14th DIA JAPAN ANNUAL MEETING 2017

Final Program

Toward Valuable Medicine Developments for Patients -Expectations for the Future through Effective Utilization of Artificial Intelligence and Big Data

患者さんにとって価値ある医療を生み出すために —人工知能(AI)やビックデータの有効利用と次世代への期待—

DIA

Endorsement by MHLW, PMDA, AMED, JPMA, PhRMA, EFPIA, PDA, ISPE and ISPOR Japan

後援：厚生労働省／独立行政法人 医薬品医療機器総合機構／国立研究開発法人 日本医療研究開発機構／日本製薬工業協会
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In accordance with the revised Personal Information Protection Law, attendees list is not distributed this year.

本年5月に施行された改正個人情報保護法により事前承諾なしに個人情報を第三者に提供することが困難となったため、参加者リストの配布を中止いたします。

Message From DIA's Global Chief Executive

On behalf of the organizing committee, the program committee, and DIA, it is my pleasure to welcome you to the *14th DIA Japan Annual Meeting*!

Japan has helped discover and advance much of the scientific progress made globally over the last decades. Since our very first DIA *Japan Annual Meeting* in 2003, Japan has been honored with two Nobel Laureates in Chemistry, three in Physiology or Medicine, and SEVEN in Physics. We are privileged to have one of these eminent scientists, 2016 Nobel Laureate in Physiology or Medicine, Professor Yoshinori Ohsumi deliver a Keynote Address at this year's meeting. Professor Ohsumi's discovery that mature human cells can be reprogrammed to return to their pluripotent state has made an indelible impact on the field of genomic medicine. Today, we continue to advance this field of genomic medicine and health care product development in its entirety via big data and artificial intelligence, the focus of this year's *DIA Japan Annual Meeting*.

Last year's *13th DIA Japan Annual Meeting* introduced DIAmond sessions, specifically designed to transcend professional disciplines or departmental silos and create a shared, comprehensive, and multidisciplinary understanding of issues vital to better meeting patient needs. This year's program features two visionary, future-looking DIAmond sessions that I encourage you to attend – look forward to learning about the future of drug development using next-generation ICT, and to hearing from regulatory authorities on timely drug delivery to patients. The program you will enjoy over the next few days is most impressive for its consistent pursuit of a new scientific, clinical, and regulatory vision for therapeutic product development, in Japan and globally. Special thanks to all who served on our volunteer program committee, our Program Chair Dr. Yasuhiro Fujiwara, Program Vice-Chair Ms. Akiko Ikeda, and Program Advisors Mr. Junichi Nishino, Mr. Yoshihiko Ono, and Dr. Junko Sato.

DIA is an association of global health care professionals that works towards the advancement of lifesaving medicines and technologies globally through our online DIA Communities platform, learning solutions, and conferences such as this one. DIA Japan continues to work towards this mission, building a community of health care professionals. Please use this opportunity to get involved with DIA. We need all voices engaged as we continue on our mission; thank you for joining us.

Sincerely,

Barbara Lopez Kunz

Global Chief Executive, DIA

SCHEDULE AT-A-GLANCE

SUNDAY, NOVEMBER 12

9:00-9:30	Registration for Student Session
9:30-12:00	Student Session
9:30-	Exhibitor Registration
11:45-	Attendee Registration
11:45-19:45	Exhibit Hall Open
12:00-13:00	Orientation at Exhbit Hall
13:30-14:00	Welcome & Opening Remarks
14:00-14:15	2017 DIA Japan's Inspire Awards Ceremony
14:15-15:15	Keynote Address 1
	Dr. Yoshinori Ohsumi, Tokyo Institute of Technology
15:15-15:45	Coffee Break & Exhibit Hall Innovation Theater Presentations
15:45-16:45	Keynote Address 2
	Dr. Tomohiro Sawa, Teikyo University
16:45-17:45	DIAmond Session 1 "Vision of Future Drug Development in Utilizing Next-Generation Medical ICT"
18:00-19:30	Networking Reception

MONDAY, NOVEMBER 13

8:30-	Attendee & Exhibitor Registration
9:00-19:00	Exhibit Hall Open
9:00-10:30	DIAmond Session 2 "To Deliver Innovative Drugs to the Patients Appropriately and Quickly – Recent Topics and Visions for Future of Regulatory Authorities among US, EU and Japan."
10:30-11:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30	Sessions 1
12:30-14:00	Lunch Break / Poster Session / Luncheon Seminars
14:00-15:30	Sessions 2
15:30-16:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30	Sessions 3
17:45-19:00	Engage and Exchange: Special Chat Session

TUESDAY, NOVEMBER 14

8:30-	Attendee & Exhibitor Registration
9:00-16:00	Exhibit Hall Open
9:00-10:30	Sessions 4
10:30-11:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30	Sessions 5
12:30-14:00	Lunch Break / Luncheon Seminars
14:00-15:30	Sessions 6
15:30-16:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30	PMDA Town Hall
17:30-17:40	Closing Remarks

11月12日（日）

9:00-9:30	スチューデントセッション受付
9:30-12:00	スチューデントセッション
9:30-	展示受付
11:45-	参加者受付オープン
11:45-19:45	展示会場（レセプションホール）オープン
12:00-13:00	オリエンテーション@展示会場
13:30-14:00	開会の挨拶 & 大会長挨拶
14:00-14:15	2017 DIA Japan's Inspire Awards 授賞式
14:15-15:15	基調講演1（東京工業大学　大隅 良典先生）
15:15-15:45	コーヒーブレイク & 出展者プレゼンテーション
15:45-16:45	基調講演2（帝京大学　澤 智博先生）
16:45-17:45	DIAmond Session 1「次世代医療ICTを活用した医薬品開発の将来像」
18:00-19:30	情報交換会

11月13日（月）

8:30-	受付
9:00-19:00	展示会場（レセプションホール）オープン
9:00-10:30	DIAmond Session 2 「革新的な医薬品をより迅速に必要とする患者へ届けるために - 日米欧三極規制当局の最新動向」
10:30-11:00	コーヒーブレイク & 出展者プレゼンテーション
11:00-12:30	セッション 1
12:30-14:00	ランチブレイク / ポスターセッション / ランチョンセミナー
14:00-15:30	セッション 2
15:30-16:00	コーヒーブレイク & 出展者プレゼンテーション
16:00-17:30	セッション 3
17:45-19:00	Engage and Exchange: スペシャルチャッティングセッション

11月14日（火）

8:30-	受付
9:00-16:00	展示会場（レセプションホール）オープン
9:00-10:30	セッション 4
10:30-11:00	コーヒーブレイク & 出展者プレゼンテーション
11:00-12:30	セッション 5
12:30-14:00	ランチブレイク / ランチョンセミナー
14:00-15:30	セッション 6
15:30-16:00	コーヒーブレイク & 出展者プレゼンテーション
16:00-17:30	PMDAタウンホール
17:30-17:40	閉会の挨拶

14th DIA Japan Annual Meeting 2017

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GENERAL INFORMATION

Accessing Presentations

During the meeting: available pre-meeting presentations are accessible to full conference registrants by logging in to My Account and going to the "My Presentation Downloads" section of the DIA website. You will need to enter your DIA User ID and password to verify your status in order to log in to My Account. If you have forgotten your DIA User ID and password, use our Login Reminder. Please note that this does not include all of the presentations but only those that were provided to DIA by a submission date and that the presenters agreed to put on the website. The pre-meeting presentations are available until November 21. Post-meeting presentations will become available to full conference registrants on or around December 1 and all applicable registrants will be notified by email when the upload is completed.

Coffee Break

Refreshment drinks are served in the Exhibition Hall during coffee breaks.

Lunch Voucher

A lunch box will be served to attendees on Day 2, November 13 and Day 3, November 14. Vouchers are included in the meeting materials you receive at registration. Please store them in a secure location, as replacement vouchers will not be issued. Please pick up your lunch box at the lunch voucher exchange area located in the Exhibition Hall between 12:00pm and 2:30pm on Day 2 and Day 3. Please enjoy your lunch in the sitting areas located in and around the Reception Hall.

If you are attending a luncheon seminar offered by the Platinum and Gold Supporters, please come to the seminar room and give the lunch voucher and your business card to the staff at the entrance. *Advance registration is required for Luncheon Seminar.

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DIA is providing free wireless internet access in the Exhibition Hall.

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As for the survey, hard copies will be distributed. You can take survey either on App or paper.

Collecting Series of Stamps at Exhibit Booths

Please find a stamp rally card in the congress bag. Please visit exhibitors' booths and get their stamps. DIA Japan will provide you a small gift with more than 15 stamps, and a big present with over 20 stamps in a drawing by DIA Japan later the meeting. Please note that all stamps of supporting companies that are listed on this card with company logos are required. Please return your card back to the registration and information desk on the 1st floor by 16:00 on November 14th. We will give you a small gift in exchange for your card.

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 15 and 16 for more details.

DIAmond SESSIONS

Private Social Function Policy

DIA does not allow hospitality functions to be held during any DIA meeting sessions, scheduled exhibit hours or social events. Therefore, the hours noted below are the only hours that are acceptable for hospitality functions.

Saturday, November 11	All times are acceptable
Sunday, November 12	Before 8:00 and after 20:00
Monday, November 13	Before 8:00 and after 20:00
Tuesday, November 14	Before 8:00 and after 18:30

Unless otherwise disclosed, the statements made by speakers represent their own opinion and not necessarily those of the organization they represent or that of the DIA.

Speakers and agenda are subject to change without notice.

講演資料のウェブサイト掲載

本年会の会期中、プログラム参加登録者はDIAウェブサイトに掲載している事前公開講演資料を閲覧できます。DIAグローバルサイトhttp://www.DIAglobal.orgのMy Accountからログインし、My Presentation Downloadsのページから各講演資料にアクセスしてください。My Accountにログインするには、DIA User IDとパスワードの入力が必要です。IDとパスワードがわからない場合は、forgot IDをクリックして、登録メールアドレスを入力すると、そのアドレスにIDとパスワードへのリンクが送信されます。詳しくは、クイックガイドをご覧ください。

http://www.diajapan.org/file/DIA_Account_QuickGuide.pdf

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年会終了後の最終講演資料は、12月1日前後にDIAウェブサイトに掲載します。掲載が完了次第、参加登録者宛に案内メールが配信されます。

コーヒーブレイク

コーヒーブレイクのお時間には、展示会場にてお飲み物を提供いたします。

昼食引換券

第2日(11/13)と第3日(11/14)に、展示会場で昼食（ランチボックス）をご用意しています。受付でお渡しする資料の中に昼食引換券が入っていますので、各日とも12:00-14:30の間に展示会場内の昼食配布所で本券と引き換えにランチボックスをお受け取りください。引換券の再発行はいたしませんので、失くさないように保管してください。展示会場内、会場入口前及び会場裏手に設置しております休憩スペースにて昼食をおとりください。

なお、プラチナサポーターとゴールドサポーター主催のランチョンセミナーにご参加の方は、セミナールームの入口で昼食引換券と名刺を受付スタッフにお渡しください。*ランチョンセミナーは事前登録制です。

WiFi

展示会場では、WiFiが利用できます。

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尚、アンケートは紙でも配布いたします。アプリか用紙か、いずれかでご回答ください。

展示会場スタンプラリー

スタンプラリー用のカードがコングレスバッグに入っています。このカードを持参して各出展企業を訪問し、スタンプを押してもらってください。15個以上集まればもれなく粗品を、更に20個以上集めた方にはDIA Japanにて抽選を行い、後日賞品を郵送にてお送りいたします。なお、このカードにロゴが記載されている協賛企業のスタンプは必ず押してもらい、11月14日（火）の16:00までに1Fの総合受付にご提出ください。カードと引き換えに景品をお渡しします。

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

発表者および講演タイトルは予告なく変更されることがあります。

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

日本臨床薬理学会認定CRC制度による研修会・講習会

本年会は、日本臨床薬理学会認定CRC制度による研修会・講習会として認定されています。
以下のプログラムのうち、4時間以上受講した参加者には、希望により修了証を発行します。

11月12日（日）
- 基調講演1、基調講演2
- DIAmond Session 1

11月13日（月）
- DIAmond Session 2
- セッション1〜3

11月14日（火）
- セッション4〜6
- PMDAタウンホール

修了証の発行を希望される方は、年会終了後、2017年11月21日（火）までに受講証明申請書をDIA Japan <Japan@diaglobal.org> 宛にメール添付にて提出してください。受講証明申請書は、下記リンクよりダウンロードできます。

http://www.diaglobal.org/productfiles/6371290/17303_CRC_certificate.pdf

受講証明申請書を受理した後、申請者の参加の有無及び申告された受講時間を確認のうえ、修了証を送付します。

日本薬剤師研修センター認定の集合研修会

本年会のDIAmond Session 2（11月13日9:00-10:30）とセッション1〜6（11月13日のセッション1〜3、11月14日のセッション4〜6）は、公益財団法人日本薬剤師研修センターより認定された集合研修会となっており、参加者は1セッションにつき1単位（研修受講シール1枚）を取得できます。

研修受講シールの交付を希望される方は、ご来場時と退場時に総合受付にお越しください。

ご受講されたセッション数に応じ、研修受講シールをお渡しいたします。

2017年11月13日 (月)		2017年11月14日 (火)	
入場時刻	:	入場時刻	:
入場確認印 (DIA Japan)		入場確認印 (DIA Japan)	
退出時刻	:	退出時刻	:
退出確認印 (DIA Japan)		退出確認印 (DIA Japan)	

ご受講されたセッションにチェックをお願いいたします。			
□DIAmond Session 2		□セッション1	□セッション2
□セッション3	□セッション4	□セッション5	□セッション6

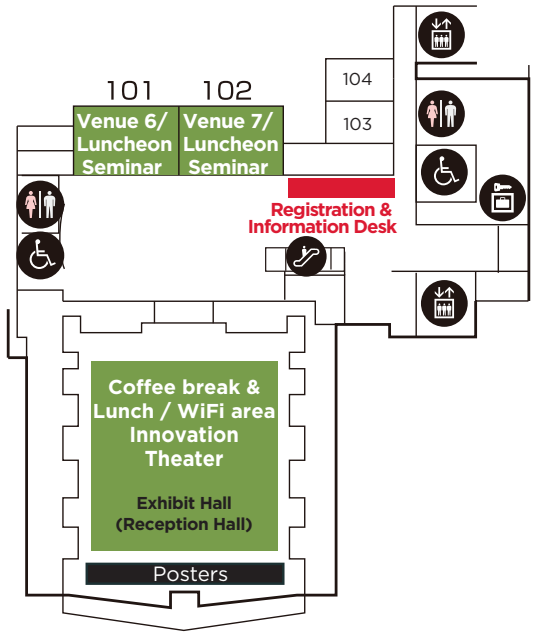
Private Social Function Policy

本年会開催期間中、当プログラム外の会議、展示、懇親会等のイベントの開催はご遠慮ください。下記時間帯につきましては、これに限りません。

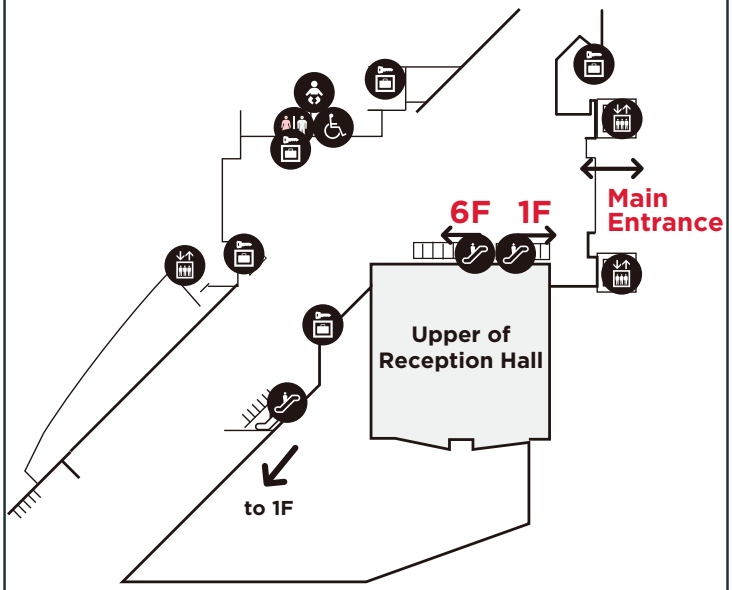
11月11日（土）	終日
11月12日（日）	午前8時以前、午後8時以降
11月13日（月）	午前8時以前、午後8時以降
11月14日（火）	午後8時以前、午後6時半以降

FLOOR PLAN

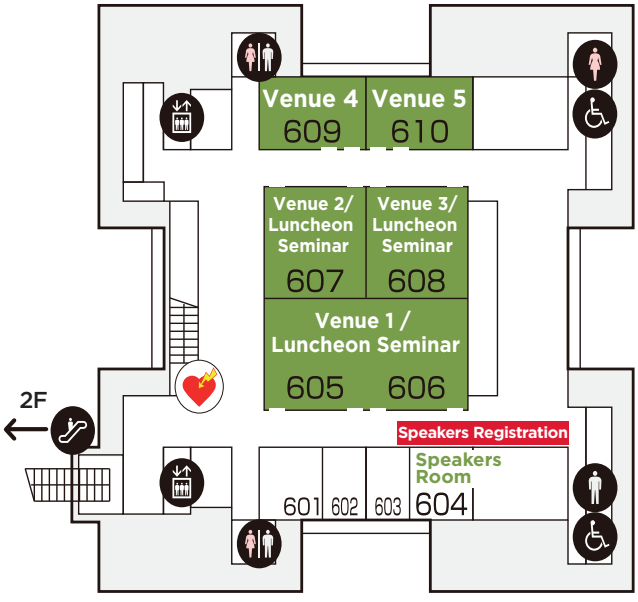
Conference Tower 1F



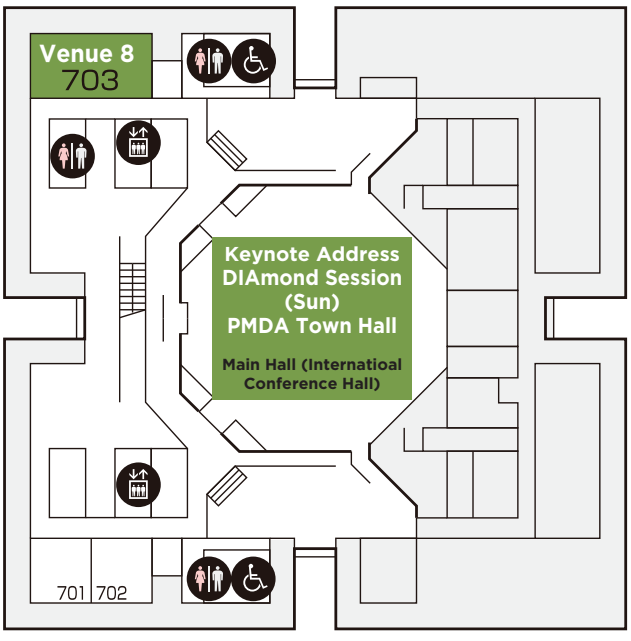
Conference Tower 2F



Conference Tower 6F



Conference Tower 7F



2017 DIA Japan's Inspire Award Winners

Outstanding Contribution to Health Award

Yuji Kumagai, MD, PhD
Director of Clinical Trial Center, Kitasato University Hospital
北里大学病院
熊谷　雄治

Dr. Yuji Kumagai is a clinical pharmacologist and he graduated from Medical College of Oita, Oita, Japan in 1985. He got training on clinical pharmacology especially in cardiac drugs in Post Graduate School, Medical College of Oita, Oita, Japan in 1989. He moved to the department of clinical pharmacology in Jichi Medical School and started clinical researches in the field of hypertension. As an official fellow of Japanese Society of Clinical Pharmacology and Therapeutics (JSCPT), he studied chronobiology under the supervision of Prof. Franz Halberg at University of Minnesota, USA from 1991 to 1992, where he published several papers concerning biological rhythms in blood pressure and heart rate using ambulatory blood pressure monitoring and Holter ECG monitoring. He moved to Kitasato university and concentrated to works in clinical trials.

He started Japanese Society of Clinical Pharmacology Study in 1999 to contribute to establishment of clinical pharmacology in Japan. Besides the domestic activity he noticed the importance of Asian collaboration in clinical trials and started to make networks among clinical pharmacologists in Asian region. He started an international meeting, "Asian Clinical Trial Update" in 2008 to promote Asian collaboration in early clinical trials.

He is now a professor of Kitasato Clinical Research Center, School of Medicine, Kitasato University, and the director of Clinical Trial Center at Kitasato University Hospital. He is managing all of the clinical trials in the hospital, he himself has performed many clinical trials including PK studies, PK/PD studies in patients, first in human studies, microdose studies and QT studies. He is a board member of JSCPT, a council of Japanese Pharmacological Society, and an editor of Translational & Clinical Pharmacology, an official journal of Korean Society of Clinical Pharmacology and Therapeutics. He will organize the 38th Annual Scientific Meeting of JSCPT under the theme of "Bridging Across" as the president in Yokohama this year. He is also the president of Japanese Association of Contract Institutes for Clinical Pharmacology and devotes himself to the activity to protect healthy subjects who participate in clinical trials.

Excellence in Service Award

Katsuhiko Ichimaru
Director, Information Disclosure Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人 医薬品医療機器総合機構
一丸　勝彦

Mr. Katsuhiko Ichimaru currently serves as Director of Information Disclosure Division in Office of Review Management in Pharmaceuticals and Medical Devices Agency (PMDA).

He graduated from Faculty of Pharmaceutical science, the University of Tokushima in 2000. He joined Pharmaceuticals and Medical Devices Evaluation Center of National Institute of Health Science (PMDEC), the predecessor of PMDA, in 2002 and continues his career on drug review in PMDA since April 2004. He was engaged in a review of central or peripheral nervous system drugs, antibacterial drugs and antiviral drugs.

<Activities in DIA>

DIA, Contents committee member (2014–present)

DIA, Program committee member of 6th–9th Regulatory Affairs training course (2013–2017)

DIA, Facilitator of 3rd and 4th Advanced Regulatory Affairs training course (2015-2016)

DIA, Facilitator of 5th Regulatory Communication training course (2017)

DIA, Student Group Advisor (2016–present)

DIA, Session presenter of "Changes in International Drug Development: Effects on Common Technical Document Preparation in Japan" in 45th DIA US annual meeting (2009)

DIA, presenter of 3rd Regulatory Affairs training course (2011)

DIA, Session co-chair and presenter of "How Does the Introduction of RMP Change Drug Development" in 9th DIA Japan annual meeting (2012)

DIA, Session panelist of "Vision for the Future: Global Simultaneous Filing to the World First Approval – Strategies for Early NDA Approval" in 11th DIA Japan annual meeting (2014)

DIA, Session presenter of "Future of Clinical Development Strategy in Asia after ICH E17 Guideline Implementation" in 13th DIA Japan annual meeting (2016)

Koichi Miyazaki, PhD
Senior Director, Clinical Development Group, Asia Development Department, R&D Division, Daiichi Sankyo Co., Ltd.
第一三共株式会社
宮崎　浩一

Koichi Miyazaki is currently Senior Director, Clinical Development Group, Asia Development Department, Daiichi Sankyo Co., Ltd. In this capacity, he is responsible for developing clinical research strategies, and designing and conducting clinical trials in a wide range of disease areas in Asia region. Prior to taking current position, he was the Asia region head of regulatory affairs and was responsible for IND, NDA, and post-NDA approval in Asia. He also has experience of project leader responsible for Asia in mega-global studies. Before taking project leader position, he spent 4 years in US as project manager with overall responsibilities for study operational aspects of clinical trials both in US local studies and global studies in cardiovascular field.

He is a long time DIA member and served on the program committees for multiple DIA meetings. His contribution to DIA includes the following:

Program committee member for annual workshop in Japan for progress in clinical trials (2002–2005)

Vice chair of program committee for DIA Japan Annual Meeting (2013)

Program committee member for DIA Japan Annual Meeting (2014)

Program committee member for DIA Asia New Drug Conference in Japan (2013, 2014)

Vice chair of program committee for DIA Asia New Drug Conference in Japan (2015–2017)

Additionally, he has been a speaker/session chair at various DIA meetings.

Leader of Tomorrow Award

Hiromi Okabe, PhD
Manager, New Drug Regulatory Affairs Department, R&D Division, Daiichi Sankyo Co., Ltd.
第一三共株式会社
岡部　裕美

Hiromi Okabe earned a Ph.D. in Pharmaceutical Sciences in 2004.

Whilst in graduate school, she was a research fellow at the Japan Society for the Promotion of Science (DC2). Dr. Okabe started her career at Daiichi Pharmaceutical Co. Ltd. in 2004 (Daiichi Sankyo Co. Ltd. from 2007). After she engaged in clinical pharmacology department, she expanded her interests to regulatory, and joined regulatory affairs department in 2015.

Apart from her role in Daiichi Sankyo, she joined DIA Japan Operation Team and contributed many programs.

DIA, Operation team member (2015–2017), leader (2016–2017)

DIA, Program committee member of 2nd Cell therapy product symposium (2017)

DIA, Program committee member of 14th DIA Japan annual meeting (2017)

DIA, Sub-facilitator in the Chatting Session (RA) in 13th DIA Japan annual meeting (2016)

【Programs supported by her】

DIA, 3rd and 4th Advanced Regulatory Affairs training course (2015, 2016)

DIA, 3rd and 4th European Medicines Regulations and the EU-Network training course (2016, 2017)

DIA, 1st Cell therapy product symposium (2016)

DIA, 11th DIA Asia New Drug Conference in Japan (2017)

Related Interest Areas: Clinical Research (CR), Regulatory Affairs (RA), Statistics (ST), Clinical Data Management (DM), Clinical Safety and Pharmacovigilance (CP), Project Management (PM), Chemistry, Manufacturing and Controls (CMC), Academia (AC), Medical Affairs (MA), Others (O)

JP *Japanese Language Only*

SUN NOV 12	MAIN VENUE International Conference Room	VENUE 1 Room 605/606	VENUE 2 Room 607	VENUE 3 Room 608	VENUE 4 Room 609
9:30-12:00					
12:00-13:30	ORIENTATION AT EXHIBIT HALL (12:00-13:00)				
13:30-13:45	WELCOME				
13:45-14:00	OPENING REMARKS DR.YASUHIRO FUJIWARA				
14:00-14:15	2017 DIA JAPAN'S INSPIRE AWARDS CEREMONY				
14:15-15:15	KEYNOTE ADDRESS1 DR. YOSHINORI OHSUMI / TOKYO INSTITUTE OF TECHNOLOGY				
15:15-15:45	COFFEE BREAK				
15:45-16:45	KEYNOTE ADDRESS2 DR. TOMOHIRO SAWA / TEIKYO UNIVERSITY				
16:45-17:45	**[DIAmond Session 1]** Vision of Future Drug Development in utilizing Next-Generation Medical ICT **ALL**	DIAmond SESSIONS			
17:45-18:00	SHORT BREAK				
18:00-19:30	NETWORKING RECEPTION AT RECEPTION HALL				

MON NOV 13	MAIN VENUE International Conference Room	VENUE 1 Room 605/606	VENUE 2 Room 607	VENUE 3 Room 608	VENUE 4 Room 609
9:00-10:30		**[DIAmond Session 2]** To Deliver Innovative Drugs to the Patients Appropriately and Quickly – Recent Topics and Visions for Future of Regulatory Authorities among US, EU and Japan **ALL**		DIAmond SESSIONS	
10:30-11:00		COFFEE BREAK (RECEPTION HALL)			
11:00-12:30 SESSION 1		**V1-S1** To Manage Global Phase I Study - Oncology Development - **CR,AC**	**V2-S1** [Educational Session] Panel Discussion on Health Technology Assessment (HTA) in Japan **RA, O: HEOR**	**V3-S1** [Educational Session] Comparison of Post-Marketing Safety Measures among Japan, the U.S. and the EU – From the Point of View of Risk Management - **CP, RA**	**V4-S1** Let's Think about Drug/Device Combination Use for Treatment **RA, Medical Device**
12:30-14:00		LUNCHEON SEMINAR (A2 HEALTHCARE CORPORATION) JP	LUNCH BREAK (POSTER SESSION AT RECEPTION HALL)		
14:00-15:30 SESSION 2		**V1-S2** Raise the Curtain of "Patient Centricity" in Japan (Part I): Share and Discuss the Common Value **CR,AC, CR, RA, O: Patients**	**V2-S2** Mobile / Digital Health Data Driven Innovation for Clinical Development **AC, CP, CR, DM, PM, RA, ST**	**V3-S2** [Educational Session] Understand the Rules and Process of the US and EU Labeling **CP, RA**	**V4-S2** Concerning the Issues of Clinical Study by Revision of the Personal Information Protection Law **CP, PM, AC, O: MA** JP
15:30-16:00		COFFEE BREAK (RECEPTION HALL)			
16:00-17:30 SESSION 3		**V1-S3** Raise the Curtain of "Patient Centricity" in Japan (Part 2): Share and Discuss the Common Value **CR,AC, CR, RA, O: Patients**	**V2-S3** Artificial Intelligence Leads to Realize Medical Innovation **AC, CR, ST**	**V3-S3** What Needs to Be Done for Creating Labeling Based on the New Revision of Items to be Included? **CP, RA**	**V4-S3** What is the Role of Medical Science Liaison (MSL) as New Function of Pharmaceutical Company? **AC, CP, CR, DM, PM, RA, ST** JP
17:30-17:45	SHORT BREAK				
17:45-19:00	**Engage and Exchange** 'LET'S CHAT! - SPECIAL CHAT SESSION - AT RECEPTION HALL				

TUE NOV 14	MAIN VENUE International Conference Room	VENUE 1 Room 605/606	VENUE 2 Room 607	VENUE 3 Room 608	VENUE 4 Room 609
9:00-10:30 SESSION 4		**V1-S4** The Changing Environment in the World and the Impact on the Pharmaceutical Industry **ALL**	**V2-S4** How to Use Statistics Correctly - Understand the Meaning of P Values and Eliminate Misuse **AC, CP, CR, DM, RA, ST** JP	**V3-S4** What is the New GPSP Ordinance Requirements for Post-Marketing Studies Using Healthcare Database? **CR, RA** JP	**V4-S4** Are the Drugs Appropriately Reaching to the Pediatrics in Needs? - Current Development Status and Future Steps of Pediatric Drugs in Japan - **AC, CR, PM, RA** JP
10:30-11:00		COFFEE BREAK (RECEPTION HALL)			
11:00-12:30 SESSION 5		**V1-S5** Regulations for Conditional Accelerated Approval System and Early Access to Drug Products **AC, CR, PM, RA**	**V2-S5** For RMP That can be Utilized by Healthcare Professionals **CP, RA** JP	**V3-S5** Changing Landscape of Phase 1 Trials in Oncology **AC, CP, CR, DM, PM, RA, ST**	**V4-S5** Quality by Design; Strategically Building the Quality of Clinical Study by Academia **DM, CR, ST, AC, O: MA** JP
12:30-14:00		LUNCH BREAK	LUNCHEON SEMINAR (CROEE INC.) JP	LUNCHEON SEMINAR (INVENTIV HEALTH)	LUNCH BREAK
14:00-15:30 SESSION 6		**V1-S6** Optimal Use Guidelines - Future Direction of the System, Discussion of the NDA Review Process, and Status of Actual Medical Practice **AC, CR, RA, O: PV, MA**	**V2-S6** RMP in the Era of Medical Big Data **CP, RA**	**V3-S6** Drug Developments for Rare Cancer and Fraction Areas **AC, CP, CR, DM, PM, RA, ST**	**V4-S6** How Should a Collaboration between Academia and Industry be Promoted for an Efficient Medicine/ Medical Device Development **ALL** JP
15:30-16:00	COFFEE BREAK (RECEPTION HALL)				
16:00-17:30	PMDA TOWN HALL				
17:30-17:40	CLOSING REMARKS				

Related Interest Areas: Clinical Research (CR), Regulatory Affairs (RA), Statistics (ST), Clinical Data Management (DM), Clinical Safety and Pharmacovigilance (CP), Project Management (PM), Chemistry, Manufacturing and Controls (CMC), Academia (AC), Medical Affairs (MA), Others (O)

JP *Japanese Language Only* ▭ *Japanese / English Language (simultaneous interpretation not available)*

VENUE 5 Room 610	VENUE 6 Room 101	VENUE 7 Room 102	VENUE 8 Room 103	EXHIBITION Reception Hall
		[Student Session] Global Development and Benefit and Risk Assessment of Drugs **O: Students** JP		
ORIENTATION AT EXHIBIT HALL (12:00-13:00)				
SHORT BREAK				
NETWORKING RECEPTION AT RECEPTION HALL				
VENUE 5 Room 610	VENUE 6 Room 101	VENUE 7 Room 102	VENUE 8 Room 103	EXHIBITION Reception Hall
COFFEE BREAK (RECEPTION HALL)				
V5-S1 Future Steps and Challenges for Drug Development Based on National Action Plan on Antimicrobial Resistance (AMR) **AC, CP, CR, RA, O: MA** JP	**V6-S1** Industry-Academia-Government Collaboration Schemes in Japan **AC, RA**	**V7-S1** Draft Regulatory Guidance for Patient Registry and the Current Situation **ALL**	**V8-S1** "The negotiation" – things you need to know for your team and project management **PM, O: ALL**	
LUNCH BREAK	LUNCHEON SEMINAR (MEDIDATA SOLUTIONS K.K.) JP	LUNCHEON SEMINAR (INC RESEARCH)	LUNCH BREAK (POSTER SESSION AT RECEPTION HALL)	
V5-S2 Approaches to Enhance Appropriate Communication on Pharmaceutical Product Information - Part 1 **AC, CR, RA, MA, O: Labeling, Marketing, Medical Writing, Medical Information** JP	**V6-S2** Paradigm Shift in Global Development Strategy - How to Utilize ICH E17 GL in New Drug Development? **AC, CR, RA, ST**	**V7-S2** Patient Participation – Patient Centric Approach to Clinical Trials **AC, CR, RA**	**V8-S2** Update on Current Status and Future Directions of Proarrhythmic Risk Assessment **AC, CP, CR, RA, O: Cardiac Safety**	
COFFEE BREAK (RECEPTION HALL)				
V5-S3 Approaches to Enhance Appropriate Communication on Pharmaceutical Product Information - Part 2 **AC, CP, RA, MA, O: Labeling, Marketing, Medical Writing, Medical Information** JP	**V6-S3** The Way toward Commercialization, Regenerative Medical Products **AC, CMC, CP, RA, PM, ST**	**V7-S3** Current Status on Counterfeit Medicines in Global and Issues on Japanese Market **CP, CMC, RA, O: Counterfeit**	**V8-S3** Call for Abstract Session **CP, CR, RA, O: ROD**	
SHORT BREAK				
Engage and Exchange 'LET'S CHAT! - SPECIAL CHAT SESSION - AT RECEPTION HALL				
VENUE 5 Room 610	VENUE 6 Room 101	VENUE 7 Room 102	VENUE 8 Room 103	EXHIBITION Reception Hall
V5-S4 How Do You Set in the First Step of the Project Manager Development? **ALL** JP	**V6-S4** Quality by Design; Strategically Building the Quality of Clinical Study by Academia **RA, DM, CR, ST, AC, O: MA**	**V7-S4** More Advanced Approach of Medical Big Data - Part 1 **ALL**	**V8-S4** Clinical Development of Biosimilar Products **RA, CR, ST, PM, CMC, AC**	
COFFEE BREAK (RECEPTION HALL)				
V5-S5 What Are You Going to Do? How Will You Develop Young Staff's Careers? How Will We Make Our Organization More Productive? **ALL** JP	**V6-S5** CRO Management for Effective Collaboration Related Interest Area(s) **CR, PM**	**V7-S5** More Advanced Approach of Medical Big Data - Part 2 **ALL**	**V8-S5** Drug Development Activation in Pan-Asia Region **AC, CR, PM, RA, O: MA**	
LUNCH BREAK	LUNCHEON SEMINAR (PAREXEL INTERNATIONAL) JP	LUNCHEON SEMINAR (OMNICOMM SYSTEMS INC.)	LUNCH BREAK	
V5-S6 Quality Management and Lean Six Sigma in Clinical Trials in ARO and Pharmaceutical Companies **AC, RA** JP	**V6-S6** Rethinking Quality in Clinical Trials - What are Quality Tolerance Limits (QTLs) and How Should they be Adapted in Clinical Studies to Fulfill New ICH-E6 Requirement? **AC, CR, DM, PM, RA, ST, O: MA**	**V7-S6** Future of Development Strategy and Lifecycle Management in Asia after ICH Q12 Guideline Implementation **RA, CMC, AC,**	**V8-S6** For Providing the Most Appropriate Medicine - The Current State of Use and Development of Companion Diagnostics (Mainly on Next Generation Sequencers) **AC, CP, DM, PM, RA, ST, O: Diagnostics company**	
COFFEE BREAK (RECEPTION HALL)				


SAVE THE DATE!
DIA 2018
Boston Convention
& Exhibition Center
June 24–28
#DIA2018
DIAglobal.org/DIA2018

Student Session / Orientation

Room 102 9:30-12:00

Student Session
Clinical Trial Protocol Development

Related Interest Area(s): RA, AC

Level: Beginner

SESSION CO-CHAIRS

Maori Ayabe
Chiba University

Shohei Iimura
Keio University

Aya Okada
Nihon University

Miho Sato
Showa University

Clinical trials are essential for evaluating drug safety and efficacy. Moreover, consideration of subjects and choices such as trial designs and evaluation methods are important in conducting them. Therefore, how are ethical and scientific clinical trials designed?

This session will provide a lecture on the essence of developing a clinical trial protocol. Subsequently, you will conduct a protocol development by group work and improve understanding. Through active discussion, we would like you to experience the drafting process of a trial plan.

In addition, it is desirable to read the following reference because we will deal with antidiabetic drugs as materials for group work:

Ministry of Health, Labour and Welfare. "Guideline for Clinical Evaluation of Oral Hypoglycemic Agents". https://www.pmda.go.jp/files/000208194.pdf (accessed 2017-05-23)

Points to Consider for Developing Clinical Study Protocol - Based on the Experience and Actual Cases - (Tentative)

Hideki Mizusako
Clinical Development Department, Daiichi Sankyo Co., Ltd.

Commentator

Yuka Sakagami
Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA)

Advisers

Motoki Arakawa, PhD
Lecturer, Laboratory of Pharmaceutical Regulatory Science, Nihon University

Kasumi Daidoji, MSc, RPh
Associate Director, Corporate Medical Affairs Headquarters, Drug Fostering and Evolution Coordination Department, Eisai Co., Ltd.

Yasuhiro Honsho
Associate Director, Global Medical Writing Group, New Drug Regulatory Affairs Department, Daiichi Sankyo Co., Ltd.

Katsuhiko Ichimaru
Director, Information Disclosure Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA)

Eri Sekine
Department Head, Trial Monitoring, Japan Development, Global Development Operations, Global Drug Development, Novartis Pharma K.K.

Meiko Fukagai
DIA Japan Student Group OBOG
Asia Development Department, Daiichi Sankyo Co., Ltd.

Emi Hachisuka, MS
DIA Japan Student Group OBOG
Japan-Asia Clinical Development 2, Astellas Pharma Inc.

Reception Hall 12:00-13:00

Orientation

SESSION CO-CHAIRS

DIA Japan Contents Committee

Welcome to the 14th DIA Japan Annual Meeting!

For the first time attendees, contents committee members present how you can maximize the value of your time at DIA Japan Annual Meeting 2017.

Contents:

- What is DIA
- Site Map
- Program Architecture
- Exhibition
- Navigation for Food and Coffee/Refreshment
- DIA App

DAY 1 | SUNDAY | NOVEMBER 12

Welcome and Keynote Sessions

WELCOME
International Conference Room **13:30-13:45**

Ko Sekiguchi
Director, DIA Japan

Barbara Lopez Kunz
Global Chief Executive, DIA

Kazumichi Kobayashi
Chair, DIA Advisory Council of Japan
Senior Vice President, Business Development and Planning, Otsuka Holdings Co., Ltd.

OPENING REMARKS
International Conference Room **13:45-14:00**

PROGRAM CHAIR

Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

2017 DIA JAPAN'S INSPIRE AWARDS PRESENTATION
International Conference Room **14:00-14:15**

PRESENTER:

Barbara Lopez Kunz
Global Chief Executive, DIA

AWARD WINNERS:

Outstanding Contribution to Health Award
Yuji Kumagai, MD, PhD
Director of Clinical Trial Center, Kitasato University Hospital

Excellence in Service Award
Katsuhiko Ichimaru
Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA)

Excellence in Service Award
Koichi Miyazaki, PhD
Senior Director, Clinical Development Group, Asia Development Department, R&D Division, Daiichi Sankyo Co., Ltd.

Leader of Tomorrow Award
Hiromi Okabe, PhD
Manager, New Drug Regulatory Affairs Department, R&D Division, Daiichi Sankyo Co., LTD.

KEYNOTE ADDRESS 1
International Conference Room **14:15-15:15**

SESSION CHAIR:

Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

In this keynote lecture, Dr. Ohsumi will reflect on his 40 year research career, from his early studies on the yeast vacuole to his latest findings in the field of autophagy. He will describe the role and evolution of analytical technologies, such as microscopy, in his research. Dr. Ohsumi will also give his thoughts on what are important personal attributes for researchers, as well his opinion on recent trends in academic research.

Looking Back on 40 Years of Yeast Research
Yoshinori Ohsumi, PhD
Honorary Professor, Cell Biology Center, Institute of Innovative Research, Tokyo Institute of Technology

COFFEE BREAK **15:15-15:45**

KEYNOTE ADDRESS 2
International Conference Room **15:45-16:45**

SESSION CHAIR:

Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

It is expected that healthcare will make dramatic progress by utilization of IT in the future.

If enormous amount of healthcare data is digitized, processed, and structured with the use of artificial intelligence, big data, and IoT (Internet of Things), clinical, research, education, and even patients will make an ecosystem, which realizes various forms of services by IT .

In this keynote lecture, the future of healthcare, especially the future of drug and medical device development will be described from the viewpoint of medical informatics.

The Digital Future of Healthcare – IT Utilization and Drug Development
Tomohiro Sawa, MD, PhD
Professor, Department of Anesthesia, Teikyo University
Chief Information Officer, Headquarters, Teikyo University

DIAmond Session

DIAmond SESSIONS

DIAmond Session 1

International Conference Room **16:45-17:45**

Vision of Future Drug Development in Utilizing Next-Generation Medical ICT

SESSION CHAIR:

Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

Yoshihiko Ono, RPh
Executive Director, Head of Regulatory Affairs, Japan Development, MSD K.K.

Recently, under the Healthcare Policy, discussions are ongoing for Next-Generation Medical ICT on aiming to build and to utilize digital infrastructure in the areas of medical, nursing care, and health care. In this session, we will hold a panel discussion to offer respective views from industrial, academic, and government perspectives on the future direction of Next-Generation Medical ICT, and vision of future Drug Development including utilization or potential impact of ICT on clinical studies or on review for drug approval.

Future Outlook for Next-Generation Medical ICT (Tentative)
Kouji Fujimoto
Deputy Director-General, Office of Health and Medical Policy, Cabinet Secretariat

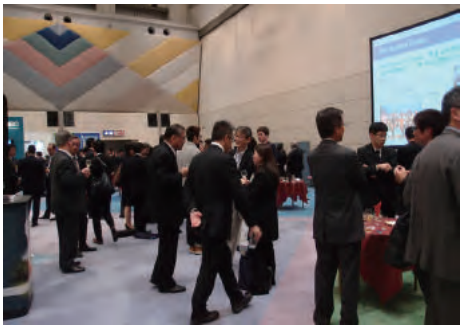
Additional Remarks
Kazuhiko Mori, MSc
Councilor for Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare

Drug Development Utilized Next Generation ICT - PMDA's Efforts -
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Tomohiro Sawa, MD, PhD
Professor, Department of Anesthesia, Teikyo University
Chief Information Officer, Headquarters, Teikyo University

NETWORKING RECEPTION

Reception Hall **18:00-19:30**



DAY 2 | MONDAY | NOVEMBER 13

DIAmond Session 2

Room 605/606/607/608 **9:00-10:30**

DIAmond SESSIONS

To Deliver Innovative Drugs to the Patients Appropriately and Quickly – Recent Topics and Visions for Future of Regulatory Authorities among US, EU and Japan

Related Interest Area(s): ALL

Level: Beginner, Intermediate

SESSION CO-CHAIRS

Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

To deliver innovative drugs to the patients appropriately and quickly – recent topics and visions for future of regulatory authorities among US, EU and Japan."

Lots of efforts have been made by academia, industry and regulatory agencies, in order to deliver innovative drugs to patents quickly. In this session, representative from FDA, EMA and MHLW will introduce their own activities as well as examples and they will discuss future direction under the recent high-uncertainly environment. The discussion includes their accelerated approval process (ie. FDA: Breakthrough designation, EU: PRIME and Japan: Sakigake) would how to be applied to accelerate appropriate medicine to patients. Also, how efficacy and safety of new therapy to rare disease, where usually typical double-blind trial is difficult to be conducted, is to be evaluated with sufficient validity from scientific and ethical point of views, in order to be delivered to the patients. Efforts by regulatory authorities to incorporate emerging novel science and regulatory science into the processes to establish new medicine, as well as the various collaboration among academia, industry and regulatory agencies globally, will be discussed by the presenters as panel discussion format.

TBC

Francesco Pignatti, MD
Head of Oncology, Haematology, Diagnostics, European Medicines Agency (EMA)

TBC

Kazuhiko Mori, MSc
Councilor for Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare

US Food and Drug Administration Expedited Programs for Serious Conditions

Rajeshwari Sridhara, PhD
Director, Division of Biometric V, Office of Biostatistics, OTS, CDER, FDA

Panel Discussion

All Session Speakers

COFFEE BREAK **10:30-11:00**

SESSION 1 11:00-12:30

V1-S1 Room 605/606 11:00-12:30

To Manage Global Phase I Study - Oncology Development -

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

SESSION CHAIR

Hironobu Saito, PhD
Vice President, Oncology Clinical Development Department, Oncology Function, R&D Division, Daiichi Sankyo Co., Ltd.

Even in the case that a new seed has been found in Japan, US/ Europe is leading the clinical development, in which global phase I study is started in US/Europe and the first approval is planned in US/EU. To lead global development, Japan need the skill to manage global Phase I and develop global human resource.

In the oncology area, the transformation from Step by step (Phase I,II,III) to patients oriented development (Expanded Phase I, Confirmed Phase II, Conditional Approval) is discussed and challenged.

The most important action is to develop global human resource in Japan. For example the person who is able to find the dose in the case of limited data and limited time.

In the first session, the presenters will share how the sponsor prepares non-clinical data, CMC data to set up global phase I study. In the second session, the global site (US/EU/Asia/Japan) will share the efforts and the experiences to deal with global Phase I study.

The Experience of Global Phase I Study in Japanese Site
Noboru Yamamoto, MD, PhD
Director, Department of Experimental Therapeutics Department of Thoracic Oncology, National Cancer Center

The Experience of Global Phase I Study in Asian Site
Chia-Chi (Josh) Lin, MD, PhD
Director of Phase I Center Department of Oncology, National Taiwan University Hospital

Global Phase I Study : The Experience and the Outcome
Kaku Saito, MSc, PMP
Manager, Oncology Clinical Development Department, DaiichiSankyo Inc.

Experiences in Joining Oncology Global First-in-Human Studies
Hideyasu Ishibashi, PhD
Head, Translational Clinical Oncology, Novartis Pharma K.K.

Panel Discussion
All Session Speakers

V2-S1 Room 607 11:00-12:30

[Educational Session] Panel Discussion on Health Technology Assessment (HTA) in Japan

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

SESSION CHAIR

Kuniko Shoji
Director and Corporate Advisor, Terumo Corporation

As innovative and expensive pharmaceuticals and medical devices are increasingly used in clinical practice, Health Technology Assessment (HTA) is attracting serious attention as a policy making tool to enable sustainability of universal access.

The HTA, which has been implemented on a trial basis since 2016, is actively discussing how the system should be designed in readiness for a full-scale implementation.

At the Japan Annual Meeting in 2017, we will give an overview of insurance reimbursement, drug pricing system, etc. of both foreign countries and Japan, and will conduct a free and open panel discussion from various viewpoints concerning cost-effectiveness assessment in Japan.

In this way, we plan to discuss the methodology of a comprehensive evaluation of HTA in Japanese and the value of life for Japanese people (ICER threshold).

Introduction of Insurance Reimbursement, Drug Pricing System of Both Foreign Countries and Japan
Ataru Igarashi, PhD
Associate Professor, Department of Drug Policy and Management Graduate School of Pharmaceutical Sciences, The University of Tokyo

Current Status of Cost-Effectiveness Assessment in Japan
Makoto Kobayashi, MEng, PhD
Director and Chief Operating Officer, Crecon Medical Assessment Inc.

Panel Discussion
All Session Speakers and

Takeo Nakayama, MD, PhD
Professor, Graduate School of Medicine and Faculty of Medicine, Kyoto University

Rei Goto, MD, PhD
Associate Professor, Graduate School of Business Administration, Keio University

Harumichi Okamura
Corporate Officer, Head of Market Access & Public Affairs, Novartis Pharma K.K.

V3-S1 Room 608 11:00-12:30

[Educational Session] Comparison of Post-Marketing Safety Measures among Japan, the U.S. and the EU – From the Point of View of Risk Management –

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

SESSION CHAIR

Yomei Matsuoka, MSc, RPh
Senior Director, Safety Planning Group 1, Pharmacovigilance Department, Daiichi Sankyo Co., Ltd.

As multi-regional clinical trials increase, global application and approval and elimination of drug lag are about to be realized, while data of clinical trials in each country tend to decrease compared to before the implementation of multi-regional clinical trials. Therefore, the importance of safety measures in post-marketing phase are relatively increasing for clarifying details of drug safety and efficacy profiles in timely manner. In this context, we will share the difference in concept of risk management between Japan, the U.S., and the EU and the current status and challenges of post-marketing safety measures during this educational session.

Drug Safety Measures in Japan
Emiko Kondo, PhD
Office Director, Office of Safety II, Pharmaceuticals and Medical Devices Agency (PMDA)

Post-Marketing Safety Measures in the United States
Robert F. Reynolds, MSc, ScD, FISPE
Vice President, Epidemiology, Worldwide Safety, Pfizer Inc

Post-Marketing Surveillance and Safety Measures in the EU
Peter Bachmann, PhD
Chair, CMDh, Federal Institute For Drugs and Medical Devices (BfArM)

Panel Discussion
All Session Speakers

V4-S1 Room 609 11:00-12:30

Let's Think about Drug/Device Combination Use for Treatment

Related Interest Area(s): RA, O: Medical Device
Level: Intermediate
Language: Japanese Language Only

SESSION CHAIR

Kensuke Ishii, PhD
Director, Office of Medical Devices II, Pharmaceuticals and Medical Devices Agency (PMDA)

Drug-device combination products and therapies are currently the subject of much attention given the increasing difficulties in developing truly innovative new pharmaceuticals and medical devices. This session focuses on clinical development issues with regard to combination products or therapies by discussing a number of concrete examples. The session will include a discussion of how to manage the simultaneous development of devices and pharmaceuticals more efficiently and how various hurdles and issues during clinical development could be potentially addressed.

Prospect and Issues of Drug-Device Combination Products and Therapies
Yoshihiro Muragaki, MD, PhD
Professor, Institute of Advanced Biomedical Engineering and Science, Tokyo Women's Medical University

TBC
Keiichi Sasaki, DDS, PhD
Director, Tohoku University Graduate School of Dentistry Dean, Tohoku University School of Dentistry

TBC
Masayoshi Shibatsuji
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Takehiko Arima
Senior Director, Quality & Regulatory Affairs, Medtronic Japan Co., Ltd.
Kazumichi Kobayashi
Senior Vice President, Business Development and Planning, Otsuka Holdings Co., Ltd.

V5-S1 Room 610 11:00-12:30

Future Steps and Challenges for Drug Development Based on National Action Plan on Antimicrobial Resistance (AMR)

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

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

Overcoming Antimicrobial-resistant Infection (ARI) has become a global issue. In 2016, the "Ministerial Meeting on Measures on Emerging Infectious Diseases" has announced the National Action Plan on Antimicrobial Resistance (AMR), and as well as a commitment demonstrated in G7 Health Ministers Meeting to solve AMR task.

In addition, for a Guideline for the Clinical Evaluation of Antibiotics for ARI, the three regional regulatory agencies (PMDA/FDA/EMA) are cooperating to continue the discussion. This session will discuss future steps based on AMR action plan, about clinical studies in different framework to date, and on international cooperation.

The Japanese Government's Efforts on AMR
Yasuhide Yamada, MSc, MPM

Therapeutic Drug for Antimicrobial Resistance (AMR) Infections: from Regulatory Standpoint
Wataru Asakura, PhD
Office Director, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)

Challenges in Clinical Development of Drugs for AMR Infections
Akiko Takase, MSc
Senior Scientist, Regulatory Strategy & Liaison 1, Regulatory Affairs Area, Japan Development, MSD K.K.

Panel Discussion
All Session Speakers

V6-S1 Room 101 11:00-12:30

Industry-Academia-Government Collaboration Schemes in Japan

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

SESSION CHAIR
Toichi Takenaka, DVM, PhD
Chairman, Japan Health Sciences Foundation

The Japan Agency for Medical Research and Development (AMED) was established two years ago. In order to minimize the boundaries of the industry, academia, and government in drug research, we host grant programs such as: the Department of Innovative Drug Discovery and Development (iD3) which is the first public program in Japan to deliver drug seeds from academia to clinical application, the GAPFREE program which grants public-private joint clinical research, and the Cyclic Innovation for Clinical Empowerment (CiCLE) which began in FY2017 to fund infrastructure and open innovation for medical needs based on industry-academia-government collaboration. Through these programs, we would like to discuss about the perspectives of industry-academia-government collaboration.

Drug Discovery Support Network Recent Development & Future Perspectives
Yoichi Kurebayashi, DVM, PhD
Senior Director, Japan Agency for Medical Research and Development

About the Funding for Research to Expedite Effective Drug Discovery by Government, Academia and Private Partnership (GAPFREE) Program
Kazuki Yasuda, MD
Department of Metabolic Disorder, Diabetes Research Center, Research Institute, National Center for Global Health and Medicine

Development of the Innovative Vaccine Technology Based on Nucleic Acid Encapsulated in Nanoparticle Supported by the Ciclic Innovation for Clinical Empowerment (CiCLE) Program
Fumihiko Takeshita, MD, PhD
Senior Director (R&D), Vice President, Vaccine Research Laboratories, Daiichi Sankyo Co., Ltd.

V7-S1 Room 102 11:00-12:30

Draft Regulatory Guidance for Patient Registry and the Current Situation

Related Interest Area(s): ALL
Level: Intermediate

SESSION CHAIR
Akihiro Hirakawa, PhD
Project Associate Professor, Department of Biostatistics and Bioinformatics, Graduate School of Medicine, The University of Tokyo

Under the Clinical Innovation Network (CIN) scheme, which aims for promoting medicine development by effective utilization of medical information generated by patient registries, an intensive development of patient registry has been preceded by an industry wide consortium of National Medical Research Centers (NCs) and Pharmaceutical companies, which was proposed by Ministry of Health, Labuor and Welfare. Under this circumstance, academic societies and PMDA have been dedicating to discuss data quality standard regarding the registry data which to be used for Japan NDA. There are various perspectives about data quality and way of registry operation. Is this session, we will discuss regulations surrounding the patient registry and issues for the ideal effective utilization of registry data.

Discussion on "Draft: Basic Principles on the Reliability of Patients Registry Data When Utilized in the Application for Marketing Authorization and Post-Marketing Surveillance of Medical Products"
Taro Shibata, PhD
Director, Biostatistics Division, Center for Research Administration and Support, National Cancer Center

Current Status and Issues of Remudy in an Effort to Promote Clinical Innovation Network
Harumasa Nakamura, MD
Section Chief of the Department of Clinical Research Support and Section Chief of the Clinical Research/Trial Promotion Section, Translational Medical Center, the National Center of Neurology and Psychiatry

Expectation for The Disease Registry Data from a Pharmaceutical Company

Kazuhito Shiosakai
Biostatistics & Data Management Department, R&D Division, Daiichi Sankyo Co., Ltd.

Panel Discussion

All Session Speakers and
Shimon Tashiro, PhD
Head, Office for Bioethics, Center for Public Health Science, National Cancer Center

V8-S1 Room 703 11:00-12:30

"The Negotiation" – Things You Need to Know for Your Team and Project Management

Related Interest Area(s): PM, O: ALL
Level: Beginner, Intermediate
Language: English/Japanese

SESSION CHAIR

Atsushi Tsukamoto, PhD, MSc
Senior Director, RD Strategy and Coordination Group, RD Planning and Management Department, Daiichi Sankyo Co., Ltd.

In order to build strong and productive project team, various project management tools and skills are generally used. Especially "negotiation" plays important role to be effective and capable project leaders and project managers. Negotiation may be perceived as skill to "pursue to your own win only", such as discounting car price, however, it is actually more than that. In efficient project team, project members, including leader and manager, would speak up and listen appropriately even in difficult situation, and the right communication will lead to be efficient project team. In this session, theories and practices of negotiation in Japan as well as US, together with actual experiences, are introduced, and there will be discussion to appropriately engage project members and stakeholders with the right negotiation skills for ultimately achieving project goals.

Speakers

Shuji Sumida, MSc, RPh
Department Manager, Business Strategy & Compliance Deparatment, Quality & Regulatory Compliance Unit, Chugai Pharmaceutical Co., Ltd.

Robert Hilke
CEO, Hilke Communications

Gareth Monteath, DBA, MBA
Senior Program Director, Link Global

Panel Discussion

All Session Speakers

LUNCH BREAK 12:30-14:00

POSTER SESSION 13:30-14:00

POSTER SESSION Reception Hall 13:30-14:00

Ten researches or topics out of more than large number of applications from Japan and overseas compared to the last year from various themes were selected for poster session through a rigorous selection process. Current hot topics will be presented and discussed.

(Note: Apostrophes (*) indicates presenters. The others are co-authors.)

[PO-01] Use of Juvenile Animal Studies to Support Oncology Medicine Development in Children

Dinah Duarte, PharmD, MSc *
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED

Children use of new cancer medicines requires early prediction of specific safety. Juvenile animal studies (JAS) could screen for age-related toxicities and differences during postnatal development. This review of EU oncology medicines revealed a steady use of JAS to better characterise safety: 1 in 3 medicine has conducted JAS; 6 medicines have different toxicity profile between adult and juvenile animals.

[PO-02] Utilizing Regulatory Intelligence of Precision Medicine Products for Building Business Strategy

Gloria Hung, RPh, MPhil *
Director, Regional Regulatory Strategist, Pfizer Inc.

The US FDA has increased focus on Precision Medicines (PM) and expedited regulatory tools are available. The US-approved PM product database constructed in this study shows that strategic use of expedited pathway(s) shortens development time and expedites patient access. Information relating to biomarkers was indicated across various label sections which may impact usage. Growth potential for non-oncology therapeutic areas is also noted.

[PO-03] Possible Causes of Failing to Meet Oncology Primary Endpoints: Systematic Review

Mitsugu Ikeda, MSc *
Nagoya City University

We performed a systematic review of oncology phase 3 trials. The common primary endpoints were overall survival (OS) and progression-free survival (PFS). The success rate of non-small-cell lung cancer trials was 33%. More "Negative" results were found for OS that could be prolonged even in the control arm, while more "Positive" results were found for PFS, which could be consistent with the pre-estimation.

[PO-04] Pipeline Portfolio Management Using Agent-Based Modeling with Gaming Simulation

Kosuke Iwasaki, MBA *
Director, Japan Healthcare Practice & Data Analytics, Milliman, Inc.

[PO-05] How Japanese Pharm Industry Challenge Simultaneous J-NDA filing? -Survey of Characteristics of 20 Products Simultaneously Filed and the Number of Japanese Subjects in Those Data Packages-

Yoshiaki Kato *
Medical Writing, Regulatory Affairs Area, Japan Development, MSD K.K.

Keiko Tsumori
Associate Director, Medical Writing, Regulatory Affairs Area, Japan Development, MSD K.K.

Makoto Suzuki, PhD
Director, Medical Writing, Regulatory Affairs Area, Japan Development, MSD K.K.

We examined the time lag in filing and approval of drugs which were simultaneously (within 4-month time lag) filed in Japan, US and EU based on the open information for the products approved in Japan between October 2009 and December 2014, to investigate their actual status. In addition, we also examined the numbers of Japanese subjects included in data package of Japanese CTD.

[PO-06] Survey of Organization-Specific and Occupation-Specific Training Needs for RBM Related Tasks in Japan

Hidenobu Kondo, MPharm *
Centralized Monitoring Department, Development Strategy Division, A2 Healthcare Corporation

A questionnaire survey about training needs for RBM related tasks with 86 people from 7 organization, 3 pharmaceutical companies, 3 universities, and 1 CRO, was conducted in January 2017. The aim of this research is to identify the needs of training for RBM studies by organization and occupation. Results suggested that organization-specific and occupation-specific training program should be developed and implemented for the tasks achieved in RBM studies.

[PO-07] Rates of Safety Issues for Low Risk Medical Devices: A Cross Sectional Study Between US,UK to Philippines

Cezar Manansala Jr, RPh* Mark Scyld Magboo, RPh Maileen Beley, RPh
Centro Escolar University

[PO-08] Evaluation of Signal Detection and Validation Approaches in Pharmacovigilance: US Perspective

Sanjeev Miglani, MD *
Vice President-PV and Clinical Safety North America and Global Medical Affairs, APCER Life Sciences

Spontaneous reporting (SR) adverse event system databases, large clinical projects and health records databases contain data that may be valuable for timely detection of potential risks associated with Pharmaceutical products. This Poster will provide recommendations for using data from different databases to provide insight into safety signals and offer guidance regarding appropriate statistical methods to use in various situations.

[PO-09] Partner Collaboration in Quality Assurance, between the Quality Groups from 2 Companies

Keiko Shiratori, MSc *
Bristol-Myers Squibb K.K.

Hiromichi Ishikawa, MSc
Quality Management Associate, Ono Pharmaceutical Co., Ltd.

We will share how we have put in place an effective partnership between the quality groups of 2 companies, co-developing a new compound, to ensure the quality throughout the development and to be approved by health authorities smoothly. The session indicates the specific activities, on-going achievements with the case example of challenges and synergetic effects we had, and future prospects of collaborations.

[PO-10] Approach to Gaps between Ideal and Reality in Clinical Operations and Monitoring

Kazumasa Sugao * Masayuki Iijima Shiho Sugiura Eisuke Nakata
DIA COM (Clinical Operations and Monitoring) Community

In 2016 COM community, we had three sessions with community members to identify gaps between the ideal and the reality in clinical trials and monitoring. And also we analyzed the mechanism of the gaps, and sought best solutions/ behaviors for us to overcome the gaps.

[PO-11] Accelerated Development of Anti-Sense Oligonucleotides for Orphan Drug Indications

Yasuhiro Okamoto, PhD *
Associate Director, RA-CMC, Biogen Japan Ltd.

Biogen is developing several Anti-Sense Oligonucleotide (ASO) drug candidates for treatment of orphan indications. "SPINRAZA Intrathecal Injection 12 mg" is the only first "Disease-modifying drug" for Spinal Muscular Atrophy (SMA) in the world. Capabilities to develop new ASO products under CMC regulation, ASO platform manufacturing and analytical procedures has been established and is expanding. Especially, we considered that these management strategies using LC-MS is very important to control the

SESSION 2 14:00-15:30

V1-S2 Room 605/606 14:00-15:30

Raise the Curtain of "Patient Centricity" in Japan (Part I): Share and Discuss the Common Value

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

SESSION CHAIR

Norie Miki-Yasuda, PhD
Head of Japan Clinical Operations Division, Janssen Pharmaceutical K.K.

Kaori Muto, PhD
Professor, Department of Public Policy, The Institute of Medical Science, The University of Tokyo

The idea of Patient Centricity and Patient and Public Engagement are increasingly attracting interest in Japan, while their concept and idea have not been organized among various stakeholders. To deepen the understanding about Patient Centricity and Patient and Public Engagement, a researcher on Science, Technology and Society, an expert on clinical studies and representative of a patient support organization will present their thoughts and activities on Patient Centricity and Patient and Public Engagement.

In part 2 session, pharmaceutical companies will share their activities for patient centricity in clinical trials and discuss Patient Centricity and Patient and Public Engagement together with the speakers of this session

Patient and Public Involvement in Research: From Concept to Practice

Jin Higashijima, PhD
Associate Professor, Faculty of Global and Science Studies, Yamaguchi University

Project to Train Patients and Citizens to Actively Participate in Various Committees: Necessity and Practice

Ikuko Yamaguchi
Board Chairperson, COML

V1-S3 Follows

V2-S2 Room 607 14:00-15:30

Mobile / Digital Health Data Driven Innovation for Clinical Development

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

SESSION CHAIR

Takuhiro Yamaguchi, PhD
Professor, Biostatistics, Tohoku University Graduate School of Medicine

The spread of smart phones and wearable devices will increase both the type and volume of data in clinical trial. However the use of such mobile/digital health data might have potential issues of quality, statistical approach, interpretation of analysis results and software packages for processing. This session gives an insight into innovations in clinical drug development by mobile / digital data.

Utilization of Digital Health Data; Recent Trends and Challenges

Kazuteru Sugiura, MBA
Research Fellow, Office of Pharmaceutical Industry Research

Driving Innovation: Our Experience in the Industry

Mei Haruya, PhD
Manager, Strategic Innovation Department, GlaxoSmithKline K.K.

Patient Retention by Smartphone Apps in Japan - The Case of Smartphone Apps for Pediatric Subject in the Central Nervous System Area -

Hidekazu Takahashi
Executive Officer & Headquarters Manager of a Comunication Serivce Department, CROèe Inc.

Considerations in Big Data Handling with Statistical Software

Akihiro Nakajima
Pharmaceutical Development Administration Department, Statistics Analysis Group, Teijin Pharma Limited
Data Science Expert Committee, Japan Pharmaceutical Manufacturers Association

Panel Discussion

All Session Speakers

V3-S2 Room 608 14:00-15:30

[Educational Session] Understand the Rules and Process of the US and EU Labeling

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

SESSION CHAIR

Rie Matsui, RPh
Director, Regional Labeling Head for Asia, International Labeling Group, Pfizer Japan Inc.

Centralized labeling within global companies has been further facilitated by MRCT progress. It is necessary to revisit the rules of US and EU labeling to identify the difference between the US/EU and Japan in order to properly understand the global headquarters' intention. Moreover, the ruling process such as US PRA or CBE, and EU labeling process such as CP or MRP will be discussed for greater understanding. This session is important for people who are actually involved in the division of labeling management, as well as for people in divisions related to the new drug development.

Regulatory Procedures for Changing the Content of Healthcare Professional Labeling and Associated Patient Labeling: USA

A. Leander Fontaine, MD
President, Pharmiceutics, LLC

Regulatory Procedures for Changing the Content of SmPC and Package Leaflet: EU?

Francesco Pignatti, MD
Head of Oncology, Haematology, Diagnostics, European Medicines Agency (EMA)

V4-S2 Room 609 14:00-15:30

Concerning the Issues of Clinical Study by Revision of the Personal Information Protection Law

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

SESSION CHAIR

Shigeto Yonemura, MD
Associate Professor, the Graduate Schools for Law and Politics, The University of Tokyo

Explaining the revised Personal Data Protection Act enforced on May 30, 2017 and the revision of "the ethical guideline for clinical study" clearly.

Introducing a concrete measure for the solution with the issues occurring newly on the fields of the clinical study in particular and discussing around the smooth and effective enforcement method of the clinical study.

The Outline and Problems of Revised Personal Data Protection Act
Shigeto Yonemura, MD
Associate Professor, the Graduate Schools for Law and Politics, The University of Tokyo

Addressing Changes in the Climate Surrounding Research Regulations at National Cancer Center
Shimon Tashiro, PhD
Head, Center for Public Health Sciences, National Cancer Center

TBC
Ryousuke Fukuda
Deputy Director, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare

Issues Clinical Research Faces Now
Koji Miura, MD, MPH, PhD
Professor, Clinical and Translational Research Center, Keio University Hospital

Panel Discussion
All Session Speakers

V5-S2 Room 610 14:00-15:30

Approaches to Enhance Appropriate Communication on Pharmaceutical Product Information - Part 1

Related Interest Area(s): RA, CP, AC, MA, O: Labeling, Marketing, Medical Writing, Medical Information
Level: Intermediate
Language: Japanese Language Only

SESSION CO-CHAIRS

Mamoru Narukawa, PhD
Professor, Graduate School of Pharmaceutical Sciences, Development of Clinical Medicine (Pharmaceutical medicine), Kitazato University

Yuko Kojima
Director, Biometrics, Medicine Development Unit - Japan, Eli Lilly Japan K.K.

It is highly important that pharmaceutical product information is appropriately provided by regulatory authorities and pharmaceutical companies, and utilized in the medical field. In the Japan annual meeting in 2016, we discussed issues arising from provision of pharmaceutical product information materials provided to healthcare professionals or patients, and handling of these issues. We have found that pharmaceutical product information is not necessarily fully utilized by the medical professionals: duplicate information is provided using various materials from the regulatory authorities and companies, necessary information for medical professionals is not provided, and the real intentions of the authors are not fully conveyed. In 2017, we will discuss approaches and future perspectives to enhance appropriate communication on pharmaceutical product information to medical professionals based on the previous discussion by summarizing the objectives and utilization methods of a wide range of information materials provided by the regulatory authorities and companies.

Provision of Drug Information by Regulators: Overview and Challenges
Tomoko Tanita
Risk Communication Promotion Division, Office of Safety I, Pharmaceuticals and Medical Devices Agency (PMDA)

Proposals for Providing Drug Information from the Viewpoint of Medical Staff
Susumu Wakabayashi
Department of Pharmacy, Kyorin University Hospital

To Enable the Patient Centered Risk Communication -The Industry Perspective-
Shinya Takemoto, MSc
Group Manager, Safety Information Strategy Group, Risk communication Department, Chugai Pharmaceutical Co., Ltd.

Information Required by Medical Institutions and Judgment of Provision for it from Industries Point of View
Junichi Nishino, MSc, RPh
Head, RA Functions Department, Regulatory Office Japan, Novartis Pharma K.K.

V5-S3 Follows

V6-S2 Room 101 14:00-15:30

Paradigm Shift in Global Development Strategy - How to Utilize ICH E17 GL in New Drug Development? –

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

SESSION CHAIR

Manabu Yanagisawa, PhD
Associate Director, Japan Regulatory Affairs, Eisai Co., Ltd.

The ICH E17 guideline is expected to reach Step 4 in 4Q 2017. This session will provide an opportunity to discuss how to utilize E17 appropriately, where global development strategy move toward, and what can be done to induce a change in our strategy. We have experienced so many evaluations of consistent or similar results among ethnic groups under E5 guideline and we know how difficult evaluation of ethnic differences and consistency among ethnic groups are. Given those experiences, this session will also address the points to consider in planning a global development program by means of E17, newly introduced pooling strategies (pooled region, pooled subpopulation), what kind of information is need for pooling, when such information to be obtained, how to present results from the Multi-Regional Clinical Trials. Those discussions would contribute to your readiness for the paradigm shift in global development strategy.

How should be the Future of Simultaneous Global Drug Development? - Road to Implementation of ICH E17 -
Nobushige Matsuoka, PhD
Clinical Statistics, Pfizer Japan Inc.

Ethnic Differences on Efficacy and Safety in a Multi-Regional Clinical Trial
Masahiro Tohkin, PhD
Medicinal Safety Science, Regulatory Science, Graduate School of Pharmaceutical Sciences, Nagoya City University

The Impact of ICH-E17 on Clinical Development Strategy and Operations
Koichi Miyazaki, PhD
Senior Director, Clinical Development Group, Asia Development Department, R&D Division, Daiichi Sankyo Co., Ltd.

Remarks through Internet
Osamu Komiyama
Senior Manager, Regulatory Policy, Regulatory Affairs, Pfizer Japan Inc.
Yoshiaki Uyama, PhD
Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals, and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Hiroshi Takeda, MS
Reviewer, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA)

V7-S2 Room 102 14:00-15:30

Patient Participation – Patient Centric Approach to Clinical Trials

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

SESSION CHAIR
Yukihiro Matsuda, MSc
Research Scientist, Trial Management, Clinical Development Operations & Innovations, Medicines Development Unit Japan, Eli Lilly Japan K.K.

To realize healthcare truly valuable to patients, a more patient-centric approach to clinical trials/clinical research is one of the essential steps. Outside Japan, even a mobile app is now available, which enables patients to find a clinical trial targeting the disease they suffer from or to look for their nearest study site.

In this session, we will look at how a patient-centric approach can make clinical trials/clinical research more relatable to patients. We will also introduce some useful mobile apps, websites, and data use ideas for Patient Participation and data collection. A panel discussion will be held to discuss the possible challenges these tools must overcome to be widely used in Japan.

A Thought about Patient Centered Clinical Trial ~ From the PRO (Patient Recruitment Organization) Perspective
Daisuke Maki
PRO Business Promotion Headquarters Office Head, CROèe Inc.

Digital Trial Guide: Awareness Activities to Clinical Trials in Eli Lilly and Company Corporate
Maki Uchimura, MBA
Clinical Innovation & Business Integration, Clinical Development Operations & Innovations, Medicines Development Unit Japan, Eli Lilly Japan K.K.

GlucoNote ResearchKit-Based Cinical Study for Type 2 Diabetes and IGT Patients
Kayo Waki, MD, PhD
Project Associate Professor, Department of Ubiquitous Health Informatics, School of Medicine, The University of Tokyo

Panel Discussion
All Session Speakers

V8-S2 Room 703 14:00-15:30

Update on Current Status and Future Directions of Proarrhythmic Risk Assessment

Related Interest Area(s): RA, CP, CR, AC, O: Cardiac Safety
Level: Intermediate

SESSION CHAIR
Kaori Shinagawa, MD, PhD
Senior Scientist for Clinical Medicine, Office of New Drug II, Pharmaceuticals and Medical Devices Agency (PMDA)

Proarrhythmic potential remains a major concern during drug development and in 2005, ICH adopted the ICH-S7B (non-clinical) and ICH-E14 (clinical) guidelines outlining the evaluation of the potential to delay ventricular repolarization. In late 2015, E14 Q&A was revised to allow the use of concentration response modeling applied to data from early phase clinical studies as an acceptable alternative to the Thorough QT/QTc Study. For more efficient and more specific proarrhythmic risk assessment, further research on clinical and non-clinical methodologies, such as novel ECG biomarkers, and use of human stem cell-derived cardiomyocytes (hSC-CMs) has been progressing. This session will provide an overview of current and future research in non-clinical and clinical proarrhythmic risk assessment, and points to consider for Japanese implementation of concentration response modeling for QT analysis. Speakers and panelists from academia, industry and regulatory agency will also discuss future perspectives of proarrhythmic risk assessment in drug development.

Potential of in Vitro TQT Study Using iPS Cell Technology
Tadahiro Shinozawa, PhD
Associate Director, Drug Safety Research Lab, Regenerative Medicine Unit, Takeda Pharmaceutical Company Limited

Role of Early Phase Clinical Trials on Proarrhythmic Risk Evaluation
Hiroyuki Fukase, MD, PhD
Director, Clinical Research Center, Clinical Research Hospital Tokyo

Assessment of QT Prolongation Risk Using Concentration Response Modeling – The Clinical Perspective -
Kaori Shinagawa, MD, PhD
Senior Scientist for Clinical Medicine, Office of New Drug II, Pharmaceuticals and Medical Devices Agency (PMDA)

Assessment of QT Prolongation Risk Using Concentration Response Modeling – Viewpoint of Model Analysis -
Yoshinori Ochiai, PhD
Advanced Review with Electronic Data Promotion Group/Office of New Drug 1, Reviewer, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Yasunari Kanda, PhD
Head of Division of Pharmacology, National Institute of Health Sciences
Yuji Kumagai, MD, PhD
Director of Clinical Trial Center, Kitasato University Hospital
Atsushi Sugiyama, MD, PhD
Professor and Chairman, Department of Pharmacology, School of Medicine, Toho University Faculty of Medicine

COFFEE BREAK 15:30-16:00

SESSION 3 16:00-17:30

V1-S3 Room 605/606 16:00-17:30

Raise the Curtain of "Patient Centricity" in Japan (Part II): Learn by Trial and Error

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

SESSION CHAIR
Norie Miki-Yasuda, PhD
Head of Japan Clinical Operations Division, Janssen Pharmaceutical K.K.
Kaori Muto, PhD
Professor, Department of Public Policy, The Institute of Medical Science, The University of Tokyo

The idea of Patient Centricity and Patient and Public Engagement are increasingly attracting interest in Japan, while their concept and idea have not been organized among various stakeholders. In this session , pharmaceutical companies will share their activities for patient centricity in clinical trials and discuss Patient Centricity and Patient and Public Engagement together with the speakers of the part 1 session.

Innovating with the Patient, for the Patient
Andreas Koester, MD, PhD
Head of R&D Operations Innovation, Janssen Research & Development, LLC

Pharma Company's Patient Centric Activities
Atsushi Kitamura
Director, Clinical Operations and Compliance, Development Japan, Pfizer Japan Inc.

Utilization of Patient Voice to Study Planning
Kazuyuki Suzuki
Oncology Trial Management Group, Trial Management Department, Japan Development, Novartis Pharma K.K.

Panel Discussion
All Speakers for V1-S2 and V1-S3

V2-S3 Room 607 16:00-17:30

Artificial Intelligence Leads to Realize Medical Innovation

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

SESSION CHAIR

Hiroyuki Mano, MD, PhD
Director, National Cancer Center Research Institute
Professor, Department of Cellular Signaling, Graduate School of Medicine, The University of Tokyo

The advancement of digital tools and technologies such as artificial intelligence (AI), which aims at creating new industries and improvements of efficiency in research and development, raises more expectations on medical innovation including three major components (Government, Academia and Industry), quality and safety of medical care, advanced medical care and more efficient medical service,

This session will provide an overview of the future of digital health by introducing an example of better use AI; Watson for Genomics for gene therapy and Watson for Drug Discovery for transforming drug discovery and health. At the panel discussion, the current situation and challenges surrounding advancing AI technologies and ideal medical use will be discussed. In addition, the session will provide real AI use with Watson as a hands on experience.

IBM Watson Health – Transforming Drug Discovery & Health
Toshifumi Mizokami
Business Development Executive, IBM Japan, Ltd.

Precision Medicine Based on Genome Analysis: Actual and Future Prospect for Medical Artificial Intelligence Development
Toshifumi Wakai, MD, PhD, FACS
Professor and Chairman, Division of Digestive and General Surgery, Niigata University Graduate School of Medical and Dental Sciences

V3-S3 Room 608 16:00-17:30

What Needs to Be Done for Creating Labeling Based on the New Revision of Items to be Included?

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

SESSION CHAIR

Ken Nakajima, PhD
Deputy Head of Medical Safety, Pharmacovigilance Department, Otsuka Pharmaceutical Co., Ltd.

The Japan labeling regulations has been amended for the first time in 20 years and will be implemented in 3 years, which means that each company needs to prepare labeling according to the new revision of the labeling regulations. In order to do so, various preparations including verification of rationale of the current items and review of the latest data may be needed. In this session, PMDA will provide details on not just the summary of the new revision of items to be included, but points to be practically considered from the standpoint of PMDA. Also, as we need to observe our reality, action items will be picked up from a corporate perspective and will be discussed. The best practices and challenges for revision of labeling should be shared and discussed. A speaker from multinational companies will describe points to be considered as foreign-based companies, especially how to proceed this project including the communication between HQ. In addition, a difference in approach between foreign-based companies and domestic HQ companies will be discussed.

Points to Revision of Package Inserts Based on the New Revision of Guide to Drafting Package Inserts -from the Standpoint of PMDA-
Akifumi Kamata, PhD
Reviewer, Office of Safety II, Pharmaceuticals and Medical Devices Agency (PMDA)

Discussion of Best Practice and Challenges for Revision of Labeling
Hanako Saito
Senior Director, Safety and Risk Management Department, Safety Information Management Group, Daiichi Sankyo Co., Ltd.

Issues and Solutions for Addressing the New Revision of Guide to Drafting Package Inserts -from the Standpoint of Global Company-
Jun Ishikawa
International Labeling Group Asia, Japan Team Lead, Pfizer Japan Inc.

Panel Discussion
All Session Speakers

V4-S3 Room 609 16:00-17:30

What is the Role of Medical Science Liaison (MSL) as New Function of Pharmaceutical Company?

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

SESSION CHAIR

Koji Iwasaki, PhD
Professor, Academic Clinical Research Center, Department of Medical Innovation, Osaka University Hospital

The pharmaceutical companies are starting to establish medical science liaison (MSL) as the new type of job to assume and exchange medical scientific information.

In this session, we will discuss an appropriate profit of the drug information about an activity of MSLs

In addition to catch the situation of MSL activities in the pharmaceutical company, we will clarify recognition of MSLs by Academia and MHLW. And then we discuss around the future appropriate drug information and the talent of MSLs.

The Role of MSL - Expectation from Academia -
Masaru Iwasaki, MD, PhD
Vice President, Director of Center for Advancing Clinical Research, University of Yamanashi

The Positioning and Activity Principles of MSL - EFPIA Japan -
Yoshihiko Otoguro
Chair of Corporate Ethics Sub-committee / Governance and Legal Committee, European Federation of Pharmaceutical Industries and Associations

MSL: Their Role and What They Should be Equipped for
Michiko Tomiyasu, MS
Manager, Medical Excellence & Training, Medical Affairs, Sanofi K.K.

Expectation to Medical Science Liaison (MSL) in the Utilization of Drug Information from Regulatory Authorities
Yoshifumi Banzai, PhD
Deputy Director, Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Panel Discussion
All Session Speakers

V5-S3 Room 610 16:00-17:30

Approaches to Enhance Appropriate Communication on Pharmaceutical Product Information - Part 2

Related Interest Area(s): RA, CP, AC, MA, O: Labeling, Marketing, Medical Writing, Medical Information
Level: Intermediate
Language: Japanese Language Only

SESSION CO-CHAIRS

Mamoru Narukawa, PhD
Professor, Graduate School of Pharmaceutical Sciences, Development of Clinical Medicine (Pharmaceutical Medicine), Kitazato University

Yuko Kojima
Director, Biometrics, Medicine Development Unit - Japan, Eli Lilly Japan K.K.

It is highly important that pharmaceutical product information is appropriately

provided by regulatory authorities and pharmaceutical companies, and utilized in the medical field. In the Japan annual meeting in 2016, we discussed issues arising from provision of pharmaceutical product information materials provided to healthcare professionals or patients, and handling of these issues. We have found that pharmaceutical product information is not necessarily fully utilized by the medical professionals: duplicate information is provided using various materials from the regulatory authorities and companies, necessary information for medical professionals is not provided, and the real intentions of the authors are not fully conveyed. In 2017, we will discuss approaches and future perspectives to enhance appropriate communication on pharmaceutical product information to medical professionals based on the previous discussion by summarizing the objectives and utilization methods of a wide range of information materials provided by the regulatory authorities and companies.

Panel Discussion

All speakers for V5-S2 and

Toyotaka Iguchi, MD, PhD

Risk Management Director, Office of Safety II, Pharmaceuticals and Medical Devices Agency (PMDA)

V6-S3 Room 101 16:00-17:30

The Way toward Commercialization, Regenerative Medical Products

Related Interest Area(s): RA, CP, ST, PM, CMC, AC

Level: Beginner

SESSION CHAIR

Yoji Sato, PhD

Head, Division of Cell-Based Therapeutic Products, National Institute of Health Sciences

The long way is lying from the discovery of regenerative medical seeds toward the commercialization. In this session, hot topics in academia study and current development case in company will be presented. And also, the considering points in clinical trial of approved regenerative medical products from reviewer point of view will be explained.

The issues emerging in the various development stages will be identified and the solutions will be explored through the lectures and panel discussion.

Challenge from Academia to Remove Knee Pain by Regenerative Medicine

Ichiro Sekiya, MD, PhD

Professor, Tokyo Medical and Dental University

Developing Regenerative Medicine using Cell Sheet Engineering

Setsuko Hashimoto, PhD

President and CEO, CellSeed Inc.

Safety and Efficacy Evaluation of Regenerative Medical Products

Yoshiaki Maruyama, PhD

Review Director, Office of Cellular and Tissue-Basaed Product, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All Session Speakers

V7-S3 Room 102 16:00-17:30

Current Status on Counterfeit Medicines in Global and Issues on Japanese Market

Related Interest Area(s): RA, CP, CMC, O: Counterfeit

Level: Beginner

SESSION CHAIR

Yoshiaki Ohashi, PhD

Head of Quality & Regulatory Compliance Unit, Chugai Pharmaceutical Co., Ltd.

The threat of counterfeit medicines is increasing worldwide, and it creates serious risks to patient safety. In particular, many cases of medicines purchased over the internet have been found to be counterfeit. Therefore, it is necessary that pharmaceutical companies take initiatives including implementation of anti-counterfeiting technologies and working with Customs and law enforcement agencies.

In Japanese medicine market, it has been traditionally considered that counterfeit medicines would not be distributed, however, the "Harvoni" case indicates it would no longer true and can be a tip of the iceberg. In this session, trend of counterfeit medicines in global market, as well as the corrective actions, would be first introduced. And then, panelists from NPO, industry and academia will discuss potential risks and necessary actions in Japanese market, in order to secure patient safety as well as medicine quality.

Global Situation Report 2016

Martin Blair

Asia Pacific Regional Manager, Pharmaceutical Security Institute (PSI)

TBC

Kazuko Kimura, PhD

Researching Professor Emerita, Kanazawa University

TBC

Pius Waldmeier

F. Hoffmann-La Roche, Ltd.

A Company Framework, Objectives and Risk

Scott Kammer, MA

Head, Global Product Protection, Takeda Pharmaceuticals U.S.A., Inc.

Panel Discussion

All Session Speakers

V8-S3 Room 703 16:00-17:30

Call for Abstract Session

Related Interest Area(s): RA, CP, CR, O: ROD

Level: Beginner

SESSION CO-CHAIRS

Kazuhiro Kanmuri, PhD

Pfizer Japan Inc.

Koichiro Yuji, MD, PhD, FACP

Project Associate Professor, Project Division of International Advanced Medical Research, The Institute of Medical Science, The University of Tokyo

Four outstanding research speakers are selected for this year's Call for Abstract session out of more than large number of applications from Japan and overseas compared to the last year from various themes through a rigorous selection process. Speakers show their knowledge, experience, and research suited to the theme of this annual meeting. Current hot topics will be beneficial to your future business in medicine development.

Transforming Pharmacovigilance through Robotic Process Automation and Cognitive Technologies

Glenn Carroll, MBA

Principal, Strategy and Operations, Life Sciences, Deloitte Consulting LLP

Rare Diseases in the Era of Precision Medicine

Dinah Duarte, PharmD, MSc

Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED

ASEAN Therapeutic Product Market Access & Regulatory Strategy

Kenny Peng, MASc, RAC, P.Eng

Managing Director, PharmEng Technology Pte. Ltd., Singapore

Integration of ICH E14 Cardiac Safety in Phase I studies and Validation of Exposure-QTc Relationships

Jörg Täubel, MD, FFPM

Chief Executive Officer, Richmond Pharmacology Ltd.

ENGAGE AND EXCHANGE: SPECIAL CHAT SESSION

LET'S CHAT! "WHAT'S THE DIA WORLD 2017"

RECEPTION HALL

17:45-19:00

Related Interest Area(s): ALL

Level: ALL

SESSION CHAIR
Keiichi Inaizumi, MSc
Manager, Clinical Operations and Compliance 1, Development Operations, Pfizer Japan Inc.

FACILITATORS
DIA Japan Contents Committee / Community

"Special Chat Sessions" will be provided for members to exchange opinions, questions, or issues and to build networking among attendees. Young or experienced attendees, academia or students, investigational sites or PMDA – please sit around our table and be our companions! Let's talk together.

This session will be a casual discussion in a free-discussion format of small groups of people. We are going to provide some discussion topics. Please visit your interest table and join the discussion of a theme in which you are interested. The views and opinions expressed in Chatting are those of the individual participants and should not be attributed to DIA, affiliates, or any organization with which the participants is employed or affiliated.

<List of Topics>

#	Category	Topic	Facilitators	Abstract
1	Statistics	Current Trend of Statistics for Clinical Trials	**Naokazu Gion** Ono Pharmaceutical Co., Ltd. **Akihiro Hirakawa, PhD** The University of Tokyo	We will focus on the recent topics on clinical trials/researches such as MRCT, construction of estimand, drug development for rare diseases, use of big data, integrity of clinical trials, modeling and simulation, education of biostatistics, and biosimilars. For these topics, this session intends to share the basic principles, tasks, and measures that statisticians should consider. Through this discussion, we expect that the deeper understanding of these topics would be expanded between industry, regulatory, and academia.
2	PV	Big Data, What Is Its Value from PV Perspective? How to Use It? Is It Really Creditable?	**Kotonari Aoki, MS** Chugai Pharmaceutical Co., Ltd. **Rei Maeda** Eli Lilly Japan K.K.	Time has come to implement Japan DBs into PMS and PV, such as MID-NET available in 2018 and marketed DBs that are becoming large. Regulations, e.g., GPSP, are being prepared; however, circumstance including capable people allocation is still insufficient. In this session, let us talk about possibility and issues of DBs and practical use of deliverables from DB research.
3	Labeling	What Will Be Affected by Newly Revised "Guide to Drafting Package Inserts for Ethical Drugs"	**Rie Matsui, RPh** Pfizer Japan Inc.	Since the Japan labeling guidelines have been amended for the first time in 20 years and will be implemented in 3 years, each company has been started to discuss how to proceed according to the new labeling guidelines. In this session, the information related to the new labeling guideline will be shared widely and the expected issues & solution will be discussed.
4	Six Sigma	How We Enjoy Problem Solving Workshop?	**Hirotaka Inoue, PhD, MBA** GlaxoSmithKline K.K.. **Goshi Ozawa, MS, Lean Six Sigma Certified BB** Real Discovery Outdoors Co.,Ltd.	Problem solving techniques are used for better progress of our business. We often use problem solving workshop but many of facilitators always look for the better ways of "design" and "execution" We will expect sharing success/failure experiences to obtain some insgihts on better problem solving.
5	Clinical Strategy	Let's Discuss "Career Plan Deign" - Nobody Designs Your Career Plan. You Need to Own It!	**Chika Kiryu, DVM, PhD** Otsuka Parmaceutical Co., Ltd. **Yukiko Matsushima, MS, CCRC** Clinical and Translational Research Center, Keio University Hospital **Shizuko Ueno, RPh** Daiichi Sankyo Co., Ltd.	You seem that you are always strategic in your work. Can you still say you are also strategic for your career? What do you want to be in the future? Do you have a strategy or a plan of your future career? The chatting session led by the Clinical Strategy Community will provide a great opportunity for the people participating to the DIA Japan Annual Meeting. It doesn't matter where you belong to and we are also welcome anyone seeking your career goal. The important thing is that you are the most important player to own your career. We strongly hope you will find various ideas to realize your career dream come true. Your time to grow is so valuable for yourself as well as the people waiting for new treatment. Be strategic, proactive and feel free to join us!
6	Project Management	How Do You Set in the First Step of the Project Manager Development?	**Koichi Konno, PMP** DIA Japan Project Management Community Lead **Takashi Sato, MSc, PMP** Kyowa Hakko Kirin Co., Ltd.	To lead a project to the success, PM is playing a significant role and a responsibility. As for the development of the competency of PM, it is implemented in many organizations but the trial and error still continues. In this session, we share the example of the PM training among the participants and want to explore the point of the PM development in the future.
7	Regulatory Affairs	Let's Have Better Communication between PMDA and Industries, Understanding Each Other's Situations	**Toshinori Higashi, PhD** CTD Inc. **Masato Komuro, PhD** Novartis Pharma K.K.	In order to have smooth correspondences between PMDA and industries, let's talk about each real thoughts and situations. In addition, let's discuss a proposed improvement regarding the process of getting NDA approval. <Example> 1) Why PMDA give a micro query at unexpected timing? 2) Why industries take a long time for answer preparation with regardless of easy questions? PMDA wants to know a working procces by industries end. 3)Let's discuss a proposed improvement of reiew process with understanding each other situations.
8	Clinical Operations and Monitoring	Patient Centricity Efforts and Expectations in Clinical Trials - Patient-Centered Changes Clinical Trial -	**Mitsuo Hayashi, MSc** MSD K.K. **Yukihiro Matsuda, MSc** Eli Lilly Japan K.K.	Each company raises "Patient first", and new efforts on Patient Centricity are increasing in clinical trials as well. Why now Patient Centricity? What kind of initiatives does each company do? And how will clinical trials change? Let's talk about Patient Centricity!
9	Medical Communication	Consider Ideal Handling of Pharmaceutical Information from The Patient Perspectives! - Appropriate Use of Pharmaceutical Products and Proper Handling of Pharmaceutical Information -	**Junichi Nishino, MSc, RPh** Novartis Pharma K.K. **Keiko Tsumori** MSD K.K.	We are now living in the world where various kinds of pharmaceutical information is readily available on the internet and almost everyone can easily access to such pharmaceutical information using their smartphones or PCs. Is the information true and based on evidence? What if patients made wrong decisions based on wrong information? We, as an pharmaceutical information provider, want to openly exchange opinions on how we communicate appropriate and right information to patients in this information-flooded era.
10	Data Management	Let's Chat about How Postmarketing Clinical Trials Change with Utilization of ICT (Patient Registry, Big Data Analytics, DB Studies, etc.)	**Motohide Nishi, MBA** Medidata Solutions K.K. **Yumi Sugiura, MRCP** Bristol-Myers Squibb K.K.	Recently, the use of Real World Data for clinical development, post-marketing surveillance is drawing attention. Utilization of medical information database will be accelerated because of the revision of GPSP and the start of operation of MID-NET. Let's talk about points to be noted and issues concerning future medical information database utilization.

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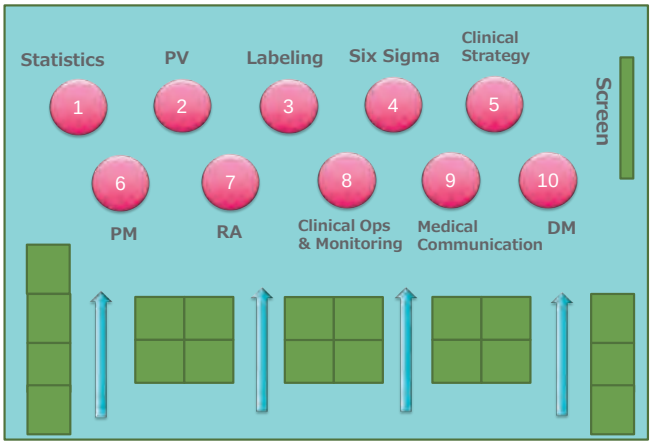

SESSION 4 9:00-10:30

V1-S4 Room 605/606 9:00-10:30

The Changing Environment in the World and the Impact on the Pharmaceutical Industry

Related Interest Area(s): RA, O: ALL

Level: Beginner

SESSION CHAIR

Kihito Takahashi, MD, PhD
Vice President and Senior Managing Director, Development & Medical Affairs Division, GlaxoSmithKline K.K.

There was a worldwide impact event such as Brexit in EU and presidential election in US last year.

This session is made up of 2 parts, the first part is Brexit. We would like to discuss the influence of Brexit for pharmaceutical companies in the world.

On the other hand," the international Summit of Heads of Medicines Regulatory Agencies" and" meeting of the International Coalition of Medicines Regulatory Authorities (ICMRA)" will convene for the first time in Japan, at the Kyoto in October and the representatives from a variety of countries and industries will discuss innovative technological developments and their practical applications, both current status and future expectations.

In this session, we would like to confirm the movement in the world and discuss about the impacts and prospect in Japan.

The Brexit and the Possible Implications for Marketing Authorisation Holders

Peter Bachmann, PhD
Chair, CMDh, Federal Institute For Drugs and Medical Devices (BfArM)

TBC

Kazuhiko Mori, MSc
Councilor for Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare

Panel Discussion

All Session Speakers and

Alberto Grignolo, PhD
Corporate Vice President, Global Strategy, PAREXEL International

Takuko Sawada
Director of the Board, Senior Executive Officer, Senior Vice President, Corporate Strategy Division, Shionogi & Co., Ltd.

Tadaaki Taniguchi, MD, PhD
Director & Vice President, R&D Japan, AstraZeneca K.K., Japan

V2-S4 Room 607 9:00-10:30

How to Use Statistics Correctly - Understand the Meaning of P Values and Eliminate Misuse

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

Level: Beginner

Language: Japanese Language Only

SESSION CHAIR

Yoichi M. Ito, PhD
Associate Professor, Department of Biostatistics, Hokkaido University Graduate School of Medicine

There are many statistical perspectives that should be discussed in planning clinical trials and inferring their results. It is necessary to understand statistical methods and results (p value, summary statistics, etc.) correctly. Especially misuse will lead to incorrect interpretation of the results. In The ASA Statement on Statistical Significance and P-values (2016) presented six important principles. Meanwhile, the recommendation on reviewing the advertising method of medical drugs (October 22, 2014: Meeting of Health Labor Science Research Group) suggests about accuracy of product information brochures and advertisements provided by pharmaceutical companies after launch doing. DIA Statistics WS has conducted a statistical workshop for those who are not biostatistics experts engaged in drug development over five times. This session explains the concept of p-value interpretation and statistical methods based on the contents of that statistical workshop. In addition, we introduce points to be noted about the result display in product information brochures and advertisements.

General Commentary on Misuse of P-Value : According to ASA Statement on P-Values

Ayano Takeuchi, PhD
Department of Preventive Medicine and Public Health, School of Medicine. Lecturer, Keio University

Pitfalls Surrounding P-Value in Drug Development

Moriyuki Miyasato, MBA
Director, Biostatistics Department, Janssen Pharmaceutical K.K.

Providing Information on Medical Drugs with Consideration of Evidence Level

Kazumasa Takenouchi
Senior Manager, Biostatistics Group, Data Science, Astellas Pharma Inc.

V3-S4 Room 608 9:00-10:30

What is the New GPSP Ordinance Requirements for Post-Marketing Studies Using Healthcare Database?

Related Interest Area(s): RA, CR

Level: Beginner

Language: Japanese Language Only

SESSION CHAIR

Mitsune Yamaguchi, PhD
Director for MID-NET project, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

Kunio Itoh
Director & PMS Manager, Clinical Research & Pharmacoepidemiology Department, Taiho Pharmaceuticals Co., Ltd.

The new GPSP, which is planned to be effect in April 2018, will accept the database utilization as the post-marketing surveillance for re-examination submission package. First, in this session, PMDA (Office of Non-clinical and Clinical Compliance) is going to explain the basic principles on assurance of data reliability for post-marketing studies based on electronic health information data. Second, the data holders including MID-NET® will introduce their activities for complying with the GPSP. Third, from industry's point of view, efforts for establishing internal system will be present. At the end, in the panel discussion, current issues and future perspectives will be discussed.

Basic Principles on Warranty of Reliability of Data when Preparing Re-examination Application Dossier by Using Electric Medical Record Database

Satoru Nakamura
Inspection Director, Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Devices Agency (PMDA)

How to Utilize Data from MID-NET® for Re-Examination Application

Sayoko Harada, MPharm, RPh
Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

Readiness for GPSP among Database Vendors

Jin Uesawa, MBA
President, Japan Medical Data Center

Pilot Study Using the Healthcare Database Looking ahead to GPSP Inspection

Shimpei Niwa, PhD
Safety and Risk Management Department, Daiichi Sankyo Co., Ltd.

Panel Discussion

All Session Speakers

V4-S4 Room 609 9:00-10:30

Are the Drugs Appropriately Reaching to the Pediatrics in Needs? - Current Development Status and Future Steps of Pediatric Drugs in Japan -

Related Interest Area(s): RA, CR, PM, AC

Level: Intermediate

Language: Japanese Language Only

SESSION CHAIR

Natsuko Hamada
Japan Regulatory Affairs, Eli Lilly Japan K.K.

While drug-lag is being solved with the advance in Global drug development, currently, development of pediatric drugs in Japan is lagging behind. The development of pediatric drugs is ongoing in EMA under PIP (Pediatric Investigation Plan), and in FDA under PSP (Pediatric Study Plan). Now that Global drug development including Japan is becoming a main stream, a discussion has started for Japan to join in Global drug development also for pediatric drugs. In US and Europe, over 10 years have passed since the development of pediatric drugs (PSP, PIP) were promoted by the national governments. With Addendum to ICH E11 is currently at Step3, upon receiving future prospects in Japan from MHLW and PMDA, this session will hold a progressive discussion on promoting the development of pediatric drugs in Japan from government-industry-academia stance, respectively.

New Approach for Pediatric Medicines in Japan
Masakatsu Imoto, MD, PhD
Director, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare

The Role of Japan Pediatric Society for Promotion of Pediatric Drug Development
Masao Nakagawa, MD
Japan Pediatric Society

Pediatric Drug Development in Japan and International Regulatory Collaboration
Masakazu Hirata, PhD
Review Director, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Katsuaki Sato
GlaxoSmithKline K.K.

V5-S4 Room 610 9:00-10:30

How Do You Set in the First Step of the Project Manager Development?

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

SESSION CHAIR

Koichi Konno, PMP
DIA Japan Project Management Community Lead

To lead a project to the success, PM is playing a significant role and a responsibility.

As for the development of the competency of PM, it is implemented in many organizations but the trial and error still continues. One of the reasons is because the ideal way of desired PM depends on the structure and the culture of each organization. Therefore, it thinks that it is difficult to build a standard development method.

In this session, as the example to create the guidance for the participant to be advanced "PM which is wanted to / want to be ", we introduce Project Manager Competency Development Framework (PMCDF).

Then, we find out the point to consider in case of PM development in the future after sharing the case of the PM development by the panelists engaged in the PM education.

TBC
Kotone Matsuyama, RPh
Professor, Medical Management, Nippon Medical University / Vice President, Integrated Clinical Research Center, Educational Institute, Nippon Medical University

TBC
Noriko Fujiwara, MS, RN, OCNS, CCRP
The University of Tokyo

TBC
Noriko Yoshida
Project Planning & Management Forum

How Do You Set in the First Step of the Project Manager Development?
Michiyo Ohshima, MBA
Director, Japan Portfolio & Project Management Development, Pfizer Japan Inc.

Panel Discussion
All Session Speakers

V6-S4 Room 101 9:00-10:30

Quality by Design; Strategically Building the Quality of Clinical Study by Academia

Related Interest Area(ts): RA, DM, CR, ST, AC, O: MA
Level: Beginner

SESSION CHAIR

Koji Iwasaki, PhD
Professor, Academic Clinical Research Center, Department of Medical Innovation, Osaka University Hospital

Recently, it is necessary to keep the quality of clinical studies that organized by pharmaceutical company. Creating clinical study protocol by the method of "Quality by Design (QbD)" and it's risk based monitoring (RBM) will be expected with ICH-E6 and ICH-E8 renovation. The pilot study around RBM was progressed, however the method of QbD will discuss deeply. In this session, we will discuss around the strategic manner to create the quality of clinical study by the method of QbD.

QMS in ICH E6 (R2)
Tsukasa Ikeda
Director, Quality Assurance AsiaPac, AstraZeneca K.K.

Implement Quality by Design in Clinical Studies ~ for a Practical Application of Quality Tools ~
Hirotaka Inoue, PhD, MBA
Head, Leading Changes Office, Development & Medical Affairs Division, GlaxoSmithKline K.K.

Quality by Design from the View of Clinical Operation
Tatsuya Koishi, MSc
Clinical Development Department 3, Clinical Development Division 1, Development Business Headquarters, EPS Corporation

Quality by Design from the Viewpoint of Reliability
Makoto Hirose, MSc
Office Director, Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Device Agency (PMDA)

Panel Discussion
All Session Speakers

V7-S4 Room 102 9:00-10:30

More Advanced Approach of Medical Big Data - Part 1

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

SESSION CO-CHAIRS

Hisahi Urushihara, DrPH, MS
Professor, Division of Drug Development & Regulatory Science, Faculty of Pharmacy, Keio University

Yuji Yamamoto, MD, MBA
Founder and CEO, MinaCare Co., Ltd.

Medical big data have become indispensable in medicine development. Many people have been making decision by reference to information come from big data analysis. In this session, we will comprehensively review the advanced approach for big data utilization and future perspective with pioneering experts from Global as well as Japan. We will share advanced examples of clinical trial design and operations including randomized pragmatic trials, outcomes research and post-marketing safety assessments. The potential impact of GCP renovation will also be discussed.

Real-World Evidence and Next Generation Regulatory Decision Making
Nancy A. Dreyer, PhD, MPH, FISPE, FDIA
Head, Center for Advanced Evidence Generation, Global Chief, Scientific Affairs, Quintiles IMS

Application of Medical Big Data to Clinical Trial Simulation
Akiyuki Suzuki, MS
Senior Manager, Pharmacometrics Group, Clinical Pharmacology, Pfizer Japan Inc.

Application Case –Outcomes Research using Real World Data–
Shinzo Hiroi, MPH, RPh, PMP
Head, HEOR Program, Japan Medical Affairs, Takeda Pharmaceutical Company Limited

V7-S5 Follows

V8-S4 Room 703 9:00-10:30

Clinical Development of Biosimilar Products

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

SESSION CHAIR
Teruyo Arato, PhD
Professor, Hokkaido University Hospital

Biosimilar products have been actively developed globally, and it has been widely discussed how to evaluate the biosimilarity with reference product. This session will focus mainly on scientific considerations of clinical development and clinical trial for biosimilar products. Speakers will introduce key features of clinical data package and study design in the development of biosimilar products. In addition, some statistical issues will be discussed. We would also like to discuss the differences of approaches among countries/regions, which could be the challenges in global development.

Biosimilar Challenges from the Point of View of Project Management
Yuko Kawakita, RPh
Global Project Management Department, Daiichi Sankyo Co., Ltd., Japan

[Call for Abstract] Regulatory and Scientific Issues on Biosimilar Development in the U.S: Lessons Learned from Recent Approvals
Duu-Gong Wu, DrSc, PhD
Senior Director, Global Regulatory Consulting, PPD

Statistical Considerations for the Development of Biosimilar Products [Recorded Presentation]
Nan Zhang, PhD
Biostatistics Senior Manager, Biosimilar Division, Amgen Inc.

Comparative Clinical Study Designs for Biosimilar Development Program
Kota Tokushige, MS
Integrated Biostatistics Japan, Clinical Development, Novartis Pharma K.K.

COFFEE BREAK 10:30-11:00

SESSION 5 11:00-12:30

V1-S5 Room 605/606 11:00-12:30

Regulations for Conditional Accelerated Approval System and Early Access to Drug Products

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

SESSION CHAIR
Toshio Fujimoto, MD, MBA
Japan Development Leader, Development Center of Excellence Japan, Eli Lilly Japan K.K.

Recently, various regulations have been developed to make realize early access to drug products. In addition to the conventional Orphan Designation, Priority Review and Advanced Medical Care, plans for SAKIGAKE Designation, Conditional Accelerated Approval System, Expanded Access Trial and Patient-requested Treatment System have been established.

This session will clarify the outline of Conditional Accelerated Approval System and compartmentalization with other regulations, discuss in depth for Expanded Access Trial and Patient-requested Treatment System including actions to be taken by pharmaceutical industry and in medical practice.

Conditional Early Approval System and Other Comparable Approval System in Japan
Yasuhiro Araki
Deputy Director, Pharmaceutical Evaluation and Licensing Division, Ministry of Health, Labour and Welfare

Conditional Early Approval System and Expanded Access Trials - Expectations and Challenges from Industry Perspective -
Kae Nakashima, DVM, PhD, MS
Pfizer Japan Inc.

Can We, Academic Researchers, Contribute for an Expediting Access Scheme in Japan?
Taro Shibata, PhD
Director, Biostatistics Division, Center for Research Administration and Support, National Cancer Center

Panel Discussion
All Session Speakers and

Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

V2-S5 Room 607 11:00-12:30

For RMP That can be Utilized by Healthcare Professionals

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

SESSION CHAIR
Kazuhiko Ishida, MSc, RPh
Associate Director, Pharmacovigilance, Astellas Pharma Inc.

PMDA and AMED study results show that "awareness of RMP" among healthcare professionals (particularly hospital pharmacists) and "utilization of RMP for pharmacy operations in medical institutions" have been increasing every year. Meanwhile, many of the companies preparing RMP consider RMP only as documents to be submitted to the regulatory authority. In these situations, some hospital pharmacists say that many points of the current RMP are difficult to understand and use for pharmacy operations at medical institutions in terms of naming risks or reasons of setting. We will discuss what healthcare professionals expect from RMP and how companies and the regulatory authority should respond to expectations from healthcare professionals when we think about the utilization of RMP for pharmacy operations at medical institutions.

Current Status of RMP Utilization in Hospitals and Recommendations for RMP - Based on AMED Research Narukawa Team Results
Masahiro Hayashi, PhD
Director, Department of Pharmacy, Toranomon Hospital

RMP Utilization for ADR Reporting in the Community Health Care Setting
Taku Obara, PhD
Associate Professor, Tohoku University Tohoku Medical Megabank Organization, Tohoku University Graduate School of Medicine, Tohoku University Hospital

Pharmaceutical Company's Approach for the Usage of Risk Management Plan (RMP) in Medical Settings
Shinya Takemoto, MSc
Group Manager, Safety Information Strategy Group, Risk communication Department, Chugai Pharmaceutical Co., Ltd.

Regulatory Efforts to Promote Broader Use of Risk Management Plan in Clinical Practice
Yusuke Matsunaga, PhD
Reviewer, Office of Safety II, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

V3-S5 Room 608 11:00-12:30

Changing Landscape of Phase I Trials in Oncology

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

SESSION CHAIR

Akihiro Hirakawa, PhD
Project Associate Professor, Department of Biostatistics and Bioinformatics, Graduate School of Medicine, The University of Tokyo

The role of phase I trial is changing to streamline cancer clinical development. It is common to carry out a dose escalation trial using 3 + 3 design, but in recent years various novel designs including global phase 1 trials are drawing attention. By knowing various options related to phase 1 trials, development strategies can be optimized. In this session, we will discuss on the novel designs, multiregional phase 1 trial, and phase 1 trials based on the characteristic of investigational drug.

Changing Landscape of Phase I Trials in Oncology: Overview
Akihiro Hirakawa, PhD
Project Associate Professor, Department of Biostatistics and Bioinformatics, Graduate School of Medicine, The University of Tokyo

Points to be Consider when Joining Multi-Regional First-In-Human Studies in Oncology
Tomoyuki Kakizume, PhD
Clinical Development Japan, Integrated Biostatistics Japan Department, Biostatistics Oncology Group, Novartis Pharma K.K.

Strategic Phase I Trials based on the Characteristic of Investigational Drug
Tomohiro Tanaka, MS
Clinical Science & Strategy Department, Chugai Pharmaceutical Co., Ltd.

PMDA Perspective
Hiroyuki Sato, PhD
Reviewer, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

V4-S5 Room 609 11:00-12:30

Quality by Design; Strategically Building the Quality of Clinical Study by Academia

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

SESSION CHAIR

Takuhiro Yamaguchi, PhD
Professor, Division of Biostatistics, Tohoku University Graduate School of Medicine

How to secure critical quality for clinical trials is attracting worldwide attention as a design or management issue and that also introduced into the reflection paper of the E6 guidelines agreed last November and the E8 guidelines issued in January 2017.

In this session, we outline the Quality by design and the Risk based approach to secure quality of clinical trials with an exit strategy, and make discussions.

Building Quality in Academic Clinical Trials –Challenges to Overcome–
Takuhiro Yamaguchi, PhD
Professor, Division of Biostatistics, Tohoku University Graduate School of Medicine

Key Concepts of TransCelerate RBM Methodology
Satoshi Saeki, MSc
Associate Director, Business Process Improvement, Astellas Pharma Global Development, Inc.

Protocol Development Process Using Quality by Design Method
Kotone Matsuyama, RPh
Professor, Medical Management, Nippon Medical University / Vice President, Integrated Clinical Research Center, Educational Institute, Nippon Medical University

Clinical Trial Act and Quality Control and Assurance
Masakatsu Imoto, MD, PhD
Director, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare

Panel Discussion
All Session Speakers

V5-S5 Room 610 11:00-12:30

What Are You Going to Do? How Will You Develop Young Staff's Careers? How Will We Make Our Organization More Productive?

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

SESSION CHAIR

Chika Kiryu, DVM, PhD
Associate Manager, Oncology, Department of Clinical Management, Headquarters of Clinical Development, Otsuka Pharmaceutical Co., Ltd., Otsuka Parmaceutical Co., Ltd.

The paradigm shift in new drug development is accelerating. The business model has changed due to changes in regulations, enormous R & D expenses, increase in development difficulty, furthermore, IT and globalization, and the transformation of the industry is a pressing matter.

On the other hand, are we responding sufficiently to securing human resources and improved skills? With limited time and money, how can we secure the talent who will take responsibility for change and improved productivity?

In this session, we would like to provide a forum for both the young and the experienced staff to learn from each other, and to have a substantive discussion about career development.

We also share the voice of 100 young responders to our questionnaires regarding "career" in the session.

The Voice of 100 Young Staffs - From our Questionnaires Regarding "Career" -
Kenta Nakaji, RPh
Clinical Development Department 3, Clinical Development Division 1, Development Business Headquarters, EPS Corporation
Tokuhito Sumitani, MS, RPh
Clinical Development Department, R&D Division, Daiichi Sankyo Co., Ltd.
Sho Mizokawa, MSc, RPh
Japan-Asia Clinical Development 2, Development, Astellas Pharma Inc.

CEO of Your Own Career
Miyako Ishiwata, RPh
Senior Manager, Head of Induction Manager Group, Clinical Operation Japan, PAREXEL International

Human Resource Strategies for Recruitment, Talent Training and Career Advance to Develop Global Players
Youji Miyatake
Director, Office of Talent Development, HQ of Clinical Development, Otsuka Pharmaceutical Co., ltd.

Talent Development in "Post-Globalization" Era
Shogo Tsuyuki, PhD
Head of Global Development University, Japan Development, Novartis Pharma K.K.

Panel Discussion
All Session Speakers and
Shizuko Ueno, RPh
Senior Director, Group VI, Clinical Development Department, R&D Division, Daiichi Sankyo Co., Ltd.

V6-S5 Room 101 11:00-12:30

CRO Management for Effective Collaboration

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

SESSION CHAIR

Nobuhiro Koga, MBA, PMP
Portfolio Director, Portfolio Leadership, PAREXEL International

Strategic pharma-CRO collaboration aiming for quality assurance and efficiency of clinical trials has been expanded. Such collaboration is taking various forms: the number of outsourced services varies from particular service to multiple/ full services; and many international pharma companies work with CROs covering different countries under single global contracts. Although sponsors do oversee as their responsibility defined clearly in the current ICH-E6R2, they do it in a wide variety of ways. In this session, we will discuss point for considerations in CRO management for more effective collaboration, including the topics of how to develop effective CRO outsourcing plans, and effective CRO managements from each perspective of pharma, medical institutions and CRO.

Local Outsourcing Strategy Planning at a Global Pharmaceutical Company
Toshiharu Sano, RPh
Executive Director, Head of Clinical Operations Area, Japan Development, MSD K.K.

Effective Collaboration among Japanese Affiliates of Pharmaceutical Company and CRO under Global Contract Situation
Yusuke Yoshimoto
Senior Manager, Clinical Development Operations & Innovations, Medicines Development Unit Japan, Eli Lilly Japan K.K.

Cooperation with CRO from the Viewpoint of the Institutions Based on the Investigator Initiated Clinical Trials
Yuto Fujiki, RPh
Research Associate, Planning and Management Office, Clinical and Translational Research Center, Keio University Hospital

CRO Management under a Strategic Partnership from a CRO Perspective
Masakazu Kobayashi, RPh
Division Head, Clinical Research 2nd Division, CMIC Co.,Ltd.

V7-S5 Room 102 11:00-12:30

More Advanced Approach of Medical Big Data - Part 2

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

SESSION CO-CHAIRS

Hisahi Urushihara, DrPH, MS
Professor, Division of Drug Development & Regulatory Science, Faculty of Pharmacy, Keio University

Yuji Yamamoto, MD, MBA
Founder and CEO, MinaCare Co., Ltd.

Medical big data have become indispensable in medicine development. Many people have been making decision by reference to information come from big data analysis. In this session, we will comprehensively review the advanced approach for big data utilization and future perspective with pioneering experts from Global as well as Japan. We will share advanced examples of clinical trial design and operations including randomized pragmatic trials, outcomes research and post-marketing safety assessments. The potential impact of GCP renovation will also be discussed.

TBC
Kotonari Aoki, MS
Director, Safety Real World Data and Science, Drug Safety Data Management Department, Chugai Pharmaceutical Co., Ltd.

The Application of Big-Data in Bayer Yakuhin
Shunichi Takahashi, PhD
Head, Open Innovation Center Japan, Bayer Yakuhin, Ltd.

Panel Discussion
All Session Speakers

V8-S5 Room 703 11:00-12:30

Drug Development Activation in Pan-Asia Region

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

SESSION CHAIR

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

In drug development, East Asia region, such as Japan, China, Taiwan and Korea, tends to be focused as "Asia" region, however, an environment to conduct multinational clinical trials in ASEAN region has been significantly improved. Indeed, ICH-GCP-complied multinational clinical study results with ASEAN countries have become on public.

With this context, in this session, actual practice and situations of clinical study conduct in ASEAN region are to be introduced, and then potential activities in order to further enhance the momentum will be discussed. In order to achieve an ultimate goal, ie. early access to innovative new drug in Asian region, collaboration between East Asia and South East Asia as well as the joint contribution, ie. All Asia, to the drug development will be extensively discussed.

TBC
Hiroshi Watanabe, MD, PhD
National Center for Global Health and Medicine

Current Status and Future Expectation of Clinical Studies by Academia
Jianzhong Zhao
Senior Reviewer, Center for Drug Evaluation, China Food and Drug Administration (CFDA)

PMDA's Experiences with New Drug Applications including Data from Multi Regional (Asian) Clinical Trials
Yasuto Otsubo, RPh
Planning and Coordination Officer, Office of International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

LUNCH BREAK 13:30-14:00

SESSION 6 14:00-15:30

V1-S6 Room 605/606 14:00-15:30

Optimal Use Guidelines (Future Direction of the System, Discussion of the NDA Review Process, and Status of Actual Medical Practice)

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

SESSION CHAIR

Yuji Kashitani
Director, Regulatory Development, Regulatory Affairs Department, Takeda Development Center Japan, Takeda Pharmaceutical Company Limited

Discussion on the direction toward the official introduction of 'Optimal Use Guidelines' being in trial operation from FY2016.

This session will discuss including the future issues, the target products planned for the Guidelines, impact on creating NDA dossiers or review for NDA approval when introduced the Guidelines, or any change or impact to the actual medical practice when Guidelines are introduced.

About a Background and a Summary of Optimal Clinical Use Guidelines
Eri Sugiyama, MS
Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Optimal Use Guidelines : from the Viewpoints of Pharmaceutical Industry
Hiroyuki Muta
Senior Director, Regulatory Management, Ono Pharmaceutical Co., Ltd

Optimal Use Guidelines: Impact on Medical Practice
Makoto Tahara, MD, PhD
Head and Neck Medical Oncology, National Cancer Center Hospital East

Panel Discussion
All Session Speakers and
Yasuhiro Fujiwara, MD, PhD
Principle Reviewer, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

V2-S6 Room 607 14:00-15:30

RMP in the Era of Medical Big Data

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

SESSION CHAIR

Rei Maeda
Senior Regulatory Scientist, Global Patient Safety Japan, Quality and Patient Safety, Eli Lilly Japan K.K.

Medical Information Database research will soon be included in additional pharmacovigilance activities as one of the post-marketing surveillance. Going back to the concept of ICH E2E "Pharmacovigilance Planning," we will discuss what pharmacovigilance activities should be like in RMP in general.

Guidance of ICH E2E "Pharmacovigilance Planning"
Tsugumichi Sato, PhD
Junior Associate Professor, Department of Pharmacy, Faculty of Pharmaceutical Sciences, Tokyo University of Science

Epidemiological Review for Pharmacovigilance Planning in New Drug Applications
Chieko Ishiguro, MPH
Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

Is Your RMP Optimal?
Kotonari Aoki, MS
Director, Safety Real World Data and Science, Drug Safety Data Management Department, Chugai Pharmaceutical Co., Ltd.

Panel Discussion
All Session Speakers and
Wataru Asakura, PhD
Office Director, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)

V3-S6 Room 608 14:00-15:30

Drug Developments for Rare Cancer and Fraction Areas

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

SESSION CHAIR

Akihiro Hirakawa, PhD
Department of Biostatistics and Bioinformatics, Graduate School of Medicine, The University of Tokyo

In rare cancer and fraction areas, phase 2 trials are conducted as pivotal trials, but their regulatory requirements differ depending on the target disease, standard treatment, and so on. It is important to organize the basic ideas of clinical development in rare cancer and fraction areas and make it easier to establish a path for drug approval. In this session, we will focus on the industry-academia cooperation to make development more efficient along with the clarification of regulatory requirements. The basic idea of clinical development in these area are organized.

Collaborative Challenge for Drug Development in Rare Cancer Field
Kan Yonemori, MD, PhD
Department of Breast and Medical Oncology, National Cancer Center Hospital, National Cancer Center

The Current Status and the Issue of Drug Development for Rare Cancer and Rare Fraction Area from the Pharmaceutical Industry Perspective
Miki Harumiya, MPharm
Japan Development, Solid Tumor Clinical Development Department, Novartis Pharma K.K.

PMDA Perspective
Noriyuki Komiyama, MSc
Deputy Review Director, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

V4-S6 Room 609 14:00-15:30

How Should a Collaboration between Academia and Industry be Promoted for an Efficient Medicine/ Medical Device Development - Lessons Learned from the Case of Simultaneous Approval in Combination Product of Medicine and Medical Device with Investigator Initiated Clinical Trial for Registration -

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

SESSION CHAIR

Hiroi Kasai, PhD
Head of Study Management Department, Institute for Advancement of Clinical and Translational Science (iACT), Kyoto University Hospital

A strategic collaboration such as an investigator initiated clinical trial (IICT) for registration between academia and industry is the key to success to develop medicine/medical device more efficiently. Actually, there are successful cases of the strategic collaboration led to regulatory approval with IICT collaboration. There is the one advanced example of the three-way collaboration for a combination product consisting of medicine and medical device. In this session, an ideal collaboration model will be discussed from various points of view, academia, industry, and PMDA plays as the Japan NDA review.

Point of Consider to Collaborate with Industry on Investigator Initiated Clinical Trial for Registration –Academia's Standpoint-
Manabu Muto, MD, PhD
Professor, Department of Therapeutic Oncology, Graduate School of Medicine, Kyoto University

A Better Academia-Industry Collaboration Aiming for Regulatory Approval - The Experience of Cooperation with Investigator Initiated Clinical Trials -
Izumi Okugaito
Department Manager, Prescription Products Development Department, Zenyaku Kogyo Co., Ltd.

Effective Coordination Between Academia and Industry from the Reviewer Side
Ken Hatogai, MD, PhD
Reviewer, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers and
Fumiaki Kobayashi, PhD
President, CTD Inc

V5-S6 Room 610 14:00-15:30

Quality Management and Lean Six Sigma in Clinical Trials in ARO and Pharmaceutical Companies

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

SESSION CHAIR

Toshihiko Watanabe
Advisor, Japan CRO Association

To manage qualities in clinical research and clinical studies, introduction of Quality by Design (QbD), Risk Based Approach and Critical to Quality (CTQ) was expected based on enactment of Clinical Study Law and GCP renovation. However, no tangible example was reported as of today and field level ingenuity with limited resources is being applied to clinical trials.

In this session, Lean Six Sigma (LSS) Outline, QbD example and improvement example of quality in clinical studies at pharmaceutical industry and ARO

by LSS method, that is ISO certified quantitative process improvement and worldwide efficient quality management tool, will be presented.

Lean Six Sigma, an International Standard for Quality Management

Hirotaka Inoue, PhD, MBA
Head, Leading Changes Office, Development & Medical Affairs Division, GlaxoSmithKline K.K.

Case Introduction – How Lilly Japan Leverage Lean Six Sigma Methodology

Souta Mizumoto, MPharm
Director & Six Sigma Champion, Global Patient Safety, Medicines Development Unit Japan, Eli Lilly Japan K.K.

A Practical Example of Applying Lean Six Sigma Method at the Academic Clinical Research Site

Yuko Kageyama, PhD
Clinical Research Support Center, Phase I Unit, The University of Tokyo Hospital

V6-S6 Room 101 14:00-15:30

Rethinking Quality in Clinical Trials - What are Quality Tolerance Limits (QTLs) and How Should they be Adapted in Clinical Studies to Fulfill New ICH-E6 Requirement?

Related Interest Area(s): RA, DM, CR, ST, PM, AC, O: MA
Level: Intermediate

SESSION CHAIR

Satoshi Saeki, MSc
Associate Director, Business Process Improvement, Astellas Pharma Global Development, Inc.

ICH-E6 (R2) is focusing on risk-based quality management system to ensure human subject protection and reliability of trial results in clinical studies. Although Quality Tolerance Limit (QTL) is one of key components in the quality management system, and despite Japan's 60 plus year history on Quality and QTLs in other industries, there has not been enough discussion in Japan of their application in clinical trials. This session will invite Andy Lawton, a global expert on risk-based clinical quality management system and a core member of RBM initiative in TransCelerate to speak about the key concept and actual approaches of QTLs. In addition, a panel discussion is planned to discuss how to apply the QTL approaches into actual trials with PMDA and industry representatives for the successful implementation in Japan.

Quality Tolerance Limits – A history and the Why, How, What and Where of Implementation in Clinical Trials

Andy Lawton
Director / Consultant, Risk Based Approach Ltd

Panel Discussion

All Session Speakers and
Hiromichi Isaka
Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Device Agency (PMDA)
Yumi Sugiura, MRCP
Senior Central Monitor, Global Data Strategies and Solutions, Bristol-Myers Squibb K.K.

V7-S6 Room 102 14:00-15:30

Future of Development Strategy and Lifecycle Management in Asia after ICH Q12 Guideline Implementation

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

SESSION CHAIR

Yukio Hiyama, PhD
Visiting Researcher, National Institute of Health Sciences

For global pharmaceutical companies, the management of change control processes difference among the countries is one of the factors that prevent continuous improvements and innovations.

The ICH Q12 guideline "Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management", that is currently under consideration, provides a framework to facilitate the management of post-approval CMC changes in a more predictable and efficient manner.

Regulators and companies from Asia will present the challenges toward ICH Q12 guideline implementation and the changes in the drug development strategy in their countries.

ICH Q12 (Pharmaceutical Product Lifecycle Management): PMDA Perspective

Yasuhiro Kishioka, PhD
Principal Reviewer, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency (PMDA)

CFDA's View on Implementation of ICH Q12 in China as well as Current Quality Compliance System such as PQS in China (Tentative)

Yang Wang
Senior Reviewer, Center for Drug Evaluation, China Food and Drug Administration (CFDA)

Pharmaceutical Quality System and Change Management Expectation to ICH Q12 from Industry

Tomonori Nakagawa, MA
Manager, Manufacture Process Development Department (API) / Global Supply Chain PJ, Otsuka Pharmaceutical Co., Ltd.

Panel Discussion

All Session Speakers

V8-S6 Room 703 14:00-15:30

For Providing the Most Appropriate Medicine - The Current State of Use and Development of Companion Diagnostics (Mainly on Next Generation Sequencers)

Related Interest Area(s): RA, DM, CP, ST, PM, AC, O: Diagnostics Company
Level: Beginner

SESSION CHAIR

Kazuto Nishio, MD
Professor, Kindai University Faculty of Medicine

The existence of companion diagnostics is important for delivering medicine suitable for each patient. Genomic analysis is performed using next generation sequencer in cancer genome medical treatment, and genomic mutation for each patient and cell is revealed.

In this session, present current status of "Precision Medicine" using Next Generation Sequencer, Issues in using next-generation sequencers, and issues of companion diagnostic drug development from the standpoint of each industry, government and academia. And also discuss the solution on panel-discussion.

Regulatory Perspectives on NGS-based CDx

Reiko Yanagihara, PhD
Principal Reviewer, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Device Agency (PMDA)

NGS-Based Clinical Sequencing System for Precision Cancer Medicine in Japan

Takashi Kohno, PhD
Division of Genome Biology, National Cancer Center Research Institute

Issue on the Development of CoDxs from Diagnostics Company's Points of View

Miwa Nishida
Sr. Manager, Clinical Operations, Medical, Quality & Regulatory, Roche Diagnostics K.K.

Panel Discussion

All Session Speakers and
Michio Tanaka
Senior Director, Science Affairs Division, Research & Development, AstraZeneca K.K.

COFFEE BREAK 15:30-16:00

PMDA Town Hall / Closing Remarks

PMDA TOWN HALL

International Conference Room **16:00-17:30**

Related Interest Area(s): ALL

Level: All

SESSION CO-CHAIRS

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

Kihito Takahashi, MD, PhD
Vice President and Senior Managing Director, Development & Medical Affairs Division, GlaxoSmithKline K.K

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

Panelists

Makoto Hirose, MSc
Office Director, Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Device Agency (PMDA)

Motoko Honda, PhD
Review Director, Office of New Drug II, Pharmaceuticals and Medical Device Agency (PMDA)

Chieko Ishiguro, MPH
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Naoyuki Yabana, PhD
Office Director, Office of In Vitro Diagnostics, Pharmaceuticals and Medical Device Agency (PMDA)

CLOSING REMARKS

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

Akiko Ikeda, RPh
Program Vice-Chair / Senior Manager, Policy Intelligence Department, Janssen Pharmaceutical K.K.

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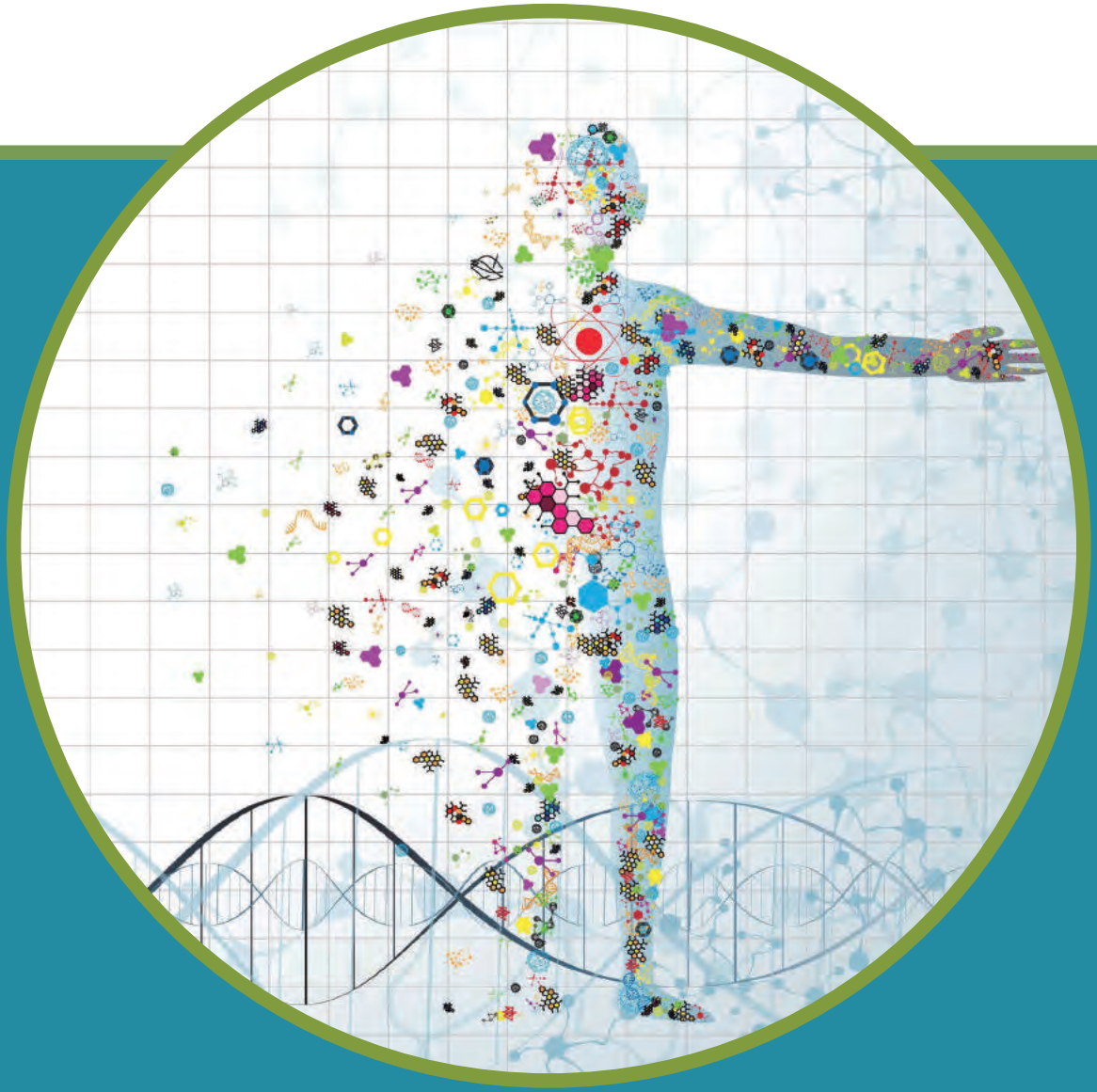

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関連領域: CR=臨床オペレーション/臨床戦略、RA=薬事、ST=統計、CDM=データマネジメント、CP=安全性及びファーマコビジランス、PM=プロジェクトマネジメント、CMC=品質管理、AC=アカデミア

JP 日本語のみ

11月12日（日）	メイン会場 国際会議場	第1会場 605/606会議室	第2会場 607会議室	第3会場 608会議室	第4会場 609会議室
9:30-12:00					
12:00-13:30	オリエンテーション@展示会場 (12:00-13:00)				
13:30-13:45	開会の挨拶				
13:45-14:00	大会長挨拶				
14:00-14:15	2017 DIA Japan's Inspire Awards 授賞式				
14:15-15:15	基調講演1 （東京工業大学　大隅良典先生）				
15:15-15:45	コーヒーブレイク				
15:45-16:45	基調講演2 （帝京大学医療情報システム研究センター 澤智博先生				
16:45-17:45	**[DIAmond Session 1]** 次世代医療ICTを活用した医薬品開発の将来像	DIAmond SESSIONS			
17:45-18:00	ショートブレイク				
18:00-19:30	情報交換会（レセプションホール）				

11月13日（月）	メイン会場 国際会議場	第1会場 605/606会議室	第2会場 607会議室	第3会場 608会議室	第4会場 609会議室
9:00-10:30		**[DIAmond Session 2]** 革新的な医薬品をより迅速に必要とする患者へ届けるために―日米欧三極規制当局の最新動向 DIAmond SESSIONS			
10:30-11:00		コーヒーブレイク（レセプションホール）			
11:00-12:30 セッション1		**V1-S1** GlobalPhase I 試験をリードするためには - がん開発を中心に - R, AC JP	**V2-S1** [教育セッション]日本型HTA（医療技術評価）のあり方 RA, HEOR	**V3-S1** [教育セッション] 日米欧の製販後安全対策の比較　～リスクマネジメントの観点から～ RA, CP	**V4-S1** 医薬品・医療機器のコンビネーションを考える RA, Medical Device JP
12:30-14:00		ランチョンセミナー （A2 HEALTHCARE CORPORATION）	ランチブレイク（レセプションホール）		
14:00-15:30 セッション2		**V1-S2** 日本の「患者中心主義」の幕開け（第1部）：共通の価値創出を目指して RA, CR, AC, Patients	**V2-S2** モバイル・デジタルヘルスのデータが導く新時代の臨床開発 RA, DM, CP, CR, ST, PM, AC	**V3-S2** [教育セッション]米国、欧州の添付文書の規制とプロセスについて理解しよう RA, CP	**V4-S2** 個人情報保護法の改正に伴う、臨床研究をめぐる諸問題 RA, DM, CP, CR, AC JP
15:30-16:00		コーヒーブレイク			
16:00-17:30 セッション3		**V1-S3** 日本の「患者中心主義」の幕開け（第2部）：試行錯誤の実践例から学ぼう RA, CR, AC, Patients	**V2-S3** 人工知能を利用した医療のデジタル革命の実現に向けて CR, ST, AC	**V3-S3** 新記載要領改正に基づく添付文書作成のためにすべきことは何か？ RA, CP	**V4-S3** 新職種メディカルサイエンスリエゾン（MSL）の役割とは何か？ CP, PM, AC, MA JP
17:30-17:45		ショートブレイク			
17:45-19:00		Engage and Exchange 'Let's Chat! - Special Chat Session -'（レセプションホール）			

11月14日（火）	メイン会場 国際会議場	第1会場 605/606会議室	第2会場 607会議室	第3会場 608会議室	第4会場 609会議室
9:00-10:30 セッション4		**V1-S4** 変わりゆく世界の情勢と製薬業界に対する影響 ALL	**V2-S4** 統計を正しく使うためには―p値の意味を理解して誤用をなくそう― RA, DM, CP, CR, ST, AC JP	**V3-S4** データベース調査を再審査申請資料とするための信頼性確保とは？ ～改正GPSP省令への対応～ RA, CR JP	**V4-S4** 小児に必要な医薬品は適切に届いているのか？―日本の小児開発の現状と今後の取り組み― RA, CR, PM, AC JP
10:30-11:00		コーヒーブレイク（レセプションホール）			
11:00-12:30 セッション5		**V1-S5** 条件付き早期承認制度ほか、医薬品の早期アクセスを実現する各種制度について RA, CR, PM, AC	**V2-S5** 医療従事者が利活用できるRMPに向けて RA, CP JP	**V3-S5** 変化するがん第1相試験の役割 RA, DM, CP, CR, ST, PM, AC	**V4-S5** Quality by Design；アカデミアが実施する臨床試験の品質を戦略的に構築する DM, CR, ST, AC, MA JP
12:30-14:00		ランチブレイク	ランチョンセミナー （CROEE INC.） JP	ランチョンセミナー （INVENTIV HEALTH）	ランチブレイク
14:00-15:30 セッション6		**V1-S6** 最適使用推進ガイドライン（今後の制度の方向性、新薬承認審査過程における議論、医療現場での実際について） RA, CR, AC, PV, MA	**V2-S6** 医療Big Data時代のRMP RA, CP	**V3-S6** 希少がん・希少フラクション領域の臨床開発オプションを考える RA, DM, CP, CR, ST, PM, AC	**V4-S6** 効率的な医薬品・医療機器開発のために、アカデミアと企業はどう連携すべきか？―医師主導治験で実施した医薬品、医療機器の同時開発・承認事例から考える― ALL JP
15:30-16:00	コーヒーブレイク（レセプションホール）				
16:00-17:30	PMDAタウンホール				
17:30-17:40	閉会の挨拶				

関連領域: CR=臨床オペレーション/臨床戦略、RA=薬事、ST=統計、CDM=データマネジメント、CP=安全性及びファーマコビジランス、PM=プロジェクトマネジメント、CMC=品質管理、AC=アカデミア

JP 日本語のみ　日本語 / 英語（同時通訳なし）

第5会場 610会議室	第6会場 101会議室	第7会場 102会議室	第8会場 703会議室	展示会場 レセプションホール
		ST [Student Session] 臨床試験のプロトコール作成 JP		
オリエンテーション@展示会場 (12:00-13:00)				
ショートブレイク				
情報交換会（レセプションホール）				
第5会場 610会議室	第6会場 101会議室	第7会場 102会議室	第8会場 703会議室	展示会場 レセプションホール
コーヒーブレイク（レセプションホール）				
V5-S1 薬剤耐性（AMR）対策アクションプランに基づく今後の取り組みと、医薬品開発へのチャレンジ RA, CP, CR, AC, MA JP	**V6-S1** 我が国の産学官共同の創薬研究スキームについて RA, AC	**V7-S1** 疾患レジストリーデータを取り巻く規制案と現状 ALL	**V8-S1** ザ・ネゴシエーション―あなたのプロジェクトをうまく進めるための社内外調整そして交渉 ALL	
ランチブレイク	ランチョンセミナー（MEDIDATA SOLUTIONS K.K.） JP	ランチョンセミナー（INC RESEARCH）	ランチブレイク（ポスターセッション（レセプションホール））	
V5-S2 適切な医薬品情報コミュニケーションの更なる推進に向けて（第1部） RA, CP, AC, MA, Labeling, Marketing, Medical Writing, Medical Information JP	**V6-S2** 国際共同治験戦略のパラダイムシフト―ICH E17ガイドラインは新薬開発の中でどう利用できるのか？― RA, CR, ST, AC	**V7-S2** 患者中心主義との親和性が導く新たなPatient Participationのアプローチ RA, CR, AC	**V8-S2** 催不整脈リスク評価の最新動向 RA, CP, CR, AC, Cardiac Safety	
コーヒーブレイク				
V5-S3 適切な医薬品情報コミュニケーションの更なる推進に向けて（第2部） RA, CP, AC, MA, Labeling, Marketing, Medical Writing, Medical Information JP	**V6-S3** 再生医療等製品の製品化への道 RA, DM, CP, ST, PM, CMC, AC	**V7-S3** Globalにおける偽造医薬品の現状と日本における課題 RA, CP, CMC, Counterfeit	**V8-S3** 演題公募セッション RA, CP, CR, ROD	
ショートブレイク				
Engage and Exchange 'Let's Chat! - Special Chat Session -'（レセプションホール）				
第5会場 610会議室	第6会場 101会議室	第7会場 102会議室	第8会場 703会議室	展示会場 レセプションホール
V5-S4 プロジェクトマネジャー（PM）の能力開発"成功に向かうはじめの一歩" ～そもそも、あなたはどんなPMになりたくて、どんなPMになることを期待されているのか～ ALL JP	**V6-S4** Quality by Design：企業が実施する臨床試験の品質を戦略的に構築する RA, DM, CR, ST, AC, O: MA	**V7-S4** 更に進んだ医療ビッグデータの利活用(第1部) ALL	**V8-S4** バイオシミラーの臨床開発 RA, CR, ST, PM, CMC, AC	
コーヒーブレイク（レセプションホール）				
V5-S5 どうする?若手のキャリア?組織の生産性? ALL JP	**V6-S5** CROとの効果的な協業のために必要なCROマネジメント CR, PM	**V7-S5** 更に進んだ医療ビッグデータの利活用(第2部) ALL	**V8-S5** Pan-Asiaによる医薬品開発の活性化 RA, CR, PM, AC, MA	
ランチブレイク	ランチョンセミナー（PAREXEL INTERNATIONAL） JP	ランチョンセミナー（OMNICOMM SYSTEMS INC.）	ランチブレイク（レセプションホール）	
V5-S6 AROと製薬企業における臨床試験の品質管理とLean Six Sigma RA, AC JP	**V6-S6** Rethinking Quality in Clinical Trials - What are Quality Tolerance Limits (QTLs) and How Should they be Adapted in Clinical Studies to Fulfill New ICH-E6 Requirement? RA, DM, CR, ST, PM, AC, MA	**V7-S6** ICH Q12ガイドライン実装をとおしたアジア地域でのライフサイクルマネジメントと開発戦略の将来展望 RA, CMC, AC	**V8-S6** 最適な薬を提供するために～コンパニオン診断薬の利用と開発の現状（次世代シークエンサーを中心に）～ RA, DM, CP, ST, PM, AC, Diagnostics company	
コーヒーブレイク（レセプションホール）				

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スチューデントセッション/オリエンテーション

102会議室　9:30–12:00

スチューデントセッション
臨床試験のプロトコール作成

関連領域：薬事、アカデミア
レベル：初級

座長

千葉大学
綾部　眞織

慶應義塾大学大学院
飯村　翔平

日本大学
岡田　安矢

昭和大学
佐藤　美帆

臨床試験は医薬品の有効性・安全性評価に必須であり、実施する上で試験デザイン、評価方法等の選択や被験者への配慮は重要である。では、科学的かつ倫理的な臨床試験はどのように計画されているのだろうか。

本セッションでは、臨床試験の実施計画書（プロトコール）を作成するためのエッセンスを講演していただく。その後、グループワークによるプロトコール作成演習を行い、理解の深化を図る。積極的なディスカッションを通して、試験計画の立案過程を体験して欲しい。

なお、グループワークでは糖尿病治療薬を題材とするため、下記の文献を読んでおくことが望ましい。

厚生労働省."経口血糖降下薬の臨床評価方法に関するガイドライン"
https://www.pmda.go.jp/files/000208192.pdf, (accessed 2017-05-23).

※本セッションの参加対象者は学生です。社会人の方も見学は可能ですが、見学スペースが限られておりますことを予めご了承の程お願い申し上げます。聴講をご希望の方は9:00–9:30に1Fの受付までお越しください。

※本セッションにおけるグループワークの結果を1階レセプションホール前のホワイエに掲示する予定です。是非お立ち寄りください

プロトコール作成上の留意点～経験、実例を踏まえての苦労した点、注意すべき点～（仮題）

第一三共株式会社
水迫　英己

講評

独立行政法人 医薬品医療機器総合機構
坂上　祐香

アドバイザー

日本大学
荒川　基記

エーザイ株式会社
大道寺　香澄

第一三共株式会社
本荘　泰広

独立行政法人 医薬品医療機器総合機構
一丸　勝彦

ノバルティス ファーマ株式会社
関根　恵理

DIA Japan Student Group OBOG/第一三共株式会社
深貝　明子

DIA Japan Student Group OBOG/アステラス製薬株式会社
蜂須賀　絵美

レセプションホール　12:00–13:00

オリエンテーション

発表者
DIA Japan Contents Committee

はじめてDIA日本年会へ参加される方を対象に『DIA日本年会の歩き方』をご紹介します。年会をより有意義かつ快適に過ごすために、ぜひご参加ください。

説明内容：

- DIAとは
- 会場案内
- プログラム構成
- 展示会
- 飲食の案内
- DIA Globalアプリの使い方

1日目 | 11月 12日（日）

開会の挨拶および基調講演

開会の挨拶
国際会議場 **13:30-13:45**

DIA Japan
関口　康

DIA
Barbara Lopez Kunz

DIA Advisory Council of Japan議長 / 大塚ホールディングス株式会社
小林　和道

大会長挨拶
国際会議場 **13:45-14:00**

第14回DIA日本年会大会長 / 国立がん研究センター
藤原　康弘

2017 DIA Japan's Inspire Awards授賞式
国際会議場 **14:00-14:15**

プレゼンター

DIA
Barbara Lopez Kunz

アワード受賞者：

Outstanding Contribution to Health Award
北里大学病院
熊谷　雄治

Excellence in Service Award
独立行政法人 医薬品医療機器総合機構
一丸　勝彦

Excellence in Service Award
第一三共株式会社
宮崎　浩一

Leader of Tomorrow Award
第一三共株式会社
岡部　裕美

基調講演 1
国際会議場 **14:15-15:15**

座長

独立行政法人 医薬品医療機器総合機構
近藤　達也

40年前にはじめた酵母液胞の研究から、今日までのオートファジー研究の展開を歴史的にふりかえる。その過程における研究における顕微鏡を始め、分析技術の進化と果たした役割について考察する。研究に最も重要な研究者のマインド、研究システムについての私見を述べる。

40年の酵母研究を振り返って
東京工業大学
大隅　良典

コーヒーブレイク
15:15-15:45

基調講演 2
国際会議場 **15:45-16:45**

座長

国立がん研究センター
藤原　康弘

ITの利活用により、近未来の医療健康分野における劇的な進歩が予想されている。

膨大な医療健康データがデジタル化・処理・構造化されれば、人工知能、ビッグデータ、そしてIoT (linternet of Things)の利活用により、医療現場、研究、教育、さらには健常人・患者の連携が進み、ITによるさまざまな形の支援が実現するであろう。

本講演では、今後の医療、特に医薬品・医療機器開発の将来像について、医療情報学的観点から述べる。

医療の未来像：ITの利活用と医薬品開発
帝京大学
澤　智博

DIAmond Session

DIAmond SESSIONS

DIAmond Session 1
国際会議場 **16:45-17:45**

次世代医療ICTを活用した医薬品開発の将来像

座長
国立がん研究センター
藤原　康弘
MSD株式会社
小野　嘉彦

健康・医療戦略等に基づき、医療・介護・健康分野のデジタル基盤の構築とその利活用を目的に、次世代医療ICTの議論が進められている。当該セッションでは、産学官それぞれの立場から、次世代医療ICTの方向性、臨床試験及び承認審査への活用や影響を含め、医薬品開発の将来像についてパネルディスカッションを行う。

次世代医療ICTの展望について
内閣官房
藤本　康二

追加発言
厚生労働省
森　和彦

Drug Development Utilized Next Generation ICT - PMDA's Efforts -
独立行政法人 医薬品医療機器総合機構
近藤　達也

パネルディスカッション
本セッションの講演者および
帝京大学
澤　智博

情報交換会
レセプションホール **18:00-19:30**

42

2日目 | 11月 13日(月)

DIAmond Session 2

605/606/607/608会議室 **9:00-10:30**

DIAmond SESSIONS

革新的な医薬品をより迅速に必要とする患者へ届けるために ー 日米欧三極規制当局の最新動向

関連領域: 全領域
レベル:初級・中級

座長

国立がん研究センター / 国立がん研究センター　中央病院
藤原　康弘

革新的な新薬をより早く患者へ届けるために、アカデミア、企業、規制当局が一丸となって様々な新しい取り組みがなされてきているが、本セッションではグローバルの規制当局の取り組みやその考え方、実例について紹介頂き、今後の方向性を議論する。特に、それぞれのもつ迅速審査システム（FDA: Breakthrough Designation, EU: PRIME, 日本:先駆け申請）を、困っている患者さんに必要な治療を早く確実に届けるためにどのように適応していくことを期待しているのか、あるいは、希少疾患などの従来型の二重盲検比較試験が実施出来ない様な疾患に対して、どのように科学的・倫理的担保を保ちながら有効性・安全性を評価し、患者に届けていくのか。日々進化するサイエンス、規制科学をとりこみながら新たな医療の確立につなげていくための当局の取り組み、さらには未来に向けた産官学連携ならびにグローバルコラボレーションについて討議する。

欧州における革新的な医薬品開発の取り組み(仮題)
European Medicines Agency (EMA)
Francesco Pignatti

日本における革新的な医薬品開発の取り組み(仮題)
厚生労働省
森　和彦

US Food and Drug Administration Expedited Programs for Serious Conditions
FDA
Rajeshwari Sridhara

パネルディスカッション
本セッションの講演者

コーヒーブレイク **10:30-11:00**

SESSION 1　11:00-12:30

V1-S1　605/606会議室　11:00-12:30

Global Phase I 試験をリードするためには ー がん開発を中心に ー

関連領域: 臨床、アカデミア
レベル：中級

座長

第一三共株式会社
齋藤　宏暢

現在日本のシーズが得られても欧米主導の開発となり、欧米での承認が優先されるケースが多い。日本がglobal開発をリードするためには、Global Phase Ⅰ をmanageできる環境および人材育成が重要である。

がんの領域では、Phase Ⅰ, Ⅱ, Ⅲ といったStep by Stepな進め方ではなく、Phase Ⅰ から有効性を検討し、効果が高いことがわかれば、Phase Ⅰ を拡大し、有効性POCや長期安全性を評価し、 Accelerate Review を勝ち取りながら、条件付け承認に向けた開発戦略を取るケースが出てきた。試験のAdaptiveな運用が重要となる。

一番大事なのは、限られたデータ、時間の中で、推奨用量を判断できる人材育成であり、昔から変わらない。

前半では Global Phase I をどのように準備するかを、後半では実施施設側の苦労話を欧米・アジア・日本から情報シェアして、今後の進め方を探る。

日本のSiteにおけるGlobal Phase I の経験について
国立がん研究センター　中央病院
山本　昇

アジアのSiteにおける Phase I 試験について
National Taiwan University Hospital
Chia-Chi (Josh) Lin

Global Phase I 試験の経験
第一三共株式会社
齊藤　格

Oncology Global Phase I 試験への参加経験
ノバルティス ファーマ株式会社
石橋　秀康

パネルディスカッション
本セッションの講演者

V2-S1　607会議室　11:00-12:30

日本型HTA（医療技術評価）のあり方

関連領域: 薬事、HEOR
レベル：初級、中級

座長

テルモ株式会社
昌子　久仁子

革新的かつ高額な医薬品・医療機器が臨床現場で利用されるようになったことに伴って、ユニバーサルアクセスの持続可能性を可能にするための政策立案の判断根拠として、医療技術評価（HTA）に注目が集まっています。

2016年試行的導入されましたHTAは、本格導入に向けてその制度設計のあり方の議論が活発に行われています。

2017年の日本年会では、諸外国と日本の保険償還及び薬価制度等を概観したうえで、日本の費用対効果評価を巡る論点について、様々な視点から自由闊達なパネルディスカションを行います。

具体的には、日本版HTAにおける総合的評価のありかたや日本人の命の値段（ICER閾値）を巡る議論を行う予定です。

日本と諸外国と対比した保険償還、薬価の制度紹介
東京大学
五十嵐　中

費用対効果評価の試行的導入の現状
クレコンメディカルアセスメント株式会社
小林　慎

パネルディスカッション
本セッションの講演者および
京都大学大学院
中山　健夫

慶應義塾大学
後藤　励

ノバルティス ファーマ株式会社
岡村　晴道

V3-S1　608会議室　11:00-12:30

［教育セッション］日米欧の製販後安全対策の比較 ～リスクマネジメントの観点から～

関連領域: 薬事、安全性
レベル：初級

座長

第一三共株式会社
松岡　洋明

国際共同治験の増加に伴い、世界同時申請・同時承認が実現されドラッグラグがほぼ解消した一方で、各国における治験時のデータは、国際共同治験が実施される以前の時代と比較して減少する傾向にある。そのため、医薬品の安全性及び有効性のプロファイルをより詳細により早く明らかにする上で、製販後における安全対策の重要性が相対的に高まっている。このような背景を踏まえ、本教育セッションでは、日米欧におけるリスクマネジメントの考え方の違い及び製販後安全対策の現状・課題を共有する。

日本における医薬品の安全対策について
独立行政法人 医薬品医療機器総合機構
近藤　恵美子

USにおける市販後安全対策
Pfizer Inc.
Robert Reynolds

EUにおける市販後調査及び安全対策
Federal Institute For Drugs and Medical Devices (BfArM)
Peter Bachmann

パネルディスカッション
本セッションの講演者

V4-S1　609会議室　11:00-12:30

医療機器と医薬品のコンビネーション治療を考える

関連領域 : 薬事、医療機器
レベル: 中級
言語: 日本語のみ

座長

独立行政法人 医薬品医療機器総合機構
石井　健介

新医薬品および新医療機器の開発分野で、新規かつイノベーティブなものを生み出すことが難しい環境となっている昨今、医薬品と医療機器のコンビネーション製品あるいは医薬品と医療機器のコンビネーション治療の新たな取り組みが脚光を浴びつつある。本セッションでは、医薬品と医療機器のコンビネーション治療の開発に焦点をあて、具体的な事例を紹介する。さらに、より効率的に医療機器と医薬品を同時に開発し、コンビネーション治療として臨床現場に出し、かつ事業として成立させるための様々

な課題とそれに対処するためのヒントについて議論する。

医療機器と医薬品のコンビネーション治療の課題と将来
東京女子医科大学
村垣　善浩

過酸化水素水の光分解によるラジカル殺菌歯周病治療器の開発
東北大学大学院
佐々木　啓一

演題未定
独立行政法人 医薬品医療機器総合機構
柴辻　正喜

パネルディスカッション
本セッションの講演者および
日本メドトロニック株式会社
有馬　毅彦
大塚ホールディングス株式会社
小林　和道

V5-S1　610会議室　11:00-12:30
薬剤耐性（AMR）対策アクションプランに基づく今後の取り組みと、医薬品開発へのチャレンジ

関連領域: 薬事、安全性、臨床、アカデミア、MA
レベル：中級
言語: 日本語のみ

座長

独立行政法人 医薬品医療機器総合機構
佐藤　淳子

薬剤耐性菌感染症の克服は、国際的な課題となっており、昨年、“国際的に脅威となる感染症対策関係閣僚会議”より、薬剤耐性（AMR）対策アクションプランが発表され、G7保健大臣会合においては、薬剤耐性に対する課題解決のコミットメントが打ち出された。また、薬剤耐性菌感染症における、臨床評価ガイドラインについては、PMDA/FDA/EMA三極が協働して議論を進めている。AMRアクションプランに基づく今後の取り組みや、これまでの枠組みとは違う臨床試験のあり方、国際協力について議論する。

薬剤耐性対策に関する日本政府の取り組み
山田　安秀

薬剤耐性菌感染症の治療薬について：審査の立場から
独立行政法人 医薬品医療機器総合機構
朝倉　渡

薬剤耐性菌感染症に対する医薬品開発へのチャレンジ
MSD株式会社
高瀬　明子

パネルディスカッション
本セッションの講演者

V6-S1　101会議室　11:00-12:30
我が国の産学官共同の創薬研究スキームについて

関連領域: 薬事、アカデミア
レベル：初級

座長

公益財団法人ヒューマンサイエンス振興財団
竹中　登一

AMEDが発足し２年が経過したところであるが、産学官の創薬研究の垣根をなくす新たな取り組みとして、日本初の公的創薬支援スキームである「創薬支援ネットワーク」、産学官共同プロジェクト「GAPFREE」を始め、平成２９年度からスタートした医療研究開発革新基盤創成事業（CiCLE）の事業の紹介を通じて、今後の産学官連携について議論を進める。

創薬支援ネットワークの取り組みについて
国立研究開発法人 日本医療研究開発機構
樽林　陽一

GAPFREEプロジェクトについて
国立国際医療研究センター研究所
安田　和基

医療研究開発革新基盤創成事業を活用した核酸搭載ナノ粒子ワクチン開発について
第一三共株式会社
武下　文彦

V7-S1　102会議室　11:00-12:30
疾患レジストリデータを取り巻く規制案と現状

関連領域: 全領域
レベル：中級

座長

東京大学大学院
平川　晃弘

疾患レジストリ情報の活用による医薬品開発の促進を目的としたクリニカルイノベーションネットワーク構想に基づき、厚生労働省により提案された国立高度専門医療研究センター（NC）と企業との協働スキームにより疾患レジストリ構築が進められている。その中で、疾患レジストリデータを承認申請に活用する際のデータの信頼性に関する考え方がアカデミアとPMDAにより検討されている。患者レジストリデータの目的や運用方法はさまざまであり、データの質に関する課題も多種多様である。本セッションでは、疾患レジストリを取り巻く規制とレジストリ運用と活用の現状と課題について取り上げる。

患者レジストリデータを医薬品等の承認申請資料等として活用する場合におけるデータの信頼性担保に関する基本的考え方（案）について
国立がん研究センター　研究支援センター
柴田　大朗

Remudyの現状とこれから、Clinical Innovation Networkの推進に向けて
国立精神・神経医療研究センター　トランスレーショナル・メディカルセンター
中村　治雅

疾患レジストリーへの企業からの期待
第一三共株式会社
塩境　一仁

パネルディスカッション
本セッションの講演者および
国立がん研究センター
田代　志門

V8-S1　703会議室　11:00-12:30
ザ・ネゴシエーション ― あなたのプロジェクトをうまく進めるための社内外調整そして交渉

関連領域: PM、ALL
レベル：初級、中級

言語: 日本語/英語（同時通訳なし）
座長

第一三共株式会社
塚本　淳

プロジェクトは利害関係の異なる個々が寄せ集められた状態（集団）からスタートするが、その集団が1つのゴールに向かい成果を上げるチームとなるために様々なプロジェクトマネジメントツールが用いられている。優れたプロジェクトリーダー・マネジャーに重要な対人関係スキルとして「ネ

ゴシエーション」が大きく位置づけられている。ネゴシエーションは英語(Negotiation)では勝ち負けをつけるような駆け引きのイメージもあるが、集団をチームにし、成果を挙げていくためには、こちらの主張を納得してもらい相手の不利益も回避するような、Win-Winにつながる「ネゴシエーション」力が重要である。本セッションでは海外・国内におけるネゴシエーションの理論・実践について、経験も踏まえてわかりやすく討議し、メンバーや他のステークホルダーを巻き込みながら、プロジェクトをうまく進めていくことについて考察・討議する。

講演者

中外製薬株式会社
住田　秀司

Hilke Communications
Robert Hilke

Link Global
Gareth Monteath

パネルディスカッション

本セッションの講演者

ランチブレイク 12:30-14:00

POSTER SESSION　13:30-14:00

ポスターセッション
レセプションホール　13:30-14:00

関連領域: 薬事、安全性、臨床、FI、NC、RD、QC、SE
レベル：初級

本年会では国内外から昨年を大幅に上回る多くの公募の中から査読委員による厳正な審査を経て10演題がポスターセッションとして選出された。最新のトピックスについて活発な議論が期待される。

（注：◎は発表者。その他は共著者）

[PO-01] Use of Juvenile Animal Studies to Support Oncology Medicine Development in Children

INFARMED
◎Dinah Duarte

Children use of new cancer medicines requires early prediction of specific safety. Juvenile animal studies (JAS) could screen for age-related toxicities and differences during postnatal development. This review of EU oncology medicines revealed a steady use of JAS to better characterise safety: 1 in 3 medicine has conducted JAS; 6 medicines have different toxicity profile between adult and juvenile animals.

[PO-02] Utilizing Regulatory Intelligence of Precision Medicine Products for Building Business Strategy

Pfizer Inc.
◎Gloria Hung

The US FDA has increased focus on Precision Medicines (PM) and expedited regulatory tools are available. The US-approved PM product database constructed in this study shows that strategic use of expedited pathway(s) shortens development time and expedites patient access. Information relating to biomarkers was indicated across various label sections which may impact usage. Growth potential for non-oncology therapeutic areas is also noted.

[PO-03] がん領域で主要評価項目を達成できなかった原因の探求：非小細胞肺癌を対象とした第3相臨床試験のシステマティックレビュー

名古屋市立大学
◎池田　貢

癌患者を対象とした第3相臨床試験のシステマティックレビューを行った。主な主要評価項目は全生存期間（OS）および無増悪生存期間（PFS）であった。非小細胞肺癌を対象とした第3相臨床試験の成功確立は33%であり、OSを主要評価項目とした試験ではNegativeな結果が多く、PFSを主要評価項目とした試験ではPositiveな結果が多かった。

[PO-04] Pipeline Portfolio Management Using Agent-Based Modeling with Gaming Simulation

ミリマン
◎岩崎　宏介

[PO-05] 世界同時申請を目指す製薬企業の取り組み　－同時申請品20品目の概要及びデータパッケージ内の日本人例数の調査－

MSD株式会社
◎加藤　義朗　　津森　桂子　　鈴木　実

医薬品の日米欧同時申請の実態を調査するために、公開情報に基づき2009年10月から2014年12月までに日本で承認された医薬品のうち、日本と欧米の申請時期の差が4ヵ月以内の製品の承認及び申請のタイムラグを検討した。さらにこれらの品目の申請データパッケージに含まれる日本人症例数についても合わせて検討したので報告する。

[PO-06] 日本におけるRBM関連業務に対する教育研修ニーズの組織別・職種別意識調査

エイツーヘルスケア株式会社
◎近藤　秀宣

臨床試験でのRBMの導入と実施に際し必要なタスクについて、組織・職種別の教育研修のニーズを明らかにするため、製薬企業3社、3大学、CRO1社の計86名に、2017年1月にアンケート調査を実施した。アンケートの回答は組織・職種別で異なり、対象別の教育研修プログラムを構築する必要性が示唆された。

[PO-07] Rates of Safety Issues for Low Risk Medical Devices: A Cross Sectional Study Between US,UK to Philippines

Centro Escolar University
◎Cezar Manansala Jr　Mark Scyld Magboo　Maileen Beley

[PO-08] Evaluation of Signal Detection and Validation Approaches in Pharmacovigilance: US Perspective

APCER Life Sciences
◎Sanjeev Miglani

Spontaneous reporting (SR) adverse event system databases, large clinical projects and health records databases contain data that may be valuable for timely detection of potential risks associated with Pharmaceutical products. This Poster will provide recommendations for using data from different databases to provide insight into safety signals and offer guidance regarding appropriate statistical methods to use in various situations.

[PO-09] 医薬品共同開発における2社のQAコラボレーションから得られる相乗的効果について

ブリストル・マイヤーズ スクイブ株式会社
◎白鳥　敬子

小野薬品工業株式会社
石川　弘道

医薬品の共同開発において、その品質を高く維持し、かつ、スムースな承認取得を目的として、パートナー会社のQA部門双方が取り組んだ具体的内容およびその経過について、直面した課題やコラボレーションから得られる相乗的効果を含めて報告する。また、当該取組みの今後の展望についても考察する。

[PO-10] クリニカルオペレーションモニタリングにおける、理想と現実のギャップに対するアプローチ

DIA COM (Clinical Operations and Monitoring) Community
◎菅生　和正　　飯島　雅之　　杉浦　志保　　仲田　瑛亮

COM Communityでは、臨床試験の最前線である医療機関において、「理想と現実のGap」が何故生じるのか？を検討しました。さらに，それらのGapをSite Selection, Start up, Enrollment, Processの4つに分類し、各々において私たちはどう行動するのか？を議論しました。我々はGapが生じる原因を他に求めるのではなく、自分が如何にして改善させるか？を追求しました。

[PO-11] 希少疾患領域におけるアンチセンスオリゴヌクレオチド医薬品の開発促進

バイオジェン・ジャパン株式会社
◎岡本　安弘

バイオジェンは，アンチセンスオリゴヌクレオチド医薬品（ASO）における希少疾患領域で様々な研究を実施し，その中で脊髄性筋萎縮症（SMA）を適応症として世界で唯一のASO治療薬である「スピンラザ髄注12 mg」を開発し，この新規分野におけるASO製剤の研究開発を促進している。この開発にあたり薬事戦略も十分に考慮し，CMCにおける製造方法定常化のためにプラットフォームを確立し，ASOの分析方法について探求した。特に製造時における出発物質及び精製されたASO製剤の不純物を管理することはとても重要であり，LC-MSを用いたこれらの管理戦略について考察した。

SESSION 2　14:00-15:30

V1-S2　605/606会議室　14:00-15:30

日本の「患者中心主義」の幕開け（第1部）：共通の価値創出を目指して

関連領域: 薬事、臨床、アカデミア、患者さん
レベル：中級

座長

ヤンセンファーマ株式会社
三木-安田　倫栄

東京大学医科学研究所
武藤　香織

近年、患者中心主義（Patient Centricity）や患者・市民参画（Patient and Public Engagement）について国内での注目が急激に高まっているが、ステークホルダーが多岐に渡ることもあり、その概念や理念の整理は進んでいない。本セッションでは、科学技術社会論の研究者、患者支援団体の代表、そして臨床研究の専門家から、それぞれの考えや取り組みについて紹介し、患者中心主義と患者参画についての理解を深める。なお、本セッションに続いて、第2部では企業が実際に治験の中で実施している取り組みを共有し、パネルディスカッションを通じて医薬品開発における患者参画活動の現状と課題について整理する。

研究への患者・市民参画－理念から実践へ

山口大学
東島　仁

患者・市民の委員養成の必要性と取り組み

NPO法人 ささえあい医療人権センターCOML
山口　育子

V1-S3に続く

V2-S2　607会議室　14:00-15:30

モバイル・デジタルヘルスのデータが導く新時代の臨床開発

関連領域: 薬事、DM、安全性、臨床、統計、PM、アカデミア
レベル：初級

座長

東北大学大学院
山口　拓洋

スマートフォンやウェアラブルデバイスなどの急速な普及に伴い、臨床試験で利用可能なデータの種類と量が増加しつつある。他方で、このようなモバイル・デジタルヘルスデータについては、データの質の問題、データ解析と結果解釈、ソフトウェアパッケージに係る課題も多い。本セッションでは、これらの課題を紹介する共に、これらのデータが新薬の開発にもたらす変革について議論する。

医療健康分野のビッグデータ活用の現状と課題 ― モバイル・デジタルヘルスのデータを中心に ―

医薬産業政策研究所
杉浦　一輝

イノベーション創出を目指して：製薬企業における先行事例

グラクソ・スミスクライン株式会社
張家　銘

中枢神経領域における小児対象のアプリ提供事例

株式会社クロエ
高橋　秀和

統計ソフトウェアを用いてビッグデータを扱う際の留意点

日本製薬工業協会 / 帝人ファーマ株式会社
中島　章博

パネルディスカッション

本セッションの講演者

V3-S2　608会議室　14:00-15:30

[教育セッション] 米国、欧州の添付文書の規制とプロセスについて理解しよう

関連領域: 薬事、安全性
レベル：中級

座長

ファイザー株式会社
松井　理恵

グローバル企業における添付文書のセントラル化は、MRCTが進む中で、より促進されてきている。グローバル本社の意図することを理解するためには、米国、欧州の添付文書の規制をもう一度立ち戻り、日本との違いを理解することが重要である。そして、米国のPRA、CBE等のプロセスの規制やCP、MRP等の欧州の添付文書のプロセスについて、議論し、理解する。本セッションは、実際に添付文書作成の部門のみならず、新薬開発に関連する部門の方々にとっても重要である。

米国における医療用医薬品の添付文書及び患者向け添付文書の改訂に関するレギュラトリープロセス

Pharmiceutics, LLC
A. Leander Fontaine

Regulatory Procedures for Changing the Content of SmPC and Package Leaflet: EU?

European Medicines Agency (EMA)
Francesco Pignatti

パネルディスカッション

本セッションの講演者

V4-S2　609会議室　14:00-15:30

個人情報保護法の改正に伴う、臨床研究をめぐる諸問題

関連領域: 薬事、DM、安全性、臨床、アカデミア
レベル：初級
言語: 日本語のみ

座長

東京大学大学院
米村　滋人

2017年5月30日から施行された改正個人情報保護法と、それに伴う「人を対象とする医学系研究に関する倫理指針」の改訂について分かりやすく解説したうえで、これら改訂が臨床研究に及ぼす具体的な影響について検討する。

特に臨床研究の現場で新たに生じている問題点とその解決に向けた具体的な施策を紹介し、臨床研究の円滑かつ効率的な実施方法について議論する。

改正法の概要と臨床研究における問題点
東京大学大学院
米村　滋人

Addressing Changes in the Climate Surrounding Research Regulations at National Cancer Center
国立がん研究センター
田代　志門

演題未定
厚生労働省
福田　亮介

臨床研究が当面する課題
慶應義塾大学病院
三浦　公嗣

パネルディスカッション
本セッションの講演者

V5-S2　610会議室　14:00-15:30
適切な医薬品情報コミュニケーションの更なる推進に向けて（第1部）

関連領域: 薬事、安全性、アカデミア、MA、Labeling、Marketing、Medical Writing、Medical Information
レベル：中級
言語: 日本語のみ

座長

北里大学
成川　衛

日本イーライリリー株式会社
小嶋　祐子

医薬品情報は、適切に提供され活用されることが重要である。昨年の年会では、規制当局や企業から医療従事者及び患者さんへ提供される資材を対象に課題や取り組みを議論した。その中で、規制当局や企業からは重複する情報を様々な媒体で提供しているが、医療現場の視点で必要な情報がなかったり、作成側の意図が十分伝わっておらず、医療現場で活用されていない状況があることがわかった。前回の議論を踏まえ、規制当局及び企業から医療機関に提供される情報媒体について、目的及び活用方法を整理し、適切な医薬品情報コミュニケーションの推進に向けた取り組みや今後の展望について、規制当局、企業及び医療機関共同でさらなる議論をする。

当局からの医薬品の情報提供と課題
独立行政法人 医薬品医療機器総合機構
谷田　智子

薬剤師の立場からの医薬品の情報提供資材に対する提案
杏林大学医学部付属病院
若林　進

製薬企業の立場からの医薬品の情報提供資材に対する提案1（仮題）
中外製薬株式会社
竹本　信也

医薬品情報に関する医療機関からの問合せの現状と企業としての提供判断について
ノバルティス ファーマ株式会社
西野　潤一

V5-S3に続く

V6-S2　101会議室　14:00-15:30
国際共同治験戦略のパラダイムシフト　－ ICH E17ガイドラインは新薬開発の中でどう利用できるのか？ －

関連領域: 薬事、臨床、統計、アカデミア
レベル：中級

座長

エーザイ株式会社
柳澤　学

本年末にE17GL最終化が期待されている。本セッションでは、本格導入後の適切な利用方法について検討するとともに、今後国際共同治験による開発戦略がどう変化していくのか、どう変化させることができるのかを考える機会としたい。　E5　ガイドラインを踏まえた民族差の検討をこれまでも数多く経験し、民族差の有無や一貫性の評価の困難さを経験してきた。これらの経験に基づきE17GLを活用した開発戦略を検討する際に考慮するべき点、新しく導入される　Pooling　Strategy（Pooled Region, Pooled　subpopulation）の考え方や、Poolingを行うためにどのような情報が必要で、開発のどの段階で集めるべきか、国際共同治験の結果をどのように示すべきかを議論し、今後のパラダイムシフトに繋げていきたい。

今後の国際同時開発はどうあるべきか－ICH-E17の実践に向けて
ファイザー株式会社
松岡　伸篤

国際共同試験を実施するうえでの有効性と安全性における民族差
名古屋市立大学
頭金　正博

ICH-E17が医薬品開発戦略およびオペレーションに与える影響を考える
第一三共株式会社
宮崎　浩一

【インターネット経由での発言】
ファイザー株式会社
小宮山　靖

独立行政法人 医薬品医療機器総合機構
宇山　佳明

パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
竹田　寛

V7-S2　102会議室　14:00-15:30
患者中心主義との親和性が導く新たなPatient Participationのアプローチ

関連領域: 薬事、臨床、アカデミア
レベル：初級

座長

日本イーライリリー株式会社
松田　幸大

患者さんにとって価値ある医療を生み出すための1つのステップとして、患者さんに適切に治験／臨床研究をお届けするアプローチが欠かせない。すでに海外では、疾患に対する臨床試験の有無や近隣の治験実施医療機関を患者さんご自身が検索できるモバイルアプリも登場している。

本セッションでは、患者さんを中心に考えるアプローチをとることによって、患者さんが治験／臨床研究を身近に感じることができ、さらにPatient Participationやデータ収集につながるモバイルアプリやウェブサイト、データ活用の事例を紹介するとともに、日本で発展していく上での課題についてパネルディスカッションする。

治験における患者中心の考え方について
～PRO（Patient Recruitment Organization）の立場から～
株式会社クロエ

牧　大輔

トライアルガイド：デジタル社会における米国イーライリリー社の治験啓発活動
日本イーライリリー株式会社
内村　真紀

2型糖尿病・糖尿病予備群を対象としたスマホアプリ - GlucoNote - による臨床研究
東京大学
脇　嘉代

パネルディスカッション
本セッションの講演者

V8-S2　703会議室　14:00-15:30
催不整脈リスク評価の最新動向

関連領域: 薬事、安全性、臨床、アカデミア、Cardiac Safety
レベル：中級

座長

独立行政法人 医薬品医療機器総合機構
品川　香

催不整脈リスク評価は、薬剤開発時の重要な論点であり、ICH E14/S7B ガイドラインが施行されてきたが、近年 E14 Q&A 5.1改訂により、薬物濃度－反応モデルを利用したQT延長リスク評価が認められるようになった。また心電図上のJ-Tpeak間隔や、iPS細胞由来心筋及び in silico モデルの利用等の、新たな評価法の研究も進んで来ている。本セッションでは、催不整脈リスク評価の現状と国内外の最新の研究の動向を紹介し、薬物濃度－反応モデルを利用した評価の日本での実施上の留意点についても紹介する。さらにパネルディスカッションにおいて、産官学の立場から、心臓安全性評価の今後の展望を議論する。

iPS細胞を用いたin vitro TQT試験の可能性
武田薬品工業株式会社
篠澤　忠紘

催不整脈リスク評価における早期・探索的臨床試験の役割
一般社団法人ＩＣＲ　附属　クリニカルリサーチ東京病院
深瀬　広幸

薬物濃度―反応モデルを利用したQT延長リスク評価の日本での実施について
独立行政法人 医薬品医療機器総合機構
品川　香

薬物濃度―反応モデルを利用したQT延長リスク評価
– モデル解析について –
独立行政法人 医薬品医療機器総合機構
落合　義徳

パネルディスカッション
本セッションの講演者および
国立医薬品食品衛生研究所
諫田　泰成

北里大学病院
熊谷　雄治

東邦大学医学部
杉山　篤

コーヒーブレイク　15:30-16:00

SESSION 3　16:00-17:30

V1-S3　605/606会議室　16:00-17:30
日本の「患者中心主義」の幕開け（第2部）：試行錯誤の実践例から学ぼう

関連領域: 薬事、臨床、アカデミア、患者さん
レベル: 中級
座長

ヤンセンファーマ株式会社
三木-安田　倫栄

東京大学医科学研究所
武藤　香織

近年、患者中心主義 (Patient Centricity) や患者・市民参画 (Patient and Public Engagement) について国内での注目が急激に高まっているが、ステークホルダーが多岐に渡ることもあり、その概念や理念の整理は進んでいない。本セッションでは第1部に続いて、企業が実際に臨床試験の中で実施している取り組みを共有し、第1部の演者と共にパネルディスカッションを行い、医薬品開発における患者参画活動の現状と課題を整理し、今後の展開について議論する。

Innovating with the Patient, for the Patient
Janssen Research & Development, LLC
Andreas Koester

グローバルと連携した「患者さん志向」の医薬品開発
ファイザー株式会社
北村　篤嗣

患者さんの声を治験計画に反映させる試み
ノバルティス ファーマ株式会社
鈴木　和幸

パネルディスカッション
V1-S2の講演者および本セッションの講演者

V2-S3　607会議室　16:00-17:30
人工知能を利用した医療のデジタル革命の実現に向けて

関連領域: 臨床、統計、アカデミア
レベル：初級

座長

国立がん研究センター　研究所 / 東京大学大学院
間野　博行

デジタルツールの医療への利活用に対する期待は増し、医療のデジタル革命を実現することで、医療の質・安全性の向上、高度化、効率化の三位一体の革新を実現しながら、新産業の創出や研究・開発の効率化を目指すことが期待されている。本セッションでは、最先端医療用AI；Watson for Genomics及びWatson for Drug Discoveryを医療・創薬に導入した事例を紹介するとともに医療現場から導入の実際と課題、今後の展開を共有し、ディスカッションしたい。セッションの中ではWatsonを使ったデモンストレーションを行い、実際に最先端のAIを体感する。

ゲノム解析に基づくPrecision Medicine：医療用人工知能AI開発に向けた実際と将来展望
新潟大学大学院医歯学総合研究科
若井　俊文

IBM Watson Health – 医療・創薬への挑戦
日本アイ・ビー・エム株式会社
溝上　敏文

V3-S3　608会議室　16:00-17:30

新記載要領改正に基づく添付文書作成のためにすべきことは何か？

関連領域: 薬事、安全性
レベル：中級

座長

大塚製薬株式会社
中島　謙

2017年6月、20年ぶりに医療用医薬品の添付文書等の記載要領の改正通知が発出され、3年後の2020年に施行されるため、各企業は、新記載要領に基づいた改訂添付文書を準備する必要がある。そのためには、現行の記載根拠の確認、最新データのレビュー等の実施が考えられる。本セッションでは、PMDAから、新記載要領についての要点のみならず、実際に新記載要領に基づき改訂する際に検討すべき点について、PMDAの観点からご説明いただく。また、現実を見据え、企業の観点から新記載要領に基づく改訂についての課題を取り上げ議論する。改訂を進める上でのベストプラクティス及び問題点を共有し、検討していく。特に、外資系企業として、考慮すべき点、グローバル本社へとのコミュニケーションを含めプ本プロジェクトの進め方として注意すべき点について言及する。また、国内企業とのアプローチの違いについても言及する。

新記載要領に基づく添付文書改訂時のポイント　～PMDAの観点から～
独立行政法人 医薬品医療機器総合機構
鎌田　暁史

新記載要領対応に向けての課題と解決に向けて　～日系企業の観点から～
第一三共株式会社
齋藤　華子

新記載要領対応に向けての課題と解決に向けて　～外資系企業の観点から～
ファイザー株式会社
石川　淳

パネルディスカッション
本セッションの講演者

V4-S3　609会議室　16:00-17:30

新職種メディカルサイエンスリエゾン（MSL）の役割とは何か？

関連領域: 安全性、PM、アカデミア、MA
レベル：初級
言語: 日本語のみ

座長

大阪大学医学部附属病院
岩崎　幸司

最近、製薬企業は高度な医科学的情報交換を主たる業務とする新職種としてメディカルサイエンスリエゾン（MSL）を設置しはじめている。

このセッションでは、医薬品情報の適正な利活用におけるMSLの活動について議論する。製薬企業におけるMSLの活動状況等の現状把握に加えて、MSLの認知度、アカデミア、規制当局のMSLに対する捉え方を整理し、今後の適正な医薬品情報の伝達とそれを担う人材のあり方について議論する。

アカデミアからのMSLに対する期待
山梨大学
岩崎　甫

EFPIA JapanがMSLの位置づけと活動指針
欧州製薬団体連合会（EFPIA）
乙黒　義彦

MSLの役割と身に付けておくべきこととは？
サノフィ株式会社
冨安　美千子

規制当局からみた医薬品情報の利活用におけるMSLへの期待
厚生労働省
坂西　義史

パネルディスカッション
本セッションの講演者

V5-S3　610会議室　16:00-17:30

適切な医薬品情報コミュニケーションの更なる推進に向けて（第2部）

関連領域: 薬事、安全性、アカデミア、MA、Labeling、Marketing、Medical Writing、Medical Information
レベル：中級
言語: 日本語のみ

座長

北里大学
成川　衛

日本イーライリリー株式会社
小嶋　祐子

医薬品情報は、適切に提供され活用されることが重要である。昨年の年会では、規制当局や企業から医療従事者及び患者さんへ提供される資材を対象に課題や取り組みを議論した。その中で、規制当局や企業からは重複する情報を様々な媒体で提供しているが、医療現場の視点で必要な情報がなかったり、作成側の意図が十分伝わっておらず、医療現場で活用されていない状況があることがわかった。前回の議論を踏まえ、規制当局及び企業から医療機関に提供される情報媒体について、目的及び活用方法を整理し、適切な医薬品情報コミュニケーションの推進に向けた取り組みや今後の展望について、規制当局、企業及び医療機関共同でさらなる議論をする。

パネルディスカッション
V5-S2の講演者および
独立行政法人 医薬品医療機器総合機構
井口　豊崇

V6-S3　101会議室　16:00-17:30

再生医療等製品の製品化への道

関連領域: 薬事、安全性、統計、PM、CMC、アカデミア
レベル：初級

座長

国立医薬品食品衛生研究所
佐藤　陽治

再生医療等製品の製品化には、シーズの発見から臨床試験着手まで多くの人の手を経て進められている。本セッションでは、今話題のアカデミア研究の状況、企業開発の事例を紹介するとともに、既承認の品目における審査のポイントを臨床の視点を中心に紹介する。

再生医療等製品ならではの課題や開発及び審査を行う上で工夫した点等を、それぞれの立場から議論して行く。

膝痛を再生医療で治す！　アカデミアの挑戦
東京医科歯科大学
関矢　一郎

細胞シート工学に基づいた再生医療製品の開発
株式会社 セルシード
橋本　せつ子

再生医療等製品の審査上の留意点（有効性・安全性評価を中心として）
独立行政法人 医薬品医療機器総合機構
丸山　良亮

パネルディスカッション
本セッションの講演者

V7-S3　102会議室　16:00-17:30
Globalにおける偽造医薬品の現状と日本における課題

関連領域: 薬事、安全性、CMC、Counterfeit
レベル：初級

座長

中外製薬株式会社
大箸　義章

偽造医薬品の脅威は世界的に増大しており、患者の安全のリスクとなっている。とりわけ、インターネットサイトで購入された医薬品の多くが偽造医薬品であったとの報告もある。そのため、製薬企業による製剤的工夫、税関や警察機関と連携した対応が必要となってきている。

日本市場においても、「ハーボニー」の事例により、正規流通では偽造薬品は流通しないとの神話は崩れており、現状の課題を直視した対応が求められている。

本セッションでは、Globalにおける偽造医薬品の現状と業界の取組みを紹介するとともに、日本市場に潜むリスクとその対応について、NPO、アカデミア、製薬企業からパネラーをお招きし、議論を行いたい。

世界の現状（仮題）
Pharmaceutical Security Institute (PSI)
Martin Blair

日本の現状（仮題）
金沢大学
木村　和子

欧米会社の対応状況（仮題）
F. Hoffmann-La Roche, Ltd.
Pius Waldmeier

国内会社の取組み状況と課題（仮題）
Takeda Pharmaceuticals U.S.A., Inc.
Scott Kammer

パネルディスカッション
本セッションの講演者

V8-S3　703会議室　16:00-17:30
公募演題セッション

関連領域: 薬事、安全性、臨床、ROD
レベル：初級

座長

ファイザー株式会社
冠　和宏

東京大学
湯地　晃一郎

本年会では国内外から昨年を大幅に上回る多くの応募の中から査読委員による厳正な審査を経て4つの演題が口頭発表として選出された。査読基準でもあるDIAのビジョンや年会テーマとの一致性、科学・学術性、国際性・社会性といった視点からも興味深いトピックスであり、当日は講演にとどまらず、フロアとの双方向での議論を行う時間も用意される。

Transforming Pharmacovigilance through Robotic Process Automation and Cognitive Technologies
Deloitte Consulting LLP
Glenn Carroll

Rare Diseases in the Era of Precision Medicine
INFARMED
Dinah Duarte

ASEAN Therapeutic Product Market Access & Regulatory Strategy
PharmEng Technology Pte. Ltd., Singapore
Kenny Peng

Integration of ICH E14 Cardiac Safety in Phase I studies and Validation of Exposure-QTc Relationships
Richmond Pharmacology Ltd.
Jörg Täubel

ENGAGE AND EXCHANGE: LET'S CHAT! "WHAT'S THE DIA WORLD 2017"

レセプションホール **17:45-19:00**

関連領域: 全領域
レベル：全て

総合司会
ファイザー株式会社
稲泉　恵一

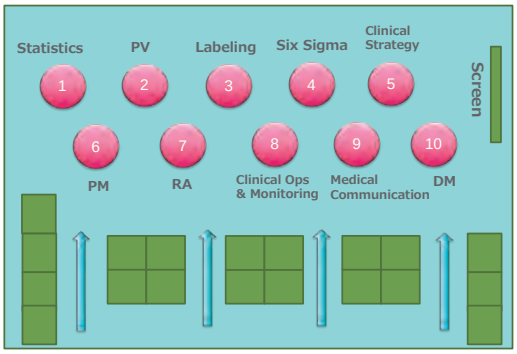
ファシリテーター
DIA Japan Contents Committee / Community

毎年ご好評いただいておりますスペシャルチャッティングセッションを今年も2日目の夜にご用意しました。DIAの活動の大きな目的の1つは人材交流です！参加者同士が気軽にネットワーキング、意見交換ができる場ですので、是非、積極的にこの場をご利用頂ければ嬉しく思います。若手も、ご意見番も、大学の学生や先生も、医療機関の先生方、PMDAの方も、同じテーブルを囲んでしまえば、皆、仲間！年会にお一人で参加される方もぜひ、輪に入っていただき一緒に語り合いましょう。

テーブルごとにテーマを割り振りました。当日、ご興味のあるテーブルの周りにお集まりください。会場ではドリンクと軽食もご用意しています。ビールやワインを飲みながら、熱くそして楽しくおしゃべりしましょう！

なお、このセッションでの発言はすべて個人の見解に基づくものとさせていただきますので、予めご理解願います。

〈会場レイアウト〉



テーマー覧：

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

#	カテゴリー	トピック名	ファシリテーター	概略
1	Statistic	統計解析の最近の潮流、どう思う？	小野薬品工業株式会社 祇園　直数 東京大学 平川　晃弘	臨床試験、臨床研究におけるHot Topicとして、MRCT、estimandの構成、希少疾患の開発、Big Data、臨床試験のインテグリティ、M&S、統計教育、バイオシミラーなどがあり、これらの項目について統計担当者として考えるべき、基本原則、課題、対応方法など共有し、参加者の理解を深めるとともに、産官学それぞれの立場の相互理解の場とする。
2	PV	世の中Big　Dataと騒がしいけど、どうしたら使いこなせるの？信じていいの？PVの観点からどんな価値があるの？	中外製薬株式会社 青木　事成 日本イーライリリー株式会社 前田　玲	2018年より利用可能となるMID-NETや規模が拡大する商用データベース(DB)をPMSやPVに実装する時代がきた。改正GPSP等の制度面は整いつつある一方、利活用に要する人材面を含む環境は未整備である。今回は、DBの可能性と問題点、更にはDBを利用して得られる情報の活用の仕方について様々な観点から話してみたいと思う。
3	Labeling	添付文書新記載要領で何が変わるの？	ファイザー株式会社 松井　理恵	2017年6月、20年ぶりに医療用医薬品の添付文書等の記載要領の改正通知が発出され、2019年に施行されるため、各企業は、新記載要領に対応を検討中である。今回は、新記載要領に関連して、幅広く情報交換をしながら、想定される課題及びその対応策を議論していきたい。
4	Six Sigma	問題解決のワークショップってどうやるの？	グラクソスミスクライン株式会社 井上　宏高 株式会社Real Discovery Outdoors 小澤　郷司	問題解決の手法はビジネスをよりよく進めるために広く用いられています。よく用いられるのが、ワークショップによる問題解決ですが、どのように設計し、どのように進めていくか、は多くのファシリテーターが悩むところです。 当日は、成功・失敗体験を共有し、より良い問題解決への手がかりを得たいと思います。
5	Clinical Strategy	キャリアプランをデザインしよう!! - 本気であなたのキャリアを考えてくれるのはだれ？あなた自身でしょ！	大塚製薬株式会社 桐生　千花 慶應義塾大学病院 松嶋　由紀子 第一三共株式会社 上野　司津子	あなたは職場ではどんなときでも戦略的であると思っているでしょう。キャリアについても同じことが言えますか？将来どんな風になりたいですか？将来のキャリアに向けた戦略やプランはありますか？ クリニカルストラテジーコミュニティはキャリア構築のチャッティングテーブルを企画しました。日本年会に参加いただいた方はどなたでも参加できます。現在の所属や役割は関係ありません。キャリアを模索中の人も大歓迎。大事なことはあなたが自分のキャリアのオーナーであるということです。ご自身のキャリア実現に向けて、いろいろなアイデアを持ち帰ってください。あなたが成長するための時間は、あなたにとっても、新しい治療を待っている人にとっても大切です。さあ、戦略的かつ積極的に！お気軽にご参加ください。
6	Project Management	プロジェクトマネジャ（PM）育成の"はじめの一歩"　～あなたはどんなPMになりたくて、どんなPMになることを期待されているのか～	PMコンサルティング　ポジティブ・インテンション 今野　浩一 協和発酵キリン株式会社 佐藤　隆	プロジェクトを成功に導くためにPMは重大な役割と責任を果たしている。しかし、PM育成については多くの組織で実施されているが、依然として試行錯誤が続いている。本セッションでは、PMトレーニングの具体的取り組み事例を参加者同士で共有し、今後のPM育成のポイントを探求する。
7	Regulatory Affairs	企業の事情、PMDAの事情を分かりあい、よりよいコミュニケーションを実現しよう！	株式会社CTD 東　利則 ノバルティスファーマ株式会社 小室　真人	当局・企業のやり取りをよりスムーズにするため、お互いの考え方や事情を本音ベースで語り合いましょう。また、承認までのプロセスに関する改善提案を話し合いましょう。 例：①なぜPMDAはこんな時期にこんな細かいことを聞いてくるのか？　②簡単な照会を出しているつもりなのになぜ回答作成に時間がかかるのか？企業のワークプロセスが知りたい。③お互いの事情を知ったうえで、審査プロセスの改善提案を議論してみよう。
8	Clinical Operations and Monitoring	臨床試験におけるPatient Centricityの取り組みと期待 ～患者さん中心で、変わる臨床試験～	MSD株式会社 林　光夫 日本イーライリリー株式会社 松田　幸大	各社が"Patient first"を掲げ、臨床試験においてもPatient Centricityに関する新たな取り組みが増えています。なぜ、今Patient Centricityなのか？各社はどのような取り組みをおこなっているのか？そして、臨床試験はどの様に変わっていくのか？について語りましょう！
9	Medical Communication	患者さんの視点に立って医薬品情報のあるべき姿を語ろう！～医薬品の適正使用と氾濫する情報～	ノバルティス ファーマ株式会社 西野　潤一 MSD株式会社 津森　桂子	今は誰でもスマホやPCで医薬品情報を簡単に入手でき、様々な医薬品に関する情報が飛び交っている。それらはすべて正しいエビデンスレベルで記載された情報なのか？患者さんが、誤った解釈をもとに誤った判断をしたら・・・。医薬品情報を提供する立場から、情報が氾濫する時代に、いかに適正な情報を患者さんに届けていくか、オープンに意見交換を行いたい。
10	Data Management	医薬品の適正使用を確立するために行われる製造販売後臨床試験，医療ICT（レジストリー研究，リアルワールドデータ）の活用で何が変わるの？	メディデータ・ソリューションズ株式会社 西　基秀 ブリストル・マイヤーズ　スクイブ株式会社 杉浦　友雅	近年、リアルワールドデータ（RWD: Real World Data）の臨床開発、製造販売後調査への活用が注目されています。また、医療情報データベース活用を鑑みGPSP省令改正も予定され、独立行政法人医薬品医療機器総合機構（PMDA）が構築を進めている医療情報データベースシステム、MID-NET　の本格的な運用が開始される予定です。今後の医療情報データベース活用における留意点や課題について語りましょう。

SESSION 4 9:00-10:30

V1-S4 605/606会議室 9:00-10:30
変わりゆく世界の情勢と製薬業界に対する影響

関連領域: 薬事、ALL
レベル：初級

座長

グラクソ・スミスクライン株式会社
高橋　希人

欧米においてEUからの英国離脱や米国の大統領選挙等世界的にもインパクトを与える出来事があった。

その一つであるEUから英国離脱について、その現状と製薬業界にとって今後どのような影響か生じる可能性があるのか等議論する。

一方で、10月に京都にて薬事規制当局サミットが開催され、医薬品等のイノベーションと規制の新しい関係について各国規制当局が議論を行う。薬事規制当局サミット後の合意や議論を踏まえ、世界の動向を確認するとともに日本における影響等を話し合う。

The Brexit and the Possible Implications for Marketing Authorisation Holders
Federal Institute For Drugs and Medical Devices (BfArM)
Peter Bachmann

薬事規制当局サミットを終えて　～今後の薬事規制の行方～（仮題）
厚生労働省
森　和彦

パネルディスカッション
本セッションの講演者および
PAREXEL International
Alberto Grignolo

塩野義製薬株式会社
澤田　拓子

アストラゼネカ株式会社
谷口　忠明

V2-S4 607会議室 9:00-10:30
統計を正しく使うためには ― p値の意味を理解して誤用をなくそう ―

関連領域: 薬事、DM、安全性、臨床、統計、アカデミア
レベル：初級

言語: 日本語のみ

座長

北海道大学大学院医学研究院
伊藤　陽一

臨床試験の立案や推論の際に議論すべき統計的な観点は多くあり、統計手法や結果（p値、要約統計量など）を正しく理解する必要がある. 特に誤用は試験の結果解釈を誤ったものに導くことになる. The ASA Statement on Statistical Significance and P-values, 2016では、統計的有意差やp値に対する重要な6つの原則を提示している. 一方、医療用医薬品の広告の在り方の見直しに関する提言（平成26年10月22日：厚生労働科学研究班会議）では、製薬企業が上市後に提供する製品情報概要書や広告に関する正確性について示唆している.

統計WSでは、5回にわたり医薬品開発に携わる生物統計専門家でない方のための統計ワークショップを実施しており、その内容も踏まえ本セッションではp値の解釈、統計手法のコンセプトを解説する. また、製品情報概要書や広告の記載に関する留意点を紹介する.

よくあるp値の誤用　―ASA statementより―
慶應義塾大学
竹内　文乃

医薬品開発におけるp値を取り巻く落とし穴
ヤンセンファーマ株式会社
宮里　盛幸

エビデンスレベルに配慮した医療用医薬品の情報提供
アステラス製薬株式会社
竹ノ内　一雅

V3-S4 608会議室 9:00-10:30
データベース調査を再審査申請資料とするための信頼性確保とは？　～改正GPSP省令への対応～

関連領域: 薬事、臨床
レベル：初級

言語: 日本語のみ

座長

独立行政法人 医薬品医療機器総合機構
山口　光峰

大鵬薬品工業株式会社
伊藤　国夫

改正GPSP省令では、平成30年4月から製造販売後調査のひとつとして、各種診療情報等のデータベース利用が認められる。この改正により、製造販売業者は、GPSP省令等を遵守し実施した各種診療情報等のデータベースを用いた調査の結果を再審査申請に利用することができるようになる。今回のシンポジウムでは、PMDA信頼性保証部から再審査申請に利用する際の信頼性担保の基本的な考え方を解説するとともに、MID-NET®を始めとするデータベースの保有者の立場から信頼性確保への取り組みについて報告する。さらに、データベースを用いた調査を実施する立場である申請者の立場から、社内体制整備の試みについて報告する。最後に、今後の課題、展望について議論する。

電子診療情報DBを利用して再審査申請資料を作成する場合におけるデータの信頼性担保に関する基本的考え方について
独立行政法人 医薬品医療機器総合機構
中村　悟

MID-NET® のデータを再審査申請資料に活用するには？
独立行政法人 医薬品医療機器総合機構
原田　紗世子

データベース事業者におけるGPSP対応状況
日本医療データセンター
上沢　仁

GPSP対応を見据えた医療情報データベースを用いた試行的調査の経験から
第一三共株式会社
丹羽　新平

パネルディスカッション
本セッションの講演者

V4-S4 609会議室 9:00-10:30
小児に必要な医薬品は適切に届いているのか？ ― 日本の小児開発の現状と今後の取り組み ―

関連領域: 薬事、臨床、PM、アカデミア
レベル：中級

言語: 日本語のみ

座長

日本イーライリリー株式会社
浜田　奈津子

Global開発が進みドラッグラグが解消しつつある一方で、日本における小児医薬品開発については遅れている現状がある。

EMAではPIP、FDAではPSPによる小児開発が進められており、日本も参加

するGlobal開発が一般化しつつある現在において、小児医薬品についてもGlobal開発を検討する時期ではないかという議論が始まってきている。

欧米では政府による小児開発推進(PSP, PIP)が行われて10年以上が経過しており、ICH E11 のAddendumもStep3となる現状を踏まえ、日本における今後の展望をMHLW/PMDAから説明いただき、日本での小児開発の促進について、産官学のそれぞれの立場で発展的な議論をする。

日本における小児医薬品開発推進について
厚生労働省
井本　昌克

アカデミアからみた日本における小児医薬品開発について（仮題）
日本小児科学会
中川　雅生

Pediatric Drug Development in Japan and International Regulatory Collaboration
独立行政法人 医薬品医療機器総合機構
平田　雅一

パネルディスカッション
本セッションの講演者および
グラクソ・スミスクライン株式会社
佐藤　且章

V5-S4　610会議室　9:00-10:30

プロジェクトマネジャー（PM）の能力開発 "成功に向かうはじめの一歩" ～そもそも、あなたはどんなPMになりたくて、どんなPMになることを期待されているのか～

関連領域: 全領域
レベル：初級
言語: 日本語のみ
座長
DIA PMコミュニティ リード
今野　浩一

プロジェクトを成功に導くためにPMは重大な役割と責任を果たしている。しかし、その能力育成については多くの組織で実施、検討されているが、依然として試行錯誤が続いている。理由のひとつは、求められるPM像が組織環境により異なるため画一的な方法では育成できないことであろう。本セッションでは、参加者が「なりたい／求められるPM」へと成長するためのガイダンスの一例として、米国 PMI が提唱する Project Manager Competency Development Framework (PMCDF) を紹介したうえで、PM育成に携わるパネリストによるPM育成への具体的取り組みや米国の教育機関の事例を共有し、今後のPMの能力開発において最優先すべき戦略課題を探求する。

臨床研究プロジェクトマネジャー育成においてProject Manager Competency Development Framework（PMCDF）を戦略的に適用する
日本医科大学
松山　琴音

カリフォルニア大学サンディエゴ校（UCSD）のプロジェクトマネジメント教育の基本方針とカリキュラムの事例　ー受講者の視点から感じた能力開発の方向性ー
東京大学医科学研究所
藤原　紀子

製薬企業PMによる企業横断的自主勉強会の20年のあゆみとこれからの課題
プロジェクト・プランイング・マネジメントフォーラム
吉田　則子

製薬企業の環境変化に伴うPM人材育成戦略の変遷と今後の展開を考える
ファイザー株式会社
大島　三千世

パネルディスカッション
本セッションの講演者

V6-S4　101会議室　9:00-10:30

Quality by Design；企業が実施する臨床試験の品質を戦略的に構築する

関連領域：薬事、DM、臨床、統計、アカデミア、MA
レベル: 初級
座長
大阪大学医学部附属病院
岩崎　幸司

近年、企業が実施する臨床試験の質の確保に関する具体的施策が求められ、更にICH-E6、E8の改正が医薬品医療機器等法に与える影響を考慮して臨床試験の質を確保する方法としての QbD および Risk Based Monitoring (RBM) が2本の柱として期待されている。RBM は既にパイロットスタディ等より知見が蓄積され実装化が進んでいるが、QbD については概念の理解はあるものの、どのような観点・プロセスで進めていく必要があるのか等の方法論は更に議論を深化させる必要性がある。専門家を招き、医薬品開発の品質向上と効率化向上のために、QbDの観点から臨床試験の品質を戦略的に構築する手法を議論する場を提供する。

ICH E6 (R2)におけるQMS
アストラゼネカ株式会社
池田　司

Implement Quality by Design in Clinical Studies ~ for a Practical Application of Quality Tools ~
グラクソ・スミスクライン株式会社
井上　宏高

オペレーションサイドから考えるQuality by Design
イーピーエス株式会社
小石　達也

Quality by Design from the Viewpoint of Reliability
独立行政法人 医薬品医療機器総合機構
廣瀬　誠

パネルディスカッション
本セッションの講演者

V7-S4　102会議室　9:00-10:30

更に進んだ医療ビッグデータの利活用（第1部）

関連領域: 全領域
レベル：中級、上級
座長
慶應義塾大学
漆原　尚巳

株式会社 ミナケア
山本　雄士

医薬品開発において医療ビッグデータの利活用は不可欠になってきた。医療ビッグデータ解析から得られた結果を意思決定の参考にすることも増えてきた。本セッションでは、治験計画策定、治験オペレーション、更にはアウトカムリサーチ、製造販売後安全対策のようなエリアで、特に革新的な医療ビッグデータの利活用を提案・実践している専門家を招いて、医療ビッグデータの利活用の手法、将来展望についてディスカッションする。冒頭でRWDを用いた検討における世界的なエキスパートに米国での活用事例を網羅的に紹介してもらい、日本における幅広いエリアでの最新の活用事例、またGCPリノベーションを見据えたデータ利活用について徹底討論する。

リアルワールドエビデンスと次世代薬事承認
Quintiles IMS
Nancy A. Dreyer

医療データベースの用量反応推定モデルへの応用
ファイザー株式会社
鈴木　昭之

リアルワールドデータを使ったアウトカム研究の応用事例
武田薬品工業株式会社
廣居　伸蔵

V7-S5に続く

V8-S4　703会議室　9:00-10:30
バイオシミラーの臨床開発

関連領域: 薬事、臨床、統計、PM、CMC、アカデミア
レベル：中級

座長

北海道大学病院
荒戸　照世

昨今、日本を含めグローバルでバイオシミラー（バイオ後続品）の開発が活発化している。そのような中で、バイオシミラーと先発医薬品の品質、有効性及び安全性の同等性をどのように評価すべきかについて、様々な議論がされてきた。本セッションでは、主に臨床開発や臨床試験に焦点をあて、議論を深めたい。はじめに、バイオシミラーの臨床データパッケージの特徴、バイオシミラーに特有な臨床試験デザインを説明する。また、臨床試験での同等性に関する統計的な考え方も紹介する。さらに、バイオシミラーをグローバル開発する際に課題となる国・地域ごとの相違点などを整理する。

Biosimilar Challenges from the Point of View of Project Management
第一三共株式会社
川北　由布子

【公募演題】Regulatory and Scientific Issues on Biosimilar Development in the U.S: Lessons Learned from Recent Approval
PPD
Duu-Gong Wu

Statistical Considerations for the Development of Biosimilar Products <ビデオによる講演>
Amgen Inc.
Nan Zhang

Comparative Clinical Study Designs for Biosimilar Development Program
ノバルティス ファーマ株式会社
徳茂　広太

コーヒーブレイク　10:30-11:00

SESSION 5　11:00-12:30

V1-S5　605/606会議室　11:00-12:30
条件付き早期承認制度ほか、医薬品の早期アクセスを実現する各種制度について

関連領域: 薬事、臨床、PM、アカデミア
レベル：中級

座長

日本イーライリリー株式会社
藤本　利夫

医薬品の早期アクセスを実現する制度が近年整備され、従来からあるオーファン指定、優先審査、先進医療に加え、先駆け審査指定制度、条件付き早期承認制度、拡大治験、患者申出療養が策定されてきた。条件付き早期承認制度の概要及び、他の制度との棲み分けを確認するとともに、拡大治験、患者申出療養については、企業及び、医療現場での対応などを含めて議論を深めていきたいと考える。

条件付き早期承認制度の概要と医薬品の早期承認に向けた各制度の比較について
厚生労働省
荒木　康弘

企業からみた条件付き早期承認制度および人道的見地から実施される治験への期待や課題
ファイザー株式会社
中島　香恵

Can We, Academic Researchers, Contribute for an Expediting Access Scheme in Japan?
国立がん研究センター　研究支援センター
柴田　大朗

パネルディスカッション
本セッションの講演者および
国立がん研究センター / 国立がん研究センター中央病院
藤原　康弘

V2-S5　607会議室　11:00-12:30
医療従事者が利活用できるRMPに向けて

関連領域: 薬事、安全性
レベル：中級

言語: 日本語のみ

座長

アステラス製薬株式会社
石田　和彦

PMDAやAMEDの研究結果によると、年々医療従事者（特に病院薬剤師）の「RMPの認知度」および「医療機関での薬剤業務へのRMPの利活用」は上昇している。一方で、RMPを作成している企業側は、まだまだRMPを規制当局との文書としかとらえていないところも多い。そのような中で、病院薬剤師の一部の方からは、現状のRMPは医療機関で薬剤業務に利活用するには、リスク名の付け方や設定理由の記載方法等においてまだまだわかりにくい点が多いとの声もある。医療機関でのRMPの薬剤業務での利活用を考える際、医療従事者はRMPに何を望み、企業および規制当局は医療従事者からの期待にどのように対応すべきかを議論する。

医療機関におけるRMP利活用の現状と提言－AMED研究成川班での検討結果を踏まえて－
虎の門病院
林　昌洋

地域医療においてRMPを医薬品安全性情報報告に活かす
東北大学病院
小原　拓

医療現場における医薬品リスク管理計画（RMP）の利活用に向けた製薬企業の取組み
中外製薬株式会社
竹本　信也

医療現場における医薬品リスク管理計画の利活用に向けたPMDAの取組み
独立行政法人 医薬品医療機器総合機構
松永　雄亮

パネルディスカッション
本セッションの講演者

V3-S5　608会議室　11:00-12:30
変化するがん第1相試験の役割

関連領域: 薬事、DM、安全性、臨床、統計、PM、アカデミア
レベル：初級、中級

座長

東京大学大学院
平川　晃弘

がん臨床開発の合理化に向けて第1相試験の役割が変化してきている。従来は3+3デザインを用いた用量漸増試験を実施することが一般的であったが、近年では様々な試験デザインやグローバル第1相試験が注目されつつある。第1相試験に関する様々なオプションを知ることで、開発戦略の選択肢は増えると考えられる。本セッションでは、新規がん第I相試験デザイン、多地域共同FIH、薬剤特性を考慮した第I相試験等に焦点を当て、産官学の立場からこれらの有用性について議論する。

変化するがん第1相試験の役割
東京大学大学院
平川　晃弘

オンコロジー多地域共同FIH試験に参加する際に考慮すべき点
ノバルティス ファーマ株式会社
柿爪　智行

薬剤特性を考慮した戦略的第1相試験計画
中外製薬株式会社
田中　智宏

PMDAの立場から
独立行政法人 医薬品医療機器総合機構
佐藤　宏征

V4-S5　609会議室　11:00-12:30
Quality by Design；アカデミアが実施する臨床試験の品質を戦略的に構築する

関連領域：DM、臨床、統計、アカデミア、MA
レベル：初級
言語：日本語のみ
座長

東北大学大学院
山口　拓洋

臨床研究法案の成立に伴い臨床研究の「質」を確保するための手法を具体化する必要がある。Critical to Quality(CTQ) factorを明確にしたうえで、臨床研究のRiskを特定し、そのRiskの顕在化を予測又は検出できるように計画段階からQuality by Design(QbD)の考え方を導入することが重要である。

このセッションでは、アカデミアにおける臨床研究法への具体的な対応として、TransCelerateにおける最新動向、出口戦略を見据えたQbDによる臨床研究計画の立案及びリスクベーストアプローチによるモニタリングについて、研究者、規制当局及び製薬企業等の立場で今後の方向性を議論する。

Building Quality in Academic Clinical Trials –Challenges to Overcome–
東北大学大学院.
山口　拓洋

Key Concepts of TransCelerate RBM Methodology
Astellas Pharma Global Development, Inc.
佐伯　訓

演題未定
京都府立医科大学
松山　琴音

臨床研究法と試験の質の担保
厚生労働省
井本　昌克

パネルディスカッション
本セッションの講演者

V5-S5　610会議室　11:00-12:30
どうする？若手のキャリア？組織の生産性？

関連領域：全領域
レベル：初級
言語：日本語のみ
座長

大塚製薬株式会社
桐生　千花

新薬開発をとりまく環境のパラダイムシフトが加速している。規制の変化、膨大な研究開発費、開発難易度の増加、さらにIT化やグローバル化によってビジネスモデルは変化し、業界の変革は急務である。

一方で人材の確保およびスキルアップにかける対応は充分か？限られたコストと時間で、変革や生産性の向上を担う人材をどのように確保するのか？

当セッションは、若手のキャリア開発について、育成される側及び育成する側の双方に登壇いただき、有意義なキャリア開発とは何かを議論する場を提供したい。

若手アンケート100名の声を紹介する。

若手100人の声～キャリアに関するアンケート結果～
イーピーエス株式会社
中路　健太

第一三共株式会社
炭谷　徳人

アステラス製薬株式会社
溝河　祥

CEO of Your Own Career
パレクセル・インターナショナル株式会社
石渡　都

グローバル人材育成のための採用戦略からトレーニング　そしてキャリアアップ
大塚製薬株式会社
宮竹　容司

“ポスト・グローバリゼーション” 時代の人材育成
ノバルティス ファーマ株式会社
露木　省吾

パネルディスカッション
本セッションの講演者および
第一三共株式会社
上野　司津子

V6-S5　101会議室　11:00-12:30
CROとの効果的な協業のために必要なCROマネジメント

関連領域：臨床、PM
レベル：中級
座長

パレクセル・インターナショナル株式会社
古賀　信宏

試験の品質確保および効率化を進めるための戦略的なCROとの協業が進んでいる。しかしCROへのアウトソースの形態は、一部門のアウトソースから、マルチファンクションのアウトソースまで多種多様である。またグローバルレベルでアウトソースの契約を締結するケースも多い。一方で、ICH E6R2にもCROのオーバーサイトが明記されたものの、そのオーバーサイトの方法は各社さまざまである。そこで、本セッションでは、CROとの効果的な協業のために留意すべきCROマネジメントのポイントを、「CROへの効果的なアウトソース戦略（計画）の構築方法」および「製薬会社・実施医

療機関・CROのそれぞれの観点から考えるCROマネジメントの在り方」に基づいて検討する。

グローバル製薬企業の日本法人におけるアウトソーシング戦略立案
MSD株式会社
佐野　俊治

製薬会社・CRO間のグローバル契約下において双方の日本法人が効果的に協働するには？
日本イーライリリー株式会社
吉本　雄祐

医師主導治験をもとにした実施医療機関の観点からのCROとの協業の在り方
慶應義塾大学病院
藤木　勇人

CROの観点からの戦略的パートナーシップ下におけるCROマネジメント
シミック株式会社
小林　正和

V7-S5　102会議室　11:00-12:30
更に進んだ医療ビッグデータの利活用（第2部）

関連領域: 全領域
レベル：中級、上級

座長

慶應義塾大学
漆原　尚巳

株式会社 ミナケア
山本　雄士

医薬品開発において医療ビッグデータの利活用は不可欠になってきた。医療ビッグデータ解析から得られた結果を意思決定の参考にすることも増えてきた。本セッションでは、治験計画策定、治験オペレーション、更にはアウトカムリサーチ、製造販売後安全対策のようなエリアで、特に革新的な医療ビッグデータの利活用を提案・実践している専門家を招いて、医療ビッグデータの利活用の手法、将来展望についてディスカッションする。冒頭でRWDを用いた検討における世界的なエキスパートに米国での活用事例を網羅的に紹介してもらい、日本における幅広いエリアでの最新の活用事例、またGCPリノベーションを見据えたデータ利活用について徹底討論する。

演題未定
中外製薬株式会社
青木　事成

バイエル薬品におけるビックデータの活用例
バイエル薬品
高橋　俊一

パネルディスカッション
V7-S4の講演者および本セッションの講演者

V8-S5　703会議室　11:00-12:30
Pan-Asiaによる医薬品開発の活性化

関連領域: 薬事、臨床、PM、アカデミア、MA
レベル：中級

座長

独立行政法人 医薬品医療機器総合機構
佐藤　淳子

Asiaにおける医薬品開発というと、日本、中国、台湾、韓国など、東アジアばかりが注目されがちである。しかしながら、昨今、ASEAN地域（東アジアを含むアジア全般）においても国際共同臨床試験の実施環境が整ってきており、ICH-GCPに準拠した国際共同臨床試験の成績等も公表されるようになってきている。本セッションでは、ASEAN地域における臨床試験環境の実際について紹介した上で、更なる活性化に向けた活動について議論を行い、東アジアのみならず東南アジア地域も交えてアジア一丸となった医薬品開発への貢献、アジア地域での画期的新薬への早期アクセスを目的とした協働について議論をする。

演題未定
国立国際医療研究センター
渡邉　裕司

Current Status and Future Expectation of Clinical Studies by Academia
Center for Drug Evaluation, China Food and Drug Administration (CFDA)
Jianzhong Zhao

PMDA's Experiences with New Drug Applications including Data from Multi Regional (Asian) Clinical Trials
独立行政法人 医薬品医療機器総合機構
大坪　泰斗

パネルディスカッション
本セッションの講演者

ランチブレイク　12:30-14:00

SESSION 6　14:00-15:30

V1-S6　605/606会議室　14:00-15:30
最適使用推進ガイドライン（今後の制度の方向性、新薬承認審査過程における議論、医療現場での実際について）

関連領域: 薬事、臨床、安全性、アカデミア、MA
レベル：中級

座長

武田薬品工業株式会社
柏谷　祐司

昨年度より試行導入が行われている最適使用推進ガイドラインについて、今後の正式導入に向けての方向性を議論する。ガイドラインの策定対象品目、ガイドラインを策定した場合の申請資料作成や承認審査への影響、また、ガイドライン策定により、実際の医療現場ではどのような変化や影響があるのか、今後の課題も含め議論する。

最適使用推進ガイドライン作成の背景と概要について
厚生労働省
杉山　恵梨

最適使用推進ガイドライン：製薬企業の立場から
小野薬品工業株式会社
牟田　博之

最適使用推進ガイドライン：医療現場への影響
国立がん研究センター　東病院
田原　信

パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
藤原　康宏

V2-S6　607会議室　14:00-15:30
医療Big Data時代のRMP

関連領域: 薬事、安全性

レベル：中級
言語: 日本語のみ
座長
日本イーライリリー株式会社
前田　玲

まもなく医療情報データベース研究が製造販売後調査のひとつとして追加の安全性監視活動に利用されるようになる。 そこで、ICH E2E 「医薬品安全性監視の計画」の考えに立ち返り、RMPの中の医薬品安全性監視のあり方全般について議論を行う。

ICH E2E「医薬品安全性監視の計画」の基本的考え
東京理科大学
佐藤　嗣道

医薬品承認審査における安全性監視活動計画の疫学的検討
独立行政法人 医薬品医療機器総合機構
石黒　智恵子

そのRMP、最適ですか？
中外製薬株式会社
青木　事成

パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
朝倉　渡

V3-S6　608会議室　14:00-15:30
希少がん・希少フラクション領域の臨床開発オプションを考える

関連領域: 薬事、DM、安全性、臨床、統計、PM、アカデミア
レベル：初級、中級
座長
東京大学大学院
平川 晃弘

希少がん・希少フラクション領域では、pivotal trialとして少数例の第2相試験が実施されるが、その規制要件は対象疾患や標準治療等により異なるため、開発は常に手探り状態である。希少がん・希少フラクション領域の臨床開発の基本的考えを整理し、承認申請に向けた道筋を立て易くすることが重要である。本セッションでは、開発を効率化させるための産学連携のあり方、規制要件の明確化について取り上げ、当該領域の臨床開発の基本的考え方の整理につなげたい。

産官学連携による希少がん領域の治療開発の取り組み
国立がん研究センター
米盛　勧

希少がん・希少フラクション領域の開発の現状と課題 ー 製薬企業の立場から ー
ノバルティス ファーマ株式会社
春宮　美希

希少がん・希少フラクション領域の開発の現状と課題 ー PMDAの立場から ー
独立行政法人 医薬品医療機器総合機構
込山　則行

V4-S6　609会議室　14:00-15:30
効率的な医薬品・医療機器開発のために、アカデミアと企業はどう連携すべきか？ー医師主導治験で実施した医薬品、医療機器の同時開発・承認事例から考えるー

関連領域: 全領域
レベル：中級、上級
言語: 日本語のみ
座長
京都大学大学院
笠井　宏委

医薬品・医療機器開発を効率的に進めるためには、医師主導治験の活用等、アカデミアと企業との戦略的連携が重要である。これまで、医師主導治験を用い薬事承認を取得した事例も複数あり、最近では、企業のみでは実施が難しい製造販売業者が異なる薬剤と機器を組み合わせて使用する治療に対する同時承認を取得した品目もある。本セッションでは、アカデミア・企業、及び審査を担当するPMDAの視点から、効率的な医薬品・医療機器開発に必要なアカデミアと企業の連携方法について議論する。

タラポルフィンナトリウム及びPDT半導体レーザの同時開発の経験（非臨床～承認・保険償還まで）ー効率的な開発のために企業とアカデミアはどのように連携すべきかー
京都大学大学院
武藤　学

承認申請を踏まえたアカデミアと企業のよりよい連携とは ー弊社の医師主導治験への協力の経験ー
全薬工業株式会社
奥垣内　泉

審査側からみたアカデミア・企業との効果的な連携
独立行政法人 医薬品医療機器総合機構
鳩貝　健

パネルディスカッション
本セッションの講演者および
株式会社CTD
小林　史明

V5-S6　610会議室　14:00-15:30
AROと製薬企業における臨床試験の品質管理とLean Six Sigma

関連領域: 薬事、アカデミア
レベル：初級
言語: 日本語のみ
座長
日本CRO協会
渡辺　敏彦

臨床研究法案成立や GCP renovation により臨床研究・臨床試験の品質を管理する方法として、Quality by DesignおよびRisk Based ApproachやCritical to Quality（CTQ）設定など品質管理手法や考えを導入することが期待されている。しかしながら、現時点で具体的な事例はなく、限られたリソースで臨床試験の現場レベルで品質確保する工夫をしているのが現状である。

本セッションでは、国際標準化機構 International Organization for Standardization（ISO）にも規定された定量的プロセス改善手法であり、世界的に品質管理・効率化の手法として活用されている Lean Six Sigma（LSS）の概要を示すと共に、製薬企業でLSSを用いて試験デザイン構築段階における品質の作り込みを行ったQbD具体例及びAROでLSSを導入し臨床試験の品質を現場レベルで改善した具体例を示す。

品質マネジメントの国際標準としてのLean Six Sigma
グラクソ・スミスクライン株式会社
井上　宏高

日本イーライリリーにおけるLean Six Sigmaの活用事例

日本イーライリリー株式会社
水本　聡太

アカデミアでLean Six Sigmaを応用した品質活動事例
東京大学医学部附属病院
影山　祐子

V6-S6　101会議室　14:00-15:30

Rethinking Quality in Clinical Trials - What are Quality Tolerance Limits (QTLs) and How Should they be Adapted in Clinical Studies to Fulfill New ICH-E6 Requirement?

関連領域: 薬事、DM、臨床、統計、PM、アカデミア、MA
レベル：中級

座長

Astellas Pharma Global Development, Inc.
佐伯　訓

ICH-E6 (R2) の section 5.0では品質マネージメントのアプローチとして riskに基づくQualityManagementSystemの考え方が新たに追加され、現在、国内の実装に向けた議論が進んでいる段階である。Quality Management System の中でも特に重要な component である Quality Tolerance Limit (QTL) に関して、海外においては TransCelerate を中心に活発な議論がなされているものの、残念ながら国内ではあまり議論されていないのが現状である。本セッションでは global expert であり、TransCelerate の RBM initiative における key member であった Andy Lawton からQTLの考え方、実際のアプローチ及びその評価方法について講演いただく。また、講演の中で紹介されたQTLのアプローチについて、PMDA及び製薬企業の方々を交えたうえで、国内での適切な実装に向けたパネルディスカッションを予定している。

Quality Tolerance Limits – A History and the Why, How, What and Where of Implementation in Clinical Trials
Risk Based Approach Ltd
Andy Lawton

パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
井坂　弘道

Bristol-Myers Squibb
杉浦　友雅

V7-S6　102会議室　14:00-15:30

ICH Q12ガイドライン実装をとおしたアジア地域でのライフサイクルマネジメントと開発戦略の将来展望

関連領域 : 薬事、CMC、アカデミア
レベル: 初級
座長

国立医薬品食品衛生研究所
檜山　行雄

グローバルでの開発、販売を目指す医薬品グローバル企業にとって、各国毎の異なる承認後変更手続きの管理が、継続的改善やイノベーションを妨げる要因の一つになっている。

現在検討中のICH Q12ガイドライン「医薬品のライフサイクルマネジメントに関するガイドライン」は、CMCに関する承認後の変更管理を、より予測可能かつ効率的な方法で促進する枠組みを提供するものである。

本セッションではICH　Q12ガイドラインの実装にあたって想定される課題点、アジア地域での開発戦略の変化について、アジアの規制当局関係者及び企業関係者から紹介いただく予定である。

ICH Q12 (Pharmaceutical Product Lifecycle Management): PMDA Perspective
独立行政法人 医薬品医療機器総合機構
岸岡　康博

CFDA's View on Implementation of ICH Q12 in China as well as Current Quality Compliance System such as PQS in China (仮題)
Center for Drug Evaluation, China Food and Drug Administration (CFDA)
Yang Wang

Pharmaceutical Quality System and Change Management Expectation to ICH Q12 from Industry
大塚製薬株式会社
仲川　知則

パネルディスカッション
本セッションの講演者

V8-S6　703会議室　14:00-15:30

最適な薬を提供するために　～コンパニオン診断薬の利用と開発の現状（次世代シークエンサーを中心に）～

関連領域: 薬事、DM、安全性、統計、PM、アカデミア、Diagnostics Company
レベル：初級

座長

近畿大学
西尾　和人

個々の患者さんに合った薬を届けるためにはコンパニオン診断薬の存在は重要であり、がんゲノム医療では次世代シークエンサーを用いてゲノム解析行い、患者さんごと、細胞ごとのゲノム変異を明らかにした治療が行われている。

本セッションでは、次世代シークエンサーを用いたプレシジョンメディシンの現状、次世代シークエンサーを用いるうえでの問題点及びコンパニオン診断薬開発の課題について、産官学それぞれの立場から発表を行い、パネルディスカッションで解決策について議論を行う。

次世代シークエンサーを用いたコンパニオン診断システムの開発における課題と今後の方向性　～審査側の立場で～（仮題）
独立行政法人 医薬品医療機器総合機構
柳原　玲子

進行がん患者の次世代シークエンサー遺伝子パネル検査の開発
国立がん研究センター　研究所
河野　隆志

診断薬企業からみたコンパニオン診断薬・診断システムの開発における課題
ロッシュ・ダイアグノスティックス株式会社
西田　美和

パネルディスカッション
本セッションの講演者および
アストラゼネカ株式会社
田中　倫夫

コーヒーブレイク　15:30-16:00

PMDAタウンホール&閉会の挨拶

PMDAタウンホール
国際会議場 **16:00-17:30**

関連領域：全領域
レベル：中級

座長

独立行政法人 医薬品医療機器総合機構
佐藤　淳子

グラクソ・スミスクライン株式会社
高橋　希人

本セッションは、PMDAの担当者をパネリストに迎え、参加者からの質問についてお答えするセッションです。有意義なセッションとするため、参加者からのの積極的なご発言、ご質問を期待しています。
パネリスト：

独立行政法人 医薬品医療機器総合機構
信頼性保証部　部長
廣瀬　誠

独立行政法人 医薬品医療機器総合機構
新薬審査第二部　審査役
本多　基子

独立行政法人 医薬品医療機器総合機構
医療情報活用推進室
石黒　智恵子

独立行政法人 医薬品医療機器総合機構
新薬審査第三部　部長 / 国際研修シニアコーディネーター
加藤　直人

独立行政法人 医薬品医療機器総合機構
審査マネジメント部　審査マネジメント課　課長補佐
杉田　敏樹

独立行政法人 医薬品医療機器総合機構
先駆け審査業務調整役 / イノベーション実用化支援業務調整役
柴辻　正喜

独立行政法人 医薬品医療機器総合機構
体外診断薬審査室　室長
矢花　直幸

閉会の挨拶
国際会議場 **17:30-17:40**

第14回DIA日本年会副大会長 / ヤンセンファーマ株式会社
池田　晶子

14th DIA Japan Annual Meeting 2017

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SPEAKER INDEX

Kotonari Aoki, MS

Mr. Kotonari Aoki is Department Manager of Real World Data Science and Group Manager of Epidemiology Group at Chugai Pharmaceutical Co.,Ltd. Mr. Aoki has over 20 years experience in clinical data management, programming, statistical analysis and epidemiology in the field of healthcare data science. Mr. Aoki is a senior epidemiologist at the Japan Clinical Epidemiology Association and as a councilor at the Japanese Pharmac Epidemiology Association participates in many projects. Mr. Aoki is also a representative of a pharmaceutical company of MID-NET which is a national project to utilize medical data.

Yasuhiro Araki

Mr. Yasuhiro Araki is Deputy Director in the Pharmaceutical Evaluation and Licensing Division, Ministry of Health, Labour and Welfare (MHLW). Mr. Araki is at the leading position for activities reviewing and approving new drugs in the division. He has career experience in pharmaceutical authority not only as an MHLW officer but, as a reviewer in Pharmaceuticals and Medical Devices Agency (PMDA). Currently, he is working intensively to introduce "Conditional Early Approval System for drugs" and post-marketing surveys using Real World Data. Mr. Araki graduated from Graduate School of Pharmaceutical Sciences, The University of Tokyo in 1999.

Wataru Asakura, PhD

Apr 1999: Office of Review III, Pharmaceuticals and Medical Devices Evaluation Center (PMDEC), National Institute of Health Sciences.
Jan 2000: Clinical Trial Guidance Department, Organization of Pharmaceutical Safety and Research (OPSR/KIKO).
Apr 2004: Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA).
Apr 2009: Office of New Drug V, PMDA.
Apr 2013: Office of General Affairs, PMDA.
Aug 2014: Office of New Drug IV, PMDA.

Peter Bachmann, PhD

Following a Japan Society for Promotion of Science Postdoctoral Fellowship at Kyoto University (Japan), and a German Research Foundation Fellowship at the Institute of Food Research in Norwich (UK), Dr. Bachmann worked at the Institute of Pharmaceutical Biology at the Technical University Braunschweig (Germany), until joining the German Federal Institute for Drugs and Medical Devices (BfArM) Department of Drug Approval in 1999. He currently serves as Head of the Unit of European Coordination and as Deputy-Head of the Division of European and International Affairs. Dr. Bachmann studied biology and chemistry and has a Doctorate of Natural Sciences (Pharmaceutical Biology) from the University of Wuerzburg (Germany).

Yoshifumi Banzai, PhD

Dr. Yoshifumi Banzai is Deputy Director of Compliance and Narcotics Division at Ministry of Health, Labour and Welfare, Japan.

March 2004	Graduated from Graduare School of Pharmaceutical Sciences, the University of Tokyo, Japan and received Ph.D. degree in Pharmaceutical Sciences
April 2004	Joined Ministry of Health, Labour and Welfare, Japan
April 2014	Joined Toyama Prefectural Government of Japan
April 2015	Director of Pharmaceutical Policy Division, Toyama Prefectural Government of Japan
April 2017	Joined Ministry of Health, Labour and Welfare, Japan

Glenn Carroll, MBA

Glenn Carroll is a Principal in the Life Science practice with over 15 years of Pharmaceutical and Biotechnology experience. Glenn has significant consulting experience in Compliance, R&D, Medical Affairs and Pharmacovigilance. He leads Deloitte's Drug Safety and Pharmacovigilance and Medical Affairs practices. His experience includes:

- Leading global teams to implement new global operating model strategies within Clinical, Medical and Drug Safety and Pharmacovigilance, that have included large compliance remediation efforts
- Glenn has also published several eminence papers on Research & Development, including Uses of EHR in Clinical Development and Post Launch, new operating models in Pharmacovigilance, Medical Affairs and Commercial Glenn holds a BE in Biochemical Engineering from University College Dublin and an MBA from Imperial College London.

Nancy A. Dreyer, PhD, MPH, FISPE, FDIA

Nancy Dreyer is global chief of scientific affairs for QuintilesIMS Real-World Insights and is responsible for advanced evidence development for regulators, payers, clinicians, and patients. She leads research using minimally interventional and non-interventional study design that use primary and/or secondary data collection. She has worked with the FDA, most recently helping to plan a medical device evaluation network, and also has worked with the European Medicines Agency testing new methods for pharmacovigilance. She is a Fellow of both the International Society of Pharmacoepidemiology and the Drug Information Association, and is Adjunct Professor of Epidemiology at the UNC Gillings School of Global Public Health in North Carolina.

Dinah Duarte, PharmD, MSc

Dr. Dinah Duarte is the Head of the Scientific Evaluation Unit at the Directorate of Medicinal Products, in the Portuguese regulatory authority for medicines and health products (INFARMED). She is an expert member at the European Medicines Agency (EMA); the current Committee for Orphan Medicinal Products member for Portugal and the representative in the Steering Group of ENCePP (European Network of Centres for Pharmacoepidemiology & Pharmacovigilance). Former CHMP (Committee for Medicinal Products for Human Use) member for Portugal and the CHMP representative in the EMA's group Human Scientific Committees Working Party With Healthcare Professionals Organisations. She is also Assistant Professor at the Lisbon University.

A. Leander Fontaine, MD

President of Pharmiceutics LLC, a consulting firm based in Pennsylvania, USA. Pharmiceutics offers consulting, training and services for labeling. Before founding Pharmiceutics in 2005, Leander served as Vice President and Head of Global Labeling Division and Vice President, International Labeling Liaison, for Wyeth, USA. He started his career in global labeling in 1991 and has served as head of global labeling functions for Hoechst (Germany) and Hoechst Marion Roussel (USA). He has also held positions in clinical development and clinical pharmacology with Behringwerke (Germany). Before joining the pharmaceutical industry, he worked as a physician in internal medicine as well as in anesthesiology, intensive care and emergency medicine.

Yuto Fujiki, RPh

Yuto Fujiki is Research Associate at Clinical and Translational Research Center of Keio University Hospital. Fujiki is a Project Manager of Investigator Initiated Clinical Trials. After doing CRA in CRO for 10 years, Fujiki is doing Project Manager for 2 years by Keio University Hospital. Fujiki holds a RPh.

Toshio Fujimoto, MD, MBA

Toshio Fujimoto, MD, MBA, entered Eli Lilly Japan in 2006. Engaged in drug development initially in oncology area as a clinical research physician, he became Medical Director in 2009. Currently, Dr. Fujimoto is Vice President in Medicines Development Unit Japan, and responsible for the drug development and Medical Affairs in all therapeutic areas in Lilly. He also serves as a chair in Science and Regulatory Leadership Committee, PhRMA, and as an external board member for Foundation for Biomedical Research and Innovation in Kobe Biocluster.

Prior to joining Lilly, Dr. Fujimoto served as a thoracic surgeon in Japan, Germany, and the U.S., after having received his MD degree from Kyoto University in 1994.

Noriko Fujiwara, MS, RN, OCNS, CCRP

Ms. Noriko Fujiwara is Director of Planning and Coordination Office, at JORTC (Japanese Organisation for Research and Treatment of Cancer), and Research Nurse of Advanced clinical Research Center, The Institute of Medical Science, The University of Tokyo. She has over 10 years' experience in research field. She is a Certified Nurse Specialist in Cancer Nursing with the Japanese Nursing Association and a Certified Clinical Research Professional with the SoCRA and got the certification of Project Management from UCSD, CA, USA. She then completed a research internship at MD Anderson Cancer Center, TX, USA. She is currently a president of the Japan chapter of the International Association of Clinical Research Nurses.

Yasuhiro Fujiwara, MD, PhD

Dr.Yasuhiro Fujiwara is Principle Reviewer at Pharmaceuticals and Medical Devices Agency (PMDA). Dr.Fujiwara has about 5 years' experience in the office of New Drug V (Oncology Unit). Dr. Fujiwara holds a PhD in Medicine from Okayama University.

Hiroyuki Fukase, MD, PhD

Dr. Hiroyuki Fukase is Director of Clinical Research Center, Clinical Research Hospital Tokyo. Dr. Fukase, as a principal investigator, has conducted various types of clinical pharmacology studies including first-in-human studies, bridging studies and thorough QT/QTc studies for approximately 24 years.

Rei Goto, MD, PhD

Dr. Rei Goto is an associate professor of health economics and health policy at Graduate School of Business Administration, Keio University. He received M.D. from Kyoto University. After two year's residency of medicine in Kobe City General Hospital, he started research in health economics. He received Ph.D. in Economics from Kyoto University in 2005. His research area includes

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health economics, behavioral economics (addiction, measurement of time and risk preferences parameters, preventive behaviour, prescription and treatment choice of physicians) and health technology assessment. He serves as a board member of Japanese Health Economics Association (JHEA).

Alberto Grignolo, PhD

Alberto Grignolo, Ph.D. is a Corporate Vice President at PAREXEL Consulting. A 25-year veteran of the firm, he recently established the firm's Japan Regulatory Consulting Services during a two-year assignment in Tokyo. He has been an active member of DIA since 1984, served on the DIA Board from 2000 until 2004, is the Editor of DIA Global Forum magazine, received DIA's Global Inspire Award (Global Connector) in 2015 and was named a Fellow of DIA in 2017. He was a Member (2008-2011) of the first Executive Committee of the Clinical Trials Transformation Initiative (CTTI), a Public Private Partnership between the FDA and Duke University aiming to increase the quality and efficiency of clinical trials.

Sayoko Harada, MPharm, RPh

Sayoko Harada is coordinator for MID-NET project, Office of Medical Informatics and Epidemiology, Pharmaceuticals & Medical Devices Agency (PMDA) of Japan. She was assigned to this office in July 2014 and has worked to improve the data quality of the MIDNET system.
She joined PMDA in April 2008. She was assigned to Office of Conformity Audit (Apr. 2008 - Sep. 2009, Apr. 2013 - Jun. 2014) and Office of Relief Funds (Oct. 2009 - Mar. 2013).
She holds a Master's degree in Pharmacy from the Mukogawa Women's University and has a license as a pharmacist.

Miki Harumiya, MPharm

Ms. Miki Harumiya is in Solid Tumor Clinical Development at Novartis Pharma K.K. Ms.Harumiya has 15 years' experience in the pharmaceutical inductries including onlology, organ transplantation and others. Ms.Harumiya holds Master of pharmacy in Tokyo Unibersity of Science.

Mei Haruya, PhD

Dr. Mei Haruya is Manager of Strategic Innovation Department in R&D Japan at GlaxoSmithKline K.K. He is currently responsible for incubating innovation across the company with leveraging digital technologies and Real World Data. Dr. Haruya has 9 years' experience in the pharmaceutical industry, including Medicinal Chemistry Research, Clinical Research, R&D Project Management, Corporate Strategy Planning, and President's Office. Dr. Haruya received his PhD and MS from the University of Tokyo.

Setsuko Hashimoto, PhD

Dr. Hashimoto is the President and CEO of CellSeed Inc. and the Director of FIRM (The Forum for Innovative Regenerative Medicine). Dr. Hashimoto has over 30 years' commercial experience in bio-industry with proven expertise in creating bridges between Japanese and overseas organizations including experience as Senior Investment Advisor at Invest in Sweden Agency (currently Business Sweden) at the Embassy of Sweden in Japan responsible for Life Science field. Dr. Hashimoto is well networked globally to academia, government and industry, and serves for a few committees including Industry Committee of International Society for Stem Cell Research (ISSCR). Dr. Hashimoto holds a PhD in molecular biology from Heidelberg University in Germany.

Ken Hatogai, MD, PhD

Dr. Hatogai is a reviewer in Pharmaceuticals and Medical Devices Agency (PMDA), Japan. Dr. Hatogai is in charge of consultations and reviews regarding hematology/oncology agents, and also belongs to the working group of companion diagnostics and clinical innovation network in PMDA representing the hematology/oncology department. Dr. Hatogai is originally a medical oncologist, and joined PMDA after five years experience in oncology practice, phase 1 to 3 clinical trials, and translational researches at the National Cancer Center, Japan. Dr. Hatogai holds a PhD in Medicine from Chiba University.

Jin Higashijima, PhD

Jin Higashijima is an associate professor in the Faculty of Global Science Studies at Yamaguchi University in Yamaguchi, Japan. Her primary research interests include the ethical and social aspects of biomedical sciences. She currently studies patient and public involvement in scientific research in Japan as a means to examine dynamic changes in the relationship among the general public, especially patients, and the scientific community in Japan.

Robert Hilke

Robert Hilke is the CEO of Hilke Communications Corporation, a firm specializing in providing intercultural communications and TOEIC training for global businesspeople, many of whom work in the pharmaceutical industry. Mr. Hilke's primary research interest is the management of diverse teams working in a global business environment. Mr. Hilke has made presentations at more than ten DIA conferences since 2009. In addition, he has authored more than 90 books on preparing for standardized examinations, mainly TOEIC, but also including TOEFL, GRE, and GMAT.

Akihiro Hirakawa, PhD

Akihiro Hirakawa is a Project Associate Professor at the Department of Biostatistics and Bioinformatics, Graduate School of Medicine, at the University of Tokyo. His areas of specialty are biostatistics, clinical trial methodologies, and bioinformatics. Prior to joining the University of Tokyo, he served as the Lecturer of Biostatistics at the Center Advanced Medicine and Clinical Research, Nagoya University Hospital, where he leaded the Statistical Analysis Section. He also served as a reviewer in the Office of New Drug V (clinical oncology) at the Pharmaceutical and Medical Devices Agency (PMDA). Dr. Hirakawa received his PhD from the Graduate School of Engineering at Tokyo University of Science.

Masakazu Hirata, PhD

Dr. Masakazu Hirata is a review director in Office of Cellular and Tissue-based Products (2017-current) and a member of Pediatric Drug WG of PMDA. He joined PMDA in 2008 and worked as senior reviewer of Office of New Drugs I (2008-2013), review director of Office of Cellular and Tissue-based products (2013-2014), and as division director of Pharmaceutical Strategic Consultation in Kansai Branch (2014-2017). He grew up in Osaka and studied medicine at Kyoto University. Dr. Hirata has PhD in pharmacology from Kyoto University. Between 2014-2017, he served as Regulatory Chair of EWG for ICH E11(R1) guidance, which was completed as ICH Step 4 document in August 2017.

Shinzo Hiroi, MPH, RPh, PMP

Mr. Shinzo Hiroi is Head of HEOR (health economics and outcomes research) of Japan Medical Affairs at Takeda Pharmaceutical Co., Ltd. In this position, Mr. Hiroi is responsible for leading all projects across several therapeutic areas. Mr. Hiroi has 30 years' experience in the pharmaceutical industries, including clinical operation, clinical science, post marketing surveillance and HEOR. Mr. Hiroi is a registered pharmacist, and holds MPH from Kyoto University and PMP.

Makoto Hirose, MSc

Mr. Makoto Hirose is Office Director, Office of Non-clinical and Clinical Compliance Pharmaceuticals and Medical Devices Agency (PMDA).
In this position, Mr. Hirose is responsible for GLP/GCP/GPSP compliance assessments in Drugs, Medical Devices and Cellular and Tissue-based Products.
Mr. Hirose holds a Master of Pharmaceutical Sciences from Meiji college of Pharmacy in 1990, and the same year Mr. Hirose entered Ministry of Health and Welfare.
Mr. Hirose has over 20 years' experience in the pharmaceutical affairs and food hygiene Administration.

Yukio Hiyama, PhD

Dr. Yukio Hiyama is Visiting (retired) Scientist at National Institute of Health Sciences. He received Ph.D. degree in Chemistry from the University of Tokyo in 1979. He led an industry-government Human Science project on evaluation methods for pharmaceutical development and manufacturing control. He also led MHLW's study groups to draft GMP related guidance and to propose the regulatory framework under the revised Pharmaceutical Affairs Law (2005). He has been involved in the ICH discussion for Q8, Q9 and Q10. His previous work experiences include positions in Pharmaceutical Development in Upjohn Co. in US and in Japan, scientist at National Institutes of Health, USA and post-doctoral fellow at University Illinois.

Motoko Honda, PhD

Dr. Motoko Honda joined Pharmaceticals and Medical Devices Agency (PMDA) in 2006 and now she is a Review Director of Office of New Drug II.

Toyotaka Iguchi, MD, PhD

Dr. Toyotaka Iguchi is a Risk Manegement Director, Office of Safety II, Pharmaceutical and Medical Devices Agency. Dr. Iguchi is a hematologist/oncologist, graduated from Keio University School of Medicine and has over 10 years' review experience at PMDA as Review Director/Risk irector and a medical reviewer. Dr. Iguchi holds a MD, PhD from Keio University, and is now also Visiting lecturer, Department of Internal Medicine, Keio University, School of Medicine (concurrent position), Part-time lecturer, Faculty of Science and Engineering, Cooperative Major in Advanced Biomedical Sciences Tokyo Women's Medical University and Waseda University Joint Graduate School (concurrent position).

Tsukasa Ikeda

Mr. Tsukasa Ikeda is Director, Quality Assurance AsiaPac, AstraZeneca. Mr. Ikeda has experience with quality assurance activities in clinical studies more than 20 years. Mr. Ikeda is responsible for conducting various types of audit in Asia Pac region. Mr. Ikeda was deputy topic leader as the representative from Japan industry on ICH E6 (R2).

Masakatsu Imoto
Mr. Masakatsu Imoto is Director of Office of Clinical Trial Promotion, Research and Development Division Ministry of Health, Labour and Welfare(MHLW). In this position, Mr. Imoto is responsible for promotion of clinical trial. Mr. Imoto has over 20 years' experience in the pharmaceutical affairs regulation, pricing of drug and research and development of medicinal products as a Japanese government officer. And Mr. Imoto also has experience of reviewing the pharmaceutical application for the approval of drugs and medical devices as a reviewer in PMDA.

Hirotaka Inoue, PhD, MBA
Dr. Hirotaka Inoue is Head of Leading Changes Office at GlaxoSmithKline KK. He is working on business improvement activities such as quality/process improvement, change management, strategy deployment. He holds a PhD in Pharmacology and MBA. He also has a Master Black Belt of Six Sigma and a committee member of ISO18404 - a standard for Six Sigma.

Hiromichi Isaka
Mr. Hiromichi Isaka is Inspector of office of Non-clinical and Clinical Compliance Pharmaceuticals and Medical Divice Agency(PMDA). Mr. Isaka engages in document-based inspection to assess whether the submitted data comply with the data integrity standards for regulatory submission documentation. Mr.Isaka also has experience in reviewing of drug applications and planning Post-marketing safety measures for 7 years as a staff of PMDA.

Hideyasu Ishibashi, PhD
Dr. Ishibashi is currently Head, Translational Clinical Oncology Japan, Novartis. He received his PhD degree from Tokyo University of Science. He joined Novartis in 2009, and worked on several oncology clinical development projects as a senior program leader. After serving as Head of Oncology Program Management, he moved to the oncology translational research in 2015.
Before joining Novartis, he worked for Ono Pharmaceutical Co. Ltd., and had experiences of drug development in a variety of therapeutic areas in Japan and US.

Kazuhiko Ishida, MSc, RPh
Mr. Kazuhiko Ishida is Associate Risk Management Director of Pharmacovigilance at Astellas Pharma Inc. In this position, Mr. Ishida is responsible for providing clinical, methodologic and strategic input to global or regional project/product management teams for development of risk management activities. Mr. Ishida has over 20 years' experience in the pharmaceutical industry, including Clinical Development, Post Marketing Study and Pharmacovigilance. Mr. Ishida holds a MSc in Pharmaceutical Sciences from Okayama University.

Chieko Ishiguro, MPH
Ms.Chieko Ishiguro is Leader of Epidemiology team in Office of Medical Informatics and Epidemiology at PMDA. In this position, she is responsible for leading epidemiological studies using healthcare information databases. She has over 10 years' experience in pharmacoepidemiology in PMDA and also experiences in FDA and Boston University. She hold a MPH in Epidemiology from Kyoto University. She has been a councilor of Japanese Society for Pharmacoepidemiology since 2015 and is the recipient of the Best Reviewer Award of the Pharmacoepidemiology and Drug Safety for 2016.

Kensuke Ishii, PhD
Dr. Kensuke Ishii is a Director for Medical Devices, Office of Medical Devices II, Pharmaceuticals and Medical Devices Agency (PMDA). He is a pharmacist and had experience of the work in the national hospital for about nine years. He moved to Ministry of Health, Labour and Welfare (MHLW) in 1996. During the period, he worked in Safety Division, Pharmaceutical and Food Safety Bureau, and in Medical Economics Division, Health Insurance Bureau etc. Thereafter, he moved to Medical Device Safety Division, Office of Safety, PMDA for post-marketing safety measures in 2004 and he became a director in Medical Device Safety Division in 2007 and moved to Office of Medical Devices as a review director in 2014. In 2014, he gained his doctoral degree from Graduate School of Medical Sciences, Yamagata University.

Jun Ishikawa
Jun Ishikawa is International Labeling Group Asia, Japan Team Lead and his role is accountable for overseeing day-to-day planning, implementation, and problem solving activities for his team whom are responsible for Japan market. Mr. Ishikawa will ensure that content management of Package Insert and Patient Leaflet for all registered products including Generic products in Pfizer Japan according to global Pfizer policy and SOPs and that regionally-set compliance targets are met on a monthly basis. Mr. Ishikawa has over 24 years' labeling and regulatory experience in Pfizer Japan, and also has experiece of participating in Pfizer Japan project of all Package Insert revision based on the new Guidelines 20 years ago.

Miyako Ishiwata, RPh
Ms. Miyako Ishiwata is the head of the Clinical Operations Induction Manager Group at PAREXEL International Japan. In this position, Ms. Ishiwata is responsible for leading the group, delivering well trained and motivated, newly hired staff to the organization. In addition, Ms. Ishiwata collaborates with PAREXEL's Learning & Development teams, to strengthen overall staff development within Clinical Operations Japan, focusing on the development of existing employees and managers. Ms. Ishiwata has over 15 years' experience working in the CRO sector starting as a Clinical Research Associate and subsequently a Clinical Operations Leader including acting as the coordinator for people management for a large partnership program.

Yoichi M. Ito, PhD
Dr. Yoichi M. Ito is an associate professor of Hokkaido University Graduate School of Medicine. He is engaged in a special committee member of PMDA since 2012. He holds a PhD in Health sciences from the University of Tokyo and his specialty is biostatistics.

Kunio Itoh
Mr. Kunio Itoh is Director of Clinical Research and Pharmacoepidemiology Department at Taiho Pharmaceutical Co.,Ltd. Mr. Ito is responsible for the Post Marketing Surveillance and Clinical Trial. Mr. Ito has more than 25 years of experince in Post Marketing Surveillance. Mr. Ito is Vice-Chairperson of Post Marketing Surveillance Expert Committee at Japan Pharmaceutical Manufacturers Association, JPMA.

Masaru Iwasaki, MD, PhD
Masaru Iwasaki received his MD degree from the University of Tokyo in 1973.
From 1974 to 1983 he made his clinical fellowship in surgery at the University Hospital Tokyo, and received his PhD in 1983. From 1983 to 1984 he was a clinical fellow at the Hannover Medical School in Germany. After returning to Japan, he moved to the department of surgery at the Yamanashi Medical University, where he held a position of Assistant Professor.
In April 1993, he joined Hoecst Japan, and began to be involved in the drug development in the industry. In January 2000, he was assigned to a Deputy Head of R&D Division of Aventis Pharma. In 2005, he moved to GlaxoSmithKline Japan, and has been working as V.P., Managing Director of Drug development & Medical Affairs Division at GSK Japan, taking responsibility of not only pharmaceutical drugs, but also vaccine development in Japan, coordinating with the global head located in UK and US. In 2011, he moved back to University of Yamanashi, and assigned to be a professor of Department of Clinical Research.
In 2012, he was appointed as the director of Center for Advancing Clinical Research (CACR) , constructing the system of translational research at this university. In 2015, he was assigned to be a vice president at this university, and a professor of Department of Advanced Biomedical Research. Concurrently he has been working as a Program Officer at AMED.
His URL is miwasaki@yamanashi.ac.jp

Yuko Kageyama
Ms. Yuko Kageyama is Assistant Head of The Phase 1 Unit (P1 Unit) of the Clinical Research Support Center at the University of Tokyo Hospital. In this position, Ms. Kageyama is responsible for supervising 7 Medical Technologist. Ms. Kageyama has 10 years' experience in the field of Clinical Laboratory. Ms. Kageyama got a degree in medical laboratory science from Tokyo Medical and Dental University, in 2014.

Tomoyuki Kakizume, PhD
Dr. Tomoyuki Kakizume graduated from the University of Tsukuba, College of natural science and finished master course of Mathematics, graduated school of pure and applied sciences, University of Tsukuba. He got a Ph.D. from the Yokohama City University, graduate school of Medicine.
He Joined Yamanouchi Pharmaceutical Co.,LTD in 2002 and worked as a biostatistician. In 2009, he joined Novartis Japan as a biostatistician in Oncology business unit. Currently, he is a biostatistician in Biostatistics Oncology Group, Integrated Biostatistics Japan Department.

Akifumi Kamata, PhD
Dr. Akifumi Kamata is a reviewer of Office of Safety II in Pharmaceuticals and Medical Devices Agency (PMDA). In this position, Dr. Kamata is responsible for risk management and pharmacovigilance of vaccines and blood products. Dr. Kamata has 8 years' experience in PMDA. Dr. Kamata holds a PhD in Pharmaceutical science from Tohoku University.

Scott Kammer, MA
Scott Kammer is responsible for leading Global Product Protection for Takeda Pharmaceuticals. Scott provides 28 years corporate security experience in the pharmaceutical industry. He has been instrumental in the development and implementation of a global strategy to combat illicit trade using a multi-prong

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approach. This multi-prong approach involves enforcement, product protection technologies, forensics, supply chain security and education.
Scott serves on the Rx360 Board where he has provided external training on supply chain security to regulators, customs and industry. In addition, he has served on the APEC Life Sciences Innovation Forum as a technical advisor on supply chain security.

Yasunari Kanda, PhD

Dr. Kanda is Head of Division of Pharmacology, National Institute of Health Sciences. In this position, Dr. Kanda is responsible for all-japan project for cardiac safety assessment of human iPS cells. Dr. Kanda has over 20 years' experience in the pharmacology and toxicology field. Dr. Kanda hold a Ph. D. from the University of Tokyo and is also the recipient of the Metallomics Young Scientist Award for 2013.

Hiroi Kasai, PhD

Dr. Hiroi Kasai is Head of Study Management Department in Institute for Advancement of Clinical and Translational Science (iACT) of Kyoto University Hospital. In this position, Dr. Kasai is responsible for study management activities of iACT's multihospital clinical trials. Dr. Kasai has about 20 years' experience as a CRC and a project manager in the academic clinical research organizations. Dr. Kasai holds a PhD in Medical Laboratory Science from Tokyo Medical and Dental University.

Yuji Kashitani

Mr. Yuji Kashitani is Head of Regulatory Development Group of Regulatory Affairs at Takeda Pharmaceutical company Ltd.
In this position, Mr. Kashitani is responsible for leading all regulatory activities across new drug application of Takeda's products.
Mr. Kashitani has over 25 years' experience in the pharmaceutical industries, including Regulatory affairs only.
Mr. Kashitani has been serving as vice chairperson of the Regulatory Affairs Committee and chairperson of the Regulatory Development Division at Japan Pharmaceutical Manufacturing Association since 2016.

Naoto Kato

Naoto Kato joined Pharmaceuticals and Medical Devices Agency (PMDA) as a Reviewer in Office of New Drug III in 2004 and is the Office Director of Office of New Drug III, a position he has held since October 2015. He worked as a board-certified Pharmacist more than 15 years at Pharmacy Department at University of Tsukuba Hospital right after he graduated from Nihon University in 1982.

Kazuko Kimura, PhD

Dr. Kazuko KIMURA, served at the Ministry of Health and Welfare for 20 years, and was dispatched to WHO HQ in Geneva in 1996-1999. She was coordinator of the WHO project on counterfeit drugs and then worked on the promotion of GMP implementation. After returning, she became Professor of the Department of Drug Management Policy at Kanazawa University, where she focused on the epidemic of substandard and falsified medicines, mainly in Asia. She also checked medicines imported via the internet. She won Kanazawa University Female Researcher Award. In October 2017, she inaugurates the Medi-Quality Security Institute, whose mission is to promote good quality and authentic medical products globally through GMP/GDP. This is the target 3.8 of SDG.

Chika Kiryu, DVM, PhD

Chika Kiryu graduated with a PhD in veterinary medicine from Hokkaido University in 1999 and subsequently did postdoc work in various fields. In 2003 she joined JIMRO, an Otsuka Group company, as a member of a team for introducing Chinese medical devices to Japan. In 2004 she transferred to the Free Radical Research Institute of Otsuka Pharmaceutical, moving to the Clinical Research and Development Department in 2007. She has 13 years of clinical and drug development experience, including in such areas as the CNS and inborn metabolic disorder. She is currently in charge of clinical management for oncology.

Yasuhiro Kishioka, PhD

Dr. Kishioka is a principal reviewer in the Office of Cellular and Tissue-based Products of the Japanese regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA). Since joining PMDA in 2008, his main work is the pharmaceutical quality review of biotechnological/biological products. His areas of expertise also include biosimilars and he currently works as review team leader. Dr. Kishioka has been assigned as the ICH Q12 topic leader of Japanese regulatory authorities. He holds a Ph.D from Hokkaido University in Meat Science with emphasis in Molecular Biology.

Atsushi Kitamura

Mr. Atsushi Kitamura is Head of Oncology Clinical Operations at Pfizer Japan. He has more than 20 years' experience in the pharmaceutical industry, including domestic pharma, global CRO, and global pharma companies, with focus on clinical operations. He has been leading Pfizer Japan patient centricity task force for 4 years.

Fumiaki Kobayashi, PhD

Dr. Fumiaki Kobayashi is a president at CTD inc. Dr.Kobayashi is now responsible for supporting many investigator initiate clinical trials.
Business experience

April 1989-	Hospital Pharmacy, Toyama Medical and Pharmaceutical University
July 1997-	Pharmaceutical and Medical Devices Evaluation Center, National Institute of Health Sciences
July 2000-	Organization for Pharmaceutical Safety and Research
September 2002-	Safety Division / Evaluation and Licensing Division, Ministry of Health and Welfare
January 2004-	Center for Clinical Trials, Japan Medical Association
April 2010-	CTD inc.

Kazumichi Kobayashi

Kazumichi Kobayashi is an Senior Vice President of Otsuka Holdings Co., Ltd., and Executive Director of Otsuka Medical Devices. He joined Otsuka Pharmaceutical Co., Ltd. as a regulatory affairs staff in 1982. He was assigned as Director of Regulatory Affairs, Otsuka Pharmaceuticals in 1999. Thereafter, he was assigned to take care of clinical development and quality & safety assurance headquarter as well as regulatory affairs, as Corporate Officer.
He is the first CEO of Otsuka Pharmaceutical Development and Commercialization Inc. in the US in 2007. Otsuka sent him on loan to Office of Pharmaceutical Industry Research (OPIR) in JPMA, as Senior Research Fellow, from 2012 to 2015. He works for Otsuka Holdings Co., Ltd. from April 2015.

Makoto Kobayashi, MEng, PhD

Makoto Kobayashi, Ph.D., M. Eng. is Director and Chief Operating Officer at CRECON Medical Assessment Inc. based in Tokyo, Japan. Dr. Kobayashi joined CRECON in 1994 and has been engaged in health economics and outcomes researches for more than 20 years. He has written/published numerous articles on pharmacoeconomic analysis and has presented at various local and international conferences. He is a member of the steering committee of the ISPOR Japan Chapter (serves as Secretary General) and the DPC Management Association in Japan. He is also a project professor at the Graduate School of Japan University of Economics and a senior fellow at the Healthcare Risk Management Center at Tama University.

Masakazu Kobayashi, RPh

Mr. Masakazu Kobayashi is the head of "Clinical Research 2nd Division" of CMIC Co.,Ltd.
In this position, Mr. Kobayashi is responsible for leading all oncology, ICCC (in-country clinical care taker) and medical device projects contracts and operations.
Mr. Kobayashi has over 20 years' experience in pharmaceutical industry, mainly in oncology, infectious and endocrine.
Mr. Kobayashi had moved to the CRO from a pharmaceutical company in 2010, and since then has mainly been in charge of the oncology therapeutic area.

Andreas Koester, MD, PhD

As Head of Innovation, Research & Development Operations at Janssen, Dr. Andreas Koester is leading the company's efforts to optimize the clinical trial process and bring medical innovations to patients faster. Beyond Janssen, Andreas is active in the pre-competitive space, e.g. as the oversight committee member representing Janssen at TransCelerate Biopharma.
Andreas has 20+ years' experience in pharmaceutical companies and CROs (Contract Research Organizations). His background is in drug development, and worked in leadership roles for trials that led to approvals of Prezista®, Intelence® and Reminyl®. Andreas is a graduate of Leipzig Medical School and earned his Ph.D. in Clinical Pharmacology from Humboldt University in Berlin.

Nobuhiro Koga, MBA, PMP

Nobuhiro Koga is a Portfolio Director at PAREXEL International. In this position, Mr. Koga is responsible for clinical development business with pharmaceutical companies. Mr. Koga has 17 years' experience in the pharmaceutical industries, including CRA, global study management in US, clinical team leader, clinical project management, management of approximately 250 CRAs as head of CRA division. In addition to assignments of clinical operation, Mr. Koga led organizational transformation, global integration activities, productivity improvement activities and many KAIZEN activities. Mr. Koga received pharmacist license in 1997, master of pharmacology in 1999, PMP (Project Management Professional) in 2010 and MBA in 2010.

Takashi Kohno, PhD

Dr. Takashi Kohno is currently a Chief in Division of Genome Biology of National Cancer Center Research Institute, Japan. Dr. Kohno graduated from

Kyoto University in 1989. He received PhD from Tokyo University. From 1995, he has studied lung cancer genetics and genomics in National Cancer Center. His representative research product is the finding of RET fusion in lung adenocarcinoma and its translation to lung cancer clinic.
He is also a Chief of Division of Translational Research, Exploratory Oncology Research and Clinical Trial Center, National Cancer Center Research Institute.

Yuko Kojima

Ms. Yuko Kojima is Head of the Biometrics in the Medicine Development Unit Japan at Eli Lilly Japan K.K. In this position, Ms. Kojima is responsible for leading Scientific Communications, Statistical Science, and Pharmacokinetics/Pharmacodynamics to provide balanced, objective, and accurate scientific data and information to our customers. Ms. Kojima has over 25 years' experience in the pharmaceutical industry and 18 years' experience in medical communications, including 4-year experience based in Shanghai. She graduated from Kyoto Pharmaceutical University and is a registered pharmacist.

Noriyuki Komiyama, MSc

Mr. Noriyuki Komiyama is a Deputy Review Director, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA) and engages in review and scientific consultation of new oncology drugs. He joined PMDA in 2004 and served as a reviewer or a risk manager of these drugs. In the meantime, from 2011 to 2013, he served as a technical officer at Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare (MHLW).

Emiko Kondo, PhD

Dr. Emiko Kondo is the Office Director of the Office of Safety 2, Pharmaceuticals and Medical Devices Agency (PMDA). The Office of Safety 2 is responsible for post-marketing safety measures concerning pharmaceuticals.
She started her job at Ministry of Health, Labor and Welfare (MHLW) in 1991. During the period, she worked in Pharmaceutical and Food Safety Bureau, MHLW, and PMDA. In 2014, she gained her doctoral degree from Graduate School of Medical Sciences, Yamagata University.

Tatsuya Kondo, MD, PhD

Dr. Tatsuya Kondo is Chief Executive of PMDA since 2008.
He spent most of his career as a neurosurgeon after his graduation from the University of Tokyo in 1968. He has various experiences including a hospital doctor, a fellowship in Max-Planck Institute for brain tumor research, and visiting staff surgeon in China-Japan Friendship Hospital in Beijing. Currently, he is also serving as the Advisor on Health and Medical Strategy for Cabinet Secretariat of Japanese Government.

Yuji Kumagai, MD, PhD

Dr. Yuji Kumagai is a clinical pharmacologist and he graduated from Medical College of Oita, Oita, Japan. He got training on clinical pharmacology especially in cardiac drugs in Post Graduate School, Medical College of Oita, Oita, Japan. After his several important works in the field of clinical pharmacology and chronobiology, he moved to Kitasato university and concentrated to works in clinical trials. He is now a professor of Clinical Research Center, School of Medicine, Kitasato University and the director of Clinical Trial Center at Kitasato University Hospital, East Hospital.

Yoichi Kurebayashi, DVM, PhD

Dr. Yoichi Kurebayashi is Senior Director of Japan Agency for Medical Research and Development (AMED). In this position, Dr. Kurebayashi is responsible for leading all project activities across AMED's drug discovery and development programs pursued by Division of Innovative Drug Discovery and Development (iD3). Dr. Kurebayashi has over 30 years' drug discovery experience at Daiichi, Bayer, and Pfizer. Taking advantage of the long industry experience, Dr. Kurebayashi became a professor of the Kobe University Graduate School of Medicine, where he was engaged in translational research and technology transfer. In Apr. 2013, he rose to the new challenge at AMED to lead innovate drug discovery and development in Japanese academia.

Andy Lawton

Andy Lawton has extensive experience in computing, statistics, data management, RDE/RDC, system design, RBA in CSV and clinical trials. He is currently consultant and director of Risk Based Approach Ltd. Previously, Andy held the position of Global Head of CDM at Boehringer Ingelheim, and during that time he was a Founding Committee Member of ACDM, Member of TransCelerate RBM work stream and a Member of EFPIA WG on Data Transparency.
His most notable publications is the paper with Dr. Alistair Ross on GP Audit - throughout 80's and 90's this was the most quoted paper in the BMJ, and he won "best author of the year 2015 and 2016" from the DIA, for the TransCelerate papers on SDV and Central Monitoring in the TIRS Journal.

Chia-Chi (Josh) Lin, MD, PhD

Chia-Chi (Josh) Lin is the Director of Phase I Center, Department of Oncology, National Taiwan University Hospital and Clinical Associate Professor, Department of Urology, National Taiwan University College of Medicine. His research interests include early phase drug development and novel therapies for thoracic (lung cancer, esophageal cancer, thyroid cancer) malignancies. Dr. Lin was appointed as the executive secretary of Taiwan Oncology Phase I Trial Consortium (TOPIC).

Daisuke Maki

Mr. Daisuke Maki's responsibility within CROèe, Inc is to spread outward recognition of the patient recruitment business.
He also serves as a consultant in dealing with the laws and guidelines of patient recruitment in Japan and in planning patient recruitment strategies.
Mr. Maki has 15 years of experience in the pharmaceutical development industry, but is also knowledgeable in the IT field, which was his major in university.
Mr. Maki also has experience as a psychological counselor, and his experiences are utilized in clinical development related to the central nervous system area.

Hiroyuki Mano, MD, PhD

Professor Hiroyuki Mano is the Director of National Cancer Center Research Institute as well as the Professor of Department of Cellular Signaling, Graduate School of Medicine, The University of Tokyo. Professor Mano plays a central role for the organization of basic-to-clinical research activities in National Cancer Center, and for the genomic medicine platform in Japan. He discovered EML4-ALK and other oncogenes, and is still actively involved in the identification of essential growth drivers in cancer in his laboratory in The University of Tokyo. Given these tremendous achievements, he has received many prestigious awards including The Medal with Purple Ribbon from The Japanese Emperor and The Keio Medical Science Prize.

Yukihiro Matsuda, MSc

Mr. Yukihiro Matsuda is research scientist of Clinical Development Operations & Innovations at Eli Lilly Japan K.K. Mr. Matsuda has over 15 year's experience in the pharmaceutical companies, including clinical operation, trial management and medical writing. Mr. Matsuda holds a MSc in Biology from Kyoto University, and is also the program vice-chair of DIA COM Japan from 2016.

Yusuke Matsunaga, PhD

I have served as a reviewer with the office of Safety II, the Pharmaceuticals and Medical Devices Agency (PMDA) since April 2013. I am responsible for the review and evaluation of the safety of metabolic agents. I joined PMDA in April 2008. From April 2008 to March 2013, I worked as a reviewer in the Office of New Drugs. I received my Ph.D. in Medical Sciences from Kumamoto University, Japan in 2008.

Nobushige Matsuoka, PhD

Nobushige Matsuoka (Ph.D.) now is a clinical statistician in the Pfizer Japan. He joined Pfizer in 2005 and has over 10 years' experience of drug development. He got his Ph.D. at Tokyo University of Science.

Yomei Matsuoka, MSc, RPh

Mr. Matsuoka is Senior Director of Pharmacovigulance Department at Daiichi Sankyo Co., LTD. He joined Sankyo Co., LTD. in 1991, and has worked for Daiichi Sankyo Co., LTD.since 2007. After engagement in clinical development department and regulatory affairs department for over 20 years, and moved to pharmacovigilancedepartment. Currently, he is in charge of safety planning for the several therapeutic areas such as CV, oncology, CNS, vaccines and contrast agents.

Kotone Matsuyama, RPh

Kotone Matsuyama is currently a Professor, Medical Management, Nippon Medical University and Vice President of Integrated Clinical Research Center, Educational Institute of Nippon Medical University. She started her R&D carrier as a data manager in 2003. She has been worked as project manager since 2005. She spent 12 years at Translational Research Informatics Center, Foundation for Biomedical Research and Innovation and 2.5 years as Lecturer at Kyoto Prefectural University of Medicine. She has been managed or supported many R&D projects oriented academia, not only for drugs, but also medical devices and regenerative medicines. She graduated Kyoto University Faculty of Pharmaceutical Science and obtained a license of Pharmacist.

Norie Miki-Yasuda, PhD

PhD. Norie Miki-Yasuda is Head of Japan Clinical Operations as Janssen Pharmaceutical K.K. Prior to join Janssen, PhD Miki-Yasuda has successfully led Global Clinical Operations Japan and Clinical Operation and Biostatistics/Data Management in global pharma companies and led the R&D Strategic Business Operation Development and the prioritization for the global organization. The first county lead of Japan TransCelerate during her assignment in Japan.

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Earned a PhD from Hiroshima University in Japan and completed Postdoctoral Fellowship at School of Public Health in the University of South Carolina, and served as a Research Associate at the division of Oncology and Hematology at School of Medicine in the same university in Columbia, SC.

Koji Miura, MD, MPH, PhD

Graduated from Keio University School of Medicine, Japan, Professor Koji MIURA entered Ministry of Health and Welfare in 1983. He received Master of Public Health from Harvard School of Public Health and Ph.D from Keio University respectively. He had occupied many significant posts in the ministry and other ministries including Ministry of Education, Culture, Sports, Science and Technology(MEXT). During the career as a medical officer, he had long committed with health policy based on science and technology. After serving as Director General of Health and Welfare Bureau of Ministry of Health, Labour and Welfare for two years, he now teaches in Keio University School of Medicine.

Moriyuki Miyasato, MBA

Moriyuki Miyasato is Director, Head of Biostatistics Department in Quantitative Science Division of Japan R&D at Janssen Pharmaceutical K.K., Pharmaceutical company of Johnson & Johnson. Moriyuki is responsible for leading all activities related to biostatistics and statistical programming/data analyses for clinical development and post-marketing surveillances in Japan. Moriyuki joined Janssen in Aug2012. Prior to joining Janssen, Moriyuki has over 20 years' experiences in biostatistics and statistical data analyses for clinical development in some global pharma companies, including Pfizer, Wyeth, and Hoechst Marion Roussel (currently known as Sanofi). He holds MBA degree from Bond University, Australia.

Youji Miyatake

Mr.Youji Miyatake is Director, Office of Talent Development and Training, Headquarters of Clinical Development, Otsuka Pharmaceutical Co.,Ltd. In this position, Mr.Miyatake is responsible for developing and performing education & training programs for all personnel within Clinical Development.
Mr.Miyatake worked on GLP in QA, focusing on safety study reliability operations for 15 years.
In addition to QA activities worldwide he involved in QA training as a member of Steering Committee and Director of the GLP Department in the Japan Society of QA. After QA activities he dealt with inspections by the regulatory authorities as the person responsible for QC within GCP while managing Global SOPs, providing GCP training for 17years.

Koichi Miyazaki, PhD

Koichi Miyazaki is currently Senior Director, Clinical Development Group, Asia Development Department. In this capacity, he is responsible for developing clinical research strategies, and designing and conducting clinical trials in a wide range of disease areas in Asia region. Prior to taking current position, he was the Asia region head of regulatory affairs and was responsible for IND, NDA, and post-NDA approval in Asia. He also has experience of project leader responsible for Asia in mega-global studies. Before taking project leader position, he spent 4 years in US as project manager with overall responsibilities for study operational aspects of clinical trials both in US local studies and global studies in cardiovascular field.

Sho Mizokawa, MSc, RPh

Sho Mizokawa is working as a clinical study manager at Japan-Asia Clinical Development 2 in Astellas Pharma Inc. Sho Mizokawa entered Astellas as a new graduate in 2011, and has experience of new drug development in Immunology and Nephrology disease area, etc.

Souta Mizumoto, MPharm

Mr.Souta Mizumoto is Director of Global Patient Safety and also Six Sigma Champion for R&D functions at Eli Lilly Japan K.K. In this position, Mr.Mizumoto is responsible to lead safety activities for drugs and devices and lead Six Sigma and transformation activities across R&D functions. Mr.Mizumoto has 17 years experiences in the pharmaceutical industry especially in Clinical Operation, Clinical Project Management, Patient Safety, and Six Sigma, etc.

Gareth Monteath, DBA, MBA

Dr. Gareth ("Gaz") Monteath is Executive Director at Link Global Solution Inc., an HR and OD consulting firm based in Tokyo. In his position, Gaz is responsible for the overall content and quality of programmes. LGS has long experience of working with pharmaceutical and medical instruments companies in Japan, Europe, and the United States in order to help them to develop their individuals, teams, and organisations as a whole. Gaz has been a speaker at the annual June DIA conference in the United States each year since 2011, and 2017 will mark his second appearance at the annual DIA conference in Japan. His doctorate is in Business Administration (University of Manchester Alliance Manchester Business School, 2015).

Kazuhiko Mori, MSc

Kazuhiko Mori, MSc., is currently Councilor for Pharmaceutical Affairs, Minister's Secretariat of the Ministry Health, Lobour and Welfare (MHLW). Mr. Mori has led many of MHLW/PMDA's drug initiatives. He contributed to introduce new approaches to drug safety regulation including the concept of Japanese risk management plan (J-RMP) and he also initiate SAKIGAKE designation system for promoting innovative new drug development and review. He served as director of Evaluation and Licensing division, Pharmaceutical and Food Safety Bureau of the MHLW from 2014-2015, and Chief Safety Officer of PMDA from 2010-2013. He also served as director of Safety division, Pharmaceutical and Food Safety Bureau of the MHLW from 2008-2010.

Yoshihiro Muragaki, MD, PhD

Dr. Yoshihiro Muragaki is a directer of Faculty of Admanced Techno-Surgery at Tokyo Women's Medical University (TWMU). Dr. Muragaki is a board neurosurgeon specializing in malignant brain tumor, and his reseach fields include clinical trials for gliomas and developments of new therapuetic medical devices including a smart cyber operating theater (SCOT). Dr. Muragaki has also developed combination products for cancer therapy. Dr. Muragaki holds two PhDs in medicine from TWMU and in Biomedical Science from Waseda University, and is also recipient of the Award of 18th Advanced Technology Award in 2004, the Award of Sankangaku Renkeikourousya in 2010, and Good Design Award in 2016.

Hiroyuki Muta

Mr. Hiroyuki Muta is Head of Regulatory Affairs at ONO pharmaceutical Co., Ltd. Mr. Muta has over 20 years' experience in the pharmaceutical industries, including clinical development planning, medical writing and regulatory affairs.

Manabu Muto, MD, PhD

Dr. Manabu Muto is Professor of Department of Therapeutic Oncology, Graduate School of Medicine at Kyoto University since April 2013, and also a Head of Department of Clinical Oncology at Kyoto University Hospital Cancer Center. His areas of specialties are Molecular biology, Genetic medicine, Gastroenterology, GI Oncology and Clinical trial, especially of esophageal cancer and precision cancer medicine. He won 18 awards, and one of them was the Princess Takamatsu Cancer Research Found, Prize-winner award 2010. His membership of Medical Societies are ASCO, ASGE, ISDE, and 16 Japanese associations. He has 14 Japanese Patents. His English original articles for now are 191 and 5 English books.

Masao Nakagawa, MD

Dr. Masao Nakagawa is Chairman of the Committee on Pharmaceutical Affairs of the Japan Paediatric Society. In this position, Dr. Nakagawa is responsible for organizing networks which will be set up with affiliated pediatric subspecialty or other academic societies to support and conduct global industry-sponsored clinical trials. Dr. Nakagawa had worked on inspections of the new drugs as a Medical Reviewer in the Pharmaceuticals and Medical Devices Evaluation Center, National Institute of Health Sciences from 2002 to 2003. Dr. Nakagawa also had worked for quality control of the clinical trials as the Director of the Center for Clinical Research and Advanced Medicine, Shiga University of Medical Science Hospital from 2004 to 2014.

Tomonori Nakagawa, MA

Joined Otsuka and worked on the API process development, technical transfer, CMC preparations, inspection readiness, and supply chain. After 10 years of experiences, joined QC Department to work on the inspections readiness globally, quality audits, and quality responses to overseas. Currently, working on the project to develop supply (CMC) strategy and supply risk analysis throughout Product CMC lifecycle. A member of Japan Pharmaceutical Manufacturing Association (JPMA) Quality and Technical Committee since 2007 and ICH Project since 2010 and joined EWG for ICH Q11 and ICH Q7 Q&A and have been a JPMA topic leader for ICH Q12 guideline. Have Master's degree for Organic Chemistry from US Graduate School.

Kenta Nakaji, RPh

Mr. Kenta Nakaji is a CRA at EPS Co.,Ltd, the Contract Research Organization.
Mr. Nakaji has 3 years' experience as a CRA in the Clinical Development, including Phase III and IV trials in Endocrine/Metabolic area.
Mr. Nakaji is a registered pharmacist and holds a Bachelor of Pharmacy from Meiji Pharmaceutical University.

Akihiro Nakajima

2007.3 Master of Engineering, Tokyo University of Science
2007.4- Pharmaceutical Development Administration Department, Teijin Pharma Limited

Ken Nakajima, PhD

Mr. Ken Nakajima is Deputy Head of Medical Safety of Pharmacovigilance Department at Otsuka Pharmaceutical Co., Ltd. He has over 20 years' experience in the pharmacovigilance in the Pharmaceutical Company, including the other Company. And he is Pharmacist.

Harumasa Nakamura, MD

Dr. Nakamura is Section Chief of the Department of Clinical Research Support at the Translational Medical Center and Section Chief of the Clinical Research/Trial Promotion Section, Department of Clinical Research Promotion at the National Center Hospital. Dr. Nakamura is a neurologist who is certified to practice as a specialist of clinical neurology by the Japanese Society of Neurology. He specializes in the treatment of neuromuscular disorders, neurodegenerative disorders, and neuroimmunological disorders. He previously worked as a medical reviewer for the Office of New Drug 3 at the Pharmaceuticals and Medical Devices Agency (2005-2008, 2012-2014) and was a member of the PMDA's Orphan Medicine Working Group.

Satoru Nakamura

From April.1993 to March.2003, I had worked at the hospital pharmacy, hospital of the University of Occupational and Environment Health, Japan, and mainly been in charge of dispensing, hospital preparation, and clinical trial.
From April.2003 to March.2004, I had worked at the Kajiwara Pharmacy as a pharmacist.
I have been working at the Pharmaceuticals and Medical Devices Agency (PMDA,Japan) since March.2005, and been in charge of GPSP at the Office of Non-clinical and Clinical Compliance since July.2016.

Kae Nakashima, DVM, PhD, MS

Dr. Kae Nakashima is Japan Regulatory Portfolio Lead for oncology products in Pfizer Japan Inc. In this position, Dr. Nakashima leads the Japan regulatory team responsible for Pfizer Japan's oncology portfolio, from early development stages to post-approval activities such as re-examination and post-approval commitments.
Dr. Nakashima holds a Doctor of Veterinary Medicine from the University of Tokyo, a MS in Biological and Biophysical Science from the State University of New York at Buffalo (Roswell Park Cancer Institute) and a PhD in Pharmaceutical Medicine from Kitasato University.

Miwa Nishida

Miwa Nishida is Head of Clinical Development at Roche Diagnostics K.K. In this position, she is responsible for planning registration strategies and conducting clinical studies in Japan. She has over 10 years' experience in the diagnostics company, including regulatory affairs and clinical operations, and also she previously worked at the pharmaceutical company as a researcher for 15 years.

Junichi Nishino, MSc, RPh

Junichi started his career as a researcher in pre-clinical department in Novartis. He moved to Regulatory Affairs in 2000, he was in charge of lots of HA meetings and NDA submissions as a regulatory manager for development projects. From 2010, he was assigned Head of Process Improvement & Excellence in RA. He had responsible for Intelligence, training, external communications etc. as a regulatory expert. He has served Head of Regulatory Operation & Labeling from 2014 to 2016. Junichi now serves Head of RA Functions dept. since Jan 2017.
Junichi has taken a leadership in several industrial associations. He has a Master degree of Pharmacy and Pharmacist. He was the "2014 DIA Outstanding service award" winner.

Kazuto Nishio, MD

1986 Graduate of Wakayama Medical University, M.D. Degree
1988-1990 Staff, Fourth Department of Internal Medicine, Wakayama Medical University Hospital
1990-1992 Research Resident, Foundation for Promotion of Cancer Research at National Cancer Center Research Institute
1992-1996 Research Staff, Pharmacology Division, National Cancer Center Research Institute
1994 Ph.D. Degree, Wakayama Medical University
1996-2006 Head, Section of Drug Resistance, National Cancer Center Research Institute
2006-present Professor and Chairman, Department of Genome Biology, Kinki University School of Medicine
2014-present Director, Genome Center, Life Science Research Institute, Kindai University

Shimpei Niwa, PhD

Dr. Shimpei Niwa is working in Safety and Risk Management Department at Daiichi Sankyo Co., Ltd. He is responsible for planning and management of key issues in the department. Dr. Niwa has over 15 years' experience in pharmaceutical industry, including clinical safety, pharmacovigilance, and epidemiology. He is a member of Working Team 3, which covers emerging topics related to healthcare database and epidemiology, of Safety Committee at the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ). Dr. Niwa holds a PhD in Medicine from Jikei University School of Medicine, and belongs to International Society for Pharmacoepidemiology.

Taku Obara, PhD

Dr. Taku Obara is Associate Professor of Department of Pharmaceutical Sciences at Tohoku University Hospital. Dr. Obara is also belonging to Department of Molecular Epidemiology, Tohoku University Graduate School of Medicine and Division of Preventive Medicine and Epidemiology, Tohoku Medical Megabank Organization, Tohoku University. The field of specialty of Dr. Obara is pharmacoepidemiology especially in perinatal period. Dr. Obara holds a PhD in Clinical Pharmaceutical Sciences from Tohoku University.

Yoshinori Ochiai, PhD

Dr. Yoshinori Ochiai is reviewer for clinical pharmacolgy at Pharmaceuticals and Medical Devices Agency (PMDA). After graduating, he worked at reserch institute International Medical Center of Japan as postdoctoral fellow. He explored a genetic basis of multi-factorial diseases such as hypertension, diabetes mellitus and vascular complications. After postdoctoral fellow, he worked at CRO company and he analyezd clincal data and pharmacokinetic data. Since 2014, he has been working at PMDA.

Yoshiaki Ohashi, PhD

Dr. Yoshiaki Ohashi is Head of Quality and Regulatory Compliance Unit and General Manager of Drug Safety Division at Chugai Pharmaceutical Co., Ltd. Dr. Ohashi acts as General Marketing Authorization Holder Manager and is responsible for the quality and safety of all marketed products of Chugai. Dr. Ohashi has nearly 30 years' experience in the pharmaceutical industry, including in project management and regulatory affairs, and he established the first document management system at Chugai. Dr. Ohashi holds a PhD in Pharmacy and has given numerous lectures on quality and safety and acted as a chair, panelist, and moderator at a wide range of pharmaceutical industry symposiums and conferences.

Yoshinori Ohsumi, PhD

Dr. Yoshinori Ohsumi is Honorary Professor and Head of Cell Biology Center, Institute of Innovative Research at Tokyo Institute of Technology. Dr. Ohsumi is the forerunner of autophagy research and has been studying yeast for 40 years. Dr. Ohsumi's discoveries laid the foundation for a better understanding of the ability of cells to manage malnutrition and infections, the causes of certain hereditary and neurological diseases, and cancer. Dr. Ohsumi holds a PhD in Science from The University of Tokyo at 1974, and is also the laureate of The Nobel Prize in Physiology or Medicine 2016 for his discoveries of mechanisms for autophagy.

Harumichi Okamura

Mr. Harumichi Okamura is Head of Market Access and Public Affairs at Novartis Pharma. Mr. Okamura has 18 years' experience of market access and pricing in pharmaceutical industry, and contributed to drug pricing reform debate as the chairman of Economic Affairs Committee of PhRMA Japan for 16 years. Mr. Okamura also has experience in dealing with health care policy at IHEP (Institute of Health Economics and Policy) and Nomura Research Institute.

Izumi Okugaito

Mr. Izumi Okugiato is Head of Prescription Products Development at Zenyaku Kogyo Co., Ltd. He has over 20 years' experience in the pharmaceutical company including regulatory affairs and clinical development.

Michiyo Ohshima, MBA

Ms. Michiyo Ohshima is Head of Japan Portfolio and Project Management at Pfizer Japan Inc. In this position, Ms. Ohshima leads the pan-Business Unit project management support and portfolio operations. Ms. Ohshima has over 20 years experience in the pharmaceutical and biotechnology industries, including project management across several therapeutic areas, and project management office. Ms. Ohshima holds an MBA.

Yoshihiko Otoguro

Yoshihiko Otoguro is a Chair of Corporate Ethics sub-Committee, Governance and Legal Committee of EFPIA Japan.
He is a member of steering committee of the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry and a member of Code Compliance Committee of JPMA.
He is a qualified pharmacist, and has experienced in several fields at GlaxoSmithKline for over 30 years, such as regulatory affairs, drug information, quality assurance, training, sales and compliance.

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Yasuto Otsubo, RPh

Mr. Yasuto Otsubo is reviewer of Office of New Drug V at Pharmaceuticals & Medical Devices Agency (PMDA). In this position, Mr. Otsubo is responsible for reviewing new anti-cancer drugs and clinical trial consultations as the team leader. Mr. Otsubo has over 10 years' experience in the regulatory agencies. Mr. Otsubo is also a menber of Companion Diagnostics Project Team and Omics Project Team of PMDA.

Kenny Peng, MASc, RAC, P.Eng

Kenny Peng, MASc, RAC, P.Eng., is Managing Director, Asia, for PharmEng Technology, a professional consultancy headquartered in Canada, with regional operations for US, Greater China, and Southeast Asia. Kenny is a Masters graduate in Mechanical Engineering from University of Waterloo, Canada, a licensed professional engineer, and a certified regulatory affairs professional, and primarily consults in North America, Southeast Asia, and East Asia. He specializes in cross-border projects, sample work included as international technology transfers, international business development, and region-wide regulatory affairs for medical devices, pharmaceuticals, nutraceuticals, biosimilars, and biologics.

Francesco Pignatti, MD

Francesco Pignatti graduated as medical doctor at the University of Rome La Sapienza.
In 1995 he became research fellow at the EORTC Data Center, Brussels, Belgium, where he was involved in numerous activities including clinical trial design, conduct, analysis, and reporting. In 1997 he became Medical Advisor for the Gastrointestinal Tract Cancer Cooperative Group, and Brain Tumor Cooperative Group.
In 1997 he obtained a Master of Science degree in Biostatistics from the University of Limbourg, Belgium.
In 1999 he joined the European Medicines Agency (EMA) in London. Since 2009 he holds the position of Head of Oncology, Haematology and Diagnostics in the Division for Human Medicines Development and Evaluation.

Robert F. Reynolds, MSc, ScD, FISPE

Dr. Reynolds is Vice President, Epidemiology in Worldwide Safety at Pfizer. He heads a group of epidemiologists and statistical analysts responsible for developing epidemiologic programs to support drug development and safety assessment. He is also an Adjunct Associate Professor of Epidemiology at Tulane School of Public Health and Tropical Medicine where he teaches pharmacoepidemiology. He is a Fellow and former Board member of the International Society for Pharmacoepidemiology. He holds a BA in Biology from Bard College and a MSc in Epidemiology and ScD in Population and International Health from the Harvard School of Public Health.

Satoshi Saeki, MSc

Satoshi Saeki has over 20 years of experience on clinical development and operations in Astellas. He is currently working in Astellas US as an expatriate for clinical business process improvement. He has been heavily involved in global initiatives such as RBM and cQMS in TransCelerate and working on external engagement activities to bring more familiarization of RBM and cQMS concepts in Japan. Satoshi served as a program vice chair for DIA Japan annual meeting in 2015 and engaged in a member of program committee for DIA Japan annual meeting 2014 and 2016. He has also been a member of program committee for DIA clinical operation and monitoring workshop from 2013.

Hanako Saito

Ms. Hanako Saito is Leader of Safety Information Management Group in Safety and Risk Management Department at DAIICHI SANKYO Co.,LTD. In this position, Ms.Saito is responsible for Japanese package inserts of DAIICHI SANKYO's products. Ms.Saito has over 20 years' experience in the pharmaceutical industries.

Hironobu Saito, PhD

Dr. Saito received his Ph.D. from Chiba University in Japan.
At first, he was the member of Research division and moved to clinical strategic team and became team leader . From 2006, he also had the responsibility for Asian development section. From 2012, he became vice president of new drug regulatory affairs Department in Japan. From 2016, he has become vice president of oncology clinical development in Japan.He had been Chairman of DIA Asian Workshop in Japan for 5 years. He got DIA outstanding award in 2007. He is now member of DIA advisory Committee of Japan in 2015. He has been JPMA rep. of ICH steering Committee and chairperson of ICH project committee in JPMA from 2012 to 2016.

Kaku Saito, MSc, PMP

Kaku Saito is a Manager, Oncology Clinical Development Department at Daiichi Sankyo Co., Ltd., Japan. He serves as an East Regional Project Lead of the early phase product. Saito received Bachelor's and Master's degrees from Tohoku University and is currently attending Rutgers Business School, NJ. He worked for 7 years in Japan and 7 years in the US, working on multiple global phase 1, 2, and 3 studies. His recent research activities include the oversight of several global early phase and POC studies in Oncology by leveraging his expertise on novel designs/idea such as accelerated titration, modified CRM (Continual Reassessment Method) and backfill. His works have been published in several scientific journals to date.

Yuka Sakagami

Yuka Sakagami is a reviewer in the Office of New Drug I at Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, reviewing new drugs for metabolic disorders. She joined PMDA in 2014 after graduating with a master's degree in pharmaceutical sciences from Tokyo University of Science.

Toshiharu Sano, RPh

Mr. Toshiharu Sano, R.Ph. joined Banyu Pharmaceutical Co., Ltd. in April 1990, and currently serves as the head of Clinical Operations, Japan Development.
Mr. Sano has over 27 years of experience in pharmaceutical industry and has broad experiences in Clinical Research, R&D planning and Business Operations for Clinical Development in Japan.
He also worked as several initiative leads and change manager on behalf of MRL in Japan through his career.
Mr. Sano holds a B.S. in Pharmacy from Showa Pharmaceutical University in 1990. He is a registered pharmacist in Japan.

Keiichi Sasaki, DDS, PhD

Dr, Keiichi Sasaki is Dean at the School of Dentistry and Professor in Division of Advanced Prosthetic Dentistry, Tohoku University, Sendai, Japan. He received his basic training (DDS, 1981) and neurophysiology (PhD, 1985) at Tohoku University. He was involved in the biomechanical researches with Prof. A. G Hannam at University of British Columbia, Canada (1987-1989). In 2000 he was appointed head of the Department of Prosthodontics, Tohoku University. Professor Sasaki has been involved in both clinical and research works, particularly in biomechanics and mechanobiology of stomatognathic components related to dental implants. He is past president of Japan Prosthodontic Society (2009-2011).

Akira Sato, MSc

Director, Global Project Management Department, Daiichi Sankyo Co., Ltd.
Akira Sato has 15 years' experience in CMC and project management for bio-pharmaceutical projects. From the entry into biosimilar business in 2011, Mr Sato was taking a lead for several biosimilar projects. From 2016, Mr Sato is overseeing biosimilar projects in present post.

Hiroyuki Sato, PhD

Dr. Hiroyuki Sato is a Biostatistics Reviewer in PMDA. Dr. Sato started his career as a Biostatistics Reviewer of new drugs for psychiatric disease and CNS in 2009. Currently Dr. Sato is working for the review office for oncology drugs, which frequently face to advanced and complicated clinical study designs.

Katsuaki Sato

Mr Katsuaki Sato is Manager of Safety Evaluation and Risk Management at GlaxoSmithKline (GSK) Japan. In this position, Mr Sato is responsible for leading pharmacovigilance activities for Japan marketed products. Mr Sato has 15 years' experience in GSK Japan, including study operation for respiratory products, development strategy for infection/psychiatry/neuroscience products, and Japan project lead for neuroscience products. Mr Sato is a member of ICH E11 (Clinical Investigation of Medicinal Products in the Pediatric Population) Revision 1 Expert Working Group. Mr Sato is leading Pediatric Drug Development team, Clinical Evaluation Committee, Japan Pharmaceutical Manufacturers Association.

Tomohiro Sawa, MD, PhD

Dr. Sawa is a professor of Medical Information System Research Center and Chief Information Officer at Teikyo University in Japan. Dr. Sawa is a board certified anesthesiologist in Japan and the U.S. and an ABPM board certified specialist in medical informatics in the U.S. Dr. Sawa has been serving for Division of Patient Safety in Japanese Society of Anesthesiologists and has been leading a project of developing and maintaining a nation-wide perioperative case registry. Dr. Sawa is a Vice-President of Japan Association for Medical Informatics. Dr. Sawa's research interest focuses on large-scale clinical and research databases. Dr. Sawa has been applying a range of big data technologies and machine learning algorithms to healthcare data.

Takuko Sawada

Deirector of the Board, Senior Executive Officer , Senior Vice President, Corporate Strategy Division, Shionogi & Co., Ltd.
Following her graduation from Kyoto Universty, Takuko Sawada joinde SHionogi

& CO., Ltd. in 1977. Since then, she has served for over 40 years, leading a number of pharmaceutical development projects and corporate stategy planning. Ms. Sawada successively held various posts in the company including the senior vice president of Global Pharmaceutical Development Divesion, the senior vice president of Corporates Strategy Division and Corporate Planning Department, and the board director.

Ichiro Sekiya, MD, PhD

Professor Ichiro Sekiya is a director of Center for Stem Cell and Regenerative Medicine at Tokyo Medical and Dental University, Japan. He received his MD at Tokyo Medical and Dental University in 1990. He completed a specialization in orthopedics and passed the Japan Orthopedic Association (JOA) Exam in 1996. He earned a PhD at Tokyo Medical and Dental University in 2000. Ichiro Sekiya's research has been focused on cartilage and meniscus regeneration with autologous synovial stem cells. He started a clinical study for cartilage regeneration in 2008, and now he is doing a clinical trial for meniscus treatment with synovial MSCs. He received the clinical award of the Japanese Society for Regenerative Medicine in 2016.

Taro Shibata, PhD

Mr. Taro Shibata is Chief of Biostatistics Division, Center for Research Administration and Support at National Cancer Center, Japan. In this position, Mr. Shibata is responsible for leading all biostatistical activities in the NCC: collaboration, consultation, training, and methodological development. Especially, as a division chief, he contributes for more than 100 ongoing clinical trials/ancillary clinical studies with division members. He is also a member of the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council.

Kaori Shinagawa, MD, PhD

Dr. Kaori Shinagawa is Senior Scientist for Clinical Medicine, PMDA. She has been involved in clinical trial consultations and reviews of new drugs, assessments of cardiac safety of new drugs, and in creating new guidelines for Japanese drug applications. She has also been involved in ICH activities since 2005 including the E14 topic on clinical QT assessment. She is an executive committee member of the Cardiac Safety Research Consortium. She is a cardiologist and holds a doctoral degree of Medical Science. Dr Shinagawa's main research field was electrophysiology, and she has published in a variety of prestigious cardiovascular journals. She received the Kimura Memorial Award from the Japanese Heart Rhythm Society in 2000.

Tadahiro Shinozawa, PhD

Dr. Tadahiro Shinozawa is associate director of Drug Safety Research Laboratories and Regenerative medicine Unit at Takeda Pharmaceutical Company. In these positions, Dr. Shinozawa is responsible for leading the predictive toxicology group and T-CiRA PJ as Co-PI. Dr. Shinozawa has over 10 years' experience in the pharmaceutical industry and joined Cincinnati Children's Hospital Medical Center as a visiting scholar in 2016. Dr. Shinozawa holds a PhD in Agriculture from Tohoku University, and is also the recipient of Award of Graduate School of Agricultural Science in Tohoku University.

Kazuhito Shiosakai

Kazuhito Shiosakai is Manager of Statistical Analysis Group in Biostatistics & Data Management Department at Daiichi-Sankyo Co., Ltd.

Kuniko Shoji

Kuniko Shouji was Executive Officer at Terumo Corporation for six years, Director for seven years and retired as of the end of June, 2017. She is currently a corporate advisor.

Her major job responsibilities with Terumo Corporation, included leading all operational activities across clinical development department and regulatory affairs, acquisition of necessary licenses and approvals for product sales and promotion of global optimization of clinical development. She has over 30 years' experience in this field.

She is subcommittee member of The Central Social Insurance Medical Council (Chuikyo) and Chair person of Medical Insurance Committee of Medical Technology Association of Japan (MTJapan).

Toshiki Sugita, PhD

Mr. Toshiki Sugita joined PMDA in 2008. He is in the Review Management Division, Office of Review Management.

Kazuteru Sugiura, MBA

Mr. Kazuteru Sugiura is Research Fellow at Office of Pharmaceutical Industry Research. Mr. Sugiura is responsible for conducting research on recent trends and challenges of utilization of "Medical Big Data" and "Digital Health Technology", and making public policy recommendations based on its research. Mr. Sugiura holds a MBA from GLOBIS University.

Atsushi Sugiyama, MD, PhD

Dr. Sugiyama became a professor of Pharmacology of Toho University in April 2010 and remains active in the field of Cardiac Safety Pharmacology and its strategic direction. Dr. Sugiyama also maintains clinical practice as a cardiologist as well as a clinical pharmacologist. He has published over 170 peer-reviewed scientific original articles and is considered as an international expert of Cardiac Safety Pharmacology. He received his MD and PhD from Yamanashi Medical University, and is a Councilor of Japanese Pharmacological Society, Japanese Heart Rhythm Society and Japanese Safety Pharmacology Society.

Eri Sugiyama, MS

Ms. Eri Sugiyama is Section Chief in charge of oncology and gastrointestinal drugs in the Pharmaceutical Evaluation Division, Ministry of Health, Labour and Welfare (MHLW) from 2016 until now. She entered Pharmaceuticals and Medical Devices Agency (PMDA) in 2008.

Shuji Sumida, MSc, RPh

Mr. Shuji Sumida is Department Manager of Business Strategy & Compliance Dept. at CHUGAI PHARMACEUTICAL CO., LTD. In this position, Mr. Sumida is responsible for oversight of GxP Compliance and Quality Management System. Mr. Sumida has over 30 years' experience in the pharmaceutical industries, including Formulation Technology, Project Management, and Quality & Regulatory Compliance. Mr. Sumida holds a MSc in Pharmacoscience from Tokyo University of Science, and is also a registered pharmacist.

Tokuhito Sumitani, MS, RPh

DAIICHI SANKYO CO.,LTD.
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Clinical Development Department
Tokuhito Sumitani joined DAIICHI SANKYO CO.,LTD. in 2012. After experiencing CRA/Clinical Study Manager Associate in several trials through Phase1 to Phase 3, he has served as a Clinical Study Manager.

Akiyuki Suzuki, MS

Akiyuki Suzuki is Head of Pharmacometrics Group at Pfizer Japan Inc. Suzuki has over 20 years working on pharmacometrics in pharmaceurtical industory. Suzuki had obtained a Master's degree in Gifu Pharmaceutical University. After that Suzuki joined in Bristrol-Myers Squib KK in Japan. In 2001, Suzuku joined in Pfizer Japan Inc. Suzuki is a part-time teacher in Kitasato University School of Pharmacy.

Kazuyuki Suzuki

Mr. Kazuyuki Suzuki is a member of Trial Management Department at Novartis Pharma K.K. Mr. Suzuki is responsible for leading clinical trials from start to end. Mr. Suzuki has 20 years' experience in pharmaceutical industries in clinical development strategy and operations.

Makoto Tahara, MD, PhD

Dr. Makoto Tahara is Chief of Department of Head and Neck Medical Oncology, National Cancer Center Hospital East, Kashiwa, Japan. He has worked in the filed of Medical Oncology since 1998, became a board-certified specialist in Medical Oncology in 2006, and received his PhD in Medical Sciences in 2004 from Hiroshima University School of Medicine. He has established a Head and Neck cancer Group in Japanese Clinical Oncology Group (JCOG). He is a member of steering committee of ten global trials of new drugs for head and neck cancer. He received Award of an alumni association of National Cancer Center in 2005 and "Paper of the year 2005" in Japanese Journal of Clinical Oncology.

Kihito Takahashi, MD, PhD

Dr. Takahashi is currently Vice President and Senior Managing Director of Japan Development and Medical Affairs, GlaxoSmithKline Japan. He graduated from Hokkaido University School of Medicine in 1981, and received his PhD in Medical Science in 1986. He served as Research Assistant Professor of Medicine at Vanderbilt University from 1990 to 1992, and joined Merck Research Laboratories in 1992 and served as Vice President, Merck Research Laboratories from 2003 to 2008. After retiring from Merck, he served as a President & CEO of LOTUS Pharmaceutical Co. Ltd, a bio-venture company before joining GSK.

Shunichi Takahashi, PhD

Dr. Shunichi Takahashi is Head of Open Innovation Center Japan (ICJ) in Bayer Yakuhin, Ltd. In this position, he is responsible for leading all research alliance activities with academic institutions in Japan. He is also leading a team to explore new opportunities using Big-Data, advanced analytics, and digital devices for patients and pharma companies. He has over 20 years' experience in Research, Product Development (PD), and Medical Affairs (MA):
1993: Scientist / Drug Discovery / Mitsui Pharmaceuticals
2001: Scientist / Cardiovascular / Nihon Schering
2007: Sr. Scientist / Stem Cell Based Drug Discovery / Bayer

PRESENTERS' BIOGRAPHIES

2008: Cardiovascular Project Manager / PD / Bayer
2013: Head of Primary Care / MA / Bayer
2014: Head of ICJ / Bayer

Akiko Takase, MSc

Akiko Takase is a Senior Scientist, Regulatory Affairs Area, Japan Development, MSD K.K. She is currently engaged in new drug development in Infectious Diseases area as a Regulatory Strategy & Liaison. Her career was started at Banyu Pharmaceutical. CO., LTD (currently MSD K.K.) after finishing her master's degree in Pharmaceutical Sciences from Toyama Medical and Pharmaceutical University (currently Toyama University). She has been engaged in clinical development as CRA, Medical Writer, Clinical Scientist and Clinical Monitor at MSD K.K. She served as a Sponsor's Representative for clinical studies of antimicrobial agents in Clinical Research Area before current assignment. She is a member of The Japan Society of Chemotherapy.

Hiroshi Takeda, MS

Hiroshi Takeda is a reviewer of Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA). He is currently engaged in review of drugs for neurology and psychiatry.

Shinya Takemoto, MSc

Mr. Shinya Takemoto, MSc, is a pharmacist. He joined Chugai Pharmaceutical in 2002. He was engaged in the whole process of Drug Safety/Pharmacovigillance. In 2011 he moved to Roche in Switzerland, responsible for risk management until 2013. He, then came back to Chugai and now he is a Group Manager of Safety Information Strategy Group in Risk communication dept.. He is now responsible for preparation of risk minimization materials and development of ICT based safety communication tool including Web-site and application.
As an industry activity, he joined JPMA (Japan Pharmaceutical Manufacturers Association), Task force 1 (TF1) to manage RMP related issues. In 2016, he became a leader on KT1 continued from TF1, to handle RMP related issues.

Toichi Takenaka, DVM, PhD

Dr.Toichi Takenaka is Chairman of Japan Health Sciences Foundation. Dr.Takenaka has 50 years' experience in Yamanouchi and Astellas Pharm.Co. including Head of R&D,President and CEO,and Chairman.He was an inventor and patent holder of 4 products such as Perdipin(nicardipin),Logan(amosulalol),Hypoca(barnidipine) and Harnal(tamuslosin) in his drug discovery research. He holds DVM from Gifu University and PhD in pharmacology from Toho University,and also the resipient of the Medal with Purple Ribbon (2000) and the Order of the Rising Sun ,Gold and Silver Star (2012).

Kazumasa Takenouchi

Mr. Kazumasa Takenouchi is member of Biostatistics Group, Data Science, Astellas Pharma Inc and has over 20 years' experience in the pharmaceutical as statistician.
Mr. Takenouchi is one of biostatistics subgroup leaders, taking charge of instructing and managing biostatistics operation and progress of clinical studies and NDA submission.
Mr. Takenouchi has been participating in the Data Science Division of the Japan Pharmaceutical Manufacturers Association as a representative of Astellas from 2012.

Fumihiko Takeshita, MD, PhD

Fumihiko Takeshita is Senior Director, Vaccine Business Oversight Dept in Daiichi Sankyo, Co., Ltd. and Vice President, Vaccine Research Labs in Kitasato Daiichi Sankyo Vaccine, Co., Ltd. He has his expertise in vaccine R&D in both academia and industry. Based on his experiences in basic research on innate immunity, adjuvants, and genetic vaccines and industrial R&D of novel vaccines, he is leading several different R&D teams through the open innovation network. He has clinical experience in internal medicine and experience of post-doc fellowship in Office of Vaccine Research and Review CBER/FDA with more than 80 academic publications. He was Organizing Committee President of the annual meeting of Japanese Society for Vaccinology in 2016.

Michio Tanaka

Michio Tanaka has mainly worked in global drug development of oncology products for more than 20 years at AstraZeneca. He is now Head of Science Affairs Division which is leading a broad range of drug development activities incl. development of companion diagnostics, after taking Product Leader roles in local and Global organisation as well as Heads of Regulatory and Clinical Opereations in Japan. His recent involvement with co-development of CDx with a diagnostic company is the one using circulating tumour DNA for osimertinib indicated for NSCLC with EGFR T790M mutation.

Tomohiro Tanaka, MS

Tomohiro Tanaka is Group Manager of Clinical Science & Strategy Dept. at Chugai pharmceutical Co., Ltd. Mr. Tanaka graduated from Graduate School of Kyushu University in 2000. Mr. Tanaka joined Nippon Roche K.K. after graduation and now work for Chugai pharmceutical Co., Ltd. Mr. Tanaka has 17 years' experience in the clinical development. In the current position, Mr. Tanaka is responsible for leading the activities of the clinical science in the oncology field.

Tomoko Tanita

After experiences of working as a pharmacist at hospitals, she started to work at Pharmaceuticals and Medical Device Agency (PMDA) from 2008 and assigned to Office of OTC Drugs and Generic Drugs, involved with review of OTC drugs.
From 2014, she was transferred to Pharmaceutical Safety and Environmental Health Bureau of Ministry of Health, Labour and Welfare (MHLW) and assigned to Safety Division, involved with post-marketing safety measures for drugs, followed by relief services for adverse health effects.
In May 2016, she was back to PMDA and assigned to Office of Safety I, involved with promotion of risk communication to the healthcare professionals and the public.

Shimon Tashiro, PhD

Shimon Tashiro is Head of the Section on Bioethics in the Center for Public Health Sciences at the National Cancer Center, Tokyo, Japan. Dr. Tashiro received his undergraduate degree and his Ph.D. in sociology from the Tohoku University. His research interests focus primarily on research ethics, such as issues on the distinction between research and practice, the ethics of innovative therapy and the ethics of RCTs. He is also interested in the end-of-life care, professional ethics, and history of bioethics.

Masahiro Tohkin, PhD

2011-Present: Professor. Nagoya City University, Graduate School of Pharmaceutical Sciences, Nagoya, Japan.
2002-2011: Section Chief, National Institute of Health Sciences, Tokyo, Japan.
1997-1999: Guest Researcher, National Institute of Health, National Cancer Institute, Bethesda, MD USA.
1994-2002: Senior Research Officer, National Institute of Public Health, Tokyo, Japan.
1984-1994: Researcher, Shionogi Research Laboratories, Osaka ,Japan.
1984: Graduated from Graduate School of Pharmaceutical Sciences, Tohoku Univ. , Sendai, Japan.

Kota Tokushige, MS

Mr. Kota Tokushige works for Novartis Pharma K.K. as a statistician engaged in clinical development activities, and has over 10 years' experience as a statistician in the pharmaceutical industry regarding clinical development of new drugs, biosimilar products, and a cell and gene therapy product in oncology therapeutic area. He holds a master's degree from Graduate School of Engineering, Tokyo University of Science.

Michiko Tomiyasu, MS

M.TOMIYASU now belongs to Medical Excellence & Training in Medical Affairs Sanofi. In Ithis position, M. TOMIYASU is responsible for supprting the training contents in MA and has established MSL Certification Program inside this company in 2016. Before then, M. TOMIYASU had worked in AstraZeneca over a period of many years. M.TOMIYASU has over 20 years experience in the pharmaceutial industries, including Sales and Marketing, pricing and governmen affairs in Market Access, MSL and Scientist on HEOR/Pharmacoepidemiology in Medical Department. M.TOMIYASU is pharmacist, studied in Meiji Pharmaceutical University and Master of engineering, studied in Graduate School of Keio University. Available languages are English and French.

Shogo Tsuyuki, PhD

Dr Shogo Tsuyuki is Head of Global Development University Japan at Novartis Pharma K.K. where he leads education and talent development in drug development division. Dr Tsuyuki has over 20 years' experience in the pharmaceutical industry, including exploratory research, early clinical research and project management. Dr Tsuyuki holds a PhD in pharmaceutical science in Immunology.

Jörg Täubel, MD, FFPM

Dr Jörg Täubel is a medical practitioner and CEO of Richmond Pharmacology. He has worked in clinical pharmacology for 24 years, conducted more than 400 early phase studies ranging from first time in man to proof of concept and is author of over 50 publications in scientific journals with extensive experience in cardiology, neurology, gastroenterology and ethnic bridging studies.
He is a Fellow of the Faculty of Pharmaceutical Medicine of the RCP (UK), the Institute of Directors and Honorary Fellow at St George's University London. He is a member of the AHPPI, the RSM, JSCPT and the ACCP, Regent of the AGAH and a founding member of EUFEMED. He lectures on the AGAH basic human pharmacology course and at the University Pompeu Fabra, Barcelona.

Maki Uchimura, MBA

Maki Uchimura, MBA, is a member of Clinical innovation & business integration of Medical Development Unit at Eli Lilly Japan K.K. Uchimura has 7-year GCP computer validation expeience, and transformation project experience. (e.g. Medidata RAVE Japan launch for PMSS market) Before joining Eli Lilly, leading life science industory consultancy at PricewaterhouseCoopers Japan for change management and computer system implementation

Shizuko Ueno, RPh

Ms. Shizuko Ueno is Senior Director, Group VI, Clinical Development Department, DAIICHI SANKYO CO.,LTD. She joined the Pharmaceutical Division of Suntory Co., Ltd. after graduating from university and transferred to Daiichi Suntory Pharma Co., Ltd. (current Asubio Pharma Co., Ltd., subsidiary of DAIICHI SANKYO) in 2002. She works for DAIICHI SANKYO since 2010 (including 3 years for DAIICHI SANKYO RD NOVARE CO., LTD.). She has over 25 years' experience in clinical development.

Jin Uesawa, MBA

Jin Uesawa is the president of Japan Medical Data Center. The company builds claims database and offers real world data and analytical services. It participated a pilot project by PMDA and pharma companies to conduct a PM study using JMDC database in a GPSP-compliant manner. He also leads, as a member of Association of Medical Database in Japan, to develop an industry's voluntary GPSP guideline for database vendors.

After the completion of MBA program at Carnegie Mellon University, he joined McKinsey and Company where he worked on many aspects of pharma industry and healthcare system, such as initiatives to enhance productivity in clinical trial and PV operations, and to solve the drug lag problem working with regulatory agencies.

Hisashi Urushihara, DrPH, MS

Dr. Hisashi Uruhihara is a Professor, Division of Drug Development and Regulatory Science, Faculty of Pharmacy, Keio University. His research area is pharmacoepidemiology, pharmacovigilance, and regulatory science. His academic training and experiences were based on epidemiological methodology at Kyoto University School of Public Health, where he received his doctoral degree in public health. He has also job experience in clinical development and pharmacovigilance at Eli Lilly Japan for 13 years before starting his academic career. He is an active executive board member of Japan Society for Pharmacoepidemiology and the Japanese Association of Pharmaceutical Medicine, a member of DIA Advisory Committee of Japan, the vice-chairman of the East Japan ethics committee of Japan Epidemiological Association, and a member of the international affairs committee of Japanese Society of Pharmaceutical Health Care and Sciences.

Susumu Wakabayashi

I am Pharmacist of Kyorin University Hospital and in charge of Drug Information section of Hospital Pharmacy and HIV care team. I graduated from school of Pharmaceutical Science of Toho University. I am a visiting lecturer of school of pharmacy of Tokyo University of Pharmacy and Life Sciences. I am a councilor of Kyorin Medical Society. I am a director of the Japanese Society of Drug Information. I have a license to Drug Information Sepcialist, Healthcare Information Technologist, Sports Pharmacist, Regulatory Science Expert (Pharmacovigilance).

Toshifumi Wakai, MD, PhD, FACS

Education

3/1999	PhD (Doctor of Philosophy) in Surgical Oncology Niigata University, Graduate School of Medicine, Niigata, Japan
3/1992	MD (Doctor of Medicine) Yamanashi University, School of Medicine, Yamanashi, Japan

Professional Experience

12/2012 -	Professor and Chairman Niigata University Graduate School of Medical and Dental Sciences, Division of Digestive and General Surgery, Niigata, Japan
4/2010 - 12/2012	Associate Professor Niigata University Medical and Dental Hospital, Division of Digestive and General Surgery, Niigata, Japan
10/2003 - 3/2010	Assistant Professor Niigata University Medical and Dental Hospital, Division of Digestive and General Surgery, Niigata, Japan
4/1992 - 9/2003	Surgical Resident-Fellow Niigata University Medical and Dental Hospital, Division of Digestive and General Surgery, Niigata, Japan

Toshihiko Watanabe

Mr. Toshihiko Watanabe is the Advisor of Japan CRO Association he used to be their Vice President. In DIA-Japan Mr. Watanabe was a Program Committee Member of CDM, the Program Chairperson of MIP, a Steering Committee Member and is also a recipient of the Outstanding Service Award in 2008. Mr. Watanabe has over 30 years of experience in Pharmaceutical and CRO Companies, including Management of Biostatistics, Clinical Data Management and Quality System of ISO9000. Mr. Watanabe is a Managing Director of Bio Venture company, PRO and IT Venture company. He is also the Advisor of some IT Companies.

Duu-Gong Wu, DrSc, PhD

Dr. Duu-Gong Wu is the Senior Director of Regulatory Consulting with expertise in biosimilar regulatory strategy. He previously worked at US FDA with the last position as Deputy Division Director in CDER/ONDC, before joining PharmaNet/i3, then PPD. At US FDA, he participated in the reviews and approvals of many biotech products and worked as a member of internal and ICH working groups and committees, including FDA Follow-on Biologics (biosimilars) Workig Group and ICH Q5E and CTD-Q. At PPD, he participated in in the development of many MAb and therapeutic protein biosimilars at various clincal stages. Dr. Wu completed his Ph.D. degree in Biochemistry and Molecular Biology at University of Maryland School of Medicine and postdoctoral study at Johns Hopkins University School of Medicine, before he joined FDA.

Naoyuki Yabana, PhD

Dr. Naoyuki Yabana is Director of Office of In Vitro Diagnostics. He joined PMDA in 2006, and since 2011 to 2014 he was Review Director in Office of New Drug III and responsible for the review and scientific consultation of psychiatric and neurological drugs. Since 2014 to 2016 Dr. Yabana was Head of Japanese Pharmacopoeia Secretariat. He holds PhD in biophysical and biochemical science from the University of Tokyo.

Yasuhide Yamada, MSc, MPM

Ex-Director-General, Office for Pandemic Influenza and New Infectious Diseases Preparedness and Response, Coordination Office of Measures on Emerging Infectious Diseases (EIDs), Cabinet Secretariat, Government of Japan

Mr. Yamada's academic background is environmental science and policy administration. He has a Master of Science from Hokkaido University (Japan) and a Master of Public Management from Carnegie Mellon University (USA). Mr. Yamada, as an officer of Ministry of Economy, Trade, and Industry (METI) and Cabinet Secretariat, has long career in policy-making and negotiation with foreign governments. Through July 2014 to July 2017, Mr. Yamada led to plan and implement preparedness and response on infectious disease threats; Ebola, MERS, Zika, AMR, etc.

Takuhiro Yamaguchi, PhD

Dr. Takuhiro Yamaguchi is currently a Professor at Division of Biostatistics, Tohoku University Graduate School of Medicine and a Director of Clinical Research Data Center, Tohoku University Hospital. He is also a former Project Professor at Department of Clinical Trial Data Management, Graduate School of Medicine, The University of Tokyo. He has about 20 years experiences as clinical trial statistician especially in the flied of oncology and palliative care. His research interests include quality management system and clinical outcome assessments.

Noboru Yamamoto, MD, PhD

Dr. Noboru Yamamoto is a director of the department of experimental therapeutics, National Cancer Center Hospital (NCCH), Tokyo. Having graduated from Hiroshima University School of Medicine in 1991, Dr. Yamamoto specialized in oncology and is working at NCCH since 1995. In 2013, he became a director of the department of experimental therapeutics, and his current main interest is in lung cancer chemotherapy, the early development of new anticancer drugs, and the development of biomarkers.

Yuji Yamamoto, MD, MBA

Yuji Yamamoto is a founder and chief executive officer at MinaCare, Co., Ltd. which manages over three million people health data for better care. He concurrently serves as an advisor of the Ministry of Health, Labour and Welfare, dedicating health care system innovation.

Before starting these careers, Yuji worked as a cardiologist in Japan, specialized in electro-physiology. He spent six years as a practitioner in several leading hospitals including University of Tokyo Hospital and Tokyo Metropolitan hospitals.

Yuji received his M.D. degree from University of Tokyo and his medical license. He is a board certified member of the Japanese Society of Internal Medicine, and holds an M.B.A. from Harvard Business School.

PRESENTERS' BIOGRAPHIES

Reiko Yanagihara, PhD
Dr. Reiko Yanagihara is Deputy Review Director of Office of in vitro Diagnostics in Pharmaceuticals & Medical Devices Agency (PMDA). She joined PMDA in 2009 and served as reviewer in the area of biopharmaceuticals, biosimilars and in vitro diagnostics. She is responsible for leading companion diagnostics working group in PMDA which discusses regulatory issues and the development of relevant guidances. Dr. Yanagihara holds a PhD in Molecular Biology from Osaka University and served as an Assistant Professor at Graduate School of Medicine in Kyoto University after postdoctoral training at Carnegie Institute of Washington/Howard Hughes Medical Institute.

Manabu Yanagisawa, PhD
Dr. Manabu Yanagisawa is an Associate Director of Japan Regulatory Affairs at Eisai.Co., Ltd. in these 13 years. He joined Eisai in 1992 after graduate from Tokyo Institute of Technology with a master degree. His carrier in Eisai started as a medicinal chemist at the Tsukuba Research Laboratory. After 6 years, he was dispatched to the Tokyo University of Science (Prof. Mukaiyama) for 2 years and 7 months, and received a Ph. D. in pharmacology.
His carrier of regulatory affairs started in 2004. Scince then, he has been in charge of many projects and comitted promoting the development and obtaining the approval. He is a member of the RA committee of JPMA. Furthermore, he contributes to DIA as a facilitator of RA-Training Course.

Kazuki Yasuda, MD
Dr Kazuki Yasuda is Director of Department of Metabolic Disorder at Diabetes Research Center, National Center for Global Health and Medicine. Dr Yasuda is a physician scientist whose special focuses are diabetes mellitus and other lifestyle-related diseases. Dr Yasuda has been engaged in nation-wide research projects such as the Millennium Genome Project for type 2 diabetes mellitus in Japan and the multi-omics analysis projects of human disease samples including adipose tissues (obesity) and liver (NASH). He is now one of the coordinating scientists for GAPFREE Program.

Kan Yonemori, MD, PhD
Kan Yonemori is Chief physician of Department of Breaset and Medical Oncology/ Experimental Therapeutics at National Cancer Center Hospital, Tokyo, Japan. Dr Yonemori had medical revierwer experience in Pharmaceuticals and Medical Devices Agency and for visiting reasearcher in US National Cancer Institute and Food and Drug Administaration. Dr Yonemori is one of lead Principle Investigators in National Cancer Center Hospital, Tokyo and he lead the field of oncology drug development scene for rare cancer.

Shigeto Yonemura, MD
Shigeto Yonemura is an associate Professor of civil law and medical law in the Graduate Schools for Law and Politics in the University of Tokyo (Japan). He graduated from the Faculty of Medicine in the University of Tokyo in 2000, and worked as a cardiologist in several hospitals in Japan (2000-2013). He was given a master's degree in law by the University of Tokyo (the Graduate Schools for Law and Politics) in 2004. He was an associate professor in the Graduate School of Law in the Tohoku University (2005-2013), and since 2013 he has been in the University of Tokyo. He published many papers on civil law and medical law. His research areas are tort liability, product liability, medical malpractice, regulation of biomedical research etc.

Yusuke Yoshimoto
Mr. Yusuke Yoshimoto is Senior Manager in Trial Management groupat Eli Lilly Japan K.K. In this position, Mr. Yoshimoto is responsible for leading study management activities in BioMedicine therapeutic area, which focuses on Neurodegeneration, Immunology and Pain diseases. Mr. Yoshimoto has over 20 years' experience in Eli Lilly working for study management, project management, strategic outsourcing and organization management. Mr. Yoshimoto has granted Master degree for Organic chemistry from Nagasaki University in 1996.

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DIA とは

DIA とは、医薬品、医療機器、再生医療製品をはじめとする医療用製品の研究開発、ライフサイクルマネジメントにおけるイノベーションの実現をサポートするために教育活動および規制当局・企業・アカデミア・患者さんとの間の立場を超えた情報交換やディスカッションの場を提供するグローバルな非営利団体です。世界中で創薬、開発、薬事、安全性、CMC、PM、DM、統計など様々な専門分野の専門家、一万数千名の会員を有しています。

ミッション、ビジョン、コアバリュー

DIA は、以下の 3 つの理念に基づき、事業活動を行っています。

組織構成

理事会（Board of Directors）

DIA 理事会メンバー、役員、地域諮問委員会委員長は、会員による選挙で選出され、DIA の全般的な運営方針、基本戦略、基本政策目標の策定を行います。米国の DIA 本部及び、欧州、日本、インド、中国の DIA オフィスがこれらをサポートしています。各 DIA オフィスには、理事会の指示により戦略と年間計画の実行の為の日々の業務を行うスタッフがいます。

日本諮問委員会（Advisory Council of Japan：ACJ）

日本諮問委員会は、DIA Japan の更なる発展と会員の成長に向けて日本における DIA の活動方針を決定し、本部理事会に対して戦略的な情報提供や助言、提案を行っています。開催される各種会議、トレーニングは、コンテンツ コミッティーからの提案を受け、ACJ で決定され、会議、トレーニング毎に編成されるボランティアからなるプログラム委員会によって具体化、実施されます。

会員のベネフィットとキャリアパス

産官学と患者さんが一堂に会する唯一の中立的国際的イベント

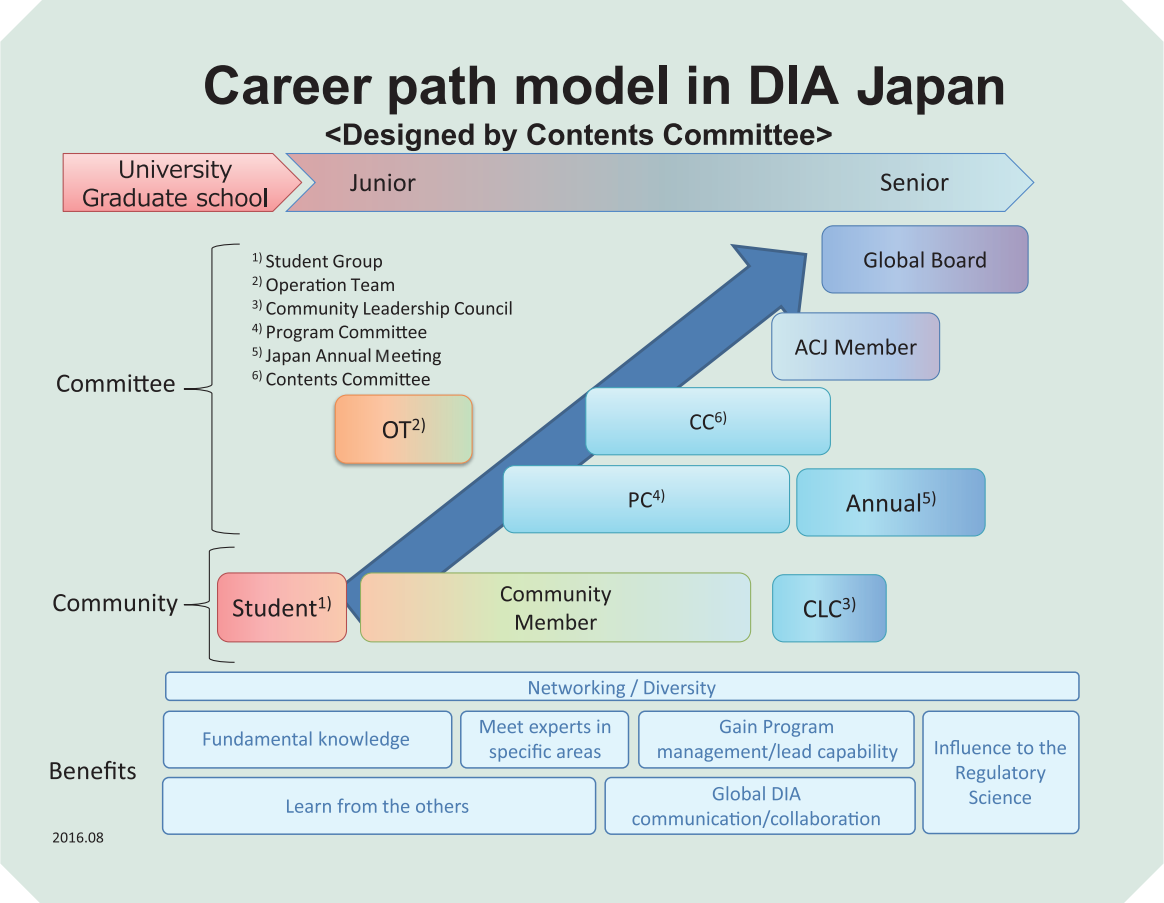
いかなる組織や団体からも影響を受けることのない、産官学、患者さんが一堂に会する中立的で国際的なイベントは DIA だからこそ開催できるものです。会員の方はイベントに参加することで、世界の規制当局・企業・アカデミア・患者さんの第一人者から、グローバルで最新の業界や規制の動向を直接聞ける貴重な機会を得ることが出来ます。また、聴講だけでなく、議論を交えて双方向的に情報が提供されるので、仕事に役立つ実践的な知識、情報を学ぶことができます。更には、グローバルな産官学や患者さんとのネットワーキングを作り育てることもできます。

メンバーシップ主体のボランティア活動

DIA は、会員が主体のボランティア活動によって支えられています。業界団体とは違い、会員の方は個人の立場でボランティアベースで活動に参加しているので、組織の方針にしばられない、自由な発想でスピーディな活動を行うことが可能となっています。その代表的活動がコミュニティ活動で、グローバルベースで専門領域別に産官学の会員が自発的にコミュニティを作り、共通の経験や話題を共有したり、課題を検討したり、イベントの企画などを行っています。

キャリアディベロップメント

会員の方は、DIA が提供するイベントの企画、準備、運営に関する様々な役割を経験することで、専門性を高め、視野を拡げ、マネジメント能力を磨き、自らのキャリアを発展させることができます。
そして、世界中の人々の健康と福利の向上につながるイノベーションの促進に貢献することができます。
下記が DIA Japan での活動を通じたキャリアパスモデルです。



DIA 会員資格

DIA の会員資格は、全世界における健康と福祉の向上に貢献することに関心を持つすべての個人に与えられます。

◇ 会員特典

- 出版物の定期購読
  - TIRS（Therapeutic Innovation & Regulatory Science）
  - Global Forum
  - e-Newsletter : "DIA Daily" "DIA Global Smart Brief"
- 年会、カンファレンス、ワークショップ、トレーニングコース、オンラインイベントへの会員価格での参加
- 業界や規制の動向に関するグローバルな最新トピックについての情報へのアクセス
- コミュニティ会員としてのグローバルな専門知識の強化と人脈作りの機会
- 講演者やセッション座長、著者としての活動や各種委員会への参加を通じた様々な役割の経験
- DIA の出版物への投稿

◇ 入会方法

DIA のホームページからオンラインで登録することができます。
また、DIA Japanのホームページ上の「会員へのお誘い」から申込用紙をダウンロードし、必要事項をご記入の上、FAX（03-3278-1313）にてお送りいただくか、E メールにて Japan@DIAglobal.org 宛てにお送りください。

DIA WEB：http://www.diaglobal.org/get-involved/membership

DIA Japan WEB: http://www.diajapan.org

※WEBサイトでは各種情報を提供しています。

◇ 会員登録費・有効期限

• Membership	¥17,500（税抜）
• 2-Year Membership（有効期間：2年間 /10%割引）	¥31,500（税抜）
• Academia（対象：大学関係・医療従事者）	¥12,000（税抜）
• Student	¥5,000（税抜）

会員登録を行った日から1年間、翌年同月末まで有効（2-Year Membership を除く）

出版物・情報提供

◇ TIRS（Therapeutic Innovation & Regulatory Science）

医薬品を始めとする医療用製品の研究開発とライフサイクルマネジメントに関する情報提供および、規制当局・企業・アカデミア・患者さん間の情報交換をサポートすることを目的とした DIA の公式出版物です。各分野の専門家監修のもと年 6 回発行しています。

◇ Global Forum

世界中での DIA の活動や業界、規制の動向など、会員の間での情報交換を目的とした隔月発行のデジタルマガジンです。

◇ DIA Daily

DIA 会員向けのニュース配信です。過去 24 時間にグローバルで発信された医療用製品関連ニュースの概要をメール配信します。

Thousands of Members in 78 Countries, Across 20+ Communities

DIA Members work together to speed innovation in global health care product development to encompass your own health care system and the broader region.

Neutrality is key to the DNA of DIA. As the only global, membership organization, DIA is dedicated to bringing health care product development professionals together in a trusted, neutral environment to share insights and make advancements in health care product development and life cycle management. With thousands of engaged, global members comprised of professionals from pharmaceuticals, biotechnology, government, academia, and patient groups, DIA is the premium resource for individuals seeking to increase their knowledge, connect with global stakeholders, and truly drive insights to action in their everyday job functions.

Why Join DIA?

- DIA communities, a dynamic network of like-minded individuals looking for solutions, providing a discussion forum, and seeking to find solutions by harnessing the power of a network beyond your own organization
- Access to a broad range of focused conferences, meetings, and training opportunities that will allow you to enrich your own knowledge, your understanding of the health care system you work in, and give you the ability to integrate best practices from multiple health care systems
- Member-exclusive subscriptions to the DIA Daily and Therapeutic Innovation & Regulatory Science (TIRS)
- Be part of a global forum where everyone can freely, openly, and accurately share information on diseases, treatment modalities, regulatory policies, clinical trial development, value and access, and more
- Unique access to thought leadership that is not available elsewhere
- Favorable rates on conferences and trainings

Learn More and Join at DIAglobal.org/Membership

DIA

ABOUT COMMUNITY

DIA Community

What is "DIA Community"?

DIA Communities are one of the many member benefits that DIA offers. Each Community provides a discipline-specific community where members can share common experiences and knowledge and connect with others in their field.

The core purpose of Communities is to bring industry, vendor, academic, regulator, payer, healthcare provider, and patient groups together to interact in a neutral forum to network, share learning, discuss topics and issues, and develop resolutions of relevance to a particular functional area or topic associated with drug development. While learning sharing (including program development) and networking are core to Communities, identifying and dealing with industry issues can be where Communities bring value back to the drug development industry and ultimately their membership.

Communities also assist DIA in identifying professional development needs in particular interest areas, and in providing information to members to meet their career and professional development needs.

Benefit s of DIA Communities

Members share common experiences and knowledge and connect with others in their field. Members can involve directly or indirectly to program development of relevant DIA Workshops.

Members are part of Japan and global community, and can participant meetings, learning sessions or events of both.

Global DIA Communities

(as of Oct 2017)

- Clinical Data Management
- Clinical Pharmacology
- Clinical Research
- Clinical Safety & Pharmacovigilance
- Clinical Trial Disclosure
- Devices & Diagnostics
- Document & Records Management
- Electronic Regulatory Submissions
- Good Clinical Practice & Quality Assurance
- Information Quality, Compliance, & Technology
- Legal Affairs
- Medical Communications
- Medical Science Liaison
- Medical Writing
- Patient Engagement
- Pediatric
- Preclinical Sciences & OSWG
- Professional Education, Training & Development
- Project Management
- Quality Risk Management
- Regulatory Affairs
- Statistics
- Students
- Study Endpoints

Introduction of Japan DIA Communities

Clinical Operation・Monitoring (COM) (Representative: Kazumasa Sugao, Mitsubishi Tanabe Pharma Corporation)

We launched "Clinical Operation・Monitoring Community (COM Community)"in 2014 with the aim of offering a program to exchange information for Clinical Operation and Monitoring. And we have proactively exchanged views and opinions about the participants' perspectives, where participants' impression showed high level of satisfactions to our activities. We continue our activities periodically and extend discussions.

We have focused on the topic of "What's the gap between the actual and ideal conditions at the clinical trial sites and how to overcome the GAP" and continued discussions since last year. This year, we specifically focused on our concrete actions to solve the GAP and enjoy discussions.

Every COM community participant is an important player. Let's discuss how to make Clinical Operations better with us!

Pharmacovigilance & Labeling (Representative: Rei Maeda, Eli Lilly Japan / Rie Matsui, Pfizer Japan Inc.)

DIA Japan Risk Management workshop and DIA Japan Labeling workshop were annually held from March 2014 and November 2011, respectively. The 4th RM workshop was held in May 2017, which objective was to deeply consider what risk minimization materials are proper for patient-centric tools from risk communication perspective. The 7th Labeling workshop to discuss mainly new labeling guidelines will be held in February 2017. We will gather trends of regulations worldwide regarding risk management system and Labeling that consist of key elements of pharmacovigilance, share them and discuss issues.

Clinical Strategy Community (Representative: Yoshinobu Tanaka, MSD K.K.)

This is a new community that started in 2015. Under the key words "strategy" and "tactics", we have a meeting every 2 months and share methods and ideas to address daily work issues. Taking advantage of the varied backgrounds and strengths of our members, we are aiming for active participation by all attendees. Members are from Industry, CRO, and Academia. Feel free to join us!

Clinical Data Management (Representative: Motohide Nishi, Medidata Solutions Co., Ltd.)

The activities of DIA's Clinical Data Management (CDM) began with the first DIA CDM annual workshop in Japan held in 1998. Since data is a common language in the world, the need for DIA CDM activities, which is a place of global communication, is high, and Workshop has been held continuously every year. From 2017, we started to exchange opinions in the CDM community as we respond to changes in the environment surrounding CDM. Let's further strengthen collaboration with the European and US communities as the CDM community in Japan, sharing the latest technology and information, and proposing new idea from Japan.

Medical Communication (Representative: Keiko Tsumori, MSD K.K.)

Medical Communication Community is newly launched in 2017 which aims to discuss"what" and"how" to better deliver drug information from health authorities and pharma to patients, to identify remained as an unattended or emerged issues, and to address solutions collaboratively. We discuss continuity and planning of drug information, consistency of message in CTD, RMP, package circular and post-marketing materials, various issues related to publications and others.

Examples for our activities are support for drug information session (V5-S2, V5-S3) and chatting session at this DIA Japan annual meeting, and 1st DIA medical communication workshop on the 12th December 2017.

We will welcome all members from different divisions of health authorities, academia and pharma (pharmacovigilance, product labeling, medical affairs, medical information, medical writing, and regulatory affairs and others) for new activities. Please contact DIA Japan to know more about the details if you would be interested in our activities.

Project Management (Representative: Koichi Konno, PM Consulting Positive Intention)

The primary purpose of Japan based "PM Community" of DIA is to improve "entire throughput of drug development" in Japan. Any health care / drug development related stakeholders, not only pharmaceutical industries, but academia, regulatory authorities, investigational sites, are welcomed to participate in the community for their learning and networking, The concrete activities are as follows:

- Planning and executing project management track of DIA annual meetings
- Planning and executing project management symposium
- Development and holding Project management training program (very entry level to application level)
- Holding community regular meeting
- Activities to introduce project management in academic research and regulatory affairs processes related to drug development
- Planning and participating in US/EU DIA annual meeting as project management community.
- Learning knowledge, technique, tools and operations of project management with collaboration, and sharing recent experiences

Please join us if you are interested in participating in the above activities. Not only project managers and project management office members, but study leader, study manager, coordination staff, team members are all welcomed as long as s/he is interested in team activities, project management, leadership development, and so on. Join us!

Regulatory Affairs (Representative: Manabu Yanagisawa, Eisai Co., Ltd.)

We have provided including of planning and management various Training courses regarding regulatory during the past in DIA Japan, such as RA Training course, FDA IND/NDA Training course, EMA RA Training course, Regulatory Communication Training course and Cell Therapy Products Symposium. The attendees of these training courses are not only persons in companies but also persons in health authority and academia, and we hear that every course has a high reputation. Regulatory Affairs Community has started since 2014, our community members keep contribution and support for these planning and management.

To accommodate the various regulatory environments, we will try to prepare the opportunity for exchanging information and building up a personal network among the RA community members. The chatting session at this DIA annual meeting is one of examples for the activity.

Six Sigma (Representative: Kazuo Ichikawa, Daiichi Sankyo Co., Ltd.)

The Six Sigma Community was established to expand its concept/tools in R&D sector, to provide opportunities to utilize Six Sigma in real-life setting. Six Sigma was developed as a quality management system but it has been embedded as a systematic approach in problem solving. The members consist of the certificated Six Sigma experts/consultants as well as beginners working in clinical development. The members meet monthly to discuss the specific Six Sigma topics with real-life examples, to make a proposal at DIA Japan Annual Meeting/Workshops. The topics include various fields related to clinical operation, data management, and so on. If you feel there is any problem around you, let's discuss to resolve it by Six Sigma together.

Statistics (Representative: Satoru Tsuchiya, Sumitomo Dainippon Pharma, Co., Ltd.)

The Japan Statistics Community was first established in 2004 as a part of "Program Support Team" for the Biostatistics track at the DIA Japan Annual Workshop, and it was formally established as the Japan Statistics Community (at that time, called SIAC) in 2007. The Japan Statistics Community meets quarterly to share and discuss various matters in the process of drug development from statistical perspectives, and propose sessions for DIA Japan Annual Workshops. Examples of topics include adaptive design, model-based drug development, CDISC, efficient safety information after launch, drug evaluation with small clinical trials. Addition to that, "Basic Statistical Concept Workshop for All Non-Statistical Clinical Research Professionals" is provided by this community.

Japan Communities to be established in the future

There are many DIA Communities which exist as Global Communities, but not as Japan Communities. If you are interested in any of such communities, please join Global Community. You can communicate with DIA members outside of Japan. Or you can newly establish Japan Community! Please contact DIA Japan if you would like to know more details.

How to join DIA Communities

To join Japan Community:

Please contact to DIA Japan

(Tel: +81-3-6214-0574, Fax: +81-3-3278-1313, Japan@DIAglobal.org)

To join a Global Community:

Login into DIA Global Site http://www.diaglobal.org/en

- Please become DIA Member if you are not.

Move to Move to My Communities, and pick up the community of your choice from EXPLORE COMMUNITIES tab.

Please visit "DIA Booth at Japan Annual" to get more information!

コミュニティとは

DIAコミュニティ

“DIAコミュニティ”とは?

DIAコミュニティとは、DIA会員のみが参加可能なDIAの活動の一つです。様々な専門領域のコミュニティがあり、それぞれのコミュニティは専門領域における経験や話題を共有するためのDIA会員同士のネットワークです。

コミュニティの主な目的は、企業、アカデミア、規制当局、医療機関、患者さんなど医薬品開発に関連する全ての立場の人が参加できる中立なネットワークを形成し、そのコミュニティの専門領域や医薬品開発全般に関わる経験や最新の話題の共有、課題検討、提言、ワークショップのプログラム作成などを行うことにあります。これらの活動を通じて、コミュニティは医薬品開発に関する革新に貢献し、またDIA会員にも有益なフォーラムを提供します。

またコミュニティは、DIAが開催する会合やその他の企画に対して各専門領域におけるキャリア開発のニーズを特定し、DIA会員の目的にあった教育研修の場を提供します。

DIAコミュニティのベネフィット

コミュニティのメンバーは、その専門領域での経験や最新の話題が共有でき、他のメンバーとのネットワークが得られます。またDIAのワークショップやトレーニングのプログラム作成に直接的あるいは間接的に関わることができます。

メンバーは日本およびグローバルのコミュニティに所属でき、様々なミーティングやセッションに参加することができます。

グローバルコミュニティ

(2017年10月時点)

- Clinical Data Management
- Clinical Pharmacology
- Clinical Research
- Clinical Safety & Pharmacovigilance
- Clinical Trial Disclosure
- Devices & Diagnostics
- Document & Records Management
- Electronic Regulatory Submissions
- Good Clinical Practice & Quality Assurance
- Information Quality, Compliance, & Technology
- Legal Affairs
- Medical Communications
- Medical Science Liaison
- Medical Writing
- Patient Engagement
- Pediatric
- Preclinical Sciences & OSWG
- Professional Education, Training & Development
- Project Management
- Quality Risk Management
- Regulatory Affairs
- Statistics
- Students
- Study Endpoints

コミュニティとは

日本コミュニティの紹介

Clinical Operation･Monitoring (COM) (代表者：菅生　和正、田辺三菱製薬株式会社)

2014年にクリニカルオペレーションやモニタリング業務に関する情報交換を目的に"Clinical Operation･Monitoring Community (COM Community)"を立ち上げました。COM Communityでは参加者が興味あるテーマについて活発に意見交換してきました。満足度もとても高いことから、今後も3ヵ月に1回程度の頻度で会合を開催していく予定です。

私たちは昨年より、「臨床現場における理想と現実のGap」に着目し、意見交換を行っています。今年は特に、Gapを解決するために各自が実践している具体的な行動にこだわり議論を継続しています。

COM　communityでは参加者全員が主役です!オペレーションの有るべき姿について、仲間と共に方向性を創り上げていきませんか?

Pharmacovigilance &Labeling (代表者：前田　玲、日本イーライリリー株式会社 / 松井　理恵、ファイザー株式会社)

DIA Risk Management workshop in Japan は2014年3月より、DIA添付文書workshop in Japanは2011年11月より、それぞれ毎年開催されています。本年5月開催のRisk Management workshopではリスクコミュニケーションを取り上げ、患者さんへのリスク最小化策を担う資材のあり方について考えるという第4回workshopを開催しました。添付文書workshopは来年2月に第7回を開催し、改正添付文書記載要領に基づく添付文書改訂を議論する予定です。本コミュニティでは、ファーマコビジランスの根幹をなすリスクマネジメントや添付文書に関する国内外の規制や動向について情報共有し議論をしていく予定です。

Clinical Strategy (代表者：田中　義信、MSD株式会社)

2015年2月に臨床開発を中心とした幅広い話題の情報・意見の交換を目的として立ち上げました。2ヶ月毎に会合を開いて、メンバーの日々の業務における悩みを解決する戦略と戦術をキーワードとした方策/アイデアの共有や意見交換を行っています。製薬企業、CRO、アカデミアという多様な背景をもつメンバーの特性や強みを生かし、全員参加型の活動を目指しています。是非、お気軽にご参加ください。興味のある方はDIA事務局まで!!!

Clinical Data Management (代表者：西　基秀、メディデータ・ソリューションズ株式会社)

DIAのClinical Data Management (CDM) の活動は、1998年に開催された第一回DIA CDM annual workshop in Japanから始まりました。データは世界の共通語であり、共有資源であることから、グローバルコミュニケーションの場であるDIAへのニーズは高く、Workshopを毎年継続開催して来ました。2017年からは、CDMを取り巻く環境の変化に対応していくため、CDMコミュニティでの意見交換を開始しました。日本のCDMコミュニティとして欧米のコミュニティとも連携し、最新技術や情報の共有、および国際標準への場としての日本からの提案などを更に強化していきましょう。

Medical Communication (代表者：津森　桂子、MSD株式会社)

メディカル・コミュニケーションコミュニティは、患者さんに適切な医薬品情報を適切に届けるためにあるべき姿を検討し、顕在化されている又は顕在化されていない課題を特定し、協力して改善提案を行うために、2017年に立ち上げた新しいコミュニティです。医薬品情報の連続性と計画のあり方、CTD、RMP、添付文書や市販後資材のメッセージの一貫性、論文に関する様々な課題などを取り扱います。本年会での情報提供セッション（V5-S2, V5-S3）及びチャッティングセッション並びに、12/12に実施します第1回メディカル・コミュニケーションワークショップをサポートしております。

メディカル・コミュニケーションコミュニティでは、規制当局、アカデミア及び製薬企業（ファーマコビジランス、添付文書、メディカルアフェアーズ、メディカルインフォメーション、メディカルライティング、開発薬事など）の医薬品情報に関わる幅広いメンバーと今後新たな活動を開始します。ご興味のある方はDIA事務局までご連絡ください。

Project Management (代表者：今野　浩一、PMコンサルティング ポジティブ・インテンション)

PMコミュニティの活動の目的は、日本における医薬品開発のスピード・質・コストの全体最適化です。製薬企業、アカデミア、医療機関、行政など、医薬品開発にかかわるすべてのステークホルダーが参加する「学習するコミュニティ」を目指していきます。そのための取組として以下のアクティビティーを実行しています。

・DIA年会PMトラックの企画・実行
・プロジェクトマネジメントシンポジウムの企画・開催
・PMトレーニングプログラムの開発・開催（超入門から応用編まで）
・コミュニティ例会・意見交換会の開催
・アカデミア、行政等へのPM導入支援活動
・US/EU　DIA Annual Meetingへのコミュニティーセッションの企画・参加
・US　PMコミュニティとのPMの知識、技法、ツール等に関する最新事例の共有

PMコミュニティでは、上記活動について、楽しくご参加いただけるメンバーを募集しています。プロジェクトマネジャー、PMOメンバーはもちろん、PI、スタディーリーダー、スタディーマネジャー、チームメンバーなど、プロジェクトマネジメント、チーム開発、リーダーシップ等に興味のある方はぜひご参加ください!お待ちしています!

Regulatory Affairs (代表者：柳澤　学、エーザイ株式会社)

これまでDIA Japanでは、薬事に関連する各種Training course（RAトレーニングコース、FDA IND/NDAトレーニングコース、欧州RAトレーニングコース、Regulatory Communicationトレーニングコース、再生医療製品シンポジウム）を提供（企画・運営）してきました。いずれも企業だけでなく規制当局、アカデミアからも参加いただき、高い評価をいただいております。Regulatory Affairs Communityは2014年より本格的に活動を開始し、これらのトレーニングの運営・立案及び日本年会の薬事関連セッションの企画立案をサポートしています。

医薬品を取り巻く環境は常に変化していることから、hot　topicsを題材に、気軽に意見交換できるような場の創出やネットワーキングのきっかけ作りを進めていきます。DIA日本年会においてはチャッティングセッションを設けておりますので、ネットワーク構築の機会としてご活用ください。

Six Sigma (代表者：市川　和雄、第一三共株式会社)

シックスシグマコミュニティは医薬品研究開発に従事している方々がより良くシックスシグマのコンセプトやツールを使っていただける機会を提供するために設立されました。シックスシグマはもともと品質マネジメント手法として体系化されましたが、最近では品質マネジメントだけでなく、課題解決の手法としても定着しています。メンバーには、企業のシックスシグマ専門家に加え、コンサルタントや、臨床開発に従事されている企業やアカデミアのシックスシグマ初心者の方々がいらっしゃいます。月1回会合を開き、具体的な事例を通して議論を重ね、DIA年会やワークショップへの提案を行っています。これまで、企業及びアカデミアにおける臨床試験オペレーション、データマネジメントなどの領域における課題解決をシックスシグマを活用して実践してきました。日頃から問題・課題を感じている方、一緒にシックスシグマで課題解決について考えていきましょう。

Statistics (代表者：土屋　悟、大日本住友製薬株式会社)

日本統計コミュニティは2004年にDIA年会生物統計トラックの「プログラムサポートチーム」として発足し、2007年に正式に日本統計コミュニティ（当時はSIAC）となりました。現在、3か月に1回程度会合を設け、医薬品開発のプロセス全体を統計的視点から共有・議論し、DIA日本年会へのセッション提案を行っています。今まで取り上げた話題としては、Adaptive Design、Model-based　Drug　Development、CDISC、意義のある安全性情報の提供、Small　Clinical　Trialsによる薬効評価の考え方、など様々です。また、「DIA医薬品開発に携わる生物統計専門家でない方のための統計ワークショップ」も本コミュニティが計画・実施しています。

その他のCommunityについて

現時点では、グローバルコミュニティが存在するものの、日本コミュニティが立ち上がっていないものが数多くあります。そのようなコミュニティへの参加ご希望があれば、グローバルコミュニティにご参加ください。海外のDIA会員とのネットワークを通じてコミュニティ活動が可能です。もちろんご自身で、あるいはお仲間と日本のコミュニティを立ち上げていただくことも可能です。ご興味のある方はDIA Japanまでお問い合わせください。

DIAコミュニティへの参加方法

Japan DIA コミュニティへの参加方法：

DIA Japanオフォスまでご連絡ください
Tel: +81-3-6214-0574, Fax: +81-3-3278-1313, Japan@DIAglobal.org

Global DIAコミュニティへの参加方法：

DIA Global Siteへログインしてください。http://www.diaglobal.org/en

- DIA会員でない方はDIA Global Siteから会員登録してください。

My Communitiesへ移動し、EXPLORE COMMUNITIESのタブからご希望のコミュニティを選択してください

"DIAブース"にてコミュニティの紹介をしております
是非お立ち寄りください

DIA Learning

Online Solutions

Improve the knowledge of your team using DIA's eLearning programs. Reduce training costs, eliminate time out of the office, and meet your organization's training needs.

Designed by learning experts using the latest instructional strategies to improve retention and make learning convenient for busy professionals. DIA eLearning courses include:

- Microlearning
- Gamification
- High level of interaction
- Scenario-based learning activities to apply learning
- Case studies and real-world examples
- Resources section for quick access to important regulations
- Printable module summaries of key lesson points
- Glossary of terms
- Mobile friendly, modern design containing multimedia and animation
- Voiceover
- 24/7 Access

Drug Safety

Drug safety is a primary concern throughout the medical product development life cycle. This eLearning program provides the knowledge you need, from regulations and requirements through premarket review and postmarket monitoring. The comprehensive program includes six self-paced modules that have been designed using the latest instructional strategies.

- Introduction to Drug Safety
- Drug Safety Regulatory Requirements
- Premarketing Clinical Trial Safety
- Postmarketing Safety Management
- Basics of Signal Detection and Pharmacoepidemiology
- Safety Audits and Inspection

Drug Development and Life Cycle Management

Drug development is an incredibly complex and risky endeavor, one that even experienced organizations will fail at more often than they succeed. This six module program will help you understand how companies structure their efforts and utilize their resources to improve the odds of successful development, and minimize the risks associated with shepherding a new drug candidate through the development process.

- Overview of Drug Development
- Phase 2 Studies
- Discovery and Preclinical Testing Phases
- Phase 3 Studies and Regulatory Review
- Phase 1 Studies
- Phase 4 and Life Cycle Management

Medical Communications

DIA's Medical Communications Program includes eight modules that cover topics any medical and scientific communications professional needs to know.

- Literature Searching
- Literature Evaluation
- Database Management and Medical Inquiries
- Medical Response Excellence
- Statistics for Medical Affairs
- US Regulatory and Compliance Considerations
- Crisis Management
- Product Labeling

Clinical Trial Fundamentals

This program designed to provide a practical context to help clinical research professionals learn about conducting clinical trials. Using an interactive case study with realistic scenarios designed to illustrate the learning points, this three module program follows the activities of a fictitious clinical investigator and her staff as they conduct a clinical trial.

- Clinical Trials: Study Preparation
- Clinical Trials: Study Initiation
- Clinical Trials: Conducting the Study

Informed Consent: Comprehensive Concepts and Components

This comprehensive module explains the components of a complete and appropriate consent form as specified by the International Conference on Harmonisation (ICH) and the US FDA, as well as guidance for the creation and appropriate wording of these components. It also includes a discussion on the benefits and concerns with electronic informed consent, and presents publications and projects that explore the use of eConsent.

To get a Free Trial of Our eLearning Solutions, Ask Questions, or Request a Custom Proposal, Contact **Heej.Ko@Diaglobal.org**

Visit **DIAglobal.org/eLearning** for more information

DIA 2017-2018 JAPAN

Event Calendar

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

DECEMBER

1st DIA Medical Communication Workshop in Japan
DECEMBER 12 | NIHONBASHI LIFE SCIENCE HUB

2nd DIA Cell Therapy Products Symposium in Japan
DECEMBER 15 | KFC HALL, RYOGOKU

JANUARY, 2018

2nd DIA Project Management Symposium in Japan
JANUARY 12 | NIHONBASHI LIFE SCIENCE BUILDING

FEBRUARY, 2018

21st DIA Annual Workshop in Japan for Clinical Data Management
FEBRUARY 19–20 | HULIC HALL, ASAKUSABASHI

8th DIA Labelling Workshop in Japan
FEBRUARY 23 | NIHONBASHI LIFE SCIENCE HUB

MARCH, 2018

6th DIA Clinical Operations and Monitoring Workshop in Japan
MARCH 8–9 | KFC HALL, RYOGOKU

12th DIA Asia New Drug Conference in Japan
MARCH 26–27 | TOC ARIAKE

APRIL, 2018

4th DIA Medical Device Symposium
APRIL 16 | NIHONBASHI LIFE SCIENCE HUB

JUNE, 2018

11th DIA Regulatory Affairs Training Course
JUNE 2018–MARCH 2019 | TKP TOKYO STATION CONFERNCE CENTER

7th DIA CMC Forum in Japan
TBC | TBC(TOKYO)

TBC, 2018

7th DIA FDA IND/NDA Training Course in Japan
TBC | TBC

8th DIA Project Management Training Course in Japan
TBC | TBC(TOKYO)

Visit **DIAglobal.org** for more information.

Booth #14

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CRScube America Inc. (USA)
12410 Milestone Center Drive, Suite 600,
Germantown, MD, USA, 20876
Tel: 1-240-499-2836

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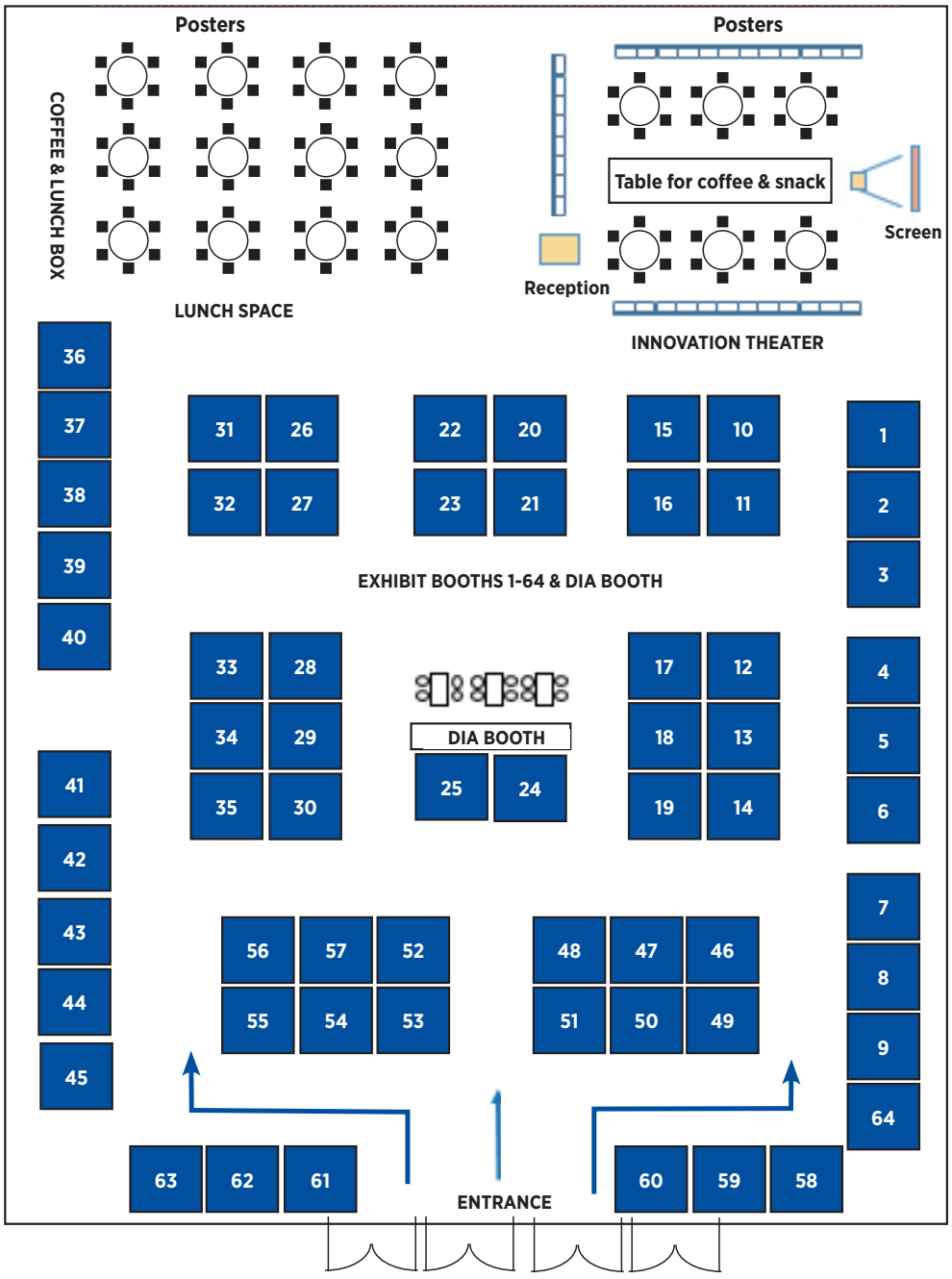
Minato-ku, Tokyo, Japan, 105-0004
Tel: +81-3-5425-7047

Email : help@crscube.co.kr ● www.crscube.net

EXHIBITOR LIST AND EXHIBIT FLOOR PLAN



EXHIBITORS' SHOWCASE

Luncheon Seminar by Platinum & Gold Supporters

November 13th, Monday
12:45–13:30
VENUE 1: 605/606 Seminar room
Platinum Supporter: A2 Healthcare Corporation
Japanese language only

11月13日(月)12:45–13:30
VENUE 1: 605/606セミナールーム
主催:エイツーヘルスケア株式会社

エイツーヘルスケアの生物統計家サービスの紹介
～試験統計家からCentralized Monitoringなど多岐にわたるソリューションのご提案～

近年、臨床試験における生物統計業務に加え、Risk Based MonitoringにおけるCentralized Monitoring、Real World Data解析など、生物統計専門家に求められる業務はより広範になっております。

A2Hは、従来から統計解析を強みとして発展してまいりました。試験計画時の生物統計専門サービスをコアとし、これまで多くの試験において、生物統計家として他の専門家とともに試験デザインを行う業務やプロトコル統計解析部分の作成を担当してまいりました。統計解析コンサルテーション、FDA対応セカンドオピニオンなど多種多様な業務も実施してまいりました。また、A2Hの生物統計家は近年注目を集めている再生医療領域おいて、その提供審査に関わる特定認定再生医療等委員会において生物統計学専門委員としても活動をしております。

また、近年さらに広範化する生物統計家業務に対応すべく、A2Hでは生物統計学だけではなくベイズ統計学にも明るい統計専門家を有し、臨床試験データの解析のみならず、統計学を必要とする様々な領域での対応を強化しております。
A2Hの生物統計家はRBMのCentralized Monitoringにおいても統計家としてソリューションの提案を行っており、ベイズ流の解析方法の提案を行っております。また、その成果を国際学会にておいても発表しております。加えて、今後発展の予想されるベイズ流アダプティブデザインについては他社に先んじて研究を開始し、成果を国際学会誌へ掲載もしております。

本ランチョンセッションでは、これまでA2Hが対応してまいりました生物統計専門家業務の経験の一部をお示しし、専門性を生かしつつ、広範囲な生物統計専門家サービス業務のご紹介をいたします。

November 13th, Monday
12:45–13:30
VENUE 6: 101 Seminar room
Gold Supporter: Medidata Solutions K.K.
Japanese language only

11月13日(月)12:45–13:30
VENUE 6: 101セミナールーム
主催:メディデータ・ソリューションズ株式会社

臨床試験プロセスを変革するエンドツーエンドのNext Generation Clinical Platformとサービスのご紹介

メディデータは、業界最先端のクラウドソリューションでより良い治療を待ち望む人々の手に1日でも早く新薬や医療機器を届けるために、毎年100億円以上をITテクノロジーのR&D開発に投資しています。2016年世界の売上高上位15薬品のうち13薬品が、メディデータのテクノロジーを用いて開発されました。メディデータの次世代クリニカルプラットフォームは、これまで業務ごとに分断された非効率的なプロセスを一つのプラットフォーム上に融合することにより、臨床試験の効率と生産性をエンドツーエンドで向上させます。本セッションでは、試験開始から終了まで用いられるソリューションのほか、患者中心のソリューション、ビックデータを用いるアナリティクスツール、また、製造販売後調査への取り組みなどを事例と共にご紹介いたします。

November 13th, Monday
12:45–13:30
VENUE 7: 102 Seminar room
Gold Supporter: INC Research Japan

Current and Emerging trends in Real World Evidence access and use

11月13日(月)12:45–13:30
VENUE 7: 102セミナールーム
主催:アイエヌシー・リサーチ・ジャパン株式会社

リアルワールドエビデンスの入手と使用における、現在および今後の傾向について

医薬品開発プロセスにおいて影響力のある主なステークホルダーとして、規制当局、保険機関、医師、患者の４つのグループが挙げられます。意思決定のプロセスでは、 これらのステークホルダーがリアルワールドエビデンスの素早い見識を必要とし、かつ、真に信頼できるデータを求めています。このニーズを満たすため、医薬品開発企業はデータへのアクセス及びデータ作成の両方の目的で、より旧来の企業だけでなく新興企業にも注目しています。このランチョンセミナーでは、このニーズに基づいたマーケットがどのようにして出現する可能性があるかについてディスカッションします。

本プレゼンテーションの主な内容:
①現在のグローバルヘルスケアの展望、現在および今後の傾向を反映したリアルワールドエビデンスの妥当性(特に日本に関連する事項)
②以下の内容に関する確認
　A 起こり得る競争的な環境
　B テクノロジーの変化についての進捗
　C 分析論への注目
　D 今後のデータビジネスモデル
③リアルワールドエビデンスの臨床開発部門におけるイノベーションが、パートナーシップにおいて提供されるデータおよびテクノロジーの応用により大きく躍進することを、上述の分析を通じて示す。

November 14th, Tuesday
12:45–13:30
VENUE 2: 607 Seminar room
Gold Supporter: CROèe Inc
Japanese language only

11月14日(火)12:45–13:30
VENUE 2: 607セミナールーム
主催:株式会社クロエ

「患者中心主義」を医薬品開発に取り入れる
～現場の声を患者さんと医師に直接聞いてみよう!～

「患者中心主義」をテーマに患者・医師・PROのパネルディスカッションを開催します。
昨年のDIAでもFDAから、開発の初期段階から正しい患者像をとらえ、それを上市後の販売戦略まで継承し続ける事の意義が発表されました。米国の取り組みとして24の疾患領域において患者の声を集め、それを公開・活用しており、日本との取り組みや意識の格差が顕著に表れた場でもありました。

それを受けて、日本においても「患者中心主義(Patient Centricity)」が大きな広まりを見せ、今年の業界における大きなトレンドと言えます。製薬企業は自社の製品開発の初期段階において、いかに「患者の声」を取入れるか、検討を行っている状況です。

しかし、一言で「患者さんの声を開発に」と言っても、具体的にどのようにしたら良いかという事については、各社手さぐりの状況でもあり、現在いろいろなアプローチ方法が検討されています。

はたして、それらの取り組みは患者さんや医師に受け入れられるのでしょうか。

クロエは日本におけるPRO(Patient Recruitment Organization)のリーディング・カンパニーとして2009年からサービスを提供しており、グループ会社の運営する「臨床試験情報サイト 生活向上WEB」「がん情報サイト オンコロ」に登録されている75万人のボランティア・データベースを中心に、臨

EXHIBITORS' SHOWCASE
Luncheon Seminar by Platinum & Gold Supporters

床試験の被験者リクルートメントを行っています。
その中で、臨床試験に参加された多くの患者さんの声をいただいており、それらはまさに患者中心主義の流れによってフォーカスされ、臨床開発の場にフィードバックされようとしています。
そこで本ランチョンセミナーでは、「患者中心を意識した臨床開発におけるソリューションや考え方」を紹介し、患者さんご自身や医師に見ていただき、意見交換を行う、パネルディスカッション形式で進行します。
実際に製薬企業で、患者の声を開発にフィードバックするための方法を検討されている方にはご参加いただき、現在皆さんが悩まれている事について質問や共有ができる、インタラクティブなセッションも行います。
患者中心主義で開発を進めていく事は、日本の医薬品開発において、それぞれの立場の垣根を越えて検討すべき課題と考えます。クロエの考える「患者中心のソリューション」を通じて、各社の課題解決のヒントとなるセッションを提供します。

November 14th, Tuesday
12:45–13:30
VENUE 3: 608 Seminar room
Gold Supporter: inVentiv Health Japan G.K.
Supporting the product lifecycle through database evaluations

11月14日（火）12：45–13：30
VENUE 3: 608セミナールーム
主催：インヴェンティヴ・ヘルス・ジャパン合同会社
データベース評価を通じた製品ライフ サイクル管理のサポート

医薬品開発のプロセスにおいて、医療データベースはこれまでにも様々な面で用いられてきました。疫学と治療パターンの評価を通じた早期疾患の理解、試験シミュレーションによる患者数及び転帰の予測、有効性及び安全性に関する比較解析の実施において、医療データベースが不可欠となっています。昨今、「市販後調査の基準に関する省令」（GPMSP）から「医薬品の製造販売後の調査及び試験の基準」（GPSP）への移行が進み、2018 年 4 月に改正GPSPの施行が予定されています。この改正により、医療データベースを再審査申請資料として用いることが可能になります。医療データベースには、国民健康保険の診療報酬レセプト、病院の医療記録や管理記録、電子カルテ等の情報が含まれます。
このような医療データベースは、リアルワールド・データとして医療技術及び疾患に対する有効な洞察をもたらします。また、データベースから導き出されるリアルワールド・エビデンスが、製品ライフ サイクル管理及び安全性報告の容易化を促すことでしょう。本ワーク ショップでは、こうした医薬品開発の全段階をサポートするためのデータベース分析に関する最新実務について議論します。

本プレゼンテーションの主な内容：
①日本で利用率の高いデータベースの概要
②日本におけるデータベース分析の現況
③医療技術評価(HTA)、疫学研究、安全性情報など、医薬品開発及び商品化のサポートに用いたデータベース分析の具体的事例

November 14th, Tuesday
12:45–13:30
VENUE 6:101 Seminar room
Gold Supporter: PAREXEL International
Japanese language only

11月14日（火）12：45–13：30
VENUE 6: 101セミナールーム
主催：パレクセル・インターナショナル株式会社
Patient Centric Protocol Optimization

優れたデザインのプロトコールは、有効性・安全性の目標を達成するだけでなく、施設や患者さんから見ても魅力的なものでなければなりません。パレクセルの独自のアプローチにより、治験デザインに関するスマートな決断をするための洞察を提供します。結果として、患者リクルート期間の短縮、プロトコール遵守率の向上、そしてプロトコール改訂を最小限に抑えることができます。

November 14th, Tuesday
12:45–13:30
VENUE 7: 102 Seminar room
Gold Supporter: OmniComm Systems
A Unique Advance Preview of the Next Release of TrialMaster, the World's Most Innovative EDC System

11月14日（火）12：45–13：30
VENUE 7: 102セミナールーム
主催：OmniComm Systems
TrialMasterの次期リリースの本邦初公開イベント

最も革新的なEDCと自負しております、TrialMasterの次期リリースの本邦初公開イベントへ謹んでご招待申し上げます。本年、日本市場へ正式参入いたしましたTrialMasterですが、次期リリースではユーザーインターフェイスが刷新され、さらに最新のモバイル技術が実装されます。2018年初頭より提供を開始いたします。

本イベントにおいて、下記についてご紹介いたします。
・日本語と英語で、平行してデータ入力を行う
・iPadを用いたデータ入力とモニタリング業務
・患者さん自身の携帯端末を用いたデータ入力（別のeProソリューションの使用は不要）

セミナーは、OmniComm SystemsのChief Technology OfficerであるKeith Howellsが行います（日本語への同時通訳あり）。また、アップグレードランチを提供いたします。

Please find the content in English from the link below:
http://diaexhibit.org/luncheon-seminar

EXHIBITORS' SHOWCASE

coffee break presentation by silver Supporters
Venue: InnovationTheater (Reception Hall)

November 12th, Sunday
15:25–15:35
Silver Supporter : MarkLogic

Pharmaceuticals and Medical Device Manufacturers leverage real world data to characterize diseases and patient populations develop products and therapies, and assess use of current competitive in-market products. With its flexible data model, MarkLogic empowers these companies with faster data integration and harmonization, assured data governance, and the enhanced insight they need to accelerate development of real world evidence.

November 13th, Monday
10:40–10:50
Silver Supporter : Oracle Corporation Japan

11月13日(月)10:40–10:50
主催:日本オラクル株式会社
臨床R&Dイノベーション

臨床開発の効率化やコスト削減、リアルワールドデータやAIの活用など、現在および将来のトレンドに向けたオラクルヘルスサイエンスのソリューションをご紹介します。

November 13th, Monday
15:40–15:50
Silver Supporter : PPD-SNBL

11月13日(月)15:40–15:50
主催:株式会社新日本科学PPD
アジア及びグローバルにおけるメディカルインフォメーション・コンタクトセンター(DI)サービス

PPD Medical Communicationsは、25年以上にわたり弊社独自の医療・医薬・医療機器に関するインフォメーションサポート業務を提供してまいりました。弊社は企業コンプライアンスを遵守しながら、パフォーマンス・エクセレンス、業務の効率化および一貫した業務遂行を達成するための洗練されたプロセスと革新的な技術を基に、業界トップのコンタクトセンターサービスを展開してきました。PPDが保有する知識、グローバル規模のリソース、柔軟性を駆使し日本とアジアパシフィック地域でも専門チームが包括的なメディカルインフォメーション・ソリューションを提供しております。
このセッションではPPDメディカルコミュニケーションズの担当者が日本並びにアジアパシフィック地域における事業概要の説明をさせて頂きます。

More than 25 years of experience with customized medical, drug and device information support. PPD's Medical Communications team provides industry-leading contact center services built on strong processes and innovative technologies that deliver performance excellence, operational efficiency and consistent results while ensuring regulatory compliance. PPD has the capabilities, global resources and flexibility to offer a single-source medical information solution, with specialized teams in Japan and Asia Pacific. In this session, we will explain our general capabilities in Asia Pacific region.

November 14th, Tuesday
10:40–10:50
Silver Supporter : ArisGlobal KK

11月14日(火)10:40–10:50
主催:アリスグローバル株式会社
新たなクラウドプラットフォーム　LIFESPHEREにより、従来プロセスを大幅に一新

史上初の企業規模での統合型クラウドプラットフォーム　ArisGlobal LifeSphereは、ライフサイエンス業界において、製品開発の合理化、規制遵守の改善、効率の向上およびリスクの低減のために、システム統合およびデータ管理上の課題を解決します。

November 14th, Tuesday
15:40–15:50
Silver Supporter : Vitalograph Japan Co.,Ltd.

11月14日(火)15:40–15:50
主催:バイタログラフ・ジャパン株式会社
Centralized Data Capture System

VitalographはSpirometry、e-DiaryやECGのデータなどをCentral Databaseで一元管理できるサービスを提供しています。受領したデータはOverReaderと呼ばれる専門家が品質のチェックを行い、CTのデータ品質向上に寄与します。
終了時には、Sponsorの指定フォーマットでデータを提供いたします。

EXHIBIT BOOTHS STAMP RALLY

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Please find a stamp rally card in the congress bag. Please visit exhibitors' booths and get their stamps. DIA Japan will provide you a small gift with more than 15 stamps, and a big present with over 20 stamps in a drawing by DIA Japan later the meeting. Please note that all stamps of supporting companies that are listed on this card with company logos are required. Please return your card back to the registration and information desk on the 1st floor by 16:00 on November 14th. We will give you a small gift in exchange for your card.

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DIA日本年会の興奮の余韻がのこる12月初め、DIA Japan よりスタンプラリーに応募された方の中から厳選に抽選した結果デジタルカメラが当選しましたとの連絡をいただきました。時節柄思いがけずサンタさんからの贈り物が届いた気分でした。いただいたデジタルカメラはスポーツ観戦に望遠機能を使って活用させていただいております。ありがとうございました。（某 外資系製薬会社）

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せっかくスタンプを集めたので・・・という感じで応募しましたが、まさかタブレットをいただけるとは思っておりませんでした。ご連絡をいただいた際には本当にびっくりで、「ドッキリか？」と疑ってしまいました。思いがけないクリスマスプレゼントをいただいたようで、とてもうれしかったです。ありがとうございました。（某 外資系製薬会社）

第13回DIA日本年会にてチラシの豪華景品に釣られてスタンプラリー制覇に挑戦しました。日頃こうしたイベントで賞が当たった経験がないだけに、受賞の連絡、しかも2017年 DIA日本年会参加無料券、をメールでいただいた時には目を疑いました。とても感謝しています。昨年はブースの方もスタンプラリーに協力的でスムーズに回ることができ、また普段は聞かないような話を聞けたことも有用でした。今年も引き続き楽しみにしています。（某 国内製薬会社）

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EXHIBITORS' SUMMARIES

A2 Healthcare Corporation 53/54
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Agatha Inc. 55
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ArisGlobal KK 18/19
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Covance 34/35

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Envision Pharma Ltd 62

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IBM Watson Health 2/3

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ICON plc 33

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Japan Medical Association Center for Clinical Trials　8
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Center for Clinical Trials, Japan Medical Association (JMACCT) runs the Project Promoting Clinical Trials for Development of New Drugs and Medical Devices of the AMED. Under this project, we are conducting for 'Research on Investigator-Initiated Clinical Trial Support' and 'Research on Clinical Trial Promotion'. One of those implementation is a cloud computing system, "Cut-Do-Square". Its purpose is to ensure efficiency in preparation and electronic storage of documents in uniform formats.

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Japan Medical Data Center Co.,Ltd　40
株式会社　日本医療データセンター

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Lionbridge Technologies　61

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LSK Global PS　17

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MarksMan Healthcare Solutions 9

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PQE Japan K.K. 37

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EXHIBITORS' SUMMARIES

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Trinity Co.,Ltd. 45
株式会社トリニティ

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Veeva Japan K.K. 12
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MarkLogic's flexible database platform reduces the time and cost of delivering real world evidence by enabling faster integration of all data, regardless of source. With government-grade security and bitemporal features, MarkLogic's database platform also equips organizations to meet strict data governance requirements—ensuring data quality by addressing provenance, traceability, completeness and accuracy. MarkLogic further supports enhanced discovery and faster analysis with advanced semantics capabilities that allow users to harmonize and query across all data—and its critical metadata—to find deeper context and hidden connections within it.

Visit www.marklogic.com or jp.marklogic.com

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medidata

メディデータ ブースでお待ちしております！

見どころ

ブレイクタイム中に、
メディデータの
各ソリューションのデモを実施

ソリューションデモ タイムテーブル（各5分間）

詳細はブースにて
ご確認ください

11月12日(日)

11:45	Patient Cloud ePRO
12:30	Centralized Statistical Analytics (CSA)
13:00	Balance RTSM
15:20	RaveX
15:35	Strategic Monitoring
17:35	Medical Imaging Clinical Solutions

11月13日(月)

10:35	Regulated Content Management
10:50	Patient Cloud ePRO
15:35	Centralized Statistical Analytics (CSA)
15:50	Balance RTSM
17:35	RaveX

11月14日(火)

10:35	Strategic Monitoring
10:50	Medical Imaging Clinical Solutions
13:00	Patient Cloud ePRO
13:40	Centralized Statistical Analytics (CSA)
15:35	Balance RTSM
15:50	RaveX

※デモ時間・内容は、予告なく変更する可能性がございます。予めご了承ください。

特典 1

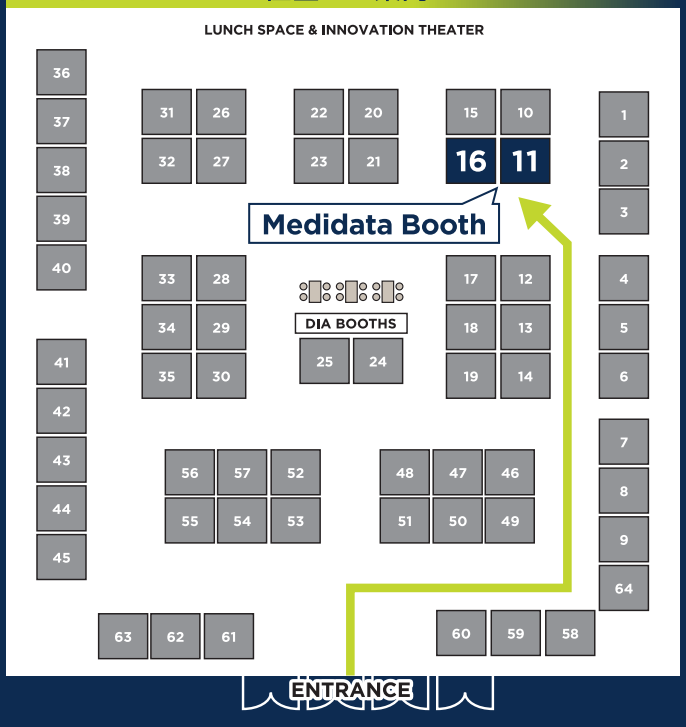
デモ聴講後、アンケートにご回答
いただいた方へ
2018年版メディデータの
オリジナルカレンダーをプレゼント

特典 2

名刺交換をさせていただいた方、
Facebookページに『いいね!』
または『記事投稿』してくれた方へ
ノベルティをプレゼント

*数量に限りがありますので、なくなり次第終了となります。

メディデータ ブース位置のご案内



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臨床研究　治験　PMS

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詳しくは、www.c3isolutions.com をご覧ください。

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THE EXPERIENCE MATTERS

SAVE THE DATE

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