15th DIA Japan Annual Meeting 2018

Promoting Better Collaboration to Drive Global Health and Innovation in an Era of Medical and Scientific Transformation

November 11-13, 2018
Tokyo Big Sight | Ariake
DIAglobal.org/Japan2018

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!

Endorsement by MHLW, PMDA, JPMA, PhRMA, EFPIA and PDA.

Exhibit Opportunities Available

For more information, contact DIA Japan
Tel: +81.3.6214.0574 | Fax: +81.3.3278.1313
Email: Japan@DIAglobal.org

Simultaneous Translation Available

DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.

DIAglobal.org

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 Email: Japan@DIAglobal.org

Drug Information Association
Global Center: Washington, DC | Americas | Europe, Middle East & Africa | China | Japan | India

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)

[ ] *Japanese Language Only*

SUN NOV 11	MAIN VENUE International Conference Room	VENUE 1 Room 605/606	VENUE 2 Room 607	VENUE 3 Room 608	VENUE 4 Room 609
9:30-12:00					
12:00-13:00	ORIENTATION AT EXHBIT HALL (12:00-13:00)				
13:00-13:30	PRE OPENING				
13:30-13:45	WELCOME				
13:45-14:00	OPENING REMARKS MS.TAKUKO SAWADA				
14:00-14:15	2018 DIA JAPAN'S INSPIRE REGIONAL AWARDS CEREMONY				
14:15-15:00	**K1** KEYNOTE ADDRESS 1 PROFESSOR. GUIDO RASI / EUROPEAN MEDICINES AGENCY (EMA)				
15:00-15:30	COFFEE BREAK				
15:30-16:15	**K2** KEYNOTE ADDRESS 2 DR. SATORU MIYANO / THE UNIVERSITY OF TOKYO				
16:15-17:45	**D1 [DIAmond Session 1]** New Challenges for Innovation –ICMRA Innovation Project– **RA, AC**	DIAmond SESSIONS			
17:45-18:00	SHORT BREAK				
18:00-19:30	NETWORKING RECEPTION AT RECEPTION HALL				
MON NOV 12	**MAIN VENUE International Conference Room**	**VENUE 1 Room 605/606**	**VENUE 2 Room 607**	**VENUE 3 Room 608**	**VENUE 4 Room 609**
9:00-10:30 SESSION 1		**V1-S1** The Experience of Global Phase 1 Study (Japan/US) – Oncology Area- **RA, CR, AC**	**V2-S1** Changes Required for Risk Minimization Materials **CP, MA, RA**	**V3-S1** Utilize Know-how and Experiences of Medicine/Device Development Obtained through Investigator Initiated Clinical Trials for Forthcoming Japan Venture Promotion **ALL**	**V4-S1** Overview of Cancer Genome Precision Medicine in Medical Practice – Oncology Panels and CDxs - **RA, AC**
10:30-11:00		COFFEE BREAK (RECEPTION HALL)			
11:00-12:30 SESSION 2		**V1-S2** Recent Trend of Pharmaceutical Regulation in the World **RA, AC**	**V2-S2** Current Activity on Utilization of Patient Registry Data **ALL**	**V3-S2** Technical and Operational Know-How for Conducting Clinical Studies under Limited Manpower **RA, CR, ST, PM, AC, O: Six Sigma**	**V4-S2** How to Read and Future Prospects for PMDA Review Reports **RA, CP, PM, AC, O: Medical Writing**
12:30-14:00		LUNCHEON SEMINAR (Clinipace)	LUNCHEON SEMINAR (Medidata Solutions K.K.)	LUNCHEON SEMINAR (Medrio)	LUNCH BREAK
14:00-15:30 SESSION 3		**V1-S3** Current Situation and Future Perspectives of Risk Based Monitoring **CR, AC**	**V2-S3** The Sakigake Designation System: Challenges and Points for Improvement **RA, PM**	**V3-S3** TransCelerate: Innovation through Collaboration **ALL**	**V4-S3** New Methods to Clinical Evaluation of Anticancer Drugs in the Era of Immune Oncology Therapy **RA, ST, AC, O: Clinical Strategy, Medica lWriting**
15:30-16:00		COFFEE BREAK (RECEPTION HALL)			
16:00-17:30 SESSION 4		**V1-S4** How Can We Define and Manage Quality Goals for Clinical Trials Using a Quality Tolerance Limit (QTL) Approach? **RA, DM, CP, CR, ST, PM, AC, O: MA**	**V2-S4** Further Perspective of Development of Medicines for RD/ Pediatric **RA, CR, AC**	**V3-S4** Future Perspectives of Effective Drug Interaction Evaluation ~ Comparison among Japan, US and EU Regulatory Documents ~ **RA, CP, CR, PM**	**V4-S4** It's Time to Think about Compliance to Deliver Value Added Medical Information – Current and Ideal Situation of Medical Information Provision **AC, MA, Compliance**
17:30-17:45	SHORT BREAK				
17:45-19:00	**E1 Engage and Exchange** 'LET'S CHAT! - SPECIAL CHAT SESSION - AT RECEPTION HALL				
TUE NOV 13	**MAIN VENUE International Conference Room**	**VENUE 1 Room 605/606**	**VENUE 2 Room 607**	**VENUE 3 Room 608**	**VENUE 4 Room 609**
9:00-10:30 SESSION 5		**V1-S5** What Information and Communication do Patients Want in Clinical Trials? How We Can provide them? (Part 1) **ALL, O: Patient, CRC**	**V2-S5** Efforts to Raise Drug Literacy ~How should We Take Care It in Citizens Themselves Learn about Drugs~ (Part 1) **O: ALL(incl. patients)**	**V3-S5** Chance and Challenge to Maximize Product Value - Key Findings from Collaboration between Medicine Development Division and Medical Affairs Division **CR, PM, MA, Pharmacology**	**V4-S5** New Developments on Microbiome Research **AC**
10:30-11:00		COFFEE BREAK (RECEPTION HALL)			
11:00-12:30 SESSION 6		**V1-S6** What Information and Communication Do Patients Want in Clinical Trials? How We Can Provide Them? (Part 2) **ALL, O: Patient, CRC**	**V2-S6** Efforts to Raise Drug Literacy ~How should We Take Care It in Citizens Themselves Learn about Drugs~ (Part 2) **O: ALL(incl. patients)**	**V3-S6** The Near Future of Clinical Operation - ICT Leading Virtual Clinical Trial - **RA, DM, CR, PM, AC**	**V4-S6** Possibility of AI for Future New Drug Evaluation and Review Process **ST, O**
12:30-14:00		LUNCHEON SEMINAR (A2 Healthcare Corporation)	LUNCHEON SEMINAR (Pharma Consulting Group Japan K.K.)	LUNCHEON SEMINAR (ArisGlobal KK)	LUNCH BREAK
14:00-15:30	**D2 [DIAmond Session 2]** Innovative Clinical Trials: A Painting of the Future **ALL**	DIAmond SESSIONS			
15:30-16:00	COFFEE BREAK				
16:00-17:30	**D3 [DIAmond Session 3]** PMDA TOWN HALL	DIAmond SESSIONS			
17:30-17:40	CLOSING REMARKS				

Japanese Language Only

VENUE 5 Room 610	VENUE 6 Room 101	VENUE 7 Room 102	VENUE 8 Room 703	EXHIBITION Reception Hall
		[Student Session] Understanding the Drug Development through Thinking of the Approval Review **RA, AC**		
ORIENTATION AT EXHBIT HALL (12:00-13:00)				
SHORT BREAK				
NETWORKING RECEPTION AT RECEPTION HALL				
VENUE 5 Room 610	VENUE 6 Room 101	VENUE 7 Room 102	VENUE 8 Room 703	EXHIBITION Reception Hall
V5-S1 Call for Abstract Session **RA, DM, CR**	**V6-S1** Challenges and Issues to Product Development for Gene Therapy **RA, AC**	**V7-S1** Implementing Quality Management System(QMS) in Your Trials and Understanding the Purpose and Concept **RA, DM, CR, ST, PM, AC**	**V8-S1** Target Product Profile - Better Way to Build Up R&D Management Plan **RA, PM**	
COFFEE BREAK (RECEPTION HALL)				
V5-S2 Oligonucleotide Therapeutics as Next Generation of New Medicine - Regulatory & Quality Considerations **RA, PM, CMC, AC**	**V6-S2** Think about the Exit Strategy in Drug Discovery Processes of Academia **RA, PM, AC**	**V7-S2** Use and Application of Real World Data/Evidence based on Next Generation Medical Infrastructure Act **CR, ST, AC, HO, MA, Digital**	**V8-S2** The Latest Regulatory Trend and Counter Measures for Data Integrity **RA, CMC**	
LUNCH BREAK	LUNCHEON SEMINAR (PAREXEL International)	LUNCHEON SEMINAR (PPD-SNBL K.K.)	LUNCH BREAK (POSTER SESSION AT RECEPTION HALL)	
V5-S3 New Pharmaceutical Technical Innovation – Continuous Manufacturing and its Driving Forces **RA, PM, CMC, AC**	**V6-S3** Patient Empowerment: Status Update of Patient Participation Support Program **ALL**	**V7-S3** Various Initiatives after Marketing of Regenerative Medical Products **RA, AC, O: Safety**	**V8-S3** Let's Discuss How Our Values Are Related to Life and Work! **ALL**	
COFFEE BREAK (RECEPTION HALL)				
V5-S4 What ICH E17 Would Bring to Global Drug Development **TBC**	**V6-S4** New Drug Development Approaches to Realize Precision Medicine (Registry Study, Platform Trial) **ALL**	**V7-S4** Future of e-Labeling in Japan **RA, CP, AC, O: Medical affairs and Medical information**	**V8-S4** Leader of You! Are you OK for Your Motivation? How About Your Team Member? Let's Get Together and Dialogue How We Maintenance Motivation! **ALL**	
SHORT BREAK				
SP1 Engage and Exchange 'LET'S CHAT! - SPECIAL CHAT SESSION - AT RECEPTION HALL				
VENUE 5 Room 610	VENUE 6 Room 101	VENUE 7 Room 102	VENUE 8 Room 703	EXHIBITION Reception Hall
V5-S5 Responses Against the Global Threat of Antimicrobial Resistance **RA, CP, CR, AC**	**V6-S5** Various Issues Related to HTA -Looking at on a Micro and Macro Scale- **O: MA, RA, CR, AC**	**V7-S5** Pharmacovigilance Activities in Japan, the USA, and Europe – How to Utilize Real World Data- **CP**	**V8-S5** Improving Clinical Operation and Data Quality - eSource Is Transforming Clinical Trials -- **CR, DM, AC**	
COFFEE BREAK (RECEPTION HALL)				
V5-S6 The Latest Trend of Vaccine Policy, Regulatory Regulation in Japan, the United States and Europe **RA, AC**	**V6-S6** Evidence Generation under Japan's New Clinical Trials Act **O: MA, CR, AC**	**V7-S6** Paradigm Shift in Pharmacovigilance Activities - How to Conceptualize Research Questions- **CP**	**V8-S6** Approaches to Implement Revision for New Format of Labeling and Discussion How to Provide Information by Other Materials **RA, CP**	
LUNCH BREAK	LUNCHEON SEMINAR (Oracle Corporation Japan)	LUNCHEON SEMINAR (Syneos)	LUNCH BREAK	

Schedule At-A-Glance

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	Sessions - 1
10:30-11:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30	Sessions - 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	Sessions - 5
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.

DIAmond SESSIONS

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.

Student Session / Orientation

Room 102 **9:30-12:00**

Understanding the Drug Development through Thinking of the Approval Review

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

SESSION CO-CHAIRS

Misato Mimura
Meiji Pharmaceutical University

Takuya Kaneko
Meiji Pharmaceutical University

Kanako Iwasaki
Showa University

Yuri Sugiura
Showa University

It is necessary to get an approval from the Ministry of Health, Labour and Welfare (MHLW) for manufacturing and marketing drugs.

In this session, we are going to gain a better understanding of the drug development by thinking about examination for the approval of drugs.

This session will consist of:

1. Lecture on the important points when thinking about examination for the approval of drugs.

2. Discussion about the approval of one virtual drug by assessing efficacy and safety of the drug.

3. Presentation about the process to the conclusion of approving the drug or not by each group.

It will be a great opportunity for students to learn the drug development and enhance the communication skills.

Since the subject of this discussion is sleep-inducing drugs, reading a guideline (written in Japanese) in the URL (or QR) below is recommended.

https://www.pmda.go.jp/files/000208186.pdf

The Basic Concept for Approval Review

Katsuhiko Ichimaru
Director, Information Disclosure Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA)

Understanding the Drug Development through Thinking of Approval Review

Misa Mori
Integrated Engagement Services Division, IQVIA Servicies Japan K.K.

Commentator

Ryosuke Araki
Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA)

Advisers

Motoki Arakawa, PhD
Lecturer, Laboratory of Pharmaceutical Regulatory Science, School of Pharmacy, Nihon University

Katsuhiko Ichimaru
Director, Information Disclosure Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA)

Reio Nakajo
DIA Japan Student Group OB/OG

Clinical Sciences, Clinical Research, Development Japan, Pfizer Japan Inc.

Ryuta Yoshida
DIA Japan Student Group OB/OG

Medical Device Development Department, EPS Corporation

Reception Hall **12:00-13:00**

Orientation

SESSION CO-CHAIRS

DIA Japan Contents Committee

Welcome to the 15th DIA Japan Annual Meeting!

For the first time attendees, contents committee members present how you can maximize the value of your time at DIA Japan Annual Meeting 2017.

Contents:

- What is DIA
- Site Map
- Program Architecture
- Exhibition
- Navigation for Food and Coffee/Refreshment
- DIA App

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 environmentand

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 SESSIONS

DIAmond Session 1

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 form 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

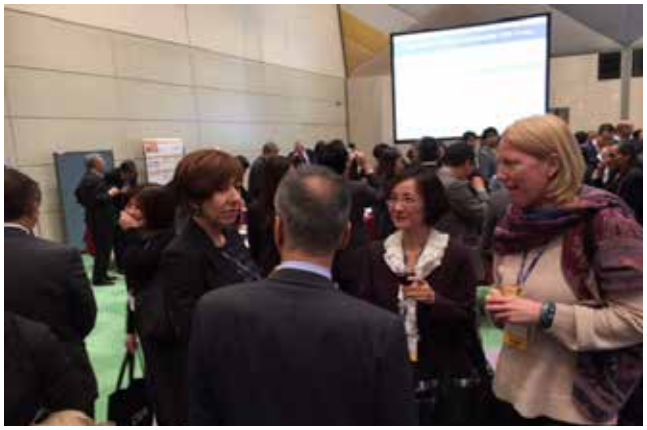
Nikolai Brun, MD, PhD
Director of Division, Medical Evaluation & Biostatics, Danish Medicines Agency

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 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
Toshio 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, MA, RA
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
Director, Department of Pharmacy, Toranomon Hospital

Current Status and Future of Information Providing Materials for Risk Minimization
Asami Ezaki, MSc
Senior Reviewer, Office of Safety II / Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

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

Fumiaki 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 cases 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 1 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
Noriaki Nagao, MPharm, PMP
Clinical Development Department, Pharmaceutical Division, Japan Tobacco Inc.

Quaity 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. / JPMA 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/legislations. 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 Oseania
Alison Cossar
Manager, Product Regulation Branch, Medsafe, Ministry of Health

Panel Discussion
All Session Speakers and
John Graham, PhD, MBA
Director, Office of Research Center for Veterinary Medicine, FDA

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

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

Akihiro 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

Toward 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.

Review Reports - Introduction and Future Perspectives

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

Utilization of Review Reports in Clinical Setting

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.

Current Situation and Future Prospects of PMDA Review Reports

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

In recent years, industry-academia collaboration has progressed in the field of drug / medical device development, and worldwide innovative new drug / treatment method from domestic academia has become a reality. When Academia conducts drug discovery research, it is important that both company and academia collaborate with early stages of development, because it will be manufactured and sold by a company, finally. However, academia researchers are not professionals of development, and there are cases where it is difficult to negotiate before cooperation. In this session, we will clarify the "gap between what each other wishes and what is required", and also based on actual examples overcoming this, we will discuss the ideal way of cooperation approaches of industry, government, academia from their respective perspectives.

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
Shinichi 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

Generation Medical Infrastructure Act.

In addition, as cases from pharmaceutical company, some presenters will share practices of data application using EHR (electric 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 Clincal 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.

Data Integrity:Regulatory expectation and findings on GMP Inspection

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 Readinessand Outcome of FDA Inspection

Atsuto Kobe

Pharmaceutical Technology Quality Dept, Chugai Pharmaceutical Co., Ltd.

Panel Discussion

All Session Speakers

LUNCH BREAK 12:30-14:00

POSTER SESSION 13:30-14:00

POSTER SESSION Reception Hall 13:30-14:00

Nine researches or topics out of large number of applications from Japan and overseas from various themes were selected for poster session through a rigorous selection process. Current hot topics will be presented and discussed.

[PO-01] Analysis of Adverse Drug Reactions in Taiwan

Yu-Hong Lin, MS

Pharmacist, Kaohsiung Veterans General Hospital Tainan Branch

Objectives:

The severity of Adverse Drug Reactions (ADRs) may vary greatly from person to person. The most severe situation can be a life-threatening event. In order to make healthcare professionals become aware of the importance of ADR, we do data analysis from our hospital.

Method:

It was a retrospective study in 2016. Assessment of ADRs contains age, gender, occurring sources, sources of ADRs reporting, Classification of ADRs and so on. In addition, we do a sub-analysis regarding Anatomical Therapeutic Chemical (ATC) classification of suspected drugs and Adverse Effects.

Results:

The investigation included eighty-nine ADRs reported. The average age was 67.6 year. 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

Tomoko Kondo, PhD, RPh

Assistant Professor, Yamaguchi University Hospital

Objectives:

Package inserts are printed leaflets accompanying marketed drugs. Recently, it is difficult to understand which the package insert is the latest due to 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 the respondents' 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

Kyotaka Matsumoto, MPharm
DIA Clinical Operation & Monitoring Community (Novartis Pharma K.K.)

Learning Objectives:

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 documents should be maintained by site.

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 are 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 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 share various behaviors, and also it helped us to reflect on our behaviors. Therefore, we consider that continuous Community activities with 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 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.

[PO-04] Categorization of Medical Information Databases; Are Real World Data Sources Treasure Islands?

Yumi Wakabayashi, MBA
Associate Director, Lecturer, Integrated Center for Advanced Medical Technologies, Kochi Medical School, Kochi University

Learning Objectives:

- To learn what medical information databases and real world data sources are available for database studies, non-interventional studies, or epidemiological researches
- To learn how to leverage medical information data and real world data and to generate evidences by considering characteristics of data sources

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 of the world as well; FDA Sentinel in the U. S., EMA Encepp 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 than conducting an interventional study. 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 to what research.

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 have crucial data such as biomarker values and information about preclinical subjects.

[PO-05] Insight into Challenges and Complexities in Safety Reporting Requirements: US, EU and Asia Perspective

Sanjeev Miglani, MD
Founder and Director at AWINSA Life Sciences, AWINSA Life Sciences

Learning Objectives:

1. Know the important differences in regulations in clinical trials and post marketing 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 complexeties

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 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 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 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 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 safety reporting requirements in clinical trials and post marketed products 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

Dinah Duarte, PharmD, MSc
Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED

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 body of evidence, however, that there is a substantial difficulty in choosing/accessing an optimal model or choosing measurements which would be truly informative of the product's efficacy. We intend to present a possible application 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, AWINSA Life Sciences

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.

SESSION 3 14:00-15:30

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 still 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 the Clinical Trial Process

Nagako Umino
Project Management Department, Technical Solution Section, I'rom Co., Ltd.

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

Hideaki Ueda
Clinical Operations, PAREXEL International

Continuous Improvement of RBM Including PMDA Inspection Lesson Learnt

Misato Kuwagaki, MS
Clinical Development Organization – Clinical Information & Process Automation, Eli Lilly Japan K.K.

We Can't Look Back, Only Ahead to RBM

Yumi Sugiura, MRCP
Global Clinical Operations, Global Data Management and Centralized Monitoring, Bristol-Myers Squibb

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 Shibatsuji, 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—cures?

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

Senior Vice President and Head of Global Portfolio Management, Shionogi Inc.

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

Key Initiative Update: Pharmacovigilance
Ken Kubota, PhD
Vice President for Pharmacovigilance Operations, Astellas Pharma Inc.

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): CR, RA, ST, AC, O: Clinical Strategy, Medica lWriting
Level: Beginner, Intermediate

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

Immnuno-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
Toshio 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

Restricted Mean Survival Time as Summary Measure of Time-to-Event Outcome
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
Kohei 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
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 in 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 oversees. 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

Patient and Public Involvement in AMED: for the Future of Medical Research and Development
Keiko Katsui, PhD
Deputy Manager, Department of Research Infrastructure, Japan Agency for Medical Research and Development (AMED)

Panel Discussion
All Session Speakers

V7-S3 Room 102 14:00-15:30

Various Initiatives after Marketing of Regenerative Medical Products

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

SESSION CHAIR

Yoji Sato, PhD
Head, Division of Cell-Based Therapeutic Products, National Institute of Health Sciences

Currently 4 products are approved for regenerative medicine and other products, moreover, efforts are underway for various research and business development.

In this session, we need to understand the outline of the National Consortium established by the Society of Regenerative Medicine, explain the status of support at the academic society and the data registration system and the patient registration system.

We discuss the future issues and expectations by asking their opinions from each point of view on issues and expected outcome from databases and ongoing operations.

Safety Measures of Regenerative Medical Products in PMS
Kazuhisa Koike, PhD
Principal Inspector, Medical Device Safety Division, Office of Safety I, Pharmaceuticals and Medical Devices Agency (PMDA)

Collaboration with Academia for Patient Registration System from Industry Standpoint
Mariko Okada
Manager, PV, JCR Pharmaceuticals Co., Ltd.

Outline of Regenerative Medical National Consortium
Kiyoshi Okada, MD, PhD
Vice Director, Medical Center for Translational Research, Department of Medical Innovation, Osaka University Hospital

Panel Discussion
All Session Speakers

V8-S3 Room 703 14:00-15:30

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

Minori 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

SESSION 4 16:00-17:30

V1-S4 Room 605/606 16:00-17:30

How Can We Define and Manage Quality Goals for Clinical Trials Using a Quality Tolerance Limit (QTL) Approach?

Related Interest Area(s): RA, DM, CP, CR, ST, PM, AC O: MA
Level: Intermediate, Advanced

SESSION CHAIR

Satoshi Saeki, MSc
Associate Director, Business Process Improvement & Innovation, QuILS, Astellas Pharma Global Development, Inc.

In the 1920s, Walter Shewhart pioneered statistical approaches for setting control/tolerance limits in manufacturing, and his protégé W. Edwards Deming built on this work to establish the renowned Plan-Do-Study-Act "Deming Wheel" as a comprehensive quality management framework. These concepts in quality management are about to be applied in clinical trials as Quality Tolerance Limits (QTLs). ICH E6 (R2) clearly defines QTLs as a measure for identifying systematic issues that can impact subject safety or reliability of trial results, thus QTLs can be considered quality goals for these clinical studies. Last year provided conceptual discussions around QTLs. This year a more practical discussion will be presented that focuses on actual approaches in real-world situations, e.g., identification of QTL parameters, setting tolerance limits, and QTL monitoring using a mock protocol synopsis. Existing tools from risk-based monitoring will be highlighted for their use in developing and managing QTLs.

Risk-based Quality Management in Clinical Trials Using Quality Tolerance Limits (QTLs)
Christopher Hanna, PhD, MBB, PMP
Principal, Kattner-Thalmann Partners

V2-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-marketing 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 Remudy
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

V3-S4 Room 608 16:00-17:30

Future Perspectives of Effective Drug Interaction Evaluation ~ Comparison Among Japan, US and EU Regulatory Documents ~

Related Interest Area(s): RA, CP, CR, PM

Level: Beginner

SESSION CHAIR

Naomi Nagai, PhD
Professor, Faculty of Pharmacy, Musashino University

In July 2018, 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 the 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, Lecturer, 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 activity surveillance monitor system began and entered the second year. It seems that the time has come when we must consider our actions and ethical standards together with key stakeholders instead of considering the compliance by a single organization.

In this session, we are going to discuss the current or future direction in Japan following global trend regarding medical information provision with compliance experts from each pharmaceutical association (JPMA, PhRMA, EFPIA), academia and regulatory authority.

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
Professor, Faculty of Pharmaceutical Sciences, Teikyo Heisei University

Guidelines on Pharmaceutical Product Communications
Takamasa Horio, JD
Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

Panel Discussion
All Session Speakers and
Kunio Kawajiri
Healthcare Compliance Group, Ethics & Compliance Department, Astellas Pharma Inc.

Kana Matsumura, Attorney at law
Legal Counsel, Legal, Sanofi K.K.

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 MRCTs 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 MRCTs 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 MRCTs, 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(ts): 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

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

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

Motivation!

Related Interest Area(s): ALL
Level: Beginner
Language: Japanese Language Only

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

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DAY 2 | MONDAY | NOVEMBER 12

ENGAGE AND EXCHANGE: SPECIAL CHAT SESSION

LET'S CHAT! "WHAT'S THE DIA WORLD 2018"

RECEPTION HALL **17:45-19:00**

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>

#	Communities	Topic	Facilitators	Abstracts
1	Clinical Operations & Monitoring (COM) Clinical Data Management (CDM)	Let's Discuss Ideas for Getting Out of "Error Free Seeking Mind"!	Clinical Operations & Monitoring (COM) Yukihiro Matsuda, MSc Eli Lilly Japan K.K Clinical Data Management (CDM) Misato Kuwagaki, MS Eli Lilly Japan K.K.	RBA 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".
2	Clinical Strategy (CS) Project Management (PM)	Let's Discuss Your Career Plan (Even a Chance Meeting is due to the Karma in Previous Life.)	Clinical Strategy (CS) Minori Niso I.L. Japan Co.,Ltd Project Management (PM) Noriko Fujiwara, MS. RN. OCNS. CCRP The University of Tokyo	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.
3	Regulatory Affairs (RA) Project Management (PM)	What is an Efficient Role Sharing in Developmental Team?	Regulatory Affairs (RA) Toshinori Higashi CTD inc. Project Management (PM) Noriaki Nagao, MPharm, PMP Japan Tobacco Inc.	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.
4	Regulatory Affairs (RA) Pharmacovigilance & Labeling (PV)	ICH-E17 - Let's Discuss Changes in Clinical Development Strategy -	Regulatory Affairs (RA) Kazumi Sunamura Pfizer Japan Inc. Pharmacovigilance & Labeling (PV) Rei Maeda Eli Lilly Japan K.K.	Do you understand E17 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 E17 in our chatting session.
5	Six Sigma (SS) Clinical Data Management (CDM)	How We Implement the Quality Tools for ICH E6 R2 - Clinical QMS	Six Sigma (SS) Hirotaka Inoue, PhD, MBA GlaxoSmithKline K.K. Clinical Data Management (CDM) Yukikazu Hayashi A2 Healthcare Corporation	Upon ICH-E6 (R2) agreement, JPMA has issued "Practical approaches to implement QMS in clinical trials -use case of quality management tool by using case studies-". Using quality management tool correctly is important for QMS implementation. So, let's deepen our understating of the tools and the statistical background of the tools together!
6	Statistics Clinical Strategy (CS)	Let's Talk about Measures of Treatment Effect on Survival Analysis Including Novel Ones that Become a Hot Topic Recently	Statistics Hiroyuki Ugai Nippon Boehringer Ingelheim Clinical Strategy (CS) Kazuhiro Kanmuri, PhD CTD Inc.	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.
7	Medical Communications (MC) Patient Engagement (PEC)	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-	Medical Communication (MC) Junichi Nishino Novartis Pharma K.K. Patient Engagement (PEC) Yoshikata Furuya MSD K.K.	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.
8	Patient Engagement (PEC) Clinical Operations & Monitoring (COM)	If My Family or I Join Clinical Trial...?	Patient Engagement (PEC) Keiko Ebihara, PhD Amicus Therapeutics K.K. Clinical Operations & Monitoring (COM) Norio Shimazaki Bristol-Myers Squibb K.K.	"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 !
9	Medical Communications (MC) Pharmacovigilance & Labeling (PV)	Is the Material Used for Patients? Is That True? - Current Status and Future of Drug Information Communication for Proper Use -	Medical Communication (MC) Keiko Tsumori MSD K.K. Pharmacovigilance & Labeling (PV) Kazuhiko Ishida, MSc, RPh Astellas Pharma Inc.	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.
10	Statistics Six Sigma (SS)	Scope of Work and Career Pass to Data Scientist from Statistician - Drug Discovery to Post-marketing -	Statistics Yoichi M. Ito, PhD The Institute of Statistical Mathematics Six Sigma (SS) Goshi Ozawa, MS, Lean Six Sigma Certified BB Real Discovery Outdoors Co.,Ltd.	Pharmaceutical company has lots of talented person who can be a data scientist, but they don't realize to maximize their value. In addition to the current statistical work, knowledge of statisticians is required for company management. Let's chat about the new scope of work and career path of the statistician.

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 Fujiwara, 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 stared 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

Nobuko 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 -1 - 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

Tomiko Tawaragi
RAD-AR, 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 - S6, 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 toPatients 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 ofView -

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.

Chance and Challenge to Maximize Product Value - Key Findings from Collaboration Between Medicine Development Division and Medical Affairs Division -

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

Collaboration between Medical Information and Clinical Pharmacology

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

Panel Discussion

All Session Speakers and

Kosuke Kozaiwa, 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.

Can we develop antimicrobials for AMR infections? We can do it!
Satoshi Iwata, MD, PhD
Director, Department of Infectious Diseases, National Cancer Center Hospital / Visiting Professor, Keio University School of Medicine

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, Kyoto 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.

Real World Data Development for the Drug Evaluation
Koji Kawakami, MD, PhD
Professor and Chairman, Department of Pharmacoepidemiology, Graduate School of Medicine and Public Health, Kyoto 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 Portfolio Board, European Medicines Agency (EMA)

Effective Use of RWD in PMDA for Pharmacovigilance
Takashi Ando
Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

V8-S5 Room 703 9:00-10:30

Improving Clinical Operation and Data Quality - eSource Is Transforming Clinical Trials -

Related Interest Area(s): CR, DM, AC
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR

Takuhiro Yamaguchi, PhD
Professor, Biostatics, Tohoku University Graduate School of Medicine

ICT infrastructure is essential for the future clinical research and medical technology to provide scientific evidence. Project for Accelerating Medical Research through Cross-regional ICT Utilization is underway in Japan Agency for Medical Research and Development. The US FDA is driving the use of eSource. However, the adoption of eSource in clinical research has been delayed due to the difficulty of data manipulation.

Data collection from eSource will be a more efficient way that will benefit patients, medical institutions and sponsors. In this session we will discuss challenges related to the use of eSource. We will also discuss how we can overcome them among industry, government and academia together.

Direct Capture of Electronic Medical Record Data for Clinical Research
Yasushi Matsumura, Professor, MD, PhD
Professor, Division of Medicine, Graduate School of Medicine, Osaka University

Learning from EHR Data Utilization for Clinical Research (tentative)
Yoshihiro Aoyagi, MS
Section Head, Information Technology Management Section, Clinical Research Support Office, Research Management Division, National Cancer Center Hospital East

Challenges of Using Mobile in Clinical Research and Virtual Trial (tentative)
Tenpei Miyaji, MSc
Project Assistant Professor, Department of Clinical Trial Data Management, Graduate School of Medicine, The University of Tokyo

TransCelerate eSource Initiatives (Tentative)
Mika Ogasawara
Manager, Japan Clinical Informatics & Innovation, Biometrics and Data Management, Pfizer Japan Inc.

COFFEE BREAK 10:30-11:00

SESSION 6 11:00-12:30

V1-S6 Room 605/606 11:00-12:30

What Information and Communication Do Patients Want in Clinical Trials? How We Can Provide Them? (Part 2)

Related Interest Area(s): ALL
Level: Intermediate

SESSION CO-CHAIRS

Yasuhiro Fujiwara, 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 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.

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

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

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

Tomiko Tawaragi, MD, MPH, PhD
RAD-AR, 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, 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.

Future Drug Information for Patients-
Mayumi Mochizuki, PhD
Professor, Evaluation & Analysis of Drug Information, Faculty of Pharmacy, Keio University

Panel Discussion
All Speakers of V2-S5 and V2-S6

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
Global Program Lead, Digital Development Novel Settings / Decentralized Clinical Trials Lead, Digital Development, Portfolio, Strategy & Innovation (PS&I), Novartis Pharma AG

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.

V4-S6 Room 609 11:00-12:30

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 Obanayama
Digital Transformation Product Leader & PMO, Digital Transformation, Commercial Operations Management, Bayer Yakuhin, Ltd.

Creation of Package Inserts Post-marketing Materials Using XML
Megumi Sato
Japan Product Labeling Group, MSD K.K.

Panel Discussion
All Session Speakers

V5-S6 Room 610 11:00-12:30

The Latest Trend of Vaccine Policy, Regulatory Regulation in Japan, the United States and Europe

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

SESSION CHAIR

Nobuhiko Okabe, MD
Director General, Kawasaki City Institute for Public Health

Although vaccination has largely contributed to the improvement and promotion of public health, prevention of infection by vaccination will become increasingly important for the Tokyo Olympic Games to be held in 2020.

In this session, we introduce the vaccination system and examination in Japan, the United States and Europe, and discuss how the differences in the system influence vaccination promotion from various viewpoints.

We will also discuss experiences on benefits gained by vaccination and expectations for future vaccine administration.

Immunization System in Japan - Recent Progress and Challenges -
Akihiko Saitoh, MD
Professor, School of Medicine Department of Pediatrics, Niigata University

Regulatory Trends and Current Challenges for Vaccine Development in the USA
Ercem Atillasoy, MD
Vice President, Global Regulatory Affairs & Clinical Safety, Merck & Co., Inc.

Immunisation in Europe: an overview
Shazia Sheikh, MSc
Director, Communications & Government Affairs, Emerging Markets and Intercontinental, GSK Vaccines

Panel Discussion
All Session Speakers and
Andrew Otoo, PharmD, MBA
VP, Japan Vaccines Country Lead, Pfizer Japan Inc.

V6-S6 Room 101 11:00-12:30

Evidence Generation under Japan's New Clinical Trials Act

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

SESSION CHAIR

Shinzo Hiroi, PhD, MPH, RPh, PMP
Head of Global Medical Affairs, Shionogi & Co., Ltd.

It would become more complicated to conduct interventional studies due to new clinical trials act, effective in April 2018 in Japan.

The importance of observational studies has been focused to generate the medical evidence originated from Japan.

In this session, the advantages and limitations of observational studies will be discussed, compared with those of interventional studies.

Impact of Clinical Trial 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

Case Studies of Real World Evidence in HEOR of Pharmaceutical Industry
Akihito Uda, MPH
Manager, Medical Research, Capabilities and Excellence HEOR Program, Japan Medical Affairs, Takeda Pharmaceutical Company Limited

Panel Discussion
All Session Speakers

V7-S6 Room 102 11:00-12:30

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

Related Interest Area(s): CP

Level: Beginner

SESSION CHAIR

Rei Maeda
Senior Regulatory Scientist, Global Patient Safety Japan, Quality and Patient Safety, Eli Lilly Japan K.K.

"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
Takuhiro 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

V8-S6 **Room 703** **11:00-12:30**

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

Related Interest Area(s): RA, CP
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Takashi Ohira, MSc
Associate Director, Safety Management, Global Patient Safety Evaluation Japan, Takeda Development Center Japan, Takeda Pharmaceutical Company Limited

In April 2019 official guidelines for new format of labeling will be enforced. Prior to that, PMDA consultation with some drugs to align with the new guidelines was started from July this year (first wave), and feedback from PMDA has been notified each company. Based on the disclosure of labeling of some model drugs, we introduce examples of them and discuss case studies and initiatives concerning tasks until actual implementation of revision of the labeling of the new guideline. Also, we would like to discuss contrivances in thinking about effective information provision with other materials such as interview form based on new format of labeling, and viewpoints from healthcare providers as readers of new format of labeling and points to note when providing information.

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 the Pharmaceutical Industry Perspective
Tatsumi Inamura
Group Manager, Prescribing Information Group, RA Functions Department, Regulatory Affairs Japan, Regulatory Office Japan, Novartis Pharma K.K.

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
Shinya Takemoto, Msc
Group Manager, Safety Information Strategy Group, Risk Communication Department, Drag Safety Division, Chugai Pharmaceutical Co., Ltd.

Panel Discussion
All Session Speakers

LUNCH BREAK **12:30-14:00**

DIAmond Sessions / Closing Remarks

DIAmond Session 2

International Conference Room **14:00-15:30**

DIAmond SESSIONS

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

DIAmond Session 3

International Conference Room **16:00-17:30**

DIAmond SESSIONS

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 / Direcor, CTD Inc.

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第15回DIA日本年会

未曾有の変革の時代、イノベーション創出とグローバルヘルスへの貢献を、どのような連携の下で進めていくか

2018年11月11日（日）-13日（火）
東京ビッグサイト | 有明
DIAglobal.org/Japan2018

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なすべきことは何か。また、世界のイノベーション創出をどのような連携の下に進めていくべきか。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かたちは様々であり、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画期的な治療への挑戦や、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 DIAmond Sessionが開催されます。また、3日目の午後のDIAmond 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だきます。その他、日本年会では恒例となったPMDAタウンホールやチャッティングセッション、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／
国立研究開発法人 日本医療研究開発機構／日本製薬工業協会／
米国研究製薬工業協会／欧州製薬団体連合会／
日本PDA製薬学会／国際製薬技術協会（ISPE）

日本語・英語間の同時通訳あり

展示申し込み受付中
詳細については、ディー・アイ・エー ジャパンまでお問い合わせください。
〒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　Fax: 03-3278-1313　E-mail: Japan@DIAglobal.org

DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.

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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　Email: Japan@DIAglobal.org

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関連領域: CR=臨床オペレーション/臨床戦略、RA=薬事、ST=統計、DM=データマネジメント、CP=安全性及びファーマコビジランス、PM=プロジェクトマネジメント、CMC=品質管理、AC=アカデミア

日本語のみ

11月11日（日）	メイン会場 国際会議場	第1会場 605/606会議室	第2会場 607会議室	第3会場 608会議室	第4会場 609会議室
9:30-12:00					
12:00-13:00	オリエンテーション@展示会場 (12:00-13:00)				
13:00-13:30	プレオープニング				
13:30-13:45	開会の挨拶				
13:45-14:00	大会長挨拶				
14:00-14:15	2018 DIA JAPAN'S INSPIRE REGIONAL AWARDS授賞式				
14:15-15:00	**K1** 基調講演1 (EMA / Professor Guido Rasi)				
15:00-15:30	コーヒーブレイク				
15:30-16:15	**K2** 基調講演2 (東京大学医科学研究所 / 宮野悟先生)				
16:15-17:45	**D1 [DIAmond Session 1]** Innovation への新たなチャレンジ ~ICMRA Innovation Project~	DIAmond SESSIONS			
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)				

11月12日（月）	メイン会場 国際会議場	第1会場 605/606会議室	第2会場 607会議室	第3会場 608会議室	第4会場 609会議室
9:00-10:30 セッション1		**V1-S1** Global Phase 1の経験(米国の施設の実態とmanagement方法)-癌の開発を中心に- RA, CR, AC	**V2-S1** 医薬品リスク最小化資材に求められる変革 CP, MA, RA	**V3-S1** 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 ALL	**V4-S1** 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～ RA, AC
10:30-11:00		コーヒーブレイク (レセプションホール)			
11:00-12:30 セッション2		**V1-S2** 各国薬事規制当局の最新動向 RA, AC	**V2-S2** 疾患レジストリデータ利活用の最新の動向 ALL	**V3-S2** 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--- RA, CR, ST, PM, AC, Six Sigma	**V4-S2** 審査報告書の読み方と今後のあり方 RA, CP, PM, AC, Medical Writing
12:30-14:00		ランチョンセミナー (Clinipace)	ランチョンセミナー (Medidata Solutions K.K.)	ランチョンセミナー (PPD-SNBL K.K.)	ランチブレイク
14:00-15:30 セッション3		**V1-S3** Risk Based Monitoringの現状と展望 CR, AC	**V2-S3** 承認事例からみた先駆け審査指定制度の課題・改善点 RA, PM	**V3-S3** TransCelerate: コラボレーションでイノベーションに挑戦する ALL	**V4-S3** 免疫療法時代の抗がん剤の臨床評価の新たな方法 RA, ST, AC, Clinical Strategy, Medical Writing
15:30-16:00		コーヒーブレイク			
16:00-17:30 セッション4		**V1-S4** How Can We Define and Manage Quality Goals for Clinical Trials Using a Quality Tolerance Limit (QTL) Approach? RA, DM, CP, ST, PM, AC, MA	**V2-S4** 希少疾病用医薬品/小児用医薬品開発の今後の展望 RA, CR, AC	**V3-S4** 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～ RA, CP, CR, PM	**V4-S4** 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あるべき姿- AC, MA, Compliance
17:30-17:45		ショートブレイク			
17:45-19:00		**E1** Engage and Exchange 'Let's Chat! - Special Chat Session -' (レセプションホール)			

11月13日（火）	メイン会場 国際会議場	第1会場 605/606会議室	第2会場 607会議室	第3会場 608会議室	第4会場 609会議室
9:00-10:30 セッション5		**V1-S5** 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) ALL, Patient, CRC	**V2-S5** 医薬品リテラシー向上への取り組み ～国民自らが医薬品について知る時代に我々はどのように対応すべきか～ Part1 ALL, incl. patients	**V3-S5** 製品価値最大化に向けてのチャンスと挑戦 -開発部門とメディカルアフェアーズ部門の連携を通じて- CR, PM, MA, Pharmacology	**V4-S5** マイクロバイオームの新展開 AC
10:30-11:00		コーヒーブレイク (レセプションホール)			
11:00-12:30 セッション6		**V1-S6** 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2部) ALL, Patient, CRC	**V2-S6** 医薬品リテラシー向上への取り組み ～国民自らが医薬品について知る時代に我々はどのように対応すべきか～ Part2 ALL, incl. patients	**V3-S6** クリニカルオペレーションの近未来 ―ICTが導くVirtual Clinical Trial― RA, DM, CR, PM, AC	**V4-S6** AIの可能性と将来の承認審査 ST, O
12:30-14:00		ランチョンセミナー (A2 Healthcare Corporation)	ランチョンセミナー (Pharma Consulting Group Japan K.K.)	ランチョンセミナー (ArisGlobal KK)	ランチブレイク
14:00-15:30	**D2 [DIAmond Session 2]** Innovative Clinical Trials: 臨床試験の未来予想図	DIAmond SESSIONS			
15:30-16:00	コーヒーブレイク				
16:00-17:30	**D3 [DIAmond Session 3]** PMDAタウンホール	DIAmond SESSIONS			
17:30-17:40	閉会の挨拶				

関連領域: CR=臨床オペレーション/臨床戦略、RA=薬事、ST=統計、DM=データマネジメント、CP=安全性及びファーマコビジランス、PM=プロジェクトマネジメント、CMC=品質管理、AC=アカデミア

日本語のみ

第5会場 610会議室	第6会場 101会議室	第7会場 102会議室	第8会場 703会議室	展示会場 レセプションホール
		ST [Student Session] 承認審査を通じた医薬品開発の理解		
オリエンテーション@展示会場 (12:00-13:00)				
ショートブレイク				
情報交換会（レセプションホール）				
第5会場 610会議室	**第6会場 101会議室**	**第7会場 102会議室**	**第8会場 703会議室**	**展示会場 レセプションホール**
V5-S1 公募演題セッション RA, DM, CR	**V6-S1** 遺伝子治療用製品開発への挑戦と課題 RA, AC	**V7-S1** 臨床試験におけるQuality Management System ～現場レベルでの実装～ RA, DM, CR, ST, PM, AC	**V8-S1** Target Product Profile戦略マネジメント -より良い研究開発計画を目指して RA, PM	
コーヒーブレイク （レセプションホール）				
V5-S2 次世代の新薬 核酸医薬品 - どうする!?その規制と品質保証 RA, PM, CMC, AC	**V6-S2** アカデミア創薬の出口戦略を考える RA, PM, AC	**V7-S2** 次世代医療基盤法を踏まえたリアルワールドデータ/エビデンスの利活用 CR, ST, AC, HO, MA, Digital	**V8-S2** データの完全性確保に向けた最近の動向 RA, CMC	
ランチブレイク	**ランチョンセミナー (PAREXEL International)**	**ランチョンセミナー (Medrio)**	**ランチブレイク（ポスターセッション（レセプションホール））**	
V5-S3 製薬業界の技術革新 - 連続生産を推進するための環境及びその動向 RA, PM, CMC, AC	**V6-S3** 患者参画推進：教育プログラムの最新動向 ALL	**V7-S3** 再生医療等製品の市販後における様々な取り組み RA, AC, Safety	**V8-S3** 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？ ALL	
コーヒーブレイク				
V5-S4 ICH E17がグローバル開発にもたらすもの TBC	**V6-S4** Precision Medicineの実現に向けた新たな医薬品開発アプローチ ALL	**V7-S4** 日本におけるe-Labelingの将来 RA, CP, AC, Medical affairs and Medical information	**V8-S4** 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？ ALL	
ショートブレイク				
SP1 Engage and Exchange 'Let's Chat! - Special Chat Session -'（レセプションホール）				
第5会場 610会議室	**第6会場 101会議室**	**第7会場 102会議室**	**第8会場 703会議室**	**展示会場 レセプションホール**
V5-S5 薬剤耐性菌感染症（AMR）の世界的脅威への対応 RA, CP, CR, AC	**V6-S5** HTAを巡る諸問題 ーミクロとマクロの視点からー MA, RA, CR, AC	**V7-S5** 日米欧の医薬品安全性監視活動 ーリアルワールドデータをどう活用していくかー CP	**V8-S5** 臨床試験の効率化とデータの信頼性向上 ーeSourceはClinical Trialをこう変えるー CR, DM, AC	
コーヒーブレイク（レセプションホール）				
V5-S6 日米欧におけるワクチン政策、薬事規制の最新動向 RA, AC	**V6-S6** 臨床研究法を見据えたエビデンスジェネレーション MA, CR, AC	**V7-S6** 医薬品安全性監視活動のパラダイムシフトーリサーチ・クエスチョンをいかに考えるかー CP	**V8-S6** 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、その他の資材による情報提供のあり方 RA, CP	
ランチブレイク	**ランチョンセミナー (Oracle Corporation Japan)**	**ランチョンセミナー (Syneos)**	**ランチブレイク（レセプションホール）**	

15th DIA Japan Annual Meeting 2018

Schedule At-A-Glance

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
9:30-	展示受付
11:45-	参加者受付オープン
11:45-19:30	展示会場（レセプションホール）オープン
12:00-13:00	オリエンテーション@展示会場
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	DIAmond 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	DIAmond 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	DIAmond Session 3 「PMDAタウンホール」
17:30-17:40	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閲覧できます。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、全ての講演資料が閲覧できるのではなく、指定の期日までに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、これに限りません。

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。

発表者および講演タイトルは予告なく変更されることがあります。

書面における合意なく、DIAイベントの情報を録音することは、いかなる形態であっても禁止されています。

DIAmond SESSIONS

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.

詳細につきましては6、25ページをご覧ください。

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　9:30–12:00

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、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。

https://www.pmda.go.jp/files/000208186.pdf

承認審査の考え方
独立行政法人 医薬品医療機器総合機構
一丸　勝彦

承認審査を通じた医薬品開発の理解
IQVIAサービシーズジャパン株式会社
森　美彩

講評
独立行政法人 医薬品医療機器総合機構
荒木　亮祐

アドバイザー
日本大学 薬学部
荒川　基記

独立行政法人 医薬品医療機器総合機構
一丸　勝彦

DIA Japan Student Group OB/OG /ファイザー株式会社
中條　麗櫻

DIA Japan Student Group OB/OG /イーピーエス株式会社
吉田　龍太

レセプションホール　12:00–13:00

オリエンテーション

発表者

DIA Japan Contents Committee

はじめて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

6

1日目 | 11月11日(日)

開会の挨拶および基調講演 / DIAmond Session 1

プレオープニング 13:00-13:30

開会の挨拶
国際会議場 13:30-13:45

DIA Japan
植村　昭夫

DIA
Barbara Lopez Kunz

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

大会長挨拶
国際会議場
13:45-14:00

第15回DIA日本年会大会長 / 塩野義製薬株式会社
澤田　拓子

2018 DIA Japan's Inspire Awards授賞式
国際会議場 14:00-14:15

プレゼンター

DIA Chair/ Bayer AG
Joseph Scheeren

アワード受賞者：

Outstanding Contribution to Health Award
TBA

Excellence in Service Award
TBA

Leader of Tomorrow Award
TBA

基調講演 1
国際会議場 14:15-15:00

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に向けての展望を予測するプロセスを構築して、薬事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、ベネフィットリスクバランスとアクセスを、患者さんのライフスパンにおいて確保するための信頼できるエビデンスを、迅速かつ効率良く手に入れることである。これには、患者さんのみならず、医療技術評価（HTA）組織やPayer等の関係者の積極的な関与が必要である。また、EMAはゲートキーパーとして、新規技術の提供を受ける患者さんを守るため、薬事行政へのチャレンジに対応する体制を整えている。ICMRAに参加することにより、ホライゾンスキャニングのBest Practiceを我々のパートナーである各国の薬事当局と共有し、未曾有の変革の時代に適した規制の枠組みを準備することで、世界中の患者さんのために貢献することが可能となる。

Innovation and Regulatory Science
European Medicines Agency (EMA)
Guido Rasi

コーヒーブレイク 15:00-15:30

基調講演 2
国際会議場 15:30-16:15

座長

グラクソ・スミスクライン株式会社
高橋　希人

ゲノムシーケンス技術の革新は、エピゲノム・RNAデータを含め、ペタバイト単位のデータを生み出している。さらには画像や生理データなどを含む高精度臨床データも大規模に蓄積されている。これらの大規模データと個々人の病態の分子メカニズムの統合的理解には、人智・手技をはるかに超えた複雑さの解明が必要である。

東京大学医科学研究所は、スパコンや人工知能の活用により、ゲノムから環境・生体時空間的に全身を捉えることで、統合計算生命科学の研究成果を個別化・予防医療へ返す支援基盤構築を目指している。

本基調講演では、研究成果ならびにゲノム医療の現状と展望について概括し、産官学によるイノベーション創出についても議論する。

統合計算生命科学のもたらすゲノム医療の展望（仮題）
東京大学医科学研究所ヒトゲノム解析センター
宮野　悟

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

薬事規制当局連携組織（ICMRA）は各国薬事規制当局の幹部から構成され、各国の経験の共有や共通の課題解決のための取り組みなどをすすめている。ICMRAが現在、最も力を入れているプロジェクトがイノベーションプロジェクトである。このプロジェクトは1）各国のホライゾンスキャンニング方法の調査・研究、2）ホライゾンスキャニング結果の共有・活用、3）承認制度の最新動向　の3つの作業を実施しており、本セッションではそれぞれのリーダーから、その最新の調査・検討結果を紹介する。

The report form WS1; Analysis of Global Best Practice in Horizon Scanning Methodologies
独立行政法人 医薬品医療機器総合機構
近藤　達也

The Report from WS2; Leveraging from Outcomes of Horizon Scanning
European Medicines Agency (EMA)
Agnès Saint-Raymond

The Report from WS3; Novel Approaches to Licensing
Health Canada
Pierre Sabourin

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

SESSION 1　9:00-10:30

V1-S1　605/606会議室　9:00-10:30

Global Phase 1の経験(米国の施設の実態とmanagement方法）-癌の開発を中心にー

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。日本が欧米のメンバーとともに世界をリードするためには、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 を実際行っているExpertから実際進め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とともに、日本人がGlobal Phase1をmanageした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、日本を含めたGlobal Phase1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
第一三共株式会社
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、MA、薬事
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て、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

米国ではベンチャーオリジンの薬剤が承認品目のかなりの割合を占めるようになってきた。ベンチャー振興が遅れていた日本ではアカデミア創薬にその代わりとしての役割が期待されてきた。

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っており、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も含む開発方法を学ぶ機会を提供する。

白熱！医師主導治験の現場
埼玉医科大学病院
宮川　義隆

医師主導治験や特定臨床研究における試験遂行の効率化と必要な組織体制
国立病院機構名古屋医療センター
齋藤　俊樹

CROの観点から医師主導治験の支援業務経験
DOTワールド株式会社
折戸　哲也

パネルディスカッション
本セッションの講演者

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とりまとめられている。

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、医療機器たる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における実例も踏まえ、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。

東大オンコパネルを用いたクリニカルシ―クエンス(先進医療B)
東京大学大学院
織田　克利

演題未定
国立研究開発法人 国立がん研究センター
角南　久仁子

がん遺伝子パネル検査に関する規制の考え方
独立行政法人 医薬品医療機器総合機構
柳原　玲子

パネルディスカッション
本セッションの講演者および

中外製薬株式会社
飯島　康輔

株式会社PFDeNA
石倉　清秀

V5-S1　610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

東京大学
湯地　晃一郎

本年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
INFARMED
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

遺伝子治療用製品開発への挑戦と課題

関連領域: 薬事、アカデミア
レベル：初級

座長

国立成育医療研究センター
小野寺　雅史

近年、遺伝治療用製品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る様になってきた。一方で、遺伝子組み換え製品を使用する上で、本邦及びEUではカルタヘナ議定書に批准しており、本邦では国内法による規制にもとづく生物多様性に対する環境影響を考慮する必要がある。USは批准国ではないものの、EUと同様に治験開始時及び承認申請時には環境影響評価を行っている。本セッションでは、遺伝子治療用製品の概要を解説し、日米欧の制度の違い、日本独自の取り扱いにフォーカスをあて、日本で治験を実施するうえでクリアすべき点をカルタヘナ法第一種の使用規定に着目し議論するとともに、今後の実用化に向けて検討すべき課題について議論を行う。

日米欧における生物多様性に係る規制の比較と日本における課題
日本薬科大学
山口　照英

カルタヘナ法第1種使用規定申請で考慮する点（企業からの視点）
オンコリスバイオファーマ株式会社
須田　浩幸

カルタヘナ第１種使用規定申請作成上の留意点（PMDAからの視点）
独立行政法人 医薬品医療機器総合機構
尾山　和信

V7-S1　102会議室　9:00-10:30

臨床試験における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QMSの実装に向けた対応や取組みが進められてきた。いまだ現場レベルでは試行錯誤が続いているが、How toのみにとらわれず、本質にフォーカスし、基本的な考え方を理解することが解決への近道ではないだろうか。本セッションでは、規制当局の立場から、改めてQMS実装の目的と要求事項を解説するともに、企業の立場からPMBOK Guide®（Project Management Body of Knowledge）のRisk Management及びQuality Managementのフレームワーク等を活用したトライアルベースのQMS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

臨床QMSの実装に向けて必要な考え方、品質ツールやスキル　～ケーススタディを用いた解説～
グラクソ・スミスクライン株式会社
日本製薬工業協会データサイエンス部会
井上　宏高

治験における品質マネジメントについて～ICH-E6（R2）の実装を見据えて～
独立行政法人 医薬品医療機器総合機構
三浦　百合香

V8-S1　703会議室　9:00-10:30

【公募演題】Target Product Profile戦略マネジメント-より良い研究開発計画を目指して

関連領域: 薬事、PM
レベル：初級
言語：日本語のみ

座長

山口大学医学部附属病院
丸本　芳雄

近年AMEDは、「研究マネジメントに関するチェック項目（医薬品）」の運用を平成30年度より段階的に開始した。研究のGo/no-go判断を行うために、医薬品の研究開発の4つのステージゲートを設定し、それぞれの時期に満たしているべき項目を記載し提出させるツールとしても活用されている。本セッションでは本来の最終目的である「候補化合物に対して最適な開発戦略の立案と開発マネジメント」を補佐するTPPのあり方を検討する

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

コーヒーブレイク　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
Rong 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　淳子

Recent Trend of Pharmaceutical Regulation in Oseania
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　晃弘

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議論する。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、創意工夫について討論し、アカデミアのみならず、本セッションの全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的、物的リソースの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利活用だけでなく、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・報告の体制作りが重要である。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たい。

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応事例
日本イーライリリー株式会社
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

北里大学大学院
成川　衛

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への期待、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）や今後への期待と、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

臨床現場における審査報告書の利活用
慶應義塾大学
望月　眞弓

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

PMDAにおける審査報告書作成の現状と今後の課題
独立行政法人 医薬品医療機器総合機構
村上　裕之

パネルディスカッション
本セッションの講演者

V5-S2　610会議室　11:00-12:30
次世代の新薬 核酸医薬品 - どうする！？その規制と品質保証

関連領域: 薬事、PM、CMC、アカデミア
レベル：初級、中級

座長

国立医薬品食品衛生研究所
井上　貴雄

次世代の新薬として開発が活発化している核酸医薬のICHでのトピック化が提案されている。日本の規制当局が提案しているもので、今後核酸医薬の品質保証のあり方及びその動向は非常に注目されている。

本セッションでは，核酸医薬品の品質に関する課題及び展望を規制当局及び業界の関係者が議論する。

核酸医薬品の開発動向と規制整備の現状
国立医薬品食品衛生研究所
井上　貴雄

核酸医薬品のCMCに関する考慮事項（仮題）
独立行政法人 医薬品医療機器総合機構
伊藤　浩介

オリゴ核酸製造における分析の実例と課題
株式会社ジーンデザイン
南海　浩一

V6-S2　101会議室　11:00-12:30
アカデミア創薬の出口戦略を考える

関連領域: 薬事、PM、アカデミア
レベル：中級

座長

日本医科大学
松山　琴音

近年、医薬品/医療機器の開発現場では産学連携が進み、国内アカデミア発の世界的革新的新薬・治療法も現実のものとなってきた。アカデミアが創薬研究を行う場合、最終的には企業が製造・販売を行うことになるため、開発早期の段階から両者が連携しておくことは重要と考えられる。しかし、アカデミアの研究者は開発のプロではなく、連携前の交渉に苦労するケースもみられている。本セッションでは、両者が連携する際の阻害要因となる「お互いが望むものと要求されるもののギャップ」を明らかにするとともに、これを乗り越えた実例をベースにして、理想的な連携のあり方や最近の取り組みを産官学それぞれの視点から共有・議論したい。

医薬品開発におけるPMDAの役割
独立行政法人 医薬品医療機器総合機構
小池　恒

再生医療等製品開発に関する出口戦略の実例
北海道大学病院臨床研究開発センター
林　宏至

先駆け審査指定された希少疾患領域医療機器開発における出口戦略の実例
名古屋市立大学
讃岐　徹治

パネルディスカッション
本セッションの講演者および

東北大学病院臨床研究推進センター
大塚　佑基

バイオジェン・ジャパン株式会社
鳥居　慎一

V7-S2　102会議室　11:00-12:30
次世代医療基盤法を踏まえたリアルワールドデータ/エビデンスの利活用

関連領域: 臨床、統計、アカデミア、HO、MA、Digital
レベル：初級、中級

座長

バイエル薬品株式会社
高橋　俊一

次世代医療基盤法が今年5月11日に施行され、我々は適切な情報管理の下、医療に関するビッグデータを利用することが可能になった。

このセッションでは、オールジャパンで構築しているリアルワールドデータ/エビデンスの総括および次世代医療基盤法の重要なトピックをご紹介いただく。更に、製薬企業の事例として、EHRまたはPHRによるデータ利活用や医療従事者にもたらす価値についてご紹介頂く。

最後に、製薬産業の中でどのようにリアルワールドデータ/エビデンスの利用価値を高めていくのか？を議論する時間を設ける。

リアルワールドデータ利活用の総括（仮題）
国立保健医療科学院
水島　洋

次世代医療基盤法の解説（仮題）
国立研究開発法人 国立がん研究センター
中田　はる佳

Electronic/personal health recordの事例（仮題）
グラクソ・スミスクライン株式会社
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

国立研究開発法人 日本医療研究開発機構
井本　昌克

V8-S2　703会議室　11:00-12:30
データの完全性確保に向けた最近の動向

関連領域: 薬事、CMC
レベル：初級、中級
言語：日本語のみ

座長

中外製薬株式会社
住田　秀司

医薬品の品質、有効性および安全性を確保する上で、前提となる科学的データやプロセス記録の完全性（DI）が注目されている。

背景としては、一部の医薬品製造所においてデータや記録の改竄・捏造が行われたことから、アクセス管理や監査証跡レビュー等による、意図をもった不正への対応が求められており、ここ数年、FDAが発出した警告文書においても、DI確保への対応不備が理由となる案件が散見されている。

これらは、GMPのみならずGxP全般におけるガイダンス発出といったDI確保の厳格化につながっている。

そこで、本セッションでは、最近の規制の内容や査察での指摘事項等を事例として掲げ、取り組むべき課題と解決のポイントについて議論したい。

Data Integrityに関する企業への期待とGMP調査における指導事例（仮題）

独立行政法人 医薬品医療機器総合機構
川北　弘之

Data Integrityに関する最新の欧米規制動向と製薬業界としての取り組むべき課題

エーザイ株式会社
守野　智

査察対応準備におけるData Integrity対策とFDA査察実績

中外製薬株式会社
光部　篤人

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

POSTER SESSION　13:30-14:00

ポスターセッション　レセプションホール　13:30-14:00

関連領域: 薬事、安全性、臨床、FI、NC、RD、QC、SE
レベル：初級

本年会では国内外から多くの公募の中から査読委員による厳正な審査を経て9演題がポスターセッションとして選出された。最新のトピックスについて活発な議論が期待される。

[PO-01] Analysis of Adverse Drug Reactions in Taiwan

Kaohsiung Veterans General Hospital Tainan Branch
Yu-Hong Lin

Objectives:

The severity of Adverse Drug Reactions (ADRs) may vary greatly from person to person. The most severe situation can be a life-threatening event. In order to make healthcare professionals become aware of the importance of ADR, we do data analysis from our hospital.

Method:

It was a retrospective study in 2016. Assessment of ADRs contains age, gender, occurring sources, sources of ADRs reporting, Classification of ADRs and so on. In addition, we do a sub-analysis regarding Anatomical Therapeutic Chemical (ATC) classification of suspected drugs and Adverse Effects.

Results:

The investigation included eighty-nine ADRs reported. The average age was 67.6 year. 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 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 the respondents' 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 documents should be maintained by site.
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 are 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 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 share various behaviors, and also it helped us to reflect on our behaviors. Therefore, we consider that continuous Community activities with 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 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.

[PO-04] Categorization of Medical Information Databases; Are Real World Data Sources Treasure Islands?

高知大学医学部附属病院　次世代医療創造センター
若林　由美

Learning Objectives:
- To learn what medical information databases and real world data sources are available for database studies, non-interventional studies, or epidemiological researches
- To learn how to leverage medical information data and real world data and to generate evidences by considering characteristics of data sources

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 of the world as well; FDA Sentinel in the U. S., EMA Encepp 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 than conducting an interventional study. 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 to what research.
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 have crucial data such as biomarker values and information about preclinical subjects.

[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 post marketing 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 complexeties

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 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 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 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 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 safety reporting requirements in clinical trials and post marketed products 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 body of evidence, however, that there is a substantial difficulty in choosing/accessing an optimal model or choosing measurements which would be truly informative of the product's efficacy. We intend to present a possible application 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

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.

SESSION 3 14:00-15:30

V1-S3 605/606会議室 14:00-15:30

Risk Based Monitoringの現状と展望

関連領域: 臨床、アカデミア
レベル: 初級、中級

座長

ブリストル・マイヤーズ スクイブ株式会社
嶋崎　規夫

多くの治験依頼者がRBMを導入、運用し始めて数年が経過したが、現在でも臨床試験を実施する現場では混乱が続いている。特に医療機関からは「RBM導入によって治験依頼者からの要求事項が多くなり負担が増大した」「各社のやり方が違うので統一してほしい」といった意見が出ている。この混乱は、RBMの実施手法の差異といった品質管理の手段に着目する事に起因していないだろうか。

本セッションでは、RBM実施試験での信頼性調査の経験から得た知見とともに、CRAや医療機関など各担当者のRole & Responsibilityを踏まえた取り組みの現状と今後の方向性について議論する。

本セッションがData Integrityを担保するための本質への理解を深める一助となれば幸いである。

RBMへの対応 ー業務プロセス可視化に向けての取り組みー

株式会社アイロム
海野　祥子

RBMの経験から見えてきた、実施現場（CRA・CRC）の新たな課題

パレクセル・インターナショナル株式会社
上田　英輝

RBMの継続的な改善ーPMDA査察経験をふまえてー

日本イーライリリー株式会社
桑垣　美里

RBMの本質とは？ーCentralized Monitoring を中心にー

Bristol-Myers Squibb
杉浦　友雅

V2-S3 607会議室 14:00-15:30

承認事例からみた先駆け審査指定制度の課題・改善点

関連領域: 薬事、PM
レベル：初級
言語：日本語のみ

座長

塩野義製薬株式会社
佐藤　洋一

世界最先端の治療薬を患者に最も早く提供することを目的として、2015年から先駆け審査指定制度がスタートした。医薬品、医療機器、体外診断用医薬品、再生医療等製品について本制度の対象品目が指定され、それぞれ開発が進められる中、2017年度には医薬品の2品目、医療機器の1品目が製造販売承認を受けた。本年会では、承認事例を基にして、企業及び規制当局の双方の立場で承認申請から承認・薬価収載までを振り返り、本制度を活用する上での課題や改善すべき点を議論する。

演題未定

国立研究開発法人 国立がん研究センター
柴辻　正喜

先駆け指定審査を振り返るーより良い成果に繋げるためにー

ノーベルファーマ株式会社
島崎　茂樹

ゾフルーザの事例からみた課題，改善点

塩野義製薬株式会社
土屋　賢二

パネルディスカッション

本セッションの講演者

V3-S3 608会議室 14:00-15:30

TransCelerate: コラボレーションでイノベーションに挑戦する

関連領域: 全て
レベル：初級

座長

Boehringer Ingelheim Pharma GmbH & Co. KG
三木-安田　倫栄

"もしあなたが早く行きたいならば、一人で行ってください。もしあなたが遠くに行きたいならば、一緒に行きましょう。"

コラボレーションの力を利用することで、医療の現場を真に変えることができます。このセッションでは次世代のコラボレーションによるTransCelerateの展望を紹介します。

規制当局、スポンサー、患者、施設、技術者として一緒に、どうやって連携していけばよいでしょうか？どうすればコラボレーションによってイノベーションの限界に挑戦し、病気の予防、診断、治療、そして最終的には治癒を加速することができるでしょうか？

このような思いのもとにTransCelerateの代表者が集まり、臨床試験のパ

ラダイム変革のためにTransCelerate加盟19社が進めてきた多くのソリューションを議論します。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、斬新な技術を用いた治験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

主要イニシアティブ アップデート: Pharmacovigilance
アステラス製薬株式会社
久保田　健

主要イニシアティブ アップデート: SIP (Shared Investigator Platform)
MSD株式会社
三橋　晃一

主要イニシアティブ アップデート: 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: 臨床、薬事、統計、アカデミア、Clinical Strategy、Medical Writing
レベル：初級、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

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ダンスでは、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なかで、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

生存時間型応答の要約指標である境界内平均生存時間
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及びその動向

関連領域: 薬事、PM、CMC、アカデミア
レベル：初級、中級

座長
岐阜薬科大学
竹内　洋文

医薬品の製造コストを大幅に引き下げる新技術として期待される「連続生産」。

連続生産について、国際調和された定義はまだない。だが、石油精製や食品などの他業種ではメジャーな生産方式だ。製造稼働中に原料や混合物を連続的に供給し、最終生産物を継続的に取り出す生産方式のことを指す。医薬品もここ10年で一気に機運が盛り上がってきた。

本セッションでは製薬業界における連続生産を取り巻く環境とその最新動向を紹介する。

医薬品製造における連続球形晶析法の開発 (仮題)
岐阜薬科大学
田原　耕平

ヤンセンファーマにおける革新的な連続生産の導入事例 (仮題)
ヤンセンファーマ株式会社
下野　龍太郎

医薬品連続生産に関する規制要件の検討状況と今後の課題
独立行政法人 医薬品医療機器総合機構
高山　一成

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

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た。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非常に重要である。国内外で産官学による患者・市民教育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、治験に参加する患者さんの心得ともいえるガイダンスを作成した日本難病・疾病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・疾病団体協議会
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

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登録システムについて解説頂くとともに、市販後に課せられた患者登録制度に基づくアカデミアと連携した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
本セッションの講演者

V8-S3　703会議室　14:00-15:30

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、あらためて、自分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発見してみませんか。本セッションでは、元グーグルの人事担当者で、長年、人材開発・育成に取り組んできたピョートル氏を迎え、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」；キャリアアンカーを、多様な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。

演題未定
プロノイア・グループ株式会社
ピョートル・フェリクス・グジバチ

SESSION 4　16:00-17:30

V1-S4　605/606会議室　16:00-17:30

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ようとしている。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ノプシスをベースに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

V2-S4　607会議室　16:00-17:30

希少疾病用医薬品/小児用医薬品開発の今後の展望

関連領域: 薬事、臨床、アカデミア
レベル：初級
言語: 日本語のみ

座長

浜松医科大学
渡邉　裕司

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可能性について議論する。

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
本セッションの講演者

V3-S4　608会議室　16:00-17:30

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出された。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&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利用することで、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。日米欧の薬物相互作用についての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あるべき姿-

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開始となり2年目に入った。今まさに単一の組織だけで独自のコンプライアンスのあり方を考えずに、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　誠

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
川尻　邦夫

サノフィ株式会社
松村　佳奈

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ゆくか、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て頂き、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ごと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などのベイズ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ノベ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のホームページで提供されているが、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ー行政の立場からー
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出さなければ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」って、きいたことはあるけど、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、参加して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あ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。

https://www.diaglobal.org/productfiles/7240118/18303_CRC_Certificate.pdf

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なっており、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、ご来場時と退場時に総合受付にお越しください。

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。

DIA CHINA Annual Meeting

May 20-23, 2019 | Beijing International Convention Center

14+ Themes

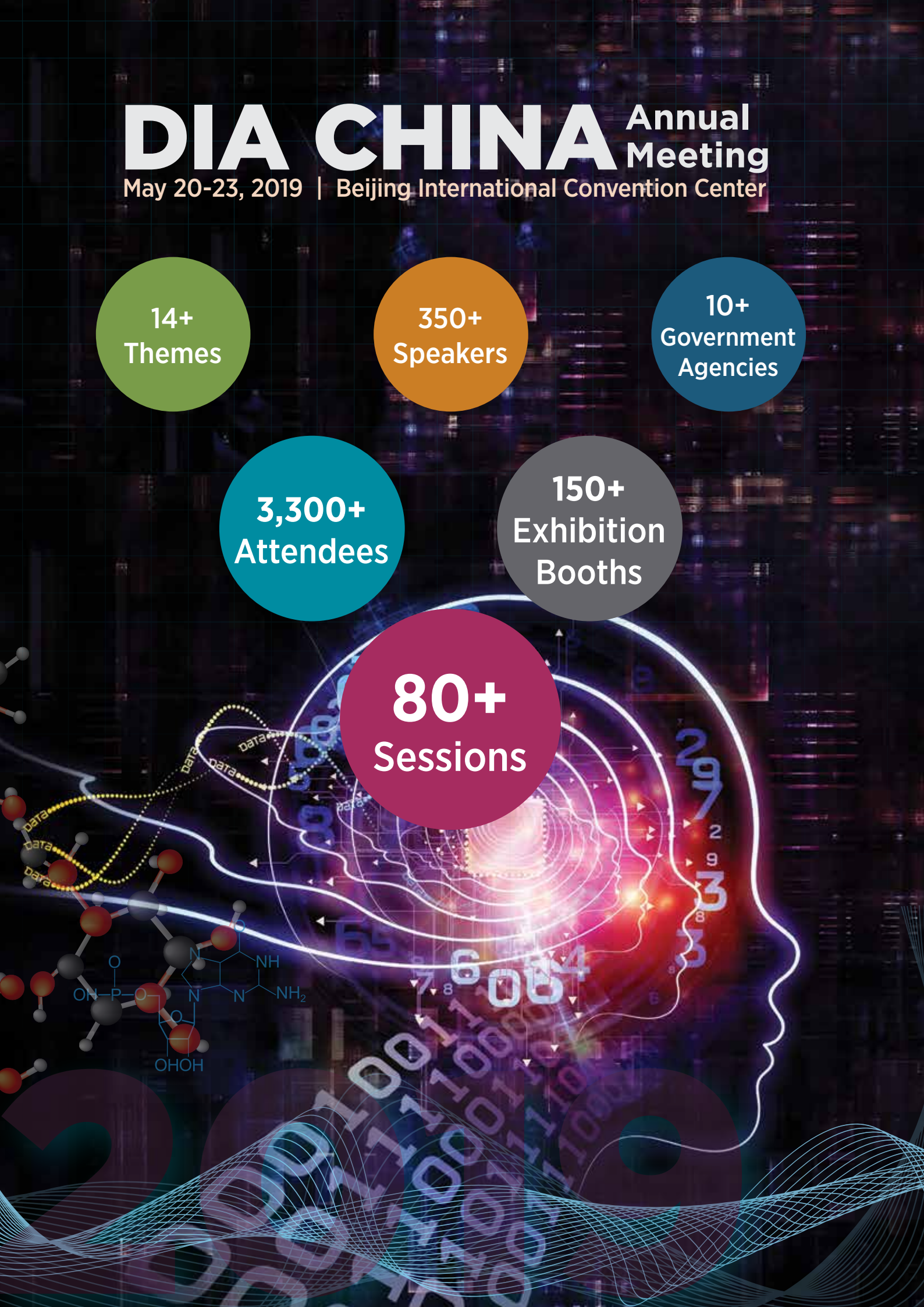
350+ Speakers

10+ Government Agencies

3,300+ Attendees

150+ Exhibition Booths

80+ Sessions



ENGAGE AND EXCHANGE: LET'S CHAT! "WHAT'S THE DIA WORLD 2018"

レセプションホール　17:45-19:00

関連領域: 全領域
レベル：全て

総合司会
ファイザー株式会社
稲泉　恵一

ファシリテーター
DIA Japan Contents Committee / Community

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キング、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嬉しく思います。若手も、ご意見番も、大学の学生や先生も、医療機関の先生方、PMDAの方も、同じテーブルを囲んでしまえば、皆、仲間！年会にお一人で参加される方もぜひ、輪に入っていただき一緒に語り合いましょう。

今年は、テーブルごとに10個のテーマを用意しました。いずれも、興味深いホットトピックばかりです。また、2つのコミュニティーが共同ファシリテーターとして進行しますので、コミュニティーの枠を超えた意見交換も期待できます。当日、ご興味のあるテーブルの周りにお集まりください。会場ではドリンク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に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。

テーマ一覧：

当日ご興味のあるテーブルにお立ち寄りください。途中参加、退席、移動も可能です。

#	コミュニティ	テーマ	ファシリテーター	概　略
1	Clinical Operations & Monitoring (COM) Clinical Data Management (CDM)	「エラーフリーを求めるマインド」から抜け出すためのアイデアを考えよう！	Clinical Operations & Monitoring (COM) 日本イーライリリー株式会社 松田　幸大 Clinical Data Management (CDM) 日本イーライリリー株式会社 桑垣　美里	品質管理システムにRBAが求められています。エラー0を追求してきた我々にとって、「一定の範囲にエラーを収める」ことも「エラーを原因毎に分類する」ことも、まだまだ馴染みがないかもしれません。「エラーフリーを求めるマインド」から治験関係者の全員が抜け出せるにはどうすればいいか、一緒にアイデアを考えましょう。
2	Clinical Strategy (CS) Project Management (PM)	偶然の出会いをキャリアに活かそう！！！（袖摺りあうも他生の縁、あなたと私のキャリアの関わりは？）	Clinical Strategy（CS） アイ・エル・ジャパン株式会社 二宗　みのり Project Management（PM） 東京大学医科学研究所附属病院 藤原　紀子	キャリアってどんなイメージを持っていますか？キャリアは仕事だけでなく、人生の軸の一つです。環境が目まぐるしく変化していく中で、自分の価値探しは決して簡単ではないけれど、縁あって出会った仲間と少し話すことで、新たな気づきが得られるかもしれません。気軽な雰囲気でキャリアのことを考えてみませんか？
3	Regulatory Affairs (RA) Project Management (PM)	医薬品開発における効率的な役割分担とは？	Regulatory Affairs（RA） 株式会社CTD 東　利則 Project Management（PM） 日本たばこ産業株式会社 長尾　典明	様々な背景を持つ専門家や部署の意見を集約するのに苦労した経験はありませんか？医薬品開発に必須な幅広い専門知識をうまく活用するための効率的な役割分担について、じっくりと気楽に、なによりも楽しく語り合いましょう！PM Communityメンバーが盛り上げます！産官学いずれの方々のご参加をお待ちしています！
4	Regulatory Affairs (RA) Pharmacovigilance &Labeling (PV)	E17～開発ストラテジーの変化について考える～	Regulatory Affairs（RA） ファイザー株式会社 砂村　一美 Pharmacovigilance & Labeling (PV) 日本イーライリリー株式会社 前田　玲	皆様はE17を読んで正しく理解できていますか？考えれば考えるほど、知れば知るほど、謎が深まる・・と感じていませんか？ Pooled　Populationの安全性はどう評価するの？世界は皆兄弟？今までのMRCTとどう違うの？CTDの書き方は変わる？など、日頃感じているE17に対する疑問や意見を、本チャッティングセッションでみんなで共有してみませんか？
5	Six Sigma (SS) Clinical Data Management (CDM)	ICH E6 R2-臨床QMSの実装に向けて現場で使える品質ツールの正しい使い方	Six Sigma (SS) グラクソ・スミスクライン株式会社 井上　宏高 Clinical Data Management (CDM) エイツーヘルスケア株式会社 林　行和	ICH-E6(R2)が合意され，製薬協からも「臨床試験におけるQMS　の実装に向けた実践的な取り組み～ケーススタディを用いた品質管理ツールの現場での活用事例～」が発行されました。QMSの実装には品質管理ツールを正しく使うことが重要です。ツールやその背景にある統計的な考え方について皆で理解を深めましょう。
6	Statistics Clinical Strategy(CS	生存時間解析での評価指標　～最近話題になっている生存時間解析の要約指標についても話す？そだねー。～	Statistics (ST) 日本ベーリンガーインゲルハイム株式会社 鵜飼　裕之 Clinical Strategy（CS） 株式会社CTD 冠　和宏	死亡や特定の有害事象の発現などイベントが発現するまでの時間を評価する臨床試験では，Kaplan-Meier法で生存関数を図示し，log-rank検定で生存関数の群間比較を行い，Cox比例ハザードモデルで評価指標であるハザード比を推定し，治療効果の大きさを議論することが多い。これってそういうもんだということでやっていませんでしたか？ そもそもハザード比って何だろう。患者さんや医療人にとって分かりやすい指標とは何なのかという点について，最近統計界隈で話題になっているトピックも含めてざっくばらんにお話しましょう。
7	Medical Communication (MC) Patient Engagement (PEC)	患者さんの医療選択のための医薬品情報のあり方　～医療現場・患者さん・行政・企業で今後のメディカルコミュニケーションを考えていこう～	Medical Communication (MC) ノバルティスファーマ株式会社 西野　潤一 Patient Engagement(PEC) MSD株式会社 古屋　義方	誰でも医薬品情報へ容易にアクセスすることができる時代となったが，webからアクセスできる情報の中には疑わしいものも見受けられる。規制当局や製薬企業が提供している情報は信頼性は高いものの医療関係者向け情報が多く、一般の方には難解である。「患者向医薬品ガイド」など既存情報の更なる活用や、患者さん中心でのメディカルコミュニケーションあるべき姿について意見交換をしたい。
8	Patient Engagement (PEC) Clinical Operations & Monitoring (COM)	もしも自分や家族が治験に参加するとしたら？	Patient Engagement(PEC) Amicus Therapeutics株式会社 海老原　恵子 Clinical Operations & Monitoring (COM) ブリストル・マイヤーズ スクイブ株式会社 嶋﨑　規夫	“患者さん”とは何か特別な人達ではなく、私たち全員が時には“患者さん”になります。そして将来、自分や家族が治験に参加する日がくるかも？ 参加してもいいな、と思える治験。絶対ヤダ！と感じる治験。何が不安か。どんな情報やどんなサポートが欲しいのか。そんなことを考える時を、一緒に過ごしてみませんか？
9	Medical Communications (MC) Pharmacovigilance & Labeling (PV)	その資材ほんとに使われてる？～適正使用のための医薬品／医療機器情報に関するコミュニケーションの現状と将来～	Medical Communication(MC) MSD株式会社 津森　桂子 Pharmacovigilance & Labeling(PV) アステラス製薬株式会社 石田　和彦	企業では数多くの資材を作成し、適正使用を推進しようとしています。しかし、医療機関、患者さん、規制当局、MA、PVなど立場により「適正使用」の定義が異なるかもしれません。また、その違いによる、情報提供の方法や内容に課題があるかもしれません。これらについて、様々な立場の皆さんで意見交換します。
10	Statistics Six Sigma (SS)	統計担当者はデータサイエンティストになりえるか？創薬からポストマーケティングまで！	Statistics 統計数理研究所 伊藤　陽一 Six Sigma(SS) 株式会社Real Discovery Outdoors 小澤　郷司	多くの業種でデータサイエンティストが求められる中、製薬会社はその素養を持った人材を統計担当者として多く抱えているが、その価値の最大化については気づいていない。現在の統計業務だけでなく、全社的な経営に統計担当者の知識が必要とされている。統計担当者の新たなフィールド、キャリアパスについてチャッティングしよう。

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）

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

MSD株式会社
古屋　義方

患者さんを医薬品開発のパートナーとしてEngageし、参画を推進していくためには、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の提供等が行われ始めている。本セッションでは、治験参加時、参加中、及び参加後に患者さんが望んでいる情報やコミュニケーションについて理解すると共に、それをどの様に提供していくかを、国内外の規制、事例を踏まえディスカッションする。第1部では、国内の状況について、企業の取り組み、治験施設の考え、そして患者さんの意見を共有する。なお本セッションに続いて行われる第2部では海外の取り組みを紹介し、第1部の演者と共にパネル ディスカッションを行う。

治験に関する患者さんへの情報提供、コミュニケーション：企業の取り組みと課題（仮題）
ファイザー株式会社
北村　篤嗣

治験に関する患者さんへの情報提供、コミュニケーション：治験実施機関の考え（仮題）
国立研究開発法人 国立がん研究センター
後澤　乃扶子

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？
一般社団法人CSRプロジェクト
桜井　なおみ

患者が求める治験に関する情報とコミュニケーション
特定非営利活動法人 日本慢性疾患セルフマネジメント協会
武田　飛呂城

V2-S5 607会議室 9:00-10:30

医薬品リテラシー向上への取り組み ～国民自らが医薬品について知る時代に我々はどのように対応すべきか～（第1部）

関連領域: 全領域、患者さん
レベル：中級
言語: 日本語のみ

座長

くすりの適正使用協議会
俵木　登美子

ノバルティスファーマ株式会社
西野　潤一

薬機法には「国民は、医薬品等を適正に使用するとともに、これらの有効性及び安全性に関する知識と理解を深めるよう努めなければならない。」と記載されている。インターネットの普及もあり情報は氾濫しているが、すべて信頼できる情報なのか？また患者さんの視点に立った情報は十分揃っていると言えるのか？患者さんが求める情報は多種多様であり、まずは医師・薬剤師へ相談することが推奨されるが、それに加え患者さん自らが入手できる信頼性の高い情報も必要である。

本セッションでは日本における医薬品情報の現状について整理するとともに、立場の異なる演者から患者さんへの情報提供に関する取組みや課題を紹介する。また、V2-S6のPart2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、患者さんに説明する側、当局関係者により議論する。

製薬企業が作成・提供する患者さん向け医薬品情報の現状と課題について
ノバルティスファーマ株式会社
西野　潤一

患者が必要としている情報とは　～現状における問題点と将来への期待～
認定NPO法人　ささえあい医療人権センター コムル
山口　育子

患者さんが必要としている医薬品情報とは　～医療現場の薬剤師の立場から～
杏林大学医学部付属病院
若林　進

PMDAから患者さんへの医薬品情報提供の現状と課題
独立行政法人 医薬品医療機器総合機構
上野　清美

V3-S5 608会議室 9:00-10:30

製品価値最大化に向けてのチャンスと挑戦　-開発部門とメディカルアフェアーズ部門の連携を通じて-

関連領域: 臨床、PM、MA、Pharmacology
レベル：初級、中級

座長

大日本住友製薬株式会社
相野　博司

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関連部門とメディカルアフェアーズ部門がより密接に連携し、開発戦略・論文戦略・KOL Cal 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
古座岩　宏輔

V4-S5 609会議室 9:00-10:30

マイクロバイオームの新展開

関連領域：アカデミア
レベル: 初級
言語: 日本語のみ

座長

東京大学医科学研究所
湯地　晃一郎

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おり、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診断薬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括し、創薬・製薬業界での利活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
株式会社テクノスルガ・ラボ
久田　貴義

パネルディスカッション
本セッションの講演者

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、適正使用にいた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、いかに効率的かつ早期に新規抗菌薬を創出していくか、産官学における現状の課題と相互にサポートすべき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

薬剤耐性菌感染症に対する抗菌薬の開発ーアカデミアができることー
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

V6-S5　101会議室　9:00-10:30
HTAを巡る諸問題　ーミクロとマクロの視点からー

関連領域: MA, 薬事、臨床、アカデミア
レベル：初級

座長

京都大学
川上　浩司

費用対効果評価（HTA）の本格導入に向けて、製薬企業、医療機器企業においては、新しい医療技術の価値の説明がこれまで以上に求められています。

HTAの最新動向を紹介するだけでなく、HTAを行ううえで必要不可欠なReal World Dataの利活用について具体的な事例を紹介します。

費用対効果分析のみならず疾病負担や医療費への影響などの多くアプローチが行われている欧米のHEOR機能について説明します。

中医協の費用対効果評価ガイドラインで基づいて費用対効果分析を実施する際の留意点を解説します。

最後にパネルディスカッションを通して、参加者との意見交換を行います。

HTAの最新動向とRWDの利活用事例
京都大学
川上　浩司

欧米のHEOR機能
Shionogi Limited
Mark Hill

中医協ガイドラインの留意点
ミリマン
岩崎　宏介

パネルディスカッション
本セッションの講演者

V7-S5　102会議室　9:00-10:30
日米欧の医薬品安全性監視活動 ―リアルワールドデータをどう活用していくか―

関連領域: 安全性
レベル：中級

座長

慶應義塾大学
漆原　尚巳

GPSPが改正に伴い、日本においてデータベース調査が医薬品安全性監視活動として利用できるようになり環境が大きく変化している。本セッションでは、欧米におけるリアルワールドデータ（RWD）を活用したファーマコビジランスの取り組みについて、実例の紹介や今後の課題等を交えて共有いただくとともに、日本におけるRWDを活用した医薬品安全性監視活動の進むべき方向性を議論したい。

はじめに
慶應義塾大学
漆原　尚巳

FDAにおけるRWDを活用した医薬品安全性監視活動
FDA
Gerald J. Dal Pan

EMAにおけるRWDを活用した医薬品安全性監視活動
European Medicines Agency (EMA)
Agnès Saint-Raymond

PMDAにおけるRWDを活用した医薬品安全性監視活動
独立行政法人 医薬品医療機器総合機構
安藤　孝

V8-S5　703会議室　9:00-10:30
臨床試験の効率化とデータの信頼性向上 ーeSourceはClinical Trialをこう変えるー

関連領域: 臨床、DM、アカデミア
レベル：初級
言語: 日本語のみ

座長

東北大学大学院

山口　拓洋

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きます。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？それを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

MSD株式会社
古屋　義方

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ためには、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の提供等が行われ始めている。本セッションでは、治験参加時、参加中、及び参加後に患者さんが望んでいる情報やコミュニケーションについて理解すると共に、それをどの様に提供していくかを、国内外の規制、事例を踏まえディスカッションする。第2部では、海外の状況について、EUの規制当局及び企業の考えや取り組みを共有し、その後、第1部の演者と共にパネル ディスカッションを行う。

治験に関する患者さんへの情報提供、コミュニケーション：EUの規制と取り組み（仮題）
European Medicines Agency (EMA)
Agnès Saint-Raymond

治験に関する患者さんへの情報提供、コミュニケーション：EU企業の取り組み
UCB, Inc.
Iris Loew-Friedrich

パネルディスカッション
V1-S5および本セッションの講演者、並びに
厚生労働省
森　和彦

V2-S6　607会議室　11:00-12:30
医薬品リテラシー向上への取り組み ～国民自らが医薬品について知る時代に我々はどのように対応すべきか～（第2部）

関連領域: 全領域、患者さん
レベル：中級
言語: 日本語のみ

座長

くすりの適正使用協議会
俵木　登美子

ノバルティスファーマ株式会社
西野　潤一

薬機法には「国民は、医薬品等を適正に使用するとともに、これらの有効性及び安全性に関する知識と理解を深めるよう努めなければならない。」と記載されている。インターネットの普及もあり情報は氾濫しているが、すべて信頼できる情報なのか？また患者さんの視点に立った情報は十分揃っていると言えるのか？患者さんが求める情報は多種多様であり、まずは医師・薬剤師へ相談することが推奨されるが、それに加え患者さん自らが入手できる信頼性の高い情報も必要である。

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、患者さんに説明する側、当局関係者により議論する。

医薬品情報の姿の5年後を想像できますか？　～変革期における適正使用の推進～
慶應義塾大学
望月　眞弓

パネルディスカッション
V2-S5および本セッションの講演者

V3-S6　608会議室　11:00-12:30
クリニカルオペレーションの近未来 ーICTが導くVirtual Clinical Trialー

関連領域: 薬事、DM、臨床、PM、アカデミア
レベル：中級

座長

MSD株式会社
林　光夫

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、例えば、CRF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されている。

本セッションでは、欧米で展開されつつあるVirtual Clinical Trialの現状と、日本での展開と課題を紹介する。

患者さんを中心にEnrollmentやVisitのあり方が大きく変わる世界を皆さんと創造できれば幸いである。

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
Novartis Pharma AG
Bryan McDowell

Application of Mobile Health in Clinical Development
PAREXEL International
Sy Pretorius

Virtual Clinical Trialは日本の臨床試験を変革するか？ ー訪問型治験の実績から
日本イーライリリー株式会社
岡本　麻紀子

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くる。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に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 & Co., 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予想されます。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再評価されるようになっています。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
漆原　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　晃仁

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 ーリサーチ・クエスチョンをいかに考えるかー

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革している。治験等の情報及び対象となる疾患や医薬品の特性も踏まえ、リサーチ・クエスチョンを明確にした上で、過不足なく適正に安全性監視活動を実施することが重要である。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、それをいかに明確なリサーチ・クエスチョンへと結び付け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のあり方

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PMDA相談が本年7月から開始（FirstWave）され、PMDA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ふまえ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を終えての所感
独立行政法人 医薬品医療機器総合機構
鎌田　暁史

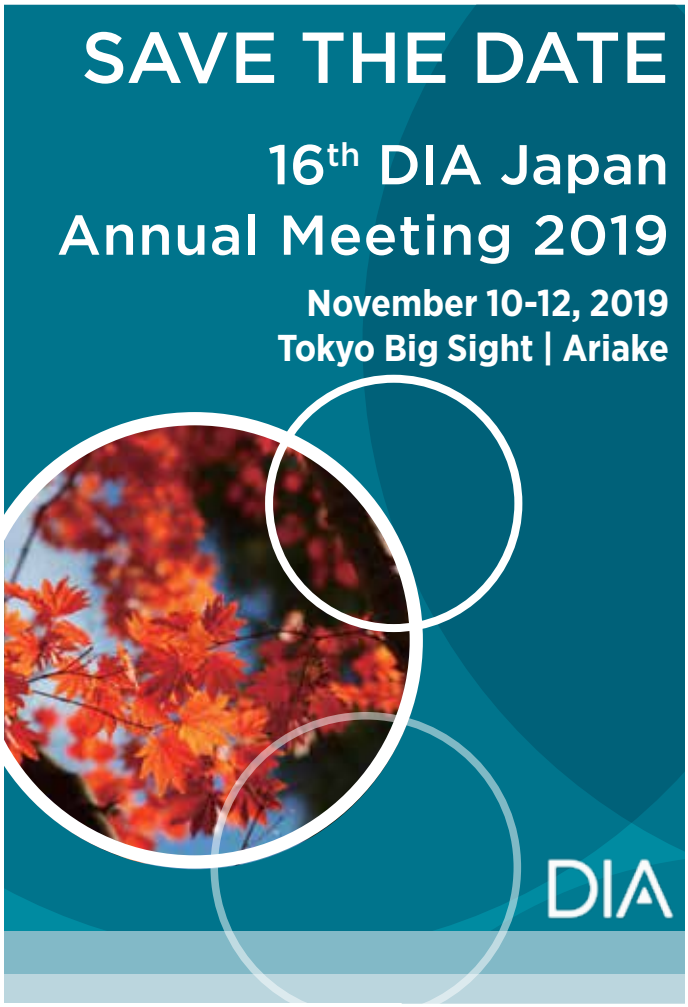
新記載要領添付文書改訂の実際へ向けて-企業の立場から
ノバルティスファーマ株式会社
稲村　達海

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
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 Sessions & 閉会の挨拶

DIAmond Session 2
国際会議場 **14:00-15:30**

DIAmond SESSIONS

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precisionmedicine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**

DIAmond SESSIONS

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

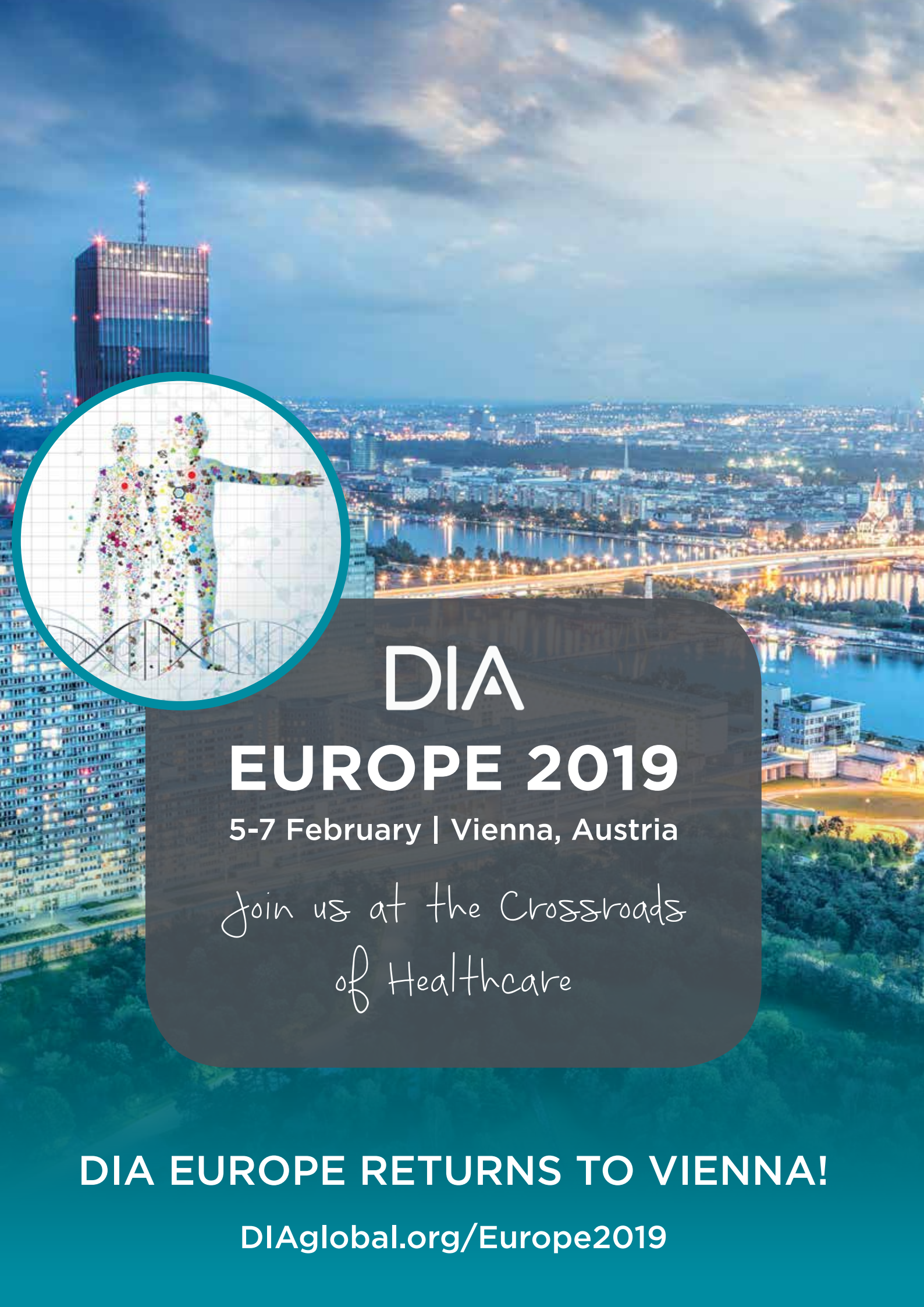
独立行政法人 医薬品医療機器総合機構
医療機器審査第一部長
高江　慎一

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可能です。

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ご活用ください。

3 REACH OUT YOUR POTENTIAL CUSTOMER

DIA日本年会へは、製薬業界、アカデミア、医学生など多数の参加者があり、年々参加者は増加しています。この機会を利用され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

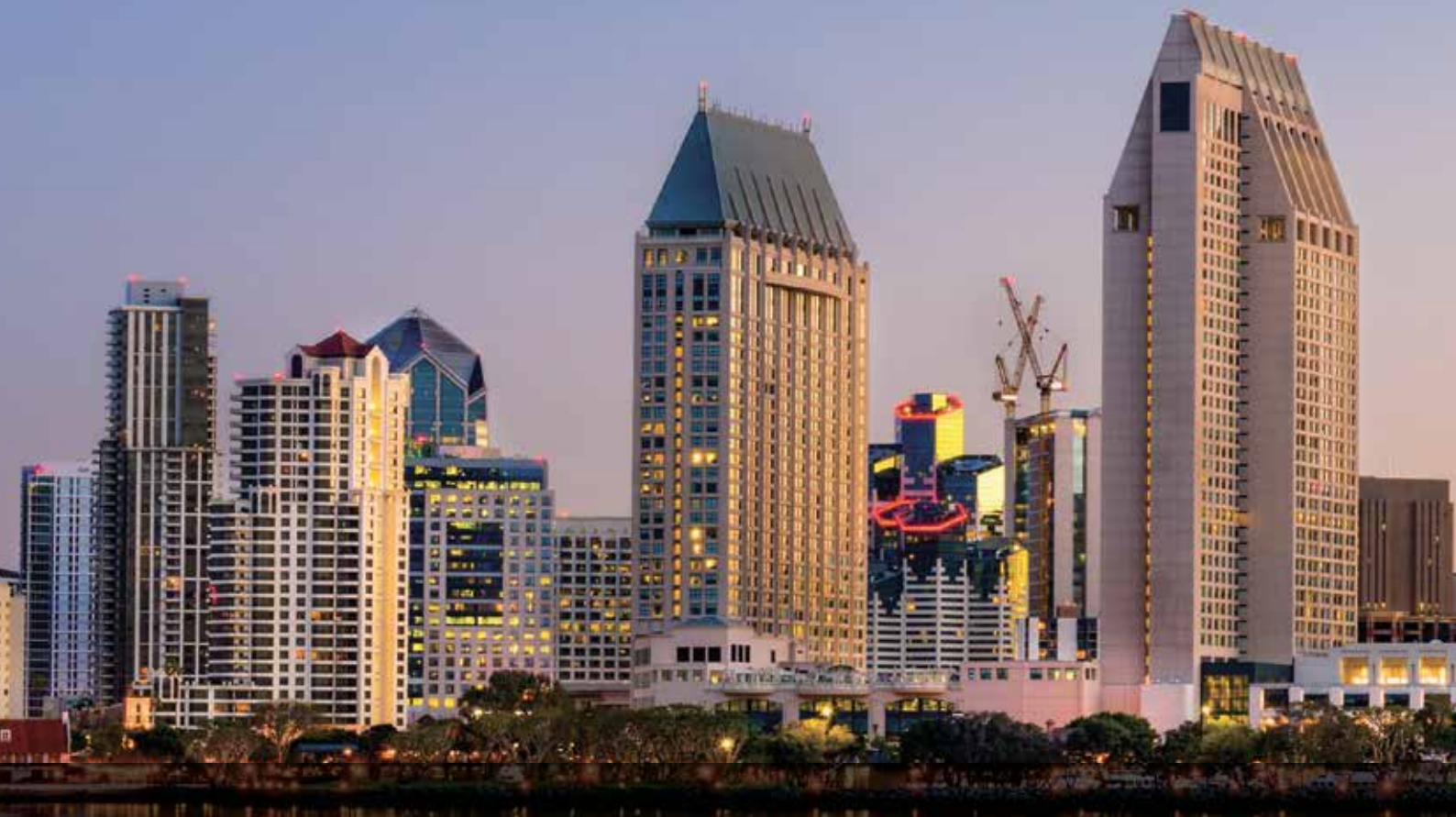
展示ブースでは、最新の革新的な製品やサービスのご紹介をすることにより、顧客からの注目を引き付けることが可能です。

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。またコングレスバッグ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。

DIA 2019

GLOBAL ANNUAL MEETING



SAN DIEGO | JUNE 23-27

DIAglobal.org/DIA2019

#DIA2019

DIAglobal.org

DIA

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

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.

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks and reception (if applicable), and will be accepted by mail, fax, or online.
* If you wish to register as a Young Professional please use Young Professional registration form.

Join DIA now to save on future meetings and to enjoy the benefits of membership for a full year: www.DIAglobal.org/Membership

❑ I **DO** want to be a DIA member

❑ I **DO NOT** want to be a DIA member

REGISTRATION FEE			8% TAX INCLUDED
MEMBER	Industry	Super Early-bird (until Sept 11)	❑ ¥101,520
		Early-bird (from Sept 12 to Oct 22)	❑ ¥106,920
		On and after Oct 23	❑ ¥117,720
	Government, Non-profit	Early-bird (until Oct 22)	❑ ¥36,720
		On and after Oct 23	❑ ¥42,120
	Academia, Medicals	Early-bird (until Oct 22)	❑ ¥20,520
		On and after Oct 23	❑ ¥25,920
NON-MEMBER	Industry		❑ ¥136,620
	Government, Non Profit		❑ ¥61,020
	Academia, Medicals		❑ ¥38,880
STUDENT *	Entire Meeting		❑ ¥5,400
	Student Session only		❑ ¥2,160

MEMBERSHIP	8% TAX INCLUDED
Membership	❑ ¥18,900❑
2-Year Membership	❑ ¥34,020❑
Academia Membership (Academia, Non-profit, Medicals)**	❑ ¥12,960❑

** Student registation 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 M.I.

Department ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Address (As required for postal delivery to your location)

City State Zip/Postal Country

email **Required for confirmation**

Phone Number **Required** Fax Number

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
Address: 3-7-11 Ariake, Koto-ku, Tokyo 135-0063
Telephone: +81-3-5564-0111
URL: http://tokyobay.washington-hotels.jp/

Hotel Sun Route Ariake
Address: 3-6-6 Ariake, Koto-ku, Tokyo 135-0063
Telephone: +81-3-5530-3610
URL: http://www.sunroute.jp/english/hotelinfo/tokyo_kanagawa/ariake/index.html

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.

DIA does NOT allow registrants to pass name badges to others. DIA may ask attendees to show identifications, if necessary.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

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**.
(https://www.DIAglobal.org/general/photography-policy)

PRIVACY STATEMENT

DIA respects the privacy of all of its members and customers. To view our privacy policy, click **here**. (https://www.DIAglobal.org/about-us/privacy-policy)

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 booking. These are available from the office or online by clicking **here**.
(https://www.diaglobal.org/General/Terms-and-Conditions?productIDs=7240118)

Signature Date

PAYMENT OPTIONS

Register online at **www.DIAglobal.org** or check payment method.

❑ **BANK TRANSFER:**
You will recieve an invoce 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)**
❑ **VISA** ❑ **MC** ❑ **JCB** 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
email: Japan@DIAglobal.org

DIA

YOUNG PROFESSIONAL REGISTRATION FORM

To register please complete the registration form below and fax to +81-3-3218-1313 or email Japan@DIAglobal.org.
NO ONLINE REGISTRATION AVAILABLE.

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

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❑ I **DO** want to be a DIA member

❑ I **DO NOT** want to be a DIA member

ELIGIBILITY FOR YOUNG PROFESSIONALS RATE

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

YOUNG PROFESSIONALS REGISTRATION FEE			8% TAX INCLUDED
MEMBER	Industry	Super Early-bird (until Sept 11)	❑ ¥60,912
		Early-bird (from Sept 12 to Oct 22)	❑ ¥64,152
		On and after Oct 23	❑ ¥70,632
NON-MEMBER	Industry		❑ ¥81,972

Please complete the form below.

Date of Birth (mm/dd/yyyy) **Required**

** Please note that we may ask you to show your Identification at a venue.*

MEMBERSHIP	8% TAX INCLUDED
Membership	❑ ¥18,900❑
2-Year Membership	❑ ¥34,020❑

Please compleate the form below in block capital letters:

Last Name

First Name M.I.

Department ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Address (As required for postal delivery to your location)

City State Zip/Postal Country

email **Required for confirmation**

Phone Number **Required** Fax Number

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Telephone: +81-3-5564-0111
URL: http://tokyobay.washington-hotels.jp/

Hotel Sun Route Ariake
Address: 3-6-6 Ariake, Koto-ku, Tokyo 135-0063
Telephone: +81-3-5530-3610
URL: http://www.sunroute.jp/english/hotelinfo/tokyo_kanagawa/ariake/index.html

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Government/Academia/Nonprofit (Member or Nonmember) = ¥10,000

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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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Signature Date

PAYMENT OPTIONS

Please check payment method.

❑ **BANK TRANSFER:**
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❑ **CREDIT CARD (VISA, MASTERCARD OR JCB ONLY)**
❑ **VISA** ❑ **MC** ❑ **JCB** 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
email: Japan@DIAglobal.org

DIA

会議参加申込書

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

DIAウェブサイト(www.DIAglobal.org)よりお申し込み頂くか、この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E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各種機関紙の入手、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。

＊＊ アカデミア会員資格にお申し込みの方は、本申込書をディー・アイ・エー・ジャパンまでFAXもしくはメールにてお送りください。

Membership（有効期間：1年間）	❑	￥17,500（税抜）	￥18,900（税込）
2-Year Membership（有効期間：2年間/10%割引）	❑	￥31,500（税抜）	￥34,020（税込）
Academia Membership ＊＊ （対象：大学関係・非営利・医療従事者、有効期間：1年間）	❑	￥12,000（税抜）	￥12,960（税込）

②参加費

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。
＊若手割引でのお申込みは、専用の申込書をご使用下さい。

会員	一般	*超早期割引（9月11日まで）	❑	¥94,000（税抜）	¥101,520（税込）
		*早期割引（9月12日から10月22日まで）	❑	¥99,000（税抜）	¥106,920（税込）
		10月23日以降	❑	¥109,000（税抜）	¥117,720（税込）
	政府 非営利団体	*早期割引（10月22日まで）	❑	¥34,000（税抜）	¥36,720（税込）
		10月23日以降	❑	¥39,000（税抜）	¥42,120（税込）
	大学関係 医療従事者	*早期割引（10月22日まで）	❑	¥19,000（税抜）	¥20,520（税込）
		10月23日以降	❑	¥24,000（税抜）	¥25,920（税込）
非会員	一般		❑	¥126,500（税抜）	¥136,620（税込）
	政府・非営利団体		❑	¥56,500（税抜）	¥61,020（税込）
	大学関係・医療従事者		❑	¥36,000（税抜）	¥38,880（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下さい。

学生 （企業/団体に籍をおいている方は対象外）	年会全体への参加	❑	￥5,000（税抜）	￥5,400（税込）
	スチューデントセッションのみ参加	❑	￥2,000（税抜）	￥2,160（税込）

<注意>
1) 学生の参加につきましては、事前申込制とさせていただきます。10月30日（月）までにFAXもしくはメールにてお申し込みください。なお、学生証の提示をお願いする場合がございます。ご了承ください。
2) 学生で年会全体への参加登録をされる方は、11月11日（日）9:30-12:30に行うスチューデントセッションへの参加の有無について以下に印を入れてください。
❑スチューデントセッションに参加する　❑スチューデントセッションに参加しない

DIA Japan 使用欄（W10）	
Date	
No.	
受領書送付	
Invoice	
入金	

＊ 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**は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、学生については1,000円を申し受けます。それ以降のキャンセルについては参加費全額を申し受けますのでご注意ください。**同一会社からの参加変更は可能ですが、その際はお早めにディー・アイ・エー・ジャパンまでお知らせください。（会員資格の譲渡はできませんので、非会員としての参加費を申し受ける場合があります。）**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。

＊ 本年会では、DIAの宣伝活動に使用する目的で、開催期間中に参加者を含む会場内の映像・写真を撮影することがあります。本年会の参加者は、DIAが記録した映像・写真等について、DIAの宣伝資料、出版物及びインターネット等への掲載その他一切の利用に係る権利（肖像権、パブリシティ権等を含みます）はDIAに帰属することを認め、DIAが無償で任意に利用できることを許諾するものとします。

＊ 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。

◆ 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。

[支払方法] ☐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。

☐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）☐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名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）　❑ Dr.　❑ Mr.　❑ Ms.　First name（名）　Company

Job Title　Department

Address　City　State　Zip/Postal　Country

Email（必須）　Phone Number（必須）　Fax Number

【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。また当日は、ご参加いただく皆様の会社名または組織名とご氏名を記載したリストをプログラム関係者に限り配布する場合がございます。本申込書の提出をもって以上の個人情報のお取扱いご同意いただいたものと解釈いたしますが、ご同意いただけない場合はDIA Japanまでご連絡ください。

YOUNG PROFESSIONAL

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E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各種機関紙の入手、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。

Membership（有効期間：1年間）	❑	￥17,500（税抜）	￥18,900（税込）
2-Year Membership（有効期間：2年間/10%割引）	❑	￥31,500（税抜）	￥34,020（税込）

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。

			通常		若手割引
会員	一般	*超早期割引（9月11日まで）	¥101,520（税込）	❑	¥60,912（税込）
		*早期割引（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）
非会員	一般		¥136,620（税込）	❑	¥81,972（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下さい。

DIA Japan 使用欄 (W10)	
Date	
No.	
受領書送付	
Invoice	
入金	

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。

[支払方法] ☐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。

☐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）☐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名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）　❑ Dr.　❑ Mr.　❑ Ms.　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**は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については参加費全額を申し受けますのでご注意ください。**同一会社からの参加変更は可能ですが、その際はお早めにディー・アイ・エー・ジャパンまでお知らせください（会員資格の譲渡はできませんので、非会員としての参加費を申し受ける場合があります。）**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。

＊ 本年会では、DIAの宣伝活動に使用する目的で、開催期間中に参加者を含む会場内の映像・写真を撮影することがあります。本年会の参加者は、DIAが記録した映像・写真等について、DIAの宣伝資料、出版物及びインターネット等への掲載その他一切の利用に係る権利（肖像権、パブリシティ権等を含みます）はDIAに帰属することを認め、DIAが無償で任意に利用できることを許諾するものとします。

＊ 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。また当日は、ご参加いただく皆様の会社名または組織名とご氏名を記載したリストをプログラム関係者に限り配布する場合がございます。本申込書の提出をもって以上の個人情報のお取扱いご同意いただいたものと解釈いたしますが、ご同意いただけない場合はDIA Japanまでご連絡ください。