17th DIA Japan Annual Meeting 2020

-Beyond Innovation-

November 8-10, 2020
DIAglobal.org/Japan2020

Program Overview

Amidst the backdrop of the fourth industrial revolution, recent years have seen the launch of initiatives related to various innovations that will create new value and bring about major changes for our society. These innovations are an outcome of the creation and application of new techniques and technologies exemplified by the use of artificial intelligence, big data, and medical and genomic information in various fields, including research and development and lifecycle management of medical devices.

Currently, the global COVID-19 pandemic has reaffirmed the importance of the role played by medical products in providing treatment and medications to support the health and safety of people everywhere. At the same time however, efforts to take on new challenges aimed at creating new innovations that break away from conventional wisdom are underway around the globe.

As society adapts to the ongoing presence of COVID-19, it is becoming more and more important that we actively seek to learn the latest technologies and initiatives that will underpin various innovations, consider how our jobs will change and how we should reimagine those jobs moving forward, and develop the skills and mindset that will allow us to respond and adapt to these major changes. But we should also ask ourselves: do the new values and changes brought about through innovation really play a role in improving the health and welfare of patients? Perhaps it's time for each and every stakeholder to return to the starting line and chart a path forward together.

With the theme of "Beyond Innovation", the 17th DIA Japan Annual Meeting offers programs that are based on session proposals submitted by DIA members in an open call for submissions. We hope these will be attractive and informative for participants. In addition to a commemorative address marking 30 years of ICH activities, there will be lectures covering patient-focused drug development, overcoming drug-induced illnesses, international contributions to drug development, and the future of healthcare. Additionally, the hugely popular PMDA town hall will once again be held this year. We hope this event serves to provide a space where stakeholders—including patients—from industry, government, and academia can learn the latest information and enjoy interactive discussions.

Due to the COVID-19 pandemic, this year's Japan Annual Meeting will be held in a virtual capacity with sessions delivered through of combination of the following formats:

1. On-demand: pre-recorded sessions made available to view via the online event platform from early November.
2. Semi-live: pre-recorded session presentations available on-demand through the online event platform from early November. Session panel discussion held live during the event (8-10 Nov).
3.Live: entire session delivered live during the event (8-10 Nov)

In addition to more than 60 sessions, there will be 1-2-1 chat and Community meetups, live Q&A, our annual poster session and much more. Breaking walls and boundaries, the virtual platform will enable you to join the event from wherever you may be and to connect with fellow professionals from across the world. We look forward to seeing you there!

Endorsement by
MHLW, PMDA, JPMA, EFPIA, PDA and ISPE
Endorsement pending by PhRMA, MEJ

PROGRAM CHAIR
Yuji Kumagai, MD, PhD
Kitasato University Hospital

PROGRAM VICE-CHAIR
Keiichi Inaizumi, MSc
Pfizer R&D Japan

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

DIAglobal.org

Japanese English Simultaneous Translation

Related Interest Areas: *Clinical Research and Clinical Strategy (CR), Regulatory Affairs (RA), Statistics (ST), Clinical Data Management (DM), Clinical Safety and Pharmacovigilance (CP), Project Management (PM), Academia (AC), Medical Affairs (MA), Medical Communication (MC), Others (O)*

11月8日（日）

Track 1	Track 2	Track 3	Track 4
Pre Opening：ALL			
Live Session 01：ALL Opening			
Semi-Live Session 01：RA、AC Diamond Session 1：ICH 30th Anniversary: Summary of 30 Years and Future Prospects with the Role of Japan	**Live Session 02**：CR、ST、PM Quantitative Decision Making in Drug Development	**Live Session 03**：AC、O: Translational Research Realization of Personalized Medicine through Reverse Translational Research	
Live Session 04：ALL What Covid-19 Has Brought to Us	**Semi-Live Session 02**：ALL Next Generation Leadership for Successful Future	**Live Session 05**：CR、RA、AC Student Session：Protocol Development in Oncology Clinical Trials	
Live Session 06：PM、AC How do We Collaborate with Current Patients in Drug Development Process for Future Patients? Let's Think about "PPI" as If it Would be Your Action Tomorrow.	**Semi-Live Session 03**：RA、AC ICH Anniversary: Summary of 30 Years and Future Prospects in Q Area with the Role of Japan		
Semi-Live Session 04：RA、CP Scientific Benefit-Risk Management and Communication for the Future	**Semi-Live Session 05**：RA、AC ICH Anniversary: Summary of 30 Years and Future Prospects in S Area with Role of Japan	**Live Session 07**：RA、PM、AC、CS Overcome Challenges in Complex Drug Development: Let's Learn More About Program Management	
Live Session 08：Young Professionals Exchange & Networking Session			

11月9日（月）

Track 1	Track 2	Track 3	Track 4
Live Session 09：CR、AC Driving Toward Further Operational Efficiency and Innovation in Clinical Trials	**Semi-Live Session 06**：ALL New Approaches in Knowledge Management for Significant Advances	**Semi-Live Session 07**：CR、PM Possibility of Applying "Training / Learning Innovation" to Clinical Development Projects	**Semi-Live Session 08**：RA、AC ICHE：ICH Anniversary: Summary of 30 Years and Future Prospects in E Area with Role of Japan
Live Session 10：RA、AC ICH M11: Clinical Electronic Structured Harmonized Protocol	**Semi-Live Session 09**：CR、DM How Do Quality Risk Management and Risk-Based Monitoring Work Together? Gaps Between Ideal and Actual Experience During COVID-19	**Semi-Live Session 10**：RA、AC Current Status and Challenges of Regulatory Decision Making in Development Using Model Informed Drug Development	**Live Session 11**：ALL Keynote Adress：Patient-Focused Drug Development
	Luncheon Seminar 1	Luncheon Seminar 2	Luncheon Seminar 3
Semi-Live Session 11：MA、MC How Can industry Play a Role through Publications to Elevate Patient Voice?	**Live Session 12**：O: Patient Creating an Insightful Patient Journey Map On-Site: Let's look at and feel the patients' voice together and think about what we can do! (part 1) **Part 2 is Live Session 14**	**Live Session 13**：O: Career Development Let's Broaden Young Peoples' Horizons from the Multidisciplinary Perspective	**Semi-Live Session 12**：RA、DM、AC ICH Anniversary: Summary of 30 years and Future Prospects in M Area with Role of Japan
Semi-Live Session 13：CR、RA、AC、O: Patient Impact of Patient Engagement Initiatives in Clinical Trial Design and Execution	**Live Session 14**：O: Patient Creating an Insightful Patient Journey Map On-Site: Let's look at and feel the patients' voice together and think about what we can do! (part 2) **Part 1 is Live Session 12**	**Live Session 15**：PM、O: Career Development in New Healthcare Era	**Live Session 16**：ALL Current Status and Future of Digital Therapeutics (DTx): How DTx Are Developed and Penetrate Medical Care
Semi-Live Session 14：RA、CP WHAT'S NEW? Risk Communication and Pharmaceutical Information in the Digital Era in Japan, Europe, and the US	**Semi-Live Session 15**：MC Digital Transformation of Medical Information in Japan from Development to Post-Marketing	**Semi-Live Session 16**：CR、PM、AC Paradigm Shift of Clinical Trial Site Cost: Challenges in Implementing Benchmark Cost	**Semi-Live Session 17**：CR、RA、O: Clinical Strategy Current Status of Drug Development and Current Challenges for Clinical Trials and Regulations in China
Live Session 17：ALL Special Chatting Session：Engage and Exchange: Let's Chat! "What's The Dia World 2020"			

11月10日（火）

Track 1	Track 2	Track 3	Track 4
Live Session 18：ALL Global Oncology Development – 2nd	**Semi-Live Session 18**：RA、AC Challenge for promotion of new style global study at KOBE	**Live Session 19**：RA、CP Data Reliability and Quality for Post-Marketing Database Study	**Semi-Live Session 19**：MA Let's Talk Digital Engagement with External Stakeholders in Medical Affairs
Live Session 20：RA、AC Measures Against Antimicrobial Resistance (AMR): Toward New Phase	**Semi-Live Session 20**：RA、CP Opportunity for International Harmonization of Implementing Early Access to Pharmaceuticals	**Semi-Live Session 21**：CR、AC、O: Patient "Where, What, and How" of Clinical Trial Information Required by Patients: Disclosure of Investigator Site Name and Clinical Trial Results	**Semi-Live Session 22**：DM、CO、O: Patient Patient-Centric Approach to Clinical Research: Challenges to Improving Efficiency and Quality
	Luncheon Seminar 4	Luncheon Seminar 5	Luncheon Seminar 6
Live Session 21：CR、RA、PM、AC Clinical Trial Innovation: Learning from Case Study and Accelerating Adaptation in Japan	**Semi-Live Session 23**：RA、AC How to Promote Use of Centralized IRB in Clinical Trials	**Semi-Live Session 24**：RA、O: Regulatory Policy "Rule of Rules" for Development Tool Qualification	
Live Session 22：CR、AC Real Operations in Regenerative Medicine Product Clinical Trials	**Live Session 23**：ALL Diamond Session 2：PMDA Town Hall	**Semi-Live Session 26**：AC、MA Operational Innovation in Medical Affairs for Improved Patient Outcomes	**Live Session 24**：RA、AC Utilization of "Pharmaceuticals for Specific Use" for Pediatric Drug Development.
Semi-Live Session 27：O: Health Care Diamond Session 3：Beyond Innovation – What is Future Healthcare?	**Semi-Live Session 28**：RA、CP、ST、AC Recent Advances in Pharmacovigilance: Machine Learning and Statistical Pattern Discovery Case Studies from Around the World		**Semi-Live Session 29**：CR、DM、AC Improving the Clinical Trial Processes of A Sponsor By Utilizing the Voice of Clinical Study Sites
Live Session 25：ALL Closing Remarks			

Schedule At-A-Glance

SUNDAY, NOVEMBER 8

9:00-9:30	Pre Opening
9:30-10:00	Opening (LS01)
10:00-10:15	Break
10:15-	LS02, LS03, DIAMOND Session1 (SLS01)
11:45-12:00	Break
12:00-	LS04, SLS02, Student Session (LS05)
13:30-13:45	Break
13:45-	LS06, SLS03
15:15-15:30	Break
15:30-	LS07, SLS04, SLS05
17:00-17:15	Break
17:15-18:15	Young Professionals Exchange and Networking Session (LS08)

MONDAY, NOVEMBER 9

9:00-	LS09, SLS06, SLS07, SLS08
10:30-10:45	Break
10:45-	LS10, SLS09, SLS10, Keynote Address (LS11)
11:45-12:45	Lunch Break / Luncheon Seminar
12:45-	LS12, LS13, SLS11, SLS12
14:15-14:30	Break
14:30-	LS14, LS15, LS16, SLS13
16:00-16:15	Break
16:15-17:15	SLS14, SLS15, SLS16, SLS17
17:15-17:30	Break
17:30-19:00	Engage and Exchange (LS17) - Special Chatting Session

TUESDAY, NOVEMBER 10

9:00-	LS18, LS19, SLS18, SLS19
10:30-10:45	Break
10:45-	LS20, SLS20, SLS21, SLS22
11:45-12:45	Lunch Break / Luncheon Seminar
12:45-	LS21, SLS23, SLS24, SLS25
14:15-14:30	Break
14:30-	LS22, Diamond Session2 (LS23), LS24, SLS26
16:00-16:15	Break
16:15-17:15	SLS27, SLS28, SLS29
18:00-18:15	Closing (LS25)
18:00-18:15	Closing Remarks

This year's DIA Japan Annual Meeting will be held entirely online. Sessions will be delivered through the below formats:

1. OS (On-demand Session): On-demand sessions are those recorded in advance and made available approximately 1 week prior to the live event. On-demand sessions will be available to view for approximately 2 months following the event.
2. SLS (Semi-Live Session): Semi-live sessions are a combination of pre-recorded presentations available on-demand in advance of the event and a live panel discussion held during the live event. A summary of the presentations will be provided by the Session Chair at the top of the panel discussion.
3. LS (Live session): Live sessions are held entirely live with no pre-recorded content.

The format of delivery is indicated by each session title using the shorthand OS, SLS and LS.

Accessing Presentations

Available presentations will become accessible to Full-Program registrants about a week before the meeting and an e-mail announcement on how to access presentations will be sent to the registrants. Please note that this does not include all of the presentations but only those that were provided to DIA by a submission date. Meeting handouts will NOT be provided.

Private Social Function Policy

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

Saturday, November 7	All times are acceptable
Sunday, November 8	Before 8:00 and after 20:30
Monday, November 9	Before 8:00 and after 20:00
Tuesday, November 10	Before 8:00 and after 18:30

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

DIAmond SESSIONS

Conversations on Today's Priorities

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

See page 6, 26 and 29 for more details.

Sunday | November 8

PRE OPENING
Track 1 **9:00-9:30**

LS01 WELCOME
Track 1 **9:30-9:40**

Hajime Saijo, PhD
Director, DIA Japan

Barbara Lopez Kunz, MSc
Global Chief Executive, DIA

Hironobu Saito, PhD
Chair, DIA Advisory Council of Japan
Corporate Officer, Head of Medical Affairs Division, Daiichi Sankyo Co., Ltd.

OPENING REMARKS 9:40-9:50

PROGRAM CHAIR

Yuji Kumagai, MD, PhD
Director of Clinical Trial Center, Kitasato University Hospital

2020 DIA JAPAN'S INSPIRE REGIONAL AWARDS PRESENTATION 9:50-10:00

PRESENTER:

Hajime Saijo, PhD
Director, DIA Japan

AWARD WINNERS:

Outstanding Contribution to Health Award
Haruko Yamamoto, MD, PhD
Chief Medical Officer, Associate Executive Director, Pharmaceutical and Medical Devices Agency

Excellence in Service Award
Yoshikata Furuya, MSc
Manager, General Affairs Division, Sankeien Hoshoukai Foundation
/ Former Director, Vaccine Policy, Health Policy, MSD K.K.

Yoshiko Komuro, PhD
Inspection Director in Office of Non-clinical and Clinical Compliance,
Pharmaceuticals and Medical Devices Agency (PMDA)

Leader of Tomorrow Award
Ryuta Yoshida, MSc
Regulatory Affairs Department, NIDEK Co. Ltd.,

BREAK 10:00-10:15

LS02 Track 2 10:15-11:45

Quantitative Decision Making in Drug Development

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

SESSION CHAIR

Satoru Fukimbara, PhD
Senior Director, Data Science, Ono Pharmaceutical Co., LTD.

In drug development, making various decisions (e.g., go/no-go, drug development strategy, clinical study design) are required to identify the most promising projects, and to determine reasonable expectations for the "potential value of the drug," which can contribute to the most effective use of a company's limited resources. But the potential value of the drug can also be measured quantitatively through analysis of available data, which is also expected to contribute to better decision making. Although a variety of quantitative decision-making approaches have been proposed, none have been widely recognized or utilized. This session will introduce quantitative decision-making approaches from the individual study to the development portfolio level and culminate in panel discussion of what we can do to make better decisions in drug development

Bayesian Aspect of Statistical Power Using Assurance in Phase 2 and 3 Studies
Kosuke Ishida, MS
Biostatistics Manager, Development Division, Rakuten Medical Japan, K.K.

How Does Statistics/Statistician Contribute to Decision Making of Drug Development?
Yoichi Satoi
Director, Global Statistical Science Japan, Eli Lilly Japan K.K.

Value-driven Simulation for Program and Portfolio Strategy
Masanori Ito, PhD
Group Lead for Enterprise Analytics Services, Advanced Informatics and Analytics, Astellas Pharma Inc.

Panel Discussion
All Session Speakers and
Yoichi M. Ito, PhD
Director, Biostatistics Division, Hokkaido University Hospital Clinical Research and Medical Innovation Center
Ryo Tainaka, MS
Executive Director, Portfolio Strategy, Astellas Pharma Inc.
Takashi Toraishi, PhD
Chief Operating Officer and President, Rakuten Medical Inc.

LS03 Track 3 10:15-11:45

Realization of Personalized Medicine through Reverse Translational Research

Related Interest Area(s): AC, O: Translational Research
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Yuichi Kubo, MSc
Corporate Advisor, Daiichi Sankyo Co., Ltd.

The realization of personalized medicine requires a combination of translational research (TR) and reverse TR (rTR) in the drug discovery process to identify disease biomarkers and responders to therapy. Presenters will discuss a large-scale biobank from the viewpoint of clinical information and samples that can be used for clinical research, and then introduce the concepts of rTR and GAPFREE2, an industry-government-academia collaborative drug discovery project. This session will also present examples of development and data management systems specialized for TR and rTR analysis that integrates non-clinical and clinical data of different quality levels. Introduction of new drug discovery approaches that can bring the results of TR and rTR analysis to realization as personalized medicine will conclude with comprehensive panel discussion.

Establishing a Large-Scale Integrated Biobank of Healthy People: Operations for Consent and Health-Clinical Data
Masayuki Yamamoto, MD, PhD
Executive Director, Professor, Tohoku University graduate School of Medicine, Tohoku Medical Megabank organization

Reverse Translational Research and GAPFREE Program
Takao Shimizu, MD, PhD
Project Manager, Department of Lipid Signaling, National Center for Global Health and Medicine

Establishment and Outcomes of a Platform for Integrated, High-Quality Management and Operation of Clinical and Non-Clinical Data and Samples
Masato Murakami, MD, PhD, MBA
VP, Global Chair of Precision Medicine, R&D Division, Daiichi Sankyo, Co., Ltd.

Student Session

Creating a Cancer Vaccine by AI Based on Genetic Information of Cancer Patients

Akira Kitamura
General Manager, NEC Corporation, AI Drug Development Division

Panel Discussion

All Session Speakers

BREAK 11:45-12:00

LS04 TRACK 1 12:00-13:30

What Covid-19 Has Brought to Us

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

SESSION CHAIR

Eri Sekine
Region Head Trial Monitoring Japan, Novartis Pharma K.K.

COVID-19 has brought various constraints to the field of drug development and had a major impact on a global level. In such circumstances, people involved in drug development remain passionate not only for ensuring patient safety but also for devising ways to prevent development delays. It is time to share and discuss what is needed to strengthen the foundation of drug development, to use this occasion to accept challenges we have avoided, to respond as a result of reviewing new aspects of development, and to reconfirm what is really necessary by returning to the origin of drug development.

Desired Changes and Initiatives in Japan Clinical Development Based on the COVID-19 Experience

Toshiharu Sano, RPH
Executive Director, Head of Clinical Operations, MSD K.K. / TransCelerate

The Situation of Telemedicine in the Pre and Post-Covid-19 World

Ryoichi Kusama, MS
SVP of Business / Co-founder, MICIN, Inc.

Panel Discussion

All Session Speakers and
Toshihiko Doi, MD. PhD
Deputy Director / Chief, Experimental Therapeutics, National Cancer Center Hospital East
Kenichi Mikami, MS
Office Director, Office of Review Management, Pharmaceutical and Medical Device Agency (PMDA)
Noriko Morishita, MNS
Clinical Trial Promotion Office / Manager, National Hospital Organization Headquater

LS05 Student Session TRACK 3 12:00–14:30

Protocol Development in Oncology Clinical Trials

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

SESSION CHAIRS

Ayaka Kato
Showa University
Shunta Oka
Nihon University
Teppei Shibata
Nihon University
Hiroki Sugano
Nihon University

Cancer has been the leading cause of death in Japan and the unmet medical needs of cancer patients remain high not only in Japan but around the world. Therefore, oncology drug development will continue to receive worldwide attention in the foreseeable future, and it safe to say that clinical trials are the most important process in new drug development. This session will begin with an overview of clinical trials, outcomes of each trial phase, and protocol development. Participants will then be divided into groups for an exercise that simulates the protocol development process for a clinical trial of aPD-1 blo ckade therapy in non-small-cell lung cancer to learn how oncology clinical trials work. Since we will discuss PD-1 Blockade in this session, reading the material (we will notify you at a later date) is recommended.

TBD

Hideki Maeda, PhD
Department of Regulatory Science / Professor, Meiji Pharmaceutical University

TBD

Atsushi Ujihara
Deputy Manager, Office of Research Integrity / Department of Pharmacy, Kitasato University Kitasato Institute Hospital

Group work description

Erika Fujii
School of Pharmacy, Tokyo University of Science

Advisor

Motoki Arakawa, PhD
Junior Associate Professor, School of Pharmacy, Nihon University
Katsuhiko Ichimaru
Pharmaceuticals and Medical Devices Agency (PMDA)
Hideki Maeda, PhD
Professor, Department of Regulatory Science, Meiji Pharmaceutical University
Jun Yamakami, PhD
R&D Regulatory 1, Regulatory Affairs., Sanofi K.K.
Ryohei Sato, MS
DIA Japan Student Group OB/OG / Department of Clinical Research and Development, Otsuka Pharmaceutical Co.,Ltd.
Saki Watanabe
DIA Japan Student Group OB/OG / Monitoring Group, Pfizer R&D Japan

BREAK 13:30-13:45

LS06 TRACK 1 13:45-15:15

How do We Collaborate with Current Patients in Drug Development Process for Future Patients? Let's Think about "PPI" as If it Would be Your Action Tomorrow.

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

SESSION CHAIR

Nao Horie, MSc
Clinical Research and Medical Innovation Center, Research and Development Division, Hokkaido University Hospital

In the United States, citizens and patients started contributing to the promotion of drug development since 1980s, and now EMA and FDA have encouraged Patient Centricity in clinical development. In JapanPatient and Public In-volvement in clinical research (PPI) which began in Europe

and the United States is well known in Japan, ,so the concept of Patient Centricity is beginning to be introduced into clinical development.

Let's us think again, why, for what and for whom is Patient Centricity in clinical development necessary? Hasn't the purpose become merely to perform PPIatient Centricity? What are the benefits of including a patient's perspective in clinical development?

What kind of patients can be the "partners" who performs clinical research and development together for future patients? And how do we approach PPI? Now that there are various seminars and materials about PPI, let's think from the perspective of "what should I do?" LPatient Centricity in clinical development is encouraged, let's take a time to revisit, let's discuss PPI that will be useful for you tomorrow, while listening to the experiences of the participants.the need for Patient Centricity and potential application in Japan from the standpoints of patients, government, industry and academia.

What Is Patient and Public Involvement

Nao Horie, MSc
Clinical Research and Medical Innovation Center, Research and Development Division, Hokkaido University Hospital

Let's Think and Chat for Future Patients?

Naoki Tsutsumi
University of Tokyo Graduate School

Panel Discussion

All Session Speakers and
Noriko Fujiwara, MS, RN, OCNS, CCRP
Department of Palliative Medicine and Advanced Clinical Oncology, IMSUT Hospital, Institute of Medical Science, The University of Tokyo
Kayoko Kikuchi, PhD
Clinical research center, Division of Management and Strategy, National Center For Child Health and Development

BREAK 15:15-15:30

LS07 TRACK 3 15:30-17:00

Overcome Challenges in Complex Drug Development: Let's Learn More About Program Management

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

SESSION CHAIR

Atsushi Tsukamoto, PhD
Vice president, New Drug Regulatory Affairs Department, Daiichi Sankyo Co., Ltd.

While executing multiple drug development projects that intersect and interact, building an effective and efficient management strategy is essential. Past experiences may no longer apply, and intuition or feeling may not always work, so we must learn from the program management (PGM) knowledge and skill developed in other industries to build our own strategies. This session will introduce the common language and concept of PGM across different industries. A non-pharmaceutical PGM expert will provide examples where PGM helped build an effective development strategy, followed by PGM experiences shared by experts from the pharmaceutical and other industries. Closing panel discussion will further address how to create value with an efficient development strategy.

Program Management for Academic Clinical Research and Their Training Curriculum

Koji Iwasaki, PhD
Professor, Academic Clinical Research Center, Osaka University Hospital

Application of Program Management in Clinical Operations

Kenichi Kurumada
Senior Director, Clinical Operations, Takeda Development Center Japan, Takeda Pharmaceutical Company Limited

Strategy Execution by Program Management – Practice in Automotive Industry

Yoshiaki Shibao, PhD
CEO & President, Partner, Innovation Management Co., Ltd.

Toward Integrated Engineering Firm for Urban Creation

Kentarou Hayashi
General Manager, CSR Promotion Department, Head Office, Takenaka Corporation

Panel Discussion

All Session Speakers

BREAK 17:00-17:15

LS08 TRACK 1 17:15-18:15

Young Professionals Exchange Networking Session

Related Interest Area(s): ALL (Those 35 years old or under)
Level: Beginner
Language: Japanese Language Only

Semi-Live Sessions

DIAmond SESSIONS

SLS01 DIAmond Session 1 TRACK 1 10:15-11:15

ICH 30th Anniversary: Summary of 30 Years and Future Prospects with the Role of Japan

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

SESSION CHAIRS

Kazuhiko Mori, MSc
Director General, Japan Pharmaceutical Manufacturers Association(JPMA)

Toshiyoshi Tominaga, PhD
Senior Advisor, Japan Self-Medication Industry / Former ICH Management

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was established in 1990 to streamline and standardize pharmaceutical review for approval, and this year marked the 30th anniversary of its foundation. ICH has developed more than 60 technical harmonized guidelines and contributed to supplying drugs faster to patients worldwide.

In 2015, the organization and operation were totally renewed ("ICH reform") to further globalize with an increased number of participants. Activities for strategic development of guidelines, secure implementation of guidelines, and trainings for disseminating guidelines, are ongoing.

In this session, current ICH executives will meet with representatives of regulatory authorities and industry who have played central roles in ICH's 30 year history to introduce ICH achievements to date, current ICH issues, and the future role of Japan in ICH.

History and Achievements of ICH
Lenita Lindström-Gommers
Senior Expert, Directorate General for Health and Food Safety
European Commission / Chair of the ICH Assembly

ICH as a Global Organization Perspective from Assembly Member
Celia Lourenco, PhD
Director General, Biologic and Radiopharmaceutical Drugs Directorate of Health Products and Food Branch, Health Canada / Vice Chair of the ICH Assembly

History and Achievements Perspective from Japan
Nobumasa Nakashima, PhD
Associate Executive Director for International Programs, Associate Executive Director for Asian Training Center(ATC), Pharmaceuticals and Medical Devices Agency (PMDA) / Vice Chairof the ICH Management

Perspectives from the Industry - The Important Role of ICH and Our Responsibility -
Hironobu Hiyoshi, PhD
Executive Director of Government Relations, Eisai Co., Ltd.

Engagement of Patients and Academia as ICH Stakeholders
Theresa Mullin, PhD
Associate Director for Strategic Programs, OCD, CDER, Food and Drug Administration(FDA) /Chair of the ICH Management Committee

Perspectives from Japan - Japan Regulators' Efforts to Cooperate with Patients and Academia
Naoyuki Yasuda, MSc
Director, Office of International Regulatory Affairs, Division of General Affairs, Ministry of Health, Labour and Welfare (MHLW)

Perspectives from the Industry - Industry Perspectives on Engaging Patients in ICH Activities -
Hironobu Hiyoshi, PhD

ICH Supports Innovation
Celia Lourenco, PhD

Perspectives from Japan - The Importance of Innovative Technologies Guidelines for Japan
Naoyuki Yasuda, MSc

The Future of ICH
Lenita Lindström-Gommers

Presentation from Japan
Nobumasa Nakashima, PhD

SLS02 TRACK 2 12:00-13:00

Next Generation Leadership for Successful Future

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

SESSION CHAIR

Koichi Konno, PMP
Chief Executive, PM Consulting Positive Intention

New creative mindsets and capabilities are required for project teams managing drug development or clinical trials in the current VUCA (Volatility, Uncertainty, Complexity and Ambiguity) world, to adjust to external environments becoming more complicated and unstable. We need high-performance teams with diverse team member expertise, with abilities to sensitively detect external changes, and with habitual behaviors that repeatedly optimize learnings to create new and deeper value. This session will highlight the "authentic leadership" required for global leaders by examining typical leadership theories and exchanging individual views from personal leadership styles, and also discuss the fundamental paradigm shift that recognizes the importance of organizational agility to adapt to changes in our surroundings.

Authentic Leadership to Make a Highly Adaptable Team
Yasuo Fukushima, PhD
Global Project Management Department, Daiichi Sankyo co., Ltd.

Significance of Supportive Leadership through Regulatory Consultation and Review Process in PMDA
Tomoko Okudaira
Deputy Review Director, Office of New Drug 2
Pharmaceuticals and Medical Devices Agency (PMDA)

Supportive Leadership from Experience in Drug Development Projects (Tentative)
Masahiko Ichimura, MSc, PMP
Clinical Research Support Office, National Cancer Center Hospital

Panel Discussion
All Session Speakers

SLS03 TRACK 2 13:45-15:15

ICH Anniversary: Summary of 30 Years and Future Prospects in Q Area with the Role of Japan

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

SESSION CHAIRS

Junichi Koga, MD
Daiichi Sankyo Co., Ltd.

Haruhiro Okuda, PhD
Former Director General, National Institute of Health Sciences

From the beginning of ICH into the early 2000's, the basic quality guidelines for marketing authorization for pharmaceuticals (ICH Q1 to Q7) were published. In 2003, ICH Quality Vision: A harmonized pharmaceutical quality system applicable across the lifecycle of the product emphasizing

an integrated approach to risk management and science was adapted as the new policy for developing guidelines. The reflection paper on quality was adopted in 2018 to advance ICH Quality Vision 2003 and promote continual improvement and innovation of manufacturing technology. The Quality Discussion Group is now discussing the ICH strategic approach in quality. In this session, regulatory and industry representatives will explain ICH's quality achievements to date, current efforts on these issues, and the role of Japan in the future of ICH.

Biologics Challenges in ICH over 30 Years
Junichi Koga, MD
Daiichi Sankyo Co., Ltd.

Evolution of ICH Q-Guidelines over the Decades Future Developments
Jean-Louis Robert
Former EC-EU ICH Q12 topic lead. Former chair of CHMP QWP

API Development and Quality Assurance
Tomonori Nakagawa, MA
Manager, Manufacturing Process Development Dept. (API), Production HQ, Otsuka Pharmaceutical Co., Ltd.

Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
Yasuhiro Kishioka, PhD
International Liaison Officer, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

SLS04 TRACK 1 15:30-16:30

Scientific Benefit-Risk Management and Communication for the Future

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

SESSION CHAIR

Mamoru Narukawa, PhD, RPh
Professor, Graduate School of Pharmaceutical Sciences, Kitasato University, Japan

There is a variety of information for proper use of drugs for healthcare providers and patients. In addition, with the diversification of dissemination methods such as digital tools, it has become important to verify a series of cycles to ensure that adequate information reaches the target population in a timely and appropriate manner, is correctly understood, and has led to behavioral change for risk prevention and mitigation.

Overseas, frameworks and guidance documents for risk minimization have already been implemented, but such initiatives and approaches are not established enough in Japan.

In this session, we would like to learn about overseas regulations and practice on effective measurement of benefit risk management/communication and discuss the future direction we should take among industry, government and academia.

Best Practices for Risk Management and Communication at the US FDA
Gerald Dal Pan, MD, MHS
Director
Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration (FDA)

Best Practices for Risk Management and Communication in the European Union
Juan Garcia-Burgos, MD
Head of Public and Stakeholders Engagement Department, EMA

Future Risk Communication in Japan -Focusing on Additional Risk Minimization Measures-
Kazuhiko Ishida, MS, RPh
Director, Pharmacovigilance, Astellas Pharma Inc.

Panel Discussion
Toyotaka Iguchi, MD
Pharmaceuticals and Medical Devices Agency (PMDA)
Kazuhiko Ishida, RPh
Director, Pharmacovigilance, Astellas Pharma Inc.
Rei Maeda
Global Patient Safety & Solutions, Eli Lilly Japan K.K.
Tomoko Yamada
Associate Director, Pharmacovigilance, MSD.K.K.

SLS05 TRACK 2 15:30-17:00

ICH Anniversary: Summary of 30 Years and Future Prospects in S Area with Role of Japan

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

SESSION CHAIRS

Yoko Hirabayashi, MD
Director, Center for Biological Safety and Research, National Institute of Health Sciences

Kazuto Watanabe, PhD
Principal Scientist, Translational Research Division, Chugai pharmaceutical Co, LTD

ICH has made much progress in harmonization activities of non-clinical safety guidelines for not only basic toxicity evaluation (such as carcinogenicity, genotoxicity, and reproductive toxicity) but also for assessing impurity in the quality area and the timing of multidisciplinary study implementation. These ICH guidelines have contributed to drug safety, reducing animal tests, and streamlining drug development. Currently, guidelines for new modalities are also being developed; for example, discussion has begun to develop the guideline for non-clinical biodistribution studies for gene therapy products (S12; MHLW/PMDA's proposal). In this session, regulatory and industry representatives will introduce and explain ICH's achievements in non-clinical safety, current efforts for the issues mentioned, and the future role of Japan in this area of ICH.

Revision of ICH S5 Guideline
Kazushige Maki, PhD
Senior Scientist (Toxicology), Office of Vaccines and Blood Products, Pharmaceuticals and Medical Devices Agency (PMDA)

Outline of Guideline for Nonclinical Safety Testing in Support of Development of Paediatric Pharmaceuticals
Takuya Nishimura, PhD
Principal Reviewer, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

Revision of ICH S1 Carcinogenicity Testing Guideline from the View Point of Japanese Pharmaceutical Companies
Shigeru Hisada
Innovative Drug Discovery Division, ASKA Pharmaceutical Co, Ltd

ICH S6 –The History and Relevance for the Case-by-Case Approach
Joy A. Cavagnaro, PhD
President and Founder, Access BIO L.C.

Panel Discussion
All Session Speakers and
Kiyoshi Kinoshita, PhD

Manager, Regulatory Affairs, Area Japan Development, MSD K.K.

LIVE SESSIONS

LS09 Track 1 9:00-10:30

Driving Toward Further Operational Efficiency and Innovation in Clinical Trials

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

SESSION CHAIR

Satoshi Saeki, MSc

Senior Director, Clinical Operation and Innovation Group, Japan-Asia Clinical Development, Astellas Pharma Inc.

The international, non-profit Association of Clinical Research Professionals (ACRP) supports the clinical research industry as a platform for disseminating through workforce protocols (for PIs, CRCs, site monitors, etc.) and learning practical strategies, best practices, and creative solutions needed to improve clinical trial quality. ACRP also works closely with technology providers and in process improvement collaborations to help drive implementation of innovative tools and processes. To give participants the benefit of ACRP's knowledge and experience in driving operational innovation and efficiency, this session will convene a panel discussion with ACRP and DIA Japan leadership on the best ways to incorporate these new clinical operational efficiency and innovation approaches in our clinical environment in Japan.

Clinical Research Workforce of the Future
Jim Kremidas
Executive Director, ACRP, United States, Association of Clinical Research Professionals (ACRP)

Clinical Operational Efficiency and Innovation in Clinical Trials from Site's Perspective
David Morin
Director of Research at Holston Medical Group and ACRP board of trustees, United States, Holston Medical Group

Panel Discussion
All Session Speakers and
Yuji Kumagai, MD, PhD
Director of Clinical Trial Center, Kitasato University Hospital
Keiichi Inaizumi, MSc
Pfizar R&D Japan

BREAK 10:30-10:45

LS10 Track 1 10:45-12:15

ICH M11: Clinical Electronic Structured Harmonized Protocol

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

SESSION CHAIR

Ken Sakushima, MD, MPH, PhD

Principal Reviewer(Clinical medicine), Office of New Drug 3, Pharmaceuticals and Medical Devices Agency (PMDA)

This session presents the background, purpose, and development of the ICH M11 guideline Clinical Electronic Structured Harmonized Protocol. In this session, several ICH M11 Expert Working Group members and a guest speaker from academia will explain the key objectives of the ICH M11 Expert Working Group, its interdependences with other ongoing ICH efforts, and its high-level design, deliverables, and benefits, to raise stakeholder awareness of the harmonized clinical protocol template.

ICH M11: Clinical Electronic Structured Harmonized Protocol CeSHarP
Motoki Mikami
Reviewer, Office of New Drug Ⅱ, Pharmaceuticals and Medical Devices Agency (PMDA)

Benefit of Utilizing a Harmonized Clinical Protocol Template
Azusa Tsukida
Head, Biostatistics & Programming, Sanofi KK

Technical Specification for M11 (Protocol Template)
Manabu Inoue
Drug Safety Information, MSD K.K.

Expectations for ICH M11: Perspectives from Academia
Hiroshi Watanabe, MD, PhD
Executive Director/ Vice President, Hamamatsu University School of Medicine

Panel Discussion
All Session Speakers

LS11 Keynote Address Track 4 10:45-12:15

Patient-Focused Drug Development

SESSION CHAIR

Yasuhiro Fujiwara, MD, PhD

Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

PFDD is based on recognition that patients living with a disease have firsthand knowledge of the disease impact on how they feel and function. They bring a unique and valuable perspective to drug development, one that cannot be provided by the clinical, scientific, legal and other experts. Throughout the drug development process there are opportunities to increase the quality of the development program through effective inclusion of the patient's perspective. These opportunities include but are not limited to: understanding the clinical context for medicines development and evaluation; product design features including formulation and delivery modes that minimize burden and support adherence; development of endpoints that reflect benefits that matter most to patients; designing trials that support better enrollment and retention; and informing regulatory decision making including patient acceptability of benefits vs risks. This presentation discusses how regulators and industry can enhance drug development and decision making with a more patient-focused approach.

An FDA Perspective
Theresa Mullin, PhD
Associate Director for Strategic Programs, OCD, CDER, Food and Drug Administration (FDA)

LUNCH BREAK & LUCHEON SEMINAR 11:45-12:45

LS12 Track 2 12:45-14:15

Creating an Insightful Patient Journey Map On-Site: Let's look at and Feel The Patients' Voice Together and Think about What We Can Do! (part 1) Part 2 is LS14

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

SESSION CHAIRS

Fumihiko Okada, PhD

Associate Director, New Drug Regulatory Affairs Department, DAIICHI SANKYO CO., LTD.

Natsuko Yamada
CEO, Shigoto Soken,Inc.

Exhibited at last year's DIA Japan Annual Meeting 2019, the Patient Journey Map (PJM) is a half-life history map of patients, their families, and their experience with the patient's disease. PJMs can be created to visually represent not only the patient's disease information but also their parents' experiences and emotions by using a method called graphic facilitation. Named "insightful PJM (iPJM)," this new tool can inspire patients to face their illnesses, by visualizing their thoughts, as one among several concerned parties. In this session, we will demonstrate how to create an iPJM together with session participants at the venue. Look at the patient's voice, feel it, and then let's think together about what we can do for patients from our minds and hearts!

Inherited Metabolic Disease Experience from Perspective of The Patient's Parents
Hideyuki Sawada, PhD
Hidamari Tanpopo (Self-help group of Organic Acidemias and Fatty Acid Oxidation Disorders)

Inherited Metabolic Disease Experience from Perspective of the Patient's Parents
Jun Sawada
Hidamari Tanpopo (Self-help group of Organic Acidemias and Fatty Acid Oxidation Disorders)

LS13 TRACK 3 12:45-14:15

Let's Broaden Young Peoples' Horizons from the Multidisciplinary Perspective

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

SESSION CHAIR

Kazuhiro Kanmuri, PhD
CEO, Inter-Professional Inc.

Promoting the efficiency and efficacy of drug development efficiently in the turbulence of today's pharmaceutical industry requires more industry-government-academia collaboration than ever. However, for many stakeholders, opportunities to access ideas across industry, government, and academia remain limited. In this session, experts with experience in more than one category (among regulatory agencies, pharmaceutical companies, and medical institutions or academia) will demonstrate how they engage in clinical research and drug development.

This interactive session will include group discussion of insights and experience across multiple careers to broaden the view of young people and help them network across all of industry, government, and academia.

What I Saw: Experience at Clinical Research Sites and Pharmaceutical Companies
Toshiko Ishibashi, PhD
Clinical Operation I, Clinical Operation, Ono Pharmaceutical Co., Ltd.

Insights Gained from The Experience in Medical Institution and Regulatory Agency
Ryusuke Abe, MD, PhD
Office of Standards and Compliance for Medical Devices, Pharmaceuticals and Medical Devices Agency (PMDA)

Group Discussion

BREAK 14:15-14:30

LS14 TRACK 2 14:30-16:00

Creating an Insightful Patient Journey Map On-Site: Let's look at and feel the patients' voice together and think about what we can do! (part 2) Part 1 is LS12

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

SESSION CHAIRS

Fumihiko Okada, PhD
Associate Director, New Drug Regulatory Affairs Department, Daiichi Sankyo Co., Ltd.

Natsuko Yamada
CEO, Shigoto Soken, Inc.

In Part 1, we listened to the stories of patients and their families, looked at and felt the patient's voice, and created an an insightful Patient Journey Map (iPJM).

In Part 2, we will experience what we can do for patients from our own respective positions. We will then think about what we experience when we exchange our own positions with other panelists who represent patients, healthcare professionals, regulatory authorities, and the pharmaceutical and clinical research industries. We will then return to our own position and reconsider what we can do for patients after that new experience.

Panel Discussion
Madoka Inoue
Pharmaceuticals and Medical Devices Agency (PMDA)

Akiko Kashiwagi
Representative, Hidamari Tanpopo (Self-help group of Organic Acidemias and Fatty Acid Oxidation Disorders)

Mitsuru Kubota, MD, PhD
Chair, Department of General Pediatrics & interdisciplinary Medicine, National Center for Child Health and Development

Haruka Yoshimatsu, PhD
New Drug Regulatory Affairs Department, Daiichi Sankyo Co., Ltd.

LS15 TRACK 3 14:30-16:00

Career Development in New Healthcare Era

Related Interest Area(s): PM, O:Career Development in Pharmaceutical Industry
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR

Shuji Sumida, MPharm, RPh, PMS
Senior Director, HR Business Partner, Quality & Regulatory Compliance Unit, Chugai Pharmaceutical Co., Ltd.

In the pharmaceutical development industry, the work mainstream involves many stakeholders, such as global development, joint development / research, and consulting, and now includes new technologies like artificial intelligence and collaboration with other industries with the intent of making drug development faster, but also more complex. Surrounded by all these changes, it is important to keep our minds wide open to these broad information horizons and boldly step into creating careers unaffected by preconceived stereotypes, to contribute to society as leaders in the new healthcare era. In this session, we will introduce various examples of career development in the pharmaceutical industry, discuss what skills and mindsets are required from now on, and other considerations for career development.

Career Change from Pharmaceutical Company to Academia
Masahiko Ichimura, MSc, PMP
Clinical Research Support Office, National Cancer Center Hospital

Career Change to Freelance: My Career Development and Utilization of Pharmaceutical Company Experience
Noriko Yoshida, PMS
Executive, Project Counseling Office cocokara

Career Development within Pharmaceutical Industries
Satoshi Suzuki
Project Manager, Japan Portfolio & Project Management, Pfizer R&D Japan

Panel Discussion
All Session Speakers

LS16 **TRACK 4** **14:30-16:00**

Current Status and Future of Digital Therapeutics (DTx): How DTx Are Developed and Penetrate Medical Care

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

SESSION CHAIR

Takashi Sawada
Oncology Clinical Development, MSD K.K.

Interest in Digital Therapeutics (DTx) is increasing not only in pharmaceutical companies but also in venture companies. However, obstacles remain because there is no fixed consensus on the DTx development process or on the treatment / management system required after launch. From the clinical development perspective, points to consider when applying for approval of DTx include management, security and protection of patient personal information, adherence data, and PRO (Patient Reported Outcome) data. The medical perspective must also consider synergies with medicines the patient may already be taking. Representatives of suppliers, developers, and regulators will discuss these and other developments in the DTx market in this session.

DTx, New Business Challenge in Pharma.
Yuta Watanabe
Astellas Pharma Inc.

DTx Development and the Future of DTx Drawn by Startups
Yusuke Yajima
SUSMED, Inc

Role of CXO That Matches the Value Chain of DTx
Takanori Sando
Planning & Promotion Dept., CMIC HOLDINGS Co., Ltd.

Regulations on DTx and Future Expectations
Ayako Tomiyasu
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Minori Niso
Associate Brand Marketing Director, APAC Marketing, Parexel International

BREAK **16:00-16:15**

SEMI-LIVE SESSSION 14,15,16,17 **16:15-17:15**

BREAK **17:15-17:30**

ENGAGE AND EXCHANGE: SPECIAL CHAT SESSION

LET'S CHAT! "WHAT'S THE DIA WORLD 2020" TRACK 1

RECEPTION HALL 17:30-19:00

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

Session Chair
Yukihiro Matsuda, MSc
Research scientist, Site Engagement Breakthrough Center, Clinical Development, Eli Lilly Japan K.K

Facilitator
COM Program Committee Chair / COM Community

Special "Chat Sessions" will be provided for members and attendees to exchange opinions, insights and challenges, and to network freely. These sessions are intended to be casual in style and will feature small group discussions on selected topics. DIA Japan will shortly send out an online questionnaire asking all attendees to indicate which group you would like to join. Please don't forget to complete the questionnaire to reserve your spot.

All are welcome so come along with a beer or bottle of wine and join the conversation!

<List of Topics>

#	Category	Abstract
1	Clinical Data Management (CDM)	Can we tell standardization vs uniformization? Let's discuss how the standardization should be with innovation!
2	Clinical Innovation (CI)	What is innovation of new drug development in the corona era ?
3	Clinical Operations & Monitoring (COM)	Looking beyond Innovation, let's talk about the skills we need to acquire! —Aiming to reform the working style of Clinical Operation—
4	Medical affairs (MA)	Evidence Generation for patient: Let's talk innovative approach you are thinking!!
5	Medical Communication (MC)	What should we do to provide drug information from the perspective of "for patients" (if you are: a healthcare professional, a person involved in reviewing drug applications/ safety/drug information, or an author of CTDs/RMPs/package inserts/interview forms/ other drug information materials, medical affairs)?
6	Patient Engagement (PE)	Thinking about Patient Public Involvement (PPI) - The clinical trials the patients are clearly understood and participated-
7	Pharmacovigilance & Labeling (PL)	COVID-19 and PV / Labeling: Let's look back at what happened from December 2019 to November 2020 and discuss what we have learned from it and what we should do from December 2020.
8	Project Management (PM)	How will project managers contribute to drug development in 2050? -Let's get on the time machine and see it!-
9	Regulatory Affairs (RA)	"Let's deepen our understanding PAD Law revision!" and "Tips for being Regulatory Experts!"
10	Six Sigma (SS)	"To establish new processes in organization, what are the critical points in change management after business improvement"
11	Statistics (ST)	COVID-19 – If you don't think about it now, you may be in trouble later

DIA 2021

GLOBAL ANNUAL MEETING

PHILADELPHIA, PA | JUNE 27-JULY 1

SLS06 Track 2 9:00-10:00

New Approaches in Knowledge Management for Significant Advances

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

SESSION CHAIR

Kazuo Ichikawa, PhD

Senior Staff Advisor, Project Management Department, Daiichi Sankyo Co., Ltd.

The use of Artificial Intelligence (AI) to increase efficiency is spreading at an accelerated pace across all fronts in clinical research and development. However, the primary decisions in clinical research and development should be made by healthcare professionals, so human interaction and knowledge inheritance are also important. Interactions between the "tacit knowledge" embedded in individuals and the "explicit knowledge" verbalized in documents are essential for value creation. For example, significant tacit-explicit knowledge management can make meetings more productive as a result of the appropriate application of tacit knowledge transformed by explicit knowledge provided by sources such as manuals. In this session, we will share hints for value creation "beyond innovation" through examples of knowledge inheritance based on current applications of AI through the perspective of knowledge management (KM).

Changes in Knowledge in the Age of Declining Birthrate and Aging Population
Junichi Abe
Tokyo Central Business Offices, Japaniace Co., Ltd.

Knowledge Management in Academic Hospital: Verification of Examples
Kotone Matsuyama, RParma, GFMD
Professor, Department of Health Policy and Management, Nippon Medical School

Practices of Knowledge Transfer in Pharma Company
Souta Mizumoto, MSc
Director, Global Patient Safety and Solutions, Eli Lilly Japan K.K.

SLS07 Track 3 9:00-10:00

Possibility of Applying "Training / Learning Innovation" to Clinical Development Projects

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

SESSION CHAIR

Michihito Kawauchi

Clinical Operation, Japan Development, MSD K.K

Are you prepared for the wave of innovation coming to professional training and learning? Modern industries have developed and implemented innovative training and learning methods (such as Instructional System Design) based on research. Emerging technologies such as VR (virtual reality) training and personalized learning based on artificial intelligence (AI) have also been introduced by utilizing information and communication technologies (ICT). Until recently, although many different stakeholders (Sponsor, CRO, Trial Site, SMO, etc.) participate in clinical development, training is often delivered in one set package. But as current discussions raise the importance of training in clinical quality management system (QMS) discussions, this session will highlight the applicability of incorporating training / learning innovations to transform clinical development projects.

Training in Clinical Development
Daisuke Sugahara
Manager, Clinical Development Operations, Celgene K.K.

ICT Utilization Example in the Competitive Sports
Shimpei Aihara
Researcher,Department of Sports Science , Japan Institute of Sport Sciences

Instructional Design: A Systematic Approach to Increasing the Effectiveness, Efficiency, and Attractiveness of Learning
Shigeki Tsuzuku, MD, PhD, MID, MPh
Professor, Kumamoto University Graduate School of Instructional Systems

Panel Discussion
All Session Speakers

SLS08 Track 4 9:00-10:30

ICH Anniversary: Summary of 30 Years and Future Prospects in E Area with Role of Japan

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

SESSION CHAIRS

Hironobu Saito, PhD

Corporate Officer, Head of Medical Affairs Division, Daiichi Sankyo Co., Ltd.

Yoshiaki Uyama, PhD

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

Many guidelines in the ICH efficacy area, including basic clinical guidelines, have been developed based on advancements in identifying disease characteristics and other scientific achievements plus the growing globalization of drug development. The "GCP Renovation" reflection paper, aimed at modernization of E8 and subsequent renovation of E6, was adopted in 2017 and each guideline is now being developed. In addition, ICH Real World Data / Real World Evidence activities continue. In this session, regulatory and industry representatives introduce ICH efficacy area achievements to date, current efforts for issues mentioned above, and the future role of Japan in ICH.

Contribution of ICH and E5 guideline in Japan Drug Development and Approval
Kazuhiko Mori, MSc
Director General, Japan Pharmaceutical Manufacturers Association (JPMA)

The Past and Future of Clinical Studies in the Evolution of E6 and E8
Osamu Komiyama
Senior Manager, Statistical Research & Data Science, Pfizer R&D Japan

Paradigm Shift in Clinical Evaluation driven by E9(R1)
Satoru Tsuchiya
Senior Director, Global Data Design Office, Sumitomo Dainippon Pharma, Co., Ltd.

ICH E11 and Pediatric Drug Development
Michiyo Sakiyama, MD, PhD
Associate Senior Scientist for Clinical Medicine, Office of Vaccines and Blood Products, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

SLS09 TRACK 2 10:45-11:45

How Do Quality Risk Management and Risk-Based Monitoring Work Together? Gaps Between Ideal and Actual Experience During COVID-19

Related Interest Area(s): CR, DM
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Kazumi Yabe
Manager, Regional Clinical Operations, Bristol Myers Squibb K.K.

There is a synergistic relationship between Quality Risk Management (QRM) and Risk-Based Monitoring (RBM) programs, such as the concept of Quality Tolerance Limits (QTLs), and while the scope of each program is different, their underlying principles are similar. Alignment on fundamental risk principles such as risk tolerance, identification of significant risks, and potential controls between these two programs, drive a more efficient and dynamic Quality Management System (QMS) as a result. This session will describe these concepts by sharing experiences in QRM and RBM program implementation. Further discussion will highlight implementation challenges from the sponsor and site perspective that illuminate potential gaps between ideal and actual implementation experiences, especially during this COVID-19 pandemic.

Establishing End-To-End Quality Management Approach to Enable Successful QRM with Experiences Implementing QTL
Tomoko Asakawa
Clinical Process Strategy Dept., Chugai Pharmaceutical Co., LTD.

Challenges We Faced during COVID-19 Situations and Ideal RBM Implementation
Yoko Kurose
Senior Manager, Monitoring Group, Pfizer R&D Japan.

Panel Discussion
All Session Speakers and (Speaker 1 won't join panel discussion)
Toshiya Hara
Executive Vice President, I'rom Co., Ltd
Minoru Koizumi
Clinical Development Operations and Innovations
Medicines Development Unit Japan, Eli Lilly Japan K.K.
Naomi Misaki, MPham
Research Management, St. Luke's International Hospital
Noriko Morishita, MNS
Manager, Clinical Trial Promotion Office, National Hospital Organization Headquarter

SLS10 TRACK 3 10:45-11:45

Current Status and Challenges of Regulatory Decision Making in Development Using Model Informed Drug Development

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

SESSION CHAIR

So Miyoshi, PhD
Head of Clinical Pharmacology, Pfizer R&D Japan

In 2004, the US FDA announced the FDA Critical Path Initiative to tackle the issue of drug development efficiency together with pharmaceutical companies. Model & Simulation (M&S) was actively used, focused on dose optimization, especially for QT tests and extrapolation in development of epilepsy drugs to children. Promotion of Model Informed Drug Development (MIDD) is also one of the goals of the 2018 reauthorization of the US Prescription Drug User Fee Act (PDUFA VI), further advancing M&S. In 2019, the "Population Pharmacokinetics / Pharmacodynamic Analysis Guideline" and the drug exposure-response relationship analysis guideline (draft) were issued in Japan, establishing a basis for MIDD in Japan. This session will discuss this current situation and other analysis issues related to applications for drug development approval faced by pharmaceutical companies in Japan.

Challenges and Ambitions of Midd by an Employee in a Pharmaceutical Company
Takayuki Imaeda, MSr
Head of Regulatory Affairs, Pfizer R&D Japan

Industry View - M&S as Standard Practice During Drug Development
Sanae Yasuda, PhD
Global Head of Clinical Pharmacology Science, Medicine Development Center, Eisai Co., Ltd.

Current State and Review Cases of Modelling & Simulation in New Drug Reviews
Hiroki Sekiguchi, MS
Office of New Drug Ⅲ, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Yuji Kumagai, MD, PhD
Director of Clinical Trial Center, Kitasato University Hospital

SLS11 TRACK 1 12:45-13:45

How Can industry Play a Role through Publications to Elevate Patient Voice?

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

SESSION CHAIR

Shinichi Nishiuma, MD
Executive Director, Head of Medical Affairs, Bristol-Myers Squibb K.K.

Because improving patient life is a common theme throughout pharmaceutical companies, healthcare professionals trust sources such as peer-reviewed publications for meaningful information they can receive in a timely manner. These professionals are expected to use this published information to make better healthcare decisions, which helps to translate the published data into evidence. To address all the different stakeholder needs in this process, research sponsors develop publication plans to ensure that their research findings are published and presented in an ethical, complete, and timely manner. In this session, various publication experts will discuss best practices and challenges in publication planning, plus enhanced patient involvement approaches in response to strong current trends, in today's fast-moving healthcare and pharmaceutical environment.

Elevating the Patient Voice
Victoria Elegant, MD, PhD
Vice President, Region Head Medical, Amgen

A Company's Practice and Challenges in Publication Planning with More Patient-Centric Mindset
Yuko Kojima, RPh, EMBA
Director, Biometrics, Medicine Development Unit-Japan & Medical Affairs, Eli Lilly Japan K.K.

Panel Discussion
All Session Speakers and
Hideo Nakada, RPh
Assistant Professor, Division of Hospital Pharmacy Science, Keio University Faculty of Pharmacy
Yukiko Nishimura, MS
President, NPO ASrid

SLS12 TRACK 4 12:45-14:15

ICH Anniversary: Summary of 30 years and Future Prospects in M Area with Role of Japan

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

SESSION CHAIRS
Manabu Inoue
Manager, Drug Safety Information, MSD K.K.
Junko Sato, PhD
Office Director, Office of International Programs
Pharmaceuticals and Medical Devices Agency (PMDA)

ICH has been actively working on developing guidelines for its multidisciplinary area, which includes quality, safety and efficacy, guidelines which have greatly contributed to more efficient drug development and pharmacovigilance. Specifically, MedDRA (M1) which was utilized in 125 countries or regions in 14 languages by more than 6,000 organizations by the end of 2019, has provided the opportunity to exchange safety information rapidly and accurately among countries/regions. The CTD (M4), which specifies the format of the document submitted for marketing approval, and the electronic version (M8, eCTD), which enables efficient submission of this application document, are among the most important achievements of ICH. In this session, representatives of regulatory authorities and industry will introduce ICH's achievements to date in the ICH multidisciplinary area, current efforts to address the above issues, and the role of Japan in the future of ICH.

Electronic Standards in ICH - First Decade, Second Decade, and Next -
Mihoko Okada
Institute of Health Data Infrastructure for All (IDIAL)

Experiences on E2B (Tentative)
Ta-Jen Chen
Project Management Officer, Office of Strategic Programs (OSP)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

"Merit and Demerit" and Future Aspiration of ICH Guidelines of M Area (from Industry Point of View)
Takeshi Adachi
President, PPG Inc.

Panel Discussion
All Session Speakers

SLS13 TRACK 1 14:45-15:30

Impact of Patient Engagement Initiatives in Clinical Trial Design and Execution

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

SESSION CHAIR
Makiko Okamoto
Strategy & Policy Afairs, Medicine Development Unit Japan, Lilly Research Laboratories Japan・Sr. Manager, Eli Lilly Japan K.K.
(Patient Experience Workstream in TransCelerate)

While expectations placed on the process and outcomes of patient engagement have recently increased, there is still no standard tool for protocol discussion with patients or the utilization of their opinions. TransCelerate has developed two tools through collaborations with patients: The first tool is for obtaining patient input before the study start (during protocol development), and the second is a questionnaire survey to determine patient satisfaction, to be used after participation in the study. This session will present one patient, one HCP, one global TransCelerate member and one TransCelerate member from Japan, to discuss the need for conducting patient-centered new drug development in Japan; the importance of cooperation with patients in drug development; and the status of use and future expectations of these tools in Japan and overseas

Possibility of Realizing "Social Drug Development" Originating from Patients in Japan
Tomoaki Shinohara
Director, Koinobori Associate Inc.

Importance of Cooperation with Patients & Families in Drug Development - From the Standpoint of a Principal Investigator
Kayoko Saito, MD, PhD
Professor (Fixed Term) , Institute of Medical Genetics, Tokyo Women's Medical University

Introduction of TransCelerate Japan Patient Experience Initiative
Shintaro Omuro, MS
Senior Manager, Clinical Operation and Innovation Group, Japan/Asia Clinical Development 2, Astellas Pharma Inc.
(Patient Experience Workstream in TransCelerate)

TransCelerate Patient Experience Initiative
Samantha Reyes
Patient Engagement Lead, Amgen, Inc. / Patient Experience Workstream in TransCelerate

SLS14 TRACK 1 16:15-17:15

WHAT'S NEW? Risk Communication and Pharmaceutical Information in the Digital Era in Japan, Europe, and the US

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

SESSION CHAIR
Rie Matsui, MPharm
International Labeling, APAC Senior Director, Pfizer R&D Japan

The full digitalization movement in the healthcare and pharmaceuticals fields has launched various initiatives worldwide. Japan will implement providing digitalized and structured pharmaceutical information and excluding paper-based labeling in the package box well ahead of the US and Europe, while discussion on next-generation pharmaceutical information is proceeding in Japan at the Cabinet Office. Meanwhile, EMA published the electronic product information key principle in January 2020, and IMI is considering a digital health information project and also discussing eLabeling as a component of digital health in Europe. In the US, digital risk communication has been actively discussed and providing pharmaceutical information in different methods has been considered. This session will share the latest digital risk communication updates from Europe and the US, similar initiatives on pharmaceutical information, the status of progress on next-generation pharmaceutical information in Japan, and the best way to plan future risk communication on a global level in the digital era

Electronic Product Information (ePI) for EU Medicines: Key Principles and Beyond
Juan Garcia-Burgos, MD
Head of Stakeholders and PE, EMA

Improving Patient Access, Understanding and Adherence to Healthcare Information: An Integrated Digital Health Information Project
Deborah Bebbington
Vice President, Head Labeling, Bayer Plc, UK

Digital Risk Minimization: Where Are We Now? What is the Future
Meredith Y. Smith, PhD, MPA
Director, Risk Management, Global Drug Safety, Research & Development, Alexion Pharmaceuticals, Inc.

What's new? Providing Labeling in Japan in the Digital Age
Masayuki Muraoka
Ministry of Health, Labour and Welfare (MHLW)

Panel Discussion
All Session Speakers

SLS15 Track 2 16:15-17:15

Digital Transformation of Medical Information in Japan from Development to Post-Marketing

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

SESSION CHAIR

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

Aggregating and organizing drug information that is collected after development and after marketing is essential for prompt and accurate provision of information to promote the proper use of drugs. Currently, drug information is available on the PMDA website, but from the perspective of promoting the effective use of AI/ICT for drug information, the package insert is being converted to XML, but available data is available. The major obstacle is that the data preparation to utilize the new technology is still inadequate, for example, many are only PDF.

In this session, we will discuss the use of ICT and AI to utilize the data that is the basis of drug information, discuss the solution to the issues and future prospects by sharing the current situation, and discuss the future digital transformation of drug information. I would like to start a concrete examination of what should be done to achieve

Research on Utilization of Common Technical Document(CTD)
Masahiko Nakatsui,PhD
Yamaguchi University

Structuring "Interview Form" Data for Utilizing of Drug Information Using RDF in LINC (Life Intelligence Consortium).
Rika Abe, RPh
Partnership-Promotion Coordinator, RIKEN Cluster for Science, Technology and Innovation Hub

Current Situation and Future Prospect of Medical Information Data Utilization at Pfizer Japan
Kayo Abe
Pfizer R&D Japan

Panel Discussion
All Session Speakers and
Kenichi Mikami, MS
Office Director, Office of Review Management, Pharmaceutical and Medical Device Agency (PMDA)

SLS16 Track 3 16:15-17:15

Paradigm Shift of Clinical Trial Site Cost: Challenges in Implementing Benchmark Cost

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

SESSION CHAIR

Tatsuya Murakami
Senior Director, Head of Clinical Operations, Pfizer R&D Japan

As global clinical trials have increased in number and scope throughout pharmaceutical development, the need for cost "optimization" and "transparency" in these trials has grown more visible as the concept of Fair Market Value (FMV) has emerged in Japan. In response, the document Toward Realization of Appropriate Clinical Trial Expenses in Japan issued by the JPMA Clinical Evaluation Committee TF4 in May 2019 recommended a benchmark cost based on FMV but this has proven difficult to implement. This session will overview and present examples of the measures that will introduce benchmark costs based on FMV.

Clinical Trial Cost Optimization In Light Of Transparency
Kenta Yamada, MS
Site Engagement / Manager, Clinical Development / Eli Lilly Japan K.K.

Experience of Introducing Benchmark Cost in Japan
Kimiyoshi Sato, MPharm
Japan Study Manager, Study & Site Operations Group 2, Pfizer R&D Japan

Case study of the benchmark cost-From the Standpoint of Medical Institution-
Masahiko Ozaki, MS
Head, Clinical Trial Administration Section, National Cancer Center Hospital East

Panel Discussion
All Session Speakers and
Yumiko Nomura
Director, Office of Clinical Trial Promotion, Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare (MHLW)
Satoshi Saeki, MSc
Senior director, Clinical Operation and Innovation Group, Astellas Pharma Inc.
Noriko Morishita, RN, MNS
Manager, Clinical Trial Promotion Office, National Hospital Organization Headquarter

SLS17 Track 4 16:15-17:15

Current Status of Drug Development and Current Challenges for Clinical Trials and Regulations in China

Related Interest Area(s): CR, RA, O:Clinical Strategy
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Yuko Kikuchi, MS, RPh
Senior Director, Asia Regulatory Affairs, Medicine Development Center, Eisai Co., Ltd.

Promoting clinical trials and obtaining therapeutic product marketing approval in China remains one of the most important basic strategies for prospering in Asia's expanding market. China is currently in the midst of rapid and dramatic changes to the regulatory environment related to clinical trials, adding potential difficulty of operation to the complexity of specific requirements for conducting clinical research in medical institutions and other competitive aspects of the environment in China. But aren't these common issues for everyone working on clinical

trials in China? This session will introduce recent dramatic changes in Chinese regulatory requirements and the unique challenges they present to conducting clinical trials based on experience in the field and the knowledge gained through these efforts. Panel discussion will focus on points to note when leading projects in China from Japan.

Update on Regulatory Environment in Clinical Development in China

Tetsuomi Takano, RPh
Senior Strategy Director, Strategy & Planning, Clinical Development Services, Covance Japan Co., Ltd.

Challenges and Proposals for China Clinical Trial Operation

Ying Jiang
VP, Head of Clinical Development Service, ClinChoice Inc.

Challenges and Proposals obtained from China Clinical Trials

Takamitsu Hirano
Trial Management, Global Trial Director, Novartis K.K.

Panel Discussion

All Session Speakers

Tuesday | November 10

LIVE SESSIONS

LS18 TRACK 1 9:00-10:30

Global Oncology Development – 2nd

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

SESSION CHAIR

Hironobu Saito, PhD
Corporate Officer Head of Medical Affairs Division, DaiichiSankyo Co., Ltd.

This session will continue conversations from last year's discussion of oncology development titled "Global Oncology Development – Aiming to be a game changer for oncology development." We have since seen an increase in innovative therapies such as regenerative medicine and in the active use of technology in oncology development. We have also seen the unprecedented experience of COVID-19, which has revealed new challenges in clinical development unique to oncology. In this session, we will discuss what we can do in oncology development to maximize the medical benefits of innovation. This is a pre-session for DIA Global Oncology Development 2021 scheduled for January 2021.

Challenge and Initiatives Identified under Covid-19; Understanding The Overall Picture from Data on Global Trend
Nobuyuki Hanamura, PhD, MBA
Senior Director, Project Leadership/Therapeutic Science & Strategy Unit, IQVIA Services Japan K.K.

Efforts to Conduct Clinical Trials Safely under The COVID-19
Tomohiro Nishina, MD, PhD
Director, Department of Cancer Genomic Medicine, National Hospital Organization Shikoku Cancer Center

How Can We Conduct Clinical Trials Safely while Looking into The Post-Corona Era?
Kazuhiko Mori, MSc
Director General, Japan Pharmaceutical Manufacturers Association (JPMA)

Panel Discussion
All Session Speakers and
Toshihiko Doi, MD, PhD
Deputy Director, Chief, Experimental Therapeutics, National Cancer Center Hospital East
Noboru Yamamoto, MD, PhD
Deputy Director, Chief, Experimental Therapeutics, National Cancer Center Hospital

LS19 TRACK 3 9:00-10:00

Let's Talk Digital Engagement with External Stakeholders in Medical Affairs

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

SESSION CHAIR

Makoto Miyazaki
Pharmacovigilance, MSD K.K

Recently, digital channel utilization between Health care professionals and pharmaceutical company has been increasing, furthermore, it's mandatory under COVID-19 pandemic.

The important thing is the value that Medical affairs Digital Engagement can represent toward medical care evolution.

In the session, we will talk about

1. Current situation and direction of MSL Digital Engagement

2. Agile development method in Medical affairs

3. Point of view about Digital Engagement from Tech side

4. Consideration and expectation for valuable scientific exchange using technology from Physician side

Finally, we will discuss prospects for innovative engagement with speakers

Trends for Post-marketing database study. -Concept of reliability assurance-
Tatsuya Matsuda
Inspector, Office of Non-clinical and Clinical Compliance Pharmaceuticals and Medical Devices Agency (PMDA)

Data Reliability and Quality for Post-Marketing Database Study: Pharmaceutical Company Perspectives
Hitoshi Hamano
Pharmacovigilance, Japan Pharmaceutical Manufacturers Association (JPMA)

MDV's Engagement to Quality Assurance
Masaki Nakamura
Director, Medical Data Vision Co., Ltd.

Panel Discussion
All Session Speakers and
Mitsune Yamaguchi, PhD
Inspector Director, Office of Non-clinical and Clinical Compliance Pharmaceuticals and Medical Devices Agency (PMDA)

BREAK 10:30-10:45

LS20 TRACK 1 10:45-12:15

Measures Against Antimicrobial Resistance (AMR): Toward New Phase

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

SESSION CHAIR

Masahito Nagashima, PhD
Head of Clinical Research, Pfizer R&D Japan

Drug resistance is one of the global issues. Once drug resistance/viral infection disease occurs, to secure therapeutic measures becomes an urgent task. In Japan, various initiatives have been undertaken based on the Antimicrobial Resistance (AMR) action plan (2016-2020). However, it is difficult to say that the current environment is sufficient for promoting the development of AMR infection drugs, and thus serious problems may occur due to the delay of measures against AMR infection. COVID-19 has occurred in 2020 and prophylaxis/therapeutic methods are being developed worldwide rapidly, but the pandemic is not converged yet. In this session, toward the next phase of AMR action plans, consider and discuss how to establish and strengthen the anti-infectious drug development promotion system by strengthen the cooperation among industry, government and academia in addition to the international collaboration, with taking the experiences of COVID-19 into account.

[Opening Remark] Importance of Measures Against AMR and Future Measures Against Infectious Disease; Based on the Experience of COVID-19 Pandemic
Shigeru Omi, MD, PhD
President, JAPAN Community Health care Organization

To Promote Research and Development of AMR Drugs through Industry, Government, Academia and International Collaboration; from Academia
Kazuhiro Tateda, MD, Phd
Professor, Department of Microbiology and Infectious Diseases, Toho University

Issues on Development of Drugs for AMR Infections
Mari Ariyasu
Head of Project Management 4 (Infectious Disease), Shionogi & Co., Ltd.

Panel Discussion
All Session Speakers and
Kazuhiko Mori, MSc
Director General, Japan Pharmaceutical Manufacturers Association (JPMA)
Keiji Hirai, PhD
Advisor, KYORIN Pharmaceutical CO., Ltd

LUNCH BREAK & LUCHEON SEMINAR
11:45-12:45

LS21 TRACK 1 12:45-14:15

Clinical Trial Innovation: Learning from Case Study and Accelerating Adaptation in Japan

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

SESSION CHAIR

Kazuhiko Kamiyama
Director, Project Leadership, IQVIA Services Japan K.K

Although there is increasing interest in virtual trials in Japan, various challenges and obstacles still exist when trying to actually implement virtual studies in Japan. Because the virtual approach is so new, there are still only a limited number of use cases, and study managers must consider many details for their own virtual studies while facing many unknowns. In this session, we will introduce a case study from the US and a pilot study from Japan to discuss the challenges and approaches of using virtual trials to increase innovation in individual organizations and the clinical research industry in Japan.

US Case Study as Decentralized Clinical Trial (DCT) and its Consideration for Japan
Kazuto Yamada
Otsuka Pharmaceutical Co., Ltd

Home Health Nurse-Supported Clinical Trials in Japan
Yosuke Hagiwara
Clinical Lead, Janssen Pharmaceutical K.K.

Challenges and Approaches to Implement Innovation
Mami Ujihara, MS
Vice President, IQVIA Services Japan K.K

Panel Discussion
All Session Speakers

BREAK 14:15-14:30

LS22 TRACK 1 14:30-16:00

Real Operations in Regenerative Medicine Product Clinical Trials

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

SESSION CHAIR

Akiko Tamamori
Clinical Study Management, Chugai Pharmaceutical Co., Ltd.

In recent years, as many new regenerative and other advanced therapies have been developed at an unprecedented speed, more and more people are facing challenges at the practical level of clinical trials, but there are not many forums that focus on problems that practical staff face. In this session, we will introduce the initiatives and issues faced by practical staff in conducting clinical trials of regenerative medical products, and solutions found through collaboration. Based on our experience in regenerative medical product clinical trials, our panel discussion will focus on how we should collaborate to tackle the challenges expected in clinical trials for new therapies in the future.

Learnings through Experiences of Developing Gene Therapy from Pfizer
Hiroshi Miyashita, MSc
Japan Clinical Project Manager, Pfizer R&D Japan G.K.

Learnings through Experiences of Developing Gene Therapy from Chugai
Kyoko Yamada, MSc
Clinical Study Management, Chugai Pharmaceutical Co., Ltd.

Regenerative Medicine Product Clinical Trial Monitoring
Yuji Nishimura
Clinical Development Department, CMIC Co., Ltd.

Implementation System for Clinical Trials of Regenerative Medicine at Hokkaido University Hospital
Yuki Sasaki
Clinical Research and Medical Innovation Center, Hokkaido University Hospital

Panel Discussion
All Session Speakers, and
Yoshiaki Maruyama, PhD
Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency (PMDA)

DIAmond SESSIONS

LS23 DIAmond Session 2 TRACK 2 14:30-16:00

PMDA Town Hall

Related Interest Area(s): ALL
Level: Intermediate

SESSION CHAIRS

Yuji Kumagai, MD, PhD
Director of Clinical Trial Center, Kitasato University Hospital

Hironobu Saito, PhD
Corporate Officer, Head of Medical Affairs Division, Daiichi Sankyo., Ltd.

This session is provided for you to discuss your interests with members of the Pharmaceuticals and Medical Devices Agency (PMDA). Your active participation is welcome to make this session most meaningful.

Panelists
Kensuke Ishi
Director, Office of Medical Devices 1
Pharmaceuticals and Medical Devices Agency (PMDA)

Koshin Kiyohara, MSc, MPharm
Director, Office of New Drug 5
Pharmaceuticals and Medical Devices Agency (PMDA)

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

Daisaku Sato, PhD, RPh, MPharm
Chief Management Officer & Associate Centre Director for Regulatory Science
Pharmaceuticals and Medical Devices Agency (PMDA)

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

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

Masanobu Yamada, MS
Associate Center Director
Pharmaceuticals and Medical Devices Agency (PMDA)

LS24 TRACK 4 14:30-16:00

Utilization of "Pharmaceuticals for Specific Use" for Pediatric Drug Development.

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

SESSION CHAIR

Kayoko Kikuchi, PhD
Chief, Division of Management and Strategy, National Center For Child Health and Development

Currently, pediatricians are forced to use drugs whose dosages and/or indications are not officially approved for pediatric patients. 2019 revision of the Pharmaceuticals and Medical Devices Law (PMDL) included the introduction of the new category "pharmaceuticals for specific use" (PSUs). PSUs are drugs for specific indications that can be administered to combat unmet medical needs (especially for pediatrics) and antimicrobial resistance. Products designated as a PSU can benefit from specific measures to promote their development, review, and approval, including priority face-to-face consultation services and priority reviews. In this session, we focus on this 2019 revision of the PMDL law, the impact of the PSU designation, possible challenges and obstacles, and the international and domestic environment for pediatric drug development. Stakeholders from industries, regulatory agencies, and academia will discuss how we can best utilize the PSUs and promote pediatric drug development in Japan.

Review of Pharmaceutical Products for Children
Atsushi Noguchi
Office of New Drug V・Principal Reviewer,
Pharmaceuticals and Medical Devices Agency (PMDA)

Introduction of Lilly Japan's Approach to Pediatric Drug Development
Keiji Wada, PhD, MBA
Japan Regulatory Affairs / Regulatory Scientist, Eli Lilly Japan K.K.

The Activity of the Japan Pediatric Society Drug Development Network (JPedNet) and Promotion of Pediatric Drug Development
Kazumoto Iijima, MD, PhD
Professor and Chairman, Department of Pediatrics, Kobe University Graduate School of Medicine

Panel Discussion
All Session Speakers and
Hidefumi Nakamura, MD, PhD
Director for Clinical R&D, Clinical Research Center, National Center For Child Health and Development

BREAK 16:00-16:15

SEMI-LIVE SESSION 27,28,29 16:15-17:15

LS25 TRACK 1 17:15-17:30

CLOSING REMARKS

Keiichi Inaizumi, MSc
Pfizar R&D Japan

SLS18 TRACK 2 9:00-10:00

Challenge for Promotion of New Style Global Study at KOBE

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

SESSION CHAIR

Takeyuki Sato
Advisor, Foundation for Biomedical Research and Innovation at Kobe

Clinical trials attempting to use new methods such as information and communications technology (ICT) and decentralized clinical trials (DCT) to streamline clinical trial processes and quantitative case study data collection are now being conducted worldwide. Japan is now taking corresponding innovative measures. Since 2019, the Kobe Biomedical Innovation Cluster (KBIC) in Kobe has been working on ways to reduce the speed and cost of effective case data collection, which have been recurring issues in conventional clinical trials in Japan, and to reduce the burden on patients who participate in these trials. KBIC has also been promoting DCT and discussing challenges to incorporate the new method through collaborative ties between and among the business, academic, government, and healthcare sectors in Japan. This session will introduce and explain specific measures taken by KBIC to promote advancements in clinical trials in Japan.

New challenges from the Recent Us Decentralized Clinical Trial, and Current Situation in Japan - Future Outlook from Recent Experience
Michiyo Ohshima, MBA
Senior Director, Head of Portfolio & Project Management, Pfizer R&D Japan

Does Decentralization Become the Key to a Solution for Problems of Clinical Trials in Children's Hospital? : Current State and Future Perspectives.
Daiichiro Hasegawa, MD, PhD
Head, Department of Hematology and Oncology; Clinical Research Support Office, Hyogo Prefectural Kobe Children's Hospital

Feasibility of Decentralized Clinical Trial through Our Experience of COVID-19 Crisis. ~from the Standpoint of an Investigational Site~
Toshihiko Odai
Pharmacist, Center for clinical research and innovation; Department of pharmacy, Kobe City Medical Center General Hospital

Panel Discussion
All Session Speakers

SLS19 TRACK 4 9:00-10:00

Innovative Engagement: Talk with External Expert in Medical Affairs Activity

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

SESSION CHAIR

Taro Goto, MD, PhD
Head of Medical, Bristol Myers Squibb

Use of digital channels for meetings between external experts and internal Medical Affairs teams had already been increasing; the COVID-19 pandemic has made digital meetings mandatory for the foreseeable future. What value can this new digital engagement model contribute to the evolution of value in medical care? In this session, we will discuss the current use and future directions of such digital engagement, challenges and success factors in utilizing this technology, end-to-end digital engagement throughout the product lifecycle, expectations and considerations of scientific information exchange between Medical Affairs teams and external experts, and other prospects for innovative digital engagement.

Digital Engagement with External Experts in MA/MSL Activity:Learning from COVID-19

Tadashi Urashima、PhD
Manager, Medical Division, MSL Specialty Care dept, MSL Specialty Care 2, GlaxoSmithKline K.K.

Challenge to Sleep Hygiene Problems with MSD Agile Culture
Masakazu Okada, PhD
MSL manager, Primary Care, Medical Affairs, MSD K.K.

Is it Technology or UX That You Needfor Digital Engagement?
Hideki Ninomiya, MD
CEO, Datack Inc.

What is the Valuable "Digital Science Discussion"?
Hisashi Wada, MD, PhD
Department of Clinical Research in Tumor Immunology, Osaka University Graduate School of Medicine

Panel Discussion
All Session Speakers

SLS20 Track 2 10:45-11:45

Opportunity for International Harmonization for Implementing Early Access to Pharmaceuticals

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

SESSION CHAIRS

Masafumi Yokota, PhD, DVM
Senior Director, R&D Strategy & Coordination Group, R&D Planning & Management Department, R&D Division, Daiichi Sankyo Co., Ltd.

Rie Matsui, RPh
Senior Director, Regional Labeling Head for APAC, Pfizer R&D Japan

The number of new pharmaceuticals approved for the market continues to increase thanks in part to faster review and approval, including early approval systems that utilize limited pre-market (clinical) data. Because early approvals are based on limited data, the collection and evaluation of post-market safety information is more important than ever. This post-market safety information is key to future product use among healthcare professionals and patients and will also help improve medication adherence in patients and proper use of medicines. This session will discuss the current and future utilization of real world data / real world evidence (RWD/RWE) in Japan and other regions based on the current status of the Pharmacoepidemiology Discussion Group (DG) and applicability of RWD sorted out by ICH region. We will also discuss risk communication for patients, including one new risk minimization measure newly introduced to ICH, the concept of patient labeling, and global trends in regulatory guidance, to search for and identify opportunities for international harmonization of implementing earlier access to medicines.

Current status of Pharmacoepidemiology Discussion Group (DG) at ICH
Haruka Shida, MPh
Pharmaceuticals and Medical Devices Agency (PMDA)

Postmarket Safety Label Changes – Relationship to Development Pathways
Gerald Dal Pan, MD, MHS
Director, Office of Surveillance & Epidemiology, Food and Drug Administration (FDA)

Global Trends in Patient Risk Communication: Patient Labeling
Rie Matsui, RPh
Senior Director, Regional Labeling Head for APAC, Pfizer R&D Japan

Panel Discussion
All Session Speakers and
William Gregory, PhD
Senior Director, WSR-Safety, EP & Generics Reg, Pfizer Inc
Makoto Miyazaki
MSD K.K.

SLS21 Track 3 10:45-11:45

"Where, What, and How" of Clinical Trial Information Required by Patients: Disclosure of Investigator Site Name and Clinical Trial Results

Related Interest Area(s): CR, AC, O:Patient
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR

Miyoko Yamauchi
Clinical Research Dept.1, Manager, Chugai Clinical Research Center CO., LTD

Disclosure of clinical trial and study information is now required in Japan in accordance with PSEHB/PED Notification No.0326-(3) issued in March 2018, and some sponsors are aggressively addressing this in line with the increasing need for patient-centric drug development. In this session, we will discuss appropriate disclosure of clinical trials focused on (1) disclosing the names of the trial sites and (2) disclosing clinical trial results. We will also introduce sponsors' activities and relate their findings to how we can disseminate action throughout industry while tackling the issue of what information the patients need. This session will also include a panel discussion based on the opinions expressed by patients in Session 1073.

Current Status and Problem for Disclosure of Investigator Site Name
Ryuji Hattori, MPharm
Clinical Operation, Monitoring Group Lead, Pfizer R&D Japan

Current Status and Problem of Study Result Disclosure
Kazuyuki Suzuki, MSc
Group manager, Oncology Study Management, Novartis Pharma K.K.

Panel Discussion
All Session Speakers and
Noriko Morishita, MNS
Manager, Clinical Trial Promotion Office, National Hospital Organization Headquarter
Kyoko Yoshioka
Research and Development Division, Health Policy Bureau Ministry of Health, Labor and Welfare (MHLW)

SLS22 Track 4 10:45-11:45

Patient-Centric Approach to Clinical Research: Challenges to Improving Efficiency and Quality

Related Interest Area(s): DM, CO, Patient
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Tempei Miyaji, MSc
Graduate School of Medicine, Department of Clinical Trial Data Management, Project t Assistant Professor, The University of Tokyo

The importance of increasing patient engagement in drug development, and incorporating patient feedback into the development process, is increasingly evident. For example, patient involvement can result in plans for clinical trials and studies that are easier for patients to access. At the same time, expectations for virtual trials that will improve access to clinical trials continues to rise, and an increasing number of clinical trials using digital devices and eSources in Japan are expected to reduce the burden of clinical research on patients. This session will present case studies illustrating the benefits and challenges of patient-centered clinical trials and virtual trials.

Conducting Clinical Trials Based on Patient Insights: Protocol Improvement through Collaboration with Patients

Atsushi Kitamura, MS
Clinical Study Innovation Lead/Patient Centricity Lead, Pfizer R&D Japan

Practical Situations of the Clinical Trial Using Digital Scales and Devices

Takuro Mizukami, MD, PhD
Department of Clinical Oncology, St. Marianna University School of Medicine

Challenges to Patient Centricity for Clinical Trials by eSource Method

Junhei Matsuzawa, MSc, MBA
Chief, Development Department2, The Research Foundation for Microbial Diseases of Osaka University

Panel Discussion

All Session Speakers

SLS23 TRACK 2 12:45-13:45

How to Promote Use of Centralized IRB in Clinical Trials

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

SESSION CHAIR

Akihiro Inano, PhD
Clinical Research Center, Fukushima Medical University Hospital

The quality and efficiency of examinations in clinical research are being advanced by consolidating IRBs in accordance with the Clinical Research Act enacted in April 2018. At the same time, collective examination by Centralized IRBs (CRB) has been promoted to improve efficiency and speed in clinical trials as an outcome of the FY2017 Central Clinical Trial Review Board Infrastructure Development Project. However, utilization of CRB is not progressing as expected. With the recent increase in clinical trials targeting rare diseases, the quality of examination and IRB expertise, as well as improving the speed and efficiency of clinical trials, are very important issues. In this session, we will discuss what we can do for promoting the use of CRB in clinical trials.

Utilization of Centralized IRB in University Hospital

Tadao Takano, MD, PhD
Clinical Research, Innovation, and Education Center, Tohoku University Hospital

Promoting the Centralized Institutional Review Board (CIRB) R&D Head Club Recommendations from the "Clinical Trial Environment Improvement Task Force"

Takeshi Yamazaki
Clinical Trial Environment Task Force, R&D Head Club

Improving the Productivity of Clinical Trials with Central IRBs – the US Experience

David Borasky, MPh, CIP
Vice President, IRB Compliance, WIRB-Copernicus Group (WCG)

Panel Discussion

All Session Speakers and
YumikoNomura
Director, Office of Clinical Trial Promotion, Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare (MHLW)
Toshiya Hara
Executive Vice President, I'rom Co., Ltd

SLS24 TRACK 3 12:45-13:45

"Rule of Rules" for Development Tool Qualification

Related Interest Area(s): RA, O:Regulatory Policy
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Shingo Kano, PhD

Professor, Bio-Innovation Policy Unit, Department of Computational Biology and Medical Sciences, The University of Tokyo, Graduate School of Frontier Science

As Qualification Programs are progressing in the fields of drugs and medical devices in the US, including the launch of "roles of rules for using medical evaluation technology," this session will describe how to develop guidances for development tools and test methods for product evaluation – development tools such as biomarkers, animal models, and clinical outcome assessments, in particular. Japan, on the other hand, does not have a rule-of-rule type rule or qualified certification system for development tools. This session will also present the conditions for establishing these policy systems, for making them available (including consensus building on the evaluation method), and rapid authorization of a new evaluation method for regulatory use.

Rule of Rules in Policy Making in The Medical Field and Its Applications
Shingo Kano, PhD
Professor, Bio-Innovation Policy Unit, Department of Computational Biology and Medical Sciences, The University of Tokyo, Graduate School of Frontier Science

Policy System for Medical Product Development Tool Qualification in Japan
Taku Oohara
Deputy Director, Head of Regenerative Medicine Product Evaluation Office, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW

Inside-Out Approach for Rule Making From Japan
Yuko Sekino, PhD
Project Professor, The University of Tokyo, Graduate School of Pharmaceutical Sciences

System of Rule for Rule-Making - Suggestion from ISO System
Hiroki Nakae, PhD
Director-General, Japan Multiplex bio-Analysis Consortium

Panel Discussion
All Session Speakers and
Tomiko Tawaragi
Chief Director, RAD-AR Council, JAPAN

SLS26 TRACK 3 14:30-15:30

Operational Innovation in Medical Affairs for Improved Patient Outcomes

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

SESSION CHAIR

Shinichi Nishiuma, MD

Executive Director, Head of Medical Affairs, Bristol-Myers Squibb K.K.

As presented at the 2019 DIA Annual Meeting and JAPhMed Annual Meeting: "Resolving unmet medical needs through evidence generation" has become one of the tasks of Medical Affairs (MA). It has also been said that one of the missions of MA is to build evidence and deliver the information to healthcare professionals for optimal medical care to all patients (Japan Pharmaceutical Manufacturers Association, 2019). This session will present examples of the types of technical and other innovative thinking required to develop and deliver this evidence, in collaboration with internal and external stakeholders and in line with these MA roles and responsibilities, and also the challenges and skill sets necessary for meeting these expectations.

PhRMA-J RWD/RWE White Paper
Katsutoshi Hiramatsu
Evidence Generation Lead, Director, Amgen K.K.

Current status and issues of MA(Tentative)
Shinzo Hiroi, PhD, RPh, MPh, PMP
Head of Global Medical Affairs, Shionogi & Co., Ltd.

Challenges in Evidence Generation
Shuji Uno
Medical, Bristol-Myers Squibb K.K.TBD

Panel Discussion
All Session Speakers

DIAmond SESSIONS

SLS27 DIAmond Session 3 TRACK 1 16:15-17:15

Beyond Innovation – What is Future Healthcare?

Related Interest Area(s):O:Health Care
Level: Advanced
Language: Japanese Language Only

SESSION CHAIR

Kazuhiro Kanmuri, PhD
Vice President, Clinical Development, Ascent Development Services Inc.

Takashi Moriya, PhD, MBA

Director, R&D Division, Data Sciences Department, Janssen Pharmaceutical K.K.

As the 4th Industrial Revolution continues to progress, new technologies and ideas (such as telemedicine, artificial intelligence, sensor technology, image analysis technology, etc.) are creating values and changes in our healthcare systems through "innovation." This session will feature one lecture with two different directional perspectives, and a future-looking panel discussion that will introduce the activities of two major companies tackling the fundamental questions: What lies beyond "innovation?" And, what does the future of healthcare look like?

Featured speakers represent a leading camera manufacturer that has entered the medical / nursing care fields with the goal of building a better long-term care system, and better life for patients in it; and a global healthcare company striving to move beyond existing pharmaceutical, medical device and consumer healthcare businesses to develop "holistic" healthcare.

What is a Care Support System Fused by Advanced Technologies? What is a Safe and Secure Life Through Nursing Care? (Tentative)
Yuji Ichimura
Senior Executive Officer, Responsible for Digital Transformation and Public Relations, KONICA MINOLTA

What Lies Beyond "Innovation"? Smart Healthy Aging Society and Holistic Care (Tentative)
Reiko Akizuki, MD
Director, Medical Affairs Division, Oncology Department , Janssen Pharmaceutical K.K.

Panel Discussion
All Session Speakers

SLS28 TRACK 2 16:15-17:15

Recent Advances in Pharmacovigilance: Machine Learning and Statistical Pattern Discovery Case Studies from Around the World

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

SESSION CHAIR

Rika Wakao, PhD

Director, Office of Research Promotion, Pharmaceuticals and Medical Devices Agency (PMDA)

The emerging discipline of data science, which blends statistical and computational methods and embraces novel technologies such as machine learning and statistical pattern discovery, continues to grow in impact in clinical research and drug development. Pharmacovigilance is the related science supporting the detection, assessment, understanding, and prevention of adverse drug effects or other possible drug-related problems. This session will focus on research in machine learning and statistical pattern discovery to achieve better patient outcomes in pharmacovigilance. International regulatory authorities and industry organizations will share their insights and experiences (and the regulatory implications thereof) based on what machine learning and statistical pattern discovery may achieve as well as barriers and success factors for their effective use. The importance of effective and appropriate governance and quality assurance will also be emphasized.

TBD

Sameen Desai

Sr. Director, PV Innovation, Bristol Meyers Squibb

Sandeepa Raina

Director, Safety Info Mgmt, Analytics & Process Excellence, Bristol Meyers Squibb

Prospects for Artificial Intelligence in Pharmacovigilance

Niklas Norén, PhD

Chief Science Officer, Uppsala Monitoring Centre, Sweden

AI and MHRA Current Thinking

Phil Tregunno

Group Manager, Vigilance, Intelligence and Research, Medicines and Healthcare products Regulatory Agency (MHRA)

Panel Discussion

All Session Speakers and

Shinichi Matsuda, PhD

Safety Data Science, Real World Data Science Department, Group Manager, Chugai Pharmaceutical Co., Ltd.

SLS29 TRACK 4 16:15-17:15

Improving the Clinical Trial Processes of A Sponsor By Utilizing the Voice of Clinical Study Sites

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

SESSION CHAIR

Atsushi Kitamura, MS

Clinical Study Innovation Lead, Pfizer R&D Japan

Global clinical trial protocols are generally prepared from a global perspective. However, there have been recent instances when Japan healthcare professionals have pointed out that some study protocols do not adequately consider the environment and processes in a medical setting in Japan, leading to implementation issues. Indeed, there are few cases of systematic collection of study site insights (site voices) in recent global clinical trials. Pfizer has been gathering voices directly from clinical sites in medical institutions in the US, Europe, Japan, and China, to improve their clinical site processes. In this session, a Pfizer representative, an investigator, and a clinical research coordinator will exchange issues and proposals for clinical trial process improvement, with the aim of improving clinical trials in the future.

Challenges and Improvements of the Clinical Trial Process - from the Perspective of the Sponsor –

Michinori Terada, PhD

Head of Clinical Sciences, Clinical Research, Pfizer R&D Japan

Challenges and Improvements of the Clinical Trial Process - from the Perspective of the Principal Investigator –

Kenichi Ishizawa, MD

Professor, Department of Third Internal Medicine, Yamagata University Faculty of Medicine

Challenges and suggestions of the clinical trial process

Yukie Kimura

Chief of Clinical Research Coordinating Section, Clinical Research Coordinator/ Clinical Research Coordinating Section, National Cancer Center Hospital East

Panel Discussion

All Session Speakers

On-Demand Sessions

ORIENTATION VIDEO

Featured on the DIA Japan Annual Meeting Website Homepage

SESSION CHAIRS
Production Team: DIA Japan Operations Team

Mitsuo Ishikaswa
Sales. Derector, Oishi Kenko Inc.

Yuina Tajima
Reviewer, Office of New Drug I
Pharmaceuticals and Medical Devices Agency (PMDA)

This video provides a handy introduction to the Japan Annual Meeting website to help you navigate your way around the platform. It will lead you through your journey from logging on and updating your profile, to accessing sessions and networking with fellow attendees. We recommend watching the video in advance and familiarizing yourself with the platform's many fantastic functions.

Contents:
- Lecture format
- Program Highlights
- Evaluation

OS01 Special Session 1

Overcoming Drug-Induced Suffering

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

SESSION CHAIR
Kazuhiko Ishida, MS, RPh
Director・Pharmacovigilance, Astellas Pharma Inc.

As medicinal products are an essential for public health service, it is important for them to provide their benefits to patients/consumers with minimized risk. This session will discuss the mission and role of medical industry professionals to prevent drug-induced sufferings, based on personal experience as a thalidomide victim. Cases of drug-induced suffering in Japan (including thalidomide) and lessons learned from these cases will be outlined and reviewed, followed by examples of pharmacoepidemiological studies which can contribute to greater value in and better understanding of drug safety. We will also consider the ethics of what medical industry professionals should consider, and how, in drug-induced suffering.

Preventing Drug-Induced Suffering and The Mission & Role of Medical Industry Professionals

Tsugumichi Sato, PhD
Junior Associate Professor, Department of Pharmacy, Faculty of Pharmaceutical Sciences, Tokyo University of Science

OS02 Special Session 2

The Importance of R&D of and Access to Affordable Essential Medicines and Vaccines, for Achieving the Universal Health Coverage and SDGs

Related Interest Area(s): RA, CP, MA, O:MI
Level: Beginner/Intermediate

SESSION CHAIR
Keiichi Inaizumi, MSc
Pfizar R&D Japan

The SDGs (Sustainable Development Goals) adopted by all United Nations Member States in 2015, are 17 Goals to be achieved by 2030, which are an urgent call for action by all countries - developed and developing - in a global partnership.

Acknowledging the impact of TB, malaria and Neglected Tropical Diseases (NTDs) on human development, SDGs have set several health-related targets, including the targets under SDG3 to end the epidemics of these diseases and achieve UHC by 2030.

SDG3 further highlights the importance of research and development on new medicines and vaccines for diseases primarily affecting developing countries, and the concurrent need to enable affordable access to these health technologies. Since health and development challenges are interconnected, effectively tackling these diseases will also contribute towards achieving not only other SDG 3 targets, but also SDGs related to poverty and inequality.

In this special session, Dr. Mandeep Dhaliwal will give remarks on SDGs and the role of UHC, in particular, the importance of target 3b (R&D of and access to affordable essential medicines and vaccines on diseases mainly affecting developing countries), in the era of COVID-19 pandemic. In addition, Mr. Uji will introduce how the promotion equitable and sustainable access to new health technologies will contribute towards achieving UHC. Furthermore, Ms. Sakaue will present good practices of strengthening the value-chain of health technology innovation, access & delivery. This includes a Japan-funded UNDP-led initiative, the Access and Delivery Partnership (ADP), which supports countries to strengthen the policies, human capacities, systems, regulations, and innovations (such as digital health, regional regulatory harmonization), needed to ensure that medicines, vaccines and diagnostics ultimately reach the people who need them.

To achieve SGDs, we must accelerate the discovery and development of medicines, diagnostics and vaccines (referred to as health technologies) for TB, malaria, NTDs and other diseases, as well as the promotion of access to and delivery of health technologies. This special session will provide the guidance on how the experts on R&D, access and delivery can work together, to address the unmet health needs, towards achieving SDG Goal3 and UHC.

SDGs and the Role of UHC,R&D and Access to Affordable Essential Medicines and Vaccines

Mandeep Dhaliwal, MD
Director, HIV, Health and Development Group, United Nations Development Programme (UNDP)

Access and Delivery Partnership /UHC

Kazuyuki Uji
Policy Specialist at the HIV, Health and Development Group of the United Nations Development Programme (UNDP)

Access and Delivery of Essential Medicines and Health Technologies -Towards the Achievement of SDGs and Universal Health Coverage

Akiko Sakaue
Programme Specialist, Global Health, HIV, Health and Development Group, United Nations Development Programme (UNDP)

OS03

Utilization of Real-World Data: Current Situation, Research Use and Future Direction

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

SESSION CHAIR
Hironobu Tokumasu, MD, MPh
Director, Real World Data Co.

The foundation for the modern clinical research enterprise draws from many factors, including the revision of GPSP and the progress of artificial intelligence (AI) and other digital technology in introducing more efficient research utilizing clinical databases, clinical study data, post-marketing survey (PMS) data, registry data, etc. However, there are few cases of PMS and clinical studies utilizing databases to date. In this session, we will share the current state of using "real world data" databases to improve the quality of efficacy and safety evaluation in clinical research of pharmaceuticals in Japan and overseas, and for improving the quality of medical care in Japan.

Present and Future of Real World Data

Masakatsu Hattori, MD, PhD
Sales and Business Solutions, Real World Data Co.

Utilization of Real-World Data: Current Situation, Research Use and Future Direction

Masato Takeuchi, MD PhD

Associate Professor, Kyoto University Department of Pharmacoepidemiology

Optimal Usage of Real World Data: Experience of Outcome Validation Research

Takashi Fujiwara, MD, PhD
Department of Clinical Research , Kurashiki Central Hospital

The First Step of Utilizing Real World Data for New Drug Application

Yoshiharu Horie, PhD
the Head of Data Science at AstraZeneca Japan

Panel Discussion

All Session Speakers

OS04

Aiming for Further Acceleration of Gene Therapy Product Development

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

SESSION CHAIR

Sumimasa Nagai, MD, PhD
Senior Assistant Professor, TR center, The University of Tokyo Hospital

The first gene therapy product with a virus vector (Zolgensma) was approved in 2020. Some gene therapy products such as virus vector gene therapy also require pharmaceutical companies, hospitals, health authorities, and other stakeholders to prepare to manage Cartagena Type 1 and Type 2 products. This session shares actual experiences with and challenges of gene therapy product development from several perspectives, including from a pharmaceutical company which has prepared, submitted, and had interaction with regulatory and health authorities during their BLA review, and a hospital's experience with handling gene therapy products, all for the purpose of helping gene therapy development proceed more quickly in Japan.

Development of Gene Therapy Products from Submission to Approval

Shunsuke Tominaga
Head, RA Medical Devices and Regulatory Innovation Japan, Novartis Pharma K.K.

Multidisciplinary Oncolytic Virotherapy for Human Cancer

Toshiyoshi Fujiwara, MD
Professor, Department of Gastroenterological Surgery, Okayama University

Aiming for Further Acceleration of Gene Therapy Product Development from Regulatory View

Atsushi Nishikawa
Reviewer, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers

OS05

Beyond the Artificial Intelligence (AI) Revolution: What Does the Future Hold for the Healthcare and Pharmaceutical Industries?

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

SESSION CHAIR

Yasuyuki Kobayashi, MD, PhD
Advanced Biomedical Imaging Informatics, Professor, St. Marianna University School of Medicine

In recent times, the healthcare industry is facing the unprecedented challenge of epidemic burnout among healthcare providers. Adding to the challenge is the necessity to ensure safe and high-quality care by preventing human error. Meanwhile, the pharmaceutical industry is grappling with skyrocketing R&D costs and dauntingly longer development times.

How can these two industries overcome these challenges? Various Industries are beginning to embrace Artificial Intelligence (AI) and are implementing innovative data-driven solutions. In this session, we will introduce you to solutions such as AI supported "monshin" (monshin; Japanese for medical interview) and medical image diagnosis as examples of AI solutions which are expected to reduce the burden on healthcare providers. These applications are also expected to provide meaningful insights to the pharmaceutical industry via data analytics. In addition, the official discusionson AI in healthcare, set forth by the Ministry of Health, Labor and Welfare will be covered as well. We hope this session will entice you to begin adopting AI in healthcare.

Future of Clinical Development and Drug Development Utilizing AI Interview

Yoshinori Abe, MD
Co-founder, Ubie, Inc.

Possibility of Early Disease Detection, Prognosis, and Predicting Side Effect by Medical Image Diagnosis Support Technology Utilizing AI

Nozomi Takino
Director, Business Development, LPIXEL Inc.

Current Status and Expectations of AI Technology in the Healthcare Field

Akimasa Takeuchi, PhD
Deputy Director, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau Ministry of Health, Labour and Welfare (MHLW)

OS06

The Challenge for Drug Development Incorporating the Perspective of the Patient: Lessons Learned from the "System of Patient Engagement in Regulatory Review" by the Us Food and Drug Administration/European Medicines Agency.

Related Interest Area(s): ALL
Level: Beginner

SESSION CHAIR

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

Nanae Tanemura, PhD
Department of Food Function and Labeling・Head of section, National Institutes of Biomedical Innovation, Health and Nutrition

In 2018, "patient engagement / public involvement in clinical research" was defined for the first time in Japan by the Japanese Agency for Medical Research and Development as "incorporation of patients' insights in every process of clinical research." This engagement/involvement applies not only to clinical research but also to the regulatory review process, which had already been under consideration by some regulatory agencies and has been institutionalized in one US FDA regulatory review process since 2001. This session will address the challenge of patient/public engagement in the regulatory review of drug development in Japan, and will help industry members, patients/public, and researchers in Japan promote patient engagement in all aspects of drug development.

Patient-Public Involvement in Japan

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

New Drug Development and Medical Services as Seen from Our Organization

Kyoko Asai, PhD, DVM
Representative Director & CEO, Hypersomnia & Long Sleeper Support

Organization in Japan

Towards the Utilization of PRO Patient-Reported Outcome in Rare and Intractable Diseases
Yukiko Nishimura, MS
President, NPO ASrid

Patient Engagement in the EU – the Experience from EMA
Juan Garcia-Burgos, MD
Head of Public and Stakeholders Engagement Department, EMA

Challenges to Incorporating Patient Perspectives in Drug DevelopmentFDA Perspective
Theresa Mullin, PhD
Associate Director for Strategic Programs, OCD, CDER, Food and Drug Administration (FDA)

OS07 9:00-10:30

Hot Topics in Using RWD in Drug Development

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

SESSION CHAIR

Hideharu Yamamoto, PhD
Deputy Department Manager, Biometrics Dept., Chugai Pharmaceutical Co., Ltd

Expectations for using patient registry data, electronic medical record data, and other real world data (RWD) in drug development continue to grow all over the world. At the same time, data reliability and relevance and appropriate statistical analyses approaches are well-known challenges in RWD utilization. Addressing these decisions with the proper rigor is critical to transform RWD into evidence suitable for making regulatory and other healthcare decisions. This session will introduce the latest efforts in Japan and the US to deal with these challenges.

Issues for Utilization of Patient Registry: AMED Research Project
Taro Shibata
Chief, Biostatistics Division, Center for Research Administration and Support, National Cancer Center

How De-identification and Privacy Preserving Record Linkage Unlock the Value of Real-World Data
Jason LaBonte, PhD
Chief Strategy Officer, Datavant

Use of Flatiron Health Real-World Data for Drug Development
Shintaro Nakagawa
Biometrics Department, Chugai Pharmaceutical Co., Ltd.

RWE in Regulatory Submissions of Single Arm Trials in Lymphoma
Nigel Yateman, PhD
Director, Biostatistics, Novartis AG

OS08

What's Really Needed to Transform Information Flow in Clinical Development

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

SESSION CHAIR

Stacy Tegan
Senior Program Manager, Info Sharing and Harmonization, TransCelerate Biopharma Inc.

CDISC and HL7 were introduced some time ago, drawing their future view of end-to-end digital data flow in combination with clinical document contents. While we have various data standards and buzzwords such as automation, artificial intelligence (AI), and digitization, our actual roadmap to this future view remains unclear and the path ahead is not straightforward. This session will present TransCelerate initiatives and collaborating consortiums as examples of driving and transforming the clinical research information flow from multiple angles: from point solutions to platforms that make data available to other systems; from documents to content as data, to advance narrative- and prose-based documents into structured content that can be automated and reused; and from transcription to interoperability through standards that enable connections between clinical and healthcare data. Global TransCelerate updates, and TransCelerate updates from Japan, will also be shared

TransCelerate update from Japan
Toshiharu Sano, RPh
Executive Director, Head of Clinical Operations, MSD K.K. (TransCelerate)

TransCelerate's Digital Data Flow Initiative: Digitized Protocols and a Common Data Model to Enable Automation
Todd Georgieff, RPh, MBA
Global Consortia Program Lead, Roche (DDF Workstream in TransCelerate)

TransCelerate's CC&R Initiative: Flow of Content through Document
Madhavi Gidh-Jain, PhD
Medical Writing Head, Clinical Documentation, Sanofi (CC&R Workstream in TransCelerate)

From Transcription to Interoperability: eSource and Data Standards
Amy Cramer, MMCI, RN, CPHQ
Global Product Development Strategic Partnerships, Pfizer Inc. (Vulcan, HL7 Accelerator Consortium)

OS09

Applying Quality Management Principles from Engineering to Clinical Trials

Related Interest Area(s): DM, CO, ST, PM
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Yumiko Asami
Senior Manager, Biostatistics, CSL Behring

Implementation of ICH E6(R2) requires drastic changes in clinical trial quality management (QM). The engineering field has introduced such quality management methods as "(new) seven tools for QC," "statistical quality control," and "Total Quality Management." Several quality management methods have been established in the field of medical safety through collaborations between the engineering and medical fields which have been active for several decades. At the February 2020 DIA Japan CDM Workshop, discussions based on practical examples of issue management quickly led to two realizations: (1) the basic principle of quality management is important and (2) quality management tools in engineering and medical safety can also be applied to clinical trials. In this session, we will discuss how to apply QM from engineering and medical safety to clinical trials, with a special focus on statistical contributions.

The Fundamentals of Quality Management
Masahiko Munechika, PhD
Prof. Dept. of Industrial & Management Systems Eng, Waseda University

Engineering for Quality Management in Clinical Trial
Masataka Sano, PhD
Associate professor, Department of Management Information Science, Chiba Institute of Technology

Implementation of Clinical Quality Management System in Sponsor - Successes and Challenges -
Tatsushi Tsuda
Development Planning & Management, Drug Development Division, Sumitomo Dainippon Pharma Co.,Ltd.

Panel Discussion
All Session Speakers

OS10

What Should We Consider for Using Wearable Sensor in Clinical Research?

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

SESSION CHAIR

Hayato Kondo
President, Acti Japan Co., Ltd.

The impact of the wearable sensors market boom is expected to increase in healthcare settings through their use in daily self-health checks, medical care practice, and clinical research. But to truly maximize the potential of wearable sensors, we should first understand exactly what they are, how to use them, and what kind of regulations we should follow in clinical research and development. This session will present activity monitoring as an example of the basic use of wearable sensors, and will also introduce and discuss considerations for using sensors in basic and clinical research in the global setting, as well as the global regulatory environment.

Wearable Device Basics and Technology; Vendor's Challenges for Adoption in Clinical Trials
RJ Kasper, MD, PhD
Senior Named Accounts Manager, ActiGraph

Academia Perspective: Basic Research Perspectives & Use Case
Shigeru Inoue, MD, PhD
Professor and Chair, Department of Preventive Medicine and Public Health

Advancing Clinical Trials in the Digital Era: Industry Learning: Incorporating Digital Endpoints and Wearable Technologies
Hao Zhang, PhD
Senior Manager, Biomedical Engineering, Pfizer Inc.

Key Considerations for Wearables and Sensors for Clinical Development
Aman Thukral
Director, Clinical Systems and Digital Operations, Abbvie (eSource Workstream in TransCelerate)

Panel Discussion
All Session Speakers

OS12

Changes Accelerated by Innovation: Clinical Operation & Data Management

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

SESSION CHAIR

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

Several new data sources have become available through the introduction of eSource such as ePRO, and the progress of digital technology has led to implementation of eConsent and decentralized clinical trials, all of which will greatly change the patient experience in clinical trials. Other new ways of thinking have already introduced the risk-based approach as the key to clinical trial operations and data management in the next era. How should our own work change to reflect advancements in the modern clinical trial environment? Many discussions have begun on changes in specific roles, but should this conversation not be more universal? This session will discuss the evolution of clinical operations "beyond innovation" by sharing new expectations and linking them to the challenges of each role.

Evolution of Clinical Data Management
Yasuharu Shibata, MSc
Head of Clinical Data Management, Clinical Operations Area, Japan Development, MSD K.K

What is Required for Monitoring Now and in the Future
Kazumasa Sugao
Associate Director,
Clinical Research & Development I, Department Ikuyaku.
Integrated Value Development Division, Mitsubishi Tanabe Pharma Corporation

Expectation and Concern of Medical Institution for Innovation
Kiyoko Adachi, MPharma
Study coordinator, National Cancer Center Hospital East

Digital Transformation: Innovative Dashboards to Reshape The Way of Working in DM & Medical Monitoring
Yun Ma, MS
Asia Regional Head of Statistical Programming, Boehringer Ingelheim

OS13

Considering the "Where, What, and How" of Clinical Trial Information Required by Patients from the Standpoint of Individual Stakeholders -Opinions of Study Participants and Updates from Study Sites in 2020

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

SESSION CHAIR

Naomi Sakurai
Representative Director, Cancer Survivors Recruiting Project, general incorporated association

At the 2018 DIA Annual Meeting, we held a session regarding "Information required by patients in clinical trials" where stakeholders including patients discussed their needs. The concept of PPI has become more well understood in the past two years. Moreover, the opportunities for presentation by patients at academic conferences increased. During that period, the difficulty of obtaining accurate clinical trial information, and the limited access to clinical trial site information were recognized.

In this session, two patients who have participated in clinical trials will share the most recent issues. In addition, an HCP will share the latest status of medical institutions. Then, the stakeholders will discuss how to improve future clinical trials.

In addition, the members at SLS21 will discuss regarding "Disclosure of names of the trial sites" and "PLS" based on information from this session.

Information Sought by Participants in Clinical Trials
Akane Murakami

Participating in a Rare Disease Clinical Trial: Voice of a Patient with Myasthenia Gravis
Masato Oniki
Assistant branch chief, Hokkaido, Japan Myasthenia Gravis Association

Clinical Trial Information Required by Oncology Patients and

Recent Updates for Participation

Noboru Yamamoto, MD, PhD
Deputy Director of the Hospital (Research), National Cancer Center Hospital

OS14

For Implementing the Revision of Pharmaceutical Affairs Law: Current and Future e-Labeling from Each Perspective

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

SESSION CHAIR

Masahiro Hayashi, PhD
Director, Department of Pharmacy, Toranomon Hospital

Many considerations are being discussed in preparation for implementing the revised Pharmaceutical Affairs Law regarding labeling digitalization next year, such as initiatives for excluding labeling in the package box and the distribution method of paper-based labeling for medical institutions. While PMDA has already provided examples of digitalized/constructed labeling on its website, constructed pharmaceutical information remains underutilized in Japan. In this session, we will provide the latest information on digital labeling under the revised Pharmaceutical Affairs Law. We will discuss initiatives for wide use of digitalized pharmaceutical information in pharmaceutical companies, as well as current digitalized pharmaceutical information usage and initiatives in medical institutions. We will also discuss future provision and utilization of digitalized pharmaceutical information from the perspective of government, companies, healthcare providers, and patients in Japan.

Preparation and Future Prospects for Computerization Of Package Inserts Accompanying Revision of The Pharmaceutical Affairs Law -from An Goverment Perspective-

Mai Okamoto
Pharmaceuticals and Medical Devices Agency (PMDA)

Survey Results and Prospects for Utilization of Drug Labels (in Package) for Prescription Drugs

Yoshiro Saito, PhD
Director, Division of Medicinal Safety Science, National Institute of Health Sciences

Current Status and Future Possibilities of the Use of Electronic Drug Information in Medical Practice

Shinya Suzuki, PhD
Showa University Northern Yokohama Hospital

Current and Future Status for Electronic Labeling in Company

Naotaka Ono
Pharmacovigilance, AstraZeneca Japan

Panel Discussion

All Session Speakers and
Kazuo Hasegawa
Representative Director, Lung Cancer Patient Network ONE STEP

OS15

Considering the Role of Additional Pharmacovigilance Plan in Japan

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

SESSION CHAIR

Yumiko Suzuki
Head of Post-marketing Study Strategy and Management, Pfizer R&D Japan

As ICH standards continue to become more widely accepted, and global simultaneous drug development in international clinical trials has become mainstream, the question of why additional pharmacovigilance (PV) plans are different between the US, the EU and Japan for the same Safety Specification remains unanswered. To answer to this question, a joint EFPIA/PhRMA taskforce has investigated differences in the drug risk management processes between these countries along with the position of Post Marketing Surveillance (PMS) in Japan. This session will share the output of this joint EFPIA/PhRMA taskforce, plus expert opinions from academia and PMDA on the future prospects for PV, how PV should improve drug risk management in Japan, the purpose and necessity of PMS, and how to connect the results of PMS with drug risk minimization.

Risk Management in EU

Tetsuya Kanayama, MSc
Head, CDD3 CDD & Re-examination Clinical Development & Analytics, Novartis Pharma K.K.

Risk Management in US

Kanami Sugimoto
Drug Safety Surveillance department, Safety Risk Management Group, Janssen Pharmaceutical K.K.

Comparison of Safety Specifications and Pharmacovigilance Plan for New Drugs in EU, US and Japan

Ryo Nakajima, MS
Manager, Medical Pharmacovigilance Group, AbbVie GK

Panel Discussion

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

OS16

What is the Quality of Real World Evidence?

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

Session Chair

Daisaku Sato, PhD
Chief Management Officer & Associate Centre Director for Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA)

Various data collected through our day-to-day activities in the real world (Real World Data, or RWD) are now being widely used in Japan to create evidence regarding the effectiveness, safety, and health technology assessment (HTA) of drugs and medical devices. At the same time, because these are considered secondary data, issues regarding the quality of the data itself and the quality of the real world evidence (RWE) developed and obtained from RWD continue to emerge; as a result, incorporation of RWE into new drug application review and approval application, post-marketing safety measures, and other regulations has not progressed as expected. In this session, experts will explain RWE as a deliverable from data science, how RWE can be utilized in regulatory science, and explore the touch points between data science and regulatory science.

Data Validation Around the World

Masao Iwagami, MD, PhD
Assistant Professor, Faculty of Medicine, University of Tsukuba

Reporting Guidelines for RWE – f rom EQUATOR Network –

Hisashi Urushihara, PhD
Professor, Faculty of Pharmacy, Division of Drug Development and Regulatory Science, Keio University

Electronic Health Records and Real-world Evidence

Eight researches or topics out of large number of applications from Japan and overseas about various themes were selected for poster session through a rigorous selection process. Current hot topics will be presented and discussed

[PO-01] Technology Use to Reduce a Patient's Emotional Burden in Clinical Trials

Related Area(s): CR, O:Patient

Tomoko Horii

Senior associate, Clinical Innovations & Business Integration, Clinical Development, Eli Lilly Japan

Objectives:
There are challenges in pediatric drug development such as recruitment and their emotional care. To overcome the challenges, we tested the effectiveness of digital technologies in clinical trials.

Method:
DWe introduced digital technologies in some pediatric clinical trials, and evaluated whether they helped a patient understand a clinical trial and reduced anxiety for the trial. Tested digital technologies; Communication robot,Mobile Application,Streaming delivery short video Evaluation; 5-point rating survey to the participants and healthcare providers,the number of access to digital technologies

Results:
As for the communication robot, we created short videos to explain a clinical trial and the trial procedure for candidate patients, and a journey map to explain a progress of the clinical trial for the "on-study" patient. We then installed them in the robot. We heard patients' positive feedback on the digital technologies so far; "The explanation for the trial was easy to understand", and "I look forward to meeting them at site". As for the mobile application, we created the mobile app for pediatric patient support. It was installed to their own devices/smartphones so that the app can remind next visit and medication of the participant as well as to provide the fun content showing the patient's progress of the clinical trial. As for the short video, we created a short video about a clinical trial to help patients understand visually and put its QR code in the informed consent document. We are going to introduce and publish all the results on the poster session.

Conclusion:
From the results, it was suggested that digital technologies could contribute to reduce anxiety and to emotionally support in pediatric clinical trials. To realize patient-centric clinical trials, a company should consider using digital technologies proactively to reduce patients' emotional burden.

[PO-02] A Technology Focused Model for Cost-Effective Clinical Document Translations

Related Area(s): MC

Nao Kobayashi, MSc

Senior Manager, Development Operations, Medical Writing,
Incyte Biosciences Japan GK

Objectives:
Present a cost-effective approach on clinical document translations based on win-win collaboration between a pharma company and a translation vendor, in the aspect of technology and human resources.

Method:
New technologies such as MS Word macro and specialized review tools were implemented to maximize the use of glossary, style guide, and translation memories. These tools ensured high-quality translation even with limited time. In the aspect of human resource support, the translation vendor assigned a dedicated quality manager to meet endorsed KPIs for performance and quality.

Results:
Before implementing these new tools and approach, the pharma company had to spend many hours double-checking glossary and style guide compliance as well as accuracy of translations. After implementations of the new technology tools, tremendous reduction in review time at the pharma company was realized. Because the tools had maximized glossary terms, style guide rules, and translation memories, the reviewer can focus only on checking the accuracy of the translations. When the translation vendor provides a dedicated quality manager, the consistency among multiple documents can be achieved. By having a single point of contact from the translation vendor, the pharma company''s feedback can be quickly incorporated into the next translation project. In order to objectively measure and assess the quality improvement over time, establishing KPIs is very effective. Qualitative and quantitative findings will be visually presented.

Conclusion:
Minimizing internal resources is one of the key strategies for many pharma companies. Win-win collaboration between the pharma company and the translation vendor shows a new model of collaboration to reduce costs (i.e. timelines, financial costs, and human resources) in pharma companies.

[PO-03] Introducing e-Consent to Help a Patient Have Better Understand Clinical Trials

Related Area(s): CR

Yasuhiro Masuda

Senior associate, Trial Capability, Clinical Development, Eli Lilly Japan

Objectives:
The objectives are to evaluate the effectiveness of e-Consent in understanding clinical trials (CTs) and to assess the e-Consent usability from the perspective of the site and patient.

Method:
12 patients were consented by e-Consent and 6 healthcare providers (HCPs) explained about CTs by e-Consent. By using questionnaires and conducting interviews (only HCPs), we asked the patients and the HCPs about the overall satisfaction, usability, and readability of e-Consent. Overall satisfaction was an indicator of contribution to help a patient have better understanding about CTs.

Results:
The overall patients' satisfactions were "very useful" (42%) and "useful" (58%), while the HCPs' satisfactions were "partially satisfied" (50%), "neither" (33%), and "not satisfied" (17%). The reason that the HCPs were less satisfied with e-Consent compared to the patients was assumed that the HCPs were unfamiliar with a devise and the e-Consent operation was complicated (e.g., charging the device, connecting to the internet and login, etc.). In fact, the following comment was obtained from the interview with the HCPs. -It took a long time for reading a new content and it kept the patient waiting. On the other hand, the following positive comment was also obtained. -It was time-consuming at the first time, but once it was done, it was easy and not too confusing. The following hurdles were suggested in the actual introduction that it is important to reduce not only the physical barriers such as operability and usability of e-Consent but also the mental barriers of the site user.

Conclusion:
The results suggested that e-Consent could help a patient have better understanding about CTs and the usability of e-Consent was not yet enough for the HCPs. For further expansion of e-Consent, it is essential not only to improve its function but to share the know-how to remove the mental barrier.

[PO-04] Pfizer's Drug Information Searching Chatbot for Health Care Professionals: MAIBO

Related Area(s): MC

Riho Tanaka

Medical Information Group, Pfizer Japan Inc.

Objectives:
Pfizer Medical Information (MI) handles inquiries from health care professionals (HCP). MI has developed chatbot service for HCPs in order to get information in a timely manner whenever they need.

Method:
Chatbot(MAIBO) features landing page with the most frequently asked questions to our call center -"drug stability", "request materials" and "product expiration date", which has been decided by project members and then collaborated with digital team to develop it. We also developed action that need to raise awareness such as create the leaflet and distributed it.

Results:
In Nov 2019, MAIBO started service for "drug stability" and "request materials". We are planning to expand this feature to s "product expiration date" in May 2020. In Mar 2020, phone inquiries to the call center about "stability" decreased by 22% and "material requests" decreased by 16% from the same month last year. These results suggested that HCP could get information by self-search with help of MAIBO. At the DIA meeting, we will present the result of customer satisfaction with our expanded features of MAIBO. On the other hand, the monthly average of access to MAIBO is about 230. (Dec 2019 to Mar 2020) . We considered low recognition of MAIBO among MR as an issue. We are planning to collaborate with sales department and public relations department. The outcomes of these actions will also be reported on the meeting.

Conclusion:
From around 2019, other pharmaceutical companies have begun providing information using chatbots. Through the development and recognition of chatbots, we would like to increase ready to use information by customer yet easy to find answer. We hope chatbot can help and promote this information service.

[PO-05] Business Case for Development of Clinical Quality Management System and Benefits

Related Area(s): CR

Ryoichi Ieda

Pfizar R&D Japan / TransCelerate BioPharma Inc. cQMS Japan Community of Practice

The business case in which the clinical Quality Management System (cQMS) framework and its effects will be provided, and the benefits associated with a cQMS will be clarified.

Methods:
In July 2016, TransCelerate BioPharma Inc. (TCBI) published clinical quality management system framework to mitigate quality issues and risks in clinical development. TCBI collected the business cases of cQMS implementation from TCBI member company and identified its benefits associated with a cQMS.

Results:
As one of the business case that a TCBI member company implemented, it was reported CAPAs for findings were decreased by 70% by adapting the concept of "Issues that Matter". Implementation of a cQMS is expected to provide an overall picture by (1) efficiently achieving an organization's quality and organizational objectives, (2) reducing recurring quality-related issues within limited resources, (3) increasing confidence in clinical research and its results, and (4) integrating individual trial-level quality and risk management activities to provide a holistic view. It is important to begin with fundamental components of cQMS, and by continuing to improve, the maturity level of cQMS will also be increased. The maturity level of cQMS was divided into 5 stages: "Reactive" "Repeated" "Defined" "Controlled" and "Optimized". This maturity will help sponsors to understand the current state of their cQMS and move to the next step.

Conclusion:
If the sponsor properly implements a cQMS, it is considered that significant benefits can be obtained. These benefits are expected to positively influence not only the sponsor but external stakeholders such as patients, academia/clinical sites, and regulatory authorities.

[PO-06] Comparison on Products Information for Patients from Different Markets

Related Area(s): RA, O:Patient

Zhonglei Chen, MPh

Senior manager, International labeling group, Pfizer

Objectives:
Get aware of the difference on the products information for patients from several markets; Reveal how to make our patients could understand what may impact their life during using our medicines, etc..

Methods:
Get the products information for patients via internet for the markets of Japan, US, EU and other Asia markets. Safety related information on products information for patients will be compared. Investigate the guidance from health authorities of each market.

Results:
Revealed the difference on the products information for patients from several markets (Japan, US, EU and other Asia markets). PMDA, FDA, EMA issued the guidance on creation of the products information for patients on their markets, which is mandatory for pharmaceutical companies to follow that guidance. It is asked to convert the medical or pharmaceutical terminologies to lay language, which should be easily understood by patients. The safety related information is located different sections among these markets. FDA requests to put the warning and precautions at the beginning of medication guidance, meanwhile, safety related information is in the middle of Patient Leaflet for EU and Drug Guide for Patients for Japan. Products information for patients is available in the commercial packages in EU, on the other hand, patients in Japan and US could get Drug Guide for Patients on PMDA website or medication guidance on FDA website.

Conclusion:
The user experience is crucial to products, especially for the medicines, pharmaceutical companies should ensure our patients to get products information for them easily, consider carefully how to put the warning and precautions at a appropriate location on products information for patients.

[PO-07] How Can We Manage Drug Development in China from Japan?

Related Area(s): CR, PM

Takamitsu Hirano, Master

Global Trial Director, Novartis Pharma K.K.

Objectives:
Novartis has had multiple experiences managing China trials as trial directors from Japan. Therefore, we'll share the issues and the countermeasures to be taken from our experience.

Methods:
Total of 5 studies including Phase 2-3 and China Post-authorization safety study (PASS) from 2019 to 2020 has been conducted. We'll present the issues that occurred when preparing or during studies and also the countermeasures in separate themes such as: timeline, local regulation (HGRAC, etc.), Leading site, CTA, Investigational product, handling of lab specimen, vendor, and PASS.

Results:
We would like to share the latest information on the results of the currently running studies so we will not be sharing at the time of Abstract submission.

Conclusion:
China studies can be managed from Japan if the trial directors understand their local regulation & process and provide adequate support. Moreover, we can provide solutions and new proposals based on our experience in Japan and assumptions on what risks that could occur in China studies.

[PO-08] Estimating Evaluation on Medicines from Disease Blogs Using BERT for PV

Related Area(s): CP, O:Patient

Shinichi Matsuda, PhD

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Objectives:
To estimate evaluation on medicines since it is beneficial for future patient-centric pharmacovigilance to understand whether patients are satisfied or unsatisfied with the treatments.

Methods:
We analyzed textual data collected from the Japanese disease blogs on the Internet: tōbyōki blogs, which translate literally as a diary-like account of a struggle with disease. Using one of the NLP techniques, BERT, we not only created a model which predicts 7 classes (-1, -0.67, -0.33, 0, +0.33, +0.67, +1) according to satisfaction based on the patients' texts but also evaluated the validity.

Results:
Our preliminary BERT model showed moderately good result in classifying patients' evaluation for each text. For instance, "I did not have my goals and dreams for a long time, but I ate well, drank well, laughed, and enjoyed 6 and a half hours" and "[...] It took a lot of time to make one thing together, and there were a lot of hard times, but I had a lot of fun and fulfilling time. It was like a treasure for me" were classified as +0.67 (Probability: 0.392 and 0.371, respectively). Similarly, "[...] This Monday is the 4th day of anti-cancer treatment. I did not want to do it again because I had suffered from side effect last time" and "[...] I vomited once, but I didn't have taken the medicine to avoid side effects" were classified as -0.67 (Prob: 0.250) and -1 (Prob: 0.220). At this moment, we also observed some unreasonable classification results. Since the current BERT was pretrained using Wikipedia, we believe that pretraining using tōbyōki blogs would improve the accuracy of the model.

Conclusion:
Patients' evaluation on medicines could be estimated based on the text data written by patients. Our approach should be helpful to identify the transition of patients' evaluation before and after the critical event for patients such as disease notification or initiation of the drug treatment.