14th DIA JAPAN
ANNUAL MEETING
2017
Final Program

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

患者さんにとって価値ある医療を生み出すために
—人工知能 (AI) やビッグデータの有効利用と次世代への期待—
Clinical Development Services for Pharma, Biotech, Medical Device and Diagnostics

ICON provides a full range of clinical development services to support global, pan Asia Pacific, and local trials in Japan.

Our locally based project management capabilities and regulatory consultancy expertise give you the insight, innovation and performance that will make a difference in cycle times and quality.

Contact us today for more information on our expertise and experience.
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In accordance with the revised Personal Information Protection Law, attendees list is not distributed this year.

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

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

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

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

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

Sincerely,
Barbara Lopez Kunz
Global Chief Executive, DIA
SUNDAY, NOVEMBER 12
9:00-9:30  Registration for Student Session
9:00-9:00  Student Session
9:30-  Attendee Registration
9:45-  Exhibit Hall Open
10:00-13:00  Keynote Address 1
Dr. Yoshinori Ohsumi, Tokyo Institute of Technology
11:45-11:45  Poster Session 1
11:45-19:45  Keynote Address 2
Dr. Tomohiro Sawa, Teikyo University
12:00-13:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
14:00-14:15  Keynote Address 1
Dr. Yoshinori Ohsumi, Tokyo Institute of Technology
14:15-15:15  Keynote Address 2
Dr. Tomohiro Sawa, Teikyo University
15:15-16:15  Coffee Break & Exhibit Hall Innovation Theater Presentations
15:45-16:45  Coffee Break & Exhibit Hall Innovation Theater Presentations
16:45-17:45  Coffee Break & Exhibit Hall Innovation Theater Presentations
18:00-19:30  Networking Reception

MONDAY, NOVEMBER 13
8:30-  Attendee & Exhibitor Registration
9:00-9:00  Exhibit Hall Open
9:00-9:30  Keynote Address 1
Dr. Yoshinori Ohsumi, Tokyo Institute of Technology
10:30-11:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
12:30-14:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
14:00-15:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
15:30-16:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
17:45-19:00  Coffee Break & Exhibit Hall Innovation Theater Presentations

TUESDAY, NOVEMBER 14
8:30-  Attendee & Exhibitor Registration
9:00-9:00  Exhibit Hall Open
9:00-9:30  Keynote Address 1
Dr. Yoshinori Ohsumi, Tokyo Institute of Technology
10:30-11:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
11:00-12:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
12:30-14:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
14:00-15:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
15:30-16:00  Coffee Break & Exhibit Hall Innovation Theater Presentations
16:00-17:30  Coffee Break & Exhibit Hall Innovation Theater Presentations
17:30-17:40  Closing Remarks

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

11月13日（月）
8:30-  受付
9:00-9:00  展示会場（レセプションホール）オープン
9:00-10:30  DIAmond Session 2 「革新的な医薬品をより迅速に必要とする患者へ届けるために - 日米欧三極規制当局の最新動向」
10:30-11:00  コーヒープレイク & 出展者プレゼンテーション
11:00-12:30  セッション 1
12:30-14:00  ランチプレイク / ポスターセッション / ランチョンセミナー
14:00-15:30  セッション 2
15:30-16:00  コーヒープレイク & 出展者プレゼンテーション
16:00-17:30  セッション 3
17:45-19:00  Engage and Exchange: スペシャルチャッティングセッション

11月14日（火）
8:30-  受付
9:00-9:00  展示会場（レセプションホール）オープン
9:00-10:30  DIAmond Session 3 「次世代医療ICTを活用した医薬品開発の将来像」
10:30-11:00  コーヒープレイク & 出展者プレゼンテーション
11:00-12:30  セッション 4
12:30-14:00  ランチプレイク / ボスターセッション / ランチョンセミナー
14:00-15:30  セッション 5
15:30-16:00  コーヒープレイク & 出展者プレゼンテーション
16:00-17:30  セッション 6
17:30-17:40  閉会の挨拶
PROGRAM COMMITTEE

PROGRAM CHAIR

Yasuhiro Fujiwara, MD, PhD
National Cancer Center
藤原 康弘

PROGRAM VICE CHAIR

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池田 晶子

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National Cancer Center
藤原 康弘

Akkiko Ikeda, RPh
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池田 晶子

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Daiichi Sankyo Co., Ltd.

Yoshihiko Uno, RPh
MSD K.K.

Hiromi Okabe, PhD
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PROGRAM ADVISORS

PROGRAM SUPPORT
# ADVISORY COUNCIL OF JAPAN / 日本諮問委員会

## CHAIR 委員長

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<tr>
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<tbody>
<tr>
<td>Kazumichi Kobayashi, RPh</td>
<td>Otsuka Holdings Co., Ltd.</td>
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<td>Eli Lilly Japan K.K.</td>
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## VICE CHAIR 副議長

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<td>Noriatsu Kono</td>
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## CONTENTS COMMITTEE

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## ADVISORY COUNCIL OF JAPAN / 日本諮問委員会

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

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

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

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

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

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

Conversations on Today’s Priorities
Hear from top thought leaders on global, interdisciplinary topics about the future of therapeutics, and how they affect you. Our DIAmmond Sessions will bring together innovators from industry, academia, and government agencies to discuss key concepts, and have a conversation on today’s priorities. See page 15 and 16 for more details.

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.

<table>
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<th>Date</th>
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<tr>
<td>Saturday, November 11</td>
<td>All times are acceptable</td>
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<td>Sunday, November 12</td>
<td>Before 8:00 and after 20:00</td>
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<td>Monday, November 13</td>
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<tr>
<td>Tuesday, November 14</td>
<td>Before 8:00 and after 18:30</td>
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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講演資料を閲覧できます。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とパスワードが必要です。IDとパスワードがわからない場合は、DIA Japanese Websiteにログインできます。http://www.diajapan.org/file/DIA_Account_QuickGuide.pdf
なお、全ての講演資料が閲覧できるのではなく、指定の日までにDIAに提出され、発表者がウェブサイトへの掲載を承諾した講演資料が掲載されます。この事前公開資料は、11月21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お送りされます。

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ご用意いたします。

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

DIA Globalアプリ（会員アプリ）
以下のQRコードをスキャンして便利なDIA Globalアプリをダウンロードしてください。スケジュール管理、アンケートの回答や情報収集にぜひご活用ください。使い方の詳細はクイックガイドをご覧ください。
尚、アンケートは紙でも配布いたします。アプリか用紙か、いずれかでご回答ください。

展示会場スタンプラリー
スタンプラリー用のカードがコンクレックスに入っています。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うと、15個以上集まればもれなく粗品を、更に20個以上集めた方にはDIA Japanにて抽選を行い、後日賞品を郵送にてお送りいたします。なお、このカードにロゴが記載されている協賛企業のスタンプは必ず押してもらい、11月14日(火)の16:00までに1Fの総合受付にてお提出ください。カードを引き換えに景品をお渡しします。

日本臨床薬理学会認定CRC制度以外の研修会、講習会
本年会は、日本臨床薬理学会認定CRC制度以外の研修会、講習会とされております。
以下のプログラムのうち、4時間以上受講した参加者には、希望により修了証を発行します。

11月12日(日)
基調講演1, 基調講演2
DIAmond Session 1
11月13日(月)
DIAmond Session 2
セッション1-3
11月14日(火)
セッション4-6
PMDAタウンホール

修了証の発行を希望される方は、年会終了後、2017年11月21日(火)までに受講証明書をDIA Japan <Japan@diaglobal.org> 宛にメール添付にて提出してください。受講証明申請書は、下記リンクよりダウンロードできます。
受講証明申請書を受理した後、申請者の参加の有無及び申告された受講時間を確認のうえ、修了証を送付します。

日本薬剤師研修センター認定の集合研修会
本年会のDIAmond Session 2 (11月13日9:00-10:30) とセッション1-6 (11月13日のセッション1-3、11月14日のセッション4-6) は、公益財団法人日本薬剤師研修センターより認定された集合研修会となっており、参加者は1セッションにつき1単位 (研修受講シール1枚) を取得できます。
研修受講シールの交付を希望される方は、ご来場時と退場時に総合受付にお越しください。
ご受講されたセッション数に応じ、研修受講シールをお渡しいたします。

11月11日（土）
11月12日（日）
11月13日（月）
11月14日（火）

特別に公表しない限り、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。
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Private Social Function Policy
本年会開催期間中、当プログラム外の会議、展示、懇親会等のイベントの開催はご遠慮ください。下記時間帯につきましては、これを限りません。
11月11日（土）
11月12日（日）
11月13日（月）
11月14日（火）
### Outstanding Contribution to Health Award

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

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

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

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

### Excellence in Service Award

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

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

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

<Activities in DIA>

- DIA, Contents committee member (2014-present)
- DIA, Program committee member of 6th-9th Regulatory Affairs training course (2013-2017)
- DIA, Facilitator of 3rd and 4th Advanced Regulatory Affairs training course (2015-2016)
- DIA, Facilitator of 5th Regulatory Communication training course (2017)
- DIA, Student Group Advisor (2016-present)
- DIA, presenter of 3rd Regulatory Affairs training course (2011)
- DIA, Session co-chair and presenter of “How Does the Introduction of RMP Change Drug Development” in 9th DIA Japan annual meeting (2012)

### Leader of Tomorrow Award

Hiromi Okabe, PhD  
Manager, New Drug Regulatory Affairs Department, R&D Division, Daiichi Sankyo Co., Ltd.

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

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

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### Leader of Tomorrow Award

Hiromi Okabe, PhD  
Manager, New Drug Regulatory Affairs Department, R&D Division, Daiichi Sankyo Co., Ltd.

Hiromi Okabe earned a Ph.D. in Pharmaceutical Sciences in 2004. Whilst in graduate school, she was a research fellow at the Japan Society for the Promotion of Science (DC2). Dr. Okabe started her career at Daiichi Pharmaceutical Co. Ltd. in 2004 (Daiichi Sankyo Co. Ltd. from 2007). After she joined the activity to protect healthy subjects who participate in clinical trials.

- DIA, Program committee member of 14th DIA Japan annual meeting (2017)
- DIA, Sub-facilitator in the Chatting Session (RA) in 13th DIA Japan annual meeting (2016)

<Programs supported by her>

- DIA, 3rd and 4th Advanced Regulatory Affairs training course (2015, 2016)
- DIA, 1st Cell therapy product symposium (2016)
- DIA, 11th DIA Asia New Drug Conference in Japan (2017)
<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
<th>Venue 1 Room 605/606</th>
<th>Venue 2 Room 607</th>
<th>Venue 3 Room 608</th>
<th>Venue 4 Room 609</th>
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<tbody>
<tr>
<td>9:30-12:00</td>
<td><strong>ORIENTATION AT EXHIBIT HALL (12:00-13:00)</strong></td>
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<td>12:00-13:30</td>
<td><strong>WELCOME</strong></td>
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<td>13:30-14:00</td>
<td><strong>OPENING REMARKS</strong></td>
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<td>13:45-14:00</td>
<td><strong>Dr. Yasuhiro Fujimura</strong></td>
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<td>14:00-14:15</td>
<td><strong>2017 DIA JAPAN’S INSPIRE AWARD CEREMONY</strong></td>
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<td>14:15-15:15</td>
<td><strong>KEYNOTE ADDRESS</strong></td>
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<td>15:15-15:45</td>
<td><strong>COFFEE BREAK</strong></td>
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<td>15:45-16:45</td>
<td><strong>KEYNOTE ADDRESS</strong></td>
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<tr>
<td>16:45-17:45</td>
<td><strong>DIAmond Session 1</strong> Vision of Future Drug Development in utilizing Next-Generation Medical ICT ALL</td>
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<td>17:45-18:00</td>
<td><strong>SHORT BREAK</strong></td>
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<td>18:00-19:30</td>
<td><strong>NETWORKING RECEPTION AT RECEPTION HALL</strong></td>
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<td>9:00-10:30</td>
<td><strong>COFFEE BREAK (RECEPTION HALL)</strong></td>
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<td>10:30-11:00</td>
<td><strong>SESSION 1</strong></td>
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<tr>
<td>11:00-12:30</td>
<td><strong>LUNCHEON SEMINAR</strong></td>
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<td>12:30-14:00</td>
<td><strong>SESSION 2</strong></td>
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<td>14:00-15:30</td>
<td><strong>SESSION 3</strong></td>
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<td>15:30-16:00</td>
<td><strong>SESSION 4</strong></td>
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<tr>
<td>16:00-17:30</td>
<td><strong>SESSION 5</strong></td>
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<tr>
<td>17:30-17:45</td>
<td><strong>SESSION 6</strong></td>
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<tr>
<td>9:00-10:30</td>
<td><strong>DIAmond Session 2</strong> To Deliver Innovative Drugs to the Patients Appropriately and Quickly - Recent Topics and Visions for Future of Regulatory Authorities among US, EU and Japan ALL</td>
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<td>10:30-11:00</td>
<td><strong>V1-S1 To Manage Global Phase I Study - Oncology Development - CR, AC</strong></td>
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<td>11:00-12:30</td>
<td><strong>V1-S2 Raise the Curtain of “Patient Centricity” in Japan (Part 1): Share and Discuss the Common Value CR, AC, CR, RA, O: Patients</strong></td>
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<td>12:30-14:00</td>
<td><strong>V1-S3 Raise the Curtain of “Patient Centricity” in Japan (Part 2): Share and Discuss the Common Value CR, AC, CR, RA, O: Patients</strong></td>
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<td>14:00-15:30</td>
<td><strong>V2-S1 Educational Session] Panel Discussion on Health Technology Assessment (HTA) in Japan RA, O: HEOR</strong></td>
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<td>15:30-16:00</td>
<td><strong>V2-S2 Mobile / Digital Health Data Driven Innovation for Clinical Development AC, CR, RA, DM, RA, ST</strong></td>
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<td>16:00-17:30</td>
<td><strong>V2-S3 Artificial Intelligence Leads to Realize Medical Innovation CR, AC, ST</strong></td>
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<td>17:30-17:45</td>
<td><strong>V2-S4 How to Use Statistics Correctly - Understand the Meaning of P Values and Eliminate Misuse AC, CR, CR, DM, RA, ST</strong></td>
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<td>9:30-10:30</td>
<td><strong>V3-S1 What Needs to Be Done for Creating Labeling Based on the New Revision of Items to be Included? CR, RA</strong></td>
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<td>10:30-11:00</td>
<td><strong>V3-S2 Understanding the Rules and Process of the US and EU Labelling CP, RA</strong></td>
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<td>11:00-12:30</td>
<td><strong>V3-S3 What is the Role of Medical Science Liaison (MSL) as New Function of Pharmaceutical Company? AC, CR, CR, DM, RA, ST</strong></td>
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<td>12:30-14:00</td>
<td><strong>V3-S4 What is the New GPSP in the Era of Medical Big Data CR, RA</strong></td>
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<td>14:00-15:30</td>
<td><strong>V3-S5 Changing Landscape of Phase 1 Trials in Oncology AC, CR, CR, DM, RA, ST</strong></td>
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<td>15:30-16:00</td>
<td><strong>V3-S6 How Should a Collaboration be Utilized by Healthcare Professionals CR, RA</strong></td>
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<td>16:00-17:30</td>
<td><strong>V4-S1 Developing a New System, in the World and the Impact on the Pharmaceutical Industry ALL</strong></td>
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<td>17:30-17:45</td>
<td><strong>V4-S2 Are the Drugs Appropriately Reaching to the Pediatrics in Needs? - Current Development Status and Future Steps of Pediatric Drugs in Japan - AC, CR, CR, RA, RA</strong></td>
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<td>9:00-10:30</td>
<td><strong>SESSION 4</strong></td>
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<td>10:30-11:00</td>
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<td>12:30-14:00</td>
<td><strong>SESSION 7</strong></td>
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<td>14:00-15:30</td>
<td><strong>SESSION 8</strong></td>
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<td>15:30-16:00</td>
<td><strong>SESSION 9</strong></td>
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<td>16:00-17:30</td>
<td><strong>SESSION 10</strong></td>
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<td>17:30-18:00</td>
<td><strong>SESSION 11</strong></td>
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**Related Interest Areas:** Clinical Research (CR), Regulatory Affairs (RA), Statistics (ST), Clinical Data Management (DM), Clinical Safety and Pharmacovigilance (CP), Project Management (PM), Chemistry, Manufacturing and Controls (CMC), Academia (AC), Medical Affairs (MA), Others (O)
<table>
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<th>VENUE 5</th>
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<th>EXHIBITION</th>
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<tr>
<td>Room 610</td>
<td>Room 101</td>
<td>Room 102</td>
<td>Room 103</td>
<td>Reception Hall</td>
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**ORIENTATION AT EXHIBIT HALL (12:00-13:00)**

**VENUE 5**
- Room 610

**VENUE 6**
- Room 101

**VENUE 7**
- Room 102

**VENUE 8**
- Room 103

**EXHIBITION**
- Reception Hall

**SHORT BREAK**

**NETWORKING RECEPTION AT RECEPTION HALL**

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<th>VENUE 5</th>
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<td>Room 101</td>
<td>Room 102</td>
<td>Room 103</td>
<td>Reception Hall</td>
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</tbody>
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**COFFEE BREAK (RECEPTION HALL)**

**V5-S1** Future Steps and Challenges for Drug Development Based on National Action Plan on Antimicrobial Resistance (AMR)
- AC, CP, CR, RA, O: MA

**V6-S1** Industry-Academia-Government Collaboration Schemes in Japan
- AC, RA

**V7-S1** Draft Regulatory Guidance for Patient Registry and the Current Situation
- ALL

**V8-S1** “The negotiation” – things you need to know for your team and project management
- PM, O: ALL

**LUNCH BREAK**

**LUNCHEON SEMINAR (MEDIDATA SOLUTIONS K.K.)**

**V5-S2** Approaches to Enhance Appropriate Communication on Pharmaceutical Product Information - Part 1
- AC, CR, RA, MA, O: Labeling, Marketing, Medical Writing, Medical Information

**V6-S2** Paradigm Shift in Global Development Strategy - How to Utilize ICH E17 GL in New Drug Development?
- AC, CR, RA, ST

**V7-S2** Patient Participation – Patient Centric Approach to Clinical Trials
- AC, CR, RA

**V8-S2** Update on Current Status and Future Directions of Proarrhythmic Risk Assessment
- AC, CP, CR, RA, O: Cardiac Safety

**COFFEE BREAK (RECEPTION HALL)**

**V5-S3** Approaches to Enhance Appropriate Communication on Pharmaceutical Product Information - Part 2
- AC, CR, RA, MA, O: Labeling, Marketing, Medical Writing, Medical Information

**V6-S3** The Way toward Commercialization, Regenerative Medical Products
- AC, CMC, CP, RA, PM, ST

**V7-S3** Current Status on Counterfeit Medicines in Global and Issues on Japanese Market
- CPM, CMC, RA, O: Counterfeit

**V8-S3** Call for Abstract Session
- CP, CR, RA, O: ROD

**SHORT BREAK**

**ENGAGE AND EXCHANGE “LET’S CHAT!” SPECIAL CHAT SESSION - AT RECEPTION HALL**

**VENUE 5**
- Room 610

**VENUE 6**
- Room 101

**VENUE 7**
- Room 102

**VENUE 8**
- Room 103

**EXHIBITION**
- Reception Hall

**COFFEE BREAK (RECEPTION HALL)**

**V5-S4** How Do You Set in the First Step of the Project Manager Development?
- ALL

**V6-S4** Quality by Design; Strategically Building the Quality of Clinical Study by Academia
- RA, DM, CR, ST, AC, O: MA

**V7-S4** More Advanced Approach of Medical Big Data - Part 1
- ALL

**V8-S4** Clinical Development of Biosimilar Products
- RA, CR, ST, PM, CMC, AC

**LUNCH BREAK**

**LUNCHEON SEMINAR (PAREXEL INTERNATIONAL)**

**V5-S5** What Are You Going to Do? How Will You Develop Young Staff’s Careers? How Will We Make Our Organization More Productive?
- ALL

**V6-S5** CRO Management for Effective Collaboration Related Interest Area(s)
- CB, PM

**V7-S5** More Advanced Approach of Medical Big Data - Part 2
- ALL

**V8-S5** Drug Development Activation in Pan-Asia Region
- AC, CB, PM, RA, O: MA

**COFFEE BREAK (RECEPTION HALL)**

**V5-S6** Quality Management and Lean Six Sigma in Clinical Trials in ARO and Pharmaceutical Companies
- AC, CR

**V6-S6** Rethinking Quality in Clinical Trials - What are Quality Tolerance Limits (QTLs) and How Should they be Adapted in Clinical Studies to Fulfill New ICH E5 Requirements?
- AC, CR, DM, PM, RA, ST, O: MA

**V7-S6** Future of Development Strategy and Lifecycle Management in Asia after ICH Q12 Guideline Implementation
- RA, CMC, AC

**V8-S6** For Providing the Most Appropriate Medicine - The Current State of Use and Development of Companion Diagnostics (Mainly on Next Generation Sequencers)
- AC, CP, DM, PM, RA, ST, O: Diagnostics company

**LUNCH BREAK**

**LUNCHEON SEMINAR (OMNICOMM SYSTEMS INC.)**

**COFFEE BREAK (RECEPTION HALL)**
### Student Session / Orientation

**Room 102**

**Student Session**

**Clinical Trial Protocol Development**

<table>
<thead>
<tr>
<th>Related Interest Area(s):</th>
<th>RA, AC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level:</strong></td>
<td>Beginner</td>
</tr>
</tbody>
</table>

**SESSION CO-CHAIRS**

- Maori Ayabe
  Chiba University
- Shohei Iimura
  Keio University
- Aya Okada
  Nihon University
- Miho Sato
  Showa University

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

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

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


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

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

**Commentator**

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

**Advisers**

- Motoki Arakawa, PhD
  Lecturer, Laboratory of Pharmaceutical Regulatory Science, Nihon University
- Kasumi Daidoji, MSc, RPh
  Associate Director, Corporate Medical Affairs Headquarters, Drug Fostering and Evolution Coordination Department, Eisai Co., Ltd.
- Yasuhiro Honsho
  Associate Director, Global Medical Writing Group, New Drug Regulatory Affairs Department, Daiichi Sankyo Co., Ltd.
- Katsuhiko Ichimaru
  Director, Information Disclosure Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA)
- Eri Sekine
  Department Head, Trial Monitoring, Japan Development, Global Development Operations, Global Drug Development, Novartis Pharma K.K.
- Meiko Fukagai
  DIA Japan Student Group OBOG, Asia Development Department, Dainichi Sankyo Co., Ltd.
- Emi Hachisuka, MS
  DIA Japan Student Group OBOG, Japan-Asia Clinical Development 2, Astellas Pharma Inc.

---

**RECEPTION HALL**

**Orientation**

**SESSION CO-CHAIRS**

DIA Japan Contents Committee

Welcome to the 14th DIA Japan Annual Meeting!

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

**Contents:**

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

---

You’ve never seen a Global Forum like this.

[globalforum-online.org](http://globalforum-online.org)
WELCOME
International Conference Room 13:30-13:45
Ko Sekiguchi
Director, DIA Japan
Barbara Lopez Kunz
Global Chief Executive, DIA
Kazumichi Kobayashi
Chair, DIA Advisory Council of Japan
Senior Vice President, Business Development and Planning, Otsuka Holdings Co., Ltd.

OPENING REMARKS
International Conference Room 13:45-14:00
Program Chair
Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

2017 DIA JAPAN'S INSPIRE AWARDS PRESENTATION
International Conference Room 14:00-14:15
Presenter:
Barbara Lopez Kunz
Global Chief Executive, DIA

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

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

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

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

KEYNOTE ADDRESS 1
International Conference Room 14:15-15:15
Session Chair:
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)
Looking Back on 40 Years of Yeast Research
Yoshinori Ohsumi, PhD
Honorary Professor, Cell Biology Center, Institute of Innovative Research, Tokyo Institute of Technology

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

COFFEE BREAK 15:15-15:45

KEYNOTE ADDRESS 2
International Conference Room 15:45-16:45
Session Chair:
Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center
The Digital Future of Healthcare – IT Utilization and Drug Development
Tomohiro Sawa, MD, PhD
Professor, Department of Anesthesia, Teikyo University
Chief Information Officer, Headquarters, Teikyo University
DIAmond Session

DIAmond Session 1
INTERNATIONAL CONFERENCE ROOM  16:45-17:45

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

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

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

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

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

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

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

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

NETWORKING RECEPTION
Reception Hall  18:00-19:30

Register Today!

Brexit Summit | Ensuring Continuity for Patients and Business
8 December 2017
London, UK

As the timeframe for Brexit quickly approaches, governments, regulators, companies, healthcare systems and patients are all seeking ways to prepare for the “known unknowns” and to brace for the “unknown unknowns”.

This conference will bring stakeholders together to help you to take action towards minimising impacts to the development, manufacturing, regulation and supply of medicines.

Conference Programme Highlights
• Regulatory Planning – Preparing for Day 1
• Supply Chain – Ensuring Patients’ Access
• Brexit Time Check: What’s Next for Medicines?

Find out more at
www.DIAglobal.org/Brexit
To Deliver Innovative Drugs to the Patients Appropriately and Quickly – Recent Topics and Visions for Future of Regulatory Authorities among US, EU and Japan

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

SESSION CO-CHAIRS
Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

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

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

DAY 2 | MONDAY | NOVEMBER 13

DIAmond Session 2

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

DIAmond SESSIONS

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

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

SESSION CO-CHAIRS
Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

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

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

US Food and Drug Administration Expedited Programs for Serious Conditions
Rajeshwari Sridhara, PhD
Director, Division of Biometric V, Office of Biostatistics, OTS, CDER, FDA

Panel Discussion
All Session Speakers

COFFEE BREAK 10:30-11:00

UNIFY YOUR CLINICAL DEVELOPMENT WORLD WITH CLINICAL ONE™

ORACLE HEALTH SCIENCES
UNIFYING ACTION, ACCELERATING RESULTS.
V1-S1 Room 605/606 11:00-12:30
To Manage Global Phase I Study - Oncology Development -
Related Interest Area(s): CR, AC
Level: Intermediate
SESSION CHAIR
Hironobu Saito, PhD
Vice President, Oncology Clinical Development Department, Oncology Function, R&D Division, Daiichi Sankyo Co., Ltd.
Even in the case that a new seed has been found in Japan, US/Europe is leading the clinical development, in which global phase I study is started in US/Europe and the first approval is planned in US/EU. To lead global development, Japan need the skill to manage global Phase I and develop global human resource.
In the oncology area, the transformation from Step by step (Phase I/II) to patients oriented development (Expanded Phase I, Confirmed Phase II, Conditional Approval) is discussed and challenged.
The most important action is to develop global human resource in Japan. For example the person who is able to find the dose in the case of limited data and limited time.
In the first session, the presenters will share how the sponsor prepares non-clinical data, CMC data to set up global phase I study. In the second session, the global site (US/EU/Asia/Japan) will share the efforts and the experiences to deal with global Phase I study.

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

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

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

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

Panel Discussion
All Session Speakers

V2-S1 Room 607 11:00-12:30
[Educational Session] Panel Discussion on Health Technology Assessment (HTA) in Japan
Related Interest Area(s): RA, O: HEOR
Level: Beginner, Intermediate
SESSION CHAIR
Kuniko Shoji
Director and Corporate Advisor, Terumo Corporation
As innovative and expensive pharmaceuticals and medical devices are increasingly used in clinical practice, Health Technology Assessment (HTA) is attracting serious attention as a policy making tool to enable sustainability of universal access.
The HTA, which has been implemented on a trial basis since 2016, is actively discussing how the system should be designed in readiness for a full-scale implementation.
At the Japan Annual Meeting in 2017, we will give an overview of insurance reimbursement, drug pricing system, etc. of both foreign countries and Japan, and will conduct a free and open panel discussion from various viewpoints concerning cost-effectiveness assessment in Japan.
In this way, we plan to discuss the methodology of a comprehensive evaluation of HTA in Japanese and the value of life for Japanese people (ICER threshold).

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

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

Panel Discussion
All Session Speakers and
Takeo Nakayama, MD, PhD
Professor, School of Medicine and Faculty of Medicine, Kyoto University
Rei Goto, MD, PhD
Associate Professor, Graduate School of Business Administration, Keio University
Harumichi Okamura
Corporate Officer, Head of Market Access & Public Affairs, Novartis Pharma K.K.

V3-S1 Room 608 11:00-12:30
[Educational Session] Comparison of Post-Marketing Safety Measures among Japan, the U.S. and the EU – From the Point of View of Risk Management –
Related Interest Area(s): RA, CP
Level: Beginner
SESSION CHAIR
Yomei Matsuoka, MSc, RPh
Senior Director, Safety Planning Group I, Pharmacovigilance Department, Daiichi Sankyo Co., Ltd.
As multi-regional clinical trials increase, global application and approval and elimination of drug lag are about to be realized, while data of clinical trials in each country tend to decrease compared to before the implementation of multi-regional clinical trials. Therefore, the importance of safety measures in post-marketing phase are relatively increasing for clarifying details of drug safety and efficacy profiles in timely manner. In this context, we will share the difference in concept of risk management between Japan, the U.S., and the EU and the current status and challenges of post-marketing safety measures during this educational session.

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

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

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

Panel Discussion
All Session Speakers

V4-S1 Room 609 11:00-12:30
Let’s Think about Drug/Device Combination Use for Treatment
Related Interest Area(s): RA, O: Medical Device
Level: Intermediate
Language: Japanese Language Only
SESSION CHAIR
Kensuke Iishi, PhD
Director, Office of Medical Devices II, Pharmaceuticals and Medical Devices Agency (PMDA)
Drug-device combination products and therapies are currently the subject of much attention given the increasing difficulties in developing truly innovative new pharmaceuticals and medical devices. This session focuses on clinical development issues with regard to combination products or therapies by discussing a number of concrete examples. The session will include a discussion of how to manage the simultaneous development of devices and pharmaceuticals more efficiently and how various hurdles and issues during clinical development could be potentially addressed.

**Prospect and Issues of Drug-Device Combination Products and Therapies**

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

**TBC**

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

**TBC**

Masayoshi Shibatsuji  
Pharmaceuticals and Medical Devices Agency (PMDA)

**Panel Discussion**

All Session Speakers and

Takehiko Arima  
Senior Director, Quality & Regulatory Affairs, Medtronic Japan Co., Ltd.

Kazumichi Kobayashi  
Senior Vice President, Business Development and Planning, Otsuka Holdings Co., Ltd.

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

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

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

**SESSION CHAIR**

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

**Overcoming Antimicrobial-resistant Infection (ARI) has become a global issue. In 2016, the “Ministerial Meeting on Measures on Emerging Infectious Diseases” has announced the National Action Plan on Antimicrobial Resistance (AMR), and as well as a commitment demonstrated in G7 Health Ministers Meeting to solve AMR task. In addition, for a Guideline for the Clinical Evaluation of Antibiotics for ARI, the three regional regulatory agencies (PMDA/FDA/EMA) are cooperating to continue the discussion. This session will discuss future steps based on AMR action plan, about clinical studies in different framework to date, and on international cooperation.**

**The Japanese Government’s Efforts on AMR**

Yasuhide Yamada, MSC, MPM

**Therapeutic Drug for Antimicrobial Resistance (AMR) Infections: from Regulatory Standpoint**

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

**Challenges in Clinical Development of Drugs for AMR Infections**

Akiko Takase, MSC  
Senior Scientist, Regulatory Strategy & Liaison 1, Regulatory Affairs Area, Japan Development, MSD K.K.

**Panel Discussion**

All Session Speakers

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

**Industry-Academia-Government Collaboration Schemes in Japan**

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

**SESSION CHAIR**

Toichiro Takenaka, DVM, PhD  
Chairman, Japan Health Sciences Foundation

The Japan Agency for Medical Research and Development (AMED) was established two years ago. In order to minimize the boundaries of the industry, academia, and government in drug research, we host grant programs such as: the Department of Innovative Drug Discovery and Development (ID3) which is the first public program in Japan to deliver drug seeds from academia to clinical application, the GAPFREE program which grants public-private joint clinical research, and the Cyclic Innovation for Clinical Empowerment (CICLE) which began in FY2017 to fund infrastructure and open innovation for medical needs based on industry-academia-government collaboration. Through these programs, we would like to discuss about the perspectives of industry-academia-government collaboration.

**Drug Discovery Support Network Recent Development & Future Perspectives**

Yoshihide Muragaki, MD, PhD  
Senior Director, Japan Agency for Medical Research and Development

**About the Funding for Research to Expedite Effective Drug Discovery by Government, Academia and Private Partnership (GAPFREE) Program**

Kazuki Yasuda, MD  
Department of Metabolic Disorder, Diabetes Research Center, Research Institute, National Center for Global Health and Medicine

**Development of the Innovative Vaccine Technology Based on Nucleic Acid Encapsulated in Nanoparticle Supported by the Cyclic Innovation for Clinical Empowerment (CICLE) Program**

Fumihiko Takeshita, MD, PhD  
Senior Director (R&D), Vice President, Vaccine Research Laboratories, Daiichi Sankyo Co., Ltd.

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

**Draft Regulatory Guidance for Patient Registry and the Current Situation**

**Related Interest Area(s):** ALL  
**Level:** Intermediate

**SESSION CHAIR**

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

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


Taro Shibata, PhD  
Director, Biostatistics Division, Center for Research Administration and Support, National Cancer Center

**Current Status and Issues of Remedy in an Effort to Promote Clinical Innovation Network**

Harumasa Nakamura, MD  
Section Chief of the Department of Clinical Research Support and Section Chief of the Clinical Research/Trial Promotion Section, Translational Medical Center, the National Center of Neurology and Psychiatry
**Expectation for The Disease Registry Data from a Pharmaceutical Company**

Kazuhiro Shiosakai

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

**Panel Discussion**

All Session Speakers and Shimon Tashiro, PhD

Head, Office for Bioethics, Center for Public Health Science, National Cancer Center

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

Gloria Hung, RPh, MPhil *

Director, Regional Regulatory Strategist, Pfizer Inc.

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

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

Mitsugu Ikeda, MSc *

Nagoya City University

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

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

Kosuke Iwaseki, MBI *

Director, Japan Healthcare Practice & Data Analytics, Milliman, Inc.


Yoshiaki Kato *

Medical Writing, Regulatory Affairs Area, Japan Development, MSD K.K.

Keiko Tsumori

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

Makoto Suzuki, PhD

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

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

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

Hidenobu Kondo, MPharm *

Centralized Monitoring Department, Development Strategy Division, A2 Healthcare Corporation

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

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

Cezar Manansala Jr, RPh *  Mark Scyld Magboo, RPh  Maileen Beley, RPh

Centralized Monitoring Department, Development Strategy Division, A2 Healthcare Corporation

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

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

Sanjeev Miglani, MD *

Vice President-PV and Clinical Safety North America and Global Medical Affairs, APCLR Life Sciences

Spontaneous reporting (SR) adverse event system databases, large clinical projects and health records databases contain data that may be valuable for timely detection of potential risks associated with Pharmaceutical products. This Poster will provide recommendations for using data from different databases to provide insight into safety signals and offer guidance regarding appropriate statistical methods to use in various situations.
[PO-09] Partner Collaboration in Quality Assurance, between the Quality Groups from 2 Companies
Keiko Shiratori, MSc *
Bristol-Myers Squibb K.K.
Hiromichi Ishikawa, MSc
Quality Management Associate, Ono Pharmaceutical Co., Ltd.

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

[PO-10] Approach to Gaps between Ideal and Reality in Clinical Operations and Monitoring
Kazumasa Sugao * Masayuki Iijima Shiho Sugiuira Eisuke Nakata
DIA COM (Clinical Operations and Monitoring) Community

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

[PO-11] Accelerated Development of Anti-Sense Oligonucleotides for Orphan Drug Indications
Yasuhiro Okamoto, PhD *
Associate Director, RA-CMC, Biogen Japan Ltd.

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

SESSION 2 14:00-15:30

V1-S2 Room 605/606 14:00-15:30
Raise the Curtain of “Patient Centricity” in Japan (Part I): Share and Discuss the Common Value
Related Interest Area(s): ra, CR, AC, O: Patients
Level: Intermediate

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

The idea of Patient Centricity and Patient and Public Engagement are increasingly attracting interest in Japan, while their concept and idea have not been established and is expanding. Especially, we considered that these management strategies using LC-MS is very important to control the.

Patient and Public Involvement in Research: From Concept to Practice
Jin Higashijima, PhD
Associate Professor, Faculty of Global and Science Studies, Yamaguchi University

Project to Train Patients and Citizens to Actively Participate in Various Committees: Necessity and Practice
Ikuo Yamaguchi
Board Chairperson, COML

V1-S3 Follows
Concerning the Issues of Clinical Study by Revision of the Personal Information Protection Law

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

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

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

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

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

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

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

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

Panel Discussion
All Session Speakers

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

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

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

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

It is highly important that pharmaceutical product information is appropriately provided by regulatory authorities and pharmaceutical companies, and utilized in the medical field. In the Japan annual meeting in 2016, we discussed issues arising from provision of pharmaceutical product information materials provided to healthcare professionals or patients, and handling of these issues. We have found that pharmaceutical product information is not necessarily fully utilized by the medical professionals: duplicate information is provided using various materials from the regulatory authorities and companies, necessary information for medical professionals is not provided, and the real intentions of the authors are not fully conveyed. In 2017, we will discuss approaches and future perspectives to enhance appropriate communication on pharmaceutical product information to medical professionals based on the previous discussion by summarizing the objectives and utilization methods of a wide range of information materials provided by the regulatory authorities and companies.
V7-S2  **Room 102  14:00-15:30**

**Patient Participation – Patient Centric Approach to Clinical Trials**

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

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

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

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

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

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

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

**Panel Discussion**
All Session Speakers

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

**Update on Current Status and Future Directions of Proarrhythmic Risk Assessment**

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

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

Proarrhythmic potential remains a major concern during drug development and in 2005, ICH adopted the ICH-S7B (non-clinical) and ICH-E14 (clinical) guidelines outlining the evaluation of the potential to delay ventricular repolarization. In late 2015, E14 Q&A was revised to allow the use of concentration response modeling applied to data from early phase clinical studies as an acceptable alternative to the Thorough QT/QTc Study. For more efficient and more modeling applied to data from early phase clinical studies as an acceptable alternative to the Thorough QT/QTc Study.

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

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

Hiroyuki Fukase, MD, PhD
Director, Clinical Research Center, Clinical Research Hospital Tokyo

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

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

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

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

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

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

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

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

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

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

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Yoshinori Ochiai, PhD
Advanced Review with Electronic Data Promotion Group/Office of New Drug 1, Reviewer, Pharmaceuticals and Medical Devices Agency (PMDA)

**Panel Discussion**
All Session Speakers and
Hiroshi Takeda, MS
Reviewer, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA)
Communication on Pharmaceutical Product Information - Part 2

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

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

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

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

Panel Discussion
All speakers for V5-S2 and
Toyotaka Iguchi, MD, PhD
Risk Management Director, Office of Safety II, Pharmaceuticals and Medical Devices Agency (PMDA)

V6-S3 Room 101 16:00-17:30
The Way toward Commercialization, Regenerative Medical Products

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

SESSION CHAIR
Yoji Sato, PhD
Head, Division of Cell-Based Therapeutic Products, National Institute of Health Sciences

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

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

Challenge from Academia to Remove Knee Pain by Regenerative Medicine
Ichiro Sekiya, MD, PhD
Professor, Tokyo Medical and Dental University

Developing Regenerative Medicine using Cell Sheet Engineering
Setsuko Hashimoto, PhD
President and CEO, CellSeed Inc.

Safety and Efficacy Evaluation of Regenerative Medical Products
Yoshiaki Maruyama, PhD
Review Director, Office of Cellular and Tissue-Based Product, Pharmaceuticals and Medical Devices Agency (PMDA)

Panel Discussion
All Session Speakers

V7-S3 Room 102 16:00-17:30
Current Status on Counterfeit Medicines in Global and Issues on Japanese Market

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

SESSION CHAIR
Yoshiaki Ohashi, PhD
Head of Quality & Regulatory Compliance Unit, Chugai Pharmaceutical Co., Ltd.

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

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

Global Situation Report 2016
Martin Blair
Asia Pacific Regional Manager, Pharmaceutical Security Institute (PSI)

TBC
Kazuko Kimura, PhD
Researching Professor Emerita, Kanazawa University

TBC
Plus Waldmeier
F. Hoffmann-La Roche, Ltd.

A Company Framework, Objectives and Risk
Scott Kammer, MA
Head, Global Product Protection, Takeda Pharmaceuticals U.S.A., Inc.

Panel Discussion
All Session Speakers

V8-S3 Room 703 16:00-17:30
Call for Abstract Session

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

SESSION CO-CHAIRS
Kazuhiro Kanmuri, PhD
Pfizer Japan Inc.

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

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

Transforming Pharmacovigilance through Robotic Process Automation and Cognitive Technologies
Glenn Carroll, MBA
Principal, Strategy and Operations, Life Sciences, Deloitte Consulting LLP

Rare Diseases in the Era of Precision Medicine
Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED

ASEAN Therapeutic Product Market Access & Regulatory Strategy
Kenny Peng, MASc, RAC, P.Eng
Managing Director, PharmEng Technology Pte. Ltd., Singapore

Integration of ICH E14 Cardiac Safety in Phase I studies and Validation of Exposure-QTc Relationships
Jörg Täubel, MD, FFPM
Chief Executive Officer, Richmond Pharmacology Ltd.
“Special Chat Sessions” will be provided for members to exchange opinions, questions, or issues and to build networking among attendees. Young or experienced attendees, academia or students, investigational sites or PMDA – please sit around our table and be our companions! Let’s talk together.

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

### <List of Topics>

<table>
<thead>
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<th>#</th>
<th>Category</th>
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<th>Abstract</th>
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<tbody>
<tr>
<td>1</td>
<td>Statistics</td>
<td>Current Trend of Statistics for Clinical Trials</td>
<td>Naoki Gion (Tno Pharmaceutical Co., Ltd.)</td>
<td>We will focus on the recent topics on clinical trials/researches such as MRCT, construction of evidence, drug development for rare diseases, use of big data, integrity of clinical trials, modeling and simulation, education of biostatistics, and biosimilars. For these topics, this session intends to share the basic principles, tasks, and measures that statisticians should consider. Through this discussion, we expect that the deeper understanding of these topics would be expanded between industry, regulatory, and academia.</td>
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<td>2</td>
<td>PV</td>
<td>Big Data, What Is Its Value from PV Perspective? How to Use It? Is it Really Creditable?</td>
<td>Kotonari Aoki, MS (Chugai Pharmaceutical Co., Ltd.), Rei Maeda</td>
<td>Time has come to implement Japan DBs into PMS and PV, such as MID-NET available in 2018 and marketed DBs that are becoming large. Regulations, e.g., GPSP, being prepared; however, circumstance including capable people allocation is still insufficient. In this session, let us talk about possibility and issues of DBs and practical use of deliverables from DB research.</td>
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<td>3</td>
<td>Labeling</td>
<td>What Will Be Affected by Newly Revised “Guide to Drafting Package Inserts for Ethical Drugs”</td>
<td>Rie Matsu, RPh (Pfizer Japan Inc.)</td>
<td>Since the Japan labeling guidelines have been amended for the first time in 20 years and will be implemented in 3 years, each company has started to discuss how to proceed according to the new labeling regulations. In this session, the information related to the new labeling guideline will be shared widely and the expected issues &amp; solution will be discussed.</td>
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<td>4</td>
<td>Six Sigma</td>
<td>How We Enjoy Problem Solving Workshop?</td>
<td>Hirota Inoue, PhD, MBA (Daiichi Sankyo Co., Ltd.), Goshi Ozawa, MS, Lean Six Sigma Certified BB (Neal Discovery Outdoors Co., Ltd.)</td>
<td>Problem solving techniques are used for better progress of our business. We often use problem solving workshop but many of facilitators always look for the better ways of “design” and “execution”. We will expect sharing success/failure experiences to obtain some insights on better problem solving.</td>
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<td>5</td>
<td>Clinical Strategy</td>
<td>Let’s Discuss “Career Plan Design” - Nobody Designs Your Career Plan. You Need to Own It!</td>
<td>Chika Kinyu, DVM, PhD (Toyoma Pharmaceutical Co., Ltd.), Yukiko Matsuhashi, MS, CCRC (Clinical and Translational Research Center, Keio University Hospital), Shizuko Uno, RPh (Saito Sanyo Co., Ltd.)</td>
<td>You seem that you are always strategic in your work. Can you still say you are also strategic for your career? What do you want to be in the future? Do you have a strategy or a plan of your future career? The chatting session led by the Clinical Strategy Community will provide a great opportunity for the people participating to the DIA Japan Annual Meeting. It doesn’t matter where you belong to and we also welcome anyone seeking your career goal. The important thing is that you are the most important player to own your career. We strongly hope that you find various ideas to realize your career dream come true. Your time to grow is so valuable for yourself as well as the people waiting for new treatment. Be strategic, proactive and feel free to join us!</td>
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<td>6</td>
<td>Project Management</td>
<td>How Do You Set in the First Step of the Project Management Development?</td>
<td>Koichi Konno, PMP (DIA Japan Project Management Development Ltd.), Takashi Sato, MSc, PMP (Kyowa Hakko Kirin Co., Ltd.)</td>
<td>To lead a project to the success, PM is playing a significant role and a responsibility. As for development of the competency of PM, it is implemented in many organizations but the trial and error still continues. In this session, we share the example of the PM training among the participants and want to explore the point of the PM development in the future.</td>
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<td>7</td>
<td>Regulatory Affairs</td>
<td>Let’s Have Better Communication between PMDA and Industries, Understanding Each Other’s Situations</td>
<td>Toshinori Higashi, PhD (CTD Inc.), Masato Komuro, PhD (Novartis Pharma K.K.)</td>
<td>In order to have smooth correspondences between PMDA and industries, let’s talk about each real thoughts and situations. In addition, let’s discuss a proposed improvement regarding the process of getting NDA approval. (Example) 1) Why PMDA give a micro query at unexpected timing? 2) Why industries take a long time for answer preparation with regardless of easy questions? PMDA wants to know a working process by industries and let’s discuss a proposed improvement of new process with understanding each other situations.</td>
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<td>8</td>
<td>Clinical Operations and Monitoring</td>
<td>Patient Centricity Efforts and Expectations in Clinical Trials - Patient-Centered Changes Clinical Trial -</td>
<td>Mitsuo Hayashi, MSc (MDS K.K.), Yukihiko Matsuoka, MSc (Eli Lilly Japan K.K.)</td>
<td>Each company raises “Patient first” and new efforts on Patient Centricity are increasing in clinical trials as well. Why new Patient Centricity? What kind of initiatives does each company do? And how will clinical trials change? Let’s talk about Patient Centricity!</td>
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<td>9</td>
<td>Medical Communication</td>
<td>Consider Ideal Handling of Pharmaceutical Information from The Patient Perspective! - Appropriate Use of Pharmaceutical Products and Proper Handling of Pharmaceutical Information -</td>
<td>Junichi Nishino, MSc, RPh (Novartis Pharma K.K.), Keiko Tsumori</td>
<td>We are now living in the world where various kinds of pharmaceutical information is readily available on the internet and almost everyone can easily access to such pharmaceutical information using their smartphones or PCs. Is the information true and based on evidence? What if patients made wrong decisions based on wrong information? We, as pharmaceutical information provider, want to openly exchange opinions on how we communicate appropriate and right information to patients in this information-flooded era.</td>
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<td>10</td>
<td>Data Management</td>
<td>Let’s Chat about How Postmarketing Clinical Trials Change with Utilization of KCT (Patient Registry, Big Data Analytics, DB Studies, etc.)</td>
<td>Motohide Nishi, MBA (Medical Solutions K.K.), Yumi Sugiyura, MRCP (Bristol-Myers Squibb K.K.)</td>
<td>Recently, the use of Real World Data for clinical development, post-marketing surveillance is drawing attention. Utilization of medical information database will be accelerated because of the revision of GPSP and the start of operation of MID-NET. Let’s talk about points to be noted and issues concerning future medical information database utilization.</td>
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SESSION 4  9:00-10:30

V1-S4 Room 605/606  9:00-10:30
The Changing Environment in the World and the Impact on the Pharmaceutical Industry

Related Interest Area(s): RA, O: ALL
Level: Beginner
SESSION CHAIR
Kihito Takahashi, MD, PhD
Vice President and Senior Managing Director, Development & Medical Affairs Division, GlaxoSmithKline K.K.

There was a worldwide impact event such as Brexit in EU and presidential election in US last year.
This session is made up of 2 parts, the first part is Brexit. We would like to discuss the influence of Brexit for pharmaceutical companies in the world.
On the other hand, the international Summit of Heads of Medicines Regulatory Agencies and meeting of the International Coalition of Medicines Regulatory Authorities (ICMRA) will convene for the first time in Japan, at the Kyoto in October and the representatives from a variety of countries and industries will discuss innovative technological developments and their practical applications, both current status and future expectations.
In this session, we would like to confirm the movement in the world and discuss about the impacts and prospect in Japan.

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

TBC
Kazuhiro Mori, MSc
Councillor for Pharmaceutical Affairs, Minister’s Secretariat, Ministry of Health, Labour and Welfare

Panel Discussion
All Session Speakers and
Alberto Grignolo, PhD
Corporate Vice President, Global Strategy, PAREXEL International
Takuko Sawada
Director of the Board, Senior Executive Officer, Senior Vice President, Corporate Strategy Division, Shionogi & Co., Ltd.
Tadaaki Taniguchi, MD, PhD
Director & Vice President, R&D Japan, AstraZeneca K.K., Japan

V2-S4 Room 607  9:00-10:30
How to Use Statistics Correctly - Understand the Meaning of P Values and Eliminate Misuse

Related Interest Area(s): RA, DM, CP, CR, ST, AC
Level: Beginner
Language: Japanese Language Only
SESSION CHAIR
Yoichi M. Ito, PhD
Associate Professor, Department of Biostatistics, Hokkaido University Graduate School of Medicine

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

General Commentary on Misuse of P-Value: According to ASA Statement on P-Values
Ayano Takeuchi, PhD
Department of Preventive Medicine and Public Health, School of Medicine, Lecturer, Keio University

Pitfalls Surrounding P-Value in Drug Development
Moriyuki Miyasato, MBA
Director, Biostatistics Department, Janssen Pharmaceutical K.K.

Providing Information on Medical Drugs with Consideration of Evidence Level
Kazumasa Takenouchi
Senior Manager, Biostatistics Group, Data Science, Astellas Pharma Inc.

V3-S4 Room 608  9:00-10:30
What is the New GPSP Ordinance Requirements for Post-Marketing Studies Using Healthcare Database?

Related Interest Area(s): RA, CR
Level: Beginner
Language: Japanese Language Only
SESSION CHAIR
Mitsune Yamaguchi, PhD
Director for MID-NET project, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

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

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

Basic Principles on Warranty of Reliability of Data when Preparing Re-examination Application Dossier by Using Electric Medical Record Database
Satoru Nakamura
Inspection Director, Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Devices Agency (PMDA)

How to Utilize Data from MID-NET® for Re-Examination Application
Sayoko Harada, MPHarm, RPh
Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

Readiness for GPSP among Database Vendors
Jin Uesawa, MBA
President, Japan Medical Data Center

Pilot Study Using the Healthcare Database Looking ahead to GPSP Inspection
Shimpei Niwa, PhD
Safety and Risk Management Department, Daiichi Sankyo Co., Ltd.

Panel Discussion
All Session Speakers

V4-S4 Room 609  9:00-10:30
Are the Drugs Appropriately Reaching to the Pediatrics in Needs? - Current Development Status and Future Steps of Pediatric Drugs in Japan -

Related Interest Area(s): RA, CR, PM, AC
Level: Intermediate
Language: Japanese Language Only
SESSION CHAIR
Natsuko Hamada
Japan Regulatory Affairs, Eli Lilly Japan K.K.

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

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

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

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

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

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

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

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

SESSION CHAIR
Koichi Konno, PMP
DIA Japan Project Management Community Lead

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

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

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

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

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

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

**TBC**
Noriko Yoshida
Project Planning & Management Forum

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

Panel Discussion
All Session Speakers

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

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

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

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

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

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

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

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

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

Panel Discussion
All Session Speakers

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

**More Advanced Approach of Medical Big Data - Part 1**

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

SESSION CO-CHAIRS
Hisashi Urushihara, DrPH, MS
Professor, Division of Drug Development & Regulatory Science, Faculty of Pharmacy, Keio University

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

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

**TBC**

**TBC**

**TBC**

**TBC**
Recently, various regulations have been developed to make realize early access to drug products. In addition to the conventional Orphan Designation, Priority Review and Advanced Medical Care, plans for SAKIGAKE Designation, Conditional Accelerated Approval System, Expanded Access Trial and Patient-requested Treatment System have been established. This session will clarify the outline of Conditional Accelerated Approval System and compartmentalization with other regulations, discuss in depth for Expanded Access Trial and Patient-requested Treatment System including actions to be taken by pharmaceutical industry and in medical practice.

**Conditional Early Approval System and Other Comparable Approval System in Japan**

Yasuhiro Araki
Deputy Director, Pharmaceutical Evaluation and Licensing Division, Ministry of Health, Labour and Welfare

**Conditional Early Approval System and Expanded Access Trials - Expectations and Challenges from Industry Perspective**

Kae Nakashima, DVM, PhD, MS
Pfizer Japan Inc.

**Can We, Academic Researchers, Contribute for an Expediting Access Scheme in Japan?**

Taro Shibata, PhD
Director, Biostatistics Division, Center for Research Administration and Support, National Cancer Center

**Panel Discussion**

All Session Speakers and
Yasuhiro Fujiwara, MD, PhD
Director, Strategic Planning Bureau, National Cancer Center

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

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

**SESSION CHAIR**

Toshiro Fujimoto, MD, MBA
Japan Development Leader, Development Center of Excellence Japan, Eli Lilly Japan K.K.

**For RMP That can be Utilized by Healthcare Professionals**

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

**SESSION CHAIR**

Yuki Kawakita, RPh
Head, HEOR Program, Japan Medical Affairs, Takeda Pharmaceutical Company Limited

**Current Status of RMP Utilization in Hospitals and Recommendations for RMP - Based on AMED Research Narukawa Team Results**

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

**RMP Utilization for ADR Reporting in the Community Health Care Setting**

Takuro Obara, PhD
Associate Professor, Tohoku University Tohoku Medical Megabank Organization, Tohoku University Graduate School of Medicine, Tohoku University Hospital

**Pharmaceutical Company’s Approach for the Usage of Risk Management Plan (RMP) in Medical Settings**

Shinya Takamoto, MSc
Group Manager, Safety Information Strategy Group, Risk communication Department, Chugai Pharmaceutical Co., Ltd.

**Regulatory Efforts to Promote Broader Use of Risk Management Plan in Clinical Practice**

Yusuke Matsumaga, PhD
Reviewer, Office of Safety II, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA)
### DAY 3 | TUESDAY | NOVEMBER 14

#### Panel Discussion
All Session Speakers

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

**Changing Landscape of Phase I Trials in Oncology**

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

**SESSION CHAIR**

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

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

**Changning Landscape of Phase I Trials in Oncology: Overview**

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

**Points to be Consider when Joining Multi-Regional First-In-Human Studies in Oncology**

Tomoyuki Kikizume, PhD  
Clinical Development Japan, Integrated Biostatistics Japan Department, Biostatistics Oncology Group, Novartis Pharma K.K.

**Strategic Phase I Trials based on the Characteristic of Investigational Drug**

Tomohiro Tanaka, MS  
Clinical Science & Strategy Department, Chugai Pharmaceutical Co., Ltd.

**PMDA Perspective**

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

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

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

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

**SESSION CHAIR**

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

How to secure critical quality for clinical trials is attracting worldwide attention as a design or management issue and that also introduced into the reflection paper of the E6 guidelines agreed last November and the E8 guidelines issued in January 2017. In this session, we outline the Quality by design and the Risk based approach to secure quality of clinical trials with an exit strategy, and make discussions.

**Building Quality in Academic Clinical Trials—Challenges to Overcome—**

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

**Key Concepts of TransCelerate RBM Methodology**

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

**Protocol Development Process Using Quality by Design Method**

Kotone Matsuyama, RPh

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

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

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

**SESSION CHAIR**

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

The paradigm shift in new drug development is accelerating. The business model has changed due to changes in regulations, enormous R & D expenses, increase in development difficulty, furthermore, IT and globalization, and the transformation of the industry is a pressing matter. On the other hand, are we responding sufficiently to securing human resources and improved skills? With limited time and money, how can we secure the talent who will take responsibility for change and improved productivity? In this session, we would like to provide a forum for both the young and the experienced staff to learn from each other, and to have a substantive discussion about career development. We also share the voice of 100 young responders to our questionnaires regarding “career” in the session.

**The Voice of 100 Young Staffs - From our Questionnaires Regarding “Career” -**

Kenta Nakaji, RPh  
Clinical Development Department 3, Clinical Development Division 1, Development Business Headquarters, EPS Corporation

Tokuhiito Sumitani, MS, RPh  
Clinical Development Department, R&D Division, Daichi Sankyo Co., Ltd.

Sho Mizokawa, MSc, RPh  
Japan-Asia Clinical Development 2, Development, Astellas Pharma Inc.

**CEO of Your Own Career**

Miyako Ishiwata, RPh  
Senior Manager, Head of Induction Manager Group, Clinical Operation Japan, PAREXEL International

**Human Resource Strategies for Recruitment, Talent Training and Career Advance to Develop Global Players**

Youji Miyatake, RPh  
Director, Office of Talent Development, HQ of Clinical Development, Otsuka Pharmaceutical Co., Ltd.

**Talent Development in “Post-Globalization” Era**

Shogo Tsuyuki, PhD  
Head of Global Development University, Japan Development, Novartis Pharma K.K.

**Panel Discussion**

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

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

**CRO Management for Effective Collaboration**

**Related Interest Area(s):** CR, PM  
**Level:** Intermediate
SESSION CHAIR
Nobuhiko Koga, MBA, PMP
Portfolio Director, Portfolio Leadership, PAREXEL International

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

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

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

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

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

V7-S5  Room 102  11:00-12:30
More Advanced Approach of Medical Big Data - Part 2
Related Interest Area(s): All
Level: Intermediate, Advanced

SESSION CO-CHAIRS
Hisashi Urushihara, DrPH, MS
Professor, Division of Drug Development & Regulatory Science, Faculty of Pharmacy, Keio University
Yui Yamamoto, MD, MBA
Founder and CEO, Minacare Co., Ltd.

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

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

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

Panel Discussion
All Session Speakers

LUNCH BREAK  13:30-14:00

SESSION 6  14:00-15:30

V1-S6  Room 605/606  14:00-15:30
Optimal Use Guidelines (Future Direction of the System, Discussion of the NDA Review Process, and Status of Actual Medical Practice)
Related Interest Area(s): RA, CR, AC, O: PV, MA
Level: Intermediate

SESSION CHAIR
Yuii Kashitani
Director, Regulatory Development, Regulatory Affairs Department, Takeda Development Center Japan, Takeda Pharmaceutical Company Limited

Discussion on the direction toward the official introduction of ‘Optimal Use Guidelines’ being in trial operation from FY2016. This session will discuss including the future issues, the target products planned for the Guidelines, impact on creating NDA dossiers or review for NDA approval when introduced the Guidelines, or any change or impact to the actual medical practice when Guidelines are introduced.

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

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

Optimal Use Guidelines: Impact on Medical Practice
Makoto Tahara, MD, PhD
Head and Neck Medical Oncology, National Cancer Center Hospital East
The basic idea of on the industry-academia cooperation to make development more efficient and easier to establish a path for drug approval. In this session, we will focus on the idea of clinical development in rare cancer and fraction areas and make it possible to conduct phase 2 trials, but their regulatory requirements differ depending on the target disease.

**RMP in the Era of Medical Big Data**

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

*Level: Intermediate*

*Language: Japanese Language Only*

**SESSION CHAIR**

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

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

**Guidance of ICH E2E “Pharmacovigilance Planning”**

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

**Epidemiological Review for Pharmacovigilance Planning in New Drug Applications**

Chieko Ishiguro, MPH
Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA)

**Is Your RMP Optimal?**

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

**Panel Discussion**

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

**Drug Developments for Rare Cancer and Fraction Areas**

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

*Level: Beginner, Intermediate*

**SESSION CHAIR**

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

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

**Collaborative Challenge for Drug Development in Rare Cancer Field**

Kan Yonemori, MD, PhD
Department of Breast and Medical Oncology, National Cancer Center Hospital, National Cancer Center

**The Current Status and the Issue of Drug Development for Rare Cancer and Rare Fraction Area from the Pharmaceutical Industry Perspective**

Miki Harumiya, MPharm
Japan Development, Solid Tumor Clinical Development Department,

Novartis Pharma K.K.

**PMDA Perspective**

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

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

*Related Interest Area(s): ALL*

*Level: Intermediate, Advanced*

*Language: Japanese Language Only*

**SESSION CHAIR**

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

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

**Point of Consider to Collaborate with Industry on Investigator Initiated Clinical Trial for Registration -Academia’s Standpoint-**

Manabu Muto, MD, PhD
Professor, Department of Therapeutic Oncology, Graduate School of Medicine, Kyoto University

**A Better Academia-Industry Collaboration Aiming for Regulatory Approval - The Experience of Cooperation with Investigator Initiated Clinical Trials -**

Izumi Okugaito
Department Manager, Prescription Products Development Department, Zenyaku Kogyo Co., Ltd.

**Effective Coordination Between Academia and Industry from the Reviewer Side**

Ken Hatogai, MD, PhD
Reviewer, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA)

**Panel Discussion**

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

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

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

*Level: Beginner*

*Language: Japanese Language Only*

**SESSION CHAIR**

Toshihiko Watanabe
Advisor, Japan CRO Association

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

In this session, Lean Six Sigma (LSS) Outline, QbD example and improvement example of quality in clinical studies at pharmaceutical industry and ARO
ICH-E6 Requirement? they be Adapted in Clinical Studies to Fulfill New Quality Tolerance Limits (QTLs) and How Should continuous improvements and innovations. 

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

SESSION CHAIR 

Level: Beginner 

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

Implementation Management in Asia after ICH Q12 Guideline Future of Development Strategy and Lifecycle V7-S6 room 102 14:00-15:30

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

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

SESSION CHAIR 

SESATOSHI SAEKI, MSc 
Associate Director, Business Process Improvement, Astellas Pharma Global Development, Inc. 

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

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

Andy Lawton Director/Consultant, Risk Based Approach Ltd

Panel Discussion 
All Session Speakers and 

Hiromichi Isaka 
Office of Non-clinical and Clinical Compliance, Pharmaceuticals and Medical Device Agency (PMDA) 

Yumi Sugiyama, MRCP 
Senior Central Monitor, Global Data Strategies and Solutions, Bristol-Myers Squibb K.K.

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

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

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

SESSION CHAIR 

YUKIO HIYAMA, PhD 
Visiting Researcher, National Institute of Health Sciences 

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

ICH Q12 guideline “Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management”, that is currently under consideration, provides a framework to facilitate the management of post-approval CMC changes in a more predictable and efficient manner. Regulators and companies from Asia will present the challenges toward ICH Q12 guideline implementation and the changes in the drug development strategy in their countries.

ICH Q12 (Pharmaceutical Product Lifecycle Management): 

PMDA Perspective 

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

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

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

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

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

Panel Discussion 
All Session Speakers 

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

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

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

SESSION CHAIR 

KAZUTO NISHIO, MD 
Professor, Kindai University Faculty of Medicine 

The existence of companion diagnostics is important for delivering medicine suitable for each patient. Genomic analysis is performed using next generation sequencer in cancer genome medical treatment, and genomic mutation for each patient and cell is revealed. In this session, present current status of “Precision Medicine” using Next Generation Sequencer, Issues in using next-generation sequencers, and issues of companion diagnostic drug development from the standpoint of each industry, government and academia. And also discuss the solution on panel-discussion.

Regulatory Perspectives on NGS-based CDx 

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

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

Takashi Kohno, PhD 
Division of Genome Biology, National Cancer Center Research Institute Approval CMC changes in a more predictable and efficient manner.

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

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

Panel Discussion 
All Session Speakers and 

Michio Tanaka 
Senior Director, Science Affairs Division, Research & Development, AstraZeneca K.K.

COFFEE BREAK 15:30-16:00
PMDA Town Hall / Closing Remarks

PMDA TOWN HALL
International Conference Room  16:00-17:30

Related Interest Area(s): ALL
Level: All

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

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

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

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

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

Chieko Ishiguro, MPH
Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Device Agency (PMDA)

Naoto Kato
Office Director, Office of New Drug III / International Senior Training Coordinator, Pharmaceuticals and Medical Device Agency (PMDA)

Toshiki Sugita, PhD
Review Management Division, Office of Review Management, Pharmaceuticals and Medical Device Agency (PMDA)

Masayoshi Shibatsuji
Coordination Officer for Review of Breakthrough Products (SAKIGAKE) / Coordination Officer for the Practical Application of Innovation, Advancements, Pharmaceuticals and Medical Device Agency (PMDA)

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

CLOSING REMARKS
International Conference Room  17:30-17:40

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

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DIA China Annual Meeting
May 22-25, 2018
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<td>[Diamond Session 2] 革新的な医薬品をより迅速に必要とする患者へ届けるために – 日米欧三極規制当局の最新動向</td>
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<td>V1-S1 GlobalPhase 1試験をリードするためには - がん開発を中心に</td>
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<td>V2-S1 (教育セッション)日本型HTA（医薬技術評価）のあり方</td>
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<td>V3-S1 (教育セッション) 日米欧の製薬後安全対策の比較</td>
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<td>V4-S1 医薬品 - 医療機器のコンビネーションを考える</td>
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<td>V1-S2 日本の 「患者中心主義」の幕開け (第1部) : 共通の価値創出を目指して</td>
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<td>V3-S2 新記載要領改正に基づく添付文書作成のためにすべきことは何か?</td>
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<td>V4-S2 個別情報保護法の改正に伴う、臨床研究をめぐる多問題</td>
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<td>V1-S3 日本の 「患者中心主義」の幕開け (第2部) : 試行錯誤の実践例から学ぼう</td>
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<td>V2-S3 医療情報を利用した医療のデジタル革命の実現に向けて</td>
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<td>V3-S3 新規薬剤承認法に基づく添付文書作成のためにすべきことは何か?</td>
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<td>V4-S3 新薬剤管理サイエンスリーグ (MSL)の役割とは何か?</td>
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関連領域:
CR=臨床オペレーション/臨床戦略、RA=薬事、ST=統計、CDM=データマネジメント、CP=安全性及びファーマコビジナンス、PM=プロジェクトマネジメント、CMC=品質管理、AC=アカデミア
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| V5-S1 | 薬剤耐性 (AMR) 対策アクションプランに基づく今後の取り組みと、医薬品開発へのチャレンジ RA, CP, CR, AC, MA |
| V6-S1 | 我が国の大変普及している開発研究機関について RA, AC |
| V7-S1 | 臨床試験のプロトコール作成 RA, AC |
| V8-S1 | サイエンスデー～あなたのプロジェクトをもう進めるための社内外調整そして交渉 ALL |

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| V5-S2 | 適切な医薬品情報コミュニケーションの更なる推進に向けて (第1部) RA, CP, AC, MA, Labelling, Marketing, Medical Writing, Medical Information |
| V6-S2 | 国際共同治験戦略のパラダイムシフト～ICH E17ガイドラインは新規薬物の中でどう利用できるのか？ RA, CR, ST, AC |
| V7-S2 | 病者中心主義との親和性が導く新たなPatient Participationのプロトコル RA, CR, AC |
| V8-S2 | 未だ未解決リスク評価の最新動向 RA, CP, CR, AC, Cardiac Safety |

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| V5-S3 | 臨床試験のプロトコール作成 (MEDIDATA SOLUTIONS K.K.) |
| V6-S3 | 臨床試験のプロトコール作成 (INC RESEARCH) |
| V7-S3 | 臨床試験のプロトコール (ポスターセッション) |
| V8-S3 | 演題公募セッション RA, CP, CR, ROD |

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| V5-S4 | プロジェクトマネジメント (PM) の効率関係～“PMがうまくいかなければ～”～もをそれを、あなたはどんなPMになりたいか？～ ALL |
| V6-S4 | Quality by Design:企業が実施する臨床試験の品質を戦略的に構築する RA, DM, CR, ST, AC, O: MA |
| V7-S4 | 更に進んだ医薬製品化への道 RA, DM, CP, ST, PM, CMHC, AC |
| V8-S4 | 更に進んだ医薬製品化への道 RA, CP, CMC, Counterfeit |

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| V5-S5 | プロジェクトマネジメント (PM) の効率関係～“PMがうまくいかなければ～”～もをそれを、あなたはどんなPMになりたいか？～ ALL |
| V6-S5 | CROとの効果的な協業のために必要なコミュニケーション RA, CP, CR, ST, PM |
| V7-S5 | 更に進んだ医薬製品化への道 RA, DM, CP, ST, PM, CMHC, AC |
| V8-S5 | Pan-Asiaによる医薬品開発の活性化 RA, CR, PM, AC, MA |

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| V5-S6 | AROと製薬企業における臨床試験の品質管理とLean Six Sigma RA, AC |
| V6-S6 | Rethinking Quality in Clinical Trials - What are Quality Acceptance Limits (QALs) and How Should they be Adapted in Clinical Studies to Fulfill ICH E6 Requirement? RA, DM, CR, ST, PM, CMHC, AC |
| V7-S6 | ICH E17ガイドラインをとおりたアジア地域でのライフサイクルマネジメントと開発戦略の将来展望 RA, CMC, AC |
| V8-S6 | 最適な薬を提供するために～コンペティット製薬の利用法と開発の現状 (次世代社内外調整を中心に)～ RA, DH, DM, CP, ST, PM, AC, Diagnostics company |
各分野に特化した翻訳ソリューション

医薬
バイオテクノロジー
医療機器

LIONBRIDGE.COM/LIFE-SCIENCES
スチューデントセッション/オリエンテーション

102会議室
9:30–12:00
スチューデントセッション
臨床試験のプロトコール作成

関連領域：薬事、アカデミア
レベル：初級
座長
千葉大学
綾部 眞織
慶應義塾大学大学院
飯村 翔平
日本大学
岡田 安矢
昭和大学
佐藤 美帆

臨床試験は医薬品の有効性・安全性評価に必須であり、実施する上で試験デザイン、評価方法等の選択や被験者への配慮は重要である。では、科学的かつ倫理的な臨床試験はどのように計画されているのだろうか。本セッションでは、臨床試験の実施計画書（プロトコール）を作成するためのエッセンスを講演していただく。その後、グループワークによるプロトコール作成演習を行い、理解の深化を図る。積極的なディスカッションを通じて、試験計画の立案過程を体験して欲しい。

なお、グループワークでは糖尿病治療薬を題材とするため、下記の文献を読んでおくことが望ましい。
厚生労働省．「経口血糖降下薬の臨床評価方法に関するガイドライン」

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

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

プロトコール作成上の留意点～経験、実例を通じての苦労した点、注意すべき点～（仮題）
第一三共株式会社
水迫 英己

講評
独立行政法人 医薬品医療機器総合機構
坂上 祐香

アドバイザー
日本大学
荒川 基記
エーザイ株式会社
大道寺 香澄
第一三共株式会社
本荘 泰広
ノバルティス ファーマ株式会社
関根 恵理
DIA Japan Student Group OBOG/第一三共株式会社
深見 明子
DIA Japan Student Group OBOG/アステラス製薬株式会社
蜂須賀 絵美
開会の挨拶および基調講演

開会の挨拶
国際会議場
13:30-13:45

DIA Japan
関口 康
DIA
Barbara Lopez Kunz

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

大会長挨拶
国際会議場
13:45-14:00

藤原 康弘
第14回DIA日本年会大会長 / 国立がん研究センター

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

プレゼンター
DIA
Barbara Lopez Kunz

アワード受賞者:

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

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

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

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

基調講演 1
国際会議場
14:15-15:15

座長
独立行政法人 医薬品医療機器総合機構
近藤 達也

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

コーヒーブレイク
15:15-15:45

基調講演 2
国際会議場
15:45-16:45

座長
国立がん研究センター
藤原 康弘

ITの利活用により、近未来の医療健康分野における劇的な進歩が予想されている。膨大な医療健康データをデジタル化・処理・構造化すれば、人工知能、ビッグデータ、そしてIoT（Internet of Things）の利活用により、医療現場、研究、教育、さらには健常人・患者の連携が進み、ITによるさまざまな形の支援が実現するであろう。

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

医療の未来像：ITの利活用と医薬品開発
帝京大学
澤 智博

40年の酵母研究を振り返って
東京工業大学
大隅 良典
DIAmond Session 1
国際会議場  16:45-17:45
次世代医療ICTを活用した医薬品開発の将来像

座長
国立がん研究センター
藤原 康弘
MSD株式会社
小野 嘉彦

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

次世代医療ICTの展望について
内閣官房
藤本 康二

追加発言
厚生労働省
森 和彦

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

パネルディスカッション
本セッションの講演者および
帝京大学
澤 智博

情報交換会
レセプションホール  18:00-19:30

ArisGlobal LifeSphere™
製品のライフサイクル全体をサポートする
最も完全なコグニティブコンピューティングプラットフォーム

オープンアーキテクチャー
アリスグローバル製品と他社製品との容易な統合の促進

コグニティブコンピューティング
コアプロセスの自動化による意思決定力を改善

マルチテナント型クラウドデプロイメント
絶えず変化する規制、アップグレード、メンテナンスコストの影響を受けず、規制に準拠しつつセキュリティ保護され、プライバシーディスクロッケートされたプラットフォーム

業界標準のベストプラクティス
すべてのコアプロセスに反映し、製品開発のライフサイクルを一変
革新的な医薬品をより迅速に必要とする患者へ届けるために — 日米欧三極規制当局の最新動向

関連領域: 全領域
レベル: 初級・中級
座長
国立がん研究センター / 国立がん研究センター 中央病院
藤原 康弘

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

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

日本における革新的な医薬品開発の取り組み（仮題）
厚生労働省
森 和彦

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

パネルディスカッション

本セッションの講演者

コーヒーブレイク
10:30-11:00
Global Phase I 試験をリードするためには — がん開発を中心に —

座長
第一三共株式会社
齋藤 宏暢

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

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

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

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

Global Phase I 試験の経験
第一三共株式会社
齋藤 格

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

パネルディスカッション
本セッションの講演者

日本と諸外国と対比した保険償還、薬価の制度紹介
東京大学
五十嵐 中

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

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

慶應義塾大学
後藤 助

ノバルティス ファーマ株式会社
岡村 晴道

日本型HTA (医療技術評価) のあり方
関連領域: 薬事、HEOR
レベル: 初級、中級
座長
テルモ株式会社
昌子 久仁子

革新的かつ高額な医薬品・医療機器が臨床現場で利用されるようになってきたことによって、ユニークな新製品の持続可能性を可能にするための政策立案の判断根拠として、医療技術評価（HTA）に注目が集まっています。

2016年研究の導入されたHTAは、本格導入に向けてその制度設計のあり方の議論が活発に行われています。

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

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

医療機器と医薬品のコンビネーション治療を考える
関連領域: 薬事、医療機器
レベル: 中級
言語: 日本語のみ
座長
独立行政法人 医薬品医療機器総合機構
石井 健介

新医薬品および新医療機器の開発分野で、新規かつイノベーションなものを作り出すことが難しい環境となっている昨今、医薬品と医療機器のコンビネーション製品あるいは医薬品と医療機器のコンビネーション治療の新たな取り組みが御光を浴びつつある。本セッションでは、医薬品と医療機器のコンビネーション治療の開発に焦点を当て、具体的な事例を紹介する。さらに、より効率的に医療機器と医薬品を同時開発し、コンビネーション治療として臨床現場に出し、かつ事業として成立させるための様々な
な課題とそれに対処するためのヒントについて議論する。

医療機器と医薬品のコンプレクション化における課題と将来
東京女子医科大学
村垣 善浩

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

パネルディスカッション

11:00-12:30

V5-S1 610会議室

薬剤耐性（AMR）対策アクションプランに基づく今後の取り組みと、医薬品開発へのチャレンジ
関連領域: 薬事、安全性、臨床、アカデミア、MA
レベル: 中級
言語: 日本語のみ
座長
独立行政法人 医薬品医療機器総合機構

薬剤耐性（AMR）対策アクションプランに基づく今後の取り組みと、医薬品開発へのチャレンジ

薬剤耐性（AMR）対策アクションプランが発表され、G7保健大臣会合に提出された。高齢化社会の進行に伴い、薬剤耐性（AMR）対策アクションプランは、医薬品開発に対する課題の解決を目的とした。

薬剤耐性（AMR）対策アクションプランに基づく今後取り組み

講演者

山田 安秀

薬剤耐性（AMR）対策アクションプランに基づく今後の取り組み

講演者

平川 晃弘

疾患レジストリへの企業からの期待

講演者

塩境 一仁
白鳥 敬子
小野薬品工業株式会社
石川 弘道
医薬品の共同開発において、その品質を高く維持し、かつ、スムーズな承認取得を目的として、パートナー会社のQA部門双方が取り組んだ具体的内容およびその経過について、直面した課題やコラボレーションから得られる相乗的効果を含めて報告する。また、当該取組みの今後の展望についても考察する。

[PO-10] クリニカルオペレーションモニタリングにおける、理想と現実のギャップに対するアプローチ
DIA COM (Clinical Operations and Monitoring) Community
菅生 和正  飯島 雅之  杉浦 志保  仲田 瑛亮
COM Communityでは、臨床試験の最前線である医療機関において、「理想と現実のGap」が何故生じるのかを検討しました。さらに、それらのGapをSite Selection, Start up, Enrollment, Processの4つに分類し、各々において私たちはどう行動するのかを議論しました。我々はGapが生じる原因を他に求めるのではなく、自分が如何にして改善させるかを追求しました。

2日目 | 11月13日 (月)
バイオジェン・ジャパン株式会社

バイオジェンは、アンチセンスオリゴヌクレオチド医薬品（ASO）における希少疾患領域で様々な研究を実施し、その中で脊髄性筋萎縮症（SMA）を対応症とし、世界で唯一のASO治療薬である「スピンラザ髄注12mg」を開発し、この新規分野におけるASO製剤の研究開発を促進している。この開発にあたり薬事戦略も十分に考慮し、CMCにおける製造方法定常化のためにプラットフォームを確立し、ASOの分析方法について探求した。特に製造時における出発物質及び精製されたASO製剤の不純物を管理することはとても重要であり、LC-MSを用いたこれらの管理戦略について考察した。
改正法の概要と臨床研究における問題点
東京大学大学院
米村 滋人
Addressing Changes in the Climate Surrounding Research Regulations at National Cancer Center
国立がん研究センター
田代 志門
演題未定
厚労省
福田 亮介
臨床研究が当面する課題
慶應義塾大学病院
三浦 公嗣
パネルディスカッション
本セッションの講演者

V5-S2 610会議室 14:00-15:30
適切な医薬品情報コミュニケーションの更なる推進に向けて（第1部）
関連領域: 薬事、安全性、アカデミア、MA、Labeling、Marketing、Medical Writing、Medical Information
レベル: 中級
言語: 日本語のみ
座長
北里大学
成川 衛
日本イーライリー株式会社
小崎 祐子
医薬品情報は、適切に提供され活用されることが重要である。昨年の年会では、規制当局や企業から医療従事者及び患者さんへ提供される資材を対象に課題や取り組みを議論した。その中で、規制当局や企業からは重複する情報を様々な媒体で提供しているが、医療現場の視点で必要な情報がなかったり、作成側の意図が十分伝わっておらず、医療現場で活用されていない状況があることがわかった。前回の議論を踏まえ、規制当局及び企業から医療機関に提供される情報媒体について、目的及び活用方法を整理し、適切な医薬品情報コミュニケーションの推進に向けた取り組みや今後の展望について、規制当局、企業及び医療機関共同でさらなる議論をする。

V7-S2 102会議室 14:00-15:30
患者中心主義との親和性が導く新たなPatient Participationのアプローチ
関連領域: 薬事、臨床、統計、アカデミア
レベル: 中級
座長
日本イーライリー株式会社
松田 幸大
患者さんにとっって価値ある医療を生み出すための1つ上のステップとして、患者さんから適切に治療/臨床研究をお届けするアプローチを模索した。すでに海外では、疾患に対する臨床試験の有無や近隣の治験実施医療機関を患者さんご自身で検索できるモバイルアプリも登場している。本セッションでは、患者さんを中心になるアプローチをとることによって、患者さんが治療/臨床研究を身近に感じることができ、さらにPatient Participationやデータ収集につながるモバイルアプリやウェブサイト、データ活用の事例を紹介するとともに、日本で発展していく上での課題についてパネルディスカッションする。

イドラインは新薬開発の中でどう利用できるのか？- ICH-E17の実践に向けて
関連領域: 薬事、臨床、統計、アカデミア
レベル: 中級
座長
エーザイ株式会社
松岡 伸篤
国際共同試験を実施するうえでの有効性と安全性における民族差
名古屋市立大学
頭金 正博
ICH-E17が医薬品開発戦略およびオペレーションに与える影響を考える
第一三共株式会社
宮崎 浩一
パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
竹田 寛
V6-S2 101会議室 14:00-15:30
国際共同治験戦略のパラダイムシフトーICH E17ガ
牧 大輔
トライアルガイド：デジタル社会における米国イーライリリー社の治験啓発活動
日本イーライリリー株式会社
内村 真紀
2型糖尿病・糖尿病予備群を対象としたスマホアプリ - GlucoNote - による臨床研究
東京大学
脇 嘉代
パネルディスカッション
本セッションの講演者

V8-S2  703会議室  14:00-15:30
催不整脈リスク評価の最新動向
関連領域: 薬事、安全性、臨床、アカデミア、Cardiac Safety
レベル: 中級
座長
独立行政法人 医薬品医療機器総合機構
品川 香

催不整脈リスク評価は、薬剤開発時と重要な論点であり、ICH E14/S7Bガイドラインが施行されてきたが、近年E14 Q&A5.1改訂により、薬物濃度-反応モデルを利用したQT延長リスク評価が認められているようになった。また心電図上のJ-Tpeak間隔や、iPS細胞由来心筋及びin silicoモデルの利用等の、新たな評価法の研究も進んでいる。本セッションでは、催不整脈リスク評価の現状と国内外の最新の研究の動向を紹介し、薬物濃度-反応モデルを利用した評価の日本での実施上の留意点についても紹介する。

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

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

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

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

パネルディスカッション
本セッションの講演者および本セッションの講演者

V2-S2  607会議室  16:00-17:30
人工知能を利用した医療のデジタル革命の実現に向けて
関連領域: 臨床、統計、アカデミア
レベル: 初級
座長
国立がん研究センター 研究所 / 東京大学大学院
間野 博行

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

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

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

V1-S3  605/606会議室  16:00-17:30
日本の「患者中心主義」の幕開け（第2部）：試行錯誤の実践例から学ぼう
関連領域: 薬事、臨床、アカデミア、患者さん
レベル: 中級
座長
ヤンセン ファーマ株式会社
三木-安田 倫栄

近年、患者中心主義（Patient Centricity）や患者・市民参画（Patient and Public Engagement）について国内での注目が急激に高まっているが、ステークホルダーが多岐に渡ることもあり、その概念や理念の理解はまだである。本セッションでは、患者中心主義の幕開けの実践例を共有し、第1部の講演者と共にパネルディスカッションを行い、医薬品開発における患者参画活動の現状と課題を整理し、今後の展開について議論する。

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

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

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

パネルディスカッション
V1-S2の講演者および本セッションの講演者

V3-S3  608会議室  16:00-17:30
人工知能を利用した医療のデジタル革命の実現に向けて
関連領域: 臨床、統計、アカデミア
レベル: 初級
座長
国立がん研究センター 研究所 / 東京大学大学院
間野 博行
新記載要領改正に基づく添付文書作成のためにすべきことは何か？
関連領域: 薬事、安全性
レベル: 中級
座長
大塚製薬株式会社
中島 謙
2017年6月、20年ぶりに医療用医薬品の添付文書等の記載要領の改正通知が発出され、3年後の2020年に施行されるため、各企業は、新記載要領に基づいた改訂添付文書を準備する必要がある。そのためには、現行の記載根拠の確認、最新データのレビュー等の実施が考えられる。本セッションでは、PMDAから、新記載要領についての要点のみならず、実際に新記載要領に基づき改訂する際に検討すべき点について、PMDAの観点から説明いただく。また、現実を見据え、企業の観点から新記載要領に基づく改訂についての課題を取り上げ、議論する。特に、外資系企業として、考慮すべき点、グローバル本社とのコミュニケーションを含めプロジェクトの進め方についても論じる。

MSLの役割と身に付けておくべきこととは？
サノフィ株式会社
富安 美千子
規制当局から見た医薬品情報の利活用におけるMSLへの期待
厚生労働省
坂西 義史
パネルディスカッション
本セッションの講演者

新記載要領に基づく添付文書改訂時のポイント～PMDAの観点から～
独立行政法人 医薬品医療機器総合機構
鎌田 暁史
新記載要領対応に向けての課題と解決に向けて～日系企業の観点から～
第一三共株式会社
齋藤 華子
新記載要領対応に向けての課題と解決に向けて～外資系企業の観点から～
ファイザー株式会社
石川 淳
パネルディスカッション
本セッションの講演者

新職種メディカルサイエンスリエゾン（MSL）の役割とは何か？
関連領域: 安全性、PM、アカデミア、MA
レベル: 初級
言語: 日本語のみ
座長
大阪大学医学部附属病院
岩崎 幸司
最近、製薬業は高度な医科学的信頼交換を主たる業務とする新職種としてメディカルサイエンスリエゾン（MSL）を設置し始めている。このセッションでは、医薬品情報の適正な利活用におけるMSLの活動について議論する。薬事業におけるMSLの活動状況等の現状把握に加えて、MSLの認知度、アカデミア、規制当局のMSLに対する捉え方を整理し、今後の適正な医薬品情報の伝達とそれを担う人材のあり方について議論する。

再生医療等製品の製品化への道
関連領域: 薬事、安全性、統計、PM、CMC、アカデミア
レベル: 初級
座長
国立医薬品食品衛生研究所
佐藤 陽治
再生医療等製品の製品化には、シーズの発見から臨床試験着手まで多くの人の手を経て進められている。本セッションでは、今話題のアカデミア研究の状況、企業開発の事例を紹介するとともに、既承認の品目における審査のポイントを臨床の視点を中心に紹介する。再生医療等製品は、新たな課題や開発の経過を通じて、フィードバックが得られる。
再生医療等製品の審査上の留意点（有効性・安全性評価を中心として）
独立行政法人 医薬品医療機器総合機構
丸山 良亮
パネルディスカッション
本セッションの講演者

V7-S3 102会議室 16:00-17:30
Globalにおける偽造医薬品の現状と日本における課題
関連領域: 薬事、安全性、CMC、Counterfeit
レベル: 初級
座長
中外製薬株式会社
大著 義章
偽造医薬品の脅威は世界的に増大しており、患者の安全のリスクとなっている。とりわけ、インターネットサイトで購入された医薬品の多くが偽造医薬品であったとの報告もある。そのため、製薬企業による製剤的工夫、税関や警察機関と連携した対応が必要となっている。
日本市場においても、「ハーボニー」の事例により、正規流通では偽造薬品は流通しないとの神話は崩れており、現状の課題を直視した対応が求められている。
本セッションでは、Globalにおける偽造医薬品の現状と業界の取組みを紹介するとともに、日本市場に潜むリスクとその対応について、NPO、アカデミア、製薬企業からパネラーをお招きし、議論を行うたい。

世界の現状（仮題）
Pharmaceutical Security Institute (PSI)
Martin Blair
日本の現状（仮題）
金沢大学
木村 和子
欧米会社の対応状況（仮題）
F. Hoffmann-La Roche, Ltd.
Pius Waldmeier
国内会社の取組み状況と課題（仮題）
Takeda Pharmaceuticals U.S.A., Inc.
Scott Kammer
パネルディスカッション
本セッションの講演者

V8-S3 703会議室 16:00-17:30
公募演題セッション
関連領域: 薬事、安全性、臨床、ROD
レベル: 初級
座長
ファイザー株式会社
冠 和宏
東京大学
湯地 晃一郎
本年会では国内外から昨年を大幅に上回る多くの応募の中から査読委員による厳正な審査を経て4つの演題が口頭発表としんで選出された。査読基準でもあるDIAのビジョンや年会テーマとの一致性、科学・学術性、国際性・社会性といった視点からも興味深いトピックスであり、当日は講演にとどまりず、フロアとの双方向での議論を行う時間も用意される。

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

You’ve never seen a Global Forum like this.
レセプションホール

総合会に

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

毎年好評いただいておりますスペシャルチャレンジセッションを今年も2日目の居にご用意しました。DIAの活動の大切な目的の1つは人材交流です！参加者同士の気軽なネットワーキング、意見交換ができる場ですので、是非、積極的にこの場をご利用頂ければ幸いです。

テーマ

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

なお、このセッションでの発言はすべて個人の見解に基づくものとさせていただきますので、予めご了承ください。

テーマ一覧

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

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<td>小澤薬品工業株式会社 杉浦 友雅</td>
<td>臨床試験、臨床研究におけるHot topicsとして、MRCT、estimandの構成、希少疾患の問題、Big Data、臨床薬理学的インテグレーションなど、統計教育、バイオインサイニングなどがあります。これらに関する議論が行われる予定です。</td>
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<td>当日ご興味のあるテーブルの周りにお集まりください。当日は、成功・失敗体験を共有し、より良い問題解決への手がかりを得たいと思います。</td>
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<td>サイクルプランをデザインしよう！に取り組むプロジェクトマネージャ（PM）育成の&quot;一緒に考えよう！～あなたはどんなPMになりたいの？～を期待されているのか～で、戦略的である主張は持つか、は多くのファシリテーターが悩むところです。</td>
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<td>なぜPMDAはこんな時期にこんなことに取り組むのか？</td>
<td>協和発酵キリン株式会社 井上 宏世</td>
<td>なぜPMDAはこんな時期にこんなことに取り組むのか？は多くのファシリテーターが悩むところです。イスラエル企業のワークショップにおいても、企業のワークショップにおいても、PMは起こさなかったことから始めるべきか、将来の会社のPMとして、あるべき企業になりたいとは、個人のキャリアを考えるうえで大切な課題です。</td>
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<td>プロジェクトマネージメント（PMI）育成のための取り組みと期待に取り組むプロジェクトマネージャ（PM）育成の&quot;一緒に考えよう！～あなたはどんなPMになりたいの？～を期待されているのか～で、戦略的である主張は持つか、は多くのファシリテーターが悩むところです。</td>
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V1-S4 605/606会議室 9:00-10:30
変わりゆく世界の情勢と製薬業界に対する影響
関連領域:薬事、ALL
レベル:初級
座長
グレゴ・スミスクリーン株式会社
高橋 希人
欧米においてEUからの英国離脱や米国の大統領選挙等世界的にもインパクトを与える出来事があった。
その一つであるEUからの英国離脱について、その現状と製薬業界にとって今後どのような影響か生じる可能性があるのか等議論する。
一方で、10月に京都にて薬事規制当局サミットが開催され、医薬品等のイノベーションと規制の新しい関係について各国規制当局が議論を行う。薬事規制当局サミット後の合意や議論を踏まえ、世界の動向を確認するとともに日本における影響等を話し合う。

V2-S4 607会議室 9:00-10:30
統計を正しく使うためには - p値の意味を理解して誤用をなくそう
関連領域:薬事、DM、安全性、臨床、統計、アカデミア
レベル:初級
言語:日本語のみ
座長
北海道大学大学院医学研究院
伊藤 陽一
臨床試験の立案や推論の際に議論すべき統計的な観点は多くあり、統計手法や結果（p値、要約統計量など）を正しく理解する必要がある。特に誤用は結果の過度を誘ったものに導くことになる。The ASA Statement on Statistical Significance and P-values, 2016では、統計的有意差やp値に対する重要な6つの原則を提示している。一方、医療用医薬品の広告の在り方の見直しに関する提言（平成26年10月22日:厚生労働科学研究班会議）では、製薬企業が上市後に提供する製品情報概要書や広告に関する正確性について示唆している。

V3-S4 608会議室 9:00-10:30
データベース調査を再審査申請資料とするための信頼性確保とは？ - 改正GPSP省令への対応～
関連領域:薬事、臨床
レベル:初級
言語:日本語のみ
座長
独立行政法人 医薬品医療機器総合機構
山口 光峰
改正GPSP省令では、平成30年4月から製造販売後調査のひとつとして、各種診察情報等のデータベース利用が認められる。この改正により、製造販売業者は、GPSP省令等を遵守し実施した各種診察情報をデータベースに用いた結果を再審査申請に利用することができるようになる。

V4-S4 609会議室 9:00-10:30
小児に必要な医薬品は適切に届いているのか？- 小児の小児開発の現状と今後の取り組み -
関連領域:薬事、臨床、PM、アカデミア
レベル:中級
言語:日本語のみ
座長
日本イーライリー株式会社
浜田 奈津子
Global開発が進みドラッグラグが解消しつつある一方で、日本における小児医薬品開発については遅れている現状がある。
EMAではPfP、FDAではPSPによる小児開発が進められおり、日本も参加
するGlobal開発が一般化しつつある現在において、小児医薬品についてもGlobal開発を検討する時期ではないかという議論が始まっている。欧米では政府による小児開発推進(PSP, PIP)が行われて10年以上が経過しており、ICH E11のAddendumもStep3となる現状を踏まえ、日本における今後の展望をMHLPW/PMDAから説明いただき、日本での小児開発の促進について、産官学のそれぞれの立場で発展的議論をする。

パネルディスカッション
本セッションの講演者

V6-S4 101会議室 9:00-10:30
Quality by Design: 企業が実施する臨床試験の品質を戦略的に構築する
関連領域: 薬事、DM、臨床、統計、アカデミア、MA
レベル: 初級
座長: 大阪大学医学部附属病院
岩崎 幸司
近年、企業が実施する臨床試験の質の確保に関する具体的施策が求められ、更にICH-E6、E8の改正が医薬品医療機器等法に与える影響を考慮して臨床試験の質を確保する方法としてのQbD および Risk Based Monitoring (RBM) が2本の柱として期待されている。RBM は既にバイオレスリスタディ等より実績が蓄積され実装化が進んでいるが、QbDについては概念の理解はあるものの、どのような観点・プロセスで進めていく必要があるのか等の方法論は更に議論を深化させる必要性がある。専門家を招き、医薬品開発の品質向上と効率化向上のために、QbDの観点から臨床試験の品質を戦略的に構築する手法を議論する場を提供する。

V7-S4 102会議室 9:00-10:30
更に進んだ医療ビッグデータの利活用（第1部）
関連領域: 全領域
レベル: 中級、上級
座長: 慶應義塾大学
漆原 尚巳
医薬品開発において医療ビッグデータの利活用は不可欠になってきた。医療ビッグデータ解析から得られた結果を意思決定の参考にすることも増えてきた。本セッションでは、治療計画策定、治験オペレーション、更にはアウトカムリサーチ・製造販売後安全対策のようなエリアで、特に革新的な医療ビッグデータの利用法を探求・実践している専門家を招いて、医療ビッグデータの利用手法の将来展開についてディスカッションする。冒頭でRWDを用いた検討における世界的なエキスパートに米国の活用事例を網羅的に紹介してもらい、日本における幅広いエリアでの最新の活用事例、またGCPリノベーションを見据えたデータ利用法について徹底討論する。
医療データベースの用量反応推定モデルへの応用
ファイザー株式会社
鈴木 昭之
リアルワールドデータを使ったアウトカム研究の応用事例
武田薬品工業株式会社
廣居 伸蔵
V7-S5に続く

バイオシミラーの臨床開発
関連領域: 薬事、臨床、統計、PM、CMC、アカデミア
レベル: 中級
座長
北海道大学病院
荒戸 照世
昨今、日本を含めグローバルでバイオシミラー（バイオ後続品）の開発が活発化している。そのような中で、バイオシミラーと先発医薬品の品質、有効性及び安全性の同等性をどのように評価すべきかについて、様々な議論がされてきた。本セッションでは、主に臨床開発や臨床試験に焦点をあて、議論を深めたい。はじめに、バイオシミラーの臨床データパッケージの特徴、バイオシミラーに特有な臨床試験デザインを説明する。また、臨床試験での同等性に関する統計的な考え方も紹介する。さらに、バイオシミラーをグローバル開発する際に課題となる国・地域ごとの相違点などを整理する。

Biosimilar Challenges from the Point of View of Project Management
第一三共株式会社
川北 由布子
【公募演題】Regulatory and Scientific Issues on Biosimilar Development in the U.S: Lessons Learned from Recent Approval
PPD
Duu-Gong Wu
Statistical Considerations for the Development of Biosimilar Products <ビデオによる講演>
Amgen Inc.
Nan Zhang
Comparative Clinical Study Designs for Biosimilar Development Program
ノバルティスファーマ株式会社
徳茂 広太

コーヒーブレイク
10:30-11:00

SESSION 5
11:00-12:30

条件付き早期承認制度ほか、医薬品の早期アクセスを実現する各種制度について
関連領域: 薬事、臨床、PM、アカデミア
レベル: 初級、中級
座長
日本イーライリー株式会社
藤本 利夫
医薬品の早期アクセスを実現する制度が近年整備され、従来からあるオーファン薬、優先審査、先進医薬品、先駆け審査制度、条件付き早期承認制度、拡大治験、患者申出薬療養が策定されてきた。条件付き早期承認制度の概要及び、他の制度との関連性を確認するとともに、拡大治験、患者申出薬療養については、企業及び、医療機関での対応などを含めて議論を深めていきたいと考える。

条件付き早期承認制度の概要と医薬品の早期承認に向けた各制度の比較について
厚生労働省
荒木 康弘
企業からみた条件付き早期承認制度および人道的見地から実施される治験への期待や課題
ファイザー株式会社
中島 香恵
Can We, Academic Researchers, Contribute for an Expediting Access Scheme in Japan?
国立がん研究センター 研究支援センター
柴田 大朗
パネルディスカッション
本セッションの講演者および
国立がん研究センター/国立がん研究センター中央病院
藤原 康弘

医療従事者が利活用できるRMPに向けて
関連領域: 薬事、安全性
レベル: 中級
言語: 日本語のみ
座長
アステラス製薬株式会社
石田 和彦
PMDAやAMEDの研究結果によると、年々医療従事者（特に病院薬剤師）の「RMPの認知度」および「医療機関での薬剤業務へのRMPの利活用」は上昇している。一方で、RMPを作成している企業側は、まだまだRMPを規制当局との文書としかとらえていないところも多い。そのような中で、病院薬剤師の一部からは、現状のRMPは医療機関で薬剤業務に利活用するには、リスクの付け方や設定条件の記載方法等においてまだわかりにくい点が多いとの声もある。医療機関でのRMPの薬剤業務での利活用を考える際、医療従事者たちはRMPに何を望み、企業および規制当局は医療従事者からの期待にどのように対応すべきかを議論する。

地域医療においてRMPを医薬品安全性情報報告に活かす
東北大学病院
林 昌洋

地変れるがん第1相試験の役割
関連領域: 薬事、DM、安全性、臨床、統計、PM、アカデミア
レベル: 初級、中級
座長
日本イーライリー株式会社
藤本 利夫
医薬品の早期アクセスを実現する制度が近年整備され、従来からあるオーファン薬、優先審査、先進医薬品、先駆け審査制度、条件付き早期承認制度、拡大治験、患者申出薬療養が策定されてきた。条件付き早期承認制度の概要及び、他の制度との関連性を確認するとともに、拡大治験、患者申出薬療養については、企業及び、医療現場での対応などを含めて議論を深めていきたいと考える。

条件付き早期承認制度の概要と医薬品の早期承認に向けた各制度の比較について
厚生労働省
荒木 康弘
企業からみた条件付き早期承認制度および人道的見地から実施される治験への期待や課題
ファイザー株式会社
中島 香恵
Can We, Academic Researchers, Contribute for an Expediting Access Scheme in Japan?
国立がん研究センター 研究支援センター
柴田 大朗
パネルディスカッション
本セッションの講演者および
国立がん研究センター/国立がん研究センター中央病院
藤原 康弘

医療従事者が利活用できるRMPに向けて
関連領域: 薬事、安全性
レベル: 中級
言語: 日本語のみ
座長
アステラス製薬株式会社
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地域医療においてRMPを医薬品安全性情報報告に活かす
東北大学病院
林 昌洋

医療従事者が利活用できるRMPに向けて
関連領域: 薬事、安全性
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地域医療においてRMPを医薬品安全性情報報告に活かす
東北大学病院
林 昌洋

医療従事者が利活用できるRMPに向けて
関連領域: 薬事、安全性
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地域医療においてRMPを医薬品安全性情報報告に活かす
東北大学病院
林 昌洋

医療従事者が利活用できるRMPに向けて
関連領域: 薬事、安全性
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地域医療においてRMPを医薬品安全性情報報告に活かす
東北大学病院
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がん臨床開発の合理化に向けて第1相試験の役割が変化してきている。従来は3+3デザインを用いた用量漸増試験を実施することが一般的であったが、近年では様々な試験デザインやグローバル第1相試験が注目されている。本セッションでは、新規がん第1相試験デザイン、多地域共同FIH、薬剤特性を考慮した第1相試験等に焦点を当て、産官学の立場からこれらの有用性について議論する。

座長
東京大学大学院
平川 晃弘

変化するがん第1相試験の役割
東京大学大学院
平川 晃弘

オンコロジー多地域共同FIH試験に参加する際の考慮すべき点
ノバルティス ファーマ株式会社
柿爪 智行

薬剤特性を考慮した戦略的第1相試験計画
中外製薬株式会社
田中 智宏

PMDAの立場から
独立行政法人 医薬品医療機器総合機構
佐藤 宏征

臨床研究法案の成立に伴い臨床研究の「質」を確保するための手法を具題する必要がある。Critical to Quality(CTQ) factorを明確にしたうえで、臨床研究のRiskを特定し、そのRiskの顕在化を予測又は検出できるように計画段階からQuality by Design(QbD)の考え方を導入することが重要である。

このセッションでは、アカデミアにおける臨床研究法への具体的な対応として、TransCelerateにおける最新動向、出口戦略を見据えたQbDによる臨床研究計画の立案及びリスクベーストアプローチによるモニタリングを用いて、研究者、規制当局及び製薬企業等の立場で今後の方向性を議論する。

座長
東北大学大学院
山口 拓洋

臨床研究法と試験の質の担保
厚生労働省
井本 昌克

パネルディスカッション
本セッションの講演者

座長
大塚製薬株式会社
桐生 千花

新薬開発を通じて大きく環境のパラダイムシフトが加速している。規制の変化、膨大な研究開発費、開発難易度の増加、さらにIT化やグローバル化によってビジネスモデルが変化し、業界の変革は急務である。

一方で人材の確保およびスキルアップにかける対応は充分か？限られたコストと時間で、変革や生産性の向上に定める人材をどのように確保するのか？

当セッションは、若手のキャリア開発について、育成される側及び育成する側の両方に登壇いただき、有意義なキャリア開発とは何かを議論する場を提供したい。

手アンケート100名の声を紹介する。

『ポスト・グローバリゼーション』時代の人材育成
ノバルティス ファーマ株式会社
露木 省吾

パネルディスカッション
本セッションの講演者および
第一三共株式会社
上野 司津子

試験の品質確保および効率化を進めるための戦略的なCROとの協業が進んでいる。しかしCROへのアウトソースの形態は、一部門のアウトソースから、マルチファンクションのアウトソースまで多種多様である。またグローバルレベルでアウトソースの契約締結するケースも多い。一方で、ICH E6R2にCROのオーバーサイドが明記されたものの、そのオーバーサイドの方法は各社さまざまな。そこで、本セッションでは、CROとの効果的な協業のために必要なCROマネジメントについて深く議論する。

座長
パレクセル・インターナショナル株式会社
古賀 信宏

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療機関・CROのそれぞれの観点から考えるCROマネジメントの在り方

グローバル製薬企業の日本法人におけるアウトソーシング戦略立案
MSD株式会社
佐野 俊治
製薬会社・CRO間のグローバル契約下において双方の日本法人が効果的に協働するには?
日本イーライリー株式会社
吉本 雄祐
医師主導治験をもとにした実施医療機関の観点からのCROとの協業
慶應義塾大学病院
藤木 勇人
CROの観点からの戦略的パートナーシップ下におけるCROマネジメント
シミュック株式会社
小林 正和

更に進んだ医療ビッグデータの利活用 (第2部)
関連領域: 全領域
レベル: 中級、上級
座長
慶應義塾大学
漆原 尚巳
株式会社 ミナケ ア
山本 雄士
医薬品開発において医療ビッグデータの利活用は不可欠になってきた。医療ビッグデータ解析から得られた結果を意思決定の参考にすることも増えてきた。本セッションでは、治験計画策定、治験オペレーション、更にはアウトカムリサーチ、製造販売後安全対策のようなエリアで、特に革新的な医療ビッグデータの活用を提案・実践している専門家を招いて、医療ビッグデータの活用手法、将来展望についてディスカッションする。

V7-S5 102会議室 11:00-12:30
更に進んだ医療ビッグデータの利活用（第2部）
関連領域: 全領域
レベル: 中級、上級
座長
慶應義塾大学
漆原 尚巳
株式会社 ミナケ ア
山本 雄士
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最適使用推進ガイドライン（今後の制度の方向性、新薬承認審査過程における議論、医療現場での実際について）
関連領域: 薬事、臨床、安全性、アカデミア、MA
レベル: 中級
座長
武田薬品工業株式会社
柏谷 祐司
昨年度より試行導入が行われている最適使用推進ガイドラインについて、今後の正式導入に向けての方向性を議論する。ガイドラインの策定対象品目、ガイドラインを策定した場合の申請資料作成や承認審査への影響、また、ガイドライン策定により、実際の医療現場ではどのような変化や影響があるのか、今後の課題も含め議論する。

V2-S6 607会議室 14:00-15:30
最適使用推進ガイドライン作成の背景と概要について
厚生労働省
杉山 恵梨

最適使用推進ガイドライン: 製薬企業の立場から
小野薬品工業株式会社
牟田 博之

最適使用推進ガイドライン: 医療現場への影響
国立がん研究センター 東病院
田原 信

最適使用推進ガイドライン: 法規制枠組み
独立行政法人 医薬品医療機器総合機構
藤原 康宏

V7-S4の講演者および本セッションの講演者

Panelディスカッション

V8-S5 703会議室 11:00-12:30
Pan-Asiaによる医薬品開発の活性化
関連領域: 薬事、臨床、PM、アカデミア、MA
レベル: 中級
座長
独立行政法人 医薬品医療機器総合機構
佐藤 淳子

Asiaにおける医薬品開発というと、日本、中国、台湾、韓国など、東アジアばかりが注目されるであります。しかしながら、昨今のASEAN地域（東アジアを含むアジア全体）においても国際共同臨床試験の実施環境が整ってきており、ICH-GCPに準拠した国際共同臨床試験の成績等も公表されるようになっています。本セッションでは、ASEAN地域における臨床試験環境の実際について紹介した上で、更なる活性化に向けた活動について議論を行います。東アジアのみならず東南アジア地域も交えてアジアールとなった医薬品開発への貢献、アジア地域での画期的新薬への早期アクセスを目的とした協働について議論をする。

演題未定
国立国際医療研究センター
渡邊 裕司

Current Status and Future Expectation of Clinical Studies by Academia
Jianzhong Zhao
PMDA’s Experiences with New Drug Applications including Data from Multi Regional (Asian) Clinical Trials
大坪 泰斗

パネルディスカッション

本セッションの講演者
レベル:中級
言語:日本語のみ
座長
日本イーライリー株式会社
前田 玲

医薬品・医療機器開発を効率的に進めることで、医師主導治療の活用等、アカデミアと企業との戦略の連携が必要である。これまで、医師主導治療を用いた承認申請を取得した事例を複数あり、最近では、企業のみで実施が難しい製造販売業者による新開発薬剤を組み合わせて製造する治療に関する承認申請を取得した事例などもみられる。本セッションでは、アカデミア・企業、及び審査を担当するPMDAの視点から、効率的な医薬品・医療機器開発に必要なアカデミアと企業の連携方法について議論する。

ICH E2E「医薬品安全性監視の計画」の基本的考え方
東京理科大学
佐藤 嗣道

医薬品承認審査における安全性監視活動計画の疫学的検討
独立行政法人 医薬品医療機器総合機構
石黒 智恵子

そのRMP、最適ですか？
中外製薬株式会社
青木 事成

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

希少がん・希少フラクション領域の臨床開発オプションを考える
関連領域:薬事、DM、安全性、臨床、統計、PM、アカデミア
レベル:初級、中級
座長
東京大学大学院
平川 晃弘

希少がん・希少フラクション領域では、pivotal trialとして少数例の第2相試験が実施されるが、その規制要件は対象疾患や標準治療等により異なるため、開発は常に手探り状態である。希少がん・希少フラクション領域の臨床開発の基本の考え方を整理し、承認申請に向けた道筋を立てることが重要である。本セッションでは、開発を効率化させるための産学連携のあり方、規制要件の明確化について取り上げ、当該領域の臨床開発の基本的考え方の整理につなげたい。

産官学連携による希少がん領域の治療開発の取り組み
国立がん研究センター
米盛 勧

希少がん・希少フラクション領域の開発の現状と課題
－製薬企業の立場から－
ノバルティス ファーマ株式会社
春宮 美希

希少がん・希少フラクション領域の開発の現状と課題
－PMDAの立場から－
独立行政法人 医薬品医療機器総合機構
込山 則行

AROと製薬企業における臨床試験の品質管理とLean Six Sigma
関連領域:薬事、アカデミア
レベル:初級
言語:日本語のみ
座長
日本CRO協会
渡辺 敏彦

臨床研究法案成立やGCP renovationにより臨床研究・臨床試験の品質を管理する方法として、Quality by DesignおよびRisk Based ApproachやCritical to Quality (CTQ) 設定など品質管理手法が導入されることがある。しかししながら、現時点において具体的な事例はなく、限られたリソースで臨床試験の現場レベルでの品質確保には工夫をしているのが現状である。本セッションでは、国際標準化機構 International Organization for Standardization (ISO) にも規定された定量的プロセス改善手法であり、世界的に品質管理・効率化の手法として活用されているLean Six Sigma (LSS) の概要を示すと共に、製薬企業でLSSを用いて試験デザイン構築段階における品質の作成込みを行ったQbD具体例及びAROでLSSを導入し臨床試験の品質を現場レベルで改善した具体例を示す。
V6-S6 101会議室 14:00-15:30
Rethinking Quality in Clinical Trials - What are Quality Tolerance Limits (QTLs) and How Should they be Adapted in Clinical Studies to Fulfill New ICH-E6 Requirement?
関連領域:薬事、DM、臨床、統計、PM、アカデミア、MA
レベル:中級
座長
Astellas Pharma Global Development, Inc.
佐伯 訓
ICH-E6 (R2) の section 5.0 では品質マネジメントのアプローチとして risk に基づく Quality Management System の考え方が新たに追加され、現在、国内の実装に向けた議論が進んでいる段階である。Quality Management System の中でも特に重要な component である Quality Tolerance Limit (QTL) に関して、海外においては TransCelerate を中心に活発な議論がなされているものの、残念ながら国内ではあまり議論されていないのが現状である。本セッションでは global expert であり、TransCelerate の RBM initiative における key member であった Andy Lawton から QTL の考え方、実際のアプローチ及びその評価方法について講演いただく。また、講演の中で紹介された QTL のアプローチについて、PMDA 及び製薬企業の方々を交えたうえで、国内での適切な実装に向けたパネルディスカッションを予定している。

Quality Tolerance Limits – A History and the Why, How, What and Where of Implementation in Clinical Trials
Risk Based Approach Ltd
Andy Lawton
パネルディスカッション
本セッションの講演者および
独立行政法人 医薬品医療機器総合機構
岸岡 康博
CFDA’s View on Implementation of ICH Q12 in China as well as Current Quality Compliance System such as PQS in China (仮題)
Center for Drug Evaluation, China Food and Drug Administration (CFDA)
Yang Wang
Pharmaceutical Quality System and Change Management Expectation to ICH Q12 from Industry
大塚製薬株式会社
仲川 知則
パネルディスカッション
本セッションの講演者

V8-S6 703会議室 14:00-15:30
最適な薬を提供するために～コンパニオン診断薬の利用と開発の現状（次世代シークエンサーを中心に）～
関連領域:薬事、DM、安全性、統計、PM、アカデミア、Diagnostics Company
レベル:初級
座長
近畿大学
西尾 和人
個々の患者さんに合った薬を届けるためにはコンパニオン診断薬の存在は重要であり、がんゲノム医療では次世代シークエンサーを用いてゲノム解析を行い、患者さんごと、細胞ごとのゲノム変異を明らかにした治療が行われている。
本セッションでは、次世代シークエンサーを用いたプレシジョンメディシンの現状、次世代シークエンサーを用いるうえでの問題点及びコンパニオン診断薬開発の課題について、座長を含めた各位から発表を行い、パネルディスカッションで解決策について議論を行う。

ICH Q12 (Pharmaceutical Product Lifecycle Management):
PMDA Perspective
独立行政法人 医薬品医療機器総合機構
岸岡 康博
進行がん患者の次世代シークエンサー遺伝子パネル検査の開発
国立がん研究センター 研究所
河野 隆志
診断薬企業からみたコンパニオン診断薬・診断システムの開発における課題
ロッシュ・ダイアグノティックス株式会社
西田 美和
パネルディスカッション
本セッションの講演者および
アストラゼネカ株式会社
田中 倫夫

コーヒーブレイク 15:30-16:00
PMDAタウンホール&閉会の挨拶

PMDAタウンホール
国際会議場 16:00-17:30

関連領域：全領域
レベル：中級
座長
独立行政法人 医薬品医療機器総合機構
佐藤 淳子
グラクソ・スミスクライン株式会社
高橋 希人

本セッションは、PMDAの担当者をパネリストに迎え、参加者からの質問についてお答えするセッションです。有意義なセッションとするため、参加者からの積極的なご発言、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
担当者

関連機関

閉会の挨拶
国際会議場 17:30-17:40

第14回DIA日本年会副大会長 / ヤンセンファーマ株式会社
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Mr. Kotonari Aoki is Department Manager of Real World Data Science and Group Manager of Epidemiology Group at Chugai Pharmaceutical Co., Ltd. Mr. Aoki has over 20 years experience in clinical data management, programming, statistical analysis and epidemiology in the field of healthcare data science. Mr. Aoki is a senior epidemiologist at the Japan Clinical Epidemiology Association and as a councilor at the Japanese Pharmace Epidemiology Association participates in many projects. Mr. Aoki is also a representative of a pharmaceutical company of MID-NET which is a national project to utilize medical data.

Yasuhiro Araki
Mr. Yasuhiro Araki is Deputy Director in the Pharmaceutical Evaluation and Licensing Division, Ministry of Health, Labour and Welfare (MHLW). Mr. Araki is at the leading position for activities reviewing and approving new drugs in the division. He has career experience in pharmaceutical authority not only as an MHLW officer but, as a reviewer in Pharmaceuticals and Medical Devices Agency (PMDA). Currently, he is working intensively to introduce “Conditional Early Approval System for drugs” and post-marketing surveys using Real World Data. Mr. Araki graduated from Graduate School of Pharmaceutical Sciences, The University of Tokyo in 1999.

Wataru Asakura, PhD
Apr 1999: Office of Review III, Pharmaceuticals and Medical Devices Evaluation Center (PMDEIC), National Institute of Health Sciences.
Jan 2000: Clinical Trial Guidance Department, Organization of Pharmaceutical Safety and Research (OPSR/KIKO).
Apr 2004: Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA).
Apr 2009: Office of New Drug V, PMDA.
Apr 2013: Office of General Affairs, PMDA.
Aug 2014: Office of New Drug IV, PMDA.

Peter Bachmann, PhD
Following a Japan Society for Promotion of Science Postdoctoral Fellowship at Kyoto University (Japan), and a German Research Foundation Fellowship at the Institute of Food Research in Norwich (UK), Dr. Bachmann worked at the Institute of Pharmaceutical Biology at the Technical University Braunschweig (Germany), until joining the German Federal Institute for Drugs and Medical Devices (BfArM) Department of Drug Approval in 1999. He currently serves as Head of the Unit of European Coordination and as Deputy-Head of the Division of European and International Affairs. Dr. Bachmann studied biology and chemistry and has a Doctorate of Natural Sciences (Pharmaceutical Biology) from the University of Wuerzburg (Germany).

Yoshifumi Banzai, PhD
Dr. Yoshifumi Banzai is Deputy Director of Compliance and Narcotics Division at Ministry of Health, Labour and Welfare (Japan). March 2004: Graduated from Graduate School of Pharmaceutical Sciences, the University of Tokyo, Japan and received Ph.D. degree in Pharmaceutical Sciences
April 2004: Joined Ministry of Health, Labour and Welfare, Japan
April 2014: Joined Toyama Prefectural Government of Japan
April 2015: Director of Pharmaceutical Policy Division, Toyama Prefectural Government of Japan
April 2017: Joined Ministry of Health, Labour and Welfare, Japan

Glenn Carroll, MBA
Glenn Carroll is a Principal in the Life Science practice with over 15 years of Pharmaceutical and Biotechnology experience. Glenn has significant consulting experience in Compliance, R&D, Medical Affairs and Pharmacovigilance. He leads Deloitte’s Drug Safety and Pharmacovigilance and Medical Affairs practices. His experience includes:

- Leading global teams to implement new global operating model strategies within Clinical, Medical and Drug Safety and Pharmacovigilance, that have included large compliance remediation efforts
- Glenn has also published several eminence papers on Research & Development, including Uses of EHR in Clinical Development and Post Launch, new operating models in Pharmacovigilance, Medical Affairs and Commercial Glenn holds a BE in Biochemical Engineering from University College Dublin and an MBA from Imperial College London.

Nancy A. Dreyer, PhD, MPH, FISPE, FDia
Nancy Dreyer is global chief of scientific affairs for QuintilesMS Real-World Insights and is responsible for advanced evidence development for regulators, payers, clinicians, and patients. She leads research using minimally interventional and non-interventional study design that use primary and/or secondary data collection. She has worked with the FDA, most recently helping to plan a medical device evaluation network, and also has worked with the European Medicines Agency testing new methods for pharmacovigilance. She is a Founding Board of both the International Society of Pharmaeoeconomics and the Drug Information Association, and is Adjunct Professor of Epidemiology at the UNC Gillings School of Public Health in North Carolina.

Dinah Duarte, PharmD, MSc
Dr. Dinah Duarte is the Head of the Scientific Evaluation Unit at the Directorate of Medicinal Products, in the Portuguese regulatory authority for medicines and health products (INFARMED). She is an expert member at the European Medicines Agency (EMA); the current Committee for Orphan Medicinal Products member for Portugal and the representative in the Steering Group of ENCePP (European Network of Centres for Pharmacoepidemiology & Pharmacovigilance).

Dr. Glenn Carroll offers consulting, training and services for labeling. Before founding Pharmaceutics 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 at a Head of global labeling Functions for Hoechst (Germany) and Hoechst Marion Roussel (USA). He has also held positions in clinical development and clinical pharmacology with Behringwerke (Germany). Before joining the pharmaceutical industry, he worked as a physician in internal medicine as well as in anesthesiology, intensive care and emergency medicine.

Yuto Fujiki, RPh
Yuto Fujiki is Research Associate at Clinical and Translational Research Center of Keio University Hospital. Fujiki is a Project Manager of Investigator Initiated Clinical Trials. After doing CRA in CRO for 10 years, Fujiki is doing Project Manager for 2 years by Keio University Hospital. Fujiki holds a RPh.

Toshio Fujimoto, MD, MBA
Toshio Fujimoto, MD, MBA, entered Eli Lilly Japan in 2006. Engaged in drug development initially in oncology area as a clinical research physician, he became Medical Director in 2009. Currently, Dr. Fujimoto is Vice President in Medicines Development Unit Japan, and responsible for the drug development and Medical Affairs in all therapeutic areas in Lilly. He also serves as a chair in Science and Regulatory Leadership Committee, PhRMA, and as an external board member for Foundation for Biomedical Research and Innovation in Kobe Biocluster.

Prior to joining Lilly, Dr. Fujimoto served as a thoracic surgeon in Japan, Germany, and the U.S., after having received his MD degree from Kyoto University in 1994.

Noriko Fujiwara, MS, RN, OCNS, CCRP
Ms. Noriko Fujiwara is Director of Planning and Coordination Office, at JORTC (Japanese Organisation for Research and Treatment of Cancer), and Research Nurse of Advanced Clinical Research Center, The Institute of Medical Science, The University of Tokyo. She has over 10 years’ experience in research field. She is a Certified Nurse Specialist in Cancer Nursing with the Japanese Nursing Association and a Certified Clinical Research Professional with the SoCRA and got the certification of Project Management from UCSD, CA, USA. She then completed a research internship at MD Anderson Cancer Center, TX, USA. She is currently a president of the Japan chapter of the International Association of Clinical Research Nurses.

Yasuhiro Fujiwara, MD, PhD
Dr. Yasuhiro Fujiwara is Principle Reviewer at Pharmaceuticals and Medical Devices Agency (PMDA). Dr. Fujiwara has about 5 years’ experience in the office of New Drug V (Oncology Unit). Dr. Fujiwara holds a PhD in Medicine from Okayama University.

Hiroyuki Fukase, MD, PhD
Dr. Hiroyuki Fukase is Director of Clinical Research Center, Clinical Research Hospital Tokyo. Dr. Fukase, as a principal investigator, has conducted various types of clinical pharmacology studies including first-in-human studies, bridging studies and thorough QT/Qc studies for approximately 24 years.

Rei Goto, MD, PhD
Dr. Rei Goto is an associate professor of health economics and health policy at Graduate School of Business Administration, Keio University. He received M.D. from Kyoto University. After two year’s residency of medicine in Kobe City General Hospital, he started research in health economics. He received Ph.D. in Economics from Kyoto University in 2005. His research area includes...
health economics, behavioral economics (addiction, measurement of time and risk preferences parameters, preventive behaviour, prescription and treatment choice of physicians) and health technology assessment. He serves as a board member of Japanese Health Economics Association (JHEA).

Alberto Grignolo, PhD
Alberto Grignolo, PhD, is a Corporate Vice President at Parexel Consulting. A 25-year veteran of the firm, he recently established the firm’s Japan Regulatory Consulting Services during a two-year assignment in Tokyo. He has been an active member of DIA since 1984, served on the DIA Board from 2000 until 2004, is the Editor of DIA Global Forum magazine, received DIA’s Global Inspire Award (Global Connector) in 2015 and was named a Fellow of DIA in 2017. He was a Member (2006-2011) of the first Executive Committee of the Clinical Trials Transparency Initiative (CTTI), a Public-Private Partnership between the FDA and Duke University aiming to increase the quality and efficacy of clinical trials.

Sayoko Harada, MPH, Pharm
Sayoko Harada is coordinator for MID-NET project. Office of Medical Informatics and Epidemiology, Pharmaceuticals & Medical Devices Agency (PMDA) of Japan. She was assigned to this office in July 2014 and has worked to improve the data quality of the MIDNET system. She joined PMDA in April 2008. She was assigned to Office of Conformity Audit (Apr. 2008 - Sep. 2009, Apr. 2013 - Jun. 2014) and Office of Relief Funds (Oct. 2009 - Mar. 2013). She holds a Master’s degree in Pharmacy from the Mukogawa Women’s University and has a license as a pharmacist.

Miki Harumiya, MPharm
Ms. Miki Harumiya is in Solid Tumor Clinical Development at Novartis Pharma K.K. Ms. Harumiya has 15 years’ experience in the pharmaceutical industries including oniology, organ transplantation and others. Ms. Harumiya holds Master of pharmacy in Tokyo University of Science.

Mei Haruya, PhD
Dr. Mei Haruya is Manager of Strategic Innovation Department in R&D Japan at GlaxoSmithKline K.K. He is currently responsible for incubating innovation across the company with leveraging digital technologies and Real World Data. Dr. Haruya has 9 years’ experience in the pharmaceutical industry, including Medicinal Chemistry Research, Clinical Research, R&D Project Management, Corporate Strategy Planning, and President’s Office. Dr. Haruya received his PhD and MS from the University of Tokyo.

Setsuko Hashimoto, PhD
Dr. Hashimoto is the President and CEO of CellSeed Inc. and the Director of FIRM (The Forum for Innovative Regenerative Medicine). Dr. Hashimoto has over 30 years’ commercial experience in bio-industry with proven expertise in creating bridges between Japanese and overseas organizations including experience as Senior Investment Advisor at Invest in Sweden Agency (currently Business Sweden) at the Embassy of Sweden in Japan responsible for Life Science field. Dr. Hashimoto is well networked in academia, government and industry, and serves for a few committees including Industry Committee of International Society for Stem Cell Research (ISSCR). Dr. Hashimoto holds a PhD in molecular biology from Heidelberg University in Germany.

Ken Hatogai, MD, PhD
Dr. Hatogai is a reviewer in Pharmaceuticals and Medical Devices Agency (PMDA), Japan. Dr. Hatogai is in charge of consultations and reviews regarding hematologic/oncology agents, and also belongs to the working group of companion diagnostics and clinical innovation network in PMDA representing the hematology/oncology department. Dr. Hatogai is originally a medical oncologist, and joined PMDA after five years experience in oncology practice, phase 1 to 3 clinical trials, and translational researches at the National Cancer Center, Japan. Dr. Hatogai holds a MD in Medicine from Chiba University.

Jin Higashijima, PhD
Jin Higashijima is an associate professor in the Faculty of Global Science Studies at Yamaguchi University in Yamaguchi, Japan. Her primary research interests include the ethical and social aspects of biomedical sciences. She currently studies patient and public involvement in scientific research in Japan as a means to examine dynamic changes in the relationship among the general public, especially patients, and the scientific community in Japan.

Robert Hilke
Robert Hilke is the CEO of Hilke Communications Corporation, a firm specializing in providing intercultural communications and TOEIC training for global businesspeople, many of whom work in the pharmaceutical industry. Mr. Hilke’s primary research interest is the management of diverse teams working in a global business environment. Mr. Hilke has made presentations at more than ten DIA conferences since 2009. In addition, he has authored more than 90 books on preparing for standardized examinations, mainly TOEIC, but also including TOEFL, GRE, and GMAT.

Akihiro Hirakawa, PhD
Akihiro Hirakawa is a Project Associate Professor at the Department of Biostatistics and Bioinformatics, Graduate School of Medicine, at the University of Tokyo. His areas of specialty are biostatistics, clinical trial methodologies, and bioinformatics. Prior to joining the University of Tokyo, he served as the Lecturer of Biostatistics at the Center Advanced Medicine and Clinical Research, Nagoya University Hospital, where he led the Statistical Analysis Section. He also served as a reviewer in the Office of New Drug V (clinical oncology) at the Pharmaceutical and Medical Devices Agency (PMDA). Dr. Hirakawa received his PhD from the Graduate School of Engineering at Tokyo University of Science.

Masakazu Hirata, PhD
Dr. Masakazu Hirata is a review director in Office of Cellular and Tissue-based Products (2017-current) and a member of Pediatric Drug WG of PMDA. He joined PMDA in 2008 and worked as senior reviewer of Office of New Drugs I (2008-2013), review director of Office of Cellular and Tissue-based products (2013-2014), and as division director of Pharmaceutical Strategic Consultation in Kansai Branch (2014-2017). He grew up in Osaka and studied medicine at Kyoto University. Dr. Hirata has PhD in pharmacology from Kyoto University. Between 2014-2017, he served as Regulatory Chair of EWG for ICH E1(R1) guidance, which was completed as ICH Step 4 document in August 2017.

Shinzo Hiroi, MPH, RPh, PMP
Mr. Shinzo Hiroi is Head of HEOR (health economics and outcomes research) of Japan Medical Affairs at Takeda Pharmaceutical Co., Ltd. In this position, Mr. Hiroi is responsible for leading all projects across several therapeutic areas. Mr. Hiroi has 30 years’ experience in the pharmaceutical industries, including clinical operation, clinical science, post marketing surveillance and HEOR. Mr. Hiroi is a registered pharmacist, and holds MPH from Kyoto University and PMP.

Makoto Hirose, MSc
Mr. Makoto Hirose is Office Director, Office of Non-clinical and Clinical Compliance Pharmaceuticals and Medical Devices Agency (PMDA). In this position, Mr. Hirose is responsible for GLP/GCP/GPSP compliance assessments in Drugs, Medical Devices and Cellular and Tissue-based Products. Mr. Hirose holds a Master of Pharmaceutical Sciences from Meiji college of Pharmacy in 1990, and the same year Mr. Hirose entered Ministry of Health and Welfare. Mr. Hirose has over 20 years’ experience in the pharmaceutical affairs and food hygiene Administration.

Yukio Hijyama, PhD
Dr. Yukio Hijyama is Visiting (retired) Scientist at National Institute of Health Sciences. He received Ph.D. degree in Chemistry from the University of Tokyo in 1979. He led an industry-government Human Science project on evaluation methods for pharmaceutical development and manufacturing control. He also led MHLW’s study groups to draft GMP related guidance and to propose the regulatory framework under the revised Pharmaceutical Affairs Law (2005). He has been involved in the ICH discussion for Q8, Q9 and Q10. His previous work experiences include positions in Pharmaceutical Development in Upjohn Co. in US and in Japan, scientist at National Institutes of Health, USA and post-doctoral fellow at University Illinois.

Motoko Honda, PhD
Dr. Motoko Honda joined Pharmaceuticals and Medical Devices Agency (PMDA) in 2006 and now she is a Review Director of Office of New Drug II.

Toyotaka Iguchi, MD, PhD
Dr. Toyotaka Iguchi is a Risk Management Director, Office of Safety II, Pharmaceutical and Medical Devices Agency. Dr. Iguchi is a hematologist/oncologist, graduated from Keio University School of Medicine and has over 10 years’ review experience at PMDA as Review Director/Risk rector and a medical reviewer. Dr. Iguchi holds a MD, PhD from Keio University, and is now also Visiting lecturer, Department of Internal Medicine, Keio University, School of Medicine (concurrent position), Part-time lecturer, Faculty of Science and Engineering, Cooperative Major in Advanced Biomedical Sciences Tokyo Women’s Medical University and Waseda University Joint Graduate School (concurrent position).

Tsunasa Ikeda
Mr. Tsunasa Ikeda is Director, Quality Assurance AsiaPac, AstraZeneca. Mr. Ikeda has experience with quality assurance activities in clinical studies more than 20 years. Mr. Ikeda is responsible for conducting various types of audit in Asia Pac region. Mr. Ikeda was deputy topic leader as the representative from Japan industry on ICH E6 (R2).
Masakatsu Imoto
Mr. Masakatsu Imoto is Director of Office of Clinical Trial Promotion, Research and Development Division Ministry of Health, Labour and Welfare (MHLW). In this position, Mr. Imoto is responsible for promotion of clinical trial. Mr. Imoto has over 20 years’ experience in the pharmaceuticals regulations, pricing of drug and research and development of medicinal products as a Japanese government officer. And Mr. Imoto also has experience of reviewing the pharmaceutical application for the approval of drugs and medical devices as a reviewer in PMDA.

Hirotaka Inoue, PhD, MBA
Dr. Hirotaka Inoue is Head of Leading Changes Office at GlaxoSmithKline KK. He is working on business improvement activities such as strategy improvement, change management, strategy development. He holds a PhD in Pharmacology and MBA. He also has a Master Black Belt of Six Sigma and a committee member of ISO18404 - a standard for Six Sigma.

Hiromichi Isaka
Mr. Hiromichi Isaka is Inspector of office of Non-clinical and Clinical Compliance Pharmaceuticals and Medical Divice Agency (PMDA). Mr. Isaka engages in document-based inspection to assess whether the submitted data comply with the data integrity standards for regulatory submission documentation. Mr. Isaka also has experience in reviewing of drug applications and planning Post-marketing safety measures for 7 years as a staff of PMDA.

Hideyasu Ishibashi, PhD
Dr. Ishibashi is currently Head, Translational Clinical Oncology Japan, Novartis. He received his PhD degree from Tokyo University of Science. He joined Novartis in 2009, and worked on several oncology clinical development projects as a senior program leader. After serving as Head of Oncology Program Management, he moved to the oncology translational research in 2015. Before joining Novartis, he worked for Ono Pharmaceutical Co., Ltd., and had experiences of drug development in a variety of therapeutic areas in Japan and US.

Kazuhiko Ishida, MSc, RPh
Mr. Kazuhiko Ishida is Associate Risk Management Director of Pharmacovigilance at Astellas Pharma Inc. In this position, Mr. Ishida is responsible for providing clinical, methodologic and strategic input to global or regional project/product management teams for development of risk management activities. Mr. Ishida has over 20 years’ experience in the pharmaceutical industry, including Clinical Development, Post Marketing Study and Pharmacovigilance. Mr. Ishida holds a MSc in Pharmaceutical Sciences from Okayama University.

Chieko Ishiguro, MPH
Ms. Chieko Ishiguro is Leader of Epidemiology team in Office of Medical Informatics and Epidemiology at PMDA. In this position, she is responsible for leading epidemiological studies using healthcare information databases. She has over 10 years’ experience in pharmacoeconomics in PMDA and also experiences in FDA and Boston University. She hold a MPH in Epidemiology from Kyoto University. She has been a councilor of Japanese Society for Pharmacoepidemiology since 2015 and is the recipient of the Best Reviewer Award of the Pharmacoeconomics and Drug Safety for 2016.

Kensuke Ishii, PhD
Dr. Kensuke Ishii is a Director for Medical Devices, Office of Medical Devices II, Pharmaceuticals and Medical Devices Agency (PMDA). He is a pharmacist and had experience of the work in the national hospital for about nine years. He moved to Ministry of Health, Labour and Welfare (MHLW) in 1996. During the period, he worked in Safety Division, Pharmaceutical and Food Safety Bureau, and in Medical Economics Division, Health Insurance Bureau etc. Thereafter, he moved to Medical Device Safety Division, Office of Safety, PMDA for post-marketing safety measures in 2004 and he became a director in Medical Device Safety Division in 2007 and moved to Office of Medical Devices as a review director in 2014. In 2014, he gained his doctoral degree from Graduate School of Medical Sciences, Yamagata University.

Jun Ishikawa
Jun Ishikawa is International Labeling Group Asia, Japan Team Leader and his role is accountable for overseeing day-to-day planning, implementation, and problem solving activities for his team whom are responsible for Japan market. Mr. Ishikawa will ensure that content management of Package Insert and Patient Leaflet for all registered products including Generic products in Pfizer Japan according to global Pfizer policy and SOPs and that regionally-set compliance targets are met on a monthly basis. Mr. Ishikawa has over 24 years’ labeling and regulatory experience in Pfizer Japan, and also has experience of participating in Pfizer Japan project of all Package Insert revision based on the new Guidelines 20 years ago.

Miyako Ishiwata, RPh
Ms. Miyako Ishiwata is the head of the Clinical Operations Induction Manager Group at PAREXEL International Japan. In this position, Ms. Ishiwata is responsible for leading the group, delivering well trained and motivated, newly hired staff to the organization. In addition, Ms. Ishiwata collaborates with PAREXEL’s Learning & Development teams, to strengthen overall staff development within Clinical Operations Japan, focusing on the development of existing employees and managers. Ms. Ishiwata has over 15 years’ experience working in the CRO sector starting as a Clinical Research Associate and subsequently a Clinical Operations Leader including acting as the coordinator for people management for a large partnership program.

Yoichi M. Ito, PhD
Dr. Yoichi M. Ito is an associate professor of Hokkaido University Graduate School of Medicine. He is engaged in a special committee member of PMDA since 2012. He holds a PhD in Health sciences from the University of Tokyo and his specialty is biostatistics.

Kunio Itoh
Mr. Kunio Itoh is Director of Clinical Research and Pharmacoeconomics Department at Taiho Pharmaceutical Co. Ltd. Mr. Ito is responsible for the Post Marketing Surveillance and Clinical Trial. Mr. Ito has more than 25 years of experience in Post Marketing Surveillance. Mr. Ito is Vice-Chairperson of Post Marketing Surveillance Expert Committee at Japan Pharmaceutical Manufacturers Association, JPMMA.

Masaru Iwasaki, MD, PhD
Masaru Iwasaki received his MD degree from the University of Tokyo in 1973. From 1974 to 1983 he made his clinical fellowship in surgery at the University Hospital Tokyo, and received his PhD in 1983. From 1983 to 1984 he was a clinical fellow at the Hannover Medical School in Germany. After returning to Japan, he moved to the department of surgery at the Yamashita Medical University, where he held a position of Assistant Professor. In April 1991, he joined Hoest Japan, and began to be involved in the drug development in the industry. In January 2000, he was assigned to a Deputy Head of R&D Division of Aventis Pharma. In 2005, he moved to GlaxoSmithKline Japan, and has been working as V.P., Managing Director of Drug Development & Medical Affairs Division at GSK Japan, taking responsibility of not only pharmaceutical drugs, but also vaccine development in Japan, coordinating with the global head located in UK and US. In 2011, he moved back to University of Yamanashi, and assigned to be a professor of Department of Clinical Research. In 2012, he was appointed as the director of Center for Advancing Clinical Research (CACR) constructing the system of translational research at this university. In 2015, he was assigned to be a vice president at this university, and a professor of Department of Advanced Biomedical Research. Concurrently he has been working as a Program Officer at AMED. His URL is miwasa@yamanashi.ac.jp

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Dr. Tomoyuki Kazizime graduated from the University of Tsukuba, College of natural science and finished master course of Mathematics, graduated school of pure and applied sciences, University of Tsukuba. He got a Ph.D. from the Yokohama City University, graduate school of Medicine. He joined Yamanouchi Pharmaceutical Co., LTD in 2002 and worked as a biostatistician. In 2009, he joined Novartis Japan as a biostatistician in Oncology business unit. Currently, he is a biostatistician in Biostatistics Oncology Group, Drug Safety & Development, at Novartis Pharma. He has extensive experience in the field of clinical research and has worked in the biostatistics team at various pharmaceutical companies, including Shimizu Pharmaceutical Co., Ltd., Toray Pharmaceuticals Co., Ltd., and Daiichi Sankyo Co., Ltd. He has also worked in the biostatistics department at the University of Tsukuba as a visiting researcher. He has authored and co-authored numerous publications in the field of biostatistics and clinical research.

Akifumi Kamata, PhD
Dr. Akifumi Kamata is a reviewer of Office of Safety II in Pharmaceuticals and Medical Devices Agency. In this position, Dr. Kamata is responsible for risk management and pharmacovigilance of vaccines and blood products. Dr. Kamata has 8 years’ experience in PMDA. Dr. Kamata holds a PhD in Pharmaceutical science from Tohoku University.

Scott Kammer, MA
Scott Kammer is responsible for leading Global Product Protection for Takeda Pharmaceuticals. Scott provides 28 years corporate security experience in the pharmaceutical industry. He has been instrumental in the development and implementation of a global strategy to combat illicit trade using a multi-prong
He has more than 20 years' experience in the pharmaceutical industry, including regulatory authorities. He holds a Ph.D from Hokkaido University in Meat Science areas of expertise also include biosimilars and he currently works as review team leader of the Japanese regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA) as a Reviewer in Office of New Drug III in 2004 and is the Office Director of Office of New Drug III, a position he has held since October 2015. He worked as a board-certified Pharmacist more than 15 years at Pharmacy Department at University of Tsukuba Hospital right after he graduated from Niho University in 1982.

Kazuko Kimura, PhD
Dr. Kazuko KIMURA, served at the Ministry of Health and Welfare for 20 years, and was dispatched to WHO HQ in Geneva in 1996-1998. She was coordinator of the WHO project on counterfeit drugs and then worked on the promotion of GMP implementation. After returning, she became Professor of the Department of Drug Management Policy at Kanazawa University, where she focused on the epidemic of substandard and falsified medicines, mainly in Asia. She also checked medicines imported via the internet. She won Kanazawa University Related Pharmacist Award. In October 2017, she inaugurates the Medi-Quality Security Institute, whose mission is to promote good quality and authentic medical products globally through GMP/GDP. This is the target 3.8 of SDG.

Chika Kiryu, DVM, PhD
Chika Kiryu graduated with a PhD in veterinary medicine from Hokkaido University in 1999 and subsequently did postdoc work in various fields. In 2003 she joined JIMRO, an Otsuka Group company, as a member of a team for introducing Chinese medical devices to Japan. In 2004 she transferred to the Free Radical Research Institute of Otsuka Pharmaceutical, moving to the Clinical Research and Development Department in 2007. She has 13 years of clinical and drug development experience, including in such areas as the CNS and inborn metabolic disorder. She is currently in charge of clinical management for oncology.

Yasuhiro Kishioka, PhD
Dr. Kishioka is a principal reviewer in the Office of Cellular and Tissue-based Products of the Japanese regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA). Since joining PMDA in 2008, his main work is the pharmaceutical quality review of biotechnological/biological products. His areas of expertise also include biosimilars and he currently works as review team leader. Dr. Kishioka has been assigned as the ICH Q12 topic leader of Japanese regulatory authorities. He holds a Ph.D from Hokkaido University in Meat Science with emphasis in Molecular Biology.

Atsushi Kitamura
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Kazumichi Kobayashi is an Senior Vice President of Otsuka Holdings Co., Ltd., and Executive Director of Otsuka Medical Devices. He joined Otsuka Pharmaceutical Co., Ltd. as a regulatory affairs staff in 1982. He was assigned as Director of Regulatory Affairs, Otsuka Pharmaceuticals in 1999. Thereafter, he was assigned to take care of clinical development and quality & safety assurance headquarters as well as regulatory affairs, as Corporate Officer. He is the first CEO of Otsuka Pharmaceutical Development and Commercialization Inc. in the US in 2007. Otsuka sent him on loan to Office of Pharmaceutical Industry Research (OPIR) in JPMF, as Senior Research Fellow, from 2012 to 2015. He works for Otsuka Holdings Co., Ltd., from April 2015.

Makoto Kobayashi, MEng, PhD
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Andreas Koester, MD, PhD
As Head of Innovation, Research & Development Operations at Janssen, Dr. Andreas Koester is leading the company's efforts to optimize the clinical trial process and bring medical innovations to patients faster. Beyond Janssen, Andreas is active in the pre-competitive space, e.g. as the oversight committee member representing Janssen at TransCelerate Biopharma. Andreas has 20+ years’ experience in pharmaceutical companies and CROs (Contract Research Organizations). His background is in drug development, and worked in leadership roles for trials that led to approvals of Prezista®, Intrelence® and Remmaryl®. Andreas is a graduate of Leipzig Medical School and earned his Ph.D. in Clinical Pharmacology from Humboldt University in Berlin.

Nobuhiro Koga, MBA, PMP
Nobuhiro Koga is a Portfolio Director at PAREXEL International. In this position, Mr. Koga is responsible for clinical development business with pharmaceutical companies. Mr. Koga has 17 years’ experience in the pharmaceutical industries, including CRA, global study management in US, clinical team leader, clinical project management, management of approximately 250 CROs as head of CRA division. In addition to assignments of clinical operation, Mr. Koga led organizational transformation, global integration activities, productivity improvement activities and many KAIZEN activities. Mr. Koga received pharmacist license in 1997, master of pharmacology in 1999, PMP (Project Management Professional) in 2010 and MBA in 2010.

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Kyoto University in 1989. He received PhD from Tokyo University. From 1995, he has studied lung cancer genetics and genomics in National Cancer Center. His representative research product is the finding of RET fusion in lung adenocarcinoma and its translation to lung cancer clinic. He is also a Chief of Division of Translational Research, Exploratory Oncology Research and Clinical Trial Center, National Cancer Center Research Institute.

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Ms. Yuko Kojima is Head of the Biometrics in the Medicine Development Unit Japan at Eli Lilly Japan K.K. In this position, Ms. Kojima is responsible for leading Scientific Communications, Statistical Science, and Pharmacokinetics/Pharmacodynamics to provide balanced, objective, and accurate scientific data and information to our customers. Ms. Kojima has over 25 years’ experience in the pharmaceutical industry and 18 years’ experience in medical communications, including 4-year experience based in Shanghai. She graduated from Kyoto Pharmaceutical University and is a registered pharmacist.

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Mr. Noriyuki Komiyama is a Deputy Review Director, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA) and engages in review and scientific consultation of new oncology drugs. He joined PMDA in 2004 and served as a reviewer or a risk manager of these drugs. In the meantime, from 2011 to 2015, he served as a technical officer at Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare (MHLW).

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Dr. Emiko Kondo is the Office Director of the Office of Safety 2, Pharmaceuticals and Medical Devices Agency (PMDA). The Office of Safety 2 is responsible for post-marketing safety measures concerning pharmaceuticals. She started her job at Ministry of Health, Labor and Welfare (MHLW) in 1991. During the period, she worked in Pharmaceutical and Food Safety Bureau, MHLW, and PMDA. In 2014, she gained her doctoral degree from Graduate School of Medical Sciences, Yamagata University.

Tatsuya Kondo, MD, PhD
Dr. Tatsuya Kondo is Chief Executive of PMDA since 2008. He spent most of his career as a neurosurgeon after his graduation from the University of Tokyo in 1968. He has various experiences including a hospital doctor, a fellowship in Max-Planck Institute for brain tumor research, and visiting staff surgeon in China-Japan Friendship Hospital in Beijing. Currently, he is also serving as the Advisor on Health and Medical Strategy for Cabinet Secretariat of Japanese Government.

Yuji Kumagai, MD, PhD
Dr. Yuji Kumagai is a clinical pharmacologist and he graduated from Medical College of Oita, Oita, Japan. He got training on clinical pharmacology especially in cardiac drugs in Post Graduate School, Medical College of Oita, Oita, Japan. After his several important works in the field of clinical pharmacology and chronobiology, he moved to Kitasato university and concentrated to works in clinical trials. He is now a professor of Clinical Research Center, School of Medicine, Kitasato University and the director of Clinical Trial Center at Kitasato University Hospital, East Hospital.

Yoichi Kurebayashi, DVM, PhD
Dr. Yoichi Kurebayashi is Senior Director of Japan Agency for Medical Research and Development (AMED). In this position, Dr. Kurebayashi is responsible for leading all project activities across AMED’s drug discovery and development programs pursued by Division of Innovative Drug Discovery and Development (DiS). Dr. Kurebayashi has over 30 years’ drug discovery experience at Daiichi, Bayer, and Pfizer. Taking advantage of the long industry experience, Dr. Kurebayashi became a professor of the Kobe University Graduate School of Medicine, where he was engaged in translational research and technology transfer. In Apr. 2013, he rose to the new challenge at AMED to lead innovative drug discovery and development in Japanese academia.

Andy Lawton
Andy Lawton has extensive experience in computing, statistics, data management, RDE/RDC, system design, RBA in CSV and clinical trials. He is currently consultant and director of Risk Based Approach Ltd. Previously, Andy held the position of Global Head of CDM at Boehringer Ingelheim, and during that time he was a Founding Committee Member of ACDM, Member of TransCelerate RBM work stream and a Member of EFPIA WG on Data Transparency. His most notable publications is the paper with Dr. Alistair Ross on GP Audit - throughout 80’s and 90’s this was the most quoted paper in the BMJ, and he won “best author of the year 2015 and 2016” from the DIA, for the TransCelerate papers on SDV and Central Monitoring in the TIRS Journal.

Chia-Chi (Josh) Lin, MD, PhD
Chia-Chi (Josh) Lin is the Director of Phase I Center, Department of Oncology, National Taiwan University Hospital and Clinical Associate Professor, Department of Surgery, National Taiwan University College of Medicine. His research interests include early phase drug development and novel therapies for thoracic (lung cancer, esophageal cancer, thyroid cancer) malignancies. Dr. Lin was appointed as the executive secretary of Taiwan Oncology Phase I Trial Consortium (TOPIC).

Daisuke Maki
Mr. Daisuke Maki’s responsibility within CR006. Inc is to spread outward recognition of the patient recruitment business. He also serves as a consultant in dealing with the laws and guidelines of patient recruitment in Japan and in planning patient recruitment strategies. Mr. Maki has 15 years of experience in the pharmaceutical development industry, but is also knowledgeable in the IT field, which was his major in university. Mr. Maki also has experience as a psychological counselor, and his experiences are utilized in clinical development related to the central nervous system area.

Hiroyuki Mano, MD, PhD
Professor Hiroyuki Mano is the Director of National Cancer Center Research Institute as well as the Professor of Department of Cellular Signaling, Graduate School of Medicine, The University of Tokyo. Professor Mano plays a central role for the organization of basic-to-clinical research activities in National Cancer Center, and for the genomic medicine platform in Japan. He discovered EML4-ALK and other oncogenes, and is still actively involved in the identification of essential growth drivers in cancer in his laboratory in The University of Tokyo. Given these tremendous achievements, he has received many prestigious awards including The Medal with Purple Ribbon from The Japanese Emperor and The Keio Medical Science Prize.

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Mr. Yukihiro Matsuda is research scientist of Clinical Development Operations & Innovations at Eli Lilly Japan K.K. Mr. Matsuda has over 15 years’ experience in the pharmaceutical companies, including clinical operation, trial management and medical writing. Mr. Matsuda holds a MSc in Biology from Kyoto University, and is also the program vice-chair of DIA COM Japan from 2016.

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I have served as a reviewer with the Office of Safety II, the Pharmaceuticals and Medical Devices Agency (PMDA) since April 2013. I am responsible for the review and evaluation of the safety of metabolic agents. I joined PMDA in April 2008. From April 2008 to March 2013, I worked as a reviewer in the Office of New Drugs. I received my Ph.D. in Medical Sciences from Kumamoto University, Japan in 2008.

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Kotone Matsuyma is currently a Professor, Medical Management, Nippon Medical University and Vice President of Integrated Clinical Research Center, Educational Institute for Nippon Medical University. She started her R&D carrier as a data manager in 2003. She has been worked as project manager since 2005. She spent 12 years at Translational Research Informatics Center, Foundation for Biomedical Research and Innovation and 2.5 years as Lecturer at Kyoto Prefectural University of Medicine. She has been managed or supported many R&D projects oriented academia, not only for drugs, but also medical devices and regenerative medicines. She graduated Kyoto University Faculty of Pharmaceutical Sciences and obtained a license of Pharmacist.

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PRESENTERS’ BIOGRAPHIES

Kazuhiro Mori, MSc
Kazuhiro Mori, MSc, is currently Councilor for Pharmaceutical Affairs, Minister’s Secretariat of the Ministry Health, Labour and Welfare (MHLW). Mr. Mori has led many of MHLW/PMDA’s drug initiatives. He contributed to introduce new approaches to drug safety regulation including the concept of Japanese risk management plan (J-RMP) and he also initiate SAKIGAKE designation system for promoting innovative new drug development and review. He served as director of Evaluation and Licensing division, Pharmaceutical and Food Safety Bureau of the MHLW from 2014-2015, and Chief Safety Officer of PMDA from 2010-2013. He also served as director of Safety division, Pharmaceutical and Food Safety Bureau of the MHLW from 2008-2010.

Yoshihiro Muragaki, MD, PhD
Dr. Yoshihiro Muragaki is a director of Faculty of Advanced Techno-Surgery at Tokyo Women’s Medical University (TWMU). Dr. Muragaki is a board neurosurgeon specializing in malignant brain tumor, and his research fields include clinical trials for gliomas and developments of new therapeutic medical devices including a smart computer operating theater (SCOT). Dr. Muragaki has also developed combination products for cancer therapy. He supports two PhDs in medicine from TWMU and in Biomedical Science from Waseda University. He is also recipient of the Award of 18th Advanced Technology Award in 2004, the Award of Sankangaku Renkeikourousya in 2010, and Good Design Award in 2016.

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Manabu Muto, MD, PhD
Dr. Manabu Muto is Professor of Department of Therapeutic Oncology, Graduate School of Medicine at Kyoto University since April 2013, and also a Head of Department of Clinical Oncology at Kyoto University Hospital Cancer Center. His areas of specialties are Molecular biology, Genetic medicine, Gastroenterology, GI Oncology and Clinical trial, especially of esophageal cancer and precision cancer medicine. He won 18 awards, and one of them was the Princess Takamatsu Cancer Research Found, Prize-winner award 2010. His membership of Medical Societies are ASCO, ASGE, ISDE, and 16 Japanese associations. He has 14 Japanese Patents. His English original articles for now are 191 and 5 English books.

Masao Nakagawa, MD
Dr. Masao Nakagawa is Chairman of the Committee on Pharmaceutical Affairs of the Japan Paediatric Society. In this position, Dr. Nakagawa is responsible for organizing networks which will be set up with affiliated pediatric subspecialty or other academic societies to support and conduct global industry-sponsored clinical trials. Dr. Nakagawa has performed on inspections of the new drugs as a Medical Reviewer in the Pharmaceuticals and Medical Devices Evaluation Center, National Institute of Health Sciences from 2002 to 2003. Dr. Nakagawa also had worked for quality control of the clinical trials as the Director of the Center for Clinical Research and Advanced Medicine, Shiga University of Medical Science Hospital from 2004 to 2014.

Tomonori Nakagawa, MA
Joined Otsuka and worked on the API process development, technical transfer, CMC preparations, inspection readiness, and supply chain. After 10 years of experiences, joined QC Department to work on the inspections readiness globally, quality audits, and quality responses to overseas. Currently, working on the project to develop supply (CMC) strategy and supply risk analysis throughout Product CMC lifecycle. A member of Japan Pharmaceutical Manufacturing Association (JPMA) Quality and Technical Committee since 2007 and ICH Project since 2010 and joined EWG for ICH Q11 and ICH Q7 Q&A and have been a JPMA topic leader for ICH Q12 guideline. Have Master’s degree for Organic Chemistry from US Graduate School.

Kenta Nakaji, RPh
Mr. Kenta Nakaji is a CRA at EPS Co., Ltd. the Contract Research Organization. Mr. Nakaji has 5 years’ experience as a CRA in the Clinical Development, including Phase III and IV trials in Endocrine/Metabolic area. Mr. Nakaji is a registered pharmacist and holds a Bachelor of Pharmacy from Meiji Pharmaceutical University.

Akihiro Nakajima
2007.3 Master of Engineering, Tokyo University of Science
2007.4 Pharmaceutical Development Administration Department, Teijin Pharma Limited

Earned a PhD from Hiroshima University in Japan and completed Postdoctoral Fellowship at School of Public Health in the University of South Carolina, and served as a Research Associate at the division of Oncology and Hematology at School of Medicine in the same university in Columbia, SC.

Koji Miura, MD, MPH, PhD
Graduated from Keio University School of Medicine, Japan, Professor Koji MIURA entered Ministry of Health and Welfare in 1983. He received Master of Public Health from Harvard School of Public Health and PhD from Keio University respectively. He had occupied many significant posts in the ministry and other ministries including Ministry of Education, Culture, Sports, Science and Technology(MEXT). During the career as a medical officer, he had long committed with health policy based on science and technology. After serving as Director General of Health and Welfare Ministry of Health, Labour and Welfare for two years, he now teaches in Keio University School of Medicine.

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Mr.Nakajima has 14 Japanese Patents. His English original articles for now are 191 and 5 English books.

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Sho Mizokawa is working as a clinical study manager at Japan-Asia Clinical Development 2 in Astellas Pharma Inc. Sho Mizokawa entered Astellas as a new graduate in 2011, and has experience of new drug development in Immunology and Nephrology disease area, etc.

Mr.Miyatake is responsible for leading all activities related to biostatistics and statistical programming/data analyses for clinical development and post-marketing surveillances in Japan. Moriyuki joined Janssen in Aug2012. Prior to joining Janssen, Moriyuki has over 20 years’ experiences in biostatistics and statistical data analyses for clinical development in some global pharmaceutical companies, including Pfizer, Wyeth, and Hoechst. Marion Roussel (currently known as Sanofi). He holds MBA degree from Bond University, Australia.

Koichi Miyazaki, PhD
Koichi Miyazaki is currently Senior Director, Clinical Development Group, Asia Development Department. In this capacity, he is responsible for developing clinical research strategies, and designing and conducting clinical trials in a wide range of disease areas in Asia region. Prior to taking current position, he was the Asia region head of regulatory affairs and was responsible for IND, NDA, and post-NDA approval in Asia. He also has experience of project leader responsible for Asia in mega-global studies. Before taking project leader position, he spent 4 years in US as project manager with overall responsibilities for study operational aspects of clinical trials both in US local studies and global studies in cardiovascular field.
Ken Nakajima, PhD
Mr. Ken Nakajima is Deputy Head of Medical Safety of Pharmacovigilance Department at Otsuka Pharmaceutical Co., Ltd. He has over 20 years’ experience in the pharmacovigilance in the Pharmaceutical Company, including the other Company. And he is Pharmacist.

Harumasa Nakamura, MD
Dr. Nakamura is Section Chief of the Department of Clinical Research Support at the Translational Medical Center and Section Chief of the Clinical Research/Trial Promotion Section, Department of Clinical Research Promotion at the National Center Hospital. Dr. Nakamura is a neurologist who is certified to practice as a specialist of clinical neurology by the Japanese Society of Neurology. He specializes in the treatment of neuromuscular diseases, neurodegenerative disorders, and neuroimmunological disorders. He previously worked as a medical reviewer for the Office of New Drug 3 at the Pharmaceuticals and Medical Devices Agency (2005-2008, 2012-2014) and was a member of the PMDA’s Orphan Medicine Working Group.

Satoru Nakamura
From April 1993 to March 2003, I had worked at the hospital pharmacy, hospital of the University of Occupational and Environment Health, Japan, and mainly been in charge of dispensing, hospital preparation, and clinical trial. From April 2003 to March 2004, I had worked at the Kajiwara Pharmacy as a pharmacist. I have been working at the Pharmaceuticals and Medical Devices Agency (PMDA, Japan) since March 2005, and been in charge of GSUP at the Office of Non-clinical and Clinical Compliance since July 2016.

Kae Nakashima, DVM, PhD, MS
Dr. Kae Nakashima is Japan Regulatory Portfolio Lead for oncology products in Pfizer Japan Inc. In this position, Dr. Nakashima leads the Japan regulatory team responsible for Pfizer Japan’s oncology portfolio, from early development stages to post-approval activities such as re-examination and post-approval commitments. Dr. Nakashima holds a Doctor of Veterinary Medicine from the University of Tokyo, a MS in Biomedical and Biophysical Science from the State University of New York at Buffalo (Roswell Park Cancer Institute) and a PhD in Pharmaceutical Medicine from Kitasato University.

Miwa Nishida
Miwa Nishida is Head of Clinical Development at Roche Diagnostics K.K. In this position, she is responsible for planning registration strategies and conducting clinical studies in Japan. She has over 10 years’ experience in the diagnostics company, including regulatory affairs and clinical operations, and also she previously worked at the pharmaceutical company as a researcher for 15 years.

Junichi Nishino, MSc, RPh
Junichi started his career as a researcher in pre-clinical department in Novartis. He moved to Regulatory Affairs in 2000, he was in charge of lots of HA meetings and NDA submissions as a regulatory manager for development projects. From 2010, he was assigned Head of Process Improvement & Excellence in RA. He had responsible for Intelligence, training, external communications etc. as a regulatory expert. He has served Head of Regulatory Operation & Labeling from 2014 to 2016. Junichi now serves Head of RA Functions dept. since Jan 2017. Junichi has taken a leadership in several industrial associations. He has a Master degree of Pharmacy and Pharmacist. He was the “2014 DIA Outstanding service award” winner.

Kazuto Nishio, MD
1986 Graduate of Wakayama Medical University, M.D. Degree 1988-1990 Staff, Fourth Department of Internal Medicine, Wakayama Medical University Hospital 1990-1992 Research Resident, Foundation for Promotion of Cancer Research at National Cancer Center Research Institute 1992-1996 Research Staff, Pharmacology Division, National Cancer Center Research Institute 1994 Ph.D. Degree, Wakayama Medical University 1996-2006 Head, Section of Drug Resistance, National Cancer Center Research Institute 2006-present Professor and Chairman, Department of Genome Biology, Kinki University School of Medicine 2014-present Director, Genome Center, Life Science Research Institute, Kindai University

Shimpei Niwa, PhD
Dr. Shimpei Niwa is working in Safety and Risk Management Department at Daiichi Sankyo Co., Ltd. He is responsible for planning and management of key issues in the department. Dr. Niwa has over 15 years’ experience in pharmaceutical industry, including clinical safety, pharmacovigilance, and epidemiology. He is a member of Working Team 5, which covers emerging topics including healthcare database and epidemiology, of Safety Committee at the Federation of Pharmaceutical Manufacturers’ Associations of Japan (FPMAJ). Dr. Niwa holds a PhD in Medicine from Jikei University School of Medicine, and belongs to International Society for Pharmacoepidemiology.

Taku Obara, PhD
Dr. Taku Obara is Associate Professor of Department of Pharmaceutical Sciences at Tohoku University Hospital. Dr. Obara is also belonging to Department of Molecular Epidemiology, Tohoku University Graduate School of Medicine and Division of Preventive Medicine and Epidemiology, Tohoku Medical Megabank Organization, Tohoku University. The field of specialty of Dr. Obara is pharmacoepidemiology especially in postmarketing period. Dr. Obara holds a PhD in Clinical Pharmaceutical Sciences from Tohoku University.

Yoshinori Ochiai, PhD
Dr. Yoshinori Ochiai is reviewer for clinical pharmacology at Pharmaceuticals and Medical Devices Agency (PMDA). After graduating, he worked at research institute International Medical Center of Japan as postdoctoral fellow. He explored a genetic basis of multi-factorial diseases such as hypertension, diabetes mellitus and vascular complications. After postdoctoral fellow, he worked at CRO company and he analyzed clinical data and pharmacokinetic data. Since 2014, he has been working at PMDA.

Yoshiaki Ohashi, PhD
Dr. Yoshiaki Ohashi is Head of Quality and Regulatory Compliance Unit and General Manager of Drug Safety Division at Chugai Pharmaceutical Co., Ltd. Dr. Ohashi acts as General Marketing Authorization Holder Manager and is responsible for the quality and safety of all marketed products of Chugai. Dr. Ohashi has nearly 30 years’ experience in the pharmaceutical industry, including project management and regulatory affairs, and he established the first document management system at Chugai. Dr. Ohashi holds a PhD in Pharmacy and has given numerous lectures on quality and safety and acted as a chair, panelist, and moderator at a wide range of pharmaceutical industry symposiums and conferences.

Yoshinori Ohsumi, PhD
Dr. Yoshinori Ohsumi is Honorary Professor and Head of Cell Biology Center, Institute of Innovative Research at Tokyo Institute of Technology. Dr. Ohsumi is the forerunner of autophagy research and has been studying yeast for 40 years. Dr. Ohsumi’s discoveries laid the foundation for a better understanding of the ability of cells to manage malnutrition and infections, the causes of certain hereditary and neurological diseases, and cancer. Dr. Ohsumi holds a PhD in Science from The University of Tokyo at 1974, and is also the laureate of The Nobel Prize in Physiology or Medicine 2016 for his discoveries of mechanisms for autophagy.

Harumichi Okamura
Mr. Harumichi Okamura is Head of Market Access and Public Affairs at Novartis Pharma. Mr. Okamura has 18 years’ experience of market access and pricing in pharmaceutical industry, and contributed to drug pricing reform debate as the chairman of Economic Affairs Committee of PhRMA Japan for 16 years. Mr. Okamura also has experience in dealing with health care policy at IHEP (Institute of Health Economics and Policy) and Nomura Research Institute.

Izumi Okugaito
Mr. Izumi Okugaito is Head of Prescription Products Development at Zenyaku Kogyo Co., Ltd. He has over 20 years’ experience in the pharmaceutical company including regulatory affairs and clinical development.

Michiyo Ohshima, MBA
Ms. Michiyo Ohshima is Head of Japan Portfolio and Project Management at Pfizer Japan Inc. In this position, Ms. Ohshima leads the pan-Business Unit project management support and portfolio operations. Ms. Ohshima has over 20 years experience in the pharmaceutical and biotechnology industries, including project management across several therapeutic areas, and project management office. Ms. Ohshima holds an MBA.

Yoshikiko Otaguro
Yoshikiko Otaguro is a Chair of Corporate Ethics sub-Committee, Governance and Legal Committee of EFPIA Japan. She is a member of steering committee of the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry and a member of Code Compliance Committee of JPMA. She is a qualified pharmacist, and has experienced in several fields at GlaxoSmithKline for over 30 years, such as regulatory affairs, drug information, quality assurance, training, sales and compliance.
PRESENTERS’ BIOGRAPHIES

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Mr. Yasuto Otsubo is reviewer of Office of New Drug V at Pharmaceuticals & Medical Devices Agency (PMDA). In this position, Mr. Otsubo is responsible for reviewing new anti-cancer drugs and medical trial consultations as the team leader. Mr. Otsubo has over 10 years’ experience in the regulatory agencies. Mr. Otsubo is also a member of Companion Diagnostics Project Team and Omics Project Team of PMDA.

Kenny Peng, MAsc, RAC, P.Eng
Kenny Peng, MAsc, RAC, P.Eng., is Managing Director, Asia, for PharmEng Technology, a professional consultancy headquartered in Canada, with regional operations for US, Greater China, and Southeast Asia. Kenny is a Masters graduate in Mechanical Engineering from University of Waterloo, Canada, a licensed professional engineer, and a certified regulatory affairs professional, and primarily consults in North America, Southeast Asia, and East Asia. He specializes in cross-border projects, sample work included as international technology transfers, international business development, and region-wide regulatory affairs for medical devices, pharmaceuticals, nutraceuticals, biosimilars, and biologics.

Francesco Pignatti, MD
Francesco Pignatti graduated as medical doctor at the University of Rome La Sapienza. In 1995 he became research fellow at the EORTC Data Center, Brussels, Belgium, where he was involved in numerous activities including clinical trial design, conduct, and reporting. In 1997 he became Medical Advisor for the Gastrointestinal Tract Cancer Cooperative Group, and Brain Tumor Cooperative Group. In 1997 he obtained a Master of Science degree in Biostatistics from the University of Limbourg, Belgium. In 1999 he joined the European Medicines Agency (EMA) in London. Since 2000 he holds the position of Head of Oncology, Haematology and Diagnostics in the Division for Human Medicines Development and Evaluation.

Robert F. Reynolds, MSc, ScD, FISPE
Dr. Reynolds is Vice President, Epidemiology in Worldwide Safety at Pfizer. He heads a group of epidemiologists and statistical analysts responsible for developing epidemiologic programs to support drug development and safety assessment. He is also an Adjunct Associate Professor of Epidemiology at Tulane School of Public Health and Tropical Medicine where he teaches pharmacoepidemiology. He is a Fellow and former Board member of the International Society for Pharmacoepidemiology. He holds a BA in Biology from Bard College and a MSc in Epidemiology and ScD in Population and International Health from the Harvard School of Public Health.

Satoshi Saeki, MSc
Satoshi Saeki has over 20 years of experience on clinical development and operations in Astellas. He is currently working in Astellas USA as an expatriate for clinical business process improvement. He has been heavily involved in global initiatives such as RBM and eQS in TransCelerate and working on external engagement activities to bring more familiarization of RBM and eQS concepts in Japan. Satoshi served as a program vice chair for DIA Japan annual meeting in 2015 and engaged in a member of program committee for DIA Japan annual meeting 2014 and 2016. He has also been a member of program committee for DIA clinical operation and monitoring workshop from 2013.

Hanako Saito
Ms. Hanako Saito is Leader of Safety Information Management Group in Safety and Risk Management Department at DAIICHI SANKYO Co., Ltd. In this position, Ms. Saito is responsible for Japanese package inserts of DAIICHI SANKYO’s products. Ms.Saito has over 20 years’ experience in the pharmaceutical industries.

Hironobu Saito, PhD
Dr. Saito received his Ph.D. from Chiba University in Japan. At first, he was the member of Research division and moved to clinical strategic team and became team leader . From 2006, he also had the responsibility for Asian development section. From 2012, he became vice president of new drug regulatory affairs Department in Japan. From 2016, he has become vice president of oncology clinical development in Japan.He had been Chairman of DIA Asian Workshop in Japan for 5 years. He got DIA outstanding award in 2007. He is now member of DIA advisory Committee of Japan in 2015. He has been JPMA rep. of ICH steering Committee and chairperson of ICH project committee in JPMFA from 2012 to 2016.

Kaku Saito, MSc, PMP
Kaku Saito is a Manager, Oncology Clinical Development Department at Daiichi Sankyo Co., Ltd., Japan. He serves as an East Regional Project Lead of the early phase product. Saito received Bachelor’s and Master’s degrees from Tohoku University and is currently attending Rutgers Business School, NJ. He worked for 7 years in Japan and 7 years in the US, working on multiple global phase 1, 2, and 3 studies. His recent research activities include the oversight of several global early phase and ROC studies in Oncology by leveraging his expertise on novel designs/idea such as accelerated titration, modified CRM (Continual Reassessment Method) and backfill. His works have been published in several scientific journals to date.

Yuka Sakagami
Yuka Sakagami is a reviewer in the Office of New Drug I at Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, reviewing new drugs for metabolic disorders. She joined PMDA in 2014 after graduating with a master’s degree in pharmaceutical sciences from Tokyo University of Science.

Toshiharu Sano, RPh
Mr. Toshiharu Sano, R.Ph, joined Banyu Pharmaceutical Co., Ltd. in April 1990, and currently serves as the head of Clinical Operations, Japan Development. Mr. Sano has over 27 years of experience in pharmaceutical industry and has broad experiences in Clinical Research, R&D planning and Business Operations for Clinical Development in Japan. He also worked as several initiative leads and change manager on behalf of MRL in Japan through his career. Mr. Sano holds a B.S. in Pharmacy from Showa Pharmaceutical University in 1990. He is a registered pharmacist in Japan.

Keichi Sasaki, DDS, PhD
Dr. Keichi Sasaki is Dean at the School of Dentistry and Professor in Division of Advanced Prosthetic Dentistry, Tohoku University, Sendai, Japan. He received his basic training (DDS, 1983) and neurophysiology (PhD, 1985) at Tohoku University. He was involved in the biomechanical researches with Prof. A. G Hannam at University of British Columbia, Canada (1987-1989). In 2000 he was appointed head of the Department of Prosthodontics, Tohoku University. Professor Sasaki has been involved in both clinical and research works, particularly in biomechanics and mechanobiology of stomatognathic components related to dental implants. He is past president of Japan Prosthodontic Society (2009-2011).

Akira Sato, MSc
Director, Global Project Management Department, Daiichi Sankyo Co., Ltd. Akira Sato has 15 years’ experience in CMC and project management for bio-pharmaceutical projects. From the entry into biosimilar business in 2011, Mr Sato was taking a lead for several biosimilar projects. From 2016, Mr Sato is overseeing biosimilar projects in present post.

Hiroyuki Sato, PhD
Dr. Hiroyuki Sato is a Biostatistics Reviewer in PMDA. Dr. Sato started his career as a Biostatistics Reviewer of new drugs for psychiatric disease and CNS in 2009. Currently Dr. Sato is working for the review office for oncology drugs, which frequently face to advanced and complicated clinical study designs.

Katsuki Sato
Mr. Katsuki Sato is Manager of Safety Evaluation and Risk Management at GlaxoSmithKline (GSK) Japan. In this position, Mr Sato is responsible for leading pharmacovigilance activities for Japan marketed products. Mr Sato has 15 years’ experience in GSK Japan, including study operation for respiratory products, development strategy for infection/psychiatric/neuroscience products, and Japan project lead for neuroscience products. Mr Sato is a member of ICH E11 (Clinical Investigation of Medicinal Products in the Pediatric Population) Revision 1 Expert Working Group. Mr Sato is leading Pediatric Drug Development team, Clinical Evaluation Committee, Japan Pharmaceutical Manufacturers Association.

Tomohiro Sawa, MD, PhD
Dr. Sawa is a professor of Medical Information System Research Center and Chief Information Officer at Teikyo University in Japan. Dr. Sawa is a board certified anesthesiologist in Japan and the U.S. and an ABPM board certified specialist in medical informatics in the U.S. Dr. Sawa has been serving for Division of Patient Safety in Japanese Society of Anesthesiologists and has been leading a project of developing and maintaining a nation-wide perioperative case registry. Dr. Sawa is a Vice-President of Japan Association for Medical Informatics. Dr. Sawa’s research interest focuses on large-scale clinical and research databases. Dr. Sawa has been applying a range of big data technologies and machine learning algorithms to healthcare data.

Takuko Sawada
Director of the Board, Senior Executive Officer , Senior Vice President, Corporate Strategy Division, Shionogi & Co., Ltd. Following her graduation from Kyoto University, Takuko Sawada joined Shionogi
Mr. Taro Shibata is Chief of Biostatistics Division, Center for Research Administration and Support at National Cancer Center, Japan. In this position, Mr. Shibata is responsible for leading all biostatistical activities in the NCC: collaboration, consultation, training, and methodological development. Especially, as a division chief, he contributes for more than 100 ongoing clinical trials/ancillary clinical studies with division members. He is also a member of the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council.

Kaori Shinagawa, MD, PhD
Dr. Kaori Shinagawa is Senior Scientist for Clinical Medicine, PMDA. She has been involved in clinical trial consultations and reviews of new drugs, assessments of cardiac safety of new drugs, and in creating new guidelines for Japanese drug applications. She has also been involved in ICH activities since 2005 including the E14 topic on clinical QT assessment. She is an executive committee member of the Cardiac Safety Research Consortium. She is a cardiologist and holds a doctoral degree of Medical Science. Dr. Shinagawa’s main research field was electrophysiology, and she has published in a variety of prestigious cardiovascular journals. She received the Kimura Memorial Award from the Japanese Heart Rhythm Society in 2000.

Kazuhito Shiosakai
Kazuhito Shiosakai is Manager of Statistical Analysis Group in Biostatistics & Pharmaceutical Co. Ltd. Mr. Shiosakai has over 10 years’ experience in the pharmaceutical industry and joined Cincinnati Children’s Hospital Medical Center as a visiting scholar in 2016. Dr. Shinozawa holds a PhD in Agriculture from Hokkaido University and is currently a member of the steering committee of ten global trials of new drugs for head and neck cancer.

Makoto Tahara, MD, PhD
Dr. Makoto Tahara is Chief of Department of Head and Neck Medical Oncology, National Cancer Center Hospital East, Kashiwa, Japan. He has worked in the field of Medical Oncology since 1993, became a board-certified specialist in Medical Oncology in 2006, and received his PhD in Medical Sciences in 2004 from Hiroshima University School of Medicine. He has established a Head and Neck cancer Group in Japanese Clinical Oncology Group (JCOG). He is a member of steering committee of ten global trials of new drugs for head and neck cancer. He received Award of an alumni association of National Cancer Center in 2005 and “Paper of the year 2005” in Japanese Journal of Clinical Oncology.

Kazuuki Suzuki
Mr. Kazuki Suzuki is a member of Trial Management Department at Novartis Pharma K.K. Mr. Suzuki is responsible for leading clinical trials from start to end. Mr. Suzuki has 20 years’ experience in pharmaceutical industries in clinical development and operations.

Kihito Takahashi, MD, PhD
Dr. Takahashi is currently Vice President and Senior Managing Director of Japan Development and Medical Affairs, GlaxoSmithKline Japan. He graduated from Hokkaido University School of Medicine in 1981, and received his PhD in Medical Science in 1986. He served as Research Assistant Professor of Medicine at Vanderbilt University from 1990 to 1992, and joined Merck Research Laboratories in 1992 and served as Vice President, Merck Research Laboratories from 2003 to 2008. After retiring from Merck, he served as a President & CEO of LOTUS Pharmaceutical Co. Ltd, a bio-venture company before joining GSK.

Shunichi Takahashi, PhD
Dr. Shunichi Takahashi is Head of Open Innovation Center Japan (ICJ) in Bayer Yakuhin, Ltd. In this position, he is responsible for leading all research alliance activities with academic institutions in Japan. He is also leading a team to explore new opportunities using Big-Data, advanced analytics, and digital devices for patients and pharma companies. He has over 20 years’ experience in Research, Product Development (PD), and Medical Affairs (MA):
1993: Scientist / Drug Discovery / Mitsui Pharmaceuticals
2001: Scientist / Cardiovascular / Nihon Schering
2007: Sr. Scientist / Stem Cell Based Drug Discovery / Bayer
2008: Cardiovascular Project Manager / PD / Bayer
2013: Head of Primary Care / MA / Bayer
2014: Head of ICI / Bayer

Akiko Takase, MSc
Akiko Takase is a Senior Scientist, Regulatory Affairs Area, Japan Development, MSD K.K. She is currently engaged in new drug development in Infectious Disease area, as a Regulatory Strategy & Liaison. Her career was started at Banyu Pharmaceutical, CO., LTD (currently MSD K.K.) after finishing her master’s degree in Pharmaceutical Sciences from Toyama Medical and Pharmaceutical University (currently Toyama University). She has been engaged in clinical development as CRA, Medical Writer, Clinical Scientist and Clinical Monitor at MSD K.K. She served as a Sponsor’s Representative for clinical studies of antimicrobial agents in Clinical Research Area before current assignment. She is a member of The Japan Society of Chemotherapy.

Hiroshi Takeda, MS
Hiroshi Takeda is a reviewer of Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA). He is currently engaged in review of drugs for neurology and psychiatry.

Shinya Takemoto, MSc
Mr. Shinya Takemoto, MSc, is a pharmacist. He joined Chugai Pharmaceutical in 2002. He was engaged in the whole process of Drug Safety/Pharmacovigilance. In 2011 he moved to Roche in Switzerland, responsible for risk management until 2013. He then came back to Chugai and now he is a Group Manager of Safety Information Strategy Group in Risk communication dept.. He is now responsible for preparation of risk minimization materials and development of ICT based safety communication tool including Web-site and application.

As an industry activity, he joined JPMA (Japan Pharmaceutical Manufacturers Association), Task force 1 (TF1) to manage RMP related issues. In 2016, he became a leader on KTI continued from TF1, to handle RMP related issues.

Toichi Takenaka, DVM, PhD
Dr. Toichi Takenaka is Chairperson of Health Research Society of Toyama University. He has over 20 years’ experience in the pharmaceutical industry as statistician. Mr. Takenouchi has over 25 years’ experience in Animal Research in Animal Research and Development Division of Chugai Pharmaceutical Co., Ltd. He has been involved in the creation and management of Drug Safety/Pharmacovigilance/Regulatory Affairs Area of Chugai Pharmaceutical Co., Ltd. Mr. Tanaka graduated from Graduate School of Kyushu University in 2000. Mr. Tanaka joined Nippon Roche K.K. after graduation and now work for Chugai pharmaceutical Co., Ltd. Mr. Tanaka has 17 years’ experience in the clinical development. In the current position, Mr. Tanaka is responsible for leading the activities of the clinical science in the oncology field.

Taketo Takenouchi, MSc
Mr. Takenouchi is one of biostatistics subgroup leaders, taking charge of instructing and managing biostatistics operation and progress of clinical studies and NDA submission. Mr. Takenouchi has been participating in the Data Science Division of the Japan Pharmaceutical Manufacturers Association as a member of Biostatistics Group. He has over 20 years’ experience in the pharmaceutical industry as statistician.

Kazumasa Takenouchi
Mr. Kazumasa Takenouchi is member of Biostatistics Group, Data Science, Astellas Pharma Inc and has over 20 years’ experience in the pharmaceutical industry as statistician.

Fumihiko Takeshita, MD, PhD
Fumihiko Takeshita is Senior Director, Vaccine Business Oversight Dept in Daiichi Sankyo, Co., Ltd. and President, Vaccine Research Labs in Kitasato. He has expertise in vaccine and infectious diseases and has over 20 years of experience in developing vaccines and diagnostics.

Michio Tanaka
Michio Tanaka has mainly worked in global drug development of oncology products for more than 20 years at AstraZeneca. He is now Head of Science Affairs Division which is leading a broad range of drug development activities incl. development of companion diagnostics, after taking Product Leader roles in local and Global organisation as well as Heads of Regulatory and Clinical Operations. He has a PhD in molecular biology and has been involved in the development of several drugs, including imatinib, rilpivirine and osimertinib. He is currently responsible for overseeing the clinical development of several new drugs in the pipeline.

Tomohiro Tanaka, MS
Tomohiro Tanaka is Group Manager of Clinical Science & Strategy Dept. at Chugai Pharmaceutical Co., Ltd. Mr. Tanaka graduated from Graduate School of Kyushu University in 2000. Mr. Tanaka joined Nippon Roche K.K. after graduation and now work for Chugai pharmaceutical Co., Ltd. Mr. Tanaka has 17 years’ experience in the clinical development. In the current position, Mr. Tanaka is responsible for leading the activities of the clinical science in the oncology field.

Shimon Tashiro, PhD
Shimon Tashiro is Head of the Section on Bioethics in the Center for Public Health Sciences at the National Cancer Center, Tokyo, Japan. Dr. Tashiro received his undergraduate degree and his Ph.D. in sociology from the Tohoku University. His research interests focus primarily on research ethics, such as issues on the distinction between research and practice, the ethics of innovative therapy and the ethics of RTIs. He is also interested in the end-of-life care, professional ethics, and history of bioethics.

Michiko Tomiyasu, MS
M.TOMIYASU now belongs to Medical Excellence & Training in Medical Affairs Sanofi. In this position, M. TOMIYASU is responsible for supporting the training programs in MA and has established MSL Certification Program inside this company. Before then, M. TOMIYASU had worked in AstraZeneca over a period of many years. M.TOMIYASU has over 20 years experience in the pharmaceutical industries, including Sales and Marketing, pricing and government affairs in Market Access, MSL and Scientist on HEOR/Pharmacoepidemiology in Medical Department. M.TOMIYASU is pharmacist, studied in Meiji Pharmaceutical University and Master of engineering, studied in Graduate School of Keio University. Available languages are English and French.

Shogo Tsuyuki, PhD
Dr. Shogo Tsuyuki is Head of Global Development University Japan at Novartis Pharma K.K. where he leads education and talent development in drug development division. Dr. Tsuyuki has over 20 years’ experience in the pharmaceutical industry, including exploratory research, early clinical research and project management. Dr. Tsuyuki holds a PhD in pharmaceutical science in Immunology.

Jörg Täubel, MD, FFPM
Dr Jörg Täubel is a medical practitioner and CEO of Richmond Pharmacology. He has worked in clinical pharmacology for 24 years, conducted more than 400 early phase studies ranging from first time in man to proof of concept and is author of over 50 publications in scientific journals with extensive experience in cardiology, neurology, gastroenterology and ethnic bridging studies. He is a Fellow of the Faculty of Pharmaceutical Medicine of the RCP (UK), the Institute of Directors and Honorary Fellow at St George’s University London. He is a member of the AHPPI, the RSM, JSCEPT and the ACCP, Regent of the AGAH and a founding member of ENFEMED. He lectures on the AGAH basic human pharmacology course and at the University Pompeu Fabra, Barcelona.
Maki Uchimura, MBA

Maki Uchimura, MBA, is a member of Clinical innovation & business integration of Medical Development Unit at Eli Lilly Japan K.K. Uchimura has 7-year GCP, computer validation experience, and transformation project experience. (e.g. Medidata RAVE, Japan launch for PMMS market) Before joining Eli Lilly, leading life science industry consultancy at PricewaterhouseCoopers Japan for change management and computer system implementation.

Shizuko Ueno, RPh

Ms. Shizuko Ueno is Senior Director, Group VI, Clinical Development Department, DAICHI SANKYO CO., LTD. She joined the Pharmaceutical Division of Sunrty Co., Ltd. after graduating from university and transferred to Daichi Suntory Pharma Co., Ltd. (current Asubio Pharma Co., Ltd., subsidiary of DAICHI SANKYO) in 2002. She works for DAICHI SANKYO since 2010 (including 3 years for DAICHI SANKYO BD NOVARE CO., LTD.). She has over 25 years’ experience in clinical development.

Jin Uesawa, MBA

Jin Uesawa is the president of Japan Medical Data Center. The company builds claims database and offers real world data and analytical services. It participated a pilot project by PMDA and pharma companies to conduct a PM study using JMDC database in a GPSP-compliant manner. He also leads, as a member of Association of Medical Database in Japan, to develop an industry’s voluntary GPSP guideline for database vendors. After the completion of MBA program at Carnegie Mellon University, he joined McKinsey and Company where he worked on many aspects of pharma industry and healthcare system, such as initiatives to enhance productivity in clinical trial and PV operations, and to solve the drug lag problem working with regulatory agencies.

Hisashi Uruishiha, DrPH, MS

Dr. Hisashi Uruishiha is a Professor, Division of Drug Development and Regulatory Science, Faculty of Pharmacy, Keio University. His research area is pharmacoepidemiology, pharmacovigilance, and regulatory science. His academic training and experiences were based on epidemiological methodology at Kyoto University School of Public Health, where he received his doctoral degree in public health. He has also job experience in clinical development and pharmacovigilance at Eli Lilly Japan for 13 years before starting his academic career. He is an active executive board member of Japan Society for Pharmacoepidemiology and the Japanese Association of Pharmaceutical Medicine, a member of DIA Advisory Committee of Japan, the vice-chairman of the East Japan ethics committee of Japan Epidemiological Association, and a member of the international affairs committee of Japanese Society of Pharmaceutical Health Care and Sciences.

Susumu Wakabayashi

I am Professor of University Hospital and in charge of Drug Information section of Hospital Pharmacy and HIV care team. I graduated from school of Pharmaceutical Science of Toho University. I am a visiting lecturer of school of pharmacy of Tokyo University of Pharmacy and Life Sciences. I am a councilor of Kyorin Medical Society. I am a director of the Japanese Society of Drug Information. I have a license to Drug Information Specialist, Healthcare Information Technologist, Sports Pharmacist, Regulatory Science Expert (Pharmacovigilance).

Toshifumi Wakai, MD, PhD, FACS

Education
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Professional Experience
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4/2010 - 12/2012  Associate Professor  Niigata University Medical and Dental Hospital, Division of Digestive and General Surgery, Niigata, Japan
10/2003 - 3/2010  Assistant Professor  Niigata University Medical and Dental Hospital, Division of Digestive and General Surgery, Niigata, Japan
4/1992 - 9/2003  Surgical Resident-Fellow  Niigata University Medical and Dental Hospital, Division of Digestive and General Surgery, Niigata, Japan

Toshihiko Watanabe

Mr. Toshihiko Watanabe is the Advisor of Japan CRO Association he used to be their Vice President. In DIA-Japan Mr. Watanabe was a Program Committee Member of CDM, the Program Chairperson of MIP, a Steering Committee Member and is also a recipient of the Outstanding Service Award in 2008. Mr. Watanabe has over 30 years of experience in Pharmaceutical and CRO Companies, including Management of Biostatistics, Clinical Data Management and Quality System of ISO9000. Mr. Watanabe is a Managing Director of Bio venture company, PRO and IT Venture company. He is also the Advisor of some IT Companies.

Duu-Gong Wu, DrSc, PhD

Dr. Duu-Gong Wu is the Senior Director of Regulatory Consulting with expertise in biosimilar regulatory strategy. He previously worked at US FDA with the last position as Deputy Division Director in CDER/DNDc, before joining PharmaNet/IG, then PPD. At US FDA, he participated in the reviews and approvals of many biotech products and worked as a member of internal and ICH working groups and committees, including FDA Follow-on Biologics (biosimilars) Workig Group and ICH Q5E and CTD-Q. At PPD, he participated in in the development of many MAB and therapeutic protein biosimilars at various clinical stages. Dr. Wu was hired from his PhD degree at Biostatistics and Biometry at University of Maryland School of Medicine and postdoctoral study at Johns Hopkins University School of Medicine, before he joined FDA.

Naoyuki Yabana, PhD

Dr. Naoyuki Yabana is Director of Office of In Vitro Diagnostics. He joined PMDA in 2006, and since 2011 to 2014 he was Review Director in Office of New Drug III and responsible for the review and scientific consultation of psychiatric and neurological drugs. Since 2014 to 2016 Dr. Yabana was Head of Japanese Pharmacopoeia Secretariat. He holds PhD in biophysical and biochemical science from the University of Tokyo.

Yasuhide Yamada, MSc, MPM

Ex-Director-General, Office for Pandemic Influenza and New Infectious Diseases Preparedness and Response, Coordination Office of Measures on Emerging Infectious Diseases (EIDs), Cabinet Secretariat, Government of Japan Mr. Yamada’s academic background is environmental science and policy administration. He has a Master of Science from Hokkaido University (Japan) and a Master of Public Management from Carnegie Mellon University (USA). Mr. Yamada, as an officer of Ministry of Economy, Trade, and Industry (METI) and Cabinet Secretariat, has long career in policy-making and negotiation with foreign governments. Through July 2014 to July 2017, Mr. Yamada led to plan and implement preparedness and response on infectious disease threats; Ebola, MERS, Zika, AMR, etc.

Takuhiro Yamaguchi, PhD

Dr. Takuhiro Yamaguchi is currently a Professor at Division of Biostatistics, Tohoku University Graduate School of Medicine and a Director of Clinical Research Data Center, Tohoku University Hospital. He is also a former Project Professor at Department of Clinical Trial Data Management, Graduate School of Medicine, The University of Tokyo. He has about 20 years experiences as clinical trial statistician especially in the field of oncology and palliative care. His research interests include quality management system and clinical outcome assessments.

Noboru Yamamoto, MD, PhD

Dr. Noboru Yamamoto is a director of the department of experimental therapeutics, National Cancer Center Hospital (NCCH), Tokyo. Having graduated from Hiroshima University School of Medicine in 1991, Dr. Yamamoto specialized in lung cancer chemotherapy, the early development of new anticancer drugs, and the development of biomarkers.

Yuji Yamamoto, MD, MBA

Yuji Yamamoto is a founder and chief executive officer at MinaCare, Co., Ltd. which manages over three million people health data for better care. He concurrently serves as an advisor of the Ministry of Health, Labour and Welfare, dedicating health care system innovation. Before starting these careers, Yuji worked as a cardiologist in Japan, specialized in electro-physiology. He spent six years as a practitioner in several leading hospitals including University of Tokyo Hospital and Tokyo Metropolitan hospitals. Yuji received his M.D. degree from University of Tokyo and his medical license. He is a board certified member of the Japanese Society of Internal Medicine, and holds an M.B.A. from Harvard Business School.
Reiko Yanagihara, PhD
Dr. Reiko Yanagihara is Deputy Review Director of Office of in vitro Diagnostics in Pharmaceuticals & Medical Devices Agency (PMDA). She joined PMDA in 2009 and served as reviewer in the area of biopharmaceuticals, biosimilars and in vitro diagnostics. She is responsible for leading companion diagnostics working group in PMDA which discusses regulatory issues and the development of relevant guidances. Dr. Yanagihara holds a PhD in Molecular Biology from Osaka University and served as an Assistant Professor at Graduate School of Medicine in Kyoto University after postdoctoral training at Carnegie Institute of Washington/Howard Hughes Medical Institute.

Manabu Yanagisawa, PhD
Dr. Manabu Yanagisawa is an Associate Director of Japan Regulatory Affairs at Eisai Co., Ltd. in these 13 years. He joined Eisai in 1992 after graduate from Tokyo Institute of Technology with a master degree. His carrier in Eisai started as a medicinal chemist at the Tsukuba Research Laboratory. After 6 years, he was dispatched to the Tokyo University of Science (Prof. Mukaiyama) for 2 years and 7 months, and received a Ph. D. in pharmacology. His carrier of regulatory affairs started in 2004. Since then, he has been in charge of many projects and commited promoting the development and obtaining the approval. He is a member of the RA committee of JPMA. Furthermore, he contributes to DIA as a facilitator of RA-Training Course.

Kazuki Yasuda, MD
Dr. Kazuki Yasuda is Director of Department of Metabolic Disorder at Diabetes Research Center, National Center for Global Health and Medicine. Dr. Yasuda is a physician scientist whose special focuses are diabetes mellitus and other lifestyle-related diseases. Dr. Yasuda has been engaged in nation-wide research projects such as the Millennium Genome Project for type 2 diabetes mellitus in Japan and the multi-omics analysis projects of human disease samples including adipose tissues (obesity) and liver (NASH). He is now one of the coordinating scientists for GAPFREE Program.

Kan Yonemori, MD, PhD
Kan Yonemori is Chief physician of Department of Breast and Medical Oncology/ Experimental Therapeutics at National Cancer Center Hospital, Tokyo, Japan. Dr. Yonemori had medical reviewer experience in Pharmaceuticals and Medical Devices Agency and for visiting researcher in US National Cancer Institute and Food and Drug Administration. Dr. Yonemori is one of lead Principle Investigators in National Cancer Center Hospital, Tokyo and he lead the field of oncology drug development scene for rare cancer.

Shigeto Yonemura, MD
Shigeto Yonemura is an associate Professor of civil law and medical law in the Graduate Schools for Law and Politics in the University of Tokyo (Japan). He graduated from the Faculty of Medicine in the University of Tokyo in 2000, and worked as a cardiologist in several hospitals in Japan (2000-2013). He was given a master’s degree in law by the University of Tokyo (the Graduate Schools for Law and Politics) in 2004. He was an associate professor in the Graduate School of Law in the Tohoku University (2005-2013), and since 2013 he has been in the University of Tokyo. He published many papers on civil law and medical law. His research areas are tort liability, product liability, medical malpractice, regulation of biomedical research etc.

Yusuke Yoshimoto
Mr. Yusuke Yoshimoto is Senior Manager in Trial Management group at Eli Lilly Japan K.K. In this position, Mr. Yoshimoto is responsible for leading study management activities in BioMedicine therapeutic area, which focuses on Neurodegeneration, Immunology and Pain diseases. Mr. Yoshimoto has over 20 years’ experience in Eli Lilly working for study management, project management, strategic outsourcing and organization management. Mr. Yoshimoto has granted Master degree for Organic chemistry from Nagasaki University in 1996.
All efforts for patients,
All professional works for clients.

ライフサイエンス分野のプロフェッショナルとして、高品質で専門的なサービス・ソリューションを提供し、医薬・医療の発展と人々のQOLの向上に貢献します。

- Full Services Monitoring, DM, STAT, MW, etc
- eSource/eTMF/eCTD/CDISC
- Real-World Data Database Research Support
- Risk-based Monitoring
- Regenerative Product Development support
- Multi-national Study
- Regulatory Consulting
- PMS Full Services
DIAとは

DIAとは、医薬品、医療機器、再生医療製品をはじめとする医療用製品の研究開発、ライフサイクルマネジメントにおけるインパケーションの実現をサポートするために教育活動および規制当局・企業・アカデミア・患者さんとの間の立場を超えた情報交換やディスカッションの場を提供するグローバルな非営利団体です。世界中で創薬、開発、薬事、安全性、CMC、PM、DM、統計など様々な専門分野の専門家、一万数千名の会員を有しています。

ミッション、ビジョン、コアバリュー

DIAは、以下の3つの理念に基づき、事業活動を行っています。

ミッション

DIAは、世界中の人々の健康と福祉の向上に役立つイノベーションの発展を助けるための、グローバルな情報と意見交換の場を提供します。

ビジョン

DIAは、皆様の大切なパートナーとして、医療用製品の開発をより早く進めることにより役立つ知識の創造と共有化を手助けしていきます。

コアバリュー

中立性と誠実さ
説明責任と信頼
敬意と尊厳
責任と多様性
情熱と絆

組織構成

 espera (Board of Directors)

DIA理事会メンバー、役員、地域諮問委員会委員長は、会員による選挙で選出され、DIAの全般的な運営方針、基本戦略、基本政策目標の策定を行います。米国のDIA本部及び、欧州、日本、インド、中国的DIAオフィスがこれらをサポートしています。各DIAオフィスには、理事会の指示により戦略と年間計画の実行の為の日々の業務を行うスタッフがいます。

日本諮問委員会（Advisory Council of Japan：ACJ）

日本諮問委員会は、DIA Japanの更なる発展と会員の成長に向けて日本におけるDIAの活動方針を決定し、本部理事会に対して戦略的な情報提供や助言、提案を行っています。開催される各種会議、トレーニングは、コンテツ コミッティーからの提案を受け、ACJで決定され、会議、トレーニング毎に編成されるボランティアからなるプログラム委員会によって具体化、実施されます。
会員のベネフィットとキャリアパス

産官学と患者さんが一堂に会する唯一の中立的国際的イベント
いかなる組織や団体からも影響を受けることのない、産官学、患者さんが一堂に会する中立的で国際的なイベントはDIAだからこそ開催できるものです。会員の方はイベントに参加することで、世界の規制当局・企業・アカデミア・患者さんの第一人者から、グローバルで最新の業界や規制の動向を直接聴ける貴重な機会を得ることができます。また、聴講だけでなく、議論を交えて双方向的に情報が提供されるので、仕事に役立つ実践的な知識、情報を学ぶことができます。更には、グローバルな産官学や患者さんとのネットワーキングを作り育てることもできます。

メンバーシップ主体のボランティア活動
DIAは、会員が主体のボランティア活動によって支えられています。業界団体とは違い、会員の方は個人の立場でボランティアベースで活動に参加しているので、組織の方針にしばられない、自由な発想でスピーディな活動を行うことが可能となっています。その代表的活動がコミュニティ活動で、グローバルベースで専門領域別に産官学の会員が自発的にコミュニティを作り、共通の経験や話題を共有したり、課題を検討したり、イベントの企画などを行っています。

キャリアディベロップメント
会員の方は、DIAが提供するイベントの企画、準備、運営に関する様々な役割を経験することで、専門性を高め、視野を拡げ、マネジメント能力を磨き、自らのキャリアを発展させることができます。そして、世界中の人々の健康と福祉の向上につながるイノベーションの促進に貢献することができます。下記がDIA Japanでの活動を通じたキャリアパスモデルです。

Career path model in DIA Japan
<Designed by Contents Committee>

2016.08
Neutrality is key to the DNA of DIA. As the only global, membership organization, DIA is dedicated to bringing health care product development professionals together in a trusted, neutral environment to share insights and make advancements in health care product development and life cycle management.

With thousands of engaged, global members comprised of professionals from pharmaceuticals, biotechnology, government, academia, and patient groups, DIA is the premium resource for individuals seeking to increase their knowledge, connect with global stakeholders, and truly drive insights to action in their everyday job functions.

Thousands of Members in 78 Countries, Across 20+

- DIA communities, a dynamic network of like-minded individuals looking for solutions, providing a discussion forum, and seeking to find solutions by harnessing the power of a network beyond your own organization
- Access to a broad range of focused conferences, meetings, and training opportunities that will allow you to enrich your own knowledge, your understanding of the health care system you work in, and give you the ability to integrate best practices from multiple health care systems
- Member-exclusive subscriptions to the DIA Daily and Therapeutic Innovation & Regulatory Science (TIRS)
- Be part of a global forum where everyone can freely, openly, and accurately share information on diseases, treatment modalities, regulatory policies, clinical trial development, value and access, and more
- Unique access to thought leadership that is not available elsewhere
- Favorable rates on conferences and trainings

Why Join DIA?

Learn More and Join at DIAglobal.org/Membership

DIA Members work together to speed innovation in global health care product development to encompass your own health care system and the broader region.

出版物・情報提供

❖ TIRS (Therapeutic Innovation & Regulatory Science)

医薬品を始めとする医療用製品の研究開発とライフサイクルマネジメントに関する情報提供および、規制当局・企業・アカデミア・患者さん間の情報交換をサポートすることを目的とした DIA の公式出版物です。各分野の専門家監修のもとで年 6 回発行しています。

❖ Global Forum

世界中での DIA の活動や業界、規制の動向など、会員の間での情報交換を目的とした隔月発行のデジタルマガジンです。

❖ DIA Daily

DIA 会員向けのニュース配信です。過去 24 時間にグローバルで発信された医療用製品関連ニュースの概要をメール配信します。
Neutrality is key to the DNA of DIA. As the only global, membership organization, DIA is dedicated to bringing health care product development professionals together in a trusted, neutral environment to share insights and make advancements in health care product development and life cycle management. With thousands of engaged, global members comprised of professionals from pharmaceuticals, biotechnology, government, academia, and patient groups, DIA is the premium resource for individuals seeking to increase their knowledge, connect with global stakeholders, and truly drive insights to action in their everyday job functions.

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Learn More and Join at DIAnetglobal.org/Membership
DIA Community

What is “DIA Community”?  
DIA Communities are one of the many member benefits that DIA offers. Each Community provides a discipline-specific community where members can share common experiences and knowledge and connect with others in their field.

The core purpose of Communities is to bring industry, vendor, academic, regulator, payer, healthcare provider, and patient groups together to interact in a neutral forum to network, share learning, discuss topics and issues, and develop resolutions of relevance to a particular functional area or topic associated with drug development. While learning sharing (including program development) and networking are core to Communities, identifying and dealing with industry issues can be where Communities bring value back to the drug development industry and ultimately their membership.

Communities also assist DIA in identifying professional development needs in particular interest areas, and in providing information to members to meet their career and professional development needs.

Benefits 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 participate meetings, learning sessions or events of both.

Global DIA Communities  
(as of Oct 2017)

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<td>Students</td>
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Introduction of Japan DIA Communities

Clinical Operation·Monitoring (COM) (Representative: Kazumasa Sugao, Mitsubishi Tanabe Pharma Corporation)
We launched “Clinical Operation·Monitoring Community (COM Community)” in 2014 with the aim of offering a program to exchange information for Clinical Operation and Monitoring. And we have proactively exchanged views and opinions about the participants’ perspectives, where participants’ impression showed high level of satisfactions to our activities. We continue our activities periodically and extend discussions.

We have focused on the topic of “What’s the gap between the actual and ideal conditions at the clinical trial site and how to overcome the GAP?” and continued discussions since last year. This year, we specifically focused on our concrete actions to solve the GAP and enjoy discussions.

Every COM community participant is an important player. Let’s discuss how to make Clinical Operations better with us!

Pharmacovigilance & Labeling (Representative: Rei Maeda, Eli Lilly Japan / Rie Matsui, Pfizer Japan Inc.)
DIA Japan Risk Management workshop and DIA Japan Labeling workshop were annually held from March 2014 and November 2017, respectively. The 4th RM workshop was held in May 2017, which objective was to deeply consider what risk minimization materials are proper for patient-centric tools from risk communication perspective. The 7th Labeling workshop to discuss mainly new labeling guidelines will be held in February 2017. We will gather trends of regulations worldwide regarding risk management system and Labeling that consist of key elements of pharmacovigilance, share them and discuss issues.

Clinical Strategy Community (Representative: Yoshinobu Tanaka, MSD K.K.)
This is a new community that started in 2015. Under the key words “strategy” and “tactics”, we have meeting every 2 months and share methods and ideas to address daily work issues. Taking advantage of the varied backgrounds and strengths of our members, we are aiming for active participation by all attendees. Members are from Industry, CRO, and Academia. Feel free to join us!

Clinical Data Management (Representative: Motohide Nishi, Medidata Solutions Co., Ltd.)
The activities of DIA’s Clinical Data Management (CDM) began with the first DIA CDM annual workshop in Japan held in 1998. Since data is a common language in the world, the need for CDM CDM activities, which is a place of global communication, is high, and Workshop has been held continuously every year. From 2017, we started to exchange opinions in the CDM community as we respond to changes in the environment surrounding CDM. Let’s further strengthen collaboration with the European and US communities as the CDM community in Japan, sharing the latest technology and information, and proposing new idea from Japan.

Medical Communication (Representative: Kelko Tsumori, MSD K.K.)
Medical Communication Community is newly launched in 2017 which aims to “publishing” and “holding” to better deliver drug information from health authorities and pharma to patients, to identify remained as an unattended or emerged issues, and to address solutions collaboratively. We discuss the message and planning of drug information, consistency of message in CTD, RMP, package circular and post-marketing materials, various issues related to publications and others.

Examples for our activities are support for drug information session (VS-SZ, VS-S3) and chatting session at this DIA Japan annual meeting, and 1st DIA medical communication workshop on the 12th December 2017.

We will welcome all members from different divisions of health authorities, academia and pharma (pharmacovigilance, product labeling, medical affairs, medical information, medical writing and regulatory affairs) for new activities. Please contact DIA Japan to know more about the details if you would be interested in our activities.

Project Management (Representative: Koichi Konno, PM Consulting Positive Intention)
The primary purpose of Japan based “PM Community” of DIA is to improve “entire throughput of drug development” in Japan. Any health care / drug development related stakeholders, not only pharmaceutical industries, but academia, regulatory authorities, investigational sites, are welcomed to participate in the community for their learning and networking. The concrete activities are as follows:
- Planning and executing project management track of DIA annual meetings
- Planning and executing project management symposium
- Development and holding Project management training program (very entry level to application level)
- Holding community regular meeting

- Activities to introduce project management in academic research and regulatory affairs processes related to drug development
- Planning and participating in US/EU DIA annual meeting as project management community
- Learning knowledge, technique, tools and operations of project management with collaboration, and sharing recent experiences

Please join us if you are interested in participating in the above activities. Not only project managers and project management office members, but study leaders, study manager, coordination team members are all welcomed as long as s/he is interested team activities, project management, leadership development, and so on. Join us!

Regulatory Affairs (Representative: Manabu Yanagisawa, Eisai Co., Ltd.)
We have provided including of planning and management various Training courses regarding regulatory during the past in DIA Japan, such as RA Training course, FDA IND/NDA Training course, EMA RA Training course, Regulatory Communication Training course and Cell Therapy Products Symposium. The attendees of these training courses are not only persons in companies but also persons in health authority and academia, and we hear that every course has a high reputation. Regulatory Affairs Community has started since 2014, our community members keep contribution and support for these planning and management.

To accommodate the various regulatory environments, we will try to prepare the opportunity for exchanging information and building up a personal network among the RA community members. The chatting session at this DIA annual meeting is one of examples for the activity.

Six Sigma (Representative: Kazuo Ichikawa, Daiichi Sankyo Co., Ltd.)
The Six Sigma Community was established to expand its concept/tools in R&D sector, to provide opportunities to utilize Six Sigma in real-life setting. Six Sigma was developed as a quality management system but it has been embedded as a systematic approach in problem solving. The members consist of the certificated Six Sigma experts/consultants as well as beginners working in clinical development. The members meet monthly to discuss the specific Six Sigma topics with real-life examples, to make a proposal at DIA Japan Annual Meeting/Workshops. The topics include various fields related to clinical operation, data management, and so on. If you feel there is any problem around you, let’s discuss to resolve it by Six Sigma together.

Statistics (Representative: Satoru Tsuchiya, Sumitomo Dainippon Pharma Co., Ltd.)
The Japan Statistics Community was established in 2007 which aims to “Program Support Team” for the Biostatistics track at the DIA Japan Annual Workshop, and it was formally established as Japan Statistics Community in 2014 (at that time, called SIAC). 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, safety information after launch, drug evaluation with small clinical trials. Addition to that, “Basic Statistical Concept Workshop for All Non-Statistical Clinical Research Professionals” is provided by this community.

Japan Communities to be established in the future
There are many DIA Communities which exist as Global Communities, but not as Japan Communities. If you are interested in any of such communities, please join Global Community. You can communicate with DIA members outside of Japan. Or you can newly establish Japan Community! Please contact DIA Japan if you would like to know more details.

How to join DIA Communities
To join Japan Community:
Please contact to DIA Japan
(Tel: +81-3-6214-0574, Fax: +81-3-3278-1313, Japan@DiAGlobal.org)

To join a Global Community:
Login into DIA Global Site http://www.diaglobal.org/en
• Please become DIA Member if you are not.
Move to My Communities, and pick up the community of your choice from EXPLORE COMMUNITIES tab.

Please visit “DIA Booth at Japan Annual” to get more information!
DIAコミュニティ

“DIAコミュニティ”とは？
DIAコミュニティとは、DIA会員のみが参加可能なDIAの活動の一つです。様々な専門領域のコミュニティがあり、それぞれのコミュニティは専門領域における経験や話題を共有するためのDIA会員同士のネットワークです。

コミュニティの主な目的は、企業、アカデミア、規制当局、医療機関、患者さんなど医薬品開発に関連する全ての立場の人が参加できる中立なネットワークを形成し、そのコミュニティの専門領域や医薬品開発全般に関す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となります。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もできます。

メンバーは日本およびグローバルのコミュニティに所属でき、様々なミーティングやセッションに参加することができます。

グローバルコミュニティ
（2017年10月時点）

Clinical Data Management  Clinical Pharmacology
Clinical Research  Clinical Safety & Pharmacovigilance
Clinical Trial Disclosure  Devices & Diagnostics
Document & Records Management  Electronic Regulatory Submissions
Good Clinical Practice & Quality Assurance  Information Quality, Compliance, & Technology
Legal Affairs  Medical Communications
Medical Science Liaison  Medical Writing
Patient Engagement  Pediatric
Preclinical Sciences & OSWG  Professional Education, Training & Development
Project Management  Quality Risk Management
Regulatory Affairs  Statistics
Students  Study Endpoints
日本のコミュニティの紹介

Clinical Operation・Monitoring (COM) (代表者：菅生 和正、田辺三菱製薬株式会社)

2014年に新設されたClinical Operation・Monitoring (COM)コミュニティは、参加者の意見交換を目的としています。COMコミュニティでは、参加者全員が主役で自由に意見交換をすることを目指しています。参加希望者はDIA事務局までご連絡ください。

Pharmacovigilance & Labeling (代表者：前田 琳、日本イライリー株式会社)（松井 理恵、ファイザー株式会社）

日本で初めてのPharmacovigilance & Labelingのコミュニティが始まりました。このコミュニティでは、医薬品の安全情報の共有を通じて、医薬品の適正な使用を促進することを目指しています。参加希望者はDIA事務局までご連絡ください。

Clinical Strategy (代表者：田中 義信、MSD株式会社)

2015年にClinical Strategyのコミュニティが始まりました。このコミュニティでは、臨床試験の開発プロセスについての意見交換を行い、臨床試験の効率化を促進することを目指しています。参加希望者はDIA事務局までご連絡ください。

Clinical Data Management (代表者：西本 基秀、メディテーラ・ソリューションス株式会社)

臨床試験のデータ管理についての意見交換を行っています。参加希望者はDIA事務局までご連絡ください。

Medical Communication (代表者：津森 桂子、MSD株式会社)

臨床試験の医薬品情報の共有と情報の交換に関する意見交換を行っています。参加希望者はDIA事務局までご連絡ください。

Project Management (代表者：今野 浩一、PMコンサルタント・インキュベーション)

臨床試験のプロジェクト管理についての意見交換を行っています。参加希望者はDIA事務局までご連絡ください。

Regulatory Affairs (代表者：柳瀬 学、エーザイ株式会社)

DIA Japanでは、薬事に関する新たなトレーニングコースを設け、参加を募集しています。参加希望者はDIA事務局までご連絡ください。
DIA Learning

Online Solutions

Improve the knowledge of your team using DIA’s eLearning programs. Reduce training costs, eliminate time out of the office, and meet your organization’s training needs.

Designed by learning experts using the latest instructional strategies to improve retention and make learning convenient for busy professionals. DIA eLearning courses include:

- Microlearning
- Gamification
- High level of interaction
- Scenario-based learning activities to apply learning
- Case studies and real-world examples
- Resources section for quick access to important regulations
- Printable module summaries of key lesson points
- Glossary of terms
- Mobile friendly, modern design containing multimedia and animation
- Voiceover
- 24/7 Access

Drug Safety

Drug safety is a primary concern throughout the medical product development life cycle. This eLearning program provides the knowledge you need, from regulations and requirements through premarket review and postmarket monitoring. The comprehensive program includes six self-paced modules that have been designed using the latest instructional strategies.

- Introduction to Drug Safety
- Drug Safety Regulatory Requirements
- Premarketing Clinical Trial Safety
- Postmarketing Safety Management
- Basics of Signal Detection and Pharmacoepidemiology
- Safety Audits and Inspection

Drug Development and Life Cycle Management

Drug development is an incredibly complex and risky endeavor, one that even experienced organizations will fail at more often than they succeed. This six module program will help you understand how companies structure their efforts and utilize their resources to improve the odds of successful development, and minimize the risks associated with shepherding a new drug candidate through the development process.

- Overview of Drug Development
- Phase 2 Studies
- Discovery and Preclinical Testing Phases
- Phase 3 Studies and Regulatory Review
- Phase 1 Studies
- Phase 4 and Life Cycle Management

Medical Communications

DIA’s Medical Communications Program includes eight modules that cover topics any medical and scientific communications professional needs to know.

- Literature Searching
- Literature Evaluation
- Database Management and Medical Inquiries
- Medical Response Excellence
- Statistics for Medical Affairs
- US Regulatory and Compliance Considerations
- Crisis Management
- Product Labeling

Clinical Trial Fundamentals

This program designed to provide a practical context to help clinical research professionals learn about conducting clinical trials. Using an interactive case study with realistic scenarios designed to illustrate the learning points, this three module program follows the activities of a fictitious clinical investigator and her staff as they conduct a clinical trial.

- Clinical Trials: Study Preparation
- Clinical Trials: Study Initiation
- Clinical Trials: Conducting the Study

Informed Consent: Comprehensive Concepts and Components

This comprehensive module explains the components of a complete and appropriate consent form as specified by the International Conference on Harmonisation (ICH) and the US FDA, as well as guidance for the creation and appropriate wording of these components. It also includes a discussion on the benefits and concerns with electronic informed consent, and presents publications and projects that explore the use of eConsent.
Drug development is an incredibly complex and risky endeavor, associated with shepherding a new drug candidate through the development life cycle. This eLearning program provides the knowledge you need, from regulations and requirements through premarket review and postmarket monitoring. The comprehensive program includes six self-paced modules that have been designed using the latest instructional strategies to improve retention and make learning convenient for busy professionals. DIA eLearning courses include:

- Glossary of terms
- Resources section for quick access to important examples
- Case studies and real-world publications and projects that explore the use of eConsent.
- Activities to apply learning

High level of interaction

Gamification

Microlearning

Scenario-based learning

Online Solutions

Voiceover

Design containing multimedia

Mobile friendly, modern

24/7 Access

Glossary of terms

Printable module summaries

of key lesson points

Regulations

Quick access to important

Resources section for quick access to important examples

Case studies and real-world publications and projects that explore the use of eConsent.

This comprehensive module explains the components of a complete and appropriate consent form as specified by the International Conference on Harmonisation (ICH) and the US FDA, as well as guidance for the creation and appropriate wording of these components. It also includes a discussion on the benefits as well as guidance for the creation and appropriate wording of these components. It also includes a discussion on the benefits.
CRScube Solutions

- cubeCDMS®
  臨床試験のデータ収集
- cubeWRS®
  無作為化および治験薬の供給管理
- cubeCTMS®
  臨床試験のプロセス管理
- cubeSAFETY®
  AEs/SAEsデータマネジメント
- cubeBUILD®
  臨床試験のデザインおよび構築管理
- cubePRO®
  臨床データのリアルタイムのPRO
- cubeRBM®
  リスク基盤モニタリング

CRScube はアジア初で
CDISC ODM 認証を獲得しました。
他システムとの総合運用性が保証され、臨床試験プロセスの効率を向上させます。

アジアでは初めてSCDM CCDM Industry Partnerとなった
e-クリニカルソリューション企業
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<tr>
<th>Company Name</th>
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<td>Nippon Control System Corporation</td>
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<tr>
<td>IBM Watson Health</td>
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<td>OpenText K.K.</td>
<td>4</td>
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<td>Medi Help Line</td>
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Luncheon Seminar by Platinum & Gold Supporters

November 13th, Monday
12:45–13:30
VENUE 1: 605/606 Seminar room
Platinum Supporter: A2 Healthcare Corporation
Japanese language only

11月13日(月)12:45–13:30
VENUE 1: 605/606
セミナー ルーム
主催: エイツーヘルスケア株式会社
日本語のみ

A2Hは、従来から統計解析を強みとして発展してまいりました。試験設計時に統計計画を含め、主に臨床試験における生物統計専門業務に加え、リスクベッドモニタリングにおける集中モニタリング、リアルワールドエビデンス解析など、多岐にわたります。このセッションでは、これらのステークホルダーやアピールであるデータを求めております。

本プレゼンテーションの主な内容:
①現在のドライバーヘルスケアの展開、現在および今後の傾向を反映したリアルワールドエビデンスの妥当性（特に日本に関連する事項）
②以下の内容に関する確認
A 起こり得る競争的な環境
B テクノロジーの変化についての進捗
C 分析論への注目
D 今後のデータビジネスモデル
③リアルワールドエビデンスの臨床開発部門におけるイノベーションが、パーソナライズにおいて提供されるデータおよびテクノロジーの応用により大きく躍進することを、上述の分析を通じて示す。

November 14th, Tuesday
12:45–13:30
VENUE 2: 607 Seminar room
Gold Supporter: CROëe Inc
Japanese language only

11月14日(火)12:45–13:30
VENUE 2: 607
セミナー ルーム
主催: 株式会社クロエ
「患者中心主義」を医薬品開発に取り入れる
～現場の声を患者さんと医師に直接聞いてみよう！～
「患者中心主義」をテーマに患者・医師・PROのパネルディスカッションを開催します。
昨年のDIAでもFDAから、開発の初期段階から正しい患者像をとらえ、それを上市後の販売戦略まで継承し続ける事の意義が発表されましたが、アメリカの取り組みとして24の疾患領域において患者の声を集め、それを公開・活用しており、日本との取り組みや意識の格差が顕著に表れた場でもありました。
それを受けて、日本においても「患者中心主義(Patient Centricity)」が大きな広まりを示し、今年の業界における大きなトレンドと言えるでしょう。製薬企業は自社の製品開発の初期段階において、いかに「患者の声」を取入れるか、検討を行っている状況です。

クロエは日本におけるPRO(Patient Recruitment Organization)のリーディングカンパニーとして2009年からサービスを提供しており、グループ会社の運営する「臨床試験情報サイト」や「がん情報サイト オンコ」に登録されている75万人のボランティア・データベースを中心に、臨床試験における患者参加を支援しております。
床試験の被験者リクルートを行っています。その中で、臨床試験に参加された多くの患者さんの声をいただいており、それらはまさに患者中心主義の流れによってフォーカスされ、臨床開発の場にフィードバックされる形をしています。そこで本ランチセミナーでは、「患者中心を意識した臨床開発におけるソリューションや考え方」を紹介し、患者さんご自身や医師に見ていたとき、意見交換を行うパネルディスカッション形式で進行します。実際に製薬企業で、患者の声を通じてのフィードバックするための方法を検討されている方にご参加いただき、現在皆さんが悩まれている事について質疑応答が織り交ぜられ、パネルディスカッションも行います。患者中心主義で開発を進めていくことは、日本の医薬品開発において、それらの立場の垣根を越えて検討すべき課題と考えます。クロエの考える「患者中心のソリューション」を通じて、各社の課題解決のヒントとなるセッションを提供します。

November 14th, Tuesday 12:45–13:30 VENUE 3: 608 Seminar room Gold Supporter: inVentiv Health Japan G.K. Supporting the product lifecycle through database evaluations

主催:インベンティブ・ヘルス・ジャパン合同会社データベース評価を通じた製品ライフサイクル管理のサポート医薬品開発のプロセスにおいて、医療データベースはこれまでにも様々な面で用いられてきました。疫学と治療パターンの評価を通じた早期疾患の理解、試験シミュレーションによる患者数及び転帰の予測、有効性及び安全性に関する比較解析の実施において、医療データベースが不可欠となっています。昨今、「市販後調査の基準に関する省令」（GPMSP）から「医薬品の製造販売後の調査及び試験の基準」（GPSP）への移行が進み、2018年4月に改正GPSPの施行が予定されています。この改正により、医療データベースの再審査申請資料として用いることが可能になります。医療データベースには、国民健康保険の診療報酬レセプト、病院の医療記録や管理記録、電子カルテ等の情報が含まれています。このような医療データベースは、リアルワールド・データとして医療技術及び疾患に対する有効な洞察をもたらします。また、データベースから導き出されるリアルワールド・エビデンスが、製品ライフサイクル管理及び安全性報告の容易化を図ります。本ワークショップでは、こうした医薬品開発の全段階をサポートするためのデータベース分析に関する最新実務について議論します。

本プレゼンテーションの主要な内容:
①日本で利用率の高いデータベースの概要
②日本におけるデータベースの現況
③医療技術評価（HTA）、疫学研究、安全性情報など、医薬品開発及び商品化のサポートに用いたデータベース分析の具体的事例


主催:パレクセル・インターナショナル株式会社優れたデザインのプロトコールは、有効性・安全性の目標を達成するだけでなく、施設や患者さんから見て魅力的なものでなければなりません。パレクセルの独自のアプローチにより、治験デザインに関するスマートな判断をするための洞察を提供します。結果として、リクルート期間の短縮、プロトコール遵守率の向上、そしてプロトコール改訂を最小限に抑えることができます。

November 14th, Tuesday 12:45–13:30 VENUE 7: 102 Seminar room Gold Supporter: OmniComm Systems A Unique Advance Preview of the Next Release of TrialMaster, the World’s Most Innovative EDC System

主催:OmniComm SystemsTrialMasterの次期リリースの本邦初公開イベント最も革新的なEDCと自負しておりますTrialMasterの次期リリースの本邦初公開イベントにてご招待申しあげます。本年、日本市場へ正式参入いたしましたTrialMasterですが、次期リリースではユーザーインターフェイスが刷新され、さらに最新のモバイル技術が実装されます。2018年初頭より提供を開始いたします。

本イベントにおいて、下記についてご紹介いたします。
・日本語と英語で、平行してデータ入力を行う
・iPadを用いたデータ入力とモニタリング業務
・患者さん自身の携帯端末を用いたデータ入力（別のeProソリューションの使用は不要）

セミナーは、OmniComm SystemsのChief Technology OfficerであるKeith Howellsが行います（日本語への同時通訳あり）。また、アップグレードランチを提供いたします。

Please find the content in English from the link below: http://diaexhibit.org/luncheon-seminar
Pharmaceuticals and Medical Device Manufacturers leverage real world data to characterize diseases and patient populations, develop products and therapies, and assess use of current competitive in-market products. With its flexible data model, MarkLogic empowers these companies with faster data integration and harmonization, assured data governance, and the enhanced insight they need to accelerate development of real world evidence.

More than 25 years of experience with customized medical, drug and device information support. PPD’s Medical Communications team provides industry-leading contact center services built on strong processes and innovative technologies that deliver performance excellence, operational efficiency and consistent results while ensuring regulatory compliance.

Vitalograph provides services to help with Spirometry, e-Diary and ECG data, which are centralized and managed in a database. They also offer OverReader for quality checks on received data.

ArisGlobal offers a unified cloud platform, LifeSphere, for life sciences, focusing on improving product development processes, regulatory compliance, and risk management.
Win a prize by participating in our “Stamp Rally“

Stanplarrie用のカードがコンプレックスに入っています。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個以上集まればそれらの商品を、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、このカードでロゴが記載されている協賛企業のスタンプは必ず押してもらい、11月14日（火）の16:00までにIFの総合受付にて提出ください。カートと引き換えに景品をお渡しします。

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

Stanplarrie協賛企業 / Supporters

昨年の賞 / Last Year’s Prizes

デジタルカメラ（CASIO EXILIM）
ASUS LTE対応タブレット
2017年DIA日本年会参加無料券
JTB旅行券（10,000円）

受賞者のコメント / Winner’s Comments

DIA日本年会の興奮の余韻がのこる12月初め、DIA Japanよりスタンプラリーに応募された方の中から厳選に抽選した結果デジタルカメラが当選しましたとの連絡をいただきました。時節柄思いがけずサンタさんの贈り物が届いた気分でした。いただいたデジタルカメラはスポーツ観戦に望遠機能を使って活用させていただいております。ありがとうございました。（某外資系製薬会社）

昨年、スタンプラリーを行って、各社の情報（最新のシステム等）が得られた上に、さらに景品が当たって良い事つづくでした。ありがとうございます。次回のDIA参加の際も、是非、参加したいと思っています。（某外資系製薬会社）

せっかくスタンプを集めたので・・・という感じで応募しましたが、まさかタブレットをいただけるとは思っておりませんでした。ご連絡をいただいた際には本当にびっくりで、「ドッキリか？」と疑ってしまいました。思いがけないクリスマスプレゼントをいただいたようで、とてもうれしかったです。ありがとうございました。（某外資系製薬会社）

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P1ユニットは、厚生労働省「早期・探索的臨床試験拠点整備事業」（平成23～27年度）の支援のもと、東大病院が、開発早期の臨床試験を安全で効率的に実施する部署として設立しました。（平成24年5月竣工）

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11月12日（日）
11:45 Patient Cloud ePRO
12:30 Centralized Statistical Analytics (CSA)
13:00 Balance RTSM
15:20 RaveX
15:35 Strategic Monitoring
17:35 Medical Imaging Clinical Solutions

11月13日（月）
10:35 Regulated Content Management
10:50 Patient Cloud ePRO
15:35 Centralized Statistical Analytics (CSA)
15:50 Balance RTSM
17:35 RaveX

11月14日（火）
10:35 Strategic Monitoring
10:50 Medical Imaging Clinical Solutions
13:00 Patient Cloud ePRO
13:40 Centralized Statistical Analytics (CSA)
15:35 Balance RTSM
15:50 RaveX

特典1
デモ聴講後、アンケートにご回答 いただいた方へ
2018年版メディデータの オリジナルカレンダーをプレゼント

特典2
名刺交換をさせていただいた方、 Facebookページに「いいね！」 または『記事投稿』してくれた方へ ノベルティをプレゼント

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