How do countries across the globe collaborate effectively in delivering innovative pharmaceutical products, medical devices, and regenerative medical products to patients, in the fastest and most efficient way possible? With healthcare product development becoming increasingly global, the time has come to deepen the discussion on how to leverage the individual strengths of countries, promote better collaboration, and strengthen global partnerships, in order to build the ideal ecosystem for creating medicines, medical devices, and regenerative medical products. Furthermore, innovative technologies such as artificial intelligence (AI), big data/genomics, and cell/gene therapies are poised to transform healthcare product development across the globe – join us at the DIA Japan Annual Meeting 2018, to discuss these topics and the future of healthcare!

Our two invited keynote speakers will be Professor Guido Rasi, Executive Director of the European Medicines Agency (EMA) and Professor Satoru Miyano of Tokyo University, a leading expert in the fields of genome informatics and AI. On day one of our agenda, our first DIA Japan Annual Meeting innovative DIAmond session will be convened by members of the “Innovation Project” led by The International Coalition of Medicines Regulatory Authorities (ICMRA). Our second DIAmond Session, Innovative Clinical Trials, will be led by top leaders from industry, government, and academia, and share their expert insights into clinical trials of the future in the evolving contexts of innovative technologies and environmental changes. General sessions will address other critical “hot topics,” and the meeting also features our popular special chat session and PMDA Town Hall Meeting.

We look forward to welcoming you with very special program at Tokyo Big Sight on November 11-13, 2018 for stimulating discussions around promoting better collaboration to drive global health and innovation in this era of medical and scientific transformation. We hope to see you there!
## Japanese Language Only

### Short Break

**ORIENTATION AT EXHIBIT HALL (12:00-13:00)**

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- **VENUE 5**
  - Room 610
  - Orientation at Exhibit Hall (12:00-13:00)

### Networking Reception at Reception Hall

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- **VENUE 5**
  - Room 610
  - Networking Reception at Reception Hall (12:00-13:00)

### Coffee Break (Reception Hall)

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- **VENUE 5**
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  - Coffee Break (Reception Hall)

### Lunch Break

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- **VENUE 5**
  - Room 610
  - Lunch Break

### Short Break

**SHORT BREAK**

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- **VENUE 5**
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  - Short Break

### COFFEE BREAK (Reception Hall)

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- **VENUE 5**
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- **VENUE 5**
  - Room 610
  - Lunch Break

### SPI Engage and Exchange - Let's Chat - Special Chat Session - At Reception Hall

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- **VENUE 5**
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  - SPI Engage and Exchange - Let's Chat - Special Chat Session - At Reception Hall

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- **VENUE 5**
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- **VENUE 5**
  - Room 610
  - LUNCH BREAK

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**Related Interest Areas:** Clinical Research (CR), Regulatory Affairs (RA), Statistics (ST), Clinical Data Management (DM), Clinical Safety and Pharmacovigilance (CP), Project Management (PM), Chemistry, Manufacturing and Controls (CMC), Academia (AC), Medical Affairs (MA), Others (O)
SUNDAY, NOVEMBER 11
9:00-9:30  Registration for Student Session
9:30-12:00  Student Session
9:30-  Exhibitor Registration
11:45-  Attendee Registration
11:45-19:30  Exhibit Hall Open
12:00-13:00  Orientation at Exhibit Hall
13:30-14:00  Welcome & Opening Remarks
14:00-14:15 2018 DIA Japan’s Inspire Regional Awards Ceremony
14:15-15:00  Keynote Address 1 by Professor Guido Rasi, European Medicines Agency (EMA)
15:00-15:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
15:30-16:15  Keynote Address 2 by Dr. Satoru Miyano, The University of Tokyo
16:15-17:45  DIAmond Discussion 1 ‘New Challenges for Innovation ~ICMRA Innovation Project~
18:00-19:30  Networking Reception

MONDAY, NOVEMBER 12
8:30-  Attendee & Exhibitor Registration
9:00-19:00  Exhibit Hall Open
9:00-10:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30-11:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30  Session - 2
12:30-14:00  Lunch Break / Poster Session / Luncheon Seminar
14:00-15:30  Sessions - 3
15:30-16:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30  Sessions - 4
17:45-19:00  Engage and Exchange - Special Chat Session

TUESDAY, NOVEMBER 13
8:30-  Attendee & Exhibitor Registration
9:00-16:00  Exhibit Hall Open
9:00-10:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30-11:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30  Sessions - 6
12:30-14:00  Lunch & Exhibit Hall Innovation Theater Presentations / Luncheon Seminars
14:00-15:30  DIAmond Discussion 2 ‘Innovative Clinical Trials: A Painting of the Future’
15:30-16:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30  DIAmond Discussion 3 ‘PMDA Town Hall’
17:30-17:40  Closing Remarks

Accessing Presentations
Available presentations will become accessible to Full-Program registrants about a week before the meeting and an e-mail announcement on how to access presentations will be sent to the registrants. Please note that this does not include all of the presentations but only those that were provided to DIA by a submission date. Meeting handouts will NOT be provided.

Private Social Function Policy
DIA does not allow hospitality functions to be held during any DIA educational offerings, scheduled Exhibit Hall hours, or social events. Below are the only hours that are acceptable for hospitality functions:
Saturday, November 10  All times are acceptable
Sunday, November 11  Before 8:00 and after 20:30
Monday, November 12  Before 8:00 and after 20:00
Tuesday, November 13  Before 8:00 and after 18:30

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers/instructors are their own opinions and not necessarily that of the organization they represent, or that of the DIA. Speakers/instructors and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media is prohibited without prior written consent from DIA.

Conversations on Today's Priorities
Hear from top thought leaders on global, interdisciplinary topics about the future of therapeutics, and how they affect you. Our DIAmond Sessions will bring together innovators from industry, academia, and government agencies to discuss key concepts, and have a conversation on today’s priorities. See page 7 and 26 for more details.
You've never seen a Global Forum like this.
DAY 1 | SUNDAY | NOVEMBER 11

Welcome and Keynote Address

PREOPENING

WELCOME
International Conference Room 13:30-13:45
Akio Uemura
Director, DIA Japan
Barbara Lopez Kunz
Global Chief Executive, DIA
Kazumichi Kobayashi
Chair, DIA Advisory Council of Japan
Operating Officer / Director, Business Development and Planning, Otsuka Holdings Co., Ltd.
Joseph Scheeren, PharmD
Chair, DIA / Senior Advisor R&D, Bayer AG

OPENING REMARKS
International Conference Room 13:45-14:00
PROGRAM CHAIR
Takuko Sawada
Program Chair
Director of the Board, Executive Vice President, Shionogi & Co., Ltd.

2018 DIA JAPAN'S INSPIRE REGIONAL AWARDS PRESENTATION
International Conference Room 14:00-14:15
PRESENTER:
Joseph Scheeren, PharmD
Chair, DIA / Senior Advisor R&D, Bayer AG

AWARD WINNERS:
Outstanding Contribution to Health Award
TBA
TBA

Excellence in Service Award
TBA
TBA

Leader of Tomorrow Award
TBA
TBA

KEYNOTE ADDRESS 1
International Conference Room 14:15-15:00
SESSION CHAIR:
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)
The EMA has set up a Regulatory Science Observatory, including Horizon Scanning methodology, analysis and use, to get ahead of innovation coming to regulators in EU. The observatory outcomes allow to identify the experts needed, especially if their expertise is outside of the usual scope of regulatory expert work. The EMA, as enabler, focuses its effort in facilitating and streamlining the generation of robust and reliable evidence supporting a lifecycle approach to benefit/risk and access to patients. This requires active involvement of stakeholders, not only patients but also health technology assessment bodies and payers. As gatekeeper, the EMA is ready to respond to regulatory challenges to ensure the right protection of patients receiving innovative medicines. Working with ICMRA allows to share with our international partners best practices and outcomes of horizon scanning, while preparing the regulatory framework to opportunities brought by disruptive innovation, in the interest of patients globally.

Innovation and Regulatory Science
Guido Rasi, MD
Executive Director, European Medicines Agency (EMA)

COFFEE BREAK 15:00-15:30

KEYNOTE ADDRESS 2
International Conference Room 15:30-16:15
SESSION CHAIR:
Kihito Takahashi, MD, PhD
Vice President and Director, Japan Development, GlaxoSmithKline K.K.
For realization of genomic medicine, we need to elucidate characteristics, temporal-spatial diversity and origin of cancer by using large-scale sequencing data analyses obtained from whole genome sequence, RNA sequence, and methylation sequence.
The Institute of Medical Science, The University of Tokyo, aims to establish the integrated computational life science that constitutes the basis for personalized/preventive medicine. This requires a methodology for comprehensive understanding of pathological states and exploration of their effective treatments through a view from genome to the whole body, both environment and organism-spatiotemporally. We consider that this methodology can be realized by “information technology”, “application of physics principles”, and “utilization of big data”.
In this keynote lecture, the perspective on the genomic medicine and the innovation strategy for drug development will be described, from the viewpoints of the integrated computational life science.

Perspective on the Genomic Medicine Based on the Integrated Computational Life Science (Tentative)
Satoru Miyano, PhD
Professor, Human Genome Center, The Institute of Medical Science, The University of Tokyo
DIAmond Session 1

INTERNATIONAL CONFERENCE ROOM 16:15-17:45

New Challenges for Innovation -ICMRA Innovation Project-

Related Interest Area(s): RA, AC
Level: Beginner

SESSION CHAIR:
Rita Purcell
Deputy Chief Executive, Health Products Regulatory Authority (HPRA)

Guido Rasi, MD
Executive Director, European Medicines Agency (EMA)

The International Coalition of Medicines Regulatory Authorities (ICMRA) is composed of executives from each participating national/regional regulatory agency, and discusses each agency's experiences as well as strategies for resolving common issues. One of the top strategic priorities of ICMRA is the Innovation Project. This project is composed of three work streams, which aims to 1) investigate and research each agency's horizon scanning methodology, 2) share and leverage outcomes of horizon scanning, and 3) discuss the latest trends in novel pathways to licensing. In this session, the leads of each work stream will present the latest findings and discussions.

The Report from WS1; Analysis of Global Best Practice in Horizon Scanning Methodologies
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

The Report from WS2; Leveraging from Outcomes of Horizon Scanning
Agnès Saint-Raymond, MD
Head of International Affairs, Head of International Affairs, Head of Portfolio Board, European Medicines Agency (EMA)

The Report from WS3; Novel Approaches to Licensing
Pierre Sabourin, MBA
Assistant Deputy Minister, Health Products and Food Branch, Health Canada

Panel Discussion
ALL SESSION SPEAKERS AND
Nikolai Brun, MD, PhD
Director of Division, Medical Evaluation & Biostatics, Danish Medicines Agency

Alison Cossar
Manager, Product Regulation Branch, Medsafe, Ministry of Health

John Graham, PhD, MBA
Director, Office of Research Center for Veterinary Medicine, FDA

NETWORKING RECEPTION
Reception Hall 18:00-19:30
SESSION 1  9:00-10:30

V1-S1  Room 605/606  9:00-10:30

The Experience of Global Phase 1 Study (Japan/US) –Oncology Area–
Related Interest Area(s): RA, CR, AC
Level: Intermediate

SESSION CHAIR
Hironobu Saito, PhD
Vice President, Oncology Clinical Development Department, Oncology Function, R&D Division, Daiichi Sankyo Co., Ltd.

In recent years, First in Human (FIH) study is often carried out in the US, and the development in Japan is started later based on the data of FIH study in the US. In order to lead global development, it is necessary for Japanese sites to join global phase 1 study with US sites.

In this session, the US expert will introduce the experiences of global phase 1 studies in the US, and the Japanese expert will introduce the experience of global phase 1 study management from Japan. Finally, Japanese academia experts and US experts of Phase 1 will discuss about the way and efficiency of global phase 1 study including sites in Japan.

How is Global Phase 1 Managed?
Carol Woodward, MSc
Vice President, Development, Innovations and European Operations, Sarah Cannon

The Experience of “Japan-US” First-In-Human Study in Oncology
Yutaka Noguchi, MSc
Manager, Oncology Clinical Development Department, Daiichi Sankyo Co., Ltd.

Panel Discussion
All Session Speakers and
Toshihiko Doi, MD, PhD
Deputy Director / Chief, Experimental Therapeutics, National Cancer Center Hospital East

Johanna Bendell, MD
Chief Development Officer, Director, Drug Development Unit Nashville, Sarah Cannon

Tosio Shimizu, MD, PhD
Head of Physician (Oncology Phase 1 Unit), Department of Experimental Therapeutics, National Cancer Center Hospital

V2-S1  Room 607  9:00-10:30

Changes Required for Risk Minimization Materials
Related Interest Area(s): CP
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Mamoru Narukawa, PhD, RPh
Professor, Department of Clinical Medicine (Pharmaceutical Medicine), Graduate School of Pharmaceutical Sciences, Kitasato University

It has been 5 years since the RMP was implemented in Japan. The risk minimization measure, which is vital in considering the RMP as well as the Benefit Risk balance, is becoming more important. With regard to materials for healthcare professionals and for patients which have been part of the risk minimization measure in Japan, this session will discuss the direction of changes required in the future, based on current issues.

Points to Consider for Implementation of Risk Minimization Materials
Kazuhiko Ishida, MSc, RPh
Director, Pharmacovigilance, Astellas Pharma Inc.

Recognition and Expectation of Hospital Pharmacists on Risk Minimization Materials
Masahiro Hayashi, PhD

V3-S1  Room 608  9:00-10:30

Utilize Know-how and Experiences of Medicine/Device Development Obtained through Investigator Initiated Clinical Trials for Forthcoming Japan Venture Promotion
Related Interest Area(s): ALL
Level: Intermediate

SESSION CHAIR
Fumiki Kobayashi, PhD
President, CTD Inc.

Nowadays, about 50% of new therapeutics approved in US are originated by small bio-tech company and academia.

In Japan, drug discovery and research work by academic organization have been expected to make up for the delay of venture promotion.

“Investigator-initiated clinical trials for registration (IICT)” have been available since 2003 with the revision of the Pharmaceutical Affairs Law (at that time).

So far, it has been approved by many drugs and medical devices developed by the IICTs, contributed as one effective approach to develop additional indications as an idea of drug repositioning.

Recently, Japan government intensively promotes drug discovery, research and medicine development by venture companies and academic organizations. This session will provide a great opportunity to learn a way of project management to be applied into a translational medicine and early clinical development from the case examples from the investigator initiated clinical trials.

Exciting Scenes in Investigator-initiated Clinical Trials
Yoshitaka Miyakawa, MD
Professor, Thrombosis and Hemostasis Center, Saitama Medical University Hospital

Cost-effective Management and Essential Component of Investigator-initiated Drug Trial
Toshiki Saito, MD, PhD
Director, Department of Regenerative Medicine, Clinical Research Center, National Hospital Organization Nagoya Medical Center

Our Knowledge for Clinical Operation of Investigator’s Initiative Registration Studies from CRO Point of View
Tetsuya Orito, MPharm
President, DOT WORLD CO.,LTD.

Panel Discussion
All Session Speakers

V4-S1  Room 609  9:00-10:30

Overview of Cancer Genome Precision Medicine in Medical Practice – Oncology Panels and CDxs –
Related Interest Area(s): RA, AC
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Yasuhiro Fujiwara, MD, PhD
Director-GeneraL, Strategic Planning Bureau, Deputy-Director of the Hospital (Research), Department of Breast and Medical Oncology, National Cancer Center

A number of CDx have been developed towards implementation of precision medicine.
To promote precision medicine in cancer treatment, related issues are discussed and possible approaches were proposed in the report of “Consortium on Promotion for Cancer Genome Medicine” held in 2017. In this session, current status of oncology panel and CDx in Japan as well as in Senshin Iryo-B will be overviewed and the remaining issues for the implementation of cancer precision medicine in Japan will be discussed from industry, academia and government point of view.

**Clinical Sequencing by Todai Oncopanel, a Multiplex Cancer-related Gene Panel Testing**
Katsutoshi Oda, MD, PhD
Department of Obstetrics and Gynecology, Graduate School of Medicine, The University of Tokyo

**Implementation of the NGS-based test “NCC-Oncopanel” for Precision Cancer Medicine**
Kuniko Sunami, MD, PhD
Department of Pathology and Clinical Laboratories, National Cancer Center

**PMDA Perspectives on Oncology Panel**
Reiko Yanagihara, PhD, Sc
Deputy Review Director, Office of In Vitro Diagnostics, Pharmaceuticals and Medical Devices Agency (PMDA)

**Panel Discussion**
All Session Speakers and
Kosuke Iijima
Department Manager, PHC Strategy Dept. Project & Lifecycle Management Unit, Chugai Pharmaceutical Co., Ltd.

Kiyo Ishikura, PhD
PFDeNA Inc.

**V5-S1 Room 610 9:00-10:30**

**Call for Abstract Session**

*Related Interest Area(s): RA, DM, CR Level: Intermediate*

**SESSION CO-CHAIRS**

Keiji Imai, MSc
Acute Care, Medical Affairs, Pfizer Essential Health, Pfizer Japan Inc.

Koichiro Yuji, MD, PhD, FACP
Project Associate Professor, Project Division of International Advanced Medical Research, The Institute of Medical Science, The University of Tokyo

Three outstanding research speakers are selected for this year’s Call for Abstract session out of large number of applications from Japan and overseas through a rigorous selection process. Speakers show their knowledge, experience, and research suited to the theme of this annual meeting. Current hot topics will be beneficial to your future business in medicine development.

**Why the New Data-Rich Collaborations May Risk Harming Us More than Helping Us**
Kit Howard, MS
Director of Education, CDISC

**Therapeutic Needs of Older Patients in the Era of Mobile Health**
Dinah Duarte, PharmD, MSc
Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED

**Applications and Challenges of Machine Learning in Clinical Trials for Safety, Efficacy, and Operational Integrity Endpoints**
Kelci Miclaus, PhD
Advanced Analytics R&D Senior Manager, SAS Institute Inc., JMP Division

**V6-S1 Room 101 9:00-10:30**

**Challenges and Issues to Product Development for Gene Therapy**

*Related Interest Area(s): RA, AC Level: Beginner*

**SESSION CHAIR**

Masafumi Onodera, MD, PhD
Head of Genetic Research Department, National Center for Child Health and Development

In recent years, the development of products for genetic therapy became popular all over the world, and concrete discussions on commercialization have been carried out recently in Europe and US. On the other hand, in using genetically modified products, Japan and the EU have ratified the Cartagena Protocol, and in Japan it is necessary to consider environmental impacts on biosafety based on regulations by Japan original law.

In this session, we focus on the differences in the system of Japan, the US and Europe, and discuss the point to be cleared for conducting clinical trials in Japan when we submit the Cartagena Law type I usage application. We discuss issues to be considered for future practical application.

**Environmental Assessments and Shedding Studies for Gene Therapy Products in the US and in the EU**
Teruhide Yamaguchi, PhD
Professor, Nihon Pharmaceutical University

**Points to Consider in the Cartagena Law Type 1 Usage Application (Point of View from a Company)**
Hiroyuki Suda
Senior Director, Clinical Operation Department, Oncolys BioPharma Inc.

**Points to Consider for Creating Cartagena Type 1 Usage Application (From PMDA Point of View)**
Kazunobu Oyama, PhD
Principal Reviewer, Office of Cellular and Tissue-Based Products, Pharmaceuticals and Medical Devices Agency (PMDA)

**V7-S1 Room 102 9:00-10:30**

**Implementing Quality Management System (QMS) in Your Trials and Understanding the Purpose and Concept**

*Related Interest Area(s): RA, DM, CR, ST, PM, AC Level: Intermediate*

**SESSION CHAIR**

Hirotaka Inoue, PhD, MBA, Master Black Belt of Six Sigma
Head, Leading Changes Office, GlaxoSmithKline K.K.

Since ICH E 6 (R2) requires new responsibilities for Sponsors, each sponsor organization has to implement new measures and efforts for QMS. Although the current implementation is still trial and error at the field level, the majority of clinical trial operational staff at most companies have still not fully understood the fundamental concepts of QMS.

In this session, from the standpoint of the regulatory authority, they will explain the purpose and requirements of the QMS implementation, and from the point of view of the sponsor, they will introduce the proper method for implementation using PMBOK Guide (Project Management Body of Knowledge) and others in Risk Management and Quality Management / Quality Management System (QMS)

**Frame Work and Case Study of Clinical QMS by Using Project Management Skill**
Norikazu Nagao, MPHarm, PMP
Clinical Development Department, Pharmaceutical Division, Japan Tobacco Inc.

**Quality Tools and Skills for Clinical QMS - A Practical Application in Case Studies -**
Hirotaka Inoue, PhD, MBA, Master Black Belt of Six Sigma
Head, Leading Changes Office, GlaxoSmithKline K.K. / JPMJ DataScience Dept.

**Quality Management in a Clinical Trial - Regard to the Implementation of ICH-E6 (R2)-**
Yurika Miura
Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Devices Agency (PMDA)

**V8-S1 Room 703 9:00-10:30**

**Target Product Profile - Better Way to Build Up R&D Management Plan [Call for Abstract Session]**
Related Interest Area(s): RA, PM
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Yoshio Marumoto, MD, PhD
Associate Professor, Center for Clinical Research, Yamaguchi University Hospital

In this session, general TPP configuration items will be outlined with reference to FDA guidance. Furthermore, from the viewpoint of program management and scope management in the R & D process, we examine how effective TPP should be.

**Project Management Checklist in AMED**
Michiko Ishida, DrSc
Japan Agency for Medical Research and Development (AMED)

**Toward Implementation of Investigator-initiated Clinical Trial in Academia**
Shinobu Shimizu, PhD
Clinical Lecturer, Center for Advanced Medicine and Clinical Research, Nagoya University Hospital

**Basic Concept and Utilization of TPP in Pharmaceutical Company**
Atsushi Tsukamoto, PhD
Vice President, New Drug Regulatory Affairs, Daiichi Sankyo Co. Ltd.

Panel Discussion
All Session Speakers

COFFEE BREAK 10:30-11:00

SESSION 2 11:00-12:30

**V1-S2 Room 605/606 11:00-12:30**

**Recent Trend of Pharmaceutical Regulation in the World**
Related Interest Area(s): RA, AC
Level: Beginner

SESSION CO-CHAIRS
Jens Pierre Quartarolo, MD, MSc, MBA
Division of Director, Pharmacovigilance & Medical Devices, Danish Medicines Agency

Guido Rasi, MD
Executive Director, European Medicines Agency (EMA)

To respond to issues such as innovative technologies, globalization, and the increased awareness about drug safety among the general public, regulators around the world are introducing or revising existing regulation/legislation. In this session, executives from leading regulatory agencies will introduce the latest regulatory trends, as well as cooperation among agencies (e.g. ICH) and other topics.

**Recent Trend of Pharmaceutical Regulation in Europe**
Agnès Saint-Raymond, MD
Head of International Affairs, Head of International Affairs, Head of Portfolio Board, European Medicines Agency (EMA)

**Recent Trend of Pharmaceutical Regulation in Americas**
Rong Sun, PhD
Policy Advisor, Office of Policy and International Affairs, Health Canada

**Recent Trend of Pharmaceutical Regulation in Asia**
Junko Sato, PhD
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA)

**Recent Trend of Pharmaceutical Regulation in Oceania**
Alison Cossar
Manager, Product Regulation Branch, Medsafe, Ministry of Health

Panel Discussion

**V2-S2 Room 607 11:00-12:30**

**Current Activity on Utilization of Patient Registry Data**
Related Interest Area(s): ALL
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Akihito Hirakawa, PhD
Project Associate Professor, Department of Biostatistics and Bioinformatics, Graduate School of Medicine, The University of Tokyo

Following last year’s discussion, the utilization of patient registry data in drug development will be discussed again. For this year, we focus on recent engagements on this area and trends in the regulatory. Also, we introduce a way of operation and maintenance control of accumulated patient registry data by academia or society.

**Global Activity on Patient Registry**
Daisuke Koide, PhD, RPh, HIM
Project Professor, Department of Biostatistics and Bioinformatics, Graduate School of Medicine, The University of Tokyo

**SS-MIX2 Based Clinical Registry - Challenges of Leveraging Real World Data**
Mihoko Okada, PhD
President, Institute of Health Data Infrastructure for All

**Establishment of National Regenerative Medicine Database**
Kiyoshi Okada, MD, PhD
Vice Director, Medical Center for Translational Research, Department of Medical Innovation, Osaka University Hospital

**V3-S2 Room 608 11:00-12:30**

**Technical and Operational Know-How for Conducting Clinical Studies under Limited Manpower**
Related Interest Area(s): RA, CR, ST, PM, AC, O: Six Sigma
Level: Beginner

SESSION CHAIR
Chie Sakanaka, MD, PhD
Vice Director, Associate Professor, Clinical Research Support Center, The University of Tokyo Hospital

This session will provide you with a forum of hints and tips for efficient operation in clinical studies in order to overcome issues and prepare for risks during the operation.

To contribute to development of innovative NCE/NBEs and medical devices, cooperation among the 3 stakeholders, academia, government agencies and pharma companies are necessary. Especially, under constraints of resources, not only efficient use of time but also efficient process designs such as staff specialization and reporting/submission are required. As we are in the middle of rapid globalization, input from a speaker outside Japan will contribute to the discussions.

**Challenges in Conducting Clinical Trials**
Jie Willey, MSN
Administrative Director, Protocol Research, University of Texas, MD Anderson Cancer Center

**Towards Implementation of Investigator-Initiated Clinical Trial in Academia**
Shinobu Shimizu, PhD
Clinical Lecturer, Center for Advanced Medicine and Clinical Research, Nagoya University Hospital
How Lilly Japan Applied Six Sigma to Improve Productivity
Souta Mizumoto, MPHarm
Director, Global Patient Safety-Japan; Six Sigma Champion, Eli Lilly Japan K.K.
V4-S2  Room 609  11:00-12:30
How to Read and Future Prospects for PMDA Review Reports
Related Interest Area(s): RA, CP, PM, AC, O: Medical Writing
Level: Intermediate, Advanced
Language: Japanese Language Only
SESSION CHAIR
Mamoru Narukawa, PhD, RPh
Professor, Graduate School of Pharmaceutical Sciences, Development of Clinical Medicine (Pharmaceutical Medicine), Kitasato University
PMDA review report of similar drugs is a very useful reference for considering development strategies.
The tips of reading PMDA review report will be introduced as the short presentation of "point of the innovative drug supply review" author.
Following this, pharmacists will opinion with them how they are using the review report in the HCPs. Pharmaceutical will explain how to use review report for development strategies (including the perspective of drug price negotiations) and future expectations. Additionally, PMDA will show the previous initiatives and future prospects.

TBC
Mamoru Narukawa, PhD, RPh
Professor, Graduate School of Pharmaceutical Sciences, Development of Clinical Medicine (Pharmaceutical Medicine), Kitasato University

TBC
Mayumi Mochizuki, PhD
Professor, Evaluation & Analysis of Drug Information, Faculty of Pharmacy, Keio University

Utilization of Review Reports for Safe/Successful Launch of New Drugs
Fusako Oura, PhD
Pricing Group, Market Access, MSD K.K.

TBC
Hiroyuki Murakami
Duputy Review Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

V5-S2  Room 610  11:00-12:30
Oligonucleotide Therapeutics as Next Generation of New Medicine - Regulatory & Quality Considerations
Related Interest Area(s): RA, PM, CMC, AC
Level: Beginner, Intermediate
SESSION CHAIR
Takao Inoue, PhD
Chief of laboratory, Laboratory of Oligonucleotide Therapeutics, Division of Molecular Target and Gene Therapy Products, National Institute of Health Sciences
The Oligonucleotide therapeutics is currently one of the hottest topics as a next generation of new medicines. It is also proposed for a new ICH topic by the Japanese regulators, and is just started to discuss the regulatory and quality considerations.
In this session, the key experts from the regulator, industry and academia will discuss how the oligonucleotide-based drugs are assured from the regulatory and quality viewpoints.

Trend of Development and Regulation of Oligonucleotide Therapeutics
Takao Inoue, PhD
Chief of laboratory, Laboratory of Oligonucleotide Therapeutics, Division of Molecular Target and Gene Therapy Products, National Institute of

Health Sciences

CMC Considerations for Oligonucleotide Therapeutics
Kosuke Ito, PhD
Reviewer, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

Examples and Issues of Analysis in Oligonucleotides Manufacturing
Hirokazu Nankai, PhD
General Manager, Research & Development Division, GeneDesign, Inc.

V6-S2  Room 101  11:00-12:30
Think about the Exit Strategy in Drug Discovery Processes of Academia
Related Interest Area(s): RA, PM, AC
Level: Intermediate
SESSION CHAIR
Kotone Matsuyama, RPh
Professor, Department of Health Policy and Management, Nippon Medical School

Role of PMDA for Drug Development
Hisashi Koike, PhD
Review Director, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)

Actual Developmental Strategy for Regenerative Medicine Products
Hiroshi Hayashi, MS
Associate Professor, Clinical Research and Medical Innovation Center, Hokkaido University Hospital

First SAKIGAKE Designated Medical Device to Treat Adductor Spasmodic Dysphonia
Tetsuji Sanuki, MD, PhD
Associate Professor, Nagoya City University Graduate School of Medical Sciences

Panel Discussion
All Session Speakers and
Yuki Otsuka, BPHRM
Research Associate, Department of Development Promotion, Clinical Research Innovation and Education Center, Tohoku University Hospital
Shinich Torii, PhD
President, Managing Director, Board of Director, Head of R&D Japan, Biogen Japan Ltd.

V7-S2  Room 102  11:00-12:30
Use and Application of Real World Data/Evidence Based on Next Generation Medical Infrastructure Act
Related Interest Area(s): CR, ST, AC, O: HO, MA, Digital
Level: Beginner, Intermediate
SESSION CHAIR
Shunichi Takahashi, PhD
Director, Head of Open Innovation Center Japan, Bayer Yakuhin, Ltd.

Next Generation Medical Infrastructure Act become effective on 11th May 2018 and we are able to use medical related big data under proper information management.
In this session, presenters will share overview of real world data/evidence which is being established under all Japan system and important topics of Next
In addition, as cases from pharmaceutical company, some presenters will share practices of data application using EHR (electronic health record) or PHR (personal health record) and the value to health care professionals. This session will have a time to discuss how we should enhance the value of real world data / evidence in pharmaceutical industry.

TBC
Hiroshi Mizushima, PhD
Chief Senior Researcher, Center for Public Health Informatics, National Institute of Public Health

Overview of Next Generation Medical Infrastructure Act
Haruka Nakada, JD, PhD
Division of Bioethics and Healthcare Law, Center for Public Health Sciences, National Cancer Center

Our Challenge for Innovation: Real World Data
Masayuki Katsumata
Manager, RWD Management Group, Strategic Innovation Department, GlaxoSmithKline K.K.

Value of Real World Evidence to Clinicians
Jovelle Fernandez, MD, PhD, FPOGS
Vice President, Japan Medical Officer and Head, Japan Medical Affairs, Takeda Pharmaceutical Company Limited

Panel Discussion
All Session Speakers and
Masakatsu Imoto
Managing Director, Department of Clinical Research and Trials, Japan Agency for Medical Research and Development (AMED)

V8-S2  Room 703  11:00-12:30
The Latest Regulatory Trend and Counter Measures for Data Integrity
Related Interest Area(s): RA, CMC
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Shuji Sumida, MSc, RPh
Department Manager, Business Strategy & Compliance Department, Chugai Pharmaceutical Co., Ltd.
The integrity of required scientific data and process records in ensuring the quality, efficacy, and safety of drugs has come under the spotlight.

One major reason for this trend is instances of the alteration and falsification of data and records at a number of drug manufacturing sites. Steps such as access controls and review of audit trails are thus needed to stop intentional fraud, and the FDA has issued some warning letters in the last few years because of insufficient measures to ensure data integrity.

Such factors have led to data integrity coming under closer scrutiny, with guidances issued for all GxP areas, not only GMP.

In this session, we will discuss the main issues and what we can do to resolve them, taking a look at the latest regulations and recent inspection findings.

Regulatory Expectation for Industrial Efforts on Data Integrity and Observations on GMP Inspection (tentative)
Hiroyuki Kawakita
Specialist (for Inspection), Pharmaceuticals and Medical Devices Agency (PMDA)

The Latest Global Regulatory Trends on Data Integrity and Issues to be Addressed by the Pharmaceutical Industries
Satoshi Morino
Kashima Quality Assurance, Japan Regional Quality, Global Quality HQs, Eisai Co., Ltd.

Data Integrity Remediation Activities for Inspection Readiness and Outcome of FDA Inspection
Atsuto Kobe
Pharmaceutical Technology Quality Dept, Chugai Pharmaceutical Co., Ltd.

Panel Discussion
**Learning Objectives:**
- To leverage medical information data and real world data and to generate evidences by considering characteristics of data sources
- To share real world evidence
- To improve current situation and establish ideal clinical trial environment

**Methods:**
- Using PDCA Cycle concept, COM Community Members worked on PLAN, DO, and CHECK for each GAPS to minimize them. Addition to that, in order to understand site and site staff preparations, an Annual DIA Community session was held between COM Community and Hokkaido University Hospital.

**Results:**
- To minimize GAPS which were identified in 2016 COM Community, based on PLAN-DO-CHECK concept, actual cases for DOs and CHECKs by each member were shared and discussed. Here are some examples.

**<Gaps in study-start-up>**
- PLAN: Have sessions to advance to understand role and responsibilities on each CRA and site staff and to prepare for PDCA study files and investigator files.
- DO: Provide standard form but not customize for each site based on a principle that study protocols should be maintained and consistent.
- CHECK: Some sites understand the principle. By the action of not customizing work sheet, site staff have become to refer protocol directly. Some sites still request customization by CRA.

**<Gaps in Process>**
- PLAN: Implement risk assessments in clinical study
- DO: Implement pre-assessments on clinical sites based on various database for past site performances in site selection phase. Perform regular risk assessments on site performance by utilizing EDC metrics and other tracking tools.
- CHECK: Risk assessments based on metrics parameters already have become popular and standardized in each company, however, since risk indicators have been set by central, customization of the parameters or methods of the assessment according to study specific aspects is not possible.

**In the GAP discussion, the needs of deep understanding of site view and environment were recognized, and as a purpose of understanding clinical site’s view “Knowing each other” session was held with Hokkaido University Hospital. 10 staff from Hokkaido Univ Hospital and 6 COM members had discussion based on the questionnaires from sites staff in advance. In the session, the questions or concerns in daily operations were shared from both sides. Key learnings are that site staff feels sponsors have various opinions and provide different reason for their behaviors. Even if CRAs in same company, it seems some CRAs may not understand true meaning of their behaviors.

**Conclusion:**
- In our ongoing discussions on actual PDCA cases to minimize GAPS, more clearly and detailed discussion theme were set, then more deeply and actively we were able to advance the dialogues, and also it helped us to reflect on our behaviors. Therefore, we consider that continuous Community activities with various participants were vital to be future in order to look into real root cause of issues and to explore the essence in operations for clinical trials.
- COM community, since establishment in 2014, has been voluntarily conducting sessions among DIA members and has continued various discussions on the theme of problems related to clinical trials. In 2017, through approaches on efforts to minimize GAPS with PDCA Cycle concept, and deep dive with more sites to exchanging opinions, it is confirmed that there are lots of opportunities for us to improve current situation and establish ideal clinical trial environment.
- COM community continues providing opportunity to participants such as not only industry side but also clinical site staff that they can extend their perspectives and reflect meaning of mutual behaviors in clinical trials. This contents were presented at the 6th DIA COM workshop.

**Full Description:**
- MID-NET (Medical Information Database Network) has been launched since April 2018 in Japan. When clinical researchers take the mandatory MID-NET training courses, they are granted access right to the MID-NET database so that they can conduct database studies and/or epidemiological researches by extracting necessary data and analyzing it by running statistical programs. Lots of medical information databases are available in other regions as well; FDA Sentinel in the U.S., EMA Enceps in the Europe, NIH SEER (Surveillance, Epidemiology, and End Results Program) in the U.S., etc. When a researcher has a clinical question, database research is a potential measure to get the answer. It costs less time and reducing an interventional clinical trial. What points should the researcher consider to choose better method; database research or interventional study? It would be helpful for them to know what medical information database is applicable and how it is conducted. We reviewed existing database researches/studies by focusing on therapeutic area, patient number, diagnostic sensitivity, lethality, and so on. Database studies are practical in therapeutic areas with chronic diseases such as hypertension, because diagnostic measures are established and disease itself is not life-threatening thus enough patient data are collected easily.
- Database investigation of orphan diseases such as hemophilia is realistic and reasonable, because the number of patients with such disease is too limited to conduct interventional study prospectively. Researchers are likely to refer to existing patient database rather than newly conducting interventional studies, in progressive areas such as Alzheimer-type dementia, where biomarkers have just been found, database researches might not be necessarily successful, because medical information databases don’t crucial data such as biomarker values and information about preclinical subjects.

**Learning Objectives:**
- Know the important differences in regulations in clinical trials and post marketing safety reporting requirements.
- Understand the pharmacovigilance requirements in Asia and how they are different from the US and EU.
- Comprehend various challenges associated with safety reporting in Asian countries and explore measures to successfully manage the complexities.

**Full Description:**
- Pharmacovigilance (PV), demands a high degree of regulatory expertise. PV activities in the EU and US have continued to change and evolve as the public asks for greater transparency and protection. However, it has been a continuous challenge to harmonize the PV regulations in Asia due to diverse geographical, cultural and clinical practices in different region. Nonetheless, as the volume of clinical trials being conducted in the Asian countries has been growing rapidly in recent years as emerging markets grow, they are moving towards a trend of higher quality requirements with their tougher regulations. This increased demand necessitates an intensified focus on PV and drug safety in this region. PV in Asia has become an important public health issue as regulators, drug manufacturers, consumers, and HCPs are faced with a number of challenges. Lack of harmonization, diversity in regulatory requirements, lack of PV experts, lack of awareness amongst physicians and public and underreporting of spontaneous reports have been the major challenges in PV that need to be mitigated to build a robust system for drug safety in this region. To illustrate, a local representation is quintessential in China, India, and Taiwan, while that is not the case in some of the other countries. Further, the translation of safety reports to the local language is obligatory in some countries whereas it is not in Japan and South Korea; however, the English version is still acceptable in many others.

**Differences also exist in the mode of submission of reports, with different countries opting for manual/in-person submission or electronic submission. The virtual mode is not yet universal, because data entry measures are extended across many Asian countries.**

- In the GAP discussion, the needs of deep understanding of site view and environment were recognized, and as a purpose of understanding clinical site’s view “Knowing each other” session was held with Hokkaido University Hospital. 10 staff from Hokkaido Univ Hospital and 6 COM members had discussion based on the questionnaires from sites staff in advance. In the session, the questions or concerns in daily operations were shared from both sides. Key learnings are that site staff feel sponsors have various opinions and provide different reason for their behaviors. Even if CRAs in same company, it seems some CRAs may not understand true meaning of their behaviors.

**Conclusion:**
- In our ongoing discussions on actual PDCA cases to minimize GAPS, more clearly and detailed discussion theme were set, then more deeply and actively we were able to advance the dialogues, and also it helped us to reflect on our behaviors. Therefore, we consider that continuous Community activities with various participants were vital to be future in order to look into real root cause of issues and to explore the essence in operations for clinical trials.

**Method:**
- Using PDCA Cycle concept, COM Community Members worked on PLAN, DO, and CHECK for each GAPS to minimize them. Addition to that, in order to understand site and site staff preparations, an Annual DIA Community session was held between COM Community and Hokkaido University Hospital.

**Results:**
- To minimize GAPS which were identified in 2016 COM Community, based on PLAN-DO-CHECK concept, actual cases for DOs and CHECKs by each member were shared and discussed. Here are some examples.

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**<Gaps in Process>**
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- In the GAP discussion, the needs of deep understanding of site view and environment were recognized, and as a purpose of understanding clinical site’s view “Knowing each other” session was held with Hokkaido University Hospital. 10 staff from Hokkaido Univ Hospital and 6 COM members had discussion based on the questionnaires from sites staff in advance. In the session, the questions or concerns in daily operations were shared from both sides. Key learnings are that site staff feel sponsors have various opinions and provide different reason for their behaviors. Even if CRAs in same company, it seems some CRAs may not understand true meaning of their behaviors.

**Conclusion:**
- In our ongoing discussions on actual PDCA cases to minimize GAPS, more clearly and detailed discussion theme were set, then more deeply and actively we were able to advance the dialogues, and also it helped us to reflect on our behaviors. Therefore, we consider that continuous Community activities with various approach would be necessary in future.

- Through exchanging views with clinical site staff this time, we were able to know the realities of clinical trial at site and recognized that there are still many issues to be solved (gaps between industry side and clinical site). In addition, the way to capture the problem and cope with them are not standardized, and depends on individuals. Therefore, we consider that our continuous activities with various participants in various positions would be vital in order to look into real root cause of issues and to explore the essence in operations for clinical trials.

- COM community, since establishment in 2014, has been voluntarily conducting sessions among DIA members and has continued various discussions on the theme of problems related to clinical trials. In 2017, through approaches on efforts to minimize GAPS with PDCA Cycle concept, and deep dive with more sites to exchanging opinions, it is confirmed that there are lots of opportunities for us to improve current situation and establish ideal clinical trial environment.

- COM community continues providing opportunity to participants such as not only industry side but also clinical site staff that they can extend their perspectives and reflect meaning of mutual behaviors in clinical trials. This contents were presented at the 6th DIA COM workshop.

**Full Description:**
- Medical big data have become indispensable in medicine development. Many stakeholders in medicines development have been making decision by reference to information come from big data analysis. Many diseasespecific models have been developed to test experimental medicines in neurodegenerative diseases. However, evidence, however, that there is a substantial difficulty in choosing/accepting an optimal model or choosing measurements which would be truly informative of the potential drug efficacy. We describe a new method of Big Data analysis in the retrieval of information of in vivo models that may be used to support orphan drug designations in rare neurodegenerative conditions, which are validated for each condition and to evaluate assays pertinent to the core features of selected conditions or otherwise relevant from the clinical standpoint. The pioneering analysis will help identify models with best predictive value as well as those acceptable based on their face value, highlighting the areas of most
unmet need where development of better pre-clinical tools is necessary. We will discuss the importance of the availability of this information in encouraging sponsors to develop innovative medicines in rare neurological conditions and comprehensively review the advanced approach for big data utilization and future perspectives.

**[PO-07] Insight into New Regulations in Medical Device PV Arena – US and EU Perspective**

Mugdha Chopra, DDS
Co-Founder and Director, AWINS Life Sciences

Learning Objectives:
1. Understand how the management of safety for medical devices differs from other pharmaceutical agents.
2. Differentiate between medical device pharmacovigilance regulations in the US and EU.
3. Describe the challenges and complexities in the device regulations in the US and EU and, how the upcoming new rules will address them.

Full Description:
In recent times, there has been a very high level of public interest and active debate regarding the regulation of medical devices especially with regards to the pharmacovigilance aspect. This is in light of the safety concerns originating from poly-implant-prosthesis (PIP) breast and metal-on-metal hip implants. Although medicines and devices are regulated under European Union and the United States law, the regulatory regimes are very different, and some have argued that features of the pharmaceutical regime should be applied to medical devices. The United States and the European Union approach these challenges in different ways. Whereas the United States has always relied on a strictly centralized process through 1 agency, the Food and Drug Administration (FDA), the European Commission synchronized the regulations of 28 different countries as they combined to create the European Union. The FDA historically developed as a consumer protection agency, whereas the regulations from the European Commission arose out of a need to harmonize inter-state commercial interests while preserving national “autonomy.” The EU system has drawn criticism for conflicts of interest in its evaluation process, and a recent recall of a popular silicone breast implant that was approved only in the European Union has reinforced European concerns about the clinical evaluation of high-risk devices. In order to strengthen the regulations in medical devices, the European Parliament adopted new regulations on 5 April 2017. They will be published in the official Journal. The new rules will apply three years after publication with regards to the medical devices. US FDA too at the same time is taking initiatives to ensure that safety monitoring is robust both preapproval as well as post approval. This presentation explores some of the similarities and differences in European and US regulation of devices, and discusses challenges facing each.

**SESSION 3**

**V1-S3**

**Room 605/606**

**14:00-15:30**

**Current Situation and Future Perspectives of Risk Based Monitoring**

**Related Interest Area(s): CR, AC**

**Level: Beginner, Intermediate**

**SESSION CHAIR**

Norio Shimazaki
Senior Manager, Regional Clinical Operations Japan, Korea and Taiwan, Bristol-Myers Squibb K.K.

Several years have passed since many sponsors began implementing Risk Based Monitoring (RBM), however confusion continues at the site where clinical trials are ongoing. Especially from the perspective of medical institutions, the following comments have been made: “The introduction of RBM has increased the requirements from sponsors and the number of procedures has increased”; “Some companies want to unify the method of performing RBM”. It is likely that the confusion has been caused by paying attention to only to procedures and not to what matters most: the core meaning of RBM.

In this session, we will discuss the current situation and future perspectives based on Roles & Responsibilities of CRAs and CRCs and others in addition to the knowledge gained from GCP inspection in RBM implementation trials. We hope this session will help you deepen your understanding of the essence of securing Data Integrity.

**Response to RBM - Efforts to Visualize Clinical Trial Process -**

Nagako Umino
Project Management Department, Technical Solution Section, PAREXEL International

**New Challenges in Actual Scene by CRA/CRC from RBM Experience**

Hideaki Ueda
Clinical Operations, PAREXEL International

**Continuous Improvement of RBM Including PMDA Inspection**

**V2-S3**

**Room 607**

**14:00-15:30**

**The Sakigake Designation System: Challenges and Points for Improvement**

**Related Interest Area(s): RA, RM**

**Level: Beginner**

**Language: Japanese Language Only**

**SESSION CHAIR**

Yoichi Sato
VP, Head of Clinical Research Department, Shionogi & Co., Ltd.

The Sakigake Designation System was introduced in 2015 to provide innovative treatments to patients as early as possible. Pharmaceuticals, medical devices, in vitro diagnostics and regenerative medicines designated under the system are currently under development, and in 2017, two pharmaceuticals and one medical device received approval from PMDA. In this session, the challenges and points for improvement of the scheme will be discussed, based on the case studies of the approved products and by reviewing the approval and pricing procedures from the perspectives of the industry and regulatory authority.

**TBC**

Masayoshi Shibatsufu, MPHarm
Center for Research Administration and Support, National Cancer Center

**Look Back on the SAKIGAKE - Lead to Successful OUTPUT -**

Shigeki Shimasaki
Vice President & COO, Head of Research & Development, Nobelpharma Co., Ltd.

**From the Experiences of Xofluza**

Kenji Tsuchiya, MSc
Project Manager, Project Management Department, Shionogi & Co., Ltd.

**Panel Discussion**

All Session Speakers

**V3-S3**

**Room 608**

**14:00-15:30**

**TransCelerate: Innovation through Collaboration**

**Related Interest Area(s): ALL**

**Level: Beginner**

**SESSION CHAIR**

Norie Miki-Yasuda, PhD
Head of Clinical Operations Europe, Canada, Australia & New Zealand, Boehringer Ingelheim Pharma GmbH & Co. KG

“If you want to go fast, go alone; if you want to go far, go together.” Harnessing the power of collaboration can truly alter the healthcare landscape. This session will present TransCelerate’s perspectives around the next generation of collaborations. How will we need to work together differently as regulators, sponsors, patients, sites, and technologists are brought together? How can collaborations defy the bounds of innovation and accelerate disease prevention, diagnosis, treatment, and—ultimately—cure?

This thought-provoking conversation will bring together a diverse panel of senior executives from TransCelerate Member Companies to discuss the many solutions that have been developed across 19 companies to evolve the clinical trials paradigm. Attendees will learn about how TransCelerate has been solving challenges with Regulators in the Pharmacovigilance space, redefining the Site Investigator experience through novel technologies, and utilizing model frameworks for eConsent and eLabels to progress the industry towards digitally-supported, patient-centric trials.

**TBC**

Gareth Morgan
SESSION CHAIR
Hirofumi Takeuchi, PhD
Professor, Laboratory of Pharmaceutical Engineering, Gifu Pharmaceutical University

“Continuous Manufacturing” is a quite new innovative technology in the pharmaceutical industry, which will achieve the big cost reduction in manufacturing of the pharmaceutical drugs, while the continuous manufacturing is a major process in other industries, e.g., petroleum or food products. The continuous manufacturing is a process that the material(s) and product are continuously charged and discharged from the system, respectively, throughout the duration of the process in the drug manufacturing. In this session, the key experts from the regulator, industry and academia will discuss the regulatory and quality considerations for the continuous manufacturing and its driving forces.

Continuous Spherical Crystallization Used for Integrated Pharmaceutical Manufacturing
Kohoi Tahara, PhD
Associate Professor, Laboratory of Pharmaceutical Engineering, Gifu Pharmaceutical University

Janssen’s Experience to Introduce Innovative Continuous Manufacturing (CM)
Ryutaro Shimono
CMC Sciences Department, Regulatory Affairs Division, R&D Division, Janssen Pharmaceutical K.K.

Current Regulatory Considerations and Challenges for Continuous Manufacturing of Pharmaceuticals (tentative)
Issei Takayama, PhD
Reviewer, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)

V6-S3 Room 101  14:00-15:30
Patient Empowerment: Status Update of Patient Participation Support Program
Related Interest Area(s): ALL
Level: Beginner

SESSION CHAIR
Eri Sekine
Department Head, Trial Monitoring, Japan Development, Global Development Operations, Global Drug Development, Novartis Pharma K.K. Japan Patient Engagement Committee

In recent years, awareness and interest in Patient Centricity have increased, and even in Japan, patients are included as a member in meetings or committees government and medical institutions. In order to promote patients/citizens participation, efforts to provide necessary knowledge and skills for participation are very important. Various attempts at education of patients/citizens by industry, health authority and academia have been conducted both in Japan and overseas. Knowing such cases and objectives and thinking about what we should do is needed. In this session, we will introduce the efforts of European Patient Forum, the efforts of the Japan Intestinal Disease and Sickness Group Association that created guidance for patients’ participation in clinical trials, and the efforts to promote patient participation by AMED, and discuss the achievement, tasks and others.

Patient Engagement - a European Perspective
Paul Robinson, MD
EU Patient Engagement Lead, MSD

Regarding Rare and Intractable Diseases (NANBYO) Preparation of Guidelines for Research Cooperation and Collaboration Challenges of Research Participation from the Patient’s Perspective
Yukiko Mori
President, Japan Patients Association

TBC

V5-S3 Room 610  14:00-15:30
New Pharmaceutical Technical Innovation – Continuous Manufacturing and its Driving Forces
Related Interest Area(s): RA, PM, CMC, AC
Level: Beginner, Intermediate

SESSION CHAIR
Keiko Katsui, PhD
Reviewer, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)

Regarding Rare and Intractable Diseases (NANBYO) Preparation of Guidelines for Research Cooperation and Collaboration Challenges of Research Participation from the Patient’s Perspective
Yukiko Mori
President, Japan Patients Association

TBC

Toshiharu Sano, PhD
Executive Director, Head of Clinical Operations Area Japan Development, MSD K.K.

Key Initiative Update: Pharmacovigilance
Songlin Xue, MD, PhD
Executive Vice President and Global Head of Pharmacovigilance, Astellas Pharma US

Key Initiative Update: SIP (Shared Investigator Platform)
Kouichi Mitsuhashi
Regional Business System Lead, Clinical Operations Area, MSD K.K

Key Initiative Update: eLabel
Yosuke Chiyomori, MS
Clinical Development Manager, Clinical Development Operations and Innovations Trial Management, Eli Lilly Japan K.K.

V4-S3 Room 609  14:00-15:30
New Methods to Clinical Evaluation of Anticancer Drugs in the Era of Immune Oncology Therapy
Related Interest Area(s): RA, ST, AC, O: Clinical Strategy, Medical Writing
Level: Beginner

SESSION CHAIR
Yasuhiro Fujiwara, MD, PhD
Director-General, Strategic Planning Bureau, Deputy-Director of the Hospital (Research), Department of Breast and Medical Oncology, National Hospital Organization, National Cancer Center

Immunno-Oncology (I-O) is really a unique and innovative approach to treat cancer patients. And, I-O agents pose unique challenges to the design of clinical trial as the treatment effect may be delayed. Thus, several statistical approaches have been developed to address the violation of proportional hazard assumption. In this session, a comprehensive summary for such approaches including the use of the restricted mean survival time (RMST) will be provided from not only statistical but also clinical perspectives. Finally, this session will provide a comprehensive discussion of the clinical evaluation of I-O.

We will also discuss appropriateness of the clinical endpoints, the determination of development strategies, and the patient early access to new drugs as the treatment system evolves significantly regardless of I-O.

Clinical Questions and Application of Restricted Mean Survival Time for Immuno-oncology Clinical Trials
Tosio Shimizu, MD, PhD
Head of Priscian (Oncology Phase 1 Unit), Department of Experimental Therapeutics, National Cancer Center Hospital

TBC
Takeharu Yamanaka, PhD
Professor, Department of Biostatics, School of Medicine, Yokohama City University

TBC
Takahiro Hasegawa, DPH
Director, Biostatistics Center, Shionogi & Co., Ltd.

Panel Discussion
All Session Speakers and
Takahiro Nonaka, PhD
Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

V6-S3 Room 101  14:00-15:30
Patient Empowerment: Status Update of Patient Participation Support Program
Related Interest Area(s): ALL
Level: Beginner

SESSION CHAIR
Eri Sekine
Department Head, Trial Monitoring, Japan Development, Global Development Operations, Global Drug Development, Novartis Pharma K.K. Japan Patient Engagement Committee

In recent years, awareness and interest in Patient Centricity have increased, and even in Japan, patients are included as a member in meetings or committees government and medical institutions. In order to promote patients/citizens participation, efforts to provide necessary knowledge and skills for participation are very important. Various attempts at education of patients/citizens by industry, health authority and academia have been conducted both in Japan and overseas. Knowing such cases and objectives and thinking about what we should do is needed. In this session, we will introduce the efforts of European Patient Forum, the efforts of the Japan Intestinal Disease and Sickness Group Association that created guidance for patients’ participation in clinical trials, and the efforts to promote patient participation by AMED, and discuss the achievement, tasks and others.

Patient Engagement - a European Perspective
Paul Robinson, MD
EU Patient Engagement Lead, MSD

Regarding Rare and Intractable Diseases (NANBYO) Preparation of Guidelines for Research Cooperation and Collaboration Challenges of Research Participation from the Patient’s Perspective
Yukiko Mori
President, Japan Patients Association

TBC

Toshiharu Sano, PhD
Executive Director, Head of Clinical Operations Area Japan Development, MSD K.K.

Key Initiative Update: Pharmacovigilance
Songlin Xue, MD, PhD
Executive Vice President and Global Head of Pharmacovigilance, Astellas Pharma US

Key Initiative Update: SIP (Shared Investigator Platform)
Kouichi Mitsuhashi
Regional Business System Lead, Clinical Operations Area, MSD K.K

Key Initiative Update: eLabel
Yosuke Chiyomori, MS
Clinical Development Manager, Clinical Development Operations and Innovations Trial Management, Eli Lilly Japan K.K.

V4-S3 Room 609  14:00-15:30
New Methods to Clinical Evaluation of Anticancer Drugs in the Era of Immune Oncology Therapy
Related Interest Area(s): RA, ST, AC, O: Clinical Strategy, Medical Writing
Level: Beginner

SESSION CHAIR
Yasuhiro Fujiwara, MD, PhD
Director-General, Strategic Planning Bureau, Deputy-Director of the Hospital (Research), Department of Breast and Medical Oncology, National Hospital Organization, National Cancer Center

Immunno-Oncology (I-O) is really a unique and innovative approach to treat cancer patients. And, I-O agents pose unique challenges to the design of clinical trial as the treatment effect may be delayed. Thus, several statistical approaches have been developed to address the violation of proportional hazard assumption. In this session, a comprehensive summary for such approaches including the use of the restricted mean survival time (RMST) will be provided from not only statistical but also clinical perspectives. Finally, this session will provide a comprehensive discussion of the clinical evaluation of I-O.

We will also discuss appropriateness of the clinical endpoints, the determination of development strategies, and the patient early access to new drugs as the treatment system evolves significantly regardless of I-O.

Clinical Questions and Application of Restricted Mean Survival Time for Immuno-oncology Clinical Trials
Tosio Shimizu, MD, PhD
Head of Priscian (Oncology Phase 1 Unit), Department of Experimental Therapeutics, National Cancer Center Hospital

TBC
Takeharu Yamanaka, PhD
Professor, Department of Biostatics, School of Medicine, Yokohama City University

TBC
Takahiro Hasegawa, DPH
Director, Biostatistics Center, Shionogi & Co., Ltd.

Panel Discussion
All Session Speakers and
Takahiro Nonaka, PhD
Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

V5-S3 Room 610  14:00-15:30
New Pharmaceutical Technical Innovation – Continuous Manufacturing and its Driving Forces
Related Interest Area(s): RA, PM, CMC, AC
Level: Beginner, Intermediate

SESSION CHAIR
Hirofumi Takeuchi, PhD
Professor, Laboratory of Pharmaceutical Engineering, Gifu Pharmaceutical University

“Continuous Manufacturing” is a quite new innovative technology in the pharmaceutical industry, which will achieve the big cost reduction in manufacturing of the pharmaceutical drugs, while the continuous manufacturing is a major process in other industries, e.g., petroleum or food products. The continuous manufacturing is a process that the material(s) and product are continuously charged and discharged from the system, respectively, throughout the duration of the process in the drug manufacturing. In this session, the key experts from the regulator, industry and academia will discuss the regulatory and quality considerations for the continuous manufacturing and its driving forces.

Continuous Spherical Crystallization Used for Integrated Pharmaceutical Manufacturing
Kohoi Tahara, PhD
Associate Professor, Laboratory of Pharmaceutical Engineering, Gifu Pharmaceutical University

Janssen’s Experience to Introduce Innovative Continuous Manufacturing (CM)
Ryutaro Shimono
CMC Sciences Department, Regulatory Affairs Division, R&D Division, Janssen Pharmaceutical K.K.

Current Regulatory Considerations and Challenges for Continuous Manufacturing of Pharmaceuticals (tentative)
Issei Takayama, PhD
Reviewer, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)
V1-S4 Room 605/606 16:00-17:30
How Can We Define and Manage Quality Goals

SESSION 4 16:00-17:30

forward to meeting with you at this session.

Let’s Discuss How Our Values Are Related to Life and Work!

Related Interest Area(s): ALL
Level: Beginner
Language: Japanese Language Only
SESSION CHAIR
Minoru Niso
Acute Care Diagnostics Product Manager, Instrumentation Laboratory, I.L. Japan Co., Ltd.

In recent years, the awareness of diversity of workers has increased, and the way of thinking for “Shaping own life” including how to work / how to form career has been changing. Now we are facing an era of rapid change. Why don’t we use this opportunity to find out about our true values and how it’s related to our life and work?

In this session, we will have Mr. Piotr Feliks Grzywacz who is an expert of human resources development and used to work with Google for 6 years. Participants in this session have an opportunity to talk about diversity of the way to work, and to clarify ‘carrier anchors’ which weigh with your core value or competence through discussion among participants. Make your tomorrow life more positive with awareness of that! Let’s encourage innovation inside you! We are looking forward to meeting with you at this session.

TBD
Piotr Feliks Grzywacz
Founder & CEO, Pronoia Group

V4-S4 Room 607 16:00-17:30
Further Perspective of Development of Medicines for RD / Pediatric

Related Interest Area(s): RA, CR, AC
Level: Beginner
Language: Japanese Language Only
SESSION CHAIR
Hiroshi Watanabe, MD, PhD
Professor, Dept of Clinical Pharmacology & Therapeutics, Hamamatsu University School of Medicine

Pharmaceutical companies do not encourage the development of medicines for rare diseases / pediatric etc. because it is difficult to conduct clinical trials and collect the number of Japanese patient in the clinical data package so far. This session will be discussed the possibility of further development based on utilizing disease registry, RWD, etc. Model & Simulation, Post-market data, and planning development strategies that utilize new regulations such as ICH E17, conditional early approval system, etc.

Innovative Clinical Development Strategies for Rare Diseases and Pediatric Indications
Michinori Terada, PhD
Japan Clinical Leader, Rare Disease, Clinical Research, Pfizer Japan Inc.

Drug Development for Orphan Drugs by Utilization of Patient Registry Current Status and Issues of Remedy
Harumasa Nakamura, MD, PhD
Chief of Clinical Research Support Office, Translational Medical Center, National Center of Neurology and Psychiatry

Outlook of Orphan and Pediatric Drug Development from Regulatory Perspectives
Takashi Saito, MD, PhD
Clinical Reviewer, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers
Session Chair: Naomi Nagai, PhD
Professor, Faculty of Pharmacy, Musashino University

In July 2018, the Japanese drug interaction guideline was released. Although an international harmonization is being pursued with the cutoff criteria in decision trees and index drugs recommended for use in drug interaction studies, there are still some differences in the Japanese, US, and EU regulatory documents. In recent years, physiologically-based pharmacokinetic (PBPK) modeling & simulation have been effectively used, and its usefulness is mentioned in the documents. Application of appropriate models to predict drug interactions enables to improve the efficiency of drug interaction studies at the drug development stage. We discuss how to examine future drug interaction studies with comparing the regulatory documents for drug interaction studies announced from Japan, US, and EU.

Outline of Japanese Drug Interaction Guideline and its Scientific Significance
Akihiro Hisaka, PhD
Professor, Laboratory of Clinical Pharmacology and Pharmacometrics, Graduate School of Pharmaceutical Sciences, Chiba University

International Harmonization of the Regulatory Documents for Drug Interaction
Kazuya Maeda, PhD
Laboratory of Molecular Pharmacokinetics, Graduate School of Pharmaceutical Sciences, The University of Tokyo

Investigation of Drug Interaction Using PBPK Model
Yuki Matsumoto, MS
Clinical Pharmacokinetics & Pharmacometrics Group, Clinical Pharmacology Development, Clinical Research Area, Japan Development, MSD K.K.

Panel Discussion
All Session Speakers

V4-S4 Room 609 16:00-17:30
It's Time to Think About Compliance to Deliver Value Added Medical Information - Current and Ideal Situation of Medical Information Provision -

Related Interest Area(s): AC O: MA, Compliance
Level: Beginner, Intermediate

Session Chair: Stuart Sowder, PharmD, JD, MBA
Developed Asia Regional Compliance Lead, Pfizer Holdings

Following the daily changing scientific and ethical approach, data building that collected our wisdom will be the basis of application for approval. How should we provide the approved data adequately to health care professionals and contribute to the improvement of medical care quality? The advertisement should we provide the approved data adequately to health care professionals that collected our wisdom will be the basis of application for approval. How

It’s Time to Think About Compliance to Deliver Value Added Medical Information - Current and Ideal Situation of Medical Information Provision -
Yasuyuki Katayama, MD, PhD
Corporate Officer, Country Medical Director and Head of Medical Japan, Pfizer Japan Inc.

TBC
Tokuo Tanaka
Managing Director, Japan Pharmaceutical Manufacturers Association

Problems of Drug Promotion Activities Emerging from Report from Advertisement Surveillance Monitoring
Makoto Shiragami, PhD

Panel Discussion
All Session Speakers

V5-S4 Room 610 16:00-17:30
What ICH E17 Would Bring to Global Drug Development

Related Interest Area(s): TBC
Level: Intermediate

Session Chair: Taro Ishibashi, PhD
Senior Director, Head of Clinical Research, Pfizer Japan Inc.

Now that ICH E17 passed Step 5, and MRCs utilizing the Guideline will be used for the global drug development from now on. The Guideline defines the fundamental rules in designing MRCTs for drug development, but it doesn’t define how the result of MRCs should be analyzed and used for the judgment for drug approval. It will be the decision of each regulatory agency. In this session, we invite experts from various regions such as Japan, US, Europe or China, and ask them to discuss what changes this Guideline would bring to MRCs, and what implications the Guideline would have for the submissions of new drugs. And then we will discuss what ICH E17 would bring to global drug development.

E17 Implication for Global Drug Development: US Perspective
Joseph Scheeren, PharmD
Senior Advisor R&D, Bayer AG

E17 Implication for Global Drug Development: China Perspective
Ling SU, PhD
Professor and Director, Institute of Drug Regulatory Science, Shenyang Pharmaceutical University

E17 Implication for Global Drug Development: Statistical Consideration
Norisuke Kawai, PhD
Senior Director, Pfizer Japan Inc.

Panel Discussion
All Session Speakers and
Ryuta Nakamura, PhD
Review Director, Office of New Drug II, Pharmaceuticals and Medical Devices Agency (PMDA)

V6-S4 Room 101 16:00-17:30
New Drug Development Approaches to Realize Precision Medicine (Registry Study, Platform Trial)

Related Interest Area(s): ALL
Level: Beginner

Session Chair: Akihiro Hirakawa, PhD
Project Associate Professor, Department of Biostatistics and Bioinformatics, Graduate School of Medicine, The University of Tokyo

Precision Medicine, which provides optimal treatment for each disease subtype, has been proposed from the viewpoint of providing appropriate treatment individually tailored and patients first. In a conventional clinical trial, basically, a single study treatment / group / disease is a subject, and a more efficient approach is required to evaluate multiple treatment candidates for each more detailed subtype. In this session, new approaches in Japan and overseas in therapeutic areas such as oncology, neuroscience, etc, will be introduced about...
implementation of disease registry including Master Key Project in Japan, new designs using the Bayesian statistics such as Platform design, consortium building, etc. and will be discussed future directions and challenges.

**TBC**

Akiko Okamoto, ScD  
Senior Director, Global Head of Clinical Biostatistics for Neuroscience, Statistics & Decision Sciences, Quantitative Science, Janssen R&D, Johnson & Johnson

**MASTER KEY Project – a Basket/Umbrella Trial and a Registry Study for Rare Cancers in Japan**

Hitomi Okuma, MD, PhD  
Clinical Trial Management Section, Research Management Division, Clinical Research Support Office / Dept. of Breast and Medical Oncology, National Cancer Center Hospital

**TBC**

Takahiro Nonaka, PhD  
Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

**Global Regulatory & Industry Situation about Platform Trials (Tentative)**

Michael Krams, MD  
Global Head of Quantitative Sciences, Janssen R&D, Johnson & Johnson

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**V7-S4 Room 102 16:00-17:30**

**Future of e-Labeling in Japan**

*Related Interest Area(s): RA, CP, AC O: Medical affairs and Medical information  
Level: Intermediate*

**SESSION CHAIRS**

Rie Matsui, RPh  
Director, Regional Labeling Head for Asia, International Labeling Group, Pfizer Japan Inc.

The use of technology to transform the delivery, content and readability of product labeling has recently become a topic of great interest worldwide. In the EU, electronic labeling has been raised as a topic in the EMA action plan. With the US already using Structured Product Labeling (SPL) and many other markets introducing digital innovation to enhance delivery of the label. In Japan, although product labeling has been provided on the PMDA website for many years, an opportunity now exists to further transform the experience of the patient and healthcare professional. Linkage of the label with electronic medical records and digital health educational materials, coupled with production of personalized and multi-format versions of the label may offer the chance to dramatically improve understanding of health and treatment, and ultimately patient safety.

The future of e-labeling and the continuing role of the paper label in Japan will be discussed.

**Opportunities and Challenges with e-labeling from the Global Perspective**

Shimon Yoshida, PhD  
Exceptive Director, International Labeling, Pfizer Inc.

**Current Progress of e-labeling in Japan from Regulator’s Perspective**

Hidehito Sekino  
Director, Safety Division, Ministry of Health, Labour and Welfare (MHLW)

**Panel Discussion**

All Session Speakers and

Haruko Yamamoto, MD, PhD  
Director, Department of Advanced Medical Technology Development, Research and Development Initiative Center, National Cerebral and Cardiovascular Center

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**V8-S4 Room 703 16:00-17:30**

**Leader of You! Are You OK For Your Motivation? How About Your Team Member? Let’s Get Together and Dialogue How We Maintenance**

**SESSION CO-ORGANIZERS**

Koji Iwasaki, PhD  
Professor, Academic Clinical Research Center, Department of Medical Innovation, Osaka University Hospital

Takashi Sato, MSc, PMP, CPCC  
R&D Planning Department, Kyowa Hakko Kirin Co., Ltd.

This session is workshop style and use Japanese.

What is your feeling as an active leader or candidate of that roll under the pressure and responsibilities? You have heard of “motivation”, but what is it? Where does it come from? Let us get together and dialogue them!

In this session, organizers will introduce approaches and examples of motivation for leaders from the viewpoints of coaching and counseling, and participants dialogue, feel and think what the motivation is for yourself and your team member.

**SHORT BREAK 17:30-17:45**
DIA EUROPE 2019
5-7 February | Vienna, Austria

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DIA EUROPE RETURNS TO VIENNA!
DIAglobal.org/Europe2019
## Let's Chat! “What’s the DIA World 2018”

### Reception Hall

**Related Interest Area(s):** ALL

**Level:** ALL

**SESSION CHAIR**
Keiichi Inaizumi, MSc
Manager, Clinical Operations and Compliance 1, Development Operations, Pfizer Japan Inc.

**FACILITATORS**
DIA Japan Content Committee / Community

“Special Chat Sessions” will be provided for members to exchange opinions, questions, or issues and to build networking among attendees. Young or experienced attendees, academia or students, investigational sites or PMDA – please sit around our table and be our companions! Let's talk together.

This session will be a casual discussion in a free-discussion format of small groups of people. We are going to provide some discussion topics. This year, we prepare ten hot topics, and two Communities will facilitate one topic so that you can enjoy discussions beyond Communities. Please visit your interest table and join the discussion of a theme in which you are interested. The views and opinions expressed in Chatting are those of the individual participants and should not be attributed to DIA, affiliates, or any organization with which the participants is employed or affiliated.

### <List of Topics>

<table>
<thead>
<tr>
<th>#</th>
<th>Communities</th>
<th>Topic</th>
<th>Facilitators</th>
<th>Abstracts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clinical Operations &amp; Monitoring (CDM)</td>
<td>Let's Discuss Ideas for Getting out of &quot;Error Free Seeking Mind&quot;</td>
<td>Clinical Operations &amp; Monitoring (CDM)</td>
<td>MBA is required in Quality Management System. For the members who pursued error free, it may not be familiar to put errors in a certain range or to classify errors according to causes; Let's think about ideas together as to how we can get out of all the participants in the clinical trial from “Error Free Seeking Mind”.</td>
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<tr>
<td>2</td>
<td>Clinical Strategy (CS) Project Management (PM)</td>
<td>Let's discuss your career plan (Even a chance meeting is due to the karma in previous life.)</td>
<td>Clinical Strategy (CS)</td>
<td>Could you imagine “Career”? Career is a part of your life, not only your job. In the fast-changing society, it might be hard to create or consider your value. However, you definitely can have your Aha-moment regarding your career. Let's talk about your brilliant future with your new friends.</td>
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<tr>
<td>3</td>
<td>Regulatory Affairs (RA) Project Management (PM)</td>
<td>What is an efficient role sharing in developmental team?</td>
<td>Regulatory Affairs (RA)</td>
<td>Concentrating a wide range of specialized knowledge is indispensable for drug development. Is there anything struggling and devising to consolidate opinions of experts and departments with various backgrounds? We would like to exchange information easily about current situation at each industry, government, academia and chat freely with the topic of efficient work / role sharing to deliver the necessary medicine to patients as soon as possible.</td>
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<td>4</td>
<td>Regulatory Affairs (RA) Clinical Strategy (CS)</td>
<td>ICH-E7 - Let's Discuss Changes in Clinical Development Strategy -</td>
<td>Regulatory Affairs (RA)</td>
<td>Do you understand E7 correctly? The more you think about it, the more you know it, don't you feel that the mystery deepens? How do you evaluate the safety of Pooled Population? Are all human beings brothers? How is it different from MRCT so far? Will contents of CTD be changed? Let's share your questions and opinions on E7 in our chatting session.</td>
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<td>5</td>
<td>Six Sigma (SS) Clinical Data Management (CDM)</td>
<td>How we implement the quality tools for ICH E6 R2 - Clinical QMS</td>
<td>Six Sigma (SS)</td>
<td>Upon ICH-E6 (R2) agreement, JPMA has issued “Practical approaches to implement QMS in clinical trials - use of quality management tool by using case studies -”. Using quality management tool correctly is important for QMS implementation. So, let's deepen our understanding of the tools and the statistical background of the tools together!</td>
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<td>6</td>
<td>Statistics (ST) Pharmacovigilance &amp; Labeling (PV)</td>
<td>Let's Talk about Measures of Treatment Effect on Survival Analysis Including Novel Ones that Become a Hot Topic Recently</td>
<td>Statistics (ST)</td>
<td>In clinical trials, when evaluating the time to event data such as death or the occurrence of a specific adverse event, we usually use the Kaplan-Meier curve to show the survival function, compare the survival functions by log-rank test and estimate the hazard ratio by Cox proportional hazard model. Have you ever thought about the meaning of this approach? In this session, we will talk about the topics below including the hot topic in the statistical community in Japan. What is the hazard ratio? What are the best endpoints/measures for patients and physicians? Let's talk openly.</td>
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<td>7</td>
<td>Medical Communications (MC) Patient Engagement (PEC)</td>
<td>The Drug information for the choice of therapeutic option by patients - Let's think about medical communication in the future among medical experts, patient, government and marketing authorizing holders:</td>
<td>Medical Communication (MC)</td>
<td>Nowadays everyone has access to drug information easily, but some suspicious information can be seen in some information from the web. Although information provided by regulatory authority and pharmaceutical companies is highly reliable the most of information is for medical experts, which is difficult for the general public. We would like to exchange opinions on further utilization of existing information such as: ‘The Medication Guides for Patients’, and on what should be medical communication focusing on patients.</td>
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<tr>
<td>8</td>
<td>Patient Engagement (PEC) Clinical Operations &amp; Monitoring (CDM)</td>
<td>If My Family or I Join Clinical Trial...?</td>
<td>Patient Engagement (PE)</td>
<td>Patients are not special people – all of us, at some point, become ‘patients’. And maybe a day will come when you or a family member will participate in a clinical trial. What kind of trial would you consider joining? Which ones would you absolutely avoid? What would make you anxious? What kind of information/support would you want? Let's join in thinking about such topics in a relaxed atmosphere!</td>
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<tr>
<td>9</td>
<td>Medical Communications (MC) Pharmacovigilance &amp; Labeling (PV)</td>
<td>Is the Material Used for Patients? Is That Trust? - Current Status and Future of Drug Information Communication for Proper Use -</td>
<td>Medical Communication (MC)</td>
<td>The company is trying to lead to proper use by creating a lot of kinds of materials. However, the definition of “proper use” is not constant depending on the position such as HCP, patients, authorities, medical affairs, pharmacovigilance etc. Also, depending on the definition, there may be issues in the providing method and contents of information materials. For those issues, we will exchange opinions with everyone in various positions.</td>
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SESSION 5 9:00-10:30

V1-S5 Room 605/606 9:00-10:30
What Information and Communication Do Patients Want in Clinical Trials? How We Can Provide Them? (Part 1)

Related Interest Area(s): ALL
Level: Intermediate

SESSION CO-CHAIRS

Yasuhiro Fujimura, MD, PhD
Director-General, Strategic Planning Bureau, Deputy-Director of the Hospital (Research), Department of Breast and Medical Oncology, National Cancer Center

Yoshikata Furuya, MSc
Director, Vaccine Policy, Health Policy, MSD K.K.

In order to engage patients as a partner in drug development and promote their involvement, it is important to understand patients’ needs in information and communication in clinical trials then provide them to patients. Disclosure of clinical trial information and provision of lay summaries of clinical trial results are beginning to be carried out in Japan. This session aims to understand what information and communication patients are seeking before, during and after clinical trials, and discuss how we should provide them to patients based on the regulations and case studies in Japan and global. In part 1 session, industry’s efforts, opinions from clinical trial sites and patients in Japan will be shared. In part 2 session, global status on patient communication will be shared and all speakers of part 1 and 2 sessions will have a panel discussion.

Clinical Trial Information for Patients - Current Status and Obstacles in Pharma Company -
Atsushi Kitamura
Director, Clinical Operations and Compliance 3, Pfizer Japan Inc.

Providing Information to Patients Who Participate in Clinical Trials: Efforts by Trial Sites
Novuko Ushirozawa, RN
Chief, Research Administration Section, Center for Research Administration and Support, National Cancer Center

Patients’ Needs in Communication and Information Sharing in Clinical Trials - A cancer patient’s perspective-
Naomi Sakurai
Head of the Board, The Association of Cancer Survivors Recruiting Project in Japan

Patients’ Needs in Patient Communication and Information Sharing in Clinical Trials
Hiroki Takeda
Executive Director, Japan Chronic Diseases Self-Management Association

V2-S5 Room 607 9:00-10:30
Efforts to Raise Drug Literacy - How Should We Take Care It in Citizens Themselves Learn about Drugs - (Part 1)

Related Interest Area(s): O: ALL(incl. patients)
Level: Intermediate
Language: Japanese Language Only

SESSION CO-CHAIRS

Tatsuo Kurokawa, PhD, DIA Fellow
Chief Director, RAD-AR Council, Japan

Junichi Nishino, MSc, RPham
Head, Regulatory Affairs Functions, Novartis Pharma K.K.

“The citizen must strive to deepen knowledge and understanding on the effectiveness and safety of these products as well as properly using medicines and the like” in the Pharmaceuticals and Medical Devices Law. Because of the spread of the Internet, information is flooded, but is it all reliable information? Is it possible to say that the information from the patient’s point of view is now enough prepared? The information that the patient sought is diverse and it is recommended to consult a doctor / pharmacist first, but in addition to that, highly reliable information that the patient themselves can obtain is also necessary.

In this session, we will organize the current status of pharmaceutical information in Japan and introduce efforts and issues relating to providing information to patients from speakers with different positions.

In Part 2 of V2 - 56, experts from industry, government and academia will discuss the future directions of drug information provision in Japan on each side of those who prepare and provide drug information, patients, people who explain to patients, and PMDA.

Current Situation and Issues for Providing Drug Information to Patients in Industries
Junichi Nishino, MSc, RPham
Head, Regulatory Affairs Functions, Novartis Pharma K.K.

What Kind of Drug Information are Needed By Patients? – Current Issues & Future Perspective from Patients Point of View -

Ikuko Yamaguchi
Board Chairperson, COML

What Kind of Drug Information are Needed By Patients? – Current Issues & Future Perspective from Pharmacist Point of View -

Susumu Wakabayashi
Department of Pharmacy, Kyorin University Hospital

Current Situation and Issues for Providing Drug Information from PMDA to Patients
Kiyomi Ueno, PhD
Director, Office of Safety I, Pharmaceuticals and Medical Devices Agency (PMDA)

V3-S5 Room 608 9:00-10:30
Chance and Challenge to Maximize Product Value

Related Interest Area(s): CR, PM, MA, Pharmacology
Level: Beginner, Intermediate

SESSION CHAIR
Hiroshi Aino, MD, PhD
Senior Medical Officer, Sumitomo Dainippon Pharma Co., Ltd.

Aiming to maximize product value seamlessly from the medicine development stage to launch stage, some pharmaceutical companies are creating or implementing key strategies such as development strategy, publication strategy, KOL engagement strategy etc with more closer partnership between medicine development related division and medical affairs division. Also, Medical Science Liaisons (MSLs) play key role which collects unmet medical needs from healthcare professionals and their contribution would be crucial one to find new development opportunity or to generate valuable evidence.

In this session, presenters will provide some examples of collaboration in each company and we are going to discuss how medicine development division and medical affairs division should collaborate to maximize product value.

TBC
Yasuyuki Katayama, MD, PhD
Corporate Officer, Country Medical Director and Head of Medical Japan, Pfizer Japan Inc.

TBC
Sotaro Enatsu, MD, PhD
Eli Lilly Japan K.K.

TBC
Manabu Murakami, PhD
Vice President, Clinical Pharmacology Development, Astellas Pharma Inc.

Panel Discussion
All Session Speakers and
Kosuke Kozaïwa, MD
VP & Vice Head, Japan Development, GlaxoSmithKline K.K.

V4-S5 Room 609 9:00-10:30
New Developments on Microbiome Research
Related Interest Area(s): AC
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Koichiro Yuji, MD, PhD, FACP
Project Associate Professor, The Institute of Medical Science, The University of Tokyo

The human body is colonized by a vast number of microbes, collectively referred to as the human microbiota. Each person’s microbiome is unique, and it impacts health and diseases, such as obesity, inflammatory bowel disease (IBD), diabetes mellitus, metabolic syndrome, atherosclerosis, alcoholic liver disease (ALD), colon cancer, and autoimmune disease. Metagenomic whole genome shotgun sequencing provided insights into the functions and pathways present in the human microbiome, and microbiome-derived biomarkers, drug targets, and bioactive molecules as potential treatments and companion diagnostics have been developed.

In this session, the perspective on microbiome research and utilization will be discussed.

TBC
Seiya Imoto, PhD
Professor, Health Intelligence Center, The Institute of Medical Science, The University of Tokyo

TBC
Kosuke Fujimoto, MD, PhD
Assistant Professor, Osaka City University Graduate School of Medicine
Project Assistant Professor, The Institute of Medical Science, The University of Tokyo

Use of Gut Microbiota Analyses and Metabolite Measurements
Takayoshi Hisada
TechnoSuruga Laboratory Co., Ltd.

Panel Discussion
All Session Speakers

V5-S5 Room 610 9:00-10:30
Responses Against the Global Threat of Antimicrobial Resistance
Related Interest Area(s): RA, CP, CR, AC
Level: Intermediate

SESSION CHAIR
Junko Sato, PhD
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA)

By 2050, the global mortality attributable to antimicrobial resistance (AMR) is estimated to be 10 million, exceeding the mortality attributable to cancer if no actions are taken. In response to this issue, the Japanese government has proposed the “National Action Plan on AMR.” Various measurements against AMR have been considered by industry, government and academia, in areas ranging from drug discovery to the development of new antimicrobials, surveillance and appropriate use of antimicrobials. Focusing on the clinical research and development to tackle AMR, the current issues of the industry, government and academia and future steps for collaboration to efficiently and rapidly develop antimicrobials will be discussed in this session from local and global perspectives.

Therapeutic Drug for AMR Infections: from Regulatory Standpoint
Wataru Asakura, PhD
Office Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA)

Development Issues of Drugs for AMR Infections
Mari Ariyasu, BPharm
Senior Director, Project Management Dept., Shionogi & Co., Ltd.

TBC
Satoshi Iwata, MD, PhD
Director, Department of Infectious Diseases, National Cancer Center

Panel Discussion
All Session Speakers

V6-S5 Room 101 9:00-10:30
Various Issues Related to HTA -Looking at on a Micro and Macro Scale-
Related Interest Area(s): O: MA, RA, CR, AC
Level: Beginner

SESSION CHAIR
Koji Kawakami, MD, PhD
Professor and Chairman, Department of Pharmacoepidemiology, Graduate School of Medicine and Public Health, Kyotto University

For pharmaceutical and medical device industry, it becomes more and more important to explain the value of new technology, facing the introduction of HTA in Japan.

Following presentations will be made in this session:
• Examples of the utilization of Real World Data, as well as the latest trend of HTA in Japan.
• The function of HEOR in US and EU, which covers various approaches such as cost-effectiveness analysis, budget impact and disease burden.
• Tips of the Guideline of Central Social Insurance Medical Council

Finally, an opportunity for an exchange of views between panelists and audience will be provided through panel-discussion.

The Latest Trend of HTA and Utilization of RWD
Koji Kawakami, MD, PhD
Professor and Chairman, Department of Pharmacoepidemiology, Graduate School of Medicine and Public Health, Kyotto University

The Use of HEOR in the US and EU
Mark Hill, MD, PhD
Head, Global Market Access, Shionogi Limited

Remarks on Chuikyo Guideline
Kosuke Iwasaki, MBA
Director, Japan Healthcare Practice and Data Analytics, Milliman, Inc

Panel Discussion
All Session Speakers

V7-S5 Room 102 9:00-10:30
Pharmacovigilance Activities in Japan, the USA, and Europe – How to Utilize Real World Data-
Related Interest Area(s): CP
Level: Intermediate

SESSION CO-CHAIRS
Hisashi Urushihara, DrPH
Professor, Division of Drug Development and Regulatory Science, Faculty of Pharmacy, Keio University

The 2018 GPSP revision allows the marketing authorization holders to select database studies including EHRs, claims records, and registries as the pharmacovigilance activities in Japan, changing the post-marketing regulatory climate. This session introduces the actual examples of effective use of real world data in Western countries for the purpose of pharmacovigilance and discuss the challenges and policies to make effective use of real world data available in Japan.

Introduction
Hisashi Urushihara, DrPH
Professor, Division of Drug Development and Regulatory Science, Faculty of Pharmacy, Keio University

Effective Use of RWD in FDA for Pharmacovigilance
Gerald J. Dal Pan, MD, MHS
Director, Office of Surveillance and Epidemiology, CDER, FDA

Effective Use of RWD in EMA for Pharmacovigilance
Agnès Saint-Raymond, MD
Head of International Affairs, Head of International Affairs, Head of
In order to engage patients as a partner in drug development and promote their involvement, it is important to understand patients' needs in information and communication in clinical trials then provide them to patients. Disclosure of clinical trial information and provision of lay summaries of clinical trial results are beginning to be carried out in Japan. This session aims to understand what information and communication patients are seeking before, during and after clinical trials, and discuss how we should provide them to patients based on the regulations and case studies in Japan and global. In part 2 session, status in EU on patient communication will be shared and all speakers of part 1 and 2 sessions will have a panel discussion.

**Panel Discussion**

All Speakers of V1-S5 and V1-S6 and Kazuhiko Mori, MSc
Counselor for Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW)

**DAY 3 | TUESDAY | NOVEMBER 13**

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**SESSION 6 11:00-12:30**

**V2-S6 Room 607 11:00-12:30**

**Efforts to Raise Drug Literacy -How Should We Take Care It in Citizens Themselves Learn about Drugs - (Part 2)**

Related Interest Area(s): O: ALL(incl. patients)
Level: Intermediate
Language: Japanese Language Only

**SESSION CO-CHAIRS**

Tatsuo Kurokawa, PhD, DIA Fellow
Chief Director, RAD-AR Council, Japan

Junichi Nishino, MSc, RPham
Head, Regulatory Affairs Functions, Novartis Pharma K.K.

**Panel Discussion**

All Speakers of V2-S5 and V2-S6

**Efforts and Status in EU on Patient Communication and Information Sharing in Clinical Trials**

Agnès Saint-Raymond, MD
Head of International Affairs, Head of International Affairs, Head of Portfolio Board, European Medicines Agency (EMA)

**Industry’s Efforts on Patient Communication and Information Sharing in Clinical Trials in EU**

Iris Lawn-Friedrich, DrMed
Executive Vice-President, Chief Medical Officer, UCB, Inc.

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**SESSION 6 11:00-12:30**

**V3-S6 Room 608 11:00-12:30**

**The Near Future of Clinical Operation - ICT Leading Virtual Clinical Trial -**

Related Interest Area(s): RA, DM, CR, PM, AC
Level: Intermediate

**SESSION CHAIR**

Mitsuo Hayashi, MSc, RPh
Director & Head, Clinical Enablement, MSD K.K.
The progress of ICT is remarkable. We are already in such a world that you can easily measure your vital sign if wearing iWatch and you can get various information quickly if speaking to a smart speaker. Clinical trials have also experienced changes due to ICT innovation. For example, RBM is a way of thinking developed by CRF changing from paper based to electronic one. However clinical trials are areas where it is still possible to make innovative approach using ICT technology.

In this session, we will introduce the present situation of Virtual Clinical Trial in EU and US, and the development and challenge of Virtual Clinical Trial in Japan.

We would appreciate it if you could create a world where enrollment and site visit will change dramatically by thinking about patient engagement.

**Will Decentralized Clinical Trials be the Game-changer for Drug Development? A Deep Dive into the Opportunities, Benefits, and Challenges of Patient-centric Disruptive Trials Models**

Bryan McDowell, MSc, MBA  

**Application of Mobile Health in Clinical Development**

Sy Pretorius, MD, MBA, MS  
Senior Vice President, Chief Scientific Officer, PAREXEL International

**Could Virtual Clinical Trial Lead Transformation for Clinical Trial in Japan? - From the Experience of Home Visit Trial -**

Makiko Okamoto  
Sr. Manager, Clinical Innovations & Business Integration, Medical Development Unit Japan, Eli Lilly Japan K.K.

**Possibility of AI for Future New Drug Evaluation and Review Process**

Related Interest Area(s): ST, O  
Level: Intermediate  
Language: Japanese Language Only

SESSION CHAIR  
Makoto Suzuki, PhD  
Medical Writing Director, MSD K.K.

Share what next innovation technology is available in global drug development, such as AI translation in the medical field using multi-language speech translation technology of Ministry of Internal Affairs and Communications, and discuss shortening of approval review period using innovation such as AI.

**High Quality Automatic Translation By Using AI**

Eiichiro Sumita, PhD  
NICT Fellow, Associate Director General of ASTREC, National Institute of Information and Communications Technology (NICT)

**The Development and Impact of Digital Technology**

Kazuya Obayama  

**Creation of Package Inserts Post-marketing Materials Using XML**

Megumi Sato  
Japan Product Labeling Group, MSD K.K.

**Impact of Clinical Trials Act on Generating Medical Evidence**

Koji Iwasaki, PhD  
Professor, Academic Clinical Research Center, Department of Medical Innovation, Osaka University Hospital

**Basics of Observational Study**

Hisashi Urushihara, DrPH  
Professor, Division of Drug Development and Regulatory Science, Faculty of Pharmacy, Keio University

**Real World Evidence in EU and US; Direction and Best Example Sharing**

Akihito Uda, MPH  
Manager, Medical Research, Capabilities and Excellence HEOR Program, Japan Medical Affairs, Takeda Pharmaceutical Company Inc.

**Paradigm Shift in Pharmacovigilance Activities - How to Conceptualize Research Questions**

Related Interest Area(s): CP  
Level: Beginner
“Review on planning of post-marketing surveillance” released from the PMDA in January this year is significantly changing the approach to conducting a review of pharmacovigilance. It is important to clarify research questions beforehand based on the information from clinical trials and target diseases as well as the characteristics of medicinal products, after which point pharmacovigilance activities can be conducted sufficiently and appropriately. This session will focus on and discuss how to consider clinical questions and link them with clear research questions.

**Fit-For-Purpose Research Design in Pharmacovigilance Activities**
Takuihro Yamaguchi, PhD  
Professor, Biostatics, Tohoku University Graduate School of Medicine

**Current Situation and Challenges of Pharmacoepidemiology and Data Utilization in Pharmaceutical Companies**
Sayuri Nakane, MPH  
PMS Data Management Group, Real World Data Science Department, Drug Safety Division, Chugai Pharmaceutical Co., Ltd.

**Clinical & Research Question in Pharmacovigilance Planning**
Chieko Ishiguro, MPH, PhD  
Department of Epidemiology, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

**Panel Discussion**
All Session Speakers and  
Gerald J. Dal Pan, MD, MHS  
Director, Office of Surveillance and Epidemiology, CDER, FDA

**Approaches to Implement Revision for New Format of Labeling and Discussion How to Provide Information by Other Materials**

**Official Guidelines for New Format of Labeling and Findings of First Wave of Consultation for Labelling Revision**
Akifumi Kamata, PhD  
Reviewer, Office of Safety II, Pharmaceuticals and Medical Devices Agency (PMDA)

**Provision of Approaches to Implement Revision for New Format of Labeling from Pharmacist of Medical Institute Perspective**
Hideo Nakata  
Deputy Associate Manager, Department of Hospital Pharmacy, Keio University Hospital

**Provision with Other Materials such as Interview Form based on New Format of Labeling and Providing Information (Tentative)**
Shinya Takemoto, Msc  
Group Manager, Safety Information Strategy Group, Risk Communication Department, Drug Safety Division, Chugai Pharmaceutical Co., Ltd.

**Panel Discussion**
All Session Speakers

**Panel Discussion**
All Session Speakers

**LUNCH BREAK**
12:30-14:00
Innovative Clinical Trials: A Painting of the Future

Related Interest Area(s): ALL
Level: ALL

SESSION CHAIR
Takuko Sawada
Director of the Board, Executive Vice President, Shionogi & Co., Ltd.

Technological innovation surrounding clinical trials such as introduction of IoT, AI, secondary use of clinical data, applying simulation etc. is progressing at an unprecedented speed. There is also a growing need for clinical trials in a new framework, such as precision medicine or development of regenerative medicinal products and/or gene therapy. On the other hand, the development cost and productivity improvement challenges are still large, and Japan specific regulations could be a hurdle to implement innovative way. Under such an environment, the real value of Japan in global development is being sought after. In this session, following the overview of the whole session, the current state of remote trial model and new evidence building by secondary data use will be shared. With such background information, the direction Japan should go and what is necessary will be discussed.

Paradigm Shift of Clinical Development
Hiromitsu Shirasawa, MD
Vice President and Executive Officer, Head of Japan Development, MSD K.K.

Embracing Technologies to Enable Smarter, Patient-focused, Drug Development
Bryan McDowell, MSc, MBA
Global Program Lead, Digital Development, Novartis Pharma AG

Panel Discussion
All Session Speakers and
Dalvir Gill, PhD
Chief Executive Officer, TransCelerate Biopharma, Inc
Jackie Kent
Senior Vice President, Product, Medidata Solutions, Inc
Kazuhiko Mori, MSc
Councilor for Pharmaceutical Affairs, Minister’s Secretariat, Ministry of Health, Labour and Welfare (MHLW)

COFFEE BREAK
15:30-16:30

PMDA Town Hall
Related Interest Area(s): ALL
Level: ALL

SESSION CO-CHAIRS
Takuko Sawada
Director of the Board, Executive Vice President, Shionogi & Co., Ltd.
Naoki Uchida MD, PhD
Professor, Department of Clinical Pharmacology, Clinical Research Institute for Clinical Pharmacology and Therapeutics, Showa University Karasuyama Hospital

This session is provided for you to discuss with Pharmaceuticals and Medical Devices Agency (PMDA) members on your interests. To make this session really meaningful, we welcome your active participation. See you at the session!

Panelists
Tetsunari Kihira, PhD
Director, Office of Vaccines and Blood Products, Pharmaceuticals, and Medical Devices Agency (PMDA)
Daisaku Sato, PhD
Chief Management Officer / Associate Center Director for Advanced Evaluation with Electronic Data and Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)
Shinichi Takae
Director, Office of Medical Device I, Pharmaceuticals and Medical Devices Agency (PMDA)
Yoshiaki Uyama, PhD
Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals, and Medical Devices Agency (PMDA)
Shinobu Uzu, MSc
Associate Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA)

CLOSING REMARKS
International Conference Room
17:30-17:40
Kazuhiro Kanmuri, PhD
Program Vice-Chair / Director, CTD Inc.
YOUR PATH TO SUCCESS: BENEFITS OF EXHIBITING

DIA Japan Annual Meeting Exhibit Website: https://diaexhibit.org/

1. MAXIMISE YOUR BRAND EXPOSURE

Increase your exposure at the DIA Annual Meeting. Happy to offer an extensive list of old and new marketing, advertising, and support opportunities.

2. LUNCHEON SEMINAR AND COFFEE BREAK PRESENTATION

Platinum and Gold level supporter can hold luncheon seminar in the lunch time in the closed seminar room. Silver level supporter can hold coffee break presentation in the Innovation Theater. Great opportunity to present new strategy, product, tool and services.

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Our integrated international platform invites you to meet new clients, reunite with existing customers and create multiple opportunities for meaningful face-to-face meetings.

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The DIA Japan Annual Meeting is where talent and experience meet. Launch your latest product innovations or scout for the industry’s top employees.

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With your company profile listed in the exhibit guide and exhibit web site, attendees will know right where to find you.
医薬品・医療機器等開発のグローバル化が急速に進んでいる状況において、革新的な医薬品・医療機器等をいち早く患者さんに届けるために我々がすべきことは何か。また、世界的イノベーション創出をどのように連携の下で進めていくか、立場の壁を取り払って、理想的な医薬品・医療機器等創出システムをどうやって構築していくかの議論を深める時が来たのではないでしょうか。国際連携を推進・強化していくためには、自国のみならず、他国の状況についても客観的な評価を行い、また、産学官の垣根を越えて、お互いの強みを活かす連携を選択することが重要です。

本年の日本年会では、将来の国際連携を見据え、日本および各国のステークホルダーがどのようにそれぞれの役割を果たしていくべきかについて、様々な視点からの議論を深めていきたいと考えます。

一方で、イノベーション創出のカタログは様々であり、近年では、デジタルツール等のグローバルヘルスへの導入は期待も大きく、人工知能を活用した医療テクノロジーの利活用での戦略的国際連携の拡大や、遺伝子治療および細胞治療のようないくつかの治療への挑戦や、レギュラトリーサイエンスにおける国際的なハーモナイゼーションが期待されています。

イノベーション創出により今後の医療に貢献できることとして、既に検討していること、これから挑戦したいことを含め、様々な角度から議論を展開していきたいと考えています。

本年の基調講演では、欧州医薬品庁 (EMA) のGuido Rasi長官、並びにゲノム医療における情報処理やAI活用のパイオニアである東京大学の宮野悟先生に御登壇いただきます。また、日本年会では初の試みとなる薬事規制当局国際連携組織 (ICMRA : International Coalition of Medicines Regulatory Authorities) のInnovation ProjectメンバーによるDIAmend Sessionが開催されます。また、3日目の午後のDIAmend Sessionでは、Innovative Clinical Trials: 臨床試験の未来予想図と題して、様々な技術革新と環境変化を想定した臨床試験の将来の姿について産学官のトップに熱い議論を展開いたします。他、日本年会では恒例となったPMDAタウンホールやチャッタリングセッション、そして多岐にわたるホットトピックで構成された一般セッション群で参加者の皆さまをお迎えしたいと思います。

皆様のご参加を心よりお待ちしております。

後援： 厚生労働省／独立行政法人医薬品医療機器総合機構／国際研究開発法人日本製薬開発機構／日本製薬工業協会／日米研究製薬工業協会／国際製薬技術協会 (ISPE)
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### コービーレブ | 開会の挨拶 | 13:45-14:00 大会長挨拶 | 14:00-14:15 2018 DIA JAPAN INSPIRE REGIONAL AWARDS授賞式 | 14:15-15:00 2018 DIA JAPAN INSPIRE REGIONAL AWARDS授賞式 | 15:00-15:30 コービーレブ | 15:30-16:15 コービーレブ | 16:15-17:45 DIAの組織であるEMRAの新しいプロジェクト（DIA DIAMOND SESSIONS）への新たなチャンジ | 17:45-18:00 ショートブレイク | 18:00-19:30 情報交換会 (レセプションホール) | 19:30-21:00 E1 Engage and Exchange Let's Chat! Special Chat Session (レセプションホール) |
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#### 情報交換会

- **情報交換会 (レセプションホール)**

#### コーヒーブレイク

- **コーヒーブレイク (レセプションホール)**

#### ランチブレイク

- **ランチブレイク (レセプションホール)**

#### SP1 Engage and Exchange 'Let's Chat! - Special Chat Session -' (レセプションホール)

#### コーヒーブレイク

- **コーヒーブレイク (レセプションホール)**

#### ランチブレイク

- **ランチブレイク (Oracle Corporation Japan)**

#### ランチブレイク (レセプションホール)
11月11日（日）
9:00-9:30 スチューデントセッション受付
9:30-12:00 スチューデントセッション
11:45- 参加者受付オープン
12:00-13:00 展示会場（レセプションホール）オープン
13:30-14:00 開会の挨拶 & 大会長挨拶
14:00-14:15 2018 DIA Japan's Inspire Regional Awards授賞式
14:15-15:00 基調講演1（European Medicines Agency (EMA) / Guido Rasi長官）
15:00-15:30 コーヒーブレイク & 出展者プレゼンテーション
15:30-16:15 基調講演2（東京大学医科学研究所 / 宮野悟先生）
16:15-17:45 DIAlmond Session 1 「Innovationへの新たなチャレンジ～ICMRA Innovation Project～」
18:00-19:30 情報交換会

11月12日（月）
8:30- 受付
9:00-19:00 展示会場（レセプションホール）オープン
9:00-10:30 セッション1
10:30-11:00 コーヒーブレイク & 出展者プレゼンテーション
11:00-12:30 セッション2
12:30-14:00 ランチブレイク / ポスターセッション / ランチョンセミナー
14:00-15:30 セッション3
15:30-16:00 コーヒーブレイク & 出展者プレゼンテーション
16:00-17:30 セッション4
17:45-19:00 Engage and Exchange - スペシャルチャッティングセッション

11月13日（火）
8:30- 受付
9:00-16:00 展示会場（レセプションホール）オープン
9:00-10:30 セッション5
10:30-11:00 コーヒーブレイク & 出展者プレゼンテーション
11:00-12:30 セッション6
12:30-14:00 ランチブレイク / ランチョンセミナー
14:00-15:30 DIAlmond Session 2 「Innovative Clinical Trials: 臨床試験の未来予想図」
15:30-16:00 コーヒーブレイク & 出展者プレゼンテーション
16:00-17:30 DIAlmond Session 3 「PMDAタウンホール」
17:30-18:00 閉会の挨拶

講演資料のウェブサイト掲載
プログラム参加登録者は、会議開催の約1週間前にDIAウェブサイトに掲載する講演資料を開覧できます。掲載でき次第、アクセス方法の案内メールが配信されます。但し、全ての講演資料が開覧できるのではなく、指定の期間までにDIAに提出された資料のみが掲載されます。ハンドアウト資料（スライドコピー）の配布はありません。

Private Social Function Policy
本年会開催期間中、当プログラム外の会議、展示、懇親会等のイベントの開催はご遠慮ください。下記時間帯につきましては、これに限ります。
11月10日（土） 終日
11月11日（日） 午前8時以前、午後8時半以降
11月12日（月） 午前8時以前、午後8時以降
11月13日（火） 午後8時以前、午後6時半以降

特に公表しない限り、本会議にて発表される内容は発表者本人の見解であり、所属する組織、あるいはDIAのものとは限りません。
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スチューデントセッション/オリエンテーション

102会議室
承認審査を通じた医薬品開発の理解

関連領域：薬事、アカデミア
レベル：初級

座長
明治薬科大学
三村 美智
明治薬科大学
金子 拓也
昭和大学
岩崎 加奈子
昭和大学
杉浦 由莉

医薬品を製造販売するためには、厚生労働大臣の承認が必要である。本セッションでは、当局の立場から医薬品の承認審査について考え、医薬品開発の理解を深める。

始めに、医薬品の承認審査を考える際の留意点について講演していただく。その後、グループワークにおいて架空の医薬品の有効性および安全性を評価し、承認の可否について考える。最後に、各グループの承認可否に至るプロセスを発表し、共有する。本セッションを通じて、医薬品開発に関する知識を修得し、コミュニケーション能力を高める場として欲しい。

本グループワークでは睡眠導入剤を題材とするため、「睡眠薬の臨床評価方法に関するガイドライン」を予習しておくことが望ましい。


発表者
DIA Japan Contents Committee

はじめめてDIA日本年会へ参加される方を対象に『DIA日本年会の歩き方』をご紹介します。年会をより有意義かつ快適に過ごすために、ぜひご参加ください。

説明内容：
・DIAとは
・会場案内
・プログラム構成
・展示会
・飲食の案内
・DIA Globalアプリの使い方

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開会の挨拶および基調講演 / DIAmond Session 1

プレオープン 13:00-13:30
開会の挨拶 国際会議場
DIA Japan 植村 昭夫
DIA Advisory Council of Japan議長 / 大塚ホールディングス株式会社
小林 和道
DIA Chair/ Bayer AG Joseph Scheeren

基調講演 1
国際会議場 13:30-13:45
座長 独立行政法人 医薬品医療機器総合機構 近藤 達也
EMAでは、ホライズンスキャンニングの手法を取り入れ、レギュラトリーサイエンスの将来へと向かう予測をするプロセスを構築して、業界当局がこれから直面するであろう技術革新に備えている。このプロセスにより、従来の当局専門家で対応できないような新たな分野の専門家を特定することがで
きるようになる。EMAが特に注力して働きかけていることは、患者のライフスタイルに対する技術革新を含む、新しい薬の開発と利用法の導入である。この業界のアイデアから、ある意味では、業界全体の課題に直面している。

基調講演 2
国際会議場 13:45-14:00
座長 グロクソ・スミスクライン株式会社 高橋 希人

DIAmond Session 1
国際会議場 16:15-17:45
Innovationへの新たなチャレンジ ~ICMRA Innovation Project~
関連領域: 薬事、アカデミア
レベル: 初級
座長 Health Products Regulatory Authority (HPRA) Rita Purcell
European Medicines Agency (EMA) Guido Rasi

パネルディスカッション
本セッションの講演者および
Danish Medicines Agency Nikolai Brun
Medsafe Alison Cossar
FDA John Graham
V1-S1 9:00-10:30
Global Phase 10経験(米国の施設の実態とmanagement方法) -癌の開発を中心に-

関連領域: 薬事、臨床、アカデミア
レベル: 中級
座長
第一三共株式会社
齋藤 宏暢

近年First in Human Studyは米国中心に行われる場合が多く、日本では、欧米の臨床データを踏まえ、臨床試験に着手する場合が多い。日本が欧米とともにFirst In Human試験を行い、世界に貢献していく必要がある。本セッションでは、米国におけるFirst in Human試験のManagementを実際進行しているExpertから実際進行している米国におけるFirst in Human試験の経験を紹介してもらう。最後に、日本でFirst in Human試験を実施した経験をもつExpertも含め、日本が含まれたGlobal Phase 1のあり方、効率化を議論する。

米国では、どのように臨床試験をmanagementしているか?
Sarah Cannon
Carol Woodward

日本と米国の病院におけるGlobal Phase 1の経験
野口 泰

パネルディスカッション
本セッションの講演者および
国立がん研究センター東病院
土井 俊彦
Sarah Cannon
Johanna Bendell
国立がん研究センター中央病院
清水 俊雄

V2-S1 607会議室 9:00-10:30
医薬品リスク最小化資材に求められる変革

関連領域: 安全性
レベル: 初級
言語: 日本語のみ
座長
北里大学大学院
成川 衛

日本においてRMPが実装されて5年が経過し、RMPとともにベネフィット・リスクバランスを考えるうえで重要となる医薬品リスク最小化策の重要性が増している。日本における医薬品リスク最小化策の一つとして実施されている医療従事者向け資材および患者向け資材について、現状の課題を踏まえ、これから求められるであろう変革の方向性について議論したい。

医薬品リスク最小化資材の実施において考慮すべき事項
アステラス製薬株式会社
石田 和彦

医薬品リスク最小化資材への病院薬剤師の理解と期待
虎の門病院
林 昌洋

医薬品リスク最小化のための情報提供資材の現状と今後
独立行政法人 医薬品医療機器総合機構
江崎 麻美

パネルディスカッション
本セッションの講演者

V3-S1 608会議室 9:00-10:30
医師主導治験から学ぶ治験の効率化と早期臨床開発への応用

関連領域: 全て
レベル: 中級
座長
株式会社CTD
小林 史明

医師主導治験は2003年より薬事法（当時）の改正により実施可能になり、これまでに多くの医薬品・医療機器で承認取得に至ており、ドラッグリポジショニングをベースとした効能追加などの1つのアプローチとして貢献してきた。

最近、我が国でもベンチャー振興が本格化しようとしており、本セッションでは、開発マネジメントについて医師主導治験の事例から学び、橋渡し研究や早期臨床試験を含む開発方法を学ぶ機会を提供する。

V4-S1 609会議室 9:00-10:30
がんゲノム医療の実用化に向けて ～遺伝子パネル検査・コンパニオン診断薬の現状と未来～

関連領域: 薬事、アカデミア
レベル: 初級
言語: 日本語のみ
座長
国立研究開発法人 国立がん研究センター
藤原 康弘

個別化医療の実現に向け、個々の患者さんにあった医薬品の投与を判断するためのコンパニオン診断薬がこれまでに数多く開発されてきた。また、平成29年に「がんゲノム医療推進コンソーシアム懇談会」が開催され、NGSを用いたゲノム解析結果に即したがんゲノム医療の推進に向けた報告書がまとめられている。

本セッションでは、個別化医療における医薬品開発を念頭に、医療機器のNGSや解析プログラムを活用した遺伝子パネル検査やコンパニオン診断薬を取り巻く現況を概説した上で、先進医療Bにおける実例を踏まえ、今後の我が国におけるがんゲノム医療の進展に向けた課題の洗い出しとその解決策について産官学の視点からディスカッションする。

パネルディスカッション
本セッションの講演者

東大オンコパネルを用いたクリニカルシーケンス（先進医療B）
東京大学大学院
織田 克利
本会では国内外から多数の応募の中から査読委員による厳正な審査を経て、3つの演題が口頭発表として選出された。査読基準でもあるDIAのビジョンや年会テーマとの一致性、科学・学術性、国際性・社会性といった視点からも興味深いトピックスであり、当日は講演にとどまらず、フロアとの双方向での議論を行う時間も用意される。

Why the New Data-Rich Collaborations May Risk Harming Us More than Helping Us
CDISC
Kit Howard

Therapeutic Needs of Older Patients in the Era of Mobile Health
INFORMED
Dinah Duarte

Applications and Challenges of Machine Learning in Clinical Trials for Safety, Efficacy, and Operational Integrity Endpoints
SAS Institute Inc., JMP Division
Kelci Miclaus

V6-S1  101会議室  9:00-10:30
公募演題セッション
関連領域: 薬事、DM、臨床
レベル: 中級
座長
ファイザー株式会社
今井 啓之

近年、遺伝的治療薬の開発が世界で盛んになり、欧米では昨今、商業化に関する具体的な議論が行われている。一方で、遺伝子組換え製品の使用による環境影響を考慮する必要がある。このセッションでは、異常からも興味深いトピックスであり、当会は講演にとどまらず、フロアとの双方向での議論を行う時間も用意される。

遺伝子治療薬の開発におけるQuality Management System
〜現場レベルでの実装〜
関連領域: 薬事、DM、臨床、統計、PM、アカデミア
レベル: 中級
座長
グラクソ・スミスクライン株式会社
井上 宏高

ICH E6(R2)では、Sponsor (治験依頼者) にRiskに基づくQuality Management System (QMS) が求められているため、各組織でのQMSの実装に向けて対応や取組みが進められてきた。本セッションでは、製品の立ち上がりからQMSの実装の目的と要求事項を解説するとともに、企業の立場からPMBOK Guide® (Project Management Body of Knowledge) のRisk Management及びQuality Managementフレームワーク等を活用したQMSの導入事例を紹介する。

プロジェクトマネジメントを活用した臨床QMSのフレームワークと導入事例の実際
日本たばこ産業株式会社
長尾 典明

治験における品質マネジメントについて～ICH-E6 (R2)の実装を視点として～
関連領域: 薬事、PM
レベル: 初級
言語: 日本語のみ
座長
山形大学医学部附属病院
丸本 芳雄

遺伝子治療薬の開発におけるQuality Management System
〜現場レベルでの実装〜
関連領域: 薬事、DM、臨床
レベル: 中級
座長
ファイザー株式会社
今井 啓之

Why the New Data-Rich Collaborations May Risk Harming Us More than Helping Us
CDISC
Kit Howard

Therapeutic Needs of Older Patients in the Era of Mobile Health
INFORMED
Dinah Duarte

Applications and Challenges of Machine Learning in Clinical Trials for Safety, Efficacy, and Operational Integrity Endpoints
SAS Institute Inc., JMP Division
Kelci Miclaus
のために、FDAガイダンスを参考として一般的なTPPの構成項目を概観する。その上で、研究開発プロセスにおけるプログラムマネジメント、スコープマネジメントの観点から、効果的なTPPがどのようにあるべきかについて検討を行う。

**演題未定**
国立研究開発法人 日本医療研究開発機構
石田 三智子
アカデミアにおけるTPPの使用（仮題）
名古屋大学医学部附属病院
清水 忍
企業におけるTPPの考え方、活用について（仮題）
第一三共株式会社
塚本 淳
パネルディスカッション
本セッションの講演者

**コーヒーープレイク** 10:30-11:00

**SESSION 2** 11:00-12:30

**V1-S2 605/606会議室** 11:00-12:30

各国薬事規制当局の最新動向

関連領域: 薬事、アカデミア
レベル: 初級
座長
Danish Medicines Agency
Jens Pierre Quartarolo
European Medicines Agency (EMA)
Guido Rasi

革新的な技術、グローバル化、国民の安全意識の向上などに対応するため、各国規制当局は新たな薬事規制の導入や既存の制度の見直しをすすめている。本セッションでは、世界の主要規制当局の幹部から各国の薬事規制の最新動向、各国規制当局間の協力活動（ICHなど）を紹介する。

Recent Trend of Pharmaceutical Regulation in Europe
European Medicines Agency (EMA)
Agnès Saint-Raymond
Recent Trend of Pharmaceutical Regulation in Americas
Health Canada
Ron Sun
Recent Trend of Pharmaceutical Regulation in Asia
独立行政法人 医薬品医療機器総合機構
佐藤 恥子
Recent Trend of Pharmaceutical Regulation in Oceania
Medsafe
Alison Cossar
パネルディスカッション
本セッションの講演者および
FDA
John Graham
Health Products Regulatory Authority (HPRA)
Rita Purcell

**V2-S2 607会議室** 11:00-12:30

疾患レジストリデータ利活用の最新の動向

関連領域: 全領域
レベル: 初級
言語: 日本語のみ
座長
東京大学大学院
平川 元弘

昨年からの継続セッションとして、医薬品開発における疾患レジストリデータの利活用について論議する。本年度は、国内外の患者レジストリに関する取組や規制の最新の動向を報告すると共に、大学・学会が運用している患者レジストリの管理・運用方法を紹介する。

疾患レジストリに関する国際的動向
東京大学大学院
小出 大介
SS-MIX2を用いた疾患レジストリの構築 - リアルワールドデータ活用のチャレンジ
一般社団法人 医療データ活用基盤整備機構
岡田 美保子
再生医療普及化のためのNational Regenerative Medicine Databaseの構築について
大阪大学医学部附属病院
岡田 潔

**V3-S2 608会議室** 11:00-12:30

限られたマンパワーのもとで医療現場の視点も入れて臨床試験を巧くまわすコツ ---支援・実施のノウハウ---

関連領域: 薬事、臨床、統計、PM、アカデミア、Six Sigma
レベル: 初級
座長
東京大学医学部附属病院
坂中 千恵

本セッションでは海外も含めた臨床試験の運用の現場で遭遇する問題点の解決、創意工夫について論議し、アカデミアのみならず、全セッションの参加者に業務効率化やそのヒントを考える場を提供する。

革新的な医薬品・医療機器等の開発を通してイノベーション創出に貢献するためには、アカデミア、企業および規制当局との連携が欠かせない。特に医療現場の限られた人材、時間やリソースのあるもとで臨床試験を実施していくには、臨床研究や治験に費やす時間の効率的な活用だけでなく、プロセスや仕組みの面、すなわち、関係者の分業体制、効率的な申請・報告の体制作業が重要である。また海外の実施施設からのインプットを得て議論を深めていただき。

Challenges in Conducting Clinical Trials
University of Texas, MD Anderson Cancer Center
Jie Willey

医師主導治験の実施に向けた取組み
名古屋大学医学部附属病院
清水 忍

製薬企業における生産性向上を目的としたシックスシグマの適用事例
日本イーライリー株式会社
水本 聡太

**V4-S2 609会議室** 11:00-12:30

審査報告書の読み方と今後のあり方
関連領域: 薬事、安全性、PM、アカデミア、Medical Writing
レベル: 中級、上級
言語: 日本語のみ

座長
大阪大学医学部附属病院
坂中 千恵
開発戦略を検討するのに、類薬の審査報告書は大変有用な参考書である。この参考書の読むためのこつを「革新的医薬品審査のポイント」著者成川先生のショートプレゼンテーションに続き、医療現場での利用方法と今後の期待、企業で審査報告書をどのように開発戦略や申請戦略に利用しているか（薬価交渉の観点を含む）や今後の期待と、PMDAでのこれまでの取り組みと今後の展望について、ご講演いただいた上で、意見交換する。

演題未定
北里大学大学院
成川 衛

新薬の上市を見据えた審査報告書の活用
MSD株式会社
大浦 房子

パネルディスカッション
本セッションの講演者および

バイエル薬品株式会社
高橋 俊一

次世代医療基盤法の解説（仮題）
国立がん研究センター
中田 はる佳

Electronic/personal health recordの事例（仮題）
グراكソスミスクリン株式会社
勝又 昌幸

デジタルヘルス活用事例
武田薬品工業株式会社
Jovelle Fernandez

パネルディスカッション
本セッションの講演者および

2日目	| 11月	12日 (月)
The investigation included eighty-nine ADRs reported. The average age was 37.1 years. Most of ADRs reported were occurring in outpatient department (87.6%). Majority of all ADRs reported were females (55.1%). Also, the major Naranjo scores of all ADRs reported ranged from 1 to 4 points (92.1%), which represents a possible correlation between ADRs reported and suspected drugs. According to ATC classification system, the major classification of suspected drugs were Sensory organs (32.6%) and Dermatologic Effects (37.1%) were the major adverse effects.

Conclusion:
ADR reporting certainly is still a very important process for healthcare professionals. For that reason, we have put ADRs reporting information into our medical computer system. By medical computer system, it can remind clinical physician to consider prescribing medication. There is always a potential risk while taking medicines. Consequently, it is truly the best way to improve medication safety by spontaneous reporting of ADRs by healthcare professionals for all patients.

[PO-02] A Proposal for Useful Measure of Access to the Latest Package Insert

山口大学医学部附属病院
近藤 智子

Objectives:
Package inserts are printed leaflets accompanying marketed drugs. Recently, it is difficult to understand which the package insert is the latest due to frequent revision soon after approving from time to time. In this study, we evaluated the current awareness of pharmacists to use the package inserts.

Method:
A paper questionnaire survey was conducted of Japanese pharmacists in 2018. The questionnaire was anonymous and included demographic background and circumstances of the usage of package inserts. The consent of each respondent was implied by filling out the questionnaire.

Results:
A Total of 1628 pharmacists responded to the survey, including 551 hospital pharmacists (33.8%) and 1077 community pharmacists (66.2%). Among the responders, 76.0% of hospital pharmacists and 43.4% of community pharmacists had obtained the package inserts from the website of Pharmaceuticals and Medical Devices Agency or pharmaceutical companies, i.e. electronic-based source. In contrast, 17.2% of hospital pharmacists and 48.8% of community pharmacists had obtained the package inserts from attached to the drug packaging, i.e. paper-based source. Approximately 80% of both hospital and community pharmacists considered that "paper" but not "electronic" package inserts were necessary (79.1%, 82.5%, respectively). The principal reasons for needing paper package inserts were "readily available" and "necessary in case of disaster". Nevertheless 80.7% of hospital pharmacists and 77.7% of community pharmacists did not confirm whether the paper package insert was the latest.

Conclusion:
Pharmacists need to constantly obtain the latest drug information in order to provide optimal medication therapy for patients. Package inserts are the most fundamental tools to provide drug information to healthcare professionals and promote the proper use of drugs. As far as our survey, although both hospital and community pharmacists had a high psychological dependence on paper package inserts, electronic package inserts were often used in daily work. In addition, it was not sufficient to confirm whether the paper package insert was the latest. From these facts, it was suggested that it is not possible to grasp important drug information by merely the use of paper package inserts.

The utilization of electronic package inserts is useful for constantly referring to the latest drug information. It would be useful to not only the website of Pharmaceuticals and Medical Devices Agency or pharmaceutical companies, but also QR code on the drug packaging linked to the URL of the latest package insert included in the website.

[PO-03] Approach to Gaps between Ideal and Reality in Clinical Operations and Monitoring – Continued Report to 2017 Japan Annual

DIA Clinical Operation & Monitoring Community (ノバルティス ファーマ株式会社)
松本 恭尚

Objectives:
Lots of Gaps between ideal and actual in clinical trial process around sites have been already identified in 2016 COM Community discussion. In 2017, from various efforts were executed including deep discussion to minimize the Gaps and direct dialogue with site to understand basic root cause at site.

Method:
Using PDCA Cycle concept, COM Community Members worked on PLAN, DO, and CHECK for each Gaps to minimize them. Addition to that, in order to understand site perspectives, “Knowing Each Other” session was held between COM Community and Hokkaido University Hospital.
Results:
To minimize GAPs which were identified in 2016 COM Community, based on
PLAN-DO-CHECK concept, actual cases for DOs and CHECKs by each member
were shared and discussed. Here are some examples.

<Gaps in study-start-up>
PLAN: Have sessions in advance to understand role and responsibility
on each CRA and site staff in preparations of essential documents such as work
sheet, study files and investigator files.
DO: Provide standard form but not customize for each site based on a
principle that site conduct should be maintained by them.
CHECK: Some sites understand the principle. By the action of not customizing
work sheet, site staff have become to refer protocol directly. Some sites still
request customization by CRA.

<Gaps in Process >
PLAN: Implement risk assessments in clinical study
DO: Provide list of critical sites based on various database
for past site performances in site selection phase. Perform regular risk
assessments on site performance by utilizing EDC metrics and other tracking
tools.
CHECK: Risk assessments based on metrics parameters already have become
popular and standardized in each company, however, since risk indicators
have been set by central, customization of the parameters or methods of the
assessment according to study specific aspects are not possible.

In the GAP discussion, the needs of deep understanding of site view and
engagement with the site was raised, as a purpose of understanding clinical
case’s view “Knowing each other” session was held with Hokkaido University
Hospital. 10 staff from Hokkaido Univ Hospital and 6 COM members had
discussion based on the questionnaires from staff site in advance. In the session,
the evidences and concerns in daily operations were shared from both sides.
Key learnings are that site staff feel sponsors have various opinions and
provide different reason for their behaviors. Even if CRAs in same company, it
seems some CRAs may not understand true meaning of their behaviors.

Conclusion:
In the ongoing discussions on actual PDCA cases to minimize GAPs, more
clearly and detailed discussion theme were set, then more deeply and
actively we were able to share various behaviors, and also it helped us to
reflect on our behaviors. Therefore, we consider that continuous Community
activity and similar approach would be necessary in future.

Through exchanging views with clinical site staff this time, we were able to
know the realities of clinical trial at site and recognized that there are still
many issues to be solved (gaps between industry side and clinical site). In
addition, the way to capture the problem and cope with them are not
standardized, and depends on individuals. Therefore, we consider that our
continuous activities with various participants in various positions would be
vital in order to look into real root cause of issues and to explore the essence
in operations for clinical trials.

COM Community, since establishment in 2014, has been voluntarily
conducting sessions among Dia members and has continued various
discussions on the theme of problems related to clinical trials. In 2017,
through approaches on efforts to minimize GAPs with PDCA Cycle concept,
and deep dives to essential opinions, it is considered that there are lots of opportunities for us to improve current situation and
establish ideal clinical trial environment.

COM community continues providing opportunity to participants such as
not only industry side but also clinical site staff that they can extend their
perspectives and reflect meaning of mutual behaviors in clinical trials.

This contents were presented at the 6th Dia COM workshop.

[PO-05] Insight into Challenges and Complexities in Safety Reporting Requirements: US, EU and Asia Perspective
AWINSA Life Sciences
Sanjeev Miglani
Learning Objectives:
1. Know the important differences in regulations in clinical trials and discuss the safety reporting requirements 2. Understand the pharmacovigilance requirements in Asia and how they are different from the US and EU
3. Comprehend various challenges associated with safety reporting in Asian countries and explore measures to successfully manage the complexities

Full Description:
Pharmacovigilance (PV), demands a high degree of regulatory expertise. PV activities in the EU and US have continued to change and evolve as the public asks for greater transparency and protection. However, it has been a continuous challenge to harmonize the PV regulations in Asia due to diverse geographical, cultural and clinical practices in this region. Nonetheless, as the volume of clinical trials being conducted in the Asian countries has been growing rapidly in recent years as emerging markets grow, they are moving towards a trend of higher quality requirements with their tougher regulations. This increased demand necessitates an intensified focus on PV and drug safety in this region. PV in Asia has become an important public health issue as regulators, drug manufacturers, consumers, and HCPS are facing with a number of challenges. Lack of cross-cultural expertise and knowledge of regulatory requirements, lack of PV experts, lack of awareness amongst physicians and public and underreporting of spontaneous reports have been the major challenges in PV that need to be mitigated to build a robust system for the future. To illustrate, a local representative is quintessential in China, Japan, and Taiwan, while that is not the case in some of the other countries.

Further, the translation of safety reports to the local language is obligatory in some countries such as Japan and South Korea; however, the English version of the report is also available in many other countries.

Differences also exist in the mode of submission of reports, with different countries opting for manual/in-person submission or electronic submission. The variations are not just limited to these examples but extend across many other nuances in the methodology of PV. This session will focus on differences in the safety reporting requirements for clinical trials across the countries in EU, US and Asia; challenges and complexities of PV regulations and effective management of safety reporting processes in EU, US and Asia.

[PO-06] Big Data Use to Inform Ideal Models in Rare Neurodegenerative Disease
INFARMED
Dinah Duarte
Learning Objectives:
Discuss the importance and value of big data analysis to choose the ideal
model in rare neurodegenerative disease; Share real world experience from
available historical data on models use and build up the experience on utility
of the models in therapeutic area of neurology.

Full Description:
Medical big data have become indispensable in medicine development. Many stakeholders in medicines development have been making decision by reference to information come from big data analysis. Many diseasespecific models have been used to test emergent medicines in neurology. There is a focus now that sites that may not have access to large clinical databases may be
Lexical to use Big Data to support orphan drug designations in rare
neurodegenerative conditions, which are validated for each condition and
to evaluate assays pertinent to the core features of selected conditions or
otherwise relevant from the clinical standpoint. The pioneering analysis will
help identify models with best predictive value as well as those acceptable
based on their face value, highlighting the areas of most unmet need where
research or interventional study? It would be helpful for them to know what
medical information database is applicable to what research. We reviewed existing database researches/studies by focusing on therapeutic
area, patient number, diagnostic sensitivity, lethality, and so on. Data
studies are practical in therapeutic areas with chronic diseases such as hypertension, because diagnostic measures are established and
disease itself is not life-threatening thus enough patient data are collected easily. Database investigation of orphan diseases such as hemophilia is a challenge and feasible, because accurate and sufficient patient data with such disease is too limited to conduct interventional study prospectively. Researchers are likely to refer to existing patient database rather than newly conducting interventional studies. In progressive areas such as Alzheimer-type dementia, where biomarkers have just been found, database researches might not be necessarily successful, because medical information databases don’t crucial data such as biomarker values and information about preclinical subjects.
development of better pre-clinical tools is necessary. We will discuss the importance of the availability of this information in encouraging sponsors to develop innovative medicines in rare neurological conditions and comprehensively review the advanced approach for big data utilization and future perspectives.

[PO-07] Insight into New Regulations in Medical Device PV Arena – US and EU Perspective

AWINSA Life Sciences
Mugdha Chopra

Learning Objectives:
1. Understand how the management of safety for medical devices differs from other pharmacological agents.
2. Differentiate between medical device pharmacovigilance regulations in the US and EU
3. Describe the challenges and complexities in the device regulations in the US and EU and, how the upcoming new rules will address them

Full Description:
In recent times, there has been a very high level of public interest and active debate regarding the regulation of medical devices especially with regards to the pharmacovigilance aspect. This is in light of the safety concerns originating from poly-implant-prosthesis (PIP) breast and metal-on-metal hip implants. Although medicines and devices are regulated under European Union and the United states law, the regulatory regimes are very different, and some have argued that features of the pharmaceutical regime should be applied to medical devices. The United States and the European Union approach these challenges in different ways. Whereas the United States has always relied on a strictly centralized process through 1 agency, the Food and Drug Administration (FDA), the European Commission synchronized the regulations of 28 different countries as they combined to create the European Union. The FDA historically developed as a consumer protection agency, whereas the regulations from the European Commission arose out of a need to harmonize inter-state commercial interests while preserving national “autonomy.” The EU system has drawn criticism for conflicts of interest in its evaluation process, and a recent recall of a popular silicone breast implant that was approved only in the European Union has reinforced European concerns about the clinical evaluation of high-risk devices. In order to strengthen the regulations in medical devices, the European Parliament adopted two new regulations on 5 April 2017. They will be published in the official Journal. The new rules will apply three years after publication with regards to the medical devices. US FDA too at the same time is taking initiatives to ensure that safety monitoring is robust both preapproval as well as post approval. This presentation explores some of the similarities and differences in European and US regulation of devices, and discusses challenges facing each.
システムの議論します。TransCelerateの活動として、規制当局と共に取り組むPharmacovigilanceにおける課題、革新技術を用いた治療施設や医師の経験の再定義、eConcentやeLabelなどデジタル活用による患者中心の臨床試験を実現、を紹介します。

演題未定
Shionogi Inc.
Gareth Morgan

日本におけるTransCelerateの活動
MSD株式会社
佐野 俊治

主要インタビュープロジェクト: Pharmacovigilance
Astellas Pharma US
Songlin Xue, MD, PhD

主要インタビュープロジェクト: SIP (Shared Investigator Platform)
MSD株式会社
三橋 晃一

主要インタビュープロジェクト: eLabel
日本イーライリリー株式会社
千代森 陽介

V4-S3 609会議室 14:00-15:30
免疫療法時代の抗がん剤の臨床評価の新たな方法
関連領域: 薬事、統計、アカデミア、Clinical Strategy、Medical Writing
レベル: 初級
座長
国立研究開発法人 国立がん研究センター
藤原 康弘

現在、がん免疫療法はがんに対する画期的な治療法の1つとして確立されている。その特徴の1つとして、効果の遅発性などが議論されており、2016年に発行された後期臨床試験の考え方に関するガイドラインでは、統計学的に、比例ハザード性が成立しない場合に対する留意点や、RMST (Restricted Mean Survival Time) のような評価項目が記載された。本セッションでは、これらの背景を踏まえた上で、がん免疫療法に対する臨床評価を包括的に議論する。また、がん免疫療法に関わらず、治療体系が大きく進化していく中で、臨床評価項目の妥当性、開発戦略の決定、新薬の患者への早期アクセス、などについても同様に議論する予定である。

演題未定
国立がん研究センター中央病院
清水 俊雄

演題未定
横浜市立大学
山中 竹春

演題未定
塩野義製薬株式会社
長谷川 貴大

パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
野中 孝浩

V5-S3 610会議室 14:00-15:30
製薬業界の技術革新 - 連続生産を推進するための環境

V7-S3 102会議室 14:00-15:30
患者参画推進: 教育プログラムの最新動向
関連領域: 全領域
レベル: 初級
座長
ノバルティスファーマ株式会社
関根 恵理

近年、Patient Centricityへの意識・関心が高まり、日本でも、行政や医療機関などにおける検討会や委員会に患者側委員が含まれるようになっている。患者・市民参画を推進していくためには、参加する患者・市民に必要な知識とスキルを提供する取り組みが必要である。国内外で産官学によっての様々な試みがなされており、その事例や目的を知ることで、自分達がすべきことを改めて考える必要がある。本セッションでは、European Patient Forumによる欧州での取り組み、臨床に参加する患者さんの心得とといえるガイダンスを作成した日本難病・疾患団体協議会の取り組み、AMEDによる患者参画推進に向けた取り組みを紹介し、その意義、実績、課題などについて議論する。

Patient Engagement - a European Perspective
MSD
Paul Robinson
演題未定
一般社団法人日本難病・疾患団体協議会
森 幸子

演題未定
国立研究開発法人 日本医療研究開発機構
勝井 恵子

パネルディスカッション
本セッションの講演者

V6-S3 101会議室 14:00-15:30
患者参画推進 : 教育プログラムの最新動向
関連領域: 全領域
レベル: 初級
座長
ノバルティスファーマ株式会社
関根 恵理

演題未定
国立がん研究センター 国立がん研究センター中央病院
清水 俊雄

演題未定
横浜市立大学
山中 竹春

演題未定
塩野義製薬株式会社
長谷川 貴大

パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
野中 孝浩

V5-S3 610会議室 14:00-15:30
製薬業界の技術革新 - 連続生産を推進するための環境

V7-S3 102会議室 14:00-15:30
再生医療等製品の市販後における様々な取り組み
関連領域: 薬事、アカデミア、Safety
レベル: 初級
座長
国立医薬品食品衛生研究所
佐藤 陽治
再生医療等製品は現時点で4品目が承認されており、現時点でも様々な研究やビジネス化に向けた取り組みが行われている。本セッションでは、再生医療学会の構築したナショナルコンソーシアムの概要を理解し、学会における支援の状況やデータベース構築の現状と課題、データベースから期待するアウトカムや継続的な運用について、企業及び当局の立場からそれぞれの意見を伺い、今後の課題と期待について議論する。

再生医療の市販後の安全対策
独立行政法人 医薬品医療機器総合機構
小池 和央
患者登録制度とアカデミアとの連携 ~ 企業の立場から ~
JCRファーマ株式会社
岡田 麗理子
再生医療ナショナルコンソーシアムの概要
大阪大学医学部附属病院
岡田 潔
パネルディスカッション
大阪大学医学部附属病院
岡田 潔

多様な生き方・働き方が意識される現在において、あなたのキャリアの軸について一緒に考えてみませんか?
関連領域: 全て
レベル: 初級
言語: 日本語のみ
座長
アイ・エル・ジャパン株式会社
二宗 みのり
近年、働き方のダイバーシティの意識が高まり、人々の仕事、キャリア形成を含む「生き方」への考え方が変わりつつあります。変化の激しい時代だからこそ、あなたが自身の価値観が生き方や働き方の選択とどのように関係しているのか考えてみてませんか。本セッションでは、元グーグルの人事担当者で、長期的に入社したピョートル氏を招聘し、働き方についての考えを伺ったり、あなたの「判断や選択の軸となる価値観」をキャリアアカウントとして、多様に立場の参加者との対話を通じて明らかにします。明日からの働き方を前向きなものにしてみませんか。あなたの中にイノベーションを起こしましょう！参加をお待ちしています。

How Can We Define and Manage Quality Goals for Clinical Trials Using a Quality Tolerance Limit (QTL) Approach?
関連領域: 薬事、DM、安全性、臨床、統計、PM、アカデミア、MA
レベル: 中級、上級
座長
Astellas Pharma Global Development, Inc.
佐伯 訓
Control/Tolerance Limitsを用いた統計的品質管理は1920年代にWalter Shewhartが提唱し、その後、W. Edwards Demingが品質マネジメントのフレームワークとしてPDSA Cycleを考案した。これらのアプローチは主に製造業における品質管理手法として発展してきたが、今まさに、臨床試験にも取り入れられるようになった。ICH-E6 (R2) ではQuality Tolerance Limits (QTLs)として定義され、被験者の安全性及び臨床試験結果の信頼性にインパクトを与える体系的なissuesをQTLsとして事前に設定し、臨床試験における可視化された品質ゴールとして用いられることが期待されている。昨年の日本年会でもQTLsを取り上げ、概念的な議論を実施したが、今年は実装を強く意識し、ケーススタディーとしてプロトコルシンプスをベースにQTL Parameterの同定やTolerance Limitの設定およびモニタリング等の具体的なアプローチを議論する予定である。

Risk-based Quality Management in Clinical Trials Using Quality Tolerance Limits (QTLs)
Kattner-Thalmann Partners
Christopher Hanna

希少疾病用医薬品/小児用医薬品等今まで臨床試験の実施や臨床データパッケージにおける日本人症例数の収集が困難なため、企業が開発に躊躇してきた領域において、疾患レジストリ、RWD、Model & Simulation、市販後データ、並びにICH E17、条件付き早期承認制度などの新しいレギュレーションを活用した開発戦略を立案・実行することが、さらなる開発推進に繋がることが示唆されている。本セッションでは、これらのフレームワークを活用した開発戦略の構築に向けてのケーススタディーを紹介する予定である。

演題未定
ファイザー株式会社
寺田 道徳
演題未定
国立精神・神経医療研究センター
中村 治雅
演題未定
独立行政法人 医薬品医療機器総合機構
齊藤 崇
パネルディスカッション

効果的な薬物相互作用の検討に向けて～日米欧の規制文書を比較しながら～
関連領域: 薬事、安全性、臨床、PM
レベル: 初級
座長
武蔵野大学
永井 尚美
2018年7月、日本の薬物相互作用ガイドラインが発表された。Decision treeのカットオフ基準や薬物相互作用の検討に用いることが推奨される指標薬等に関して、国際調和が図られているものの、日米欧の対応する規
制文書において異なる点も見受けられる。また近年、生理学的薬物速度論（PBPK）に基づくモデリングとシミュレーションが積極的に利用されるようになっており、その有用性が言及されている。薬物相互作用の予測に活用できる適切なモデルを用いることで、医薬品開発段階における薬物相互作用の検討の効率化に資する可能性がある。米欧の薬物相互作用に対する規制文書を比較しながら、今後の薬物相互作用の検討のあり方について議論する。

本邦における薬物相互作用ガイドラインの概要とその科学的意義
千葉大学大学院
樋坂 章博

薬物相互作用に関する規制文書の国際調和
東京大学大学院
前田 和哉

PBPKモデルを活用した薬物相互作用の検討
MSD株式会社
松本 有毅

パネルディスカッション
本セッションの講演者

V4-S4  609会議室  16:00-17:30
価値ある医薬品情報を提供するためにコンプライアンスを考えるときが来た。
-医薬品情報提供の現状とべき姿-

関連領域: アカデミア、MA、コンプライアンス
レベル: 初級、中級

座長
Pfizer Holdings
Stuart Sowder

日々変わりゆく科学的・倫理的アプローチを踏襲しながら、我々の英知を結集したデータ構築が承認申請資料の基になる。承認されたデータを我々はどのように医療関係者へ適切に提供し、医療の質の向上に貢献するべきか、広告活動監視モニター制度が始まる20年目に入った。今まさに単一の組織だけでなく独自のコンプライアンスのあり方を考えず、行動や倫理基準についてステークホルダーと共に考える時期が来たのではないかだろうか。

本セッションでは、各製薬団体（JPMA, PhRMA, EFPIA）のコンプライアンスの専門家、アカデミア、当局の専門家とともに、日本の医薬品情報提供に関してグローバルの流れを踏まえ現状と今後の在り方について議論する。

演題未定
ファイザー株式会社
片山 泰之

演題未定
日本製薬工業協会
田中 徳雄

演題未定
帝京平成大学
白神 彰

演題未定
厚生労働省
堀尾 貴将

パネルディスカッション
本セッションの講演者およびアステラス製薬株式会社

V5-S4  610会議室  16:00-17:30
ICH E17がグローバル開発にもたらすもの

関連領域: TBC
レベル: 中級

座長
ファイザー株式会社
石橋 太郎

ICH E17がStep 5を迎え、当ガイドラインに基づく国際共同治験が世界各国の承認申請に用いられる時代が到来した。当ガイドラインは国際共同治験の計画及びデザインについての基準が示されたものであるが、それを用いた医薬品の効果や安全性についての解釈や承認基準を示すものではない。その部分は各国当局の判断に委ねられる。本セッションでは、当ガイドラインに基づいて行われる国際共同治験が今後どのように変わってくるか、またそれら試験を用いた承認申請が各国においてどのような影響を受けるか、について、日欧米中の各局の専門家に議論をし、当ガイドラインがグローバル開発に与える影響を論じる。

E17 Implication for Global Drug Development: US Perspective
Bayer AG
Joseph Scheeren

E17 Implication for Global Drug Development: China Perspective
Shenyang Pharmaceutical University
Ling SU

E17 Implication for Global Drug Development: Statistical Consideration
ファイザー株式会社
河合 統介

パネルディスカッション
本セッションの講演者および独立行政法人 医薬品医療機器総合機構
中村 龍太

V6-S4  101会議室  16:00-17:30
Precision Medicineの実現に向けた新たな医薬品開発アプローチ

関連領域: 全領域
レベル: 初級

座長
東京大学大学院
平川 晃弘

個々の患者により適した医療を提供し患者のメリットをまず考えるという観点から、詳細な疾患Subtypeそれぞれに最適な治療を提供するPrecision Medicineが提唱されている。従来の臨床試験では基本的に単独の試験治療・集団・疾患が対象であり、より詳細なSubtypeに複数の治療候補を評価するには、より効率的なアプローチが求められる。本セッションではPlatform designなど DJs統計を活用した新たなデザインやコンソーシアム構築、疾患レジストリなどの実施アプローチについて、本邦でのマスターキープロジェクトを含め、がん、アルツハイマーなどでの国内外での事例を紹介し、今後の方向性と課題について議論したい。

演題未定
Janssen R&D, Johnson & Johnson
Akiko Okamoto
希少がんに対するバスケット型レジストリ付き臨床試験
～MASTER KEY Project～
国立がん研究センター中央病院

大熊 ひとみ

演題未定

独立行政法人 医薬品医療機器総合機構

野中 孝浩

演題未定

Johnson & Johnson

Mike Krams

V7-S4 102会議室 16:00-17:30

日本におけるe-Labelingの将来
関連領域: 薬事、安全性、アカデミア、Medical affairs and Medical information
レベル: 中級
座長
ファイザー株式会社

松井 理恵

昨今、医療従事者及び患者向け添付文書情報の提供方法や読み易さを一変させるテクノロジーの利用が注目されている。 E-labelingは、欧州においてEMA action planとして議論が始まっており、米国においては既にStructured Product Labelingが使用されている。それ以外の地域でも添付文書の情報提供を強化するためデジタルインプラメーションの導入が進められている。日本においては、SGML化された添付文書がPMDAのホームページ上に公開されているが、今後、電子医療カルテや教育用資料を電子的にリンクさせ、パーソナライズまたは多様化された添付文書が入手可能になれば、患者さんの治療や薬剤への理解が改善され、最終的に安全性向上に寄与する。このセッションでは、日本のe-labelingの将来と紙の添付文書の継続的な役割について議論する。

e-labelingの将来～Opportunities and Challenges～グローバルの立場から
Pfizer Inc.
Shimon Yoshida

日本における添付文書の電子化に関する検討の現状～行政の立場から～
厚生労働省
関野 秀人

パネルディスカッション
本セッションの講演者および
国立循環器病研究センター
山本 晴子

V8-S4 703会議室 16:00-17:30

リーダーのあなた！あなたのモチベーションは大丈夫？チームメンバーは？
さあ！ここで一緒に考えてみませんか？
関連領域: 全て
レベル: 初級
言語: 日本語のみ
オーガナイザー
大阪大学医学部附属病院
岩崎 幸司

協和発酵キリン株式会社
佐藤 隆

今、リーダーとして活躍しているあなた、リーダー候補のあなた、チームをまとめ成果を見せてならない責任やプレッシャーのなかで、何を感じていますか？
「モチベーション」とて、できることはあるけど、いったい何だろう？どこからやってくるのでしょう？
そんな疑問について、一緒に考えてみませんか？
このセッションでは、リーダーのモチベーションについて、セッションを担当する私達からコーチングとカウンセリングの観点でのアプローチや事例を紹介しながら、参加いただいた方々同士や私達が感じていることや思っていることを話し合うインタラクティブな方法でモチベーションの新時代について考えていきます。

ショートブレイク 17:30-17:45

日本臨床薬理学会認定CRC制度による研修会・講習会
本年会は日本臨床薬理学会認定CRC制度による研修会・講習会として認定されています。
以下のプログラムのうち、4時間以上受講した参加者には、希望により修了証を発行します。
11月11日（日）
・基調講演1、基調講演2
・DIAMond Session 1
11月12日（月）
・セッション1〜4
11月13日（火）
・セッション5〜6
・DIAMond Session 2 / 3

修了証の発行を希望される方は、年会終了後、2018年11月20日（火）までに受講証明申請書をDIA Japan <Japan@DIAGlobal.org>宛にメール添付にて提出してください。受講証明申請書は、下記リンクよりダウンロードできます。

受講証明申請書を受理した後、申請者の参加の有無及び申告された受講時間を確認のうえ、修了証を送付します。

日本薬剤師研修センター認定の集合研修会
本年会の基調講演1〜2、セッション1〜6（11月12日のセッション1〜4、11月13日のセッション5〜6）、DIAMond Session1〜3は、公益財団法人日本薬剤師研修センターより認定された集合研修会としており、参加者は1セッションにつき1単位（研修受講シール1枚）を取得できます。
研修受講シールの交付を希望される方は、来場時と退場時に必ずシールを掲示してください。
ご受講されたセッション数に応じ、研修受講シールをお渡しいたします。
毎年ご好評いただいておりますスペシャルチャッティングセッションを今年も2日目の夜にご用意しました。DIAの活動の大きな目的の1つは人材交流です。参加者同士が気軽にネットワークを深め、意見交換ができる場ですので、是非、積極的にこの場をご利用頂ければと思います。若手も、意見番を、大学の学生や先生方、医療機関の先生方、PMDAの方も、同じテーブルを囲んでみれば、皆、仲間！来年にまで一人で参加される方も多いので、輪を入れていきたいと思います。

今年は、テーブルごとに100のテーマをお用意しました。これらの中で、皆さんが興味のあるテーブルをお選びください。途中参加、退席、移動も可能です。基づくものとさせていただきますので、予めご理解願います。と軽食もご用意しています。ビールやワインを飲みながら、熱くそして楽しくおしゃべりしましょう！なお、このセッションでの発言はすべて個人の見解として進める予定です。コミュニティの枠を超えた意見交換も期待できましょ。当日、ご興味のあるテーブルの周りに集まりください。会場でドリンクも用意しております。
 SESSION 5 9:00-10:30

V1-S5  605/606会議室 9:00-10:30
患者さんが治験で求める情報、コミュニケーションとは何か？それをどう提供していくか？（第1部）

座長
国立研究開発法人 国立がん研究センター
藤原 康弘

座長
 MSD株式会社
古屋 義方

患者さんが治験で求める情報、コミュニケーションとは何か？それをどう提供していくか？（第1部）
関連領域: 全領域、患者さん、CRC
レベル: 中級

V3-S5  608会議室 9:00-10:30
製品価値最大化に向けてのチャレンジと挑戦 -開発部門とメディカルアフターズ部門の連携を通じて-

座長
大日本住友製薬株式会社
相野 靖司

医薬品の開発段階から上市後に向けてシームレスに製品価値を最大化させるために、いくつかの製薬企業では医薬品開発部門とメディカルアフターズ部門がより密接に連携し、開発戦略・論文戦略・KOL Science Liaison (MSL) は医療従事者からUnmet Medical Needsを収集する役割を担い、彼らの貢献は新しい開発の機会や価値のあるエビデンス想出のためには欠かせない。

本セッションでは、それぞれの企業での連携事例を共有頂き、医薬品の価値を向上させるためにどのような工夫を行っているのか？を議論する。

演題未定
ファイザー株式会社
片山 泰之

演題未定
日本イーライリリー株式会社
江夏 総太郎

演題未定
アステラス製薬株式会社
村上 学

パネルディスカッション
本セッションの講演者および
グラクソ・スミスクライン株式会社
古座宏

V4-S5  609会議室 9:00-10:30
マイクロバイオームの新展開

座長
東京大学医学科学研究
湯地 宏一

腸内、皮膚、鼻、口、食道、胃、生殖器など、人体中には多様多種な細菌が存在し、この細菌全体をマイクロバイオームと呼ぶ。
マイクロバイオームは個々人により異なり、健康維持、そして炎症性腸疾患、糖尿病、大腸癌、自閉症、自己免疫性疾患などの疾病発症、さらには薬効に関与することが明らかになっている。これらの疾患の診断、治療薬に加え、創薬シーズ、さらにはコンパニオン薬物としての役割が期待されている。

本セッションではマイクロバイオームの研究の進展について概説し、創薬・製薬業界での利用の展望について議論する場を提供する。

腸内細菌叢・微生物叢の解析と治療開発
東京大学医科学研究所 ヘルスインテリジェンスセンター
井元 清哉
腸内細菌叢と加齢（仮題）
大阪市立大学/東京大学医科学研究所
藤本 康介
腸内フローラ解析と代謝物分析サービスの活用
株式会社テクノルガ・ラボ
久田 貴義
パネルディスカッション

V5-S5  610会議室 9:00-10:30
薬剤耐性菌感染症（AMR）の世界的脅威への対応
関連領域: 薬事、安全性、臨床、アカデミア
レベル: 中級
座長
独立行政法人 医薬品医療機器総合機構
佐藤 淳子
対策をとらなければ、2050年には癌による死亡数を超え、世界で1000万人の死亡が予想されるAMRの脅威に対し、国は「薬剤耐性(AMR)対策アクションプラン2016-2020」を発表した。現在、産官学において様々なAMRに対する施策が検討され、創薬から新規抗菌薬の開発、サーベイランス、適正使用に至る様々な具体的な議論が進められている。本年会では、AMRに対する臨床研究開発を中心として、グローバルな視点も含め、いかに効率的な本格的な実用化が進められていくか、産官学における現状の課題と相互に協力を図った取り組みについて議論する。

AMR感染症治療薬：審査の立場から
独立行政法人 医薬品医療機器総合機構
朝倉 渡
AMR感染症薬の開発における課題
塩野義製薬株式会社
有安 まり
演題未定
国立がん研究センター中央病院／慶應義塾大学
岩田 敏
パネルディスカッション
本セッションの講演者
国立研究開発法人日本医療研究開発機構で検討が進んでいるように、臨床研究等ICT基盤構築は、将来の医療技術・臨床開発に必要なエビデンスを提供するために必要不可欠です。米国においても、FDAがeSourceの使用を増やすよう求めています。しかしながら、臨床開発・臨床研究分野でのeSourceの利用は、データ操作の難しさから採用が遅れています。eSourceの利用は、患者様、医療機関、スポンサーそれぞれに利益をもたらす、より効率的なデータ収集手法となっているといいます。本セッションでは、eSourceの利用に関する課題の認識と、それらを克服する上での今後の産官学の協力について議論していきます。

電子カルテからの臨床研究データの直接取り込み
大阪大学
松村 泰志

電子カルテデータの利用と課題（仮題）
国立がん研究センター東病院
青柳 吉博

モバイルヘルスとVirtual Trialの利用と課題（仮題）
東京大学大学院
宮路 天平

TransCelerate eSourceの取り組み（仮題）
ファイザー株式会社
小笠原 美香

コーヒーブレイク 10:30-11:00

SESSION 6 11:00-12:30

V1-S6 605/606会議室 11:00-12:30
患者さんが治験で求める情報、コミュニケーションとは何か？それどう提供していくか？ （第2部）
関連領域：全領域、患者さん、CRC
レベル：中級
座長
国立研究開発法人 国立がん研究センター
藤原 康弘

患者さんを医薬品開発のパートナーとしてEngageし、その参画を推進していくには、患者さんが治験で求める情報、関係者とのコミュニケーションを理解し、それに応えていくことが重要であり、日本でも治験情報の開示や、Patient Lay Summaryの提供が行われています。ICTの発展は目覚ましく、iWatchによってバイタルサインの測定がいつでも簡単に実施でき、スマートスピーカーに話しかければ様々な情報が瞬時に手に入る世界が訪れている。臨床試験におけるICTによる変化は、治療が紙から電子になった事に端を発するRBMなどが挙げられるが、まだまだ発展の余地は残っている。

本セッションでは産官学の有識者により、今後の日本における医薬品情報提供のあり方について、作成・提供する側、使用する側、患者さん側に説明する側、当局関係者により議論する。
V4-S6 609会議室 11:00-12:30
AIの可能性と将来の承認審査
関連領域: 統計、その他
レベル: 中級
言語: 日本語のみ
座長: MSD株式会社
鈴木 実
総務省の多言語音声翻訳技術を使用したAI翻訳の医療分野での今後の展開など、グローバル医薬品開発において、どのような技術が使用可能な状態で、どのようなことが次にできるようになるかを共有し、AIなどのイノベーションを利用した承認審査期間の短縮を議論する。

AIによる高精度自動翻訳
国立研究開発法人情報通信研究機構
隅田 英一郎
デジタル技術の発達と影響（仮題）
バイエル薬品株式会社
尾花山 和哉
XMLを利用した添付文書の作成と、市販後資材への応用
MSD株式会社
佐藤 めぐみ
パネルディスカッション
本セッションの講演者

V5-S6 610会議室 11:00-12:30
日米欧におけるワクチン政策、薬事規制の最新動向
関連領域: 薬事、アカデミア
レベル: 初級
座長: 川崎市健康安全研究所
岡部 信彦
予防接種は、公衆衛生の向上及び増進に大きく寄与してきたが、2020年に開催される東京オリンピックに向けて今後予防接種による感染症予防が、ますます重要になっている。本セッションでは、日米欧の予防接種制度及び審査について紹介し、その制度の違いが予防接種促進にどのよう影響しているかを様々な角度から議論する。
また、予防接種をすることによって得られる利益に関する経験談と今後のワクチン行政に対する期待についても議論していく。

日米における予防接種制度について
新潟大学
斎藤 昭彦
USのワクチン開発のポリシーと規制動向と課題
Merck & Company Inc.
Ercem Atillasoy
EUにおける予防接種とワクチン開発（仮題）
GSK Vaccines
Shazia Sheikh
パネルディスカッション
本セッションの講演者および
Pfizer Japan Inc.
Andrew Otoo

V6-S6 101会議室 11:00-12:30
臨床研究法を見据えたエビデンスジェネレーション
関連領域: MA、臨床、アカデミア
レベル: 初級
座長: 塩野義製薬株式会社
廣居 伸蔵
2018年4月に施行が予定されている臨床研究法により、日本の介入研究の実施が従来に比べてより困難になることが示唆されます。日本発のエビデンスを構築するために、リアルワールドデータを使った研究などの観察研究が重要になることでしょう。観察研究の可能性と限界について介入研究と対比する形で議論します。

臨床研究法がエビデンス構築に与えるインパクト
大阪大学医学部附属病院
岩崎 幸司
観察研究のABC
慶應義塾大学
塩原 尚巳
欧米におけるリアルワールドエビデンス：その方向性と事例紹介
武田薬品工業株式会社
宇田 映仁
パネルディスカッション
本セッションの講演者

V7-S6 102会議室 11:00-12:30
医薬品安全性監視活動のパラダイムシフト－リサーチ・クエスチョンをいかに考えるか－
関連領域: 安全性
レベル: 初級
座長: 日本イーライリリー株式会社
前田 玲
PMDAより本年1月発出された文書「製造販売後調査等の実施計画の策定に関する検討の進め方について」により、医薬品安全性監視活動の検討の進め方が大きく変更しています。治療等の情報を対象とする薬物は、安全監視活動を強化する必要がある。そこで本セッションでは、クリニカル・クエスチョンをどのように考え、それをいかにして解決するかに焦点をあてて議論したい。

ファーマコビジランス活動における目的に沿った研究デザイン
東北大学大学院
山口 拓洋
企業における疫学・データ活用の現状と課題
中外製薬株式会社
中根 早百合
医薬品安全性監視計画におけるクリニカル&リサーチクエスチョン
独立行政法人 医薬品医療機器総合機構
石黒 智恵子
パネルディスカッション
本セッションの講演者および
FDA
Gerald J. Dal Pan

V8-S6 703会議室 11:00-12:30
添付文書新記載要領改正に基づく添付文書改訂の実際に向けてと、その他の資材による情報提供にあり
関連領域: MA、臨床、アカデミア
レベル: 初級
座長: 塩野義製薬株式会社
廣居 伸蔵
2018年4月に施行が予定されている臨床研究法により、日本の介入研究の実施が従来に比べてより困難になることが示唆されます。日本発のエビデンスを構築するために、リアルワールドデータを使った研究などの観察研究が重要になることでしょう。観察研究の可能性と限界について介入研究と対比する形で議論します。
関連領域：薬事、安全性
レベル：中級
言語：日本語のみ
座長
武田薬品工業株式会社
大平 隆史
2019年4月に添付文書新記載要領が施行される。それに先立ち、一部の薬剤に関して新記載要領対応のPMDDA相談が本年7月から開始（First Wave）され、PMDDAからのフィードバックが各企業へ行われている。モデル医薬品の添付文書の公開を通じてその実例の紹介や、新記載要領施行後実際に添付文書改訂を行うまでの課題について、検討や取組みの事例を紹介する。また、新記載要領添付文書においてインタビューフォーム等のその他の資材での効果的な情報提供を考える上での工夫や、添付文書を活用する側からの視点及び情報提供の留意点について議論したい。

添付文書新記載要領と改訂相談First Waveを経ての所感
独立行政法人 医薬品医療機器総合機構
鎌田 暁史
新記載要領添付文書改訂の実際へ向けて-企業の立場から（仮題）
ノバレティスファーマ株式会社
稲村 達海
新記載要領添付文書改訂の実際へ向けて-薬剤師の立場から
慶應義塾大学病院
中田 英夫
新記載要領添付文書改訂に伴うその他の資材の展望及び情報提供（仮題）
中外製薬株式会社
竹本 信也
パネルディスカッション
本セッションの講演者

ランチブレイク 12:30-14:00
DIAmond Session 2
国際会議場 14:00-15:30

Innovative Clinical Trials: 臨床試験の未来予想図
関連領域：全領域
レベル：全て
座長
塩野義製薬株式会社
澤田 拓子

IoTやAIの導入、データの2次利用の推進やシミュレーションの活用など、臨床試験を取り巻く技術革新は未曾有のスピードで進んでいる。またprecision medicineの適用や遺伝子治療、再生医療品等製品の開発など、新たな枠組みでの臨床試験の必要性も高まっている。一方で増大する開発コストや生産性向上への課題は依然として大きく、日本独自の様々な規制も存在する中で、グローバル開発の中での日本の真価が問われつつある。

本セッションでは、セッション全体のOverviewに続いてグローバルでのリモート治験やデータ2次利用等による新たなエビデンス構築の現状を共有した後、このような背景の中で日本の進むべき方向性と、そのために何が必要かを議論する。

臨床開発のパラダイムシフト
MSD株式会社
白沢 博満

Embracing Technologies to Enable Smarter, Patient-focused, Drug Development
Novartis Pharma AG
Bryan McDowell

パネルディスカッション
本セッションの講演者およびTransCelerate Biopharma, Inc
Dalvir Gill
Medidata Solutions, Inc.
Jackie Kent

厚生労働省
森 和彦

コーヒーブレイク 15:30-16:00

DIAmond Session 3
国際会議場 16:00-17:30

PMDAタウンホール
関連領域：全領域
レベル：中級
座長
塩野義製薬株式会社
澤田 拓子
昭和大学
内田 直樹

本セッションは、PMDAの担当者をパネリストに迎え、参加者からの質問についてお答えするセッションです。有意義なセッションとするため、参加者からの積極的なご発言、ご質問を期待しています。

パネリスト：
独立行政法人 医薬品医療機器総合機構
ワクチン等審査部長
紀平 哲也

独立行政法人 医薬品医療機器総合機構
組織運営マネジメント役
佐藤 大作

独立行政法人 医薬品医療機器総合機構
医療機器審査第一部長
高江 慎一

独立行政法人 医薬品医療機器総合機構
医療情報活用部長
宇山 佳明

独立行政法人 医薬品医療機器総合機構
上席審議役（新薬審査等担当）
宇津 忍

閉会の挨拶
国際会議場 17:30-17:40
第15回DIA日本年会副大会長 /株式会社CTD
冠 和宏
DIA EUROPE 2019
5-7 February | Vienna, Austria

Join us at the Crossroads of Healthcare

DIA EUROPE RETURNS TO VIENNA!
DIAglobal.org/Europe2019
DIA日本年会 展示のベネフィット
日本年会展示専用ウェブサイト：http://diaexhibit.org/

1. MAXIMISE YOUR BRAND EXPOSURE
展示会ではブランディングの為のあらゆる場が提供されています。新しい製品やサービスのご紹介、マーケティング戦略や企業のブランドイメージを高めることができます。

2. LUNCHEON SEMINAR AND COFFEE BREAK PRESENTATION
プラチナやゴールドサポーターはお昼休みにセミナールームで、独自のランチョンセミナーを開催することが出来ます。またシルバーサポーターはコーヒーブレイクの時間にプレゼンテーションが出来ます。御社のご紹介、新しいサービス、ツールのご紹介などに活用ください。

3. REACH OUT YOUR POTENTIAL CUSTOMER
DIA日本年会では、製薬業界、アカデミア、医学生など多数の参加者がおり、年々参加者は増加しています。この機会を利用して新しい顧客とのパートナーシップの構築に期待することが可能です。

4. GROW YOUR NETWORK
DIAのグローバルに統合されたプラットフォームにより、新しい顧客に巡り会う機会があり、既存の顧客との再会やフェイス・トゥ・フェイスでの有意義なミーティングをする機会が得られます。

5. SHOWCASE YOUR PRODUCTS & SERVICES
展示ブースでは、最新の革新的な製品やサービスのご紹介することにより、顧客からの注目を引き付けることが可能です。

6. COMPANY PROFILE IN CONFERENCE MATERIAL
年会のプログラム冊子に御社のプロファイルを掲載したり、展示のサイトでもご紹介します。またコングレスパッケージへのパンフレットの同封などで製品やサービスの宣伝をする事も可能です。

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5-7 February | Vienna, Austria
Join us at the Crossroads of Healthcare
SAN DIEGO | JUNE 23-27
DIAglobal.org/DIA2019
#DIA2019
15th DIA Japan Annual Meeting 2018

Event #18303 • November 11-13 | Tokyo Big Sight | Ariake
Address: 3-11-1 Ariake, Koto-ku, Tokyo 135-0063
DIA will send participants a confirmation mail within 10 business days after receipt of their registration.

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* If you wish to register as a Young Professional please use Young Professional registration form.

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- DO want to be a DIA member
- DO NOT want to be a DIA member

REGISTRATION FORM: Register online or forward to DIA Japan, Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashihoncho, Chuo-ku, Tokyo 103-0023 Japan
tel +81-3-6214-0574 | fax +81-3-3278-1313

TRAVEL AND HOTEL
To reserve your room at the Washington Hotel Tokyo Bay Ariake or the Sun Route Hotel Ariake being located close to the venue, please contact below:
Washington Hotel Tokyo Bay Ariake
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Telephone: +81-3-5564-0111
URL: http://tokyobay.washington-hotels.jp/
Sun Route Hotel Ariake
Address: 3-6-6 Ariake, Koto-ku, Tokyo 135-0063
Telephone: +81-3-5530-3610

DIA Terms and Conditions
CANCELLATION POLICY: On or before November 4, 2018

Administrative fee that will be withheld from refund amount:
- Member or Nonmember = ¥20,000
- Government/Academia/Nonprofit (Member or Nonmember) = ¥10,000

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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EVENT STREAM AND RECORDING
If you attend a DIA event, we make video and audio recordings of events (both face to face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click here.

PRIVACY STATEMENT
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You agree that your personal data will be transferred to DIA in the US. The personal information provided when you register for an event will be used to contact you with information about upcoming events, programs, products and services of DIA. In addition, your name and organization name will be listed in the Attendee List which will be distributed on site to the participants of an event for which you have registered. By submitting this information with a registration you are regarded as having agreed to this handling of information, but if you do not agree, please contact DIA Japan.

By signing below I confirm that I agree with DIA's Terms and Conditions of participation.

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* Student registration must be made by October 30, 2018. Please send this form with a copy of your student ID to DIA Japan office by fax or e-mail.

**To register for Academia Membership, please send this form to DIA Japan office by fax or e-mail.

Please check the applicable category:
- Academia
- Government
- Industry
- Student

Last Name
First Name
Mr. M.I.
Department
Dr. Mr. Ms.
Job Title
Company
Address (As required for postal delivery to your location)
City
State
Zip/Postal
Country

Phone Number
Fax Number

PAYMENT OPTIONS
Register online at www.DIAGlobal.org or check payment method.

- BANK TRANSFER:
  You will receive an invoice with bank information detail by email after registration completion.
  All local and overseas charges incurred for the bank transfer must be borne by payer.

- CREDIT CARD (VISA, MASTERCARD OR JCB ONLY)
  Exp.(mm/yy)

Card No.

Cardholder Name

Signature

CONTACT INFORMATION
Contact the DIA Japan office in Tokyo for further information.
tel: +81.3.6214.0574 | fax: +81.3.3278.1313
e-mail: Japan@DIAGlobal.org

REGISTRATION FEE

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<th>STUDENT*</th>
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<td>¥5,400</td>
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<td>Student Session only</td>
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* Student registration must be made by October 30, 2018. Please send this form with a copy of your student ID to DIA Japan office by fax or e-mail.

** To register for Academia Membership, please send this form to DIA Japan office by fax or e-mail.

MEMBERSHIP

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8% TAX INCLUDED

- Membership
- 2-Year Membership
- Academia Membership (Academia, Non-profit, Medicals)**

* Student registration must be made by October 30, 2018. Please send this form with a copy of your student ID to DIA Japan office by fax or e-mail.

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BY SIGNING BELOW I CONFIRM THAT I AGREE WITH DIA'S TERMS AND CONDITIONS OF PARTICIPATION.

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Date

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Card No.

Cardholder Name

Signature
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Professionals working in health product development, regulation and related fields, under the age of 35.

Please complete the form below in block capital letters:

Date of Birth (mm/dd/yyyy)  Required
* Please note that we may ask you to show your Identification at a venue.

Please complete the form below:

Last Name
First Name  M/L
Department  Dr.  Mr.  Ms.
Job Title
Company
Address (As required for postal delivery to your location)
City  State  Zip/Postal  Country

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Exp.(mm/yy)
Signature  Date

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Please check payment method.

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Telephone: +81-3-5530-3610
URL: http://www.sunroute.jp/english/hotelinf/paris/paris/index.html

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By signing below I confirm that I agree with DIA’s Terms and Conditions of booking. These are available from the office or online by clicking here (https://www.dia.global/General/Terms-and-Conditions?productIDs=7240118) if you do not agree, please contact DIA Japan.

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会議参加申込書
会議参加申込書

第15回 DIA日本年会
(カンファレンスID #18303)

2018年11月11日(日)-13日(火) 東京ビッグサイト（有明） 東京都江東区有明3丁目11番1号

◆ 参加申込方法
DIAウェブサイト（www.DIAglobal.org）よりお申し込み頂けます。 お申し込みの際に、ご連絡先の電話番号・メールを記入の上、FAXまたはメール添付にてお申し込みください。お申し込み後、10営業日以内にEメールにて申込受理書を送付いたします。

◆ 参加費用（該当する記入欄チェックして下さい）
会員資格が有効である方は、一般会員・非会員とも20,000円、政府/大学関係者については会員・非会員とも10,000円、学生については1,000円を申し受けます。それ以降の参加は全額を申し受けますのでご注意ください。

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非会員の方及び会員資格が有効である方で、ご参加登録をお申し上げになる場合は、希望する年度会費の欄に印をつけてください。

②参加費
所属カテゴリー及び会員資格により異なりますので、該当欄に印をつけてください。

③合計金額（①+②）：
合計 円

※最終確定金額はDIA Japanからお送りする申込書メインにてご確認ください。

◆ お支払方法
ご希望の支払方法にチェックを入れてください。

◇ 銀行振込
お客様のご都合に応じて、振込手数料が発生する場合があります。

◇ クレジットカード
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◆ 注意事項

アルファベット（英語）でご記入ください

Last Name (姓) Dr. Mr. Ms. First name (名) Company

Address City State Zip/Postal Country

Email (必須) Phone Number (必須) Fax Number

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会議参加申込書 若手割引専用
一般社団法人ディー・アイ・エー・ジャパン  
Fax:03-3278-1313
〒103-0023 東京都中央区日本橋本町2-3-11
日本橋ライフサイエンスビルディング6F  
Tel: 03-6214-0574

第15回 DIA日本年会
【カンファレンスID #18303】

2018年11月11日(日)-13日(火) 東京ビッグサイト（有明） 東京都江東区有明3丁目11番1号

◆ 参加申込方法
本申込書に必要事項をご記入の上、FAXまたはメール添付Japan@DIAglobal.orgにてお申し込みください。受理後、10営業日以内にメールにて申込受領書を送付いたします。

◆ 参加費用 (該当する☑にチェックしてください)
会員資格が失効している方および非会員の方は、会員登録(更新)することにより会員価格にてご参加いただけます。会員資格はお支払いいただいてから翌年同月末まで1年間有効です。また、DIA各種機関の入会、DIAウェブサイトの会員専用ページへのアクセス等、種々の特典が得られます。
不明な点がございましたら、ディー・アイ・エー・ジャパンまでお問い合わせください。本会議の参加申し込みは日本年会当日も受け付けています。

①年会費
非会員の方及び会員資格が失効している方で、会員登録をされる場合は希望する年会費の欄に印を入れてください。
* 早期割引価格は、現会員の方または会員登録と同時にお申し込みされる方のみに適用されます。会員資格が失効している方及び非会員の方は、ぜひこの機会にご登録ください。

<table>
<thead>
<tr>
<th>会員資格</th>
<th>通常</th>
<th>若手割引</th>
</tr>
</thead>
<tbody>
<tr>
<td>会員 一般</td>
<td>¥17,500 (税抜)</td>
<td>¥16,900 (税込)</td>
</tr>
<tr>
<td>2-Year Membership</td>
<td>¥31,500 (税抜)</td>
<td>¥34,020 (税込)</td>
</tr>
</tbody>
</table>

②若手割引参加費
所属カテゴリーと会員資格の有無により異なりますので、該当欄に印を入れてください。
若手割引は申込時点で35歳以下の方が対象となります。下欄に生年月日をご記載下さい。

| キャンセル料金（9月11日まで） | ¥101,520 (税込) | ¥60,912 (税込) |
| キャンセル料金（9月12日から10月22日まで） | ¥106,920 (税込) | ¥64,152 (税込) |
| 10月23日以降 | ¥117,720 (税込) | ¥70,632 (税込) |

③合計金額（①+②）: 合計 円
※最終確定金額はDIA Japanからお送りする受領書メールにてご確認ください。

生年月日 (必須)
西暦 年 月 日

なお、当日受付にて身分証を確認させていただく場合がございます。ご了承ください。

◆ お支払方法
ご希望の支払方法にチェックを入れてください。
<table>
<thead>
<tr>
<th>支払方法</th>
</tr>
</thead>
<tbody>
<tr>
<td>□銀行振込 請求書を送付しますので、その案内に従って振込手続きを行ってください。</td>
</tr>
<tr>
<td>□クレジットカード 使用可能クレジットカード (どちらか1つにチェック)</td>
</tr>
</tbody>
</table>

□VISA 
□MasterCard
□JCB

カード有効期限 (mm/yy)
カード番号
カードご名義
ご署名

ご入金の際は、ご依頼人の欄に必ず参加者名および会社を記載してください。同一会社で複数名の参加費を同時に振り込まれる場合は、書面にて参加者名と振込日をディー・アイ・エー・ジャパンまでお知らせください。振込に関する手数料は、振込人負担でお願いいたします。

アルファベット(英語)でご記入ください

Last Name ( 姓 )  
First name ( 名 )
Company

Job Title  
Department

Address  
City  
State  
Zip/Postal  
Country

Email ( 必須 )  
Phone Number ( 必須 )  
Fax Number

参加のキャンセルは、お申し込み受理後、2018年11月4日まで手数料として一般会員・非会員とも20,000円、政府・大学関係者については会員・非会員とも10,000円を申し受けます。それ以降のキャンセルは、無条件で参加費全額を申し受けますのでご注意ください。

参加をキャンセルされる際には、必ず書面にてディー・アイ・エー・ジャパンまでご連絡願います。会場は変更される場合がありますので予めご了承ください。

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DIA主催の会議には、必ず登録者ご本人にご参加いただくようお願いしております。ネームバッジの貸し借りはご遠慮ください。必要に応じて、会場にてスタッフが本人確認をさせていただく場合がございます。

【DIAが取り扱う個人情報について】お申し込みいただいた個人情報はDIAからの会議案内送付等の目的に使用させていただきます。また、参加者名と機関名を含む個人情報はDIAのお知らせメール等の配信に限りますので、個人情報の保護に努めます。