Join the Conversation #DIA2018

DIA2018

PROGRAM

Boston Convention & Exhibition Center
June 24-28 | Boston

driving insights to action

DIAglobal.org/DIA2018

Global Development
Global Launch
Global **IMPACT**

SHORTEN STUDY TIMELINES AND STREAMLINE PATIENT ENGAGEMENT

- E-Clinical Technologies
- Pharmacovigilance and Safety Solutions
- Regulatory Consulting
- Translation and Language Services
- Multilingual Call Centers
- Global Product Launch

TRANSPERFECT LIFE SCIENCES

BOOTH #1703
lifesciences.transperfect.com

TRIAL INTERACTIVE

BOOTH #1602
www.trialinteractive.com

Message from DIA Global Chief Executive

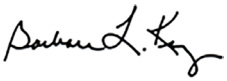
Welcome to the DIA 2018 Global Annual Meeting! With leading healthcare companies, educational institutions, and medical research facilities, Boston has established itself as a leader in global healthcare innovation. We're at an ideal venue to advance thought leadership through the transparent, neutral platform that DIA provides regulators, academia, industry, patients, payers, and other stakeholders in the healthcare product continuum to come together and work towards our mission to accelerate access to medicines globally. We're thrilled to have you join us.

We have made significant progress in advancing healthcare worldwide; however, there is much yet to do, and we haven't a moment to waste. The June 2017 United Nations World Drug Report estimated 190,000 drug-related deaths globally in 2015. According to the US Centers for Disease Control and Prevention, more than 42,000 Americans were killed in 2016 from opioids alone, the highest number of fatalities from any year on record. Forty percent of those opioid overdose deaths involved a prescription medication. This year's keynote speaker, Nora D. Volkow, MD, Director of the National Institute on Drug Abuse (NIDA), NIH, will present her views on the misuse and addiction to opioids, the criticality of public-private partnerships in addressing these issues, the important emergence of cerebral and other stimulation devices as alternative treatments, and how we can all work together to reverse the current situation. Dr. Volkow was recently named one of Time Magazine's "Top 100 People Who Shape Our World" and one of "34 Leaders Who Are Changing Health Care" by Fortune Magazine. We are honored that she joins us in Boston.

We're also in the midst of the Fourth Industrial Revolution where big data, artificial intelligence, wearable technology, and more are poised to revolutionize healthcare. A June 2017 survey of global healthcare executives showed that more than 50% believe that artificial intelligence will be ubiquitous in healthcare by 2025, but nearly 50% of these same respondents believe that our industry needs to be further convinced of return on investments in artificial intelligence or machine learning. How can we get there from here? How do we make sure that patients benefit? Be a part of the conversation, and the solution, here at DIA.

I encourage you to make the most of this year's Global Annual Meeting by engaging with expert speakers, fellow attendees, and exhibitors, and by joining the conversation on Twitter using #DIA2018 to discuss ways to turn insights into action, both in your own career and across healthcare product development. We've already accomplished so much. Let's see how much further we can go together.

Sincerely Yours,



Barbara Lopez Kunz
Global Chief Executive
DIA

DIA 2018 Honorary Chairs

Julie Louise Gerberding, MD, MPh
Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy, and Population Health
Merck & Co., Inc.

As Chief Patient Officer, Dr. Gerberding leads efforts to engage with patients and patient organizations to bring their perspectives into Merck and MSD to help inform company decisions and represents Merck globally on patient-related matters. In addition, she is building new initiatives designed to accelerate Merck's ability to contribute to improved population health, a measure increasingly valued by consumers, health organizations, and communities.

Dr. Gerberding has received more than 50 awards and honors, including the United States Department of Health and Human Services (DHHS) Distinguished Service Award for her leadership in responses to anthrax bioterrorism and the September 11, 2001 attacks. She was named to Forbes Magazine's "100 Most Powerful Women in the World" in 2005 through 2008 and TIME Magazine's "100 Most Influential People in the World" in 2004.

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

As Chief Executive of the PMDA, Dr. Tatsuya Kondo is responsible for all operations related to adverse health effects of drugs, drug/medical devices reviews, post-marketing safety measures, and more. He is also an active participant in the International Coalition of Medicines Regulatory Authorities (ICMRA), comprised of top Drug Regulatory Agencies.

Dr. Kondo also serves as the Advisor on Health and Medical Strategy for the Cabinet Secretariat of the Japanese Government, and as the Vice President of Medical Excellence JAPAN, a general incorporated association.

DIA 2018

Follow **#DIA2018** for real-time updates

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Booth #1519

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DIA2018
GLOBAL ANNUAL MEETING
driving insights to action!

Schedule At-A-Glance
As of 5/10/2018. Schedule subject to change.

BOSTON | JUNE 24-28
DIAglobal.org/DIA2018

SATURDAY, JUNE 23

Registration Hours

8:00AM-5:00PM	Exhibitor Registration

SUNDAY, JUNE 24

Registration Hours

8:00-9:00AM	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 and Emerging Professional Forum
1:00-4:30PM	Half Day Afternoon Preconference Short Courses*
3:00-5:30PM	Professional Development Sessions

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

MONDAY, JUNE 25

Registration Hours

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

Schedule

6:30-8:15AM	CISCRP Medical Heroes Appreciation 5K
7:30-8:30AM	Coffee and Light Refreshments
7:30-8:15AM	Annual Meeting Orientation
8:30-10:00AM	Opening Plenary Session and Keynote Address
10:00AM-6:00PM	Exhibit Hall Open Student Posters Open (Exhibit Hall)
10:00-11:00AM	Coffee Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Content Hub (NE Lobby) Student Poster Session and Oral Presentations (Exhibit Hall)
11:00AM-12:30PM	DIAmond and Educational Sessions
12:00-2:00PM	Luncheon Service
12:30-2:45PM	Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Sessions (Exhibit Hall) Content Hub and Community Rounds (NE Lobby) Student Poster Session and Oral Presentations (Exhibit Hall)
2:00-3:30PM	2018 CRO Leadership Awards Ceremony by Life Science Connect (Press Room)
3:00-4:30PM	DIAmond and Educational Sessions
4:30-6:00PM	Opening Reception (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Student Poster Session and Oral Presentations (Exhibit Hall)

TUESDAY, JUNE 26

Registration Hours

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

Schedule

7:00-8:00AM	Coffee and Light Refreshments
8:00-9:30AM	DIAmond and Educational Sessions
9:00AM-5:00PM	Exhibit Hall Open
9:00AM-4:00PM	Professional Posters Open (Exhibit Hall)
9:00-10:30AM	Coffee Break (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Content Hub and Community Rounds (NE Lobby) Innovation Theater Presentations (Exhibit Hall)
10:30AM-12:00PM	DIAmond and Educational Sessions
11:30AM-1:30PM	Luncheon Service
12:00PM-2:00PM	Innovation Theater Presentations (Exhibit Hall) Content Hub (NE Lobby) Engage and Exchange Sessions (Exhibit Hall) Professional Poster Session and Oral Presentations (Exhibit Hall)
2:00-3:30PM	DIAmond and Educational Sessions Community Rounds (NE Lobby) Engage and Exchange Session (Exhibit Hall)
3:00-4:15PM	Refreshment Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Content Hub and Community Rounds (NE Lobby) Professional Poster Session (Exhibit Hall)
4:15-5:30PM	Educational Sessions Community Rounds (NE Lobby)

WEDNESDAY, JUNE 27

Registration Hours

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

Schedule

7:00-8:00AM	Coffee and Light Refreshments
8:00-9:30AM	DIAmond and Educational Sessions Community Rounds (NE Lobby)
9:00AM-4:00PM	Exhibit Hall Open Professional Posters Open (Exhibit Hall)
9:00-10:30AM	Coffee Break (Exhibit Hall) Content Hub and Community Rounds (NE Lobby) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Professional Poster Session (Exhibit Hall)
10:30AM-12:00PM	DIAmond and Educational Sessions
11:30AM-1:30PM	Luncheon Service
12:00PM-2:00PM	Content Hub and Community Rounds (NE Lobby) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Professional Poster Session and Oral Presentations (Exhibit Hall)
2:00-3:15PM	Educational Sessions Engage and Exchange Sessions (Exhibit Hall) Content Hub (NE Lobby)
3:00-4:00PM	Refreshment Break (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Content Hub and Community Rounds (NE Lobby) Professional Poster Session (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall)
4:00-5:15PM	Educational Sessions

THURSDAY, JUNE 28

Registration Hours

8:00-11:00AM	Attendee and Speaker Registration

Schedule

8:00-9:00AM	Coffee and Light Refreshments Content Hub and Community Rounds (NE Lobby)
9:00-10:30AM	DIAmond and Educational Sessions
10:30-10:45AM	Coffee Break
10:45AM-12:00PM	FDA Town Hall

Learning Formats at DIA 2018

DIAmond Sessions

- Acclaimed panelists from around the world participate in open conversations on controversial topics
- 90 minutes

Concurrent Educational Sessions

- Traditional workshops or interactive educational format
- Panel discussions or didactic presentations
- 60-75 minutes
- Over 175 sessions spanning 12 educational tracks

Content Hubs

- Led by DIA Community Members
- Designed to have high-interaction between audience and speaker
- 30 attendees, 30 minutes
- Relaxed, casual learning environment

Engage and Exchange

- Peer-to-peer information exchange
- 10 minute presentation/30 minute small group discussions/20 minutes of sharing
- Collaborative learning
- 50 attendees, 45–60 minutes

Innovation Theaters

- Exhibitor-led and sponsored
- Held in the Exhibit Hall
- Limited seating
- 45 minutes

Community Round Tables

- Led by DIA Community Members
- Designed to carry learning and debate from sessions to real-life application and discussion
- Content topics discussed are based off of concurrent educational sessions
- Intimate and conversational, 60 minutes

Plenary Session and Keynote Address

Monday, June 25 | 8:30-10:00AM | Ballroom - Level 3

All Hands on Deck: Using Science to Help Solve the Opioid Crisis

Nora D. Volkow, MD
Director, National Institute on Drug Abuse (NIDA), NIH

Every day, more than 115 Americans die after overdosing on opioids. The misuse of and addiction to opioids — including prescription pain relievers, heroin, and synthetic opioids such as fentanyl — is a serious national crisis that affects public health as well as social and economic welfare. The Centers for Disease Control and Prevention estimates that the total "economic burden" of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

Yet the need for pain management therapies is great. More than 25 million Americans suffer from chronic pain and are in need of therapies to manage it. As the Director of the National Institute on Drug Abuse (NIDA) at NIH, Dr. Nora Volkow will present her vision for therapeutics and devices in pain modulation and opioid addiction, with a focus on developing better overdose-reversal and prevention interventions to reduce mortality, saving lives for future treatment and recovery; finding new, innovative medications and technologies to treat opioid addiction; and finding safe, effective, non-addictive interventions to manage chronic pain. Public-private partnerships will play a key role in meeting these challenges through the development of new technologies, regulatory science, and exploratory basic research.

Dr. Volkow will discuss the need for development of new molecules and formulations, technologies for stimulation of the brain and neurocircuitry, advances in biofeedback, and unique opportunities for wireless and mobile technologies to assist in pain management. She will also emphasize the importance of public-private partnerships in addressing these issues and how to get involved.

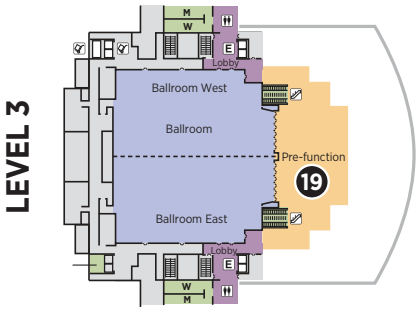
Dr. Volkow's work at the NIDA has been instrumental in demonstrating that drug addiction is a disease of the human brain. She has been named one of Time magazine's "Top 100 People Who Shape Our World", "One of the 20 People to Watch" by Newsweek magazine, Washingtonian Magazine's "100 Most Powerful Women" in both 2015 and 2017, "Innovator of the Year" by U.S. News & World Report, and one of "34 Leaders Who Are Changing Health Care" by Fortune Magazine. Dr. Volkow was the subject of a 2012 profile piece by CBS's 60 Minutes and was a featured speaker at TEDMED 2014.

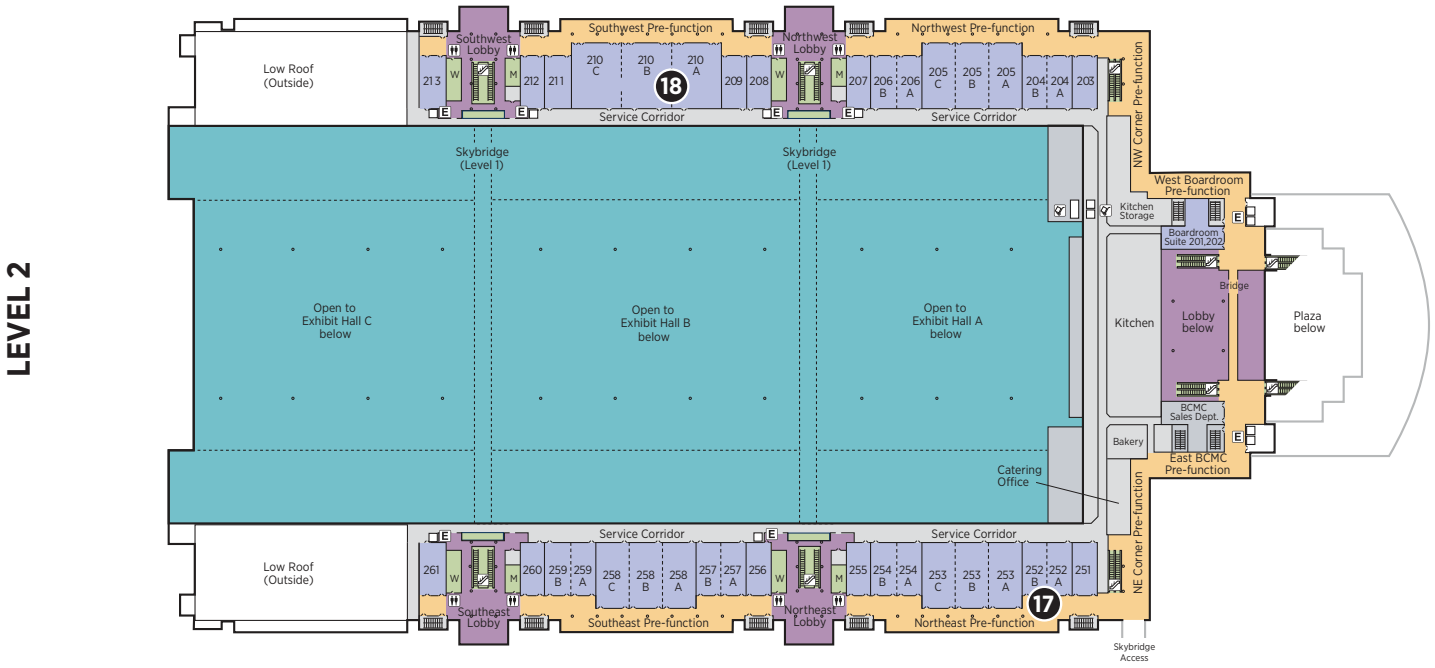
"In order for us to be successful in our mission, which is to bring the power of knowledge into solutions for the prevention and treatment of substance abuse disorders, for us to succeed, we have to partner with multiple institutions...Being able to bring that knowledge into practice requires collaboration."

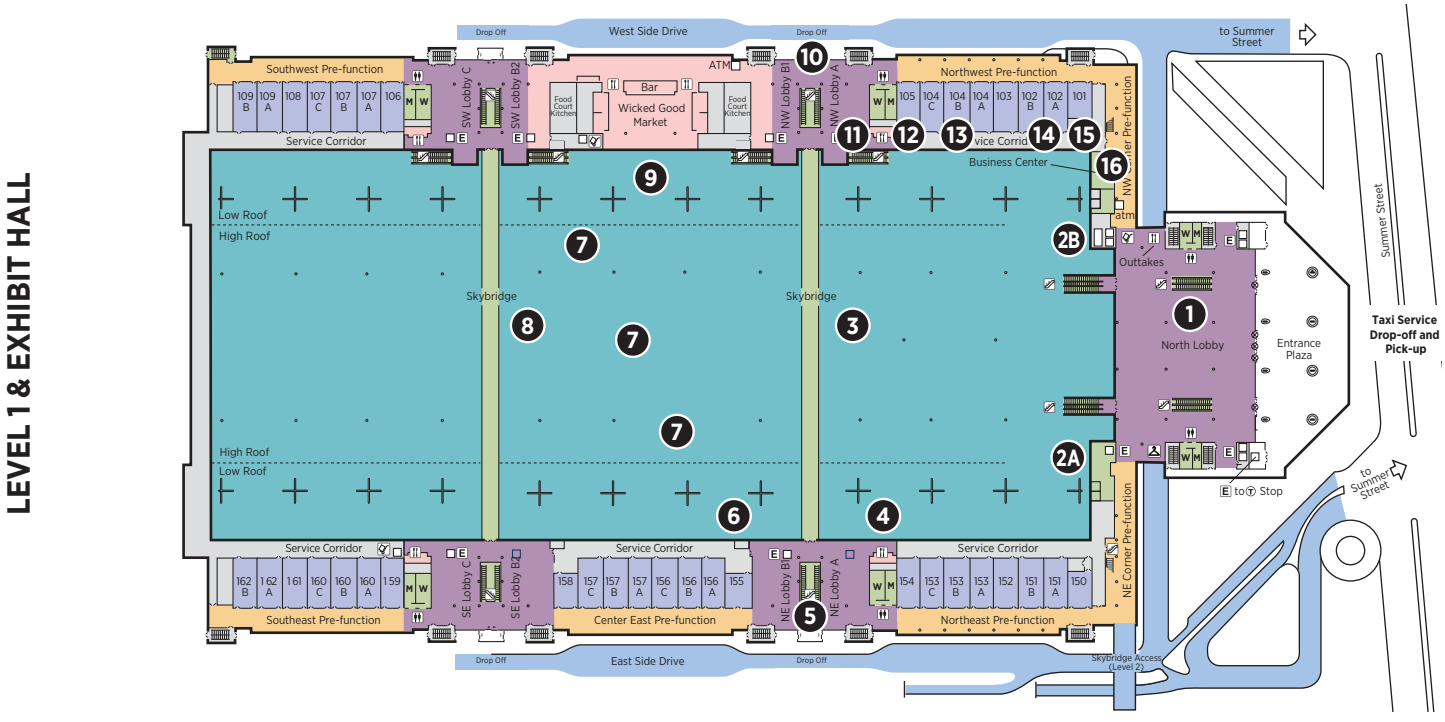
Getting Around the Convention Center

SIX TIPS TO NAVIGATING THE BCEC

1. Use the two skybridges on Level One to move quickly between the BCEC's east and west sides.
2. The skybridges also offer a bird's eye view of the exhibit floor. Save time by planning your booth visits from above!
3. Meeting rooms are numbered by floor—Level One rooms begin with "1," and Level Two rooms begin with "2."
4. An express elevator to the Grand Ballroom is located in the North Lobby on Level One.
5. Public Safety Stations are located at the North Lobby entrance.
6. Guest Service Ambassadors (wearing the red coats) are available throughout the convention center to help you with directions.







The content noted on this page was made available to DIA as of May 17, 2018

Map Key

17 **Annual Meeting Orientation**
Monday: 7:30–8:15AM
Room 252AB | Level 2

11 **Baggage Check**
NW Lobby | Level 1

16 **Business Center (FedEx Office)**
NW Prefunction (Near Room 101)

3 **Career Center**
Exhibit Hall | Booth #1519

Coffee/Refreshment Breaks
(Early Morning)
19 Monday: 7:30–8:30AM
Ballroom Lobby | Level 3

1 Tuesday and Wednesday: 7:00–8:00AM
Thursday: 8:00–9:00AM
North Lobby | Level 1

Coffee/Refreshment Breaks
(Mid-morning and Mid-afternoon)
7 Monday: 10:00–11:00AM
Tuesday: 9:00–10:30AM | 3:00–4:15PM
Wednesday: 9:00–10:30AM | 3:00–4:00PM
Exhibit Hall

1 Thursday: 10:30–10:45AM
North Lobby | Level 1

5 **Content Hub**
NE Lobby | Level 1

5 **DIA Community Zone**
NE Lobby | Level 1

19 **DIA Community Luncheon**
Tuesday: 12:00–1:30PM
Ballroom Lobby | Level 3

3 **DIA Booth**
Exhibit Hall | Booth #1519

18 **DIAmond Sessions**
Room 210AB | Level 2

4 **Engage and Exchange**
Exhibit Hall | Left of Aisle 600/700

6 **Exhibit Sales Office**
Exhibit Hall | Left of Aisle 600/700

12 **First Aid**
Room 105 | Level 1

1 **Housing Desk**
North Lobby | Level 1

Innovation Theaters
Exhibit Hall – North Lobby Entrance
2A Theater 1 – Aisle 800/900
2B Theater 2 – Aisle 2200/2300

1 **Lost and Found**
North Lobby | Onsite Attendee Registration

8 **Luncheon Service**
Monday: 12:00–2:00PM
Tuesday and Wednesday: 11:30AM–1:30PM
Rear of Exhibit Hall

13 **Media/Press Room**
Room 104B | Level 1

19 **Plenary Session and Keynote Address**
Monday: 8:30–10:00AM
Ballroom | Level 3

Poster Sessions
9 *(Student)*
Monday: 10:00AM–6:00PM
Oral Presentations: 10:20–11:00AM | 12:45–2:55PM | 4:45–5:15PM
Exhibit Hall Aisle 2800

(Professional)
Tuesday and Wednesday: 9:00AM–4:00PM
Tuesday Oral Presentations: 12:10–2:00PM
Wednesday Oral Presentations: 12:20–2:00PM
Exhibit Hall Aisle 2800

19 Student Poster Awards Ceremony
Tuesday: 12:00–1:30PM
Ballroom | Level 3

7 **Reception**
Monday: 4:30–6:00PM
Exhibit Hall

1 **Recharge Station**
Supported by DXC Technology
North Lobby | Level One

1 **Registration**
North Lobby | Level One

10 **Shuttle Drop off and Pick up**
NW Lobby | Level One

14 **Speaker Preparation Room**
Room 102AB | Level One

15 **Speaker Training Room**
Room 101 | Level One

1 **Taxi**
North Lobby Entrance | Level One

1 **Visitor Service Desk**
North Lobby Entrance | Level One

Breaks & Lunches

Refreshment Breaks

Meet up with your colleagues to plan your day. Early Morning:

Monday, June 25 | 7:30-8:30AM | Ballroom Lobby | Level 3
Tuesday, June 26 | 7:00–8:00AM | North Lobby | Level 1
Wednesday, June 27 | 7:00–8:00AM | North Lobby | Level 1
Thursday, June 28 | 8:00–9:00AM | North Lobby | Level 1

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

Monday, June 25 | 10:00–11:00AM
Tuesday, June 26 | 9:00–10:30AM; 3:00–4:15PM
Wednesday, June 27 | 9:00–10:30AM; 3:00–4:00PM
Thursday, June 28 | 10:30–10:45AM (North Lobby | Level 1)

Luncheon Service 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 25 | 12:00–2:00PM
Tuesday, June 26 | 11:30AM–1:30PM
Wednesday, June 27 | 11:30AM–1:30PM

Innovation Theater Schedule

Monday, June 25

PAREXEL International Innovation Theater | Theater 1 | 10:15AM
Innovation's Greater Purpose - How Technology Can Increase Commercial Success

Deloitte Innovation Theater | Theater 2 | 10:15AM
Engage. Innovate. Execute. - How Digital Technologies are Transforming Clinical Development

IQVIA Innovation Theater | Theater 1 | 12:45PM
Re-Imagine Clinical Development with Human Data Science

PPD Innovation Theater | Theater 2 | 12:45PM
Patient-Centered Study Planning and Feasibility Drives Speed, Certainty, and Quality at a Lower Cost

PAREXEL International Innovation Theater | Theater 1 | 1:30PM
The Innovation Imperative: The Future of Drug Development

Covance Innovation Theater | Theater 2 | 1:30PM
Evidenced-Based Approaches to Accelerating Patient Recruitment and Improving Patient Retention

DiagnoSearch Life Sciences Innovation Theater | Theater 1 | 2:15PM
Disruptive Innovation - 'Wide-Angle-Data' - Intuitive Algorithms and Artificial Intelligence for Real-Time Safety and Risk Management

SAS Institute Innovation Theater | Theater 2 | 2:15PM
Real World Evidence - Better, Faster, More!

Advanced Clinical Innovation Theater | Theater 1 | 4:45PM
Preparing for the Next Generation of Clinical Research

ArisGlobal Innovation Theater | Theater 2 | 4:45PM
A Clinical Perspective - How Cognitive E-2-E Pharma Platforms can Transform Productivity in Pharma - Introducing LifeSphere from Clinical to Regulatory

Cognizant Innovation Theater | Theater 1 | 5:30PM
Powering New Possibilities for Site-Sponsor Collaboration with the Shared Investigator Platform in Partnership with TransCelerate

Appian Innovation Theater | Theater 2 | 5:30PM
Moving Beyond Cloud with Digital Transformation to Unify Process, Connect Data, and Turbocharge Innovation

Tuesday, June 26

Covance Innovation Theater | Theater 1 | 9:45AM
Case Study - Driving Clinical Transformation Through a Next-Generation of Data Integration and Analytic Technologies with a GlaxoSmithKline-Covance Partnership

Veeva Systems Innovation Theater | Theater 2 | 9:45AM
Global Industry Report - New Findings from the 2018 Unified Clinical Operations Survey

IQVIA Innovation Theater | Theater 1 | 12:10PM
Real World Evidence to Enhance Drug Development

AmPLEXOR Innovation Theater | Theater 2 | 12:10PM
How Regulatory Information Will Become Part of Your Company Big Data Architecture

BioClinica Innovation Theater | Theater 1 | 1:10PM
Transformational Trends in Investigator Site Payments 2018

Veeva Systems Innovation Theater | Theater 2 | 1:10PM
Tufts Research - Strategies from Data Management Leaders to Speed Clinical Trials

WIRB-Copernicus Group Innovation Theater | Theater 1 | 3:40PM
Clinical Research Sites: Your Competitive Battleground for Study Success

Veeva Systems Innovation Theater | Theater 2 | 3:40PM
Simplifying Variation Management

Wednesday, June 27

ArisGlobal Innovation Theater | Theater 1 | 9:45AM
A Regulatory Perspective - How Cognitive E-2-E Pharma Platforms can Transform Productivity in Pharma - Introducing LifeSphere from Clinical to Regulatory

SAS Institute, JMP Division Innovation Theater | Theater 2 | 9:45AM
RECIST Criteria and Their Impact on Safety and Efficacy Reporting in Oncology Studies

ZS Associates Innovation Theater | Theater 1 | 12:10PM
Building an RWE Bridge from Population Health to Personalized Medicine

Salesforce Innovation Theater | Theater 2 | 12:10PM
Accelerate R&D Innovation with Salesforce for Life Sciences

IQVIA Innovation Theater | Theater 1 | 1:10PM
The Digital Future is Now

PAREXEL International Innovation Theater | Theater 2 | 1:10PM
Patient Centricity - From Postulation to Performance - Advancing Data Capture in Clinical Trials with Wearables

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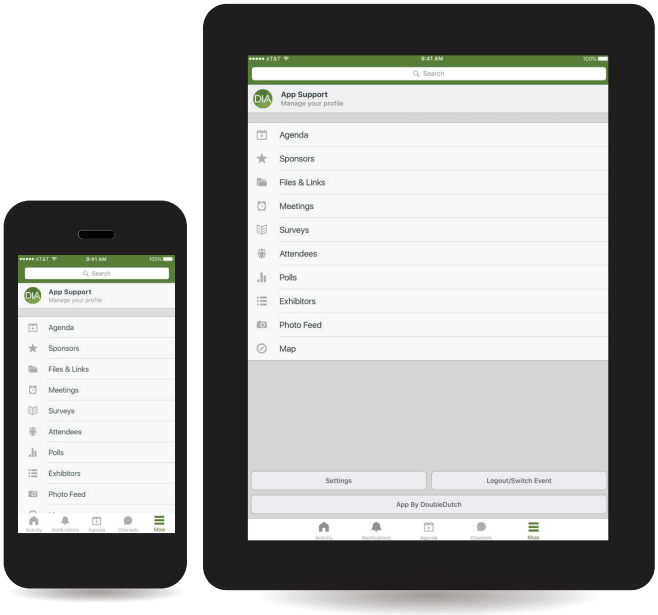
Stay Connected

Navigate DIA Meetings from Your Mobile Device with DIA's Global App

The DIA Global App is designed to enhance your meeting experience and provide valuable information in one place.

Benefits of the App:

- Manage your meeting agenda by viewing all sessions and selecting which ones you want to attend
- Connect and network with meeting attendees
- Activity stream provides real-time updates
- View interactive floor plans
- Browse exhibiting companies with their booth numbers
- Integrate your social media channels
- Participate in the DIA Scavenger Hunt to win prizes



Download on the App Store

GET IT ON Google Play

Log-in using your email address used to register and select "Reset Password." An email will be sent to you.

Win Prizes and Make Connections

Get Social!

Stay connected with your colleagues from around the world and all the innovation happening in Boston by following #DIA2018 on your social media channels. Connect by:

- Uploading pictures to Instagram
- Live-Tweeting sessions and your experiences throughout the meeting
- Following new connections on LinkedIn
- Sharing what you've learned on Facebook

Search **DrugInfoAssn** to follow DIA.

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Play Games and Win Prizes

Exhibitor Passport | Scavenger Hunt | DIA Global App Leaderboard

For more details, see the flyer in your registration bag or visit us at DIA Booth #1519.

Program Commitee

Teresa Ancukiewicz, MA, Senior Manager, Clinical Data Management, Boston Scientific Corporation

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Kristin Voorhees, MA, Senior Manager, Patient Advocacy, Ultragenyx Pharmaceutical

Michael Neidl, MBA, MS, Senior Clinical Research Executive, Clinical Research Consultant, LLC

Nancy Smerkanich, DrSc, MS, Assistant Professor, Clinical Pharmacy; Educational Liaison and Instructor, ICRS, University of Southern California

Karen Weiss, MD, MPH, Vice President, Global Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

David Pepperl, PhD, Senior Consultant and Nonclinical Group Leader, Biologics Consulting

Meredith Smith, PhD, MPA, Global Risk Management Officer, Global Patient Safety, Amgen Inc.

Robin Whitsell, President, Whitsell Innovations, Inc

Kim Quaintance-Lunn, Vice President, Regulatory Policy, North America, Bayer

Elizabeth Somers, MSc, PMP, Executive Director of Infectious Disease, Global Project and Alliance Management, Merck & Co., Inc.

Annette Williams, MBA, RPh, Vice President, Lifecycle Safety, IQVIA

Margaret Richards, PhD, MPH, Executive Director, Scientific Affairs, Real-World Solutions, PRA Health Sciences

Margaret Stiltner-Richmond, Senior Global Project Manager, Paragon Global CRS

Michael Williams, Sales Director and Business Development, Synergistix

Peter Richardson, PhD, Head of Quality, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), United Kingdom

Jeffrey Stuart, PhD, RAC, Global Regulatory Director, Oncology, Immunology, and InVitro Diagnostics, Merck & Co., Inc.

Amy Xia, PhD, Executive Director, Biostatistics, Amgen Inc.

Steven Roberds, PhD, Chief Scientific Officer, Tuberous Sclerosis Alliance

Ling Su, DIA Fellow, PhD, Past President, DIA Board of Directors; Professor, Shenyang Pharmaceutical University, China

Judith Zander, MD, Director, Office of Pharmacovigilance and Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA

The content noted on this page was made available to DIA as of May 11, 2018

General Information

Access Presentations

Full-conference and one-day registrants can access speaker presentations (PDF version only) by visiting DIAglobal.org/DIA2018Presentations, 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.

Please note that this includes all speaker presentations provided to DIA to-date, and will be continually updated as new presentations are received.

Baggage Check

There is an area of the NW Lobby (near shuttle drop-off/pickup) where you can check 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-6:00PM

Wednesday: 7:00AM-6:30PM

Thursday: 8:00AM-12:30PM

Business Center

The FedEx Office, located in the NW corner of the Boston Convention & Exhibition Center (near Room 101), offers an array of business services and products tailored to meet your needs. FedEx Office 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 617.954.2203 or email usa1323@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 (build your agenda!)
- Play the DIA Exhibitor Scavenger Hunt and win prizes
- Interact 1:1 with other attendees (private message others)
- Comment real-time on sessions and your DIA 2018 experience
- 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 quality industry professionals, quick and easy job posting, online job activity reports, and access to the National Healthcare Career Network of more than 60 top healthcare associations and professional organizations.

For additional information, visit the DIA Booth #1519, located in the Exhibit Hall.

Free DIA WiFi

IMS Health & Quintiles are now IQVIA™

Complimentary WiFi service is available throughout the Boston Convention & Exhibition Center, and is supported by IQVIA. To utilize this service, simply connect to **DIA Free WiFi** and enter the password diaglobal. Once you accept the Terms and Conditions, you will be redirected to the DIA website.

First Aid Center

First Aid is available for routine health problems and emergency care. The First Aid Center is located in Room 105. To report an emergency, please call extension 2222 from any convention center house phone, or 617.954.2222 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.

Lost and Found

Misplaced items will be stored at Onsite Attendee Registration, located in the North Lobby, until the end of the meeting. Items remaining at the close of the meeting will be turned over to Boston Convention & Exhibition security. After the meeting, please call 617.954.2222 or check signatureboston.com/attend/lost-and-found regarding any misplaced items.

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General Information

DIA Luncheon Service

Lunch will be provided in the back of Exhibit Hall on Monday, 12:00-2:00PM, and Tuesday-Wednesday, 11:30AM-1:30PM. Your name badge will be scanned when entering the lunch service area each day. Re-entry will not be permitted. Service includes one entrée and one beverage per person.

Meeting Name Badge

There will be a $25 fee for badge reprints. Please visit the cashier at Attendee Registration if you require a badge reprint. Identification will be required.

Also, please note that the QR code on your meeting badge contains your contact information. Allowing exhibitors to scan the QR code will provide them with your contact information.

Private Social Functions Policy

DIA does not allow any hospitality functions to be held during educational sessions, Exhibit Hall hours, or social events. Therefore, the hours noted below are the only hours acceptable for hospitality functions:

Saturday, June 23 | All times are acceptable

Sunday, June 24 | All times are acceptable

Monday, June 25 | Before 8:00AM and after 6:00PM

Tuesday, June 26 | Before 8:00AM and after 5:30PM

Wednesday, June 27 | Before 8:00AM and after 5:30PM

Thursday, June 28 | Before 9:00AM and after 12:15PM

Selection of Offerings

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

Getting Around Boston

By Taxi: Taxi service is readily available throughout the city. Taxi fares between Logan Airport and the Boston Convention & Exhibition Center range between $25 and $35. Taxi stands are located outside of the baggage claim area.

Taxi fares from downtown DIA hotels to the Boston Convention & Exhibition Center are between $35 and $45 per ride. Taxis pick up and drop off at the North Lobby.

By Public Transit: MBTA “The T” has a tool called “Trip Planner”. Access MBTA.com and enter your starting location and your destination, and it will provide you with stop-by-stop directions via subway or bus.

Logan Airport to the BCEC:

1. MBTA Silver Line SL1 route to World Trade Center Station
2. Exit at the World Trade Center Station, and take the elevator up to Level 2 and follow directions to BCEC/ World Trade Center Avenue
3. Take a left onto World Trade Center Ave, to the BCEC across Summer Street

Show Your Badge Discounts

Select restaurants, shops, and vendors throughout Boston are extending exclusive discounts to DIA 2018 Attendees who show their name badge. Visit bostonusa.com/DIA2018 for a list of participants.

Visitor Services Desk

A Visitor Service Desk is located in the North Lobby, and will be available throughout the meeting. The professional staff is happy to assist you with restaurant reservations, theater information, sporting event tickets, and information on other Boston attractions. Please feel free to stop by the desk with any questions you may have about Boston or access bostonusa.com/DIA2018. This website includes information on Show Your Badge discounts, restaurants, things to do, as well as a calendar of events. The hours for the Visitor Service Desk are:

Monday: 9:00AM-6:30PM

Tuesday: 9:00AM-6:00PM

Wednesday: 9:00AM-5:30PM

Thursday: 8:00AM-12:30PM

DIA Courtesy Shuttle to/from the Boston Convention & Exhibition Center

Complimentary shuttle service will be provided between the convention center and all official DIA hotels Monday-Thursday, with the exception of Aloft Boston Seaport, Element Boston Seaport, Renaissance Boston Waterfront, Seaport Boston, and Westin Boston Waterfront Hotel. The shuttle will be available in the morning and at the conclusion of DIA events each day.

Shuttles will arrive and depart from the NW Lobby, (near room 105). Please note that you must be staying at an official 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.

DIAmond SESSIONS *Conversations on Today's Priorities!*

Our DIAmond sessions provide you with rare opportunities to listen to and engage with a variety of key stakeholders participating in open conversations on controversial topics such as the opioid crisis, the future of PharmaTech, global perspectives on patient engagement, international regulatory convergence, and forums with the FDA.

All DIAmond Sessions will be held in Room 210AB.

Monday, June 25 | 11:00AM–12:30PM

#124 Analyzing Innovations Progress in the Gottlieb Era

This DIAmond Session will bring together top regulatory thought leaders from FDA, industry, and the venture capital world, for an interactive, forward-looking discussion of FDA's modernization plan and its impact on development of innovative therapies.

Monday, June 25 | 3:00–4:30PM

#156 International Regulatory Convergence

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

Tuesday, June 26 | 8:00–9:30AM

#217 Triple-A RWE: Adequate Data, Appropriate Study Designs, and Actionable Evidence

This session will use key takeaways from stakeholder case studies to highlight progress to date on addressing these key questions and furthering the regulatory acceptability of RWE.

Tuesday, June 26 | 10:30AM–12:00PM

#243 Global Perspectives on Patient Engagement

A diverse panel representing patient groups, regulators, and industry from regions such as Asia and Latin America will talk about current experience, hopes, and aspirations for patient engagement worldwide.

Tuesday, June 26 | 2:00–3:30PM

#268 Future of PharmaTech

Examine how innovative technologies in drug development are impacting the pharmaceutical and biotech industry.

Wednesday, June 27 | 8:00–9:30AM

#318 Value-Based Assessment and Contracting: What Needs to be Done to Make it a Best Practice?

This DIAmond session will bring clarity by discussing solutions and their implementation across different healthcare systems. Learn what has been successfully applied globally on the key aspects of VBC (data collection, finding suitable metrics, and trust building between partners).

Wednesday, June 27 | 10:30AM–12:00PM

#346 Precision Medicine, Gene Editing, and Gene Therapy: Current Status and Regulatory Challenges of Integrating Genetic Medicine into Clinical Care

This DIAmond session will discuss the scientific, regulatory, and ethical/access issues surrounding these emerging technologies as they progress through the development process and become more integrated into clinical practice.

Thursday, June 28 | 9:00-10:30AM

#415 EMA/FDA Question Time

EMA and FDA leadership come together at a round table discussion on areas covered by the EMA/FDA confidentiality arrangements and how both agencies contribute to global development and supervision of medicines.

Thursday, June 28 | 10:45AM–12:00PM

#416 FDA Town Hall

This forum will include discussions and updates from FDA leadership on regulatory issues and the audience will be invited to submit questions of general interest.

The content noted on this page was made available to DIA as of May 11, 2018

Regulatory Affairs Around the World: Map Your Sessions at DIA 2018

Monday, June 25 | 11:00AM–12:30PM

#124 Analyzing Innovations Progress in the Gottlieb Era–*Room 210AB*
This DIAmond Session will bring together top regulatory thought leaders from FDA, industry, and the venture capital world, for an interactive, forward-looking discussion of FDA's modernization plan and its impact on development of innovative therapies.

Monday, June 25 | 3:00–4:30PM

#156 International Regulatory Convergence–*Room 210AB*
Join senior leadership from international regulatory agencies to hear the latest on multi and bilateral initiatives to avoid duplication and increase mutual reliance, strategic governance, and their impact on industry.

Monday, June 25 | 3:00–4:00PM

#152 FDA Expectations for Demonstration of Interchangeability–*Room 206AB*
This session will detail our current understanding of FDA expectations for demonstration of interchangeability of a biological product with a reference product with regards to study designs, duration of switches, PK/PD immunogenicity sampling, statistical analysis, and product presentation considerations.

Monday, June 25 | 3:00–4:15PM

#150 TFDA Town Hall–*Room 208*
TFDA will share the updated information of regulatory management of drug development, challenges of MRCT implementation, the application of real world evidence, and innovative biotechnological medicine.

Tuesday, June 26 | 8:00–9:15AM

#204 FDA Data Standards Update–*Room 209*
FDA's Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) will implement a joint data standards strategy, with supporting action plan. In this session, FDA will present their joint strategy, action plan, and updates.

Tuesday, June 26 | 10:30–11:30AM

#226 Regulators' Utilization of Real-World Data in Pharmacovigilance Activities–*Room 253AB*
During this session, FDA, PMDA, and Health Canada will discuss the challenges faced in exploring new methods and designing and conducting these studies, and future areas of research, including opportunities for international collaborative research.

Tuesday, June 26 | 10:30–11:45AM

#239 Generic Drug Town Hall–*Room 205AB*
A panel of senior FDA staff will share information related to the implementation, policy, and regulatory science updates related to the Generic Drug User Fee Amendments (GDUFA).

Tuesday, June 26 | 10:30AM-12:00PM

#243 Global Perspectives on Patient Engagement–*Room 210AB*
A diverse panel representing regulators, patient groups, and industry from regions such as Asia and Latin America will talk about current experience, hopes, and aspirations for patient engagement worldwide.

Wednesday, June 27 | 8:00–9:15AM

#313 Global Rare Disease Town Hall–*Room 205AB*
Join FDA in this forum that will address the unique regulatory complexities and challenges specific to orphan drug development.

Wednesday, June 27 | 2:00–3:15PM

#373 PMDA Town Hall–*Room 205AB*
PMDA will share its activities to promote high-quality, innovative medical research and clinical trials meeting or exceeding international standards, as well as its advocacy for the application of "Big Data" in medical practice.

Wednesday, June 27 | 4:00–5:00PM

#394 Update on BREXIT–*Room 205AB*
Gain an overview of the current state of play of the political process from a UK as well as an EU perspective.

Thursday, June 28 | 9:00–10:30AM

#415 EMA/FDA Question Time–*Room 210AB*
EMA and FDA leadership come together at a round table discussion on areas covered by the EMA/FDA confidentiality arrangements and how both agencies contribute to global development and supervision of medicines. Attendees are encouraged to come prepared with questions for the EMA/FDA Question Time panel.

Thursday, June 28 | 10:45AM-12:00PM

#416 FDA Town Hall–*Room 210AB*
This forum will include discussions and updates from FDA leadership on regulatory issues and the audience will be invited to submit questions of general interest.

The content noted on this page was made available to DIA as of May 11, 2018

Meeting Highlights: Professional Development

Sunday, June 24 | 10:30AM–12:00PM | Westin Boston Waterfront | NE Lobby, Level 1

Emerging Professionals and Student Forum (Complimentary)
Explore the numerous opportunities that come with the student membership that DIA offers.

Sunday, June 24 | 3:00–4:00PM | Room 252AB

#001 Effective Use of Social Media
Focus on Twitter and LinkedIn but also discuss Facebook, Snapchat, and Instagram. We will look at a specific tool for social media management and talk about best practices for incorporation of social media, personally and professionally.

Sunday, June 24 | 4:15–5:30PM | Room 252AB

#002 The Power of Networking
Explore personality assessments and discuss the role they play in networking. Introvert, extrovert, centrovert (ambivert), and how these types interact and network will be demonstrated.

Monday, June 25 |3:00–4:15PM | Room 254AB

#157 Courageous Leadership
This workshop will focus on decision-making, the power of the leader's shadow, and the importance of deliberate leadership choices.

Tuesday, June 26 | 8:00–9:15AM | Room 254AB

#218 Building Your Brand
Personal branding is the ongoing process of establishing a prescribed image or impression in the mind of others about yourself. Here, you will work on your own brand as well as a fictitious person's.

Wednesday, June 27 | 8:00–9:00AM | Room 157AB

#319 PowerUp: Career Transforming Moments
In this session you'll experience powerful and real-life stories from leaders who took a career negative and transformed it into a career positive.

Wednesday, June 27 | 2:00–3:15PM | Room 254AB

#376 Courageous Hiring
Attention to detail, integrity, leadership problem–solving, and dependability. These "soft skills" can be the difference that makes employees exceed job performance standards. Discuss these skills and how to incorporate them into your day-to-day functions.

Engage and Exchange Sessions
E and E | Exhibit Hall

Full Engage and Exchange schedule will be posted in the Exhibit Hall next to the Engage and Exchange session space.

Monday, June 25 | 10:15–11:00AM
#103 Networking Do's and Don'ts

Tuesday, June 26 | 3:30–4:15PM
#272 LinkedIn Profile Exchange Review

Wednesday, June 27 | 1:15–2:00PM
#356 The Worst Co-Worker on the Block

Content Hub Sessions
Community Zone | NE Lobby, Level 1

Full Content Hub schedule will be posted in the Community Zone.

Monday, June 25 | 10:30–11:00AM
#103 LinkedIn Review

Tuesday, June 26 |3:30–4:00PM
#272 DIA Insights: Expert Clinical and Regulatory Content – Timely Global and Regional Reports, New Digital Platform – Can We Help You?

Wednesday, June 27 | 1:30–2:00PM
#357 Difficult Conversations

Community Round Table Discussions
Community Zone | NE Lobby, Level 1

Discussions inspired by sessions from within the DIA 2018 program. Open to all attendees. A full Community Round Table Discussion schedule will be posted in the Community Zone.

Student Poster Session and Oral Presentations
Poster Area | Exhibit Hall

Monday, June 25 | 10:00AM–6:00PM
Students from around the world will showcase their research in this year's Poster Session.

10:20–11:00AM | 12:45–3:00PM | 4:45–5:15PM
Student Oral Presentations

Tuesday, June 26 | 12:00–1:30PM | Ballroom Lobby 3, Level 3
Student Poster Awards Ceremony
Student Poster Awards to be held during the DIA Community Luncheon.

Monday, June 25 | 7:30–8:15AM | Room 252AB | Level 2

Annual Meeting Orientation
Meet long-time Annual Meeting attendees and learn what they get out of the meeting each year, flag can't miss sessions and content, and discover how you can maximize the value of your time at DIA 2018.

The content noted on this page was made available to DIA as of May 11, 2018

Meeting Highlights: Professional Development, cont'd

Professional Poster Sessions and Oral Presentations

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

Tuesday, June 26 | 9:00AM–4:00PM | Poster Area - Exhibit Hall
Professional Poster Session 1
Presenters available at posters 9:30–10:30AM; 12:00–2:00PM; 3:00-4:00PM

Tuesday, June 26 | 12:10–2:00PM | Poster Area - Exhibit Hall
Professional Oral Poster Presentations 1

Wednesday, June 27 | 9:00AM–4:00PM | Poster Area - Exhibit Hall
Professional Poster Session 2
Presenters available at posters 9:30–10:30AM; 12:00–2:00PM; 3:00-4:00PM

Wednesday, June 27 | 12:20–2:00PM | Poster Area - Exhibit Hall
Professional Oral Poster Presentations 2

Opening Reception

Monday, June 25 | 4:30–6:00PM | Exhibit Hall
Network with thousands of attendees and 450+ exhibitors.

Meeting Highlights: DIA Members

DIA Members: Get Engaged Booth #1519 | Exhibit 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 #1519, 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 healthcare 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 #1519 in the Exhibit Hall so we can show you how!

Community Zone | NE Lobby, Level 1

DIA community members, this is your dedicated space! Meet up and collaborate with fellow members, participate in round table discussions, check out the Content Hub, and/or take a few minutes to reflect on the sessions you've attended.

DIA Community Luncheon

Tuesday, June 26 | 12:00–1:30PM | Ballroom Lobby 3

Attend the DIA Community Luncheon to celebrate the many exciting contributions DIA Community members have made throughout the year to improve global healthcare and to congratulate our emerging professional winners from DIA's Leader of Tomorrow challenge and the student poster competition.

Tuesday, June 26 | 3:30–3:45PM | DIA Booth #1519
Annual Meeting for Members

CONTINUING EDUCATION

The DIA 2018 Global 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 lifecycle management of healthcare products. DIA 2018 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 2018, 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 in preclinical and clinical development
- Identify relevant data, document and systems standards, and integration approaches for medical product development and explain their impact on quality and end-to-end efficiency in data collection, management, and submission and approval processes
- 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 post-market assessment to improve patient outcomes
- Discuss the role of big data and analytics, approaches, and methodologies for their application throughout the product lifecycle, and legal, privacy, and security implications for their use
- Discuss the role of Real World Evidence (RWE) in medical product development and throughout the product lifecycle
- Identify challenges and emerging standards and methodologies to ensure the appropriate use of real-world data in developing evidence for regulatory decision-making and lifecycle applications
- Identify legal, advertising, and marketing issues related to providing product information
- Apply principles of risk assessment and management to development and post-market phases of new healthcare 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 healthcare 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 and scientific communications 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
- Examine the challenges and opportunities in assessing medical product value and access to medicines
- Describe meaningful engagement of patients with sponsors, regulators, and other stakeholders throughout the medical product lifecycle
- Identify policies, practices, and resources to ensure integration of the patient voice in decision-making throughout the medical product lifecycle
- Interpret and apply quality standards, regulations, and guidelines for medical product development and lifecycle management to ensure that products are safe, efficacious, and available to patients who need them

Specific learning objectives for each offering are found on the DIA 2018 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 2018 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, or Community Rounds.

ACCREDITATION AND CREDIT DESIGNATION STATEMENTS — *Monday, June 25–Thursday, June 28*

Joint Accreditation Statement

JOINTLY ACCREDITED PROVIDER™ INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, this activity has been planned and implemented by the Postgraduate Institute for Medicine and DIA. Postgraduate Institute for Medicine is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Physician Continuing Medical Education

The Postgraduate Institute for Medicine designates this live activity for a maximum of 17.5 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CONTINUING NURSING EDUCATION

The maximum number of hours awarded for this Continuing Nursing Education activity is 17.5 contact hours.

Accreditation Council for Pharmacy Education (ACPE)

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants can earn up to 17.5 contact hours or 1.75 continuing education units (CEUs) for participating in the Annual Meeting program offerings.

ACPE Credit Requests MUST BE SUBMITTED BY FRIDAY, AUGUST 10, 2018

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

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 2018 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, or Community Rounds.

The content noted on this page was made available to DIA as of May 11, 2018.

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 2018 Annual Meeting website at DIAglobal.org/DIA2018CE and in the final program.

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 13.75 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 2018 Global Annual Meeting website at DIAglobal.org/DIA2018CE 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 3.2 CEUs for this program.

CONTINUING LEGAL EDUCATION

For attorneys who would like to receive continuing legal education credits for attending DIA 2018, 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 24–28

Credit amounts range based upon the length of time for each offering. This program offers up to 24 *AMA PRA Category 1 Credits™*; 3.9 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 24 contact hours; Pharmacy 24 contact hours or 2.4 CEUs; and 17 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 2018 short courses. See specific units that are available for each offering noted on the DIA 2018 website. For more information on DIA's Certificate Program, visit DIAglobal.org/CertificatePrograms.

STATEMENTS OF CREDIT

Participants who would like to receive continuing education credit for DIA 2018 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 to 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, July 3, 2018

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 EVENTS 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 2018 online evaluations can be found at DIAglobal.org/DIA2018evals. 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 24 and closes on Friday, July 27, 2018.

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 2019 Global 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 6, 2018.

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.

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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 2018 website.

The content noted on this page was made available to DIA as of May 11, 2018.

DIA 2018 TRACKS AND FEATURED TOPICS

Track #	Core Interest Area
Track 01	Clinical Safety and Pharmacovigilance
Track 02	Clinical Trials and Clinical Operations
Track 03	Data and Data Standards
Track 04	Medical Affairs and Scientific Communication
Track 05	Patient Engagement
Track 06	Preclinical Development and Early-Phase Clinical Research
Track 07	Project Management and Strategic Planning
Track 08	R&D Quality and Compliance
Track 09	Regulatory
Track 10	Regulatory CMC and Product Quality
Track 11	Statistics
Track 12	Value and Access
Track 13	DIAmond
Track 14	Innovation Theater
Track 15	Engage and Exchange
Track 16	Content Hubs
Track 17	Community Rounds
Track 18	Professional Development
Track 19	Posters

Featured Topics	
1.	Real World Evidence
2.	ExUS Regulatory
3.	Mobile Technology
4.	Outsourcing
5.	Devices and Combination Products
6.	Biomarkers - Diagnostics
7.	Rare Diseases
8.	Biosimilars
9.	Generics
10.	Gene Therapy
11.	Career Development
12.	Pediatrics
13.	Student - Emerging Professionals Programming
14.	Regulatory Agency Presenters
15.	Translational Science and Medicine

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.

The content noted on this page was made available to DIA as of May 11, 2018.

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
SUNDAY, JUNE 24							
3:00–5:30PM							
#001	18	Effective Use of Social Media	252AB	WORKSHOP	60	Level: ●	
#002	18	The Power of Networking	252AB	WORKSHOP	75	Level: ●	
MONDAY, JUNE 25							
8:30-10:00AM							
#100		**PLENARY SESSION AND KEYNOTE ADDRESS | BALLROOM** Welcome Remarks, Awards, and Keynote Address • All registrants are encouraged to attend.					
10:00–11:00AM		**STUDENT POSTER SESSION AND ORAL PRESENTATIONS | EXHIBIT HALL**					
10:15-11:00AM							
#101	14A	PAREXEL International Innovation Theater: Innovation's Greater Purpose - How Technology Can Increase Commercial Success	Theater 1 Exhibit Hall	SESSION	30		
#102	14B	Deloitte Innovation Theater: Engage. Innovate. Execute. - How Digital Technologies are Transforming Clinical Development	Theater 2 Exhibit Hall	SESSION	30		
#103	15	Networking Do's and Don'ts	E and E Exhibit Hall	WORKSHOP	45	Level: ●	
#104	16	LinkedIn Review	Content Hub NE Lobby	SESSION	30	Level: ●	IACET
11:00AM–12:30PM							
#105	01A	Cardiac Safety in Drug Development and the Critical Role of Public-Private Partnerships: The Cardiac Safety Research Consortium Model	253AB	SESSION	60	Level: ●	ACPE, CME, IACET, RN
#106	01B	Signal Management: Separating Needles from Haystacks	253C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#107	02A	The Metamorphosis of Clinical Trials: Evolving Roles of Stakeholders in Digital Trials	257AB	FORUM	60	Level: ●	ACPE, CME, IACET, RN
#108	02B	From Patients and Advocacy Groups to Operations and Beyond: Obtaining and Incorporating Input from Stakeholders in Protocol Design	258AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#109	02C	The Who, What, How, When, and Why of Using Mobile Technology in Clinical Trials	258C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#110	03A	Using Fast Healthcare Interoperability Resources (FHIR®) for Clinical Research	208	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#111	03B	Data Integrity Playbook: A Cross-Functional, Risk-Based, Analytics-Driven Approach to Monitor Data Integrity	209	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#112	04	Scientific Communication Key Message Development, Management, and Dissemination	210C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#113	05A	Patient-Focused Medicines Development: Where it has Led Us to Today, What Challenges Remain, and What do We Still Need to do to Achieve Success?	151AB	FORUM	75	Level: ●	ACPE, CME, IACET, RN
#114	05B	A Hot Debate: Perspectives on Benefit and Risk from Patients Across Diseases	153ABC	FORUM	75	Level: ■	ACPE, CME, IACET, RN

Welcome Remarks
Barbara Lopez Kunz, MSc
Global Chief Executive, DIA

Keynote Address
Nora D. Volkow, MD
Director, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH)

Honorary Chair
Julie Louise Gerberding, MD, MPh
Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy, and Population Health, Merck & Co., Inc.

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

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
MONDAY, JUNE 25, CONTINUED							
#115	06	Regenerative Medicine Advanced Therapies: Facilitating Product Development and Approval	156ABC	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#116	07	Culture: The Link Between Team Culture and Productivity - An Interactive Workshop	254AB	WORKSHOP	75	Level: ■	CME, IACET, PMI, RN
#117	08	Beyond Robotics Process Automation: Next Generation Integrated QMS for R&D	205C	FORUM	60	Level: ◆	ACPE, CME, IACET, RN
#118	09A	How Can We Optimally Incorporate Real World Evidence into Regulatory Decision-Making?	205AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#119	09B	'Target'ing Pediatric Oncology Development: New Global Pediatric Considerations Under FDARA 2017	204AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#120	10	FDA Innovation in Pharmaceutical Quality Assessment and Inspection	206AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#121	11	Use of Historical Information in Clinical Trial Design	256	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#122	12A	Contracting for Value: From Outcomes-Based Contracts to Bundled Payment Programs: What's Working and Why	252AB	FORUM	60	Level: ●	ACPE, CME, IACET, RN
#123	12B	Unmet Medical Need: Diversity of Definitions and Viewpoints – Detangling the Challenge	157AB	SESSION	90	Level: ●	ACPE, CME, IACET, RN
#124	13	Analyzing Innovations Progress in the Gottlieb Era	210AB	FORUM	90	Level: ■	ACPE, CME, IACET, RN
12:30–2:15PM							
#125	15	Organizational Change and Knowledge Management for Cybersecurity Threats	E and E Exhibit Hall	WORKSHOP	60	Level: ●	
#126	16	EU Global Data Protection Regulation and Impact on US Companies	Content Hub NE Lobby	SESSION	30	Level: ■	IACET
#127	14A	IQVIA Innovation Theater: Re-Imagine Clinical Development with Human Data Science	Theater 1 Exhibit Hall	SESSION	30		
#128	14B	PPD Innovation Theater: Patient-Centered Study Planning and Feasibility Drives Speed, Certainty, and Quality at a Lower Cost	Theater 2 Exhibit Hall	SESSION	30		
#129	16	Using Quality-Inspired Dashboards to Track Patient Engagement	Content Hub NE Lobby	SESSION	30	Level: ■	IACET
#130	14A	PAREXEL International Innovation Theater: The Innovation Imperative: The Future of Drug Development	Theater 1 Exhibit Hall	SESSION	30		
#131	14B	Covance Innovation Theater: Evidenced-Based Approaches to Accelerating Patient Recruitment and Improving Patient Retention	Theater 2 Exhibit Hall	SESSION	30		
#132	15	New Approaches, Novel Endpoints, and Next-Generation Trials	E and E Exhibit Hall	WORKSHOP	60	Level: ■	
#133	17	DIA Good Clinical Practices and QA Community Round Table Discussion: Data Integrity Playbook: A Cross-Functional, Risk-Based, Analytics-Driven Approach to Monitor Data Integrity	Community Zone NE Lobby	FORUM	60		
#134	17	DIA Medical Writing Community Round Table Discussion: Scientific Communication Key Message Development, Management, and Dissemination	Community Zone NE Lobby	FORUM	60		
12:45–3:00PM		**STUDENT POSTER SESSION AND ORAL PRESENTATIONS | EXHIBIT HALL**					
2:00–2:45PM							
#135	09	On the Soapbox: Right to Try	157AB	SESSION	30	Level: ■	IACET
#136	16	Drug Safety: A Continuum Approach Linking Pre-Market and Post-Market Safety Assessment	Content Hub NE Lobby	SESSION	30	Level: ■	IACET
#137	14A	DiagnoSearch Life Sciences Innovation Theater: Disruptive Innovation - 'Wide-Angle-Data' - Intuitive Algorithms and Artificial Intelligence for Real-Time Safety and Risk Management	Theater 1 Exhibit Hall	SESSION	30		
#138	14B	SAS Institute Innovation Theater: Real World Evidence - Better, Faster, More!	Theater 2 Exhibit Hall	SESSION	30		

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
3:00–4:30PM							
#139	01A	Novel Approaches to Pharmacovigilance Collaboration	253C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#140	01B	How Inspection-Ready is Your Organization?	253AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#141	02A	eSource: The Road to Real World Evidence – Are We There Yet?	257AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#142	02C	Mobile Accelerometry in Clinical Trials: Potential Applications and Meaningful Outcomes	258AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#143	03	Applying Artificial Intelligence, Machine Language, Natural Language Processing, and Predictive Models in Clinical Trials to Deliver Value to Stakeholders	209	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#144	04	The Evolving Biosimilars Landscape: A Medical Affairs Perspective	210C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#145	05	A New Ecosystem: The Nature of Relationships Between Patient Advocacy Groups and Sponsors	153ABC	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#146	06A	Development of Microbiome-Derived Therapeutics	156ABC	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#147	06B	Facilitating Nonclinical Data Sharing and Access Across the Industry	151AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#148	07	Essential Project Leadership in Navigating an Evolving Regulatory Landscape in Asia-Pacific	258C	SESSION	60	Level: ■	CME, IACET, PMI, RN
#149	08	A Quality-by-Design Approach to Trial Design and Conduct: Case Studies from the Clinical Trials Transformation Initiative	205C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#150	09A	TFDA Town Hall	208	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#151	09B	Using Real World Evidence for Regulatory Support: Time to Embrace the Future	205AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#152	09C	FDA Expectations for Demonstration of Interchangeability	206AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#153	10	New Technologies in Pharmaceuticals and Biopharmaceuticals: Opportunities and Regulatory Challenges	204AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#154	11	Bayesian Application in Small-Sized Clinical Trials	256	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#155	12	Real World Evidence for Value and Access	252AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#156	13	International Regulatory Convergence	210AB	FORUM	90	Level: ■	ACPE, CME, IACET, RN
#157	18	Courageous Leadership	254AB	WORKSHOP	75	Level: ■	CME, IACET, PMI, RN
4:30–6:00PM		**STUDENT POSTER SESSION AND ORAL PRESENTATIONS | EXHIBIT HALL**					
4:45–6:00PM							
#158	14A	Advanced Clinical Innovation Theater: Preparing for the Next Generation of Clinical Research	Theater 1 Exhibit Hall	SESSION	30		
#159	14B	ArisGlobal Innovation Theater: A Clinical Perspective - How Cognitive E-2-E Pharma Platforms can Transform Productivity in Pharma - Introducing LifeSphere from Clinical to Regulatory	Theater 2 Exhibit Hall	SESSION	30		
#160	14A	Cognizant Innovation Theater: Powering New Possibilities for Site-Sponsor Collaboration with the Shared Investigator Platform in Partnership with TransCelerate	Theater 1 Exhibit Hall	SESSION	30		
#161	14B	Appian Innovation Theater: Moving Beyond Cloud with Digital Transformation to Unify Process, Connect Data, and Turbocharge Innovation	Theater 2 Exhibit Hall	SESSION	30		

TUESDAY, JUNE 26

8:00–9:30AM

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#201	01	Generic Drug Products: Comparison of Safety Profile With Branded Cousin	253AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#202	02A	Quantifying the Impact of Credentialed Clinical Research Site Professionals on Clinical Trial Conduct Quality	257AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#203	02B	Utilizing and Understanding Real World Evidence Solutions to Efficiently Recruit the Most Appropriate Patients and Sites for Clinical Trials	258AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#204	03	FDA Data Standards Update	209	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#205	04	Best Practices for Implementing Lay Summaries and Communicating Results to Patients	210C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#206	05	Incorporating Patient Input into US Food and Drug Administration's Medical Product Development and Regulatory Decision-Making	151AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#207	06	Novel Approaches for Accessing the CNS: Nonclinical and Clinical Challenges	156ABC	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#208	07	Effective Management of Internal Stakeholders and External Strategic Partners from Multiple Perspectives: Non-Profit, CRO, and Pharmaceutical Industry	153ABC	FORUM	75	Level: ■	ACPE, CME, IACET, PMI, RN
#209	08	Oversight in the Era of E6 (R2)	205C	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#210	09A	Artificial Intelligence: The Future of Regulatory Affairs	206AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#211	09B	Update on Collaboration and Trends in Global Companion Diagnostics	208	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#212	09C	Global Regulatory Strategies for Biosimilars	204AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#213	09D	2018 Policy Mash-Up: New Shifts in the Healthcare Market and What They May Mean for Patients and the Biopharma Industry	205AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#214	10	CMC Challenges for Breakthrough Therapies and Other Worldwide Accelerated Approval Programs	253C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#215	11	Pediatric and Rare Disease Drug Development	256	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#216	12	Early HTA Scientific Advice: Does it Improve Internal Company Decision-Making and Ensure Predictability of HTA Outcome?	258C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#217	13	Triple-A RWE: Adequate Data, Appropriate Study Designs, and Actionable Evidence	210AB	FORUM	90	Level: ◆	ACPE, CME, IACET, RN
#218	18	Building Your Brand	254AB	WORKSHOP	75	Level: ●	

9:15-10:30AM

#219	16	FDA Warning Letters on Data Integrity	Content Hub NE Lobby	SESSION	30	Level: ●	IACET
#220	15	Brexit: Practical Real World Solution Planning	E and E Exhibit Hall	WORKSHOP	60	Level: ●	
#221	17A	DIA Regulatory Community Round Table Discussion: Artificial Intelligence: The Future of Regulatory Affairs	Community Zone NE Lobby	FORUM	60		
#222	17B	DIA Patient Engagement Community Round Table Discussion: New Ecosystem: The Nature of Relationships Between Patient Advocacy Groups and Sponsors	Community Zone NE Lobby	FORUM	60		
#223A	06	On the Soapbox: Blockchain and Genomics	157AB	SESSION	30	Level: ■	
#223B	14A	Covance Innovation Theater: Case Study - Driving Clinical Transformation Through a Next-Generation of Data Integration and Analytic Technologies with a GlaxoSmithKline-Covance Partnership	Theater 1 Exhibit Hall	SESSION	30		
#224	14B	Veeva Systems Innovation Theater: Global Industry Report - New Findings from the 2018 Unified Clinical Operations Survey	Theater 2 Exhibit Hall	SESSION	30		

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#225	16	Building a Dynamic Presentation: Rethinking Audience Engagement	Content Hub NE Lobby	SESSION	30	Level: ●	IACET

9:30–10:30AM PROFESSIONAL POSTER SESSION | EXHIBIT HALL

10:30AM–12:00PM

#226	01	Regulators' Utilization of Real-World Data in Pharmacovigilance Activities	253AB	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#227	02A	Digital Data Flow from Protocol to Report: TransCelerate's Common Protocol Template and the Art of the Possible	257AB	SESSION	75	Level: ■	CME, IACET, RN
#228	02B	Global Clinical Trials: Lessons in Effective Execution	258AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#229	02C	Mobile Reported Outcomes: A Forum on Patient and Caregiver Assessments	258C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#230	03A	Common Data Model Harmonization for Evidence Generation	208	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#231	03B	Automation with Intelligence: From Standard-Based Solution to Metadata-Driven Automation	209	SESSION	60	Level: ●	ACPE, CME, IACET, RN
#232	04	Digital Data and New Technologies to Drive Customer Impact in Medical Affairs, Medical Writing, and Medical Communications	210C	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#233	05	The Patient's Assessment of the Patient-Focused Drug Development Meeting Initiatives	151AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#234	06	Personalized Medicine Approaches During Early-Phase Clinical Research	156ABC	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#235	07	The Adventures of Patient Experience in Drug Development	252AB	SESSION	75	Level: ■	ACPE, CME, IACET, PMI, RN
#236	08	Executives Respond to the State of the Industry Report on Risk-Based Approaches in Clinical Trials: Opportunity or Threat?	205C	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#237	09A	Expanded Access: Where Are We Now?	206AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#238	09B	The European Medical Devices Regulation and MDUFA IV: One Year On - Is it Any Clearer?	204AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#239	09C	Generic Drug Town Hall	205AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#240	10	Biosimilars: Demonstrating Structural and Functional Similarity	253C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#241	11	Time-to-Event Analysis in Clinical Trials	256	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#242	12A	Unmet Medical Need: Can the Stakeholders Align? Progress to Date	153ABC	FORUM	90	Level: ■	ACPE, CME, IACET, RN
#243	13	Global Perspectives on Patient Engagement	210AB	FORUM	90	Level: ■	ACPE, CME, IACET, RN

12:00–2:00PM PROFESSIONAL POSTER SESSION AND ORAL PRESENTATIONS | EXHIBIT HALL

12:00–2:00PM

#244	15	Yes, No, Maybe: Sharing Health and Other Data for Research - Enthusiasm and Concern from the Patient Community	E and E Exhibit Hall	WORKSHOP	60	Level: ■	
#245	14A	IQVIA Innovation Theater: Real World Evidence to Enhance Drug Development	Theater 1 Exhibit Hall	SESSION	45		
#246	14B	AMPLEXOR Innovation Theater: How Regulatory Information Will Become Part of Your Company Big Data Architecture	Theater 2 Exhibit Hall	SESSION	45		
#247	14A	BioClinica Innovation Theater: Transformational Trends in Investigator Site Payments 2018	Theater 1 Exhibit Hall	SESSION	45		
#248	14B	Veeva Systems Innovation Theater: Tufts Research - Strategies from Data Management Leaders to Speed Clinical Trials	Theater 2 Exhibit Hall	SESSION	45		
#249	15	Global Evolution in Regulatory Science and Medicine: Novel Modalities and Intersection with Rare Disease Development	E and E Exhibit Hall	WORKSHOP	45	Level: ■	
#250	16	Developing Standards to Support the Use of Wearables and Sensors for Objective Data Collection During Clinical Trials	Content Hub NE Lobby	SESSION	30	Level: ■	IACET

TUESDAY, JUNE 26, CONTINUED

2:00–3:30PM

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#251	01A	Risk Management: New Directions	253AB	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#252	02A	Do the End(point)s Justify the Means? A Peak at Endpoints Accepted by FDA with an Eye Towards Mobile Technology Collection	257AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#253	02B	Digitizing a Patient-Focused Clinical Trial Experience	258AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#254	02C	Risk-Based Monitoring for Master Protocol Study: A Dilemma and Possible Ways to Go	258C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#255	03	Use of Electronic Health Records (EHRs) as eSource in Clinical Investigations	208	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#256	04A	CTD Regulatory Defense Strategies: How Best to Prepare Your Response to Health Authority Queries	210C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#257	04B	Globalizing and Regionalizing Medical Information Contact Centers	209	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#258	05	Reaching the Underserved: Methods to Ensure Diversity and Inclusion for Patient Research, Clinical Trials, and Advisory Panels	151AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#259	05B	Measuring the Impact of Patient Engagement: What to Ask Depends on Who You Ask	254AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#260	06	Optimizing Clinical Development with Adaptive Trial Designs	156ABC	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#261	07	Project Management Throwdown: How Not to Get Chopped	153ABC	FORUM	75	Level: ●	ACPE, CME, IACET, PMI, RN
#262	08	The Risk Assessment Is Done: Now What? A Guide to Setting up a Centralized Monitoring Plan	205C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#263	09A	Navigating the Regulatory Landscape of Drug-Device Combination Products	204AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#264	09B	Global Development Using Expedited Pathways in Established and Emerging Markets	206AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#265	10	ICH M9 BCS-Based Biowaivers	253C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#266	11	User-Friendly Tools for Study Planning and Analysis	256	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#267	12	Developing and Partnering on Evidence for Outcomes and Value Assessment: Standardizing Measurement for Patient-Centered Care	252AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#268	13	Future of PharmaTech	210AB	FORUM	90	Level: ■	ACPE, CME, IACET, RN

2:00–4:15PM

#269A	17A	DIA Regulatory Community Round Table Discussion: Global Regulatory Strategies for Biosimilars	Community Zone NE Lobby	FORUM	60		
#269B	15	Avoiding Rejection on your "First Date" with EMA Policy 0070	E and E Exhibit Hall	WORKSHOP	60	Level: ◆	
#270	17A	DIA Medical Writing Community Round Table Discussion: Digital Data and New Technologies to Drive Customer Impact in Medical Affairs, Medical Writing, and Medical Communications	Community Zone NE Lobby	FORUM	60		
#271	17B	DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Risk Management - New Directions	Community Zone NE Lobby	FORUM	60		
#272	15	LinkedIn Profile Exchange Review	E and E Exhibit Hall	WORKSHOP	45	Level: ●	
#273	16	DIA Insights: Expert Clinical and Regulatory Content - Timely Global and Regional Reports, New Digital Platform - Can We Help You?	Content Hub NE Lobby	SESSION	30	Level: ●	IACET
#274	14A	WIRB-Copernicus Group Innovation Theater: Clinical Research Sites: You're Competitive Battleground for Study Success	Theater 1 Exhibit Hall	SESSION	30		

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#275	14B	Veeva Systems Innovation Theater: Simplifying Variation Management	Theater 2 Exhibit Hall	SESSION	30		
3:00–4:00PM		**PROFESSIONAL POSTER SESSION | EXHIBIT HALL**					
4:15–5:30PM							
#276	01A	Patient Engagement in Pharmacovigilance	253AB	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#277	01B	Pharmacovigilance: No Longer Going it Alone	253C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#278	01C	Challenges and Opportunities in Data Access and Methodology Development for Post-Market Generic Drug Monitoring	252AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#279	02A	Redefining the Site Investigator's Experience	153ABC	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#280	02B	Debunking Decentralized Trials: Sharing Breakthroughs and Deal Breakers	254AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#281	02C	Future of Endpoints	258C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#282	03	Building up Efficiencies, Breaking Down Barriers: Using Mobile Technology for Data Capture in Clinical Trials	209	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#283	04	Evolving Roles and Responsibilities for Medical Affairs Professionals	210C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#284	05	Using Advocacy Partnerships to Improve Real World Evidence in Clinical Trials	151AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#285	06	Gene Therapy: Advances in Translating Technology	156ABC	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#286	07	Which Regulatory Project Management Staff at FDA Should You Engage With? When and How?	157AB	FORUM	75	Level: ■	ACPE, CME, IACET, PMI, RN
#287	08	The Letter and Spirit of Risk-Based Monitoring: How to Creatively Implement Risk-Based Modeling and Unlock the Potential of the Team	205C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#288	09A	Is it Time to Change the Content and Format of Labeling?	205AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#289	09B	Electronic Submissions Demystified	204AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#290	09C	Priority Review Vouchers: Here to Stay and Worth the Effort?	206AB	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#291	10	ICH Q12: A Paradigm Changing Guidance for Post-Approval Changes?	208	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#292	11	Complex Innovative Designs and Model-Informed Drug Development Related: PDUFA VI Pilot Programs	256	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#293	12A	Medical Monitoring in Non-Interventional Studies: Need for Medical Leadership and Study Primary Care Management	257AB	SESSION	60	Level: ●	ACPE, CME, IACET, RN
#294	12B	Sustainable Healthcare Funding	258AB	SESSION	60	Level: ◆	ACPE, CME, IACET, RN
4:30–5:30PM							
#295	17A	DIA Devices and Diagnostics Community Round Table Discussion: Navigating the Regulatory Landscape of Drug-Device Combination Products	Community Zone NE Lobby	FORUM	60		
#296	17B	DIA Medical Writing Community Round Table Discussion: CTD Regulatory Defense Strategies - How Best to Prepare Your Response to Health Authority Queries	Community Zone NE Lobby	FORUM	60		

WEDNESDAY, JUNE 27

8:00-9:30AM

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#301	01A	Automation in Pharmacovigilance: Doing More with Less	253C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#302	01B	Risk Communication and Patient Safety: Recent Learnings and New Approaches	253AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#303	02A	Regulatory and Ethical Considerations with Placebo Administration Using a Central Venous Access Device in a Pediatric Trial	258C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#304	02B	Data and Quality Approaches to Informing Global Investigative Site Selection	258AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#305	03	Building a Roadmap to the Implementation of the Risk-Based Monitoring Process: Facilitating the Perspectives of All Stakeholders	254AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#306	04	phactMI: A Collaborative Approach to Advancing the Practice of Medical Information and Enabling Innovative Customer Solutions	210C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#307	05	Maintaining Patient Engagement in the Development of Patient-Reported Outcome (PRO) Measures	153ABC	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#308	05A	How do Patients and Other Multi-Disciplinary Stakeholders Collaborate to Develop Patient Registries Which Accelerate Research?	151AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#309	06	Evolution and Harmonization of First-in-Human Guidelines	156ABC	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#310	07	Becoming Highly Self-Aware: Leading in the Midst of Ambiguity	252AB	WORKSHOP	75	Level: ■	CME, IACET, PMI, RN
#311	08	Harnessing the Power of Data and Analytics to Enhance Quality	205C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#312	09A	Harmonizing Regulatory Science Through the International Council for Harmonisation (ICH)	206AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#313	09B	Global Rare Disease Town Hall	205AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#314	09C	What Can We Say About Combination Products? Labeling, Advertising, and Promotion of Combination Products	204AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#315	10	Can I Implement That Now? Efficiently Managing Post-Approval CMC Changes	208	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#316	11	Opportunities for Efficient and Innovative Study Designs	256	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#317	12	Operationalizing Real World Evidence and Value	257AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#318	13	Value-Based Assessment and Contracting: What Needs to be Done to Make it a Best Practice?	210AB	FORUM	90	Level: ■	ACPE, CME, IACET, RN
#319	17B	DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Pharmacovigilance: No Longer Going it Alone	Community Zone NE Lobby	FORUM	60		
#320	17B	DIA Patient Engagement Community Round Table Discussion: Reaching the Underserved: Methods to Ensure Diversity and Inclusion for Patient Research, Clinical Trials, and Advisory Panels	Community Zone NE Lobby	FORUM	60		
#321	18	PowerUp: Career Transforming Moments	157AB	SESSION	60	Level: ●	

9:15-10:30AM

#322	16	New Resource from the DIA Interdisciplinary Disclosure Working Group	Content Hub NE Lobby	SESSION	30	Level: ■	IACET
#323	15	Good Things Come in Small Packages: Product Development Strategies for Small Companies	E and E Exhibit Hall	WORKSHOP	60	Level: ■	
#324	17B	DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Patient Engagement in Pharmacovigilance	Community Zone NE Lobby	FORUM	60		
#325	17B	DIA Clinical Data Management Community Round Table Discussion: The Letter and Spirit of Risk-Based Monitoring - How to Creatively Implement the RBM and Unlock the Potential of the Team	Community Zone NE Lobby	FORUM	60		

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#326	14A	ArisGlobal Innovation Theater: A Regulatory Perspective - How Cognitive E-2-E Pharma Platforms can Transform Productivity in Pharma - Introducing LifeSphere from Clinical to Regulatory	Theater 1 Exhibit Hall	SESSION	30		
#327	14B	SAS Institute, JMP Division Innovation Theater: RECIST Criteria and Their Impact on Safety and Efficacy Reporting in Oncology Studies	Theater 2 Exhibit Hall	SESSION	30		
#328	16	Getting the Questions Right	Content Hub NE Lobby	SESSION	30	Level: ●	IACET
9:30–10:30AM		**PROFESSIONAL POSTER SESSION | EXHIBIT HALL**					
10:30AM–12:00PM							
#329	01	Reducing the Burden of Drug Safety Risk Minimization Programs on the Healthcare System: How do We do so and What Has Been Learned to Date?	253AB	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#330	02A	Artificial Intelligence: Robots Taking Over Clinical Research	253C	FORUM	75	Level: ●	ACPE, CME, IACET, RN
#331	02B	Rebuilding or Building a Research Site in the Year 2020	254AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#332	03A	Clinical Data: Let's Get to the Source and Streamline it to the End	208	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#333	03B	Streamlining Vendor Reconciliation	209	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#334	04A	Clinical Trial Disclosure: Learnings from EMA Policy 0070, NIH Final Rule, and FDA's Clinical Data Summary Pilot Program	210C	SESSION	90	Level: ■	ACPE, CME, IACET, RN
#335	04B	Collaboration Across the Medical Affairs Ecosystem to Advance Patient Care	257AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#336	05	Addressing the Elephant in the Room: A Hard Look at Metrics, Legal, Payers, and Other Leading Obstacles Facing the Sustainability of Patient Engagement	153ABC	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#337	06	Balancing Regulatory, Medical, and Operational Pillars to Get Pediatric Trials Done Globally	156ABC	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#338	07	You've Got Data #now what?	157AB	SESSION	75	Level: ◆	ACPE, CME, IACET, PMI, RN
#339	08	Determining Data Integrity: Decoding the Impact of Inspectional Observations	258AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#340	09A	Harmonization Beyond ICH	206AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#341	09B	New FDA Draft Guidance on Part 11 in Clinical Investigations	204AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#342	09C	Sex Considerations in the FDA Drug Review Pipeline: The Where, When, and How	205C	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#343	11	Innovative Visualization Approaches	256	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#344	12A	Biosimilar Interchangeability: A Global Perspective	205AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#345	12B	Unmet Medical Need: Path Forward – Creating a Commonly Agreed Criteria Globally	252AB	WORKSHOP	90	Level: ◆	ACPE, CME, IACET, RN
#346	13	Precision Medicine, Gene Editing, and Gene Therapy: Current Status and Regulatory Challenges of Integrating Genetic Medicine into Clinical Care	210AB	FORUM	90	Level: ■	ACPE, CME, IACET, RN
12:00–2:00PM							
#347	15	Just the Right Tool: ICH E6 (R2) Compliance Tools for Small- to Mid-Size Companies	E and E Exhibit Hall	WORKSHOP	60	Level: ■	
#348	16	Making Better Portfolio Prioritization Decisions	Content Hub NE Lobby	SESSION	30	Level: ■	IACET
#349	14A	ZS Associates Innovation Theater: Building an RWE Bridge from Population Health to Personalized Medicine	Theater 1 Exhibit Hall	SESSION	45		
#350	14B	Salesforce Innovation Theater: Accelerate R&D Innovation with Salesforce for Life Sciences	Theater 2 Exhibit Hall	SESSION	45		

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
WEDNESDAY, JUNE 27, CONTINUED							
#351	16	Moving Forward with the EU Vigil: The Patient Contact in Pharmacovigilance	Content Hub NE Lobby	SESSION	30	Level: ■	IACET
#352	17A	DIA Clinical Pharmacology Community Round Table Discussion: Evolution and Harmonization of First-in-Human Guidelines	Community Zone NE Lobby	FORUM	60		
#353	17B	DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Automation in Pharmacovigilance: Doing More with Less	Community Zone NE Lobby	FORUM	60		
#354	14	IQVIA Innovation Theater: The Digital Future is Now	Theater 1 Exhibit Hall	SESSION	45		
#355	14B	PAREXEL International Innovation Theater: Patient Centricity - From Postulation to Performance - Advancing Data Capture in Clinical Trials with Wearables	Theater 2 Exhibit Hall	SESSION	30		
#356	15	The Worst Co-Worker on the Block	E and E Exhibit Hall	WORKSHOP	45	Level: ●	
#357	16	Difficult Conversations	Content Hub NE Lobby	SESSION	30	Level: ●	IACET
12:00–2:00PM		**PROFESSIONAL POSTER SESSION AND ORAL PRESENTATIONS | EXHIBIT HALL**					
2:00–3:15PM							
#358	01A	Expedited E2B Safety Reporting in Interventional Clinical Trials: Convergence of Global Expectations?	253AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#359	01B	IMEDS: A Collaboration Based on the FDA's Sentinel Initiative	253C	FORUM	75	Level: ●	ACPE, CME, IACET, RN
#360	02B	Implementation of eConsent and Other Digital Clinical Trial Innovations	258AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#361	02	A New Way of Authoring and Reviewing Documents for Clinical Development	258C	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#362	03	Do the Evolution: The Future Role of Clinical Data Management	209	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#363	04A	Innovative and Effective Authoring Strategies to Facilitate Accelerated Regulatory Submissions	157AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#364	04B	Achieving Customer Centricity to Advance Patient Care Through Innovative Communication Channels	210C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#365	05	Engaging the Rare Disease Community to Design Clinical Trials	151AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#366	06	Gene Therapy Clinical Trials: Current Challenges	156ABC	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#367	07A	Real Life Strategies for Collaborative Stakeholder Management	252AB	WORKSHOP	75	Level: ●	ACPE, CME, IACET, PMI, RN
#368	07B	Predicting Future Generic Drug Competition: Powering Strategic Planning Using Quantitative Methods and Modeling	153ABC	FORUM	75	Level: ■	ACPE, CME, IACET, PMI, RN
#369	08	Virtual Audits: Do They Achieve the Objective?	257AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#370	09	Clinical Outcome Assessments (COA) Endpoints for Use in Rare and Ultra-Rare Disease Clinical Trials	204AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#371	09A	What's New in Health Canada: Updates and New Endeavors	205C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#372	09B	AdPromo: Assessing Risk in the Current Regulatory Environment	206AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#373	09C	PMDA Town Hall	205AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#374	10	Modernization and Harmonization of Inspectional Approaches	208	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#375	11	Statistical Challenges in Assessing Drugs' Efficacy by Utilizing Biomarker Endpoints	256	SESSION	75	Level: ■	ACPE, CME, IACET, RN

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#376	18	Courageous Hiring	254AB	WORKSHOP	75	Level: ●	
3:00–4:00PM		**PROFESSIONAL POSTER SESSION | EXHIBIT HALL**					
3:15–4:00PM							
#377	16	First-in-Human Studies: An Examination of the Evolving Regulatory and Clinical Practices to Ensure Subject Safety	Content Hub NE Lobby	SESSION	30	Level: ■	IACET
#378	17A	DIA Devices and Diagnostics Community Round Table Discussion: What Can We Say About Combination Products? Labeling, Advertising, and Promotion of Combination Products	Community Zone NE Lobby	FORUM	60		
#379	17B	DIA Clinical Trial Disclosure and DIA Medical Communication Communities' Round Table Discussion: Clinical Trial Disclosure: Learnings from EMA Policy 0070, NIH Final Rule, and FDA's Clinical Data Summary Pilot Program	Community Zone NE Lobby	FORUM	60		
#380	15	Use of New Data Sources and Evidence Types for Regulatory Decision-Making in Drug Development	E and E Exhibit Hall	WORKSHOP	45	Level: ■	
#381	16	Project Management's Role in Developing and Securing Governance Approval of a Drug Development Program Strategy	Content Hub NE Lobby	SESSION	30	Level: ■	IACET
4:00–5:15PM							
#382	01A	Artificial Intelligence: A Disruptive Journey for Pharmacovigilance	253AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#383	01C	Safe Use and Prescribing of Opioid Medications: An In-Depth Look at the Strategies and Their Evaluation	253C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#384	02A	Innovations in Managing Global Clinical Supplies	258AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#385	02B	Does Sourcing Strategy Matter? Executives Debate the Influence of Outsourcing Model on Clinical Trial Execution	258C	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#386	02C	Bring Your Own Device ePRO: Hold the Relish, or No Holds Barred?	257AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#387	03	Evolving CDISC Standards and Technologies	208	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#388	04	Using Patient-Centric Outcomes to Engage Patients in Shared Treatment Decision-Making	210C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#389	05A	Patient Observation Versus Patient Engagement: Optimizing Development	151AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#390	06	Special Population Study Challenges	156ABC	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#391	07A	How to De-Risk Alliances for Success	209	SESSION	75	Level: ■	CME, IACET, PMI, RN
#392	07B	FUNdamentals of Project Management	153ABC	SESSION	75	Level: ●	ACPE, CME, IACET, PMI, RN
#393	08	Think Like a Regulator: Evaluating Trial Integrity	252AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#394	09A	Update on BREXIT	205AB	FORUM	60	Level: ■	
#395	09B	PDUFA VI: Improving Transparency and Accountability of Electronic Submission and Data Standards Activities	205C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#396	10	Current and Future Perspective on Mutual Recognition, Work Sharing, and Global Regulatory Convergence	254AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#397	11	Design and Statistical Considerations for Real World Evidence to Support Regulatory Decision-Making	256	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#398	12	The Impact of Cell and Gene Therapy on the Payer System	204AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN

THURSDAY, JUNE 28

8:00–9:00AM

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#401	17A	DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Risk Management: Artificial Intelligence - A Disruptive Journey for Pharmacovigilance	Community Zone NE Lobby	FORUM	60		
#402	17B	DIA Patient Engagement Community Round Table Discussion: Addressing the Elephant in the Room: A Hard Look at Metrics, Legal, Payers, and Other Leading Obstacles Facing the Sustainability of Patient Engagement	Community Zone NE Lobby	FORUM	60		
#403	16	General Data Protection Regulation (GDPR): Impact, Self-Assessment, and Practical Solutions for Compliance	Content Hub NE Lobby	SESSION	30	Level: ●	IACET

9:00–10:30AM

#404	01	Payers, Industry, and Academia Collaborating on Post-Marketing Surveillance	204AB	FORUM	75	Level: ●	ACPE, CME, IACET, RN
#405	02	Putting Patient Experience First	205AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#406	03	Improving Efficiency and Effectiveness in Data Management of Pediatric, Rare Disease, and Oncology Trials	205C	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#407	05	Beyond Adult Patients, Untapped Advisors in Clinical Development: Adolescents, Parents, Siblings, and Spouses	209	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#408	06	Innovative Funding Models for Novel Therapeutics	206AB	FORUM	60	Level: ■	CME, IACET, RN
#409	07	Emerging Best Practices and Challenges in Strategic Drug Development and Design Decision-Making	256	SESSION	75	Level: ■	ACPE, CME, IACET, PMI, RN
#410	08	Assessing Your Clinical Quality Management System: An In-Depth Look at TransCelerate's Assessment Tool	252AB	WORKSHOP	75	Level: ■	CME, IACET, RN
#411	09A	Regulatory and Industry Perspectives on the Common Protocol Template	253C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#412	09B	Metrics and Meaning: Evolving Metrics in Generic Drug Application Review and Communications to Improve ANDA Submission Planning and Approvability	257AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#413	11	The Correlation Between Patient-Reported Outcomes and Clinician-Reported Outcomes	254AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#414	12	Unmet Medical Need: What Did We Create Together and Where to Take It?	208	SESSION	90	Level: ■	ACPE, CME, IACET, RN
#415	13	EMA/FDA Question Time	210AB	FORUM	90	Level: ■	ACPE, CME, IACET, RN

10:45AM–12:00PM

416	13	FDA Town Hall	210AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN

The following agenda details were made available to DIA on or before May 11. 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 23

Registration Hours

8:00AM–5:00PM Exhibitor Registration

SUNDAY, JUNE 24

Registration Hours

8:00–9:00AM 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*, Meeting 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 and Emerging Professional Forum

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

3:00–5:30PM Professional Development Sessions

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

TRACK 18 - PROFESSIONAL DEVELOPMENT

10:30AM–12:00PM LEVEL: ● FORMAT: FORUM

Room: Commonwealth Ballroom, Concourse Level, Westin Boston Waterfront

Emerging Professionals and Student Forum

CHAIRPERSON

Raleigh E. Malik, PhD
Senior Scientific Liaison, DIA

PANELIST

Ranjini Prithviraj, PhD
Senior Managing Editor/Associate Director, DIA

#001 TRACK 18 - PROFESSIONAL DEVELOPMENT

3:00–4:00PM LEVEL: ● FORMAT: WORKSHOP

Room: 252AB

Effective Use of Social Media

CHAIRPERSON

Robin Whitsell
President, Whitsell Innovations, Inc

#002 TRACK 18 - PROFESSIONAL DEVELOPMENT

4:15–5:30PM LEVEL: ● FORMAT: WORKSHOP

Room: 252AB

The Power of Networking

CHAIRPERSON

Chris Matheus, MBA
President, Matheus BD Connections

FACILITATOR

Michelle Esposito
Director, Institutional Services and Sites, Advarra

MONDAY, JUNE 25

Registration Hours

7:00AM–6:00PM Attendee, Speaker, and Exhibitor Registration

7:30–8:30AM

Coffee and Light Refreshments

Ballroom Lobby | Level 3

7:30–8:15AM

Annual Meeting Orientation

Room: 252AB | Level 2

#100 TRACK 00 - PLENARY

8:30–10:00AM LEVEL: ■ FORMAT: SESSION

Room: Ballroom *CME, Pharmacy, and Nursing*

Opening Plenary Session and Keynote Speaker

CHAIRPERSON

Barbara Lopez Kunz, MSc
Global Chief Executive, DIA

SPEAKER(S)

Welcome Remarks
Julie Louise Gerberding, MD, MPH
Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health Merck & Co., Inc.

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

All Hands on Deck: Using Science to Help Solve the Opioid Crisis
Nora D. Volkow, MD
Director, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH)

10:00–11:00AM

Coffee Break
Exhibit Hall

#101 Track 14A - Innovation Theater

10:15–10:45AM Format: SESSION
Room: Theater 1 | Exhibit Hall

PAREXEL International Innovation Theater: Innovation's Greater Purpose - How Technology Can Increase Commercial Success

#102 Track 14B - Innovation Theater

10:15–10:45AM Format: SESSION
Room: Theater 2 | Exhibit Hall

Deloitte Innovation Theater: Engage. Innovate. Execute. - How Digital Technologies are Transforming Clinical Development

#103 Track 15 - Engage and Exchange

10:15–11:00AM Level: ● Format: WORKSHOP
Room: E and E | Exhibit Hall

Networking Do's and Don'ts

CHAIRPERSON

Chris Matheus, MBA
President, Matheus BD Connections

SPEAKER(S)

Details of Networking
Michelle Esposito
Director, Institutional Services and Sites, Advarra

#104 Track 16 - Content Hubs

10:30–11:00AM Level: ● Format: SESSION
Room: Content Hub | NE Lobby *IACET*

LinkedIn Review

CHAIRPERSON

Tom McPhatter
Director Business Development, Whitsell Innovations, Inc

#105 Track 01A - Clinical Safety and Pharmacovigilance

Featured Topic(s): Translational Science and Medicine

11:00AM–12:00PM Level: ● Format: SESSION
Room: 253AB *CME, Pharmacy, and Nursing*

Cardiac Safety in Drug Development and the Critical Role of Public-Private Partnerships: The Cardiac Safety Research Consortium Model

CHAIRPERSON

Rick Turner, DrSc, PhD
President, Turner Consulting and Communications LLC

SPEAKER(S)

The Cardiac Safety Research Consortium: Current Accomplishments and Future Goals
Mitchell W. Krucoff, MD
Professor of Medicine/Cardiology, Duke University

New Approaches to Regulatory Science in Cardiac Safety
Norman Stockbridge, MD, PhD
Director, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

The Comprehensive *In Vitro* Proarrhythmia Assay (CiPA)
Philip T. Sager, MD
Adjunct Professor, Stanford University

#106 Track 01B - Clinical Safety and Pharmacovigilance

Featured Topic(s): Real World Evidence

11:00AM–12:15PM Level: ■ Format: SESSION
Room: 253C *CME, Pharmacy, and Nursing*

Signal Management: Separating Needles from Haystacks

CHAIRPERSON

Stephen Knowles, MD, MRCP
Vice President, Drug Safety and Pharmacovigilance, Halozyme Therapeutics

SPEAKER(S)

Experiences with the EVDAS Requirements
Uwe Trinks, DrSc, PhD
Partner and Director, Foresight Group, An IQVIA Company

From Clinical Trial to Post-Marketing Signal Management: A Continuum
Rosa A. Piccirillo, MD
Senior Director and Global Head, Medical Safety, Core Safety Services, IQVIA

Major Issues with the New Eudravigilance System (EVDAS) that Were Outlined Within the Recent Q&A Document Published by EMA
Mick Foy
Head of Pharmacovigilance Strategy, Vigilance Intelligence and Research Group, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

#107 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Mobile Technology, Translational Science and Medicine

11:00AM–12:00PM Level: ● Format: FORUM
Room: 257AB *CME, Pharmacy, and Nursing*

The Metamorphosis of Clinical Trials: Evolving Roles of Stakeholders in Digital Trials

CHAIRPERSON

Josh Rose, MBA
Vice President, Global Head of Strategy, IQVIA

PANELISTS

Murray A. Abramson, DrMed, MPH
Vice President, Global Clinical Operations, Biogen Inc.

Angela Botto-van Bemden, PhD
Director, OA Programs, Arthritis Foundation

#108 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine

11:00AM–12:00PM | Level: ■ | Format: SESSION

Room: 258AB | *CME, Pharmacy, and Nursing*

From Patients and Advocacy Groups to Operations and Beyond: Obtaining and Incorporating Input from Stakeholders in Protocol Design

CHAIRPERSON

Andrea Lukes, MD, MHS
Co-Founder, OB/GYN, Carolina Research and Wellness Clinic

SPEAKER(S)

Best Ways to Partner with Advocacy Group: From a CRO Perspective
Clint Dart, MS
Senior Director, Biometrics, Health Decisions

The Advocacy Group's Voice
Michelle Witkop, DrSc
Head of Research, National Hemophilia Foundation

#109 Track 02C - Clinical Trials and Clinical Operations

Featured Topic(s): Mobile Technology, Translational Science and Medicine

11:00AM–12:15PM | Level: ■ | Format: FORUM

Room: 258C | *CME, Pharmacy, and Nursing*

The Who, What, How, When, and Why of Using Mobile Technology in Clinical Trials

CHAIRPERSON

Robert A. DiCicco
Executive Consultant, TransCelerate Biopharma Inc.

PANELISTS

Cynthia Geoghegan
Patient Representative, Patients and Partners LLC

Philip Coran, JD, MBA
Principal, Global Compliance and Strategy, Medidata Solutions

Jan Hewett
Regulatory Counsel for Policy, Office of Scientific Investigations, CDER, FDA

#110 Track 03A - Data and Data Standards

Featured Topic(s): Translational Science and Medicine

11:00AM–12:15PM | Level: ■ | Format: SESSION

Room: 208 | *CME, Pharmacy, and Nursing*

Using Fast Healthcare Interoperability Resources (FHIR®) for Clinical Research

CHAIRPERSON

Wayne R. Kubick, MBA
Chief Technology Officer, HL7 International

SPEAKER(S)

Fast Healthcare Interoperability Resources: An Evolving Data Standard for Interoperability in the Life Sciences Industry
Kunal Dubey, MBA
Healthcare Consultant, Citius Tech Healthcare Technology Pvt. Ltd., India

eSource and FHIR: The TransCelerate Experience
Jesper Kjaer, MS
Manager, Novo Nordisk A/S, Denmark

#111 Track 03B - Data and Data Standards

11:00AM–12:00PM | Level: ■ | Format: SESSION

Room: 209 | *CME, Pharmacy, and Nursing*

Data Integrity Playbook: A Cross-Functional, Risk-Based, Analytics-Driven Approach to Monitor Data Integrity

CHAIRPERSON

Nareen Katta, MBA, MS
Director, Data Sciencies, AbbVie, Inc.

SPEAKER(S)

Data Integrity: It's Not Just for Clinical Data
Gene Vinson
Senior Director, Global Data Technologies, Biometrics, Syneos Health

Round Table: This discussion will continue at 1:45PM on Monday, June 25 in the DIA Community Zone, NE Lobby, Level 1

#112 Track 04 - Medical Affairs and Scientific Communication

Featured Topic(s): ExUS Regulatory

11:00AM–12:15PM | Level: ■ | Format: SESSION

Room: 210C | *CME, Pharmacy, and Nursing*

Scientific Communication Key Message Development, Management, and Dissemination

CHAIRPERSON

David B. Clemow, PhD
Advisor, Scientific Communications Information Strategy, Eli Lilly and Company

SPEAKER(S)

Scientific Narrative Development: Medical Message Inputs and Disclosure Outputs
David B. Clemow, PhD
Advisor, Scientific Communications Information Strategy, Eli Lilly and Company

The Advisory Board 'Laboratory' for Key Message Development
Kristine Jolliffe
Director, Scientific Content, Six Degrees Medical Consulting, Canada

Innovating Medical Communications: Transformative Approaches for Adding Value Through Improved Medical Decision-Making
Wesley Portegies, MBA
Chief Executive Officer, Medicalwriters.Com

Round Table: This discussion will continue at 1:45PM on Monday, June 25 in the DIA Community Zone, NE Lobby, Level 1

#113 Track 05A - Patient Engagement

11:00AM–12:15PM | Level: ● | Format: FORUM

Room: 151AB | *CME, Pharmacy, and Nursing*

Patient-Focused Medicines Development: Where it has Led Us to Today, What Challenges Remain, and What do We Still Need to do to Achieve Success?

CHAIRPERSON

Lode Dewulf, MD, FFPM
Chief Patient Officer, Servier, France

PANELISTS

David Gray
Senior Director, Pfizer Inc

Sarah Krug, MS, MSc
Chief Executive Officer, CANCER101

Pamela Tenaerts
Executive Director, Clinical Trials Transformation Initiative (CTTI)

Lisa Cone
Patient, Parkinson's Disease Foundation Initiative

#114 Track 05B - Patient Engagement

Featured Topic(s): Translational Science and Medicine, Rare Diseases

11:00AM–12:15PM Level: ■ Format: FORUM
Room: 153ABC *CME, Pharmacy, and Nursing*

A Hot Debate: Perspectives on Benefit and Risk from Patients Across Diseases

CHAIRPERSON

Deborah E. Collyar
President, Patient Advocates In Research (PAIR)

PANELIST(S)

Benefit-Risk Communication: Lessons from Patients
Dinah Duarte, PharmD, MSc
Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

PREFERing to Advocate for Patient Preferences
Rebecca A. Noel, DrPH
Global Benefit-Risk Lead, Global Patient Safety, Eli Lilly and Company

Living with Tuberous Sclerosis Complex (TSC): A Case Study
Marlo Schepper
Volunteer, Tuberous Sclerosis Alliance

#115 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Gene Therapy, Translational Science and Medicine

11:00AM–12:00PM Level: ■ Format: SESSION
Room: 156ABC *CME, Pharmacy, and Nursing*

Regenerative Medicine Advanced Therapies: Facilitating Product Development and Approval

CHAIRPERSON

Peter W. Marks, MD, PhD
Director, Center for Biologics Evaluation and Research, FDA

SPEAKER(S)

FDA Perspective
Tejashri Purohit-Sheth, MD
Chief Medical Officer, Office of Tissues and Advanced Therapies, CBER, FDA

EMA Perspective
Marie-Helene Pinheiro
Industry Stakeholder Liaison, Corporate Stakeholders Division, European Medicines Agency (EMA), European Union

Industry Perspective
Robert W. Mays, PhD
Vice President of Regenerative Medicine and Head of Neuroscience Programs, Athersys, Inc.

Jane S. Lebkowski, PhD
President of Research and Technology, Regenerative Patch Technologies

Joshua M. Hare, MD, FACC
Founding Director, Interdisciplinary Stem Cell Institute; Professor of Medicine, University of Miami

#116 Track 07 - Project Management and Strategic Planning

Featured Topic(s): Career Development

11:00AM–12:15PM Level: ■ Format: WORKSHOP
Room: 254AB *CME, Nursing, and PMI PDUs*

Culture: The Link Between Team Culture and Productivity - An Interactive Workshop

CHAIRPERSON

Nancy Slater, MBA
Senior Director, AbbVie, Inc.

FACILITATORS

Carrie Furin
Manager, Clinical Trial Management, Eli Lilly and Company

Nancy Watanabe
Senior Director, BeiGene, Inc.

#117 Track 08 - R&D Quality and Compliance

Featured Topic(s): Real World Evidence

11:00AM–12:00PM Level: ◆ Format: FORUM
Room: 205C *CME, Pharmacy, and Nursing*

Beyond Robotics Process Automation: Next Generation Integrated QMS for R&D

CHAIRPERSON

Christina R. Morris
Senior Manager, Advisory Services, Ernst & Young, LLP

PANELISTS

Brad Haby
Senior Director, IT - Data Science, PRA

Kimberly A. Tableman
Digital, Data, and Analytics Drug Development, UP/UM Women's Leadership Initiative Site Co-Lead, GlaxoSmithKline

#118 Track 09A - Regulatory

Featured Topic(s): Real World Evidence, Regulatory Agency Presenters, ExUS Regulatory

11:00AM–12:15PM Level: ■ Format: FORUM
Room: 205AB *CME, Pharmacy, and Nursing*

How Can We Optimally Incorporate Real World Evidence into Regulatory Decision-Making?

CHAIRPERSON

Jeffrey N. Stuart, PhD, RAC
Global Regulatory Director, Oncology, Immunology, and InVitro Diagnostics, Merck & Co., Inc.

SPEAKER(S)

EMA Perspective
Tânia Teixeira
FDA Liaison Official, European Medicines Agency (EMA), European Union

Regulatory Perspective
Nikolai Constantin Brun, MD, PhD
Chief Medical Officer, Director of Division for Medical Evaluation and Biostats, Danish Medicines Agency, Denmark

Patient Perspective
Jeff Allen, PhD
President and Chief Executive Officer, Friends of Cancer Research

FDA Perspective
Jacqueline A. Corrigan-Curay, JD, MD
Director, Office of Medical Policy, CDER, FDA

#119 Track 09D - Regulatory

Featured Topic(s): Pediatrics

11:00AM–12:15PM Level: ■ Format: SESSION
Room: 204AB *CME, Pharmacy, and Nursing*

'Target'ing Pediatric Oncology Development: New Global Pediatric Considerations Under FDARA 2017

CHAIRPERSON
Melodi J. McNeil, MS, RPh
Director, AbbVie, Inc.

SPEAKER(S)

Industry Perspective
Christina Bucci-Rechtweg, MD
Global Head, Pediatric and Maternal Health Policy, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

FDA Perspective
Lynne P. Yao, MD
Director, Division of Pediatric and Maternal Health, Office of New Drugs, CDER, FDA

EMA Perspective
Agnès Saint-Raymond
Head of International Affairs, Head of Portfolio Board, European Medicines Agency (EMA), European Union

#120 Track 10 - Regulatory CMC and Product Quality

Featured Topic(s): Regulatory Agency Presenters, Generics

11:00AM–12:15PM Level: ● Format: SESSION
Room: 206AB *CME, Pharmacy, and Nursing*

FDA Innovation in Pharmaceutical Quality Assessment and Inspection

CHAIRPERSON
Christine M. V. Moore, PhD
Global Head and Executive Director, GRACS CMC - Policy, Merck Research Laboratories

SPEAKER(S)

Modernization of Quality Assessment of Generic Drugs
Susan M. Rosencrance, PhD
Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Patient-Focused Quality Within OPQ: Clinically Relevant Specifications and Quality Overall Summary
Ashley Boam
Director, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, FDA

#121 Track 11 - Statistics

Featured Topic(s): Regulatory Agency Presenters, Rare Diseases, Translational Science and Medicine

11:00AM–12:15PM Level: ■ Format: SESSION
Room: 256 *CME, Pharmacy, and Nursing*

Use of Historical Information in Clinical Trial Design

CHAIRPERSON
Sara Jimenez, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

SPEAKER(S)

Efforts to Combine Data Across Companies
Edward Bowen, MBA, MS
Lead, Placebo as Standard of Care Workstream, TransCelerate BioPharma

Using Historical Data to Transform Clinical Trials: Statistical Considerations
Jessica Lim, MA
Director, Clinical Statistics, GlaxoSmithKline

Converging Lines of Evidence: Using Modern Structural Meta-Analysis to Advance Multisite Knowledge Discovery - A Case Study
Andrew Wilson, PhD, MS
Director, Pharmacoepidemiology and Statistics RWDS, PAREXEL

#122 Track 12A - Value and Access

Featured Topic(s): Real World Evidence

11:00AM–12:00PM Level: ● Format: FORUM
Room: 252AB *CME, Pharmacy, and Nursing*

Contracting for Value: From Outcomes-Based Contracts to Bundled Payment Programs: What's Working and Why

CHAIRPERSON
Richard Gliklich, MD
Chief Executive Officer, OM1

SPEAKER(S)

Payer Perspective
Jim Clement, MHA
Executive Director, Cost of Care and Supply Chain Strategy, Aetna, Inc.

Industry Perspective
Robert Duffield, II, JD
Counsel, Novo Nordisk A/S

#123 Track 12B - Value and Access

11:00AM–12:30PM Level: ● Format: SESSION

Room: 157AB *CME, Pharmacy, and Nursing*

Unmet Medical Need: Diversity of Definitions and Viewpoints – Detangling the Challenge

CHAIRPERSON

Lawrence Eugene Liberti, PhD, RPh, RAC
Executive Director, Centre for Innovation in Regulatory Science (CIRS)

SPEAKER(S)

FDA Definition and How it is Interpreted in Decision-Making
Larry Bauer, MA, RN
Regulatory Scientist, Rare Diseases Program, Office of New Drugs, CDER, FDA

Vewpoint from a Maturing Market Regulator
Representative Invited
Director- President, Agência Nacional de Vigilância Sanitária (ANVISA), Brazil

Unmet Medical Need in Economic Evaluation
Karen Lee
Director, Health Economics, Canadian Agency For Drugs & Technologies In Health (CADTH), Canada

Patients View on How the Concept Works
Marc M. Boutin, JD
Chief Executive Officer, National Health Council (NHC)

#124 Track 13

DIAmond SESSIONS

11:00AM–12:30PM Level: ■ Format: FORUM

Room: 210AB *CME, Pharmacy, and Nursing*

Analyzing Innovations Progress in the Gottlieb Era

CHAIRPERSON

Nancy Bradish Myers, Esq., JD
President and Founder, Catalyst Healthcare Consulting, Inc

PANELISTS

Sandra A. Milligan, DIAFellow, JD, MD
Senior Vice President, Head of Global Regulatory Affairs and Clinical Safety, Merck Research Laboratories

Kathy Hibbs
Chief Legal and Regulatory Officer, 23 and Me

Representative Invited
Deputy Commissioner for Policy, Planning, Legislation and Analysis, Office of the Commissioner, FDA

Doug Cole, MD
Managing Partner, Flagstone Pioneering

12:00–2:00PM

Luncheon Service
Exhibit Hall

#125 Track 15 - Engage and Exchange

12:30–1:30PM Level: ● Format: WORKSHOP

Room: E and E | Exhibit Hall

Organizational Change and Knowledge Management for Cybersecurity Threats

CHAIRPERSON

Diane Cooney, MBA
Senior Consultant, CGI

#126 Track 16 - Content Hubs

12:30–1:00PM Level: ■ Format: SESSION

Room: Content Hub | NE Lobby *IACET*

EU Global Data Protection Regulation and Impact on US Companies

CHAIRPERSON

Terry Katz, MS
Director, Global Data Management and Statistics, Merck Animal Health

#127 Track 14A - Innovation Theater

12:45–1:15PM Format: SESSION

Room: Theater 1 | Exhibit Hall

IQVIA Innovation Theater: Re-Imagine Clinical Development with Human Data Science

#128 Track 14B - Innovation Theater

12:45–1:15PM Format: SESSION

Room: Theater 2 | Exhibit Hall

PPD Innovation Theater: Patient-Centered Study Planning and Feasibility Drives Speed, Certainty, and Quality at a Lower Cost

#129 Track 16 - Content Hubs

1:15–1:45PM Level: ■ Format: SESSION

Room: Content Hub | NE Lobby *IACET*

Using Quality-Inspired Dashboards to Track Patient Engagement

CHAIRPERSON

Mary Stober Murray, MBA
Associate Director, Diversity and Patient Engagement, Bristol-Myers Squibb

#130 Track 14A - Innovation Theater

1:30–2:00PM Format: SESSION

Room: Theater 1 | Exhibit Hall

PAREXEL International Innovation Theater: The Innovation Imperative: The Future of Drug Development

#131 Track 14B - Innovation Theater

1:30–2:00PM Format: SESSION

Room: Theater 2 | Exhibit Hall

Covance Innovation Theater: Evidence-Based Approaches to Accelerating Patient Recruitment and Improving Patient Retention

#132 Track 15 - Engage and Exchange

1:45–2:45PM Level: ■ Format: WORKSHOP

Room: E and E | Exhibit Hall

New Approaches, Novel Endpoints, and Next-Generation Trials

CHAIRPERSON

Jennifer C. Goldsack, MA, MBA
Senior Project Manager, Clinical Trials Transformation Initiative (CTTI)

FACILITATORS

Jessie Bakker, PhD, MS
Senior Manager, Clinical Trials, Philips Resperonics

Daniel Rollings Karlin, DrMed, MA, FAPA
Head of Clinical, Informatics, and Regulatory Strategy, Pfizer Inc

Komathi Stem, MS
Founder and Chief Executive Officer, monARC Bionetworks

#133 Track 17 - Community Rounds

1:45–2:45PM Format: FORUM

Room: Community Zone | NE Lobby

DIA Good Clinical Practices and QA Community Round Table Discussion: Data Integrity Playbook: A Cross-Functional, Risk-Based, Analytics-Driven Approach to Monitor Data Integrity

CHAIRPERSON

Terry Katz, MS
Director, Global Data Management and Statistics, Merck Animal Health

#134 Track 17 - Community Rounds

1:45–2:45PM Format: FORUM

Room: Community Zone | NE Lobby

DIA Medical Writing Community Round Table Discussion: Scientific Communication Key Message Development, Management, and Dissemination

CHAIRPERSON

David B. Clemow, PhD
Advisor, Scientific Communications Information Strategy, Eli Lilly and Company

#135 Track 09 - Regulatory

2:00–2:30PM Level: ■ Format: SESSION

Room: 157AB *IACET*

On the Soap Box: Right to Try

CHAIRPERSON

Beth E. Roxland, JD, MA
Senior Consultant On Law, Health Policy, and Ethics

#136 Track 16 - Content Hubs

2:00–2:30PM Level: ■ Format: SESSION

Room: Content Hub | NE Lobby *IACET*

Drug Safety: A Continuum Approach Linking Pre-Market and Post-Market Safety Assessment

CHAIRPERSON

Susan Duke, MSc
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

#137 Track 14A - Innovation Theater

2:15–2:45PM Format: SESSION

Room: Theater 1 | Exhibit Hall

DiagnoSearch Life Sciences Innovation Theater: Disruptive Innovation - 'Wide-Angle-Data' - Intuitive Algorithms and Artificial Intelligence for Real-Time Safety and Risk Management

#138 Track 14B - Innovation Theater

2:15–2:45PM Format: SESSION

Room: Theater 2 | Exhibit Hall

SAS Institute Innovation Theater: Real World Evidence - Better, Faster, More!

2:00–3:30PM

2018 CRO Leadership Awards Ceremony by Life Science Connect

Press Room | Room 104A | Level 1

#139 Track 01A - Clinical Safety and Pharmacovigilance

Featured Topic(s): Real World Evidence

3:00–4:15PM Level: ■ Format: SESSION

Room: 253C *CME, Pharmacy, and Nursing*

Novel Approaches to Pharmacovigilance Collaboration

CHAIRPERSON

Jose Vega, MD
Vice President, Chief Safety Officer, Merck & Co., Inc.

SPEAKER(S)

Industry Collaboration to Improve Patient Safety: TransCelerate's Long-Term Vision to Address Pharmacovigilance Challenges
Jose Vega, MD
Vice President, Chief Safety Officer, Merck & Co., Inc.

Evaluating the Value of Safety Information Data Sources: Gathering Evidence to Illustrate a Hierarchy of Value
Peter Verdru, MD
Vice President, Head of Patient Safety, UCB Biopharma S.P.R.L., Belgium

Interpretation of PV Regulations
Ajay B. Singh
Team Leader, Safety Evaluation and Risk Management, GlaxoSmithKline

Value of Safety Information Data Sources
Jeremy Jokinen, PhD, MS
Senior Director, Safety Decision Analytics, AbbVie, Inc.

FDA Perspective
Gerald J. Dal Pan
Director, Office of Pharmacovigilance and Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA

#140 Track 01B - Clinical Safety and Pharmacovigilance

3:00–4:15PM Level: ● Format: SESSION
Room: 253AB *CME, Pharmacy, and Nursing*

How Inspection-Ready is Your Organization?

CHAIRPERSON
Annette S. Williams, MBA, RPh
Vice President, Lifecycle Safety, IQVIA

SPEAKER(S)

Inspection Readiness: How Prepared are Your Systems for Global Regulatory Inspections?
Shelley Gandhi, MS
Strategic Advisor, NDA Group, United Kingdom

One Pharmacovigilance System to Satisfy FDA and MHRA's Inspections
Anil K. Hiteshi, RAC
Vice President, Global Regulatory Affairs, QA, PV and Drug Safety, and CDM, Spectrum Pharmaceuticals, Inc.

MHRA Perspective
Joanna Harper
Expert Inspector, GPvP, Medicines and Healthcare products Regulatory Agency (MRHA), United Kingdom

#141 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Real World Evidence, Translational Science and Medicine

3:00–4:00PM Level: ■ Format: SESSION
Room: 257AB *CME, Pharmacy, and Nursing*

eSource: The Road to Real World Evidence – Are We There Yet?

CHAIRPERSON
Jonathan Palmer
Senior Director, Product Strategy, Digital Trials, Oracle Health Sciences, United Kingdom

PANELIST
Daniel Rollings Karlin, DrMed, MA, FAPA
Head of Clinical, Informatics, and Regulatory Strategy, Pfizer Inc

#142 Track 02C - Clinical Trials and Clinical Operations

Featured Topic(s): Mobile Technology, Translational Science and Medicine

3:00–4:15PM Level: ■ Format: WORKSHOP
Room: 258AB *CME, Pharmacy, and Nursing*

Mobile Accelerometry in Clinical Trials: Potential Applications and Meaningful Outcomes

CHAIRPERSON
Martin Daumer, DrSc
Scientific Director, Sylvia Lawry Centre For Multiple Sclerosis Research - The Human Motion Institute, Germany

FACILITATORS

Bill Byrom, PhD
Vice President, Product Strategy and Innovation, CRF Health, United Kingdom

Bernd Grimm, PhD
Senior Engineer, Sylvia Lawry Centre, The Human Motion Institute, Germany

Kate Lyden, PhD
Clinical Research Scientist, PAL Technologies Ltd., United Kingdom

#143 Track 03 - Data and Data Standards

Featured Topic(s): Translational Science and Medicine

3:00–4:15PM Level: ■ Format: SESSION
Room: 209 *CME, Pharmacy, and Nursing*

Applying Artificial Intelligence, Machine Language, Natural Language Processing, and Predictive Models in Clinical Trials to Deliver Value to Stakeholders

CHAIRPERSON
Prasanna Rao
Offering Leader, Clinical Trial Transformation, IBM Watson Health

SPEAKER(S)

Application of Artificial intelligence and Machine Learning in Clinical Trials
Sunil Agarwal, MS
Associate Vice President and Practice Lead, Pharma R&D, HCL America Inc.

Why Big Data and Machine Learning will Change the Paradigm for Demonstrating and Delivering Value to Multiple Stakeholders
Costas Boussios, PhD
Vice President, Data Science, OM1

#144 Track 04 - Medical Affairs and Scientific Communication

Featured Topic(s): Biosimilars

3:00–4:15PM Level: ■ Format: SESSION
Room: 210C *CME, Pharmacy, and Nursing*

The Evolving Biosimilars Landscape: A Medical Affairs Perspective

CHAIRPERSON
Bryan Katz, MBA
Managing Director, Syneos Health

SPEAKER(S)

Medical Affairs Perspective
Richard Markus, MD, PhD
Vice President, Global Development, Amgen Inc.

#145 Track 05 - Patient Engagement

Featured Topic(s): Translational Science and Medicine

3:00–4:15PM | Level: ■ | Format: FORUM

Room: 153ABC

CME, Pharmacy, and Nursing

A New Ecosystem: The Nature of Relationships Between Patient Advocacy Groups and Sponsors

CHAIRPERSON

Kristin Voorhees, MA
Senior Manager, Patient Advocacy, Ultragenyx Pharmaceutical

PANELISTS

The Business of Patient Engagement
Alice Bast
Chief Executive Officer, Beyond Celiac

Necessary Relationships: The Effect of Pharmaceutical Relationships on Rare Disease Patient Advocacy Organizations
Katie Jensen, MPA
Development Director, The LAM Foundation

A Day in the Life: Making Patient Engagement Real
Suzanne Schrandt, JD
Director, Patient Engagement, Arthritis Foundation

Round Table: This discussion will continue at 9:30AM on Tuesday, June 26 in the DIA Community Zone, NE Lobby, Level 1

#146 Track 06A - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Gene Therapy

3:00–4:15PM | Level: ■ | Format: SESSION

Room: 156ABC

CME, Pharmacy, and Nursing

Development of Microbiome-Derived Therapeutics

CHAIRPERSON

Philip Brooks, PhD
Program Director, Office of Rare Diseases Research and Division of Clinical Innovation, NIH, National Center for Advancing Translational Sciences (NCATS)

SPEAKER(S)

FDA Perspective
Taruna Khurana, PhD, MS
Regulatory Biologist, Office of Vaccines Research and Review, CBER, FDA

Applying Principles of Rational Drug Development to Living Medicines
Aoife Brennan
Chief Medical Officer, Synlogic

FMT Study in Hepatic Encephalopathy
Zain Kassam, MD, MPH, FRCPC
Chief Scientific Officer, Vice President of Clinical Development, Finch Therapeutics

#147 Track 06B - Preclinical Development and Early-Phase Clinical Research

3:00–4:00PM | Level: ■ | Format: SESSION

Room: 151AB

CME, Pharmacy, and Nursing

Facilitating Nonclinical Data-Sharing and Access Across the Industry

CHAIRPERSON

William Houser
Capability Manager, Bristol-Myers Squibb

SPEAKER(S)

BioCelerate Toxicology Data-Sharing Initiative: Development of a Centralized, Searchable, Preclinical Data Repository
William Houser
Capability Manager, Bristol-Myers Squibb

US Regulatory Compliance with the Standard for Exchange of Nonclinical Data (SEND)
Kaitlyn Nicole Riffel, MSc
Consultant, Scientific Consulting, Cardinal Health Regulatory Sciences

#148 Track 07 - Project Management and Strategic Planning

Featured Topic(s): ExUS Regulatory

3:00–4:00PM | Level: ■ | Format: SESSION

Room: 258C

CME, Nursing, and PMI PDUs

Essential Project Leadership in Navigating an Evolving Regulatory Landscape in Asia-Pacific

CHAIRPERSON

Hwee Hwee Tey
Director, CMIC Asia-Pacific Pte Ltd, Singapore

SPEAKER(S)

The Regulatory Landscape and Development Pathways of Regenerative Medicine and Orphan Drugs in Japan
Gregg Mayer, PhD
President, Gregg L. Mayer Company, Inc.

Balancing Unity and Individuality: Leadership Skills for Managing Culturally Divergent Clinical Teams
Phoevos Hughs, PhD
Regional Director, Project Management- Asia, Biorasi

Including the APAC Region into a Global Study: An Operational Perspective
Winnie Lim, MSc
Manager Clinical Operations - Asia, Aurinia Pharmaceuticals Inc., Canada

#149 Track 08 - R&D Quality and Compliance

Featured Topic(s): Translational Science and Medicine

3:00–4:15PM | Level: ■ | Format: SESSION

Room: 205C

CME, Pharmacy, and Nursing

A Quality-by-Design Approach to Trial Design and Conduct: Case Studies from the Clinical Trials Transformation Initiative

CHAIRPERSON

Annemarie Forrest, MPH, MS, RN
Director of Projects, Clinical Trials Transformation Initiative (CTTI)

SPEAKER(S)

Case Study: How a Large Pharma Company Integrates QbD into Clinical Development
Julie Dietrich, MS
Director, Clinical Development, Amgen Inc.

A Collaborative Approach to Applying QbD in a CV Outcomes Trial: Lessons Learned
Sabrina Comic-Savic
Vice President, Quality Assurance, The Medicines Company

#150 Track 09A - Regulatory

Featured Topic(s): ExUS Regulatory

3:00–4:15PM | Level: ■ | Format: FORUM

Room: 208 | *CME, Pharmacy, and Nursing*

TFDA Town Hall

CHAIRPERSON

Shou-Mei Wu, PhD
Director General, TFDA, Chinese Taipei

SPEAKER(S)

TFDA Perspective on Regulatory Management of Drug Development
Shou-Mei Wu, PhD
Director General, TFDA, Chinese Taipei

Global Challenges in Conducting MRCT and Interpreting Data
James Chih-Hsin Yang, MD, PhD
Director, Department of Oncology, NTU Hospital, Chinese Taipei

Using Real World Evidence in Regulatory Decision-Making
Churn-Shiouh Gau, PhD, MS
Executive Director, Center for Drug Evaluation, Chinese Taipei

The Development of Biotechnological Medicine in Taiwan
Annie Tsu-Hui Liu
Director, Office of Science and Technology, Executive Yuan, Chinese Taipei

#151 Track 09B - Regulatory

Featured Topic(s): Real World Evidence, Regulatory Agency Presenters

3:00–4:15PM | Level: ● | Format: SESSION

Room: 205AB | *CME, Pharmacy, and Nursing*

Using Real World Evidence for Regulatory Support: Time to Embrace the Future

CHAIRPERSON

Nancy A. Dreyer, DIAFellow, PhD, MPH, FISPE
Global Chief, Scientific Affairs; Senior Vice President, Head, Center for Advanced Evidence Generation, IQVIA

SPEAKER(S)

Lessons from Approval of a Drug to Treat Metastatic Merkel Cell Carcinoma
Tarek Hammad, MD, PhD, MS, MSc, FISPE
Head, Signal Detection, Benefit-Risk Assessment, Global Drug Safety Innovation, EMD Serono, Inc.

FDA Perspective
Tamy Kim, PharmD
Associate Director for Regulatory Affairs, Office of Hematology and Oncology Drug Products and Oncology Center of Excellence, (Acting), CDER, FDA

Rethinking the Process for Post-Market Requirements
Andrew Robertson, JD, PhD
Head, Global Regulatory Science and Policy, NA, Sanofi

#152 Track 09C - Regulatory

Featured Topic(s): Biosimilars

3:00–4:00PM | Level: ■ | Format: SESSION

Room: 206AB | *CME, Pharmacy, and Nursing*

FDA Expectations for Demonstration of Interchangeability

CHAIRPERSON

Kamali Chance, PhD, MPH, RAC
Chief Regulatory Officer, Biosciences Corporation

SPEAKER(S)

FDA Overview of Considerations in Demonstrating Interchangeability with a Reference Product
Leah Christl, PhD
Associate Director for Therapeutic Biologics, TBBS, Office of New Drugs, CDER, FDA

Industry Perspective of the FDA Interchangeability Guidance
Hillel Cohen, PhD
Executive Director, Scientific Affairs, Sandoz Inc.

#153 Track 10 - Regulatory CMC and Product Quality

3:00–4:15PM | Level: ■ | Format: SESSION

Room: 204AB | *CME, Pharmacy, and Nursing*

New Technologies in Pharmaceuticals and Biopharmaceuticals: Opportunities and Regulatory Challenges

CHAIRPERSON

Representative Invited
Head of Quality, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), European Union

SPEAKER(S)

Global Approval and Acceptance of Continuous Manufacturing: Regulatory Opportunities
Leslie Weiss, MBA, RPh
Director, CMC Regulatory Affairs, Janssen Research and Development LLC

Regulatory Challenges and Solutions for New Technology Development
Lucy Chang, PhD
Director, Merck & Co., Inc.

Gene and Cell Therapies: Innovations and New Technologies
Peter Richardson, PhD
Head of Quality, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), European Union

FDA Perspective
Michael Havert, PhD
Biologist/CMC Reviewer, Gene Therapy Branch, Office of Tissues and Advanced Therapies, CBER, FDA

#154 Track 11 - Statistics

Featured Topic(s): Rare Diseases, Pediatrics, Translational Science and Medicine

3:00–4:15PM | Level: ◆ | Format: SESSION

Room: 256 | *CME, Pharmacy, and Nursing*

Bayesian Application in Small-Sized Clinical Trials

CHAIRPERSON

Fei Wang
Senior Manager, Biostatistics, Amgen

SPEAKER(S)

Incorporating Adult Study Data into Pediatric Clinical Trials: Is Bayesian Borrowing the Solution?
James Travis, PhD
Staff Fellow, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Approaches to Medical Device Evaluation Using Real World Evidence
Sharon-Lise Normand
Professor of Health Care Policy (Biostatistics), Harvard Medical School

Bayesian Applications for Extrapolation from Adult to Pediatric Data
Amy Xia, PhD
Executive Director, Biostatistics, Amgen Inc.

#155 Track 12 - Value and Access

Featured Topic(s): Real World Evidence

3:00–4:15PM | Level: ■ | Format: SESSION
Room: 252AB | *CME, Pharmacy, and Nursing*

Real World Evidence for Value and Access

CHAIRPERSON
Marianne Hamilton Lopez, PhD, MPA
Research Director, Value-Based Payment Reform, Duke-Margolis Center For Health Policy

SPEAKER(S)

The Use of Real World Evidence and Data in Clinical Research and Post-Marketing Safety Applications
Josephine Awatin
Research Analyst, Tufts Center For the Study of Drug Development

How Real World Evidence is Rapidly Changing Drug Development and Value Demonstration
Charles Makin, MBA, MS
Vice President and Global Head, RWE Late Phase Research, ICON

#156 Track 13

DIAmond SESSIONS

3:00–4:30PM | Level: ■ | Format: FORUM
Room: 210AB | *CME, Pharmacy, and Nursing*

International Regulatory Convergence

CHAIRPERSON
Agnès Saint-Raymond
Head of International Affairs, Head of Portfolio Board, European Medicines Agency (EMA), European Union

INTRODUCTION

Ivo Claassen, PhD
Head of Veterinary Medicines Division, European Meidicines Agency (EMA), European Union

PANELISTS

Representative Invited
Office of the Commissioner, FDA

Guido Rasi, MD
Executive Director, European Medicines Agency (EMA), European Union

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

Julio Sánchez Y Tépoz
Federal Commissioner, COFEPRIS, Mexico

#157 Track 18 - Professional Development

3:00–4:15PM | Level: ■ | Format: WORKSHOP
Room: 254AB | *CME, Nursing, and PMI PDUs*

Courageous Leadership

CHAIRPERSON
Michael Williams
Sales Director and Business Development, Synergistix

#158 Track 14A - Innovation Theater

4:45–5:15PM | Format: SESSION
Room: Theater 1 | Exhibit Hall

Advanced Clinical Innovation Theater: Preparing for the Next Generation of Clinical Research

#159 Track 14B - Innovation Theater

4:45–5:15PM | Format: SESSION
Room: Theater 2 | Exhibit Hall

ArisGlobal Innovation Theater: A Clinical Perspective - How Cognitive E-2-E Pharma Platforms can Transform Productivity in Pharma - Introducing LifeSphere from Clinical to Regulatory

#160 Track 14A - Innovation Theater

5:30–6:00PM | Format: SESSION
Room: Theater 1 | Exhibit Hall

Cognizant Innovation Theater: Powering New Possibilities for Site-Sponsor Collaboration with the Shared Investigator Platform in Partnership with TransCelerate

#161 Track 14B - Innovation Theater

5:30–6:00PM | Format: SESSION
Room: Theater 2 | Exhibit Hall

Appian Innovation Theater: Moving Beyond Cloud with Digital Transformation to Unify Process, Connect Data, and Turbocharge Innovation

NOTES

TUESDAY, JUNE 26

Registration Hours

7:00AM–5:15PM Attendee, Speaker, and Exhibitor Registration

7:00–8:00AM

Coffee and Light Refreshments
North Lobby | Level 1

#201 Track 01 - Clinical Safety and Pharmacovigilance

Featured Topic(s): Generics, Regulatory Agency Presenters

8:00–9:15AM Level: ■ Format: FORUM
Room: 253AB *CME, Pharmacy, and Nursing*

Generic Drug Products: Comparison of Safety Profile with Branded Cousin

CHAIRPERSON
Howard Chazin, MD, MBA
Director, Clinical Safety Surveillance Staff, Office of Generic Drugs, CDER, FDA

SPEAKER(S)

FDA Perspective
Karen Feibus, MD
Lead Medical Officer, Clinical Safety Surveillance Staff, Office of Generic Drugs, CDER, FDA

Academic Perspective
Aaron Kesselheim, JD, MD, MPH
Associate Professor of Medicine, Brigham and Women's Hospital/Harvard Medical School

Industry Perspective
Kiran Krishnan, PhD
Senior Vice President, Global Regulatory Affairs, Apotex Inc

#202 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Outsourcing, Translational Science and Medicine, Career Development

8:00–9:00AM Level: ■ Format: SESSION
Room: 257AB *CME, Pharmacy, and Nursing*

Quantifying the Impact of Credentialed Clinical Research Site Professionals on Clinical Trial Conduct Quality

CHAIRPERSON
Kenneth A. Getz
Director of Sponsored Research Programs and Associate Professor, Center For the Study of Drug Development, Tufts University School of Medicine

SPEAKER(S)

Update on Quantifying the Impact of Credentialed Clinical Research Site Professionals on Clinical Trial Conduct Quality
Beth D. Harper, MBA
Workforce Innovation Officer, Association of Clinical Research Professionals

Assessing the Impact of Credentialing on Clinical Trial Quality and Performance
Suzanne Caruso
Vice President, Clinical Solutions, WIRB-Copernicus Group

#203 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Real World Evidence, Translational Science and Medicine

8:00–9:00AM Level: ■ Format: SESSION
Room: 258AB *CME, Pharmacy, and Nursing*

Utilizing and Understanding Real World Evidence Solutions to Efficiently Recruit the Most Appropriate Patients and Sites for Clinical Trials

CHAIRPERSON
Nancy Mulligan
Executive Director, Patient and Physician Services, United Biosource Corporation

SPEAKER(S)

Heat Maps: Using PBM Data, Predictive Modeling, Medical Expertise in Understanding, Targeting, and Conducting Effective Patient Recruitment Strategies
Nancy Mulligan
Executive Director, Patient and Physician Services, United Biosource Corporation

Using Consumer Data to Improve Patient Segmentation and Targeting for Clinical Trials Recruitment
Andrew Kress
Chief Executive Officer, HealthVerity, Inc.

TBD
David M. Freeman, MA, MBA
General Manager, Information Ventures, Quest Diagnostics

#204 Track 03 - Data and Data Standards

Featured Topic(s): Regulatory Agency Presenters, Mobile Technology

8:00–9:15AM Level: ■ Format: SESSION
Room: 209 *CME, Pharmacy, and Nursing*

FDA Data Standards Update

CHAIRPERSON
Ron D. Fitzmartin, DIAFellow, PhD, MBA
Senior Advisor, Office of Strategic Programs, CDER, FDA

SPEAKER(S)

CDER Perspective
Mary Anne Slack
Deputy Director, Office of Strategic Programs, CDER, FDA

CBER Perspective
Virginia Hussong
Chief, Data Standards Program, CBER, FDA

#205 Track 04 - Medical Affairs and Scientific Communication

8:00–9:15AM Level: ■ Format: SESSION

Room: 210C *CME, Pharmacy, and Nursing*

Best Practices for Implementing Lay Summaries and Communicating Results to Patients

CHAIRPERSON

Behtash Bahador
Senior Manager, Quality and Compliance, CISCRP

SPEAKER(S)

Preparing for the Clinical Trial Report Lay Summary
Barry Drees, PhD
Senior Partner, Trilogy Writing & Consulting, Germany

Beyond Lay Summaries: A Vision for Comprehensive Post-Trial Communications
Paulo Moreira
Vice President, Global Clinical Operations, Head of External Innovation, EMD Serono, Inc.

Promotional and Misleading Lay Summaries: Addressing the Elephant in the Room
Behtash Bahador
Senior Manager, Quality and Compliance, CISCRP

#206 Track 05 - Patient Engagement

Featured Topic(s): Regulatory Agency Presenters

8:00–9:15AM Level: ■ Format: FORUM

Room: 151AB *CME, Pharmacy, and Nursing*

Incorporating Patient Input into US Food and Drug Administration's Medical Product Development and Regulatory Decision-Making

CHAIRPERSON

Pujita Vaidya, MPH
Acting Director, Decision Support and Analysis Team, Office of Strategic Programs, CDER, FDA

SPEAKER(S)

How FDA Involves Patients and Advocates
Andrea Furia-Helms, MPH
Patient Representative Program, Office of Health and Constituent Affairs, Office of the Commissioner, FDA

Partnering for Patients: A Regulatory Framework to Advance Patient-Focused Drug Development
Eleonora Ford, PhD
Global Regulatory Affairs and Policy, Amgen Inc.

Panelists
Theresa Mullin, PhD
Associate Director for Strategic Initiatives, CDER, FDA

Anindita Saha
Director, External Expertise and Partnerships, Office of the Center Director, CDRH, FDA

Telba Irony, PhD
Deputy Director, Office of Biostatistics and Epidemiology, CBER, FDA

#207 Track 06 - Preclinical Development and Early-Phase Clinical Research

8:00–9:00AM Level: ■ Format: SESSION

Room: 156ABC *CME, Pharmacy, and Nursing*

Novel Approaches for Accessing the CNS: Nonclinical and Clinical Challenges

CHAIRPERSON

Richard Scheyer, MD
Vice President, Medical Affairs, Medpace

SPEAKER(S)

Novel Approaches to Confirming CNS Penetration and Target Engagement
Richard Scheyer, MD
Vice President, Medical Affairs, Medpace

Nonclinical Models Supporting Orphan Drug Designations in Rare Neurodegenerative Conditions
Dinah Duarte, PharmD, MSc
Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

Novel Central Nervous System Delivery Methods in the Era of Targeted Therapeutics
William Elmquist, PharmD, PhD
Director, Brain Barriers Research; Distinguished Professor, Department of Pharmaceutics, Univerity of Minnesota

#208 Track 07 - Project Management and Strategic Planning

Featured Topic(s): Outsourcing

8:00–9:15AM Level: ■ Format: FORUM

Room: 153ABC *CME, Pharmacy, Nursing, and PMI PDUs*

Effective Management of Internal Stakeholders and External Strategic Partners from Multiple Perspectives: Non-Profit, CRO, and Pharmaceutical Industry

CHAIRPERSON

Jing Li, MBA, MS, PMP
Head of Program Management Office, Castle Creek Pharmaceuticals

SPEAKER(S)

Stakeholder Management: From Non-Profit and Industry/Academic/Government Consortium
Debora Merrill, MBA
Vice President, COPD Biomarker Qualification Consortium, COPD Foundation

Stakeholder Management: From CRO Perspective
Steven Innaimo, MS
Head, Program Management Office, Covance

Stakeholder Management: From Sponsor Medical Affairs Perspective
Stephen Apple, MD
Senior Medical Director, Mitsubishi Tanabe Pharma America

#209 Track 08 - R&D Quality and Compliance

Featured Topic(s): Outsourcing

8:00–9:00AM Level: ■ Format: SESSION
Room: 205C *CME, Pharmacy, and Nursing*

Oversight in the Era of E6 (R2)

CHAIRPERSON

Melissa Bomben, MS
Vice President, Strategic Resourcing, Syneos Health

SPEAKER(S)

Outsourcing Models
Cristin MacDonald, PhD
Executive Director, Client Delivery, The Avoca Group

#210 Track 09A - Regulatory

Featured Topic(s): Devices and Combination Products

8:00–9:15AM Level: ■ Format: FORUM
Room: 206AB *CME, Pharmacy, and Nursing*

Artificial Intelligence: The Future of Regulatory Affairs

CHAIRPERSON

Linda Bowen, MSc, RAC
Assistant Professor, Temple University

SPEAKER(S)

Regulatory 2.0: The Future of Regulatory Affairs and Advanced Technologies
Oliver Steck
Principal, Deloitte & Touche LLP

Exploring New Ways of Working Using Artificial Intelligence
Dany De Grave
Senior Director, Innovation Programs and External Networks, Sanofi Pasteur

FDA Update
Bakul Patel, MD
Associate Director for Digital Health, Office of the Center Director, CDRH, FDA

#211 Track 09B - Regulatory

Featured Topic(s): Biomarkers - Diagnostics, Regulatory Agency Presenters, ExUS Regulatory

8:00–9:15AM Level: ■ Format: FORUM
Room: 208 *CME, Pharmacy, and Nursing*

Update on Collaboration and Trends in Global Companion Diagnostics

CHAIRPERSON

Karen D. Weiss, MD, MPH
Vice President, Global Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

SPEAKER(S)

PMDA Perspectives on Companion Diagnostics Development in Japan
Reiko Yanagihara, PhD
Deputy Review Director, Office of In Vitro Diagnostics, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

FDA Perspective
Yun-Fu Hu, PhD
Deputy Director, Division of Molecular Genetics and Pathology, CDRH, FDA

EMA Perspective
Marie-Helene Pinheiro, PharmD
Industry Stakeholder Liaison, Corporate Stakeholders Division, European Medicines Agency (EMA), European Union

#212 Track 09C - Regulatory

Featured Topic(s): Biosimilars

8:00–9:15AM Level: ■ Format: SESSION
Room: 204AB *CME, Pharmacy, and Nursing*

Global Regulatory Strategies for Biosimilars

CHAIRPERSON

Oxana Iliach, PhD
Senior Director, Regulatory Affairs, Biosimilars Center of Excellence, IQVIA, Canada

SPEAKER(S)

The Evolving Regulatory Guidelines for Biosimilars and Biologics
Brittany Scott
Creative Director, Addison Whitney

Industry Perspective: Developing Biosimilars and Biologics in a Crowded Market
Yatika Kohli, PhD
Vice President, Regulatory Affairs, Medicago Inc, Canada

Health Canada Perspective
Agnes V. Klein, MD
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

Round Table: This discussion will continue at 2:00PM on Tuesday, June 26 in the DIA Community Zone, NE Lobby, Level 1

#213 Track 09D - Regulatory

8:00–9:15AM Level: ■ Format: FORUM
Room: 205AB *CME, Pharmacy, and Nursing*

2018 Policy Mash-Up: New Shifts in the Healthcare Market and What They May Mean for Patients and the Biopharma Industry

CHAIRPERSON

Nancy Bradish Myers, Esq., JD
President and Founder, Catalyst Healthcare Consulting, Inc

PANELISTS

Larry Kocot, JD
Principal, National Leader of the Center for Healthcare Regulatory Insight, KPMG

Darshak Sanghavi, MD
Chief Medical Officer and Senior Vice President of Translation, Optum Labs

Rick Weissenstein, MA
Managing Director, Health Care Services and Pharmaceutical Policy, Cowen Washington Research Group

#214 Track 10 - Regulatory CMC and Product Quality

Featured Topic(s): ExUS Regulatory

8:00–9:15AM Level: ■ Format: SESSION

Room: 253C *CME, Pharmacy, and Nursing*

CMC Challenges for Breakthrough Therapies and Other Worldwide Accelerated Approval Programs

CHAIRPERSON

Peter Richardson, PhD
Head of Quality, Specialized Scientific Disciplines Department, European Medicines Agency (EMA), European Union

SPEAKER(S)

CMC Challenges and Opportunities for the Expedited Development Program
T. G. Venkateshwaran, PhD
Associate Vice President and Global Head CMC Biologics, Medical Devices and Combination Products, Merck & Co., Inc.

CMC Challenges for Breakthrough Therapies
Ronald Imhoff, MS
Senior Director, CMC Regulatory Affairs, Janssen Biologics, Netherlands

Taking the Leap: CMC Strategies for Supporting External Clinical Studies for a Breakthrough Therapy Designation Product
Christine Kolz, PhD
Associate Director, Global Regulatory CMC, Pfizer Inc

#215 Track 11 - Statistics

Featured Topic(s): Rare Diseases, Pediatrics, Translational Science and Medicine

8:00–9:15AM Level: ◆ Format: SESSION

Room: 256 *CME, Pharmacy, and Nursing*

Pediatric and Rare Disease Drug Development

CHAIRPERSON

Munish Mehra, PhD
Executive Director, Tigermed Co., Ltd.

SPEAKER(S)

The Use of Historical Controls from Register Data in Randomized Clinical Trials in Rare Diseases
Thomas Zwingers
Director of Consultancy, CROS DE Gmbh, Germany

Concerns Related to Pediatric Trials
Yeh-Fong Chen, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

#216 Track 12 - Value and Access

8:00–9:15AM Level: ■ Format: SESSION

Room: 258C *CME, Pharmacy, and Nursing*

Early HTA Scientific Advice: Does it Improve Internal Company Decision-Making and Ensure Predictability of HTA Outcome?

CHAIRPERSON

Neil McAuslane, PhD, MSc
Director, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

SPEAKER(S)

Early Scientific Advice from HTA Agencies: How Does the Effective Use of the Various Kinds of Advice Support a Positive HTA Recommendation?
Neil McAuslane, PhD, MSc
Director, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

Early HTA Scientific Advice: What's in it for the Agency?
Amy Sood, PharmD
Manager, Scientific Advice Program, Canadian Agency For Drugs & Technologies In Health (CADTH), Canada

How Can This Aid Companies in Their Development of New Medicines and How Would a Successful Scientific Meeting be Defined?
Matthew Lamb, PharmD, RPh
Vice President, Regulatory Affairs, Inflammation and Immunology, Celgene Corporation

#217 Track 13 DIAmond SESSIONS

8:00–9:30AM Level: ◆ Format: FORUM

Room: 210AB *CME, Pharmacy, and Nursing*

Triple-A RWE: Adequate Data, Appropriate Study Designs, and Actionable Evidence

CHAIRPERSON

Gregory Daniel, PhD, MPH, RPh
Deputy Director and Clinical Professor, Duke-Margolis Center For Health Policy

PANELISTS

Jacqueline A. Corrigan-Curay, JD, MD
Director, Office of Medical Policy, CDER, FDA

Paul A. Bleicher, MD, PhD
Chief Executive Officer, OptumLabs

Pall Jonsson, PhD, MS
Associate Director, Research and Development, National Institute for Health and Care Excellence (NICE), United Kingdom

#218 Track 18 - Professional Development

8:00–9:15AM Level: ● Format: WORKSHOP

Room: 254AB

Building Your Brand

CHAIRPERSON

Chris Matheus, MBA
President, Matheus BD Connections

FACILITATOR

Margaret Stiltner-Richmond
Senior Global Project Manager, Paragon Global CRS

9:00–10:30AM

Coffee Break

Exhibit Hall

#219 Track 16 - Content Hubs

9:15–9:45AM Level: ● Format: SESSION
Room: Content Hub | NE Lobby *IACET*

FDA Warning Letters on Data Integrity

CHAIRPERSON
Anu Virkar, MA, MS
Vice President, Quality and Compliance, eClinical, Merge eClinical, An IBM Watson Health Company

#220 Track 15 - Engage and Exchange

9:30–10:30AM Level: ● Format: WORKSHOP
Room: E and E | Exhibit Hall

Brexit: Practical Real-World Solution Planning

CHAIRPERSON
Parastoo Karoon, PhD, MS
Principle Consultant, PAREXEL International, United Kingdom

#221 Track 17A - Community Rounds

9:30–10:30AM Format: FORUM
Room: Community Zone | NE Lobby

DIA Regulatory Community Round Table Discussion: Artificial Intelligence: The Future of Regulatory Affairs

CHAIRPERSON
Linda Bowen, MSc, RAC
Assistant Professor, Temple University

#222 Track 17B - Community Rounds

9:30–10:30AM Format: FORUM
Room: Community Zone | NE Lobby

DIA Patient Engagement Community Round Table Discussion: New Ecosystem: The Nature of Relationships Between Patient Advocacy Groups and Sponsors

CHAIRPERSON
Mary Stober Murray, MBA
Associate Director, Diversity and Patient Engagement, Bristol-Myers Squibb

#223A Track 06 Preclinical Development and Early-Phase Clinical Research

9:45– 10:15AM Level: ◆ Format: SESSION
Room: 157AB

On the Soap Box: Blockchain and Genomics

CHAIRPERSON
Dennis Grishin
Chief Scientific Officer and Co-Founder, Nebula Genomics

#223B Track 14A - Innovation Theater

9:45–10:15AM Format: SESSION
Room: Theater 1 | Exhibit Hall

Covance Innovation Theater: Case Study - Driving Clinical Transformation Through a Next-Generation of Data Integration and Analytic Technologies with a GlaxoSmithKline-Covance Partnership

#224 Track 14B - Innovation Theater

9:45–10:15AM Format: SESSION
Room: Theater 2 | Exhibit Hall

Veeva Systems Innovation Theater: Global Industry Report - New Findings from the 2018 Unified Clinical Operations Survey

#225 Track 16 - Content Hubs

10:00–10:30AM Level: ● Format: SESSION
Room: Content Hub | NE Lobby *IACET*

Building a Dynamic Presentation: Rethinking Audience Engagemen

CHAIRPERSON
Robin Whitsell
President, Whitsell Innovations, Inc

#226 Track 01 - Clinical Safety and Pharmacovigilance

Featured Topic(s): Regulatory Agency Presenters, Real World Evidence

10:30–11:45AM Level: ◆ Format: SESSION
Room: 253AB *CME, Pharmacy, and Nursing*

Regulators' Utilization of Real-World Data in Pharmacovigilance Activities

CHAIRPERSON
Michael D. Blum, MD, MPH
Deputy Director, Office of Pharmacovigilance and Epidemiology, CDER, FDA

SPEAKER(S)

Regulator's Utilization of Real-World Data in Pharmacovigilance Activities
Yoshiaki Uyama, PhD
Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

FDA's Sentinel Program
Michael D. Nguyen, MD
Medical Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA

EMA Perspective
Agnès Saint-Raymond, MD
Head of International Affairs, Head of Portfolio Board, European Medicines Agency (EMA), European Union

Improving the Use of Real World Evidence in the Regulatory Environment: Where Are We Heading in Canada?
Rhonda Kropp, BSN, MPH
Director General, Marketed Health Products Division, Health Canada

#227 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine

10:30–11:45AM Level: ■ Format: SESSION

Room: 257AB *CME, and Nursing*

Digital Data Flow from Protocol to Report: TransCelerate's Common Protocol Template and the Art of the Possible

CHAIRPERSON

Robert A. DiCicco, PharmD
Executive Consultant, TransCelerate Biopharma Inc.

PANELISTS

Richard Buckley, JD, MBA
Clinical Innovation, TransCelerate Program Lead, Operations Center of Excellence, Pfizer Inc

Jeff Beeler
Vice President, Product Innovation, eClinical, Clinical Development, IBM Watson Health

Michel Rider, DrMed
Managing Director, Life Sciences Cloud Strategy, Accenture

Round Table: This discussion will continue at 3:15PM on Tuesday, June 26 in the DIA Community Zone, NE Lobby, Level 1

#228 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine

10:30–11:30AM Level: ■ Format: SESSION

Room: 258AB *CME, Pharmacy, and Nursing*

Global Clinical Trials: Lessons in Effective Execution

CHAIRPERSON

Mitchell Parrish, JD, RAC
Vice President, Legal and Regulatory Affairs, Kinetiq, A divsion of Quorum Review IRB

SPEAKER(S)

Site Network Perspective
Kathy Lenhard
President, Panamerican Clinical Research, Mexico

CRO Perspective
Jason Ezzelle, MT
Chief Commercial and Government Contracts Officer, Pharm-Olam

#229 Track 02C - Clinical Trials and Clinical Operations

Featured Topic(s): Mobile Technology, Translational Science and Medicine

10:30–11:45AM Level: ■ Format: FORUM

Room: 258C *CME, Pharmacy, and Nursing*

Mobile Reported Outcomes: A Forum on Patient and Caregiver Assessments

CHAIRPERSON

Christopher Jones, PhD
Executive Vice President, iTakeControl

SPEAKER(S)

Patient Perspective
Christine McSherry, BSN, RN
Executive Director, Jett Foundation

PANELISTS

Michelle K. White, PhD
Senior Scientist, Optum

Reenie McCarthy
Chief Executive Officer, Stealth BioTherapeutics

Linsey Walker
Senior Clinical Trial Manager, Sarepta Therapeutics

#230 Track 03A - Data and Data Standards

Featured Topic(s): Regulatory Agency Presenters, Real World Evidence, Mobile Technology

10:30–11:45AM Level: ■ Format: SESSION

Room: 208 *CME, Pharmacy, and Nursing*

Common Data Model Harmonization for Evidence Generation

CHAIRPERSON

Mitra Rocca, MSc
Associate Director, Medical Informatics, Office of Translational Sciences, CDER, FDA

SPEAKER(S)

Unlocking Real-World Value from EHRs: FDA's Harmonization of CDMs for Real World Evidence
Michael A. Ibara, PharmD
Head of Digital Healthcare, Michael Ibara Consulting

Common Data Models: Implementation and Use
Jeffrey Brown, PhD, MA
Associate Professor, Department of Population Medicine, Harvard Pilgrim Health Care Institute/Harvard Medical School

TBD
Christian G. Reich
Vice President, Real World Evidence Systems, IQVIA; Principal Investigator, Observational Health Data Sciences and Informatics (OHDSI)

#231 Track 03B - Data and Data Standards

10:30–11:30AM Level: ● Format: SESSION

Room: 209 *CME, Pharmacy, and Nursing*

Automation with Intelligence: From Standard-Based Solution to Metadata-Driven Automation

CHAIRPERSON

Hanming H. Tu, MSc
Vice President, Clinical IT and Database Administration, Frontage Laboratories, Inc.

SPEAKER(S)

Rapid Transformations to Standard Data Models via Automation and Machine Learning
Silas McKee, MSc
Technology Consulting Manager, Accenture

The Growing Impact of Big Data and Emerging Technologies: Increased Commercial Visibility, Efficiency, Outcomes, and Safety
David Kiger
Chief Commercial Officer, BioClinica

The Perfect Partnership: Machine Learning and CDISC
Kevin Lee, MS
Director of Data Science, ClinData Insight

#232 Track 04 - Medical Affairs and Scientific Communication

Featured Topic(s): Mobile Technology

10:30–11:45AM Level: ● Format: SESSION
Room: 210C *CME, Pharmacy, and Nursing*

Digital Data and New Technologies to Drive Customer Impact in Medical Affairs, Medical Writing, and Medical Communications

CHAIRPERSON
Madhavi Gidh-Jain, PhD
Senior Director, Head Medical Writing (US), Sanofi

SPEAKER(S)

Artificial Intelligence for the Clinical Study Report
Madhavi Gidh-Jain, PhD
Senior Director, Head Medical Writing (US), Sanofi

Understand the Unknown: How Health-Specific Cognitive Services Accelerate Innovation by Unlocking New Insights
Timothee Bouhour
Lead Offering Manager, Watson Health Cognitive Services, IBM Watson Health

Reusing Regulatory Information Across Documents and Divisions
Steffen Frederiksen, MSc
Founder and CSO, DitaExchange, Denmark

#233 Track 05 - Patient Engagement

Featured Topic(s): Regulatory Agency Presenters, Rare Diseases

10:30–11:45AM Level: ■ Format: FORUM
Room: 151AB *CME, Pharmacy, and Nursing*

The Patient's Assessment of the Patient-Focused Drug Development Meeting Initiatives

CHAIRPERSON
James E. Valentine, JD, MHS
Attorney, Hyman, Phelps & McNamara, PC

SPEAKER(S)

FDA Perspective on the Value and Potential of PFDD
Theresa Mullin, PhD
Associate Director for Strategic Initiatives, CDER, FDA

Experience from an FDA-Led PFDD Meeting - NTM Case Study
Amy Leitman, JD
Director of Policy and Advocacy, NTM Info & Research

Experience from an Externally Led PFDD Meeting; TSC Case Study
Steven L. Roberds, PhD
Chief Scientific Officer, Tuberous Sclerosis Alliance

#234 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Translational Science and Medicine

10:30–11:45AM Level: ■ Format: SESSION
Room: 156ABC *CME, Pharmacy, and Nursing*

Personalized Medicine Approaches During Early-Phase Clinical Research

CHAIRPERSON
David J. Pepperl, PhD
Senior Consultant and Nonclinical Group Leader, Biologics Consulting

SPEAKER(S)

Regulatory Implications of Utilizing Biomarkers in Drug Development
Kate A. Simon, PhD
Senior Consultant, Biologics Consulting

Biomarker Strategy and Clinical Implementation for H3B-6527; A FGFR4 Specific Inhibitor in Hepatocellular Carcinoma
Pavan Kumar, PhD
Director of Biomarkers and Companion Diagnostics, H3 Biomedicine, Inc.

Biomarkers as an Integral Part of Modern Drug Discovery and Development
Jannik N. Andersen, PhD, MSc
Vice President, Head of Research, Xios Therapeutics

#235 Track 07 - Project Management and Strategic Planning

10:30–11:45AM Level: ■ Format: SESSION
Room: 252AB *CME, Pharmacy, Nursing, and PMI PDUs*

The Adventures of Patient Experience in Drug Development

CHAIRPERSON
Abby Jeske, PharmD
Clinical Project Manager, Eli Lilly and Company

SPEAKER(S)

Mapping the Patient and Site Experience During a Clinical Trial
Abby Jeske, PharmD
Clinical Project Manager, Eli Lilly and Company

How Patient Advisory Boards Can Help Teams Elicit Feedback
Tanja Keiper, DrSc
Director, GCO External Innovation, Merck KGaA, Germany

Patient Perspective
T.J. Sharpe, PMP
Patient Advocate, Starfish Harbor LLC

#236 Track 08 - R&D Quality and Compliance

Featured Topic(s): Outsourcing

10:30–11:30AM Level: ■ Format: FORUM
Room: 205C *CME, Pharmacy, and Nursing*

Executives Respond to the State of the Industry Report on Risk-Based Approaches in Clinical Trials: Opportunity or Threat?

CHAIRPERSON
Dennis Salotti, MBA, MS
Vice President, Operations, The Avoca Group

PANELISTS

Neil McCullough
Executive Vice President, Clinical Quality and Compliance, ICON Clinical Research

Elizabeth Luczak, MBA
Vice President, R&D Quality Assurance, Vertex Pharmaceuticals

#237 Track 09A - Regulatory

10:30–11:30AM Level: ■ Format: SESSION

Room: 206AB *CME, Pharmacy, and Nursing*

Expanded Access: Where Are We Now?

CHAIRPERSON

Anne B. Cropp, PharmD
Chief Scientific Officer, Early Access Care

SPEAKER(S)

Stakeholder Tools to Facilitate Patients Access: A Trade-Off of Uncertainties?
Richard Huckle, MSc
Senior Consultant, Regulatory Affairs, Pope Woodhead and Associates Ltd, United Kingdom

Global Patient Access Process
Sarah Alummootil
Early Access Care Coordinator, Early Access Care LLC

Global Patient Access Process: Advocate Perspective
Jennifer McNary
Patient Advocacy Consultant

#238 Track 09B - Regulatory

Featured Topic(s): Devices and Combination Products

10:30–11:45AM Level: ■ Format: SESSION

Room: 204AB *CME, Pharmacy, and Nursing*

The European Medical Devices Regulation and MDUFA IV: One Year On - Is it Any Clearer?

CHAIRPERSON

Angela Stokes, MS
Senior Director, Global Regulatory Consulting, Syneos Health, United Kingdom

SPEAKER(S)

Industry Perspective
Theresa Jeary MSc
Technical Manager, Lloyds Register Quality Assurance (LRQA), United Kingdom

LeeAnn L. Chambers, MS
Principal Research Scientist, Global Regulatory Affairs, CMC - Devices, Eli Lilly and Company

#239 Track 09C - Regulatory

Featured Topic(s): Generics, Regulatory Agency Presenters

10:30–11:45AM Level: ■ Format: FORUM

Room: 205AB *CME, Pharmacy, and Nursing*

Generic Drug Town Hall

CHAIRPERSON

Kathleen Uhl, MD
Director, Office of Generic Drugs, CDER, FDA

PANELISTS

Maryll Toufanian, JD
Acting Director, FDA Office of Generic Drug Policy, FDA

Robert A. Lionberger, PhD
Director, Office of Research and Standards, Office of Generic Drugs, CDER, FDA

Susan M. Rosencrance, PhD
Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Ashley Boam, MS
Director, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, FDA

Alonza E. Cruse
Director (Acting), Pharmaceutical Quality Program, Office of Regulatory Affairs, FDA

#240 Track 10 - Regulatory CMC and Product Quality

Featured Topic(s): Biosimilars

10:30–11:45AM Level: ■ Format: SESSION

Room: 253C *CME, Pharmacy, and Nursing*

Biosimilars: Demonstrating Structural and Functional Similarity

CHAIRPERSON

Emily Shacter, PhD
Independent Consultant, ThinkFDA, LLC

SPEAKER(S)

Biosimilar Development: The Product Defines the Process
Richard Markus, MD, PhD
Vice President, Global Development, Amgen Inc.

Industry Perspective
Rajesh Ullanat
Head, Global Biologics Scientific Affairs, Mylan Pharmaceuticals, India

Christopher Downey
CMC Quality Product Lead, Office of Biostatistics, Office of Pharmaceutical Quality, CDER, FDA

#241 Track 11 - Statistics

Featured Topic(s): Translational Science and Medicine

10:30–11:45AM Level: ■ Format: SESSION

Room: 256 *CME, Pharmacy, and Nursing*

Time-to-Event Analysis in Clinical Trials

CHAIRPERSON

Brenda Crowe, PhD
Senior Research Advisor, Global Statistical Sciences, Eli Lilly and Company

SPEAKER(S)

The Challenges of Analyzing Drug Safety Data with Competing Risk Events and Some Thoughts
William Wang, PhD
Executive Director, Clinical Safety Statistics, BARDS, Merck Research Laboratories

Academic Perspective
Tim Friede, PhD
Professor of Biostatistics and Chair, Department of Medical Statistics, University Medical Center Goettingen, Germany

#242 Track 12A - Value and Access

10:30AM–12:00PM | Level: ■ | Format: FORUM
Room: 153ABC
CME, Pharmacy, and Nursing

Unmet Medical Need: Can the Stakeholders Align? Progress to Date

CHAIRPERSON

Inkatuuli Heikkinen, MS
Senior Scientist, DIA, Switzerland

SPEAKER(S)

How Should Unmet Medical Needs be Addressed in the US?
Kenneth I. Kaitin, PhD
Director, Tufts Center for the Study of Drug Development; Professor of Medicine, Tufts University School of Medicine

Criteria Developed Between Stakeholders in Europe in the DIA Working Group
Claudine Sapéde, PharmD, MSc
Global HTA and Payment Policy Lead, F. Hoffmann-La Roche, Switzerland

CIRS Experience and Outcomes of Stakeholder Discussions
Lawrence Eugene Liberti, PhD, RPh, RAC
Executive Director, Centre for Innovation in Regulatory Science (CIRS)

#243 Track 13

DIAmond SESSIONS

10:30AM–12:00PM | Level: ■ | Format: FORUM
Room: 210AB
CME, Pharmacy, and Nursing

Global Perspectives on Patient Engagement

CHAIRPERSON

Representative Invited

PANELISTS

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

Hee-sun Kim, MPharm
Head of Clinical Development Center, Daewoong Pharmaceuticals, Republic of Korea

Julie Louise Gerberding, MD, MPH
Executive Vice President and Chief Patient Officer, Merck & Co., Inc.

11:30AM–1:30PM

Luncheon Service

Exhibit Hall

#244 Track 15 - Engage and Exchange

12:00–1:00PM | Level: ■ | Format: WORKSHOP
Room: E and E | Exhibit Hall

Yes, No, Maybe: Sharing Health and Other Data for Research - Enthusiasm and Concern from the Patient Community

CHAIRPERSON

Sara Loud, MBA, MS
Chief Operating Officer, Accelerated Cure Project

#245 Track 14A - Innovation Theater

12:10–12:55PM | Format: SESSION
Room: Theater 1 | Exhibit Hall

IQVIA Innovation Theater: Real World Evidence to Enhance Drug Development

#246 Track 14B - Innovation Theater

12:10–12:55PM | Format: SESSION
Room: Theater 2 | Exhibit Hall

AMPLEXOR Innovation Theater: How Regulatory Information Will Become Part of Your Company Big Data Architecture

#247 Track 14A - Innovation Theater

1:10–1:55PM | Format: SESSION
Room: Theater 1 | Exhibit Hall

BioClinica Innovation Theater: Transformational Trends in Investigator Site Payments 2018

#248 Track 14B - Innovation Theater

1:10–1:55PM | Format: SESSION
Room: Theater 2 | Exhibit Hall

Veeva Systems Innovation Theater: Tufts Research - Strategies from Data Management Leaders to Speed Clinical Trials

#249 Track 15 - Engage and Exchange

1:15–2:00PM | Level: ■ | Format: WORKSHOP
Room: E and E | Exhibit Hall

Global Evolution in Regulatory Science and Medicine: Novel Modalities and Intersection with Rare Disease Development

CHAIRPERSON

Nina S. Cauchon, PhD, RAC
Regulatory Affairs - CMC, Amgen Inc.

#250 Track 16 - Content Hubs

1:30–2:00PM | Level: ■ | Format: SESSION

Room: Content Hub | NE Lobby | *IACET*

Developing Standards to Support the Use of Wearables and Sensors for Objective Data Collection During Clinical Trials

CHAIRPERSON

Jennifer C. Goldsack, MA, MBA
Senior Project Manager, Clinical Trials Transformation Initiative (CTTI)

FACILITATORS

Susan Marie Vallow, MA, MBA, RPh
Vice President, eCOA Solutions, Medavante-Prophase

Marie McCarthy, MBA, MS
Senior Director of Product Innovation, ICON plc, Ireland

Paul O'Donohoe, MS
Scientific Lead, eCOA and Mobile Health, Medidata Solutions, United Kingdom

#251 Track 01A - Clinical Safety and Pharmacovigilance

2:00–3:15PM | Level: ◆ | Format: SESSION

Room: 253AB | *CME, Pharmacy, and Nursing*

Risk Management: New Directions

CHAIRPERSON

Emily Freeman, PhD, MSc
Director, Patient Centered Outcomes, AbbVie, Inc.

SPEAKER(S)

Organizing for Digital Risk Minimization
Helen Kathryn Edelberg, MD, MPH, FACP
Head, Medical Safety Assessment, Innovative Medical and Global Safety Risk Management, Bristol-Myers Squibb

Preparing for Digital in Benefit-Risk Management: Get Ready for the Revolution
Mark Perrott, PhD
Head of Development Consulting, Pope Woodhead, United Kingdom

Round Table: This discussion will continue at 3:15PM on Tuesday, June 26 in the DIA Community Zone, NE Lobby, Level 1

#252 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Mobile Technology, Translational Science and Medicine

2:00–3:15PM | Level: ■ | Format: SESSION

Room: 257AB | *CME, Pharmacy, and Nursing*

Do the End(point)s Justify the Means? A Peak at Endpoints Accepted by FDA with an Eye Towards Mobile Technology Collection

CHAIRPERSON

Wayne Amchin, MA, MPA, RAC
Senior Consumer Safety Officer, DCRP, ODE I, Office of New Drugs, CDER, FDA

SPEAKER(S)

Clinical Trials Using Mobile Technology
Mintu Turakhia, MD, MS
Executive Director, Center for Digital Health; Chief of EP, Palo Alto VA, Stanford University

FDA Perspective
Bakul Patel, MD
Associate Director for Digital Health, Office of the Center Director, CDRH, FDA

Industry Perspective
Stephen Amato, PhD
Project Manager for Digital Innovation, Pfizer Inc

#253 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine, Real World Evidence

2:00–3:15PM | Level: ■ | Format: FORUM

Room: 258AB | *CME, Pharmacy, and Nursing*

Digitizing a Patient-Focused Clinical Trial Experience

CHAIRPERSON

Jeff Ramsey
Project Leader, Clinical Innovation, Eli Lilly and Company

PANELISTS

Munther Baara, MS
Senior Director, Development Business Technology, Pfizer Inc

Wayne R. Kubick, MBA
Chief Technology Officer, HL7 International

T.J. Sharpe, PMP
Patient Advocate, Starfish Harbor LLC

#254 Track 02C - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine, Outsourcing

2:00–3:15PM | Level: ■ | Format: SESSION

Room: 258C | *CME, Pharmacy, and Nursing*

Risk-Based Monitoring for Master Protocol Study: A Dilemma and Possible Ways to Go

CHAIRPERSON

Rachael Cui Song, MBA
Senior Project Manager - Hematology/Oncology, PPD

SPEAKER(S)

ICH E6 (R2): A Miracle Pill for Clinical Research
Stephen Young, MSc
Chief Operations Officer, CluePoints

Applying Risk-Based Monitoring to Operationally Complex Studies: Opportunities for Improved Quality and Flexibility
Mary Arnould, BSN, MSN
Director, Clinical Science Operations, Astellas Pharma Global Development, Inc.

#255 Track 03 - Data and Data Standards

Featured Topic(s): Real World Evidence, Translational Science and Medicine, Regulatory Agency Presenters

2:00–3:00PM | Level: ■ | Format: SESSION
Room: 208 | *CME, Pharmacy, and Nursing*

Use of Electronic Health Records (EHRs) as eSource in Clinical Investigations

CHAIRPERSON

Mitra Rocca, MSc
Associate Director, Medical Informatics, Office of Translational Sciences, CDER, FDA

SPEAKER(S)

Utilizing EHR Data: How to Enable More Efficient Digital Data Gathering Practices to Benefit Patients, Sites, and Sponsors
Aman Thukral, DrSc, MBA, MPharm
Assistant Director, AbbVie, Inc.

eSource, Interoperability, and the Problem of 'Second Order Heterogeneity' in Clinical Research: A Real-World Implementation
Michael A. Ibara, PharmD
Head of Digital Healthcare, Michael Ibara Consulting

Structured Sourcing in EHRs
Adam L. Asare, PhD
Chief Data Officer, Quantum Leap Healthcare Collaborative

#256 Track 04A - Medical Affairs and Scientific Communication

Featured Topic(s): ExUS Regulatory

2:00–3:15PM | Level: ■ | Format: SESSION
Room: 210C | *CME, Pharmacy, and Nursing*

CTD Regulatory Defense Strategies: How Best to Prepare Your Response to Health Authority Queries

CHAIRPERSON

Frank Hubbard, PhD
President, Global Regulatory Writing Solutions, Inc.

SPEAKER(S)

Field Tested Strategies for How Best to Prepare Responses to Health Authority Questions
Julia Forjanic Klapproth, PhD
President, Trilogy Writing & Consulting, Germany

Finding the Right Balance of Preparation and Structure for Regulatory Defense
Steve Sibley, MS
Vice President, Global Submissions and Submissions Leadership, Synchrogenix, a Certara Company

Round Table: This discussion will continue at 4:30PM on Tuesday, June 26 in the DIA Community Zone, NE Lobby, Level 1

#257 Track 04B - Medical Affairs and Scientific Communication

Featured Topic(s): ExUS Regulatory

2:00–3:15PM | Level: ■ | Format: SESSION
Room: 209 | *CME, Pharmacy, and Nursing*

Globalizing and Regionalizing Medical Information Contact Centers

CHAIRPERSON

Christopher J. Keenan
Head, Worldwide Medical Customer Engagement, Bristol-Myers Squibb

SPEAKER(S)

Globalizing and Regionalizing Medical Information Contact Centers
Christopher J. Keenan
Head, Worldwide Medical Customer Engagement, Bristol-Myers Squibb

Globalizing and Regionalizing Medical Information Contact Centers
Philippe Sorel Takam, PharmD, MSc, RPh
Global Medical Information Manager, Primevigilance Ltd, United Kingdom

Regionalizing Medical Information: Bringing Global Standards to Regional Needs
Sabine Lischka-Wittmann, DrSc
Director, Medical Information Europe, Lilly Deutschland GmbH, Germany

#258 Track 05 - Patient Engagement

2:00–3:15PM | Level: ■ | Format: FORUM
Room: 151AB | *CME, Pharmacy, and Nursing*

Reaching the Underserved: Methods to Ensure Diversity and Inclusion for Patient Research, Clinical Trials, and Advisory Panels

CHAIRPERSON

Hollie Schmidt, MS
Vice President of Scientific Operations, Accelerated Cure Project

SPEAKER(S)

Strengthening the Bridge Between Diverse Patient Populations and the Clinical Trial Journey
Yaritza Peña
Research Analyst, Tufts Center For the Study of Drug Development

Best Practices for Patient Insights Research: Engaging a Diverse Population
Valerie Powell, MS
Senior Director, Patient Insights and Engagement, ICON plc

Strength in Diversity: How a Multi-Stakeholder Partnership Network is Addressing Minority Underrepresentation in MS Research
Hollie Schmidt, MS
Vice President of Scientific Operations, Accelerated Cure Project

Round Table: This discussion will continue at 8:00AM on Wednesday, June 27 in the DIA Community Zone, NE Lobby, Level 1

#259 Track 05B - Patient Engagement

2:00–3:15PM Level: ■ Format: SESSION
Room: 254AB *CME, Pharmacy, and Nursing*

Measuring the Impact of Patient Engagement: What to Ask Depends on Who You Ask

CHAIRPERSON

Roslyn F. Schneider
Global Patient Affairs Lead, Pfizer Inc

SPEAKER(S)

Thank You! The Power of Gratitude to Improve Clinical Development Quality
Mary Stober Murray, MBA
Associate Director, Diversity and Patient Engagement, Bristol-Myers Squibb

Patient Engagement
Ellen Coleman, MPH, MS
Senior Vice President, MK&A

#260 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Translational Science and Medicine

2:00–3:00PM Level: ■ Format: SESSION
Room: 156ABC *CME, Pharmacy, and Nursing*

Optimizing Clinical Development with Adaptive Trial Designs

CHAIRPERSON

Stanley C. McDermott
Managing Director, Clinical Research, Cardinal Health Regulatory Sciences

SPEAKER(S)

Adaptive Trial Designs for Early Phase Clinical Development
Jignesh Patel
Senior Director, Data Services, Clinical Pharmacology and PK, Early Development Services, PRA Health Sciences

The Range of Flexibility Being Shown in Clinical Trial Designs at the FDA in Oncology with Emphasis on Adaptive Trials
Mark Thornton, MD, PhD, MPH
Senior Clinical Consultant, Biologics Consulting

#261 Track 07 - Project Management and Strategic Planning

Featured Topic(s): Career Development

2:00–3:15PM Level: ● Format: FORUM
Room: 153ABC *CME, Pharmacy, Nursing, and PMI PDUs*

Project Management Throwdown: How Not to Get Chopped

CHAIRPERSON

Kemi Yusuf, MBA, PMP
Senior Director, Office of the PST and PPS Portfolio Management, AbbVie, Inc.

SPEAKER(S)

What Makes the Master Project Manager?
Eva M. Finney, PhD, PMP
Director, Global Project and Alliance Management, Merck & Co., Inc.

Technical Specialty? Certifications? School of Hard Knocks? The Mix of Qualifications that Makes the Best Program Manager
Dan Tierno, MA, MBA
Strategic Implementation Manager, Bayer

Project Management 2030: Anatomy of an Exceptional Project Manager
Kemi Yusuf, MBA, PMP
Senior Director, Office of the PST and PPS Portfolio Management, AbbVie, Inc.

#262 Track 08 - R&D Quality and Compliance

Featured Topic(s): Outsourcing

2:00–3:15PM Level: ■ Format: SESSION
Room: 205C *CME, Pharmacy, and Nursing*

The Risk Assessment is Done: Now What? A Guide to Setting up a Centralized Monitoring Plan

CHAIRPERSON

Linda B. Sullivan, MBA
Co-Founder and President, Metrics Champion Consortium LLC

SPEAKER(S)

Industry Perspective
Nurcan Coskun, PhD, MSc
Global Risk Based Monitoring Program and Technology Solutions Manager | MC2, Medtronic International Trading Sàrl, Switzerland

Industry Perspective
Keith Dorricott
MCC Ambassador; Director, Dorricott Metrics and Process Improvement Ltd., United Kingdom

Industry Perspective
Olgica Klindworth
Associate Director, Data Analytics, PPD, Inc.

#263 Track 09A - Regulatory

Featured Topic(s): Devices and Combination Products

2:00–3:15PM Level: ■ Format: SESSION
Room: 204AB *CME, Pharmacy, and Nursing*

Navigating the Regulatory Landscape of Drug-Device Combination Products

CHAIRPERSON

Rebecca Lipsitz, PhD
Associate Director, Janssen

SPEAKER(S)

MHRA Perspective
Representative Invited
Group Manager Licensing Division, Medicines and Healthcare products Regulatory Agency (MRHA), United Kingdom

FDA Perspective
Representative Invited
Associate Director, Policy and Product Classification Officer, Office of Combination Products, Office of the Commissioner, FDA

Industry Perspective
Kirsten H. Paulson, MS, RAC
Senior Director, Global CMC Medical Devices, Pfizer Inc

Round Table: This discussion will continue at 4:30PM on Tuesday, June 26 in the DIA Community Zone, NE Lobby, Level 1

#264 Track 09B - Regulatory

2:00–3:15PM Level: ■ Format: SESSION
Room: 206AB *CME, Pharmacy, and Nursing*

Global Development Using Expedited Pathways in Established and Emerging Markets

CHAIRPERSON

Maria Cristina Mota Pina, MBA
Director, Scientific Regulatory Policy and Intelligence - Latin America, AbbVie, Inc.

SPEAKER(S)

ANVISA Perspective
Jarbas Barbosa, MD, PhD
Director- President, Agência Nacional De Vigilância Sanitária (ANVISA), Brazil

Facilitated Regulatory Pathways in Maturing Agenices: The Benefits of Reliance and Alignment
Lawrence Eugene Liberti, PhD, RPh, RAC
Executive Director, Centre for Innovation in Regulatory Science (CIRS)

Update on the Status of Expedited Pathways in the Mature Markets
Alberto Grignolo, DIAFellow, PhD
Corporate Vice President, Global Strategy, PAREXEL

EFPIA Position Paper: White Paper on Reliance and Expedited Pathways in Emerging Markets
Denise Bonamici, MSc
Head of Regulatory Science and Policy - LATAM, Sanofi, Brazil

#265 Track 10 - Regulatory CMC and Product Quality

Featured Topic(s): Regulatory Agency Presenters

2:00–3:15PM Level: ■ Format: SESSION
Room: 253C *CME, Pharmacy, and Nursing*

ICH M9 BCS-Based Biowaivers

CHAIRPERSON

Roger Nosal, PhD
Vice President, Global CMC, Pfizer Inc

SPEAKER(S)

ICH M9 BCS-Based Biowaivers: Progress and Challenges
Roger Nosal, PhD
Vice President, Global CMC, Pfizer Inc

Revisiting Classification Criteria for Demonstrating Solubility, Permeability, and Comparative Dissolution
Paul Seo, PhD
Director, Division of Biopharmaceutics, ONDP, Office of Pharmaceutical Quality, CDER, FDA

Regional Challenges for Comparative Dissolution and Post-Approval Changes: Excipients
Talia Flanagan, PhD
Associate Principal Scientist, Biopharmaceutics, AstraZeneca, United Kingdom

#266 Track 11 - Statistics

Featured Topic(s): Translational Science and Medicine

2:00–3:15PM Level: ● Format: SESSION
Room: 256 *CME, Pharmacy, and Nursing*

User-Friendly Tools for Study Planning and Analysis

CHAIRPERSON

Brenda Crowe, PhD
Senior Research Advisor, Global Statistical Sciences, Eli Lilly and Company

SPEAKER(S)

ShinyRAP: A Workflow for Analysis Planning, Organization, and Reporting Using Shiny
Xiao Ni, PhD
Group Head, Biostatistics, Novartis Institue for Biomedical Research

Empower Your Physicians and Enhance Communication via Self-Service Tools
Rebeka Revis, MS
Statistician, Eli Lilly and Company

R Shiny Review Tools
Jonathon J. Vallejo, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, FDA

#267 Track 12 - Value and Access

2:00–3:00PM Level: ■ Format: SESSION
Room: 252AB *CME, Pharmacy, and Nursing*

Developing and Partnering on Evidence for Outcomes and Value Assessment: Standardizing Measurement for Patient-Centered Care

CHAIRPERSON

Richard Gliklich, MD
Chief Executive Officer, OM1

SPEAKER(S)

Standardized Outcomes Measurement
Elise Berliner, PhD
Director, Technology Assessment Program, Agency For Healthcare Research and Quality (AHRQ)

Patient Perspective
Cara Kraft
Director of Research and Evaluation, Allergy & Asthma Network

#268 Track 13

DIAmond SESSIONS

2:00–3:30PM Level: ■ Format: FORUM

Room: 210AB *CME, Pharmacy, and Nursing*

Future of PharmaTech

CHAIRPERSON

Patrick K. Brady, PharmD
Regulatory Policy and Intelligence, Bayer

PANELIST

Dave Meyers
National Director, Life Sciences, Microsoft

Dina Katabi, PhD, MS
Professor, MIT

Sudip Parikh, PhD
Senior Vice President and Managing Director, DIA Americas

Henry "Skip" Francis, MD
Director for Data Mining and Informatics Evaluation and Research, Office of Translational Sciences, CDER, FDA

#269A Track 17 - Community Rounds

2:00–3:00PM Format: FORUM

Room: Community Zone | NE Lobby

DIA Regulatory Community Round Table Discussion: Global Regulatory Strategies for Biosimilars

CHAIRPERSON

Linda Bowen, MSc, RAC
Assistant Professor, Temple University

#269B Track 15 - Engage and Exchange

2:15–3:15PM Level: ◆ Format: WORKSHOP

Room: E and E | Exhibit Hall

Avoiding Rejection on Your "First Date" with EMA Policy 0070

CHAIRPERSON

Jo Anne-Marie Blyskal, MS
Head of Global Regulatory Medical Writing, Teva Pharmaceuticals

3:00–4:15PM

Refreshment Break
Exhibit Hall

#270 Track 17A - Community Rounds

3:15–4:15PM Format: FORUM

Room: Community Zone | NE Lobby

DIA Medical Writing Community Round Table Discussion: Digital Data and New Technologies to Drive Customer Impact in Medical Affairs, Medical Writing, and Medical Communications

CHAIRPERSON

David B. Clemow, PhD
Advisor, Scientific Communications Information Strategy, Eli Lilly and Company

#271 Track 17B - Community Rounds

3:15–4:15PM Format: FORUM

Room: Community Zone | NE Lobby

DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Risk Management - New Directions

CHAIRPERSON

Catherine Baldridge, MS
Clinical Safety and Pharmacovigilance, PV Compliance, Indivior

3:30–3:45PM

Annual Meeting for Members
DIA Booth #1519

#272 Track 15 - Engage and Exchange

3:30–4:15PM Level: ● Format: WORKSHOP

Room: E and E | Exhibit Hall

LinkedIn Profile Exchange Review

CHAIRPERSON

Chris Matheus, MBA
President, Matheus BD Connections

SPEAKER(S)

LinkedIn Overview
Tom McPhatter
Director, Business Development, Whitsell Innovations, Inc

Shailesh Chavan, MD
Biotest Pharmaceutical Corporation

#273 Track 16 - Content Hubs

3:30–4:00PM Level: ● Format: SESSION

Room: Content Hub | NE Lobby *IACET*

DIA Insights: Expert Clinical and Regulatory Content - Timely Global and Regional Reports, New Digital Platform - Can We Help You?

CHAIRPERSON

Chris M. Slawecki
Senior Digital Copywriter, DIA

#274 Track 14A - Innovation Theater

3:40–4:10pm Format: SESSION

Room: Theater 1 | Exhibit Hall

WIRB-Copernicus Group Innovation Theater: Clinical Research Sites: You're Competitive Battleground for Study Success

#275 Track 14B - Innovation Theater

3:40–4:10pm Format: SESSION

Room: Theater 2 | Exhibit Hall

Veeva Systems Innovation Theater: Simplifying Variation Management

#276 Track 01A - Clinical Safety and Pharmacovigilance

4:15–5:30pm Level: ◆ Format: SESSION

Room: 253AB *CME, Pharmacy, and Nursing*

Patient Engagement in Pharmacovigilance

CHAIRPERSON

Deborah E. Collyar
President, Patient Advocates In Research (PAIR)

SPEAKER(S)

Patient Engagement and Pharmacovigilance: Risk Interventions and Strategic Communications (RISC)
Emily Freeman, PhD, MSc
Director, Patient Centered Outcomes, AbbVie, Inc.

How Will EU Public Hearings Help with Patient and Public Engagement and How Should the Industry Prepare?
Shelley Gandhi, MS
Strategic Advisor, NDA Group, United Kingdom

Can Patient-Generated Real-World Data Illuminate Real World Evidence of Safety Concerns Sooner than Traditional Sources?
David Blaser, PharmD
Director, Health Informatics, PatientsLikeMe

How Well Are We Doing Conveying Drug Safety Information to Patients? An Analysis of the Quality of REMS Educational Materials
Meredith Y. Smith, PhD, MPA
Global Risk Management Officer, Global Patient Safety, Amgen Inc.

Round Table: This discussion will continue at 9:30am on Wednesday, June 27 in the DIA Community Zone, NE Lobby, Level 1

#277 Track 01B - Clinical Safety and Pharmacovigilance

4:15–5:30pm Level: ■ Format: SESSION

Room: 253C *CME, Pharmacy, and Nursing*

Pharmacovigilance: No Longer Going it Alone

CHAIRPERSON

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

SPEAKER(S)

Evolving the Strategic Framework for the Safety Department
Alan M. Hochberg
Scientific Enablement Leader, F. Hoffmann-La Roche Ltd., Switzerland

Building Better Governance: The Maturity of Safety Governance Models and Considerations for Organizations
Ellenie Nichols, MEd
Global Patient Safety and Labeling, Safety Governance Lead, Amgen Inc.

Multi-Disciplinary Approach for Successful Collaboration: Improving Conversations to Achieve Impact in Drug Development
Amit Bhattacharyya, PhD
Vice President, Biometrics, ACI Clinical

Round Table: This discussion will continue at 8:00am on Wednesday, June 27 in the DIA Community Zone, NE Lobby, Level 1

#278 Track 01C - Clinical Safety and Pharmacovigilance

Featured Topic(s): Real World Evidence, Regulatory Agency Presenters

4:15–5:30pm Level: ■ Format: FORUM

Room: 252AB *CME, Pharmacy, and Nursing*

Challenges and Opportunities in Data Access and Methodology Development for Post-Market Generic Drug Monitoring

CHAIRPERSON

Liang Zhao, PhD
Director, Office of Research and Standards, DQMM, Office of Generic Drugs, CDER, FDA

PANELISTS

Joshua Gagne, DrSc, PharmD
Associate Professor, Department of Epidemiology, Harvard Medical School

Sarah K. Dutcher, PhD, MS
Epidemiologist, Office of Surveillance and Epidemiology, CDER, FDA

Joseph Ross, MD, MHS
Associate Professor of Medicine and Public Health, Yale University School of Medicine

#279 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine, Outsourcing

4:15–5:30pm Level: ■ Format: FORUM

Room: 153ABC *CME, Pharmacy, and Nursing*

Redefining the Site Investigator's Experience

CHAIRPERSON

Dan Milam
Vice President, Global Engagement, Society for Clinical Research Sites

SPEAKER(S)

Bullseye! Hitting the Mark from Long Distance: Partnering with Sites to Better Plan for Study Conduct in Feasibility
Earl Seltzer, MBA
Director, Global Feasibility-Site and Patient Access, Syneos Health

Update on Redefining the Site Investigator Experience
Lisa Bartoli Moneymaker
CTMS Process Architect and SIP Implementation Lead, Amgen Inc.

#280 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine, Outsourcing

4:15–5:30PM | Level: ■ | Format: FORUM

Room: 254AB | *CME, Pharmacy, and Nursing*

Debunking Decentralized Trials: Sharing Breakthroughs and Deal Breakers

CHAIRPERSON

Jane E. Myles, MS
Head, Operational Intelligence and Innovation, Genentech, A Member of the Roche Group

PANELISTS

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

Komathi Stem, MS
Founder and Chief Executive Officer, monARC Bionetworks

Jennifer C. Goldsack, MA, MBA
Senior Project Manager, Clinical Trials Transformation Initiative (CTTI)

#281 Track 02C - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine

4:15–5:30PM | Level: ■ | Format: FORUM

Room: 258C | *CME, Pharmacy, and Nursing*

Future of Endpoints

CHAIRPERSON

Bill Byrom, PhD
Vice President, Product Strategy and Innovation, CRF Health, United Kingdom

SPEAKER(S)

Use of an Electronic Diary to Capture Subject-Reported Data for the Evaluation of Primary and Secondary Endpoints
Elizabeth Garner, MD, MPH
Chief Medical Officer, Senior Vice President of Clinical Development, Agile Therapeutics

Game On: Leveraging Video Game Platforms to Measure Clinical Endpoints
Bill Byrom, PhD
Vice President, Product Strategy and Innovation, CRF Health, United Kingdom

Digital Biomarkers: Towards Modernized Endpoints
Christian Gossens, PhD
Global Head, Early Development Workflows, F. Hoffmann-La Roche Ltd., Switzerland

#282 Track 03 - Data and Data Standards

Featured Topic(s): Mobile Technology, Translational Science and Medicine

4:15–5:30PM | Level: ■ | Format: SESSION

Room: 209 | *CME, Pharmacy, and Nursing*

Building up Efficiencies, Breaking Down Barriers: Using Mobile Technology for Data Capture in Clinical Trials

CHAIRPERSON

Christopher Miller, MSc
Biometrics and Information Sciences Therapeutic Head, Respiratory, AstraZeneca Pharmaceuticals LP

SPEAKER(S)

CTTI's Recommendations: Building up Efficiencies, Breaking Down Barriers - Using Mobile Technology for Data Capture in Clinical Trials
Christopher Miller, MSc
Biometrics and Information Sciences Therapeutic Head, Respiratory, AstraZeneca Pharmaceuticals LP

Transforming Clinical Trials with the Use of eSource and Wearable Technology
Sunil Agarwal, MS
Associate Vice President and Practice Lead, Pharma R&D, HCL America Inc.

New Horizons: Healthcare, Big Data, and Devices in Clinical Research
James Streeter
Global Vice President, Life Sciences Product Strategy, Oracle

#283 Track 04 - Medical Affairs and Scientific Communication

Featured Topic(s): Career Development

4:15–5:30PM | Level: ■ | Format: FORUM

Room: 210C | *CME, Pharmacy, and Nursing*

Evolving Roles and Responsibilities for Medical Affairs Professionals

CHAIRPERSON

Dannis Chang, PharmD
Senior Director, Global Medical Information and Scientific Communications, Halozyme Therapeutics Inc.

PANELISTS

Suzanne Soliman, PharmD, RPh
Chief Academic Officer, Accreditation Council for Medical Affairs

Ketra Bouvier, BSN, RN
Manager, Global Medical Information, Eli Lilly and Company

Sotirios G. Stergiopoulos, MD
Chief Medical Officer, Senior Vice President and Head of Global Medical Affairs, IPSEN

#284 Track 05 - Patient Engagement

Featured Topic(s): Real World Evidence, Translational Science and Medicine

4:15–5:15PM | Level: ■ | Format: SESSION

Room: 151AB | *CME, Pharmacy, and Nursing*

Using Advocacy Partnerships to Improve Real World Evidence in Clinical Trials

CHAIRPERSON

Shazia Ahmad
Director, Patient and Physician Services, UBC

PANELISTS

How do You Integrate the Patient Voice into the Drug Development Process?
Isabelle Lousada, MA
Chief Executive Officer and President, Amyloidosis Research Consortium

Mary Dunkle
Vice President of Educational Initiatives, National Organization For Rare Disorders (NORD)

Nadia Bodkin
President and Chief Executive Officer, EDSers United Foundation

#285 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Translational Science and Medicine

4:15–5:30PM LEVEL: ■ FORMAT: SESSION
Room: 156ABC *CME, Pharmacy, and Nursing*

Gene Therapy: Advances in Translating Technology

CHAIRPERSON

Peter W. Marks, MD, PhD
Director, Center for Biologics Evaluation and Research, FDA

SPEAKER(S)

How has Adeno-Associated Virus (AAV) Evolved?
Terence Flotte, MD
Dean, Provost and Executive Deputy Chancellor, University of Massachusetts Medical School

Update on the Development of the LentiGlobin Program
David Davidson, MD
Chief Medical Officer, bluebird bio, Inc.

Eva Essig
Vice President, Regulatory Affairs, Intellia Therapeutics, Inc.

Michael Havert, PhD
Biologist/CMC Reviewer, Gene Therapy Branch, OTAT, CBER, FDA

#286 Track 07 - Project Management and Strategic Planning

Featured Topic(s): Regulatory Agency Presenters

4:15–5:30PM LEVEL: ■ FORMAT: FORUM
Room: 157AB *CME, Pharmacy, Nursing, and PMI PDUs*

Which Regulatory Project Management Staff at FDA Should You Engage With? When and How?

CHAIRPERSON

Wayne Amchin, MA, MPA, RAC
Senior Consumer Safety Officer, DCRP, ODE I, Office of New Drugs, CDER, FDA

PANELISTS

Renmeet Grewal, PharmD, MS, RAC
Chief, Project Manager, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

Sean K. Bradley, PharmD, RPh
Chief Project Manager, Safety Regulatory Management Staff, Office of Surveillance and Epidemiology, CDER, FDA

Hamet M. Toure, PharmD, MPH
Program Management, OPRO, Office of Pharmaceutical Quality, CDER, FDA

#287 Track 08 - R&D Quality and Compliance

Featured Topic(s): Outsourcing

4:15–5:30PM LEVEL: ■ FORMAT: SESSION
Room: 205C *CME, Pharmacy, and Nursing*

The Letter and Spirit of Risk-Based Monitoring: How to Creatively Implement Risk-Based Modeling and Unlock the Potential of the Team

CHAIRPERSON

Teresa Ancukiewicz, MA
Senior Manager, Clinical Data Management, Boston Scientific Corporation

SPEAKER(S)

Creative Implementation of Risk-Based Monitoring by Unlocking the Potential of Study Team
Teresa Ancukiewicz, MA
Senior Manager, Clinical Data Management, Boston Scientific Corporation

Risk-Based Study Management: From Risk Identification to the Study Closure for In-House and Outsourced Studies
Johann Proeve, PhD
Chief Scientific Officer, Cyntegrity, Germany

Best Practices and Observations from Implementing TransCelerate's Risk-Based Monitoring Model Framework
Suzanne Lukac
Director, Risk-Based Monitoring Implementation, Merck & Co., Inc.

Round Table: This discussion will continue at 9:30AM on Wednesday, June 27 in the DIA Community Zone, NE Lobby, Level 1

#288 Track 09A - Regulatory

Featured Topic(s): Regulatory Agency Presenters

4:15–5:15PM LEVEL: ■ FORMAT: FORUM
Room: 205AB *CME, Pharmacy, and Nursing*

Is it Time to Change the Content and Format of Labeling?

CHAIRPERSON

Ingrid Stahl Bryzinski, MS, RPh
Senior Director, Global Labeling, AbbVie, Inc.

SPEAKER(S)

FDA Perspective
Eric Brodsky, MD
Associate Director, Labeling Development Team (LDT), Office of New Drugs, CDER, FDA

Patient Perspective
Jeff Allen, PhD
President and Chief Executive Officer, Friends of Cancer Research

Industry Perspective
Kathy A. Clark, BSN, RN
Director, Global Regulatory Affairs, US Advertising and Promotion, Eli Lilly and Company

#289 Track 09B - Regulatory

Featured Topic(s): Regulatory Agency Presenters

4:15–5:30PM Level: ■ Format: SESSION

Room: 204AB *CME, Pharmacy, and Nursing*

Electronic Submissions Demystified

CHAIRPERSON

Tessa Brown, MPH, RN
Deputy Director, Division of Data Management Services and Solutions, Office of Business Informatics, CDER, FDA

SPEAKER(S)

FDA Perspective
Jonathan Resnick
Project Management Officer, Office of Business Informatics, Office of Strategic Programs, CDER, FDA

Submission Lifecycle Maintenance: Managing the Chaos
Sandra A. Krogulski, MA
Regulatory Operations Submission Manager, Accenture

Are You Prepared for the Change? New and Updated Requirements in Drug Registration and Listing
Julian Chun, PharmD, MBA
Pharmacist, DRLS, OPRO, Office of Compliance, CDER, FDA

#290 Track 09C - Regulatory

4:15–5:30PM Level: ◆ Format: SESSION

Room: 206AB *CME, Pharmacy, and Nursing*

Priority Review Vouchers: Here to Stay and Worth the Effort?

CHAIRPERSON

Kim Quaintance-Lunn
Vice President, Regulatory Policy, NA, Bayer

SPEAKER(S)

Value
Andrew Robertson, JD, PhD
Head, Global Regulatory Science and Policy, NA, Sanofi

Strategy
John Jenkins, DrMed, MD
Principal, Drug and Biological Products, Greenleaf Health

Process
Larry Bauer, MA, RN
Regulatory Scientist, Rare Diseases Program, Office of New Drugs, CDER, FDA

#291 Track 10 - Regulatory CMC and Product Quality

Featured Topic(s): Regulatory Agency Presenters

4:15–5:30PM Level: ■ Format: FORUM

Room: 208 *CME, Pharmacy, and Nursing*

ICH Q12: A Paradigm Changing Guidance for Post-Approval Changes?

CHAIRPERSON

Christine M. V. Moore, PhD
Global Head and Executive Director, GRACS CMC - Policy, Merck Research Laboratories

SPEAKER(S)

ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
Representative Invited

Pathways for Decreasing Regulatory Burden Through ICH Q12
Christine M. V. Moore, PhD
Global Head and Executive Director, GRACS CMC - Policy, Merck Research Laboratories

#292 Track 11 - Statistics

Featured Topic(s): Regulatory Agency Presenters, Translational Science and Medicine

4:15–5:30PM Level: ■ Format: SESSION

Room: 256 *CME, Pharmacy, and Nursing*

Complex Innovative Designs and Model-Informed Drug Development Related: PDUFA VI Pilot Programs

CHAIRPERSON

Yeh-Fong Chen, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

PANELISTS

Laura Lee Johnson, PhD
Director (Acting), Division III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Issam Zineh, PharmD, MPH
Director, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

Dionne Price, PhD
Acting Deputy Director, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

#293 Track 12A - Value and Access

4:15–5:15PM Level: ● Format: SESSION

Room: 257AB *CME, Pharmacy, and Nursing*

Medical Monitoring in Non-Interventional Studies: Need for Medical Leadership and Study Primary Care Management

CHAIRPERSON

Xavier Fournie, MD
Corporate Medical Director, Medial Affairs, ICON plc, France

SPEAKER(S)

Perspective of a Pharmacoepidemiologist Involved in Study Design and Analysis Data
Margaret Richards, PhD, MPH
Executive Director, Scientific Affairs, Real World Solutions, PRA Health Sciences

#294 Track 12B - Value and Access

4:15–5:15PM Level: ◆ Format: SESSION

Room: 258AB *CME, Pharmacy, and Nursing*

Sustainable Healthcare Funding

CHAIRPERSON

Vaidyanathan Srikant
Senior Partner and Managing Director, The Boston Consulting Group, Switzerland

PANELISTS

Kenneth I. Kaitin, PhD
Director, Tufts Center for the Study of Drug Development; Professor of Medicine, Tufts University School of Medicine

Panos Kanavos
Deputy Director, LSE Health, London School of Economics, United Kingdom

Luca Pani, MD
Former, AIFA; Professor, Department of Psychiatry and Behavioral Sciences, University of Miami

Indranil Bagchi, PhD, MS
Vice President and Franchise Head, Global Value and Access, Novartis Oncology

#295 Track 17A - Community Rounds

4:30–5:30PM Format: FORUM

Room: Community Zone | NE Lobby

DIA Devices and Diagnostics Community Round Table Discussion: Navigating the Regulatory Landscape of Drug-Device Combination Products

CHAIRPERSON

Kerri-Anne Mallet, MBA
Vice President, Clinical and Regulatory Affairs, Pharmatech Associates, Inc.

#296 Track 17B - Community Rounds

4:30–5:30PM Format: FORUM

Room: Community Zone | NE Lobby

DIA Medical Writing Community Round Table Discussion: CTD Regulatory Defense Strategies - How Best to Prepare Your Response to Health Authority Queries

CHAIRPERSON

David B. Clemow, PhD
Advisor, Scientific Communications Information Strategy, Eli Lilly and Company

NOTES

WEDNESDAY, JUNE 27

Registration Hours

7:00AM–5:15PM Attendee, Speaker, and Exhibitor Registration

7:00–8:00PM

Coffee and Light Refreshments
North Lobby | Level 1

#301 Track 01A - Clinical Safety and Pharmacovigilance

8:00–9:15AM Level: ■ Format: SESSION
Room: 253C *CME, Pharmacy, and Nursing*

Automation in Pharmacovigilance: Doing More with Less

CHAIRPERSON
Axel Hagel
Partner, Foresight Group International, Canada

SPEAKER(S)

Data Visualization and Analytics for Medical Monitors: Tech Adoption and Best Practices
Masha Hoffey, MS
Director of Clinical Analytics, PerkinElmer Informatics, Inc.

Signal Detection in Social Media: Feasibility Assessment of Methods
Neal Grabowski, MS
Signal Management Officer, Amgen Inc.

Round Table: This discussion will continue at 1:00PM on Wednesday, June 27 in the DIA Community Zone, NE Lobby, Level 1

#302 Track 01B - Clinical Safety and Pharmacovigilance

8:00–9:15AM Level: ■ Format: SESSION
Room: 253AB *CME, Pharmacy, and Nursing*

Risk Communication and Patient Safety: Recent Learnings and New Approaches

CHAIRPERSON
Meredith Y. Smith, PhD, MPA
Global Risk Management Officer, Global Patient Safety, Amgen Inc.

SPEAKER(S)

Engaging Patients and Healthcare Professionals in Evaluating Risk Minimization Measures: How Can Regulators Best Listen to Medicine Users for Improved Regulatory Decision-Making and Risk Communication
Juan Garcia-Burgos, MD
Head of Public Engagement Department, European Medicines Agency (EMA), European Union

New Risk Communication Approaches for Patients: The FDA's Benefit-Risk Counseling Framework and Other Tools
Michael S. Wolf
Associate Professor, Medicine and Learning Sciences, Associate Division Chief, Northwestern University

Marina Serper, MD, MS
Assistant Professor of Medicine and Gastroenterology, University of Pennsylvania School of Medicine

#303 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Pediatrics, Translational Science and Medicine

8:00–9:15AM Level: ■ Format: SESSION
Room: 258C *CME, Pharmacy, and Nursing*

Regulatory and Ethical Considerations with Placebo Administration Using a Central Venous Access Device in a Pediatric Trial

CHAIRPERSON
Robert Nelson, MD, PhD
Senior Director, Pediatric Drug Development, Johnson & Johnson

SPEAKER(S)

Additional Safeguards for Children in Research and Protocol Review Under 21 CFR 50.54
Donna L. Snyder, MD
Pediatric Ethicist and Team Lead, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

Sponsor Perspective
John Lu
Medical Director, Sarepta

Principle Investigator Perspective
Perry Shieh, MD, PhD
Neuromuscular Medicine Specialist, UCLA Medical Center

Parent Perspective
Brett Bullers
Parent

Erin Bullers
Parent

Patient Perspective
Nicholas Bullers
Patient

#304 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine, Outsourcing

8:00–9:15AM Level: ● Format: SESSION
Room: 258AB *CME, Pharmacy, and Nursing*

Data and Quality Approaches to Informing Global Investigative Site Selection

CHAIRPERSON
Stella Stergiopoulos, MPH, MS
Research Fellow, Tufts Center for the Study of Drug Development

SPEAKER(S)

Challenges and Solutions in Integrating Data Sources to Support Evidence-Based Site Selection and Study Planning
Claire Sears, PhD
Communications Director, Data Solutions, DrugDev, United Kingdom

Empowering Our Investigators: How New Investigator Qualification Approaches Could Improve Quality Conduct of Clinical Trials
James Kremidas
Executive Director, Association of Clinical Research Professionals (ACRP)

#305 Track 03 - Data and Data Standards

Featured Topic(s): Translational Science and Medicine

8:00–9:15AM Level: ■ Format: WORKSHOP

Room: 254AB *CME, Pharmacy, and Nursing*

Building a Roadmap to the Implementation of the Risk-Based Monitoring Process: Facilitating the Perspectives of All Stakeholders

CHAIRPERSON

Mary Banach, PhD, MPH
Project Manager, CTSpedia, Vanderbilt University

SPEAKER(S)

Where We Are: Where We Are Going
Stephen Young, MSc
Chief Operations Officer, CluePoints

Vendor Selection for Risk-Based Monitoring
Nimita Limaye, PhD
Chief Executive Officer, Nymro Clinical Consultancy Services, India

#306 Track 04 - Medical Affairs and Scientific Communication

8:00–9:15AM Level: ■ Format: SESSION

Room: 210C *CME, Pharmacy, and Nursing*

phactMI: A Collaborative Approach to Advancing the Practice of Medical Information and Enabling Innovative Customer Solutions

CHAIRPERSON

Jennifer L. Riggins, DIAFellow, PharmD
Advisor, Global Medical Channels and eCapabilities, Eli Lilly and Company

SPEAKER(S)

phactMI: Collaborating to Bring Additional Value to Healthcare Professionals
Jennifer L. Riggins, DIAFellow, PharmD
Advisor, Global Medical Channels and eCapabilities, Eli Lilly and Company

phactMI Benchmark Study: Trends, Drivers, Success Factors, and Value of Globalization in Medical Information
Suzana Giffin, PharmD

Benchmarking in Medical Information: A Comprehensive Study of Structure, Services, and Technologies Among Medical Information Departments
Jung Lee, PharmD
Senior Director, Medical Information, AstraZeneca

#307 Track 05 - Patient Engagement

8:00–9:15AM Level: ● Format: SESSION

Room: 153ABC *CME, Pharmacy, and Nursing*

Maintaining Patient Engagement in the Development of Patient-Reported Outcome (PRO) Measures

CHAIRPERSON

Sarah Clifford, PhD, MSc
Senior Principal, Patient-Centered Outcomes, ICON Clinical Research, Inc

SPEAKER(S)

Ways in Which Patient and Caregiver Recorded Outcomes and Assessments Will Affect Regulators, Industry, and Patients and Payers in the Coming Years
Christine McSherry, BSN, RN
Executive Director, Jett Foundation

Patient Affairs Perspective
Michele Rhee, MBA, MPH
Head, Patient Affairs, Enzyvant, Inc.

Clinical Outcomes
Alison M. Skrinar
Executive Director, Clinical Outcomes Research and Evaluation, Ultragenyx Pharmaceutical

#308 Track 05A - Patient Engagement

Featured Topic(s): Rare Diseases, Translational Science and Medicine

8:00–9:15AM Level: ● Format: SESSION

Room: 151AB *CME, Pharmacy, and Nursing*

How Do Patients and Other Multi-Disciplinary Stakeholders Collaborate to Develop Patient Registries Which Accelerate Research?

CHAIRPERSON

Steven L. Roberds, PhD
Chief Scientific Officer, Tuberous Sclerosis Alliance

SPEAKER(S)

United We Stand: How Can Patients and Other Stakeholders Develop Registries to Speed up Research into Rare Diseases?
Stella Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Early Access and Risk Management, IQVIA, United Kingdom

Patient Registry Data Governance: Considering the Priorities of a Diverse Group of Stakeholders
Kate Avery, MPH
Director of Research and Patient Engagement, Beyond Celiac

Tânia Teixeira
FDA Liaison Official, European Medicines Agency (EMA), European Union

#309 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Regulatory Agency Presenters, Translational Science and Medicine

8:00–9:15AM Level: ■ Format: SESSION

Room: 156ABC *CME, Pharmacy, and Nursing*

Evolution and Harmonization of First-in-Human Guidelines

CHAIRPERSON

William B. Smith, MD
Chief Executive Officer, Alliance for Multispecialty Research/NOCCR

SPEAKER(S)

Changes to First-in-Human Studies Following the 2017 Revision of the EMA Guidance on Risks for FiH and Early Clinical Trials
Mattheus Paulus Van Iersel, MD
Senior Director, Scientific Affairs - Clinical Pharmacology, PRA Health Sciences, Netherlands

Industry Perspective
Sarah Robertson, PharmD
Senior Director, Clinical Pharmacology, Vertex Pharmaceuticals

Round Table: This discussion will continue at 1:00PM on Wednesday, June 27 in the DIA Community Zone, NE Lobby, Level 1

#310 Track 07 - Project Management and Strategic Planning

Featured Topic(s): Career Development

8:00–9:15AM Level: ■ Format: WORKSHOP
Room: 252AB *CME, Nursing, and PMI PDUs*

Becoming Highly Self-Aware: Leading in the Midst of Ambiguity

CHAIRPERSON
Nicky Rousseau, CPA, MBA
Senior Director, Sales Organization Development, IQVIA

FACILITATOR
Jennifer Cubino, MA
Senior Global Customer Operations Director, IQVIA

#311 Track 08 - R&D Quality and Compliance

8:00–9:15AM Level: ■ Format: SESSION
Room: 205C *CME, Pharmacy, and Nursing*

Harnessing the Power of Data and Analytics to Enhance Quality

CHAIRPERSON
Ann Meeker-O'Connell, MS
Vice President, Global Head, Quality Assurance, IQVIA

SPEAKER(S)

Augmenting Clinical Research Site Audits with Statistical Analysis Tools
Gloria Miller, RAC
Associate Director QARC, Premier Research

Leveraging Audit Data and Metrics for Risk Identification and Evaluation
Shehnaz Kairas Vakharia, MSc
Managing Director, ADAMAS Clinical Quality Consulting Pvt Ltd, India

Industry Perspective
David Donohue, MBA
Head, Quality Data Analytics, Systems, Operations, and Optimum, GlaxoSmithKline

#312 Track 09A - Regulatory

Featured Topic(s): Regulatory Agency Presenters

8:00–9:15AM Level: ■ Format: FORUM
Room: 206AB *CME, Pharmacy, and Nursing*

Harmonizing Regulatory Science Through the International Council for Harmonisation (ICH)

CHAIRPERSON
Amanda Marie Roache, MS
Operations Research Analyst, Office of Strategic Programs, CDER, FDA

PANELISTS

Theresa Mullin, PhD
Associate Director for Strategic Initiatives, CDER, FDA

C. Michelle Limoli, PharmD
Senior International Health Sciences Advisor, Office of the Director, CBER, FDA

Jerry Stewart, JD, MS, RPh
Deputy Vice President, Scientific and Regulatory Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA)

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

Celia Lourenco, PhD
Interim Senior Executive Director, Therapeutic Products Directorate, Health Canada

Nicholas Cappuccino, PhD, MBA
Vice President, Quality and Scientific Affairs, Dr. Reddy's Laboratories

Wassim Nashabeh, PhD., MBA
Vice President, Technical Regulatory Policy and International Operations, F. Hoffmann-LaRoche, Switzerland

#313 Track 09B - Regulatory

Featured Topic(s): Rare Diseases, ExUS Regulatory

8:00–9:15AM Level: ■ Format: FORUM
Room: 205AB *CME, Pharmacy, and Nursing*

Global Rare Disease Town Hall

CHAIRPERSON
James E. Valentine, JD, MHS
Attorney, Hyman, Phelps & McNamara, PC

SPEAKER(S)

EMA Perspective
Kristina Larsson, MS
Head of Office for Orphan Medicines, European Medicines Agency (EMA), European Union

Perspectives on Rare Diseases and Gene Therapies
Ilan Irony, MD
Deputy Director, DCEPT, Office of Tissues and Advanced Therapies, CBER, FDA

FDA Perspective
Lucas Kempf, MD
Acting Associate Director, Rare Diseases Program, Office of New Drugs, CDER, FDA

#314 Track 09C - Regulatory

Featured Topic(s): Devices and Combination Products

8:00–9:15AM Level: ■ Format: FORUM

Room: 204AB *CME, Pharmacy, and Nursing*

What Can We Say About Combination Products? Labeling, Advertising and Promotion of Combination Products

CHAIRPERSON

Kerri-Anne Mallet, MBA
Vice President, Clinical and Regulatory Affairs, Pharmatech Associates, Inc.

SPEAKER(S)

Utilization of Human Factors Studies
Darin Seth Oppenheimer, DrSc, MS, RAC
Executive Director, Drug Device Center of Excellence, Merck & Co., Inc.

Cross Labeling and Devices Referencing Drugs
Alexander Varond, JD
Associate, Goodwin Procter LLP

Labeling and Ad/Promo Challenges for Combination Products
Anthony Genovese, PharmD
Deputy Director, Advertising and Promotion, Bayer Healthcare

Round Table: This discussion will continue at 3:00PM on Wednesday, June 27 in the DIA Community Zone, NE Lobby, Level 1

#315 Track 10 - Regulatory CMC and Product Quality

8:00–9:15AM Level: ◆ Format: SESSION

Room: 208 *CME, Pharmacy, and Nursing*

Can I Implement That Now? Efficiently Managing Post-Approval CMC Changes

CHAIRPERSON

Leonard Lescosky, JD, MS
Vice President, CMC Regulatory Affairs, AbbVie, Inc.

SPEAKER(S)

Compliance and Change Control: Checking that the Manufacture/CMC is Maintained in Accord with the Terms of the License
Peter Lassoff, PharmD
Vice President and Head, Global Regulatory Affairs, IQVIA, United Kingdom

Changing Landscape of Managing CMC Post-Approval Changes: Challenges Now and How Global Regulations Impacts Us Going Forward
Pascha Clark-Higgs, RAC
Associate Director, Regulatory Development Solutions, CMC, PPD

Pharmacopoeia Harmonization and Global Compendial Compliance
J. Mark Wiggins, MS
Director, Compendial Compliance and Advocacy, Merck & Co., Inc.

#316 Track 11 - Statistics

Featured Topic(s): Translational Science and Medicine

8:00–9:15AM Level: ■ Format: SESSION

Room: 256 *CME, Pharmacy, and Nursing*

Opportunities for Efficient and Innovative Study Designs

CHAIRPERSON

Amy Xia, PhD
Executive Director, Biostatistics, Amgen Inc.

SPEAKER(S)

Understanding the Special Importance of Phase 2 Clinical Studies
Ron Marks, PhD
Chief Scientific Officer, Clinipace Worldwide

Leveraging Natural History Data for Rare Diseases Drug Development: A Bayesian Perspective
Shu Han, PhD, MBA
Head of Biostatistics, Moderna Therapeutics

A Bayesian Approach in the Non-Inferiority Setting
Cristiana Mayer, PhD
Scientific Director, Statistical Modeling and Methodology, SDS, Janssen Research and Development LLC

#317 Track 12 - Value and Access

Featured Topic(s): Real World Evidence

8:00–9:00AM Level: ■ Format: SESSION

Room: 257AB *CME, Pharmacy, and Nursing*

Operationalizing Real World Evidence and Value

CHAIRPERSON

Michelle Hoiseth
Corporate Vice President, Real-World Data Services, PAREXEL International

SPEAKER(S)

Using Artificial Intelligence and Big Data to Improve Operational Efficiency
Vandana Menon, MD, PhD, MPH
Vice President, Research, OM1

Effective Use of Real World Evidence to Overcome Data Challenges in the Rare Disease Setting
Ashish Dugar, PhD, MBA
Vice President, Global Medical Affairs, Sarepta Therapeutics

#318 Track 13

DIAmond SESSIONS

8:00–9:30AM Level: ■ Format: FORUM

Room: 210AB *CME, Pharmacy, and Nursing*

Value-Based Assessment and Contracting: What Needs to be Done to Make it a Best Practice?

CHAIRPERSON

Michael Rosenblatt, MD
Chief Medical Officer, Flagship Pioneering

PANELISTS

Ellen Zane
CEO Emeritus and Vice Chair, Board of Trustees, Tufts Medical Center

Samuel R. Nussbaum, MD
Strategic Consultant, EBG Advisors, Inc.

Luca Pani, MD
Former, AIFA; Professor, Department of Psychiatry and Behavioral Sciences, University of Miami

#319 Track 17A - Community Rounds

8:00–9:00AM Format: FORUM

Room: Community Zone | NE Lobby

DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Pharmacovigilance: No Longer Going it Alone

CHAIRPERSON

Catherine Baldridge, MS

Clinical Safety and Pharmacovigilance, PV Compliance, Indivior

#320 Track 17B - Community Rounds

8:00–9:00AM Format: FORUM

Room: Community Zone | NE Lobby

DIA Patient Engagement Community Round Table Discussion: Reaching the Underserved - Methods to Ensure Diversity and Inclusion for Patient Research, Clinical Trials, and Advisory Panels

CHAIRPERSON

Laura Kolaczkowski

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

#321 Track 18 - Professional Development

8:00–9:00AM Level: ● Format: SESSION

Room: 157AB

PowerUp: Career Transforming Moments

CHAIRPERSON

Kimberly Belsky, MS

Senior Director, Regulatory Affairs, Regulatory Policy and Intelligence, Mallinckrodt Pharmaceuticals

SPEAKER(S)

Don't Trade Authenticity for Approval
Kimberly Belsky, MS
Senior Director, Regulatory Affairs, Regulatory Policy and Intelligence, Mallinckrodt Pharmaceuticals

Surviving and Thriving When You are Shown the Door
Margaret Richards, PhD, MPH
Executive Director, Scientific Affairs, Real-World Solutions, PRA Health Sciences

Re-Routing: Navigating Wrong Turns in Your Career Path
Scott Van Buren McGoohan
Director, US Regulatory Policy and Intelligence, Vertex Pharmaceuticals, Inc.

Handling Your Furst (and Hopefully Last) Downsizing
Adora Ndu, JD, PharmD
Executive Director, Global Regulatory Policy, Research and Engagement, BioMarin Pharmaceutical Inc.

Career Transition
Aman Thukral, DrSc, MBA, MPharm
Assistant Director, AbbVie, Inc.

9:00–10:30AM

Coffee Break
Exhibit Hall

#322 Track 16 - Content Hubs

9:15–9:45AM Level: ■ Format: SESSION

Room: Content Hub | NE Lobby *IACET*

New Resource from the DIA Interdisciplinary Disclosure Working Group

CHAIRPERSON

Eileen Girten, MS

Principal Medical Writer, PRA Health Sciences

#323 Track 15 - Engage and Exchange

9:30–10:30AM Level: ■ Format: WORKSHOP

Room: E and E | Exhibit Hall

Good Things Come in Small Packages: Product Development Strategies for Small Companies

CHAIRPERSON

Lauren Neighbours, PhD, RAC

Head of Regulatory Affairs, PSI CRO

#324 Track 17A - Community Rounds

9:30–10:30AM Format: FORUM

Room: Community Zone | NE Lobby

DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Patient Engagement in Pharmacovigilance

CHAIRPERSON

Catherine Baldridge, MS

Clinical Safety and Pharmacovigilance, PV Compliance, Indivior

#325 Track 17B - Community Rounds

9:30–10:30AM Format: FORUM

Room: Community Zone | NE Lobby

DIA Clinical Data Management Community Round Table Discussion: The Letter and Spirit of Risk-Based Monitoring - How to Creatively Implement the RBM and Unlock the Potential of the Team

CHAIRPERSON

Peter Stokman, MSc

Senior Expert Data Manager, Bayer, Netherlands

#326 Track 14A - Innovation Theater

9:45–10:15AM Format: SESSION

Room: Theater 1 | Exhibit Hall

ArisGlobal Innovation Theater: A Regulatory Perspective - How Cognitive E-2-E Pharma Platforms Can Transform Productivity in Pharma - Introducing LifeSphere from Clinical to Regulatory

#327 Track 14B - Innovation Theater

9:45–10:15AM Format: SESSION

Room: Theater 2 | Exhibit Hall

SAS Institute, JMP Division Innovation Theater: RECIST Criteria and Their Impact on Safety and Efficacy Reporting in Oncology Studies

#328 Track 16 - Content Hubs

10:00–10:30AM Level: ● Format: SESSION

Room: Content Hub | NE Lobby *IACET*

Getting the Questions Right

CHAIRPERSON

Joan Buenconsejo, PhD, MPH
Director and Biometrics Team Leader, AstraZeneca

#329 Track 01 - Clinical Safety and Pharmacovigilance

Featured Topic(s): Translational Science and Medicine

10:30–11:45AM Level: ◆ Format: SESSION

Room: 253AB *CME, Pharmacy, and Nursing*

Reducing the Burden of Drug Safety Risk Minimization Programs on the Healthcare System: How do We do so and What has Been Learned to Date?

CHAIRPERSON

Meredith Y. Smith, PhD, MPA
Global Risk Management Officer, Global Patient Safety, Amgen Inc.

SPEAKER(S)

An Update on the FDA's Design and Standardization Workstream in Regard to Integrating REMS into the Healthcare System
Gerald J. Dal Pan
Director, Office of Pharmacovigilance and Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA

What are the Factors that Facilitate Integration Within the Healthcare Delivery System: A Case Study of the Vandetanib Risk Minimization Program
Sarah A. Frise, PhD, MSc
Global Director Risk Management, AstraZeneca, Canada

What are the Policy Options for Facilitating the Integration of REMS Strategies into the Healthcare System?
Gregory Daniel, PhD, MPH, RPh
Deputy Director and Clinical Professor, Duke-Margolis Center For Health Policy

#330 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine

10:30–11:45AM Level: ● Format: FORUM

Room: 253C *CME, Pharmacy, and Nursing*

Artificial Intelligence: Robots Taking Over Clinical Research

CHAIRPERSON

Gregory Jones
Health Sciences Global Business Unit, Oracle Health Sciences

SPEAKER(S)

Are You Ready for Artificial Intelligence in Your Clinical Trial?
Gregory Jones
Health Sciences Global Business Unit, Oracle Health Sciences

Passive In-Home Patient Monitoring: The Role of AI and Contactless Sensors
Dina Katabi, PhD, MS
Professor, MIT

The High ROI of Using Artificial Intelligence for Clinical Trials Recruitment
Wout Brusselaers, MA
Chief Executive Officer, Deep 6 AI

#331 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine, Outsourcing

10:30–11:45AM Level: ■ Format: WORKSHOP

Room: 254AB *CME, Pharmacy, and Nursing*

Rebuilding or Building a Research Site in the Year 2020

CHAIRPERSON

Christian Burns
Vice President of BTC Network; President, ClinEdge

FACILITATORS

Sean Stanton
Srategy and Innovation Consultant, BioClinica

Jennifer Byrne
Founder and President, Greater Gift

#332 Track 03A - Data and Data Standards

Featured Topic(s): Translational Science and Medicine, Mobile Technology, Real World Evidence

10:30–11:45AM Level: ■ Format: SESSION

Room: 208 *CME, Pharmacy, and Nursing*

Clinical Data: Let's Get to the Source and Streamline it to the End

CHAIRPERSON

Jennifer Price
Senior Director, Clinical Data Management, Paidion Research

SPEAKER(S)

Implementation of Direct Data Capture at Industry-Sponsor Sites
Rakesh Maniar, MS
Global Head, Business Technology Services, Novartis Pharmaceuticals Corporation

Implementation of Direct Data Capture at Academic Sites
Michael Buckley, MBA, MS
Manager of Enterprise Innovation, CR Informatics and Technology, Memorial Sloan Kettering Cancer Center

A Case Study of Real-Time Data Capture in eClinical Systems
Randall Paulk
Group Leader, Clinical Data Management, Johnson & Johnson Vision Care

#333 Track 03B - Data and Data Standards

Featured Topic(s): Outsourcing

10:30–11:30AM | Level: ■ | Format: SESSION
Room: 209 | *CME, Pharmacy, and Nursing*

Streamlining Vendor Reconciliation

CHAIRPERSON

Kelley Chrisman, MBA, MPH
Lead Data Manager, PRA Health Sciences

SPEAKER(S)

Streamlining the Process of Vendor Reconciliation: The Puzzle Method
Kelley Chrisman, MBA, MPH
Lead Data Manager, PRA Health Sciences

Reconciling Novel External Data Sources (Wearable Devices and Mobile Technology) with Clinical Databases
Angela Lee
Associate Director, Data Management, Otsuka Pharmaceutical Development & Commercialization, Inc

#334 Track 04A - Medical Affairs and Scientific Communication

Featured Topic(s): ExUS Regulatory

10:30AM–12:00PM | Level: ■ | Format: SESSION
Room: 210C | *CME, Pharmacy, and Nursing*

Clinical Trial Disclosure: Learnings from EMA Policy 0070, NIH Final Rule, and FDA's Clinical Data Summary Program

CHAIRPERSON

Robert Paarlberg, MS
Principal, Paarlberg & Associates LLC

SPEAKER(S)

The Evolution of Clinical Data Transparency: Managing Policy 0070 Requirements of the Future to Maximize Compliant Efficiency
Rosalynd Cole
Senior Manager, Jazz Pharmaceuticals, United Kingdom

Disclosing Data: EMA Policies 0043/0070, EudraCT, and the Clinical Trial Regulation - Where are We Now?
Marie Isabel Manley, LLM
Partner, Head of the UK Life Sciences, Sidley Austin LLP, United Kingdom

Update from ClinicalTrials.gov
Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov, NCBI, National Library of Medicine, NIH

Beyond Disclosure: Working Toward Better Outcomes for Patients
Olivia Shopshear, MS
Senior Director, Science and Regulatory Advocacy, PhRMA

FDA's Pilot to Enhance Transparency of Clinical Trial Information
Ann M. Witt, JD
Counselor to DC for Policy, Office of New Drugs, CDER, FDA

EMA Update
Anne-Sophie Henry-Eude, PharmD
Head of Documents Access and Publication Service, European Medicines Agency (EMA), European Union

Round Table: This discussion will continue at 3:00PM on Wednesday, June 27 in the DIA Community Zone, NE Lobby, Level 1

#335 Track 04B - Medical Affairs and Scientific Communication

Featured Topic(s): Translational Science and Medicine

10:30–11:45AM | Level: ■ | Format: FORUM
Room: 257AB | *CME, Pharmacy, and Nursing*

Collaboration Across the Medical Affairs Ecosystem to Advance Patient Care

CHAIRPERSON

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

PANELISTS

J. Lynn Bass, PharmD
Director, Medical Science Liaisons, Americas, Santen, Inc.

Olivier Chateau
Co-Founder, Chief Executive Officer, Health Union, LLC

Upal Basu Roy, PhD, MPH
Director of Translational Research Program/Director of Patient FoRCe, LUNGevity Foundation

Tanja Keiper, DrSc
Director, GCO External Innovation, Merck KGaA, Germany

#336 Track 05 - Patient Engagement

10:30–11:45AM | Level: ■ | Format: FORUM
Room: 153ABC | *CME, Pharmacy, and Nursing*

Addressing the Elephant in the Room: A Hard Look at Metrics, Legal, Payers, and Other Leading Obstacles Facing the Sustainability of Patient Engagement

CHAIRPERSON

Katherine Capperella
Global Patient Engagement Leader, Janssen Pharmaceutical Companies of Johnson & Johnson

SPEAKER(S)

Industry Perspective
Rebecca A. Vermeulen, RPh
Head, Customer Strategy Global Medical Affairs, Hoffmann-La Roche Ltd., Switzerland

Patient Perspective
Jayne C. Gershkowitz
Chief Patient Advocate, Amicus Therapeutics

Legal Perspective
Patrik Florencio, JD
Senior Vice President, Global Chief Compliance and Risk Officer, Amicus Therapeutics

Payer Perspective
Samuel R. Nussbaum, MD
Strategic Consultant, EBG Advisors, Inc.

Round Table: This discussion will continue at 8:00AM on Thursday, June 28 in the DIA Community Zone, NE Lobby, Level 1

#337 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Translational Science and Medicine

10:30–11:30AM | Level: ■ | Format: FORUM

Room: 156ABC | *CME, Pharmacy, and Nursing*

Balancing Regulatory, Medical, and Operational Pillars to Get Pediatric Trials Done Globally

CHAIRPERSON

Earl Seltzer, MBA
Director, Global Feasibility-Site and Patient Access, Syneos Health

SPEAKER(S)

Initiation and Development of Pediatric Clinical Trials: Regulatory and Ethical Issues
Donna L. Snyder, MD
Pediatric Ethicist and Team Lead, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

DIY Toy Box: Operational Considerations and Insights for Pediatric Clinical Trials
Gina Calarco, BSN, MPH
Associate Director, Pediatric Center of Excellence, IQVIA

#338 Track 07 - Project Management and Strategic Planning

10:30–11:45AM | Level: ◆ | Format: SESSION

Room: 157AB | *CME, Pharmacy, Nursing, and PMI PDUs*

You've Got Data #now What?

CHAIRPERSON

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

SPEAKER(S)

Planning in Anticipation of the Availability of Key Clinical Study Results
Diane Rintzler Yen, PhD, PMP
Director, Project Management, Merck Research Laboratories

Danielle Neveles
Global Communications Manager, Lilly Immunology, Eli Lilly and Company

#339 Track 08 - R&D Quality and Compliance

Featured Topic(s): Regulatory Agency Presenters, ExUS Regulatory, Outsourcing

10:30–11:45AM | Level: ■ | Format: SESSION

Room: 258AB | *CME, Pharmacy, and Nursing*

Determining Data Integrity: Decoding the Impact of Inspectional Observations

CHAIRPERSON

Jean M. Mulinde, MD
Senior Policy Advisor, Office of Scientific Investigations, Office of Compliance, CDER, FDA

PANELISTS

Anabela Marcal, PharmD
Head of Compliance and Inspections Department, European Medicines Agency (EMA), European Union

David C. Burrow, JD, PharmD
Acting Director, Office of Scientific Investigations, Office of Compliance, CDER, FDA

Sally Choe, PhD
Deputy Director, OSIS, Office of Translational Sciences, CDER, FDA

Jenn W. Sellers, MD
Medical Officer, Office of Scientific Investigations, Office of Compliance, CDER, FDA

#340 Track 09A - Regulatory

Featured Topic(s): Regulatory Agency Presenters

10:30–11:45AM | Level: ■ | Format: FORUM

Room: 206AB | *CME, Pharmacy, and Nursing*

Harmonization Beyond ICH

CHAIRPERSON

Camille Jackson
Senior Director, Science and Regulatory Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA)

SPEAKER(S)

C. Michelle Limoli, PharmD
Senior International Health Sciences Advisor, Office of the Director, CBER, FDA

Jerry Stewart, JD, MS, RPh
Deputy Vice President, Scientific and Regulatory Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA)

Celia Lourenco, PhD
Interim Senior Executive Director, Therapeutic Products Directorate, Health Canada

Carol Zhu, MBA
Senior Vice President and Managing Director, DIA China

#341 Track 09B - Regulatory

Featured Topic(s): Regulatory Agency Presenters, Mobile Technology

10:30–11:45AM | Level: ■ | Format: FORUM

Room: 204AB | *CME, Pharmacy, and Nursing*

New FDA Draft Guidance on Part 11 in Clinical Investigations

CHAIRPERSON

Ron D. Fitzmartin, DIAFellow, PhD, MBA
Senior Advisor, Office of Strategic Programs, CDER, FDA

PANELISTS

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

Cheryl A. Grandinetti, PharmD
Health Scientist, Policy Analyst, OSI, Office of Compliance, CDER, FDA

#342 Track 09C - Regulatory

10:30–11:45AM Level: ● Format: SESSION
Room: 205C *CME, Pharmacy, and Nursing*

Sex Considerations in the FDA Drug Review Pipeline: The Where, When, and How

CHAIRPERSON

Marsha B. Henderson
Associate Commissioner, Office of Women's Health, FDA

SPEAKER(S)

Inclusion and Analysis of Sex and Gender Differences in Clinical Trials Supporting Drug Approvals
Marsha B. Henderson
Associate Commissioner, Office of Women's Health, FDA

Sex Considerations in Drug Development: A Nonclinical Perspective
John H. Dubinion, PhD
Pharmacologist, Office of Antimicrobial Products, Office of New Drugs, CDER, FDA

Clinical Evaluation of a New Drug: Looking for Sex Differences
Milena M. Lolic, MD, MS
Lead Medical Officer, FDA

#343 Track 11 - Statistics

10:30–11:45AM Level: ■ Format: SESSION
Room: 256 *CME, Pharmacy, and Nursing*

Innovative Visualization Approaches

CHAIRPERSON

Richard Zink, PhD
Director of Statistical Services, TARGET Pharmasolutions

SPEAKER(S)

Understanding Our Brain's Graphical Superpowers Leads to Amazing Data Interpretation
Susan Duke, MSc
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Data-Driven Interactive Treatment Pathway Visualization
Sharon Hensley Alford, PhD, MPH
Associate Chief Health Officer, Life Science, Data, and Evidence, IBM Watson Health

Understanding the Individual Contributions to Multivariate Outliers in Assessments of Data Quality
Richard Zink, PhD
Director of Statistical Services, TARGET Pharmasolutions

#344 Track 12A - Value and Access

Featured Topic(s): Biosimilars

10:30–11:45AM Level: ■ Format: FORUM
Room: 205AB *CME, Pharmacy, and Nursing*

Biosimilar Interchangeability: A Global Perspective

CHAIRPERSON

Nielsen Hobbs
Executive Editor, US Policy and Regulatory, The Pink Sheet/Scrip

PANELIST(S)

Steinar Madsen, MD
Medical Director, Norwegian Medicines Agency, Norway

Molly Burich, MPH
Director, Public Policy, Biosimilars and Reimbursements, Boehringer Ingelheim

Chad Pettit, MBA
Executive Director, Biosimilars Global Value Access and Policy, Amgen Inc.

#345 Track 12B - Value and Access

10:30AM–12:00PM Level: ◆ Format: WORKSHOP
Room: 252AB *CME, Pharmacy, and Nursing*

Unmet Medical Need: Path Forward – Creating a Commonly Agreed Criteria Globally

CHAIRPERSON

Lawrence Eugene Liberti, PhD, RPh, RAC
Executive Director, Centre for Innovation in Regulatory Science (CIRS)

SPEAKER(S)

Industry Round Table
Magdalena Bujar, MSc
Project Manager, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

Industry Round Table
Indranil Bagchi, PhD, MS
Vice President and Franchise Head, Global Value and Access, Novartis Oncology

Regulator Round Table
Kristina Larsson, MS
Head of Office for Orphan Medicines, European Medicines Agency (EMA), European Union

Patient Round Table
Suzanne Schrandt, JD
Director, Patient Engagement, Arthritis Foundation

#346 Track 13

DIAmond SESSIONS

10:30AM–12:00PM | Level: ■ | Format: FORUM

Room: 210AB

CME, Pharmacy, and Nursing

Precision Medicine, Gene Editing, and Gene Therapy: Current Status and Regulatory Challenges of Integrating Genetic Medicine into Clinical Care

CHAIRPERSON

Tshaka Cunningham, PhD
Associate Director, Scientific Collaboration, DIA

SPEAKER(S)

From Next Generation Sequencing to Gene Editing and Beyond: The Future of Gene-Based Medicine
George Church, PhD
Robert Winthrop Professor of Genetics, Harvard University

Patient Perspective on Gene Editing and Gene Therapy: Can We Move Faster for a Cure for Sickle Cell Disease
Michael A. Friend
Founder, Minority Coalition For Precision Medicine and Health Ministries Network

PANELISTS

Samarth Kulkarni, PhD
Chief Executive Officer, CRISPR Therapeutics

Christopher O'Donnell, MD
Chief Scientist, Million Veteran Program, US Department of Veteran Affairs

Peter W. Marks, PhD, MD
Director, Center for Biologics Evaluation and Research, FDA

11:30AM–1:30PM

Luncheon Service

Exhibit Hall

#347 Track 15 - Engage and Exchange

12:00–1:00PM | Level: ■ | Format: WORKSHOP

Room: E and E | Exhibit Hall

Just the Right Tool: ICH E6 (R2) Compliance Tools for Small- to Mid-Size Companies

CHAIRPERSON

Maryrose Petrizzo, MS
President and Principal Consultant, Clinical Quality Assured, LLC

FACILITATOR

Sandy Mohan, PhD
Vice President, Quality and Compliance, Immune Design

#348 Track 16 - Content Hubs

12:00–12:30PM | Level: ■ | Format: SESSION

Room: Content Hub | NE Lobby

IACET

Making Better Portfolio Prioritization Decisions

CHAIRPERSON

Matthew Steven Curin, PharmD
Director, Project and Process Excellence, Astellas Pharma US, Inc.

#349 Track 14A - Innovation Theater

12:10–12:55PM | Format: SESSION

Room: Theater 1 | Exhibit Hall

ZS Associates Innovation Theater: Building an RWE Bridge from Population Health to Personalized Medicine

#350 Track 14B - Innovation Theater

12:10–12:55PM | Format: SESSION

Room: Theater 2 | Exhibit Hall

Salesforce Innovation Theater: Accelerate R&D Innovation with Salesforce for Life Sciences

#351 Track 16 - Content Hubs

12:45–1:15PM | Level: ■ | Format: SESSION

Room: Content Hub | NE Lobby

IACET

Moving Forward with the EU Vigil: The Patient Contact in Pharmacovigilance

CHAIRPERSON

Brian Edwards, DrMed
Principal Consultant, Pharmacovigilance and Drug Safety, Vice President ACRES, NDA Group, United Kingdom

SPEAKER(S)

Patient Engagement in Pharmacovigilance
Herve Le Louet, MD, PhD
Head of PV Department, Henri-Mondor Hospital, France

#352 Track 17A - Community Rounds

1:00–2:00PM | Format: FORUM

Room: Community Zone | NE Lobby

DIA Clinical Pharmacology Community Round Table Discussion: Evolution and Harmonization of First-in-Human Guidelines

CHAIRPERSON

Beatrice Setnik, PhD
Vice President, Clinical Pharmacology, Early Phase, Syneos Health

#353 Track 17B - Community Rounds

1:00–2:00PM | Format: FORUM

Room: Community Zone | NE Lobby

DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Automation in Pharmacovigilance: Doing More with Less

CHAIRPERSON

Catherine Baldridge, MS
Clinical Safety and Pharmacovigilance, PV Compliance, Indivior

#354 Track 14A - Innovation Theater

1:10–1:55PM | Format: SESSION

Room: Theater 1 | Exhibit Hall

IQVIA Innovation Theater: The Digital Future is Now

#355 Track 14B - Innovation Theater

1:10–1:40PM Format: SESSION

Room: Theater 2 | Exhibit Hall

PAREXEL International Innovation Theater: Patient Centricity - From Postulation to Performance - Advancing Data Capture in Clinical Trials with Wearables

#356 Track 15 - Engage and Exchange

1:15–2:00PM Level: ● Format: WORKSHOP

Room: E and E | Exhibit Hall

The Worst Co-Worker on the Block

CHAIRPERSON

Robin Whitsell
President, Whitsell Innovations, Inc

#357 Track 16 - Content Hubs

1:30–2:00PM Level: ● Format: SESSION

Room: Content Hub | NE Lobby *IACET*

Difficult Conversations

CHAIRPERSON

Lisa Kim, MS
Director of Capstone / Lecturer, Rutgers School of Health Professions

#358 Track 01A - Clinical Safety and Pharmacovigilance

Featured Topic(s): Translational Science and Medicine

2:00–3:45PM Level: ■ Format: FORUM

Room: 253AB *CME, Pharmacy, and Nursing*

Expedited E2B Safety Reporting in Interventional Clinical Trials: Convergence of Global Expectations?

CHAIRPERSON

William Gregory, PhD
Safety and Risk Management, Pfizer Inc

SPEAKER(S)

Safety Reporting Practices: Current State, Efforts to Streamline the Process, and the Case for a Global Safety Database
Tamy Kim, PharmD
Associate Director for Regulatory Affairs, OHOP and Oncology Center of Excellence (Acting), CDER, FDA

Emerging New PV World: Comparison of and Exploring New Guidelines for Clinical Research in Japan
Teiki Iwaoka, PhD, MS
Director, Pharmacovigilance, Clinical Development, Nanocarrier Co., Ltd., Japan

Directional Roadmap for ICSR Data Standards and Harmonized Case Reporting
Ta-Jen Chen, MS
Project Management Officer, Office of Strategic Programs, CDER, FDA

FAERS II
Suranjan De, MBA, MS
Deputy Director, Regulatory Science, Office of Surveillance and Epidemiology, CDER, FDA

Industry Perspective
Dieter Kempf, MS
Head, Pharmacovigilance Information and Systems, Genentech, A Member of the Roche Group

#359 Track 01B - Clinical Safety and Pharmacovigilance

Featured Topic(s): Real World Evidence

2:00–3:15PM Level: ● Format: FORUM

Room: 253C *CME, Pharmacy, and Nursing*

IMEDS: A Collaboration Based on the FDA's Sentinel Initiative

CHAIRPERSON

June S. Wasser, MA
Executive Director, Reagan-Udall Foundation for the FDA

PANELISTS

Cheryl Walraven, PhD
Director, Informatics, Aetna

Jeffrey Brown, PhD, MA
Associate Professor, Department of Population Medicine, Harvard Pilgrim Health Care Institute/Harvard Medical School

Claudia Salinas, PhD
Senior Research Scientist, GPS Pharmacoepidemiology, Eli Lilly and Company

#360 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine

2:00–3:15PM Level: ■ Format: FORUM

Room: 258AB *CME, Pharmacy, and Nursing*

Implementation of eConsent and Other Digital Clinical Trial Innovations

CHAIRPERSON

Jennifer Lentz
Consultant, Global Informed Business Lead, Eli Lilly and Company

SPEAKER(S)

Transforming Informed Consent: Current Landscape and Tools to Enable the Future of eConsent
Jennifer Lentz
Consultant, Global Informed Business Lead, Eli Lilly and Company

Driving Clinical Outsourcing Innovation Forward with Machine Learning: Self-Driving Systems to Automate and Accelerate
MaryAnne Rizk, PhD
Vice President, Global BioPharma Partnerships, Oracle

eConsent: A Patient-Centric Program to Improve Enrollment, Recruitment, and Retention
Eric Delente, MA
President, Patient Solutions, DrugDev

Are Your Sites Prepared for eConsent?
Cami Gearhart, JD
Chief Executive Officer, Quorum Review

#361 Track 02 - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine

2:00–3:00PM Level: ■ Format: SESSION

Room: 258C *CME, Pharmacy, and Nursing*

A New Way of Authoring and Reviewing Documents for Clinical Development

CHAIRPERSON

David Twomey

Director, Scientific Informatics Systems, Novartis Institute for Biomedical Research

SPEAKER(S)

TBD

#362 Track 03 - Data and Data Standards

Featured Topic(s): Real World Evidence, Mobile Technology

2:00–3:00PM Level: ■ Format: SESSION

Room: 209 *CME, Pharmacy, and Nursing*

Do the Evolution: The Future Role of Clinical Data Management

CHAIRPERSON

Derek Lawrence

Operational Service Lead, Clinical Data Management, Rho, Inc.

SPEAKER(S)

Data Management to Data Science: Let's Mutate, Not Just Evolve!
Jonathan Palmer
Senior Director, Product Strategy, Digital Trials, Oracle Health Sciences, United Kingdom

#363 Track 04A - Medical Affairs and Scientific Communication

Featured Topic(s): ExUS Regulatory

2:00–3:15PM Level: ■ Format: SESSION

Room: 157AB *CME, Pharmacy, and Nursing*

Innovative and Effective Authoring Strategies to Facilitate Accelerated Regulatory Submissions

CHAIRPERSON

Kent Cochran, III, MS

Director, Regulatory Medical Writing, Janssen Pharmaceutical Companies of Johnson & Johnson

SPEAKER(S)

Accelerated Submissions: Influencing Skills and Strategies for Medical Writers
Kent Cochran, III, MS
Director, Regulatory Medical Writing, Janssen Pharmaceutical Companies of Johnson & Johnson

Revisiting Section 2.7.4, Summary of Clinical Safety
Nancy Katz, PhD
President and Principal, Medical Writing, Illyria Consulting Group, Inc.

Clinical Core Dossier: A Sustainable Model to Expedite Market Expansion?
Michael Hoffman, DrSc
Head of Clinical Scientific Writing, Shire Pharmaceuticals

#364 Track 04B - Medical Affairs and Scientific Communication

Featured Topic(s): Translational Science and Medicine

2:00–3:15PM Level: ■ Format: SESSION

Room: 210C *CME, Pharmacy, and Nursing*

Achieving Customer Centricity to Advance Patient Care Through Innovative Communication Channels

CHAIRPERSON

Debra Bello, PhD, RN

Director, HCV& Virology, Global Medical Information, AbbVie, Inc.

SPEAKER(S)

Evolution of Medical Information Response Delivery Channels
Philippe Sorel Takam, PharmD, MSc, RPh
Global Medical Information Manager, Primevigilance Ltd, United Kingdom

Medical Information Journey to Health Literate Style of Writing
Cheryl Hanson, PharmD
Senior Medical Information Manager, AbbVie, Inc.

#365 Track 05 - Patient Engagement

Featured Topic(s): Rare Diseases

2:00–3:15PM Level: ● Format: SESSION

Room: 151AB *CME, Pharmacy, and Nursing*

Engaging the Rare Disease Community to Design Clinical Trials

CHAIRPERSON

Scott Schliebner, MPH

Senior Vice President, Center for Rare Diseases, PRA Health Sciences

SPEAKER(S)

Nothing About Us, Without Us: Best Practices for Engaging with the Rare Disease Patient Community
Scott Schliebner, MPH
Senior Vice President, Center for Rare Diseases, PRA Health Sciences

Enrollment: Using Patient Advocacy Groups to Design a Better Trial, Find Participants, and Manage Studies in Rare Diseases
Bruce Wynne, PharmD
Director, Clinical Operations Lead, CSL Behring

Early Engagement with the Kabuki Syndrome Community to Design a Clinical Development Plan
Deborah Hartman, PhD
Vice President, Global Program Leader, Takeda Pharmaceuticals International, Inc.

#366 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Translational Science and Medicine

2:00–3:15PM Level: ● Format: SESSION

Room: 156ABC *CME, Pharmacy, and Nursing*

Gene Therapy Clinical Trials: Current Challenges

CHAIRPERSON

Kirsten Messmer, PhD, RAC

Principal Regulatory Affairs Specialist, PPD

SPEAKER(S)

Successfully Operationalizing Gene Therapy Clinical Trials
Venkata Jaggumantri
Clinical Scientist, PRA Health Sciences, Canada

Update on Gene Therapy Trials
Janet C. Rae
Vice President, Global Head, Gene Therapy Regulatory Affairs, Ultragenix

#367 Track 07A - Project Management and Strategic Planning

2:00–3:15PM Level: ● Format: WORKSHOP
Room: 252AB *CME, Pharmacy, Nursing, and PMI PDUs*

Real Life Strategies for Collaborative Stakeholder Management

CHAIRPERSON

M. Christine Morris, MBA
Executive Director, Strategy and Operations, Transperfect Life Sciences Solutions

FACILITATORS

Marina Acosta Enslen
Clinical Team Manager, PPD

Lydia Sbityakov
Playwright, Cary Playwrights' Forum

#368 Track 07B - Project Management and Strategic Planning

Featured Topic(s): Generics, Regulatory Agency Presenters

2:00–3:15PM Level: ■ Format: FORUM
Room: 153ABC *CME, Pharmacy, Nursing, and PMI PDUs*

Predicting Future Generic Drug Competition: Powering Strategic Planning Using Quantitative Methods and Modeling

CHAIRPERSON

Liang Zhao, PhD
Director, Office of Regulatory Science, Division of Quantitative Methods and Modeling, Office of Generic Drugs, CDER, FDA

SPEAKER(S)

Path to Bioequivalence
Charles DiLiberti, MS
President, Montclair Bioequivalence Services, LLC

FDA Perspective
Meng Hu, PhD
Scientist, Division of Quantitative Methods and Modeling, Office of Regulatory Science, Office of Generic Drugs, CDER, FDA

Industry Perspective
Nicholas Cappuccino, PhD, MBA
Vice President, Quality and Scientific Affairs, Dr. Reddy's Laboratories

#369 Track 08 - R&D Quality and Compliance

Featured Topic(s): Regulatory Agency Presenters

2:00–3:15PM Level: ■ Format: SESSION
Room: 257AB *CME, Pharmacy, and Nursing*

Virtual Audits: Do They Achieve the Objective?

CHAIRPERSON

Sarah Ann Silvers, MS
Director, GCP Process Control and Compliance, Ce3

SPEAKER(S)

Industry Perspective
Sophie Moya
Quality Assurance Manager, Development, Medical, and Regulatory Affairs, Guerbet, France

Kara Harrison, MS, RAC
Project Manager, FDA Quality and Regulatory Consultants LLC

Paul E. Houri, MBA, MS
Vice President, Quality Assurance, Janssen Pharmaceutical Companies of Johnson & Johnson

#370 Track 09 - Regulatory

Featured Topic(s): Rare Diseases

2:00–3:15PM Level: ■ Format: FORUM
Room: 204AB *CME, Pharmacy, and Nursing*

Clinical Outcome Assessments (COA) Endpoints for Use in Rare and Ultra-Rare Disease Clinical Trials

CHAIRPERSON

Andrew E. Mulberg, MD
Vice President, Global Regulatory Affairs, Amicus Therapeutics

PANELISTS

Ebony N. Dashiell-Aje, PhD
Clinical Outcome Assessments Reviewer, COA Staff, Office of New Drugs, CDER, FDA

Chad Gwaltney, PhD
President, Gwaltney Consulting

Kate Delaney
Director, Regulatory Patient Engagement and Outcomes Research, BioMarin Pharmaceutical Inc.

#371 Track 09A - Regulatory

Featured Topic(s): ExUS Regulatory

2:00–3:15PM Level: ■ Format: FORUM
Room: 205C *CME, Pharmacy, and Nursing*

What's New in Health Canada: Updates and New Endeavors

CHAIRPERSON

Agnes V. Klein, MD
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

SPEAKER(S)

Improving Access to Necessary Therapeutic Products in Canada
Michèle Chadwick, MBA
Lead, Regulatory Review of Drugs and Devices, HPFB, Health Canada

Updates on Biosimilars
Agnes V. Klein, MD
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

Regulator Perspective on the Opioid Crisis
Marilena Bassi, MA
Director of the Bureau of Policy, Health Canada

#372 Track 09B - Regulatory

2:00–3:00PM | Level: ■ | Format: SESSION
Room: 206AB | *CME, Pharmacy, and Nursing*

AdPromo: Assessing Risk in the Current Regulatory Environment

CHAIRPERSON

Mark Gaydos
Vice President, NA General Medicines/US Advertising and Promotion, Global Regulatory Affairs, Sanofi

PANELISTS

Coleen Klasmeier, JD
Partner and Global Coordinator, Food, Drug and Medical Device Regulatory Practice, Sidley Austin, LLP

Alan G. Minsk, JD
Partner, Head of Food and Drug Team, Arnall Golden Gregory LLP

#373 Track 09C - Regulatory

Featured Topic(s): ExUS Regulatory

2:00–3:15PM | Level: ■ | Format: FORUM
Room: 205AB | *CME, Pharmacy, and Nursing*

PMDA Town Hall

CHAIRPERSON

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

SPEAKER(S)

Recent Regulatory Topics and International Cooperation of MHLW
Kazuhiko Mori, MSc
Councilor for Pharmaceutical Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW), Japan

PMDA's Regulatory Science and Innovation
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Real-World Data Utilization: A New Approach to Pharmacovigilance
Shinobu Uzu, MSc
Associate Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#374 Track 10 - Regulatory CMC and Product Quality

2:00–3:15PM | Level: ● | Format: SESSION
Room: 208 | *CME, Pharmacy, and Nursing*

Modernization and Harmonization of Inspectional Approaches

CHAIRPERSON

Stephen Mahoney, JD, MS
Senior Director, Compliance and External Collaboration, Pharma Technical Quality, Genentech, A Member of the Roche Group

SPEAKER(S)

Moving Beyond Compliance
Vivianne Arencibia
Global Vice President, Head External Relations, Novartis Pharmaceuticals Corporation

Reforming FDA's Enforcement Process
Howard Sklamberg, JD, MA
Partner, Health Group, Akin Gump Strauss Hauer & Feld LLP

International Inspections Issues and Successful Remediation
Thomas J. Cosgrove, JD
Partner, Covington & Burling LLP

#375 Track 11 - Statistics

Featured Topic(s): Biomarkers - Diagnostics, Regulatory Agency Presenters, Translational Science and Medicine

2:00–3:15PM | Level: ■ | Format: SESSION
Room: 256 | *CME, Pharmacy, and Nursing*

Statistical Challenges in Assessing Drugs' Efficacy by Utilizing Biomarker Endpoints

CHAIRPERSON

Min Min, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

SPEAKER(S)

Individualized Treatment Recommendation Through Machine Learning Algorithms
Haoda Fu
Senior Research Scientist, Eli Lilly and Company

Validation of Biomarkers as a Surrogate for Clinical Endpoints: The Global PBC Experience
Bettina Hansen
Associate Professor, Senior Biostatistician, Institute of Health Policy, Management and Evaluation (IHPME), University of Toronto, Canada

Assessment of Concordance Between BNiomarkers and Clinical Outcomes Response to Drug Interventions
Aloka Chakravarty, PhD
Acting Director, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

#376 Track 18 - Professional Development

2:00–3:15PM Level: ● Format: WORKSHOP
Room: 254AB

Courageous Hiring

CHAIRPERSON
Vicky Martin
Senior Director, US Business Development, IDDI

FACILITATOR
Chris Matheus, MBA
President, Matheus BD Connections

#377 Track 16 - Content Hubs

2:15–2:45PM Level: ■ Format: SESSION
Room: Content Hub | NE Lobby *IACET*

First-in-Human Studies: An Examination of the Evolving Regulatory and Clinical Practices to Ensure Subject Safety

CHAIRPERSON
Beatrice Setnik, PhD
Vice President, Clinical Pharmacology, Early Phase, Syneos Health

3:00–4:00PM

Refreshment Break
Exhibit Hall

#378 Track 17A - Community Rounds

3:00–4:00PM Format: FORUM
Room: Community Zone | NE Lobby

DIA Devices and Diagnostics Community Round Table Discussion: What Can We Say About Combination Products? Labeling, Advertising, and Promotion of Combination Products

CHAIRPERSON
Kerri-Anne Mallet, MBA
Vice President, Clinical and Regulatory Affairs, Pharmatech Associates, Inc.

#379 Track 17B - Community Rounds

3:00–4:00PM Format: FORUM
Room: Community Zone | NE Lobby

DIA Clinical Trial Disclosure and DIA Medical Communication Communities' Round Table Discussion: Clinical Trial Disclosure: Learnings from EMA Policy 0070, NIH Final Rule, and FDA's Clinical Data Summary Pilot Program

CHAIRPERSON
Robert Paarlberg, MS
Principal, Paarlberg & Associates LLC

#380 Track 15 - Engage and Exchange

3:15–4:00PM Level: ■ Format: WORKSHOP
Room: E and E | Exhibit Hall

Use of New Data Sources and Evidence Types for Regulatory Decision-Making in Drug Development

CHAIRPERSON
Eamon O'Loinsigh, PhD
Vice President, Regulatory Strategy and Policy, Synchrogenix, United Kingdom

#381 Track 16 - Content Hubs

3:30–4:00PM Level: ■ Format: SESSION
Room: Content Hub | NE Lobby *IACET*

Project Management's Role in Developing and Securing Governance Approval of a Drug Development Program Strategy

CHAIRPERSON
Nathan R. Kreischer, MS, PMP
Associate Director, Global Project and Alliance Management, Merck & Co., Inc.

#382 Track 01A - Clinical Safety and Pharmacovigilance

4:00–5:15PM Level: ■ Format: FORUM
Room: 253AB *CME, Pharmacy, and Nursing*

Artificial Intelligence: A Disruptive Journey for Pharmacovigilance

CHAIRPERSON
Annette S. Williams, MBA, RPh
Vice President, Lifecycle Safety, IQVIA

SPEAKER(S)

Training Artificial Intelligent System for Pharmacovigilance: Practical Considerations and Guidance
Cartic Ramakrishnan, PhD
Senior Technical Staff Member, Lead Cognitive Scientist, Life Sciences, IBM Watson Health

The Future of Pharmacovigilance After Full Industry Disruption from Cognitive Automation
Glenn Carroll, MBA
Principal, Strategy and Operations, Life Sciences, Deloitte Consulting

Our Journey Toward Touchless Case Management
Caroline Rosewell, MBA
Senior Director, Global Patient Safety, Clinical Case Management, Eli Lilly and Company

Round Table: This discussion will continue at 8:00AM on Thursday, June 28 in the DIA Community Zone, NE Lobby, Level 1

#383 Track 01C - Clinical Safety and Pharmacovigilance

4:00–5:15PM Level: ■ Format: SESSION
Room: 253C *CME, Pharmacy, and Nursing*

Safe Use and Prescribing of Opioid Medications: An In-Depth Look at the Strategies and Their Evaluation

CHAIRPERSON
Sydney H. Schnoll, MD, PhD
Vice President, Pharmaceutical Risk Management, Pinney Associates, Inc

SPEAKER(S)

Safe Use of Opioids: FDA Perspective
Judy Anne Staffa, PhD, RPh
Associate Director for Public Health Initiatives, Office of Surveillance and Epidemiology, CDER, FDA

Opiates: A Patient Experience
Alton Johnson, PhD, RPh
Vice President, Global Technology Services, Pfizer Inc

Clinician/Drug Development Perspective
Veeraindar Goli
Senior Director, CNS Center of Excellence, IQVIA

Prescribing Opioid Medicines for Patients
Daniel Alford, MD, MPH, FACP
Professor of Medicine, Director, Clinical Addiction Research and Education (CARE), Boston University School of Medicine, Boston Medical Center

#384 Track 02A - Clinical Trials and Clinical Operations

Featured Topic(s): Translational Science and Medicine

4:00–5:15PM | Level: ■ | Format: FORUM
Room: 258AB | *CME, Pharmacy, and Nursing*

Innovations in Managing Global Clinical Supplies

CHAIRPERSON
Mark Wade
Executive Director, Transperfect

SPEAKER(S)

Uncorking the Bottleneck in Labeling for Investigational Medicinal Products in Multicultural Clinical Trials
Mark Wade
Executive Director, Transperfect

The Near-Term Viability and Benefits of eLabels for Clinical, Sites, and Patients
Hans Von Steiger
Director/Team Leader, Clinical Strategy and Management, Pfizer Inc

The Future of Randomization and Trial Supply Management
Jennifer Bush, MS
Director, Life Sciences Product Strategy, Oracle

#385 Track 02B - Clinical Trials and Clinical Operations

Featured Topic(s): Outsourcing, Translational Science and Medicine

4:00–5:15PM | Level: ◆ | Format: SESSION
Room: 258C | *CME, Pharmacy, and Nursing*

Does Sourcing Strategy Matter? Executives Debate the Influence of Outsourcing Model on Clinical Trial Execution

CHAIRPERSON
Mitchell A. Katz, PhD
Head of Clinical Research and Drug Safety Operations, Purdue Pharma L.P.

PANELISTS

David M. Johnston, PhD
Executive Vice President, Clinical Development, PPD

John J. Oidtman
Senior Vice President, Head of Global Clinical Operations, EMD Serono, Inc.

Jeremy G. Chadwick, PhD, MSc
Group Vice President, Clinical Development Operations, Shire

#386 Track 02C - Clinical Trials and Clinical Operations

Featured Topic(s): Mobile Technology, Translational Science and Medicine

4:00–5:15PM | Level: ■ | Format: SESSION
Room: 257AB | *CME, Pharmacy, and Nursing*

Bring Your Own Device ePRO: Hold the Relish, or No Holds Barred?

CHAIRPERSON
Bill Byrom, PhD
Vice President, Product Strategy and Innovation, CRF Health, United Kingdom

SPEAKER(S)

Migrating to Electronic Formats: Lessons Learned from a Meta-Synthesis of Cognitive Interview Studies
Willie Muehlhausen, DVM
Head of Innovation, ICON Clinical Research, Ireland

PRO Measurement Properties Using BYOD: Conclusions from a Formal Quantitative Equivalence Study
Bill Byrom, PhD
Vice President, Product Strategy and Innovation, CRF Health, United Kingdom

A Regulatory Perspective on BYOD
Sarrit Kovacs, PhD
Clinical Outcome Assessments (COA) Staff, Office of New Drugs, CDER, FDA

#387 Track 03 - Data and Data Standards

4:00–5:15PM | Level: ■ | Format: SESSION
Room: 208 | *CME, Pharmacy, and Nursing*

Evolving CDISC Standards and Technologies

CHAIRPERSON
Rhonda Facile, MS
Vice President, Standards and Development, CDISC

SPEAKER(S)

CDASH and SDTM: Why You Need Both
Kit Howard, MS
Director of Education, CDISC

SHARE Metadata Repository
Lauren Becnel
Vice President, Strategy and Innovation, CDISC

#388 Track 04 - Medical Affairs and Scientific Communication

Featured Topic(s): Real World Evidence

4:00–5:15pm Level: ■ Format: SESSION
Room: 210C *CME, Pharmacy, and Nursing*

Using Patient-Centric Outcomes to Engage Patients in Shared Treatment Decision-Making

CHAIRPERSON

Sara Doshi, PharmD
Director, Medical Information Strategy and Capabilities, GMI, Eli Lilly and Company

SPEAKER(S)

How Can Patient-Reported Data Inform Shared Treatment Decision-Making?
Emily Freeman, PhD, MSc
Director, Patient Centered Outcomes, AbbVie, Inc.

Generating Patient-Reported Outcomes Evidence to Provide Meaningful Insights for Treatment Decision-Making
Agnes Hong, PharmD
Associate Outcomes Research Scientist, Oncology, Genentech, A Member of the Roche Group

Bringing Patient-Centric Outcomes to Customers
Linda Wang, PharmD
Medical Communications Leader, Genentech, A Member of the Roche Group

#389 Track 05A - Patient Engagement

4:00–5:15pm Level: ■ Format: FORUM
Room: 151AB *CME, Pharmacy, and Nursing*

Patient Observation Versus Patient Engagement: Optimizing Development

CHAIRPERSON

Nadina Jose, MD
Assistant Professor, Clinical Trial Sciences, BioPharma Educational Initiative, Rutgers, The State University of New Jersey

SPEAKER(S)

Processes to Develop a Comprehensive Patient Engagement Program
Ellen Coleman, MPH, MS
Senior Vice President, MK&A

#390 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Pediatrics, Translational Science and Medicine

4:00–5:15pm Level: ■ Format: SESSION
Room: 156ABC *CME, Pharmacy, and Nursing*

Special Population Study Challenges

CHAIRPERSON

William B. Smith, MD
Chief Executive Officer, Alliance for Multispecialty Research/NOCCR

SPEAKER(S)

Critical Challenges in Conducting PK Studies in Patients and Special Populations
Charu Gautam, MD
Head-Early Clinical Development, Asia Pacific, IQVIA, India

Special Population Studies: Thirty Years Experience Shared
Harry Alcorn, PharmD
Chief Scientific Officer, DaVita Clinical Research

#391 Track 07A - Project Management and Strategic Planning

Featured Topic(s): Outsourcing

4:00–5:15pm Level: ■ Format: SESSION
Room: 209 *CME, Nursing, and PMI PDUs*

How to De-Risk Alliances for Success

CHAIRPERSON

Candice Hughes, PhD, MBA
Chief Executive Officer and Founder, Hughes BioPharma Advisers LLC

SPEAKER(S)

De-Risking Alliances, The Sponsor Perspective: Transforming Expectations and Implementing Innovations for Joint Oversight
Jessica Dero, PMP
Vendor Strategy, Janssen Pharmaceutical Companies of Johnson & Johnson

The Vendor Perspective on De-Risking Partnerships for Shared Success
Candice Hughes, PhD, MBA
Chief Executive Officer and Founder, Hughes BioPharma Advisers LLC

Sponsor Perspective
Alison Schecter, MD, FACC
Global Project Head, Rare Disease, Sanofi-Genzyme

#392 Track 07B - Project Management and Strategic Planning

Featured Topic(s): Career Development

4:00–5:15pm Level: ● Format: SESSION
Room: 153ABC *CME, Pharmacy, Nursing, and PMI PDUs*

FUNdamentals of Project Management

CHAIRPERSON

Shann Williams, PMP
Senior Director, Operations, Rho, Inc.

SPEAKER(S)

Can a Trial be Agile? Exploring Agile Methodology for Clinical Project Management
Shann Williams, PMP
Senior Director, Operations, Rho, Inc.

Critical Chain Project Management: Running the Relay Race to Project Success
Matthew Steven Curin, PharmD
Director, Project and Process Excellence, Astellas Pharma US, Inc.

#393 Track 08 - R&D Quality and Compliance

Featured Topic(s): Regulatory Agency Presenters, ExUS Regulatory

4:00–5:15PM Level: ■ Format: WORKSHOP

Room: 252AB *CME, Pharmacy, and Nursing*

Think Like a Regulator: Evaluating Trial Integrity

CHAIRPERSON

Ann Meeker-O'Connell, MS
Vice President, Global Head, Quality Assurance, IQVIA

FACILITATORS

Hitoshi Ozawa
GCP Inspector, Office of Non-Clininical and Clinical Compliance, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Jean M. Mulinde, MD
Senior Policy Advisor, Office of Scientific Investigations, Office of Compliance, CDER, FDA

Anabela Marcal, PharmD
Head of Compliance and Inspections Department, European Medicines Agency (EMA), European Union

#394 Track 09A - Regulatory

Featured Topic(s): ExUS Regulatory

4:00–5:00PM Level: ■ Format: FORUM

Room: 205AB

Update on BREXIT

CHAIRPERSON

Agnès Saint-Raymond
Head of International Affairs, Head of Portfolio Board, European Medicines Agency (EMA), European Union

SPEAKER(S)

Marie-Helene Pinheiro, PharmD
Industry Stakeholder Liaison, Corporate Stakeholders Division, European Medicines Agency (EMA), European Union

#395 Track 09B - Regulatory

Featured Topic(s): Regulatory Agency Presenters

4:00–5:15PM Level: ■ Format: SESSION

Room: 205C *CME, Pharmacy, and Nursing*

PDUFA VI: Improving Transparency and Accountability of Electronic Submission and Data Standards Activities

CHAIRPERSON

Ron D. Fitzmartin, DIAFellow, PhD, MBA
Senior Advisor, Office of Strategic Programs, CDER, FDA

SPEAKER(S)

FDA Update
Virginia Hussong
Chief, Data Standards Program, CBER, FDA

Ethan Chen, MBA
Director, Division of Data Management Services and Solutions, Office of Business Informatics, Office of Strategic Programs, CDER, FDA

#396 Track 10 - Regulatory CMC and Product Quality

Featured Topic(s): ExUS Regulatory

4:00–5:15PM Level: ■ Format: WORKSHOP

Room: 254AB *CME, Pharmacy, and Nursing*

Current and Future Perspective on Mutual Recognition, Work Sharing, and Global Regulatory Convergence

CHAIRPERSON

Terrance Ocheltree, PhD, RPh
Chief Executive Officer and Executive Director, Regulatory CMC, Pharmtree Consultants, LLC

FACILITATOR

Industry Perspective
Mic McGoldrick, MT
Associate Director Regulatory Policy and Compendial Affairs, Merck Sharp & Dohme Corp.

EMA Perspective
Tânia Teixeira
FDA Liaison Official, European Medicines Agency (EMA), European Union

#397 Track 11 - Statistics

Featured Topic(s): Real World Evidence, Translational Science and Medicine

4:00–5:15PM Level: ■ Format: SESSION

Room: 256 *CME, Pharmacy, and Nursing*

Design and Statistical Considerations for Real World Evidence to Support Regulatory Decision-Making

CHAIRPERSON

Ankit Pahwa, MS
Manager, Biostatistics, BioClinica, India

SPEAKER(S)

Real World Evidence in Regulatory Decision-Making
Ankit Pahwa, MS
Manager, Biostatistics, BioClinica, India

Design and Statistical Considerations in Real World Evidence
Jennifer Hsiang-Ling Lin, PhD
Associate Director, RWE Design and Analytics, Janssen Pharmaceuticals

Pragmatic Clinical Trials: The Future is Now
David Thompson, PhD
Senior Vice President, Real World and Late Phase Research, Syneos Health

#398 Track 12 - Value and Access

Featured Topic(s): Gene Therapy

4:00–5:00PM Level: ■ Format: FORUM

Room: 204AB *CME, Pharmacy, and Nursing*

The Impact of Cell and Gene Therapy on the Payer System

CHAIRPERSON

Marianne Hamilton Lopez, PhD, MPA
Research Director, Value-Based Payment Reform, Duke-Margolis Center For Health Policy

SPEAKER(S)

Cell and Gene Therapy Development and the Impact on the Payer System
Dan Tierno, MA, MBA
Strategic Implementation Manager, Bayer

NOTES

NOTES

THURSDAY, JUNE 28

Registration Hours

7:00AM–11:00AM Attendee and Speaker Registration

8:00–9:00AM

Coffee and Light Refreshments
North Lobby | Level 1

#401 Track 17A - Community Rounds

8:00–9:00AM Format: FORUM
Room: Community Zone | NE Lobby

DIA Clinical Safety and Pharmacovigilance Community Round Table Discussion: Risk Management: Artificial Intelligence: A Disruptive Journey for Pharmacovigilance

CHAIRPERSON
Catherine Baldridge, MS
Clinical Safety and Pharmacovigilance, PV Compliance, Indivior

#402 Track 17B - Community Rounds

8:00–9:00AM Format: FORUM
Room: Community Zone | NE Lobby

DIA Patient Engagement Community Round Table Discussion: Addressing the Elephant in the Room: A Hard Look at Metrics, Legal, Payers, and Other Leading Obstacles Facing the Sustainability of Patient Engagement

CHAIRPERSON
Mary Stober Murray, MBA
Associate Director, Diversity and Patient Engagement, Bristol-Myers Squibb

#403 Track 16 - Content Hubs

8:30–9:00AM Level: ● Format: SESSION
Room: Content Hub | NE Lobby *IACET*

General Data Protection Regulation (GDPR): Impact, Self-Assessment, and Practical Solutions for Compliance

CHAIRPERSON
Anu Virkar, MA, MS
Vice President, Quality and Compliance, eClinical, Merge eClinical, An IBM Watson Health

#404 Track 01 - Clinical Safety and Pharmacovigilance

Featured Topic(s): Real World Evidence, Biosimilars

9:00–10:15AM Level: ● Format: FORUM
Room: 204AB *CME, Pharmacy, and Nursing*

Payers, Industry, and Academia Collaborating on Post-Marketing Surveillance

CHAIRPERSON
Charles E. Barr, MD, MPH
Chief Science Officer, BBCIC, AMCP BBCIC, LLC

SPEAKER(S)

Payer Contributions to Biosimilar Safety Surveillance
Mark J. Cziraky, PharmD
Vice President of Research, Anthem HealthCore

Pharmaceutical Industry Experience with Biosimilar Post-Marketing Safety
Hillel Cohen, PhD
Executive Director, Scientific Affairs, Sandoz Inc.

Research Challenges in Biosimilar Safety and Surveillance
Nancy Lin, DrSc, MS
Senior Scientist, Epidemiology, Optum

#405 Track 02 - Clinical Trials and Clinical Operations

9:00–10:15AM Level: ● Format: SESSION
Room: 205AB *CME, Pharmacy, and Nursing*

Putting Patient Experience First

CHAIRPERSON
Michele Skibsted
Director, Client Relations, CRF Health

SPEAKER(S)

Revolutionizing Trial Information Exchange: Improving Recruitment and Retention by Satisfying Patients' Communications Needs
Paulo Moreira
Vice President, Global Clinical Operations, Head of External Innovation, EMD Serono, Inc.

Supporting Patients Decision to Enroll in a Clinical Study: Lessons Learned
Juliane Mills, MPH, MS
Director, Scientific Affairs, Real World Solutions, PRA Health Sciences

Diabetes: It's a Beach and the Three Waves that Have Hit It
Robert Sala
Senior Clinical Science Liaison, Dexcom

#406 Track 03 - Data and Data Standards

Featured Topic(s): Pediatrics, Rare Diseases

9:00–10:15AM Level: ◆ Format: SESSION
Room: 205C *CME, Pharmacy, and Nursing*

Improving Efficiency and Effectiveness in Data Management of Pediatric, Rare Disease, and Oncology Trials

CHAIRPERSON
Joby John
Senior Director, eHealth Operations, BioClinica

SPEAKER(S)

Improving Efficiency and Effectiveness in Data Management of Oncology Studies
Vijayalakshmi Angaiyan, MS
Principal Clinical Data Manager, Syneos Health

Conducting Pediatric Clinical Trials: Challenges and Rewards for Clinical Data Management
Joseph Anderson
Senior Director, Clinical Data Management, Paidion Research, Inc.

Technology in Data Management of Pediatric, Rare Disease, and Oncology Trials
Joby John
Senior Director, eHealth Operations, BioClinica

#407 Track 05 - Patient Engagement

Featured Topic(s): Pediatrics

9:00–10:15AM Level: ■ Format: SESSION
Room: 209 *CME, Pharmacy, and Nursing*

Beyond Adult Patients, Untapped Advisors in Clinical Development: Adolescents, Parents, Siblings, and Spouses

CHAIRPERSON
Jennifer Helfer, PhD, MA
Patient Advocacy, bluebird bio, Inc.

SPEAKER(S)

2017–2018 National Rare Diseases Caregiver Survey Findings
C. Grace Whiting, JD
President and Chief Executive Officer, National Alliance for Caregiving

Establishing a European Network of Young Persons Advisory Groups to Increase the Involvement in Pediatric Clinical Research
Begonya Nafria Escalera, MEd
Patient Advocacy - Coordinator, Fundacio Sant Joan De Déu, Spain

What's Love Got to do with It? Illuminating the Caregiver Treatment Journey
Ann M. Moravick
President, Rx4good

#408 Track 06 - Preclinical Development and Early-Phase Clinical Research

Featured Topic(s): Translational Science and Medicine

9:00–10:00AM Level: ■ Format: FORUM
Room: 206AB *CME, and Nursing*

Innovative Funding Models for Novel Therapeutics

CHAIRPERSON
Dan Tierno, MA, MBA
Strategic Implementation Manager, Bayer

SPEAKER(S)

The Responsibility Industry, Agencies, and Early Education Own in Cure-Model Based Therapeutics
Dan Tierno, MA, MBA
Strategic Implementation Manager, Bayer

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)

#409 Track 07 - Project Management and Strategic Planning

9:00–10:15AM Level: ■ Format: SESSION
Room: 256 *CME, Pharmacy, Nursing, and PMI PDUs*

Emerging Best Practices and Challenges in Strategic Drug Development and Design Decision-Making

CHAIRPERSON
Cara Willoughby, MS
Principal Scientific Advisor, IQVIA

SPEAKER(S)

Lessons Learned Translating Data to Meaningful Design Insights
Cara Willoughby, MS
Principal Scientific Advisor, IQVIA

Leveraging Big Data to Help Design Clinical Program Strategies
Kyle Holen, MD
Head, Development Design Center, AbbVie, Inc.

Patient Engagement Strategies in Design
Florian Bieber, MD
Global Head, Clinical Development and Analytics, Novartis Pharma AG, Switzerland

#410 Track 08 - R&D Quality and Compliance

9:00–10:15AM Level: ■ Format: WORKSHOP
Room: 252AB *CME, and Nursing*

Assessing Your Clinical Quality Management System: An In-Depth Look at TransCelerate's Assessment Tool

CHAIRPERSON
Janis A. Little, MS
Vice President, Global R&D Quality, Allergan Inc

SPEAKER(S)

Overview of TransCelerate Clinical Quality Management System Framework Tools
Janis A. Little, MS
Vice President, Global R&D Quality, Allergan Inc

Assessing the Clinical Quality Management System: An In-Depth Look at TransCelerate's Assessment Tool
Michael Husovich
Director, Global R&D Quality, Amgen Inc.

#411 Track 09A - Regulatory

Featured Topic(s): Translational Science and Medicine

9:00–10:15AM Level: ■ Format: FORUM
Room: 253C *CME, Pharmacy, and Nursing*

Regulatory and Industry Perspectives on the Common Protocol Template

CHAIRPERSON
Robert A. DiCicco, PharmD
Executive Consultant, TransCelerate Biopharma Inc.

SPEAKER(S)

Industry Perspective
Kenneth A. Getz, DIAFellow, MBA
Director of Sponsored Research Programs and Associate Professor, Center For the Study of Drug Development, Tufts University School of Medicine

FDA Perspective
Vaishall Popat, MD
Associate Director of Biomedical Informatics and Regulatory Review Science, CDER, FDA

#412 Track 09B - Regulatory

Featured Topic(s): Generics, Regulatory Agency Presenters

9:00–10:15AM | Level: ● | Format: SESSION
Room: 257AB | *CME, Pharmacy, and Nursing*

Metrics and Meaning: Evolving Metrics in Generic Drug Application Review and Communications to Improve ANDA Submission Planning and Approvability

CHAIRPERSON

Jason Woo, MD, MPH
Senior Medical Officer, Office of Generic Drugs, CDER, FDA

SPEAKER(S)

FDA Update
Rong (Gloria) Fu, PhD
Visiting Scientist, Office of Biostatistics and Epidemiology, CBER, FDA

Abbreviated New Drug Application (ANDA) First Cycle Approvability: A GDUFA I Preliminary Report
Jingyu (Julia) Luan, PhD
Deputy Division Director (Acting), Office of Biostatistics, Office of Translational Sciences, CDER, FDA

FDA Update
Geoffrey Wu, PhD
Associate Director, OLDP, Office of Pharmaceutical Quality, CDER, FDA

#413 Track 11 - Statistics

Featured Topic(s): Rare Diseases, Translational Science and Medicine

9:00–10:15AM | Level: ■ | Format: WORKSHOP
Room: 254AB | *CME, Pharmacy, and Nursing*

The Correlation Between Patient-Reported Outcomes and Clinician-Reported Outcomes

CHAIRPERSON

Eric Gemmen, MA
Senior Director, Epidemiology and Outcomes Research, IQVIA

#414 Track 12 - Value and Access

9:00–10:30AM | Level: ■ | Format: SESSION
Room: 208 | *CME, Pharmacy, and Nursing*

Unmet Medical Need: What Did We Create Together and Where to Take It?

CHAIRPERSON

Inkatuuli Heikkinen, MS
Senior Scientist, DIA, Switzerland

SPEAKER(S)

Wrap-Up
Lawrence Eugene Liberti, PhD, RPh, RAC
Executive Director, Centre for Innovation in Regulatory Science (CIRS)

#415 Track 13 DIAmond SESSIONS

9:00–10:30AM | Level: ■ | Format: FORUM
Room: 210AB | *CME, Pharmacy, and Nursing*

EMA/FDA Question Time

CHAIRPERSONS

Tânia Teixeira
FDA Liaison Official, European Medicines Agency (EMA), European Union

Sandra L. Kweder, MD
Deputy Director, Liaison to the EMA, Office of International Programs, Office of the Commissioner, FDA

SPEAKER(S)

Challenges in Product Quality in Expedited Development Programs
Giuseppe Randazzo
Director, Office of Program and Regulatory Operations, Office of Pharmaceutical Quality, CDER, FDA

Peter Richardson, PhD
Head of Quality, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), European Union

Issues in Data Transparency
Ann M. Witt, JD
Counselor to DC for Policy, Office of New Drugs, CDER, FDA

Anne-Sophie Henry-Eude, PharmD
Head of Documents Access and Publication Service, European Medicines Agency (EMA), European Union

Pediatrics
Lynne P. Yao, MD
Director, Division of Pediatric and Maternal Health, Office of New Drugs, CDER, FDA

Agnès Saint-Raymond, MD
Head of International Affairs, Head of Portfolio Board, European Medicines Agency (EMA), European Union

Tackling Challenges in Rare Disease Treatments
Lucas Kempf, MD
Acting Associate Director, Rare Diseases Program, Office of New Drugs, CDER, FDA

Kristina Larsson, MS
Head of Office for Orphan Medicines, European Medicines Agency (EMA), European Union

10:30–10:45AM

Coffee Break

North Lobby | Level 1

#416 Track 13

DIAmond SESSIONS

10:45AM–12:00PM | Level: ■ | Format: FORUM

Room: 210AB

CME, Pharmacy, and Nursing

FDA Town Hall

CHAIRPERSON

Sudip Parikh, PhD
Senior Vice President and Managing Director, DIA Americas

PANELISTS

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA

Peter W. Marks, MD, PhD
Director, Center for Biologics Evaluation and Research, FDA

Tamy Kim, PharmD
Associate Director for Regulatory Affairs, OHOP and OCE, FDA

Student Poster Session

Monday, June 25 | 10:00AM–6:00PM | Posters will be displayed in the 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 during the Community Luncheon on Tuesday, June 26 from 12:00–1:30PM in the Ballroom Lobby.

Track 1 Clinical Safety and Pharmacovigilance

M-01 Impact on the Cost and Safety of Generic Sildenafil Citrate in the USA
Alexander Agyei Marfo
Touro College of Pharmacy
ORAL PRESENTATION: 10:20AM

M-02 Comparative Study of Efficacy and Safety of Metformin with Metformin and Sitagliptin in Type 2 Diabetic Patients in Hospital
WITHDRAWN

M-03 Assessment of the United States REMS Program Requirements for NDAs and BLAs
Nina Alexandria Johnson
Western New England University College of Pharmacy
ORAL PRESENTATION: 1:05PM

Track 2 Clinical Trials and Clinical Operations

M-04 Exploring and Addressing Gaps in GCP Training: Practical Approaches to Monitoring
Annie Xie
University of Southern California
ORAL PRESENTATION: 10:30AM

M-05 Effect of Transplant Status in CD19-Targeted CAR T-Cell Therapy: A Systematic Review and Meta-Analysis
Kathleen Mary Nagle, MS
Rutgers University
ORAL PRESENTATION: 1:15PM

M-06 Drug-Eluting Bead (DEB) Versus Conventional Transarterial Chemoembolization for Intermediate Stage Hepatobiliary Malignancies
Henrietta Ofuluozor
Touro College of Pharmacy NY
ORAL PRESENTATION: 2:25PM

Track 4 Project Management and Strategic Planning

M-07 Impact of Sofosbuvir/Velpatasvir/Voxilaprevir Intervention on Recent Remission Rates of Direct Acting Antivirals
Ryan Wolfe
Touro College of Pharmacy

M-08 Utilization, Assessment, and Return-on-Investment of Drug Information (DI) Websites in the US Pharmaceutical Industry
Christian Vogt
Hudson University
ORAL PRESENTATION: 10:40AM

Track 5 Patient Engagement

M-09 The Impact of Direct-to-Consumer Advertisements on Patient Decision-Making in an Urban Environment
Noreen Hussain
Touro College of Pharmacy
ORAL PRESENTATION: 1:25PM

M-10 Pharmacogenomics in Opioid Use Disorder Managment
Casey Walker
Howard University College of Pharmacy
ORAL PRESENTATION: 2:35PM

M-11 Contemporary Trends and Issues in Medication Non-Adherence: A Systematic Review
Enav Zusman
University of British Columbia, Canada
ORAL PRESENTATION: 10:50AM

M-12 Completing Patient-Reported Outcome Measures Electronically: A Review of the Literature on Subject Burden in Clinical Trials
Shannon Vaffis, MPH, PMP
University of Arizona
ORAL PRESENTATION: 1:55PM

Track 6 Preclinical Development and Early-Phase Clinical Development

M-13 Synthesis of Tetrahydrobenzonaphthyridines as a Novel Series of Antimalarial Compounds
John Wageh
Rutgers University
ORAL PRESENTATION: 12:45PM

M-14 Deep Learning for Pharmaceutical Formulation Prediction
Zhuyifan Ye
University of Macau, Macau

M-15 Fenofibrate Prevents Monocrotaline - Induced Pulmonary Hypertension in Rats Through Inhibition of NOX-1 Over Expression
Palak Galhotra, MSc
All India Institute of Medical Sciences, India

M-16 Inhibition of Interferon-Gamma or Palmitate-Induced Inflammation in Type 2 Diabetes by Prebiotic Dietary Metabolites
Millicent Yeboah-Awudzi, MSc
Louisiana State University

Track 7 Project Management and Strategic Planning

M-17 Awareness of HIV and Transmission Routes, Access to Health Knowledge in Western China: A Cross-Sectional Questionnaire Study
Tianqi Zhang, MSc
University of Macau, Macau

Track 9 Regulatory

M-18 Analysis of Drug Labeling for Information Specific to Geriatric Populations
Jacqueline Chen
University of Southern California
ORAL PRESENTATION: 12:55PM

M-19 Disparities Between FDA and EMA Regulatory Review Processes
Bijan Motamedi
USC School of Pharmacy
ORAL PRESENTATION: 2:45PM

M-20 Analysis of Indian National Guidelines for Stem Cell Research: A Path to Good Clinical Practice and Patient Care
Muntazir Ali Parvez Akhtar Sayed
RCSM Government Medical College; CPR General Hospital, India

M-21 Thirty Years Later: A Look Back at the Impact of AIDS Activism on Drug Development
Sydney Hoiseth
Bedford High School
ORAL PRESENTATION: 1:35PM

Track 10 Regulatory CMC and Product Quality

M-22 Quality Challenges in Cellular Therapy: An Examination of Regulatory Compliance in Manufacturing Institutions
Katherine St. Martin, MS, RAC
University of Southern California
ORAL PRESENTATION: 4:45PM

M-23 Analysis of FDA Warning Letters (2013-2017) of Active Pharmaceutical Ingredients (APIs) Made in China and India
Nahae Hannah Kim
University of Southern California
ORAL PRESENTATION: 2:05PM

Track 11 Statistics

M-24 Factors Associated with Treatment Outcomes for Patients with Extremely Drug Resistant TB: A Random Survival Forest
Justine Nasejje, MSc
University of Kwazulu-Natal, South Africa
ORAL PRESENTATION: 4:55PM

M-25 Reliability and Validity of Outcomes Data Using Statistical Methods for Wearable Medical Devices: A Systematic Review
Cezar Ocampo Manansala Jr., RPh
Centro Escolar University, Philippines

Track 12 Value and Access

M-26 Like We Have a Choice: A Qualitative Study of Patients' Views on Epoietin Biosimilars for Anemia of Chronic Kidney Disease
Nicole Tsao, MPharm, RPh
University of British Columbia, Canada
ORAL PRESENTATION: 1:45PM

M-27 Effect of Drug Shortages on Pricing of Competitor Products
Mark Hanna
St. John's University
ORAL PRESENTATION: 5:05PM

Professional Poster Session 1

Tuesday, June 26 | 9:00AM–4:00PM | 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 Clinical Safety and Pharmacovigilance

T-01 A Novel Approach to Standardizing Data and Detecting Duplicates Across Adverse Events Data Sources Using Machine Learning
Sameen Desai, MBA, MS
Celgene

T-02 Assessing the Value of a Comprehensive, Global Web-Based Pharmacovigilance Educational Platform
Irina Yermilov, MBA
Otsuka Pharmaceutical Development & Commercialization, Inc.

T-03 Pharmacovigilance and Data Process Enhancement with the Help of Automation
Tanveer Khan, MPharm
IQVIA

T-04 Understanding Pharmacovigilance Challenges and Complexities in Medical Devices: US and EU Perspective
Sanjeev Miglani, MD
AWINSA Life Sciences
ORAL PRESENTATION: 12:10PM

T-05 Aggregate Reports: Quality Control, Feedback, and Continuous Improvement
Beth Stockstill, BSN, MS, RN
IQVIA

Track 2 Clinical Trials and Clinical Operations

T-06 Investigating the Utility of Minimally Invasive Sample Collection Technologies and Their Role in Clinical Trials
Maria Cusano, PharmD, RPh
Novartis Institute of Biomedical Research
ORAL PRESENTATION: 12:30PM

T-07 Incremental Implementation of Risk-Based Monitoring in a Resource-Constrained
Erin Sizemore, MPH
US Centers For Disease Control & Prevention
ORAL PRESENTATION: 1:30PM

T-08 Analyzing Real-World Data To Target Hard-to-Identify Patient Populations for Clinical Trials: A Case Study in Blood Cancers
Stelios Tzellos, PhD, MS
IQVIA, United Kingdom

T-09 Use of Real-World Data to Optimize Identification of Systemic Lupus Erythematosus (SLE) Patients for Clinical Trial Enrolment
Michael Gregory Cushion, PhD, MSc
IQVIA, United Kingdom

T-10 Real-World Data Meets Real World Evidence in Patient Recruitment and Engagement
Aaron Fleishman
BBK Worldwide

T-11 Assessing Patient Availability and Patient Burden: Where Trials Go Wrong Today and How They Can Improve Tomorrow
Diane Carozza
Medidata Solutions Inc.

T-12 Risk-Adapted Monitoring Approach in Academic Medical Center: What We Learned from Multi-Center Investigator Sponsored Trials
Hong Young Lan
ASAN Medical Center, Republic of Korea
ORAL PRESENTATION: 1:00PM

Track 3 Data and Data Standards

T-13 Protocol Deviation Reporting and Tracking Without a Deviations Case Report Form
Kia Bryant, MPH
Centers For Disease Control and Prevention
ORAL PRESENTATION: 12:50PM

T-14 Automate the Process to Ensure the Compliance with FDA Business Rules in SDTM Programming for FDA Submission
Xiangchen Cui, DrSc
Alkermes Inc.

T-15 Mapping Items in the Case Report Form to CDISC SDTM Standards Using Pre-Map Function in the Electronic Data Capture System
Toshiki Saito, MD, PhD
National Hospital Organization Nagoya Medical Center, Japan

Track 4 Medical Affairs and Scientific Communication

T-16 The Non-Traditional Role: Pharmacists in Medical Information
Cambrey Nguyen, PharmD
University of Kansas School of Pharmacy
ORAL PRESENTATION: 1:10PM

Track 5 Patient Engagement

T-17 Making Clinical Trials More Patient-Centered: Results of a Key Stakeholder Engagement Workshop
Meredith Y. Smith, PhD, PMP, RAC
Amgen Inc.
ORAL PRESENTATION: 1:20PM

T-18 Understanding the Decision-Making Process for Clinical Trial Volunteers: Using Data to Shape Better Experiences
Jasmine Benger
CISCRP

T-19 Role of Social Media in Patient-Reported Outcomes (PRO) Research
Amit Dang, MD
Marksman Healthcare Solutions LLP, India

T-20 Aging with a Rare Disease: The Transition from Pediatric to Adult Care - Success Stories and Lessons Learned
Lisa Dilworth, MS
Premier

T-21 Best Practices and Lessons Learned in Raising Clinical Research Literacy Through Public and Patient Education and Outreach
Ellyn Getz
CISCRP

T-22 Current Genetics Literacy, Perspectives, and Experiences of Cancer, Chronic, and Rare Disease Patients and Caregivers
Kathleen Hoffman
Inspire

Track 6 Preclinical Development and Early-Phase Clinical Research

T-23 New Methodology to Evaluate a Drugs Effect on Respiratory Depression
Erik Hansen
PRA HealthSciences

T-24 A Phase 1 Pilot Trial to Explore Safety, Pharmacokinetics, and Bioavailability of Intranasal Remimazolam in Health Subjects
Lynn Webster, MD
PRA HealthServices

T-25 Understanding the Human Challenges Facing Oncologists Who Treat NSCLC
Emer Byrne
Accenture

Track 7 Project Management and Strategic Planning

T-26 Prior Assessment Consultation for Cell Therapy Products to Enhance the Investigational New Drug Application Quality in Chinese Taipei
Yu-Chun Teng, MS
TFDA/Center for Drug Evaluation, Chinese Taipei
ORAL PRESENTATION: 12:40PM

Track 9 Regulatory

T-27 MADDERS: A Systematic Approach to Meeting Regulatory Requirements for Evaluating Abuse-Related Events in Clinical Trials
Ryan Lanier, PhD
Analgesic Solutions
ORAL PRESENTATION: 1:40PM

T-28 Assessment of the Quality Decision-Making Practices; Case Studies with a Pharmaceutical Company, Regulatory, and HTA Agency
Magdalena Bujar, MSc
Centre For Innovation In Regulatory Science (CIRS)
ORAL PRESENTATION: 12:20PM

T-29 Implementing Distinguishable Suffixes for Biologics: Considerations for Application to Previously Licensed Products
Brad Jordan, PhD
Amgen

T-30 The Evolution of Privacy Protections in the US and EU
Barbara Rusin
MMS Holdings Inc.

T-31 Regulatory and Clinical Perspectives on Non-Comparable Biologics
Nicola Mathieson, MPharm
Sandoz Biopharmaceuticals

Track 10 Regulatory CMC and Product Quality

T-32 CMC Outsourcing Through Contract Manufacturing Organization (CMO): Opportunities, Risks, and Mitigation
Rajan Thumar, MS
Syner-G Pharma Consulting, LLC

Track 12 Value and Access

T-33 Assessing the Implementation of Value-Based Payments for Oncology Treatment Within the Existing Care Structure
Monika Schneider, PhD
Duke-Margolis Center For Health Policy

Professional Poster Session 2

Wednesday, June 27 9:00AM-4:00PM | Posters will be displayed in the Exhibit Hall

Track 1 Clinical Safety and Pharmacovigilance

W-01 Comparison of Predictive Power of ECG Biomarkers for Detection of Drug-Induced Cardiac Ion Channel Block
Brian Brockway, MS
VivaQuant, LLC

W-02 Regulatory Implications for the Safety of CAR-T Gene Therapy
Jaspal (JP) Ahluwalia, MD, MPH
FDA

W-03 Full Scale Implementation of Medical Information Database Network (MID-NET®) of 23 Hospitals for Drug Safety Assessment
Sono Sawada, MPH
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

W-04 Understanding Safety Reporting Requirements: Perspectives from Asia, US, and Europe
Mugdha Chopra, DDS
AWINSA Life Sciences
ORAL PRESENTATION: 12:50PM

W-05 QPPV, CO, and None: Which is Working and Which is Not Working?
Teiki Iwaoka
Nanocarrier Co., Ltd.

Track 2 Clinical Trials and Clinical Operations

W-06 Challenges, Outcomes, and Benefits of Leveraging eSource Solution in Clinical Trials
Yerramalli Subramaniam, MBA
Cliniops, Inc, India

W-07 Aligning Strategies and Deliverables for Global eCOA Translation Submissions to Ethics Committees in Clinical Trials
Shawn McKown, MA
RWS Life Sciences

W-08 Taming the Study Data Explosion: How to Leverage KPIs to Maximize Performance
Erica Mercado
BBK Worldwide

W-09 Data Quality in a Longitudinal, Observational Registry Without On-Site Monitoring: Findings From the ORBIT AF II Registry
Tara Melton, MS
Duke Clinical Research Institute
ORAL PRESENTATION: 1:50PM

W-10 How Evaluating Human Emotions Could Provide Valuable Evidence to Support Clinical Trial Endpoints
Rinah Yamamoto
ERT
ORAL PRESENTATION: 1:20PM

W-11 Innovations in the Management of Study Drug Inventory Through a Web-Based System
Nigel Scott, MS
Centers For Disease Control and Prevention
ORAL PRESENTATION: 12:30PM

Track 3 Data and Data Standards

W-12 The Clinical Development Design (CDD) Framework: Assisting and Improving Decision-Making for Product Development
Mary Banach, PhD, MPH
Vanderbilt University

W-13 Comparing Two Drug Treatment Coding Approaches: Coding Challenges and Lessons Learned
Sherry Chang, PharmD
FDA

W-14 SDTM and CDASH: Why You Need Both
Kit Howard, MS
CDISC
ORAL PRESENTATION: 1:00PM

W-15 Cross-Industry Collaboration Evaluating how Blockchain can Transform the Pharmaceutical and Healthcare Industry
Adama Ibrahim
Biogen Inc

Track 4 Medical Affairs and Scientific Communication

W-16 The Cost Effectiveness of Metastatic Melanoma Treatment in Taiwan
Li-Shan Jian, MS
Center For Drug Evaluation

Track 5 Patient Engagement

W-17 A Digital Health Platform to Create Personalized Care Experiences for Patients with Chronic Disease
Jyotsna Mehta, PharmD, MS
Keva Health
ORAL PRESENTATION: 1:10PM

W-18 Monitoring and Evaluating Community Stakeholder Engagement Strategies in Populations at High Risk of HIV in Pattaya, Thailand
Kirsten Seay Smith, PhD, PMP, RAC
Armed Forces Research Institute of Medical Sciences

W-19 Gene Therapy Clinical Trials in Rare Diseases: Considerations and Tools for Observing Delayed Adverse Events
Amy Raymond, PhD, PMP
PRA Health Sciences

W-20 Designing a Patient-Centric Web-Based Registry
Valerie Powell, MS
ICON plc

W-21 Effective Engagement Between Sponsors and Patient Groups: A Structured Process and Use Cases from CTTI
Zachary Hallinan
Clinical Trials Transformation Initiative (CTTI)

W-22 Leveraging Physician Referral Networks in Rare Disease Genotyping
Nariman Nasser
Continuum Clinical

W-23 Participation Barometer: Learn What Influences Patient Decision-Making
Kelly Franchetti, BSN, RN
Mapi Group, An ICON plc Company
ORAL PRESENTATION: 12:40PM

W-24 Where High Touch Meets High Tech: Reimagining Innovation In Clinical Trials
Abbe Steel, MSc
HealthiVibe, LLC

W-25 The Use of Voice Assistant Technology to Increase Engagement in Clinical Trials
Karin Beckstrom
ERT

Track 6 Preclinical Development and Early-Phase Clinical Development

W-26 A Novel Eyedrop to Treat Myopia
Matt Lin, MD
China Medical University, China
ORAL PRESENTATION: 1:30PM

W-27 Placebo Response Reduction Training in Chronic Low Back Pain: Comparison to Other Published Studies on Chronic Low Back Pain
Nathalie Erpelding, PhD
Analgesic Solutions

Track 7 Project Management and Strategic Planning

W-28 Visualizing Clinical Trial Endpoints
Matt Eberle, MLIS
BizInt Solutions, Inc.

Track 9 Regulatory

W-29 Analysis of Pediatric Investigation Plans and Post-Approval Pediatric Requirements of Monoclonal Antibodies for Asthma
Kristina Vishnevetskaya, PharmD
University of North Carolina/GlaxoSmithKline
ORAL PRESENTATION: 1:40PM

W-30 Making Regulations a Linkable Resource for Semantic Web Applications
Rashedul Hasan, PhD
FDA
ORAL PRESENTATION: 12:20PM

W-31 An Adaptive Seamless Phase II/III Design in Drug Development for Binary Endpoints
Lien-Cheng Chang, PhD
TFDA, Chinese Taipei

W-32 Analysis of Prescription Drug Direct-to-Consumer (DTC) Television Commercials Released Between 2000-2017
Kristina Babayan, PharmD
Novo Nordisk

W-33 Evaluation Process for Bulk Drug Substances for Use in Pharmacy Compounding at the FDA: Weighing in the Nonclinical Assessment
Wafa A. Harrouk
FDA

Track 11 Statistics

W-34 Effect of Randomization Schemes in the Master Protocol Framework When There Are Unknown Interactions Between Biomarkers
Janet Li, MS
Pfizer Inc

AWARD WINNERS

DIA Inspire Awards recognize significant individuals or group accomplishments in the discovery, development, or lifecycle management of biopharmaceutical, device, or related therapeutic healthcare 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.

TB ALLIANCE

President's Award for Outstanding Contribution to Global Health
TB Alliance

The mission of the **TB Alliance** is to help foster the creation of faster acting tuberculosis (TB) drugs and eventually find a cure for TB. TB Alliance was conceived at a February 2000 meeting in Cape Town, South Africa, where 120 representatives from academia, industry, major agencies, non-governmental organizations, and donors gathered to discuss the need for new TB treatments. At the time, there were no TB drugs in clinical development and, therefore, little hope for better cures. Participants stressed the need for new TB drugs, highlighted the unprecedented scientific opportunities, and underscored the lack of market incentive for pharmaceutical companies to develop new TB treatments.

Global Connector
John Lim, MD, MSc
Executive Director, Centre of Regulatory Excellence, Duke-NUS Medical School
Senior Advisor, Ministry of Health, Singapore
Chairman, Singapore Clinical Research Institute

Excellence in Service
Munish Mehra, PhD
Managing Director, Principal Biostatistician
Tigermed Co., Ltd.

INSPIRE AWARDS: AMERICAS

FRIENDS of CANCER RESEARCH

President's Award for Outstanding Contribution to Global Health
Friends of Cancer Research

During the past 20-plus years, Friends of Cancer Research (Friends) has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. They've been successful due to their ability to convene the right people at the right time and put forth revolutionary, yet realistic ideas. Friends is energized now more than ever to continue this critical work with their trusted partners, creating innovative solutions to overcome barriers standing in the way of conquering cancer.

Excellence in Service
Alicia Cadogan, PharmD, RPh
Director, Oncology Medical Information
Pfizer, Inc

Excellence in Service
Leah Christl, PhD
Associate Director for Therapeutic Biologics, TBBS, Office of New Drugs
CDER, FDA

Excellence in Service
Leigh Shultz, PhD
Associate Vice President, Project Management
Merck & Co., Inc.

Excellence in Service
Mark Gaydos
Vice President, NA General Medicines/US Advertising and Promotion, Global Regulatory Affairs
Sanofi

DIA AUTHOR(S) OF THE YEAR AWARD

The DIA Author(s) of the Year Award is an annual award presented to the author(s) of an article published in *Therapeutic Innovation & Regulatory Science* (TIRS), DIA's official peer-reviewed scientific journal, that has made a significant contribution to advancing healthcare product development. The article and its author(s) are chosen based on two criteria: the total number of web accesses for the article on the journal website, and the total number of full-text downloads the article has had during the past year.

Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap
Author: Jan Geissler, MBA, Director, European Patients Academy on Therapeutic Innovation (EUPATI), Germany
Volume 51, Issue 5: 612-619

FELLOWS OF DIA CLASS OF 2017

Fellow Chair of DIA
Tatsuo Kurokawa, PhD
Member, Executive Committee
President
Japan Self-Medication Industry, Japan

Fellow of DIA
Martin Harvey Allchurch, LLM
Principal International Affairs Officer
European Medicines Agency, European Union

Fellow of DIA
E. Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Director, Corporate Medical Affairs HQ
Eisai Co., Ltd., Japan

Fellow of DIA
Sandra L. Kweder, MD
Deputy Director, FDA Liaison to the EMA, Office of International Programs, Office of the Commissioner
FDA

The content noted on this page was made available to DIA as of May 11, 2018.

SPEAKER INDEX

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 25

Number	Session Title	Assigned UAN	Type of Activity
100	Opening Plenary Session and Keynote Speaker	0286-0000-18-517-L04-P	Knowledge
105	Cardiac Safety in Drug Development and the Critical Role of Public-Private Partnerships: The Cardiac Safety Research Consortium Model	0286-0000-18-518-L04-P	Knowledge
106	Signal Management: Separating Needles from Haystacks	0286-0000-18-519-L04-P	Knowledge
107	The Metamorphosis of Clinical Trials: Evolving Roles of Stakeholders in Digital Trials	0286-0000-18-520-L04-P	Knowledge
108	From Patients and Advocacy Groups to Operations and Beyond: Obtaining and Incorporating Input from Stakeholders in Protocol Design	0286-0000-18-521-L04-P	Knowledge
109	The Who, What, How, When, and Why of Using Mobile Technology in Clinical Trials	0286-0000-18-522-L04-P	Knowledge
110	Using Fast Healthcare Interoperability Resources (FHIR®) for Clinical Research	0286-0000-18-523-L04-P	Knowledge
111	Data Integrity Playbook: A Cross-Functional, Risk-Based, Analytics-Driven Approach to Monitor Data Integrity	0286-0000-18-524-L04-P	Knowledge
112	Scientific Communication Key Message Development, Management, and Dissemination	0286-0000-18-525-L04-P	Knowledge
113	Patient-Focused Medicines Development: Where it has Led Us to Today, What Challenges Remain, and What do We Still Need to do to Achieve Success?	0286-0000-18-526-L04-P	Knowledge
114	A Hot Debate: Perspectives on Benefit and Risk from Patients Across Diseases	0286-0000-18-527-L04-P	Knowledge
115	Regenerative Medicine Advanced Therapies: Facilitating Product Development and Approval	0286-0000-18-528-L04-P	Knowledge
117	Beyond Robotics Process Automation: Next Generation Integrated QMS for R&D	0286-0000-18-529-L04-P	Knowledge
118	How Can We Optimally Incorporate Real World Evidence into Regulatory Decision-Making?	0286-0000-18-530-L04-P	Knowledge
119	'Target'ing Pediatric Oncology Development: New Global Pediatric Considerations Under FDARA 2017	0286-0000-18-531-L04-P	Knowledge
120	FDA Innovation in Pharmaceutical Quality Assessment and Inspection	0286-0000-18-532-L04-P	Knowledge
121	Use of Historical Information in Clinical Trial Design	0286-0000-18-533-L04-P	Knowledge
122	Contracting for Value: From Outcomes-Based Contracts to Bundled Payment Programs: What's Working and Why	0286-0000-18-534-L04-P	Knowledge
123	Unmet Medical Need: Diversity of Definitions and Viewpoints – Detangling the Challenge	0286-0000-18-698-L04-P	Knowledge
124	Analyzing Innovations Progress in the Gottlieb Era	0286-0000-18-535-L04-P	Knowledge
139	Novel Approaches to Pharmacovigilance Collaboration	0286-0000-18-536-L04-P	Knowledge
140	How Inspection-Ready is Your Organization?	0286-0000-18-537-L04-P	Knowledge
141	eSource: The Road to Real World Evidence – Are We There Yet?	0286-0000-18-538-L04-P	Knowledge
142	Mobile Accelerometry in Clinical Trials: Potential Applications and Meaningful Outcomes	0286-0000-18-540-L04-P	Knowledge
143	Applying Artificial Intelligence, Machine Language, Natural Language Processing, and Predictive Models in Clinical Trials to Deliver Value to Stakeholders	0286-0000-18-541-L04-P	Knowledge
144	The Evolving Biosimilars Landscape: A Medical Affairs Perspective	0286-0000-18-542-L04-P	Knowledge
145	A New Ecosystem: The Nature of Relationships Between Patient Advocacy Groups and Sponsors	0286-0000-18-543-L04-P	Knowledge
146	Development of Microbiome - Derived Therapeutics	0286-0000-18-544-L04-P	Knowledge
147	Facilitating Nonclinical Data-Sharing and Access Across the Industry	0286-0000-18-545-L04-P	Knowledge
149	A Quality-by-Design Approach to Trial Design and Conduct: Case Studies from the Clinical Trials Transformation Initiative	0286-0000-18-546-L04-P	Application
150	TFDA Town Hall	0286-0000-18-547-L04-P	Knowledge
151	Using Real World Evidence for Regulatory Support: Time to Embrace the Future	0286-0000-18-548-L04-P	Knowledge
152	FDA Expectations for Demonstration of Interchangeability	0286-0000-18-549-L04-P	Knowledge
153	New Technologies in Pharmaceuticals and Biopharmaceuticals: Opportunities and Regulatory Challenges	0286-0000-18-550-L04-P	Knowledge
154	Bayesian Application in Small-Sized Clinical Trials	0286-0000-18-551-L04-P	Application
155	Real World Evidence for Value and Access	0286-0000-18-552-L04-P	Knowledge
156	International Regulatory Convergence	0286-0000-18-553-L04-P	Knowledge

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202	Quantifying the Impact of Credentialed Clinical Research Site Professionals on Clinical Trial Conduct Quality	0286-0000-18-555-L04-P	Knowledge
203	Utilizing and Understanding Real World Evidence Solutions to Efficiently Recruit the Most Appropriate Patients and Sites for Clinical Trials	0286-0000-18-556-L04-P	Application
204	FDA Data Standards Update	0286-0000-18-557-L04-P	Knowledge
205	Best Practices for Implementing Lay Summaries and Communicating Results to Patients	0286-0000-18-558-L04-P	Application
206	Incorporating Patient Input into US Food and Drug Administration's Medical Product Development and Regulatory Decision-Making	0286-0000-18-559-L04-P	Knowledge
207	Novel Approaches for Accessing the CNS: Nonclinical and Clinical Challenges	0286-0000-18-560-L04-P	Knowledge
208	Effective Management of Internal Stakeholders and External Strategic Partners from Multiple Perspectives: Non-Profit, CRO, and Pharmaceutical Industry	0286-0000-18-561-L04-P	Application
209	Oversight in the Era of E6 (R2)	0286-0000-18-562-L04-P	Application
210	Artificial Intelligence: The Future of Regulatory Affairs	0286-0000-18-563-L04-P	Application
211	Update on Collaboration and Trends in Global Companion Diagnostics	0286-0000-18-564-L04-P	Knowledge
212	Global Regulatory Strategies for Biosimilars	0286-0000-18-565-L04-P	Application
213	2018 Policy Mash-Up: New Shifts in the Healthcare Market and What They May Mean for Patients and the Biopharma Industry	0286-0000-18-702-L04-P	Knowledge
214	CMC Challenges for Breakthrough Therapies and Other Worldwide Accelerated Approval Programs	0286-0000-18-567-L04-P	Knowledge
215	Pediatric and Rare Disease Drug Development	0286-0000-18-568-L04-P	Knowledge
216	Early HTA Scientific Advice: Does it Improve Internal Company Decision-Making and Ensure Predictability of HTA Outcome?	0286-0000-18-569-L04-P	Knowledge
217	Triple-A RWE: Adequate Data, Appropriate Study Designs, and Actionable Evidence	0286-0000-18-570-L04-P	Knowledge
226	Regulators' Utilization of Real-World Data in Pharmacovigilance Activities	0286-0000-18-571-L04-P	Knowledge
228	Global Clinical Trials: Lessons in Effective Execution	0286-0000-18-572-L04-P	Knowledge
229	Mobile Reported Outcomes: A Forum on Patient and Caregiver Assessments	0286-0000-18-573-L04-P	Application
230	Common Data Model Harmonization for Evidence Generation	0286-0000-18-574-L04-P	Knowledge
231	Automation with Intelligence: From Standard-Based Solution to Metadata-Driven Automation	0286-0000-18-575-L04-P	Knowledge
232	Digital Data and New Technologies to Drive Customer Impact in Medical Affairs, Medical Writing, and Medical Communications	0286-0000-18-576-L04-P	Knowledge
233	The Patient's Assessment of the Patient-Focused Drug Development Meeting Initiatives	0286-0000-18-577-L04-P	Knowledge
234	Personalized Medicine Approaches During Early-Phase Clinical Research	0286-0000-18-578-L04-P	Knowledge
235	The Adventures of Patient Experience in Drug Development	0286-0000-18-579-L04-P	Knowledge
236	Executives Respond to the State of the Industry Report on Risk-Based Approaches in Clinical Trials: Opportunity or Threat?	0286-0000-18-580-L04-P	Knowledge
237	Expanded Access: Where Are We Now?	0286-0000-18-581-L04-P	Knowledge
238	The European Medical Devices Regulation and MDUFA IV: One Year On – Is it Any Clearer?	0286-0000-18-582-L04-P	Knowledge
239	Generic Drug Town Hall	0286-0000-18-583-L04-P	Knowledge
240	Biosimilars: Demonstrating Structural and Functional Similarity	0286-0000-18-584-L04-P	Knowledge
241	Time-to-Event Analysis in Clinical Trials	0286-0000-18-585-L04-P	Knowledge
242	Unmet Medical Need: Can the Stakeholders Align? Progress to Date	0286-0000-18-700-L04-P	Knowledge
243	Global Perspectives on Patient Engagement	0286-0000-18-586-L04-P	Knowledge
251	Risk Management: New Directions	0286-0000-18-587-L04-P	Knowledge
252	Do the End(point)s Justify the Means? A Peak at Endpoints Accepted by FDA with an Eye Towards Mobile Technology Collection	0286-0000-18-588-L04-P	Knowledge
253	Digitizing a Patient-Focused Clinical Trial Experience	0286-0000-18-589-L04-P	Knowledge
254	Risk-Based Monitoring for Master Protocol Study: A Dilemma and Possible Ways to Go	0286-0000-18-590-L04-P	Knowledge
255	Use of Electronic Health Records (EHRs) as eSource in Clinical Investigations	0286-0000-18-591-L04-P	Knowledge

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257	Globalizing and Regionalizing Medical Information Contact Centers	0286-0000-18-593-L04-P	Knowledge
258	Reaching the Underserved: Methods to Ensure Diversity and Inclusion for Patient Research, Clinical Trials, and Advisory Panels	0286-0000-18-594-L04-P	Knowledge
259	Measuring the Impact of Patient Engagement: What to Ask Depends on Who You Ask	0286-0000-18-704-L04-P	Knowledge
260	Optimizing Clinical Development with Adaptive Trial Designs	0286-0000-18-595-L04-P	Knowledge
261	Project Management Throwdown: How Not to Get Chopped	0286-0000-18-596-L04-P	Knowledge
262	The Risk Assessment is Done: Now What? A Guide to Setting up a Centralized Monitoring Plan	0286-0000-18-597-L04-P	Knowledge
263	Navigating the Regulatory Landscape of Drug-Device Combination Products	0286-0000-18-598-L04-P	Knowledge
264	Global Development Using Expedited Pathways in Established and Emerging Markets	0286-0000-18-599-L04-P	Knowledge
265	ICH M9 BCS-Based Biowaivers	0286-0000-18-600-L04-P	Knowledge
266	User-Friendly Tools for Study Planning and Analysis	0286-0000-18-601-L04-P	Knowledge
267	Developing and Partnering on Evidence for Outcomes and Value Assessment: Standardizing Measurement for Patient-Centered Care	0286-0000-18-602-L04-P	Knowledge
268	Future of PharmaTech	0286-0000-18-603-L04-P	Knowledge
276	Patient Engagement in Pharmacovigilance	0286-0000-18-604-L04-P	Knowledge
277	Pharmacovigilance: No Longer Going it Alone	0286-0000-18-605-L04-P	Knowledge
278	Challenges and Opportunities in Data Access and Methodology Development for Post-Market Generic Drug Monitoring	0286-0000-18-606-L04-P	Knowledge
279	Redefining the Site Investigator's Experience	0286-0000-18-607-L04-P	Knowledge
280	Debunking Decentralized Trials: Sharing Breakthroughs and Deal Breakers	0286-0000-18-608-L04-P	Knowledge
281	Future of Endpoints	0286-0000-18-609-L04-P	Knowledge
282	Building up Efficiencies, Breaking Down Barriers: Using Mobile Technology for Data Capture in Clinical Trials	0286-0000-18-610-L04-P	Knowledge
283	Evolving Roles and Responsibilities for Medical Affairs Professionals	0286-0000-18-611-L04-P	Knowledge
284	Using Advocacy Partnerships to Improve Real World Evidence in Clinical Trials	0286-0000-18-612-L04-P	Knowledge
285	Gene Therapy: Advances in Translating Technology	0286-0000-18-613-L04-P	Knowledge
286	Which Regulatory Project Management Staff at FDA Should You Engage With? When and How?	0286-0000-18-614-L04-P	Knowledge
287	The Letter and Spirit of Risk-Based Monitoring: How to Creatively Implement Risk-Based Modeling and Unlock the Potential of the Team	0286-0000-18-615-L04-P	Knowledge
288	Is it Time to Change the Content and Format of Labeling?	0286-0000-18-616-L04-P	Knowledge
289	Electronic Submissions Demystified	0286-0000-18-617-L04-P	Knowledge
290	Priority Review Vouchers: Here to Stay and Worth the Effort?	0286-0000-18-566-L04-P	Knowledge
291	ICH Q12: A Paradigm Changing Guidance for Post-Approval Changes?	0286-0000-18-618-L04-P	Knowledge
292	Complex Innovative Designs and Model-Informed Drug Development Related: PDUFA VI Pilot Programs	0286-0000-18-619-L04-P	Knowledge
293	Medical Monitoring in Non-Interventional Studies: Need for Medical Leadership and Study Primary Care Management	0286-0000-18-620-L04-P	Knowledge
294	Sustainable Healthcare Funding	0286-0000-18-621-L04-P	Knowledge

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302	Risk Communication and Patient Safety: Recent Learnings and New Approaches	0286-0000-18-623-L04-P	Knowledge
303	Regulatory and Ethical Considerations with Placebo Administration Using a Central Venous Access Device in a Pediatric Trial	0286-0000-18-624-L04-P	Knowledge
304	Data and Quality Approaches to Informing Global Investigative Site Selection	0286-0000-18-625-L04-P	Knowledge

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306	phactMI: A Collaborative Approach to Advancing the Practice of Medical Information and Enabling Innovative Customer Solutions	0286-0000-18-703-L04-P	Knowledge
307	Maintaining Patient Engagement in the Development of Patient-Reported Outcome (PRO) Measures	0286-0000-18-627-L04-P	Knowledge
308	How do Patients and Other Multi-Disciplinary Stakeholders Collaborate to Develop Patient Registries Which Accelerate Research?	0286-0000-18-628-L04-P	Knowledge
309	Evolution and Harmonization of First-in-Human Guidelines	0286-0000-18-629-L04-P	Knowledge
311	Harnessing the Power of Data and Analytics to Enhance Quality	0286-0000-18-630-L04-P	Knowledge
312	Harmonizing Regulatory Science Through the International Council for Harmonisation (ICH)	0286-0000-18-631-L04-P	Knowledge
313	Global Rare Disease Town Hall	0286-0000-18-632-L04-P	Knowledge
314	What Can We say About Combination Products? Labeling, Advertising, and Promotion of Combination Products	0286-0000-18-633-L04-P	Knowledge
315	Can I Implement That Now? Efficiently Managing Post-Approval CMC Changes	0286-0000-18-634-L04-P	Knowledge
316	Opportunities for Efficient and Innovative Study Designs	0286-0000-18-635-L04-P	Knowledge
317	Operationalizing Real World Evidence and Value	0286-0000-18-636-L04-P	Knowledge
318	Value-Based Assessment and Contracting: What Needs to be Done to Make it a Best Practice?	0286-0000-18-637-L04-P	Knowledge
329	Reducing the Burden of Drug Safety Risk Minimization Programs on the Healthcare System: How do We do so and What has Been Learned to Date?	0286-0000-18-638-L04-P	Knowledge
330	Artificial Intelligence: Robots Taking Over Clinical Research	0286-0000-18-639-L04-P	Knowledge
331	Rebuilding or Building a Research Site in the Year 2020	0286-0000-18-640-L04-P	Knowledge
332	Clinical Data: Let's Get to the Source and Streamline it to the End	0286-0000-18-641-L04-P	Application
333	Streamlining Vendor Reconciliation	0286-0000-18-642-L04-P	Knowledge
334	Clinical Trial Results Disclosure: Learnings from EMA Policy 0070, NIH Final Rule, and FDA's Clinical Data Summary Pilot Program	0286-0000-18-643-L04-P	Knowledge
335	Collaboration Across the Medical Affairs Ecosystem to Advance Patient Care	0286-0000-18-644-L04-P	Knowledge
336	Addressing the Elephant in the Room: A Hard Look at Metrics, Legal, Payers, and Other Leading Obstacles Facing the Sustainability of Patient Engagement	0286-0000-18-645-L04-P	Knowledge
337	Balancing Regulatory, Medical, and Operational Pillars to Get Pediatric Trials Done Globally	0286-0000-18-646-L04-P	Knowledge
338	You've Got Data #now What?	0286-0000-18-647-L04-P	Knowledge
339	Determining Data Integrity: Decoding the Impact of Inspectional Observations	0286-0000-18-648-L04-P	Knowledge
340	Harmonization Beyond ICH	0286-0000-18-649-L04-P	Knowledge
341	New FDA Draft Guidance on Part 11 in Clinical Investigations	0286-0000-18-650-L04-P	Knowledge
342	Sex Considerations in the FDA Drug Review Pipeline: The Where, When, and How	0286-0000-18-651-L04-P	Knowledge
343	Innovative Visualization Approaches	0286-0000-18-652-L04-P	Knowledge
344	Biosimilar Interchangeability: A Global Perspective	0286-0000-18-653-L04-P	Knowledge
345	Unmet Medical Need: Path Forward – Creating a Commonly Agreed Criteria Globally	0286-0000-18-699-L04-P	Knowledge
346	Precision Medicine, Gene Editing, and Gene Therapy: Current Status and Regulatory Challenges of Integrating Genetic Medicine into Clinical Care	0286-0000-18-654-L04-P	Knowledge
358	Expedited E2B Safety Reporting in Interventional Clinical Trials: Convergence of Global Expectations?	0286-0000-18-655-L04-P	Knowledge
359	IMEDS: A Collaboration Based on the FDA's Sentinel Initiative	0286-0000-18-656-L04-P	Knowledge
360	Implementation of eConsent and Other Digital Clinical Trial Innovations	0286-0000-18-657-L04-P	Knowledge
361	A New Way of Authoring and Reviewing Documents for Clinical Development	0286-0000-18-658-L04-P	Knowledge
362	Do the Evolution: The Future Role of Clinical Data Management	0286-0000-18-659-L04-P	Knowledge
363	Innovative and Effective Authoring Strategies to Facilitate Accelerated Regulatory Submissions	0286-0000-18-660-L04-P	Knowledge
364	Achieving Customer Centricity to Advance Patient Care Through Innovative Communication Channels	0286-0000-18-661-L04-P	Knowledge
365	Engaging the Rare Disease Community to Design Clinical Trials	0286-0000-18-662-L04-P	Knowledge
366	Gene Therapy Clinical Trials: Current Challenges	0286-0000-18-663-L04-P	Knowledge

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368	Predicting Future Generic Drug Competition: Powering Strategic Planning Using Quantitative Methods and Modeling	0286-0000-18-665-L04-P	Knowledge
369	Virtual Audits: Do They Achieve the Objective?	0286-0000-18-666-L04-P	Application
370	Clinical Outcomes Assessments (COA) Endpoints for Use in Rare and Ultra-Rare Disease Clinical Trials	0286-0000-18-667-L04-P	Application
371	What's New in Health Canada: Updates and New Endeavors	0286-0000-18-668-L04-P	Knowledge
372	AdPromo: Assessing Risk in the Current Regulatory Environment	0286-0000-18-669-L04-P	Knowledge
373	PMDA Town Hall	0286-0000-18-670-L04-P	Knowledge
374	Modernization and Harmonization of Inspectional Approaches	0286-0000-18-671-L04-P	Knowledge
375	Statistical Challenges in Assessing Drugs' Efficacy by Utilizing Biomarker Endpoints	0286-0000-18-672-L04-P	Knowledge
382	Artificial Intelligence: A Disruptive Journey for Pharmacovigilance	0286-0000-18-673-L04-P	Knowledge
383	Safe Use and Prescribing of Opioid Medications: An In-Depth Look at the Strategies and Their Evaluation	0286-0000-18-674-L04-P	Knowledge
384	Innovations in Managing Global Clinical Supplies	0286-0000-18-675-L04-P	Knowledge
385	Does Sourcing Strategy Matter? Executives Debate the Influence of Outsourcing Model on Clinical Trial Execution	0286-0000-18-676-L04-P	Knowledge
386	Bring Your Own Device ePRO: Hold the Relish, or No Holds Barred?	0286-0000-18-677-L04-P	Knowledge
387	Evolving CDISC Standards and Technologies	0286-0000-18-678-L04-P	Knowledge
388	Using Patient-Centric Outcomes to Engage Patients in Shared Treatment Decision-Making	0286-0000-18-679-L04-P	Knowledge
389	Patient Observation Versus Patient Engagement: Optimizing Development	0286-0000-18-680-L04-P	Knowledge
390	Special Population Study Challenges	0286-0000-18-681-L04-P	Knowledge
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393	Think Like a Regulator: Evaluating Trial Integrity	0286-0000-18-683-L04-P	Knowledge
395	PDUFA VI: Improving Transparency and Accountability of Electronic Submission and Data Standards Activities	0286-0000-18-684-L04-P	Knowledge
396	Current and Future Perspective on Mutual Recognition, Work Sharing, and Global Regulatory Convergence	0286-0000-18-685-L04-P	Application
397	Design and Statistical Considerations for Real World Evidence to Support Regulatory Decision-Making	0286-0000-18-686-L04-P	Knowledge
398	The Impact of Cell and Gene Therapy on the Payer System	0286-0000-18-687-L04-P	Knowledge

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405	Putting Patient Experience First	0286-0000-18-689-L04-P	Knowledge
406	Improving Efficiency and Effectiveness in Data Management of Pediatric, Rare Disease, and Oncology Trials	0286-0000-18-690-L04-P	Application
407	Beyond Adult Patients, Untapped Advisors in Clinical Development: Adolescents, Parents, Siblings, and Spouses	0286-0000-18-691-L04-P	Knowledge
409	Emerging Best Practices and Challenges in Strategic Drug Development and Design Decision-Making	0286-0000-18-692-L04-P	Knowledge
411	Regulatory and Industry Perspectives on the Common Protocol Template	0286-0000-18-693-L04-P	Knowledge
412	Metrics and Meaning: Evolving Metrics in Generic Drug Application Review and Communications to Improve ANDA Submission Planning and Approvability	0286-0000-18-694-L04-P	Knowledge
413	The Correlation Between Patient-Reported Outcomes and Clinician-Reported Outcomes	0286-0000-18-695-L04-P	Knowledge
414	Unmet Medical Need: What did We Create Together and Where to Take It?	0286-0000-18-701-L04-P	Knowledge
415	EMA/FDA Question Time	0286-0000-18-696-L04-P	Knowledge
416	FDA Town Hall	0286-0000-18-697-L04-P	Knowledge

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AdaptaLogix	Booth: 2528	114
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Adaptive Clinical Systems
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Alliance for Safe Biologic Medicines
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The Alliance for Safe Biologic Medicines is a group of physicians, pharmacists, patients, manufacturers of both biologics and biosimilars, researchers, and others working together to promote the safe introduction and use of biosimilars.

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Artcraft Health focuses on the key elements of education, awareness, and creativity to facilitate the successful completion of clinical trials. Our solutions have been proven in hundreds of trials to reduce costs and increase recruitment and compliance, while aiding communication, consent, and retention. Our trademarked CARE™ principles underscore all of our work, ensuring that our custom tactics are Clear, Actionable, Relevant, and Engaging without compromising quality. www.artcrafthealth.com

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As a nonprofit, academic enterprise of the University of Utah, ARUP is at the forefront of innovative laboratory research. We are a CLIA-certified diagnostic lab with more than 25 years of experience supporting clinical trials. Our clients include contract research organizations, global and startup organizations, pharmaceutical companies, and biotechnology companies. Our focus on quality and service is unparalleled in the industry. Visit www.aruplab.com/trials for more information.

Asia CRO Alliance
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The Asia CRO Alliance supports drug, biotech, medical device companies, and CROs planning studies in Asia. The ACA led by LSK Global Pharma Services, the largest local Korean CRO, meets the increasing demand for Asian studies. ACA members function individually or in team as the sponsor demands. At present LSK is engaged in a pivotal oncology study of 95 sites from 12 countries in Asia, US, and Europe with some ACA members. ACA services are of global quality, timely and price-conscious.

Assistek
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Association of Clinical Research Professionals, Inc.
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The Association of Clinical Research Professionals works with its members and clinical research organizations to provide support, training, certification, and networking opportunities that improve clinical research. ACRP is a Washington, DC-based non-profit organization with more than 13,000 members who work in clinical research around the world. Our mission is to promote excellence in clinical research. Put our 40 years of experience driving quality in clinical research to work for you.

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Atlant Clinical is an international CRO, offering a full range of clinical trial (Phases I-IV) and relevant support services throughout the US, Europe, Russia, and Middle Asia. Our company has over 10 years of strong experience, including conduct of 200+ clinical trials in all major therapeutic areas. Atlant Clinical employs a capable team of over 150 experienced employees worldwide. All our people have strong background in natural sciences and/or medicine.

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August Research is an American-owned CRO working exclusively in Central and Eastern Europe. August Research has operations in Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia and Slovakia, with office-based clinical staff. With more than 15 years of clinical trials experience in the region, the August Research team combines deep local expertise, American-style customer service and reasonable pricing to optimize our clients' clinical trials.

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Axiom is the premier provider of unified eClinical solutions and services tailored to fit all needs. Axiom Fusion eClinical Suite, with 15 optional modules, delivers unified functionality via a single log-on platform. EDC, IWRS, CTMS, IRT, IVR, Patient ePRO, AE/SAE, Safety Database, Central Lab, Imaging, eTMF, Clinical/PM Reporting and much more. Services include: Project Management, Data Management, Clinical Science, Pharmacovigilance, Randomization, Inventory Management, Medical Monitoring

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Backpack Health enables medical foundations, drug and device developers and advocacy groups to collect data, and build and support their communities. Capture meaningful, de-identified, aggregated data that serves a variety of clinical, commercial and community uses.

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BARC Global Central Laboratory is a unique central lab, for we are also experts in specialty testing such as molecular diagnostics, genomics, NGS, flow cytometry, anatomic pathology and companion diagnostics. We combine this scientific expertise with a global team that is flexible, collaborative and focused on developing solutions.

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Leaders in Clinical Research Training Barnett helps clients get the most out of their research and development dollars by managing change effectively, improving organizational performance, and enhancing staff knowledge. The Barnett approach is a unique combination of strategy development and practical, hands-on implementation. The "Barnett Difference" is evident in our deep understanding of the clinical research process and in the rapid and tangible performance improvements we deliver.

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Barrington James is a Global specialist recruitment consultancy with offices in the USA, Europe and APAC that works across the healthcare sector. Our structure, with separate divisions and dedicated consultants for the markets we serve, ensures a thorough, professional and intelligent approach in both permanent and interim solutions. Our tailored methodologies include contingency database search and executive search.

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BBK Worldwide is the patient experience company, providing a range of patient recruitment and engagement solutions to pharmaceutical and biopharmaceutical companies and their outsourced suppliers. Committed to providing creative and technology-driven solutions needed to enhance the patient experience, enroll clinical studies on time, and expedite time-to-market, BBK delivers a suite of integral products to address patient and site engagement challenges in multinational studies.

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Beacon Hill Pharma partners with Pharmaceutical, Medical Device, Clinical Research Outsourcing, and other corporations delivering the very best Clinical Development/R&D resourcing solutions in the market today. Committed to identifying and delivering quality candidates that fit your objectives and company culture, we place clinical research contractors in all 50 states, seamlessly coordinating recruiting resources in local and regional markets with Beacon Hill Pharma's National Delivery.

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Beijing Clinical Service Center, an outstanding expertise in the area of medicinal clinical research.Beijing Clinical Service Center is a full service provider of medicinal science and technology providing clinical researches, regulatory registration, medical writing, biometrics and data management, quality assurance, training and consultation services.

BERG
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BERG Analytics provides predictive & prescriptive solutions optimizing patient treatments and improving population health by validating clinical trials. Our AI platform, bAIcis®, integrates virtually any patient-related clinical, demographic and biological data examining the cellular activity of health and diseased biology, interrogating the differences, which leads to breakthrough discoveries and advances in patient outcomes.

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BGO Software is noted for its custom software, web and mobile apps development , along with covering full-lifecycle IT training and consultancy. Our company is a Platinum Telerik Partner, Government Procurement Service Supplier and official supplier to the Health Research Authority (HRA) of the Department of Health in the UK. We are specialised in medical software development, including our latest product Clinicubes CTMS.

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BioFortis is a leading provider of clinical development technology solutions, which empower total biospecimen lifecycle management. Its flagship product, Labmatrix, provides data management for subjects, clinical trial samples & consent tracking, and biobanking. With enterprise-level capabilities for integrating eClinical and research data in a harmonized & regulatory-compliant manner, Labmatrix users can easily ask sophisticated ad hoc questions, and generate insights from reports & dashboards.

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Bioforum is a data-focused CRO with over 10 years of clinical research experience. With clinical data management and biostatistics at our core, Bioforum offers life science organizations services to help accelerate the clinical development process. Bioforum is 100% CDISC (SDTM and ADAM) compliant. Our core services include: EDC to SDTM conversions in less than 1 Day Clinical Data Management (DM) Biostatistics Submission Ready Package Regulatory Operations Pharmacovigilance Innovative visualization tool

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Bio-Optronics, the creator of Clinical Conductor CTMS, is a leading software and services company offering user-focused healthcare management solutions, positively impacting the lives of patients around the world. Clinical Conductor CTMS is an industry leading clinical trial management system that gives CROs the configurability, trial oversight, communication & advanced business insight reporting needed to efficiently manage multiple trials, locations, & research partners.

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BioPoint provides a flexible client driven consulting and staff augmentation engagement model to our clients in the Pharmaceutical, Biotechnology and Medical Device Industries. Our focus spans Clinical and Postmarketed Drug Safety & Pharmacovigilance, Regulatory Affairs, Quality Assurance and Health Economics & Outcomes Research.

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Biorasi is a CRO widely recognized for delivering success in complex clinical trials. This is possible through TALOS™, an innovative operating model that unifies systems and teams with a powerful project management methodology to ensure high quality delivery. Overall, Biorasi balances power, time, acceptance, cost and service level to optimize the delivery of clinical studies.

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BioSensics is a globally recognized leader in wearable movement sensors for healthcare, providing medical-grade solutions for mobility and movement assessment. We provide turnkey technology solutions for ePRO and movement-based digital biomarkers in clinical trials. We offer a suite of contract research services including protocol design, sensor and data management, technical support, analytics support, and custom algorithm development for disease specific endpoints.

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As leaders in clinical trials services, experts from Cardiocore and VirtualScopics are the Research division of BioTelemetry, Inc., one of the world's largest connected health companies. As BioTel Research, they offer global operational support for cardiovascular monitoring in all therapeutic areas, and advanced imaging services in oncology, cardiovascular, metabolic, musculoskeletal, neurologic and medical device studies. For more information please visit www.gobio.com/clinical-research/

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The BloodCenter of Wisconsin is a world-renowned organization with medical and scientific expertise in diagnostics and cellular therapies. We support preclinical and phase I-IV trials, including: specialty laboratory testing, custom assay development, specimen collections, sample storage and electronic data transfer. BCW is a part of Versiti, an affiliation of successful healthcare organizations whose vision is to become the national leader in transfusion medicine and blood disorder research.

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A global collaborative network connecting stakeholders in a private system with common adjudication ensuring identity of healthcare professionals to protect and ensure safety of data exchange. In 165 countries and used by over 1 million healthcare professionals, Sponsors, research sites and thousands of organizations to connect, centralize and share verifiable information in real-time. Expediting study start and ensuring transparency and compliance thus modernizing industry using connectivity.

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C3i Solutions is a multi-channel customer engagement services provider, specializing in global, high-touch consumer, patient and end user engagement. Our network of global contact centers provides unparalleled, 24/7, multi-lingual support to customers in over 175 countries. For the past 35 years, our unique, multi-channel approach and experience in highly regulated industries have made us the partner-of-choice for some of the world's most trusted brands. www.c3isolutions.com

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CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs and medical devices in our health care system.

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Cambridge Healthtech Institute (CHI) is the preeminent life science network for leading researchers and business experts from top pharmaceutical, biotech and academic organizations. CHI's portfolio of products includes Cambridge Healthtech Institute Conferences, Insight Pharma Reports, Cambridge Marketing Consultants, Barnett International, Cambridge Meeting Planners and Healthtech Publishing, which includes Bio-IT World, Clinical Informatics News and Diagnostics World.

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Cambridge Semantics is an enterprise data management and analytics software company that delivers data access and analytics on demand to support initiatives involving sources such as Real World Data, Clinical Trials, and Unstructured text (such as publications) just to name just a few. Anzo Smart Data Lake® allows IT and business users to semantically link, analyze and manage all diverse data with speed, at big data scale and at fraction of implementation costs of traditional approaches.

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Canfield Scientific, Inc. is the global leader in photography services and products for clinical research and healthcare applications, including the pharmaceutical, biotechnology, cosmetics, medical, and skin care industries. Driven by a quality-focused mission to provide best-in-class imaging solutions and services, Canfield has achieved an industry-wide reputation for excellence and innovation throughout its product lines, industry services and customer support.

Cardiabase by Banook Group
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Banook Group is one of the few established international providers capable of supplying cardiac safety, central imaging and endpoint adjudication services to pharmaceutical, medical device and biotech companies, CROs and nonprofit organizations. Founded in 1999, Banook Group is a non-listed family company. Financially stable and strong, the group operates on an international scale, maintaining offices at its headquarters in Nancy (France), Montreal (Canada) and Shanghai (China).

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For 40 years, Cardinal Health Regulatory Sciences (CHRS) has assisted global companies with the development of pharmaceutical, biotechnology and medical device products. Our industry- and FDA-trained regulatory consultants provide expertise throughout the entire product development continuum to help companies get their products to market quickly and keep those products on the market.

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Center for Information and Study on Clinical Research Participation (CISCRP)

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The Center for Information and Study on Clinical Research Participation (CISCRP) is a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. CISCRP is committed to engaging and building relationships among members of the public, clinical research volunteers, and clinical research professionals.

CGI

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Chiba University Hospital is eager to carry out clinical research with new medication/treatment/etc. Projects on going are nationwide and global studies. ARO of Chiba University Hospital has many Medical Doctors, Project Managers, CRAs, Data Managers, Biostatisticians, CRCs, Pharmacists with more than 100 staff. Chiba University Hospital is recognized as one of Core Hospitals on Medical Law for clinical research. We are at the key position of multi-sites clinical studies.

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Online Education for Research Ethics and Compliance CITI Program is a leading provider of research ethics and compliance education. Our web-based training materials serve millions of learners at academic institutions government agencies, and commercial organizations in the U.S. and around the world. Learn more about our content offerings at www.citiprogram.org - 888.529.5929 - sales@citiprogram.org

Clariness

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Clariness's global reach accelerates your study's enrollment in all study countries. With 13 years of patient recruitment and engagement experience, we quickly and cost effectively find well qualified subjects that sites will enroll. Our ClinLife technology is live in 45 counties and has been used by thousands of sites. Our Enrollment Management Center, staffed by 70+ Clariness employees who speak 29 languages, is the key to success. They help sites convert referrals to randomizations.

ClinCapture

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At ClinCapture our mission is to build software that saves lives. Our technology lowers the cost of clinical trials by streamlining data capture processes while providing a platform that protects patient privacy. ClinCapture advances the evaluation and development of drugs, biologics, and devices that demonstrate promise for the diagnosis and/or treatment of a wide range of diseases or medical conditions.

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ClinDatrix is committed to providing world class, full service clinical research capabilities and expertise to the biotechnology, medical device, and pharmaceutical industries. Partnering with its clients, ClinDatrix manages, monitors, collects, validates, analyzes, reports, and delivers quality global clinical data with efficiency and accuracy. The company offers pre-clinical and Phase I through Phase IV services to drug developers and pre-IDE, IDE and 501K support to device innovators.

ClinEdge, LLC

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ClinEdge and BTC Network provide a full range of clinical and outsourced business services to clinical research sites, pharmaceutical companies and CROs. Together, ClinEdge & BTC Network are comprised of: two global networks of research clinics with over 1,000 physician investigators, a division of site financial services, and a division of patient recruitment/retention services, which includes online advertising, patient travel services, and an in-house call center, among other services.

Clinerion

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Clinerion provides leading software solutions for patient recruitment in clinical trials to support pharmaceutical innovation, especially in the development of new medicines by life sciences companies and hospitals. Clinerion big data analytics support the generation of data for real-world evidence, and market access for precision medicines for rare and orphan diseases. Clinerion is a Swiss-based software and services company with operations in Turkey, Europe, the Americas, and Asia.

Clinical Ink

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Founded in 2007, Clinical Ink® is transforming clinical development with innovative technologies that make clinical research easier for sites, sponsors and patients. Clinical Ink's SureSource® platform directly captures eSource data and documents and improves patient engagement while streamlining clinical development. Clinical Ink maintains offices in Winston-Salem, NC, and Philadelphia, PA.

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Established by Malaysian Ministry of Health in 2012, Clinical Research Malaysia exists to advance global health solutions for a brighter, more hopeful future for the people by providing speedy & reliable end-to-end clinical research support for quality studies. Our innate understanding of the local clinical research landscape with the international standards of operations coupled with fundamental backing of the government ministries provide us an incomparable advantage.

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The Clinical Trials Transformation Initiative (CTTI)-co-founded by Duke University and the U.S. Food and Drug Administration-is a public-private partnership whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. The CTTI vision is a high quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based therapeutic prevention and treatment options.

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CliniSpan Health is a innovative company accelerating clinical trial recruitment through nonprofit organization fundraisers. This unique platform is a low-cost and effective way for Pharma/CRO's to greatly expand their available base for trial enrollment. We are a community-based resource that is moving to lower health care costs by reducing the time needed for clinical trial enrollment.

Clinlogix
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Clinlogix is a Global Clinical Research Organization working to improve human quality of life by supporting and accelerating innovation in the life science industry. Our full suite of clinical research services supports the regulatory and clinical development pathway of devices, pharmaceuticals, biologics and diagnostics from bench to bedside. The company delivers this global expertise by way of its regional office locations in the US, Europe, Latin America, and Asia Pacific.

ClinPlus
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Clintec is an award-winning full service CRO and Functional Service Provider (FSP) expert in global Clinical Research, with operations in over 80 developed and emerging countries. We work with the world's best clinical experts in diverse geographical locations to deliver a unique mix of technical, operational and scientific expertise from Phase I-IV. Our 'focused, flexible, forward' approach enables us to provide precision tailored solutions for our clients and deliver global trial excellence.

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CluePoints is the premier provider of Risk-Based Monitoring and Data Quality Oversight Software. Our products utilize statistical algorithms to determine the quality, accuracy, and integrity of clinical trial data both during and after study conduct. Aligned with guidance from the FDA, EMA, and the new ICH (E6) addendum, CluePoints is deployed to support traditional monitoring and data management and can be implemented as the ultimate engine to drive Risk-Based Monitoring.

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CNS Healthcare
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Commonwealth Informatics is a global provider of cloud-based analytics products and services for the life sciences industry. Medical product developers, healthcare providers and government agencies use Commonwealth analytics to answer complex clinical and safety questions quickly and accurately.The experienced Commonwealth team is a trusted collaborator with regulators, academia, life sciences companies and government agencies to improve the way clinical data is analyzed.

Comprehend Systems
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Comprehend offers a suite of SaaS Clinical Intelligence applications to help ClinOps Execs, Data Managers and Medical Monitors significantly improve the speed, safety and quality of clinical trials. Across portfolios, studies, sites, systems and CROs, Comprehend's solutions are particularly effective for centralized monitoring, risk monitoring, CRO oversight, data review and medical monitoring initiatives. Comprehend solutions address complex FDA guidelines for quality, risk and oversight.

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Conduent is the world's largest provider of diversified business process services with leading capabilities in transaction processing, automation, analytics and constituent experience. We work with both government and commercial customers in assisting them to deliver quality services to the people they serve. Learn more at www.conduent.com.

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"We find the data provenance and collaboration capabilities of Blockchain very powerful. Coupled with other technologies this technology disruption can dramatically impact clinical trials and patient health outcomes" LifeLedger™ is a patient centered Blockchain platform to manage processes for Consent management, Patient engagement and Supplies tracking in a single application. ConsilX is founded by senior executives with experience in clinical drug development, service industries and academia

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Corementum helps clients with the Trial Master File Management and Regulatory Submissions Operations necessary to acquire agency approval for regulatory applications in the biotech and pharmaceutical organizations. Corementum is an information management company that works primarily with those in the biotech and pharmaceutical organizations.

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CSOFT International is a leader in global communication, providing turnkey solutions for companies facing the challenges of engaging customers and markets across linguistic and cultural barriers. Led by an award-winning, multinational team, CSOFT was recognized as one of the Top Innovative Companies by IDC. Our CEO was named one of Fortune Magazine's 10 Most Powerful Women Entrepreneurs, a Tech Disruptor by CNN Money, and is also a standing Committee Member of CCG - a leading China Think Tank.

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CSSi is a global full-service patient recruitment and retention company that focuses on providing customized services to help sites maximize their enrollment. Lead by our Local Enrollment Specialist, CSSi is able to reduce the costs and timelines associated with recruitment and retention of subjects for clinical studies.

CTI Clinical Trial & Consulting Services
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DiagnoSearch is an India-headquartered, international full-service CRO that leverages in-house developed cutting-edge technology platforms for Phase I-IV clinical trial management across a wide therapeutic spectrum. Since inception in 1995, DiagnoSearch has supported 220+ clinical programs for services such as Clinical Operations, Data Management, Biostatistics, CAP Accredited Central Laboratory, Medical Monitoring and Writing, Pharmacovigilance, IWRS & Consulting.

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DPharm Clinical Trials is the first industry forum dedicated to applying disruptive thinking to modernize clinical trials. The 8th annual Boston event led by Pfizer's Craig Lipset and Janssen's Dr Andreas Koester is scheduled for September 25-26 with a full day pre-conference on Mobile in Clinical Trials and is expected to attract 500 innovative thinkers and doers.

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DXC Technology
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Early Access Care
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eClinical Solutions
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EDETEK, Inc.
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Founded in 2004, Elite Research Network is a group of independently owned investigator sites which conduct clinical studies in all therapeutic areas and phases, including Phase I. Sites within the network are pre-qualified and must abide by established quality standards. We have earned a reputation for accelerated study start-up timelines, rapid enrollment, and consistent quality data. Our sites utilize central IRBs and can offer centralized contracts and budgets.

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EMB is a CRO specializing in the Data Management and Statistical Analysis/Reporting of clinical research data. EMB was formed in 2000 with a dedicated team of senior level associates each with over 15 years of industry experience and a proven track record of success. With experience on more than 40 NDAs, EMB associates streamline the process, effectively represent your results, & support your presentations to the FDA. EMB is associate owned, has had ZERO turnover, and is "Powered by Experience".

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Q2 (Q-square Business Intelligence) is a global Clinical Research Organization, with over 16 years pharmaceutical research and development experience, providing a broad range of services. Our principle is "Quality Work for Quality World". Janus Clinical Research Institute (Janus) is a Q2 based company in China. Janus possesses the capacity with extraordinary talented people for any large or small projects in clinical research.

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KWIPPED, Inc.
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National Association of Veterans' Research and Education Foundations
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The Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency focuses on three key service areas: scientific reviews of medical products, safety measures, and relief services for persons suffering from adverse health effects, in collaboration with the Ministry of Health, Labour and Welfare (MHLW). PMDA will continue to endeavor proactively to safeguard and promote the nation's health and safety, while strengthening its partnerships with other countries and regions.

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Richmond Pharmacology is a UK based research institute with a global reputation for excellence in clinical research. Founded in 2001. Richmond Pharmacology offers its clients a full service for early Phase clinical trials including: Consultancy and Expert Advice, Protocol Writing & CRF Design, Regulatory and Ethics Committee Applications, Volunteer/ Patient Recruitment, Clinical Conduct, Pharmacy services, Safety Lab and Bioanalytical services, Data Management & Statistics and Report Writing.

RMPDC
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RMPDC has a highly skilled Medical Information contact center and an extensive Research and Consulting group that has been serving pharmaceutical companies, the healthcare industry, and government agencies since 1956. We are world-renowned for the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System, which is a surveillance system that collects product- and geographically-specific data on abuse, misuse, and diversion of prescription drugs.

RWS Life Sciences
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RWS Life Sciences is the world's second largest life sciences translation practice providing a full suite of language solutions exclusively for life sciences. Our proven methodology and specialized translation professionals make us well qualified to translate all types of content across the life sciences industry. Our Quality Management System (QMS) is certified to ISO 9001, ISO 13485 and ISO 17100 and our life science expertise is crucial to our success.

RxLogix Corporation
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RxSolutions
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RxSolutions is the innovator of the RxStudy Card™, which utilizes the pharmacy network to deliver medicine and supplies to subjects participating in phase I-IV clinical studies. The RxStudy Card™ provides a safe and efficient method of dispensing medicines and supplies to study subjects, saving administrative effort, time and capital expense required for the purchase and distribution of study medicine and supplies. RxStudy Card™ eliminates more than 16 clinical supply steps.

Saama
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Saama Technologies is the first advanced hybrid analytics company delivering actionable business insights for life sciences and the Global 2000. We are singularly focused on driving fast, flexible, impactful business outcomes for our clients through data & analytics. Our unique "hybrid" approach integrates expertise across management consulting, life sciences, data science, automated data management, software and big data technologies.

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Safeguard by Innovative – the full-service marketing and printing company providing solutions for all of your needs: from print management to promotional products; from creative to direct mail; from product inserts and labels to cartons; from kitting to fulfillment and distribution. As part of the Safeguard/Deluxe Corp. we have access to numerous facilities across North America, allowing us to deliver upon your needs in a responsive and timely manner.

SafetyCall International
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SafetyCall International is a multidisciplinary health care practice that provides manufacturers with adverse event management, regulatory reporting, post-market surveillance, and consulting services. It operates the world's largest 24/7 human and animal adverse event call center, providing clients and their customers with immediate, around-the-clock access to trusted health, safety and medical information.

Salesforce
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Sarah Cannon, the Cancer Institute of HCA Healthcare, offers integrated cancer services with convenient access to cutting-edge therapies for those facing cancer in communities across the United States and United Kingdom. Sarah Cannon Development Innovations is a full-service contract research organization (CRO) that is uniquely focused in oncology.To learn more about Sarah Cannon, visit sarahcannon.com.

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Sciformix
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seQure Life Sciences
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seQure Life Sciences is a specialized company that provides Pharmacovigilance, Quality Assurance and Management as well as Regulatory Compliance Solutions in all areas of GxP. These services are provided as consultancy, as projects or on a functional service provision basis where a team is selected to provide a customer with ongoing services. Our experts have 30+ years of experience in the Regulatory Compliance field.

Sidley Austin LLP
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Signet Accel
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Sonic Clinical Trials
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Sonic Clinical Trials and TDL Trials (Sonic Healthcare companies) provide central laboratory services across AP and EU. In Australia, SCT provides site management services within the GP setting, facilitating access to Australia's largest network of GP sites (10M patient consultations annually by over 2,000 physicians). Services include: Laboratory Testing, Project Management, Sample Management, Kit Production, Collection Services as well as GP-based Patient Recruitment and Study Feasibility.

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Southern Star Research is an award-winning Australian CRO. Our expertise in a broad range of indications is supplemented by a Clinical Team who have an average of 19 years direct clinical research experience. With a willingness to provide every Client with exceptional customer service and a history of success in clinical trials from Phase I to IV, Southern Star Research has the capability and the drive to support your R&D objectives in Australia.

Sparta Systems

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Splash Clinical, LLC
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spmd Safety Strategies for Health Inc.
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spmd – safety strategies for health Inc. (spmd) is a contract pharmacovigilance service provider working with various pharmaceutical companies from all over the world. We are a new company with German roots in the USA with plenty of entrepreneurial spirit. We collaborate on a daily basis with our well-established pharmacovigilance partner enterprise in Germany, spm^2 - safety projects & more GmbH.

SRG Woolf Group, Inc.
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SRG Woolf is a provider of clinical research staffing solutions in the biotechnology, medical device, pharmaceutical and CRO industries. Since 1995, SRG Woolf has placed top talent in contract, contract-to-hire, project –based and permanent positions. Our specialists apply industry experience to successfully screen and match candidates to client-specific needs, whether for a single clinical research professional or an entire research team. SRG Woolf Group is a division of Impellam, NA.

Statistics & Data Corporation (SDC)
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Stefanini
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Stefanini Life Sciences Services is a branch of Stefanini focusing on technology services for the Life Sciences industry. Stefanini provides 24x7 support services in 32 languages to eClinical End Users globally, including patients using ePro devices and investigative site personnel and study teams using EDC and other clinical applications.

Sterling Institutional Review Board
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SubjectWell
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Symbio, LLC
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Symphony Clinical Research
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Symphony Clinical Research takes clinical study visits to patients where they live, work or play. We provide in-home and alternate-site care on six continents. Sponsor benefits include accelerated recruitment, enhanced retention, improved compliance, increased site productivity and increased patient satisfaction. A Certified Women Owned Business Enterprise.

Synchrogenix Information Strategies, Inc.
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Synchrogenix provides regulatory and communications strategy, science, and solutions to pharmaceutical, device diagnostics, and tobacco companies worldwide. From global submission strategy and regulatory operations leadership, to regulatory and medical writing, to transparency and disclosure compliance, we combine our expertise with our innovative technology-enabled solutions to propel products from model to patient access.

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Syneos Health is the only fully integrated biopharmaceutical solutions organization. Our company, including a Contract Research Organization and Contract Commercial Organization, is purpose-built to accelerate customer performance to address modern market realities. Created through the merger of two industry leading companies – INC Research and inVentiv Health – we bring together more than 21,000 clinical and commercial minds with the ability to support customers in more than 110 countries.

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Synteract is an innovative, full-service CRO supporting biopharmaceutical companies in all phases of clinical development to help bring clinical trials to life. Synteract has conducted nearly 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and nearly 750,000 patients. Synteract offers a notable depth of expertise in oncology and neuro-degenerative indications, as well as rare and orphan, and pediatric studies.

Target Health Inc.
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Target Health Inc., is full service, technology driven CRO, with staff dedicated to all aspects of drug, device and diagfnostic development including Regulatory Affairs (represent over 50 companies at the FDA), Strategic Planning, Clinical Research, Biostatistics, Data Management & Medical Writing. All of our software is web based, 21 CFR part 11 compliant. THI has received the first FDA approval for a product using our eSource software, Target eCTR(eSource; Electronic Clinical Trial Record)

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TConneX combines the disciplines of business strategy, technology solution expertise and user experience to solve today's life sciences problem. Our innovPV is an innovative post-market drug safety analytic tool that generates drug safety intelligence proactively and strategically with advanced data analytics, signal detection algorithms, and cutting-edge data visualizations of data mining outputs from spontaneous data sources and literature.

TechData Service Company
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Technical Resources International, Inc.
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Techsol Corporation
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Techsol Corporation is a leading global technology service organization, providing pharmaceutical industry focused services in the areas of Medical Information, Drug Safety, Signal Detection and Management, Clinical Development and Pharmaceutical Sales Management. Techsol' global pharmaceutical – information technology focus and techno-functional expertise enables it to provide technology services and consultancy across the drug life cycle.

Telelingua Translations
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Telelingua performs clinical research and clinical trial translations across all stages of the product development and registration process, including clinical research, phases 0 - IV, surveys, drug testing, regulatory approval dossiers, registration submission and review, production and marketing.

TFDA / Center for Drug Evaluation, Taiwan
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Taiwan Food and Drug Administration is the regulator of medical product registration in Taiwan, and Center for Drug Evaluation was established to assist in technical dossier review. Taiwan has one of fastest regulatory submissions processes in the Asia and hosts more than 100 clinical research sites, providing high quality medical care and clinical data. Taiwan adopts and recognizes all ICH guidelines, which are applied to NDA, BSE, IND review process and GMP inspection.

TFS International
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The Clinical Resource Network
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The Engaged Database
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The Reagan-Udall Foundation for the FDA
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The Reagan-Udall Foundation is an independent 501(c)(3) not-for-profit organization created by Congress to advance the mission of the FDA by advancing regulatory science and research. With the ultimate goal of improving public health, the Foundation provides a unique opportunity to bring all parties to the table (FDA, Patient Groups, Academia, other Government entities, and Industry) to work together in a transparent way to create exciting new regulatory science.

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Transcend Trials
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Transcend Trials is a company dedicated to streamlining and advancing the underserved administrative tasks facing sponsors and CROs throughout the clinical trial process. Engaging Transcend Trials means sponsors and CROs no longer need to lose sleep over things like investigator budgets and standard of care, negotiation of contracts, and managing site payments. In the hands of our experts, you still maintain control, just without the heavy lifting.

TransPerfect
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Trial By Fire Solutions - SimpleTrials CTMS
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TrialX Inc.
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Trifecta
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Trilogy Writing & Consulting
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At Trilogy, medical writing is our passion. As specialists in clinical regulatory documentation, we provide a service that is more than just writing. Our writers are integral parts of our clients' teams. We proactively plan, coordinate and write clinical documents to meet timelines, with a readability that reduces the time for review and approval. Our goal is to help teams streamline their documentation process and make sure their documents communicate clearly and effectively.

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uMotif Ltd.
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Unicon Pharma provides end to end strategic solutions to Pharmaceutical, Biotech, Medical device companies as well as CROs/CMOs nationwide. Our quality service and therapeutic expertise has allowed us to bring exceptional value to our clients. Our unique consulting approach supplies staff, training, support and expertise in the areas of Pharmacovigilance/ Drug Safety, Validation, Quality and Compliance, Clinical Data Management and Regulatory Affairs.

United BioSource Corporation
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As part of University of the Sciences provides education in specialized fields like Biomedical Writing, Pharmaceutical and Healthcare Business, Health Policy and Public Health, and provides students with hands-on learning experiences, internships, and personal connections.

University of Utah Clinical Trials Office
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Website: www.utah.clinicaltrialsoffice.org

The University of Utah Clinical Trials Office provides dedicated clinical research support to clinical investigators and sponsors providing them with the personnel and facilities necessary to conduct and facilitate pediatric and adult clinical trials. Our team provides a centralized infrastructure of research support for study budgets and contracts, regulatory affairs, participant recruitment, IND/IDE support, internal monitoring, project management and coordination of clinical research studies.

UTMB Sealy Center for Vaccine Development
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The SCVD Clinical Trials Group conducts all phases of vaccine clinical trials from first-in-human Phase I studies through Phase IV post-marketing studies for sponsors including the NIH DMID, major pharmaceutical companies and smaller biotech companies. Study populations include infants and toddlers, children, adolescents, adults and the elderly.

Validated Cloud Inc.
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Veeva Systems, Inc.
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Verified Clinical Trials
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Veristat
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Viedoc
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Vita Data Sciences, a division of Softworld, Inc.
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Vital Transformation
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Vitalograph, Inc.
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Vitrana Inc.
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Vitrana has a vision to drive major advances in the quality, efficiency and cost of clinical research, development and patient care through Vitrana's integrated healthcare and life sciences IT platform. Clinical research, development and patient care can be significantly improved through the adoption of key technology innovations in information management, focusing both on bottom line costs and on top line growth, leveraging information assets for improved insights and service quality.

WCCT Global
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WCG
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