20th DIA Japan Annual Meeting 2023

Rebuilding Drug Development through Society 5.0: The Fusion of Knowledge and Technology that Transcends Time and Space

NOVEMBER 5-7
ARIAKE CENTRAL TOWER HALL&CONFERENCE

Program Overview

The 20th DIA Japan Annual Meeting will be held over three days under the theme of "Rebuilding Drug Development through Society 5.0: The Fusion of Knowledge and Technology that Transcends Time and Space.

In the conventional society (Society 4.0), there was a problem that knowledge and information were not shared and cross-disciplinary collaboration was insufficient. The society realized by Society 5.0 will overcome these problems by connecting all people and things through the Internet of Things (IoT), sharing various knowledge and information, and creating new value that has never existed before.

In the field of drug development, this social trend will require the emergence and active utilization of systems that highly integrate physical space (real space) and cyber space (virtual space) in ways that have never been envisioned before.

Under such circumstances, it is expected that we will be able to anticipate new trends in the future by fusing the knowledge and skills we have cultivated in our respective fields of expertise in drug development, or by connecting new collaborations. We hope that this meeting will be a forum where we can discuss the future of drug development by combining the knowledge and skills of past, present, and future with our stakeholders.

The meeting will be held at the Ariake Central Tower Hall & Conference. In addition to the traditional open call sessions, the conference will also feature a highly topical program in specialized fields from each community.

Endorsement by

MHLW, PMDA, AMED, JPMA, PhRMA, EFPIA, PDA, ISPE, ISPOR, MEJ

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

DIAglobal.org

Schedule

SUNDAY, NOVEMBER 5

9:30-12:45	Student Session, Short Course 1, 2, 3
12:45-13:45	Lunch Break
12:55-13:35	Orientation, Luncheon Seminar
13:45-14:15	Opening
14:15-14:45	Program Chair Session
14:45-15:00	Break
15:00-16:30	Keynote Address 1
16:30-17:00	Break
17:00-18:30	Keynote Address 2, S01, S02, S03, S04
18:30-18:45	Break
18:45-20:15	Young Professionals Exchange and Networking Session

MONDAY, NOVEMBER 6

9:30-11:00	Special Session 1, S05, S06, S07, S08
11:00-11:15	Break
11:15-12:45	DIAmond Session1, S09, S10, S11, S12
12:45-13:45	Lunch Break
12:55-13:35	Luncheon Seminar
13:45-15:15	Special Session 2, S13, S14, S15, S16
15:15-16:15	Break
15:30-16:00	Poster Sessions, Afternoon Seminar
16:15-17:45	Special Session 3, S17, S18, S19, S20
17:45-18:00	Break
18:00-19:30	Special Chatting Session

TUESDAY, NOVEMBER 7

9:30-11:00	S21, S22, S23, S24, S25
11:00-11:15	Break
11:15-12:45	DIAmond Session 2, S26, S27, S28, S29
12:45-13:45	Lunch Break
12:55-13:35	Luncheon Seminar
13:45-15:15	S30, S31, S32, S33, S34
15:15-16:15	Break
15:30-16:00	Poster Sessions, Afternoon Seminar
16:15-17:45	DIAmond Session 3, S35, S36, S37, S38
17:45-18:00	Break
18:00-18:30	Closing

This year's DIA Japan Annual Meeting will be held at the venue as follows.
After the event ends, it will be possible to watch on demand.

TRACK and ROOM

Track 1 : 4F Hall B
Track 2 : 3F Reception 1
←Simultaneous interpretation is included
Track 3 : 3F Room 1
Track 4 : 3F Room 6
Track 5 : 3F Board room

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. In addition, lectures that have been approved for viewing will be available until the end of December.

Private Social Function Policy

DIA does not allow hospitality functions to be held during any DIA educational offerings, scheduled Exhibit Hall hours, or social events. Below are the only hours that are acceptable for hospitality functions:

Saturday, November 4	Before 8:00 and after 21:00
Sunday, November 5	Before 8:00 and after 20:30
Monday, November 6	Before 8:00 and after 20:30
Tuesday, November 7	Before 8:00 and after 19:30

Unless otherwise disclosed, DIA acknowledges that the statements made by speak-ers/instructors are their own opinions and not necessarily that of the organization they repre-sent, 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 thera-peutics, and how they affect you. Our DIAmond Sessions will bring together innovators from industry, AC, and government agencies to discuss key concepts, and have a conversation on today's priorities.

See page 7, 15 and 18 for more details.

Related Interest Area ※[ ] after the Title is the crowned session of the community etc.

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

Sunday | November 5

STUDENT SESSION TRACK1 9:30-12:45

Appropriateness of Placebo-Controlled Trials : Consider Ethical Issues and Patient Consideration from Multiple Perspectives

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

SESSION CHAIR

Rensei Kazuhama
Tokyo University of Science Graduate School

One Sawasaki
Meiji Pharmaceutical University

Shunki Miyata
Tokyo University of Pharmacy and Life Sciences

While placebo-controlled trials are necessary in the drug development process to evaluate the efficacy of investigational products, ethical consideration for the subjects is also essential.

This session will first, introduce the concept of bioethics required for drug development and ethical considerations for subjects. Next, participants will consider the appropriateness of placebo-controlled trials and the necessary ethical considerations from various perspectives, using dementia as the target disease, in group work. Finally, we will look back on the group work and consider Patient Centricity activities, which utilize the voices of patients in drug development. We would like to think about the sense of ethics required in drug development and our feelings toward patients from multiple perspectives together with all participants.

Overview of Clinical Trials and Placebo Use in Medical Institutions
Atsushi Ujihara
Kitasato Univ. Kitasato Institute Hospital

Adviser
Motoki Arakawa, PhD
School of Pharmacy Nihon University
Katsuhiko Ichimaru
Pharmaceuticals and Medical Devices Agency (PMDA)
Mitsuo Ishikawa
Medii
Jun Yamakami, PhD
Sanofi K.K.

SHORT COURSE 01 : LIFE CYCLE MANAGENET TRACK 2 9:30-12:45

SHORT COURSE 02 : MEDICAL AFFAIRS TRACK 4 9:30-12:45

SHORT COURSE 03 : REGULATORY COMMUNICATION TRAINING TRACK 3 9:30-12:45

LUNCH BREAK 12:45-13:45

ORIENTATION TRACK 1 12:55-13:35

Junichi Nishino
Otsuka Pharmaceutical Co., Ltd.
Yukihiro Matsuda, MSc
Program Vice-Chair / ICOM Japan Plc.
DIA BAND

LUNCHEON SEMINAR 12:55-13:35

OPENING TRACK 1 13:45-14:15

Shogo Nakamori, MSc, RPh, MBA
SH DIA Japan
Marwan Fathallah
DIA Global.inc
Haruko Yamamoto, MD, PhD
ACJ Chair / National Cerebral and Cardiovascular Center
Koji Iwasaki, PhD
Program Chair / Osaka University Hospital

PROGRAM CHAIR SESSION TRACK 1 14:15-14:45

Management of Pharmaceutical R&D in the New Era ~Society 5.0~ with Integrating Knowledge and Skills that Transcend Time and Space

Related Interest Area(s): PM, SS, AC, COM, MA, PV, RA
Level: Intermediate, Advanced

SESSION CHAIR

Haruko Yamamoto, MD, PhD
National Cerebral and Cardiovascular Center

With the further development of the Internet of Things (IoT) and artificial intelligence (AI), it is expected that many stakeholders will be instantly connected and vast amounts of information will become intricate, transcending the boundaries of time, place, and language.

In this context, we will discuss the pursuit of new values required for future pharmaceutical medicine and the necessity of applying new management methods that integrate knowledge and skills cultivated to date with the latest methods in view of Society 5.0 for the research and development of pharmaceutical medicines.

Koji Iwasaki, PhD
Osaka University Hospital

BREAK 14:45-15:00

KEYNOTE ADDRESS 1 TRACK 1 15:00-16:30

Creating a Society in the near Future that Realizes Ultra-Early Disease Prediction and Prevention - Moonshot-type Research and Development Project-

Related Interest Area(s): TBD
Level: All

SESSION CHAIR

Koji Iwasaki, PhD
Osaka University Hospital

Until now, medicine has focused on treating diseases after their onset. In contrast, there are attempts to prevent the onset of disease by detecting the signs of disease and treating it in ultra-early stages. This new “medicine” aims to prevent the onset of various diseases by constructing a continuous bio-dataset from the healthy state through the ultra-early to the onset of disease, and by modeling mathematical analysis of the data. This type of new preventive medicine, on the other hand, faces many challenges, including medical insurance issues, patients privacy issues, appropriateness of intervention in the absence of symptoms, and society’s understanding of its value.

This session will introduce the current status of this Moonshot project to realize its comprehensive goals, which include medical biology and mathematics as well as Ethical, Legal, and Social Issues (ELSI) presented by experts from the social sciences.

Gen Sobue, MD, PhD
Aichi Medical University

BREAK 16:30-17:00

KEYNOTE ADDRESS 2 TRACK 1 17:00-18:00

Regulatory Innovation in Oncology Drug Development

Related Interest Area(s): RA
Level: Intermediate

SESSION CHAIR

Yasuhiro Fujiwara, MD, PhD

Pharmaceuticals and Medical Dvices Agency (PMDA)

Dr. Pazdur will review key milestones in oncology drug development based on his 25-year history of leading oncology at the US Food and Drug Administration. Topics will include past and current regulatory innovations, and review of ongoing and future challenges in oncology drug development.

Richard Pazdur, MD, PhD
Food and Drug Administration (FDA)

S01 TRACK 2 17:00-18:30

Think About the *Medical DX Reiwa Vision 2030* and Future Drug Information

Related Interest Area(s): RA, PV, MA, MC, CE
Level: Intermediate

SESSION CHAIR

Rie Matsui, RhD

Pfizer R&D Japan G.K.

Delays in conversion to DX (digital) in the medical field have been pointed out. The government has positioned the digitalization of medical care as one of its national strategies and launched the *Medical Reiwa DX Vision 2030* to deal with this issue.

This session will share the status of electronic prescriptions that started in January 2023, the status of personal health records, and the implementation status of HL7FHIR, an international standard that is accelerating overseas, based on the latest status of *Medical Reiwa DX Vision 2030*. To provide appropriate information to patients in light of the progress of patient guides that more fully consider health literacy, and other efforts that support the provision of information to patients using digital technology, we will discuss the future of digitalized drug information in Japan from the patient's point of view.

Updates on Japanese "Healthcare DX"
Yuji Ikai, MBA
Ministry of Health,Labour and Welfare (MHLW)

Points to Consider in Providing Information for Patients
Michiko Yamamoto, PhD
Kumamoto University

Impact of Global Health Informatics Standards on Digital Health
Mihoko Okada, PhD
Institute of Health Data Infrastructure For All

Panel Discussion
All Session Speakers

S02 TRACK 3 17:00-18:30

Cutting Edge Series - Future Life with Connected Technologies - from Food and FemTech Perspectives [CE]

Related Interest Area(s): CE, CI, OI
Level: Beginner, Intermediate
Language: Japanese Only

SESSION CHAIR

Takashi Moriya, PhD, MBA

CMIC Holdings, Inc.

Cutting Edge FoodTech or FemTech Innovations in the EU and US are significant and can change our daily life in such as diet, exercise, sleep, mental health, female and child care areas. These changes can even transform future "disease structures" in our society that may significantly impact our current medicine, healthcare, pharmaceutical and medical device industries. This session will deep dive into these future trends and discuss how they could apply to our works today.

Current Status and Future Innovations in Food
Yuki Tsuchioka
Health Table

Innovation within the Women's Health Space
Saki Oshima, MBA
Scrum Ventures, Inc.

Panel Discussion
All Session Speakers

S03 TRACK 4 17:00-18:30

Open Science Accelerated by COVID-19 and Followed by Evidence Generation in the Era of Artificial intelligence and Digital Transformation [MA]

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

SESSION CHAIR

Tadashi Urashima, PhD

GlaxoSmithKline K.K.

After the outbreak of the COVID-19 pandemic, there was a rapid increase in COVID-19-related preprints. This has enabled the swift dissemination of research findings, allowing researchers worldwide to monitor and draw insights for further studies and policy considerations, illustrating how the early release of data contributes to the acceleration of scientific progress. It is worth considering whether open science could also be beneficial in medical fields beyond COVID-19.

This session will discuss the utilization of open science, including its challenges, and explore the future of evidence generation and utilization.

Behind the COVID-19 Frontlines: Deciphering the Unknown in Emerging Infectious Disease
Toshibumi Taniguchi, MD, PhD
Chiba University Hospital

Current Situation of RWD Utilization in Pharmaceutical Companies and Case Studies of Evidence Building
Ayano Hata
Shionogi & Co., Ltd

Current Status and Outlook of Data Generation by Patients
Shinsuke Muto, MD,PhD, MBA
Integrity Healthcare Co., Ltd.

Panel Discussion
All Session Speakers

S04 TRACK 5 17:00-18:30

Introfuction to Project Management for Beginner : What is a Project? [Student OB/OG Educational Session]

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

SESSION CHAIR

Masato Koizumi

Tokyo Medical and Dental University Graduate School

The methodology of project management (hereinafter referred to as PM) is spreading throughout the medical and healthcare industries. There is a tendency to think that only project managers need to learn PM but if all project members (including young working adults) understand the concept, they can contribute to the smooth progress of the project.

Furthermore, it is expected that this understanding will lead to improved daily problem solving and work efficiency for each individual.

This session is aimed mainly at students and young working adults to learn and experience the concept of PM through lectures and group work. Another purpose is to provide an opportunity for participants to have interactive discussions with colleagues and feel closer to "project management."

Takashi Sato, MSc, PMD
PM Orchestra 310takashi

Masaki Kawai, MSc
The University of Tokyo

Groupwork
All Session Speakers

BREAK 18:30-18:45

YOUNG PROFESSIONALS EXCHANGE AND NETWORKING SESSION
3F and 4F Foyers 18:45-20:15

Monday | November 6

SPECIAL SESSION 1 TRACK 1 9:30-11:00

Orphan Drug Development Update : Issues and Measures for Global Cooperation

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

SESSION CHAIR

Kenichi Tamiya
Pharmaceuticals and Medical Devices Agency (PMDA)

This session will review the current regulations and status of Japan, the European Union (EU) and the US with respect to orphan drug development. This will allow us to recognize the differences between the regulations and the approaches to drug development in each region. We will subsequently discuss the management of these differences with the goal of getting better treatments to patients faster. We also invite representatives of regulatory authorities and/or academia from other emerging Asian economies into this discussion.

Orphan Drug Development Update: Issues and Measures for Global Cooperation
Sandra Retzky, MPH
Food and Drug Administration (FDA)

Orphan Drug Development Update : Issues and Measures for Global Cooperation
Christine Nguyen, MD
Food and Drug Administration (FDA)

European Orphan Medicines Regulations
Kristina Larsson
European Medecines Agency (EMA)

Regulatory Approach to Promote Orphan Drug Development in Japan
Koshin Kiyohara
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

S05 TRACK 2 9:30-11:00

CDM : A Basis for Clinical Research Collaborations [CDM]

Related Interest Area(s): CDM, PC, AC, ST
Level: Intermediate, Advanced

SESSION CHAIR

Kaye Fendt, MSPH
Data Quality Research Institute (DQRI)

At the 2023 DIA Japan CDM Workshop session What Are We Missing Going Forward in CDM?, the DIA CDM Core Committee discussed the rapid changes in clinical development environment due to new technologies and methodologies.

This session will present and build on sentient points from that CDM Workshop session to show how CDM is the cornerstone for all present and future collaborations. CDM has the central responsibilities for designing, implementing, and integrating information to support quality data for clinical research conduct and analysis. Without CDM, one cannot communicate, direct, and support quality data integration into clinical research.

Quality Data Communications for All Stakeholders in the New Environment
Mary Banach, MPH, PhD
Vanderbilt University Medical Center

Coding for the New Environment
Samina Qureshi, MD, MSc
MSSO

Industry Perspective on Risk-Based Quality Management (RBQM) in the New Environment
Johann Proeve, PhD
Cyntegrity

Panel Discussion
All Session Speakers and
Stephen Wilson, PhD
Food and Drug Administration (FDA)
Mika Ogasawara
Pfizer R&D Japan

S06 TRACK 3 9:30-11:00

Let's Dialogue about the Future of Treatment Development for Rare Cancers - Steps Toward Unmet Needs -

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

SESSION CHAIR

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

A rare cancer is defined as an annual incidence of less than 6 cases per 100,000 population. Although it accounts for about 15-22% of all cancer types, the number of patients is small, so elucidation of the pathology and clinical trials have not progressed, and the establishment of treatment methods has become an issue. While several efficient strategies such as the MASTER KEY project, a platform trial for rare cancers under industry-academia-patient collaboration, have been performed in Japan, there remain many issues such as unresolved patient needs and innovative development methodology that have not yet been started.

In this session, we will look back on the knowledge and techniques of treatment development for rare cancers. We would like to envision the future of treatment development in Society 5.0, the value that each stakeholder wants to provide, and what stakeholders can do as One Team.

A Platform Study for Rare Cancers : MASTER KEY Japan and Asia
Hitomi Okuma, MD, PhD
National Cancer Center Hospital

Consideration of Unmet Needs from the Cancer Patient's Perspective
Sumito Nishidate
Rare Cancers Japan

Pharmaceutical Company Perspective on Current and Future Clinical Development in Rare Cancers
Yuichi Hirata, MD, PhD
Nippon Boehringer Ingelheim Co., Ltd.

Panel Discussion
All Session Speakers and
Takuji Ueno
Ministry of Health, Labour and Welfare (MHLW)

S07 TRACK 4 9:30-11:00

Your Life Data for the Sake of Greater Good ? How to Deploy Wearable Devices [OT Educational Session]

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

SESSION CHAIR

Akiko Nishioka
Novartis Pharma

In recent years, it has become commonplace for individuals to obtain

their own life data with wearable devices. Although many companies are trying to utilize data from wearable devices to improve work productivity or maintain health, there are other cases of utilization that can lead to behavior modification. On the individual level, there may still be people who have not fully used their life data for daily health monitoring.

This session will introduce through panel discussion the individual use of life data and the development of guidelines for disease prevention and health maintainance using digital health technology, and provide an opportunity to consider an individual lifestyle that makes use of these data.

Health Promotion Program with Wearable Devices
Yoshimasa Ogawa
Pfizer Health Insurance Society

A Smartphone App for Improving Physical Activity and Mental Health among Workers
Kazuhiro Watanabe, PhD
Kitasato University School of Medicine

Data Use and Analysis with Pep Up
Masakatsu Hattori, MD
JMDC inc.

Panel Discussion
All Session Speakers and
Masato Koizumi
Tokyo Medical and Dental University Graduate School

S08 TRACK 5 9:30-11:00

Patient-Centric Informed Consent : How We Can Design IC Process and Empower Participants?

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

SESSION CHAIR
Junichi Kawana
Pharmaceuticals and Medical Devices Agency (PMDA)

The adoption of eConsent enables various approaches to support the diverse decision-making needs of patients. This session will discuss how to design the consent process and support the diverse decision-making process of patients in future clinical trials, based on clinical trial eConsent experiences and other research including patient survey results. To provide a variety of consent options tailored to the needs of patients, it is essential to have prior operational consultations with the implementing medical institutions providing these consent explanations. We hope to discuss patient-centered clinical trials and patient empowerment from the perspective of various stakeholders to consider changes in the consent process.

Designing eConsent : – Considerations and Challenges for Improving Understanding and Engagement of the Patients -
Yumi Inadome, MPH
IQVIA Servicies Japan K.K.

Patient-Centered IC Considered thorough eConsent Adoption in Clinical Trials in Japan
Mami Takahashi
Chugai Pharmaceutical Co., Ltd.

e-Consent Initiated by Osaka University Hospital
Kento Asano, MHS
Osaka University Hospital

Panel Discussion
All Session Speakers and
Yoshiyuki Majima, MPH
Pancreatic Cancer Action Network Japan

BREAK 11:00-11:15

DIAmond SESSIONS

DIAMOND SESSION 1 TRACK 1 11:15-12:45

China Townhall

Related Interest Area(s): RA, COM, CDM, CG, CMC
Level: Advanced

SESSION CHAIR
Ling SU, PhD
Shenyang Pharmaceutical University, Yeehong Business School
Naoyuki Yasuda
Pharmaceuticals and Medical Devices Agency (PMDA)

The Chinese government and NMPA are integral to the global regulatory system, particularly in Asia. At the same time, China has the magnificent goal of leapfrogging to be a great pharmaceutical power in the following years. In this Japan Annual Meeting (JAM), we set up the China Townhall, inviting the NMPA delegation and professionals in the Chinese drug R&D industry to share a wonderful Chinese drug R&D outlook for JAM's audience via presentations and panel discussions.

China's IND Policy and International Cooperation & Exchange
Jiangping DONG
China Center for Food and Drug International Exchange (CCFDIE), National Medical Products Administration (NMPA), China

Progress and Achievements of China's Drug Evaluation and Clinical Trials
Jun WANG, PhD
Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA), China

Progress and Achievements of China's Drug Inspections
Congfan HAN
Center for Food and Drug Inspection (CFDI), National Medical Products Administration (NMPA), China

Panel Discussion
All Session Speakers and
Meng YU
Jiangsu Medical Products Administration (Provincial)
Wendy YAN
BeiGene (Beijing) Co., Ltd.
Joyce LIU
Takeda Greater China
Connie CHEN
Tigermed Consultng Co., Ltd.

S09 TRACK 2 11:15-12:45

FDA and PMDA Update : Oncology Drug Development and Regulation [PMDA]

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

SESSION CHAIR
Shinichi Okudaira, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)
R. Angelo de Claro, MD
Food and Drug Administration (FDA)

Experts from FDA and PMDA have been meeting monthly since January 2014 to discuss marketing applications and other issues in drug development for cancer drugs. In this session, FDA and PMDA will share their respective approaches on expediting cancer drug development and discuss opportunities for collaboration between FDA and PMDA. Panelists and the audience can discuss a wide range of topics including novel regulatory review programs (i.e., Project Orbis), Real-Time Oncology Review and Assessment Aid, and multi-regional clinical trials with a special focus on Administrative initiatives related to drug development for rare cancers and companion diagnostics.

Oncology Drug Development and Regulation : US FDA Perspective
R. Angelo de Claro, MD
Food and Drug Administration (FDA)

Regulatory Framework for Facilitating Development of Oncology Drugs in Japan
Masakazu Hirata, MD
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Richard Pazdur, MD
Food and Drug Administration (FDA)
Hiroshi Yaginuma
Pharmaceuticals and Medical Devices Agency (PMDA)
Yoko Aoi, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)
Dianne Spillman
Food and Drug Administration (FDA)
Kristina Larsson
European Medecines Agency (EMA)

S10 TRACK 3 11:15-12:45

What's the Neighborhood Do ? A Quality Strategy for all Stakeholders

Related Interest Area(s): CDM, ST, COM, MA, MC, SS
Level: Intermediate
Language: Japanese Only

SESSION CHAIR
Yuko Yamahara
Kobe University Hospital

Ensuring the "quality of trial data" required for clinical trials is a matter of forming a common understanding among stakeholders. Discussions for the future can only begin when everyone shares a common understanding of the true nature of trial data. The conventional approach to ensuring quality has been to discuss the issue within the context of roles that emphasize expertise. But communication that transcends role boundaries could become a new strategy for clinical development from now on. Discussions by all stakeholders will effectively realize trials based on the "Critical Quality Factor."

In this session, multidisciplinary professionals will present their efforts in their respective roles, and discuss the results as a first step to gain mutual trust and establish a good relationship.

Perspectives of Medical Institutions (Clinical Study Coordinator)
Masumi Yamazaki, PhD
Cancer Institute Hospital of JFCR

A Quality Strategy for All Stakeholders
Yuta Inoue
A2Healthcare Corporation

Quality for CDM
Emi Shibusawa, Master
Japan Tobacco Inc.

Panel Discussion
All Session Speakers and
Hideki Suganami, PhD
Kowa Company. Ltd.

S11 TRACK 4 11:15-12:45

Challenges in Transforming Interactive Communication in Drug Development Using Open Source Software

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

SESSION CHAIR
Hiroyuki Ugai, MSc
MSD K.K

In various aspects of drug development, data utilization through use of open source software (OSS) such as R and Python has been widely increasing. Examples of OSS utilization include data visualization and an efficient tool that can create not only analysis results but pre-set descriptions by running a program.

The R Consortium in the US has recently tried to submit the electronic data generated by R to the US FDA as a pilot case. This session will present the basic topics and company efforts related to OSS; panel discussion will focus on use of OSS considering our current industry status and future prospects.

Utilization and Consideration of Open-Source Software
Taku Sakaue, MSc
Chugai Pharmaceutical Co., Ltd.

Promoting Interactive Communication with R Shiny
Kento Emori, MSc
MSD K.K

Creating Reproducible Analysis Documents with R Markdown
Yoshihiko Kunisato, PhD
Department of Psychology, Senshu University / Agency for wellness assessment research and development

Effective R Submission Readiness: Sponsor's Point of View
Yuichi Nakajima, MSc
Novartis Japan

Panel Discussion
All Session Speakers and
Satoru Tsuchiya, MS
Japan Pharmaceutical Manufacturers Association (JPMA) / Sumitomo Pharma Co., Ltd.

S12 TRACK 5 11:15-12:45

Fundamental Question of Trial Participation : What are the Ethical Issues in Clinical Trials ? Let's Talk About It Together

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

SESSION CHAIR
Kento Asano, MHS
Osaka University Hospital

With the launch of the ICH E8 R1 guideline, we have entered an era in which many relevant stakeholders engage in dialogue to produce fit-for-purpose clinical trial plans. However, what are the beneficial aspects of decision-making in clinical trial participation with the patient family, the healthcare provider, and trial sponsor?

This session will focus on new technologies such as eConsent and ePRO, the patient-healthcare specialist relationship, and the use of data in clinical trials, with the aim of raising awareness of participation in clinical trials. This session is organized to help everyone think about, and take away insights from, the fundamental questions of participating in a clinical trial.

Barriers to Informed Consent and Shared Decision Making in Clinical Trials
Nao Moriyama, Msp
Teikyo University Hospital

Barriers to Patient Participation in Clinical Trials
Sachie Yoshida, PhD
Chiba University Hospital

Barriers Associated with New Technologies and Data Sciences in Clinical Trials
Nobutaka Yagi, Msc
Nippon Boehringer Ingelheim Co. Ltd.

Panel Discussion
All Session Speakers and
Toru Sugimoto
Buzzreach Inc.
Noriko Iwaya
Intractable Disease Society Support Familia Yamaguchi

LUNCH BREAK 12:45-13:45

LUNCHEON SEMINAR 12:55-13:35

SPECIAL SESSION 2 TRACK 1 13:45-15:15

Let's Talk About Ensuring the Ethics, Science, and Reliability of Post-Marketing Surveillance (PMS) for the New Era of Society 5.0.

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

SESSION CHAIR
Hideki Oi
National Center of Neurology and Psychiatry
Keisuke Suzuki, MD, PhD
National Center for Geriatrics and Gerontology

The revision of the Good Post-Marketing Study Practice (GPSP) in April 2008, enabled the use of databases in the PMS. However, there are no clear rules regarding informed consent and ethical review in PMS, and ethical issues still remain. In addition, the PMS system and its operation to ensure reliability are still insufficient at many medical institutions that implement the PMS.

In this session, speakers from the perspectives of academia, medical institutions, pharmaceutical companies, bioethics, and regulatory authorities (Drug Safety Division, Ministry of Health, Labor and Welfare) will present the results of at Japanese survey, initiatives by pharmaceutical companies, ethical issues, and the future direction of post-marketing pharmacovigillance, and exchange views on PMS for the new era of Society 5.0.

Issues with the Drug Use-Results Surveys Revealed through a Nationwide Questionnaire Survey of Hospitals and Pharmaceutical Companies
Manabu Hirashima
National Hospital Organization Nagoya Medical Center

Status on Post-Marketing Surveillance, after Revision of Good Post-Marketing Study Practice
Makoto Miyazaki, PhD
Japan Pharmaceutical Manufacturers Association(JPMA)/MSD K.K.

TBD
Megumu Yokono
Waseda University

TBD
Yumiko Nomura
Ministry of Health, Labor and Welfare (MHLW)

Panel Discussion
All Session Speakers and
Nao Moriyama
Teikyo University Hospital
Mami Yoshioka
Tokyo Metropolitan Institute for Geriatrics and Gerontology

S13 TRACK 2 13:45-15:15

The Direction of Regenerative Medical Product Review from the Experiences of Ten Years and the Future [CG]

Related Interest Area(s): CG, CMC, RA, PV, AC, MA, BE
Level: Beginner

SESSION CHAIR
Kiyoshi Okada, MD, PhD
Osaka University

In the ten years since the revision of the PMD Act, the number of approved regenerative medical products has increased and the concept of review of these products has matured. In addition, the MHLW study group has started preparing a guideline to illustrate the thinking behind the level of evidence required for approval of regenerative medical products and post-marketing evaluation of conditional and time-limited approval products. Lectures in this session will present points to consider in the review of regenerative medical products and the principles shown in the draft guideline. A PMDA reviewer will explain unique points to consider for regenerative medical products based on past experience. We will also discuss issues that should be addressed by product developers when they apply for product approval.

Review Experience of 10th anniversary Regenerative Medical Products
Shinichi Noda, PhD
Pharmaceuticals and Medical Dvices Agency (PMDA)

Background and Direction of the Draft Evaluation Guideline for Conditional and Term-limited Approval of Regenerative Medical Products and Subsequent Development of Efficacy Evaluation Plans
Yoji Sato, PhD
National Institute of Health Sciences

Panel Discussion
All Session Speakers and
Mitsuaki Chujo, PhD
AnGes, Inc.
Takashi Moritoyo, MD
Tokyo University

S14 TRACK 3 13:45-15:15

Toward Society 5.0 : What We Should Do / Can Do Now for Delivery of and/or Access to Correct Medical Information [PV]

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

SESSION CHAIR
Kasumi Daidoji, PhD, RPh
Eisai Co., Ltd.

Currently in Society 4.0, there is a flood of information on medical care and pharmaceutical products, and patients and their families cannot access the information they are searching unless their active effort. Even if they can access the information, there is no guarantee that it is correct, and they needs to improve their literacy in order to make the right decisions.

This situation is becoming more and more common with the spread of chat GPT. Society 5.0 is expected to make use of technologies such as AI, robots, and IoT to realize a society where people can easily access the correct information when they want it, without forcing them to improve their search skills or literacy. In this session, we will discuss what we should do / can do now towards the upcoming Society 5.0.

Enhancing Health Literacy for All
Kyoko Kitazawa, MSc
Kyoto Pharmaceutical University

Current Status and Issues in Providing Cancer Information
Fumihiko Wakao, MD
National Cancer Center

From a Corporate Perspective : Challenges and Expectations in Utilizing Medical Information
Kazumitsu Kanatani
Chugai Pharmaceutical, Co., Ltd.

Panel Discussion
All Session Speakers

S15 TRACK 4 13:45-15:15

Data Integrity from Electronic Health Record (EHR) to Electronic Data Capture (EDC) from the Medical Practice and Clinical Trial Views

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

SESSION CHAIR

Eri Sekine
CMIC Co., Ltd.

The promotion of EHR to EDC data integration in Japan has been discussed among sponsors, clinical trial sites, and IT vendors using laboratory data as an example. In this case, we first extracted laboratory data from three EHRs to understand the operational status of EHR data. After that, discussions were held on trial information, study participants' data, visit data, standardization of provided data contents, file format, traceability, etc. A versatile data integration model and the relationships among relevant parties were also examined.

This session will share the results of these discussions and consider the future of EHR data in Japan and what industry should work on to promote its secondary use in clinical trials.

Data Integrity from EHR to EDC ~ From the View of Medical Practice and Clinical Trial ~
Mika Ogasawara
Pfizer R&D Japan
Hiroyuki Yamada, MSc
Novartis Pharma K.K.

Initiatives for Improvement of Clinical Trial Operation at Shikoku Cancer Center - From the Point of View of CRC -
Mika Okamoto
National Hospital Organization Shikoku Cancer Center

Efforts at National Cancer Center Hospital East (Tentative)
Mikina Takiguchi
National Cancer Center Hospital East

Panel Discussion
All Session Speakers and
Munenori Senzaki, MSc
IBM Japan, Ltd.
Mitsune Yamaguchi, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

S16 TRACK 5 13:45-15:15

Hints for Utilization of Real World Data in Drug Development -Maximization of RWD Utilization Value Corresponding to the Issue to be Solved-

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

SESSION CHAIR

Yoshifumi Ukyo, PhD, MPH
Janssen Pharmaceutical K. K.

There is growing momentum for the use of real-world data (RWD) in drug development in Japan. However, progress in the use of RWD in Japan has been slower than in western countries, and a mismatch between application opportunities and objectives is one of the factors preventing progress in RWD use. In addition, RWD is less important when the purpose of application can be otherwise achieved through clinical trials or post-marketing surveillance, so its use should focus mainly on rare diseases and other aspects that are more difficult to evaluate. To address the mismatch between application opportunities and objectives, it is important to sort through and discuss past cases to gain better understanding of the issues and methodologies.

This session will present tips and directions for the use of RWD.

Experience and Challenges of RWE Generation for Regulatory Purposes as a Database Provider
Masakatsu Hattori, MD
Real World Data Co., Ltd.

Consideration of Using RWD in Drug Evaluation
Sachiko Tanaka, PhD
Graduate School of Medicine Kyoto University

Pharmacoepidemiological Perspective on the Use of Medical Information Databases in the New Drug Application
Chieko Ishiguro, PhD, MPH
National Center for Global Health and Medicine

Panel Discussion
All Session Speakers

BREAK 15:15-16:15

POSTER SESSIONS, AFTERNOON SEMINAR 15:30-16:00

S17 TRACK 1 16:15-17:45

Field-Based Reconsideration of Protocol Design [COM]

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

SESSION CHAIR

Toshiko Ishibashi, RN, PhD
Daiichi Sankyo Co., Ltd.

Patient and public involvement in drug development is becoming more important, with a growing trend of investigators seeking opinions from doctors, clinical research coordinators (CRCs), and patient groups. However, the burden points experienced by patients in reality are still not adequately understood or utilized in the development and design phase of protocols. This international panel discussion will explore future initiatives for field-based reconsideration of protocol design in Japan based on global examples. We will also share the results of a site management organization (SMO) survey conducted in Japan regarding reasons why patients refuse to participate in a study, and discuss corporate initiatives and challenges in incorporating the patient's voice into protocols.

Assessing Patient and Site Participation Burden to Optimize Protocol Design
Kenneth Getz, MBA
Executive Director and Professor CISCRP

Sponsor Perspectives - Stakeholder Involvement in Protocol Development -
Ryoichi Tanaka
Daiichi Sankyo Co., Ltd.

Investigator Perspectives - Own Experiences and Initiatives at Various Academic Societies -
Jiichiro Sasaki
Kitasato University Hospital

Panel Discussion
All Session Speakers and
Naomi Sakurai
CSR-Project, NPO

S18 TRACK 2 16:15-17:45

We've Come this Far! Implementation of Automation of Safety and Regulatory Authority Initiatives

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

SESSION CHAIR

Hirotami Ohara, RPh, MBA, PharmD, PMP
TransCelerate /Sanofi K.K.

A presentation from TransCelerate on the automatic acquisition of Individual Case Safety Reports (ICSR) by Robotic Process Automation (RPA) and machine learning based on Artificial Intelligence (AI) was conducted in the *DIA Japan Annual Meeting 2021.* In addition to this TransCelerate report, the activities of the PV Committee of the Japan Pharmaceutical Manufacturers Association were introduced. Two years have since passed.

This session will update information on implementation of automation of safety management information processing such as ICSRs and the status of acceptance and utilization by regulatory authorities including Japan. In addition, an expert panel will discuss current issues, furthering industry-government-academia collaboration on automation of pharmacovigilance activities, improving the PV environment, streamlining operations, etc., and share the vision of this future with everyone.

Considerations for Validating Artificial Intelligence (AI)-based Static Systems in Pharmacovigilance
Oeystein Kjoersvik
TransCelerate Biopharma / MSD

Automation of Safety Management Information Processing Operations using Advanced AI, ML, and NLP Technology
Inderdip.S Khorana
IQVIA Services Japan.K.K

Initiatives by Regulatory Authorities for Operations of Processing Safety Management Information including ICSRs
Kenji Kuramochi
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Makoto Morita, PhD
Japan Pharmaceutical Manufacturers Association (JPMA) / Pfizer Japan Inc.

SPECIAL SESSION 3 TRACK 3 16:15-17:45

Consider the Future of the Pharmaceutical Industry : What Value Can DIA Create?

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

SESSION CHAIR

Goshi Ozawa
Real Discovery Outdoors Co,.Ltd.

The environment surrounding the pharmaceutical industry has been changing dramatically in recent years, and the development of therapeutic products is not limited to the development of pharmaceuticals and medical devices but also extends to healthcare. What value can DIA Japan create for these industries, including healthcare? This session will share the problems currently facing each specialty area, and discuss with participants the value that DIA can create in response.

Reflections from 3rd DIA Community Day - Current Tasks and what can be done with DIA
Noriaki Nagao
JAPAN TOBACCO INC.

Horizon Scanning from 2040 ; Discussion at DIA Cutting Edge #1
Keita Asato, MBA, PhD
Amgen K.K.

Panel Discussion
All Session Speakers and
Kotone Matsuyama, RPh
Nippon Medical School
Yukihiro Matsuda, MS
ICON.plc
Sonoko Misawa MD, MPH, PhD
Chiba University Graduate School of Medicine
Akira Nakanishi
Ministry of Economy, Trade and Industry (METI)

S19 TRACK 4 16:15-17:45

How We Drive the Changes : A Change Framework with Psychological Safety [SS]

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

SESSION CHAIR

Hirotaka Inoue, PhD, MBA
GlaxoSmithKline K.K.

As uncertainty in the modern business environment continues to increase, teams and projects must be agile to meet these changes and uncertainties. Change management often depends on an individual's skills/expertise, but systematic/standardized execution will increase the speed and the probability of success. Engagement with those involved in the change, and ensuring psychological safety among the team and stakeholders, are two foundations for successfully driving change. In addition to explaining effective change management methods, this session will introduce how to ensure psychological safety during change from the leadership and community-based perspectives using actual business cases, so the audience can identify clues for successfully implementing changes.

How Do We Apply the Organizational Change Management Framework
Naomi Yoshida
GlaxoSmithKline K.K.

Psychological Safety at Work : Leaders' Perspectives
Michiko Ono-Kishino, PhD
Sumitomo Pharma Co., Ltd.

Psychological Safety at Work : Case Study : Community-Based Approach
Satoshi Suzuki
Pfizer R&D Japan

Panel Discussion
All Session Speakers

S20 TRACK 5 16:15-17:45

What Will Happen to SaMD Development Under the Revised Next Generation Medical Infrastructure Act ?

Related Interest Area(s): CDM, CI, RA, O
Level: Intermediate
Language: Japanese Only

SESSION CHAIR

Kensuke Ishii, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

The development of Software as a Medical Device (SaMD) is gaining momentum and regulatory authorities are strengthening their review and consultation systems for these new products. The Next Generation Medical Infrastructure Act (NGMIA) was revised against this backdrop to allow the use of real-world data in regulatory applications. It is expected that the utilization of image data, which has been a bottleneck in the development of AI for diagnostic-imaging SaMD, will make significant progress in the future. This session will discuss the impact of the amendment of the NGMIA on the development of SaMD and on drug development.

Next Generation Medical Infrastructure Act Revision Promotes Utilization of Medical Information
Naoko Amino, Master
National Healthcare Policy Secretariat

Development of the SaMD for Colonoscopy and Hope for Next Generation Medical Infrastructure Act
Masashi Misawa, MD, PhD
Digestive Disease Center, Showa University, NorthernYokohama Hospital

Frontiers of Medical Imaging AI
Yuki Shimahara, PhD
LPIXEL Inc.

Panel Discussion
All Session Speakers and
Naoki Nakashima, MD, PhD
Medhical Information Center, Kyushu University Hospital
Junichi Oishi, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

BREAK **17:45-18:00**

SPECIAL CHATTING SESSION
4F Foyers and Meeting Rooms **18:00-19:30**

LET'S CHAT! "WHAT'S THE DIA WORLD 2023"

4F FOYERS AND MEETING ROOMS

18:00-19:30

Related Interest Area(s): ALL
Level: ALL

Session Chair

Miyoko Yamauchi

Chugai Pharmaceutical Co., Ltd. / COM Program Committee Chair

The Special Chatting Session will be held on the evening of the second day of the meeting. One of the main purposes of DIA is to exchange our opinions!

We hope you will take advantage of this opportunity to network and exchange ideas with other participants. Whether you are a younger or a more experienced person, or work in academia, investigational sites, or with PMDA, please join our chat. Even if you are attending this event alone, we invite you to join our circle and discuss with us the topics that interest you – then, we are ALL companions!

This year, we offer fifteen (15) themes, including a theme from a new community, for you to enjoy chatting about. Facilitators from each community will be present, so please join us the table that will discuss the topic of your interest. So let's have a fun chat at the venue!!

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

<List of Topics>

Please stop by the table of your interest on the day of the meeting. You can join, leave, or move around during the meeting.

***Details will be available in October.**

#	Committee	Topic	Abstract
1	Bioethics	How to ensure diversity in clinical trials in the era of digital transfor-mation	In order to conduct clinical trials in the era of digital transformation, it is necessary to improve the environment for clinical trial participation and decision-making support from various perspectives. Participation of the elderly and other socially vulnerable groups Information from ePRO, eConsent, and DCTs Diversity as a human right: Inclusive decision-making process
2	Clinical Data Management	Toward Society 5.0: Challenges in data collection and expectations for CDM	In the days of Society 5.0, the topic of "data" is inevitable. With a view toward innovation and ICHE6 (R3), we would like to discuss topics from CRFs to new types of data, any questions around data collection, and expectations for CDMs toward the new era, with people outside the CDM field.
3	Clinical Innovation	What is the current state of innovation in clinical development?	The development of various digital technologies is accelerating innovation in clinical trials. We would like to explore industry trends and the future of drug development by exchanging opinions on how participants perceive and intend to incorporate the current paradigm shifts such as digitization, remote access, AI, utilization of RWD, and regulatory applications using RWE.
4	Clinical Operation & Monitaring	Decentralized Clinical Trial (DCT) Risk Based Approach (RBA)	Let's talk frankly about DCT and RBA: Why they are highly desired, who is con-sidering introduction, who have already introduced them, and who still needs to introduce them!
5	Clinical Pharmacology	Early clinical development, which is being changed by Project Optimus and Big-Boned Policy 2023!	Regulatory agencies in the US and Japan recently announced an initiative and policy which will have major impacts on early clinical development. We will exchange opinions about how clinical pharmacology can play an important role in this new framework and expand our influence in clinical development.
6	Medical Affairs	Shall we talk about the value of MA activity in the development and submission phases	Shall we talk together about how MA can collaborate with other functions such as drug development or regulatory, from the development to the submission phase, to successfully launch novel drugs, or what value MA brings to that?
7	Medical Communication	How can we efficiently deliver appropriate pharmaceutical information to patients in a timely manner?	To achieve the ideal state of efficiently delivering appropriate pharmaceutical information to patients in a timely manner, we will discuss key challenges that require further consideration, given the environmental changes such as digital transformation and the increasing significance of leveraging patient insights and real-world data.
8	Open Innovation	Let's learn about the current mainstream of drug development: Open Innovation	Drugs are not created only by pharmaceutical companies. The interface 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 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	Let's think about what and to what extent patients' voices would influence.	The GCP Renovation includes using the patient voice in drug development. The purpose of this session is to clarify which processes will be able to utilize the patient voice and how to define and measure successful use.
10	Pharmacovigilance & Labeling	How do RMP & risk communication in Japan look from the global perspective?	Concerning RMP & risk communication currently being implemented in Japan, we will think about outstanding points that should be globalized and spread around the world, and conversely, points that are worth reconsidered from a global perspective, objectively looking at Japan in the world. Furthermore, let's think freely and discuss the future, the state they should be, and ideal state of RMP & risk communication!
11	Project Management	Let's talk about leadership that creates new value by fusing knowledge and technology.	-
12	Regulatory Affairs	Regulatory Issues to Solve Drug Lag/Drug Loss	Discussions are continuing at the study group* on pharmaceutical regulations to strengthen drug discovery capabilities and ensure stable supplies in Japan. We would like to discuss the impact on drug development and regulatory activity based on the proposal and discussions from the study group. *the study group on pharmaceutical regulations to strengthen drug discovery capabilities and ensure stable supplies in Japan.
13	Six Sigma	Discuss the concept of risk-based quality management necessary for QbD (Quality by Design) in clinical trials, open dialogue with stakeholders, and necessary facilitation methods.	QbD defined in the ICH E6(R3) requires quality management plan based on a risk-proportionate approach for CTQ items and other items during protocol planning its proper execution. Let's talk about the challenges and team facilitation methods for realizing QbD through open dialogue with stakeholders.
14	Statistics	What changes will generative AI such as Chat GPT bring to drug development?	In the pharmaceutical industry, efforts have begun to improve the efficiency and productivity of daily business using generation AI, such as ChatGPT. What is generation AI in the first place? What new benefits will it bring to our industry, especially in drug development? Let's chat frankly.
15	Health Economics and Outcomes Research	Rainbow-Colored Value: Various Important Factors HEOR / Market Access / Medical & Health Policy / Clinical Development	Value of a care takes many forms depending on our perspective or the disease. Dementia? Skin disease? Cancer? Diabetes mellitus? Infectious disease? What form will it take from the perspective of patients, HCPs, the caregivers, society, etc.? Let's feel free to talk together !

Tuesday | November 7

S21 TRACK 1 9:30-11:00

Exploring IRBs with a Global Twist!

Related Interest Area(s): AC, COM
Level: Intermediate, Advanced

SESSION CHAIR

Kiyomi Hirayama, PhD
MSD K.K.

IRBs have an important responsibility from the viewpoint of subject protection, but are Japan's current IRBs adequately fulfilling this responsibility? Compared to IRBs in other countries, there are significant differences in the method and scope of review (e.g., use of expedited review, review of safety information, etc.). Shouldn't IRBs consider adopting a risk-based approach and focus on important matters within a limited resource? In Japan, the Central IRB has not been utilized like other countries, making it more inefficient. While other countries are moving toward having IRBs conduct audits to ensure the quality of clinical trials at their sites, we will discuss with the audiences the role of IRBs in Japan based on the situation in other countries.

FDA Regulation of Institutional Review Boards
Jan Hewett
Food and Drug Administration (FDA)

IRBs in Australia and New Zealand – Risk-based and Centralised Approach
Rebecca Boesenberg
Novartis Pharmaceuticals

IRB in Taiwan Collaborative IRB Process and IRB Inspection
Fung-Wei Chang, MD, PhD
Taiwan Association of Institutional Review Boards

Panel Discussion
All Session Speakers and
Naoto Uemura, MD, PhD
Oita University
Yusuke Fukuda
Ministry of Health, Labor and Welfare

S22 TRACK 2 9:30-11:00

Beyond ICH M11-How will the Digitalization of Protocol Data Transform Drug Development? -Future Perspective- [MC]

Related Interest Area(s): MC, CI, RA, CP, CDM, OI, AC, PM, CE, ST (MC)
Level: Intermediate, Advanced

SESSION CHAIR

Satoru Tsuchiya, MS
Japan Pharmaceutical Manufacturers Association (JPMA) / Sumitomo Pharma Co., Ltd.

Ken Sakushima, MD, MPH, PhD
Hokkaido University Hospital

The utilization of clinical trial information as data is expected to improve the efficiency of clinical trials and increase the interaction between clinical practice and clinical trials. The ICH M11 Guideline may be an opportunity to start this these digital transformation. The ICH M11 Guideline will standardize and structure protocol information in a form that can be exchanged digitally. The utilization of this standard specification may lead to change from document-based communication to component-based communication.

This session will present the efforts of various organizations regarding these future prospects and discuss the expectations and the challenges for future drug development. This session and S26 are a series of sessions.

TBD
Ronald Fitzmartin, MBA, PhD
Food and Drug Administration (FDA)

Expectations and Challenges for ICH M11 as a standard development organization. (Tentative)
David A. Evans
CDISC

TransCelerate Digital Data Flow (DDF) Overview
Hideo Takaura, MBA
TransCelerate / Novartis Pharma K.K.

What Can Be Anticipated ?
Noemie Manent
European Medecines Agency (EMA)

Panel Discussion
All Session Speakers and
Hiroshi Sakaguchi
Pharmaceuticals and Medical Devices Agency (PMDA)
Yoshihiro Aoyagi, MS
National Cancer Center Hospital East

S23 TRACK 3 9:30-11:00

What are the Challenges of Medical Technology Development and Innovation Assessment in the New Healthcare Era? [HEOR]

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

SESSION CHAIR

Kentaro Kogushi, PhD
AbbVie GK

The healthcare industry is currently moving toward personalization and promoting preventive care through technological innovation. Digital biodata on lifestyle and behavior realized in Society 5.0 could be used to properly demonstrate these values. In addition, a new risk of "drug loss" due to the declining value of investment in Japan has recently been identified, and the importance of appropriately valuing and incentivizing highly innovative drugs has also been raised.

In this session, experts from various fields will share the latest information and discuss important topics related to the sustainability of the Japanese healthcare and pharmaceutical industries.

Recommendations for the Future of Health (Primary Care, Health Data Utilization, VBHC)
Masaki Kawasaki
The Japan Research Institute, Limited

TBD
Ataru Igarashi, PhD
Yokohama City University

Society 5.0 Data Use and Value Creation in Pharma
Kanae Togo
Pfizer Japan Inc

TBD
Ken Ishi, MD, PhD
Tokyo University

Panel Discussion
All Session Speakers and
Hisashi Urushihara, DrPH
Keio University

S24 TRACK 4 9:30-11:00

What Industry, Government, and Academia should do to Accelerate Drug Development in the Field of Neurological Diseases

Related Interest Area(s): AC, CI, MA, CE
Level: Intermediate, Advanced
Language: Japanese Only

SESSION CHAIR

Harumasa Nakamura, MD, PhD
National Center of Neurology and Psychiatry

Although various therapies have been clinically applied to neurological diseases and many new drugs have been developed in recent years, no curative treatment has yet been achieved.

The Japanese Society for Neurological Therapeutics (JSNT) has been working vigorously to establish treatments for neurological diseases, focusing on industry-government-academia exchanges, support for conducting clinical trials, and education for clinical research.

In this session, we will introduce the activities of JSNT, the status and challenges in the development of disease modifying therapies for neurodegenerative disorders, the efforts of academia in the field of refractory peripheral nerve diseases, and the status of regulatory review and requirements from the standpoint of the regulatory authorities. The session will conclude with general discussion involving pharmaceuticals and active exchange of opinions among industry, government, and academia.

Therapy Development for Neurodegenerative Diseases
Masahisa Katsuno, MD, PhD
Nagoya University

TBD
Sonoko Misawa, MD, PhD
Chiba University

TBD
Tomoko Okudaira
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Keisuke Suzuki, MD, PhD
National Center for Geriatrics and Gerontology

S25 TRACK 5 9:30-11:00

Let's Dialogue about Drug Development Research in the Era of Super Smart Society in Collaboration with Academia, Government, Industry, and Public – Academia PM Cafe Spin-Off in *DIA Japan Annual Meeting*.

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

SESSION CHAIR

Nao Horie
Hokkaido University Hospital

Minoru Imai, PhD
Tokyo Medical and Dental University

Twenty years have passed since it became possible to conduct investigator-initiated clinical studies based on bedside clinical questions, and drug development research in academia is now being developed in Japan. However, there is a lag in the creation of an ecosystem that connects academia and industry. To solve various issues, it is important to increase opportunities for dialogue among academia, government, industry, and the public. For this reason, we have organized this Academia PM Café, a web-based dialogue, since 2021. The diverse DIA Japan Annual Meeting platform and diverse group of participants see this as a great opportunity for dialogue in an an interactive event about drug development research in modern super-smart society.

TBD
Masahiko Ichimura
National Cancer Center Hospital

TBD
Ai Okazaki
Tokyo Medical and Dental University

TBD
Naoya Kamiyama, PhD
Asahikawa Medical University Hospital

Panel Discussion
All Session Speakers and
Yu Komura, BA
National Cancer Center Hospital East
Takashi Sato
PM Orchestra TSA
Noriaki Nagao
JAPAN TOBACCO INC.

BREAK 11:00-11:15

DIAmond SESSIONS

DIAMOND SESSION 2 TRACK 1 11:15-12:45

Modernizing Clinical Research Globally : A Multi-Stakeholder Discussion Focused on Accelerating Innovation & Improving Patient Experiences

Related Interest Area(s): All
Level: Intermidiate

SESSION CHAIR

Takuko Sawada
Shionogi & Co., Ltd.

Kazuhiko Mori, MSc
Japan Pharmaceutical Manufacturers Association

The recent past seen unprecedented events from global pandemics and public distrust of biopharma to international conflicts between countries. The biopharma R&D ecosystem responded by innovating on a rapid scale to ensure clinical trial continuity and serve the needs of patients. The success of these efforts is a direct result of all stakeholders working together for the benefit of humanity.

To continue this positive trajectory towards more innovative clinical trials and improved patient experience, all stakeholders—including global Health Authorities—will need to collaborate.

This DIAmond session will show how stakeholders across biopharma R&D have come together to develop pragmatic solutions that are foundational to enabling the future of drug development. This panel will feature biopharma industry leaders at the top of their field candidly discussing why everyone must work together to drive innovation in the R&D ecosystem, shape the future of healthcare, and bridge the gap between clinical research and clinical care.

Modernizing Clinical Research Globally : A Multi-Stakeholder Discussion Focused on Accelerating Innovation & Improving Patient Experiences
Janice Chang, BA, BSc
TransCelerate BioPharma Inc.

Panel Discussion
All Session Speakers and
Kenichi Nakamura, MD, PhD, MBA
National Cancer Center Hospital
Tadaaki Taniguchi, MD, PhD
Astellas Pharma Inc.
Kenichi Tamiya, MSc, RPh
Pharmaceuticals and Medical Devices Agency (PMDA)

S26 TRACK 2 11:15-12:45

Beyond ICH M11-How will the Digitalization of Protocol Data Transform Drug Development? -Challenge in Japan -

Related Interest Area(s): MC, RA, CDM, CI, CP, OI, AC, PM, CE, ST

Level: Intermediate

SESSION CHAIR

Ken Sakushima, MD, MPH, PhD
Hokkaido University Hospital

Satoru Tsuchiya, MS
Japan Pharmaceutical Manufacturers Association (JPMA) / Sumitomo Pharma Co., Ltd.

This session is a series withand S22 are a series of sessions. The ICH M11 guideline not only standardizes and organizes protocol information, but also includes technical specifications for electronic exchange and promotes its reuse, making this informationit useful in a wide range of applications. TIn this session, we will focus on Japan's specific challenges in maximizing the potential of M11 based on the Medical Communication Community session (S22) on future prospects. We will discuss issues related to using protocol information for clinical trial notifications, Japan Registry of Clinical Trials (jRTC), etc., from the industry, government, and academic perspectives, and gainet a foothold for solving issues through industry-government-academia collaboration.

Expectations for ICH M11 - Sponsor's Perspectives –
Yuka Ito, PhD
MSD K.K.

Expectations for ICH M11 from Healthcare Professionals
Yoshihiro Aoyagi, MS
National Cancer Center Hospital East

Initiatives for Automated Generation of Clinical Trial Documents Originating from Clinical Trial Protocol, and Expectations for ICH M11
Satoshi Umehara
NTT DATA

Panel Discussion
All Session Speakers and
Daisuke Sato
Ministry of Health, Labor and Welfare (MHLW)
Hideo Takaura, MBA
TransCelerate BioPharma Inc. / Novartis Pharma K.K.
Ronald Fitzmartin, MBA, PhD
Food and Drug Administration (FDA)

S27 TRACK 3 11:15-12:45

Discussion with Patients for Development of Rare Disease Treatments to Improve Drug Loss in Japan [RA]

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

SESSION CHAIR

Harumasa Nakamura, MD, PhD
National Center of Neurology and Psychiatry

Although the Drug Lag has been solved through the cooperation of industry, government and academia, Drug Loss has recently become a major issue in Japan.

For example, in rare disease areas where the number of patients is limited, additional clinical trials are required to develop new drugs in Japan, which makes it difficult for drugs to reach the rare disease patients in Japan who need them.

This session will discuss why emerging global bioventures are not targeting Japan in new drug development. We will also discuss how patients, their families, and their caregivers and other healthcare professionals close to them, as well as regulatory authorities, think about this issue.

Is the Patient's Wish to Live Shared with You?
Tomoaki Shinohara
Parent of a patient with mitochondrial disease

Developing a New Pipeline to Overcome the Drug Lag of Amyotrophic Lateral Sclerosis
Osamu Kano, MD, PhD
Toho University Faculty of Medicine

Aiming to Solve Drug Loss - Challenges of Aculys Pharma -
Shinichi Nishiuma, MD
Aculys Pharma, Inc.

MHLW's Action to Enhance Access to Orphan Drugs
Yuji Matsukura
Ministry of Health, Labour and Welfare (MHLW)

Panel Discussion
All Session Speakers

S28 TRACK 4 11:15-12:45

Paradigm Shift in Oncology Drug Development : Challenging Dose Optimization with Clinical Pharmacology Approach [CP]

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

SESSION CHAIR

Naoki Kotani, MSc
Chugai Pharmaceutical Co., Ltd.

The US FDA's launch of Project Optimus in 2021 has caused significant change in oncology drug development trends. In the current era of oncology drug development, where molecularly targeted drugs and cancer immune therapy become the mainstream, we now seek a paradigm shift in dose selection strategy from the traditional Maximum Tolerated Dose-based approach, which had been established as standard for dose selection of cytotoxic drugs.

This session will discuss the roles and expectations of Clinical Pharmacology and/or Model-Informed Drug Development in dose optimization of oncology drugs from the industry, clinic, and regulatory perspectives.

Clinical Pharmacology Approaches Contributing to Optimal dose Finding in Oncology Drug Development
Saki Takahashi, BSc
Chugai Pharmaceutical Co., Ltd.

Utilization of MIDD on dose Optimization for T-DXd (Enhertu)
Emi Kamiyama, PhD
Daiichi Sankyo Co., Ltd.

Dose Optimization from the Viewpoint of Phase 1 Trialist
Takafumi Koyama, MD, PhD
National Cancer Center Hospital

Panel Discussion
All Session Speakers and
Takahiro Ito
Pharmaceuticals and Medical Devices Agency (PMDA)

S29 TRACK 5 11:15-12:45

How Can People Evolve and Adapt in the Era of Society 5.0? Let's Chat about Our Value in Healthcare Platform [PM]

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

SESSION CHAIR

Koichi Konno, BS, PMP
PM lab. Positive Intention

During the COVID-19 pandemic, we experienced the possibility of adaptation through the coordination of advances in technology with changes in people's mindsets. However, in the realization of Society 5.0, the theme of this conference, we are rapidly approaching the era where conventional methods no longer work due to the drastic changes in technology and social structure.

As members of this healthcare platform, we want to achieve further evolution and adaptation in this transitional period and realize through social co-creation "a society where no one is left behind."

This session will discuss the value of driving value creation and social co-creation in the near future through dialogue with all participants to transcend the boundaries between industry, government, academia, and the public, and envision the era to come.

Society 5.0 Perspective from Outside Japan
Atsushi Tsukamoto, PhD
Daiichi Sankyo Inc.

What is "Social Co-Creation" for Society 5.0?
Keiko Katsui, PhD
Japan Agency for Medical Research and Development (AMED)

Democratizing Clinical Development : The Fusion of Innovation and Well-being through Technology
Yu Komura, BA
National Cancer Center Hospital East

Panel Discussion
All Session Speakers and
Takashi Sato, MSc, RPh, PMP
PM Orchestra TSA
Noriaki Nagao
JAPAN TOBACCO INC.

LUNCH BREAK 12:45-13:45

LUNCHEON SEMINAR 12:55-13:35

S30 TRACK 1 13:45-15:15

Pharmaceutical Company's Initiatives and Challenges in Health Literacy & Statistical Literacy

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

SESSION CHAIR
Yuko Kojima, RPh, EMBA
Eli Lilly Japan

In shared decision-making, patients understand their own disease and drug information and choose their own medical care together with healthcare professionals. In recent years, pharmaceutical companies have implemented a variety of development and post-marketing activities, as well as new approaches in terms of information provision, under the banner of "patient-centeredness." For example, clinical trial results are delivered to patients who participated in the trials as Plain Language Summary (PLS), avoiding medical jargon and taking participants' health literacy and statistical literacy into consideration to aid understanding. The PLS and data visualization are also designed to be easily understood by non-specialists when the results are published. How are these efforts received in clinical practice and what do regulators expect from them? We will discuss the challenges and future expectations of pharmaceutical companies from the perspective of experts in healthl literacy and statistical literacy.

Health Literacy Challenges and Solutions in Creating Plain Language Summaries of Clinical Trial Results
Kimbra Edwards, PhD
Center for Information & Study on Clinical Research Participation (CISCRP)

Statistical Literacy : An Industry Perspective
Fanni Natanegara, PhD
Eli Lilly & Company

From "Health Literacy" For "Decision Making"
Takeo Nakayama, MD, PhD
Kyoto University

Panel Discussion
All Session Speakers and
Shinichi Nishiuma, MD
Aculys Pharma Inc.
Haruko Yamamoto, MD, PhD
National Cerebral and Cardiovascular Center

S31 TRACK 2 13:45-15:15

Full Remote DCT Implementation in Clinical Trials for Cancer Patients

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

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

Recently, there has been rapid integration of Decentralized Clinical Trials (DCTs) in the field of oncology. One of the primary motivations for this trend is the significant lack of opportunities for cancer patients living in rural areas to participate in clinical trials. Several fully remote DCTs have been implemented in several investigator-initiated registration-directed trials in oncology to address this issue.

This session aims to discuss the challenges involved in the adoption of DCTs based on actual case studies and workflows, taking into consideration perspectives from the clinical trial site, partner site, regulatory authority, and other relevant stakeholders.

Full Remote DCT Implementation in Clinical Trials for Cancer Patients
Tetsuya Sasaki, PhD
National Cancer Center Hospital

Establishment of DCT Co-Work System at Partner Institution
Kenjiro Aogi, MD, PhD
National Hospital Organization Shikoku Cancer Center

From the Standpoint of Consultation and GCP Inspection Regarding Issues in Implementing DCT
Hironori Seto, MS
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Masahiro Wanikawa, MS
Chugai Pharmaceutical Co. Ltd.
Ryoichi Kusama, MS
MICIN, Inc.

S32 TRACK 3 13:45-15:15

Reboot Patient Engagement for GCP Renovation [PE]

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

SESSION CHAIR
Mika Maeda, PhD
School of Pharmacy, Kitasato University / Section for Human Research Protections, Kitasato University Hospital

Some observers have commented that patient engagement activities in Japan are not making progress. It is said that the stakeholders are not seeing eye to eye; no common GOAL to improve objectives and achievement levels has been established; the right patients have not been matched to the right efforts; and the accumulated patient voices have not resulted in sufficient input. With the major Good Clinical Practice (GCP) ICH E6 R3 revision fast approaching, many anticipate that the voice of Japanese patients will not be reflected in clinical studies if we fail to

DIAmond Session 3

resolve these issues.

In this session, we will redefine our GOAL: What should be improved and achieved on the basis of patients' voices? In addition, we will discuss how to proceed with the patient matching process for patient engagement activities.

TBD
Shun Emoto, PhD
NPO ASrid

TBD
Toshihiko Ogura
MSD K.K.

Platform for Effective Patient Engagement
Takashi Kimura
Pfizer R&D Japan G.K.

Panel Discussion
All Session Speakers and
Takeshi.Shukunobe
PPeCC,Inc.

S33 TRACK 4 13:45-15:15

Developing Talent in the Society 5.0 Era: Who are the Critical R&D Personnel for Open Innovation? [OI]

Related Interest Area(s): OI, AC, CI, MC, O
Level: Beginner
Language: Japanese Only

SESSION CHAIR
Fumitaka Noji, Master
Moderna Japan Co., Ltd.

The necessity of open innovation in drug development has recently been emphasized, but concrete strategies have not yet been discussed and there are barriers to collaboration in both industry and academia. The international consortium "Translation Together" defines a Translational Scientist (TRS) as a professional who conducts translational research for the utilization of new drug seeds and is investigating ways of being and developing TRSs. TRSs are the key to open innovation because they understand the status of each research stage and collaborate with each stakeholder organization.

This session will recognize the importance of TRSs in open innovation in the era of Society 5.0 and discuss specific possibilities for their development and utilization.

Policies and Programs on University Startups
Kenkichi Sakoda
Ministry of Education, Culture, Sports, Science and Technology (MEXT)

Pharma's Expectations vs. Reality Gap in Academia
Takeshi Kono, PhD
Nippon Boehringer Ingelheim Co.,Ltd. / Kobe Pharma Research Institute

TBD
Tomoyoshi Koyanagi, PhD
Kyoto University Hospital

International Cooperation Through Translation Together
Mitsuo Sato, PhD
Japan Agency for Medical Research and Development (AMED)

Panel Discussion
All Session Speakers and
Makoto Nagaoka, PhD
BeiGene Japan GK

S34 TRACK 5 13:45-15:15

Regulatory Documents for Innovative Drug Development and Effective Drug Application Review in Society 5.0 Era

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

SESSION CHAIR
Kazuhiko Mori, MSc, PhD
Japan Pharmaceutical Manufacturers Association (JPMA)

As we move toward the Society 5.0 era, communication between regulatory authorities and clinical trial sponsors during drug development is changing from conventional paper documents to various digital technologies. This panel discussion among representatives of industry, PMDA, and academia will address PMDA's use case of electronic data application review, new digital technology from sponsor and research companies, and review transparency. These discussions will maximize the benefits of various changes (e.g., data visualization, new digital technology, increasing needs for transparency in PMDA review, etc.) in the external environment.

How should be Regulatory Document for Innovative Drug Development and Effective Drug Application Review in Society 5.0 Era?
Tsuyoshi Ishiki
Eli Lilly Japan K.K.

Utilization of Electronic Study Data and Changes in New Drug Review in the PMDA
Yuki Ando, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

Initiatives and Challenges in Generative AI Utilization
Kazumitsu Kanatani
Chugai Pharmaceutical Co., Ltd.

Utilization of Accumulus Synergy and Expectation from Pharmaceutical Campany
Takayuki Imaeda, MS, MPharm
Pfizer R&D Japan

Panel Discussion
All Session Speakers and
Mamoru Narukawa, PhD
Kitasato University School of Pharmacy

BREAK 15:15-16:15

POSTER SESSIONS, AFTERNOON SEMINAR 15:30-16:00

DIAmond SESSIONS

DIAMOND SESSION 3 TRACK 1 16:15-17:45

PMDA Townhall

Related Interest Area(s): All
Level: All

SESSION CHAIR
Koji Iwasaki, PhD
Osaka University Hospital
Eri Sekine
CMIC Co., Ltd.

Panel Discussion
Pharmaceuticals and Medical Devices Agency (PMDA)
Kenichi Tamiya, MSc, RPh
Associate Executive Director (New Drug Evaluation)

Naoyuki Yasuda, MSc
Associate Executive Director (International Programs)
Mitsune Yamaguchi, PhD
Office Director, Office of Non-clinical and Clinical Compliance I
Toyotaka Iguchi, MD, PhD
Office Director, Office of Pharmacovigilance II
Kensuke Ishii, PhD
Office Director, Office of Medical Devices I
Koshin Kiyohara
Office Director, Office of Review Management

S35 TRACK 2 16:15-17:45

Incorporating the Patient Voice into Clinical Trials with Digital Biomarkers (dBM)

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

SESSION CHAIR

Naoto Awaji
Chugai Pharmaceutical Co., Ltd.

Digital biomarkers (dBM) are broadly classified into physiological data such as heart rate, motor function, voice, etc., which are objectively and quantitatively measured by a digital device for clinical evaluation. In Europe and the US, regulatory authorities have published literature on the utilization of dBM, and the results of discussions by JPMA have been published in Japan, showing increasing global interest. The lecture will explain the latest products of the JPMA - "the significance of using dBM" - and then introduce specific clinical studies and research cases conducted in Japan using voice dBM and sleep dBM. Panel discussion will explore data to meet the purpose, device selection, validation, patient participation (PPI), and other details when setting dBM as an endpoint.

Significance of Using dBM in Drug Development and Trials for Its Use
Norihiro Kawabata
Japan Pharmaceutical Manufacturers Association (JPMA) / Chugai Pharmaceutical Co., Ltd.

Application of Voice Biomarkers in Clinical Trial
Shinichi Tokuno, PhD
The University of Tokyo

Sleep dBM – Possibilities and Challenges in Research
Thomas Svensson, MD, PhD
Kanagawa University of Human Services

Panel Discussion
All Session Speakers and
Yoshihiko Furusawa, MD, PhD
Takeda Pharmaceutical Company Limited
Kuniko Shoji
Kanagawa University of Human Services

S36 TRACK 3 16:15-17:45

Society 5.0 in the Healthcare Domain Aimed for with the Supercomputer "Fugaku"

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

SESSION CHAIR

Rika Abe, RPh
RIKEN Center for Computational Science

The supercomputer "Fugaku" was developed to contribute to Japan's growth and achieve world-class results. Fugaku plays a role in verifying problem-solving solutions through simulations in virtual societies and implementing their new value in the real world. In fields such as drug discovery and healthcare, Fugaku is already being utilized for challenging simulations like complex surgeries and whole-brain simulations; its utilization of large amounts of accumulated medical big data is expected in the future. With a focus on adapting the concept of digital twins (a mechanism that replicates the environment of the physical space into a virtual space through AI data analysis and processing of extensive real-world information) in clinical trials and real-world healthcare settings, we will discuss the utilization of Fugaku and its potential in realizing Society 5.0.

Several Cardiac Surgical Procedures That Cannot Save Lives without Large Scale Numerical Calculations
Keiichi Itatani, MD, PhD
Nagoya City University

Toward a Large-Scale Health State Prediction Model for Personalized Intervention
Eiichiro Uchino, MD
Graduate School of Medicine, Kyoto University

Panel Discussion
All Session Speakers and
Chinzei Kiyoyuki, PhD
National Institute of Advanced Industrial Science and Technology (AIST)
Kazuhisa Tsunoyama
Astellas Pharma Inc.

S37 TRACK 4 16:15-17:45

Challenges and the Future of Sharing and Integrating Medical Data [CI]

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

SESSION CHAIR

Keiichi Yamamoto, PhD
Osaka Dental University

While there is a vast amount of medical data under the universal health insurance system in Japan, the effective utilization of this data remains limited because it is dispersed and stored in various medical institutions. In 2022, the Liberal Democratic Party's policy research committee proposed the *Medical DX Reiwa Vision 2030* and is promoting cross-agency efforts based on the three pillars of a national medical information platform, standardization of electronic medical records, and the digital transformation of medical fee revisions. If realized, these initiatives are expected to improve the quality of medical care, increase the productivity of research and development, and enable patients and citizens to lead even healthier lives.

This session will promote discussion among industry, government, and academia on issues that must be overcome and what we must do to prepare for the future.

Measures of the MHLW in Medical DX and the Future Image
Shiho Yoshii
Ministry of Health, Labour and Welfare (MHLW)

Current Status, Challenges, and Future Prospects of Data Utilization in the Healthcare Field
Keiichi Yamamoto, PhD
Osaka Dental University

What Does Real World Data Mean for Clinical Development ?
Kasumi Daidoji, PhD, RPh
Eisai Co., Ltd.

Panel Discussion
All Session Speakers and
Toshiki Saito MD, PhD
NHO Headquarters, NHO Nagoya Medical Center
Yutaka Matsuyama, PhD
The University of Tokyo
Seiji Iwatsu
Fujitsu Japan Limited

S38 TRACK 5 16:15-17:45

Real-World Clinical Pharmacology in Global Drug Development

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

SESSION CHAIR

Tomoko Hasunuma, MD, PhD
Kitasato University

To avoid drug lag/loss, it is necessary for Japan to take part in phase 2 and subsequent multiregional clinical trials (MRCTs) without delay. In early development, however, there are many cases where candidate products are associated with uncertainties (e.g., presence or absence of PK ethnic differences). Therefore, it is important to generate critical data from clinical pharmacology studies including first-in-human (FIH) studies strategically, as supplementary information. Recently, we have seen the possibility of waiving conventional clinical drug-drug interaction (DDI) studies by measuring endogenous biomarkers in FIH studies. Home PK sampling techniques accelerated by the pandemic are also important.

In this session, clinical pharmacology experts with important roles in these fields will demonstrate their real-world experience and discuss the possibilities of more efficient drug development.

Qualities and Roles of Clinical Pharmacology Scientists for Drug Development in Japan – A Case Study : Which is the Key Factor Influencing PK profiles, Ethnicity or Formulation? –
Hiroyuki Yoshitsugu, PhD
MSD K.K.

Patient-Centric Sampling : How the COVID-19 Pandemic is Shifting the Landscape
Mototsugu Ito, PhD
IQ Consortium

Recent Progress in Human in vivo Phenotyping Methods for Pharmacokinetics-Related Molecules
Kazuya Maeda, PhD
Kitasato University

Panel Discussion
All Session Speakers and
Motohiro Hoshino, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

BREAK 17:45-18:00

CLOSING 18:00-18:30

Koji Iwasaki, PhD
Program Chair / Osaka University Hospital
Yukihiro Matsuda, MSc
Program Vice-Chair / ICOM Japan Plc.

[P-01] Review Efficiency and Timeline Predictability of Pre-Review and Online Registration Systems in Asian countries

Related Interest Area(s): RA

Yuto Kurooka
Otsuka Pharmaceutical Co., Ltd.

Co-author:
Masaaki Kanno, Kunihiko Kiyono, Yukio Washio, Yoshiaki Ito, Junichi Nishino / Otsuka Pharmaceutical Co., Ltd.

Objectives:
In order to achieve early access to patients, we made a survey on the role and actual operation of pre-review and online registration systems in Asia, and considered from the view point of efficiency, transparency and predictability.

Methods:
We conducted a survey in 13 Asian countries to examine their review processes. This included investigating whether a pre-review stage, and its role, as well as the regulated vs. actual review times, timing of official acceptance, and the starting point of the review time-clock, and availability of online registration system. We analyzed responses from our local affiliates, and considered the efficiency, transparency and predictability of the review system.

Results:
Of the 13 countries surveyed, 8 have implemented a pre-review system, 9 conduct a formal verification before officially accepting the application, and 3 countries immediately acknowledge official acceptance at the time of submission and proceed directly to full scale NDA review. The pre-review system serves to evaluate the completeness of submission dossiers in preparation for the subsequent full scale NDA review, thereby enhancing review efficiency and predictability.
Out of the 13 countries, 10 have implemented online registration systems or eCTD for submitting application data. Although some countries faced challenges, such as the review time for input information not being included in the regulated review period, or the applicant requiring a significant amount of time for inputting the information into the system. However, in countries like Singapore and China, applicants can confirm the progress of review milestones through online registration systems or regulatory authorities' websites. This has been recognized as improving transparency and predictability of the review process.

Conclusion:
Implemented in 8 countries, pre-review system confirms requirements and documents' completeness improving the efficiency and predictability of review process. Furthermore, online registration systems could facilitate applicants to track the progress of review milestones, while contributing to the transparency of review processes.

[P-02] Completion rate and time analysis of electronic quality of life measures

Related Interest Area(s): PE, CDM

Reina Davis-Aoki, PhD
Clario

Co-author:
Kelly Dumais / Clario

Objectives:
Quality of life (QOL) measures are critical to assess patients' health in clinical trials. With regulatory attention on reducing burden, we analyzed the impact of QOL type on completion rate and time.

Methods:
Patients completed assessments electronically on Clario Tablet devices at clinical trial sites. Operational data for completion status (Done or Not Done) and duration of time to complete (in seconds) was extracted for 4 commonly used patient-reported QOL measures: EQ-5D-5L (5 levels or severity), EQ-5D-3L (3 levels of severity), SF-36v2 Standard and SF-36v2 Acute.

Results:
The sample included 119 studies across different phases, with 120,565 instances of completion status analyzed for the 4 QOL measures. The mean completion rates were 95.4% (EQ-5D-5L), 96.5% (EQ-5D-3L), 96.1% (SF-36v2 Standard) and 99.0% (SF-36v2 Acute). The study specific median time for form completion was 80s for EQ-5D-5L (range 43-157s), 65s for EQ-5D-3L (range 17-114s), 354s for SF-36v2 Standard (range 129-455s) and 384s for SF-36v2 Acute (range 256-7840s). Completion rate was not associated with the form completion time. The analysis of instances where the assessments were completed at home was not feasible due to the limited sample size. Additional analysis of home-based assessments will determine whether the compliance is location dependent.

Conclusion:
Completion compliance was high for all tablet QOL measures regardless of completion time or number of questions. This suggests that longer QOL measures may not negatively impact compliance at site, and that electronic measures have benefits of yielding high compliance and enhanced data quality.

[P-03] Toward Clinical Trials which Patients and Citizens Know: Innovations to Resolve Information Asymmetrics

Related Interest Area(s): PM, COM

Takumi Furuichi
Nippon Boehringer Ingelheim Co., Ltd.

Co-author:
Takao Kurusu / INTAGE Healthcare Inc.
Nobutaka Yagi, Kenma Nozaki / Nippon Boehringer Ingelheim Co., Ltd.

Objectives:
Collect the patient's live voice through a customer experience test on the JPRN Search Portal, identify improvements, including the site's searchability and accessibility, and gain new knowledge.

Methods:
Online interview survey (required 90 minutes). Survey targets patients registered in a market research panel (both those with and without experience participating in clinical trials [oncology or other indications] were recruited). Participants followed interviewers' instructions to search for studies at the JPRN Search Portal and other sites and were interviewed about their usability.

Results:
12 patients (4 with no experience participating in clinical trials, 4 with experience participating in oncology clinical trials, and 4 with experience participating in clinical trials other than oncology) participated in this survey. The results of this survey revealed that the most important issues were that the purpose of the site was not clear, that users could not easily conduct the searches they intended, and that even when they were able to conduct a search, it was difficult to understand the contents of the search results. A qualitative analysis of the participants' impressions of the portal site and its operation suggested the need for improvement in the following areas. 1) Regarding the visual impression given when the site is opened, the visuals should be changed so that users can visualize the purpose of using the site, 2) "clinical research" should be changed to "clinical trial" or other words that are easy for users to imagine. 3) Regarding operability, conditional search, simple search, and detailed search functions should be implemented to meet the needs of various users. For the contents (search results), the display method should be changed to a simple structure that is easy for users to understand, and pop-ups should be created to assist users with explanations for some difficult words to understand.

Conclusion:
JPRN Search Portal has proven difficult for users who do not have basic knowledge of clinical research and clinical trials and high IT literacy to search for information and understand its contents on their own. The site needs to be updated to better reflect user perspectives so that patients and citizens can research clinical research and clinical trials when they want to and make use of the information for their treatments.

[P-04] Overcoming Challenges in Disposition Data Collection-Flexibility/Design thinking

Related Interest Area(s): CDM, OI

Lv, Cong, Master
Global Data Management and Standards, MRL China

Co-author:
Song, Yu Qing / Global Data Management and Standards, MRL China

Objectives:
Disposition data collection in clinical trials presents challenges such as the need to meet the variable submission requirements, pandemic-related disruptions, and adherence to protocol requirements. To address these challenges, the design

of the electronic case report form (eCRF) and the data collector must be carefully considered to ensure maximum flexibility and compatibility.

Methods:
This discussion explores the importance of flexibility and design thinking in CDASH and SDTM for overcoming challenges in disposition data collection. The Disposition domain and related models will be introduced, including categories and their applications. Several cases will show how to inject flexibility into data collection design. Robust design thinking enables to explore the ways in which CDASH and SDTM can be customized to fit the specific needs of each trial.
CDASH provides a set of common data elements for disposition data, and SDTM also provides a standard format for the submission of clinical trial data, but both can be adapted to fit the needs of each study.

Results:
Design thinking is essential for ensuring that the eCRF and data collector are user-friendly and adaptable to changes in the trial design. By using CDASH and SDTM with design thinking principles, clinical trial sponsors can ensure the quality and integrity of their data and increase the likelihood of regulatory approval. Below cases will be shared in the poster

1. Clinical trials for oncology drug involve complex design and gathering comprehensive disposition data from trial participants which is crucial for accurate analysis and decision-making. We will present a case demonstrating how design thinking can be employed to collect different disposition data by specifying disposition in different phase or different analytical objectives to make a clear identification of endpoint and sorting out target data accurately in a tumor-specific clinical trial.
2. The COVID-19 pandemic has posed significant challenges to the conduction of clinical trials. In response to the pandemic, regulatory agencies have provided guidance and requirements for conducting clinical trials amidst the COVID-19 pandemic. For instance, the FDA has mandated sponsors to provide explanations for missing data and subject discontinuations due to COVID-19, which can explain bias into the trial results. we will present a specific example illustrating how increasing flexibility in data collection systems can help meet the evolving requirements of trial organizations in both the long term and short term.
3. The collection of associated person-related data has become increasingly important in some clinical research. we aim to provide a detailed discussion on how to effectively collect data related to the associated person status in clinical trials.

Conclusion:
In conclusion, flexibility and design thinking are crucial for overcoming challenges in disposition data collection. By customizing CDASH and SDTM to fit the unique needs of each trial and designing user-friendly and adaptable eCRFs and data collectors, clinical trial sponsors can optimize the collection and submission of disposition data.

[P-05] Enhancing drug development by collating clinical trial data with real-world patient data.

Related Interest Area(s): OI, PV

Sumana Ramayanam, Bachelor of Engineering and MBA
PAREXEL

Co-author:
Andy Wilson, Martin Roessner / Parexel

Objectives:
Generate insights to inform future clinical trials designs about patient risks by combining adverse events (AE) data from clinical trials with post-market AE public reporting data.

Methods:
Combining clinical trials data with real-world AE data will help in risk assessment, leading to more informed trial designs, where patient safety is prime concern. Given known disparities and challenges, their potential is mostly unexplored, while AEs from EMR/Claims are not readily evident. We analyzed the overlap and the lack thereof of two publicly available data sources with sample protocols.

Results:
We used publicly available data sources - AACT, a relational database providing information about protocols and results from clinicaltrials.gov and FAERS post market AE reporting data. To validate the value-add, we analyzed protocols that involved certain drug interventions and compared the AEs reported in past clinical trials with the AEs reported in FAERS involving similar drugs, such as Keytruda-Lenvima, Krystexxa-Methotrexate etc. As we expected, we found some AEs common across both sources confirming pattern of AEs in trials with those in real-world. However, we also found differences between both data sources; thus, confirming that several types of S/AEs manifest in the real-world versus in clinical trials. In addition, AEs that occurred in trials aren't always or haven't yet been reported in the real-world. We identified various combinations of concomitant drugs used in real-world that provide insights into potential serious AEs likely to occur in future trials or care settings.

Conclusion:
The findings validate our hypothesis. By leveraging available data, researchers can anticipate AEs and improve study designs to minimize patient risks. Further work is needed to apply ML/NLP to refine FAERs data in reactions; reason(s) for use; and patient characteristics to meld with trials data.

[P-06] Clinical Trial Ambassadors - aiming at better understanding of drug development and easier access to clinical trial information

Related Interest Area(s): PE, COM

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Objectives:
The clinical trial ambassadors project provides educations and dialogues to deepen mutual understanding between patients and pharmaceutical companies regarding drug development and clinical trials.

Methods:
In 2022, the clinical trial ambassadors project was launched in Japan with patient organizations, academia, and several pharmaceutical companies. The project team provided patients (e.g., representatives of patient organizations) with classroom trainings prepared in cooperation with EUPATI. The participants who received trainings became ambassadors of clinical trials and explored ways to raise awareness on clinical trials persistently.

Results:
The following 4 steps of trainings were completed: 1) Orientation for ambassadors from several patient organizations in Japan, 2) Classroom trainings prepared in cooperation with EUPATI, 3) Hands-on training on accessing clinical trial information, 4) Workshop to review the ambassadors' activities and ways to improve the awareness on clinical trials.
The following outcomes were achieved: 1) EUPATI training materials on the basics of drug development and patient involvement in drug development were localized for Japan based on discussions with patient organizations, 2) A report was prepared on the hands-on training, summarizing the opinions of participants regarding the search for clinical trial information.
Several challenges for the project were identified: 1) Differentiation to the characteristics and complementarities of the program compared to other similar patient education programs, 2) Requirements for trainers and certification system/criteria for the ambassadors, 3) Method of selecting candidates to serve as clinical trial ambassadors, 4) Creating system that allows co-sponsoring companies or organizations to freely join or leave the project.

Conclusion:
We have completed the first training program for the clinical trial ambassadors in Japan, which promotes mutual understanding between patients and pharmaceutical companies in drug development. It is vital to promote understanding and patient involvement to deliver new treatments reflecting their needs to patients faster.

[P-07] Megasite Solution

Related Interest Area(s): CI, SS, RA

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Objectives:
To understand use cases and operational feasibility of a megasite model, defined as a decentralized model that involves a central site(s) overseeing remote study conduct for a large region or country and in what cases this model offers most benefit to study participants, sites, and sponsors.

Methods:
To understand use cases and feasibility of a megasite model, workshops were held with cross-functional subject matter experts to identify potential benefits as well as operational, regulatory, and legal considerations that dictate model viability.
This included considerations for in what situations CRO partners may provide investigative site services and what protocol designs are most amenable to oversight by a central coordinating.
Learnings from an ongoing case study operating with a megasite model was also examined to identify lessons learned and understand global acceptability based on regulatory feedback.

Results:
Centralizing remote study conduct under a megasite has potential to reduce start up timelines and costs related to investigator fees and monitoring which has benefit to sponsors. The model also has the opportunity to improve diversity and inclusivity, allowing patients to participate remotely from a broader geographic area and include patients who may not have access to traditional brick and mortar clinics.
Findings from the workshop indicated that megasite models are optimal for non-interventional, observational, low-risk studies driven by patient reported outcomes. These studies can incorporate technologies such as eConsent and virtual study platforms that allow participants to provide all required study data remotely without impact to patient safety.
Consumer health studies that are minimal risk may benefit from a megasite approach.
Additionally, studies that incorporate remote contact with study participants may be subject to local laws concerning telehealth.

Conclusion:
A megasite model presents the opportunity to realize efficiencies in study startup and improve inclusivity by removing geographic barriers to participation. However, protocol and regulatory requirements (eg. telehealth and data privacy) must be considered to determine if a megasite model is fit for purpose and it's acceptance will be country-specific, dependent on the site selected to fulfill the role of PI and the associated responsibilities.

[P-08] Make DCT land better: Close gaps between regulations and process

Related Interest Area(s): CI, SS, RA

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Objectives:
Identify gaps between the constantly changing regulations about Decentralized Trials and Digital Health Technologies world wide, and Syneos health processes, using Kaizen and lean six sigma methodology , to determine opportunities and solutions that bring Syneos full allignment with regulations and benchmark against the industry to become leaders.
Provide competitive advantages considerign market need, improving quality on Syneos studies involving DCT, working on client retention, providing operational efficiencies that ensure patient safety, avoid audit and inspection findings and GDPR penalities.

Methods:
Phase 1: Close review of the regulations existing at that time, including draft guidelines from FDA, EMA guidance on computarized systems, and some country guidelines on DCT, and the review of the company processes related to those topics in bussiness units.
Phase 2: Review processes with stakeholders and identify the gaps, segmenting a summary matrix in to four high level themes 1, Data management and clinicla endpoints, 2, Validation, 3. Risk data and data integrity and 4. submissions.
Phase 3: The core Kaizen team performed an analysis of the insights and gaps discussed and created and Opportunities PICK chart identified by theme and type.
Phase 4: Once opportiunites were discussed wiuth the key stakeholders per theme, distinct worksteams agreed with accountable leads, assessed baseline from the improvements required, created action plans for each workstream, consolidate timelines on deliverable to be achieved, and started to measure impact.

Results:
The Decentralized trial team and the core Kaizen team was able to identify the key stakeholders needed in the discussions to really address the gaps and opportunities identified.
Synoes has a current process of controlled document review that involves leads from each bussiness unit, in constant coimmunication with all other units as to have crossfunctional review of the processes with ongoing periodicity. That is promiting the continuous improvement.
The area with more challenges and opportunities identified was validation, as even if the company has validation managers and processes in place, they mainly focused on internal systems, but with this analysis the company is seeing how efficiencies can be applied to have this knowledge passed to other study areas like the use of DCT and any other Digital Health technology , specially after the guidance from EMA on computrized systems.

Conclusion:
The Decentralized trial team and the core Kaizen team was able to identify the key stakeholders needed in the discussions to really address the gaps and opportunities identified, makign awareness not just on the regulations existing but on the importance of working together to gain efficiencies.
Syneos Health has a department of Decentralized trials with dedicated Subject Matter Experts that are able to work crossfunctonally and worldwide, provide input to other bussiness units processess and participate in productive risk assessment discussions, which is the pillar to most of the regulations published to date.

[P-09] Reimagining Cancer Care & Drug Development through Real-World Data Creation

Related Interest Area(s): O

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Objectives:
This ongoing study aims to contribute to improving cancer treatment and outcomes in Japan by constructing electronic health record (EHR)-based, longitudinal, patient-level real-world data (RWD).

Methods:
Flatiron Health is constructing oncology RWD by processing information from clinical systems in Japanese hospitals, based on over 10 years of expertise developed in the US. By adapting the US-proven approach of abstraction, Flatiron Health is developing local methodologies to create high-quality data, in compliance with local regulations, laws, and ethical guidelines to safeguard patient privacy.

Results:
RWD are data on health status and healthcare delivery, routinely collected from a variety of sources. In the US, Flatiron Health's nationwide de-identified EHR-derived database has supported research critical to improving patient outcomes, leading to regulatory approvals in 11 unique cancer indications, >15 health technology assessments (HTA), and >560 scientific publications and presentations. These include a label expansion for males with metastatic breast cancer, label updates in metastatic colorectal cancer, and collaborative research with NICE on the applications of RWD in HTA decision-making. In Japan, given the paucity of RWD appropriate to assess real-world clinical outcomes, Flatiron Health and National Cancer Center Hospital East are collaboratively constructing EHR-based RWD, to accelerate international research and improve outcomes. Work is underway to process data and develop RWD fit for evaluating real-world outcomes in patients with gastric and colorectal cancer.

Conclusion:
Flatiron Japan RWD are anticipated to inform cancer research and decision-making by clinicians, health authorities, and industry stakeholders. This presentation will showcase RWD initiatives in the US, as well as discuss the current state and potential for constructing and utilizing RWD in Japan.