



境界を踏み越えて、
新結合
で拓く、予想を超えた
未来

PROGRAM <ENGLISH>

The 23rd DIA Japan Annual Meeting 2026

Crossing Boundaries, Shaping a Future Beyond Imagination with Innovation
October 18-20, 2026 | Tokyo Big Sight

Endorsement by MHLW, PMDA, AMED, JPMa, PhRMA, EFPIA, PDA, MEJ, and LINK-J

As of October 14, 2026

DIA

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Overview



Today, the fields of healthcare and pharmaceutical development are undergoing a transformation of unprecedented proportions. Rapid advances in digital technologies and artificial intelligence (AI), diversification of drug discovery and development models, open innovation, regulatory reforms, patient-centric approaches, engagement of diverse stakeholders, and the pursuit of sustainability and social value are all progressing simultaneously — ushering in an era of change unlike any before. Medicine and healthcare have been traditionally confined to biological and chemical domains. In recent years, however, collaboration with engineering and information technology (IT) has accelerated, and integration with human and social sciences—such as addressing ELSI (ethical, legal, and social issues)—has become indispensable. The concept of “Neue Kombinationen” (literally “new combination,” rendered as “innovation”) proposed by economist Joseph Schumpeter refers not merely to invention or technological innovation, but to the creative act of combining existing elements in new ways. Such “new combinations” drive discontinuous change (what Schumpeter called “creative destruction”), bringing new value to society and industry.

In today’s world, connecting knowledge and technologies across disciplines through “innovation ” is more critical than ever. While AI has dramatically improved the efficiency of information processing and output, what AI generates remains an extension of existing knowledge and patterns. Therefore, creative attempts to combine existing elements in unprecedented ways represent a uniquely human endeavor—one that may hold the key to shaping the future in the AI era. The 23rd DIA Japan Annual Meeting provides a forum where participants from diverse fields, roles, organizations, and countries come together to explore possibilities beyond imagination through “innovation” born of interdisciplinary collaboration. We hope that each participant will bring their expertise and experience, engage in discussion and cooperation across disciplines, and seize this opportunity to open new horizons in healthcare and pharmaceutical development.

“Kintsugi” and “innovation”

Kintsugi is a traditional Japanese technique in which broken ceramics are repaired with lacquer and the seams are decorated with gold or silver. Rather than hiding the damage, it embraces the breakage as part of the object’s beauty, cultivating a unique aesthetic sensibility. As Japan’s long-established medical field continues to evolve through the integration of new technologies, we chose Kintsugi as a motif to symbolize “new synthesis”—the act of connecting past and future to create new value.



Program Committee



Program Chair

Haruko Yamamoto

National Cerebral and Cardiovascular
Center



Program Vice-Chair

Miyoko Yamauchi

Chugai Pharmaceutical Co., Ltd.

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Yukiko Nishimura NPO Asrid

Tomohiro Obana PPD-SNBL K.K.

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Chiharu Onozaki EPS Corporation

Yuki Sasaki Hokkaido University Hospital

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Eri Toyoshima ZeeDia life science Inc.

Shinya Watanabe

Pharmaceuticals and Medical Devices Agency(PMDA)

DIA Japan

Mitsuhiro Niimi

Program



October 18 (Sunday)

9:30-12:30 Student Session
10:30-12:00 Public Lecture
12:30-14:00 Lunch Break
12:55-13:35 Luncheon Seminar
14:00-14:45 Orientation and Opening
14:45-15:45 Program Chair Session
15:45-16:30 Break
16:30-18:00 Keynote Session
18:00-18:15 Break
18:15-19:45 Networking Session

October 19 (Monday)

9:00-10:30 iPS Session1, ASIA-1, S01, S02, S03, S04, S05, S06
10:30-11:15 Break
11:15-12:45 Special Session1, ASIA-2a, S07, S08, S09, S10, S11, S12
12:45-14:15 Lunch Break
13:10-13:50 Luncheon Seminar
14:15-15:45 Special Session2, ASIA-2b, Pitch Session, S13, S14, S15, S16, S17
15:45-16:30 Break
16:30-18:00 Regulatory Session1, ASIA-3, Sponsored Seminar, S18, S19, S20, S21, S22, S23
18:00-19:00 Break
18:15-18:55 Poster Session/Pitch Session Award Ceremony
19:00-20:45 Special Chatting Session

October 20 (Tuesday)

9:00-10:30 DIAMond Session1, S24, Regulatory Session2, S25, S26, S27, S28, S29
10:30-11:15 Break
11:15-12:45 DIAMond Session2, S30, S31, S32, S33, S34, S35, S36
12:45-14:15 Lunch Break
13:10-13:50 Luncheon Seminar
14:15-15:45 DIAMond Session3, S37, S38, S39, S40, S41, Media Seminar, S42
15:45-16:30 Break
16:30-18:00 DIAMond Session4
18:00-18:30 Closing

Related Interested Area :

All=All areas, **CD&O**=Clinical Development & Operations, **CS&PV**=Clinical Safety & Pharmacovigilance, **D&DS**=Data & Data Standards, **MA&SC**=Medical Affairs & Scientific Communication, **PE**=Patient Engagement, **P&EPR**=Preclinical & Early Phase Research, **PM&SP**=Project Management & Strategic Planning, **QAC**=Quality Assurance, Control & others, **RA**=Regulatory, **Stat**=Statistics, **V&A**=Value & Access, **Others**=Others



Program

The event will be held onsite. On-demand viewing will be available after the event.

TRACK and ROOM

TRACK 1 : 7F International Conference Room Oct. 18th, 19th, 20th

TRACK 2 : 7F 701+702 Oct. 19th, 20th

TRACK 3 : 6F 703

TRACK 4 : 6F 605 Oct. 19th, 20th

TRACK 5 : 6F 606

TRACK 6 : 6F 607 ☐ : Simultaneous translation by AI system

TRACK 7 : 6F 608

TRACK 8 : 1F 101

TRACK 9 : 1F 102

TRACK 10 : 1F Reception Hall Poster Session: 1F Foyer



Conversations on Priorities

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

Accessing Presentations

Registered participants of the DIA Japan Annual Meeting will be able to access presentation slides on the DIA Global website approximately one week prior to the meeting. Instructions on how to access the materials will be provided in advance by email. Please note that not all presentation materials will be available. Only those materials submitted to DIA by the designated deadline will be posted on the website. Printed handout materials will not be distributed. For presentations for which public release has been authorized, registered attendees will be able to view the recordings on demand after the meeting. On-demand access will be available through December 31, 2026.

Unless otherwise stated, the views and opinions expressed during the meeting are those of the individual presenters and do not necessarily reflect those of their affiliated organizations or DIA. Speakers and presentation titles are subject to change without notice. In addition, the recording or audio recording of any DIA event, in any form or by any means, is strictly prohibited without prior written consent from DIA.

Day 1 | Sunday October 18



Student Session TRACK 4 (6F Room 605+606) 9:30-12:30

Related: ALL | Level : Beginner | Japanese / Theater Style

Can You Trust the Health Info on Social Media?-Rethinking Risk Communication for the Next Generation

Pharmaceutical companies share information based on scientific evidence, but it is often too technical for the public to understand. On social media, anyone can easily spread information, and emotional message or personal experience can create misunderstandings about drug effects, increasing patients' anxiety and affecting trust in healthcare. This session will discuss how pharmaceutical information is communicated today and explore what ideal risk communication should look like in the social media era.

Public Lecture TRACK 8 10:30-12:00

Related: ALL | Level : Beginner/Intermediate | Japanese / Theater Style

Understanding Stroke through Lived Experience: Insights from the Stroke Speakers Bank

Stroke is the fourth leading cause of death and the leading cause of long-term disability in Japan. Despite its impact, the lived experiences of stroke survivors remain insufficiently understood. In collaboration with the Japan Stroke Association, this session will feature firsthand perspectives from the Stroke Speakers Bank, aiming to share real-world challenges and promote greater awareness of patient-centered care.

※ Japanese Only



Day1 | Sunday October 18

Orientation and Opening TRACK 1 14:00-14:45

Related : ALL | Level : Beginner/Intermediate | Japanese and English / Theater Style

Chair

Mitsuhiro Niimi

DIA Japan

Speaker

Marwan Fathallah

DIA President & Chief Executive Officer

Kenichi Nakamura

Advisory Council of Japan Chair/ National Cancer Center Hospital

Haruko Yamamoto

National Cerebral and Cardiovascular

DIA Japan inspire Award 2026



Day 1 | Sunday October 18



Program Chair Session TRACK 1 14:45-15:45

Related: ALL | Level : Beginner/Intermediate | Japanese / Theater Style | Simultaneous translation by AI system

Reflections of “New Combinations”

The concept of “new combinations,” which appears in the theme of the 23rd Japan Annual Meeting, is essentially synonymous with innovation. Coined by Joseph Schumpeter a century ago, it describes the creation of new value through the recombination of existing elements. Such creation, however, is inseparable from the creative destruction of existing value. What kinds of environments and conditions enable the emergence of novelty with such transformative power? This lecture will examine from various perspectives the environments and conditions that foster the creation of new value.

Chair

Kenichi Nakamura

National Cancer Center Hospital



Reflections of “New Combinations”

Haruko Yamamoto

National Cerebral and Cardiovascular Center



Day 1 | Sunday October 18



Keynote Session TRACK 1 16:30-18:00

Related: ALL | Beginner / Intermediate | Japanese / Theater Style | Simultaneous translation by AI system

Trio-span Paradigm for Future Healthcare in the 100+ Year Life Era

Japan has long advanced medicine through the power of invention, exemplified by the discovery of iPS cells. Our group has driven breakthroughs in human organoid technologies, including vascularization, multi-organ integration, and functional reconstruction. We further introduced enteral ventilation, a non-pulmonary oxygen delivery approach that redefines systemic oxygenation. Building on these innovations, we are advancing scalable organoid manufacturing and bioartificial organ systems toward donor-independent medicine. In this lecture, I present a national vision centered on the Trio-span strategy—Joyspan, Healthspan, and Lifespan—integrating prediction and prevention, regeneration and replacement, and adaptation and evolution to establish a new paradigm for medicine and society in the 100+ year life era.

Chair

Aya Kubota

Nikkei Business Publications, Inc.

Trio-Span Paradigm for Future Healthcare in the 100+ Year Life Era

Takanori Takebe

Professor, Graduate School of Medicine / Premium Research Institute for Human Metaverse Medicine (WPI-PRiME), The University of Osaka

Professor, Human Biology Research Unit, Institute of Integrated Research, Institute of Science Tokyo

Associate Professor, Division of Gastroenterology, Hepatology and Nutrition and Division of Developmental Biology / Director of Commercial Innovation, Center for Stem Cell and Organoid Medicine (CuSTOM), Cincinnati Children's Hospital Medical Center

Director, Communication Design Center, Yokohama City University

Panel Discussion

All Session Speakers and

Hiroyoshi Toyoshiba

FRONTEO, Inc.



Day1 | Sunday October 18

Networking Session Reception Hall 18:15-19:45



Day 2 | Monday October 19

iPS Session TRACK 1 9:00-10:30

Related: RA:PM&SP:V&A:Other | Level : Beginner/Intermediate | Japanese / Theater Style | Simultaneous translation by AI system



The World's First iPSC-Based Product: Journey to Commercialization and Future Outlook

What does the approval of the world's first iPSC-based products mean for the future of regenerative medicine? Nearly 20 years after the discovery of induced pluripotent stem (iPS) cells, RiHEART® and AMCHEPRY® have marked a major milestone in the field. This session will bring together experts from academia and industry to share their experiences from early research through regulatory approval and commercialization. Speakers will discuss key challenges, lessons learned, academia–industry collaboration, regulatory interactions, and post-approval considerations.

Chair

Sumimasa Nagai

Kyoto University

The Trajectory of RiHEAET from Drug Discovery and Development to Practical Application

Yoshiki Sawa

Osaka Keisatsu Hospital

AMCHEPRY: Collaboration with Academia and the Path to Practical Application

Kenji Yoshida

RACTHERA Co., Ltd./Sumitomo Pharma Co., Ltd.

Induced Pluripotent Stem Cell-Derived Corneal Epithelial Cell Sheet Transplantation

Yoshinori Oie

The University of Osaka

Panel Discussion

All Session Speakers and

Daisaku Sato

Formerly with the Ministry of Health, Labour and Welfare

Day 2 | Monday October 19



Asia Track - 1 TRACK 2 9:00-10:40 ※10:40-11:15 Networking Break

Related: ALL | Level : Beginner/Intermediate English / Theater Style | Simultaneous translation by AI system

Regulatory Science in Asia: Advancing Drug Development with Collaboration in Asia

This session will explore current initiatives and collaborative mechanisms that are strengthening regulatory science in Asia. The session will begin with an overview of the OPEN Collaborative Procedure and proposed initiatives for its further advancement, highlighting how international regulatory cooperation can accelerate access to innovative medicines. This will be followed by a discussion on Asian Clinical Trial network as a strategic platform for promoting drug development in Asia, emphasizing their role in harmonizing evidence generation and facilitating efficient drug development. The session will also examine emerging Real-World Data (RWD)–driven collaborations in Asia, presenting current examples and discussing future opportunities to leverage real-world evidence in regulatory decision-making and post-market evaluation.

The session will conclude with a panel discussion featuring experts from regulatory authorities, academia, and industry to explore the future vision of an Asia regulatory system.

Chair

Masao Iwagami

Tsukuba University

Joonwoo Bahn

Asan Medical Center



OPEN framework

(Opening Procedures at EMA to Non-EU authorities)

Hodei Cuenca Grao

EMA

ATLAS: A Cancer Clinical Trial Network of Asia, by Asia, for Asia

Kenichi Nakamura

National Cancer Center Hospital

Real-World Data (RWD)–Driven Collaboration in Northeast Asia: Current Cases

Sungkyunkwan University

Judy (Ju-Young) Shin

Panel Discussion : Future: Toward an Asia Regulatory System

All Session Speakers and

Ling Su

DIA Fellow

Yil-Seob Lee

CHA Medical Center

Ayumi Endo

PMDA

Ines Lenic

AstraZeneca

Day 2 | Monday October 19

S-01 TRACK 4 9:00-10:30

Related : CD&O:D&DS:MA&SC:RA | Level : Intermediate | Japanese and English/ Theater Style | Simultaneous translation by AI system

Utilizing DX: The Global and Japanese Status of Clinical Trial Data Concepts Pioneered by Generative AI and ICH M11

Data standardization and Gen AI drive digitalization for faster reviews, real-time risk assessment, and trial efficiency. ICH M11 reached Step 4 in Nov 2025; Step 5 is expected in Japan within 2026, enabling automatic EDC integration to shorten trials and improve quality. The session covers FDA/PMDA AI trends, sponsor proposals for ICH M11 protocols, expectations for data use at medical institutions, and directions and challenges for building next-generation review and development systems through industry-government-academia collaboration.

Chair

Satoru Tsuchiya

JPMA/Sumitomo Pharma Co.,Ltd.

ICH M11: FDA Update

Janice Maniwang

FDA

Integration with Gen AI and Next-Gen Clinical Trial Data Platforms, Including the Implementation Status of ICH M11 in Japan

Yuji Matsukura

Pharmaceuticals and Medical Devices Agency (PMDA)

From ICH M11 Compliance to Digital Study Design: MSD's Journey to One Operational SOA for All

Mitzi Allred

Merck & Co., Inc.

Panel Discussion

All Session Speakers and

Yoshihiro Aoyagi

National Cancer Center Hospital East

Guillaume Schoch

EFPIA/Roche



Day 2 | Monday October 19

S-02 TRACK 5 9:00-10:30

Related : CS&PV:CD&O:D&DS | Level : Beginner/Intermediate | English / Theater-style | Simultaneous translation by AI system

Advancing Pharmacovigilance: ICSR Management, RWE Usage, and Their Combined Value for Patient Safety

This session brings together global and Japan specific perspectives on PV modernization by:

- Examining limitations of push based ICSR model highlighting how duplication, replication, and fragmented reporting undermine signal detection and regulatory collaboration.
- Exploring emerging ecosystem approaches, including canonical safety data access and respective use under ICH M14.

Chair

Osamu IDA

Novartis Pharma KK



Reframing Pharmacovigilance Modernization: Resonating with the Kintsugi Concept

Samuel WALLIS

Bristol Myers Squibb

Challenges in the Current Ecosystem and Practical Insights from Trials and Findings

Sarah VAUGHAN

Medicines and Healthcare Products Regulatory Agency (MHRA)

Strengthening Patient Safety in Japan: The Role of ICSRs and Collaboration

Rieko SAITO

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers

Hirokami OHARA

Johnson & Johnson

Koji Kawamura

CMIC Co., Ltd.

Day 2 | Monday October 19

S-03 TRACK 6 9:00-10:30

Related : RA:CD&D | Level : Intermediate/Advanced Japanese / Theater Style

The Potential of New Combinations to Accelerate Drug Development for Rare Diseases

More than 6,000 rare diseases have been identified worldwide, affecting an estimated 300 million people. However, effective treatments remain unavailable for more than 90% of these diseases. Accelerating rare disease development requires not only new discoveries and innovation, but creative approaches that recombine existing elements. This session will review current regulatory pathways and discuss more effective development processes, including orphan drug designation, conditional approval, Early Consideration, Consultation on Package Insert, IIT, RWD, use of overseas data and Reliance Review Procedure.

Chair

Yojiro Sato

Janssen Pharmaceutical K.K, Global Regulatory Affairs



Alexion Pharma's Experience, Strategy and Outlook in Rare Disease Drug Development

Osamu Asano

Alexion Pharma GK

Sanofi's Strategy and Challenges in Rare Disease Development

Susumu Kitamura

Sanofi K.K.

Rare Disease Drug Development from an Academic Perspective: Current Status and Future Initiatives

Ozeki Michio

Gifu University Hospital

Facilitating Rare Diseases Drug Development: PMDA's Perspective

Akifumi KAMATA

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers

Day 2 | Monday October 19

S-04 TRACK 7 9:00-10:30

Related : CD&O:PM:RA:ST: Other | Level : Intermediate | Japanese / Theater Style

The Value Japan Can Contribute to Global Clinical Trials and the Role of Clinical Scientists 【Clinical Science & Strategy】

This session aims to clarify the value Japan can contribute to global drug development through participation in multi-regional clinical trials (MRCTs), and to discuss the roles and perspectives required of professionals in future global development.

Japan's MRCT participation has become a standard development strategy. However, the value this brings to global development still warrants renewed discussion. This session will examine the significance of Japan's participation and future directions from multiple perspectives, including scientific, patient, and regulatory considerations.

Chair

Kazuhiro Kanmuri

Tanabe Pharma Corporation



The Value of Clinical Scientists :From a Japan-Led Study to Global Drug Development

Yoshinori Kawaguchi*

Daiichi Sankyo Co., Ltd.

*Recording is not available for viewing. (Speakers who informed us by October 9 that post-event on-demand access is not permitted.)

The value of Japan in global clinical trials: a global perspective

Koshima Soma

Pfizer Inc.

What Skill Sets and Expectations Are Needed to Succeed in Clinical Development?

Yoshito Takeuchi

Nippon Boehringer Ingelheim Co., Ltd.

Panel Discussion

All Session Speakers, and

Takayoshi Toriyabe

Pharmaceuticals and Medical Devices Agency (PMDA)

Day 2 | Monday October 19

S-05 TRACK 8 9:00-10:30

Related : CD&O:D&DS:MA&SC:P&EPR:PM&SP:Stat:Other | Level : Intermediate | Japanese / Theater Style

Reimagining Drug Development Through Virtual Experimentation: Lessons from Digital Twin Adoption in Other Industries

"We used to test only on real patients." Will we say this in ten years? Digital Twin, already adopted in several industries, replicates reality virtually to optimize design and testing. Can pharma be next? This session explores cross-industry lessons for clinical trials and RWE, discussing Digital Twin's potential, benefits, and challenges in drug development.

Chair

Marie Shiga

Pfizer Japan Inc.



*The Potential of IoT, CPS, and Digital Twins
—A New World of Drug Discovery, Medication Adherence,
and Healthcare—*

Masaki Minami

PwC Consulting LLC

Applications of Digital Twins for Urban Resilience

Takeshi Sato

KOZO KEIKAKU ENGINEERING Inc.

*Digital Twins in Manufacturing and Logistics
- Testing the Future Before It Becomes Reality -*

Shumpei Shimizu

NTT DATA Group Corporation

Panel Discussion

All Session Speakers

Day 2 | Monday October 19

S-06 TRACK 9 9:00-10:30

Related : EN:V&A | Level : Beginner/Intermediate | Japanese / Theater Style

Refining IC Beyond Boundaries: Dialogue on Informed Consent in Emergency Clinical Trials – Lessons from Hyperacute Stroke

Clinical trials in medical emergencies must be conducted under severe time constraints while protecting participants' safety and rights. This session will focus on hyperacute stroke treatment to discuss ethical and practical issues in informed consent from the perspectives of clinicians, industry, regulators, and patients/public contributors. We will examine the relevance of EFIC (Exception from Informed Consent), deferred consent, and other international approaches to Japan's legal, ethical, and social context, and explore directions for practical resolution through real-time polling and dialogue.

Chair

Manabu Minami

National Cerebral and Cardiovascular Center



Challenges in Informed Consent for Emergency Clinical Trials : Perspectives in Light of International Trends

Mayumi Fukuda-Doi

National Cerebral and Cardiovascular Center

Emergency Clinical Trials in Global Drug Development: Preventing Drug Loss and Enabling Multi-Regional Trials

Minetake Kitagawa

Japan Pharmaceutical Manufacturers Association

Perceptions of Informed Consent in Emergency Clinical Trials: Implications for Decision-Making Support

Etsuko Arita

Kitasato University

Panel Discussion

All Session Speakers and

Hiroyuki Kawakatsu

The Japan Stroke Association

Haruko Yamamoto

National Cerebral and Cardiovascular Center



Special Session-1 TRACK 1 11:15-12:55

Related: P&EPR:CD&O: Others | Level : Beginner | Japanese / Theater Style | Simultaneous translation by AI system

Contributions of Japan's Collaborative Innovation Hubs to the Drug Discovery Ecosystem

This session will revisit the roles and unique strengths of drug discovery clusters by exploring the similarities and differences among the clusters located throughout Japan, through the perspectives of leading representatives of these clusters. In addition, by discussing the current adequacy of drug discovery clusters as collaborative innovation hubs, as well as future expectations for them — incorporating viewpoints from academia — we aim to create an opportunity to consider the ideal vision of a drug discovery ecosystem anticipated by both industry and academia.

Chair

Kaori Iida

Institute of Science Tokyo

Hiroyuki Kanou

LINK-J

Fire Side Chat

Shunichi Takahashi

LINK-J

Ayano Kagami

CIC Institute

Hiroshi Atsumi

Kawasaki Institute of Industrial Promotion (KIIP)

Kaori Iida

Institute of Science Tokyo

Panel Discussion

All Session Speakers and

Kazuyoshi Nagata

Kyoto Research Park Corp.

Haruhiko Koike

Foundation for Biomedical Research and Innovation at Kobe (FBRI)

Hiroshi Atsumi

Kawasaki Institute of Industrial Promotion (KIIP)

Keisuke Watanabe

iPark Institute Co., Ltd

Ikuo Hayashi

MITSUI FUDOSAN Co., LTD.

Masahide Goto

Astellas Pharma Inc.

Day 2 | Monday October 19



Asia Track – 2a TRACK 2 11:15-12:45

Related: ALL | Level : Beginner/Intermediate English / Theater Style | Simultaneous translation by AI system

Beyond E17 - Holistic Implementation of E5 and E17 to Lead Global Drug Development from Asia

This session discusses the holistic and integrated implementation of ICH E5 and E17 to lead global drug development from Asia.

Building on the principles of the guidelines, the discussion will focus on practical challenges such as determining the appropriate sample size for each participating country and interpreting the results derived from multi-regional clinical trials (MRCTs).

We will explore specific pathways to overcome differences in regional requirements and construct efficient, scientifically robust development strategies from a pan-Asian perspective. Through this session, participants are expected to gain practical insights for achieving true global harmonization and optimizing clinical development in the Asian region.

Chair

Masafumi Yokota

Daiichi Sankyo Co., Ltd.

TBD

Ministry of Food and Drug Safety (MFDS)



Scientific Principles Bridging E5 and E17: Trial Design Focusing on Effect Modifiers

Shuji Kamada

Pharmaceuticals and Medical Devices Agency (PMDA)

Beyond Consistency Assessment: Statistical and Regulatory Considerations for Integrated Evidence Evaluation from China Perspective

Yan Hou

Peking University

Asia-led Simultaneous Global Development Strategy: Case Studies

Hyejong Yoo

AstraZeneca

Leveraging Asia in Global Development Planning through E17/E5 Implementation

William Wang

Merck US

Panel Discussion : Strategic Recommendations to Improve Patient Access in Asia, leveraging E5/E17 Implementation

All Session Speakers and

Janet Lu

Shanghai Zhiqiaohang Medical Consulting Co.

Day 2 | Monday October 19

S-07 TRACK 4 11:15-12:45

Related: CS&PV:MA&SC:PE | Level : Beginner | Japanese and English/ Theater Style | Simultaneous translation by AI system

Co-Creating Patient-Centered Drug Information Through Structured Data and AI in Practice

Widespread adoption of conversational AI has enabled patients to proactively access drug information. In 2026, Japan launched the Essential Patient Medication Guides, introducing HTML-based structured data for use with generative AI. This session will explain Retrieval-Augmented Generation (RAG) as a key technology for improving the reliability of AI-generated responses and present examples from a patient advocacy organization on the use of conversational AI to support patient information seeking. Panel discussion will explore how structured data and generative AI can support patient engagement in drug development.

Chair

Madoka INOUE

Pharmaceuticals and Medical Devices Agency(PMDA)



Improving Information Accessibility Through Structured Data

Mikiko Shitara

Gene and Serve Ltd

Structured Data, Its Extensibility, and the Current State of Reliability Assurance Technologies, Including RAG

Koji Hazama

Exa MD Inc.

How Patients Use Gen AI to Manage Health and Medical Conditions

Melissa Lim

Brain Tumour Society Singapore (BTSS)

Panel Discussion

All Session Speakers

Day 2 | Tuesday October 20.

S-08 TRACK 5 11:15-12:45

Related: CD&O:D&DS:PM&SP:Others | Level : Intermediate/ Advanced | Japanese / Theater Style

Have You Looked Up at the Blue Sky? Project SOUTEN: Data-Driven Accelerated Trial Enrollment Model From Japan

Japan's clinical trial environment faces structural challenges, including low patient enrollment per site, which reduce global competitiveness. To address them, Takeda and Tohoku University launched Project SOUTEN, a regional, data-driven model integrating real-world data, clinical networks, and streamlined feasibility processes. Takeda and Tohoku University will present early outcomes and pilot insights in this session. RWD platform provider NEC will provide their insights and MHLW will share the national policy and action directions to accelerate clinical trials in Japan.

Chair

Terao Yasuko

Takeda Pharmaceutical Company Ltd.

Data-Driven Accelerated Trial Enrollment Model: Background and Rationale from a Global Pharma Perspective

Enya Kazuaki

Takeda Pharmaceutical Company Ltd.

Insights from a Real-World Pilot Study: What Works? and What Must Change? to Enhance Trial Feasibility and Enrollment

Tatsuro Misu

Tohoku University Hospital

Accelerating Clinical Trials through Real-World Data Integration Insights from Building and Analyzing Japan's Healthcare Data Infrastructure

Masahiro Kubo

NEC Research and Development Division Biometrics Lab.

Japan as a Chosen Location for Clinical Trials: Future Directions for Strengthening Japan's Clinical Trial Ecosystem

Yasuhiro Araki

Ministry of Health, Labour and Welfare

Panel Discussion

All Session Speakers



Day 2 | Monday October 19

S-09 TRACK 6 11:15-12:45

Related: ALL | Level : Beginner | Japanese / Interactive Workshop

The Power of the DIA Community: Co-Creation of the Lifecycle for Next-Generation Drugs and Medical Devices Led by Japan 【Contents Committee】

DIA Community is a platform for exchanging ideas that transcends specialties and positions, aiming to address common challenges in the pharmaceutical and medical device development industries. This session will share the outcomes and learnings from this year's DIA Community Day while engaging in dialogue with participants to collaboratively explore ideas, from identifying challenges to finding solutions. This is an excellent opportunity to experience the value and passion of the DIA Community, and we look forward to welcoming participants from various industries and professions.

Chair

Kotone Matsuyama

National Center for Child Health and Development



Dialogue: Our Challenges, Our Future

Naoki Isogawa

UCB Japan Co., Ltd.

Kentaro Kogushi

Novartis Pharma K.K.

Satoshi Suzuki

Pfizer R&D Japan

Kana Maruyama

Viartis Pharmaceuticals Japan G.K.

Panel Discussion

All Session Speakers and

Day 2 | Monday October 19

S-10 TRACK 7 11:15-12:45

Related: CD&O:PM&SP:RA:Stat | Level : Intermediate/Advanced | Japanese / Theater Style

"Smart" MIDD in the ICH-M15 Era: An Industry-Government Paradigm Shift in Drug Development 【Clinical Pharmacology】

ICH-M15 (General Principles for Model-Informed Drug Development [MIDD]), recently reaching Step 4, advances global harmonization in the use of MIDD. It provides a common basis for regulatory–industry dialogue on if MIDD can be accepted as “MIDD evidence” to support or replace clinical data, depending on context of use. Improving predictability of regulatory decisions is expected to expand MIDD adoption. Approvals based on the “smart” use of MIDD have increased with appropriate regulatory communication. This session will highlight recent successes and discuss effective strategies and the impact of full implementation.

Chair

Naoto Uemura

Oita University



Overview of the background for ICH-M15 as it reaches Step 4

Shuya Yoshida

Pharmaceuticals and Medical Devices Agency (PMDA)

MIDD-Guided Dose Justification of Tirzepatide in Japanese patients with T2D

Hanaka Mimura

Eli Lilly Japan K.K.

MIDD Strategies to Overcome Clinical Pharmacology Challenges for Regulatory Approvals

Mayumi Hasegawa

Certara Inc.

MIDD to Support Dose Selection for Sevabertinib During Clinical Development

Yoshiyuki Tsuda

Bayer Yakuhin, Ltd.

Panel Discussion

All Session Speakers and

Atsunori Kaibara

Eli Lilly Japan K.K.

Day 2 | Monday October 19

S-11 TRACK 8 11:15-12:45

Related: RA:CD&O:CS&PV | Level : Intermediate | Japanese / Theater Style

Marketing Authorization and Review in the AI Era: What Must We Do Now for an AI-Enabled Future??Beyond Expectations 【Regulatory Affairs】

Recent advances in AI, including generative AI, are creating opportunities to improve regulatory affairs activities such as document drafting, literature review, dossier organization, and regulatory information analysis. Beyond efficiency, AI may support human decision-making throughout drug development, marketing authorization applications, regulatory review, and post-marketing safety. This session will examine the potential and challenges of AI, including reliability, transparency, governance, and accountability, from industry, regulatory authority, and academic perspectives.

Chair

Seiji Sato

Takeda Pharmaceutical Company Limited



Generative AI Fundamentals and Its Potential Applications in Regulatory Affairs

Tadashi Tsubota

Takeda Pharmaceutical Company Limited

AI in Regulatory Affairs: Current Practice and Future Vision

Tsuzuki, Toshinori

Astellas Pharma Inc.

AI in Regulatory Authority: Current Status and Future Directions

Tomoharu NUMANYU

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers and

Satoshi Kusakabe

NTT DATA Group Corporation

Day 2 | Monday October 19

S-12 TRACK 9 11:15-12:45

Related: PM&SP:RA:Stat | Level : Intermediate | Japanese / Theater Style

Evidence Requirements for Conditional and Time-Limited Approval: Statistical Evaluation of Small-Sample Regenerative Products

The conditional and time-limited approval systems for regenerative medical products assess efficacy and safety using limited cases and short-term data, and address uncertainties through post-marketing evidence. This session examines statistical evaluation in small-sample settings, shifting from significance testing to uncertainty quantification and rational decision-making. From regulatory science and practical perspectives, it discusses evidence requirements at approval and post-marketing verification methods, balancing scientific validity with timely patient access.

Chair

Junichi Asano

Pharmaceuticals and Medical Devices Agency (PMDA)



Pre-specification of Success Criteria and Efficient Post-Marketing Clinical Trial Designs

Satoshi Teramukai

Kyoto Prefectural University of Medicine

How Can We Demonstrate the Value of Regenerative Medical Products?

Current Status and Future Perspectives on Clinical Evaluation

Yoshiaki Maruyama

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers and

Akihiro Hirakawa

Institute of Science Tokyo

Day 2 | Monday October 19



Special Session-2 TRACK 1 14:15-15:45

Related: ALL | Level : Intermediate/Advanced | Japanese / Theater Style | Simultaneous translation by AI system

Healthcare Revenue Models in the Era of Population Decline: Co-Creating Innovation Through Public Private Partnerships

Amid population decline and mounting healthcare financial pressures, both pharmaceutical and medical institutions in Japan must transform their business models. This session explores how Japanese hospitals can build new revenue streams and shift toward sustainable management from multiple perspectives: management, data utilization, clinical practice, and business development/finance. Starting from leading domestic examples of hospital-driven revenue diversification, the panel presents the next steps that pharma, medical institutions, and industry can co-create.

Chair

Masanari Jinnouchi

peaceful Inc

TBD

Hiroyuki Kageyama
Konan Medical Consortium

TBD

Keita Masui
Industrial Drive LLC

Panel Discussion

All Session Speakers



Asia Track – 2b TRACK 2 14:15-15:45

Related: ALL | Level : Beginner/Intermediate | English / Theater Style | Simultaneous translation by AI system

Transformation in Quality Management Approach for Global Clinical Trials - Strategic E6(R3) Implementation to Realize “Flexible” GCP Leveraging CTQ Factors

This session highlights the transformation in quality management approaches driven by ICH E6(R3) and discusses the realization of “flexible” GCP operations in global clinical trials. The focus will be on the importance of identifying Critical to Quality (CTQ) factors that are directly linked to protocol objectives during the planning stage and continuously reviewing them throughout the trial.

Furthermore, we will examine practical connections with other guidelines, such as using estimands (ICH E9(R1)) to identify potential CTQ factors and determining how to communicate priority risk management issues across all participating countries and sites (ICHE17). Through this session, participants will comprehensively learn about next-generation quality management strategies leveraging a risk-proportionate approach.

Chair

Izumi Oba

Pharmaceuticals and Medical Devices Agency (PMDA)

NaYoung Lee

Parexel



Paradigm Shift Driven by ICH E6(R3): Realizing ‘Flexible’ GCP Leveraging CTQ

Osamu Komiyama

ex E8(R1) Expert

Quality By Design from A Statistical Perspective

Yang Zhao

Nanjing Medical University

Practical CTQ Factor Management in Asian MRCTs

Bokjin Hyun

Handok

Expectations for GCP Renovation Implementation: Opportunities in Asia from a Global Development Perspective

Rebecca Stanbrook

RESaltas GmbH

Panel Discussion : From Asian Practice to Global Practice: Considerations for Realizing Flexible GCP

All Session Speakers

Day 2 | Monday October 19

Pitch Session TRACK 4 14:15-15:45

Related : ALL | Level : Intermediate/Advanced | Japanese and English / Theater Style | Simultaneous translation by AI system



Pitch session

This session is DIA Japan's first Whale Tank-style pitch event: Four Japan-based healthcare and life-sciences startups pitch their strategies to decision-makers from pharma, regulatory authorities, clinical KOLs, CVCs, and VCs, gaining market validation and practical feedback toward market launch and global expansion. The winning team is recommended for a seed-stage slot at the DIA Global Annual Meeting 2027. During the judges' deliberation, evaluation perspectives from each decision-maker are shared, creating a 90-minute format that maximizes learning for all participants.

Note: Pitch evaluations will be conducted after the session, and the awards ceremony will take place **on Monday, October 19, from 18:15 to 18:55 in Venue 4.**

Chair

Hiroyuki Kanou

LINK-J

Mitsuhiro Niimi

DIA Japan

Presenter

Toshihiko Tsukamoto

Illumi Medical Inc.

Yumesaku Ishigaki

rVirogen, Inc.

Atsushi Mizuno

iXgene, Inc.

Toshi Matsuoka

General Prognostics Inc. (GPx)

Judge

Toshihiko Doi

National Cancer Center Hospital East

Toru Jay Seo

Newsight Tech Angels

Tadayoshi Hirata

Astellas Venture Management LLC

Yasunori Yoshida

Japan Pharmaceutical Manufacturers Association

Day 2 | Monday October 19

S-13 TRACK 5 14:15-15:45

Related: D&DS:CD&O:Others | Level : Intermediate | Japanese / Theater Style

Connecting Data, Opening the Future: Standardization, Integration, and AI for the Next-Generation Drug Discovery Pipeline

This session explores the data, AI, and frameworks underpinning drug discovery DX, as previously siloed domains begin to converge. With real-world data, standardization, and patient-centric approaches advancing together, crossing these boundaries is now key to accelerating the pipeline. The Life Intelligence Consortium (LINC), an academia-industry collaboration of life science and IT companies, drives key initiatives forming the foundation of this transformation. This session introduces four core areas at the heart of these efforts.

Chair

Mari Nogami-Itoh

Graduate School of Pharmaceutical Sciences, The University of Osaka



Connecting Diverse Health Data : Toward a Cohort Catalog and Global Standards Integration

Rika Abe
RIKEN

Potential of Knowledge Graph-Based Open Databases in Clinical Development

Saki Katayama
Chugai Pharmaceutical Co., Ltd

Clinical Trial Simulation with Quantitative Systems Pharmacology Model and Virtual Patient Generation with AI Technologies

Ryuuta Saitou
Tanabe Pharma Corporation

Development of a Clinical Trial Participant Recruitment System Incorporating Patient Self-Access and PHR Data Utilization

Rika Okamoto
Foundation for Biomedical Research and Innovation at Kobe, Center for Medical Innovation

Panel Discussion

All Session Speakers and

Yukako Hinohara
Cabinet Office

Day 2 | Monday October 19

S-14 TRACK 6 14:15-15:45

Related : PM&SP, Others | Level : Beginner/Intermediate | Japanese / Interactive Workshop

Dialogue That Sparks Innovation: A Bridge Crossing Boundaries 【Project Management】

Innovation arises when new technologies or systems are accepted by society. However, when diverse stakeholders collaborate, differences in values and other factors often prevent innovation from taking root.

In this session, we will share case studies of challenges encountered during the innovation process, and dialogue among participants. We aim to provide a space where participants can experience firsthand how building bridges between stakeholders through dialogue enables them to transcend boundaries and create new value. And also sharing practical tips from a project management framework.

Chair

Nao Horie

Hokkaido University Hospital

Case 1 : In Academia

Yu Komura

National Cancer Center Hospital East

Case 2 : In Industry

Tomofumi Setta

Otsuka Pharmaceutical Co., Ltd.

No Voice Left Behind- Project Management Perspective

Takashi Sato

PM Orchestra TS

Closing

Kayoko Kikuchi

FUJITA HEALTH UNIVERSITY

Panel Discussion

Yoshio Marumoto

Yamaguchi University Hospital

Ai Okazaki

Institute of Science Tokyo Hospital

Yukana Murahashi

Chugai Clinical Research Center CO., LTD.



Day 2 | Monday October 19

S-15 TRACK 7 14:15-15:45

Related: CD&O:MA&SP:RA | Level : Intermediate/Advanced | Japanese / Theater Style

The Role of Academia and Public–Private Partnerships in Accelerating Drug Development for Neurological Diseases

Neurological disorders are a rapidly advancing area of drug development, driven by breakthroughs in biologics, nucleic acid medicines, and gene and cell therapies. This session will examine the evolving role of academia and the future of academia–industry–government collaboration in accelerating innovation. Through multi-stakeholder dialogue, participants will explore strategies to strengthen Japan’s neurological drug development ecosystem and promote globally competitive innovation.

Chair

Keisuke Suzuki

National Center for Geriatrics and Gerontology



JSNT Initiative for Therapy Development

Masahisa Katsuno

Nagoya University Graduate School of Medicine

Transforming Japan’s Drug Development Ecosystem: Challenges and Opportunities from an EBP Perspective

Haruhiko Morita

Modalis Therapeutics Corporation

Collaboration between the Regulatory Authority and Academic Societies to Advance Drug Development: Expectations for Academia

Toshinori Takagi

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers

Harumasa Nakamura

National Center of Neurology and Psychiatry

Day 2 | Monday October 19

S-16 TRACK 8 14:15-15:45

Related: CS&PV:RA:MA&SC | Level : Beginner/Intermediate | Japanese / Theater Style

RMP 2.0 Evolving Pharmaceutical Risk Management with the Revised PMD Act: Toward Patient-Centered Safety 【Pharmacovigilance & Labeling】

The 2025 revision of the PMD Act established Risk Management Plans (RMPs) as a regulatory requirement, reinforcing their role as the core of lifecycle safety measures beyond the re-examination system. With their implementation in 2027, focus is shifting to optimizing risk minimization activities and evaluating their effectiveness. This session brings together regulators, academia, and industry to discuss key challenges in metrics, data, and implementation, and to explore how evaluation can support RMP revision and termination toward patient-centered safety.

Chair

Mamoru Narukawa

Kitasato University



Revision of the RMP Framework under the 2025 PMD Act

Kazuya Ichikawa*

Ministry of Health, Labour and Welfare

*Recording is not available for viewing. (Speakers who informed us by October 9 that post-event on-demand access is not permitted.)

Overview of the Study on Evaluation Methods for Risk Minimization Activities in Pharmaceutical RMP

Masafumi Shimokawa

Sanyo-Onoda City University

Impact of the New RMP System on the Pharmaceutical Industry: Focusing on Risk Minimization Activities

Kazuhiko Ishida

Japan Pharmaceutical Manufacturers Association

Panel Discussion

All Session Speakers and

Makoto Miyazaki

Japan Pharmaceutical Manufacturers Association

Nobuhiro Narii

Takeda Pharmaceutical Company Limited

Day 2 | Monday October 19

S-17 TRACK 9 14:15-15:45

Related: CD&O:CS&PV:RA | Level : Intermediate/Advanced | Japanese / Theater Style

Medical Devices Today: Experience with RWD in Regulatory Submissions and Post-Market Surveillance【Device】

In the field of medical devices, registries have increasingly been utilized for both marketing authorization applications and post-marketing surveillance. The Alliance Registry, focusing on drug-coated balloons for coronary interventions, has provided supporting data for indication expansion. The J-CIC registry has established a framework for post-market studies in pediatric cardiology, including the development of standard operating procedures and the streamlining of data collection. This session will present recent advances in RWD utilization and discuss key challenges and perspectives.

Chair

Kensuke ISHII

Kochi Medical School Hospital, Kochi University



ALLIANCE Registry: Indication Expansion via Real-World Data

Masato NAKAMURA

Ohashi Medical Center, Toho University

Outcomes of the JCIC Registry Initiative (tentative)

Takanari FUJII

Showa Medical University Hospital

Real-World Data in Medical Devices: Practice and Challenges

Naoyuki YABANA

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers and

Michiaki IWATA

Japan Agency for Medical Research and Development (AMED)

Kazuo KAWAHARA

Boston Scientific Japan K.K.

Day 2 | Monday October 19



Regulatory Session-1 TRACK 1 16:30-18:00

Related: CD&O:P&EPR:PM&SP:RA | Level : Beginner/ Intermediate | Japanese / Theater Style | Simultaneous translation by AI system

Delivering Innovation to Patients: Perspectives from PMDA, Startups, and Venture Capital

TBD

Chair

Hirokazu Shimoda

Japan Agency for Medical Research and Development (AMED)

Regulatory Science as Innovation Infrastructure

Takuya KAGEYAMA

Pharmaceuticals and Medical Devices Agency (PMDA)

What Venture Capital Looks for in Drug Development - Key Requirements for Investment and a Path to Value Creation

HIROYUKI HASEGAWA

Mitsubishi UFJ Capital Co., Ltd

TBD

Hikaru Miyazaki

Restore Vision Inc.

Panel Discussion

All Session Speakers

Day 2 | Monday October 19

Asia Track - 3 TRACK 2 16:30-18:05

Related: ALL | Level : Beginner/Intermediate | English / Theater Style | Simultaneous translation by AI system

Advancing Patient-Focused Drug Development: From Clinical Trials to Real-World Medication Use

Patient focus is increasingly recognized as a critical component of drug development and medication use. Integrating patient perspectives can improve the relevance of clinical research, reduce participation burden, and support better treatment adherence and health outcomes.

This session will discuss practical approaches to implementing patient-focused strategies across the drug development lifecycle. Topics will include patient-centric clinical trial design to reduce burden, such as simplified protocols, decentralized trials, and digital tools that facilitate participation and data collection. The investigator's perspective on how to collect patient voice will be addressed and discussion will explore how patient preference studies may inform drug development, risk-benefit assessment, regulatory submission and evaluation. The session will also discuss considerations in promoting patient-centric product information (PCPI) worldwide. Through examples and discussion, participants will gain insights into how patient-focused approaches can strengthen evidence generation, improve real-world use of medicines and better empower patients.

Chair

Ling Su

DIA Fellow

Dorothy Toh

HSA



Advancing Patient-Centric Product Information(PCPI) across regions: Enhancing Understanding, Adherence and Patient Empowerment

Rie Matsui

Pfizer R&D Japan G.K.

Decentralized Clinical Trials in Asia: From Implementation to Risk Management

Wenjing Zhou

University of Hong Kong, Shenzhen Hospital Clinical Trial Centre

Patient Focus from the Investigator's Point of View - How to Collect Patient

Kyu-pyo Kim

Asan Medical Center

Panel Discussion: Advancing Patient-Focused Drug Development Across the Product Lifecycle: From Patient Voice to Real-World Impact

All speakers

Day 2 | Monday October 19



Sponsored Seminar TRACK 3 16:30-18:00

Related: CD&O:CS&PV:D&DS:RA:P&EPR | Level : Intermediate | English / Theater Style | Simultaneous translation by AI system

From Discovery to Submission: Operationalizing Next-Gen AI and Agentic Workflows in Drug R&D

As biological and clinical data surpass traditional processing capacities, AI is rapidly expanding across the drug development lifecycle—from early target discovery to regulatory submission. However, transitioning from experimental pilots to routine regulatory and clinical practice requires rigorous scientific validation, "glass-box" traceability, and human-in-the-loop governance. This session examines the latest advancements in scientific foundation models and agentic AI frameworks for life sciences. Through live demonstrations, speakers will illustrate how (1) biomolecular structure prediction (AlphaFold 3) and single-base non-coding genomic interpretation (AlphaGenome) accelerate early discovery workflows, and (2) multi-agent regulatory systems automate ICH E3-aligned Clinical Study Report (CSR) drafting, perform statistical quality verification, and anticipate Health Authority queries. Attendees will gain practical insights into operationalizing trustworthy AI to shorten development timelines and bring therapies to patients faster.

Chair

Jundo Araki

Google Cloud Japan G.K.



Joe Ledsam

Google for Health

Jundo Araki

Google Cloud Japan G.K.

Panel Discussion

All Session Speakers

Day 2 | Monday October 19

S-18 TRACK 4 16:30-18:00

Related: CD&O:CS&PV:D&DS:MA&SC:P&EPR:V&A | Level : Intermediate | English / Theater Style | Simultaneous translation by AI system

Creating a Sustainable Digital Biomarker Ecosystem: A Future Unlocked by “New Connections” Beyond Clinical Trials

Digital biomarkers (dBM) are objective, quantitative physiological data captured by sensors and wearable devices, enabling continuous collection in daily life. Once limited to in-clinic settings, such data can now be obtained longitudinally, advancing use in drug development and clinical trials. However, challenges remain in real-world adoption and sustainability. This session will explore “new integration” beyond trials, engaging industry, academia, and regulators to discuss expansion into care, post-marketing, and daily life, along with sustainable value creation and cost sharing across the ecosystem.

Chair

Yang Liu

Chugai Pharmaceutical Co., Ltd.



Creating New Value Through Digital Biomarkers

Norihiro Kawabata

Chugai Pharmaceutical Co., Ltd. / JPMA

Accelerate Digital Transformation of Healthcare via Multi-stakeholder Partnerships — Insights from DECODE Programs

Christine Guo

Ametris, LLC (formerly known as ActiGraph)

From Consumer Wearables to Digital Biomarkers Building Evidence for Personalized and Precision Health in Society

AKIKO KISHI SVENSSON

The University of Tokyo

Panel Discussion

All Session Speakers and

Use of Device-Collected Data for Marketing Approval

Hina FUKUTA

Pharmaceuticals and Medical Devices Agency (PMDA)

Benjamin Vandendriessche

Digital Medicine Society (DiMe)

Day 2 | Monday October 19

S-19 TRACK 5 16:30-18:00

Related: CD&O:QAC:P&EPR:Others | Level : Intermediate/Advanced | Japanese / Theater Style

Roundtable Discussion: Toward Implementation of a Single IRB

The revised J-GCP including the principle of a single IRB will be promulgated within this fiscal year. While the overall direction has been set, several issues remain to be addressed. Significant unresolved challenges include clinical trial acceptance decisions and safety oversight at trial sites, handling of ongoing trials, standardizing the contract format (sponsors and IRBs), and transparency in associated costs. In this session, speakers from industry, government and academia will discuss these challenges with the audience, to identify solutions supporting the implementation.

Chair

Kiyomi Hirayama

Quad Industry Alliance Taskforce /MSDK.K.



Overview the revised J-GCP - Single IRB

Tomoko Kataoka

Ministry of Health, Labour and Welfare

Building Institutional Governance Toward Single IRB Implementation

Sachiko Ichijo

The University of Osaka Hospital

JPMA Activities for the Implementation of Single IRB

Shin Nisikawa

Japan Pharmaceutical Manufacturers Association

Panel Discussion

All Session Speakers and

Yasuhiro Araki

Ministry of Health, Labour and Welfare

Kihiro Inano

Fukushima Medical University

Day 2 | Monday October 19

S-20 TRACK 6 16:30-18:00

Related: CD&O:Others | Level : Beginner/Intermediate | Japanese / Interactive Workshop

Interactive Session: The Value of Continuous Thinking-Exploring the Essence of Work Shaped by Junior and Senior Professionals【Operation Team】

In clinical development, junior professionals often feel uneasy due to the unclear purpose of procedures or lack of understanding of decision-making criteria, but have limited chances to raise these concerns. Meanwhile, senior professionals rely on experience shaped by changes in the clinical environment but do not always fully share their reasoning. This gap is a key challenge and an opportunity to foster mutual understanding. This session will use survey results to highlight differences, encourage reflection on the purpose of tasks, and provide actionable insights for behavioral change.

Chair

Yusho Kubota

A2 Healthcare Corporation

***The Gap between Junior and Senior Professionals:
Findings from over 700 Survey Cases from the
Client's Perspective***

Eri Toyoshima

ZeeDia life science Inc.

***The Gap between Junior and Senior Professionals:
Findings from over 700 Survey Cases from the
Healthcare Provider Perspective***

Yui Furihata

Shonan Kamakura General Hospital

Panel Discussion

All Session Speakers



Day 2 | Monday October 19

S-21 TRACK 7 16:30-18:00

Related: Stat:RA:CD&O | Level : Beginner/Intermediate | Japanese / Theater Style

Real-World Applications of Generative AI: Practical Implementation and Considerations in Drug Development 【Statistics】

Generative AI is spreading rapidly in drug development, yet few practical examples show which tasks it suits, to what extent, and how. This session share the current state of practical AI adoption from the viewpoint of working professionals rather than AI specialists. Examples include automating document retrieval, drafting semi-automating statistical deliverables with cross-functional effort, and implementing previously difficult statistical methods via an AI agent. The panel addresses quality assurance, accountability, and talent development for the AI-native generation.

Chair

Hiroyuki Ugai

Eli Lilly Japan K.K.



Enhancing Efficiency of Medical Writing and Development Regulatory Affairs in Pharma Using Generative AI

Naohiro Kawazoe

Shionogi & Co., Ltd.

AI-Powered Approach to Automated Generation of Statistical Analysis Plans and Analysis Table Shells for Clinical Trials

Emma Sasaki

Takeda Pharmaceutical Co., Ltd.

Collaboration between Statisticians and AI Agents: Exploring Trustworthy Implementation in Statistical Practice

Tomonori Oura

Eli Lilly Japan K.K.

Panel Discussion

All Session Speakers and

Takashi Sozu

Tokyo University of Science

Day 2 | Monday October 19

S-22 TRACK 8 16:30-18:00

Related: CD&O:CS&PV:D&DS:RA:Stat | Level : Intermediate | Japanese / Theater Style

Modernizing Clinical Trials with Pragmatic Elements: Regulatory and Sponsor Perspectives from Japan and Beyond

Clinical trials with pragmatic elements may include broader eligibility criteria, use of electronic health records, and selective safety data collection. These trials reduce burden on sites and participants and can support efficient evidence generation for regulatory decision making. However, misalignment between practices and regulatory expectations remains. To reduce regulatory barriers, TransCelerate collaborated with FDA to convene tabletop exercises. Speakers will reflect on these engagements, followed by discussion to identify key considerations for continued regulatory dialogue.

Chair

Harumasa Nakamura

National Center of Neurology and Psychiatry

Pragmatic Elements in Clinical Trials: Overview and Recent TransCelerate Initiatives

Mizuki Yoshida

TransCelerate BioPharma Inc./ Pfizer R&D Japan G.K.

Insights from Tabletop Exercises: Sponsor and Regulatory Perspectives

Fumie Yamazaki

TransCelerate BioPharma Inc./ UCB Japan Co., Ltd.

JPMA's Perspective on the ICH E19 Guideline

Hironori Sakai

Eisai Co., Ltd.

Panel Discussion

All Session Speakers and

Yuki Ando

Pharmaceuticals and Medical Devices Agency (PMDA)



Day 2 | Monday October 19

S-23 TRACK 9 16:30-18:00

Related: MA&SC:PC:CD&O | Level : Beginner/Intermediate | Japanese / Theater Style

Why Do Unmet Needs Persist Despite Advances in Treatment and Diagnosis? Bridging the Gap with RWD and AI 【Medical Affairs】

Unmet needs from a patient-centered perspective persist not only in areas lacking therapies but where treatments and diagnostics fail to fully address patients' symptoms, life contexts, and values. These gaps are driven by fragmentation across R&D, policy design, and clinical practice. Grounded in the principle of "leaving no one behind," this session will convene stakeholders from academia, industry, RWD organizations, and patient groups to leverage RWD and AI as a shared foundation, visualize differences in perspectives, and explore pathways to bridge gaps towards RW implementation.

Chair

Shinichi Nishiuma

Oceanus Bio Inc.



Defining Healthcare Challenges for 'No One Left Behind': AIMGAIN Insights on RWD and Cross-Sector Collaboration

Manabu Muto

Kyoto University

Where Does "Patient-Centered Care" Break Down?— Three Gaps from a Physician's Perspective

Sonoko Misawa

Institute of Science Tokyo

Making Patient-Centered Unmet Needs Actionable

Chang, Chia-Hsien

Amgen K.K

Panel Discussion

All Session Speakers and

Takeshi Shukunobe

PPeCC, Inc.

Yosuke Nishida

PwC Consulting LLC



Day 2 | Monday October 19

Special Chatting Session Reception Hall 19:00-20:45

We are excited to bring back our highly anticipated signature event, the "Special Chatting Session," on the evening of Day 2!

One of the primary missions of DIA is to foster professional networking and human connection.

This session offers a relaxed, casual environment for all participants to network and exchange ideas freely. Whether you are an early-career professional, a seasoned expert, a student or faculty member from academia, a representative from the pharmaceutical or medical device industry, a healthcare professional, or a member of PMDA—once you gather around the table, you are all peers! Even if you are attending the DIA Annual Meeting on your own, please don't hesitate to join the circle and dive into the conversations.

This year's chatting topics have been carefully selected by each Community and cover a wide range of timely and thought-provoking subjects. Some topics are even the result of cross-Community collaborations, creating unique synergistic discussions. Facilitators from each Community will be at the tables to guide the conversations, so simply head over to any table that sparks your interest.

Drinks (including alcohol) and light refreshments will be served. Let's enjoy some passionate, fun, and engaging discussions together!

Please note that all remarks made during this session are based on personal opinions and do not represent the official views of any organizations.

General MC

Kumiko Okada

Pfizer R&D Japan G.K.





Day 2 | Monday October 19

Special Chatting Session Reception Hall 19:00-20:45

No	Table	Facilitator			Theme	Abstract
1	MC/PV&L	PV&L	Viartis Pharmaceuticals Japan G.K.	Kana Maruyama	The Lifecycle of Drug Information in the DX Era - Perspectives from Healthcare Professionals and Patients-	As generative AI becomes the norm, how should Drug Information be created, delivered, and used, and by whom? Moving beyond conventional frameworks, we will openly explore and discuss the value that can be created throughout the information lifecycle.
		PV&L	Eisai Co., Ltd.	Kasumi Daidoji		
		MC	GlaxoSmithKline K.K.	Hiroki Nagahama		
2	OI/Six Sigma	Six Sigma	Create BioVentures	Goshi Ozawa	Is Your Open Innovation Really Open?	We all use the words "open innovation," yet collaboration still tends to stay inside the contract. Is what holds us back a legal limit, or a habit we have inherited, and do others outside Japan work differently? What
		OI	ortrea Japan KK	Makoto Nagaoka		
3	CP/ CS&S	CP	Eli Lilly Japan K.K.	Atsunori Kaibara	Beyond Patient Enrollment: How Can Japan Contribute to Global Drug Development Through Patient-Centric Approaches and MIDD?	Japan's contribution to global clinical trials extends beyond patient enrollment. Let's discuss how patient perspectives, healthcare practice, MIDD, and RWD can create value in drug development, while building on discussions from Sessions S-04 and S-10.
		CS&S	Bayer Yakuhin, LTD	Masaaki Jitsu		
4	CDM/ COM	COM	The University of Tokyo Hospital	Kaori Watanabe	"Just in Case"... But for Whom? Rethinking Query Management in the RBQM Era	COM × CDM Joint Session! "Do we really need that query?" Join us for an open discussion on query management in the RBQM era. Let's share perspectives across functions and explore ideas beyond traditional role boundaries.
		COM	National Cancer Center	Kazuma Tamaru		
		COM	Takeda Pharmaceutical Company Limited	Kazuyoshi Nanjou		
		CDM	Shionogi & Co. Ltd.	Akiko Kumagai		
		CDM	Kaken Pharmaceutical Co. Ltd.,	Naoya Takahashi		
5	Bioethics/ HEOR+ / PM	Bioethics	National Center for Child Health and Dev	Ayano Miyake	How Can We Integrate Everyone's "Values" into Drug Development and Business? Exploring Common Ground Among Patients, Ethics, Evidence, and Business Goals	In this session, we will share and explore how different stakeholders define and perceive "value." Through open dialogue among patients, industry, regulators, healthcare professionals, and others, we will identify common ground and discuss how these shared values can be translated into drug development and business practices to create greater impact and better outcomes for society.
		HEOR+	Novartis Pharma K.K.	Kogushi, Kentaro		
		PM	Institute of Science Tokyo Hospital	Ai OKAZAKI		
		PM	Hokkaido Univeisity Hospital	Nao Horie		
6	PEC	PEC	National Cancer Center	Nobuko Ushirozawa	Can AI Represent the Patient Voice?	Can AI help bring patient and public voices into healthcare and drug development? How far can AI go in understanding and representing patients' experiences, perspectives, and needs? Join the conversation on the future of Patient Engagement in the age of AI.
		PEC	A2 Healthcare Corporation	Yusho Kubota		
7	Stat	Stat	UCB Japan	Naoki Isogawa	Real-World Applications of Generative AI	An open discussion on how generative AI is actually used in day-to-day work — practical examples in document drafting, information retrieval, and statistical analysis, plus approaches to quality assurance and insights for future use.
		Stat	Eli Lilly Japan	Hiroyuki Ugai		
8	CI	CI	MSD K.K.	Yusuke Kajimoto	How Will We Use RCTs and RWD Differently in the Future?	How will RCTs and RWD evolve in the years ahead? Join us in exploring the future of evidence generation.
9	MA	MA	Amgen.Inc	Madoka Takeuchi	Closing the UMN Gap : Leveraging RWD for Patient-Centric Care	Why Do Unmet Needs Persist Despite Advances in Treatment and Diagnosis? — Bridging the Gap Between Patient-Centricity and Real-World Implementation with RWD and AI
10	RA	RA	Rhythm Pharma K.K.	Ichiro Ueki	How Could AI Transform Regulatory Affairs?	Advances in AI are creating new opportunities and challenges for regulatory affairs. Building on current experiences from both industry and regulatory authorities, this interactive session will explore how AI may reshape regulatory functions, accelerate development and approval processes, and redefine the role and skills of future regulatory professionals.

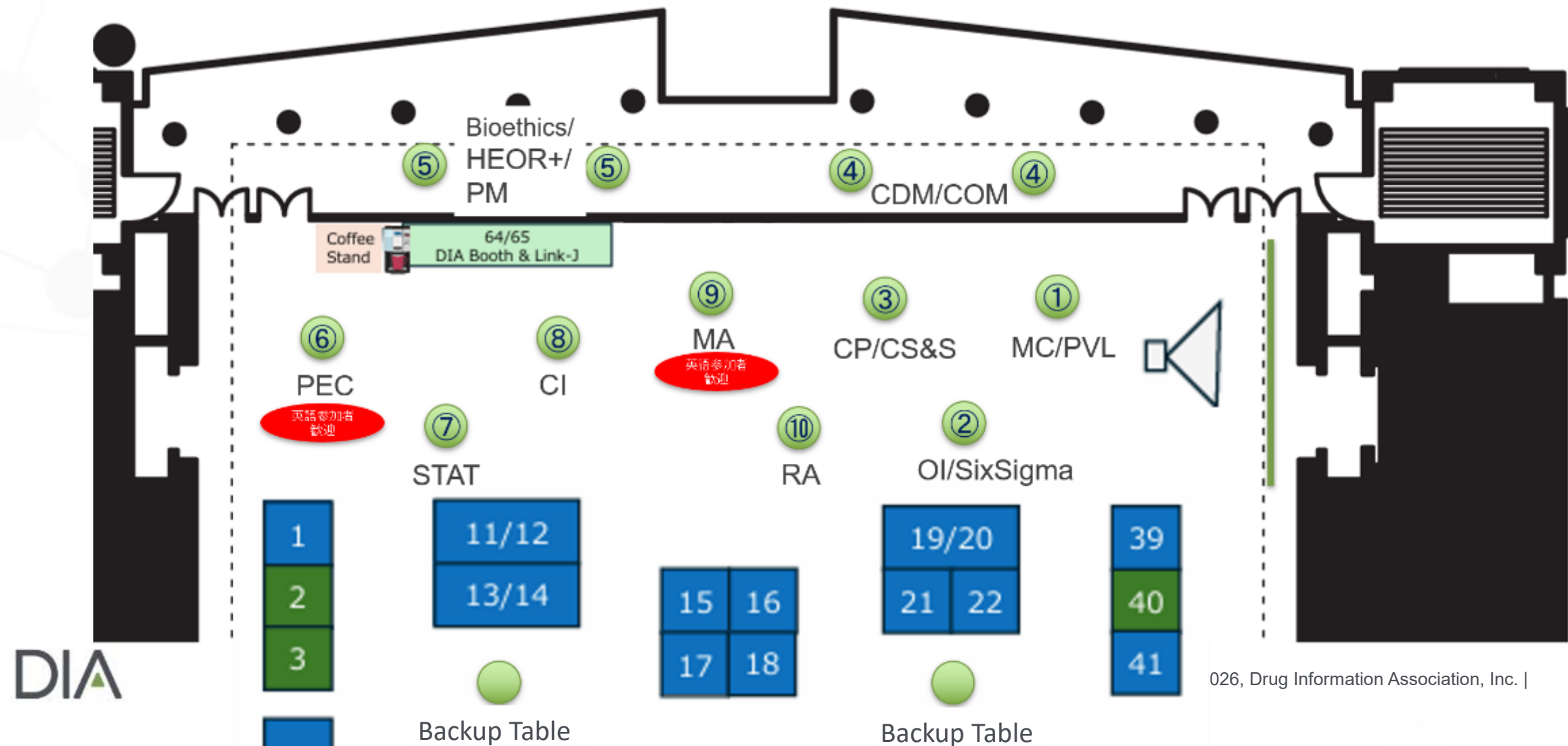


Bioethics, CDM: Clinical Data Management, CI: Clinical Innovation, COM: Clinical Operations & Monitoring, CP: Clinical Pharmacology, CS&S: Clinical Science & Strategy, HEOR+: Health Economics and Outcomes Research and Beyond, MA: Medical Affairs, MC: Medical Communication, OI: Open Innovation, PEC: Patient Engagement, PV&L: Pharmacovigilance & Labeling, PM: Project Management, RA: Regulatory Affairs, Six Sigma: Lean Six Sigma & Healthcare Process Excellence, Stat: Statistics



Day 2 | Monday October 19

Special Chatting Session Reception Hall 19:00-20:45



Day 3 | Tuesday October 20



DIAmond Session-1 TRACK 1 9:00-10:30

Related :ALL | Level : Intermediate | Japanese / Theater Style | Simultaneous translation by AI system

From Japan to the World: Bringing Next-Generation Treatments to Patients

Japan's R&D ecosystem is at a turning point. Public investment, regulatory science, and industry's global ambitions are creating new pathways for Japanese innovation to reach patients worldwide. This session brings together leaders from research, regulation, and industry to discuss how next-generation medicines can be delivered from Japan to the world.

The first half features a keynote presentation by Dr. Hitoshi Nakagama, President of AMED. In the second half, Dr. Yasuhiro Fujiwara (PMDA) and Dr. Osamu Okuda (Chugai Pharmaceutical) join Dr. Nakagama for a panel discussion on cross-sector collaboration and strengthening Japan's global competitiveness.

Chair

Yasuhiro Fujiwara

Pharmaceuticals and Medical Devices Agency (PMDA)



AMED's Third-Phase Initiatives to Advance Medical R&D

Hitoshi Nakagama

Japan Agency for Medical Research and Development (AMED)

Panel Discussion

All Session Speakers and

Osamu Okuda

Chugai Pharmaceutical Co.,LTD

Day 3 | Tuesday October 20

S-24 TRACK 2 9:00-10:30

Related: CD&O:CS&PV:PE:PM&SP:RA:V&A | Level : Beginner/Intermediate | Japanese / Theater Style | Simultaneous translation by AI system

Reframing Vulnerability: Toward Inclusion of Pregnant and Lactating Women in Clinical Research through ICH E21【Bioethics】

Pregnant and lactating women have long been excluded from clinical research, creating critical evidence gaps in medication during pregnancy and lactation. Recognizing the limitations of "protection by exclusion," the ICH E21 guideline promotes a more balanced approach to evidence generation and participant protection. This session will explore the ethical, regulatory, and practical implications of including pregnant and lactating women in clinical research and discuss pathways toward more equitable and evidence-based healthcare.

Chair

Kotone Matsuyama

National Center for Child Health and Development



Regulatory Framework for Inclusion of Pregnant and Lactating Women in Clinical Research

Yoko Motoki

Pharmaceuticals and Medical Devices Agency (PMDA)

Advancing the Inclusion of Pregnant and Lactating Women in Clinical Research: EMA's Experience and Expectations for Japan

Corinne de Vries

European Medicines Agency

Implementing ICH E21 in Japan: The JDIIP Experience in Pregnancy Medicine and Evidence Generation

Mikako Goto

National Center for Child Health and Development

Panel Discussion

All Session Speakers and

Mihoko Kobayashi

Pfizer R&D Japan

Taeko Wada

Jichi Medical University Hospital

Day 3 | Tuesday October 20



Regulatory Session 2 TRACK 4 9:00-10:30

Related : ALL | Level : Intermediate | English and Chinese / Theater Style | Simultaneous translation by AI system

China Town Hall

The China Town Hall features three insightful presentations by subject matter experts covering key advances in China, in the areas of national regulatory and reimbursement policies, patient-centric clinical trials, and AI-driven drug development. The first speaker will present the latest updates on drug regulations, GCP, regulatory initiatives such as NAMs, as well as reimbursement policies supporting innovation. The second speaker will share practical application of electronic Patient-Reported Outcomes (ePROs) in clinical trials in China and discuss how to implement patient-centered concept in drug development. The third speaker will explore innovative clinical development approaches in the AI era, illustrating how data and modeling technologies can accelerate clinical evidence generation for new drugs.

Chair

Ling Su

DIA Fellow

Hironobu Saito

DIA Fellow



Update from China: Regulation, Innovation, and Access

Wendy Yan

DIA China Strategic Advisor

Practical Application of ePROs in Clinical Trials in China

Kevin Lin

Xincere Med.

Clinical Development of Innovative Drugs in the AI Era: Accelerating Evidence Generation through Data and Models

Terry Hu

Blueballon Medical Research Co. Ltd.

Q&A and Panel Discussion

James Cai

Shanghai Pharma Holding

Day 3 | Tuesday October 20

S-25 TRACK 5 9:00-10:30

Related: V&A:PE | Level : Intermediate | Japanese / Theater Style

Can Patient-First Care Survive Drug Lag? Finding the Right Balance Between Universal Healthcare and Innovation [HEOR+]

How seriously can we truly grapple with the concept of "Patient-First"? As drug lag and drug loss accelerate and healthcare cost debates intensify over expensive treatments, this session takes real messages from rare cancer patients as our starting point. Patients, academia, and industry will reassess what each can contribute. While confronting the trade-off between innovation valuation and universal healthcare sustainability, this session will explore how to integrate patient perspectives into drug development and evaluation. Let's discuss the realization of "patient-first" care through candid dialogue!

Chair

Hisashi Urushihara

Keio University



Patient First: What Patients Look for in Drug Development

Tomomi Kawakami

Cure Sarcoma

Co-Creation for Patient-First: Aligning Government, Academia, Industry, and Patients

Yasunori Yoshida

Japan Pharmaceutical Manufacturers Association (JPMA)

Turning Patient Voice into Action: Empowering Patients to Drive Patient-First Healthcare

Midori Senoo

DM-Family

Redefining Healthcare Value: From Trade-offs to Co-Existence of Patient Needs, Innovation, and System Sustainability

Rei Goto

Keio University

Panel Discussion

All Session Speakers

Day 3 | Tuesday October 20

S-26 TRACK 6 9:00-10:30

Related:PE:CD&O:MA&SC:RA | Level : Beginner/Intermediate | Japanese / Interactive Workshop

Bringing Your "?" to Everyone: The PEC 120 Million Dialogue Session 【Patient Engagement】

While collaboration with patients is becoming more common, patients are still often regarded as “special entities” in drug development and decision-making, and equal partnerships remain insufficient. This session positions patients as integral members of these lifecycles, bringing together stakeholders from industry, academia, regulatory authorities, and patient communities to share questions and challenges related to healthcare and drug development. Through interactive dialogue and diverse perspectives, the session aims to explore solutions and reconsider approaches to advancing patient engagement.

Chair

Takashi Kimura

Pfizer R&D Japan G.K.

TBD

Naomi Sakurai

General Incorporated Association CSR Project

***We All Pondered the “?”
~Based on Participants’ Feedback from the Pre-Event~***

Yukiko Nishimura

NPO ASrid

Panel Discussion

All Session Speakers and

Eiji Aramaki

Nara Institute of Science and Technology (NAIST)



Day 3 | Tuesday October 20

S-27 TRACK 7 9:00-10:30

Related: CS&PV:RA | Level : Intermediate/Advanced | Japanese / Theater Style

Rebooting PMS: Redefining PMS in Light of RMP Formalization and Evolving Development

Japan's post-marketing surveillance (PMS) environment has built a strong foundation through GPSP and real-world data. However, a quality-focused approach has highlighted the need to better balance scientific value and efficiency. The formalization of RMP under the 2025 PMD Act and the diversification of development environments mark a key turning point, making PMS redesign essential. Shifting to appropriate study design and leveraging results across the product lifecycle are critical. This session will discuss challenges and future directions from global perspectives to inform the future of PMS in Japan.

Chair

Nomura Kaori

Fukushima Medical University



From Compliance to Science: Redefining PMS under the Revised PMD Act

Daisuke TANAKA

Osaka Metropolitan University

Rebooting PMS: Redefining PMS in Light of RMP Formalization and Evolving Development Environments

Nomura Kaori

Fukushima Medical University

An Industry Perspective — Proposals for Advancing PMS

Wataru Takada

Eli Lilly Japan K.K./PhRMA

Panel Discussion

All Session Speakers

Day 3 | Tuesday October 20

S-28 TRACK 8 9:00-10:30

Related: CD&O:MA&SC:PE:RA:Stat:V&A | Level : Beginner/Intermediate | Japanese / Theater Style

The Practice of Patient Preference Study and Its Value as Evidence: Connecting the Patient's Voice to Decision-Making

While ICH E22 General Principles on Patient Preference Studies (PPS) will achieve Step 4 by the end of 2026, PPS in Japan remain limited and numerous practical challenges persist. This session will bring together experts and leaders from industry, regulatory authorities, and the patient community to discuss, from multiple perspectives, the challenges and prospects for conducting PPS and translating its findings into evidence. In particular, the session will provide insights into the importance of grounding PPS in scientific methodology and how its value can be returned to patients.

Chair

Inaha Okuda

JPMA / GlaxoSmithKline K.K.



The Significance and Methodology of Patient Preference Studies

Yasuo Sugitani

JPMA / Chugai Pharmaceutical Co., Ltd.

Practical Challenges in Patient Preference Studies

Masayuki Hamakawa

SSRI Co., Ltd.

The Value of Patient Preference Studies from the Patient Perspective

Kazuo Hasegawa

NPO Lung Cancer Patients Network ONE STEP

The Value of Patient Preference Studies: A Regulatory Perspective

Shun Tezuka

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers

Day 3 | Tuesday October 20

S-29 TRACK 9 9:00-10:30

Related: Stat:CS&PV:MA&SC:CD&O:RA:PE:D&DS:Others | Level : Intermediate | Japanese / Theater Style

Estimand in Medicinal Product Information: Challenges and Perspectives from Development to Post-Marketing 【Medical Communications】

Clinical trial design has evolved, with the concept of estimand increasingly incorporated into study planning. However, clear descriptions of estimand and treatment effects in prescribing information and other medical information materials remain limited. This session will explore how the clinical question of a trial and the meaning of treatment effects can be effectively communicated to healthcare professionals, patients, and other stakeholders. Through an overview of estimand concepts and practical examples, participants will discuss applications to medical information and scientific communication.

Chair

Rika Abe

RIKEN Center for computational Science



Understanding Treatment Effects Through the Estimands Framework

Koji Oba

The University of Tokyo

Case-Based Perspectives on Estimands and Drug Information Development

Isogawa Naoki

UCB Japan Co. Ltd.

Challenges in Communicating Estimand in Post-Marketing Product Information Materials

Kanae Ogiwara

Pfizer

Panel Discussion

All Session Speakers and

Hideo Nakada

Keio University Hospital

Day 3 | Tuesday October 20



DIAmond Session-2 TRACK 1 11:15-12:45

Related : Others | Level : Intermediate | Japanese / Theater Style | Simultaneous translation by AI system

Advancing Next-Generation Medical Research Beyond Gravity — Microgravity as a Transformative Frontier —

Microgravity reveals biological processes and responses difficult to reproduce on Earth, offering new perspectives for medical research. This session presents JAXA's space research infrastructure ; insights from small-animal ISS studies on gene expression changes, bone loss, and muscle atrophy ; and advances in applying a unique organoid culture technology? capable of reconstituting human organs from multiple iPSC-derived cell types? to microgravity. The session explores how these findings may contribute to understanding disease mechanisms, identifying therapeutic targets, and advancing regenerative medicine

Chair

Mitsugu Yamada

Japan Aerospace Exploration Agency



Advancing Life Science Research using the Japanese Experiment Module "Kibo" on the International Space Station

Masaki Shirakawa

Japan Aerospace Exploration Agency

Elucidation of Skeletal Muscle Regulation Mechanisms Using Mouse Space Experiments

Satoru Takahashi

University of Tsukuba

Development of innovative regenerative therapies for liver disease using human iPSC cells

Hideki Taniguchi*

The University of Tokyo

*Recording is not available for viewing. (Speakers who informed us by October 9 that post-event on-demand access is not permitted.)

Panel Discussion

All Session Speakers



Evolving Review Collaboration Among ICH Founders: Combining Regulatory and Global Development Experiences for Patient Benefit

Faster patient access to innovative medicines is a goal shared by industry and regulators. Yet simultaneous approvals across countries remain difficult, leaving drug lag/loss a burden for both. To address this, PMDA has advanced cooperation through reliance, cluster activities, observer engagement in Project Orbis, and initiating Project NOZOMI, building a base of information sharing and discussion. This session focuses on the original ICH founders, with stakeholders sharing experiences and challenges to explore how cooperation can advance further and what each stakeholder can do.

Chair

Shinobu Uzu

Pharmaceuticals and Medical Devices Agency (PMDA)

TBD

Julian Beach

Medicines and Healthcare Products Regulatory Agency (MHRA)

PMDA's initiatives in regulatory collaboration with overseas agencies

Koshin KIYOHARA

Pharmaceuticals and Medical Devices Agency (PMDA)

Initiatives and Challenges in Global Drug Development for Japan-Based Pharmaceutical Companies (Working Title)

Atsushi Tsukamoto

Daiichi-Sankyo

Initiatives and Challenges in Global Drug Development for US-Based Pharmaceutical Companies (Working Title)

Wataru Takada

Eli Lilly Japan

Panel Discussion

All Session Speakers and

Hideki Maeda

Meiji Pharmaceutical University

Day 3 | Tuesday October 20

S-31 TRACK 4 11:15-12:45

Related: D&DS:RA:V&A:MA&SC:PM&SP | Level : Beginner/Intermediate | Japanese and English/ Theater Style | Simultaneous translation by AI system

The Frontier of Evidence Generation through Clinical Trial Data × RWD: Data Ecosystems Shaping RWD/RWE and Japan's Place 【Clinical Data Management】

Patient-level data linkage is a prerequisite for robust RWE. Regions advance

Chair

Yoshiharu Horie

Astra Zeneca Japan



The Value Created by Data Integration and Its Impact on Clinical Practice and Medical Research

Hideaki Bando

National Cancer Center Hospital East

Current State and Policy Trends of Healthcare Data Protection Regulations Toward the Realization of Data Integration

Hiroki Yoshihara

Nishimura & Asahi (Gaikokuho Kyodo Jigyo)

Why is “Patient-Level Data Linkage” Necessary? A Review of Technological, Legal, and Environmental Factors in Japan, the Unit

Ryo Koto

Japan Pharmaceutical Manufacturers Association (JPMA)

Panel Discussion

All Session Speakers and

Introduction to the Flatiron Health-Foundation Medicine Clinico-Genomic Database (CGDB) Combining Clinical Electronic Health Record (EHR) Data with Comprehensive Genomic Profiling

Cheryl Cho-Phan

Flatiron Health

Day 3 | Tuesday October 20

S-32 TRACK 5 11:15-12:45

Related: RA:Others | Level : Intermediate/Advanced | Japanese / Theater Style

Dialogue Between Regulators and Startups: PMDA and AMED Public Support Programs and the Reality for Founders 【Open Innovation】

While public support programs for startups keep expanding, chances to systematically share the voices of those who actually used them remain scarce. Starting from PMDA's consultation schemes and Japan Agency for Medical Research and Development (AMED) (AMED)'s translational research support, this session brings regulators, drug-discovery startup founders, and VCs into dialogue. How can the gap between research and development phases be bridged? How do investors view regulatory risk and public support? Sharing not only successes but also candid reflections and failures from program users, this session examines how their effectiveness and challenges interact.

Chair

Mitsuyo Ohmura

Tokyo Medical University



PMDA's Support and Consultation Program for Startups and Venture Companies

Yusaku YOSHIOKA

Pharmaceuticals and Medical Devices Agency (PMDA)

Introduction of the AMED Program for Supporting Academia-Launched Medical Startups

Yoshikatsu Koga

Japan Agency for Medical Research and Development (AMED)

Panel Discussion

All Session Speakers and

Yuki Kamiya

Imel therapeutics

Saho Murakami

Bioengineering capital Inc.

Day 3 | Tuesday October 20

S-33 TRACK 6 11:15-12:45

Related: CD&O:PM&SP:CS&PV:D&DS:MA&SC | Level : Intermediate | Japanese / Interactive Workshop

Creating a Collaborative Communication Platform to Support Clinical Trials in Accordance with ICH E6 (R3) 【Six Sigma】

To enhance the quality and reliability of clinical trials, an effective communication framework is essential to foster mutual understanding and collaboration among industry, government, academia, and patients, based on the principles of “collaboration and risk-based communication” outlined in ICH E6(R3). This session aims to redefine communication—specifically, the reporting, consultation, and coordination of information—not merely as the transmission of information, but as a practical mechanism that underpins clinical trials. We will work together to co-create concrete improvement measures from various perspectives, including academic insights and real-world examples.

Chair

Hironobu Tokumasu

Ohara HealthCare Foundation, Clinical Research Institute



Hokkaido University’s “Better Reporting, Communication, and Consultation Project”

Sumire Mogi

Hokkaido University

Communication by Design: From Information Sharing to Structured Decision-Making

Tango Maki

Novartis Pharma K.K.

Quality Improvement, Organizational Communication and Service Management

Junichi UCHIDA

Otaru University of Commerce

Panel Discussion

All Session Speakers

Day 3 | Tuesday October 20

S-34 TRACK 7 11:15-12:45

Related: CD&O:PE:RA | Level : Beginner/Intermediate | Japanese / Theater Style

”Reach” Before Recruitment: Rethinking Clinical Trial Information Flow: Perspectives from Patients, Industry, and Regulators 【Clinical Operations & Monitoring】

Efforts to promote clinical trial participation have long focused on strengthening recruitment. Yet recruitment cannot succeed unless patients can reach the information they need. Difficulties in finding studies, understanding information, and acting remain barriers upstream of participation. In Japan, database renewals and regulatory updates are prompting a review of trial information delivery. This session brings together patients, industry Clinical Operations, regulators, and a Korean CRC to discuss rebuilding "Reach"—making information easier to find, understand, and act on.

Chair

Toshiko Ishibashi

Daiichi Sankyo Co., Ltd.



A Regulator's Perspective — Current Status and Outlook of Initiatives on Clinical Trial Information

Eiji Kobayashi

Ministry of Health, Labour and Welfare

”Reach” Before Recruitment: Rethinking Clinical Trial Information Flow

Elisabet Kim

Asan Medical Center(Seoul)

Current Trends in Clinical Trial Transparency in Japan: Takeda’s Initiatives and the jRCT Landscape

Masahiro Ishihata

Takeda Pharmaceutical Company Limited

Panel Discussion

All Session Speakers and

Naomi Sakurai

CSR Project, General Incorporated Association

Day 3 | Tuesday October 20

S-35 TRACK 7 14:15-15:45

Related: CD&O:CS&PV:D&DS:MA&SC:PM&SP:RA:V&A | Level : Intermediate | Japanese / Theater Style



Healthcare DX 2030: Unlocking the Next Moves in Vaccines, Medicine, and Real-World Data from Vaccination Digitalization

Under the Healthcare DX Reiwa Vision 2030, Japan is advancing healthcare data utilization through a nationwide health information platform, standardized electronic health records, and digital reimbursement systems. Vaccination digitalization planned for June 2026 will enable access to vaccination records, smartphone reminders, and automated data sharing. Linkage of vaccination and healthcare databases may support public health, real-world evidence, research, and vaccine development. This session will discuss future opportunities for secondary data use in clinical development and research.

Chair

Yusuke kajimoto

The University of Tokyo

Digitalization of Vaccination Administration and Development of a Vaccination Database

Ryunosuke Yanagi

Ministry of Health, Labour and Welfare

Secondary Use of Vaccination Data: Challenges and Implications for Japan from International Case Studies

Shintaro Kurotaki

PwC Consulting LLC

Shaping the Future of Healthcare: Healthcare DX Reiwa Vision 2030 and the Digitalization of Immunization in the Pharma Industry

Shintaro Hiro

Pfizer R&D Japan G.K / Japan Pharmaceutical Manufacturers Association

Panel Discussion

All Session Speakers and

Day 3 | Tuesday October 20

S-36 TRACK 9 11:15-12:45

Related: PM&SP:CD&O | Level : Intermediate/Advanced | Japanese / Theater Style

Implementing Go/No-Go Decision-Making in Drug Development and Healthcare Ecosystems Across Sectors

This session examines Go/No-Go decision-making in healthcare development, including pharmaceuticals and medical devices, by sharing practices from industry, academia, and investors. Despite progress in ecosystem building, gaps remain in decision criteria and timelines. Case studies on corporate portfolio strategy, academic research and translation to market, and investor evaluation frameworks provide a cross-cutting perspective. The latter half discusses how these sectors can collaborate more effectively to drive value creation.

Chair

Taku Seriu

APCER Life Sciences



Decision-Making in Drug Development TPP, CDP, PTS, Productivity, and Go/No-Go Decisions

Norihiro Kawabata

Chugai Pharmaceutical Co., Ltd.

Decision-Making in Clinical Development and Research: Go/No-Go Decisions and the Role of AROs

Minoru Imai

Institute of Science Tokyo Hospital

Decision-Making in Healthcare and Drug Development Ecosystems: A Venture Capital Perspective

Tomoko Inoue

Red Capital Co., Ltd.

Panel Discussion

All Session Speakers and

Koichi Hashimoto

University of Tsukuba, Tsukuba Clinical Research & Development Organization
(T-CReDO)

Day 3 | Tuesday October 20



DIAmond Session-3 TRACK 1 14:15-15:45

Related ALL | Level : Beginner/Intermediate | Japanese / Theater Style | Simultaneous translation by AI system



Driving Drug Discovery Innovation with AI

Advances in AI and robotics are transforming the drug development lifecycle, from early-stage discovery to clinical development. This session explores AI applications across the R&D process, including AI-driven target identification and hypothesis generation, integrated human-AI-robot experimental platforms, and generative AI for clinical documentation. Led by the latest real-world case studies, we will discuss how AI is driving scientific discovery, improving R&D efficiency, and enhancing decision-making, while highlighting the opportunities, challenges, and future of drug discovery innovation.

Chair

Manabu Wada

Iwate Medical University

AI-Driven Discovery of Novel Targets and Hypothesis Generation from Existing Knowledge

Hiroyoshi Toyoshiba

FRONTEO, Inc.

The Future Shaped by the Convergence of Humans, AI, and Robotics

Haruna Iwaoka

Astellas Pharma Inc.

AI-Driven Transformation of Clinical Development Operations — Focusing on Streamlining Medical Writing with Generative AI

Satomi Hirano

CMIC Co., Ltd.

Panel Discussion

All Session Speakers



New Insights, Strategies and Practices to Optimize Protocol Data Collection

This session provides robust, empirical evidence from a recent study characterizing the high and rising volume of data collected in clinical trials and the underlying reasons for collecting that data. Insights from the study identify practical ways to optimize protocol design including protocol simplification and the reduction of participant and investigative site burden. Presenters will also discuss new tools and ways of thinking about designing clinical trials that are fit for purpose and more feasible to execute.

Chair

Abigail Dirks

Tufts Center for the Study of Drug Development (Tufts CSDD)

New Insights, Strategies and Practices to Optimize Protocol Data Collection

Abigail Dirks

Tufts Center for the Study of Drug Development (Tufts CSDD)

From Insights to Practice: New Frameworks and Tools to Support Optimized, Fit for Purpose Protocol Design

Laura Galuchie

Merck (known as MSD outside USA and Canada)

Panel Discussion

All Session Speakers and

Yumiko Tatsukawa

Pharmaceutical and Medical Devices Agency (PMDA)

Kenichi Nakamura

National Cancer Center Hospital

Day 3 | Tuesday October 20

S-38 TRACK 4 14:15-15:45

Related: RA:D&DS:CS&PV:PE:MA&SC | Level : Intermediate | English / Theater Style | Simultaneous translation by AI system

Risk Communication: Today and Tomorrow: The Emerging Convergence of Behavioral Science and Digital/AI Innovation

In the digital and AI era, patient product information (PI) must go beyond providing accurate facts to support patient understanding, engagement, and informed action. This session will explore how behavioral science can strengthen risk communication and promote informed health decisions. International examples of structured PI and global standards enabling AI-driven solutions will be presented. Regulators, industry, academia, patients, and technology stakeholders will discuss the future of patient centric PI and emerging frameworks for assessing its impact and value in the digital age.

Chair

Michiko Yamamoto

Kumamoto University



TBD

Hana Hayashi

Down to Earth, Inc

FHIR Electronic Product Information · ePI

Mohammad Rabi

Jordan Food and Drug Administration (JFDA)

The Present and Future of Drug Guide for Patients

Makoto OGAWA

Pharmaceutical and Medical Devices Agency(PMDA)

Panel Discussion

All Session Speakers and

TORU KISHIDA

Cancer Note (Nonprofit Organization)

Rie Matsui

Pfizer R&D Japan G.K

Day 3 | Tuesday October 20

S-39 TRACK 5 14:15-15:45

Related: CD&O:RA | Level : Beginner/Intermediate | Japanese / Theater Style

Assessing Real-World Data Relevance and Reliability for Regulatory Submission Across Stakeholder Views

While expectations are rising for the use of RWD in regulatory submissions, determining its suitability and reliability requires a multifaceted examination that takes into account the perspectives of industry, regulators, and academia. In this session, stakeholders from diverse backgrounds—including applicants, regulatory authorities, and academic experts—will bring their respective viewpoints together to clarify the key issues surrounding the use of RWD.

Chair

Mitsune YAMAGUCHI

Pharmaceuticals and Medical Devices Agency (PMDA)



*Recommendations for generating real-world evidence with
regulatory-grade relevance and reliability*

Hideaki Bando

National Cancer Center Hospital East

*Regulatory Use of Real-World Data in Medical Devices and
Mental Disorders: Current Landscape and Future Outlook*

Kazuyoshi Takeda

Regulatory Case Examples and Future Perspectives in Medical Devices and
Mental Health Disorders

*Development of RWD Utilization Environment and Future
Outlook Based on Discussions on Japan Adapted EHDS*

Ryosuke Annaka

Japan Pharmaceutical Manufacturers Association

*Regulatory Trends and Reliability Assurance in the Use of
Real-World Data (RWD)*

Miho Suzuki

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers and

Hideharu Yamamoto

Chugai Pharmaceutical Co., Ltd.

Yosuke Nishida

PwC Consulting LLC

Day 3 | Tuesday October 20

S-40 TRACK 6 14:15-15:45

Related: CS&PV:MA&SC:RA:Stat | Level : Intermediate/Advanced | Japanese / Interactive Workshop

Final Outputs Don't Tell the Whole Story: Walking Through Design Processes in Routine PV and Post-Marketing Database Studies 【Life Cycle Management】

Now, uniform post-marketing requirements for new drugs are no longer mandatory, and study planning is expected to be driven by emerging research questions (RQs). However, the number of studies described in RMPs has declined, and the status of studies triggered by new RQs remains unclear. With the release of ICH M14 and enhancements to MID-NET, pharmaceutical companies are exploring optimal approaches. This session will examine routine PV activities and post-marketing database studies, focusing on the rationale behind design choices and sharing practical challenges and insights to inform decision-making.

Chair

Sachiko ONO

The University of Tokyo



Beyond GPSP: What Companies Can Do with RWD for Patient Safety

Shinichi MATSUDA

CHUGAI PHARMACEUTICAL CO., LTD.

The Design Journey of a Post-Marketing Database Study -- From Five Questions to Key Decisions

Yosuke FUJII

Pfizer R&D Japan G.K.

The Comparator Can Change the Conclusion — Pitfalls in Comparator Selection When Evaluating PV Signals —

Akira OKADA

The University of Tokyo

Progress and Updates on the MID-NET® Enhancement Project

Yuka SAIGO

Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers and

Daisuke KOIDE

The University of Tokyo

Tomoaki HASEGAWA

Pharmaceuticals and Medical Devices Agency (PMDA)



Adaptive BE Trials for Better Decision-Making

Adaptive design has long been recognized as an innovative clinical trial methodology that can improve trial efficiency and decision-making in late-stage drug development under uncertainty. However, its use remains limited due to complex design and analysis procedures, operational constraints, and regulatory challenges. This symposium will review practical issues and solutions in planning, conduct, statistical analysis, and regulatory interactions through examples of adaptive BE studies, and discuss future applications to broader clinical development.

Chair

Shinichi Tsuchiwata

Pfizer R&D Japan G.K.

Adaptive Design in BE Studies : Overview and Considerations

Kensuke Aida

The Japan Pharmaceutical Manufacturers Association (JPMA)、Johnson & Johnson Innovative Medicine

Practical Examples and Considerations for the Design, Conduct, and Analysis of Adaptive BE Studies

Ryoji Yoshinaka

UCB Japan Co., Ltd.

Planning and Operational Challenges of BE Studies Using Adaptive Design

Takeshi Kanou

NIPPON KAYAKU CO.LTD.

Panel Discussion

All Session Speakers and

Tatsuya Yoshihara

SOUSEIKAI Fukuoka Mirai Hospital

Sae MATSUDAIRA

Pharmaceuticals and Medical Devices Agency (PMDA)

Day 3 | Tuesday October 20



Media Session TRACK 8 14:15-15:45

Related: ALL | Level : Beginner | Japanese / Theater Style

Addressing Information Asymmetry Between Patients and Healthcare Stakeholders in Drug Development

In healthcare, "information asymmetry" is often discussed in the context of the relationship between clinicians and patients. But it also exists in the development of pharmaceuticals and other medical products, where it can hinder the meaningful participation of patients and the public. Drawing on insights from the information sharing practices of those involved in drug and medical product development and the perspectives of patients and the public in receiving and interpreting that information, this session will discuss strategies for more effective information sharing and communication.

Chair

Daisaku Yamasaki

Nikkei Business Publications, Inc

Does Drug Development Information Reach Patients? — From the Standpoint of Cancer Patients

Shinsuke Amano

Japan Federation of Cancer Patient Groups

TBD

Mamoru Ichikawa

Musashi University

Invimestrocel (HLCM051): Clinical Evidence in ARDS and Stroke, and Expansion into Kidney Protection

Tadahisa "Hardy" Kagimoto

HEALIOS K.K.

Panel Discussion

All Session Speakers and

Mayumi Fukuda-Doi

National Cerebral and Cardiovascular Center

Day 3 | Tuesday October 20

S-42 TRACK 9 14:15-15:45

Related: RA:CD&O | Level : Intermediate | Japanese / Theater Style

Reflecting on the Integration of Regulatory Requirements for Clinical Trials in Japan: Focusing on Interventional Research

The regulatory requirements governing clinical trials in Japan are extremely complex. Promoting “data-driven clinical research”— exemplified by the use of patient registry data under the “Ethical Guidelines for Life Science and Medical Research Involving Human Subjects” and clinical research data under the “Clinical Trials Act” for regulatory purposes — is one of the key themes for the future. This session will discuss the integration of regulatory requirements in Japan, with a focus on interventional clinical research.

Chair

Keisuke Suzuki

National Center for Geriatrics and Gerontology



On the Consolidation of Regulatory Requirements for Clinical Trials in Japan: Perspectives from Support Professionals

Hideki Oi

Kyorin University School of Medicine / Kyorin University Hospital

On the Consolidation of Regulatory Requirements for Clinical Trials in Japan: Perspectives from IRB Secretariat

Takeshi Ioroi

Kobe University Hospital

On the Consolidation of Regulatory Requirements for Clinical Trials in Japan: Perspectives from Pharmaceutical Company's

Mitsuaki Aoyagi

Japan Pharmaceutical Manufacturers Association(JPMA) / Eisai Co., Ltd.

Panel Discussion

All Session Speakers and

Nobumasa Nakashima

Kyoto Prefectural University of Medicine

Day 3 | Tuesday October 20



DIAmond Session-4 TRACK 1 16:30-18:00

Related: ALL | Level :ALL | Japanese / Theater Style | Simultaneous translation by AI system

PMDA Town Hall

In this session, we are pleased to welcome panelists from the Pharmaceuticals and Medical Devices Agency (PMDA), who will kindly respond to a wide range of questions from participants. The session will feature an interactive panel discussion based on your inquiries. It offers a valuable opportunity for direct exchange with PMDA representatives on a broad range of topics, primarily related to pharmaceutical development, post-marketing activities, clinical practice, and patient perspectives. We hope that through open and candid dialogue, you will gain meaningful insights to support your future activities. We warmly encourage your active participation and thoughtful questions.

Chair

Yoshiaki UYAMA

Pharmaceuticals and Medical Devices Agency (PMDA)

Takahiro MIZUI

Chugai Pharmaceutical Co., Ltd.



Pharmaceuticals and Medical Devices Agency (PMDA)

Daisuke KOGA

Koshin KIYOHARA

Mimei TAKAHASHI

Go YAMAMOTO

Yoshiaki MARUYAMA



Day 3 | Tuesday October 20

Closing TRACK 1 18:00-18:30

Related : ALL | Level: ALL | Japanese / Theater Style | Simultaneous translation by AI system

In this session, participants will reflect on this year's Annual Meeting and recognize outstanding presentations selected from the scientific sessions and poster sessions through awards and commendations. An overview of the 2027 DIA Japan Annual Meeting will also be provided, offering participants an opportunity to share expectations for next year's meeting. This closing session will connect the knowledge and achievements gained throughout the meeting to future innovation and collaboration.

Chair

Haruko Yamamoto

National Cerebral and Cardiovascular Center

Miyoko Yamauchi

Chugai Pharmaceutical Co., Ltd.

The 24th DIA Annual Meeting 2027

Program Chair

Vice-Program Chair

Award Ceremony

Session

Outstanding Achievement Award

Excellence Award

Entertainment Excellence Award

Poster Session

Grand Prize

Participant Award



How to Register

Registration Form



DIA 日本年会への参加を考えていらっしゃる皆さまへお得な情報をお届けします。

**今年のDIA日本年会、参加登録における
"6つのお得"なポイント！**
をご紹介します。



第23回 DIA 日本年会2026 特設サイト
<https://www.diajapan.org/meetings/26303/index.html>

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

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

Online Registration

<https://www.diaglobal.org/en/conference-listing/meetings/2026/10/the-23rd-dia-japan-annual-meeting-2026/register>