01/2017

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PROGRAM

McCormick Place | June 18-22 | Chicago, IL

Advancing Health Care Product Development | Educating | Collaborating

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STOP BY DIA **BOOTH #1427** TO GET YOUR PHOTO TAKEN!

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DIA driving insights to action!



Schedule At-A-Glance

As of April 21, 2017. Schedule subject to change.

SATURDAY, JUNE 17

Registration Hours

8:00am-5:00pm **Exhibitor Registration**

SUNDAY, JUNE 18

Registration Hours

8:00-9:00_{AM} Registration for Full Day and Morning Preconference

Short Courses'

8:00am-6:00pm **Exhibitor Registration**

12:30-6:00рм Registration for Afternoon Preconference Short

Courses*, Conference Attendees, and Speakers

Schedule

Half Day Morning Preconference Short Courses* 8:30am-12:00pm

9:00am-5:00pm Full Day Preconference Short Courses*

10:30am-12:00pm Student Program

12:00-6:00рм Career Fair (Hyatt Regency McCormick Place) Half Day Afternoon Preconference Short Courses* 1:00-4:30pm

2:45-5:30pm **Professional Development Sessions**

*Space is limited for Preconference Short Courses. Onsite Registration is available, but not guaranteed.

MONDAY, JUNE 19

Registration Hours

7:00ам-6:00рм Attendee, Speaker, and Exhibitor Registration Schedule

CISCRP Medical Heroes Appreciation 5K 6:30-8:15_{AM}

7:30-8:30_{AM} Coffee and Light Refreshments **Annual Meeting Orientation** 7:30-8:15_{AM}

8:30-10:00AM **DIAmond Sessions**

10:00ам-6:00рм Exhibit Hall Open

Student Posters Open (Exhibit Hall)

10:00-11:00AM Coffee Break (Exhibit Hall)

Innovation Theater Presentations (Exhibit Hall)

11:00am-12:15pm Engage and Exchange Session (Exhibit Hall)

11:00 ам-12:15 рм **Educational Opportunities** 12:00-2:45рм Luncheon (Exhibit Hall)

> Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Sessions (Exhibit Hall)

Student Poster Session and Oral Presentations

(Exhibit Hall)

3:00-4:30_{PM} Plenary Session and Keynote Address

4:30-6:00рм Opening Reception (Exhibit Hall)

Innovation Theater Presentations (Exhibit Hall) Student Poster Session and Oral Presentations

(Exhibit Hall)

TUESDAY, JUNE 20

Registration Hours

7:00am-5:15pm Attendee, Speaker, and Exhibitor Registration

Schedule

7:00-8:00_{AM} Coffee and Light Refreshments

8:00-9:30_{AM} **DIAmond Sessions** 9:30AM-5:00PM Exhibit Hall Open

Professional Posters Open (Exhibit Hall)

9:30-10:30am Coffee Break (Exhibit Hall)

Innovation Theater Presentations (Exhibit Hall)

9:30-10:30_{AM} Engage and Exchange Session (Exhibit Hall)

Professional Poster Session and Oral Presentations

(Exhibit Hall)

Educational Opportunities 10:30-11:45AM

10:45-11:45_{AM} Engage and Exchange Session (Exhibit Hall)

11:30 АМ-2:00 РМ Luncheon (Exhibit Hall)

Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Professional Poster Session and Oral Presentations

(Exhibit Hall)

1:30-3:30рм **Exhibit Guest Passes**

Educational Opportunities 2:00-3:15рм

Engage and Exchange Session (Exhibit Hall)

Refreshment Break (Exhibit Hall) 3:00-4:00pm Innovation Theater Presentations (Exhibit Hall)

4:00-5:15рм **Educational Opportunities**

Engage and Exchange Session (Exhibit Hall)

WEDNESDAY, JUNE 21

Registration Hours

7:00ам-5:15рм Attendee, Speaker, and Exhibitor Registration

Schedule

7:00-8:00_{AM} Coffee and Light Refreshments

8:00-9:30_{AM} **DIAmond Sessions**

9:30am-4:00pm Exhibit Hall Open

Professional Posters Open (Exhibit Hall)

9:30-10:30_{AM} Coffee Break (Exhibit Hall)

Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Professional Poster Session and Oral Presentations

(Exhibit Hall)

10:30-11:45_{AM} **Educational Opportunities**

10:45-11:45_{AM} Engage and Exchange Session (Exhibit Hall)

11:30 АМ-2:00 РМ Luncheon (Exhibit Hall)

Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Professional Poster Session and Oral Presentations

(Exhibit Hall)

1:30-3:30_{PM} **Exhibit Guest Passes**

2:00-3:15рм **Educational Opportunities**

Engage and Exchange Session (Exhibit Hall)

3:00-4:00_{PM} Refreshment Break (Exhibit Hall)

Innovation Theater Presentations (Exhibit Hall)

Engage and Exchange Session (Exhibit Hall) 3:15-4:00pm

4:00-5:15_{PM} **Educational Opportunities**

THURSDAY, JUNE 22

Registration Hours

8:00-11:00_{AM} Attendee and Speaker Registration

Schedule

8:00-9:00AM Coffee and Light Refreshments

9:00-10:30am **DIAmond Sessions** 10:30-10:45_{AM} Coffee Break

Educational Opportunities 10:45AM-12:00PM

Plenary Session and Keynote Address

Monday, June 19 | 3:00-4:30_{PM} | Arie Crowne Theater

Interactive Storytelling and Personal Health Data Drives Unprecedented Patient Empowerment



Alexander Tsiaras *Editor and Founder/CEO of theVisualMD LLC*

In medicinal product and device development, personal health data and patient engagement are critical to the long term viability of research. If patients aren't willing to participate in drug development research or share their data, the research model falls apart. Additionally, if patients aren't engaged in participating and staying in clinical studies then there are significant flow on effects to patient recruitment, patient retention, and overall study success.

With this realization, Tsiaras created StoryMD. Through a single dashboard, StoryMD collects, stores, organizes, and interprets medical data, turning the statistics of you into the "Story of You" and empowering patients to drive insights into action. In this engaging keynote address, Mr. Tsiaras tells the personal stories of diseases, the power of patient data, and interactive experiences to drive greater patient engagement. He'll share tales of empowered patients and how they, along with enlightened researchers, drove these insights into action.

Tsiaras has lectured and keynoted many conferences including the National Library of Medicine (NLM/NIH) Scientific Visualization Conference, TED, TEDMED, Ink Conference (in association with TED India), Google Health Conference "ThinkHealth 2012", and Medicine Meets Virtual Reality (MMVR), and has lectured with Stephen Hawking at the MIT Media Lab.

"It is stories that give a soul to our data."

Alexander Tsiaras



Attractions at DIA 2017



DIAmond Sessions are offered Monday-Thursday, and include 11 global hot topics with regulatory, payer, industry, and patient perspectives. These panel conversations are can't-miss opportunities to listen to and engage with many of the key stakeholders involved in each topical area. DIAmond topics include diversity in clinical trials, international regulatory convergence, pediatric therapeutics, patient engagement and measurement, payer science, radical technologies, digital listening, real world evidence, drug repurposing, FDA forum, and EMA/FDA question time.

Content Hubs

New this year: DIA Community Members drive the agenda and topics for this new learning format!

Presentations will be led by DIA Community members in an intimate and informal setting. Engage with DIA Members and Community leaders, who have designed a 30 minute interactive exchange that will offer you rapid insight in a subject of value, or a deeper perspective of a compelling session given earlier in the meeting. The innovative Content Hub setting encourages participation with an open feel designed around a mix of seating styles to encourage relaxed conversations among the audience and the leader.

Seating is limited to 30 participants. Expect opportunity for Q&A and come away with new perspectives!

Engage and Exchange Sessions (E&E)

Share ideas, exchange experiences, and enhance your understanding of a topic that's important to you!

Actively participate in this collaborative learning environment, with a one hour session led by a facilitator. E&E's begin with a 10 minute presentation by the facilitator and then the audience will break out into smaller groups for 20-30 minutes of group discussion. The session ends with 10-20 minutes of larger group sharing and actionable insights.

Find your seat at one of these sessions! Space is limited to 50 participants.

DIA Drug Development and Life Sciences Career Fair

Attend the Complimentary Career Fair on Sunday, June 18!

Mingle with leading employers in the clinical and product development space who will be showcasing their career opportunities available within their organizations. Connect with CRO, biotech, and pharma companies all in one venue. Whether you are a recent graduate or a seasoned professional, the DIA Career Fair is the premier event to discover your next career move.

Stop by booth #1427 to learn more about DIA's professional development resources.



Innovation Theater Schedule

Participating Exhibiting Companies will showcase their expertise and solutions.

Theaters 1 and 2 are located in Exhibit Hall B.

Monday, June 19

DBMS Consulting | Theater 1 | 10:15AM

Cenduit | Theater 2 | 10:15AM

Tata Consultancy Services | Theater 1 | 12:30 pm

Global Regulatory Information Portal (GRIP) - A Regulatory Information Strategic Effectiveness Portal

QuintilesIMS | Theater 2 | 12:30pm

The Next Generation of Clinical Development is Here

PAREXEL International | Theater 1 | 1:15pm

Developing Drugs in the New Era of Personalized Medicines

Covance | Theater 2 | 1:15pm

Lessons Learned from Deploying Clinical Data Review: Ensuring Patient Safety, Increasing Operational Efficiency, and Creating New Insights

Deloitte Consulting | Theater 1 | 2:00pm

SAS Institute | Theater 2 | 2:00pm

Clinical Analytics Workflow Optimization

Advanced Clinical | Theater 1 | 4:45pm

Educational Measures | Theater 2 | 4:45pm

EM Array™ Live Meeting Technology

DBMS Consulting | Theater 1 | 5:30pm

Appian Corporation | Theater 2 | 5:30pm

Product Lifecycle Management in the Digital Era

THANK YOU! Thank you for participating in the Medical Heroes Appreciation 5K to celebrate study volunteers who give the gift of participation in clinical research and make new medical discoveries possible! SPECIAL THANKS TO OUR 2017 MED HERO 5K - CHICAGO SPONSORS OLYMPIAD LEVEL SPONSOR -CISCRP wcg MEDIA SPONSOR CHAMPION SPONSORS CenterWatch BM Watson Health ELITE SPONSORS Lilly Artcraft Health synchrogenix PARTICIPATING SPONSORS Amicus OprugDey OUTREACH SUPPORTER — GLOBAL OUTREACH AGENCY —

Tuesday, June 20

Veeva Systems | Theater 1 | 9:45AM

2017 Unified Clinical Operations Survey

Covance | Theater 2 | 9:45AM

Overcoming Study Complexity Through Data-Driven Design

AMPLEXOR | Theater 1 | 12:00PM

QuintilesIMS | Theater 2 | 12:00pm

Changing Trials Through Analytics: How it Works

Veeva Systems | Theater 1 | 1:00pm

Using Clinical Data to Create Site-Centric Culture by Design

Bioclinica | Theater 2 | 1:00pm

Veeva Systems | Theater 1 | 3:25pm

Unified RIM: End-to-End Submissions Development—From Planning Through Archival

BBK Worldwide | Theater 2 | 3:25PM

Building a Patient-Centric Mindset Through Theatrical Contemplation

Wednesday, June 21

Synchronoss | Theater 1 | 9:45AM

Applying Telecom's Mobility Best Practices to Life Sciences

SAS Institute, JMP Division | Theater 2 | 9:45AM

Work with Me Here...(or There or Anywhere!): Practical Cloud Collaboration with JMP Clinical

QuintilesIMS | Theater 2 | 1:00pm

Connecting People and Trials Through Innovative Technologies

Thank You to our Media Partners











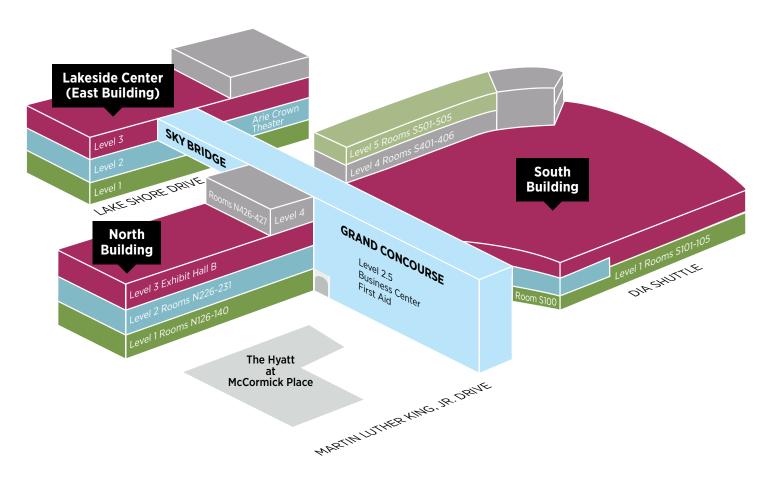


Pharmaceutical Executive





McCormick Place Site Map



Annual Meeting Orientation – South | Level 1 | Room S102bc

Baggage Check – South | Level 1 | Room S101a Business Center – Grand Concourse Level 2.5 Career Center – North | Level 3 | Exhibit Hall B, Booth #1427

Chicago Concierge and Restaurant Service – North | Level 3 | Exhibit Hall B Grand Concourse Lobby

Coffee/Refreshment Breaks (Early Morning) – South | Level 1 | Room S102 Lobby

- Monday: 7:30-8:30 AM
- Tuesday and Wednesday: 7:00-8:00AM
- Thursday: 8:00-9:00AM

Coffee/Refreshment Breaks (Mid-morning and Mid-afternoon)

- Monday: 10:00–11:00_{AM} North | Level 3 | Exhibit Hall B
- Tuesday and Wednesday: 9:30-10:30_{AM}, 3:00-4:00_{PM} - North | Level 3 | Exhibit Hall B
- Thursday: 10:30-10:45_{AM} South | Level 4 | S400 Concourse

Content Hubs - South | Level 4 | S400 Concourse

DIA Community Corner – North | Level 3 | Exhibit Hall B Grand Concourse Lobby

DIA Community Luncheon – North | Level 4 | Room N427bc

Tuesday: 12:00–1:00рм

DIA Booth – North | Level 3 | Exhibit Hall B, Booth #1427

DIAmond Sessions – South | Level 1 | Rooms S100a, S100c, S105

- Monday: 8:30-10:00AM
- Tuesday and Wednesday: 8:00-9:30AM
- Thursday: 9:00ам-12:00рм

Engage and Exchange - North | Level 3 | Exhibit Hall B | Aisle 300/400

Exhibit Sales Office - North | Level 3 | Exhibit Hall B | Aisle 2700/2800

First Aid - Grand Concourse Level 2.5

Housing Desk - North | Level 3 | Exhibit Hall B Grand Concourse Lobby

Innovation Theaters – North | Level 3 | Exhibit Hall B

- Theater 1 Aisle 300/400
- Theater 2 Aisle 2500/2600

Lost and Found – North | Level 3 | Exhibit Hall B Grand Concourse Lobby | Attendee Onsite Registration

Lunch Service – North | Level 3 | Rear of Exhibit Hall B

- Monday: 12:00-2:45рм
- Tuesday and Wednesday: 11:30AM-2:00PM

Media/Press Room - North | Level 1 | Room N140

Plenary Session and Keynote Address -

Lakeside Center | Level 2 | Arie Crown Theater

Monday: 3:00–4:30рм

Poster Sessions – North | Level 3 | Exhibit Hall B | Aisle 2500/2600

- Students: Monday: 10:00AM-6:00PM
- Oral Presentations: 12:30–2:45рм, 4:45–5:30рм
- Student Poster Awards Ceremony: 5:30pm
- Professionals: Tuesday and Wednesday: 12:00-1:45pm

Reception - North | Level 3 | Exhibit Hall B

• Monday: 4:30-6:00рм

Recharge Station (Supported by Covance) – North | Level 3 | Exhibit Hall B Grand Concourse Lobby

Registration

- Attendee Preregistration (barcode required)
 South | Level 1 | Room S103 Lobby
- Exhibitor, Speaker, and Attendee Onsite Registration – North | Level 3 | Exhibit Hall B Grand Concourse Lobby

Shuttle and Taxi Service Drop off and Pick up

- DIA Shuttle South | Level 1 | Gate 3
- Taxi South | Level 1 | Gate 4

Speaker Preparation Room – North | Level 2 | Room N231

Speaker Training Room – North | Level 2 | Room N230a

General Information

Access Presentations

Full-meeting and one-day registrants will have access to presentations (PDF version only). Please note that this includes all of the presentations provided to DIA by speakers to date, and will be continually updated as new presentations come in.

View presentations for DIA 2017 by visiting **DIAglobal.org/ DIA2017 presentations** and entering your User ID and Password (if you do not have a User ID and Password, click "Forgot User ID?" and enter the email address you provided at registration).

Baggage Check

Room S101a is available for checking your belongings (\$3 per item) Monday-Thursday. The Baggage Check will be available on the following days and times:

Monday: 7:00AM-6:30PM Tuesday: 7:00AM-5:30PM Wednesday: 7:00AM-6:30PM Thursday: 8:00AM-12:30PM

Business Center

The FedEx Office at McCormick Place, located on Level 2.5 of the Grand Concourse, offers an array of business services and products, tailored to meet your needs. Business hours are:

Sunday: 8:30AM-5:00PM Monday: 8:00AM-5:00PM Tuesday: 8:00AM-5:00PM Wednesday: 8:00AM-6:00PM Thursday: 8:30AM-5:00PM

For more information, call 312.949.2100 or email usa5020@fedex.com.

DIA App

Search "DIA Global" in your app store and download our interactive mobile meeting experience! The DIA Global app allows you to:

- View schedules, room locations, speakers, and explore sessions to build your schedule
- Play the DIA Exhibitor Scavenger Hunt and win prizes
- Interact 1:1 with other attendees (private message others)
- Get notified of premier events to attend and receive important reminders

DIA Career Development

DIA's interactive, online Career Center is your premier resource for job-seekers and talent recruitment.

The DIA Career Center offers employers targeted access to highly-qualified industry professionals, quick and easy job posting, online job activity reports, and access to the National Healthcare Career Network of over 60 top health care associations and professional organizations. Job-seekers receive free and confidential resume posting, automated weekly email notification of new job listings, and the ability to save jobs for later review. DIA's bi-weekly newsletter, *Leading Edge*, is an exclusive DIA Member benefit that alerts job-seekers of featured career opportunities, upcoming professional development trainings, and more!

For additional information, visit the DIA Booth (#1427), located in Exhibit Hall B.

Attending the DIA Drug Development and Life Sciences Career Fair? It is complimentary to attend and open to the public on Sunday, June 18 from 12:00-6:00_{PM} in the Regency Ballroom of Hyatt Regency McCormick Place.

Free DIA WiFi

DIA provides complimentary WiFi service throughout the space utilized by DIA in McCormick Place. To utilize this service, simply connect to "DIA Free WiFi" and enter the key "diaglobal". Once you accept the Terms and Conditions, you will be redirected to the DIA website. Don't forget to download the DIA Global App by searching "DIA Global" in your app store.

First Aid Center

First Aid is available for routine health problems and emergency care. The First Aid Center is located on Level 2.5 of the Grand Concourse. In case of emergency, dial 6060 from any convention center phone or 312.791.6060 from your cell phone and provide the location of your emergency. The Convention Center will dispatch medical personnel at once. **Please do not dial 911.** We also urge you to complete the emergency contact information card, available at Attendee, Speaker, and Exhibitor Registration, and keep it in your badge holder at all times.

Ask Me Stations

Ask Me Stations are located in key locations throughout the Convention Center. Should you need directional information, or additional assistance, please do not hesitate to stop by one of the stations.

General Information

Lost and Found

Misplaced items will be stored at Attendee Onsite Registration, located in the registration area outside Exhibit Hall B, until the end of the event. Items remaining at the close of the meeting will be turned over to McCormick Place security. At that point, you can call 312.791.6060.

DIA Lunch Service

Lunch will be provided in the back of Exhibit Hall B on Monday, 12:00-2:45pm, and Tuesday-Wednesday, 11:30 AM-2:00 PM. Lunch vouchers will not be used for DIA 2017. Your name badge will be scanned when entering the lunch service area each day.

Meeting Name Badge

There will be a \$25 fee for badge reprints. If you require a badge reprint, please visit the Cashier at Attendee Onsite Registration, located in the registration area outside Exhibit Hall B. Identification will be required. Additionally, the QR code on your conference badge contains your contact information. Allowing exhibitors to scan the QR code will provide them this contact information.

Private Social Functions Policy

DIA does not allow any hospitality functions to be held during any Annual Meeting offerings, scheduled Exhibit hours, or social events. The hours noted below are the only hours acceptable for hospitality functions:

Saturday, June 17 | All times Sunday, June 18 | All times Monday, June 19 | Before 8:00AM and after 6:00PM Tuesday, June 20 | Before 8:00AM and after 5:00PM Wednesday, June 21 | Before 8:00AM and after 5:00PM Thursday, June 22 | Before 9:00_{AM} and after 12:15_{PM}

Selection of Offerings

Seating for educational offerings is on a first-come, firstserved basis. You should be prepared with an alternate selection in the event that a room is filled to capacity. Those with press passes are only able to attend sessions when room is available.

Getting Around Chicago

By Taxi: Taxi service is readily available throughout the city. Taxi fares to/from O'Hare range between \$50 and \$60, and fares to/from Midway range between \$30 and \$40. Taxi stands are located outside of the baggage claim area at both airports.

Taxi fares from DIA hotels to McCormick Place are between \$15 and \$25 per ride. Taxis pick up and drop off at McCormick Place South at Gate 4.

By Public Transit: The Chicago Transit Authority (CTA) operate buses, commuter trains, and rapid transit throughout the metropolitan area. The CTA offers a 24 hour rapid transit train (the Blue Line) from O'Hare Airport to the Chicago Loop area for \$5. The Blue Line is located in the lower level between terminals 2 and 3. Travel time to the downtown hotels is approximately one hour.

The Orange Line from Midway Airport to downtown is accessible by following airport signage to the station, and operates from 4:00-1:00am on weekdays and 4:30-1:00am on weekends for \$3. Travel time to the downtown hotels is approximately 35 minutes.

The new CTA Green Line "Cermak-McCormick Place" station is located just 2.5 blocks from McCormick Place. Around-theclock CTA travel information and maps to various locations in the city are available by calling 312.836.7000 or visiting transitchicago.com.

Show Your Badge Discounts

Show your DIA badge to many vendors, shops, and restaurants around the city to receive special exclusive discounts for DIA 2017 Attendees. Go to chicagoconcierge. com/dia/deals to find out where and how to redeem.

Chicago Concierge Services

Chicago Concierge, located at the Exhibit Hall B entrance, will be available throughout the meeting. The professional staff is happy to assist you with restaurant reservations, theater, attractions, and sporting event tickets. Please feel free to stop by with any questions you may have about Chicago, or visit chicagoconcierge.com/dia.

DIA Courtesy Shuttle to/from McCormick Place



Complimentary shuttle service will be provided between the convention center and all DIA hotels, with the exception of Hyatt Regency McCormick Place, Monday-Thursday. The shuttle will be available in the morning

and at the conclusion of DIA events each day.

Shuttles will arrive and depart from Gate 3, (entrance near room S100). Please note that you must be staying at a DIA hotel to utilize the complimentary shuttle. A shuttle pass and shuttle schedule will be provided to all participants when checking into their hotel.

Use of the shuttle pass will be strictly enforced.

Meeting Highlights



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

Please note: Due to the interactive, unprecedented dialog that takes place in these sessions, DIAmonds are well attended. Seating is available on a first-come, first-served basis.

Monday, June 19 | 8:30-10:00AM

#101 Drug Repurposing: Where Will It Take Us? -Room \$105

Will "repurposing" disrupt the current market? How can academia, industry, and health authorities collaborate to advance drug repurposing efforts? What is needed to overcome economic, patent, and regulatory hurdles to get repurposed drugs to patients faster? These guestions and others will be addressed by an esteemed panel of representatives from NIH NCATS, Cures Within Reach, industry, and academia.

#102 The Evolution of Evidence Generation: Real World Evidence and the Next Generation of Decision-Making-Room \$100a

Prominent thinkers on scientific evidence for support of biomedical decision-making will discuss our readiness to tap RWE for safety and efficacy questions and consider its uses for regulatory purposes. The benefits and challenges of using RWE to generate evidence of sufficient quality for decision-making, following the concept of using fit-forpurpose research tools, will be examined.

#103 The Future of Patient Engagement: **Measuring What Matters-***Room S100c*

Patient, industry, and regulatory stakeholders will share perspectives on today's meaning of effective patient engagement and what its future will look like. Panelists will discuss how patients can be engaged to identify the outcomes that matter most, and how we can build a future in which achieving what matters most to the patient is the measure of our success.

Tuesday, June 20 | 8:00-9:30AM

#202 People Will Talk: Gathering Insights from **Digital Listening-***Room S100c*

Panelists in this DIAmond session will address how digital health information can be analyzed to support medical affairs, pharmacovigilance, and commercialization efforts. Topics addressed include an overview of techniques, use cases, compliance with regulatory guidelines, and patient privacy.

#201 Paying for Value in Biopharmaceuticals: Trends in the United States-Room S105 RESEARCH AMERICA

(In collaboration with Research America) Gain better context on how drug pricing, reimbursement, and access decisions are made in the US. Panelists from industry and payer groups will evaluate how the concept of value has impacted health care spending, and describe where we are today with value-based health care decision-making.

#203 Radical Technologies: Changing the Future of Biopharmaceuticals-Room \$100a

Innovative thinkers will project the impact of some of the most radical emerging technologies on the future of biomedical research. The expert panel will explore extreme changes that will improve the biopharmaceutical development process of the future and the radical technologies that will make them possible.

Meeting Highlights: DIAmond Sessions, cont.

Wednesday, June 21 | 8:00-9:30 AM

#302 Does Diversity Matter in Clinical Trials?

-Room S100c

A multi-stakeholder panel takes a 360-degree view of the issue of diversity in clinical trials. Questions such as, "What does diversity mean in the context of personalized medicine?", "How are we doing today?", and "What is the outlook for current efforts and initiatives to better diversify trial populations?" will be explored.

#303 International Regulatory Convergence

-Room S100a

Join senior leadership from international regulatory authorities to hear the latest on multi- and bilateral initiatives that avoid duplication and increase mutual reliance, their strategic governance, and their impact on industry.

#301 Progress in Pediatric Therapeutics

-Room \$105

FDA's 2016 status report on the BPCA and PREA concluded that progress has been made in obtaining pediatric studies and new labeling, but significant challenges remain in studies for neonates, infants, pediatric cancer, and international coordination of pediatric trials. This panel will discuss recent progress in global pediatric research and regulatory science and new developments in pediatric research networks such as the Pediatric Trials and the International Neonatal Consortia.

Thursday, June 22 | 9:00-10:30 AM

#401 FDA Forum-Room S100a

The FDA Forum will focus on inter-center collaboration between CDER, CDRH, CBER, and the Office of Combination Products. The recently established Oncology Center of Excellence will be highlighted as a new area of collaboration. FDA representatives will share how they collaborate to provide advice regarding products in development, review marketing applications, and help accelerate medical product approvals.

Thursday, June 22 | 10:45AM-12:15PM

#412 EMA/FDA Question Time-Room S100a
EMA and FDA leadership will engage in a round table
discussion on areas covered by the EMA/FDA confidentiality
arrangements and discuss how both agencies contribute to
global development and supervision of medicines. Experts
from both Agencies who are at the forefront of EMA/
FDA collaboration will explore topics such as innovation
support to industry, use of real-world data, development of
medicines in rare diseases, and data transparency.

Meeting Highlights: Global Regulatory Sessions

Regulatory Affairs Around the World: Map Your Sessions at DIA 2017

Monday, June 19 | 11:00 AM-12:15 PM

#127 The Evolving International Landscape of FDA Inspections: Data Integrity Violations in Bioequivalence Studies in India-Room \$405a

Panelists will use a case-study format and present the risk-based approach used to select sites for inspection and discuss the role of FDA's international offices in facilitating inspections and engaging with regulatory counterparts in country.

Monday, June 19 | 11:00 AM-12:30 PM

#115 Update from the CFDA-Room S403ab This session will provide an overview of CFDA regulatory reform and an update on key important initiatives.

Tuesday, June 20 | 10:30-11:30 AM

#217 Update from CBER: Advancing the Development of Complex Biologic Products

-Room S404a

Panelists will provide an overview of how the Center for Biologics Evaluation and Research (CBER) works to advance the development of biological products such as vaccines, live biotherapeutics, and cellular and gene therapies.

Tuesday, June 20 | 10:30-11:45AM

#214 Recent Trends in Asian Regulations for Drug Development: What is Coming Next?-*Room N227b*

Regulatory agencies from major East Asian countries including Japan, Singapore, and Taiwan, together with the industry representation, will give an overview of the recent regulatory environment changes in each country.

#216 International Collaboration in Times of Public Health Crisis-Room N229

Learn how regulators have and are demonstrating a willingness to find new and pragmatic ways of working together with industry with the ultimate goal of providing health care solutions which are in high-demand by society.

Tuesday, June 20 | 4:00-5:15pm

#278 PMDA Town Hall-Room S404a

PMDA's executive staff will discuss progress made towards achieving the goals outlined in its "PMDA International Strategic Plan 2015", as well as other initiatives currently underway and new initiatives to further PMDA's contributions to global health.

Tuesday, June 20 | 4:00-5:15_{PM}

#279 Brexit: Where Are We Now?-Room S404bc Gain an overview of the current state of play of the political process from a UK as well as an EU perspective.

Wednesday, June 21 | 8:00-9:30_{AM}

#303 International Regulatory Convergence

-Room S100a

Join senior leadership from international regulatory authorities to hear the latest on multi- and bilateral initiatives that avoid duplication and increase mutual reliance, their strategic governance, and their impact on industry.

Wednesday, June 21 | 2:00-3:15pm

#345 Global Perspective on ICH: Part 1 of 2 -Room N228

A panel of experts will discuss the benefits of ICH and global regulatory harmonization, including views on key strategic topics that will enhance simultaneous global drug development.

Wednesday, June 21 | 4:00-5:00pm

#373 FDA - Health Canada Regulatory Cooperation Council Town Hall-*Room S401d*

FDA and Health Canada will highlight their work under RCC Phase 2 and request stakeholder input on their current initiatives.

Wednesday, June 21 | 4:00-5:15pm

#374 Global Perspective on ICH: Part 2 of 2

-Room N228

The expert panel will continue the discussion on the benefits of ICH and global regulatory harmonization, including views on key strategic topics that will enhance simultaneous global drug development.

Thursday, June 22 | 10:45AM-12:00PM

#412 EMA/FDA Question Time-Room S100a EMA and FDA leadership will engage in a round table discussion on areas covered by the EMA/FDA confidentiality arrangements and discuss how both agencies contribute to global development and supervision of medicines.

Meeting Highlights: Professional Development

Leadership: How to Organize and Lead People in a Work Group

Sunday, June 18 | 8:30 AM-12:00 PM | Room S401a

Explore the various types of work groups, how they can be more effective, and how individuals can correct group dynamics and help the group achieve higher levels of performance.

Influencing Culture, Avoiding Bureaucracy, and Encouraging Innovation

Sunday, June 18 | 1:00-4:30_{PM} | Room S403ab

Gain a better understanding of what culture, bureaucracy, and innovation really are, and the impact they can have on actual business results by stripping away the vagueness and assumptions that so commonly surround these topics.

To Change or Not to Change, That is the Career Question: Knowing When it's Time to Move On (Not, Run From)

Sunday, June 18 | 2:45-4:00pm | Room S404d

Hear from industry leaders on how they knew it was time to make a career change and how to prepare for the move. Learn techniques you can use to assess a negative performance review, being passed over for a promotion or similar, and how to avoid an emotionally-based (and regretful) decision.

Networking Within Your Company

Sunday, June 18 | 4:15-5:30_{PM} | Room S404d

Internal networking is when you reach out to colleagues within your organization by looking outside your immediate, day-to-day activities and thinking about how you can connect with and create value for others in your company. The differences between external and internal networking will be discussed in-depth, as well as various personality types and how they can impact networking.

This session will be followed by an informal gathering at a local venue to practice your newly acquired networking skills.

Student Program (Complimentary)

Sunday, June 18 | 10:30_{AM}-12:00_{PM} | Hyatt Regency McCormick Place - Prairie Room

Explore the numerous opportunities that come with the student membership that DIA offers. Students will find the information and networking opportunities DIA provides can help shape and guide course and track selections as they proceed through their educational experiences. The session will also include a panel discussion.

Annual Meeting Orientation

Monday, June 19 | 7:30-8:30_{AM} | Room S102bc

Ask a panel of long-time Annual Meeting attendees what they get out of the meeting each year, find out about the can't miss sessions and content, and discover how you can maximize the value of your time at DIA 2017.

Student Forum - Engage and Exchange

Monday, June 19 | 11:00 AM-12:15 PM | Exhibit Hall B

Examine and discuss the three areas of interest to advanced students in pharmacy, pharmaceutics, life sciences, and related programs: 1) The uses and abuses of business cards. 2) Opportunities in the pharmaceutical industry for recent graduates. 3) What recruiters want and how to help them advance your career.

Student Poster Session and Oral Presentations

Monday, June 19 | 10:00AM-6:00PM

Student Oral Presentations

12:30-2:45рм: 4:45-5:30рм | Exhibit Hall В

Students from around the world will showcase their research in this year's Poster Session.

Student Poster Awards Ceremony

Monday, June 19 | 5:30-6:00pm | Poster Area - Exhibit Hall

Professional Poster Sessions and Oral Presentations

Learn about cutting edge research from a diverse group of life science professionals on various topics.

Professional Poster Session 1

Tuesday, June 20 | 9:30AM-5:00PM | Exhibit Hall Presenters available at posters 9:30-10:30AM; 12:00-1:45PM

Professional Oral Poster Presentations 1

Tuesday, June 20 | 12:00-1:45pm | Exhibit Hall

Professional Poster Session 2

Wednesday, June 21 | 9:30am-4:00pm | Exhibit Hall Presenters available at posters 9:30-10:30am; 12:00-1:45pm

Professional Oral Poster Presentations 2

Wednesday, June 21 | 12:00-1:45pm | Exhibit Hall

Opening Reception

Monday, June 19 | 4:30–6:00pm | Exhibit Hall B Network with 7000+ attendees and 450+ exhibitors.

Meeting Highlights: Breaks & Lunches

Refreshment Breaks

Meet up with your colleagues to plan your day. Morning coffee and light refreshments will be available in the S102 Lobby.

Monday, June 19 | 7:30-8:30AM Tuesday, June 20 | 7:00-8:00AM Wednesday, June 21 | 7:00-8:00AM Thursday, June 22 | 8:00-9:00AM

Visit our 450+ exhibitors during mid-morning and midafternoon breaks, available in the Exhibit Hall.

Monday, June 19 | 10:00-11:00AM Tuesday, June 20 | 9:30-10:30AM; 3:00-4:00PM Wednesday, June 21 | 9:30-10:30AM; 3:00-4:00PM Thursday, June 22 | 10:30-10:45AM (S400 Concourse)

Luncheon in the Exhibit Hall

Discuss what you've learned and engage with your colleagues and exhibitors during the daily luncheons in the Exhibit Hall.

Monday, June 19 | 12:00-2:45pm Tuesday, June 20 | 11:30am-2:00pm Wednesday, June 21 | 11:30am-2:00pm

Meeting Highlights: DIA Members

DIA Members: Get Engaged Booth #1427 | Exhibit Hall B – Grand Hall

Are you looking to make the most of your DIA membership? DIA Communities, an exclusive member benefit, keep members connected across the globe, providing the ability to interact with peers and form cross-disciplinary teams.

Stop by the DIA Booth #1427, to learn how to take advantage of volunteer opportunities to raise your visibility and enjoy a tour of the Community platform. Becoming a DIA member is the first step to joining a global network where you can play an important role advancing health care product development through global collaboration, communication, and education.

Join any of the 20+ communities and share information, raise concerns, mentor one another, and publish your work—accomplish more as a group than any one person could alone.

- Keep up with current topics and Community-generated content
- Share best practices, knowledge resources, articles, and more
- Get involved and be part of the future in advancing therapeutic innovation

Join at DIAglobal.org/Communities. Stop by Booth #1427 in Exhibit Hall B so we can show you how!

Community Corner | Exhibit Hall B Grand Concourse Lobby

A dedicated area is available for you to meet with your fellow Community members throughout the week to learn more about DIA's Communities, or to continue the conversation about a specific session or presentation. Look for scheduled discussions on signage near the entrance to the Exhibit Hall.

DIA Community Luncheon

Tuesday, June 20 | 12:00-1:00pm | Room N427bc

Join fellow Community members and interested attendees at the Community Luncheon. Take this exciting opportunity to learn more about DIA's Communities and new ways to volunteer!

CONTINUING EDUCATION

The DIA 2017 Annual Meeting brings together key thought leaders and innovators from industry, academia, regulatory and government agencies, health, patient, and philanthropic organizations from around the globe—across all disciplines involved in the discovery, development, and life cycle management of health care products. DIA 2017 is intended to strengthen professionals' understanding of the value of cross-discipline integration and to foster innovation for better health outcomes.

LEARNING OBJECTIVES

At the conclusion of DIA 2017, participants should be able to:

- Compare the current regional regulatory and public policy environment pertaining to pharmaceuticals and related products
- Discuss the regulatory and economic factors that impact the global biopharmaceutical industry
- · Recognize the challenges facing regulatory agencies and industry in research study design and statistical methodology
- · Identify relevant data, document, and systems standards and integration approaches; explain their impact on quality and endto-end efficiency in data collection, management, submission, and approval processes for medical products
- Describe the current and future scope of innovative technology, including wearables and other mobile devices, in the generation and collection of electronic source data in clinical research and postmarket assessment to improve patient outcomes
- Discuss the role of big data and analytics, their applications throughout the product life cycle, and their ethical, legal, and security implications for patient data
- Identify legal, advertising, and marketing issues related to providing product information
- Apply principles of risk assessment and management to development and postmarket phases of new health care products
- Summarize issues in safety reporting and data analysis regarding adverse events
- Distinguish regional approaches to integration of evidence-based

- medicine and comparative effectiveness research into health care decision-making
- Describe current issues in designing and implementing clinical trials, including patient recruitment, site selection, and management of multi-regional clinical trials
- Discuss the evolving role of medical affairs in the medical product development landscape
- Identify current opportunities and challenges in the area of personalized medicine for disease treatment
- Examine ways to provide appropriate support to the clinical trial process that will ultimately impact patient care

Specific learning objectives for each offering are found on the DIA 2017 website under the program description details and will be shown in all meeting rooms.

Select program offerings (including sessions, forums, and workshops) may be approved for AMA PRA Category 1 Credits™, pharmacy or nursing contact hours, Project Management Institute (PMI) professional development units (PDUs), or International Association for Continuing Education and Training continuing education units (CEUs). Continuing education (CE) credit information will be clearly identified in the final program and on the DIA 2017 website with the statement CME, Pharmacy, Nursing. or PMI PDUs. IACET continuing education units (CEUs) are offered for most program offerings; CE credits are NOT AVAILABLE for the Engage and Exchange sessions, the Innovation Theater presentations, Content Hubs, or the Opening Plenary session.

ACCREDITATION AND CREDIT DESIGNATION STATEMENTS

Accreditation Council for Continuing Medical Education (ACCME)



for Medicine

Postgraduate Institute This activity has been planned and implemented in accordance with the accreditation requirements and policies of the

Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Postgraduate Institute for Medicine (PIM) and the Drug Information Association (DIA). PIM is accredited by the ACCME to provide continuing medical education for physicians.

The Postgraduate Institute for Medicine designates this live activity for a maximum of 16.25 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Accreditation Council for Pharmacy Education (ACPE)



DIA is accredited by the Accreditation Council for Pharmacy DIA is accredited by the Accreditation.

Education as a provider of continuing pharmacy education.

Participants can earn up to 14.5 contact hours or 1.45 continuing education units (CEUs) for participating in the Annual Meeting program offerings.

ACPE Credit Requests MUST BE SUBMITTED BY FRIDAY, AUGUST 4, 2017

DIA is required by the ACPE to report pharmacy-requested CEUs through the CPE Monitor. If ACPE credit requests are not submitted within date noted above, the ACPE credit request will not be processed to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile ID, please visit www.cpemonitor.net.

All approved ACPE UANs and activity types are on the DIA 2017 Annual Meeting website at DIAglobal.org/DIA2017CE and in the final program.

American Nurses Credentialing Center (ANCC)



This educational activity for 16.25 contact hours is provided by PIM.

PIM is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Select program offerings (including sessions, forums, and workshops) may be approved for AMA PRA Category 1 Credits", pharmacy or nursing contact hours, or Project Management Institute (PMI) professional development units (PDUs), or International Association for Continuing Education and Training (IACET) continuing education units (CEUs). Continuing education credit information will be clearly identified in the final program and on the DIA 2017 website with the statement CME, Pharmacy, Nursing, or PMI PDUs. IACET CEUs are offered for majority of the program offerings. Continuing education credits are NOT AVAILABLE for the Engage and Exchange sessions, the Innovation Theater presentations, Content Hubs, or the Opening Plenary session.

Project Management Institute (PMI)



DIA has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI).

Participants may receive up to 8.75 professional development units (PDUs) for attending the Annual Meeting program offerings.

All approved DIA designated PMI numbers for approved offerings are found on the DIA 2017 Annual Meeting website at DIAglobal.org/DIA2017CE and on each designated offering description.

The PMI Registered Education Provider logo is a registered mark of the Project Management Institute, Inc.

International Association for Continuing Education and Training (IACET)



DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET accredited provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 1.9 CEUs for this program.

CONTINUING LEGAL EDUCATION

For attorneys who would like to receive continuing legal education credits for attending DIA 2017, please complete your state's application for credit and submit accordingly. If you require additional information, please contact CE@DIAglobal.org.

CE CREDIT ALLOCATION

Annual Meeting Program Offerings, Sunday-Thursday, June 18-22

Credit amounts range based upon the length of time for each offering. This program offers up to 16.25 *AMA PRA Category 1 Credits*™, 1.9 IACET CEUs (.2 IACET CEUs are offered for a 1.5 hour program offering and .1 IACET CEU is offered for a 1.25 hour program offering); Nursing 16.25 contact hours; Pharmacy 14.5 contact hours or 1.45 CEUs; and 8.75 PMI PDUs.

DIA CERTIFICATE PROGRAMS

Individuals enrolled in DIA Certificate Programs may receive elective units for the designated programs noted below:

- Clinical Research Certificate Program: 12 Elective Units
- Clinical Safety and Pharmacovigilance Certificate Program:
 4 Elective Units
- Project Management Certificate Program: 8 Elective Units
- Regulatory Affairs Certificate Program: 12 Elective Units

In addition, DIA's Certificate Program units will be available for DIA 2017 short courses. See specific units that are available for each offering noted on the DIA 2017 website. For more information on DIA's Certificate Program, visit DIAglobal.org/CertificatePrograms.

Participants who would like to receive continuing education credit for DIA 2017 must scan their DIA name badge at each offering to record their attendance. Participants must scan their badges within 45 minutes for the 1.5 hour offerings, and 30 minutes for the 1.25 hour offerings. Participants who do not scan their badges within the allotted time will not be eligible to request the available continuing education credits for that offering. If a participant attends multiple offerings within the same timeframe, only the last scanned entry will be recorded.

My Transcript Opens Tuesday, June 27

To access My Transcript:

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Choose MENU, found in the upper left corner
- Under CONFERENCES select "Continuing Education"
- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for each offering and for each day of the meeting

If you experience any difficulties, please contact DIA at MyTranscript@DIAglobal.org.

EVALUATION

DIA 2017 online evaluations can be found at DIAglobal.org/DIA2017evals. All participant scanned data will be uploaded into the evaluation portal so only the offerings you attended will appear in your record. Attendees will sign into the evaluation portal using their email address and Badge ID.

The evaluation portal opens on Sunday, June 18 and closes on Friday, July 21, 2017.

Evaluation feedback is very important to DIA. To thank you for your feedback, DIA will conduct a drawing with a chance for one attendee to win a free registration to the DIA 2018 Annual Meeting. Eligible attendees must complete an evaluation from each program offering attended, as well as the overall evaluation. The winner of the drawing will be contacted by DIA the week of August 1, 2017.

DISCLAIMER

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of DIA. Speakers, agenda, and CE information are subject to change without notice.

Recording of any DIA educational material in any type of media is prohibited without prior written consent from DIA.

Disclosure of Conflicts of Interest

The Postgraduate Institute for Medicine (PIM) and DIA require instructors, planners, managers, and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly vetted by PIM and DIA for fair balance, scientific objectivity of studies mentioned in the materials or used as the basis for content, and appropriateness of patient care recommendations. Disclosure statements will be included on a slide in the meeting room, as well as on the DIA 2017 website.

DIA 2017 TRACKS AND FEATURED TOPICS

Track #	Core Interest Area	Feat	ured Topics
Track 01	Data/Big Data/eHealth	1.	Clinical Operations
Track 02	Disruptive Innovation	2.	Statistics
Track 03	Medical Affairs and Scientific Communication	3.	Quality/GXP
Track 04	Patient Engagement	4.	Medical Writing
Track 05	Regulatory	5.	CMC
Track 06	Safety and Pharmacovigilance	6.	eSubs
Track 07	Special Populations	7.	Outsourcing
Track 08	Strategic Planning/Execution and Partnerships	8.	Public Policy
Track 09	Translational Science: Preclinical/Clinical and Product Development	9.	Rare Disease
Track 10	Value and Access	10.	Patient-Centric
Track 11	Quality	11.	Project Management
Track 12	DIAmond	12.	Global Regulatory
Track 13	Innovation Theater	13.	Career Development
Track 14	Professional Development	14.	Devices/Combination Products
Track 15	Engage and Exchange	15.	Wearables/Mobile Health
Track 16	Poster Presentations	16.	Data Management
Track 17	Content Hubs	17.	Academic Clinical Researcher
Track 18	Plenary	18.	Real World Evidence
		19.	RBM
		20.	Pediatrics

CONTENT LEVEL GUIDE

The difficulty level of each offering has been determined by the program offering chair and is indicated by one of the following symbols. This provides a guide for registrants in their selection of program offerings to attend.

- Basic Level Content
 - Appropriate for individuals new to the topic/subject area.
- Primarily Intermediate Level Content
 Appropriate for individuals who already
 have a basic understanding of the topic/
 subject area.
- Primarily Advanced Level Content Appropriate for individuals with an in-depth knowledge of the topic/ subject area.

DIFFERENT FORMATS FOR DIFFERENT LEARNERS

FORUM

SESSION

A 60- or 75-minute blended presentation and panel discussion.

A 60- or 75-minute presentation delivered lecture-style from the podium.

WORKSHOP

A 90-minute conceptual presentation delivered in an interactive/simulation or role playing format.

SATURDAY, JUNE 17-MONDAY, JUNE 19

The following agenda details were made available to DIA on or before May 9. Speaker names identified as "Invited" will be published once confirmation and disclosure forms are completed.

■ Basic-level content; ■ Primarily intermediate-level content; ◆ Primarily advanced-level content

SATURDAY, JUNE 17

Registration Hours

9:00_{AM}-5:00_{PM} Exhibitor Registration

SUNDAY, JUNE 18

Registration Hours

8:00–9:00_{AM} Registration for Full Day and Morning

Preconference Short Courses*

8:00AM-6:00PM Exhibitor Registration

12:30–6:00PM Registration for Afternoon Preconference Short

Courses*, Conference Attendees, and Speakers

Schedule

8:30AM-12:00PM Half Day Morning Preconference Short Courses*

9:00am-5:00pm Full Day Preconference Short Courses*

10:30AM-12:00PM Student Programming | Hyatt Prairie Room

12:00–6:00_{PM} Drug Development and Life Sciences Career Fair |

Hyatt Regency Ballroom

1:00–4:30_{PM} Half Day Afternoon Preconference Short Courses*

*Space is limited for Preconference Short Courses. Onsite Registration is available, but not quaranteed.

12:30-12:45рм

Annual Meeting of Members

Boulevard A - Hilton Chicago

#001 Track 14 - Professional Development

Featured Topic(s): Career Development, Student Programming

2:45-4:00pm Level: ■ Format: WORKSHOP

Room S404d

To Change or Not to Change, That is the Career Question: Knowing When it's Time to Move On (Not, Run From)

CHAIRPERSON

Kimberly Belsky, MS

Senior Director, Regulatory Affairs, Regulatory Intelligence, Mallinckrodt Pharmaceuticals

PANELISTS

Leigh Shultz, PhD

Associate Vice President, Project Management, Merck & Co., Inc.

Margaret S. Richards, PhD, MPH

Vice President, Data Analytics and Epidemiology, RW Strategy and Analytics, Mapi

Stephen Knowles, MD, MRCP

Senior Director, Global Patient Safety, Medical and Benefit Risk Management, Eli Lilly and Company

#002 Track 14 - Professional Development

Featured Topic(s): Career Development, Student Programming

4:15−5:30pm Level: ■ FORMAT: WORKSHOP

Room S404d

Networking Within Your Company

CHAIRPERSON

Chris Matheus, MBA

Executive Director, Business Development, Lexitas Pharma Services

SPEAKER(S)

Facilitator

Bob Muzerall

Vice President, Sales and Sales Training, AMPLEXOR Life Sciences, LLC

Facilitator

Nadia Bracken

Founder and Chief Connector, ClinOps Toolkit

MONDAY, JUNE 19

Registration Hours

7:00_{AM}-6:00_{PM} Attendee, Speaker, and Exhibitor Registration

7:30-8:30AM

Coffee and Light Refreshments

S102 Lobby

7:30-8:15_{AM}

Annual Meeting Orientation

Room S102bc

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#101 TRACK 12A



Featured Topic(s): Academic Clinical Researcher, Public Policy, Rare Disease, Student Programming

8:30-10:00am Level: ■ Format: FORUM

Room S105 CME, Pharmacy, and Nursing

Drug Repurposing: Where Will it Take Us?

CHAIRPERSON

Bruce E. Bloom, DDS, JD

President and Chief Science Officer, Cures Within Reach

SPEAKER(S)

Christine Colvis, PhD

Director, Drug Development Partnership Programs, National Center for Advancing Translational Sciences (NCATS)

Jill Pulley, MBA

Executive Director of the Institute for Clinical and Translational Research, Vanderbilt University

Craig Wegner, PhD

Head, Boston Emerging Innovations, AstraZeneca

K. Gary Barnette, PhD

Senior Vice President of Scientific and Regulatory Affairs, Camargo Pharmaceutical Services, LLC

#102 TRACK 12B



Featured Topic(s): Real World Evidence, Patient-Centric, Public Policy, Student Programming

8:30-10:00am Level: ■ Format: SESSION

Room S100a CME, Pharmacy, and Nursing

The Evolution of Evidence Generation: Real World Evidence and the Next Generation of Decision-Making

CHAIRPERSON

Iris Loew-Friedrich, DrMed

Chief Medical Officer, Executive Vice President and Head, Development and Medical Practices, UCB, Inc.

PANELISTS

Nancy A. Dreyer, PhD, MPH

Global Chief, Scientific Affairs; Senior Vice President, Head, Advanced Center for Evidence Generation, Quintiles IMS

Robert J. Temple, MD

Deputy Center Director for Clinical Science, Office of the Center Director, CDER, FDA

Alison Cave, PhD

Principal Scientific Administrator, European Medicines Agency, European Union

Stephanie Devaney, PhD, MPH

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Brian M. Bradbury

Executive Director, Head, Data and Analytics, Center for Observational Research, Amgen, Inc.

#103 TRACK 12C



Featured Topic(s): Patient-Centric, Clinical Operations, Wearables-Mobile Health, Student Programming

8:30-10:00am Level: ■ Format: SESSION

Room S100c *CME, Pharmacy, and Nursing*

The Future of Patient Engagement: Measuring What Matters

CHAIRPERSON

Debra Lappin, JD

Head, Health Biosciences Practice, FaegreBD Consulting

PANELIST

Anne C. Beal, MD, MPH

Senior Vice President, Chief Patient Officer, Center of Excellence for Patient Centricity, Sanofi, France

Juan Garcia-Burgos, MD

Head of Public Engagement Department (Interim), European Medicines Agency, European Union

Kimberly McCleary

Managing Director, FasterCures, A Center of the Milken Institute

Representative Invited

Friends of Cancer Research

Representative Invited

CDER, FDA

10:00-11:00am

Coffee Break

Exhibit Hall

#104 Track 13A - Innovation Theater

10:15-10:45AM FORMAT: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

Cenduit LLC Innovation Theater

#105 Track 13B - Innovation Theater

10:15–10:45am Format: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

DBMS Consulting Innovation Theater

#106 TRACK 1 - DATA/BIG DATA/EHEALTH

Featured Topic(s): Real World Evidence, Clinical Operations, Academic Clinical Researcher

11:00am-12:15pm Level: ■ Format: SESSION

Room N229 CME, and Nursing

Leveraging Big Data/Real-World Data in Enabling Efficient and Data-Driven Clinical Research from Sponsor, Vendor, and National Health System Perspective: Case Studies

CHAIRPERSON

Crystal Ancona, MS

Operational Data Analyst, AbbVie, Inc.

SPEAKER(S)

Big Data: Unleashing the Full Potential of Big Data to Make the Buzzword Tangible

Crystal Ancona, MS

Operational Data Analyst, AbbVie, Inc.

From Trial to Launch: Closing the Innovation Loop and Designing Smarter Trials with Real World Evidence

Andrew Cassel

Managing Director, Analytics, Medidata Solutions Worldwide

Big Data Utilization Experience in Clinical Trial Feasibility Kelly Han, PMP

Manager, KoNECT, Republic of Korea

#107 Track **02A** - Disruptive Innovation

Featured Topic(s): Patient-Centric, Data Management, Wearables-Mobile Health

11:00am-12:15pm Level: ■ Format: SESSION

Room S501abc CME, and Nursing

Leveraging Wearables and Sensors in Clinical Trials and mHealth

CHAIRPERSON

Bill Byrom, PhD

Senior Director of Product Innovation, and Vice Director of ePRO Consortium, ICON, plc, United Kingdom

SPEAKER(S)

Selection of Wearable Devices and Validation of Health Outcome Assessments Derived from Wearables Data

Bill Byrom, PhD

Senior Director of Product Innovation, and Vice Director of ePRO Consortium, ICON, plc, United Kingdom

Challenges of Using Consumer Wearables in Beyond the Pill Programs: A Pharma and Patient Perspective

Chris Watson, PhD

Director of Product Strategy, Exco InTouch, United Kingdom

Transitioning Wearables from Pilot Evaluations to Trials and mHealth Programs

Daragh Ryan

eClinical and mHealth Consultant, Cliniphy, United Kingdom

#108 Track 02B - DISRUPTIVE INNOVATION

Featured Topic(s): Academic Clinical Researcher

11:00am−12:15pm Level: ■ Format: SESSION

Room S502ab CME, and Nursing

Artificial Intelligence/Machine Learning

CHAIRPERSON

Badri Rengarajan, MD

Medical Affairs Lead, ASPIRE Unit, Actelion

SPEAKER(S)

Al for Beginners: Impact of Artificial Intelligence on eClinical Technology

Vladimir Dvag

Vladimir Pyagay

Product Manager, TransPerfect, United Kingdom

Deep Learning for Data-Driven Predictions Based on Medical Images,

Videos, and Data

Andrea Cherubini, PhD

Chief Technical Advisor, Linkverse, Italy

Intelligent Automation and Robotics in Clinical Development:

A Case Study

Aman Thukral, DrSc, MBA, MPharm

Assistant Director, AbbVie, Inc.

#109 TRACK 03A - MEDICAL AFFAIRS AND SCIENTIFIC COMMUNICATION

Featured Topic(s): eSubs, Quality-GXP, Medical Writing, Global Regulatory

11:00am−12:15pm Level: ■ Format: SESSION

Room \$503ab CME, and Nursing

Submission Dossiers: Communications Excellence to Drive Speed and Quality

CHAIRPERSON

Frank Hubbard, PhD

President, Global Regulatory Writing Solutions, Inc.

SPEAKER(S)

Agreeing Submission Document Timelines Six Months in Advance and Sticking to Them: Fairy Tale or Reality?

Steve Sibley, MS

Vice President, Global Submissions and Submission Leadership, Synchrogenix, a Certara Company

It is a Complex Team Sport to Prepare Global Simultaneous Submissions in an Alliance Project Team

Lei C. Chuang, MSc

Advisory Consultant, Global Drug Development Consulting

Regulatory Medical Writing Strategies for Accelerating Submissions Kent Cochran, III, MS

Director, Janssen Pharmaceutical Companies of Johnson & Johnson

#110 Track O3B - Medical Affairs and Scientific COMMUNICATION

Featured Topic(s): Global Regulatory

11:00ам-12:15рм LEVEL: FORMAT: FORUM

Room S504abc CME, and Nursing

Globalization of Medical Affairs Departments

CHAIRPERSON

Rebecca A. Vermeulen

Head, Customer Strategy Global Medical Affairs, Hoffmann-La Roche Ltd., Switzerland

SPEAKER(S)

Solutions Developed to Improve Customer Experiences Globally Anja Schaefer, DrSc

Chief Executive Officer, TaRes GmbH, Germany

Advancing Patient Care with Digital Biomarkers

Mike Baker, MSc

Group Leader, Digital Health, F. Hoffmann-La Roche AG, Switzerland

Panelist

Jay F. Mouser, PharmD, RPh

Regional Director, MSLs, AstraZeneca

TRACK **O4A** - PATIENT ENGAGEMENT

Featured Topic(s): Patient-Centric

11.00 AM-12.15 PM I EVEL · ■ FORMAT: SESSION

Room N426a CME, Pharmacy, and Nursing

Patient Engagement: 4 W's and an H

CHAIRPERSON

Jane E. Myles, MS

Head, Operational Intelligence and Innovation, Genentech, A Member of the Roche Group

SPEAKER(S)

Driving Engagement in All Phases of Alzheimer's Disease: Creating **Lasting Engagement and Achieving Trial Success**

Barbara Zupancic, MBA, MSc

Director, Global Patient Recruitment and Retention, Worldwide Clinical

From Design to Dissemination: How iConquerMS Engages People with MS Throughout the Research Continuum

Hollie Schmidt, MS

Vice President of Scientific Operations, Accelerated Cure Project

#112 Track O4B - Patient Engagement

Featured Topic(s): Data Management, Public Policy, Patient-Centric, Global Regulatory

11:00 ам-12:15 рм LEVEL: FORMAT: SESSION

Room N426b CME, Pharmacy, and Nursing

Data Sharing: 2017 and Beyond

CHAIRPERSON Rebecca Li, PhD

Executive Director, Harvard MRCT Clinical Trials Center, Brigham and

Women's Hospital

SPEAKER(S)

Data Sharing and Transparency: A Global Neutral Platform

Rebecca Li. PhD

Executive Director, Harvard MRCT Clinical Trials Center, Brigham and Women's Hospital

Patient Engagement: Meaningful Approaches to Sharing the Data **Patients Want and Deserve**

Jill McNair, MBA

Senior Director, Patient Engagement, CISCRP

Plain Language Summaries: Questions, Challenges, and New **Developments**

Susannah Chang, PhD

Manager, Oncology Regulatory Medical Writing, Janssen Pharmaceutical Companies of Johnson & Johnson

#113 TRACK O4C - PATIENT ENGAGEMENT

Featured Topic(s): Pediatrics, Patient-Centric, Academic Clinical Researcher, Clinical Operations

FORMAT: FORUM 11:00AM-12:15PM FVFI:

Room N426c CME, Pharmacy, and Nursing We Can't Forget the Children in This Process

CHAIRPERSON

Lisa Palladino Kim, MS

Director of Capstone/Lecturer, Rutgers, The State University of New Jersey

SPEAKER(S)

Children Should Be Seen and Heard: The Smallest Voice May be the **Most Important**

Jerry A. Hall, MD

Medical Director, AbbVie, Inc.

Virtual/Global Engagement of the Caregiver/Patient Community in **Research Study Design**

Korey Capozza

Director, Electronic Care Coordination Initiative, The Children's Partnership

Tales from the Front: A Young Adult Recounts Her Own Clinical Trial Experiences and the Efforts of iCAN to Improve the Experiences of Others

Katie Palermo

Member, Ann and Robert H. Luie Childrens' Hospital Kids Advisory Board

#114 TRACK O5A - REGULATORY

Featured Topic(s): Public Policy

11:00am-12:15pm FORMAT: FORUM FVFI:

Room N228 CME, and Nursing

PDUFA at 25: A Historical View of the Prescription Drug User Fee Agreement and a Look to the Future - PDUFA VI

CHAIRPERSON

Kim M. Quaintance-Lunn

Vice President and Head, US Regulatory Policy, Bayer

SPEAKER(S)

Panelist

Theresa M. Mullin, PhD

Director, Office of Strategic Programs, CDER, FDA

Patrick Frey

Chief of Staff, Office of New Drugs, CDER, FDA

Sandra A. Milligan, JD, MD

Senior Vice President, Head of Global Regulatory Affairs and Clinical Safety, Merck Research Laboratories

Lucy Vereshchagina, PhD

Deputy Vice President, Science and Regulatory Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA)

#115 TRACK O5B - REGULATORY

Featured Topic(s): Clinical Operations, Global Regulatory

11:00am-12:30pm Level: ■ Format: SESSION

Room \$403ab CME, and Nursing

Update from the CFDA

CHAIRPERSON

Ling Su, PhD

Venture Partner, Lilly Asia Ventures, China

SPEAKER(S)

CDE Reform Measures

Zhimin Yang, MD

Division Director, Center for Drug Evaluation, China Food and Drug Administration (CFDA), China

Strengthen Regulatory Enforcement on Clinical Trial Integrity and Data Quality

Rong Zhang

Deputy Chief Technician Inspector, Center for Food and Drug Inspection, China Food and Drug Administration (CFDA), China

Overview of CFDA Morning and Pharmacovigilance

Duo Dong

Deputy Division Director, National Center for ADA Monitoring, China Food and Drug Administration (CFDA), China

#117 Track O6A - SAFETY AND PHARMACOVIGILANCE

11:00 AM−12:15 PM LEVEL: ■ FORMAT: SESSION Room S401a CME, Pharmacy, and Nursing

Postmarketing Safety Studies: Approaches and Regulatory Insights

CHAIRPERSON

Elsie Grace, PhD, MS

Epidemiologist, Global Patient Safety, Eli Lilly and Company

SPEAKER(S)

Take-Home Learnings on Do's and Dont's on the Planning and Conduct of a PASS

Javier Cid, DrPH, MD, MBA, MSc

Research Scientist, Evidera, Spain

How to Maximize the Impact of Postmarketing Research: Considerations for Effective Execution and Compliance

Aarthi B. Iyer, JD, MPH

Regulatory Attorney, Kinetiq, a Division of Quorum IRB

An Innovative Patient-Centric Approach to Conducting Postmarketing Safety Studies

Deborah Covington, DrPH

Senior Research Scientist, Evidera

#118 Track O6B - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Global Regulatory, Statistics

11:00am−12:15pm Level: ■ Format: FORUM

Room S401d CME, Pharmacy, and Nursing

Counting on Safety

CHAIRPERSON

William Wang, PhD

Executive Director, Clinical Safety Statistics, BARDS, Merck Research Laboratories

SPEAKER(S)

Overview and Update of the FDA IND Safety Reporting Guidance Stephanie L. Shapley, MBA

Health Science Policy Analyst, Office of Medical Policy, CDER, FDA

Systems Theoretic Process Analysis: A New Way to Strengthen Pharmacovigilance Processes - A Case-Study

Alan M. Hochberg

Scientific Enablement Leader, F. Hoffmann-La Roche Ltd., Switzerland

Safety Assessment Committees: More Than One Way to Navigate the Pharmacovigilance Seas

Barbara A. Hendrickson, MD

Senior Medical Director, AbbVie, Inc.

#119 Track O6C - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Global Regulatory, Public Policy

11:00am−12:15pm Level: ■ Format: SESSION

Room S401bc *CME, Pharmacy, and Nursing*

Designing and Implementing a Robust Pharmacovigilance System for Vaccines

CHAIRPERSON

Sanjeev Miglani, MD

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

SPEAKER(S)

Special Safety Considerations in Vaccines: US Perspective Sanjeev Miglani, MD

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

Active Vaccine Safety Surveillance in Low- and Middle-Income Countries

Walter Straus, MD, MPH, FACP

Associate Vice President, Therapeutic Area Head, Clinical Safety and Risk Management, Merck & Co., Inc.

GVP Module for Vaccine Pharmacovigilance

Seema Jaitly

Managing Director, Essjay Solutions Ltd, United Kingdom

#120 Track 7 - Special Populations

Featured Topic(s): Rare Disease

11:00am-12:15pm LEVEL: FORMAT: FORUM

Room N227b CME, Pharmacy, and Nursing

FDA Rare Disease Town Hall

CHAIRPERSON

James E. Valentine, JD. MHS

Attorney, Hyman, Phelps & McNamara, PC

PANELISTS

Gayatri R. Rao, JD, MD

Director, Office of Orphan Products Development, Office of the Commissioner, FDA

Jonathan C. Goldsmith, MD, FACP

Associate Director for Rare Diseases, Office of New Drugs, CDER, FDA

Deputy Director, Division of Clinical Evaluation and Pharmacology/ Toxicology, Office of Tissues and Advanced Therapies, CBER, FDA

Michael Pacanowski

Associate Director for Genomics and Targeted Therapy, Office of Clinical Pharmacology, CDER, FDA

#121 Track 8 - Strategic Planning/Execution and **PARTNERSHIPS**

11:00am-12:15pm FVFI: FORMAT: SESSION

Room S505ab CME, Nursing, and PMI PDUs

Effective Life Cycle Management

CHAIRPERSON

Keith Ruark

Executive Director, Strategy Consulting, INC Research

SPEAKER(S)

The State of Life Cycle Management Planning Today: Observations and **Lessons Learned**

Keith Ruark

Executive Director, Strategy Consulting, INC Research

From Lab to Launch: Optimizing Intellectual Property Rights in Life **Cycle Management Strategy**

Maria Isabel Manley, LLM

Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

#122 Track 9 - Translational Science: Preclinical/ CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Statistics

11:00am-12:15pm LEVEL: ♦ FORMAT: SESSION

Room S404a CME, Pharmacy, and Nursing

GBM AGILE: A Transformative Global Adaptive Platform Clinical Trial

CHAIRPERSON

Donald A. Berry, PhD

Professor, Department of Biostatistics, M.D. Anderson Cancer Center

PANELISTS

Mustafa Khasraw, MD

Associate Professor, University of Sydney, Australia

Amy Heimberger, MD

Professor in the Department of Neurosurgery, University of Texas M.D.

Anderson Cancer Center

Brian Alexander, MD

Associate Professor, Harvard, Radiation Oncology, CNS Cancers, Dana-Farber Cancer Institute

#123 Track O9A - Translational Science: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Academic Clinical Researcher, Clinical Operations

FORMAT: FORUM 11:00am-12:15pm LEVEL:

Room S405b CME, and Nursing

Calling All Angels to the Valley of Death

CHAIRPERSON

David Vulcano, MBA

Assistant Vice President and Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

SPEAKER(S)

What Angel Investors Think About Medical Product Investing David Vulcano, MBA

Assistant Vice President and Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

NCATS Small Business Opportunities

Lili M. Portilla, MA

Director, Office of Strategic Alliances, National Center for Advancing

Translational Sciences (NCATS), NIH

#124 Track 09B - Translational Science: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher

11:00am-12:15pm LEVEL: FORMAT: SESSION

Room S402ab CME, and Nursing

Exploration of PK/PD in NDA Enabling or Early Proof of **Concept Studies**

CHAIRPERSON

Galina Bernstein, PhD

Director of Pharmacometrics, Early Phase, INC Research, Canada

SPEAKER(S)

Proof of Concept in Early Phase Studies Through PK/PD Modeling: Clinical CRO Perspective

Galina Bernstein, PhD

Director of Pharmacometrics, Early Phase, INC Research, Canada

FDA Perspective

Nitin Mehrotra, PhD, MPharm

Pharmocometrics Team Leader, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

Drug-Disease Modeling Applied to Drug Development and Regulatory Decision-Making

Stephan Schmidt, PhD

Associate Director, Center for Pharmacometrics and Systems Pharmacology, University of Florida

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#125 Track O9C - Translational Science: Preclinical/Clinical and Product Development

Featured Topic(s): Real World Evidence, Statistics, and Data Management

11:00am−12:15pm Level: ■ Format: SESSION

Room S404bc CME, and Nursing

Hybrid Study Designs: An Innovative Approach to Obtaining Valuable Information by Combining Existing Data with New Data Length

CHAIRPERSON

Margaret S. Richards, PhD, MPH

Vice President, Data Analytics and Epidemiology, RW Strategy and Analytics, Mani

SPEAKER(S)

Leveraging Real-World Data to Plan and Execute Hybrid Studies for Peri- and Postapproval Drug and Device Research

Hady Khoury, MD

Vice President, Global Head, Research Services, Commercialization and Outcomes, ICON, plc

Why Choose a Hybrid Design? Insights from a Study with Duchenne Muscular Dystrophy Patients and Caregivers

William C. Maier, PhD, MPH

Chief Scientific Officer, Head, Patient-Centered Sciences, Mapi, United Kingdom

Feedback from a Hybrid Study in Oncology: Benefits of Combining Prospective Data and Existing Retrospective Data in One Place Bertrand Le Bourgeois, MSc

Sales and Marketing Director, Medsharing, France

#126 TRACK 10 - VALUE AND ACCESS

Featured Topic(s): Real World Evidence

11:00am−12:15pm Level: ■ Format: FORUM

Room N226 CME, and Nursing

Breaking Down the Wall for FDA to Leverage Real-World Data

CHAIRPERSON

Iris Loew-Friedrich, DrMed

Chief Medical Officer, Executive Vice President and Head, Development and Medical Practices, UBC, An Express Scripts Company, Germany

SPEAKER(S)

A Study on the Use of Real World Evidence in Clinical Research and Postmarketing Safety Monitoring

Mary Jo Lamberti, PhD, MA

Senior Research Fellow, Tufts University

FDA Perspective

Jonathan P. Jarow, MD, PhD

Senior Medical Advisor, FDA

How Are Innovators Bringing Real-World Data to the Table? John Reites

Chief Product Officer, Partner, THREAD

#127 TRACK 11A - QUALITY

Featured Topic(s): Global Regulatory

11:00am−12:15pm Level: ■ Format: FORUM

Room \$405a CME, and Nursing

The Evolving International Landscape of FDA Inspections: Data Integrity Violations in Bioequivalence Studies in India

CHAIRPERSON

Leslie Ball, MD

Assistant Commissioner and Deputy Director, Office of International Programs, Office of the Commissioner, FDA

PANELISTS

Sean Y. Kassim, PhD

Director, Office of Study Integrity and Surveillance, Office of Translational Sciences, CDER, FDA

Mathew T. Thomas, MD

Country Director, India Office, Office of International Programs, Office of the Commissioner, FDA, India

Arindam Dasgupta, PhD

Deputy Director, Division of New Drug Bioequivalence, Office of Study Integrity and Surveillance, Office of Translational Sciences, CDER, FDA

#128 TRACK 11B - QUALITY

11:00am−12:15pm Level: ■ Format: FORUM

Room N230b CME, and Nursing

Office of Pharmaceutical Quality Update: Innovative Approaches in Regulatory Assessment

CHAIRPERSON

Patrick Ricucci, PMP

Associate Director of Regulatory Affairs (Acting), Office of New Drug Products, Office of Pharmaceutical Quality, CDER, FDA

PANELISTS

Laurie Graham

Acting Director, Division of Internal Policies and Program, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, FDA

Wendy Wilson-Lee

Acting Branch Chief, Office of New Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Lucinda F. Buhse, PhD

Director, Office of Testing, Office of Pharmaceutical Quality, CDER, FDA

#129 Track 15 - Engage and Exchange

Featured Topic(s): Student Programming

11:00am−12:15pm Level: • Format: SESSION

Exhibit Hall | Aisle 300/400

Student Forum

CHAIRPERSON

Danny Beanu, PhD

Director, Biomedical Writing Programs, Mayes College, University of the Sciences

FACILITATORS

Emily Cox

Staffing Manager, Synchrogenix

Sameer Thapar

Director, Global Pharmacovigilance, Oracle

#130 TRACK 17 - CONTENT HUB

Featured Topic(s): Career Development

11:00-11:30ам

FORMAT: SESSION

S400 Concourse

Career Opportunities in Transitions in Life Science

CHAIRPERSONS

Representative Invited

US Regulatory Science and Policy, Sanofi

SPEAKER(S)

Linda F. Bowen

Senior Director, Global Regulatory Science and Policy, Sanofi

Beverly Hudson

Vice President of Sales Life Sciences, AMPLEXOR Life Sciences, LLC

#131 TRACK 17 - CONTENT HUB

Featured Topic(s): Career Development

11:45am-12:15pm Format: SESSION

S400 Concourse

A Day in the Life of A....

CHAIRPERSON

Beverly Hudson

Vice President of Sales Life Sciences, Amplexor Life Sciences, LLC

12:00-2:45рм

Luncheon

Exhibit Hall

#132 Track 13A - Innovation Theater

12:30-1:00pm Level: ■ Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

QuintilesIMS Innovation Theater: The Next Generation of Clinical Development is Here

#133 Track 13B - Innovation Theater

12:30-1:00pm Format: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

Tata Consultancy Services Innovation Theater: Global Regulatory Information Portal (GRIP) – A Regulatory Information Strategic Effectiveness Portal

#134 STUDENT POSTER SESSION AND ORAL PRESENTATIONS

12:30-2:45рм

Exhibit Hall

#135 Track 13A - Innovation Theater

1:15-1:45PM FORMAT: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

PAREXEL International Innovation Theater: Developing Drugs in the New Era of Personalized Medicines

#136 Track 13B - Innovation Theater

1:15–1:45pm Level: ■ Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

Covance Innovation Theater: Lessons Learned from Deploying Clinical Data Review: Ensuring Patient Safety, Increasing Operational Efficiency, and Creating New Insights

#137 TRACK 15 - ENGAGE AND EXCHANGE

1:15-2:15pm Level: ■ Format: SESSION

Exhibit Hall

The Worst Coworker on the Block: Can YOU Work with Difficult People? Yes, You Can!

CHAIRPERSON

Robin Whitsell

President, Whitsell Innovations, Inc.

#138 TRACK 17 - CONTENT HUB

1:15-1:45pm Format: SESSION

S400 Concourse

Managing Change

CHAIRPERSON

Representative Invited

Content Lead, DIA

SPEAKER(S)

TBD

#139 Track 13A - Innovation Theater

2:00-2:30pm Level: ■ Format: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

Deloitte Consulting Innovation Theater

#140 Track 13B - Innovation Theater

2:00-2:30pm Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

SAS Institute Innovation Theater: Clinical Analytics Workflow Optimization

#142 TRACK 18 - PLENARY

3:00-4:30_{PM}

Arie Crowne Theater

FORMAT: SESSION

Plenary Session and Keynote

OPENING REMARKS

Barbara Lopez Kunz, MSc

Global Chief Executive, DIA

KEYNOTE ADDRESS

Interactive Storytelling and Personal Health Data Drives

Unprecedented Patient Empowerment

Alexander Tsiaras

Founder, Chief Executive Officer, and Editor-in-Chief, The Visual MD.com

#143 Track 13 - Innovation Theater

4:45-5:15pm Format: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

Advanced Clinical Innovation Theater

#145 Track 13A - Innovation Theater

4:45-5:15pm Level: ■ Format: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

Educational Measures Innovation Theater: EM Array™

Live Meeting Technology

#146 STUDENT POSTER SESSION AND ORAL PRESENTATIONS

4:45-5:30_{PM}

Session and Oral Presentations 1B

#147 Track 13B - Innovation Theater

5:30-6:00pm Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

Appian Corporation Innovation Theater: Product

Lifecycle Management in the Digital Era

#148 Track 13A - Innovation Theater

5:30-6:00pm Format: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

DBMS Consulting Innovation Theater

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TUESDAY, JUNE 20

Registration Hours

7:00_{AM}-5:15_{PM} Attendee, Speaker, and Exhibitor Registration

7:00-8:00_{AM}

Coffee and Light Refreshments S102 Lobby

#201 TRACK 12A



Featured Topic(s): Real World Evidence, Public Policy, Student Programming

8:00-9:30am Level: ■ Format: SESSION

Room S105 CME, Pharmacy, and Nursing

Paying for Value in Biopharmaceuticals: Trends in the United States

CHAIRPERSON

Susan Dentzer, MA

President and Chief Executive Officer, NEHI (Network for Excellence in Health Innovation)

PANELISTS

Sloane W. Salzberg

Executive Director, Prescriptions for a Healthier America; Vice President, Council for Affordable Health Coverage

Shawn Davis

Senior Director, Formulary Solutions, Express Scripts

Joel Beetsch, PhD

Vice President, Patient Advocacy Group, Celgene Corporation

Phillip J. Lerner, MD, MPH

Vice President and National Medical Director, Aetna, Inc.

Indranil Bagchi, PhD

Vice President and Head, Payer Insights and Access, Patient and Health Impact, Pfizer Inc

#202 TRACK 12B



Featured Topic(s): Clinical Operations, Statistics, Quality-GXP, Patient-Centric, Global Regulatory, Data Management, Real World Evidence, Student Programming

8:00-9:30am Level: ■ Format: FORUM

Room S100c *CME, Pharmacy, and Nursing*

People Will Talk: Gathering Insights from Digital Listening

CHAIRPERSON

Lorrie Schifano, PharmD

Director, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

SPEAKER(S)

Current Techniques for Analyzing Text That Can be Used in Medical Affairs, Benefit-Risk Assessment, and the Voice of the Customer Jeffery Lanier Painter, JR, JD, MS

Chief Executive Officer/Founder, Jivecast

Digital Listening Throughout a Product Life Cycle

Chi Bahk, MS

Epidemico, Booz Allen Hamilton

Current Parameters for Collecting/Utilizing This Data Compliantly Phil Tregunno

Signal Management Unit Manager, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Panelist

Gerald J. Dal Pan, MD, MHS

Director, Office of Surveillance and Epidemiology, CDER, FDA

#203 TRACK 12C



Featured Topic(s): Real World Evidence, Wearables-Mobile Health,
Devices-Combination Products, Student Programming

8:00-9:30am Level: ■ Format: SESSION

Room \$100a CME, and Nursing

Radical Technologies: Changing the Future of Biopharmaceuticals

CHAIRPERSON

Craig H. Lipset, MBA

Head of Clinical Innovation, Global Product Development, Pfizer Inc

PANELISTS

Peter Bergethon, MD

Vice President and Head of Quantitative and Digital Medicine, Pfizer Inc

Jeffry G. James, MBA

Chief Executive Officer, Wilmington Health, PLLC

Alicia Staley, MBA, MS

Patient Advocate, Cure Forward

Julian M. Jenkins, PhD, MSc

Vice President, Innovation Performance and Technology, GlaxoSmithKline

#204 Track 15 - Engage and Exchange

Featured Topic(s): Clinical Operations

9:30-10:30am Level: ■ Format: SESSION

Exhibit Hall

Effective Team Management in Global Trials

CHAIRPERSON

Peter A. DiBiaso, MHA

Global Vice President, Managing Director, QuintilesIMS

#205 Professional Poster Session 2A

9:30-10:30_{AM} **Exhibit Hall**

#206 Track 13A - Innovation Theater

9:45–10:15am Level: ■ Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

Covance Innovation Theater: Overcoming Study Complexity Through Data-Driven Design

#207 Track 13B - Innovation Theater

9:45–10:15AM FORMAT: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

Veeva Systems Innovation Theater: 2017 Unified Clinical Operations Survey

#208 TRACK 01A - DATA/BIG DATA/EHEALTH

10:30-11:45am Level: ■ Format: FORUM

Room N226 CME, and Nursing

Big Data: Regulatory Information

CHAIRPERSON

Vada A. Perkins, BSN, MS, MSc, RN

Founder and Managing Principal, IDENTIFICA, LLC

SPEAKER(S)

FDA Perspective

David Martin, MD, MPH

Liaison to the Reagan-Udall Foundation IMEDS Program, Office of Medical Products, CDER, FDA

Health Canada Perspective

Representative Invited

Associate Director, Business Informatics Division, Health Products and Food Branch, Health Canada, Canada

#209 Track 01B - Data/Big Data/eHealth

Featured Topic(s): Data Management, Statistics

10:30-11:45am Level: ■ FORMAT: SESSION Room N228 CME, and Nursing

Evolving Data Standards and Regulations

CHAIRPERSON

Ron D. Fitzmartin, PhD, MBA

Senior Advisor, Office of Strategic Programs, CDER, FDA

SPEAKER(S)

Impact of the Binding Guidance for Standardized Study Data Internally at the FDA

Vaishali Popat, MD, MPH

Associate Director of Biomedical Informatics and Regulatory Review Science, Office of New Drugs, CDER, FDA

CDASH v2.0: Whats New and What Does it Mean for Me?

Dawn Marie Kaminski

Director, Clinical Data Strategies, Accenture

CDISC Standards for Regulatory Submissions

Barrie Nelson

Vice President, Standards, Terminology and Technical Services, CDISC

Metadata Driven Data Operations: What is it and How Can it Transform Traditional Clinical Data Management/Analysis/Reporting

Benedikt Egersdoerfer, DrSc

Vice President, Global Data Operations, PAREXEL International

#210 Track 3 - Medical Affairs and Scientific Communication

10:30-11:45am Level: ■ Format: FORUM

Room S401d CME, and Nursing

The New Business Reality for the Medical Science Liaison Community

CHAIRPERSON

Kevin Charles Henderson, PharmD, MBA

MSL Field Operations and Resources Manager, Genentech, A Member of the Roche Group

SPEAKER

Small Start-Up, Single Pipeline Molecule

Dipam Doshi, PharmD

Senior Medical Science Liaison, ZS Pharma

PANELIST

Paul James, PharmD, MBA

Associate Director, Medical Science Liaisons, Genentech, A Member of the Roche Group

#211 TRACK O4A - PATIENT ENGAGEMENT

Featured Topic(s): Patient-Centric, Clinical Operations

10:30-11:45am Level: ■ Format: SESSION

Room N426bCME, Pharmacy, and Nursing

Sharing the Burden

CHAIRPERSON

Deborah Howe

Associate Director, Vendor Alliance Lead, Bristol-Myers Squibb

SPEAKER(S)

How Appropriate Use of Technology can Share and Reduce the Burden of Modern Clinical Trials

Paul O'Donohoe, MSc

Director, Health Outcomes, CRF Health, United Kingdom

Patient Perspective

Deborah E. Collyar

President, Patient Advocates In Research (PAIR)

#212 TRACK O4B - PATIENT ENGAGEMENT

Featured Topic(s): Patient-Centric

10:30-11:45am Level: ■ Format: FORUM

Room N426a CME, Pharmacy, and Nursing

Walking the Walk in Patient-Focused Medicines Development: From Theory to Practice What Have We Learned?

CHAIRPERSON

Marc M. Boutin, JD

Chief Executive Officer, National Health Council (NHC)

SPEAKER(S)

EMA Perspective

Juan Garcia-Burgos, MD

Head of Public Engagement Department (Ad Interim), European Medicines Agency, European Union

FDA Perspective

Theresa M. Mullin, PhD

Director, Office of Strategic Programs, CDER, FDA

Patient Perspective

Jan Geissler, MBA

Patient Representative, EUPATI, Germany

Industry Perspective

Anton Hoos, MD, PhD, MBA

Vice President and Medical Director Europe, Amgen GmbH, Switzerland

#213 Track O5A - Regulatory

Featured Topic(s): Rare Disease

10:30-11:45am Level: ■ Format: FORUM

Room \$403ab CME, and Nursing

Regulatory Frameworks: How Can Regulators Facilitate Disruptive Innovation?

CHAIRPERSON

Nancy Bradish Myers, JD

President, Catalyst Healthcare Consulting, Inc

SPEAKER(S)

Richard Moscicki, MD

Representative Invited

Deputy Center Director for Science Operations, Office of the Center Director, CDER, FDA

Gene Therapy Cures: How Will They Break the Mold?

Anne-Virginie L. Eggimann, MS

Vice President, Regulatory Science, Bluebird Bio

#214 Track O5B - Regulatory

Featured Topic(s): Student Programming, Global Regulatory

10:30-11:45am Level: ■ Format: SESSION

Room N227b CME, and Nursing

Recent Trends in Asian Regulations for Drug Development: What is Coming Next?

CHAIRPERSON

Akio Uemura, PhD

Executive Director, Head of Japan Development, Allergan Japan K.K.

SPEAKER(S)

Successful Regional Collaborative Experience in Global New Drug

Development: TFDA Perspective

Chao-Yi Joyce Wang, MSc

Director, Division of Medicinal Products, TFDA, Taiwan

Recent Development on Expedited Regulatory Pathway in Asia Pacific Region

Shun Jin, MBA

Head, Regulatory Affairs, APAC, Abbott Laboratories (Singapore) Pte. Ltd.

The Latest Japanese Regulatory Situations to Promote Drug Development and Advance Regulatory Science

Yoshiaki Uyama, PhD

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

#215 Track O5C - Regulatory

10:30-11:45am Level: ■ Format: SESSION

Room S404d CME, and Nursing

The Evolving Model of Using Artificial Intelligence to Deliver Actionable Regulatory Intelligence

CHAIRPERSON

Linda F. Bowen, MSc, RAC

Regulatory Science and Policy, Sanofi

SPEAKER(S)

Advances in Regulatory Intelligence Through Artificial Intelligence:

Industry Perspective

Patrick K. Brady, PharmD

Senior Director, Global Regulatory Policy and Intelligence, Bayer

Enigma Variations: The Use of Artificial Intelligence in Regulatory Decision-Making

Tom Macfarlane, RAC

Director, Life Sciences, Accenture, United Kingdom

#216 Track O5D - REGULATORY

Featured Topic(s): Public Policy, Global Regulatory

10:30-11:45AM LEVEL: ■ FORMAT: FORUM

Room N229 *CME, and Nursing*

International Collaboration in Times of Public Health Crisis

CHAIRPERSON

Ian Hudson, MD, FFPM, FRCP

Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

SPEAKER(S)

Crisis Management in the Face of a Global Health Pandemic: How Can We Leverage International Efforts?

Jarbas Barbosa, MD, PhD

ICMRA Project Lead; Director- President, Agência Nacional De Vigilância Sanitária (ANVISA), Brazil

Update from the FDA

Carmen T. Mayher, BSN, MA, RAC

Acting Assistant Commissioner for Counterterrorism Policy, Office of the Chief Scientist, Office of the Commissioner, FDA

Update from the EMA

Agnes Saint-Raymond, MD

Head of Portfolio Board, European Medicines Agency, European Union

#217 TRACK OSE - REGULATORY

Featured Topic(s): Student Programming, Global Regulatory

10:30-11:30AM LEVEL: FORMAT: FORUM

Room S404a CME, and Nursing

Update from CBER: Advancing the Development of Complex Biologic Products

CHAIRPERSON

Peter W. Marks, MD, PhD

Director, Center for Biologics Evaluation and Research, FDA

#218 TRACK OSF - REGULATORY

Featured Topic(s): Public Policy, Clinical Operations

10:30-11:30AM FORMAT: SESSION I EVEL: ■

Room S404bc CME, Pharmacy, and Nursing

ClinicalTrials.gov: Complying with Requirements in the Final Rule (42 CFR Part 11) and Impacts of 21st Century **Cures Act**

CHAIRPERSON

Rebecca Li. PhD

Executive Director, Harvard MRCT Clinical Trials Center, Brigham and Women's Hospital

SPEAKER

Perspective from ClinicalTrials.gov

Rebecca J. Williams, PharmD, MPH

Assistant Director, ClinicalTrials.gov, NCBI, National Library of Medicine, NIH

#219 Track O6A - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Real World Evidence, Academic Clinical Researcher. Clinical Operations

10:30-11:45AM FVFI: FORMAT: SESSION

Room S401a CME, Pharmacy, and Nursing

Safety Evaluation: Transforming Information into Evidence

CHAIRPERSON

Olga V. Marchenko, PhD, MS

Vice President, Advisory Analytics, QuintilesIMS

SPEAKER(S)

Sources of Safety Data and Statistical Strategies for Design and **Analysis in Clinical Trials**

Richard C. Zink, PhD

Principal Research Statistician Developer, JMP Life Sciences Division, SAS Institute Inc.

Traditional Sources of Pharmacovigilance Data and how Social Media Listening has Been Used as a Complementary Data Source Lorrie Schifano, PharmD

Director, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Transforming Data into Evidence

Olga V. Marchenko, PhD, MS

Vice President, Advisory Analytics, QuintilesIMS

#220 Track 06B - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Academic Clinical Researcher

10:30-11:30AM LEVEL: FORMAT: FORUM

Room S401bc CME, and Nursing

Cardiac Safety

CHAIRPERSON

Snehal N. Kothari, MD. FACC

Chief Medical and Scientific Officer, QuintilesIMS, India

Evaluating Attitudes and Experiences with Evolving Cardiac Safety Assessment Solutions

Kenneth A. Getz. MBA

Director of Sponsored Research Programs and Associate Professor, Center For the Study of Drug Development, Tufts University School of

The Power of Phase 1 Studies to Detect Clinical Relevant QTc Prolongation

Jörg Täubel, MD, FFPM

Chief Executive Officer, Richmond Pharmacology Ltd., United Kingdom

#221 TRACK O6C - SAFETY AND PHARMACOVIGILANCE

10:30-11:45AM I EVEL: ■ FORMAT: SESSION

Room N230b CME, and Nursing

Pharmacovigilance Inspections: Hot Topics and Proactive Approaches

CHAIRPERSON

Michael Bean

Senior Director, Regulatory Compliance R&D, Janssen Pharmaceutical Companies of Johnson & Johnson, United Kingdom

SPEAKER(S)

MHRA Perspective

Joanna Harper

IE&S Division, PV Inspector, Medicines and Healthcare products

Regulatory Agency (MHRA), United Kingdom

Industry Perspective

Carolyn Winter, RN

Director, PV and RA Quality Assurance, AbbVie, Inc., United Kingdom

#222 Track O7A - Special Populations

Featured Topic(s): Rare Disease

10:30-11:45AM LEVEL: FORMAT: SESSION

Room S505ab CME, Pharmacy, and Nursing

Serving the Patient Who Needs Early Access to Treatments and Achieving Meaningful Outcomes

CHAIRPERSON

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP

Vice President, Global Head of Risk Management, QuintilesIMS, United Kingdom

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SPEAKER(S)

So Near Yet so Far: How do We get Early Access for Patients with Unmet Medical Needs and Life-Limiting Diseases?

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP

 $\label{thm:continuous} \mbox{ Vice President, Global Head of Risk Management, Quintiles IMS, United Kingdom}$

Aligning Objectives of Drug Development and Patient Access Richard Scheyer, MD

Vice President, Medical Affairs, Medpace

Reagan-Udall Foundation for the FDA Expanded Access Navigator June S. Wasser, MA

Executive Director, Reagan-Udall Foundation for the FDA

#223 TRACK O7B - SPECIAL POPULATIONS

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Rare
Disease, Statistics

10:30-11:45am Level: ■ Format: SESSION

Room S503abCME, and Nursing

Introduction to Rare Disease Studies: Challenges of Rare Disease from a Statistical, Protocol Development, and Operations Perspective

CHAIRPERSON

William B. Smith, MD

President, New Orleans Center for Clinical Research

SPEAKER(S)

FDA Perspective

Yeh-Fong Chen, PhD

Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Industry Perspective

Robert P. Homolka, MBA, MS

Clinical Pharmacology Group Lead, Shire

Panelist

Marc L. Hoffman, MD

Chief Medical Officer, Celerion

#224 Track O7C - Special Populations

Featured Topic(s): Academic Clinical Researcher

10:30-11:45am Level: ■ Format: SESSION

Room S504abc *CME, Pharmacy, and Nursing*

Success in Early CNS Drug Development: Getting Proof-of-Principle by Stacking the Deck with Biomarkers

CHAIRPERSON

Bruce Morimoto, PhD

Vice President, Scientific Affairs, Celerion

SPEAKER(S)

Public/Private Partnerships in Alzheimer's Biomarkers

James A. Hendrix, PhD

Director, Global Science Initiatives, Medical and Scientific Relations, Alzheimer's Association

The Use of fMRI in Early Clinical Research for Drug Development in Psychiatry

Mitul Mehta, PhD, MA

Reader and Head of Neuropharmacology Section, Department of Neuroimaging, King's College London, United Kingdom

Small Clinical Trials: Alternative Design and Analysis

Michael Gold, MD

Head of Neuroscience. AbbVie. Inc.

#225 Track 08A - Strategic Planning/Execution and Partnerships

Featured Topic(s): Career Development, Student Programming

10:30-11:45am Level: ● Format: FORUM

Room S501abcCME, Nursing, and PMI PDUs

So You Say You're an Extrovert: Being an Effective Leader When All You Really Want is a Stage

CHAIRPERSON

Alice Ford-Hutchinson, PhD, PMP

Director, Global Project and Alliance Management, Merck & Co., Inc.

SPEAKER(S)

A Path Towards High Performance Teams: Sharing the Stage as an Extroverted Leader

Alice Ford-Hutchinson, PhD, PMP

Director, Global Project and Alliance Management, Merck & Co., Inc.

One Ambivert's Tale of Two Personalities

Cathie Snyder

Senior Director, Operations, Rho, Inc.

#226 Track 08B - Strategic Planning/Execution and Partnerships

10:30-11:45am Level: ■ Format: SESSION

Room S502ab CME, Nursing, and PMI PDUs

Accelerating Drug Development Through Innovation

CHAIRPERSON

John Reites

Chief Product Officer, Partner, THREAD

SPEAKER

Five Ways to Move Digital Health Innovation from Pilot to Platform

Chief Product Officer, Partner, THREAD

#227 Track 09A - Translational Science: PRECLINICAL / CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Wearables-Mobile Health, Data Management. Quality-GXP, Statistics

10.30-11.45AM FORMAT: SESSION I EVEL · ■

Room S405b CME, and Nursing

At the Cornerstone of Wearable Technology and Patient-**Focused Clinical Trial Endpoints**

CHAIRPERSON

Leonard Sacks, MD

Associate Director for Clinical Methodology, Office of Medical Policy, CDER, FDA

SPEAKER(S)

FDA Perspective

Nikunj B. Patel, PharmD

Clinical Outcome Assessments Reviewer, Office of New Drugs, CDER, FDA

Industry Perspective

Robert A. DiCicco, PharmD

Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline

Academia Perspective

E. Ray Dorsey, MD, MBA

David M. Levy Professor of Neurology and Director of the CHET, University of Rochester Medical Center

#228 Track O9B - Translational Science: PRECLINICAL / CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Statistics, Rare Disease

10:30-11:45AM I EVEL: ◆ FORMAT: SESSION

Room S405a CME, and Nursing

Master Protocols: New Approaches to Enrolling Hard-to-**Find Subjects and Expediting Drug Development**

CHAIRPERSON

Theresa Crofts Ashton, PhD

Senior Director, Clinical Statistics, GlaxoSmithKline

SPEAKER(S)

The Use of Statistical Innovation to Increase Efficiency in Difficult-to-**Enroll Clinical Trials**

Kert Viele, PhD

Director and Senior Statistical Scientist, Berry Consultants

Combined Adaptive Early Phase Trials: From First-Time-in-Human to **Proof of Concept in One Protocol**

Ulrike Lorch, MD, FFPM

Medical Director, Richmond Pharmacology Ltd., United Kingdom

Beat AML: Practicalities and Lessons Learned from the Construct of a 10-Study Leukemia Umbrella Trial

Amy Burd

Vice President, Research Strategy, Leukemia & Lymphoma Society

Panelist

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Nicholas Kenny, PhD

Executive Vice President, Oncology and Hematology, INC Research

#229 TRACK 10 - VALUE AND ACCESS

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Rare Disease

10:30-11:45_{AM} FORMAT: FORUM

Room N426c CME, Pharmacy, and Nursing

Outcomes Standardization: An Imperative to Value **Assessments**

CHAIRPERSON

Richard Gliklich, MD

Chief Executive Officer, OM1, Inc.

SPEAKER

Standardizing Outcomes for Patient Registries: Early Results from the **Outcome Measures Framework Pilot Test**

Elise Berliner, PhD

Director, Technology Assessment Program, Agency For Healthcare Research and Quality (AHRQ)

PANELISTS

Paul Stang, PhD, FISPE

Vice President, Global Epidemiology, Janssen Research & Development, LLC

John H. Powers, MD, FACP

Professor of Clinical Medicine, George Washington University School of Medicine

#230 TRACK 11 - QUALITY

10:30-11:45AM I EVEL: ■ FORMAT: SESSION

Room S402ab CME, and Nursing

Global Harmonization: Mutual Recognition

CHAIRPERSON

Roger Nosal

Vice President and Head, Global CMC, Pfizer Inc

SPEAKER(S)

EU-FDA Mutual Recognition Agreement for GMP Inspections Niraj Mehta, PhD

Associate Director for Global Regulatory Policy, GO, Office of the Commissioner, FDA

#232 TRACK 15 - ENGAGE AND EXCHANGE

10:45-11:45am Level: ■ Format: SESSION

Exhibit Hall

Healthy CRO/Sponsor Relations: "Sole" Mate or Flavor of the Month

CHAIRPERSON

David Burnham

Senior Vice President Strategic Alliance, INC Research

11:30 АМ-2:00 РМ

Luncheon Exhibit Hall

12:00-1:00рм

DIA Community Luncheon Room N427bc

#234 Track 13A - Innovation Theater

12:00-12:45pm Level: ■ Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

QuintilesIMS Innovation Theater: Changing Trials

Through Analytics: How it Works

#235 Track 13B - Innovation Theater

12:00-12:45PM FORMAT: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

AMPLEXOR Innovation Theater

#236 Professional Poster Session and Oral Presentations 2B

12:00-1:45рм

Exhibit Hall B

#237 TRACK 15 - ENGAGE AND EXCHANGE

12:45–1:45pm Level: ■ FORMAT: SESSION

Exhibit Hall

Strategies for Communicating with FDA

CHAIRPERSONS

Leah Christl, PhD

Associate Director for Therapeutic Biologics, Therapeutic Biologics and Biosimilars Staff, Office of New Drugs, CDER, FDA

Kim M. Quaintance-Lunn

Vice President and Head, US Regulatory Policy, Bayer

#238 Track 13A - Innovation Theater

1:00-1:45pm Format: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

Veeva Systems Innovation Theater: Using Clinical Data to Create Site-Centric Culture by Design

#239a Track 13B - Innovation Theater

1:00-1:45pm Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

BioClinica Innovation Theater

#239B TRACK 17 - CONTENT HUB

1:15–1:45pm Format: SESSION

S400 Concourse

Strategies for Managing Difficult Stakeholders

CHAIRPERSON

Leigh Shultz, PhD

Associate Vice President, Project Management, Merck & Co., Inc.

#240 Track O1A - Data/Big Data/eHealth

Featured Topic(s): Real World Evidence, Patient-Centric, Wearables-Mobile Health

2:00-3:15pm Level: ■ Format: FORUM

Room N426c CME, and Nursing

Mobile Health: Participatory Research

CHAIRPERSON

Wayne Amchin, MA, MPA, RAC

Senior Consumer Safety Officer, DCRP, ODE I, Office of New Drugs, CDER,

SPEAKER(S)

FDA in the Mobile App Space: It's not Your Flip-Phone FDA Anymore! Wayne Amchin, MA, MPA, RAC

Senior Consumer Safety Officer, DCRP, ODE I, Office of New Drugs, CDER, FDA

Conducting Clinical Trials in Digital Health: What Could Go Possibly Wrong?

Mintu P. Turakhia, MD, MS

Senior Director, Center for Digital Health; Chief of EP, Palo Alto VA, Stanford University

Digital in the Age of People-Centered Research: An Industry Perspective

Craig H. Lipset, MBA

Head of Clinical Innovation, Global Product Development, Pfizer Inc

#241 Track O1B - DATA/BIG DATA/EHEALTH

Featured Topic(s): eSubs, Data Management, Statistics

2:00-3:15рм LEVEL: FORMAT: FORUM

Room N228 CME, and Nursing

FDA Session: Electronic Submissions and Data

CHAIRPERSON

Ron D. Fitzmartin, PhD, MBA

Senior Advisor, Office of Strategic Programs, CDER, FDA

SPEAKER(S)

Moving Forward: Statistical Review of CDISC ADaM Standardized Data at CDER

Weiya Zhang, PhD

Mathematical Statistician, OB, Office of Translational Sciences, CDER, FDA

Results from the CDISC-SEND Fit for Use Pilot: A Structured Assessment of Nonclinical Pilot Submissions to FDA

Elaine Thompson, PhD

Senior Staff Fellow, Office of Computational Science, Office of Translational Sciences, CDER, FDA

CDER Perspective

Colleen Ratliffe

Project Management Officer, Office of Strategic Programs, CDER, FDA

CBER Perspective

Virgina Hussong

Data Standards Program Manager, OD, BSS, CBER, FDA

#242 Track O1C - Data/Big Data/eHealth

Featured Topic(s): Data Management, Patient-Centric

2:00-3:15рм LEVEL: FORMAT: SESSION

Room N227b CME, and Nursing

Big Data: Current and Emerging Technologies

CHAIRPERSON

David Kiger

Vice President, Product Strategy, PAREXEL International

SPEAKER(S)

Obtaining Better Outcomes with Unstructured/Structured Data: How to Improve Clinical, Regulatory, and Commercial Convergence

Vice President, Product Strategy, PAREXEL International

Generating Meaningful Clinical Evidence from Electronic Health Record Data: Oncology as a Case-Study

Amy Abernethy, MD, PhD

Chief Medical Officer and Senior Vice President Oncology, Flatiron Health

Shouldn't Patient Registries Be Attractive to Patients? Implementing **Thoughtful Technology for Richer Data**

Mildred Menos, MA

Director of Project Management, The Life Raft Group

#243 TRACK O1D - DATA/BIG DATA/EHEALTH

Featured Topic(s): Data Management

2:00-3:00pm LEVEL: FORMAT: SESSION

Room N426a CME, and Nursing

Data and Privacy Protection

CHAIRPERSON

Peter S. Alterman, PhD

Chief Operating Officer, SAFE-BioPharma Association

SPEAKER(S)

The €10 Million Penalty: Are You Ready for EU's New PII Regulation? Peter S. Alterman, PhD

Chief Operating Officer, SAFE-BioPharma Association

Data Protections, Data Directives, and Clinical Trial Data: How Can I **Collect and Use My Global Clinical Trial Data?**

Jonathan Raymond Andrus, MS

Chief Operating Officer and Data Officer, Clinical Ink

Emerging Technologies Coupled with the Ever Increasing Globalization of Data and Information Demand New Ways to Discuss and Protect Personal Information

Debra N. Diener, JD. MA

Consultant, Privacy and Identity Management

#244 Track O2A - DISRUPTIVE INNOVATION

Featured Topic(s): Clinical Operations, Academic Clinical Researcher

2:00-3:15_{PM} FORMAT: SESSION

Room S501abc CME, and Nursing

New Trial Design Approaches: Including New Endpoints

CHAIRPERSON

John Reites

Chief Product Officer, Partner, THREAD

SPEAKER(S)

Happy 2nd Birthday ResearchKit: New Opportunities and Limitations Using ResearchKit in Your Mobile Health Studies

Chief Product Officer, Partner, THREAD

Digital Biomarkers from Real-World Mobile Sensor Data in Clinical Trials: How Relevant are They?

Christian Gossens, PhD, MBA

Global Head, Early Development Workflows, F. Hoffmann-La Roche Ltd. Switzerland

Generating Novel Endpoints Through Mobile Technology: A Promising and Realistic New Approach to Trial Design

Robert A. DiCicco. PharmD

Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline

#245 TRACK O2B - DISRUPTIVE INNOVATION

Featured Topic(s): Data Management, Quality-GXP, Wearables-Mobile Health, Clinical Operations

2:00-3:15pm FVEL: FORMAT: SESSION

Room S502ab CME, and Nursing

Leveraging Wearables and Sensors in Clinical Trials: Case Studies

CHAIRPERSON

Michael Phinney, MBA

Engagement Leader, QuintilesIMS

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How Can Wearables Improve Patient Care and Enhance Research in Autoimmune Diseases?

Michael Phinney, MBA

Engagement Leader, QuintilesIMS

Mobile Accelerometry in Clinical Trials: Towards Regulatory Decision-Making

Martin Daumer, PhD

Scientific Director, Sylvia Lawry Centre For Multiple Sclerosis Research, The Human Motion Institute, Germany

Novel Technology for Continuous Arrhythmia Monitoring: The Role in Assessing CV Arrhythmic Safety

Richard Clark

Consultant

#246 Track 03A - Medical Affairs and Scientific Communication

Featured Topic(s): Patient-Centric, Medical Writing

2:00-3:15pm Level: ■ Format: SESSION

Room S503ab CME, Pharmacy, and Nursing

Medical Information and the Patient: Effective Communication and Handling of Requests

CHAIRPERSON

Sara Doshi, PharmD

Director, Medical Information Strategy and Capabilities, GMI, Eli Lilly and Company

SPEAKER(S)

Tailoring Medical Information to Patients: Answering Questions Effectively and Efficiently

Hanady Elhadidy, PharmD

Associate Director, Medical Information, Bristol-Myers Squibb

Engaging Patients in Latin America

Viviane M. Arid de Lima, PharmD, MBA

Medical Information Regional Lead, Latam; Global Lead, Patient Strategy, Pfizer Inc, Brazil

Driving New Experiences Forward: Implementing Consumer Response Documents

Brandi Fannon Gregg, PharmD

HCP Associate, UCBCares Inc.

#247 Track 03B - Medical Affairs and Scientific Communication

Featured Topic(s): Medical Writing

2:00-3:15pm Level: ■ Format: FORUM

Room S504abc CME, and Nursing

Best Practice for Advisory Committee Meeting Preparation

CHAIRPERSON

Chris Miller, MS

Biostatistician, Communications Strategist, Medical Writer, 3D Communications

SPEAKER(S)

Effective Preparation for an FDA Advisory Committee Meeting: Applying Lessons from Abuse-Deterrent Opioids

Jeffrey M. Dayno

Chief Medical Officer, Egalet Corporation

John Markman, MD

Professor, School of Medicine and Dentistry, University of Rochester

FDA Advisory Committee Slide Preparation: Doing More with Less

Michael Bourque, MS

Associate Director, Synchrogenix, a Certara company

#248 Track 03C - Medical Affairs and Scientific Communication

2:00-3:15pm Level: ■ Format: SESSION

Room S401a CME, and Nursing

Building the Medical Strategy and Tactics

CHAIRPERSON

Anny Chen, PharmD

Senior Director, Global Scientific Communications, Novartis Pharmaceuticals Corporation

SPEAKER(S)

How to Build Medical Strategy from the Perspective of a Biotech Company

Chung H. (Lou) Lu, PharmD

Senior Director, Medical Affairs and Medical Information, Otonomy, Inc

Scientific Communications Planning

Bhakti Kshatriya, PharmD

Founder, Publication Practice Counsel, Truposha, LLC

#249 Track O4A - Patient Engagement

Featured Topic(s): Patient-Centric

2:00-3:15pm Level: ■ Format: FORUM

Room S402abCME, Pharmacy, and Nursing

Not Your Grandma's Patient Advocacy Group Anymore

CHAIRPERSON

Laura Kolaczkowski

Lead Patient Representative, Co-Principal Investigator, PCORnet, iConquerMS PPRN

PANELISTS

Upal Basu Rov. PhD. MPH

Director of Translational Research Program/Director of Patient FoRCe, LUNGevity Foundation

Melissa Hogan, Esq, JD

Founder/President, Saving Case & Friends, Inc.

Margaret Anderson, MA

Executive Director, FasterCures, A Center of the Milken Institute

#250 Track O4B - Patient Engagement

Featured Topic(s): Clinical Operations, Patient-Centric

2:00-3:15pm Level: ■ Format: SESSION

Room S401d CME, Pharmacy, and Nursing

If You See Something (About a Clinical Trial), Do You Say Something (to Your Doctor)?

CHAIRPERSON

Tyler Ludlow, MBA

Senior Decision Scientist, Eli Lilly and Company

The Role of Shared Decision-Making in Clinical Trial Enrollment: A Pilot Intervention

Tyler Ludlow, MBA

Senior Decision Scientist, Eli Lilly and Company

How TransCelerate is Expanding Clinical Research Awareness Candice E. Junge. PhD

Development Design Director, Amgen Inc.

Leverage EHR Data and the Physician-Patient Relationship to Raise Patient Awareness of Trials and Accelerate Recruitment

Vice President, Life Sciences, ePatientFinder

#251 Track O4C - Patient Engagement

Featured Topic(s): Patient-Centric

2:00-3:15pm Level: ■ Format: FORUM

Room N226 *CME, Pharmacy, and Nursing*

Defining the Science of Patient Input to Enhance Drug Development and Approval: Regulatory

CHAIRPERSON

Bennett Levitan

Senior Director, Benefit-Risk Assessment, Department of Epidemiology, Janssen Research & Development, LLC

SPEAKER(S)

The Voice of the Patient: Setting the Therapeutic Context for Regulatory Decision-Making

James E. Valentine, JD, MHS

Attorney, Hyman, Phelps & McNamara, PC

Incorporating Patient Preferences in Benefit-Risk Assessments: Interpreting ICH M4E (R2)

Lesley Wise, PhD, MSc

Managing Director, Wise Pharmacovigilance and Risk Management Ltd.

Advancing the Science of Patient Inputs in the Regulatory Setting Telba Irony, PhD

Deputy Director, Office of Biostatistics and Epidemiology, CBER, FDA

#252 TRACK O5A - REGULATORY

Featured Topic(s): Student Programming, Devices-Combination Products, Global Regulatory

2:00-3:15pm Level: ■ Format: SESSION

Room \$404a CME, and Nursing

What's New in Devices: European Medical Device Regulations and MDUFA IV

CHAIRPERSON

Angela Stokes, MS

Senior Director, Global Regulatory Consulting, INC Research, United Kingdom

SPEAKER(S)

Are You Ready for the Medical Devices Regulation? What Should Manufacturers be Considering Now

Angela Stokes, MS

Senior Director, Global Regulatory Consulting, INC Research, United Kingdom

The EU Medical Device Regulations: The Notified Body View Theresa Jeary

Theresa Jeary

Technical Manager, Lloyds Register Quality Assurance, United Kingdom

#253 Track O5B - Regulatory

2:00-3:00pm Level: ■ Format: SESSION

Room S404bc CME, and Nursing

Regulatory Challenges with Next Generation Sequencing

CHAIRPERSON

Kim Tyrrell-Knott, JD

Partner, Epstein Becker & Green, P.C.

SPEAKER(S)

What's Next for Next Gen Sequencing

Kim Tyrrell-Knott, JD

Partner, Epstein Becker & Green, P.C.

FDA Perspective

Laura Koontz, PhD

Office of InVitro Diagnostics and Radiological Health (OIR), CDRH, FDA

#254 Track 6 - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Global Regulatory

2:00-3:15pm Level: ■ Format: SESSION

Room S403ab CME, and Nursing

New Considerations in Benefit-Risk Management

CHAIRPERSON

Meredith Y. Smith, PhD, MPA

Global Risk Management Officer, Global Patient Safety, Amgen Inc.

SPEAKER(S)

Implementing Benefit-Risk Management More Effectively

Steve Mayall, PhD

Principal Consultant, Pope Woodhead & Associates Ltd, United Kingdom

The Revised ICH M4E Benefit-Risk Assessment Guidance: Update and Practical Implications

Tarek Hammad, MD, PhD, MS, MSc, FISPE

Executive Director, Pharmacoepidemology, Merck Research Laboratories

The Revised ICH M4E Benefit-Risk Assessment Guidance: Practical Implications for Regulators, Industry, and Patients - Part 2

Rebecca A. Noel, DrPH, MPH

Global Benefit-Risk Lead, Global Patient Safety, Eli Lilly and Company

Regulatory Perspective on the New ICH Guidance and the Evolving Nature of Benefit-Risk Assessment

Patrick Frey

Chief of Staff, Office of New Drugs, CDER, FDA

#255 Track 7 - Special Populations

Featured Topic(s): Clinical Operations, Rare Disease

2:00-3:15pm Level: ■ Format: SESSION

Room S505abCME, Pharmacy, and Nursing

Integrating the Patient's Voice Across the Development Program of Rare Diseases: Translation into Meaningful Outcomes

CHAIRPERSON

David H. Schubert

 $\label{lem:continuous} \mbox{ Vice President of Regulatory and Quality, Stealth BioTherapeutics}$

The Importance of Meaningful Endpoints for Rare Disease Clinicians and Patients

Lisa Marie Dilworth, MS

Director of Therapeutic Expertise, Scientific Affairs, Rare Diseases, PRA Health Sciences

Developing the PKU-QOL: A Long Journey to Integrate the Patients' Voice into Phenylketonuria Drug Development Programs

Benoit Arnould, PhD, MSc

Senior Director, Global, Patient-Centered Outcomes, Patient Centered Sciences, Mapi, France

Rare Disease Drug Development: Incorporating Patients' Perspective Through the Use of Patient Exit Interviews

Lili Garrard, PhD

Mathematical Statistician, Office of Translational Sciences, CDER, FDA

#256 Track O8A - Strategic Planning/Execution and Partnerships

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Patient-Centric

2:00-3:15pm Level: ◆ Format: SESSION

Room N230b CME, Pharmacy, Nursing, and PMI PDUs

Post-Trial Access: Ensuring Patient Access Across the Development Spectrum

CHAIRPERSON

Karla Childers, MS

Senior Director, Strategic Projects, Office of the Chief Medical Officer, Johnson & Johnson

SPEAKER(S)

Development of a Common Ethical Framework for Post Trial Responsibilities

Rebecca Li, PhD

Executive Director, Harvard MRCT Clinical Trials Center, Brigham and Women's Hospital

Luann E. Van Campen, PhD, MA, MS

Senior Advisor and Head of Bioethics, Eli Lilly and Company

Walter Straus, MD, MPH, FACP

Associate Vice President, Therapeutic Area Head, Clinical Safety and Risk Management, Merck & Co., Inc.

#257 Track 08B - Strategic Planning/Execution and Partnerships

Featured Topic(s): Public Policy

2:00–3:15pm Level: ■ FORMAT: SESSION Room N426b CME, Nursing, and PMI PDUs

Strategic Planning Across Research Organizations

CHAIRPERSON

Shurjeel Choudhri, DrMed, FRCPC

Senior Vice President and Head, Medical and Scientific Affairs, Bayer, Canada

SPEAKER(S)

Initiatives for Enhancing the Canadian Clinical Research Environment: A Showcase of Cross-Sectoral Collaborations

Shurieel Choudhri, DrMed, FRCPC

Senior Vice President and Head, Medical and Scientific Affairs, Bayer, Canada

Innovative Approaches to Getting Products to Market: The Experience in an Academic Medical Center

Bambi Grilley, RPh, RAC

Director, Clinical Research and Early Product Development, Center for Cell and Gene Therapy, Baylor College of Medicine

Industry Perspective for Strategic Collaboration

Janice Chang

Senior Vice President, Global Operations, TransCelerate Biopharma Inc.

#258 TRACK 09A - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher,
Patient-Centric, Statistics

2:00-3:15pm Level: ◆ Format: SESSION

Room S404d CME, Pharmacy, and Nursing

Patient-Reported Outcomes (PROs): Hot Topics - Part 1 of 2

CHAIRPERSON

Selena Daniels, PharmD, MS

COA Staff Team Leader, CDER, FDA

SPEAKER(S)

Capturing the Patient's Voice in Evaluating Safety and Tolerability: Industry Perspective

Arnold Degboe, MD, PhD, MBA

Director, Patient Science Oncology, Patient Centricity, Global Medical Affairs, AstraZeneca

Capturing the Patient's Voice in the Evaluation of Safety and Tolerability: FDA Perspective

Paul Kluetz, MD

Associate Director, Office of Hematology and Oncology, Office of New Drugs, CDER, FDA

Capturing the Patient's Voice in the Evaluation of Safety and Tolerability: FDA Perspective

Ann Marie Trentacosti, MD

Medical Officer, Labeling Development Team, Office of New Drugs, CDER, FDA

#259 TRACK 09B - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher,
Patient-Centric

2:00–3:15pm Level: ■ FORMAT: SESSION Room S405a CME, Pharmacy, and Nursing

Novel Techniques for Improving Clinical Trial Subject

RetentionCHAIRPERSON

Karen M. Hauda, JD, MS

Senior Director, Regulatory Policy, Novo Nordisk A/S

Lost to Follow Up No More: Lessons Learned from Increasing Patient Retention in Diabetes Trials

Francine Wormley Williams, MPH

Associate Director, Project Management, Trials, Novo Nordisk A/S

Using Innovative Technology to Improve Subject Retention in Clinical Trials

Jill Platko, PhD

Senior Scientific Advisor, CRF Health

One Size Does Not Fit All: Retention Methods Custom-Designed for Your Specific Patient Population

Valerie Powell, MS

Director, Patient Insights and Engagement, Mapi

#260 TRACK 10 - VALUE AND ACCESS

2:00-3:00pm Level: ■ Format: SESSION

Room S405b CME, Pharmacy, and Nursing

Comparative Effectiveness: State of the Art and Stakeholder Perspectives

CHAIRPERSON

Robert W. DuBois, MD, PhD

Executive Vice President and Chief Science Officer, National Pharmaceutical Council

SPEAKER(S)

Mind the 'Efficacy-Effectiveness' Gap: Will Changes in Regulations on Real-World Research Revolutionize Health Technology Assessment? David Thompson, PhD

Senior Vice President, Real World Evidence Consulting, in Ventiv Health

Update from PCORI

Jean Slutsky, MPH

Chief Engagement and Dissemination Officer, Patient-Centered Outcomes Research Institute (PCORI)

#261 Track 11A - Quality

2:00-3:15pm Level: ■ Format: SESSION

Room N229 CME, and Nursing

Comparison of Inspection Findings and Recommendations of Registration Trials Submitted in Support of Marketing Applications of New Drug Products to EMA and FDA

CHAIRPERSON

Sandra L. Kweder, MD, FACP

Deputy Director, Liaison to the EMA, Office of International Programs, Office of the Commissioner, FDA

SPEAKER(S)

An Overview of EMA-FDA Good Clinical Practice (GCP) Collaboration: Focus on Comparison of Inspection Findings Project

Kassa Ayalew, MD, MPH

Branch Chief, Office of Scientific Investigations, Office of Compliance, CDER, FDA

EMA Perspectives

Anabela Marcal, PharmD

Head of Committees and Inspections Department, European Medicines Agency, European Union

Preliminary GCP Inspection Findings from Common Marketing Applications: Differences and Similarities

Jenn W. Sellers, MD

 $\label{eq:Medical Officer} \mbox{Medical Office of Scientific Integrity, Office of the Commissioner, $\operatorname{CDER}, \operatorname{FDA}$}$

Comments from Industry Perspectives

Ann Meeker-O'Connell, MS

Senior Director, Head, BioResearch Quality and Compliance, Consumer Products, Johnson & Johnson

#262 TRACK 11B - QUALITY

Featured Topic(s): Quality-GXP, Clinical Operations, Global Regulatory

2:00-3:15pm Level: ■ Format: SESSION

Room S401bc CME, and Nursing

Clinically Relevant Specifications: Leveraging Principles of QbD

CHAIRPERSON

Laurie Graham

Acting Director, Division of Internal Policies and Programs, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, FDA

SPEAKER(S)

FDA Perspective

Sarah Pope Miksinski, PhD

Director, Office of New Drug Products; Director (Acting), Office of Surveillance, Office of Pharmaceutical Quality, CDER, FDA

Using QbD Principles to Establish Launch Program Specifications John Joly, PhD

Senior Director Analytical Development and Quality Control, Genentech, Inc., A Member of the Roche Group

Ganapathy Mohan, PhD

Representative Invited

Head of Global CMC, Merck & Co., Inc.

EMA Perspective

Representative Invited

Head of Quality, Human Medicines R&D Support Division, European Medicines Agency, Europen Union

#263 TRACK 15 - ENGAGE AND EXCHANGE

2:00-3:00pm Level: ■ FORMAT: SESSION

Exhibit Hall

Mergers and Acquisitions: Due Diligence Considerations

CHAIRPERSON

Donny Chen, MBA

Senior Director, Medical Affairs Research Operations, PPD

#264 TRACK 17 - CONTENT HUB

2:00-2:30pm Format: SESSION

S400 Concourse

Biomedical Innovation: Delivering Value-Based Outcomes from an Innovation Pipeline

CHAIRPERSON

Vicki Barbur

Technology Transfer Associate, The MITRE Corporation

#265 TRACK 17 - CONTENT HUB

2:45-3:15pm Format: SESSION

S400 Concourse

Patient Engagement in Study Endpoints: Will the Rising Tide Lift All Boats

CHAIRPERSON

Matthew Reaney

Global Head of Clinical Outcomes, Sanofi

3:00-4:00рм

Refreshment Break

Exhibit Hall

#266 Track 13A - Innovation Theater

3:25-3:55pm Level: ■ Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

BBK Worldwide Innovation Theater: Building a Patient-Centric Mindset through Theatrical Contemplation

#267 Track 13B - Innovation Theater

3:25-3:55pm Format: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

Veeva Systems Innovation Theater: Unified RIM: End-to-End Submissions Development—from Planning Through Archival

#268 Track O1A - Data/Big Data/eHealth

Featured Topic(s): Data Management

4:00-5:00pm Level: ■ Format: SESSION

Room N227b CME, and Nursing

FDA Session: Health IT at FDA

CHAIRPERSON

Mitra Rocca, MSc

Associate Director, Medical Informatics, Office of Translational Sciences,

CDER, FDA

SPEAKER(S)

Ongoing Health Information Technology Activities at the FDA Mitra Rocca, MSc

Associate Director, Medical Informatics, Office of Translational Science, CDFR, FDA

What are the Most Promising and Likely to be Adopted Technologies to Enhance Clinical Research?

John J. Lewis, MA

Senior Vice President, Policy and Public Affairs, Association of Clinical Research Organizations (ACRO)

#269 Track O1B - Data/BIG Data/eHealth

Featured Topic(s): Rare Disease, Academic Clinical Researcher

4:00-5:15pm Level: ■ Format: SESSION

Room N226 CME, Pharmacy, and Nursing

Big Data: Genomics and Personalized Medicine

CHAIRPERSON

Arpit Dave, MS

Executive Director and Head of Enterprise Information Management Solutions, Bristol-Myers Squibb

SPEAKER(S)

Conundrum of Analytics in R&D: How to Drive Science by Leveraging

Arpit Dave, MS

Executive Director and Head of Enterprise Information Management Solutions, Bristol-Myers Squibb

The Path from Big Data to Precision Medicine: Leveraging Population Analytics to Prevent, Intercept, and Cure Complex Disease

Bevan Emma Huang, PhD

Associate Scientific Director, Janssen Research & Development, LLC

Panelist

Michael Mentesana, MA

Partner, Global Pharmaceutical and Life Sciences R&D, Advisory Services Leader, PriceWaterhouseCoopers LLP

#270 TRACK O1C - DATA/BIG DATA/EHEALTH

Featured Topic(s): Quality-GXP, Data Management, RBM

4:00-5:15pm Level: ■ Format: SESSION

Room N426a CME, and Nursing

Data Quality

CHAIRPERSON

Teresa Ancukiewicz, MA

Senior Manager, Clinical Data Management, Boston Scientific Corporation

SPEAKER(S)

A Quality by Design Approach to Data Quality

Erik Doffagne, MSc

Product Manager, CluePoints, Belgium

Going Beyond Data Collection to Ensure Data Quality

Kenneth Stoltzfus

Clinical Data Strategies, Accelerated R&D Life Sciences, Accenture

Model Data Management Plan

Scott Brand, PhD

Principal Scientist Data and BioInformatics, FEFA, LLC

#271 Track O2A - Disruptive Innovation

Featured Topic(s): Patient-Centric, Clinical Operations

4:00-5:15pm Level: ■ Format: SESSION

Room S501abc *CME, and Nursing*

Next Generation Patient Recruitment: Part 1 of 2

CHAIRPERSON

Melanie Goodwin

Patient Recruitment Planning, ICON, plc

Next Generation Patient Recruitment: Transforming Recruitment

Melanie Goodwin

Patient Recruitment Planning, ICON, plc

Can Artificial Intelligence Transform Patient Recruitment? Wout Brusselaers, MA

Chief Executive Officer, Deep 6 Al

Artificial Intelligence and Other Disruptive Technologies for Patient Recruitment in Clinical Studies

Manish Khatri, MS

Manager, Advisory Services, Life Sciences, Ernst and Young

#272 Track O2B - DISRUPTIVE INNOVATION

4.00-5.00pm I EVEL · ■ FORMAT: FORUM

Room S502ab CME, and Nursing

Microbiome: Innovative Therapeutics, Challenges, and **Opportunities**

CHAIRPERSON

Caroline B. Kurtz, PhD

Head of Translational Science and Product Development, Synlogic

SPEAKER(S)

Overview of the Microbiome and Approaches to Therapeutic Development

Caroline B. Kurtz. PhD

Head, Translational Science and Product Development, Synlogic

Regulatory Aspects of Microbiome Product Development James R. Weston, MBA

Vice President, Regulatory Affairs, Seres Therapeutics, Inc.

Clinical Development Challenges for Microbiome Drug Development

Founder, President, and Chief Executive Officer, Rebiotix

#273 Track O3A - Medical Affairs and Scientific COMMUNICATION

Featured Topic(s): Medical Writing

4:00-5:15pm LEVEL: FORMAT: SESSION

Room S503ab CME, and Nursing

Creating Adaptive Contents for a Multichannel World

CHAIRPERSON

Cecil Lee. RPh

Knowledge Management Consultant, Global Medical Information, Eli Lilly and Company

SPEAKER(S)

Becoming the Next Content Super Model: Introducing Content Modeling - A Key Skill to Develop Reusable Adaptive Contents Cecil Lee, RPh

Knowledge Management Consultant, Global Medical Information, Eli Lilly and Company

Regulatory Content Management for Web, Tablet, and Mobile Media: **Designing Your Content for Multichannel Targets**

Susan Bairnsfather, MSc

Chief Executive Officer, Regulatory Writer, Regulatory Affairs Professional and Statistical Analyst, EPharmaTech LLC

Creating Adaptive Contents for a Multichannel World Samuel Rosen

Technical Architect, Mayens

#274 Track O3B - Medical Affairs and Scientific COMMUNICATION

Featured Topic(s): Medical Writing

4:00-5:15_{PM} LEVEL: FORMAT: SESSION

Room S403ab CME, and Nursing

Effective Collaboration Between Sponsors and Medical Writing Vendors

CHAIRPERSON

Tammy Franklin, MSc

Senior Director, Global Medical Writing, UBC, An Express Scripts Company

SPEAKER(S)

Strategic Partnerships for Medical Writing: The Sponsor's Perspective Tammy Franklin, MSc

Senior Director, Global Medical Writing, UBC, An Express Scripts Company

Keys to a Successful Specialized Medical Writing Partnership: The **Vendor's Perspective**

Timothy D. Garver, PhD

Chief Operating Officer and Executive Vice President, Impact Pharmaceutical Services. Inc.

Medical Writing Vendor Infrastructure Supports Strategic and Collaborative Partnerships: A Project Manager's Perspective Nancy Pultorak

Project Manager, Audubon PM Associates

#275 Track 04A - Patient Engagement

Featured Topic(s): Patient-Centric

4:00-5:15_{PM} FORMAT: FORUM LEVEL:

Room S401d CME, and Nursing

Partnering with Patients: Virtual and Traditional Communities - When for What

CHAIRPERSON

Kevin Ray Campbell, DrMed, FACC

Assistant Professor of Medicine, Division of Cardiology, University of North Carolina

The Effective Use of Social Media In Medicine: Engaging Patients and Improving Outcomes

Kevin Ray Campbell, DrMed, FACC

Assistant Professor of Medicine, Division of Cardiology, University of North Carolina

Create and Engage the Organically Developed Patient Network

T.J. Sharpe

Cancer Blog Author, www.Philly.com

Mobile Device Perspective

David Albert, MD

Founder and Chief Scientific Officer, AliveCor, Inc.

Traditional Patient Communities

Representative Invited

#276 TRACK 04B - PATIENT ENGAGEMENT

Featured Topic(s): Real World Evidence, Patient-Centric

4:00–5:15pм Level: ■ FORMAT: SESSION Room S402ab CME, Pharmacy, and Nursing

Defining the Science of Patient Input to Enhance Drug Development and Approval: Tools

CHAIRPERSON

Roslyn F. Schneider

Global Patient Affairs Lead, Pfizer Inc

SPEAKER(S)

Evolving Methods of Including Patients' Input in Drug Development Roslyn F. Schneider

Global Patient Affairs Lead, Pfizer Inc

Incorporating Patient Preferences in Drug Development and Approval Kevin Marsh, PhD, MSc

Executive Director, Evidera, United Kingdom

Incorporating the Patient Perspective into a Target Product Profile for Intercepting Alzheimer's Disease

Bennett Levitan

Senior Director, Benefit-Risk Assessment, Department of Epidemiology, Janssen Research & Development, LLC

#277 TRACK O5A - REGULATORY

Featured Topic(s): Public Policy

4:00-5:15pm Level: ■ Format: FORUM

Room N228 CME, and Nursing

The Reauthorization of BsUFA and its Impact on Both the Regulator and Industry

CHAIRPERSON

Juliana Marguerite Reed, MS

Vice President, Government Affairs, Coherus BioSciences

SPEAKER(S)

FDA Perspective

Leah Christl, PhD

Associate Director for Therapeutic Biologics, TBBS, OND, CDER, FDA

SPEAKER(S)

Hillel Cohen, PhD

Executive Director, Scientific Affairs, Sandoz Inc.

Kimberly Greco

Director, Research and Development Policy, Amgen Inc.

John Pakulski, RPh

Head, Regulatory Science, Biologics, Mylan Inc.

#278 TRACK O5B - REGULATORY

Featured Topic(s): Student Programming, Global Regulatory

4:00-5:15pm Level: ■ Format: FORUM

Room \$404a CME, and Nursing

PMDA Town Hall

CHAIRPERSON

Toshiyoshi Tominaga, PhD

Associate Executive Director (for International Programs), Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PANELISTS

Tatsuya Kondo, MD, PhD

Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Shinobu Uzu, MPharm

Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Kazuhiko Mori, MSc

Councilor for Pharmaceutical Affairs, Minister's Secretariat Ministry of Health, Labour and Welfare (MHLW), Japan

#279 TRACK OSC - REGULATORY

Featured Topic(s): Global Regulatory, Public Policy

4:00-5:15pm Level: ■ Format: FORUM

Room S404bc CME, and Nursing

Brexit: Where Are We Now?

CHAIRPERSON

Sandra L. Kweder, MD, FACP

Deputy Director, Liaison to the EMA, Office of International Programs, OC, FDA

PANELISTS

Virginia Lee Acha, PhD, MSc

Executive Director, Research, Medical and Innovation Association of the British Pharmaceutical Industry (ABPI), United Kingdom

Jonathan Mogford

Director of Policy, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Agnès Saint-Raymond, MD

Head of Portfolio Board, European Medicines Agency, European Union

Nicola Bedlington

Secretary General, European Patients Forum, Belgium

#280 Track 6 - Safety and Pharmacovigilance

Featured Topic(s): Quality-GXP, Public Policy

4:00-5:15_{PM} LEVEL: FORMAT: SESSION

Room S401bc CME, and Nursing

Developing Pharmacovigilance Policy Based on Impact

CHAIRPERSON

Alan M. Hochberg

Scientific Enablement Leader, F. Hoffmann-La Roche Ltd., Switzerland

SPEAKER(S)

Future Regulatory Goals of the Periodic Benefit-Risk Evaluation Reports (PBRER): Are They Being Achieved?

Shelley Gandhi, MS

Strategic Advisor, Pharmacovigilance and Drug Safety, NDA Group, United Kingdom

Assessment of the Impact of Scheduled Postmarketing Safety **Summary Analyses on Regulatory Actions**

Gerald J. Dal Pan, MD, MHS

Director, Office of Surveillance and Epidemiology, CDER, FDA

#281 Track O7A - Special Populations

Featured Topic(s): Rare Disease, Clinical Operations

4:00-5:15pm LEVEL: FORMAT: SESSION

Room S505ab CME, Pharmacy, and Nursing

Integrating the Patient's Voice Across the Development Program of Rare Diseases: At the Table - Where to Sit?

CHAIRPERSON

David H. Schubert

Vice President of Regulatory and Quality, Stealth BioTherapeutics

The Importance of the Patient Voice and Patient-Industry Partnerships in Rare Disease

Christine McSherry, RN

Executive Director, The Jett Foundation

The Rare Disease Patient Voice: Not One-Size-Fits-All

James E. Valentine, JD, MHS

Attorney, Hyman, Phelps & McNamara, PC

Mobile App for Pulmonary Arterial Hypertension

Wayne Amchin, MA, MPA, RAC

Senior Consumer Safety Officer, DCRP, ODE I, Office of New Drugs, CDER, FDA

#282 Track 07B - Special Populations

Featured Topic(s): Academic Clinical Researcher, Clinical Operations, Rare Disease

4:00-5:15рм LEVEL: FORMAT: SESSION

Room S504abc CME, Pharmacy, and Nursing

Challenges and Issues in Early-Phase Oncology Trials

CHAIRPERSON

Elaine Marie Paul, PhD

Senior Director Clinical Development, GlaxoSmithKline

SPEAKER(S)

The Evolving Complexity of Early Phase Clinical Trials

Elaine Marie Paul, PhD

Senior Director Clinical Development, GlaxoSmithKline

Challenges and Issues to Consider in the Implementation of Phase I **Oncology Trials**

Leanne Cartee, PhD

Director, Protocol Development, UNC Lineberger Cancer Center

Oncology Trials: A Study in Adaptation

Sharon Cornell Murray, PhD

Associate Director, Biostatistics, PAREXEL International

Unique Ethical Issues in Early Stage Oncology Research

Lindsay McNair, MD, MPH, MS

Chief Medical Officer, WIRB-Copernicus Group

#283 Track 8 - Strategic Planning/Execution and **PARTNERSHIPS**

Featured Topic(s): Academic Clinical Researcher, Quality-GXP

4.00-5.15pm FORMAT: FORUM

Room N426b CME, Nursing, and PMI PDUs

The Impact of Industry Consortia on Creating Collaborative Solutions to Drug Development Challenges: What Does the **Future Hold?**

CHAIRPERSON

Patricia Leuchten

President and Chief Executive Officer, The Avoca Group

SPEAKER(S)

Industry Consortia are Propelling Collaborative, Creative Solutions in Drug Development: How Have We Enabled Partnering Between Sponsors, CROs, and Other Industry Stakeholder Groups to Foster **Change and Create Streamlined Solutions?**

Steven B. Whittaker

Executive Director, Quality Consortium, The Avoca Group

Change Management Requires Processes, Technology, AND PEOPLE: A New Paradigm in Innovative Workforce Development Through **Previously Unused Forms of Collaboration**

James Kremidas

Executive Director, Association of Clinical Research Professionals (ACRP)

Industry-Based GCP, GLP, GMP, and Nonregulated Outsourcing Oversight Maturity Model: Partnering on Solutions to Reduce the Gap **Between Sponsors and CROs**

Barbara Kristina Beck, MS

Director, Written Standards and Governance, Third Party Resourcing, GlaxoSmithKline

#284 Track O9A - Translational Science: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, **Statistics**

4.00-5.15pm FORMAT: SESSION LEVEL:

Room S401a CME, and Nursing

Use of Novel Trial Designs to Accelerate Decision-Making: To 'P' No More

CHAIRPERSON

Jonathan Haddad

Director, Clinical Statistics, GlaxoSmithKline

Biomarker-Guided Adaptive Trial Designs

Nusrat Rabbee, PhD

Senior Statistical Fellow, Covance Inc.

Kert Viele, PhD

Director and Senior Statistical Scientist, Berry Consultants

#285 TRACK 09B - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Statistics

4:00-5:15pm Level: ■ Format: SESSION

Room S405aCME, and Nursing

What Question Are You Trying to Answer? The Use of Estimands, Potential Revisions to ICH E-9, and the Impact to Trial Design and Analysis

CHAIRPERSON

Thomas J. Permutt, PhD

Director, Division of Biometrics II, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

SPEAKER(S)

Measuring Effectiveness of Treatment Regimens in Diabetes Clinical Trials Fanny Ki Wong, PhD

Director and Biometric Team Leader, AstraZeneca

Industry Perspective

Michael P. O'Kelly, Esq, PhD, MA

Senior Director, Centre for Statistics in Drug Development, Innovation, QuintilesIMS. Ireland

FDA Perspective

Thomas J. Permutt, PhD

Director, Division of Biometrics II, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

#286 Track O9C - Translational Science: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, RBM, Quality-GXP

4:00-5:00pm Level: Format: SESSION

Room \$405b CME, and Nursing

Audits and Agency Inspections of Risk-Based Monitored Studies: The Results Are In...

CHAIRPERSON

John Hicks, MBA, MSc

Global Quality Auditing Manager, Eli Lilly and Company

SPEAKER(S)

Evaluation of Risk-Based Monitoring from the Perspective of the Sponsor's GCP Auditor

John Hicks, MBA, MSc

Global Quality Auditing Manager, Eli Lilly and Company

Results from Five Years of Risk-Based Monitoring Studies: Experience with Health Authorities and Internal Auditors

Esther Huffman, MA

Business Partner, Monitoring Excellence, Bristol-Myers Squibb

Industry Perspective

Maryrose Petrizzo, MS

President and Principal Consultant, Clinical Quality Assured, LLC

#287 TRACK O9D - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Patient-Centric, Statistics

4:00–5:15pm Level: ■ FORMAT: SESSION Room S404d CME, Pharmacy, and Nursing

Patient-Reported Outcomes (PROs): Hot Topics - Part 2 of 2

CHAIRPERSON

Dennis Revicki, PhD

Senior Vice President, and Executive Director, COE for Outcomes Research, Evidera

SPEAKER(S)

Developing and Evaluating PRO Instruments in Clinical Trials: Risks and Advantages for Applications Using Registration Trials

Dennis Revicki, PhD

Senior Vice President and Executive Director, COE for Outcomes Research, Evidera

Developing and Evaluating PRO Instruments in Clinical Trials: Overview and Importance of Key Psychometric Characteristics Wen-Hung Chen, PhD

Social Science Analyst, Office of New Drugs, CDER, FDA

Developing and Evaluating PRO Instruments in Clinical Trials: Statistical Issues for Applications Using Registration Trials

Lisa A. Kammerman, PhD, MS

Senior Statistical Science Director, AstraZeneca

#288 Track 10A - Value and Access

Featured Topic(s): Real World Evidence

4:00-5:15pm Level: ■ Format: FORUM

Room N230b CME, and Nursing

Breaking Down the Wall for Global Regulators to Leverage Real-World Data

CHAIRPERSON

Duane Schulthess, MBA

Managing Director, VitalTransformation, Belgium

SPEAKER(S)

Lessons Learned from the EMA Adaptive Pathways Pilot Project: The Need for a Real-World Data Strategy for Success

Dimitra Lamprelli, PhD

Evidera, Greece

PANELISTS

Alison Cave, PhD

Principal Scientific Administrator, European Medicines Agency, European Union

Representative Invited

Brigham and Women's Hospital; Harvard Medical School

Nicola Bedlington

Secretary General, European Patients Forum, Belgium

#289 TRACK 10B - VALUE AND ACCESS

Featured Topic(s): Patient-Centric

4:00-5:15pm Level: ■ Format: SESSION

Room N426c CME, and Nursing

Value and Access for Special Populations: From Access Restriction to Drug Mortgages

CHAIRPERSON

Roxanne Tavakkol, MS

Vice President, Regulatory Affairs, Autoimmune and Rare Diseases, Mallinckrodt Pharmaceuticals

SPEAKER(S)

Addressing Urgent Access to Therapeutic Treatment Needs: Meeting the Need for Urgent Access to Therapeutic Treatments

Roxanne Tavakkol, MS

Vice President, Regulatory Affairs, Autoimmune and Rare Diseases, Mallinckrodt Pharmaceuticals

William A. Sarraille

Partner, Sidley Austin, LLP

Gaining Access to Orphan/Special Drug Therapies

John J. Maddox, Jr, MBA, RPh

Founder and Managing Director, Infusion Pharma Consulting LLC

#290 Track 11 - Quality

4:00-5:15pm Level: ■ Format: SESSION

Room N229 CME, and Nursing

Quality Metrics: The Carrot or the Stick?

CHAIRPERSON

Sarah Pope Miksinski, PhD

Director, Office of New Drug Products; Director (Acting), Office of Surveillance, OPQ/CDER, FDA

SPEAKER(S)

Industry Perspective

Steven Mendivil

Senior Advisor International Quality, Amgen Inc.

Michael G. Davidson

Vice President, Quality Systems and Compliance, Pfizer Inc

Barbara Allen, PhD

Senior Director Global Quality Systems, Eli Lilly and Company, Ireland

PANELIST(S)

Tara Gooen Bizjak, MS

Program Management, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, FDA

Alex M. Viehmann

Operations Research Analyst, OS, Office of Pharmaceutical Quality, CDER, FDA

#291 Track 15 - Engage and Exchange

Featured Topic(s): Devices-Combination Products

4:00-5:00pm Level: ■ Format: SESSION

Exhibit Hall

Combination Products

CHAIRPERSON

Khaudeia Bano

Senior Medical Director, Medical Affairs, Diagnostics, Abbott Laboratories

SPEAKER(S)

TBD

#292 TRACK 17 - CONTENT HUB

4:00-4:30pm Format: SESSION

S400 Concourse

How eSource Solutions are Impacting Clinical Research Sites, Patients, Regulators, and Drug and Device Companies

CHAIRPERSON

Jules Mitchel, PhD, MBA

President, Target Health Inc

#293 TRACK 17 - CONTENT HUB

Featured Topic(s): Statistics

4:45-5:15pm Format: SESSION

S400 Concourse

Conversations That Matter: How Do Regulatory Affairs Professionals Wish to Engage in with Statisticians and Vice Versa

CHAIRPERSON

Susan P. Duke

Consultant, Safety Statistics

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WEDNESDAY, JUNE 21

Registration Hours

7:00_{AM}-5:15_{PM} Attendee, Speaker, and Exhibitor Registration

7:00-8:00_{AM}

Coffee and Light Refreshments S102 Lobby

#301 TRACK 12A



Featured Topic(s): Pediatrics, Patient-Centric, Academic Clinical Researcher, Global Regulatory, Student Programming

8:00-9:30am Level: ■ Format: SESSION

Room S105 *CME, Pharmacy, and Nursing*

Progress in Pediatric Therapeutics

CHAIRPERSON

Ronald Portman, MD

Executive Director, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corporation

PANELISTS

Susan McCune, MD

Director, Office of Pediatric Therapeutics, Office of Special Medical Programs, OC, FDA

Mark Turner, MD, PhD, MRCP

Senior. Lecturer in Neonatology; Co-Director International Neonatal Consortium, United Kingdom

Robert M. Ward, MD

Professor Emeritus of Pediatrics, Neonatology, Clinical Pharmacology, University of Utah

Christopher Male, MD

Associate Professor of Paediatrics Medical University of Vienna, Austria

#302 TRACK 12B



Featured Topic(s): Clinical Operations, Statistics, Rare Disease, Patient-Centric, Academic Clinical Researcher, Real World Evidence, Student Programming

8:00-9:30am Level: ■ Format: SESSION

Room S100c *CME, Pharmacy, and Nursing*

Does Diversity Matter in Clinical Trials?

CHAIRPERSON

Joe V. Selby, MD, MPH

Executive Director, Patient-Centered Outcomes Research Institute (PCORI)

PANELISTS

John Whyte, MD, MPH

Director, Professional Affairs and Stakeholder Engagement, Office of the Center Director, CDER, FDA

Sam S. Oh, PhD, MPH

Director of Epidemiology, Asthma Collaboratory, UCSF School of Medicine

Jonca C. Bull, MD

Assistant Commissioner for Minority Health, Office of the Commissioner, FDA

Karen Brooks, PhD

Senior Director, Clinical Operations, Adare Pharmaceuticals, Inc.

Regina Greer-Smith, MPH

President, Healthcare Research Associates LLC

#303 TRACK 12C



Featured Topic(s): Global Regulatory, Student Programming

8:00-9:30am Level: ■ Format: FORUM

Room S100a CME, and Nursing

International Regulatory Convergence

CHAIRPERSON

Agnes Saint-Raymond, MD

Head of Portfolio Board, European Medicines Agency, European Union, United Kingdom

PANELISTS

Guido Rasi, MD

Executive Director, European Medicines Agency, European Union

Stephen M. Ostroff, MD

Acting Commissioner, FDA

Tatsuya Kondo, MD, PhD

Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Ian Hudson, MD, FFPM, FRCP

Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Lorraine Nolan, PhD

Vice-Chair of the ICMRA; Chief Executive, Health Products Regulatory Authority (HPRA), Ireland

Jarbas Barbosa, MD, PhD

ICMRA Project Lead; Director-President, Agência Nacional De Vigilância Sanitária (ANVISA), Brazil

Pierre Sabourin

Assistant Deputy Minister, Health Products and Food Branch, Health Canada

9:30-10:30AM

Refreshment Beak

Exhibit Hall

#304 Track 15 - Engage and Exchange

Featured Topic(s): Clinical Operations

FORMAT: SESSION 9:30-10:30AM LEVEL:

Exhibit Hall

Mergers and Acquisitions: First, Do No Harm

CHAIRPERSON

Margaret S. Richars, PhD, MPH

Vice President, Data Analytics and Epidemiology, RW Strategy and Analytics, Mapi

#305 Professional Poster Session and Oral PRESENTATIONS 3A

9:30-10:30AM I EVEL · ■ FORMAT: SESSION

Exhibit Hall B

#306 Track 13 - Innovation Theater

9:45-10:15_{AM} LEVEL: FORMAT: SESSION

Exhibit Hall | Theater 1 | Aisle 300/400

Synchronoss Innovation Theater: Applying Telecom's **Mobility Best Practices to Life Sciences**

#307 Track 13 - Innovation Theater

Exhibit Hall | Theater 2 | Aisle 2500/2600

SAS Institute-JMP Division, Innovation Theater: Work with Me Here...(or There or Anywhere!): Practical Cloud **Collaboration with JMP Clinical**

#308 Track 01A - Data/Big Data/eHealth

Featured Topic(s): Wearables-Mobile Health, Student Programming

10:30-11:30AM FORMAT: SESSION LEVEL:

Room N227b CME, and Nursing

Quantified Self Tracking

CHAIRPERSON

Jonathan Solomon Helfgott, MS

Coordinator for Regulatory Science Program, Johns Hopkins University

Getting Down to the Nitty-Gritty: Addressing the Specific Challenges of Electronic Data and Mobile Devices in Clinical Trials

Jonathan Solomon Helfgott, MS

Coordinator for Regulatory Science Program, Johns Hopkins University

How Will Wearables and Biosensors Transform Clinical Trials? Scott Weidley

Chief Executive Officer, ClinCapture

My Fitbit Heart Rate Data is Clinical Trial Grade, Right?

Keith W. Wenzel

Senior Director, Solution Incubator, PAREXEL International

#309 Track O1B - Data/Big Data/eHealth

Featured Topic(s): eSubs, Real World Evidence, Clinical Operations, Academic Clinical Researcher

10:30-11:45AM I EVEL: ■ FORMAT: SESSION

Room S505ab CME, and Nursing

Big Data: Combining Registries and Legacy Clinical Trial Databases

CHAIRPERSON

Eric Peterson

Director, Duke Clinical Research Institute

SPEAKER(S)

Supporting Open Access to Clinical Trials Data for Researchers:

Challenges and Learnings

Eric Peterson

Director, Duke Clinical Research Institute

Synthetic Control Arms: A Scientific Alternative to Historical Controls

Michael R. Elashoff, PhD

Medidata Solutions Worldwide

#310 Track **02A - DISRUPTIVE INNOVATION**

Featured Topic(s): Patient-Centric, Clinical Operations, Academic Clinical Researcher

10:30-11:45AM FORMAT: SESSION I EVEL: ■

Room N229 CME, Pharmacy, and Nursing

New Site Paradigm: Just in Time Sites

CHAIRPERSON

Christine Pierre, RN

President, Society for Clinical Research Sites

PANELISTS

Jeanne Regnante

Executive Director, Global Patient Engagement Strategy Office, Merck & Co., Inc.

Craig H. Lipset, MBA

Head of Clinical Innovation, Global Product Development, Pfizer Inc.

Joseph Kim

Senior Advisor, Clinical Innovation, Eli Lilly and Company

#311 Track **O2A** - DISRUPTIVE INNOVATION

Featured Topic(s): Patient-Centric, Clinical Operations

10:30-11:45_{AM} LEVEL: FORMAT: SESSION

Room S501abc CME, Pharmacy, and Nursing

Next Generation Patient Recruitment: Part 2 of 2

CHAIRPERSON

Neil Weisman

Executive Vice President and General Manager, Continuum Clinical

Leveraging Patient-Centricity for Faster and More Cost-Efficient Patient Enrollment

Neil Weisman

Executive Vice President and General Manager, Continuum Clinical

One Compound/Many Indications: Connecting the Right Patients to the Right Trials Across Your Portfolio

Kelly A. White, MSN, RN

Director, Clinical Operations, Merck & Co., Inc.

Innovative Use of Social Media in Patient Recruitment

Kevin Bickford

Executive Director, Clinical Operations, Health Decisions

#312 Track O2B - DISRUPTIVE INNOVATION

Featured Topic(s): Patient-Centric, Rare Disease, Public Policy, Academic Clinical Researcher

10:30-11:45am Level: ■ Format: FORUM

Room N228 *CME, and Nursing*

CRISPR: Regulatory Challenges in the Gene Editing Revolution

CHAIRPERSON

Nancy Bradish Myers, JD

President, Catalyst Healthcare Consulting, Inc.

SPEAKER

FDA Perspective

Ritu Nalubola, PhD

Senior Policy Advisor, Office of Policy, Office of the Commissioner, FDA

PANELISTS

Kurt von Emster, CPA

Managing Partner, Abingworth

Eva Essig

Head of Regulatory Affairs, Intellia Therapeutics, Inc.

#313 Track O2B - Disruptive Innovation

10:30-11:45am Level: ■ Format: SESSION

Room \$502ab CME, and Nursing

New Frontiers in Pharmaceutical Manufacturing

CHAIRPERSON

Christine M. V. Moore, PhD

Global Head and Executive Director, GRACS CMC - Policy, Merck Research Laboratories

SPEAKER(S)

Anticipated Regulatory Challenges for Worldwide Approval of Continuous Manufacturing

Christine M. V. Moore, PhD

Global Head and Executive Director, GRACS CMC - Policy, Merck Research Laboratories

Translational Pharmaceutics and Integrating GMP Manufacture and Clinical Testing: A Game Changer for R&D Productivity

Peter Scholes, PhD, RPh

Chief Scientific Officer, Quotient Clinical, United Kingdom

FDA Perspective

Akm Khairuzzaman, PhD

Branch Chief (Acting), Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

#314 TRACK O3A - MEDICAL AFFAIRS AND SCIENTIFIC COMMUNICATION

Featured Topic(s): Patient-Centric

10:30-11:45AM LEVEL: ■ FORMAT: SESSION

Room S401d CME, and Nursing

Digital Channels and Artificial Intelligence in Medical Information and Communications

CHAIRPERSON

Peter Baumeister, PhD

Senior Manager, Global Scientific Communications, Amgen Inc.

SPEAKER(S)

Ron Segal, MBA, PMP

Senior Director, Business Technology, Pfizer, Inc

Artificial Intelligence

Joseph D. Scrocco

President and Chief Executive Officer, OneWorld Inc.

#315 TRACK 03B - MEDICAL AFFAIRS AND SCIENTIFIC COMMUNICATION

Featured Topic(s): Patient-Centric

10:30-11:45am Level: ■ Format: SESSION

Room S403ab CME, Pharmacy, and Nursing

How to Engage Patients Within Medical Affairs

CHAIRPERSON

Iris Tam, PharmD

Vice President, Patient Access and Quality, Otonomy, Inc.

SPEAKER(S)

The Value of a Patient Voice Strategy

Kevin John Fowler, SR

President, The Voice of the Patient, Inc.

Medical Communications: Integrating the Patient Voice

Valerie Powell, MS

Director, Patient Insights and Engagement, Mapi

Patient Perspective

Suzanne Schrandt, JD

Director, Patient Engagement, Arthritis Foundation

#316 Track 04 - Patient Engagement

Featured Topic(s): Clinical Operations, Patient-Centric

10:30-11:45am Level: ■ Format: SESSION

Room N426aCME, Pharmacy, and Nursing

Quantitative Metrics to Capture the Value of Patient Engagement

CHAIRPERSON

Kenneth A. Getz, MBA

Director of Sponsored Research Programs and Associate Professor, Center For the Study of Drug Development, Tufts University School of Medicine

Defining Metrics for ROE of Patient-Centric Initiatives Across the Product Life Cycle

Stella Stergiopoulos, MPH, MS

Senior Research Project Manager, Tufts Center for the Study of Drug Development

Getting Down to the Bottom Line: Measuring the Financial Impact of Patient Engagement

Bennett Levitan

Senior Director, Benefit-Risk Assessment, Department of Epidemiology, Janssen Research & Development, LLC

#317 TRACK O5A - REGULATORY

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Patient-Centric

10:30-11:45am Level: ■ Format: SESSION

Room S404bc CME, Pharmacy, and Nursing

Evolution of Novel Registration Endpoints as Diseases Become Chronic

CHAIRPERSON

Irene Nunes, PhD

Executive Director, Global Regulatory Affairs, Daiichi Sankyo Co., Ltd.

SPEAKER(S)

Evolution of Novel Efficacy Registration Endpoints to Quantitate Improved Long Term Survial Effects of New Drugs

Irene Nunes, PhD

Executive Director, Global Regulatory Affairs, Daiichi Sankyo Co., Ltd.

Challenges in Evaluating Immuno-Oncology Products

Rajeshwari Sridhara, PhD

Director, Division of Biometric V, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Endpoint Minimal Residual Disease Used for Novel Multiple Myeloma Therapies

C. Ola Landgren, MD, PhD

Profesor of Medicine and Chief of Myeloma Service, Memorial Sloan Kettering Cancer Center

Regulatory Considerations for Novel Endpoints in Immuno-Oncology Marc Theoret, MD

Lead Medical Officer, Office of Hematology and Oncology Products, Office of New Drugs, CDER, FDA

#318 Track 06 - Safety and Pharmacovigilance

Featured Topic(s): Real World Evidence

10:30-11:45am Level: ■ FORMAT: SESSION

Room \$404a CME, and Nursing

IMEDS: A Public-Private Partnership to Facilitate Real World Evidence Generation Based on the FDA's Sentinel System

CHAIRPERSON

June S. Wasser, MA

Executive Director, Reagan-Udall Foundation for the FDA

SPEAKER(S)

Overview of the IMEDS Program

David Martin, MD, MPH

Liaison to the Reagan-Udall Foundation IMEDS Program, Office of Medical Policy, CDER, FDA $\,$

PANELISTS

Robert Reynolds, DrSc, MSc, FISPE

Vice President, Global Head, Epidemiology, Pfizer Inc

Kevin Haynes, PharmD

Director of Clinical Epidemiology, HealthCore Inc.

Jeffrey Brown, PhD

Associate Professor, Department of Population Medicine, Harvard Pilgrim Health Care Institute/Harvard Medical School

#319 Track O6A - Safety and Pharmacovigilance

Featured Topic(s): Patient-Centric

10:30-11:45AM LEVEL: ■ FORMAT: SESSION

Room S404d CME, and Nursing

A New Age for Physician and Patient Labeling: Recommendations for Innovative Change in How We Communicate

CHAIRPERSON

Tracy D. Rockney, JD

Co-Founder and Managing Partner, OneSource Regulatory

SPEAKER(S)

An Innovative Approach to the Development and Testing of Health Literate Patient Labeling

Laurie M. Myers, MBA

Global Health Literacy Director, Merck & Co., Inc.

Academic Perspective

Michael S. Wolf, PhD, MPH

Associate Professor, Medicine and Learning Sciences, Associate Division Chief, Northwestern University

FDA Perspective

Kellie Taylor, PhD, MPH

Acting Director, Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology, CDER, FDA

#320 Track 06B - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Global Regulatory

10:30-11:45am Level: ■ Format: FORUM

Room N226 *CME, and Nursing*

The Brave New World: The Ongoing Globalization of Pharmacovigilance

CHAIRPERSON

Glenn Carroll

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

Best Practices and Lessons Learned in Globalizing and Harmonizing a Pharmacovigilance Organization

Mirza Rahman, MD, MPH

Vice President, Global Head of Pharmacovigilance and Medical Affairs, Otsuka Pharmaceutical Development & Commercialization, Inc.

Developing a Global Pharmacovigilance System for Expanding Markets: How You May Steer Your Boat Across Safe Waters

Sandra van der Poel

Principal Consultant, Xendo Pharmacovigilance B.V., Netherlands

Successes and Challenges in Achieving and Maintaining Oversight of Pharmacovigilance Affiliates

Jeffrey Ho

Principal, Navitas Life Sciences, United Kingdom

#321 Track 07 - Special Populations

Featured Topic(s): Clinical Operations, Rare Disease, Patient-Centric

10:30–11:45am Level: ■ FORMAT: SESSION Room S503ab CME, Pharmacy, and Nursing

Engagement, Education, Networks, Media, and Societies in Rare Diseases: The MUST Haves

CHAIRPERSON

Scott Douglas Schliebner, MPH

Vice President, Scientific Affairs, Rare Diseases, PRA Health Sciences

SPEAKER(S)

A Mutually Beneficial Partnership: Engaging Advocacy and Patient Groups to Assist with Clinical Trial Recruitment

Kelly Franchetti, BSN, RN

Vice President, Global Head Patient Insights and Engagement, Mapi

Engaging the Rare Disease Patient Voice Through Social Media, Social Listening, and Online Communities

Scott Douglas Schliebner, MPH

Vice President, Scientific Affairs, Rare Diseases, PRA Health Sciences

Leveraging Referring Physician Networks for Rare Disease Research Bonnie A. Brescia

Founding Principal, BBK Worldwide

Utilizing the Power of Many to Direct the Development of the Few: The Entrepreneurial Scope of the New Generation of Scientists Tasked with Developing Rare Disease Therapies

Dan Tierno, MA, MBA

Strategic Implementation Manager, Bayer

#322 Track 07 - Special Populations

Featured Topic(s): Academic Clinical Researcher, Patient-Centric

10:30-11:45am Level: ■ FORMAT: SESSION Room S504abc CME, Pharmacy, and Nursing

Is the Future Bright for Treatment of Neurodegenerative Diseases?

CHAIRPERSON

Susan Yule

Senior Global Regulatory Leader, F. Hoffmann-La Roche AG, Switzerland

SPEAKER(S)

Neurodegenerative Diseases: Progress, Challenges, and the Future of Alzheimer's Disease Treatment

Susan Yule

Senior Global Regulatory Leader, F. Hoffmann-La Roche AG, Switzerland

Recent Approaches and the Future of Neurodegenerative Diseases Conrad Hawkins

Associate Consultant, KMR Group Inc.

Challenges in Drug Development of Disease Modifying Drugs in Alzheimer's Disease

Laura Gault

Group Project Leader, AbbVie, Inc.

#323 TRACK 08 - STRATEGIC PLANNING/EXECUTION AND PARTNERSHIPS

10:30-11:45am Level: ♦ Format: FORUM

Room N426bCME, Nursing, and PMI PDUs

Effective Collaborations: Navigating the Grey Space

CHAIRPERSON

Andrew Townshend

Senior Vice President, Alliance Development, INC Research

SPEAKER(S)

Outside the Contract: Best Practices for Alliance Relationship

Maintenance

Andrew Townshend

Senior Vice President, Alliance Development, INC Research

Navigating Governance in a Partnership: Are the Players Really Equal? How to Navigate the Potential Imbalance

Stephane Marzabal, PhD

Co-Founder, SYNOV Solutions LLC

Making the Most of Your Collaboration: What to do When the Contract is Silent

Matthew J. Meitzner, MS

Associate Director, Project Management, Merck & Co., Inc.

#324 Track 08A - Strategic Planning/Execution and Partnerships

10:30-11:45am Level: ■ Format: SESSION

Room N426c CME, Nursing, and PMI PDUs

Keys to Effective Product Launch Preparation

CHAIRPERSON

Stephanie F. Brown, MA

Senior Director, Medical Affairs Launch Readiness, Eli Lilly and Company

SPEAKER(S)

Preparation and Partnership: The 'Secret Sauce' in Launch Readiness Stephanie F. Brown, MA

Senior Director, Medical Affairs Launch Readiness, Eli Lilly and Company

Everything You Wanted to Know About Launching a Drug but Were Afraid to Ask!

Matthew Steven Curin, PharmD

Associate Director, Project Management, Astellas Pharma US, Inc.

#325 Track 08B - Strategic Planning/Execution and Partnerships

Featured Topic(s): Career Development, Student Programming

10:30-11:45am Level: ■ Format: WORKSHOP

Room S401bc CME, Nursing, and PMI PDUs

Leading in the Midst of Ambiguity

CHAIRPERSON

Nicky Rousseau, CPA, MBA

Senior Director, Sales Organization Development, QuintilesIMS

SPEAKER(S)

Making Sense Out of Chaos: Leading in the Midst of Ambiguity

Nicky Rousseau, CPA, MBA

Senior Director, Sales Organization Development, QuintilesIMS

Facilitator

Jennifer Cubino, MA

Delivery Head, Senior Director, Customer Operations, QuintilesIMS

#326 TRACK O9A - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher

10:30-11:45am Level: ■ Format: FORUM

Room S401a CME, and Nursing

Optimizing Early Clinical Strategies to Support Breakthrough Therapy Designation

CHAIRPERSON

Alexander Varond, JD

Associate, Goodwin Procter

SPEAKER(S)

Aiming for a Breakthrough: Strategies to Maximize the Chance of Gaining Breakthrough Designation

Alexander Varond, JD

Associate, Goodwin Procter

Patient Advocacy Perspective

Jeff Allen, PhD

President and Chief Executive Officer, Friends of Cancer Research

FDA Perspective

Ilan Irony, MD

Deputy Director, DCEPT, OTAT, CBER, FDA

#327 TRACK O9B - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Statistics, Global Regulatory

FORMAT: SESSION

10:30-11:45am Level: ■

Room \$402ab CME, and Nursing

Multiregional Clinical Trials and the ICH E17

CHAIRPERSON

William Wang, PhD

Executive Director, Clinical Safety Statistics, BARDS, Merck Research

Laboratories

SPEAKER(S)

Update from the ICH E17 Chair

Yoshiaki Uyama, PhD

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

Update from the Society-of-Clinical-Trial Working Group

Bruce Binkowitz, PhD, MSc

Vice President, Biometrics, Shionogi, Inc.

Thoughts from the China Perspective

Ling Su, PhD

Venture Partner, Lilly Asia Ventures, China

#328 Track 10 - Value and Access

Featured Topic(s): Real World Evidence

10:30-11:45AM LEVEL: ■ FORMAT: SESSION

Room N230b CME, Pharmacy, and Nursing

Real-World Data to Real World Evidence for Assessing Efficacy and Effectiveness

CHAIRPERSON

Lawrence Eugene Liberti, MS, RPh, RAC

Executive Director, Centre For Innovation In Regulatory Science (CIRS)

SPEAKER(S)

Using Real World Evidence and Real-World Data to Build Confidence in Regulatory Decision-Making

Jonathan P. Jarow, DrMed, MD, PhD

Senior Medical Advisor, FDA

Using Real World Evidence and Real-World Data to Inform New Indications and Build Confidence in a Development Plan

James Harnett, PharmD, MS

Senior Director, Lead, Real-World Data and Analytics, Patient and Health Impact, Pfizer Inc

How Various Stakeholders are Using or Thinking of Using Real World Evidence and Real-World Data to Inform Their Decisions

Jean Slutsky, MPH

Chief Engagement and Dissemination Officer, Patient-Centered Outcomes Research Institute (PCORI)

#329 TRACK 11A - QUALITY

10:30-11:45am Level: ■ Format: FORUM

Room \$405a CME, and Nursing

Measuring and Advancing the Clinical Quality Management System

CHAIRPERSON

Robert Studt

Benefit Risk Quality Control Head, Quality Analytics, Janssen Pharmaceutical Companies of Johnson & Johnson

#330 TRACK 11B - QUALITY

10:30-11:45am Level: ■ Format: SESSION

Room S405b *CME, and Nursing*

Managing Acceleration and Quality In Product Development

CHAIRPERSON

Diane J. Zezza

Vice President and Global Head, Regulatory CMC, Novartis Pharmaceuticals Corporation

SPEAKER(S)

Industry Perspective

Nirdosh Jagoa, PhD

Vice President and Head, Regulatory CMC, Merck & Co., Inc.

FDA Perspective

Sarah Pope Miksinski, PhD

Director, Office of New Drug Products; Director (Acting), Office of Surveillance, Office of Pharmaceutical Quality, CDER, FDA

#331 TRACK 17 - CONTENT HUB

Featured Topic(s): Statistics

10:30-11:00am Format: SESSION

S400 Concourse

Conversations That Matter: How Do Pharmacovigilance Professionals Wish to Engage with Statisticians and Vice Versa

CHAIRPERSON

Joan Buenconsejo, PhD

Statistics Team Leader, Inflammation, Neuroscience and Respiratory TA, B&I Science, AstraZeneca

#332 TRACK 15 - ENGAGE AND EXCHANGE

Featured Topic(s): Clinical Operations

10:45–11:45am Level: ■ Format: SESSION

Exhibit Hall

Patient Perspective

CHAIRPERSON

James A. Seaton

Executive Consultant; PatientsLikeMe Team of Advisors, Seaton Associates, LLC

11:30 АМ-2:00 РМ

Luncheon

Exhibit Hall

#334 Professional Poster Session and Oral Presentation 3B

12:00-1:45рм

Exhibit Hall

#335 Track 15 - Engage and Exchange

Featured Topic(s): Clinical Operations, RBM

12:45-1:45pm Level: ■ Format: SESSION

Exhibit Hall

Real-World Application of Risk-Based Monitoring

CHAIRPERSON

Esther Huffman, MA

Business Partner, Monitoring Excellence, Bristol-Myers Squibb

#336 Track 13 - Innovation Theater

1:00-1:45pm Level: ■ Format: SESSION

Exhibit Hall | Theater 2 | Aisle 2500/2600

QuintilesIMS Innovation Theater: Connecting People and Trials Through Innovative Technologies

#337 TRACK O1A - DATA/BIG DATA/EHEALTH

2:00-3:15pm Level: ■ Format: SESSION

Room N426a CME, and Nursing

Big Data: Management and Analytics

CHAIRPERSON

David Olaleye, PhD, MS

Senior Manager and Principal Research Statistician, SAS Institute Inc.

SPEAKER(S)

Big Data Analytics to Historical Cancer Research Data: Project Data Sphere Oncology Data-Sharing Experiment

David Olaleye, PhD, MS

Senior Manager and Principal Research Statistician, SAS Institute Inc.

Indication Expansion and Drug Positioning: Opportunities for Translational Sciences

Lun Yang, PhD

Deputy Director, Bayer, Germany

Project Data Sphere: Building a Data Sharing Platform and Research Community to Advance Cancer Treatment

Dave Handelsman

Vice President of Development, Project Data Sphere, LLC

#338 TRACK O1C - DATA/BIG DATA/EHEALTH

Featured Topic(s): Quality-GXP, RBM, Clinical Operations

2:00-3:15pm Level: ■ Format: SESSION

Room N226 CME, and Nursing

Risk-Based Monitoring: Convergence of Technology, Processes, and People

CHAIRPERSON

Mary Arnould, BSN, MSN

Business Partner, Monitoring Excellence, Bristol-Myers Squibb

Five Years of Global Risk-Based Monitoring Implementation: Where We've Been and Where We're Going - Best Practices and Lessons

Mary Arnould, BSN, MSN

Business Partner, Monitoring Excellence, Bristol-Myers Squibb

Risk-Based Monitoring Centralized Monitoring: What's Needed to be Effective?

Stephen Young, MSc

Senior Vice President, Head of US Operations, CluePoints

The Evolving Area of Central Monitoring: What is it? What Data is Being Reviewed? Who is Responsible?

Keith Dorricott

Ambassador, MCC; Director, Dorricott Metrics and Process Improvement Itd., United Kingdom

#339 Track O3A - Medical Affairs and Scientific COMMUNICATION

Featured Topic(s): Patient-Centric

2:00-3:15pm LEVEL: FORMAT: FORUM

Room N229 CME, Pharmacy, and Nursing

Off-Label Communications to Health Care Providers and **Consumers**

CHAIRPERSON

John Kamp

Executive Director, Coalition For Healthcare Communication

SPEAKER(S)

Scientific Exchange in the Digital Age

Todd M. Hobbs, DrMed

Vice President, Chief Medial Officer, Novo Nordisk A/S

Panelist

Kellie B. Combs, JD

Partner, Ropes & Gray LLP

Beyond the Product Label

James M. Spears, JD

Consultant

#340 Track O3B - Medical Affairs and Scientific COMMUNICATION

2:00-3:15рм LEVEL: FORMAT: SESSION

Room S401a CME, and Nursing

Digital Innovations for Medical Information Contact Centers

CHAIRPERSON

Holli Simmons-Little, MS

Director, The Lilly Answers Center, Lilly USA, LLC

SPEAKER(S)

Industry Perspective

Andrea Marie Tenbarge, PharmD

Consultant, Medical Digital Strategy and Capabilities, Eli Lilly and Company

Panelist

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Joseph Falcone

Lead, Medical Digital Solutions, Bristol-Myers Squibb

#341 TRACK O3C - MEDICAL AFFAIRS AND SCIENTIFIC COMMUNICATION

Featured Topic(s): Medical Writing, Global Regulatory

2:00-3:15_{PM} LEVEL: FORMAT: FORUM

Room N227b CME, and Nursing

EMA Policy 0070: A Game Changer for Industry

CHAIRPERSON

Robert Paarlberg, MS

Principal, Paarlberg & Associates LLC

SPEAKER(S)

EMA Update

Marie-Helene Pinheiro, PharmD

Industry Stakeholder Liaison, Corporate Stakeholders Division, European Medicines Agency, European Union

EMA Policy 0070: Insights from the CRO Perspective

Dairine Dempsey, PhD, RPh

Vice President, Strategic Regulatory Affairs, ICON, plc, Ireland

EMA Policy 0070: Industry Perspective

Julie G. Holtzople

Clinical Trial Transparency Operations Director, AstraZeneca

#342 Track 04 - Patient Engagement

Featured Topic(s): Real World Evidence, Patient-Centric

2.00-3.15pm LEVEL: FORMAT: SESSION

Room N426c CME, and Nursing

Adoption and Implementation of Digital Platforms to Further Patient Interactions

CHAIRPERSON

Betsy Fallen, RN

Consultant, BAFallen Consulting LLC

SPEAKER(S)

Leveraging Technology to Improve Pilot Studies, Patient Engagement, and the Informed Consent Process

Vincent Miller

Project Coordinator, Duke Clinical Research Institute

Patient Engagement: Holy Grail or a Passing Fad?

Keith W. Wenzel

Senior Director, Solution Incubator, PAREXEL International

Utilization of eSignatures to Facilitate the Clinical Trials Process Jenny Lester, MPH

Research Manager, Samuel Oschin Comprehensive Cancer Institute

#343 TRACK O5A - REGULATORY

Featured Topic(s): Patient-Centric, Rare Disease

2:00-3:15_{PM} FORMAT: FORUM

Room N230b CME, and Nursing

Expanded Access and Compassionate Use

CHAIRPERSON

Ramana Sontv. PhD

Strategic Business Planning and Execution, Global Medical Organization, Janssen Research & Development, LLC

Proactive Implementation of Expanded Access in Drug Development Kevin Bugin, MS, RAC

Change Management Lead, Office of New Drugs, CDER, FDA

Making Compassion Work: Challenges and Next Steps Elena Gerasimov, MA, MPH

Director, Compassionate Use Navigator Program, Kids V Cancer

Independent Evaluation of Compassionate Use Requests to Benefit Patients: The NYU J&J CompAC

Ramana Sonty, PhD

Strategic Business Planning and Execution, Global Medical Organization, Janssen Research & Development, LLC

Navigating the Regulatory Pathways of Early Access to Medicines in the EU

Grant Strachan, LLM

Senior Associate, Regulatory, Bristows LLP, United Kingdom

#344 TRACK O5B - REGULATORY

Featured Topic(s): Rare Disease, Clinical Operations

2:00-3:15pm Level: ■ Format: SESSION

Room \$404a CME, and Nursing

Minding the Gaps: Using Totality of Evidence in the Clinical and CMC Contexts to Support Regulatory Approval

CHAIRPERSON

Alexander Varond, JD

Associate, Goodwin Procter

SPEAKER(S)

Short of Perfect - Approval with Data That's Less Than Optimal Alexander Varond. JD

Associate, Goodwin Procter

Clinical Evidence to Support Marketing Authorizations: Focus on Regulatory Approvals Based on a Single Pivotal Trial

Anne Vinther Morant, PhD, MSc

Senior Regulatory Intelligence Lead, H. Lundbeck A/S, Denmark

FDA's Totality-of-Evidence Approach in Botanical New Drug Approval Charles G. Wu, PhD

Senior Pharmacologist, Office of Pharmaceutical Quality, CDER, FDA

#345 Track O5C - REGULATORY

Featured Topic(s): Student Programming, Statistics, Global Regulatory, Academic Clinical Researcher

2:00-3:15pm Level: ■ Format: FORUM

Room N228 CME, and Nursing
Global Perspective on ICH: Part 1 of 2

CHAIRPERSON

Amanda Marie Roache

Operations Research Analyst, Office of Strategic Programs, CDER, FDA

SPEAKER(S)

Regulatory Perspective on ICH

Toshiyoshi Tominaga, PhD

Associate Executive Director (for International Programs), Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Recap of Recent ICH Meeting

Cathy A. Parker

Director General, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada

PANELISTS

Theresa M. Mullin, PhD

Director, Office of Strategic Programs, CDER, FDA

Samvel Azatyan, MD, PhD

Group Lead, Regulatory Networks and Harmonization, RSS, RHT, EMP, World Health Organization (WHO), Switzerland

#346 Track O5D - Regulatory

Featured Topic(s): Academic Clinical Researcher, Patient-Centric

2:00-3:15pm Level: ■ Format: FORUM

Room N426b CME, Pharmacy, and Nursing

Understanding the New Common Rule and Its Impact to Industry

CHAIRPERSON

James Riddle, MS

Vice President of Client Services, Kinetiq, a Division of Quorum IRB

SPEAKER(S)

Perspective from the Office of Human Subject Protection Laura Odwazny, JD, MA

Senior Attorney, Office of Human Subject Protection, Office of General Counsel, Department of Health and Human Services

Common Rule Changes: Impact on Industry

James Riddle, MS

Vice President of Client Services, Kinetig, a Division of Quorum IRB

#347 TRACK O6A - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Patient-Centric

2:00-3:15pm Level: ■ Format: SESSION

Room S401dCME, Pharmacy, and Nursing

Integrated Life Cycle Approaches to Benefit-Risk Assessment, Communication, and Evaluation

CHAIRPERSON

Simon Ingate, PhD, MBA

Principal Consultant, Safety Gauge Product Manager, Pope Woodhead & Associates Ltd, United Kingdom

Digital Strategies for Communicating Benefit-Risk and Gathering Effectiveness and Other Data Used to Optimize the Benefit-Risk Ratio Simon Ingate, PhD, MBA

Principal Consultant, Safety Gauge Product Manager, Pope Woodhead & Associates Ltd, United Kingdom

Learnings from Implementing Risk Minimization Measures Effectiveness Evaluation PASS Studies

Helen Kathryn Edelberg, MD, MPH, FACP

Head, Global Safety Risk Management, Bristol-Myers Squibb

Benefit-Risk Communication Strategies: The Patient as a Partner Dinah Duarte, PharmD, MSc

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

#348 Track O6B - Safety and Pharmacovigilance

Featured Topic(s): Quality-GXP, Statistics, Data Management

2:00-3:15pm LEVEL: FORMAT: SESSION Room S402ab CME, Pharmacy, and Nursing

Exploring the Evolution of Signal Detection

CHAIRPERSON

Stephen Knowles, MD, MRCP

Senior Director, Global Patient Safety, Medical and Benefit Risk Management, Eli Lilly and Company

SPEAKER(S)

Evolving Signal Detection: Frequency-Based Approaches to Data Mining

Jeremy Jokinen, PhD, MS

Senior Director, Safety Decision Analytics, AbbVie, Inc.

Advances in Signal Management: Process, Data, and Methods

William Blackwell

Director, Commonwealth Informatics, Belgium

GVP Module 9

Representative Invited

Head of Signal Management, European Medicines Agency, European

#349 Track O6C - Safety and Pharmacovigilance

Featured Topic(s): Patient-Centric

2.00-3.15_{PM} FORMAT: SESSION LEVEL:

Room S403ab CME, Pharmacy, and Nursing

Pharmacovigilance 2.0: Redesigning for the Future

CHAIRPERSON

Annette S. Williams, MBA, RPh

Vice President, Lifecycle Safety, QuintilesIMS

SPEAKER(S)

Pharmacovigilance and the Promise of Artificial Intelligence

Annette S. Williams, MBA, RPh

Vice President, Lifecycle Safety, QuintilesIMS

Pharmacovigilance Innovation

John Whitebrook, PhD

Managing Director, Deloitte Consulting LLP

Unlocking Incredible Value in Safety Databases Together: The Platform Opportunity

Sundeep Surendra Sethi, MD, MBA

Vice President, AbbVie, Inc.

Patient Safety is Everyone's Focus in Research and Development: Not Just in Pharmacovigilance

Robert A. Taylor

Director, Safety Systems Management, Merck & Co., Inc.

#350 Track O7A - Special Populations

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Statistics, Rare Disease, Pediatrics

2:00-3:15_{PM} FORMAT: SESSION LEVEL:

Room S502ab CME, Pharmacy, and Nursing

Innovative Designs and Statistical Approaches for Small Trials: Rare Disease or Pediatric Indications

CHAIRPERSON

Susan Wang, PhD

Director, Biostatistics, Boehringer Ingelheim Pharmaceuticals Inc.

SPEAKER(S)

Statistical Challenges in Assessing Treatment Efficacy from Small-**Sized Clinical Trials**

Yeh-Fong Chen, PhD

Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Adaptive Cloud Based eClinical Design Vital to Embrace Value-Based **Outcomes in Rare Disease**

MaryAnne Rizk, PhD MSc

Vice President, Global CRO Partner Business, Oracle Health Sciences

Innovative Statistical Methods for Measuring Benefit to Patients with **Rare Diseases**

Munish Mehra, PhD

Executive Director, Tigermed

#351 Track O7B - Special Populations

Featured Topic(s): Public Policy

2:00-3:15_{PM} FORMAT: SESSION LEVEL:

Room S501abc CME, Pharmacy, and Nursing

Pregnancy and Lactation Labeling Rule: Unique Challenges to Meet Requirements

CHAIRPERSON

Leslie Driver, PharmD

Director, Regulatory Affairs, GlaxoSmithKline

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P-L-L-R: Not as eXtraordinarily Simple as A-B-C-D

Leslie Driver, PharmD

Director, Regulatory Affairs, GlaxoSmithKline

Pregnancy and Breastfeeding, Drug Development, and the Public Health

Helen Chen, MSc, RAC

Senior Manager, Regulatory Affairs, Novo Nordisk A/S

Innovative Approaches for Conducting a Lactation Study

Nicole R. Hurst

Director, Project Management, PPD

#352 Track O7C - Special Populations

Featured Topic(s): Rare Disease

2:00-3:15pm Level: ■ Format: FORUM

Room S504abcCME, Pharmacy, and Nursing

Collaborative Efforts to Accelerate Rare Disease Research and Development

CHAIRPERSON

Judith Ng-Cashin

Chief Scientific Officer, INC Research

SPEAKER(S)

Rare Disease Clinical Research: Collaboration the Key To Success Judith Ng-Cashin

Chief Scientific Officer, INC Research

Collaborative Efforts to Accelerate Rare Disease Research and Development

Harry W. Alcorn, JR, PharmD

Chief Scientific Officer, DaVita Clinical Research

Patient Organization and Sponsor Collaborations in Rare Disease Therapeutics Research

Trish Caruana, MA

President/Chief Executive Officer, CurePSP- Patient Engagement Program

#353 TRACK O9A - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Student Programming, Statistics

2:00−3:15pm Level: ● Format: WORKSHOP

Room S401bc CME, and Nursing

What do the Experts Believe? Translating Expert Knowledge and Judgment into a Quantitative Belief Distribution

CHAIRPERSON

Timothy H. Montague, PhD, MS

Director, Clinical Statistics, GlaxoSmithKline

SPEAKER(S)

What Do the Experts Believe? Translating Expert Knowledge and Judgment Into a Quantitative Belief Distribution

Timothy H. Montague, PhD, MS

Director, Clinical Statistics, GlaxoSmithKline

Facilitator

Michael Sonksen, PhD, MS

Research Scientist, Eli Lilly and Company

#354 Track 09B - Translational Science: Preclinical/Clinical and Product Development

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Statistics

2:00-3:15pm Level: ■ Format: SESSION

Room \$405a CME, and Nursing

Experimental Studies: New Approaches to Study Designs to Facilitate Early Phase Decision-Making

CHAIRPERSON

Adam F. Cohen, MD, PhD

Chief Executive Officer, Centre for Human Drug Research, Netherlands

SPEAKER(S)

Adam F. Cohen, MD, PhD

Chief Executive Officer, Centre for Human Drug Research, Netherlands

Quantitative Approaches to Design and Analysis of Experimental Medicine Clinical Trials

Genggian Cai, DrSc

Director, Statistics and Programming, GlaxoSmithKline

#355 TRACK O9C - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

2:00-3:15pm Level: ■ Format: FORUM

Room S404bc CME, Pharmacy, and Nursing

FDA, NIH, and TransCelerate Collaborate to Accelerate Drug Development Through Protocol Harmonization

CHAIRPERSON

Robert A. DiCicco, PharmD

Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline

#356 TRACK 10A - VALUE AND ACCESS

Featured Topic(s): Clinical Operations, Academic Clinical Researcher

2:00-3:15pm Level: ■ Format: SESSION

Room S503ab CME, and Nursing

Value-Based Conversations with Payers: Issues, Opportunities, and Barriers

CHAIRPERSON

Richard Gliklich, MD

Chief Executive Officer, OM1, Inc.

SPEAKER(S)

Aligning Stakeholder Needs for Value-Based Contracts

Richard Gliklich, MD

Chief Executive Officer, OM1, Inc.

Moving "Beyond the Pill": A Value-Based Model for Pharma

Robert Duffield

Senior Attorney, Novo Norodisk Inc.

Payer Perspective

Jim Clement, MHA

Executive Director, Cost of Care and Supply Chain Strategy, Aetna, Inc.

#357 TRACK 10B - VALUE AND ACCESS

Featured Topic(s): Clinical Operations, Academic Clinical Researcher

2:00-3:00pm Level: ■ Format: FORUM

Room S405b CME, and Nursing

Biosimilars and Generics: Access Versus Innovation

CHAIRPERSON

Kurt R. Karst, JD

Director, Prescription Drugs and Biologics, Corporate Transactions, Enforcement, Hyman, Phelps & McNamara, PC

PANELISTS

Christine Simmon, JD

Senior Vice President, Policy and Strategic Alliances, Association for Accessible Medicines (AAM)

Crystal Kuntz, MPA

Vice President, Policy, America's Health Insurance Plans (AHIP)

#358 Track 11 - Quality

2:00-3:15pm Level: ■ Format: SESSION

Room S404d CME, and Nursing

Life Cycle Management: ICH Q12

CHAIRPERSON

Moheb M. Nasr, PhD, MS

Vice President, CMC Regulatory Strategy, GlaxoSmithKline

SPEAKER(S)

Technical and Regulatory Consideration of Pharmaceutical Product Life Cycle Management: ICH Q12

Andrew Chang, PhD

Vice President, Quality and Regulatory Compliance, Product Supply Quality, Novo Nordisk A/S

PANELISTS

Sarah Pope Miksinski, PhD

Director, Office of New Drug Products; Director (Acting), Office of Surveillance, Office of Pharmaceutical Quality, CDER, FDA

Mahesh R. Ramanadham, PharmD, MBA

Division Director (Acting), Division of Inspectional Assessment, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

#359 Track 15 - Engage and Exchange

2:00-3:00pm Level: ■ Format: SESSION

Exhibit Hall

Cultural Diversity

CHAIRPERSON

Atsushi Tsukamoto, PhD, MSc

Senior Director, R&D Strategy and Coordination Gr., R&D Planning and Management Department, Daiichi Sankyo Co., Ltd., Japan

#361 TRACK 17 - CONTENT HUB

2:45-3:15pm Format: SESSION

S400 Concourse

Online Health Communities: A New Frontier in Health Research

CHAIRPERSON

Olivier Chateau

Health Union LLC. Health Union LLC

3:00-4:00рм

Refreshment Break

Exhibit Hall

#362 Track 15 - Engage and Exchange

3:15-4:00pm Level: ■ Format: SESSION

Exhibit Hall

Medical Affairs and KOL Management

CHAIRPERSON

Rebecca A. Vermeulen

Head, Customer Strategy Global Medical Affairs, Hoffmann-La Roche Ltd., Switzerland

#363 TRACK O1A - DATA/BIG DATA/EHEALTH

Featured Topic(s): Real World Evidence

4:00-5:15pm Level: ■ Format: FORUM

Room N230b CME, and Nursing

EHRs/eSource and Emerging Data Streams

CHAIRPERSON

Mitra Rocca, MSc

Associate Director, Medical Informatics, Office of Translational Sciences, CDER, FDA

SPEAKER(S)

TransCelerate and HL-7 Opportunities in the World of eSource Julian M. Jenkins, PhD, MSc

Vice President, Innovation Performance and Technology, GlaxoSmithKline

Japan Nationwide HL7 Based EHR Storage SS-MIX2 and Applications from Local Case Cards to Nationwide Adverse Event Detection

Michio Kimura, MD, PhD

Professor and Director, Department of Medical Informatics, Hamamatsu University School of Medicine, Japan

eSource and Building the Learning Health Care System

Michael A. Ibara, PharmD

Head, Digital Healthcare, CDISC

Unlocking the Value of Electronic Health Record Data in Clinical Research

Mary Varghese Presti, BSN, MPH

Executive Director, Emerging Services, athenahealth

#364 TRACK O1B - DATA/BIG DATA/EHEALTH

Featured Topic(s): RBM, Clinical Operations

4:00-5:15pm Level: ■ Format: FORUM

Room N226 CME, and Nursing

Risk-Based Monitoring: Convergence of Technology, Processes, and People: Panel Discussion

CHAIRPERSON

Francois Torche, MBA

Chief Executive Officer, CluePoints, Belgium

SPEAKER(S)

Risk-Based Monitoring Implementation Demystified

Francois Torche, MBA

Chief Executive Officer, CluePoints, Belgium

Monitoring the Evolving Regulatory Landscape: Understanding New Implications for Risk-Based Monitoring

Jill Collins, MS

Executive Director, Global Operations Management, Innovation, INC Research

The Decisive Role of a Risk-Based Quality System and Risk-Based Monitoring Based on an Example of Two Phase 3 Clinical Trials: A Case-Study

Artem Andrianov, PhD, MBA

Chief Executive Officer, Cyntegrity Germany Gmbh, Germany

#365 Track O2A - Disruptive Innovation

Featured Topic(s): Real World Evidence, Statistics, Clinical Operations, Academic Clinical Researcher

4:00-5:15pm Level: ■ Format: SESSION

Room \$503ab CME, and Nursing

Next Generation Predictive Analytics

CHAIRPERSON

Lucas Glass, MS

Head of Machine Learning Research, QuintilesIMS

SPEAKER(S)

Real-World Data and Machine Learning to Predict Study Enrollment Rates During Early Planning

Lucas Glass, MS

Head of Machine Learning Research, QuintilesIMS

With Our Powers Combined: Using Predictive Analytics for Boosting Model Accuracy and Future Applications

Petra Lebeau, DrSc

Senior Biostatistician III, Rho, Inc.

Looking Beyond What's Already Known to Map Future Clinical Outcomes

Aris Persidis, PhD

President, Biovista Inc.

#366 Track O2B - DISRUPTIVE INNOVATION

Featured Topic(s): Clinical Operations

4:00-5:15pm Level: ■ Format: SESSION

Room S504abc CME, Pharmacy, and Nursing

Are We Ready for Telemedicine-Powered Clinical Trials?

CHAIRPERSON

Karen D. Weiss, MD, MPH

Vice President, Global Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

SPEAKER(S)

Straight from the Horse's Mouth: Lessons Learned from Legal and Regulatory Challenges of Real Remote Trials

Gerrit Hamre, MA

Clinical Project Manager, Clinical Trials Transformation Initiative (CTTI)

A Telemedicine Proof of Concept Study Evaluating the Remote Detection of Alzheimer's Disease and Categorization of Severity Penny Randall, MD

Global Therapeutic Head, CNS, QuintilesIMS

Can Mobile Apps Faciltate the Use of Telemedicine Wayne Amchin, MA, MPA, RAC

Senior Consumer Safety Officer, DCRP, ODE I, Office of New Drugs, CDER, FDA

#367 Track O3A - Medical Affairs and Scientific Communication

Featured Topic(s): Patient-Centric, Medical Writing, Global Regulatory

Writing of Layperson Summaries of Clinical Trial Results According to the EU: Regulation and its Impact on Global Pharmaceutical Activities

CHAIRPERSON

Susannah Chang, PhD

Manager, Oncology Regulatory Medical Writing, Janssen Pharmaceutical Companies of Johnson & Johnson

SPEAKER(S)

Plain Language Summaries: Large Scale Writing and Process Implementation

Tatyana V. Wanderer, PhD

Director, Strategic Partnership Alliances, Synchrogenix, a Certara Company

Layperson Summaries: Gathering Patient Insights and Evolving Processes

Amber Barnes, PhD, RAC

Associate Director, Global Medical Writing, UBC, An Express Scripts Company

Meeting the EU Mandate for Plain Language Trial Results Summaries: Successes, Challenges, and Key Considerations

Behtash Bahador

Program Manager, CISCRP

FORMAT: SESSION

#368 Track O3B - Medical Affairs and Scientific COMMUNICATION

4:00-5:15рм LEVEL: FORMAT: FORUM

CME, Pharmacy, and Nursing Room N227b **FDA Update on Prescription Drug Promotion**

CHAIRPERSON

John Kamp

Executive Director, Coalition For Healthcare Communication

SPEAKER(S)

OPDP Enforcement and Guidance Updates

Thomas W. Abrams, MBA

Director, Office of Prescription Drug Promotion, Office of Medical Policy, CDER. FDA

Social Science Research

Helen W. Sullivan, PhD, MPH

Social Science Analyst, Office of Prescription Drug Promotion, CDER, FDA

#369 Track 04 - Patient Engagement

Featured Topic(s): Clinical Operations, Patient-Centric

4:00-5:15pm FORMAT: SESSION FVFI:

Room S404a CME, and Nursing

How Is Digital Patient Engagement Impacting Trial Participation?

CHAIRPERSON

Abbe Steel, MSc

Founder and Chief Executive Officer, HealthiVibe, LLC

Mindfulness in Design: Leveraging The Patient Perspective In Virtual **Clinical Trials**

Abbe Steel, MSc

Founder and Chief Executive Officer, HealthiVibe, LLC

Digital Patient Engagement Case-Study: Key Metrics and Insights Kai Langel

Founder and Director, Patient Solutions, eClinicalHealth, United Kingdom

Senior Director, R&D Operations, Innovation, Janssen Pharmaceutical Companies of Johnson & Johnson

#370 TRACK O5A - REGULATORY

Featured Topic(s): Patient-Centric, Rare Disease, Public Policy

FORMAT: FORUM 4:00-5:15pm LEVEL:

Room S404bc CME, Pharmacy, and Nursing

Lessons Learned from the Sarepta Exondys 51 Approval

CHAIRPERSON

Shamim Ruff, MSc

Senior Vice President of Regulatory Affairs and Quality, Sarepta Therapeutics

SPEAKER(S)

A Challenging Path: Bridging Patient Needs with Regulatory Approval Requirements

Shamim Ruff, MSc

Senior Vice President of Regulatory Affairs and Quality, Sarepta

Therapeutics

The Role of the Patient Perspective in the Approval of Exondys 51 Christine McSherry, RN

Executive Director, The Jett Foundation

The Evolving Role of Orphan Drug and Subpart H Flexibility in Drug **Approval**

Alexander Varond, JD

Associate, Goodwin Procter

#371 TRACK O5B - REGULATORY

Featured Topic(s): Global Regulatory

4:00-5:15_{PM} FORMAT: SESSION LEVEL:

Room S403ab CME, and Nursing

Global and Regional Collaboration Initiatives: Challenges, **Opportunities, and Case Studies**

CHAIRPERSON

Joseph C. Scheeren, PharmD

Senior Vice President, Head Regulatory Affairs, Pharma and Consumer Health, Bayer, Switzerland

SPEAKER(S)

Regulatory Collaboration Initiatives in Order to Accelerate Approval **Process in Developing Countries**

Petra Doerr, PharmD, PhD, RPh

Deputy Executive Director, Swissmedic, Switzerland

Collaborative Registration Procedure, A Tool to Accelerate Regulatory Approvals: Life-Saving Drugs Case-Study in Africa

Mercè Caturla Goñi, DrSc, PhD

Global Access Regulatory Leader, Regulatory Policy (Africa and WHO), Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium

A Novel Tool to Support Optimized Regulatory Strategies for Emerging Markets: A Case Study

Rajneesh Taneja, PhD

Senior Director, Pharmaceutical Product Development, TB Alliance

#372 TRACK O5C - REGULATORY

4:00-5:15_{PM} LEVEL: FORMAT: SESSION

Room N229 CME, and Nursing

The Reauthorization of GDUFA and its Impact on Sponsor and Regulator

CHAIRPERSON

Linda F. Bowen, MSc, RAC

Senior Director, Global Regulatory Science and Policy, Sanofi

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Complex Generics: How Pre-ANDA Interactions with the Office of Generic Drugs Work

Robert A. Lionberger, PhD

Director, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

GDUFA II and Regulatory Science Initiatives: Complex Generic Drug Enhancements for GII

Scott Tomsky

Vice President, Regulatory Affairs, Generics, North America, Teva Pharmaceutical

Industry Perspective

Keith Webber, PhD

Senior Director, Rx Regulatory Affairs, Perrigo Company plc

#373 TRACK O5D - REGULATORY

Featured Topic(s): Student Programming, Global Regulatory

4:00–5:00pm Level: ■ FORMAT: FORUM Room S401d CME, and Nursing

FDA-Health Canada Regulatory Cooperation Council Town Hall

CHAIRPERSON

Sema D. Hashemi, MSc

Director, Office of Regional and Country Affairs, Office of International Programs, Office of the Commissioner, FDA

PANELIST

Ed Morgan

Director General, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Health Canada

#374 TRACK OSE - REGULATORY

Featured Topic(s): Student Programming, Global Regulatory, Statistics, Clinical Operations, Academic Clinical Researcher

4:00-5:15pm Level: ■ Format: FORUM

Room N228 CME, Pharmacy, and Nursing

Global Perspective on ICH: Part 2 of 2

CHAIRPERSON

Patrick K. Brady, PharmD

Regulatory Policy and Intelligence, Bayer

SPEAKER(S)

Fostering Simultaneous Global Development via Regulatory Harmonization and ICH Reforms

Camille Jackson

Senior Director, Science and Regulatory Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA)

Partnership and Global Connectivity After ICH's Reform: New Opportunities for Global Regulatory Harmonization and Advancing Regulatory Science

Jerry Stewart, JD, MS, RPh

Deputy Vice President, Scientific and Regulatory Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA)

PANELIST

Lawrence Eugene Liberti, MS, RPh, RAC

Executive Director, Centre For Innovation In Regulatory Science (CIRS)

#375 Track O6A - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Statistics

4:00-5:15pm Level: ■ Format: SESSION

Room \$402ab CME, and Nursing

Automation and Innovation in Clinical Trial Safety Assessment

CHAIRPERSON

Susan P. Duke, MSc

Consultant, Safety Statistics

SPEAKER(S)

Removing an ICH Bottleneck: Efficient Safety Assessment Using Computer-Generated Adverse Event Narratives

Richard C. Zink, PhD

Principal Research Statistician Developer, JMP Life Sciences Division, SAS Institute Inc.

How We do Safety Review Using Spotfire?

Wei Wang, MD, MPH

Research Scientist, Eli Lilly and Company, Canada

Algorithmic Approach for Real-Time Safety Data Review to Make Safety Management Subject Centric and Reduce Inherent Trial Risk Vasudeo Ginde, MD

President, DiagnoSearch Life Sciences, India

#376 TRACK O6B - SAFETY AND PHARMACOVIGILANCE

Featured Topic(s): Global Regulatory, Devices-Combination Products

4:00-5:15pm Level: ■ Format: SESSION

Room S404d CME, Pharmacy, and Nursing

Changing Environments Within Pharmacovigilance

CHAIRPERSON

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP

Vice President, Global Head of Risk Management, QuintilesIMS, United Kingdom

SPEAKER(S)

Navigating Through the World of Combination Product Safety Khaudeja Bano, DrMed, MS

Senior Medical Director, Medical Affairs, Diagnostics Abbott Laboratories

Regulatory Scientific Significance of Japan's Postmarketing Adverse Event Relief System

Toshiyoshi Tominaga, PhD

Associate Executive Director (for International Programs), Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Overview of Changes to the FDA Pharmacovigilance Regulatory Landscape

LaShanda Long, MS

Supervisor, Office of Scientific Investigations, Office of the Commissioner, CDER_EDA

#377 Track O7A - Special Populations

Featured Topic(s): Clinical Operations, Patient-Centric

4:00-5:15pm Level: ■ Format: SESSION

Room S505ab CME, Pharmacy, and Nursing

Increasing Participation in Clinical Trials Among Under-Represented Populations

CHAIRPERSON

Mary Stober Murray, MBA

Associate Director, Diversity and Patient Engagement, Bristol-Myers Squibb

SPEAKER(S)

Young Adults Matter in Cancer Clinical Research

Mary Stober Murray, MBA

Associate Director, Diversity and Patient Engagement, Bristol-Myers Squibb

Needle in a Haystack: Using Digital Recruitment to Reach Your Target Population

Emily Cortez

Vice President, Program Director, TBWA/WorldHealth

Diversity Is Not a "Trending Topic"

Kim Ribeiro, MS, MT

Manager, Strategic Patient Recruitment and Retention, AbbVie, Inc.

The Inclusive Clinical Trial: Involving Diverse Populations in Clinical Trial Design

Kelly Franchetti, BSN, RN

Vice President, Global Head Patient Insights and Engagement, Mapi

#378 Track O7B - Special Populations

Featured Topic(s): Pediatrics, Global Regulatory

4:00-5:15pm Level: ■ FORMAT: SESSION

Room S501abc CME, Pharmacy, and Nursing

Looking to the Future for EU Pediatric Investigation Plans

CHAIRPERSON

Grant Strachan, LLM

Senior Associate, Regulatory, Bristows LLP, United Kingdom

SPEAKER(S)

Growing up with the EU Pediatric Regulation: The Opportunities and Obstacles of Developing Pediatric Medicines in Europe

Grant Strachan, LLM

Senior Associate, Regulatory, Bristows LLP, United Kingdom

European Pediatric Investigation Plans (PIPs) Need Better Scientific Processing by Pharmaceutical Industry

Klaus Rose, MD, MS

Chief Executive Officer, klausrose Consulting, Switzerland

A Comparison of the US and EU Pediatric Regulatory Requirements and the Impact to Global Drug Development

Melodi J. McNeil, MS, RPh

Director, AbbVie, Inc.

#379 Track O8A - Strategic Planning/Execution and Partnerships

Featured Topic(s): Career Development, Student Programming

4:00-5:15pm Level: ● FORMAT: WORKSHOP

Room S401bc CME, Nursing, and PMI PDUs

The Art of Negotiation: Preparing Yourself and Your Team for Their Seat at the Table

CHAIRPERSON

Jennifer A. Emerson, PhD, PMP

Owner, Emerson Consulting & Clinical Research Services, Germany

SPEAKER(S)

The Art of Negotiation: Strategies for Success and Leadership at the Bargaining Table

Jennifer A. Emerson, PhD, PMP

Owner, Emerson Consulting & Clinical Research Services, Germany

Stakeholder Engagement and Effective Governance Decision-Making Nathan R. Kreischer. MS. PMP

Associate Director, Global Project and Alliance Managment, Merck & Co., Inc.

#380 Track 08B - Strategic Planning/Execution and Partnerships

Featured Topic(s): Clinical Operations, Student Programming

4:00-5:15pm Level: ● Format: SESSION

Room N426a CME, Nursing, and PMI PDUs

Effective Portfolio Management and how to Ensure You Get the Value out of the Decisions Made

CHAIRPERSON

Kemi Yusuf, MBA, PMP

Director, Business Solutions Project Management, AbbVie, Inc.

SPEAKER(S)

The Art and Science of Effective Portfolio Management: How to Make the Right Portfolio Decisions and Make Them Stick

Kemi Yusuf, MBA, PMP

Director, Business Solutions Project Management, AbbVie, Inc.

Defining and Obtaining Value as a Result of Portfolio Management: Considerations for Pharma and Biotech Companies

Dan Tierno, MA, MBA

Strategic Implementation Manager, Bayer

When it's Time to Call it Quits: Close Out of Late-Stage Clinical Programs

Larissa Wilsie, MS, PMP

Senior Specialist, Project Management, Merck & Co., Inc.

#381 Track OSC - Strategic Planning/Execution and Partnerships

Featured Topic(s): Academic Clinical Researcher, Clinical Operations, Devices-Combination Products

4:00-5:15pm Level: ■ Format: SESSION

Room N426b CME, Nursing, and PMI PDUs

Maximizing Success in Partner Collaborations

CHAIRPERSON

Shann Williams, PMP

Senior Director, Operations, Rho, Inc.

Competing or Complementary Demands? How Seemingly Opposing Needs from Government and Pharmaceutical Clients Created Cohesion Shann Williams. PMP

Senior Director, Operations, Rho, Inc.

Beat AML: A Ground Breaking Master Trial Run by a Consortium of AROs, Global Drug Companies, CRO, and eClinical Vendors

Len Rosenberg, PhD, RPh

Head, Clinical Operations, Leukemia and Lymphoma Society

The Execution Evolution: Exploring the Untapped Value in Medical Device CRO Partnerships

Charles Raymond, MBA

Manager, Commercial Affairs, ICON, plc

#382 TRACK O9A - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Patient-Centric

4:00-5:15pm Level: ■ Format: SESSION

Room \$405a CME, and Nursing

Patient-Relevant, Fit-For-Purpose Endpoints: If You Can Believe It, You Can Achieve It

CHAIRPERSON

Electra Johanna Papadopoulos, MD, MPH

Associate Director, Clinical Outcome Assessments Staff, Office of New Drugs, CDER, FDA

SPEAKER(S)

Best Practices for Facilitating the Development and Use of Patient-Focused, Fit-For-Purpose COA Endpoints in Clinical Trials Ebony N. Dashiell-Aie, PhD

Clinical Outcome Assessments Reviewer, COA Staff, Office of New Drugs, CDER_EDA

Industry Initiatives: Cultural Shifts Impacting COA Development and Implementation in Clinical Trials

Lisa A. Kammerman, PhD, MS

Senior Statistical Science Director, AstraZeneca

Practical Experiences in Designing Patient-Focused COAs for Use as Endpoints in Clinical Trials: An Instrument Developer's Perspective Chad Gwaltney, PhD

Principal Consultant, Gwaltney Consulting

#383 TRACK O9B - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher

4:00-5:15pm Level: ■ Format: SESSION

Room S405b CME, and Nursing

Safety Issues in First-in-Human Studies

CHAIRPERSON

David R. Jones, MS

Expert Pharmacotoxicologist, Clinical Trials Unit, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

SPEAKER(S)

The New EU Guidance for First-In-Human Clinical Trials

David R. Jones, MS

Expert Pharmacotoxicologist, Clinical Trials Unit, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Safety Issues in First-in-Human Studies

Charu Gautam, MD

Head, Early Clinical Development, Asia Pacific, QuintilesIMS, India

First-In-Human Nonclinical Testing and Starting Dose Considerations Paul Baldrick, PhD

Covance Inc., United Kingdom

#384 TRACK 10 - VALUE AND ACCESS

Featured Topic(s): Clinical Operations, Academic Clinical Researcher

4:00-5:15pm Level: ■ Format: SESSION

Room S401a CME, Pharmacy, and Nursing

The Increasing Role for Big Data for Late Phase Drug and Postapproval Purposes

CHAIRPERSON

Gregory Daniel, PhD, MPH, RPh

Deputy Director and Clincial Professor, Duke-Margolis Center For Health Policy

SPEAKER(S)

Fulfilling the Vision of Sentinel as a National Resource: Public Access Through the Reagan-Udall Foundation for the FDA

David Martin, MD, MPH

Liaison to the Reagan-Udall Foundation IMEDS Program, Office of Medical Policy, CDER, FDA

PCORI Perspective

Joe V. Selby, MD, MPH

Executive Director, Patient-Centered Outcomes Research Institute (PCORI)

#385 TRACK 11 - QUALITY

4:00-5:15pm Level: ■ Format: SESSION

Room N426c CME, and Nursing

Patient-Centric Development Assessment

CHAIRPERSON

Mahesh R. Ramanadham, PharmD, MBA

Division Director (Acting), Division of Inspectional Assessment, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

SPEAKER(S)

Industry Perspective

Michael R. De Felippis, PhD

Senior Research Fellow, Biopharmaceutical Research and Development, Eli Lilly and Company

Incorporating Clinical Needs of Products into Quality Assessment Diane J. Zezza

Vice President and Global Head, Regulatory CMC, Novartis Pharmaceuticals Corporation

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THURSDAY, JUNE 22

Registration Hours

8:00-11:00am Attendee and Speaker Registration

8:00-9:00am

Coffee and Light Refreshments S102 Lobby

#401 TRACK 12



Featured Topic(s): Public Policy, Devices-Combination Products,

Student Programming 9:00-10:30AM

Room S100a

LEVEL:

FORMAT: FORUM

CME, and Nursing

FDA Forum

CHAIRPERSON

Representative Invited

United States

PANELISTS

Peter W. Marks, MD, PhD

Director, Center for Biologics Evaluation and Research, FDA

Angela C. Krueger

Acting Deputy Director, Office of Device Evaluation, CDRH, FDA

Douglas C. Throckmorton, MD

Deputy Director, Regulatory Programs, Office of the Center Director, CDER. FDA

John Barlow Weiner, JD

Associate Director, Policy and Product Classification Officer, Office of Clinical Pharmacology, Office of the Commissioner, FDA

Richard Pazdur, MD

Director, Oncology Center of Excellence, FDA

10:30-10:45_{AM}

Refreshment Break

S400 Concourse

#402 Track 02 - Disruptive Innovation

Featured Topic(s): Patient-Centric, Clinical Operations, Academic Clinical Researcher

10:45AM-12:00PM FORMAT: FORUM LEVEL:

Room S404a CME, Pharmacy, and Nursing

Online Patient Networking

CHAIRPERSON

Lindsay McNair, MD, MPH, MS

Chief Medical Officer, WIRB-Copernicus Group

SPEAKER(S)

Online Patient Networking: Should We Have Concerns for Impact on Clinical Research?

Lindsay McNair, MD, MPH, MS

Chief Medical Officer, WIRB-Copernicus Group

Engaging Patient Social Networks in the Design of Clinical Studies Eric J. Peacock, MBA

Co-founder and Chief Executive Officer, MyHealthTeams

2.5 Billion Opinions from 50 Million Health Care Users: A Guide to Health-Related Social Media

Andrew Paul Cox, PhD

Research Scientist, Evidera, United Kingdom

#403 Track 03 - Medical Affairs and Scientific **COMMUNICATION**

Featured Topic(s): Medical Writing, Global Regulatory

10:45-11:45_{AM} FORMAT: SESSION

Room S403ab CME, and Nursing

Driving International Awareness and Use of Regulatory Writing Guidelines: Case Studies of the Clarity and **Openness in Reporting (CORE) Reference Guidelines**

CHAIRPERSON

Art Gertel

President and Principal Consultant, MedSciCom, LLC

SPEAKER(S)

Best Practices for Driving Awareness and Use of International Guidelines: CORE Reference Guideline Case-Study - EU, US, Japan

Hiroko Ebina, MBA, MPharm, RPh

Principal Writer I, Proscribe KK, Japan

Case Study for (CORE) Reference Guidelines

Vivien Fagan

Director, Global Medical Writing and Document Publishing, QuintilesIMS, United Kingdom

#404 Track 04A - Patient Engagement

Featured Topic(s): Patient-Centric

10:45AM-12:00PM FORMAT: FORUM LEVEL:

Room N426b CME, and Nursing

How Do You Build a Collaborative Community? What **Advice Would You Give?**

CHAIRPERSON

Roni Zeiger, MD

Chief Executive Officer, Smart Patients

Creating Online Communities Where Patients and Pharma Collaborate to Improve Clinical Trials

Roni Zeiger, MD

Chief Executive Officer, Smart Patients

iConquerMS™: Accelerating Research into Multiple Sclerosis Through **Collaboration and Community**

Sara Loud, MBA, MS

Chief Operating Officer, Accelerated Cure Project

Driving the Future: Unique Partnerships to Harness Clinical Trial Innovation and Optimization

Christina Marie Fawcett, PMP

Director of Operations, PRA Health Sciences

The Collaborative Process of Creating the Cystic Fibrosis Care Model of the Future

Erin Moore

ePatient Advisor, Eli Lilly and Company

#405 Track 04B - Patient Engagement

Featured Topic(s): Clinical Operations, Patient-Centric

10:45ам-12:00рм FORMAT: SESSION

Room N426c CME, Pharmacy, and Nursing

How Do We Retain Patients in Studies? Using the Patients' **Words to Explore Treatment Acceptance and Patient Engagement**

CHAIRPERSON

Benoit Arnould, PhD, MSc

Senior Director, Global, Patient-Centered Outcomes, Patient Centered Sciences, Mapi, France

SPEAKER(S)

Did You Get Why Patients Accept (or Not) Their Long-Term Treatment? Results from an EU Study Via Carenity Social Platform

Benoit Arnould, PhD, MSc

Senior Director, Global, Patient-Centered Outcomes, Patient Centered Sciences, Mapi, France

Panelist

Hellen Kitchen, MSc

Senior Consultant, DRG Abacus, United Kingdom

Patient Perspective

James A. Seaton

Executive Consultant; PatientsLikeMe Team of Advisors, Seaton Associates, LLC

Online Platform Perspective

Brian Burns

Director, Member Communications, PatientsLikeMe

#406 Track O7A - Special Populations

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Rare Disease

10:45AM-12:00PM FORMAT: SESSION

Room S401a CME, Pharmacy, and Nursing

Recruiting Rare Disease Patients: A Unique Set of **Challenges**

CHAIRPERSON

William B. Smith. MD

President, New Orleans Center for Clinical Research

SPEAKER(S)

Sharing the Mission to Conquer Rare Diseases: Partnering with **Advocacy Groups for Trial Recruitment**

Heather Gartman, MA

Consultant, Gartman PR

Big Data with Investigator and Patient Advocacy Outreach in **Idiopathic Pulmonary Fibrosis: A More Complete Picture**

Adina Kay Knight, MD

Medical Director, QuintilesIMS

#407 Track 07B - Special Populations

Featured Topic(s): Academic Clinical Researcher

10:45AM-12:00PM LEVEL: FORMAT: SESSION

Room S401d CME, and Nursing

Exploration of Metabolic Diseases: Is the Liver the New Heart?

CHAIRPERSON

Clavton Dehn, MS

Senior Vice President, Early Phase Service and Strategic Development. Clinical Trials of Texas, Inc.

SPEAKER(S)

Liver Let Die: Challenges and Opportunities in Developing Early **Interventions for Fatty Liver Disease**

Clavton Dehn, MS

Senior Vice President, Early Phase Service and Strategic Development, Clinical Trials of Texas, Inc.

Challenges and Opportunities in Clinical Development in Non-Alcoholic Steatohepatitis (NASH): Drugs for NASH Paving the Way Claudia M. Filozof, DrMed

Executive Medical Director, Covance Inc., United Kingdom

Understanding the Natural History and Health Burden of Nonalcoholic Fatty Liver Disease (NAFLD): America's Newest Epidemic

Naim Alkhouri, MD

Director of the Metabolic Center, Texas Liver Institute

The DASH to Treat NASH

Melissa Palmer

Global Development Lead, NASH, Shire

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#408 Track 08 - Strategic Planning/Execution and Partnerships

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Student Programming, Patient-Centric

Student Programming, Patient-Centric
10:45am−12:00pm Level: ■ Format: SESSION

Room S404d CME, Nursing, and PMI PDUs

Flexing Your Project Management Muscles Outside of Traditional Roles

CHAIRPERSON

Gina Maria Johns, PMP

Founder and Project Manager, Ocean Consulting Solutions LLC

SPEAKER(S)

Getting Out of Your Comfort Zone: A Drug Development Project Manager on a Patient-Centered Initiative

Carrie Furin

Pharmaceutical Project Manager, Eli Lilly and Company

From Bench Chemist to Business Owner: How a Career in Nontraditional Project Management Roles Created Career Opportunity Gina Maria Johns, PMP

Founder and Project Manager, Ocean Consulting Solutions LLC

Associate Project Manager, Coordinator, Planner: PM Roles and Their Link to Departmental Structure and Vision

Juan Castano, MBA, PMP

Associate Director, Asset Planner, Pfizer Inc.

#409 Track 09A - Translational Science: Preclinical/Clinical and Product Development

Featured Topic(s): Quality-GXP

10:45am-12:00pm Level: ■ Format: SESSION

Room \$402ab CME, and Nursing

Trial Master File: MHRA/EMA Inspections and Sponsor Audit Learnings

CHAIRPERSON

Renne S. Heuser

Program Lead, Clinical Program Development, AbbVie, Inc.

SPEAKER(S)

Trial Master File: Telling the Study Story Through Documentation Renne S. Heuser

Program Lead, Clinical Program Development, AbbVie, Inc.

Industry Perspective

Bryan Christopher Souder

Associate Director, Global Operations, Merck & Co., Inc.

Industry Perspective

Tipsuda Kongtong, MPH

Manager, Clinical Quality Assurance, Eisai, Inc.

#410 TRACK O9B - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Quality-GXP, Data Management

10:45am−12:00pm Level: ■ Format: SESSION

Room S405a CME, and Nursing

Of Course My Data Has Integrity...And I Can Prove It

CHAIRPERSON

David William Fryrear, MSc

Senior Director, R&D Quality Assurance, AbbVie, Inc.

SPEAKER(S)

Applying Data Integrity to Clinical Trials and Regulator Expectations: Comparing Standards from the FDA, EMA, and MHRA

Sherri A. Hubby

Senior Director, Quality Assurance, Risk, and Compliance, Premier Research

Data Integrity in FDA-Regulated Clinical Trials

Adam C. Donat, MS

Branch Chief, CEB, Office of Scientific Investigations, Office of Compliance, CDER, FDA

Data Integrity: Not an Act But a Habit

Cinzia Piccini

Medical Quality Organization, Biometrcis Consultant, Eli Lilly and Company, Italy

#411 TRACK O9C - TRANSLATIONAL SCIENCE: PRECLINICAL/CLINICAL AND PRODUCT DEVELOPMENT

Featured Topic(s): Clinical Operations, Academic Clinical Researcher, Quality-GXP

10:45-11:45AM LEVEL: ■ FORMAT: SESSION

Room \$405b CME, and Nursing

Evolving Clinical Trial Guidance and Regulations: Am I Ready?

CHAIRPERSON

Liz Wool, BSN

Global Head of Training, Barnett International

SPEAKER(S)

ICH GCP E6 R2 Addendum Overview and Impact Assessment Liz Wool, BSN

Global Head of Training, Barnett International

EU Clinical Trial Regulation 536/2014 Overview and Impact Assessment

Mary Mills, RN

President, Mary Mills & Associates, LLC





Featured Topic(s): Global Regulatory, Public Policy, Pediatrics, Student Programming

10:45am−12:00pm Level: ■ Format: FORUM

Room \$100a CME, and Nursing

EMA/FDA Question Time

CHAIRPERSON

Sabine Haubenreisser, PhD

Liaison to the US FDA, European Medicines Agency, European Union

SPEAKER(S)

Sandra L. Kweder, MD, FACP

Deputy Director, Liaison to the EMA, Office of International Programs, Office of the Commissioner, FDA

Real-World Data

EMA and FDA Representative Invited

Mutual Recognition Agreement

EMA and FDA Representative Invited

Quality

EMA and FDA Representative Invited

Transparency

EMA and FDA Representative Invited

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POSTER PROGRAM

Student Poster Session

Monday, June 19 10:00AM-6:00PM | Posters will be displayed in the Exhibit Hall Award Ceremony at 5:30PM | Exhibit Hall

This year's Student Poster Program features students from various academic institutions from all over the world who will showcase their latest research. Student Poster presenters will be judged for their poster and onsite presentation on Monday and recognized at the Student Poster Award Ceremony held at 5:30_{PM} on Monday in the poster area of the Exhibit Hall.

Track 1 Data/Big Data/eHealth

M-01 Does Medication Therapy Management by Pharmacists Lower Cost-Related Medication Nonadherence in Medicare Beneficiaries

Taylor Walsh, PharmD

South Carolina College of Pharmacy
ORAL PRESENTATION: Session #134, 12:30PM

Track 2 Disruptive Innovation

M-02 Study of Cerebrospinal Fluid Adenosine Deaminase for Differential Diagnosis of Tuberculous and Non-tuberculous Meningitis

Seema Singh, DrMed, MD

Sasoon Medical College and Hospital, India

M-03 To Evaluate Efficacy of Aerobic Exercise as an Addition to the Existing Treatment in Primary Open Angle Glaucoma Patients

Akhil Agrawal, DrMed

Sinhagad Institute, India

ORAL PRESENTATION: Session #134, 12:39PM

Track 3 Medical Affairs and Scientific Communication

M-04 Characterizing a Good Drug Review

Yen Ping Lim, MPharm

National University of Singapore, Singapore

Track 5 Regulatory

M-05 Public Knowledge and Perception of Clinical Research in Mumbai

Ashnik Chauhan

Seth GS Medical College and KEM Hospital, India ORAL PRESENTATION: Session #134, 12:48PM

M-06 Analysis of FDA Guidance of Off-Label Medical Product Advertising

Kirolous Makarious

Touro College of Pharmacy

ORAL PRESENTATION: Session #134, 12:57pm

M-07 Efficacy of Unapproved Drugs in Compassionate use in Comparison with Clinical Trial Results: A Systematic Review

Mio Saito

Keio University, Japan

ORAL PRESENTATION: Session #134, 1:06PM

M-08 Postmarketing Drug Dosage Changes of 413 FDA-Approved New Molecular Entities, 2000-2014

Anh Duong

Touro College of Pharmacy

ORAL PRESENTATION: Session #134, 1:15pm

M-09 Priority Review Voucher: Can the Objective be Realized?

Sanjana Sahetya

St. John's University

ORAL PRESENTATION: Session #134. 1:24pm

M-10 Trend Analysis of the Top 20 Most Frequently Issued Form 483's by the Food and Drug Association (FDA) From 2006 to 2016.

Priyal Soni

Rutgers University

ORAL PRESENTATION: Session #134, 1:33pm

Track 6 Safety and Pharmacovigilance

M-11 Pharmacovigilance Summary Reports: Global Challenges with Harmonization of Canadian, American and European Perspectives

Eliane Barras, MS

Humber College, Canada

ORAL PRESENTATION: Session #134, 1:42PM

Track 7 Special Populations

M-12 Prevalence and Characteristics of Electronic Cigarette use Among Individuals with COPD in the United States

Anne Shah, PhD, MS

Virginia Commonwealth University
ORAL PRESENTATION: Session #134, 1:51PM

Track 8 Strategic Planning/Execution and Partnerships

M-13 Development Challenges for Maternal and Child Health Care Institutions in China: A Qualitative Study in Chengdu

Mena Li. MSc

University of Macau, Macau

ORAL PRESENTATION: Session #134, 2:00pm

Track 9 Translational Science: Preclinical/Clinical and Product Development

M-14 Assessing Consistency of Subgroup Specific Treatment Effects in Clinical Trials with Binary Endpoints

Susann Grill

University of Bremen, Germany

ORAL PRESENTATION: Session #134, 2:09PM

M-15 Clinical Trials of Medical Devices: Decisional Trees for Optimizing the Choice of Study Design

Célia Bouharati, MPharm

Université Claude Bernard - Institut De Pharmacie Industrielle De Lyon, France

ORAL PRESENTATION: Session #134, 2:18pm

M-16 Protective Effect of Juice, Ether and Ethyl Acetate Extracts of Benincasa Hispida Fruit in PTZ Induced Seizures in Zebra Fish

Deena D'Souza

Bombay College of Pharmacy, India ORAL PRESENTATION: Session #134, 2:27pm

M-17 Therapeutic Cancer Vaccines: Overview of Phase 3 Clinical Trials

Noreen Hussain

Touro College of Pharmacy

ORAL PRESENTATION: Session #134, 2:36PM

Track 10 Value and Access

M-18 Cost Utility Analysis of Fixed Versus Free Dose Antihypertensiv Combinations: Evidence From the 2014 MEPS

Mona Nili, PharmD, MBA

St. John's University

ORAL PRESENTATION: Session #146, 4:45pm

M-19 The Rising Cost of Generic Drugs (2013 - 2016): A Review

Gian King

Ernest Mario School of Pharmacy

ORAL PRESENTATION: Session #146, 4:54PM

Track 11 Quality

M-20 Quality and Report of Subgroup Analysis in Randomized Controlled Trials

Aurélien Grolleau, MSc

Université Claude Bernard - Institut De Pharmacie Industrielle De Lyon, France

ORAL PRESENTATION: Session #146, 5:03pm

Clinical Research

M-21 Can Laughter Therapy be Used as an Add-on Therapy Along with Anti-Anxiety and Anti-Depression Drugs? An Interventional Research.

Muntazir Ali Sayed

RCSM Government Medical College and CPR General Hospital, India ORAL PRESENTATION: Session #146, 5:12PM

Professional Poster Session

Tuesday, June 20 9:00AM-5:00PM | Posters will be displayed in the Exhibit Hall

Life Sciences Professionals from all fields related to the mission of DIA will participate in this year's Professional Poster Program. There will also be oral presentations where select poster authors will deliver an overview of their work. Presentations will be held in the Poster Area located in the Exhibit Hall.

Track 1 Data/Big Data/eHealth

T-01 An Innovation: Automated Statistical Programming with CDISC Analysis Results Metadata

Zhongwei Zhou, MS

Pfizer Inc

T-02 Collaborative Efforts Toward Full-Scale Utilization of Medical Information Database Network (MID-NET*)

Maori Ito, MSc

Pharmaceuticals and Medical Devices Agency (PMDA), Japan ORAL PRESENTATION: Session #236, 12:00PM

T-03 Diabetes Defender - Changing At-Risk Population Behavior

Fatima Paruk, MD

Allscripts

ORAL PRESENTATION: Session #236, 12:09PM

T-04 Incorporating HIT Within REMS Programs to Address REMS Stakeholder Burden

Kevin White

Celgene

ORAL PRESENTATION: Session #236, 12:18PM

T-05 SDTM and CDASH: Why You Need Both

Kit Howard, MS

CDISC

ORAL PRESENTATION: Session #236. 12:27pm

Track 2 Disruptive Innovation

T-06 Fresh Insights on Health: Lessons Learned from Mobile Game Use to Train Attention and Planning in Teens

Candice Hughes, PhD, MBA

Hughes BioPharma Advisers LLC

Track 3 Medical Affairs and Scientific Communication

T-07 An Analysis of Medical Call Center Response Among Consumer Healthcare Companies in the United States

Vineeth Nair, PharmD

Rutgers, The State University of New Jersey

T-08 A Quantitative Analysis to Determine Whether Clinical Trials are Proportionately Distributed Across Cancer Indications

Jennifer A. Emerson, PhD, PMP

Emerson Consulting & Clinical Research Services, Germany ORAL PRESENTATION: Session #236, 12:36PM

T-09 See W-05.1

T-10 Patient Perceptions & Utilization of Patient Information Leaflets (PILs)

Judith Thompson, PharmD

UCB, Inc.

T-11 Pragmatic Randomized Clinical Trials: Key Insights from Investigators in COPD and Diabetes

Priscilla Velentgas, PhD

QuintilesIMS

Track 4 Patient Engagement

T-12 Asthma and COPD Patients Consider Training Necessary in Clinical Trials, Preferring Interactive Electronic Training

Jenny Ly, PhD

ERT

T-13 Exploring Subjects' Opinions about Option to Skip Items in ePRO: An Online Survey Study

Rinah Yamamoto, PhD (presenting on behalf of Jenny Ly)
ERT

T-14 Engaging Patients in the Consent Process Through Virtual Reality

Meghan Donahue

QuintilesIMS

ORAL PRESENTATION: Session #236, 12:45PM

T-15 WITHDRAWN

T-16 Patients With Gastrointestinal Disorders Prefer Electronic and Interactive Training When Participating in a Clinical Trial

Nadeeka Dias, PhD

ERT

Track 5 Regulatory

T-17 An Evaluation of Global Over-The-Counter Medical Device Labeling Regulations

Daina Nanchanatt, PharmD

Rutgers University

ORAL PRESENTATION: Session #236, 12:54PM

T-18 Analysis of US Food and Drug Administration (FDA)'s Process for Evaluating Bulk Drug Substances for Use in Compounding

Yen-Ming Chan, PhD

FDA

T-19 Assessing Trends in Clinical Data Packages for Orphan Indications

Dayna LeSueur, PharmD

Alnylam Pharmaceuticals

T-20 Assessment of Patient Perceptions Towards Direct-to-Consumer Advertising

Tina Chhabra, PharmD

T-21 Benchmarking Regulatory Processes in Emerging Markets Through Key Performance Indicators

Lawrence Liberti, MS, RPh, RAC

Centre For Innovation In Regulatory Science (CIRS), United Kingdom

T-22 Current Trends in Global Regulations of Human Cells and Tissue
Products

Chi-Tun Ruan, DrSc, RPh

TFDA, Taiwan

ORAL PRESENTATION: Session #236, 1:03pm

T-23 Delegation of Responsibilities-Guidance in Response to FDA Audits

Katelyn Patterson

Leidos Biomedical

T-24 Evaluating the Approval Pathway of Biosimilars in the U.S. Market

Basirat Adeyemi, PharmD

Rutgers, The State University of New Jersey ORAL PRESENTATION: Session #236, 1:12_{PM}

T-25 Impact of US Breakthrough Therapy Designation on Approval Timelines of Drugs and Biologics in the EU.

Masooma Razvi, PharmD

University of North Carolina and GlaxoSmithKline ORAL PRESENTATION: Session #236, 1:21PM

Track 6 Safety and Pharmacovigilance

T-26 Case Study: Computing Complexity Scores to Identify Patients of Interest from Inspire.com Forums for Safety and Beyond

Presenter Invited

GlaxoSmithKline

T-27 Key Aspects and Lessons Learnt for Maintaining a Robust and Efficient Global 24/7 Medical Emergency Coverage Service

Vincent Philiponis, MD, PhD

ICON Clinical Research Gmbh, United Kingdom

T-28 Safety Evaluation of Bulk Drug Substances for Use in Compounding

Jennifer Shing, PhD

FDA

T-29 Term Indexing Technology to Support the Feasibility Assessment of a Network Meta-Analysis to Support Benefit-Risk Assessment

Scott Snyder, PharmD

AbbVie, Inc.

ORAL PRESENTATION: Session #236, 1:30pm

T-30 Trends in Response Rate for Recurrent REMS Surveys

Kristin Veley, PharmD, MPH

Evidera

T-31 What's in a Name? Distinguishable Naming and its Role in PV for

Biosimilars: What do Australian Physicians Think?

Harry Gewanter, MD

Alliance For Safe Biologic Medicines

Track 8 Strategic Planning/Execution and Partnerships

T-32 Development of a Cognitive Assessment Score Transformation
(CAST) System to Support the TOMMORROW Study

Alexandra Atkins, PhD

NeuroCog Trials, United Kingdom

T-33 Impact of Strategic Partnerships With Clinical Trial Sites and Role of Alliance Managers in Execution

Srinivas Pai Raikar

QuintilesIMS, Singapore

T-34 Implement Refuse to File (RTF) Mechanism on Drug Review Process to Enhance the Quality and Submission of Application Submissi

Yi-Tzu Hsu, MS

TFDA/Center For Drug Evaluation, Taiwan

T-35 Improving Probability of Success – Better Project Outcomes through Scale Appropriate Stage Gating

Catherine De Castro

QuintilesIMS

T-36 Precision Enrollment in Oncology: Accelerating Start-up and Recruitment

Rod Walker

Rou walkei

QuintilesIMS

T-37 Remote Site Management - A Rising Star in Our Clinical Research Ecosystem

Melissa Mielcarz

QuintilesIMS

T-38 So You Want to Redesign a Website Supporting a Complex, Global, Multi-Stakeholder Clinical Research Enterprise...Now What?

Jui Shah, PhD

National Institutes of Health (NIH)

Professional Poster Session 2

Wednesday, June 21 9:00AM-4:00PM | Posters will be displayed in the Exhibit Hall

Track 1 Data/Big Data/eHealth

W-01 Developing Research Partnerships with Health Networks for Real World Evidence Generation

Nancy A. Drever, PhD. MPH

QuintilesIMS

W-02 Healthcare Link Project in Japan: Development of a New Seamless Data Stream from EHR to EDC System Using SS-MIX2 Storages

Kiyoteru Takenouchi, PhD

Translational Research Informatics Center, Japan

W-03 Searching the Registries for Trial Submission QA and Competitor Intelligence - Comparing ClinicalTrials.gov and EudraCT

Matt Eberle, MLIS

BizInt Solutions, Inc.

W-04 Treatment Comparisons of Timed Tests in Neurology

David Bristol, PhD

Statistical Consulting Services, Inc.

W-05 What's the Best Download Format from NIH ClinicalTrials.gov? Comparing Data Availability in Different Export Options

John Willmore

Bizint Solutions

Track 3 Medical Affairs and Scientific Communication

W-05.1 Do the Variables that Predict the Number of Cancer Clinical Trials in the United States Differ by Sponsor Type?

Jennifer A. Emerson, PhD, PMP

Emerson Consulting & Clinical Research Services, Germany

Track 4 Patient Engagement

W-06 Preferred Method for Answering Questions About Suicidal Ideation and Behaviors (SIB) in Patients at Greater Risk for SIB

Jenny Ly, PhD

ERT

W-07 REMS Call Center Survey: REMS Stakeholder Perceptions on Call Center Performance and REMS Program Administrative Burden

Cathy Marino

Celgene Corporation

W-08 The Benefits of Knowing Patient Preferences in the Clinical Trial Continuum

Saumya Nayak, MSc

QuintilesIMS, Singapore

W-09 The Development and Launch of a Unique Retention Focused Patient Centric Online Community for the TOMMORROW Study

Meredith Culp

Takeda, United Kingdom

ORAL PRESENTATION: Session #334, 12:00PM

W-10 Use of Digital Mobile App to Keep Clinical Trial Participants
Engaged - Driving Innovation in Early Clinical Trials at Roche

Kamal Abbassi, MSc

Roche

ORAL PRESENTATION: Session #334. 12:09pm

Track 5 Regulatory

W-11 Faster Approvals? Trends in the Use of FDA's Expedited Approval Programs for Oncology Medications

Robin Whitsell

Whitsell Innovations, Inc.

W-12 FDA Inspections in Japan: A Comparison with PMDA inspections

Eunhee Chung, PhD, MSc SOUSEIKAI Global Clinical Research Center, Japan

W-13 Influence of Orphan Drug Designation, Breakthrough Therapy
Designation, and Advisory Committees on NDA/BLA Review
Timelines

Brittany Dustman, PharmD, MS

University of North Carolina

W-14 IRB Submissions and Approvals in Japan: A review

Nozomu Miyawaki, MA

SOUSEIKAI Global Clinical Research Center, Japan

W-15 Pediatric Development of Molecularly Targeted Oncology Drugs

Shivam Patel, PharmD

University of North Carolina

ORAL PRESENTATION: Session #334, 12:18pm

W-16 Precepting Pharmacy Students in a Regulatory Affairs Rotation

Robert Wittenberg, PharmD, RPh

Baxter

W-17 Racial Effect Analysis in Supporting Drug Application for ST-101, A Fixed Dose Combination of Olmesartan and Rosuvastatin

Cynthia Lee, PhD

Autotelic Inc

W-18 SDTM/ADaM Compliant or Sufficient Submission for Legacy Studies

Nancy Wang, PhD

Celerion

ORAL PRESENTATION: Session #334, 12:27PM

Track 7 Special Populations

W-19 Expanded Access Programs (EAP): A Look at 2015-2016 Orphan **Designated New Molecular Entities**

Anastasia McManus, PharmD, RPh

Alnylam Pharmaceuticals

W-20 Honesty in Reporting Suicidal Ideations and Behaviors in Alzheimer's Disease, Mild Cognitive Impairment, and Other Dementias

Rinah Yamamoto, PhD

W-21 Prevalent Issue with Patient Selection in Oncology Clinical Trials Jia Ma. MD. MS

ICON Clinical Research

W-22 Recent Pharmacokinetic Studies in Patients with Hepatic Function Impairment at a Phase 1 Clinical Research Site in Japan

Andrew Melli

SOUSEIKAI Global Clinical Research Center, Japan ORAL PRESENTATION: Session #334, 12:36pm

W-23 Representation of Adult Obese Subjects in Pivotal Clinical Trials for Products approved by FDA in 2015

Sruthi Gaddam, PharmD

Rutgers University

W-24 Role of the Pharmacist in Global Health: A Cross-Sectional Survey of Pharmaceutical Industry PharmD Fellows

Amanda Nguyen, PharmD

Novartis/MCPHS

Track 9 Translational Science: Preclinical/Clinical and Product Development

W-25 More of What Works: Detection of Informative Sites During the **Conduct of Clinical Trials Using Machine Learning**

Kevin Craig, MD

Covance, United Kingdom

ORAL PRESENTATION: Session #334, 12:45PM

W-26 Statistical Issues in Human Drug Abuse Study - Two Different Types of Studies

Qianyu Dang, PhD

FDA

ORAL PRESENTATION: Session #334, 12:54PM

W-27 The Balance between Compassion, Cost, & Commercialization in **Expanded Access Programs: Managing Complexities**

Jack Bush, MA, MBA, MT

Quintilesims

W-28 Two Independent Phase 3 Studies Did Not Meet Pre-specified **Endpoints, What's Next?**

Gaianan Bhat, PhD

Spectrum Pharmacueticals

ORAL PRESENTATION: Session #334, 1:03pm

Track 10 Value and Access

W-29 Quality of Decision-Making Process in the Development, Review and Reimbursement of Medicines; its Importance and Implication

Magdalena Bujar, MSc

Centre For Innovation In Regulatory Science (CIRS), United Kingdom ORAL PRESENTATION: Session #334, 1:12pm

W-30 How a Centralized Feasibility Service Attracts Sponsors and **Contract Research Organizations to Malaysia**

Khairul Faizi Khalid, MD

Clinical Research Malaysia, Malaysia

W-31 Retrospective Chart Review Studies: Opportunities and Challenges to Post-Market Evidence Generation

Krista Payne

Evidera, Canada

ORAL PRESENTATION: Session #334, 1:21pm

Track 11 Quality

W-32 A U.S. REMS Quality Strategy: A Comprehensive Approach

Jorge Hechavarria, MBA

Celgene Corporation

W-33 Promoting a Data-driven Simulation Model to Enhance Quality in **Rare Disease Clinical Trials**

Stacey Boyer, PhD, MA

Takeda

ORAL PRESENTATION: Session #334, 1:30pm

W-34 Risk Management and Recalls

Darin Oppenheimer, PhD, MS, RAC

Merck

W-35 The Importance of Measuring TMF Health for Continuous Inspection Readiness.

Dawn Niccum, BSN, MS, RN, PMP

Endocyte

AWARD WINNERS

DIA Inspire Awards recognize significant individuals or group accomplishments in the discovery, development, or life cycle management of biopharmaceutical, device, or related therapeutic health care products, and/or exceptional volunteer contributions to advancing DIA's Mission and Vision.

GLOBAL INSPIRE AWARDS

Awarded to an individual, group, or organization for significant and innovative contribution to advancing global health. Evaluated and selected by the DIA Fellows. Approved by DIA Board of Directors.



President's Award for Outstanding Contribution to Global Health

PATH is the leader in global health innovation. An international nonprofit organization, they save lives and improve health, especially among women and children. PATH accelerates innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness their entrepreneurial insight, scientific and public health expertise, and passion for health equity.

By mobilizing partners around the world, they take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, they deliver measurable results that disrupt the cycle of poor health.



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UNIVERSAL ACTIVITY NUMBERS

Below are the pharmacy designated Universal Activity Numbers (UANs) and type of activity that is applicable for each of the following program offerings:

MONDAY, JUNE 19

Number	Session Title	Assigned UAN	Type of Activity
101	Drug Repurposing: Where Will it Take Us?	0286-0000-17-562-L04-P	Knowledge
102	The Evolution of Evidence Generation: Real World Evidence and the Next Generation of Decision-Making	0286-0000-17-565-L04-P	Knowledge
103	The Future of Patient Engagement: Measuring What Matters	0286-0000-17-568-L04-P	Knowledge
111	Patient Engagement: 4 W's and an H	0286-0000-17-520-L04-P	Knowledge
112	Data Sharing: 2017 and Beyond	0286-0000-17-523-L04-P	Knowledge
113	We Can't Forget the Children in This Process	0286-0000-17-528-L04-P	Knowledge
117	Postmarketing Safety Studies: Approaches and Regulatory Insights	0286-0000-17-533-L04-P	Knowledge
118	Counting on Safety	0286-0000-17-536-L04-P	Knowledge
119	Designing and Implementing a Robust Pharmacovigilance System for Vaccines	0286-0000-17-539-L04-P	Knowledge
120	FDA Rare Disease Town Hall	0286-0000-17-541-L04-P	Knowledge
122	GBM AGILE: A Transformative Global Adaptive Platform Clinical Trial	0286-0000-17-572-L04-P	Knowledge

TUESDAY, JUNE 20

Number	Session Title	Assigned UAN	Type of Activity
201	Paying for Value in Biopharmaceuticals: Trends in the United States	0286-0000-17-563-L04-P	Knowledge
202	People Will Talk: Gathering Insights from Digital Listening	0286-0000-17-566-L04-P	Knowledge
211	Sharing the Burden	0286-0000-17-521-L04-P	Knowledge
212	Walking the Walk in Patient Focused Medicines Development: From Theory to Practice What Have We Learned?	0286-0000-17-524-L04-P	Knowledge
218	ClinicalTrials.gov: Complying with Requirements in the Final Rule (42 CFR Part 11) and Impacts of 21st Century Cures Act	0286-0000-17-571-L04-P	Knowledge
219	Safety Evaluation: Transforming Information into Evidence	0286-0000-17-534-L04-P	Knowledge
222	Serving the Patient Who Needs Early Access to Treatments and Achieving Meaningful Outcomes	0286-0000-17-545-L04-P	Knowledge
224	Success in Early CNS Drug Development: Getting Proof-of-Principle by Stacking the Deck with Biomarkers	0286-0000-17-553-L04-P	Knowledge
229	Outcomes Standardization: An Imperative to Value Assessments	0286-0000-17-559-L04-P	Knowledge
246	Medical Information and the Patient: Effective Communication and Handling of Requests	0286-0000-17-516-L04-P	Knowledge
249	Not Your Grandma's Patient Advocacy Group Anymore	0286-0000-17-522-L04-P	Knowledge
250	If You See Something (About a Clinical Trial), Do You Say Something (to Your Doctor)?	0286-0000-17-525-L04-P	Knowledge
251	Defining the Science of Patient Input to Enhance Drug Development and Approval: Regulatory	0286-0000-17-529-L04-P	Knowledge
255	Integrating the Patient's Voice Across the Development Program of Rare Diseases: Translation into Meaningful Outcomes	0286-0000-17-542-L04-P	Knowledge
256	Post-Trial Access: Ensuring Patient Access Across the Development Spectrum	0286-0000-17-555-L04-P	Knowledge
258	Patient-Reported Outcomes (PROs): Hot Topics - Part 1 of 2	0286-0000-17-556-L04-P	Knowledge
259	Novel Techniques for Improving Clinical Trial Subject Retention	0286-0000-17-557-L04-P	Knowledge
260	Comparative Effectiveness: State of the Art and Stakeholder Perspectives	0286-0000-17-510-L04-P	Knowledge
269	Big Data: Genomics and Personalized Medicine	0286-0000-17-511-L04-P	Knowledge
276	Defining the Science of Patient Input to Enhance Drug Development and Approval: Tools	0286-0000-17-526-L04-P	Knowledge
281	Integrating the Patient's Voice Across the Development Program of Rare Diseases: At the Table - Where to Sit?	0286-0000-17-546-L04-P	Knowledge
282	Challenges and Issues in Early-Phase Oncology Trials	0286-0000-17-550-L04-P	Knowledge
.87	Patient-Reported Outcomes (PROs): Hot Topics - Part 2 of 2	0286-0000-17-558-L04-P	Knowledge

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WENESDAY, JUNE 21

Number	Session Title	Assigned UAN	Type of Activity
301	Progress in Pediatric Therapeutics	0286-0000-17-564-L04-P	Knowledge
302	Does Diversity Matter in Clinical Trials?	0286-0000-17-567-L04-P	Knowledge
310	New Site Paradigm: Just in Time Sites	0286-0000-17-513-L04-P	Knowledge
311	Next Generation Patient Recruitment: Part 2 of 2	0286-0000-17-514-L04-P	Knowledge
315	How to Engage Patients Within Medical Affairs	0286-0000-17-518-L04-P	Knowledge
316	Quantitative Metrics to Capture the Value of Patient Engagement	0286-0000-17-569-L04-P	Knowledge
317	Evolution of Novel Registration Endpoints as Diseases Become Chronic	0286-0000-17-530-L04-P	Application
321	Engagement, Education, Networks, Media, and Societies in Rare Diseases: The MUST Haves	0286-0000-17-543-L04-P	Knowledge
322	Is the Future Bright for Treatment of Neurodegenerative Diseases?	0286-0000-17-544-L04-P	Knowledge
328	Real-World Data to Real World Evidence for Assessing Efficacy and Effectiveness	0286-0000-17-560-L04-P	Knowledge
339	Off-Label Communications to Health Care Providers and Consumers	0286-0000-17-517-L04-P	Knowledge
346	Understanding the New Common Rule and its Impact to Industry	0286-0000-17-570-L04-P	Knowledge
347	Integrated Life Cycle Approaches to Benefit-Risk Assessment, Communication, and Evaluation	0286-0000-17-535-L04-P	Knowledge
348	Exploring the Evolution of Signal Detection	0286-0000-17-537-L04-P	Knowledge
349	Pharmacovigilance 2.0: Redesigning for the Future	0286-0000-17-540-L04-P	Knowledge
350	Innovative Designs and Statistical Approaches for Small Trials: Rare Disease or Pediatric Indications	0286-0000-17-547-L04-P	Knowledge
351	Pregnancy and Lactation Labeling Rule: Unique Challenges to Meet Requirements	0286-0000-17-551-L04-P	Knowledge
352	Collaborative Efforts to Accelerate Rare Disease Research and Development	0286-0000-17-554-L04-P	Application
355	FDA, NIH, and TransCelerate Collaborate to Accelerate Drug Development Through Protocol Harmonization	0286-0000-17-573-L04-P	Knowledge
366	Are We Ready for Telemedicine-Powered Clinical Trials?	0286-0000-17-515-L04-P	Knowledge
368	FDA Update on Prescription Drug Promotion	0286-0000-17-519-L04-P	Knowledge
370	Lessons Learned from the Sarepta Exondys 51 Approval	0286-0000-17-531-L04-P	Knowledge
374	Global Perspective on ICH: Part 2 of 2	0286-0000-17-532-L04-P	Knowledge
376	Changing Environments Within Pharmacovigilance	0286-0000-17-538-L04-P	Knowledge
377	Increasing Participation in Clinical Trials Among Under-Represented Populations	0286-0000-17-548-L04-P	Knowledge
378	Looking to the Future for EU Pediatric Investigation Plans	0286-0000-17-552-L04-P	Knowledge
384	The Increasing Role for Big Data for Late Phase Drug and Postapproval Purposes	0286-0000-17-561-L04-P	Knowledge

THURSDAY, JUNE 22

Number	Session Title	Assigned UAN	Type of Activity
402	Online Patient Networking	0286-0000-17-512-L04-P	Knowledge
405	How Do We Retain Patients in Studies? Using the Patients' Words to Explore Treatment Acceptance and Patient Engagement	0286-0000-17-527-L04-P	Knowledge
406	Recruiting Rare Disease Patients: A Unique Set of Challenges	0286-0000-17-549-L04-P	Knowledge

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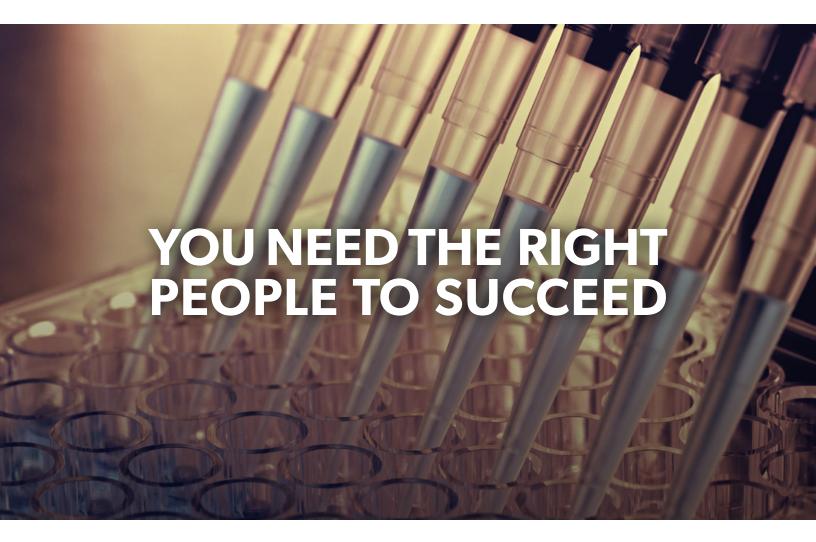
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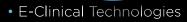
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