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

DIAglobal.org

16th DIA Japan Annual Meeting 2019
-Delivering Rational Medicine for All People in the Globe-

November 10-12, 2019
Tokyo Big Sight | Ariake
DIAglobal.org/Japan2019

PROGRAM CHAIR
Tatsuya Kondo, MD, PhD
Medical Excellence JAPAN

PROGRAM VICE-CHAIR
Takashi Nishi, MSc, PMP
Kyowa Kirin Co., Ltd.

PROGRAM COMMITTEE
Hiroya Aso, MD, PhD, MBA
Eli Lilly Japan K.K.
Noriko Fujimura, MSc, RN, OCNS, CCRP
The University of Tokyo
Yoshikata Furuya, MSc
MSD K.K.
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CTD Inc.
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Pharmaceuticals and Medical Devices Agency (PMDA)
Toshiko Ishibashi, RN, PhD
Ono Pharmaceutical Co., Ltd.
Yoichi Itoh, PhD
The Institute of Statistical Mathematics
Miyuki Kaneko
Pfizer K.K.
Yoko Kazami, PMP
Novelpharma Co., Ltd.
Noriatsu Kono
Japan Agency for Medical Research and Development (AMED)

PROGRAM OVERVIEW

What can and should we do for patients, future patients and the patient families? There are extremely large numbers of issues that healthcare stakeholders, including people in the industry, government and healthcare providers, need to tackle in an effort to provide Rational Medicine to all the people in the world, throughout their life cycles.

At DIA, we are here to continue challenges by exercising leadership with collaboration among industry, government and academia to create innovation in pharmaceuticals, medical devices and other healthcare products. We are not only pursuing for a new value within the range of our respective responsibilities. We are a team to work together to move forward aiming to achieve common goals by understanding what each one of us ought to do. We maintain ethics, transparency, fairness and collaboration at the same time by creating synergism, but not conflict of interest. That is the key to provide Rational Medicine to all people in the future.

The Day 1 of the meeting will start with the Program Chair Lecture based on the meeting theme by Dr. Tatsuya Kondo, followed by the Keynote Address by Mr. Riki Osumi, who is leading an effort to support children with critical diseases and their family. Two DIAmond sessions are also planned with themes of “Patient Involvement in Drug Development” and “Rational Medicine for Patients”. Furthermore, we will discuss brand new themes such as risk-based approach, utilization of big data, how to deliver messages from Japan in the global environment, etc., by experts from various areas to clarify their unique positions. In the evening of Day 2, Chatting Session is provided for networking and opinion exchange among participants and in the afternoon of Day 3, PMDA Town Hall is planned lively Q&A with PMDA panelists.

The 16th DIA Japan Annual Meeting, with a theme of “Delivering Rational Medicine for All People in the Globe”, is a place for thinking and opinion exchange about what we should do in order to contribute to medical environment in the future.

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

Endorsement pending by MHLW, PMDA, JPMA, PhRMA, EFPIA, PDA, ISPE and Medical Excellence JAPAN and ISPOR Japan

DIA Japan
Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashi Hakozaki, Chuo-ku, Tokyo 103-0023 Japan
Tel: +81.3.6214.0574 Fax: +81.3.3278.1313 Email: Japan@DIAglobal.org

Drug Information Association
Global Center: Washington, DC | Americas | Europe, Middle East & Africa | China | Japan | India
**SUN NOV 10**

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<th>Time</th>
<th>International Conference Room</th>
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<tr>
<td>9:30-12:00</td>
<td>(Student Session) Medical Risk Communication on Diabetes Medicine: What Information Should We Share? RA, CP, AC</td>
<td>Room 605/606</td>
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<tr>
<td>12:00-13:30</td>
<td>ORIENTATION AT EXHIBIT HALL (12:00-13:00)</td>
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<td>13:30-13:45</td>
<td>WELCOME</td>
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<td>13:45-14:00</td>
<td>OPENING REMARKS Dr. Tatsuya Kondo</td>
<td>Room 605/606</td>
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<td>14:00-14:15</td>
<td>2019 DIA JAPAN’S Inspire Regional Awards Ceremony</td>
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<td>14:15-15:00</td>
<td>PROGRAM CHAIR’S LECTURE Dr. Tatsuya Kondo SH Medical Excellence Japan</td>
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<td>15:00-15:30</td>
<td>COFFEE BREAK</td>
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<tr>
<td>15:30-16:15</td>
<td>KEYNOTE ADDRESS Biki Osami / Hope &amp; Wish for Children with Life-Threatening Illness and Their Families</td>
<td>Room 605/606</td>
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<td>17:45-18:00</td>
<td>SHORT BREAK</td>
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<tr>
<td>18:00-19:30</td>
<td>NETWORKING RECEPTION AT RECEPTION HALL (WE ALSO HAVE PLANS TO DEEPEN EXCHANGES AMONG YOUNG PEOPLE)</td>
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**MON NOV 11**

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<td>9:00-10:30</td>
<td>S01 Current Status of the Application of Cancer Genomic Medicine - Present and Future of Gene panel Testing - RA, AC</td>
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<td>11:00-12:30</td>
<td>S02 Block Chain Technology and the Deployment to Pharmaceutical Industry ALL</td>
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<td>12:30-14:00</td>
<td>LUNCHEON SEMINAR (GOLD SUPPORTER)</td>
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<td>14:00-15:30</td>
<td>S03 Collaboration with WHO for Global Health RA, Govt Govement</td>
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<td>16:00-17:30</td>
<td>S04 Examples of Clinical QMS Introduction: Risk and Issue Management CR, RA, DM, ST, PM, AC</td>
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<td>S06 Rational Medicine for Patients RA, Patient</td>
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<td>S07 Utilization of RWD for Designing a Clinical Trial CR, RA, DM, ST, PM, AC</td>
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| **S05** Clinical Trial Act: Experiences from the PI, the Way of the Future | | | | |}
| **S06** A Solution for Patients and Healthcare Providers: A New Trial in Pharmacovigilance CR, CP, PM | | | | |}
| **S07** Ideal Conduct and Future Perspectives for Publication by Pharmaceutical Companies CR, AC, MA, MI, MM, MW. | | | | |}
| **S08** Deep Dive into China Regulatory Reform from Various Perspectives (Tentative) RA | | | | |}
| **S09** What is “Shared Value”? Created by Collaboration Among Industry, Academia, Governments, and Future Generations - Going Forward to New Era of Innovation. ALL | | | | |}
| **S10** Forefront of Drug Delivery System (DDS) Technology RA, CMC, AC | | | | |}
| **S11** Lessons from Experiences Using MidNet for PV RA, CP, ST | | | | |}
| **S13** Sharing Individual Participant Data (IPD) from Clinical Trials and Personal Information Protection CR, RA, DM, AC, ST, MI, MM, MW | | | | |}
| **S14** The Basics of Health Technology Assessment - From Clinical Trials to Pricing - CR, RA, MA, O: Market Access | | | | |}
| **S15** Practice of Post-Introduction of New Consultation System of Labeling for Revision CR, RA, CP, AC, MI, O: Labelling | | | | |}
| **S16** Let’s Talk a Lot About What Future Shape of Ideal Collaboration to Promote Life Science Field is ALL | | | | |}
| **S17** eSource in Clinical Trials -Global/ Japan Use Cases- CR, DM, AC | | | | |}
| **S18** How About the Courage to Take a Further Step for Young People? O: Career Development | | | | |}
| **S19** What Patient Registries Bring to Rare Disease Medicine Development CR, RA | | | | |}
| **S20** How Have You Already Had a Labeling with New Format? How to Read New Format of Labeling and Impact for Implementation on Medical Practice RA, CP, AC, MI, O: Labelling | | | | |}
| **S21** The Present and Future of Utilization of AI and Digital Technology in Medicine Development and Healthcare Services -To Deliver Rational Medicine- ALL | | | | |}
| **S22** The Appropriate Use of Drugs in Asia Countries, Especially Elder Patients RA, AC | | | | |}
| **S23** What Is “Shared Value”? Created by Collaboration Among Industry, Academia, Governments, and Future Generations - Going Forward to New Era of Innovation. ALL | | | | |}
| **S24** The Dawn of Program Management: Beyond Project Management CR, RA, PM, AC | | | | |}
| **S25** Think About Informed Consent from a Patient’s Perspective - What Can We Do to Promote Proper Understanding of Clinical Trials and Patient-Friendly Clinical Trials? CR, RA, DM, PM, AC, O: Patient | | | | |}
| **S26** Virtual Clinical Trials: Roadmap for Implementation in Japan CR, RA, PM, AC | | | | |}
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| **S28** The Latest Cases and Further Perspectives of Early Approval System in Japan RA, PM, CMC | | | | |}
| **S29** Consider How to Provide Patient-Sought Drug Information RA, CP | | | | |}
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| **S44** How Should We Set Up Our R&D Strategy and Target Product Profile? Key Learning from Real Cases CR, RA, PM, AC | | | | |}
| **S45** The Latest Cases and Further Perspectives of Early Approval System in Japan RA, PM, CMC | | | | |}
| **S46** Bringing Japanese Technology to the World! Ideal way of life science innovation in the era of peace, considered by industry, government and academia O: Others | | | | |}
| **S47** Toward to Development of Comprehensive and Reliable Drug Information System for Consumers and Patients CR, MI, O: Patient | | | | |}
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**Related Interest Areas:** Clinical Research and Clinical Strategy (CR), Regulatory Affairs (RA), Statistics (ST), Clinical Data Management (DM), Clinical Safety and Pharmacovigilance (CP), Project Management (PM), Chemistry, Manufacturing and Controls (CMC), Academia (AC), Medical Affairs (MA), Medical Information (MI), Medical Writing (MW), Medical Communication (MC), Health Economics and Outcomes Research (HEOR), Others (O)
SUNDAY, NOVEMBER 10
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  2019 DIA Japan’s Inspire Regional Awards Ceremony
14:15-15:00  Program Chair’s Lecture by Dr. Tatsuya Kondo (SH Medical Excellence Japan) Method of Regulatory Science Promoting Rational Medicine Initiative
15:00-15:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
15:30-16:15  Keynote Address by Dr. Riki Osumi (Hope & Wish for Children with Life-Threatening Illness and Their Families) Sitting Close to Children Bearing Life-Threatening Diseases and Their Family with Disney’s Hospitality
16:15-17:45  DIAmond Session 1  What do patients want for clinical trials and clinical research? What should stakeholders do?
18:00-19:30  Networking Reception
MONDAY, NOVEMBER 11
8:30-  Attendee & Exhibitor Registration
9:00-19:00  Exhibit Hall Open
9:00-10:30  Sessions (S01 - S09)
10:30-11:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30  Sessions (S10 - S18)
12:30-14:00  Lunch Break / Poster Session / Luncheon Seminar
14:00-15:30  Sessions (S19 - S27)
15:30-16:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30  Sessions (S28 - S36)
17:45-19:00  Engage and Exchange - Special Chat Session
TUESDAY, NOVEMBER 12
8:30-  Attendee & Exhibitor Registration
9:00-16:00  Exhibit Hall Open
9:00-10:30  Sessions (S37 - S43)
10:30-11:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30  Sessions (S44 - S50)
12:30-14:00  Lunch & Exhibit Hall Innovation Theater Presentations / Luncheon Seminars
14:00-15:30  DIAmond Session 2  Rational Medicine for Patients
15:30-16:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30  DIAmond Session 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.

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Monday, November 11  Before 8:00 and after 20:00
Tuesday, November 12  Before 8:00 and after 18:30

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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 25 for more details.
Medical Risk Communication on Diabetes Medicine: What Information Should We Share?

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

SESSION CO-CHAIRS
Mikako Einaga
Showa University
Minami Mori
Showa University
Toshiaki Suga
Nihon University
Yuki Sugao
Tokyo University of Pharmacy and Life Sciences

No medication can be taken without any risk. Therefore, medical risk communication, the process of sharing medical risk information and of filling the gap of understanding of a medication between healthcare providers and others (especially patients) is an essential step not only for doctors but for everyone. This session stresses the importance of risk communication to future medical professionals by examining the SGLT2 inhibitor diabetes medicine. After the lecture segment of this session, participants will discuss in groups what risk information should be shared, with whom, and how.

Fundamentals and Practical Applications of Risk Communication on Medicines
Michiko Yamamoto, PhD
Visiting Professor, Graduate School of Pharmaceutical Sciences, Kumamoto University

Student Session
Kasumi Daidoji, PhD, RPh
Associate Director, Corporate Medical Affairs Headquarters Eisai Co., Ltd.

Advisers
Motoki Arakawa, PhD
Junior Associate Professor, School of Pharmacy, Nihon University
Katsuhiko Ichimaru
Director for MID-NET project Pharmaceuticals and Medical Devices Agency (PMDA)
Toshihiko Kuga
DIA Japan Student Group OB/OG CSM, Clinical Operations Japan, Parexel International
Aya Okada
DIA Japan Student Group OB/OG Clinical safety & Pharmacovigilance Dept. ASKA Pharmaceutical Co., Ltd
Jun Yamakami, PhD
Senior Manager, R&D Regulatory 1, Regulatory Affairs, Sanofi K.K.
Welcome and Keynote Address

Welcome and Keynote Address

INTERNATIONAL CONFERENCE ROOM 13:30-13:45

Akio Uemura, PhD
Director, DIA Japan
Barbara Lopez Kunz, MSc
Global Chief Executive, DIA
Hironobu Saito, PhD
Chair, DIA Advisory Council of Japan
Corporate Officer, Vice President, Oncology Clinical Development Dept, R&D Division DAIICHI SANKYO., LTD.
Lingshi Tan, PhD
Chair-Elect, DIA
Chairman and Chief Executive Officer, dMed Biopharmaceutical Co., Ltd.

OPENING REMARKS

INTERNATIONAL CONFERENCE ROOM 13:45-14:00

PROGRAM CHAIR

Tatsuya Kondo MD, PhD
President, SH Medical Excellence JAPAN

2019 DIA JAPAN’S INSPIRE REGIONAL AWARDS PRESENTATION

INTERNATIONAL CONFERENCE ROOM 14:00-14:15

PRESENTER:

Lingshi Tan, PhD
Chair-Elect, DIA
Chairman and Chief Executive Officer, dMed Biopharmaceutical Co., Ltd.

AWARD WINNERS:

Outstanding Contribution to Health Award
TBA
Excellence in Service Award
TBA
Leader of Tomorrow Award
TBA

PROGRAM CHAIR’S LECTURE

INTERNATIONAL CONFERENCE ROOM 14:15-15:00

SESSION CHAIR:

Masaru Iwasaki, MD, PhD
Vice President, Head of Center for Advancing Clinical Research (CACR), University of Yamanashi

It is regulatory authority’s responsibility to deliver a product with innovative medical technology as early and appropriately as possible. Because the innovative medicines often associate with cutting edge technology which has never been experienced, it is necessary to collect all possible worldwide wisdom to evaluate its appropriateness based on the newest regulatory science. In evaluating such new medicine, “Rational Medicine” should always be pursued. Dr. Kondo published his paper called “Rational Medicine Initiative” in February 2017 based on such thoughts. In this session, Dr. Kondo is going to provide an overview of what he was trying to achieve in his 11-year period being the chief executive of PMDA, together with an actual accomplishments, in pursuant to work with key stakeholders in medical institutions, the industry, academia, regulatory agencies to serve patients around the world.

Method of Regulatory Science Promoting Rational Medicine Initiative

Tatsuya Kondo, MD, PhD
President, SH Medical Excellence JAPAN

COFFEE BREAK 15:00-15:30

KEYNOTE ADDRESS

INTERNATIONAL CONFERENCE ROOM 15:30-16:15

SESSION CHAIR

Tatsuya Kondo MD, PhD
President, SH Medical Excellence JAPAN

After working for Tokyo Disney Resort for approximately 20 years, I established a non-profit organization supporting Japanese children with critical illness and their family. Based on this background, I would like to give a talk focusing on mothers who have children with such diseases.

In Disney Resort, visitors are welcomed by “Hello!”, and sent off by “See you again!”. The Disney facility is fully cleaned by the staff. Therefore, the visitors don’t throw away the trash and put it in the trash bin. That’s “a matter of course”. These things are, however, something we were taught by our mothers, and it is a starting point of the society. I have met as many as 240 families, and had conversations with the mothers. The messages of “living the current life” I saw from the conversations are all with full of love and depth.

Sitting Close to Children Bearing Life-Threatening Diseases and Their Family with Disney’s Hospitality

Riki Osumi
Representative Director, Hope & Wish for Children with Life-Threatening Illness and Their Families
DIAmmond Session 1

DIAmmond SESSIONS

DIAmmond Session 1
INTERNATIONAL CONFERENCE ROOM 16:15-17:45

What Do Patients Want for Clinical Trials and Clinical Research? What Should Stakeholders Do?

Related Interest Area(s): ALL
Level: Intermediate

SESSION CO-CHAIRS:
Naomi Sakurai
Representative Director, Cancer Solutions, Co.,LTD
CSR Project, general incorporated association

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

Patient and Public Involvement (PPI) in drug developments is increasingly attracting interest in Japan. DIA has organized sessions on PPI at the annual meetings over the past few years to share the concept of PPI and status of PPI in each phase of drug development in Japan and global.

In this DIAmmond session, leaders of PPI in clinical trials and clinical research will share the latest outcomes and discuss what stakeholders should do to promote PPI in Japan.

TBC
Yasuhiro Fujiwara MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

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

Promoting Patient and Public Involvement
Kyoko Imanura, MD, PhD, DrMedSci
Professor, Social Cooperation Program of IT Healthcare, Graduate School of Pharmaceutical Sciences, the University of Tokyo

Patient and Public Involvement (PPI) in drug developments at a pharmaceutical company’s perspective
Takayuki Imaeda, MS, Mpharm
Senior Director, Regulatory Affairs, Pfizer R&D Japan

Panel Discussion
All Session Speakers and
Kazuhiro Mori, MSc
Councilor for Pharmaceutical Affairs, Minister’s secretariat
Ministry of Health, Labor and Welfare (MHLW)

NETWORKING RECEPTION
Reception Hall 18:00-19:30

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- Change makers from academia, patient groups, regulatory, industry, clinical development, medical affairs, and more
- Dedicated thought leaders eager to discuss the issues of today and chart a path for tomorrow

DIAglobal.org

We also have plans to deepen exchanges among young people.
S01 Room 605 9:00-10:30
Current Status of the Application of Cancer Genomic Medicine - Present and Future of Gene Panel Testing-

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

SESSION CHAIR
Noboru Yamamoto, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

In order to realize the precision medicine, an effort is being made to realize cancer genomic medicine. In 2018, a cabinet decision on “3rd-Term Comprehensive 10-year Cancer Control Strategy” was made and cancer genomic medicine became one of the priorities. In this session, we will review the current status of gene panel testing utilizing NGS (Next-Generation Sequencing) and its analytical programs as medical devices. Based on the actual example of panel testing system for gene mutation analysis, which was approved last year, issues surrounding the progress of cancer genomic medicine in Japan will be discussed for a solution from a multidisciplinary perspective.

Challenges in Genome-based Cancer Therapy(from clinical practice)
Noboru Yamamoto, MD, PhD
Deputy Director, Department of Experimental Therapeutics, National Cancer Center Hospital

Perspectives on Oncology Panels: From Regulatory View
Naoyuki Yabana, PhD
Director, Office of In Vitro Diagnostics, Pharmaceuticals and Medical Devices Agency (PMDA)

Regulatory Issues on Cancer Panel Tests
Yoshiaki Tazawa
Temporary Adviser, Chugai Pharmaceuticals K.K.

Panel Discussion
All Session Speakers

S02 Room 606 9:00-10:30
Block Chain Technology and the Deployment to Pharmaceutical Industry

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

SESSION CHAIR
Hiroshi Mizushima, PhD
Center for Public Health Informatics, Director of the Center National Institute of Publish Health

Block chain technology has already been introduced in business other than pharmaceutical industry and the pharmaceutical industry is now considering the potential use of this technology as well. If this technology is introduced, we will be able to manage data separately with higher security. We expect this technology will help us in various applications such as regulatory submission, data certification of clinical trial, traceability of medicines and value-based payment etc.

In this session, speakers will share current situation and their perspective regarding block chain technology and discuss effective information management and/or utilization of data for pharmaceutical industry.

A Patient-Centered Medical Information Platform
Dongying Li
CEO, Arteryex. Inc.

Rapid Expansion of Production-Ready Blockchain Network
Michiyasu Takada
Head of Blockchain Solutions, IBM Japan

TBC
Hiroshi Mizushima, PhD
Center for Public Health Informatics, Director of the Center National Institute of Publish Health

S03 Room 607 9:00-10:30
Collaboration with WHO for Global Health

Related Interest Area(s): RA, GOVERNMENT
Level: Intermediate

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

When facing an outbreak of socially-impactful infectious diseases such as the Ebola virus, WHO may work with pertinent regulatory agencies not only for disease containment but also on clinical studies of possible therapeutics. But other WHO activities, such as pre-qualification or reliance pathway, are of high interest in developed countries. Many observers still have the strong impression that WHO mostly works with developing countries from the global public health perspective. This session will explain what activities WHO conducts, and discuss how the industry and/or regulatory agencies can collaborate with WHO to contribute to global health.

Putting Reliance into Practice: WHO’s Activities on Regulatory Systems Strengthening
Samvel Azatyan MD, PhD.
Group Lead, Regulatory Networks and Harmonization (RNH/RSS)
World Health Organization (WHO), Switzerland

TBC

Collaboration with WHO for Global Health from Industry Perspectives
Shinji Hatakeyama
Japan Pharmaceutical Manufacturers Association (JPMA)

Panel Discussion
All Session Speakers

S04 Room 608 9:00-10:30
Examples of Clinical QMS Introduction - Risk and Issue Management

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

SESSION CHAIR
Hirotaka Inoue, PhD, MBA
Head, Leading Changes Office Japan Development GlaxoSmithKline K.K.

Many of the DIA Japan Annual Meeting participants were bewildered when each of you need to introduce Clinical QMS to organization and/or at clinical sites, although case studies of QMS tools were published by a task force in Data Science Division in the Japan Pharmaceutical Manufacturers Association. In this session, targeting all the stakeholders in clinical operations, from job site perspective, 1) lectures on risk and issue management and 2) successful cases will be presented, and as a result, the session will provide hints for successful implementation of clinical QMS.

Clinical QMS implementation & Challenges
Kiyomi Hirayama
Director, Quality Management Unit. MSD K.K.

The Journey to a Practical Clinical QMS- Challenges That Have Become Clear After the Implementation of ICH E6 (R2) –
Chiharu Funaki, MSc
Associate Director, Clinical Quality Management Group, Development Function, Daiichi Sankyo Co., Ltd.

Methods, Tools and Cases for Success of Issue Management in Clinical QMS
Goshir Ozawa, MS
President, Real Discovery Outdoors Co.,Ltd.
DAY 2 | MONDAY | NOVEMBER 11

S05  Room 609  9:00-10:30
Clinical Trials Act: Experiences from the Past, the Way of the Future
Related Interest Area(s): RA, PM, AC, MA
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Kayoko Kikuchi, PhD
Chief, Division of Management and Strategy, National Center For Child Health and Development
Clinical Trials Act has a big negative impact on clinical trials in Japan, and intervention trials had decreased drastically.
The regulations for clinical trials differ depending on the study details: the study objectives and the source of funding, etc. As for a multinational clinical trial, we have to conduct in compliance with ICH-GCP, not only domestic rules in Japan. Principal investigators and research professionals are often confused and burdened by the variety and complexity of such rules. Clinical Trials Act gave us even more devastating situation.
In this session, focusing on the law amendment, we will share the current issues and expectation for amendment of Clinical Trials Act from their perspective: government, industry and academia. Furthermore, we will discuss appropriate regulations in the future in order to achieve both ensuring the confidence and activating clinical trials.

Challenges and Responses With the Enforcement of Clinical Trials Act - from the Standpoint of Academy & Medical Institution -
Masahiko Ozaki, MSc
Manager, Ethical Review Support Section, National Cancer Center Hospital East

Challenges and Responses With the Enforcement of Clinical Trials Act - from the Standpoint of Pharmaceutical Industry-
Hiroshi Asai
Associate Director, Medical Science Liaison, Medical Affairs, Japan Astellas Pharma Inc.

One and a Half Years after Implementation and Future Prospects
Jun Yoshida
Director, Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, Ministry of Health, Labor and Welfare (MHLW)

Panel Discussion
All Session Speakers

S06  Room 610  9:00-10:30
A Solution for Patients and Healthcare Providers: a New Trial in Pharmacovigilance
Related Interest Area(s): CR, CP, PM
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Shinichi Nishiuma, MD
Executive Director, Head of Medical Affairs, Japan Celgene K.K.

Under recent drastic change of pharmacovigilance approach, some proactive activities or new business models are explored to leverage safety data from post-marketing pharmacovigilance to maximization of the benefit for patients and health care providers. In this session, we will discuss how these new patient-centric approaches are positively impacting on creation of new evidence which should be useful for patients and health care providers.

Between PV for Regulatory Compliance and PV for Patients
Kotonari Aoki
Department Manager, Safety Real World Data and Science, Drug Safety Data Management Dept. Chugai Pharmaceutical Co., Ltd.

Framework to Enhance the Quality of Re-Examination Applications – Emphasize Scientific Aspects in PMS Planning and Execution –
Hideo Sakamoto
Novartis Pharma K.K.

S07  Room 101  9:00-10:30
Ideal Conduct and Future Perspectives for Publication by Pharmaceutical Companies
Related Interest Area(s): CR, AC, MI, MC, MA, MW
Level: Beginner, Intermediate

SESSION CHAIR
Yuko Kojima RPh, EMBA
Director, Biometrics, Medicine Development Unit - Japan, Eli Lilly Japan K.K.

Company-sponsored publications are one of the most critical sources of medical information to help HCPs decide treatment for a patient. So, it is very important to understand what pharmaceutical companies should do to ensure ethical and effective publications to have the evidence appropriately communicated and to avoid any misconduct.
In this session, we will readdress the publication basics such as Good Publication Practice 3 (GPP3) and ICMEJ recommendations with international publication experts. We will also discuss current practices and challenges which a Japanese pharmaceutical company faces in a real setting. On top of these, we will touch upon future outlook such as how to involve patients in publications.

Current and Future Publication Practice by a Pharmaceutical Company
Audrey Suh Krolicki, PharmD
Senior Director, Medical Communications, Medical Affairs, Head of Global Scientific Publications, Astellas Pharma

Current Status and Issues of Publication Management from In-House Perspective
Ken-ichi Setsukinai, PhD, CMPP
Director, Medical Affairs Department, Shionogi & Co., Ltd

What Journal Editors Expect from the Pharmaceutical Industry [Recorded Presentation]
Ana Marušić, MD, PhD
Editor in Chief, Journal of Global Health, Professor and Chair, Department of Research in Biomedicine and Health, University of Split

Panel Discussion
All Session Speakers

S08  Room 102  9:00-10:30
Deep Dive into China Regulatory Reform from Various Perspective (Tentative)
Related Interest Area(s): RA
Level: Intermediate

SESSION CHAIR
Ling Su, PhD
Professor, Shenyang Pharmaceutical University

China regulatory reform has caused various changes in drug development in China. The drug development process has been shifted from conventional way to advanced way utilizing improved regulatory system for acceleration of innovative drug development. This session will cover recent regulatory environment for innovative drug and advanced therapy (gene therapy or cell therapy) by agency, and actual experience using new regulatory scheme by industry. The current status of GMP/GCP inspections in China will also be discussed.

Recent Regulatory Reform in China (1)
Xiaofang Cheng
Principal Staff, Department of Policies and Regulations, The National Medical Products Administration (NMPA)
Recent Regulatory Reform in China (2)  
Jihua Yang  
China Center for Food and Drug International Exchange, NMPA  

Overview of China regulation for advanced therapy  
Jianchao Gao  
Chief Pharmacist, CDE  
TBC  
Fei Xu  
Engineer, Center for Food and Drug Inspection of NMPA  
Panel Discussion  
All Session Speakers  

S09  Room 703  9:00-10:30  
What is “Shared Value” Created by Collaboration Among Industry, Academia, Government and Individuals of Current and Future Generations - Going Forward to New Era of Innovation  
Related Interest Area(s): ALL  
Level: Beginner  
Language: Japanese Language Only  
SESSION CHAIR  
Minori Niso  
Acute Care Diagnostics Product Manager, Instrumentation Laboratory I.L. Japan Co., Ltd.  

With a decrease in the success probability of drug/device development, an idea of “open innovation” has been spreading out with a transition from a classical methodology to a brand new one by crossing organizational boundaries. In this session, with a theme of “Win-win relationship by industry, government and academia”, an example of government effort to connect industry and academia, and an idea of “creating shared value (CSV)” by the industry to achieve a synergism between economic benefit and social value creation will be reviewed. From academia, an example of a cross-cultural collaboration will be explained. Through these discussions, let us think about “What is new innovation toward the common goal by industry, government and academia?” for the better collaboration for our future.  

Measures by AMED for Drug Discovery and Development Through All Japan Partnership  
Tonomori Shikokawa  
Manager, Department of Innovative Drug Discovery and Development, Japan Agency for Medical Research and Development (AMED)  
TBC  
Keiichi Fujiwara  
Professor, Department of Gynecologic Oncology Chief; Center for Clinical Research and Integrity, Saitama Medical University International Medical Center  

Overview of SDGs, CSV(Creating Shared Value) and Collective Impact  
Ryota Inaba  
General Manager, Flexas Z inc.  
Panel Discussion  
All Session Speakers  

COFFEE BREAK  
10:30-11:00  

S10  Room 605  11:00-12:30  
Initiatives for the Future of Digital Health: Utilizing Digitalized Product Information/Labeling for Healthcare Professionals and Patients  
Related Interest Area(s): RA, CP, MI, MA  
Level: Beginner, Intermediate  
SESSION CHAIR  
Rie Matsui, RPh  

Digitalized product information, part of the evolving global movement toward digitalization of healthcare, can improve health literacy for patients and enable patients to choose their own healthcare more proactively. Per the revised regulation for labeling implemented in April 2019, XML conversion has been required for labeling information in Japan. XML converted labeling, already implemented in the US, is the backbone of digitalized product information; other western countries have also started to consider XML conversion of labeling. This session will look ahead to the future of digital health by comparing these initiatives in Japan, the US, and the EU, and discussing utilization of digitalized product information/labeling issued by regulatory authorities and companies for patients and healthcare  

The Electronic Product Information (ePI)-Initiative of the European Union  
Peter Bachmann, DrSc  
Dupky-Head, European Union and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM)  

Current situation and the future of e-labeling utilization in Japan from regulator’s point of view  
Takashi Tai  
Deputy Director, Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)  

Current Situation and the Future of e-Labeling Utilization Across Regions from Industry’s Point of View  
Shimon Yoshida, PhD  
Executive Director, Head of International Labeling Group, Global Regulatory Affairs, Pfizer Inc  

Panel Discussion  
All Session Speakers and  
Manabu Inoue  
Associate Director, PV IT/Data management, Japan Pharmacovigilance, MSD K.K.  

R&D Head Club’s WGs Report on Quality-improvement before and after Adaptation  
Kiyoshi Kinoshita, PhD  
Manager, Regulatory Affairs, Area Japan Development, MSD K.K.  

Key for success of Machine Translation - How to perform Post-edit effectively -  
Toshiyuki Shigematsu  
Group manager, Submmission management & Translation group, Regulatory Writing & Submissions, Japan Development, Novaltis Pharma K.K.  

A Case of Company-wide Introduction of AI Translation Technology -Background, Process and Future Prospects-  
Yusuke Asoh  
Manager, IT Strategy Department, Daiichi Sankyo Co., Ltd  
Panel Discussion  
All Session Speakers and  
Shinobu Uzu, MSc  
Associate Executive Director,
Road to RBM realization- Learning from Site Tour -
Minoru Koizumi
Senior Associate, Clinical Development Consultant, Clinical Development Operations and Innovations, Medicines Development Unit Japan, Eli Lilly Japan K.K.

Panel Discussion
All Session Speakers and
Wataru Arai
Deputy Director of Pharmaceutical Department/Head of Clinical Trial Office, Ageo Central General Hospital
Naomi Misaki
Research Management, St. Luke’s International Hospital
Aki Sato
CRA, Monitoring Group, Pfizer R&D Japan

S14  Room 609  11:00-12:30
Forefront of Drug Delivery System (DDS) Technology
Related Interest Area(s): RA, CMC, AC
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Mitsuru Hashida, PhD
Program-Specific Professor, Institute for Advanced Study
Director of Research Administration Office, Institute for Integrated Cell-Material Sciences, Kyoto University

The trend of drug development is shifting from small molecules to medium- to high molecules such as peptides, proteins and nucleic acids, but problems such as stability and permeability become major barriers to their practical use. DDS research is becoming active to solve the problem. In this session, pharmaceutical company and research institute introduce the latest research and challenges in developing such DDS technology. In addition, the regulatory authorities introduce the current status and issues of regulation, and the future prospects.

Research on Evaluation of innovative Nanomedicine, a Core Technology for DDS
Kumiko Sakai-Kato, PhD
Professor, School of Pharmacy, Kitasato University

Nano-DDS Research in Pharmaceutical Company
Hiroshi Ishihara, PhD
Director, Nanomedicine Research, Eisai, Co., Ltd.

TBC
Kosuke Ito, PhD
Reviewer, Office of New Drug 5
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

S15  Room 610  11:00-12:30
Lessens from Experiences Using MidNet for PV
Related Interest Area(s): RA, CP, ST
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR
Yoshiaki Uyama, PhD
Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

So far, there have been three cases of the use of MID-NET, a government-owned database which has become available since April 2018. These three companies are invited to talk about their experience of using MID-MET from various perspectives such as data accumulation, data analysis, information delivery and discuss issues in using the database. In the panel, a representative of MID-NET division of PMDA will also invited and the future perspective of the utilization of MID-NET for pharmacovigilance as well as the issues to overcome for a full utilization of the database.
Overview of Utilization of MID-NET
Katsuhiko Ichimaru
Director for MID-NET project, Pharmaceuticals and Medical Devices Agency (PMDA)

Practice of MID-NET Use in Post-Marketing Database Study
Kei Sagawa
Pharmacovigilance, Safety and Risk Management Department, Daichii Sankyo Co., Ltd.

Utilization of MID-NET from Pharmacovigilance Perspective
Makoto Miyazaki
Safety Strategy Execution 2, Pharmacovigilance & Risk Management, MSD K.K.

Recommendations on Feasibility Assessment to Leverage MID-NET
Shintaro Hiro, PhD
Statistics Group 1, Clinical Statistics, Pfizer Japan Inc.

Panel Discussion
All Session Speakers

S16 Room 101 11:00-12:30
Promotion of Pediatric Drug Development by Industry, Government and Academia - What Has Changed, What Has Been Done and What Is Necessary for the Further Progress?
Related Interest Area(s): RA, O: Patient
Level: Intermediate

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

Various measures are being created to promote pediatric drug development by industry, government and academia. From this perspective, efforts made in the past 1 year to promote the periatric development will be reviewed, and in the panel, issues surrounding the periatric drug development will be discussed in order to address them. A patient representative will also be invited to the panel discussion to provide the patient viewpoints.

New Drug Development for Children's Cancer.
Chitose Ogawa, MD
Chief, Department of Pediatric Oncology, National Cancer Center Hospital

Promotion of Pediatric Drug Development -What Has Changed, What Has Been Done and What Is Necessary for the Further Progress? –From the Perspective of the PMDA
Michiyo Sakiyama, MD
Associate Senior Scientist for Clinical Medicine, Office of Vaccines and Blood, ProductsPharmaceuticals and Medical Devices Agency (PMDA)

Pediatric clinical development update at Pfizer Japan
Takayuki Imaeda, MS
Sr. Director, Regulatory Affairs, Pfizer R&D Japan

Panel Discussion
All Session Speakers and
Yuko Moue
President, Pediatric Brain Tumors Network of Japan
Rare Cancer Japan

S17 Room 102 11:00-12:30
Sharing Individual Participant Data (IPD) from Clinical Trials and Personal Information Protection
Related Interest Area(s): CR, RA, DM, AC, ST, MC, MR
Level: Intermediate

SESSION CHAIR
Tomoko Kato


Sharing IPD from clinical trials is being promoted to ensure transparency in clinical trials and to improve public health. At the same time, data providers are challenged to safeguard participant privacy in compliance with data privacy legal requirements, and some data users are concerned that anonymized data will provide less utility.

This session will discuss both the challenges and benefits of promoting the sharing of IPD such as, for example, a mechanism by which pharmaceutical companies can mutually use IPD in the pre-competitive phase. We will also discuss legal restrictions on personal information protection and the appropriate balance between data utility and privacy in sharing IPD.

Approach to Clinical Trial Data Sharing Using Consortium Platform
Wataru Ohtsuka, MSc
Clinical Information & Intelligence Dept. Chugai Pharmaceutical Co., Ltd

An experience of data sharing utilization
Akihiro Hirakawa, PhD
Project Associate Professor, Graduate School of Medicine The University of Tokyo

EU, Japan and US Privacy Law: Implications for Data Sharing
Mark Barnes, J.D, LL.M
Partner, Ropes & Gray LLP

Data De-Identification Technology to Ensure a Proper Balance Between Data Utility and Privacy Protection
Kazuhiro Minami, PhD
Associate professor, Department of Statistical Modeling Institute of Statistical Mathematics

Panel Discussion
All Session Speakers and
Jun Yoshida
Director, Office of Promotion of Clinical Trials, Research and Development Division, Health Policy Bureau, Ministry of Health, Labor, and Welfare (MHLW)

S18 Room 703 11:00-12:30
How to Handle Conflict in the Workplace?
Encourage, Engage, and Innovate with People Around You
Related Interest Area(s): ALL
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Yoko Kazami, BPharm, RPh, PMP
Research & Development, Nobelpharma Co., Ltd.

From time to time, we all encounter “difficult people.” They may easily dismiss your proposals, express a lot of complaints or criticisms, or demonstrate extreme emotional “ups and downs.” Even if you think about ways to improve your work or organization, their difficult attitudes or behaviors can demotivate you. Why do these persons assume such attitudes? What feelings underlie this attitude? How can you deal with “difficult people”? This session will share experiences with overcoming the attitudes of difficult people and explore these tips from the perspective of communication theory, psychology, brain science, and other disciplines. Regardless of your position or authority, you can resolve these difficulties with the appropriate mindset.

HARD THINGS: How to Get Over Difficulties in Introducing New Ideas
Yasushi Ishikawa, MSc
Manager, Global Marketing Interventional Systems Division Cardiac & Vascular Company Terumo Corporation

SOFTWARE: Getting Things Done Through Others
Noriko Fujinawa, MS, RN, OCNS, CCRP
IMSUT Hospital, Institute of Medical Science, The University of Tokyo

Panel Discussion
All Session Speakers
[PO-01] Ethnicity-Specific Drug Safety Data in EMA Registration Dossiers, European Public Assessment Reports and European and Singapore Drug Labels. Lost in Translation?

Senior Clinical Pharmacology Assessor, Dutch Medicines Evaluation Board, The Netherlands
Marc Mallepaard, PhD

Objectives:
To compare the extent of drug safety data in detailed ethnic populations available in drug registration dossiers and in the EU Public Assessment Reports (EPARs), SmPCs or Singapore Package Inserts (SGPI).

Method:
Drugs with large scale clinical studies, registered via the Centralised Procedure (CP) at the EMA between January 2008 and December 2012 and also registered in Singapore were selected in February 2018. The final selection consisted of 25 drugs in various indications. Next, drug registration dossiers and EPARs, SmPCs and SGPIs for this selection of 25 drugs were compared. Actual registration dossiers were retrieved at the Dutch Medicines Evaluation Board.

Results:
Detailed safety data in ethnic groups were present in 23 of 24 (96%) of the drug registration dossiers, but only in 12 of 25 (48%) of the EPARs, 8 of 25 (32%) of the SmPCs and 9 of 25 (36%) of the SGPIs. Further, in many cases where ethnicity specific safety information was provided in the SmPC or SGPIs, the ethnic subpopulations were not mentioned explicitly.

The ethnic groups mostly reported in the registration dossiers were Whites/Caucasians (23 of 24, 96%), Blacks/African Americans (22 of 24, 92%), Asians (20 of 24, 83%), and Hispanic (15 of 24, 63%). In most cases, different Asian subpopulations were reported as “Asian”. However, in some registration dossiers, a distinction was made with defined subpopulations like “Japanese” of “Korean”. Specific safety data relevant for the major ethnic groups in Singapore, i.e., Chinese, Indian and Malay, were seldom present in the screened documents.

Despite the fact that safety data analysed with respect to ethnicity are available in almost all screened registration dossiers, this information is often unknown to patients or prescribers as it often was not included in the EPARs, EU SmPCs or SGPIs.

Conclusion:
In order to increase availability of potentially important safety information, it is recommended to provide the investigated ethnic populations and group sizes in public regulatory documents. In this way, trust in drugs for different ethnic populations may be increased, and more robust treatment decisions may be obtained in clinical practice.

[PO-02] Raising Awareness of Patient Centricity in a Pharmaceutical Company Through the Patient Journey Map Creation

Daichi Sankyo Co., Ltd
Mika Ikeda, PhD

Objectives:
PJM (Patient Journey Map) was created to understand patient’s feelings and individual situation and shared among patients and their families, physicians, and our employees.

Method:
The graphic facilitator drafted PJM based on talks of patients and their families about their experiences and feelings from the day they were born. Creation of PJM was completed after the audience (patients and their family, physicians, and employees) added their thoughts and feelings. The questionnaire was carried out to attendees to evaluate the change of consciousness to Patient Centricity through PJM creation.

Results:
PJM deepened the understanding of the individual patients’ feelings and situation day-by-day. About 90% of the responders answered that PJM creation would be useful for drug discovery and development to meet patients’ and their families’ needs. Drawing and visualizing as PJM make audience empathize with the speakers. Participants could share their feelings and awareness with others by adding their thoughts on PJM. PJMs will be useful to promote the understanding on diseases within patients’ associations and also useful for medical transition from pediatrics to adult clinics. PJM would be effective to understand not only in the aspect of “disease”, but also “living people with diseases”. It was found to be difficult for employees who didn’t participate in the PJM creation to have similar understanding and empathy to participants. To deepen the understanding on patients and diseases for more stakeholders including pharma employees, it is important to consider more effective ways to utilize PJM.

Conclusion:
The patients and their families, the physicians, and the pharma employees well understood not only the disease itself, but also patients’ feelings and individual situation through PJM creation. In the future, we will consider how PJM can be used to deepen understanding patients and diseases for more stakeholders.

[PO-03] Suggestions for Improvement of the Electronic Version of Informed Consent Document Based on the Usability Test Evaluation

Manager, Clinical Innovations & Business Integration, Clinical Development Operation, Eli Lilly Japan
Yumiko Miyazaki, MSc

Objectives:
Propose informed consent documents (ICF) that are easy to read for patients participating in clinical trials by evaluating user satisfaction using the method of usability test (UX test)

Method:
Evaluation content: Electronic version of ICF
Target: 5 simulated users
Method: UX test

Usability generally refers to effectiveness, efficiency, and user satisfaction with products and systems, and can also be used as a standard for measuring the quality of user experience. We evaluated user satisfaction based on quantitative data using eye tracking system, qualitative data using behavior observation and interviews

Results:
Qualitative and quantitative findings were obtained regarding the content and structure of the consent documents in addition to the electronic functional findings.

Functional findings of the electronic version consent statement:
- Felt reading smoother than paper
- Did not intuitively understand the function button by the size and color of the button
- Did not have high user satisfaction for the robot’s voice guidance
- Felt long because of not seeing which page out of the whole, when reading
- Felt the importance of the video but I feel stress for a long time-
- Observed from the eye tracking data skipping or not read halfway since the amount of characters per page is large requiring to scroll many times

Findings about the structure of the consent statement:
- Did not confirm all the contents within the test time because the item the user wants to see is in the lower area
- Took time to understand from the difficulty of words such as technical terms

Conclusion:
The evaluation of the usability of the electronic version of the consent document using UX test suggested not only the improvement of the electronic function but also the need for the improvement of the composition of the consent document and the style.

[PO-04] Verification of Clinical Trial Enlightenment Effect by the Difference Between a Humanoid Robot “Pepper” and a Traditional Poster in the Institution

Manager, Clinical Innovations & Business Integration, Clinical Development Operation, Eli Lilly Japan
Yumiko Miyazaki, MSc

Objectives:
This pilot was conducted to verify the hypotheses concurrently to different media, a traditional poster in the institution and a humanoid robot “Pepper”, but of the same content about clinical trials.

Method:
Period: From early September to early December 2018
Subject institutions: 4 medical institutions in Tokyo and Osaka etc.
This pilot was conducted at three medical institutions over about one to three months. A humanoid robot “Pepper” developed by SoftBank Robotics Corp.
was installed in a waiting room to give information on topics such as "What is a clinical trial?" and "On-going clinical trials at this institution." The patients interested in the topics can hear further information from their medical doctor or CRC.

Results:
- Influence to Number of inquiries/enrollments
  - The posters in the institutions did not lead to inquiries about trial participation, while Pepper received inquiries from the patients in all the three institutions, which resulted in consent to participation and register
- Questionnaire to be answered by the medical institutions
  - It is suggested that Pepper has a possibility to contribute to building the better relationship between a patient, a medical doctor and a CRC.

Conclusion:
- Some reported increase in number of inquiries about clinical trials from the patients.
- Some reported improved recognition of clinical trials in the institution, CRCs, medical and nursing staff who came into contact with the patients also gave positive feedbacks.
- Regarding the Pepper's role in facilitating clinical trials, there were comments like "a great conversation with patients," "an improved image of clinical trials," and "a friendly atmosphere created in the medical institution."
- Some patients reported "I got to know about clinical trials by Pepper." I made an inquiry as I got interested in clinical trials by Pepper "Getting information from Pepper before explanation from doctor and nurse was helpful.”

Conclusion:
As a result of the pilot use case, the posters did not lead to inquiries about participation, while Pepper received inquiries from patients in which resulted in register. The medical institutions reported "trigger a conversation," "an improved image," and "better recognition/understanding." Thus, it is suggested that Pepper could be effective to improve public recognition of clinical trials.

This is our own implementation by using a humanoid robot "Pepper" developed by SoftBank Robotics Corp.

[PO-05] EPTRI-European Paediatric Translational Research Infrastructure: Facilitating the Future Development of Medicines Addressed to Paediatric Population
Professor, Department of Pharmacy University of Bari “Aldo Moro”
Nunzio Denora, PhD, PharmD

Objectives:
The EPTRI project aims to design the framework for the new Research Infrastructure (RI) to cover technological and scientific gaps in paediatric research affecting the field of medicinal products.

Methods:
During the EPTRI Context Analysis a survey was developed to map the competences, experience and services of Research Units in European C countries related to four scientific domains: paediatric medicines discovery and early drug development; paediatric biomarkers and biosamples; developmental pharmacology; paediatric medicines formulations and medical devices.

Results:
The online survey was run from April to June 2018 and reopened in January 2019 with four specific questionnaires delving on the areas of expertise in the fields of drug discovery and early development. More than 240 units from 26 countries answered to the survey. In details, 82 units (33.8%) declared to perform research on Human Development and Paediatric Medicines Discovery (pluripotent stem cell, 3D cell cultures, etc), 73 units (30.1%) on biomarkers identification/validation in paediatric diseases (16 of them host also biobanks of paediatric samples). Regarding the Developmental Pharmacology, 52 units (21.4%) declared to provide services such as microdosing, PBPK, pop PK and PK/PD, and innovative facilities such as placental platform for drug evaluation. In addition, 35 units (14.4%) declared to have expertise in Paediatric Medicines Formulations and 12 units (5%) Paediatric Medical Devices.

Conclusion:
The survey allowed to map research units and services bridging together all the available competences and technologies useful to support paediatric research, creating an open science space for researchers to collaborate in order to face the challenges in the development of new paediatric drugs.

Acknowledgement:
The research leading to these results has received funding from the European union’s Horizon 2020 programme under Grant Agreement No.777554.

[PO-06] Launching and Activity Report of DIA Japan Student Graduates Group
Foundation Medicine Business Department, Chugai Pharmaceutical Co., Ltd.
Hayato Sasao, RPh

Objectives:
1. Make opportunity where we can exchange information.
2. Make opportunity studying by oneself in adopting information from the outside.
3. Make opportunity that each person makes motivation.

Methods:
At the end of 2016, members who had participated in the Student Group discussed the needs for a place to study ourselves continuously. We recruited participants, and in May 2017 we proposed the launch of this group. At the end of 2017, we formulated the group’s activity guidelines (hereinafter charter). Based on the charter we planned learning sessions several times a year.

Results:
We have planned seven learning sessions below. 1. What do you want to do? (05/27/17) 2. Make one’s career plan (10/15/17) 3. Opportunity to think about the future (02/03/18) 4. The statistical viewpoint that is found for drug development (06/30/18) 5. Medicine charge system drastic reform and the effect (11/03/18) 6. Thinking about the figure which should have the monitoring for future (Joint plan with the DIA COM community)(02/15/19) 7. Taking a look-back on one’s duties and understanding other types of job (04/17/19) From the 1st learning session, we selected some themes that meet above purpose and which are highly desirable and feasible. Participants from the other DIA organizations were also accepted in our activity. The average satisfaction “more than expected” is about 70% or more. In addition to the above, we participate the regular Student Group meeting, and we are working together to make their learning sessions and the sessions at the Japan annual meetings successful.

Conclusion:
From 2017, we constructed a charter to systematize the group organization, and achieved the group’s objectives. In the future, we would like to expand the scale of activities by carrying out more active exchanges with other Communities, Student Group and making activity reports to the outside.
**Collaboration for International Multi-Center Clinical Trials: Industry perspective**

**J. Brockman, MBA**
Principal Medical Science Director--NCI--National Clinical Trial Network and Scientific Collaborations, Genentech BioOncology

**Collaboration for International Multi-Center Clinical Trials: Industry perspective**

**Masayoshi Naruoka, MBA**
Project leader, AstraZeneca K.K.

**Panel Discussion**

All Session Speakers

**S20** **Room 606** 14:00-15:30

**Drug Information on the Pharmacokinetics Section in the Japan Package Insert Can Be Evolve Furthermore Attractively?**

**Related Interest Area(s):** CR, RA, CP, MW, MI, O: Clinical Pharmacology, Labeling  
**Level: Beginner, Intermediate**  
**Language: Japanese Language Only**

**SESSION CHAIR**

Seongryul Kim, PhD
Director, Clinical Pharmacology, Headquarters of Clinical Development Otsuka Pharmaceutical Co., Ltd.

Information of pharmacokinetics in Japan package insert is based on traditional practice so far. Providing DDI information and utilization of modeling and simulation data on Japan package insert is described in the DDI guideline issued in 2018 and Population PK/PD analysis guideline issued in 2019 in Japan. In this session, we will share issues and proposals in such a change and consider collaboration with industry, government and academia for appropriate presentation of drug information based on the latest science, such as the utilization of forest plots on drug interactions and covariates, and the simulation data based on PopPK, PKPD and PBPK.

**Issues and Proposal on the Pharmacokinetics Section in the Japan Package Insert**

Masanobu Sato, PhD  
Senior Scientist Clinical Pharmacokinetics & Pharmacometrics Clinical Pharmacology Development Clinical Research, Japan Development MSD K.K.

**Provision of Pharmacokinetics Information in the Japan Package Inserts Focusing on Administrative Guidelines (Tentative)**

Taishi Horiuichi  
Reviewer, Office of New Drug 4, Pharmaceuticals and Medical Devices Agency (PMDA)

**Issues and Expectations of Pharmacokinetics Information in the Japan Package Insert at Medical Field**

Yoshiyuki Ohno, PhD  
The university of Tokyo Hospital

**Panel Discussion**

All Session Speakers

**S21** **Room 607** 14:00-15:30

**What Kind of Information Should Medical Deliver in Compliance with Promotional Activity Guideline?**

**Related Interest Area(s):** MA, MC  
**Level: Beginner**

**SESSION CHAIR**

Stuart Sowder, JD, PharmD, MBA  
Vice President, Compliance Lead, Asia, Pacific, Africa, Middle East, Pfizer

MHLW issued “the Guidelines on Pharmaceutical Product Communications” and “the matters related to the supervisory division of Pharmaceutical Product Communications” on 1st April 2019 and 1st October 2019 respectively. Also, JPMA issued Consensus Statement for MA/MSL on 1st April. These mean Medical is now required to have proper information provision with higher ethics and transparency than ever. Currently, many pharmaceutical companies are implementing various actions or governance process to meet with MHLW guideline. In this session, speakers will share practices or lessons learned about the operation with understanding of MHLW guideline or Consensus Statement of MA/MSL. During this session, we will be able to clarify information Medical should deliver in compliance with guideline.

**Implementation of Sales Information Provision Guidelines in Pharma companies**

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

**Pfizer Japan’s New Governance and QMS for MHLW Promotion GL**

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

**A Practical Approach to the Guidelines on Pharmaceutical Product Communications**

Takamasa Horiho, JD  
Legal Advisor, Compliance and Narcotics Division Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

**Panel Discussion**

All Session Speakers

**S22** **Room 608** 14:00-15:30

**Enabling More Efficient Clinical Studies through TransCelerate Solutions**

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

**SESSION CHAIR**

Makiko Okamoto  
Senior, Manager, Clinical Development Operations & Innovation / Clinical Innovation & Business Integration, Eli Lilly Japan K.K.

TransCelerate was founded with a mission to collaborate across biopharmaceutical and R&D communities to identify and help implement solutions to drive the delivery of new medicines. Since its inception, TransCelerate’s membership of 20 leading biopharmaceutical companies has believed that there is significant opportunity to improve the speed, quality and efficiency for all stakeholders in the industry by introducing consistent digital solutions throughout a patient’s clinical trial journey. This session will give a general overview and update on activities across TransCelerate, the tools currently being implemented in Japan, and a roadmap of TransCelerate initiatives and their statuses.

**TransCelerate Activities General Update**

Toshiharu Sano, RPh  
Executive Director, Head of Clinical Operations MSD K.K.

**Initiative Update: SIP (Shared Investigator Platform)**

Masahide Matsuhashi, MSc  
Clinical Operations / Japan Clinical Project Manager, Pfizer R&D Japan

**Initiative Update: CPT (Clinical Protocol Template)**

Sian Ratcliffe, PhD  
Vice President, Head of Medical Writing Pfizer Inc

**Initiative Update: Pharmacovigilance**

Kouji Kawamura, MSc  
Vice President, Pharmacovigilance JP Astellas Pharma Inc.

**S23** **Room 609** 14:00-15:30

**What Patient Registries Bring to Rare Disease Medicine Development**

**Related Interest Area(s):** CR, RA  
**Level: Beginner**  
**Language: Japanese Language Only**

**SESSION CHAIR**

Harumasa Nakamura, MD, PhD  
Translational Medical Center, Chief of Clinical Research/Trial Promotion Section, National Center of Neurology and Psychiatry

In drug development for rare diseases, the small number of target patients...
often makes it difficult to collect the number of patients required to verify the drugg's effectiveness in a clinical trial. Therefore, pharmaceutical companies often do not encourage drug development for rare diseases. But in recent years, development of patient registries [for rare diseases?] has been vigorously promoted. This session will introduce practical use of, and current utilization problems with, patient registries for drug development from different expert points of view.

**Current Situation and Future Perspectives of Review and Scientific Consultation about Orphan Drugs**
Yoko Aoi, PhD  
Principal Reviewer, Office of New Drug 5, Pharmaceuticals and Medical Devices Agency (PMDA)

**The Role of Patient Registry in the Drug Development of HTLV-1-Associated Myelopathy**  
Yoshihisa Yamano, MD, PhD  
Director, Department of rare diseases research Institute of Medical Science, St. Marianna University Graduate School of Medicine

**Patient Registry Study in Novel Drug Development for Intractable Vascular Malformations**  
Hiroshi Nagabukuro, PhD  
COO/CSO, ARTham Therapeutics, Inc

**Panel Discussion**  
All Session Speakers

**S24**  
**Room 610**  
**14:00-15:30**

**Have You Already Had a Labeling with New Format? How to Read New Format of Labeling and Impact for Implementation on Medical Practice**

**Related Interest Area(s):** RA, CP, AC, MI, O; Labeling  
**Level:** Beginner  
**Language:** Japanese Language Only

**SESSION CHAIR**  
Hideo Nakada, RPh  
Teaching Assistant, Hospital pharmacology, Faculty of Pharmacy, Keio University

In April 2019, the official guidelines for the new labeling format came into force, and certain specific products with labeling in line with these new guidelines have actually begun to reach the medical field. This session will present practical examples of actions taken by pharmaceutical companies in response to these guidelines, their impact on other materials (interview forms, etc.), the impact of delivering products with labeling in this new format, and points to consider when reading labeling in this new format. We will also discuss how information should be disseminated and how to provide information to advance use of the new labeling format in future medical practice.

**Points of New Format of Labeling and Impact on Other Materials**

Natsumi Kinoshita  
Reviewer, Office of Safety, 1 Pharmaceuticals and Medical Devices Agency (PMDA)

**Company initiatives in Delivery of Labeling with New Format to Medical Practice**

Naoto Tone  
Regulatory Scientist, Regulatory, Eli Lilly Japan K.K.

**Impact for Delivery of Labeling with New Format on Medical Practice from Pharmacists of Medical Institute Perspective**

Yuuki Sasaki  
Chief, Pharmaceutical Department, Nihon University Hospital

**Impact of New Format PI for Other Materials**

Yukio Ikiejima  
Manager, Japan and Asia Pharmacovigilance Department, CMA HQ, Eisai Co., Ltd.

**Panel Discussion**  
All Session Speakers

**S25**  
**Room 101**  
**14:00-15:30**

**Let's Talk a Lot about What Future Shape of Ideal Collaboration to Promote Life Science Field Is**

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

**SESSION CHAIR**  
Yasushi Okuno, PhD  
Professor, Department of Biomedical Data Intelligence, Graduate School of Medicine Kyoto University

**AI Development on Medicine Development and Post Marketing Safety Measures**

Rika Okamoto, PhD  
Program-Specific Associate Professor, Department of Biomedical Data Intelligence, Graduate School of Medicine Kyoto University

**AI for Pharmacovigilance Can We Work on This Project as Team “All Japan”?**

Yusuke Sugiura, MSc  
Manager, PV Operations Department and Pharmacovigilance Department, Pharmacovigilance and QA Division Kyowa Kirin Co., Ltd.

**Challenges of Using Medical and Scientific Information by AI in Japan - Seek Solutions through the AI Consortium “LINC” -**

Rika Abe, RPh  
Partnership-Promotion Coordinator, RIKEN Cluster for Science, Technology and Innovation Hub

**Panel Discussion**  
All Session Speakers and  
Toyotaka Iguchi, MD, PhD  
Office Director, Office of Pharmacovigilance II, Pharmaceuticals and Medical Devices Agency

**S26**  
**Room 102**  
**14:00-15:30**

**eSource in Clinical Trials - Global/Japan Use Cases -**

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

**SESSION CHAIR**  
Toshihiko Doi, MD, PhD  
Head, Programming, Biostatistics & Programming Clinical Services & Operations Research & Development, National Cancer Center East

The value of eSource is indisputable. TransCelerate member companies and other select organizations will share experiences of eSource implementation and discuss lesson learned to continue to progress towards the digitalization of clinical trials.

Discuss the application of eSource in clinical trials from an industry member consortium and others; identify important lessons learned for future application and adoption of eSource within their organizations and continue to uncover unknowns in this emerging space related to technology and standards in need of further advancement.
How About the Courage to Take a Further Step?

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

SESSION CHAIR
Keiichi Inaizumi MSc
Manager, Japan Clinical Project, Clinical Project Management Group, Pfizer R&D Japan

For young people, with speakers leading regulatory agencies and pharmaceutical companies, give talks with specific experiences, such as how did they increase their motivation when they were hard, how did they challenge themselves not creating walls or ceilings, how did they have the courage to take a further step, and how they have challenged. Through the lecture, you will unleash yourself from the spell of your own limitations that you have made yourself unconsciously, and this will be a session that will be a catalyst for young people to realize that you can make further leaps, or want to do so. This session is not a one-way presentation, but it also includes group discussions to broaden the scope, and conduct young networking beyond industry, government and academia.

Yoshiaki Uyama, PhD
Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

Atsushi Tsukamoto, PhD, MSc
Vice President, R&D Division, New Drug Regulatory Affairs Department, Daiichi Sankyo Co., Ltd

Group Discussion

COFFEE BREAK

15:30-16:00

S28 Room 605 16:00-17:30

Global Oncology Development - Be a Game Changer in Oncology Development -

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

SESSION CHAIR
Hironobu Saito, PhD
Corporate Officer, Vice President, Oncology Clinical Development, Daiichi Sankyo Co., Ltd.

The world surrounding cancer treatment continues to evolve rapidly. New, emerging products include not only immuno-oncology drugs, but also regenerative medicine and medical devices, that expand the therapeutic choice in the field of cancer treatment. Thanks to the rapidly evolving digital applications, artificial intelligence (AI), and the Internet of Things (IoT) that affect clinical trial operations, clinical development faces both challenge and opportunity to keep the evaluation of novel therapeutic products simple and reliable. This session provides a great opportunity to discuss how we can move towards ideal future direction of global clinical trial in oncology. This is a pre-session for DIA Global Oncology Development 2020 held on Jan 31, 2020.

Opportunities for More Contribution to Clinical Trials
Eri Sekine
Head, Trial Monitoring Japan, Novartis Pharma K.K.

Site Capability for Global Study - from Both “Sites and Sponsors” Perspectives -
Toshikdo Doi, MD, PhD
Clinical Operation Management, ONO Pharmaceutical Co., Ltd.

Panel Discussion
All Session Speakers and
Toshihiro Kido, MD, PhD
Deputy Director, Chief, Experimental Therapeutics, National Cancer Center Hospital East

Noboru Yamamoto, MD, PhD
Deputy Director, Chief, Experimental Therapeutics, National Cancer Center Hospital

S29 Room 606 16:00-17:30

Leveraging Physiological Pharmacokinetic (PBPK) Analysis for Development After Issuing Official Guidance the Potential Impacts of PBPK Analysis on Japan Submission

Related Interest Area(s): CR, RA, CP, MW, MI, O: Clinical Pharmacology, Labeling
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Atsunori Kaibara, PhD
Research Advisor, Pharmacokinetics/Pharmacodynamics Biometrics Medicines Development Unit Japan, Eli Lilly Japan K.K.

This session outlines the potential impact of PBPK after issuing the new guideline for non-clinical pharmacology experts. Throughout the session, we will share the perspectives of experts from industry, government, and academia on the number of clinical pharmacology studies necessary in submission by appropriately utilizing PBPK and how to balance actual clinical practice and simulation in drug development. In the panel discussion, the PBPK experts will discuss how to effectively utilize PBPK as an efficient tool for clinical development as well as useful bed-side information for appropriate drug use. We will also discuss the necessity and danger of applying simulation data as an alternative of actual clinical data.

Application of PBPK Modeling Leading to More Efficient Drug Development – Overview and Case Examples –
Chieko Nuto, PhD
Senior Manager, Clinical Pharmacology Clinical Research Development Japan, Pfizer R&D Japan

Current State of New Drug Review Utilizing PBPK Modeling and Developing PBPK Modeling Guideline
Shinichi Kijima
Principal Reviewer, Office of Advanced Evaluation with Electronic Data Office of New Drug 4, Pharmaceuticals and Medical Devices Agency (PMDA)

TBC
Naoto Uemura, MD, PhD
Department of Pharmaceutical Medicine, Oita University Faculty of Medicine

Panel Discussion
All Session Speakers and
Masanobu Sato, PhD
Senior Scientist, Clinical Pharmacokinetics & Pharmacometrics Clinical Pharmacology Development, Clinical Research, Japan Development, MSD K.K.

Masayo Oishi, PhD
Research Fellow, Quantitative Systems Pharmacology, Analysis and Pharmacokinetics Research Labs., Astellas Pharma Inc.
In this session, we would like to consider ways to ensure that patients can participate in clinical trials with peace of mind and that it is safe and appropriate by reviewing current problems in clinical trials and considering the goal of the clinical trial that should be achieved and for both parties to aim for the same goal of the clinical trial.

It is important for pharmaceutical companies and medical institutions to share consideration in the conduct of clinical trials, but the emphasis is on ensuring the reliability of the trial results. Moreover, the use of tools for implementing QMS and compliance with the newly examined Quality Management (QM) procedures themselves appear to be objectives. However, in the conduct of clinical trials, protection of human subjects is also essential, so it is necessary to consider what QM means, including human subject protection. To this end, it is important for pharmaceutical companies and medical institutions to share the goal of the clinical trial that should be achieved and for both parties to aim for the same goal of the clinical trial.

In this session, we would like to consider ways to ensure that patients can participate in clinical trials with peace of mind and that it is safe and appropriate by reviewing current problems in clinical trials and considering how pharmaceutical companies and medical institutions can work together.

**What is Estimand?**
Hideki Suganami, PhD
Director, Clinical Data Science Dept. Kowa Company, Ltd.

**Expectation on future implementation of E9(R1) guideline**
Ayako Hara, MSc
Biostatistics Reviewer, Office of New Drug 3, Pharmaceuticals and Medical Devices Agency (PMDA)

**Impact of Estimand from Regulatory and Clinical Viewpoints**
Takayuki Imaeda, MS, MPharm
Senior Director, Regulatory Affairs, Pfizer R&D Japan

**Estimands: A Clinical Perspective**
Charis Papavassiliou, MD, PhD
Therapeutic Area Head, Dermatology Immunology, Hepatology & Dermatology Development Unit, Novartis Pharma AG

**How to Become Quality Management for Patients**
Noriko Kobayashi
Clinical Research Support Office, National Cancer Center Hospital

The development of a Quality Management System (QMS) is currently under consideration in the conduct of clinical trials, but the emphasis is on ensuring the reliability of the trial results. Moreover, the use of tools for implementing QMS and compliance with the newly examined Quality Management (QM) procedures themselves appear to be objectives. However, in the conduct of clinical trials, protection of human subjects is also essential, so it is necessary to consider what QM means, including human subject protection. To this end, it is important for pharmaceutical companies and medical institutions to share the goal of the clinical trial that should be achieved and for both parties to aim for the same goal of the clinical trial.

In this session, we would like to consider ways to ensure that patients can participate in clinical trials with peace of mind and that it is safe and appropriate by reviewing current problems in clinical trials and considering how pharmaceutical companies and medical institutions can work together.

**What Doctors (Investigators) Can Do for Patients?**
Toshio Shimizu, MD, PhD
Department of Experimental Therapeutics, National Cancer Center Hospital

**What CRCs Can Do for Patients?**
Junko Yamazaki
Clinical & Translational Research Center, Kobe University Hospital

**What CRAs Can Do for Patients?**
Takashi Asahi
Clinical Research 2nd Div, CMIC Co., Ltd.

**What Sponsors Can Do for Patients**
Noriaki Nagao, MParm, PMP
Director, Quality Control Team Leader, Clinical Development Dept., Japan Tobacco Inc

**Panel Discussion**
All Session Speakers
A Case That the Labeling Was Not Revised as a Result of Consultation for Package Insert Revision
Yoshiaki Toyomori
Respiratory, Pharma Regulatory Affairs Japan, Regulatory Office Japan, Novartis Pharma K.K.

A Case That the Labeling Revision Succeeded by the New Consultation System
Kazuaki Sakakura
Deputy Director, Regulatory Affairs Dept. TAIHO Pharmaceutical Co., Ltd.

Panel Discussion
All Session Speakers and Chie Kishimoto
Vice President, Regulatory Affairs Department, Global Development Division, Shionogi & Co., Ltd.
Satoru Nakamura
Inspection Director, Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Devices Agency (PMDA)

The Present and Future of Utilization of AI and Digital Technology in Medicine Development and Healthcare Services -To Deliver Rational Medicine-
Related Interest Area(s): ALL
Level: Intermediate
SESSION CHAIRS
Kazuhiro Kanmuri, PhD
Vice President, Clinical Development Ascent Development Services Co., Ltd.
DIA Japan organized a symposium entitled “Cutting Edge Series - The Present and Future of Utilization of AI and Digital Technology in Drug Development -. The key elements that become the driving force of continuous innovation promotion regardless of industries are: (1) promoting technological innovation as the core of innovation, (2) application technology in needs including commercialization, and assess a level of utility and improvement, (3) fostering talent with high potential and find experts, and connect them to promote further innovation.
In this session, experts (engaging AI application using multi-omics and promoting education for coming AI and digital era) from academia, pharmaceutical companies, technology vendors and regulators will be invited to share their insights and discuss how we contribute to deliver rational medicine.

AI Empowers Biomarker Discoveries Using Multi-Omics Technologies
Wong, Catherine CL, PhD
Professor/Director, Center for Precision Medicine MultiOmics Research, Health Science Center, Peking University

Education Program for Value Creator Who Can Construct Bright Future in Kobe University and Future.
Hiroki Tsuruta, PhD
Associate Professor, Office for Academic and Industrial Innovation / Creative Dojo, Graduate School of Engineering, Kobe University

Key Points for Introducing RPA in the Pharmaceutical Industry
Hiroyasu Sugihara
Manager, Direct Sales, Automation Anywhere Japan, Co., Ltd.

Panel Discussion
All Session Speakers

The Appropriate Use of Drugs in Asia Countries, Especially Elder Patients
Related Interest Area(s): RA, AC
Level: Intermediate
SESSION CHAIR
Junko Sato, PhD
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA)
Although Japan is famous for centenarian population, the aging of population is a common problem in Asia.
Weight fluctuations and organ dysfunction associated with aging are well-known facts. However, only few of the drug package inserts include information about the elderly.
We will share the current status of the appropriate use of drugs for the elderly and cautionary statements included in package inserts in the aging Asian countries and consider more appropriate pharmacotherapy for the elderly by cooperating with other Asian countries that are experiencing the same situation.

TBC
Mingyan Liu, MD, PhD
Dept. of Pharmacology, School of Pharmacy, China Medical University.

‘The Appropriate Use of Drugs in Elder Patients: A Malaysian Perspective’
Azri Bin Nasruddin
Senior Principal Assistant Director, Centre for Product Registration, (NPRA)

Outlook of the Current Labeling in Asia and the Future for Elderly Patients
Rie Matsui, RPh
Director/ Regional Labeling Head for APAC, International Labeling, Global Regulatory Affairs, Pfizer R&D Japan

Panel Discussion
All Session Speakers

Related Interest Area(s): O:
Level: Intermediate
Language: Japanese Language Only
SESSION CHAIR
Kei Tanaka, Master
Manager, Nippon Boehringer ingelheim
Tips for breaking the sense of closure in life science industry in Japan will be provided by uncovering the success of startup company in life science field that are making remarkable and innovative efforts. In the first half of the session, perspectives from industry, government, and academia or from the successful startup company will be provided and an overview of Japan’s situation in the life sciences sector will be given. Then what we should do to revitalize Japanese life sciences will be discussed in a panel discussion format. Through discussions on themes that cannot be involved in daily work, further growth and career hints to audiences who will lead the pharmaceutical industry in the future will be provided. Also “importance of the challenge” in the pharmaceutical industry that requires innovation will be delivered through examples.

Innovations around Academia and Startups
Mikio Kawahara, MBA, MEM
Chief Investment Officer, UTokyo Innovation Platform Co., Ltd.

How does Pharma create “Innovation”?
Akira Suwa, PhD
Business Producer, Rx+ Business Accelerator Division, Astellas Pharma Inc.

The Fate of Innovative Bio Ventures
Yoshikazu Nakamura, PhD
President and CEO RIBOMIC Inc.

Initiatives for the Promotion of Healthcare Ventures by the Ministry of Health, Labour and Welfare
Hiroya Kuwahara, MD, PhD
Health Policy Bureau, Research and Development Division/Economic Affairs Division, Ministry of Health Labour and Welfare (MHLW)

Panel Discussion
All Session Speakers and Yoshinobu Tanaka
Clinical Director, Oncology clinical development, Oncology science unit, MSD K.K.

SHORT BREAK
17:30-17:45

DAY 2 | MONDAY | NOVEMBER 11
DAY 2 | MONDAY | NOVEMBER 11

ENGAGE AND EXCHANGE: SPECIAL CHAT SESSION

Let’s Chat! “WHAT’S THE DIA WORLD 2019”

Reception Hall

17:45-19:00

Related Interest Area(s): ALL
Level: ALL

SESSION CHAIR
Keiichi Inaizumi, MSc
DIA Japan Content Committee / Community

Manager, Japan Clinical Project, Clinical Project Management Group, Pfizer R&D Japan

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

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

<List of Topics>

<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Topic</th>
<th>Facilitators</th>
<th>Abstract</th>
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<tbody>
<tr>
<td>2</td>
<td>Clinical Innovation (CI) Project Management (PM)</td>
<td>What are the competency required for person in clinical development in the AI era?</td>
<td>Clinical Innovation (CI) Pfizer Japan Kei Tanaka, Master Project Management (PM) Pfizer &amp; R&amp;D Satoshi Suzuki</td>
<td>What are the important competency required for us working on drug development in the upcoming AI era? Let’s discuss necessary skills or future careers ahead of time.</td>
</tr>
<tr>
<td>3</td>
<td>Pharmacovigilance &amp; Labeling (PL) Medical affairs(MA)</td>
<td>Let’s discuss ecosystem for post-marketing (RWD/E)</td>
<td>Pharmacovigilance &amp; Labeling (PL) Eli Lilly Japan K.K. Rei Maeda Medical affairs(MA) Celgene K.K. Shinichi Nishimura, MD</td>
<td>Expedited approved products might be welcomed from early access point of view by patients, however it is important to enhance benefit risk information after launch as quickly as possible. In order to realize this situation, we should seek various ways to create and share evidence together with other countries. Let’s talk freely about next generation evidence creation and utilization globally.</td>
</tr>
<tr>
<td>4</td>
<td>Clinical Data Management (CDM) Patient Engagement (PE)</td>
<td>How is everyone doing; PRO/COA study Design and PRO/COA validation?</td>
<td>Clinical Data Management (CDM) the University of Tokyo Tempei Miyaji, MSc Patient Engagement (PE) MSD K.K. Yoshikata Furuya, MSc</td>
<td>Let’s discuss the use of Patient Reported Outcome (PRO). How can we incorporate and apply PROs to the clinical research? What others do for the translation of PROs? How can we validate the PROs? Note: The system validation of ePRO will not be discussed in this session. However, we can discuss the differences between PRO and ePRO.</td>
</tr>
<tr>
<td>5</td>
<td>Project Management(PM) Six Sigma(SS)</td>
<td>How to keep and manage Quality in clinical study</td>
<td>Project Management(PM) JAPAN TOBACCO INC. Nonatri Nagae Six Sigma(SS) Daichi Sanyo Co., Ltd Kazuo Ichikawa, PhD, RMP</td>
<td>As rather a long time has passed since QMS was proposed, it might be a good idea to discuss what the qualities are in clinical studies and how we should manage and control them.</td>
</tr>
<tr>
<td>6</td>
<td>Regulatory Affairs(RA) Pharmacovigilance &amp; Labeling (PL)</td>
<td>What will change with revision of the Pharmaceutical and Medical Devices Act (PMD Act)?</td>
<td>Regulatory Affairs(RA) Chugai Pharmaceutical Co., Ltd Hayao Sasa, RPh Pharmacovigilance &amp; Labeling (PL) Pfizer R&amp;D Japan Rei Matsui, RPh</td>
<td>PMD Act revision is under discussion on the following points: latest drug information provided electrically (not paper), new review process for “CIBM change” based on PACMP, advertising regulation and strengthening governance of companies. Also, the discussion on the clarification of complicated clinical studies such as the basket umbrella study has started. Let’s discuss on the impacts of these latest trends on our business.</td>
</tr>
<tr>
<td>7</td>
<td>Six Sigma(SS) Statistics(ST)</td>
<td>How should QTL be adopted in clinical trials?</td>
<td>Six Sigma(SS) Takeda Pharmaceutical Co., Ltd / Otsuka Medical Devices Co., Ltd. Kazuhiro Sawai, MSc Statistics(ST) The Institute of Statistical Mathematics Yoshie M. Ito, PhD</td>
<td>Although QTL was discussed as a session at DIA Annual Meeting in 2017, further improvement and evaluation of QTL in clinical studies are really intriguing from both statisticians’ and R&amp;A viewpoints. In this chatting session, we can enjoy free discussions on the topic related to QTL.</td>
</tr>
<tr>
<td>8</td>
<td>Statistics(ST) Clinical Innovation (CI)</td>
<td>A Discussion on utilization of RWD/RWE for drug development</td>
<td>Statistics(ST) Sumitomo Dainippon Pharma Co., Ltd. Satomi Tsuchiyuka, MSc Clinical Innovation (CI) Showa University Tatsuya Taniyama</td>
<td>How can RWD be used in drug development process? Let’s discuss from various viewpoints, such as what kind of data can be used, comparison with overseas situations, etc.</td>
</tr>
<tr>
<td>9</td>
<td>Medical Communication (MC) Medical affairs(MA)</td>
<td>Status of response to “Guidelines for Prescription Drug Marketing Information Provision” and its issues.</td>
<td>Medical Communication (MC) Astellas Pharma Inc. Kosuke Hayashi, MSc Medical affairs(MA) GlassSmithKline K. Takada, US</td>
<td>How do you understand the medical information that should be communicated as a pharmaceutical company based on the new promotional guidelines and what measures are taken? Are these initiatives able to provide better medical information for patients and medical professionals? Let’s discuss the current situation and challenges.</td>
</tr>
<tr>
<td>10</td>
<td>Patient Engagement (PE) Clinical Operations &amp; Monitoring (COM)</td>
<td>Think about informed consent from a patient’s perspective and how should the results of clinical studies be published for patients and/or citizens?</td>
<td>Patient Engagement (PE) Novartis Pharma Kazuyuki Suzuki Clinical Operations &amp; Monitoring (COM) Chugai Clinical Research Center Co., Ltd. Miyoji Taniyama</td>
<td>1. Recently, volume and complexity of informed consent documents are increasing. Let’s discuss how we can improve informed consent documents and communication to patient’s perspective. 2. Last year, became a requirement to disclose the results of clinical studies. Let’s talk about what actions we should take for patients and the public.</td>
</tr>
<tr>
<td>11</td>
<td>Regulatory Affairs(RA) Medical Communication Community(MC)</td>
<td>Tips for Mutual Regulatory Communication Improvement</td>
<td>Regulatory Affairs(RA) Eli Lilly Japan K.K. Yuka Hata Medical Communication Community(MC) MSD K.K. Keiko Tsunoi</td>
<td>Are you having trouble communicating with a company regulatory colleague or a PMDA reviewer? Perhaps when you call a company no one answers the phone, or when you call PMDA they are always in a meeting, you are on the horns of a dilemma between the authorities and the public. Let’s share our tips to improve communication gained from your experience.</td>
</tr>
</tbody>
</table>
9:00-10:30  
S37  Room 605/606  9:00-10:30  
The Future of Medical Big Data Based on the Next Generation Medical Infrastructure Act  
Related Interest Area(s): CR, ST, AC  
Level: Beginner  

SESSION CHAIRS  
Hiroyuki Yoshihara, MD, PhD  
Professor emeritus, Kyoto University  

Recently, the utilization of medical DB has been promoted in the medical industry, and the collection, accumulation and utilization of real world data such as EHR have been actively promoted regardless of the initiative of the government or private sector. The Next-Generation Medical Infrastructure Act, which took effect last year, sets new rules for the medical database industry. In this session,  
*What is the Next Generation Medical Infrastructure Act?  
*Medical DB based on the Next-Generation Medical Foundation Act  
*Future of Medical DBs under the Next-Generation Medical Infrastructure Act  
*What is the 1000 Medical Records Project?  
This paper introduces the future state of the medical DB industry, utilization of the medical DB, and how the medical DB industry will develop in the future, and proposes a method to contribute to future medical DB research.  

Development of Genomic Medicine and Drug Discovery Using Medical Database in Genome Cohort Study  
Soichi Ogishima, PhD  
Professor, Medical Information ICT Division Genomic Medical Information Division, Tohoku Medical Megabank Organization of Tohoku University  

Millennial Medical Record: Large Clinical Database for Medical Research  
Hiroyuki Yoshihara, MD, PhD  
Professor emeritus, Kyoto University  

Reconsidering “Real World Data”  
Takeo Nakayama, MD, PhD  
Professor, Department of Health Informatics, School of Public Health, Kyoto University Graduate School of Medicine  

S38  Room 607  9:00-10:30  
Regenerative Medical Products – Learn from the Latest Approved Products -  
Related Interest Area(s): CR, RA, AC  
Level: Beginner  

SESSION CHAIR  
Daisaku Sato, PhD, MPharm  
Associate Center Director for Advanced Evaluation with Electronic Data and Medical Informatics and Epidemiology / Chief Management Officer, Pharmaceuticals and Medical Devices Agency (PMDA)  

Two new regenerative medical products were approved in 2018, after 3 years since last approval. Many academics and the industries are working on researches and development toward the commercialization of regenerative medical products to cure the intractable diseases. In this session, we will have speakers from the companies that had recently approved products and from PMDA. The issues to address which occurred during the development and/or after launch will be presented, in addition, reviewer’s points of view will be explained. Attendees will expect to learn the cases from the lectures and panel discussion.  

Strategy, Issues, and Challenges - the Case of Stemirac -  
Yoshihiro Yoshikawa  
Research and Development Center for Regenerative Medicine, NIPRO Corporation  

Development Strategy and Challenges for Practical Application in Kymriah  
Yayoi Kitawaki, MS  
Senior Japan Program Head, Development Department, Oncology Development Unit, Novartis Pharma K.K.  

S40  Room 609  9:00-10:30  
Consider How to Provide Patient-Sought Drug Information  
Related Interest Area(s): RA, CP  
Level: Beginner, Intermediate  
Language: Japanese Language Only  

SESSION CHAIR  
Tomiko Tawaragi  
Chief Director, RAD-AR Council, Japan  

Drug information required by patients receiving medical care in Japan is diversifying, and the language of patients is also diversifying. Digitization has also advanced as a method of providing drug information, and various methods have been used. What are the challenges of current methods of providing drug information from a citizen perspective? In this session, we will share current approaches, challenges (limitations and difficulties of current schemes), and expectations for the future. In addition, we will consider what to do in the future through industry-government-academia collaboration and what to prepare from now in the panel discussion.  

Measures to Deliver Reliable Drug Information to Patients  
Yoichiro Takahashi  
Vice Chief Director, RAD-AR Council, Japan  

How Do Patients Feel They Want to Be Provided with Reliable Drug Information?  
Kensuke Nose  
Sponsor, MYSTAR Japan
**Information Provision at Pharmacies - From Information, To Communication**

Toshiaki Suzuki
Area Manager, Pharmacist Solution Department, Fuji Yakuhin Co., LTD.

**How to Meet Patients’ Needs for Health Information in Hospitals Focus on “Health Information Plaza Kenko-Joho-Hiroba “ in Keio University Hospital**

Hideo Nakada, RPh
Teaching Assistant, Hospital pharmacology, Faculty of Pharmacy, Keio University

**Panel Discussion**
All Session Speakers and
Takamasa Horio, JD
Legal Advisor, Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labor and Welfare (MHLW)

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**The Dawn of Program Management: Beyond Project Management**

Related Interest Area(s): CR, RA, PM, AC
Level: Intermediate
Language: Japanese Language Only

**SESSION CHAIR**
Koji Iwasaki, PhD
Specially Appointed Professor, Academic Clinical Research Center, Department of Medical Innovation, Osaka University

Recently, not only industry but also academia are utilizing program management skills and techniques, to produce deliverables under cost and time constraints. In addition, recent new therapy development, such as oncology, requires simultaneous development of multiple indications and/or concurrent CDx development, and simple project management tools may not fully solve organizational problems. Thus “program management”, where multiple projects are managed effectively and efficiently, plays critical roles. In this session, basic concept and examples program management implementation will be introduced and participants are encouraged to participate in discussion, so that we can deeply understand and discuss effective and efficient management for recent complex new therapy development.

**What is Program Management?**
Toru Kato
President, Japan Project Management Association

**Perspective for Academic Project Management and its Variety for Exit Strategies in Japan**
Shoji Sanada, MD, PhD
Professor and Chief in Clinical Research Support Group, Center for Clinical Research and Innovation, Osaka City University Hospital, Japan

**Program Management Implementation in Pharmaceutical Company**
Atsushi Tsukamoto, PhD, MSc
Vice President, New Drug Regulatory Affairs, Daiichi Sankyo., Co., Ltd.

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**Think About Informed Consent from a Patient’s Perspective – What Can We Do to Promote Proper Understanding of Clinical Trials and Patient-Friendly Clinical Trials?**

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

**SESSION CHAIR**
Kazuo Hasegawa
Representative Director, Lung Cancer Patient Network ONE STEP

Informed consent is the first important process for patients to learn about and understand clinical trials. Recently, volume and complexity of informed consent documents are increasing. In this session, we will discuss how we can improve informed consent documents and communication from a patient’s perspective based on the recent efforts in Japan and global.

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**How Do We Make “Easy-to-Understand ICF” Come True?**
Yumiko Miyazaki, MSc
Manager, Clinical Innovations & Business Integration, Clinical Development Operation & Innovation, Eli Lilly Japan K.K.

**From the Standpoint of CRC That Uses Various ICFs and Supports Many Subjects (Tentative)**
Yukari Suzuki, R.N.
Chief Clinical Research Coordinator, Clinical and Translational Research Center, Niigata University Medical & Dental Hospital

**TBC**
Shinsuke Amano
Director, Group Nexus Japan

**Panel Discussion**
All Session Speakers

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**Virtual Clinical Trials: Roadmap for Implementation in Japan**

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

**SESSION CHAIR**
Takayuki Imaeda, MS, MPharm
Senior Director, Regulatory Affairs, Pfizer R&D Japan

Virtual clinical trial (VCT) is one of the hot topics in drug development as a way to enhance patients’ access to clinical trials. In contrast to several used cases available globally, only a few examples exist in Japan. In this session, we will discuss the benefits and obstacles to implement VCT in Japan from the study site and sponsor’s perspective after the global sponsor’s presentation. We will also introduce new technologies and approaches for VCT including eConsent, direct-to & from-patient, remote medicine, wearable device, ePRO, and smartphone apps and the challenges associated with them. Lastly, we will discuss the roadmap towards successful implementation, including what needs to evolve and potential disease areas, with key stakeholders from patients, study sites and pharmaceutical companies.

**Direct-to-Patient Clinical Trial Model -Promises and Challenges-**
Soyoku Nobeyama, MSc
Clinical Innovation Leader, Janssen Clinical Innovation, Janssen R&D, LLC.

**Implementation of “Home Visits” in Clinical Trials in Japan: Impact on Patients and Challenges**
Atsushi Kitamura, MS
Clinical Innovation Lead, Clinical Operations, Pfizer R&D Japan

**Virtual Clinical Trials: Roadmap for Implementation in Japan**
Haruo Kuroki, MD, PhD
Director, Sotobo Children’s Clinic

**Panel Discussion**
All Session Speakers and
Saori Watanabe
Research Center for Advanced Science and Technology, University of Tokyo

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

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**Innovative Drug Development: Is the Placebo Arm Really Necessary?**

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**COFFEE BREAK**
11:00-12:30
Points to Consider in the Development of Gene Therapy in Japan. (Tentative)
Takaaki Yoshida
Reviewer, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

S46 Room 608 11:00-12:30
Establishing Real-World-Evidence in Japan, from the Perspective of Database Utilization

Related Interest Area(s): MA, HEOR
Level: Beginner

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

Real-world-evidence (RWE) has become more important, in association with increasing recognition of value-based medicine or healthcare. In Japan, the healthcare industry, government and academia are making great efforts to establish various databases or patient registries to be utilized for clinical development, pharmacovigilance or research purpose. However, RWE in Japan is still very much behind compared with those of western countries. The purpose of this session is to discuss how to promote RWE generation in Japan, especially from the perspective of utilization of database. The overviews of RWE in Japan or other countries will be provided. Also, the speaker from Japanese pharmaceutical industry will share recent experience of RWE generation.

The Largest Clinical RWD Database Development in Japan: Overview and Future Opportunities
Koji Kawakami, MD, PhD
Professor and Chair, Graduate School of Medicine and Public Health, Kyoto University

RWD Frontline: Expectation for RWD and Its Limitation in Japan
Eiko Shimizu, MSc, MMA, PhD
Graduate Project Associate Professor, Graduate School of Pharmaceutical Sciences, The University of Tokyo

Work Productivity and Disease Burden in Patients with Pain Using Japanese Web Survey
Toshinaga Tsuji, PhD
Scientific Leader (CNS), Medical Affairs, Shionogi & Co., Ltd

Real-world databases for effectiveness, safety and value: A view from outside Japan
Nancy A. Dreyer, PhD, MPH
Chief Scientific Officer & Senior Vice President, IQVIA Real-World & Analytic Solutions

All Session Speakers

S47 Room 609 11:00-12:30
Toward Development of Comprehensive and Reliable Drug Information System for Consumers and Patients

Related Interest Area(s): MC, MI, O: Patient
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Michiko Yamamoto, PhD
Visiting Professor, Graduate School of Pharmaceutical Sciences, Kumamoto University

While pharmaceutical information is abundant on the media and the Internet, people do not know where they can obtain the correct information. When we evaluated medical information on the Internet based on international evaluation criteria, few sites met the criteria in Japan. It may be considered that the scheme for securing whether it is reliable information is not spreading. Pharmaceutical information does not provide sufficiently for the general public in the flow from clinical trial, approval to post-marketing.
It is required to develop the comprehensive information infrastructure for shared decision making, considering the consumers and patients’ health literacy. It should be necessary to discuss the prospects and issues from the perspective of industry, government, academia and patients.

**Medical Information: Evidence-Based Public Information and Shared Decision Making**
Takeo Nakayama, MD, PhD
Professor, Department of Health Informatics, School of Public Health, Kyoto University Graduate School of Medicine

**Current Status and Future Prospects of Providing Information by Pharmaceutical Companies**
Kazuhiro Keitoku
The Federation of Pharmaceutical Manufacturers’ Associations of JAPAN (FPMAJ)

**Toward Development of Comprehensive and Reliable Drug Information System for Consumers and Patients**
Michiko Yamamoto, PhD
Visiting Professor, Graduate School of Pharmaceutical Sciences, Kumamoto University

**How Should We Set Up Our R&D Strategy and Target Product Profile? Key Learning from Real Cases**

**Panel Discussion**

**Forefront of Patient Technology in Clinical Trials**
Related Interest Area(s): CR, RA, DM, PM, AC; O: Patient
Level: Intermediate

**Significance and Examples of TPP and R&D Strategic Documents in a Pharmaceutical Company**
Michiyoshi Oshima, MBA
Senior Director, Japan Portfolio & Project Management Development Japan, Pfizer R&D Japan

**Tools for Enabling and Accelerating Patient-facing Digital Technology Use**
Matthew Moyer, MSc, MBA, PMP
Director, Clinical Supply Technology, Merck & Co., Inc.

**eConsent Implementation in Japan**
Ryo Masada
Pharma Clinical Study Management, Trial Monitoring, Global Drug Development, Novartis Pharma K.K.

**Marching Toward Patient-Centricity: How Technologies Are Transforming Clinical Research**
Jiao Song, PhD
Associate Director, Janssen Clinical Innovation, Janssen R&D, LLC.
Regulatory approval using the Conditional Early Approval System
Junko Sugita
Expert Manager, Regulatory Affairs, Regulatory Labeling Group, Pfizer R&D Japan

Application of SAKIGAKE designation for Xospata tablets from CMC point of view
Goshi Murakami, MSc
Manager, Quality and Process Management section, Manufacturing technology 1, Astellas Pharma Tech Co., Ltd.

Panel Discussion
All Session Speakers

LUNCH BREAK 12:30-14:00
SESSIONS

Rational Medicine for Patients

Related Interest Area(s): RA, O: Patient
Level: Advanced

SESSION CHAIR
Tatsuya Kondo, MD, PhD
President, Medical Excellence Japan

All the regulatory agencies in the world have been trying to work for the benefit to the patients by establishing new regulations in response to the needs of their citizens. In this session, we invite speakers who once worked as a physician in the medical institutions, where they observed what regulatory agencies do, and then later became a leader of agencies, or a leader of pharmaceutical industry. Speakers will be asked to discuss “Rational Medicine” from the patients’ viewpoint. Rational Medicine is something that patients want, and not only healthcare providers but also people working in the industry and regulatory agencies would want to deliver it to the patients. What did they think about when they were healthcare providers? Did it change when they became a leader of agency or industry? Let us relook at what Rational Medicine really mean through these discussions.

Panel Discussion
Yasuhiro Fujiwara, MD, PhD
Chief Executive, Pharmaceutical and Medical Device Agency (PMDA)

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

Kihito Takahashi, MD, PhD
Vice President, GSK Japan K.K.

COFFEE BREAK
15:30-16:00

Panelists
Toyotaka Iguchi, MD, PhD
Risk Management Director, Office of Safety 2, Pharmaceuticals, and Medical Devices Agency (PMDA)

Kenichi Mikami, MPHarm
Office Director, Office of Review Management, Pharmaceuticals, and Medical Devices Agency (PMDA)

Daisaku Sato, PhD, MPHarm
Associate Center Director for Advanced Evaluation with Electronic Data and Medical Informatics and Epidemiology / Chief Management Officer, Pharmaceuticals and Medical Devices Agency (PMDA)

Shinichi Takae
Director, Office of Medical Device 1, 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

Takashi Sato, MSc, PMP
Program Vice-Chair / Manager, Resource Management Group, R&D Planning Department, Kyowa Kirin Co., Ltd.
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湯地晃一郎 東京大学 医学研究所

プログラム概要

患者さん、未来の患者さん、そしてその家族の方々のために私たち何ができ、何をするべきでしょうか。すべての人々に会期から人生の最終段階までのあらゆる局面で最適で合理的な医療を提供するために、企業、行政、医療関係者を含むステークホルダーが抱えている課題はあまりにも多くあります。

DIAでは産・官・学が患者さんや市民と伴にリーダーシップを発揮することで医薬品・医療機器のイノベーションを生み出すためのチャレンジを日々重ね、対話しています。それぞれの役割の範囲で個々に新しい価値を追求することに留まらず、倫理性、透明性、公平性を確保しながら、それぞれの利益が相互補完することなく相乗する環境を育むことでお互いが協働し、それぞれがなすべきことを互いに理解し合う共通の目標に向かって邁進するチームであるからこそ、未来のすべての人々に最新の科学的な知識を踏まえたRationalな（理性にかなった・納得した）医療を届けることができるのです。

本会では、近藤達也大会長による大会テーマに基づいた大会長講演を皮切りに、難病の子供さんとその家族の方々に寄り添われている大住力先生にそのご貢献を共有いただく基調講演、患者・市民の医薬品開発への参画と、提供すべき合理的な医療の2つのテーマで各分野からの演者にご議論頂くダイヤモンドセッションを企画しております。また、臨床試験におけるRisk Based Approach、Big Dataの活用、Global環境にて日本から世界の人々にいかに発信していくか、など最新の話題について立場の異なる演者がそれぞれの試みを紹介し、聴講者を含めたパネルディスカッションを行うことにより、ひとりひとりの足場を目指すべきポイントを明らかにしていきます。2日目の夕刻には“チャッキングセッション”にて参加者同士のネットワークや意見交換ができる場があり、3日目明けには“PMDAタウンホール”としてPMDAからのパネリストとの質疑応答を楽しむ機会も設けています。

第16回DIA日本年会は『Rational Medicineを世界の人々に届けるために』を大会テーマにして、明日の医療環境に貢献するためになすべきことを考え、伝えあう場です。

後援予定
厚生労働省／独立行政法人 医薬品医療機器総合機構／国立研究開発法人 日本医療研究開発機構／日本製薬工業協会／米国研究製薬工業協会／欧州製薬団体連合会／日本PDA製薬学会／国際製薬技術協会(ISPE)／一般社団法人 Medical Excellence JAPAN／ISPOR日本部会

展示申込募集中
詳細については、DIA Japanまでお問い合わせ下さい。
〒103-0023 東京都中央区日本橋人形町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 | Email: Japan@DIAglobal.org

DIA Japan
Nihonbash Life Science Building 6F,
2-3-11 Nihonbashihoncho, Chuo-ku, Tokyo 103-0023 Japan
Tel: +81.3.6214.0574 Fax: +81.3.3278.1313 Email: Japan@DIAglobal.org

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

DIAglobal.org

Drug Information Association
Global Center: Washington, DC | Americas | Europe, Middle East & Africa | China | Japan | India
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**オリエンテーション&展示会場 (12:00-13:00)**

### ショートブレイク

### 情報交換会 (レセプションホール) *若手の方向を交流を深めて頂く企画も用意しています

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### ランチブレイク

### コーヒーブレイク

### ショートブレイク

### Engage and Exchange ‘Let’s Chat!’ - Special Chat Session 2 (レセプションホール)

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</table>

### ランチブレイク

### コーヒーブレイク

### ショートブレイク

### 参考情報

- **オフィシャルウェブサイト**
- **オフィシャルアプリ**
- **動画チャレンジ**
- **Twitter**

### 参考資料

- **プログラム書**
- **携帯アプリ**
- **スマートフォンアプリ**
- **電子書籍**

### 資料ダウンロード

- **PDFファイル**
- **冊子**
- **メモリカード**
- **CDディスク**

### 更新情報

- **最新のプログラム**
- **変更情報**
- **参加者リスト**
- **追加のセッション**

### 聯絡先

- **オフィス**
- **事務局**
- **事務局担当者**
- **事務局電話番号**

### その他

- **参加条件**
- **参加費用**
- **参加手続き**
- **参加者登録**

---

**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
- MA=医薬品情報
- MI=医薬品情報提供
- HEOR=ヘルスエコノミックス
- O=その他

**日本語のみ**

**セッション1**

- CR=効果評価
- RA=患者さんの求める医薬品情報
- MI=医薬品情報提供
- CMC=品質管理
- AC=アカデミア
- MA=医薬品情報
- MI=医薬品情報提供

**セッション2**

- CR=効果評価
- RA=患者さんの求める医薬品情報
- MI=医薬品情報提供
- CMC=品質管理
- AC=アカデミア
- MA=医薬品情報
- MI=医薬品情報提供

---

**参加者情報**

- **参加者名**
- **所属機関**
- **役職**
- **連絡先**

---

**入場口**

- **東京駅**
- **新宿駅**
- **池袋駅**
- **台場駅**

---

**交通手段**

- **電車**
- **バス**
- **タクシー**
- **自転車**

---

**駐車場**

- **内部駐車場**
- **外部駐車場**

---

**パーソナルサービス**

- **子連れの利用可能**
- **フードサービス**
- **無料Wi-Fi**

---

**チケット情報**

- **一般価格**
- **学生価格**
- **企業価格**

---

**アメニティ**

- **シャワールーム**
- **コンベンションセンター**
- **商談室**

---

**関連アクティビティ**

- **ショッピング**
- **レストラン**
- **コンサート**

---

**出展企業**

- **企業名1**
- **企業名2**
- **企業名3**

---

**質問・お問い合わせ**

- **管理部門**
- **電話番号**
- **メールアドレス**
11月10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
11:30-12:00 オリエンテーション@展示会場
12:30-13:00 開会の挨拶 開会の挨拶
13:00-13:30 コーヒーブレイク  コーヒーブレイク
13:30-15:30 基調講演 基調講演
15:30-18:00 DIAmond Session 1 DIAmond Session 1
18:00-19:30 情報交換会

11月11日（月）
8:30- 受付
9:00-9:30 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（S01 〜 S09）
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（S10 〜 S18）
12:30-14:00 ランチブレイク / ボスターセッション / ランチョンセミナー
14:00-15:30 セッション（S19 〜 S27）
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（S28 〜 S36）
17:45-19:00 Engage and Exchange Engage and Exchange

11月12日（火）
8:30- 受付
9:00-10:30 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（S37 〜 S43）
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（S44 〜 S50）
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 DIAmond Session 2
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、指定の期間までにDIAに提出された資料のみが掲載されます。ハンドアウト資料（スライドコピー）の配布はありません。

Private Social Function Policy
本年会開催期間中、当プログラム外の会議、展示、懇親会等のイベントの開催はご遠慮ください。下記時間帯につきましては、これに限りません。

11月9日（土） 終日
11月10日（日） 午前8時以前、午後8時半以降
11月11日（月） 午前8時以前、午後8時以降
11月12日（火） 午後8時以降、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のものがとは限りません。

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、24ページをご覧ください。
スチューデントセッション/オリエンテーション

605/606会議室
9:30–12:00
リスクコミュニケーションの考え方 - 患者さんに伝えるべきリスクとは？糖尿病治療薬を題材に-
関連領域：RA, CP, AC
レベル：初級
座長
昭和大学
榮長 実佳子
昭和大学
森 南美
東京薬科大学
菅生 夕貴
日本大学
菅 俊明

医薬品の使用に際し予測される効果や副作用について、医療従事者・患者さん・その家族等が情報共有を行い、関係者間の理解度の差を埋める「リスクコミュニケーション」は医療を提供・享受するうえで非常に重要なプロセスである。

私達は将来医療に携わる者として、リスクコミュニケーションを学ぶべきであると考え本年度のテーマとした。

本セッションでは糖尿病治療薬のSGLT2阻害薬を題材に取り上げる。当該薬剤に関して患者さんやその家族に伝えるべき情報は何か、リスクコミュニケーションに関する議論を元にグループワークで議論し、その重要性を学ぶ機会を提供する。

本グループワークでは糖尿病治療薬のSGLT2阻害薬を題材とするために、SGLT2阻害薬の適正使用に関する Recommendation を予習しておくことが望ましい。

SGLT2阻害薬の適正使用に関する Recommendation:

SAVE THE DATE
17th DIA Japan
Annual Meeting 2020
November 8-10, 2020
Tokyo Big Sight | Ariake

1日目 | 11月 10日 (日)
レセプションホール
12:00–13:00
オリエンテーション

発表者
DIA Japan Contents Committee／ファイザーR&D合同会社
稲泉 恵一

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

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

DIA Japan Student Group OB/OG/パレクセル・インターナショナル
久我 俊彦
DIA Japan Student Group OB/OG/あすか製薬株式会社
岡田 安矢
サノフィ株式会社
山上 潤
開会の挨拶および基調講演 / DIAmmond Session 1

開会の挨拶
国際会議場
13:30-13:45

DIA Japan
植村 昭夫
DIA
Barbara Lopez Kunz
DIA Advisory Council of Japan議長 / 第一三共株式会社
齋藤 宏暢
DIA Chair-Elect
Lingshi Tan

基調講演
国際会議場
15:30-16:15

座長
一般社団法人 Medical Excellence Japan
近藤 達也

東京ディズニーランドで約20年間務めた後、日本全国の難病を患う子どもとその家族を支援する医療法人を設立し、経営する現場から、その難病児を持つ母達の話を中心にお話しします。

ディズニーのホスピタリティで難病を患う子どもとその家族に寄り添う
公益社団法人 難病の子どもとその家族へ夢を
大住 力

DIAmond Session 1
国際会議場
16:15-17:45

座長
キャンサーソリューションズ株式会社 / 一般社団法人CSRプロジェクト
桜井 なおみ
MSD株式会社
古屋 義方

医薬品開発における患者・市民参画（Patient and Public Involvement：PPI）は近年、国内で急激に注目が高まっているテーマである。DIA日本年会では過去数年に渡って、PPIをテーマにしたセッションを企画し、PPIの概念や経験、及び医薬品開発の各フェーズにおける国内外の最新のPPIの取り組みや課題を共有し、ディスカッションを行ってきた。今年のDIAmmondセッションでは、日本の治験や臨床研究の代表的な関係者を集まり、PPIに関する最新の取り組みや成果を共有すると共に、日本におけるPPIを推進している関係者が取り組むべきことについて総合的に議論する。

情報交換会
レセプションホール
18:00-19:30

*若手の方同士で交流を深めて頂く企画も用意しています。
9:00-10:30

S01  605会議室
がんゲノム医療の実用化の現状を知る ～遺伝子パネル検査の現状と未来～

関連領域: RA, AC
レベル: 初級
座長
独立行政法人 医薬品医療機器総合機構
藤原 康弘

患者さんが一人一人にあった個別化医療の実現に向けて、がんゲノム医療への取り組みがすみ分けられている。平成30年に「第3期がん対策推進基本計画」が閣議決定され、がん医療の充実としてがんゲノム医療が取り上げられた。本セッションでは、個別化医療における医薬品開発を念頭に、医療機器のNGSや解析プログラムを活用した遺伝子パネル検査やコンパニオン診断薬を取り巻く現況を概説した上で、昨年末に承認された遺伝子変異解析を行うパネル検査システムの実例も踏まえ、今後の我が国におけるがんゲノム医療の進展に向けた課題の洗い出しとその解決策について産官学の視点からディスカッションする。実臨床におけるゲノム医療の課題
国立がん研究センター中央病院
山本 昇

PMDAからみるがん遺伝子パネル検査の行方
独立行政法人 医薬品医療機器総合機構
矢花 直幸

企業から見るがん遺伝子パネル検査のレギュラトリー課題
中外製薬株式会社
田澤 義明

パネルディスカッション

S02  606会議室
ブロックチェーン技術と医薬産業への展開

関連領域: ALL
レベル: 初級
言語: 日本語のみ
座長
国立保健医療科学院
水島 洋

既に他業種で導入実績のある“ブロックチェーン”技術は現在医薬領域への展開の可能性が検討されている。この技術を導入すれば、高いセキュリティを保つ上で、分散したデータを管理することが可能になる。特に、医薬領域での活用事例として薬事申請、治療のデータ認証、医薬品の流通監視、value based paymentなど多岐の応用が期待される。本セッションでは医薬におけるブロックチェーン技術の展望と課題を討議し、医薬産業を取り巻く情報管理や活用の可能性を議論する。

ブロックチェーンによって実現される患者中心のデータ活用基盤
Arteryex株式会社
李 東瀛

日本製薬工業会 (JPMA) / エーザイ株式会社
畠山 伸二

パネルディスカッション
本セッションの講演者

S03  607会議室
WHOとの協働による世界貢献

関連領域: RA, Government
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

WHOの活動の中には、Pre-QualificationやReliance Pathway等、先進国の関心が大きい案件も多い。エボラウイルス感染症のような社会的影響が大きい感染症が発生した時、封じ込めばかりでなく、治療薬の臨床研究等にWHOがかかわることもあり、各国規制当局との関係も少なくず存在する。しかしながら、我々の中には、WHOは、世界保健の観点から新興国の支援をしているイメージが強く、その活動や我々との連携可能性について考え及んでいない。本セッションでは、WHOの活動について十分な情報を得た上で、規制当局や企業がWHOとのような連携が可能かについて議論する。

未定
未定
未定
WHOとの協働による世界貢献、企業の観点から
日本製薬工業会 (JPMA) / エーザイ株式会社
高田 充康

パネルディスカッション

S04  608会議室
Clinical QMS対応の具体策 - RiskおよびIssue Management -

関連領域: RA, DM, CR, ST, PM, AC
レベル: 中級
座長
グラクソスミスクライン株式会社
井上 宏高

2018年7月に日本製薬業界協議会からClinical QMS実装の取組み事例を公開されている。しかし組織レベル、現場レベルでの具体的な対応にはまだ戸惑うことも多い。本セッションではClinical QMSの全体像をまずとらえ、実装に不可欠な要素の中でRisk ManagementとIssue Managementを中心に説明するとともに、実装に成功した事例、遭遇した課題と対応などClinical QMS実装に資する話題と議論の場を提供する。

Clinical QMSの実装 と課題
MSD株式会社
平山 清美

臨床QMS実践への道 ～ICH E6(R2)導入後に見えてきた課題～
第一三共株式会社
船木 千春

Clinical QMSにおけるIssue managementを成功に導く考え方・ツール及び具体的事例
株式会社Real Discovery Outdoors
小澤 郷司

パネルディスカッション

S05  609会議室
臨床研究法、施行から1年半の今とこれから

関連領域: RA, PM, AC, MA
レベル: 初級
言語: 日本語のみ

未定
臨床研究法の施行は研究の現場に大きな影響を与え、介入試験の数は激減した。日本は、臨床研究を行う際のルールが研究の目的や資金源などにより異なる。さらに、国際共同試験を行う場合には、国内ルールに加えICH-GCPも加わる。このようなルールの多さや複雑さで現場は混乱し、負担となっている。そこに、臨床研究法が追い打ちをかけた。

このセッションでは、産・学・官それぞれの立場で、臨床研究法の施行で抱える問題点と今後の法改正に向けて望むことを共有し、それぞれの視点から、臨床研究の信頼の確保と臨床研究の活性化を両立するため、将来的な臨床研究の法規制のあり方についても議論したい。

臨床研究法施行後の課題と今後の対応 ~アカデミア・医療機関の立場から~
国立がん研究センター東病院
尾崎 雅彦

臨床研究法施行後の課題と今後の対応 ~製薬企業の立場から～
アステラス製薬株式会社
浅井 洋

関連領域: CP、CR、PM
レベル: 初級、中級

規制対応のためのPV、患者さんのためのPV
中西製薬株式会社
青木 事成

高品質な再審査申請を行うための体制整備 - より科学的な製造販売後調査を計画・実施するために -
ノバルティス・ファーマ株式会社
坂本 秀夫

RWDとmHealthを活用したPV
IQVIA Solutions株式会社
松井 信智

患者からの医薬品作用報告
独立行政法人 医薬品医療機器総合機構
小林 可菜英

企業によるPublicationのあるべき姿と今後の展望
関連領域: CR、AC、MA、MI、MC、MW
レベル: 初級、中級

製薬会社がスポンサーになるPublicationは、医療関係者が患者さんの治療を決定する際に、最も重要な医学的判断資料の一つである。したがって、製薬会社がエビデンスを適切にコミュニケーションするために、倫理的にかつ効果的なPublicationの実施を確実なものにすることが非常に重要である。

本セッションでは、国際的なPublication expertと共にGPP3やICMJEの目的に基づき、日本の製薬会社の現場で起きている実際や課題を議論する。その上で、患者に関与いただくPublicationなど、将来への展望にも触れる。

医薬品業界におけるPublication –現状と将来展望–
Astellas Pharma Inc.
Audrey Suh Krolicki
自社におけるPublication Managementの現状と課題（仮題）
塩野義製薬株式会社
瀬野 健一

What Journal Editors Expect from the Pharmaceutical industry <ビデオによる講演>
University of Split School of Medicine
Ana Marušić

医薬品業界におけるPublication –現状と将来展望–
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自社におけるPublication Managementの現状と課題（仮題）
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What Journal Editors Expect from the Pharmaceutical industry <ビデオによる講演>
University of Split School of Medicine
Ana Marušić

未定

中国の薬事規制改革は、種々の変化を中国における医薬品開発にもたらしている。医薬品開発プロセスが革新され、安全・効果性の確認が強化された結果、革新的な医療機器や薬物の開発が可能になっている。

中国の医薬品開発事情を様々な視点から読み解く（仮題）
関連領域: RA
レベル: 中級

未定
パネルディスカッション
本セッションの講演者

S09  703会議室 9:00-10:30
産官学と市民のコラボレーションで創る共通価値（Shared Value）とは？～新時代のイノベーションを考える～
関連領域: ALL
レベル: 初級
言語: 日本語のみ
座長
アイ・エル・ジャパン株式会社
二宗 みのり
医薬品・医療機器開発における成功確率が低下する中、従来の開発手法から、会社や組織の枠を超えた共同作業が求められている。各々の強みを生かしたオープンイノベーションの実現が注目されている。本セッションでは、個別のアプローチでは解決の難しい現代社会の課題に取り組み、産官学のwin-winの協働をテーマに、官主導の産・学をつなぐプラットフォーム作りなどの連携推進の取り組み、企業が経済利益と社会的価値創出の間に相乗効果を生み出すCSV（Creating Shared Value）の概念を解説し、アカデミアからは異文化連携について話題提供いただく。

オールジャパンでの医薬品創出に向けたAMEDの取組み
国立研究開発法人 日本医療研究開発機構
塩川 智規
未定
埼玉医科大学国際医療センター
藤原 恵一
SDGs,CSV,コレクティブインパクトの概要
株式会社Flexas Z
稲葉 涼太
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

S10  605会議室 11:00-12:30
将来のデジタルヘルスへの取り組み: 規制当局及び企業から医療従事者及び患者さんへの医薬品情報/添付文書の電子情報の活用について考える
関連領域: RA, CP, MA, O: MI
レベル: 初級/中級
座長
ファイザーR&D合同会社
松井 理恵
医薬に対するデジタル化は、世界中で急速に進んでいる。その一環として医薬品情報のデジタル化により、患者や医師のヘルスカバーの向上、より主体的な医療を選択できるようになることが期待される。本年4月から添付文書新記載要領の施行に伴い、日本でも添付文書情報のXML化が実施された。添付文書のXML化は、医薬品情報のデジタル化のベースポーンであり、USでは既に導入され、他の欧米諸国でも検討が始められている。本セッションでは、将来のデジタルヘルスを見据えて、デジタル化された添付文書の活用について、海外と日本薬の取り組みを比較し、日本の患者さん及び医療従事者に対する規制当局及び企業内での活用について議論する。

R&D Head ClubのWGでのアダプテーション前後での品質改善の報告
MSD株式会社
木下 潔
機械翻訳の成功の鍵 – 効果的なPost-editの方法 –
ノバルティスファーマ株式会社
重松 俊礼
AI翻訳技術の全社導入事例～その経緯と将来展望～
第一三共株式会社
朝生 祐介

パネルディスカッション
本セッションの講演者、並びに

MSD株式会社
井 上 学

S11  606会議室 11:00-12:30
AI翻訳の将来を見据えると、日本国内の開発及び申請業務がどのように変わるのか
関連領域: ALL
レベル: 初級、中級
言語: 日本語のみ
座長
アストラゼネカ株式会社
田中 健夫
昨年の年会に引き続き、医薬品分野でのAI翻訳の最新の状況をレビューする。製薬企業での、アダプテーション前後での品質向上の状況や課題、他業界での成功事例などから、今後、さらなる品質向上のために、産官学での連携をどのように進めていくべきかを議論する。

R&D Head ClubのWGでのアダプテーション前後での品質改善の報告
MSD株式会社
木下 潔
機械翻訳の成功の鍵 – 効果的なPost-editの方法 –
ノバルティスファーマ株式会社
重松 俊礼
AI翻訳技術の全社導入事例～その経緯と将来展望～
第一三共株式会社
朝生 祐介

パネルディスカッション
本セッションの講演者、並びに

MSD株式会社
井 上 学

S12  607会議室 11:00-12:30
MA/MSLのあるべき姿
関連領域: MA
レベル: 初級
座長
ファイザー株式会社
松井 理恵
近年、多くの製薬企業はメディカルの機能を強化してきた。特にMA/MSLはメディカル活動における中心的役割であるが、業績範囲や求められるスキルが多種多様である。ここ数年各製薬団体よりMA/MSLのあり方や役割が明確に規定されるつつある。

本セッションでは、今後のMA/MSLのあるべき姿を製薬団体の代表および
アカデミア、規制当局からの見解や期待を踏まえて、参加者ともに考えるワークショップ形式で議論してみたい。

本ワークショップを通じて、業界団体間の認識の共通点・相違点を洗い出し、日本の製薬業界としてのMA/MSLの立場・役割を明確にする。

メディカル・アフェアーズ、メディカル・サイエンス・リエゾンとは？ー医師からの疑問ー
東京医科大学
西部 俊哉
厚生労働省
堀尾 貴将
大日本住友製薬株式会社
西村 剛
PhRMAの考えるMA/MSLのあるべき姿
日本イライリリー株式会社
今岡 丈士
パネルディスカッション
本セッションの講演者

S13 608会議室 11:00-12:30
Risk Based Approachの導入に見るモニタリングの現状および今後の展望
関連領域: CR、DM
レベル: 中級
座長
ブリストル・マイヤーズ・スクイブ株式会社
横川 重吉
ICH E6 R2 実装に伴い、製薬会社各社およびCRO各社のニーズとしてRisk Based Monitoring (RBM) 導入が年々高まっているものの、いまだ様子見のモードであることは否めない。RBM導入の目的は質の高いデータの確保、医療機関における各種プロセス構築と問題点の早期発見の相乗効果を期待するものであるが、一部では方法論の議論が先行している現状もある。本セッションでは、医療機関に対して行ったアンケート結果をふまえ、業界団体や医療機関との協業などについて紹介し、本来のRBM実践のために取り組むべき課題について議論したい。

今一度、RBMの原点に戻ろう
ファイザーR&D合同会社
黒瀬 陽子
RBMでCRAに求められるものは何？ー医療機関からのサーベイ結果から見えた課題ー
株式会社アイロム
原 命寿
真のRBM実装に向けて ～site tourからの学び～
日本イライリリー株式会社
小泉 稔
パネルディスカッション
本セッションの講演者

S14 609会議室 11:00-12:30
DDS最前線
関連領域: RA、CMC、AC
レベル：初級
言語：日本語のみ
座長
京都大学
橋田 充
医薬品開発は、かつて主流であった低分子化合物からペプチド、タンパク質や核酸などの中～高分子薬がトレンディになりつつあるが、安定性や膜透過性等の問題が実用化の大きな壁となっており、その課題解決のためのDDS研究が活発になっている。
本セッションではこのようなDDS技術について、企業・研究機関から最新の研究やその開発にあたっての課題をご紹介いただく。
また、規制当局からは規制の現状や課題、今後の展望について紹介していただく。

革新的ナノ医薬品・DDS基幹技術の評価研究
北里大学
加藤 くみ子
製薬企業におけるナノ DDS研究
エーザイ株式会社
石原 比呂之
未定
独立行政法人 医薬品医療機器総合機構
伊藤 浩介
パネルディスカッション
本セッションの講演者

S15 610会議室 11:00-12:30
MID-NETの活用から見えてきたこと
関連領域: RA、CP、ST
レベル: 中級
言語：日本語のみ
座長
独立行政法人 医薬品医療機器総合機構
宇山 佳明
平成30年4月より運用開始したMID-NETは、製薬企業では、3件の利活用が承認されている。使用成績調査を実施せずMID-NETによるデータベース調査を市販後の安全監視活動として実施した三社の製薬企業から、集積、データ解析、情報提供の現状、MID-NET利用の利点や課題について意見を述べていただき、規制当局の担当者を交え、今後のMID-NETのPVへの活用に関する展望と、克服すべき課題について明らかにする。

MID-NET概要
独立行政法人 医薬品医療機器総合機構
一丸 勝彦
製造販売後データベース調査におけるMID-NET利用の実践
第一三共株式会社
佐川 慶
ファーマコビジランスの視点からのMID-NET利用
MSD株式会社
宮崎 真
MID-NET利用におけるフィージビリティ評価のすすめ
ファイザーR&D合同会社
弘 新太郎
パネルディスカッション
本セッションの講演者
S16 101会議室 11:00-12:30
小児開発推進の取り組み（産官学）と患者団体からの期待～この1年間で何が変わりましたか？何をしてきましましたか？もと推進させるためには何が必要でしょうか？～
関連領域: RA、O: Patient
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

小児開発については、産官学で推進のための様々な施策を打ち出してきている。まずは、産官学の立場からこの一年間小児開発を推進するために行った取り組みを簡単に紹介頂き、パネルディスカッションを中心に小児開発を進め上での障害は何か、それは産官学でどのような活動を行えば改善されるのかを議論する。パネルディスカッションには患者団体の代表の方にも参加頂き、患者さん目線での意見も頂きながら議論を進める。

S17 102会議室 11:00-12:30
臨床試験の個別被験者データの共有と個人情報保護の課題
関連領域: CR、RA、DM、AC、ST、MC、MW
レベル: 中級
座長
サノフィ株式会社/日本製薬工業協会
加藤 智子

臨床試験の透明性確保と公衆衛生の向上を目的とし、臨床試験の個別被験者データ（IPD）を共有する取り組み（Clinical Trial Data Sharing）が活発化している。一方、個人情報をめぐる規制強化を受け、データ提出者は匿名化のためのデータ加工処理に苦慮しており、利用者側には、データの有用性が下がるといった懸念がある。

S18 703会議室 11:00-12:30
職場の人間関係のもやもや、解決します！？～周りの人を勇気づけ、巻き込み、イノベーションを起こそう
関連領域: ALL
レベル: 初級
言語: 日本語のみ
座長
ノーベルファーマ株式会社
風見 葉子

仕事においてときどき「困った人」に遭遇することがあります。あなたの提案を却下する、愚痴や批判ばかり言う、感情の起伏が激しいなど。せっかく業務や組織改革を考えても、こうした抵抗勢力にモチベーションが下がる場合も少なくないでしょう。なぜ、その人はそんな態度をとるのでしょうか。どんな感情が隠れているのでしょうか。どんなアプローチができるのでしょうか。どのような立場でも、権限があってもなくても、課題や問題を解決していくのに必要なマインドセットは同じ。このセッションでは、社内で困難に立ち向かった事例をご紹介いただき、あなたやあなたの周囲の人気が持ちよう稼げるよう、様々なスキルを駆使してヒントを探ります。
Suggestions for Improvement of the Electronic
stakeholders.
PJM can be used to deepen understanding patients and diseases for more
individual situation through PJM creation. In the future, we will consider how
The patients and their families, the physicians, and the pharma employees
culture to consider more effective ways to utilize PJM.

Conclusion:
diseases for more stakeholders including pharma employees, it is important
demand and empathy to participants. To deepen the understanding on patients and
also "living people with diseases". It was found to be difficult for employees
and also useful for medical transition from pediatrics to adult clinics. PJM
useful to promote the understanding on diseases within patients' associations
and awareness with others by adding their thoughts on PJM. PJMs will be
audience empathize with the speakers. Participants could share their feelings
patients' and their families' needs. Drawing and visualizing as PJM make
creation would be useful for drug discovery and development to meet
situation day-by-day. About 90% of the responders answered that PJM
PJM deepened the understanding of the individual patients' feelings and

PO-03] Suggestions for Improvement of the Electronic

Marc Maliepaard
Objectives:
To compare the extent of drug safety data in detailed ethnic populations
available in drug registration dossiers and in the EU Public Assessment
Reports (EPARs), SmPCs or Singapore Package Inserts (SGPI).
Method:
Drugs with large scale clinical studies, registered via the Centralised
Procedure (CP) at the EMA between January 2008 and December 2012 and
also registered in Singapore were selected in February 2018. The final
selection consisted of 25 drugs in various indications. Next, drug registration
dossiers and EPARs, SmPCs and SGPIs for this selection of 25 drugs
were compared. Actual registration dossiers were retrieved at the Dutch
Medicines Evaluation Board.
Results:
Detailed safety data in ethnic groups were present in 23 of 24 (96%) of the
drug registration dossiers, but only in 12 of 25 (48%) of the EPARs, 8 of 25
(32%) of the SmPCs and 9 of 25 (36%) of the SGPIs. Further, in many cases
where ethnicity specific safety information was provided in the SmPC or
SGPIs, the ethnic subpopulations were not mentioned explicitly.
The ethnic groups mostly reported in the registration dossiers were
Whites/Caucasians (23 of 24, 96%), Blacks/African Americans (22 of 24,
92%), Asians (20 of 24, 83%), and Hispanic (15 of 24, 63%). In most cases,
different Asian subpopulations were reported as "Asian". However, in some
registration dossiers, a distinction was made with defined subpopulations
like "Japanese" of "Korean". Specific safety data relevant for the major ethnic
groups in Singapore, i.e., Chinese, Indian and Malay, were seldom present in
the screened documents.
Despite the fact that safety data analysed with respect to ethnic population
are available in almost all screened registration dossiers, this information
is often unknown to patients or prescribers as it often was not included in
the EPARs, EU SmPCs or SGPIs.
Conclusion:
In order to increase availability of potentially important safety information, it
is recommended to provide the investigated ethnic populations and group
sizes in public regulatory documents. In this way, trust in drugs for different
ethnic populations may be increased, and more robust treatment decisions
may be obtained in clinical practice.

[PO-02] Raising Awareness of Patient Centricity in a
Pharmaceutical Company Through the Patient Journey
Map Creation

第一三共株式会社
池田 未佳

Objectives:
PJM (Patient Journey Map) was created to understand patient’s feelings and
individual situation and shared among patients and their families, physicians,
and our employees.
Method:
The graphic facilitator drafted PJM based on talks of patients and their families
about their experiences and feelings from the day they were born. Creation of
PJM was completed after the audience (patients and their family, physicians,
and employees) added their thoughts and feelings. The questionnaire was
carried out to attendees to evaluate the change of consciousness to Patient
Centricity through PJM creation.
Results:
PJM deepened the understanding of the individual patients’ feelings and
situation day-by-day. About 90% of the responders answered that PJM
creation would be useful for drug discovery and development to meet patients’
and their families’ needs. Drawing and visualizing as PJM make audience empathize with the speakers. Participants could share their feelings
and awareness with others by adding their thoughts on PJM. PJMs will be
useful to promote the understanding on diseases within patients’ associations
and also useful for medical transition from pediatrics to adult clinics. PJM
would be effective to understand not only in the aspect of “disease”, but also
“living people with diseases”. It was found to be difficult for employees
who didn’t participate in the PJM creation to have similar understanding and
empathy to participants. To deepen the understanding on patients and
diseases for more stakeholders including pharma employees, it is important
to consider more effective ways to utilize PJM.
Conclusion:
The patients and their families, the physicians, and the pharma employees
well understood not only the disease itself, but also patients’ feelings and
individual situation through PJM creation. In the future, we will consider how
PJM can be used to deepen understanding patients and diseases for more
stakeholders.

[PO-04] Verification of Clinical Trial Enlightenment
Effect by the Difference Between a Humanoid Robot
"Pepper" and a Traditional Poster in the Institution

日本イーライリリー株式会社
宮崎 由美子

Objectives:
This pilot was conducted at three medical institutions over about one to
three months. A humanoid robot “Pepper” developed by SoftBank Robotics
Corp. was installed in a waiting room to give information on topics such as
What is a clinical trial?” and “On-going clinical trials at this institution.” The
patients interested in the topics can hear about further information from
their medical doctor or CRC.
Results:
- Influence to Number of inquiries/enrollments
The posters in the institutions did not lead to inquiries about trial participation, while Pepper received inquiries from the patients in all the three institutions,
which resulted in consent to participation and register
- Questionnaire to be answered by the medical institutions
It is suggested that Pepper has a possibility to contribute to building the better relationship be-tween a patient, a medical doctor and a CRC.
- Some reported the increase in number of inquiries about clinical trials from the patients
- Some reported improved recognition of clinical trials in the institution,
CRCs, clerical and nursing staff who came into contact with the patients also

Version of Informed Consent Document Based on the
Usability Test Evaluation

日本イーライリリー株式会社
宮崎 由美子

Objectives:
Propose informed consent documents (ICF) that are easy to read for patients
participating in clinical trials by evaluating user satisfaction using the method
of usability test (Us test)
Method:
Evaluation content: Electronic version of ICF
Target: 5 simulated users
Method: UX test
Usage: Generally refers to effectiveness, efficiency, and user satisfaction
with products and systems, and can also be used as a standard for measuring
the quality of user experience. We evaluated user satisfaction based on
quantitative data using eye tracking system, qualitative data using behavior
observation and interviews
Results:
Qualitative and quantitative findings were obtained regarding the content
and structure of the consent documents in addition to the electronic
functional findings,
Functional findings of the electronic version consent statement•
- Felt reading smoother than paper
- Did not intuitively understand the function button by the size and color
of the button
- Did not have high user satisfaction for the robot's voice guidance
- Felt long because of not seeing which page out of the whole, when reading
- Felt the importance of the video but I feel stress for a long time-

Observered from the eye tracking data skipping or not read halfway since the
amount of characters per page is large requiring to scroll many times
Findings about the structure of the consent statement•
- Did not confirm all the contents within the test time because the item
the user wants to see is in the lower area
- Took time to understand from the difficulty of words such as technical terms

Based on the findings of UX test, it is concluded that it is necessary to
improve the user’s satisfaction by changing the style and configuration of the
document, as well as improving the content that can be checked intuitively,
such as the size and color
Conclusion:
The evaluation of the usability of the electronic version of the consent
document using UX test suggested not only the improvement of the
electronic function but also the need for the improvement of the composition
of the consent document and the style.

[PO-04] Verification of Clinical Trial Enlightenment
Effect by the Difference Between a Humanoid Robot
"Pepper" and a Traditional Poster in the Institution

日本イーライリリー株式会社
宮崎 由美子

Objectives:
This pilot was conducted to verify the hypotheses concurrently to different
me-dia, a traditional poster in the institution and a humanoid robot “Pepper”,
but of the same content about clinical trials.
Method:
Period: From early September to early December 2018
Subject institutions: 4 medical institutions in Tokyo and Osaka etc.
This pilot was conducted at three medical institutions over about one to
three months. A humanoid robot “Pepper” developed by SoftBank Robotics
Corp. was installed in a waiting room to give information on topics such as
What is a clinical trial?” and “On-going clinical trials at this institution.” The
patients interested in the topics can hear about further information from
their medical doctor or CRC.
Results:
- Influence to Number of inquiries/enrollments
The posters in the institutions did not lead to inquiries about trial participation, while Pepper received inquiries from the patients in all the three institutions,
which resulted in consent to participation and register
- Questionnaire to be answered by the medical institutions
- Some reported the increase in number of inquiries about clinical trials from the patients
- Some reported improved recognition of clinical trials in the institution,
CRCs, clerical and nursing staff who came into contact with the patients also
Results:  
Based on the charter we planned learning sessions several times a year. After the end of 2017, we formulated the group's activity guidelines (hereinafter referred to as the “charter”). The medical institutions reported “trigger a conversation,” “an improved image,” and “better recognition/understanding.” Thus, it is suggested that Pepper could be effective to improve public recognition of clinical trials.

Conclusion:  
As a result of the pilot use case, the posters did not lead to inquiries about participation, while Pepper received inquiries from patients in which resulted in registration. The average satisfaction “more than expected” is about 70% or more. In addition to the above, we participate the regular Student Group meeting, and we are working together to make their learning sessions and the sessions at the Japan annual meetings successful.

[PO-05] EPTRI-European Paediatric Translational Research Infrastructure: Facilitating the Future Development of Medicines Addressed to Paediatric Population
Department of Pharmacy University of Bari “Aldo Moro”
Nunzio Denora

Objectives:  
The EPTRI project aims to design the framework for the new Research infrastructure(RI) to cover technological and scientific gaps in paediatric research affecting the field of medicinal products.

Methods:  
During the EPTRI Context Analysis a survey was developed to map the competences, experience and services of Research Units in European Countries related to four scientific domains; paediatric medicines discovery and early drug development; paediatric biomarkers and biosamples; developmental pharmacology; paediatric medicines formulations and medical devices.

Results:  
The online survey was run from April to June 2018 and reopened in January 2019 with four specific questionnaires delving on the areas of expertise in the fields of drug discovery and early development. More than 240 units from 26 countries answered to the survey. In details, 82 units(33.8%) declared to perform research on Human Development and Paediatric Medicines Discovery (pluripotent stem cell, 3D cell cultures, etc), 73 units(30.1%) on biomarkers identification/ validation in paediatric diseases (16 of the host also biobanks of paediatric samples). Regarding the Developmental Pharmacology, 52 units(82.1%) declared to provide services such as microdosing, PBPK, pop-PK and PK/PD, and innovative facilities such as placental platform for drug evaluation. In addition, 35 units(14.4%) declared to have expertise in Paediatric Medicines Formulations and 12 units(5%) Paediatric Medical Devices.

Conclusion:  
The survey allowed to map research units and services bridging together all the available competences and technologies useful to support paediatric research, creating an open science space for researchers to collaborate in order to face the challenges in the development of new paediatric drugs.

Acknowledgement:  
The research leading to these results has received funding from the European union’s Horizon 2020 programme under Grant Agreement No.777554.

[PO-06] Launching and Activity Report of DIA Japan Student Graduates Group
中外製薬株式会社
篠尾 卿人

Objectives:  
1. Make opportunity where we can exchange information.
2. Make opportunity studying by oneself in adopting information from the outside.
3. Make opportunity that each person makes motivation.

Methods:  
At the end of 2016, members who had participated in the Student Group discussed the needs for a place to study ourselves continuously. We recruited participants, and in May 2017 we proposed the launch of this group. At the end of 2017, we formulated the group’s activity guidelines (hereinafter referred to as the “charter”). Based on the charter we planned learning sessions several times a year.

Results:  
We have planned seven learning sessions below. 1. What do you want to do? (05/27/17) 2. Make one’s career plan (10/15/17) 3. Opportunity to think about the future (02/03/18) 4. The statistical viewpoint that is found for drug development (06/30/18) 5. Medicine charge system drastic reform and the effect (11/03/18) 6. Thinking about the figure which should have the monitoring for future (Joint plan with the DIA COM community)(02/15/19) 7. Taking a look-back on one’s duties and understanding other types of job (04/17/19) From the 1st learning session, we selected some themes that meet above purpose and which are highly desirable and feasible. Participants from the other DIA organizations were also accepted in our activity. The average satisfaction “more than expected” is about 70% or more. In addition to the above, we participate the regular Student Group meeting, and we are working together to make their learning sessions and the sessions at the Japan annual meetings successful.

Conclusion:  
From 2017, we constructed a charter to systematize the group organization, and achieved the group’s objectives. In the future, we would like to expand the scope of activities by carrying out more active exchanges with other Communities, Student Group and making activity reports to the outside. We have planned seven learning sessions below. 1. What do you want to do? (05/27/17) 2. Make one’s career plan (10/15/17) 3. Opportunity to think about the future (02/03/18) 4. The statistical viewpoint that is found for drug development (06/30/18) 5. Medicine charge system drastic reform and the effect (11/03/18) 6. Thinking about the figure which should have the monitoring for future (Joint plan with the DIA COM community)(02/15/19) 7. Taking a look-back on one’s duties and understanding other types of job (04/17/19) From the 1st learning session, we selected some themes that meet above purpose and which are highly desirable and feasible. Participants from the other DIA organizations were also accepted in our activity. The average satisfaction “more than expected” is about 70% or more. In addition to the above, we participate the regular Student Group meeting, and we are working together to make their learning sessions and the sessions at the Japan annual meetings successful.
パネルディスカッション
本セッションの講演者

S20 606会議室 14:00-15:30

添加文書の薬物動態に関する医薬品情報は、さらに進化できないか？！

関連領域: CR、RA、CP、MI、MW、O: Labeling、Clinical Pharmacology
レベル: 初級、中級
言語: 日本語のみ

座長
大塚製薬株式会社
金 盛烈

現在、添加文書上の薬物動態に関する情報は、従来からの慣習に基づき記載されている。2018年に薬物相互作用ガイドラインが、2019年に母集団薬物動態／薬力学解析ガイドラインが発表され、それらのガイドラインでは、添加文書における薬物相互作用の情報提供のあり方やシミュレーション結果の活用について言及されている。このような変化の中、薬物相互作用や共変量に関するフォレストプロットの活用や、PopPK、PK/PD及びPBPKに基づくシミュレーション結果など、最新のサイエンスに基づく医薬品情報の適切な提示方法としての課題及びそれに対する提案などを共有し、産学交流を深めることを検討する。

S22 608会議室 14:00-15:30

よりよい臨床試験を目指すTransCelerateの活動

関連領域: ALL
レベル: 初級
言語: 日本語のみ

座長
日本イーライリー株式会社
岡本 麻紀子

TransCelerateは、新薬の提供を促進するためのソリューションの特定と実装を支援するために、医薬品および研究開発のコミュニティ間で協力するという使命をもって設立されました。創業以来、20社の大手製薬会社のTransCelerateの会員は、臨床試験の全過程を通じてデジタルソリューションを導入することによって、医薬品開発に関わる全ての人たちのために、スピード、品質、効率を改善する大きなチャンスがあると信じています。このセッションでは、TransCelerate全体の活動、現在日本で導入されているツール、および様々なイニシアチブのロードマップをご紹介します。

S21 607会議室 14:00-15:30

メディカルが担うべき医薬品の情報提供とは何か？-販売情報提供活動に関するガイドラインを踏まえて

関連領域: MA、MC
レベル: 初級

座長
Pfizer Inc.
D. Stuart Sowder

"医療用医薬品の販売情報提供活動に関する厚労省ガイドライン"および"販売情報提供活動の監督部門に関する事項"が本年それぞれ2019/4/1と2019/10/1に施行された。また、製薬協からもMA/MSLの基本的な考え方方4/1に公表され、メディカルが担う情報提供に高い倫理感、透明性が求められることになった。

現在、多くの製薬企業では厚労省ガイドラインの要件を満たすために様々な取り組みや管理体制を実行しているところである。

本セッションでは、販売情報提供活動に関するガイドラインやMA/MSLの基本的な考え方の理解を踏まえ、施行・管理の実践事例を共有・議論するものである。

このセッションを通じて、メディカルが担うべき医薬品の情報提供のあり方について明確にしたい。

S23 609会議室 14:00-15:30

疾患レジストリが希少疾病の医薬品開発にもたらすもの

関連領域: CR、RA
レベル: 初級
言語: 日本語のみ

座長
国立精神・神経医療研究センター
中村 治雅

希少疾病を対象とした医薬品開発は、対象患者さんの少ない状況で、有効性的検証に必要とされる症例数が困難なため、企業が開発に踏み出す状況が多く存在する。

近年、精力的に整備が進められている疾患レジストリについて、企業およびアカデミアからの医薬品開発における具体的な活用事例や、現行の問題点を紹介し、最新の情報を共有する。

その上で、産学交流の場としての立場から希少疾病用医薬品の承認申請に向けた活用のための方策や、解決すべき問題点について議論したい。
オーファン医薬品の承認審査及び治験相談における現状と今後の展望
独立行政法人 医薬品医療機器総合機構
青井 陽子

HTLV-I関連脊髄症の医薬品開発における患者レジストリの役割
聖マリアンナ医科大学 大学院附属研究所 難病治療研究センター
山野 嘉久

難治性脈管奇形に対する新薬開発における患者レジストリ研究
アー サムセラピーティクス 株式会社
長袋 洋

パネルディスカッション
本セッションの講演者

S24 610会議室 14:00-15:30
あなたはもう手に取りましたか？ - 新記載要領添付文書の読み方と、現場でのインパクト
関連領域: RA、CP、AC、MI、O: Labeling
レベル: 初級
言語: 日本語のみ
座長
慶應義塾大学
中田 英夫

2019年4月に添付文書の新記載要領が施行され、新しい記載要領の添付文書が実際に医療現場に届き始めている。新記載要領の添付文書の読み方のポイントを、実例を示して解説する。製薬企業での対応と、他の資材（インタビューフォームなど）への影響、実際に新記載要領の添付文書を医療現場へ届けたときのインパクトについて紹介する。

今後、医療現場で新記載要領添付文書の活用が進むために、どのように情報を発信していくのがよいのか、新記載要領添付文書の情報提供方法について議論したい。

新記載要領添付文書の読み方のポイントと他の資材へのインパクト
独立行政法人 医薬品医療機器総合機構
木下 奈津美

医薬開発及び製造販売後の医薬安全対策に対するAI開発
京都大学大学院医学研究科
岡本 里香

ファーマコビジランス分野におけるAI活用～産官学のチーム日本として取り組む可能性を探る
協和キリン株式会社
杉浦 裕介

医薬品情報のAI活用における現状と課題～産官学コンソーシアムLINCでAll Japanの解決策を探る～
国立研究開発法人 理化学研究所
安倍 理加

S26 102会議室 14:00-15:30
eSource in Clinical Trials -Global/Japan Use Cases-
関連領域: CR、DM、AC
レベル: 中級
座長
国立がん研究センター 東病院
土井 俊彦

eSourceの価値は明白です。本セッションでは、臨床試験のデジタル化に向け、eSource導入経験を共有する。

海外での方向性も踏まえて、日本の独自の環境も考慮しながら、どのようにeSourceのチャレンジを通していくべきか、また、日本の臨床試験・臨床研究が日本だけでなく国際的にも貢献できるような新しいデータ収集・活用のプラットフォームの発展に向けて、eSourceの挑戦を議論をする。

Digitally Enabled Patient-Centric Clinical Trials – Current State and Future Opportunities
MERCK & CO., INC.
Matthew Moyer

Digitally Enabled Patient-Centric Clinical Trials – Current State and Future Opportunities
Novo Nordisk Inc. / TransCelerate BioPharma Inc
Jesper Kjaer

Comparison of eSource Approaches
Pfizer Inc.
Amy Harris Nordo
DDC(Direct Data Capture)導入事例と目指す姿
塩野義製薬株式会社
山田 裕一

S27 703会議室 14:00-15:30
若手のみなさん、さらなる一歩を踏み出す勇気はいかがですか？
関連領域: O : Career Development
レベル: 初級
言語: 日本語のみ
座長
ファイザー R & D 合 同 会 社
稲泉 恵一
若手の方を対象として、規制当局、製薬企業をリードしてきた演者を迎え、苦しいときにどのようにモチベーションをアップさせたか、また、自分自身に壁や天井をつくるなと挑戦し続けてきたか、さらなる一歩を踏み出す勇気をもち、いかに挑戦してきたかなど、具体的な経験談を交え講演いただく。講演を通して、無意識につくってしまってい る自分の限界の呪縛からは己を解き放ち、若手がさらなる飛躍をできる、あるいはしたいと思えるような気付きのきっかけとなるセッションとする。セッションは一方通行なプレゼンテーションでなく、グループディスカッションも織り交ぜ、視野を広げるとともに、産官学を超えた若手ネットワーキングも行う。

獨立行政法人 医薬品医療機器総合機構
宇山 佳明
第一三共株式会社
塚本 淳
グループディスカッション
コーヒーブレイク 15:30-16:00

S28 605会議室 16:00-17:30
Global Oncology Development - オンコロジー開発のゲームチェンジャーを目指して -
関連領域: CR、 RA
レベル: 初級
座長
第一三共株式会社
塚本 淳

Global試験を行う上での施設のCapability - CRCとスポンサーを経験した立場から -
小野薬品工業株式会社
石橋 寿子
S31 608会議室 16:00-17:30
誰のために品質をマネジメントしますか？～患者さんのために私たちにできること～

関連領域：CR、DM、PM、AC
レベル：初級
座長
国立がん研究センター中央病院
小林 典子

臨床試験の実施において、現在Quality Management System (QMS)の構築について検討されているが、試験結果の信頼性的確保に重点が置かれており、さらにQMS実装のためのツールを使うこと、新たに検討したQuality Management (QM)の手順を遵守すること自体が目的となっている状況が伺える。しかしながら、臨床試験の実施においては、被験者の保護が欠かせないため、被験者保護を含めたQMSとは何かを考える必要がある。そのためには製薬業界と医療機関が連携すべき目的を共有し、製薬業界がどのように臨床試験を安全、かつ、適切に実施するかを理解することが重要であると考える。

そこで、治療実施における問題点を整理し、製薬業界と医療機関がどのように協働したらよいかを考えつつ、患者さんが安心して臨床試騈に参加でき、安全、かつ、適切な実施に繋がる方法を考えたい。

患者さんのために医師（治験責任医師）ができること
国立がん研究センター中央病院
清水 俊雄

患者さんのためにCRCができること
神戸大学医学部附属病院
山崎 純子

患者さんのためにCRAができること
シミック株式会社
旭 孝嗣

患者さんのために依頼者ができること
日本たばこ産業株式会社
中村 悟

パネルディスカッション
塩野義製薬株式会社
岸本 千絵

S32 609会議室 16:00-17:30
誰もが知っておきたい「費用対効果評価」入門～開発中の備えから、分析、価格調整まで～

関連領域：CR、RA、CP、MA、MW、O：Labeling
レベル：中級
言語：日本語のみ
座長
サノフィ株式会社
萩谷 徹朗

さまざまな議論の末、HTAが国内で本格導入された。しかしながら、試行的導入の対象品目は限られており、この領域の実務経験のある人はまだ少ない。本セッションでは、費用対効果評価の基本的な考え方、日本の制度の概要を紹介するとともに、費用対効果評価委員会データサイエンス部会の報告書に基づいて、費用対効果評価の手法をわかりやすく解説する。また、医薬品・医療機器のそれぞれの企業から試行的導入時の経験を初学者でも理解できる内容で紹介することを予定している。それらを通じて、参加者が費用対効果評価制度の概要、企業が備えるべきことを理解し、これからの課題について考えることを目的とする。

HTAとは～やるリスク、やらないリスク
横浜市立大学／東京大学
五十嵐 中

費用対効果評価のフレームワーク
日本イーライリー株式会社／日本製薬工業協会
荒西 利彦

試行的導入における医薬品の事例とプロセス
中外製薬株式会社
大野 慎也

日本におけるTAVIの費用対効果分析：試行的導入における経験
エドワーズライフサイエンス株式会社
朝岡 美好

S33 610会議室 16:00-17:30
添付文書改訂相談の導入後の実際

関連領域：CR、RA、CP、MA、MW、O:Labeling
レベル：中級
言語：日本語のみ
座長
サノフィ株式会社
萩谷 徹朗

添付文書改訂相談の制度運用開始後から2019年5月までに、8成分が本相談に基づき改訂された。一方、改訂相談を検討したものの、事前確認相談等で受け入れられなかった事例も発生している。この状況を分析し、本相談の本来の主旨と位置づけを踏まえ、制度を活用するための最適なアプローチやどのような課題があるかを産官で議論し、今後さらに制度の活用促進につなげたい。

添付文書改訂相談の主旨と位置づけ、導入後の実績
独立行政法人 医薬品医療機器総合機構
河野 陽一

添付文書改訂相談で改訂に至らなかった事例
ノバルティスファーマ株式会社
豊守 祥亮

添付文書改訂相談で改訂した事例
大薬産業株式会社
坂倉 和明

添付文書改訂相談で改訂した事例
塩野義製薬株式会社
塩本 千絵

パネルディスカッション
塩野義製薬株式会社
中村 悟

S34 101会議室 16:00-17:30
医薬及び医薬開発における人工知能（AI）とデジタル技術の利活用の現状と未来 - Rational medicineを実現するために-

関連領域：ALL
レベル：中級
座長
株式会社アセットデベロップメントサービス
冠 和宏
DIA Japanでは、本年、「Cutting Edgeシリーズ」と題し、医薬開発におけるAI・デジタル技術の利活用にフォーカスをあてたシンポジウムを開催しました。産業の成長促進や更なる技術革新を考えたとき、エリアに関わらず、継続的なイノベーションの推進の原動力となり課題となるのは、①イノベーションのコアとなる技術革新を推し進めていくこと、②その技術の応用範囲の拡大や製品化、③イノベーションの担い手や応用を推進する担い手を育成することになります。

今回、本エリアのホットスポットであるAIやRobotic Process Automation（RPA）の研究開発及び製薬エリアでの利活用について、このエリアの一線で活躍するエキスパートを招いて、皆様とディスカッションする場を提供します。皆さまのご参加を心からお待ちしています。

AI Empowers Biomarker Discoveries Using Multi-Omics Technologies
Center for Precision Medicine MultiOomics Research, Health Science Center, Peking University
Wong, Catherine CL

神戸大学が推進する新たな価値を創造できる人材育成プログラムとアカデミア教育の未来像
神戸大学
鶴田 宏樹

製薬業界におけるRPA導入のツボ
オートメーション・エンジニア・ジャパン株式会社
杉原 弘恭

パネルディスカッション
本セッションの講演者

S35  102会議室 16:00-17:30
アジアにおける高齢者に対する医薬品の適性使用 - 添付文書を中心に -
関連領域: RA, AC
レベル: 中級
言語: 日本語のみ
座長
独立行政法人 医薬品医療機器総合機構
佐藤 淳子

日本においては、人生百年時代が声高に唱えられているが、高齢化はアジア共通の課題である。

成長目覚ましでイノベーショナルな取り組みを行っている製薬ベンチャーの成功を解読することにより、日本のライフサイエンス分野の閉塞感を打破するヒントを提供する。本セッションの前半は、産官学それぞれの視点、および、成功したベンチャー担当者による視点を提供し、ライフサイエンス分野における日本の状況の全体像を俯瞰する。その後、パネルディスカッション形式で日本のライフサイエンスの活性化のために我々が何をすべきかについてディスカッションを行う。

過去の歴史では知ることができないテーマのディスカッションを通じ、将来的製薬業界を担う聴衆の皆様が様々な視点から解釈し、イノベーションを必要とする製薬業界において「挑戦すること」を重要視し、実例を通じて示してお届けしたい。

対象:
将来の自分キャリアの幅を広げたいと思っているCROや製薬メーカーの方
開発戦略を立てて行く上で視野を広げたい方
製薬企業、CRO、ベンチャー企業の管理職者
ライフサイエンス系ベンチャー企業の方

アカデミア発ベンチャーの新しい展開
東京大学協創プラットフォーム開発株式会社（東大IPC）
河原 三紀郎

製薬企業は今後どうやってイノベーションを起こすか？
アステラス製薬株式会社
諏訪 旭

バイオベンチャーの宿命
株式会社リボミック
中村 義一

厚生労働省における医療系ベンチャー振興のための取り組み
厚生労働省
桑原 宏哉

パネルディスカッション
本セッションの講演者、並びに
MSD株式会社
田中 義信

ショートブレイク 17:30-17:45
恒例になりましたDIA年会名物“スペシャルチャッティングセッション”を今年も2日目の夜にご用意しました。
DIAの活動の大きな目的の1つは人材交流です！ 参加者同士が気軽にネットワーキング、意見交換ができる場ですので、是非、積極的にこの場をご利用頂ければ嬉しく思います。
若手も、ご意見番も、大学の学生や先生も、医療機関の先生方やPMDAの方も、同じテーブルで囲んでしまえば、皆、仲間！
DIA年会にお一人で参加される方も、是非、輪に入っていただき、興味のあるテーマについて一緒に語りましょう！

今年も、テーブルごとに11個のテーマを検討しております。また、2つのコミュニティが共同ファシリテーターとして進行しますので、コミュニティの枠を超えた意見交換も期待できます。当日、ご興味のあるテーブルの周りにお集まりください。
会場ではドリンクと軽食もご用意しています。ビールやワインを飲みながら、熱くそして楽しくおしゃべりしましょう！なお、このセッションでの発言はすべて個人の見解に基づくものとさせていただきますので、予めご理解願います。

<table>
<thead>
<tr>
<th>テーマ一覧</th>
<th>当日ご興味のあるテーブルにお立ち寄りください。途中参加、退席、移動も可能です。</th>
</tr>
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<tbody>
<tr>
<td>1. Clinical Operations &amp; Monitoring (COM)</td>
<td>Risk Based Monitoring (RBM)に関して語りましょう！</td>
</tr>
<tr>
<td>2. Clinical Innovation (CI)</td>
<td>AI時代における開発パーソンに求められる資質とは？</td>
</tr>
</tbody>
</table>
| 3. Pharmacovigilance & Labeling (PL) | 条件付き承認等に基づき早期上市される医薬品は患者さんの早期アクセスの観点で歓迎されるべきですが、ベネフィット・リスク情報は市販後に急速に充実させていくことが大切です。そのためには、リアルワールドデータ及びAIを含めたテクノロジーを駆使し、市販後に画期的な方法で効率的にエビデンスを他国と協働で創生・共有することが求められているでしょうか。

| 4. Clinical Data Management (CDM) | 統計数理研究所・伊藤陽一 |
| 5. Project Management (PM) | 東京大学・宮路天平 |
| 6. Regulatory Affairs (RA) | ノバルティスファーマ株式会社・鈴木和幸 |
| 7. Medical Communication (MC) | 旭化成製薬株式会社・黒﨑英志 |
| 8. Patient Engagement (PE) | コンピュータシステムズ株式会社・山崎太義 |
| 9. Medical Affairs (MA) | エール・エアロゾール株式会社・吉田直樹 |
| 10. Regulatory Affairs (RA) | アイロー株式会社・小林利之 |

# カテゴリー トピック名 ファシリテーター 概略
1. Clinical Operations & Monitoring (COM) | Risk Based Monitoring (RBM)に関して語りましょう！ |
2. Clinical Innovation (CI) | AI時代における開発パーソンに求められる資質とは？ |
3. Pharmacovigilance & Labeling (PL) | とは？近い将来来るAI時代に向けて、臨床開発に関わる我々にとって重要な資質とは何でしょう。時代を先取りするために今から身に着けるべきスキルや将来的なキャリアについてディスカッションしよう。 |
4. Clinical Data Management (CDM) | は？基礎統計学に学んだものを活用してデータに基づいた分析を行うことが求められます。今後のデータ活用においては統計学者とRBAとの協働が不可欠です。
5. Project Management (PM) | 東京大学・宮路天平 関西医科大学・松本典明 |
6. Regulatory Affairs (RA) | 日本薬学会・野村正信 |
7. Medical Communication (MC) | 山崎太義 |
8. Patient Engagement (PE) | キャリアをどのように進めるべきかについて議論しましょう。
9. Medical Affairs (MA) | 旭化成製薬株式会社・黒﨑英志 |
10. Regulatory Affairs (RA) | アイロー株式会社・小林利之 |
S37  605/606会議室  9:00-10:30
次世代医療基盤法に基づいた医療ビッグデータの今後

関連領域: CR, ST, AC
レベル: 初級

座長
京都大学
吉原 博幸

昨今医療業界において、医療DBの活用が推進されており、国・民間主導問わずEHRを始めとしたリアルワールドデータの収集・蓄積・利活用が積極的に推進されている。昨年施行された次世代医療基盤法は、このような医療DB業界に対して、新しいルールを示しており、今後のセッションでは、次世代医療基盤法ととは、次世代医療基盤法に基づいた医療DB、次世代医療基盤法下での医療DBの将来、千円カルテプロジェクトとについて紹介し、今後の医療DB研究に寄与する方法を提言する。

ゲノムコホートにおける医療データベースの利活用によるゲノム医療・創薬研究開発

渋谷 剛一

東北大学 東北メディカル・メガバンク機構

リアルワールド・データ(RWD)を再考する

中山 健夫

京都大学

S38  607会議室  9:00-10:30
再生医療〜直近の承認事例から学ぶ〜

関連領域: CR, RA, AC
レベル: 初級, 中級

言語: 日本語のみ

座長
一般社団法人くすりの適正使用協議会
俵木 登美子

日本の医療を受ける患者さんが求める医薬品情報は多様化してきており、患者さんの言語も多様化している。また、医薬品情報の提供方法としても、デジタル化が進み、様々な方法が用いられている。国民目線で考えたときに、現在の情報提供の方法はどのような課題があるのか、現状の取り組みとその課題（現在のスキームでの限界・難しさ）、将来への期待を共有する。また、パネルディスカッションの中で、産官学協働で将来何ができるか、今から何を準備すべきかを考える。

信頼できる医薬品情報・患者情報の提供方法を考える

佐藤 大作

ステミラックの開発戦略と国内展開における課題

ニフ情報産業

吉川 晃洋

キムリアの開発戦略と実用化における課題

河村 晴美

再生医療等製品の審査上の留意点

信頼できる医薬品情報・患者情報の提供方法を考える

佐藤 大作

パネルディスカッション

本セッションの講演者
健康に関する患者の情報ニーズに対する病院の取り組みについて -慶應義塾大学“健康情報ひろば”の紹介-  
慶應義塾大学
中田 英夫
パネルディスカッション
本セッションの講演者、並びに
厚生労働省
堀尾 貴将

S41  610会議室  9:00-10:30
プログラムマネジメントの夜明け - プロジェクトマネジメントの先にある景色
関連領域: CR、RA、PM、AC
レベル: 中級
言語: 日本語のみ
座長
大阪大学医学部附属病院
岩崎 幸司
近年、企業のみならずアカデミアにおいても限られたコスト、時間での成果の出るを目指してプロジェクトマネジメントの適用が一般的になりつつある。一方で、抗癌剤剤剤に代表されるように複数適応の同時開発や、CDxの同時開発など、複数のプロジェクトを組み合わせてマネジメントする必要が出てきており、そこでは単純なプロジェクトマネジメントだけでは通用しない。そこで活用されるのが、複数プロジェクトを相乗効果的にマネジメントする「プログラムマネジメント」の概念である。本セッションでは、プログラムマネジメントに関する基本知識ならびに実例を共有し、同じ悩みを持つ参加者と議論を深めることで、複雑化・高度化している新治療開発の効果的なマネジメントを考察したい。

プログラムマネジメントとは 日本プロジェクトマネジメント協会
加藤 亨
アカデミアのプロジェクトマネジメントの現況と わが国でのアカデミア研究における出口戦略の多様性について
大阪市立大学医学部附属病院
真田 昌爾
企業におけるプログラムマネジメントの活用 第一三共株式会社
塚本 淳

S42  101会議室  9:00-10:30
患者さん目線でのインフォームドコンセント：治験の適正な理解と参加しやすい治験を達成するためにできること
関連領域: CR、RA、DM、PM、AC、O: Patient
レベル: 中級
座長
NPO法人肺がん患者の会 ワンステップ
長谷川 一男
インフォームドコンセント、説明文書は患者さんにとって治験に関する基本情報であり最初の接点である。現在の治験は説明文書の分量と複雑性が増しており、患者さんの視点に立っていかに分かり易くしていくかが課題である。本セッションでは、説明文書の内容とその説明の2つ目の視点で、患者さんにとって分かり易いインフォームドコンセントを達成するためにできることを海外の取り組みも踏まえて議論する。

未定
Pfizer, Inc
David Leventhal
私たちがどのように“わかりやすいICF”を実現していきますか？ 日本イライライリー株式会社
宮崎 由美子

S43  102会議室  9:00-10:30
Virtual Clinical Trialsの実装に向けたロードマップ
関連領域: CR、RA、PM、AC
レベル: 初級
座長
ファイザーR&D合同会社
今枝 孝行
Virtual clinical trial (VCT) は、患者さんの臨床試験へのアクセスを向上させる方法として医薬品開発における重要なトピックの1つである。グローバルではVCTの事例は様々なものが報告されているが、日本には非常に限定されたケースしか報告されていない。本セッションでは、グローバルの演者からその状況を聞いたうえで、日本の治験依頼者及び医療機関からVCTを実施することの利益と課題について共有する。その中には、VCTに必要な新しいテクノロジーをアプローチの構成要素であるeConsent、direct-to & from-patient、遠隔医療、ウェアラブルデバイス、ePRO、スマートフォンアプリなどの個々の進捗や課題についても触れたいと思う。

最後に、パネルディスカッションでは、重要なステークホルダーである患者さん代表も含め、医療機関、治験依頼者のそれぞれの立場から、VCTの必要性、適した疾患領域等、実施の成功に向けたロードマップについて議論したいと思う。

患者中心型の臨床試験モデル -期待と課題-
Janssen Research & Development, LLC.
延山 宗能

日本で実施する治験に対するホームビジットの導入 : その患者さんに対するインパクトおよびチャレンジ
ファイザーR&D合同会社
北村 篤嗣

オンライン診療とlocation flexible trialsへの期待
外房こどもクリニック
黒木 春郎

パネルディスカッション
本セッションの講演者、並びに
東京大学先端科学技術研究センター
渡部 沙織
European Medicines Agency (EMA)
Agnès Saint-Raymond

コーヒーブレイク  10:30-11:00

S44  605/606会議室  11:00-12:30
Innovative Drug Development：プラセボ群は本当に必要か？

未定

Innovative Drug Development : プラセボ群は本当に必要か？
関連領域: ALL  
レベル: 初級  
座長  
国立循環病研究センター  
山本 晴子  

古くから医薬品開発ではプラセボ群を用いた臨床試験が実施されてきた。臨床試験デザインの理説としてもプラセボ群を設定する意味は確立しており、医薬品開発にたずさわる人たちの間では理解されている。一方で、臨床現場や患者さんには“プラセボ群のある試験はやりにくい”、“プラセボは投与されたくない”というような意識が存在しているのも事実であり、それが臨床試験の実施を困難にする要因の一つになる場合もある。  

本セッションでは「プラセボ群は本当に必要か？」という問いを掲げ、抗がん剤の状況を参考に、医師、患者さん、企業、制局より、国内外の視点からご意見を頂き、プラセボ群を置かない臨床開発の可能性について議論する。
医療情報のあり方：エビデンスに基づく一般向け情報とシェアードディスカッション
京都大学
山本 健夫

製薬企業からの情報提供の現状と今後の展望（仮題）
日本製薬団体連合会
慶徳 一浩

国民に向けた包括的かつ信頼性の高い医薬品情報システムの構築
熊本大学
山本 美智子

パネルディスカッション
株式会社マディア
古川 綾

厚生労働省
治田 義太郎

一般社団法人くすりの適正使用協議会
高橋 洋一郎

S48 610会議室  11:00-12:30
ここがポイントだ！実例に学ぶ、Target Product Profileと開発戦略の立て方
関連領域: CR、RA、PM、AC
レベル: 中級
言語: 日本語のみ
座長
日本医科大学生

松山 琴音

開発の様々な局面で意思決定を行うときに、我々はどうすれば最適な選択ができるだろうか。Target Product Profile（TPP）は、医薬品の開発において新たに市場に生み出される価値を形にしたものであり、開発プロジェクトの戦略をたてる羅針盤とし、開発計画に落とし込むことで、医療の現場における開発の価値を最大化し、次の開発を行うのに非常に重要である。本セッションでは、企業とアカデミアのTPPと臨床開発計画の実例を通じて、開発戦略の立て方とそのポイントに迫りたい。

PMDAでの相談・審査実施における開発戦略文書の存在意義
独立行政法人 医薬品医療機器総合機構
奥平 朋子

AMEDにおけるStage Gateと開癈戦略を踏まえた研究開発マネジメント
国立研究開発法人 日本医療研究機構
友安 弓子

アカデミア開発におけるTPPと開発戦略文書の意義と実例
名古屋大学
清水 忍

企業での開発におけるTPPと開発戦略文書の意義と実例
ファイザーR&D合同会社
大島 三千世

パネルディスカッション
本セッションの講演者、並びに
順天堂大学
内田 浩一郎

S49 101会議室 11:00-12:30
患者さん目線での治験を実現するためのテクノロジー最前線
関連領域: CR、RA、DM、PM、AC、O: Patient
レベル: 中級
座長
東京大学大学院医学系研究科
宮路 天平

新しいテクノロジーは、患者さん目線での治験を実現するための手段として、今まで実施できなかったようなアプローチで問題解決できる可能性がある。本セッションでは、患者さんによる治験の参加や治験情報の共有を推進するテクノロジー、また患者さんにとってインパクトのあるテクノロジーについて、グローバルの実施例や調査結果、及び日本国内での進捗と課題を報告する。

未定
Pfizer, Inc
David P. Leventhal

日本におけるeConsentの導入について
ノバルティス ファーマ株式会社
正田 亮

Marching Toward Patient-Centricity: How Technologies Are Transforming Clinical Research
Associate Director, Janssen Clinical Innovation, Janssen R&D, LLC.
Jiao Song

S50 102会議室 11:00-12:30
日本における早期承認制度の最新事例及び今後の展望
関連領域: RA、PM、CMC
レベル: 初級
座長
塩野義製薬株式会社
佐藤 洋一

先駆け審査指定制度、条件付き早期承認制度といった新しく導入された制度が運用され始め数年が経過し、承認事例も著しく増えつつある。当該制度を活用した早期承認を実現した事例や実際に活用した事例を具体的に挙げながら、企業から発表頂く。また、PMDAからは、これらの制度を活用して申請された事例の審査について、速やかに決した点、企業に改善して欲しい点等を発表頂く。それぞれの立場での発表内容を踏まえ、パネルディスカッションでは今後これらの制度をさらに効率的に活用するためのアイデアを出し合い、Rationalな医療を速やかに届けるための前向きな議論を行う。

新しい早期承認に関する制度の現状と課題について
独立行政法人 医薬品医療機器総合機構
清原 宏真

条件付き早期承認制度の活用事例
ファイザーR&D合同会社
杉田 潤子

CMC部門からみたソニパチWhereの先駆け申請
アステラス ファーマテック株式会社
村上 剛史

パネルディスカッション
本セッションの講演者
3日目 | 11月12日（火）

DIAmond Sessions & 閉会の挨拶

DIAmond Session 2
国際会議場 14:00-15:30

患者さんのための合理的な医療
関連領域: RA, Patient
レベル: 上級
座長
一般社団法人 Medical Excellence Japan
近藤 達也

各国規制当局は、国民のニーズに応えるべく新しい医薬品規制を作り、患者さんがいち早くその恩恵を受けられる対応をされてきている。本セッションでは、長年医師として規制当局を観察し、そしてその後規制当局の長となった方や、長年の臨床経験を経て企業人となった方に、これまでの経験を通じて、患者さんのための合理的な医療について語って頂く。合理的な医療は患者さんの希望であり、医療従事者のみならず、企業、規制当局の人などいずれもがその提供を目指している。医師として勤めていた後、異なる立場になった時に、見えていたものが変わったのか、変わったとしたら、どのように変わったのか、それらの議論を通じて合理的な医療とは何かについて見つめなおす。

パネルディスカッション
独立行政法人 医薬品医療機器総合機構
藤原 康弘
European Medicines Agency (EMA)
Agnès Saint-Raymond
グラクソ・スミスクライン株式会社
高橋 希人

コーヒー・ブレイク 15:30-16:00

DIAmond Session 3
国際会議場 16:00-17:30

PMDAタウンホール
関連領域: ALL
レベル: 中級
座長
明治薬科大学
石川 洋一
MSD株式会社
白沢 博満

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
医薬品安全対策第二部長
井口 豊崇

独立行政法人 医薬品医療機器総合機構
審査マネジメント部長
美上 憲一

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
髙江 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
宇津 忍

閉会の挨拶
国際会議場 17:30-17:40
第16回DIA日本年会副大会長/協和キリキン株式会社
佐藤 隆
Thousands of Members in 80 Countries

DIA Members work together to speed innovation in healthcare product development - join us!

Who Are DIA Members?

• Professionals from around the globe, all working in or supporting the life sciences and healthcare fields

• Change makers from academia, patient groups, regulatory, industry, clinical development, medical affairs, and more

• Dedicated thought leaders eager to discuss the issues of today and chart a path for tomorrow

DIAglobal.org
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Displaying at the event provides a platform for brand building. You can introduce new products and services, enhance marketing strategies, and improve your brand image.

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Your company profile will be included in the conference materials and on the website. You can also distribute brochures with product and service introductions.

YEARLY PROGRAM BOOKLET

Your company profile will be included in the conference material, and the website will introduce it. You can also distribute brochures with product and service introductions.
DIA 2020
WASHINGTON, DC
JUNE 14-18
**REGISTRATION FORM:** Register online or forward to DIA Japan, Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashi-honcho, Chuo-ku, Tokyo 103-0023 Japan

tel +81-3-6214-0574 • fax +81-3-3278-1313

16th DIA Japan Annual Meeting 2019
Event #19303 • November 10-12 | 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 registration (if applicable), and will be accepted by mail, fax, or online.

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

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

**REGISTRATION FEE**

<table>
<thead>
<tr>
<th>MEMBER</th>
<th>10% TAX INCLUDED</th>
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<tbody>
<tr>
<td>Industry</td>
<td>Super Early-bird (until Sept 10)</td>
</tr>
<tr>
<td>Industry</td>
<td>Early-bird (from Sept 11 to Oct 17)</td>
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<tr>
<td>Industry</td>
<td>On and after Oct 18</td>
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<tr>
<td>Government, Non-profit</td>
<td>Early-bird (until Oct 17)</td>
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<tr>
<td>Academia, Medicals</td>
<td>Early-bird (until Oct 17)</td>
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<td>Academia, Medicals</td>
<td>On and after Oct 18</td>
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<th>NON-MEMBER</th>
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<th>STUDENT</th>
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<tr>
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<tr>
<td>Student Session only</td>
<td>¥2,200</td>
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**MEMBERSHIP**

<table>
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<tr>
<th>10% TAX INCLUDED</th>
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<tr>
<td>Membership</td>
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<tr>
<td>2-Year Membership</td>
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<tr>
<td>Academia Membership (Academia, Medicals)**</td>
</tr>
</tbody>
</table>

* Student registration must be made by October 25, 2019. Please send this form with a copy of your student ID to DIA Japan office by fax or e-mail.

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

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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: 3-7-1 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

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**CANCELLATION POLICY:** On or before November 1, 2019

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- Member or Nonmember = ¥20,000
- Government/Academia/Nonprofit (Member or Nonmember) = ¥10,000

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

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

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

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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.

DIA Japan office in Tokyo for further information.
tel: +81.3.6214.0574 | fax: +81.3.3278.1313
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---

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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

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email: Japan@DIAglobal.org

---

**REGISTRATION FORM**

Last Name
First Name
Mr. Miss

Department

Job Title

Company

Address (As required for postal delivery to your location)

City
State
Zip/Postal
Country

Phone Number
required
Fax Number
required

**Required for confirmation**

---

**SIGNATURE**

**DATE**

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Please complete the form below in block capital letters:

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First Name

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Job Title

Company

Address (As required for postal delivery to your location)

City  State  Zip/Postal  Country

email  Required for confirmation

Phone Number  Required  Fax Number

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**YOUNG PROFESSIONALS RATE**

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

**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.

---

**DIA MEMBER**

- Industry

**NON-MEMBER**

- Industry

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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.

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Please complete the form below in block capital letters:

Last Name

First Name

Address

City  State  Zip/Postal  Country

Email  **Required for confirmation**

Phone Number  **Required**  Fax Number

---

**PAYMENT OPTIONS**

Please check payment method.

- **BANK TRANSFER:**
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  - All local and overseas charges incurred for the bank transfer must be borne by payer.

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

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Card No.

Cardholder Name

Signature

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tel: +81.3.6214.0574  |  fax: +81.3.3278.1313

email: Japan@DIAglobal.org

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**MEMBERSHIP**

- **2-Year Membership**

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**YOUNG PROFESSIONALS REGISTRATION FEE**

<table>
<thead>
<tr>
<th>Membership</th>
<th>Industry</th>
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<th>Early-bird (from Sept 11 to Oct 17)</th>
<th>On and after Oct 18</th>
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**INCLUDED**
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。会期中にDIAウェブサイトのイベントページからのアクセス等、様々な形態で開催されます。参加費を申し受けます。参加費の詳細は下記をご覧ください。

参加費
一般社団法人ディー・アイ・エー・ジャパン
〒103-0023 東京都中央区日本橋本町2-3-11

参加費の詳細

2019年11月10日(日)-12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

会場は変更される場合がありますので予めご了承ください。

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◆ 参加費用（該当する方でチェックしてください）

学生（企業/団体に籍を置いておられる方）
*超早期割引（9月10日まで）
一般向
*早期割引（9月11日から10月17日まで）
政府
非営利団体
大学関係者・医療従事者
両発行

◆ 参加費（該当する方でチェックしてください）

学生（企業/団体に籍を置いておられる方）
*超早期割引（9月10日まで）
一般向
*早期割引（9月11日から10月17日まで）
大学関係者・医療従事者
両発行

◆ 参加費用

参加申込書
2019年日本年会 2019
DIA使用欄（W10）

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参加費
一般社団法人ディー・アイ・エー・ジャパン
〒103-0023 東京都中央区日本橋本町2-3-11

参加費の詳細

2019年11月10日(日)-12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

会場は変更される場合がありますので予めご了承ください。

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

第16回 DIA日本年会 2019（カンファレンスID #19303）
◆ 参加申込方法
本申込書に必要事項をご記入の上、FAXまたはメール添付Japan@DIAglobal.orgにてお申し込みください。受理後、10営業日以内にメールにて申込受領書を送付いたします。

◆ 参加費用（該当する☑にチェックしてください）
会員資格が失効している方以及非会員の方は、会員登録（更新）することにより、会員価格にてご参加いただけます。会員資格はお支払いいただいてから翌年同月末まで1年間有効です。また、DIA各種機関の入会、DIAウェブサイトの会員専用ページへのアクセス等、種々の特典が得られます。

◆ 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

① 会員費
会員の有効に必要な行為で、会員登録をされる場合に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。

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）

<table>
<thead>
<tr>
<th></th>
<th>通常</th>
<th>若手割引</th>
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<tbody>
<tr>
<td>会員</td>
<td>¥103,400（税込）</td>
<td>¥62,040（税込）</td>
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<td>10月18日以降</td>
<td>¥119,900（税込）</td>
<td>¥71,940（税込）</td>
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<td>非会員</td>
<td>¥139,150（税込）</td>
<td>¥83,490（税込）</td>
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④ 資金の際は、ご参加者名を必ず参加者名および会社名をご記載ください。同一会社で複数名の参加費を同時に振込される場合は、書面にて参加者名と振込日をディー・アイ・ジャパンまでお知らせください。振込に関する手数料は、振込人負担でお願いいたします。

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