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!
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<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Venue 1</th>
<th>Venue 2</th>
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<tbody>
<tr>
<td>9:30-12:00</td>
<td>ORIENTATION AT EXHIBIT HALL (12:00-13:00)</td>
<td>Room 605/606</td>
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<td>12:00-13:00</td>
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<td>13:00-13:30</td>
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<td>14:00-15:30</td>
<td>2018 DIA JAPAN’S INSPIRE REGIONAL AWARDS CEREMONY</td>
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<td>16:15-17:45</td>
<td>D3 [DIAMOND Session 1] New Challenges for Innovation ~ICMRA Innovation Project - RA, AC</td>
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<td>9:00-10:30</td>
<td>SESSION 1</td>
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<td>11:00-12:30</td>
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<td>12:30-14:00</td>
<td>LUNCHEON SEMINAR</td>
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<td>14:00-15:30</td>
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<td>17:45-19:00</td>
<td>ELI Engage and Exchange ~LET’S CHAT ~ SPECIAL CHAT SESSION ~ AT RECEPTION HALL</td>
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<td>9:00-10:30</td>
<td>SESSION 5</td>
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<td>11:00-12:30</td>
<td>SESSION 6</td>
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<td>12:30-14:00</td>
<td>LUNCHEON SEMINAR</td>
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<td>14:00-15:30</td>
<td>D2 [DIAMOND Session 1] Innovative Clinical Trials: A Painting of the Future ALL</td>
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<td>16:00-17:30</td>
<td>D3 [DIAMOND Session 2] PMDA TOWN HALL</td>
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<td>17:30-17:40</td>
<td>CLOSING REMARKS</td>
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### VENUE 5
Room 610

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<tbody>
<tr>
<td>V5-S1 Call for Abstract Session</td>
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### VENUE 6
Room 101

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<th>SHORT BREAK</th>
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<tbody>
<tr>
<td>V6-S1 Challenges and Issues to Product Development for Gene Therapy</td>
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<td>RA, AC</td>
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### VENUE 7
Room 102

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<tbody>
<tr>
<td>V7-S1 Implementing Quality Management System (QMS) in Your Trials and Understanding the Purpose and Concept</td>
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<td>RA, DM, CR, ST, PM, AC</td>
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### VENUE 8
Room 703

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<tbody>
<tr>
<td>V8-S1 Target Product Profile - Better Way to Build Up R&amp;D Management Plan</td>
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<td>RA, PM</td>
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### EXHIBITION
Reception Hall

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<th>SHORT BREAK</th>
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<tbody>
<tr>
<td>V8-S2 The Latest Regulatory Trend and Counter Measures for Data Integrity</td>
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<td>RA, CMC</td>
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### Networking Reception at Reception Hall

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<thead>
<tr>
<th>COFFEE BREAK (RECEPTION HALL)</th>
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<tbody>
<tr>
<td>V5-S2 Oligonucleotide Therapeutics as Next Generation of New Medicine - Regulatory &amp; Quality Considerations</td>
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<td>RA, PM, CMC, AC</td>
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<th>LUNCH BREAK</th>
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<tbody>
<tr>
<td>V6-S2 Think about the Exit Strategy in Drug Discovery Processes of Academia</td>
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<td>RA, PM, AC</td>
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<th>COFFEE BREAK (RECEPTION HALL)</th>
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<tbody>
<tr>
<td>V7-S2 Use and Application of Real World Data/Evidence based on Next Generation Medical Infrastructure Act</td>
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<tr>
<td>CR, ST, AC, HO, MA, Digital</td>
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<tbody>
<tr>
<td>V8-S2 Let’s Discuss How Our Values Are Related to Life and Work!</td>
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### Post-Lunch Session

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<thead>
<tr>
<th>COFFEE BREAK (RECEPTION HALL)</th>
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<tbody>
<tr>
<td>V5-S3 New Pharmaceutical Technical Innovation - Continuous Manufacturing and its Driving Forces</td>
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<tr>
<td>V6-S3 Patient Empowerment: Status Update of Patient Participation Support Program</td>
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<th>COFFEE BREAK (RECEPTION HALL)</th>
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<tr>
<td>V7-S3 Various Initiatives after Marketing of Regenerative Medical Products</td>
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<td>RA, AC, Or Safety</td>
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<th>LUNCH BREAK</th>
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<tbody>
<tr>
<td>V8-S3 Leader of You! Are you OK for Your Motivation? How About Your Team Member? Let’s Get Together and Dialogue How We Maintenance Motivation!</td>
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### Short Break

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<tr>
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<tr>
<td>V5-S4 What ICH E17 Would Bring to Global Drug Development</td>
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<tr>
<td>V6-S4 New Drug Development Approaches to Realize Precision Medicine (Registry Study, Platform Trial)</td>
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<tr>
<td>V7-S4 Future of e-Labeling in Japan</td>
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<td>RA, CP, AC, Or Medical affairs and Medical information</td>
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<tr>
<td>V8-S4 Let’s Discuss How Our Values Are Related to Life and Work!</td>
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### SPI Engage and Exchange ‘LET’S CHAT! - SPECIAL CHAT SESSION - AT RECEPTION HALL

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<tr>
<th>COFFEE BREAK (RECEPTION HALL)</th>
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<tbody>
<tr>
<td>V5-S5 Responses Against the Global Threat of Antimicrobial Resistance</td>
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<tr>
<td>V6-S5 Various Issues Related to HTA -Looking at on a Micro and Macro Scale-</td>
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<td>Or, RA, RA, CR, AC</td>
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<tr>
<td>V7-S5 Pharmacovigilance Activities in Japan, the USA, and Europe – How to Utilize Real World Data-</td>
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<tr>
<td>V8-S5 Improving Clinical Operation and Data Quality - eSource Is Transforming Clinical Trials --</td>
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<td>CR, DM, AC</td>
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### The Latest Trend of Vaccine Policy, Regulatory Regulation in Japan, the United States and Europe

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<th>COFFEE BREAK (RECEPTION HALL)</th>
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<tr>
<td>V5-S6 Evidence Generation under Japan’s New Clinical Trials Act</td>
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<tr>
<td>V6-S6 Paradigm Shift in Pharmacovigilance Activities - How to Conceptualize Research Questions-</td>
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<tr>
<td>V7-S6 Approaches to Implement Revision for New Format of Labeling and Discussion How to Provide Information by Other Materials</td>
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<td>RA, CP</td>
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**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
- 16:00-17:00: 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.

**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.
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.

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 Services 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
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
Takuko Sawada
Program Chair
Director of the Board, Executive Vice President, Shionogi & Co., Ltd.

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

AWARD WINNERS:
Outstanding Contribution to Health Award
TBA
TBA

Excellence in Service Award
TBA
TBA

Leader of Tomorrow Award
TBA
TBA

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

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

COFFEE BREAK 15:00-15:30

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

In this keynote lecture, the perspective on the genomic medicine and the innovation strategy for drug development will be described, from the viewpoints of the integrated computational life science.

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

**INTERNATIONAL CONFERENCE ROOM** 16:15-17:45

**New Challenges for Innovation –ICMRA Innovation Project**

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

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

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

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

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

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

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

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

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

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

**NETWORKING RECEPTION**
Reception Hall 18:00-19:30

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SESSION 1 9:00-10:30

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

The Experience of Global Phase 1 Study (Japan/US) –Oncology Area–

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

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

In recent years, First in Human (FIH) study is often carried out in the US, and the development in Japan is started later based on the data of FIH study in the US. In order to lead global development, it is necessary for Japanese sites to join global phase 1 study with US sites.
In this session, the US expert will introduce the experiences of global phase 1 studies in the US, and the Japanese expert will introduce the experience of global phase 1 study management from Japan. Finally, Japanese academia experts and US experts of Phase 1 will discuss about the way and efficiency of global phase 1 study including sites in Japan.

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

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

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

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

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 Pharmaceutical Science, 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, Pharmavigilance, Astellas Pharma Inc.

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

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

Utilize Know-how and Experiences of Medicine/Device Development Obtained through Investigator Initiated Clinical Trials for Forthcoming Japan Venture Promotion

Related Interest Area(s): ALL
Level: Intermediate

SESSION CHAIR
Fumiki Kobayashi, PhD
President, CTD Inc.

Nowadays, about 50% of new therapeutics approved in US are originated by small bio-tech company and academia.
In Japan, drug discovery and research work by academic organization have been expected to make up for the delay of venture promotion.
“Investigator-initiated clinical trials for registration (IICT)” have been available since 2003 with the revision of the Pharmaceutical Affairs Law (at that time).
So far, it has been approved by many drugs and medical devices developed by the IICs, 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
Toshiaki 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, MPH
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 Yuiji, MD, PhD, FACP
Project Associate Professor, Project Division of International Advanced Medical Research, The Institute of Medical Science, The University of Tokyo

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

**Why the New Data-Rich Collaborations May Risk Harming Us More than Helping Us**

Kit Howard, MS
Director of Education, CDISC

**Therapeutic Needs of Older Patients in the Era of Mobile Health**

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

**Applications and Challenges of Machine Learning in Clinical Trials for Safety, Efficacy, and Operational Integrity Endpoints**

Kelci Miclaus, PhD
Advanced Analytics R&D Senior Manager, SAS Institute Inc., JMP Division

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

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

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

**SESSION CHAIR**

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

In recent years, the development of products for genetic therapy became popular all over the world, and concrete discussions on commercialization have been carried out recently in Europe and US.

On the other hand, in using genetically modified products, Japan and the EU have ratified the Cartagena Protocol, and in Japan it is necessary to consider environmental impacts on biosafety based on regulations by Japan original law.

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

**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**

Norikage Nagao, MPHarm, PMP
Clinical Development Department, Pharmaceutical Division, Japan Tobacco Inc.

**Quality Tools and Skills for Clinical QMS - A Practical Application in Case Studies -**

Hirotaka Inoue, PhD, MBA, Master Black Belt of Six Sigma
Head, Leading Changes Office, GlaxoSmithKline K.K. / JPMAdaScience 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
Yosio 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 Oceania
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 Machizuki, 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

**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.

**Use and Application of Real World Data/Evidence Based on Next Generation Medical Infrastructure Act**

**Related Interest Area(s):** CR, ST, AC, O: HO, MA, Digital  
**Level:** Beginner, Intermediate  

**SESSION CHAIR**
Shunichi Takahashi, PhD  
Director, Head of Open Innovation Center Japan, Bayer Yakuhin, Ltd.

**Next Generation Medical Infrastructure Act become effective on 11th May 2018**  
and we are able to use medical related big data under proper information  
management.  
In this session, presenters will share overview of real world data/evidence  
which is being established under all Japan system and important topics of Next
In addition, as cases from pharmaceutical company, some presenters will share practices of data application using EHR (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.

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

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

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

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

**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**
Shuiji 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 the FDA and overseas from various themes were selected for poster session through a rigorous selection process. Current hot topics will be presented and discussed.

**POSTER SESSION**  
**Reception Hall 13:30-14:00**

**[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:  
We conducted 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 into 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 Inset**
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 “necessity 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.
  - 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 perspective the results of the session was held between COM Community and Hokkaido University Hospital.

Results:
- To minimize GAPS which were identified in 2016 COM Community, based on PLAN-DO-CHECK concept, actual cases for DOs and CHECKs by each member were shared and discussed. Here are some examples.
  - Gaps in study-start-up:
    - PLAN: Have sessions to advance to understand role and 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 staff will continue to maintain it.
    - 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 Protocol:
    - PLAN: Implement risk assessments in clinical study
    - DO: Implement pre-assessments on clinical sites based on various database for past site performances in site selection phase. Perform regular risk assessments on site performance by utilizing EDC metrics and other tracking tools.
    - CHECK: Risk assessments based on metrics parameters already have become popular and standardized in each company, however, since risk indicators have been set by central, customization of the parameters or methods of the assessment according to study specific aspects is not possible.

In the GAP discussion, the needs of deep understanding of site view and environment were recognized, and as a purpose of understanding clinical site’s view “Knowing each other” session was held with Hokkaido University Hospital. 10 staff from Hokkaido Univ Hospital and 6 COM members had discussion based on the questionnaires from site 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 understand site’s view and 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 there 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 provided 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 MID-NET information databases are available in other regions as well; FDA Sentinel in the U.S., EMA Enevpe in the European, 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 trial. When 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 for their 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 complexities.

Full Description:
Pharmacovigilance (PV), demands a high degree of regulatory expertise. PV across the EU and US have changed to be more stringent 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.

Safety reporting in this region varies significantly. Some countries have relatively less stringent 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 region.

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 India, China, 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 submissions are not limited to toxicities are being expanded across various aspects 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 diseases. Share real world evidence on how 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 made decision by reference to information come from big data analysis. Many diseasespecific models lack in evidence to test operational models in neurology. However, there is a substantial difficulty in choosing/accessing an optimal model or choosing measurements which would be truly informative of therapeutic efficacy. We present a practical 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

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

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

Full Description:
In recent times, there has been a very high level of public interest and active debate regarding the regulation of medical devices especially with regards to the pharmacovigilance aspect. This is in light of the safety concerns originating from poly-implant-prosthesis (PIP) breast and metal-on-metal hip implants. Although medicines and devices are regulated under European Union and the United States law, the regulatory regimes are very different, and some have argued that features of the pharmaceutical regime should be applied to medical devices. The United States and the European Union approach these challenges in different ways. Whereas the United States has always relied on a strictly centralized process through one 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 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 CRCCs 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, Tsumura 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

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 Shibatsuchi, 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, Medical Writing
Level: Beginner, Intermediate

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

Immuno-Oncology (I-O) is a unique and innovative approach to treat cancer patients. And, I-O agents pose unique challenges to the design of clinical trials 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 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 Biostatistics, 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
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)

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

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
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
Minoru Niso
Acute Care Diagnostics Product Manager, Instrumentation Laboratory, I.L. Japan Co., Ltd.

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

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

TBD
Piotr Feliks Grzywacz
Founder & CEO, Pronoia Group

SESSION 4 16:00-17:30
V1-S4 Room 605/606 16:00-17:30
How Can We Define and Manage Quality Goals
Related Interest Area(s): RA, 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, Kattnner-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, CR, CR, PM

SESSION CHAIR
TBD
Panel Discussion
All Session Speakers
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 Pharmaceutometrics, 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 & Pharmaceutometrics 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

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

**Future of e-Labeling in Japan**

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

*Level: Intermediate*

**SESSION CHAIRS**

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

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

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

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

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

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

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

**Panel Discussion**

All Session Speakers and

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

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

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

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**SESSION CO-ORGANIZERS**

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

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

This session is workshop style and use Japanese.

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

Let us get together and dialogue them!

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

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

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DIA EUROPE RETURNS TO VIENNA!
DIAglobal.org/Europe2019
## Let’s Chat! “WHAT’S THE DIA WORLD 2018”

### Reception Hall

**Level:** ALL  
**SESSION CHAIR:** Keiichi Inaizumi, MSc  
**Manager, Clinical Operations and Compliance 1, Development Operations, Pfizer Japan Inc.**  
**FACILITATORS:** DIA Japan Content Committee / Community

### Related Interest Area(s): ALL

### List of Topics

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| 1  | Clinical Operations & Monitoring | Let’s Discuss Ideas for Getting Out of “Error Free Seeking Mind”? | Clinical Operations & Monitoring (CDM) Yukihiko Matsuda, MSc  
Eli Lilly Japan K.K.  
Clinical Data Management (CDM) Misato Kuzawa K.C.  
Eli Lilly Japan K.K. | RBA is required in Quality Management System. For the members who pursed 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) Minor Inaizumi  
L. Japan Co.,Ltd.  
Project Management (PM) Noriko Fujimera, M.Sc., RN, DCNSL, 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 bright future with your new friends. |
| 3  | Regulatory Affairs (RA) Project Management (PM) | What is an Efficient Role Sharing in Developmental Team? | Regulatory Affairs (RA) Yoshinori Higashi  
CTD Inc.  
Project Management (PM) Noraki Nagao, MPHarm, PMP  
Japan Tobacco Inc. | Concentrating a wide range of specialized knowledge is indispensable for drug development. Is there anything struggling and deciding 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) | CH-E17 - Let’s Discuss Changes in Clinical Development Strategy - | Regulatory Affairs (RA) Kazumi Sunamura  
Pfizer Japan Inc.  
Pharmacovigilance & Labeling (PV) Rei Maida  
Eli Lilly Japan K.K. | Do you understand E17 correctly? The more you think about it, the more you know it, don’t you that the mystery deepens? How do you evaluate the safety of Pooled Population? 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) Hirokata Inoue, PhD, MBA  
GloboSmithKline 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 understanding of the tools and the statistical background of the tools together! |
| 6  | Clinical Strategy (CS) Clinical Strategy (CS) | Let’s Talk about Measures of Treatment Effect on Survival Analysis Including Novel Ones that Become a Hot Topic Recently | Statistics Hirokichi Ujii  
Nippon Boehringer Ingehelm  
Clinical Strategy (CS) Kazunori Kamnuri, 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) Sachiko Nishida, PhD  
Novartis Pharma K.K.  
Patient Engagement (PEC) Yoshikata Funaya  
MDS 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 what should be medical communication focusing on patients. |
| 8  | Patient Engagement (PEC) Clinical Operations & Monitoring (CDM) | If My Family or I Join Clinical Trial…? | Patient Engagement (PEC) Keiko Ebihara, PhD  
Amicus Therapeutics K.K.  
Clinical Operations & Monitoring (CDM) Noriko 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! |
MDS K.K.  
Pharmacovigilance & Labeling (PV) Kazuko 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 | Six Sigma (SS) Statistics | Scope of Work and Career Pass to Data Scientist from Statistician - Drug Discovery to Post-marketing | 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 statistician 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 shared and all speakers of part 1 and 2 sessions will have a panel discussion.

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

Providing Information to Patients Who Participate in Clinical Trials: Efforts by Trial Sites
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 - 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 to Patients in Industries
Junichi Nishino, MSc, RPham
Head, Regulatory Affairs Functions, Novartis Pharma K.K.

What Kind of Drug Information Are Needed by Patients? – Current Issues & Future Perspective from Patients' Point of View -
Ikuko Yamaguchi
Board Chairperson, COML

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 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 Kozaïwa, MD
VP & Vice Head, Japan Development, GlaxoSmithKline K.K.
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
TechnoSuruiga Laboratory Co., Ltd.

Panel Discussion
All Session Speakers

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

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

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
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

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.

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
Counselor for Pharmaceutical Affairs, Minister’s Secretariat, Ministry of Health, Labour and Welfare (MHLW)

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

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

DAY 3 | TUESDAY | NOVEMBER 13 23
Mitsuo Hayashi, MSc, RPh
Director & Head, Clinical Enablement, MSD K.K.

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

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

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

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

Bryan McDowell, MSc, MBA

**Application of Mobile Health in Clinical Development**

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

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

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

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**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

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

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

**Panel Discussion**

All Session Speakers

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**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 Saitoy, 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 Otto, PharmD, MBA
VP, Japan Vaccines Country Lead, Pfizer Japan Inc.

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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

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

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

**Panel Discussion**

All Session Speakers
“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
Takuro Yamaguchi, PhD
Professor, Biostatistics, 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

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

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

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

Panel Discussion
All Session Speakers
DAY 3 | TUESDAY | NOVEMBER 13

DIAmond Sessions / Closing Remarks

DIAmond Session 2
INTERNATIONAL CONFERENCE ROOM  14:00-15:30

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

PMDA Town Hall
Related Interest Area(s): ALL
Level: ALL
SESSION CO-CHAIRS
Takuko Sawada
Director of the Board, Executive Vice President, Shionogi & Co., Ltd.
Naoki Uchida MD, PhD
Professor, Department of Clinical Pharmacology, Clinical Research Institute for Clinical Pharmacology and Therapeutics, Showa University Karasuyama Hospital

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

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

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

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医薬品・医療機器等開発のグローバル化が急速に進んでいる状況において、革新的な医薬品・医療機器等をいち早く患者さんに届けるために我々がすべきことは何か。また、世界的イノベーション創出をどのように連携の下で推進していくべきか。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、他国の方々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カーストは様々であり、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きたいと考えています。

本年の基調講演では、オーストリアのGuido Rasi氏長官、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垣根を越える議論を展開いたします。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チャセッション、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。

日本語・英語間の同時通訳あり

【第二放送会期】

詳しくは、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
### 11月11日（日）
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<tr>
<td>9:30-12:00</td>
<td>オリエンテーションの展示会場 (12:00-13:00)</td>
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<tr>
<td>12:00-13:30</td>
<td>プレオーフニング</td>
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<td>13:30-13:45</td>
<td>開会の挨拶</td>
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<td>13:45-14:00</td>
<td>大会長挨拶</td>
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<td>14:00-14:15</td>
<td>2018 DIA JAPAN'S INSPIRE REGIONAL AWARDS授賞式</td>
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<tr>
<td>14:15-15:00</td>
<td>K1 基調講演 (EMA / Professor Guido Rasi)</td>
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<tr>
<td>15:00-15:30</td>
<td>コーヒーブレイク</td>
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<td>15:30-16:15</td>
<td>K2 基調講演 (東京大学医科学研究所 / 宮野悟先生)</td>
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<td>16:15-17:45</td>
<td>DI [Diamond Session 1] Innovationへの新たなチャレンジーICMRA Innovation Project~</td>
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<td>17:45-18:00</td>
<td>ショートブレイク</td>
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<td>18:00-19:30</td>
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### 11月12日（月）
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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

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<th>第5会場</th>
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<tr>
<td>公募演題セッション</td>
<td>遺伝子治療用製品開発への挑戦と課題</td>
<td>次世代の薬物 - 核酸医薬品 - どうする？その規制と品質保証</td>
<td>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</td>
<td>ICH E17がグローバル開発にもたらすもの</td>
<td>素食・植物性食品のリスクと対策</td>
<td>日米におけるワクチン政策、薬事規制の最新動向</td>
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<td>情報交換会</td>
<td>データの安全性確保に向けた新たな統合データベースの開発</td>
<td>アカデミア創薬の出口戦略を考える</td>
<td>日本におけるe-Labelingの将来</td>
<td>日米におけるワクチン政策、薬事規制の最新動向</td>
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<tr>
<td>情報交換会</td>
<td>臨床試験におけるQuality Management System ～開発レベルでの実装～</td>
<td>次世代医療基盤を踏まえたリアルタイムデータの活用</td>
<td>日米におけるe-Labelingの将来</td>
<td>素食・植物性食品のリスクと対策</td>
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<tr>
<td>情報交換会</td>
<td>Target Product Profile相関、マネジメント - りより良い研究開発計画を目指して</td>
<td>データの完全性確保に向けた最近の動向</td>
<td>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</td>
<td>素食・植物性食品のリスクと対策</td>
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11月11日(日)

9:00-9:30 スチューデントセッション受付
9:30-12:00 スチューデントセッション
11:45-19:30 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」
17:30-18:00 閉会の挨拶

講演資料のウェブサイト掲載
プログラム参加登録者は、会議開催の約1週間前にDIAウェブサイトに掲載する講演資料を閲覧できます。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、これに限ります。
11月10日（土） 終日
11月11日（日） 午前8時以前、午後8時半以降
11月12日（月） 午前8時以前、午後8時以降
11月13日（火） 午後8時以前、午後6時半以降

特に公表しない限り、本会議にて発表される内容は発表者本人の見解であり、所属する組織、あるいはDIAのものとは限りません。
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。

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。
承認審査を通じた医薬品開発の理解

102会議室

承認審査を通じた医薬品開発の理解

関連領域：薬事、アカデミア
レベル：初級

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

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

1. 医薬品の承認審査を考える際の留意点について講演
2. 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。
3. 各グループの承認可否を発表、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。

1日目 | 11月11日（日）

### 開会の挨拶および基調講演 / DIAmond Session 1

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<td>国際会議場</td>
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<td>13:30-13:45</td>
<td>開会の挨拶</td>
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<td>13:45-14:00</td>
<td>第15回DIA日本年会大会長</td>
<td>国際会議場</td>
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<td>14:00-14:15</td>
<td>2018 DIA Japan’s Inspire Awards授賞式</td>
<td>国際会議場</td>
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<td>15:30-16:15</td>
<td>基調講演 2</td>
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### 開会の挨拶

- **開会の挨拶**
  - 国際会議場 13:30-13:45
  - DIA Japan
  - 植村 昭夫  
  - DIA Advisory Council of Japan議長 / 大塚ホールディングス株式会社
  - 小林 和道  
  - DIA Chair/ Bayer AG

- **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

### 基調講演 1

- **座長**
  - 独立行政法人 医薬品医療機器総合機構
  - 近藤 達也

- **座長挨拶**
  - エクスペリエンスの枠組みにおけるホライゾンスキャニングの手順を含むプレイベントの枠組み
  - 今後の研究に向けた新しい視点を提供する

- **プレゼンター**
  - DIA Chair/ Bayer AG
  - Joseph Scheeren

### 基調講演 2

- **座長**
  - グラクソ・スミスクライン株式会社
  - 髙橋 希人

- **座長挨拶**
  - エクスペリエンスの枠組みにおけるホライゾンスキャニングの手順を含むプレイベントの枠組み
  - 今後の研究に向けた新しい視点を提供する

- **プレゼンター**
  - DIA Chair/ Bayer AG
  - Joseph Scheeren

### DIAmond Session 1

- **座長**
  - Health Products Regulatory Authority (HPRA)
  - Rita Purcell

### The report form WS1; Analysis of Global Best Practice in Horizon Scanning Methodologies

- **座長**
  - 独立行政法人 医薬品医療機器総合機構
  - 近藤 達也

- **座長挨拶**
  - エクスペリエンスの枠組みにおけるホライゾンスキャニングの手順を含むプレイベントの枠組み
  - 今後の研究に向けた新しい視点を提供する

- **プレゼンター**
  - 独立行政法人 医薬品医療機器総合機構
  - 近藤 達也

- **パネルディスカッション**
  - DIA Chair/ Bayer AG
  - Joseph Scheeren
  - DIA Chair/ Bayer AG
  - Guido Rasi
  - European Medicines Agency (EMA)
  - Agnès Saint-Raymond
  - Health Canada
  - Pierre Sabourin
  - Danish Medicines Agency
  - Nikolai Brun
  - FDA
  - John Graham
Global Phase 10の経験(米国の施設の実態とmanagement方法) -癌の開発を中心に-

座長
第一三共株式会社
齋藤 宏暢

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

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

日本と米国の病院におけるGlobal Phase 1の経験
第一三共株式会社
野口 泰

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

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

医薬品リスク最小化資材への病院薬剤師の理解と期待
虎の門病院
林 昌洋

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サルタント懇談会」が開催され、NGSを用いたゲノム解析結果に基づいたがんゲノム医療の推進に向けた報告書がまとめられている。

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。

東京大学大学院
織田 克利
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
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
国立がん研究センター

柳原 理子
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

国立研究開発法人 国立がん研究センター

がん遺伝子パネル検査に関する規制の考え方
国立がん研究センター

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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

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で選出された。演題基準である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、フロアとの両方向での議論を行う時間も用意される。

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

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

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

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、遺伝子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報道が見られることになってきた。一方で、遺伝子組換え製品の安全性・効果性を考慮する必要がある。EUは、国内で導入された臨床試験の事例に基づき、安全性・効果性の確認を求める規制を適用する。このため、研究者に取り組むべき課題は多く、その中でも特に重要視されているのは、治験の実施、特に安全性面でのチェックポイントの設定である。本セッションでは、国内外で開発されている遺伝子治療用製品の開発事例とその課題について議論を行う。

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・スミソックライン株式会社
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。今回現場レベルでは試行錯誤が続いているが、 Howe toのみにとらわれず、根本的な考え方が重要である。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リアルベースのQMS導入事例を紹介する。

医薬品の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。薬剤のGo/no-go判断を行うため、医薬品の研究開発の4つのステージーを設定し、それぞれの段階においては、研究の推進に向けたチェック項目を設けている。本セッションでは、研究開発の過程におけるメディカル情報の役割とその重要性について議論を行う。
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 恵
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 Quarrarolo
European Medicines Agency (EMA)
Guido Rasi
革新的な技術、グローバル化、国民の安全意識の向上などに対応するため、各国規制当局は新たな薬事規制の導入や既存の制度の見直しを進めていく。本セッションでは、世界的な薬事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)
Agnés 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 美智子
Recent Trend of Pharmaceutical Regulation in Oceania
Medsafe
Alison Cossar
パネルディスカッション
本セッションの講演者および
FDA
John Graham
Health Products Regulatory Authority (HPRA)
Rita Purcell

V2-S2 607会議室 11:00-12:30

疾患レジストリデータ利活用の最新の動向
関連領域: 全領域
レベル: 初級
言語: 日本語のみ
座長
東京大学大学院
平川 幸弘
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提供する。

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 恵
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例
日本イーライリー株式会社
水本 聡太

V4-S2 609会議室 11:00-12:30

審査報告書の読み方と今後のあり方
関連領域: 薬事、安全性、PM、アカデミア、Medical Writing
レベル: 中級、上級
言語: 日本語のみ
座長
東京大学大学院
平川 幸弘
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, 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.
Results: To minimize GPs 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, site specific information should be maintained by CRA.

CHECK: Some sites understand the principle. By the action of not customizing work sheet, site staff have become to refer protocol directly. Some sites still request customization by CRA.

<Gaps in Process >

PLAN: Implement risk assessments in clinical study.

DO: Provide a list of potential clinical risks 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 been 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 need 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 site staff in advance. In the session, the main 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.

Conclusions:

In the ongoing discussions on actual PDCA cases to minimize GPs, 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 GPs with PDCA Cycle concept, and deep dialogues to exchange opinions, it is considered that there are lots of opportunities for us to improve current situation and establish ideal clinical trial environment.

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

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

Dinah Duarte

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.

Many stakeholders in medicines development have been making decision by reference to information from big data analysis. Many diseasespecific 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 research 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 complexities.

Full Description:

Pharmacovigilance (PV) demands a high degree of regulatory expertise. PV activities in the EU and US have continued to change and evolve as the public asks for greater transparency and protection. However, it has been a continuous challenge to harmonize the PV regulations in Asia due to diverse geographical, cultural and clinical practices in this region. Nonetheless, as the volume of clinical trials being conducted in the Asian countries has been growing rapidly in recent years as emerging markets grow, they are moving towards a trend of higher quality requirements with their tougher regulations. This increased demand necessitates an intensified focus on PV and drug safety in this region. PV in Asia has become an important public health issue as regulators, drug manufacturers, and hospitals 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 aspects in the method of PV. This presentation will focus on differences in safety reporting requirements in clinical trials and post marketed products in EU, US and AS; 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 from big data analysis. Many diseasespecific 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 research might not be necessarily successful, because medical information databases don't have crucial data such as biomarker values and information about preclinical subjects.
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, the regulatory systems 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.
プラティックのためには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、革新的な技術を用いた治療施設や医師の経験の再定義、eConcentやeLabelなどデジタル活用に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
日本イライラリー株式会社
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治療法の1つとして確立されている。その特徴の1つとして、効果の遅発性などが議論されており、2016年に発行された後期臨床試験の考え方に関するガイドラインでは、統計学的に、比例ハザード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、がん免疫療法に関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、石油製品や食品などの他の業種ではメジャーな生産方式だ。製造環境中に原料や溶媒を連続的に供給し、最終製品を継続的に取り出す生産方式のことを指す。医薬品ではごく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の開発（仮題）
岐阜薬科大学
田原 貴子

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ている。患者・市民参画を推進していくためには、参加する患者・市民に必要な知識とスキルを提供する取り組みが重要である。国内外で産官学の様々な試みがなされており、その事例をもとに、本セッションでは、患者参画推進の取り組みを紹介し、その意義、実績、課題などについて議論する。

Patient Engagement - a European Perspective
MSD
Paul Robinson

演題未定
一般社団法人日本難病・疾患団体協議会
森 幸子

演題未定
国立研究開発法人 日本医療研究開発機構
勝井 恵子

パネルディスカッション
本セッションの講演者
再生医療等製品の市販後における様々な取り組み

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、再生医学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するとともに、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

近年、働き方のダイバーシティの意識が高まり、人々の仕事、キャリア形成を含む「生き方」への考え方が変わりつつあります。変化の激しい時代だからこそ、あなたが自ら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を広げてみませんか。本セッションでは、元グーグルの人材開発・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。
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ら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いるため、その有用性が発表されている。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いるため、その有用性が発表されている。

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 博夫
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化するか、またそれら試験を用いた承認申請が各国においてどのような影響を受 けるか、について、日欧米中の各局の専門家に議論をし、当ガイドラインがグローバル開発に与える影響を論じる。

E17 Implication for Global Drug Development: US Perspective
Bayer AG
Joseph Scheeren
E17 Implication for Global Drug Development: China Perspective
Shenyang Pharmaceutical University
Ling SU
E17 Implication for Global Drug Development: Statistical Consideration
ファイザー株式会社
河合 統介
パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
中村 龍太

V6-S4 101会議室 16:00-17:30
Precision Medicineの実現に向けた新たな医薬品開 発アプローチ
関連領域: 全領域
レベル: 初級
座長
東京大学大学院
平川 晃弘
個々の患者により適した医療を提供し患者のメリットをまず考えると いう観点から、詳細な疾患Subtypeそれぞれに最適な治療を提供する Precision Medicineが提唱されている。従来の臨床試験では基本的に単 独の試験治療・集団・疾患が対象であり、より詳細なSubtype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などのデザイン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 薬事医療機器総合機構
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いるが、今後も電子医療カルテや教育用資料を電子的にリンクさせ、パーソナライズまたは多様化された添付文書が入手可能になれば、患者さんの治療や薬剤への理解が改善され、最終的に安全性向上に寄与する。このセッションでは、日本のe-labelingの将来と紙の添付文書の継続的な役割について議論する。

e-labelingの将来～Opportunities and Challenges～グローバルの立場から
Pfizer Inc.
Shimon Yoshida
日本における添付文書の電子化に関する検討の現状—行政の立場から—
厚生労働省
関野 秀人
パネルディスカッション
本セッションの講演者および国立循環器病研究センター
山本 晴子

V8-S4 703会議室 16:00-17:30
リーダーのあなた！ あなたのモチベーションは大丈夫？チームメンバーは？
さあ！ここで一緒に考えてみませんか？
関連領域: 全て
レベル: 初級
言語: 日本語のみ
オーガナイザー
大阪大学医学部附属病院

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・講習会として開催されています。
以下のプログラムのうち、4時間以上受講した参加者には、希望により修了証を発行します。
11月11日（日）
・基調講演1、基調講演2
・DIAmond Session 1
11月12日（月）
・セッション1～4
・11月13日（火）
・セッション5～6
・DIAmond Session 2 / 3
修了証の発行を希望される方は、年会終了後、2018年11月20日（火）までに受講証明申請書をDIA Japan <Japan@DIAglobal.org>宛にメール添付にて提出してください。受講証明申請書は、下記リンクよりダウンロードできます。
受講証明申請書を受理した後、申請者の参加の有無及び申告された受講時間を確認のうえ、修了証を送付します。

日本薬剤師研修センター認定の集合研修会
本年会の基調講演1-2、セッション1～6（11月12日のセッション1～4、11月13日のセッション5～6）、DIAmond Session1～3は、公益財団法人日本薬剤師研修センターより認定された集合研修会となっており、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
テーマの説明

このディア会議では、医薬品開発を専門とする企業、大学、行政、医療機関、PIPMなどの関係者を対象に、ディアのサイエンスをテーマにしたディバーシティとイノベーションを促進するための活動を行います。

参加を機に、新しい視点を見つけることができる一時です。

参加の条件

・年会に参加する方には、ディア会議の参加者一覧を提供するものとします。

参加者一覧

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参加者の対象

企業、大学、行政、医療機関、PIPMなどの関係者

参加者のメリット

・新しい視点を見つけることができる一時です。

参加者の注意点

・年会に参加する方には、ディア会議の参加者一覧を提供するものとします。

参加者の対応

・参加者の対象は、企業、大学、行政、医療機関、PIPMなどの関係者です。

参加者の応援

・参加者の対象は、企業、大学、行政、医療機関、PIPMなどの関係者です。

参加者の支援

・参加者の対象は、企業、大学、行政、医療機関、PIPMなどの関係者です。

参加者の感謝

・参加者の対象は、企業、大学、行政、医療機関、PIPMなどの関係者です。

参加者の情報

・参加者の対象は、企業、大学、行政、医療機関、PIPMなどの関係者です。

参加者の連絡

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参加者の資料

・参加者の対象は、企業、大学、行政、医療機関、PIPMなどの関系者です。
会議室：V1-S5  9:00-10:30

患者さんが治療で求める情報、コミュニケーションとは何か？それをどう提供していくか？（第1部）

座長：国立がん研究センター 藤原 康弘

座長： MSD株式会社 古屋 義方

患者さん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、患者さんが治療で求める情報、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、日本でも治療情報の開示や、Patient Lay Summaryの提供等が行われている。本セッションでは、治療参加時、参加中、及び参加後で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、それの提供方法について議論を行う。

治療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

治療に関する患者さんへの情報提供、コミュニケーション：治療実施機関の考え（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

患者さんが治療で求める情報、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

患者さんが求める治療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

会議室：V2-S5  9:00-10:30

医薬品リテラシーの向上への取り組み～国民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）

座長：くすりの適正使用協議会 俵木 登美子

座長：ノバルティスファーマ 株式会社 西野 潤一

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

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

本セッションでは、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、企業の取り組み、課題等について議論を行う。
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、治療薬に加入、創薬シーズ、さらにはコンビナゾ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
東京大学医学研究科ヘルスインテリジェンツセンター
井元 清哉

腸内細菌叢と加齢（仮題）
大阪市立大学/東京大学医学研究科
藤本 康介

腸内フローラ解析と代謝物分析サービスの活用
株式会社テクノルガ・ラボ
久田 貴義

パネルディスカッション
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、サービス、適正使用にいたる様々な具体的な課題が進められている。本年会では、AMRに対する臨床研究開発を中心として、グローバルな視点を含め、いかに効率をとるか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—アカデミアができること—
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 —ミクロとマクロの視点から—

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る。

HTAの最新動向を紹介するだけでなく、HTAを行ううえで必要な事項、費用対効果分析のみならず疾患負担や医療費への影響などの多くの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。

HTAの最新動向とRWDの生活用事例
京都大学
川上 浩司

HTAの生活用事例
|
欧米のHEOR機能
Shionogi Limited
Mark Hill

メディカル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ョシアン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き、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视活動
|
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—eSourceはClinical Trialをどう変える—

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
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、将来的な医療技術・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の使用を増やそう求めています。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るようです。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

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

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の提供等が行われている。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。

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？－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、クロール式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の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バイオメトリー、その制度の違いが予防接種進歩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.

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
広居 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は、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
塩原 尚巳
欧米におけるリアルワールドエビデンス：その方向性と事例紹介
武田薬品工業株式会社
宇田 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－リサーチ・クエスチョンをいかに考えるか－
関連領域: 安全性
レベル: 初級
座長
日本イーライリリー株式会社
前田 玲
PMDAより本年1月発出された文書「製造販売後調査等の実施計画の策定に関する検討の進め方について」により、医薬品安全性監視活動の検討の進め方が大きく変革している。治療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、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
Pfizer Japan Inc.

Andrew Otoo
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（First Wave）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の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けるインタビュー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
篠村 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
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。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。

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

コーヒーブレイク
15:30-16:00

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
内田 直樹

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

パネリスト：
独立行政法人 医薬品医療機器総合機構
ワクチン等審査部長
紀平 哲也
独立行政法人 医薬品医療機器総合機構
組織運営マネジメント役
佐藤 大作
独立行政法人 医薬品医療機器総合機構
医療機器審査第一部長
高江 慎一
独立行政法人 医薬品医療機器総合機構
医療情報活用部長
宇山 佳明
独立行政法人 医薬品医療機器総合機構
上席審議役（新薬審査等担当）
宇津 忍
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Administrative fee that will be withheld from refund amount:

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

All cancellations must be in writing and 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 canceling 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.diajapan.com/terms-and-conditions?productID=724018)

PAYMENT OPTIONS

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

☐ BANK TRANSFER:

You will receive an invoice with bank information detail by email after registration completion.

All local and overseas charges incurred for the bank transfer must be borne by payer.

☐ CREDIT CARD (VISA, MASTERCARD OR JCB ONLY)

☐ 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
e-mail: Japan@DIAglobal.org
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
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.

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

ELIGIBILITY FOR YOUNG PROFESSIONALS RATE
Professionals working in health product development, regulation and related fields, under the age of 35

YOUNG PROFESSIONALS REGISTRATION FEE

<table>
<thead>
<tr>
<th></th>
<th>8% TAX INCLUDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEMBER Industry</td>
<td></td>
</tr>
<tr>
<td>Super Early-bird (until Sept 11)</td>
<td>¥60,912</td>
</tr>
<tr>
<td>Early-bird (from Sept 12 to Oct 22)</td>
<td>¥64,152</td>
</tr>
<tr>
<td>On and after Oct 23</td>
<td>¥70,632</td>
</tr>
<tr>
<td>NON-MEMBER Industry</td>
<td></td>
</tr>
<tr>
<td></td>
<td>¥81,972</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>8% TAX INCLUDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membership</td>
<td>¥18,900</td>
</tr>
<tr>
<td>2-Year Membership</td>
<td>¥34,020</td>
</tr>
</tbody>
</table>

Please complete 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

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/

Sun Route Hotel Ariake
Address: 3-6-6 Ariake, Koto-ku, Tokyo 135-0063
Telephone: +81-3-5530-3610

DIA Terms and Conditions

CANCELLATION POLICY: On or before November 4, 2018

Administrative fee that will be withheld from refund amount:

Member or Nonmember ¥20,000

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

Cancellations must be in writing and receive 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.

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By signing below I confirm that I agree with DIA’s Terms and Conditions of booking. These are available from the office or online by clicking here (https://www.DIAglobal.org/General/Terms-and-Conditions?productIDs=7240118).

DIA Terms and Conditions: URL: http://www.DIAglobal.org/general/Terms-and-Conditions?productIDs=7240118

PAYMENT OPTIONS

Please check payment method.

☑️ BANK TRANSFER:

You will recieve an invoice with bank information detail by email after registration completion.

All local and overseas charges incurred for the bank transfer must be borne by payer.

☐ CREDIT CARD (VISA, MASTERCARD OR JCB ONLY)

☐ VISA ☐ MC ☐ JCB Exp. (mm/yyyy) _______________

Card No.

Cardholder Name

Signature Date

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
参加申込書

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

◆ 参加申込方法
DIAウェブサイト（www.DIAGlobal.org）よりお申し込み頂けます。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。
受領後、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（該当する枠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 参加費
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。

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。

③ 合計金額（①+②）： 合計 円

◆ お支払方法
ご希望の支払い方法にチェックを入れてください。
支払い方法 □ 銀行振込 [□ VISA □ MasterCard □ JCB]
□ 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）
□ ビザ □ マスターカード □ ジェイ・エヌ・シー
□ カード有効期限（mm/yy） □ カード番号 □
□ カードご名義 □ Dr. □ Mr. □ Ms. □
□ ご署名 □

予習参加者の方は、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。
学生で年会全体への参加登録をされる方は、11月1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。また会期中は、十五回DIA年会のプログラム関係者に限り配布され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、同意いただけない場合はDIA Japanまでご連絡ください。
2018年11月11日(日)~13日(火) 東京ビッグサイト（有明） 東京都江東区有明3丁目11番1号

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

◆ 参加費用 (該当する「」にチェックしてください）
会費は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。

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

<table>
<thead>
<tr>
<th>会員資格</th>
<th>通常年会費</th>
<th>若手割引年会費</th>
</tr>
</thead>
<tbody>
<tr>
<td>一般</td>
<td>¥17,500 (税抜)</td>
<td>¥16,900 (税込)</td>
</tr>
<tr>
<td>非会員</td>
<td>¥31,500 (税抜)</td>
<td>¥34,020 (税込)</td>
</tr>
</tbody>
</table>

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

③合計金額 (①+②):
合計 円

※最終確定金額はDIA Japanからお送りする受領書メールにてご確認ください。

生年月日（必須）
西暦 年 月 日

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

◆ お支払方法
ご希望の支払方法にチェックを入れてください。

[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) 卡ード番号
カードご名義 ご署名

ご利用の際は、ご親族の間、または会社内での複数名の参加費を同時に振り込まれる場合には、書面にて参加者名と振込日をディー・アイ・エージャンス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）
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、お申し込み受付後、2018年11月4日まで手数料として一般会員・非会員とも20,000円、政府/大学関係者については会員・非会員とも10,000円を申し受けます。それ以後のキャンセルは、参加費全額を申し受けますのでご注意ください。

* DIA主催の会議において、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。

* 本会議においては、DIAの宣伝活動に使用する目的で、開催期間中に参加者を包括的に映像・写真撮影をすることがあります。参加者の皆様にご了承願います。