12th Annual Meeting

DIA JAPAN 2015

A New Horizon of Innovation in Medicine Development

Final Program

DIA DEVELOP INNOVATE ADVANCE

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

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国立研究開発法人日本医療研究開発機構/
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UPCOMING EVENTS

JANUARY 28-29, 2016

19th DIA Annual Workshop in Japan for Clinical Data Management
- The Evolution of Clinical Data Management Capabilities -
KFC HALL, RYOGOKU, TOKYO

FEBRUARY 10, 2016

6th DIA Labelling Workshop in Japan
SOLA CITY CONFERENCE CENTER
OCHANOMIZU, TOKYO

MARCH 3-4, 2016

4th DIA Clinical Operations and Monitoring Workshop
- Clinical Operation Changes Clinical Trial -
KFC HALL, RYOGOKU, TOKYO

APRIL 13-14, 2016

10th DIA Asia New Drug Conference in Japan
TOC ARIAKE, TOKYO

JUNE 8, 2016

3rd DIA Risk Management Workshop in Japan
NIHONBASHI LIFE SCIENCE BUILDING, TOKYO

NOVEMBER 13-15, 2016

13th Annual Meeting DIA Japan 2016
TOKYO BIG SIGHT, ARIAKE, TOKYO

Message From DIA's Global Chief Executive

On behalf of our dedicated members, volunteers, global association, and our DIA Japan Team—welcome to the *12th Annual Meeting: DIA Japan 2015*!

This year's meeting highlights the continual evolution of health care product development in Japan, and is appropriately themed "A New Horizon of Innovation in Medicine Development." We recently learned that Satoshi Omura, an emeritus professor at Kitasato University, along with Irish-born William Campbell, received the 2015 Nobel Prize in Physiology or Medicine for discoveries concerning a novel therapy that helps in the fight against infections caused by roundworm parasites. Omura and Campbell will share the prize with China's Tu Youyou, who discovered a drug that has helped significantly reduce the mortality rates of malaria patients. These accomplishments serve as a reminder of the power of international and interdisciplinary collaboration to promote innovations in medicine development for the benefit of patients worldwide.

Japan has long recognized the importance of getting safe and effective drugs to patients faster. We see this in practice through the Ministry of Health, Labour and Welfare's release of the Strategy of SAKIGAKE, which will help lead the practical application of innovative medical products initially developed in Japan, especially for products to treat serious and life-threatening diseases. We will also hear about other initiatives at DIA Japan 2015 that directly benefit people not only by extending their lifespans but by improving their quality of life, including a Keynote speech from Dr. Makoto Suematsu of the recently launched Japan Agency for Medical Research and Development (AMED), whose goal is to first-track medical R&D through leadership for new drug/device R&D partnerships between academia and industry. Throughout the meeting, we will discuss what Japan can do for global medicines and medical products development, and how the country can actively engage patients throughout the development process, as patient-centricity becomes a cornerstone of health care.

At DIA, we continue to integrate ourselves more deeply into the local and global health care community in order to actively engage our key stakeholders, as we work to catalyze the knowledge exchange that will make real differences in the lives of so many. DIA is uniquely positioned to carry out our mission, and our recent Japan regional office relocation to the Nihonbashi area of Tokyo symbolizes our commitment to be "at the table" alongside so many leaders of Japan's biopharmaceutical ecosystem, working together, learning from each other, and making a difference.

Innovation in health care will not be generated only by industry, associations, government, and academia in Japan, but by each and every individual in Japan. I wish to close by thanking those individuals who shared their expertise and leadership to create this educational forum to discuss these innovations, including and especially our Program Chair Akihisa Harada, MD, PhD; Program Vice-Chair Satoshi Saeki, MSc; Program Advisors Junko Sato, PhD, and Shingo Hasetoh; and everyone who served on our Program Committee, whose names you will find on the front page of our meeting program.

Thank you for choosing to join the progressive discussions at our 12th Annual Meeting: DIA Japan 2015.

Sincerely,

Barbara Lopez Kunz

Global Chief Executive, DIA

SCHEDULE AT-A-GLANCE

SUNDAY, NOVEMBER 15

9:00-9:30	Registration for Student Session
9:30-12:00	Student Session
9:30-	Exhibitor Registration
12:30-	Attendee Registration
12:30-19:45	Exhibit Hall Open
13:30-14:00	Welcome & Opening Remarks
14:00-14:15	2015 DIA Japan's Inspire Regional Awards Ceremony
14:15-14:55	Keynote Speech 1 by Dr. Christopher P. Austin, NIH
14:55-15:35	Keynote Speech 2 by Dr. Makoto Suematsu, AMED
15:35-16:05	Coffee Break & Exhibit Hall Innovation Theater Presentations
16:05-16:45	Keynote Speech 3 by Dr. Murray M. Lumpkin, Bill and Melinda Gates Foundation
16:45-17:45	Special Panel Discussion
18:00-19:30	Networking Reception

MONDAY, NOVEMBER 16

8:30-	Attendee & Exhibitor Registration
9:00-19:00	Exhibit Hall Open
9:00-10:30	Session 1
10:30-11:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30	Session 2
12:30-14:00	Lunch & Exhibit Hall Innovation Theater Presentations / Luncheon Seminars*
14:00-15:30	Session 3
15:30-16:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
	Poster Session
16:00-17:30	Session 4
17:45-19:30	Special Chat Session

TUESDAY, NOVEMBER 17

8:30-	Attendee & Exhibitor Registration
9:00-16:00	Exhibit Hall Open
9:00-10:30	Session 5
10:30-11:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30	Session 6
12:30-14:00	Lunch & Exhibit Hall Innovation Theater Presentations / Luncheon Seminars*
14:00-15:30	Round Table
15:30-16:00	Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30	PMDA Town Hall
17:30-17:45	Closing Remarks

*Registration required.

11月15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
12:30-	参加者受付オープン
12:30-19:45	展示会場オープン
13:30-14:00	開会の挨拶 & 大会長挨拶
14:00-14:15	2015 DIA Japan's Inspire Regional Awards 授賞式
14:15-14:55	基調講演1（AMED 末松 誠先生）
14:55-15:35	基調講演2（NIH Dr. Christopher P. Austin）
15:35-16:05	コーヒーブレイク & 出展者プレゼンテーション
16:05-16:45	基調講演3（ビル&メリンダ・ゲイツ財団 Dr. Murray M. Lumpkin）
16:45-17:45	スペシャルパネルディスカッション
18:00-19:30	情報交換会

11月16日（月）

8:30-	受付
9:00-19:00	展示会場オープン
9:00-10:30	セッション 1
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 2
12:30-14:00	ランチ & 出展者プレゼンテーション
	ランチョンセミナー（申し込み制）
14:00-15:30	セッション 3
15:30-16:00	コーヒーブレイク & 出展者プレゼンテーション
	ポスターセッション
16:00-17:30	セッション 4
17:45-19:30	スペシャルチャッティングセッション

11月17日（火）

8:30-	受付
9:00-16:00	展示会場オープン
9:00-10:30	セッション 5
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 6
12:30-14:00	ランチ & 出展者プレゼンテーション
	ランチョンセミナー（申し込み制）
14:00-15:30	ラウンドテーブル
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
17:30-17:45	閉会の挨拶

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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. The pre-meeting presentations are available until November 24. 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 16 and Day 3, November 17. 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 Reception 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.

WIFI

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

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 14	All times are acceptable
Sunday, November 15	Before 8:00 and after 20:00
Monday, November 16	Before 8:00 and after 20:00
Tuesday, November 17	Before 8:00 and after 18:30

Web App

Access the free Web App designed for this meeting to get a wide range of information, as well as the ability to:

- Manage your meeting agenda by Events List and My Events
- Stay in the know with Announcements and FAQ
- Send comments and questionnaire
- Connect to social media channels

To download, access to the following link:

http://diajapan2015.com/en/

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 17th. We will give you a small gift in exchange for your card.

Exhibit Website

Please visit exhibit website below. By clicking the logo, you can get exhibitor's information.

http://diaexhibit.org/exhibitors

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.

Recording of any DIA tutorial/workshop/meeting information in any type of media is prohibited without prior written consent from DIA.

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。なお、全ての講演資料が閲覧できるのではなく、指定の期日までにDIAに提出された資料が掲載されます。この事前公開資料は、11月24日まで閲覧可能です。

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(11/16)と第3日(11/17)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。

WIFI

展示会場では、WIFIが利用できます。

日本年会ウェブアプリ

便利な日本年会専用アプリhttp://diajapan2015.com にアクセスして、スケジュール管理や情報収集にぜひご活用ください。

例えば、Events Listのセッション一覧から参加したいセッションを選んでMy Eventsで聴講スケジュールを管理、AnnouncementやFAQ（よくある質問）で 情報を入手、QuestionnaireやCommentからDIA Japanへコメントや感想を送信、Social Mediaへのアクセスなど。

展示WEBサイトのご案内

出展企業各社の情報が掲載されています。是非ご覧ください。ロゴをクリックすると各社の情報がご覧いただけます。

http://diaexhibit.org/exhibitors

Private Social Function Policy

本年会開催期間中、当プログラム以外の会議、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14日（土）	終日
11月15日（日）	午前 8時以前、午後8時以降
11 月16日（月）	午前 8時以前、午後8時以降
11月17日（火）	午後8時以前、午後6時半以降

日本臨床薬理学会認定CRC制度

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15日（日）

- 基調講演1、基調講演2、基調講演3
- スペシャルパネルディスカッション

11月16日（月）

- セッション1〜4

11月17日（火）

- セッション5〜6
- ラウンドテーブル
- PMDAタウンホール

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日本薬剤師研修センター認定の集合研修会

本年会のセッション1〜6（11月16日のセッション1〜4、11月17日のセッション5〜6）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。

2015年11月16日（月）				2015年11月17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。					
□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

展示会場スタンプラリー

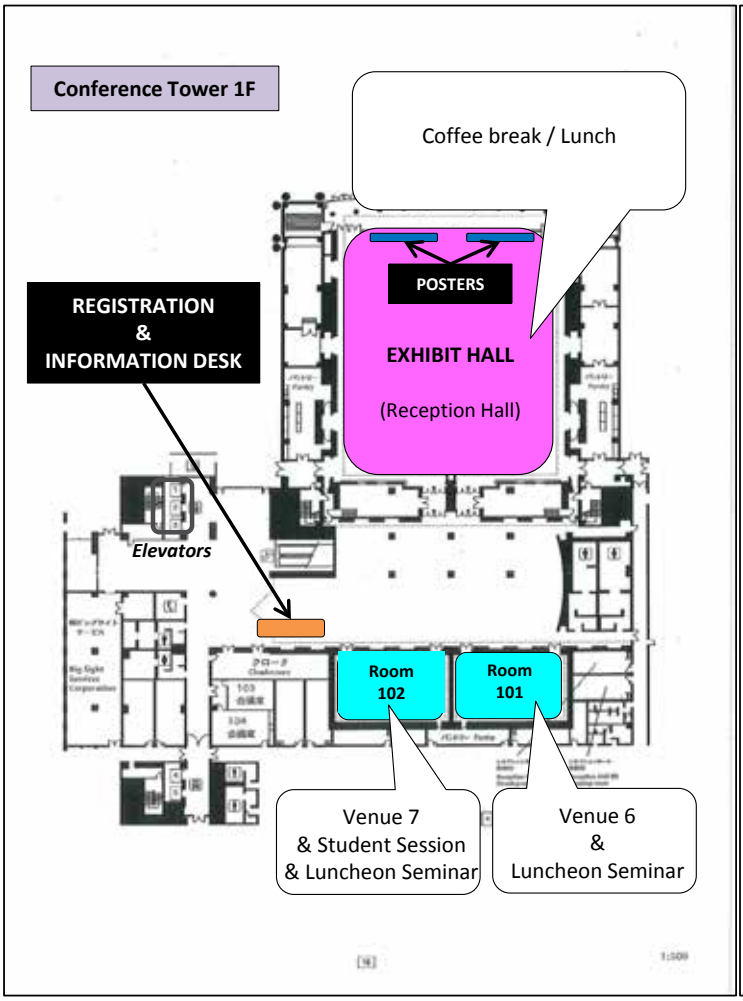
スタンプラリー用のカードがコングレスバッグに入っています。このカードを持参して各出展企業を訪問し、スタンプを押してもらってください。15個以上集まればもれなく粗品を、更に20個以上集めた方にはDIA Japanにて抽選を行い、後日賞品を郵送にてお送りいたします。なお、このカードにロゴが記載されている協賛企業のスタンプは必ず押してもらい、11月17日（火）の16:00までに1Fの総合受付にご提出ください。カードと引き換えに景品をお渡しします。

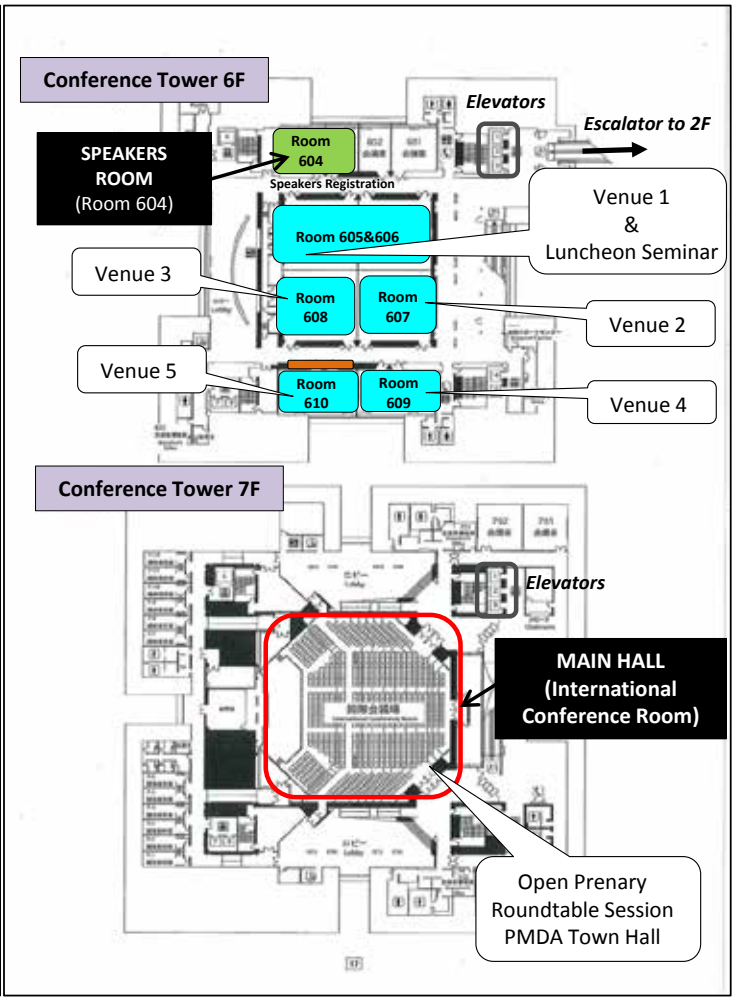
特に公表しない限り、本会議にて発表される内容は発表者本人の見解であり、所属する組織、あるいはDIAのものとは限りません。

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。

FLOOR PLAN





2015 DIA Japan's Inspire Regional Award Winners

Outstanding Contribution to Health Award

Hiroshi Watanabe, MD, PhD
Professor, Department of Clinical Pharmacology and Therapeutics, Director of the Clinical Research Center, Hamamatsu University School of Medicine

浜松医科大学
渡邉　裕司

After graduation from Hokkaido University and getting his medical license, Hiroshi Watanabe started working as a cardiologist in Hamamatsu University Hospital in 1983. He received his PhD in 1988. From 1989-1991 he studied abroad as a research fellow under the supervision of Prof. H. M. Piper in Dusseldorf University, Germany. Due to his growing interest in drug development and research, he transferred to the Department of Clinical Pharmacology and Therapeutics in Hamamatsu University School of Medicine as an Assistant Professor in 1998.

He is now Professor of that department as well as the Director of the Clinical Research Center at Hamamatsu University School of Medicine. He has devoted considerable time to advancing the promotion of research and drug development in Japan, taking leadership roles such as the Program Chairperson of the Annual Scientific Meeting of Japanese Society of Clinical Pharmacology and Therapeutics (JSCPT) in 2011 as well as the Meeting President of JSCPT-KSCPT-ASCPT Joint Conference in the same year. He has served as a member of the Japan Regional Advisory Council of DIA from 2011-2015 and helped establish the first joint symposium with DIA in the annual scientific meeting of JSCPT. He also took a role as the Program Chairperson of "the 11th Annual Meeting DIA Japan 2014".

He is currently the President of JSCPT, a council member of the International Union of Basic and Clinical Pharmacology and a Program Officer of Japan Agency for Medical Research and Development (AMED), and serves on several national committees with purposes closely aligned with the aim of improving health and healthcare by encouraging the advancement of clinical trials in Japan. He also sits on the Editorial Boards for Cardiovascular Research and the Journal of Pharmaceutical Sciences and was the Chief Editor of Translation of "Principles of Pharmacology 3rd Edition" (2015). His research interests focus on clinical pharmacology of cardiovascular drugs, endothelial cell signaling, pulmonary hypertension, and vascular biology.

Excellence in Service Award

Yoshihiro Higashiuchi, MSc
Senior Regulatory Scientist, Therapeutic Area Regulatory Affairs, Japan Regulatory Affairs, Medicines Development Unit Japan, Eli Lilly Japan K.K.

日本イーライリリー株式会社
東内　祥浩

Yoshihiro Higashiuchi joined Nippon Zoki Pharmaceutical Co. Ltd., in 1986 after obtaining Master degree in Agricultural Science from Kobe University. He started his career in Research Planning division in Institute of Bio-Active Science. From 1999 to 2004, he moved to Schering-Plough K.K. and developed a new MOA compound in cardiovascular disease in Clinical Development division. In June 2004, he joined Eli Lilly Japan K.K. as a regulatory scientist in Japan Regulatory Affairs. Now he is responsible for the projects of autoimmune, bone/muscle/joint, cardiovascular and urology as a senior regulatory scientist.

In DIA Japan 2012, he was a session co-chair of "Regulatory Communication between PMDA and an Industry for Smooth NDA Review". In 2014, he was a one of panelists in "Virtual Meeting of PMDA's Scientific Consultation: Points to Maximize an Efficiency of the Meeting". He has been a Program Committee member of DIA Regulatory Affairs Training Course since 2008. It is a training course for the development and fostering of people from pharmaceutical companies, regulatory authorities and academia engaged in drug development. The course consists of ten separate sessions and each session consists of a lecture, small group discussion and mock exercise. So far, about 400 students including 100 PMDA young reviewers graduated from this course. He has been a Program Committee Chairperson of this course since 2013.

Excellence in Service Award

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

ファイザー株式会社
松井　理恵

Rie Matsui is currently Director, Regional Labeling Head for Asia, International Labeling Group, Worldwide Safety & Regulatory, Pfizer Japan. She has established Asia Labeling Hub at Pfizer in July 2012 and the Asia Labeling Hub has created local label updates for more than 20 countries in Asia ever since its launch and she works with 14 affiliates in Asia. Previously, she was a Senior Manager for Post-marketing Regulatory Department at Pfizer Japan. She has driven Japan labeling for global pharmaceutical products within Pfizer since 1993. She led responses to support post-marketing label changes in Japan arising from both new data and regulatory requests. In addition, she has successfully led development of Japan submission labels for new global products. She is a proponent of proactive collaboration between global teams and local teams in labeling management and risk management plans prior to PMDA submissions.

Apart from her roles in Pfizer, she is a fundamental member of SIAC (now community) for the global labeling working group. Furthermore, since 2012 she has been a member of the content committee in DIA Japan and has contributed enormously to establishing new workshops/ trainings in Japan.

DIA, Contents committee member (2012-present)

DIA, Program committee member of Global Labeling conferences (2012 and 2014)

DIA, Program committee member of US and International Prescription Drug Labeling conference (2010)

DIA, Program chair of 4th and 5th Labeling workshops in Japan (2014 and 2015)

DIA, Program committee member of 1st, 2nd and 3rd Labeling workshops in Japan (2011-2013)

DIA, Program committee member of 1st and 2nd Risk Management workshop in Japan (2014 and 2015)

DIA, Facilitator of 1st Risk Management and Safety Communication training in Japan (2015)

DIA, Session chair of 5th China annual meeting (2013)

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

Japanese Language Only

SUN NOV. 15	MAIN VENUE INTERNATIONAL CONFERENCE ROOM	VENUE 1 ROOM 605/606	VENUE 2 ROOM 607	VENUE 3 ROOM 608
9:30-12:00				
12:00-13:30	LUNCH BREAK			
13:30-13:45	WELCOME			
13:45-14:00	OPENING REMARKS			
14:00-14:15	DIA JAPAN'S INSPIRE AWARDS PRESENTATION			
14:15-14:55	KEYNOTE SPEECH 1 (DR. SUEMATSU)			
14:55-15:35	KEYNOTE SPEECH 2 (DR. AUSTIN)			
15:35-16:05	COFFEE BREAK			
16:05-16:45	KEYNOTE SPEECH 3 (DR. LUMPKIN)			
16:45-17:45	SPECIAL PANEL DISCUSSION			
17:45-18:00	SHORT BREAK			
18:00-19:30	NETWORKING RECEPTION AT RECEPTION HALL			
MON NOV. 16		**VENUE 1 ROOM 605/606**	**VENUE 2 ROOM 607**	**VENUE 3 ROOM 608**
9:00-10:30 SESSION 1		<Start from 10:00> **V1-S1-S2** What Can Japan Do for Global Medicine Development? (Part 1) ALL	**V2-S1** Network Meta-Analysis: New Analytical Approaches in HTA and Drug Development - Introduction of Methodology and Its Application RA, ST, PM	**V3-S1** New Era of Benefit-Risk Balance Evaluation - Will Risk Information Keep Increasing? - (Part 1) CP
10:30-11:00		COFFEE BREAK	COFFEE BREAK	
11:00-12:30 SESSION 2			**V2-S2** ICH E14: Update on Current Status and Future Directions of Cardiac Safety Assessment CO, RA, ST, CP, PM	**V3-S2** New Era of Benefit-Risk Balance Evaluation - Will Risk Information Keep Increasing? - (Part 2) CP
12:30-14:00		LUNCH SEMINAR(PPD-SNBL)	LUNCH BREAK	
14:00-15:30 SESSION 3		**V1-S3** For Enhancement of Industry-Government-Academia Collaboration in Japan (Part 1) CO, AC, O: Translational Research	**V2-S3** Promoting Clinical Development for Patients with Rare Diseases - Patient Focused Drug Development in Japan RA, CO, AC, O: Patient	**V3-S3** Implication of Medical Big Data Usage – Applicability and Challenges in Clinical Development ALL
15:30-16:00		COFFEE BREAK (POSTER SESSION AT RECEPTION HALL)		
16:00-17:30 SESSION 4		**V1-S4** For Enhancement of Industry-Government-Academia Collaboration in Japan (Part 2) CO, AC, O: Translational Research	**V2-S4** What Drug Information Do Patients and Their Families Really Want? RA, AC, O: Patient	**V3-S4** Global Direction of Safety Assessment with Pharmaco-Epidemiology CO, RA, ST, DM, CP, PM
17:30-17:45	SHORT BREAK			
17:45-19:30	LET'S CHAT! "WHAT'S THE DIA WORLD 2015"' AT RECEPTION HALL			
TUE NOV. 17		**VENUE 1 ROOM 605/606**	**VENUE 2 ROOM 607**	**VENUE 3 ROOM 608**
9:00-10:30 SESSION 5		**V1-S5** Future Drug Development with Multi-Regional Clinical Trials Based on ICH E17 Guideline CO, RA, ST, DM, CP, PM, AC	**V2-S5** Present Condition of Regulation for Regenerative Medical Products in Japan CO, RA, CP, PM, CMC, AC	**V3-S5** Risk Communication in EU, US, and Japan - Goals and Objectives of Various Tools including Labeling - (Part 1) CP, AC
10:30-11:00		COFFEE BREAK		
11:00-12:30 SESSION 6		**V1-S6** Patient-Focused Medical Affairs Roles and Activities Beyond the Pill with Patient Support Programs CO, DM, CP, CMC, AC, O: Patient	**V2-S6** Perspectives for Development of Regenerative Medical Products in PMD Act CO, RA, CP, PM, CMC, O: MA, AC, MW	**V3-S6** Risk Communication in EU, US and Japan - Goals and Objectives of Various Tools including Labeling - (Part 2) CP, AC
12:30-14:00	LUNCH BREAK	LUNCH SEMINAR(A2 Healthcare)	LUNCH BREAK	
14:00-15:30	ROUND TABLE Let's Hear from AROs and R&D Heads - Towards New Medicine Development			
15:30-16:00	COFFEE BREAK			
16:00-17:30	PMDA TOWN HALL			
17:30-17:45	CLOSING REMARKS			

Japanese Language Only

VENUE 4 ROOM 609	VENUE 5 ROOM 610	VENUE 6 ROOM 101	STUDENT VENUE ROOM 102
			[Student Session] Understanding an Intention of Making Package Inserts as Pharmaceutical Companies - Comparing with What We Think of Providing Drug Information - RA, CP, AC
LUNCH BREAK			
SHORT BREAK			
NETWORKING RECEPTION AT RECEPTION HALL			
VENUE 4 ROOM 609	VENUE 5 ROOM 610	VENUE 6 ROOM 101	VENUE 7 ROOM 102
V4-S1 Use of Human Organ/Tissue for New Drug Development RA, CO, AC, O: Translational Research	**V5-S1** Introduction of Project Management Basic Process on Clinical Research Activities Planned and Conducted by Medical Institutes CO, DM, CP, PM, AC,	**V6-S1** The Difference between Pharmaceuticals and Medical Devices CO, DM, CP	**V7-S1** Call for Abstract Session CO, DM, CP, CMC
COFFEE BREAK			
V4-S2 Intellectual Property Strategies about Medical Technologies and Products in the Future - Let's Think about Effective Intellectual Property Strategies to Grow Seeds of New Technologies through Cooperation by Industry, Government, and Academia CO, RA, PM, AC, O: Intellectual Property	**V5-S2** Leading Innovation Leveraged by a Project Leadership ALL	**V6-S2** Contributions of Statistics and Behavior Observation to Drug and Medical Device Development ALL	**V7-S2** How to Succeed in "The Personalized Medicine Business" CO, RA, AC
LUNCH BREAK		LUNCH SEMINAR(Quintiles)	LUNCH SEMINAR(Medidata)
V4-S3 The Next Generation Drug Development for Personalized Health Care CO, RA, ST, CP, PM	**V5-S3** Fostering Further Collaboration between PMDA, Company and Academia with Efficient "Project Management" in Drug Development CO, RA, PM	**V6-S3** Tips for Better Drug Development Strategy in Asia - Let's Give Honest Opinions CO, RA	**V7-S3** Let's Think about Selecting Adverse Reactions for Labeling and How to Describe Their Frequency RA, CP
COFFEE BREAK (POSTER SESSION AT RECEPTION HALL)			
V4-S4 Future Perspective of Personalized Medicines in Oncology Disease Area - Can You Imagine How NGS Technology is Being Expanded in Japan? CO, RA, PM, CMC, AC, O: Government	**V5-S4** Career-Building for Entry-Level and Mid-Level R&D Personnel CO, RA, ST, DM, CP, PM	**V6-S4** HTA in Japan – What Should Pharmaceutical Companies Do? RA, ST, CP, PM, O: Pricing, Label	**V7-S4** Future of Pharmacovigilance from Development to Commercial – Where is the Spirit of ICH E2E Guideline in Japan? CP
SHORT BREAK			
LET'S CHAT! "WHAT'S THE DIA WORLD 2015"' AT RECEPTION HALL			
VENUE 4 ROOM 609	VENUE 5 ROOM 610	VENUE 6 ROOM 101	VENUE 7 ROOM 102
V4-S5 CRO Outsourcing Model – History and Future Outlook – Sponsor's & CRO's Perspective CO, O: CRO	**V5-S5** With the Aim of Developing Pediatric Drugs Being Triggered by Japan ALL	**V6-S5** The Future of Electronic Data Submission in Japan - Strategy for CDISC Correspondence CO, RA, ST, DM	**V7-S5** To Fight Against Superbugs - Future Development of Antibacterial Drugs Surrounding Drug-Resistant Pathogens CO, DM, CP, CMC
COFFEE BREAK			
V4-S6 ICH E9 (R1): Discussion on the Appropriate Estimands for Clinical Trials CO, ST, AC	**V5-S6** Industrial Development and Growth Strategy for Biosimilars - From the Viewpoint of the Acceleratation of Biosimilars Use ALL	**V6-S6** Towards ICH E6 Revision - Think about How Quality Management System (QMS) Can be Introduced in Clinical Trials CO, RA, ST, DM, PM, AC, O: QA, QC	**V7-S6** Rethinking Vaccine Policy-Making in an Era of Vaccine Hesitancy RA, O: Policy, Access
LUNCH BREAK		LUNCH SEMINAR(INC Research)	LUNCH SEMINAR(OmniComm)

関連領域: CO=臨床, RA=薬事, ST=統計, DM=CDM, CP=安全性, PM=PM, CMC=CMC, AC=アカデミア, O=その他

日本語のみ

11月15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
9:30-12:00				
12:00-13:30	ランチブレイク			
13:30-13:45	開会の挨拶			
13:45-14:00	大会長挨拶			
14:00-14:15	DIA JAPAN'S INSPIRE REGIONAL AWARDS授賞式			
14:15-14:55	基調講演1（末松 誠先生）			
14:55-15:35	基調講演2（DR. CHRISTOPHER P. AUSTIN）			
15:35-16:05	コーヒーブレイク			
16:05-16:45	基調講演3（DR. MURRAY M. LUMPKIN）			
16:45-17:45	スペシャルパネルディスカッション			
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16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
9:00-10:30 セッション1			**V2-S1** HTAや効果的な医薬品開発のための新たな解析的アプローチ - ネットワークメタアナリシスとその適用事例の紹介 RA, ST, PM	**V3-S1** ベネフィット・リスク バランスの評価の夜明け　～リスク情報は増え続けるだけか?～（第1部）　CP
10:30-11:00		< 10時より開始> **V1-S1-S2** 世界の医療へ貢献するために我々ができること ALL	コーヒーブレイク	
11:00-12:30 セッション2			**V2-S2** ICH E14：心臓安全性評価の最新動向 CO, RA, ST, CP, PM	**V3-S2** ベネフィット・リスク バランスの評価の夜明け　～リスク情報は増え続けるだけか?～（第2部）　CP
12:30-14:00		ランチョンセミナー(PPD-SNBL)	ランチブレイク	
14:00-15:30 セッション3		**V1-S3** 日本における産官学連携の推進を考える（第1部） CO, AC, O: Translational Research	**V2-S3** 難病・希少疾患の開発促進を患者さんと共に考える -日本におけるPatient Focused Drug Developmentの将来像 - RA, CO, AC, O: Patient	**V3-S3** ここまで使える医療情報ビッグデータRWD! - 医薬品開発における活用の可能性と今後に向けた課題 - ALL
15:30-16:00		コーヒーブレイク（1Fレセプションホールでポスターセッションあり）		
16:00-17:30 セッション4		**V1-S4** 日本における産官学連携の推進を考える（第2部） CO, AC, O: Translational Research	**V2-S4** 患者さんや家族が本当に必要としている薬の情報とは何か? RA, AC, O: Patient	**V3-S4** 薬剤疫学を利用した安全性評価に関する国際的動向 CO, RA, ST, DM, CP, PM
17:30-17:45	ショートブレイク			
17:45-19:30	Let's Chat! "What's the DIA World 2015"（レセプションホール）			

11月17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
9:00-10:30 セッション5		**V1-S5** ICH E17ガイドラインに基づく、今後の国際共同治験　CO, RA, ST, DM, CP, PM, AC	**V2-S5** 再生医療等製品に関する規制と審査の現状　CO, RA, CP, PM, CMC, AC	**V3-S5** 日米欧におけるrisk communication ～リスクコミュニケーションの目的とゴールについて、添付文書をはじめとしたツール類の観点から考えてみよう～（第1部） CP, AC
10:30-11:00		コーヒーブレイク		
11:00-12:30 セッション6		**V1-S6** 患者にフォーカスしたメディカルアフェアーズの役割と活動 - 患者サポートプログラムによる「Beyond the pill」 CO, DM, CP, CMC, AC, O: Patient	**V2-S6** 薬事法改正による再生医療等製品開発の変化と今後の展望 CO, RA, CP, PM, CMC, O: MA, AC, MW	**V3-S6** 日米欧におけるrisk communication ～リスクコミュニケーションの目的とゴールについて、添付文書をはじめとしたツール類の観点から考えてみよう～（第2部） CP, AC
12:30-14:00	ランチブレイク	ランチョンセミナー(A2 Healthcare)	ランチブレイク	
14:00-15:30	ラウンドテーブル AROとR&D Headに聞く ～新たな医薬品開発に向けて～			
15:30-16:00	コーヒーブレイク			
16:00-17:30	PMDAタウンホール			
17:30-17:45	閉会の挨拶			

関連領域: CO=臨床, RA=薬事, ST=統計, DM=CDM, CP=安全性, PM=PM, CMC=CMC, AC=アカデミア, O=その他

日本語のみ

第4会場 609会議室	第5会場 610会議室	第6会場 101会議室	スチューデント会場 102会議室
			スチューデントセッション 企業が考える添付文書への理解 ～私たちが考える情報提供との違いを通して～ RA, CP, AC
ランチブレイク			
ショートブレイク			
情報交換会（レセプションホール）			
第4会場 609会議室	第5会場 610会議室	第6会場 101会議室	第7会場 102会議室
V4-S1 創薬創出へのヒト細胞・組織の利用 RA, CO, AC, O: Translational Research	**V5-S1** 医療機関で計画・実施される臨床研究活動におけるプロジェクトマネジメント基本プロセスの導入 CO, DM, CP, PM, AC	**V6-S1** 医薬品と医療機器の違い CO, DM, CP	**V7-S1** 公募演題セッション CO, DM, CP, CMC
コーヒーブレイク			
V4-S2 医療分野のこれからの知財戦略 ～シーズを産官学が連携して育てるうえでの理想的な知財戦略を考えよう～ CO, RA, PM, AC, O: Intellectual Property	**V5-S2** Project Leadershipの発揮により迎えるイノベーション ALL	**V6-S2** 医薬品・医療機器開発への統計学・行動観察の寄与 ALL	**V7-S2** 個別化医療ビジネスの成功の鍵を探そう CO, RA, AC
ランチブレイク		ランチョンセミナー(Quintiles)	ランチョンセミナー（Medidata）
V4-S3 個別化医療を目指す次世代医薬品開発 CO, RA, ST, CP, PM	**V5-S3** 医薬品開発における規制当局と企業を繋ぐ効果的プロジェクトマネジメントCO, RA, PM	**V6-S3** 円滑なアジア開発にむけて ～もっと本音で語ってみよう～ CO, RA	**V7-S3** 今、“副作用”を考えてみよう ～添付文書への反映と発現頻度～ RA, CP
コーヒーブレイク（1Fレセプションホールでポスターセッションあり）			
V4-S4 オンコロジー領域における個別化医療の展開と将来展望 CO, RA, PM, CMC, AC, O: Government	**V5-S4** 若手～中堅開発マンのキャリア構築 CO, RA, ST, DM, CP, PM	**V6-S4** 日本のHTA - 製薬会社がなすべきことは何か RA, ST, CP, PM, O: Pricing, Label	**V7-S4** これからのPharmacovigilance ～開発から市販後へ続く安全対策。ICH E2Eは何処へ？ CP
ショートブレイク			
Let’s Chat! “What’s the DIA World 2015”（レセプションホール）			
第4会場 609会議室	第5会場 610会議室	第6会場 101会議室	第7会場 102会議室
V4-S5 CROアウトソーシングモデルの変遷と将来像 - スポンサー及びCROの立場から CO, O: CRO	**V5-S5** 日本発の小児医薬品開発を目指して ALL	**V6-S5** 電子申請はどのように変わっていくのか?CDISCの活用と企業の戦略について CO, RA, ST, DM	**V7-S5** Superbugsに対抗するために（耐性菌感染症をめぐる今後の抗菌薬の医薬品開発について） CO, DM, CP, CMC
コーヒーブレイク			
V4-S6 ICH E9 (R1): 臨床試験の “estimand” を考える CO, ST, AC	**V5-S6** バイオ後続品産業の育成と成長戦略（バイオ後続品の使用促進の観点から）ALL	**V6-S6** ICH E6の改訂に向けて - 臨床試験におけるQuality Management System (QMS) のあり方を考える - CO, RA, ST, DM, PM, AC,O: QA, QC	**V7-S6** イノベーティブな医薬品の価値を最大化するための環境、インフラについて考える～予防接種制度と政策の再考 - 予防接種に対する躊躇の時代を迎えて～ RA, O: Policy, Access
ランチブレイク		ランチョンセミナー(INC Research)	ランチョンセミナー(OmniComm)

DIA 2016

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STUDENT SESSION

STUDENT SESSION Room 102 9:30–12:00

Understanding an Intention of Making Package Inserts as Pharmaceutical Companies - Comparing with What We Think of Providing Drug Information

Related Interest Area(s): RA, CP, AC

Level: Beginner

Language: Japanese Language Only

SESSION CO-CHAIRS

Kotaro Kogo
Graduate Student
Graduate School and Faculty of Pharmaceutical Sciences
Chiba University

Tatsuya Sakuma
Graduate Student
Graduate School of Pharmaceutical Sciences
Tokyo University of Science

Ryohei Sato
Graduate Student
Keio Graduate School of Pharmaceutical Science

"The package insert" is the only public document with legal grounds as medical information and most important drug information in clinical practice. On the other hand, it is said that the drug information can't be mentioned enough because of the quantitative limit of the space of the papers. Then how do pharmaceutical companies choose the information for the package insert?

In this session, we will have a lecture about the basic concepts and role of package inserts. After that, to gain a better understanding of medical information, we'll have a discussion about "an intention of making package inserts as pharmaceutical companies" and "the drug information that medical workers demand for package inserts." Also we would like you to acquire knowledge and learn communication skills actively through discussion and presentation.

Measures for Ensuring Drug Safety by Pharmaceutical Company (Role of Package Insert)

Kenichi Akimoto
Former GlaxoSmithKline K.K.

ADVISERS

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

Yasuhiro Honsho
Global Regulatory Management
Daiichi Sankyo Co., Ltd.

Hironobu Saito, PhD
VP, New Drug Regulatory Affairs Dept.
Daiichi Sankyo Co., Ltd.

Eri Sekine
Head of Oncology Biometrics and DM Department, Oncology Development, Novartis Pharma K.K.

DAY 1 | NOVEMBER 15

WELCOME AND KEYNOTE SESSIONS

WELCOME

INTERNATIONAL CONFERENCE ROOM **13:30-13:45**

Ko Sekiguchi
Director, DIA Japan

Barbara Lopez Kunz (Prerecorded Speech)
Global Chief Executive, DIA

Tatsuo Kurokawa, PhD
President Elect, DIA
Professor, Division of Drug Development & Regulatory Sciences
Faculty of Pharmacy, Keio University

Kazumichi Kobayashi
Chair, DIA Advisory Council of Japan
Operating Officer / Director, Business Development and Planning
Otsuka Holdings Co., Ltd.

OPENING REMARKS

INTERNATIONAL CONFERENCE ROOM **13:45-14:00**

PROGRAM CHAIR

Akihisa Harada, MD, PhD
Vice President - Development Japan
Chief Scientist - Japan
Pfizer Japan Inc.

2015 DIA JAPAN'S INSPIRE REGIONAL AWARDS PRESENTATION CEREMONY

INTERNATIONAL CONFERENCE ROOM **14:00-14:15**

PRESENTER

Tatsuo Kurokawa, PhD
President Elect, DIA
Professor, Division of Drug Development & Regulatory Sciences
Faculty of Pharmacy, Keio University

AWARD WINNERS

Outstanding Contribution to Health Award

Hiroshi Watanabe, MD, PhD
Professor, Department of Clinical Pharmacology & Therapeutics,
Director of the Clinical Research Center,
Hamamatsu University School of Medicine

Excellence in Service Award

Yoshihiro Higashiuchi, MSc
Senior Regulatory Scientist, Therapeutic Area, Regulatory Affairs, Japan Regulatory Affairs, Medicines Development Unit Japan, Eli Lilly Japan K.K.

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

KEYNOTE SPEECH 1

INTERNATIONAL CONFERENCE ROOM **14:15-14:55**

SESSION CHAIR

Akihisa Harada, MD, PhD
Vice President - Development Japan
Chief Scientist - Japan
Pfizer Japan Inc.

With the establishment of AMED, R&D budgets in the medical sector which various ministries and agencies have possessed separately until now, were integrated into one. It therefore became possible to manage research consistently, from the basic research stage to practical application. As a result, information on drug discovery seeds, which is found at universities and government research institutions in Japan, will be sorted out and organized, and development of drugs at the early stages is anticipated to move forward, all at once. In his lecture, Dr. Suematsu will be asked to describe AMED's organization, projects and research areas, and discuss his views on the cooperative setup between patients and industry-government-academia which the AMED should aim at, going forward.

The Mission and Challenges of AMED

Makoto Suematsu, MD, PhD
President
Japan Agency for Medical Research and Development (AMED)

KEYNOTE SPEECH 2

INTERNATIONAL CONFERENCE ROOM **14:55-15:35**

SESSION CHAIR

Akihisa Harada, MD, PhD
Vice President - Development Japan
Chief Scientist - Japan
Pfizer Japan Inc.

The National Center for Translational Sciences (NCATS) is one of the 27 centers affiliated with the US National Institutes of Health (NIH). It was established in 2012 with the aim of accelerating the process of translational research, and becoming able to deliver new treatment methods to patients as quickly as possible. From the past measures carried out by NCATS and NIH, as well as among corporations, patients and NCATS, Dr. Austin will consider what obstacles exist in translational research, and what the tasks and challenges are, thereby showing a bridgehead for AMED's future activities.

NCATS' Past Activities and Future Challenges

Christopher P. Austin, MD
Director
National Center for Advancing Translational Sciences
US National Institutes of Health (NIH)

COFFEE BREAK 15:35-16:05

KEYNOTE SPEECH 3

INTERNATIONAL CONFERENCE ROOM **16:05-16:45**

SESSION CHAIR

Tatsuo Kurokawa, PhD
Professor, Division of Drug Development & Regulatory Sciences
Faculty of Pharmacy, Keio University

The Bill and Melinda Gates Foundation was founded in 2000. Since then, based on the idea that every life has equal value, the Foundation has been offering assistance to enable all people to lead a healthy and enriching life. Specifically, the Foundation carries out programs in the following three divisions: global development, global health, and United States. It also carries out charity assistance as well. Dr. Lumpkin invites all participants to think about the relationship between drug development, which is showing dramatic progress, and global health and welfare.

Advancement of Global Health by New Medicine Development (Tentative)

Murray M. Lumpkin, MD, MSc
Deputy Director, Regulatory Affairs
Lead Global Regulatory Systems Initiatives
Bill and Melinda Gates Foundation

NETWORKING RECEPTION

SPECIAL PANEL DISCUSSION

INTERNATIONAL CONFERENCE ROOM **16:45-17:45**

SESSION CO-CHAIRS

Akihisa Harada, MD, PhD
Vice President - Development Japan
Chief Scientist - Japan
Pfizer Japan Inc.

Tatsuo Kurokawa, PhD
Professor, Division of Drug Development & Regulatory Sciences
Faculty of Pharmacy, Keio University

The three speakers will be asked to use their experiences as the basis to share examples of best practices and issues to pay attention to when implementing private-public cooperation, and discuss what form future private-public cooperation should take, going forward. We also hope to discuss, together with the three speakers, what things we can do to deliver new treatments and diagnoses to patients as quickly as possible, and, furthermore, think about what we can do to contribute to global health and welfare.

PANELISTS

Christopher P. Austin, MD
Director, National Center for Advancing Translational Sciences
US National Institutes of Health (NIH)

Murray M. Lumpkin, MD, MSc
Deputy Director, Regulatory Affairs
Lead Global Regulatory Systems Initiatives
The Bill and Melinda Gates Foundation

Makoto Suematsu, MD, PhD
President
Japan Agency for Medical Research and Development (AMED)

NETWORKING RECEPTION

RECEPTION HALL **18:00-19:30**

Please join us at the Opening Networking Reception in the Reception Hall for an excellent opportunity to see your old friends and to make new acquaintances, while visiting the booths of exhibiting companies and academic affiliations.

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

SESSION 1 9:00-10:30

V1-S1-S2 Room 605/606 10:00-12:30

What Can Japan Do for Global Medicine Development?

Related Interest Area(s): ALL
Level: Intermediate

SESSION CO-CHAIRS

Akihisa Harada, MD, PhD
Vice President - Development Japan
Chief Scientist - Japan
Pfizer Japan Inc.

Tatsuo Kurokawa, PhD
Professor, Division of Drug Development & Regulatory Sciences
Faculty of Pharmacy, Keio University

Japan medical system has been highly rated by WHO World Health Report because of Japanese unique universal care system and accessibility to hospital, and has achieved a goal of providing high-quality medical service with patients.

On the other hand, medical science and advanced medicine technology are making remarkable advance, and they will lead to not only academic medical research but also new medical treatment, and will expected to contribute to global and citizen's medicine. Consider what Japan can do for the global medicine in the field of national health by using Japanese medical and research infrastructure.

According to the relief of device/drug lag in Japan, now Japan approach for regenerative medicine and drug development is catching up and is going to overtake US/EU Given the situation, in this session, speakers and panelists from regulatory, industry and academia perspective would discuss what are Japanese strengths and how Japan can play an important role in a field of global medicine development.

Healthcare and Medical Research in the Information Age

Ryozo Nagai, MD
President, Jichi Medical University

TBA

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

Toward Acceleration of Innovative Drug Discovery

Masafumi Nogimori
Representative Director, Chairman of the Board
Astellas Pharma Inc.

Realizing Japan's Potential in Global Drug Development

Carsten Brunn, PhD
President and Representative Director,
Bayer Yakuhin, Ltd.

Panel Discussion

All speakers above

V2-S1 Room 607 9:00-10:30

Network Meta-Analysis: New Analytical Approaches in HTA and Drug Development - Introduction of Methodology and Its Application

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

SESSION CHAIR

Koji Oba, PhD
Associate Professor, Dept of Biostatistics, School of Public Health
The University of Tokyo

This session will introduce the new analytical approach "Network meta-analysis", which can be used for quantitative decision making in drug development and health technology assessment (HTA). In this session, we would like to show you how effective Network meta-analysis is and what we need to consider for the appropriate use of Network meta-analysis.

Network meta-analysis is the methodology of generalizing the meta-analysis of the comparison between two drugs. It can provide the following effective information by combining the study results with more than 2 drugs (e.g. Drug A vs Drug B, Drug B vs Drug C, Drug A vs Drug C).

(i) In-direct pairwise comparison of two drugs; even if no direct comparison results available.

(ii) Higher precision of treatment difference between two drugs; by combining all of the study results of direct and indirect pairwise comparison.

The results from the network meta-analysis can be widely used when comparing new drug in development with a standard drug, determining margin of non-inferiority or bio-similar studies or health technology assessment.

Application and Consideration of Network Meta-analysis for Effectiveness Evaluation of Pharmaceutical Product

Yosuke Fujii, PhD
Pfizer Japan Inc.

Application of Network Meta-Analysis Aiming to Establishment of Target Product Profile

Shumpei Arano
Analytical Specialist, Japan Tobacco Inc. / Data4C's K.K.

Implementation of Bayesian Network Meta-analysis to Improve Medical Product Development

Karen L Price, PhD
Research Advisor, Eli Lilly and Company

V3-S1 Room 608 9:00-10:30

New Era of Benefit-Risk Balance Evaluation - Will Risk Information Keep Increasing? - (Part 1)

Related Interest Area(s): CP
Level: Intermediate

SESSION CO-CHAIRS

Osamu Komiyama
Senior Manager, Pfizer Japan Inc.

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

In general, safety information increases depending upon drug exposure. Within few years after launch, reporting rates incrementally decrease until reporting is flat. In this session, experts from three regions will present the difference between ADRs and risk, and the difference between efficacy and benefit, which situations mean that "benefits outweigh risks" and how to express it, who assesses the benefit-risk balance, and how to utilize it. Organization, specification of responsible persons, and current and future issues regarding tis benefit-risk balance assessment will be addressed in a panel discussion representing these three regions.

Personalized Medicine and Benefit-Risk: Impact on REMS and Other Approaches to Safety

Stephen P. Spielberg, MD, PhD
Editor-in-Chief, Therapeutic Innovation and Regulatory Science (TIRS), the official journal of the DIA

Current Trends in Benefit/Risk Assessment of Medicines and Regulatory Impact from EU Perspective

Xavier Luria, MD
Chair and Senior Consultant, Drug Development and Regulation
Former Head of Safety and Efficacy of Medicines at the EMA

TBA

Shinobu Uzu
Director, Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

V4-S1 Room 609 9:00-10:30

Use of Human Organ/Tissue for New Drug Development

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

SESSION CHAIR

Satoshi Toyoshima, PhD
Professor,
Faculty of Pharmacy, Graduate School of Pharmaceutical Sciences
Musashino University

It is essential to utilize human organ/tissue (biomaterial) for new drug development. Unnecessary organ/tissue in case of human organ transplantation is effectively utilized in the US/EU. However Japanese scientific society tends to hesitate to utilize unnecessary human organ/tissue for drug development because Japanese feel it is morally at fault. The first speaker will provide a summary of the background, including the current situation and problems. The second speaker will provide his opinion from the legal and the ethical viewpoint. Then, two speakers from academia and a pharmaceutical company will discuss the matter from their standpoints.

Usage of Human Organs, Tissues and Cells for Research in Japan - Past Activities and Challenges For Future -

Katashi Fukao, MD, PhD
President, HAB Research Organization

Use of Human Tissue for Medical Research: Its Ethical and Legal Basis

Saku Machino
Professor Emeritus
Sophia University

Utilization of Human Cell/Tissue for Drug Discovery and Development: Expansion toward Precision Medicine

Ikuo Horii, PhD
DSRD Global Consultant
Global Research & Development, Pfizer Inc.

Significance of Human Tissues in Drug Development: Prediction of Pharmacokinetics of Investigational Drugs in Humans

Hiroyuki Kusuhara, PhD
Professor
Graduate School of Pharmaceutical Sciences
The University of Tokyo

Q&A AND SUMMARY

V5-S1 Room 610 9:00-10:30

Introduction of Project Management Basic Process on Clinical Research Activities Planned and Conducted by Medical Institutes

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

SESSION CHAIR

Shuji Sumida
Department Manager, Quality & Regulatory Compliance Dept.,
Quality & Regulatory Compliance Unit, Chugai Pharmaceutical Co., Ltd.
DIA Japan PM Community

In order to effectively manage a multicenter, investigator-initiated clinical study (hereinafter abbreviated as a "multicenter IIS"), especially to clarify roles and responsibilities and share work and activities among institutions, a business unit which conducts managing activities for that study (hereinafter referred to as a "central office") is often placed. One of the critical success factors here includes, but not limited to, making sure the communication and collaborations are secured and effectively working among all stakeholders, including the"central office," medical institutions, contractors and so on.

In this session, we will introduce an effective and practical application of project management skills and techniques which can maximize the utility of limited human resources in medical institutions. In addition, we will discuss what is necessary to fulfill individual work responsibilities and optimize communications among stakeholders of IIS and leverage their strength based on the practical experiences from project management points of view.

Lecturers

Yoko Kazami
Kitasato Academic Research Organization, Kitasato University

Kayoko Kikuchi, PhD
Research Associate
The Center for Clinical Research, Keio University School of Medicine

Koichi Konno, PMP
Chief Executive, PM Consulting Positive Intention
DIA Japan PM Community

Atsuo Nakagawa, MD, PhD
Assistant Professor
The Center for Clinical Research, Keio University School of Medicine

Ai Okazaki
Translational Research Center, The University of Tokyo Hospital

V6-S1 Room 101 9:00-10:30

The Difference between Pharmaceuticals and Medical Devices

Related Interest Area(s): CO, DM, CP
Level: Beginner

SESSION CHAIR

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

Since the Cabinet has approved to position the health care and medical field as one of major growth strategies of the Japanese government, it inevitably gives way to new entrants from different industries to the field and encourages innovative technology introduced for medical treatment. While a boundary between pharmaceuticals and medical devices is shown by the newly-enacted Pharmaceutical and Medical Device Act (PMD Act), combination products related to both areas have been actively developed and from a viewpoint of medical devices area there are some cases where pharmaceutical companies have difficulties in the development of such products due to a lack of knowledge about medical devices. In this session, we focus on the differences between pharmaceuticals and medical devices from various points of view and expect to improve understanding of the medical devices in the pharmaceutical industry.

TBA

Kazuo Kawahara
Terumo Corporation

TBA

Isao Tsuchii
Business Operator, Green Field

The Difference between Pharmaceuticals and Medical Devices from A Standpoint of A Clinician Involved with Development of Photodynamic Therapy

Yoshihiro Muragaki, MD, PhD
Institute of Advanced Biomedical Engineering and Science
Tokyo Women's Medical University

The Difference on Clinical Trials

Koji Ikeda, PhD
Professor, Clinical Research Innovation and Education Center
Tohoku University Hospital

'Medical Devices and Pharmaceuticals' Comparison of Approval Review (Reviewer's Point of View)

Takashi Ouchi
Office of Medical Devices III
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All speakers above and

Yuka Suzuki, PhD
Director, Office of Medical Devices II
Pharmaceuticals and Medical Devices Agency (PMDA)

V7-S1 Room 102 9:00-10:30

Call for Abstract Session

Related Interest Area(s): CO, DM, CP, CMC
Level: Beginner

SESSION CO-CHAIRS

Junko Sato, PhD
International Coordination Officer
Pharmaceuticals and Medical Devices Agency (PMDA)

Koichiro Yuji, MD, PhD, FACP
Project Associate Professor,
Project Division of International Advanced Medical Research
The Institute of Medical Science, The University of Tokyo

Three researches, two for oncology disease area and one for cardiovascular disease area, wide range of challenges in drug development in Japan, such as a promoting early stage clinical development, efficient usage of global development and optimization of postmarketing activities. Various approaches to address these challenges will be presented and comprehensive discussion will be held.

1. Characterization of toxic reactions of oncology development products observed in Japan phase 1 studies.
2. Determination of affecting factors in drug lag (gap of approval timing) between western counties and Japan in oncology drug development.
3. Medical data base research for evaluation of safety profile in anti-thrombotic agents

Do All Patients in the Phase I Trials Need to Be Hospitalized? - Domestic But Outstanding Issues for Globalization in Japan -

Akihiko Shimomura. MD
Attending Staff
Dept. of Experimental Therapeutics/Breast and Medical Oncology,
National Cancer Center Hospital

Background: Most trials investigating new drugs, including phase 1 trials are conducted in outpatient clinics. In Japan, study participants for phase 1 often require hospitalization for certain duration according to the regulatory authority requirements and traditional domestic guidelines. Requirement of hospitalization is a barrier to globalization of early drug development, and the scientific rationale of hospitalization has not been elucidated. In this study, we analyzed the toxicities in cycle 1 in patients participating in single-agent phase 1 trials and the number of patients requiring hospitalization for toxicities to reconsider the framework of early drug development for the future.

Materials and methods: Patients participating in single agent phase 1 clinical trials at our institute between Dec 1996 and Aug 2013 were monitored. Toxicity requiring hospitalization is defined as the toxicity that needs intensive treatment. Study designs were classified into three types; first-in-human study (FIH), phase 1 study (conventional dose escalation study to determine MTD in Japanese patients), and dose finding study (to assess safety and pharmacokinetic profiles up to the MTD previously determined in the West).

Results: A total of 945 patients participated in phase 1 trial. Median age was 58 years (range 18-76). 537 patients (57%) were male. 207 (22%), 690 (73%), and 48 (5%) patients were assigned to receive cytotoxic drugs, molecular-targeted drugs, and immune checkpoint inhibitors, respectively. 582 patients (62%), 129 (14%), and 234 (25%) patients participated in phase 1 study, FIH, and dose-finding study, respectively. 126 patients (13.3%) developed toxicities equivalent to dose-limiting toxicity (DLT), and in cycle 1, 96 patients (10.2%) developed toxicities equivalent to DLT. 36 patients (3.8%) showing toxicities equivalent to DLT in cycle 1 needed hospitalization. The number of hospitalizations and/or grade 4 toxicities was (5.0%). In cycle 1, 33 patients (15.9%) receiving cytotoxic drugs and 65 patients (9.5%) receiving molecular-targeted drugs developed toxicity equivalent to DLT. However, patients taking immune checkpoint inhibitors did not develop any toxicity equivalent to DLT. 72 patients (12.4%) in phase 1 study, 14 patients (10.9%) in FIH, and 11 patients (4.7%) in dose-finding study developed DLT-equivalent toxicity. 27 (4.6%) phase 1 study participants, 4 (3.1%) FIH participants, and 5 (2.1%) dose-finding study participants required hospitalization for toxicity.

Conclusion: The frequency of hospitalization was unexpectedly low, and our data could not demonstrate the need for hospitalization in the phase 1 trials. We believe that phase 1 trials could be conducted as outpatient settings for globalization.

Meaningful Use of DPC Claim database for Postmarketing Surveillance of New Drugs

Masahiro Inoue, MD, PhD
Division Manager
Ota Memorial Hospital

Background: The Diagnosis Procedure Combination (DPC) is a case-mix system, which is similar to the Diagnosis-related Groups (DRGs) used in Medicare in the United States..However DPC claim database is rarely used for Drug safety in Japan. We evaluate the safety of NOAC (New Oral Anticoagulants) to use this database comparing Warfarin.

Methods: We analyzed the patients under anticoagulation who had Gastrointestinal bleeding and Intra-cranial bleeding then admitted to acute care hospitals between October 2012 and September 2014. Using DPC analytic software girasol for nationwide database. The event rates and outcome were investigated.

Results: Of the 64,648 patients from 352 hospitals were analyzed. 50,027 (77.3%) received Warfarin treatment, 9,741(24.8%) received. Switching and combination case were 1367(2.1%) and 47(0.07%). 1025(Warfarin 872, NOAC:153) Endoscopic hemostasis treatments ware done. The event rate was 0.48 %/Year in NOAC group and 0.87%/Year in Warfarin group. 773 patients(Warfarin:679, NOAC:94) had intra cranial bleeding, the event rate of NOAC group was 0.29 %/Year, and Warfarin group was 0.68.

Conclusions: Our findings suggest that NOAC resulted in a reduction in rates of the patients with gastrointestinal bleeding and intracranial bleeding compared with Warfarin. This study suggests the utility of pharmacovigilance and postmarketing study instead of postmarketing surveillance of new drugs in Japan. The DPC data is lacking patient's background data and risk factor in Out clinic. However this approach is useful for establishing drug safety in early stage of the launch.

Study on Drug Lag between Japan and the US in Oncology Drugs. Considerations of Changes and Factors Affecting Difference with the US

Hideki Maeda, PhD
Vice President
Astellas Pharma Inc.

Background: Oncology drugs target cancer, a serious and lethal disease. Because of this, compared with drugs in other therapeutic areas, the issue of drug lag between Japan and Europe/United States has posed a greater problem. In this study, we exhaustively and historically studied the status of drug lag for oncology drugs that have been approved in Japan over the years.

Methods: In this study, we comprehensively investigated oncology drugs approved in Japan from April 2001 to July 2014, using publicly available information, and historically studied changes over time in the characteristics of such drugs. We also examined changes in the status of drug lag between Japan and the US and review time by the regulatory authorities for oncology drugs in Japan and US.

Results: This study included 120 applications for approval of oncology drugs in Japan between April 2001 and July 2014. The median difference over a 13-year period in the approval date between the United States and Japan was 875.0 days (29 months). This figure peaked in 2002, and showed a tendency to decline gradually each year thereafter, and a significant reduction was seen. The 13-year median duration of review time was 366.5 days (12 months). The review time peaked with 732.0 days (24 months) in 2005, and showed a tendency to decline gradually each year thereafter. Multiple regression analysis identified the following factors that reduce drug lag: "participation in global clinical trials;" "bridging strategies;" "designation of receiving priority review;" and "molecular drugs." This research also identified factors that influenced "delays in starting development" and "duration of the review time."

Conclusions: From 2001 to 2014, molecular target drugs have increasingly become the target of oncology drug development in Japan. And the method of development has changed from full development in Japan or bridging strategy to global simultaneous development by Japan's taking part in global clinical trials. In line with these changes, the drug lag between Japan and the US has significantly reduced to less than one year.

SESSION 2 11:00-12:30

V1-S1-S2 Room 605/606 10:00-12:30

What Can Japan Do for Global Medicine Development?

Related Interest Area(s): ALL
Level: Intermediate

SESSION CO-CHAIRS

Akihisa Harada, MD, PhD
Vice President - Development Japan
Chief Scientist - Japan
Pfizer Japan Inc.

Tatsuo Kurokawa, PhD
Professor, Division of Drug Development & Regulatory Sciences
Faculty of Pharmacy, Keio University

Japan medical system has been highly rated by WHO World Health Report because of Japanese unique universal care system and accessibility to hospital, and has achieved a goal of providing high-quality medical service with patients.

On the other hand, medical science and advanced medicine technology are making remarkable advance, and they will lead to not only academic medical research but also new medical treatment, and will expected to contribute to global and citizen's medicine. Consider what Japan can do for the global medicine in the field of national health by using Japanese medical and research infrastructure.

According to the relief of device/drug lag in Japan, now Japan approach for regenerative medicine and drug development is catching up and is going to overtake US/EU Given the situation, in this session, speakers and panelists from regulatory, industry and academia perspective would discuss what are Japanese strengths and how Japan can play an important role in a field of global medicine development.

Healthcare and Medical Research in the Information Age

Ryozo Nagai, MD
President, Jichi Medical University

TBA

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

Toward Acceleration of Innovative Drug Discovery

Masafumi Nogimori
Representative Director, Chairman of the Board
Astellas Pharma Inc.

Realizing Japan's Potential in Global Drug Development

Carsten Brunn, PhD
President and Representative Director,
Bayer Yakuhin, Ltd.d

Panel Discussion

All speakers from Part 1 and Part 2

V2-S2 Room 607 11:00-12:30

ICH E14: Update on Current Status and Future Directions of Cardiac Safety Assessment

Related Interest Area(s): CO, RA, ST, CP, PM
Level: Beginner, Intermediate

SESSION CHAIR

Boaz Mendzelevski, MD
Vice President of Cardiology
BioClinica Inc, UK.

Drug-induced QT prolongation may lead to cardiac arrhythmia and sudden cardiac death, and has resulted in the withdrawal and non-approval of several drugs. The regulatory response to concerns regarding the cardiac safety of new drugs also led to the development of the ICH S7B (non-clinical) and ICH E14 (clinical) guidelines. The hallmark of the ICH E14 guideline is the Thorough QT (TQT) study. Recently, an early phase Intensive QT (IQT) clinical assessment, using exposure response (ER) modeling as its primary analysis, was advocated as an alternative to the TQT study and is currently under regulatory discussions. In a separate initiative, presently under development, the US FDA proposed a platform of non-clinical investigations, the 'Comprehensive Pro-arrhythmia *In vitro* Assay' (CiPA), as a replacement for the above guidelines. This session will provide an introduction to cardiac safety and an overview of the current and future clinical research and regulatory landscape in Japan and globally.

Drug-induced QT Prolongation: From Ion Channels and Cardiac Arrhythmia to Regulatory Guidance

Atsushi Sugiyama, MD, PhD
Professor, Department of Pharmacology,
Faculty of Medicine, Toho University

The ICH E14 Guideline: Overview of its Status in Japan and Future Directions

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

QT Assessment in Clinical Drug Development: Are We There Yet?

Boaz Mendzelevski, MD
Vice President of Cardiology
BioClinica Inc, UK

Panel Discussion /Q&A
Future Evaluation of Cardiac Safety in Clinical Development

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

Koki Nakamura MD, PhD
Vice President, Global Medical Affairs-Japan
Takeda Pharmaceutical Co., Ltd.

V3-S2 Room 608 11:00-12:30

New Era of Benefit-Risk Balance Evaluation - Will Risk Information Keep Increasing? - (Part 2)

Related Interest Area(s): CP
Level: Intermediate

SESSION CO-CHAIRS

Osamu Komiyama
Senior Manager
Pfizer Japan Inc.

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

In general, safety information increases depending upon drug exposure. Within few years after launch, reporting rates incrementally decrease until reporting is flat. In this session, experts from three regions will present the difference between ADRs and risk, and the difference between efficacy and benefit, which situations mean that "benefits outweigh risks" and how to express it, who assesses the benefit-risk balance, and how to utilize it. Organization, specification of responsible persons, and current and future issues regarding tis benefit-risk balance assessment will be addressed in a panel discussion representing these three regions.

Benefit-Risk Assessment - Introduction to Quantitative Approach (MCDA) -

Akihiro Nakajima
Pharmaceutical Development Administration Department, Teijin Pharma Limited. / Data Science Expert Committee, Japan Pharmaceutical Manufacturers Association

Recent Progress in Benefit-Risk Evaluation Methodology and Practices: An Industry Perspective

Filip Mussen, PhD
Vice President, Regional Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

Panel Discussion

All speakers from Part 1 and Part 2

V4-S2 Room 609 11:00-12:30

Intellectual Property Strategies about Medical Technologies and Products in the Future

- Let's Think about Effective Intellectual Property Strategies to Grow Seeds of New Technologies through Cooperation by Industry, Government, and Academia

Related Interest Area(s): CO, RA, PM, AC, O: Intellectual Property
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR

Koichi Sumikura, PhD
Associate Professor, National Graduate Institute for Policy Studies

Efforts have been made to grow the seeds of new medical technologies through cooperation of industry, government and academia, like the use of regulatory strategy consultation and the increase in open innovation. The lack of intellectual property (IP) strategies is, however, still one of the causes of "death valley". AMED, established in April 2015 has "Medical IP Desk", which provides advice by consultants specializing in IP on questions from universities, research institutes, and corporations. It is possible to deal flexibly with a variety of technologies and the specific circumstances, which will result in promoting more effective cooperation. In this session, IP leaders from the industry, government, and academia will present their view on the current state and future challenges of IP strategies. In addition, they will share and discuss more effective IP strategies through cooperation by industry, government, and academia.

IP Management Initiatives of AMED

Hitoshi Amano
Managing Director, Intellectual Property Department
Japan Agency for Medical Research and Development (AMED)

Promotion of Academic Research Based on IP in Todai TLO

Keiko Honda, PhD
Director, Patent Attorney, TODAI TLO, Ltd.

Open Innovation and Partnership - Pfizer Approaches for Opportunities and Challenges -

Toru Seo, PhD
ERDI JPN Senior Director
External R&D Innovation Japan, Worldwide R&D, Pfizer Inc.

Panel Discussion

All speakers above

V5-S2 Room 610 11:00-12:30

Leading Innovation Leveraged by a Project Leadership

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

SESSION CHAIR

Koichi Konno, PMP
Chief Executive, PM Consulting Positive Intention
DIA Japan PM Community

Innovation is to create "something new" which we did not have in the past. A project is defined as to create "novel value" within the predefined limited resource and timeline, and represents the process to realize the innovation. Project management is generally regarded as a total body of knowledge, process, and tools in order to fulfill project goals; however, it is the fundamental framework for leadership to create and realize the novel value. In this session, we will discuss the project framework, which produces innovation and breakthroughs, as well as the development process of "high performing team building," from project management points of view.

Lecturers

Kouji Iwasaki, PhD
Director
Global Medical Affairs Japan Department
Takeda Pharmaceutical Co., Ltd.
DIA Japan PM Community

Takashi Sato, MS, PMP
Manager
Kyowa Hakko Kirin Co., Ltd.
DIA Japan PM Aommunity

Atsushi Tsukamoto, PhD
Senior Director
Global Project Management,
Daiichi Sankyo Co., Ltd.
DIA Japan PM Community

V6-S2 Room 101 11:00-12:30

Contributions of Statistics and Behavior Observation to Drug and Medical Device Development

Related Interest Area(s): ALL
Level: Beginner

SESSION CHAIR

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

Recently, big data has been in the news, and a new type of job for statisticians, called data scientists, has been created. However, in the pharmaceutical company, due to the influence of ICH E9, there are many trial statisticians. In other fields, business improvements due to a qualitative method called Behavior Observation are attracting attention. The ease of use of the product is directly linked to it being properly used or not. By the Behavior Observation you can discover needs that even the users weren't aware of, making it possible to really improve the user friendliness of medical products and devices. At this session, we will look back on the contribution of ICH E9 to the current development of medical products and devices, as well as explore the potential contribution of statistics and behavior observation to the future of medical product and device development.

ICH E9 Statistics Guideline: Before & After

Toshiya Sato, PhD
Professor, Kyoto University

How Private Sectors Can Generate Value from Statistics

Hiromu Nishiuchi, MS
Co-founder, Data Vehicle, Inc.

Innovation Starts from Deep Understanding of Behavior Contexts - "Behavior Observation" Method, Deriving Potential and Essential Insight

Takafumi Koshino
Principal Researcher, OGIS-RI Co.,Ltd.

V7-S2 Room 102 11:00-12:30

How to Succeed in "The Personalized Medicine Business"

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

SESSION CHAIR

Yutaka Tanaka, PhD
Executive Vice President, Member of the Board
Chugai Pharmaceutical Co., LTD.

Disease treatment is shifting towards use of personalized medicine, in search for "finding the best fit drugs for individual patients," since there are various molecular-targeted drugs available nowadays across therapeutic areas such as oncology.

Still, though, the search for "finding patients who would match individual molecular-targeted drugs" is the mainstream of treatment by molecular-targeted drugs. This usually requires involvement of various companies in order to combine development of a new medicine and companion diagnostic drugs/devices, which can become troublesome.

In this session, we will hear opinions from inside and outside the pharmaceutical and the diagnostic drugs/devices industry about current issues as well as strategy to overcome those issues, and think about what will be the key for success on developing future molecular-targeted drugs.

The Current Status of Personalized Medicine and the Expectations for the Industry

Toshio Miyata, MD
Executive Director, Health and Global Policy Institute
Professor, Office of Society-Academia Collaboration for Innovation
Kyoto University

Possibility of Personalized Medicine Business Referring the Cases in USA

Eri Himoro
Consultant, Mizuho Information & Research Institute, Inc.

The Challenges and Ideal Model Regarding the Personalized Healthcare Business: From the Viewpoint of the Pharmaceutical Company (1)

Shigeru Takeshita
Astellas Pharma Inc.

The Challenges and Ideal Model Regarding the Personalized Medicine Business: From the Viewpoint of the Pharmaceutical Company (2)

Shyh-Yuh Liou, PhD
Ono Pharmaceutical Co., LTD.

The Challenges and Ideal Model Regarding the Personalized Medicine Business: From the Viewpoint of the Diagnostics Company

Yoshiaki Tazawa
Roche Diagnostics K.K.

SESSION 3 14:00-15:30

V1-S3 Room 605/606 14:00-15:30

For Enhancement of Industry-Government-Academia Collaboration in Japan (Part 1)

Related Interest Area(s): CO, AC, O: Translational Research
Level: Beginner, Intermediate

SESSION CO-CHAIRS

Hideki Hanaoka, MD, PhD
Professor
Clinical Research Center, Chiba University Hospital

Toshio Miyata, MD
Executive Director, Health and Global Policy Institute
Professor, Office of Society-Academia Collaboration for Innovation
Kyoto University

In April 2015, AMED, Japan Agency for Medical Research and Development, was established to enhance efficient research and development, from the basic scientific research to practical application, with consistency in the field of health care science in Japan. Creating innovative drugs from Japan is one of the most important elements of Japan's growth strategy and a great chance for pharmaceutical industry at the same time. In this session, experts from academic departments, industry, and government will facilitate discussions on the challenges we have in collaboration among them, sharing the excellent practices from several ongoing activities.

AMED's Support for Translational Researches, Clinical Researches, and Clinical Trials

Yasunori Yoshida
Director, Department of Clinical Research and Trials
Japan Agency for Medical Research and Development

Activity of Duke Clinical Research Institute

John H. Alexander, MD
DCRI Faculty Associate Director, Duke Clinical Research Institute
Professor, Duke University

A Case of Succeeded Program Designed to Novel Industry-Government-Academia Collaboration

Michihiko Wada, MD, PhD
Vice President, R&D, Alexion Pharmaceuticals, Inc.

V2-S3 Room 607 14:00-15:30

Promoting Clinical Development for Patients with Rare Diseases - Patient Focused Drug Development in Japan

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

SESSION CHAIR

Kazumichi Kobayashi
Operating Officer / Director, Business Development and Planning
Otsuka Holdings Co., Ltd.

How can new drug development reflect the Voice of Patients? EU and US are devising individual policies which meet their societies' environment on this issue and are also intensifying "Patient Focused Drug Development (PFDD)." Meanwhile, Japan lacks assured direction on how to reflect the Voice of Patients. Reflecting this circumstance, the first speaker in this session is from a US company, who will share information on the current situation in the West and their activities regarding PFDD. After this, the subject of patient registry in intractable diseases, which is one of the possible activities for future Japan original PFDD, will be discussed, as will the current situation in Japan, issues, and contributions of medicine development from different perspectives. After the presentations, a panel discussion will seek Japan's future direction.

Panelists

Tateo Ito
President, Japan Patient Association

Yukiko Nishimura, PhD
Board of Director /Founder, ASrid

Hiroshi Mizushima, PhD
Chief Senior Researcher
Center for Public Health Informatics, National Institute of Public Health

Roslyn Fleischer Schneider, MD, MSc, FACP, FCCP
Senior Director
Global Patient Affairs, Pfizer Inc.

V3-S3 Room 608 14:00-15:30

Implication of Medical Big Data Usage – Applicability and Challenges in Clinical Development

Related Interest Area(s): ALL
Level: All

SESSION CHAIR

Eiko Shimizu, PhD
Project Lecturer
Pharmaco-Business Innovation
Graduate School of Phamaceutical Science
The University of Tokyo

Rising cost and increased attrition rates is one of the challenges in drug development. There is a growing need of scientifically-rationalized drug development process from clinical trial design to postmarketing

safety activities. Ranges of application of medical big data usage and infrastructure-building have been expanding. Meanwhile, many challenges for its efficient usage remain. In this session, examples of available medical big data and their utilization will be shared and potential utilization, challenges, and future perspective will be discussed with users and experts for database construction and data science.

If you have any question about big data such as, "I need this analysis," "Is it possible to use Big Data?" and "current issues," please send an e-mail to Hideo.Susa@diaglobal.org by October 31, 2015.

Current Situation and Challenges of Medical Information Database Network (MID-NET®) Project

Eiko Shimizu, PhD
Project Lecturer
Pharmaco-Business Innovation
Graduate School of Phamaceutical Science
The University of Tokyo

How to Effectively Utilize Medical Big Data in Japan and Data Limitations

Nobutomo Matsui
Principal
Consulting and Services
IMS JAPAN K.K

Advancement in IT Facilitating Utilization of Big Data and the Cases

Toru Tsunoda, MBA
Manager, Sales Support Team, Platform Group, Solution Consulting Division 1, SAS Institute Japan K.K

Current Situation and Challenges of Medical Information Database Network (MID-NET) Project

Fumitaka Takahashi
Office of Medical Informatics and Epidemiology
Pharmaceuticals and Medical Devices Agency (PMDA)

Disruptive Data Generation Way by Using Clinical Database

Daisuke Shima, PhD
Director, Cardiovascular/Metabolism, Medical Affairs,
Global Established Pharma Business, Pfizer Japan Inc.

Panel Discussion

All speakers above

V4-S3 Room 609 14:00-15:30

The Next Generation Drug Development for Personalized Health Care

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

SESSION CHAIR

Hideharu Yamamoto, PhD
Group Manager, Biostatistics Group 2, Clinical Science & Strategy Dept., Chugai Pharmaceutical Co., Ltd.

All medicines, both on the market and under research/development, can be precision medicine, when the adequate usage information for each individual is enhanced. Recently, supplying the information for the personalization of medical products has become a duty of the pharmaceutical industry. So far, most pharmaceutical companies' commitments to such activities have not resulted in much progress. In this session, we will introduce a research outcome of approved precision medicines in Japan and discuss novel drug development strategy with clinical study design that fits in with today's society.

Applied Drug Development for Personalized Medicine

Shinichi Tsuchiwata, MS
Pfizer Japan Inc.
TF Leader, JPMA DataScience Dept.

Gene Finding for Patient Selection in Academic Researches

Akihiro Hirakawa, PhD
Lecturer/Biostatistician
Nagoya University Hospital

Recent Advances in Clinical Trial Design for Personalized Medicine – Regulatory Perspective

Hiroyuki Sato, MS
Biostatistics Reviewer
Pharmaceuticals and Medical Devices Agency

Panel Discussion

All speakers above

V5-S3 Room 610 14:00-15:30

Fostering Further Collaboration between PMDA Company and Academia with Efficient "Project Management" in Drug Development

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

SESSION CHAIR

Atsushi Tsukamoto, PhD
Senior Director
Global Project Management
Daiichi Sankyo Co., Ltd.

Due to enormous efforts made by both regulatory agencies and pharmaceutical companies, various outcomes, such as shortened review periods, have been achieved. However, new challenges, such as the advancement of technologies and drug development have continued to be challenging. Under this environment, for increased high quality and short turn-around review, what can regulatory agencies and pharmaceutical companies do beyond what we have achieved? In this session, participants will learn the efforts under this challenging situation made by the regulatory agency and companies, and discuss and identify what we can do with further collaboration between the two, considering the fact that we share the common goal (i.e. patient treatment), with the project management framework.

Lecturers

Fumiaki Kobayashi, PhD
CEO, CTD inc.

Kazuishi Sekino
Review Director, Office of New Drug I
Pharmaceuticals and Medical Devices Agency (PMDA)

Shinichiro Takeuchi
Manager, Novartis Pharma K.K.

V6-S3 Room 101 14:00-15:30

Tips for Better Drug Development Strategy in Asia - Let's Give Honest Opinions

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

SESSION CHAIR

Kensuke Morimoto, MSc
Manager
Daiichi Sankyo Co., Ltd.

Recently, the number of multi-national clinical studies in Japan has increased, and Asian study has become popular as a drug development strategy owing to relatively small ethnic difference in this population. By conducting Asian studies sponsors may shorten development time and save cost, and the study results are not only leveraged for NDA in Japan but for other Asian countries and regions.

However, certain diversity is observed in this region in regulation, health care environment and culture. Therefore when conducting Asian Studies Sponsors need to take a flexible approach based on the previous experience in international arena.

In this session, we have invited speakers from Japan, China, and Taiwan who are familiar with Asian studies, to experience and share ideas. After their presentations we will open a panel discussion to discuss how Asian studies should be conducted and managed.

We hope this session contributes to your drug development strategy in Asia.

Suggestions to Promote Asian Studies - From a Japanese Perspective

Akiko Nakahama
Executive Director, Clinical Development Japan/
Asia Clinical Research Product Creation Unit
Eisai Co., Ltd.

Drug Development in China

Li Hang
Manager
Daiichi Sankyo (China) Holdings Co., Ltd.

Suggestions to Promote Asian Studies - From a Taiwanese Perspective -

Sarah Lin, MSc
Clinical Project Manager
Astellas Pharma Taiwan

Panel Discussion

All speakers above

V7-S3 Room 102 14:00-15:30

Let's Think about Selecting Adverse Reactions for Labeling and How to Describe Their Frequency

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

SESSION CHAIR

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

Performing multinational clinical studies can, in principle, offer the opportunity to propose a consistent list of adverse reactions and frequencies for inclusion in the Japan PI, US PI and EU SmPC. There are, however, differences in the criteria used in deciding which events qualify to be included in labeling as adverse reactions – for example, to what extent to follow the investigators' causality assessment. This session reviews factors that may lead to regional inconsistencies in the list of labeled ADRs. There are also differences between the regions in how frequency information for adverse reactions is expected to be generated. For example, in the J-PI, ADR frequencies should be based on the subset of reported adverse events for which investigators could not exclude a causal association with drug exposure. In the US PI and SmPC, frequency information is usually based on all reported events, irrespective of investigator's causality assessment. This session discusses these issues and other factors that lead to inconsistent selection of adverse reactions and frequency information, their impact on the preparation of regional labeling and the CCDS, and explores possible ways forward. It also discusses the internal business rules and procedures for managing regional deviations from CCDS in order to meet European GVP expectations and limit the risk of product litigation in the U.S.A.

The Current Situation from a CCDS Viewpoint

A. Leander Fontaine, Dr. med.
President, Pharmiceutics, LLC

A Comparison of the Adverse Reaction Sections of the Japanese PI, the US PI and the EU SmPC

Edward Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Eisai Co., Ltd.

Reflecting "Adverse Reactions" to Labeling for New Drugs and Marketed Drugs PMDA's Point of View

Tsutomu Mawatari
Director, Office of Safety II
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All speakers above

POSTER SESSION 15:30-16:00

POSTERS SESSION
Reception Hall 15:30-16:00

Five researches or topics from various themes such as medical database usage, postmarketing activities, clinical trial excellent (data management and risk-based monitoring) and medical affairs were selected. Current hot topics will be presented and discussed.

[PO-001] Postmarketing Benefit-Risk Assessment for Erythropoiesis Stimulating Agents using a Health Care Database

Natsuko Miyawaki
Drug Safety Division, Chugai Pharmaceutical Co., Ltd.

Purpose: This study investigated the utility and limitations of benefit-risk (B-R) assessment using a health care database by applying the Benefit Risk Action Team (BRAT) framework to compare data obtained from a health care database of actual postmarketing experience with epoetin beta pegol (genetical recombination) (Continuous erythropoietin receptor activator: C.E.R.A.) and other erythropoiesis stimulating agents (ESAs).
Methods: We assessed the B-R profile based on the BRAT framework in a health care database. Patients with chronic kidney disease (CKD) treated with C.E.R.A. (n=131: nondialysis, n=109; hemodialysis, n= 22) or other ESAs (n=542: nondialysis, n= 327; hemodialysis, n=215) between July 2011 and March 2014 were investigated from the Medical Data Vision (MDV) health care database.

Results: The B-R profile for C.E.R.A. appeared to be similar to that of other ESAs in both ND and HD patients with CKD, when benefits and risks were mainly assessed in terms of odds ratios . Despite various point estimates and various confidence intervals for each outcome, the results of subgroup analyses showed no notable differences from the overall analysis of B-R assessment.
Conclusion: The B-R assessment can be performed using the BRAT framework with a health care database, but it is important to take care of data extraction, prospective definition of outcomes of interest, imputation, database characteristics, and laboratory tests. Further research is necessary to facilitate practicalapplication of this approach.

[PO-002] An Attitude Survey in the RBM Pilot Study

Michie Yagi
Senior Associate, Astellas Pharma Inc.

We introduce the procedure of Risk Based Monitoring (RBM) used in this study and report the results of an attitude survey of RBM in CRCs belong to the SMO that is assigned to the collaborator of the study. Risk assessment was performed in the study based on RACT published by TransCelerate. RACT was a very useful tool in terms of visualizing the compound/protocol specific risks. Centralized monitoring; risks were assessed with the compound/protocol specific risk indicators as well as the general risk indicators. Centralized monitoring assesses the data based on the set risk indicators, determines the frequency of on-site monitoring at each study site, and feedbacks the results to the CRA in charge of the study site. Site monitoring; on-site/off-site monitoring is performed at the frequency indicated by centralized monitoring. CRA informs study sites of issues detected in centralized monitoring and supports for resolving their issues as necessary. For example, we recommend planning process to check EDC queries periodically to a site which spend too much time to reply EDC queries. And we also recommend improving process that causes protocol deviations in case that many protocol deviations are reported in a site. We think that this procedure, performing centralized monitoring as well as site monitoring, is very useful because we can catch the various risks of each site comprehensively even though the pilot study has not finished.

Most of the study sites were small-scale supported by SMO. The attitude survey about RBM was performed in CRCs, assigned to this study, in March 2015 and obtained answers from 86 CRCs. More than half of CRCs had positive opinions on being in charge of RBM pilot study, while many CRCs of the rest had negative opinions. Examples of negative opinions were the increase of work load at study sites, being anxious about the decrease of the frequency of visits and the amount of data checked by CRA, and the increase of man-hours for preparation. The survey was performed about half year after the start of the study. Two-thirds of the CRCs answered that the work load of study sites has not changed much compared with that of the previous. On the other hand, half of the rest of CRCs thought that the work load has increased and other half thought that the work becomes rather efficient by improving process. Our challenges for the future are to explain and train RBM appropriately as the sponsor to remove the concerns of study sites. And we also have to train CRAs in the monitoring method that focuses on the check of process for the more effective monitoring.

[PO-003] Direct Data Transfer from HIS (Hospital Information System) to Sponsor for Clinical Trials

Yoshihiro Aoyagi
Pharmacist, National Cancer Center Hospital East

Purpose: EDC systems have been utilized to collect clinical trial data efficiently from investigational sites. By directly transfer the data to the sponsor's system from the HIS which is retaining the source data, it is expected to reduce transcription error and data entry delay. Moreover, less frequent investigational site visit by the sponsor is required. This can bring increased quality of clinical data, as well as efficiency and speed-up of clinical trials. The purpose of this research is to identify the challenge and its countermeasure of the implementation and to establish the data extraction and transfer process for practical use.

Method: This tripartite collaborative research is conducted by National Cancer Center Hospital East as the investigational site, Fujitsu Advanced Engineering as the HIS vendor, and Novartis Pharma as the sponsor. Target data, frequency, technical and operational processes for this direct data transfer have been planned and implemented.

Result and Discussion: The target data for transfer has been determined as laboratory test data along with the associated patient information such as patient ID. The information which cannot be extracted from the site'lsa b system is to be merged from the data manually entered by CRC using the electronic medical record template. Two data transfer specifications are used for this research; sponsor'sp ecification and CDISC Operational Data Model. It is required to handle the double-byte character data recorded in the electronic medical record system to convert the data into the single-byte transferrable data.Issues ascertained at system implementation, validation and measurement of operational process improvement will be discussed in this presentation.

[PO-004] Publication Management in Medical Affairs Activities - The Key to Credibility and Scientific Progress

Aya Takemoto Tokaji
Scientific Director, McCann Complete Medical, MDS-CMG

Publication management that plans and executes presentations at conferences and publishing peer review articles lays the foundation of medical affairs activities. These activities disclose the data from the studies that initiate communications, but recent incidents reported as publication misconduct made public doubt the credibility of studies and the researchers. As one of the measure to restore the trust from public and communities including health care, Good Publication Practice 3 (GPP3) is the guideline to show how the publication practice can be transparent and ethical. Understanding the series of guidelines including GPP3, and reflecting to the preparations of articles and presentations is one the step to show the true level of medical science and the researchers in Japan. Also, deciding and planning on the numbers of publication and the appropriate timing, publication management, will be required. In this presentation, the member of GPP3 Steering Committee in the International Society of Medical Publication Professionals will discuss on the knowledge publication managers need to have and how we can contribute on the progress of scientific researches.

[PO-005] Where is Drug Information Found? - A Quantitative Survey of Drug-Related Articles on the Internet

Terumi Nakayama, MPharm
Drug Safety Data management dept. Drug Safety Division
Chugai Pharmaceutical Co., Ltd.

Objective: The Survey of Consumer Attitudes Regarding Pharmaceuticals and the Pharmaceutical Industry, conducted by the Japan Pharmaceutical Manufacturers Association in 2014, suggests that patients routinely gather information from general public websites. Japan's Pharmaceutical and Medical Device Law, enacted in 2014, assigns Japanese citizens the responsibility of trying to understand the safety of prescription drugs. Given that information on the appropriate use of drugs can be a matter of life or death, the quality of the information source is of vital importance. Understanding the realities and uses of drug-related articles published freely on the Internet would be useful in exploring ideal methods of disseminating information. We conducted an exploratory study to survey those general websites that publish many drug-related articles. In this study, drug-related articles are defined as "articles on drugs, adverse reactions, or specific disease areas."

Methods: We searched online news resources using Meltwater News, a news search software service, to extract drug-related articles meeting specified criteria. Extracted articles were tabulated for each source website, and measures of website characteristics were calculated, including each website's overall percentage of drug-related articles and number of visitors.

Results: From 1 August to 31 October 2014, 88,283 drug-related articles were extracted from 2035 websites, suggesting that approximately 1000 such articles are posted to the Web each day. A review of websites with a large number of drug-related articles showed that most of the higher ranking websites were news aggregation sites/Internet forums sponsored by the major Web portals.

Discussion: This study showed that it is possible to use Meltwater News to easily search and tabulate drug-related articles and that it is possible to calculate measures of website characteristics, including each website's number of articles and overall percentage of drug-related articles. In future, in addition to exploring quantitative measures such as the proportion of health care professionals visiting these websites and the number of articles shared on social networking services, it will be necessary to address qualitative measures of information quality and technical specialization. A comprehensive assessment of these measures may be able to identify those general websites that have the greatest social impact in the context of drug-related articles. Partnerships between these websites and drug companies could contribute to health care by providing new risk communication tools. With careful consideration of regulations on prescription drug advertising aimed at the general public, it is essential that we explore ideal methods of information dissemination that meet the needs of the times.

SESSION 4 16:00-17:30

V1-S4 Room 605/606 16:00-17:30

For Enhancement of Industry-Government-Academia Collaboration in Japan (Part 2)

Related Interest Area(s): CO, AC, O: Translational Research
Level: Beginner, Intermediate

SESSION CO-CHAIRS

Hideki Hanaoka, MD, PhD
Professor
Clinical Research Center, Chiba University Hospital

Toshio Miyata, MD
Executive Director, Health and Global Policy Institute
Professor, Office of Society-Academia Collaboration for Innovation
Kyoto University

In April 2015, AMED, Japan Agency for Medical Research and Development, was established to enhance efficient research and development, from the basic scientific research to practical application, with consistency in the field of health care science in Japan. Creating innovative drugs from Japan is one of the most important elements of Japan's growth strategy and a great chance for pharmaceutical industry at the same time. In this session, experts from academic departments, industry, and government will facilitate discussions on the challenges we have in collaboration among them, sharing the excellent practices from several ongoing activities.

Bayer's R&D Partnering Models

Shunichi Takahashi, PhD
Head, Open Innovation Center Japan
Bayer Yakuhin, Ltd.

Introduction of The DSANJ System –Scientific-Based Trust-Cultivating System in The Drug-Discovery Stage in Japan-

Tohru Yoshikawa
Webmaster of DSANJ
Life Science Group, Economy and Industry Division
Osaka Chamber of Commerce and Industry

Goal to Reach for ARO in Japan

Mitsuhiro Okamoto
Associate Director, Takeda Development Center Japan
Takeda Pharmaceutical Company Limited

Panel Discussion

Speakers from Part 1, Part 2 and

Kazuhiro Momose
Senior Manager, Astellas Pharma Inc.

V2-S4 Room 607 16:00-17:30

What Drug Information Do Patients and Their Families Really Want?

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

To promote proper use and maximize the value of drugs, it is critical that every stakeholder including HCPs, general public, patients, and media understand benefits and risks each drug have. Drug information is available quickly through internet. However the information can be too much, too technical, or untrustworthy and sometimes causes confusion and misunderstanding. Experts and patients will discuss what information patients and their families need and how to make it available.

SESSION CHAIR

Junko Sato, PhD
International Coordination Officer
Pharmaceuticals and Medical Devices Agency (PMDA)

Comprehensive Health Literacy in Japan is Lower Than in Europe

Kazuhiro Nakayama, PhD
Professor
College of Nursing, St. Luke's International University

A Changing Patient Environment: Who Chooses My Medications?

Nobuyuki Suzuki
Representative Director, Kan-i net

Provision of Safety Information, and Proper Use of Drugs for the Patients

Yumi Tanaka
Office of Safety II
Pharmaceuticals and Medical Devices Agency (PMDA)

TBA

Mayumi Sakaguchi
Midori Pharmacy

Panel Discussion

All speakers above

V3-S4 Room 608 16:00-17:30

Global Direction of Safety Assessment with Pharmaco-Epidemiology

Related Interest Area(s): CO, RA, ST, DM, CP, PM
Level: Intermediate

SESSION CHAIR

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

For the safety assessment of medical products, a pharmaco-epidemiological approach utilizing electronic medical records has been progressing, but the situation for usage of electronic medical records differs considerably by country.

In this session, regulators from US, EU and Japan will share the current status and challenges regarding active utilization of e-medical records to have convincing evidences for postmarketing safety measures that each regulatory authority requires. At the panel discussion, we will focus on how to build a foundation for international cooperation and discuss challenges.

PMDA's Activities Promoting Pharmaco-Epidemiological Safety Assessment (MIHARI & MID-NET Initiatives)

Yoshinori Takeuchi, DVM, PhD, MPH
Office of Medical Informatics and Epidemiology
Pharmaceuticals and Medical Devices Agency (PMDA)

FDA's Activities Promoting Pharmaco-Epidemiological Safety Assessment Including Sentinel Initiative (Tentative)

Gerald J. Dal Pan, MD, MHS
Director
Office of Surveillance and Epidemiology, CDER, US FDA

EMA's Activities Promoting Pharmaco-Epidemiological Safety Assessment Including EnCepp Initiative (Tentative) <Remote Presentation via Internet>

Peter Richard Arlett, MD
Head of Pharmacovigilance Department, Inspections & Human Medicines PV Division
European Medicines Agency

Panel Discussion

All speakers above

V4-S4 Room 609 16:00-17:30

Future Perspective of Personalized Medicines in Oncology Disease Area - Can You Imagine How NGS Technology is Being Expanded in Japan? -

Related Interest Area(s): CO, RA, PM, CMC, AC, O: Government
Level: Intermediate, Advanced
Language: Japanese Language Only

SESSION CHAIR

Tomoko Hirohashi, PhD
Director, Oncology, Clinical Research, Pfizer Japan Inc.

Scientific technology has significantly improved, and understanding of molecular mechanisms of cancer has increased considerably. With these changes, the technology for biomarker investigations or diagnostic method has been also improved. The representative example is next generation sequencing (NGS) technology. However there are lots of challenges to be cleared for its clinical and practical use whereas next generation sequencing will have a lot of potential. In this session, we will discuss the options to use this new technology for cancer patients.

Future Perspective of Personalized Medicines in Oncology Disease Area - Can You Imagine How NGS Technology is Being Expanded in Japan?

Tomoko Hirohashi, PhD
Director, Oncology, Clinical Research, Pfizer Japan Inc.

Activities on Academia of Clinical Sequencing with NGS from the Experience of Clinical Development of Multiplex Diagnostic Kit

Takayuki Yoshino, MD
Director
Department of Gastroenterology and Gastrointestinal Oncology
National Cancer Center Hospital East

Expectation and Challenge of Implementation for Multiple Marker and NGS - View Points of Both Drug and Diagnostic Companies

Mariko Yamaguchi
Senior Manager, RA/QA and Clinical Affairs, QIAGEN K.K.

Implementation of Clinical Sequencing in Kyoto University

Manabu Muto, MD, PhD
Professor, Department of Clinical Oncology
Graduate School of Medicine and Faculty of Medicine
Kyoto University

V5-S4 Room 610 16:00-17:30

Career-Building for Entry-Level and Mid-Level R&D Personnel

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

SESSION CHAIR

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

This session aims to provide opportunities for entry-level and mid-level R&D personnel to think about future career-building possibilities. Obtaining work in the pharmaceutical industry is a difficult challenge, and the majority of new graduates who enter this field are employed by contract research organizations. Due to the low success rate of new drug development projects, career development based on experience of success is not easy. Furthermore, the great diversification of careers among R&D personnel may cause some people to feel concerned about their future prospects. For these reasons, we have prepared this training session to provide you with valuable insights into career-building from a variety of R&D personnel, including personnel who have accumulated experience in R&D-related work without a career change, those who have made career changes, those who have worked for CROs after graduation, and foreign personnel engaged in R&D-related work.

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

My Views on Career-Building from Working in Clinical R&D at a CRO

Koyo Sakaguchi, RPh
Assistant Manager, EPS Corporation

Building a Career in Clinical R&D at a Japanese Pharmaceutical Company

Shizuko Ueno
Senior Director, Group VII, Clinical Execution Department, R&D Division, Daiichi Sankyo Co., Ltd.

My Views on Career-Building from Working in Clinical R&D for a Pharmaceutical Company (As a Foreigner)

Fanghong Zhang, PhD
Manager, Oncology Biometrics and Data Management Department, Oncology Development & Medical Affairs Department, Novartis Pharma K.K.

My Career in the Clinical Drug Development Fields - From Pharmaceutical Company via Site to Academia

Yukiko Matsushima
Senior Assistant Processor, Department of Drug Development and Regulatory Science, Faculty of Pharmacy, Keio University

Panel Discussion

All speakers above and

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

Yoshinobu Tanaka
Japan Clinical Director, Oncology Clinical Development, Oncology Science Unit, MSD K.K.

V6-S4 Room 101 16:00-17:30

HTA in Japan – What Should Pharmaceutical Companies Do?

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

SESSION CHAIR

Kenji Adachi, PhD
Head, Health Economics & Outcomes Research, Market Access
Bayer Yakuhin, Ltd.

The discussion of Health Technology Assessment (HTA) implementation in 2016 started in Japan several years ago. In terms of cost effectiveness, the discussion of HTA tends to be focused on drug price suppression, and the discussion is far from original intention of "HTA is the assessment of the value that health technology brings to patients, families, medical field and entire society, and it can be an index for the limited resource/finance allocation." Further, cost effectiveness is one of the major elements of HTA, and it is expected to become another indicator for patients or physicians to select a treatment. In this session, in anticipation of HTA introduction, current global and Japan situation around HTA is shared, and discuss what pharmaceutical companies should do in clinical development or post marketing stage from a scientific view including patients involvement and other factors.

Clinical Trial Design, Analysis and Reporting Strategies to Maximize Reimbursement Success <Remote Presentation via Internet>

Chrissie Fletcher, MSc
Executive Director Biostatistics, Amgen Ltd, United Kingdom

Patient-Centric Postmarketing Studies on Safety, Effectiveness and Value

Nancy A. Dreyer, PhD, MPH
Global Chief of Scientific Affairs & SVP
Quintiles Real-World & Late-Phase Research

What Should We Do During Drug Development and Postmarketing When Introducing HTA in Japan?

Kotoba Okuyama, ME
Sr. Biometrician, Biostatistics and Research Decision Sciences, Japan Development, MSD K.K.

Toshihiko Aranishi, MSc (Remote Presentation via Internet)
HTA Specialist, HTA Group, Business Assessment Dept., Chugai Pharmaceutical Co., Ltd.
Economist, HTA Statistician, MORSE Health Technology Assessment Group, JF. Hoffmann-La Roche Ltd.

Current HTA Discussion for Japan's Health Care Policy, and Roles of Academia

Takeru Shiroiwa, PhD
Senior Researcher, Department of Health and Welfare Services, National Institute of Public Health

V7-S4 Room 102 16:00-17:30

Future of the Pharmacovigilance from Development to Commercial – Where is the Spirit of ICH E2E Guideline in Japan?

Related Interest Area(s): CP
Level: Intermediate

SESSION CHAIR

Tatsuo Kagimura, MPH
Translational Research Informatics Center

It has been a long time since the guidelines for consistent safety action from development to commercial. However, typical and routine postmarketing observational studies have been conducted in Japan based on the re-examination system. This has not been changed after the publication of ICH E2E guideline in 2005 and introduction of J-RMP in 2013. On the other hand, the science of pharmacovigilance has dramatically changed and the gap between US/EU and Japan is increasing. In this session, ideal pharmacovigilance in Japan will be discussed among important stakeholders.

Pharmacovigilance in RMP and Pharmacovigilance in Post Approval Re-Examination System

Mamoru Narukawa, PhD
Associate Professor, Division of Pharmaceutical Medicine
Kitasato University Graduate School of Pharmaceutical Sciences

Why? What is the Root Cause of Current PharmacoVigilance Systems in Japan?

Kotonari Aoki
Manager, Chugai Pharmaceutical Co., Ltd.

The Transition of Pharmacovigilance in JAPAN

Akiko Ogata
Office of Safety II
Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion

All speakers above

LET'S CHAT! "WHAT'S THE DIA WORLD 2015"

RECEPTION HALL

17:45-19:30

Related Interest Area(s): ALL
Level: ALL

SESSION CHAIR	COMMENTATORS		FACILITATORS
Eri Sekine	**Fumiaki Kobayashi, PhD**	**Yoshiaki Uyama, PhD**	**DIA Japan Content Committee / Community**
Head of Oncology Biometrics and DM Department, Oncology Development, Novartis Pharma K.K.	CEO, CTD inc.	Director Office of Medical Informatics and Epidemiology Pharmaceuticals and Medical Devices Agency (PMDA)	

"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.
Non-Japanese speakers are welcomed to this session. If you are interested, please talk to a member of staff.

<List of Topics>

#	Community	Topic	Facilitators	Abstract
1	Regulatory Affairs	Requests Business Consideration from PMDA and Sponsors	Yoshihiro Higashiuchi, MSc Eli Lilly Japan K.K. Miyuki Kaneko Pfizer Japan Inc.	Let's chat about business considerations based on some actual cases genuinely each other. Ex. 1; Please do not issue some queries after 5 pm on Friday because it is difficult to set a tel-con with HQs timely. Ex. 2; Please do not file a NDA/sNDA after the middle of March, June, September or December because it is difficult to keep review time within 365 days.
2	Project Management	Project Leadership	Atsushi Tsukamoto, PhD Daiichi Sankyo Co., Ltd. Koichi Konno, PMP DIA Japan PM community	Innovation is to create "something new" which we did not have in the past. A project is defined as to create "novel value" within the predefined limited resource and timeline. In this session, we will discuss the project leadership, which produce innovation and breakthrough, from project management points of views.
3	Clinical Operation and Monitoring	Let's talk in the Real Intention!! "The Variety of GCP Inspection"	Keiichi Inaizumi Pfizer Japan Inc. TBC	We will talk about GCP Inspection in the real intention beyond each department and role. What's going to be? What kind of efforts have you made? What kind of problems are you facing? Etc..
4	CMC / Six Sigma	Immediate Opportunity for Anyone Interested in Quality Control & Management	Tadayoshi Fujisaki GlaxoSmithKline K.K. Hirotaka Inoue, PhD, MBA GlaxoSmithKline K.K	Let's chat informally about matters of the recent topical quality control & management with information exchange. Please drop by out chatting table. It must be a great space to incubate something new with a cross-functional and professional dialogues.
5	Statistics	Contribution of Statistics to the Development of Medical Products/ Devices	Satoru Tsuchiya, MS Dainippon Sumitomo Pharma Co., Ltd. Yoichi M. Ito, PhD Hokkaido University Graduate School of Medicine	As you can see, a lot of statistical topics such as HTA, real world data, ICH E9 (R1), network meta-analysis etc are discussed in this DIA Japan annual meeting. Statistics now plays key role on drug / device development. Let's chat how statistician can contribute to drug/device development. I think everyone will profit from the discussion.
6	Clinical Strategy	Medical Big Data as a New Tool for R&D Success	Kazuhiro Kanmuri, PhD Phizer Japan Inc.	A follow-up discussion of the medical big data will be held. Experts in medical big data usage include the panelists and chair at the annual session are available to answer any questions you may have. Simple/naïve questions are welcomed. New ideas are generated when different things and perceptions are brought together. You will see how useful medical big data is, and may have new idea for a clinical development success based on the quantitative decision making, from early development to post marketing safety measures.
7	Clinical Data Management	How is e-Submission Changing? What Do We Have to Do?	Kazuya Doi Eli Lilly Japan K.K. Motohide Nishi, MBA Medidata Solutions K.K.	Aren't you interested in what others are doing for e-submission? Let's share what you are doing and what your questions/concerns are to overcome roadblocks for e-submission. Discussions from regulatory aspects as well as DM and statistical aspects are welcomed!
8	Pharmacovigilance and Labeling	What is The Relation Between Risk Management and Labeling? How Do We Handle Our Labeling Revisions Based on Revisions of the CCDS? Have Any Japanese Affiliates Been Able to Contribute to Revisions of the CCDS?	Rei Maeda Eli Lilly Japan K.K. Rie Matsui, RPh Pfizer Japan Inc	We will share the information regarding how the risk management plan and labeling are individually managed and how they influence to each other. Also, we will discuss about potential issues that we may face in reality, for instance, how to implement labeling revisions including verification of justification documents/supportive documents for their sufficiency to labeling revisions. Furthermore, we will discuss about any successful cases by Japanese affiliates that have actually been made to revisions of the CCDS. Dr. Leander Fontaine of USA will also join us for this session.
9	Clinical Strategy	Career Plans for Your Bright Future - Take off for An Ideal Yourself -	Junichi Nishino, MSc, RPh Novartis Pharma K.K. Yoshinobu Tanaka MSD K.K.	Students or workers in pharmaceutical companies struggling over future plans or over everyday workforces, please get together! This will be a tremendous opportunity from which you can learn and share with experienced seniors in industry, government or academia. Supervisory personnel who have trouble with subordinates are also welcomed. Participants who will attend on "V5-S4: Career-Building for Entry-Level and Mid-Level R&D Personnel [Afternoon session in Day 2]", Please come over to this session too.

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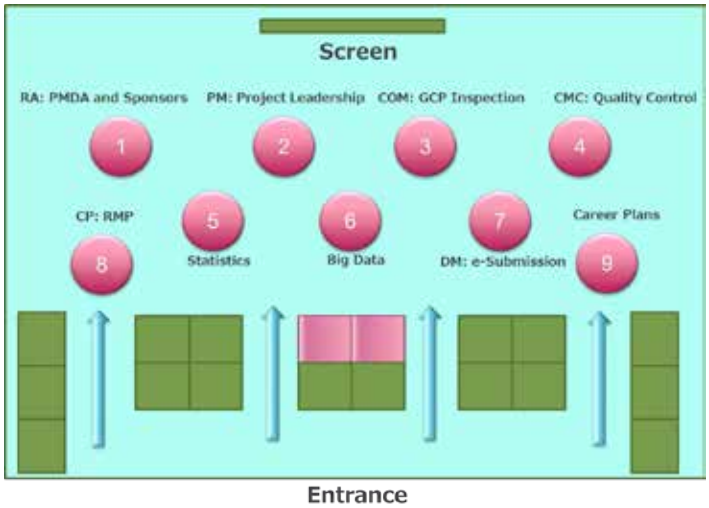

Related Interest Areas: Clinical Operations (CO), Regulatory Affairs (RA), Statistics (ST), Clinical Data Management (DM), Clinical Safety and Pharmacovigilance (CP), Project Management (PM), Chemistry, Manufacturing and Controls (CMC), Academia (AC), Others (O)

SESSION 5 9:00-10:30

V1-S5 Room 605/606 9:00-10:30

Future Drug Development with Multi-Regional Clinical Trials (MRCT) Based on ICH E17 Guideline

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

SESSION CHAIR

Ryuta Nakamura, PhD
Review Director
Office of New Drug II
Pharmaceuticals and Medical Devices Agency (PMDA)

In order to perform efficient globalized drug development, it is important to take into consideration an international harmonization. The ICH E17 guideline has been discussed to establish an international harmonized guideline focusing on designing/planning multi-regional clinical trials. In this session, recent regulatory experiences and the direction of ICH E17 guidelines including the current situation will be presented by a PMDA representative. How the ICH E17 guideline affects a future drug development strategy will also be presented by industry representatives. In a panel discussion, various topics such as the future direction of drug development and roles of Japan in Asia will be discussed.

Recent Review Experiences of MRCT Data and a Direction of ICH E17 Guideline

Shuji Kamada
Reviewer
Office of New Drug V
Pharmaceuticals and Medical Devices Agency (PMDA)

Future Drug Development and Impacts of ICH E17 Guideline: JPMA Perspective

Osamu Komiyama
Senior Manager,
Pfizer Japan Inc.
Chairman, Data Science Expert Committee, JPMA

Future Drug Development Strategies and Impact of ICH E17 Guideline: Pharmaceutical Company Perspective

Laurie Letvak, MD
Head
Clinical Development Policy, Novartis Pharmaceuticals Corporation, US

Panel Discussion

All speakers above

V2-S5 Room 607 9:00-10:30

Present Condition of Regulation for Regenerative Medical Products in Japan

Related Interest Area(s): CO, RA, CP, PM, CMC, AC
Level: Intermediate

SESSION CHAIR

Daisaku Sato, PhD
Director
Office of Cellular and Tissue-based Products
Pharmaceuticals and Medical Devices Agency (PMDA)

High expectations are placed on the regenerative medicine which may lead to a new approach to therapies of diseases that have no cure. Based on a vigorous debate on the way to facilitate practical application of regenerative medicine, the legal framework on the regenerative and cellular therapy products as well as gene therapy products was created through the revision of the Pharmaceutical Affairs Law in 2014. In this session, the present conditions of regulation and review of the regenerative medical products in Japan is discussed.

Recent Government Move Regarding Regenerative Medicine Product Regulation

Hiroshi Yaginuma
Assistant Director
Evaluation and Licensing Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

Quality Aspects of Regenerative Medical Products

Yoshiaki Maruyama
Review Director, Office for Cellular and Tissue based Products
Pharmaceuticals and Medical Devices Agency (PMDA)

Current Situation on Non-Clinical Safety Evaluation of Regenerative Medical Products

Takuya Nishimura, PhD
Principal Reviewer
Pharmaceuticals and Medical Devices Agency (PMDA)

Tumorigenicity Testing for Regenerative Medical Products

Yoji Sato, PhD
Director
Division of Cellular and Gene Therapy Products
National Institute of Health Sciences

Clinical Trial for Regenerative Medical Products

Ken Sakushima, MD, MPH, PhD
Specially Appointed Expert
Office of Cellular and Tissue-based Products
Office of New Drug III
Pharmaceuticals and Medical Devices Agency (PMDA)

V3-S5 Room 608 9:00-10:30

Risk Communication in EU, US and Japan - Goals and Objectives of Various Tools including Labeling - (Part 1)

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

SESSION CO-CHAIRS

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

Shinobu Uzu
Director, Safety Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

USPI, SmPC and Japan Package Insert are the fundamental tools for effective risk communication, with limited space. In addition, various tools for risk communication like medication guides for patients have been developed and utilized. In this session, the current risk communication strategies of FDA, EMA and MHLW/PMDA will be presented. Challenges and possible solutions for current tools will be presented from the view of health care professionals followed by a panel discussion for the future of risk communication.

The Impact of Risk Communication

Gerald J. Dal Pan, MD, MHS
Director
Office of Surveillance and Epidemiology, CDER, US FDA

Risk Minimisation Measures in The EU: Communication, Implementation Challenges and Methods for Impact Assessment <Prerecorded Presentation>

Giampiero Mazzaglia, MD, PhD
Risk Management Specialist, Scientific and Regulatory Management Department
European Medicines Agency

Awareness and Utilization of Risk Communication Tools in Medical Institutions

Mayumi Torii
Office of Safety I,
Pharmaceuticals and Medical Devices Agency (PMDA)

This Is The Important Role for Pharmacists to Protect Patients from Risk of Medicine!

Hiroyuki Furukawa, PhD
Professor, Graduate School of Yamaguchi University

V4-S5 Room 609 9:00-10:30

CRO Outsourcing Model – History and Future Outlook – Sponsor's & CRO's Perspective

Related Interest Area(s): CO, O: CRO
Level: Beginner
Language: Japanese Language Only

SESSION CHAIR

Shogo Nakamori
Representative Director
PAREXEL International

CRO outsourcing started with so-called "functional outsourcing," where only a few functions, such as monitoring or data management, are outsourced. In the past short five years, various types of outsourcing models have been developed in order to pursue higher productivity, including a "full service model," where almost all functions are outsourced to cover clinical trial implementation from the very beginning to the end, or the "partnership model," where the sponsor identifies a limited number of CROs and outsourced their entire clinical work by building a strategic alliance. Such outsourcing models vary depending on the sponsors, but there have not been many opportunities to evaluate and discuss various outsourcing models based on the experience. In this session, we invite speakers from both sponsors and CROs, and provide opportunity to compare and evaluate various outsourcing models and discuss how we should envision the future of such business models.

CRO Outsourcing Model (History and Future Outlook) - From Foreign Companies' Points of Views -

Yoshihisa Narita
Director
Clinical Operations, Allergan Japan KK

Future CRO Outsourcing Model - Best Partnership -

Kaoru Tsuda
Director
Clinical Development Administration
Global Development
Astellas Pharma Inc.

CRO Outsourcing Model – History and Future Outlook – CRO's Perspective 1

Shoji Yamada
Director, Division Manager
Clinical Development Division
A2 Healthcare Corporation

CRO Outsourcing Model – History and Future Outlook – CRO's Perspective 2

Tomoaki Miyazawa
Senior Director
Portfolio Management
PAREXEL International

Panel Discussion

All speakers above

V5-S5 Room 610 9:00-10:30

With the Aim of Developing Pediatric Drugs Being Triggered by Japan

Related Interest Area(s): ALL
Level: Intermediate

SESSION CHAIR

Fumiaki Kobayashi, PhD
CEO, CTD inc.

The Pediatric investigation plan (PIP) became effective in EU in 2007 in order to accelerate the development of drugs for pediatric. The plan of clinical trials of children should be considered during conducting the clinical trials for adults, in general.

In Japan, the re-examination period of the approval drugs is expanded by conducting clinical trials for pediatric use. However, starting development of drugs for pediatric use in parallel with development of drugs for adults is not working well.

Recently, Japan has increased opportunities to join global pediatric studies in parallel with clinical trials for adults. However, Japan should join the discussion of global development strategy for pediatric drugs in the early stage. This session will cover the current status and issues of development of pediatric drugs in Japan with speakers from pharmaceutical industry, regulatory agencies and academia. In addition, we will discuss development strategy of pediatric drugs being triggered by Japan, on the basis of an industry-government–academia cooperation for development of pediatric drugs in EU/US.

Current Status of Pediatric Drug Development: Pharmaceutical Industry Viewpoints

Takeshi Nakanishi
Department Manager, New Drug RA Department, Regulatory Affairs, Development & Medical Affairs Division, GlaxoSmithKline K.K.

Development of Pediatric Drugs in Japan: Regulatory Viewpoints

Mayumi Iwata-Okada, MD, PhD
Principle Reviewer, Office of Vaccines and Blood Products, Pharmaceuticals and Medical Devices Agency (PMDA)

With the Aim of Developing Pediatric Drugs Being Triggered by Japan: Development Viewpoints in Academia

Hidefumi Nakamura
Director for Clinical R&D, Department of Development Strategy, Center for Clinical Research and Development, National Center for Child Health and Development

Panel Discussion

All speakers above and

Stephen P. Spielberg, MD, PhD
Editor-in-Chief, Therapeutic Innovation and Regulatory Science (TIRS), the official journal of the DIA

V6-S5 Room 101 9:00-10:30

The Future of Electronic Data Submission in Japan - Strategy for CDISC Correspondence

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

SESSION CHAIR

Hironobu Saito, PhD
Vice President, New Drug Regulatory Affairs Dept.
Daiichi Sankyo Co., Ltd.

In Japan, the defined procedure for electronic data submission compliant with CDISC standards was provided according to a released guidance in April. In addition, the plans for the PMDA gateway portal system for electronic data submission have become clear recently.

In this session, approaches and issues for system implementation both in the health authority and in industry will be shared, and the next-generation review process using electronic data will be discussed.

Assuming not only Japan submission but also global submission, strategy for CDISC correspondence considering the differences in guidance between Japan and US will become increasingly important.

Effective Utilization of the Electronic Study Data - Current Status and Future Perspectives in PMDA -

Hiromi Sugano
Biostatistics Reviewer, Office of New Drug II / Advanced Review with Electronic Data Promotion Group,
Pharmaceuticals and Medical Devices Agency (PMDA)

Change of In-house Strategy for Electronic Data Submission - Japan Based Company's Perspective -

Yoshiteru Ushirogawa
Manager, Development Division, Data Science Department
Mitsubishi Tanabe Pharma Corporation

Experience on FDA and PMDA Electronic Data Submission - Foreign Pharmaceutical Company's Perspective - <Remote Presentation via Internet>

Barrie Nelson
Senior Director, Clinical Data Management
Onyx Pharmaceuticals

Panel Discussion

All speakers above and

Yuki Ando, PhD
Senior Scientist for Biostatistics, Advanced Review with Electronic Data Promotion Group, Pharmaceuticals and Medical Devices Agency (PMDA)

V7-S5 Room 102 9:00-10:30

To Fight Against Superbugs - Future Development of Antibacterial Drugs Surrounding Drug-Resistant Pathogens

Related Interest Area(s): CO, DM, CP, CMC
Level: Beginner

SESSION CHAIR

Junko Sato, PhD
International Coordination Officer
Pharmaceuticals and Medical Devices Agency (PMDA)

Known as the "Superbugs," the threat of drug-resistant pathogens to antibacterial drugs is becoming a worldwide issue. However, a wide gap exists between overseas and Japan in coping with new drug development.

In the US, the Generating Antibiotic Incentives Now (GAIN) Act was enacted to provide incentives such as exclusivity period for new drugs against drug-resistant pathogens. In 2013, a drafted clinical development guidance was issued for new drugs for serious infectious diseases with unmet medical needs. The plan is now being prepared to promote new antibacterial drugs.

In Japan, no plan exists to promote development of antibacterial drugs. For clinical evaluation, a Guideline for the Clinical Evaluation of Antibacterial Drugs (draft) for common infectious disease was issued in 2010. However, no guidance has been issued for drug-resistant pathogens.

Such difference in commitment to antibacterial drugs development against drug-resistant pathogens in and outside Japan may lead to future drug lag in antibacterial drugs for drug-resistant pathogens.

To contribute to improved public health in Japan, we will discuss the desirable future development of antibacterial drugs surrounding drug-resistant pathogens.

Current Issues in Antibacterial Drug Development for Drug-Resistant Pathogens

Seiji Hori, MD, PhD
Professor, Department of Infectious Diseases and Infection Control, The Jikei University School of Medicine

Call For Action Revolutionizing Anti-Bacterial Drugs' R&D Ecosystem

Hiromichi Shirasawa, MD
Vice President and Executive Officer, Head of Japan Development
MSD K.K.

The Evolution of Regulatory Framework towards Streamlined Antibacterial Drug Development (Tentative)

John H. Rex, MD
Senior VP and Head of Infection, Global Medicines Development, AstraZeneca

Panel Discussion

All speakers above and

Wataru Asakura, PhD
Office Director, Pharmaceuticals and Medical Devices Agency (PMDA)

SESSION 6 11:00-12:30

V1-S6 Room 605/606 11:00-12:30

Patient-Focused Medical Affairs Roles and Activities - Beyond the Pill with Patient Support Programs

Related Interest Area(s): CO, DM, CP, CMC, AC, O: Patient
Level: Beginner

SESSION CHAIR

Kihito Takahashi, MD, PhD
Vice President and Senior Managing Director
GlaxoSmithKline K.K.

Medical affairs organizations within the pharmaceutical industry are emerging to play a more important role in partnering with physicians to provide value in patient-centered health care. The purpose of this session is to provide a basic understanding of the roles and activities of Medical Affairs from a patient-focused perspective. In this session, we will also discuss the challenges and opportunities of Patient Support Programs (PSP) as part of the patient-focused medical affairs activities.

Medical Affairs 2015 and Beyond

Hiroshi Tamada, MD, PhD, MBA
Vice President, Head of Japan Medical and Development,
Bristol-Myers K.K.

Patient-Focused Medical Affairs Roles and Activities - Beyond The Pill with Patient Support Programs

Rick Tsai, DMD, MD
Head of Medical Affairs
Executive Officer
MSD K.K.

DialBetics: A Novel Smartphone-based Self-management Support System for Type 2 Diabetes Patients

Kayo Waki, MD, MPH, PhD
Associate Professor
Department of Ubiquitous Health Informatics, Graduate School of Medicine, The University of Tokyo
Department of Diabetes and Metabolic Diseases
The University of Tokyo Hospital

Panel Discussion

All speakers above

V2-S6 Room 607 11:00-12:30

Perspectives for Development of Regenerative Medical Products in PMD Act

Related Interest Area(s): CO, RA, CP, PM, CMC, O: MA, AC, MW
Level: Intermediate

SESSION CHAIR

Teruo Okano, PhD
Professor, Institute of Advanced Biomedical Engineering and Science
Tokyo Women's Medical University

For the promotion of Regenerative medicine in Japan, new special definitions and a section for regenerative medical products were established under "the PMD Act" (partially revised Pharmaceutical Affairs Law). Medical innovations are to be shared by all the beneficiaries, and international regulatory communication channels are to be developed to share the views on the new development. In this session, considering these new environments, the perspectives of industry and academia for developing regenerative medical products and cooperating will be discussed.

Perspectives for Development of Regenerative Medical Products in Japanese Industry

Keiji Yoshimura
Japan Tissue Engineering Co., Ltd.

The Role of Academia for Developing Regenerative Medical Products

Kiyoshi Okada, MD, PhD
Associate Professor
Department of Medical Innovation, Osaka University Hospital

Perspectives for Global Development of Regenerative Medical Products

Yasuko Terao, PhD
Director, Clinical Science Division, Research and Development Division
Janssen Pharmaceutical K.K

Expectation for Development of Regenerative Medical Products from Academic Society

Akihiro Umezawa, MD, PhD
Deputy Director
National Research Institute for Child Health and Development

Panel Discussion

All speakers above

V3-S6 Room 608 11:00-12:30

Risk Communication in EU, US and Japan - Goals and Objectives of Various Tools including Labeling - (Part 2)

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

SESSION CO-CHAIRS

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

Shinobu Uzu
Director, Safety Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

USPI, SmPC and Japan Package Insert are the fundamental tools for effective risk communication, with limited space. In addition, various tools for risk communication like medication guides for patients have been developed and utilized. In this session, the current risk communication strategies of FDA, EMA and MHLW/PMDA will be presented. Challenges and possible solutions for current tools will be presented from the view of health care professionals followed by a panel discussion for the future of risk communication.

Risk Communication: From Consumers' Perspective

Kyoko Kitazawa
Kyoto Pharmaceutical University

Risk Communication: A Company Perspective

Shinichi Nishiuma, MD
Senior Medical Advisor, Global Patient Safety, Eli Lilly Japan K.K.

Panel Discussion

All speakers from Part 1 and Part 2 and

Xavier Luria, MD
Chair and Senior Consultant, Drug Development and Regulation
Former Head of Safety and Efficacy of Medicines at the EMA

V4-S6 Room 609 11:00-12:30

ICH E9 (R1): Discussion on the Appropriate Estimands for Clinical Trials

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

SESSION CHAIR

Hideki Suganami, PhD
Director, Clinical Data Science Dept, Kowa Co., Ltd.

Missing data makes it difficult to evaluate the results of a randomized comparison clinical study (ICH E9). To understand how to handle missing data, it is important to understand "Estimand." "Estimand" is a relatively-new concept and it's not written in any ICH guidelines. Understanding "Estimand" is the first step of understanding how to handle missing data, however "Estimand" also helps to reach correct deductions of the clinical study. Estimand, which is being discussed as part of ICH E9 (R1), and related issues will be discussed at this session to make it clear even for non-statisticians.

Overview of ICH E9 (R1)

Yuki Ando, PhD
Senior Scientist for Biostatistics
Pharmaceuticals and Medical Devices Agency (PMDA)

Practical Issues

Masayo Miyata
Group Manager, Trial Lead Department, R&D Div.
Janssen Pharmaceutical K.K.

Missing Data, Appropriate Statistical Analytical Methods, Appropriate Sensitivity Tests

Satoru Fukinbara, PhD
Director, Data Science Development Headquarters
Ono Pharmaceutical Co., LTD.

Panel Discussion

All speakers above

V5-S6 Room 610 11:00-12:30

Industrial Development and Growth Strategy for Biosimilars - From the Viewpoint of the Acceleratation of Biosimilars Use

Related Interest Area(s): ALL
Level: Intermediate

SESSION CHAIR

Teruyo Arato, PhD
Professor, Department of Regulatory Science
Hokkaido University Graduate School of Medicine

The guidelines for quality/efficacy/safety of biosimilars and its Q and A have been issued in Japan, and currently biosimilar products have been approved in Japan. Expectations for industrial development for biosimilars will be much higher in the future.

This session will cover how to change the Japanese medical environment by using biosimilar products and how to accelerate the use of biosimilars, as well as how to the grow industry of biosimilars in Japan.

In this session, speakers from a pharmaceutical industry and academia will give a presentation about current environment and issues of the acceleration of biosimilars use. We will have a panel discussion with the above speakers and a panelist from a department of pharmacy in a hospital, who will talk about biosimilars use in a pharmacy point of view.

Launching Experiences of Biosimilars and Issues for Wider Use

Tetsuji Tsukamoto, MBA
Pharmaceuticals Development Division, Nippon Kayaku Co., Ltd.

Biosimilar: Learnings from Nearly 10 Years of Real World Experience

Sreedhar Sagi, PhD
Head Medical Affairs, APAC, Sandoz Biopharmaceuticals

Expectation for Biosimilar Insulin Products by Clinical Diabetologists

Yasuo Terauchi, MD, PhD
Professor, Endocrinology & Metabolism, Graduate School of Medicine, Yokohama City University

Panel Discussion

All speakers above and

Keiso Masuhara, PhD
Department of Pharmacy
St. Marianna University School of Medicine Hospital

V6-S6 Room 101 11:00-12:30

Towards ICH E6 Revision - Think about How Quality Management System (QMS) Can be Introduced in Clinical Trials

Related Interest Area(s): CO, RA, ST, DM, PM, AC, O: QA, QC
Level: ALL

SESSION CHAIR

Satoshi Matsushita
Director, R&D QA Department
Janssen Pharmaceutical K.K.

ICH E6 revision has been under discussion and the step 4 guideline will be published in November 2016 after step 2 in June 2016.
One of the main focuses on ICH E6 revision is to introduce quality management approach into clinical trials in order to ensure quality. There will be a high possibility that some traditional approaches need to be reconsidered fundamentally. Risk-Based Monitoring, which sponsors have already implemented, is also one of the methods of quality management, but ICH E6 revisions request a more systematic approach at the trial level. Health authorities have also encouraged development of an integrated clinical quality management system in our organization. In this session, we will discuss what the QMS is, our expectation/issues for it and how to execute it from a practical point of view.

Impact of ICH E6 Revision on Quality Management Activities in Clinical Trials - From PMDA Point of View

Naoyuki Yasuda
Director, Office of International Programs
Pharmaceuticals and Medical Devices Agency (PMDA)

TransCelerate Clinical Quality Management System Initiative Update

Ann Meeker-O'Connell, MS, CCEP
Head, Risk Management and External Engagement, Bioresearch Quality and Compliance, Johnson & Johnson

Merck/MSD Clinical Quality Management Model

Kiyomi Hirayama
Director, Clinical Research / Regional Clinical Quality Manager
Japan Clinical Quality Management, MSD K.K.

Panel Discussion

All speakers above

V7-S6 Room 102 11:00-12:30

Rethinking Vaccine Policy-Making in an Era of Vaccine Hesitancy

Related Interest Area(s): RA, O: Policy, Access
Level: Intermediate

SESSION CHAIR

Yoshikata Furuya, MSc
Director
Vaccine Policy, Health Policy, MSD K.K.

Vaccination has had an important impact on global health, eradicating or dramatically reducing the numbers of persons who die or are disabled from infectious diseases. However, vaccine hesitancy – indecision about vaccination, refusal of or delay, vaccines is spreading globally. Vaccine hesitancy causes decreasing vaccine coverage and an increasing risk of vaccine-preventable disease outbreaks and epidemics. Global experts will present the latest situation of vaccine hesitancy in Japan and global, and discuss possible measures.

Vaccine Hesitancy – Global Status and Measures (Tentative)

Kyle Hathaway, PhD
Director
Vaccine Policy, Asia Pacific, Merck & Co., Inc.

Vaccine Policy Reform in Japan - Challenge and Opportunity (Tentative)

Hajime Kamiya, MD, PhD,MPH
Chief Researcher
Infectious Diseases Surveillance Center
National Institute of Infectious Diseases

Vaccine Hesitancy – Japanese Status and Measures (Tentative)

Narumi Hori, RN, MPH, M.Ed.
Epidemic Intelligence Service, Disease Control and Prevention Center, National Center for Global Health and Medicine

Panel Discussion

All speakers above

ROUND TABLE AND PMDA TOWN HALL

ROUND TABLE

INTERNATIONAL CONFERENCE ROOM **14:00-15:30**

Let's Hear from AROs and R&D Heads - Towards New Medicine Development

Related Interested Area(s): All
Level: All

SESSION CO-CHAIRS

Yoshikazu Hayashi
Pharmaceuticals and Medical Device Agency (PMDA)

Hiroshi Watanabe, MD, PhD
Professor, Department of Clinical Pharmacology & Therapeutics,
Director of the Clinical Research Center,
Hamamatsu University School of Medicine

There are day-to-day changes in circumstances surrounding medicine development such as prevalence of Multi-Regional Clinical Trials and emerging AROs. Regulators are also introducing new regulatory approaches including consultations on regulatory strategy. However, there is still room for improvement of communication among stakeholders and we can seek further efficiency of medicine development. In addition, there are quite a few medicines developed only in foreign countries, it despite assertions the drug lag has been resolved. In this session, we will have candid discussions with pharmaceutical companies and AROs on what is needed in Japan in order to market necessary medicines for Japanese people without delay and conduct efficient medicine development through worldwide collaboration as well as possible ideas how to make Japan a more attractive country for foreign companies.

PANELISTS

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

Akihisa Harada, MD, PhD
Vice President - Development Japan
Chief Scientist - Japan
Pfizer Japan Inc.

Akira Myoi, MD, PhD
Vice Director
Associate Professor
Medical Center for Translational and Clinical Research Department of Medical Innovation
Osaka University Hospital

Takuko Sawada
Senior Executive Officer, Executive General Manager,
Global Development, Shionogi & Co., Ltd.

Hiromichi Shirasawa, MD
Vice President and Executive Officer, Head of Japan Development
MSD K.K.

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

COFFEE BREAK **15:30-16:00**

PMDA TOWN HALL

INTERNATIONAL CONFERENCE ROOM **16:00-17:30**

PMDA Town Hall

Related Interest Area(s): All
Level: All

SESSION CHAIR

Hideki Hanaoka, MD, PhD
Director of Clinical Research Center
Chiba University Hospital

Hiromichi Shirasawa, MD (TBC)
Vice President and Executive Officer, Head of Japan Development
MSD K.K.

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

PANELISTS

Wataru Asakura, PhD
Director, Office of New Drug IV
Pharmaceuticals and Medical Device Agency (PMDA)

Daisaku Sato, PhD
Director, Office of Cellular and Tissue-based Products
Pharmaceuticals and Medical Device Agency (PMDA)

Reiko Sato, PhD
Director, Office of Safety II
Pharmaceuticals and Medical Device Agency (PMDA)

Mayumi Shikano, PhD
Associate Director, Center for Product Evaluation
Pharmaceuticals and Medical Device Agency (PMDA)

Yuka Suzuki, PhD
Director, Office of Medical Devices II
Pharmaceuticals and Medical Device Agency (PMDA)

Naoyuki Yasuda
Director, Office of International Programs
Pharmaceuticals and Medical Device Agency (PMDA)

CLOSING REMARKS

INTERNATIONAL CONFERENCE ROOM **17:30-17:45**

PROGRAM VICE-CHAIR

Satoshi Saeki, MSc
Senior Manager
Immunology and Inflammation Area, Japan Asia Development
Astellas Pharma Inc.

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スチューデントセッション　102会議室
9:30–12:00
企業が考える添付文書への理解
～私たちが考える情報提供との違いを通して～

関連領域：薬事、安全性、アカデミア
レベル：初級
言語：日本語のみ

座長
千葉大学大学院
向後　晃太郎
東京理科大学大学院
佐久間　達也
慶應義塾大学大学院
佐藤　亮平

「添付文書」は、唯一法的根拠を持つ公的文書であり、臨床現場において、最も重要な医薬品情報として用いられている。一方で、紙面の量的限界により、必要な情報が十分に記載されていないとの指摘もある。添付文書に記載される情報の取捨選択はどのように行われているのだろうか。

本セッションでは、添付文書の概念や役割について講演を行って頂く。その後、「企業側の添付文書作成における意図」や「医療従事者が添付文書に求める医薬品情報」について考え、医薬品情報への理解を深める。さらに、ディスカッションや発表を通じて、知識やコミュニケーション能力を能動的に修得する場として欲しい。

企業が行う安全確保業務（添付文書の役割）
元グラクソスミスクライン株式会社
秋元　憲一

アドバイザー
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
第一三共株式会社
齋藤　宏暢
ノバルティス ファーマ株式会社
関根　恵理

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 <ビデオでの挨拶>

DIA President Elect/ 慶應義塾大学
黒川　達夫

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12回DIA日本年会大会長 /ファイザー株式会社
原田　明久

2015 DIA JAPAN's INSPIRE REGIONAL AWARDS授賞式
国際会議場 **14:00-14:15**

プレゼンター

DIA President Elect/ 慶應義塾大学
黒川　達夫

アワード受賞者：

Outstanding Contribution to Health Award
浜松医科大学
渡邉　裕司

Excellence in Service Award
日本イーライリリー株式会社
東内　祥浩

ファイザー株式会社
松井　理恵

基調講演 1
国際会議場 **14:15-14:55**

座長
ファイザー株式会社
原田　明久

AMEDの設立によって今まで各省庁それぞれが持っていた医療分野の研究開発に関する予算が一つに集約され、基礎段階から実用化まで一貫した研究のマネジメントが可能になった。これにより、国内の大学、政府研究機関にある創薬シーズの情報が整理され、早期段階の開発が一気に進んでいくことが予想される。ここでは、AMEDの組織、プロジェクト、力を入れている疾患領域を紹介していただくとともに、今後AMEDが目指すべき産官学と患者との協力体制についての考えを話してもらう。

AMEDのミッションとチャレンジ
国立研究開発法人 日本医療研究開発機構
末松　誠

基調講演 2
国際会議場 **14:55-15:35**

座長
ファイザー株式会社
原田　明久

NCATS(National Center for Translational Sciences)は、NIHの傘下にある27のセンターの一つで、トランスレーショナルリサーチのプロセスを加速させ患者さんに一刻も早く新しい治療法を提供できることを目的に2012年に設立された。NCATSとNIH、企業や患者とNCATSとのこれまでの取り組みから、トランスレーショナルリサーチの障害は何なのか、克服すべき課題は何なのかを考え、AMEDの今後の活動に対する橋頭堡を示す。

NCATSのこれまでの取り組みと今後の課題
National Institutes of Health (NIH)
Christopher P. Austin

コーヒーブレイク **15:35-16:05**

基調講演3
国際会議場 **16:05-16:45**

座長
慶應義塾大学
黒川　達夫

2000年に創設以来、「全ての生命の価値は等しい」との信念のもと、ビル&メリンダ・ゲイツ財団は全ての人々が健康で豊かな生活を送るための支援を実施してきている。具体的には国際開発プログラム、グローバルヘルスプログラム、米国プログラムの3つのプログラムを展開するほか、慈善支援も実施している。急速に進歩する医薬品開発と世界の健康や福祉との関係についてみなさんと一緒に考えてみたい。。

新薬開発がもたらすグローバルヘルスの促進（仮）
ビル&メリンダ・ゲイツ財団
Murray M. Lumpkin

ネットワーキングレセプション

スペシャルパネルディスカッション
国際会議場 **16:45-17:45**

座長
ファイザー株式会社
原田　明久

慶應義塾大学
黒川　達夫

3人の演者からそれぞれの経験をもとに、官民で協業していく際のベストプラクティスや注意すべき点について共有していただき、これからの官民の協力のあり方をディスカッションしたい。また、新しい治療や診断を一刻も早く患者さんに届けるために我々ができることは何か、またそれに留まらず、世界の健康や福祉に貢献するために我々ができることは何かを3名の演者とディスカッションしたい。

パネリスト

National Institutes of Health (NIH)
Christopher P. Austin

ビル&メリンダ・ゲイツ財団
Murray M. Lumpkin

国立研究開発法人 日本医療研究開発機構
末松　誠

情報交換会
レセプションホール **18:00-19:30**

各セッションの座長、演者やプログラム委員の方々、また他の参加者の方々との貴重なネットワーキングの機会になるものと考えております。奮ってご参加ください。

SESSION 1 9:00-10:30

V1-S1-S2 605/606会議室 10:00-12:30

世界の医療へ貢献するために我々ができること

関連領域: 全領域
レベル:中級

座長
ファイザー株式会社
原田 明久

慶應義塾大学
黒川 達夫

これまで日本の医療システムは、国民皆保険や患者の病院アクセス等からWHOの健康達成度総合評価でも高い評価を得ており、国民に一定水準以上の医療サービスを提供するという目的を達成してきた。

しかし、医学および先端技術の進歩は目覚ましく、学問的探究のみならずそれを新たな治療法に結びつけ、国民及び世界の医療に貢献をすることが望まれている。日本の医療・研究基盤を用いて、国際保健分野において日本が世界に貢献しうることは何なのであろうか。

ドラックラグ・デバイスラグが解消に向かう中で、再生医療や医薬品の開発において、いくつかの点ではようやく日本も欧米と肩を並べる状況にある。今後、日本が世界の医療に貢献していくために、日本がどのような役割を果たしていくべきかを産官学の立場で議論する。

情報化時代の医療・医学研究
自治医科大学
永井 良三

演題未定
独立行政法人 医薬品医療機器総合機構
近藤 達也

革新的新薬開発への試み
アステラス製薬株式会社
野木森 雅郁

Realizing Japan's Potential in Global Drug Development
バイエル薬品株式会社
カーステン・ブルン

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 9:00-10:30

HTAや効果的な医薬品開発のための新たな解析的アプローチ - ネットワークメタアナリシスとその適用事例の紹介

関連領域: 薬事、統計、PM
レベル:初級

座長
東京大学
大庭 幸治

医薬品開発におけるデータに基づく意思決定や、HTAに利用できる解析的アプローチとして注目を集めている"ネットワークメタアナリシス"を紹介する。本セッションでは、統計、薬事、HTA、開発の方を対象とし、実際に活用した事例を紹介し、"ネットワークメタアナリシス"がどのような場面で活用でき、どれほど有用であるか、また、適切に正しく利用するためにはどのような点に留意すべきかについて議論する。

ネットワークメタアナリシスとは、2剤比較のメタアナリシスを一般化したもので、3剤以上の比較試験の結果(A剤 vs B剤, B剤 vs C剤, A剤 vs C剤)を統合することにより、

(i) 直接比較の試験が実施されていない2剤の比較
(ii) 直接及び間接比較の試験結果を考慮することによる2剤の差の推定精度向上
が可能となる。

得られた結果は、開発中の薬剤の類薬に対する効果の推定、非劣性試験やバイオシミラー試験におけるマージンの設定、HTAなど幅広く活用することができる。

医薬品のEffectiveness評価へのネットワークメタアナリシスの利用および考慮すべき事項
ファイザー株式会社
藤井 陽介

TPP設定に向けたネットワークメタアナリシスの利用
日本たばこ産業株式会社 / 株式会社データフォーシーズ
荒野 俊平

Implementation of Bayesian Network Meta-analysis to Improve Medical Product Development
Eli Lilly and Company
Karen L Price

V3-S1 608会議室 9:00-10:30

ベネフィット・リスク バランスの評価の夜明け ～リスク情報は増え続けるだけか?～(第1部)

関連領域: 安全性
レベル:中級

座長
ファイザー株式会社
小宮山 靖

日本イーライリリー株式会社
前田 玲

医薬品の安全性情報は、一般にその曝露量に依存して増加し、上市後数年経過すると報告率は減少し、累積報告数の増加は緩やかになる。その間、企業や当局の継続的な安全管理により、リスクは適宜最小化され、添付文書には副作用情報が追加される。それでは、リスクも副作用と同様に増え続け、RMPにリスクは頻繁に追加されるのだろうか。

本セッションでは、副作用とリスク、有効性とベネフィットの違い、ベネフィットがリスクを上回るとはどういう状態で、どのように表現され、誰が評価しその結果はどのように利用されるのか、三極の専門家に意見を伺うとともに、パネルディスカッションにより現状の問題点と今後について話し合ってもらう。

Personalized Medicine and Benefit-Risk: Impact on REMS and Other Approaches to Safety
Editor-in-Chief, Therapeutic Innovation and Regulatory Science (TIRS), the official journal of the DIA
Stephen P. Spielberg

Current Trends in Benefit/Risk Assessment of Medicines and Regulatory Impact from EU Perspective
Drug Development and Regulation
Xavier Luria

演題未定
厚生労働省
宇津 忍

V4-S1 609会議室 9:00-10:30

創薬創出へのヒト臓器・組織利用

関連領域: 薬事、臨床、アカデミア、その他(Translational Research)
レベル:中級
言語:日本語のみ

座長
武蔵野大学大学院
豊島　聰

医薬品の開発にあたっては、治療対象がヒトであることから、ヒトの臓器・組織を用いることが必須である。しかしながら、欧米に比し、日本においては、臓器移植などで、不要となったヒト臓器・組織が倫理的な考え方の相違等により必ずしも有効に利用されていない。本セッションでは日本におけるヒト臓器・組織利用の現状と課題、法的・倫理的基礎、アカデミア及び製薬企業でのヒト臓器・組織利用の現状・成果を説明・紹介し、日本のヒト臓器・組織の有効利用促進を目指す。

わが国におけるヒト臓器・細胞・組織を用いた研究の抱える課題
特定非営利活動法人　エイチ・エー・ビー研究機構
深尾　立

ヒト組織利用の法的・倫理的基礎
上智大学
町野　朔

創薬に向けたヒト細胞・組織の利用：Precision Medicine への展開
ファイザー株式会社
堀井　郁夫

薬物動態の予測におけるヒト組織活用の意義
東京大学大学院
楠原　洋之

V5-S1　610会議室　9:00-10:30
医療機関で計画・実施される臨床研究活動におけるプロジェクトマネジメント基本プロセスの導入

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

座長
中外製薬株式会社
DIA Japan PMコミュニティ
住田　秀司

医師主導多施設共同臨床研究（多施設IIS）では、中央に研究の管理業務を行う部門（セントラルオフィス）を置き、各実施医療機関と業務を分担することが多い。試験関連業務を効率的かつスムーズに遂行していくためには、セントラルオフィスと実施医療機関スタッフ、業務委託先など関係者の協働が不可欠かつ非常に重要である。

今回のセッションでは、医療機関において、プロジェクトマネジメント（PM）手法による人的資源を最大限に活用するための方策に焦点を当てる。IISの関係者が互いの役割とコミュニケーションを最適化し、それぞれの強みを発揮していくためには何が必要なのかを、IISに携わるスタッフの実体験をもとに、PMの視点から考察する。

講師
北里大学臨床研究機構
風見　葉子

慶應義塾大学
菊地　佳代子

PMコンサルティング　ポジティブ・インテンション
DIA Japan PM コミュニティ
今野　浩一

慶應義塾大学
中川　敦夫

東京大学医学部付属病院
岡崎　愛

V6-S1　101会議室　9:00-10:30
医薬品と医療機器の違い

関連領域: 臨床、DM、安全性
レベル：TBC

座長
独立行政法人 医薬品医療機器総合機構
石井　健介

健康・医療分野が成長戦略の主翼を担うことが閣議決定され、異業種からの企業参入は必然となり、革新的技術が医療分野に導入されやすい背景がある。医薬品医療機器等法が施行され、医薬品と医療機器の境界が示された一方で、双方の領域に及ぶコンビネーションプロダクトのような製品の開発が活発化している。医療機器の領域からみると医療機器に対する認識不足から、製薬企業が開発において躓いているように見える事例に遭遇することも少なくない。本セッションでは、医薬品と医療機器の違いに着目し、様々な立場から双方の違いについて考察する。この議論を通じて、製薬業界に医療機器に対する正しい認識を有する助けになることを期待する。

医療機器企業の立場から（薬物溶出ステントを例にして）
テルモ株式会社
川原　一夫

医薬品と医療機器の開発を経験した立場から（総論的に背景等も整理して）
グリーンフィールド株式会社
土井　功夫

医療（開発）現場から見た違い（ＰＤＴレーザーの開発を例にして）
東京女子医科大学
村垣　善浩

治験における違い
東北大学病院
池田　浩治

審査現場から見た違い
独立行政法人 医薬品医療機器総合機構
大内　貴司

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
鈴木　由香

V7-S1　102会議室　9:00-10:30
公募演題セッション

関連領域: 臨床、DM、安全性、CMC
レベル：初級

座長
独立行政法人 医薬品医療機器総合機構
佐藤　淳子

東京大学
湯地　晃一郎

DIA日本年会を国内外に広く開かれた学会とするために、本年より一般演題を公募することとした。今回は、本邦の医薬品開発の重要課題である「早期開発の促進」および「グローバル開発の活用」、そして「市販後安全対策の最適化」というテーマにて、抗悪性腫瘍の領域から2演題、循環器系領域から1演題の計3演題が選ばれた。各演者から様々なアプローチが紹介された後、統合的な議論が行われる。

①抗がん剤開発の第1相試験で認められた副作用の特徴・評価(膨大な症例を用いた分析)

②抗がん剤の日本と海外との承認ラグに及ぼす要因の多角的分析

③医療データベースを活用した抗血栓薬の安全性評価についての検討

悪性腫瘍に対する第I 相試験の毒性評価で入院下での管理は必須か?

国立がん研究センター中央病院
下村　昭彦

背景:　日本国内の悪性腫瘍の第I　相試験では、国内のガイドラインでDLT評価期間の1コース目の入院下の観察を推奨されており、日本の早期開発のグローバル化の障壁となっている。本研究では、当院で行った第I相試験で発生したDLT相当の毒性を、入院管理の要・不要に分けて検討し、毒性の頻度と特徴について後方視的に解析した。

対象と方法:　1996年12月から2014年8月に当院で固形癌に対する単剤の第I 相試験に登録された症例を対象とした。診療録およびデータベースから臨床情報を抽出し、DLT相当の毒性について入院の要否について検討した。侵襲的な処置または静注による加療以上の治療を必要とした場合を、入院が必要な毒性と定義した。試験は、ヒトに初めて投与する試験をFirst in human study (FIH)、通常のPhase I試験でFIH以外のものをdose escalation study、日本人の安全性を確認した試験をdose finding study とした。

結果:　1996年12月から2014年8月に945例が登録された。年齢の中央値は58歳 (18-76歳) であり、男性が537例 (57%)、女性が408例 (43%) であった。207例 (22%) が殺細胞性薬、690例 (73%) が分子標的薬、48例 (5%) が免疫チェックポイント阻害剤に登録された。Dose escalation study に582例 (62%)、FIHに129例 (14%)、dose finding study に234 例 (25%)が登録された 。DLT相当の毒性は126 例 (13.3%) に認め、96 例 (10.2%)　が1コース目に発現した。1コース目のDLT相当毒性のうち、入院を要したものは36例 (3.8%)、入院が不要であったものが60例 (6.3%) であった。デザイン別では、dose escalation study で72例 (12.4%)、FIHで14例 (10.9%)、dose finding study で11例 (4.7%)がDLT相当の毒性を発現した。入院を要した毒性は、dose escalation study で27例 (4.6%)、FIH で4例 (3.1%)、dose finding study で5例 (2.1%)であった。

結論:第I相試験の入院を必要とする毒性は4%程度と少なかった。1コース目の入院は必ずしも必須でなく外来で安全に施行できると考えられる。

DPCデータを活用した新薬の市販後の安全性調査について

大田記念病院
井上　雅博

目的:　わが国にDPC(急性期入院医療を対象とす　る診断群分類に基づく1日あたり包括払い制度)が導入され、今年で12年になる。当初は大学病院を中心とした特定機能病院を対象に導入されたが、現在は国内の急性期病院1580施設がこの制度を導入している。これは全一般病床の約55%をカバーする規模である。これまでDPCデータを用いた医薬品の安全性や有効性の評価に用いた研究はあまりなされてきていなかったが、入院データと外来データを連結することで医薬品の安全性や有効性について検討が可能となったのでここに報告したい。

対象:　全国のDPC病院のうち約22%の352施設が加入しているDPCベンチマークソフトウェアgirasol(ヒラソル)を用いて、2012年10月～2014年9月までの外来処方データと、入院患者の病名、治療内容、アウトカムについてそれぞれ検討した。これを元に、医薬品の有害事象の発生率などを検討した。

方法:　外来にて抗凝固療法中の患者において、消化管出血や頭蓋内出血のために入院した患者の発生率について検討を行った。また、服用患者における脳梗塞退院後のアウトカムについて検討を行った。対象薬はワルファリンならびに新規経口凝固薬(NOAC)はダビガトラン、リバーロキサバン、アピキサバンである。

結果:24ヶ月の間に外来にて抗凝固療法中の患者64,648人のうちワルファリン投与患者数50,027人、NOAC投与患者数16,008人において(スイッチ症例1367例を含む)、同一病院への入院患者のうち消化管出血に対する内視鏡的止血術の実施率(年間)はワルファリン群0.87%、NOAC群0.48%であった。また頭蓋内出血による入院率(年間)はワルファリン群0.68%、NOAC群0.29%と有意差を持って、NOAC群の方が消化管出血ならびに頭蓋内出血による合併症が少なかった(P<0.05)。　また、頭蓋内出血での入院患者のうち死亡退院の発生率でワルファリン群は26.8%、NOAC群12.8%とNOAC群の方が死亡率が少ない傾向が認められた。

考察:　治験において一部のNOACでは消化管出血が増えるといわれていたが、リアルワールドデータを用いた今回の分析ではNOACの方が消化管出血が少ない結果であった。また頭蓋内出血の削減率もNOACにおいてRR:56.8%と治験データとほぼ同様の結果を認めている。

結論:　DPCデータは外来患者におけるリスク因子等が明らかでないなどの限界はあるが、市販後における医薬品の安全性や有効性に関する検討に活用可能であることが示唆された。

抗がん剤における日本と米国のドラッグラグの変遷とその要因に関する研究

アステラス製薬株式会社
前田　英紀

背景:　抗がん剤は重篤致死的な疾患を対象にするが故に、他の領域の薬剤に比し、日本と欧米間でのドラッグラグは重大な影響をもたらし得る。そこ本研究では日本において承認された抗がん剤のドラッグラグについて網羅的に史実を分析し、俯瞰的な検討を行った。

方法:　2001年4月から2014年7月までに日本において承認された抗がん剤に関して公的に利用可能な情報に基づき記述統計的に分析を行い、その特徴を描出した。また日本と米国のドラッグラグおよび日本における審査期間の経時的推移、変遷およびドラッグラグに影響を及ぼす要因に関して検討を行った。

結果:　2001年4月から2014年7月までの13年間にわたる120件の承認申請(approvals)を対象とした。米国と日本との承認日の差(「承認ラグ」)は13年間で中央値875.0日(29ヶ月)であった。経年的推移を検討したところ、2002年をピークに年々減少する傾向にあり、承認ラグは経年的に有意に減少していることがわかった。また審査期間の13年間の中央値は366.5日(12ヶ月)であり、2005年の732.0日(24か月)をピークに、審査期間も経年的に有意に減少した。承認ラグを短縮する要因を重回帰分析を用いて検討したところ、"国際共同試験に参加すること"、"ブリッジング戦略"、"優先審査の指定"、"分子標的薬"が要因として特定された。さらに本研究では,「開発着手ラグ」および「審査期間」に影響を及ぼす要因に関しても同様に検討を行った。

結論:　2001年から2014年までの間に、日本の抗がん剤開発においては、分子標的薬の登場・台頭、開発手法のブリッジング戦略から国際共同試験に参加する世界同時開発への変化があった。これら変化とともに日本と米国のドラッグラグは短縮し、1年未満に減少した。

SESSION 2 11:00-12:30

V1-S1-S2 605/606会議室 10:00-12:30

世界の医療へ貢献するために我々ができること

関連領域: 全領域
レベル:中級

座長
ファイザー株式会社
原田　明久

慶應義塾大学
黒川　達夫

これまで日本の医療システムは、国民皆保険や患者の病院アクセス等からWHOの健康達成度総合評価でも高い評価を得ており、国民に一定水準以上の医療サービスを提供するという目的を達成してきた。

しかし、医学および先端技術の進歩は目覚ましく、学問的探究のみならずそれを新たな治療法に結びつけ、国民及び世界の医療に貢献をすることが望まれている。日本の医療・研究基盤を用いて、国際保健分野において日本が世界に貢献しうることは何なのであろうか。

ドラックラグ・デバイスラグが解消に向かう中で、再生医療や医薬品の開発において、いくつかの点ではようやく日本も欧米と肩を並べる状況にある。今後、日本が世界の医療に貢献していくために、日本がどのような役割を果たしていくべきかを産官学の立場で議論する。

情報化時代の医療・医学研究
自治医科大学
永井　良三

演題未定
独立行政法人 医薬品医療機器総合機構
近藤　達也

革新的新薬開発への試み
アステラス製薬株式会社
野木森　雅郁

Realizing Japan's Potential in Global Drug Development
バイエル薬品株式会社
カーステン・ブルン

パネルディスカッション
本セッションの講演者

V2-S2 607会議室 11:00-12:30

ICH E14:心臓安全性評価の最新動向

関連領域: 臨床、薬事、統計、安全性、PM
レベル:初級、中級

座長
BioClinica, Inc.
Boaz Mendzelevski

薬物性QT延長は不整脈ひいては突然死に繋がるため，催不整脈リスク評価の目的でICH S7B(非臨床)及びICH E14(臨床)ガイドラインが施行されている。後者の特徴はThorough QT (TQT) 試験であるが，近年それに代わりうる評価法として，早期臨床試験における薬物濃度-反応モデルの利用が確立しつつある。又，　非臨床及び早期臨床試験による包括的な評価法である，Comprehensive Pro-arrhythmia In-vitro Assay (CiPA) の研究が進められている。本セッションでは，新薬の催不整脈リスクに関する入門的内容から評価の最新動向，さらには将来展望を議論する予定である。

薬物性QT延長:イオンチャネル・不整脈の理解からレギュラトリーガイダンスまで
東邦大学
杉山　篤

日本におけるICH E14ガイドラインの実施状況と催不整脈リスク評価の将来展望
独立行政法人 医薬品医療機器総合機構
品川　香

臨床開発におけるQT評価:我々は今どこにいるのか
BioClinica, Inc.
Boaz Mendzelevski

パネリスト
本セッションの講演者および
北里大学
熊谷　雄治

武田薬品工業株式会社
中村　浩己

V3-S2 608会議室 11:00-12:30

ベネフィット・リスク　バランスの評価の夜明け　～リスク情報は増え続けるだけか?～(第2部)

関連領域: 安全性
レベル:中級

座長
ファイザー株式会社
小宮山　靖

日本イーライリリー株式会社
前田　玲

医薬品の安全性情報は、一般にその曝露量に依存して増加し、上市後数年経過すると報告率は減少し、累積報告数の増加は緩やかになる。その間、企業や当局の継続的な安全管理により、リスクは適宜最小化され、添付文書には副作用情報が追加される。それでは、リスクも副作用と同様に増え続け、RMPにリスクは頻繁に追加されるのだろうか。

本セッションでは、副作用とリスク、有効性とベネフィットの違い、ベネフィットがリスクを上回るとはどういう状態で、どのように表現され、誰が評価しその結果はどのように利用されるのか、三極の専門家に意見を伺うとともに、パネルディスカッションにより現状の問題点と今後について話し合ってもらう。

演題未定
帝人ファーマ株式会社
日本製薬工業協会
中島　章博

Recent Progress in Benefit-Risk Evaluation Methodology and Practices: An Industry Perspective
Janssen Pharmaceutical Companies of Johnson & Johnson
Filip Mussen

パネルディスカッション
本セッション第1部、第2部の講演者

V4-S2　609会議室　11:00-12:30

医療分野のこれからの知財戦略 ～シーズを産官学が連携して育てるうえでの理想的な知財戦略を考えよう～

関連領域: 臨床、薬事、PM、アカデミア、その他(Intellectual Property)
レベル:初級
言語:日本語のみ

座長
政策研究大学院大学
隅蔵　康一

近年、薬事戦略相談の活用やオープンイノベーションの活発化等、医療分野のシーズを産官学が連携して育てる取組みが進んでいる。しかし、基礎研究から実用化までの間にある大きな障壁、いわゆる「死の谷」は、依然として知財戦略の欠如が原因の一つとして挙げられている。本年4月に設立されたAMEDでは、Medical IP Desk(医療分野の知財相談窓口)の開設等、多様なシーズ開発に柔軟に対応できる体制の整備がなされ、より"明るい"産官学連携の姿が見えてきた。そこで、産・官・学のそれぞれの立場から、今後より良い連携を目指すうえでどのような知財戦略が求められるのかをお話し頂き、さらにパネルディスカッションを通じて意見交換を行う。

AMEDにおける知的財産マネジメントへの取組
国立研究開発法人 日本医療研究開発機構
天野　斉

東京大学TLOの取組み～知財の視点を取り入れた学術研究の推進～(仮題)
株式会社東京大学TLO
本田　圭子

オープンイノベーションとパートナーシップ　～産学の連携とファイザーのアプローチ～
Pfizer Inc.
瀬尾　亨

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　11:00-12:30

Project Leadershipの発揮により迎えるイノベーション

関連領域: 全領域
レベル:初級、中級
言語:日本語のみ

座長
PMコンサルティング　ポジティブ・インテンション
DIA Japan PM コミュニティ
今野　浩一

イノベーションとは今までと何かが異なる新しい価値を創り出すこと。プロジェクトとは明確に設定された期限の中で新しい価値を創造する活動であり、イノベーションを実現するプロセスを構成している。プロジェクト・マネジメントは、一般的に、プロジェクトの目標達成のために活用すべきプロセス、ツールの知識体系ととらえがちだが、その根底には新規価値を創造・実現するためのリーダーシップの作法が組み込まれている。本セッションでは、イノベーションやブレイクスルーを生み出すプロジェクトの枠組みと、ハイパフォーマンスチームの開発プロセスについて、プロジェクト・マネジメントの視点から探求する。

講師
武田薬品工業株式会社
DIA Japan PM コミュニティ
岩崎　幸司

協和発酵キリン株式会社
DIA Japan PM コミュニティ
佐藤　隆

第一三共株式会社
DIA Japan PM コミュニティ
塚本　淳

V6-S2　101会議室　11:00-12:30

医薬品・医療機器開発への統計学・行動観察の寄与

関連領域: 全領域
レベル:初級

座長
北海道大学
伊藤　陽一

ビジネスの世界では、ビッグデータが注目され、データサイエンティストと呼ばれる統計学を専門とした職種が生まれているが、医薬品開発の世界ではICH-E9以降、既に他業種に先駆けて試験統計家が活躍している。また、サービス産業の分野では、行動観察と呼ばれる質的な研究方法によって、業務の効率化やサービスの向上が図られている。医薬品や医療機器は、医療関係者や患者が使用するものであるため、使い勝手の良さが適正使用に直結する。行動観察は使用者本人も気付かないニーズを掘り起こすことができ、医薬品・医療機器の使い勝手を改善する可能性を秘めているが、医薬品開発への応用はほとんど行われていない。本セッションでは、ICH-E9が現在の医薬品・医療機器開発に与えた寄与を振り返るとともに、今後の医薬品・医療機器開発において統計学や行動観察が果たす可能性を模索する。

ICH統計ガイドライン - なにが変わったのか?
京都大学
佐藤　俊哉

企業が統計学で価値を生む方法
株式会社データビークル
西内　啓

行動文脈を深く理解することからイノベーションが始まる - 潜在的・本質的なインサイト導出手法「行動観察」
株式会社オージス総研
越野　孝史

V7-S2　102会議室　11:00-12:30

個別化医療ビジネスの成功の鍵を探そう

関連領域: 臨床、薬事、アカデミア
レベル:中級

座長
中外製薬株式会社
田中　裕

近年、がん領域を始めとした多くの疾患領域で様々な分子標的治療薬が登場し、医療は「個々の患者さんに合う薬を探して用いる」治療、つまり個別化医療へとシフトしつつあります。

しかし、現在はまだ分子標的治療薬とコンパニオン診断技術の組合せによる「薬に合いそうな患者さんを探して薬を用いる」ケースが主流です。このケースは医薬品開発とコンパニオン診断技術開発を複数の企業が連携して進めることが多く、いくつかの課題があります。

本セッションでは、業界の内外から現在の課題と解決策についてご意見を頂き、これからの個別化医療ビジネスを成功させる鍵を検討します。

日本の個別化医療の現況、業界に対する期待
特定非営利活動法人　日本医療政策機構
京都大学
宮田　俊男

個別化医療ビジネスの理想像：業界の外の立場より
みずほ情報総研株式会社
日諸　恵利

個別化医療ビジネスの現在の課題、理想像：製薬企業の立場より (1)
アステラス製薬株式会社
竹下　滋

個別化医療ビジネスの現在の課題、理想像：製薬企業の立場より (2)
小野薬品工業株式会社
劉　世玉

個別化医療ビジネスの現在の課題、理想像：診断薬企業の立場より
ロシュ・ダイアグノスティックス株式会社
田澤　義明

SESSION 3　14:00-15:30

V1-S3　605/606会議室　14:00-15:30

日本における産官学連携の推進を考える（第1部）

関連領域: 臨床、アカデミア、その他（Translational Research）
レベル：初級、中級

座長
千葉大学医学部附属病院
花岡　英紀
特定非営利活動法人　日本医療政策機構
京都大学
宮田　俊男

日本の医療分野における基礎から実用化までの一貫した研究開発の推進を効果的に行うため、2015年４月に「国立研究開発法人日本医療研究開発機構」（AMED：Japan Agency for Medical Research and Development）が設立された。日本から革新的医薬品を創出することは、国の成長戦略にとって非常に重要な施策であり、産業界にとっても願ってもないチャンスである。本セッションでは、アカデミアから産業界への橋渡しについて、各演者に現在行われている様々な取り組みを紹介していただくとともに、その優れた点を議論し、今後の課題について基礎研究、臨床研究の両面から前向きに検討していきたい。

AMEDにおける橋渡し・臨床研究・治験の支援について
国立研究開発法人 日本医療研究開発機構
吉田　易範

デューク大学クリニカルリサーチセンターの取り組み
Duke Clinical Research Institute
John H. Alexander

新たな産学官連携を目指した一成功事例
アレクシオンファーマ合同会社
和田　道彦

V2-S3　607会議室　14:00-15:30

難病・希少疾患の開発促進を患者さんと共に考える - 日本におけるPatient Focused Drug Developmentの将来像 -

関連領域: 薬事、臨床、アカデミア、その他（患者さん）
レベル：中級

座長
大塚ホールディングス株式会社
小林　和道

“新薬開発に患者さんの声をいかに反映させるか”この課題に、欧米はそれぞれの社会環境にあわせ独自の方策を打ち出しつつあり、Patient Focused Drug Developmentと称される活動が活発化している。一方、日本においては、どのような課題に焦点をあて患者さんの声を反映させるべきか、未だコンセンサスが得られておらず、方向性が見えていない。そのような中、本セッションでは、難病・希少疾患の開発促進を目的に、患者団体が自ら作成した研究協力・連携に関するガイドラインや、患者登録制度の進捗など日本の現状と課題を紹介し、さらに、企業が行う取組の一部を紹介しながら、今後の方向性を探る。

パネリスト
一般社団法人　日本難病・疾病協議会
伊藤　たてお

特定非営利活動法人　ASrid
西村　由希子

国立保健医療科学院
水島　洋

Pfizer Inc.
Roslyn Fleischer Schneider

V3-S3　608会議室　14:00-15:30

ここまで使える医療情報ビッグデータRWD! - 医薬品開発における活用の可能性と今後に向けた課題

関連領域: 全領域
レベル：全て

座長
東京大学大学院
清水　央子

医薬品開発はその成功確率の低下に伴い、コストも増加の一途を辿っている。そのため臨床試験の設計から市販後安全対策調査に至るまで、科学的な根拠に基づく効率的な開発プロセスの必要性が増している。そのような中さまざまな医療情報ビッグデータRWDの構築も進んでおり、Real Worldを可視化できる範囲は飛躍的に広がっている。その一方、利活用における課題も多く出てきている。本セッションでは現在利用可能な医療ビッグデータRWDの概要を理解した上で、その活用例を示しながら、利用者側だけでなくデータベースの構築やデータサイエンスの専門家も交え、さらなる活用に向けた課題と将来展望について議論を行う。

本セッションではビッグデータについて「こんな分析がしたい、可能なのか？」、「現状の課題」などの事前質問を受け付けます。2015年10月31日までにDIAの須佐(Hideo.Susa@DIAglobal.org)までメールをご送付ください。

医薬品開発における医療情報ビッグデータRWDの現状と課題
東京大学大学院
清水　央子

日本における医療ビッグデータの有益な活用実例、及びその限界
アイ・エム・エス・ジャパン株式会社
松井　信智

ビッグデータ活用を促進するITの進化とその事例
SAS Institute Japan株式会社
角田　亮

電子診療情報データベース（MID-NET）プロジェクトの現状と課題
独立行政法人 医薬品医療機器総合機構
高橋　史峰

医療データベースを利用した破壊的データ構築法
ファイザー株式会社
嶋　大輔

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　14:00-15:30

個別化医療を目指す次世代医薬品開発

関連領域: 臨床、薬事、統計、安全性、PM
レベル:初級、中級
言語:日本語のみ

座長
中外製薬株式会社
山本　英晴

個別化医療用医薬品は, 特別なものではなく, すでに市販されているものを含む全ての医薬品が個別化のための情報の追加により個別化医療用医薬品になりうる。時代のニーズとして, 医薬品開発企業にはそのような個別化のための情報を積極的に収集していくことが求められているが, そうした取り組みはあまり進んでいないのが実情である。本セッションでは, これまで開発された多くの個別化医療用医薬品でみられた臨床開発での傾向を示すとともに, これからの時代の医薬品開発企業がなすべき対応, そのために考慮すべき開発戦略および臨床試験のデザインついて議論する。

個別化医療時代の医薬品開発
ファイザー株式会社
日本製薬工業協会
土綿　慎一

アカデミア研究における患者選択のための遺伝子探索
名古屋大学医学部付属病院
平川　晃弘

個別化医療のための試験デザインに関する最近の展開 - 審査および治験相談の経験を踏まえ
独立行政法人 医薬品医療機器総合機構
佐藤　宏征

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　14:00-15:30

医薬品開発における規制当局と企業を繋ぐ効果的プロジェクトマネジメント

関連領域: 臨床、薬事、PM
レベル:初級
言語:日本語のみ

座長
第一三共株式会社
塚本　淳

有効で安全な新薬を一日でも早く患者に届けるため、規制当局も製薬企業も様々な努力を尽くしており、審査期間の短縮を始めとする様々な成果が創出されている。一方、新規技術や科学の進歩による前例のない治療法の出現やアンメットニーズの変化など新たな「チャレンジ」にも直面している。このような中、規制当局と製薬企業がさらに高品質な審査をより短期間で達成するために、今以上にどの様なことが出来るのか。本セッションでは、規制当局、製薬企業が両者の取り組みを紹介しつつ、立場を超えて一つの目的を達成するためにいま何が必要なのか、プロジェクトマネジメントの概念を活用しつつ、課題の抽出ならび討議を行いたい。

講師
株式会社CTD
小林　史明
独立行政法人 医薬品医療機器総合機構
關野　一石
ノバルティス ファーマ株式会社
竹内　真一郎

V6-S3　101会議室　14:00-15:30

円滑なアジア開発にむけて　～もっと本音で語ってみよう～

関連領域: 臨床、薬事
レベル:初級

座長
第一三共株式会社
森元　健介

日本においても国際共同試験数は増加傾向にあり、特に人種差が比較的小さいと考えられるアジア試験は開発戦略の一つとして定着しつつある。アジア試験は開発期間の短縮やコスト削減が期待できるほか、試験結果を日本のみならず、アジア諸国への承認申請にも活用する事が可能であることから、その重要性は高まりつつある。

一方で、規制、医療環境、文化などが各国で異なる事から、日本における医薬品開発の手法をそのまま持ち込むのではなく、国際経験に基づく知識、柔軟な知恵を持って試験を推進することが求められる。

本セッションでは日本、中国、台湾という異なる立場でアジア試験に関わる演者の経験、アイデアについて講演いただいた後に、パネルディスカッションで、アジア試験のあるべき姿について議論を行う。

参加者のアジア開発戦略を考える一助となれば幸いである。

アジア試験の推進への提言　～日本の立場から～
エーザイ株式会社
中濱　明子

アジア試験の推進への提言　～中国の立場から～
第一三共(中国)投資有限公司
Li Hang

アジア試験の推進への提言　～台湾の立場から～
台湾アステラス製薬股份有限公司
Sarah Lin

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　14:00-15:30

今、"副作用"を考えてみよう　～添付文書への反映と発現頻度～

関連領域: 薬事、安全性
レベル:初級

座長
ファイザー株式会社
松井　理恵

USPI、SmPC、国内添付文書を見比べると同じ薬剤でも副作用の記載が異なる。副作用として記載する基準の違い、例えば、国内添付文書では医師による因果関係判断に基づき副作用として記載する。また、副作用の発現頻度は、国内添付文書では医師による因果関係が否定できない症例に基づき算出するが、欧米では医師による因果関係判断を勘案せず集積された例数に基づき算出する。

国際共同治験から得られたデータであれば、副作用や発現頻度はUSPI、SmPC、国内添付文書で原則、同じではないのか。

本セッションでは、USPI、SmPC、国内添付文書への副作用、発現頻度の記載に違いをもたらす要因、CCDS及び各国添付文書への影響について、企業及び日本当局から考え方を解説し、パネルディスカッションにより、今後のとりうる方法を模索する。 また、EUのGVP、米国での製品訴訟リスク軽減の観点から、各国のCCDS逸脱管理について、社内ルール、プロセスについても議論する。

CCDSへの副作用の反映

Pharmiceutics, LLC

A. Leander Fontaine

日本、EU、米国の添付文書の副作用の比較

エーザイ株式会社

エドワード・スチュワート・ギリー

新薬品目及び市販品目の添付文書への"副作用"の反映 ～PMDAの立場から～

独立行政法人 医薬品医療機器総合機構

馬渡　力

パネルディスカッション

本セッションの講演者

POSTER SESSION 15:30-16:00

ポスターセッション

レセプションホール 15:30-16:00

DIA日本年会を国内外に広く開かれた学会とするために、本年より一般演題を公募することとした。本ポスターセッションでは、医療データベースの活用, 市販後安全対策, 治験の効率化（データマネジメント, リスクベーストモニタリング）, メディカルアフェアーズの話題など, 幅広いテーマから5演題が選ばれた。最近のトピックスについて活発な議論が期待される。

[PO-001] ヘルスケアデータベースを基にした市販後ベネフィット-リスク評価 - ESAを例に -

中外製薬株式会社

宮脇　奈津子

目的： ヘルスケアデータベース（DB）を基にしたベネフィット-リスク（B-R）評価の実施可能性と限界を吟味するため、Benefit Risk Action Team (BRAT) フレームワークを用い、ヘルスケアDBに基づいてエポエチン ベータ ペゴル（遺伝子組換え）（Continuous erythropoietin receptor activator: C.E.R.A. ）と他の赤血球造血刺激因子製剤（ESAs）を用いて検討した。

方法： BRAT フレームワークを用いB-Rプロファイルを検討した。Medical Data Vision (MDV) ヘルスケアDBを用い、2011年7月から2014年3月の期間で抽出された慢性腎疾患の患者として、C.E.R.A.群（131例、保存期109例、血液透析22例）、その他ESAs群（542例、保存期327例、血液透析215例）を対象とした。

結果： B-Rの各項目を主にオッズ比に基づき評価した結果、保存期、血液透析期の慢性腎疾患患者におけるC.E.R.AのB-Rプロファイルは他のESAsと同様であることが示唆された。各々のアウトカムごとに点推定値および信頼区間幅は異なったが、いくつかのサブグループ解析の結果としてB-R評価全体に顕著な違いは示されなかった。

結論： ヘルスケアDBに基づき、BRAT フレームワークを用いたB-R評価は実施可能であった。しかし、データの抽出、注目すべきアウトカムの事前定義、欠測値の補完、DBの特徴や検査値の有無に合わせたDBの取扱い等への配慮が重要である。今回の方法を実用化するため更なる研究が必要である。

[PO-002] RBM Pilot試験における意識調査

アステラス製薬株式会社

八木　美知枝

RBMのPilot試験として実施中の試験について、当該試験で用いたRBMの手順の紹介と本プロジェクトの協力者としてアサインされているSMO所属のCRCを対象としたRBMの意識調査アンケートの結果を報告する。

本試験では、TransCelerateで公表しているRACTを元としてRisk Assessmentを実施した。RACTはプロジェクト固有のリスクを可視化できる点において非常に有用なツールであった。Centralized Monitoringに関しては、一般的なRisk Indicatorに, プロジェクト固有のRisk Indicatorを追加設定し、合わせて評価を実施している。Centralized Monitoringは、設定したRisk Indicatorに基づきデータの評価を行い、施設ごとにオンサイトモニタリングの頻度を判断し、施設担当CRAへフィードバックしている。Site Monitoringは、Centralized Monitoringで指示された頻度でオンサイト／オフサイトモニタリングを実施する。またCentralized Monitoringで指摘された事項について、必要に応じて施設へ伝達し、改善策を講じ内容を報告する。例えば, EDCクエリへの対応に時間を要している施設ではクエリを定期的にチェックするプロセスを構築したり、逸脱が頻発しているようなケースでは施設でその原因となっているプロセスを改善するという内容が挙げられる。試験途中ではあるが、俯瞰的に全施設で発生しているリスクを感知することができ、Centralized Monitoring を実施する有用性を感じている。

当該Pilot試験では、SMO支援の小規模医療機関での実施がほとんどであり、アサインされたCRCを対象に、2015年3月にRBMに関する意識調査アンケートを実施し、86名から回答を得た。結果から、過半数のCRCがRBMのPilot試験を担当することにポジティブな意見であった一方でネガティブな意見も多く見られた。ネガティブな意見としては、施設での負担が増える、CRAの訪問頻度や確認内容が減ることへの不安、事前準備にかかる工数の増大等が挙げられた。試験開始から半年程経過した段階での調査であったが、実際に担当されている方の感想として、施設側の負担は以前とそれほど変わらないと回答された方が2/3程度を占めていた。一方, 残りの回答者では、負担が増えたという意見と、プロセスが整備されてむしろ効率的という意見が半々であった。今後は, 施設側の不安を解消できるよう依頼者として適切に説明を行っていくこと、またモニタリングを効率化できるようプロセス確認に重点を置いたモニタリング手法をCRAにTrainingしていくことが課題である。

[PO-003] 治験における病院情報システムから治験依頼者への直接データ送信方法の構築

国立がん研究センター東病院

青柳　吉博

目的： 治験では症例データを効率よく収集する必要があり、症例報告書として現在のところEDCが多く用いられている。EDCに登録されるデータは原資料たる病院情報システム（HIS）に保存されているデータから転記されていることから、HISより直接データを治験依頼者に提供できれば、データ入力等に関する負担が軽減され、転記ミスやデータ入力の遅延などが防止できる可能性があり、治験依頼者による施設訪問頻度も削減され、治験データの品質向上、治験の効率化・スピードアップに貢献できる。本研究では上記を実現するため、HISからのデータ抽出・送信方法を構築し、実際の治験に適用し、課題の抽出および対策を施すことで実用化の手法確立を目的とする。

方法： 本研究は治験実施医療機関として国立がん研究センター東病院、HISベンダーとして富士通株式会社、および治験依頼者としてノバルティスファーマ株式会社の3者による共同研究であり、HISより直接治験依頼者へ提供するデータ種別、送信タイミング、データの授受方法、確認方法など、システム構築および運用面の検討および確立を行った。

結果・考察： 運用検討において、対象は臨床検査値データとし、検査に紐尽く患者情報なども送信の対象とした。検査システムから取得できない情報はカルテテンプレートなどを用いてCRCによる入力内容を連携させる仕様とした。データ送信の仕様は治験依頼者仕様およびCDISC Operational Data Modelにて実装した。2バイト文字の使用が制限されるため、電子カルテデータ内の2バイト文字を処理する必要があった。本会では、システム構築における課題、運用検証において業務改善効果等について明らかにする予定である。

[PO-004] メディカルアフェアーズ部門におけるパブリケーションマネジメント - 信頼性とサイエンスの進歩のために

McCann Complete Medical

戸梶　亜弥

学会発表と論文出版を行うパブリケーション業務は、メディカルアフェアーズ活動の基礎となるものです。これは研究から得られたデータを公表し、コミュニケーションの発端となるものですが、近年その信憑性が問われる事件が相次ぎました。その対策の一つが、パブリケーション関連のガイドラインGood Publication Practice 3 (GPP3)で、パブリケーションの透明性と倫理性を高める目的で発表されました。GPP3を含めた一連のガイドラインを理解し、論文や発表の準備に反映させることが日本の医科学研究と研究者のレベルを示し、向上させる手段になります。また、パブリケーションの量と発表の時期を適切に決定し実行するマネジメントが必要です。パブリケーションマネージャーが持つべき知識と、研究活動・サイエンスの進歩にどのように貢献できるかを、国際医学出版専門業協会のGPP3策定委員会メンバーからお伝えいたします。

[PO-005] 薬の情報はどこにある? - インターネットの医薬品関連記事の定量調査 -

中外製薬株式会社
中山　輝美

目的:　「くすりと製薬産業に関する生活者意識調査(日本製薬工業協会2014年実施)」によると、患者は民間の一般Webサイトから日常的に情報収集していることが窺える。一方、2014年に医薬品医療機器法が施行されて、国民には医薬品の安全性を理解する努力義務が課せられた。医薬品の適正使用情報は命に関わることもあり、一般Webサイトが配信する医薬品関連記事の実態や活用度を知ることは、情報提供のあるべき姿を考える際の参考になるだろう。そこで、医薬品関連記事が多く配信されている一般Webサイトの実態に関する探索研究を行った。本研究では、医薬品関連記事を「薬や副作用, 特定の疾患領域に関する記事」と定義した。

方法:　オンラインニュース記事を対象とし、ニュース記事の検索ソフトウェアであるMeltwater Newsを用いて、設定した条件に合う医薬品関連記事を抽出した。抽出した記事を配信サイト毎に集計し、サイト特性の指標として全記事における医薬品関連記事の割合、サイト訪問者数等を算出した。

結果:　2014年8月1日から10月31日の期間中、2,035のサイトより88,283件の医薬品関連記事が抽出され、1日に約1,000件の医薬品関連記事がWeb上に掲載されていることが推察された。医薬品関連記事数の多いサイトについて確認した結果、上位の殆どが大手ポータルサイトの提供する総合ニュース・掲示板サイトであった。

考察:　本研究では、Meltwater Newsを用いて医薬品関連記事が容易に探索、集計でき、サイト特性の指標として記事数や医薬品関連記事の割合等が算出できることを明らかにした。今後、サイト訪問者数における医療従事者の割合や記事のSNS引用数など定量的指標の更なる検討に加え、情報の質や専門性の定性的評価に取り組む必要があろう。これらの指標を総合的に評価することで、医薬品関連記事に関して社会的影響度の大きい一般Webサイトが特定できると考える。それらのサイトと製薬企業が連携すれば, 新たなリスクコミュニケーションツールとして医療貢献につながる可能性が考えられる。一般人対象の医療用医薬品に関する広告規制を考慮した上で、時代に即した最適な情報提供のあり方について今後検討される必要があろう。

SESSION 4　16:00-17:30

V1-S4　605/606会議室　16:00-17:30

日本における産官学連携の推進を考える(第2部)

関連領域: 臨床、アカデミア、その他(Translational Research)
レベル:初級、中級

座長
千葉大学医学部附属病院
花岡　英紀
特定非営利活動法人　日本医療政策機構
京都大学
宮田　俊男

日本の医療分野における基礎から実用化までの一貫した研究開発の推進を効果的に行うため、2015年４月に「国立研究開発法人日本医療研究開発機構」(AMED:Japan Agency for Medical Research and Development)が設立された。日本から革新的医薬品を創出することは、国の成長戦略にとって非常に重要な施策であり、産業界にとっても願ってもないチャンスである。本セッションでは、アカデミアから産業界への橋渡しについて、各演者に現在行われている様々な取り組みを紹介していただくとともに、その優れた点を議論し、今後の課題について基礎研究、臨床研究の両面から前向きに検討していきたい。

バイエルのR&D連携モデル
バイエル薬品株式会社
高橋　俊一

創薬シーズアライアンスDSANJについて
大阪商工会議所
吉川　徹

日本のAROの目指すべき姿
武田薬品工業株式会社
岡本　光弘

パネルディスカッション
本セッション第1部、第2部の講演者および
アステラス製薬株式会社
百瀬　和浩

V2-S4　607会議室　16:00-17:30

患者さんや家族が本当に必要としている薬の情報とは何か?

関連領域: 薬事、アカデミア、その他(患者さん)
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

医薬品の適正使用を推進しその価値を最大化するためには、個々の医薬品のリスクとベネフィットについて医療従事者だけでなく、一般市民や患者、関連学会、メディア等、様々なステークホルダーが正しく理解することが重要である。こうした情報はインターネット等を介して瞬時に入手可能であるが、情報量は膨大で信頼性やわかりやすさの点で課題も多く、混乱や誤解を招く場合もある。今回は患者やその家族の立場から本当に必要とされている情報とその発信方法について話を伺い、産官学からの情報発信の課題と今後目指すべき方向について、海外の事例も含めて議論する。

演題未定
聖路加国際大学
中山　和弘

演題未定
患医ねっと株式会社
鈴木　信行

演題未定
独立行政法人 医薬品医療機器総合機構
田中　佑実

演題未定
みどり薬局
坂口　真弓

パネルディスカッション
本セッションの講演者

V3-S4　608会議室　16:00-17:30

薬剤疫学を利用した安全性評価に関する国際的動向

関連領域: 全領域
レベル：全て

座長
独立行政法人 医薬品医療機器総合機構
宇山　佳明

医薬品の安全性評価において、電子診療情報を活用した薬剤疫学の利用が進みつつあるが、その活用状況は、各国により異なっている。本セッションでは，日米欧の規制当局担当者をお招きし、市販後にrobustなエビデンスを収集することを目的とした電子診療情報の積極的な利用に向けての現状と課題をお話しいただきます。パネルディスカッションでは、今後の方向性と課題、国際協力に向けた課題を取り上げます。

MID-NET等の電子診療情報に基づく薬剤疫学調査の促進に向けたPMDAでの取り組み
独立行政法人 医薬品医療機器総合機構
竹内　由則

FDA's Activities Promoting Pharmacoepidemiological Safety Assessment Including Sentinel Initiative (仮)
FDA
Gerald J. Dal Pan

EMA's Activities Promoting Pharmacoepidemiological Safety Assessment Including EnCepp Initiative (仮)
<インターネット経由での講演>
European Medicines Agency
Peter Richard Arlett

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　16:00-17:30

オンコロジー領域における個別化医療の展開と将来展望

関連領域: 臨床、薬事、PM、CMC、アカデミア、その他（Government）
レベル：中級、上級
言語：日本語のみ

座長
ファイザー株式会社
廣橋　朋子

サイエンスの進歩と共に癌の分子メカニズムが飛躍的に解明され，多くの分子標的治療薬が開発されるきっかけとなった。分子標的治療薬の開発・発展と共に、バイオマーカー探索のための機器も科学的および技術的に大きな進歩を遂げており、その中でも代表的なのが、診断の次世代シークエンス（NGS）技術である。次世代シークエンス技術によるがんゲノム診断は様々な可能性を秘めている一方で、その実用化、臨床応用に向けて乗り越えなければならない課題もまだ多い。このセッションでは、NGSをどのように活用し日本で発展させるべきかについて皆さんと議論したい。

オンコロジー領域における個別化医療の展開と将来展望　ー将来NGSがどのように拡大され利用されていくのか議論してみませんか？ー
ファイザー株式会社
廣橋　朋子

NGS臨床導入に向けたアカデミアの取り組み - Multiple診断薬の開発経験から -
国立がん研究センター東病院
吉野　孝之

Multiple MarkerやNGSを導入への期待と課題
- 診断薬会社と製薬会社の両方の立場から -
株式会社キアゲン
山口　真理子

京都大学　クリニカルシークエンスの導入
京都大学
武藤　学

パネルディスカッション
本セッションの講演者

V5-S4　610会議室　16:00-17:30

若手～中堅開発マンのキャリア構築

関連領域: 臨床、薬事、統計、DM、安全性、PM
レベル：初級、中級
言語：日本語のみ

座長
MSD株式会社
小野　嘉彦

このセッションは，若手から中堅世代の開発業務に従事する人が自身のキャリア構築を考える契機となることを目指します。開発職を志望する学生にとって製薬企業は狭き門となっており，多くの学生はCROに入社しています。新薬開発の成功確率は低下し、製薬企業で成功体験に基づくキャリア構築は容易ではありません。開発職者のキャリアは多様化し，将来に漠然とした不安を抱えるケースも少なくないのではないでしょうか。本セッションでは、開発職者一筋でキャリアを形成された方、キャリアチェンジをされた方、新卒でCROに入社された方、開発職で働く外国人の方の視点から、開発職に携わる方々のキャリア構築に対する考え方を学びます。

CROの臨床開発職で働く私が考えるキャリア構築（仮題）
イーピーエス株式会社
坂口　甲陽

内資系製薬企業における臨床開発部門でのキャリア構築（仮題）
第一三共株式会社
上野　司津子

製薬企業の開発職で働く私（外国人）が考えるキャリア構築（仮題）
ノバルティスファーマ株式会社
張　方紅

開発職からのキャリアチェンジについて（仮題）
慶應義塾大学
松嶋　由紀子

パネルディスカッション
本セッションの講演者および
大塚製薬株式会社
桐生　千花
MSD株式会社
田中　義信

V6-S4　101会議室　16:00-17:30

日本のHTA - 製薬会社がなすべきことは何か

関連領域: 薬事、統計、安全性、PM、その他 (Pricing, Label)
レベル：初級

座長
バイエル薬品株式会社
安立　憲司

“医療技術評価（Health Technology Assessment: HTA）の 2016年導入”の議論から数年経つが、HTAは費用対効果という側面で、価格抑制にフォーカスされた議論に陥りやすいが、本来意図している「医療技術が持つ、患者さんやその家族、さらに医療現場や社会全体にもたらす価値を評価する場を提供し、社会の限られた資源/財源の適正配分の指標になるもの」という議論は十分に尽くされていない。また、HTAを構成する大きな要素の一つである費用対効果は、患者さんや医師が治療を選択する時のもう一つの指標になることも期待されている。本セッションでは、HTA導入を見据え、科学的な目線から製薬会社が医薬品の開発段階や市販後でなすべきこと、患者さんの関与、などについて国内外の状況も踏まえて議論する。

Clinical Trial Design, Analysis and Reporting Strategies to Maximise Reimbursement Success <インターネット経由での講演>
Amgen Ltd, United Kingdom
Chrissie Fletcher

Patient-Centric Post-Marketing Studies on Safety, Effectiveness and Value
Quintiles Real-World & Late-Phase Research
Nancy A. Dreyer

日本でのHTA導入に際し, 開発及び市販後でできることは何か？
MSD株式会社
奥山　ことば
中外製薬株式会社
荒西　利彦（インターネット経由での講演）

日本における医療技術評価の現状とアカデミアの役割
国立保健医療科学院
白岩　健

V7-S4　102会議室　16:00-17:30

これからのPharmacovigilance ～ 開発から市販後へ続く安全対策。ICH E2Eは何処へ？

関連領域: 安全性
レベル：中級

座長
公益財団法人 先端医療振興財団
鍵村　達夫

開発から市販後までの一貫した安全対策の必要性が叫ばれて久しいが, 再審査制度を中心に組み立てられた我が国のファーマコビジランス制度の中で, 依然として型にはまった従来型の使用成績調査の実施が続いている。この傾向は, 2005年のICH　E2Eガイドラインの公表, 2013年のRMP制度の実装を経た現在も大きく変わっていない。一方でglobal　study主流の現状等PVを取り巻く環境や大規模DBの利用等PVのためのサイエンスは劇的に変化しており先行してリスク管理制度を導入した欧米とのギャップは埋まるどころか追いつくのが困難なほどに広がっている。本セッションでは, 今後の日本におけるPVのあり方について, 重要なステークホルダーを迎えて議論する。

リスク管理計画の中の安全性監視、再審査制度の中の安全性監視
北里大学薬学部
成川　衛

WHY？PV課題の本質を問う
中外製薬株式会社
青木　事成

日本における安全性監視の変遷
独立行政法人 医薬品医療機器総合機構
緒方　映子

パネルディスカッション
本セッションの講演者

スペシャル チャッティング セッション

Let's Chat! "What's the DIA World 2015"

レセプションホール

17:45-19:30

関連領域: 全領域
レベル:全て

総合司会	コメンテーター		ファシリテーター
ノバルティス ファーマ株式会社	株式会社CTD	独立行政法人 医薬品医療機器総合機構	DIA Japan Contents Committee / Community
関根　恵理	**小林　史明**	**宇山　佳明**	

今年も参加者同士で気軽にネットワーキング、意見交換ができる場として、スペシャル チャッティング セッションを提供します。若手も、ご意見番も、大学の学生・先生も、医療現場の先生方、PMDAの方も、同じテーブルを囲んでしまえば、皆、仲間!一緒に語り合いましょう。

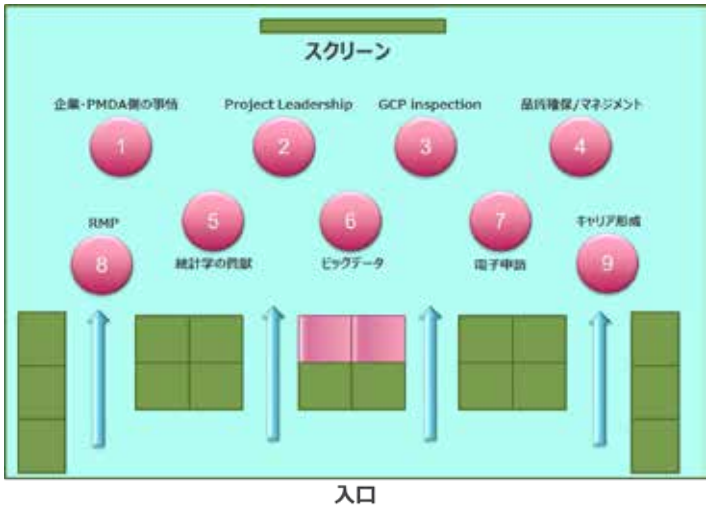
少人数のフリーディスカッション形式ですが、いくつかのお題は用意させていただく予定です。テーマをご用意しますので、ご興味のあるテーブルに是非お立ち寄りください。

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。セッションの趣旨を予めご了承ください。

【テーマ一覧:ご興味のあるテーブルにお立ち寄りください】

#	Community	トピック名	ファシリテーター	概　略
1	Regulatory Affairs	企業側の事情、PMDA側の事情を聴いてみよう	日本イーライリリー株式会社 東内　祥浩 ファイザー株式会社 金子　美由紀	業務の都合を踏まえたそれぞれの要望・本音を、事例ベースでchattingする。 例:① 相談者・申請者側:照会事項を金曜日の17時以降に出さないでほしい。外資系では、金曜日中のGlobalとの電話会議の準備が間に合わず、会議が翌週になってしまうと、週末が有効に使えない。 ② PMDA側: 3, 6, 9, 12月の中旬以降は申請しないでほしい。審査期間365日以下を死守できない確率が上がってしまう。
2	Project Management	プロジェクト・リーダーシップ	第一三共株式会社 塚本　淳 DIA Japan PM Community 今野　浩一	イノベーションとは今までと何かが異なる新しい価値を創り出すこと。プロジェクトとは明確に設定された制約や期限の中で新しい価値を創造する活動です。本セッションでは、イノベーションやブレイクスルーを生み出すプロジェクト・リーダーシップについて、プロジェクト・マネジメントの視点から話し合います。
3	Clinical Operation and Monitoring	本音で語ろう!! "GCP Inspectionのいろいろ"	ファイザー株式会社 稲泉　恵一 TBC	各部署やロールをこえて、GCP Inspectionについて、どうなっていくのか?どのような試みを行っているのか?どういう問題があるのか?等について本音で話し合う
4	CMC / Six Sigma	品質確保・マネージメントについて興味のある方募集中。	グラクソスミスクライン株式会社 藤崎　忠義 グラクソスミスクライン株式会社 井上　宏高	近年話題の品質確保・マネージメントについて、情報交換を交えて、ザックバランに話してみませんか?Risk-basedな品質管理の考え方やその手法など、各分野の皆様方による対話から、新しい何かが生まれるべく、テーブルを持ちます。是非お立ち寄り下さい。
5	Statistics	医薬品・医療機器開発への統計学の貢献	大日本住友製薬株式会社 土屋　悟 北海道大学 伊藤　陽一	今年の日本年会でもHTA, Real World Data, ICH E9 (R1), Network Meta-analysisなど数多くのテーマが取り上げられるなど、今や医薬品・医療機器開発に統計学は欠かせません。これらテーマから、統計家は今後の開発にどう貢献すべきか意見交換を行いたいと思います。あるべき統計家の貢献と自身との違いについて何かしらの気づきが得られることでしょう。
6	Clinical Strategy	ここまで来たぞビッグデータ	ファイザー株式会社 冠　和宏	年会の医療ビッグデータセッションでのディスカッションの続きを座長・演者としよう。第一線のエキスパートとワクワクするようなアイデアを考えてみませんか。ビッグデータ活用のパイオニア・エキスパートたちのナレッジとド素人ならでは発想を融合し、研究・開発から市販後安全対策のような幅広いテーマで、定量的な意思決定ができる場を拡げましょう。 ビギナーも大歓迎。今更こんなこと聞けないなんて思わずに、何でも聞いてみましょう。新しいアイデアでライバルに開発戦略に差をつけろ!
7	Clinical Data Management	電子申請はどのように変わっていくのか?今後の準備、課題は?	日本イーライリリー株式会社 土井　一也 メディデータソリューションズ株式会社 西　基秀	電子申請の本格施行に向け、皆さんの周りの企業や団体が何をしているのか、どのよう対応していくのか気になっていませんか?　皆さんの取り組みや課題を共有し、悩みを解決していきましょう。DM、統計だけでなく、薬事の観点からの課題なども大歓迎です。
8	Pharmacovigilance and Labeling	リスクマネジメントと添付文書の関係って何? CCDSの改訂に基づいて、どのように添付文書改訂の検討がされているの?日本からCCDS改訂へ貢献していますか?	日本イーライリリー株式会社 前田　玲 ファイザー株式会社 松井　理恵	リスクマネジメント管理と添付文書管理をどのようにされているか、リスクマネジメントプランと添付文書はそれぞれどのように管理され相互に影響しているのか情報共有し、また、CCDSの改訂連絡をグローバルから受けた際、どのように添付文書改訂を検討するのか、改訂根拠の検討も含め、現実に直面する問題を議論する。さらに、日本からCCDSの改訂に繋がった経験についても議論する。米国より来日予定の演者のDr. Leander Fontaineにもご同席頂きます。
9	Clinical Strategy	将来を見据えたキャリア形成 ～さぁ理想像へ向けてTake off～	ノバルティスファーマ株式会社 西野　潤一 MSD株式会社 田中　義信	将来の進路に悩む学生さん、製薬業界でのキャリアパスが思い描けない方、さらに目の前の仕事で手一杯で将来について考える暇もない若手の皆さんぜひお集まりください。心配や悩みを共有するとともに、様々なキャリア経験を積んだ産官学の先輩方のアドバイスを聞くことができるチャンス!部下の育成に悩む管理職の皆さんも是非。2日目V5-S4「若手～中堅開発マンのキャリア構築」のセッションに参加される方はこちらにも是非お立ち寄りください。

【テーブルレイアウト】



SESSION 5 9:00-10:30

V1-S5 605/606会議室 9:00-10:30

ICH E17ガイドラインに基づく今後の国際共同治験

関連領域: 臨床、薬事、統計、DM、安全性、PM、アカデミア
レベル:中級

座長
独立行政法人 医薬品医療機器総合機構
中村　龍太

医薬品の国際共同開発が進む中で、効率的な開発を行うためには、国際的整合化を考慮することが重要である。このような観点で、現在ICHにおいて国際共同治験の計画やデザインに焦点をあてたICH E17ガイドラインの作成が進んでいる。本セッションでは、ICH E17ガイドラインの検討状況とともに、PMDAにおける最近の承認審査の考え方をご紹介いただく。また、このICH E17ガイドラインを踏まえて、今後の医薬品開発はどのようになっていくのか、製薬企業の立場からもご講演いただくこととしている。パネルディスカッションにおいては、今後の医薬品開発の方向性、アジア地域における日本の役割などを取り上げる。

国際共同治験に基づく承認審査とICH E17の検討状況
独立行政法人 医薬品医療機器総合機構
鎌田　修二

これからの医薬品開発に与えるICH E17ガイドラインのインパクト:JPMAの立場から
ファイザー株式会社
日本製薬工業協会
小宮山　靖

今後の医薬品開発戦略　外資系企業の立場から
Novartis Pharmaceuticals Corporation, US
Laurie Letvak

パネルディスカッション
本セッションの講演者

V2-S5 607会議室 9:00-10:30

再生医療等製品に関する規制と審査の現状

関連領域: 臨床、薬事、安全性、PM、CMC、アカデミア、その他(MA, MW)
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　大作

再生医療は有効な治療法のない疾病に新たな治療の途を開くものとして高い期待がよせられている。再生医療の実用化に関する議論を踏まえ、日本では、2014年の薬事法改正により、再生医療等製品が新しいカテゴリとして薬事法に位置づけられ、再生医療等製品の特性を踏まえた規制の枠組みが構築された。本セッションでは、法施行後1年が経過した再生医療等製品の規制や審査の現状について議論する。

再生医療等製品規制上の注意点について
厚生労働省
柳沼　宏

再生医療等製品の品質について
独立行政法人 医薬品医療機器総合機構
丸山　良亮

再生医療等製品の非臨床安全性の実際
独立行政法人 医薬品医療機器総合機構
西村　拓也

再生医療等製品特有の造腫瘍性の考え方について
国立医薬品食品衛生研究所
佐藤　陽治

再生医療等製品の臨床試験と条件期限付承認の有効性の考え方について
独立行政法人 医薬品医療機器総合機構
佐久嶋　研

V3-S5 608会議室 9:00-10:30

日米欧におけるRisk Communication ～リスクコミュニケーションの目的とゴールについて、添付文書をはじめとしたツール類の観点から考えてみよう～(第1部)

関連領域: 安全性、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
前田　玲
厚生労働省
宇津　忍

医薬品添付文書は、その医薬品を使用する上で必要最低限の情報を限られた紙面の中で医療関係者に効率的に伝達するための重要かつ基本となるツールである。また、添付文書以外にも患者向医薬品ガイドなどリスクコミュニケーションのツールは多種多様である。このセッションでは、添付文書を中心に、日米欧の規制当局, 企業からリスクコミュニケーション戦略について提示いただき、ユーザーである医療従事者、更には患者の観点から現状のツール類に対する有効性や問題点、その解決方法について提案を提示いただく。また, スピーカーによるパネルディスカッションを行い、今後のリスクコミュニケーションのあるべき姿について議論を行う。

The Impact of Risk Communication
FDA
Gerald J. Dal Pan

Risk Minimisation Measures in The EU:
Communication, Implementation Challenges and Methods for Impact Assessment <ビデオでの講演>
European Medicines Agency
Giampiero Mazzaglia

リスクコミュニケーションツールの医療機関における認知度と利用状況
独立行政法人 医薬品医療機器総合機構
鳥井　真由美

薬のリスクから患者を守る!! これが薬剤師の役割
山口大学医学部附属病院
古川　裕之

V4-S5 609会議室 9:00-10:30

CROアウトソーシングモデルの変遷と将来像 - スポンサー及びCROの立場から

関連領域: 臨床、その他(CRO)
レベル:初級
言語:日本語のみ

座長
パレクセル・インターナショナル株式会社
中森　省吾

CROのアウトソースはモニタリングやDMのみのfunctional outsourcingから始まったが、その後、効率性の追求のために幾つかのfunctionsを組み合わせたり、臨床開発の上流から下流までを支援するfull service model、数社のCROのみに臨床開発の大部分をアウトソースするpartnership modelなど、発注元である製薬会社の要望に応じた様々のモデルが過去5年ほどの短期間で出来上がった。製薬会社によって採用するアウトソースモデルは様々であるが、今までの経験からそれらのモデルを多面的に評価する機会や、益々複雑になる臨床開発に最適なモデルについて議論する場面も少ないのが現状である。 本セッションでは、製薬会社側とCRO側から種々のアウトソースモデルを評価し、併せて将来像について議論したい。

CROアウトソーシングモデルの変遷と将来像(スポンサーの立場から)
アラガン・ジャパン株式会社
成田 佳久

CROアウトソーシングモデルの変遷と将来像(スポンサーの立場から)
アステラス製薬株式会社
津田 郁

CROアウトソーシングモデルの変遷と将来像(CROの立場から)
エイツーヘルスケア株式会社
山田 章二

CROアウトソーシングモデルの変遷と将来像(CROの立場から)
パレクセル・インターナショナル株式会社
宮澤 友明

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 9:00-10:30

日本発の小児医薬品開発を目指して

関連領域: 全領域
レベル:中級

座長
株式会社CTD
小林 史明

欧州では小児のための医薬品開発を促進するため、2007年よりPediatric investigation plan(PIP)が施行された。原則として成人に対する治験の実施中に小児治験が計画されている。一方、日本では、成人の承認後に小児の用法・用量を検証するための治験を実施する場合には、成人で付与された再審査期間が延長できるという制度があるが、小児のための医薬品開発を成人の開発と同時に開始することへの促進には繋がっていない。近年、成人での開発実施と並行して、欧米で計画された小児の国際共同治験に日本から参画する事例も増えてきている。しかしながら、今後は欧米の戦略に合わせるだけではなく、欧米における小児医薬品の開発戦略についての検討段階から日本も加わるべきであると考える。本セッションでは、欧米の制度を踏まえつつ、日本における小児医薬品開発の現状と課題について企業、規制当局及びアカデミアの立場から明らかにしていく。その上で、欧米での産官学の連携の動きも視野に入れながら、日本発の小児医薬品開発を目指すための意見交換を行う。

小児医薬品開発の現状について:企業の立場から
グラクソ・スミスクライン株式会社
中西 健

日本の小児医薬品開発について:審査の立場から
独立行政法人 医薬品医療機器総合機構
岡田 真由美

日本初の小児医薬品開発を促進するには:アカデミアの開発現場から
国立研究開発法人 国立成育医療研究センター
中村 秀文

パネルディスカッション
本セッションの講演者および
Editor-in-Chief, Therapeutic Innovation and Regulatory Science (TIRS), the official journal of the DIA
Stephen P. Spielberg

V6-S5 101会議室 9:00-10:30

電子データ申請はどのように変わっていくのか?CDISCの活用と企業の戦略について

関連領域: 臨床、薬事、統計、DM
レベル:中級

座長
第一三共株式会社
齋藤 宏暢

本年4月に、承認申請時の電子データ提出に関する実務的通知、技術的ガイドが発出されたことで、CDISC標準に準拠した電子データ提出の詳細が明確になり、さらには電子データ提出のためのシステム(ゲートウェイポータル)の枠組み、その手順も明らかになってきた。来年10月以降の本格施行に向け、規制当局、製薬企業双方の今後の準備、取り組み、課題について共有するとともに、日本の次世代審査の在り方について議論したい。また、日本のみならずグローバルでの申請を考慮した場合、このCDISC対応への戦略についても、日米のガイダンスの違い等も踏まえ考えてみたい。

申請電子データの有効活用に向けて - PMDAにおける取り組みの現状と将来展望 -
独立行政法人 医薬品医療機器総合機構
菅野 弘美

電子データ申請に対応するための社内変革 ~内資系企業の立場から~
田辺三菱製薬株式会社
後川 芳輝

米国と日本における電子データ準備および申請の経験 ~外資系企業の立場から~
<インターネット経由での講演>
Onyx Pharmaceuticals
Barrie Nelson

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
安藤 友紀

V7-S5 102会議室 9:00-10:30

Superbugsに対抗するために (耐性菌感染症をめぐる今後の抗菌薬の医薬品開発について)

関連領域: 臨床、DM、安全性、CMC
レベル:初級

座長
独立行政法人 医薬品医療機器総合機構
佐藤 淳子

抗菌薬に対する薬剤耐性菌の脅威は、"Superbugs"として世界的な問題となっている。

しかし、新たな医薬品開発への対策には、海外と日本との間に大きなギャップが存在する。

米国では、耐性菌感染症に対する新しい医薬品に対して独占期間等のインセンティブを与えるGAIN法が施行され、2013年には、アンメットメディカルニーズのある重症感染症疾患に対する新医薬品の臨床開発ガイダンス(ドラフト)が発出され、医薬品開発を促進する施策が整備されつつある。

日本においては、耐性菌感染症の医薬品開発を促進する施策はなく、臨床評価に関しては、一般感染症を対象とした抗菌薬臨床評価ガイドライン(案)が2010年に発出されているが、耐性菌感染症に関するガイダンスは存在しない。

このような海外と日本の耐性菌感染症に対する医薬品開発への取り組みの違いは、将来における耐性菌感染症に対する医薬品のドラッグラグを生じさせるものと考える。

日本の公衆衛生の向上に寄与するため、耐性菌感染症をめぐる今後の抗菌薬の医薬品開発のあり方について議論する。

薬剤耐性菌に対する医薬品開発の問題点
東京慈恵会医科大学
堀　誠治

薬剤耐性菌に対する医薬品開発の課題 (仮)
MSD株式会社
白沢　博満

The Evolution of Regulatory Framework towards Streamlined Antibacterial Drug Development (仮)
AstraZeneca
John H. Rex

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

SESSION 6　11:00-12:30

V1-S6　605/606会議室　11:00-12:30

患者にフォーカスしたメディカルアフェアーズの役割と活動 - 患者サポートプログラムによる「Beyond the Pill」

関連領域: 臨床、DM、安全性、CMC、アカデミア、その他(患者さん)
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

製薬業界におけるメディカルアフェアーズ組織は、患者中心のヘルスケアに価値をもたらす医師のパートナーとしてより重要な役割を担いつつあります。

このセッションでは、メディカルアフェアーズの一般的な役割と活動について患者重視の観点から考察します。また、その活動の一環である患者サポートプログラムの機会と課題について討議します。

これからのメディカルアフェアーズのあり方について
ブリストル・マイヤーズ株式会社
玉田　寛

患者にフォーカスしたメディカルアフェアーズ - "Beyond the Pill"
MSD株式会社
リック・サイ

2型糖尿病患者に対する自己管理支援システムーDialBetics
東京大学大学院
脇　嘉代

パネルディスカッション
本セッションの講演者

V2-S6　607会議室　11:00-12:30

薬事法改正による再生医療等製品開発の変化と今後の展望

関連領域: 臨床、薬事、安全性、PM、CMC、アカデミア
レベル:中級

座長
東京女子医科大学
岡野　光夫

再生医療を国民が迅速かつ安全に受けられるようにするための施策のひとつとして、「医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律」において「再生医療等製品」が定義され、その開発、製造・品質管理、製造販売等に係る基準も定められた。これらの基準は、今後わが国の再生医療を大きく前進させ、国際的な治療への迅速な普及を実現可能とすると期待される。本セッションでは、これらの情勢の変化をふまえ、再生医療等製品の開発等に関する企業やアカデミアの今後の展望について言及する。

日本におけるこれまでの再生医療等製品の開発と今後への展望
株式会社ジャパン・ティッシュ・エンジニアリング
吉村　圭司

再生医療等製品開発に関するアカデミアの役割について
大阪大学医学部附属病院
岡田　潔

再生医療等製品の国内開発とグローバル展開への展望
ヤンセンファーマ株式会社
寺尾　寧子

再生医療等製品開発への期待と学会の役割について
国立研究開発法人 国立成育医療研究センター
梅澤　明弘

パネルディスカッション
本セッションの講演者

V3-S6　608会議室　11:00-12:30

日米欧におけるRisk Communication ～リスクコミュニケーションの目的とゴールについて、添付文書をはじめとしたツール類の観点から考えてみよう～(第2部)

関連領域: 安全性、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
前田　玲
厚生労働省
宇津　忍

医薬品添付文書は、その医薬品を使用する上で必要最低限の情報を限られた紙面の中で医療関係者に効率的に伝達するための重要かつ基本となるツールである。また、添付文書以外にも患者向医薬品ガイドなどリスクコミュニケーションのツールは多種多様である。このセッションでは, 添付文書を中心に、日米欧の規制当局、企業からリスクコミュニケーション戦略に

ついて提示いただき、ユーザーである医療従事者、更には患者の観点から現状のツール類に対する有効性や問題点、その解決方法について提案を提示いただく。また, スピーカーによるパネルディスカッションを行い、今後のリスクコミュニケーションのあるべき姿について議論を行う。

リスクの伝え方～消費者の視点から
京都薬科大学
北澤　京子

リスクコミュニケーション：企業の観点から
日本イーライリリー株式会社
西馬　信一

パネルディスカッション
本セッション第1部、第2部の講演者および
Drug Development and Regulation
Xavier Luria

V4-S6　609会議室　11:00-12:30

ICH E9 (R1): 臨床試験の “estimand” を考える

関連領域: 臨床、統計、アカデミア
レベル：中級
言語：日本語のみ

座長
興和株式会社
菅波　秀規

ランダム化比較試験の結果を解釈困難にするものの一つとして欠測データがある（ICH E9）。欠測データをどのように扱うべきかを理解するためにはEstimandを理解する必要がある。このestimandは三極の如何なるガイドラインにも登場しない比較的新しい概念である。Estimandを理解することは欠測データを理解するための一歩であるが、Estimandの理解は欠測データの取り扱いのためだけにとどまらず、臨床試験から得るべき結論を明確にするために常に意識されるべきものである。本セッションでは、現在、ICH E9の補遺トピックでも議論がされているEstimand及び関連する事項について、非統計専門家が理解できるように解説し、議論を行う。

ICH E9 (R1) の概説
独立行政法人 医薬品医療機器総合機構
安藤　友紀

実務上の課題
ヤンセンファーマ株式会社
宮田　雅代

欠測値の取り扱いと解析方法、感度分析
小野薬品工業株式会社
冨金原　悟

パネルディスカッション
本セッションの講演者

V5-S6　101会議室　11:00-12:30

バイオ後続品産業の育成と成長戦略（バイオ後続品の使用促進の観点から）

関連領域: 全領域
レベル：中級

座長
北海道大学
荒戸　照世

日本では2009年に「バイオ後続品の品質・安全性・有効性確保のための指針」が、その後、指針のQ&Aが発出され、近年、抗体薬のバイオ後続品が承認されている。今後、バイオ後続品産業は日本においても新たな成長分野として大きな発展が期待されている。

そこで、バイオ後続品の開発が日本の医療環境をどのように変えるのか、その使用をどう促進していくのか、その上でバイオ後続品産業をどう育成していくべきかを様々な視点で討議してみたい。まずは、日本でのバイオ後続品の使用の現状と課題について企業及び医療機関の立場からのご意見を紹介いただく。次に、パネルディスカッションでは、上記演者に加え、医療機関の経営や薬剤採用の観点を踏まえた医療機関の立場からも議論に加わっていただく。

バイオ後続品の上市経験と使用促進への課題
日本化薬株式会社
塚本　哲治

Biosimilar: Learnings from Nearly 10 Years of Real World Experience
Sandoz Biopharmaceuticals
Sreedhar Sagi

バイオ後続品インスリン製剤に対する糖尿病臨床医の期待
横浜市立大学
寺内　康夫

パネルディスカッション
本セッションの講演者および
聖マリアンナ医科大学病院
増原　慶壮

V6-S6　101会議室　11:00-12:30

ICH　E6の改訂に向けて　―臨床試験におけるQuality Management System (QMS) のあり方を考える―

関連領域: 臨床、薬事、統計、DM、PM、アカデミア、その他（QA, QC）
レベル：全て

座長
ヤンセンファーマ株式会社
松下　敏

現在、ICH　E6（ICH　GCP）の改訂に関する議論が進んでおり、今後の予定としては2015年6月のStep　2を経て、2016年11月にStep　4ガイドラインが公表されることになっている。 ICH　E6改訂のメイントピックの1つとしてQuality Managementのアプローチを臨床試験の品質確保のために導入することが検討されており、従来の品質確保のアプローチを根本から見直す必要性が出てくる可能性が高い。 現在、各社が実装を開始しているRisk　Based MonitoringもQuality　Managementの1つの手法であるが、 ICH　E6が求めるものは、より体系的なアプローチであり、　組織として統合された品質管理システムの構築が必要となる。 本セッションではQuality　Management System　(QMS)のあり方や今後期待される変化及び具体的な実装方法について議論していきたい。

ICH　E6改訂が品質マネジメント活動に及ぼす影響　-　PMDAの観点から -
独立行政法人 医薬品医療機器総合機構
安田　尚之

TransCelerateのQuality　Management　System　Initiativeにおける取り組み
Janssen Pharmaceuticals, Inc.
Ann Meeker-O'Connell

Merck/MSDにおけるClinical Quality Management Modelの紹介
MSD株式会社
平山　清美

パネルディスカッション
本セッションの講演者

V7-S6　102会議室　11:00-12:30

イノベーティブな医薬品の価値を最大化するための環境、インフラについて考える　～予防接種制度と政策の再考 - 予防接種に対する躊躇の時代を迎えて～

関連領域: 薬事、その他 (Policy, Access)
レベル：中級

座長
MSD株式会社
古屋　義方

予防接種は、感染症の撲滅や感染症による死亡者数の減少等によりグローバルヘルスに大きく貢献してきた。しかしながら近年、国が推奨する予防接種であっても、さまざまな理由から接種を受けることを躊躇し、接種が遅れる、あるいは接種を受けない、いわゆるvaccine hesitancyが世界的に広がりつつある。その結果、ワクチンで予防可能な疾患のアウトブレイクが発生する等深刻な事例も報告されている。本セッションでは、vaccine hesitancyの実態と背景、そのインパクトに関する分析結果を紹介するとともに、その対策や環境整備について、国内外の産官学の専門家で議論を行う。本セッションを通じてイノベーティブなワクチンが公衆衛生に最大限貢献できる環境整備につなげたい。

Vaccine hesitancy - 世界の状況と対策 (仮)
Merck & Co., Inc.
Kyle Hathaway

日本における予防接種推進制度改革について - 課題と期待 (仮)
国立感染症研究所　感染症疫学センター
神谷　元

Vaccine Hesitancy -日本の現状と改善への取り組み (仮)
国立国際医療研究センター
堀　成美

パネルディスカッション
本セッションの講演者

ラウンドテーブル＆PMDAタウンホール

ラウンドテーブル
国際会議場 **14:00-15:30**

AROとR&D Headに聞く
～新たな医薬品開発に向けて～

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
林　憲一

浜松医科大学
渡邉　裕司

国際共同治験の浸透、AROの新興等、医薬品開発を取り巻く環境は時々刻々変化を遂げている。行政もそれらの変化に対応するため、薬事戦略相談の導入等、新たな施策を導入している。しかしながら、医薬品開発に関係するステイクホルダー間で未だ十分なコミュニケーションが築けている状況にはなく、更なる医薬品開発の効率化が期待できる。また、ドラッグラグが解消されたとはいうものの、海外のみで開発が進められる医薬品も少なくない。日本で必要とされる医薬品を海外に遅れることなく上市するために、また、世界が一丸となって効率的な医薬品開発をするために日本に欠けているもの、外資系企業にとって日本がより魅力的な国となる為の方策等、製薬企業とAROの連携等について率直な意見交換を行う。

パネリスト：

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

ファイザー株式会社
原田　明久

大阪大学医学部附属病院
名井　陽

塩野義製薬株式会社
澤田　拓子

MSD株式会社
白沢　博満

グラクソ・スミスクライン株式会社
高橋　希人

コーヒーブレイク　15:30-16:00

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：全て

座長

千葉大学医学部附属病院
花岡　英紀

MSD株式会社
白沢　博満（調整中）

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
新薬審査第四部
朝倉　渡

独立行政法人 医薬品医療機器総合機構
再生医療製品等審査部
佐藤　大作

独立行政法人 医薬品医療機器総合機構
安全第二部
佐藤　玲子

独立行政法人 医薬品医療機器総合機構
審議役（次世代審査等推進・科学委員会等推進）
鹿野　真弓

独立行政法人 医薬品医療機器総合機構
医療機器審査第二部
鈴木　由香

独立行政法人 医薬品医療機器総合機構
国際部
安田　尚之

閉会の挨拶
国際会議場 **17:30-17:45**

第12回DIA日本年会副大会長 / アステラス製薬株式会社
佐伯　訓

SPEAKER INDEX

SPEAKER INDEX

PRESENTER'S BIOGRAPHIES

Kenichi Akimoto

Former employee of GlaxoSmithKline K.K.

John H. Alexander, MD

John H. Alexander, MD, MHS, FACC, is a cardiologist and professor of medicine in the Department of Medicine, Division of Cardiology at Duke University, as well as the Vice Chief for Clinical Research in the Division of Cardiology. He is the director of cardiovascular research at the Duke Clinical Research Institute where he oversees a large group of clinical research faculty and a broad portfolio of cardiovascular clinical trials and observational clinical research programs.
Dr. Alexander's clinical interests are in acute and general cardiovascular disease, valvular heart disease, and echocardiology. His research is focused on the translation of novel therapeutic concepts into clinical data through clinical trials, specifically on the therapeutics of acute coronary syndromes and chronic coronary artery disease and cardiac surgery as well as novel methodological approaches to clinical research.

Dr. Alexander has published extensively and has served as the principle investigator of numerous multicenter clinical trials. He currently serves as the co-chair of the Clinical Trial Transformation Initiative(CTTI).

Hitoshi Amano

Managing Director, Department of Intellectual Property
Japan Agency for Medical Research and Development (AMED)

Joined Japan Patent Office (JPO), Ministry of International Trade and Industry, in April 1991. Examined concerning patent applications as an examiner and appeal examiner in the Patent Examination Department (Chemistry, Life Science and Material Science). Later served as a director of an examination division, head of the examination research office, and a chief appeals examiner. During this time, had responsibility for IP exploitation policy, university support, human resources development measures, and other matters as Director of intellectual property exploitation planning in Policy Planning and Research Division, Policy Planning and Coordination Department, JPO. In addition, collected and analyzed information on intellectual property situations in ASEAN and India as Director of Intellectual Property Rights Department, JETRO Bangkok Center, and conducted investigative research on IP policy and provided researcher training as Director of Research Department, Institute of Intellectual Property (IIP). Attained present position in April of 2015 after serving as a Cabinet Office planning officer.

Kotonari Aoki

Chugai pharmaceutical Co., Ltd.
Drug Safety Division
Drug Safety Data Management Department
Deputy Manager
Epidemiology Group Manager
Kotonari Aoki

(Biography)

1991.04. Joined Nippon Roche (Current: Chugai pharmaceutical Co., Ltd.)
Working in Biostatistics and Data Management in Drug Safety area
2002.10. Strategic alliance between Roche and Chugai.
Joined Chugai pharmaceutical Co., Ltd.
2011.01. Epidemiology Group Manager

(External activities)

The Federation of Pharmaceutical Manufacturer's Association of Japan, Drug Safety WT3 Leader
The Japan Pharmaceutical Manufacturers Association, Drug Evaluation Committee PMS Task force, Committee Task Force Leader
Association of Medical Information Infrastructure development, Observer

Councilor of Japanese Society for Pharmacoepidemiology
RMP guideline Task Force member of Japanese Society for Pharmacoepidemiology
Advisory group member of Pharmaceutical and Medical Device Regulatory Science Society of Japan

Toshihiko Aranishi

Toshihiko Aranishi is a HTA specialist in Chugai Pharmaceutical Co., Ltd. After he finished the master course at Faculty of Medicine, School of Health Sciences and Nursing, The University of Tokyo in 2007, he joined Chugai. At Chugai, he had worked as a biostatistician for 7 years. After that, since Chugai established HTA group in 2014, he has been working as a HTA specialist. He is now temporarily transferred to F. Hoffmann-La Roche Ltd as a health economist / HTA statistician. He is doing PhD at Medical and Biopharmaceutical Science, Graduate School of Pharmacy, International University of Health and Welfare Graduate School since 2013.

Wataru Asakura, PhD

Office Director, Office of New Drug IV, Pharmaceuticals and Medical Devices Agency (PMDA)

- ✓ Office of Review III, Pharmaceuticals and Medical Devices Evaluation Center of the National Institute of Health Sciences (PMDEC)
- ✓ Office of Clinical Trial Guidance, Organization of Pharmaceutical Safety and Research (OPSR/KIKO)
- ✓ Office of New Drug I, PMDA
- ✓ Office of New Drug V, PMDA
- ✓ Office of General Affairs, PMDA

Carsten Brunn

Dr. Carsten Brunn has been President of Bayer Yakuhin, Ltd. and Bayer HealthCare Representative for Japan since March 1, 2013, and President and Representative Director of Nihon Medrad K.K. since July 1, 2014. Also, he has been Chairman of EFPIA Japan since October 10, 2014.

Dr. Brunn joined Bayer HealthCare in 2011 as Global Head of Primary Care within Bayer HealthCare Pharmaceuticals. Prior to joining Bayer HealthCare, he worked for Eli Lilly, Novartis and Bausch and Lomb, experiencing management positions with increasing responsibilities.

Dr. Brunn graduated from the University of Freiburg in Germany with a Master of Science in Pharmaceutical Science in 1996. In addition, he studied at the University of Washington, USA under a research scholarship. In 1999 he received his PhD in Chemistry from the University of Hamburg, Germany. He completed his executive education at London Business School.

Born in Tuebingen, Germany, in 1970.

Nancy Dreyer

Nancy Dreyer is Global Chief of Scientific Affairs and Senior Vice President at Quintiles Real-World and Late-Phase Research where she conducts research on the safety, effectiveness, and value of medical treatments, and health and safety in professional sports. She is a senior editor of "Registries for Evaluating Patient Outcomes: A User's Guide," now in its third edition and leads the GRACE Initiative for developing Good Research Practices for Observational Studies of Comparative Effectiveness. She is a member of the FDA's National Medical Device Evaluation System Planning Board and has worked closely with the European Medicines Agency in evaluting new uses for registries and other methodologies for pharmacovigilance. She is an Adjunct Professor of Epidemiology at the University of North Carolina at Chapel Hill, a fellow of the International Society of Pharmacoepidemiology anda a former board member of DIA.
Email: nancy.dreyer@quintiles.com

Chrissie Fletcher, MSc, BSc, CStat, CSCi

Executive Director Biostatistics and Regional Head, Global Biostatistical Science, Amgen Ltd

Chrissie is a Regional Head in Global Biostatistical Science at Amgen and she leads a Health Technology Assessment (HTA) Biostatistics group. Chrissie is also leading the development of Amgen policies and processes for sharing clinical trial data with external researchers. Chrissie has worked in the Pharmaceutical Industry for over 20 years and has experience of developing and commercialising new medicines from a variety of therapeutic areas across all phases of clinical development.

Chrissie is currently the President of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI), a member of the Statisticians in the Pharmaceutical Industry (PSI)/EFSPI Regulatory Committee, chair of the PSI/EFSPI HTA Special Interest Group (SIG), member of the Integrated Data Analysis (IDA) SIG and member of the EFSPI data sharing working group. Chrissie is a member of the Clinical Development Expert Group for the European Federation of Pharmaceutical Industries and Associations (EFPIA), and she is one of 2 EFPIA representatives on the ICH E9 Revision 1 working group that is developing an addendum to E9 on estimands and sensitivity analyses. Chrissie is the Industry co-chair of the Innovative Medicines Initiative (IMI) 'GetReal' initiative Work Package 4 which is developing mathematical models and analysis tools for synthesising clinical evidence and predicting effectiveness.

Chrissie is a Chartered Statistician and Chartered Scientist of the Royal Statistical Society (RSS). Chrissie has an MSc in Applied Statistics and a BSc (Hons) in Statistics with Management Science Techniques.

Leander Fontaine, Dr. Med.

President of Pharmiceutics LLC, a consulting firm based in Pennsylvania, USA. Pharmiceutics offers consulting, training and services in the area of Core labeling, US labeling and EU labeling, including the creation of supporting rationales and documentation for core labeling implementation. Pharmiceutics' client base is in the US, in Europe and in Asia.

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.

Yosuke Fujii, PhD

Clinical Statistics, Pfizer Japan Inc.

2005 Master of Engineering, Tokyo University of Science
2007-11 Researcher, Risk Analysis Research Center, Institute of Statistical Mathematics
2011 Ph.D. in Statistical Science, Graduate University for Advanced Studies
2011- Clinical Statistics, Pfizer Japan Inc.

Katashi Fukao, MD, PhD

Education

1964 Graduated from Chiba University, School of Medicine
1969 Graduated from Chiba University, Graduate School of Medicine

Employment

1964- Japanese Red Cross Society Kyoto Daini Hospital
1969- Assistant, Department of Surgery, Chiba University Hospital
1972- Research and Clinical Fellow, Organ Transplantation Service (Prof. T.E. Starzl), Medical Center of Colorado University, USA
1975- Assistant Professor, Department of Surgery, University of Tsukuba
1983- Associate Professor, Department of Surgery, University of Tsukuba
1992- Professor, Department of Surgery, University of Tsukuba
1998- Director, University of Tukuba Hospital
2002- Director, Chiba Rosai Hospital
2007- Predident, HAB Research Organization
2013- Emeritus Director, Chiba Rosai Hospital

Satoru Fukimbara

1996/4 Ono Pharmaceutical Co., Ltd. Development Headquarters
2001/9 Kyushu Institute of Technology Faculty of Computer Science and Systems Engineering Ph.D
2003/7 Ono Pharmaceutical Co., Ltd. Manager Statistical analysis, Clinical Development Planning,
2010/4 Director Datascience Development Headquarters
2012/4 Senior Director Datascience Development Headquarters

Other

Data Science Expert Committee, Drug Evaluation Committee, JPMA

Hiroyuki Furukawa, PhD

Department of Pharmaceutical Service
Yamaguchi University Hospital
1-1-1, Minamikogushi, Ube-city, Yamaguchi, 755-8505, Japan

EDUCATION AND WORK EXPERIENCE:

1975 Mar B.S., Faculty of Pharmacy, Kanazawa University
1977 Mar M.S.Pharm., Department of Pharmaceutical Science (Pharmacology), Graduate School of Pharmacy, Kanazawa University
Apr Staff Pharmacist, Kanazawa University Hospital
2003 Mar Ph.D.., Department of Natural Science (Life Science), Graduate School of Pharmacy, Kanazawa University
Apr Associate Professor, Center for Clinical Trial Management, Kanazawa University Hospital
2009 Apr Associate Professor, Dept. of Medical Safety Management, Kanazawa University Hospital
2010 Sept Professor, Graduate School of Medicine, Yamaguchi University Director, Department of Pharmaceutical Service, Yamaguchi University Hospital
2015 Apr Director, Clinical Research Center, Yamaguchi University Hospital

Yoshikata Furuya, MSc

Yoshikata Furuya is Director, Vaccine Policy, Health Policy at MSD K.K., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., U.S.A.. He has been working on vaccine and immunization policy for over 7 years. He has delivered lectures and presentations on vaccine policy at various meetings including the government meetings. He is also an active member of Pharmaceutical Research and Manufacturers of America (PhRMA) Vaccine Committee.

Stewart Geary, MD

Senior Vice President, Chief Medical Officer
Director, Corporate Medical Affairs Headquarters, Eisai Co., Ltd.

E. Stewart Geary, M.D, has worked at Eisai since 1996 in pharmacovigilance, clinical safety and regulatory science. He is currently a member of the Executive Committee of the Japanese Association of Pharmaceutical Medicine and the DIA Advisory Committee Japan and he serves on the Editorial Advisory Boards for the publications Applied Clinical Trials and Pharmaceutical Medicine and is the Content Editor for Safety & Pharmacovigilance for the DIA Global Forum. He served on the CIOMS VII Working Group on the Development Safety Update Report, the CIOMS VIII Working Group on Signal Detection, the CIOMS Working Group on Standardized MedDRA Queries and the CIOMS IX Working Group on Medicinal Product Risk Management.

Dr Geary graduated from Harvard College summa cum laude with a bachelor's degree in chemistry in 1985. He spent a year doing basic research on insulin-like growth factor receptors at Harvard Medical School before attending Stanford Medical School from which he earned an MD degree in 1990. He went on to complete a residency in Urology at the Stanford University Medical Center in 1996. He has published on the Japanese pharmaceutical industry and lectured on global pharmaceutical regulations.

Hideki Hanaoka, MD, PhD

Dr. Hideki HANAOKA is a Director of Clinical Research Center (CCRC), Professor, Chiba University Hospital, Japan, (July, 2010 - present), and a vice director of Future Medicine Research Center, Chiba University (April 2015 – president). CCRC is an ARO that has 100 staffs and he is a leader of CCRC. He has been working at CCRC, Chiba University Hospital, since 2003 after his career at Reviewer of New Drug Evaluation Team Evaluation Division 2 Pharmaceuticals and Medical Devices Evaluating, National Institute of Health, MHLW, Japan, (2000 – 2003).

EDUCATION

Ph.D. in Medicine Chiba University Graduate School of Medicine, Japan, March 2001
Doctor of Medicine Chiba University, Medical School, Japan, March 1993

LICENSURE and CERTIFICATION

Japanese Medical License Registration, 1993
Board Certified Allergy Specialists of Japanese Society of Allergy 2004
Board Certified Member of the Japanese Society of Internal Medicine, 2004
Board Certified Clinical Pharmacology Specialists of Japanese Society of Clinical Pharmacology and Therapeutics, 2009

Li Hang, BSc

Manager/Project Lead
Clinical Research Department
Daiichi Sankyo (China) Holdings Co., Ltd.

Li Hang is a manager in Clinical Research Department, Daiichi Sankyo (China) Holdings Co., Ltd. She has worked for nearly 10 years in the area of clinical research in China. Her experience includes clinical trial design, clinical operation, clinical study report and publication etc. She graduated from Xuzhou Medical College with bachelor degree on clinical medicine.

Akihiro Hirakawa

Akihiro Hirakawa is a Lecturer of Biostatistics at the Center for Advanced Medicine and Clinical Research, Nagoya University Hospital. His areas of specialty are biostatistics, clinical trials, and bioinformatics. Prior to joining Nagoya University Hospital, he served as a reviewer in the Office of New Drug V (clinical oncology) at the Pharmaceutical and Medical Devices Agency (PMDA) from 2006 to 2011 and was an assistant professor at Tokyo University of Science, Faculty of Engineering, Management Science from 2011 to 2012.

Kiyomi Hirayama

Regional Clinical Quality Manager, Japan Clinical Quality Management, MSD K.K.

Jointed to Banyu Pharmaceuticals, in April, 1995 after graduated the Nagasaki University, Pharmacy bachelor's degree. After 2 years' experience as Medical Representative in Nagasaki, started the career in Clinical Quality area as GCP auditor. Worked as GCP auditor or management for Banyu Pharmaceuticals and MSD K.K. from 1997 to 2013, mainly responsible for Japan and Asia Pacific. From May, 2013, moved to Japan Clinical Quality Management as Regional Quality Manager, and organized the Quality Management group in MSD K.K.

Tomoko Hirohashi

Tomoko Hirohashi graduated from master course of chemical engineering in Kyusyu University Post Graduate School in 1997, and joined basic research laboratory in Banyu pharmaceutical company as a chemist. She started a new carrier in clinical development in 1999, engaged in many disease areas such as CNS, Pain, and Allergy etc. She started clinical development in oncology disease area in 2005, especially focusing on early stage programs in GI cancer and hematological malignancies. She moved to Pfizer Inc, as Japan Clinical Lead to lead several projects in oncology assets, and became Japan Development Lead to cover all oncology program from early to late stage assets. She acquired PhD degree in department of pathology and oncology, medical school of Juntendo University, 2014.

PRESENTER'S BIOGRAPHIES

Keiko Honda, PhD

I was graduated doctor degree in medicine of the graduate school of the University of Tokyo in 1994 and obtained a Ph.D. in Medicine and, following this, engaged in a 1 year post-doctoral fellowship.
I worked for YKI Patent Attorneys from 1995 to 2000. I registered as a patent attorney with the Japan Patent Attorneys Association in 2001. I joined the Center for Advanced Science and Technology Incubation in 2001 (now TODAI TLO, ltd.). In March, 2003, I joined the boards as a director of TODAI TLO,Ltd.

Ikuo Horii, PhD

Dr. Ikuo Horii is currently president & CEO of Horii-Science-Associates, and global consultant of Drug Safety Research & Development (DSRD) in Pfizer. He is a pioneer and leading scientist of toxicology field in Japan. He studied biochemistry at Hiroshima University, and pharmacology at Kyoto University. His career in a pharmaceutical company has started at F. Hoffmann-LA Roche in 1976. He studied toxicological pathology in Basel (Switzerland), and then contributed for drug discovery and development in Nippon Roche Research Center. He joined Pfizer in 2002 as a head of DSRD in Nagoya. He established Horii-Science-Associates in 2007 and accepted an appointment of Pfizer DSRD Global Consultant. He was a board member of the Japanese Society of Toxicology. As an academic and scientific activity, he is assigned as visiting professor at Showa University, Tokyo University of Science, Cambridge University and Dalian Medical University.

Koji Ikeda, PhD

Tohoku University
Clinical Research, Innovation, and Education Center, Tohoku University Hospital (CRIETO).
I graduated from Gifu Pharmaceutical University. After completing my PhD, in 2002, I got a position PMDEC (MHLW) of the predecessor of the PMDA. For about 10 years, I had been engaged in review of medical device. I have been a member of HBD (Harmonization By Doing) since the beginning, that is committed to the internationalization of medical device clinical trials. Since retirement from the PMDA in July 2012, I've been engaged in the implementation of development support of pharmaceuticals and medical devices in CRIETO and of the system development for investigator initiated clinical trial.

Masahiro Inoue, MD

Education
April. 1987 – March. 1993 Shimane Medical University Bachelors Degree. M.D.
April. 1998 – September. 2002 Graduate Medical School of Nagoya University, Internal Medicine, Nagoya, Japan. Ph.D.
April. 2010 – Mar. 2012 Graduate Medical School of International University of Welfare and Healthcare, Tokyo, Japan. Healthcare Management, h-MBA

Work Experience
Ota Memorial Hospital Dec. 2012 – present
Division head and primary physician of

Pfizer Japan Inc.
Apr. 2005 – Nov 2012
Medical Affairs in cardiovascular/Metabolism division
Medical Advisor in Clinical/Regulatory Affairs

Handa- City Hospital in Handa city, Aichi, Japan
May 2003 – Mar. 2005
Physician of Cardiovascular in Internal Medicine Department

Meijo Hospital in Nagoya city, Aichi, Japan
May 2002 – April 2003
Chief Physician of Cardiovascular in Internal Medicine Department

Residency
Tosei Hospital in Seto city, Aichi, Japan
May 1993 - March 1995

Licenses
1993 M.D.
1996 Board Certified Member of the Japanese Society of Internal Medicine
2002 Board Certified Member of The Japanese Circulation Society
2005 Fellow of the Japanese Society of Internal Medicine (FJSIM)

Kensuke Ishii

Dr. Kensuke Ishii is a Director for Medical Devices, Office of Medical Devices III, 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, Labor 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.

Mayumi Iwata-Okada, MD, PhD

Pediatrician graduated from Kumamoto University, School of Medicine, with special interest in primary immuno-deficiencies (PID). In her current position as a principal reviewer of the office of vaccines and blood products, she is in charge of review and consultation of blood products including immunoglobulins, anti-hemophilic drugs, other coagulation-associated drugs, and vaccines.

Shuji Kamada

Reviewer
Office of New Drug V
Pharmaceuticals and Medical Devices Agency (PMDA)

Kazuo Kawahara

General Manager of Clinical Affairs, Terumo Corporation
Mr. Kaz Kawahara was received the Bachelor of Science in Biology from College of Biological Sciences, University of Tsukuba, and join to Terumo Corporation in1988. General Manager of clinical affairs from 2014.

Yoko Kazami

Yoko Kazami has worked for Kitasato Academic Research Organization, Kitasato University since March 2011 and is currently a project manager, a member of operation team for Investigator initiated trials (IITs) including international multicenter trials. Prior to joining the Kitasato University, she worked for National Center for Child Health and Development as a member of IITs operation team for 2 years. Additionally, she has 7 years' of work experience as a clinical research associate at Japanese pharmaceutical companies. She obtained her BPharm from Showa University, 1997.

Kayoko Kikuchi, PhD

Kayoko Kikuchi joined Clinical and Translational Research Center, Keio University Hospital in 2009 and is currently the Head of Planning and Management Office. She has work as PM for investigator-initiated clinical trials. She has a background in clinical operation and drug development for a 10-year period in Japanese pharmaceutical companies. Additionally, she has 2 years of experience in CNS area as a CRC. She graduated from Tokyo Science University and received Ph.D. in medicine from Keio University.

Chika Kiryu, DVM, PhD

Associate Manager, Oncology, Department of Clinical Management,
Headquarters of Clinical Development, Otsuka Pharmaceutical Co., Ltd.

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.

Kyoko Kitazawa

Kyoko Kitazawa is a freelance healthcare journalist, who has been writing news and analytic health stories for over twenty years. She was a staff writer and a deputy editor of Nikkei Medical, a magazine for Japanese physicians. She finished her master degree in public health at the London School of Hygiene and Tropical Medicine in 2007. She recently published a Japanese translation of "Overdiagnosed: making people sick in the pursuit of health" written by Dr. H. Gilbert Welch, et al. She has been teaching medical sociology as a visiting professor at the Kyoto Pharmaceutical University since 2014.

Fumiaki Kobayashi, PhD

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.

PRESENTER'S BIOGRAPHIES

Koichi Konno

Koichi is a chief executive at PM consulting Positive Intention. He has started his career as a consultant of project management in 2013. He has over ten years of experience as a manager of PMO, after 10 years of working as a leader of clinical study in a pharmaceutical company. He holds certification of Project Management Professional (PMP) and he is a lead of Project Management Community of DIA Japan.

Tatsuo Kurokawa, PhD

President-Elect, DIA
Professor, Div. of Drug Development and Regulatory Sciences, Faculty of Pharmacy
Keio University

Dr. Kurokawa graduated from Chiba University, Faculty of Pharmaceutical Sciences, in 1973 and started his career as a government official of MHW (later MHLW). After 7 years of experience in GMP and drug safety/monitoring, he was dispatched to the WHO Geneva and Manila Office as an associate expert. After returning to Japan in 1982, he dealt with science and technology policy (such as Summit project). In MHW, Dr. Kurokawa worked for the promotion of bi-lateral and multi-lateral international collaboration, including trade issues among industrialized countries.

In 1989, Dr. Kurokawa was transferred to New Drug Division and involved in anti-cancer drug evaluation, and then participated in launching work of ICH with EC, USA and industry colleagues. He devoted himself as a member of ICH Steering Committee up to ICH-3, 1995. In 1994, he became Director of Office of Appropriate Use of Drug, which was responsible for drug safety and then became Director of Food Chemical Division. After 2 years of KIKO's director experience, Dr. Kurokawa was again assigned as Director of Safety Division, MHLW. With an experience of short duration assignment at PMDA, in 2004, he was appointed as Councilor, Minister's Secretariat on Pharmaceutical Affairs, MHLW. In 2008, he retired from MHLW at Councilor. Dr. Kurokawa then became a professor of international drug development and regulation, Faculty of Pharmaceutical and Medical Sciences. In 2011, he moved to his current position with Keio University. Dr. Kurokawa is a pharmacist and earned his doctorate in 1995 at Chiba University.

Hiroyuki Kusuhara, PhD

Hiroyuki Kusuhara, Ph.D. is currently Professor of Laboratory of Molecular Pharmacokinetics at Graduate School of Pharmaceutical Sciences, The University of Tokyo, Tokyo, Japan. He has graduated from the Faculty of Pharmaceutical Sciences, The University of Tokyo, in 1994, and from the Graduate School of Pharmaceutical Sciences, The University of Tokyo, in 1996 (M.S.). He started his carrier as an academic scientist in The University of Tokyo as Assistant Professor of Pharmaceutical Sciences (1998). He was promoted to Associate Professor (2004) and Professor (2012) of Graduate School of Pharmaceutical Sciences, The University of Tokyo. He received his Ph.D. from The University of Tokyo supervised by Prof. Yuichi Sugiyama in 2003. His major research interest is the role of drug transporters in the drug disposition from pharmacokinetic point of view. He has received awards: the APSTJ Global Education Seminar Presentation Award 2003 from the Academy of Pharmaceutical Science and Technology, Japan (ASPTJ); Hugh Davson Memorial Lectureship Award 2003 from the Physiological Society (London); James R. Gillette Drug Metabolism Best Papers of 2004; JSSX Award for Young Scientists from The Japanese Society of the Study of Xenobiotics (JSSX), Japan, 2006; ASPTJ Award for Young Scientists from the ASPTJ, 2006; ISSX Asian Pacific New Investigator Award from the International Society of the Study of Xenobiotics, 2009; The PSJ Award for Young Scientists from The Pharmaceutical Society Japan, 2010.

Laurie Letvak, MD

Dr. Laurie Letvak is Head of Clinical Development Policy at Novartis, a position she has held since June 2014.

Laurie has been with Novartis for over 20 years in a variety of positions. She played a key role in the development of Glivec® since 2001, responsible for Global Medical Affairs. From 2008-2012, she was the Global Program Head for Glivec and Tasigna®. In this role was responsible for leading the global development efforts for both drugs, including registration programs for new indications.

She became Global Development Head for the Critical Care Franchise in 2012. In that role she was responsible for the portfolio in specialty cardiovascular (with emphasis on heart failure) and metabolic products (lipids and atherosclerosis).

Laurie received her undergraduate and medical degrees from Cornell University. She did her internal medicine training at Boston University and her Hematology-Oncology fellowship at New York University Medical Center.

Sarah Lin

Sarah Lin is a Clinical Project Manager of Astellas Pharma Taiwan, Inc. and is currently on an exchange program in Astellas Pharma Inc. in Tokyo. Sarah is a pharmacist in profession and has been working in clinical research for 7 years with Phase 1 to Phase 4 study experience in endocrinology, transplantation and immunology, and oncology.

Shyh-Yuh Liou, PhD

Exclusive Advisor, Translational Medicine Center, Ono Pharmaceutical Co. Limited

Dr. Liou has acquired more than 30 years experience of clinical development and R&D strategy planning in several global companies' global R&D Centers, such as Pfizer, GSK, and Takeda. Currently, he serves as Exclusive Advisor in Ono to oversee the Tranlational Medicine. His expertise in pharmacogenomics allows him deliver the insightful assessment of the human genetic variance on ADME as well as the drug safety issues, and consequently, he becomes a frequent speaker in leading institutes in Japan, for example, Waseda University and Nagasaki University and other several global institutes.

His present engagements in relation to translational medicine include the following 1) the utilization of pharmacogenomics studies result in discovery and drug development; (2) ethical issues regarding pharmacogenomics in research and clinical practice across Asian countries; (3) challenges from the adoption of pharmacogenomics study in Japan.

PROFESSIONAL AFFILIATIONS

- Seat as a chairman of Japan Pharmacogenomics Data Science Consortium from 2009-2014
- Seat at PGx working Group of JMPA from Nov 2005-2008

EDUCATION

- 1986 Ph.D. in Pharmacology, Kyushu University, Japan
- 1977 B.Sc. in Pharmaceutical Science, Kaoshiung Medical University, Taiwan ROC

PROFESSIONAL EXPERIENCE

Current-04/'14

- Exclusive Advisor of Translational Medicine Center

03/'14-01/'07

- Director of Clinical Pharmacology Group, Clinic Data Science Dept., Japan Development Center, Pharmacetutical Develop. Div., Takeda Pharmaceitucal Co. Limited

PREVIOUS EXPERIENCE

12/'06-06/'02

- Head of Pharacogenetics of Asia Pacific Section; Clinical Genetic Res Office, Tsukuba Research Labs, GSK, Japan

02/'96-11/'06

- Unit Head, Pharmacology Department, Tsukuba Research Labs, Glaxo Wellcome KK (Nippon Glaxo), Tsukuba Res Labs, Japan

01/'95-09/'89

- Team leader, Research Scientist, CNS Diseases, Upjohn Pharmaceuticals Limited, Tsukuba Res Labs, Japan

08/'89-04/'87

- Research Associate at Laboratory Neuroendocrinology under Professor Dr HE Albers, Laboratory Neuroendocrinology and Behavior, Department of Biology and Psychology, Georgia State University, USA

Saku Machino

DATE & PLACE OF BIRTH
September 17, 1943, Tokyo

PRESENT STATUS
Professor Emeritus, Sophia University

LAST GRADUATION
Faculty of Law, Tokyo University, 1969

MAIN PUBLICATIONS

- Patient's Right to Self-Determination and Law, 1986
- Mental Health in Japan and the Law concerning the Observation of the Criminal Insane, 2004
- Reforming Japan's Organ Transplant Law, 2004
- To Treat the Criminal Insane, 2006
- Liberty of Bioscience Research and Its Regulation, 2011
- Bioethics and Hope in Pandora's Box for 30 years, 2013
- Life, Death and Jurisprudence, 2013

Hideki Maeda, PhD, RPh

Vice President, Medical Research, Medical Affairs, Japan, Astellas Pharma Inc.
Collaborative Researcher, Division of Drug Development and Regulatory Science, Faculty of Pharmacy, Keio University

Employment

1990-2005	Yamanouchi Pharmaceutical Co. Ltd.
2005-present	Astellas Pharma Inc

Memberships

2004-2007	Member of Clinical Evaluation Expert Committee, Drug

PRESENTER'S BIOGRAPHIES

Evaluation Committee, Japan Pharmaceutical Manufacturers Association
2005-2006 Member of new Japanese Guideline for Clinical Evaluation of Oncology Drugs, Q&A
Member of program committee for Anti-tumor Drug Development Forum
Member of board for International Symposium on Cancer Chemotherapy

Research Areas and Interests
Clinical development, Oncology, Urology, Bone metabolism, Post-marketing surveillance, Risk management plan, Safety evaluation, Regulatory science etc.

Yoshiaki Maruyama, PhD

I am currently a review director of Office of Cellular and Tissue-based Products at PMDA. I joined PMDA in 2008 and started as an officer of Office of Compliance and Standards where a secretariat for Japanese Pharmacopoeia (2008-2012). I was participated as MHLW/PMDA topic leader for the development of ICH guidelines and Annexes on "Evaluation and Recommendation of Pharmacopoeial Texts for use in the ICH Regions (Q4B)".
Before joining PMDA, I was in the University of Calgary, Canada (2001-2005) and National Center of Neurology and Psychiatry (NCNP), Tokyo, Japan (2005-2008), as a research fellow.

Nobutomo Matsui

IMS JAPAN K.K.
Commercial Effectiveness Service Principal

2000 Graduated from the Department of Pharmacy ,Tokyo University of Science
2000 Entered Yamanouchi Pharmaceutical Co., Ltd
2007 Entered BearingPoint ,Inc
2010 Entered IMS JAPAN K.K

Pharmacist
Small and Medium Enterprise Management Consultant

Yukiko Matsushima

Assistant Professor,
Keio University hospital Clinical and Translational Research Center.

After getting the Master degree of Pharmacy at Kanazawa University, Yukiko Matsushima had worked in a pharmaceutical company for several years as Clinical Research Associate, and worked in Kanazawa University Hospital as Clinical Research Coordinator for more than ten years. In 2011, she moved her working activity from the hospital to Division of Drug Development Science & Clinical Evaluation, Faculty of Pharmacy, Keio University, and has been carrying out a comparative research of CRC jobs in Japan and in other countries. In addition, she has been working as CRA at Keio University hospital Clinical and Translational Research Center since 2013.

Tsutomu Mawatari

Chief, Coordination Section / PR Section, Office of Planning and Coordination, Pharmaceuticals and Medical Devices Agency (PMDA)
He had been Reviewer, Office of Safety II and Office of New Drug IV, PMDA and had engaged in pre- and post-marketing safety information review of antibacterial drugs, vermifuge, antifungal drugs, and antiviral drugs including AIDS drugs as a risk manager until September 2015.

Ann Meeker-O'Connell

Ann Meeker-O'Connell is the Head, Risk Management and External Engagement for Johnson & Johnson's Bioresearch Quality and Compliance organization. In this role, Ann is responsible for the strategic direction and oversight of BRQC's global outreach and advocacy and risk management activities for R&D across sectors. Prior to J&J, Ann served as Director of CDER's Division of Good Clinical Practice Compliance at the U.S. Food and Drug Administration (FDA). During her tenure at FDA, Ann also served as Associate Director, Risk Science, Intelligence, and Prioritization and as a Senior Policy Advisor within the Office of Scientific Investigations. She received her M.S. in Pharmacology and B.A. in Biology from Duke University in Durham, NC. Ann is a Certified ISO 31000 Lead Risk Trainer and a Certified Compliance and Ethics Professional.

Masayo Miyata

Group manager, Trial Lead Department, Japan Clinical Operation, Janssen Pharmaceutical K.K.
My group consists of trial managers responsible for oncology clinical trials. I am responsible for the successful execution of local, regional, and/or global clinical trials. I act as the single point of accountability at the program/project level and have a direct interface with the Japan project team as well as global clinical operations in the management of clinical trials. Before current position, I had been working as a group manager of CRA for 3 years and a group manager of clinical scientist for 6 years in MSD. In another aspect, I was a vice chairperson of the clinical evaluation expert committee in the Japan Pharmaceutical Manufacturers Association up to February 2015. In the committee activity, I had discussed the issues toward the ICH E9R1 with the data science committee members.

Tomoaki Miyazawa, PhD, MBA

Portfolio Director
PAREXEL International

- Joined PAREXEL in 2013 as Associate Director of Clinical Operations managing number of cross functional matters and development projects. Assigned as Portfolio Director from January 2014 with overall operational and financial responsibilities for projects and clients in charge.
- Over 30 years professional experiences in Japanese affiliates of global pharmaceutical companies covering research (pharmacology and pharmacokinetics), preclinical and clinical development, portfolio and project management, regulatory affairs, marketing and sales as well as management of technical and commercial functions as operating officer and vice president, respectively.
- Educated in biological science and business administration with degrees of Ph.D. and MBA.

Kazuhiro Momose

Astellas Pharma Inc. 1993 Apr – Present
External Relations
Drug Discovery Research
Cabinet Secretariat 2011 Jun – 2014 Mar
Director for Office of Healthcare Policy

Kensuke Morimoto, MSc

Manager/Regional Team Leader
Asia Development Department
Daiichi Sankyo Co., Ltd.

Kensuke Morimoto is a manager in Asia Development Department, Daiichi Sankyo Co., Ltd. He was born in Japan, grew up in Japan/US, and joined Sankyo Co., Ltd in 2001 after obtaining bachelor's and master's degree in pharmacy from Kyoto University.

In Sankyo, he was initially assigned as an assistant planner/coordinator for global/local clinical studies. He later moved to Clinical Development Department then to Asia Development Department, and has been working as project/study lead since 2005. He has 12 years of experience in East/Southeast Asia clinical trials which constitutes the majority of his career, and has extensive experience in drug development covering wide range of therapeutic areas e.g., infectious disease, cardiovascular disease, diabetic complication, hematological disease and solid tumor.

Since 2006, he has been invited as a speaker/panelist for major international conferences such as DIA, ChinaTrials, and Asian Regional Drug Development Summit.

Yoshihiro Muragaki

POSITION: Professor
AFFILIATION AND ADDRESS: Faculty of Advanced Techno-Surgery(FATS), Institute of Advanced Biomedical Engineering & Science ,Graduate School of Medicine,
Tokyo Women's Medical University, 8-1 Kawada-cho Shinjuku-ku Tokyo 162-8666 Japan
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CAREER HISTORY:
Apr 2011 – present Professor
Tokyo Women's Medical University, Faculty of Advanced Techno-Surgery, Tokyo, Japan
Apr 2010 – Mar 2013 Waseda University, Graduate School of Advanced Science and Engineering PhD., Biomedical Science Tokyo, Japan
Apr 1997 Tokyo Women's Medical University PhD., Medicine Tokyo, Japan
Oct 1992 – Sep 1995 University of Pennsylvania, Department of Pathology and Laboratory Medicine, Philadelphia, USA
Apr 1987- Present Tokyo Women's Medical University, Department of Neurosurgery, Tokyo, Japan
Apr 1980 – Mar 1986 Kobe University MD., medicineKobe, Japan
SUMMARY OF PRESENT WORK:
1, Development of novel therapeutic device and therapy for cancer
2, Development of novel therapy for malignant brain tumor.
3, Establishment of information-guided surgery and precision-guided therapy
4, Development of smart cyber operating theater (SCOT)
MAJOR PUBLICATIONS:

1. Suzuki H, Aoki K, Chiba K, Muragaki Y, et al: Mutational landscape and clonal architecture in grade II and III gliomas. Nat Genet 47:458-68, 2015
2. Kinno R, Ohta S, Muragaki Y, et al: Differential reorganization of three

syntax-related networks induced by a left frontal glioma. Brain 137:1193-212, 2014
3. Muragaki Y, Akimoto J, Maruyama T, et al: Phase II clinical study on intraoperative photodynamic therapy with talaporfin sodium and semiconductor laser in patients with malignant brain tumors. J Neurosurg 119:845-52, 2013
4. Muragaki Y, Maruyama T, Iseki H, et al: Phase I/IIa trial of autologous formalin-fixed tumor vaccine concomitant with fractionated radiotherapy for newly diagnosed glioblastoma. J Neurosurg, 2011
5. Muragaki Y, Iseki H, Maruyama T, et al: Information-guided surgical management of gliomas using low-field-strength intraoperative MRI. Acta Neurochir Suppl 109:67-72, 2011
6. Muragaki Y, Chou TT, Kaplan DR, et al: Nerve growth factor induces apoptosis in human medulloblastoma cell lines that express TrkA receptors. J Neurosci 17:530-42, 1997

Filip Mussen

Filip Mussen is currently Vice President, Regional Regulatory Affairs at Janssen Research & Development. He is responsible for all regulatory activities in Asia-Pacific, Europe, Middle East and Africa, and Latin-America. Filip is based in Belgium.

Filip Mussen joined Johnson & Johnson in 2008 in the Global Regulatory Affairs – Neurosciences department. In 2011 he became the Head of the Global Labeling Centre of Excellence and had global responsibilities for end-to-end labeling for all therapeutic areas. Previously he worked at Merck & Co. since 1987, where his last position was Senior Director European Regulatory Affairs.

Filip Mussen obtained a Master of Science degree in Pharmacy from the University of Gent (Belgium), and his PhD from the Welsh School of Pharmacy at Cardiff University (UK). He has published and lectured on benefit-risk assessment, and he is the first author of a book published in 2009 about the benefit-risk appraisal of medicines.

Ryozo Nagai

Nagai was graduated from University of Tokyo Faculty of Medicine in 1974, Nagai became chairman of the department of cardiovascular medicine, director of translational research and president of the University of Tokyo Hospital.
Throughout his career Nagai has combined basic research on cardiovascular disease with clinical work. Nagai's main basic science contribution has been demonstrating that arteries have three types of smooth muscle myosin isoforms, and that in atherosclerosis and cardiac hypertrophy this reverts to the embryonic isoform (SMemb/NMHC-B). He went on to show that it was the transcription factor, KLF5 that regulates this transformation.
Leading translational research through strategic initiatives has been a recurring theme in his work. At the University of Tokyo, Nagai played a key role in the introduction of management systems to facilitate translational research and promote collaborations between scientists and industry.
As president of the Japanese Society of Cardiology (2008 - 11) Nagai established a computerised reporting systems to organise large volumes of diverse data.

Atsuo Nakagawa, MD, PhD

Dr Atsuo Nakagawa is an assistant professor of clinical research and psychiatry at Keio University School of Medicine, and is an active investigator whose research focuses on mood disorder. He obtained his medical degree at Keio University School of Medicine in 1999, and served as a resident and clinical fellow at Department of Psychiatry, Keio University Hospital. After finishing his research fellowship at Keio and Columbia University, he joined National Center of Neurology and Psychiatry in 2010 and now is the chief of clinical research training at Keio University School of Medicine.

Akihiro Nakajima

2007.3 Master of Engineering, Tokyo University of Science
2007.4- Pharmaceutical Development Administration Department, Teijin Pharma Limited

Koki Nakamura, MD, PhD

Takeda Pharmaceutical Company Limited.
2015-present: Vice President, Global Medical Affairs Japan, Takeda Pharmaceutical Company Limited.
2012-2015: Senior Director, Global Medical Affairs Japan, Takeda Pharmaceutical Company Limited.
2007-2012: Clinical Science, Takeda Pharmaceutical Company Limited.
2004-2007: Department of Cardiovascular Surgery, Shin-Tokyo Hospital.
2002-2004: Clinical Fellow, Department of Cardiothoracic Surgery, Harefield Hospital, United Kingdom.
1999-2002: Research Fellow, Department of Myocardial Preservation, Harefield Hospital, United Kingdom.
1997-1999: Department of Cardiovascular Surgery, Cardiac Center Sakakibara Hospital.
1997: PhD (Okayama University Medical School).
1992-1997: Department of Cardiovascular Surgery, Okayama University.
1992: MD (Okayama University Medical School).

Ryuta Nakamura, PhD

Review Director
Office fo new drug II
Pharmaceuticals and Medical Devices Agency (PMDA)

In 2004 I entered PMDA as a principal reviewer at Office fo new drug II* working primarily in the field of pharmacology with drugs in the Category 2, 5 and Radiopharmaceuticals. I then went on to become a Review/Consultation Team Leader for the Category 2.
In 2008 I became deputy Review Director for the Category 2.
In 2009 I became Review Director for the Category 2.
In 2011 I became Review Director for the Category 2, 5, Radiopharmaceuticals and In vivo diagnostics.

*Review Categories Covered by the Office fo new drug II
Category 2: cardiovascular drugs, antiparkinsonian drugs, anti-Alzheimer's disease drugs
Category 5: reproductive system drugs, drugs for urogenital system, combination drugs
Category Radiopharmaceuticals: Radiopharmaceuticals
Category *In vivo* diagnostics: Contrast agents, reagents for function tests (excluding *in-vitro* diagnostics)

Takeshi Nakanishi

Department Manager, New Drug Regulatory Affairs, Development & Medical Affairs Division, GSK K.K.
Takeshi Nakanishi joined GlaxoSmithKline Japan in 2013 and currently serves as Department Manager, New Drug Regulatory Affairs. He manages regulatory activities for a new drug development.

Kazuhiro Nakayama, PhD

Professor, Health Sociology & Nursing Informatics
School of Nursing, St. Luke's International University
http://www.nursessoul.info/nakayama/

Terumi Nakayama, MPharm

Drug Safety Data Management Dept.
Drug Safety Div.
Chugai Pharmaceutical Co., Ltd.

Yoshihisa Narita

For the 22 years of my career in not only Pharma but also CRO fields, I have experienced as a Monitor, Clinical Team leader, Line manager and SSU JPN head in three main therapeutic areas like Endo, CNS and Oncology in JPN & US based companies. Also I have achieved Six Sigma Black Belt. Now I have the responsible for a director of clinical operation in Allergan Japan KK.

Barrie Nelson

I have eighteen years of experience in the Biotech/Pharmaceutical industry gained within the Biostatistical Programming, Clinical Data Management, and Data Standards functional areas. I have proven ability in setting up and running data standards functions, implementing industry data standards and leading a governance body to oversee the use of data standards. I have led and, contributed to, many process improvement initiatives where standards at the heart to achieve goals of cycle time reduction, reduced operational costs and increased quality. I am currently the head of the Clinical Data Management function at Onyx Pharmaceuticals, a subsidiary of Amgen. I am a recognized CDISC SDTM expert within the BioPharma Industry. I co-lead the CDISC SDS team and a number of SDS sub teams. I have practical experience of using data standards in regulatory filings and have been involved in a number of discussion with FDA regarding the data packages included in Amgen submissions.

Takuya Nishimura, DVM, PhD

Takuya NISHIMURA, D.V.M., Ph.D., 2010-Present, Pharmaceuticals and Medical Devices Agency (PMDA)

Shinichi Nishiuma, MD

Dr Shinichi Nishiuma is currently working as Director, Global Patient Safety Japan at Eli Lilly. He graduated Kobe University School of medicine in Japan in 1997 and hold medical doctor license in Japan. He started his residency of internal medicine at Kobe city general hospital and followed by the staff in the department of Gastroenterology and Hepatology.
In 2004, he joined Eli Lilly Japan as safety physician, covering various therapeutic areas.
In 2007, he moved to clinical development group as clinical research physician,

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where he was responsible for Alzheimer's disease projects.
In 2008, he was back to safety group as lead physician and later he added his responsibility being head of surveillance group in Japan and now he is responsible for all the activities as head of safety department in Lilly Japan.
Currently he is working as vice-chairperson of Japanese association of pharmaceutical medicine and served as president of 2012 annual meeting.

Masafumi Nogimori

Masafumi Nogimori became Astellas' Representative Director and Chairman of the Company in June 2011. Concurrently, Nogimori also serves as the President of the Federation of Pharmaceutical Manufacturers' Associations of Japan and the Vice President of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) from May 2014 and October 2010 respectively.
He joined Fujisawa Pharmaceutical Co., Ltd. in 1970 and accumulated robust experience in Business Development and Corporate Strategy in key locations, including Japan, the US and Europe. He became Fujisawa's Corporate Senior Vice President of Global Corporate Strategic Planning in 2001. In 2005, Fujisawa Pharmaceutical Co., Ltd. and Yamanouchi Pharmaceutical Co., Ltd. merged to form Astellas Pharma Inc., and Nogimori became the Executive Vice President of the new company and assumed the role of the Representative Director. Immediately before assuming the current position, Nogimori served as Astellas' Representative Director, President and Chief Executive Officer from June 2006 to June 2011.

Akiko Ogata

Akiko Ogata is serves as a Review Director of Office of Safety II at Pharmaceuticals and Medical Devices Agency (PMDA). She is currently engaged in post-marketing safety measures especially in gastrointestinal drugs and drugs for metabolic disorders.
She was appointed to that position in 2014.
She joined the Organization for Pharmaceutical Safety and Research (OPSR) in 2003 and continues her career on drug review in PMDA since 2004.
She had been working as a reviewer of anesthetic drugs and sensory organ drugs for 8 years.

Kiyoshi Okada

Associate Professor, Department of Medical Innovation, Osaka University Hospital
Education
University and Medical School:
Saga medical school, Saga University, Saga, Japan.
Gradutate School:
The Department of Orthopaedics, Osaka University Graduate School of Medicine
Trainings and Professional career

2002	Intern in Dept. of Orthopaedics, Osaka National Hospital.
2005	Resident in Dept. of Orthopaedics, Kansai Rosai Hospital.
2010	Clinical fellow in Dept. of Orthop, Osaka University Hospital.
2011	Assistant Director in Office for Promotion of Regenerative Medicine Research and Development, Ministry of Health, Labour and Welfare (MHLW), Government of Japan.
2012	Medical Team Leader, Fukushima Local Nuclear Emergency Response Headquarters
2012	Assistant Director in Research and development division, Health policy Bureau, MHLW
2012	Specially appointed expert, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency.
2013	Project associate professor, Division of Medical Innovation, Osaka University Hospital
2015	Associate Professor, Division of Medical Innovation, Osaka University Hospital

Mitsuhiro Okamoto

He graduated from Kyoto Pharmaceutical University in 1986 and he had worked in clinical research for more than 20 years at Bayer, Novartis and Takeda. He had plenty of experience to develop new drugs in various therapeutic areas. He joined Takeda in 2001 and he had worked as a senior director in clinical science in 2005. Then, he served as the director of clinical coordination associated with domestic and Asian clinical trials from 2007 to 2010. In January 2011, he was seconded to Cabinet Secretariat, Government of Japan. He had been worked as the director at Office of Medical Innovation for 2 years and he was involved in government policy making for 5-year medical innovation plan. In 2013, he came back to Takeda due to his full term at Cabinet Secretariat and he is currently Associate Director of Development Management Department at Takeda Development Center Japan.

Teruo Okano, PhD

Affiliation: Tokyo Women's Medical University
8-1 Kawada-cho, Shinjuku-ku, Tokyo 162-8666 Japan

Teruo Okano is the Professor at Tokyo Women's Medical University (TWMU) in Tokyo and the Adjunct Professor of University of Utah. He received his Ph.D. from Waseda University in 1979. In 1994 he became the Full Professor of TWMU. He then became the Director of the Institute of Biomedical Engineering in 1999 and initiated the present institute, Advanced Biomedical Engineering and Science (ABMES) in 2001. He was the Vice President of TWMU and the Director of ABMES up to March, 2014. He developed temperature-responsive polymeric surfaces for harvesting cultured two-dimensional cell layers. Based on this technology, he has proposed a new concept of "Cell Sheet Engineering" which introduces an alternate path for tissue and organ regeneration. He received numerous awards including Emperor's Medal with Purple Ribbon (2009), Leona Esaki Prize (2005) and the fellow of Royal Society of Chemistry.

Ai Okazaki

Company: The University of Tokyo Hospital
Job Title: Project Specialist
March, 2002
Graduated from Kyorin University (Faculty of Health Science)
April, 2002-December, 2004
Physiological laboratory in a hospital
Duties as a Medical Technologist
December, 2004-September, 2009
Site Management Organization
Duties included: Patient screening and enrollment for clinical research study, data abstraction, treatment monitoring, adverse event reporting, regulatory maintenance and audit preparation.
October, 2009 - Jun, 2011
Non-Profit Organization Clinical Oncology Research and Education
Duties included: On site auditing of clinical trials.
Jun, 2011 - present
The University of Tokyo Hospital
Translational Research Center
Duties included: Support for translational research, monitoring of clinical trials.

Kotoba Okuyama

Kotoba Okuyama is a senior biometrician in MSD KK. After she finished the master course at Engineering Management, The Tokyo University of Science in 1995, she joined MSD KK (i.e. BANYU, the forerunner of MSD KK). At MSD KK, she had worked as a biostatistician for 20 years. She has been interested in HTA and made a poster presentation of Markov model etc. at SAS user conference last year. In this year, she has joined to a HTA task force of JPAM and then organized a planning session of HTA in SAS user conference.

Takashi Ouchi, PhD

In 2009, Takashi Ouchi, Ph.D. has graduated from the graduate school of pharmaceutical sciences. From 2009 to 2013, he was reviewer for cardiovascular devices in the Office of Medical Devices, Pharmaceuticals and Medical Devices Agency (PMDA). From 2013 to 2014, he was officer for public medical insurance in the Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare. Now, he is reviewer for cardiovascular devices in the Office of Medical Devices III, PMDA.

Sreedhar Sagi, PhD

Head of Medical Affairs Asia-Pacific
Sandoz Biopharmaceuticals,
Novartis Asia Pacific Pharmaceuticals Pte. Ltd.
Biography
Dr. Sreedhar Sagi is Head Medical Affairs Asia Pacific for Sandoz Biopharmaceuticals, a Novartis company. He oversees all Medical Affairs activities and is responsible for the Medical Affairs strategy and its implementation in the APAC region.
Prior to his current role, he was Head Safety Risk Management at Sandoz Global Headquarters in Germany, with responsibility for all Sandoz products, for Risk Management Plans and for Medical Risk Assessments for product quality issues. In a previous role, he was managing the Safety of Biosimilars, where he was responsible for the set-up, optimization and implementation of Safety Risk Management processes for Biosimilars at a global and national level. He has been with Sandoz/ Novartis since May 2007.
He holds Master's Degrees in Pharmacy (Andhra University, India) and Master's Degree in Biotechnology (Hochschule Mannheim, Germany), and a Ph.D in Medical Biotechnology from Heidelberg University in Germany.

Koyo Sakaguchi

Koyo Sakaguchi began his career in EPS Corporation which is a Clinical Research Organization after graduating from the school of pharmaceutical in 2008. He has 7 years of extensive experience in the clinical development as a Clinical Research Associate and he has worked on various fields of disease including

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Endocrine disease, Cardiovascular disease, and Gastroenterological disease. He currently serves as a Lead-CRA and supports Monitoring Leader in many ways such as negotiations with the sponsor, management of Site Management Organization, management of central laboratory, and job training for the new members.

Ken Sakushima

Pharmaceuticals and Medical Devices Agency

Experience

2013- Pharmaceuticals and Medical Devices Agency

Daisaku Sato, PhD

Daisaku Sato, PhD., Director, Office of Cellular and Tissue - based Products, Pharmaceuticals and Medical Devices Agency, JAPAN (PMDA)

Dr Daisaku Sato graduated from the Graduate School of Pharmaceutical Sciences, the University of Tokyo in 1992. He joined the Ministry of Health and Welfare (MHW) in 1992. He experienced administrational services at Ministry of Health, Labour and Welfare (MHLW) until 2011: drug reviewer, pharmacovigilance, clinical research regulations, health research funding, blood safety, ICH coordinator for MHLW.

From 1994 to 1996, he worked at Division of Drug Management and Policy, WHO (Geneva) on secondment.

In July 2011, he was assigned as Director, Office of Compliance, responsible for pharmaceutical and narcotic law enforcement at Pharmaceutical and Food Safety Bureau, MHLW. Then, in July 2013, he joined PMDA to serve as Director, Office of New Drug V, for anti-cancer drug review, and in April 2014 moved to be Director, Office of Cellular and Tissue - based Products.

Hiroyuki Sato

Biostatistics reviewer, Biostatistics Group, Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA)

Mr. Hiroyuki Sato is a Biostatistics Reviewer in PMDA. He started his career as a Biostatistics Reviewer of new drugs for psychiatric disease and CNS in 2009. Currently he is working for the review office for oncology drugs, which frequently face to advanced and complicated clinical study designs.

Takashi Sato, MS, RPh, PMP

Takashi Sato is Team Leader of Development Coordination Department, R&D Division, Kyowa Hakko Kirin Co., Ltd.

He serves as the project manager for a renewal project of an electric document management system since 2012. Prior to this project, he has been the project manager for development of several new pharmaceuticals for 8 years. He also has work experience as a CRA, and as a pharmacovigilance specialist in clinical studies.

Takashi Sato is Project Management Professional certified by Project Management Institute. Also, he started his training for coaching from 2011, has successfully completed CTI's coach training program (fundamentals and applied course), and now involve in certification program.

Tosiya Sato, PhD

Professor

Department of Biostatistics

Kyoto University School of Public Health

T. Shun Sato is the professor at Department of Biostatistics, Kyoto University School of Public Health since 2000. He worked at Department of Epidemiology, University of Tokyo, as an assistant Professor until 1991, and the Institute of Statistical Mathematics as an associate professor until 2000. His main research interests are causal inference in observational studies, epidemiologic methods, and collaborative studies in environmental and pharmaco- epidemiology and clinical trials. He was a member of the ICH E9 expert working group as a representative of the Ministry of Health and Welfare. He is a member of the Science Board at the Pharmaceuticals and Medical Device Agency since 2012.

Yoji Sato, PhD

Head, Division of Cell-Based Therapeutic Products

National Institute of Health Sciences

Dr. Yoji Sato is Head of Division of Cell-Based Therapeutic Products, National Institute of Health Sciences (Tokyo). Dr. Sato is also an Adjunct Professor of Graduate School of Pharmaceutical Sciences, Nagoya City University, a Guest Professor of Graduate School of Pharmaceutical Sciences, Osaka University, and an Adjunct Professor of Graduate School of Pharmaceutical Sciences, Kyushu University. He received his Ph.D. in Pharmaceutical Science from the University of Tokyo in 1995. While a post-doctoral fellow at the University of Cincinnati College of Medicine, he succeeded in establishing a variety of useful transgenic animal models to elucidate mechanisms of cardiac excitation-contraction coupling and heart failure. Dr. Sato's current research area is in the field of regulatory science for the quality and safety of advanced therapeutic products. He is also serving as a member of Technical Committees, Panel on Science and Technology, Health Science Council, the Ministry of Health Labour and Welfare, and as a board member of the Japanese Society for Regenerative Medicie.

E-mail: yoji@nihs.go.jp

Roslyn Schneider, MD, MSc, FACP, FCCP

Dr. Roslyn Schneider (Roz) joined Pfizer in 2006 and is the Global Patient Affairs Lead on Pfizer's Medical Leadership Team of the Chief Medical Office. In this role Roz drives patient centricity and more systematic integration of the voice of people living with illness throughout the lifecycle of medicines and their development. She has held other leadership roles in Medical Affairs, Medical Strategy and Medicine Development at Pfizer.

Roz received her Bachelor of Science from the Sophie Davis School of Biomedical Education of the City College of New York, MD from Mount Sinai School of Medicine, and later her MSc in Pharmaceutical Medicine from Hibernia College. Roz is a retired Clinical Professor of Medicine of Albert Einstein College of Medicine, an Internist, Pulmonologist, Intensivist, and cared for patients at Beth Israel Medical Center, NY, for twenty years. She presented and published primarily in the areas of pulmonary complications of HIV infection, venous thromboembolic disease, medical ethics and medical education. She is a fellow of both the American College of Physicians and the American College of Chest Physicians. She also serves on the Board of Trustees of the Physician Assistant Foundation, on the Advisory Council of the Keck Graduate Institute, and is the Co-Chair of the American College of Physicians Healthcare Roundtable.

Toru Seo, PhD

Dr. Toru Seo obtained his PhD in Molecular and Cellular Pathology from Wake Forest University and completed post-doctoral training in cardiovascular and metabolic diseases at Columbia University. He joined the faculty as an assistant professor in Department of Pediatrics at Columbia University Medical Center where he performed independent academic research as well as teaching in the field of lipid metabolism. In 2006, he moved to pursue a R&D career, focusing on target identification and preclinical pharmacology, first with GSK and then with Merck, both in Japan and the US. While at Merck in the US, his responsibilities grew to include project leader, global scientific committee member and Team Lead in Central Pharmacology, and his teams were responsible for preclinical PK/PD and pharmacology studies as well as external collaborations supporting cardiovascular and diabetes therapeutic areas. In 2012, he joined Taisho Pharmaceutical in Tokyo leading efforts in corporate strategy, scientific scouting, academic partnering, and product licensing. Leveraging his unique experience with the combination of academia and industry background, he has been actively engaging in scientific partnering efforts and he continues to lead open innovation after joining Pfizer Inc. as a head of External R&D Innovation (ERDI) in Japan, Worldwide Research & Development.

Daisuke Shima, PhD

Professional Experience

2014 – Present	Director, Cardiovascular/Metabolism, Medical Affairs, Global Established Pharma Business, Pfizer Japan
2008 – 2014	Japan Clinical Lead, Cardiovascular/Metabolism, Clinical Research, Pfizer, Japan
2006 – 2008	Study managers, Development Operation, Pfizer, Japan
2003 – 2006	CRA for Phase 1 studies, Development Operation, Pfizer, Japan

Education

2000 – 2003	PhD courses for Molecular Biology, Tokyo Institute of Technology, Tokyo, Japan

Certifications

2003	PhD in Molecular Biology

Recent additional information

2008-present	Instructor for PhD course student at Tokyo Institute of Technology

Eiko Shimizu, PhD

Pharmaco-Business Innovation, Graduate School of Pharmaceutical Sciences The University of Tokyo She obtained MS in statistics, MMA in medical regulatory science, and PhD in medical big data analytics.

With the global business management background, from 2007 to 2015 at GSK, she led an analytics team and helped GSK and other pharmaceutical companies in their R&D, epidemiology and sales/marketing based on the advanced analytics of RWD.

She is now devoting her life to build an analytics architecture for themedical Big Data in Japan.

Kaori Shinagawa, MD, PhD

Office of New Drug II

Pharmaceuticals and Medical Devices Agency

Dr. Kaori Shinagawa majored in internal medicine, with an emphasis on

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cardiology. After graduating from National Saga Medical School in 1992, she conducted medical examinations and patients treatments including clinical electrophysiological studies as a cardiologist. She received her doctoral degree of Medical Science in 2000. Her main research field was to investigate the electrophysiological mechanisms and pharmacological treatment of atrial fibrillation, and she was a postdoctoral fellow of Dr. Stanley Nattel's laboratory at Montreal Heart Institute from 1999 to 2002. She worked as a cardiologist at Eiju general hospital from 2002 to 2005. Since March 2005, she has been working at the Pharmaceuticals and Medical Devices Agency (PMDA). She is currently Senior Scientist for Clinical Medicine, PMDA. She has been involved mainly in the review and consultation of new cardiovascular drugs, and creating new guidelines for Japanese drug application. She has also been involved in International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) activities since 2005 including E14 topic.

Hiromichi Shirasawa, MD

Vice President and Executive Officer
Head of Japan Development
MSD K.K.

Professional

July 2012 - Present	Vice President and Executive Officer Head of Japan Development MSD K.K.
Jan 2010 - Feb 2012	Pfizer Japan Inc. Head of Medical Affairs, Japan and Asia Pacific
Jan 2008 – Dec 2009	Pfizer Japan Inc. Head of Regulatory Affairs
Jan 2005 – Dec 2007	Pfizer Japan Inc. Head of Development Operations
May 1999 – Dec 2004	Pfizer Japan Inc. Director, Clinical Research

Education

1995	Keio University School of Medicine

Stephen Spielberg, MD, PhD

In addition to serving as Editor-in-Chief of Therapeutic Innovation & Regulatory Science, Dr. Spielberg is currently on the Advisory Board of CASMI (Centre for Advancement of Sustainable Medical Innovation), a partnership between Oxford University and University College, London, and is a Medical Sciences Trustee, Board of Trustees of the US Pharmacopeia.

Educated at Princeton, University of Chicago, Children's Hospital Boston, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), his 40-year career in pediatrics, clinical pharmacology, drug safety, and pharmacogenomics has spanned academia in the US and Canada (including serving as Dean of Dartmouth Medical School), the pharmaceutical industry (including being VP for Pediatric Drug Development at JNJ), and drug regulation (including as Deputy Commissioner for Medical Products at the US FDA). He has published over 140 scientific papers and served on the editorial boards of numerous journals, and is a sought-after speaker on pediatrics and regulatory issues.

Hideki Suganami, PhD

1995/4	Kowa Co., Ltd.
2008/9	Tokyo university of Science Ph.D
2013/4	Director Clinical Data Science Dept.

Other
Council member of the Biometric Society of Japan
Data Science Expert Committee, Drug Evaluation Committee, JPMA
Part-time lecturer Science university of Tokyo
ICH Expert E9 (R1)

Hiromi Sugano

Hiromi Sugano is biostatistics reviewer at Office of New Drug II, and Advanced Review with Electronic Data Promotion Group, Pharmaceuticals and Medical Devices Agency(PMDA).

Shuji Sumida

Since joining CHUGAI PHARMACEUTICAL CO., LTD. in 1984, he worked in Formulation Technology, Project Management, and Quality Management function.

In Project Management functions, he was appointed the Project Leaders for R&D projects and Process Improvement Programs, and worked on Project Management Office.

At present, he is a department manager of Quality & Regulatory Compliance Dept., and in charge of oversight of Quality Management System.

Koichi Sumikura

Koichi Sumikura is Associate Professor at National Graduate Institute for Policy Studies (GRIPS). In 1998 he got a Ph.D. in engineering from the University of Tokyo, for his study on bioengineering. He had been working at Research Center for Advanced Science and Technology, the University of Tokyo, from 1998 to 2001. He has been working as Associate Professor at GRIPS since October 2001. From June 2012 to May 2015 he had also been working as Director of Research, 2nd Theory-Oriented Research Group, National Institute of Science and Technology Policy (NISTEP). He has been a board member of the Japan Society for Research Policy and Innovation Management since 2001. He is also teaching at the University of Tokyo, Tokyo University of Science, Osaka Institute of Technology and Waseda University. His main field of research is (1) intellectual property strategy, (2) policy for research and innovation and (3) innovation management.

Nobuyuki Suzuki

Nobuyuki Suzuki is testicular cancer survivor and has spina bifida. Nobuyuki Suzuki is Chief Executive Officer at Kan-i-Net Co., Ltd. which has been established to bring patients, healthcare professionals and companies together. Kan-i-Net organizes networking events for R&D professionals and patients, and provides training programs for patients at pharma companies and pharmacies. He is also Director of the NPO, Patient Speaker Bank which develops patient speakers and provides lectures by patients at universities and companies. He himself is Lectures at multiple universities.

Fumitaka Takahashi

Fumitaka Takahashi received PhD in 1997 at University of Tokyo;
1997-2000: researcher at Albert Einstein College of Medicine;
2000-2001: research assistant at Nippon Medical School;
2002-2007: research assistant at University of Tokyo;
2007-: reviewer at PMDA.

Shunichi Takahashi, PhD

Head of Open Innovation Center Japan

April 1993	Scientist / Drug Discovery Group / Mitsui Pharmaceuticals, Inc.
January 2001	Scientist / Cardiovascular Research Team / Nihon Schering K.K.
October 2001	Scientist / Cardiovascular Department / Berlex Biosciences (the US affiliate of Schering AG)
July 2007	Senior Scientist / Stem Cell Based Drug Discovery / Research Center Kobe / Bayer Yakuhin, Ltd.
October 2008	General Medicine Project Leader / Project Management / Product Development / Bayer Yakuhin, Ltd.
January 2012	Cardiovascular & Neurology Segment Manager / Project Management / Product Development / Bayer Yakuhin, Ltd.
February 2013	Head of Medical Affairs Primary Care / Medical Affairs / Bayer Yakuhin, Ltd.
June 2014	Head of Open Innovation Center Japan / Bayer Yakuhin, Ltd.
	Born on August 10, 1965 in Japan

Shigeru Takeshita, MSc, RPh

Senior Manager, Clinical Pharmacology Science Lead,
Clinical Pharmacology, Development
Astellas Pharma Inc.

Employment

1997-2005	Pharmacology Research Labs., Fujisawa Pharmaceutical Co. Ltd.
2005-2010	Pharmacology Research Labs., Astellas Pharma Inc.
2010-present	Clinical Pharmacology, Astellas Pharma Inc

Research area; Clinical pharmacology, Translational Science, Oncology, Metabolic diseases etc.

Shinichiro Takeuchi

Immunology & Dermatology Group
Drug Regulatory Affairs Dept.
Novartis Pharma K.K.

Educational record
Master degree of bioengineering at Tokyo Institute of Technology

Job record
Started working at Novartis Pharma K.K. from 2003
Experienced in CRA, Project Management and Drug regulatory Affairs department

Current position
Immunology & Dermatology Group
Drug Regulatory Affairs Department
Regulatory Affairs & Quality Assurance Division

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Yoshinori Takeuchi, DVM, PhD, MPH

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

Yoshinori Takeuchi is Pharmacoepidemiologist, Office of Medical Informatics and Epidemiology, Pharmaceuticals & Medical Devices Agency (PMDA) of Japan.

He got qualified as a veterinarian (DVM.) in 2007. He received his Ph.D. degree from the the University of Tokyo in 2011 and MPH. degree from the the University of Tokyo in 2012.

In 2012, he joined PMDA as a Pharmacoepidemiologist and assigned to the MIHARI Project which is an initiative to develop a new safety assessment system for post-marketing drugs using Japanese electronic healthcare data. As part of this project, he conducted some pharmacoepidemiological studies by using claims database. He is also serving as a statistical and epidemiological adviser for MID-NET system, which is novel electronic medical record database established by Ministry of Health, Labour & Welfare and PMDA.

Yoshinobu Tanaka

Japan Clinical Director, Oncology Clinical development, Oncology Science Unit, MSD K.K.

Yoshinobu Tanaka joined pharmaceutical company in 1999 after finishing his master in Developmental medical health course at Tokyo University graduate school. He contributed to pharmacovigilance area for 3 years and to clinical development of CNS and Oncology as clinical research associate, global study manager, clinical scientist, Asian study coordinator and Japan clinical director for 15 years. He is leading for clinical strategy community of DIA from 2015.

Yumi Tanaka

Yumi Tanaka is currently a Reviewer of Office of Safety II at Pharmaceuticals and Medical Devices Agency (PMDA) and engages in post-marketing safety measures of neurology and psychiatry drugs. She was appointed to that position in 2013.

She joined PMDA in 2008, and was involved in Office of Review Management for one year. She moved to Ministry of Health, Labor and Welfare (MHLW) from 2009 to 2010. During the period, she worked in Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau. From 2010 to 2013, she served as a OTC reviewer in the Office of OTC/Generic Drugs at PMDA .

Yutaka Tanaka, PhD

Education:

1972-1976	Faculty of Pharmaceutical Sciences, University of Tokyo
1976-1981	Graduate School of Pharmaceutical Sciences, University of Tokyo
1981	Awarded the degree of Ph. D. of Pharmaceutical Sciences (Specialized field: Oncology, Immunology and Biochemistry)

Research experience:

1981-1983	Postdoctoral Fellow at NCI Frederic Cancer Research Center, USA
1983-1984	Research Scientist at MD Anderson Cancer Center, USA

Professional experience:

Nippon Roche KK

1984-2002	Nippon Roche Research Center (NRRC) at Kamakura Discovery Research and Product Research in Oncology Area

(2002 Nippon Roche K.K. merger with Chugai Pharmaceutical CO., LTD.)

Chugai Pharmaceutical CO., LTD.

2005-2007	Renal Disease Area Department, Strategic Marketing Unit General Manager Lifecycle Leader for Erythropoiesis Stimulating Agents
2007-2009	Clinical Development Division Vice President, General Manager
2009-2011	Portfolio Management Unit Senior Vice President, Head
2011-2012	Lifecycle Management & Marketing Unit Senior Vice President, Head
2012-2014	Project & Lifecycle Management Unit Senior Vice President, Head
2014-present	Executive Vice President, Member of the Board

Yoshiaki Tazawa, VD

1981	joined Roche Diagnostics K.K. (former Nippon Roche K.K.)
2004	Division Head of Molecular Diagnostics
2007	Division Head of in-vitro Diagnostics Marketing
2014	Medical Affairs Officer

Scientific Background

Veterinary science, Molecular diagnostics, Regulatory Science of in-vitro diagnostics,

Yasuko Terao, PhD

Director, CV/Met TA leadR&D Clinical Science Division,, Janssen Pharmaceutical companies

Career at Janssen

Joined JPKK in April 2014 : 18 months in current TA lead position

Other career experiences

1996-2014 Takeda Pharmaceutical companies in Research Division,
Contributed as a biologist in broad areas, from target molecule finding to psychiatry. Spent 12 years in NS and was in charge of pre-clinical PJs for psychiatry. Planned and executed strategic and rationale management of early themes in NS from the view point of research asset portfolio. Spent one year as a research fellow in INSERM, France. Led collaborations with RIKEN, UCLA, etc. Engaged in various PJ/TFs regarding R&D management, BD, diversity, culture improvement and achieved the solid results.

Education/Certification

Bachelor and Master from Kyoto University. PhD from Kyushu University .
One year in Dr. JA Girault's lab, INSERM, France (2009-2010) as research fellow

Main role and initiatives

Responsible for the development of the Japan CVM TA strategy. Leading Regenerative medicine related activities both internally and externally.

Other interest

Loving people and science, I'm always proud of myself and colleagues in Pharma R&D. We should deliver innovative products to the people suffering from disease burden ASAP. Now I commit to deliver regenerative medicine to Japanese patients .

Aya Tokaji

Aya Takemoto Tokaji, ISMPP CMPP™, has worked in medical communication and education for 15 years and is currently the Scientific Director of the McCann Complete Medical, MDS-CMG Inc. in Tokyo. Aya is a very active member of the International Society for Medical Publication Professionals (ISMPP), serving on the Good Publication Practice 3 Steering Committee and volunteering as a workshop leader as the first ISMPP Certified Medical Publication Professional™ in Japan.

In the past several years, she undertook responsibilities in leading strategic medical communication and medical affaires activities while serving as a publication manager/planner for reputable pharmaceutical companies. She is a trusted partner and consultant for the organization aiming to achieve publication success at the global standard.

Aya holds a BA in Biology from the University of California at Berkeley and another BA in Public Health from the University of Tokyo.

Satoshi Toyoshima, PhD

Chairman of the Board of Directors, Japan Pharmacists Education Center
Professor, Faculty of pharmacy, Musashino University

Date of Birth: December 4, 1947

Education:

1970	Graduated from University of Tokyo, Faculty of Pharmaceutical Sciences
1975	Graduated from Graduate School, University of Tokyo, (Ph.D.)

Employment:

1975	Research Associate, Division of Immunochemistry, Faculty of Pharmaceutical Sciences, University of Tokyo
1977	Visiting Fellow, Laboratory of Immunology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA
1979	Research Associate, Division of Immunochemistry, Faculty of Pharmaceutical Sciences, University of Tokyo
1980	Associate Professor, Division of Immunochemistry, Faculty of Pharmaceutical Sciences, University of Tokyo
1992	Deputy Director-General, Pharmaceutical Basic Research Laboratories, Japan Tobacco Co. Ltd.
1995	Professor, Department of Biochemistry, Hoshi University
2000	Center Director, Pharmaceuticals and Medical Devices Evaluation Center, National Institute of Health Sciences
2004	Executive Director and Director, Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA)
2010	Senior Adviser of PMDA
2011	Chairman of the Board of Directors, Japan Pharmacists Education Center, from April, 2011 to present
2012	Professor, Faculty of pharmacy, Musashino University, from April, 2012 to present

PRESENTER'S BIOGRAPHIES

Rick Tsai DMD, MD

Head of Medical Affairs
Executive Offcier
MSD K.K.

Professional

2012	Head of Medical Affairs MSD K.K.
2011- 2012	Head of Medical affairs, Japan, China, Hong Kong and Taiwan Allergan
2010- 2011	Head of Regulatory Affairs, Japan Development MSD K.K.
2006- 2010	Director, Japan Development, Clinical Science, Therapeutic Area Lead for CNS and BRID (Bone, Respiratory, Immunology and Dermatology) Franchises Banyu / MSD K.K.
2004 - 2005	Chief Resident, Oral and Maxillofacial Surgery, Columbia University New York Presbyterian Hospital

Education

May 2002	Doctor of Medicine (MD) Columbia University, College of Physicians and Surgeons
May 1999	Doctor of Dental Medicine (DMD) Harvard University School of Dental Medicine

Shinichi Tsuchiwata, MS

Pfizer Japan, Ltd.

Shinichi Tsuchiwata is working as a steering committee member and Task Force Lead for clinical development of personalized medicine in Data Science Department of Japan Pharmaceutical Manufacturers Association (JPMA) since 2014. This task force is investigating development strategy, study design and statistical analysis method for personalized medicine.
He is Pharmacometrician and Clinical Pharmacologist in Pfizer Japan since 2010. He had experience of clinical development for personalized medicine includes antibody-drug conjugate and small molecule compounds metabolized by polymorphic enzyme.
Prior to joining Pfizer, he received his Bachelor and Master of Pharmaceutical Sciences degrees in biopharmaceutics from Meiji Pharmaceutical University and he is a registered pharmacist.

Atsushi Tsukamoto, PhD, MSc, PMP

Academic Background
Biochemistry Laboratory, Agrochemical
Additional Education

Tetsuji Tsukamoto

1995	Eli Lilly Japan K.K. Data Management Group, Clinical team for Oncology area
2000	AstraZeneca K.K. Clinical Development for Oncology area
2007	MSD K.K. Project Leader for Oncology area, Vaccine/infectious disease area
2012	Nippon Kayaku Co.Ltd. General Manager of Clinical Development Strategy Dept.
2015	Nippon Kayaku Co.Ltd. Head of Pharmaceutical Development Division

Toru Tsunoda

Toru Tsunoda is working for SAS Institute Japan and in charge of business development and sales support for Japanese healthcare and life sciences markets.
Before joining SAS Institute Japan in 2009, he provided management consulting services including strategy planning and business process reengineering to pharmaceutical and IT industries in global and domestic consulting firms.
He received a bachelor degree in physics from Tokyo University of Science. Also, he is a Master of Business Administration and a Ministry of Economy, Trade and Industry Registered Management Consultant.

Shizuko Ueno

Senior Director, Group VII, Clinical Execution Department, DAIICHI SANKYO CO.,LTD.
Shizuko Ueno 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 25 years experience in clinical development.

Yoshiteru Ushirogawa

EDUCATION
1991 Master of Pharmaceutics from Kyoto Pharmaceutical University

WORK EXPERIENCE
1991/04 - , Clinical Development Division, TANABE SEIYAKU Co. Ltd.
- Role was monitoring(CRA) of domestic clinical studies

1994/4 - , Pharmaceutical information Division, TANABE SEIYAKU Co. Ltd.
- Role was to learn STAT/Data Management work to bring the knowledge to clinical division and establishment of Data Management capability in the clinical division introducing new STAT/DM tools and Database.

1995/10 - , Clinical Development Division, TANABE SEIYAKU Co. Ltd.
- Role was to conduct Data Management works

2003/12 - , Assigned to an expatriate for Tanabe Pharma Development America, LLC.

2007/10 – , Project Manager, Mitsubishi Pharma America Inc.,
- Role was project management, working for two Ph3 studies

2011/4 – now, Data Science Department, Development Division, Mitsubishi Tanabe Pharma Corporation

Michihiko Wada, MD, PhD

Birth Day: April 12, 1961. 54 years old.

Current Business Title:

2014.4 – at present	Vice President & Head of Research & Development Alexion Pharma GodoKaisha.

Business:

2012.5- 2014.3	Head of Clinical Development Alexion Pharma GodoKaisha.
2010.8 – 2012.5	Director, Personalized Medicine Kanazawa Advanced Medical Center.
2007.7 – 2010.8	Manager of Specialized Medicine, Oncology Bayer Yakuhin Corporation
2001 – 2007.6	Chief Surgeon, Kobe City General Hospital Surgeon, Foundation for Biomedical Research and Innovation
2000 – 2001	Instructor, Surgery, Kyoto University
1998 – 2000	Post-doctoral Fellow, Surgery Vanderbilt University, Nashville TN, USA

Education:

1998	Ph.D. Doctor of Medical Science, Kyoto University
1986	M.D. Shiga University of Medical Science

Hiroshi Watanabe, MD, PhD

Professor, Department of Clinical Pharmacology and Therapeutics, Hamamatsu University School of Medicine
Director, Clinical Trial Center, Hamamatsu University Hospital

EDUCATION
1977-1983 M.D. Hokkaido University School of Medicine

POSITIONS HELD

1989	Research Fellow in the laboratory of Prof. H.M.Piper, Physiological Institute, University of Düsseldorf, F.R.G.
1994	Assistant Professor, Cardiovascular Division, Department of Internal Medicine III, Hamamatsu University School of Medicine
1998	Associate Professor, Department of Clinical Pharmacology and Therapeutics, Hamamatsu University School of Medicine
2005	Professor, Department of Clinical Pharmacology and Therapeutics, Hamamatsu University School of Medicine

RESEARCH FIELDS
Clinical Pharmacology and Therapeutics
Cardiovascular Medicine
Vascular Biology

MEMBERSHIPS
President: Japanese Society of Clinical Pharmacology and Therapeutics
Japanese Board Member: IUPHAR

Board Member:	Nitric Oxide Society of Japan Japanese Pulmonary Circulation Society
Councilor:	Japanese Circulation Society Japanese Society of Internal Medicine Japanese Pharmacological Society Japan Geriatrics Society Society for Regulatory Science of Medical Products

Michie Yagi

Associate Manager, Japan-Asia Clinical Development 2
Development, Astellas Pharma Inc.
Employment
2008-present Astellas Pharma Inc.

Shoji Yamada

Present Position :
Director,
Division Manager of Clinical Development Division,
A2 Healthcare Corporation
Education :
Mar. 1983 Graduated from Tokyo University of Science, Faculty of Pharmaceutical Sciences
Business Career :
Nov. 2014 Clinical Development Division / A2 Healthcare Corp.
Director, Division Manager
Jun. 2010 Development Division / ACRONET Corp.
Director, Division Manager
Dec. 2009 Development Division / ACRONET Corp.
Division Manager
Oct. 2006 Clinical Development Dept. / ACRONET Corp.
Manager
May 2005 Clinical Operations / UCB-Japan
Group Manager
Jan. 2005 Clinical Development Dept. / Aventis Pharma Japan / Sanofi-Aventis Group
Japan Project Leader
Jan. 2000 Clinical Development Dept. / Aventis Pharma Japan
Associate Clinical Manager
Apr. 1997 Clinical Development Dept.
Manager
Apr. 1991 Project Management Dept.
Assistant Manager
Apr. 1983 Laboratory for Biochemistry, Hoechst Japan

Mariko Yamaguchi

Mariko Yamaguchi, Senior Manager, RA/QA and Clinical Affairs, QIAGEN K.K.
Received Bachelor of Pharmacy from Kyoritsu College of Pharmacy (current name: Keio University), Tokyo, Japan, in 1988. Joined QIAGEN K.K. from April 2015 as the head of RAQA Japan. Before joining QIAGEN K.K., there were experiences in several IVD and pharmaceutical companies as the regulatory affairs and R&D.

Hideharu Yamamoto, PhD

CHUGAI Pharmaceutical Co., LTD.

2013-present: Statistics Group2 Manager, Clinical Science & Strategy Dept. CHUGAI Pharmaceutical Co., LTD.
2011-2012: Project Lead Statistician, Biometrics Dept., Genentech Inc.
2005-2007: Ph.D. (Tokyo University of Science)
2002-2011: Statistics Group2, Biostatistics Dept., CHUGAI Pharmaceutical Co., LTD.
1996-2002: Statistics, Biometrics Group, Pharma Development Nippon Roche

Yasunori Yoshida

Education
1988 Graduated from the University of Tokyo
Bachelor of Pharmaceutical Science
1990 Received the Master degree at the University of Tokyo
Master of Science (Pharmaceutical Science)
Business Experience
1990 Entered Ministry of Health and Welfare (MHW) of the Japanese government New Drugs Division, Pharmaceutical Affairs Bureau, MHW
1993 Evaluation and Licensing Division, Pharmaceutical Affairs Bureau, MHW
1997 Deputy Director, Medical Economics Division, Health Insurance Bureau, MHW
1998 Consul, Consulate general of Japan, Melbourne, Ministry of Foreign Affairs
2003 Director, Pharmaceutical Policy Division, Health and Welfare Department, Toyama prefecture
2008 Office Director, Office of OTC/Generic Drugs,
Pharmaceuticals and Medical Devices Agency (PMDA)
2010 Pharmaceutical Management Director, Medical Economics Division, Health Insurance Bureau, MHLW
2012 Office Director, Office of Review Management,
Leader, Advanced Review with Electronic Data Promotion Group, PMDA
2015-present
Managing Director, Department of Clinical Research and Trials
Japan Agency for Medical Research and Development (AMED)

Tohru Yoshikawa

Osaka Chamber of Commerce and Industry
2-8 Honmachi-bashi, Chuo-ku, Osaka City, JapanAddress
+81-6-6944-6484
Job title
- DSANJ program officer
- DSANJ webmaster

EDUCATION
Master of Commerce, Osaka City University, (2006)
Tohru Yoshikawa belong to Osaka Chamber of Commerce and Industry (OCCI) and his job is DSANJ (Drug Seeds Alliance Network Japan) Program officer and also a DSANJ webmaster from 2006. As a neutral position, OCCI organize DSANJ program and this program is to promote Industry-driven open innovation to realize drug discovery. DSANJ covers over 100 University, Medical College, Research Institute and Biotech Company in Japan. DSANJ gather/select their novel research result regarding Drug discovery and record to DSANJ original database. After that, DSANJ provide their information to over 70 enterprise and match up Face to Face business meeting between academia and Pharmaceutical Company. DSANJ program officer, Tohru Yoshikawa complete his degree in Master of Commerce at Osaka City University in 2006.

Keiji Yoshimura

March 26, 1985 Born
2011 3 Ph.D. (Agriculture), Graduate School of Bioagricultural Sciences, Nagoya University
2012 4 Department of Regulatory Affairs, Japan Tissue Engineering Co., Ltd. (J-TEC)
2014 11 Department of Regulatory Affairs & Consultant of Regenerative Medicine-related Laws and Regulations, J-TEC

Koichiro Yuji, MD, PhD, FACP

Koichiro Yuji is a Project Associate Professor at the Project Division of International Advanced Medical Research, the Institute of Medical Science at the University of Tokyo. He is engaged in translational research and his areas of specialty are hematology, oncology, clinical pharmacology, clinical genetics, and laboratory medicine, He has long-time clinical experience at Toranomon Hospital and the University of Tokyo and phase-I clinical trials at Kitasato Institute Hospital. He currently serves as a DIA Japan Contents Committee Member. Dr. Yuji received his Ph.D. from The University of Tokyo and his M.D. from Faculty of Medicine at The University of Tokyo.

Fanghong zhang

Fanghong Zhang, Oncology Biometrics Group, Oncology business unit, Novartis Pharma K.K.
Dr. Fanghong Zhang has joined Novartis Oncology in 2015 after 11-year experience at GlaxoSmithKline K.K. where he was responsible as a statistician for a variety of indications of Oncology compounds. He also worked for CRO as a statistical programmer for 5 years before he joined GSK. He got a PhD from Okayama University, Japan in statistics.

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クインタイルズ・トランスナショナル・ジャパン株式会社
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Email: QJPN_Global_Marketing@quintiles.com
http://www.quintiles.co.jp

i am everywhere

I've always liked being around people, but it was surprising how important that was when I started managing global clinical trials. Developing strong connections with people across the world allows me to influence events for the better. And that makes it easier to pull everything together and deliver, whether the study's in Montreal or Marrakech.

i am INC Research

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アクセス管理ツール IdentityVault™ で、各施設の治験関連ウェブサイトへのアクセスを一元管理。セントラル・ラボ、EDC、ePRO、イメージング、IWRSなどのアクセスに必要な ID/パスワード/URL/その他の関連情報を試験ごとに一元管理することで、作業の中断やフラストレーションを生じさせずに、各種サイトでのスムーズな作業をサポートします。

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トレーニングのモニタリング・ツールで治験トレーニングを標準化。施設で実施するトレーニングの記録をシステムに取り込み、インベスティゲーター・ミーティングから、Webミーティング、オンデマンド・トレーニングに至るすべてのスタイルのトレーニングを、まとめて一元管理することにより、トレーニング記録の管理にまつわる負担を劇的に減らします。また、EDC、GCP、SAEのような、複数の試験で重複するトレーニングを自動的に追跡/除去することで、施設のスタートアップ・プロセスを200%迅速化*します。

*トップ10グローバル製薬企業のお客様１社による結果

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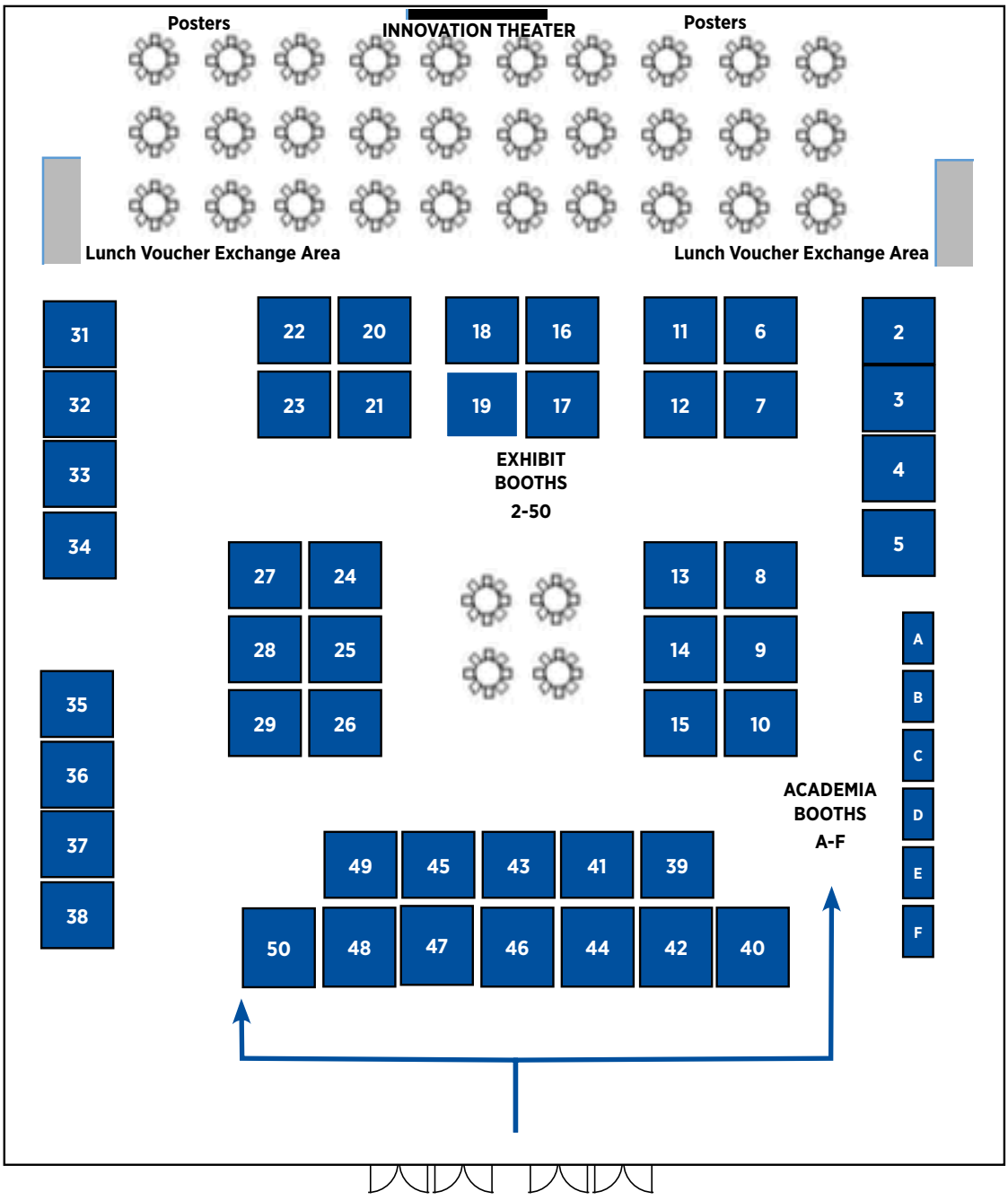
EXHIBITOR LIST AND EXHIBIT FLOOR PLAN



EXHIBITOR'S SHOWCASE

Luncheon Seminar by Plutinum Supporters
第12回DIA日本年会プラチナサポーターによるランチョンセミナー
605/606 Seminar Room

November 16th, Monday
12:45 -13:30

Plutinum Supporter : PPD-SNBL

Innovating Execution of Clinical Trials for Japanese Companies both Locally and Abroad

Through its deep global and local Japanese experience, PPD-SNBL will share real-world strategies to improve efficiency and operational delivery between CROs and Japanese pharma to help ensure success of clinical trials.

We will share our insights on:

- Cultural alignment – advancing efficient cooperation between CRO and Pharma study teams
- Making global partnerships work – aligning delivery strategy to meet the goals of global and Japanese client team
- Advanced and aligned global technologies that offer more transparency and efficiency

11月16日(月)12:45 -13:30

主催:PPD-SNBL

国内の製薬企業向けグローバル・国内臨床試験の革新的サービスの提供

新日本科学 PPD は、グローバルと国内の豊富な経験に基づき、臨床試験を確実に成功に導くため、国内製薬企業とCROとの効率的なオペレーションを実現するため以下の実践的な戦略を提供します。

- 価値観の共有 - CROと製薬会社間における臨床フェーズの効率的な協働と推進
- グローバルパートナーシップの構築 - グローバルと国内のチームの目標を一致させ成功に導くための戦略
- 透明性と効率性を向上させる先進的で機能的なグローバルテクノロジー

November 17th, Tuesday
12:45 -13:30

Plutinum Supporter : A2 Healthcare

"Think Global , Act Local"

Value-added by the exclusive partnership with PRA Health Sciences

A2 Healthcare Corporation (A2) was established in November 2014 by merger of ACRONET and GCP-CRO unit of Asklep and became one of the largest CRO in Japan with more than 860 professionals and broad therapeutic expertise.

We would like to share our experience, insights, and vision on innovative challenges for more efficient clinical development and our exclusive partnership with PRA Health Sciences (PRA), one of the top 5 global CRO.

Presentation:

I. Streamlining clinical trials utilizing eClinical Solutions
The effective usage of eClinical Solutions and implementation of RBM are the keys to streamline the clinical trials. A2 drives the paradigm shift from paper to digital such as eTMF/eCTD. A2 would like to share its experiences in Japan's local RBM study.

II. Partner experiences with PRA
How to combine local and global expertise is a critical factor for multinational studies, especially in the Japanese clinical environment. A2 and PRA have jointly developed a strategy to achieve this by combining strengths of both teams into potent project force. In this session we will introduce our Key to Success for conducting your new study.

III. FDA・EMA regulatory update & new technology
In this session, we will share updates in EU and US regulatory requirements and show how we can help Japanese clients to go globally. Finally, we will introduce our strength and advantages in Medical Informatics and the concept of data based approach to site/country selection.

11月17日(月)12:45 -13:30

主催:A2 Healthcare

Think Global , Act Localの実践

～ A2 Healthcare と PRA Health Sciences との独占提携インパクト ～

2014年11月、エイツーヘルスケア株式会社(以下"A2")はACRONETとASKLEPのGCP部門の合併により誕生いたしました。これにより、860余名を擁する国内有数のフルサービスCROとなり、豊富な受託実績と多才なリソースに基づき、顧客満足重視のサービスを幅広く展開しております。
ランチョンセミナーでは、A2の開発効率化に向けた先進的な取組みとグローバル大手CROであるPRA HEALTH SCIENCES(以下"PRA")との独占提携による協業実績についてご紹介致します。

Ⅰ. IT活用による開発効率化の最新動向
日本の治験環境に適したRBMのパイロット試験の実践、また、ETMF/ECTDなど治験プロセス全体の電子化への取り組み。これらの最新事例を踏まえた臨床開発の近未来像についてのご紹介。
Ⅱ. PRA HEALTH SCIENCES との協業実績
A2とPRAは一つのチーム体制を構築してMULTINATIONAL STUDYをサポートしております。これまでの協働プロジェクト経験を元に、成功するための「KEY TO SUCCESS」についてのご紹介。
Ⅲ. 欧米レギュラトリーUPDATE & GLOBAL最新テクノロジー
最新の規制要件(FDA・EMA)について実例紹介、および米国等でCLINICAL TRIALのFEASIBILITYを実施する際に有用なデータベースである"MEDICAL INFORMATICS"のご紹介。

Luncheon Seminar by Gold Supporters
第12回DIA日本年会ゴールドサポーターによるランチョンセミナー

November 16th, Monday
12:45 -13:30

101 Seminar Room

Gold Supporter : Quintiles

Oncology and Partnership - Innovative Clinical Development and Co-Prosperity in Oncology between Pharma and CRO

Drug makers are moving from transactional outsourcing mode to a more strategic mode with growing trend among Japanese and multi-nationals to farm out development work based on partnerships rather than project-by-project outsourcing.

With comprehensive partnership covering certain pipelines, CROs can foresee clients' long-term development plans and secure resources more efficiently than fragmentary projects consigned on a task-by-task basis. Clients are better supported for their development and regulatory filings in the US, Europe and APAC at a time when they are accelerating their drive to conduct multinational clinical trials with partnership with global CRO.

This session including panel discussion facilitated by our Oncology expert outlines with examples how Quintiles can help clients improve their probability of success with comprehensive partnership.

11月16日(月) 12:45 -13:30

101セミナールーム　　主催:Quintiles

オンコロジーとパートナーシップ – オンコロジーにおける革新的な医薬品開発および製薬メーカーとCROの共存共栄のあり方

内資・外資問わず医薬品開発の外注は、ある特定のパイプラインを包括的に網羅するパートナーシップが昨今の傾向です。この方法では、CROはお客様の長期開発計画を予見し、効率的・戦略的にリソースを確保・配分できます。特にグローバルに強い弊社の場合は、より短期間・低コストで世界市場を対象に、お客様のニーズに合わせて高品質な国際共同試験等を円滑に実施できます。弊社のオンコロジーの専門家によるパネルディスカッションを含む予定の本セミナーでは、特に全世界的の重要治療分野、オンコロジーで具体例をご紹介します。

November 16th, Monday
12:45 -13:30

102 Seminar Room

Gold Supporter : Medidata

TMedidata RBM - Fastest way to realize the quality, cost and timeline benefits of risk-based monitoring -

A comprehensive, systematic approach to risk-based monitoring, Medidata RBM includes a robust combination of technology, analytics and hands-on strategic consulting services that enable life science organizations to quickly realize the quality, cost and timeline benefits of a RBM program. We will show you the benefits of Medidata's RBM solution with case example and CSA (Centralized Statistical Analytics) demonstration.

11月16日(月) 12:45 -13:30

102セミナールーム　　主催:Medidata

Medidata RBM - リスクに基づくモニタリングの品質向上、コスト削減、時間短縮といったベネフィットを実現させる方法 -

リスクに基づくモニタリング手法への包括的かつ体系的なアプローチであるMEDIDATA　RBMは、テクノロジー、アナリティクスおよび実践的な戦略的コンサルティングサービスが緊密に連携しており、ライフサイエンス企業はRBM 導入による品質向上、コスト削減、時間短縮を実現できます。本セミナーでは、 事例やCSA のデモを交えながら、MEDIDATAのRBMソリューションをご紹介します。

November 17th, Tuesday
12:45 -13:30

101 Seminar Room

Gold Supporter : INC Research

Emerging Markets and Global Best Practices: INC Research – Your Connection to Success!

INC Research is a therapeutically aligned, full service, global Contract Research Organization. We have in 65 offices in 46 countries worldwide, with our global headquarters in Raleigh, North Carolina. In Japan, we have offices in both Osaka and Tokyo.

This luncheon talk will introduce you to INC Research and briefly discuss three ways in which we integrate and support innovation in the realm of clinical trial research- globally and within Japan. We will focus on following three innovations:

1) Strategic Data Monitoring
2) Regenerative Medicine Product Development in Japan
3) Global Outlook/Local Expertise

11月17日(火) 12:45 -13:30

101セミナールーム　　主催:INC Research

エマージング・マーケットとグローバル・ベスト・プラクティス:アイエヌシーリサーチ～成功への道～

アイエヌシー・リサーチは治療領域ごとに高い専門性を備えた、フル・サービスのグローバルCROです。本社はノースカロライナのローリーにあり、世界46カ国に65のオフィスを有しています。日本では大阪と東京にオフィスを構えています。

今回はアイエヌシー・リサーチについてご紹介させていただき、弊社が世界的に、また、日本において臨床試験研究の領域でどのようにイノベーションを統合しサポートしているかをご説明させていただきます。弊社は以下の3つのイノベーションにフォーカスしています。

1) 戦略的データモニタリングについて
2) 日本での再生医療製品の開発について
3) グローバル視点の展望/国内の専門性について

November 17th, Tuesday
12:45 -13:30

102 Seminar Room

Gold Supporter : Medidata

Risk-Based Monitoring – Best Practices for Success -

Risk-based monitoring (RBM) has become a clear imperative for the life sciences industry because of its compelling value proposition. The major regulatory authorities have provided strong endorsements for RBM, and industry groups including TransCelerate have provided additional guidance and support.

But the reality is that RBM does NOT need to be complicated or burdensome to your organization. In this presentation we will share observations and insights on RBM keys to success. The following topics will be covered:

- The Growing Evidence in Favor of Risk-Based Monitoring
- RBM Over-Engineering – Sifting through All of the Advice
- Review the Keys to RBM Success

11月16日(火) 12:45 -13:30

102セミナールーム　　主催:Medidata

リスクベースモニタリング:ベストプラクティス

近年、リスクベースモニタリング(RBM)は、その優れたバリュープロポジションから、ライフサイエンス事業において注目されるようになってきております。

RBMは、主要な規制当局により推奨されており、トランスセレレート等の企業団体よりガイダンスおよびサポートが提供されるようになりました。

しかし実際にはRBMの導入は複雑である必要も、高負担である必要もありません。本プレゼンテーションでは、RBM導入成功のキーファクターに関する見方及び考え方を下記のトピックを通じてご紹介致します。

- RBMの有用性を裏付けるエビデンス
- RBMオーバーエンジニアリング(OVER-ENGINEERING)
- RBM導入を成功へ導く鍵

EXHIBITOR'S SHOWCASE

Lunch Time & Coffee Breake Presentation
第12回DIA日本年会シルバーサポーターによるプレゼンテーション

PLACE: INNOVATION THEATER (RECEPTION HALL)

November 16th, Monday
10:30 -11:00
12:45 -13:00
November 17th, Tuesday
13:10 -13:25

Silver Supporter : Trifecta

Introduction of Clinical Trial Communication Platform "Investigator Space"

Trifecta is introducing our integrated clinical trial communication platform InvestigatorSpace(r). This platform includes online tools for secure and easy distribution/collection of documents, for managing site's access to Central Lab/EDC/ePRO/IWRS websites preventing disruption caused by lost ID/password, for centralizing training records of all types (live face-to-face, on-demand, web meetings etc.) while eliminating redundant training.

November 16th, Monday
13:10 -13:25
November 17th, Tuesday
10:30 -11:00
12:45 -13:00

Silver Supporter : Trifecta

Introduction of PAREXEL CDISC full support service

PAREXEL introduces its CDISC full support service from data collection to submission package preparation.

November 16th, Monday
13:35 -13:50
November 17th, Tuesday
13:35 -13:50
15:30 -16:00

Silver Supporter : BioTelemetry Research

Dynamic Repolarization Analysis: A New Era in Cardiovascular Safety

Daniel B. Goodman, MD, Vice President and Medical Director, BioTelemetry Research

An innovative path for determination of cardiac repolarization safety is the use of enhanced analysis of continuous 12-lead Holter recordings in early human-phase testing.

BioTelemetry Research introduces a service called Dynamic Repolarization Analysis Data collection is during typical SAD and/or MAD studies. In addition to exposure-response regression analysis using measures of QT intervals not requiring correction for heart rate, and analysis of T wave sub-intervals and morphology, it includes dynamic QT/RR beat-to-beat restitution analysis, to examine the ability of the heart to recover from one beat to the next during changes in heart rate. Together, these novel measures will allow differentiation of benign from arrhythmogenic QT prolongation.

医薬品開発の道のり（Your Journey）は、たった１つの美しい複合分子の配列から始まります。ある配列と配列が、最適な組み合わせで結ばれたとき、そこに新しい治療法や医療が生まれ、その先にある、人々の暮らしをより良くしていくことでしょう。

しかしながら、医薬品開発における製品上市までの道のりは決して平坦なものではありません―あらゆる側面において様々な課題に直面するでしょう―目標達成までの道のりは極めて困難です。しかし、達成不可能ではありません。例えば、医薬品開発の最終目標を達成するまでの全プロセスをサポートする信頼あるパートナーがいたらどうでしょうか？複雑な医薬品開発プロセスの簡素化が可能だとしたらどうでしょうか？ PAREXEL はそれら全てを実現致します。

PAREXEL の使命（Our Mission）は、より健康的な明日の実現のため、世界の患者さまのもとに一日でも早く新しい治療法をお届けする為の最適な方法を導き出すことです。わたしたちは、お客様の目標達成を実現するため、最適なプロセスや最先端のテクノロジーなど、医薬品開発に必要なあらゆるサポートをご提供致します。PAREXEL は、最新の治療法を必要としている患者さまに一日でも早くお届けすることを使命とする会社です。そして、わたしたち PAREXEL は、その使命達成の日まで立ち止まることはありません。

PAREXEL の詳細なサービスのお問い合わせに関してはこちら； **PAREXEL.co.jp**

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EXHIBITOR SUMMARIES

A2 Healthcare Corporation 48/50
エイツーヘルスケア株式会社

エイツーヘルスケア（A2）は860余名を擁する国内有数のフルサービスCROであり、豊富な受託実績と多才なリソースに基づき、顧客満足重視のサービスを展開しています。また、グローバル大手CROであるPRA Health Sciences(PRA)との独占提携により、日本を含むマルチナショナルスタディを実践しています。

今回、プラチナサポーターとしてランチョンセミナーを開催し、A2から開発効率化に向けた先進的な取組みとPRAから最新の規制要件（FDA・EMA）とフィージビリティ手法について実例を挙げてご紹介いたします。

展示会場ではA2・PRAのスタッフが、コーヒーとプレゼント企画をご用意して皆様をお待ち申し上げております。是非、お越しくださいますようお願い申し上げます。

A2 Healthcare Corporation (A2) was established in November 2014 by merger of GCP-CRO unit of Asklep and CRO ACRONET. The new integrated company became one of the largest CRO in Japan with more than 860 professionals and broad therapeutic expertise.

A2 have exclusive partnership with one of the 5 top-rating global CRO PRA Health Sciences (PRA) covering Japan.

As a Platinum Supporter of DIA, A2 and PRA plan a luncheon seminar on Tuesday 17th and will introduce how we will bring efficiency to our projects. We will also introduce A2-PRA working experience, global regulatory updates, etc.

Please make a brief stop at our booth for free coffee. We are looking forward to meet you at DIA.

営業本部　営業企画部　高橋誠吾
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Fax : 03-3830-1201

Asia CRO Alliance 4

Asia CRO Alliance (ACA) is an alliance of niche, regional CROs to partner together to enhance clinical research in Asia. Our members are well established local CROs spread over Japan, India, Korea, Malaysia and Taiwan. Our clients are small to medium size pharma, biotech and medical device companies, as well international CROs with limited in-country capability. We provide single administration, contract and management resource for global clinical trials making the process seamless.

ADM Korea Inc. 45

ADM Korea Inc. was established in 2003 and now we are one of the leading CROs in Korea. We are full-service provider and have great reputation in registration purpose clinical trials (Phase I, II and III). We also have numerous experiences in multinational studies with global partners. Our well-trained personnel with our experience will satisfy our client's needs to the fullest. Join us for your successful clinical studies!

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Fax : 82-2-722-0155
Email : ybpark@admkorea.co.kr

ArisGlobal KK 36
アリスグローバル株式会社

ArisGlobalは、ファーマコビジランスと安全性管理、薬事関連、臨床開発、医薬品情報管理等業務のための包括的ソフトウェアソリューションを提供するリーディングプロバイダです。多くのライフサイエンス企業が ArisGlobal の先進的なソリューションを採用し、日・米・欧・アジアを含めたグローバル規模での規制コンプライアンスの管理、ワークフローの自動化、より効率的な運用、情報の共有化等を実現しています。

ArisGlobal is a leading provider of integrated software solutions for pharmacovigilance and safety, regulatory affairs, clinical research and medical information. Hundreds of life science companies rely on ArisGlobal's advanced solutions for maintaining regulatory compliance, workflow automation, improving operational efficiency and easily sharing information around the globe.

Website: jp.arisglobal.com
Tel: 03-6304-5462/ Fax: 03-6304-5463
E-mail: info-jp@arisglobal.com

BioClinica Japan K.K. 21
バイオクリニカ・ジャパン株式会社

バイオクリニカは臨床試験の医療用画像判定、総合心臓安全性評価、バイオマーカーサービスのグローバルリーダーです。30年を超える経験で、アジア、欧州、北米で、規制に準拠したコアラボを運営し、各国専門知識とインフラ、医療機関や技術提供者との戦略的パートナーシップ、規制に関する専門知識を提供しています。

BioClinica is a global provider of medical image analysis, comprehensive cardiovascular safety services, and biomarker services for clinical trials. With more than 30 years of experience, BioClinica operates state of the art, regulatory compliant imaging, cardiovascular, and biomarker core labs in Asia, Europe, and the US. We offer well-established local expertise and infrastructure, strategic partnerships with regional clinics and technology providers, and regulatory expertise with the CFDA and PMDA.

www.bioclinica.com.

Office: 03-5159-2050
Hidenori Seshimo: 080-3456-2814
Misako Nakatani: 080-3380-1632

BioTelemetry Research 9

At the core of the world's largest cardiac data network

Before being acquired in 2012, Cardiocore became the world's most comprehensive core lab focused solely on cardiac safety. Now a division of BioTelemetry, Inc. (NASDAQ: BEAT), we are a member of the world's largest cardiac data network - processing over 2 billion heartbeats a day, while supporting over 20,000 sites and 30,000 devices monthly, and monitoring over 500,000 patients a year.

Expanded core services: advanced imaging and respiratory testing

In addition to industry-leading global cardiovascular monitoring, we have now expanded our clinical trial services in two important areas. First, advanced imaging services for clinical trials, including cardiovascular, oncology, neurologic, and musculoskeletal. And second, in spirometry, where we have created an exclusive alliance with Vitalograph to offer respiratory testing with one of the world leaders in comprehensive spirometry and related respiratory modalities.

www.gobio.com/research
1 Preserve Parkway
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C3i Inc. 14

C3iヘルスケアコネクションは、製薬会社およびCROへグローバル臨床試験の技術サポートサービスを提供しているトップ企業です。C3iヘルスケアコネクションはEDC, IVRS/IRT, CTMS, ePROのサポートを24時間365日多言語で、お客様のニーズに合わせてサービスデスク、トレーニング、資産管理、機器設定、サイトアセスメント、ホスティングサービスを提供しております。

Website: www.c3i-inc.com

CAC EXICARE Corporation 20
株式会社CACエクシケア

CACエクシケアは、医薬品開発と育薬に関する業務委託、およびITシステムのコンサルティング、システム開発から保守・運用まで、一貫したサービスをご提供するCROであり、ソリューションプロバイダーです。

CAC EXICARE is a CRO and solutions provider of one-stop services ranging from contract work for drug development and marketing to consulting, system development and maintenance/operations for IT systems.

株式会社CACエクシケア　広報部　マネージャー　渡邉　浩史
Tel: (03)5623-4676

Chiba University Clinical Research Center　C/D
千葉大学医学部附属病院臨床試験部

千葉大学医学部附属病院臨床試験部では、2007年にARO（アカデミック臨床研究機関）推進室を設置し、質の高い臨床研究を実施、推進する体制を整備してまいりました。2012年に、臨床研究品質確保体制整備事業に採択され、その体制をさらに充実させています。
現在、承認を目指し、4つの難病・希少疾患を対象として7件の医師主導治験を実施しており、さらに新規治験の実施を計画しています。また製薬企業との契約研究も増加しています。
総合大学として医学・薬学だけでなく、理学、工学から広くシーズを発掘し、また他の国立大学病院や希少疾患の専門医のネットワークを利用し、新たな治療法を開発していきたいと考えております。

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Fax number : +81-43-226-2629

CMIC Co.,Ltd.　35
シミック株式会社

CROのパイオニアとして多くの実績を積んできたシミックグループです。
スポンサー様に付加価値を提供するため、シミックグループは「PVC(ファーマシューティカル・バリュー・クリエイター)」として医薬品・医療機器の開発支援を中心に、非臨床・製造・営業・マーケティング・知的財産開発までのワンストップサービスを提供いたします。
Grobal対応として、米国・韓国・中国・シンガポール・マレーシア・ベトナムに拠点を構え幅広く業務を展開しています。
また、臨床試験のGlobal標準化に向けCDISC標準を導入し、臨床試験（過去の臨床試験含む）にCDASH、SDTM、ADaMを導入する際のサポートを致します。

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FAX:03-6683-7801
E-mail:info@cmic.co.jp
Web address: http://www.cmic.co.jp/

CROèe.INC　37
株式会社クロエ

クロエグループが運営する会員67万人を超える日本最大の治験情報ポータルサイト「生活向上WEB」と医家向けの広告代理店として、年間約1万人の症例登録を実施。被験者募集専門CROとして新薬開発に貢献するため、治験実施を支援しています。日本のみならず、中国・韓国などが参加するアジア被験者募集ネットワーク「A-PRO」やオンコロ領域の情報サイト「オンコロ」など様々な形で患者・被験者と製薬企業を繋げます。

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Mail：contact@croee.com

CRScube Inc.　19

完全に統合された、CRScubeのクラウドベースのソリューションは、使いやすくかつユーザーフレンドリーでありながら、治験に合わせカスタマイズすることも可能です。あらゆる治験相および領域にわたり、セットアップからデータベースのロック、そして市販後調査まで、治験の全プロセスにおいて、有用性を発揮します。治験の効率性を高める多様な機能を、リーズナブルな価格でご利用いただけます。
CRScube is a leading regional provider of integrated cloud-based clinical solutions. Developers of best-in-class software solutions to assist in all phases of clinical trials, CRScube's fully customizable, modular systems are being used to minimize costs and optimize clinical trials from planning through first launch. Find out why more and more Pharmaceuticals and CRO's are choosing CRScube to support their clinical research at www.crscube.co.kr

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http://www.crscube.co.kr

DOT international co., LTD.　6
DOTインターナショナル株式会社

弊社は、医薬品・医療機器の臨床開発ならびに臨床研究をトータルで支援しているCROです。弊社はご要望に即した最適なプランを提案し、迅速な支援を行っております。私たちのミッションは医薬品開発の効率化を計り、一日も早く安全かつ有効な医薬品を患者さんの手元にお届けすることにあります。

Tel: 03-3433-6060

ERT　43

ERTは、心臓安全性、呼吸器、自殺リスク評価、被験者・医療従事者・介護者から直接データを収集する、臨床アウトカム評価（COA）の領域で、安全性と有効性を示す高品質なエンドポイントデータ、クラウド解析、ワークフローソリューションを一元的かつグローバルに提供しています。

Tel: 03-3561-1531
ertjapan_sales@ert.com

Foresight Group International AG　49
フォーサイト・グループ・インターナショナル

フォーサイト・グループは、医薬品の安全性監視業務に特化したコンサルティングサービスを提供しております。3極（FDA/EMA/PMDA）の規制を理解したコンサルタントによる業務プロセス改善から、セーフティーデータベースの導入、リスク管理に至るまで、お客様を幅広くサポートいたします。

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Tel: +81 (0)3 5404 3440

INC Research, Inc.　40/42/44

INCリサーチは、世界100カ国以上を拠点に、第Ⅰ～Ⅳ相臨床開発のサービス全般を提供する、世界有数の医薬品開発受託機関（CRO）です。
人々に必要な新薬をとどけるために、当社の様々な患者集団を対象とする提供サービスの幅と治療に関する専門知識の深さを活かして、顧客、治験実施機関、そして患者を結びつけています。
是非40/42/44ブースにお立ち寄りください。（またはincresearch.comをご覧ください。）
INC Research is a leading CRO providing the full range of Phase I to IV clinical development services with operations across six continents in over 100 countries. Leveraging the breadth of service offerings and the depth of therapeutic expertise across multiple patient populations, INC Research connects customers, clinical research sites and patients to deliver the medicines people need. Connect with us today at stand 40/42/44 or visit incresearch.com.

Information Services International Dentsu, Ltd.　23
株式会社電通国際情報サービス

ライセンシング、治験・臨床研究、市販後調査などの領域でご利用頂いている、外部とのセキュアなドキュメント共有サービス「Intralinks（イントラリンクス）」と、グローバル製薬企業で採用されている、プロジェクト・ポートフォリオ・マネジメントに特化したクラウドサービス「Instantis　EnterpriseTrack（インスタンティス）」のご紹介を致します。

Tel: 03-6713-6167
e-Mail: g-ls-info@group.isid.co.jp

Japan Medical Data Center Co.,LTD　34
株式会社日本医療データセンター

日本で商用利用可能な最大規模のレセプトデータベースを保持するReal World Dataのパイオニア。
Population　baseでの有病割合や発生率の把握、Real　wordにおける治療

実態の把握により、開発
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のデータを保持。

client_service@jmdc.co.jp

Japan Patients Association 5
一般社団法人　日本難病・疾病団体協議会

JPAは、難病・長期慢性疾患、小児慢性疾患等の患者団体及び地域難病連で構成する患者・家族の会の中央団体です。患者・家族の交流、社会への啓発、患者サポート事〉　業による研修活動、患者団体の国際連携の推進、患者等に関する調査・研究活動及び患者レジストリの作成など患者及びその家族のため幅広い活動を展開しています。

Website : http://nanbyo.jp/
TEL : 03-6280-7734
E-mail : jpa@ia2.itkeeper.ne.jp

Kitasato Academic Research Organization, Kitasato University E
北里大学臨床研究機構

北里大学臨床研究機構は日本で随一のARO（Academic Research Organization）を目指し2010年10月に発足しました。2,000床を超える4つの総合病院、96床の治験専用病床、133名の専属スタッフが高品質な治験を実施します。臨床研究に関しては、プロトコールの立案、データマネジメント、統計解析、モニタリング、監査から報告書の作成まで一貫したサービスを提供いたします。

Tel: 03-5791-6404

LSK Global Pharma Services 3

We are the first CRO to have a Clinical Data Management department in Korea. We offer flexibility and proactive data management services domestically and globally. The expertise, efficiency, and experience of our staff will provide our sponsors high-quality service for their clinical studies. Our Pharmacovigilance Department, consisting of Medical Directors and Pharmacists, provide MFDS and ICH compliant solutions in drug safety guaranteed to integrate smoothly with your team.

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Website : www.lskglobal.com

Medidata Solutions K.K. 24
メディデータ・ソリューションズ株式会社

メディデータはライフサイエンス業界向けに臨床研究を効率化するソリューションをクラウドベースで提供するリーディングカンパニーです。卓越したアプリケーションとインテリジェントなデータ解析によって臨床開発に変革をもたらしています。Medidata Clinical Cloud® は、有望な新薬や治療法の臨床試験設計および計画から実施、管理、報告に至るまでの生産性と品質の向上をもたらします。メディデータは顧客の競争が激しくまた系統だったアプローチを必要とするゴール達成を支援することに尽力しており、その顧客には世界トップ25の製薬企業の90パーセント以上が含まれるほか、革新的なバイオテクノロジー企業や医療診断・機器の提供企業、中核的な大学病院やCRO（医薬品開発業務受託機関）などが名を連ねています。

Medidata is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud® brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

NDA Group 28

NDA is a leading drug development and regulatory consultancy in Europe. Through our comprehensive service portfolio, unmatched experience and strong partnerships in key markets we've advised and supported over 400 companies with strategic medicinal product development and registration over the past two years.
We support life science companies all over the world & across all phases of development.

Phone + 49 89 3585 4000
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NTT DATA CORPORATION 27
株式会社NTTデータ

株式会社NTTデータが提供するEDCソリューション「DATATRAK　ONETM」は、統合されたプラットフォームで効率的な臨床開発業務をご支援致します。当展示ブースでは、本製品のデモンストレーションなどを準備しておりますので是非ともお立ち寄り下さい。

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OmniComm Systems, Inc. 13

OmniComm Systemsは生命科学産業にソフトウェアソリューションを提供するリーディングカンパニーです。臨床開発の効率化、リスク管理の改善、臨床研究・開発オペレーションの管理を、最先端かつ革新的な技術を用いて実現します。全世界4,000件以上の臨床試験から得た経験を活かし、包括的なソリューションを提供します。

farnold@omnicomm.com 070-6983-3830

Oracle Corporation Japan 7/12
日本オラクル株式会社

Oracle Health Sciences delivers advanced transformative value for clinical R&D in a modular, integrated and scalable cloud environment and helps you:

- Optimize operations with technology that helps you maximize efficiency across your clinical life cycle
- Gain actionable insights from aggregated clinical and healthcare data
- Innovate by incorporating genomics, biomarkers and real-world patient data
- Future-proof your business with a significant and ongoing commitment to research and development that evolves and grows with you and the industry

healthsciences_ww_grp@oracle.com

Department of Medical Innovation, Osaka University Hospital B
大阪大学医学部附属病院　未来医療開発部

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Foundation for Biomedical Research and Innovation, Translational Research Informatics Center (TRI) A
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Trinity-biomed 25
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National Hospital Organization Nagoya Medical Center F
国立病院機構名古屋医療センター

概要　名古屋医療センターは、平成25年4月、厚生労働省の「臨床研究中核病院整備事業」の対象に選定されました。本事業の目的は、日本発の革新的な医薬品・医療機器等の創出、難治性疾患や小児疾患等の新規治療開発、最適な治療法の確立をめざした国際水準の質の高い臨床研究の推進です。私たちの最大の強みは、全国143病院からなる国立病院機構（NHO）のネットワークです。当臨床研究事業部は、医療の質の向上に資する医薬品・医療機器開発やエビデンス創出のための臨床研究を、低コストで高品質かつ迅速に推進していきます。

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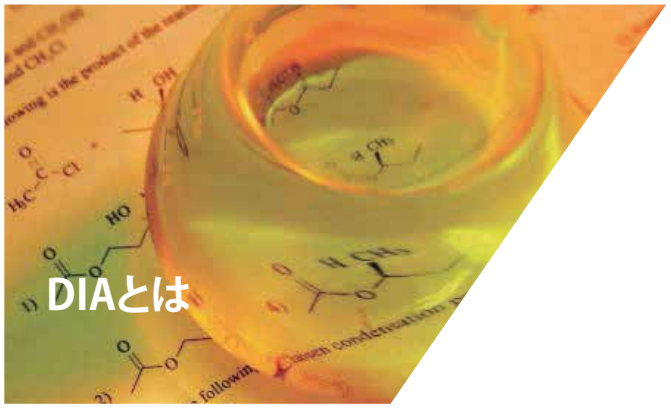

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"DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well being worldwide"

活動内容

年会の開催

年会（DIA Annual Meeting）は、医薬品、医療機器と関連製品の創出から開発、ライフサイクルマネジメントに関する全ての専門家のためのDIA最大の会合です。これほどの幅の広さと深さを提供する製薬企業関係の会合は他には見られません。25の専門領域のトラック、350のセッション20の教育コースは、参加者全ての専門性、業務内容、経験に合致したものを提供しております。この年次会は、上記に加え、貴重な専門性をまたがる学習や人的交流す。の機会も提供いたします。

欧州、日本、インド、中国においても同様の年次会を開催しており、国際的テーマと共に　各国の特有テーマが議論されています。

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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）

日本諮問委員会は、日本で開催される会合、その他の活動の運営をサポートしているDIA Japan オフィスに対し、必要な指示を出しています。各種会合は、日本諮問委員会とContents Committee における議論に基づき、会合毎に編成されるプログラム委員会によって具体化、実施されます。

議長
小林　和道（大塚ホールディングス株式会社）

副議長
関根　恵理（ノバルティスファーマ株式会社）

セミナー、ワークショップ、トレーニングコースの実施

毎年100以上のワークショップ、トレーニング、教育コースを開催しています。これらの会合の開催地は、米国、欧州、日本、インド、中国、東南アジア、アジア太平洋地域、アフリカ、中南米、中東など、世界各地に及びます。

出版物の発行

DIA会員への情報提供、教育などのために、DIAの公式刊行物であるTherapeutic Innovation & Regulatory Science (TIRS)、そして会員特典としてDIA Global Formをお届けします。

Therapeutic Innovation & Regulatory Science (TIRS)

Therapeutic Innovation & Regulatory Science (TIRS)は、DIAの公式刊行物です。この専門家の監修を受けた学術的専門誌は、国際的であり、多くの専門分野を網羅するとの評価を得ています。この本は、医薬品の研究開発と情報システムに関する情報を広めること、また、医薬品情報に携わる、教育、研究、企業、規制当局の間の情報交換を助成することを目的としており、化学、毒性、薬理、臨床からの研究データをより良く活用するための話し合いの場を提供しています。印刷物として、また電子媒体を通して、年6回お届けします。

Global Forum

Global Forumは、会員相互の情報交換を行うための隔月カラー誌です。DIAの会合からの重要なニュースやDIA会員に直接影響のある理事会や地域運営委員会からの報告のほか、実用的なヒント、規制環境の更新や各種会合の開催スケジュール、開催報告などを掲載しています。電子媒体を通して、年6回お届けします。

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DIA CSO Directoryは、企業に最も認められている情報ガイド誌の一つであり、医薬品開発と全ての臨床段階でのサービスを提供する100社を超す会社の会社
概要と窓口情報を掲載しています。

電子出版物の配信

DIA Daily

DIA Dailyは、DIAメンバーのニーズに合わせた新しい情報を提供するものです。過去24時間に発信された製薬に関するニュースの主要な記事の概要をお届けします。平日の毎日、DIAメンバーにメール配信いたします。このように速報をお送りすることで、医薬品・医療機器産業の専門家が一歩先を行くことの助けとなることが、DIA　Dailyの役割です。

会員特典および登録

会員特典の有効活用

DIAは、専門家の人々が日々直面する問題解決に取り組む、世界で唯一のグローバルで多くの専門領域にまたがる専門家の団体です。

- いかなる組織や監督官庁からの影響も受けることのない、中立でグローバルな会合に参加できます。
- 世界的企業や行政の第一人者から、規制や最も効果的な事例、業界の動向について学べます。
- DIAの会合や情報基盤を通してキャリアを伸ばしていく中で、行政、企業、アカデミーの専門家とのネットワークを構築できます。

キャリアデベロップメント

100近くある会合、ワークショップ、研修コース、Web研修など、多くの会合に会員価格でご参加いただけます。

最新情報の収集

研究、開発、薬事、安全性、CMC、マーケティングにおける規制の問題や、世界企業の最新の傾向をつかむことができます。

同じ専門領域の仲間との人脈形成

世界中の同じ専門領域の仲間との、in-personあるいはバーチャルな人脈形成を行うことにより、共通の経験を共有したり、規制と医薬品開発に関して世界的に最も注目されている話題などを学ぶことができます。

積極的な参加

DIAはボランティアの活動に支えられています。ボランティア参加することにより、視野を広げ、重要な交流を行い、企業のリーダーとの人脈を広げることができます。それらが、専門性を磨き、製品や技術、サービスの改革を推し進めることにつながります。

会員資格

DIAの会員資格は、全世界における健康と福利の改善に興味を持つ全ての個人に公平に与えられます。

会員特典

- 刊行物の定期配布
  - TIRS
  - DIA Global Forum
  - Annual Contract Service Organization Directory
  - ePublication（レギュラトリーに関する最新情報を含め、電子メールで配信）
- 年会、カンファレンス、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
- 広範囲にわたる人材バンクへのアクセス
- Community会員としての、キャリアの伸展と人脈作りの機会
- DIAで発信した記事の検索
- 講演者やセッション座長、著者としての、委員会への参加やボランティア活動
- 製薬に関わる企業の各種出版物、サービスの特別割引

入会方法

DIAのホームページ（www.diaglobal.org）からオンラインで登録することができます。
なお、各会合参加申込時点でのご登録も可能です。

会員登録費

一般会員費￥18,900（消費税8%込み）
Academia会員費 ￥12,960（消費税8%込み）
会員登録を行った日から12ヶ月間有効

ホームページによる情報提供

各種情報をウェブサイト上で提供しています。ホームページURL：http://diaglobal.org
*日本語ホームページ：http://www.diajapan.org

主なコンテンツ

- DIAが開催する会合に関する各種情報
- 会合や教育コースへの参加のオンライン登録
- 会員登録と更新、変更
- DIA出版物、e-Learningモジュール、CD-ROMその他の購入
- 掲示板（ConneX）を通じてのCommunity（専門領域集団）会員同士の交流（会員のみ）
- 職業紹介（会員のみ）
- Global Forum、TIRS等、すべてのDIA発行物の閲覧（会員のみ）

*日本語ホームページでも、上記コンテンツの一部を提供しています。

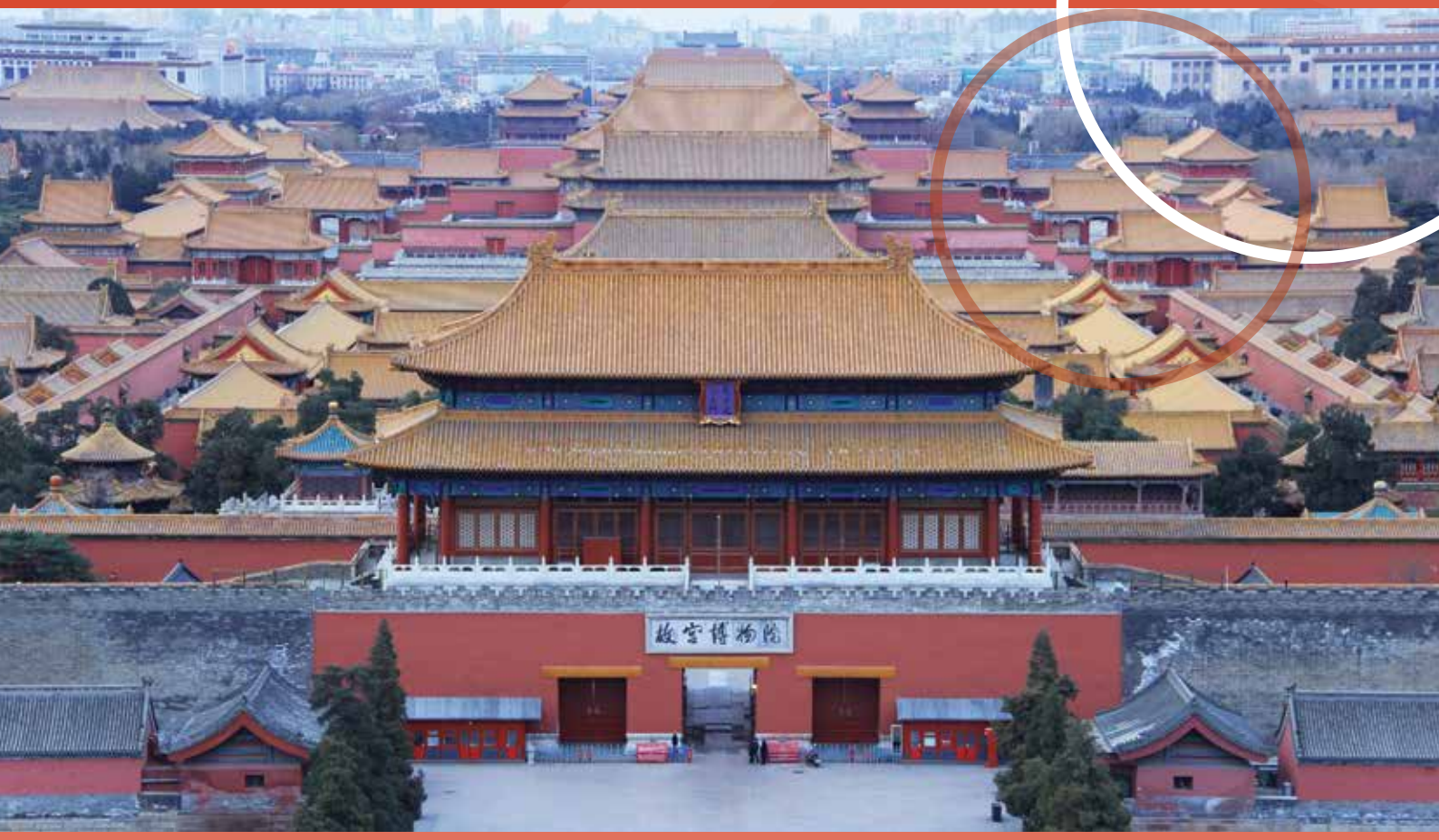
2016

The 8th DIA China Annual Meeting

May 15-18, 2016 | Beijing

China National Convention Center

http://en16975.eventdove.com/



DIA DEVELOP INNOVATE ADVANCE

DIA Global Center: Washington, DC, USA

Basel, Switzerland | Beijing/Shanghai, China

Horsham, PA, USA | Mumbai, India | Tokyo, Japan

Unit A1618, Tower A, No. 3 HaiDian Avenue, Hai Dian District Beijing 100080, China | Tel. +86 400 996 1966 | www.DIAglobal.org | China@DIAglobal.org
Unit 1519, Office Building, 99 Xian Xia Road, Chang Ning District Shanghai 200051, China | Tel. +86 21 60577239

ABOUT COMMUNITY

DIA Community (Previous SIAC)

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 Nov 2015)

- Clinical Data Management
- Clinical Pharmacology
- Clinical Research
- Clinical Safety & Pharmacovigilance
- Clinical Trial Disclosure
- Devices and Diagnostics
- Document & Records Management
- Electronic Regulatory Submissions
- Emerging Professionals
- Ethics & the Medicines Life Cycle
- Evidence Based Medicine
- Global Sourcing
- Good Clinical Practice & Quality Assurance
- Legal Affairs
- Marketing & Sales
- Medical Communications
- Medical Science Liaison
- Medical Writing
- Patient Engagement
- Pediatric
- Preclinical Sciences & OSWG
- Professional Education, Training & Development
- Project Management
- Regulatory Affairs
- Statistics
- Study Endpoints
- Validation/Electronic Information Integrity

Introduction of Japan DIA Community

Clinical Operation & Monitoring (COM Community)

Clinical Operation & Monitoring Community (COM Community) was established in 2014 to exchange views and information in the clinical operation and monitoring area. COM Community already held 2 meetings to discuss several topics. Each time, the discussion was very active and fruitful, and participants were well satisfied. Now COM Community is planning to hold meetings every quarter.

Below is 3 main objectives of COM Community. Please feel free to join us!

- Exchange opinions casually
- Collect the issues and needs in clinical operations
- Provide networking opportunity

Clinical Safety & Pharmacovigilance

DIA Risk Management workshop in Japan was held for the first time in March 2014. The third workshop will be held in June 2016. It has become common knowledge that risk management of pharmaceutical product is vitally important for safety management. We will gather trends of overseas regulations for risk management plan, share and discuss the problems of RMPs and pharmacovigilance plans.

Clinical Strategy Community

This community was established in Feb 2015 to discuss broad topics related to clinical development such as strategic approach, new technologies (biomarker, companion diagnostics, big data etc), decision making, collaboration with other area folks (medical affairs, business etc), and carrier planning. We provide the opportunities for networking among multiple companies members through frank discussion. Please feel free to contact with us!

Data Management

DIA CDM annual workshop in Japan was held for the first time in 1998. The workshop is held every year, and the 19th workshop will held in January 2016. Data is a common language and sharable resource in the world. Therefore, the needs for the DIA workshop as a place of global communication are great. It is reason why the workshop is continued for a long time. The workshop will cooperate with CDM global community team from now. New technologies and information will be shared with global team, and also proposals from Japan to global standards will be activated.

Labeling

DIA Labeling workshop in Japan was held for the first time in November 2011. The workshop is held every year, and the 6th workshop will held in February 2016. A drug labeling of pharmaceutical drug is most essential material and it is recognized that drug labeling is very important communication tool between pharmaceutical company and medical professionals. Multiple departments such as regulatory, safety, clinical departments in a pharmaceutical company are involved in development and/or revision of drug labeling. We will share problems of a development and/or revision of labeling, CCDS and labeling in Asia and discuss them. Also, we would like to raise hot topics from this community at the workshop etc.

Project Management

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:

- Learning knowledge, technique, tools and operations of project management with collaboration, and sharing recent experiences
- 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 executing project management track of DIA annual meetings
- Planning and participating in US/EU DIA annual meeting as project management community.

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

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 and Advanced RA Training course. 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.

In near future, we will try to start workshop/ study session, in order to feel free and exchange information and thought of hot topics in various regulatory environments.

Six Sigma

The Six Sigma Community was established to expand the concept/tools in R&D sector, to provide opportunities to utilize Six Sigma in real-life setting. The members consist of the certificated Six Sigma experts/consultants, academia, and 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, project management, and so on.

Statistics

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" 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 to DIA Global Site http://www.DIAglobal.org/

- Please become DIA Member if you are not.

Move to My Communities, and pick up the community of your choice from EXPLORE COMMUNITIES tab

Please visit "DIA Community 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、ベンダー、アカデミア、規制当局、医療機関、患者団体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

（2015年11月時点）

- Clinical Data Management
- Clinical Research
- Clinical Trial Disclosure
- Document & Records Management
- Emerging Professionals
- Evidence Based Medicine
- Good Clinical Practice & Quality Assurance
- Marketing & Sales
- Medical Science Liaison
- Patient Engagement
- Preclinical Sciences & OSWG
- Project Management
- Statistics
- Validation/Electronic Information Integrity
- Clinical Pharmacology
- Clinical Safety & Pharmacovigilance
- Devices and Diagnostics
- Electronic Regulatory Submissions
- Ethics & the Medicines Life Cycle
- Global Sourcing
- Legal Affairs
- Medical Communications
- Medical Writing
- Pediatric
- Professional Education, Training & Development
- Regulatory Affairs
- 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)

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おり、満足度もとても高いことから、今後は3ヵ月に1回程度の頻度で会合を開催していきたいと考えております。

本Communityでは下記の3点を目的に毎回楽しく開催しておりますので、是非お気軽にご参加ください！

- 現場目線でのカジュアルな意見交換
- 現場の問題点やニーズの吸上げ
- 参加者同士の人脈作りのきっかけ

Clinical Safety & Pharmacovigilance

DIA Risk Management workshop in Japan は2014年3月に初めて開催されました。来年6月に第3回を開催する予定にしています。医薬品の安全対策においてリスクマネジメントが今後ますます重要な役割を担うであろうことは、グローバルに広く認識されております。本コミュニティでは、今後、海外のリスクマネジメントの規制の動向の収集をしながら、医薬品リスク管理計画の問題点や製造販売後の情報収集について、情報の共有や議論をしていく予定です。

Clinical Strategy

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、2015年に本communityを立ち上げました。医薬品・医療機器開発の戦略的アプローチ、バイオマーカー、ビッグデータなど新技術の応用、メディカルアフェアーズやビジネス部門との連携、プロジェクトリーダーの役割、開発部門で働く方のキャリア構築など、communityメンバーが興味を持っている話題をベースに自由に意見交換できる場を目指しています。興味が高い話題はDIA日本年会のセッションとして取り上げています。会合の開催頻度は2か月に1回程度です。
現在、メンバー募集中です。ご興味がありましたら、まずは一歩踏み出してみませんか？

Data Management

DIA CDM annual workshop in Japan は1998年に初めて開催されました。以降、毎年開催され2016年1月に第19回を迎えます。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、ワークショップは長く継続されてきました。今後は本ワークショップのプログラム委員会を中心に日本のデータマネジメントコミュニティとして欧米のコミュニティと連携し、最新技術や情報の共有、および国際標準への日本からの提案などを更に強化していきます。

Labeling

DIA 添付文書 workshop in Japan は2011年11月に初めて開催されました。以降、毎年開催され、来年2月に第6回を開催する予定にしています。添付文書は最も基本的な医薬品の取り扱い説明書であり、製薬企業と医療関係者をつなぐ文書として、その情報の重要性は誰もが認めるところです。各企業ではその作成に、薬事部門、安全性部門、臨床開発部門等の様々な部門の方々が関わっています。今後、添付文書の作成、改訂、CCDS、アジアの添付文書等について、情報共有、活発な意見交換ができる場にしていく予定です。そして、ここで取り上げられたトピック等をworkshop等につなげていきたいと考えています。

Project Management

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ループットの向上です。製薬企業のみならず、アカデミア、医療機関、行政などの、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ます。

- グローバルPMコミュニティとの連携によるPMの知識、技法、ツール、運営に関する最新事例の共有
- PMトレーニングプログラムの開発・開催（超入門から応用まで）
- コミュニティ例会の開催
- アカデミア、行政等の医薬品開発プロセスに携わる組織へのPM導入支援活動
- DIA年会PMトラックの企画・実行
- US/EU DIA Annual Meetingへのコミュニティーセッションの企画・参加

PMコミュニティでは活動を楽しんで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、スタディーリーダー、スタディーマネジャー、進行調整スタッフ、チームメンバーなど、プロジェクトマネジメントやチーム活動、リーダーシップ開発に興味のある方はぜひご参加ください。この機会をお見逃しなく！！

Regulatory Affairs

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、Advanced RAトレーニングコース）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勉強会（仮称）を開催することも計画しています。

Six Sigma

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。メンバーには、シックスシグマ専門家やコンサルタントに加え、アカデミア、臨床開発に従事されている方々がいらっしゃいます。また、初心者の方も活動に参加されています。1カ月に1度会合を開き、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、臨床試験オペレーション、データマネジメント、プロジェクトマネジメントなどの領域事例をシックスシグマの観点から議論を重ねてきました。

Statistics

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全ての方のための基礎統計講座」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までご連絡ください

（Tel: 03-6214-0574, Fax: 03-3278-1313, 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/

- 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 Community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

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Targeted eLearning Programs

ADM Korea Inc.

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Korea has the fundamental assets in place to deliver excellence in clinical studies, including world-renowned principal investigators, highly competent and motivated research scientists, patient pools with excellent compliance and a fiercely supportive government sector. Within this environment, over 150 general hospitals enjoy unrestricted freedom to operate their multinational clinical studies. All government-mandated guidelines in Korea are in compliance with the International Conference on Harmonization.

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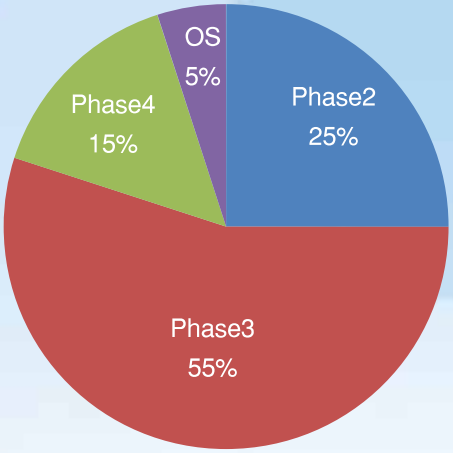
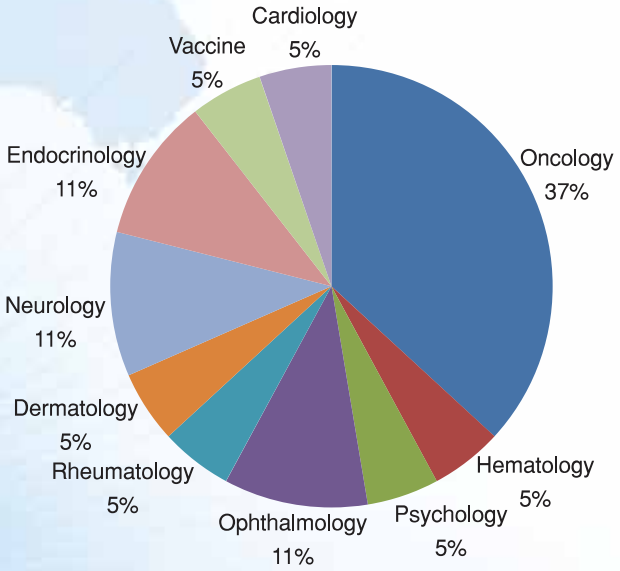
Study Phase



Therapeutic Area



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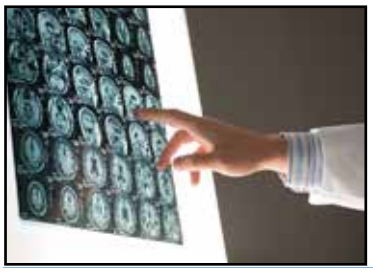

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Think Global，Act Local の実践
～ A2 Healthcare と PRA Health Sciences との独占提携インパクト ～

概要：

2014 年 11 月、エイツーヘルスケア株式会社（以下” A2”）は ACRONET と Asklep の GCP 部門の合併により誕生いたしました。これにより、860 余名を擁する国内有数のフルサービス CRO となり、豊富な受託実績と多才なリソースに基づき、顧客満足重視のサービスを幅広く展開しております。A2 は医薬品開発におけるライフサイエンス企業の真のパートナーであり続けられるよう日々努力し、進化してまいります。
今回のランチョンセミナーでは、開発効率化に向けた A2 の先進的な取組みとグローバル大手 CRO である PRA Health Sciences（以下” PRA”）との独占提携による協業実績についてご紹介させていただきます。
発表内容は以下のとおりです。

Ⅰ．IT 活用による開発効率化の最新動向（Presented by A2：日本語のみ）

臨床開発において一層の効率化を実現するため、各種 eClinical Solutions の活用と Risk-Based approach to Monitoring（以下、RBM）の実践が注目されています。A2 は日本の治験環境に適した RBM のあり方についてパイロット試験で経験を重ねています。また、eTMF/eCTD など治験プロセス全体の電子化にも取り組んでいます。最新事例を踏まえた臨床開発の近未来像についてご紹介させていただきます。

Ⅱ．PRA Health Sciences との協業実績（Presented by PRA：英語のみ）

Multinational Study を実施する際、日本の Expert である A2 と、Global Expert である PRA がいかに互いの強みを発揮し、スムーズに連携するかが成功への鍵となります。そのため、A2 と PRA は一つのチーム体制を構築 Multinational Study をサポートいたします。
これまでの協働プロジェクト経験を元に、成功するための「Key to Success」についてご紹介いたします。

PRAHEALTHSCIENCES

Ⅲ．欧米レギュラトリー Update & Global 最新テクノロジー（Presented by PRA：英語のみ）

Global 開発を志向する日本企業向けに、最新の規制要件（FDA・EMA）について実例を挙げてご紹介するとともに、主に米国で Clinical Trial の Feasibility を実施する際に有用なデータベースである “Medical Informatics” のご紹介をいたします。

11 月 17 日（火）12:45 ～ 13:30

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参加ご希望の方は下記 URL よりお申し込み下さい

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～ 皆様のご来場を心よりお待ちしております ～

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