19th DIA Japan Annual Meeting 2022

New "Quest for the future"

～Moving Creativity and Innovation Forward in "New Normal"～

October 9-11, 2022
Hybrid | Tokyo Big Sight & Virtual

Program Overview

The theme of the 19th DIA Japan Annual Meeting is "New "Quest for the future"- Moving Creativity and Innovation Forward in "New Normal" - ". This means that we who have experienced COVID-19 will explore the future in a new normal environment.

COVID-19 has brought us lives and environments that we have never experienced before. While face-to-face work declined dramatically, digital transformation accelerated at once. They also promoted extremely rapid development of vaccines and therapeutic agents, as well as new clinical trial models including telemedicine. In addition, the importance of self-care associated with refraining from visiting medical institutions and the importance of addressing the issue of infodemics were reaffirmed.

In the new normal environment that has brought about by COVID-19, we are seeking to implement new clinical trials, implement safety measures, disseminate information, develop new modalities, and respond to self-care.

There is a need for new Creativity and Innovation on pharmaceuticals, medical devices, regenerative medicine, and other products for the future. We wish to share and discuss how to proceed with this in advance, as well as the efforts, experiences and ideas of you, and to make it a conference to proceed further in advance. It is hoped that discussions will take place from a variety of positions and perspectives.

This year, we will also hold a hybrid (In-person + Live Virtual) considering the status of expansion of new coronavirus infectious diseases. The following Live Session are planned. After the Meeting you can watch the session on-demand until the end of November.

- Live lectures: Live (partially recorded) speaks (and live panel discussions) on the day and date of each session. In principle, a live video of the day is recorded and can be viewed until the end of November.

It depends on the situation of the new coronavirus infection in October, but we look forward to seeing you as realistically as possible. We sincerely look forward to your participation.

Endorsement pending by
MHLW, PMDA, AMED, JPMA, EFPIA, PDA ISPE

Please Click here for COVID-19 Measures

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

Schedule

SUNDAY, OCTOBER 9

9:00-9:30	Pre Opening
9:30-	Opening, Student Session
10:00-10:15	Break
10:15-11:15	Keynote Address
11:15-12:15	Program Chair Session
12:15-13:15	Lunch Break
12:25-13:05	Luncheon Seminar
13:15-	Special Session 1, LS-01, LS-02, LS-03
14:30-15:15	Break
14:55-15:10	Afternoon Seminar
15:15-16:30	LS-04, LS-05, LS-06, LS-07
16:30-17:00	Break
17:00-18:15	LS-08, LS-09, LS-10, LS-11
18:15-18:30	Break
18:30-	Young Professionals Exchange and Networking Session, Poster Sessions

MONDAY, OCTOBER 10

9:00-10:15	LS-12, LS-13, LS-14, LS-15, LS-16
10:15-10:30	Break
10:30-11:45	LS-17, LS-18, LS-19, LS-20, LS-21
11:45-12:45	Lunch Break
11:55-12:35	Luncheon Seminar
12:45-	Special Session 2, LS-22, LS-23, LS-24, LS-25
14:00-14:30	Break
14:30-	Special Session 3, LS-26, LS-27, LS-28, LS-29
15:45-16:30	Break
16:10-16:25	Afternoon Seminar
16:30-	DIAmond Session 1, LS-30, LS-31, LS-32, LS-33
17:45-18:15	Break
18:15-19:45	Special Chatting Session

TUESDAY, OCTOBER 11

9:00-10:15	LS-34, LS-35, LS-36, LS-37, LS-38
10:15-10:30	Break
10:30-11:45	LS-39, LS-40, LS-41, LS-42, LS-43
11:45-12:45	Lunch Break
11:55-12:35	Luncheon Seminar
12:45-	Special Session 4, LS-44, LS-45, LS-46, LS-47
14:00-14:30	Break
14:30-	DIAmond Session 2, LS-48, LS-49, LS-50, LS-51
15:45-16:30	Break
16:10-16:25	Afternoon Seminar
16:30-	DIAmond Session 3, LS-52, LS-53, LS-54, LS-55
17:45-18:15	Break
18:15-18:45	Closing

This year's DIA Japan Annual Meeting will be held on the Web as a Live Session as fellows.

LS (Live session): The Session will be broadcast live from the venue (remote lectures and panel discussions will be held).

ROOM and TRACK

605+606	: TRACK 1
607+608	: TRACK 2 (Day 1)
608	: TRACK 2 (Day 2-3)
607	: TRACK 3 (Day 2-3)
101	: TRACK 4
102	: TRACK 5
609	: Satellite

←Simultaneous interpretation is included

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, October 8	Before 8:00 and after 21:00
Sunday, October 9	Before 8:00 and after 20:30
Monday, OCTOBER 10	Before 8:00 and after 20:30
Tuesday, OCTOBER 11	Before 8:00 and after 19:30

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

DIAmond SESSIONS

Conversations on Today's Priorities

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

See page 14, 21 and 22 for more details.

Related Interest Area

All：All Areas	AC：Academia	BE：Bioethics
CDM：Clinical Data Management	CI：Clinical Innovation	CMC：Chemistry, Manufacturing and Control
COM：Clinical Operation and Monitoring	CP：Clinical Pharmacology	MA：Medical Affairs
MC：Medical Communication	OI：Open Innovation	PE：Patient Engagement
PM：Project Management	PV：Clinical Safety and Pharmacovigilance	RA：Regulatory Affairs
SS：Six Sigma	ST：Statistics	O：Others

LIVE SESSION

PRE OPENING 605+606 9:00-9:30

DIA Band

SESSION CHAIR SPEAKER:

Junichi Nishino, MSc, RPh
ACJ Vice-Chair / Otsuka Pharmaceutical Co., Ltd.

OPENING 605+606 9:30-10:00

Opening Address

Hajime Saijo, PhD
DIA Japan

Jack Foster
DIA Global

Haruko Yamamoto, MD, PhD
ACJ Chair / Pharmaceuticals and Medical Devices Agency (PMDA)

Tomiko Tawaragi
Program Chair / RAD-AR Council, Japan

AWARD:

Outstanding Contribution to Health Award
Nobumasa Nakashima, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

Excellence in Service Award
Takashi Sato, MSc, PMP
Kyowa Kirin Co., Ltd.

Leader of Tomorrow Award
Aya Suzuki
Taiho Pharmaceutical Co., Ltd.

BREAK 10:00-10:15

KEYNOTE ADDRESS 605+606 10:15-11:15

COVID-19 so Far and from Now on

Related Interest Area(s): ALL
Level: TBD

SESSION CHAIR

Tomiko Tawaragi
Program Chair / RAD-AR Council, Japan

Speaker
Shigeru Omi
Japan Anti-Tuberculosis Association

PROGRAM CHAIR SESSION 605+606 11:15-12:15

Drug Safety and Patients Engagement

Related Interest Area(s): All
Level: Beginner, Intermediate

SESSION CHAIR

Haruko Yamamoto, MD, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

Drug-safety measures are the most important issue for pharmaceutical products throughout the lifecycle from the development stage. The pharmacovigilance system in Japan has been improved in the wake of phytotoxicity and side effect incidents, and now, under the GVP and RMP, the internal system of pharmaceutical companies is being enhanced and strengthened. In recent years, efforts have been made to promptly introduce innovative drugs that patients have been waiting for into clinical practice, such as the conditional early approval system and emergency approval system. Under these circumstances, post-marketing safety measures are becoming increasingly important. In particular, patient engagement is critical to ensuring patient safety, and each stakeholder is required to cooperate to increase patient engagement in drug-safety measures.

Speaker
Tomiko Tawaragi
Program Chair / RAD-AR Council,Japan

STUDENT SESSION 607+608 9:30-12:15

Designing a Clinical Trial Protocol of Lipid-lowering Agents Based on Disease Characteristics

Related Interest Area(s): Student
Level: TBD
Language: Japanese Language Only

SESSION CHAIR

Kanan Ito
Keio University

Miu Ushiro
Meiji Pharmaceutical University

Yuina Suzuki
Meiji Pharmaceutical University

Chiwa Seki
Keio University

Hyperlipidemia is recognized as a major risk factor for serious cardiovascular diseases, such as myocardial infarction and stroke. It is common in patients with other lifestyle diseases including hypertension and diabetes mellitus, while hyperlipidemia itself does not cause disease-specific symptoms.

This session aims to offer key perspectives on clinical development process in consideration of the disease characteristics, using hyperlipidemia as an example. Through lectures, participants will learn about the basic principles of drug development and common clinical cases of hyperlipidemia, and experience preparing a clinical trial protocol of lipid-lowering agents in group work.

Participants will be expected to consider how to identify important factors and issues in designing clinical trials and how to handle them by engaging in lectures and discussions.

Speaker
Suguru Komenoi
Pharmaceuticals and Medical Devices Agency (PMDA)

LUNCH BREAK 12:15-13:15

LUCHEON SEMINAR 12:25-13:05

SPECIAL SESSION 1 605+606 13:15-14:45

Development and Application of a Vaccine Database for Comparative Assessments in the Post-Authorization Phase : VENUS Study

Related Interest Area(s): CI,OI,PV,ST,MC,PM,RA
Level: Intermediate, Advanced

SESSION CHAIR

Haruko Yamamoto, MD, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

The COVID-19 vaccines were developed and approved in a very short period of time, and vaccination has begun worldwide. As if to keep pace with the speed of development, new findings on the safety and effectiveness of post-approval vaccines have been rapidly generated through large-scale epidemiological studies utilizing various transactional data. In Japan, however, there has been no database that can quantitatively evaluate vaccine safety and effectiveness, and evaluations have centered on conventional post-marketing surveillance and adverse reaction reports.

This presentation will introduce the Vaccine Effectiveness, Networking, and Universal Safety (VENUS) Study, an effort to evaluate the safety and effectiveness of vaccines using a municipality-based database in which various transaction data are linked.

Live Session

Speaker
Chieko Ishiguro, MPH, PhD
National Center for Global Health and Medicine

LS-01 607+608 13:15-14:30

Future Directions Based on Experience Developing Drugs to Treat Novel Coronavirus Infections

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

SESSION CHAIR
Kanji Hirai, RPh
MSD K.K.

Vaccines against the novel coronavirus (COVID-19) have been developed and are playing a major role in preventing the onset of the disease and reducing its severity, while antiviral drugs, neutralizing antibody drugs, and anti-inflammatory drugs have been developed to treat patients with infectious diseases and are contributing to medical care. In the treatment of infectious diseases, it is important to prevent severe disease by providing drug therapy from the early stages of infection, and oral drugs that can be easily administered to patients at home after diagnosis of infectious diseases in outpatient clinics play an important role in this regard.

This session will summarize issues that have emerged from the development, regulatory approval, and post-marketing of oral antiviral drugs for novel coronavirus infections and discuss what companies and governments should consider in the future.

Experience in Oral Antiviral Drug (COVID-19) Development
Hiroko Kawaguchi, RN
MSD K.K.

Development of Paxlovid PACK
Hirofumi Sone, MSc
Pfizer R&D Japan

Response to Early Approval of COVID-19 Drugs
Yuji Arakawa
Ministry of Health, Labour and Welfare (MHLW)

Panel Discussion
All Session Speakers

LS-02 101 13:15-14:30

Quality Control in the E6(R3) Era: What Should the Quality-Control Process Emphasize?

Related Interest Area(s): SS,COM,PM
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Katsuhiko Sawada, Mpharm
Otsuka Medical Device Co. Ltd.

The "quality" that a clinical trial should aim for should not deviate from the "new value" that the product, the original goal of the trial, aims to achieve. However, the reality is that many stakeholders have not yet discussed the quality to aim for, including the goal of realizing products from unmet needs. In this session, companies, CROs, and medical institutions will present and discuss their approaches to the process of realizing true quality by design with an emphasis on critical to quality (CtQ) by defining and sharing with stakeholders the "quality that the trial should aim for" linked to the product development strategy. Companies, CROs, and medical institutions will present and discuss their efforts to achieve true CtQ-oriented quality by design.

Quality control activities for GCP renovation in companies
Satoko Sakai, MS
Idorcia pharmaceuticals japan k.k.

Quality Control Activities for GCP renovation in CROs
Tomonori Abe
Linical Co., Ltd.

Activities for Quality Control Required by the Field
Yuko Kageyama, PhD
The University of Tokyo Hospital, Clinical Research Promotion Center

Panel Discussion
All Session Speakers

LS-03 102 13:15-14:30

Considering Benefit-Risk Assessment in New Drug Applications

Related Interest Area(s): MC,RA,PV,PE
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Mamoru Narukawa, PhD, RPh
Kitasato University Graduate School of Pharmaceutical Sciences

In 2016, the guideline for section 2.5.6 "Benefits and Risks Conclusions" was revised in ICH M4E (R2), and the benefit-risk (BR) of the new drug has been evaluated in CTD 2.5.6. In recent years, patient and public involvement has received greater emphasis, and the draft FDA guidance Benefit-Risk Assessment for New Drug and Biological Products released in September 2021 mentions the importance of incorporating patient experience data into BR evaluation.

This session will focus on the BR assessment in New Drug Applications and discuss how industry, government, and academia should evaluate BR based on cases of approved applications in and outside of Japan.

ICH M4E(R2):Revised Guideline on CTD Section 2.5.6 "Benefits and Risks Conclusions"
Katsuhiko Ichimaru
Pharmaceuticals and Medical Devices Agency (PMDA)

Structured Benefit-Risk for Submission
Yuko Asahara, MSc
Novartis Pharma K.K.

Benefit-Risk Assessment and Communication: Perspective of Academia
Mamoru Narukawa, PhD, RPh
Kitasato University Graduate School of Pharmaceutical Sciences

BREAK 14:30-15:15

AFTERNOON SEMINAR 14:55-15:10

LS-04 605+606 15:15-16:30

Present and Future of Risk-Based Approaches in Clinical Trial Operations

Related Interest Area(s): CDM,COM
Level: Beginner, Intermediate

SESSION CHAIR
Toshiharu Sano, RPh
MSD K.K.

Risk-based approaches consist of "quality management" described in ICH E6 (R2), ICH E8 (Quality by Design), and ALCOA . In this session, a data manager, a central monitor, and a study site person will discuss risk-based approaches, and future challenges, in clinical trial operations

RBA in Data Management – Evolution or Revolution?
Paulina Szczepaniak, MS
MSD Poland

Current Status and Future Challenges of RBA in Site Monitoring
Yukihiro Matsuda, MSc, PMP
PRA Health Sciences, K.K.

Current Status and Challenges of RBA Initiatives at Clinical Trial Sites
Satoshi Kuroda, MS
Okayama University Hospital

LS-05 607+608 15:15-16:30

Social Entrepreneurial Role of Academic Research and Development

Related Interest Area(s): AC,CDM,CI,OI,PE,PM,ST
Level: Beginner, Intermediate

SESSION CHAIR
Ayae Kinoshita, MD, PhD
Kyoto University Graduate School of Medicine

A physician is often the very last person who engages in the treatment of patients with dementia. While they could visit physicians at the pre-onset stage, a variety of other treatment options are also available. A physician-scientist from Kyoto University is now focusing on PHRs related to IADLs to support elderly people before they present obvious symptoms of dementia, with the vision of improving the social side of the quality of life of elderly people before they develop dementia. As part of the medical innovation ecosystem in the US, venture-backed start-ups play pivotal roles in translational research to clinical research. The SPARK program at Stanford University has started to support basic- and physician-scientists to learn and conduct translational research from the academic side.

This session also provides topics to discuss CSTI's ongoing promotion of VC investment in Japan, including tax reform, in order to build a start-up ecosystem.

Towards a Dementia Inclusive Society
Ayae Kinoshita, MD, PhD
Kyoto University Graduate School of Medicine

Strategic Design of Academic Research Organization
Hiroyuki Nishimoto, PhD
Kochi University

SPARK as a platform to accelerate open innovations through startups
Tomoyoshi Koyanagi, PhD
iACT, Kyoto University Hospital

Panel Discussion
All Session Speakers

LS-06 101 15:15-16:30

Challenge of Total Healthcare from Inside and Outside the Medical Industry

Related Interest Area(s): Others,CI,All
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Akiko Nishioka
Novartis Pharma K.K.

Previously, pharmaceutical companies have mainly prioritized treatment, but their scope has expanded to "Total Health Care" such as disease prevention and long-term care. In addition, various industries are working to provide new healthcare services and systems. In view of this situation, it is conceivable that young people and students who aspire to work in the medical industry will have various career options other than the conventional pharmaceutical industry.

In this session, we invite young people who have multiple experiences such as drug development, healthcare services, and medical system creation to share the opportunities they engaged in the new industries, the differences from drug development work, and their challenges, giving us all an opportunity to think about our future career options.

Clinical Developer can Live along Business
Takashi Yokoyama, Master of Engineering
e-solutions, inc.

Is Career Consistency Necessary?
Taisei Matsumoto, Master of Pharmacy
Pfizer R&D Japan G.K.

Career Design in the Diverse World
Ami Okubo
FUJIFILM Holdings Corporation

Panel Discussion
All Session Speakers and
Mengyan Deng
Eisai Co., Ltd.

LS-07 102 15:15-16:30

Beyond Value Conflicts to Social Co-Creation

Related Interest Area(s): PM,PE,OI,All
Level: Intermediate, Advanced
Language: Japanese Language Only

SESSION CHAIR
Yu Komura
National Cancer Center Hospital East

We live in an era in which it sometimes seems so difficult to accept different values that "diversity and inclusion" have become keywords. In this age of diverse values complexity, and rapid pace, there is no right or wrong "answer" to any value. What is needed is not to unify values but to loosely link them, and the diverse values associated with complex and intertwined positions should be exchanged and resonate with each other in "open dialogue." So: What is the ideal society beyond "delivering treatment to future patients?" Where are we headed? We will have a fireside chat as individuals to discuss the better society that should be co-created by those in industry, government, academia, and patients.

What is "Social Co-Creation" for Medical R&D? -As a Member Involved in the Set up of AMED "Social Co-Creation"
Keiko Katsui, PhD
Japan Agency for Medical Research and Development (AMED)

Values We Value –from the Industry Stand Point
Michiyo Ohshima, BS, MBA
Pfizer R&D Japan G.K.

Values We Value –from the Clinical Trial Coordinator Stand Point
Yukie Kimura
National Cancer Center Hospital East

Values We Value –from the Patient and Public Stand Point
Shinsuke Amano
Japan Federation of Cancer Patient Groups

Panel Discussion
All Session Speakers

BREAK 16:30-17:00

LS-08 605+606 17:00-18:15

How RWE Affects Decision Making During the COVID-19 Pandemic

Related Interest Area(s): AC,BE,CDM,MA,PV,MC
Level: Beginner, Intermediate

SESSION CHAIR
Yoshiaki Uyama, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

In the last few years, the development of COVID-19 vaccines and therapeutics has become active all over the world, not only to supply effective drugs into patient medical settings faster, but also to use RWE for analyses after supply. The need for pharmacovigilance and rapid evaluation increases. Last year's DIA Japan Annual Meeting shared each region's way of thinking under the session title Guiding RWE Utilization for Regulatory Decision Making in US, EU, and Japan. This year, we would like to deepen the understanding of what types of real-world evidence were available and used for decision making by regulatory authorities based on concrete examples, and discuss the impact on future pharmacovigilance.

Monitoring the Safety of Medicines During the COVID-19 Pandemic
Gerald Dal Pan, MD, MHS
Food and Drug Administration (FDA)

Analysis of Thrombosis with Thrombocytopenia Syndrome and Myocarditis
Maria Gordillo-Maranon
European Medicines Agency (EMA)

Safety monitoring of COVID-19 vaccines in Japan
Chieko Ishiguro, MPH, PhD
National Center for Global Health and Medicine

Panel Discussion
All Session Speakers and
Toyotaka Iguchi, MD, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

LS-09 607+608 17:00-18:15

Innovative and Dynamic Statistical Analytics for Regulatory Submissions

Related Interest Area(s): CI,OI,RA,ST
Level: Beginner, Intermediate

SESSION CHAIR
Yuichi Nakajima, MS
Novartis Pharma K.K.

Innovative analytics begins with a flexible infrastructure that enables tools and practices to continually improve the quality required for human research and public health decision-making. A foundational framework designed for accuracy, reproducibility, and traceability increases health authorities' confidence in the use of innovative analytics and technical efficiencies. Opportunity exists to provide clarity and instill confidence in the use of modern software technologies, including those that generate outputs for regulatory submission. Such discussion and efforts will inspire more dynamic and modernized analyses, potentially reducing delivery time of innovative products to patients. The submission process to health authorities varies across the globe.

This session will share insights from case studies of increasing complexity; organizational and technical challenges; outcomes of health authority interactions on MSA Framework programs; and evolving trends, including open-source software for the biopharmaceutical industry.

Modernization of Statistical Analytics: Framework and case studies
Isao Tsumiyama, Master
Novartis Pharma K.K.

Effective Open Source Package Management
Ippei Akiya, Msci
A2 Healthcare Corp.

Innovative and Dynamic Statistical Analysis for Regulatory Submissions
Tadeusz Lewandowski
F. Hoffmann-La Roche AG

Utilization of innovative statistical analytics for regulatory submission: PMDA perspective
Yuki Ando, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

LS-10 101 17:00-18:15

Introduction of activities to promote the use of data in clinical trials and clinical research and associated ethical issues

Related Interest Area(s): BE,AC,MA,PE,CI,MC
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Kotone Matsuyama, RPh
Nippon Medical School

In clinical trials, new initiatives such as data sharing to utilize existing data have recently been initiated both in Japan and overseas. At the same time, ethical issues related to the protection of human subjects and the handling of data, which could not be expected in conventional clinical trials and clinical research, have arisen. What new issues are arising and how should they be resolved? What kind of governance should be implemented in terms of compliance with the revised Personal Information Protection Law and overseas data protection laws and regulations?

This session will overview the ethical issues faced in clinical development and pharmaceutical medicine and discuss how to resolve these issues.

Ethical Issues and International Current Status Regarding Blanket Cnsent
Chieko Kurihara
Kanagawa Dental College

Legal Considerations on Data Utilization Promotion and Personal Information Protection
Mariko Mimura
Nishimura & Asahi

Promoting Data Sharing and Addressing Personal Information Protection in Data Utilization and Its Challenges
Tomoko Kato
Sanofi K.K. / Japan Pharmaceutical Manufacturers Association (JPMA)

Panel Discussion
All Session Speakers

LS-11 102 17:00-18:15

Model-Informed Drug Development: Application of MIDD to the Development of Novel Drugs for Treatment of COVID-19 Has Changed the World

Related Interest Area(s): All
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
So Miyoshi, PhD
Pfizer R&D Japan

Model-Informed Drug Development (MIDD), selected as an ICH M15 topic, caused a paradigm shift in clinical development. MIDD increased the success rate of clinical trials, avoided conduct of unnecessary clinical studies, and shortened the period of clinical development. Introducing the state-of-the-art MIDD in clinical development of a novel orally administered drug for the treatment of COVID-19, this session discusses how to implement MIDD, corroboration between quantitative scientists (pharmacometricians, clinical pharmacologists, statisticians, clinicians, etc.), regulatory colleagues and project managers in a cooperative framework, and smooth communication between academia and regulatory agencies. Application of MIDD and pharmacometrics in clinical practice will also be discussed.

State of the art MIDD in Clinical Development -PAXLOVID® PACK-
Akiyuki Suzuki, PhD
Pfizer R&D Japan

Application and Expectations of MIDD / Pharmacometrics in cCinical Practice
Tsuyoshi Shiga, MD, PhD
The Jikei University School of Medicine

Utilization of MIDD and Activities of PMDA
Daisuke Iwata
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Atsunori Kaibara, PhD
Eli Lilly Japan K.K.
Hiroko Tabuchi, PhD
ssg medical Inc.

BREAK **18:15-18:30**

YOUNG PROFESSIONALS EXCHANGE AND NETWORKING SESSION
1F Reception Hall **18:30-20:00**

POSTER SESSIONS **1F Foyer** **18:45-19:45**

LIVE SESSION

LS-12 605+606 9:00-10:15

12 Initiatives in 4 Priority Areas of DTRA for Accelerating Adoption of DCTs

Related Interest Area(s): All
Level: Intermediate, Advanced

SESSION CHAIR

Shuji Ozawa
CMIC Co, Ltd

Established in December 2020, the Decentralized Trials & Research Alliance (DTRA) enables collaboration of stakeholders to accelerate adoption of patient-focused, decentralized clinical trials (DCTs) and research within life sciences and healthcare through education and research. DTRA's vision is to make research participation accessible to everyone, enabled by the consistent, widespread adoption of appropriate decentralized research methods. DTRA now consists of more than 100 member companies and more than 200 individual leaders, and is working on 12 initiatives in 4 priority areas toward the worldwide spread of DCTs. Adoption of DCTs in Japan is being widely discussed, and while efforts are being promoted from the standpoints of industry, government, and academia, opportunities to directly access the situation in the US, which is hoping to lead this adoption, are limited. DTRA Co-Chairs Amir Kalali and Craig Lipset and other DTRA core members will share DTRA's initiatives, the latest situation on DCTs, and expectations for DCTs and how to accelerate adoption in Japan.

Decentralized Trial Collaboration: Introduction
Amir Kalali, MD
Decentralized Trials and Research Alliance (DTRA)

Decentralized Trial Collaboration Initiatives: Part 1
Jane Myles
Curebase, Inc.

Decentralized Trial Collaboration Initiatives: Part 2
Craig H Lipset, MPH
Decentralized Trials and Research Alliance (DTRA)

Panel Discussion
All Session Speakers and
Kenichi Nakamura, MD, PhD, MBA
National Cancer Center Hospital

LS-13 608 9:00-10:15

Transformation of Regulatory Interaction: Challenge by Accumulus Synergy 2022

Related Interest Area(s): RA
Level: Intermediate

SESSION CHAIR

Takayuki Imaeda, MS
Pfizer R&D Japan

In the US and Europe, it has been proposed that pharmaceutical companies submit data for regulatory submissions to a common cloud system in order to streamline drug development on a global scale, increase transparency, and allow countries to make decisions quickly. To promote this goal, ten pharmaceutical companies (Amgen, Astellas, Bristol Myers Squibb, GSK, Janssen, Lilly, Pfizer,Roche,Sanofi, and Takeda) jointly established Accumulus Synergy; AstraZeneca later joined in. The cloud-based platform built by Accumulus Synergy is expected to allow pharmaceutical companies to share data and information, facilitate the evaluation of data and information by regulatory authorities in various countries, and ultimately facilitate access to innovative medicines for patients.

This session will outline the activities of Accumulus Synergy, the current status regarding collaborative review and submission and CMC data sharing to regulatory authorities, and related updates from Japan.

Transformation of Regulatory Interaction: Challenge by Accumulus Synergy 2022
Francisco Nogueira, MBA
Accumulus Synergy

Introduction of Current Status: Accumulus Synergy
Dominique LaGrave, Pharm D
IRISS.

Use Cases: From Vision to Reality
Michael Abernathy, MS, Cellular and Molecular Biology, RAPS Regulatory Affairs Certified (RAC)
Amgen Inc.

Panel Discussion
All Session Speakers and
Shinobu Uzu, MSc
Pharmaceuticals and Medical Devices Agency (PMDA)
Yuji Kashitani
Takeda Pharmaceutical Company Limited

LS-14 607 9:00-10:15

How to Use an Agile Approach to Drive Innovation

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

SESSION CHAIR

Satoru Tsuchiya
Sumitomo Pharma Co., Ltd.

Agile ways of working and thinking are gaining attention, since it has become extremely difficult to predict the future in what some people call the new VUCA (volatility, uncertainty, complexity, and ambiguity). Agile methods were originally utilized in the IT field, but in recent years their application has spread to other fields, and business terms such as "agile mindset" and "agile management" are now commonly used.

This session will provide an overview of agile methodology and examples of various methods applied to organizational management. Panel discussion will examine the relationship between agile project management systems used in drug development and how agile ways of working can be incorporated into business operations.

Dose Agile Development Dream of Changing the World? Make Your Organization Agile from the Core
Toshihiro Ichitani
Red Journey inc.

Challenge to Agile Work Style
Hidekazu Sugawara
Sumitomo Pharma Co., Ltd.

Providing Maximum Value to Patients and Customers - Agile in the Pharmaceutical Industry -
Mika Mochizuki, MBA
MSD K.K.

Panel Discussion
All Session Speakers and
Yasuo Fukushima, PhD, MBA
Daiichi Sankyo Inc.

LS-15 101 9:00-10:15

What is So Curious about eConsent? Deep Dive into Fundamental Values!

Related Interest Area(s): CI,COM,PE
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Tomohiko Takahashi, Mecc
Otsuka Pharmaceutical Co., Ltd.

In recent years, eConsent/Remote Consent (electronic/remote informed consent) has been attracting attention due to the increasing trend toward electronization of clinical trials and patient centricity. The advantages of eConsent generally include improving subjects' understanding for clinical trials and reducing dropout rates. However, the actual effects of eConsent have not yet been clarified, partly because there are only a few examples of its introduction in Japan. In addition, considering the meaning of "e-" (electronization), there are various possibilities, including remote processes, but these have not yet been fully discussed.

This session will consider the essential value of eConsent and how it can be used to maximize its value from the standpoints of service providers, sites, and pharmaceutical companies.

Industry Trend of eConsent in Clinical Trials
Takuma Matsunaga
MICIN, Inc.

The Site Landscape: State of the eConsent
Hiroka Ukita
EP-SOGO Co., Ltd

Potential of eConsent in the Future ~Maximize the Value of eConsent~
Akira Asano, ME
Mitsubishi Tanabe Pharma Corporation

Panel Discussion
All Session Speakers

LS-16 102 9:00-10:15

Current Situation and Issues for Conducting Outcome Validation Study Prior to Post-Marketing Database Study

Related Interest Area(s): AC,PV,RA
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Naoki Nakashima, MD, PhD
Kyushu University Hospital

According to the revised Good Post-Marketing Study Practices (GPSP), a post-marketing database study is planned, and an outcome validation study is required prior to conducting the post-marketing database study. While only a few validation studies have been conducted in Japan, the issues we have observed through our experiences will be shared by representatives of a pharmaceutical company, US academia, and PMDA, to discuss efficient planning and operation of validation studies in the future.

Current Situation and Issues for Validation Study Conducted Prior to the Post-Marketing Database Study (From Experience of Pharmaceutical Company)
Mari Matsui
Pfizer R&D Japan G.K.

Current Situation and Issues for Validation Study in Japan (From Experience of Academia in US)
Soko Setoguchi, MD, DPh
Rutgers Robert Wood Johnson Medical School

PMDA's Experience in Outcome Validation Studies using MID-NET®
Hotaka Maruyama
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

BREAK 10:15-10:30

LS-17 605+606 10:30-11:45

Assuring Quality: Digital Health Technologies for Remote Data Acquisition in Clinical Trials

Related Interest Area(s): CDM,COM,RA,CI
Level: Intermediate, Advanced

SESSION CHAIR
Kiyomi Hirayama, PhD
MSD K.K.

Clinical trials in which endpoints are remotely collected from digital health technologies such as wearable devices have been increasing in recent years and are expected to increase further. The US FDA issued draft guidance in December 2021 on how to assure the reliability of such data, but no guidance has yet taken effect in Japan, and there has not yet been sufficient discussion about such guidance. If the reliability of this electronic data cannot be confirmed, the reliability of the study results cannot be ensured, an important issue that may affect regulatory approval.

This session will introduce the current status of remote data acquisition using digital health technologies in clinical trials.

Current Status and Issues of Digital Biomarkers in Drug Development
Norihiro Kawabata
Chugai Pharmaceutical Co., Ltd. / Drug Evaluation Committee, JPMA

FDA Draft Guidance "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations"
Natalia Remmel, PhD, RAC
MRL GRACS (Merck Research Laboratories, Global Regulatory Affairs and Clinical Safety)

Digital Measures Enabled by Wearables: Path Forward to Regulatory Accepted Endpoints
Christine Guo, PhD
Actigraph

Panel Discussion
All Session Speakers and
Yuji Matsukura
Ministry of Health, Labour and Welfare (MHLW)

LS-18 608 10:30-11:45

Accelerating Pharmaceutical Approval through Asian International Collaborative Trials

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

SESSION CHAIR
Kenichi Nakamura, MD, PhD, MBA
National Cancer Center Hospital

As clinical trials become more and more complicated due to advances in genomic medicine, time and budget consuming strategies are needed. Instead of relying on Wester data evidence, especially for those cancer types that are common in Asia, bringing Asian countries together to form a new network for clinical trials is crucial.

This session will discuss drug development throughout the Asian network as well as new clinical trial methods such as decentralized clinical trials.

Building an Asian Network for Drug Development Through the Eyes of an Academic Research Organization
Hitomi Okuma, MD, PhD
National Cancer Center Hospital

Significance and Future Perspective of Drug Development in Asia by Pharmaceutical Copmpanies
Takashi Owa, PhD
Eisai Co., Ltd.

Practices to Resolve Issues in Clinical Development for Success in NDAs in Asia
Tomoko Eguchi, MSc
Remedy & Company Corporation

Panel Discussion
All Session Speakers and
Yasuto Otsubo, MS
Pharmaceuticals and Medical Devices Agency (PMDA)

LS-19 607 10:30-11:45

Agile Drug Development in the Rapidly Evolving R&D Environment

Related Interest Area(s): PM
Level: Intermediate, Advanced
Language: Japanese Language Only

SESSION CHAIR
Yasuo Fukushima, PhD, MBA
Daiichi Sankyo Inc.

To respond quickly and successfully to rapid changes in the new normal caused by COVID-19, creativity and innovation are becoming even more important, and agile approaches are gaining attention in a wide range of industries. We will discuss the significance of changing the mindset and working style to an agile approach, using examples such as Astellas Pharma's approach to transforming its research organization to an agile organization, and the implementation of business agility which contributed to the development of Pfizer's COVID-19 vaccine in unprecedented time during the pandemic while the external environment was changing frequently.

Aim of Transforming to Agile Research Organization
Yuichiro Sato, PhD
Astellas Pharma Inc.

Agile approach in Portfolio and Project Management
Chihiro Saito, RPh
Pfizer R&D Japan

Panel Discussion
All Session Speakers and
Satoshi Suzuki, BS
Pfizer R&D Japan

LS-20 101 10:30-11:45

Open Innovation in Drug Development in Japan: Preparations, Challenges, and Practices from Normal Times

Related Interest Area(s): AC,OI
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR
Makoto Nagaoka, PhD
BeiGene Japan

The importance of open innovation in drug development has long been recognized in Japan. However, compared to current situations in Europe, the US, and China, there are issues in terms of systems, human resources, and funding, and it is hard to say that open innovation is fully functioning as an ecosystem in Japan. This situation was apparent during the COVID-19 pandemic. As a countermeasure, in addition to regulatory measures that improve approval systems, it is essential to establish and use a consistent ecosystem including commercialization and business plan which ranges from discovery research to manufacturing and sales.

This session will clarify the current situation and issues regarding these points, and discuss what we should put into practice from the industry, government, and academic perspectives.

Comparison of Drug Development in Academia and Drug Discovery Biotechs in Japan and Overseas
Kotone Matsuyama, PhD
Nippon Medical School

How Academia-Launched Ventures Collaborate with Foreign Companies?
Keiichi Fukuda, MD, PhD
Graduate School of Medicine, Keio University.

Open Innovation in Japanese Drug Development:Preparing for Peacetime, Challenges, and Practices
Noriatsu Kono
Pharmaceuticals and Medical Devices Agency (PMDA)

Multi-channel Open Innovation to Brig Japanese Seeds to Global R/D
Lei Liu
AstraZeneca plc

LS-21 102 10:30-11:45

Applying Additional PV Effectively in Risk Management in Japan

Related Interest Area(s): PV
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR
Yumiko Suzuki, PhD
Pfizer R&D Japan

With the Good Post-Marketing Study Practices (GPSP) revision in April 2018 in Japan, comparative drug use investigations and post-marketing database (DB) studies have been added as PMS methods, making it possible to use various methods of PMS according to research questions. However, even after the revised GPSP, many conventional PMS are still aiming to assess overall safety. On the other hand, the EU and US precede Japan in utilization of medical information databases as well as registries for PV.

This session will present the results of investigation and analysis on these additional PV practices in the EU and US including their trends, their impact on risk management, and the utilization status of medical information DBs; basedon that information, we will discuss the direction that PMS should aim for in Japan.

Analysis of Risk Management Plans for Recently Approved Drugs in EU
Ryo Nakajima, MS
AbbVie GK

Analysis of the Impact of PASS Results on Risk Management
Tetsuya Kanayama, MSc
Novartis Pharma K.K.

Analysis of US Sentinel/ARIA Utilization and PMR
Masashi Katsuura, MS
Pfizer R&D Japan

Panel Discussion
All Session Speakers and
Mamoru Narukawa, PhD, RPh
Kitasato University Graduate School of Pharmaceutical Sciences
Toyotaka Iguchi, MD, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

LUNCH BREAK 11:45-12:45

LUCHEON SEMINAR 11:55-12:35

SPECIAL SESSION 2 605+606 12:45-14:15

Utilizing Data Obtained through Specific Clinical Trials for Pharmaceutical Approval Applications

Related Interest Area(s): AC,MA,MC,RA,COM
Level: Beginner, Intermediate

SESSION CHAIR

Takuhiro Yamaguchi, PhD
Tohoku University Graduate School of Medicine

Koji Iwasaki, PhD
Osaka University Hospital

The Clinical Trial Act (CTA), which was established over five years ago, includes a provision "to promptly consider a mechanism to utilize information obtained from specified clinical trial (SCT) as materials for applications for approval of drugs and medical devices." The concerns raised at the time of the CTA's passage about ensuring the reliability of data, etc., have now largely stabilized, and there have been improvements in clinical trial support functions and the quality of examinations. This year, the administrative communication Points to Consider and Ideas for Using Study Results Obtained from SCT in Applications for Approval of Drugs" was issued, but it shows only some examples from the current situation.

Thisis session will discuss the utilization of data obtained from SCT for application for approval from a wide range of perspectives in government, academia, and industry.

Utilization of the Results of Specified Clinical Research in Regulatory Processes
Yasunori Yoshida
Ministry of Health, Labour and Welfare (MHLW)

Utilization of Data Obtained through Specified Clinical Trials for Pharmaceutical Approval Applications (2)
Yasuhiro Fujiwara, MD, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

Utilization of Specified Clinical Trials from Academic viewpoint.
Kenichi NAKAMURA, MD, PhD, MBA
National Cancer Center Hospital

Potential Use of Specific Clinical Studies for Regulatory Applications from the Pharmaceutical Industry's Perspective
Mitsuaki Aoyagi
Japan Pharmaceutical Manufacturers Association (Eisai Co., Ltd.)

Panel Discussion
All Session Speakers and
Yukiko Matsushima
Keio University Hospital
Yumi Tanaka
University of Tokyo Hospital

LS-22 608 12:45-14:00

Using Real-World Data Based on the Next-Generation Medical Infrastructure Act

Related Interest Area(s): AC,CI
Level: Beginner, Intermediate

SESSION CHAIR

Hiroyuki Yoshihara, MD
Kyoto University / University of Miyazaki Hospital

The Next-Generation Medical Infrastructure Act came into effect in 2018, enabling certified providers to collect medical information including outcomes and real-world data (RWD) from multiple medical institutions, etc., according to the research and development needs of users. This session will discuss the possibilities and challenges of utilizing RWD based on the Next-Generation Medical Infrastructure Act especially in outcomes research, the overall picture of the Act, use cases of RWD utilization, features and use cases of anonymously processed medical information, and the possibility of generating outcomes from electronic medical records using AI. In addition, the possibility of further utilization of RWD based on the Next-Generation Medical Infrastructure Act, the future vision to be aimed for, and actions toward its realization will be discussed.

Over View of the Next-Generation Medical Infrastructure Act and Secondary Use of Data Based on the Act
Kenji Araki, MD
Life Data Initiative

Use Case of RWD based on the Next-Generation Medical Infrastructure Act
Kanae Togo, PhD
Pfizer Japan

Features and Use Cases of Anonymized Medical Data Based on the Next-Generation Medical Infrastructure Act Such as AI Model Development
Yoshiyuki Hasegawa, MSc, MBA
NTT DATA Corporation

Panel Discussion
All Session Speakers

LS-23 607 12:45-14:00

Next-Generation Digital Healthcare Considering Pre-Symptomatic State, Prevention, and Well-Being (Part 1)

Related Interest Area(s): TBD
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR

Yoshito Nakanishi
CHUGAI PHARMACEUTICAL CO., LTD

"Next-Generation Digital Healthcare" is being used as a growth strategy in Japan, and the actions for treatment, the pre-symptomatic state, prevention, and well-being during the course of each person's life are being considered. Similar actions were mentioned in "Healthcare III in Society 5.0 era" issued by KEIDANREN . We will need to move forward strategically with digital transformation in the healthcare area to ensure execution of these actions.

This second part of this two-part session will discuss digital therapeutics (DTx), a digital program for treatment which is used by patients under the instruction of doctors and is expected to contribute greatly to patient care, in the treatment phase. The status or future direction of DTx will also be discussed.

Toward the Diffusion of Digital Therapeutics (DTx) in Japan
Taketo Yamamoto
The Japan Research Institute, Limited

Current state of development in startups and characteristics of AI
Sho Okiyama
Aillis, Inc.

Company Initiatives for Digital Therapeutics
Yosuke Miharu
SHIONOGI & CO., LTD.

Panel Discussion
All Session Speakers

LS-24 101 12:45-14:00

Novel Strategy of Clinical Pharmacology in Global Clinical Development: Contribution to Worldwide Simultaneous NDA Submission and Approval

Related Interest Area(s): All
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR

Yuji Kumagai, MD, PhD
Kitasato University

Clinical pharmacology is an essential science to determine optimal dosage and administration of a drug. Under ICH E17, when the country/region and race/ethnicity that should be involved in a clinical trial are considered, investigation based on an effect-modifier, which influences the outcome of efficacy and safety in a clinical study, is necessary. Clinical pharmacology strongly contributes to exploring and investigating this effect-modifier. As internationalization of clinical development progresses, a united clinical pharmacology strategy which can be suitable to every country is required. The importance of a scientifically reasonable strategy of clinical pharmacology in clinical development, including the timing of Asian phase 1 and clinical pharmacology studies, will be discussed among industry, academia, and regulatory agencies.

Impact That can be Made by Clinical Pharmacology in Development of Novel Drug
Naoki Kotani, PhD
Chugai Pharmaceutical Co., Ltd.

Effective Contribution of Clinical Pharmacology Studies in Global Clinical Development
Kei Fukuhara, MSc
Pfizer R&D Japan

Contribution of Academia in Global Drug Development
Naoki Uchida, MD, PhD
Showa University

Panel Discussion
All Session Speakers and
Akihiro Ishiguro, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

LS-25 102 12:45-14:00

Digital Transformation of Drug Information: Current Utilization Situation and Challenges in Japan

Related Interest Area(s): MC,PV
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Mayumi Mochizuki, PhD
Keio University

As of 2021, the package insert is no longer included in the product and is available on the internet. However, from the perspective of data utilization in the digital transformation (DX) era, the true digitization of drug information is still a long way off, and many issues remain in the effective utilization of mutual cooperation in the flow from content creation to provision.

This session will discuss the latest information on the status of integration and cooperation by data structuring of drug information including package inserts, interview forms, and CTD. We will also summarize and discuss the current status and issues of the utilization of drug information in the J DX era in Japan, including the perspectives of PMDA and pharmaceutical companies.

Utilization of Digital Drug Information Tools in Hospital
Susumu Wakabayashi
Kyorin University Hospital

Structurization of Interview Forms and Effectvie Use of Pharmaceutical Documents
Chioko Nagao, PhD.
Osaka University

Digitization and Utilization Initiatives of "CTD-Package Insert-IF"
Rika Okamoto, PhD
Kyoto University / Foundation for Biomedical Reseaarch and Innovation at Kobe

Panel Discussion
All Session Speakers and
Yasunori Tajima
Pharmaceuticals and Medical Devices Agency (PMDA)
Seiki Yamazaki
Pfizer Japan Inc.

BREAK 14:00-14:30

SPECIAL SESSION 3 605+606 14:30-16:00

Preparing for the Next Pandemic and Improving Public and Patient Understanding of Product Information: 2030 at the Global Level and What to Think Now

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

SESSION CHAIR

Rie Matsui, RPh
Pfizer R&D Japan G.K.

Junko Sato, PhD
Pharmaceuticals and Medical Devices Agency (PMDA) *planned

Since the speed of new coronavirus infections spread was not sufficient with measures taken by each country, the importance of international cooperation was emphasized and international cooperation between regulatory authorities has dramatically improved. Companies have also improved innovative technologies in drug development, and a mechanism of delivering medicines more quickly has been put into place with the cooperation of regulatory authorities. On the other hand, has the public and patient understanding of vaccines and medicines improved? With the use of the internet and social media, information can be easily obtained across national boundaries. However, it is difficult to verify whether the correct information is obtained. Although there are differences in the medical environment in each region, it is important to improve the public and patient understanding of product information around the world and a shortcut to improve public health is to work together.

In this session, we will share efforts to improve understanding of drug information in the US and current state of the public and patient understanding from Japanese healthcare professionals' perspective. Furthermore, considering the situation in Asia in preparation for the next pandemic toward 2030, we will discuss what we should think now at the global level in order to improve the public and patient understanding of drug information.

Information on Medication Safety During the COVI-19 Pandemic
Gerald Dal Pan, MD, MHS
Food and Drug Administration (FDA)

Current Status on Patient-Centric Product Information in ASEAN Countries
Tse Siang Kang, PhD
Pfizer Singapore

Innovations and Difficulties in Making Patients Understand the Proper Use of Drugs in Healthcare Facilities
Yoshihiro Aoyagi, MS
National Cancer Center Hospital East

Panel Discussion
All Session Speakers and
E. Stewart Geary
Eisai Co., Ltd.

LS-26 608 14:30-15:45

Digital Therapeutics: Strategy as SaMD (Software as a Medical Device) and Non-SaMD

Related Interest Area(s): CI
Level: Intermediate, Advanced

SESSION CHAIR

Kensuke Ishii, PhD

Pharmaceuticals and Medical Devices Agency (PMDA) *planned

Interest in digital health has been growing in Japan in recent years, and the government has high expectations for Software as a Medical Device (SaMD). Digital Therapeutics (DTx) differ significantly from conventional medical devices from development to post-marketing stage due to their characteristics. In addition to these DTx, which require regulatory approval, many non-medical devices (e.g., healthcare products) are also on the market.

This session, focusing on these DTx, will discuss and clarify the advantages and disadvantages of medical and non-medical device options and strategies to bring value to patients more effectively, as well as more effective and sustainable DTx development and utilization for developers.

Digital Therapeutics: Development and Marketing as Software as a Medical Device

Tomoyuki Tanigawa, MD, MPH

CureApp, Inc.

Digital Therapeutics: Utilize SaMD (Software as a Medical Device) and non-SaMD

Shunichiro Nagumo, MSc

The Japan Research Institute, Limited

Digital Therapeutics: The Use of SaMD (Software as a Medical Device) and Non-SaMD from Clinical Perspective

Akihiro Nomura, MD, PhD

Kanazawa University Hospital

Panel Discussion

All Session Speakers and

Jiro Amatatsu, BA

asken Inc.

LS-27 607 14:30-15:45

Data-Driven Decision Making Using Big Data and Predictive Analytics

Related Interest Area(s): ST,CI,PM,MA,RA,PV
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR

Satoru Fukimbara, PhD

Ono Pharmaceutical Co., LTD.

In the pharmaceutical industry, the enormous time and cost required for drug development has been a concern. In order to improve the efficiency of drug development, the utilization of big data such as RWD in healthcare and historical clinical study data has been accelerated. This is supported by the establishment of platforms that enable centralized management and analysis of big data, as well as the active participation of data scientists who support decision makers using predictive analysis that takes into account uncertainties while building on various knowledge bases such as business, IT, and statistics.

This session will introduce examples of using big data in various situations in the drug lifecycle including post-marketing, followed by panel discussion of further utilization of big data and future prospects.

Predicting Subgroup Treatment Effects for a New Study

Shuhei Kaneko, PhD

Novartis Pharma K.K.

Disease Prediction Model and Social Implementation

Nobutomo Matsui

IQVIA Solutions Japan K.K.

Enterprise Insights by Data, Analytics and Modeling in Pharmaceuticals

Masanori Ito, PhD

Astellas Pharma Inc.

AI Leverage Use Case for Hospital Call Plan Scheduling Optimization

Yasuhiro Miki, MHSc

Eli Lilly Japan K.K

Panel Discussion

All Session Speakers

LS-28 101 14:30-15:45

Discussion with Patients about Rare Disease Drug Development to Improve Drug Lag in Japan

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

SESSION CHAIR

Harumasa Nakamura, MD, PhD

National Center of Neurology and Psychiatry

Multinational development has become the norm, shortening drug lags. However, development of drugs for rare diseases in Japan is sometimes delayed, especially for drugs developed by overseas bioventures. What is needed to deliver drugs from overseas to Japanese patients without a significant delay? Is it really necessary to conduct clinical trials with a small number of Japanese patients? On the other hand, is foreign evidence acceptable to patients and/or physicians? To date, these discussions have mostly been from the standpoints of health authorities and companies. We should also begin to include patients, their families, and the medical professionals who are close to them in these discussions, expecially in the context of rare disease.

Challenges and Prospects for Drug Development of Rare Diseases

Mihoko Kobayashi

Pfizer R&D Japan

My Three Years Experience of Clinical Development of Rare Disease drugs in Japan

Atsushi Nishizawa, PhD

Takeda Pharmaceutical Company Limited

Development of Drugs for Rare Diseases; Regulatory Perspective

Kosuke Ito, PhD

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers and

Tomoaki Shinohara

KOINOBORI Associate Inc.

LS-29 102 14:30-15:45

Has RMP Changed Post-Marketing Safety Management in Japan in the 10 Years Since it Started?

Related Interest Area(s): CP,MA,MC
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR

Mamoru Narukawa, PhD, RPh

Kitasato University Graduate School of Pharmaceutical Sciences

ICH E2E (Pharmacovigilance Planning), which became Step 5 in 2005, was implemented as a system according to the RMP guidelines issued in 2012 in response to the so-called hepatitis proposal in 2010. In 2013, it became mandatory to submit it as part of the application materials as CTD M1.11 at the time of application. Approximately 10 years have passed since its implementation, more than 500 RMPs have been published on the PMDA website, and utilization of RMPs in medical institutions is gradually progressing. On the other hand, it is rare for an RMP to be reviewed after approval is obtained until reexamination, and it cannot be said that the purpose of ICH E2E, which is to predetermine and proactively manage

DIAmond Session 1

serious risks, has been achieved.

This session will look back on the 10 years that RMP has been implemented from the perspectives of industries, medical institutions, and regulatory agencies, and reconsider the necessity of RMP and whether RMP has changed post-marketing safety management in Japan.

Necessity and Challenges of RMP from the Perspective of Industries
Shinya Takemoto, MSc, MBA
Japan Pharmaceutical Manufacturers Association (JPMA)
Drug Evaluation Committee Pharmacovigilance Expert Committee KT-1 / Chugai Pharmaceutical. Co. Ltd.

Necessity and Challenges of RMP from the Perspective of Healthcare Providers
Masahiro Hayashi, PhD
Toranomon Hospital

Necessity and Challenges of RMP from the Perspective of Regulatory Affairs
Eiji Saito
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

BREAK **15:45-16:30**

AFTERNOON SEMINAR **16:10-16:25**

DIAmond SESSIONS

DIAMOND SESSION 1 **605+606** **16:30-18:00**

Power of Information - Change in Healthcare DX Innovation and High Quality Healthcare in Digital Health Age

Related Interest Area(s): TBD
Level: Beginner

SESSION CHAIR
Naoki Nakashima, MD, PhD
Kyushu University Hospital, Center for Advancing Clinical Research

Real-world data (RWD) in healthcare has increasingly been utilized in many ways, but it is not so clear how the benefits and values of "sharing health data" would be returned to each individual patient. When personal health records (PHR), electronic health records (EHR), and other life-log or purchasing (POS) data are connected for each individual, shared widely, and utilized appropriately, what are the new values and benefits for each person and how can this new form of healthcare be cultivated in the future? This session will explore these questions.

New Horizon of Healthcare on Cloud Computing
Kimihiro Tohyama
Amazon Web Service, Inc. (Japan)

The Future of Medical Institutions
Hironobu Tokumasu, MD, MPH
Kurashiki Central Hospital / Real World Data, Co., Ltd

Challenges in Data-based Health Management utilizing Software as a Medical Device
Madoka Murakami
Ministry of Health, Labour and Welfare (MHLW)

Panel Discussion
All Session Speakers

LS-30 **608** **16:30-17:45**

Future Digital Labeling in Japan and Europe

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

SESSION CHAIR
Rie Matsui, RPh
Pfizer R&D Japan G.K.

The Pharmaceutical Machinery Law in Japan was amended in August 2021 to enforce digitalization of labeling ahead of the US and the EU. eLabeling has become an important topic from a global perspective, and Europe, the International Conference of Drug Regulatory Authorities (ICDRA), and the International Pharmaceutical Regulators Programme (IPRP) have addressed it. Although there is no universal definition of labeling digitalization, there is a plan to create and provide eLabeling in a standard compliant format in Europe so that it can be used as digital health. In addition, discussions are progressing in Japan regarding standardization of electronic medical records, electronic prescriptions, and browsing drug information from Myna Portal as data health.

In this session, we will share the eLabeling initiatives undertaken in Europe and projects as digital health. We will also discuss challenges and the future of the use of labeling digitalization as data health in Japan.

Current Measures of Japanese Government Toward Medical DX
Takeru Ito
Ministry of Health, Labour and Welfare (MHLW)

Electronic Product Information in the EU: The Road Ahead
Elizabeth Scanlan, MSc, PhD
European Medicines Agency (EMA)

Digital Labelling – A New Dawn for Product Information in Digital Health
Shimon Yoshida, PhD
Pfizer Inc, United Kingdom

Panel Discussion
All Session Speakers

LS-31 **607** **16:30-17:45**

Team Building for Innovation: How to Foster Psychological Safety

Related Interest Area(s): All
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Takashi Sato
PM Orchestra 310takashi

In order to create innovation, it is necessary to create an environment in which members feel safe to take on challenges and demonstrate their strengths.

Google's research team called it psychological safety, but it is not easy to form such a team. This session will explain the concept of psychological safety in forming teams for innovation from team formation consulting experts in various industries including pharmaceuticals and medical devices, share team case studies from pharmaceutical companies, and discuss in an interactive session with audience participation how to create innovative teams that can provide new value to patients in the future.

Why is It Necessary to Create Teams with a High Level of Psychological Safety?
Maika Kusunoki
Sparkle Team, LLC

Team environment that creates innovation
Takashi Sato
PM Orchestra 310takashi

Panel Discussion
All Session Speakers

LS-32 101 16:30-17:45

Current Status and Prospects for the Future of Decentralized Clinical Trials Utilizing Medical Institution Collaboration

Related Interest Area(s): CI,COM,RA
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR

Takashi Sawada
MSD K.K.

Due to the impact of COVID-19, remote approaches (decentralized clinical trials, or DCT) are making progress in the clinical study field by using digital technology, delivery services, and other tools from the standpoints of medical institutions, patients, and sponsors. Satellite medical institutions and home-visit nursing are also powerful means for successful implementation of a DCT. To take further advantage of these innovations, mutual understanding and cooperation of related persons are more important than ever. However, there are many challenges such as building understanding among stakeholders, clarification of regulations and structure of network system, etc.

This session will focus on the network of medical institutions regarding DCT that have been progressing under the COVID-19 pandemic, current status and issues, and discuss future prospects.

How to Collaborate with Satellite Hospital in DCT in Anti-Cancer Drug Development
Noboru Yamamoto, MD, PhD
National Cancer Center Hospital

How to Establish Collaboration among Medical Institutions for DCT - Approaches and Strategies -
Atsushi Kitamura
Pfizer R&D Japan G.K.

Current Situation and Issues in Clinical Trials Incorporating Home Nursing and Direct to Patient
Chika Akiyama
Parexel International Inc.

Panel Discussion
All Session Speakers

LS-33 102 16:30-17:45

Usefulness and Challenges of Telemedicine in Clinical Practice and Trials

Related Interest Area(s): COM,Others
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR

Eri Sekine
Novartis Pharma K.K.

Although decentralized clinical trials (DCTs) have been attracting attention due to COVID-19, some trials returned to normal hospital visiting styles after pandemic-related restrictions eased, giving the impression that DCTs are not widespread in Japan.

On the other hand, telemedicine (online medical care) is becoming more common in clinical practice, as it reduces the burden on patients living a long distance from and/or having difficulties visiting hospitals. Stable and widespread use of telemedicine would also contribute to the development of DCTs.

This session will discuss the actual situation of telemedicine, the needs of patients, and the usefulness and challenges of implementing DCTs, as well as the future prospects for the advancement of DCTs in Japan, with speakers from the medical field and companies already involved in DCTs.

The Issues of Telemedicine in Clinical Practice and Trials
Haruo Kuroki, MD, PhD
Sotobo Children's Clinic

Utilization of Telemedicine in Clinical Trials -from the Industry Stand Point-
Masahiro Wanikawa
Clinical Evaluation Expert Committee, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association (JPMA) (Chugai Pharmaceutical Co. Ltd.)

The Future of Telemedicine Usecase in Clinical Trials ~ Lessons Learned from a IT Solution Provider ~
Ryoichi Kusama
MICIN, Inc.

Panel Discussion
All Session Speakers

BREAK 17:45-18:15

SPECIAL CHATTING SESSION
1F Reception Hall 18:15-19:45

: SPECIAL CHAT SESSION

18:15-19:45

Related Interest Area(s): ALL

Level: ALL

Session Chair
XXXXX

Facilitators
DIA Japan Content Committee / Community

XXXXX

The "Special Chatting Session" will be held on the evening of the second day of the meeting for the first time in three years. One of the main purposes of DIA is to exchange the opinions! We hope that you will take advantage of this opportunity to network and exchange ideas with other participants. Whether you are a young or an opinionated person, a person from academia, investigational site members or PMDA, Please join the chatting together. Then, we are all companions. Even if you are attending the DIA Annual Meeting alone, we invite you to join our circle and discuss with us the topics that interest you!

This year, we have added three new communities to our table, therefore we will have 14 themes for you to enjoy chatting about. Facilitators from each community will be present, so please gather around the table of interest on the day of the event (there will be no remote, only on-site).

Due to the COVID-19 situation, only soft drinks will be served at the venue, but let's have a fun chat!

The opinion expressed in this Chatting are those of individual participants and should not be attributed in DIA, any affiliates, or any organization with which the participants is employed or affiliated.

<List of Topics>

#	Category	Topic	Facilitators	Abstract
1	Bioethics	What is a Central IRB? Will the collective review proceed for registered clinical trials as well?	Kotone Matsuyama Nippon Medical School Kento Asano Osaka university hospital	Although the Clinical Research Act and ethical guidelines now provide for collective review, a central IRB has not yet been implemented in clinical trials. In this session, we would like to have a lively discussion among sponsors, medical institutions, and CRO/SMO regarding the central IRB for clinical trials.
2	Clinical Data Management	What and how DM should do to promote innovations	Yoshiko Abe EPS Corporation TBD	Innovations, DX are necessary for more efficient drug/therapy development, and data sits in the middle. To promote innovations, what do you expect DM should do and should change? Let's discuss with you all, DM or not.
3	Clinical Innovation	What is the current state of innovation in clinical development?	TBD TBD	The development of various digital technologies is accelerating innovation in clinical trials. We would like to explore industry trends by exchanging opinions among participants on how they perceive and are trying to incorporate the current paradigm shifts, such as the digitization of clinical trials, remote access under COVID-19, and regulatory application utilizing RWE.
4	Clinical Operation & Monitaring	Continuing from the COM workshop, let's chat about QMS/DCT	Masayuki Iijima Chugai Clinical Research Center Co.,Ltd Kazumasa Sugao Mitsubishi Tanabe Pharma Corporation	At the chatting session at the COM workshop held in July, many people requested themes related to QMS and DCT, and heated discussions took place. Let's make it even more heated by including those who have not talked enough and those who want to join the discussion for the first time!
5	Clinical Pharmacology	Paradigm shift of clinical drug development by Model-Informed Drug Development (MIDD)	So Miyoshi, PhD Pfizer R&D Japan Atsunori Kaibara, PhD Eli Lilly Japan K.K.	MIDD promoted extremely rapid research and development of therapeutic agents for COVID-19. Let's discuss how to unleash the power of MIDD and the core-science, Clinical Pharmacology and Pharmacometrics, so that patients can receive benefits from them.
6	Medical Affairs	Digital Transformation in MA Activity	Tadashi Urashima Hideki Ninomiya	We are assuming that there are some practices of digital transformation (DX) in MA such as omnichannel, evidence generation by EHR/PHR, process simplification etc. Shall we share practices of DX and discuss the goals of DX in MA?
7	Medical Communication	Information needed by patients and information easy-to-understand for patients	Seiki Yamazaki Pfizer Japan Ink. Keiko Tsumori MSD K.K.	Pharmaceutical companies provide various kinds of information to patients, but sometimes, the information may be difficult for patients to understand or may be missing what patients need. In this session, we will be discussing the key causes for these challenges and sharing lessons learned, and we hope it will be an opportunity that we can make patients properly use the drug information they need.
8	Open Innovation	Open Innovation Community has been established in DIA Japan!	Kazumi Taguchi SOCIUM Inc Business Development, Director Fumitaka Noji MSD KK Oncology Scientific Affairs	Drugs are not created only by pharmaceutical companies. The encounter between good science and a good environment is important. In Japan, the foundations and systems for that purpose are being put in place, but many challenges still remain compared to Western countries. Would you like to discuss why open innovation is necessary now and the environment in which drugs are born and raised?
9	Patient Engagement	What can we do to create an environment that makes it easier for patients to participate in clinical trials?	Kazuyuki Suzuki Novartis Yuta Kawanishi Astellas	Patient Involvement has been making progress in Japan in the past few years, but the environment has not been established in which patients are easy to participate in clinical trials. There are many problems, and industry, government, academia, and patient should work hard to resolve them. We look forward to your ideas in this session.
10	Pharmacovigilance & Labeling	Future PV&Labeling for digital health	TBD TBD	Looking ahead to the future of digital health, we will discuss the future of pharmacovigilance, the general public, and patient communication. We will also look back on the past 10 years with an objective bird's eye view of Japan in the world and determine what should be invested in money, goods, and people now looking ahead to the evolution of technology in the next 10 years.
11	Project Management	What is really important to promote DX in an organization?	TBD Masaki Kawai TBD Miyako Omayama	To promote DX, it is necessary to use various digital technologies to improve business processes and In order to promote DX, it is necessary to use various digital technologies to improve business processes and to transform the organization, natural features, and culture as well. Let's talk together about what is important to promote DX.
12	Regulatory Affairs	•Changes in communication and work styles between companies and regulators due to the pandemic experience. •Regulatory environment (e.g., emergency approval system, Japanese data in MRCTs, etc.)	MSD Kanji Hirai TBD	We would like to discuss various topics such as the communication style and changes between company representatives and authorities due to the experience of the pandemic situation, and the recently discussed emergency approval system and Japanese data in MRCTs.
13	Six Sigma	What is the 'Quality' to be Achieved in Clinical Studies	Yoichi Ito Hokkaido University Hospital Katsuhiko Sawada Otsuka medical devices	Designing 'Quality' into clinical studies by considering 'Critical to Quality' is one of the fundamental concept described in the step4 ICH E8(R1). In this session, attendees will exchange opinions/issues over the common goal of 'Quality' to be achieved in clinical studies.
14	Statistics	Let's clear the MOYAMOYA for ICH E17 guidance	Osamu Komiyama Pfizer R&D Japan G.K. Yuki Ando PMDA	The ICH E17 Guidance is expected to promote its application in the future. Are you ready for effective and efficient global drug development based on this concept? During the chatting session, we hope to focus on your MOYAMOYA and try to clear them as much as possible.

LIVE SESSION

LS-34 605+606 9:00-10:15

Generating and Utilizing RWE from RWD: From Dreams to Realization

Related Interest Area(s): COM,PV,RA
Level: Intermediate

SESSION CHAIR

Yoshiaki Uyama, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

In recent years, along with the accumulation of actual cases of the use of RWD in Japan and overseas, regulatory authorities in Japan, the U.S., and Europe have issued various guidance documents outlining the requirements for the use of RWE in decision making. For pharmaceutical companies, the use of RWD, which was a dream five years ago, is now a reality.

In this session, we will discuss the current issues and future prospects of RWE, such as required quality, statistical methods, and points to consider when interpreting results, through actual cases of RWE generated in various situations from NDA to post-marketing activities.

Beginning Convergence on Conducting RWE Learned for Decision Making
Sebastian Schneeweiss, MD, ScD
Harvard Medical School

Real-World Data & Pre-Market Approval
John Concato, MD, MPH
Food and Drug Administration

Use and Limitations of RWD in Post-Marketing Phase
Yusuke Okada
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

LS-35 608 9:00-10:15

Company-Provided Information and Patients' Health Literacy: Gaps and Solutions

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

SESSION CHAIR

Yuko Kojima, RPh, EMBA
Eli Lilly Japan K.K.

The COVID-19 pandemic forced us to make vaccination decisions based on the benefits, risks, and our own values. In shared decision making, patients understand information and choose their own medical care with medical professionals such as doctors and pharmacists. In recent years, companies have begun focusing on patient-centricity and considering how to provide information to medical professionals and patients. Are companies sufficiently supporting patients to fully understand and make choices about benefit and risks?

This session will share the current situation and initiatives on health literacy from expert perspectives and discuss across stakeholders any gaps and/or solutions that companies should address.

Leveraging Health Literacy in Communications
Sarah Burns, MSc
Eli Lilly & Company

Survey about Health Literacy in Japan and Efforts by Health Care Professionals
Hideo Nakada, MSc, RPh
Keio University Hospital

Health Literacy Enriches My Life
Noriko Iwaya
Intractable disease support Familia Yamaguchi

Panel Discussion
All Session Speakers and
Shinichi Nishiuma, MD
Bristol Myers Squibb K.K.
Yoko Takaashi
Phermaceutical and Medical Devices Agency (PMDA)
Kathryn Aikin
Food and Drug Administration (FDA)

LS-36 607 9:00-10:15

Fireside Chat: How to Create an Environment for Easy Clinical Trial Participation

Related Interest Area(s): PE,BE,COM
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Eri Sekine
Novartis Pharma K.K.

Several years have passed since patient engagement was introduced in Japan, but an environment that enables patients to easily participate in clinical studies has not been fully established. A fireside chat will further exchange opinions on this issue, which DIA PEC has addressed in the past. The fireside chat will begin with a video interview of patients on the issues surrounding clinical study participation and be followed by opinion exchange based on comments from participants including patients and speakers from government agencies and medical institutions. Our aim is to share ideas on what we can do together to resolve this issue, based on our knowledge of the current situation from our respective positions. We also aim to take concrete steps toward improvement after the session.

Barriers to Clinical Study Participation Learned through DIA Patient Engagement Activities
Kimie Sakurai
NPO GISTERS

Clinical tTial Information Portal Site How to Use and Future - Points Learned from Discussions with Stakeholders
Keiko Yukawa
National Institute of Publich Health

Patient Purpose of Participating in Clinical TrialsPatient Journey from the University Hospital's Perspective
Yuki Sasaki
Hokkaido University Hospital

Panel Discussion
All Session Speakers and
Yukiko Nishimura, MSc, PhD
NPO Asrid

LS-37 101 9:00-10:15

Delivering Truly Valuable Drug Information for Clinical Practice in the New Normal

Related Interest Area(s): MA
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR

Yoshiyuki Sugimoto, PhD
Sanofi K.K.

Many drugs with novel mechanisms of action and various modalities have been developed recently. With the variety and amount of drug information such as safety, efficacy, pharmacokinetics, and pharmaceutical properties, it is necessary to discuss what is fair and neutral information for healthcare professionals and patients, the importance of academic detailing from a fair and neutral point of view, and suitable channels for accurately communicating necessary information to healthcare professionals. It is also important to bring the delivery of drug information that makes use of the expertise and strengths of the information provider in line with the needs of clinical healthcare professionals.

This session will discuss the delivery of drug information that is truly valuable in clinical practice.

Delivery of Drug Information by Medical Affairs
Koji Iwasaki, PhD
Osaka University Hospital

Providing Drug Information through Academic Detailing
Masayo Komoda, PhD
Japan Academic Detailing

Appropriate Drug Information ProvisionNeeded by Clinicians
Shunichiro Iwasawa, MD, PhD
Chugai Pharmaceutical Co., Ltd.

Panel Discussion
All Session Speakers

LS-38 102 9:00-10:15

What Systems/Infrastructure Can Be Used for Pediatric Drug Development?

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

SESSION CHAIR

Kayoko Kikuchi, PhD
National Center For Child Health and Development

Industry, governments, and academia are attempting to promote the development of pharmaceuticals in pediatrics from their respective standpoints. As a result, new systems and infrastructures have been established. One of them is the new category “Pharmaceuticals for Specific Use” (PSUs) of the Pharmaceutical and Medical Devices law that had been revised in 2020. PSUs are drugs for specific indications with unmet medical needs especially for pediatrics and antimicrobial resistance. However, only one drug has been designated as a PSU as of May 2022. This session will provide an update on the current environment for pediatric drug development in Japan. Stakeholders from industry, regulatory agencies, and academia will discuss how we can cooperate and promote pediatric drug development further utilizing current systems in Japan.

Academia’s Efforts and Achievements in Industry-Academia Collaboration to Facillitate Pediatric Drug Development
Hidefumi Nakamura, PhD,MD
National Center For Child Health and Development

Precedex Pediatric Development: Using the Support System for Pediatric Drug Development
Miyako Matsumizu
Pfizer R&D Japan

To Promote Drug Development in a Pediatrics Field
Seiko Bun
Ministry of Health, Labour and Welfare (MHLW)

The Current Situations of Pediatric Nedicines and its Children’s Perspectives.
Kana Harada
Toho University Omori Medical Center

Panel Discussion
All Session Speakers

BREAK 10:15-10:30

LS-39 605+606 10:30-11:45

Implementing Data Sharing in a Time of Pandemic

Related Interest Area(s): CI,RA,ST
Level: Intermediate

SESSION CHAIR

Azusa Tsukida
Vivli

The goal of this session is to convene a panel that will share perspectives of study sponsors and data sharing platforms of sharing data during the time of the pandemic.

The presentations will answer questions such as:

- Challenges and opportunities and key learnings from the use of data sharing platforms
- Progress and developments for multi-sponsor platform for sponsors and for researchers
- As data sharing becomes the norm, what should a sponsor consider when deciding on how to securely share clinical data?

The session will consist of 2 presentations followed by an interactive panel discussion. Merits of IPD data sharing, how to improve current data sharing efforts, experience of sharing, analyzing and requesting IPD data to conduct network meta-analysis and how it has changed in the context of the pandemic will bw shared.

Attendees should come away with a greater sense of how using a data sharing platform

Data Sharing On External Multi-sponsor Platforms - Sponsor’s Perspective
Oladayo Oyelola, PhD, SC(ASCP)
Daiichi Sankyo, Inc.

Data Sharing: 5 steps Sponsors Should Consider When Sharing Completed Clinical Trial Individual Participant-Level Data
Julie Wood
Vivli

Panel Discussion
All Session Speakers and
Tadao Akiyama, B.Sc.
Daiichi Sankyo Co., Ltd.

LS-40 608 10:30-11:45

Promoting DX (Digital Transformation) in Risk Communication to Patients

Related Interest Area(s): MC,PV,PE
Level: Intermediate

SESSION CHAIR

Kazuhiko Ishida, MSc, RPh
Astellas Pharma Inc.

The transition from paper to electronic media has advanced the provision of information from pharmaceutical companies to healthcare professionals, including the electronization of package inserts implemented in 2021. However, pharmaceutical companies still rely on healthcare professionals to deliver information to patients, and it is unlikely that they fully utilize digital technologies.

Therefore, this session will discuss the promotion of DX (digital transformation) in risk communication to patients with members of the pharmaceutical industry, academia, and regulatory agencies, based on specific cases and future perspectives, as well as points to consider in communicating with patients, and how to provide information for the next generation.

Risk Communication to Patients and Points to Consider
Michiko Yamamoto, PhD
Kumamoto University

Risk Communication to Patients with Dx -Challenges and Perspectives from Pharmaceutical Industry
Shinya Takemoto, MSc, MBA
Japan Pharmaceutical Manufacturers Association (JPMA) / Drug Evaluation Committee Pharmacovigilance Expert Committee TF-1 / Chugai Pharmaceutical. Co. Ltd.

Panel Discussion
All Session Speakers and
Junko Takahashi
Ministry of Health, Labour and Welfare (MHLW)

LS-41 607 10:30-11:45

Clinical Trial Ambassadors: Empower Patients with Knowledge

Related Interest Area(s): PE,COM
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR
Kotone Matsuyama, RPh
Nippon Medical School

Patients often have concerns about participating in clinical trials due to a lack of information and awareness. To help patients overcome their uncertainties and fears, the Clinical Trial Ambassadors project together with Patient Organizations was launched by academia and several pharmaceutical companies in Japan. This project makes representatives of patient organizations ambassadors for clinical trials and thus independent partners for the questions and concerns of patients. Knowledge is power, and this will empower patients with understandable information on clinical trials and spread awareness about clinical trials.

This session will share expectations for the role of the clinical trial ambassador in Japan, training modules based on the European Patients' Academy on Therapeutic Innovation (EUPATI) materials to patient organizations, practical approaches to increase awareness about clinical trials, and what to do and achieve as clinical trial ambassadors in the future.

Why are Clinical Trial Ambassadors needed?
Kenma Nozaki, MSc
Nippon Boehringer Ingelheim Co. Ltd.

Training Packages to Patients for Spreading Clinical Trial Awareness
Kotone Matsuyama, RPh
Nippon Medical School

Can Clinical Trial Ambassadors Increase Awareness on Clinical Trials?
Takeshi Shukunobe
PPeCC,Inc.

Panel Discussion
All Session Speakers and
Toshie Nakai
Astellas Pharma Inc.
Junko Sato, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

LS-42 101 10:30-11:45

Academia-Industry Collaboration to Promote Clinical Research Utilizing Real-World Data

Related Interest Area(s): AC,CDM,RA,COM
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR
Hiroyuki Taruno
Cancer Institute Hospital of Japanese Foundation for Cancer Research

In recent years, efforts have been made to promote clinical research using real-world data in the medical field. The Personal Information Protection Law was amended in 2017 to stipulate the utilization of anonymously processed information, and the Next-Generation Medical Infrastructure Law came into effect in 2018. Various field personnel involved in businesses related to the Next-Generation Medical Infrastructure Law, including lawyers, persons in charge of departments related to clinical research of companies, and persons in charge of contracted business operators handling certified medical information, have been assigned to investigate the relationship between the Personal Information Protection Law and the Next-Generation Medical Infrastructure Law and to discuss measures for promoting clinical research utilizing RWD through industry-academia collaboration. Here we report the results of our study.

Current Status and Challenges of the Next Generation Healthcare Infrastructure Act
Yasuhiro Himeno
Cabinet Office, Government of Japan, National Healthcare Policy Secretariat

Efforts to Promote Clinical Research by Utilizing Real-World Data ~ From the Standpoint of the Academia Research
Takahiro Horimatsu, MD, PhD
Kyoto University Hospital

Efforts to Promote Clinical Research by Utilizing Real-World Data ~ From the Standpoint of the Pharmaceutical Industry ~
Hiroshi Asai
Astellas Pharma Inc.

Panel Discussion
All Session Speakers and
Yumi Wakabayashi, PhD, MBA, BS
Janssen Pharmaceutical K.K.

LS-43 102 10:30-11:45

Current Compliance and Utilization Status and Issues for Human-Derived Data

Related Interest Area(s): BE,CDM,CI,COM,CP,OI,PE,PM,PV
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Shoichi Negishi
Deloitte Tohmatsu Consulting LLC

The healthcare industry is facing a major turning point, and promoting digital technologies (DX) and innovation and evolution through the New Normal will bring great benefits. However, the balance between use of digital technology, security measures, and legal compliance are major themes to consider when using human-derived data that includes important personal information.

This session will discuss laws and regulations for data utilization, which are essential for drug discovery, from a business and academic perspective, and panel discussion on the ideal form of industry-academia-government collaboration will be held to resolve these issues from each point of view.

Current Status and Issues for Compliance and Utilization of Human-Derived Data
Masayoshi Higuchi
Chugai Pharmaceutical Co., Ltd.

Consideration of Issues that Should Be Understood When Utilizing Healthcare Data in Business- Based on the Efforts of KUEP-DHI dot.b -
Genta Kato
Kyoto University Hospital

The Future of Medical Information Utilization
Junya Kasamatsu, MD, PhD.
Cabinet Office, Government of Japan, National Healthcare Policy Secretariat

Panel Discussion
All Session Speakers

LUNCH BREAK 11:45-12:45

LUCHEON SEMINAR 11:55-12:35

SPECIAL SESSION 4 605+606 12:45-14:15

The Future of Drug Development: Past, Current, and Future

Related Interest Area(s): All
Level: Intermediate

SESSION CHAIR

Kazuhiko Mori, MSc, PhD
Japan Pharmaceutical Manufacturers Association (JPMA)
Hironobu Saito, PhD
Daiichi Sankyo Inc.

Based on the policy "Never forget the thalidomide phytotoxicity," DIA started the activity for global communication among industry, regulators, and academia about 60 years ago. Activity of "The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use" was started by regulators and industries of the US/EU/Japan 30 years ago. Both activities have been practical and have contributed to global healthcare.

This session will discuss future activities reflecting past activities and current situations.

Panel Discussion
Yasuhiro Fujiwara
Pharmaceuticals and Medical Devices Agency (PMDA)
George Nakayama
Daiichi Sankyo Inc.
Tatsuo Kurokawa
Japan Biosimilar Association
Masaru Iwasaki, MD,PhD
Yamanashi University

LS-44 608 12:45-14:00

Challenges for the Future Realized by Digital Biomarkers

Related Interest Area(s): CI
Level: Intermediate, Advanced

SESSION CHAIR

Naoto Awaji
Chugai Pharmaceutical Co., Ltd.

It has been difficult to obtain quality-controlled physiological data in daily life, and so its use in clinical trials is limited. Today, however, digital biomarkers (dBM) are objectively and temporally measured using smartphones and other wearable devices are attracting attention. The development of dBM is carried out by selecting the equipment suitable for the data to be acquired, acquiring the data, processing and analyzing the obtained signal, and validating it. Advanced information processing is required, but there is also an opportunity to grasp the value of medicines for patients from this new perspective.

This session will discuss the opportunities and challenges of the future brought by dBM.

Care For One Project Contribution to Data Driven Medical Practice Through Symptom Monitoring
Yoshihiko Furusawa, MD, PhD.
Takeda Pharmaceutical Company Limited

Current Status of ePRO Monitoring in Oncology Practice
Naruto Taira, PhD, MD
Kawasaki Medical School

Points to Note in Developing and Applying for Symptom Monitoring SaMD
Koshitomae Hazuki
Phermaceuticals and Medical Device Agency (PMDA)

Panel Discussion
All Session Speakers

LS-45 607 12:45-14:00

Toward ICF Common Template Implementation as All Japan

Related Interest Area(s): COM,PE
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Kenji Udo
R&D Head Club Working Group2 /Pfizer R&D Japan G.K

With the complexity of clinical trials and the growing awareness of patient and public involvement (PPI), efforts are being made in each aspect, such as the patient's perspective and the response to new regulations, to improve the Informed Consent Form (ICF). However, there are a variety of templates for each sponsor or medical institution. The significance of these efforts can be impaired by replacing them, and participants in the same trial may even receive different information from medical institutions. It also takes a huge amount of time, and there is concern that the quality will decline from, for example, a lack of information. This session will introduce the Japan ICF Common Template, prepared with various stakeholders, and discuss how it will be disseminated throughout Japan in the future.

From a Institution's Perspective
Kaori Watanabe, MPharm
The University of Tokyo Hospital

Toward ICF Common Template Implementation as All Japan
Kenji Ishizuka
GlaxoSmithKline K.K.

Panel Discussion
All Session Speakers and
Hiroshi Matsuzawa, M.S., Pharmaceutical Sciences
Japan Pharmaceutical Manufacturers Association (Astellas Pharma Inc.)
Keiko Inoue
Japanese Institute for Public Engagement
Yumiko Nomura
Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare (MHLW)

LS-46 101 12:45-14:00

Advancing Risk Communication in Pregnancy through Utilizing Registry Data

Related Interest Area(s): PV,MC
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Mihoko Ota, MMA
RAD-AR Council, Japan / Takeda Pharmaceutical Co., Ltd.

In Japan, safety surveillance for maternal drug exposure relies on spontaneously reported data. The Japan Drug Information Institute in Pregnancy of the National Center for Child Health and Development (NCCHD) prospectively collects background information on pregnancy cases and birth outcomes as a source of pharmacovigilance for pregnancy. This registry is helpful for systematically evaluating the information on specific pregnancy outcomes of drug exposure.

This session will introduce the strength and utilization of this registry in pharmacovigilance as well as share information from ongoing collaboration between NCCHD and RAD-AR Council . The discussion will also cover the future perspectives to solve issues on pharmacovigilance in pregnancy.

Consultation on Medications During Pregnancy and Development of a Database of Consultation Cases
Naho Yakuwa, BPharm
National Center for Child Health and Development

Use of Pregnancy Registry Database for Pharmacovigilance
Shinichi Matsuda, PhD
RAD-AR Council, Japan / Chugai Pharmaceutical Co., Ltd.

Panel Discussion
All Session Speakers and
Megumi Sakai
Ministry of Health, Labor and Welfare (MHLW)

LS-47 **102** **12:45-14:00**

New Normal of Creating Program Value Creation in Healthcare

Related Interest Area(s): All
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Atsushi Tsukamoto, PhD.
Daiichi Sankyo Inc.

In the past, we created value by gathering people and materials in order to create new things. Through the COVID-19 experience, we began to realize that value can be created without physically gathering people and materials. Advanced information and communication technologies (ICTs) are beginning to release us from the constraints of "time" and "location," and connecting via "means defined by individuals" can create new networks and new value. The new normal offers potential to create new value based on big data from ICTs.

This session will discuss the structure of value creation to achieve overall optimization (including utilization of ICTs) to create value sustainably in drug development and medical therapies.

Panel Discussion
Koji Iwasaki, PhD.
Osaka University Hospital
Shigenobu Ohara, PhD.
Project Research Corporation
Kohichi Konno, PMP
PMconsulting Positeve Intention

BREAK **14:00-14:30**

DIAmond SESSIONS

DIAMOND SESSION 2 **605+606** **14:30-16:00**

New Style of Clinical Trial with Innovative Tools

Related Interest Area(s): TBD
Level: TBD

SESSION CHAIR
Junko Saito, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)
Hironobu Saito
Daiichi Sankyo Inc.

In this session, speakers will share ICMRA's initiatives for new normal, such as the utilization of DCT and remote inspection, and discuss the ECO-system for clinical development.

How to Evolve Global Drug Development under ICMRA's Leadership?
Junko Saito, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

WHO's Global Role in Supporting Sound Regulation of Medical Products
Mike Ward
World Health Organization

Collaboration between ICMRA and ICH
Masafumi Yokota
Daiichi Sankyo Inc.

Panel Discussion
Emer Cooke
European Medicines Agency (EMA)
V.G.Somani
The Central Drugs Standard Control Organisation (CDSCO, India)
Yasuhiro Fujiwara
Pharmaceuticals and Medical Devices Agency (PMDA)

LS-48 **608** **14:30-15:45**

Availability of Structured Data for Clinical Study Protocols after Implementing ICH M11

Related Interest Area(s): MC,CDM,COM,RA
Level: Beginner

SESSION CHAIR
Matsuzawa Hiroshi, MS
Astellas Pharma Inc.

The ICH M11 Guideline is scheduled to be agreed upon in Step 2 this year (start of the call for public comments). In addition to providing a template for standardizing and structuring protocols, the guideline includes technical specifications to enable the electronic exchange of protocol information. The electronically structured protocol information is expected to be utilized by pharmaceutical companies when preparing regulatory documents and exchanging information with regulatory authorities. However, it is not yet clear what preparations are necessary within a company and what discussions are necessary with regulatory authorities to actually use the information.

This session will propose and discuss the possibilities and issues of using structured data after M11 implementation, and consider how to maximize the use of data.

Preparation and availability of structured data for ICH M11 implementation
Manabu Inoue
MSD K.K. / Japan Pharmaceutical Manufacturers Association (JPMA)

Expectations and Impact of M11 from a Data Scientist Perspective
Hajime Osawa
Chugai Pharmaceutical Co., Ltd. / Japan Pharmaceutical Manufacturers Association (JPMA)

Structured Content Management Platform – concepts, capabilities & implementation status
Niklas Jänich, PhD
Boehringer Ingelheim International GmbH

Panel Discussion
All Session Speakers and
Ken Sakushima, MD,MPH,PhD
Pharmaceuticals and Medical Devices Agency (PMDA)
Noemie Manent
European Medicines Agency (EMA)

LS-49 **607** **14:30-15:45**

DIA Community Introduction

Related Interest Area(s): All
Level: TBD
Language: Japanese Language Only

SESSION CHAIR
Kazuhiko Ishida, MSc, RPH
Astellas Pharma Inc.

DIA Community is one of the activities that only DIA members can participate in. Currently, there are 14 specialized communities in Japan.

The main purpose of the community is to form a neutral network in

DIAmond Session 3

which people from all positions related to drug development, such as companies, academia, regulatory authorities, medical institutions, and patients, can participate, and to be involved in the community's specialized area and drug development in general. It involves sharing experiences and the latest topics, examining issues, making proposals, and creating workshop programs. Through these activities, the community contributes to fostering innovation in drug development and provides career development opportunities for DIA members.

Clinical Innovation
Tomohiko Takahashi, Mecc
Otsuka Pharmaceutical Co., Ltd.

Clinical Pharmacology
Sou Miyoshi, PhD
Pfizer R&D Japan

Medical Affairs
Yoshiyuki Sugimoto, PhD
Sanofi K.K.

Patient Engagement
Keiko Katsui, PhD
Japan Agency for Medical Research and Development (AMED)

Project Management
Noriaki Nagao
Japan Tobacco Inc.

Regulatory Affairs
Kanji Hirai, RPh
MSD K.K.

Statistics
Taro Amagasaki, PhD
Novartis Pharma K.K.

Bioethics
Kotone Matsuyama, BS, R.Ph
Nippon Medical School

LS-50 **101** **14:30-15:45**

Considerations for Providing Reliable Pharmaceutical Information and the Perspective of Information Recipients

Related Interest Area(s): AC,MA,MC,PE
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR
Tomiko Tawaragi
RAD-AR Council, Japan

Information on drugs is available not only at hospitals, pharmacies, and other medical institutions, but is also abundant on the internet, in magazines, and elsewhere. Although it has become easier to search for information using computers and smartphones, it has not become easier for patients to judge for themselves whether that information is correct or reliable. Therefore, it is increasingly important to identify reliable pharmaceutical information.

This session will discuss reliable pharmaceutical information from the viewpoints of the information sender and receiver, including how to provide reliable information, and precautions the receiver can take.

Providing Reliable Information and Consider the Point of View of the Person Receiving the Information. As the patient side.
Toru Kishida
NPO Gannote.com

Role of pharmacist in outpatient clinic
Reiko Matsui
National Cancer Center Hospital East

Providing Reliable Information ~ from a Pharmaceutical Company's Perspective~
Takako Sakai
Eisai Co., Ltd.

Panel Discussion
All Session Speakers and
Hiromi Todoroki
Certified NPO KIBOUNOKAI / Japan Federation of Cancer Patient Groups

LS-51 **102** **14:30-15:45**

Next-Generation Digital Healthcare Considering Pre-Symptomatic State, Prevention, and Well-Being (Part 2)

Related Interest Area(s): TBD
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR
Takashi Moriya, PhD, MBA
Woven Alpha Inc.

"Next-Generation Digital Healthcare" is being used as a growth strategy in Japan, and the actions for treatment, the pre-symptomatic state, prevention, and well-being during the course of each person's life are being considered. Similar actions were mentioned in "Healthcare III in Society 5.0 era" issued by KEIDANREN . We must move forward strategically with digital transformation in the healthcare area to ensure proper execution of these actions. This first part of this two-part session aims to discuss utilization of PHR (Personal Health Record) throughout the course of each person's life.

Personalized Health Care Using PHRs
Takeru Hiki
Welby inc.

Personalized Health Care Using PHRs
Hiroyuki Idone
Novo Nordisk Pharma Ltd.

Panel Discussion
All Session Speakers

BREAK **15:45-16:30**

AFTERNOON SEMINAR **16:10-16:25**

DIAmond SESSIONS

DIAMOND SESSION 3 **605+606** **16:30-18:00**

PMDA Town Hall

Related Interest Area(s): ALL
Level: TBD

SESSION CHAIR
Akihisa Harada
Pfizer Japan Inc.
Masaru Iwasaki, MD,PhD
University of Yamanashi, Center for Advancing Clinical Research

Panelists
All Session Speakers and
Kenichi Tamiya, MSc, RPh
Pharmaceuticals and Medical Devices Agency
Koshin Kiyohara
Pharmaceuticals and Medical Devices Agency
Kensuke Ishii, PhD
Pharmaceuticals and Medical Devices Agency

Mie Ikeda, MSc
Pharmaceuticals and Medical Devices Agency
Nobumasa Nakashima, PhD
Pharmaceuticals and Medical Devices Agency
Yasuhiro Araki
Pharmaceuticals and Medical Devices Agency

LS-52 608 16:30-17:45

Breaking the Document Paradigm and Digitizing Clinical Study Start-Up

Related Interest Area(s): AC,CI,CDM,COM,OI,ST,O
Level: Intermediate

SESSION CHAIR

Mika Ogasawara
Pfizer R&D Japan

TransCelerate's Digital Data Flow (DDF) initiative aims to transform clinical studies by enabling end-to-end digital exchange of study definition information. By working to help organize and automate the data and information in a study protocol, the DDF initiative is a catalyst for digital transformation of clinical trials across the industry. This session will cover current progress in TransCelerate's DDF and relevant activities:

- Recent launch of the Study Definitions Repository Reference Implementation (SDR RI) underpinning the DDF solution
- Collaborating and participating in modernizing clinical data flow through open-source principles on open-source coding platforms such as GitHub
- Exploring DDF with the SDR RI and CDISC standards covering the Unified Study Definitions Model (USDM), controlled terminology, and API specifications critical to establishing interoperability across systems
- How to engage, review, and participate in this evolutionary initiative for clinical trials
- How each TransCelerate initiative harmonizes with the others to enhance the clinical development efficiency by breaking the document paradigm and end-to-end automation of clinical trials.

Progress on TransCelerate's Digital Data Flow Initiative
Michaela Schrodt
Bayer AG

Unified Study Definitions Model and CDISC Partitipating Collaborations
Berber Snoeijer, MSc
J&J (TransCelerate's Digital Data Flow Initiatives)

Panel Discussion
All Session Speakers and
Yasuharu Shibata, MSc
MSD K.K.
Hideo Takaura, MBA
Novartis Pharma K.K.

LS-53 607 16:30-17:45

Application of RWD to Clinical Development: Discussion with Industry, Regulatory, and Academia Through Hypothetical Case Studies

Related Interest Area(s): CI,COM,OI,PV,RA,ST
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Takashi Moriya, PhD, MBA
Woven Alpha, Inc.

Use of real-world data (RWD) in clinical trials and for new drug applications has gained momentum since the notice on the use of the registry was published. Drug development generally involves randomized controlled trials. This session focuses on the issues to be addressed when RWD is used in clinical trials. Then, we will present hints and directions for solving specific issues through case studies that assume situations in which RWD is applied.

Challenges in Industry When Leveraging RWD in Clinical Development
Yoshifumi Ukyo, MPH, PhD.
Janssen Pharmaceutical K. K.

Activities for utilization of RWD in PMDA
Junichi Asano, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

The Use of External Control Database for Cancer Clinical Trials
Shogo Nomura, PhD
The University of Tokyo

Panel Discussion
All Session Speakers

LS-54 101 16:30-17:45

Branding! Let's Design Our Own Lives in the New Healthcare Era

Related Interest Area(s): All
Level: Beginner, Intermediate
Language: Japanese Language Only

SESSION CHAIR

Satoshi Suzuki
Pfizer R&D Japan

It is said, in preparation for the 100-year life society, that continuing education and developing individual abilities are important, so everyone will be able to contribute to society and lead longer and more fulfilling lives. The practice of "branding," in which people discover who they are, the feelings and attractions that exist within themselves, and recognize and verbalize what they should be, is considered to be one of the most useful methods for thriving in this new era. Through branding, people and organizations can make their daily behavior and decision-making consistent, which will greatly help them to be trusted and chosen in an ever-changing society. We will discuss the value and expected effects of branding in the healthcare industry with panelists from industry, government, and academia, and consider together how to live in this new era by utilizing branding.

The Concept of Branding and Way of Thinking
Keiichi Sato, MBA
TOPPAN INC.

Case Studies of Branding Initiatives in Pharmaceutical Company
Michiyo Ohshima, MBA
Pfizer R&D Japan

Panel Discussion
All Session Speakers and
Kotone Matsuyama, RPh
Nippon Medical School
Hisashi Koike
Pharmaceuticals and Medical Devices Agency (PMDA)

LS-55 102 16:30-17:45

Patient-Public Involvement in the Clinical Study: Findings from Simulated Clinical Study Workshops

Related Interest Area(s): All,PE
Level: Intermediate, Advanced
Language: Japanese Language Only

SESSION CHAIR

Tatsunori Shimoi, MD, PhD
National Cancer Center Hospital

Patient-public involvement (PPI) at earlier phases of clinical studies is highly expected because it enables co-planning the clinical study through collaboration between industry and patients. AstraZeneca convened

a workshop with patients who belong to a patient advocacy group to discuss the concept of simulated clinical trials and communication between physicians and patients on participation in these trials. At a subsequent open panel discussion, we invited doctors and a patient expert and further discussed the problems regarding advocation of the clinical study and promotion of PPI in clinical studies and their potential solutions.

In this session, a principal investigator, a CRC/nurse, a patient expert, and an industry employee will discuss the data/information and communications considered beneficial when patients decide to participate in clinical studies.

Patients'Needs from the Clinical Trial Education Class at NCCH
Hiroko Nakahama, RN,MS,CCRP
National Cancer Center Hospital

Mock Clinical Trial Workshop Initiatives
Hisayoshi Hashimoto, MD, PhD
Astrazeneca K.K.

More Accessible to Clinical Trials !
Naomi Sakurai
Cancer Solutions

Panel Discussion
All Session Speakers

BREAK **17:45-18:15**

CLOSING **605+606** **18:15-18:45**

Closing Remarks

Kazuhiko Ishida, MSc, RPh
Program Vice-Chair / Astellas Pharma Inc.

[PO-01] Investigation on approved cases: Discussions on the significance of combination in PMDA review reports on fixed-dose combination (FDC) drugs

Related Interest Area(s): RA

Yudai Suzuki
Regulatory Development Dept., Janssen Pharmaceutical K.K.

Objectives:
FDC is a potential solution for polypharmacy, an issue in aging society. We explored points to consider in FDC development by examining approved FDCs in Japan focusing on reasons of combination.

Methods:
FDCs should meet one of the four reasons for combination to be approved in Japan: 1) difficult to prepare before use; 2) improving safety or having synergistic effects; 3) clearly improving convenience for patients; or 4) of other scientific significance. The accepted reasons for combination in the PMDA review reports were investigated for 96 FDCs approved in Japan after 1999, with details for 4).

Results:
Hypertension/hyperlipidaemia was most common indication (18%), followed by infections (14%), respiratory diseases (14%), and ophthalmology (8%). Oral FDCs accounted for the majority (52%). The reason of combination was not discussed for some FDCs; however, no apparent tendency was observed for such cases in diseases or routes of administration. While 21 FDCs were applicable to 3), there were many cases where the applicability to 3) was not accepted by the agency despite the applicants' claim; particularly for oral FDCs, in which only 4 out of 33 such applicants' claims were accepted. The definition of "clearly improving" in the criterion 3) is deemed unclear and thus, its understandings between applicants and the agency may vary. Of 55 FDCs applicable to 4), the most common reason was superiority to monotherapy. Disease area specific reasons, such as suppression of resistance development (infection area) and non-inferiority to other combination therapies (respiratory disease area), were also seen.

Conclusion:
While patient convenience is one of the key triggers for the FDC development, it was not always regarded as the basis for its approval. Scientific explanations of the contribution to the efficacy/safety of each component, as well as the disease background, was also deemed an important factor.

[PO-02] Aiming to establish a win-win patient registration system for investigational sites and sponsors

Related Interest Area(s): AC,COM

Akiko Tamamori
Clinical Process Strategy Dept. Chugai Pharmaceutical Co., Ltd.

Objectives:
Smooth patient enrollment is important to deliver new treatment to patients as soon as possible. Therefore, to establish a win-win patient enrollment system for investigational sites and sponsors, we surveyed issues through questionnaires and discussed ways to improve the system.

Methods:
Investigational sites of different types and sizes, sponsors, and CROs were surveyed regarding patient enrollment, and the current status and issues of patient enrollment were investigated. Based on the results of the survey, discussions were held with investigational sites and sponsors to clarify the issues and to consider specific measures for improvement.

Results:
As a result of the survey, 76% (97/128 sites) of investigational sites and 93% (13/14 companies) of sponsors and CROs (hereafter referred to as "sponsor side") responded that they felt patient enrollment was a problem in some way. Regarding the creation of measures to promote patient enrollment, 51% (65/128) of investigational sites and 36% (5/14 companies) from the "sponsor side" responded that they "discuss with sponsors or investigational sites"; this result was lower than expected. In addition, 31% (40/128) of investigational sites and 57% (8/14 companies) of "sponsor side" cited "the target number of patient enrollment was not realistic" as the reason for not reaching the target number.
Patient enrollment plans, all prepared by the "sponsor side" who responded to the survey, included monthly case number targets (93% [13/14]), monthly number of consents obtained (71% [10/14]), enrollment promotion measures (86% [12/14]), and timing of enrollment promotion measures (50% [7/14]). It may be difficult to achieve planned results if the investigational site and the sponsor plan do not discuss the target number of patient enrollment and measures to promote patient enrollment.

Conclusion:
To establish a win-win patient enrollment system between the investigational site and the sponsor, it is important that all parties involved have a correct understanding of the background of the study, the implementation system, and the subject cases. To this end, it is considered important for the sponsor and investigational site to communicate information and requests to each other, discuss each other's roles in advance, and visualize the plan.

[PO-03] Best practice for digital compliance system to contribute to improved healthcare

Related Interest Area(s): BE,CI,CDM,OI,PM,O,PE

Norihisa Ohishi
Business Strategy & Compliance Dept., Chugai Pharmaceutical Co., Ltd.

Objectives:
With the development of IT technology, various data utilization movements have spread to the medical field including drug development. This presentation will examine how to establish a compliance system in a pharmaceutical company.

Methods:
Chugai defined "digital compliance" as activities to promote data utilization while complying with data protection laws and regulations regarding human-derived data and has built company-wide data utilization systems and processes since 2019. Their data handling policies and guidelines were formulated through consulting services, which is a part of digital compliance.

Results:
Chugai's digital compliance system consists of the digital compliance officer who leads activities in the data-utilization departments, the digital compliance committee composed of compliance experts, and the Digital Compliance Group (DCG) as the responsible organization. DCG consulting services show a consistent view for the cases received from various departments based on data protection laws and regulations, and collaboration with corporate departments such as legal and IT, and the Research Ethics Committee. In addition, by incorporating experts from the data utilization department into the digital compliance committee, it is possible to show realistic countermeasures. Through consulting services, DCG has organized key digital compliance policies and guidelines. These efforts lead to autonomous digital compliance activities by the digital compliance officer in the data utilization department. In addition, using the knowledge accumulated through these efforts, we are actively engaged in initiatives for industry and government, such as submitting public comments on laws and guidelines.

Conclusion:
Chugai has built a digital compliance system and process consisting of DCG and members of data-utilization departments. In consulting services, DCG can present realistic countermeasures and consistent views based on various regulations. These efforts lead to autonomous digital compliance activities by the data utilization department.

[PO-04] Introduction of the new Global RIM system: Data transfer and the challenges under the COVID 19 pandemic (Continued from Annual Meeting 2021)

Related Interest Area(s): RA,O

Hiroaki Yazaki
Regulatory Affairs Otsuka Pharmaceutical Co., Ltd.

Objectives:
This presentation discusses the way in which data was transferred from the old system to the new IDMP compliant RIM system, a new regulation in Europe, and the challenges under the COVID 19 pandemic.

Methods:
First, the old and new systems were compared module by module to understand the configuration differences, and data mapping between the extracted data and the new system was performed. Then, a tentative data transfer process was prepared to conduct several test runs. Finally, after necessary revisions, data transfer was conducted using the finalized process.

Results:
Effective in 2022, EMA requires voluntary submission of IDMP for applications under the Centralized Procedures. To meet this requirement, Otsuka has

introduced a new RIM system compliant with IDMP. This new system is not compatible with the old one and data cannot be directly transferred to the new system. To facilitate understanding of the differences between the two system configurations, the differences were visualized and a comparison table of each item from the old and new systems was created. The data to be migrated and new target modules were then specified. After several data migration tests using a verification environment, the data was transferred. Due to COVID-19, these preparations and verifications were conducted at multiple locations. The time difference between these locations hindered a smooth preparation process and caused longer time for verification than expected. Because priority was given to system implementation, some data was entered manually after the system "go live."

Conclusion:
Data transfer between incompatible systems requires sufficient preparation and it takes even longer than expected under a crisis such as COVID-19. Therefore, it is important to clarify priorities and be flexible enough to change plans. These findings can be useful for companies planning similar work.

[PO-05] Application of targeted learning to estimate the protective effects of SSRI treatment against COVID-19 severity and progression

Related Interest Area(s): CL,MA,ST,PE

Dan Housman
Graticule Inc.

Objectives:
●To evaluate treatment effects of SSRIs on preventing neuropathy progression and outcomes in COVID-19 patients using targeted learning
●To evaluate the relative performance of traditional methods, such as propensity score weighting and g-computation, and causal assumptions such as treatment positivity

Methods:
The N3C Data Enclave provides access to 12.1M patients' data from 70 contributing hospitals including 4M COVID-19 patients, ~1.2B clinical observations and 6.6B laboratory results. The study examines EHRs of patients who were tested for COVID-19 or had related symptoms. Demographic, symptom, lab result, procedure, medication, and physical measurement data of patients on Fluvoxamine will be examined. TMLE will be applied to evaluate the causal relationship between exposure and outcomes associated with COVID-19.

Results:
The database is representative of all age groups and ethnicities in the US. The database shows approximately 3.28K COVID-19 positive patients on Fluvoxamine between [X and Y]. Analyses are ongoing but indicate sufficient data components for deploying targeted learning for effect estimates.

Conclusion:
Targeted learning models will help to explore specific causal relationships between SSRI usage and COVID-19 prevention for better patient treatment and clinical care. This would pave the way to improving the precision with which treatment effects can be estimated using RWD.

[PO-06] Our challenges to save data management (DM) cost and enhance the quality in PMSs

Related Interest Area(s): COM

Yusuke Inoue
Development Novartis Pharma K.K.

Objectives:
Although the number of large-scale PMS has recently declined, Data Managers require more accurate work and the cost of PMS keeps increasing. We introduce our achievements on these challenges.

Methods:
Within the 14 PMSs we examined, we have standardized (1) CRF design using the standard EDC, (2) data management process, (3) database specifications, and (4) edit check specifications. At the same time, we also introduced the preferred CRO system with standard outsourced task list. In addition, we internally built the EDC for two PMSs by developing the new framework.

Results:
As a result of these efforts, we have reduced EDC development-related CRO costs by 35% and shortened set-up time by 20%. Additionally, pursuing standardization has minimized operational differences between PMSs and has accelerated information sharing among Novartis Data Managers along with the communication between Novartis and CROs, resulting in high PMS data quality. Furthermore, the two PMSs that were developed in-house saved almost 100% of EDC development-related CRO cost. These EDC self-development activities ultimately helped our Data Managers easily solve EDC system difficulties through their enhanced EDC knowledge and skills. We assume we are now ready to complete EDC development quickly by using in-house EDC, even in challenging situations such as all-patients-in PMS cases where swift study initiation is required.

Conclusion:
Introducing the standard DM process brings many advantages to PMS, despite considerable effort in this fast-changing environment. We can meet the diversified needs of PMS design with in-house EDC and continue our effort of driving process improvement to meet new challenges in the future.

[PO-07] Promoting use of real-world data for clinical trials within Sanofi Japan

Related Interest Area(s): CI

Yumiko Kawabata
Research & Development Sanofi K.K.

Objectives:
Considerations for promoting use of real-world data for clinical trials within Sanofi Japan

Methods:
We collected information on internal and external real-world data and investigated its characteristics, usage, and limitations in databases. Based on this information, we presented each department with a flowchart summarizing which databases can be used in which situations, past case studies, and limitations of using these databases. In addition, we discussed and reviewed how to utilize real-world data at a project-level meeting.

Results:
Sanofi Japan currently uses real-world data in many clinical trials. The global team utilized real-world data well at the beginning of our activity to promote its utilization; in contrast, the Japan team didn't because available databases and how to use them were unclear. We did not have the awareness to use databases because we did not have comprehensive database information in our company. Therefore, our activity focused on promoting data utilization to understand the actual status of Japanese patients, considering the differences in real-world data between Japan and the rest of the world, during the development planning phase and for the patient recruitment strategy. We first introduced use of real-world data to the entire department, but the utilization rate did not increase. Therefore, we conducted awareness activities such as creating a flowchart to show available databases and their usage and explaining directly to each department by preparing materials tailored to each department's situation and discussing and reviewing real-world data utilization at a project-level meeting. This approach worked.

Conclusion:
Searching databases to serve the research purpose can be confusing and present a psychological hurdle even for those interested in utilizing real-world data. It is important to lower this burden by introducing how to use these data, its benefits, usage cases, and using the data together.

[PO-08] Stability study requirement for registration application in Asian countries

Related Interest Area(s): RA,CP

Kenjiro Sasaki
Otsuka Pharmaceutical Co., Ltd., Regulatory Affairs Department

Objectives:
A stability study for Asian countries needs careful consideration due to multiple complex requirements.

Methods:
Based on the ASEAN guidance, the guidance applicable in each country, and our previous experience, we conducted a survey on the stability study requirements for the registration application in Asian countries. In particular, we focused on

site-specific stability study requirement and stability test condition based on each climatic region experienced in 13 countries (ASEAN and its neighboring countries).

Results:
Stability study requirements vary by country, making it difficult to establish the common stability plan for Asian countries due to the complexity of the requirements. In particular, the site-specific stability study requirement varied by country and many countries require strict conditions, such as the requirement that site-specific stability studies are required for each drug substance manufacturer, each drug product bulk manufacturer, and each drug product primary packaging site. These requirements are considered an issue in developing pharmaceutical products in Asian countries.

Conclusion:
It has become clear what kind of stability test should be planned from the perspective of site-specific stability study requirement and climatic region of each country. This will lead to effective pharmaceutical development and establishing an appropriate study plan in early development.