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.

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 Overview

What can and should we do for patients, future patients and the patient families? There are extremely large number 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 challenging by exerting leadership with a 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 and fairness and collaborate with each other 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 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 and 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.

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

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

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

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

DIAglobal.org
### Japanese Language Only

<table>
<thead>
<tr>
<th>SUN  NOV 10</th>
<th>International Conference Room</th>
<th>Room 605/606</th>
<th>Room 607</th>
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<tbody>
<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>
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<td>12:00-13:30</td>
<td>ORIENTATION AT EXHIBIT HALL (12:00-12:30)</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</td>
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<tr>
<td>14:00-14:15</td>
<td>2019 DIA JAPAN'S Inspire Regional Awards Ceremony</td>
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<tr>
<td>14:15-15:30</td>
<td>PROGRAM CHAIR'S LECTURE</td>
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<tr>
<td>15:00-15:30</td>
<td>COFFEE BREAK</td>
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<tr>
<td>15:30-16:15</td>
<td>KEYNOTE ADDRESS</td>
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<tr>
<td>16:15-17:45</td>
<td>D1 [DIAmond Session 1]</td>
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<tr>
<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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<tbody>
<tr>
<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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<tr>
<td>10:30-11:00</td>
<td>COFFEE BREAK &amp; EXHIBIT HALL INNOVATION THEATER PRESENTATIONS (RECEPTION HALL)</td>
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<tr>
<td>11:00-12:30</td>
<td>S02 Initiatives for the Future of Digital Health: Utilizing Digitized Product Information/Labeling for Healthcare Professionals and Patients RA, CP, MA, MI</td>
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<tr>
<td>12:30-14:00</td>
<td>LUNCHEON SEMINAR (SYNEDIS HEALTH)</td>
<td>LUNCHEON SEMINAR (IQVIA SERVICES JAPAN)</td>
<td>LUNCHEON SEMINAR (Medrio)</td>
<td>LUNCHEON SEMINAR (Oracle Corporation Japan)</td>
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<tr>
<td>14:00-15:30</td>
<td>S09 A New and Optimal Collaboration with Companies in Investigator Initiated Trials Using Government Platform ALL</td>
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<td>15:30-16:00</td>
<td>COFFEE BREAK (RECEPTION HALL)</td>
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<td>16:00-17:30</td>
<td>S10 How Will the Development and NDA Activities in Japan Change in View of the Future of AI Translation? ALL</td>
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<td>17:30-17:45</td>
<td>SHORT BREAK</td>
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<tr>
<td>17:45-19:00</td>
<td>E1 Engage and Exchange ‘LET’S CHAT!’ - SPECIAL CHAT SESSION - AT RECEPTION HALL</td>
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### TUE  NOV 12

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<tr>
<td>9:00-10:30</td>
<td>S17 The Future of Medical Big Data Based on the Next Generation Medical Infrastructure Act CR, ST, AC</td>
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<td>10:30-11:00</td>
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<td>COFFEE BREAK (RECEPTION HALL)</td>
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<tr>
<td>11:00-12:30</td>
<td>S29 Global Oncology Development - Be a Game Changer in Oncology Development - CR, RA</td>
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<tr>
<td>12:30-14:00</td>
<td>LUNCHEON SEMINAR (SYNEDIS HEALTH)</td>
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<td>15:30-16:00</td>
<td>S30 What Kind of Information Should Medical Deliver in Compliance with Promotional Activity Guideline? MA, MC</td>
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<tr>
<td>16:00-17:30</td>
<td>S31 Challenges on Implementation of Risk Based Approach and Its Foresight CR, DM</td>
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<td>17:30-17:45</td>
<td>SHORT BREAK</td>
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### Japanese & English (No Interpretation)
## Japanese Language Only

### 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)

### Room Layout
- Room 609
- Room 610
- Room 611
- Room 612
- Room 703

### Orientation at Exhibit Hall (12:00-15:00)

### Networking Reception at Reception Hall (We Also Have Plans to Deepen Exchanges Among Young People)

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<tr>
<td>S05</td>
<td>S06</td>
<td>S07</td>
<td>S08</td>
<td>S09</td>
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<tr>
<td>Clinical Trial Act: Experiences from the PI, the Way of the Future RA, PM, AC, MA</td>
<td>A Solution for Patients and Healthcare Providers: A New Trial in Pharmacovigilance CR, CP, PM</td>
<td>Ideal Conduct and Future Perspectives for Publication by Pharmaceutical Companies CR, AC, MA, MI, MW, MW.</td>
<td>Deep Dive into China Regulatory Reform From Various Perspectives (Tentative) RA</td>
<td>What is &quot;Shared Value&quot; Created by Collaboration Among Industry, Academia, Government and Future Generations - Going Forward to New Era of Innovation ALL</td>
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</table>

### Coffee Break & Exhibit Hall Innovation Theater Presentations (Reception Hall)

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<tr>
<td>S14</td>
<td>S15</td>
<td>S16</td>
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### Lunch Break

### Lunccheon Seminar (Medidata Solutions K.K.)

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<tbody>
<tr>
<td>S24</td>
<td>S25</td>
<td>S26</td>
<td>S27</td>
<td>S28</td>
</tr>
<tr>
<td>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, Or Labelling</td>
<td>Let's Talk a Lot About What Future Shape of Ideal Collaboration to Promote Life Science Field is ALL</td>
<td>eSource in Clinical Trials - Global/Japan Use Cases - CR, DM, AC</td>
<td>How About the Courage to Take a Further Step for Young People? Or Career Development</td>
<td>Bringing Japanese Technology to the World! Ideal way of life science innovation in the era of peace, considered by industry, government and academia</td>
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### Coffee Break (Reception Hall)

### Short Break

### Short Break

### Poster Session: 11:30-14:00
- Exhibition: Nov. 10th Sun 11:45-12:15
- Lunch: Nov. 11th Mon 12:30-14:00, 12th Tue 12:30-14:00
- Networking Reception: Nov. 10th Sun 16:00-18:00 (We also have plans to deepen exchanges among young people.)

### Special Chatting Session: Nov. 11th Mon 17:45-19:00

### Exhibition Hall: Reception Hall
- Room 609
- Room 610
- Room 611
- Room 612
- Room 703

### S05 Clinical Trial Act: Experiences from the PI, the Way of the Future RA, PM, AC, MA

### 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, MW, MW.

### S08 Deep Dive into China Regulatory Reform From Various Perspectives (Tentative) RA

### S09 What is "Shared Value" Created by Collaboration Among Industry, Academia, Government and Future Generations - Going Forward to New Era of Innovation ALL

### S14 Forefront of Drug Delivery System (DSS) Technology RA, CMC, AC

### S15 Lessons from Experiences Using MidNet for PV RA, CP, ST


### S17 Sharing Individual Participant Data (IPD) from Clinical Trials and Personal Information Protection CR, RA, DM, AC, ST, MI, MW

### S18 How About the Courage to Take a Further Step for Young People? Or Career Development

### S24 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, Or Labelling

### S25 Let's Talk a Lot About What Future Shape of Ideal Collaboration to Promote Life Science Field is ALL

### S26 eSource in Clinical Trials - Global/Japan Use Cases - CR, DM, AC

### S27 How About the Courage to Take a Further Step for Young People? Or Career Development

### S28 Bringing Japanese Technology to the World! Ideal way of life science innovation in the era of peace, considered by industry, government and academia

### S40 Consider How to Provide Patient-Sought Drug Information RA, CP

### S41 The Dawn of Program Management: Beyond Project Management CR, RA, PM, AC

### S42 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, Or Patient

### S43 Virtual Clinical Trials: Roadmap for Implementation in Japan CR, RA, PM, AC

### S44 Toward Development of Comprehensive and Reliable Drug Information System for Consumers and Patients CR, MI, Or Patient

### S45 How Should We Set Up Our R&D Strategy and Target Product Profile? Key Learning from Real Cases CR, RA, PM, AC

### S46 Forefront of Patient Technology in Clinical Trials CR, RA, DM, PM, AC, Or Patient

### S47 The Latest Cases and Further Perspective of Early Approval System in Japan CR, PM, CMC

### S48 The Present and Future of Utilization of AI and Digital Technology in Medicine Development and Healthcare Services - To Deliver National Medicine- ALL

### S49 The Latest Cases and Further Perspective of Early Approval System in Japan CR, PM, CMC

### S50 The Appropriate Use of Drugs in Asia Countries, Especially Elder Patients RA, AC

### S51 The Basics of Health Technology Assessment - From Clinical Trials to Pricing - CR, RA, MA, Or Market Access

### S52 Practice of Post-Introduction of New Consultation System of Labeling for Revision CR, RA, CP, MA, MM, Or Labelling

### S53 The Appropriate Use of Drugs in Asia Countries, Especially Elder Patients RA, AC

### S54 The Basics of Health Technology Assessment - From Clinical Trials to Pricing - CR, RA, MA, Or Market Access

### S55 The Appropriate Use of Drugs in Asia Countries, Especially Elder Patients RA, AC

### S56 Bringing Japanese Technology to the World! Ideal way of life science innovation in the era of peace, considered by industry, government and academia

### S57 How About the Courage to Take a Further Step for Young People? Or Career Development

### S58 The Present and Future of Utilization of AI and Digital Technology in Medicine Development and Healthcare Services - To Deliver National Medicine- ALL

### S59 What is "Shared Value" Created by Collaboration Among Industry, Academia, Government and Future Generations - Going Forward to New Era of Innovation ALL

### S60 The Latest Cases and Further Perspective of Early Approval System in Japan CR, PM, CMC

### S61 The Basics of Health Technology Assessment - From Clinical Trials to Pricing - CR, RA, MA, Or Market Access

### S62 Practice of Post-Introduction of New Consultation System of Labeling for Revision CR, RA, CP, MA, MM, Or Labelling

### S63 The Present and Future of Utilization of AI and Digital Technology in Medicine Development and Healthcare Services - To Deliver National Medicine- ALL
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
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
9:00-9:00  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
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
9:00-9:30  Exhibit Hall Open
9:00-10:30  Sessions (S37 - S43)
10:30-11:00  Coffee Break
11:00-12:30  Sessions (S44 - S50)
12:30-14:00  Lunch Break / Luncheon Seminars
14:00-15:30  DIAmond Session 2  Rational Medicine for Patients
15:30-16:00  Coffee Break
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.

Private Social Function Policy
DIA does not allow hospitality functions to be held during any DIA educational offerings, scheduled Exhibit Hall hours, or social events. Below are the only hours that are acceptable for hospitality functions:
Saturday, November 9  All times are acceptable
Sunday, November 10  Before 8:00 and after 20:30
Monday, November 11  Before 8:00 and after 20:00
Tuesday, November 12  Before 8:00 and after 18:30

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

Conversations on Today’s Priorities
Hear from top thought leaders on global, interdisciplinary topics about the future of therapeutics, and how they affect you. Our DIAmond Sessions will bring together innovators from industry, academia, and government agencies to discuss key concepts, and have a conversation on today’s priorities. See page 7 and 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.

Reception Hall
12:00-13:00
Orientation

SESSION CHAIR
DIA Japan Contents Committee
Keiichi Inaizumi, MSc
Manager, Japan Clinical Project, Clinical Project Management Group, Pfizer R&D Japan
Takashi Moriya, PhD, MBA
Director, Data Sciences Department, Janssen Pharmaceutical K.K.

Welcome to the 16th DIA Japan Annual Meeting!
For the first time attendees, contents committee members present how you can maximize the value of your time at DIA Japan Annual Meeting 2019.
Contents:
- What is DIA
- Site Map
- Program Architecture
- Exhibition
- Navigation for Food and Coffee/Refreshment
- DIA App

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

Welcome
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
Kazuhiko Mori, MSc
Councilor for Pharmaceutical, Minister’s Secretariat, Ministry of Health, Labor and Welfare (MHLW)

Excellence in Service Award
Kazumichi Kobayashi, RPh
Advisor, Otsuka Holdings Co., Ltd. and Executive Deputy President, Otsuka Medical Devices Co., Ltd.

Leader of Tomorrow Award
Kyohei Shintaku
Regulatory Strategy Group, Regulatory Affairs, Pfizer R&D Japan

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 pursuit 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
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 DIAmond 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
Kazuhiko Mori, MSc
Councilor for Pharmaceutical Affairs, Minister’s secretariat Ministry of Health, Labor and Welfare (MHLW)

NETWORKING RECEPTION
Reception Hall 18:00-19:30

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 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

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**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

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**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  
Group Lead, Regulatory Networks and Harmonization (RNH/RSS)  
World Health Organization (WHO), Switzerland  
**TBC**

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 [Recorded Presentation]**  
Samvel Azatyan MD, PhD  
Group Lead, Regulatory Networks and Harmonization (RNH/RSS)  
World Health Organization (WHO), Switzerland

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**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**  
Goshi Ozawa, MS  
President, Real Discovery Outdoors Co., Ltd.
**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 devastate 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 Academia & 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

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**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.

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**PV by Utilizing RWD and mHealth**  
Nobutomo Matsui  
RWD Consulting Senior Principal, IQVIA Solutions Japan K.K.

**Patient ADR Reporting of Drugs**  
Kanae Kobayashi  
Reviewer, Pharmaceuticals and Medical Devices Agency (PMDA)

**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 ICMJE 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  
Steering Group member, EQUATOR Network

**Panel Discussion**  
All Session Speakers

**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.

**Introduction to the Revision of the Drug Administration Law**  
Xiaofang Cheng  
Principal Staff, Department of Policies and Regulations, The National Medical Products Administration (NMPA)
Overview Requirements for Advanced Therapies Review
Jianchao Gao
Chief Pharmacist, CDE

Introduction to Overseas Inspection of Chinese Drugs
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
Minoril Niso
Acute Care Diagnostics Product Manager, Instrumentation Laboratory J.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
Tomonori Shikawa
Manager, Department of Innovative Drug Discovery and Development, Japan Agency for Medical Research and Development (AMED)

Through All Japan Partnership, AMED is reviewing measures for drug discovery and development. This session will discuss the progress of measures and their effectiveness.

TBC
Koichi Fujii
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 & EXIBIT HALL INNOVATION TEATER PRESENTATION 10:30-11:00

DAY 2 | MONDAY | NOVEMBER 11

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
SESSION CHAIR
Rie Matsui, RPh
Director, International Labeling APAC, Regulatory Affairs, Pfizer R&D Japan

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
Duply-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)

Advancements in e-Labeling Technologies and Their Global Implementation
Shimon Yoshida, PhD
Executive Director, Head of International Labeling Group, Global Regulatory Affairs, Pfizer Inc

Panel Discussion
All Session Speakers and

R&D Head Club’s WGs Report on Quality-improvement before and after Adaptation
Kiyosato 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, Submission management & Translation group, Regulatory Writing & Submissions, Japan Development, Novatis 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, Pharmaceuticals, and Medical Devices Agency (PMDA)
S12 Room 607 11:00-12:30
What is Expected to MA/MSL?
Related Interest Area(s): MA
Level: Beginner
SESSION CHAIR
Yasuyuki Katayama, MD, PhD
Corporate Officer, Country Medical Director, and Head of Medical Japan, Pfizer Japan Inc.

Many pharmaceutical companies are reinforcing function of Medical affairs in recent years. In particular, MA/MSL are the core function within medical activity and they have various responsibilities or skills. Also, some groups of pharmaceutical industry made a statement about role or responsibility of MA/MSL.

In this session, speakers from academia, pharmaceutical companies and regulatory authority will share their perspective on expectation to MA/MSL. The workshop is designed to discuss what is expected to MA/MSL with participants. During this workshop, we will be able to identify common sense or gaps about role of MA/MSL among pharmaceutical industry groups and to clarify position or responsibility of MA/MSL in Japan.

What is Medical Affairs or Medical Science Liaison? -Questions from Medical Doctor-
Toshiya Nishibe, MD, PhD
Professor, Department of Cardiovascular Surgery, Tokyo Medical University

How MA/MSL Should Be?
Takamasa Horio, JD
Legal Advisor, Compliance and Narcotics Division, Pharmaceutical Safety and Environmental, Health Bureau Ministry of Health, Labour and Welfare (MHLW)

Consensus Statement on MA / MSL activities
Takeshi Nishimura, PhD
Senior Director, Medical Affairs Regional Function Head, Sumitomo Dainippon Pharma Co., Ltd.

How MA/MSL Good Look Like? –PhRMA Perspective-
Takeshi Imaoka, MD, PhD
Operating Officer, Senior Director, Diabetes Products & Safety Medical and Epidemiology/Database Research Medicine Development Unit Japan, Eli Lilly Japan

Panel Discussion
All Session Speakers

S13 Room 608 11:00-12:30
Challenges on Implementation of Risk Based Approach and Its Foresight
Related Interest Area(s): CR, DM, Level: Intermediate
SESSION CHAIR
Shigeyoshi Yokokawa MSc
Director, Regional Clinical Operations, Bristol-Myers Squibb K.K.

Accompanied by implementation of ICH E6 R2, pharmaceutical companies and CRO companies have taken the introduction of Risk Based Monitoring (RBM) into considerations, however, their stance is just like a “wait-and-see”. The primary objectives of RBM implementation are to ensure clinical trial data with high quality and to expect synergy brought by building processes at an investigational site and detecting issues promptly. On the other hand, it’s also true the discussion around its methodology is preceded. In this session, we would like to share the cases collaborated with an industry organization and investigational in accord with the results of survey. And we would also like to discuss our challenges on implementation of RBM which we have faced.

Let’s Go Back Again to the Basics of RBM
Yoko Kurose, MPharm
Senior Manager, Monitoring Group, Pfizer R&D Japan.

What is Required of CRAs in Relation to RBM? -Problems Revealed from a Survey of Medical Institutions-
Toshiya Hara
Executive Vice President, I’rom Co., Ltd

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 Lily 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
Lessons 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, Daiichi 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
Yasuhiro 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
Nick Wallace, J.D
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
Yasuhiro Ishikawa, MSc
Manager, Global Marketing Interventional Systems Division Cardiac & Vascular Company Terumo Corporation

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

Panel Discussion
All Session Speakers

LUNCH BREAK & LUNCHEON SEMINAR
12:30-14:00
Senior Clinical Pharmacology Assessor, Dutch Medicines Evaluation Board, The Netherlands

M arc Maliepaard, 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 (SGPIs).

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.

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 Journey Map (PJM) creation.

Actual registration dossiers were retrieved at the Dutch Medicines Evaluation Board.

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.

Daiichi Sankyo Co., Ltd

M ika Ikeda, PhD

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Daiichi Sankyo Co., Ltd

M ika 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 Journey Map (PJM) creation.

Actual registration dossiers were retrieved at the Dutch Medicines Evaluation Board.

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.
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 between 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 gave positive feedback.
- 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 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 (33.6%) 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 scope 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. Michelle 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 Narouka, 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.

Regulatory Guidelines on Provision of Pharmacokinetic Information in Package Inserts of New Drugs
Taishi Horiuchi
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 Horio, 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

Enabling More Efficient Clinical Studies through TransCelerate Solutions: The CPT and Clinical Content Re-Use
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
drug’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.

**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

**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)

**Panel Discussion**
All Session Speakers

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**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

Japan industries advancement and related innovation has been promoted by
industry-academia-government collaboration in each business segment for 50
years. In the world, an innovation invented and developed in one area is applied in
other industries in recent years, has become an important driving force of future
designation approach. In the life sciences field including pharmaceuticals and healthcare, the development and application of artificial intelligence and
digital technology has advanced like other industries.

The Life Intelligence Consortium (LINC), consists of approximately 100 AI/IT companies, pharmaceutical companies, and academia with working period of 4 years from November 2016, has been established to promote innovative approach using AI for more than 30 areas from target search to clinical development, post marketing safety measures, prevention and preemptive medicine.

This time, the session will provide an opportunity to thoroughly discuss the progress and future of LINC activities, and key to success in industry-academia-government collaboration in life sciences area.

**Pharmaceutical Innovation Aimed by the AI Consortium “LINC”**

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
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” “All Japan” -**

Rika Abe, RPh
Partnership-Promotion Coordinator, RIKEN Center 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

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**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 lessons 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.
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**

Toshikio Ishibashi, PhD, RN  
Clinical Operation Management, ONO Pharmaceutical Co., Ltd.

**Panel Discussion**

All Session Speakers and  
Toshikio Doi, 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

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**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, DaiichiSankyo 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.

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**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, Medics 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.
ICH E9 (R1): Understand Estimand. Let’s Discuss the Impact on the Design of Clinical Trials

Related Interest Area(s): CR, RA, DM, ST, MA, MW, AC
Level: Beginner

SESSION CHAIR
Satoru Tsuchiya, MSc
Senior Director, Data Science, Sumitomo Dainippon Pharma Co., Ltd.

The ICH E9 (R1) guideline will be step 4 in 2019. Estimand dealt with in the guideline is an important concept in the design of the clinical trials, and it is necessary for non-statistician to understand the guideline. How does the protocol of clinical trials change and how should the results be interpreted? For non-experts in statistics, explain estimand in an easy-to-understand manner, and share real examples, discuss and points to consider on this topic.

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
Sineor Director, Regulatory Affairs, Pfizer R&D Japan

Estimands: A Clinical Perspective [Recorded Presentation]
Charis Papavassilis, MD, PhD
Therapeutic Area Head, Dermatology Immunology, Hepatology & Dermatology Development Unit, Novartis Pharma AG

How to Become Quality Management for Patients

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

SESSION CHAIR
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 Yamasaki
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?
Noritsuki 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)

S34 Room 101 16:00-17:30
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

S35 Room 102 16:00-17:30
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
Ling Su, PhD
Professor, Shenyang Pharmaceutical 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

S36 Room 703 16:00-17:30
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.
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
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, academia or students, investigational sites or PMDA – please sit around our table and be our companions! Let’s talk together.

This session will be a casual discussion in a free-discussion format of small groups of people. We are going to provide some discussion topics. This year, we prepare 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.

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<td>Let’s discuss the challenges of promoting Risk Based approach to Monitoring!</td>
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</tbody>
</table>

1. Recently, volume and complexity of informed consent documents are increasing. Let’s discuss how we can improve informed consent documents and communicate with patients’ perspectives.
2. Let’s talk about what actions we should take for patients and the public.

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 company, I can’t get in communication with him/her. Let’s share our tips to improve mutual communication gained from your experience.

Project Management (PM)

How to Keep and Manage Quality in Clinical Study

Project Management (PM)

Keiko Tsumori
Eli Lilly Japan K.K.

Yuko Hata
Regulatory Affairs (RA)

Keiichi Inaizumi, MSc
DIA Japan Content Committee / Community
<table>
<thead>
<tr>
<th>Time</th>
<th>Room</th>
<th>Session Title</th>
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<tr>
<td>9:00-10:30</td>
<td>S37 605/606</td>
<td>The Future of Medical Big Data Based on the Next Generation Medical Infrastructure Act</td>
</tr>
<tr>
<td>9:00-10:30</td>
<td>S38 607</td>
<td>Regenerative Medical Products - Learn from the Latest Approved Products -</td>
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<td>9:00-10:30</td>
<td>S39 608</td>
<td>Utilization of RWD for the Clinical Trial Design and New Drug Application</td>
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<tr>
<td>9:00-10:30</td>
<td>S40 609</td>
<td>Consider How to Provide Patient-Sought Drug Information</td>
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</tbody>
</table>

**S37 Room 605/606**

**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

- **Takeo Nakayama, MD, PhD**  
  Professor, Department of Health Informatics, School of Public Health, Kyoto University Graduate School of Medicine

**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

**Millenial 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**

**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 academias 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 -**

- **Yoshiiro Yoshikawa**  
  Research and Development Center for Regenerative Medicine, NIPRO Corporation

**S39 Room 608**

**Utilization of RWD for the Clinical Trial Design and New Drug Application**

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

**SESSION CHAIR**

- **Takashi Moriya, PhD, MBA**  
  Director, Data Sciences Department, Janssen Pharmaceutical K.K.

**Regulators, industries, and academia have been very interested in how to use Real World Data (RWD) in clinical development. This session will introduce approaches to conducting effective clinical trials using RWD and/or Electronic Health Records (EHRs), and share common current efforts to resolve problems that presently remain for more efficient use of RWD. Database research using RWDs is also actively being considered in Japan. This session will also introduce new clinical trial models in Japan from the viewpoints of industry, government, and academia.**

**Can We Use RWD for Regulatory Decision in Oncology Drug Development?**

- **Takeharu Yamanaka, PhD**  
  Professor, Department of Biostatistics, Yokohama City University School of Medicine

**Connected And Enriched Health Data To Optimize Clinical Research Across The Drug Development Cycle**

- **Tammy Guld**  
  Global Team Lead, Janssen Clinical Innovation, Janssen R&D, LLC.

**PMDA’s Activities for Regulatory Utilization of Real World Data**

- **Kinue Nishioka, PhD**  
  Review Director, Office of Advanced Evaluation with Electronic Data, Pharmaceutical and Medical Device Agency (PMDA)

**S40 Room 609**

**Consider How to Provide Patient-Sought Drug Information**

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

**SESSION CHAIR**

- **Tomikazu 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**
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 Yukinoh 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)

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 project 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 CDM 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 Sankyco., Co., Ltd.

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 Study 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
In recent years, development of gene therapy products in Japan has increased. The first gene therapy product was approved in Japan. Regulatory systems in Japan are well established and understood among those involved in drug development. The meaning of setting the placebo arm as the theory of clinical trial design is well established and understood among those involved in drug development. On the other hand, it is also a fact that the clinical trial sites or patients have a sense that “it is difficult to conduct a trial with a placebo arm”, “does not want to receive a placebo”, which makes difficult to conduct the clinical trials.

In this session, we asked the question, “Is the placebo arm really necessary?”. Referring to the state of the anticancer drug, and receiving opinions from doctors, patients, industries, and regulators in Japan and overseas viewpoints, discuss the possibility of clinical development without putting placebo arm.

**Oncology Experience**
Taro Shibata, MSc
Chief, Biostatistics Division Center for Research Administration and Support, National Cancer Center

**Patient View**
Yoshiyuki Majima
Secretary General, NPO Pancan Japan

**Innovative Drug Development: Is the Placebo Arm Really Necessary?**
Dalvir Gill, PhD
Chief Executive Officer, TransCelerate Biopharma, Inc

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

**Panel Discussion**
All Session Speakers and
Yasuhiko Fujiwara, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)
Takako Sawada
Director of the Board, Executive Vice President, Shionogi Pharmaceutical & Co, Ltd

**Gene Therapy – Learn from the Cases**
Related Interest Area(s): CR, RA, AC
Level: Beginner

**SESSION CHAIR**
Sumimasa Nagai, MD, PhD
Senior Assistant Professor, Translational Research Center, the University of Tokyo Hospital

In recent years, development of gene therapy products in Japan has increased and the first gene therapy product was approved in Japan. Regulatory systems that facilitate practical application of gene therapy (e.g., Cartagena consultation) was newly established. This session will present real world examples from the consultation and review processes in developing such products, from experts in industry and academia. This session will also discuss other issues to consider, such as the difference between these therapeutic products and pharmaceuticals.

**Practice of Oncolytic Virus - Correspondence to Cartagena Protocol**
Takashi Kojima, MD, PhD
Department of Gastrointestinal, Oncology National Cancer Center Hospital East

**Development Outline of HGF Plasmid for Conditional Approval and Future Development Plan in Japan**
Tetsuya Ishihama
Director, Clinical Development Department, AnGes, Inc.

**Points to Consider in the Development of Gene Therapy in Japan.**
Takaaki Yoshida
Reviewer, Office of Cellular and Tissue-based, Products Pharmaceuticals and Medical Devices Agency (PMDA)

**Panel Discussion**
All Session Speakers

**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, MPA, 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

**Growing Regulatory Use of RWE Outside of Japan**
Nancy A. Dreyer, PhD, MPH
Chief Scientific Officer & Senior Vice President, IQVIA Real-World & Analytic Solutions

**Toward Development of Comprehensive and Reliable Drug Information System for Consumers and Patients**
All Session Speakers
How should we set up our R&D strategy and target product profile? Key learning from real cases.

S48 Room 610 11:00-12:30

How can we make the best choice when making decisions throughout different phases of clinical development? The Target Product Profile (TPP) is a strategic document to refine new market values for the pharmaceuticals development, and serves as a compass for developing development strategy. Based on the TPP to be developed, it is very important to maximize the value of the developmental target in the clinical practice and to carry out the earliest development by putting it into a viable clinical development plan. In this session, we would like to approach development strategy and its key points through the real cases of TPP and clinical development plans in companies and academia.

Significance of R&D Strategic Document Through RegulatoryConsultation and Review Process in PMDA

Tomoko Okudaira
Deputy Review Director, Office of New Drug 2
Pharmaceuticals and Medical Devices Agency (PMDA)

AMED R&D Management Based on Stage Gate and Drug Development Strategy
Yumiko Tomoyasu, DDS, PhD
Deputy Manager, Office of Project Coordination, Japan Agency for MedicalResearch and Development (AMED)

Significance and Examples of TPP and R&D Strategic Documents in Academia
Shinobu Shimizu, PhD
Lecturer, Center for Advanced Medicine and Clinical Research, Nagoya University Hospital, Nagoya University

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
Companies give presentations on examples of projects that have achieved early approval using such system, good points, and points that were difficult to use, by giving specific examples. In addition, PMDA also give presentation on the good points and the points that PMDA want companies to improve.

In the panel discussion, based on the presentations from each presenter, we will discuss ideas for more efficient use of these systems in the future, and have positive discussions to deliver Rational medicine promptly.

**Review of New Early Approval Systems**
Koushin Kiyohara, MPPharm, MSc  
Director, Office of New Drug  
Pharmaceuticals and Medical Devices Agency (PMDA)

**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

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**LUNCH BREAK & LUNCHEON SEMINAR**

12:30-14:00
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

**PMDA Town Hall**

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

**SESSION CO-CHAIRS**

Yoichi Ishikawa  
Professor, Department of Pediatric Medication Meiiji Pharmaceutical University

Hiromichi Shirasawa, MD  
Vice President and Executive Officer, Head of Japan Development MSD K.K.

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

**Panelists**

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**

**International Conference Room**  
17:30-17:40

Takashi Sato, MSc, PMP  
Program Vice-Chair / Manager, Resource Management Group, R&D Planning Department, Kyowa Kirin Co., Ltd.
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2019年11月10日(日)-12日(火)
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DIAglobal.org/Japan2019

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は何ができ、何をするべきでしょうか。すべての人々が医療の機会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反することなく相乗する環境を育むことをお互い協力し、それぞれがあるべきことを互いに理解しあ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知見を踏まえたRationalな（理にかなった・納得した）医療を届けることができます。

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、ひとりひとりの将来と目指すべきポイントを明らかにしていきます。2日目の夕刻は“チャッティングセッション”にて参加者同士のネットワーキングや意見交換ができる場があり、3日目午後には“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”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:
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

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11月10日（日）
9:30-12:00 ST(Student Session) 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
12:00-13:30 オリエンテーション@展示会場（12:00-13:00）
13:30-14:45 開会の挨拶
14:00-14:15 大会長挨拶
14:15-15:00 2019 DIA JAPAN'S INSPIRE REGIONAL AWARDS授賞式
15:00-15:30 コーヒーブレイク
15:30-16:15 基調講演 ディズニーのホスピタルティで難病を患う子どもとその家族に寄り添う
16:15-17:45 D1[DIAmond Session 1] 患者さんの治療・臨床研究に求めるもの - 各ステークホルダーが取り組むべきことは？
17:45-18:00 ショートブレイク
18:00-19:30 情報交換会（レセプションホール） *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

11月11日（月）
9:00-10:30 S01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～
S02 フロンティア技術と医療産業への展開
S03 WHOとの協働による世界貢献
10:30-11:00 コーヒーブレイク & 出展社プレゼンテーション（レセプションホール）
11:00-12:30 S10 将来のデジタルヘルスへの取り組み: 医師に効果的なクライアントのためのもの
S11 糖尿病治療薬を題材にRA、CP、AC
S12 MA/MSLのあら应该是
S13 患者情報～プラケースと医薬品情報は、さらに進化できるか？
S14 次世代医療基盤法に基づいた医療ビッグデータの今後
S15 次世代医療基盤法に基づいた医療ビッグデータの今後
12:30-14:00 ランチョンセミナー（レセプションホール）
14:00-15:30 S19 BMS
S20 クレーシブ詳細の現状を知る ~ 遺伝子発効後の生理学的薬物速度論 (PBPK) 解析利活用-医薬品開発の最大効率化に向けて
S21 リスク分析とissue managementの明確な手法
S22 患者ケアにおけるAMC
S23 がんのディスカッションの現状を知る ~ 退行性パネル檢查の現状と未来～
S24 次世代医療基盤法に基づいた医療ビッグデータの今後
S25 再生医療~直近の承認事例から学ぶ~
S26 PMDAタウンホール
S27 次世代医療基盤法に基づいた医療ビッグデータの今後
S28 次世代医療基盤法に基づいた医療ビッグデータの今後
15:30-16:00 ショートブレイク
16:00-17:30 S29 Innovative Drug Development: プラセボ群は必要か?
S30 ICH E9 (R1); Estimandの理解を深め、臨床試験計画への影響を議論する
S31 次世代医療基盤法に基づいた医療ビッグデータの今後
S32 ショートブレイク
S33 次世代医療基盤法に基づいた医療ビッグデータの今後
17:30-18:00 本会場閉会の挨拶
関連領域: CR=臨床オペレーション/臨床戦略、RA=薬事、ST=統計、DM=データマネジメント、CP=安全性及びファーマコビジランス、PM=プロジェクトマネジメント、CMC=品質管理、AC=アカデミア、MA=メディカルエフェークス、MI=メディカルインフォーメーション、MW=メディカルライティング、MC=メディカルコミュニケーション、HEOR=ヘルスエコノミックスアンダーサーチ、O=その他

## 日本語のみ

<table>
<thead>
<tr>
<th>会議室</th>
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### オリエンテーション&展示会場 (12:00-13:00)

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<tr>
<td>情報交換会 (レセプションホール) *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</td>
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#### 午前部

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<tr>
<td>605 臨床研査法, 施行から1年半の [\ldots] RA, PM, AC, MA</td>
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<td>506 患者さん-医療関係者へのソリューション-安全性管理における [\ldots] CP, PM</td>
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<td>507 企業による Publicationの [\ldots] CR, AC, MA, MC, MI, MW</td>
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<td>508 中国の薬品開発事業様々な [\ldots] RA</td>
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<td>509 藥学と市民の コラボレーションによる [\ldots] ALL</td>
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<td>518 MID-NETの活用を見えて [\ldots] RA, CP, ST</td>
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<tr>
<td>516 小児開発研究の [\ldots] CR, AC, MA, MC, MI, MW</td>
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<td>517 臨床試験の [\ldots] CR, AC, MA, MC, MI, MW</td>
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<td>518 場景と関係者の [\ldots] RA, CP, ST</td>
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### 午後部

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<td>532 オプション選択の [\ldots] CR, RA, MA, O: Market Access</td>
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<tr>
<td>533 未定文書 [\ldots] RA, CP, MA, O: Labeling</td>
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<td>534 医療及び [\ldots] RA, CP, MA, O: Market Access</td>
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<td>535 アジア [\ldots] RA, CP, MA, O: Market Access</td>
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<td>536 日本の技術を世界へ [\ldots] ALL</td>
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### ランチブレイク

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<td>540 患者さんの求める [\ldots] CR, CP</td>
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<td>541 プログラム [\ldots] CR, CP, MA, O: Labeling</td>
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<tr>
<td>542 患者様 [\ldots] RA, CP, MA, O: Patient</td>
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<td>543 Virtual Clinical Trialsの実装 [\ldots] RA, CP, MA, O: Patient</td>
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### コーヒーブレイク

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<td>548 どこが [\ldots] CR, CP, MA, O: Patient</td>
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<td>549 患者 [\ldots] CR, CP, MA, O: Patient</td>
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<td>550 日本 [\ldots] RA, PM, CMC</td>
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### 他のセッション

#### コーヒーブレイク & 出展社プレゼンテーション (レセプションホール)

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<tr>
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<td>11:45-19:30</td>
<td>展示会場（レセプションホール）オープン</td>
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<td>12:00-13:00</td>
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<td>13:00-13:30</td>
<td>プレオープンリング</td>
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<td>14:00-17:45</td>
<td>DIAmond Session 1「患者さんが治験・臨床研究に求めていること - 各ステークホルダーが取り組むべきことは？」</td>
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<td>9:00-12:30</td>
<td>展示会場（レセプションホール）オープン</td>
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<td>コーヒーブレイク &amp; 出展者プレゼンテーション</td>
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<td>セッション（S10 ～ S18）</td>
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<td>12:30-14:00</td>
<td>ランチブレイク / ランチョンセミナー / ポスターセッション</td>
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<td>14:00-15:30</td>
<td>セッション（S19 ～ S27）</td>
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<td>16:00-17:30</td>
<td>セッション（S28 ～ S36）</td>
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### 11月12日（火）

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<td>10:30-11:00</td>
<td>コーヒーブレイク</td>
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<td>11:00-12:30</td>
<td>セッション（S44 ～ S50）</td>
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<td>12:30-14:00</td>
<td>ランチブレイク / ランチョンセミナー</td>
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<td>14:00-15:30</td>
<td>DIAmond Session 2「患者さんのための合理的な医療」</td>
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<td>15:30-16:00</td>
<td>コーヒーブレイク &amp; 出展者プレゼンテーション</td>
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<td>16:00-17:30</td>
<td>DIAmond Session 3「PMDAタウンホール」</td>
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<td>17:30-19:00</td>
<td>閉会の挨拶</td>
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### 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ものではなく、指定の期日までにDIAに提出された資料のみが掲載されます。ハンドアウト資料（スライドコピー）の配布はありません。

### Private Social Function Policy

本年会開催期間中の、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） 午前8時以前、午後6時半以降

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

発表者および講演タイトルは予告なく変更されることがあります。

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

### Conversations on Today's Priorities

Hear from top thought leaders on global, interdisciplinary topics about the future of therapeutics, and how they affect you. Our DIAmond Sessions will bring together innovators from industry, academia, and government agencies to discuss key concepts, and have a conversation on today's priorities.

詳細につきましては6、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
栄 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・受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講演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。

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
開会の挨拶および基調講演 / DIAmond 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

大会長挨拶
国際会議場  13:45-14:00

第16回DIA日本年会大会長
一般社団法人 Medical Excellence Japan
近藤 達也

2019 DIA Japan's Inspire Awards授賞式
国際会議場  14:00-14:15

プレゼンター
DIA Chair-Elect
Lingshi Tan

アワード受賞者：

Outstanding Contribution to Health Award
厚生労働省
森 和彦

Excellence in Service Award
大塚ホールディングス株式会社／大塚メディカルデバイス株式会社
小林 和道

Leader of Tomorrow Award
ファイザーR&D合同会社
新宅 恭平

大会長講演
国際会議場  14:15-15:00

座長
山梨大学
岩崎 甫

革新的な医療技術を伴う製品をより早期に、最適な形で国民に届けていくことはRegulatory Agencyの責務である。最先端の革新的な医療は、世界で先に極めて高い医療であるため、持てる頭脳を結集して、最新のレギュラトリーサイエンスに基づき、評価を実施する必要がある。その評価に際しては、常に“合理的な医療”が実現されるよう目標を念頭に、このような考えに基づき、近藤達也先生は、2017年2月にRational Medicine Initiativeを公表した。11年間に渡るPMDA理事長として、近藤先生が指導されてきたことやその成果についてご講演頂き、医療従事者、産業界、アカデミア、規制当局等のStakeholderが患者さんとともに歩んでいく方向を模索したい。

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

東京ディズニーリゾートで約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公益法人を設立し、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。

ディズニーランドは、お客様を“こんにちは”と迎えます。そして、“またね”と言って送ります。園内は掃除のスタッフが常に綺麗にしてくれます。そのためお客様は、ごみを投げ捨てず、ゴミ箱に捨てます。それが“当たり前”の世界です。しかし、これらはどれも私たちが幼い頃、母親から教わったことばかりで、社会の原点なのです。

これまで240の家族と出会い、その母親との対話から見えてきた「いま、生きる」メッセージは、どれも愛に溢れ、深みがあります。

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

患者さんが治験・臨床研究に求めるもの – 各ステークホルダーが取り組むべきことは？-

関連領域: ALL
レベル: 中級

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間に渡って、PPIをテーマにしたセッションを企画し、PPIの概念や理念、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DIAmond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が集まり、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を推進していくため関係者が取り組むべきことについて総合的に議論する。

未定
独立行政法人 医薬品医療機器総合機構
藤原 康弘

未定
European Medicines Agency (EMA)
Agnès Saint-Raymond

患者・市民参画の推進について
東京大学大学院
今村 恭子

一製薬企業からみた医薬品開発における患者・市民参画
ファイザーR&D合同会社
今枝 孝行

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
森 和彦

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
国立がん研究センター中央病院

患者一人一人にあった個別化医療の実現に向け、がんゲノム医療への取り組みがすすめられている。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

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

企業から見るがん遺伝子パネル検査のレギュラーティ課題
中外製薬株式会社
田澤 慎明

パネルディスカッション
本セッションの講演者

9:00-10:30
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

既に他業種で導入実績のある“ブロックチェーン”技術は現在医薬産業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、医薬産業での活用事例として薬事申請、治験のデータ認証、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頂き、医薬産業を取り巻く情報管理や活用の方向性を議論する

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

ブロックチェーンを加速するブロックチェーン・ネットワーク
日本ア・ビ－エム株式会社
高田 充康

未定
国立保健医療科学院

パネルディスカッション
本セッションの講演者

9:00-10:30
S03 607会議室
WHOとの協働による世界貢献
関連領域: RA, Gavernment
レベル: 中級
座長
独立行政法人 医薬品医療機器総合機構

WHOの活動の中には、Pre-QualificationやReliance Pathway等、先進国の関心が高い案件も多い。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がかかることもあり、各国規制当局との関係も少なからず存在する。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を支援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とどのような連携が可能かについて議論する。

Putting Reliance into Practice: WHO’s Activities on Regulatory Systems Strengthening<ビデオによる講演>

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
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

9:00-10:30
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

2018年7月に日本製薬業協会からClinical QMS実装の取組み事例が公開されている。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実装に資する学習ヒントを提供する。

Clinical QMSの実装 と課題
MSD株式会社
平山 清美

臨床QMS実施への道 ～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

9:00-10:30
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

未定

パネルディスカッション
本セッションの講演者
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。そこで、臨床研究法を追究することにした。

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
臨床研究法
今後の運用
厚生労働省
吉田 淳
パネルディスカッション
本セッションの講演者

S06 610会議室 9:00-10:30
患者さん・医療関係者へのソリューション：安全性監視における新しい試み
関連領域: CR, CP, PM
レベル: 初級
言語: 日本語のみ
座長
セルジーン株式会社
西馬 信一
近年の市販後安全性監視活動に関する内外環境の大きな変化に伴い、これまで以上に患者や医療関係者側に立ち、安全性情報に基づいたソリューションを積極的に提供していくビジネスモデルがいくつかの企業において立ち上がられており、本セッションでは、3つの企業からそれぞれ、安全性情報提供、安全性解析や新たなエビデンスの創出に関する新たなモデルを、PMDAから患者からの副次情報提供に関する具体的な事例について紹介いただき、特に患者や医療従事者に役立つ安全性監視、安全性情報提供、エビデンス創出と何かを議論する。

規制対応のためのPV、患者さんのためのPV
中外製薬株式会社
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－
RWDとmHealthを活用したPV
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

S08 102会議室 9:00-10:30
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
言語: 日本語のみ
座長
Shenyang Pharmaceutical University
Ling Su
中国における薬事規制改革は、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は革新的な開発を促進する改良された薬事規制システムにより、コンペティション的なものからより進歩したものとなった。このセッションでは、中国における最新の革新的・先進的医療にまつわる薬事環境について薬事規制当局に紹介して頂き、また産業側からそのような新たな薬事環境での開発の実際の経験について紹介して頂く、さらには、中国当局NMPAより、知的財産権保護についての薬事規制についてもポッドキャストとして紹介して頂き予定である。

Introduction to the Revision of the Drug Administration Law
National Medical Products Administration (NMPA)
Xiaofang Cheng
Overview Requirements for Advanced Therapies Review
CDE
Jianchao Gao
Introduction to Overseas Inspection of Chinese Drugs
Center for Food and Drug Inspection of NMPA
Fei XU
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て、それぞれの強みを生かしたオープンイノベーションが広がりつつある。このセッションでは、個別のアプローチでは解決の難しい現代の社会的課題のための「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や、企業が経済的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 &出展社セミナー 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、OMI
レベル: 初級/中級
言語: 日本語のみ
座長
ファイザー R&D 合同会社
松井 理恵
医療におけるデジタル化は、世界中で急速に進んでいる。その一環としての医薬品情報のデジタル化により、患者さんへのヘルスリテラシーを向上させ、それにより患者さんがより主体的に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バックボーンであり、USでは既に導入され、他の欧米諸国も検討が進められている。本セッションでは、将来のデジタルヘルスを見据え、デジタル化された添付文書/医薬品情報の活用について、海外と日本国内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。
電子的製品情報(ePI)のEUにおけるイニシアチブ
欧州連合/医薬品・医療機器連邦研究所 (BfArM)
Peter Bachmann

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 倫夫
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なのかを議論する。
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

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
片山 泰之
近年、多くの製薬企業はメディカル活動の機能を強化してきており、特にMA/MSLは、メディカル活動における中心的役割であり、業務範囲や求められるスキルが多岐多様である。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つつある。
本セッションでは、今後のOMA/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、参加者とともに考えるワークショップ形式で議論してみたい。
メディカル・フェアーズ、メディカル・サイエンス・リエゾンとは？—医師からの疑問—
東京医科大学
西部 備哉
MA/MSLのあり方
厚生労働省
堀尾 貴将
MA／MSL活動に関する基本的考え方
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
日本イーライリー株式会社
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 クロス株式会社
横川 重吉
RBMでCRAに求められるものは何？
－医療機関からのサーベイ結果から見えた課題
株式会社アイロム
原 寿哉
真のRBM実装に向けて　～site tourからの学び～
日本イーライリー株式会社
小泉 稔
パネルディスカッション
本セッションの講演者、並びに
上尾中央総合病院
新井 幸
聖路加国際病院
身崎 昌美
ファイザーR&D合同会社
佐藤 亜紀

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、データ解釈、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いただき、規制当局の担当者を交え、今後のMID-NETのPVへの利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の概要
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利活用の実践
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利活用
MSD株式会社
宮崎 真
MID-NET利活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

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
橘田 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～高分子薬がトレンドになりつつあるが、安定性や膜透過性等の問題が実用化の大きな障壁となっており、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るの課題を紹介いただく。
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きます。

革新的な医薬品・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

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？何をしてきましたか？もっ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って出てきている。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る上での障害は何か、それは産官学でどのような活動を経て滑らかに行われているのかを議論する。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。

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
吉田 淳

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、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、こられる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。どんな感情が隠されているのでしょうか。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が気持ちよく働くよう、様々なスキルを駆使してヒントを探ります。

HARD THINGS : 改革プロジェクトの困難にどう立ち向かうか
テルモ株式会社
石川 泰史

SOFT SKILLS: 周りの人を動かすために必要なマインドセッ트とは
東京大学医科学研究所附属病院
藤原 紀子
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 screening 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**

宮崎 由美子

**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**

日本イーライリー株式会社

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 (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:**
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.

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

日本イーライリー株式会社

宮崎 由美子

**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 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.

**Conclusion:**
- Improved and improved recognition of clinical trials in the institution, CRCs, clerical 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 atmos-phere 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 expla-nation 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.
European concerns about the clinical evaluation of high-risk devices. In order to strengthen the regulations in medical devices, the European Parliament adopted two new regulations on 5 April 2017. They will be published in the official Journal. The new rules will apply three years after publication with regards to the medical devices. US FDA too at the same time is taking initiatives to ensure that safety monitoring is robust both preapproval as well as post approval. This presentation explores some of the similarities and differences in European and US regulation of devices, and discusses challenges facing each.

[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(6) 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(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

中外製薬株式会社

菅尾 淑人

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 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 (02/03/17) 4. The statistical viewpoint that is found to do? (05/27/17) 5. Medicine charge system drastic reform (06/30/18) 6. Think about the future (02/03/18) 7. The new drug approval system (04/17/19)

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. European concerns about the clinical evaluation of high-risk devices. In order
現在、添付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ダンスが、2019年に母集団薬物動態／薬力学解釈ガイドラインが発表され、それらのガイドラインでは、添付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ターボットの活用や、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、産官学で連携することを検討する。

添付文書上の臨床薬理情報の課題と提案

 MSD株式会社
 佐藤 正延

独立行政法人 医薬品医療機器総合機構
 堀内 大士

医療現場での添付文書上の臨床薬理情報の課題と期待
 東京大学医学部附属病院
 大野 能之

パネルディスカッション
 本セッションの講演者

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.
 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連する事項"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が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を進めており、のちの薬事処理も踏まえた、新たな情報提供ガイドラインの策定が検討されている。

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、執拗な情報提供に高い倫理感、透明性が求められるようになった。

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。

販売情報提供活動ガイドラインの社内運用
 サンドフィス株式会社
 松村 佳延

ファイザー（株）における新規ガバナンスとQMS体制
 ファイザー株式会社
 片山 泰之

販売情報提供活動ガイドラインの実践
 厚生労働省
 堀尾 貴夫

パネルディスカッション
 本セッションの講演者

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

座長
 日本イクライリリー株式会社
 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で、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、効率を改善でき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。

TransCelerateの活動アップデート
 MSD株式会社
 佐藤 俊治

イニシアティブ アップデート：SIP（Shared Investigator Platform）
 ファイザーR&D合同会社
 松島 将英

Enabling More Efficient Clinical Studies through TransCelerate Solutions: The CPT and Clinical Content Re-Use
 Pfizer Inc.
 Sian Ratcliffe

イニシアティブ アップデート：ファーマコビジランス
 アステラス製薬株式会社
 河村 光二

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 政雅

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さから、有効性の検証に必要な症例数が困難なため、企業が開発に躊躇する状況が多い存在する。

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希少疾病の医薬品開発における具体的な活用事例や、現行の問題点等を紹介し、最新の情報を共有する。

その上で、産官学それぞれの立場から希少疾病用医薬品の承認申請に活用するための方策や、解決すべき問題点について確認しながら、これからの可能性について議論したい。

HTLV-1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
 壱薬リアナ医科大学 大学院附属病院
 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の役割
 生物科学医療株式会社
 長谷 洋

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

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、新記載要領の添付文書が実際に医療現場に届き始めた。新記載要領の添付文書の読み方や、実際に添付文書を医療現場に届けたときのインパクトについて示す。

S25 101会議室 14:00-15:30
我が国のライフサイエンスエリアにおける産学官連携の未来について大いに語ろう
関連領域: ALL
レベル: 中級
座長
京都大学大学院医学研究科
奥野 恭史
我が国は、高度経済成長時代から種々の産業領域において、それぞれのエリアにおける産学官連携が進展してきた。世界では、近未来、他業種で生み出されたイノベーションが他の産業で応用的に活用される。この課題について、産学官連携の重要性について議論する。

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、どのようなチャレンジを進めていくべきか、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の挑戦を議論する。

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
座長
日本イーライリー株式会社
貝原 徳紀

本セッションでは、臨床薬理の非専門家向けにPBPKを概説する。このガイドラインの施行による、臨床データバンクージに含まれる薬物相互作用試験等、必要な臨床薬理関連試験の減少を含む、医薬品開発の効率化への貢献について更に適切な実臨床とシミュレーションデータのバランスに関して産学の専門家による展開を共有する。パネルディスカッションでは、産学の専門家により、PBPKデータをどのように、臨床開発の効率化や適切な医療現場への情報提供に有効活用すべきか、またシミュレーションデータ活用の是非と限界について議論する。

Application of PBPK Modeling Leading to More Efficient Drug Development – Overview and Case Examples -
ファイザーR&D合同会社
武藤 智恵子

PBPKモデル解析に関する承認審査の現状とPBPKモデル解析ガイドライン（案）の策定
独立行政法人 医薬品医療機器総合機構
木島 慎一

未定
大分大学
上村 尚人

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
佐藤 正延
アステラス製薬株式会社
大石 昌代

座長
日本イーライリー株式会社
貝原 徳紀

本セッションでは、臨床薬理の非専門家向けにPBPKを概説する。このガイドラインの施行による、臨床データバンクージに含まれる薬物相互作用試験等、必要な臨床薬理関連試験の減少を含む、医薬品開発の効率化への貢献について更に適切な実臨床とシミュレーションデータのバランスに関して産学の専門家による展開を共有する。パネルディスカッションでは、産学の専門家により、PBPKデータをどのように、臨床開発の効率化や適切な医療現場への情報提供に有効活用すべきか、またシミュレーションデータ活用の是非と限界について議論する。

Application of PBPK Modeling Leading to More Efficient Drug Development – Overview and Case Examples -
ファイザーR&D合同会社
武藤 智恵子

PBPKモデル解析に関する承認審査の現状とPBPKモデル解析ガイドライン（案）の策定
独立行政法人 医薬品医療機器総合機構
木島 慎一

未定
大分大学
上村 尚人

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
佐藤 正延
アステラス製薬株式会社
大石 昌代

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
齋藤 宏暢

がんを取り巻く世界は急速な変化を見せています。がん免疫療法をはじめとする新規医薬品のみならず再生医療や医療機器なども次々と提案され、がん医療の選択肢は拡がりつつあります。臨床試験の環境はデジタルや人工知能(AI)、IoTの波を受けてオペレーションの大きな変革期に突入しました。新しい治療法の評価をいかにシンプルに信頼性の高いものにするかはこれらの臨床試験の課題です。

本セッションでは、がんのGlobal試験を日本で行う上での要件や今後の臨床試験の進め方について考えていく。

なお、本セッションは2020年1月31日に開催予定のDIA Global Oncology Development 2020のプレセッションです。

S30  607会議室 16:00-17:30
ICH E9 (R1) : Estimandの理解を深め、臨床試験計画への影響を議論する
関連領域: CR、RA、DM、ST、MA、AC、MW
レベル: 初級
座長
大日本住友製薬 / 日本製薬工業協会
土屋 悟

ICH E9 (R1) ガイドラインは、2019年にステップ4になる予定である。本ガイドラインで取り扱われるestimandは、臨床試験計画時に重要な概念となり、統計家以外も本ガイドラインの理解が求められる。臨床試験の治験実施計画書はどのように変わり、その結果の解釈はどうなっていくべきか？統計の非専門家を対象に、estimandを分かりやすく解説するとともに、実際の検討事例や、留意点などを共有する。

Estimandって何？
興和株式会社 / 日本製薬工業協会
菅波 秀規

E9 (R1) ガイドラインの日本での実装へ向け
独立行政法人 医薬品医療機器総合機構
原 純子

EstimandのRAH・臨床のインパクト
ファイザーR&D合同会社
今枝 孝行

Estimands: A Clinical Perspective [ビデオによる講演]
Novartis Pharma AG
Charis Papavassilis
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ができること～

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、試験結果の信頼性の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用すること、新たに検討したQuality Management (QM)の手順を遵守することが目的となっていく状況が伺える。しかしながら、臨床試験の実施においては、被験者の保護も欠かせないため、被験者保護も含めたQMSとは何かを考える必要がある。そのためには製薬企業と医療機関が達成すべき目的を共有し、双方が同じゴールを目指すことが重要であると考える。

そこで、治験実施における現在の問題点を整理して、製薬企業と医療機関がどう協働したらよいかを考えることで、患者さんが安心して臨床試験に参加でき、安全、かつ、適切に実施される方法を考えたい。

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, MA, MW, O: Market Access
レベル: 初級
言語: 日本語のみ
座長
国際医療福祉大学
池田 俊也

さまざまな議論の末、HTAが国内で本格導入された。しかししながら、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、製薬協医薬品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、薬事・医薬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

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、事前確認調査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。

S34 101会議室 16:00-17:30
医療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
株式会社アセン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た。産業の成長促進や更なる技術革新を考えたとき、継続的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あります。

今回、本エレアのホットトピックであるAIやRobotic Process Automation (RPA)の研究開発及び製薬エリアでの活用を房屋に、このエリアの第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をする場を提供します。皆様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 MultiOmics 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・エンジニアリングジャパン株式会社
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
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。高齢化に伴う体重変動や臓器機能の低下等は周知の事実であるが、医薬品の添付文書を見ても、高齢者に関する情報が記載されているものは少ない。高齢化を迎えるアジアの国々において、高齢者に対する医薬品の適性使用や添付文書における注意喚起がどのようになっているかについて、現状を共有するとともに、同様の状況を迎えている他のアジアの国々と連携することにより、より適正な高齢者薬物療法について考えてみたい。
未定
Shenyang Pharmaceutical University
Ling Su
The Appropriate Use of Drugs in Elder Patients: A Malaysian Perspective
New Drug Section Centre for Product Registration, NPRA
Azri Nasruddin
アジアにおける添付文書の現状とその将来～高齢者に対して～
ファイザーR&D合同会社
松井 理恵
パネルディスカッション
本セッションの講演者

S36 703会議室 16:00-17:30
日本の技術を世界へ！産官学で考える、令和時代のライフサイエンスイノベーションのあり方
関連領域: その他
レベル: 中級
言語: 日本語のみ
座長
日本ベーリングーインゲルハイム株式会社
田中 圭
成長目覚ましくノベティブな取り組みを行っている創薬ベンチャーの成功を経験することにより、日本のライフサイエンス分野の閉塞感を打ち破るヒントを提供する。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
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、同じテーブルを囲んでみませんか。皆仲間！

DIA年会にお一人で参加される方も、是非、輪に入れていただき、興味のあるテーマについて一緒に語り合いましょう！

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。

テーマ一覧:
当日ご興味のあるテーブルにお立ち寄りください。途中参加、退席、移動も可能です。

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3日目 | 11月12日（火）

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、今後の医療DB業界の在り方、医療DBの利活用、将来医療DB業界がどのように発展していくかについて紹介し、今後の医療DB研究に寄与する方法を提言する。

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（現在のスキルでの限界・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、今から何を見積るべきかを考える。

S39  608会議室 9:00-10:30

治験計画及び薬事申請のためのリアル・ワールド・データの活用

関連領域: CR、RA、DM、ST、PM、AC
レベル: 初級

座長
ヤンセンファーマ株式会社
森谷 隆

RWDが臨床開発の場でどのように利用可能かということについて、世界各国の規制当局、企業、アカデミアが多い関心を寄せている。そこで本セッションでは、Real World Data (RWD) / Electric Health Record (EHR) を用いて、効果的に臨床試験を実施する取組について紹介する。また、その一方で臨床現場においては、RWDのより効率的な活用のために解決すべき課題点も残されており、現状の取組についても情報共有する。今では、多くのRWDを用いたデータベース研究が検討されており、新しい治験モデル等の事例を紹介するとともに、日本における課題について産官学で検討する。

パネルディスカッション

本セッションの講演者

S40  609会議室 9:00-10:30

患者さんの求める医薬品情報の提供方法を考える

関連領域: RA、CP
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
徳木 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（現在のスキルでの限界・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、今から何を見積るべきかを考える。

パネルディスカッション

本セッションの講演者
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
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、時間を駆使した効果の創造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、抗がん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ージすることが出てきており、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ージする「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

S44  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：治療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端開である。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やすく説明するかが課題である。本セッションでは、説明文書の内容とその説明という2つの視点で、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。

コーヒー・ブレイク
10:30-11:00

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が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や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。

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：その患者さんにおけ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

European Medicines Agency (EMA)
Agnès Saint-Raymond

Bringing Patient Centricity to Informed Consent and Promoting Understanding of Clinical Research Participation
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？

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論としてもプラセボ群を設定する意味は確立しており、医薬品開発に乏しい人たちは理解されている。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ことも実事であまり、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、規制当局より、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。

抗がん剤開発での経験
国立がん研究センター中央病院
柴田 大朗

患者さんの視点から
特定非営利活動法人パンキャンジャパン
真島 喜幸

Innovative Drug Development: Is The Placebo Arm Really Necessary?
TransCelerate Biopharma, Inc
Dalvir Gill

EU Perspectives
European Medicines Agency (EMA)
Agnès Saint Raymond

パネルディスカッション
本セッションの講演者、並びに
独立行政法人 医薬品医療機器総合機構
藤原 康弘
塩野義製薬株式会社
澤田 拓子

S45  607会議室  11:00-12:30
遺伝子治療～開発の課題を事例に学ぶ～

関連領域：CR、RA、AC
レベル：初級
座長
東京大学
永井 純正

近年、遺伝子治療用製品の開発が盛んになり、日本でも初の遺伝子治療用製品が承認された。カルタヘナ法関連事項相談の新設等、実用化支援体制も着実に整えられている。

本セッションでは、アカデミアから遺伝子治療用製品の臨床治療の実際や薬事承認に向けての期待、企業から開発で苦労された点、パッケージなどを実例としてお話しいただき、PMDAからもカルタヘナ法相談とRS相談の様子をみ、相談の留意点等、ご経験を踏まえ講演いただき、アカデミアと企業におけるカルタヘナ法対応の違い、医療機関や患者さんに対する特有の対応、承認取得をする点で大変な点等、遺伝子治療医薬品を開発する上で問題となる点について議論頂く。

国内におけるHGFプラスミドの条件期限付き承認までの開発の様子と今後の開発計画
アンジェス株式会社
石原 哲也

遺伝子治療用製品の開発上の留意点
独立行政法人 医薬品医療機器総合機構
吉田 貴明

パネルディスカッション
本セッションの講演者
国内のサイトはほとんどなかった。信頼できる情報かどうかを担保する仕組みも普及していないことが考えられる。また、医薬品の治験、承認から市販後までの一連の流れに関する一般向けの情報提供も十分とはいえない。

患者・消費者のヘルスリテラシーを考慮し、shared decision makingに向かう包括的な情報提供基盤システムの構築・普及が求められている。その課題と展望について、産官学および患者の立場から、討議していく必要があると考える。

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シジョンメイキング
京都大学
中山 健夫

製薬企業からの情報提供の現状と今後の展望
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

table
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<tr>
<th>パネルディスカッション</th>
<th>本セッションの講演者、並びに</th>
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<tr>
<td>順天堂大学</td>
<td>内田 浩一郎</td>
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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
宫路 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、今まで実施できなかったようなアプローチで問題を解決できる可能性がある。本セッションでは、患者さんの治験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。

TransCelerate Patient Experience Overview
Pfizer, Inc
David P. Leventhal
Tools for Enabling and Accelerating Patient-Facing Digital Technologies
Merck & Co., Inc.
Matthew Moyer
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早期に当該審査が行われ、承認事例も着実に増えていく。当該制度を活用し早期承認を実現しようとした事例及び良かった点・活用しにくいかった点について、具体的な事例を挙げながら企業から発表頂く。

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 宏発

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部門からみたソスパタ錠の先駆け申請
アステラス ファーマテック株式会社
村上 剛史
3日目 | 11月12日（火）

DIAmound Sessions & 閉会の挨拶

DIAmound Session 2
国際会議場 14:00-15:30

DIAmound Sessions

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しています。本セッションでは、長年医師として規制当局を観察し、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して、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。医師として働いた後、異なる立場になった時に、見えている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

DIAmound 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
高江 慎一

独立行政法人 医薬品医療機器総合機構
医療情報活用部部長
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/協和キリン株式会社
佐藤 隆
DIA EUROPE 2020
17-19 March | Brussels, Belgium

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日本年会展示専用ウェブサイト：http://diaexhibit.org/

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Address: 3-6-8 Ariake, Koto-ku, Tokyo 135-0063
Telephone: +81-3-5530-3610

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Phone Number Required Fax Number

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会議参加申込書

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

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会議参加申込書　若手割引専用

第16回DIA日本年会2019

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