. Following skin cancer, diabetic retinopathy, and colonic polyps, image classification and image pickup AIs are being developed one after another in the field of Medicine. Among them, in the field of gastrointestinal endoscopy, Japanese endoscopists have produced the world's first achievements one after another.Hirasawa et al. reported for the first time in the world a AI system for detecting gastric cancer by using machine learning with deep learning [1]. Shichijo et al. reported that diagnoses the presence or absence of H. pylori infection from endoscopic images. Horie et al. reported the convolutional neural network (CNN) based AI diagnosing system to detect esophageal cancer including both ESCC and EAC [3].Artificial Intelligence is augmented intelligence in the medical field. AI is a useful assistant tool for doctors, and there will be a big difference between doctors who use AI and doctors who cannot use it.1._Hirasawa T, Aoyama K, Tanimoto T, et al. Application of artificial intelligence using a convolutional neural network for detecting gastric cancer in endoscopic image. Gastric Cancer. 2018 ;21:653-660.2._Shichijo S, Nomura S, Aoyama K, et al. Application of Convolutional Neural Networks in the Diagnosis of Helicobacter pylori Infection Based on Endoscopic Images. EBioMedicine. 2017; 25: 106-11.3._Horie Y, Yoshio T, Aoyama K, et al. The diagnostic outcomes of esophageal cancer by artificial intelligence using convolutional neural networks Gastrointest Endosc. 2019 Jan;89(1):25-32.

EDUCATION/POST GRADUATE TRAINING

College/University:
1990-1996 MD, University of Tokyo School of Medicine
2001-2005 PhD in Surgery, University of Tokyo School of Medicine
Residency:
1996-1998 Resident in Surgery, University of Tokyo Hospital
Fellowship:
1998-2001 Fellow in Surgery, University of Tokyo Hospital

MEDICAL LICENSURE
Full Medical License (Japan) #381223

BOARD CERTIFICATION
Japan Surgical Society
Japan Society of Coloproctology
Japan Gastroenterological Endoscopy Society
Japan Society of Gastroenterology

PRESENT POSITION
Director, Tada Tomohiro The Institute of Gastroenterology & Proctology, 2006 – current
CEO, AI Medical Service Inc., 2017 - current

TEACHING ACTIVITIES
Visiting Lecturer, Department of Surgical Oncology, University of Tokyo, 2012 – current

S13-2-2

AI, bridge between reality and ideal in drug development

Dukyong Yoon

Department of Biomedical Informatics, Ajou University School of Medicine, Suwon, Republic of Korea

We are facing the big wave of real world data (RWD) and artificial intelligence in clinical trial field. Real world evidence (RWE) from the RWD provide opportunity to investigate new findings which is not easily able to be discovered by the traditional randomized clinical trial approach because of the complexity of relationship (ex. Drug interactions) or the expense of conducting large trials. In this context, institutes which control drug development and drug safety in many countries have started to adopt RWE for making their decision.

However, because the RWD is not data gathered for the drug development or the safety analysis, there is a gap between reality and ideal state what the researchers or workers in the drug development field want. For example, we would like to estimate or predict effectiveness and adverse reaction profiles of new drug in drug development process, but there is no record on that drug in RWD because it has not been used yet. And patients can have visited multiple hospitals, therefore data extracted from one institute cannot ensure that it covers whole medical information on the patient.

If we use proper artificial intelligent (AI) techniques, we may overcome this gap and be able to approach to the next step to the future. To go to the right direction, we will have to understand AI techniques. For that, brief introduction on the AI and the experience while adopting AI in the drug development will be presented and discussed in this presentation.

Professional Appointments

Assistant professor, Department of Biomedical informatics, Ajou University School of Medicine, Suwon, Korea (Mar/2016 – present)
Assistant professor, Department of Artificial Intelligent and Data Science, Ajou University, Suwon, Korea (Sep/2017 – present)
Board Member, The Korean Society of Medical Informatics (Feb/2016 – present)
Board Member, The Korean Society of Health Informatics and Statistics (Mar/2019 – present)
Vice Chairman, Korean Society of Medical Big-data Research (Mar/2019 – present)
Chief Executive Officer, BUD.on (Nov/2018 – present)
Research assistant, Department of Biomedical informatics, Ajou University School of Medicine, Suwon, Korea (Mar/2009 – Feb/2016)
Internship, Ajou University Hospital (Mar/2008 – Feb/2009)

Education

PhD, Department of Biomedical informatics, Ajou University School of Medicine, Suwon, Republic of Korea (Mar/2011 – Feb/2016)
MS, Department of Biomedical informatics, Ajou University School of Medicine, Suwon, Republic of Korea (Mar/2009 – Feb/2011)
MD, Department of Medicine, Ajou University School of Medicine, Suwon, Republic of Korea (Mar/2002 – Feb/2008)

Academic Recognitions

Best reviewer, *Pharmacoepidemiology and Drug Safety, Aug.* 2016
Best paper, Research Fair, Ajou University School of Medicine, Nov. 2012Best paper, Annual Meeting, Translational Bioinformatics Conference, Oct. 2012Best researcher, Research Fair, Ajou University, Oct. 2012Best paper, Annual Meeting, The Korean Society of Medical Informatics, Jun. 2012
Best paper, Annual Meeting, The Korean Society of Medical Informatics, Oct. 2009

S13-2-3

Artificial intelligence (AI) for medical imaging

Takuya Ueda

Department of Radiology, Tohoku University Graduate School of Medicine

Machine learning and artificial intelligence (AI) is rapidly applied to the medical field.
Medical imaging has high affinity to AI, especially to convolutional neural network (CNN), which is a most successful AI model, and has been actively introduced to diagnostic tool and high-quality image processing. While the expectations for this new method are very high, there are excessive expectations. While expectations for medical diagnosis support using AI are increasing, some critics suggested now AI is on the hype in the cycle of technology. The current AI is categorized as a "narrow AI" that specializes in a specific function, and is more appropriate to be referred to as Augmented Intelligence rather than Artificial Intelligence. Therefore, it is especially important to understand the clinical questions of what needs in medical problem should be solved by AI support to provide efficient human support. Although medical professionals does not have fully to understand mathematics and programming, it is not necessary to understand the outline of the method to propose effective usage.
In this session, I am going to introduce various machine learning and discuss how medical team get along with this new technology.

Education

Graduate: Chiba University School of Medicine, (Medical Doctor)
Postgraduate: Graduate School of Medicine, Chiba University. (Doctor of Medical Science)

Professional Training and Employment:

2018/09-	Professor, Department of Clinical Imaging Tohoku University Graduate School of Medicine
2018/01-	Associate professor, Department of Diagnostic Radiology Tohoku University Hospital, Japan.
2015-2017	Director of Department of Radiology, Seikeikai Chiba Medical Center. Japan.
2011-2015	Medical Stuff, Department of Radiology, St. Luke's International Hospital, Japan
2009-2011	Lecturer, Department of Radiology, Chiba University Hospital, Japan.
2007-2009	Visiting assistant professor, Department of Radiology, Stanford University School of Medicine, USA
2005-2007	Lecturer, Department of Radiology, University of Tsukuba, Japan.
1998-2005	Teaching Stuff, Department of Radiology, Japan. Graduate School of Medicine, Chiba University, Japan.
1997-1998	Chief Medical Staff in Department of Radiology, Numazu City Hospital, Japan.
1996-1997	Medical Staff in Department of Radiology, Numazu City Hospital, Japan.
1994-1996	Resident in Department of Radiology, Chiba University Hospital, Japan.
1994	Passed the Examination of National Board, Japan.

Society Membership:
Radiological Society of North America (RSNA)
European Congress of Radiology (ECR)
Japan Radiological Society
Asian Society of Cardiovascular Imaging (ASCI)
Society of Cardiovascular CT (SCCT)

Clinical Speciality:
Cardiovascular imaging
Abdominal imaging

Research Interest:
Computational fluid dynamics
Pathologic-radiologic correlation in cardiovascular imaging

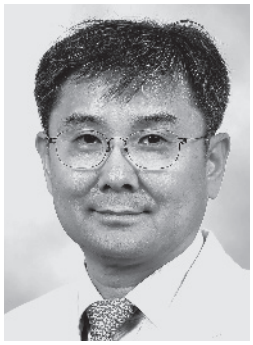
S13-2-4

JARVIS: Using RWD to Support Clinical Drug Development

Jae Yong Shim

College of Medicine, Yonsei University Health System, Seoul, Korea

Recent technical advances in big data analytics have generated interest in using EHR-based real world evidence (RWE) in the area of clinical research. However, still in the early stage are applying cutting-edge information technology (IT) for precise cohort extraction at an individual patient's level, natural language processing and automatic data analysis to visualize information. This process can be automated by machine learning and robotic process automation, which ultimately facilitate the efficient and effective clinical drug development. Examples include generation of supportive evidence for designing clinical trials, identification of potential clinical investigators based on their clinical practice experiences, study feasibility of assessing patients eligible for inclusion/exclusion criteria, retrospective observation study including comparative clinical outcome research. To fulfill these objectives, JARVIS has been created as named after 'Just Augmented Research naVIgation System'. JARVIS is currently an open-beta version and under the productizing development stage. It is composed of i) a clinical research data warehouse (CRDW) and ii) an application program with a variety of functions and specific algorithms. The user can extract precise cohorts using question-box, generate analysis dataset using automatic transposition of all relevant data variables, visualize statistically analyzed information. Since the CRDW has clinical research-related variables in addition to patients care activity data, it allows to identify a pool of researchers as potential clinical investigators who are contributing to the formation of a researcher network for study execution. Currently, this system operates at a single institution as a testing bed and is eventually growing to multi-site usage for the support of clinical development strategy and clinical trials operations involving Asian patients.



Jae Yong is a chair of Department of Family Medicine (FM) at Yonsei University College of Medicine and serves as a chief clinician of the FM clinic department at Severance Hospital.

He is currently a member of executive committee for clinical practice guideline of Korean Academy of Medical Science and also a training director of both the Korean Academy of Family Medicine and Korean Society of Hospice and Palliative Care post to a honorary fellowship in the department of palliative care at Flinders University in Australia.

For more than 10 years, he had served as a director of Global Center of Excellence in Clinical Trials as well as clinical trials center at Gangnam Severance Hospital. He had many opportunities for partnership meetings with global biopharmaceutical companies.

Those experiences lead to establishment of ALYND at Yonsei University Health System, in which the unmet needs from our industrial partners can be fulfilled through working closely with basic and clinical researchers and utilizing R&D resources only available in University Hospital.